

# Generator G11 (GEN11) Service Manual v 2.0



Group: Package Labeling Drawing  
Type: Manual Service

State: Released  
NSR/SR:



Ethicon  
Endo-Surgery

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## Overview

Please read all information carefully.

Go to [www.e-ifu.com](http://www.e-ifu.com) for the latest version of this manual.

Failure to properly follow the instructions may lead to serious surgical consequences.

**Important:** This manual is designed to provide service and repair instructions for the Generator G11. It is not a reference to surgical techniques.

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## Scope

This Service Manual contains operational and diagnostic information, repair and replacement procedures and functional test information, which has been designed to assist the Service Representative in the isolation and repair of faults as well as maintenance of the Ethicon Endo-Surgery Generator G11. This documentation assumes that the service representative is familiar with the electrical and mechanical standards applicable to medical devices. This documentation also assumes that the service representative is familiar with the use of any special tools that are required to service the Generator G11.

## Standard Conventions Used

### The Use of Caution, Warning, and Note Statements

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a Caution, a Warning, or a Note statement. These statements are found throughout the documentation.

These statements should be read before continuing to the next step in a procedure.

**Warning:** A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

**Caution:** A Caution statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in damage to or destruction of the equipment.

**Note:** A Note statement indicates an operating or maintenance problem, practice, or condition that is necessary to accomplish a task efficiently.

## Chapter 1 - General Information

### Indications

The Generator G11 provides radiofrequency power to drive ENSEAL electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive HARMONIC ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

ENSEAL and HARMONIC instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

### Contraindications

- The use of the Generator G11 and the attached instruments are contraindicated, when in the judgment of the physician, radiofrequency or ultrasonic surgery would be contrary to the best interest of the patient.
- The instruments are not indicated for incising bone.

### Device Description

The Generator G11 supplies energy to the HARMONIC and ENSEAL surgical instruments. The generator uses a touchscreen display interface and has a unique receptacle port that accepts either a HARMONIC or an ENSEAL device. Connectors (HGA11 for HARMONIC and EGA11 for ENSEAL) are used to enable the generator to power legacy devices.

## Generator G11 Service Manual

### How Supplied

The Generator G11 is supplied in a semi-ready-to-use state. The shipping box contains the Generator G11, power cord and operator's manual. The disposable Ethicon Endo-Surgery ENSEAL or HARMONIC instruments are not included in this packaging and must be purchased separately. The HARMONIC device connector (HGA11), ENSEAL device connector (EGA11), footswitch (FSW11), cart (CRT11) and verification key (GEN11VK) are also available separately.

### Illustration and Nomenclature

#### Front Panel of the Generator

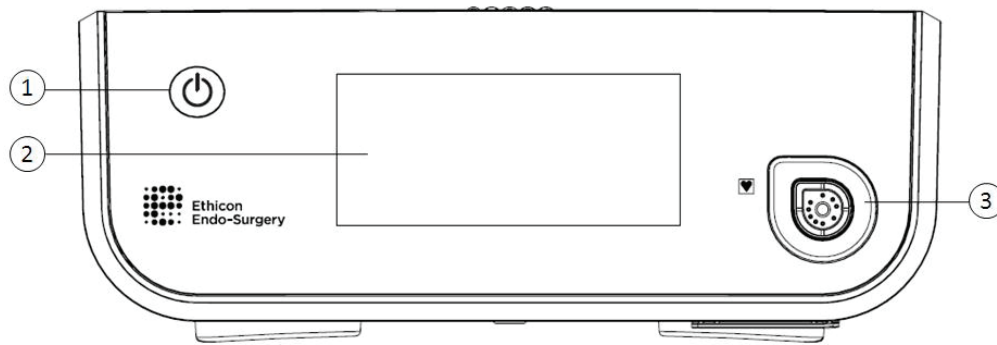


Figure 1

- |   |                                    |  |
|---|------------------------------------|--|
| 1 | POWER ON/OFF SWITCH                | Glows green when the generator is powered up.  |
| 2 | DISPLAY/<br>TOUCH SCREEN           | Displays system information and serves as interface for adjusting controls and settings. |
| 3 | CONNECTOR/<br>DEVICE<br>RECEPTACLE | Receptacle used to attach the connectors or devices to the generator.                    |

#### Back Panel of the Generator

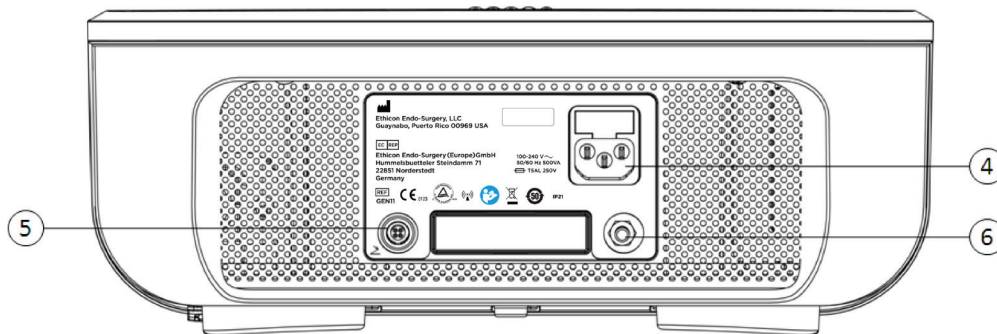


Figure 2

- |   |                          |  |
|---|--------------------------|--|
| 4 | POWER CORD<br>RECEPTACLE | Receptacle used to attach the power cord to the generator. |
|---|--------------------------|--|

- |   |                                       |  |
|---|---------------------------------------|--|
| 5 | FOOTSWITCH<br>RECEPTACLE              | Receptacle used to connect the footswitch to the generator.          |
| 6 | POTENTIAL<br>EQUALIZATION<br>TERMINAL | Provides means for connection to a potential equalization conductor. |

### Footswitch

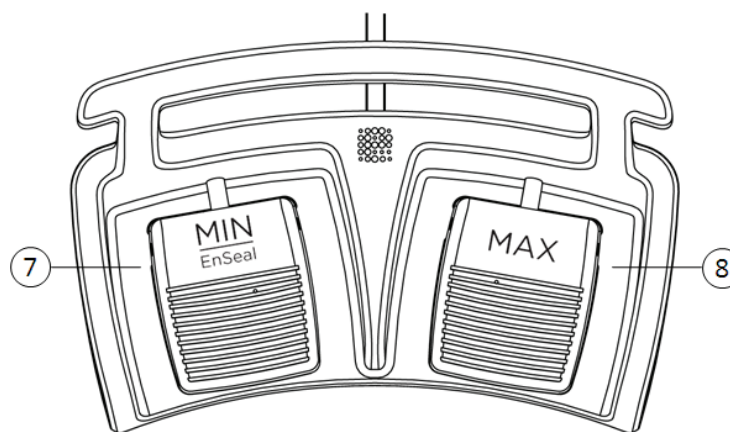


Figure 3

- |   |                   |   |
|---|-------------------|---|
| 7 | MIN (LEFT PEDAL)  | Activates power for ENSEAL or minimum power for HARMONIC. |
| 8 | MAX (RIGHT PEDAL) | Activates maximum power for HARMONIC.                     |

### General Warnings

- Read instructions prior to energy activation, and use proper electrical safety and hospital procedures when working on the generator unit. Servicing should be performed by qualified personnel only.
- Always disconnect the device from the electrical power source before servicing.
- After removing the cover, inspect the internal components for obvious damage or foreign debris. Never remove or install any parts with the power on.
- Verify that the unit is fully operational prior to administering power output.
- High voltages may be present on surfaces inside the generator. Never touch an exposed conductive surface while the cover is removed and the unit is energized.
- This equipment is for use only by qualified medical personnel trained in the use of ultrasonic surgery or electrosurgery. Inappropriate use of the equipment by untrained medical personnel may result in hazardous electrical output.
- The Generator G11 contains components that are sensitive to electrostatic discharge (ESD). Proper ESD precautions must be taken while servicing the Generator G11. Repair work must be done at a static controlled workstation. Use an antistatic container for the transport of ESD sensitive circuit boards and components.
- Do not activate in the presence of oxidizing gases such as nitrous oxide (N<sub>2</sub>O) and oxygen as explosion may occur.
- Non-flammable agents should be used for cleaning and disinfection wherever possible.
- Do not energize the Generator G11 in a moist environment as a shock hazard may exist. If liquids have entered the Generator G11 the unit must be returned to the manufacturer for testing prior to use.
- Do not activate the unit in close proximity to volatile solvents such as methanol or alcohol as explosion may occur.
- Avoid activation of Generator G11 adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the Generator G11 and the other equipment to assure normal operation.

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- Interference produced by the operation of high-frequency surgical equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems.
- Activation with accessories and cables other than those specified may result in unpredictable performance, increased electromagnetic emissions, or decreased electromagnetic immunity. No customer modification of this equipment is allowed; modification of this equipment could have a negative impact on electrical safety and electromagnetic emissions.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- To isolate the Generator G11 from supply mains power, disconnect the power cord either from the back panel of the generator or from the wall. Ensure access to these points are kept clear.

### General Cautions

- The touch screen display of the generator is very sensitive. Do not use sharp metal objects on the touch screen.
- During servicing, when the bottom screws are removed and the device is open exercise proper caution as a hazardous condition may exist.
- Replace fuses only with the appropriate type and rating. See *System Specifications*.
- Do not sterilize the Generator G11. Sterilization will damage the unit.
- Do not restrict the openings on the bottom and the back panel of the Generator G11, as they provide the required airflow for cooling.
- If electromagnetic interference with other equipment is suspected, reorient the device or remove possible sources of interference (for example, cellular phones, radios, etc.) from the room.
- Activation of a radiofrequency device when not in a position to test energy activation may cause capacitive coupling.
- Use of the Cart (CRT11) is recommended if Generator G11 is moved out of the operating room. Maintain control of the generator and cart when moving over thresholds.
- Do not replace both the main PCB and Bezel PCB simultaneously. Doing this will compromise internal electronic information stored within the generator. Replace one board and power-up the unit prior to removal of the other board.

### Maintenance and Repair

Periodic calibration is not required for Generator G11. Periodic check of output using GEN11VK is recommended per facility guidelines. Service of the Generator G11 would be required if GEN11VK shows the generator is out of tolerance. See GEN11VK instructions for use for guidance on performing the output check. For servicing activities, Generator G11 may also be returned to an authorized EES service facility at any time.

### Customer Service

#### Warranty

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 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 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 (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:

|                          |                               |
|--------------------------|-------------------------------|
| Generator and power cord | One (1) year, parts and labor |
| Footswitch               | One (1) year, parts and labor |
| Cart                     | 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 AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY 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 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 products. There are no warranties that extend beyond the terms hereof. Ethicon Endo-Surgery 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.

### Customer Service

Contact the Ethicon Endo-Surgery Customer Service Department or your local representative for any customer or technical support. Call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only.

## Chapter 2 - Theory of Operation

### Generator G11 Functionality Overview

The HARMONIC and ENSEAL instruments that connect to the generator are surgical devices that combine high compression and low heat to quickly create strong vessel seals while generating minimal smoke, tissue char, or thermal injury.

### Generator G11 Theory of Operation

The GEN11 generator is a flexible, high-power, wide band electrical surgical instrument power source. The main component of the system is a push-pull power amplifier that drives an output transformer. The output transformer is capable of stepping up the output voltage of the amplifier to a maximum of 420 Vrms @ 0.75 Arms for HARMONIC instruments, or, via an intermediate tap on the secondary coil, 100 Vrms @ 3.0 Arms for RF instruments. Different instruments will utilize different ranges of the generator's output. Therefore, depending on the particular instrument used, the maximum output of the generator may not be achieved during instrument activation. The output transformer also provides the necessary isolation from earth ground (per IEC 60601-1) of the outputs that can potentially come in contact with patients. There are DC-blocking capacitors in series with the RF output, as required by medical regulation IEC 60601-2-2.

The input to the amplifier is fed by a high-speed digital-to-analog converter (DAC) that is in turn controlled by a digital signal processor (DSP) through a field-programmable gate array (FPGA). The DSP digitally controls the wave shape, amplitude, and frequency of the output signal in closed-loop fashion by monitoring the output voltage and current through two high speed analog-to-digital converters (ADC). The output voltage and current are fed to the ADC through isolation transformers that cross the patient-isolation barrier. The wave shape is generated by the DSP using direct digital synthesis within the FPGA. The amplitude is controlled on a fine scale directly through the high-speed DAC, and on a coarse scale through a lower-speed DAC which sets the full-scale range of the high-speed DAC.

Additionally, the DSP controls a switch-mode converter which provides power to the amplifier, in order to optimize the efficiency of the system. It does this by dynamically adjusting the DC output of the converter to provide just enough overhead voltage for the amplifier to produce its currently commanded output level. The DSP also sets and periodically adjusts the bias levels of the four output FET (field effect transistors) via dedicated low-speed DAC and ADC hardware. Other functions on the patient isolation side such as monitoring handswitch states, reading and writing to EEPROM (electrically erasable programmable read-only memories) contained in handpieces, instruments, and security keys, and monitoring the health of the RF DC-blocking capacitors are performed by a second FPGA on the isolated side, under control of the DSP via a bidirectional optical communication link which conforms to the IrDA (Infrared Data Association) standard.

A user interface (UI) processor controls all other user interactions with the generator including the LCD (liquid crystal display) output, capacitive touch-screen input, and audio output. The only exception to this is the capacitive touch on/off button, which is controlled by the on/off processor located on the Bezel board, and powered by separate 5 VDC standby power that is present whenever the generator is plugged in. The on/off processor controls power to the rest of the system via a power supply enable signal to the main 48 VDC power supply. A serial port and two USB (universal serial bus) ports are also provided for data transfer. These ports are not user accessible.

The block diagram illustrates the system architecture, showing the flow of data and power between various components. The main components include:

- AC LINE**: Input power source.
- POWER SUPPLY**: Converts AC line power to system voltages.
- SYSTEM VOLTAGES**: Output of the power supply.
- POWER SUPPLY ENABLE**: Control signal for the power supply.
- SWITCH-MODE CONVERTER**: Converts system voltages to a BIAS signal.
- BIAS**: Signal used by the AMP.
- AMP**: Amplifier that outputs to the patient isolated circuits.
- PATIENT ISOLATED CIRCUITS**: A dashed box containing:
  - ADC**: Analog-to-Digital Converter.
  - SIGNAL COND. CKT.**: Signal Conditioning Circuit.
  - FPGA**: Field-Programmable Gate Array.
  - DCI**: Data Circuit Interface.
  - DATA CKT. INTERFACE**: Data Circuit Interface.
  - Outputs**: H1, E1, PR, SR, P, HS, ID.
- DSP PROCESSOR**: Digital Signal Processor that interfaces with:
  - MEMORY**: Main system memory.
  - SERIAL I/O PORT**: Serial communication port.
  - ADC**: Analog-to-Digital Converter.
  - DAC**: Digital-to-Analog Converter.
  - FPGA**: Field-Programmable Gate Array.
  - HS DAC**: High-Speed Digital-to-Analog Converter.
  - HS ADC**: High-Speed Analog-to-Digital Converter.
- UI PROCESSOR**: User Interface Processor that interfaces with:
  - MEMORY**: User interface memory.
  - USB PORTS (2)**: Two USB ports.
  - LCD**: Liquid Crystal Display.
  - AUDIO AMP**: Audio Amplifier.
  - ON / OFF PROCESSOR**: On/Off control processor.
  - TOUCH SCREEN INTERFACE**: Interface for the touch screen.
  - TOUCH SCREEN**: User input device.
- BEZEL BOARD**: A dashed box containing the **ON / OFF PROCESSOR** and **TOUCH SCREEN INTERFACE**.
- ON / OFF PROCESSOR**: Controls the **POWER SUPPLY ENABLE** signal.
- ON/OFF BUTTON**: Physical button for on/off control.
- TOUCH SCREEN**: Physical touch screen.

**Legend:**

- \* HS - High Speed
- H1 - HARMONIC Power Output
- E1 - ENSEAL (RF) Power Output
- PR - Power Return
- P - Presence
- HS - Hand Switch
- ID - Identification / EEPROM
- DCI - Data Circuit Interface

### Figure 4 Main PCB I/O Diagram



## Chapter 3 - Repair and Replacement Procedures

### Bottom Cover and EPAC Removal Procedure

1. Turn the unit upside down.



Figure 5

2. Remove the four mounting screws as shown in the image.

**Note:** During disassembly and assembly, metal shavings may be generated when screwing and unscrewing screws. Be sure to clean up any metal shavings.

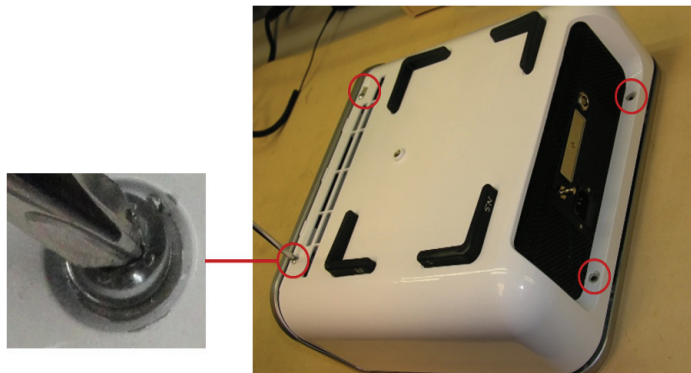


Figure 6

3. Remove the bottom enclosure by sliding it backwards.



Figure 7

## Generator G11 Service Manual

4. Separate the bottom EPAC.

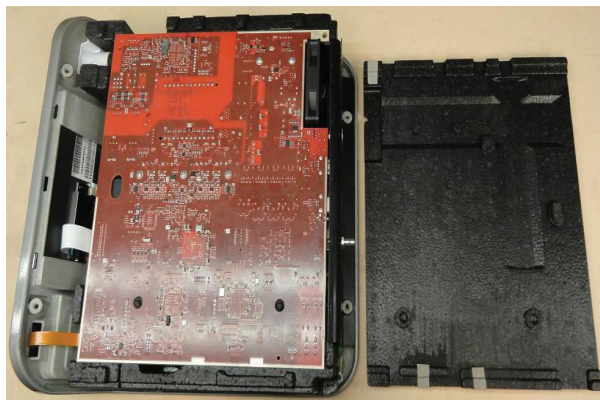


Figure 8

### Main PCB Disassembly Procedure

**Note:** The main PCB contains information that is electronically stored. Once a new PCB has been installed in the generator and powered up, it cannot be used in another generator. Please be sure you want to replace the PCB before installing the new one.

**Caution:** Do not replace both the main PCB and Bezel PCB simultaneously. Doing this will compromise internal electronic information stored within the generator. Replace one board and power-up the unit prior to removal of the other board.

1. Disconnect the J4 DC Connector and Power Grounding Cable as shown.

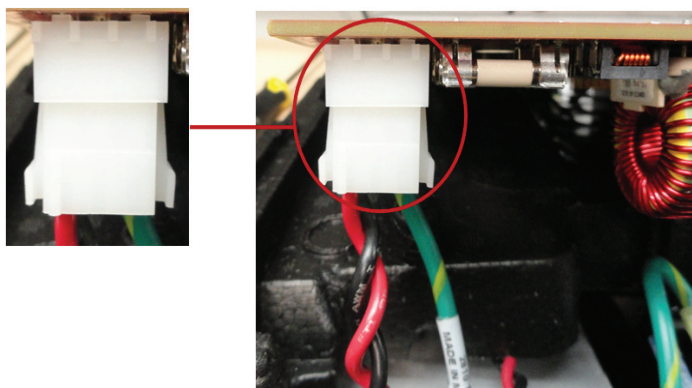


Figure 9

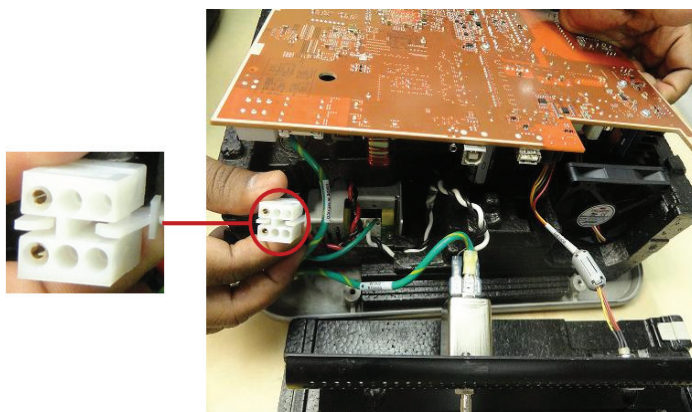


Figure 9a



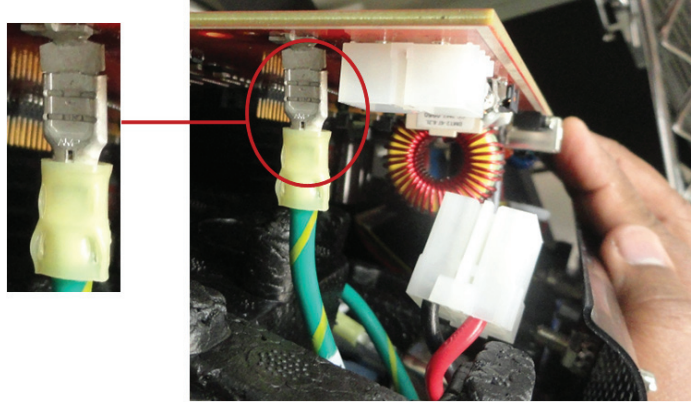


Figure 9b

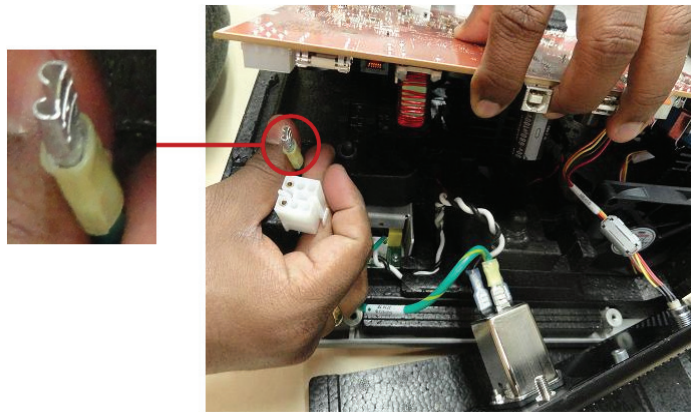


Figure 9c

2. Disconnect the following as shown in the images:
  - J5 Footswitch

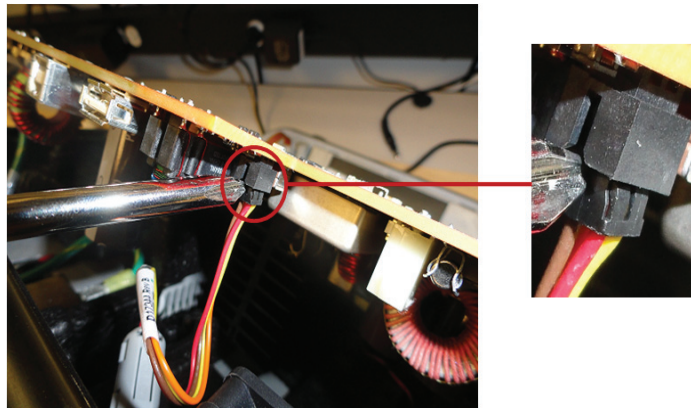


Figure 10

## Generator G11 Service Manual

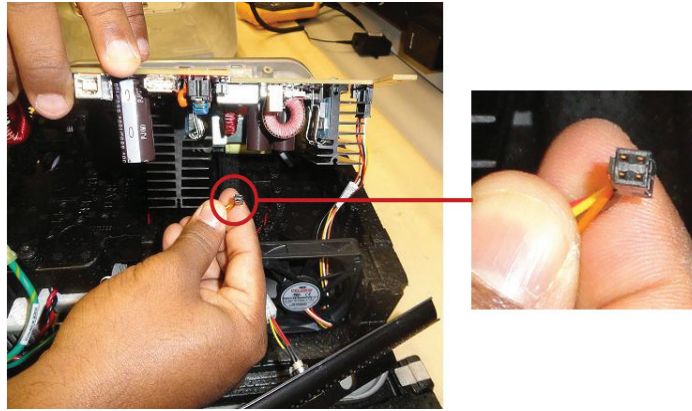


Figure 10a

- J8 Enclosure Fan

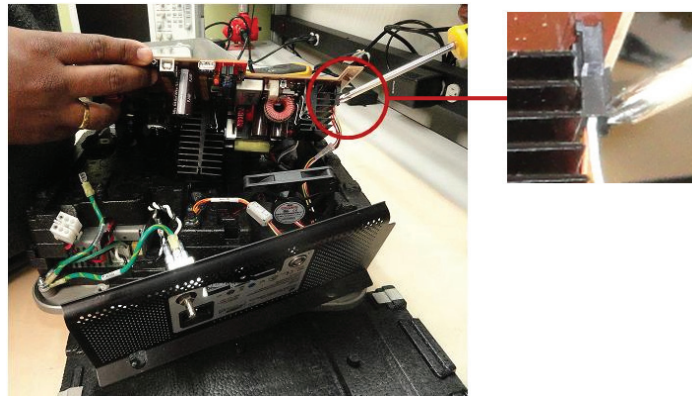


Figure 11

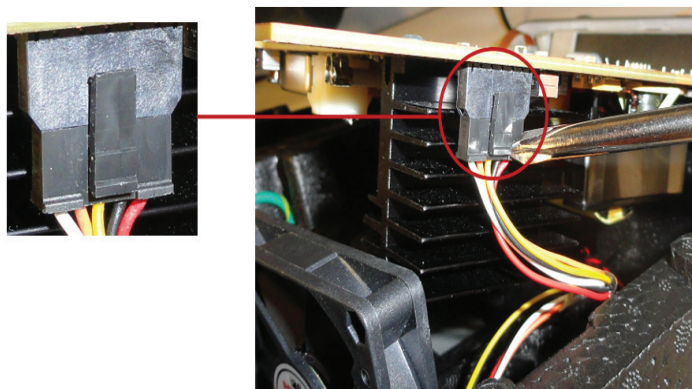


Figure 11a

3. Separate the PCB from the generator.

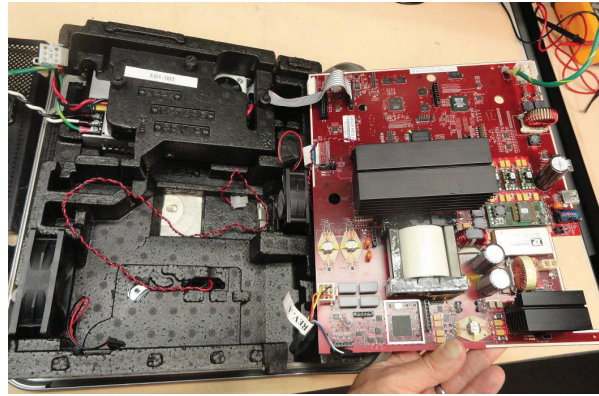


Figure 12

4. Remove the following electrical connections and route wires:
  - J21 Power Supply IO

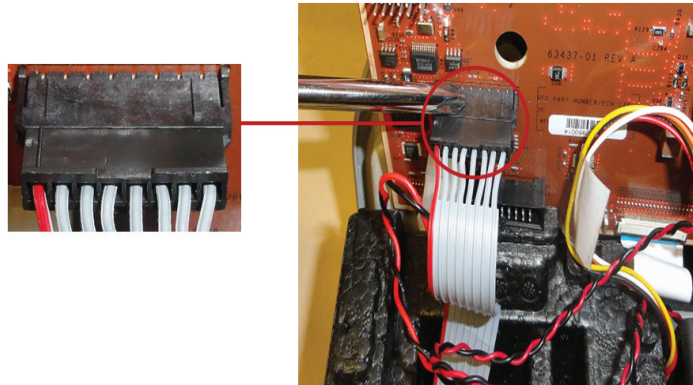


Figure 13

- J23 Speaker

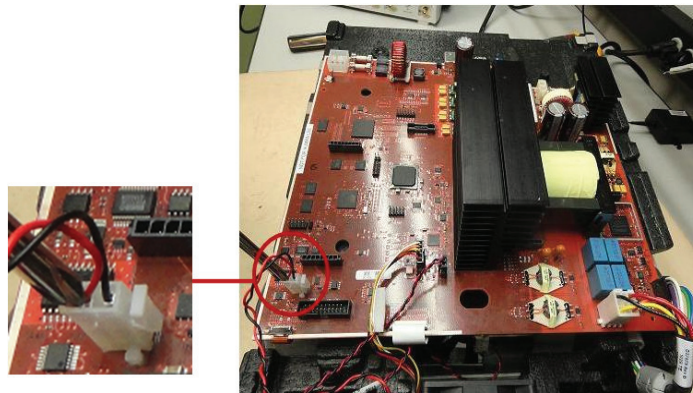


Figure 14



## Generator G11 Service Manual

- J27 Heat sink Fan

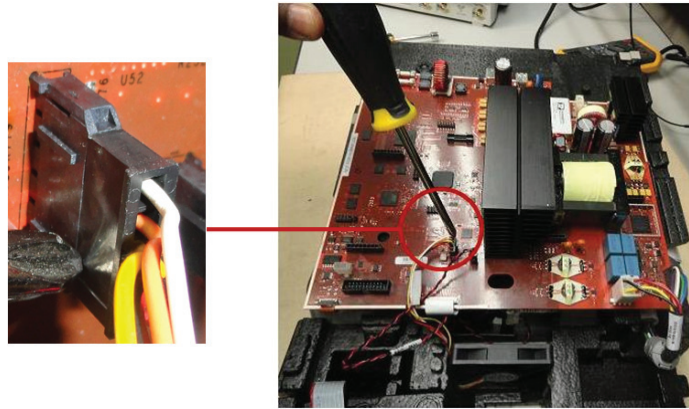


Figure 15

- J25 Backlight

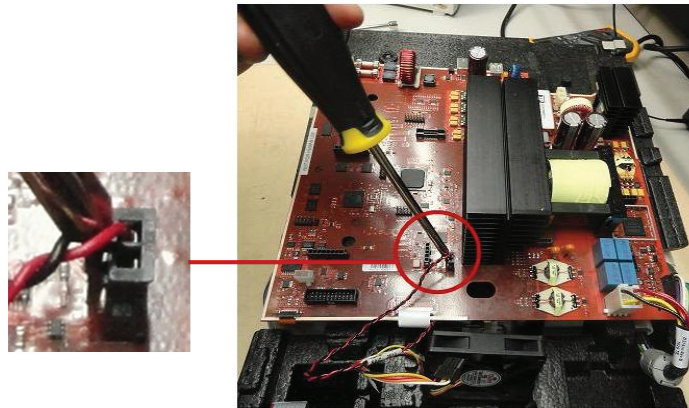


Figure 16

- J28 Receptacle 9 pin

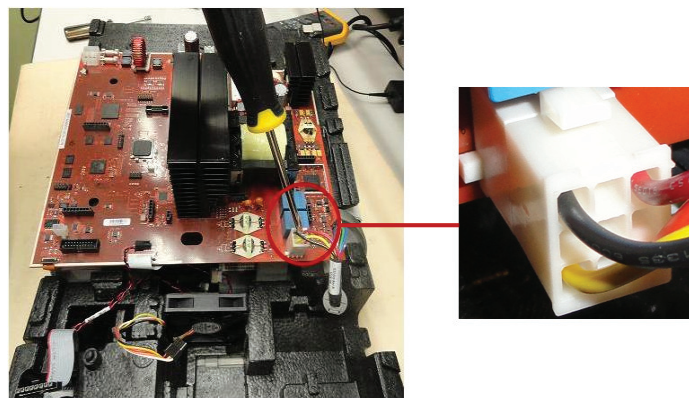


Figure 17

- J24 Receptacle 5 pin

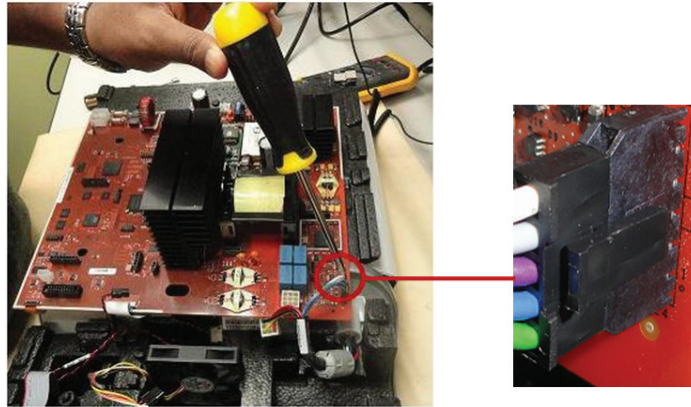


Figure 18

- J29 LCD Flat Connector

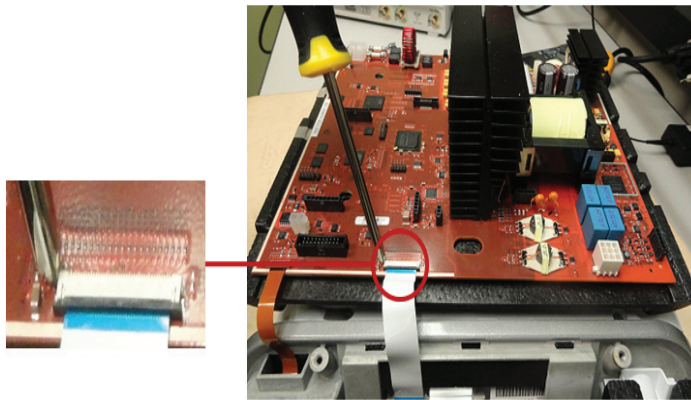


Figure 19

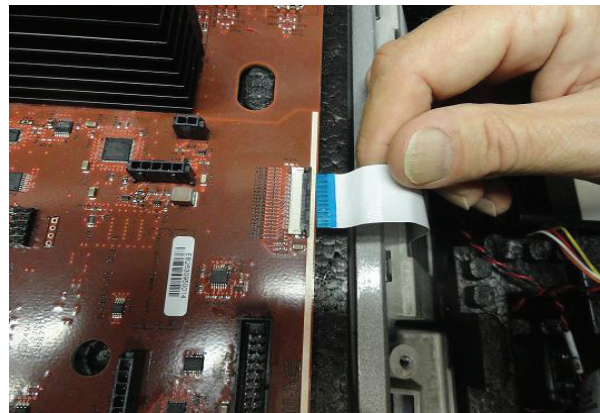


Figure 19a

## Generator G11 Service Manual

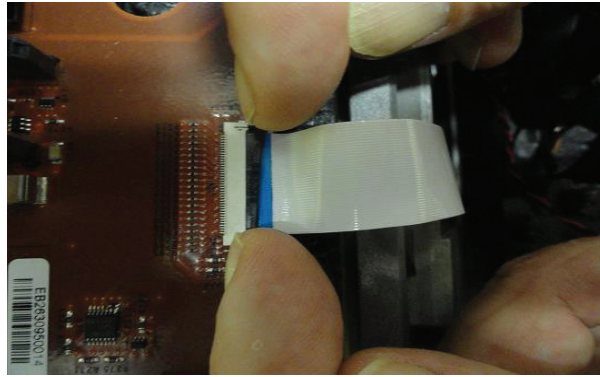


Figure 19b

- J30 Bezel Flat Connector

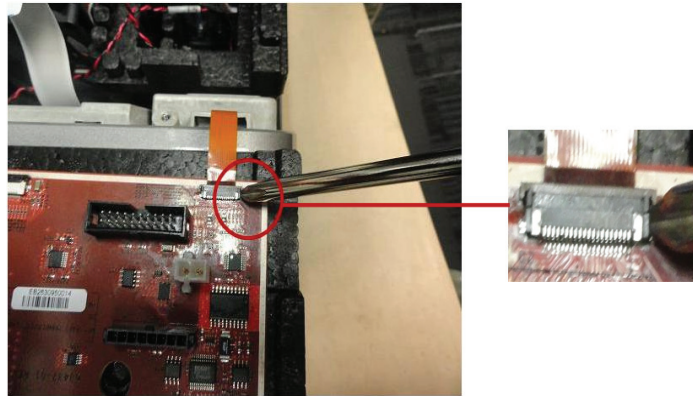


Figure 20

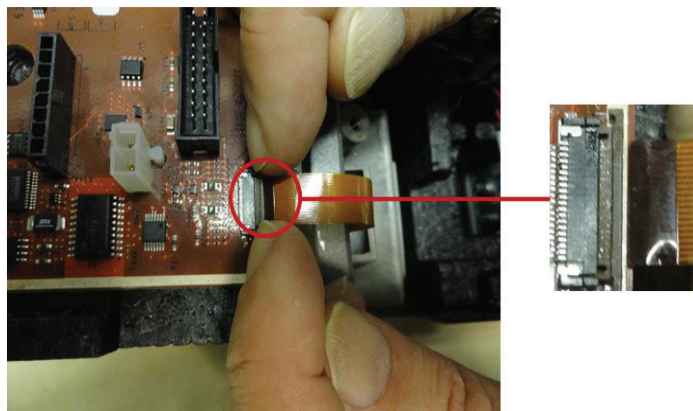


Figure 20a



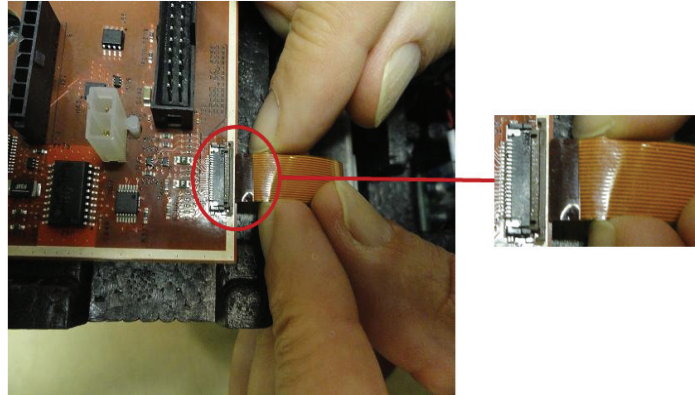


Figure 20b

### Power Module Disassembly Procedure

1. Remove the power module ground connector from the module terminal.

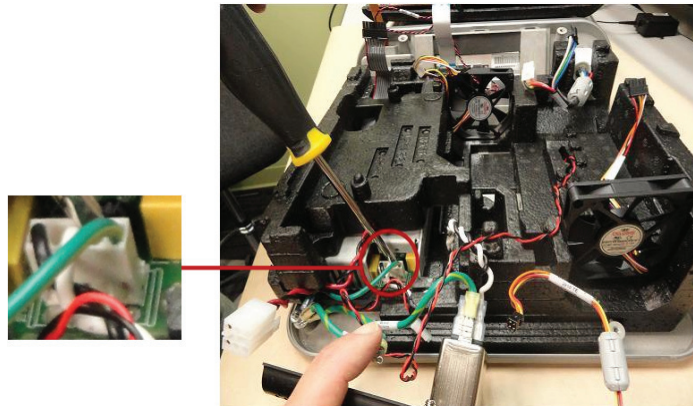


Figure 21

2. Take out the power module from the unit.

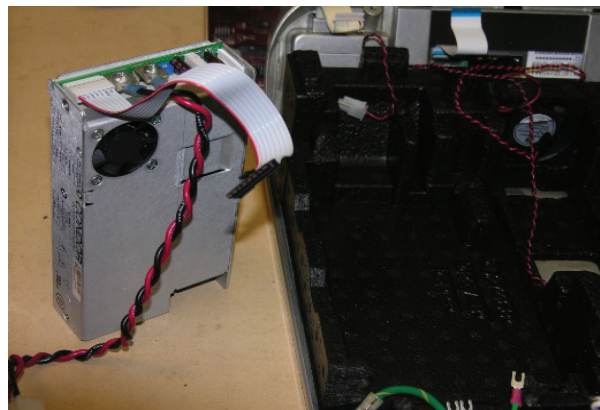


Figure 22

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### Speaker Removal Procedure

1. Remove the top EPAC from the top chassis.

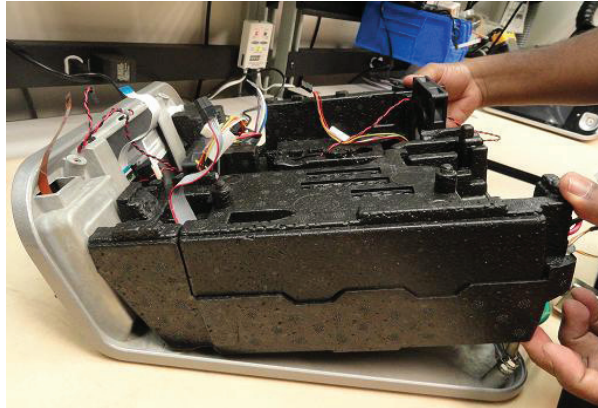


Figure 23

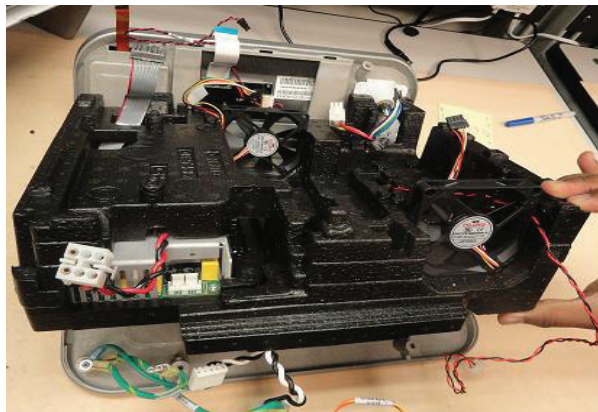


Figure 23a



Figure 23b



2. Pull out the speaker using flat head screw driver.

**Note:** The speaker is stuck to the top with tape. It is separated using a flat head screw driver.

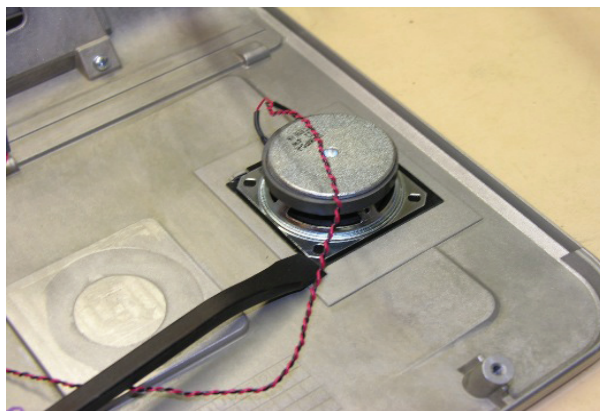


Figure 24

### Connector / Device Receptacle Removal Procedure

1. Remove the side screws of the Connector / Device Receptacle with a T15 Torx.

**Note:** During disassembly and assembly, metal shavings may be generated when screwing and unscrewing screws. Be sure to clean up any metal shavings.

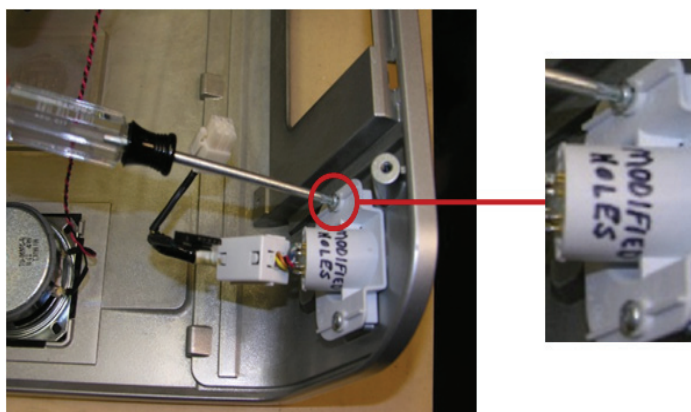


Figure 25

2. Separate the Connector / Device Receptacle from the top chassis.

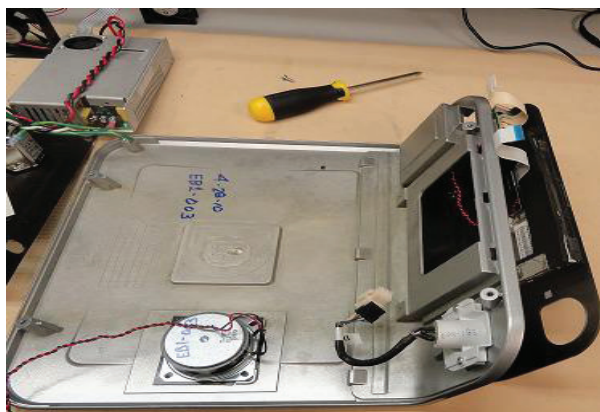


Figure 26

## Generator G11 Service Manual

### Front Panel Disassembly Procedure

1. Remove the two screws from the top chassis.

**Note:** During disassembly and assembly, metal shavings may be generated when screwing and unscrewing screws. Be sure to clean up any metal shavings.

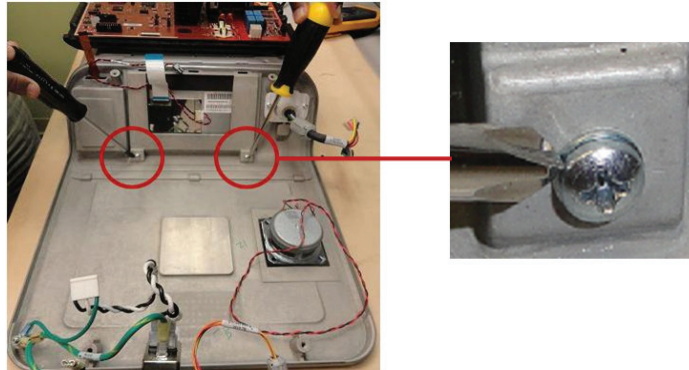


Figure 27

2. Separate the Bezel assembly from the top enclosure and LCD cables as shown below.



Figure 28

3. Remove gasket and LCD from the Bezel.

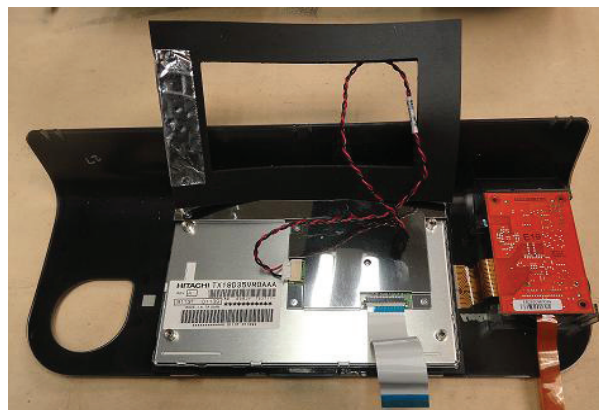


Figure 29

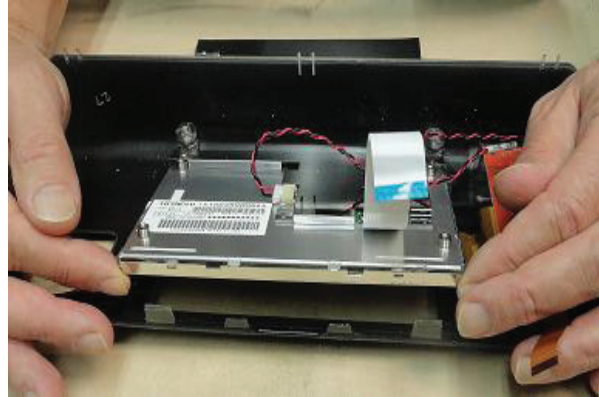


Figure 29a

4. Separate the LCD gasket from the Bezel.



Figure 30

5. Disconnect the Bezel PCB cables.

**Note:** The Bezel PCB contains information that is electronically stored. Once a new Bezel PCB has been installed in the generator and powered up, it cannot be used in another generator. Please be sure you want to replace the Bezel PCB before installing the new one.

**Caution:** Do not replace both the main PCB and Bezel PCB simultaneously. Doing this will compromise internal electronic information stored within the generator. Replace one board and power-up the unit prior to removal of the other board.

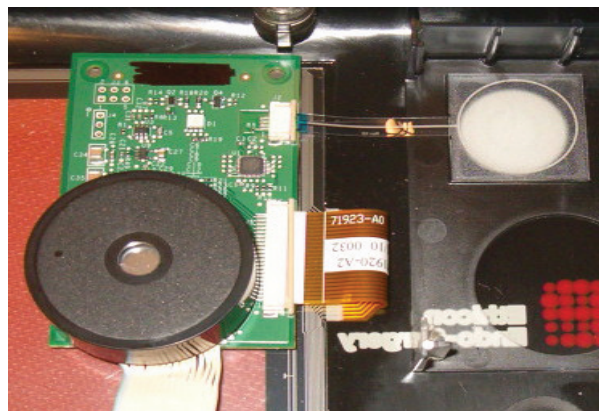


Figure 31



## Generator G11 Service Manual

6. Take out the PCB from the Bezel.

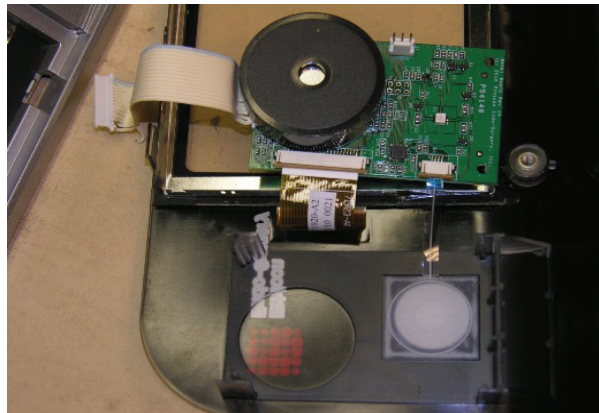


Figure 32

### Footswitch Receptacle Removal Procedure

1. Loosen the nut and separate the footswitch receptacle from the back panel.

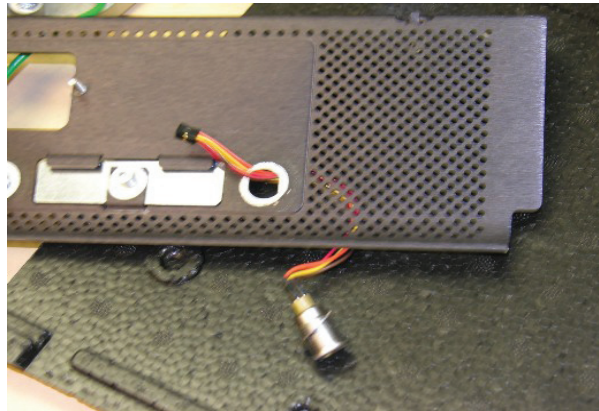


Figure 33

### Heat Sink Fan Removal Procedure

1. Separate the heat sink fan and the main board fan from the EPAC slots.



Figure 34

## Power Cord Receptacle Removal Procedure

1. Remove the side screws and separate the power cord receptacle from the back panel.

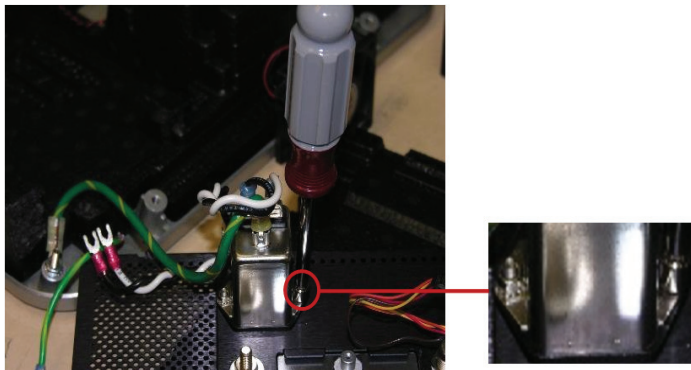


Figure 35

2. Remove the set screw and washer on the power entry ring terminal.

**Note:** Power Entry Module to the Chassis Ground must go on top of a washer and then be immediately backed up by a nut with captive washer. This is the protective earth ground and this configuration is regulated. The remaining two terminals can go on in either order and then they must be backed up with the nut with captive washer.

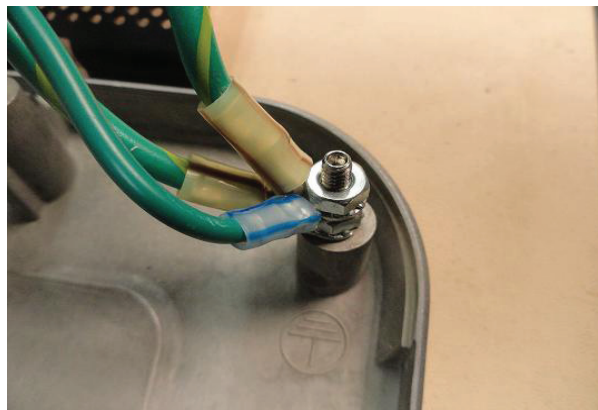


Figure 36

## Generator G11 Service Manual

### Chapter 4 - Generator G11 Functional Test

#### Device Description

The GEN11 Verification Key (GEN11VK) is a tool to verify power output by the Generator G11 (GEN11) in either HARMONIC or ENSEAL mode. The GEN11VK is for use only by medical personnel trained in medical and electrical equipment operation. Use the GEN11VK per facility guidelines to verify the output of the Generator G11.

#### Required Equipment for Procedure

The following are not included in the generator packaging:

- Verification key (GEN11VK)
- Footswitch (FSW11)
- A HARMONIC Handpiece (HP054, HPBLUE) with a hand activated instrument and corresponding torque wrench.
- An ENSEAL instrument.
- A damp chamois or paper towel.
- A wax block or cup of water.
- Standard pair of test cables to connect the Electrosurgical Analyzer to the verification key.

**Note:** Test cables length should be equal to or shorter than 3 feet (36 inches/1 meter) in length.

- Standard Electrosurgical Analyzer (Example: Model 454A by DNI NEVADA Inc. / Fluke Biomedical)

**Note:** Power measurement accuracy of the Electrosurgical Analyzer should be equal to or lower than  $\pm 10\%$  at both HARMONIC and ENSEAL drive frequencies ( $55.5 \text{ KHz} \pm 5 \text{ KHz}$  and  $330 \text{ KHz} \pm 3 \text{ KHz}$  respectively).

**Note:** Refer to Table 1 for resistor values required for the output verification, if not available within the Electrosurgical analyzer, these resistors need to be connected to the auxiliary connection of the Electrosurgical analyzer:

**Table 1 – Required Resistor Values for Output Verification**

| Load Resistor Value<br>(Ohms) | Minimum Load Resistor Power Rating<br>(Watts) |
|-------------------------------|---|
| 50                            | 150   |
| 100                           | 100   |
| 150                           | 25  |
| 200                           | 50  |
| 650                           | 100   |
| 1250                          | 50  |

#### To Verify the Energy Output of the Generator G11

The Output Verification function of the GEN11VK verifies that HARMONIC or ENSEAL power outputs are within required specifications for the Generator G11. In HARMONIC mode, perform output verification by driving two predetermined output current-drive levels into known resistors. In ENSEAL mode, perform output verification by driving a predetermined output power curve into known resistors.

If Generator G11 exhibits power output outside of the acceptable ranges, contact your local representative for instructions. For repair, Generator G11 may also be returned to an authorized Ethicon Endo-Surgery service facility at any time.

**Note:** ENSEAL is used to describe instruments driven by radiofrequency (RF) power.

## Output Drive Specifications

The maximum outputs listed in the following tables represent test points for output verification of the generator. The outputs are not the maximum that the generator is capable of producing. Instead, the test points reflect loads that are available from off-the-shelf Electrosurgical Analyzers. Not all of these outputs are currently available clinically. Access to these outputs is controlled by the GEN11VK, which places the generator in verification-only mode.

**Table 2 – HARMONIC Maximum Output Drive Specifications**

| Activation Switch | Current Amps (RMS) | Voltage VAC (RMS) | Power (Watts) |
|-------------------|--------------------|-------------------|---------------|
| MIN / ENSEAL      | 0.2                | 250               | 50            |
| MAX               | 0.4                | 250               | 100           |

**Table 3 – ENSEAL Maximum Output Drive Specifications**

| Activation Switch | Current Amps (RMS) | Voltage VAC (RMS) | Power (Watts) |
|-------------------|--------------------|-------------------|---------------|
| MIN / ENSEAL      | 3                  | 100               | 135           |

**Note:** During ENSEAL output verification, verify only the MIN / ENSEAL activation.

## Generator G11 Service Manual

### Output Verification Procedure

1. Turn off the Generator G11.
2. Connect the footswitch (FSW11) to the footswitch receptacle on the back panel of the generator.
3. Connect the output verification key (GEN11VK) to the Generator G11 front panel receptacle.

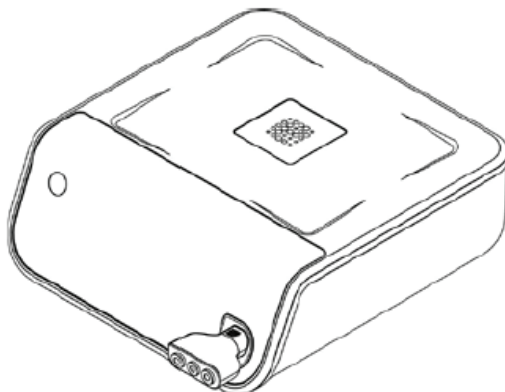


Figure 37 - GEN11 Verification Key

4. Connect two standard test leads to the HARMONIC output of the verification key.

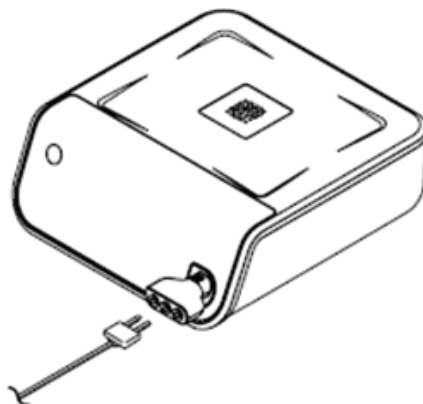


Figure 38 - Standard Test Leads

**Note:** The following figure illustrates the three active connections of the verification key when plugged into the Generator G11:

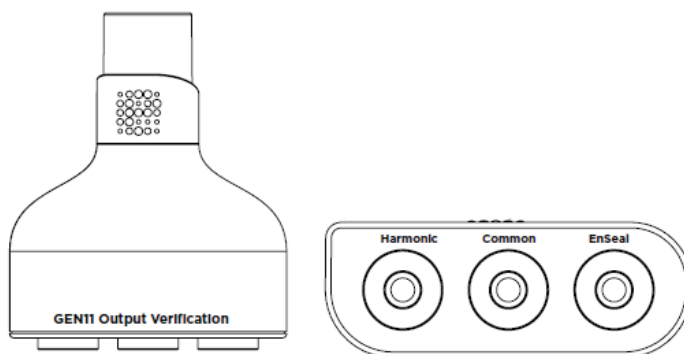


Figure 39 - Three Active Connections



5. Connect the other end of the standard test cables to the Electrosurgical Analyzer.
6. Power-up the Generator G11. After the power-up sequence, the following screen should display on the touch screen.

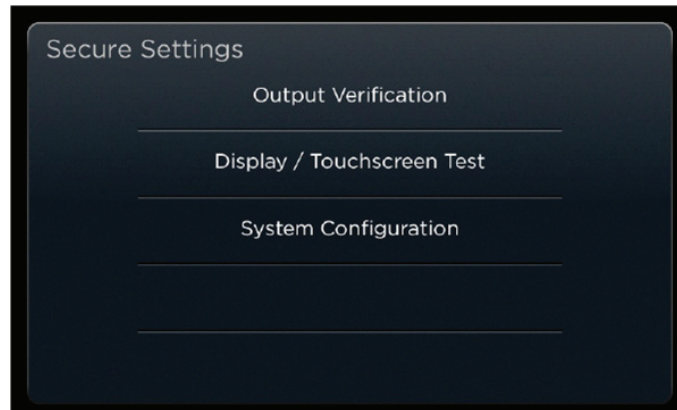


Figure 40 - Secure Settings

7. Select "Output Verification" on the touch screen, as shown below.

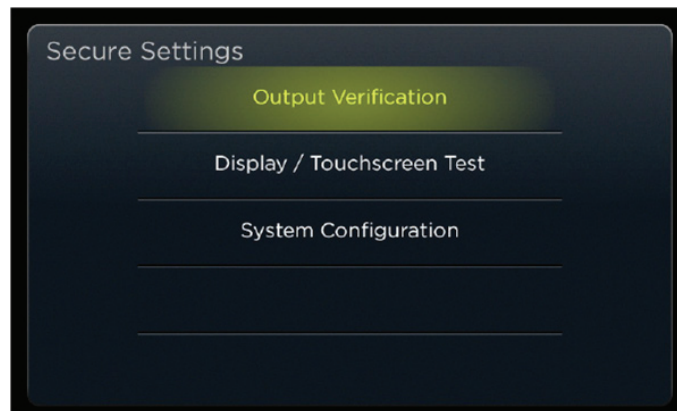


Figure 41 - Output Verification

#### To Verify HARMONIC Power Output

8. The following screen will appear:

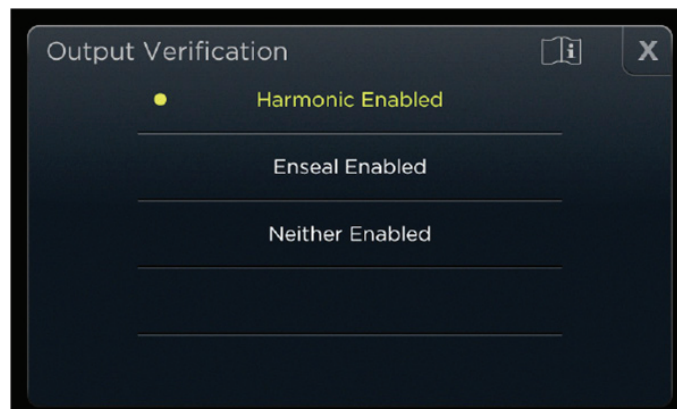


Figure 42 - HARMONIC Enabled

## Generator G11 Service Manual

**Warning:** Ensure the mode selected on the touchscreen is the same as the mode plugged into on the GEN11VK. Incorrectly plugging cables into wrong receptacles will result in incorrect output power readings.

9. Set the Electrosurgical Analyzer load resistor to 150 Ohms.
10. Activate the HARMONIC MIN output by pressing the MIN / ENSEAL foot pedal on the footswitch assembly.
11. While activating the MIN output, measure the output power and record in Table 4 - HARMONIC MIN Output Power Verification.  
**Note:** All tables referred to in this procedure are provided at the end of this section.
12. Release the MIN / ENSEAL foot pedal on the footswitch assembly to de-activate the HARMONIC MIN output.
13. Repeat steps 9 - 12 with a 650 Ohm resistor and a 1250 Ohm resistor.
14. Set the Electrosurgical Analyzer load resistor to 150 Ohms.
15. Activate the HARMONIC MAX output by pressing the MAX foot pedal on the footswitch assembly.
16. While activating the MAX output, measure the output power and record in Table 5 - HARMONIC MAX Output Power Verification.
17. Release the MAX foot pedal on the footswitch assembly to de-activate the HARMONIC MAX output.
18. Repeat steps 14 - 17 with a 650 Ohm resistor and a 1250 Ohm resistor.
19. Using the touch screen, select “Neither Enabled”, as shown below.

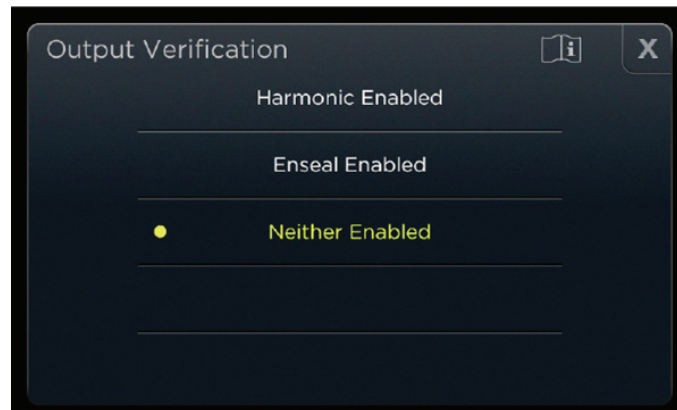


Figure 43 - Neither Enabled

20. Unplug the standard test cables from the HARMONIC output of the verification key.
21. Connect the standard test cables to the ENSEAL output of the verification key.

### To Verify ENSEAL Power Output

22. Using the touch screen, select “Enseal Enabled”, as shown below.

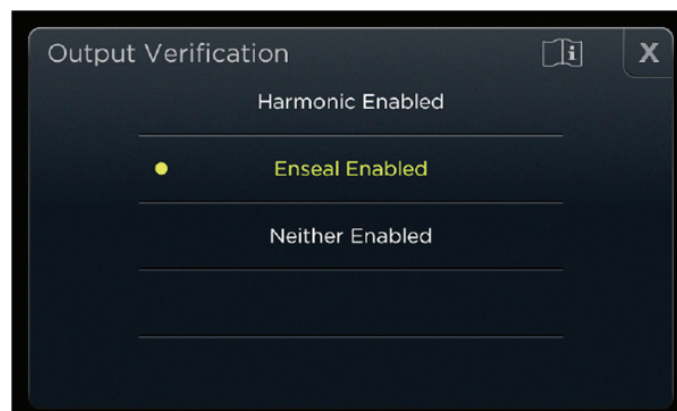


Figure 44 - ENSEAL Enabled

**Warning:** Ensure the mode selected on the touchscreen is the same as the mode plugged into on the GEN11VK. Incorrectly plugging cables into wrong receptacles will result in incorrect output power readings.

23. Set the Electrosurgical Analyzer load resistor to 50 Ohms.
24. Activate the ENSEAL output of the generator by pressing the MIN / ENSEAL foot pedal on the footswitch assembly.
25. While activating the ENSEAL output, measure the output power and record in Table 6 - ENSEAL Output Power Verification.
26. Release the MIN / ENSEAL foot pedal on the footswitch assembly to de-activate the ENSEAL output.
27. Repeat steps 23 - 26 with a 100 Ohm resistor and a 200 Ohm resistor.
28. Power the GEN11 generator down.
29. Remove the standard test cables and verification key.
30. Examine the recorded values for the HARMONIC and ENSEAL outputs, compare to acceptable minimum / maximum limits and record the PASS / FAIL column.

## Generator G11 Service Manual

Table 4 – HARMONIC MIN Output Power Verification

|              | Load Resistor (Ohms) | Target Power (Watts) | Minimum Power Limit (Watts) | Measured Power (Watts) | Maximum Power Limit (Watts) | Pass / Fail |
|--------------|----------------------|----------------------|-----------------------------|------------------------|-----------------------------|-------------|
| HARMONIC MIN | 150                  | 6                    | 4.50                        |                        | 7.70                        |             |
|              | 650                  | 26                   | 22.23                       |                        | 30.03                       |             |
|              | 1250                 | 50                   | 42.75                       |                        | 57.75                       |             |

Table 5 – HARMONIC MAX Output Power Verification

|              | Load Resistor (Ohms) | Target Power (Watts) | Minimum Power Limit (Watts) | Measured Power (Watts) | Maximum Power Limit (Watts) | Pass / Fail |
|--------------|----------------------|----------------------|-----------------------------|------------------------|-----------------------------|-------------|
| HARMONIC MAX | 150                  | 24                   | 20.52                       |                        | 27.72                       |             |
|              | 650                  | 100                  | 85.50                       |                        | 115.50                      |             |
|              | 1250                 | 50                   | 42.75                       |                        | 57.75                       |             |

Table 6 – ENSEAL Output Power Verification

|        | Load Resistor (Ohms) | Target Power (Watts) | Minimum Power Limit (Watts) | Measured Power (Watts) | Maximum Power Limit (Watts) | Pass / Fail |
|--------|----------------------|----------------------|-----------------------------|------------------------|-----------------------------|-------------|
| ENSEAL | 50                   | 135                  | 115.42                      |                        | 155.92                      |             |
|        | 100                  | 100                  | 85.50                       |                        | 115.50                      |             |
|        | 200                  | 50                   | 42.75                       |                        | 57.75                       |             |

Test Operator:

Name

Signature

Date

Generator Serial Number: \_\_\_\_\_

**Note:** The tolerances built into the minimum and maximum power limits in the HARMONIC and ENSEAL Output Power Verification Tables account for the generator output tolerances and an Electrosurgical Analyzer with a power measurement accuracy of  $\pm 10\%$ .

**Touch Screen Test (Optional)**

Perform the optional touch screen test, if the problem is suspected with touch screen.

1. Select the test.
2. Follow the on-screen prompt.
3. Each cell should change to a lighter shade when it is touched. If any cell does not change when touched, then the generator needs to be serviced.
4. After completing the test, remove the verification key. The generator will restart automatically.

## Final Inspection

Test each generator to ensure it is functional. Record results on data sheet (see sample below). Testing will include the following:

1. Plug in power cord to generator and to wall outlet. Power on the generator using the On/Off button. Ensure that the device powers on.
2. Ensure that audible beep is heard and generator power switch glows green.
3. Ensure that the LCD is functioning.
4. Touch multiple areas of the touch screen to verify that it is functioning and changes according to touch prompts.
5. Check the LCD image by selecting different options in the touch screen.
6. Plug in footswitch to receptacle in Rear Air Plate and ensure that the generator is activated by the footswitch.
7. Plug in HARMONIC device (handpiece with instrument) into the generator. Activate the instrument using footswitch for 2 seconds to run test. (If using shears, keep the jaws open.) Ensure that generator is activating by verifying with wax block or water.
8. Plug in ENSEAL device into the generator. Clamp the device jaws onto a piece of damp chamois or paper towel. Activate ENSEAL instrument using the footswitch. Ensure that generator is activated by observing water evaporation.
9. Plug in HARMONIC device (handpiece with instrument) into the generator. Activate the instrument using handswitch for 2 seconds to run test. (If using shears, keep the jaws open.) Ensure that generator is activating by verifying with wax block or water.
10. Plug in ENSEAL device into the generator. Clamp the device jaws onto a piece of damp chamois or paper towel. Activate ENSEAL instrument using the handswitch. Ensure that generator is activated by observing water evaporation.
11. During the generator activation, ensure the speaker is functioning.
12. During the generator activation, ensure that fans are functioning.

## Generator G11 Functional Test Results

Device Serial Number: \_\_\_\_\_

| Output Verification Passes | Test  | Pass | Fail |
|----------------------------|---|------|------|
| 1                          | On/Off Button Activates                             |      |      |
| 2                          | Audible Speaker Beeps / Power switch glows green    |      |      |
| 3                          | LCD Powers up                                       |      |      |
| 4                          | Touch Screen Functions                              |      |      |
| 5                          | LCD Image Changes                                   |      |      |
| 6                          | Footswitch activates the generator                  |      |      |
| 7                          | Generator activates a HARMONIC load with footswitch |      |      |
| 8                          | Generator activates an ENSEAL load with footswitch  |      |      |
| 9                          | Generator activates a HARMONIC load with handswitch |      |      |
| 10                         | Generator activates an ENSEAL load with handswitch  |      |      |
| 11                         | Speaker Function                                    |      |      |
| 12                         | Fans Function                                       |      |      |

Test Operator: \_\_\_\_\_

Name

Signature

Date

## Generator G11 Service Manual

### Chapter 5 - Assembly Diagram and Spare Parts List

#### Main Assembly Diagram

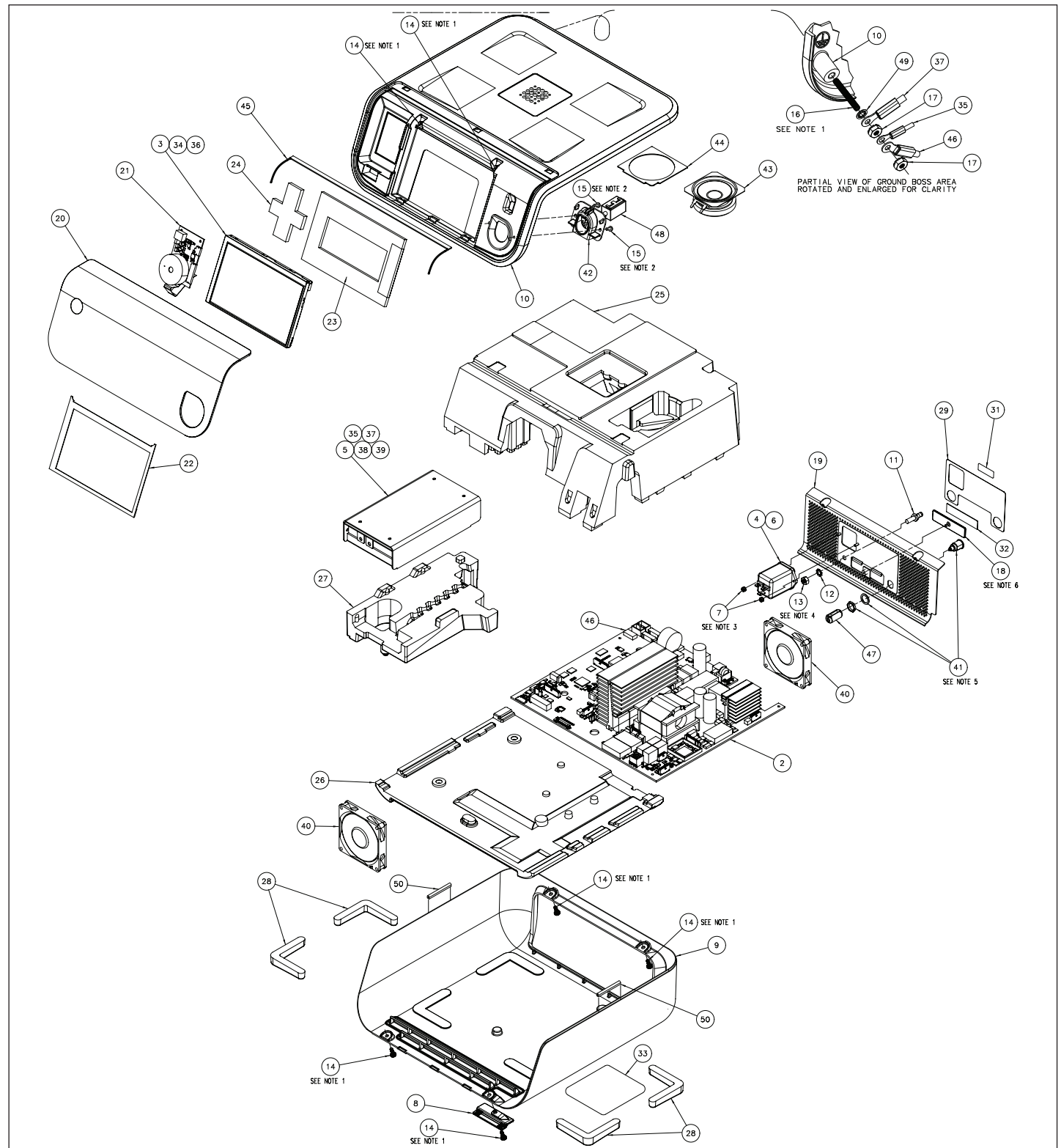


Figure 45 - Main Assembly Diagram

## Spare Parts List

The following reference numbers correspond to the numbers in *Figure 45 - Main Assembly Diagram*.

| Item No. | Part Number | Description  |
|----------|-------------|--|
| 2        | EE01-63095  | Main PCB Assembly  |
| 3        | EE65-00002  | 7" LCD Display (Hitachi)   |
| 4        | EE99-00007  | Power Entry Module, Fused 5A   |
| 5        | EE70-00001  | Power Supply, 48V 400W (Condor)                                      |
| 6        | EE40-00005  | Fuse 5A 250V Slow burn 5 x 20mm (Power Entry)                        |
| 7        | EE45-00036  | M3 Nut with captive washer (Power Entry) ( See NOTE 3)               |
| 8        | EE20-00021  | Adapter Plate  |
| 9        | EE20-00022  | Enclosure Bottom Deco Assembly                                       |
| 10       | EE20-00025  | Enclosure Top Deco Assembly  |
| 11       | EE15-00031  | POAG-S6-15 Equipotential   |
| 12       | EE45-00003  | F / M 6 Lock Washer (Equipotential)                                  |
| 13       | EE45-00002  | MUO.5D / M6 Nut (Equipotential) ( See NOTE 4)                        |
| 14       | EE45-00042  | 8-32 x 1/2" PH Phillips screw w / Washer ( See NOTE 1)               |
| 15       | EE45-00004  | M3.5 x 12mm Threadforming Torx Plus Screw (Receptacle) ( See NOTE 2) |
| 16       | EE45-00048  | 8-32 x 1.25" Set screw (Earth Ground)                                |
| 17       | EE45-00049  | 8-32 Nut w / Captive Washer (Earth Ground)                           |
| 18       | EE20-00019  | USB Cover Plate Assembly   |
| 19       | EE20-00020  | Rear Air Plate Assembly  |
| 20       | EE20-00014  | Bezel / ITO Assembly   |
| 21       | EE01-63096  | Bezel PCB Assembly   |
| 22       | EE20-00015  | Bonding Gasket Display Front   |
| 23       | EE20-00016  | LCD Gasket Display Rear  |
| 24       | EE20-00017  | Foam Pad PCB On Off  |
| 25       | EE00-00009  | EPAC Top (Condor)  |
| 26       | EE99-00010  | Bottom EPAC and Tape Sub-Assembly                                    |
| 27       | EE00-00004  | EPAC Middle (Condor)   |
| 28       | EE20-00018  | Foot Enclosure   |
| 29       | EE60-00001  | Main Label   |
| 31       | EE60-00016  | Serial Number Label with Graphics only                               |
| 32       | EE60-00004  | Magnetic Rep Label   |
| 33       | EE60-00006  | Patent Label   |
| 34       | EE05-00001  | Flex Cable Assembly, Main Board to LCD                               |
| 35       | EE05-00002  | Cable Assembly, Power Entry Module to Power Supply                   |
| 36       | EE05-00003  | Cable Assembly, Backlight to Main Board                              |
| 37       | EE05-00004  | Cable Assembly, Power Entry Module to Chassis Ground                 |
| 38       | EE05-00005  | Cable Assembly, Power Supply to Main Board                           |
| 39       | EE05-00007  | Cable Assembly, Power Supply I / O to Main Board                     |
| 40       | EE05-00008  | Cable Assembly, Enclosure / Heat sink Fan to Main Board              |
| 41       | EE05-00010  | Cable Assembly, Footswitch to Main Board (See NOTE 5)                |
| 42       | EE05-00011  | Cable Assembly, Receptacle to Main Board                             |
| 43       | EE38-00002  | Speaker (8 Ohm)  |

Group: Package Labeling Drawing  
Type: Manual Service

State: Released  
NSR/SR:



## Generator G11 Service Manual

| Item No. | Part Number | Description                                  |
|----------|-------------|--|
| 44       | EE00-00002  | Speaker Adhesive Pad                         |
| 45       | EE20-00026  | Bezel Gutter Gasket                          |
| 46       | EE05-00014  | Cable Assembly, Main Board to Chassis Ground |
| 47       | EE30-00009  | Ferrite, Footswitch                          |
| 48       | EE30-00008  | Ferrite, Receptacle                          |
| 49       | EE45-00050  | #8 Internal - Tooth Lock Washer              |
| 50       | EE99-0015   | Damping Trim                                 |
| N/A      | EE40-00009  | Fuse, 2 Amp (Main Board)                     |
| N/A      | EE40-00008  | Fuse, 8 Amp (Main Board)                     |
| N/A      | EE00-00010  | Foam End Cap - Left                          |
| N/A      | EE00-00011  | Foam End Cap - Right                         |
| N/A      | EE05-00012  | Power Cord 13 Amps, 125 V, 15 Feet           |
| N/A      | EE00-00013  | Anti-Static Bag 20" x 24"                    |
| N/A      | EE00-00014  | Corrugated Box for GEN11                     |

## NOTE:

| Note No. | Description  |
|----------|--|
| 1        | Fasteners shown should be tightened to a $7.0 \pm 1$ in / lb Torque setting.   |
| 2        | Receptacle connector fasteners should be tightened to a $14.0 \pm 1.5$ in / lb Torque setting only.<br>When initially forming threads use $27.0 \pm 3$ in / lb Torque setting. |
| 3        | Power Entry Module fasteners should be tightened to an $8.0 \pm 1$ in / lb Torque setting.   |
| 4        | Equipotential fastener should be tightened to a $19.0 \pm 2$ in / lb Torque setting.   |
| 5        | Footswitch connector fastener should be tightened to a $9.0 \pm 1$ in / lb Torque setting.   |
| 6        | USB cover plate fastener should be tightened to a $3.0 \pm 1$ in / lb Torque setting.  |



## Cart (CRT11)



Figure 46 - Cart

## Cart (CRT11) Parts List

| Item No. | Part Number | Description   |
|----------|-------------|---|
| 1        | ETH2600     | Caster, Locking (2 Places)  |
| 2        | ETH2660     | Caster, Swivel (2 Places)   |
| 3        | ETH2700     | Device Retention Screw  |
| 4        | ETH2800     | Grommet (2 Places)  |
| N/A      | ETH2900     | This is the full hardware kit that includes 8 screws, flat washers and lock washers for the upright as well as the 4 lock washers for the casters.<br>*All screws must be torqued to 70-80 in / lb. |

## Generator G11 Service Manual

### Appendix

#### Electrical Safety Test Parameters

Electrical safety tests are recommended to be performed on a regularly scheduled basis in accordance with facility guidelines. The following test processes and parameters are recommended in accordance with the safety standards specified in this manual.

**Table 1 – Ground Bond Test**

| Test Parameter             | Test Name / Description | UCL   | LCL   | Units |
|----------------------------|-------------------------|-------|-------|-------|
| Consult local requirements | Total Resistance        | 0.100 | 0.001 | Ohms  |

**Table 2 – Patient Applied Part Circuit Dielectric Test**

**Note:** It is recommended only if a service or repair to the patient connected circuit is made.

| Test ID | Test Name / Description         | UCL  | LCL  | Units |
|---------|---------------------------------|------|------|-------|
| 4000 V  | Patient Applied Part Dielectric | 10.0 | 0.15 | mA    |

**Table 3 – Chassis to mains Circuit Dielectric**

**Note:** It is recommended only if a service or repair to the AC line circuit is made.

| Test ID                               | Test Name / Description             | UCL  | LCL | Units |
|---------------------------------------|-------------------------------------|------|-----|-------|
| 1500 V for 60 sec or 1776 V for 1 sec | Chassis-to-Mains Circuit Dielectric | 10.0 | 0.5 | mA    |

**Table 4 – Earth Leakage Current (Optional, not required for servicing the device)**

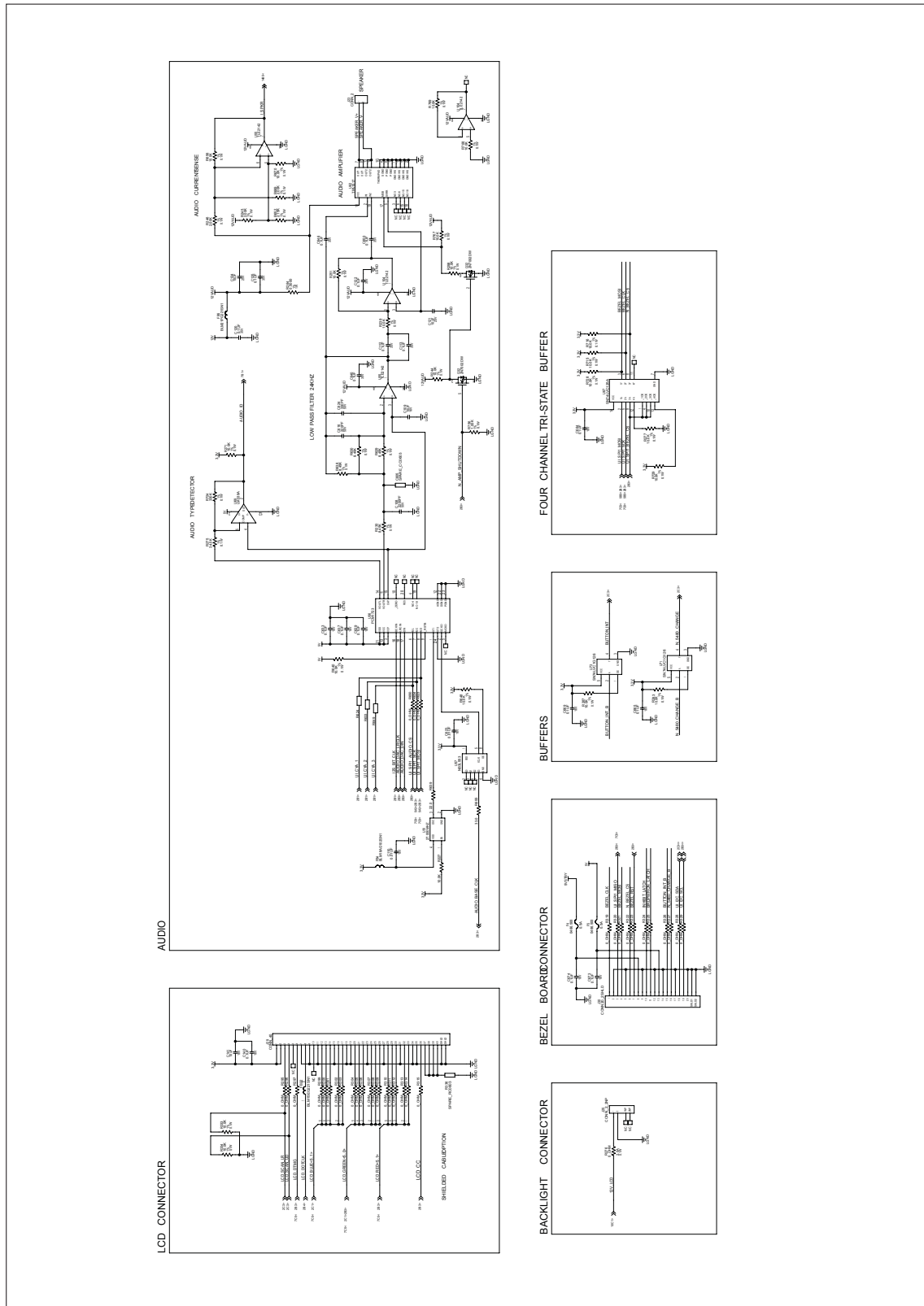
| Test Parameter             | Test Name / Description                       | UCL | LCL | Units |
|----------------------------|---|-----|-----|-------|
| Consult local requirements | Earth Current Leakage – Normal                | 300 | 0.0 | μA    |
| Consult local requirements | Earth Current Leakage – Reverse               | 300 | 0.0 | μA    |
| Consult local requirements | Earth Current Leakage Single Fault – Normal   | 1.0 | 0.0 | mA    |
| Consult local requirements | Earth Current Leakage Single Fault – Reversed | 1.0 | 0.0 | mA    |

**Table 5 – Patient Leakage Current from Applied Part to Earth (Optional, not required for servicing the device)**

| Test Parameter             | Test Name / Description                         | UCL  | LCL | Units |
|----------------------------|---|------|-----|-------|
| Consult local requirements | Patient Leakage Current – Normal                | 10   | 0.0 | μA    |
| Consult local requirements | Patient Leakage Current – Reverse               | 10   | 0.0 | μA    |
| Consult local requirements | Patient Leakage Current Single Fault – Normal   | 50.0 | 0.0 | μA    |
| Consult local requirements | Patient Leakage Current Single Fault – Reversed | 50.0 | 0.0 | μA    |

## Schematic Diagrams

### Schematic - Audio DAC and Miscellaneous Connectors

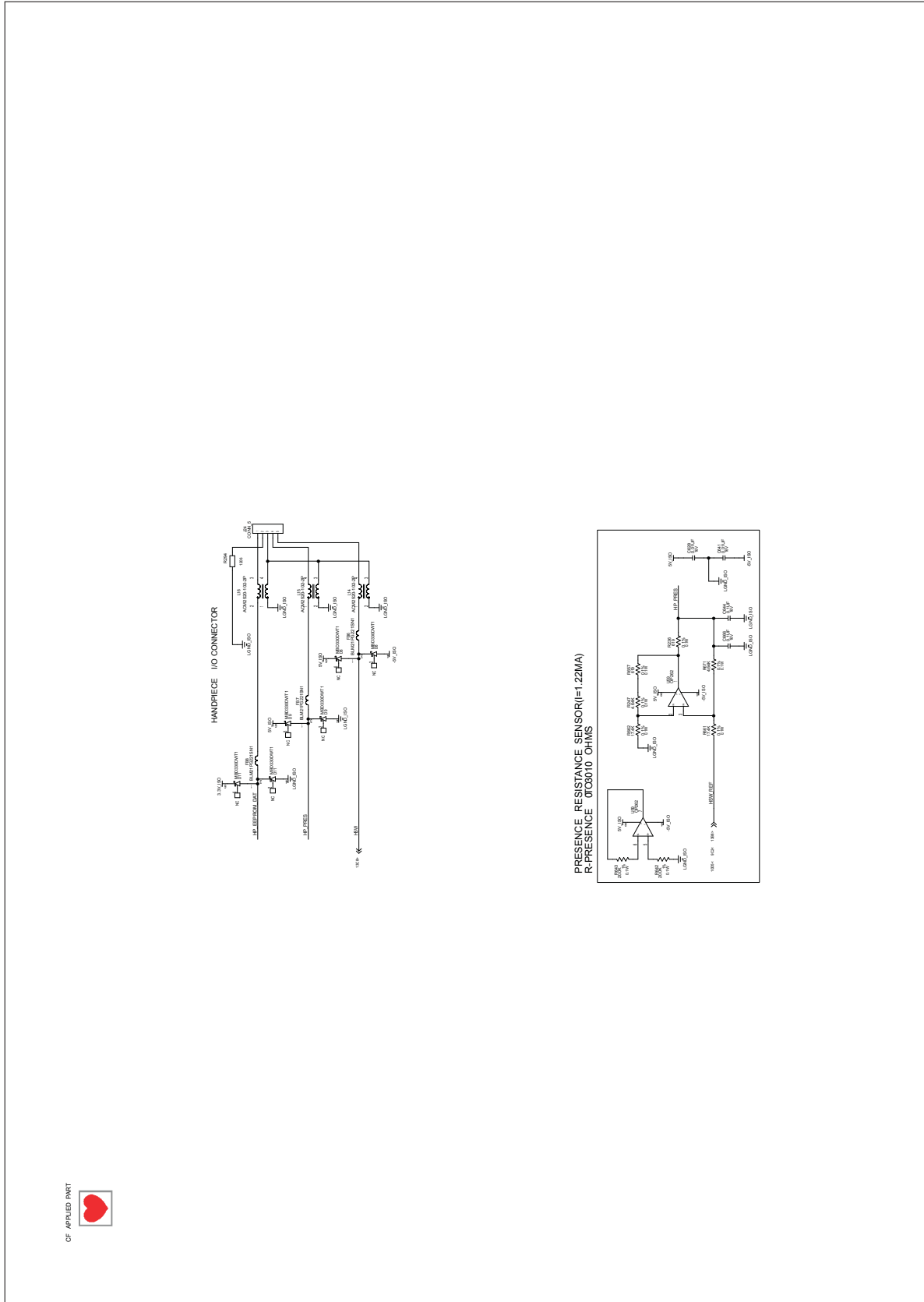


Group: Package Labeling Drawing  
Type: Manual Service

State: Released  
NSR/SR:

# Generator G11 Service Manual

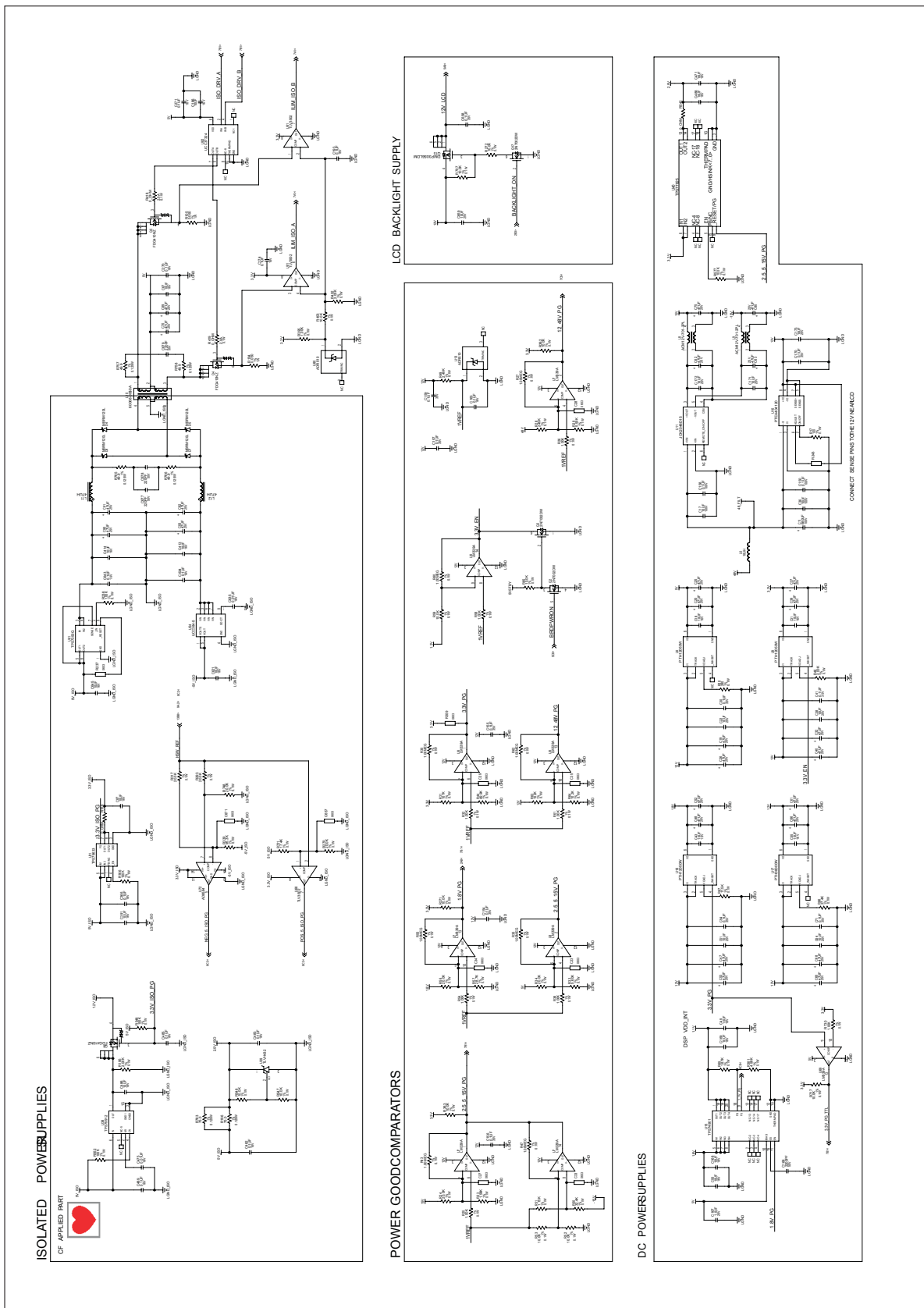
## Schematic - FPGA Minor



Group: Package Labeling Drawing  
Type: Manual Service

State: Released  
NSR/SR:

Schematic - Power Supplies



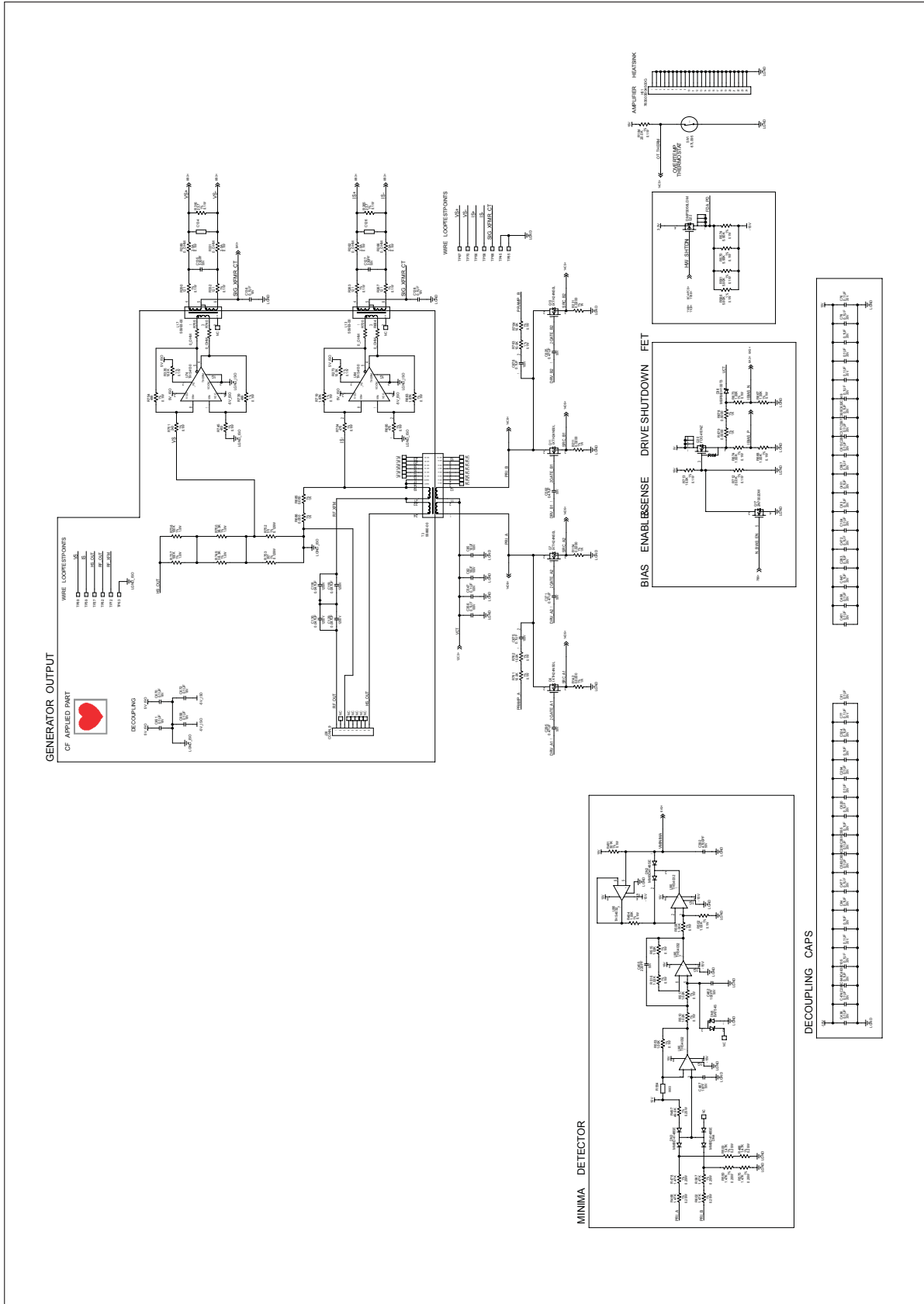
Group: Package Labeling Drawing  
Type: Manual Service

State: Released  
NSR/SR:



# Generator G11 Service Manual

## Schematic - Amplifier



Group: Package Labeling Drawing  
Type: Manual Service

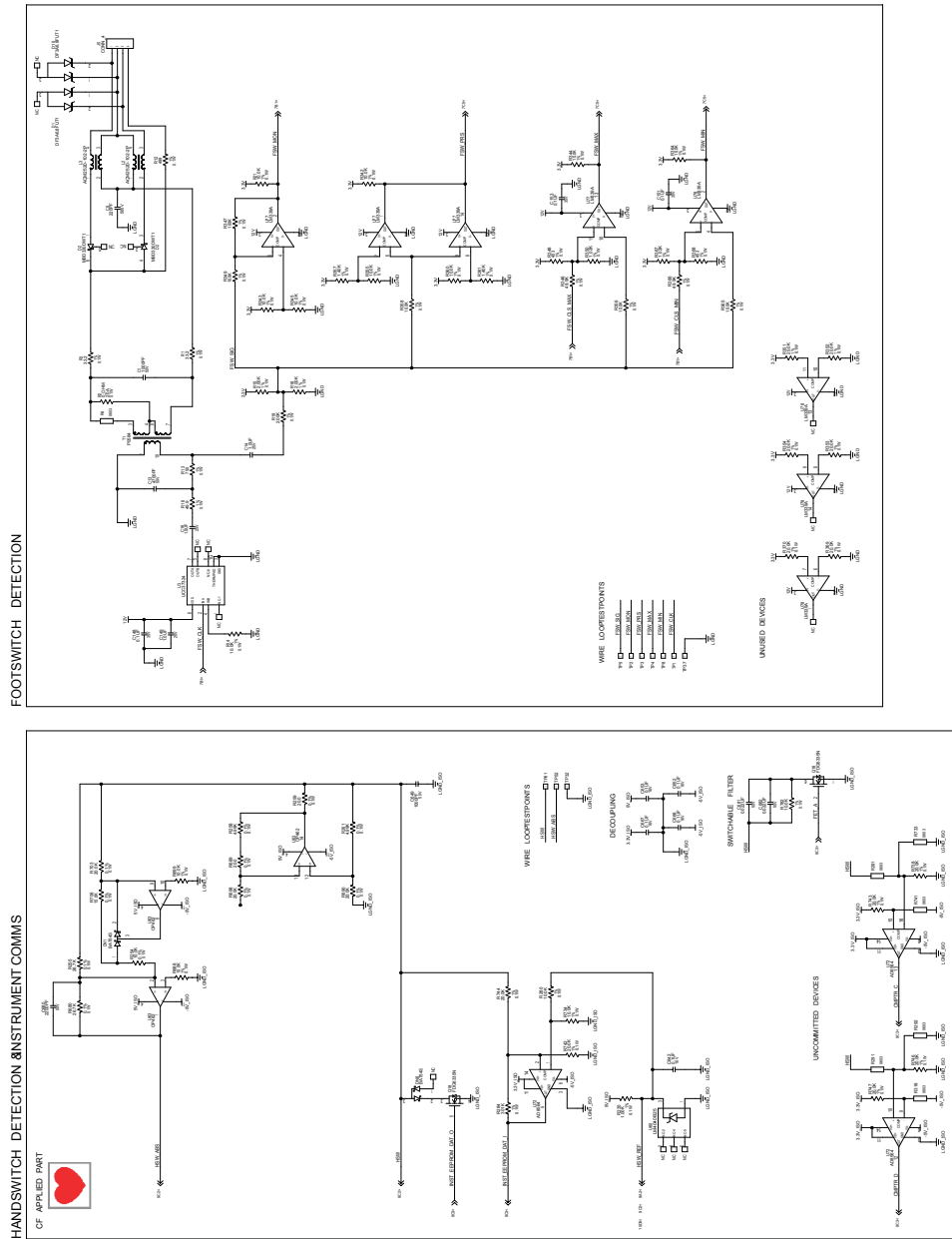
State: Released  
NSR/SR:

**State: Released**  
**NSR/SR:**



# Generator G11 Service Manual

## Schematic - Activation Switches of Instrument ID



Group: Package Labeling Drawing  
Type: Manual Service

State: Released  
NSR/SR:

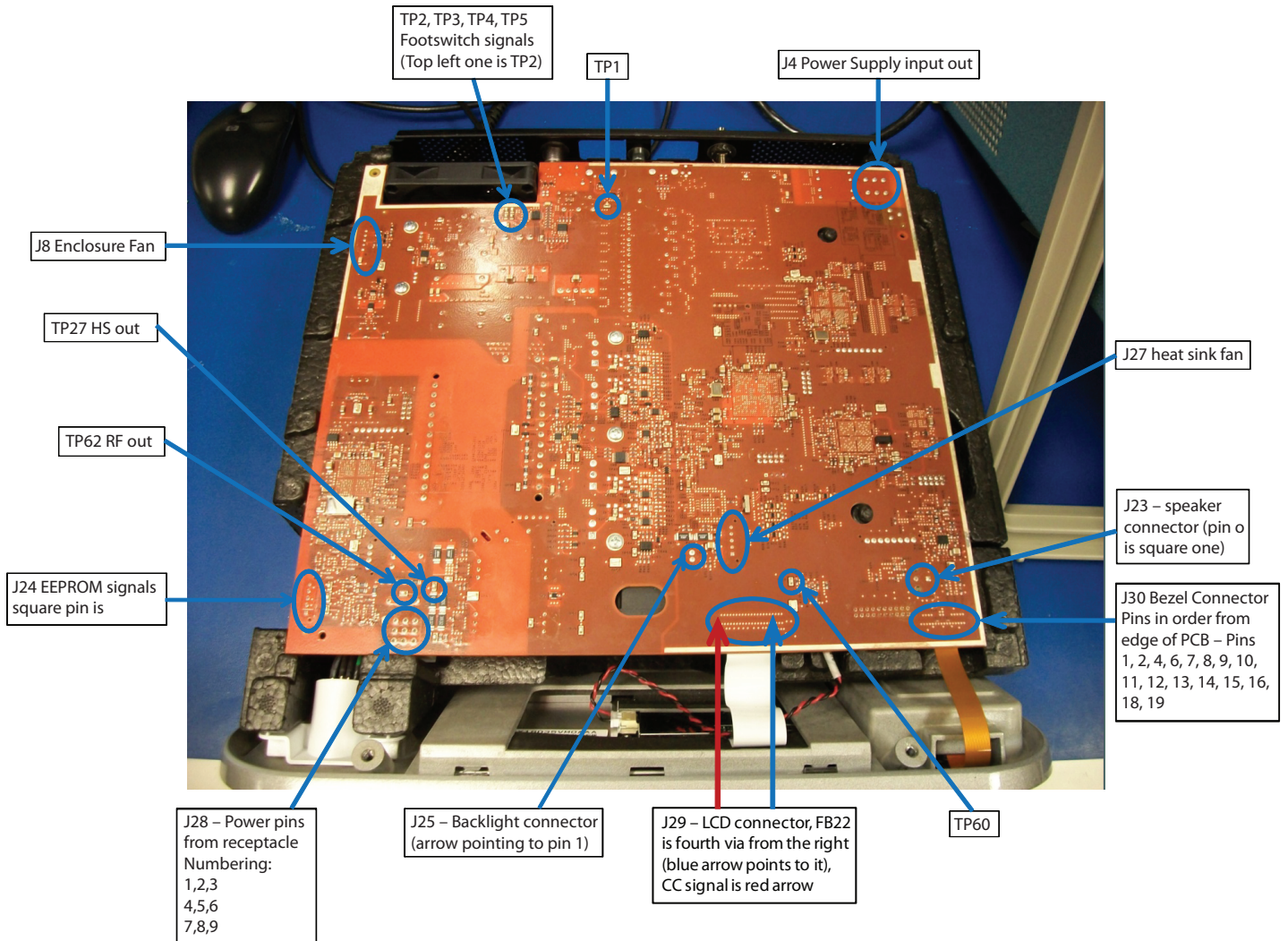
**State: Released**  
**NSR/SR:**



## Generator G11 Service Manual

### Additional Hardware Troubleshooting Information

**Note:** Voltages listed are +/-10% unless otherwise indicated.



**Figure 47 - Access Points Used For GEN11 Troubleshooting While Powered**

- Large TP are ground.
- If all the LED are continuously lit, it indicates that the PCB has failed.



**Troubleshooting Using PCB Interface Signals:**

Interface from PCB to:

## i. LCD Display

- Backlight connector (J25)
  - 12VDC at J25.1
- LCD connector (J29)
  1. Check for good connection.
  2. Check for clock on LCD\_DOTCLK (FB22 or R167) UI processor is sending a clock to LCD.

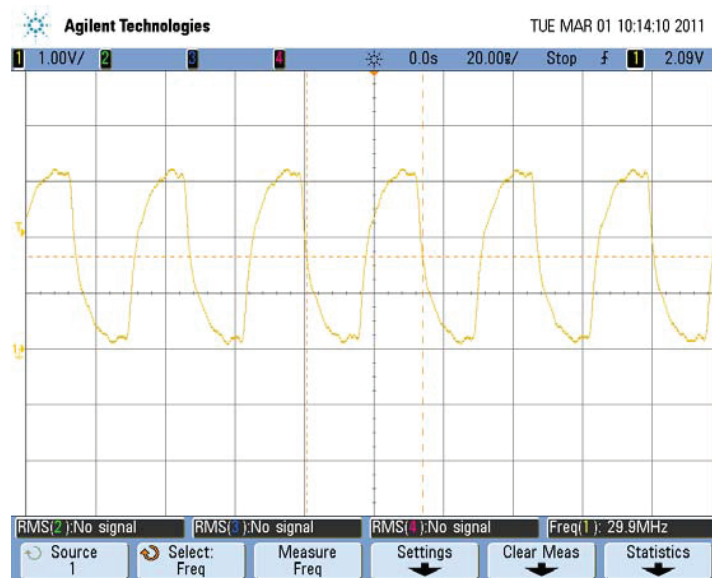


Figure 48

3. Check for data timing signal (next to dot clock signal third from the right in Figure 48). This shows the UI is properly writing and refreshing the LCD with data. If this signal does not exist, then the PCB is defective.

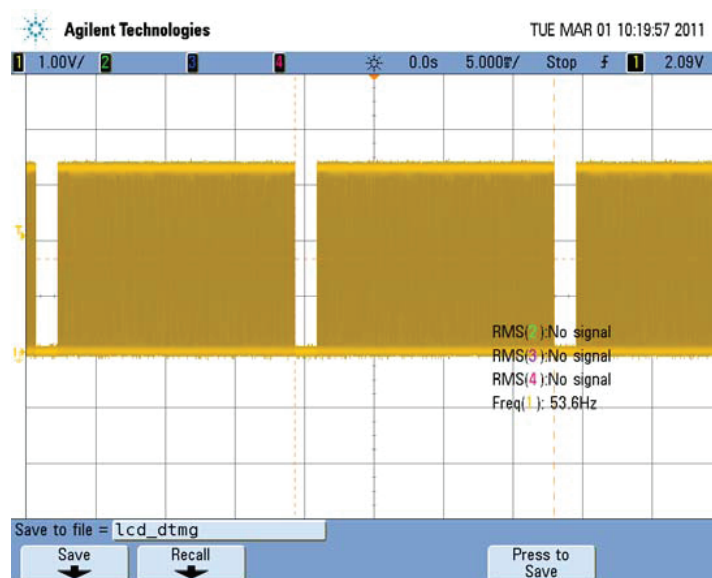


Figure 49

## Generator G11 Service Manual

4. Check for LCD CC signal (very end – first on the top left in Figure 49.) If this signal does not exist, then the LCD is defective.

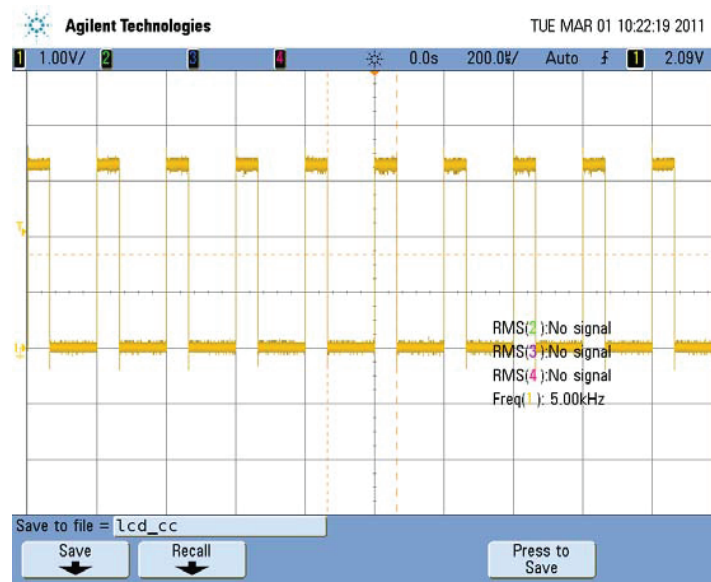


Figure 50

### ii. Speaker

- Speaker connector (J23)
  1. Check V+ (J23.1) and V- (J23.2) for activity when signal is expected.
    - No signal both pins  $\sim +5.6$  VDC
    - When activating see  $\sim 2$  Vp/p signal riding on  $\sim +5.6$  VDC
      - If this signal does not exist, then the PCB is defective.

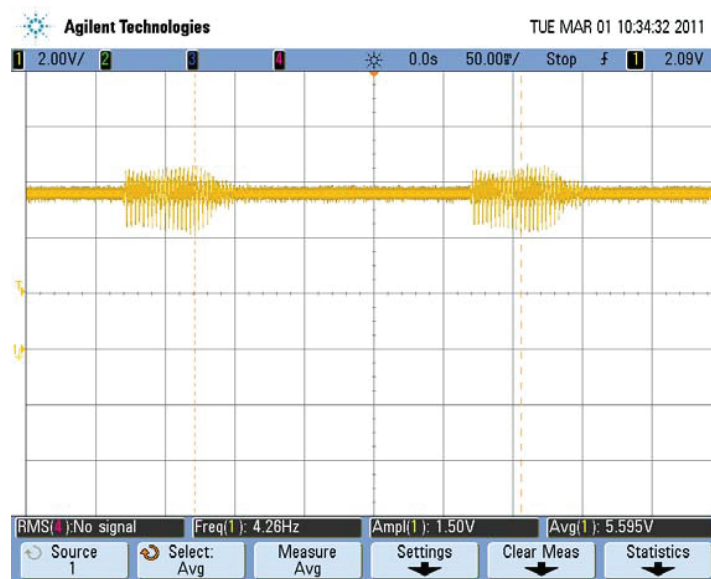


Figure 51

2. The speaker current (I\_SPKR) feeds to a comparator and outputs AUDIO\_SNS (TP60). This test point should indicate 3.3V when the speaker current passes a certain threshold. If there is activation without current, then the speaker is defective. If there is no current when audio signal in step above is present, then the speaker is defective.

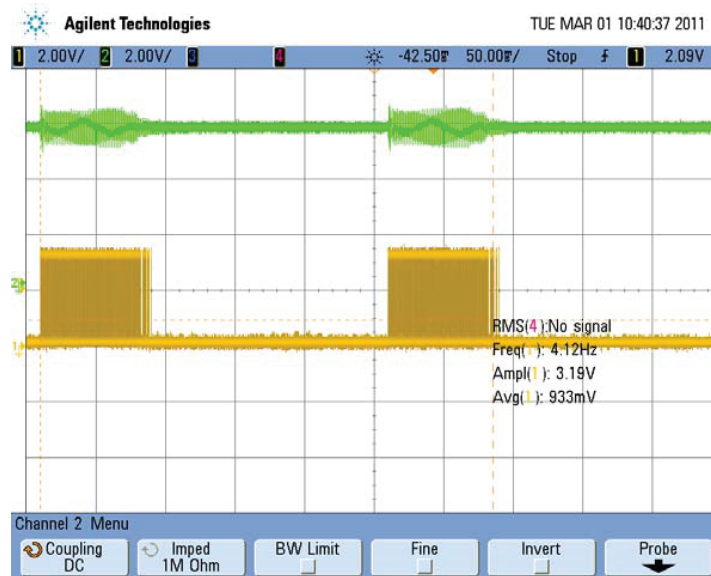


Figure 52

### iii. Handpiece Receptacle

Check for continuity between handpiece inputs and its connectors.

1. J24 pins 1-5. J24
  - Pin 4 is presence (also TP 64) - Pin 4 to Pin 3 is shorted when HP is present
  - EEPROM data on Pin 1
  - Handswitch signals on Pin 5 (and also future instrument EEPROM signal)
2. J28 power drive signals to the instruments.
  - Pin 1 (TP62) is RF out (ENSEAL output signals)
  - Pin 9 (TP27) is HS out (HARMONIC output signals)
  - Pin 3 is ground return

### iv. Footswitch Receptacle

Connects to J5.

1. FSW\_MON (TP2) is expected to follow the FSW\_CLK signal almost exactly. (Check if all the FETs are switching properly to keep track of the PCB circuitry.)

## Generator G11 Service Manual

2. FSW\_CLK (TP1) is expected to be a 2 kHz square wave (0 to 3.3V).

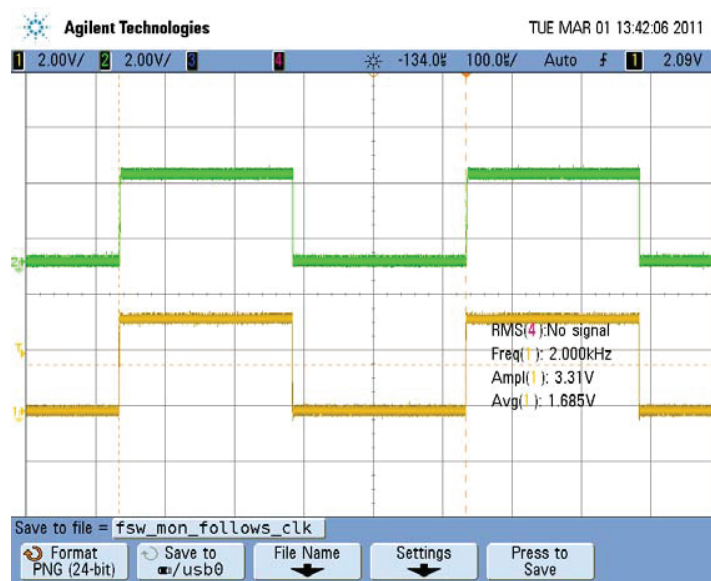


Figure 53

3. FSW\_PRS (TP3) is expected to be 3.3V when footswitch is present. FSW\_PRS signal dips low on every edge of the clock if footswitch is not present. Stays high if footswitch is present.

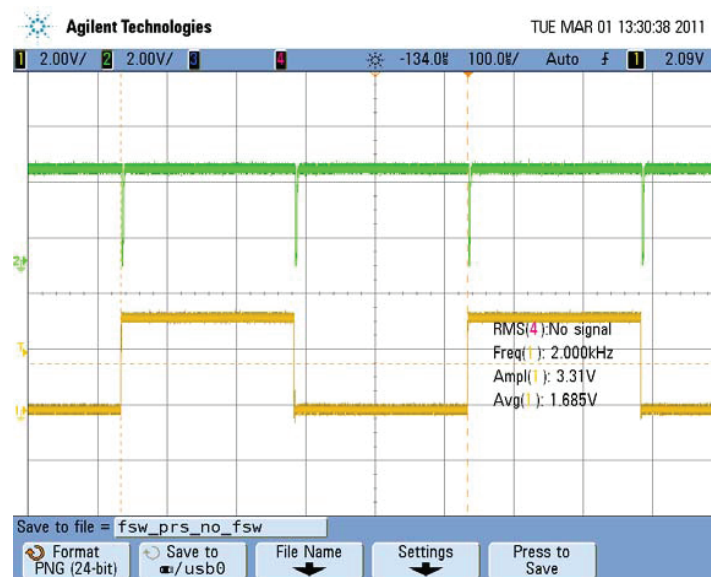


Figure 54

4. FSW\_MAX (TP4) – If “MAX” is pressed, this signal is expected to be 3.3V after the rising edge of FSW\_CLK. Dips low if MAX pedal is not pressed on rising edge of the clock.
  5. FSW\_MIN (TP8) – If “MIN” is pressed, this signal is expected to be 0V after the falling edge of FSW\_CLK. Normally low, spikes high on the falling edges of the clock when the MIN pedal is not pressed, but will stay low when the pedal is pressed.
- v. Power Supply
- AC power inlet and cable assembly.
  - Check for 48V at J4.1 with respect to GND at J4.6 or any GND test point.

## vi. Bezel PCB

## • Bezel Board Connector (J30)

1. Check UI\_SPI1\_MISO, (J30.2) for periodic activity – which means that PCB is trying to communicate to Bezel.

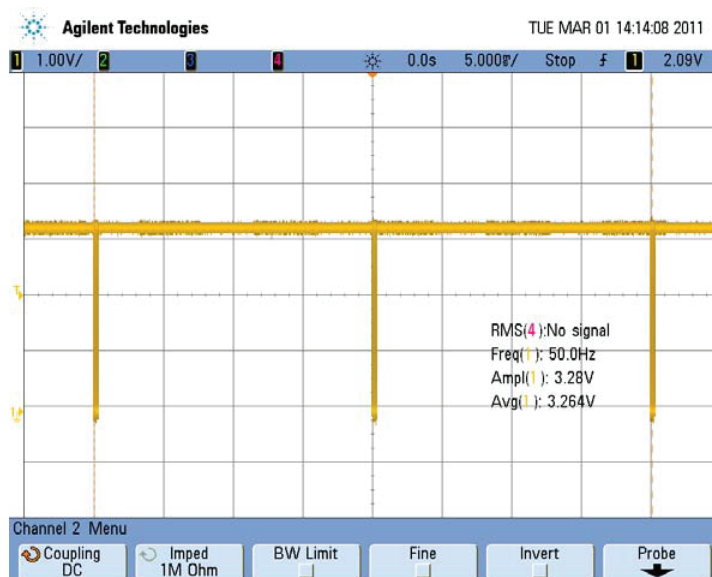


Figure 55

2. Check level of N\_BEZEL\_CS (J30.6). It should be high (3.3V) for normal activity. If it is not high, it indicates problems with the PCB.
3. Check level of BEZEL\_RST (J30.7). It should be low under normal conditions. If it is high, it indicates problems with the PCB.
4. Check level of INHIBIT\_LATCH (J30.10). It should be high (3.3V) in normal operation. If low, it indicates a problem with the Bezel PCB.
5. Check level of BRDPWRON\_LATCH (J30.11 or R325). It should be high (3.3V) in normal operation. If low, it indicates problem with the Bezel PCB.
6. Remove the power supply control cable to test if the generator does not turn on. Allows generator to turn on if Bezel PCB is not operating.

## vii. Fans

## • Enclosure Fan Connector (J8)

1. Check for 48V at J8.1. If the fan does not move and this voltage is present, then the fan is defective.
2. Pin 3 is tach signal coming back from fan.
3. Pins 4 and 5 are related to fan speed for future functionality.

## • Heat sink Fan Connector (J27)

1. Check for 48V at J27.1. If the fan does not move and this voltage is present, then the fan is defective.
2. Pin 3 is tach signal coming back from fan.
3. Pins 4 and 5 are related to fan speed for future functionality.



## Generator G11 Service Manual

### Power versus Load Curves

Power versus Load Resistance (Impedance)

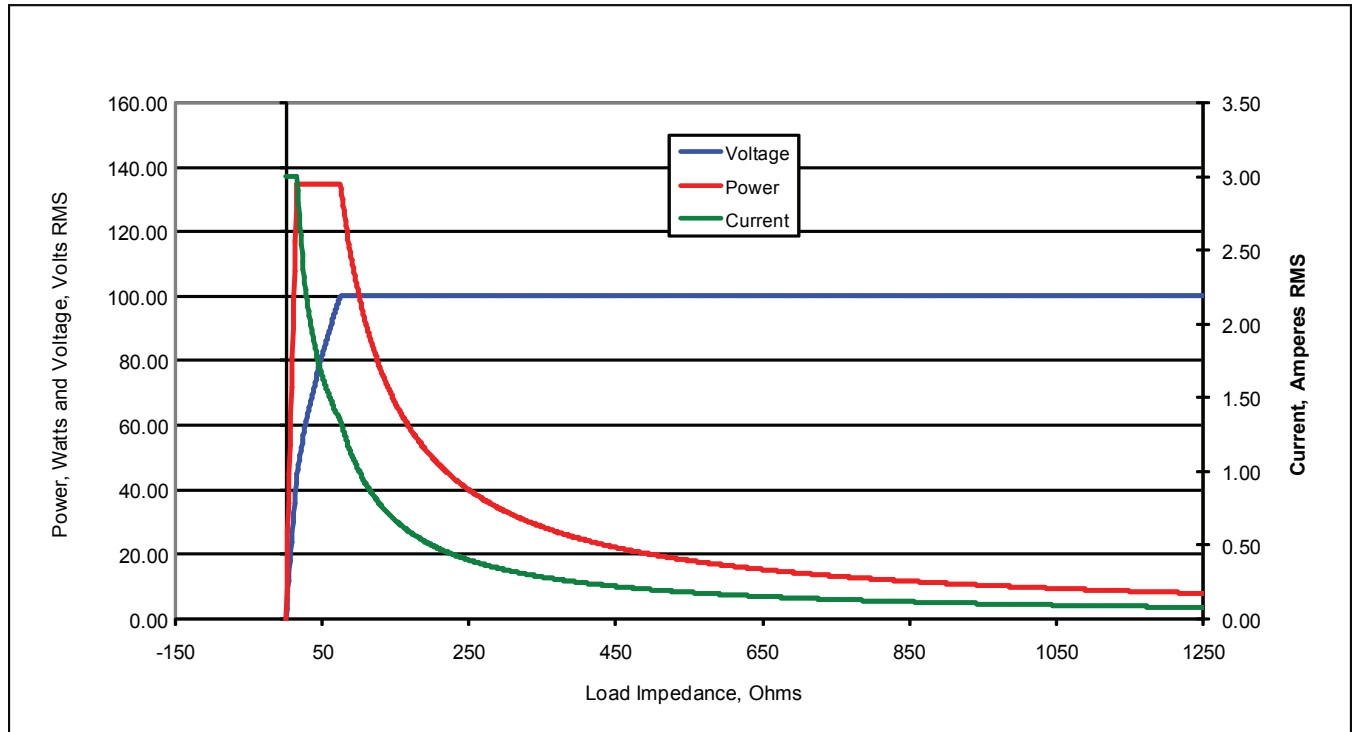


Figure 56 - Electrosurgical Power versus Load Resistance

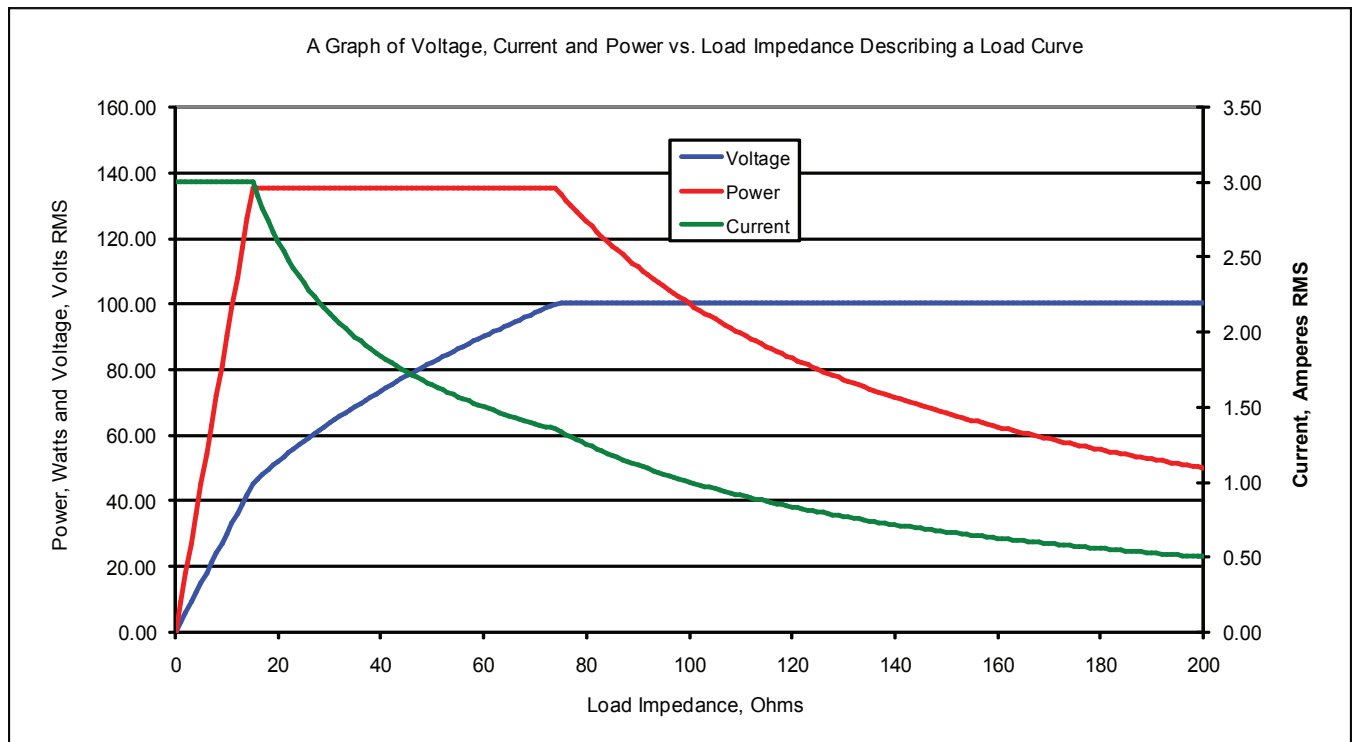


Figure 56a - Zoomed View of Electrosurgical Power Versus Load Resistance

### Voltage versus Load Resistance (Impedance)

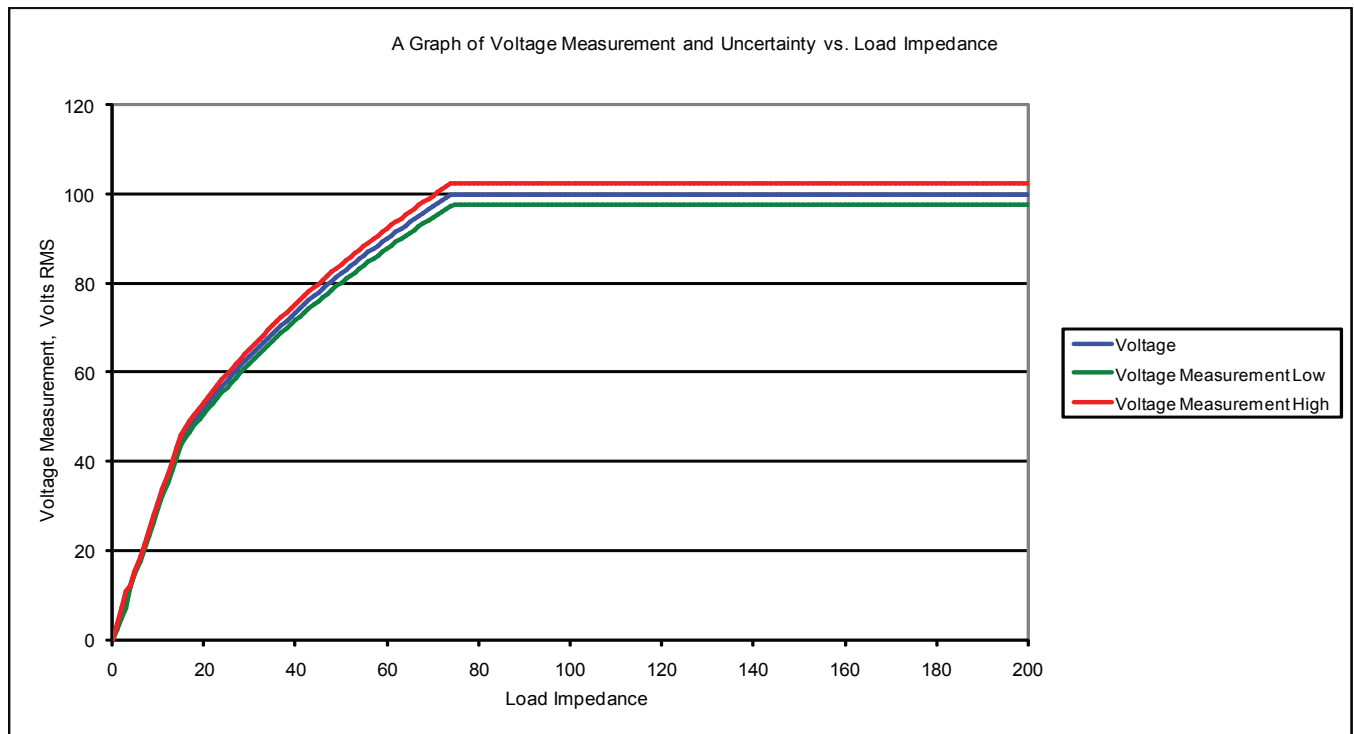


Figure 57 - Electrosurgical Voltage Measurement versus Load Impedance

### Impedance Measurement versus Load Impedance

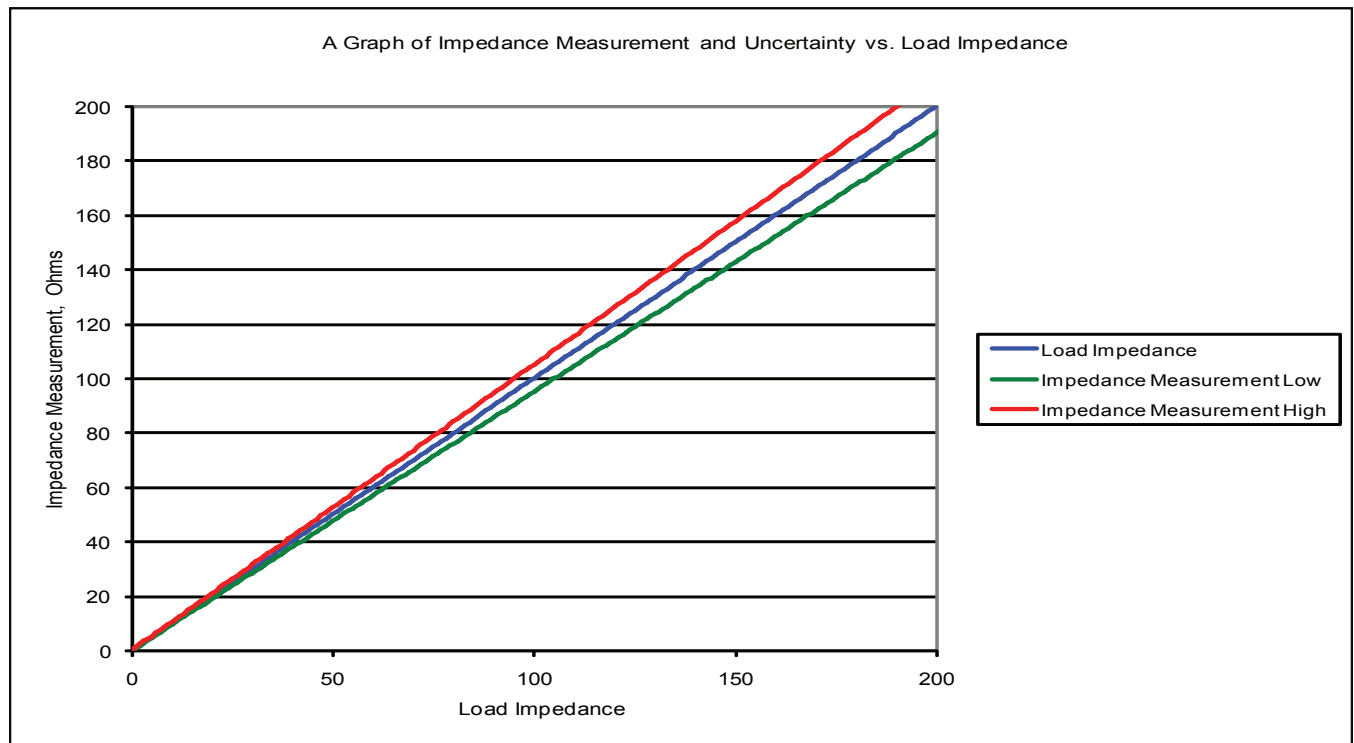


Figure 58 - Electrosurgical Impedance Measurement versus Load Impedance

# Generator G11 Service Manual

## Measurement Uncertainty versus Load Impedance

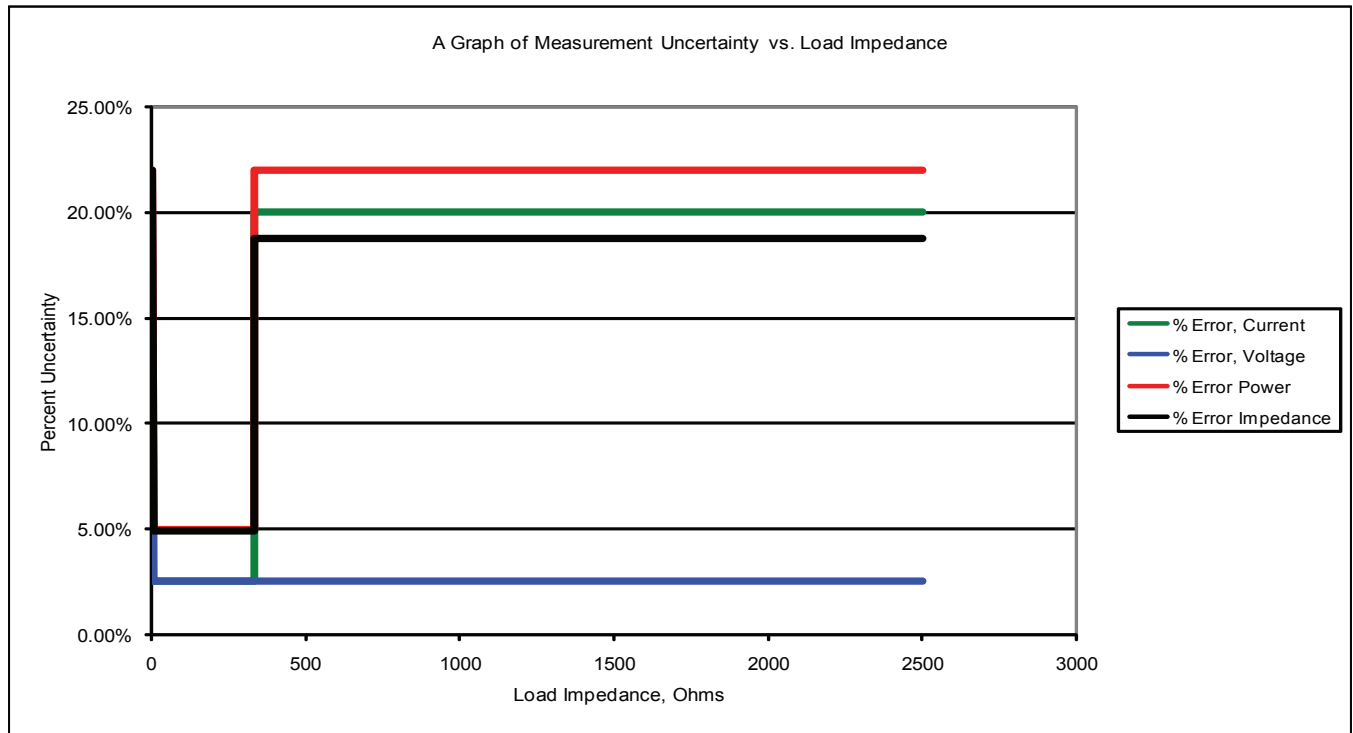


Figure 59 - Electrosurgical Measurement Uncertainty versus Load Impedance

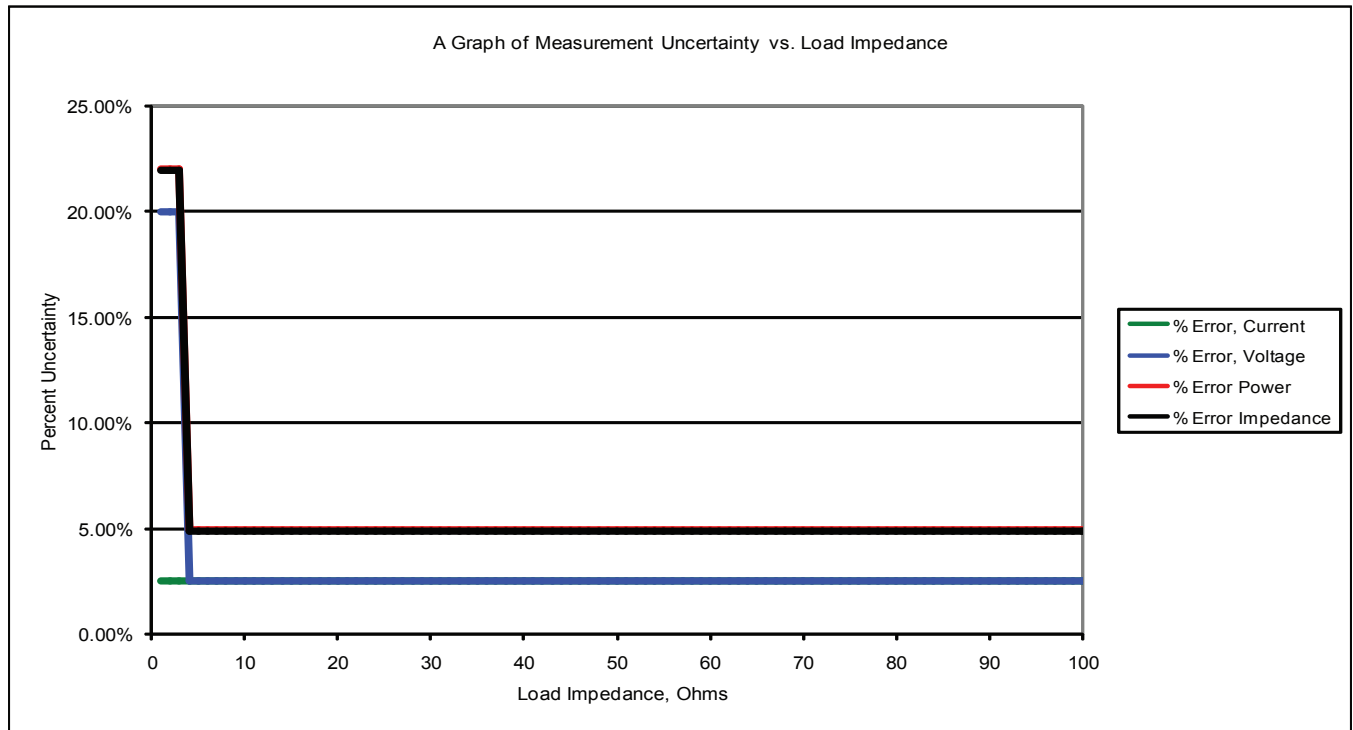


Figure 59a - Zoomed View of Electrosurgical Measurement Uncertainty versus Load Impedance

## System Specifications

|   |   |
|---|---|
| Main Fuses                                  | T5AL 250 V (Time-delay, 5 Amp, glass body, 5x20 mm package size, quantity: 2)   |
| Degree of Protection Against Electric Shock | Type CF applied part consisting of the HARMONIC or ENSEAL instruments   |
| Class of Protection Against Electric Shock  | Class 1   |
| Ingress Protection G11 Enclosure            | IP21  |
| Ingress Protection G11 Footswitch           | IP68  |
| Main Input                                  | 100 - 240 V ~, 50/60 Hz, 500 VA   |
| Output                                      | <p><b>ENSEAL Output:</b><br/> Bipolar, no neutral electrode required<br/> 100 VAC RMS maximum<br/> 135 watts maximum (rated load 15 ohms)<br/> 300 - 490 kHz (330 kHz unless otherwise marked in instrument IFU)</p> <p><b>HARMONIC Output:</b><br/> 150 VAC RMS maximum<br/> 35 watts maximum<br/> 30 - 80 kHz (55.5 kHz unless otherwise marked in instrument IFU)</p>  |
| Ambient Operating Conditions                | Temperature: 59 °F to 80.6 °F, 15 °C to 27 °C<br>Humidity: 30% - 75% non-condensing<br>Atmospheric Pressure Range: 700 hPa - 1060 hPa   |
| Transport and Storage Conditions            | Temperature: -31 °F to 129.2 °F, -35 °C to +54 °C<br>Humidity: 10% - 95% non-condensing<br>Atmospheric Pressure Range: 700 hPa - 1060 hPa   |
| Weight                                      | Generator: 13 lbs (5.9 kg)<br>Cart: 37 lbs (16.8 kg)<br>Footswitch: 8 lbs (3.6 kg)  |
| Overall Dimensions                          | Generator: 13.76" (35.0 cm) x 13.98" (35.5 cm) x 5.34" (13.6 cm)<br>Cart: 18.88" (48.0 cm) x 22.11" (56.2 cm) x 37.53" (95.3 cm)<br>Footswitch: 13.45" (34.2 cm) x 7.50" (19.0 cm) x 4.10" (10.4 cm)  |
| Power Cord                                  | <p><b>North American removable power cord set</b> with the following characteristics:<br/> Plug Style: NEMA 5-15 (clear) North American Hospital Grade<br/> Receptacle: IEC 60320 C13 with straight non-angled cord entry<br/> Cord Length: 4.6 meters nominal<br/> Current Rating: 13A<br/> Voltage Rating: 125 VAC minimum<br/> Wiring Code: North American<br/> Cordage Description: SJT (UL) or SJT (CSA)<br/> Conductors: 16 AWG 3C<br/> Agency Approvals Required: UL and CSA</p> <p><b>International removable power cord set</b> with the following characteristics:<br/> Plug Style: as needed by particular country requirements<br/> Receptacle: IEC 60320 C13 with straight non-angled cord entry<br/> Cord Length: 2.44 - 4.6 meters nominal<br/> Current Rating: 10A<br/> Minimum conductor size cross-sectional area: 1.0mm<sup>2</sup> copper<br/> Voltage Rating: 250 VAC minimum<br/> Wiring: International<br/> Cordage Type: HAR<br/> Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV</p> |

## Generator G11 Service Manual

### Electromagnetic Compatibility (EMC)

The Generator G11 requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and used in accordance with the EMC information provided in this guide. The Generator G11 is intended for use in the electromagnetic environments specified below.

**Caution:** Ensure that the Generator G11 is used only in these environments.

### Electromagnetic Emissions

| Emissions Test  | Compliance                       | Guidance  |
|---|----------------------------------|---|
| RF emissions<br>CISPR 11                                | Group 1 (per IEC 60601-2-2:2009) | The Generator G11 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.                          |
| RF emissions<br>CISPR 11                                | Class A                          | The Generator G11 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2                     | Not applicable                   |   |
| Voltage fluctuations/flicker emissions<br>IEC 61000-3-3 | Not applicable                   |   |

### Electromagnetic Immunity Guidance

For electromagnetic immunity, essential performance is: activation tones are coupled with energy output, energy output ceases when activation switches are opened, and there is no energy output without activation switch closure.

| Immunity Test                                    | IEC 60601 Test Level   | Compliance Level   | Electromagnetic Environment - Guidance  |
|--|--|--|---|
| Electrostatic Discharge<br>IEC 61000-4-2         | ± 6kV Contact<br>± 8kV Air                                   | ± 6kV Contact<br>± 8kV Air                                   | Relative humidity should be at least 30%.   |
| Electrical fast Transient/Burst<br>IEC 61000-4-4 | ± 2 kV on Power Supply Lines<br>± 1 kV on Input/Output Lines | ± 2 kV on Power Supply Lines<br>± 1 kV on Input/Output Lines | Mains power quality should be that of a typical commercial or hospital environment.   |
| Surge<br>IEC 61000-4-5                           | ± 1kV line(s) to line(s)<br>± 2kV line(s) to earth           | ± 1kV Differential Mode<br>± 2kV Common Mode                 | Mains power quality should be that of a typical commercial or hospital environment.   |
| Power Frequency Magnetic Fields<br>IEC 61000-4-3 | 3 A/m  | 3 A/m  | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |



|  |  |  |  |
|--|--|--|--|
| Voltage Dips, Short Interrupts, and Variations on Power Supply Lines<br>IEC 61000-4-11 | <5% $U_T$ (95% dip in $U_T$ for 0.5 cycles)<br><40% $U_T$ (60% dip in $U_T$ for 5 cycles)<br><70% $U_T$ (30% dip in $U_T$ for 25 cycles)<br><5% $U_T$ (>95% dip in $U_T$ ) for 5 s | <5% $U_T$ (95% dip in $U_T$ for 0.5 cycles)<br><40% $U_T$ (60% dip in $U_T$ for 5 cycles)<br><70% $U_T$ (30% dip in $U_T$ for 25 cycles)<br><5% $U_T$ (>95% dip in $U_T$ ) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Generator G11 requires continued operation during power mains interruptions, it is recommended that the Generator G11 be powered from an uninterruptible power supply or a battery.   |
| Conducted RF<br>IEC 61000-4-6  | 3 Vrms<br>150 kHz to 80 MHz  | 3 Vrms   | Portable and mobile RF communications equipment should be used no closer to any part of the Generator G11, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance:<br>$d = 1.2\sqrt{P}$  |
| Radiated RF<br>IEC 61000-4-3   | 3 V/m<br>80 MHz to 2.5 GHz   | 3 V/m  | $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz<br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup><br><br>Interference may occur in the vicinity of equipment marked with the following symbol: |



**Note:** At 80 MHz and 800 MHz, the higher frequency range applies.

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup>The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

<sup>b</sup>The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

## Generator G11 Service Manual

### Recommended separation distances between portable and mobile RF communications equipment and the Generator G11

The Generator G11 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Generator G11 can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the Generator G11 as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) |  |   |
|---|---|--|---|
|   | 150 kHz to 80 MHz<br>$d = 1.2\sqrt{P}$                        | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 1.2\sqrt{P}$ |
| 0.01  | 0.12  | 0.12                                   | 0.23                                    |
| 0.1   | 0.38  | 0.38                                   | 0.73                                    |
| 1.0   | 1.20  | 1.20                                   | 2.30                                    |
| 10  | 3.79  | 3.79                                   | 7.27                                    |
| 100   | 12  | 12                                     | 23                                      |

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Conformance to Standards

The Generator G11 conforms to the following international standards:














|  |   |
|--|---|
| <b>EN (IEC) 60601-1<br/>(with Canadian and US National Deviations)</b> | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance  |
| <b>EN (IEC) 60601-1-2</b>  | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests  |
| <b>EN (IEC) 60601-2-2</b>  | Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment  |
| <b>EN (IEC) 60601-1-8</b>  | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |













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## Generator G11 Service Manual

## Symbols

|   |   |
|---|---|
|    | Footswitch  |
|    | Non-ionizing Radiation  |
|    | Equipotential Ground Lug  |
|    | Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU. Follow decontamination instructions before returning waste. |
|    | Authorized Representative in the European Community   |
|   | Manufacturer  |
|  | On/Off Switch   |
|  | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.   |
|  | Keep Dry  |
|  | Date of Manufacture   |
|  | Reorder Number  |
|  | Serial Number   |
|  | Authorized Representative in the USA  |

|   |   |
|---|---|
|   | Refer to instructions manual / booklet.   |
| <b>NON-STERILE</b>  | Non-sterile   |
|    | CF Applied Part (Device Connector)  |
|    | The electronic information product (EIP) has met the requirements set forth by the People's Republic of China for marking of EIPs, and can be used during its environmental protection use period of 50 years. After the environmental protection period has expired, the EIP should be recycled. Applicable in the People's Republic of China. |
|    | Fuse  |
|    | Product is certified by a Nationally Recognized Testing Laboratory.   |
| <br>GEN11   | Consult the Generator G11 Operator's Manual.  |
|    | Recyclable Packaging  |
|    | Relative Humidity   |
|    | Temperature   |
|    | Low Alarm   |
|    | Medium Alarm  |





P43566P03

Group: Package Labeling Drawing  
Type: Manual Service

State: Released  
NSR/SR:

REF  
GEN11, CRT11

|    |     |
|----|-----|
| EC | REP |
|----|-----|

Ethicon Endo-Surgery (Europe) GmbH  
Hummelsbuetteler Steindamm 71  
22851 Norderstedt  
GERMANY

|     |     |
|-----|-----|
| USA | REP |
|-----|-----|

Ethicon Endo-Surgery, Inc.  
4545 Creek Road, Cincinnati, OH 45242-2839 USA  
1-800-USE-ENDO



ETHICON ENDO-SURGERY, LLC  
Guaynabo, Puerto Rico 00969 USA

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