FINESSE® II+

Electrosurgical Generator and Smoke Evacuation System

Operator's Manual

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Indications, Contraindications, Warnings, and Cautions

CAUTION: Federal (USA) law restricts this device to use by or on the order of a physician or other licensed practitioner.

Indications for Use/Intended Use

The Finesse II+ is intended to deliver high frequency electrical current for surgical procedures that can be performed with monopolar cutting and/or coagulation of tissue. One intended use of the Finesse II+ system is Loop Excision of the Transformation Zone (LETZ®).

Intended Patient Population

The Finesse II+ may be used on any patient requiring excision, ablation or coagulation of tissue, via high frequency electrical energy, using loop, blade, needle, ball or similar geometry electrodes. LETZ procedures are specifically for women with high-grade cervical intraepithelial neoplasia, that are selected for treatment in accordance with professional guidelines (e.g., ASCCP, ACOG, SGO, WHO, EFC) on treatment of these precancers.

Intended User

The Finesse II+ is for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

Contraindications for LETZ

- Positive ECC or a lesion in which the endocervical limit cannot be visualized colposcopically
- Clinically apparent invasive cervical carcinoma
- Pregnancy
- A bleeding disorder
- Severe cervicitis
- Less that six weeks postpartum
- DES-exposed patient.

Warnings

WARNING: LETZ procedures should be performed by clinicians who are trained in diagnosis and management of cervical intraepithelial neoplasia (CIN).

WARNING: Clinicians should be familiar with most recent clinical consensus guidelines regarding management of women with CIN when selecting patients for LETZ.

WARNING: The following risks are associated with LETZ procedures:

- Bleeding
- Cervical stenosis
- Infection
- Incomplete excision of CIN
- Pregnancy complications
- Cautery artifact which may interfere with ability to evaluate margin of tissue specimen.

Inspection. When the system is unpacked after transport between locations, as well as periodically with ordinary use, visually inspect the Finesse II+ system, accessories, accessory receptacles, power cord, and power cord receptacle for damage or missing parts. Do not use the system without correcting any observed or suspected damage.

No modification of this equipment is allowed. Modification of the Finesse II+ may expose operator and/or patient to hazardous electrical currents.

Failure of HF surgical equipment can result in an unintended increase in output.

Dispersive electrode pad. Always apply the dispersive pad as indicated in the dispersive pad instructions for use. Directions are provided with the dispersive pads. These directions should be rigorously followed to prepare, apply, maintain, and remove the dispersive electrode, and periodically make a visual check of the pad application to the patient.

To ensure safe contact of the dispersive pad to the patient, use only pads listed as compatible with the Finesse II+'s CQM system. The use of contact monitoring pads that are not on the list in the *Technical Specifications* section of this manual may not properly signal an error condition and result in patient injury.

If the patient moves after application of the dispersive electrode, the contact between the electrode and the patient should be rechecked before proceeding with the surgical procedure.

Skin-to-skin contact (e.g. — between the arms and body of the patient) should be avoided, for example, by the insertion of dry gauze. This practice aids in preventing the establishment of alternate current paths.

Grounding. At the frequencies and power levels used in electrosurgery, any grounded metal parts may conduct current away from the patient with sufficient concentration at the contact point to cause a burn. Although the isolated lead system of this generator is usually effective in limiting this leakage current and preventing such burns, there are circumstances where this precaution may be accidentally subverted and stray currents may flow. Therefore, the patient should not come into contact with metal parts which are grounded or which have an appreciable capacitance to ground (e.g. operating table, supports, etc.). The use of antistatic sheeting is recommended for this purpose.

Jewelry. Jewelry can concentrate electrosurgical current if placed in the vicinity of the electrosurgical procedure or in the general path that the electrosurgical current would follow, for example, the path between the surgical site and the dispersive electrode. Also, loose fitting jewelry may come into contact with objects that could enable an alternate current path. Any of

these conditions could cause patient shock or burn. Jewelry should be removed or isolated by dry gauze as much as possible.

Leads. Unshielded active and return leads should be positioned so that they cannot come into contact with the patient or with other leads connected to the patient. They should also not be allowed to run closely parallel to other leads.

Monitoring Leads. Electrodes and probes connected to monitoring, stimulating, or imaging devices (e.g. ECG electrodes) can provide paths for stray electrosurgical currents which may cause burns. This is possible even though these electrodes and probes are battery operated, insulated, or isolated at 50Hz/60Hz. The risk can be minimized by placing the electrodes or probes as far away from the surgical site and dispersive electrode as possible. Protective impedances in the monitoring leads can help reduce the risk of burns. Electrodes covering wide areas are best, and needle-type monitoring electrodes should never be used during electrosurgery. In all cases, monitoring systems incorporating high frequency current limiting devices are recommended.

Active Electrode. The surgeon handling the active electrode must, of course, avoid applying the active electrode to any point on his/her own body. The surgeon must also be aware that if the active electrode is touched to any conductive tool or appliance, that device becomes an extension of the active electrode and can cause burns to either the patient or the surgeon. When not being used, the active electrode should be stored isolated from the patient.

Ensure there is no visibly exposed metal of the active electrode shaft where it connects with its handpiece, and that the active electrode fits firmly into the handpiece to avoid it falling out during operation.

Monopolar Electrosurgery. The Finesse II+ system is a monopolar type electrosurgical system. For surgical procedures where the HF current could flow through parts of the body having relatively small cross sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.

Accessories. Any reusable accessories should be periodically tested for function and safety in accordance with their manufacturers' instructions. Use only accessories whose connectors match those on the generator. Adaptors should not be used unless they are approved by Utah Medical Products as being compatible with the Finesse II+.

The Finesse II+ system should only be used with the accessories that are offered by Utah Medical Products. However, it should be noted that certain accessories may appear to be physically compatible with the Finesse II+ system, but may not comply with quality and performance regulations, and as such may limit or impede the intended performance and safety features of the Finesse II+ system.

To ensure that the Finesse II+ system complies with electromagnetic emissions and immunity regulations, users should use only the switchpens and dispersive pads listed in the *Accessories* section of this manual. Under no circumstances should switchpen cables exceed 10 ft (3m) in length, and dispersive pad cables should never exceed 10 ft (3m) in length. The use of accessories with longer cable lengths may result in increased emissions or decreased immunity of the Finesse II+ system.

Only use active electrodes and pencils that have Rated Accessory Voltage greater than the Maximum Output Voltage for the selected output setting and mode (see Table 1 and Figure 8 in the *Technical Specifications* section).

Power Deficiencies. An apparent power deficiency in cutting or coagulation may indicate faulty application of the dispersive electrode or failure of a patient lead. It may also result from attempting to push the electrode through the tissue faster than the natural speed of the electrode for the output level set inside the generator. If a slower cut does not produce the desired results, then the patient circuit, including the active and dispersive electrodes, should be checked.

Sparks. The sparks generated in electrosurgical cutting or coagulation can easily ignite flammable substances at the surgical site. The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are drawn away. Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfection or as solvents of adhesives should be allowed to evaporate before the application of the electrosurgical device. There is a risk of pooling of flammable solution under the patient or in body depressions such as the umbilicus and body cavities such as the vagina. Any fluid pooled in these areas should be removed before the electrosurgical equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the electrosurgical generator.

Filters. After use, the external disposable filter can be a source of odor and possible viral contamination. Also, using this filter for too many procedures may compromise its particle or odor removal efficiency. For optimum performance, this filter should be discarded either daily or after 15 procedures if more than 15 procedures are performed in a single day. It should be removed with a gloved hand, placed in an appropriate plastic bag, and discarded with other plastic medical disposables. The internal filter, being protected by the disposable external filter pack, can withstand many more procedures than the external filter pack. It is recommended that this filter be replaced annually. See *Annual Maintenance*.

The Finesse II+ system contains a special internal filter on the vacuum motor exhaust, which is designed to protect the internal electronics from particulate for the life of the system.

Electromagnetic Interference. The Finesse II+ system has been tested to and certified to comply with recognized EMC (electromagnetic compatibility) standards to ensure proper operation when used near other electronic equipment, and that other similarly certified electronic equipment used near the Finesse II+ system should not be affected by it. However, users should take special precautions regarding EMC, and need to install the Finesse II+ system according to the EMC information provided in the *Electromagnetic Compatibility* section of this manual. Users should also note that portable and mobile RF communications equipment can affect medical electronic equipment.

Electrosurgical generators may interfere with other electronic devices, particularly cardiac pacemakers and other active implants Precautions should be taken to ensure the patient's well-being in the event of such interference. These precautions should include:

1. Secure attachment of the dispersive electrode,
2. Placement of the dispersive electrode away from the heart, and as close as possible to the surgical site,
3. Other precautions as directed by the pacemaker/active implant provider. Note that the use of electrosurgery is contraindicated in patients implanted with certain cardiac pacemakers.

Electrically Conductive Implants. For patients with electrically conductive implants, a possible hazard exists due to concentration or re-direction of electrosurgical currents. In case of doubt, qualified advice should be obtained.

Cautions

When installing the Finesse II+ system, do not choose a location where the Finesse II+ system will be adjacent to or stacked with other electromedical equipment. If operating the Finesse II+ system in close proximity to other equipment, observe the functioning of the Finesse II+ and other equipment to verify normal operation in the configurations that they will be used.

To avoid the risk of electric shock, the Finesse II+ system must be connected to a supply mains with protective earth (ground). To avoid damage to the power cord and receptacle, and if used, the footswitch cord and receptacle, keep the rear of the Finesse II+ system at least 3 inches (8cm) from all obstacles.

Electric Shock Hazard. Unplug Finesse II+ system before cleaning, replacing internal filter, or removing fuse holders from the rear panel.

If a single plug style pen is used, the user is not protected against inadvertent contact with the plug lead, which could result in electric shock and/or injury.

CQM circuits used in electrosurgical generators are an excellent tool to minimize the risk of a patient injury during electrosurgery. CQM is effective at detecting changes in pad contact to the patient, and can signal the user to a potentially unsafe condition. However, these circuits should not be relied on as a method for detecting improper pad application or as a substitute for user attentiveness during the procedure.

Summary

The Finesse® II+ system has been designed to implement the best principles of electrical safety. The remaining burden for patient and operator safety lies with the user of the device. The most important safety factors that are under control of the operator are delineated above. It is important that these points, as well as others made throughout this manual, be read and understood before performing surgery with this instrument.

EU NOTICE: Any serious incident (as defined in EU MDR Ch. I, Article 2 (65)) that occurs in relation to this device should be reported to the manufacturer and the competent authority of the Member State where the incident occurs.

Introduction

This manual is intended to:

- introduce you to the Finesse II+ Electrosurgical Generator and Smoke Evacuation System,
- acquaint you with the principles of electrosurgery,
- make you aware of some important concerns inherent in electrosurgery, and provide instructions for operating this instrument in performing electrosurgical procedures.

Description and Application

The Finesse II+ system combines a high-quality, class I type BF electrosurgical generator and a smoke evacuation system into a single compact unit. This integrated system was designed to perform low-power excision and coagulation procedures of short duration, but has been optimized to perform the surgical procedure currently referred to in the medical literature as LETZ® (Loop Excision of the Transformation Zone).

Electrosurgical Generator

The electrosurgical generator module in the Finesse II+ system is designed according to the same principles as the more powerful general surgery units that are commonly used in hospital operating rooms; however, its power output is limited to the range necessary for the shallower and less extensive cuts that are performed in loop excision procedures.

The output waveform and load characteristics are optimized for loop excisions in which the cut starts with only a small area of the cutting electrode in contact with tissue and proceeds to a maximum depth where the cutting line may be more than two centimeters long. The Controlled Output Circuitry of the Finesse II+ system is a negative-feedback output monitoring system that senses the changes in load resistance that occur throughout the excision and adjusts the power to match the needs of the cut. This prevents excessive tissue damage at the start and end of the cut and prevents slowing of the loop when excising at the maximum depth.

The Finesse II+ system produces a blended cut mode that performs concurrent cutting and superficial coagulation as required by standard practice for loop excision procedures. The coagulation mode provides sufficient voltage and power for spray coagulation, or fulguration, using ball electrodes.

Finesse II+ incorporates an error detection system that will produce an alert signal and shut down output power whenever one or more of the following occur:

1. both cut and coag modes are simultaneously keyed ("cross-key" error),
2. a dispersive pad cable breaks or becomes disconnected
3. a split-type dispersive pad partially separates from the patient (CQM, or contact quality monitoring), or

4. the actual output power exceeds the preset output by an unsafe margin.

Smoke Evacuation System

The smoke evacuation system is integrated with the electrosurgical generator to enhance the convenience and safety of the LETZ procedure. Its purposes are to remove the smoke that would otherwise obscure the visual field during the procedure, to filter particles from the smoke, and to adsorb the unpleasant odor.

The smoke evacuation system consists of four major components:

1. a first-stage HEPA particulate filter
2. a second-stage activated charcoal filter
3. a third-stage ULPA particulate filter
4. a vacuum motor that creates the negative pressure and the resulting airflow necessary to pull the smoke from the surgical field and through the filters.

The first two filter stages are supplied as a disposable unit (Finesse Filter Pack, catalog no. ESU-501) that is easily changed and discarded. The third-stage ULPA filter and vacuum system are installed inside the Finesse II+ system housing. The ULPA filter (Finesse II+ Internal Filter, catalog no. SSE-500) is removable for annual replacement.

Electrosurgical Procedure Guidelines

The surgical techniques used in this procedure are described in several medical journal papers and are being taught in current medical seminars. You are encouraged to learn the surgical methods from the established experts, then to read this manual carefully before using the Finesse II+ system and instruments to perform these procedures. A bibliography of papers on the subject is found later in this manual. Standard practice of these techniques may change as new findings are published.

Because of the simplicity and low complication rate of electrosurgical excision procedures, some practitioners have elected to perform these procedures in their offices. The decision whether or not to follow this trend is the responsibility of the clinician. If the decision is made to perform the procedure in the office, the clinician should be aware that no surgical procedure is performed without risk and an appropriate degree of expertise must be developed to minimize these risks.

It should also be noted that office procedures should be limited to those that do not carry significant risk of complications that may require emergency support. This criterion is met only when the excisions are not too deep and when they are performed using the same techniques that have been previously successful in the office environment.

The developers and providers of the Finesse II+ system will not presume to prescribe surgical techniques in this manual. However, there are some guidelines and warnings that may be useful in the process of the practitioner developing his/her own techniques. Some of these will be given in this manual.

Unlike most of the electrosurgical generators that are currently used in the operating rooms, the Finesse II+ generator is designed specifically for loop excision procedures in which the cutting instrument is a fine gauge wire loop. Since the power delivered by the generator is continuously controlled to a level appropriate for the length of wire exposed to the tissue, it is not necessary for the generator settings to be changed when various loop sizes are used. The Finesse II+ is pre-calibrated to a nominal output of approximately 65 watts when the load on the output terminals is 500 ohms. At other impedance levels the power will vary as it does throughout a loop excision procedure with higher powers delivered to lower impedance loads. There are no external power level controls to be adjusted by the user.

WARNING: Cutting and coagulation of ex vivo tissue is NOT adequate training for performing LETZ or any other surgical procedure involving electrosurgical techniques. Users must obtain professionally recognized training in the techniques for diagnosis and management of CIN, including LETZ.

The new user should develop confidence in the combination of the generator's characteristics and his/her own technique by practicing extensively on pieces of chicken breast or beef tongue. The objective of this practice is to determine the natural speed of the cutting electrode through the tissue and to observe how the depth of the thermal damage is influenced by the speed of the cut. After sufficient practice is obtained, the clinician should be able to develop the confidence and skill necessary to practice these procedures on patients using electrodes of different sizes and configurations for various procedures.

Coagulation of bleeding vessels after completion of an excision is usually accomplished using a ball electrode in the coagulation mode. In this mode, the ball electrode will throw sparks to the surface of the tissue with slight separation of the ball from the surface. This process, known as fulguration coagulation, should be done briefly to stop any bleeding that occurs. It should not be overdone. Other hemostatic techniques use the ball in contact with the tissue surface to coagulate by desiccation with little or no sparking. Desiccation techniques may cause unnecessarily deep thermal damage if not performed carefully. As with cutting, coagulation should be practiced on appropriate tissue simulators before performing the procedure on a patient.

The Finesse II+ coagulation mode output is pre-calibrated to a nominal output of approximately 60 watts when the load on the output terminals is 500 ohms. This setting has been found to be effective in providing hemostasis for bleeding vessels.

Loop Excision of the Transformation Zone: The LETZ® Procedure

NOTE: The following discussion of indications, contraindications, and procedure is merely intended to be a guideline for performing the LETZ procedure. The physician is encouraged to review this procedure and define his/her own protocol. Any recommendations listed are based on published articles but these articles, as well as other references listed in the Bibliography section of this manual, should be consulted and the physician's protocol defined prior to performing the procedure.

It should also be noted that the following information represents the thoughts in the LETZ procedure at the time that this document went to press. As with any medical procedure, the

views and practices regarding the LETZ procedure may change. It is therefore recommended that the clinician maintain updated information on the procedure through the medical journals and/or other sources as the procedure continues to evolve.

The LETZ procedure is a well-recognized method of treatment for Cervical Intraepithelial Neoplasia (CIN). Generally speaking, LETZ is acceptable for treatment of high-grade lesions (CIN 2 or greater), including suspected glandular abnormality, and for CIN 1 that is persistent at least 2 years, or is preceded by HSIL or AGC-NOS (atypical glandular cells - not otherwise specified) cytology. The "2019 Consensus Guidelines"[1] detail treatment recommendations for CIN, including management of CIN in "special populations" such as adolescents and young women, and should be consulted to provide the practitioner with a basis for their treatment decisions. Treatment algorithms can also be obtained online.[2]

Contraindications for LETZ are detailed in *Indications, Contraindications, Warnings, and Cautions*. It is imperative to consider the risks and benefits of treatment versus non-treatment in contraindicated patients:[3]

LETZ Procedure and Technique

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

Pre-Procedure Setup

The supplies used for the LETZ procedure should be assembled prior to the procedure. These supplies may include, but are not limited to, the following list:

- Acetic acid
- Lugol's iodine solution
- Monsel's solution
- Saline solution
- Vaginal speculum (non-conductive) with smoke evacuation port
- Lateral vaginal wall retractor
- Tissue forceps
- Large and small cotton tipped swabs
- Specimen container with preservation fluid
- Local anesthetic (such as lidocaine 1% or 2% with or without epinephrine) with delivery system (including 25 to 27 gauge needle)
- Loop and ball electrodes, various sizes in unopened sterile pouches
- Dispersive pad
- Electrosurgical pen
- Smoke evacuation filter and tubing.

Prepare generator system for use, with the exception of dispersive pad application and loop electrode selection and installation.

Performing the Procedure

Place patient in lithotomy position.

Place the vaginal speculum, with smoke evacuator tubing attached to smoke port.

Prepare the cervix for examination using acetic acid applied to a large cotton swab. Subsequently stain the cervical tissue with Lugol's solution to enhance visualization of the lesion.

If it is determined that the LETZ procedure is indicated, anesthetize the cervix. An intracervical block is typically used, injecting a total of 1.8 to 5.4 ml of lidocaine equally into four quadrants at a depth of about 2mm. The subsequent application of the dispersive pad will allow sufficient time for the anesthetic agent to take effect (typically 3 minutes).[3]

Apply dispersive pad to the patient. Complete application of the entire surface of the dispersive pad should be visually verified. **Always review the dispersive pad instructions for use before applying the pad.**

For the LETZ procedure, consider the following recommendations for placement:

- Place the dispersive pad on the thigh of the leg closest to the Finesse II+ system.
- Apply the pad to the upper thigh, anterior.
- Orient the pad so that the cord faces outward from the patient, toward the Finesse II+ system.
- Take care to avoid pad application in areas containing folds, hair, scar tissue, or dry or oily skin.
- Apply the pad by smoothing the pad from one edge to the opposite edge, in order to ensure that the full surface of the pad is adhered to the patient's skin.

Activate the Finesse II+ system's main power switch.

The loop electrode should be selected, keeping the following needs and guidelines in mind:[3,4,5]

- If possible, the loop should be wide enough to completely remove the lesion in one pass, plus allow for an adequate margin of healthy tissue so that the squamocolumnar junction can be identified by the pathologist.
- An irregular shaped lesion, or a lesion that extends into the endocervix, may indicate that more than one pass of the loop electrode and/or the use of more than one size of loop electrode will be needed.
- The endocervix is commonly not included in the loop excision, and the results of endocervical curettage (ECC) do not appear to be predictive of either residual or invasive disease after a loop excision procedure. If the ECC is positive for dysplasia, a cone biopsy should be considered.
- CIN does not typically penetrate more than 6-8mm below the surface of the cervix, therefore the excision depth should be closely monitored to avoid excessive removal of healthy tissue, yet ensure complete removal of the lesion and involved glands. Excessive removal of tissue could result in cervical stenosis, yield fertility and pregnancy effects, or have other complications.

Insert the loop electrode into the electrosurgical pen.

Perform a "test pass" to ensure that the excision path is unobstructed.

Perform the loop excision.

- It is recommended that the cut mode output be activated just before the loop makes initial contact with the tissue.
- Unless necessary, do not deactivate output power during the excision. If the loop "stalls" or output power is otherwise interrupted, the loop electrode should be removed from the tissue and the cut restarted from the opposite side of the planned excision.
- The excision should be performed from left to right or from right to left. However, if it is indicated, posterior to anterior motion may be used to remove the most suspicious areas of the lesion in the first pass. It is not recommended that the excision be performed from anterior to posterior, as the pooling of blood from the excision will tend to excessively dissipate the output power. This may cause the loop to "drag" and may result in excessively deep thermal damage to the tissue.
- Attempt to maintain the speed of the loop through the excision. Moving the loop too slow or too fast may result in excessive thermal damage to the tissue. The speed of the loop through the tissue during the excision should not be so fast as to cause the loop wire to bend back; the loop should excise the tissue with little mechanical resistance, yet still be fast enough to avoid excessive delivery of power to any given localized area of tissue.

Remove the tissue specimen using tissue forceps, mark for orientation, and place into container with preservative fluid. Label the specimen vial accordingly.

Inspect the excision bed and the endocervical canal for residual CIN, as well as ensuring that no endocervical glands remain in the excision bed.

Remove the loop electrode and insert the desired ball electrode into the electrosurgical pen.

Perform fulguration coagulation to control bleeding. Fulguration coagulation is the preferred method, as desiccation coagulation tends to cause deeper thermal tissue modification.

Monsel's solution may be used in the excision bed as a hemostatic agent following fulguration. The Monsel's solution should be a gel or paste, and is applied using a cotton swab only to the excision bed. Monsel's should not be applied to adjacent areas of tissue.

Post-Procedure Guidelines

Instruct the patient on post-procedure care and attention. These recommendations may include:

- Avoid lifting heavy objects, using tampons, douching and vaginal intercourse for 3 to 4 weeks.
- Bleeding and a dark discharge are normal, but heavy bleeding, with blood loss typical of menstruation, should be reported to the physician.
- Bleeding that occurs more than two weeks post-procedure should be reported to the physician.
- A malodorous discharge which may or may not be associated with pelvic pain should be reported to the physician.
- Instruct the patient to return to the office in three to six months for a follow-up Pap smear and/or colposcopy.

Dispose of the used electrodes, dispersive pad, and electrosurgical pen.

References

1. Perkins RB, Guido RS, Castle PE, et al, *2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors*, J Low Genit Tract Dis. 2020;24:102-131.
2. www.asccp.org.
3. Electrosurgery for HPV-related diseases of the lower genital tract, Wright TC, Richart RM, Ferenczy A, Arthur Vision, Inc., New York, 1992.
4. Large loop excision of the transformation zone, Prendiville W, Chapman & Hall, 1993.
5. Baggish MS, Ferenczy A, Gerbie M, Richart RM, *Potential complications of loop excision*, Contemp OB/GYN 1994: 39(8):93-107.

Principles of Electrosurgery

The Finesse II+ system is a monopolar generator which produces the optimal waveforms for electrosurgical cutting and coagulation. In monopolar electrosurgery, a radio frequency current is passed through the body of the patient between an active electrode, where the current is very concentrated, and a dispersive electrode, where the current is quite diffuse.

The active electrode is used as a cutting or coagulating tool at the site where surgery is to be performed. The dispersive electrode is applied at a site away from the surgical field for the purpose of returning current to the generator.

Electrosurgery results from the concentration of electrical energy in tissue to the point that the tissue is locally destroyed or modified. In electrosurgical cutting, the cells conducting the concentrated current are heated to the point where the water contained inside the cells boils and the cells explode to release steam. In electrosurgical coagulation, cells near the surface are heated so that those not exploded are dehydrated and shrunk to the point where open vessels are closed.

Cutting

To obtain cutting with minimal heating, a tool with a small cross section, such as the thin-wire loop, is driven with an electrical source having a continuous, unmodulated wave form. This kind of power source is referred to as a pure cut source. Modulating or periodically interrupting the voltage from the cutting source creates a current that will cause shallow surface coagulation as well as cutting. This kind of source is called a blended source.

The Finesse II+ system uses a blended cut mode which has been repeatedly proven successful in the LETZ procedure. The waveform produced to provide this mode is described quantitatively in the *Technical Data* section of this manual.

Coagulation

To obtain coagulation without cutting, an active electrode with a larger cross section, such as a ball electrode, is usually used. A power source with a high voltage interrupted waveform is applied to the active electrode.

Fulguration is accomplished using either a blunt or fine electrode with the coag mode waveform. The active electrode is held slightly above the surface to be coagulated so that the sparks jump across the gap. At the points on the surface where the sparks enter, very high current densities are achieved and tissue is seared. However, the area of the surface contacted by the spark and the current carried by each spark are small and the heat damage is quite shallow. This method usually produces a good cosmetic result after healing is complete.

Complications

When an appreciable electrical current is caused to flow through the patient's body, as in all monopolar electrosurgery, the common undesirable physiological effects of electric current must be considered. In the above discussions of electrosurgical theory, such words as cutting, cell explosion, burning, sparking, and searing have been used. Any of these phenomena occurring too strongly or at the wrong places are undesirable. In addition to these, there is also electric shock, which has not yet been considered.

Electric shock, or faradic effect, results from the depolarization of nerve or muscle cells by a non-physiologic electric voltage. In electrosurgery, this effect is avoided by using voltage waveforms of such high frequencies that the ions, which must migrate across a cell membrane to depolarize a cell, are only caused to vibrate over very small magnitudes. Heat is dissipated, but shock does not occur. To avoid electric shock, frequencies above 300,000 cycles per second (300 kHz) must be used. The Finesse II+ system operates at 450 kHz, which is well above this limit.

The other undesirable effects of electrical current, such as burns, are avoided by proper design of the generator, careful application of the dispersive electrode, maintenance of the patient contact with the dispersive electrode, and avoidance of all metallic contacts to the patient that may allow alternate paths for the electrosurgical current. The Finesse II+ system has been designed with isolated patient leads which minimizes the potential for currents to seek alternative routes. It also provides error indicators to signal when the dispersive electrode's connections are broken and patient contact possibly compromised.

There remains the possibility that the isolation may be destroyed by inadvertent direct or capacitive grounding in the patient connections outside the generator. The warnings and precautions given in the *Operational Safety Notes and Warnings* section of this manual must be strictly heeded.

Smoke Evacuation and Filtration

The smoke produced during electrosurgery has an odor that is unpleasant, strong, and persistent. It consists of organic gases, water vapor, visible and sub-visible solid particles and virus particles. It is generally considered good practice to remove the smoke from the surgical field and filter it. A system for this purpose is provided as part of the Finesse II+ system.

Filtering of the smoke is accomplished using a HEPA (High Efficiency Particulate Air) pre-filter, a layer of activated charcoal, and a third-stage ULPA (Ultra Low Penetration Air) particulate filter.

The effectiveness of the two stages of particle filtering has been measured on several filters using spherical latex particles. The combined particle filtration efficiency of both filters was found to be equal to or better than 99.999% efficient on 0.1 micron particles.

The vacuum motor used in the Finesse II+ system produces sufficient pressure reduction to pull approximately 80 liters per minute (2.8 cfm) through a 30cm long smoke tube with a 6mm inside diameter. This rate is effective in removing smoke from an enclosed surgical field as required by the LETZ procedure. It should be noted that a smaller diameter tube will significantly reduce the flow rate.

Device Description

The Finesse II+ system consists of two major modules, the electrosurgical generator and the smoke evacuation system. A single power switch controls both modules; the smoke evacuation system is automatically controlled relative to footswitch or handswitch activation of the electrosurgical generator.

Front Panel Indicators and Connectors

Connectors and indicators on the Finesse II+ front panel are shown in *Figure 1* and subsequently described.

Smoke Evacuation System

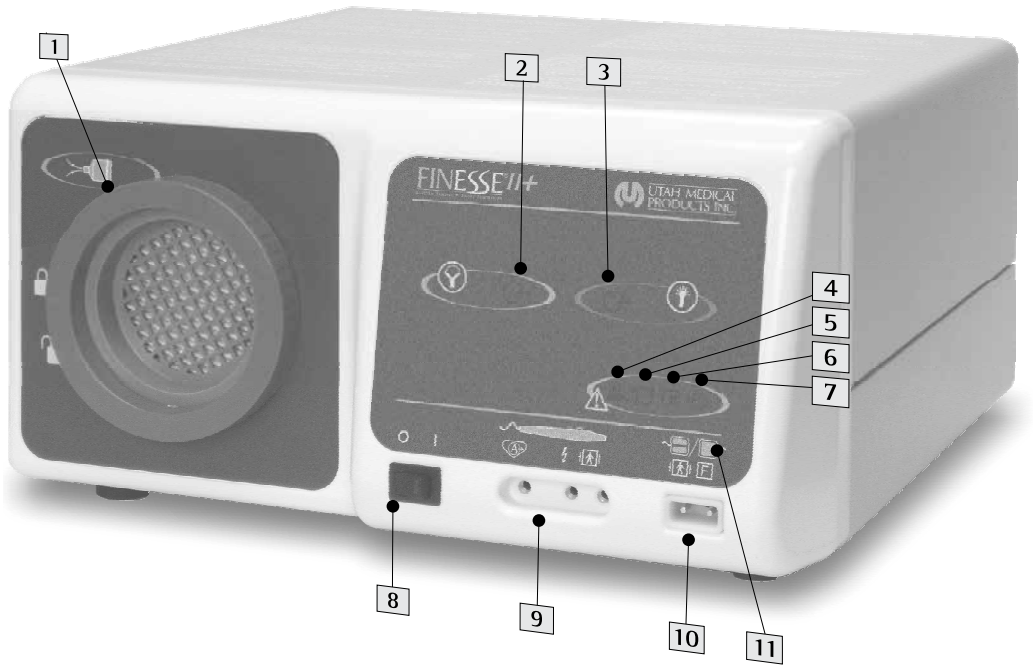


Figure 1. Finesse II+ front panel, smoke evacuation module

1. **Smoke Filter Connection.** This connection, the large circular structure on the face of the front panel, accepts the external disposable filter pack which provides first- and second-stage particulate removal and odor adsorption. The circular ring retains the Finesse Internal Filter, which is the third filtration stage of the Finesse II+ smoke evacuation module. Replacement instructions for the internal filter are found in the *Annual Maintenance* section of this manual.

The vacuum system does not have an activation switch of its own. It is automatically activated by internal circuitry whenever the cut or coag modes are activated, and shuts off after a delay of five seconds from the time the electrosurgical generator output is deactivated. In addition to its convenience, this intermittent operation is beneficial to the life of the filters and to the vacuum motor itself.

Cut Mode

Cut mode indicators are identified by the use of yellow markings and are contained within the ellipse tagged with the "cut" icon.

2. **Cut Output Activity Icon and Indicator.** This icon lights yellow whenever the cut mode is activated. Illumination of this icon is accompanied by an audio tone unique to the cut mode. This is the lowest pitch of the three audio tones used in the Finesse II+ system.

Coag Mode

Coag mode indicators are identified by the use of blue markings and are contained within the ellipse tagged with the "coag" icon.

3. **Coag Output Activity Icon and Indicator.** This icon lights blue whenever coag voltage is applied to the active lead. Illumination of this light is accompanied by an audio tone unique to the coag mode. This is the middle pitch of the three audio tones used in the Finesse II+ system.

Error Indicators

The Finesse II+ system incorporates several important safety features to minimize the risks of using electrosurgical equipment. The four error conditions detected by the Finesse II+ system will disable the output, sound an audible tone, and illuminate an orange front panel icon:

4. **"Cross-key" Error.** This condition is caused by concurrent activation of both cut and coag mode controls. A *continuous* tone will be heard until the condition is cleared. Verify that cut and coag mode buttons (and footswitch pedals, if available) are not inadvertently activated.

5. **Pad Disconnect Error.** This condition will occur whenever a dispersive pad is not plugged into the dispersive pad receptacle, a CQM (split) dispersive pad is not connected to the patient, or when one of the two redundant leads of a solid (non-CQM) type pad is broken. An *intermittent tone* will sound until the condition is corrected. Ensure pad is completely plugged into the pad receptacle and that the pad is fully attached to the patient. If the error continues, disconnect and reconnect the dispersive pad plug from the FINESSE+ system. If the error persists, replace the pad.

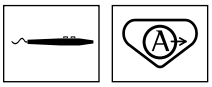
6. **CQM Error.** If using a CQM-compatible dispersive pad, an *intermittent* audible tone will sound when the pad partially or completely separates from the patient. The error will continue until the pad contact is restored to the patient. Smooth the pad back

into full contact with the patient's skin, and ensure that it remains attached. It will be necessary to use a new pad if proper adhesion to skin cannot be maintained.

7. **Output Error.** The output safety circuit continuously monitors the output of the generator  and will disable the system when an unexpected discrepancy between the preset output setting and the output power is detected. A continuous tone will sound. The Finesse II+ system main power switch must be shut off to clear this condition. If this error recurs, do not attempt to use the Finesse II+ system, and contact Utah Medical Products for instructions.

Front Panel Connectors

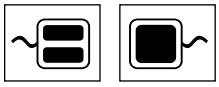
8. **Main Power (on/off) switch.** This switch must be turned on (|) to enable all functions of the instrument. A green light internal to the switch illuminates when the system is powered on. (◯) designates "off".

9. **Monopolar Handswitch Receptacle.** This connector consists of three "banana" sockets  which accommodates most hand-switching electrosurgical pens that are available. This receptacle is a Type BF Applied Part, per IEC 60601-1.

   The left-most of the three sockets, marked with the "active port" icon (the "A" icon shown beside the prior paragraph), accommodates a non-switching pen for monopolar cutting loops, balls, and other surgical tools. When these pens are used, the Finesse II+ system must be activated by a footswitch connected to the rear panel (see next section).

   CAUTION: For footswitch operation of the Finesse II+ system, it is possible to use a single-prong pen. When using a single prong pen, the user is not protected against inadvertent contact with the plug lead during insertion, which could result in electric shock and/or injury. The use of a three-prong pen (item no. ESU-305) is recommended. The operator can then choose to activate with either the hand pen or footswitch controls.

10. **Patient Dispersive Electrode Receptacle.** The dispersive pad receptacle accommodates either standard (solid) or CQM (split) style dispersive pads. The Finesse II+ System automatically detects the type of pad used. This receptacle is a Type BF Applied Part, per IEC 60601-1.

11. **Dispersive Electrode Type Indicator.** These two icons display the type of dispersive pad  detected by the Finesse II+ system. The left icon will illuminate when a CQM-style (split) pad is detected. The right icon will illuminate when a standard (solid) pad is detected. **Always verify that the illuminated icon correctly indicates the pad type being used.**

Utah Medical Products does not recommend the use of non-CQM dispersive pads with the FINESSE+ system. Use only the CQM pads listed in the *Technical Data* section of this manual.

Rear Panel Controls and Connectors

Controls and connectors on the Finesse II+ rear panel are shown in *Figure 2* and are described below.

Figure 2. Finesse II+ rear panel connectors and controls

1. **Footswitch Receptacle.** This receptacle accommodates the Finesse two-pedal footswitch (item number ESU-170), which is designed to separately control cut and coag modes.

2. **AC Power Cord Receptacle.** This receptacle is a three-contact IEC 60320 compliant connector for use with high quality three wire power cords.

3. **Equipotential Post.** This connection does not have any clinical relevance, as it is used only for testing purposes or to satisfy local electrical code requirements.

4. **Fuse Sockets.** These two pairs of sockets house the fuses that provide overcurrent protection for the electrosurgical and smoke evacuation modules of the Finesse II+ system. They are labeled with the appropriate fuse specifications for these circuits. Use only the correct fuses as specified by these labels.

5. **Audible Tone Volume Control.** This control adjusts the volume of the cut and coag mode activation tones. Due to regulatory requirements, error tones are not adjustable. Always set the volume of the audible tones so that they can be clearly heard over the smoke evacuation system.

Procedures

Initial Setup

1. Unpack the Finesse II+ system. Retain the packing material and box for future use.
2. Inspect the system for any visible damage or missing accessories. If damage is found, contact Utah Medical Products for assistance.
3. Place Finesse II+ on a flat, level surface at working height within six feet of the operating area.

   CAUTION: Do not choose a location where the Finesse II+ system will be adjacent to or stacked with other electromedical equipment. If operating the Finesse II+ system in close proximity to other equipment, observe the functioning of the Finesse II+ and other equipment to verify normal operation in the configurations that they will be used.
4. Connect the footswitch (if used).
5. **Install the Finesse II+ Internal Filter (item number SSE-500), if not already done.** Remove the internal filter retaining ring from the front of the Finesse II+ system by rotating it to the "unlocked" position, then pull outward. Place the Finesse internal filter inside the smoke evacuator port until it is nearly flush against the front panel. Replace the internal filter retaining ring, lining up the position pointer on the ring with the "unlocked" icon, inserting the ring until it is flush against the front panel, and rotating until the position pointer is aligned with the "locked" icon. **Do not operate the Finesse II+ system without the internal filter installed.**
6. Plug the Finesse II+ system into any standard power outlet, as indicated on the Finesse II+ system rear panel.

   CAUTION: To avoid the risk of electric shock, the Finesse II+ system must be connected to a supply mains with protective earth (ground). To avoid damage to the power cord and receptacle, and if used, the footswitch cord and receptacle, keep the rear of the Finesse II+ system at least 3 inches (8cm) from all obstacles.

Normal Operation

Setup

1. **Attach the Finesse Filter Pack (item no. ESU-501) to the filter connector on the front panel by gently pushing the filter end straight into the system.** The Finesse Filter Pack will not attach if the Finesse Internal Filter has not been installed (refer to prior step).

2. **Attach the flexible tubing (item no. ESU-502) to the end of the filter pack tubing and to the smoke port of the speculum to be used.** To avoid kinking the speculum tubing, drape the filter pack tubing over the patient's leg.

3. **Insert the electrosurgical pen (item no. ESU-305 is recommended for both handswitch and footswitch operation) into the pencil receptacle on the front panel.** If a single-prong type pen (for use with a footswitch) is used, it must be plugged into the port labeled with the "active port" icon.

   CAUTION: If a single plug style pen is used, the user is not protected against inadvertent contact with the plug lead, which could result in electric shock and/or injury.

4. **Prepare the patient as needed to perform the procedure, including attachment of the dispersive electrode to the patient.** The dispersive electrode should be placed as close as practical to the surgical site. Select a site that is well vascularized which will permit later inspection without disturbing the sterile field. To obtain optimal results, ensure that the site is clean, dry, and free of excessive hair. *Figure 3* shows a commonly used site for the LETZ procedure.

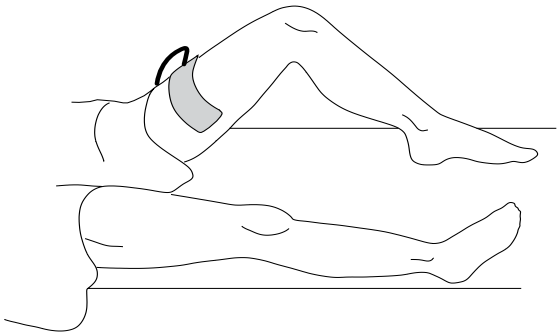


Figure 3. Dispersive electrode placement

When selecting the placement site and orientation for the pad:

a) select a site that is on the side of the patient closest to the Finesse II+ system.

b) orient the pad so that the cord faces the Finesse II+ system

c) after removing the protective backing from the pad, attach one edge of the pad to the skin, then smoothly press the pad surface into contact with the skin to the opposite side. This promotes full surface contact of the pad to the skin, avoiding entrapment of air pockets.

Pad attachment should be in compliance with the instructions included with the pad. It is essential that the pad adhesive be securely bonded with the patient's skin, that the pad not be wrinkled, and that the full available area for electrical contact is utilized.

5. **Insert the plug on the dispersive electrode (compatible dispersive pad item numbers are listed in the *Technical Data* and *Accessories* sections of this manual) into the front panel receptacle labeled with the "Dispersive Pad" icons.** If using a contact quality monitoring, or "CQM" dispersive pad, pad surface contact to the patient will be monitored. The pad should

be attached to the patient before either a) turning on the main power to the Finesse II+ system, or b) plugging the pad cable into the Finesse II+ system.

Operation

1. **Turn on the Finesse II+ by activating the main power switch.** If using a CQM-type (split) dispersive pad, it must be attached to the patient prior to either plugging the pad into the Finesse II+, or prior to turning on the main power switch.
2. **Fully insert the desired active electrode into the pen.** There should be no exposure of the uninsulated portion of the electrode's shaft.
3. **Begin the excision by pressing the Cut button of the handswitch pen or the Cut pedal of the footswitch control.** In one continuous motion and without hesitation, move the excision electrode along the desired path. Do not deactivate the output until the electrode has been completely removed from the tissue.

   The smoke evacuation system will begin drawing air when either button on the pen (or pedal on the footswitch) is activated and continue running for five seconds after the button or pedal is released.
4. **Remove the active electrode from the pen.**
5. **If fulguration is desired, insert the selected ball tip electrode. Begin coagulation by pressing the Coag button of the handswitch pen or Coag pedal of the footswitch.** Keeping a slight gap between the electrode ball and tissue, move the ball across the tissue.

Shutdown

1. Turn off power to the Finesse II+ system by toggling the main power switch.
2. Unplug and discard the used electrodes, dispersive pad, and pen per facility protocol for used medical supplies.
3. If this is the last electrosurgical procedure to be performed for the day, remove the Finesse Filter Pack. Daily disposal of the filter pack reduces the possibility of odor accumulation in the procedure room. Using appropriate protective gear, remove the filter from the front panel by pulling and twisting the filter housing. Discard the filter pack with other medical disposables per facility protocol for used medical supplies.

Daily Maintenance

For optimum odor control in the procedure room, change the external filter pack at the end of any day that the Finesse II+ system is used. See step #3 of the Shutdown procedure above.

Cleaning

CAUTION: Electric Shock Hazard.
Unplug Finesse II+ system before cleaning.

Clean the Finesse II+ system exterior with mild, soapy water applied to a damp (not soaked) clean cloth. Wipe the exterior case, including the front panel. If further contamination control is

desired, 70% isopropyl alcohol may be applied to a cloth. Do not use acetone, isopropyl alcohol concentrations exceeding 70%, or abrasive materials. Do not apply liquids directly to the system.

Consult your facility protocol for further cleaning guidance. Always wear appropriate protective gear (gloves, goggles, and/or protective clothing) if directed by protocol or product instructions.

The active electrodes, pens, dispersive pads, and speculum tubing/reducer are supplied as single patient use items. Do not attempt to clean and/or resterilize these items.

Annual Maintenance

CAUTION: Electric Shock Hazard.
Unplug Finesse II+ system before replacing internal filter.

The Finesse Internal Filter (item no. SSE-500) should be changed on an annual basis. **The following procedure should be performed using caution appropriate for the handling of contaminated medical waste:**

1. Remove the internal filter retaining ring from the front of the Finesse II+ system by rotating it to the "unlocked" (🔓) position, then pull outward. Dispose of the used filter consistent with your facility's policy.
2. Place the new Finesse Internal Filter inside the smoke evacuator port until it is nearly flush against the front panel.
3. Replace the internal filter retaining ring, lining up the position pointer on the ring with the "unlocked" icon, inserting the ring until it is flush against the front panel, and rotating until the position pointer is aligned with the "locked" (🔒) icon.

For the care and performance of your Finesse II+ electrosurgical system, Utah Medical Products recommends users establish a program for inspection and preventive maintenance (IPM). Contact Utah Medical Products at (800) 533-4984 for details regarding IPM service options. UTMD recommends annual IPM for the Finesse II+ system.

ECRI, a non-profit organization, publishes *IPM Procedure 411*. This procedure recommends that minor inspections should be performed every six months and major inspections should be done annually. Contact ECRI at (610) 825-6000, or www.ecri.org.

Service manuals (including circuit descriptions, circuit diagrams, calibration instructions and component lists) and schematics will be made available on request to qualified technical personnel.

Troubleshooting

The following are normal troubleshooting procedures that do not require the assistance of a technician. If a solution to the problem is not found after performing the procedures applicable to the problem as listed below, consult Utah Medical Products Customer Service.

- **Output is not sufficient to perform the procedure.** It is possible that the dispersive electrode is not making sufficient contact with the patient skin, and/or the active electrode is not making proper contact with the Finesse II+ system. Recheck all connections and also check the quality of the dispersive electrode contact to the patient.
- **The Finesse II+ system is not pulling smoke away from the surgical site (but smoke evacuation motor runs when activating electrosurgical system).** If there is not enough suction to pull smoke away from the surgical site, check the attachment of the tubing and filter cartridge to the Finesse II+ system. Check the tubing for any kinks (especially kinking of the flexible speculum tubing), cuts, or obstructions. Also verify that the flexible speculum tubing and speculum smoke port are both clear. If these checks do not produce an explanation for the loss of suction power, remove the Finesse Filter Pack from the Finesse II+ system and check the paper element of the cartridge to ensure that it has not become saturated with smoke particles and/or moisture. Also check for plugging of the internal filter as well as ensuring that the filter has not come dislodged from its internal mount. Re-seat the internal filter (as if replacing the internal filter – this procedure is shown in the *Annual Maintenance* section), and/or replace the Finesse Filter Pack and/or tubing as necessary.
- **Smoke evacuation system does not activate.** The smoke evacuation motor will only activate when the electrosurgical output is activated. If activation of the output does not cause the vacuum motor to start, check the smoke evacuation fuses and replace, if blown. Use only fuses of the type and rating indicated.
- **The loop electrode stops cutting during the procedure.** Unless necessary, do not deactivate output power during the excision. If the loop "stalls" or output power is otherwise interrupted, do NOT attempt to re-start the loop while it is embedded in tissue, as this will typically cause excessive thermal artifact on the specimen. The loop electrode should be removed from the tissue and the cut restarted from the opposite side of the planned excision, i.e., at the originally intended exit point of the loop excision.
- **An error indicator is activated.** Consult the error descriptions, listed in the *Front Panel Indicators and Connectors* section to identify the cause and potential steps to resolve the error.
- **Lights on the front panel go out.** If all the lights and indicators on the front panel go out you should check and replace, if necessary, the electrosurgical system fuses on the rear panel of the system. Use only fuses of the type and rating indicated.

CAUTION: Electric Shock Hazard.
Unplug Finesse II+ before removing fuse holders from the rear panel.

Technical Data

Physical Specifications

Dimensions:	14.0" (35.6 cm) W x 14.7" (37.3 cm) D x 7.3" (18.5 cm) H
Weight:	24 lbs. (11 kg)

Regulatory Information

IEC classification:	Class I, Type BF Defibrillator protected 
Patient leads:	RF Isolated 
Mode of Operation:	Continuous operation with intermittent loading (10s/30s)
Ingress protection:	IPxx (ingress protection rating is not required) Protected against spillage per IEC 60601-1 and IEC 60601-2-2
CE 1639	item no. FIN2-220 bears the CE Mark
EMC:	Complies with IEC 60601-1-2:2007 and IEC 60601-2-2:2009 requirements for electromagnetic compatibility (EMC) of medical electrical equipment. For detailed information on EMC, see the *Electromagnetic Compatibility* section of this manual.

Supply Voltage and Current Considerations

The Finesse II+ system can be obtained in 115 VAC (item no. FIN2-110) or 230 VAC (item no. FIN2-220) configurations.

Supply Voltages (voltages are AC rms)

	FIN2-110	FIN2-220
Nominal Voltage:	115 volts	230 volts
Regulated Range:	103.5-126.5 volts	207-253 volts
Frequency:	50/60 Hz	50/60 Hz

Output Power vs. Supply Voltage

Within the Regulated Range listed above, output power into a 500Ω load remains ±15% of the power delivered at the center of this range in cut mode and ±30% in coagulation mode.

Maximum Supply Current and Power

FIN2-110	System Total	ES Module	Smoke Evacuator
Idle State:	0.4 amp, 50 watts	0.4 amp, 50 watts	negligible
Cut Mode:	4.1 amps, 470 watts	2.1 amps, 240 watts	2.0 amps, 230 watts
Coag Mode:	3.5 amps, 405 watts	1.5 amps, 175 watts	2.0 amps, 230 watts

FIN2-220	System Total	ES Module	Smoke Evacuator
Idle State:	0.2 amp, 50 watts	0.2 amp, 50 watts	negligible
Cut Mode:	2.6 amps, 585 watts	1.1 amps, 240 watts	1.5 amps, 345 watts
Coag Mode:	2.3 amps, 520 watts	0.8 amps, 175 watts	1.5 amps, 345 watts

Overcurrent Protection

The Finesse II+ is protected by two sets of 5mm x 20mm, time-lag, low breaking capacity, 250VAC fuses (all fuses are type TxAL250V, where x is the rating capacity in Amps):
Electrosurgical System: a pair of fuses protect the leads connected to the primary winding of this module's main power transformer.
FIN2-110: 2.5 amp FIN2-220 1.25 amp
Smoke Evacuation System: a pair of fuses protect the smoke evacuation motor.
FIN2-110: 3.15 amp FIN2-220 2.5 amp

Output Characteristics

Output Frequencies

Output Frequency (all modes): 450 kHz ± 50 kHz.
Waveform Pattern Repetition Rate: 28.1 kHz ± 3 kHz.

Output Values at Maximum Settings

Operating Mode	*Output* [a]	*Duty Cycle* [b]	*MOV* [d]	*Maximum Output Current (Amps)*	*Maximum Heating Factor (A^2s)* [e]	*Crest Factor* [f]
Cut	65	62.5%	1120	1.03	21.4	2.2
Coag	60	c	2180	0.89	15.7	5.8

a Output specified is power in watts, plus or minus 15%, delivered into a 500Ω patient load.
b Duty Cycle is ratio of burst duration to burst-plus-rest duration.
c Coag pulse consists of two high voltage cycles followed by lower amplitude ringout for about 10 µsec, repeated at 28.1 kHz.
d Maximum Output Voltage; voltage is zero-to-peak, open circuit. Lower values are permitted. **Use only accessories with a Rated Accessory Voltage (RAV) that is greater than the MOV.**
e When used according to the rated Mode of Operation (not exceeding 10 seconds activation within a 30 second period).
f Crest factor is defined as the ratio of peak voltage to RMS ("average") voltage, and is a general quantification of an electrosurgical waveform's degree of coagulation. Data shown are typical values at 500Ω.

Table 1. Output Characteristics

Output Power vs. Load

Cut mode output is preset to be 65 watts, ±15%, and coag mode is preset to be 60 watts, ±15%, at a load of 500Ω.

In the cut mode, the negative-feedback output stage attempts to maintain the output voltage under low resistance loads so that the cutting characteristics are quite uniform throughout the entire cut. Cut mode maximum output is 90 watts at 250Ω patient load.

In Coag mode the negative-feedback stage is not used in order to achieve high open-circuit voltage, which is desirable. Coag mode maximum output is 80 watts at 250Ω patient load. See *Figure 4* for output power vs. load data.

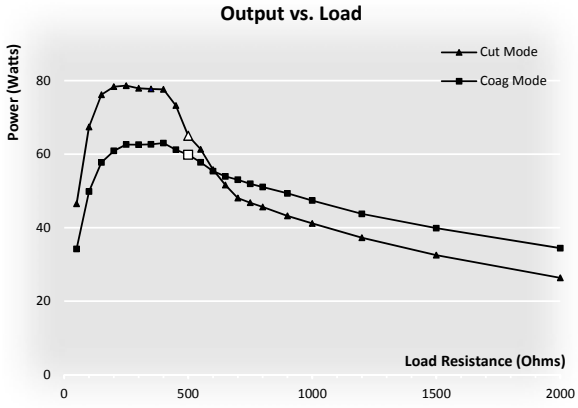


Figure 4. Typical output power vs. load resistance for cut and coag modes

Maximum Output Voltage vs. Output Mode

Table 1 shows the Maximum Output Voltage (MOV) for each mode. Only use active electrodes and pencils that have a Rated Accessory Voltage (RAV) greater than the MOV for the selected mode.

Output Error Safety Circuit Specifications

The Finesse II+ system is equipped with a safety circuit that monitors the output signal levels and disables all system functions when the output exceeds the expected "nominal" output. The error indication can only be reset by turning off the main power switch.

The output error indicator will activate if the output power exceeds the displayed output, as defined in standard IEC 60601-2-2, *Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories.* This threshold is strictly defined, but in the Finesse II+ it is generally characterized by a threshold that is approximately 25W above the nominal output at 500 ohms.

CQM Circuit Specifications

CAUTION: CQM circuits used in electrosurgical generators are an excellent tool to minimize the risk of a patient injury during electrosurgery. CQM is effective at detecting changes in pad contact to the patient, and can signal the user to a potentially unsafe condition. However, these circuits should not be relied on as a method for detecting improper pad application or as a substitute for user attentiveness during the procedure.

Always apply the dispersive pad as indicated in the dispersive pad instructions for use, and periodically make a visual check the pad application to the patient.

The Finesse II+ system is capable of monitoring dispersive pad contact to the patient. To enable this function, a split-style dispersive pad is required (see compatibility list). If a split pad is not detected, the use of a solid pad is assumed and the Finesse II+ system will not detect compromise in pad contact to the patient.

Utah Medical Products does not recommend the use of non-CQM dispersive pads with the FINESSE+ system. Use only the CQM pads listed below.

For best operation, the dispersive pad should be attached to the patient prior to plugging the pad into the dispersive pad receptacle. Once the CQM system detects the pad's contact quality to the patient, a threshold is internally set that will activate the CQM error indicator if the dispersive pad partially peels away from the patient.

When the CQM-compatible dispersive pad is properly and fully applied, tests of the Finesse II+ CQM system found that the circuit will display the error indicator when approximately 30% of the dispersive pad's surface area has separated from the patient. At the threshold of the error condition, tests performed per standard IEC/EN 60601-2-2 sec 201.15.101.5 found the following pads caused less that 6˚C temperature rise on the patient's skin.

CQM-compatible pads (UTMD item numbers and descriptions):

ESU-420 Dispersive Pad, CQM (split), precorded, Thermogard®

WARNING: To ensure safe contact of the dispersive pad to the patient, use only pads listed as compatible with the Finesse II+'S CQM system. The use of contact monitoring pads that are not on this list may not properly signal an error condition and result in patient injury.

CQM circuit frequency:	39.5 kHz
CQM pad contact range:	10-130Ω, ±5Ω
Solid pad contact range:	<10Ω±5Ω, but not greater than minimum of CQM contact range

Audio Tone Specifications

All audio tone specifications are measured in decibels, A-weighted scale, at a distance of 1m from the front of the Finesse II+ system, and are nominal values.

Cut Mode Tone:	45-70 dBA, adjustable, 625 Hz continuous tone while activated
Coag Mode Tone:	45-70 dBA, adjustable, 1.25 kHz continuous tone while activated
Error Indicator Tones:	70 dBA, not adjustable:
CQM error:	intermittent 2.5 kHz tone, 0.25 sec on/0.25 sec off
Pad disconnect error:	intermittent 2.5 kHz tone, 0.25 sec on/0.25 sec off
Cross-key error:	continuous 2.5 kHz tone
Output safety error:	continuous 2.5 kHz tone

Smoke Evacuator System

Air Flow vs. Supply Voltage

At the Nominal Supply Voltage, the air flow through a new disposable filter coupled to a 30 cm long 6 mm ID tube is not less than 80 liters per minute (2.8 cfm).

Smoke Evacuation Duration

The smoke evacuation system will begin running immediately on activation of the electrosurgery module and remain running five seconds after the output power is deactivated.

Disposable Filter Cartridge

The Finesse Filter Pack, catalog number ESU-501, consists of a pleated HEPA paper filter followed by a compartment containing activated charcoal.

The Finesse Filter Pack, to ensure total elimination of odors between procedures, should be replaced on a daily basis. However, the three-stage filtration system has been tested to effectively remove odors and particles for up to 15 electrosurgical procedures. Over a period of time the external disposable filter pack can be a source of odor and possible viral contamination. Therefore, it is recommended that the external filter pack be changed every day or after 15 procedures if more than 15 procedures are performed in a single day.

Third-Stage Internal Filter

The Finesse II+ Internal Filter, item number SSE-500, is a pleated ULPA filter element. Annual replacement is recommended.

Particle Removal Efficiency

Spherical particles with a mean diameter of 0.1 microns were removed with a minimum efficiency of 99.999%, as determined by laboratory tests via a latex particle challenge.

Vacuum Motor Exhaust Filter

The Finesse II+ smoke evacuation motor is equipped with a HEPA grade particulate filter. This filter protects the Finesse II+'s internal electronics from any particulate that may be generated by the motor. This filter should never need cleaning or changing. However, if the smoke evacuation system flow seems degraded after replacing all other filtration components, contact Utah Medical Products for information.

Environmental Specifications

Operational Environment

Temperature:	50˚F to 104˚F (10˚C to 40˚C)
Humidity:	10% to 93%
Pressure:	700 hPa to 1060 hPa (10.15 PSI to 15.36 PSI)

Storage and Transport Environment

Temperature:	-40˚F to 158˚F (-40˚C to 70˚C)
Humidity:	10% to 93%
Pressure:	500 hPa to 1060 hPa (7.25 PSI to 15.36 PSI)

After transport and/or storage at conditions outside of the operating environment range, allow time for the Finesse II+ system to reach the operating environment — typically one hour is sufficient.

Accessories

The following accessories are approved by Utah Medical Products for use with the Finesse II+ Electrosurgical and Smoke Evacuation System. All items are available from Utah Medical Products or its authorized distributor. Contact Utah Medical Products for a complete and current listing of supplies for the Finesse II+ system.

Electrodes

Item No.	*Description*
LETZ® Electrodes (11cm shaft)[ab]	
DLP-B11	UtahLoop® Electrode, 25mm x 8mm, with Safe-T-Gauge® (tan)
DLP-E11	UtahLoop® Electrode, 25mm x 22mm, with Safe-T-Gauge® (canary)
DLP-L11	UtahLoop® Electrode, 20mm x 15mm, with Safe-T-Gauge® (blue)
DLP-W11	UtahLoop® Electrode, 20mm x 12mm, with Safe-T-Gauge® (white)
DLP-M11	UtahLoop® Electrode, 15mm x 12mm, with Safe-T-Gauge® (green)
DLP-S11	UtahLoop® Electrode, 10mm x 10mm, with Safe-T-Gauge® (yellow)
DLP-SQ1	UtahLoop® Electrode, 10mm x 10mm square, with Safe-T-Gauge® (orange)
DLP-SQ2	UtahLoop® Electrode, 10mm x 4mm, 15˚ bend, 11cm shaft (brown)
DLP-T11	UtahLoop® Electrode, 5mm x 5mm, (purple)
DBL-511	UtahBall® Electrode, 5mm diameter (red)
DBL-311	UtahBall® Electrode, 3mm diameter (black)
DLP-N11	Macro Needle Electrode, 0.8 mm dia x 15mm long, 11 cm shaft (red)
DLP-U11	Micro Needle Electrode, 0.2 mm dia x 15mm long, 11 cm shaft (black)
Extender Electrode[ab]	
DXT-S06	DXTender® Electrode Extender, small displacement (blue)
DXT-L09	DXTender® Electrode Extender, large displacement (blue)
DLP-X10	Electrode Extender, 10cm (blue)

Accessories

ESU-170	Dual Pedal Waterproof Footswitch
ESU-305[ab]	Two Button Hand-switching Pen
ESU-420[b]	Dispersive Pad, CQM (split), precorded, Thermogard®
ESU-501[c]	Finesse Filter Pack (includes speculum tubing)
ESU-502[b]	Flexible Speculum Tubing with adapter
951-712	Universal Smoke Evacuation Tubing Set
SSE-500	Finesse II+ Internal Filter
SSE-610	Internal Filter Retaining Ring

Item No.	*Description*
0007-503	Fuse, 3.15 amp, 5mm x 20mm, Time Lag, for FIN2-110 smoke evacuation module (type T3.15AL250V)

0007-502	Fuse, 2.5 amp 5mm x 20mm, Time Lag, for FIN2-110 electrosurgical module and FIN-220 smoke evacuation module (type T2.5AL250V)
0007-501	Fuse, 1.25 amp 5mm x 20mm, Time Lag, for FIN2-220 electrosurgical module (type T1.25AL250V)

a supplied sterile
b disposable, intended for single patient use only
c disposable, rated for 15 procedures

Glossary

This glossary defines words and expressions used in this manual which may be new to the beginning practitioner of electrosurgery, as well as more common words that have an unusual meaning in the art of electrosurgery.

Activated charcoal: Charcoal granules that have been heated in steam for a sustained period of time so that the surfaces are free of organic gas molecules. These granules have a very large capacity for adsorbing organic gases that contact their surfaces.

Active electrode: The electrode used as a tool at the surgical site, e.g. the loop.

Adsorption: The assimilation of gas, vapor, or dissolved matter by the surface of a solid or liquid. See also activated charcoal.

Amp: Short for Ampere. The measure of electron flow in an electrical circuit. One amp represents 6.24×10^{18} electrons passing a given point in one second.

Blend mode: A mode of electrosurgical cutting wherein a periodically interrupted voltage waveform is applied to the active electrode, which causes sufficient heating of the surface exposed by the cut that desiccation coagulation occurs.

Capacitive coupling: Effective connection from one circuit to another by capacitance rather than conductance. Capacitance between circuits may accidentally come about when a conductive surface connected to one circuit lies intimately close to a conductive surface connected to the other circuit, even though the two conductive surfaces are separated by an insulating material or air. In this situation, high frequency current may flow from one circuit to the other.

Capacitive grounding: Capacitive coupling to ground. For example, in electrosurgery, the patient dispersive electrode, which was designed to be isolated from ground, may be effectively grounded by falling off the patient and lying flat on a metal table. Even though some intervening insulating material may prevent the conductive surface of the pad from actually touching the table there is nevertheless capacitive coupling and current can flow between the pad and the table. If another part of the table should be touching the patient while cutting or coagulation is being performed, a patient burn could occur at the point of contact.

Carrier frequency: The frequency of the principal radio frequency waveform produced by the electrosurgical generator.

Coag/Coagulation: The process of causing bleeding to cease by thermally clotting blood and shrinking vessel ends. Also the setting on an electrosurgical generator that produces a waveform that is effective in bringing about coagulation.

Contact Quality Monitoring (CQM): A safety circuit used in many electrosurgical systems designed to detect partial detachment of the dispersive pad from the patient's skin. When using a non-CQM dispersive pad (typically these have a single conductive surface), pad detachment can

contribute to a potentially unsafe condition, since the electrosurgical return current will be more concentrated (i.e., have a higher current density) and result in an increase of skin warming. Continuing to operate an electrosurgical generator with a partially detached dispersive pad has caused severe burns at the dispersive pad site. CQM circuits have shown to be an effective means of reducing the incidence of pad site burns due to pad detachment. Standard IEC 60601-2-2 *Particular Requirements for the Safety of High Frequency Surgical Systems* addresses the requirements for CQM system performance.

Current density: The degree of concentration of electrical current through a conductive surface or cross section. High current densities cause high power densities, causing high heat densities, causing high temperatures.

Cut: Separation of tissue. In electrosurgery, a process wherein a narrow line of cells are heated to the point of bursting as a thin active electrode or loop is moved through the tissue. Also the setting on the electrosurgical generator that will produce the best waveform for cutting with minimal coincident coagulation.

Desiccation: Drying. In electrosurgery, a mode of coagulation wherein cells are electrically heated in the vicinity of an active electrode to the point that they are dried and shrunk.

Dispersive electrode: Also referred to as dispersive pad. An electrode applied to the patient's skin, having a large area of application so that the current flowing between the patient and the electrode is diffuse rather than dense. A properly applied and connected dispersive pad is the most important consideration in preventing burns in electrosurgery.

Duty cycle: A parameter in the description of a repetitive waveform which gives the percentage of time that voltage is applied to the circuit compared with the total time over which a cycle occurs.

Electromagnetic Compatibility: The ability of electrical equipment to operate satisfactorily in the presence of other electrical equipment ("electromagnetic immunity"), without introducing radio frequency interference that would affect that other equipment ("electromagnetic emissions").

Frequency: As pertaining to an electrical waveform, the rate of repetition of identical voltage or current patterns. Frequency is measured in Hertz (Hz), cycles per second.

Fulguration: Flashing, sparking. In electrosurgery, a process wherein sparks are caused to jump across a gap between the active electrode and the patient tissue where coagulation is desired.

Isolated leads: Electrical leads upon which the voltages carried are not referenced to earth ground. Perfectly isolated leads, even though they may carry large currents at high voltages, will not convey current to earth grounded conductors that may come in contact with them or the patient to which they are connected.

Leakage current: Current flowing in a path other than the intended path. For this discussion, currents that may flow through the patient or through the bodies of attending care personnel. Depending upon their magnitudes and frequencies, leakage currents may cause shocks, burns, or fibrillation.

Load resistance: The resistance to electric current between the active electrode and the dispersive or return electrode. In actual electrosurgery, the resistance presented to current passing through the patient. In test conditions it is the resistance of a resistor of known value placed across the patient leads from the generator.

Maximum Output Voltage: The maximum possible peak voltage between patient circuit connections. For monopolar electrosurgery systems, this is typically the peak voltage between the active electrode and the dispersive electrode.

Modulation: Variation in the amplitude of a waveform. Modulation of a continuous cutting waveform creates a blend waveform that will provide shallow coagulation as well as cutting. Greater than 100% modulation creates a blend mode waveform consisting of a sequence of repeated pulses each containing a number of cycles of the carrier frequency.

Monopolar electrosurgery: Electrosurgery wherein only a single active electrode is used at the surgical site, as opposed to bipolar electrosurgery wherein current flows between two narrowly separated active electrodes at the surgical site.

Ohm: The measure of electrical resistance. One ohm is the amount of resistance that requires one volt to cause a current of one amp. Represented as Ω.

Radio frequency: Frequencies of alternating electromagnetic currents higher than 20 kHz.

Rated Accessory Voltage: The maximum peak voltage that can be applied to the active electrode, relative to the dispersive electrode. The use of an accessory where the Rated Accessory Voltage is less than the Maximum Output Voltage may lead to an unsafe operating situation and patient and/or user injury.

Sinusoid Waveform: A smoothly-oscillating waveform. A continuous sinusoid is characteristic of an electrosurgical "pure cut" mode, and an interrupted sinusoid waveform is characteristic of a blended cut waveform.

Spark: When a very high voltage is applied across a short gap containing a gas (e.g. air or water vapor), the gas molecules in the gap are ionized and current flows. When this happens, light, sound, and heat are produced. This event is a spark, also called an arc.

Spray coagulation or **spray fulguration:** A method of electrosurgical coagulation wherein a newly exposed surface is treated by spraying it with sparks from an active electrode. In this method the electrode is moved parallel to the tissue surface, but separated by a slight distance so that the electrode is not touching but is close enough for sparks to jump. The waveform used has a very high voltage and a very short duty cycle.

Volt: The measure of electrical potential or force. Higher voltage causes higher current to flow through a given resistance. Very high voltage can cause current to flow through a gas or air gap by ionizing the gas molecules in the path.

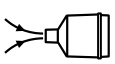
Watt: The measure of electrical power. Power in watts equates directly to rate of heat production. Concentration of power means concentrated heating which brings about high temperature.

Symbology

The following symbols are used on the Finesse II+ system and in this document. Many are defined by international standards, while others are defined specifically for use with the Finesse II+ system.

Table 2. Symbols used in conjunction with the Finesse II+ System

Symbol	Definition/Description
Standardized symbols (defined in ISO 15223-1, ISO 60417, ISO 60878, ISO 7000, and other standards)	
CE	CE Mark. The CE Mark is required for electromedical devices used in the European Union, and signifies compliance to international regulatory, electrical and safety standards.
MD	Medical Device
	Consult operating instructions
	Caution (also used to indicate system error indicators)
	Dangerous voltage
	Non-Ionizing Radiation
	Defibrillation-proof Type BF Applied Part
F	Floating patient leads
	Power off
	Power on
REF	Reference (model) number

Symbol	Definition/Description
SN	Serial Number
	Date of Manufacture
	Manufacturer
EC REP	Representative in the European Community
	Input connector, alternating current (AC) power
	Equipotential connector
	Continuously adjustable control
	Footswitch connector
AP	Do not use in presence of flammable anesthetics and air
Symbols defined for Finesse II+ System	
	Audible tone volume control
	Locked (pertaining to Finesse II+ Internal Filter retaining ring)
	Unlocked (pertaining to Finesse II+ Internal Filter retaining ring)
	Smoke evacuation system

Symbol	Definition/Description
	Cut Mode indicator
	Output activity indicator
	Coag Mode indicator
	Cross-key error indicator
	Dispersive pad not inserted, or single pad cable continuity error indicator
	CQM error indicator

Symbol	Definition/Description
	Output error indicator
	Output terminals
	Active port
	Split (CQM) dispersive pad indicator
	Solid dispersive pad indicator

Electromagnetic Compatibility

The Finesse II+ system has been designed to operate with minimal interference to nearby electronics (electromagnetic emissions), and also to perform without any effects in the presence of other electronics (electromagnetic immunity). Because electrosurgical systems use high frequency energy for therapeutic surgical effects, the following tables are provided to satisfy regulatory requirements, and so that users of the Finesse II+ have guidance on operating the system in an environment containing multiple electronic systems.

Table 3. Guidance and manufacturer's declaration — electromagnetic emissions

The FINESSE II+ System is intended for use in the electromagnetic environment specified below. The customer or the user of the FINESSE II+ System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The FINESSE II+ System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The FINESSE II+ System is suitable for use in Professional Healthcare Facility Environments. **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the FINESSE II+ or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 4. Guidance and manufacturer's declaration — electromagnetic immunity

The Finesse II+ System is intended for use in the electromagnetic environment specified below. The customer or the user of the Finesse II+ System should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Pass	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV AC supply lines ±1 kV for input/output lines	Pass	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV AC supply lines ±0.5 kV, ±1 kV and ±2 kV line to ground	Pass	Mains power quality should be that of a typical commercial or hospital environment.

Table 4. Guidance and manufacturer's declaration — electromagnetic immunity (cont.)			
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Pass	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle, 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle, 0° 70% U_T for 0.5 s, 0° 0% U_T for 5 s	Pass	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Finesse+ System requires continued operation during power mains interruptions, it is recommended that the Finesse+ System be powered from an uninterruptible power supply or battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 80% AM @1 kHz	Pass	Portable and mobile RF communications equipment should be used no closer to any part of the FINESSE+ System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	Pass	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Per Clause 8.10 of IEC 60601-1-2	Pass	See also *Table 5*
Proximity maganetic fields IEC 61000-4-39	8 A/m @30 kHz 65 A/m @ 134.2 kHz 7.5 A/m @13.56 MHz	Pass	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FINESSE+ System is used exceeds the applicable RF compliance level above, the FINESSE+ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FINESSE+ System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. i

Portable and mobile communications equipment can affect electromedical equipment. *Table 5* provides recommended separation distances for the operation of these devices in the vicinity of the Finesse II+ system. These immunity distances were established from the testing procedures and guidance of international standard IEC 61000-4-3 and IEC 61000-4-6.

Table 5. Recommended separation distances between portable and mobile RF communications equipment and the Finesse II+ System

The Finesse II+ System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Finesse II+ System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Finesse II+ System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Examples of approximate frequencies and power outputs for common RF communications devices:

- Mobile Phone: 0.01 to 1 W 700 MHz to 2.5 GHz ("5G": 28GHz, 39GHz)
- Wireless Router: 0.1 W 2.4 GHz, 5.0 GHz
- Cordless phone: 0.01 W 1.9 GHz to 5.6 GHz
- Laptop WiFi: 0.01 to 0.05 W 2.4 GHz, 5.0 GHz
- Bluetooth Device: 0.001 to 0.1 W 2.4 GHz to 2.5 GHz

Bibliography

The following references cite some of the published literature pertaining to electrosurgical procedures. These papers should provide an introduction to the technique. Further instructions should be obtained from qualified experts before performing these procedures.

Baggish MS, Campion MS, Ferenczy A, Richart RM, *Exploring excision technique with LEEP. (panel discussion)* Contemp Ob/Gyn 37(sp):81-100 (1992)

Baggish MS, Ferenczy A, Gerbie MV, Richart RM, *Potential complications of loop excision (panel discussion)* Contemp Ob/Gyn 39 (8):93-107 (1994)

Cartier R, Sopena B, Cartier I, *Use of the diathermy loop in the diagnosis and treatment of lesions of the uterine cervix (abstract).* Proceedings of the International Federation for Cervical Pathology and Colposcopy, London (1981)

Hainer BL, *Fundamentals of electrosurgery*, J Am Board Fam Prac; 4:419-26 (1991)

Luesley DM, Cullimore PC, Redman CW, et al, *Loop diathermy excision of the cervical transformation zone in patients with abnormal cervical smears.* Br Med J 300:1690-3 (1990)

McLucas B, Emens M, Hamou J, Rothburg R, *Diathermy loop treatment of CIN, international perspectives. (panel discussion)* The Female Pat. 15:79-90 (1990)

Mor-Yosef S, Lopes A, Pearson S, Monaghan JM, *Loop diathermy cone biopsy.* Obstet Gynecol 75:884-886 (1990)

Perkins RB, Guido RS, Castle PE, et al, *2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors*, J Low Genit Tract Dis. 2020;24:102-131

Prendiville W, Cullimore J, Norman S, *Large loop excision of the transformation zone (LLETZ). A new method of management for women with cervical intraepithelial neoplasia.* Br J Obstet Gynaecol 96:1054-1060 (1989)

Large loop excision of the transformation zone, a practical guide to LLETZ, ed. Prendiville, W, 1st edition 1993, Chapman & Hall Medical, London.

Soderstrom R, *Taking a colposcopic-directed loop biopsy*. Contemp Ob/Gyn 37(sp):77-78 (1992)

Electrosurgery for HPV-related diseases of the lower genital tract, Wright TC, Richart RM, Ferenczy A, 1992, Arthur Vision, New York.

The following standard is globally recognized for safety and performance certification of electrosurgical systems, and can be referenced for the basis of many specifications. This standard is not the exclusive requirement for electrosurgical system safety, as many other standards exist for electromedical equipment and supplies. Nor should it be assumed that an electrosurgical

system meets these requirements, unless the proper regulatory tests have been performed and regulatory markings are provided on the system.

Medical electrical equipment — part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, IEC 60601-2-2:2017, International Electrotechnical Commission, Geneva, Switzerland.

Warranty and Service

Finesse II+ Limited Warranty

Utah Medical Products, Inc. (UTMD) warrants each new Finesse II+ (the product) against defects in materials and/or workmanship for a period of two years from the date of purchase and agrees to repair or replace any defective product without charge. This warranty does not cover damage resulting from accident, misuse, lack of reasonable care or proper maintenance. This warranty shall be void if the product is repaired by anyone other than UTMD or an authorized service agent. This warranty does not extend to anyone other than the original purchaser nor to accessories manufactured by other vendors.

Except as provided herein, UTMD makes no warranties of any kind, either expressed or implied and specifically excluding any warranty of merchantability or warranty of fitness for a particular purpose.

UTMD will not be liable for any special, nonconsequential or incidental damages arising out of the use or inability to use the product. In no event shall UTMD's liability hereunder exceed the purchase price of the product. This warranty shall be void and of no force and effect with respect to any product which is damaged as a result of A) neglect, alteration, electric current fluctuation or accident; B) improper use, including failure to follow proper operating and maintenance instructions, and to provide proper environmental conditions prescribed in UTMD's product instruction manual; C) repair by other than UTMD or authorized service agents appointed by UTMD's service announcements; or D) use of supplies or parts which do not meet UTMD specifications.

Obtaining Service

To obtain service, please call UTMD at 800-533-4984 (outside USA and Canada – 801-566-1200) to receive specific instructions. Please be prepared to provide:

- Your UTMD account number, if known
- Your billing address
- Your shipping address
- A description of the problem with, or the service requested for, the Finesse II+ system
- A purchase order number or authorization to bill the service, if the Finesse II+ system is not under warranty.

A return goods authorization (RGA) number will be issued, and should appear on the return address label. Returns without an RGA number may be refused. To avoid shipping damage, the Finesse II+ system should only be shipped in its original packaging. If you have not retained the original packaging, UTMD can arrange for a replacement box and packing material.

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