Generator G11 (GEN11)

Operator's Manual

For use with Software Version 2016-1

ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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Table of Contents

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Overview

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences. This manual contains important information for operation of the Generator G11. It should be kept where it may be referenced during usage, especially for screen translations. Print or copy pages as necessary to keep nearby.

Important: This manual is designed to provide instructions for use of the Generator G11. It is not a reference to surgical techniques. Go to *www.e-ifu.com* for the latest version of this manual.

Standard Conventions Used

The Use of WARNING, Caution, 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 WARNING, a Caution, 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 procedure, 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 instrument. Connectors (HGA11 for HARMONIC and EGA11 for ENSEAL) are used to enable the generator to power legacy instruments.

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 ENSEAL or HARMONIC instruments are not included in this packaging and must be purchased separately. The HARMONIC instrument connector (HGA11), ENSEAL instrument connector (EGA11), footswitch (FSW11) and cart (CRT11) are also available separately.

Illustration and Nomenclature

Front Panel of the Generator

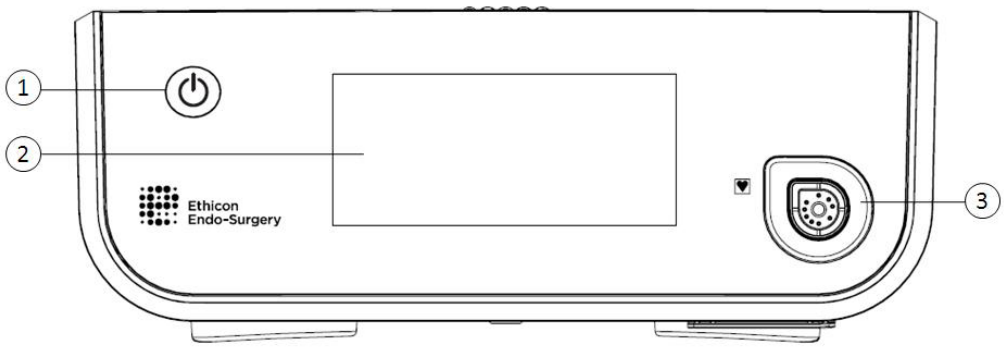


Figure 1

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

Back Panel of the Generator

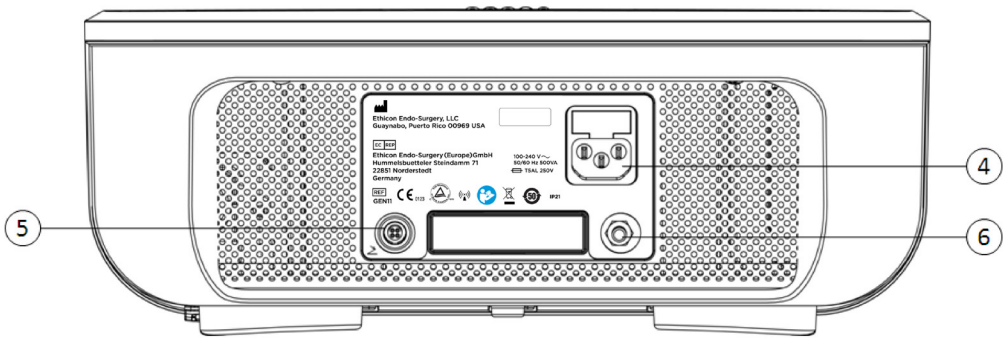


Figure 2

4	POWER CORD RECEPTACLE	Receptacle used to attach the power cord to the generator.
5	FOOTSWITCH RECEPTACLE	Receptacle used to connect the footswitch to the generator.
6	POTENTIAL EQUALIZATION TERMINAL	Provides means for connection to a potential equalization conductor.

Footswitch

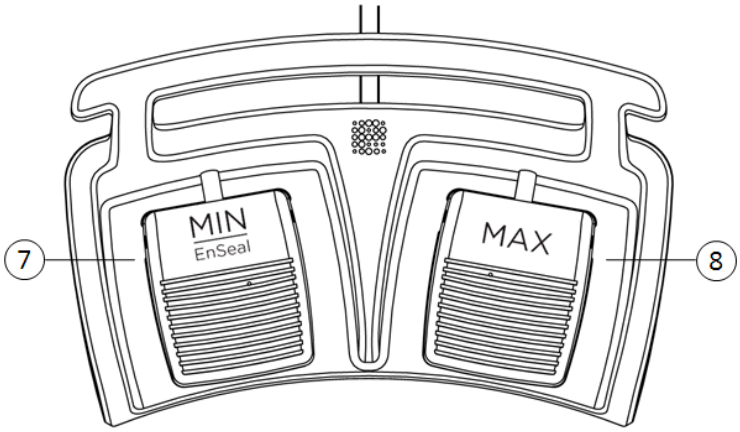


Figure 3A

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

Cart

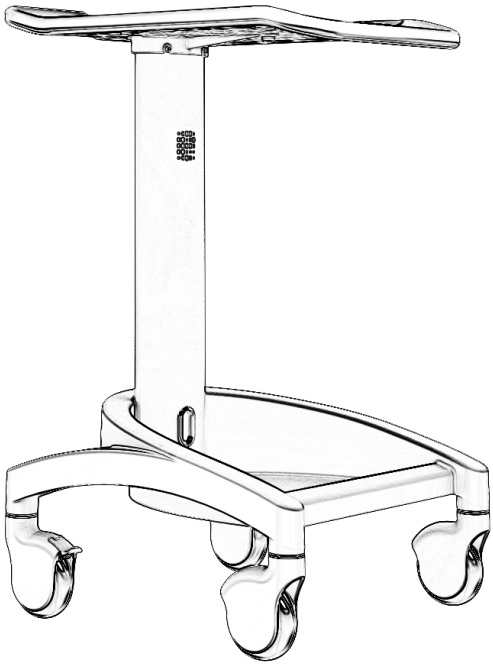


Figure 3B

General Warnings

- Verify that the unit is fully operational prior to administering power output for tissue sealing.
- 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.
- Do not use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen as combustion may occur.
- Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of electrosurgery. There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before the electrosurgery. Attention should be called to the danger of ignition of endogenous or other flammable gases. Some materials, for example cotton and gauze, when saturated with oxygen may be ignited by sparks produced in normal use during electrosurgery.
- Do not operate 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 operate the unit in close proximity to volatile solvents such as methanol or alcohol as combustion may occur.
- Avoid use of the 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.
- 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.
- For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.
- Use of 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.
- Other than fuses, the Generator G11 contains no operator-serviceable parts. For service, return the generator to an authorized Ethicon service facility.

- 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 that access to these points are kept clear.
- This device is neither MR safe nor MR compatible.
- This device seals vessels up to a maximum diameter of 7 mm depending on the instrument used. Refer to the instrument Instructions For Use (IFU) for further information.
- As with all energy sources (Electrosurgery, Lasers, or Ultrasound) there are concerns about the carcinogenic and infectious potential of the by-products such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- In case of system failure, ensure availability of the appropriate backup equipment relevant to the specific procedure.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Read instructions prior to use and follow the hospital's clinical practice guidelines for ultrasonic surgery, electrosurgery, gynecology and laparoscopic procedures.
- Replace fuses only with the appropriate type and rating. See *System Specifications*.
- Activation of a radiofrequency device when not in contact with target tissue or in a position to deliver energy may cause capacitive coupling.
- The patient should not come in contact with metal parts which are earthed (grounded) or which have appreciable capacitance to earth (for example operating table supports, etc.).
- Cables to the surgical electrodes should be positioned so that contact with patient or other leads is avoided.

General Cautions

- The touch screen display of the generator is very sensitive. Do not use sharp metal objects on the touch screen.
- Removing bottom screws or opening of this device invalidates the warranty and could create hazardous conditions.
- 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.
- Monitoring electrodes should be placed as far as possible from the disposable device tips when high frequency surgical equipment and physiological monitoring equipment are used simultaneously. Monitoring systems incorporating high frequency current-limiting devices are recommended for use.
- Needle monitoring electrodes are not recommended.
- CRT11 is recommended if the Generator G11 is moved out of the operating room. Maintain control of the generator and cart when moving over thresholds.

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 judgment, 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 Customer Service Department or your local representative for any customer or technical support.

1-877-ETHICON

+1-513-337-8901 (English)

Chapter 2 - Instructions for Use - HARMONIC Instruments

Setup

Caution: Do not block the air vents of the generator to avoid generator overheating.

1 Examine the Generator G11 and the HARMONIC instrument for damage. Do not use damaged devices.

2 Secure the generator on its cart or any other suitable fixture in the appropriate position.

3 Connect the power cord to the power cord receptacle on the back panel of the generator and to a grounded electrical outlet. The power requirements for the Generator G11 are listed on the label on the back panel of the generator.

4 Connect the footswitch connector to the footswitch receptacle on the back panel of the generator if applicable.

5 Connect the HARMONIC instrument to the Generator G11.

- If the plug looks like the image below, connect the instrument directly to the Generator G11 receptacle.

Figure 4

- If the plug looks like the image below, use the connector as an interface between the instrument and the generator.

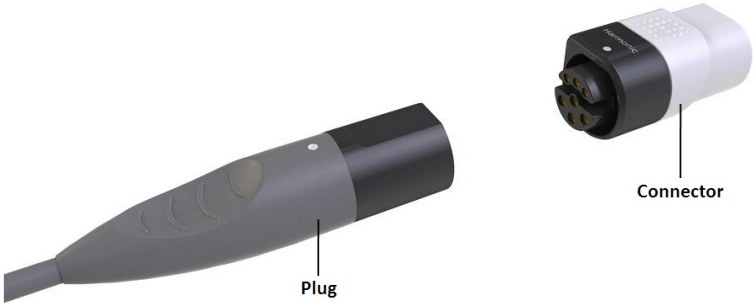


Figure 5

Caution: Verify that the generator is secured to the cart or any other suitable fixture before powering up.

6 Turn on the generator using the On/Off switch on the front panel of the generator.

7 The green standby indicator illuminates and the system will run its initiation sequence. A tone is heard during the initiation sequence. When the initiation sequence is complete the test prompt screen appears.

8 Follow the instructions on the screen to run the test.

9 The HARMONIC ready screen appears and the generator is ready for use.

Ready Screen Features

The HARMONIC ready screen has the following features:

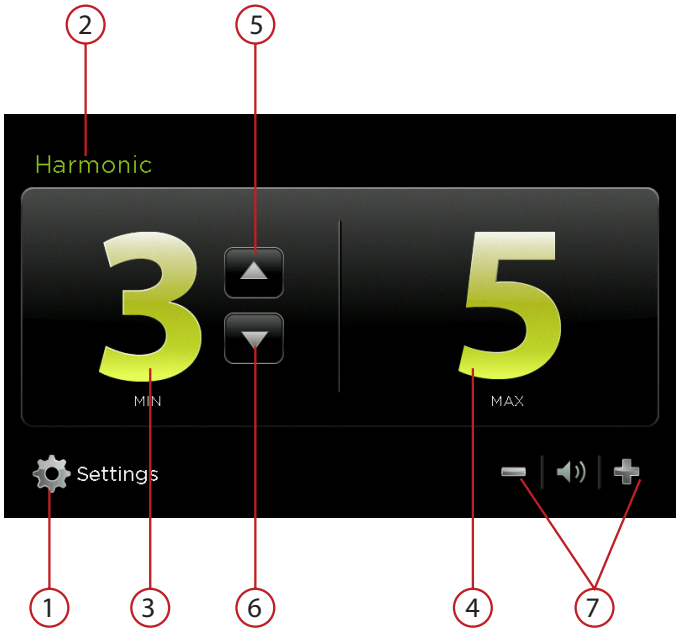


Figure 6A

1	SETTINGS	Touch this button to go to the system settings.
2	INSTRUMENT SPECIFICATION	Indicates the instrument in use.
3	MIN	Indicates the user-adjustable minimum power level setting. When this power level is activated (by footswitch or handswitch), the 'MIN' indicator will flash. The system defaults to 'MIN' power level 3. Refer to the individual instrument package inserts for the recommended minimum power level.
4	MAX	Indicates the maximum power level setting. This setting is always 5. When this power level is activated (by footswitch or handswitch) the 'MAX' indicator will flash.
5	POWER LEVEL INCREASE	Touch this button to increase the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the screen. The power level may be adjusted when the generator is ready.
6	POWER LEVEL DECREASE	Touch this button to decrease the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the screen. The power level may be adjusted when the generator is ready.
7	VOLUME	Touch the plus or minus button to adjust the volume of the activation tones. A tone is heard to indicate the volume level selected.

Operation

Minimum or maximum power is activated from the HARMONIC instrument or from the footswitch.

Use the left pedal on the footswitch for activating minimum power and use the right pedal for maximum power.

During minimum activation, the MIN area on the generator screen will glow green and pulse. During maximum activation the MAX area will glow green and pulse. As the power is activated, audio feedback is initiated.

The default power level value is 3 for the minimum. Touch the power level increase or the power level decrease button to increase or decrease the level of power to be generated in this mode.

Note: Only the MIN power level setting is adjustable. The MAX power level setting is always set to 5.

Volume

Adjust the volume using the plus or minus button. Default volume setting is 5.

Shutdown

Turn off the generator using the On/Off switch on the front panel of the unit.

The shutdown sequence cannot be initiated during power activation. During shutdown, the generator clears content from the screen, informs the user if 10 or fewer hand piece uses remain for the attached hand piece and displays the shutdown animation.

Ready Screen Features

Some HARMONIC ready screens have the following features. The instrument name will be displayed after HARMONIC on the screen.

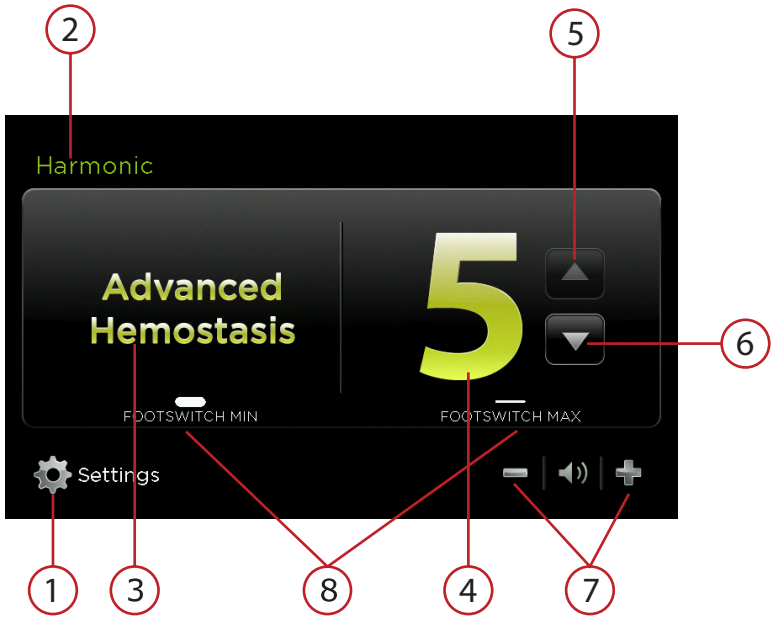


Figure 6B

1	SETTINGS	Touch this button to go to the system settings.
2	INSTRUMENT SPECIFICATION	Indicates the instrument in use.
3	ADVANCED HEMOSTASIS	Indicates the Advanced Hemostasis Mode if available on the connected instrument. Min button of the footswitch is used to activate Advanced Hemostasis functionality when this screen is displayed.
4	MAX	Indicates the adjustable power level setting between 1 and 5. The power level may be adjusted when the generator is ready. The maximum power is always 5. When this power level is activated (by footswitch or handswitch) the 'MAX' indicator will flash.
5	POWER LEVEL INCREASE	Touch this button to increase the maximum (MAX) power setting to the desired level (from 1 to 5). The level chosen will be shown on the screen. The power level may be adjusted when the generator is ready.
6	POWER LEVEL DECREASE	Touch this button to decrease the maximum (MAX) power setting to the desired level (from 1 to 5). The level chosen will be shown on the screen. The power level may be adjusted when the generator is ready.

7	VOLUME	Touch the plus or minus button to adjust the volume of the activation tones. A tone is heard to indicate the volume level selected.
8	FOOTSWITCH MIN & MAX	Footswitch MIN & MAX are available when the footswitch is connected.

Operation

Only the MAX power level setting is adjustable between 1 and 5 and is activated using HARMONIC instrument or from the footswitch.

The default power level value is 5. Touch the power level increase or the power level decrease button to increase or decrease the level of power to be generated in this mode.

Volume

Adjust the volume using the plus or minus button. Default volume setting is 5.

Shutdown

Turn off the generator using the On/Off switch on the front panel of the unit.

The shutdown sequence cannot be initiated during power activation. During shutdown, the generator clears content from the screen, informs the user if 10 or fewer hand piece uses remain for the attached hand piece and displays the shutdown animation.

Settings

Basic Navigation

Touch the 'Settings' button to make adjustments in the system settings and access system information.

The settings screen opens. Scroll down for further options.

Note: If power is activated while in the Settings menu, the Settings window automatically closes and returns to the ready screen.

Touch the close button 'X' to exit from anywhere within the Settings menu. Touch the back arrow to go to the previous menu from the submenu screens.

Note: The touch screen responses will be slower when electrosurgery is in close proximity to minimize interferences.

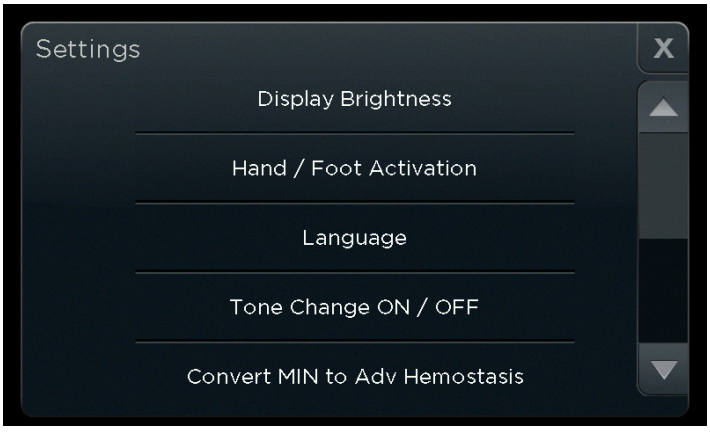


Figure 7

Display Brightness

Select 'Display Brightness' to see a preview of the ready screen while adjusting the brightness.

Touch the plus or minus button to adjust the brightness.

Touch the back arrow or close button after adjusting the settings to exit. Once a new brightness setting is selected that setting becomes the new system default.

Hand / Foot Activation

Select the handswitch activation or the footswitch activation or both on the 'Hand / Foot Activation' screen during startup. This selection can be changed during use.

A dot is used to indicate the current setting while a green glow highlights the current selection.

Touch the back arrow or close button after adjusting the settings to exit.

Language

Select the preferred language from the options in the 'Language' screen. There are multiple language options, English being the default. Once the user selects and confirms the selection of a new language, that language becomes the new system default.

Touch the desired option, a confirmation screen will appear.

Select 'OK' to confirm the language selection or 'Cancel' to cancel the language change.

Tone Change ON/OFF

Some instruments enable additional tone changes within the generator. When this option is selected, the Tone Change ON/OFF screen will appear, allowing the user to select the Tone Change ON or Tone Change OFF options. Refer to the instrument instructions for use to determine if your instrument has this feature.

Convert MIN to Adv Hemostasis

Some instruments enable this menu option. When this option is selected, the MIN button will function as the Advanced Hemostasis Mode button, and the Advanced Hemostasis Mode button will be disabled. Refer to the instrument instructions for use to determine if your instrument has this feature.

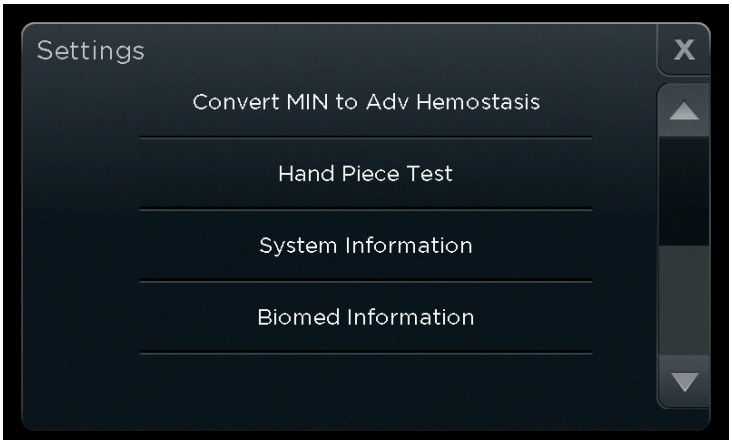


Figure 8

Hand Piece Test

Select 'Hand Piece Test' to check if the hand piece is functioning properly by installing a test tip and running the test with no instrument attached. Screen instructions and results are given for the specific hand piece to be tested. Hand Piece Test is grayed out when this option is not available for some instruments.

System Information

Select 'System Information' to see high-level information about the generator and the instrument currently connected to the generator. The hospital staff can use the information to determine if a new hand piece should be ordered. The screen will also allow determination of the currently installed generator software revision.

Biomed Information

'Biomed Information' allows the technicians to access information about each error that has occurred on the generator and allows access to a 'Biomed Mode' display that streams data during instrument use. Touch the back arrow or close button to exit.

Warning

The active blade of a HARMONIC instrument heats the tissue by friction and is intended to supply sufficient friction and shearing effect to cut and coagulate tissue in contact with the active blade. Therefore, use caution when handling the blade, clamp arm, and distal end of the shaft, as they may be hot. Additional temperature information may be contained in individual instrument instructions for use.

English

Chapter 3 - Instructions for Use - ENSEAL Instruments

Setup

Caution: Do not block the air vents of the generator to avoid generator overheating.

1 Examine the Generator G11 and the ENSEAL instrument for damage. Do not use damaged devices.

2 Secure the generator on its cart or any other suitable fixture in the appropriate position.

3 Connect the power cord to the power cord receptacle on the back panel of the generator and to a grounded electrical outlet. The power requirements for the Generator G11 are listed on the label on the back panel of the generator.

4 Connect the footswitch connector to the footswitch receptacle on the back panel of the generator if applicable.

5 Connect the ENSEAL tissue sealing instrument to the Generator G11. Refer to instrument instructions for use.

- If the plug looks like the image below, connect the instrument directly to the Generator G11 receptacle.

Figure 9

- If the plug looks like the image below, use the connector as an interface between the instrument and the generator.

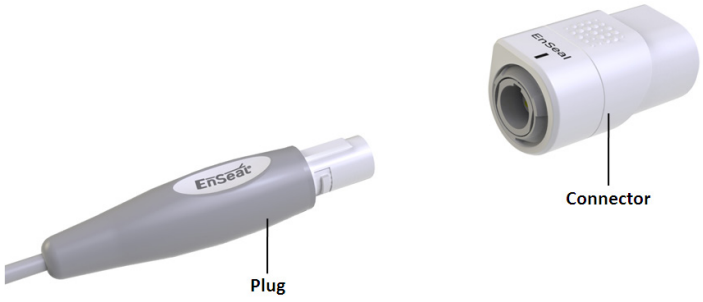


Figure 10

Caution: Verify that the generator is secured to the cart or any other suitable fixture before powering up.

6 Turn on the generator using the On/Off switch on the front panel of the generator.

7 The green standby indicator illuminates and the system will run its initiation sequence. A tone is heard during the initiation sequence. When the initiation sequence is complete, the ENSEAL ready screen appears and the generator is ready for use.

Ready Screen Features

The ENSEAL ready screen has the following features:

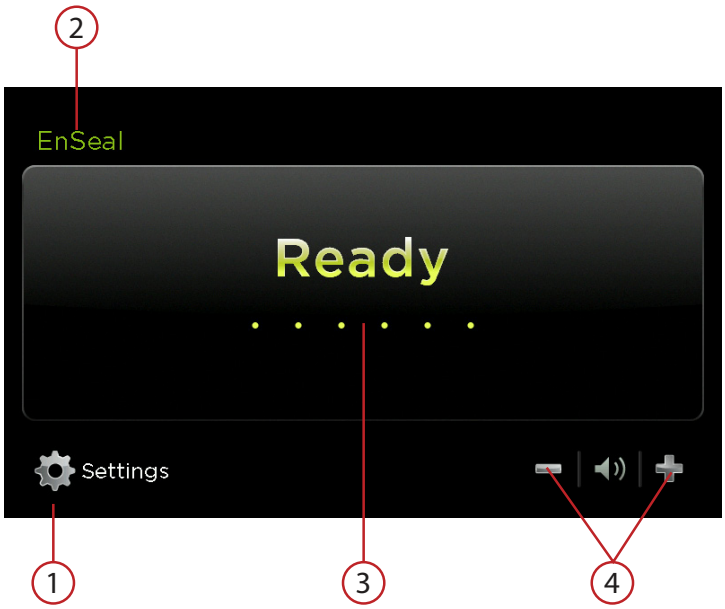


Figure 11

1	SETTINGS	Used to go to the system settings.
2	INSTRUMENT SPECIFICATION	Indicates the instrument in use.
3	READY	System ready display.
4	VOLUME	Touch the plus or minus button to adjust the volume of the activation tones. A tone is heard to indicate the volume level selected.

Operation

Power is activated from the ENSEAL instrument or from the left pedal of the footswitch. The ENSEAL instrument has only one mode of operation. There are no power level settings. When power is activated, audio feedback is initiated. When the upper impedance threshold is reached and before the knife has been fully advanced, the audio feedback changes into a higher pitch tone. When both the upper impedance threshold has been reached and the knife has been fully advanced (handle is fully closed), a single tone sounds, indicating a complete cycle. Always advance the knife under power. The single tone for a complete cycle is the only indication of a complete cycle and cut.

Volume

Adjust the volume using the plus or minus button. Default volume setting is 5.

Shutdown

Turn off the generator using the On/Off switch on the front panel of the unit.

The shutdown sequence cannot be initiated during power activation. During shutdown, the generator clears content from the screen and displays the shutdown animation.

English

Settings

Basic Navigation

Touch the 'Settings' button to make adjustments in the system setup and access system information.

The settings screen opens. Scroll down for further options.

Note: If power is activated while in the Settings menu, the Settings window automatically closes and returns to the ready screen.

Touch the close button 'X' to exit from anywhere within the Settings menu. Touch the back arrow to go to the previous menu from the submenu screens.

Figure 12A

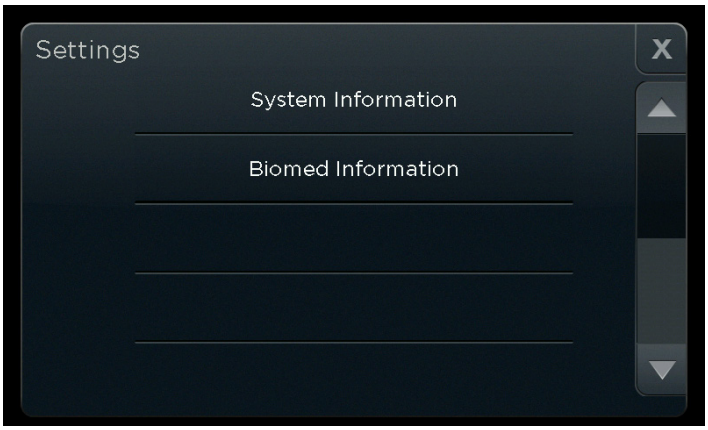


Figure 12B

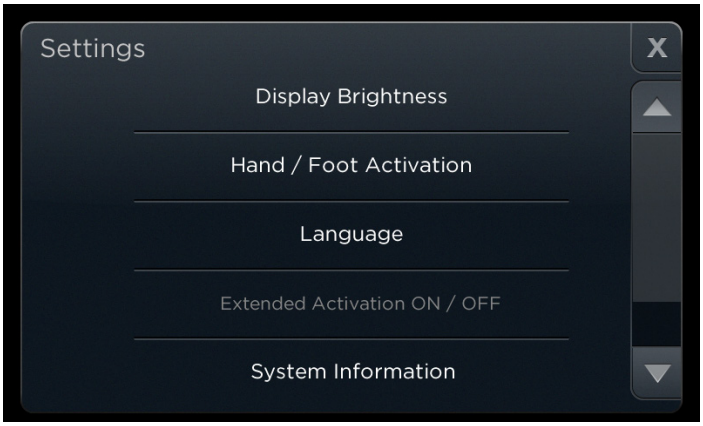


Figure 12C

Display Brightness

Select 'Display Brightness' to see a preview of the ready screen while adjusting the brightness.

Touch the plus or minus button to adjust the brightness.

Touch the back arrow or close button after adjusting the settings to exit. Once a new brightness setting is selected that setting becomes the new system default.

Hand / Foot Activation

Select the handswitch activation or footswitch activation or both on the 'Hand / Foot Activation' screen during startup. This selection can be changed during use.

A dot is used to indicate the current setting while a green glow highlights the current selection.

Touch the back arrow or close button after adjusting the settings to exit.

Language

Select the preferred language from the options in the 'Language' screen. There are multiple language options, English being the default. Once the user selects and confirms the selection of a new language that language becomes the new system default.

Touch the desired option, a confirmation screen will appear.

Select 'OK' to confirm the language selection or 'Cancel' to cancel the language change.

Extended Activation

Some ENSEAL instruments allow the ability for use in Extended Activation Mode. When this option is selected, the Extended Activation ON/OFF screen will appear, allowing the user to select the Extended Activation ON or Extended Activation OFF options. When this mode is enabled and the instrument is being activated, the generator will deliver energy for as long as 2 minutes. Tone 3 (Cycle Complete) will not be received during an activation cycle while this mode is enabled. Energy delivery can be terminated at any moment by releasing the footswitch or hand activation button. If the instrument is unplugged or the generator is powered down while 'Extended Activation ON' is selected the generator will revert to the system default setting of 'Extended Activation OFF'. This feature is grayed out when not available for some ENSEAL instruments.

System Information

Select 'System Information' to see high-level information about the generator and the instrument currently connected to the generator. The screen will also allow determination of the currently installed generator software revision.

Biomed Information

'Biomed Information' allows the technicians to access information about each error that has occurred on the generator. Touch the back arrow or close button to exit.

English

Chapter 4 - Troubleshooting and Screen Guide

General Troubleshooting

Informative Screens

The user interface for the Generator G11 has a number of informative screens to guide the efficient use of the generator. Informative screens will maintain a consistent dark background to differentiate them from the alarm screens shown below.

Alarm System

The Generator G11 includes integrated diagnostics that monitor the operation of the generator and accessories and flash either informative screens or alarms with no delay. In addition to audible alarm sounds, the display of alarms on the front panel is easily observable by the surgeon or nursing staff from the surgical field. All alarms are technical alarms and are based on electrical parameters. There are no physiological alarms that are produced by the Generator G11.

Alarm settings are not adjustable by the operator nor can priority be reassigned. Alarm settings also do not adjust to operator inputs nor do they change through power loss. The Power on Self Test (POST) verifies that the generator is operational. Since the alarms are integrated into the software algorithms responsible for running the appropriate instruments, the POST also verifies alarm operation. Therefore, a separate test for verifying the alarm output is not required. During the POST an audio tone is emitted from the generator so the user can verify that the audio output is operational. Visual output can also be verified through the start up screens. Alarm audio cannot be paused but audio automatically ends when the user discontinues activation of the instrument.

Alarms and other events are logged in the generator. The log is retained after power is removed and is accessed through the biomed screen. There is no reminder signal.

Audio Sound Pressure Levels

- Medium level alarms: Greater than 75 dBA (not adjustable)
- Low level alarms: Within 70 - 75 dBA (not adjustable)

Alarm Definitions

The following alarm priorities are used for the Generator G11. All alarms stop generator output and high priority alarms will take precedence over lower priority alarms. Only one alarm will be displayed at a time since any alarm stops output.

Low Priority Alarms

Requires surgical staff attention for continued, efficient procedural progress. A low priority issue will not generally progress to a hazardous condition even if not addressed promptly but it must be addressed to continue the procedure. The screen shows a solid yellow background with a low priority alarm symbol. A two-tone audio alarm sound accompanies a low priority alarm.

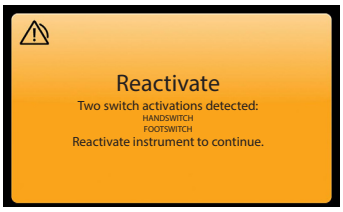
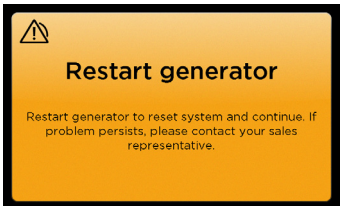
Medium Priority Alarms

Requires prompt surgical staff attention to reduce or mitigate a hazardous condition. Ignoring this alarm can result in a serious injury or death. The screen shows a solid yellow background with a flashing medium priority alarm symbol. A three-tone audio alarm sound accompanies a medium priority alarm.

High Priority Alarms

There are no high priority alarm conditions in the Generator G11.

The following are the general low priority alarms:

Visual Alarms	Description	Troubleshooting Steps
	Two activation switches are closed in the system. This may be due to a stuck switch or the inadvertent closure of an additional switch.	Reactivate instrument to continue. If the surgical staff has activated only one switch, replace the instrument or footswitch that may have the stuck switch.
	A system reset is required.	Remove the instrument from the incision and cycle the generator power using the Power On/Off switch on the front of the panel. If the problem persists, please send the generator to an authorized Ethicon service center.
	A system reset is required.	Press OK to return to the state the system was in when the error occurred. If problem persists, please send the generator to an authorized Ethicon service center.
	A general issue with the system (This screen indicates an internal error with the cooling fans of the generator)	Contact your Ethicon sales representative OR Please send the generator to an authorized Ethicon service center.
	The generator is overheating.	Remove any obstructions from the air vents at the back and bottom of the generator. If the air vents are not blocked and the problem persists return the generator to an authorized Ethicon service facility.
	The instrument requires a generator software upgrade.	Contact your Ethicon sales representative for a software upgrade.

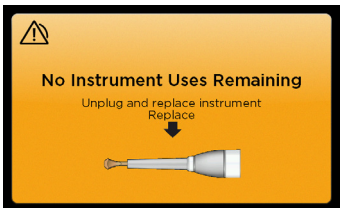
HARMONIC Troubleshooting

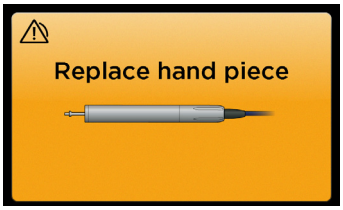
Note: The following alarms are specific to HARMONIC instrument used with the Generator G11.

Alarms

The Generator G11 supports the following alarms to help in the identification and troubleshooting of component problems when using a HARMONIC instrument. The following list is meant as an adjunct to, but not a substitute for clinical judgment and observation.

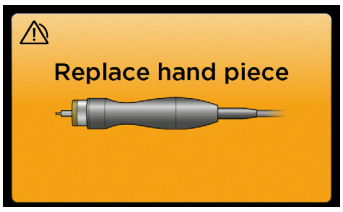
Other than fuses the Generator G11 contains no operator-serviceable parts. For replacement or service, contact the Ethicon Customer Service Department or your local representative.

Visual Alarms	Description	Troubleshooting Steps
	The hand piece has reached the end of life.	Replace the hand piece. Contact the Ethicon Customer Service Department (call 1-877-ETHICON, +1-513-337-8901 (English) or contact your local sales representative to discuss local waste disposal solutions and processes.
		
		
	The instrument has reached the end of life.	Unplug and replace instrument. Dispose of instrument per instrument instructions for use.
		
		



The hand piece has failed to perform the internal diagnostic routines and the generator will not be able to operate the hand piece reliably.

Replace the hand piece. Contact the Ethicon Customer Service Department (call 1-877-ETHICON, +1-513-337-8901 (English) or contact your local sales representative to discuss local waste disposal solutions and processes.



The instrument has been loaded to the point where output has stopped.

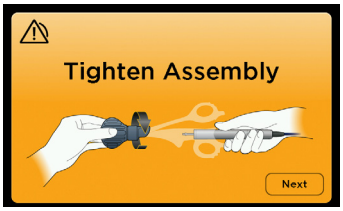
Relax pressure on the instrument or reposition so there is less tissue in the jaws. Release the activation switch and reactivate the instrument to continue.

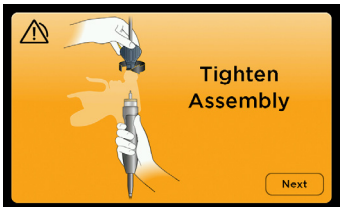
This screen is a prelude to further diagnostics. To avoid inadvertent tissue damage during diagnostics the surgeon is guided to remove the instrument from the incision before proceeding.

Remove the instrument from the incision. When the instrument is clear, touch the 'Next' button for further diagnostic guidance.

The HARMONIC instrument may be damaged and cannot be activated.

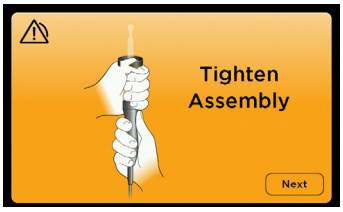
Unplug the hand piece and replace the instrument.





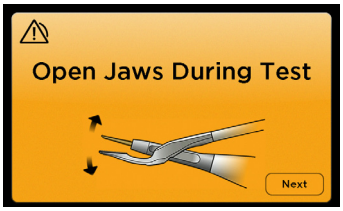
The instrument may not be properly assembled to the hand piece.

Press the 'Next' button to continue.
Re-tighten the instrument. Ensure that one hand is holding the appropriate torque wrench and the other hand is holding the hand piece (not the instrument).



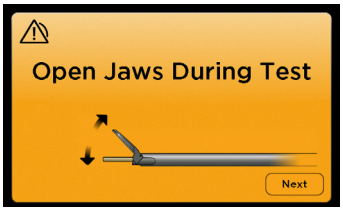
The instrument may not be properly assembled to the hand piece.

Press the 'Next' button to continue.
Re-tighten the instrument. Ensure that one hand is holding the appropriate torque wrench and the other hand is holding the hand piece (not the instrument).



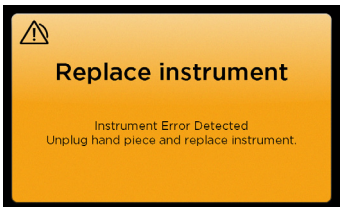
If using shears, keep jaws of instrument open during test.

Press 'Next' to advance, to retry test with jaws open.



If using shears, keep jaws of instrument open during test.

Press 'Next' to advance, to retry test with jaws open.



Indicates an internal error with the instrument that prevents it from being used.

Unplug the hand piece and replace the instrument.

Note: If multiple instruments have indicated an instrument error on the same hand piece, try replacing the hand piece to ensure that the issue is related to the instruments.

A system reset is required.

Reactivate instrument to reset system and continue.

Indicates an internal error with the identification circuitry in the instrument. Special circuitry is installed on certain advanced instruments to identify the device to the generator and tailor the generator's output to the instrument.

Unplug hand piece and replace instrument.

Instrument error detected for integrated transducer instruments

Indicates an incompatible instrument

Attach a compatible instrument

Indicates an internal error that may be either with the hand piece or the instrument.

Change hand piece first. Please contact your sales representative to screen current hand piece for errors. If problem persists, unplug hand piece and replace instrument

ENSEAL Troubleshooting

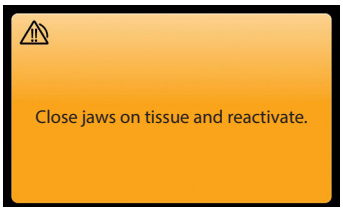
Note: The following alarms are specific to ENSEAL instrument used with the Generator G11.

Alarms

The Generator G11 supports the following alarms to help in the identification and troubleshooting of component problems when using an ENSEAL tissue sealing instrument. The following list is meant as an adjunct to, but not a substitute for clinical judgment and observation.

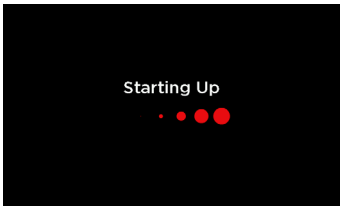
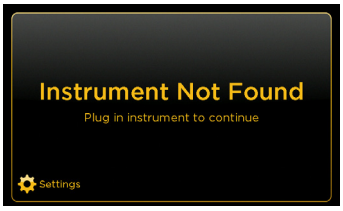
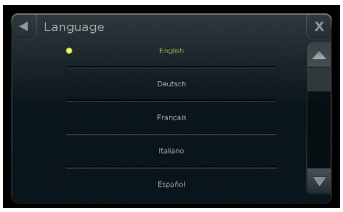
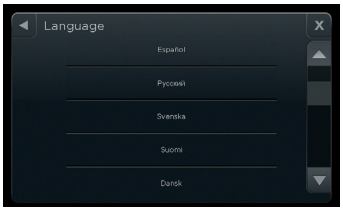
Other than fuses the Generator G11 contains no operator-serviceable parts. For replacement or service contact the Ethicon Customer Service Department or your local representative.

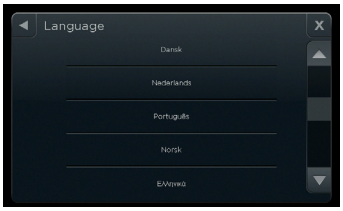
Caution: When an alarm sounds, the generator output stops. If the jaws are closed on tissue and an alarm sounds, do not advance the knife. If the knife is advanced, do not release the instrument. Add additional clamping as necessary to prevent blood loss before releasing the instrument.

Visual Alarms	Description	Troubleshooting Steps
	Instrument is being activated on low impedance (thin) tissue or metal (such as staples, clips, retractors, or clamps).	Reposition the instrument jaws and reactivate.
	The same alarm has triggered three times in a row. There may be an issue in the instrument.	Replace the instrument.
		
	Indicates an internal issue with the identification circuitry in the instrument. Special circuitry is installed on certain advanced instruments to identify the instrument to the generator and tailor the generator's output to the instrument.	Replace the instrument.
	This is a medium priority alarm. The generator cannot deliver energy. (The instrument may cut tissue without a seal if the surgeon advances the knife.)	If the instrument jaws are open, close jaws on tissue and reactivate. If the jaws are closed on tissue and this alarm sounds, do not advance the knife. If the knife is advanced, do not release the instrument. Add additional clamping as necessary to prevent blood loss before releasing the instrument.

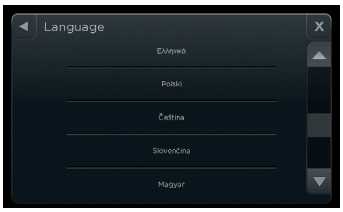
Screen Guide

General Screens

Screen	Description
	ETHICON (**Note:** Appears during system startup.)
	Starting Up (**Note:** System is starting up.)
	Instrument Not Found: Plug in instrument to continue. (**Note:** Press 'Settings' for Settings Menu.)
	System Ready (**Note:** System startup is complete.)
	Hand / Foot Activation: Both handswitch and footswitch active Only handswitch active Only footswitch active
	Language: English German French Italian Spanish
	Language: Spanish Russian Swedish Finnish Danish

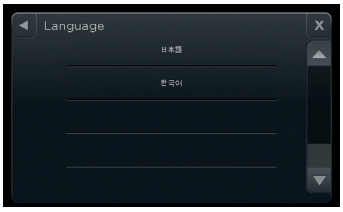


Language:
- Danish
- Dutch
- Portuguese
- Norwegian
- Greek

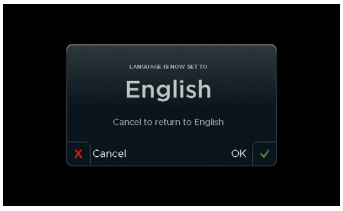


Language:
- Greek
- Polish
- Czech
- Slovak
- Hungarian

Language:
- Hungarian
- Romanian
- Turkish
- Chinese
- Japanese



Language:
- Japanese
- Korean

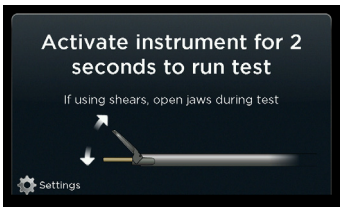
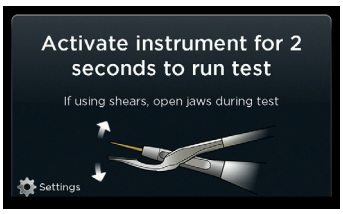
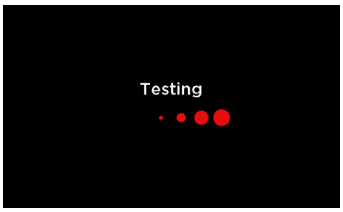


Language is now set to (name of language). Cancel to return to the previous language selected.

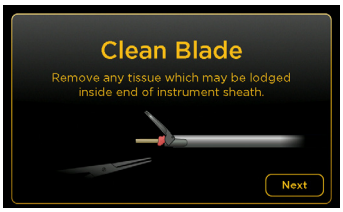
Identifying Instrument
(**Note:** System identifying new instrument just plugged into generator.)

Shutting down
(**Note:** System is shutting down.)

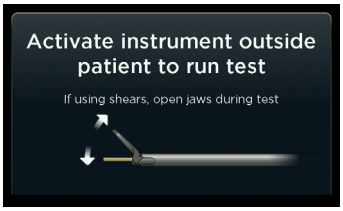
HARMONIC Screens

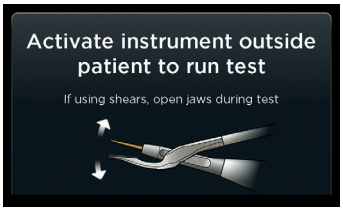
Screen	Description
	(Number of Uses) Remaining: Replace hand piece after (blank) uses.
	
	Activate instrument for 2 seconds to run test. If using shears, open jaws during test. (**Note:** Press 'Settings' for Settings Menu.)
	Activate instrument for 2 seconds to run test. If using shears, open jaws during test. (**Note:** Press 'Settings' for Settings Menu).
	Testing (**Note:** Running system test.)
	Foot Activation Off (**Note:** Reactivate with handswitch, or adjust settings. Press 'Settings' for Settings Menu.)
	Hand Activation Off (**Note:** Reactivate with footswitch, or adjust settings. Press 'Settings' for Settings Menu.)

Relax Pressure on Blade.
(**Note:** Press 'Settings' for Settings Menu.)

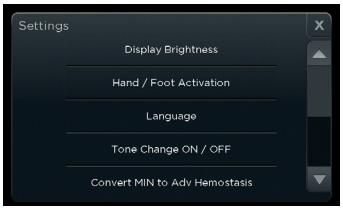


Clean Blade. Remove any tissue which may be lodged inside end of instrument sheath.
(**Note:** Press 'Next' to advance.)

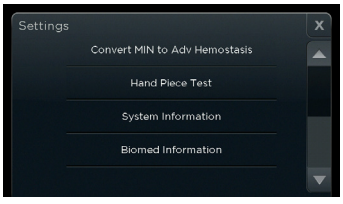




Activate instrument outside patient to run test. If using shears, open jaws during test.

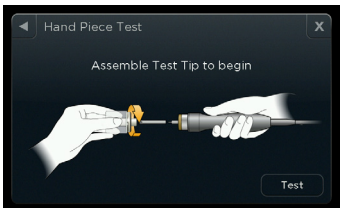


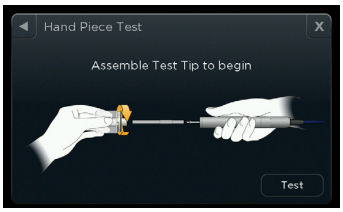
HARMONIC Settings:
- Display Brightness
- Hand / Foot Activation
- Language
- Tone Change ON/OFF
- Convert MIN to Adv Hemostasis



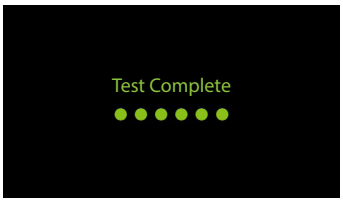
HARMONIC Settings:
- Convert MIN to Adv Hemostasis
- Hand Piece Test
- System Information
- Biomed Information

HARMONIC Display Brightness.





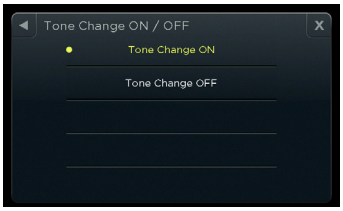
Hand Piece Test. Assemble Test Tip to begin.
(**Note:** Press 'Test' to run test.)



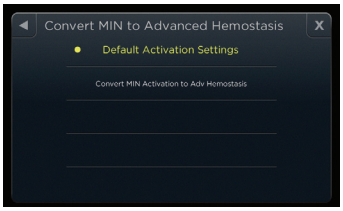
Test Complete

Hand Piece Test Results:
- Hand Piece Uses Remaining
- Phase Margin
- Impedance
- Hand Piece is Functioning Normally

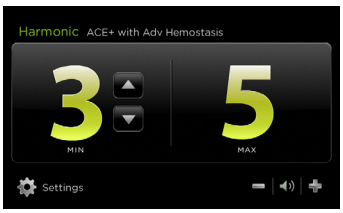
System Information:
- Software Version
- Hand Piece
- Hand Piece Uses Remaining



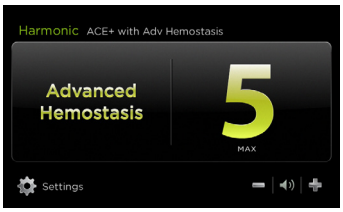
Tone Change ON/OFF
- Tone Change ON
- Tone Change OFF

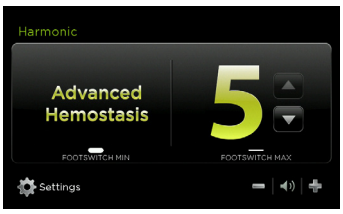


Convert MIN to Advanced Hemostasis
- Default Activation Settings
- Convert MIN Activation to Adv Hemostasis

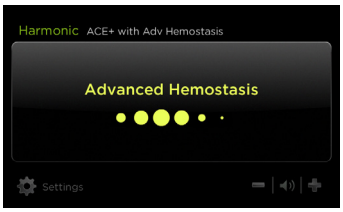


HARMONIC ACE+ with Adv Hemostasis

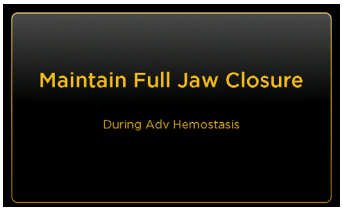




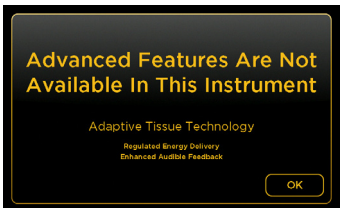
HARMONIC Shears with Advanced Hemostasis



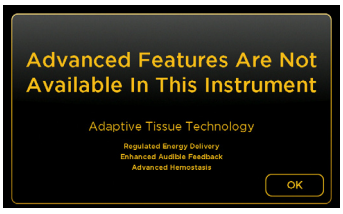
HARMONIC ACE+ with Adv Hemostasis
Advanced Hemostasis



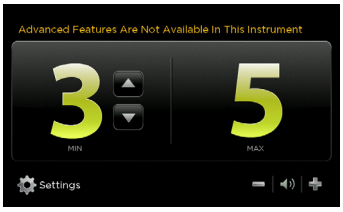
Maintain Full Jaw Closure
During Adv Hemostasis



Advanced Features Are Not Available In This Instrument
Adaptive Tissue Technology
Regulated Energy Delivery
Enhanced Audible Feedback

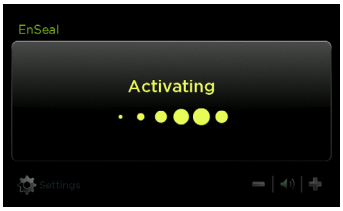
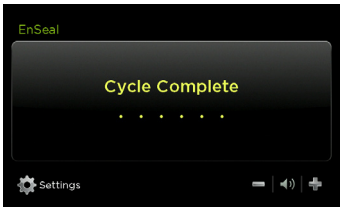
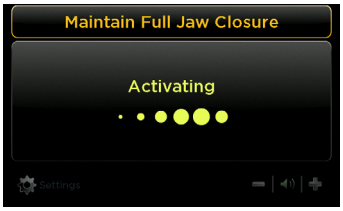
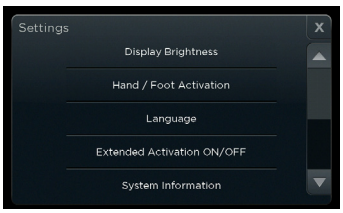
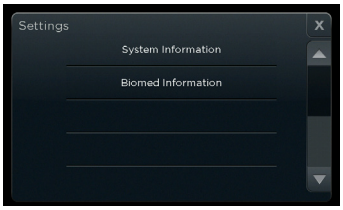
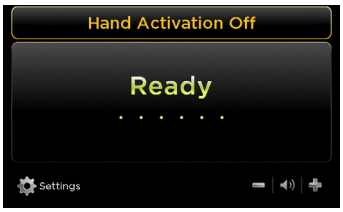


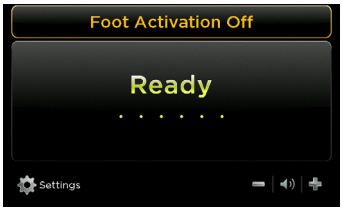
Advanced Features Are Not Available In This Instrument
Adaptive Tissue Technology
Regulated Energy Delivery
Enhanced Audible Feedback
Advanced Hemostasis Mode



Advanced features are not available in this instrument

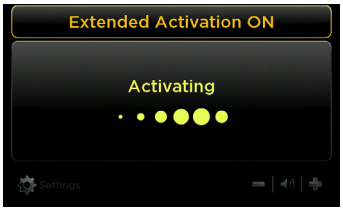
ENSEAL Screens

Screen	Description
	Activating (**Note:** Power is being activated.)
	Cycle Complete (**Note:** Cut is complete. Press 'Settings' for Settings Menu.)
	Maintain Full Jaw Closure
	Activation Cycle Timed Out: Reactivate (**Note:** Cycle Complete was not reached. Reactivate to continue. Press 'Settings' for Settings Menu.)
	ENSEAL Settings: Display Brightness Hand/Foot Activation Language Extended Activation On/Off System Information
	System Information Biomed Information
	Hand Activation Off: Ready (**Note:** Reactivate with footswitch, or adjust settings. Press 'Settings' for Settings Menu.)

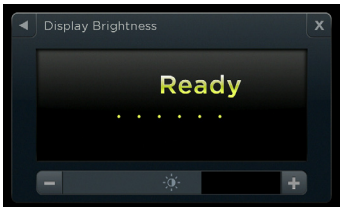


Foot Activation Off: Ready
(**Note:** Reactivate with handswitch, or adjust settings. Press 'Settings' for Settings Menu.)

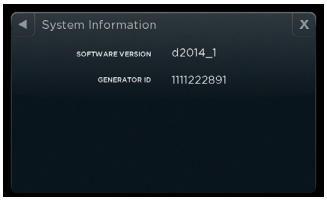
Extended Activation ON/OFF
Extended Activation OFF
Extended Activation ON



Extended Activation ON
Activating



ENSEAL Display Brightness: Ready.



System Information:
Software Version
Generator ID

Chapter 5 - Cleaning, Disinfection, Preventive Maintenance and Repair

Electrical Safety Checks

- The hospital is responsible for ensuring that the unit has an electrical safety check performed by qualified service personnel at least once a year.
- Do not remove the cover of the Generator G11. Removing the cover voids the Generator G11 warranty.

Cleaning and Disinfection Instructions

Before cleaning, thoroughly inspect the device(s) for any signs of damage, cracks, or improper mechanical function. Do not use the device(s) if there are signs of damage. Discard and replace device or send device to an authorized Ethicon service facility for repair where appropriate, if damage or degradation is present.

- Operators in North America should refer to appropriate sections of *AORN Standards & Recommended Practices* for additional guidance on cleaning. All other localities should refer to appropriate guidelines.
- The operator must qualify cleaning effectiveness when deviating from the instructions in this manual.

Generator G11 and Touchscreen

Cleaning

Clean the generator and the touchscreen following the 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 device and creates a risk of shock or fire.

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Disinfecting

If the generator becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the generator: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Connectors (HGA11 and EGA11)

Cleaning

Warning: Spilling or spraying fluids on or into the connectors or immersing the connectors may result in damage to the connectors.

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Note: Disinfection with the listed chemicals may cause discoloration or wet spots on the central metallic post of the connector that interfaces with the Generator G11 receptacle. Discoloration or wet spots on the central metallic post of the connector should not affect the connector function.

Disinfecting

If the connectors become contaminated with blood or bodily fluids, they must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the connectors: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

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Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Cart (CRT11)

Cleaning

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Disinfecting

If the cart becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the cart: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Footswitch (FSW11)

Cleaning

Note: Always keep the generator connector dry.

Proceed with wipe-down cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

If necessary, the footswitch may be immersed for cleaning as follows:

1. Immerse the footswitch and cordset (not the generator connector) in a neutral pH enzymatic detergent, prepared according to the manufacturer's recommendations.
2. Use a soft bristle brush or soft, clean cloth to manually clean the device in the detergent solution. Pay special attention to cracks and crevices.
3. Rinse off detergent thoroughly using a soft clean cloth soaked with warm tap water or by placing the footswitch under running lukewarm tap water.
4. Dry the device with a clean absorbent cloth.

Disinfecting

If the footswitch becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant or immersed in disinfectant before reuse. The following chemical disinfectants are approved for use with the footswitch: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down or immersion. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue), run affected areas under running lukewarm tap water or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Other Instruments and Accessories

For other reusable accessories not listed in this manual consult the appropriate instructions for use for guidance on disinfecting and sterilization, if required.

Maintenance and Repair

Periodic calibration is not required for the 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, the Generator G11 may also be returned to an authorized Ethicon service facility at any time.

The Generator G11 contains a Potential Equalization Terminal on the back panel. This is provided for compatibility with other medical systems requiring such connections. This conductor is not intended for protective earthing.

The software revision may be displayed on the biomed screen in the user interface.

Disposing of Ethicon Endo-Surgery Generator G11 (Environmental Protection)

The Generator G11 and accessories must not be disposed of at the end of life with other waste. To recycle waste equipment, obtain instructions from the Ethicon Customer Service Department (call 1-877-ETHICON, +1-513-337-8901 (English) or contact your local sales representative to discuss local waste disposal solutions and processes. The Generator G11 poses disposal risks similar to consumer electronics such as computers. There are no radioactive substances, batteries, or hazardous liquids that may leak in the Generator G11.

Chapter 6 - Conformance to Standards

The Generator G11 conforms to the following international standards:

EN (IEC) 60601-1 (with Canadian and US National Deviations)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN (IEC) 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN (IEC) 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
EN (IEC) 60601-1-8	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

Appendix

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 Ingress Protection G11 Footswitch	IP21 IP68
Main Input	100 - 240 V ~, 50/60 Hz, 500 VA
Output	**ENSEAL Output:** Bipolar, no neutral electrode required 100 VAC RMS maximum 135 watts maximum (rated load 15 ohms, unless otherwise specified in the instrument IFU) 300 - 490 kHz (330 kHz, unless otherwise specified in instrument IFU) **HARMONIC Output:** 150 VAC RMS maximum (Unless otherwise specified in the instrument IFU) 35 watts continuous (Unless otherwise specified in the instrument IFU) 30 - 80 kHz (55.5 kHz unless otherwise marked in instrument IFU)
Ambient Operating Conditions	Temperature: 15 °C to 27 °C Humidity: 30% - 75% non-condensing Atmospheric Pressure Range: 700 hPa - 1060 hPa
Transport and Storage Conditions	Temperature: -35 °C to +54 °C Humidity: 10% - 95% non-condensing Atmospheric Pressure Range: 700 hPa - 1060 hPa
Weight	Generator: 5.9 kg Cart: 16.8 kg Footswitch: 3.6 kg
Overall Dimensions	Generator: 35.0 cm x 35.5 cm x 13.6 cm Cart: 48.0 cm x 56.2 cm x 95.3 cm Footswitch: 34.2 cm x 19.0 cm x 10.4 cm
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

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 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 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 IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions 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 no energy output without activation switch closure.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic Discharge IEC 61000-4-2	± 6kV Contact ± 8kV Air	± 6kV Contact ± 8kV Air	Relative humidity should be at least 30%.
Electrical fast Transient/ Burst IEC 61000-4-4	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV Differential Mode ± 2kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Fields IEC 61000-4-8	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 IEC 61000-4-11	<5% U_T (95% dip in U_T for 0.5 cycles) <40% U_T (60% dip in U_T for 5 cycles) <70% U_T (30% dip in U_T for 25 cycles) <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (95% dip in U_T for 0.5 cycles) <40% U_T (60% dip in U_T for 5 cycles) <70% U_T (30% dip in U_T for 25 cycles) <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.

Electromagnetic Compatibility (EMC)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 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. Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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.

[a] 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 4,066 MHz to 4,070 MHz.

[b] 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.

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 $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	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.

Go to *www.e-ifu.com* for latest revision of service manual.

	Footswitch
	Non-ionizing Radiation
	Equipotential Grounding
	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
	Authorized Representative in the USA
	Manufacturer / Date of Manufacture

	Power On/Off Switch
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Keep Dry
	Do not use if the product sterile barrier is compromised
	Catalogue Number
	Serial Number
	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.
	Consult the Generator G11 Operator's Manual.
	Refer to instruction manual/booklet for information related to safety. (Refer to blue symbol on the Generator G11).

	Manufacturer financially contributes to the cost of recovery and recycling
	Humidity Limitation
	Temperature Limit
	Low Alarm
	Medium Alarm
	Unit Quantity
	Alternating Current

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A000031P01

REF

GEN11, HGA11, EGA11, CRT11, FSW11

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
1-877-ETHICON
+1-513-337-8901 (English)

ETHICON

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969 USA

Rev. 2015-11-30

CE 0123

A000031P01 ENG