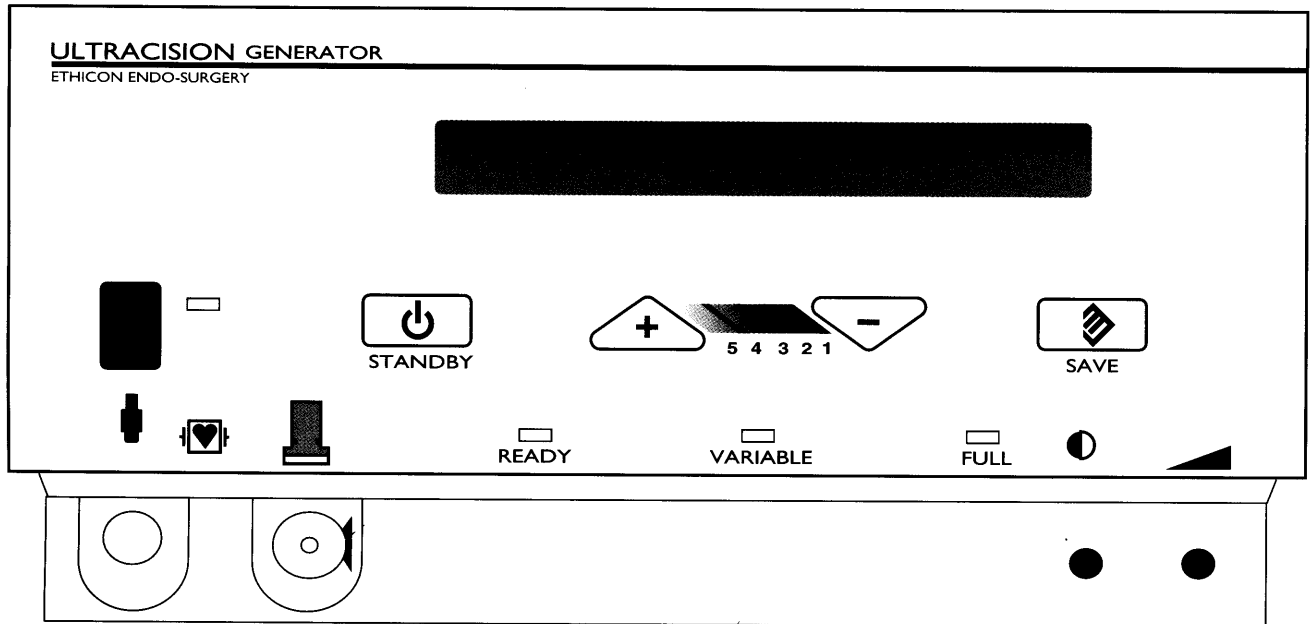


ULTRACISION

Generator Manual



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	Type CF, Isolated Applied Part		Dangerous Voltage
	Danger, Risk of Explosion. Not for use in the presence of flammable anesthetics.		

1.1 General Information

The UltraCision System utilizes ultrasonic energy to enable hemostatic cutting and/or coagulation of tissue. The System consists of an Ultrasonic Generator, a Foot Switch, a Hand Piece, and a variety of open and minimally invasive instruments.

Electrical energy produced by the Generator is converted in the Hand Piece to mechanical motion and delivered to the instrument tip. Hemostasis occurs when tissue couples with the vibrating tip as the tissue is incised. Cutting power can be adjusted during the incision to increase or decrease coagulation and speed of cutting.

1.2 Principles of Operation

The ultrasonic acoustic system is housed in the Hand Piece. The acoustic system or acoustic drive train consists of three components:

- **Acoustic Transducer:** converts the electrical energy to mechanical motion. It is the driving part of the acoustic system.
- **Acoustic Mount:** holds the acoustic system in the Hand Piece. It amplifies the motion produced by the transducer to increase the motion of the instrument.
- **Minimally Invasive or Open Surgery Instrument:** delivers ultrasonic energy to the tissue.

The UltraCision Generator senses changes in the acoustic drive train (Transducer - Mount - Instrument) that relate to an impending instrument fracture or improper use. When this occurs, the Generator alerts the user with a continuous beep.

1.3 Hand Piece

The ergonomically designed Hand Piece is compact and light weight, and is activated by a Foot Switch. The Hand Piece is permanently attached to a silicone cord which connects to the front of the Generator. The cord has clips to secure the cord to the surgical drapes.

The Hand Piece is packaged with a blade wrench and test tip. The blade wrench is used to secure the instrument blade to the Hand Piece. Additional blade wrenches can also be purchased separately. The Hand Piece and blade wrenches are packaged non-sterile and must be sterilized prior to use.

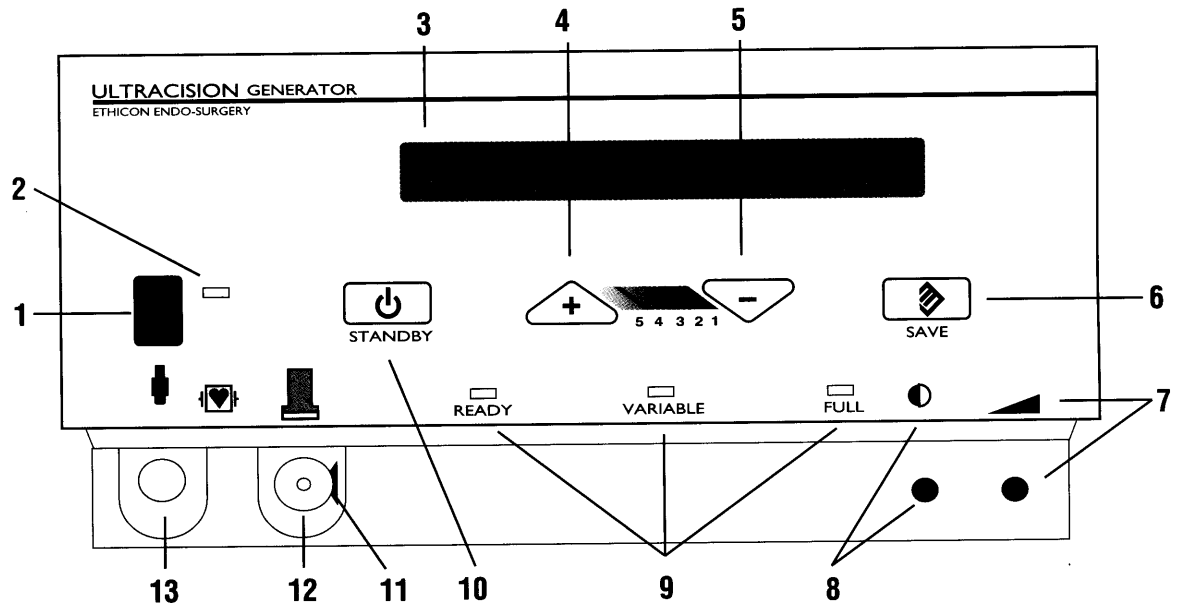
1.4 Foot Switch

The Foot Switch connects to the rear panel of the Generator and consists of two pedals:

- The **full pedal** activates the system at full power (LEVEL 5).
- The **variable pedal** activates the system at the operator-selected variable settings.

By changing the power setting, the operator changes the effect of the instrument blade on tissue. In general, greater cutting ability with less hemostasis is achieved as the power level is increased. The operator can vary the setting depending on the desired tissue effect.

2.1 Controls, Indicators, and Connections



Note: This illustration shows UltraCision Generator Model GEN01. In Models GEN22 and GEN32, the position of the air and electrical connectors is reversed.

Component	Description
1 Power Switch	Controls the electrical power for the entire Generator. Push the switch up to turn power on, push the switch down to turn power off.
2 Green Power Indicator Light	The light is illuminated when the Generator power is on.
3 20 Character Liquid Crystal Display	In READY mode, this display indicates the selected variable power level. When the Hand Piece is energized, this display indicates the active power level. "STANDBY" is displayed when the Generator is in STANDBY mode. When the Generator power is first turned on, this display briefly indicates that a SELF TEST is in progress. This display is also used for alarm messages When activated by service personnel (see UltraCision Service Manual), this display also shows diagnostic information, language selection, and Generator adjustment information.
4 Increase Power Button	Push this button to increase the variable power setting to the desired level, as displayed on the liquid crystal display, from 1 (minimum power) to 5 (maximum power).
5 Decrease Power Button	Push this button to decrease the variable power setting to the desired level between 5 (maximum power) and 1 (minimum power).
6 Save Button	Push this button to save the currently selected variable power level so that it is automatically displayed the next time the Generator power is turned on.
7 Volume	Turn this knob to adjust the sound of the Audio Annunciator. The sound level cannot be adjusted to zero.
8 Display	Turn this knob to obtain the best liquid crystal display appearance for your particular lighting and viewing angle.

2.1 Controls, Indicators, and Connections continued

9	Status Lights	Ready Light. This light is illuminated when the system is ready to use. This light is off while the Hand Piece is energized or in STANDBY mode. Variable Light. This light is flashed on and off when the Hand Piece is energized at the variable (VAR) power level. Full Light. This light is flashed on and off when the Hand Piece is energized at the full (FULL) power level.
10	Standby Button	Push this button once to enter STANDBY mode. In STANDBY mode, all power is removed from the Hand Piece. The Increase, Decrease, and Save buttons are disabled as is the Foot Switch. Use the STANDBY mode when replacing instrument blades.
11	Release Button	Push this button to detach the Hand Piece cord connection from the Cooling Air Source Connector on the Generator.
12	Cooling Air Source Connector	Air from the Generator cools the Hand Piece during activation.
13	Electrical Connector	Delivers the energy from the Generator to the Hand Piece.
*	Audio Annunciator	The annunciator beeps to indicate instrument activity or to indicate error conditions. During normal activation, the annunciator beeps on and off when either foot pedal is pressed. A slower beep indicates that LEVEL 1 through LEVEL 4 is activated and a faster beep indicates that LEVEL 5 is activated. If the generator does not energize the instrument, the annunciator will emit a continuous beep when either pedal is pressed.

Instrument Preparation and Hand Piece Attachment

2.2 Connection Instructions

Step	Instruction
1	Ensure that the Generator Power Switch is off during instrument preparation.
2	Plug the line cord into a grounded receptacle: Model GEN01: 115 Vac, 60 Hz Model GEN22, GEN32: 230 Vac, 50 Hz Note: Do Not Connect the UltraCision Generator To An Ungrounded Outlet.
3	Connect the Foot Switch to the rear panel of the Generator. Align the red dot on the Foot Switch 4-pin connector with the red dot 4-pin connector on the lower left side of the Generator back panel.

2.2 Connection Instructions continued

4	Attach the sterile UltraCision Hand Piece with two connectors (air and electric) to the front panel using the following instructions: Electrical Connector: Model GEN01: Attach the black connector to the electrical connector on the front of the Generator by orienting it so that the arrows are on top. Push the Hand Piece connector into the electrical connector. Model GEN22, GEN32: Attach the large white electrical connector by orienting the flat in the Hand Piece connector to the flat on the Generator electrical connector. Push the Hand Piece connector into the electrical connector. Cooling Air Source Connector: All Models: Attach the silver air connector by pushing it straight into the air connector on the front of the Generator. To detach the air connector, push the silver Release Button on the side while pulling the silver Hand Piece air connector away from the Generator. Note: Refer to specific UltraCision instrument package inserts for use of the Generator during surgical cases.
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Chapter 3 - System Testing

3.1 Function and Safety Testing

The Hand Piece, Generator, and Foot Switch should be periodically function and safety tested. Functional testing can be accomplished by following the instructions in the Full System Test section of this manual. The following outlines the instructions for safety testing:

Hand Piece	Examine the housing and cable for cracks or other damage and replace if damaged.
Generator	A qualified hospital technician should perform a leakage current test. The housing may be cleaned using mild detergent and a damp sponge. Do not immerse the Generator in water.
Foot Switch	Verify that both pedals are free of debris that may cause them to stick. Examine the cable for cracks or other damage.

3.2 Full System Test

Follow the instructions below for testing the proper functioning of controls, indicators, and alarms:

Step	Instruction
1	Perform complete instrument preparation and Hand Piece attachment as described in Section 2.2 - Connection Instructions. Note: Do not attach an instrument to the Hand Piece at this time.
2	Turn the Power Switch on. • Verify that the Green Power Indicator Light is illuminated. • Verify that the 20 Character Liquid Crystal Display indicates "SELF TEST" followed by the selected output level.

3.2 Full System Test continued

3	Turn the Display Knob. • Verify that the appearance of the 20 Character Display varies. • Adjust the Display for best appearance.
4	Push the Standby Button • Verify that the 20 Character Display reads “STANDBY.” • Step on either Foot Switch pedal and verify that the Foot Switch is inactive in STANDBY mode.
5	Push the Standby Button again to leave STANDBY mode and enter READY mode. • Verify that the Ready Light is illuminated. • Verify that LEVEL X is displayed.
6	Push the Increase Button several times. • Verify that the displayed LEVEL increases to a maximum level of 5.
7	Push the Decrease Button several times. • Verify that the displayed LEVEL decreases to a minimum level of 1.
8	Observe the displayed LEVEL, push the Save Button, and turn the Power Switch off. Wait 5 seconds, then turn the Power Switch on. • Verify that the displayed LEVEL is the same as the one observed prior to turning the power off.

3.3 Full System Test - Activation

Note: The following tests involve delivery of energy to the Hand Piece and ultrasonic activation of the Test Tip or instrument. Use caution when performing these tests and do not touch the blade or Test Tip while activated.

Step	Instruction
1	With no instrument attached to the Hand Piece, hold the Hand Piece so that the instrument attachment end is in air and step on the FULL Foot Switch pedal. • Verify that the Audio Annunciator emits a steady tone.
2	Release the Foot Switch pedal and push the Standby Button to enter STANDBY mode. Attach an UltraCision Test Tip to the Hand Piece according to the instructions listed in Section 3.4 of this manual and push the Standby Button again to enter READY mode. Note: A functional UltraCision instrument may be used if a Test Tip is unavailable.

3.3 Full System Test - Activation continued

3	Set the Generator to LEVEL 3 and energize the Hand Piece with the Test Tip in air by pressing the VAR Foot Switch Pedal. • Verify that the Ready Light is off while the pedal is pressed. • Verify that the Variable Light flashes on and off. • Verify that the 20 Character Display reads LEVEL 3. • Verify that the Audio Annunciator emits periodic beeps. • Turn the Volume Knob and verify that the beep volume changes.
4	Release the VAR Foot Switch pedal and step on the FULL pedal. • Verify that the Ready Light is off while the pedal is pressed. • Verify that the FULL light flashes on and off. • Verify that the 20 Character Display reads LEVEL 5. • Verify that the Audio Annunciator emits periodic beeps.
5	Hold the Hand Piece so that approximately 1 mm of the end of the Test Tip is immersed in a bowl of sterile water or saline solution. Press the VAR footswitch. • Verify that the Test Tip makes a hissing sound and causes movement of the water indicating that ultrasonic vibration of the Test Tip is occurring. Release the VAR Foot Switch and press the FULL Foot Switch. • Verify that the Test Tip makes a slightly louder hissing sound and causes slightly more movement of the water. Note: This test can splash water.

3.4 UltraCision Test Tip

The UltraCision Test Tip is a reusable tool for determining whether a broken or faulty instrument blade is causing the UltraCision system to work improperly. System failure is typically indicated by the Generator emitting a steady audible tone and displaying a non-flashing light when activated.

Note: Do not put the Test Tip in contact with hand, tissue, or any surface when in use.

System failure can also be caused by other factors that should be checked first:

- a) an improper Hand Piece connection to the Generator
- b) excessive loading of instruments
- c) excessive bending of instruments
- d) improperly torqued instruments
- e) excessive fluid and/or loose debris in the case of the Coagulating Shears.

3.4
UltraCision
Test Tip
 continued

Step	Instruction
1	Push the Save Button to store the selected variable power level.
2	Turn the Generator OFF at the power switch or enter STANDBY mode.
3	Remove the suspect instrument as indicated in its operating instructions. Do not dispose of the reusable blade wrench.
4	Remove the blade adaptor.
5	In the sterile field, attach the Test Tip manually to the Hand Piece by turning it clockwise, finger tight only.
6	Use the Blade Wrench to tighten the Test Tip. Align the flats on the wrench with the flats on the Test Tip. Turn the wrench clockwise until it “snaps,” indicating that sufficient torque has been applied to secure the Test Tip.
7	Remove the wrench. Do not dispose of the wrench. It is used for removal of the Test Tip after testing as well as for installation and removal of the instrument blades after the procedure.
8	Turn the Generator ON at the power switch or return to READY mode by pushing the Standby Button.
9	Operate the Test Tip in air by depressing either Foot Switch pedal (any power level setting may be used). The Test Tip should be activated for approximately 5 seconds. The Test Tip may get hot if activated for an extended period of time.
10	If the Generator emits intermittent beeps and flashing lights, the suspect instrument is broken or faulty. Remove the Test Tip and install a new instrument blade. Do not dispose of the Test Tip. The Test Tip is reusable and should be sent for sterilization in the same Sterilization Tray as used for the UltraCision Hand Pieces and instruments. Do Not label the Test Tip with tape, markers, or other devices.
11	If the Generator emits a steady audible tone and light, remove the Test Tip and replace the Hand Piece. Send the questionable Hand Piece to qualified hospital personnel for further testing. If the Hand Piece is discarded, discard the Test Tip. A new Test Tip is included with all new Hand Pieces.

The following section lists the probable causes and corrective actions for error conditions that may occur during operation of the UltraCision Generator. If the symptoms specified in this section are inappropriate or the corrective actions are insufficient, consult a qualified hospital technician, refer to the more detailed diagnostics listed in the UltraCision Service Manual, or call one of the following numbers for service:

- 1-800-USE-ENDO (U.S. calls)
- 1-513-483-8901 (International calls - **English speaking only**)

Symptom:

The instrument blade fails to cut or coagulate or has less power than usual, and the Generator emits intermittent beeps when the Hand Piece is activated.

Probable cause

Instrument blade is not attached securely to the Hand Piece.

Corrective Action

After pushing the Standby Button on the Generator, manually tighten the instrument onto the Hand Piece (finger tight only). Use the blade wrench to secure the instrument completely to the Hand Piece by turning the wrench clockwise until a “snap” is heard.

Symptom:

The instrument blade fails to cut or coagulate or has less power than usual, and the Generator emits a steady tone when the Hand Piece is activated.

Probable cause

Contact with tissue or fluid is excessive and is preventing the instrument blade from resonating.

Corrective Action

Withdraw the instrument from tissue or fluid and use less pressure when pushing against tissue.

Tissue fragment or coagulum is clinging to the instrument blade and preventing it from resonating.

Activate the Hand Piece for 1 or 2 seconds with the instrument in air to remove tissue, etc. If this fails, allow the blade to cool and then wipe it with a sterile cloth. **Handle the instrument with caution as it may become hot during operation in air.**

Inside of Hand Piece is still warm or wet from steam sterilization.

Leave both Hand Piece connectors attached to the Generator and leave the Generator power on and in STANDBY mode for 5 minutes to allow the Hand Piece air flow to cool and dry the Hand Piece.

Instrument blade is not attached securely to the Hand Piece.

After pushing the Standby Button on the Generator, manually tighten the instrument onto the Hand Piece (finger tight only). Use the blade wrench to secure the instrument completely to the Hand Piece by turning the wrench clockwise until a “snap” is heard.

Instrument blade has visible or invisible defect which prevents it from resonating.

Push the Standby Button on the Generator and replace instrument blade and/or sheath.

Hand Piece failure caused by immersion in liquid, damage to power cable, or end of useful life.

Replace Hand Piece.

Generator failure.

Contact a qualified hospital technician or call for service. (Numbers are listed at the beginning of Chapter 4)

Symptom:

The Generator will not enter READY mode from STANDBY mode.

Probable cause

Foot Switch button is depressed while pushing Standby Button.

Corrective Action

Release all other switches while entering READY mode.

Symptom:

The Generator beeps and/or changes mode unexpectedly.

Probable cause

The Generator is located too close to an electrosurgical generator.

Corrective Action

Locate the Generator at least one foot away from electrosurgical generators.

Hand Piece is defective.

Replace the Hand Piece.

Foot Switch is defective.

Replace the Foot Switch. Contact a qualified hospital technician or call for service. (Numbers are listed at the beginning of Chapter 4)

Electrical interference from hospital wall power or other equipment in O.R. disturbs Generator.

Contact a qualified hospital technician.

Symptom:

End of instrument blade detaches, leaving the blade extension in the Hand Piece.

Probable cause

Blade was attached to the Hand Piece with excessive force.

Corrective Action

Push Standby Button. Remove and discard the blade extender from the Hand Piece. Attach a new instrument blade to the Hand Piece.

Material between the blade and the Hand Piece has jammed the connection.

Push Standby Button. Remove and discard the blade base from the Hand Piece. Clean the end of the blade mount surface on the Hand Piece with alcohol and sterile gauze. **Do not immerse the Hand Piece in liquid.**

Symptom:

READY light is not illuminated.

Probable cause

Generator is in STANDBY mode.

Corrective Action

Push the Standby Button to enter READY mode.

Foot Switch is depressed while the Generator is turned "on" and goes through self-test.

Release the Foot Switch until the Generator self-test is completed and the READY light comes on.

Hand Piece is defective.

Replace the Hand Piece.

Generator is defective.

Turn Generator power off. Contact a qualified hospital technician or call for service. (Numbers are listed at the beginning of Chapter 4)

Symptom:

The Generator display reads, “STOP! CHECK HAND PIECE - TURN OFF, THEN ON” and Generator emits long and short beeps.

Probable cause

Hand Piece connection to Generator is faulty.

Corrective Action

Turn Generator Power Switch off, check to see that electrical Hand Piece connector is securely attached to the Generator, then turn the Power Switch back on. If problem persists, contact a qualified hospital technician or call for service. (Numbers are listed at the beginning of Chapter 4)

Symptom:

The Generator display reads, “STOP! SYSTEM ERROR - TURN OFF, THEN ON” and Generator emits bursts of long and short beeps.

Probable cause

Problem with hospital line voltage power source disturbed Generator or the Generator is faulty.

Corrective Action

Turn Generator Power Switch off and then on again. If problem persists, contact a qualified hospital technician.

Symptom:

Liquid crystal display on Generator is difficult to read.

Probable cause

Change in lighting or Generator position.

Corrective Action

Readjust display control on Generator.

Symptom:

Air connector on Hand Piece cable will not fit into air connector on Generator.

Probable cause

Silver locking button on Generator air connector is in locked position.

Corrective Action

Unlock connector by pushing the silver Release Button.

Chapter 5 - UltraCision System Warnings and Precautions

- Safe and effective ultrasonic surgery is dependent not only upon equipment design, but also, to a large extent, upon factors under control of the operator. It is important that the instructions supplied with this equipment be read, understood, and followed in order to enhance safety and effectiveness.
- Handle the Hand Piece carefully, as damage may shift resonant frequency.
 - Do not bang or drop the Hand Piece.
 - Do not clean the Hand Piece electrical connector with alcohol.
 - Do not immerse the Hand Piece in liquid.
- It is not advisable to operate the UltraCision instruments in the presence of flammable gases. Although operation of the UltraCision system does not involve electrical current flowing through the blade or tissue and the blade does not create electrical sparks, it is possible to create sparks by hitting other metal instruments. Sparks may ignite flammable gases such as anesthetics or bowel gas.
- To avoid user or patient injury in the event that accidental activation occurs, the UltraCision instrument blades should not be in contact with the patient, drapes or flammable materials while not in use. During prolonged activation in tissue, the instrument blades may become hot. Avoid unintended blade contact with tissue, drapes, surgical gowns, or other unintended sites after activation.
- To avoid user or patient injury, the UltraCision Generator should not be used prior to biomedical evaluation if it shows signs of damage or is suspected of being dropped or having fluids spilled on it.
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery, Inc. may not be compatible with the UltraCision System. Use of such products may lead to unanticipated results and possible injury to the user or patient.

Chapter 6 - UltraCision System Specifications

	GEN01	GEN22, GEN32
Device Type	Type CF, Isolated, Applied Device	Type CF, Isolated, Applied Device
Safety Standards	UL544 CSA C22.2 No 125, Risk Class 2 IEC601-1-2, Electromagnetic Compatibility Defibrillator Protected	IEC 601.1, Class 1 IEC601-1-2, Electromagnetic Compatibility Defibrillator Protected
Agency Listings	UL (No. 9B53) CSA (NO. LR89458)	TÜV (License No. 9281512)
Leakage Current	UL544 (Isolated Patient Connection) ANSI/AAMI ES1	IEC 601.1 (Type CF Device)

GEN01 Maximum Leakage Current (AC, RMS)

	Enclosure Risk Current	Patient Applied Risk Current (Source)	Patient Isolated Risk Current (Sink)	Earth Risk Current
Single Fault:	300 μ A	10 μ A	20 μ A	1000 μ A
No Fault:	100 μ A	10 μ A	Not Applicable	500 μ A

GEN22, GEN32 Maximum Leakage Current (AC, RMS)

	Enclosure Risk Current	Patient Applied Risk Current (Source)	Patient Isolated Risk Current (Sink)	Earth Risk Current
Single Fault:	500 μ A	50 μ A	50 μ A	1000 μ A
No Fault:	100 μ A	10 μ A	Not Applicable	500 μ A

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

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

Hand Pieces	Six Months, Parts and Labor
Generators	One Year, Parts and Labor
Carts	One Year, Parts and Labor
Foot Switches and Cables	One Year, Parts and Labor
Sterilization Tray	One Year, Parts and Labor

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

Ethicon Endo-Surgery, Inc. 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.