Hyfrecator Plus® Model 7-797

Operator's Manual



BIRTCHER MEDICAL SYSTEMS



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Introduction

Congratulations on your purchase of the Birtcher Medical Systems HYFRECATOR PLUS. Birtcher Medical Systems introduced the first Hyfrecator in 1937 and has since become the world's leader in office-based electrosurgery. With the latest model, the HYFRECATOR PLUS 7-797, Birtcher Medical Systems has refined the concept and utilized today's technology to produce the finest machine of its kind.

Safe and simple to use, the HYFRECATOR PLUS has a wide range of applications – from dermatology and gynecology to ophthalmology and urology. The HYFRECATOR PLUS' sophisticated electronic circuitry provides a near linear power output. Whether it's full power for broad surface coagulation, or low output for delicate facial procedures, the HYFRECATOR PLUS provides the precision you demand. Compatible with your existing Hyfrecator accessories, such as bipolar forceps and reusable electrodes, the HYFRECATOR PLUS features an ergonomic design and contemporary style that complements modern office decor.

Section 1 – Inspection

The Birtcher Medical Systems HYFRECATOR PLUS has been thoroughly tested and inspected before shipment from the factory. Please check the unit before using for any damage that may have occurred in transit to you. If any damage is evident, please immediately contact the Authorized Birtcher Medical Systems Distributor from whom you purchased the unit.

In addition, please compare the accessories you receive with the standard accessories listed below. If an item is missing, please notify your Birtcher Distributor.

To activate your warranty, return the enclosed warranty card to Birtcher Medical Systems within 10 days of receipt of your invoice.

Standard Accessories

Description	Catalog Number
Starter box of non-sterile Electrolase Blunt Tips	7-101-12
Starter box of non-sterile Electrolase Sharp Tips	7-100-12
Power up/down switching handle and cord	7-796-5
Wall mount kit	7-796-20
Operating manual with warranty card	7-797-OM

Section 2 – Operating Controls and Indicators

Front, Side and Bottom Panel Controls

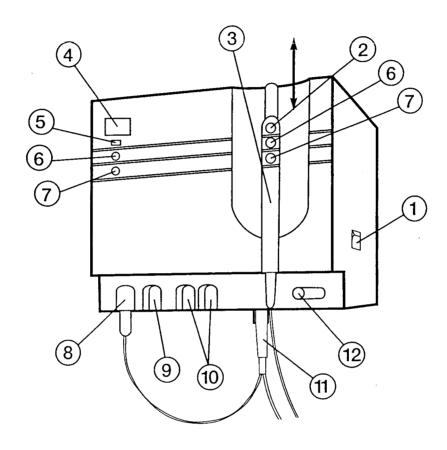


Figure 1 Front, Side and Bottom Panel Controls

Description of Front, Side and Bottom Panel Controls

- 1. ON/STANDBY OFF SWITCH Turns unit on or off. In the off mode, standby allows the unit to automatically "power up" to the setting last used.
- 2. POWER ACTIVATION BUTTON
 When pressed, high frequency energy is emitted from the electrode.
 Additionally, an audible tone is generated and the active "on" indicator illuminates.
- 3. POWER UP/DOWN SWITCHING HANDLE and CORD Remove or insert the power handle in the indicated direction.
- 4. POWER OUTPUT INDICATOR Displays the actual power being delivered. Power selection ranges from zero to 30 watts in high and bipolar outputs and zero to 15 watts in low output. In the low output, deliveries less than five watts are displayed in two-tenth increments.
- 5. ACTIVE "ON" INDICATOR Illuminates when the power activation button is pressed.
- POWER UP BUTTONS
 Increases power either incrementally or rapidly. Each "click" advances the power by one watt or by two-tenths of a watt when less than five watts in the low output. Holding the button down rapidly advances the output.
- 7. POWER DOWN BUTTONS

 Decreases power either incrementally or rapidly. Each "click" decreases the power by one watt or by two-tenths of a watt when less than five watts in the low output. Holding down the button rapidly decreases the output.
- 8. HIGH OUTPUT TERMINAL Insert the power up/down switching handle and cord single pin into this outlet for heavy desiccation and fulguration procedures requiring high intensity. Provides between zero and 30 watts with high voltage.
- 9. LOW OUTPUT TERMINAL Insert the power up/down switching handle and cord single pin into this outlet for light desiccation and fulguration procedures requiring low intensity. Provides between zero and 15 watts with a voltage lower than the high output terminal.
- 10. BIPOLAR OUTPUT TERMINAL. For coagulation procedures using either a dispersive patient plate or forceps. When using the dispersive plate, the plate plugs into either bipolar outlet and the handle plugs into the remaining outlet. When using forceps, the forceps plug into both bipolar outlets (a footswitch is required when forceps are utilized). Bipolar provides between zero and 30 watts with a voltage lower than the high or low output terminals.
- 11. SWITCHING CONNECTOR

 The power up/down switching handle and cord socket plugs into this connector.

 Be sure to align the connector pins before inserting.

 Note: The optional foot switch plugs into this same jack.
- 12. TERMINAL SELECTOR SWITCH
 Selects the desired output terminal. Output displayed will be the last setting used (0-15 watts in low power, 0-30 watts in high and bipolar).

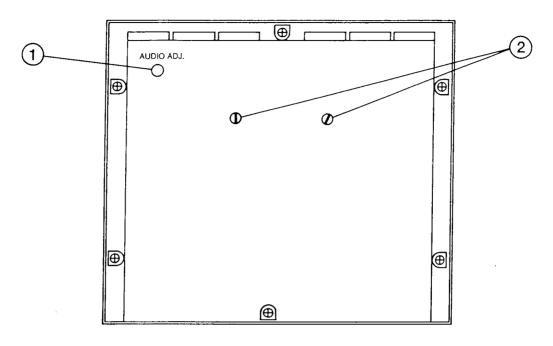


Figure 2 Back Panel Controls

1. VOLUME CONTROL

Adjusts volume of the audible tone generated when the power activation button is pressed. To increase volume, insert a screwdriver and rotate clockwise until resistance is felt. Do not force adjustment past the resistance point. For safety reasons, the tone cannot be completely turned off.

2. WALL MOUNTING STUDS

Used with standard wall mounting kit (see the kit for instructions). Instrument may also be mounted on the optional mobile pedestal stand (product number 7-796-1).

Section 3 – Safety Precautions

Contraindications and Warning

Contraindications

Users are warned against the use of the HYFRECATOR PLUS on patients with implants such as pacemakers, metal pins, metal joints, etc. Check with attending physician for patient's medical history before using the HYFRECATOR PLUS.

Warning

Remove all metal objects from treatment area before using the HYFRECATOR PLUS. It is not advisable to use this instrument in the proximity of digital watches, portable radios, pocket calculators, hearing aids, etc.

Anesthesia

As in other types of surgery, the amount and type of anesthetic required for procedures depends upon the site of the operation and the tolerance of the patient. Small lesions can sometimes be removed without anesthetics when they are not in sensitive areas. Do not use explosive or flammable anesthetics due to the presence of the spark created by the HYFRECATOR PLUS. Similarly, when the site is cleaned with alcohol or other flammable cleansing agent, dry the surface thoroughly before proceeding.

Monoterminal Shock

In all electrical devices where a current is emitted from the instrument, the current must have a return path. The return path for monoterminal applications is through the patient's body, to the ground and back to the instrument. In this mode, if any portion of the patient's body comes in contact with a grounded metal object, the current will take the path of least resistance and a slight shock may be felt. To minimize the possibility of shocking during monoterminal applications:

- · Do not let your patient come in contact with any grounded metal objects.
- Position the electrode on or close to the patient before activating the output.
- If contact with the patient is made, grasp firmly before activating the HYFRECATOR PLUS. Do not break contact during activation.

Section 4 – Suggestions for First-Time Operation

Before using the HYFRECATOR PLUS clinically, we suggest the following experiment.

Hold a quarter-pound piece of room temperature beef or chicken firmly in hand or place it on a table and touch it with your hand to improve the path of electrical flow. Starting with a low power setting, experiment as follows. (If you are not familiar with desiccation, fulguration or coagulation, please see the Terminology for Procedural Configuration section):

- Desiccation: In the monoterminal without a dispersive plate mode, using an Electrolase Tip, touch the meat and turn on the current for one to five seconds. Use different intensities with the low and the high output terminals. Cut the meat open with a scalpel and view the depth of penetration. A mild blanching of the tissue is sufficient for most conditions.
- Fulguration: Using either the low or high output terminals, bring the electrode near, but not touching the meat (one to three mm). Use various settings and observe the different degrees of fulguration that can be produced. Short bursts of a spark alternated with short cooling periods are most acceptable to the patient. Continuous application of the spark creates heat that may become intolerable. Cut the meat open at the fulgurated spots to view the relatively shallow effect.
- Coagulation: If you have purchased the optional foot switch, non-switching handle and cord and dispersive patient plate or the forceps and footswitch, you may wish to experiment with the effects of monoterminal and bipolar coagulation. You will find that monoterminal coagulation produces very deep effects while bipolar coagulation produces relatively superficial effects.

A training tape covering basic dermatological procedures utilizing the HYFRECATOR PLUS is available from your Authorized Birtcher Medical Systems Distributor (product number 7-796-21).

Section 5 – Operation of Your Instrument

- · Plug power cord into a properly grounded electrical outlet.
- Properly align and plug five-pin connector switch from the switching handle into switching connector.
- Slide terminal selector switch to high, low or bipolar position output.
- Plug single-pin connector of switching handle into chosen output terminal.
- Turn on/off standby switch to the "on" position.
- Push power up or power down buttons on switching handle (or on unit itself) to select desired wattage. The LED will display output wattage.
- Insert an Electrolase Disposable Electrode into active end of the switching handle.
- Press power activation button on switching handle to begin procedure.
- When procedure is complete, turn on/off standby switch to "standby off" position.

Section 6 – Terminology for Systems Configuration

Monoterminal (monopolar) without Dispersive Plate

The vast majority of HYFRECATOR PLUS procedures use monoterminal techniques without a dispersive plate. They are easily set up, provide excellent results and do not require any accessory equipment. The current flows from either the high or low output terminals to the electrode, then passes to the patient. The electricity "completes the circuit" by seeking its own ground through the patient to the table and across the floor, returning to your unit via the electrical outlet (see Figure 3). Monoterminal procedures without a dispersive plate produce desiccation and fulguration.

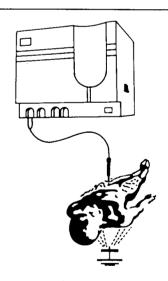


Figure 3
Monoterminal Without a
Dispersive Plate Configuration



Monoterminal (monopolar) with Dispersive Plate

Monterminal applications with a dispersive plate (See Figure 4) are less common than monoterminal applications without a dispersive plate. Here, the high-frequency current starts from either of the bipolar terminals, then travels through an electrode to your patient, where it exits through the dispersive patient plate and returns directly to the unit via the other bipolar terminal. Monoterminal applications with a dispersive plate produce coagulation.

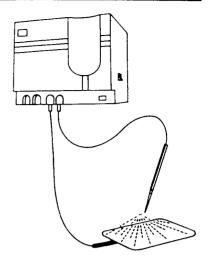
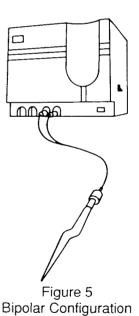


Figure 4
Monopolar with Dispersive
Plate Configuration

Bipolar

For bipolar configurations, the current flow is similar to monoterminal techniques, except the electricity never spreads deeply into the tissue. Instead, forceps – or other highly specialized electrodes – keep the current flow on the surface, travelling from one tine of the forceps to the other (see Figure 5). Bipolar techniques produce coagulation.

NOTE: Bipolar forcep procedures require the use of a footswitch.



Section 7 – Terminology for Procedural Configuration

Desiccation

Desiccation comes from the Latin word "desiccate," meaning to dry. It is a monoterminal without a dispersive plate technique. The electrode either touches, or is inserted into the tissue. The current evaporates the cellular fluids, blanching the area treated (see Figure 6). Typically, the depth of blanching is greater with desiccation than with fulguration.

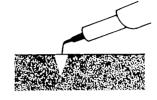


Figure 6
Desiccation

NOTE: Continued electrodesiccation at increased intensity will result in tissue destruction and charring.

NOTE: Epilation by thermolysisis a special form of desiccation where a fine-wire electrode (product number 714) destroys hair follicle. This procedure uses the low terminal at very low power settings (see Figure 7).

- Application As the power and/or time of treatment increases, the amount of desiccation also increases. You must, however, consider the effects of the size of the electrode, especially when inserting an electrode needle. For instance, a large diameter needle requires more power and time to produce the same effect as a small needle.
- Healing Small lesions usually heal completely in one to three weeks. First, granulation forms on the base, then epithelializes. A crust forms and sloughs off in seven to ten days. Large lesions may produce two to three successive crusts.

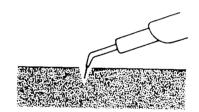


Figure 7 Epilation

NOTE: In an area of good blood supply and abundant subcutaneous tissue, healing will be rapid.

 Post-Operative Care – Small lesions may not require dressing. Larger areas of destruction will require antiseptic dressing and medication until the wound is epithelialized. As in any surgical procedure, large open wounds should be protected against secondary infection.

Fulguration

Fulguration comes from the Latin word "fulgur", meaning an act of lightning. It is a monoterminal without a dispersive plate technique where the electrode is held slightly away from the surface being treated (see figure 8), resulting in sparking to the surface. When delicately fulgurating, you must precisely position the point of the active electrode close to the area being treated or the electrical arc may divert to adjacent tissue areas. If desired, you can quickly fulgurate broad areas by holding the electrode further from the skin. Fulguration limits tissue destruction to a shallow area under the spark and is normally characterized by an eschar.

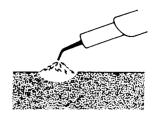


Figure 8 Fulguration

- Application Factors such as power, treatment time, electrode size and the
 moisture content of the tissue influence the area and depth destroyed with one
 application. Additionally, the distance between the electrode and the tissue is
 important.
- · Post-Operative Care Same as desiccation.
- Healing Same as desiccation.

Coagulation

Coagulation derives from the Latin word "coagulate," meaning to clot.

As seen in Figures 9 and 10, there are two types of coagulation:

- Monoterminal Coagulation Uses the dispersive patient plate (also called a "return electrode" or an "indifferent electrode") as seen in Figure 9.
- Bipolar Coagulation A technique where the current flows between two closely placed electrodes as seen with the forceps in Figure 10. A dispersive patient plate is not used.

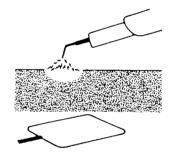


Figure 9
Monoterminal Coagulation

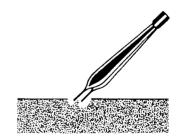


Figure 10 Bipolar Coagulation

- Application The two types of coagulation have different effects on tissue. In the
 first case, the dispersive patient plate deeply draws the current into the tissue.
 The current efficiently flows through the patient back to the HYFRECATOR PLUS
 producing heavy dehydration at the electrode site. Conversely, the use of bipolar
 forceps during bipolar coagulation produces the least tissue damage with the
 current remaining on the surface as it flows from one tine to the other.
- · Healing same as desiccation.
- Post-Operative Care Same as desiccation.

Section 8 – Applications

Dermatology

BENIGN LESIONS

The HYFRECATOR PLUS can destroy a variety of benign skin lesions. With its wide range of power settings, the HYFRECATOR PLUS treats even the most delicate facial lesions as well as the thickest scaling lesions of the trunk. Some of the clinical applications include:

- Acrochordon (skin tag): Electrodesiccation or fulguration quickly destroys these lesions. The remaining char is removed with a gauze pad or curette.
- Actinic Keratoses: These pre-malignant lesions respond well to light electrofulguration. Since these lesions occur on exposed surfaces, a cosmetic result is essential. Using a low power setting will help you control the destruction and ensure a satisfactory cosmetic result.
- Adenoma Sebaceum: Treat each papule with desiccation using a low current setting.
- Angiokeratoma: Superficial desiccation is generally sufficient.
- Angiomas, Capillary: Superficial desiccation of fulguration is usually quite successful in treating these lesions. The remaining char may be wiped away with a gauze pad.
- Angiomas Cavernous: Electrodesiccation may satisfactorily treat small lesions. Multiple needle insertions are usually necessary.

- Angiomas, Spider: Electrodesiccation of the centrum, from which the telangiectatic vessels radiate cosmetically, removes the lesions.
- Condyloma Acuminatum (Venereal Wart): Condylomata respond quickly to electrofulguration. Anesthesia is generally required and care must be taken to avoid post-operative infection in the warm, moist genital area.
- Fibroma: Light electrodesiccation or fulguration easily destroys small pedunculated fibromas.
- Keratoacanthoma: After a deep shave or "scoop" biopsy for diagnosis, the base
 of this lesion should be electrofulgurated to achieve hemostasis and destroy any
 residual tumor.
- Lymphangioma: These uncommon tumors may respond to electrodesiccation or fulguration.
- Molluscum Contagiosum: These viral lesions resolve quickly with electrodesiccation.
- Pyogenic Granuloma: This loose vascular tissue responds well to electrofulguration.
- Seborrheic Keratoses: These are perhaps the most common and most cosmetically annoying skin tumors in adults. Their presence is often associated with old age. Initial fulguration enables you to easily wipe away the charred remains with a gauze pad or gentle curette. The cosmetic result is usually excellent. Multiple small seborrheic keratoses of the face in young blacks (dermatosis papulosa nigra) may be treated without anesthesia using a low power setting. While excellent cosmetic results are achievable, it is prudent to initially treat one or two as a therapeutic cosmetic test.
- Sebaceous Papules: Seen in rosacia and older, oily-skinned patients, these lesions may be removed by light electrofulguration.
- Syringomas: Very light fulguration, followed by gentle curettage, may be curative. Test one or two lesions initially as a cosmetic trial.
- Telangiectasias: Facial telangiactasias respond well to gentle electrodesiccation. Use LOW terminal at low power settings at one or more sites along their length. This procedure has several advantages over more costly laser treatments and less controllable sclerosing injections. Leg lesions, however, are more recalcitrant to electrosurgery and more likely to recur.
- Common Warts (Verrucae Vulgaris): Most common warts respond to electrofulguration and curettage of the base. Special care must be given to warts that occur over specifically located nerves. Such sites include the digital nerves or those that occur on weight-bearing surfaces like the foot (Verruca Plantais). Care should be taken to avoid excessively deep tissue destruction which may result in painful scarring.

- Filiform Warts: Electrodestruction of the pedicle near its base yields a high cure rate with excellent cosmoses.
- Flat Warts (Verrucae Plana): Flat warts respond well to light electrofulguration.

MALIGNANT LESIONS

If malignancy is suspected, take a biopsy before treatment by electrosurgery for histopathologic examination. The most common skin cancers are basal and squamous cell carcinomas. Appropriately selected ones may be treated easily, quickly and effectively with curettage and electrofulguration. You usually need to repeat the procedure once or twice at the same sitting to achieve a high cure rate. The tumors you wish to treat generally should be less than two cm. in diameter, occurring on a sun-exposed site (face, arms, upper back, lower legs) and not involving a body fold (such as the alar groove or inner canthus of the eye). When lesions are chosen appropriately, as noted above, very acceptable cure rates for electrosurgery can be achieved. In addition, electrosurgery has the advantage of being easy to learn, simple to perform and cost-effective. Cosmeses is quite acceptable and, in many cases, may be preferable to the cosmetic results of excisional surgery or radiotherapy.

- Basal Cell Carcinoma: Obtain a shave biopsy before electrosurgery. After initial tumor delineation with a curette, fulguration is performed and followed by thorough removal of the necrotic debris with additional curettage. Curettage and fulguration is typically repeated once or twice.
- Bowen's Disease (Squamous Cell Carcinoma in Situ): These lesions respond to the same techniques for basal cell carcinomas. Since these lesions may extend further laterally than they clinically appear, anesthesia should extend one to two cm beyond the visible lesions.
- **Bowenoid Papulosis:** Occurring on the genitals, these papules respond to electrofulguration.
- Squamous Cell Carcinoma: The same techniques are again employed as with basal cell carcinoma. You should only treat lesions arising in sun-damaged areas. Squamous cell carcinomas arising in non-sun-exposed skin and in mucous membranes are more aggressive biologically.

Plastic Surgery

Many surgeons use the HYFRECATOR PLUS for hemostasis in plastic and reconstructive surgery. It saves time and produces minimal tissue reaction compared to other methods. Coagulation occurs by touching each bleeding point with an electrodesiccating current. Because blood will dissipate the energy, a sponge should be used just prior to application.

Gynecology

- Vaginal Cysts: Treat these cysts by first excising an oval strip and emptying the
 contents, then use a strong desiccating current to cauterize the interior. Gartner
 cysts extending near the vault and alongside the cervix respond to this method.
- Condylomata of the Vulva: You can effectively destroy these warts as you
 would destroy the various types of warts on the surface of the body. (See
 Venereal Warts under Dermatology and Urology).
- Cervical Polyps: Cervical polyps up to two cm in diameter respond to desiccation of the base without the need for a local anesthetic. If shallow, a fulgurating spark may blanch them thoroughly. Polyps extending into the cervical canal may require more than one treatment. Remember that endocervical and intrauterine polyps may be present. Dilation and curettage of the uterine cavity under general anesthesia may be indicated. As with all such lesions, preliminary biopsy is advisable.

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- Pruritus Vulvae: By fulgurating the entire surface using a strong current, excellent results can be achieved. Take care to prevent urethral stenosis.
- Urethral Tumors: The majority of urethral tumors are benign and respond readily to desiccation. However, treatment should be thorough to avoid recurrence.
- Cervical Erosion: Many cervical erosions are asymptomatic and require no treatment. However, if the erosions produce symptoms such as increased discharge or pain, you should treat them effectively with desiccation, fulguration or coagulation. Typically, this is done without the need for a local anesthetic.
- Cervicitis: A strong desiccating current effectively destroys the entire infected mucosa, although more than one treatment is usually necessary.
- Bartholin's Cysts or Abscesses: Aspiration alone may cure the condition. If this fails, incise the cyst or abscess, evacuate its contents and coagulate the cyst wall using a fulgurating spark. Recurrent cysts respond to marsupialization.

- Nabothian Cysts: Puncture these infected glands and cysts with a sharp needle point, then desiccate.
- Skene's Glands: Insert a sharp point into the abscess or cyst, then desiccate using a strong current. The wound closes by granulation.

Dental and Oral Surgery

- Apicoectomy: To prepare for an apicoectomy, insert a fine desiccating needle electrode (product number 705A) slightly beyond the apex of the tooth, then apply the desiccating current to the infected area. The resulting coagulation reduces capillary bleeding and minimizes the spread of infection during later root resection.
- Buccal Gingival Caries: Soft, infected gingival tissue responds to desiccating currents.
- Cysts, Mucous: Small cysts of the mouth respond to epilation. An application of the desiccating current for a few seconds will boil out the mucous fluid and destroy the cyst lining. Results are excellent with minimal scarring.
- **Dentin Desensitization:** Fulguration desensitizes hypersensitive exposed dentin. Spray the area with a topical anesthetic before the first treatment, then fulgurate with a weak current. Only two treatments are usually required.
- Frenectomy: Intense fulguration of the superfluous tissue under local anesthesia reduces abnormal labial frenum.
- **Hemostasis:** To control bleeding after exodontia, desiccation or fulguration with a small ball electrode (product number 727) can be most effective.
- **Gingivectomy:** The removal of gingival tissue, such as the exposure of the gingival margin, the preparation for taking hydrocolloid impressions and papillectomies and the elimination of gum flaps, responds to both electrodesiccation and fulguration.
- Root Canal Sterilization: The dental electrode (product number 705A) can sterilize the pulp chamber after first removing the debris. Use one-second bursts of fulguration and gradually move the electrode deeper into the chamber and root canal.

Ophthalmology

- Chalazion (Meibomian Cysts): To treat these cysts, first anesthetize the area. Next, incise and evacuate the cysts.
- Entropion: Treat each nodule by inserting a very fine needle point electrode (product number 714). Use a low-powered desiccating current. Treat only a small portion at each session.
- **Xanthelasma:** These cholesterol deposits respond effectively to light desiccation or light fulguration. Several treatments are preferable to avoid any scarring.
- Burn Entropion: Light fulguration is recommended.
- Spastic Entropion: Following surgical incision and desiccation to separate it from the orbicularis oculi muscle, desiccate the muscle lightly until it is a light brownish-green color. Suture and dress the wound with antibiotic ointment.

Otolaryngology

- Adenoid Hypertrophied Remnants: Coagulate small areas under local anesthesia and repeat the process until the hypertrophied areas are completely destroyed.
- **Epistaxis:** Electrodesiccation is very effective for hemostasis. Anesthetize the areas and carefully identify the vessels. Bring the electrode into direct contact with the ruptured arteriole and use a light current. Exercise care to avoid excessive tissue damage that could result in perforation of nasal septum. For that reason, it is inadvisable to treat both sides simultaneously.
- Granular Pharyngitis: Desiccate each point using a mild desiccating current.
- Nasal Polyps: Desiccate these polyps at the base.
- Hemostasis in Tonsilloadenoidectomy: Use either monoterminal or monopolar coagulation. The monoterminal technique uses the HIGH output. Bleeding is controlled with a sponge dampened with epinephrine (Adrenalin) 1:1,000 before activation of the electrode. Use a ball electrode (product number 727) as the active electrode.
- Tonsil Tag Destruction: Bipolar coagulation, using a specialized electrode (product number 789CC), can destroy tonsillar tissue. Insert the double needles into the tissue and destroy the tissue between them.
- Turbinate Shrinkage: Use either monoterminal or monopolar coagulation. The monoterminal mode uses a fine needle with a long, insulated sheath (product number 716). Monopolar coagulation uses the same electrodes along with the Dispersive Patient Plate (product number 7-796-7) to complete the circuit

Proctology

- Fissure-in-ano: Spray a fairly strong fulgurating current over the involved tissue. Healing is prompt, but there is some discomfort during the first three days. Do not destroy the tissue too deeply. Instruct your patient to keep the area clean and to apply an antiseptic ointment.
- **Hemorrhoids:** Some authorities advocate bipolar coagulation for office management of hemorrhoids. Individually distend the hemorrhoids with a fluid solution and then coagulate.
- Ischiorectal: Incise and drain these lesions, then desiccate the wall with strong current.
- Papilloma: Small papillomas readily respond by inserting a fine needle electrode, but a fairly strong current is needed. Larger polyps within the bowel are better treated with snares and an electrosurgical cutting current.

Urology

- Bladder: Desiccation or fulguration of various growths within the bladder are well established urological techniques. Use a cystoscope and a continuous flow of water. (Check with the manufacturer of your cystoscope to determine compatibility with the HYFRECATOR PLUS).
- Vasectomy: After your patient has been anesthetized, the lumen of the vas
 deferens can easily be desiccated, minimizing any peripheral damage to the
 surrounding muscle layers.
- Venereal Warts: Venereal warts and other small polypoid tumors respond to
 desiccation. Insert the sharp, fine needle point electrode into the base of the
 growth, intermittently applying the current until the tissue mildly blanches. It is not
 necessary to remove the desiccated tissue, as epithelialization occurs beneath it.

Section 9 – Maintenance

The HYFRECATOR PLUS requires little maintenance. To keep your instrument performing at its best, however, external cleaning should be performed on a regular basis.

NOTE: All internal service should be performed by qualified maintenance personnel only.

External Cleaning

To clean the external case of the HYFRECATOR PLUS and the up/down switching handle and cord:

- · Moisten a lint-free cloth with a mixture of mild soap and water.
- · Clean all external surfaces with this solution.
- · Dry all surfaces thoroughly using a clean, lint-free cloth.

Soap-based solutions – rather than harsh chemicals – are recommended cleaning agents for the HYFRECATOR PLUS. Evaporative solutions are preferred so as to limit exposure of internal electrical components. Material characteristics of the unit do not allow for gas, steam or cold sterilization techniques.

Steam Sterilization of Accessories

NOTE: Do not autoclave the power up/down switching handle and cord. If procedures require sterility, use Ethylene Oxide at <140°F.

[If a footswitch is utilized, a sterile disposable non-switching pencil and a reusable adapter can be utilized (product number 137657 for the pencil and 670-3 for the adapter). An autoclavable reusable non-switching pencil is also available (product number 7-796-6), which also requires a footswitch (product number 7-796-4).]

To steam sterilize accessories and electrodes:

- Place accessories in autoclavable packaging or wrap with a cloth.
- Autoclave at 121°C (250°F) ± 3°C for 15 minutes minimum/20 minutes maximum.
- Remove accessories from the autoclave and allow to cool for 30 minutes minimum.

NOTE: It is not advisable to cold sterilize surgical electrodes due to potential corrosion.



Section 10 - Optional Accessories

1. ELECTROLASE (product numbers 7-100-12, non-sterile Electrolase Sharp, 7-100-8, sterile Electrolase Sharp, 7-101-12, non-sterile Electrolase Blunt, 7-101-8, sterile Electrolase Blunt).

ELECTROLASE TIPS - THE SOLUTION TO CROSS CONTAMINATION & ACCIDENTAL NEEDLE STICKS

Contrary to popular belief, the use of an electrodesiccator does not self-sterilize the electrode. For example, the British Journal of Dermatology reported that "Contaminated electrodes [with Herpes Simplex] were not sterilized by electrical discharge and virus transfer to skin samples was demonstrated after contact treatment." Fortunately, according to a recent article in the Journal of the American Academy of Dermatology, the use of disposable electrodes can prevent the "transmission of hepatitis B and other viral-associated infections, such as AIDS."^{2,3}

Electrolase Tips are disposable electrodes for use with your HYFRECATOR PLUS. They offer a safe, economical solution to the threat of potential cross contamination or accidental transfer of a virus to you or your staff. For your convenience, Electrolase Tips are available in both Sharp and Blunt configurations: the Sharp configuration is for pinpoint procedures and the Blunt configuration is for broad based coagulation. The tips are also available in both non-sterile and sterile packaging. Non-sterile Electrolase Tips should be used in treating patients when a "hospital clean" environment is satisfactory. Sterile Electrolase Tips are available for work requiring a "sterile field."

The HYFRECATOR PLUS comes with a starter box of non-sterile Electrolase Sharp Tips and a starter box of non-sterile Electrolase Blunt Tips.

- 2 MOBILE PEDESTAL STAND (product number 7-796-1). Provides the ability to roll the HYFRECATOR PLUS from one location to another. The five-legged steel stand will not tip over and has a durable protective coating.
- 3. FOOT SWITCH (product number 7-796-4). The Foot switch can be used to power activate the HYFRECATOR PLUS. The Foot Switch plugs into the switching connector at the base of the unit. A non-switching handle and cord or forceps delivers power to your patient. Most Hyfrecator users prefer the convenience and speed of hand switching pencils and foot switches are required only when you use certain specialized electrodes and handles such as forceps, or when you require extremely precise activation.
- 4. NON-SWITCHING HANDLE AND CORD (product number 7-796-6). Identical to standard switching pencil without the power activation and up/down buttons. This handle can be sterilized and requires the use of a footswitch.
- 5. DISPERSIVE PATIENT PLATE (product number 7-796-7). Required for Monoterminal coagulation procedures. This stainless steel return plate requires no gels or adhesive.

- 6. DISPOSABLE HYFRECATOR PENCIL AND ADAPTER (product number 137657 for the pencil and 670-3 for the adapter). Sterile disposable pencil with 10-foot cord and needle electrode inserted. The pencil fits into the reusable adapter which fits into the desired output mode.
- 7. BIPOLAR FORCEPS. A variety of reusable forceps are available for bipolar procedures. Ask your Authorized Birtcher Medical Systems Distributor for details.
- 8. REUSABLE ELECTRODES. A variety of reusable electrodes for particular procedures are available. Ask your Authorized Birtcher Medical Systems Distributor for details.
- 9. HYFRECATOR PLUS TRAINING VIDEO "Common Dermatologic Procedures" (product number 7-796-21). A 15-minute physician training tape covering basic dermatologic procedure such as the treatment of moles, warts, skin tags, seborrheic keratoses, telangiectasias and skin cancers.

Section 11 – Warranty

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As manufacturer of the Birtcher Medical Systems HYFRECATOR PLUS 7-797 and other high quality medical equipment, Birtcher Medical Systems warrants all of its products to be free from defects in material and workmanship under normal operation and use. The warranty period for the Birtcher Medical Systems HYFRECATOR PLUS is twelve (12) months to the product's original owner.

NOTE: The warranty card must be returned by the original owner to Birtcher Medical Systems within ten (10) days of receipt of the invoice.

A ninety (90) day warranty is provided for standard and optional accessories. The ninety (90) day warranty includes the power up/down switching handle and cord. There is no warranty on disposable, single-use items.

The warranty is limited to the repair or replacement (at the manufacturer's discretion) of any HYFRECATOR PLUS (or part thereof) that is returned to the manufacturer within the specified warranty period and which, after examination, is found to be defective.

Transportation of the HYFRECATOR PLUS must be prepaid by the sender. The unit will be returned pre-paid to the owner by the same manner of transportation used in shipping the product to the manufacturer.

The warranty does not apply to any product, or integral part thereof, that has been altered or serviced by anyone other than the manufacturer. Nor does it apply toward any product that has been damaged as a result of accident, abuse, misuse or negligence on the part of the user.

Section 12 – Repair Return Policy

HYFRECATOR PLUS units and any standard or optional accessories should not be returned to the manufacturer for warranty or non-warranty repair without prior authorization. A "Return Goods Authorization" (RGA) number will be issued by Birtcher Medical Systems' repair department upon request. This number must be prominently written in the upper left hand corner of the shipping container. To receive an RGA number, please call (800) 888-1771 or (714) 753-9400.

NOTE: Any merchandise returned to Birtcher Medical Systems without a Return Goods Authorization number will not be accepted by the receiving department and will be returned to the sender.

The Birtcher Medical Systems Warranty and Return Policy for the HYFRECATOR PLUS 7-797supersedes all other warranties either expressed or implied and shall be governed and executed under the laws for the state of California, U.S.A.

Section 13 – Specifications

PARAMETER

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CHARACTERISTICS

Primary Power Requirements

Model 7-797

HYFRECATOR PLUS

120V 10% 50/60 Hz 1 Phase other voltages upon request

Dimension and Weight

Depth:

Width: Height: Weight: 4 inches (102 mm) 8.75 inches (222 mm)

7.5 inches (190 mm) 6 pounds (2.7 kg)

Functional Characteristics

Output Power

Bipolar: High: Low: 30 ± 6 Watts (500 Ohm load)

 30 ± 6 Watts (1000 Ohm load) 15 ± 3 Watts (500 Ohm load)

Maximum Power:

36 Watts (500 Ohm load)

Open Circuit Voltage Bipolar:

High: Low: 3000 Vp-p Max.

7000 Vp, 10,000 Vp-p Max.

4000 Vp-p Max.

Frequency:

500 KHz at 31.25 KHz rate

Output Wave Shape:

Damped sinusoidal

Output Regulation:

± 30% at 30 Watts (500 Ohm load)

for a ± 10% line voltage

Duty Cycle:

10 sec. on, 30 sec. off

Audio:

1KHz & 2 KHz, 65 db min.

Display Reading

Speed 0-30:

Accuracy

Low Ouput Terminal

0-5 range:

5-15 range:

Bipolar & High Output Terminals

1 watt increments

1% at any setting

.2 watt increments

10 seconds

0-30 range:

1 watt increments

60 Hz Leakage:

50 microamps max. third wire of

line cord open

Bipolar RF:

Power reduction ratio is greater than 80%

of max. output.

Approvals:

CSA, Standard C22.2, No. 125

Risk Class:

2G

Protection:

BF Defibrilator, Class 1

Section 14 – Symbols



CAUTION: To reduce the risk of an electric shock, do not remove the back cover of the instrument. To retain memory of the previously used power setting, 5 volts is supplied to the instrument while it is plugged into a wall outlet. Refer all servicing to qualified personnel.



CAUTION: Site is a source of high voltage.



CAUTION: Before using instrument, read operating manual.



Equipment is classified as Type BF: it has an internal electrical power source that provides an adequate degree of protection against electric shock, particularly in regard to the allowable leakage current and the reliability of the Protective Earth connection.

Section 15 – Index of Reference Material

- 1. Clover, G.B. and Peutherer, J.F., "Herpes Simplex Virus Dispersal by Hyfrecator Electrodes," *British Journal of Dermatology*, Dec., 1987, Vol 117, p. 627.
- 2. Sheretz, E.F. et al, "Transfer of Hepatitis B Virus by Contaminated Needle Electrodes after Electrodesiccation in Simulated Use," *Journal of the American Academy of Dermatology*, Dec., 1986, Vol. 15, No. 6, p. 1246.
- 3. Sebben, Jack E., <u>Cutaneous Electrosurgery</u>, Year Book Medical, Chicago, IL, 1988.