DELMARVA 2000 ™

Veterinary HFR Surgical Unit

Owner's Manual

For Veterinary Health Care use ONLY.

Read carefully before operating.

Contents

IMPORTANT: See page 24 - **OPERATIONAL DUTY CYCLE**

WARNING! Lethal electrical potentials exist within the unit:

risk of death or serious injury from accidental contact.

NEVER REMOVE THE COVER OR ATTEMPT INTERNAL REPAIRS.

Refer all servicing to Delmarva 2000 Ltd.

NOTE: This manual serves only as a guideline! Please refer to your training for application.

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INTRODUCTION – High Frequency Radio Electrosurgical Unit

Although the physics underlying electrosurgery have not changed since the introduction of the first practical instrument by Dr. W. T. Bovie in 1928, electronic technology and clinical application have evolved considerably in the interim. The HFR 2000 incorporates the most significant technologic advances which make modern hospital operating room electrosurgical units so much safer to use than their predecessors, but without any unnecessary "bell and whistle" features which raise cost without providing clinically significant benefit for veterinary medicine. The relative simplicity of the controls is a deliberate design choice to make the unit easy to learn, avoid mistakes due to a confusing array of settings, and to save set up time in emergency care situations. Never the less, the unit remains quite versatile to address the wide range of treatments encountered in Veterinary Health Care, as well the diversity of patients.

For those practitioners with electrosurgical experience, this manual will serve as a refresher and familiarize them with the controls on the HFR 2000. For those less experienced or new electrosurgery users, this manual is intended to provide the necessary information for using the HFR 2000 in clinical practice safely, effectively.

As the name "electrosurgery" implies, high frequency electrical energy is introduced into tissue to achieve surgical effects, namely, micro-smooth pressure less incision and excision, incision and excision with concurrent hemostasis, and tissue coagulation. The high frequency electrical energy reacts with the water contained within the cells to rapidly raise the internal temperature. The reaction occurs partially per Ohm's Law where the heat generated is proportional to the product of the applied current squared and the tissue electrical impedance, and partially due to a frictional effect caused by the cell electrolytes being agitated by the rapidly reversing electric field. The histologic effects follow the rules governing tissue reaction to heat: raising temperature enough to induce desiccation, or raising it enough to induce coagulation, or raising it enough to boil the intra-cellular water resulting in bursting the cells (volatizing the contents). Combining the latter two effects in proportion provides incision with concurrent hemostasis.

Although electrosurgical units are sometimes referred to as "cautery" units, this is technically inaccurate since cautery is the application of external heat to tissue, and, like any third-degree burn, causes significant injury to the tissue surrounding the point of application. The electrosurgical electrode will not become hot outside tissue. The tissue heats the electrode, not the reverse. Furthermore, electrosurgical effects are highly localized and the boundary of collateral denatured tissue resulting from electrosurgical incision is microscopic, like laser.

Patient safety is a matter of two things: first, heat induction must be controlled to allow the tissue capillary bed to safely absorb and dissipate it. Although the instrument setting and electrode geometry have a significant role, this is primarily a function of surgical technique. Secondly, the patient is a participating element of an electrical circuit. The ability of the anatomy being treated to withstand the electrical energy applied must be considered and respected. This is where the choice of using a bipolar technique, monopolar technique, or a "two-point" monopolar technique becomes significant.

INITIAL UNIT SET UP

CAUTION: **DO NOT** OBSTRUCT THE COOLING VENTS ON HFR SINCE IT RELIES ON CONVECTION (ROOM AIR) FOR COOLING. THERE ARE **NO** FLAMABLE MATERIALS IN THIS UNIT. IF IT OVERHEATS IT **WILL SMOKE**, BUT **NOT IGNITE**.

Plug the power cord into the IEC 320 style appliance entry. Be sure to push it in firmly and fully.

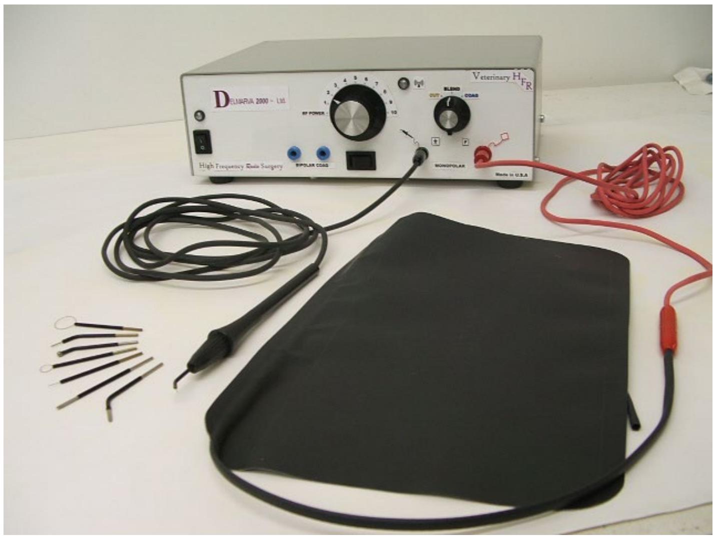
Connecting the foot switch to the unit:

Note that the widest key on the plug faces UP. Do not force it. Once the plug is in, turn the locking ring clockwise to secure the plug. It takes about 1 turn.

Turn the unit on with the I/O switch in the lower left. The green AC power indicator will illuminate.

Allow 20 to 30 seconds for stabilization before activating the unit.

MONOPOLAR SET UP



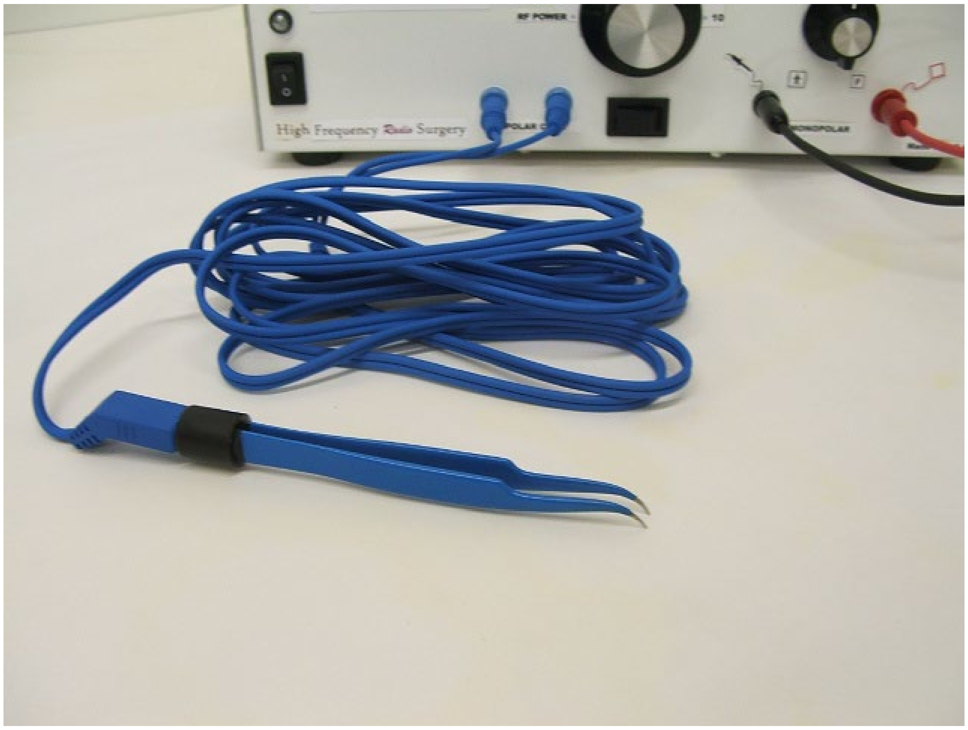
Plug the red dispersive cable into the red dispersive jack on the unit identified by the **F** symbol, and plug the lead from the "Flexi-plate" dispersive plate into the other end of the cable.

Plug the hand piece plug into the active jack on the unit, identified by the **MAN** symbol**.** Insert the electrode required for the procedure at hand into the hand piece chuck. It is necessary to loosen the nose cap a bit. Seat the electrode fully so that no bare metal part of the shaft shows and tighten the nose cap by turning clock wise, being mindful not to remove it. Note*. Between the nose cap and hand piece you will find a rubber O-ring. This O-ring's main function is grip and serves as a safety timeline for hand piece replacement*

When placing the dispersive plate on the patient (or under the patient) the objective is to obtain the maximum coverage with the plate as close to skin as possible. For example, the inner thigh generally has the least hair and is an obvious choice of position. Under the patient is less desirable since blood flow is reduced in the under-side area, however, depending on the surgery planned, this may be the only viable option. Bear in mind also that the heavier the animal, the greater the restriction of capillary flow on the underside, so this is less of an issue for smaller animals.

Note that the plate works by capacitive coupling and does not require a direct electrical contact with skin, nor any kind of gel. In fact, since the plate is fully insulated, direct electrical contact is impractical. This is also a significant protection against electrical shock hazard.

BIPOLAR SET UP



Plug the two leads from the bipolar cable into the two blue bipolar jacks. Plug the bipolar accessory appropriate the case at hand into the cable.

Note that the bipolar plugs will fit the monopolar active jack and the monopolar dispersive jack.

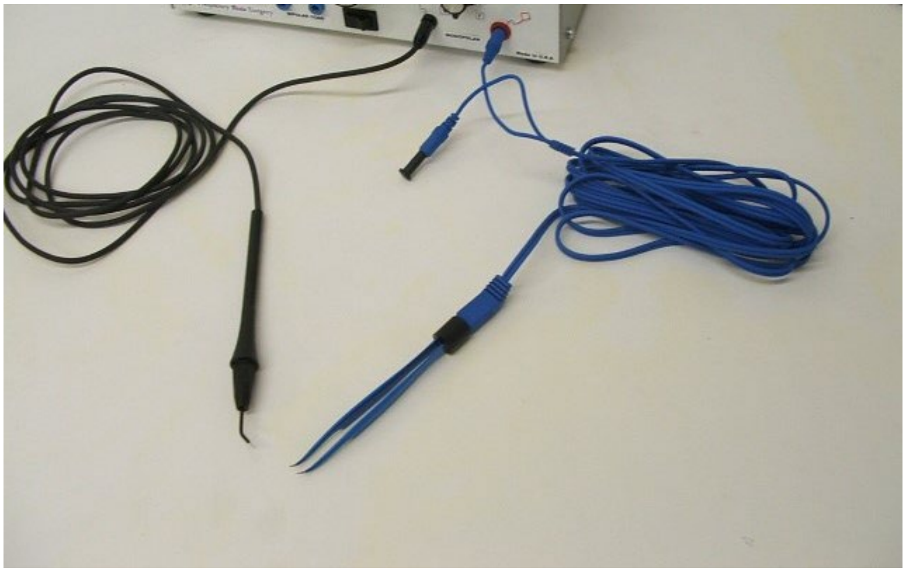
DO NOT MIX THEM UP or else you will not obtain bipolar coagulation, instead, you risk causing serious injury.

The bipolar cable is an industry standard American two pin pattern which allows the use of a wide variety of forceps from different manufacturers to be used. This versatility allows virtually any clinical indication to be addressed. Industry standard disposable bipolar split ball coagulation pens will fit as well as concentric electrode disposable pens.

Both sides of the forceps are electrically active during use. Only insulated types should be used, and these should be routinely examined for wear or damaged insulation. **The use of surgical gloves is also required**. Otherwise, if the surgeon touches bare metal a rather unpleasant tingle or shock may be felt, also there is a small risk of a minor burn.

Whenever the selector switch is moved to BIPOLAR COAGULATION, the unit automatically produces coagulation energy regardless of the waveform selector switch position. This precludes accidentally applying the wrong type of energy to the bipolar forceps.

MONOPOLAR "TWO-POINT" SET UP



By breaking the precaution against plugging the bipolar plug into the dispersive jack, the bipolar forceps become the dispersive plate. Note the insulator on the unused bipolar plug is required because the forcep is electrically active part of the circuit in this case.

The preferred alternative to the bipolar forceps in this use is dedicated monopolar forceps since these afford greater contact surface area and have a single plug eliminating the need for the insulator. The insulation precautions given for bipolar operation apply here as well.

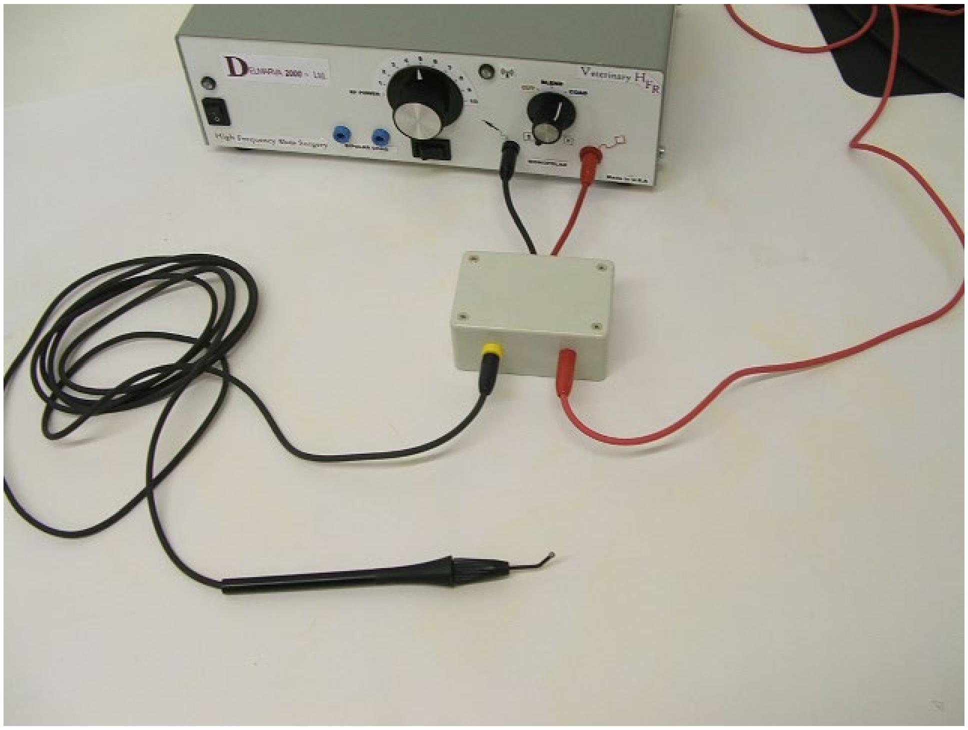
This technique is used for excision where the removed tissue is sacrificed and very tight control of the dispersive current is indicated. Note that the small contact area afforded by the forceps used as a dispersive electrode will induce thermal damage to the excised tissue and is therefore inappropriate for biopsy.

As an example, when a conventional monopolar set up is used for male neutering, sometimes the suture placed at the base of the scrotum "pops" during the procedure. This is caused by a temperature rise in the connective tissue as the dispersive current passes proximally into the body to the dispersive plate (an example of "current crowding" where the small cross section of the intervening anatomy cannot handle the amount of electrical energy applied). In contrast, using the monopolar "two-point" technique, the scrotum is grasped by the forceps acting as the dispersive electrode and current passes distally to the forceps avoiding the connective tissue and eliminating the suture "popping". Thermal damage to the scrotum is irrelevant since the tissue is sacrificed any way.

Good for ear cropping, de-clawing and other common procedures, this technique is especially beneficial in the abdomen where the thin bowel wall is at risk, or in the thorax where the lung is at risk. Also, for small animals where their low body mass does not support much current density.

Note that the proper power setting for this technique is significantly lower than for regular use.

FULGURATION SET UP



(Fulguration Not Included, part #HFR-9)

Plug the two color coded leads from the fulguration adapter into the monopolar jacks on the unit. Plug the dispersive plate cable and hand piece cable into the adapter.

The unit should not be set above “5” for this technique, and the COAG waveform setting is preferred.

Fulguration is the introduction of electrosurgical energy into tissue by means of an electrical arc, or spark. The adapter employs an Oudin coil to boost voltage enough for a useable spark since the HFR 2000 is inherently a relatively low voltage unit. The coil also limits the amount of current available to reduce the risk of injury in the event of accidental tissue contact.

Used primarily to treat dermal lesions, the histological effect of fulguration is to induce superficial tissue desiccation with some coagulation. The depth of coagulum is readily controlled to less than 1mm. This technique is also useful for treating tumor excision sites to address potential metastatic remnants, and is effective for the treatment of enucleated cysts to address residual bacteria.

When the CUT or BLEND waveforms are used, the effect is extremely aggressive. This was once a commonly used approach to necrotize lesions or tumors in situ, however, significant charring often results and this technique must be used with great caution.

BASIC SAFETY PRECAUTIONS

FIRE HAZARDS

Do not use in the presence of flammable anesthetics.

Do not use in the presence of flammable astringents or surgical cements. **Allow fumes to evaporate before applying electrosurgery. Maintain adequate ventilation.**

Do not allow concentrations of oxygen or nitrous oxide to pool in a cavity**. This situation is especially exacerbated when gauze or cotton are present. NOTE PARTICULARLY THAT THE SPACE UNDER A SURGICAL DRAPE QUALIFIES AS A "CAVITY" IN TERMS OF FIRE HAZARD since it provides a space for gas pooling *and* provides combustible material.**

Colon polypectomy is an especially serious situation due to the methane content of endogenous gasses. Fatal explosions have been reported. PROPER PREPARATION IS AN ABSOLUTE ESSENTIAL and so is constant monitoring for the presence of methane gas.

These fire precautions are not unique to electrosurgery, and apply equally to laser surgery and thermal cautery since serious incidents have been reported with the use of those modalities as well under the conditions mentioned.

ELECTROSURGICAL SMOKE

The smoke is generally considered a mild carcinogen and adequate ventilation should be maintained. The use of a smoke evacuator is recommended.

Electrosurgery volatizes bacteria and fungus, however, viruses can survive and may be present in smoke. If it is known that the patient has a viral infection capable of airborne transmission, the use of appropriate filtered masks is recommended in addition to smoke evacuation.

This is not unique to electrosurgery since laser surgery and thermal cautery incision share this.

OCCULECTOMY (eye removal)

This procedure is CONTRA-INDICATED FOR ELECTROSURGERY **since current will follow the optic nerve back to the brain and induce grand mall seizure.**

Although the use of bipolar technique or monopolar "two-point" technique show promise for doing this procedure safely and effectively, their use for this procedure has not been clinically investigated and reported, therefore, this contra-indication should be strictly adhered to.

NOTE

- ***Never coagulate directly in a tooth extraction socket.***
- ***Never preform surgery without proper surgical gloves and a sterile environment.***
- ***Never apply forced monopolar coagulation to bone.***
- ***Never use saline solution as an irrigation fluid during monopolar electrosurgery.***
- ***When an electrosurgery unit suddenly appears to lack power, DO NOT TURN UP THE POWER SETTING TO A HIGH LEVEL UNTIL THE CABLES AND DISPERSIVE PLATE HAVE BEEN CHCKED FIRST.***

Being subject to constant use, the cables have a finite life and can fail unexpectedly causing the symptom above. Similarly, if the dispersive plate is dislodged or unplugged the same symptom occurs. If the unit is turned way up, and a faulty cable or dispersive connection temporarily reconnects, a serious injury will probably result. *If power needs to be increased to compensate for tissue conditions as it sometimes is, do so a little at a time.*

- ***Never use needle monitoring electrodes.***

Although the HFR 2000 complies with IEC 60601-2-2 regulations regarding radio frequency leakage to ensure compatibility with monitoring equipment, needle electrodes are contra-indicated nevertheless. Use pads wherever practical or clips, the larger the contact area the better.

- **Do not defeat the ground connection or use the unit with any type of two pin extension cord or adapter.**
- ***Do not use in the presence of a pacemaker until a cardiologist has been consulted.***
- ***IMPORTANT: IT IS <u>STRONGLY SUGGESTED</u> TO GROUND STAINLESS STEEL OPERATING TABLES TO ELIMINATE ANY POSSIBLE TINGLING SENSATION FROM STRAY RADIO FREQUENCY.***
- ***AVOID TOUCHING ANY METALLIC OR CONDUCTIVE OBJECT IN THE FIELD.***

Any metallic object in contact with the active electrode becomes an extension of the electrode and can induce serious injury as a result. ***<u>Ensure adequate clearance so that a spark cannot possibly jump to the metallic object.</u> DOUBLE THIS PRECAUTION WHEN BIO-ELECTRIC LEADS ARE PRESENT, OR INDWELLING CATHETERS.***

- **Electrosurgery may cause interference with other equipment, adversely affecting the function of that equipment.**

Although the HFR 2000 incorporates a medical grade EMI/RFI filter, surge suppression, and first order RF band pass filtration, never the less, electrosurgery emits powerful radio waves which can adversely affect sensitive unshielded devices.

- **ALWAYS BE VERY CAREFUL OF HANDPIECE OR FORCEPS PLACEMENT, AND NEVER LEAVE A HANDPICE OR FORCEPS LYING ON THE PATIENT.**
- **Have direct view endoscopes, ureteroscopes, and arthroscopes used with electrosurgery checked regularly by qualified personnel for insulation integrity.**
- **DO NOT MODIFY ACCESSORIES OR CABLES FROM THEIR FACTORY CONFIGURATION.**

POWER SETTING

This important aspect of electrosurgery is harder to explain than to do. Perhaps the best analogy is pharmacologic treatment: an insufficient dose will not prove therapeutic; however, an adequate blood serum level will be effective, but an excess level will be toxic. The power setting in electrosurgery follows this analogy when it is thought of as a dose. There is a wide range of "therapeutically effective".

The analogy breaks down in the sense that pharmacologic dose depends primarily on body mass, whereas the correct setting for electrosurgery depends first on electrode size and geometry, then on body mass, then on tissue character. (big electrode = big setting)

The first step in power setting is to make an initial setting based on electrode size. This puts things "in the ball park". A smaller titration is made to accommodate body mass. This puts things in the right section. The last titration to accommodate tissue character puts things in the right seat.

In general, reference to an application chart gives the setting for each electrode size. See the section on incision and excision.

Compensation for body mass is more subjective, however, the logic follows the concept that the closer the electrode is to the dispersive plate, the less the loss and consequently the lower the power setting needed to compensate for loss. Once again, there is a relatively wide range of tolerance here, but the differences are also somewhat non-linear in the sense that there may be less difference in setting between a horse and a large dog, but more between an adult cat and a laboratory rat. In other words, for lower body masses, smaller differences are more significant. Once again, preparing and maintaining an application chart is advised. This becomes especially evident in "two-point" monopolar technique where power setting is much lower than for normal monopolar techniques.

The final titration for tissue character follows the logic that since electrosurgery reacts with cellular water content, lower water content tissue such as fibroids, fat, and cartilage will require a somewhat higher setting than muscle, liver, or gingival. Note that skin falls between the two extremes in the sense that the dryer epidermis differs in character from the vascular sub-dermis, with the epidermis requiring a slightly higher dose and the sub-dermis slightly lower (see the section on incision and excision).

Subjectively, the correct setting for incision and excision is evidenced by an absolutely pressure less electrode motion and freedom from sparking. Any sense of drag on the electrode indicates too low a setting. Sparking indicates too high a setting.

For bipolar coagulation, too much time to achieve tissue blanching indicates too low a setting, and rapid blanching or tissue "popping" indicates too high a setting.

There is one rather counter-intuitive aspect here: if a setting is slightly low, electrode drag will limit stroke speed and more heat will build up in the tissue as compared to a slightly high setting where the electrode is moved briskly along. In other words, too low is more harmful than somewhat too high.

SURGICAL TECHNIQUE

A fair analogy to a golf swing can be made here. A constant swing is used and the flight of the ball determined by the choice of club. In electrosurgery, when a *consistent* stroke speed is employed, the quality of the incision or excision becomes a function of unit settings and the electrode.

Consistency and deft motion are the key to predicable, reproducible results.

Note particularly that the distinction between coagulation surgical technique and incision surgical technique lies in the fact that for coagulation the electrode is held stationary, and for incision it is moved. The point here is that ***for incision or excision the electrode must be kept moving or else the histological effect becomes coagulation.***

Where a long incision is required it is better to break it up into a series of shorter segments allowing deft motion rather than slowing down to make a single motion.

Surgical technique in terms of stroke speed relates to net heat buildup in tissue. If the stroke speed is equal to the inherent parting rate of tissue ahead of the electrode, then the minimum time for heat transfer from the point of generation into adjacent tissue occurs. As the stroke speed is reduced, increasingly more time for heat transfer from the point of generation is occurring. The parting rate ahead of the electrode can approach 50mm per second, the minimum heat limit. The maximum heat limit is where the net heat induced exceeds the ability of the tissue vascular bed to safely absorb and dissipate it. Unfortunately, this limit is rather abrupt, to the effect that exceeding it has dramatic negative consequences.

It may be reasonably inferred that there is a fairly wide safe thermal dynamic range between the two extremes. On the one hand, if one has difficulty "coloring between the lines" due to haste, the stroke speed is getting too high. On the other hand, for pure cut incision or excision, the appearance of coagulum is a sure indicator that the stroke is too slow. Clearly, repeating the same stroke in the same area is contra-indicated UNLESS sufficient time is allowed between strokes for heat to dissipate.

In general, the smaller the electrode the more forgiving since less net thermal input is applied. Conversely, the larger the electrode is, the greater the net thermal input and the use of large electrodes less forgiving and adequate stoke speed more critical.

INCISIONS AND EXCISIONS

Several inter-related factors determine the quality of incision and excisions, and the degree of concurrent hemostasis.

The first is the cutting waveform choice:

> CUT (or “pure cut” in IEC terms) Minimal collateral heat, minimal concurrent hemostasis, and negligible (if any) circatrix formation.
>
> BLEND (or “blended cut” in IEC terms) Significant collateral heat, pronounced concurrent hemostasis, some circatrix formation is expected, from very minor to pronounced, depending on the degree of concurrent hemostasis applied.

The second is the electrode geometry:

> .010” diameter wires induce the least collateral effect
>
> .025” diameter wires induce significant collateral effect
>
> lancet electrodes induce very strong collateral effect

Although the HFR 2000 has a single BLEND setting, it can be seen that by selecting either the CUT or BLEND setting and using one of the three sizes of electrode, there are six distinct levels of concurrent hemostasis available.

The third significant factor in the degree of collateral hemostasis is surgical technique itself. By deliberately using a slow motion, additional heat, therefore concurrent hemostasis, may be induced. This is a technique for experienced surgeons, however, and is not recommended for new users since judgment of the effect is highly subjective and the risk of injury significant.

A working example of how to combine this information is seen in full dermal thickness initial incision. Traditionally, this is done in a single pass with the lancet electrode and BLEND current. It is relatively easy to induce more concurrent hemostasis than is actually required to the effect that healing is delayed as the denatured collateral tissue is absorbed. The alternative is to use a wire electrode and make a partial thickness incision with the CUT current, then switch to the lancet electrode and BLEND current to complete the incision. The net heat induced is thereby lowered resulting in less circatrix formation, and the BLEND current is applied only down in the sub-dermal capillary bed where the extra concurrent hemostasis is required.

As a rule of thumb, for a given incision quality, the net electrosurgical energy required varies non-linearly with electrode size and shape. In other words, a low power setting appropriate for a .010 diameter wire electrode will be inadequate for the .025 diameter wire electrode. The amount of power added to accommodate the .025 diameter wire electrode, if added again to accommodate the lancet electrode, will again be inadequate. There is a greater difference between the lancet electrode and the .025 diameter wire electrode as compared to the difference between the .010 diameter wire electrode and the .025 diameter wire electrode. This is especially significant for smaller patients where the body mass has limited current carrying capability. The smallest electrode possible to achieve the required degree of concurrent hemostasis is always the best and safest choice.

Excision follows the same pattern as incision, i.e., there is a non-linear relationship between loop electrode size and the power required.

BIOPSY is a special case of excision where thermal damage to the sample is a significant issue since thermal artifact can easily render the sample unreadable. The CUT setting is always used for biopsy, and **a deft, sure motion is essential**.

To digress a bit, the exchange of potassium and sodium across the muscle cell membrane is the mechanism for contraction. An electric field applied across the cell will force the chemical exchange and induce contraction. Since this phenomenon takes some time measured in thousandths of a second, and the energy used in electrosurgery reverses polarity in millionths of a second, not enough time elapses to force chemical migration and electrosurgical current does not induce neuro-muscular stimulation. However, like the law, there always seems to be a loop hole. In this case, it is Fourier's Theorem which describes any waveform as a fundamental wave together with the algebraic sum of an infinite series of even and odd harmonics of the fundamental, each with its own relative amplitude. When a spark occurs, the number of harmonics above, *and below,* the fundamental increase in number and intensity in proportion to the strength of the spark. No, electrosurgical energy itself does not induce neuro-muscular stimulation, but sparks most certainly do.

This has consequences in practice which are addressed by the HFR 2000. The "high frequency radio" part of the description relates to the 4.0mHz operating frequency as compared to the typical 350kHz to 1.0mHz operating frequency of general surgery instruments. For the lower frequency units, not much harmonic increase (or sparking to induce it) is required for band spread to reach down into neuro-muscular stimulation range. For the higher frequency employed by the HFR 2000, significantly more harmonic generation (or more sparking if you will) is required to reach down into neuro-muscular stimulation range. The second factor is open loop output voltage. The HFR 2000 is a comparatively low voltage unit, which reduces the propensity to spark in the first place.

Returning to biopsy, at around 5mm diameter to 7mm diameter, is where the HFR 2000 voltage compromise hits a limit. For biopsy using the 1.3cm diameter electrode (HFR-14 OR HFR-15), potentially compromising electrode drag becomes apparent. To overcome this limitation, use the fulguration adapter, and set the unit to CUT and power to "5". The requisite deft pressure less motion becomes possible without risk of sticking, albeit with some increased risk of sparking.

* * SUGGESTION * *

Creating a chart of surgical procedures with a column for procedure, a column for electrode type, a column for waveform setting, and a column for initial power setting is the easiest way to keep track of the variables involved. This allows easy integration of new experience and provides a ready format for editing.

The advice to always use the lowest power setting for the procedure at hand should now make better sense in light of the sparking issue, along with the exception of biopsy where the opposite advice is to always use a high enough setting in light of the electrode dragging issue. Although seemingly contradictory, this is actually an example of how *clinical indication* determines the appropriate configuration, settings, electrodes, and techniques.

COAGULATION

In the past, a variety of monopolar techniques were used to achieve hemostasis, seal vessels, and seal tubes. The most common application was forced monopolar coagulation where a ball electrode was brought into contact with soft tissue and the unit activated. A variation on this technique was to grasp a vessel with a hemostat and contact the hemostat with the electrode to electro-ligate the vessel. Also used was “soft” or “spray” coagulation, a form of fulguration. These have been largely supplanted with bipolar coagulation since it is much easier to control and is effective in wet fields, not to mention that stray current is contained. However, the HFR 2000 is fully capable of performing the traditional techniques whenever clinical indications require them.

Bipolar electro-ligation of vessels and tubes has a subjective aspect to it in the sense that color change is the primary means judging success. Using too high a power setting or applying coagulation current until the vessel “pops” like diced meat in a sauté pan will in all probability result in tissue weakening which will subsequently fail. A correct procedure takes some time, ranging from a second or two for a small vessel up to 20 seconds for a human fallopian tube. Very fast blanching is an indication that the power setting is too high.

Note that vessels over 3mm require suture ligation in addition to bipolar electro-ligation.

There is one common form of forced coagulation in contemporary use which deserves mention: when using a lancet electrode for incision and spot coagulation is required, it is quite easy and effective to select the COAG current setting and apply the broad side of the lancet to the site.

NOTE: When using mono polar coagulation for extended periods, we recommend to periodically remove your foot from the pedal for a few seconds. This will allow the final RF tube and transistors to settle down and cool. Normal coagulation procedures may then continue as usual.

PRACTICE EXERCISE

* * SUGGESTION * *

This is a necessary prerequisite for new users and highly advised even for experienced surgeons to gain firsthand subjective feel for the instrument behavior.

Steak provides a suitable test medium since it is readily available, cost effective, and demonstrates histologic effects. Lamb is suitable; however, pork and chicken do not demonstrate histologic change nearly as well. Liver is a very sensitive indicator of collateral hemostasis. A steak between 1# and 2# is ideal. The less expensive cuts are actually a little better since there is some fat and varying tissue character to work with, and mechanically separating thin narrow strips to practice bipolar coagulation on is easier.

Place 5 cheap kitchen towels folded in half in a plastic bag on the dispersive plate (but not the thick “Bounty” type or fan-fold types). Place the steak on the towels. If the steak is left in a Styrofoam package, unfold the towels. The point here is to simulate body mass and coupling losses, otherwise, the settings observed will be abnormally low in comparison to clinical use.

Practice incision and excision on the steak observing the motion of the electrode and collateral coagulum with different electrodes. Vary the power setting, observe the effects, and practice finding the ideal setting for the various electrodes based on the subjective criteria of free motion with no sparking. Especially do this with loop electrodes and the lancet versus the wire electrodes.

Deliberately do the wrong things and observe the effects. This will give a sense of the tolerances in effect.

Divide the steak in half, or even in quarters, and observe the effect on initial power setting as a result of varying body mass.

Practice the “two-point” monopolar technique both on the whole steak and the divided steak.

Please do note that the electrical losses imposed by the paper towels will place the steak at an elevated radio frequency electrical potential with respect to the dispersive plate. In other words, touching the steak with your bare hands during electrosurgery may give an unpleasant tingle or mild shock, so do beware of this or wear surgical gloves.

The ultimate test exercise is with a fresh cadaver, first, because actual clinical conditions are involved, and second, since neuro-muscular stimulation can be observed.

RESOLVING OPERATIONAL DIFFICULTY

Is the unit working? How do I tell?

If the yellow RF active indicator comes on when the pedal is depressed, the internal mechanism is very probably working correctly.

1) Verify that the selector switch is in the correct position.
2) Verify that the accessories are plugged in correctly.
3) Verify that the electrode is fully seated. (This can be especially problematic when hand pieces other than those supplied by Delmarva are used).

The use of a test medium placed directly on the dispersive plate may be used to verify operation. This can be a hot dog or lunch meat. Lemons and oranges can be used. A bar of Ivory soap will work, too. In that case, a plume of soap foam arising from an incision indicates concurrent hemostasis, and less foaming should occur with CUT than BLEND. Do please note that materials without water content will not work, i.e., the unit will not cut paper, plastic, wood, metal, etc.

The unit works in monopolar, but not bipolar (or bipolar, but not monopolar).

A faulty cable is the most likely cause. Occult conductor fractures may be isolated by doing an electrical continuity test (any electrician or electronic repair shop can do this), or may be disclosed by palpitation. Place the cable over the forefinger and press it with the thumbnail. A soft spot indicates an underlying conductor fracture and the cable must be replaced. Typically, these faults occur within three inches of the ends, unless the cable has been run over by a cart or chair. The cable may also be radiographed.

The power output seems to fluctuate dramatically.

A faulty cable is the most likely cause, however, in this case, an electrical continuity check should also include flexing the cable vigorously during the test to disclose the intermittent connection.

The second probability is that the dispersive plate is being dislodged during surgery. The plate position must remain secure during use to maintain a constant electrical coupling.

The unit won’t come on.

Verify that the unit is plugged into a working outlet, either by trying another appliance in the outlet or plugging the unit into a different outlet.

Verify that the power cord is fully seated into the IEC 320 appliance entry.

Temporarily substitute another power cord or try the medical grade cord from the unit in another appliance.

CARE AND MANTAINENCE

The unit itself may be cleaned with soap and water or mild astringents, however, care should be taken to avoid allowing fluid to enter the cabinet which could result in damage to the unit. The use of sprays is problematic for this reason, however, wetting a towel with a spray solution works well.

AUTOCLAVING

All electrodes and forceps are steam autoclavable, as are the cables. Use Steam autoclave at 275° F and 15 psi for 30 minutes or 30 psi for 15 minutes. These may also be cleaned with germicides prior to sterilizing, however, should be rinsed thoroughly prior to autoclave. Do not soak the accessories as this will adversely affect insulation service life. DO NOT USE DRY HEAT. Damage will occur.

*** * NOTE * ***

The “Flexi-plate” is NOT autoclavable, however, it may be cleaned with germicides. It should not be soaked.

The cables are made with neoprene (monopolar) or santoprene (bipolar) and have something in common with the tires on your car: they wear out with use. *It is strongly recommended that cables be replaced routinely once every two years, at the least to avoid the possibility of failure during a procedure.*

Electrodes typically last for years with proper care. The insulation should be inspected periodically for wear or damage. *Electrodes with faulty insulation should not be used* due to the risk of burn at the exposed metal point.

The small wire electrodes are made with surgical grade tungsten which is brittle, therefore, cleaning should be done carefully with the wire supported on a flat surface to avoid breakage. A mild abrasive such as a paste of dental aluminum oxide may be used to remove oxidation. Fine emery cloth may be carefully used to dislodge stubborn material. DO NOT SCRAPE since nicks will cause fracture during use. Mechanically clean electrodes free of oxides do work more efficiently and will require a slightly lower power setting. The stainless-steel electrodes will tolerate more aggressive cleaning; however, care should be taken not to damage the Teflon insulation.

The one exception to this rule is the lancet electrode: some carbon will build up on the lateral surfaces with use. This actually helps to prevent sticking in use and should be left on with cleaning limited to biologically clean. The leading edges should be mechanically clean, however. Obviously, any detritus should be removed since it is only the thin carbon layer which enhances performance.

Note that the “Flexi-plate” may be placed in a plastic bag for sanitary reasons and applied to the patient with no loss of efficiency or effectiveness.

The foot pedal is IP20 splash-proof rated and is rust proof, therefore, no routine maintenance is required. If, however, the pedal is inundated heavily it should not be used until carefully dried and checked. The consideration here is not the risk of electrical shock hazard since the circuit uses grounded low voltage and has two stages of electronic regulation to limit current, rather, it is the risk of conductive fluid entering the switch mechanism and causing the unit to activate on its own that is significant.

TECHNICAL SPECIFICATIONS

CLASSIFICATION	Class I medical, high frequency surgical, non-ionizing radiation device, type BF ports
CONFIGURATION	Monopolar, isolated output bipolar coag, isolated output
OPERATING MODES	**CUT:** 95%cut, 5%coag, 120watts into 300ohms, +/-10%, crest factor 1.4 **BLEND:** 50% cut 50% coag, blended 105watts into 300ohms, +/-10%, crest factor 1.9 Modulation: 2 x line frequency, 120Hz, sinosoidal **COAG:** 50% duty cycle, 55watts into 300ohms, +/-10%, crest factor 2.6 Modulation: line frequency, 60Hz, sinosoidal **BIPOLAR COAG:** 50% duty cycle, 45watts into 100ohms, +/-10%, crest factor 2.6 Modulation: line frequency, 60Hz, sinosoidal
OUTPUT VOLTAGE	1000V p-p, est. (1.0kVp p-p) in monopolar CUT mode, maximum power setting
SOURCE IMPEDANCE	300ohms, nominal
OPERATING FREQUENCY	4 MHz +/-5%, nominal
POWER CONTROL	Manual analog, continuously variable

OPERATIONAL DUTY CYCLE - Activate the unit for a maximum of 10 – 14 seconds at a time and then allow 20 seconds before the next activation. When activation is less than 10 – 14 seconds, cooling time is also proportionally less, in a 1:2 ratio. When activations are a series of short 2 or 3 second bursts, then cooling time may be ignored.

TEMPERATURE RANGE	-20C to +85C storage, 0C to +40C operating, <80% RH non-condensing
COOLING	convection
SPLASH RATING	IP0
ACTUATION	single foot pedal, IP20 splash-proof, plastic (low voltage: 12Vdc, current limited, grounded)
DISPERSIVE MONITOR	N/A
ACTIVE INDICATION	LED light
POWER REQUIREMENTS	**1**20V 60Hz, +/-10%, 300watts maximum consumption
SIZE AND WEIGHT	11 ¾” w, 4”h, 8 ¼” d, not including controls and jacks. 8# (11# shipping)
WARRANTY	**3** years (exclusive of accessories)

PERFORMANCE CHARTS AVAILABLE UPON REQUEST.

APP. “A” --- PERFORMANCE CHARACTERISTICS CHART
APP. “B” --- RF LEAKAGE CHARACTERISTICS CHART

CLEANING AND CARE

HAND PIECE STERILIZATION AND CARE

The hand piece must be steam autoclave sterilized before clinical use. FDA regulations do not recognize chemical sterilization alone as effective for electrosurgery. Dry heat WILL damage the item.

The hand piece must be visually inspected for cracks or insulation damage prior to use. If any bare metal shows, a crack is evident, or an insulation fault is evident, DO NOT use the item. Failure to observe this precaution represents significant risk of coagulation burn injury to the patient or clinician.

The hand piece must be dry prior to and during use. Frank fluid entering the nose cap represents a burn or shock hazard to the patient or clinician. Minor splashing is not hazardous.

Steam autoclave at 270^0 F (132^0 C) for 15 minutes. The nose cap should be removed during autoclave. Coil the cord loosely when placing in an autoclave bag.

To insert an electrode, loosen the cap by turning counter-clockwise one or two turns. It is not necessary to remove the cap. Do be sure that the electrode fully seats *and no part of the metal shaft shows.* Tighten the cap by clockwise rotation to secure the electrode in place. If electrode fit is a little tight, remove the nose cap and insert an electrode several times to "break in" the combination. ***Do not operate without the nose cap.***

Chemical cleaning to remove detritus and fluid stains in preparation for autoclave may be done with an EPA listed quaternary disinfectant cleaner according to manufacturer's instructions. The hand piece should not be soaked. Rinse thoroughly in clean water after pre-cleaning.

CLEANING ELECTRODES DURING SURGERY

If specks of tissue adhere to your working electrode, its efficiency will be reduced. Since RF energy heats water molecules, electrodes can be "steam cleaned" during surgery. The HFR unit should be set on the "Cut" or "Cut + Coag" waveform. Saturate a 2 x 2 gauze pad with tap water and fold the gauze in half, holding it between the thumb and index finger. With the electrode in the Handpiece, place it between the folds of the gauze. Activate the unit for one (1) to two (2) seconds while moving the electrode back and forth within the gauze using little or no finger pressure. Repeat the procedure if necessary, with a slightly increased power setting (you may hear a "sizzling" sound).

CARE & CLEANING OF ELECTRODES AFTER USE

- ✓ Do not scrub electrodes with a brush or an abrasive.
- ✓ To remove blood or tissue prior to autoclaving, place the electrodes in hydrogen peroxide or in an ultrasonic cleaner for one (1) minute. If carbon deposits cannot be wiped off, use a fine sandpaper disc to expose the metal.
- ✓ Place the electrodes in an electrode holder or stand before placing them in an autoclave bag. Steam autoclave at 275° F and 15 psi for 30 minutes or 30 psi for 15 minutes
- ✓ **NOTE:** If using the HFR-30 Electrode Block **do not exceed 200 degrees F temperature @10 minutes** when you do them all in the Block.
- ✓

PREVENTING ELECTRODE BREAKAGE

- Handle the electrodes by the **insulated shafts only.**
- **Do not bend** Rigid electrodes [this may damage the insulation].
- The correct waveform should be used. **Never** try to cut on the Coag setting.
- The Dispersive Plate should **always be used** [or normal power settings will be too low]. Not using the Dispersive Plate will cause a "drag" and may result in the electrode breaking.
- Always activate the unit **before** making contact with the tissue.
- **Never apply pressure**. Always remember that the radio waves are doing the cutting.
- The power setting is too low if there is resistance, drag, or tissue sticking to the electrode. This may cause bending and breakage. Adjust by raising power gradually.
- The power setting is **too high** if there is sparking [which causes carbonization]. Adjust by lowering power gradually.
- Loop electrodes need slightly **higher power** [adjust up gradually] than straight wires and are more fragile.
- If the electrode gets stuck in the tissue, **do not force** the electrode. De-activate the unit and carefully remove the electrode from the tissue. [In some instances, the electrode will have to be removed from the handpiece first].

TROUBLE SHOOTING

At no time, should the clinician attempt to repair the unit by removing the cover to open. This can be dangerous to both the staff and patients and will **void** the warranty.

Problem: The AC power light is not illuminated when I turn on the machine.

Resolution: Check to see that the unit is plugged in. Check to see that there is power in the wall outlet. If there is no power or if you are not sure, plug the unit into a different wall outlet. Wait for the red light to go out, then activate the foot pedal and see if the RF light (yellow) illuminates. If it does, you have power and may continue use of the unit. (The AC light bulb probably needs replacement). Do not attempt to replace the bulb yourself.

Problem: The AC light is on, but the RF light is not illuminated when I step on the Foot Pedal.

Resolution: Check the position of the Foot Pedal. Be sure it is not upside down and that it is fully depressed when you step on it. Be sure it is plugged in correctly and fully.

Problem: Both the AC and RF lights are illuminated, but there is no cutting or coagulating.

Resolution: Examine the Handpiece Cord near the plug and at the point of attachment to the Handpiece. Feel for a "soft spot" in the insulation with your fingers. This will indicate if there is a break in the wire that conducts the RF energy and the Handpiece/Cord should be replaced.

Problem: Both the AC and RF lights are illuminated, but the electrode tip does not get hot.

Resolution: RF energy never causes the tip of the active electrode to become hot. Heat is produced in the tissue when the tissue offers resistance to that energy. Call Delmarva 2000 at 1(302) 645-2226.

Problem: There is smoke coming from the unit.

Resolution: Do not attempt to use any unit that starts smoking when it is turned on and there is smoke at any time. Immediately turn the unit off and unplug from the wall socket. Call Delmarva 2000 at 1(302) 645-2226.

Problem: I have to turn the power setting much higher than usual to get normal cutting.

Resolution: Check to see that the unit is not set on "Coag". Check for correct Dispersive Plate positioning. Check to see that the Dispersive Plate is attached to the Cord and plugged into the unit. Sometimes assistants wrap the Cord around the Handpiece before placing it into an autoclave bag. This could cause the wires in the Cord to become frayed or broken, preventing the RF from being conducted efficiently. Replace the Handpiece/Cord. Replace the Dispersive Plate Cord if the problem persists.

Problem: My Handpiece is becoming worn, dull and/or corroded looking.

Resolution: This may be due to cleaning with soap or chemicals. Alcohol can be used to remove blood and debris, and the Handpiece/Cord should be autoclaved. The use of barrier handpiece covers is suggested.

Problem: When I use the HFR, I get a buzzing or static sound through my radio speakers and with my personal computer, telephone or lamp dimmer.

Resolution: Try plugging the electrosurgery unit into a different electric socket or change its location if possible.

If you are unsuccessful in resolving any problem, call Delmarva 2000 at 1(302) 645-2226 for service **REFERENCE NUMBER (number must appear on outside of box)**. **<u>LOANERS COMPLIMENTARY DURING WARRANTY PERIOD</u>**. Pack the machine carefully [original packing if possible] or if applicable loaner box, and be sure to include the Handpiece/Cord and Dispersive Plate and Cord [do not send electrodes]. Delmarva 2000 will provide you with a repair estimate after they receive the machine.

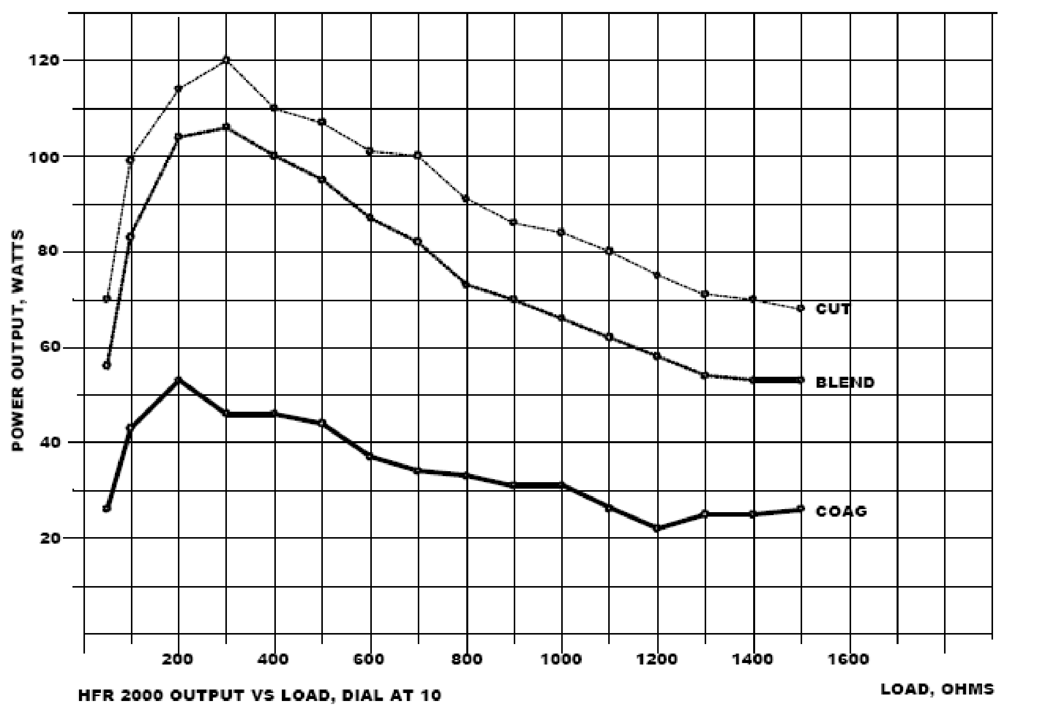
Warranty: Delmarva 2000 provides a THREE (3) year warranty on HFR unit. Be sure to fill out and return the enclosed warranty card to register for warranty coverage.

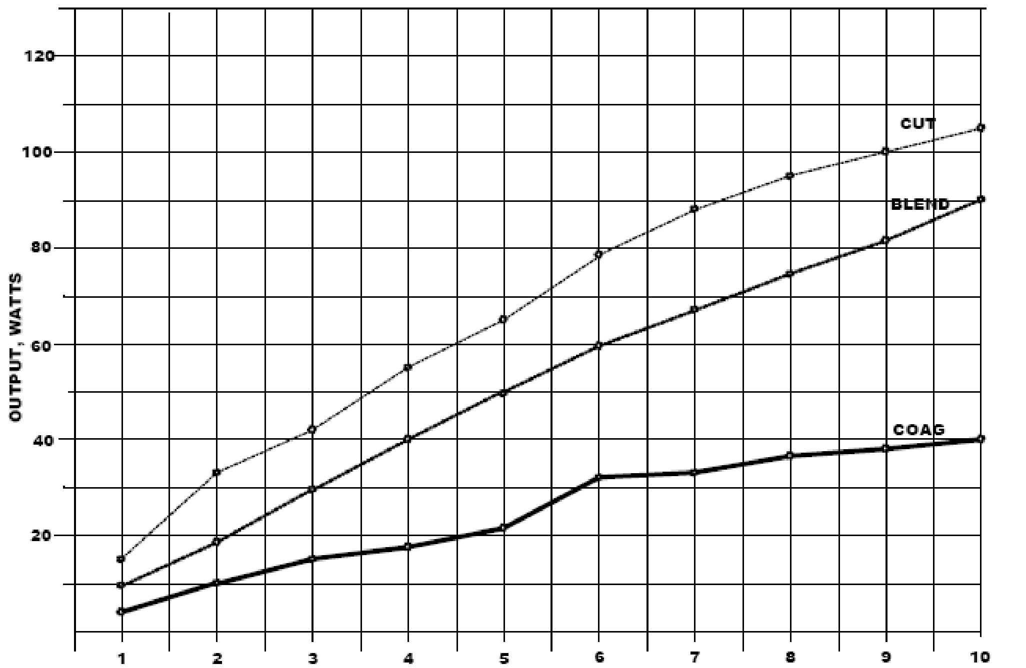
TUNING YOUR UNIT

Your HFR is designed to allow fine tuning of the power output for each patient's tissue resistance. Before your first use, it is highly recommended that you **"tune"** your unit to the optimal starting point so that only minor tuning modifications will be necessary. To do so, choose the room in which you will use your HFR most often. Put the Dispersive Plate on the surgery table and place a piece of beefsteak on the plate to simulate tissue. Turn the unit onto the **"Cut"** mode. Set the power at 4. To open the chuck on the Handpiece, rotate the Nose Cap of the Handpiece several turns counterclockwise, being mindful not to remove it from the hand piece. Place the UF-10 electrode in the Handpiece so that no metal from the shaft is visible. Tighten the Nose Cap by turning it clockwise. Note:. *Between the nose cap and hand piece you will find a rubber O-ring. This O-ring's main function is grip and serves as a safety timeline for hand piece replacement.*

Holding the electrode perpendicular to the beefsteak, activate the electrode by depressing the Foot Pedal and make an incision approximately two (2) mm in depth and one (1) inch long. The power is too high if there is sparking during movement of the electrode [a short spark when the electrode enters or is removed from the tissue is acceptable]. Turn the power down slightly and repeat the cut. If there is drag or tissue adhering to the electrode, the power is too low. Turn the power up slightly and make another cut. This procedure should be repeated and the power adjusted until you have a micro-smooth incision without sparking or drag. The setting that is registered on the Power Dial is your optimal cutting or tuned position, which becomes your starting point for all patients. It is suggested that you take a marking pen and make a small dot at the tuned number [i.e. 4.5]. Depending on factors of the Lateral Heat Formula and your clinical judgment, you may have to make fine tuning adjustments for individual patients.

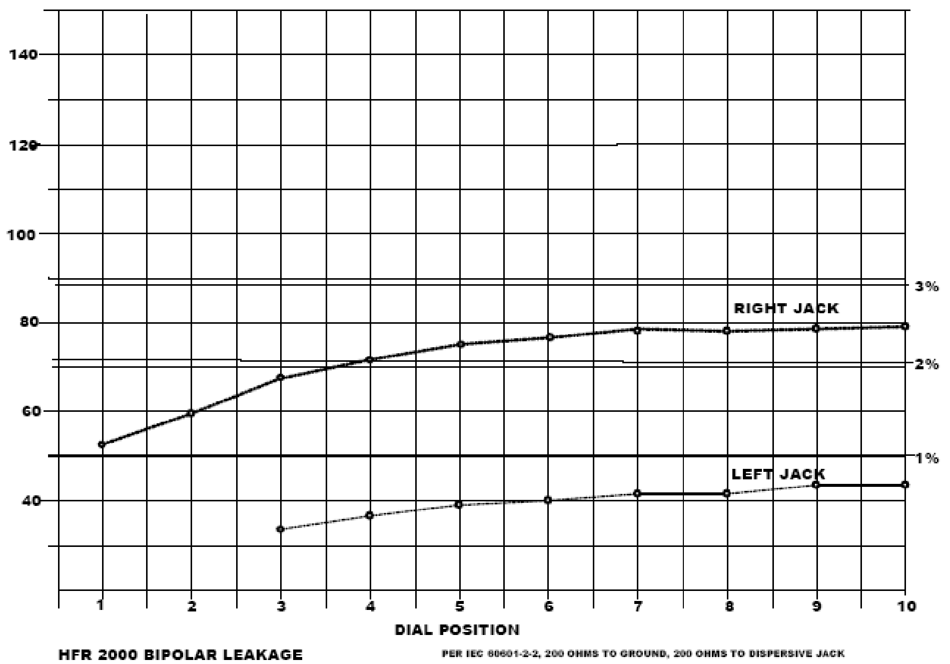
PERFORMANCE CHARACTERISTICS

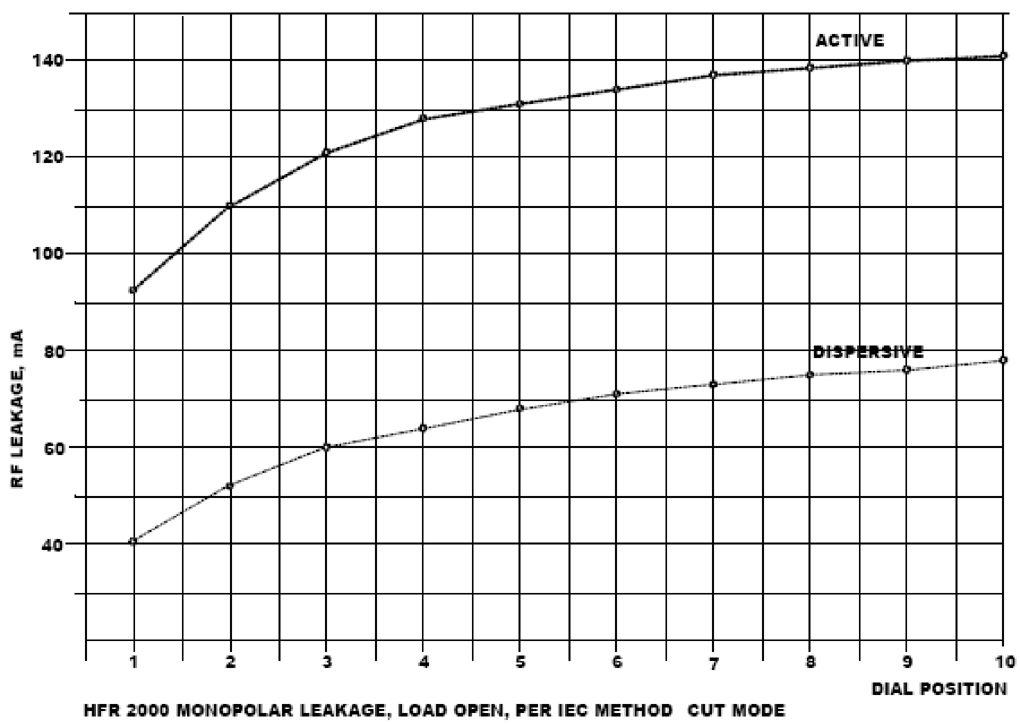




HFR 2000 OUTPUT VS DIAL POSITION, 500OHM LOAD

RF LEAKAGE CHARACTERISTICS





ELECTRODES

***HFR-20** ***HFR-19** *HFR-18 HFR-17 HFR-16 ***HFR-15** ***HFR-14** HFR-13 ***HFR-12** ***HFR-11** ***HFR-10**

***Included with HFR**

<u>SUGGESTED USES:</u>

INCISION: HFR-10, HFR-11, HFR-19
PLANE: HFR-13, HFR-14, HFR-15, HFR-20
DEEP EXCISION: HFR-14, HFR-15
BIOPSY: HFR-14, HFR-15
COAGULATION: HFR-17, HFR-18
ABLATION: HFR-17

<u>NOTE</u>: <u>the above are only suggestions— there are too many variables—please refer to your training; page 17 in your manual; and/or an experienced surgical veterinary doctor.</u>

<u>APP. C</u>