

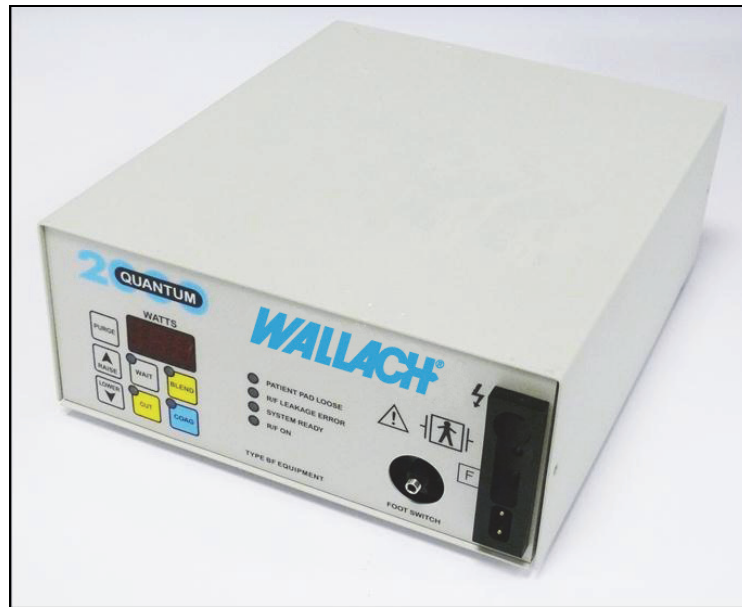
WALLACH[®]

QUANTUM 2000[®]

ELECTROSURGICAL SYSTEM

REF 909075 (120 VAC)
REF 909075-05W (220 VAC)

C €0086



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INTRODUCTION

Your Wallach® Quantum 2000® Electrosurgical System is designed with the help of leading clinicians and researchers specifically for your office. With care, it will give you years of trouble-free service.

Read this manual carefully and follow the recommended program of practice. An understanding of its contents will help you get the maximum benefit from the use of your electrosurgical system. The manual covers applications and techniques for use as well as set up and maintenance of your system.

If you have any questions or problems, call your local Wallach Representative, or write to:

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WARNINGS

A. THIS DEVICE IS A “BF” TYPE DEVICE. TYPE “BF” EQUIPMENT IS A TYPE B EQUIPMENT WITH AN F TYPE APPLIED PART.

Type B is a piece of equipment providing a particular degree of protection against electric shock, particularly regarding:

- Allowable leakage current
- Reliability of the protective earth connection.

F-Type isolated applied part. Applied part isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated mains voltage is applied between the applied part and earth.

B. AVOIDING UNINTENTIONAL PATIENT BURNS

- 1) Do not activate electrode until all components are in place
- 2) Be certain to have an unobstructed path and view
- 3) Use only non-conductive ancillary instruments
- 4) Remove patient jewelry, metal drape clips, (etc.) and needles
- 5) A patient return electrode (pad) must be used. The entire area of the grounding pad should be reliability attached to the patient’s body and as close to the operating field as possible
- 6) Place footswitch in safe position, out of traffic
- 7) Turn console “OFF” or place in “WAIT” state when not in use
- 8) Do not use unit on small appendages due to current density. Bipolar techniques may be desirable for use on small appendages.

C. THERMAL INJURY AND DEFECTS OF TISSUE TREATED WITH LOOP ELECTRODES

Possible injury to cervical tissue 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.

Loop electrosurgical excision procedures may also produce thermal defects at the periphery of the excised tissue and may make histopathologic interpretation difficult or impossible and may prevent accurate diagnosis and the evaluation of the need for further treatment.

D. FLAMMABLE GASES / SOLUTIONS

- When using a flammable preparatory solution, such as alcohol, be certain that the solution has completely evaporated before using electrosurgery.

- **Electrosurgery should not be used in the presence of flammable or explosive gases.**
 - **It is recommended that only non-flammable agents be used for cleaning and disinfection.**
- E. SMOKE FROM PROCEDURES CONTAINS LIVE CELLS WHICH MAY PRESENT BIOHAZARDS (HIV, ETC.); USE SMOKE EVACUATION DEVICE.**
- F. CONSULT THE PACEMAKER MANUFACTURER'S LITERATURE AND THE PATIENT'S PHYSICIAN BEFORE USING THIS INSTRUMENT ON A PATIENT USING A PACEMAKER.**

CAUTIONS

- **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.**
- **When in the monopolar mode, keep the voltage/power as low as possible to achieve the desired end effect (due to the potential for capacitive coupling and inadvertent burning at high voltages.)**
- **Adequate anesthesia is indicated for all electrosurgical procedures.**
- **Inspect loop and ball for adequate insulation.**
- **Avoid using electric extension cord (danger of separation).**
- **Use a smoke evacuator with this device.**
- **This device generates high-frequency energy that could, under some circumstances, cause interference to other equipment.**
- **For situations where the MAXIMUM OUTPUT VOLTAGE is less than or equal to 1600V, ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES should be selected that have a RATED ACCESSORY VOLTAGE equal to or greater than the MAXIMUM OUTPUT VOLTAGE.**
 - **ASSOCIATED EQUIPMENT and ACTIVE accessories should be selected with RATED ACCESSORY VOLTAGE \geq MAXIMUM OUTPUT VOLTAGE when the smaller of variable y [see below] or the number 6 is \leq CREST FACTOR for that HF SURGICAL MODE.**
 - **When MAXIMUM OUTPUT VOLTAGE (U_{max}) is $> 1\ 600\ V$, and the CREST FACTOR is $<$ the variable y calculated below, indicating that any ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES used with such mode or setting must be rated to withstand the combination of actual voltage and CREST FACTOR.**

$$y = \frac{U_{max} - 400 [\text{Volts}]}{600 [\text{Volts}]}$$

INDICATIONS FOR USE—OB/GYN APPLICATIONS

- The LEEP/LLETZ 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 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

CONTRAINDICATIONS FOR OB/GYN APPLICATIONS

- The following are typical contraindications for performing the LEEP/LLETZ procedure. It is imperative that the physician carefully weigh the risks and benefits of treatment versus non-treatment in contraindicated patients:
 - Pregnancy
 - Gross 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
 - Equivocal cervical abnormality

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 into steam. The significant increase in volume (approximately five times) causes cellular structure to rupture, creating the clinical effect of (CUT), with little or no hemostatic effort along the margin of the divided tissue. Delivery of short duration pulses of R/F 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) with the division of tissue. By varying the pulse to an intermediate duration, it is possible to get a clinical effect to combine, or “blend” the clinical characteristics of CUT and

COAG, yielding the effect referred to as “blend”, where tissue is divided with a desirable amount of hemostasis along the margins of the divided tissue.

The Quantum 2000 has output load characteristics that cause the electrosurgical effects to remain consistent throughout the procedure. However, under some circumstances, it may be necessary to readjust the power settings during the procedure.

ATTENDANT RISKS OF HIGH FREQUENCY ELECTROSURGERY

Electrosurgery produces sparks which can ignite flammable materials. This includes solvents, adhesives, gauze, cotton and also liquids and gases.

Further risks include:

- Pooling of flammable agents under the patient, in body depressions, in body cavities.
- Oxygen-saturated gauze and cotton wool
- Accumulated oxygen gas: under covers, drapes or clothing
- Ignition of endogenous gases in or near body cavities or osse

ELECTROSURGERY

Electrosurgery is the use of energy created by a high frequency alternating current. The resistance of the tissue to the passage of this current creates heat internally in the tissue, as in diathermy. Monopolar electrosurgery involves the use of two electrodes (an active electrode and a patient return plate or dispersive electrode) of greatly different sizes. This results in greatly increased current density at the point of the smaller electrode. While the electrode itself remains cold, the highly concentrated high frequency energy creates molecular heat inside each cell. By the choice of electrodes and selection and adjustment of the current, the operator controls the effect of this energy on the tissues to achieve the desired results.

CAUTION: WHEN IN THE MONOPOLAR MODE, KEEP THE VOLTAGE/ POWER AS LOW AS POSSIBLE TO ACHIEVE THE DESIRED END EFFECT (due to the potential for capacitive coupling and inadvertent burning at high voltages)

With electronically generated electrosurgery current, it is necessary to convert the sixty-cycle alternating current available at the wall outlet to the high frequency current needed for electrosurgery. This conversion is accomplished by a high frequency generator. The high frequency waveforms are precisely controlled for the various modes of operation. The peak average and RMS values of the desired waveforms are generated in accordance with scientifically and empirically derived standards which are known to result in the desired effects.

FUNDAMENTALS OF ELECTROSURGERY

As with any instrumentation or equipment used in your practice, there are some fundamental principles that should be learned in order to use electrosurgery safely and effectively. These principles apply generally to all procedures where electrosurgery is used. Familiarize yourself with them.

THE ACTIVE ELECTRODES

Be sure the electrodes are securely seated and firmly held in the handpiece so that the entire electrode shank is covered.

In general, straight wire electrodes are used for incisions and for removing fine tissue. Loops are used for removing heavier tissue, planing and contouring. Ball electrodes are used for coagulation.

Keep the electrode clean while operating. Tissue shreds and debris on the electrode reduce the effectiveness of the current and, by impeding the passage of the electrode through the tissue, slows down the stroke. This creates unnecessarily heavy coagulation, which can cause sloughing, and delay healing.

Inspect the electrodes for proper insulation.

BIOVAC SMOKE EVACUATOR OPERATION

AUTOMATIC MODE OPTION

The Biovac Smoke Evacuator is set up to operate automatically from the Quantum 2000. This is accomplished by means of a special IR LED (Infra Red Light Emitting Diode) in the Integration Unit, which is mounted on the rear panel of the Quantum 2000. When the “R/F Output” is activated by the operator, the rear panel LED produces an output which is received by the interface module of the Biovac interface assembly. The motor will come “ON” and stay “ON” for five (5) seconds after the energized output is terminated.

PURGE BUTTON

The Biovac may also be tested or used without the Quantum 2000 output by pressing the “Purge button” on the front panel. The motor will stay on for five (5) seconds after the button is released. Most purge operations (removing excess smoke) take only a few seconds.

SET UP AND OPERATION OF THE WALLACH QUANTUM 2000

PRACTICE

In the following section, cutting and coagulating are described. First, practice methods are suggested, including how to adjust the settings for optimal cutting and coagulating. Then general techniques are described which should help determine and develop the best specific techniques.

- 1) Place the console on a flat, stable surface near the Wallach Biovac Smoke Evacuator. Connect the AC power cord(s) accordingly. Plug the removable footswitch into the front panel, if foot control is desired. Set it up in a convenient, low traffic area.
- 2) Place the ON-OFF switch to “OFF”, and plug the console into a grounded 115 VAC electrical receptacle. This is an important safety feature.
- 3) Use only Wallach approved disposable accessories. See page 15 for further information.

- 4) Remove the disposable patient return electrode from its packaging and attach it to the patient in accordance with the instructions. Be sure to follow all instructions regarding the location of the pad ensuring that good contact is made with the patient.

Attach the disposable patient return pad (the patient electrode) securely into the black receptacle on the front panel of the instrument.

- 5) Insert the disposable active electrode (handpiece) into the black receptacle on the top right side of the Quantum 2000. Either the button-control operated handpiece or the footswitch-operated handpiece may be used. The footswitch-operated handpiece requires an adaptor to fit into the top receptacle.
- 6) Insert the selected electrode (loop) into the active electrode handpiece.
- 7) Place the ON-OFF switch to "ON". A red indicator lamp on the console (R/F ON) will indicate that the "hold" mode has been initialized. After "self-check" the green "System Ready" LED illuminates.

NOTE: If the system does not cycle to the "System Ready" status and a series of prolonged audible beeps are heard, turn the system off and check for faulty hand, foot, or panel switches. See TROUBLESHOOTING section (page 18, Section G) of this manual for additional information.

- 8) Ensure patient is connected securely to the return electrode (split pad) before beginning.

WARNING: POSITIVE CONTACT MUST BE COMPLETE BETWEEN THE PATIENT AND THE GROUNDING PAD. IF NOT, SEVERE BURNING OF TISSUE MAY RESULT. THE ENTIRE AREA OF THE GROUNDING PAD SHOULD BE RELIABLY ATTACHED TO THE PATIENT'S BODY AND AS CLOSE TO THE OPERATING FIELD AS POSSIBLE.

- 9) The output is selected by the mode selector buttons. When a mode is selected, the intensity should be set by depressing the "Raise" or "Lower" button. If either cut (pure cut/blended cut) or the coagulation mode is selected and the footswitch is depressed, the output will be active. When the footswitch or handpiece is actuated, the "R/F ON" lamp will illuminate and the beeper will emit a pulsing tone.
- 10) The system is ready for use and the "System Ready" LED will illuminate (green). If the operator feels the output of power is not sufficient, the dispersive electrode (split pad) should be checked to see that good contact is made with the patient before increasing the power setting.
- 11) "CROSS CONTROL" The sequence of operation of the Quantum 2000 is nonpreferential, that is either the footswitch (pedal) or the handswitch will activate the output (providing all safety measures are met). The footswitch and the handswitch cannot be operated simultaneously.

IMPORTANT: If using footswitch, the button on front panel must be used to control the "Output" mode. When the "Coag" mode is selected on the front panel, the "Cut" or "Blend" modes cannot be invoked by the handswitch (yellow button). The "Cut" mode, if desired, must be selected on the front panel and then invoked either by the handswitch or the footswitch operated pencil.

WARNING: Positive contact must be complete between the patient and the grounding pad. If a “Split Pad” is not securely affixed to the patient, the “Patient Pad Loose” indicator LED (Red) will indicate an improper return path. The “Patient Pad Loose” safety circuitry disables the output when an unsafe condition occurs in the return pad circuit. If a single (not split) return pad is not securely affixed to the patient, severe return electrode burning of tissue in the vicinity of the return pad may result. Poor connections or insufficient contact area can cause undesirable R/F burns. The entire area of the grounding pad should be reliability attached to the patient’s body and as close to the operating field as possible. However, it is not recommended that a single (not split) pad is used. Use only approved Wallach split return pads.

- 12) **Cable Placement: High-frequency cables should be routed clear of other instruments and arranged for minimum length. Cables to surgical electrodes should be positioned to prevent contact with PATIENT or other leads. Temporarily unused active electrodes should be stored in a location isolated from PATIENT.**

R/F LEAKAGE

The Quantum 2000 has a sensitive error detection mode that disables the output and indicates that an error condition exists by illuminating the front panel “R/F Leakage Error” LED (red). This LED will indicate that an undesirable path exists from the return (or active) electrode to “Ground”. In this context “Ground” means any undesirable path or place. If such a path exists the patient should be inspected for any contact with metallic paths to tables, chairs or other “Non Isolated” objects. The purpose of this feature is to prevent R/F current from flowing in undesirable places where it could either cause burns or damage to ancillary equipment.

13) PATIENT CONTACT

Operator-to-patient contact by direct skin-to-skin contact could make an undesired leakage path. Avoid skin-to-skin contact by insertion of dry gauze as necessary. Electrically insulating gloves should be worn by the operator. Unless absolutely necessary, the patient should not be touched when R/F power is activated. Patient should not come into contact with grounded metal parts or parts with a higher capacitance to ground (i.e. operating table supports, etc.). Use of antistatic sheeting is recommended for this purpose.

THE POWER SETTING

The operating mode (cut, blended cut, coagulate or wait) is selected by the mode selector buttons. When a mode is selected, the intensity should be set by depressing the POWER “Raise” or “Lower” buttons that control the digital display. When a mode is selected, the corresponding LED illuminates in the corner of each button to verify which mode is engaged.

To insure correct operation of the instrument, the colors are correlated to International Standards:

| | | |
|--------------|---|---------------|
| Wait | = | Green |
| Blend | = | Yellow |
| Cut | = | Yellow |
| Coag | = | Blue |

When the footswitch is depressed, or the handpiece buttons are pressed, the “R/F ON” will illuminate (yellow). If either the “Cut” (pure or blend) or “Coagulation” mode is selected and the footswitch is depressed, the output will be active. In the “Wait” mode there will be no output. The piezo electric “Beeper” will indicate with an intermittent tone when the R/F Power is present at the output. Once contact is made with the electrode to the tissue, and a small current is flowing, the tone will become steady.

The ideal power setting is the minimum settings where cutting and coagulating meet the criteria described on pages 13 and 14. If the power is too high, the tissue will be discolored and there will be considerable sparking when the electrode contacts the surface. If the power is too low, the electrode will drag through the tissue, tearing and burning, instead of cutting cleanly, and will pick up shredded and torn tissue.

Power requirements will vary with the type and size of the electrode, the area of electrode surface in contact with the tissue, the nature of the tissue, whether cutting or coagulating, and the depth of the incision desired. Larger electrodes, deeper incisions, and tough fibrotic tissue are some indications for higher power settings.

CAUTION: Do not use fine needle electrodes at high settings as they may be severely damaged by such use. When practicing with these electrodes, work up gradually from a low setting. Generally, you should not exceed a setting of 40 with fine needle electrodes.

CAUTION: Do not use monitoring needle electrodes during electrosurgery. If monitoring electrode cables are used, the monitoring electrode cables should be placed as far away from electrosurgical cables AS POSSIBLE. If it is absolutely necessary to cross over any monitoring cable or patient-connected tubes such as I/V lines, etc., the crossing should be at right angles. Use of monitoring systems incorporating high frequency current limiting devices is recommended.

CUTTING TECHNIQUES

When cutting, always activate the electrode by stepping on the footswitch or pressing the yellow button on the handpiece before contacting the tissue.

Plan the stroke. Before activating the electrode, take one or two practice strokes to be sure you can complete the planned stroke comfortably and correctly. At this time you can evaluate the size and shape of the electrode and the speed and depth of the stroke.

When the practice stroke is comfortable, step on the footswitch, or press the yellow button on the handpiece, and make the planned cut.

Use a smooth brushing motion without pressure. The electrode should pass through the tissue, without dragging, at a deliberate but not slow speed.

Keep the electrode moving. Prolonged contact with any one part of the tissue can create excessive coagulation.

CUTTING

Blend: Cutting is done, not by the electrode, but by the high frequency energy concentrated at the electrode. This high frequency energy generates molecular heat in each cell to the point where the fluids in the cell vaporize and the cell explodes. By applying this energy to individual cells in sequence, that is, by moving the electrode continuously through the tissue, the line of destruction is limited and the cutting effect is realized. At the same time the capillaries are sealed, resulting in almost bloodless cutting, hence the term “blended cut”. (This is the preferred cutting for OB/GYN procedures.)

Pure-Cut: This is almost like using a cold scalpel with very little or no hemostasis.

CRITERIA OF GOOD CUTTING TECHNIQUE

There are three criteria of good cutting technique:

- 1) The electrode should “float” through the tissue without dragging or resistance.
- 2) There should be only very slight, if any, change in the tissue color due to dehydration or charring.
- 3) No tissue shreds should adhere to the electrode.

COAGULATING

The Quantum 2000 is specially designed for high fulguration so tissue bleeders can be sealed without burning the uninvolved tissue. Coagulation takes place when the high frequency current is applied to the tissue with a current density sufficiently concentrated to dehydrate the cells and coagulate their organic contents, but without penetrating deeply into the tissue.

This procedure is almost self-limiting, since the surface coagulation first created protects the underlying tissue against excessive depth of coagulation.

Coagulation appears as a white spot on the surface of the tissue, emanating from the point of contact to the ball electrode. It is easy to determine the depth of coagulation since the depth is approximately equal to the lateral spread of coagulation.

In contrast to cutting, when coagulating the ball electrode should contact the tissue before depressing the footswitch or handswitch.

Start with a LOW power setting (15), setting mode button to “COAGULATION”.

Contact the surface of the tissue lightly with the ball electrode. Depress the footswitch or handswitch to activate the current, coagulating the area for several seconds. Then release the footswitch or handswitch and remove the electrode from the tissue.

Notice the appearance of the tissue. It should appear blanched. Turn the power intensity up step by step, repeating the procedure. Observe the characteristics of the coagulated tissue with each setting. The degree of coagulation obtained at a particular setting will vary with different tissue and different conditions. Determine which setting is best for various procedures. When treating any condition, if proper coagulation is not apparent after one application, immediately increase the intensity setting if the return pad is properly in place.

CAUTION: Never repeatedly apply the current to the same area; this may create heat and seriously damage underlying tissues.

COAGULATING TECHNIQUE

The ball electrode is extremely useful when you are controlling hemorrhage. When applied for a second or two, electronic coagulation current will coagulate small capillaries easily. Larger vessels can be picked up with hemostats which in turn may be touched by the ball electrode, using electronically generated current. This will seal all vessels which are held in the tips of the forceps.

NOTE: Always contact the tissue before depressing footswitch or handswitch when using the coagulation current.

TECHNIQUE GUIDANCE

FOR OB/GYN PROCEDURES

- A. The endocervix may not be included in the loop excision, and the results of endocervical curettage (ECC) may not be predictive of either residual or invasive disease after loop excision procedures. If the ECC is positive for dysplasia, a standard cone biopsy should be considered.
- B. Loop excision procedures performed with small diameter wire loop electrodes produce multiple small pieces of cervical tissue and may provide a less acceptable tissue specimen for histopathologic analysis.
- C. Larger lesions involving multiple quadrants of the cervix are more difficult to remove with loop electrodes.

SEVERED VESSELS

Clamp the bleeder with a hemostat.

Using electronically generated current, touch a ball electrode to any part of the hemostat.

Depress the footswitch pedal to activate the current for several seconds. Then release the pedal and remove the electrode. Be sure the current is set as high as is necessary to achieve coagulation.

After the application of coagulating current, remove the hemostat. Bleeding should have stopped; if not, repeat the procedure. Suture ligation may be required if R/F is unsuccessful.

When using electronically generated current, it is safe to hold the hemostat in a gloved hand while holding the electrode handle in the other during this procedure.

ANESTHESIA

Adequate anesthesia is indicated for all electrosurgical procedures. It is usually advisable to anesthetize tissue adjacent to the intended operative site, in the event it becomes necessary to extend the operative area.

BIOPSY

The use of electrosurgery for cervical biopsy has advantages that electrosurgery seals the capillaries and lymphatics as it cuts. The specimen should, whenever possible, include two to three millimeters of attached normal tissue.

Small (up to one half inch) masses should be removed in one piece. Using cutting current at a relatively high setting and a needle electrode, incise all around the mass in an elliptical pattern, including two to three millimeters of attached normal tissue.

Small masses may also be removed by using a suitable loop electrode, large enough so that it can excise the mass itself as well as two to three millimeters of attached normal tissue at the same time.

Specimens from larger masses should be taken in the form of pie-shaped wedges. Using a needle electrode and cutting current, start at the apex of the wedge at the center of the suspicious mass. The base of the wedge should include two to three millimeters of attached normal tissue.

THE WALLACH RETURN ELECTRODE

A return dispersive electrode must be used to operate the Quantum 2000 system. The return electrode should be of the “split or dual” type to take best advantage of the safety features for preventing R/F burns due to poor adhesion.

NOTE: For optimum patient safety with the use of the Quantum 2000 system, it is strongly recommended to use only authorized and genuine Wallach split/dual dispersive return electrode pads (Part Number 909078). No other return electrode pad has been tested or verified to the level of safety and performance of an authorized and genuine Wallach Quantum 2000 split/dual dispersive electrode pad.

WARNING: A one-piece return pad is not recommended since the one-piece pad is not continuously monitored for the integrity of the electrical connection established at the area of contact. Patient injury may result.

MAINTENANCE

After each use, the unit must be cleaned and disinfected. To sanitize unit, wipe down with a disinfectant.

While the finish on the instrument cabinet will resist scuffing and the chemical attack of most acids and alkalies, any liquids spilled on the cabinet should be wiped up immediately.

ACCESSORIES

NOTE: Use only genuine Wallach Quantum 2000 accessories (dispersive pads, hand switch pencils, footswitch operated pencils, and electrodes) for optimal system performance and patient safety. The use of non-Wallach authorized and genuine accessories is not recommended nor have been tested and verified to the level of safety and performance of a genuine Wallach accessory. Contact Wallach or your Wallach distributor for a list of current genuine Quantum 2000 accessories.

DISPOSABLE HANDSWITCH PENCILS

All Wallach disposable handswitch pencils are sold sterile and are for single patient use only.

For the Wallach Quantum 2000, use only Wallach genuine Disposable Handswitch Pencils (activated accessory with finger switch) which comply with IEC 60601-2-2: 4th edition.

Genuine Wallach Disposable Footswitch Operated Pencils and electrodes are available, sold sterile and are for single patient use only.

If you have any questions or require specific accessories, contact your Wallach Representative or local distributor. A variety of genuine Wallach disposable electrodes and accessories are available. Use only cables approved by Wallach. **Regular inspection is required for accessories, including your electrode cables for damage to the insulation. If damage is found, the accessory should be replaced to assure safe operation.**

Only use accessories specifically made for the Wallach Quantum 2000 that are specifically designed for the safe and proper operation of this unit. Use of alternate accessories or parts is not recommended, have not been tested and verified and can result in unsafe operation of this unit.

WARRANTY

The Wallach Quantum 2000 is supported by a one-year warranty from date of purchase covering any failure of the device due to defective workmanship or components, when used in compliance with the product's intended use.

Only Wallach is authorized to service or repair this unit. Do not disassemble the device. There are no user-serviceable components within the housing.

SERVICE/REPAIR

Wallach equipment is built to give maximum trouble-free service. The need for service under normal operating conditions is almost non-existent.

Almost without exception, the cause of poor performance by the machine will prove to be defective cords and/or connections. Check all cords and all connections periodically for signs of loose wires, worn insulation, or loose fit.

On all models, check the connection from cords to console. Broken wires and connections can be detected by the use of a continuity meter.

Only Wallach is authorized to service or repair this unit. If repair is attempted outside the factory, the warranty will be considered void. Wallach is not responsible for any injury resulting from repairs made by other individuals or organizations not certified by Wallach. If a repair is needed, carefully package the Quantum 2000 in a protective carton.

Return carton to:

WALLACH®

95 Corporate Drive
Trumbull, CT 06611 USA

Phone: 800-243-2463
(203) 799-2000

Fax: (203) 799-2002

customerservice@wallachsurgical.com

www.wallachsurgical.com

Products should be securely packaged in the original carton. Equipment must be sanitized before it is returned. Items that are not sanitized will be returned to the customer freight collect. All shipments must be made via pre-paid parcel post or U.S. Mail. C.O.D. packages will not be accepted.

TROUBLESHOOTING

| <u>TROUBLE</u> | <u>PROBABLE CAUSE</u> | <u>CORRECTIVE ACTION</u> |
|---|--|---|
| A. On/Off switch when in position does not illuminate | <ol style="list-style-type: none">1. Unit not plugged in2. Blown fuse | <ol style="list-style-type: none">1. Plug into wall outlet2. Replace fuse |
| B. “Patient Pad Loose”, intermittent power output, or low power | <ol style="list-style-type: none">1. Faulty application or poor contact2. Improper placement3. Worn insulation in electrical leads | <ol style="list-style-type: none">1. Check full contact to patient2. Place in accordance with instructions3. Replace |
| C. “R/F Leakage Error” | <ol style="list-style-type: none">1. Electrode touching grounding metal2. Directly grounded3. Insulation missing | <ol style="list-style-type: none">1. Remove from metal2. Locate faulty insulation between table/equipment to patient3. Locate faulty insulation |
| D. “System Ready” light (green) not on | <ol style="list-style-type: none">1. Improper connection2. One or more safety problems as indicated by other lamps or beeper3. Product failure | <ol style="list-style-type: none">1. Connect correctly2. Follow safety instructions3. Return to Wallach |

TROUBLESHOOTING (continued)

| <u>TROUBLE</u> | <u>PROBABLE CAUSE</u> | <u>CORRECTIVE ACTION</u> |
|---|--|--|
| E. “R/F ON” doesn’t light up: <ul style="list-style-type: none">• No power when footswitch is depressed• No power when switch on handpiece is depressed | <ol style="list-style-type: none">1. Electrical current not flowing2. Footswitch defective3. Pencil defective | <ol style="list-style-type: none">1. Check all connections2. Replace3. Replace |
| F. Digital readout does not illuminate | <ol style="list-style-type: none">1. Unit not connected2. Digital readout circuitry failure | <ol style="list-style-type: none">1. Plug into wall outlet2. Return to Wallach |
| G. System beeps long intervals | <ol style="list-style-type: none">1. Stuck panel switch2. Stuck foot switch3. Stuck hand switch button4. A footswitch or handswitch is active upon power up | <ol style="list-style-type: none">1. Turn unit off press each switch and make sure they depress freely |

SPECIFICATIONS FOR QUANTUM 2000

| | | | | |
|---------------------|-----------|-----------|------------|-----------------------|
| <u>SIZE:</u> | 4.25" (H) | 9.38" (W) | 11.63" (D) | Weight: 10 lbs. 9 oz. |
| | 10.8 cm | 23.8 cm | 29.5 cm | 5.25 kg |

ELECTRICAL:

| | | |
|---------------------|--|---|
| Input Voltage: | 120 VAC | 220 VAC |
| Maximum Current: | 3.15 Amps | 1.55 Amps |
| VA Ratings: | 132 VA | 242 VA |
| Power Line Leakage: | Less than 50 micro-amps | Less than 50 micro-amps |
| Fuses (5 x 20 mm) | Two T 3.15A 250V Slow Blow (Littelfuse® 02183.15 or Equivalent) | Two TT 2.5A 250 V Super Slow Blow (Bussmann® GMD-2.5A or Equivalent) |

HIGH FREQUENCY OUTPUT*:

Rated output power is 100 watts, 495 kHz ± 5% into 500 ohms, monopolar only.

| MODE | MINIMUM & MAXIMUM POWER SETTINGS | CREST FACTOR | MAXIMUM OPEN CIRCUIT VOLTAGE |
|-------|-------------------------------------|-----------------|---------------------------------|
| Cut | 10 to 100 watts | 1.2 | 600 |
| Blend | 10 to 100 watts | 2.5 | 600 |
| Coag | 10 to 100 watts | 6.5 | 4000 |

***Accuracy of output control setting:**

For output powers in excess of 10 Watts, the actual power as a function of the load resistance and output control setting shall not deviate from that shown in the diagrams shown on pages 22 and 23 by more than ± 20 %.

RF Leakage: 100 MA MAXIMUM AT MAXIMUM POWER SETTINGS

INDICATORS

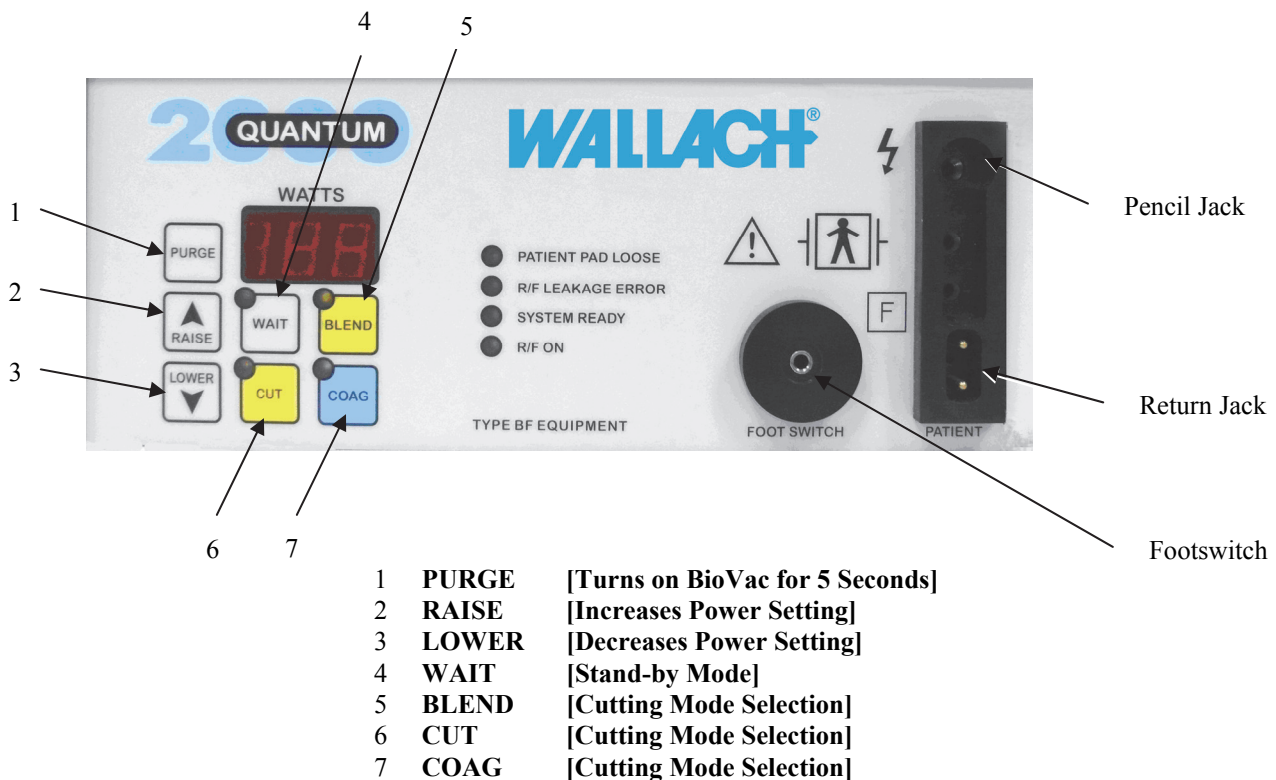
PILOT LIGHTS: Patient Pad Loose
R/F Leakage
Self-Test
Overload

INDICATOR LIGHTS: Wait Green
Cut Yellow
Blend Yellow
Coag Blue

POWER INDICATIONS: Digital LED Display

ACOUSTICAL: Piezo Annunciator

CONTROLS: Operator Push Buttons
Remote Pencil Buttons
Footswitch
A/C Power
Pencil Jack
Return Jack



REAR PANEL:

- Main ON/OFF Switch
- AC Cord Connector
- Fuse Holder

SPECIAL FEATURES

- 1) Electronic power level control
- 2) Digitally derived waveforms
- 3) Low inherent leakage
- 4) Patient return monitor disables power automatically if pad is loose
- 5) Regulated system performance traceable to NIST Standards
- 6) Automatic smoke evacuator signal function sends signal to detector for automatic smoke evacuator actuation when generator is activated
- 7) Self-monitoring of all detectors

CLASSIFICATION

| <u>Model</u> | <u>Safety Class</u> | <u>Type</u> |
|------------------------------------|---------------------|-------------|
| Q2000 Electrosurgical Units | I | BF |

- Do not get fluid into the Q2000 Electrosurgical Units. Should any liquid or solid object fall into the unit, unplug the unit and call Technical Support.
- The Q2000 Electrosurgical Units are suitable for intermittent operation with a 2 minute ON and 6 minute OFF duty cycle.
- The Q2000 Electrosurgical Units are classified as normal equipment (IPX0) according to protection against ingress of water.

ENVIRONMENT CONDITIONS

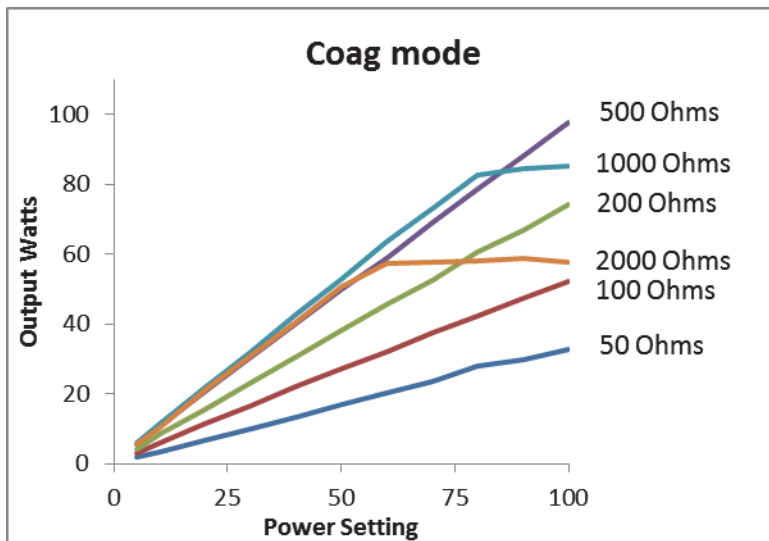
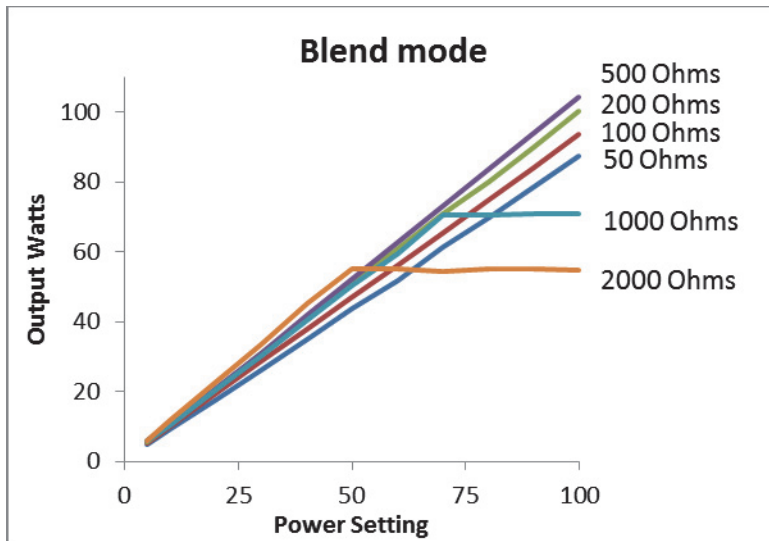
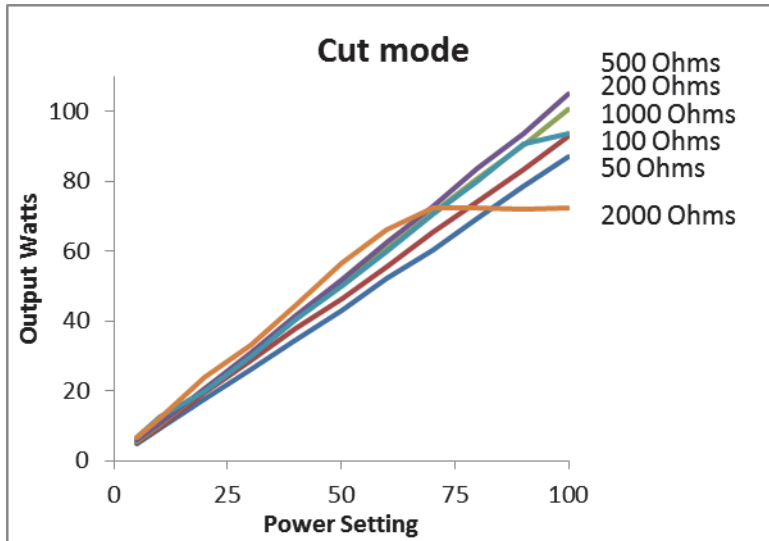
Use:

Environmental Temperature: between +10 °C and +40 °C
Relative Humidity: between 10% and 90%

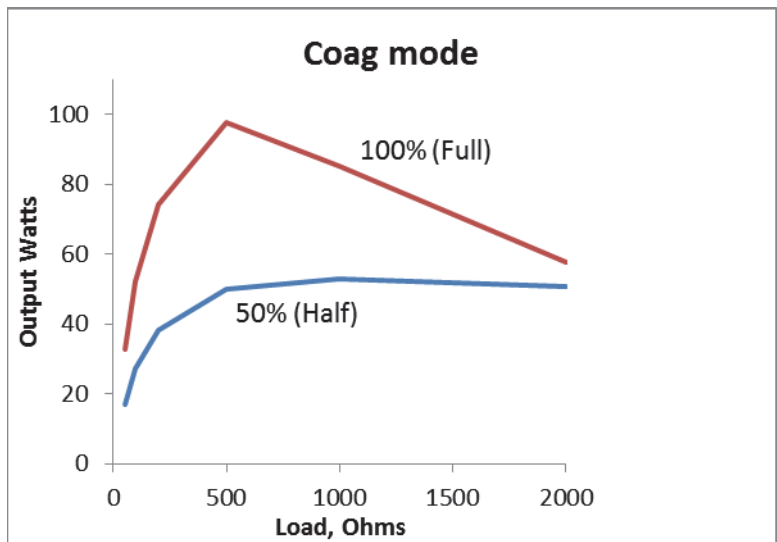
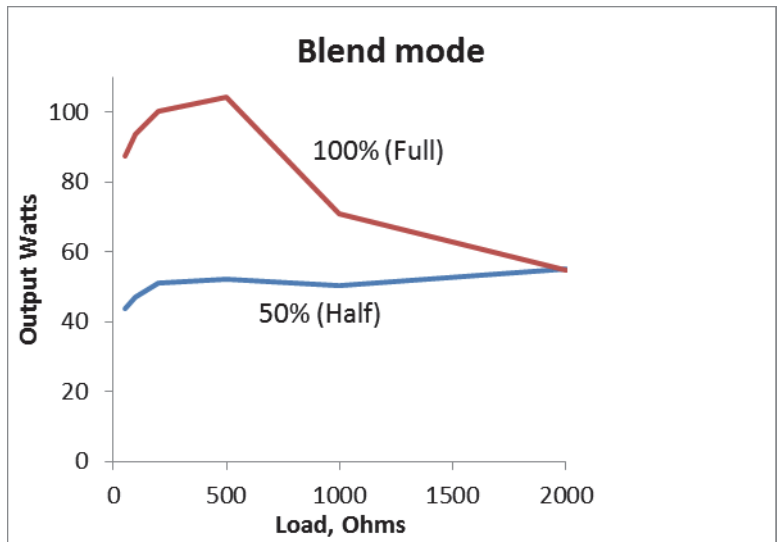
Shipping and Storage:

Environmental Temperature: between +10 °C and +40 °C
Relative Humidity: between 10% and 90%

POWER OUTPUT CHARACTERISTICS



POWER OUTPUT AT VARIOUS LOAD RESISTANCE



EXPLANATION OF SYMBOLS



CATALOG NUMBER



SERIAL NUMBER



ATTENTION: See instructions for use.



DEFIBRILLATOR PROOF SYMBOL=Indicates that the device will not be damaged if the defibrillator is active.

TYPE BF EQUIPMENT = Type of equipment is a type B equipment with an F type applied part.

Type B equipment is a piece of equipment providing a particular degree of protection against electric shock, particularly regarding:

- Allowable leakage current
- Reliability of the protective earth connection.

Type F = isolated applied part. Applied part isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equals to 1.1 times the highest rated mains voltage is applied between the applied part and earth.



APPLIED PART SYMBOL = Electrode that is connected to a patient's body.



HIGH VOLTAGE SYMBOL



ALTERNATING CURRENT SYMBOL = AC current



EARTH (GROUND)



FUSE, Replace Only with Specified Type and Ratings.



MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK,
FIRE AND MECHANICAL HAZARD ONLY
IN ACCORDANCE WITH UL60601-1 and CAN/CSA C22.2 No.601.1



Product conforms to the Medical Device Directive 93/42/EEC

Authorized Representative in the European Community:



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EMC COMPLIANCE INFORMATION WALLACH Q2000 ELECTROSURGICAL GENERATOR

- MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS


The Wallach Electrosurgical Generator is intended for use in the electromagnetic environment specified below. The customer or the end user of the Wallach Electrosurgical Generator should assure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment- guidance |
|---|-------------------|--|
| RF emissions CISPR 11 | Group 1 | Wallach Electrosurgical Generators use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | Wallach Electrosurgical Generators are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ Flicker emissions IEC 61000-3-3 | Complies | |

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Wallach Electrosurgical Generators are intended for use in the electromagnetic environment specified below. The customer or the end user of the Wallach Electrosurgical Generators should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environmental - guidance |
|--|---|---|---|
| Electromagnetic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 6 kV contact ± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | ± 1 kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | $< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec | $< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Wallach Electrosurgical Generator requires continued operation during power mains interruptions, it is recommended that the Walach Electrosurgical Generator be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE U_T is the a.c. mains voltage prior to application of the test level. In this case 230 V. | | | |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environmental – Guidance [Note 1 & 2] |
|---|---|-------------------------|---|
| Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz | 3 V 3 V/m | <p>Portable and mobile RF communications equipment should be used no closer to any part of the Wallach Electrosurgical Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

| | |
|--|---|
| <p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> | |
| <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | |
| <p>a</p> | <p>Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Wallach Electrosurgical Generator are used exceeds the applicable RF compliance level above, the Wallach Electrosurgical Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Wallach Electrosurgical Generator.</p> |
| <p>b</p> | <p>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> |

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