FINESSE®+

ELECTRO SURGERY ◆ SMOKE EVACUATION

Electrosurgical Generator and Smoke Evacuation System

Service Manual

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Introduction

This manual is intended to:

- introduce you to the FINESSE+™ 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+ 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. It is not intended for high-power procedures such as prostatic resection or for sustained operating room procedures that require continual application of electrosurgical energy with only brief periods of rest.

Electrosurgical Generator

The electrosurgical generator module in the FINESSE+ 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 office-based electrosurgical procedures.

The output waveforms and load characteristics in the pure cut and blended cut modes are optimized for 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+ 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 electrode when excising at the maximum depth.

The FINESSE+ system provides a pure cut mode and three blend modes that perform concurrent cutting and superficial coagulation as required by standard practice for excision procedures. The coagulation mode provides sufficient voltage and power for spray coagulation, or fulguration, using ball electrodes.

The generator incorporates an error detection and alerting system that will alert the user and shut down output power whenever the following occurs:

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 set 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 electrosurgical procedures, such as Loop Excision of the Transformation Zone (LETZ®). 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 may be easily changed and discarded. The third-stage ULPA filter and vacuum system are installed inside the FINESSE+ system housing. The ULPA filter (FINESSE+ Internal Filter, catalog no. SSE-500) is removable for annual replacement.

Electrosurgical Procedure Guidelines

The surgical techniques using low-power generators 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+ 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+ 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.

The output level settings appropriate for the various electrosurgical procedures are the first and most important parameters to be determined by the practitioner. The settings used by the developers of these techniques are given in their published papers. (Some of these papers are listed in the *Bibliography* section of this manual.) However, these published results were obtained using different electrosurgical generators. Every generator has its own cutting characteristics that may not be exactly duplicated by another generator using the same settings. Furthermore, the characteristics of the excision are dependent not only upon the output setting, but also upon the length and thickness of the cutting electrode, the moisture content and type of tissue, and the speed of the cut. **Always use the lowest possible setting which achieves the desired excision quality and speed.**

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 at various output settings, and to observe how the depth of the thermal damage is influenced by the speed of the cut, the cut or blend mode selected, and the output setting used. 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. Practitioners who prefer a slow cut, using a small electrode, or excising a small amount of tissue should use settings at the lower end of the output range. Those who prefer a faster cut, using a large electrode, or excising a large amount of tissue should use settings at the upper end of the output range. The cutting power required is dependent on many factors such as:

1. Nature of tissue to be excised. Fatty or cartilaginous tissues require higher power output than muscle or skin tissue. Sclerotic, fibrotic, or cicatrical tissues require higher power output than softer tissues.
2. Depth of excision. A deep excision (with the same electrode and speed of cut) requires a higher power output than a shallow incision.
3. Rate of speed at which the cutting electrode is moved. The faster the speed of the wire through the tissue during the cut requires higher power outputs than at slower speeds.
4. Type of electrode used. For a given depth of excision with an equivalent cutting speed, the longer wire requires higher power outputs than a shorter wire. Thicker wire requires higher power outputs than a thinner wire.
5. Tissue moisture content. Drier tissue requires higher power output than moist tissue.

The FINESSE+ generator diminishes the effects of some of the above variables by means of its feedback-controlled output. Because this circuit reduces the output power applied at the beginning and end of the cut to the minimum levels needed, it is generally operated at somewhat higher nominal output settings than most generators. The pure cut mode provides an excision with little hemostasis effect. Blend 1 provides an excision with minimal hemostasis effects. Blend 2

provides an excision with average hemostasis effect. Blend 3 provides an excision with maximum hemostasis effect.

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 coagulation power required is dependent on many factors such as:

1. Length of time the current is applied. Lower power outputs applied for longer periods produce a greater depth of coagulation than higher outputs applied for a shorter period of time.
2. Type of electrode used. A ball electrode will require a higher power setting than pointed electrodes, due to the larger area of tissue contact.
3. Character of surrounding media. Higher power outputs are required for coagulation under water or in a bloody field than for coagulation in relatively dry operative sites.

For typical LETZ procedures, cutting mode output settings ranging from "40" to "70" have been found to be effective, with a setting of "65" typically used. Coagulation mode output settings ranging from "40" to "75" have been found to be effective in providing hemostasis for bleeding vessels, with a setting of "60" typically used.

Operational Safety Notes and Warnings

The FINESSE+ 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 below. It is important that these points, as well as others made throughout this manual, be read and understood before performing surgery with this instrument.

Inspection. When the system is unpacked after transport between locations, as well as periodically with ordinary use, visually inspect the FINESSE+ 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.

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

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+'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.

Monopolar Electrosurgery. The FINESSE+ 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+.

The FINESSE+ 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+ 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+ system.

To ensure that the FINESSE+ 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+ 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. The output setting selected should be appropriate for the intended purpose (see the section titled "Electrosurgical Procedure Guidelines"). **Always use the lowest possible setting which achieves the desired excision quality and speed.** 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 before increasing the output settings.

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+ 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+ 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+ system should not be affected by it. However, users should take special precautions regarding EMC, and need to install the FINESSE+ 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. 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 provider. Note that the use of electrosurgery is contraindicated in patients implanted with certain cardiac pacemakers.

Principles of Electrosurgery

The FINESSE+ 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+ system has a pure cut mode and three blended cut modes. The waveforms produced to provide these modes are 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+ 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+ 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+ 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+ system produces sufficient pressure reduction to pull approximately 70 liters per minute (2.5 cfm) at the normal setting 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. Also, it is easier for smoke to escape from an open surgical field. It may be necessary to switch to the "high" flow setting to achieve effective smoke removal under these circumstances.

Installation

Initial Setup

1. Unpack the FINESSE+ 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+ on a flat, level surface at working height within six feet of the operating area.

   CAUTION: Do not choose a location where the FINESSE+ system will be adjacent to or stacked with other electromedical equipment. If operating the FINESSE+ system in close proximity to other equipment, observe the functioning of the FINESSE+ 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+ Internal Filter (item number SSE-500), if not already done.** Remove the internal filter retaining ring from the front of the FINESSE+ 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+ system without the internal filter installed.**
6. Plug the FINESSE+ system into any standard power outlet, corresponding to the voltage range indicated on the FINESSE+ system rear panel.

   CAUTION: To avoid the risk of electric shock, the FINESSE+ system must only 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+ system at least 3 inches (8cm) from all obstacles.

Functional Checks

1. Install handswitch pencil into the three-point connector on front panel.
2. Toggle the main power switch to the "on" position. Five things should happen:
   - the green lamp in the power switch should light,
   - the cut and coag output settings should display the current setting,
   - the standard dispersive pad icon, located above the pad connector, will illuminate,
   - the orange pad connection error indicator will light, and
   - an interrupted error tone should sound.

If these indications do not occur, check to verify that:

- the power cord is securely plugged in on both ends,
- the three fuses on the rear panel of the unit are installed,
- these fuses are not blown, and the room outlet is active.

3. Connect a dispersive pad to the dispersive pad receptacle on the front panel. If a standard pad is connected, the pad connection error should clear.

   WARNING: If a split style pad (which allows for pad contact quality monitoring, or CQM) is connected, the error indication will remain active, but the error will not clear until the pad is attached to skin. Doing so will expose the person connected to the pad to potentially severe injury should they come into contact with the active electrode. Therefore, only perform this functional test with a standard pad, and under no circumstances should ANY dispersive pad be attached to anyone for the purposes of testing the FINESSE+ system.

4. Briefly operate the cut control on the handswitch. The yellow "cut" lamp should light, a tone should be emitted from the internal speaker, and the vacuum pump should come on and stay on approximately five seconds after the cut control button is released. If none of this occurs try another handswitch. If the vacuum motor does not come on, check the position of the vacuum control switch and the vacuum fuses on the back panel.

5. Repeat step 4 above with the coag switch rather than the cut switch. All operation should be the same except that the blue "coag" lamp illuminates rather than the yellow "cut" lamp.

6. If a footswitch is connected to the FINESSE+'s rear panel, repeat steps 4 and 5 above using the cut and coag pedals of the foot switch. All indications should be the same as they were using the hand switch.

If any of the above items do not check good, please contact Utah Medical Products Customer Service for assistance.

Daily Maintenance

For optimum odor control in the procedure room, change the external filter pack at the end of any day that the FINESSE+ system is used.

Cleaning

CAUTION: Electric Shock Hazard.
Unplug FINESSE+ system before cleaning.

Clean the FINESSE+ 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+ 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+ 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+ 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+ system. See the *Test Procedures* section of this manual.

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.

Device Description

The FINESSE+ 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+ front panel are shown in *Figures 1 through 3* and subsequently described.

Smoke Evacuation System

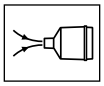
1. **Smoke Filter Connection.** This connection, the large  circular structure on the face of the front panel, accepts the external disposable filter pack which provides first- and second-stage particulate removal and odor adsorption. The circular ring retains the FINESSE+ Internal Filter, which is the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

Figure 1. FINESSE+ front panel, smoke evacuation module

2. **Vacuum Level Switch.** This two-position rocker switch controls the smoke evacuation system flow rate.

   The left, or "normal", position (▶) runs the vacuum motor at a level that is sufficient to draw the smoke plume away from the surgical site during the LETZ procedure.

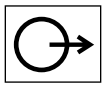
   The right, or "high", position (▶▶) of the switch runs the vacuum motor at a higher speed, creating a flow rate approximately 40% greater than the normal setting with the same tubing configuration. This setting should be used whenever the distal smoke removal tube has a very small diameter, or in any other circumstance where the smoke is not being completely removed.

   The vacuum system does not have an activation switch of its own. It is automatically activated by internal circuitry whenever the cut/blend 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/Blend Mode Controls

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

3. **Cut/Blend Output Activity Icon and Indicator.** This icon lights yellow whenever the pure cut or blended cut modes are activated. Illumination of this icon is accompanied by an audio tone unique to the cut/blend mode. This is the lowest pitch of the three audio tones used in the FINESSE+ system.

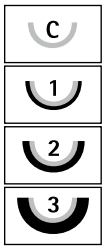


4. **Cut/Blend Output Control Knob and Display.** This knob is used to specify the output level desired for the intended cut. The adjacent digital readout indicates the current setting.

   The cut mode display can be continuously adjusted between "05" and "99". *The output setting cannot be adjusted during activation.* In general, higher output levels are required for thicker or wider loop electrodes or for deeper submersion of the cutting electrodes in the tissue. These principles are discussed in the *Principles of Electrosurgery* section of the *FINESSE+ Operator's Manual.*

   As mentioned in the safety warnings of the operator's manual, this knob should not be turned up to correct an apparent power output deficiency without first verifying that all connections are in good order and the patient dispersive electrode is still properly applied.

5. **Cut/Blend Mode Select Switch.** This switch allows the selection of the appropriate mix of cut and coagulation activity for the performed procedure. One 'pure cut' and three blended cut modes are available.



   In the 'pure cut' mode (denoted by an illuminated "C" when selected), a continuous sinusoidal voltage is applied to the surgical tool in use. If the electrode area is small enough, it will cut through tissue very cleanly with very little surface heating that would stop bleeding. In the blend modes, the same electrode will cut cleanly through the tissue while the surface of the cut is heated to accomplish a degree of coagulation. "Blend 1" (denoted by an illuminated "1" when selected) produces slight coagulation, whereas "Blend 2" (denoted by an illuminated "2" when selected) and "Blend 3" (denoted by an illuminated "3" when selected) produce successively higher degrees of coagulation.

   When switching between these modes the total output delivered to the surgical tool is maintained at a constant setting as set by the output control knob above the switch. *Changing the mode switch during activation is not allowed, and results in an error condition.* "Er Or" is displayed on the front panel, the output is deactivated, and a warning tone is produced. The FINESSE+ system main power switch must be shut off to clear this condition. If this error recurs, do not attempt to use the FINESSE+ system, and contact Utah Medical Products for instructions.

Coag Mode Controls

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

6. **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+ system.

7. **Coag Output Control Knob and Display.** This knob is used to specify the output level desired for the intended coag operation. The adjacent digital readout indicates the current setting.

   The coag mode display can be continuously adjusted between "05" and "75". *The output setting cannot be adjusted during activation.* Smaller or finer electrodes require a lower setting and larger electrodes will require a higher setting. Lower settings on this knob may be used for desiccation coagulation.

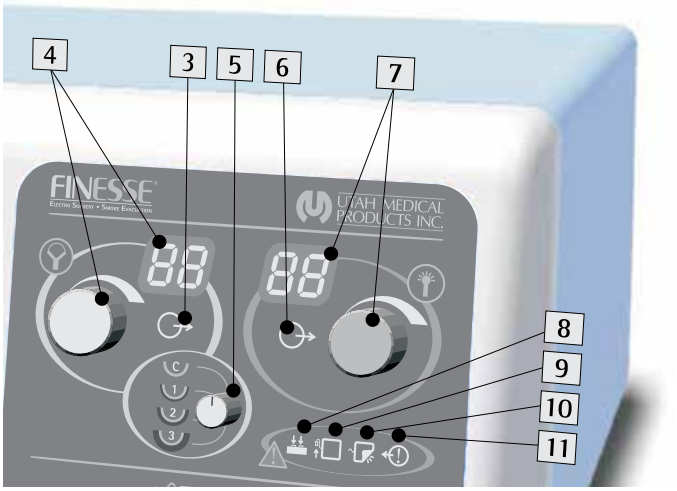


Figure 2. FINESSE+ cut, coag, and error indicator functions

The principles of coagulation by desiccation and fulguration are explored in the *Principles of Electrosurgery* section of the *FINESSE+ Operator's Manual.*

As mentioned in the safety warnings of this manual, this knob should not be turned up to correct an apparent power output deficiency without first verifying that all connections are in good order and the patient dispersive electrode is still properly applied.

Error Indicators

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

8. **"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.

9. **Pad Disconnect Error.** This condition will occur whenever a dispersive pad is not plugged into the dispersive pad receptacle, 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 cord is not cut. If the error continues, replace the pad.

10. **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.

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

Front Panel Connectors and Controls

12. **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".

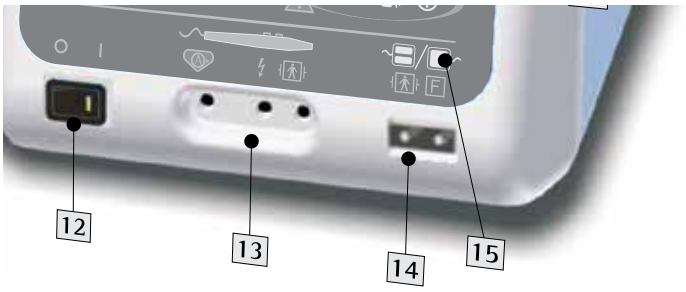


Figure 3. FINESSE+ front panel connections

13. **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+ system must be activated by a footswitch connected to the rear panel (see next section).

For footswitch operation of the FINESSE+ 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.

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

15. **Dispersive Electrode Type Indicator.** These two icons display the type of dispersive pad detected by the FINESSE+ 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.**

Rear Panel Controls and Connectors

Controls and connectors on the FINESSE+ rear panel are shown in *Figure 4* and are described below.

Figure 4. FINESSE+ 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+ 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 indicator tones are not adjustable. Always set the volume of the audible tones so that they can be clearly heard over the smoke evacuation system.

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
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 *FINESSE+ Operator's Manual.*

Supply Voltage and Current Considerations

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

Supply Voltages (voltages are AC rms)

	FIN-110	FIN-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% or ±5W, whichever is greater, of the power delivered at the center of this range in cut and blend modes and ±30% or ±10W, whichever is greater, in coagulation mode.

Maximum Supply Current and Power

FIN-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

FIN-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+ 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.
FIN-110: 2.5 amp FIN-220 1.25 amp
Smoke Evacuation System: a pair of fuses protect the smoke evacuation motor.
FIN-110: 3.15 amp FIN-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 Setting* [a]	*Duty Cycle* [b]	*MOV* [d]	*Crest Factor* [e]
Cut	99	100%	1080	1.8
Blend 1	99	62.5%	1280	2.2
Blend 2	99	50%	1420	2.5
Blend 3	99	37.5%	1500	2.8
Coag	75	c	2400	5.8

a Output Setting 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 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

Output display is calibrated to be relative power in watts at a load of 500Ω, ±15% or ±5W, whichever is greater.

In the pure cut and blend modes, 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 140 watts at 250Ω patient load. See *Figure 5* for cut and blend mode output power vs. load data.

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 100 watts at 250Ω patient load. See *Figure 6* for coag mode output power vs. load data.

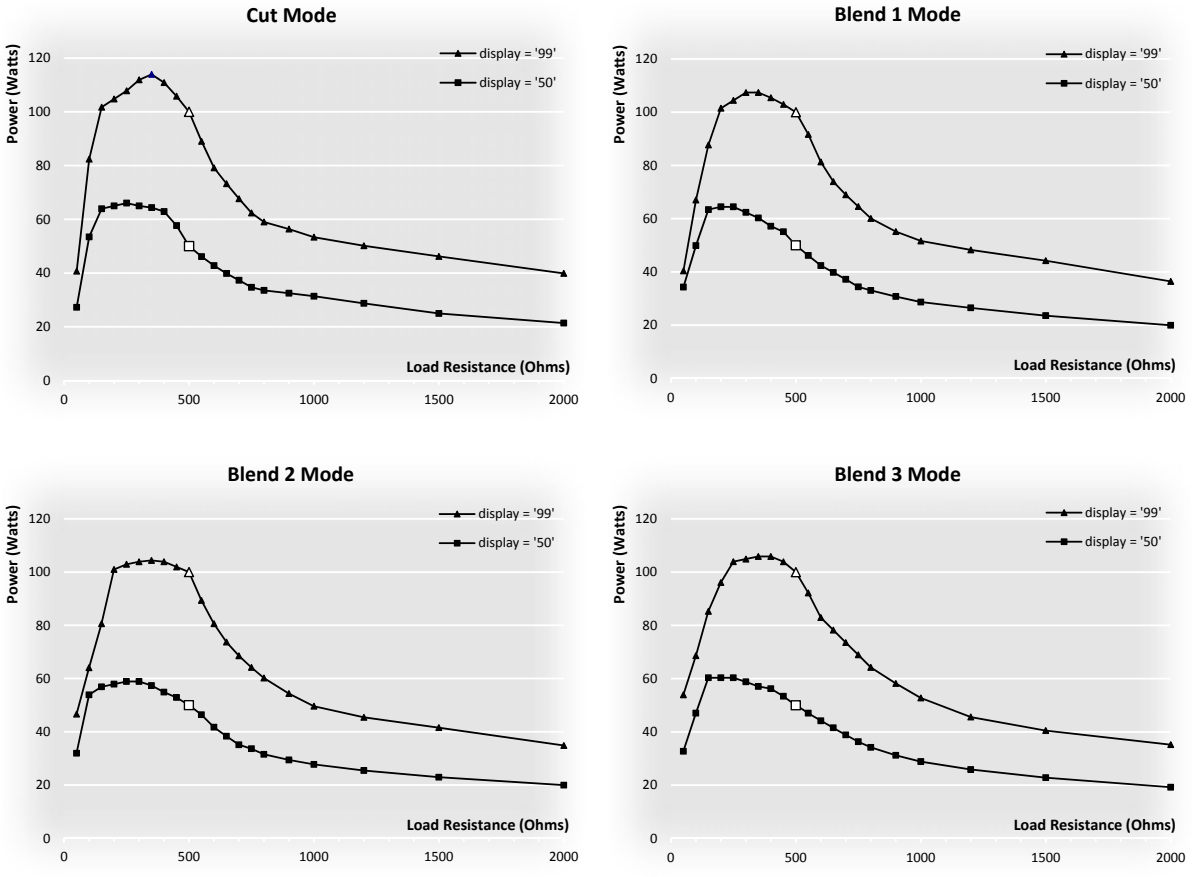


Figure 5. Typical output power vs. load resistance for cut and blend modes

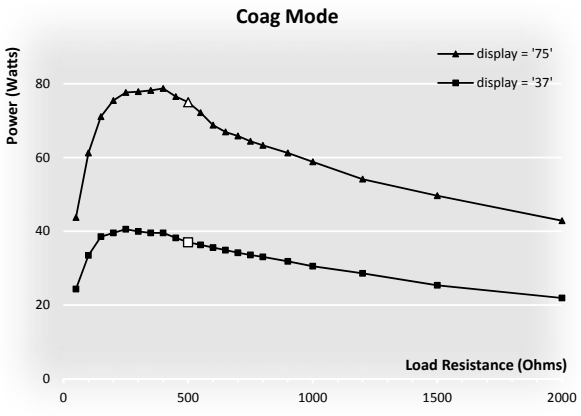


Figure 6. Typical output power vs. load resistance for coag mode

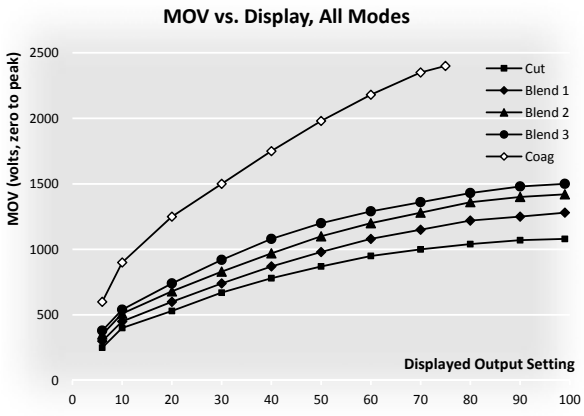


Figure 7. Maximum Output Voltage vs. displayed settings

Maximum Output Voltage vs. Output Setting and Mode

Figure 7 shows the Maximum Output Voltage (MOV) for each mode and output setting. Only use active electrodes and pencils that have a Rated Accessory Voltage (RAV) greater than the MOV for the selected output setting and mode.

Output Power vs. Displayed Setting

The output of the FINESSE+ system increases linearly with adjustment of the front panel output settings. *Figure 8* shows the typical output power of each of the five modes over the full control range. All curves shown indicate output at 500Ω load resistance.

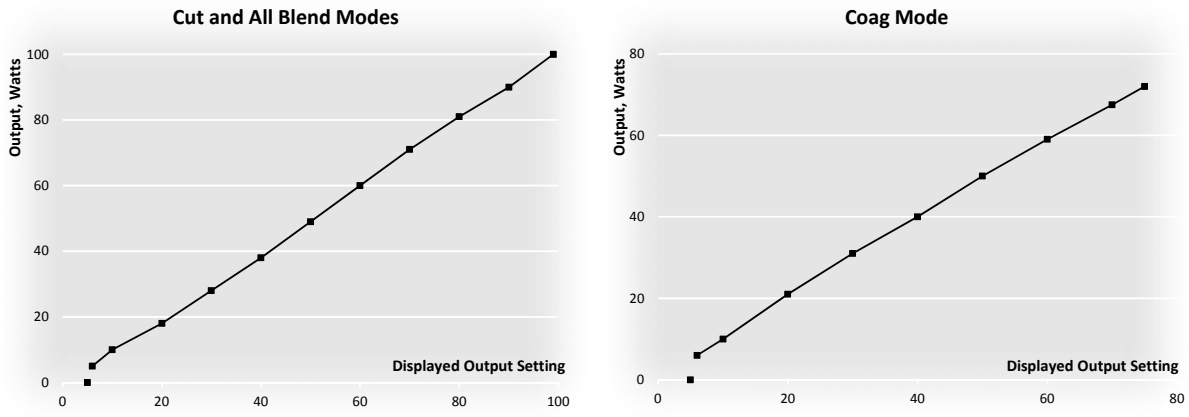


Figure 8. Typical output power vs. display setting for cut and blend modes and coag mode

Output Error Safety Circuit Specifications

The FINESSE+ 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 safety system 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+ it is generally characterized by a threshold that is 25W-30W above the selected output setting.

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+ 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+ system will not detect compromise in pad contact to the patient.

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+ 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):

ES-1179	Dispersive Pad, CQM (split), precorded
ES-1180	Dispersive Pad, CQM (split), non-corded (requires reusable cable)

WARNING: To ensure safe contact of the dispersive pad to the patient, use only pads listed as compatible with the FINESSE+'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+ 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 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 100 liters per minute (3.5 cubic feet per minute) at the "high" setting and not less than 70 liters per minute (2.5 cfm) at the "normal" setting.

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+ 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+ smoke evacuation motor is equipped with a HEPA grade particulate filter. This filter protects the FINESSE+'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+ system to reach the operating environment — typically one hour is sufficient.

Circuit Descriptions

The FINESSE+ is an electrosurgical device powered from 115VAC or 230VAC, 50Hz or 60Hz mains supplies. The power mains branch into two main modules — the electrosurgical system and the smoke evacuation system. Independent sets of fuses protect each circuit module. The main power switch is mounted on the front panel, and when toggled allows power to flow from the AC receptacle to both the main power transformer and smoke evacuation module.

The core of the FINESSE+ system contains a microprocessor and complex programmable logic device (CPLD). Many of the FINESSE+'s logic functions have been permanently embedded in the CPLD to reduce the amount of circuit components used and decrease the probability of component failure. *The microprocessor and CPLD are not user programmable or modifiable. No attempt should be made to do so.*

Power Supply

The Power Supply Board is the power interface between the other circuit boards and the power transformer. The primary functions of the Power Supply Board are to 1) supply working voltages for the FINESSE+ circuitry and 2) control the smoke evacuator vacuum motor speed, which is signaled by the Logic Board and at a speed determined by the speed control switch on the front panel.

Dual secondary windings on the main transformer provide AC power to the Power Supply Board for rectification to unregulated 200VDC and 50VDC. The 50VDC is then regulated to 15VDC and 5VDC voltages for use on the RF Power Amplifier, Logic, and Display boards.

The Power Supply Board contains a solid state relay K201 that controls the smoke evacuator motor. The smoke evacuation motor timing is controlled by the microprocessor on the Logic Board through connector P204.

RF Power Amplification and Control

The RF Power Amplifier Board's main function is to provide electrosurgical output. Two pulse width modulated signals control FINESSE+'s buck converter and waveform generator. The front panel output setting controls are fed into the microprocessor. The Buck PWM base values are determined by lookup tables in the microprocessor, and subsequently sent to the CPLD during activation. The Buck PWM controls the 200VDC line. An increase in the duty cycle provides more current to drive the output transformer. The Buck PWM is further modified according to data received by the microprocessor from the output feedback circuit. A high voltage FET drives the output of the Buck PWM circuit.

The Waveform PWM provides 450kHz switching to the other primary lead of the output transformer. The microprocessor and CPLD drive the 450 kHz wave train according to the mode selected, with pure cut mode being a continuous 450kHz wave train, Blend 1 being a train of 10 pulses followed by a rest period equivalent to 6 pulses, and so on for the other modes. The pulse

width on this PWM is also determined by lookup tables in the microprocessor, and is also used to control the output power and provide the appropriate output wave shape. A second FET drives the output of this circuit.

The RF output is coupled to the active and dispersive output terminals through series capacitors in both leads. In combination with the output transformer, this results in an electrosurgical output which is RF isolated from ground and which is incapable of conducting low frequency currents which may cause serious neuromuscular stimulation in the patient.

Controlled Output Circuitry+ Monitoring and Error Detection

Controlled Output Circuitry+ (COC+) is a three-tier output monitoring curcuit, and is an important element in the FINESSE+'s performance.

The first tier of COC+ attempts to minimize variation in the peak output voltage so that a consistent tissue effect is realized, for example, when using a loop electrode. A high voltage high frequency rectifier across the output transformer terminals on the RF Power Amplifier Board produces a signal that corresponds to the peak output voltage. The signal is optically isolated and read by the microprocessor. The microprocessor compares the signal to a lookup table value based on the output and mode settings and implements an algorithm that adjusts the Buck PWM in order to maintain the output peak voltage under low output load resistances. This prevents suppressed peak output voltages that cause desiccation and significant thermal effects on tissue.

A high voltage shunt monitor exists on the Buck PWM supply. This provides the microprocessor with output voltage and current data for monitoring the output power. The microprocessor continuously monitors these two signals and compares their product to values in a lookup table (which have been calculated according to the requirements of electromedical safety standard IEC 60601-2-2:2009 sec 12.4) for protection against hazardous output. COC+'s second tier provides protection against excessive output by use of both firmware and hardware. The FINESSE+ firmware complares the output power and current level to an absolute limit defined in lookup tables that are based on the output setting. When this limit is reached, the microprocessor will first attempt to correct the output via the COC+'s first tier circuit. The second protection is provided by current limiting hardware that will shut off pulses in the Buck PWM circuit in an attempt to lower the power available for modulation. If neither of these methods corrects the situation, COC+'s third tier circuit will enable an output error indication. In this mode, the FINESSE+ system enters a 'lockdown mode' that is only corrected by toggling off the main power switch.

COC+ circuits are instrumental in both protecting against high outputs and minimizing stress on the output amplification components.

Handswitch and Footswitch Logic

The commonly available hand switching pencils for electrosurgery have three-wire connections to the generator with independent single pole switches for cut/blend and coag. The active lead to the electrosurgical implement is the common wire for both switching functions. To maintain RF isolation of the generator output, it is necessary that the handswitch pencil circuit be electrically isolated from ground. To achieve this result, optical isolators are driven by op amp comparators

between the hand switch wires and the generator logic elements. Between periods of surgical activity the comparator outputs are low and the optical isolators stay in the "off" condition. When one of the two hand switch buttons is activated, the corresponding comparator toggles high and the optical isolator switches "on". When current flows through either of these optical isolators, the CPLD is instructed to activate the 450 kHz oscillator, select the appropriate PWM voltages, produce the correct cut/blend or coag waveforms, and activate the vacuum motor.

The footswitch operates an isolated circuit that is identical to the handswitching circuit.

CQM/Pad Detect Circuitry

The FINESSE+ is capable of using either standard (solid or single) or CQM (split or dual) dispersive pads. The CPLD generates a 39.5kHz clock signal that is buffered, filtered, and used to drive the pad detect hardware. The Logic Board produces a DC voltage that directly relates to impedance of the 39.5kHz signal between pad surfaces. The microprocessor assesses this DC voltage and the status of the mechanical pad detect switch (located in the pad receptacle), and determines whether the signal is at a level appropriate for a standard or CQM pad. If a CQM pad is detected, the microprocessor considers the DC voltage a CQM status signal, and calculates an error threshold level from this DC voltage that corresponds to roughly 25%-30% pad surface detachment. When the CQM signal level reaches the error level threshold, the system will display an error and discontinue output until the condition can be corrected. The microprocessor continuously monitors the CQM signal and is also able to set a new, lower threshold if better conditions are encountered.

The acceptable resistance ranges of a standard pad and CQM pad do not overlap, and therefore the FINESSE+ provides a redundant level of pad type detection for reliability.

Display Board and Front Panel Controls

The display board contains only indicator lights and the cut/blend and coag mode user controls. All displays are controlled by the CPLD and/or microprocessor. The cut and coag mode controls are potentiometers that relay a DC voltage to the microprocessor, while the mode select switch is wired directly to the CPLD.

Test Procedures

This checklist is intended to provide information for the preventive maintenance (PM) of the FINESSE+ Electrosurgical Generator and Smoke Evacuation Systems. It is intended for use by technical personnel who have experience with electrosurgical generator operation and maintenance, and who possess the test equipment and tools necessary to obtain the requested data. This document may not reference all tests necessary to demonstrate compliance to all regulations, nor should all tests listed be considered necessary for the safe use of the FINESSE+. Technical personnel should consult local regulations and industry recommendations to develop their own protocol for inspection and PM of the FINESSE+.

Required Equipment and Tools

- Electrosurgical analyzer and leads
- Electrical safety analyzer, with patient lead connections
- Two-button electrosurgical switchpen and/or two-pedal footswitch
- SSE-500 FINESSE+ Internal Smoke Evacuation Filter

Mechanical Inspection and Service

☐ Pass Verify front panel controls, switches, and dispersive pad receptacle/pins are not damaged.
☐ Pass Verify switchpen receptacles firmly hold switchpen.
☐ Pass Knobs and color coded knob caps are securely attached.
☐ Pass Verify power cord and its rear panel receptacle are not damaged.
☐ Pass Verify footswitch cord (if present) and its rear panel receptacle are not damaged.
☐ Done Replace FINESSE+ Internal Smoke Evacuation Filter

Performance Inspection

☐ Pass Green LED in main power switch lights when switch is toggled to the " | " position.
☐ Pass One and only one cut mode indicator ("C", "1", "2", or "3") is illuminated..
☐ Pass For all four cut/blend modes, the cut mode waveform selector knob adjusts so that light indicator for each mode illuminates when knob's index pointer corresponds to the correct indicator light.

Verify power displays can be adjusted through the full output range

☐ Pass Cut: 05-99 ☐ Pass Coag: 05-75

Press cut button on switchpen (repeat with cut pedal on footswitch, if available), and verify:

☐ Pass Yellow cut activity indicator  lights and cut mode tone is audible
☐ Pass Smoke evacuation motor activates, and remains running 5 seconds after deactivation

Press coag button on switchpen (repeat with coag pedal on footswitch, if available), and verify:

☐ Pass Blue coag activity indicator  lights and coag mode tone is audible
☐ Pass Smoke evacuation motor activates, and remains running 5 seconds after deactivation

☐ Pass Verify smoke evacuation flow rate switch changes motor speed.
☐ Done Adjust volume control so that cut and coag audible tones can be clearly heard over the smoke evacuation motor set at the 'high' flow rate position.

Output Calibration
Set cut mode output to "99", mode to "C", and electrosurgical analyzer load to 500Ω. Line voltage MUST be 114.0-116.0 VAC for FIN-110 and 228.0-232.0 VAC for FIN-220. Activate FINESSE+ system and adjust R334 until output is 97W. NOTE: Output may vary several watts due to feedback activity.

☐ Pass _____ (95W-99W)

Check system output power at the following displayed settings. All measurements should be made through a 500Ω load. Tolerances are listed in parentheses. Do not activate system for more than 10 seconds for each reading, and allow at least 20 seconds between readings. *Individual output calibration is not adjustable.*

☐ Pass	Cut	30: _____ (25-35W)	60: _____ (51-69W)	90: _____ (77-103W)
☐ Pass	Blend 1	30: _____ (25-35W)	60: _____ (51-69W)	90: _____ (77-103W)
☐ Pass	Blend 2	30: _____ (25-35W)	60: _____ (51-69W)	90: _____ (77-103W)
☐ Pass	Blend 3	30: _____ (25-35W)	60: _____ (51-69W)	90: _____ (77-103W)
☐ Pass	Coag	30: _____ (25-35W)	60: _____ (51-69W)	75: _____ (64-86W)

HF Leakage Currents
Set cut display to "99" and coag display to "75". Establish the HF leakage current path by connecting a non-inductive 200Ω load between the active electrode and mains ground. Leave dispersive connection open. Activate FINESSE+ system to check active HF leakage current:

Active HF Leakage
☐ Pass Cut _____ (<150mA) ☐ Pass Coag _____ (<150mA)

Connect non-inductive 200Ω load resistor between dispersive electrode and mains ground. Leave active connection open. Activate FINESSE+ system to check dispersive HF leakage current:
Dispersive HF Leakage
☐ Pass Cut _____ (<150mA) ☐ Pass Coag _____ (<150mA)

Touch Currents

Using an electrical safety analyzer, measure the following conditions. Acceptable conditions are listed in parentheses:

Ground lead intact

☐ Pass Normal Polarity _____ (<100µA) ☐ Pass Reverse Polarity _____ (<100µA)

Ground lead open

☐ Pass Normal Polarity _____ (<100µA) ☐ Pass Reverse Polarity _____ (<100µA)

Using the electrical safety analyzer, and following the analyzer's instructions, make the appropriate connections for the following leakage currents. Measure the leakage currents without activating the FINESSE+ system. The active electrode is the only Applied Part subject to these tests.

☐ Pass Patient Auxiliary Current _____ (<100µA)

☐ Pass Patient Leakage Current (PLC) _____ (<100µA)

☐ Pass PLC Caused by Ext Voltage (aka Mains on Applied Part) _____ (<5000µA)

CQM Circuit Tests

Do not activate the FINESSE+ system during these tests, as most ES analyzers are not designed to withstand activation during CQM testing.

Following the instructions for the ES analyzer, perform the following measurements IN THE ORDER LISTED, without disconnecting the CQM dispersive pad lead between steps. Set CQM tester (or resistor substitution box if analyzer does not have CQM test capability) to 150Ω. Connect pad plug to FINESSE+ system and turn on main power switch.

☐ Pass Verify error is active.

☐ Pass CQM dispersive pad illuminates the CQM pad icon above the pad receptacle.

☐ Pass Reduce resistance until error clears. 130Ω _____ (117Ω-143Ω)

☐ Pass Reduce to 50Ω, then raise until error activates. 68Ω _____ (61Ω-75Ω)

☐ Pass Reduce resistance until error activates. 10Ω _____ (5Ω-15Ω)

Other Error Checks

☐ Pass Pressing both cut and coag switchpen buttons or footswitch pedals simultaneously produces error and disables output

☐ Pass Activation of coag mode into open circuit conditions does not produce error

Notes:

Performed by: _____ FINESSE+ Serial No: _____

Signature: _____ Date: _____

Test Equipment	*Make/Model*	*Serial/Reference*	*Calibration Expiry*
ES Analyzer			
Safety Analyzer			

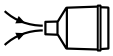
Symbology

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

Table 2. Symbols used in conjunction with the FINESSE+ System

Symbol	Definition/Description
Standardized symbols (defined in EN 980, ISO 60417, ISO 60878, ISO 7000, and other standards)	
CE 0120	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. "0120" identifies the certifying notified body (SGS)
	Consult operating instructions
	Caution (also used to indicate system error indicators)
	Dangerous voltage
	Non-Ionizing Radiation
	Defibrillation-proof Type BF Applied Part
	Floating patient leads
	Power off
	Power on

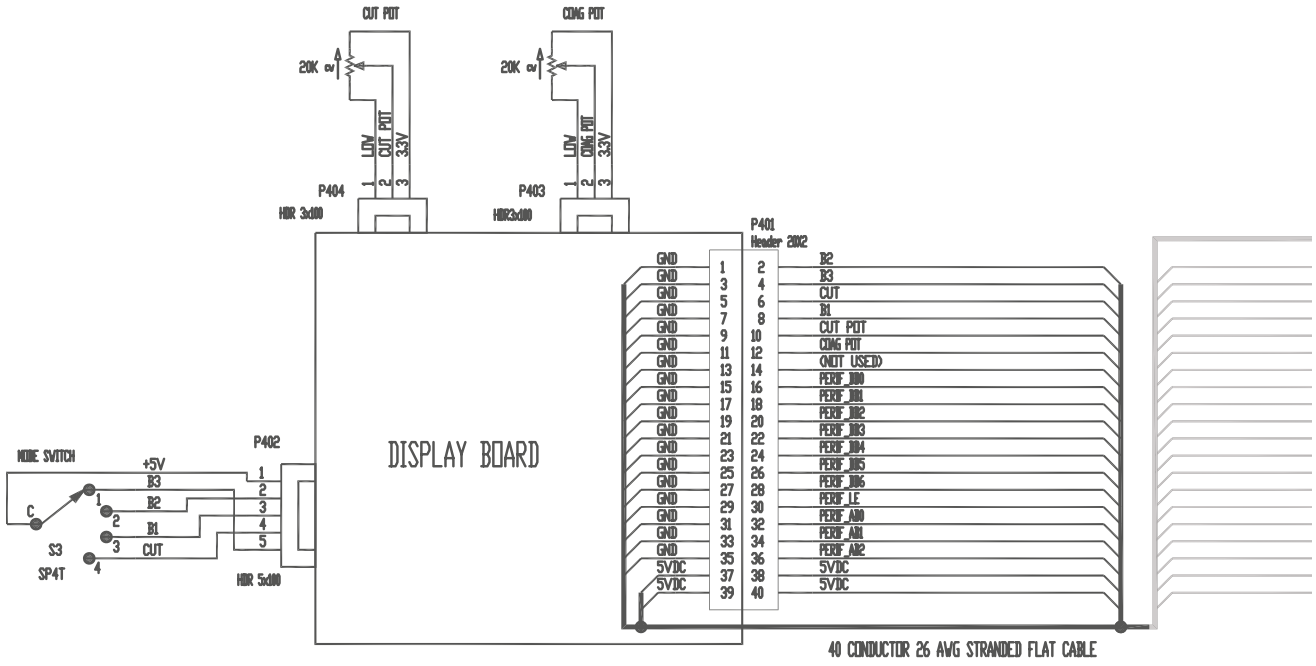
Symbol	Definition/Description
	Reference (model) number
	Serial Number
	Date of Manufacture
	Manufacturer
	Representative in the European Union
	Input connector, alternating current (AC) power
	Equipotential connector
	Continuously adjustable control
	Footswitch connector
	Do not use in presence of flammable anesthetics and air
Symbols defined for the FINESSE+ System	
	Audible tone volume control
	Locked (pertaining to FINESSE+ Internal Filter retaining ring)
	Unlocked (pertaining to FINESSE+ Internal Filter retaining ring)

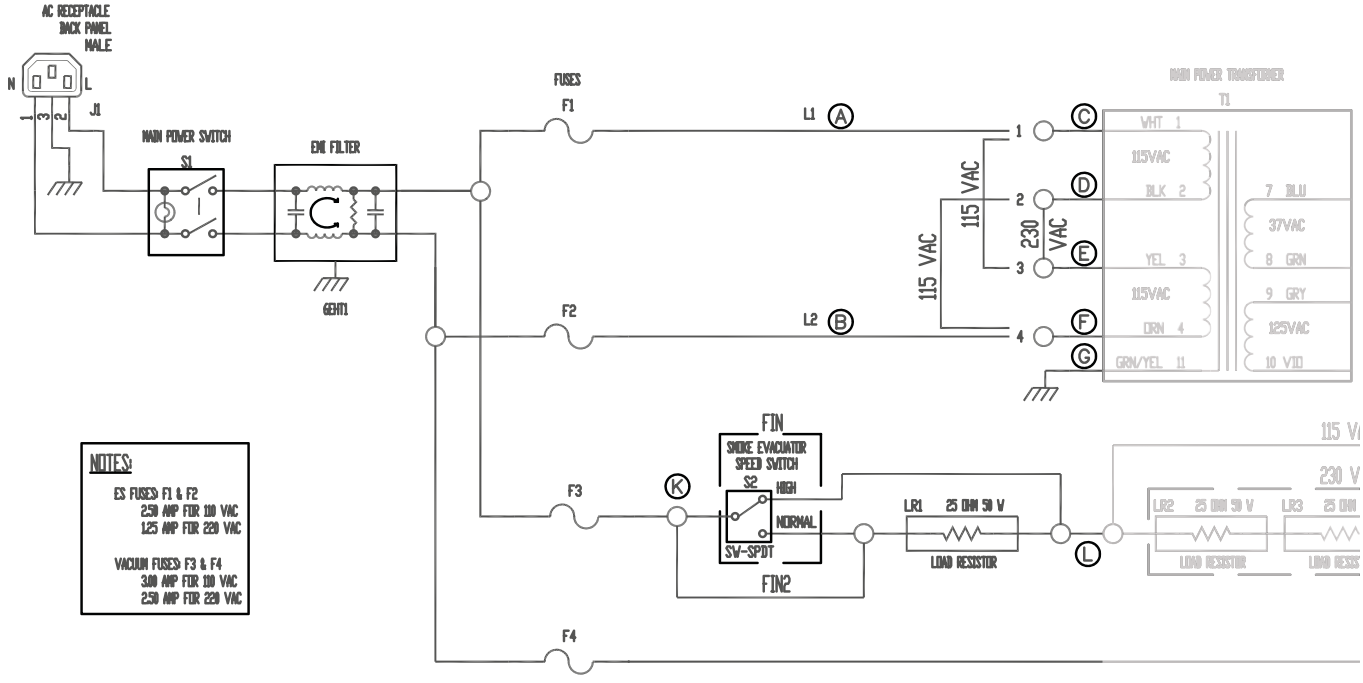
Symbol	Definition/Description
	Smoke evacuation system flow rate control
	Normal flow rate, smoke evacuation system
	High flow rate, smoke evacuation system
	Cut Mode controls and indicators
	Output activity indicator
	Pure Cut waveform
	Blend 1 waveform
	Blend 2 waveform
	Blend 3 waveform

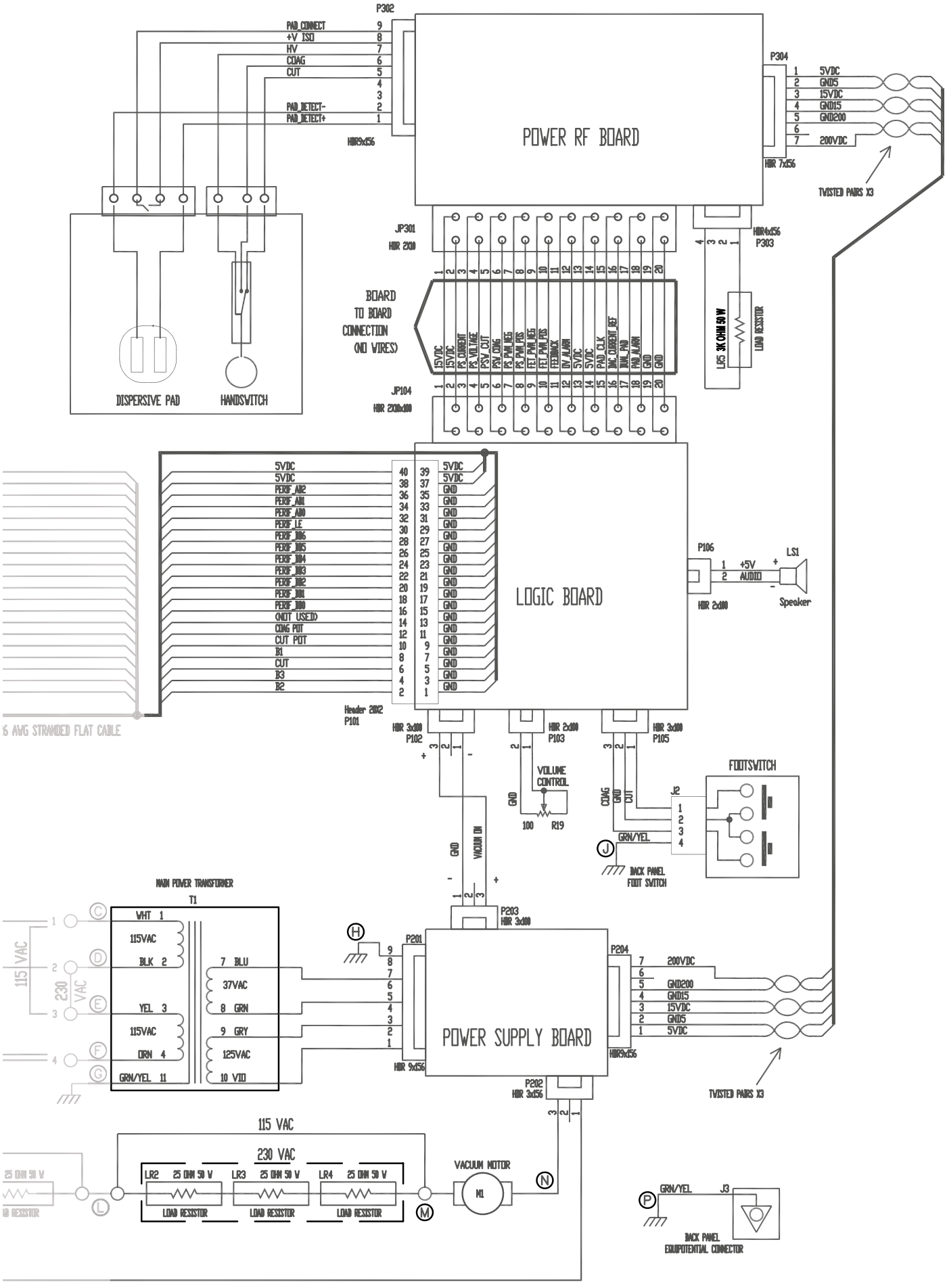
Symbol	Definition/Description
	Coag Mode control and indicator
	Cross-key error indicator
	Dispersive pad not inserted, or single pad cable continuity error indicator
	CQM error indicator
	Output error indicator
	Output terminals
	Active port
	Split (CQM) dispersive pad indicator
	Solid dispersive pad indicator

List of Drawings

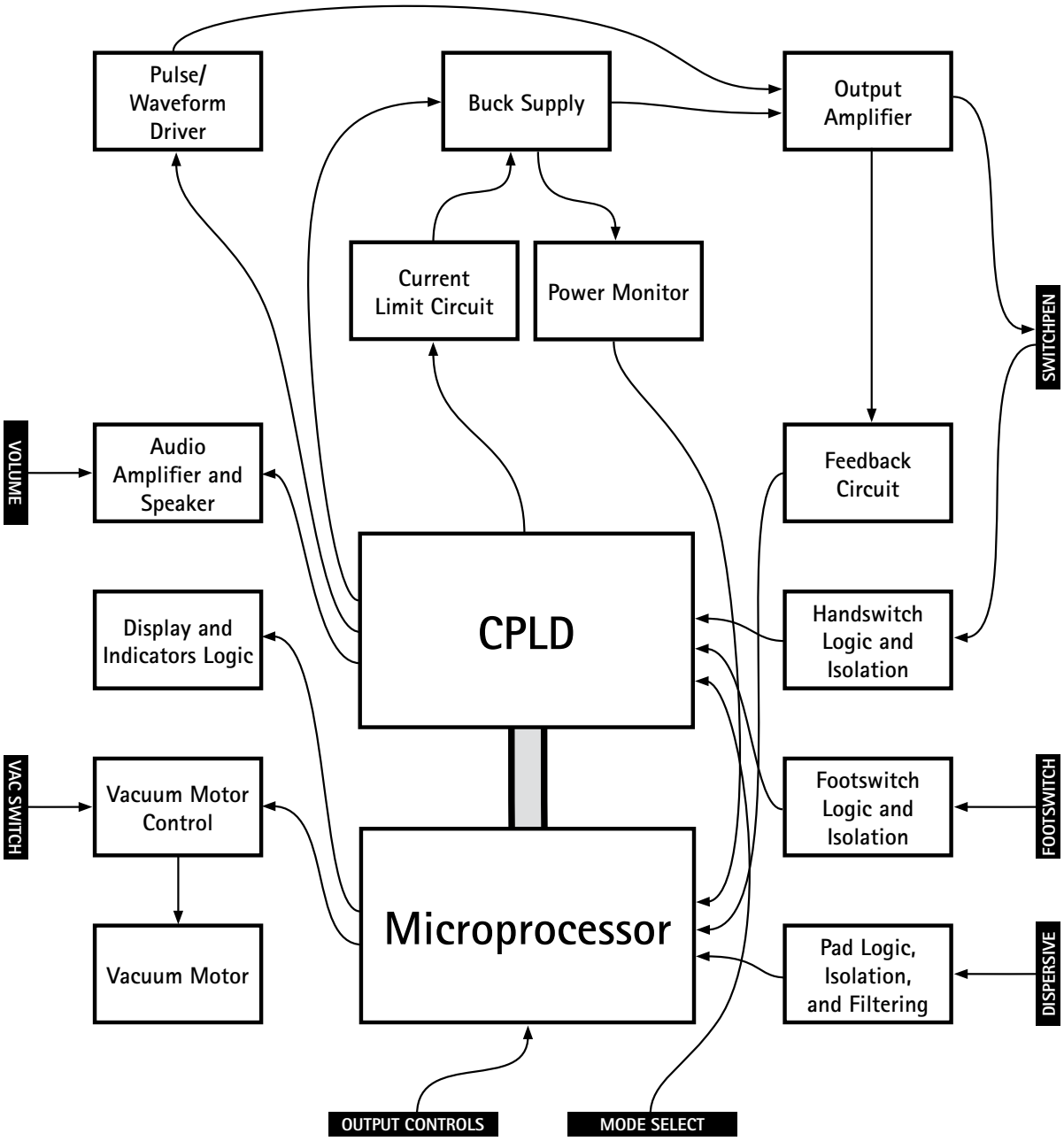
Schematics will be made available on request to qualified technical personnel.


CUT POT
20K Ω
LOW
CUT POT
3.3V
P404
HDR 3x100
CONG POT
20K Ω
LOW
CONG POT
3.3V
P403
HDR3x100
P401
Header 2002
GND
B2
B3
CUT
B1
CUT POT
CONG POT
(NOT USED)
PERF_B00
PERF_B01
PERF_B02
PERF_B03
PERF_B04
PERF_B05
PERF_B06
PERF_LE
PERF_A00
PERF_A01
PERF_A02
5VDC
MODE SWITCH
+5V
B3
B2
B1
CUT
S3
SP4T
P402
HDR 5x100
DISPLAY BOARD
40 CONDUCTOR 26 AWG STRANDED FLAT CABLE

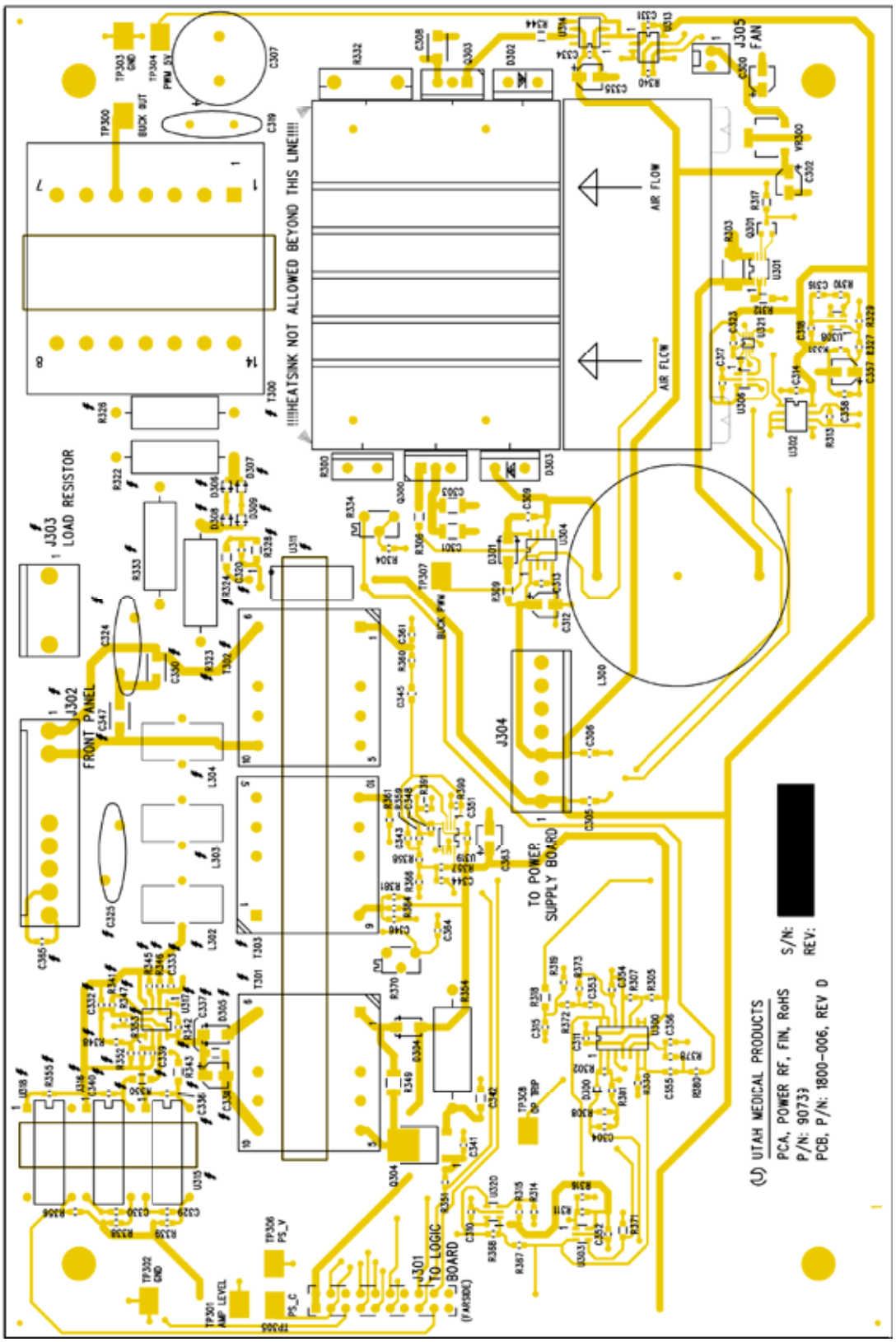

AC RECEPTACLE
BACK PANEL
MALE
N
L
J1
MAIN POWER SWITCH
S1
EMI FILTER
GEHT1
FUSES
F1
F2
F3
F4
L1
L2
115 VAC
115 VAC
230 VAC
MAIN POWER TRANSFORMER
T1
VHT
115VAC
BLK
7 BLU
37VAC
8 GRN
YEL
115VAC
9 GRY
GRN
125VAC
GRN/YEL
10 VIO
FIN
SMOKE EVACUATOR
SPEED SWITCH
S2
HIGH
NORMAL
SW-SPDT
FIN2
LR1 25 OHM 50 W
LOAD RESISTOR
NOTES:
ES FUSES: F1 & F2
2.50 AMP FOR 110 VAC
1.25 AMP FOR 220 VAC
VACUUM FUSES: F3 & F4
3.00 AMP FOR 110 VAC
2.50 AMP FOR 220 VAC


POWER RF BOARD
LOGIC BOARD
POWER SUPPLY BOARD
DISPERSIVE PAD
HANDSWITCH
BOARD TO BOARD CONNECTION (NO WIRES)
LOAD RESISTOR
Speaker
FOOTSWITCH
VOLUME CONTROL
MAIN POWER TRANSFORMER
VACUUM MOTOR
TWISTED PAIRS X3
BACK PANEL EQUIPOTENTIAL CONNECTOR
115 VAC
230 VAC

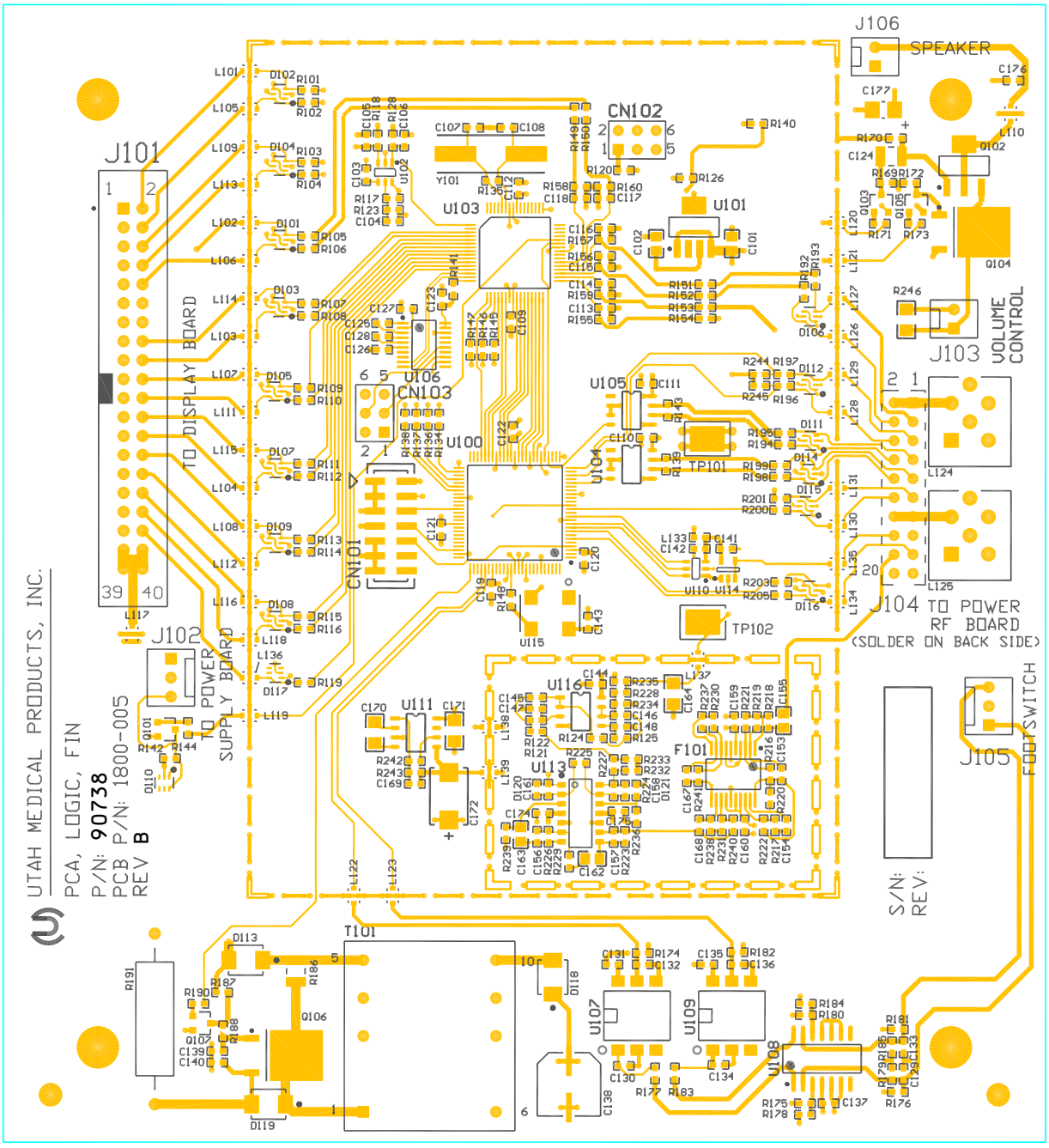
System Functional Diagram



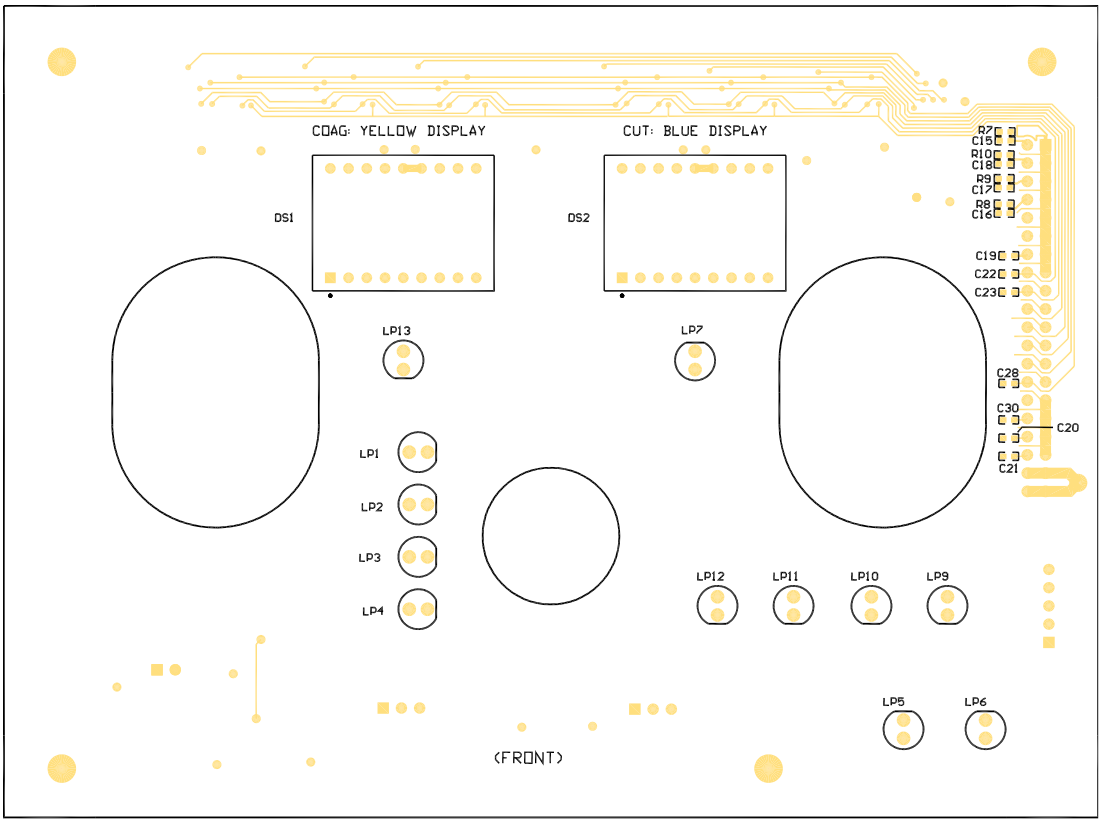
RF Power Amplifier PCB Drawing

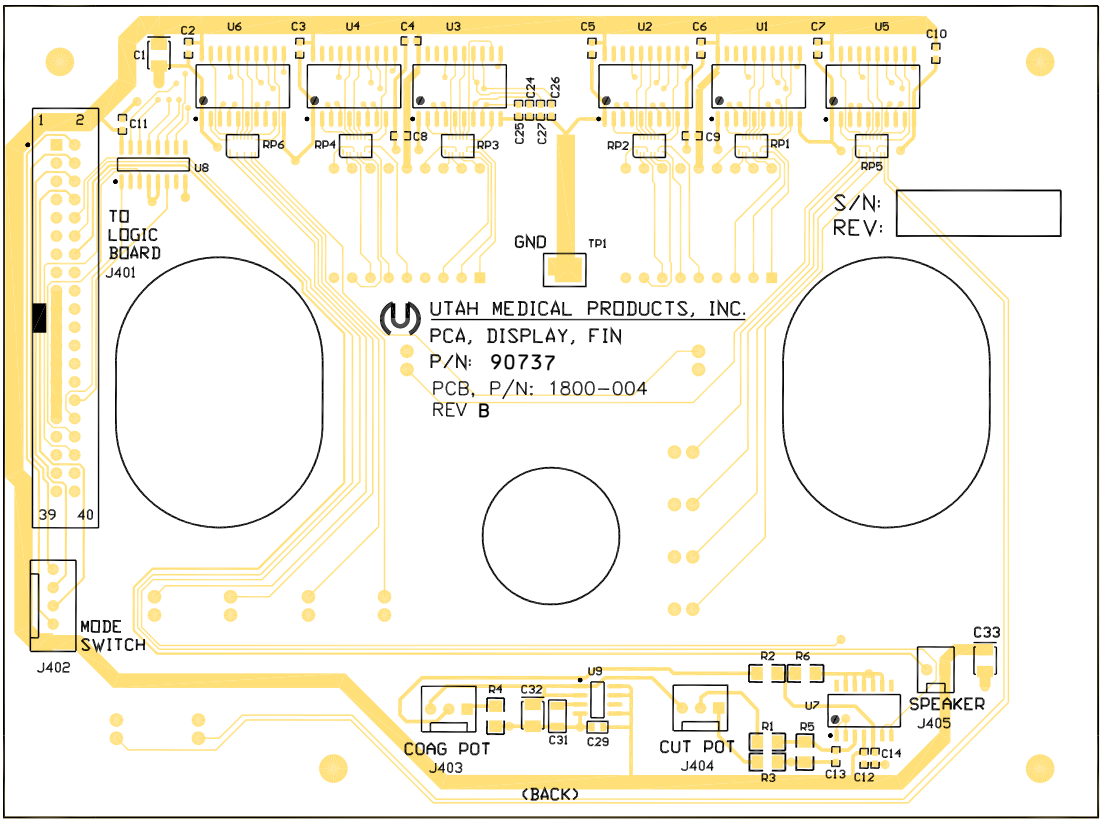


Logic PCB Drawing

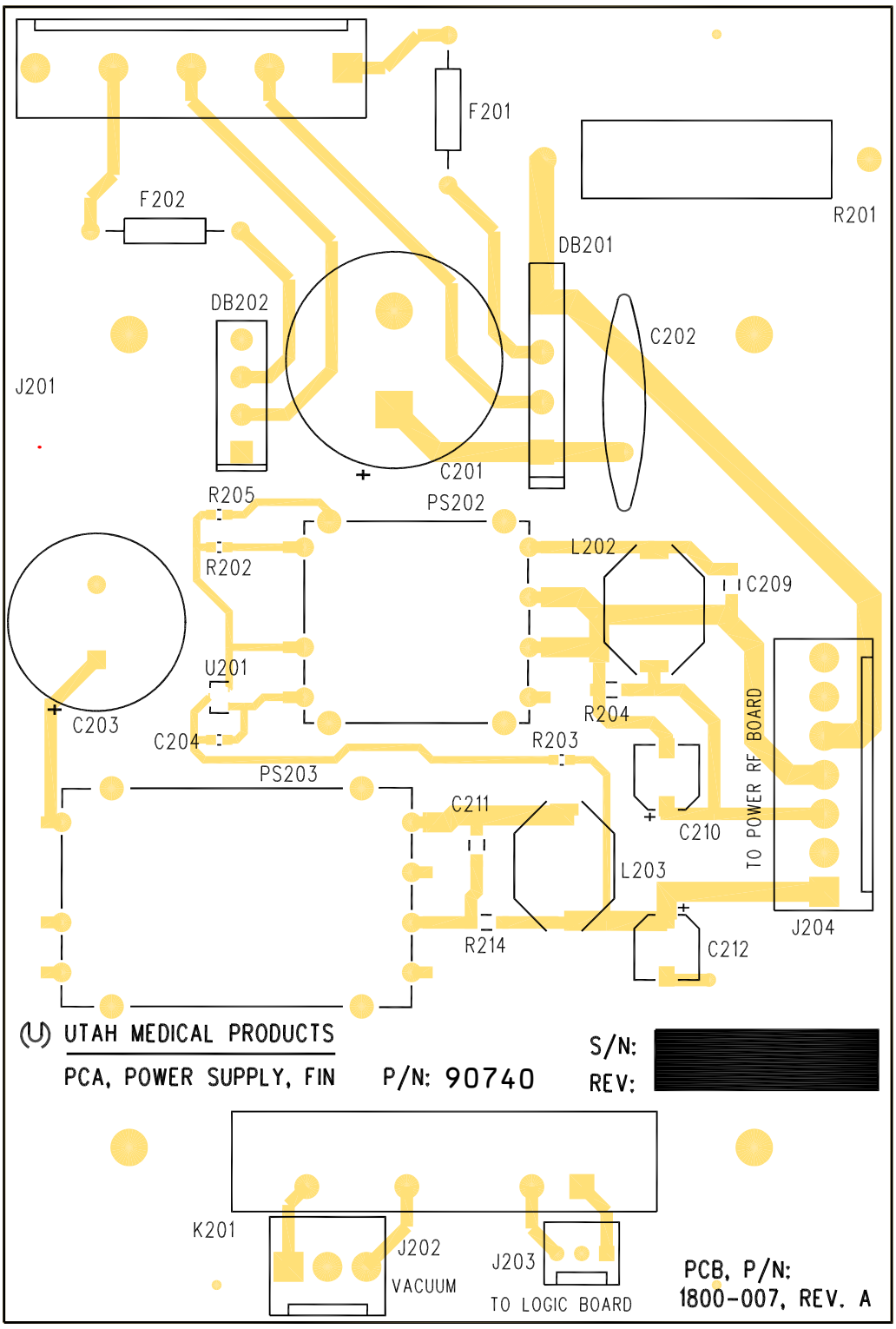


Display PCB Drawing

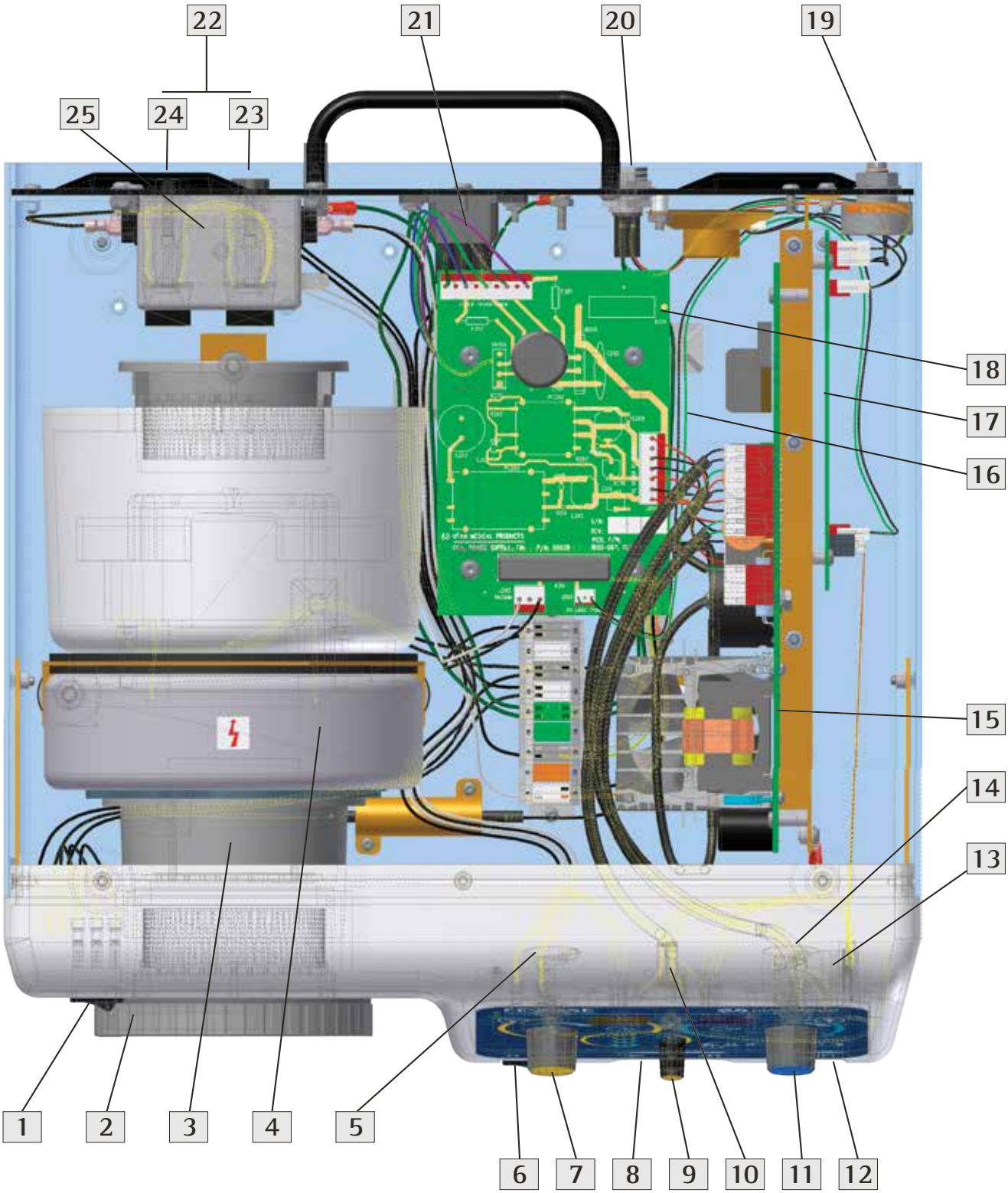




Power Supply PCB Drawing



Assembly Diagram, Internal View



Parts List

Reference number refers to the assembly diagram shown on the previous page. Utah Medical Products, Inc. will make available to qualified technical personnel these spare parts during the expected service life of the FINESSE system, for a minimum of five years from the date of last shipment of this model of the FINESSE system.

Ref	Item No.	Description
1	0012-002	Smoke Evacuation Flow Control Switch
2	SSE-610	Internal Filter Retaining Ring
3	1850-136	Internal Filter Mount (requires 1850-147 and 1850-148 gaskets)
4	0064-900	Motor, Smoke Evacuator
5	0044-800	Power Control Potentiometer, Cut Mode
6	0010-003	Main Power Switch (115VAC), or
	0010-004	Main Power Switch (230VAC)
7	0013-221	Control Knob, Cut Mode
	0013-224	Control Knob Cap (yellow), Cut Mode
8	0007-305	Switchpen Receptacles (3 required)
9	0013-222	Cut/Blend Mode Selector Knob
	0013-225	Cut/Blend Mode Selector Cap (yellow)
10	0012-004	Cut/Blend Mode Selector Switch
11	0013-221	Control Knob, Coag Mode
	0013-223	Control Knob Cap (blue), Coag Mode
12	1850-184	Dispersive Pad Receptacle, shell only
	0049-231	Dispersive Pad Pins (2 required)
	0012-003	Pad Type Detection Switch
13	90737	Display PCB Assembly
14	0044-800	Power Control Potentiometer, Coag Mode
15	90739	RF Power Amplifier PCB Assembly
16	0029-671	Main Transformer
17	6731	Logic PCB Assembly
18	90740	Power Supply PCB Assembly
19	0044-845	Volume Control Potentiometer
20	0049-400	Footswitch Receptacle
21	0006-300	Input Power Receptacle
22	0007-001	Fuse Holder (4 required)
23	0007-502	2.5 A Fuse, Slow blow for 115 VAC Electrosurgical Module, or
	0007-501	1.25 A Fuse, Slow blow for 230 VAC Electrosurgical Module
24	0007-503	3.15 A Fuse, Slow blow for 115 VAC Smoke Evacuation Module, or
	0007-502	2.5 A Fuse, Slow blow for 230 VAC Smoke Evacuation Module
25	1850-192	AC Line Filter

Warranty and Service

FINESSE+ Limited Warranty

Utah Medical Products, Inc. (UTMD) warrants each new FINESSE+ (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 warranty 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+ system
- A purchase order number or authorization to bill the service, if the FINESSE+ 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+ 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.

Notes

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