

DELMARVA 2000™

HFR Veterinary Electrosurgical Unit

Owner's Manual



Professional use only

For sale to or on the order of a licensed Veterinary Physician

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IMPORTANT: Read and comprehend this manual before using the Delmarva 2000 HFR Electrosurgical unit clinically

See page 21 - **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.**

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INTRODUCTION – High Frequency Radio Electrosurgical Unit

The Delmarva 2000 HFR electrosurgical generator incises, excises, and coagulates tissue using high radio frequency electrical current. In the cases of incision and excision, the high frequency electrical current causes fluids within the individual cells of which tissue is formed to come to a rapid boil thus causing them to rupture, in turn forming the cut. The electrode tip rides on a cloud of steam and released intracellular fluids resulting in a pressure-less cut. In the case of coagulation actual boiling does not occur, only solidification of cell content. In other words, electrosurgery is a thermodynamic process where heat is generated endogenously within the tissue itself. The electrode tip does not get hot outside tissue. It will not cut paper, plastic, hair, etc., only biological material.

The radio frequency electrical energy introduced into tissue is highly focused; therefore precision surgical intervention with minimal collateral tissue denaturing is practical with the HFR electrosurgical generator. However, all electrosurgical interventions have some degree of collateral tissue denaturing associated with them. It is this characteristic which allows incision and excision with controllable concurrent hemostasis, even in the face of hemolytic compromise, which is why electrosurgery has been a nearly indispensable mainstream surgical device for 9 decades. It is the ability to control the degree of concurrent hemostasis that makes electrosurgery such a versatile technology since all types of tissue from the delicate to highly vascular organs may be effectively surgically treated.

As with all electrical devices, electricity runs in loops. In the case of HFR, the loop begins at the active port (black jack) and travels through the handpiece with integral cable to the electrode tip. *The patient is an active part of the loop.* The dispersive pad picks up the radio frequency current and sends it back to the dispersive port (red jack) thus completing the circuit. Due to its large surface area no heat builds up at the dispersive pad, only at the electrode tip.

Because the patient is an active part of an electrical loop, and because there is great variability among anatomic structures to carry significant electrical current, there exist potential pitfalls in using electrosurgery. However, the decades of clinical experience with electrosurgical technology have identified the potential pitfalls and the means of avoiding them. They are presented within this Manual.

HFR is an “isolated” (a.k.a. “floating”) device which does not recognize electrical “ground.” It will not work without the dispersive pad in place and properly positioned. Because of this feature, radio frequency currents do not seek electrical “ground” through EKG electrodes, pulse oximeters, apnea monitors, etc., thus giving full human device safety against the risk of remote site burns within the modern and complex veterinary operating theatre where the concurrent use of multiple medical electrical devices is common.

GENERATOR SET UP

CAUTION: DO NOT OBSTRUCT THE COOLING VENTS ON HFR SINCE IT RELIES ON CONVECTION (ROOM AIR) FOR COOLING. THERE ARE NO FLAMMABLE 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.

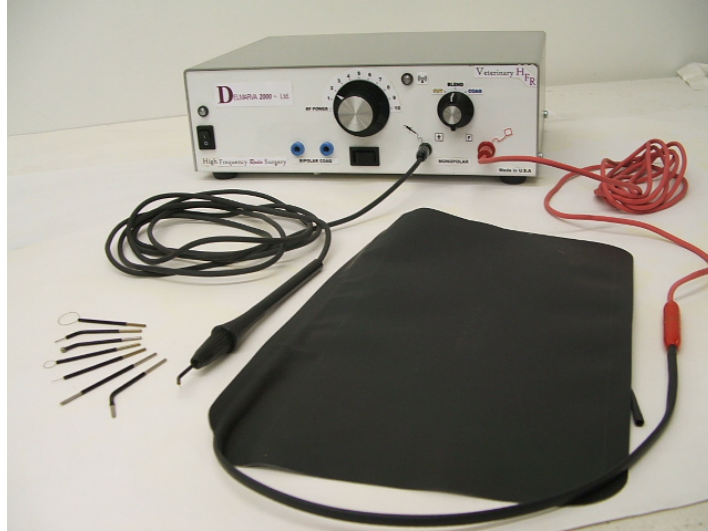
Connect the foot switch to the unit. Note that the widest key on the plug faces UP. Do not force it. Once the plug is in, turn the locking ring clockwise to secure the plug. It takes about 1 turn.



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

Allow 40 seconds for stabilization before activating the unit.

MONOPOLAR SET UP

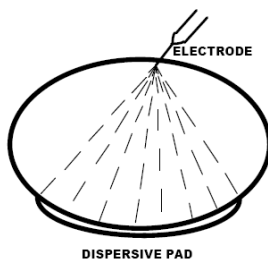


Plug the red dispersive cable into the red dispersive jack on the unit identified by the plate symbol, and plug the lead from the dispersive pad into the other end of the cable. These plugs differ and cannot be mixed up.

Plug the grey hand piece plug into the black active jack on the unit, identified by the hand piece symbol. ****(It may not seat completely – this is ok.)**** Insert the electrode required for the procedure at hand into the hand piece chuck. It may be necessary to loosen the nose cap quite 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.

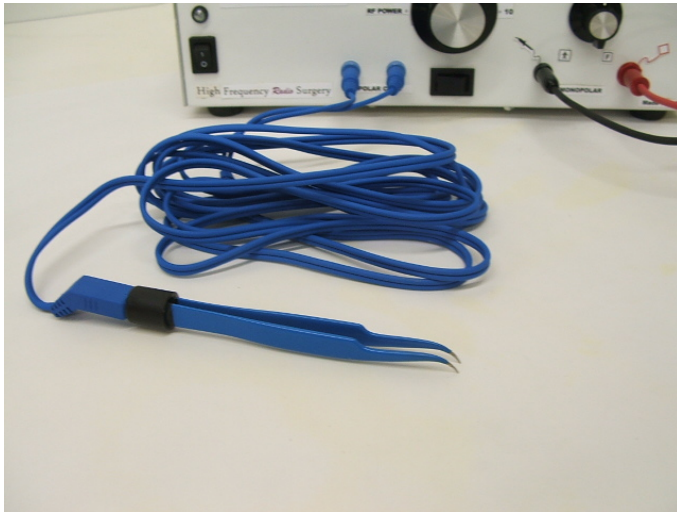
The dispersive pad works by capacitive coupling and **does not require a direct electrical contact with skin, nor any kind of gel.** In fact, since the plate is fully insulated, direct electrical contact is impractical. This is a significant protection against electrical shock hazard. **However, the pad is not autoclaveable, therefore should be placed in a clean plastic bag to preclude cross infection.**

Please see the “Dispersive Pad Placement” section for full advice.



Monopolar RF current flow through the patient

BIPOLAR SET UP



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

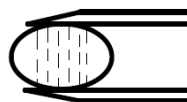
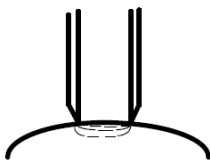
DO NOT MIX THEM UP WITH THE MONOPOLAR JACKS or else you will not obtain bipolar coagulation. Instead, you risk causing serious injury.

The bipolar cable is an industry standard American “two pin pattern” which allows the use of a wide variety of forceps to be used. This versatility allows any clinical indication for bipolar to be addressed.

Both sides of the forceps are electrically active during use. These should be routinely examined for wear or damaged insulation. The use of surgical gloves is also recommended. Otherwise, if the surgeon touches bare metal a rather unpleasant tingle or shock may be felt.

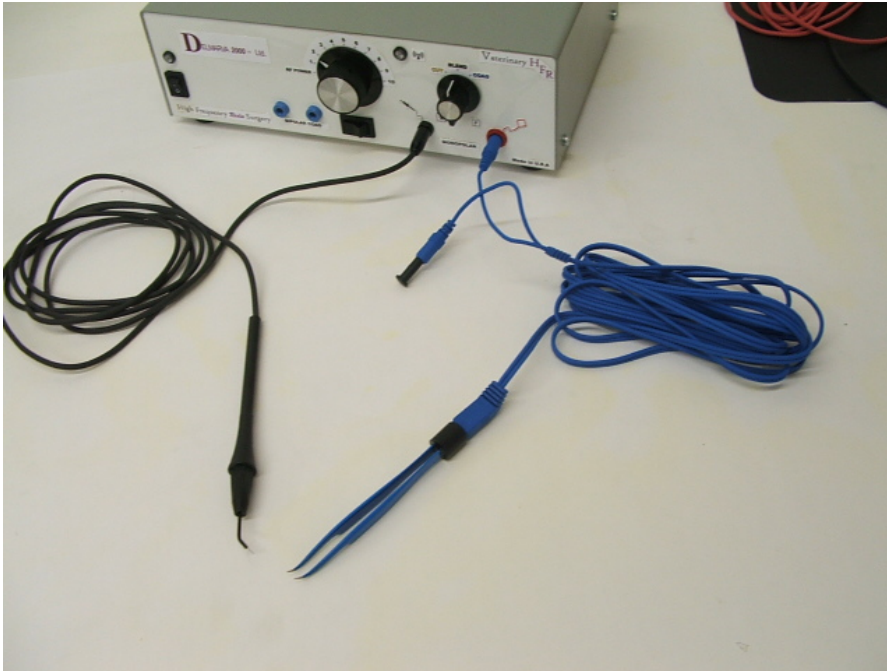
Whenever the selector switch is moved to BIPOLAR, the unit automatically produces coagulation energy regardless of the waveform selector switch position. This precludes accidentally applying the wrong type of energy to the bipolar forceps.

If the tips of the bipolar forceps touch, no proper physiological effect to tissue will occur. Be sure to grasp tissue between the forceps tips.



Bipolar RF current flow through the patient

MONOPOLAR “TWO-POINT” SET UP

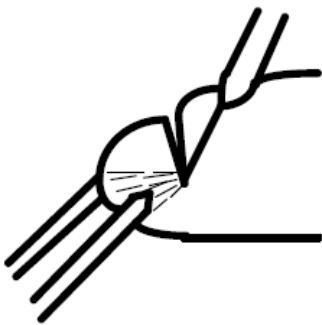


The monopolar forceps cable plugs into the red dispersive jack and the monopolar hand piece into the black jack. The monopolar forceps becomes the dispersive electrode and no dispersive pad is used.

The electrosurgical current introduced at the active electrode tip returns to the generator through a very small cross section of anatomy and not through the larger portion of the body.

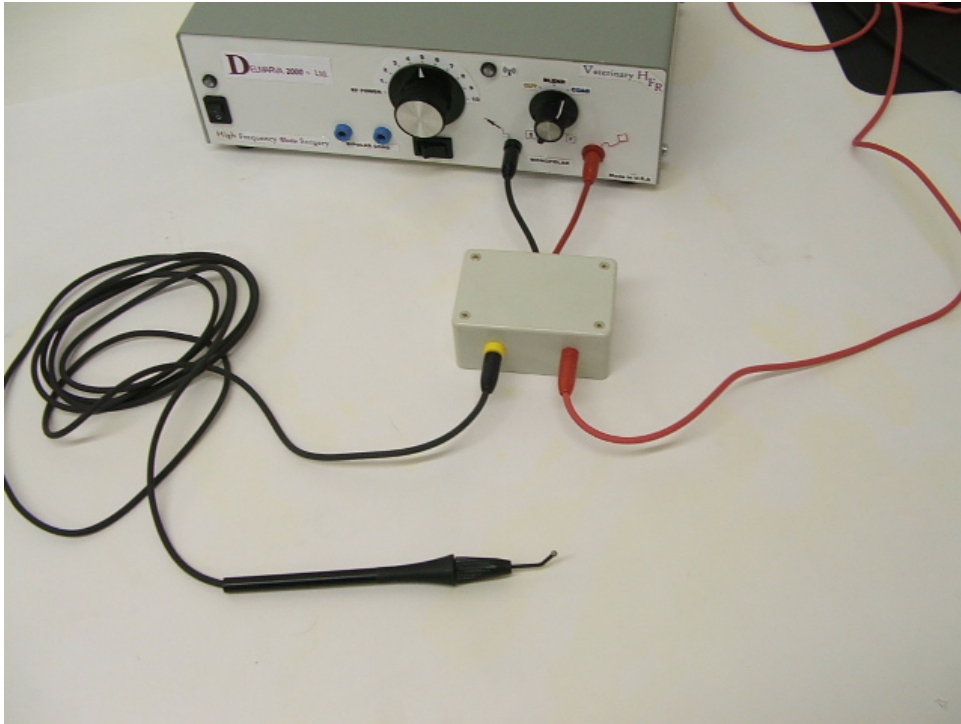
This technique is used for excision where the removed tissue is sacrificed and very tight control of the dispersive current is indicated. The small contact area afforded by the forceps used as a dispersive electrode will induce thermal damage to the excised tissue and is therefore inappropriate for biopsy.

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



Two-Point technique RF current flow through the patient

FULGURATION SET UP



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.

HFR is relatively low voltage electrosurgical generator thus the use of the fulguration adaptor is necessary to raise output voltage sufficiently to use sparking to desiccate or necrotize lesions.

SUMMARY OF BASIC OPERATION

- 1) Turn on the unit, allow 40 sec for stabilization after initial turn on before activating it
- 2) Place the dispersive pad (unless you are absolutely sure you will not need it)
- 3) Set up monopolar, bipolar, or “two-point” technique according to the intended procedure
- 4) Select the intended histological effect (CUT, BLEND, COAG knob)
- 5) Establish the initial power setting according to electrode size (RF Power knob)
- 6) Step on the foot pedal to activate the unit (produce radio frequency energy)
- 7) Perform the surgical step and release the pedal

SAFETY PRECAUTIONS (required by FDA Guidance “Premarket Notification 510(k) Submissions for Electrosurgical Devices for General Surgery”)

FIRE HAZARDS

NEVER use in the presence of flammable anesthetics.

NEVER use in the presence of flammable astringents or surgical cements. Always allow fumes to evaporate before applying electrosurgery. Maintain adequate ventilation.

NEVER 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 highly recommended.

Electrosurgery volatilizes 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 highly 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.

****NOTE****

- **Never coagulate directly in a tooth extraction socket.**
- **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 CHECKED FIRST.**

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 insure compatibility with monitoring equipment, needle electrodes are contra-indicated never the less. Use pads 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.**
- ***NEVER use in the presence of a pacemaker until a cardiologist has been consulted.***
- **IMPORTANT: IT IS STRONGLY SUGGESTED TO GROUND STAINLESS STEEL OPERATING TABLES TO ELIMINATE ANY POSSIBLE TINGLING SENSATION FROM STRAY RADIO FREQUENCY ENERGY. Alternately, place a thick pad on the table to provide electrical isolation and place the dispersive pad on top of this.**
- **ALWAYS 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. **Insure adequate clearance so that a spark cannot possibly jump to the metallic object. DOUBLE THIS PRECAUTION WHEN BIO-ELECTRIC LEADS ARE PRESENT, OR INDWELLING CATHETERS.**

- **Electrosurgery can 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 HANDPIECE OR FORCEPS LYING ON THE PATIENT.**
- **Have direct view endoscopes, urethroscopes, and arthroscopes used with electrosurgery checked regularly by qualified personnel for insulation integrity.**
- **DO NOT MODIFY ACCESSORIES OR CABLES FROM THEIR FACTORY CONFIGURATION.**

ALWAYS use the lowest RF power setting necessary to perform the surgical intervention.

THE ELECTRODE TIP WILL BE HOT AFTER SURGERY. Be very careful when placing the handpiece after use. Allow cooling time after use before changing electrodes.

SURGICAL TECHNIQUE

Consider this example: when moving one's hand briskly over a lit candle, hardly any sensation is noticed. However, as movement is slowed down, the sensation of heat becomes increasingly more painful until one slows down to the point that a burn is induced. This is a fair analogy for electrosurgical incision and excision. Several significant points follow for effective incision and excision.

Keep the electrode moving. Do not stop.

Do not repeat a stroke in the same area until 5 seconds have elapsed in order to allow the capillary bed to dissipate the heat before adding more.

Maintain a minimum stroke speed of 5 to 7 mm per second. (more is better)

Maintain as consistent a stroke speed as humanly possible.

Please note that a finite minimum amount of heat must be introduced into tissue in order to achieve volitization, otherwise, incision or excision cannot occur. In other words, tissue heat cannot be controlled by "dialing down" the electrosurgical generator power setting. This leaves surgical technique as the primary means of heat control.

Speed is the variable by which gross tissue heat is controlled in incision and excision. However, speed and accuracy are generally mutually exclusive in terms of human endeavor. Therefore, when doing longer incisions it is advised that these be divided up into as many shorter sections as necessary in order to achieve adequate accuracy while maintaining sufficient minimum stroke speed.

Remember, a high stroke speed is harmless thermo-dynamically since electrosurgical incision can easily proceed at speeds of 50 mm per second. **It is excessively slow motion that induces excess heat into tissue, and this error is one of the leading causes of poor electrosurgical clinical results.** Collateral tissue denaturing width during incision and excision increases non-linearly as incision speed decreases below 5 to 7 mm per second. The threshold between mediocre result and injury is rather abrupt, and the only way to avoid it is to maintain a steady adequate surgical technique at all times. Clearly, for those not experienced with electrosurgery, some practice before clinical use is very strongly advised.

It cannot be overemphasized that the key to predictable clinical results is consistent surgical technique.



Too slow. Excess collateral coagulum is evident, which only delays healing



7 mm/sec speed. This incision quality promises fast scar free healing.



The bottom incision was made at a power setting of 8 which should have caused havoc but which did not because of high stroke speed

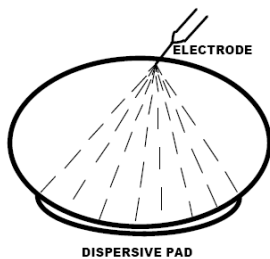
RECOMMENDED TECHNIQUES FOR VARIOUS ANATOMIC STRUCTURES

anatomic structure	incision, excision	hemostasis, coagulation
initial incision	monopolar	monopolar, bipolar forceps
large organs, open surgery	monopolar, two-point	monopolar, bipolar forceps
oral, dental	monopolar	monopolar * bipolar forceps @
pedicularly attached #	two-point	bipolar forceps
thoracic	two-point preferred	bipolar forceps preferred
abdominal	two-point preferred	bipolar forceps preferred
dermal lesions	monopolar, two-point	monopolar, bipolar forceps
eye lid, aesthetically significant	monopolar	monopolar ("soft" pin point)
laparoscopy (with instrument)	-----	bipolar (with instrument)
amputation (also de-claw)	two-point preferred	bipolar forceps
male neutering	two-point	bipolar forceps
female neutering	two-point	bipolar (instrument or forceps)

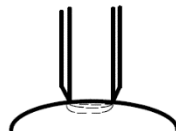
* NEVER on exposed bone @ safe on exposed bone

kidney, testes, ovaries, gall bladder, penis, extremity (the smaller the patient the more critical)

Take into account how RF current goes through the patient when selecting the best technique for the case at hand so as to avoid "current crowding" in thin cross section anatomy.



Monopolar



Bipolar



Two-point

ESTABLISHING VARYING DEGREES OF CONCURRENT HEMOSTASIS

While the quality of RF current (cut, blend, coag) is the primary factor in establishing the degree of concurrent hemostasis accompanying an incision or excision, electrode geometry also has a very significant effect. There are 6 degrees of concurrent hemostasis possible with HFR:

CUT RF Current

ELECTRODE	HEMOSTASIS	COLLATERAL DENATURING	
M-10 thin wire	minimal	minimal	see note 1
M-53 thick wire	significant	moderate	see note 2
M-72 lancet	strong	significant	see note 3

BLEND RF Current

ELECTRODE	HEMOSTASIS	COLLATERAL DENATURING	
M-10 thin wire	significant	moderate	see note 4
M-53 thick wire	strong	significant	see note 5
M-72 lancet	very strong	profound	see note 6

- 1 thin delicate tissue (eyelid, gingiva), epilation, biopsy, infants, laboratory animals, avians
- 2 thin dermis (infants, laboratory animals, avians), small animal vascular organ (hepatic, renal)
- 3 initial incision adult canine, vascular organs (hepatic, renal, spleen)
- 4 gingiva, oral mucosa, thin dermis (infants, laboratory animals, avians) infant vascular organs
- 5 canine, feline initial incision; feline, canine vascular organ; extreme hemostasis in infants
- 6 adult canine extreme concurrent hemostasis in vascular organs, large animals

Choice is a matter of clinical judgment. Adding too much concurrent hemostasis initially will only increase healing time and add scarring. **Use a conservative choice since touching up minor hemorrhagic response is relatively easy but excess collateral tissue denaturing cannot be undone.**

MONOPOLAR INITIAL RF POWER SETTING (in muscle)



M-10 M-53 M-72 M-12 M-34 M-45 M-31 M-51 M-52

incision

	CUT	BLEND
M-10 thin wire	2 ½ - 3	3 - 3 ½
M-53 thick wire	6 - 6 ½	6 ½ - 7
M-72 lancet	7 ½ - 8	8 - 8 ½

plane

	CUT	BLEND
M-12 thin wire, bent	6 - 6 ½	6 - 6 ½
M-31 triangle loop	6 - 6 ½	6 ½ - 7
M-34 9,5 mm loop	5 - 5 ½	5 - 5 ½
M-45 12,5 mm loop	6 - 6 ½	6 ½ - 7

deep excision

	CUT	BLEND
M-34 9,5 mm loop	8 - 8 ½	8 ½ - 9
M-45 12.5 mm loop	9 ½ - 10	9 ½ - 10

biopsy

		CUT	BLEND
M-34	9,5 mm loop	7 ½ - 8	not recommended
M-45	12,5 mm loop	9 ½ - 10	not recommended

coagulation

		"hard"	"soft"
M-51	small ball	4 ½ - 5 COAG current	4 - 4 ½ COAG current
M-52	large ball	6 ½ - 7 BLEND current	4 - 4 ½ BLEND current

ablation

		CUT	BLEND
M-51	small ball	3 ½ - 4	4 - 4 ½

TWO-POINT INITIAL SETTINGS (in muscle)**incision**

		CUT	BLEND
M-10	thin wire	1 ½ - 2	2 - 2 ½
M-53	thick wire	2 - 2 ½	3 - 3 ½
M-72	lancet	3 - 3 ½	4 - 4 ½

excision

		CUT	BLEND
M-34	9,5 mm loop	3 - 3 ½	4 - 4 ½
M-45	12,5 mm loop	3 - 3 ½	4 - 4 ½

BIPOLAR COAG INITIAL SETTINGS (in muscle)

	RF power (COAG)	approximate time
small vessel 1 – 2 mm	2 – 2 ½	1 – 1 ½ seconds
larger vessel, tube	2 – 2 ½	2 - 3 seconds
large area (surface)	4 *	varies **

*brushing the surface of tissue with upside down curved forceps with tips held 3 mm apart

**coagulum should begin to appear in about 1 ½ - 2 seconds. If not, increasing RF power to 4 ½ is suggested.

NOTE: wet fields may require initial bipolar COAG settings about ½ to 1 number higher.

MONOPOLAR COAGULATION EXAMPLES



"hard" coagulation with large ball using BLEND current



relative depth "hard" vs. "soft" with large ball and BLEND current



"hard" vs. "soft" with small ball using COAG current

Monopolar coagulation may be done with coag RF current or, if necessary for greater hemostatic effect, blend RF current may be employed particularly with the large ball electrode.

Remember that monopolar coagulation is marginally effective at best in wet or bloody fields. It is good practice to sponge the surgical site as dry as practical when necessary when doing monopolar coagulation.

TITRATING RF CURRENT POWER SETTING FOR OPTIMAL EFFECT

Electrode size and geometry are the major determining factors for how much RF current is needed as a function of active electrical surface is in contact with tissue. **Different tissue types require adjustment from the initial settings shown for muscle, particularly vascular organs which take a lower setting.** Actual conditions in the operatory also vary, hence the need to titrate RF power setting on a case by case basis.

- Way too low a setting will not incise, it will only induce coagulation burn
- Too low a setting will cause the electrode to “drag” and tissue detritus will adhere
- A slightly low setting will allow protein deposits to form on the electrode with slight adhesions

A proper titration allows free electrode motion without sparking, adhesion, or deposits

- A slightly high setting shows some sparking
- Too high a setting sparks noticeably and induces unnecessary extra collateral coagulum
- Way too high a setting sparks fiercely, induces significant collateral desiccation, and carbonizes the electrode

Remember to always use the lowest RF power setting necessary to perform the surgical intervention.

Suggestion: Taking notes on what settings work best for which procedures and which anatomic structures will help to gain experience and save time in future use.

Highly recommended: practice with beef steak or a fresh cadaver before using HFR clinically.

SPARKING

Radio frequency electrical currents do not induce neuro-muscular stimulation. However, when active sparking occurs during incision and excision other frequencies enter the picture as a byproduct of the spark as a function of Fourier’s Theorem. **The worse the sparking the more byproduct frequencies are generated and these unwanted byproducts can and will induce neuro-muscular stimulation.**

It is therefore imperative that RF power setting be titrated for minimal sparking while still producing good clean incisions and excisions.

Of course the above refers to incision and excision, not to “soft” coagulation or fulguration.

PLACING THE DISPERSIVE PAD

Because electricity runs in a loop it is imperative that the dispersive pad be properly positioned in order to complete the circuit.

IMPORTANT

It is essential that the maximum possible surface area of the pad is covering the patient.

The dispersive pad operates by capacitive coupling and does not require contact with bare skin to function. It was designed for human use in outpatient clinical specialties where the patient does not disrobe and has to function effectively through street clothing. This feature makes it excellent for veterinary service because of fur. Its flexibility allows it conform to the patient's body shape.

The dispersive pad is not autoclaveable; therefore, to prevent biological cross contamination it should be placed in a clean plastic bag before being placed on the patient.

The ideal placement as a general rule is over a large well vascularized muscle mass.

For adult canines this is inside the thigh.

For bovines and equines, since they are so muscular, almost anywhere close to the surgical site is appropriate. The pad may be wrapped around a leg above a surgical site.

However, for smaller animals this is not practical. For smaller animals place the dispersive pad in the valley of "V" shaped foam bed and place the animal on top of the pad. Bring the sides of the pad up around the animal as much as practical to insure that as much contact area as possible obtains.

THE TWO LEADS ON THE DISPERSIVE PAD

One of them has a plug to go into the red dispersive cable. The other is there for convenience: like the strings on an apron, they can be pulled together to hold the pad in place, for example, wrapped around a patient's leg and held together with plastic surgical drape clip.

TINGLING FROM A STAINLESS STEEL OPERATING TABLE

The dispersive pad is electrically active at radio frequency owing to the "isolated output" configuration of HFR. Because of capacitive coupling some radio frequency energy will transfer to the table, hence, to anyone touching the table. There are two ways to address this:

- Place a thick surgical pad on the table to reduce capacitive coupling, place the dispersive pad on that, and then the patient. (inherent when using a foam "V" bed for small animals)
- Connect the table to the building electrical system "ground" with the shortest wire possible.

CLINICAL APPLICATION NOTES

Take serious heed of the fire safety warnings regarding oxygen and nitrous administration and flammable astringents, disinfectants, and cements

When using irrigation, use distilled water since saline is conductive and RF current may follow it

Never attempt oculoectomy with electrosurgery

When doing eyelid surgery, always use corneal shields

The use of a smoke evacuator is highly recommended

When performing amputation at a joint, electrosurgery can sever connecting tissue and control bleeding. However, when it is necessary to cut a bone between joints, use mechanical means to sever the bone since electrosurgery cannot cut bone. To stem hemorrhagic response from severed bone, use bone wax. The application of monopolar electrosurgery directly to bone is contra-indicated.

HFR is well suited to dental surgery. Use slightly lower initial power settings than given for muscle since gingiva are delicate tissues. Never coagulate directly in an extraction socket since underlying bone will be injured. HFR cut current is effective for gathering donor graft tissue from the palate, however, use medicaments to seal the donor site and not electrosurgical monopolar coagulation due to risk of injury to the underlying bone. If hemorrhagic response exceeds medicaments to control it, use bipolar coag.

TWO POINT NOTES



An injury to a pediculated organ during monopolar electrosurgery is simulated here. A relatively high energy setting appropriate to the lancet electrode and BLEND current was used. The entire cross section of the pedicle was coagulated abruptly in a fraction of a second. In actual practice, the organ would be lost with possible fatal outcome.

The Two-Point technique is fully effective at avoiding the above “bad example” because RF current does not go proximally into the patient’s body via the delicate attaching tissues, instead moves distally into the monopolar forceps. It is the recommended technique for:

- Male neutering
- Removing “proud flesh” from equines and bovines
- Excisions on extremities
- Declawing cats
- For animals which are too small to provide good contact with the dispersive pad (use in conjunction with bipolar coagulation in such cases)

STERILIZATION AND CARE OF ACCESSORIES

Electrodes and handpiece must be steam autoclaved at 132 C (270 F) for 15 minutes followed by 15-30 minutes drying time before each use. These parameters have been validated by accredited Laboratory.

FDA does not recognize quaternary disinfectants as effective for sterilizing electrosurgical electrodes and accessories. **Should one ignore the above instructions and soak the handpiece anyway, the handpiece will fail in service due to a reaction between the quaternary disinfectant and the handpiece material induced by the RF current in the handpiece placing the surgeon at risk of burn or shock.**

Accretions of proteins develop on the electrode contact surfaces in normal use and these must be removed from time to time in order to maintain conductivity. Because electrodes come into intimate contact with living tissue the clinician cleaning them must take proper precaution against cross infection, namely, gloves and using a quaternary disinfectant to treat the electrodes prior to mechanical cleaning. The quaternary disinfectant used in this step is for the protection of the clinician and not a substitute for autoclave, nor necessary for autoclave. Rinse in clean water before autoclave.

Electrodes must be mechanically clean showing bare metal on the shaft which goes into the handpiece and the metal portions which contact tissue. Use Scotchbrite™ “maroon” pads to remove the accretions. Place the electrode on a solid surface to avoid bending the wires and gently scrub off the accretions. The disinfectant mentioned above is also useful for softening stubborn accretions (be sure to rinse); dip but do not soak the electrode. **Do this before autoclaving.**

Inspect electrodes for any signs of wear or damage to the insulation prior to autoclave. If any compromise is evident, DO NOT use the item; discard it appropriately and replace it.

Inspect handpieces for any signs of wear or damage prior to autoclave. If any compromise is evident, DO NOT use the item; discard it appropriately and replace it.

Inspect the dispersive pad for any signs of wear or damage as part of the electrode sterilization routine. If any bare metal is evident, DO NOT use the item; discard it appropriately and replace it.

Handpieces are a service item subject to wear in normal use and have a finite service life. Routine replacement is imperative. Once annually is recommended. In no case should a handpiece be used more than two years.

Dispersive cables are a service item subject to wear in normal use and have a finite service life. Routine replacement is imperative. Once annually is recommended. In no case should a dispersive cable be used more than two years.

Dispersive pads are a service item subject to wear in normal use and have a finite service life. Routine replacement is imperative. Once every two years is recommended.

Remember, **the dispersive pad is not autoclaveable.** It should not come into direct contact with tissue anyway; however, **it may be cleaned with quaternary disinfectant as needed.** Use a cloth to apply the disinfectant and to perform clean water rinse. DO NOT soak the dispersive pad. Allow it dry before use.

OPERATIONAL DUTY CYCLE

The Delmarva 2000 HFR electrosurgical generator produces powerful RF currents which develop significant heat in the internal electronics. Adequate cooling time between activations is imperative in order to prevent overheating the electrical components.

Failure to adhere to the Operational Duty Cycle of 10-14 seconds ON followed by 20 seconds OFF may cause damage to the internal electronics and subsequent failure of the electrosurgical generator.

HFR has an audible tone which sounds during activation. After approximately 10 seconds of operation the tone changes pitch and volume to alert the operator that duty cycle limitation is at hand.

The duty cycle is not electronically enforced and adherence to the duty cycle is entirely in the hands of the operator. This is out of respect for professional clinical judgement where some *short* ON time beyond the duty cycle is necessary to effect surgical treatment, in other words, the patient comes first. However, any time the HFR is activated beyond 10 seconds allow an extra 10 seconds cooling time before the next activation.

Because of the duty cycle limitation, HFR is not suitable for juvenile pubic symphysiodesis in dogs.

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.

RESOLVING OPERATIONAL DIFFICULTY

Unit fails to turn on. (no green light)

- Verify that the electrical outlet is functional by plugging in another appliance known good.
- Verify that power cord is firmly seated in the appliance entry. page 4

HFR turns on OK, but unit will not activate. (no yellow light)

- Verify that the foot pedal connector is attached and seated properly. page 4
- Verify that the foot pedal cord is not damaged.
- Check foot pedal for obvious faults: does it “click” when pressed ?

Sometimes depressing the foot pedal activates the unit, sometimes not.

- If the foot pedal is depressed on the extreme corners it may not “click”. Be sure to step on it squarely and as fully as practical to avoid this annoyance.

The yellow “active” indicator comes on OK, but I get no cutting.

Verify that the dispersive pad is plugged in at the patient and at the unit.	page 5
Verify that the electrode is clean (bare metal showing in the tissue contact area)	page 20
Verify that the electrode is fully seated and insulation is not caught in the chuck.	page 5
Verify that the dispersive cable is undamaged and functional.	This page
Verify that the hand piece cable is undamaged and functional.	<i>This page</i>

Poor operation (weak or erratic)

- Verify that proper initial power setting for the electrode selected is established. page 14-16
- Verify that COAG has not been inadvertently selected for an incision or excision. page 14
- Verify that excessively heavy, thick fur is not adversely affecting dispersive efficiency page 18
- Verify dispersive pad positioning page 18
- **Keep electrodes clean** page 20

VERIFYING CABLE INTEGRITY

Applicable to the handpieces with integral cable, dispersive cable, bipolar cable, and monopolar forceps cable, the preferred method is to perform an electrical continuity test. Any commercial electronic repair facility can do this at nominal cost and so can most automotive repair facilities.

An alternate method is to X-ray the cable to reveal optically any occult fracture in the cable conductors inside the insulation. Conductor fractures tend to occur within the first 15 cm of the ends of cables, therefore radiographic examination of the entire cable should not be necessary.

Examine any suspect cable for any signs of damage to the insulation such as occur when cables are caught mechanically by hydraulic tables or run over by heavy carts, for example. When any such insulation damage is seen, dispose of cable appropriately and replace it.

It is highly recommended that spare cables be kept on hand at all times in order to prevent rescheduling elective procedures due to faulty cable or else being forced to use inferior less effective techniques in emergency care.

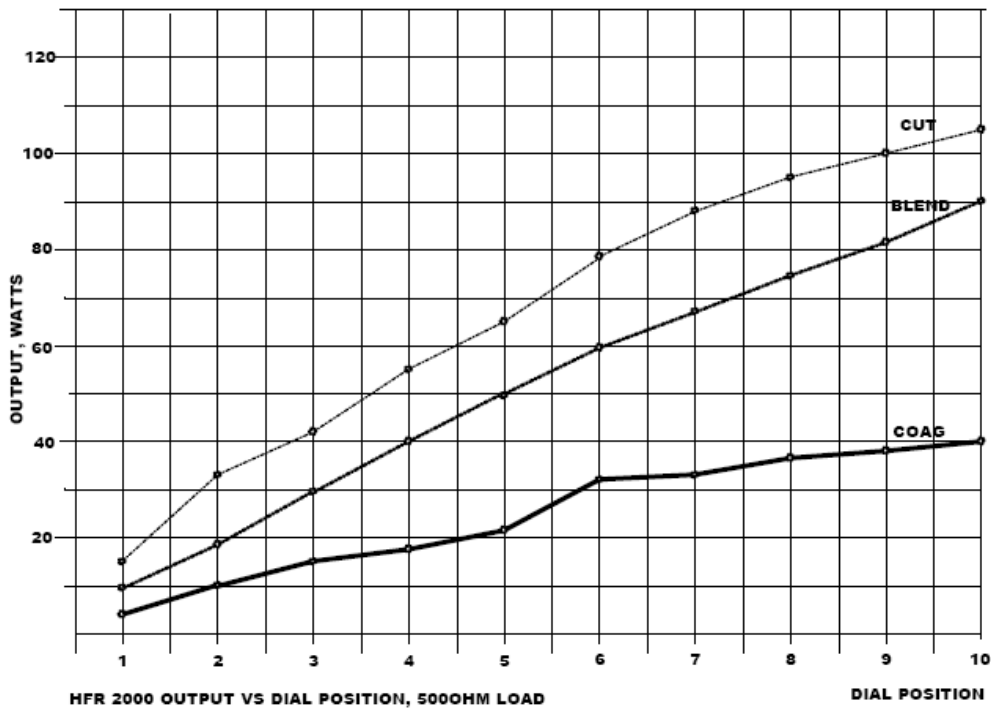
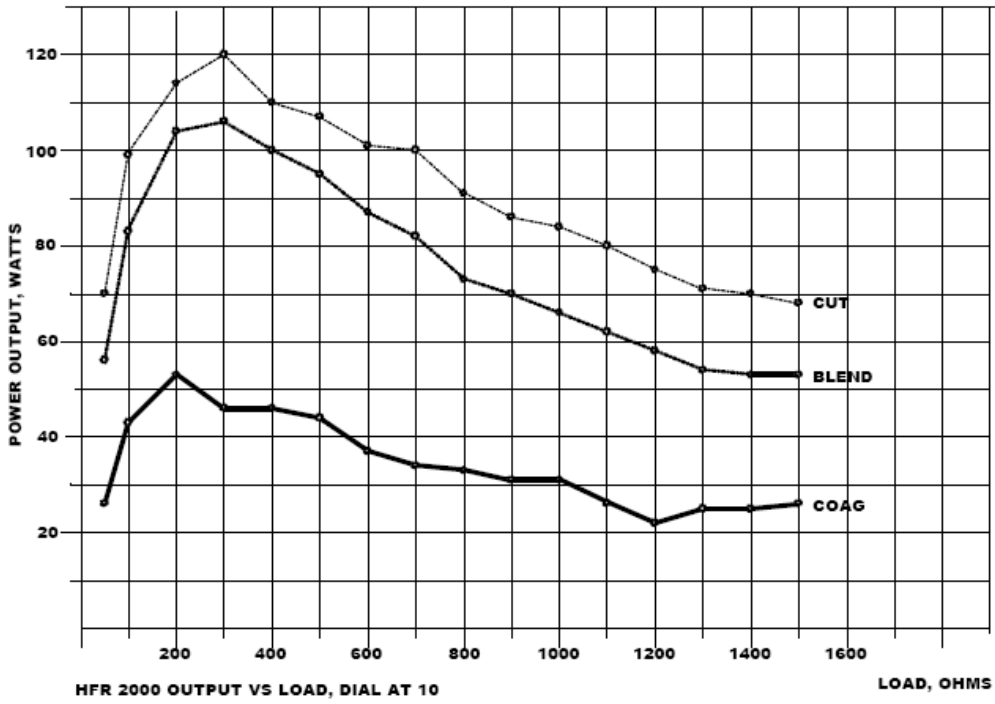
Please remember that cables have a finite service life and are exposed to the possibility of mechanical damage because of the many pieces of equipment and the number of personnel present in the modern veterinary operating suite.

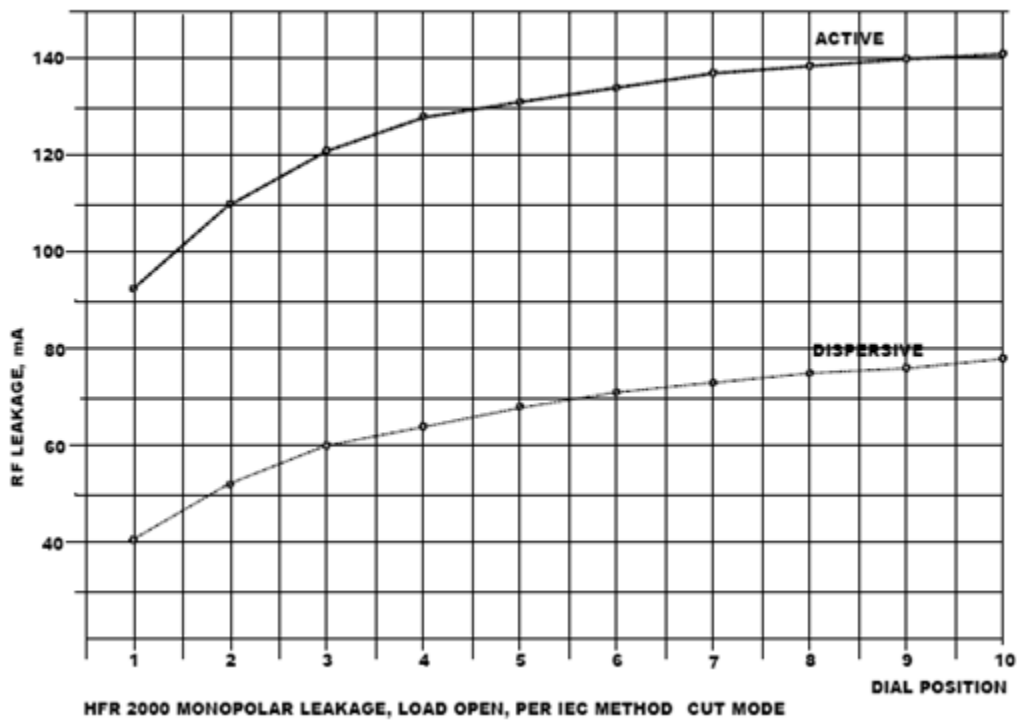
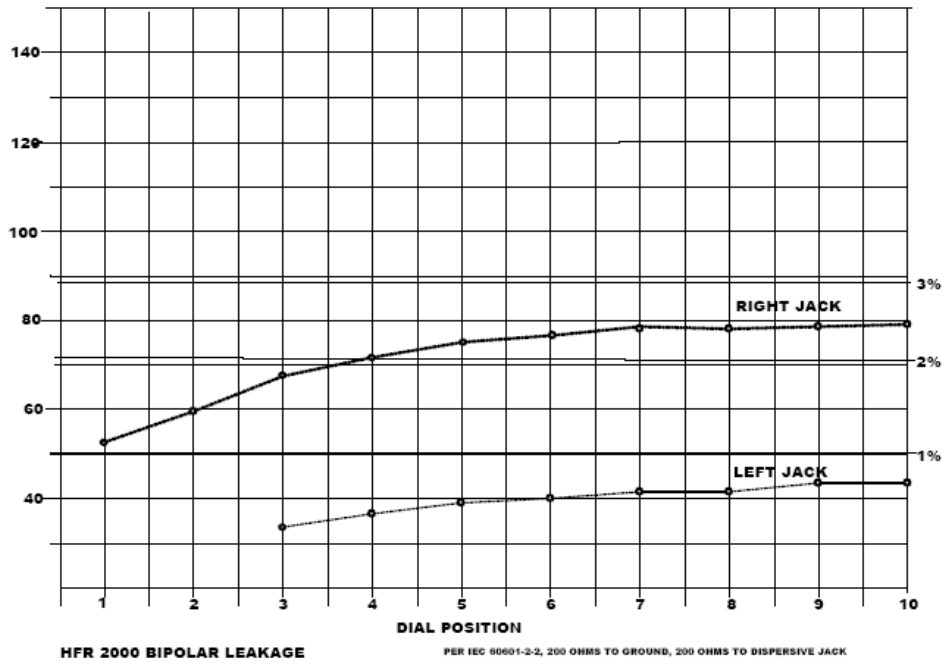
Delmarva 2000 HFR TECHNICAL SPECIFICATIONS

FDA CLASSIFICATION	class II medical, (prescription only), Device Code GEI
CONFIGURATION	high frequency surgical, non-ionizing radiation device, type BF ports, isolated output monopolar, isolated output bipolar coag
OPERATING MODES	
CUT	95% cut, 5% coag, 120 watts into 300 ohms, +/-20%, crest factor 1.4
BLEND	50% cut 50% coag, blended 105 watts into 300 ohms, +/-20%, crest factor 1.9 Modulation: 2 x line frequency (120 Hz), sinusoidal
COAG	50% duty cycle, 55 watts into 300 ohms, +/-20%, crest factor 2.6 Modulation: line frequency, 60 Hz, sinusoidal
BIPOLAR COAG	50% duty cycle, 45 watts into 100 ohms, +/-10%, crest factor 2.6 Modulation: line frequency, 60 Hz, sinusoidal
OUTPUT VOLTAGE	1000 V p-p, est. (1.0 kVp p-p) in monopolar CUT mode, maximum power setting
SOURCE IMPEDANCE	300 ohms, nominal
OPERATING FREQUENCY	4.0 MHz +/-5%, nominal
POWER CONTROL	manual analog, continuously variable
TEMPERATURE RANGE	-20 C to +85 C storage, 0 C to +40 C operating, <80% RH non-condensing
COOLING	convection
SPLASH RATING	IP0
ACTIVATION	single foot pedal, IP20 splash-proof, plastic (low voltage: 12Vdc, current limited, grounded)
DISPERSIVE MONITOR	N/A
ACTIVE INDICATION	LED light, audible tone
POWER REQUIREMENTS	120 V 60 Hz, +/-10%, 350 watts 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)

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.

PERFORMANCE GRAPHS





SERVICE ITEMS (CONSUMABLES)

Item	Catalog number
Handpiece with integral cable (grey)	
Bipolar cable	
Monopolar "Two-Point" cable	
Dispersive cable (red)	
Dispersive pad	
Electrodes	See Delmarva 2000 medical electrode catalog
Bipolar forceps	See Delmarva 2000 bipolar catalog
Monopolar forceps	See Delmarva 2000 monopolar forceps catalog

WARRANTY INFORMATION

The Delmarva 2000 HFR veterinary electrosurgical generator is warranted for 3 years from date of purchase, exclusive of accessories. The warranty is void if the unit cover is opened.

Accessories are covered individually. See page 20 regarding handpiece sterilization since damage to a consumable from failure to follow sterilization instructions is not covered under Warranty.

Please do not return a unit under warranty or for service that is biologically contaminated. Please clean a contaminated unit or accessory or else pack it in an appropriate biohazard bag and label it accordingly.

DISCLAIMER: Delmarva 2000 does not accept responsibility for the use of accessories other than those supplied by Delmarva 2000 or those authorized in writing for use with HFR. Failure to function, damage to the unit, and injury to the patient or operator arising from the use of non-approved accessories are hereby disclaimed.

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ADDITIONAL READING

Current Techniques in Small animal Surgery
Lippincott Williams & Wilkins

M. Joseph Bojrab, DVM, MS, PhD
(veterinary text book)

Medical Device Accidents and Illustrative Cases
Lawyers and Judges Publishing Co.

Leslie A. Geddes
(excellent technical information)

www.ThePetCenter.com

informative site but does not illustrate electrosurgery

www.balgownievvet.com.au/7_surgical_december.htm

illustration of electrosurgery

www.laparoscopyhospital.com/gallery7.htm

human site, general laparoscopic info

www.valleylab.com/education/poes/index.html

human site, excellent general info

www.asha.gov/SLTC/laserelectrosurgeryplume/

OSHA information on smoke

www.aafp.org/afp/20021001/1259.html

human site, dermatology, electrosurgical use