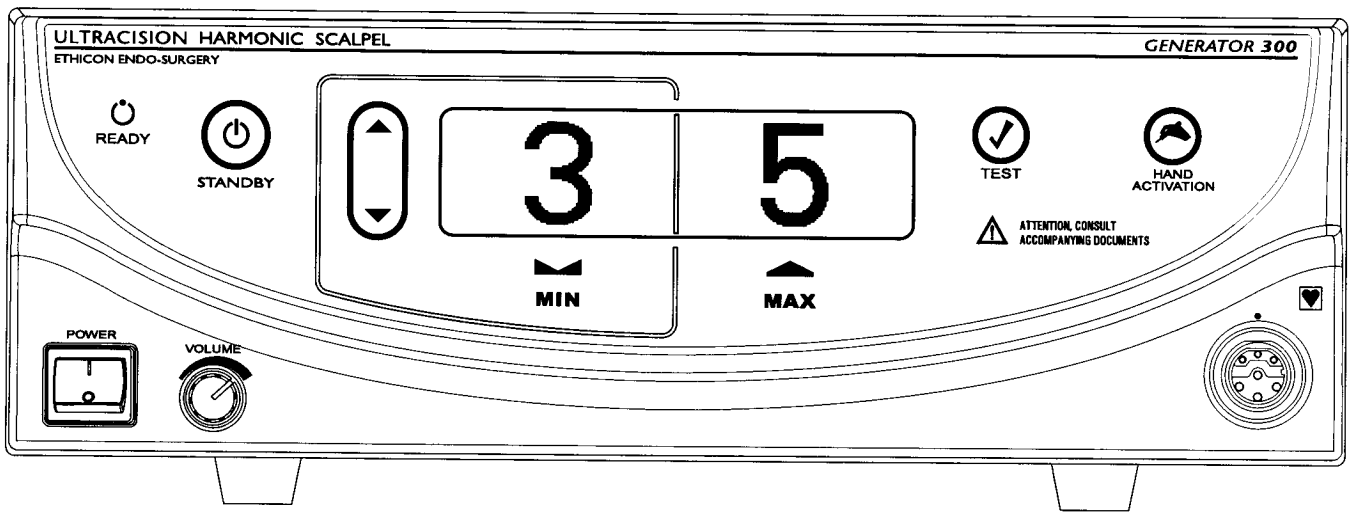
ULTRACISION® HARMONIC SCALPEL®

Generator 300 System Service Manual



ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Scope

This manual and the equipment it describes are for use only by qualified Biomedical Service Personnel. It is intended only as a guide for technical maintenance of the ULTRACISION® HARMONIC SCALPEL® Generator 300.

This manual is intended to be a companion to the ULTRACISION® HARMONIC SCALPEL® Generator 300 User Manual. A thorough understanding of the User Manual is required to properly utilize the information in this manual.

Installation Guidelines

The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the instructions in this and the ULTRACISION® HARMONIC SCALPEL® Generator 300 User Manual. The inspection shall be documented along with any test results to demonstrate proper installation.

Ethicon Endo-Surgery, Inc. reserves the right to change the electrical/electronic or mechanical configurations and components without notice. Schematic revisions may not match PCB revisions in the unit being maintained; consult Ethicon Endo-Surgery, Inc. before making any changes. When necessary, amendments to this manual will be made available by request only.

Product Information

Product Name: ULTRACISION HARMONIC SCALPEL Generator 300 System

Model Number/Product Code: GEN04
Voltage: 100 – 240 VAC

This manual is subject to revision. When referring to this manual please include the following:
Document Type: Service Manual
Document Number: P40401P0X (on back cover of manual)

Manufactured by:
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839 USA
1-800-USE-ENDO (U.S.Customers)
http://www.harmonicscalpel.com

Service

1-800-USE-ENDO (U.S. Customers)
Customers outside the U.S. should contact their Ethicon Endo-Surgery, Inc. representative for assistance.

Table of Contents

Warnings and Precautions

- This equipment, in conjunction with the accessories, is intended to produce high-frequency mechanical energy which enables hemostatic cutting and/or coagulation of soft tissue.
- Safe and effective ultrasonic surgery is dependent not only upon equipment design, but also, to a large extent, upon factors under control of the operator. It is important that the instructions supplied with this equipment be read, understood, and followed in order to enhance safety and effectiveness.
- The ULTRACISION HARMONIC SCALPEL system, including the hand piece, is not Magnetic Resonance safe and is not Magnetic Resonance compatible.
- Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. It is possible to create sparks by hitting other metal instruments. Sparks may ignite flammable gases such as bowel gas.
- The ULTRACISION HARMONIC SCALPEL system must be operated within the required ambient operating conditions. Refer to Chapter 10 – System Specifications.
- The ULTRACISION HARMONIC SCALPEL system should be tested on a periodic basis by qualified biomedical maintenance personnel to ensure proper and safe operation.
- Refer all servicing to qualified biomedical personnel. Your Ethicon Endo-Surgery, Inc. representatives are available to assist in having your equipment serviced.
- Removing the top cover of the generator unit may expose the user to parts within the generator unit which may have high surface temperatures and high voltage. These surfaces are potentially dangerous and should be treated with extreme caution.
- Always unplug the generator from the wall outlet prior to opening the cover for servicing. This poses a potential electric shock hazard.
- After removing the cover, inspect the internal components for obvious damage or foreign debris. Never power ON a suspected problem unit.
- Never remove or install any parts with power on.
- To avoid user or patient injury in the event that accidental activation occurs, the ULTRACISION HARMONIC SCALPEL Generator 300 System instrument blades should not be in contact with the patient, drapes, or flammable materials while not in use. During prolonged activation in tissue, the instrument blade, clamp arm and distal end of the shaft may become hot. Avoid unintended blade contact with tissue, drapes, surgical gowns, or other unintended sites after activation.
- The user should verify that the power receptacle with which this unit is used is properly grounded and is correctly polarized. Do not use ground cheater plugs or extension cords. Do not connect the ULTRACISION HARMONIC SCALPEL Generator 300 System to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle. (Refer to Chapter 10 – System Specifications.)
- Verify that the outlet voltage correctly corresponds to the generator's requirements. (Refer to Chapter 10 – System Specifications.) Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.

- Do not connect the ULTRACISION HARMONIC SCALPEL Generator 300 to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle.
- Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.
- Do not place liquid containers on top of the unit. Wipe spilled liquids off the unit immediately. To avoid inadvertent penetration of liquids, do not operate this unit in a tilted position.
- Locate the ULTRACISION HARMONIC SCALPEL system, including the hand piece cable, at least 3 ft. (approximately 1 m) from electrosurgical systems and their hand piece (e.g., pencil) cables. The generator should not be on the same circuit as other equipment and machines. Please note that different outlets may not necessarily mean different circuits.
- To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.
- Use proper electrical safety and hospital procedures when working on the generator unit.

Notes

- Use only Ethicon Endo-Surgery, Inc. approved replacement parts. Contact the Ethicon Endo-Surgery, Inc. representative for assistance in obtaining replacement parts by calling 1-800-USE-ENDO for customers in the United States. Customers outside the U.S. should contact their Ethicon Endo-Surgery, Inc. representative for assistance.
- Minimizing operating temperature and extreme thermal cycles will extend the life of the equipment.
- Throughout this manual "instrument(s)" refers to ULTRACISION HARMONIC SCALPEL blades, ball coagulators, or coagulating shears.

System Description

The ULTRACISION HARMONIC SCALPEL System utilizes ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue. The system consists of an ultrasonic generator, a foot switch, an optional hand switching adaptor, a hand piece, and a variety of open and minimally invasive instruments.

Note: Throughout this manual "instrument(s)" refers to ULTRACISION HARMONIC SCALPEL blades, ball coagulators, or coagulating shears.

The ULTRACISION instruments vibrate longitudinally at 55.5 kilohertz. This ultrasonic vibration at the blade enhances its cutting ability. The same vibration seals small vessels with coagulated blood and tissue proteins. Hemostasis occurs when tissue couples with the instrument. This coupling causes collagen molecules within the tissue to vibrate and become denatured, forming a coagulum.

Indications

The ULTRACISION HARMONIC SCALPEL System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The ULTRACISION HARMONIC SCALPEL System instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels.

System Components

Generator 300

The generator supplies the hand piece with electrical energy and facilitates selection of power levels, system monitoring, and system diagnostics.

Power is delivered by activating the foot switch or hand switching adaptor.

Hand Piece

The hand piece contains an acoustic transducer that converts the electrical energy supplied by the generator to mechanical motion. The transducer is connected to an ultrasonic wave guide/amplifier which amplifies the motion produced by the transducer and relays it to the instrument.

Instrument

The mechanical motion from the hand piece advances to the instrument, transmitting ultrasonic energy which enables hemostatic cutting and/or coagulation of tissue.

Power Levels

The generator delivers two power levels: minimum (MIN) and maximum (MAX). The minimum power level may be adjusted by the user from Level 1 to 5. The maximum power level is always Level 5. With all instruments except the ball coagulator, use a higher generator power level for greater tissue cutting speed and a lower generator power level for greater coagulation. For the ball coagulator, higher generator power levels will provide greater coagulation. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors including the power level selected, instrument characteristics, grip force (when applicable), tissue tension, tissue type, pathology, and surgical technique.

Note: Refer to the instruments' package inserts for additional power level information.

The ULTRACISION® HARMONIC SCALPEL® Generator 300 System consists of the following components: Generator (GEN04), hand piece, instruments, foot switch, and hand switching adaptor (if used). The generator produces an electric signal, which is transmitted via a coaxial cable to the hand piece, which then converts the electrical signal into ultrasonic, mechanical motion.

Hand Piece

The hand piece houses several major components that generate, amplify, and deliver ultrasonic energy to the instrument end-effector. When each component is attached to the other and tuned, an acoustic drive train is formed. Two key parts of the acoustic system or acoustic drive are:

Acoustic Transducer: Converts the electrical energy into motion. When an AC waveform is applied to the transducer, the piezoelectric material expands and contracts to produce longitudinal motion.

Instrument: Couples the ultrasonic energy to the tissue and amplifies motion. In a laparoscopic configuration, the instrument is elongated by means of a "Laparoscopic Extension." This extension allows the ultrasonic energy to propagate from the hand piece to the instrument with minimal loss.

Generator

The generator converts the AC line voltage to a controlled DC level. The DC level is then modulated at the resonant frequency of the hand piece. The modulated signal is then filtered and delivered to the hand piece, where it resonates the acoustic drive train. A more detailed description follows.

Power Entry Module: Accepts a standard, hospital grade utility cord. Refer to Chapter 10 – System Specifications for details. Provides susceptibility filtering from the external environment as well as suppressing electromagnetic emissions produced by the generator that could be conducted back through the power cord.

Power Supply: Provides 48 VDC to DC/DC Converter and Current/Power Regulation Circuit.

Current and Power Regulation Circuit: Provides Current/Power regulation. Current limit circuits protect these assemblies and others from overload conditions.

Patient Isolation Circuit: Provides a safety isolation barrier to patient and/or user. The voltage generated on the secondary of the transformer is isolated from the primary and thereby not referenced to earth ground.

Microprocessor: The microprocessor contains the software program that drives the ULTRACISION HARMONIC SCALPEL Generator 300 System. The software provides the user interface, frequency drive signal, as well as drive signals to the Liquid Crystal Display, front panel indicators, and generator audio circuit.

Liquid Crystal Display and Front Panel: The Liquid Crystal Display and front panel indicators report the operating mode of the ULTRACISION HARMONIC SCALPEL Generator 300 System. They are driven by the microprocessor.

Foot Switch and Hand Switching Adaptor

Foot Switch(es): The foot switch(es) allow(s) the user to activate the system in either the minimum (MIN) or maximum (MAX) modes based on which foot pedal is being pressed. Pedal activations are communicated to the microprocessor.

Hand Activation Circuit: The hand switching adaptor allows the user to activate the system in either the minimum (MIN) or maximum (MAX) modes based on which button is being pressed. Hand activations are communicated to the microprocessor.

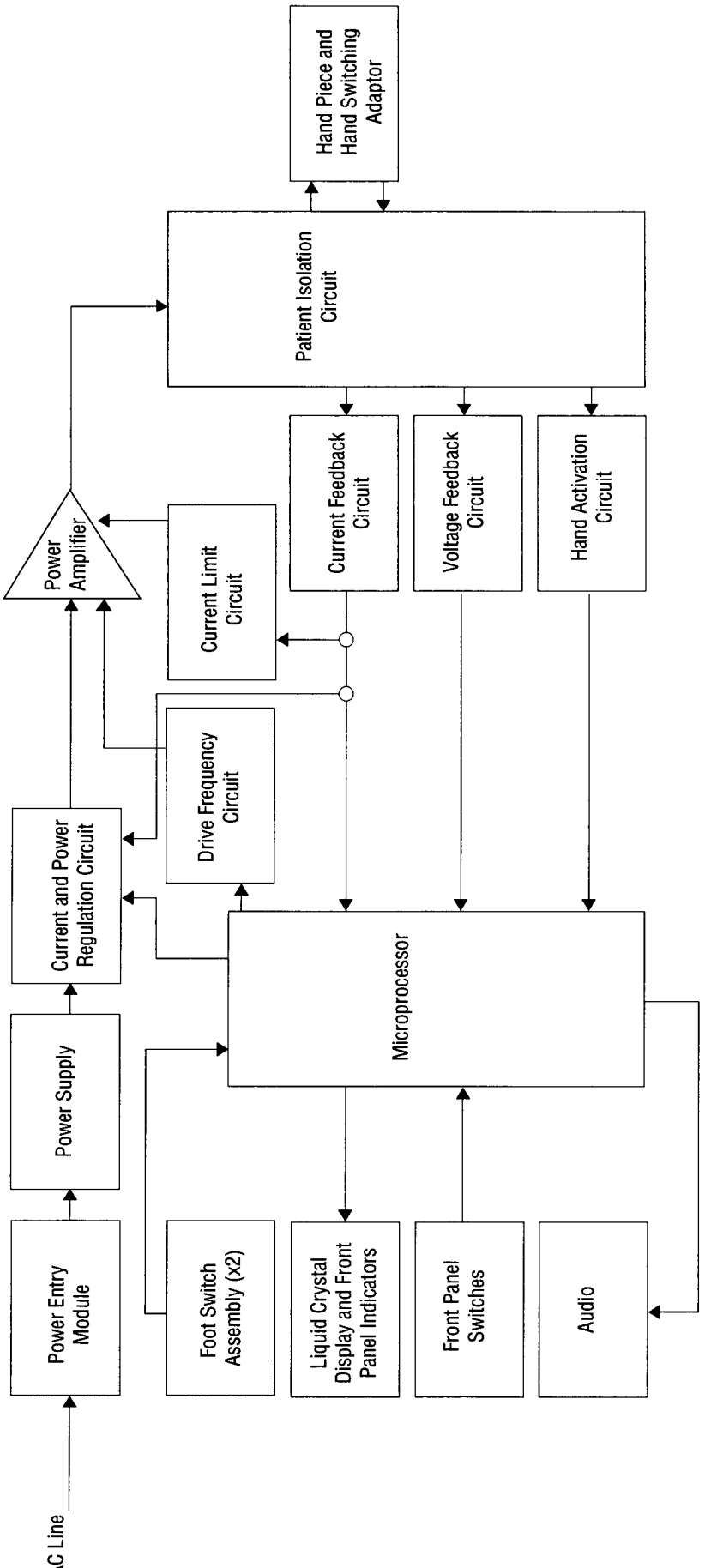


Fig. 3-1 Block Diagram

Unpacking Instructions

The ULTRACISION HARMONIC SCALPEL Generator 300 System includes several components that are purchased separately. Upon receiving the ordered components, check for visible shipping damage. Do not attempt to use any component if it appears damaged. If damage is seen, contact your Ethicon Endo-Surgery representative.

Note: The original packaging should be saved for future storing and/or transporting of the device. Warranty may be voided if the unit is not returned to the service center in the original packaging or equivalent packaging which will protect the unit from damage during shipment.

System components may include the following parts (for product codes, see Chapter 10 – System Specifications):

Generator 300 - includes the generator, power cord, user manual, and service manual.

Note: The User Manual includes a troubleshooting guide (see back pocket of manual binder). Remove the self-adhesive guide's backing and adhere the guide to the top panel of the generator. Placement guides for the Troubleshooting Guide are found on the generator's top panel.

Foot Switch - includes the foot switch and detachable cable assembly.

Note: The foot switch is required if the system will be used with coagulating shears or instruments that are not compatible with the hand switching adaptor. Since the generator has receptacles for two foot switches, two foot switches may have been shipped.

Cart - the cart is optional. It is designed to hold one ULTRACISION HARMONIC SCALPEL Generator. The cart requires assembly; instructions are included with the cart.

Initial Setup

1 Confirm that the generator power switch is OFF during setup.

Caution: To avoid injury, in the event that accidental activation occurs, the ULTRACISION HARMONIC SCALPEL instrument blades should not be in contact with drapes or flammable materials while not in use. During prolonged activation, the instrument blades may become hot. Avoid unintended blade contact with drapes, surgical gowns, or other unintended sites after activation.

2 Secure the generator on its cart or on another suitable fixture. To secure the generator on its cart, place the generator's rubber feet into the corresponding holes on the cart. Push down on the generator's top panel.

Caution: To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.

Warning: The ULTRACISION HARMONIC SCALPEL system must be operated within the required ambient operating conditions. (Refer to Chapter 10 – System Specifications for requirements.)

3 Connect the line cord into the AC inlet located on the generator's rear panel and into an appropriately-grounded outlet. If the power cord is wrapped around the cart handle, it must be completely removed from the cart handle prior to plugging it into the power outlet.

Warning: Verify that the outlet voltage correctly corresponds to the generator's requirements (Refer to Chapter 10 – System Specifications). Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.

Caution: Do not connect the ULTRACISION HARMONIC SCALPEL Generator 300 to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle.

4 **a.** Attach the foot switch cable to the foot switch:

Note: Although installation of the foot switch is optional when using the hand switching adaptor, installing the foot switch is recommended in case its use is needed during the procedure.

- Confirm that the connector and receptacle are dry and clean.
- Orient the slot on the foot switch cable's larger connector at 12 o'clock.
- Seat the connector in the foot switch receptacle.
- Turn the connector collar clockwise until tight. Ensure the collar is finger-tight to prevent inadvertent activation that may result from fluid ingress.

b. Connect the foot switch cable's smaller connector to the foot switch receptacle on the rear panel of the generator.

- Confirm that the connector and receptacle are dry and clean.
- Align the red dot on the foot switch 4-pin connector with the red dot on the 4-pin receptacle on the generator back panel.

Note: The generator has two identical foot switch receptacles. If one foot switch is used, either receptacle may be used.

Repeat steps 4a and 4b if a second foot switch will be used.

5 Connect the instrument and adaptor (or hand switching adaptor), if required, to the hand piece following instructions in their package inserts.
Note: The hand switching adaptor must be at room temperature to function properly. Do not immerse in water to cool rapidly. After steam sterilization, allow hand switching adaptor to air cool for at least 15 minutes prior to use.

6 Connect the hand piece connector to the receptacle on the front panel. Align the white dot on the connector with the white dot on the generator. Ensure the hand piece connector is clean and dry before connecting the hand piece to the generator. Fully insert the hand piece connector to assure complete, proper connection to the generator. (To disconnect the hand piece, firmly grasp the connector and pull the connector away from the generator.)

7 Turn the generator power switch on and observe the power-up sequence. During power-up, the following indicators on the front panel will briefly illuminate:

- **READY, STANDBY, MIN, MAX, TEST, ATTENTION, HAND ACTIVATION**

The system will run its start-up sequence and display the software version. An audible tone will sound during the initiation sequence.

Note: The entire power-up initiation sequence should not exceed ten seconds.

If the start-up sequence deviates from the description above, contact qualified service personnel following hospital protocol.

When the initiation sequence is complete, the system will go to Standby. If the system senses a generator, hand piece, or instrument fault during use, an audible alarm (tone with long pulses) will sound and a visual alarm indicator will appear on the control panel. (Refer to Chapter 8 – Troubleshooting or the Troubleshooting Guide located on top of the generator unit to resolve the problem.)

Controls, Indicators, and Connections

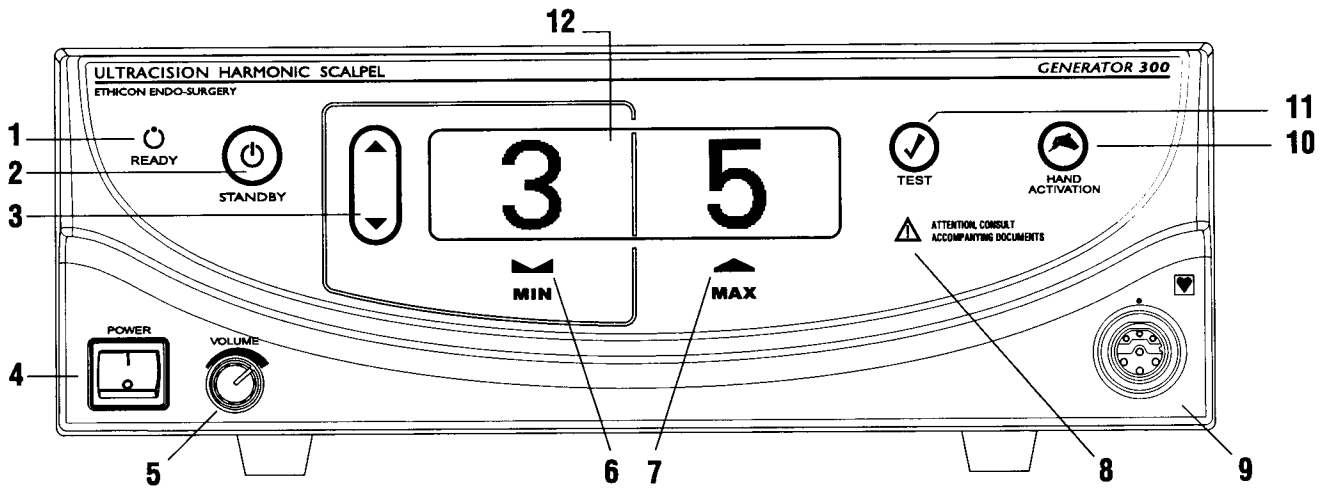


Fig. 5-1 Front Panel

1	**READY**	When this indicator is green, the system is ready for activation. Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.
2	**STANDBY**	Push this button to toggle between Standby and Ready modes. In Standby mode, this button, and the STANDBY icon, light up and all power is removed from the hand piece. Both the foot switch and hand switch are disabled. Upon power-up, the system defaults to Standby mode enabled.
3	**INCREASE/ DECREASE POWER LEVEL**	Push this button to increase or decrease the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the graphic display. The power level may be adjusted when the generator is in Ready or Standby mode.
4	**POWER**	This switch controls the main electrical power to the generator.
5	**VOLUME**	Turn this knob to adjust the volume of the activation tones. A tone will sound indicating the volume level selected.
6	**MIN**	Indicates the user-settable MIN power level setting. When this power level is activated (by foot switch or hand switch), the MIN indicator will flash. On power-up the system defaults to MIN power level 3. Refer to the instruments' package inserts for the recommended MIN power level.
7	**MAX**	Indicates the maximum power level setting. This setting is always "5". When this power level is activated (by foot switch or hand switch), the MAX indicator will flash.
8	**ALARM INDICATOR**	This red indicator appears only if a system alarm occurs in response to a component or generator problem.

9	**HAND PIECE RECEPTACLE**	This receptacle is used to connect the hand piece to the generator.
10	**HAND ACTIVATION**	When the indicator is green, hand activation on the hand switching adaptor is enabled. To disable the Hand Activation mode, depress the button. Upon power-up, the system defaults to Hand Activation mode disabled. Note: If the foot switch is installed, the foot switch is always enabled.
11	**TEST**	Depressing this button initiates the Test mode. This mode is used during troubleshooting. The generator will emit a tone when the Test mode is active and "TEST IN PROGRESS" will appear on the display.
12	**GRAPHIC DISPLAY**	In Ready or Standby modes, this display indicates the minimum (user-settable level 1 to 5) and maximum (level 5) power levels. If a system or component problem exists, error codes will appear on this display.

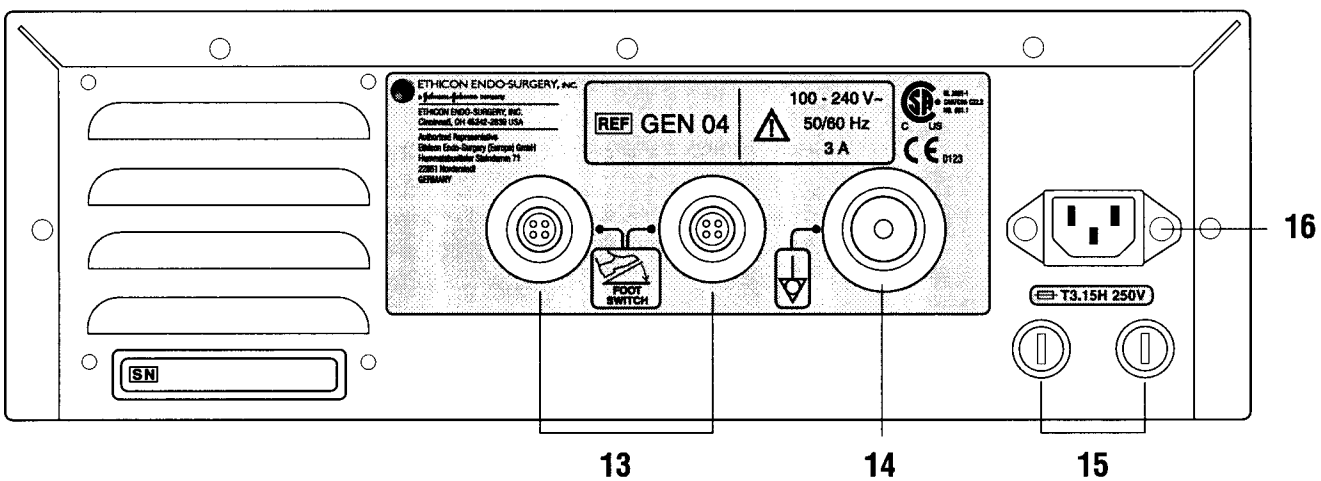


Fig. 5-2 Back Panel

13	**FOOT SWITCH RECEPTACLES**	Identical receptacles allow connection of up to two foot switch assemblies for user convenience. If only one foot switch is used, connect to either receptacle.
14	**POTENTIAL EQUALIZATION TERMINAL**	This terminal provides a means for connection to a Potential Equalization Conductor.
15	**FUSES**	Refer to the Replacement Parts drawings in the back of this manual for additional fuse locations and fuse type.
16	**POWER CORD RECEPTACLE**	This receptacle is used to attach the power cord to the generator. For power cord requirements, refer to Chapter 10 – System Specifications.
	AUDIBLE SIGNALS	The generator delivers audible tones to signal activation, test, and alarm states. The user may choose from three activation tone pitches. Refer to Chapter 11 – Adjustments for tone selection information. Upon power-up, the system defaults to the last tone chosen (the mid-pitch tone is factory-set).

Screen Descriptions

Power-Up Screen
Below is an **example** of the Software Version displayed during power-up.

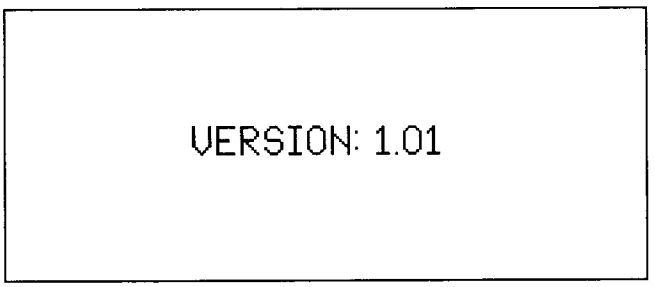


Fig. 5-3 Power-Up Screen

Tone Selection Screen
Refer to Chapter 11 – Adjustments for descriptions of the Tone Selection Screens.

User-Initiated and Pre-Activation Test Screens
The generator will cycle between the following two screens, displaying each screen briefly, for the duration of the time that the system is in the User-Initiated Test state and Pre-Activation Test state. Refer to Chapter 7 – Safety and Function Testing for details.

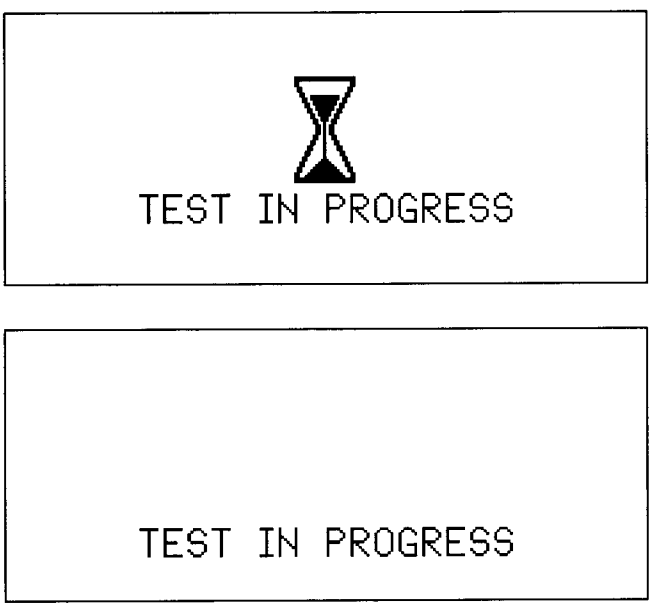


Fig. 5-4 Test in Progress Screens

Standby, Ready and Run Screens
The Standby, Ready, and Run screen appearances depend on the mode in which the system is running. In Normal mode, the Standby, Ready, and Run screens are the same and indicate the MAX power level of 5 on the right, and the user selected MIN power level on the left (1 to 5). In Developer/Biomed mode, the Standby screen indicates the user selected MIN power level on the left, and a subset of system parameters on the right. In Developer/Biomed mode, the Ready screen displays the user selected MIN Power level on the left (1 to 5) and the system run time parameters on the right. Developer/Biomed Run screen is identical to the Developer/Biomed Ready screen.

The following are all possible screens for the Standby, Ready, and Run states in Normal mode. The number on the left indicates the power level for MIN activation (1 to 5), and the number on the right is the power level for MAX activation.

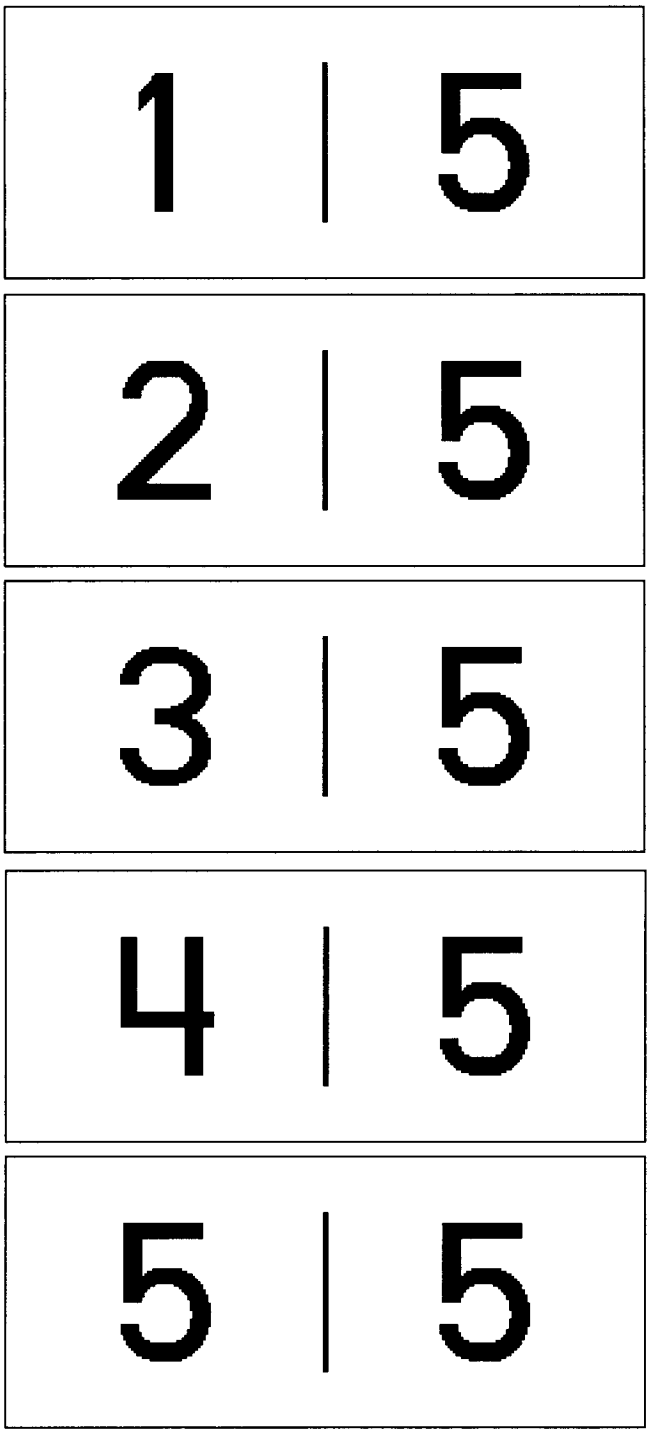


Fig. 5-5 Standby, Ready and Run Screens in Normal Mode

Error Screens

Refer to Chapter 9 – Troubleshooting for examples of each of these screens.

System Operation

For an understanding of system operation, refer to the ULTRACISION HARMONIC SCALPEL Generator 300 User Manual for instructions and specifications for use of the ULTRACISION HARMONIC SCALPEL Generator 300, Foot Switch, and Cart. Refer to package inserts provided separately for information about the Hand Piece, Hand Switching Adaptor, Adaptors, Test Tip and Instruments prior to using the system. This manual is not a reference to surgical techniques.

After completing system setup, the system may be operated.

1 Place the generator in Ready mode by depressing the STANDBY button.

Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.

2 System check and activation:

Each time the generator is activated after exiting Standby, hold the instrument in the air (if coagulating shears are used, open the clamp arm) and depress the MIN or MAX power level on the foot switch or hand switching adaptor. "TEST IN PROGRESS" will appear on the graphic display and a rapid two-tone pulse will sound while the test is occurring. During this five-second period, a system check is being performed.

- If the system is operating properly, the activation tone corresponding to the power level activated will be heard when the check is complete. Stop activation, position the instrument on tissue, and resume activation.
- If the system is not operating properly, an error code will appear (refer to Chapter 8 – Troubleshooting or the Troubleshooting Guide located on top of the generator unit).

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects during the system check. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect during the system check.

Note: The foot switch or hand switch must be depressed until the system check is complete. If the switch is released prematurely, the check will reinitiate at the next activation.

Note: The HAND ACTIVATION button on the generator control panel must be illuminated for the hand switch to be active. To deactivate the hand switch, depress the HAND ACTIVATION button (if the HAND ACTIVATION button is not illuminated, hand switch will be inactive).

Note: If the hand switch will not turn off during operation, depress the button corresponding to the power level opposite that being activated to turn it off - an alarm will sound. Press the HAND ACTIVATION button to disable the hand switching adaptor. Place the generator in Standby, and replace the hand switch; or, continue using the foot switch after deactivating the hand switch.

3 If the system senses a generator, hand piece, or instrument fault during use, an audible alarm (tone with long pulses) will sound and a visual alarm indicator will appear on the control panel. (Refer to Chapter 8 – Troubleshooting or the Troubleshooting Guide on top of the generator unit to resolve the problem.)

Warning: Place the generator in Standby before removing or replacing an instrument, hand switching adaptor or hand piece or when the system is not in use.

System Shutdown

1. Turn the generator power switch off and remove power cord from outlet.
2. Disconnect the hand piece, instrument, and adaptor or hand switching adaptor (if used) and process them as indicated in their respective package inserts.
3. Clean the generator and cart and disinfect the foot switch(es) following hospital protocol (for recommendations, refer to Chapter 6 – Cleaning and Disinfection).
4. Store foot switch(es) on the cart shelves provided. Each shelf will hold one foot switch.
5. Wrap foot switch cable(s) and the power cord on the cart's back handle for storage.

Generator and Cart Cleaning

Clean generator and cart following hospital protocol. Before cleaning, turn the generator main power off and unplug the power cord from the grounded electrical outlet.

Warning: Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.

Proceed with cleaning as follows:

1 Prepare a neutral pH detergent or neutral pH enzymatic detergent according to the detergent manufacturer's directions.

2 Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean all surfaces (including the generator's display).

3 Rinse thoroughly using a soft, clean cloth lightly moistened with warm tap water.

4 Dry with a clean, soft cloth.

Foot Switch Cleaning

The foot switch and cable should be cleaned after each use as follows:

1 Disconnect the foot switch from the generator.

2 Prepare a neutral pH enzymatic detergent according to the detergent manufacturer's directions.

3 With the cable securely attached to the foot switch, soak the foot switch and cable in the detergent solution for two minutes.

Note: Keep the foot switch cable connector that connects to the generator dry at all times to prevent inadvertent activation.

4 After soaking, use a soft-bristled brush to manually clean the foot switch and cable keeping them immersed in the detergent solution.

5 Thoroughly rinse the foot switch and cable – with the cable securely attached to the foot switch – with warm, running tap water for at least one minute.

6 Dry all surfaces with a clean, soft cloth.

Test the hand piece, generator, and foot switch for safety and function according to hospital protocol. Refer to individual package inserts for safety and function testing for other multi-patient use components.

Safety Test

Generator: A qualified hospital technician should perform a leakage current test.

Foot Switch: Examine the foot pedals, cable connectors, and cable for cracks or other damage and replace if damaged.

Other Components: Examine the components by following the instructions in their individual package inserts.

Function Test

1. Attach the hand piece to the generator as described in Chapter 4 – System Setup, then attach the test tip rather than an instrument.

2. Verify that the orange STANDBY indicator is illuminated.

3. Push the STANDBY button to leave Standby mode and enter Ready mode.

   Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.

4. Verify that the green READY indicator is illuminated.

5. Verify that MIN Power Level 3 and MAX Power Level 5 are displayed.

6. Push the Increase and Decrease Power Level button up and down to confirm the MIN Power Level changes from 1 to 5.

7. Turn the generator off. Wait five seconds, then turn the generator back on. Wait ten seconds, then confirm MIN Power Level 3 and MAX Power Level 5 are displayed. Confirm the generator is not being activated unexpectedly.

8. Press the TEST button to perform a User-Initiated Test. The system will run a series of tests to ensure the generator and hand piece are in proper working condition.

9. Place the generator in Ready mode by depressing the STANDBY button. Hold the hand piece so that the distal portion is in the air and step on the MAX foot switch pedal (before activation begins, a five-second system check will be performed – "TEST IN PROGRESS" will appear on the display). After the test is completed, verify that the MAX Power Level indicator on the control panel flashes and that the MAX activation tone is heard.

   Warning: To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.

10. Hold the hand piece so that the distal portion is in air and step on the MIN foot switch pedal. Verify that the MIN Power Level indicator on the control panel flashes and that the MIN activation tone is heard.

    Warning: To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.

The ULTRACISION HARMONIC SCALPEL Generator 300 System supports a series of audible and visual alarms, as well as error codes displayed on the unit's LCD, to help in the identification and troubleshooting of problems down to the assembly level (i.e. generator, hand piece, foot switch, hand switching adaptor, etc.). These guides are meant as an adjunct to, but not a substitute for, clinical judgment and observations.

If the problem cannot be resolved using the corrective actions below, contact the Ethicon Endo-Surgery, Inc. Customer Response Center at 1-800-USE-ENDO for assistance. Please have the model number, serial number from the rear panel of the generator, and a detailed description of the problem. The description of the problem should include power settings, accessories used, procedure being performed, and software revision of the unit.

Warning: Electric shock hazard. Always unplug the generator from the wall outlet prior to opening the cover for servicing.

Warning: After removing the cover, inspect the internal components for obvious damage or foreign debris. Never power ON a suspected problem unit.

Generator Power-Up Problems

Ensure the generator unit is plugged into a functioning wall outlet and that the power cord is attached to the rear panel of the generator. If the unit still does not respond, verify that the fuses are intact and properly installed. Note: There are both external and internal fuses in the generator unit. Refer to the Replacement Parts drawings in the back of the manual for fuse locations.

Audible Indicators and Alarms

Tone	Possible Cause and Corrective Action
No tone during power-up.	Generator failure. Contact service personnel.
No tone when system is activated.	Confirm foot switch is fully connected (if hand switching adaptor is not being used). Confirm foot switch is not faulty. If hand switching adaptor is used, confirm it is connected and not faulty. Confirm hand activation is enabled if hand switching adaptor is being used.
Activation (brief pulses)	System is being activated or is in Test mode. System is operating properly. MIN and MAX power have unique tones.
Alert (three-tone sequence)	Activation is attempted while generator is in Standby mode. Push the STANDBY button to return the generator to Ready mode. Two or more foot or hand activation switches are recognized by the generator as being activated simultaneously. Release all activation switches and reactivate using only one switch.

Constant tone	1) Instrument is in contact with too much tissue. Reduce the amount of tissue in contact with the instrument. If tone persists, carefully remove any tissue that has collected in the distal end of the instrument shaft. 2) Hand piece and/or blade fault. Press TEST to identify source of fault.
Prolonged solid tone during activation (exceeds 10 seconds)	Hand piece and/or blade fault. Press TEST to identify source of fault.
Alarm (two-tone sequence)	A component or system problem has occurred. Refer to the Error Codes section in this chapter or the Troubleshooting Guide. Note: This alarm will activate for three seconds, then will silence itself for 30 seconds. This cycle will continue until the error is resolved or the main power switch is turned off.

Error Codes and Displays

The generator will recognize specific faults in five areas: generator, hand piece, instrument, foot switch or hand switch. When a fault is identified, an alarm will sound, the alarm indicator will appear on the generator control panel, and the source of the problem will appear on the graphic display (the power levels will not be displayed).

Note: For each error code, the generator will cycle between each of the two screens shown in the examples below, with the faulty component flashing.

Follow the procedures outlined below (or in the Troubleshooting Guide on the top of the generator unit) to resolve the problem.

Error Code 1: Generator

Error Code 1 indicates either there is a functional problem with the generator or the front panel button(s) were activated during power-up sequence.
Cycle the power OFF then ON. If error persists, power off system and contact service.

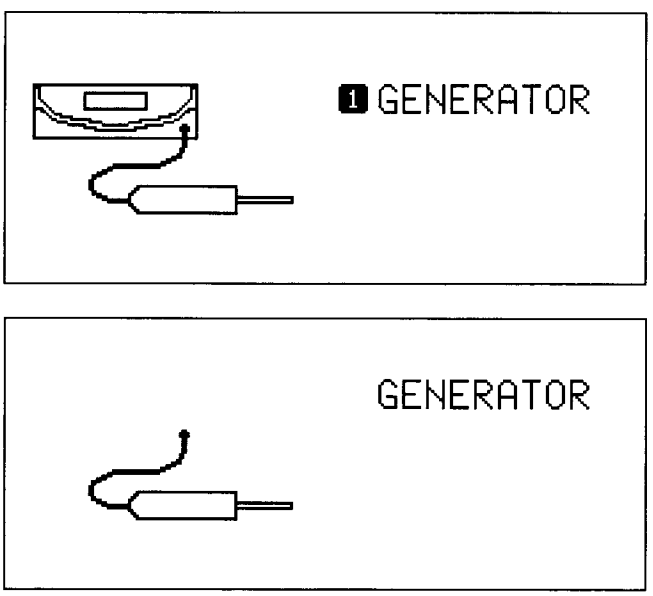


Fig. 8-1 Generator Failure Screens

Error Code 2: Generator Temperature

Error Code 2 indicates that the generator is overheating.

1. Power off system. Remove any obstructions blocking the air vents on the generator's bottom and back panels. If there is no apparent obstruction or external heat source, contact service.
2. Power on the system and wait for up to 30 minutes for generator error to clear.
3. If error code persists, contact service.

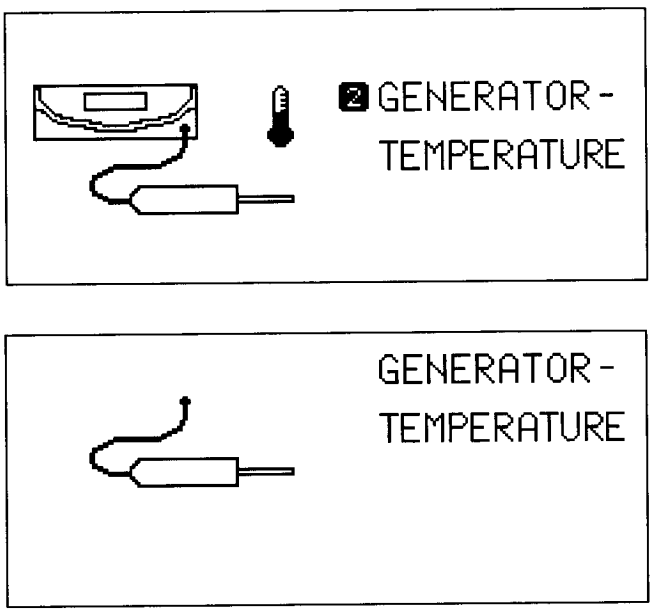


Fig. 8-2 Generator Over-Temperature Error Screens

Error Code 3: Hand Piece

Error Code 3 indicates a problem with the hand piece.

1. Confirm that the hand piece connector is fully inserted and properly oriented – white dot on hand piece is aligned with white dot on front panel. If the error code does not clear within three seconds after the hand piece is properly connected, press TEST.
2. The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

3 If the error persists, install a test tip to isolate the problem. Press TEST button.
- If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
- If no error occurs with test tip attached, replace instrument.

4 Press STANDBY to return to Ready mode. Activate system.

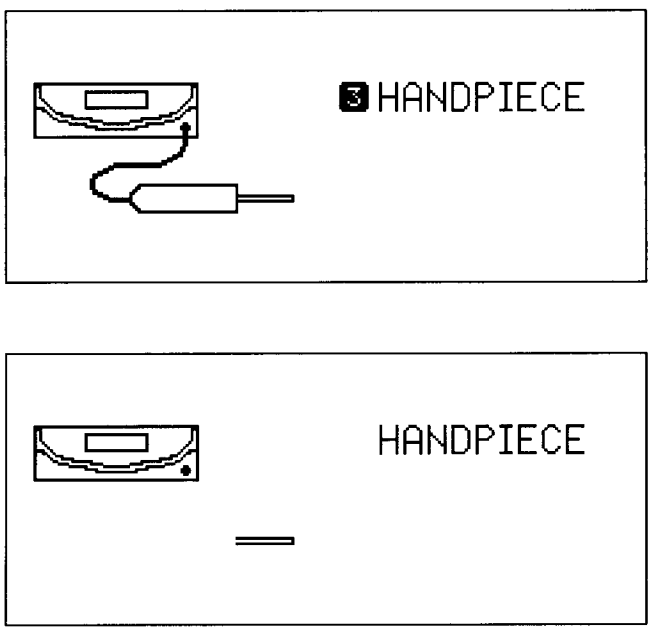


Fig. 8-3 Hand Piece Generic Error Screens

Error Code 4: Hand Piece Temperature

Error Code 4 indicates that the hand piece has exceeded its specified operating temperature. For immediate recovery, use another hand piece; or, follow the steps below to determine the cause of the error condition and alternate recovery methods.

The following are possible causes of an increase in hand piece temperature. To correct, complete the appropriate steps below and ***allow the hand piece to cool before resuming operation***.

1 The hand piece is still warm from recent steam sterilization. Allow the hand piece to cool at room temperature for at least 45 minutes or, for rapid cooling, soak it in room-temperature sterile water for 5 minutes before resuming operation.

Note: The hand switching adaptor (HSA07) should not be submerged for rapid cooling purposes. This may render the hand switching adaptor inoperable for an extended of time. After steam sterilization, allow the hand switching adaptor to air cool at least 15 minutes prior to use.

2 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

3 If the error persists, install a test tip to isolate the problem. Press TEST button.
- If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
- If no error occurs with test tip attached, replace instrument.

4 Press STANDBY to return to Ready mode. Activate system.

5 If the hand piece does not show evidence of overheating and troubleshooting steps 1-4 above do not appear to resolve the problem, perform the following:

a. Leave the hand piece at room temperature for 24 hours or more.
b. Remove any test tip or instrument from the hand piece.
c. With the generator turned off, plug the hand piece into any Generator 300.
d. Power up the generator in Biomed mode.
-Press and hold down the STANDBY button and down arrow key.
-Wait for a steady display – approximately 10 seconds.
-If a "Generator" error occurs, then one of the buttons was not properly held down. If this happens, repeat the power up procedure in Biomed mode.

e. Record the "XDUCER CAPACITANCE" value.
-Press the STANDBY button, if necessary, until it illuminates.
-Use the increase/decrease arrow keys to get to "Page 2 of 21".
-Record the number opposite "XDUCER CAPACITANCE".
-Press the STANDBY button until the Standby light turns off.
-Leave the hand piece plugged into the generator. Do not remove hand piece during entire procedure. Do not activate the MIN or MAX activation buttons on the foot switch or hand switch if either is attached.
-After a period of time that exceeds 30 or more minutes, press the STANDBY button until the STANDBY icon is illuminated.
-Again, read the "XDUCER CAPACITANCE" on Page 2 of 21.
-If the number has changed, the update was successful.
-If the number has not changed, then this update attempt did not succeed. Power down the generator and repeat Step 5.

Note: As the hand piece ages, the generator performs measurements and updates a key hand piece parameter. This function is performed when the internal temperature of the hand piece is stable at room temperature. Certain usage patterns may prevent this update from occurring and subsequently make the hand piece diagnostics more sensitive to temperature. The steps above will cause an update of the hand piece parameter and return the system to designed sensitivity.

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects before pressing TEST. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect while in Test mode.

Note: Do not run the Test mode while an electrosurgical generator is being activated in the room. Interference from the electrosurgical generator may affect test results.

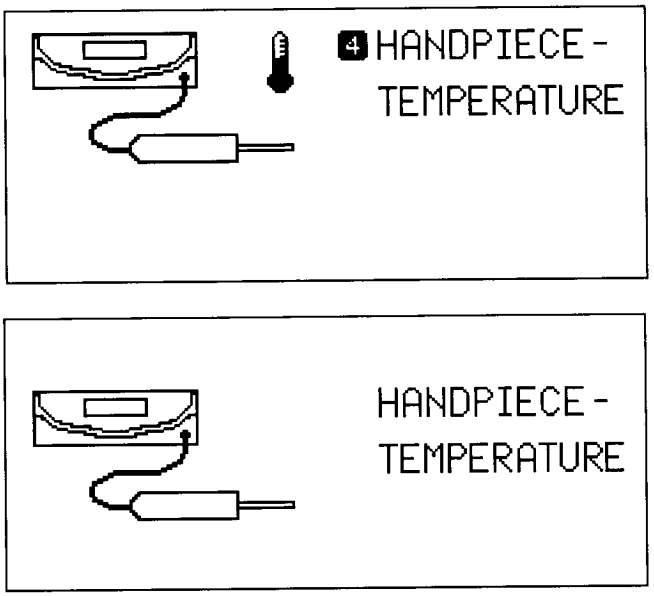


Fig. 8-4 Hand Piece Over-Temperature Error Screens

Error Code 5: Instrument

Error Code 5 indicates a problem with the instrument.

1 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

2 If the error persists, install a test tip to isolate the problem. Press TEST button.
- If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
- If no error occurs with test tip attached, replace instrument.

3 Press STANDBY to return to Ready mode. Activate system.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient, or other interference before pressing TEST. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect while in Test mode.

Note: Do not run the Test mode while an electrosurgical generator is being activated in the room. Interference from the electrosurgical generator may affect test results.

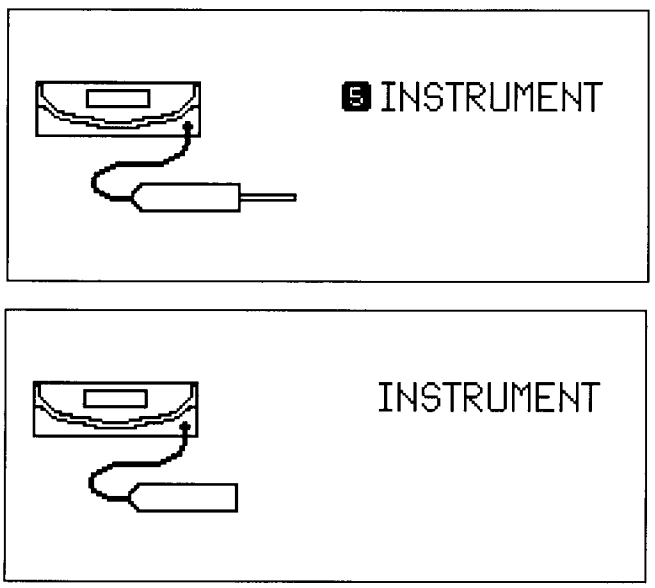


Fig. 8-5 Instrument Generic Error Screens

Error Code 6: Foot Switch

Error Code 6 indicates a foot switch pedal is stuck in the ON position. Confirm generator receptacle, foot switch receptacles and cable connectors are clean and dry or replace the foot switch.
Note: If the error persists, replace foot switch.

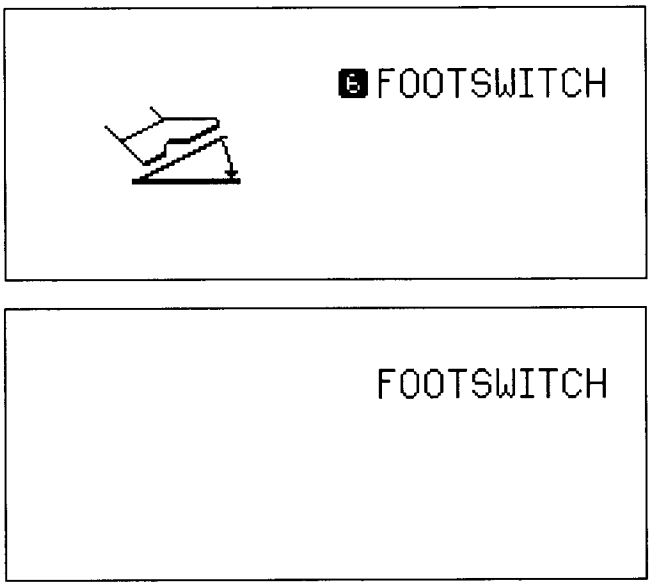


Fig. 8-6 Foot Switch Assembly Error Screens

Error Code 7: Hand Switch

Error Code 7 indicates the hand switch is stuck in the ON position. Confirm contacts in the distal end of hand piece and in the proximal end of the hand switching adaptor are dry or replace the hand switching adaptor.
Note: If the error persists, replace hand switch.

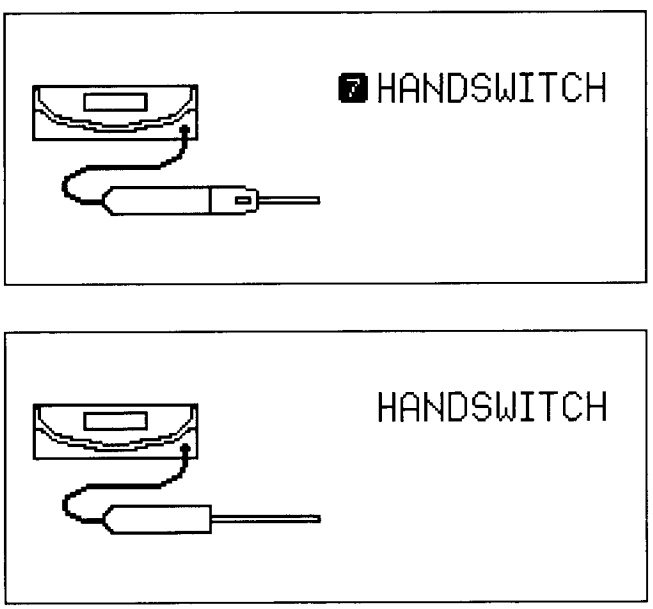


Fig. 8-7 Hand Activation Assembly Error Screens

Components Needed

- 1 UltraCision Harmonic Scalpel Hand Piece (HP054/HP055)
- 1 UltraCision Harmonic Scalpel Hand Piece Test Tip (HST02)
- 1 UltraCision Harmonic Scalpel Foot Switch (FSW01) or Hand Switching Adaptor (HSA07)
- Torque Blade Wrench (TLB01)

Equipment Needed

- DMM (Digital Multi-Meter) with the following specifications:
  - True RMS Voltage Measurements
  - 300 kHz Minimum Bandwidth
  - 4 Digits Minimum Resolution
  - ACRMS Tolerance
- Screwdriver

Required Schedule

Calibration is **required** on the UltraCision Harmonic Scalpel Generator 300 every **twelve months**.

Proof of calibration should be documented according to hospital procedures.

Generators can be returned to Ethicon Endo-Surgery, Inc. for calibration, but this is not covered in the warranty. A minimal charge will be assessed. This can be done by calling 1-800-USE-ENDO (U.S. Customers). International Customers should contact their Ethicon Endo-Surgery, Inc. representative for assistance.

Calibration Procedures

Complete the following Calibration procedures every 12 months according to hospital procedures.

Caution: Use proper hospital safety procedures when performing a calibration.

Calibration One

The Calibration One procedure is used to enter/input the Level 3 current read by an external, calibrated meter.

Step		Result
1	Unplug all connections to the generator. Remove the generator cover by removing the casing screws and sliding the cover towards the back of the unit.	☐
2	Connect hand piece and foot switch (or hand switching adaptor) to their respective connections on the uncovered generator. Attach a test tip to the hand piece, and torque on using a torque blade wrench.	☐
3	Connect a power cord to the uncovered generator. Use caution when working around generator components while the generator is powered ON.	☐
4	Enter Developer/BME mode by simultaneously holding the STANDBY button and DOWN arrow button on the generator while powering ON. The Developer/BME mode screen will be displayed. The buttons can be released when the indicator icons light up.	☐
5	Scroll to Page 2, using the UP and DOWN arrow buttons. Record the 'Current Setpoint' value.	____mA
6	75% of the value recorded in Step 5 is the Level 3 current. Calculate and record this value by **multiplying** the Step 5 value above **by 0.75**.	____mA
7	Press the STANDBY button to enter READY state.	☐
8	Set the MIN level to Level 3 (this is the default level).	☐
9	Activate the hand piece at Level 3 by pressing the MIN foot switch pedal, or activating the MIN hand switching adaptor button. Ensure the test tip is activating in air and is not in contact with anything. Allow the Pre-Run tests to complete.	☐
10	While continuing to press the MIN Level 3 foot switch pedal or MIN hand switching adaptor button, measure the RMS voltage across both current-sense resistors on the main board, R233 and R234 (which are in series). To measure using probes, place the positive and negative probes on the outside of each of the resistors R233 and R234, respectively. To measure using alligator clips, clip to the post of R229 closest to R233. and to the post of C177 closest to R234. Either of these connection schemes (probes or clips) will measure the voltage across R234 and R233 as required. Note: This measurement MUST be taken with a Digital Multi-Meter (DMM) consistent with the specifications listed in the Equipment Needed section of this manual. Using a DMM that does not meet these specifications will cause errors in the calibration procedure.	☐
11	Record the DMM voltage from Step 10, to four digits of precision. The two resistors in series are a total of 1 ohm, so the value measured in volts is equivalent to the current in amperes. (V=IR) Record this equivalent current.	____mA
12	Deactivate the hand piece by releasing the foot switch or hand switch MIN or MAX button.	☐

13	While in Developer/BME mode, press STANDBY to enter the Standby state.	☐
14	Scroll to Page 17 by using the UP and DOWN arrow buttons.	☐
15	Adjust the VOLUME knob to obtain the Level 3 current recorded in Step 11. Press the TEST button when this value is displayed on the screen.	☐
16	The text 'Value Accepted!' should flash twice if the calibration was successful.	☐
17	Power OFF the generator for a few seconds. Power ON the generator and enter Developer/BME mode by simultaneously holding down the STANDBY button and the DOWN arrow button on the generator while powering ON. The buttons can be released when the indicator icons light up.	☐
18	Press the STANDBY button to enter the Ready state.	☐
19	Activate the hand piece using the MIN foot switch pedal or MIN hand switching adaptor button at Level 3. Allow the Pre-Run tests to complete.	☐
20	While continuing to press the MIN Level 3 footswitch pedal or MIN hand switching adaptor button, again, measure the VAC RMS output voltage simultaneously across **both** of the current-sense resistors, R233 and R234, as in Step 10 above.	☐
21	Verify the current in Step 20 is within 1% of the Step 6 calculated value.	____mA
22	Power OFF the generator and continue to the Calibration Two procedure.	☐

Serial Number _____ Results _____ Pass _____ Fail

Software Version _____

_____ _____

Completed By Date

Calibration Two

The Calibration Two procedure is used to confirm the output read by the generator is correct and to enter this confirmation. This procedure is performed without an external meter. The Calibration One procedure must be performed prior to the Calibration Two procedure.

Step		Result
1	Connect hand piece and foot switch (or hand switching adaptor) to their respective connections on the generator. Attach a test tip to the hand piece, and torque on using a torque blade wrench.	☐
2	Enter Developer/BME mode by simultaneously holding the STANDBY button and DOWN arrow button on the generator while powering up. The Developer/BME mode screen will be displayed. The buttons can be released when the indicator icons light.	☐
3	Scroll up to Page 2, using the UP and DOWN arrow buttons. Record the 'Current Setpoint' value.	____mA
4	75% of the value recorded in Step 3 is the anticipated Level 3 current. Calculate and record this value by multiplying the Step 3 value above by 0.75.	____mA
5	Go to Ready mode and activate the generator at Level 3 for more than one second after the pre-run test is completed, using the MIN foot switch or hand switching adaptor button. Ensure the test tip is activating in air and is not in contact with anything.	☐
6	Deactivate the hand piece by releasing the foot switch or hand switching adaptor buttons.	☐
7	While in Developer/BME mode, press the STANDBY button.	☐
8	Scroll to **Page 18** using the UP or DOWN arrow buttons.	☐
9	Press the TEST button to accept the Level 3 calibration current value. Record the current displayed on the screen.	____mA
10	The text 'Value Accepted!' should flash twice if the calibration procedure was successful.	☐
11	Power OFF the generator. Enter Developer/BME mode by simultaneously holding down the STANDBY button and the DOWN arrow button while powering ON generator.	☐
12	Press the STANDBY button to enter the Ready state.	☐
13	Activate the hand piece at Level 3 by pressing the MIN foot switch pedal, or activating the MIN hand switching adaptor button for more than one second. Ensure The test tip is activating in air and not in contact with anything. Press the STANDBY button to enter the Standby state.	☐
14	Record the current displayed on Page 18.	____mA
15	Verify that the reading in Step 13 is within 1% of the the value from Step 4. If not, carefully re-execute both the Calibration One and Calibration Two test procedures again.	☐

Serial Number _____ Results _____ Pass _____ Fail

Software Version _____

_____ _____

Completed By Date

Product Codes

Required Components for System Operation:
GEN04: Generator 300
HP054/HP055: Hand Piece (includes HST02 Test Tip and TLB01 Torque Blade Wrench)[1]

Instruments and Adaptors:
Contact your Ethicon Endo-Surgery representative for information about instruments available for use with this system. Some instruments may require use of an adaptor.

Optional Components:
FSW01: Foot Switch[2]
HSA07: Hand Switch[1,2]
CRT01: Cart

[1] Refer to separate product insert supplied with this component.
[2] At a minimum, either the foot switch or the hand switching adaptor is required to operate the generator. When the hand switching adaptor is used, availability of the foot switch is recommended.

Degree of Protection Against Electric Shock

Type CF Applied Part

Class of Protection Against Electric Shock

Class I

Safety Standards

EN 60601

Degree of Protection Against Harmful Ingress of Water

Generator: Ordinary equipment
Footswitch: IPX8

Safety Classification

UL 2601-1
CSA C22.2 601.1
EN 60601-1

Mains Input

Voltage: 100-240 VAC
Frequency: 50/60 Hz
Current Consumption: 3 amp

Ambient Operating Conditions

Temperature 18°C to 23°C
Humidity: 10-90% non-condensing
Atmospheric Pressure Range: 700hPa-1060hPa

Transport and Storage Conditions

Temperature: -35°C to +54°C
Humidity: 10-95% non-condensing
Atmospheric Pressure Range: 700hPa-1060hPa

Date of Manufacture

The date of manufacture may be determined by viewing the serial number on the rear panel of the generator. The fourth and fifth characters indicate the year of manufacture as follows:
GN401 = year 2001
GN402 = year 2002
GN403 = year 2003
GN404 = year 2004
GN405 = year 2005

Power Cord

North American removable power cord set with the following characteristics:
Plug Style: NEMA 5-15 (clear) North American Hospital Grade
Receptacle: IEC 60320 C13 with straight non-angled cord entry
Cord Length: 4.6 meters nominal
Current Rating: 13A
Voltage Rating: 125 VAC minimum
Wiring Code: North American
Cordage Description: SJT (UL) or SJT (CSA)
Conductors: 16 AWG 3C
Agency Approvals Required: UL and CSA

International removable power cord set with the following characteristics:
Plug Style: as needed by particular country requirements
Receptacle: IEC 60320 C13 with straight non-angled cord entry
Cord Length: 2.44 - 4.6 meters nominal
Current Rating: 10A
Minimum conductor size cross-sectional area: 1.0 mm^2 copper
Voltage Rating: 250 VAC minimum
Wiring: international
Cordage Type: HAR
Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV

Duty Cycle

Duty Cycle is determined by hand piece and instrument in use. For duty cycle information, refer to applicable instrument(s) and hand piece inserts and/or Chapter 7 – Warnings and Precautions of the Generator 300 System User Manual.

Weight (unpacked)

Generator: 7.48 kg nominal

Cart: 42.0 kg nominal

Overall Dimensions

Generator 300 (HxWxD): 5.3" (13 cm) x 14.5" (37 cm) x 15.2" (39 cm)

Cart (HxWxD): 37.3" (95 cm) x 17.7" (45 cm) x 27.6" (70 cm), including handle

Disposal

Some internal components of the generator, foot switch and foot switch cable contain lead. Disposal should be performed according to local requirements and regulations.

Torque Requirements

Item	Torque	Units	Thread Locker	QTY	Comments
Front Bezel, Volume Control	6	In-Lb	No	1	long socket required
Front Bezel, Handpiece Receptacle	24	In-Lb	No	1	torqued with open-end torque wrench
Front Bezel, LCD	7	In-Oz	Yes	4	Phillips, Loctite 222
Front Bezel to Chassis	11	In-Lb	No	5	Phillips
Fan to Chassis	11	In-Lb	No	4	standard socket
Footjack Connectors to Chassis	11	In-Lb	No	2	long socket required
Speaker to Chassis	11	In-Lb	No	4	Phillips
Silver Ribbon Cable from Front Panel Switches	11	In-Lb	No	1	Phillips
Fuse Holders to Chassis	6	In-Lb	No	2	long socket required
Power Entry Module to Chassis	6	In-Lb	No	2	Phillips & hold the nut
Ground Pin-to-Chassis	6	In-Lb	No	1 nut	Special tool used to engage
Ground Pin Nut	18	In-Lb	No	1	standard socket
Ground Wires to Chassis	18	In-Lb	No	2	Phillips
Power Supply to Chassis	7	In-Lb	Yes	2	Phillips, Loctite 222
Generator PC Board to Chassis	18	In-Lb	No	15	Phillips
Cover to Chassis	18	In-Lb	No	11	Phillips

Power Level Adjustment

Upon start-up, the generator defaults to power level 3 (MIN) and 5 (MAX). The minimum (MIN) power level is user-settable from power levels 1 to 5. To adjust the power level, depress the UP/DOWN arrow button to the left of the MIN power level display. Set the power level based on surgeon preference and/or recommendations provided in the instrument's package insert (for more information, see Power Levels section in Chapter 2 – General Description).

Audible Activation Tone Adjustment

The generator has three activation tone sets from which to choose (the mid-pitch tone is factory set). To choose another tone:

1. Switch power off.
2. Switch power on. Then immediately depress and hold both the STANDBY and HAND ACTIVATION buttons. When the graphic shown in Fig. 11-1 appears on the display, release the STANDBY and HAND ACTIVATION buttons.
3. While in the Tone Selection mode, the generator will automatically sequence through the available tone pitches. To select a tone, depress any button on the control panel. The generator will return to Standby mode. The tone chosen will be saved until it is changed again by accessing the Tone Selection mode.
4. Adjust tone volume by turning the knob on the lower left corner of the control panel. A tone will sound to indicate the volume level selected.

Note: For safety reasons, the audible tone may not be disabled. The audible tone volume for alarms cannot be changed.

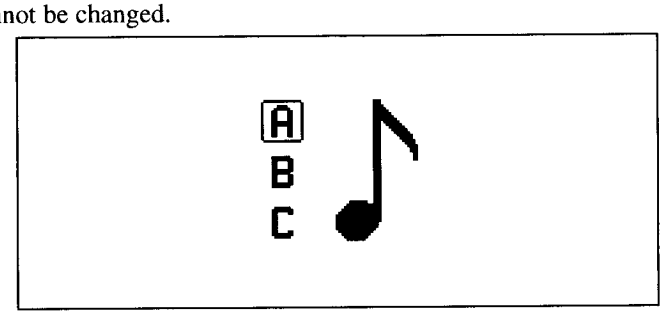


Fig. 11-1 Display: Tone Selection A

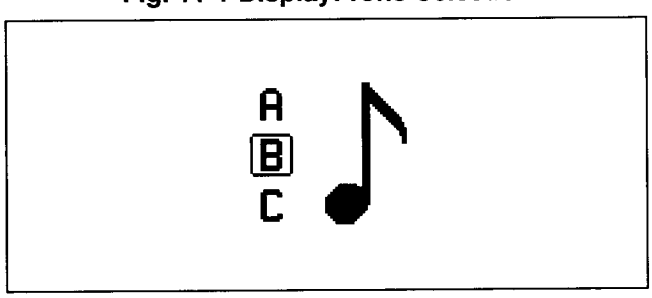


Fig. 11-2 Display: Tone Selection B

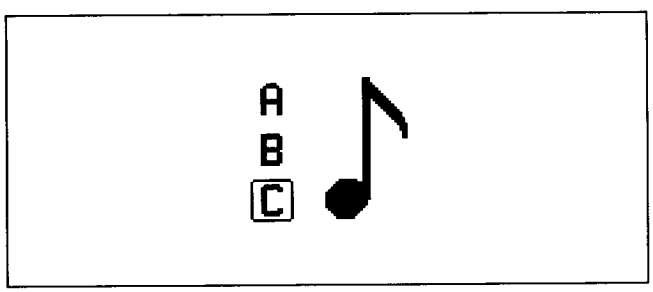


Fig. 11-3 Display: Tone Selection C

Repair Strategy

- Thorough knowledge of the ULTRACISION HARMONIC SCALPEL Generator 300 System User Manual and this manual is mandatory prior to attempting any repair.
- Loaner units may be provided free of charge for units which are being repaired under warranty.
- Calibration is not covered by any warranty. There will be a nominal charge for the manufacturer to perform the Calibration Procedure.
- Only those replacement parts designated in the Spare Parts List below are available for sale.
- Use only Ethicon Endo-Surgery, Inc. approved replacement parts. Your Ethicon Endo-Surgery, Inc. representative will be happy to assist you in obtaining replacement parts.
- Replacement parts can be purchased from Ethicon Endo-Surgery, Inc. by calling 1-800-USE-ENDO (U.S. Customers) or by contacting an Ethicon Endo-Surgery, Inc. representative (outside the U.S.).

Spare Parts List

Below is a list of spare parts which can be ordered through Ethicon Endo-Surgery, Inc. for the ULTRACISION HARMONIC SCALPEL Generator 300 System. The reference numbers below correspond to reference numbers on the Main Assembly Drawing in the back cover of this manual and the Package Assembly Drawing on p. 51 of the manual.

Reference No.	Part No.	Description
1	D06358P01	Fuse Label
2	D06363P01	Back Panel Label
3	3583.036	Bezel Sub-Assembly
4	3583.038	Cover Enclosure
5	3583.053	Cable Assembly, Hand Piece Receptacle
6	3583.060	Cable Assembly, Earth Terminal – Chassis
7	3583.061	Cable Assembly, Power Entry – Chassis
8	3583.062	Cable Assembly, Fuse Holder – AC Switch
9	3583.064	Cable Assembly, Volume Control – Generator Board
10	3583.065	Cable Assembly, Fan with Cable Assembly
11	3583.066	Cable Assembly, Speaker with Cable Assembly
12	3583.067	Cable Assembly, Power Supply – Generator Board
13	3583.070	Cable Assembly, Power Entry – Fuse Holder
14	3583.073	Cable Assembly, Foot Switch - Generator Board
15	3583.079	LCD Display PCB
16	3583.112	Wire Assembly, AC Switch – Power Supply
17	3583.123	Power Cord, 13 Amps, 125 Volts, 15 feet
18	3583.125	Label, Tamper Evident
19	600-000234	Power-on Rocker Switch
20	620-000243	Fuse 3.15 Amps, 250 Volts, Slo-Blo
21	640-000268	Ferrite Clamp/Bracket 279 @100MHz
22	700-000038	Hardware, Nut 8-32 (for fan assembly)
23	700-000394	Hardware, Phillips 8 – 32 x 5/16 (for ground to chassis)
24	700-000504	Hardware, Phillips 4 – 40 x 3/8
25	700-000884	Hardware, KNut 4-40
26	700-001497	Hardware, Ground Pin
27	700-001653	Hardware, Knob
28	700-001662	Hardware, Feet, Rubber Black, with screw
29	700-001663	Hardware, Fuseholder, 5 x 20 PNL MNT

30	700-001664	Hardware, Phillips 8 – 32 x 5/16
31	700-001665	Hardware, Phillips 8 – 32 x 1-1/4 (for fan assembly)
32	700-001666	Hardware, Lockwasher, for Hand Piece
33	700-001667	Hardware, Bushing (Wire Protectors)
34	700-001668	Hardware, Grommet
35	700-001749	Hardware, Phillips 6 – 32 x 5/16
36	700-001767	Hardware, Hnut 3/4 – 16 x 7, 8 x 5/32
37	700-001806	Hardware, Standoffs for fan
38	800-003007	Power Entry Module
39	875-000358	Power Supply, 48 Volt
40	950-000443	Packaging, Bag, Anti-Static 24 x 30; Pink
41	950-000530	Packaging, End Caps
42	950-000531	Packaging Carton, 18 x 19
43	700-000250	Hardware, Phillips 8 – 32 x 1/2, Secure Main Board
44	900-000266	Tystrap
45	3583.047	Generator PCB, Main
46	3583.042	Chassis Sub-Assembly
47	997-Q8	Quick Disconnect Foot Switch (GEN04)
48	N/A	Power Supply Fuse, 5 Amp, 250 Volt

Note: Refer to Chapter 10 - System Specifications for torque requirements.

Available Resources

- An Ethicon Endo-Surgery, Inc. Sales Representative is available for assistance.
- The Ethicon Endo-Surgery, Inc. Customer Response Center is available for Biomedical engineering support by calling 1-800-USE-ENDO (U.S. Customers). Customers outside the U.S. should contact their Ethicon Endo-Surgery, Inc. representative for assistance.

Service and Repair Returns

U.S. - All service inquiries in the US should be initiated by calling 1-800-USE-ENDO. A Customer Service representative will walk the customer through the equipment return process and identify the location where to ship the equipment.

Outside the U.S. – Customers should contact their Ethicon Endo-Surgery, Inc. representative for instructions.

Prior to sending your generator in for service:

- Obtain a Return Goods Authorization Number by calling 1-800-USE-ENDO.
- Package the generator in the original packaging with the tag indicating the return address information, a description of the problem, and your Return Goods Authorization Number.

Note: Warranty may be voided if the unit is not returned to the service center in the original packaging or equivalent packaging which will protect the unit during shipment.

- Ship the generator prepaid to Ethicon Endo-Surgery, Inc. Service Department.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Ohio, U.S.A.

Ethicon Endo-Surgery, Inc. warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below. Ethicon Endo-Surgery's obligation under this warranty is limited to the repair or replacement, at its option, of any product, or part thereof, which has been returned to Ethicon Endo-Surgery, Inc. or its Distributor within the applicable time period shown below and which examination disclosed, to Ethicon Endo-Surgery's satisfaction, to be defective. This warranty does not apply to any product, or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by parties not authorized by Ethicon Endo-Surgery, Inc. (2) repaired or altered outside Ethicon Endo-Surgery's factory in a way so as to, in Ethicon Endo-Surgery's judgement, affect its stability or reliability, (3) subjected to improper use, negligence or accident, or (4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry.

Ethicon Endo-Surgery's products are warranted for the following periods after delivery to the original purchaser:

Hand Pieces	Nine (9) Months, Parts and Labor
Generators	One (1) Year, Parts and Labor
Carts	One (1) Year, Parts and Labor
Foot Switches and Cables	One (1) Year, Parts and Labor
Sterilization Tray	One (1) Year, Parts and Labor

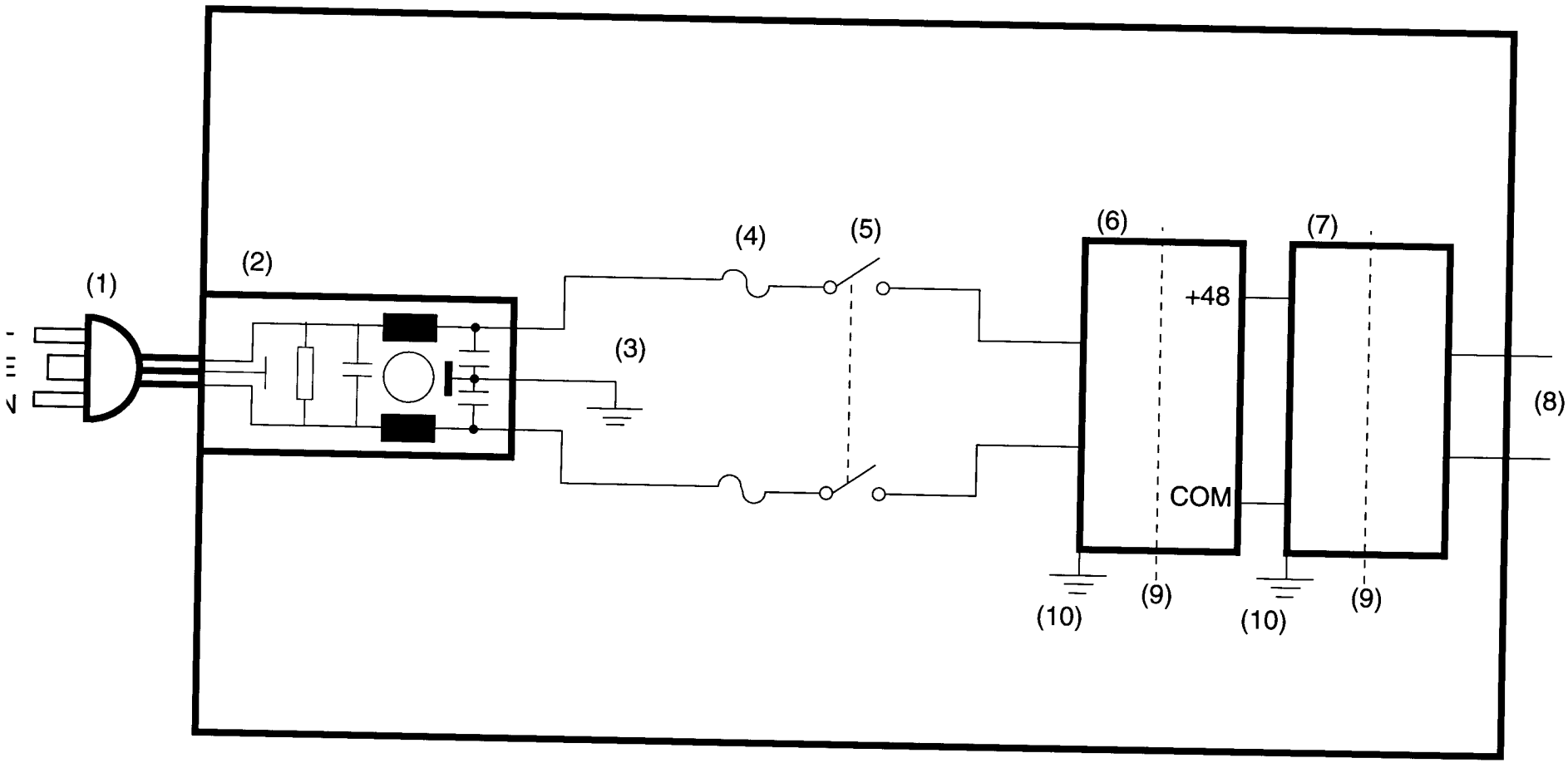
UNLESS SUPERCEDED BY APPLICABLE LOCAL LAW, THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ETHICON ENDO-SURGERY, INC. AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY, INC. BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, OTHER THAN AS EXPRESSLY PROVIDED BY A SPECIFIC LAW. Ethicon Endo-Surgery, Inc. neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Ethicon Endo-Surgery Inc. products. There are no warranties that extend beyond the terms hereof.

Ethicon Endo-Surgery, Inc. reserves the right to make changes to products built and/or sold by them at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

I	On
O	Off
	Type CF Applied Part
	Lot
	Temperature
	Relative Humidity
	Attention - Consult Accompanying Documents/See Instructions For Use
	Non-Sterile
	Date of Manufacture
	Fragile
	This end up
	Keep dry
	Increase/Decrease
	Serial Number
	Equipotential

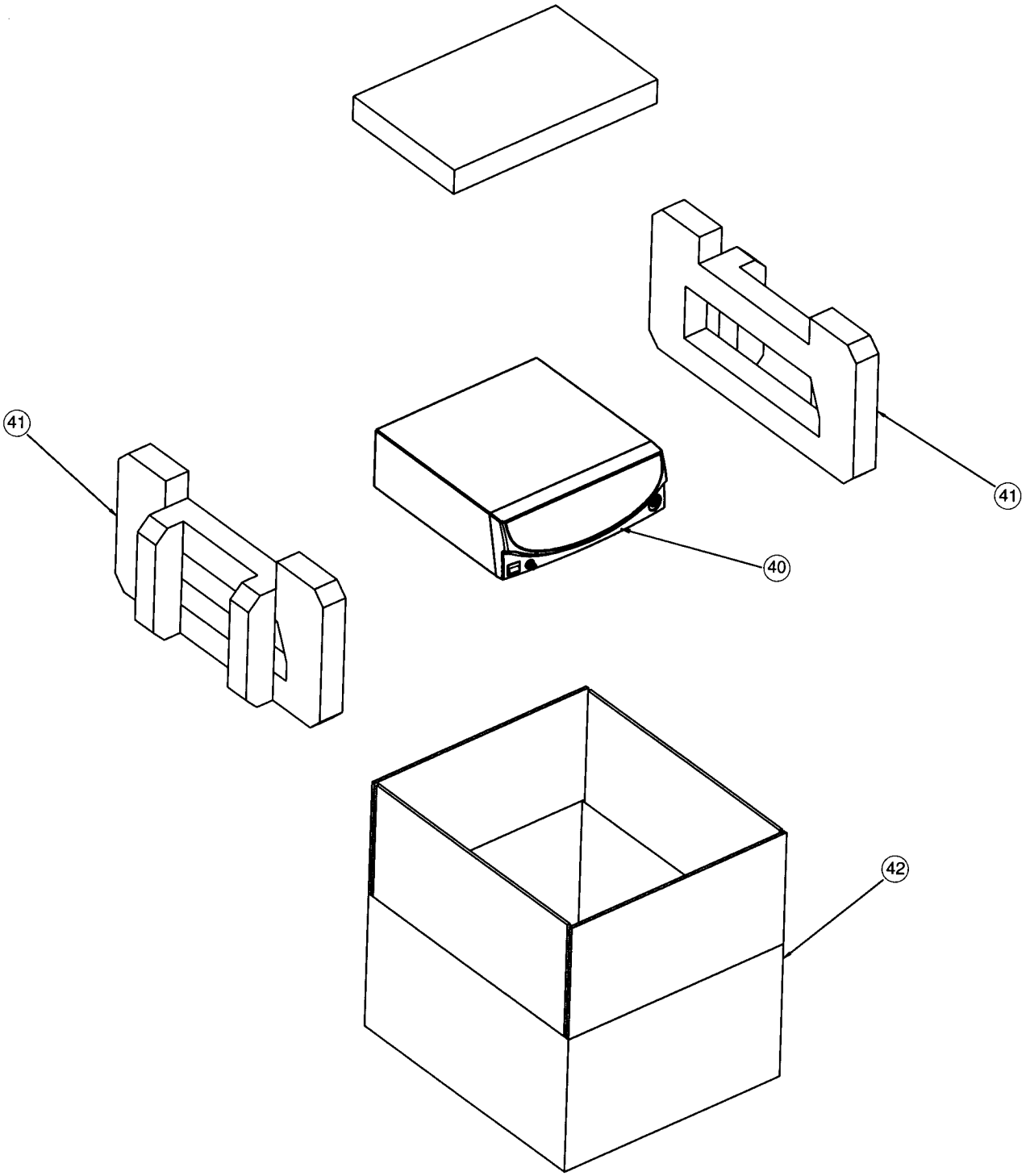
	Fuse
	Safe working load
	Test
	Hand Activation
	Volume
	Minimum
	Maximum
	Ready
	Standby
	Reorder Number
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	ON/OFF Time for Intermittent Operation. Refer to the individual package insert and/or Chapter 1 – Warnings and Precautions for additional specifications.
	Foot switch

Mains Power Wiring Diagram for Harmonic Scalpel Generator 300



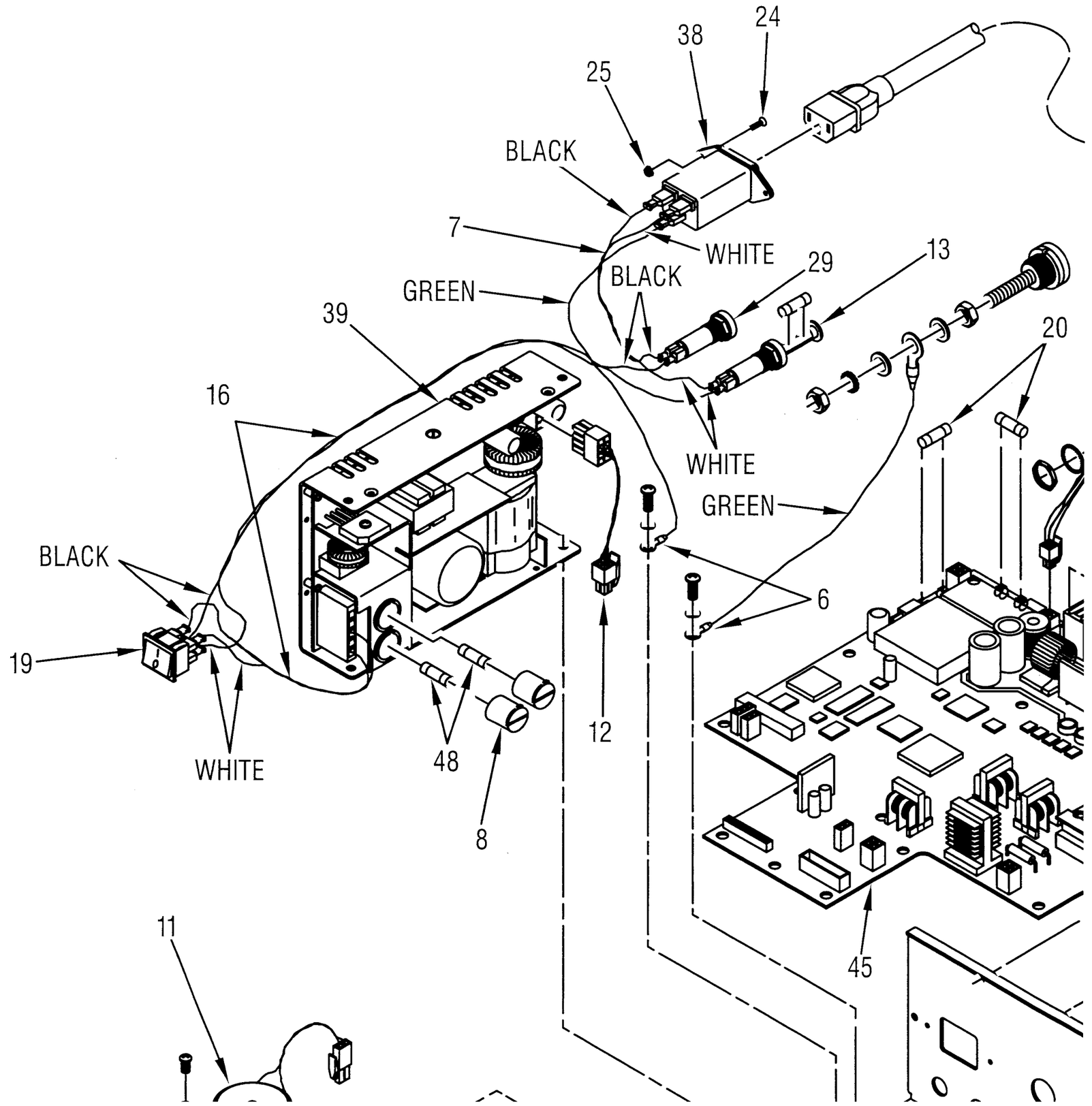
(1) - Universal AC Mains Input
(2) - Power Entry Module
(3) - Protective Earth Copnnection to Chassis
(4) - Mains Fuses, 3.15A, 250V, IEC Type 'T'
(5) - DPDT Mains Switch

(6) - 48VDC Medical Grade Power Supply
(7) - Generator PCB
(8) - Isolated Transducer Drive / Patient Connection
(9) - Isolation Barriers
(10)- Functional Earth Connections to Chassis

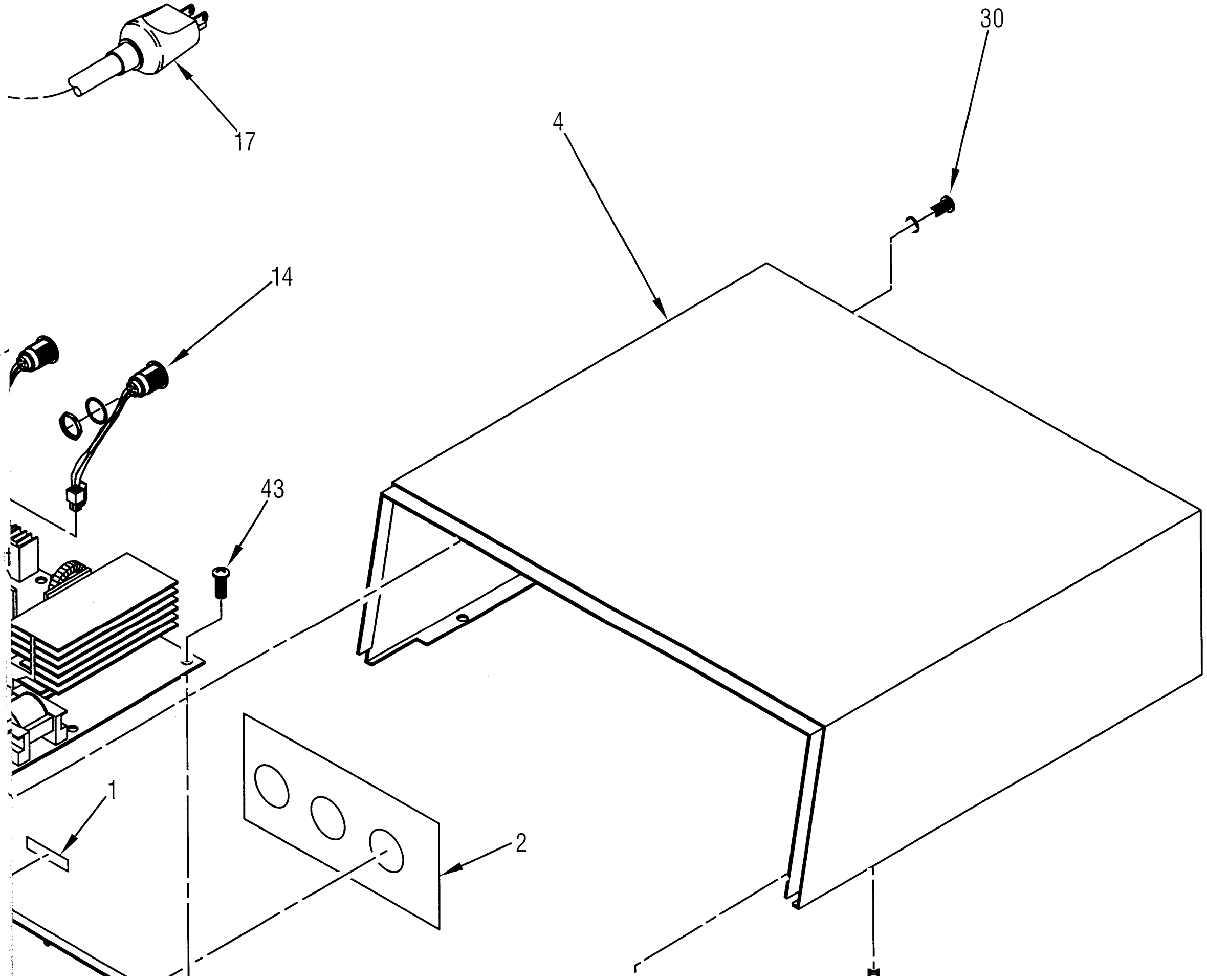

41
41
40
42

(REF)
GEN04

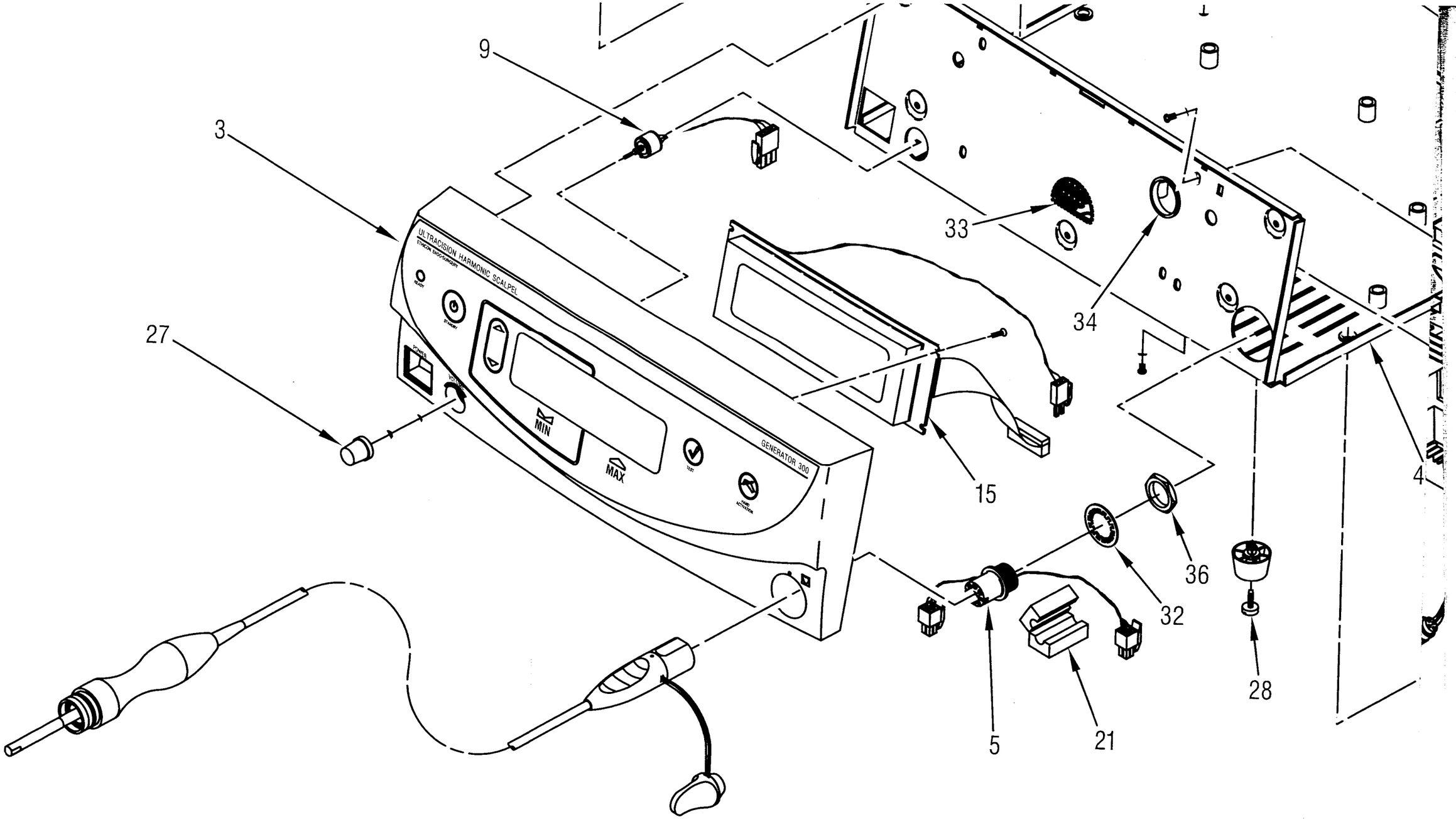
1


24
38
25
BLACK
7
WHITE
BLACK
29
13
GREEN
39
20
16
WHITE
GREEN
BLACK
6
19
12
WHITE
48
8
45
11

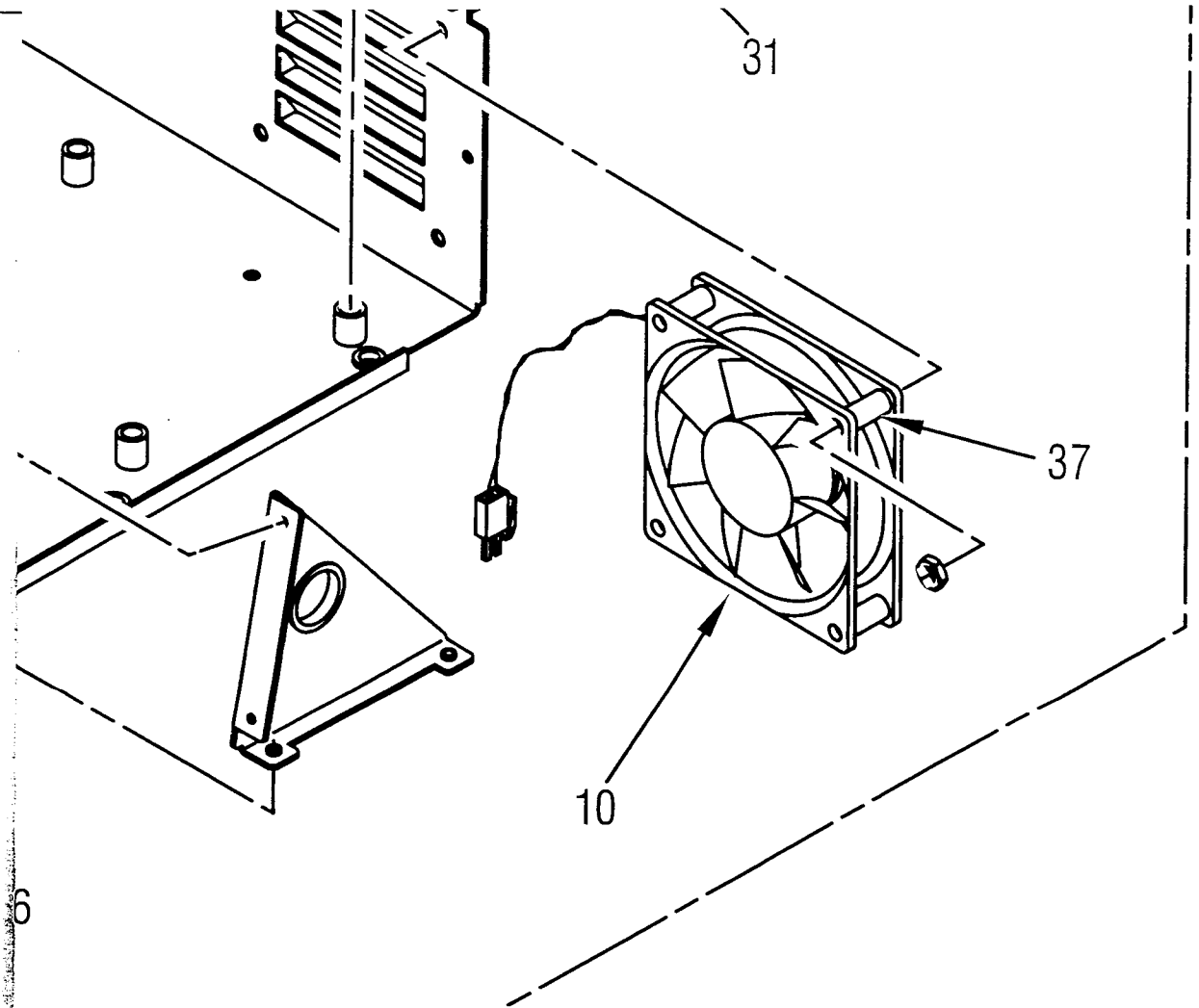
(2)

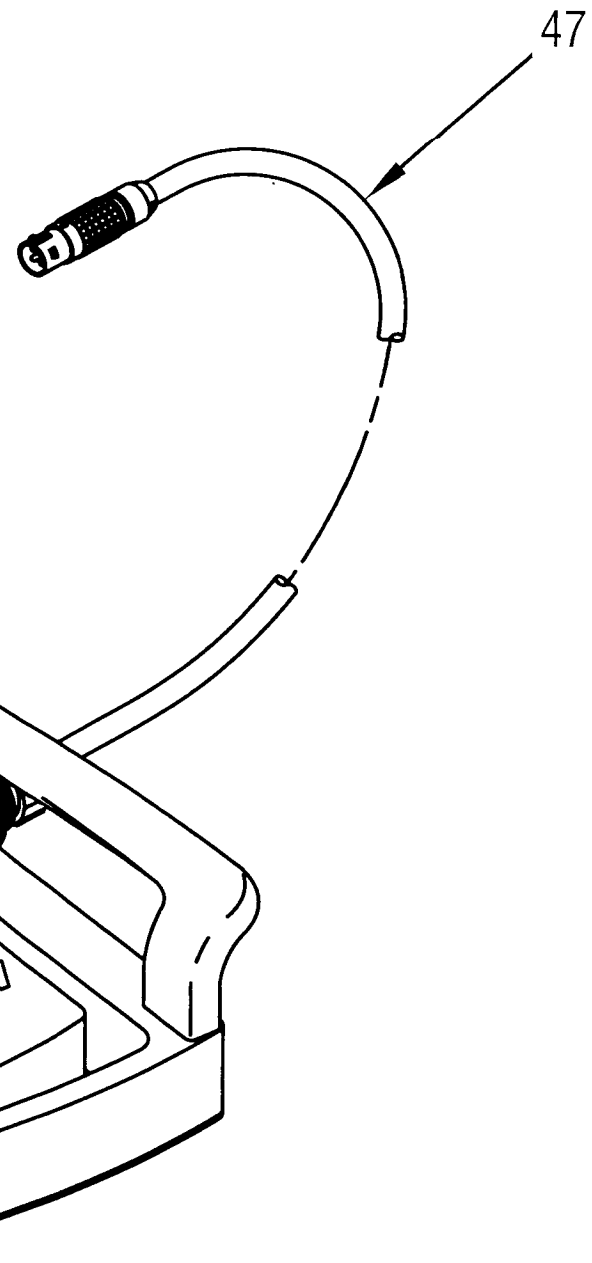


(3)


9
3
27
33
34
4
15
36
32
28
5
21
ULTRACISION HARMONIC SCALPEL
GENERATOR 300
MIN
MAX

(4)


31
37
10

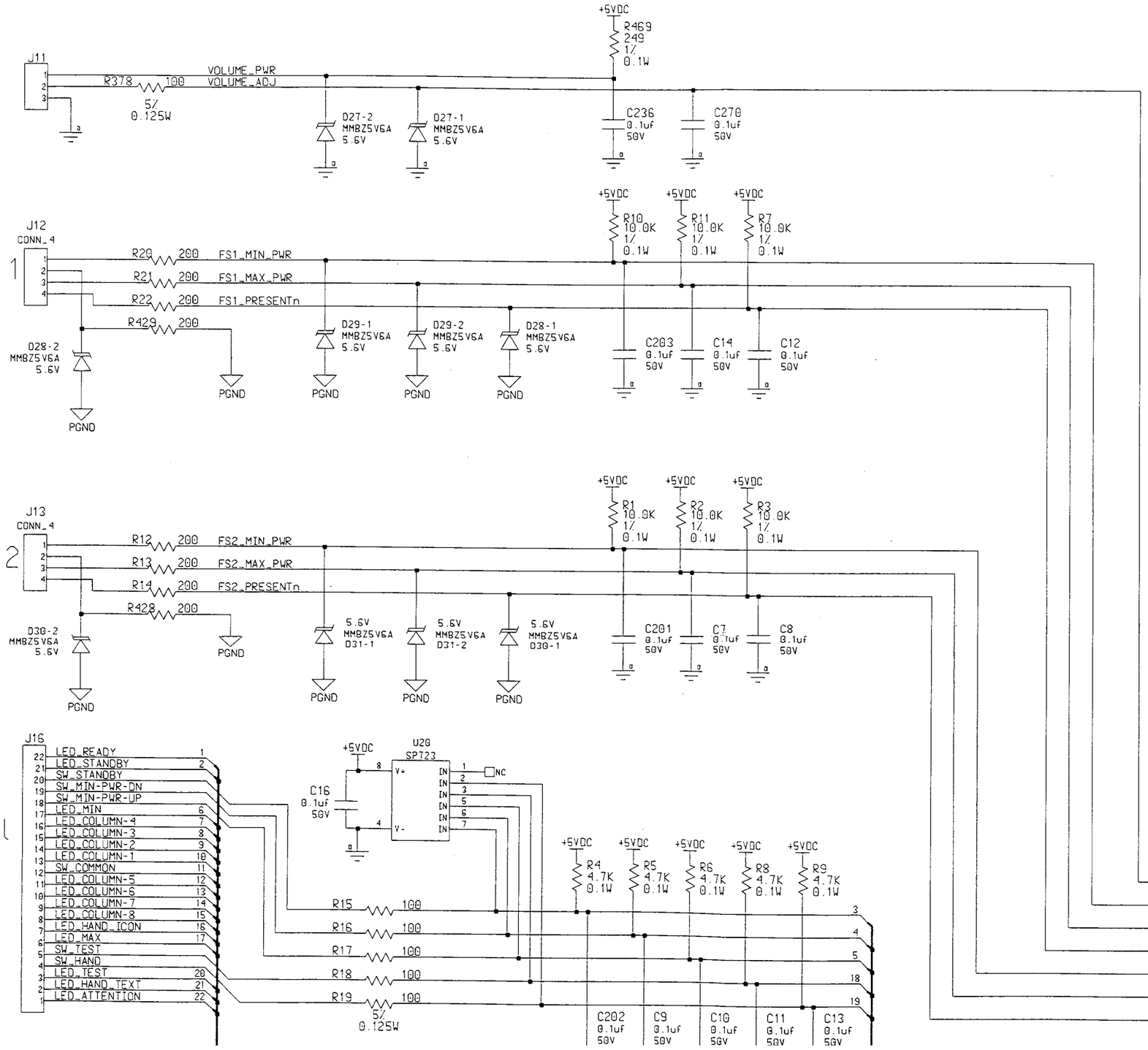

47
MIN
MAX
ULTRACISION
HARMONIC SCALPEL
ETHICON ENDO-SURGERY

olume

switch 1

switch 2

nt Panel



(2)

Digital Diagnostic

C279
0.1uf
50V

J32
CONN_16
+5VDC

1	FS1_MIN_PWR	1
2	FS1_MAX_PWR	2
3	FS1_PRESENTn	3
4	DSP_IOPB4	4
5	DSP_IOPB5	5
6	DSP_IOPB6	6
7	DSP_IOPB7	7
8	PHASE_ERROR	8
9	HIGH_CURRENT_ERRORn	9
10	+VCT-divided	10
11	HSW_MAX_SIG	11
12	HSW_MIN_SIG	12
	NC	13
	NC	14
		15
		16

J5 — LCD Module

1	LCD_FRAME_GND	1
2	LCD_VSS	2
3	LCD_VDD	3
4	LCD_VO	4
5	LCD_Wn	5
6	LCD_Rn	6
7	LCD_CEn	7
8	LCD_C_Dn	8
9	LCD_RV	9
10	LCD_RESETn	10
11	LCD_DB0	11
12	LCD_DB1	12
13	LCD_DB2	13
14	LCD_DB3	14
15	LCD_DB4	15
16	LCD_DB5	16
17	LCD_DB6	17
18	LCD_DB7	18
19	LCD_FONT_SELECT	19
20	LCD_VEE	20

J8 — Backlight

21	LCD_LED_A	1
22	LCD_LED_K	2

J7 — Speaker

	SPKR_POS	1
	SPKR_NEG	2

+5VDC
R430
47.5K
1%
0.1W

R467
100
1%
0.1W

R468
100
1%
0.1W

J4 — Hand Piece ID

	HP_ID_DATA	1
		2
	HP_PRESENTn	3
	NC	4

D26-2 MMBZ5V6A 5.6V
D26-1 MMBZ5V6A 5.6V
D25-2 MMBZ5V6A 5.6V
D25-1 MMBZ5V6A 5.6V

C278
0.1uf
50V

+5ANLG

J31
CONN_10
Analog Diagnostic

34	PWR_CLAMPED	1
39	IAVG_CLAMPED	2
37	HIGH_HS_TEMP	3
12	FET_SOAn	4
14	ZEROCROSS_I	5
7	PWR_BADn	6
15	ZEROCROSS_V	7
6	VAVG_CLAMPED	8
36		9
		10

BUCK REGULATOR

+48_PWR	+15_DIG	
	+15_DIG	
	+48_PWR	
	AGND	
	PGND	
	+VCT-divided	
27	BUCK_ENABLE	
	VMINIMA	+VCT

R466
10.0K
1%
0.1W

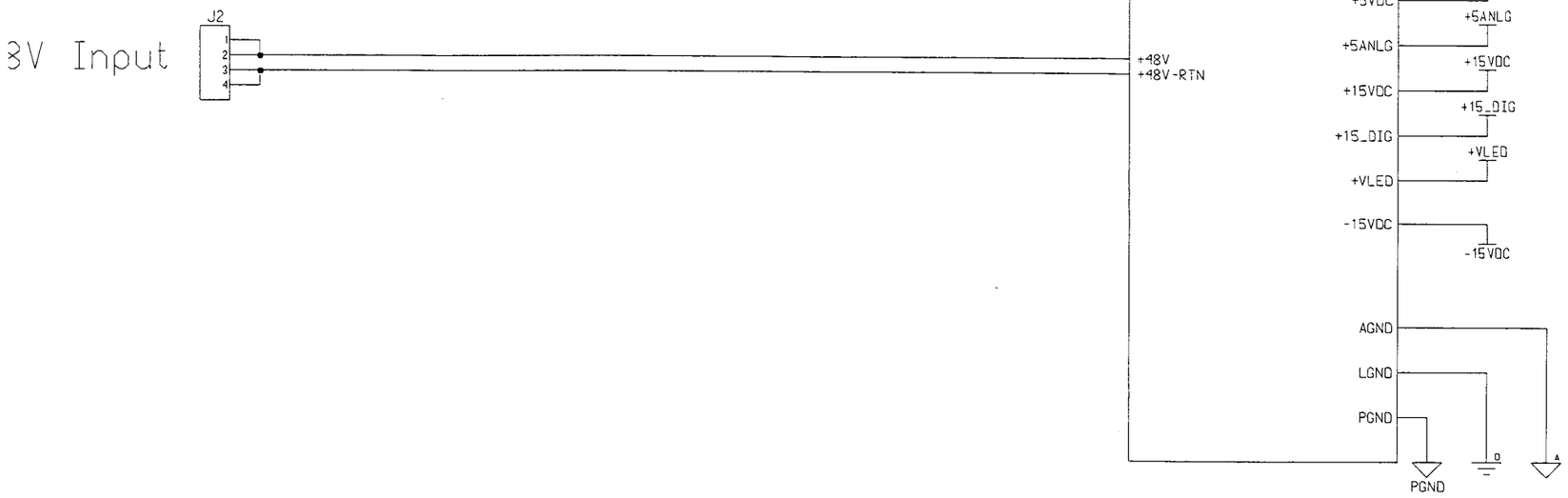
POWER AMPLIFIER

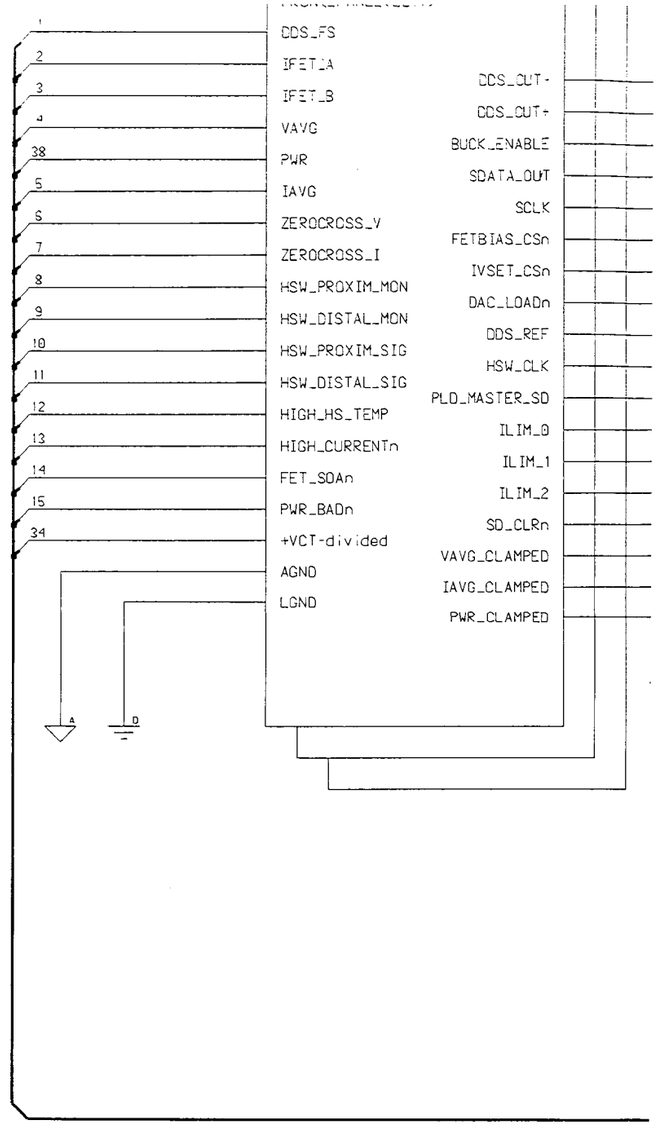
+5ANLG	+VCT	VMINIMA
-15VDC	+15VDC	
+15VDC	-15VDC	
	+5ANLG	

HP1
HP_COM

J3 — Hand Piece

3


J2
1
2
3
4
8V Input
POWER SUPPLY
+48V
+48V-RTN
+48_CTRL
+48_PWR
+5VDC
+5ANLG
+15VDC
+15_DIG
+VLED
-15VDC
AGND
LGND
PGND
+48_CTRL
+48_PWR
+5VDC
+5ANLG
+15VDC
+15_DIG
+VLED
-15VDC
PGND
D
A


1
2
3
4
38
5
6
7
8
9
10
11
12
13
14
15
34
DDS_FS
IFET_A
IFET_B
VAVG
PWR
IAVG
ZEROCROSS_V
ZEROCROSS_I
HSW_PROXIM_MON
HSW_DISTAL_MON
HSW_PROXIM_SIG
HSW_DISTAL_SIG
HIGH_HS_TEMP
HIGH_CURRENTn
FET_SOAn
PWR_BADn
+VCT-divided
AGND
LGND
DDS_OUT-
DDS_OUT+
BUCK_ENABLE
SDATA_OUT
SCLK
FETBIAS_CSn
IVSET_CSn
DAC_LOADn
DDS_REF
HSW_CLK
PLD_MASTER_SD
ILIM_0
ILIM_1
ILIM_2
SD_CLRn
VAVG_CLAMPED
IAVG_CLAMPED
PWR_CLAMPED
A
D

4

Transducer

C195
1000pf
250VAC

HANDSWITCH CIRCUIT

HSW_SIG
HP_COM
HSW_CLK
+5VDC
+15_DIG
HSW_PROXIM_MON
HSW_DISTAL_MON
HSW_PROXIM_SIG
HSW_DISTAL_SIG
LGND

SHUTDOWNn
DDS_OUT-
DDS_OUT+
SDATA
SCLK
FET8IAS_CSn
IVSET_CSn
DAC_LOADn
DDS_REF
AGND
VAVG
PWR
IAVG
IOUT
IFET_A
IFET_B
DDS_FS
ZEROCROSS_V
ZEROCROSS_I
VFET_A
VFET_B

FAULT SENSE

+5VDC +5ANLG -15VDC +15VDC +48_CTRL +48_PWR
+48_PWR
+48_CTRL
+15VDC
-15VDC
+5ANLG
+5VDC
IFET_A
IFET_B
VFET_A
VFET_B
IOUT
ILIM_0
ILIM_1
ILIM_2
SD_CLRn
PLD_MASTER_SD
AGND
SHUTDOWNn
HIGH_HS_TEMP
HIGH_CURRENTn
FET_SOAn
PWR_BADn

+48_PWR
C148
0.1uF
100V
J6
PGND

48V Fan Power

P40418P01