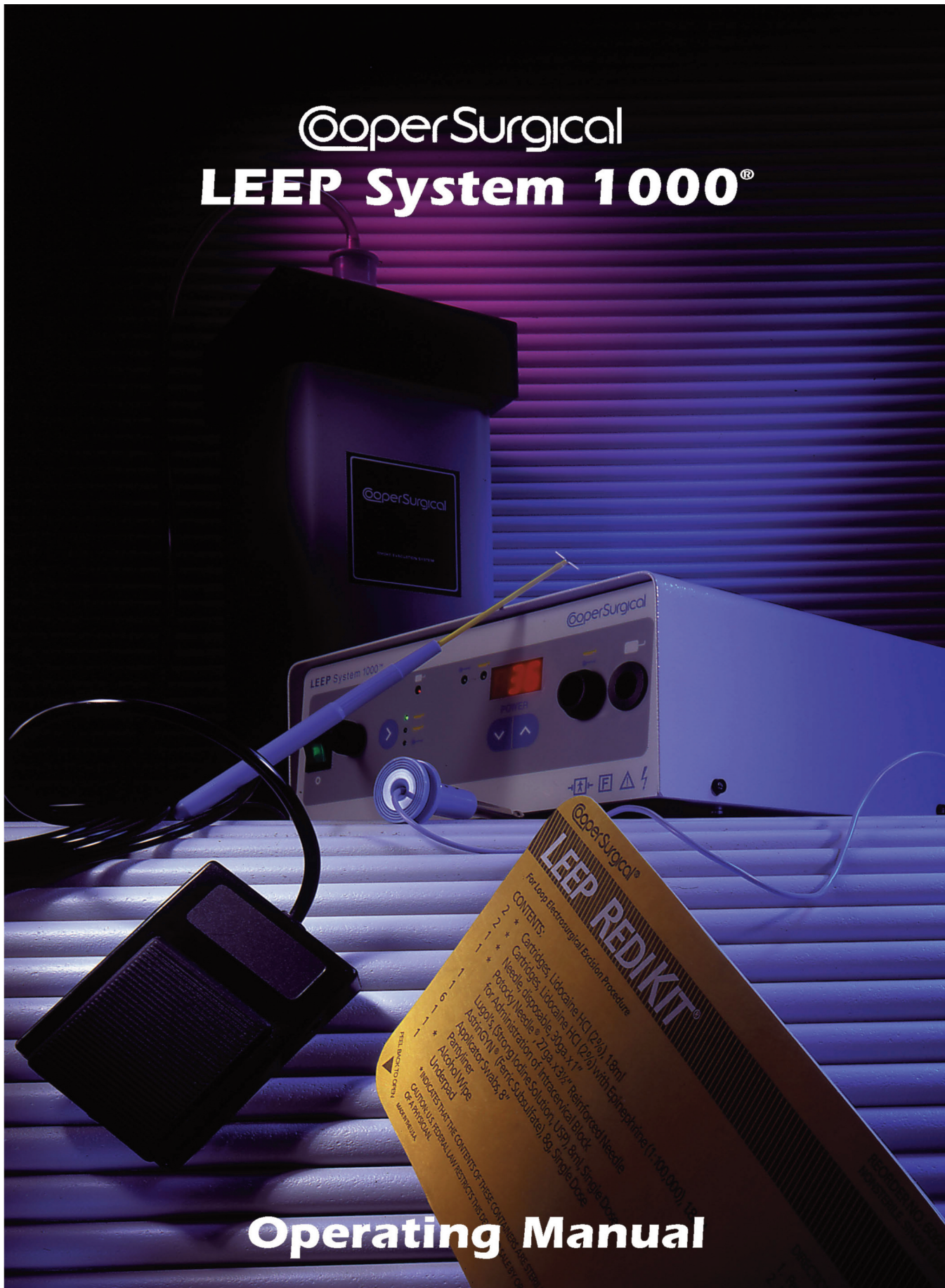


CoperSurgical LEEP System 1000®



Operating Manual

LEEP REDKIT®
For Loop Electrosurgical Excision Procedure

CONTENTS:

- * Cartridges, Lidocaine HCl (2%) 18ml
- * Cartridges, Lidocaine HCl (2%) with Epinephrine (1:100,000) 18ml
- * Needle disposable 20ga X1"
- * Popcyl Needle® 21ga X2 1/2" Reinforced Needle
- * Lugol's Strong Iodine Solution, USP, 8ml, Single Dose
- * Astrin® (Ferric Subchlorate), 8g, Single Dose
- * Applicator Swabs, 8g
- * Penicillin
- * Alcohol Wipe
- * Underpad

* Indicates that the contents of these containers are sterile.
COPERSURGICAL, TRADEMARK, RESTRICTS THEIR
© 2004

CooperSurgical

LEEP System 1000®

TABLE OF CONTENTS

I.	Professional Use Guide	2
II.	System Features	10
III.	Electrical Precautions	14
IV.	Placement of the Patient Plate	16
V.	Foot Pedal Switch	16
VI.	Power Connection, Electrode Connection & Power-Up	16
VII.	Operation	17
VIII.	Safety Circuits	17
IX.	Practical Suggestions	17
X.	Cleaning	17
XI.	Periodic Safety Checks	18
XII.	Troubleshooting	19
XIII.	Liability Statement	20
XIV.	Warranty	21
XV.	Explanation of Symbols	21

Manufactured by:

CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611

Phone: 203-601-5200

Phone: 800-243-2974

Fax: 800-262-0105

I. PROFESSIONAL USE GUIDE

IMPORTANT

The user of this equipment, LEEP System 1000®, should be thoroughly trained in the techniques of Loop Electrosurgical Excision Procedures. This equipment has been designed for use with LEEP Electrosurgical Accessories. DO NOT use this equipment for any purpose other than that for which it has been designed.

This manual contains information about the proper procedures for inspecting and preparing the equipment before its use, and its care and storage after use.

This manual does not describe how an actual procedure is to be performed, nor is it meant to teach a beginner the proper technique or any of the medical considerations regarding the use of this equipment. CooperSurgical recommends that prospective user obtain appropriate training before using this equipment as improper use could be potentially hazardous to the patient and the user.

This device SHOULD NOT be used without proper training.

Training in the use of electrosurgical equipment should include:

1. A review of the published literature regarding the procedure of interest.
2. A review of the Loop Electrosurgical Excision Procedure (LEEP) Syllabus available from CooperSurgical.
3. Attendance at a course or courses offered by Physicians experienced with the Loop Electrosurgical Excision Procedure.
4. Hands-on preceptor training from an experienced practitioner.

Please read this entire manual carefully to become familiar with each of the controls and features before making any attempt to use the equipment clinically.

Instructions contained in the operating manuals of any equipment to be used in conjunction with this equipment must be followed to avoid any possible hazard from incompatibility.

Failure to thoroughly understand and follow the instructions given in this manual may result in serious injury to the Patient and/or the Operator. Failure to follow the instructions given in this manual may result in damage to or malfunction of this equipment.

No long-term follow-up studies with this device have been performed as to recurrence rates. The effects of Loop Electrosurgical Excision Procedure on pregnancy outcome are not known.

SAFETY PRECAUTIONS MUST ALWAYS BE EXERCISED WHEN USING ELECTRICAL EQUIPMENT TO PREVENT OPERATOR/PATIENT SHOCK, FIRE HAZARD AND EQUIPMENT DAMAGE.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician. This device SHOULD NOT be used without proper training and preceptorship.

If any questions arise regarding the information contained in this manual, the operation or safety of the equipment or service, please contact your local Distributor.

I. PROFESSIONAL USE GUIDE (cont.)

A. INDICATIONS

The LEEP procedure is indicated in the diagnosis and treatment of some Cervical Intraepithelial Neoplasia (CIN) in patients where there is:

- Cytological or colposcopic suspicion of CIN 2 or worse (including micro-invasion)
- Persistent CIN 1 (of more than 12 months duration)
- CIN 1 where the likelihood of follow-up is low or when the patient requests treatment
- A transformation zone which is fully visible and fully confined to the cervix
- A suspicion (cytological or colposcopic) of a glandular intraepithelial abnormality
- A disparity between the cytological and colposcopic diagnoses
- External anogenital lesion
- large vaginal intraepithelial neoplastic (VAIN) lesions
- Cervical conization indications

B. CONTRAINDICATIONS

The following are typical contraindications for performing the LEEP procedure. It is imperative that the physician carefully weight the risks and benefits of treatment versus non-treatment in contraindicated patients:

- Pregnancy
- Apparent invasive carcinoma of the cervix
- A bleeding disorder
- Acute or active inflammation of the cervix, endometrium, fallopian tube, ovary or peritoneum (cervicitis, endometritis, tubo-ovarian inflammatory disease or pelvic inflammatory disease)
- "Positive" endocervical curettage or a lesion in which the endocervical limit cannot be visualized colposcopically
- Less than 3 months postpartum
- DES-exposed patient with known or suspected cervical changes
- equivocal cervical abnormality

C. LEEP PROCEDURE AND TECHNIQUE

It is recommended that the patient be provided with a brief description of the procedure and the equipment that will be used (ACOG, CooperSurgical, and other professional organizations and equipment manufacturers have produced patient information brochures on the LEEP procedure that address many of the questions and concerns that your patients may have regarding the procedure).

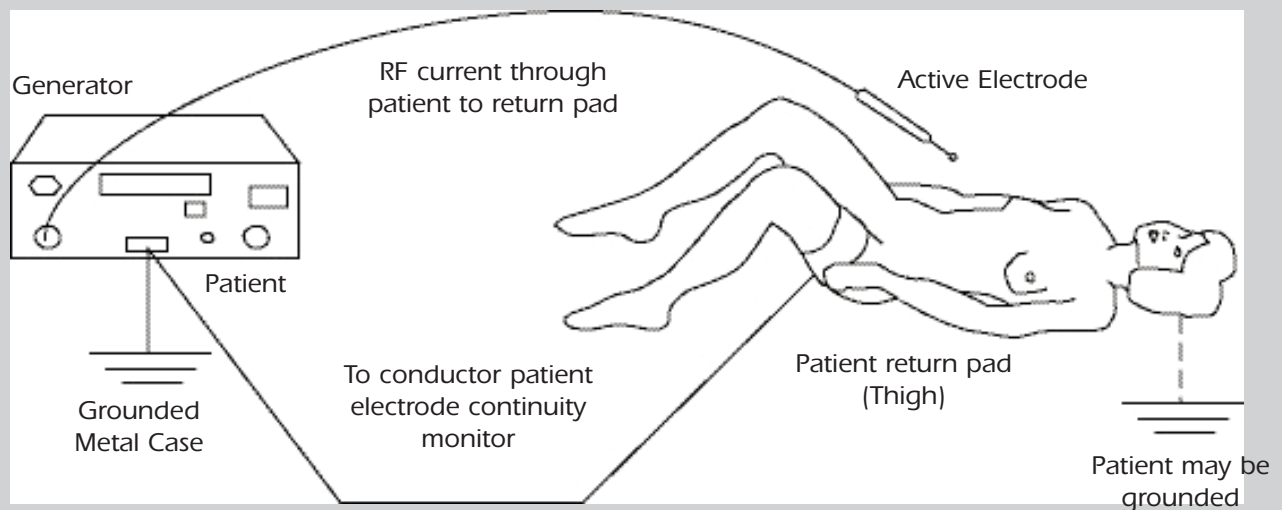
D. SAFETY PRECAUTIONS

1. This equipment should only be used by a thoroughly trained physician in an adequately equipped medical facility.

I. PROFESSIONAL USE GUIDE (cont.)

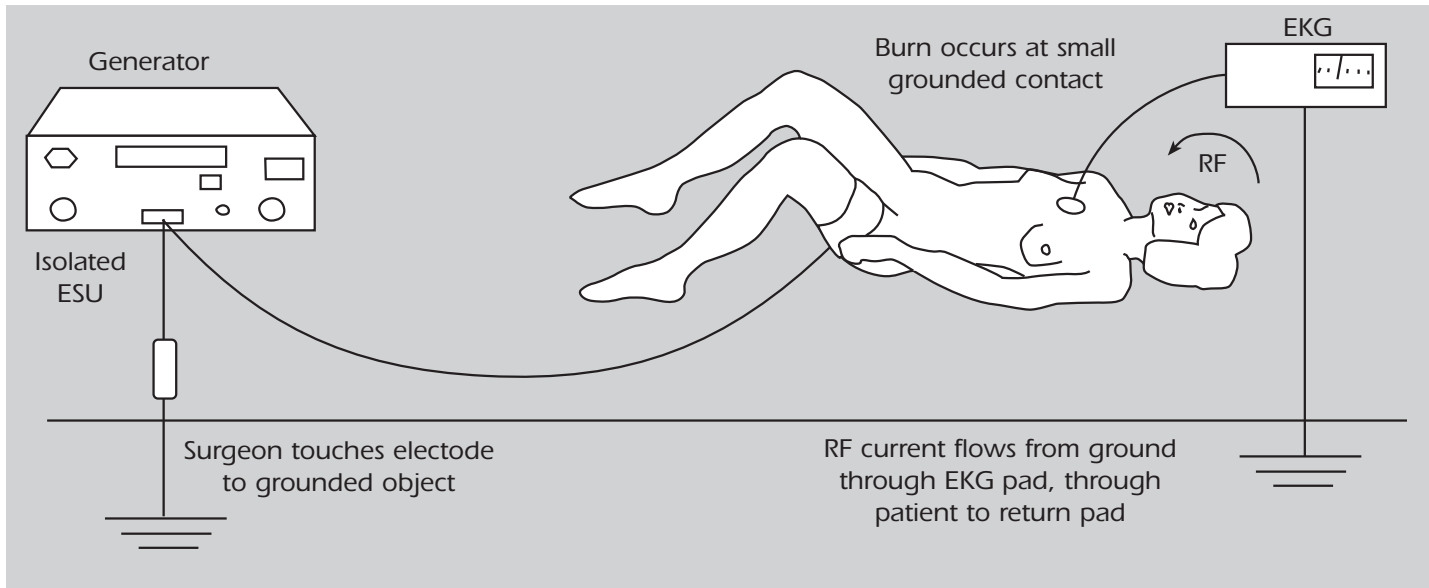
2. Replacement accessories and patient return pads should be kept on hand since defective active accessory or patient return pads can result in sub-standard performance of this equipment.
3. This equipment should only be connected to a properly grounded receptacle. NEVER use an adapter that defeats the ground of the built-in three (3) prong plug.
4. Care must be exercised when handling liquids around electrical equipment. DO NOT attempt to operate this equipment if liquids have spilled on the unit. DO NOT use flammable liquids around electrical equipment.
5. This equipment should never be used in conjunction with other equipment for which safety against leakage current has not been established.
6. When this equipment is operated:
 - a. **A Patient Return Pad (dispersive pad) of adequate surface area MUST be properly attached to the patient or the risk of accidental burns will exist.**
 - b. **The Patient Return Pad (dispersive pad) should be placed as close as possible to the site of use of the active accessory but MUST NEVER be placed so as to allow the patient's heart to be in the pathway from the active accessory to the return electrode!**

PROPER

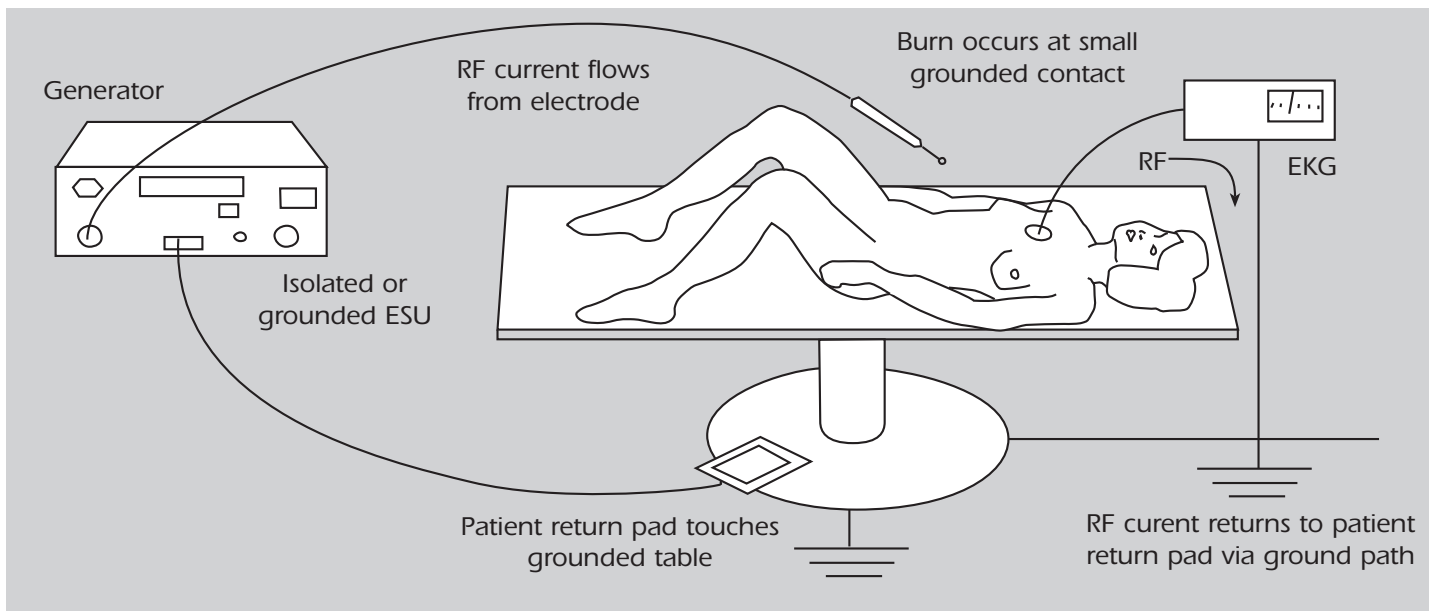


I. PROFESSIONAL USE GUIDE (cont.)

IMPROPER



IMPROPER



7. The user should thoroughly understand the principles and use of radio frequency (RF) current before using this equipment. This understanding is essential to avoid the hazard of shocks or burns to the user and/or the patient.
8. The instructions for use described in this manual must be followed; otherwise, compromised safety, malfunction, injury to the operator and/or patient, or costly damage to the unit may occur.

I. PROFESSIONAL USE GUIDE (cont.)

9. There are no user-serviceable parts within the housing. Repairs to this equipment should only be performed by authorized CooperSurgical service personnel. For service information, please contact your local Distributor (see page 1).

E. ELECTROSURGICAL PROCEDURES

This section provides only general information about the use of electro-surgical devices. Only the User can evaluate the clinical factors involved with each patient and determine if the use of this equipment is indicated. The User must then decide on the specific technique and procedure that will accomplish the desired clinical effect.

WARNING

Electrosurgical generators are designed to allow the controlled destruction of tissue and are inherently dangerous if operated improperly.

REPORTED PROBLEMS DUE TO IMPROPER OPERATION DURING ELECTROSURGICAL PROCEDURES HAVE INCLUDED:

Inadvertent activation with resultant tissue damage at the wrong site and/or equipment damage.

Alternate current pathways resulting in burns where the patient or physician or assistant is in contact with exposed metal.

Explosions caused by electro-surgical sparking in a flammable gas mixture (i.e., explosive anesthetic gases and the inappropriate use of alcohol and other flammable liquids).

Perforation and massive hemorrhage.

A proper patient return pad pathway is extremely important during any monopolar electro-surgical procedure. Every effort must be made to ensure that throughout the electro-surgical procedure, an adequate surface area is provided and remains in proper contact with the patient to reduce the current density below a level that might cause inadvertent tissue damage where the patient return pad has been applied.

I. PROFESSIONAL USE GUIDE (cont.)

1. SETTING THE CONTROLS

A. Electrosurgical Tissue Effect

Delivery of continuous sinusoid waveform currents through a small electrode at appropriate power levels can cause rapid heating of the intracellular fluids in the cells in close proximity to the electrode, turning these fluids to steam. The significant increase in volume (approximately 5 times) causes cellular structure to rupture, creating the clinical effect of "CUT", with little or no hemostatic effect along the margin of the divided tissue. Delivery of short duration pulses of RF currents through a small electrode at appropriate power levels can cause heating of intracellular fluids at a more gradual pace. This allows evaporation of these fluids without rupturing the cellular structure, creating the clinical effect of desiccation, or "COAG", without the division of tissue. By varying the pulse to an intermediate duration, it is possible to get a clinical effect that combines, or "blends", the clinical characteristics of CUT and COAG yielding the effect referred to as "BLEND", where tissue is divided with a desirable amount of hemostatis along the margins of the divided tissue.

The electrosurgical effect may vary throughout the procedure, requiring the operator to adjust the relative power setting of the generator.

B. Select the output mode (i.e., "CUT", "BLEND", or "COAG") by pushing the corresponding buttons.

Output Mode	Waveform Description	General Effect
CUT	Continuous 450 KHz sinusoid with minimal modulation	Cutting without Hemostatis
BLEND	Interrupted 450 KHz sinusoid intermediate duty cycle	Cutting with minimal Hemostatis
COAG	Bursts of 450 KHz sinusoid short duty cycle	Coagulation without Cutting

c. Set the level of output power (confirmed on the digital display) by using the output power selector buttons as desired.

WARNING

The degree and speed of electrosurgical effect is largely dependent on Current Density at the point of contact of the active electrode. Loop electrosurgical excision procedure electrodes from other manufacturers may vary in the diameter thickness, size and configuration of the cutting wire. This may result in SIGNIFICANT changes in the electrosurgical effect at a given output power level setting. The use of CooperSurgical LEEP Electrodes is recommended.

I. PROFESSIONAL USE GUIDE (cont.)

- d. If the use of other output modes is anticipated, repeat steps #1 and #2 as desired. The output power level settings selected for each output mode will be retained as long as the unit remains ON.

2. GUIDELINES FOR POWER SETTINGS

The following guidelines for power settings may vary due to the technique, clinical circumstances, accessory style, cutting wire diameter, size, configuration and user preference.

Recommended Power Settings (Watts) for the CooperSurgical LEEP System 1000® Electrodes

Style	Loop Width (cm)			Ball Electrodes	Needle Electrodes	
	1.0	1.5	2.0		Macro	Micro
CUT*	---	---	---	---	---	14-24
BLEND	22-36	30-40	34-46	---	---	---
COAG	---	---	---	40-56+	30-36	---

REMEMBER, THIS IS NOT AN ATTEMPT TO TEACH ELECTROSURGICAL TECHNIQUE.

The practitioner who lacks experience should not attempt the procedures described below based solely on this information; instead, the skills required should be acquired in the time-honored preceptor manner. Call your local Distributor (see page 1) for information on courses that still offer instruction on the proper use of electro-surgical generators and accessories.

NOTE: The best initial effect is accomplished with the cutting wire in only light contact with tissue. Tight pressure may cause desiccation of the tissue and will delay the start of the cutting effect.

IMPORTANT

The initial use of any electro-surgical generator always involves some degree of "trial and error". This is true even when only changing from numbered dials to digital display models within the same manufacturer's product line. As with any other therapeutic device, it is very helpful to experiment IN VITRO or on animal sample tissue before using any electro-surgical generator or methods which are not familiar.

The microprocessor control system of this unit was developed specifically to provide the best possible performance for loop electro-surgical excision procedures. By exhibiting patience and following the guidelines offered, the practitioner should easily become familiar with the performance characteristics of the LEEP System 1000®.

I. **PROFESSIONAL USE GUIDE (cont.)**

3. TECHNIQUE GUIDANCE

- a. When performing the procedure, the endocervix is commonly not included in the loop excision, and the results of endocervical curettage do not appear to be predictive of either residual or invasive disease after Loop Electrosurgical Excision Procedure.
- b. Loop Electrosurgical Excision Procedures performed with small diameter wire loop electrodes may produce multiple small pieces of cervical tissue, and provide a less acceptable tissue specimen for histopathologic analysis. The influence of electrode design on procedure effectiveness is not completely understood.
- c. Larger lesions involving multiple quadrants of the cervix are more difficult to remove with either the small or large diameter loop electrodes.

4. SMALL DIAMETER LOOP VS. LARGE DIAMETER LOOP

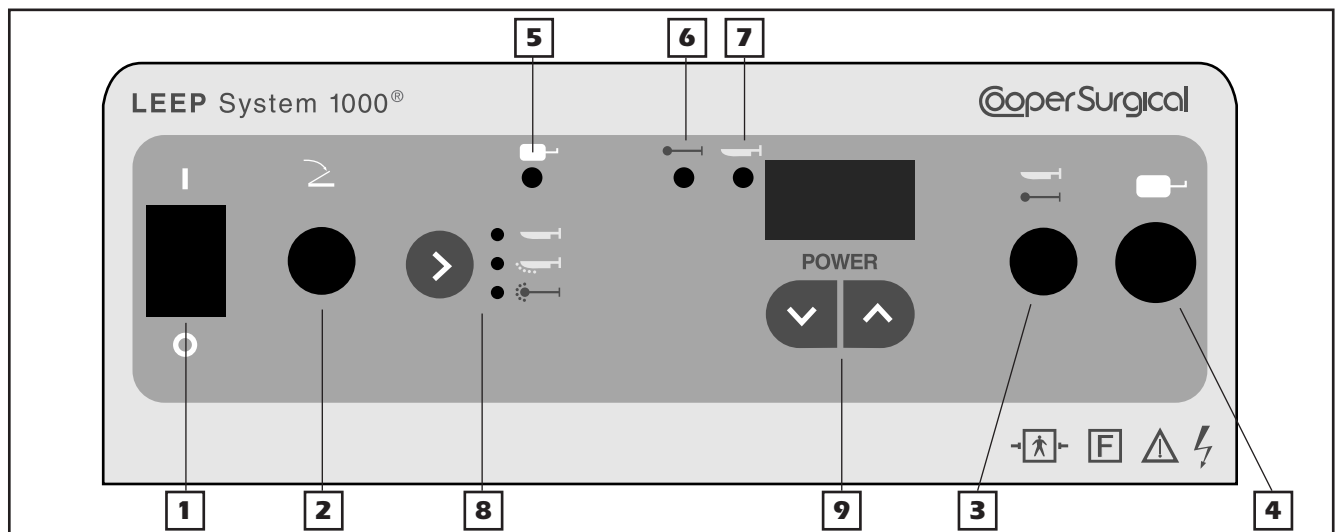
The histological quality of specimens obtained using small diameter loop electrodes may be inferior to specimens obtained using large diameter loops due to the increase contact area between loop and tissue epithelium. While the design of the LEEP electrodes has been chosen to optimize specimen quality, operative technique must take these differences into consideration. Reports of clinical evaluations of small diameter loop electrodes describe thermal damage which precluded histological evaluation of approximately 3% of the tissue specimens. In addition, since multiple, often irregular, strips of epithelium are excised from the cervix, it is often difficult for the pathologist to orient the specimens for optimal histopathological examination.

5. THERMAL EFFECTS ON TISSUE TREATED WITH LOOP ELECTRODES


Thermal effects on tissue specimens may include (1) thermal coagulation injury of the cervix, up to one-third the thickness of normal epithelium of the cervix, (2) fragmentation of squamous epithelium of the cervix attributable to long exposure periods along the excision site that allows heat to dissipate laterally, and (3) partial coagulation of the endocervical epithelium because of lateral radiation of heat. Therefore, the loop electrosurgical excision procedure (LEEP) may produce thermal effects at the periphery of the excised tissue and may make histopathologic interpretation difficult or impossible and not allow accurate diagnosis and need for further treatment.

II. SYSTEM FEATURES








- Microprocessor controlled for increased precision, accuracy, repeatability, and safety.
- Adequate power for all LEEP monopolar electrosurgical procedures.
- Accurate selection of discrete power levels.
- Digital display of output power levels.
- Choice of radio frequency wave forms including CUT, BLEND, and COAG to accommodate subtle differences in technique and accessory performance.
- Patient plate continuity monitoring with audible alarm.
- Distinct audible tones for CUT/BLEND modes and COAG mode with associated MODE light.
- Fully regulated isolated output power.
- Meets or exceeds IEC 601-2-2, second edition.
- Non-electric pneumatic foot pedal to maximize safety.
- Choice of reusable or disposable patient plate.
- Choice of reusable or disposable handpiece.
- Choice of reusable or disposable electrodes.
- Output power safety audible alarm with automatic power shut off.
- Class 1, type BF, protected for use with defibrillator.
- Membrane switching to maximize cleanliness and ease of use.



CONTROLS

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. Main switch 2. Socket for pedal switch 3. Socket for active electrodes 4. Socket for neutral electrode 5. Warning light of neutral electrode alarm (red) | <ol style="list-style-type: none"> 6. Coagulation light (blue) 7. Pure cut and blend light (yellow) 8. Mode control: <div style="margin-top: 10px;">  <ul style="list-style-type: none"> • Pure Cut • Blend Cut • Coag </div> 9. Power control |
|---|--|

II. SYSTEM FEATURES (cont.)

	Classification I Type BF protected against defibrillator effects
	Floating output circuit
	Cautions, consult this manual for safety precautions
	Pedal connection
	Active handle connection
	Patient plate connection
	High voltage

Specifications: Meets or exceeds IEC 601-1, IEC 601-1-2 and IEC 601-2-2 specifications. Meets the requirements of Annex I of Directive 93/42/EEC relating to Medical Devices.

ELECTRICAL

INPUT VOLTAGE:	95 - 135 VAC 50/60 Hz	190 - 250 VAC 50 Hz
CURRENT:	2.3 amps max.	2.3 amps max.
LOW FREQUENCY LEAKAGE:	Less than 50 micro-amps	Less than 50 micro-amps
FUSES:	2.5 amps, T type	1.6 amps, T type
POWER CORD:	American Cord Set, Hospital Grade, NEMA 5-15P/IEC 320 Female, 250cm Long	

PHYSICAL

Dimensions: 305mm x 267mm x 115mm Weight: 7.250 Kg

ELECTROSURGICAL OUTPUT

RF Output Frequency: 450 kHz

RF OUTPUT POWER:		Volts p-p Max (open circuit)	Duty Cycle	Crest Factor
CUT	0-100 watts RMS*	830	—	1.4
BLEND	0-100 watts RMS*	1200	60%	2.0
COAG	0-80 watts RMS*	3800	10%	5.5

NOTE: *Stable to >800 ohms (calibration at 500 ohms)

RF ISOLATION: Less than 150 milli-amps at 200 ohms

CLASSIFICATION I-Type BF
OUTPUT CIRCUIT Floating output. Protected against the effects of the defibrillator.
WORKING MODE Discontinuous maximum duty cycle: 10/30 sec.
COOLING Convection cooling without fan
CONTROL Foot pedal operated (pneumatic) with audible signals and mode lights

II. SYSTEM FEATURES (cont.)

AUDIBLE SIGNALS AND LIGHTS FOR OPERATION AND ALARM:

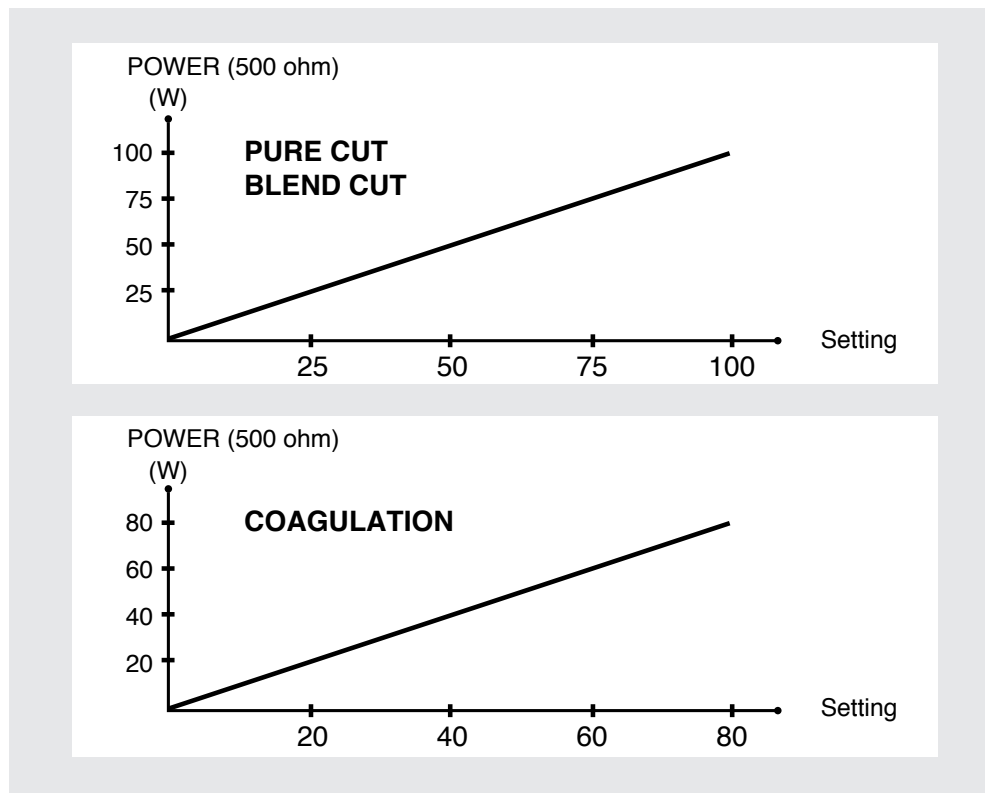
MAIN	Green light
ALARM, PATIENT PLATE CONTINUITY	Low pitch intermittent audible alarm - red light
ALARM, OUTPUT POWER	Higher pitch intermittent audible alarm
CUT AND BLEND MODES	Low pitch audible signal - yellow light
COAGULATION MODE	High pitch audible signal - blue light

NOTE: Specifications subject to change.

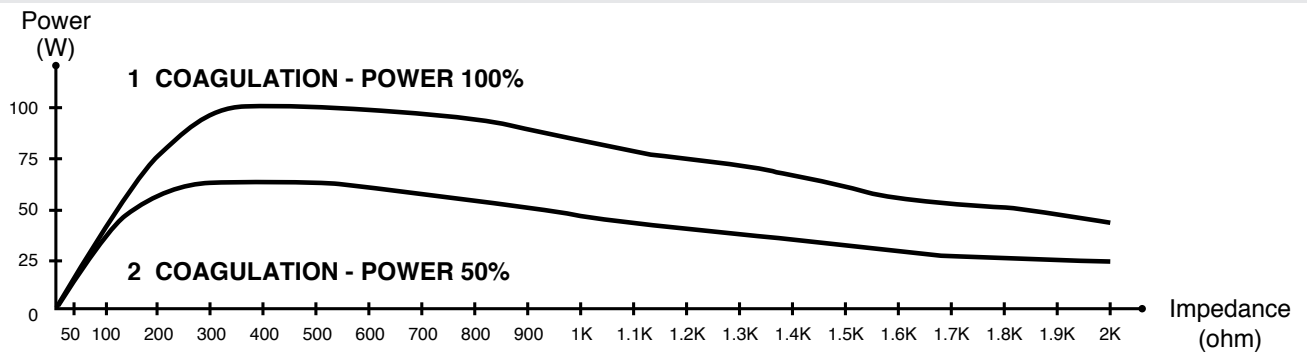
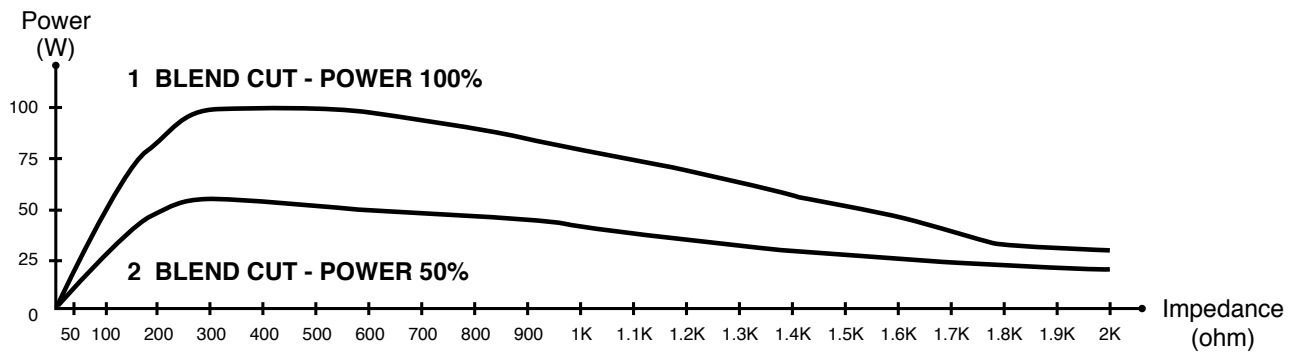
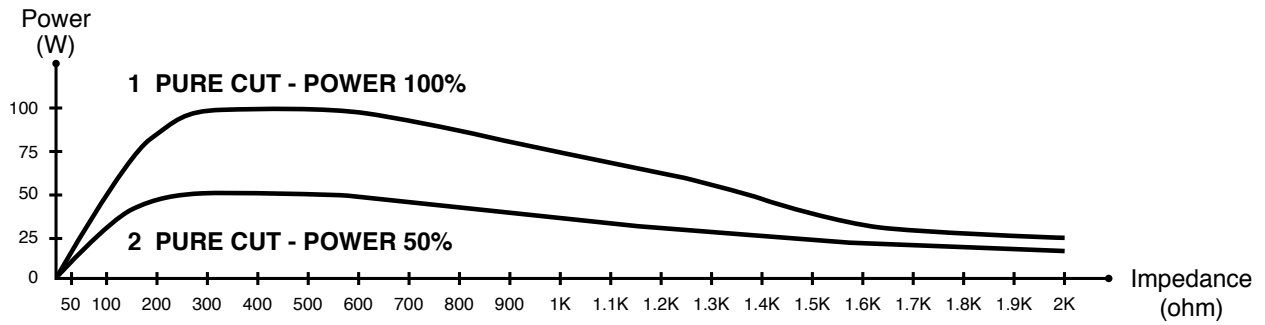
OUTPUT POWER AT 500 OHMS

PURE CUT	100 W RMS (open circuit 830 Vp-p; crest factor 1.43) Waveform: sinusoidal at 450 KHz
BLEND CUT	100 W RMS (open circuit 1200 Vp-p; crest factor 2) Waveform: sinusoidal at 450 KHz Duty cycle: 60%
COAGULATION	80 W RMS (open circuit 3800 Vp-p; crest factor 5.5) Waveform: sinusoidal at 450 KHz Duty cycle: 10%

Output Power Diagrams according to PAR.6.8.3 (IEC 601-2-2)



II. SYSTEM FEATURES (cont.)



III. ELECTROSURGICAL PRECAUTIONS

Tolerance: 20% according to PAR.50.2 (IEC 601-2-2)

The safety and effectiveness of electrosurgery is dependent, to a large degree, upon the skill of the user/operator. It is important that the user/operator read, understand, and follow the operating instructions supplied with the CooperSurgical LEEP System and thoroughly understand the principles and use of radio frequency (RF) electrosurgical systems.

WARNING: Electrosurgery uses radio-frequency energy to cut and coagulate tissue. Due to the sparking and heat associated with electrosurgery do not use with flammable anesthetics, or other flammable gases, near flammable fluids or objects or with oxidizing agents.

- DO NOT use electrosurgery in the presence of flammable gases, flammable liquids, or flammable objects in oxygen enriched atmospheres, nitrous oxide (N₂O) atmosphere or in the presence of other oxidizing agents.
- Prevent accumulation of oxygen, nitrous oxide (N₂O), and flammable gases, under surgical drapes, or within the area where electrosurgery is performed, and it should be avoided in case of thorax or head operations unless safely aspirated.
- Verify that all oxygen connections are leak-free before and during the use of electrosurgery.
- DO NOT use electrosurgery in the presence of naturally occurring flammable gases which may accumulate in body cavities such as the bowel.
DO NOT use electrosurgery in the presence of flammable liquids, such as skin prepping agents. Avoid pooling of flammable liquids near the electrosurgery site or in human body cavities such as the umbilicus or vagina.
- DO NOT place the electrosurgery active electrode near or in contact with flammable materials, such as cotton, wool or gauze. The active electrode is hot from use and can cause fire.
- It is possible that the radio frequency can interfere with the electronic circuitry in the pacemaker. To reduce the risk locate the patient return electrode as close as possible to the treatment site and ensure that the current path between the surgical site and the patient return electrode is as far removed from the heart as possible. For the gynecology procedures locate the patient return electrode on the patient's upper thigh or under buttocks.
Always monitor pacemaker patients during surgery. In case of doubt ask the pacemaker manufacturer and/or cardiology department.
- In case of loss of power, turn the system off.
- The possibility exists that the radio frequency can interfere with other medical equipment when the electrosurgical system is operating. To reduce the interference, physically separate the device, utilize different electrical outlets that are hospital grounded, do not allow cables to come in contact with each other, and utilize shielded devices where possible.
- The fixed output power level should be adjusted to the lowest power setting that will successfully complete the procedure. Refer to the following recommended power settings for the CooperSurgical LEEP System 1000[®] Electrodes.

III. ELECTROSURGICAL PRECAUTIONS (cont.)

Recommended Power Settings (Watts) for the CooperSurgical LEEP System 1000® Electrodes

Style	Loop Width (cm)			Ball Electrodes	Needle Electrodes	
	1.0	1.5	2.0		Macro	Micro
CUT*	---	---	---	---	---	14-24
BLEND	22-36	30-40	34-46	---	---	---
COAG	---	---	---	40-56 ⁺	30-36	---

The above power settings are for reference only and can be varied based on specific situations and the experience of the operator.

NOTE: * If the cut mode is desired, use the recommended settings for the blend mode.

+ The power setting can be increased beyond 56 to coagulate any bleeding points as required.

- Skin to skin contact, for instance between the patient's arm and body, should be avoided by the placement of an appropriate separating device such as two to three inches of dry gauze. This will reduce the potential for alternate site burns.
- If monitoring, stimulation, imaging or similar devices are used simultaneously with electrosurgery the monitoring electrodes must be placed as far as possible from the electrosurgery site and the patient return electrode. Position the patient return electrode close to the electrosurgery site, for example, on the thigh when treating the cervix. NOTE: Monitoring needle electrodes are not recommended.
- The electrical cord of the generator should be connected to a properly grounded receptacle. Extension cords and/or adapter plugs should not be used.
- The connecting cables to the electrosurgery electrodes should be placed so that they do not come in contact with the patient, other cables, or cross each other.
- Remove any metal items from the patient: for example, rings, chains, etc.
- Use accessories supplied by CSI; they are specifically designed for the LEEP System 1000®.
- Do not use old or worn accessories.

IV. PLACEMENT OF THE PATIENT PLATE OR DISPERSIVE ELECTRODE

When using an electrosurgical system, it is very important that all the current delivered to the patient returns correctly to the unit via the dispersive patient plate only.

- The patient must be positioned correctly on the operating table. The patient and operator must not come in contact with any metal conductive surfaces.

IV. PLACEMENT OF THE PATIENT PLATE OR DISPERSIVE ELECTRODE (cont.)

- The patient plate must securely contact a vascular area close to the operating site. For a gynecology procedure the preferred sites are the patient's thigh (disposable adhesive pads) or under the patient's buttocks (reusable metal plate). The contact area must be clean, free of body lotions, shaved, and massaged for good circulation. The contact area of the patient plate must be maximized and frequently checked for uniform contact during the procedure, especially if the patient has moved or if liquids have contacted the patient plate. A CONDUCTIVE GEL IS RECOMMENDED. The patient plate MUST NEVER be placed so as to allow the patient's heart to be in the pathway from the active electrode.
- Power delivery to the operative site may be decreased appreciably if alternate pathways exist; for example, through the metal operating table, crossed handpiece/patient plate cables, etc.

V. FOOT PEDAL SWITCH

Connect the foot pedal switch to the socket (2) without activating the pedal, and tighten the threaded plug.

This is an air (pneumatic) operated control. There is no electric current, offering maximum safety.

VI. POWER CONNECTION, ELECTRODE CONNECTION AND APPLYING POWER TO UNIT

(Refer to Diagram on Page 10)

- A. Check that power input corresponds to the technical data on the back of the unit. Plug the power cord into the appropriate grounded wall outlet, ensuring that the ESU on/off switch is in the "OFF" position.
- B. Connect dispersive patient plate to the socket (4).
- C. Connect the active electrode handpiece to the socket (3) and tighten electrode of choice in the handpiece.
- D. Turn ON the unit by the power switch (1). The unit automatically performs a SELF TEST that checks RAM memory, EPROM memory, supply voltage, signal modulation and the following displays; function selector green lights, digital display, cut and coagulant yellow light, coagulation blue light, and the audible signal. When the unit passes SELF TEST the display will show current software revision i.e., r2A, r2B for several seconds then goes blank.

VII. OPERATION

Setting Power (refer to diagram on Page 10)

- A. Control (8) sets the cut mode power output. The unit automatically powers up to cut mode when turned ON. Top LED lights on the selector (8) and control (9) sets the power.
- B. Control (8) selects blend mode (center LED) and control (9) sets the power.
- C. Control (8) selects coagulation mode (bottom LED) and control (9) sets the power.

Power settings are stored when the system is ON and will appear automatically on the display of control (9) according to the selection of power mode by the control (8) during the procedure.

Power may be changed at any time during the operation, except when the unit is activated by the foot pedal.

At the end of the procedure turn the system OFF, and safely store the equipment and accessories. Power will reset to zero.

VIII. SAFETY CIRCUITS

The LEEP System 1000® is equipped with two (2) safety circuits. The first one checks the dispersive patient plate connection. The second one turns off the power in case of an internal failure. When activating the unit by the foot pedal, a power delivery higher than the one selected will stop power delivery and at the same time give an audible signal similar to the patient plate alarm, but at a higher frequency.

IX. PRACTICAL SUGGESTIONS

To optimize the performance when using an electrosurgical unit, the active electrode must be kept clean and use the lowest possible power setting required. Some sparks or superficial carbonization of the tissue may occur and the delivered power may decrease as a result of the electrical insulation caused by the tissue charring.

Too high of a power setting results in a shorter surgical procedure, but may cause discharges and/or superficial carbonization, sparking, arcs, etc.

X. CLEANING

The unit may be cleaned with mild soap solution, but take great care that fluid does not enter the system. Wipe dry.

XI. PERIODIC SAFETY CHECKS

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- Inspect the equipment and accessories for mechanical and functional damage.
- Inspect the relevant safety labels for legibility.
- Inspect the fuse to verify compliance with rated current and breaking characteristics.
- Inspect acoustical and visual alarms/displays.
- Verify that the device functions properly as described in the instructions for use.
- Verify that the device shuts down the applied part circuit if the neutral electrode is disconnected.
- Test the protection earth resistance according to IEC 601-1/1988: Limit 0.2 ohm.
- Check that the output power is within tolerance versus the output control setting at a specified load resistance.
- Check the power output at full and half setting of the output control over the range of load resistance as specified in the instructions for use (max. deviation is $\pm 20\%$).
- Test the enclosure leakage current according to IEC 601-1/1988: Limit 100 μ A.
- Test the leakage current according to IEC 601-1/1988: Limit 100 μ A (BF).
- Test the patient leakage current under single fault condition with main voltage on the applied part according to IEC 601-1/1988: Limit: 5mA (BF).
- Verify the continuous activation of the unit and the function of the Foot Pedal. With the unit turned on and the Foot Pedal and a Patient Return Pad connected, press and hold the Foot Pedal for 60 seconds with the unit in any mode (CUT, BLEND or COAG). Both the LED and the audible indicators should remain activated while the Foot Pedal is depressed and should deactivate upon its release.

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

XII. TROUBLESHOOTING

In the event of a failure during SELF TEST the display will show one of the error codes listed below:

ALARM SIGNALS

PROBLEM	AUDIBLE TONE	DISPLAY
RAM Memory (during self-test phase)	1 kHz 100ms On 250ms OFF	"Er0"
EPROM Memory (during self-test phase)	1 kHz 100ms ON 250ms OFF	"Er1"
Signal Modulation (during self-test phase)	1 kHz 200ms ON 250ms OFF	"Er2"
Signal Modulation (during activation phase)	1 kHz 40ms ON 60ms OFF	"Er2"
Supply Voltage (during self-test phase)	1 kHz 100ms ON 250ms OFF	"Er3"
Supply Voltage (during activation phase)	1 kHz 40ms ON 60ms OFF	"Er3"
Power Output (during activation phase)	1 kHz 100ms ON 250ms OFF	Er5
Foot Pedal Circuit (during self-test phase)	1 kHz 100ms ON 250ms OFF	Er6
Microcontroller Power Supply	1 kHz 100ms ON 250ms OFF	Er7
Dispersive Electrode	1 kHz 80ms ON 125ms OFF	"nP" & Red Light

- A. If upon completion of Self Test the unit display reads Er0, Er1, Er2, Er3, Er5, Er6 or Er7 the unit must be returned to your local Distributor for repair (see page 1).
- B. If upon completion of Self Test or if the unit stops functioning and the display

XII. TROUBLESHOOTING

reads nP and the red warning light is on, check the dispersive patient plate to insure that it is properly connected to the LEEP System 1000® .

- C. If, following correct set-up of the system, it does not operate, works in an intermittent way, or stops working after a few seconds (without an audible signal), check for correct connection of pedal and its condition. The pedal is pneumatic, so even a slight leak can cause a performance problem. Proceed as follows:
 - 1. Tighten the threaded plug into the foot pedal socket.
 - 2. Then, push the pedal hard repeatedly to detect possible breaks in the tubing or in the pedal.
- D. If the unit, correctly connected, appears to deliver a lower power output than usual, check:
 - 1. The dispersive patient plate for complete contact (refer to dispersive plate sections).
 - 2. The condition of active electrodes (refer to "Practical Suggestions").
 - 3. The condition of the handpiece (cable continuity, contact of the electrode in the handpiece and the connector) by moving the cable and the connector and electrode to detect possible breaks and poor contact in the socket of the system.
- E. The LEEP System 1000® has a thermal protection circuit which will shut the unit off when internal operating temperatures exceed safe limits. Should the unit stop functioning with no alarm signal, assure that the system has adequate ventilation and that you have not exceeded the recommended duty cycle of 10 / 30 seconds. Should the thermal protection circuit be activated under normal operating conditions the system must be returned

to your local Distributor (see page 1) for servicing.

XIII. LIABILITY STATEMENT

CooperSurgical guarantees the safety, reliability and performances of the LEEP System 1000® only if the installation, recalibrations and repairs are performed by personnel authorized by CooperSurgical and if the unit is used in compliance with given instructions in an area that meets all the applicable IEC requirements.

XIV. WARRANTY

CooperSurgical, Inc. warrants that the LEEP System 1000® (the "Product") will be free from defects in materials and workmanship for a period of one (1) year from the original date of purchase.

If the product should become inoperable due to a defect in material or workmanship during this one (1) year warranty period, CooperSurgical will, at its option, repair or replace the product. This limited warranty does not include replacement or service to repair damage resulting from improper installation, external electrical fault, accident, disaster, use for a purpose other than that for which originally designed or indicated in this manual, negligence, modification, service or repair by personnel not authorized by CooperSurgical or normal wear and tear and also does not apply to disposable or single or limited use items or components. The sole and exclusive remedy under this limited warranty shall be repair or replacement as provided herein.

The foregoing limited warranty states the sole warranty made by CooperSurgical with respect to the product and all parts thereof, and is in lieu of any other warranty by CooperSurgical with respect to product. COOPERSURGICAL NEITHER MAKES NOR GRANTS ANY OTHER WARRANTY, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL COOPERSURGICAL BE LIABLE FOR ANY DAMAGES ARISING OUT OF THE LOSS OF USE OF THE PRODUCT, OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER OR NOT COOPERSURGICAL HAS ADVANCE KNOWLEDGE OF THE POSSIBILITY OF SAME.

No person, agent, distributor, dealer, or company is authorized to change or modify the terms of this limited warranty.

XV. EXPLANATION OF SYMBOLS



Reorder number



Serial number



Caution



Consult instructions for use



Non-sterile



Manufacturer



Date of Manufacturer

R_x Only

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

LEEP System 1000® is a registered trademark of CooperSurgical, Inc.

© 2015 CooperSurgical, Inc.

CooperSurgical

95 Corporate Drive
Trumbull, CT 06611 USA
Phone: (800) 243-2974
Fax: (800) 262-0105
www.coopersurgical.com



CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611 USA

International
Phone: (203) 601-9818
Fax: (203) 601-4747

35387B • Rev. A • 11/15