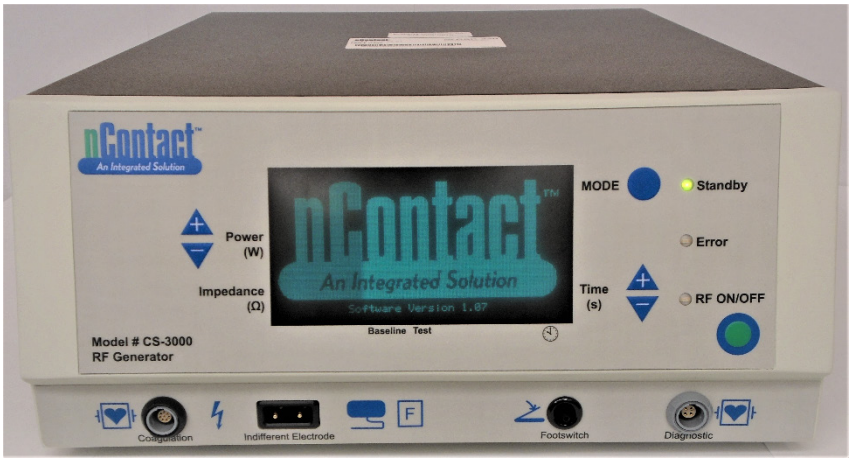
nContact
A BRAND OF AtriCure

nContact Coagulation System Radiofrequency (RF) Generator Unit - Model CS-3000



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Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

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Preface

The nContact Model CS – 3000 Radiofrequency Generator Unit is used to transmit radiofrequency (RF) energy for localized tissue heating resulting in tissue coagulation.

The unit operates in Power Control and Diagnostic Evaluation modes and is designed specifically for use with nContact coagulation devices and accessories.

Indications

For use only with nContact Coagulation Devices, RF Coagulation Cable, and Sensing Cable.

Contraindications

- The use of the nContact Model CS – 3000 RF Generator Unit, Coagulation Device and accessories is contraindicated when, in the judgment of the physician, surgical electrocoagulation procedures using RF energy would be contrary to the best interests of the patient.
- Use in the presence of internal or external pacemakers or internal cardioverter / defibrillators (ICDs) and monitoring equipment may require special considerations.

Non-Sterile

The nContact Model CS – 3000 Radiofrequency Generator Unit is provided non-sterile and is not intended to be used within the sterile field. Do not sterilize the CS-3000 RF Generator with any sterilization method or the CS-3000 RF Generator may be damaged. Follow cleaning instruction in chapter 3 to clean CS-3000 RF Generator.

⚠ Warning

- Carefully read all instructions before use.
- Use of radiofrequency energy in patients with internal or external pacemakers or ICDs and monitoring equipment may require special consideration. The attending Cardiologist and/or the pacemaker/ICD manufacturer should be consulted before electrocoagulation surgery.
- Hazardous electrical output. This equipment is for use only by qualified medical personnel trained in the use of electrocoagulation surgery. Failure of the high-frequency surgical equipment could result in unintended increase of output power.
- Electric shock hazard. Do not remove the cover of the nContact RF Generator Unit Model CS-3000. There are no user-serviceable parts inside the generator. Refer servicing to qualified personnel only (see information contained in “Customer Service / Equipment Servicing”).
- Interference produced by the operation of high-frequency surgical equipment may adversely influence the operation of other electronic medical equipment such as monitors and imaging systems.
- Never increase Power beyond what is minimally required without first inspecting the integrity and contact of the coagulating device.
- Care should be taken to ensure that the device is not in contact with tissue that is not going to be coagulated (e.g. vascular and nerve tissue), to avoid inadvertent tissue damage.
- Avoid contact between the Coagulation Device and other surgical instruments, staples or other objects while coagulating. Inadvertent contact with objects while coagulating could lead to conduction of RF energy or heat and unintentional coagulation of tissues in contact with those objects.
- Burns to the physician’s hands are possible if an RF activated device electrode comes into contact with a metal instrument or surface.
- The Coagulation Devices and RF Coagulation Cable are provided sterile and are intended for single patient use only. Do not reprocess or reuse. Reuse can cause patient injury and the transmission of infectious disease(s) from one patient to another.
- The coils on the distal end of the Coagulation Device must be kept clean of coagulum during surgery to avoid loss of power. Do not clean coagulum off the electrode of the device with an abrasive cleaner or electrosurgical tip cleaner. The electrodes could be damaged, resulting in device failure.
- The use and proper placement of an Indifferent Electrode is a key element in the safe and effective use of electrosurgery, particularly in the prevention of patient burns.

⚠ Precautions

- Radiofrequency surgery uses high-frequency energy output. Do not perform procedures if flammable or explosive media are present. Non-flammable agents should be used for cleaning and disinfection.
- Make sure the patient is not in contact to earthed metal during the operation of the CS-3000 RF Generator. Always use appropriate insulation between the patient and metal surfaces that may connect to earthed ground. Follow the manufacturer’s directions for the placement of the indifferent, dispersive electrode and for proper insulation between the patient and any metallic surfaces.
- Maintain safe handling techniques during electrocoagulation due to electric fields and hot metallic surfaces.
- Do not touch the electrode surface of the Coagulation Device and the Indifferent, Dispersive Electrode at the same time, especially when operating the Model CS-3000 RF Generator. Superficial skin burns could occur.
- This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:20151. These limits are designed to provide reasonable protection against harmful interference. This equipment generates, uses, and can radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the operator is encouraged to correct the interference by:
  - Relocating or moving the equipment
  - Increase the separation distance between the equipment
  - Connect the equipment into different outlets
  - Consult AtriCure, Inc. representatives for help
- The Coagulation Device, RF Generator, Cables and Accessories have been tested as a system. Use of another manufacturer’s accessories may cause damage to the equipment or injury to the patient.
- The use of accessory equipment not listed in this operator’s manual as complying with the equivalent safety requirements of this CS-3000 RF Generator may lead to a reduced level of safety. Accessory equipment connected to the CS-3000 RF Generator must be in compliance with IEC-60601-1 requirements. Anyone who connects additional equipment to the CS-3000 RF Generator is responsible for compliance with the requirements of industry standard IEC 60601-1-1. If in doubt, consult the technical service at AtriCure, Inc.
- While the distal portion of the Coagulation Device is designed to be malleable to conform to the anatomy of the area to be coagulated, excessive or rough shaping of the device may damage its internal components. Care should be taken when handling the distal end of the device near the electrode with surgical instruments – do not squeeze or clamp the electrode.
- Inspect the Coagulation Device, RF Coagulation Cable, and packaging before use. If any breach of the packaging is found, the sterility of the product cannot be guaranteed, and the product should not be used.
- Ensure complete separation of the Indifferent, Dispersive Electrode and EKG electrodes to prevent interference with patient monitoring equipment. Needle monitoring electrodes are not recommended. Monitoring systems incorporating high frequency current-limiting devices are recommended.

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The Model CS-3000 RF Generator is intended for use in the electromagnetic environment specified below. The user should assure that the CS-3000 is used in such an environment

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The CS-3000 RF Generator intentionally transmits RF energy as its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The CS-3000 RF Generator is suitable for use in all establishments other than domestic and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Classification in accordance with EN 60601-1

Safety Met Labs Mark Information

CLASSIFIED MET C US
E212567

CLASS 8750 01 – MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS

CLASS 8750 81 – MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS – Certified to US Standards

Radio Frequency Ablation Device, Model nContact CS-3000, rated: 100-240V~ 50-60Hz 250VA

1. Type of protection against electric shock: Class 1
2. Degree of protection against electric shock: Type CF
3. Degree of protection against ingress of water: IPX1
4. Equipment not suitable for use in presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
5. Mode of operation: Intermittent

Environmental Conditions: Normal: 10-40°C, 30-75% rH. 700-1050mb

Guidance & Manufacturer's Declaration– Electromagnetic Immunity

Product complies with the requirements of directive 93/42/EEC.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment -Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 2 kV, ± 4 kV, ± 8 kV Contact for conductive parts ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge for insulated parts	± 8 kV CD ± 15 kV AD	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	± 2 kV @ 100 kHz repetition frequency for power supply lines ± 2 kV @ 100 kHz repetition frequency for input/output lines	± 2 kV @ 100 kHz repetition frequency for power supply lines ± 2 kV @ 100 kHz repetition frequency for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Power inputs ± 0,5 kV, ± 1 kV Line-to-Line ± 0,5 kV, ± 1 kV, ± 2 kV Line-to-Ground Signal input/outputs: ± 2 kV Line-to-Ground	Power inputs ± 0,5 kV, ± 1 kV Line-to-Line ± 0,5 kV, ± 1 kV, ± 2 kV Line-to-Ground Signal input/outputs: ± 2 kV Line-to-Ground	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	0,15 MHz – 80 MHz 3V, 80 % AM at 1 kHz ISM bands between 0,15 MHz and 80 MHz 6V, 80 % AM at 1 kHz	0,15 MHz – 80 MHz 3V, 80 % AM at 1 kHz ISM bands between 0,15 MHz and 80 MHz 6V, 80 % AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips: 0 % V_t; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0 % V_t; 1 cycle and 70 % V_t; 25/30 cycles Single phase: at 0° Voltage interruptions: 0 % V_t; 250/300 cycle	Voltage Dips: 0 % V_t; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0 % V_t; 1 cycle and 70 % V_t; 25/30 cycles Single phase: at 0° Voltage interruptions: 0 % V_t; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CS-3000 RF Generator requires continued operation during power mains interruptions, it is recommended that the CS-3000 RF Generator be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: V_t is the ac mains voltage prior to application of the test level.			

Immunity test	**Band (MHz)**	**Wireless Service**	**Immunity Test Level (V/m)**	**Compliance Test Level (V/m)**
Immunity from Radiated RF EM Fields including proximity fields from RF wireless communications equipment IEC 61000-4-3	150 kHz to 80 MHz	General	< 3	< 3
	80 MHz – 2,7 GHz	General	3	3
	380 –390	TETRA 400	27	27
	430 – 470	GMRS 460, FRS 460	28	28
	704 – 787	LTE Band 13, 1	9	9
	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28	28
	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28	28
	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28	28
	5,100 – 5,800	WLAN 802.11 a/n	9	9

Portable and mobile RF communications equipment should be used no closer to any part of the CS-3000 RF Generator including cables, than the recommended separation distance calculated from the equation:

$d=6/E\times\sqrt{P}$ Where:

- d is the separation in meters
- P is the maximum output power rating of the transmitter in watts (W) according to the Service
- E is the Compliance Test Level indicated above.

Interference may occur in the vicinity of equipment marked with the following symbol: 

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASU System or any of its components are used exceeds the applicable RF compliance level above, the ASU System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating components or the entire ASU System.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the CS-3000 RF Generator

The CS-3000 RF Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CS-3000 RF Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CS-3000 RF Generator 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	1.2	1.2	2.3
10	3.8	3.8	7.3
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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Glossary of Terms

Electrocoagulation	Surgical procedures in which high-frequency electric current is used to coagulate tissues.
Coagulation Electrode	The metal conductor in the coagulation device used to transmit RF energy to tissue.
 **Indifferent, Dispersive Electrode**	Commonly referred to as the "return electrode" or "patient electrode" or "ground pad." Large surface area ground used to complete the circuit of the electrical current. Usually placed on the patient's back or thigh, the Indifferent, Dispersive Electrode is connected to the generator at the Indifferent Connector.

Symbols and Icons

	Manufacturer	REF	Catalog Number
VAC	Vacuum	RF	Radiofrequency
	Keep Upright		Perfusion
	Equipotentiality Connection		Defibrillation Proof Type CF Applied Part
	Indifferent, Dispersive Electrode		Caution
	Caution: Electrical Shock Hazard		Footswitch Connection
W	Watts		Non-ionizing Radiation
	Time	Ω	Ohms
	Follow Instructions for Use	s	Seconds
SN	Serial Number		Alarm Volume Control
~	Alternating Current	F	Neutral Electrode Isolated from Earth
+	Control Buttons to Increase Power or Time	0	AC Power Switch OFF
-	Control Buttons to Decrease Power or Time	I	AC Power Switch ON
	Protective Earth Terminal	OC	Measurement Out of Range
	Separate Collection for Electrical Equipment per WEEE Directive	CE 2797	Product complies with the requirements of directive 93/42/EEC
EC REP	Authorized Representative		Dangerous Voltage
104°F 50°F	Operating temperature range	140°F -30°F	Storage temperature range
75% 30%	Operating humidity range	85% 30%	Storage humidity range
1060 mbar 700 mbar	Operating pressure range	1060 mbar 500 mbar	Storage pressure range
NON STERILE	Non-Sterile		Non-ionizing electromagnetic radiation
Rx ONLY	Federal (US) law restricts this device to sale by or on the order of a physician.		

Chapter 1 Introduction

Overview

The nContact Model CS-3000 RF Generator Unit transmits a high-frequency alternating current through a coagulation device to coagulate soft tissue. The RF current induces ionic agitation in the tissue causing molecular friction and producing heat. Thus, the heat is generated in the tissue and not in the device.

As the temperature in the tissue increases, tissue coagulation occurs leading to cell necrosis. The tissue temperature and volume of coagulated tissue are affected by the amount of Power delivered, the surface area of coagulation device contacting the tissue, and the duration of energy delivery.

The generator operates in either the **Power Control** or **Diagnostic Evaluation** mode. When operating in Power Control mode, set the desired duration and Power level. The generator will transmit Power at the set point for the Time set by the operator. Power may be adjusted manually throughout the treatment to tailor the coagulation process but caution should be used when deviating from the recommended, pre-set power settings.

Product Description

The nContact Model CS-3000 RF Generator Unit is an electrosurgical generator that transmits RF current at a frequency of 480 kHz. The generator transmits up to 100 watts (W) of Power (+/- 20%), depending on the coagulation device connected. While the RF Energy is delivered, Power, Impedance, and Time are continually measured and updated on the generator display. The maximum output current when using an 3cm EPi-Sense is 0.9mA

Figure 1 shows the Power versus Impedance curves at set power levels of 100 Watts and 50 Watts. The RF Generator operates between 30 and 500 ohms. The RF Generator produces constant power along the operational impedance range. Figure 2 shows the relationship between Voltage and Impedance. Figure 3 shows the relationship between Set Power and Delivered Power at an impedance of 275 ohms.

Power & Voltage Output Diagrams

Figure 1. Power Output versus Impedance Load

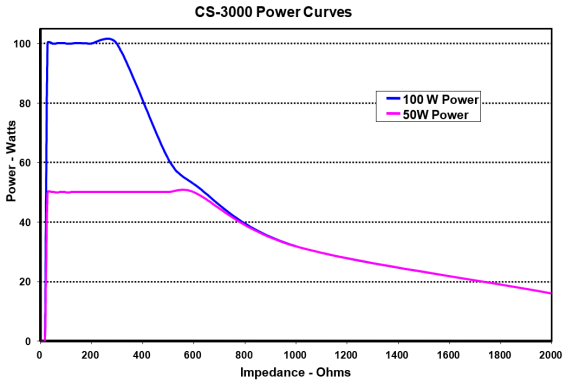


Figure 2. Voltage versus Impedance Load

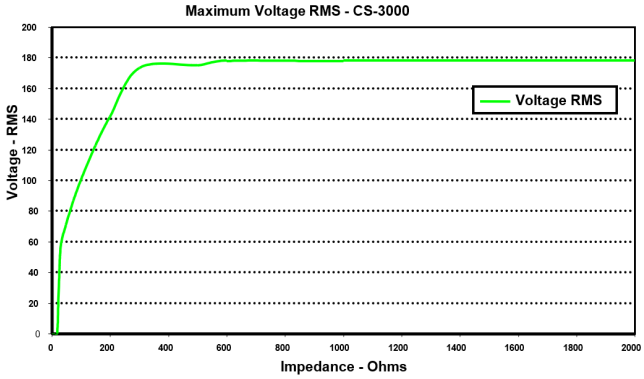
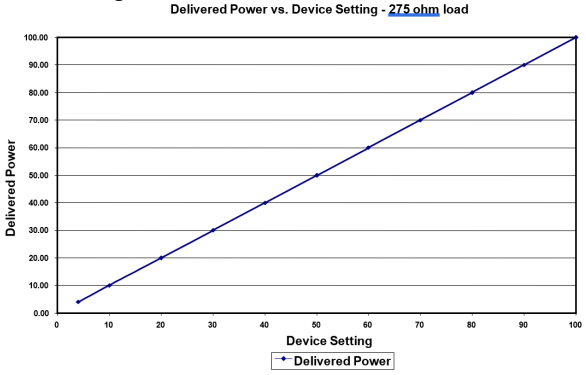


Figure 3. Delivered Power versus Set Power



Generator Operating Modes

1. Standby mode – The generator is idle; no energy is delivered, no measurements are performed. The software version is identified.
2. Ready Power Control mode – The generator detects the type of coagulation device connected and determines initial Power and Time set points accordingly. These preset Power and Time levels can be adjusted by the operator.
3. RF ON Power Control mode – The generator transmits a constant Power level until the elapsed Time equals the set point or an error is detected.
4. Diagnostic Evaluation Mode – RF energy is NOT transmitted to the coagulation device during this mode. Measurements of resistivity are taken from

electrodes on a separate accessory device (not yet available) to indicate the extent of coagulation necrosis.

System Components Supplied with the Generator

Components provided with the nContact Model CS-3000 RF Generator Unit include:

- 1 US Line power cable (US version only)
- 1 EU Line power cable (EU version only)
- 1 UK Line power cable (EU version only)
- 1 Footswitch (pedal)
- 2 Operator Manuals
- 2 Fuses – LittleFuse 2183-15, Time Delay (Slo -Blo), Rated at 3.15A, 250VAC

Components Not Supplied with the Generator

Accessories provided separately by AtriCure, Inc. for use with the CS-3000 RF Generator Unit and complying with the limits for medical devices to the IEC 60601-1 standards include:

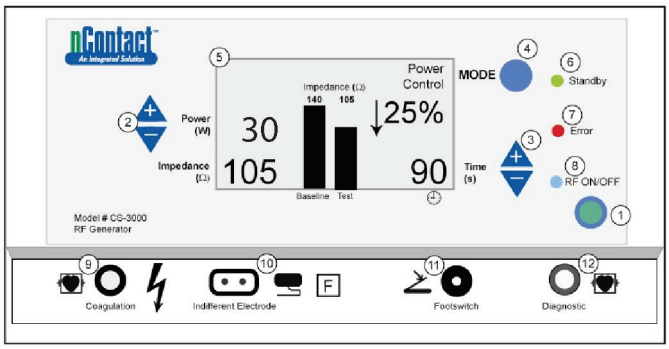
- EPI-Sense® Coagulation Devices with sensing capabilities (Single Use, Sterile) – Packaged Kit Models that may be used with the RF Generator are: CDK-1413. Refer to device Instructions for Use (IFU) for operation and disposal.
- RF Coagulation Cable (Single Use, Sterile) – Model CS-2000 Refer to CSK-2000 cable Instructions for Use (IFU) for operation and disposal.
  - Note: Packaged Kit Model CSK-2000 contains the Model CS-2000 Cable
- Sensing Cable Assembly (Multiple Use, Non-Sterile) – Model CS-2030 Refer to CSK-2030 cable Instructions for Use (IFU) for operation.
  - Note: Packaged Kit Model CSK-2030 contains the Model CS-2030 Cable

Accessories required for use with the Model CS-3000 RF Generator unit but not provided with CS-3000 RF Generator but with Coagulation Devices include:

- Patient Return Electrode (e.g. Indifferent, Dispersive Electrode), surface area of 21 square inches (136cm2) minimum.

CS-3000 RF Generator User Interface

Figure 4. Generator Front Panel – Key Features



The front panel of the generator provides connections for the Coagulation Device Cable CSK-2000 (9), the Indifferent, Electrode (10), a Footswitch (11), and connector for CSK-2030 Sensing Cable (12). The Front Panel incorporates push-buttons to set Power (2), Set Time (3), change the operating Mode (4), and turn the RF energy transmission on and off (1). The graphical display (5) shows the Operating Mode, Power, Time, Impedance, and Percent Change in Impedance during Power Control Mode. LEDs indicate when the generator is in Standby Mode (6), if an Error (7) has been detected, or when RF energy is transmitted (8).

Front Control Panel

Power Set (2)

Power is displayed in Watts (W). In Power Control mode, the Power Set point is the power level that will be transmitted to the coagulation device. The power set point is determined by the specific coagulation device and will automatically register once the coagulation device is connected. Refer to the Instructions For Use of the devices for the pre-set power and time. The maximum power allowed depends on the connected coagulation device. Power delivery may be adjusted while RF is activated by depressing the Power up or down pushbuttons to set the power in 1-Watt increments.

NOTE: If a coagulation device is not connected or identified, then Power will be set to 4 W and the maximum power will be limited to 50 W.

Actual Power (5)

The actual Power transmitted through the coagulation device replaces the set point in the graphic display once RF energy is activated. In Power Control mode, the Actual Power is adjusted to the set point but is also controlled to account for tissue response that is detected by changes in impedance.

Impedance (5)

Impedance (resistance between the coagulation device and the indifferent, dispersive electrode) is measured by the generator and displayed in ohms (Ω). A bar graph shows the change in impedance between the initiation of RF energy (baseline) and throughout tissue coagulation (test). As conductivity decreases, impedance increases. During coagulation of tissue, when the temperature of the tissue increases above 100ºC causing tissue desiccation, the impedance increases markedly. This creates an insulating barrier. The generator rapidly decreases Power if the impedance increases rapidly and terminates RF energy transmission if the impedance increases above 500Ω.

Time Set (3)

Time is preset when a coagulation device is connected and identified by the generator. The Time set point determines the duration of energy delivery unless an error is detected or the operator manually terminates the transmission of RF energy. Using the up and down arrows, Time is set in 1 second increments between 0 and 150 seconds.

Elapsed Time (5)

Elapsed time of the energy delivery replaces the Time Set value on the graphic display once RF energy is activated.

Error Indicator (7)

The Error LED Indicator illuminates when the system encounters an internal condition precluding operation of the generator. This may include a self-test failure, an incorrect connection or setting, excess heating warning, or a fault in the system. The generator will not deliver power when the Error LED is illuminated (see Chapter 6: Troubleshooting).

Mode Button (4)

The Mode button is used to adjust the operating mode between Standby, Power Control, and Diagnostic Evaluation. Pressing the Mode button during the application of RF energy will be ignored by the system.

RF ON/OFF Button (1)

The RF ON/OFF button works in parallel with the Footswitch (see Footswitch description). During Power Control Mode, the RF ON/OFF button controls the operation of the RF generator by initiating or terminating RF energy.

RF ON/OFF Indicator (8)

The RF ON/OFF indicator lights up when RF energy is being transmitted. RF energy transmission includes the periodic delivery of energy to measure impedance, even when the RF generator has not been activated. However, when RF energy is being transmitted at the power capable of causing coagulation, the RF ON/OFF indicator light is constantly illuminated.

Connections

Front Panel Connectors

The Footswitch, RF Coagulation Cable for the Device, Indifferent, Dispersive Electrode connectors allow interfacing with accessory devices.

Footswitch (11)

Depress the footswitch to begin delivering RF energy. To terminate the energy delivery and reset the Time during operation, depress the footswitch again.

Indifferent, Dispersive Electrode (10)

The indifferent, dispersive electrode provides a path for the electrical current through the patient and back to the generator. It is important to properly attach the indifferent, dispersive electrode to the patient per manufacturer's instructions (see "Setup and Operation"). The indifferent, dispersive electrode is for single use only.

Sensing Cable Connection (12)

The Sensing Cable Interface (Generator 'diagnostic' port) allows the connection of the sensing electrodes from the EPi-Sense device to the external EP Sensing (EKG) equipment, with the use of the CSK-2030 cable.

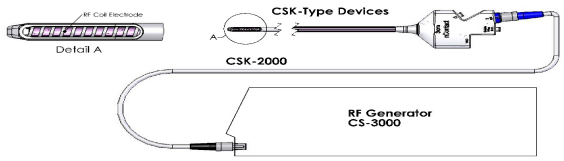
RF Coagulation Cable for the Device (9)

AtriCure manufactures the coagulation devices and RF coagulation cable for exclusive use with the Model CS-3000 RF Generator Unit. Refer to the two Figures (5 & 6) below, for the appropriate setup.

CSK Type Devices, CSK-2000 Cable and RF Generator Setup

Refer to the drawing below for the appropriate setup of the CSK devices with the CSK-2000 cable and the CS-3000 generator.

Figure 5. CSK Type Devices, CSK-2000 Cable and RF Generator Setup



CDK Type Devices, CSK-2030, CSK-2000 Cable and RF Generator Setup

Refer to the drawing below for the appropriate setup of the CDK devices with the CSK-2000 cable, CSK-2030 cable and the CS-3000 generator.

Figure 6A. CDK Type Devices, CSK-2000, CSK-2030 with over molded yoke and RF Generator Setup

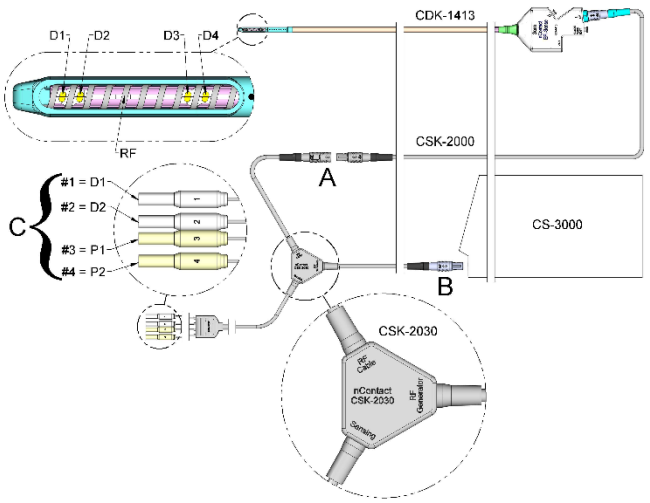
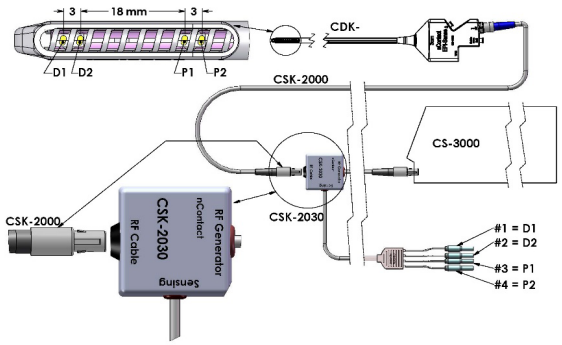


Figure 6B. CDK Type Devices, CSK-2000, CSK-2030 with enclosure box and RF Generator Setup

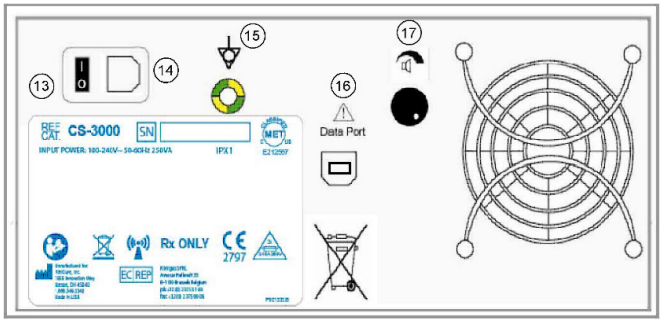


D1 = Distal Electrode 1 = Shrouded Pin #1; P1 = Proximal Electrode 1 = Shrouded Pin #3;
D2 = Distal Electrode 2 = Shrouded Pin #2; P2 = Proximal Electrode 2 = Shrouded Pin #4

⚠ **CAUTION**: Ensure that the EP Sensing (EKG) equipment comply with IEC 60601-2-25 for protection from high frequency surgical interference.

Back Panel Connectors

Figure 7. Generator Back Panel – Key Features



Power Switch (13)
Switch that powers the generator on and off.

AC Power Connector (14)
Connector for the AC line power cable.

Grounding Stud (15)
Used as a ground equalization for safety and testing.

Data Connector (16)
USB or Serial communication connector to a host computer for data display and archival purposes.

Alarm Volume Control (17)
Knob for modifying the volume of the generator alarm. Rotate the knob clockwise to increase the volume.

Chapter 2 Setup and Operation

Generator Setup and Operation

Preparing the Patient – Attaching the Indifferent, Dispersive Electrode

Prepare the patient for electrosurgery following standard protocol. Ensure patient's entire body, including extremities, is insulated against contact with grounded metal parts. Closely follow instructions for the coagulation device and manufacturer directions for the indifferent, dispersive electrode.

⚠ **CAUTION**: Failure to achieve good skin contact by the entire adhesive surface of the indifferent, dispersive electrode could result in a patient burn or poor electrical performance from the coagulation device. Note: Patient Return Electrode (e.g. Indifferent, Dispersive Electrode), surface area of 21 square inches (136cm2) minimum.

Setting up the CS-3000 RF Generator

1. Connect the supplied power cord into back mains receptacle of the CS-3000 RF Generator.
2. Plug the CS-3000 RF Generator power cord into an outlet.
3. On the back of the CS-3000, activate the mains switch and turn the RF Generator on.
4. Turning on the generator (switch on rear of generator) causes the system to enter Standby mode where no measurements or settings are possible. The nContact logo and the software version number are displayed in the message window; the Standby LED is illuminated.
5. Press the Mode button to perform a self-test and check system functionality before transitioning to Power Control mode. Subsequent depressing of the Mode button will toggle between Power Control and Diagnostic Evaluation modes.

NOTE: If an Error is detected, the red Error LED will illuminate, and a Message will display in the Graphic Display. Cycle the CS-3000 main power off and on so the RF Generator passes through self-test. (see Chapter 6: Troubleshooting).

CS-3000 Operation in Power Control Mode

When the RF Generator enters **Power Control** mode, the initial Power is set to 4 W and Time is set to 0 until a Coagulation Device is connected via the RF coagulation cable to the receptacle in the generator.

Connect a coagulation device to the appropriate receptacle (blue) of the cable then connect the cable (black) to the receptacle on the RF generator so the pre-set Power and Time values are displayed. Refer to the instruction for use of the coagulation devices for the appropriate pre-set power and time settings.

1. The Power level is automatically pre-set by the manufacturer at the recommended level for the connected coagulation device; however, the Power level may be adjusted by the user to a different setting, if desired.
2. The Time set point is automatically pre-set by the manufacturer for the connected coagulation device at the recommended treatment duration setting, however, the Time set point may be adjusted by the user to a different duration if desired.
3. Connect the indifferent, dispersive electrode to the appropriate receptacle on the RF generator.
4. Make sure the indifferent, dispersive electrode is adequately attached to the patient's back or thigh.
5. Insert the footswitch connector into the receptacle on the front panel.
6. Prepare the patient for electrosurgery following standard protocol.
7. Position the coagulation device. Depress and release the footswitch once or press the RF ON/OFF button on the front panel. The CS-3000 operates as an "Intermittent" generator so depressing and releasing the footswitch once will turn the generator ON. Standing on the footswitch may cause unwanted termination of the RF Generator.
8. Once the RF ON/OFF button or the footswitch is depressed and released, the generator enters the RF ON State and transmits RF energy to the coagulation device. If the generator needs to be terminated during operation, the RF ON/OFF button or the footswitch may be depressed and released again. The CS-3000 is an "Intermittent" generator so depressing and releasing the footswitch once will turn the generator OFF. Standing on the footswitch may cause unwanted initiation of the RF Generator.
9. Proper placement of the coagulation device and appropriate generator settings are essential to electrocoagulation. Monitor the Impedance measurements on the front panel graphic display to assist in the coagulation process.
10. At any point in the procedure, the setting for the Power delivery may be adjusted. Time may only be adjusted while RF energy is not transmitted.
11. The generator automatically stops delivering energy once it has Timed out (completed the pre-set cycle) and enters Ready state. To stop the RF delivery before the cycle duration expires, depress and release the footswitch, or the RF ON/OFF button on the front panel. When the generator is re-started, the unit re-sets to the previous set Time and Power settings.

⚠ **CAUTION**: Depress and release the footswitch once to turn the RF Generator ON or OFF. Do not stand on the footswitch because it may cause unwanted activation or termination.

NOTE: If the coagulation device must be repositioned, depress and release the footswitch or RF ON/OFF button to terminate energy delivery. To restart the generator, depress and release the footswitch or the RF ON/OFF button again.

NOTE: If the impedance rises above 500Ω, the generator stops delivering RF and transitions back to Ready state.

Chapter 3 Cleaning

NOTE*:* Do not spray or pour liquids directly on the unit.

NOTE: The unit and/or accessories cannot be sterilized.

⚠**WARNING*:* Ensure Isopropyl Alcohol (IPA) is completely dry before operating the unit.**

⚠**CAUTION*:* Avoid caustic or abrasive cleaners**

Guidelines

The following guidelines are recommended for cleaning the unit. It is the user's responsibility to qualify any deviations from these processing methods.

1. Disconnect the unit or cart from the outlet before cleaning.
2. If the unit and/or accessories are contaminated with blood or other body fluids, they shall be cleaned before the contamination can dry (within two hours of contamination).
3. The outer surfaces of the unit and/or accessories shall be cleaned with 70% -90% Isopropyl alcohol (IPA) wipes for a minimum of two minutes. Do not allow fluids to enter the chassis.
4. Pay attention to all areas where fluids or soil may gather, such as under/ around the handles or any tight crevices/ grooves.
5. Dry the unit and/or accessories with a dry, white lint-free cloth.
6. Conduct a final confirmation of the cleaning process by visually inspecting the white cloth for remaining soil.
7. If soil remains on the white cloth, repeat steps 3 through 6.

After cleaning is complete, turn the unit on to perform Power On Self-Test (POST). If any errors are received, contact AtriCure to begin return process.

Chapter 4 Technical Specifications and Safety Inspection

Device Specifications

1. Class I Equipment
2. Defibrillation Proof Type CF Applied Part. The recovery time for the CS-3000 RF Generator to be fully operational after exposure to defibrillation voltages is 5 seconds.
3. Generator meets IPX1 Requirements for protection against fluid ingress
4. Not Suitable for Flammable Anesthetics
5. Intermittent Operation – The Duty Cycle for Transmitting RF Energy at Maximum Power (100 Watts, +/-20%) is 150 Seconds ON and 10 Seconds OFF.
6. Uses LittelFuse 2183.15, Time Delay (Slo Blo) Fuse Rated at 3.15 A, 250VAC.

⚠ **CAUTION**: Only replace fuses with the LittleFuse 2183.15, Time Delay (Slo Blo) Fuse Rated at 3.15 A, 250VAC

Environmental Specifications

Operating Conditions

Temperature	10°C to 40°C, 50°F to 104°F
Humidity	30 % RH to 75 % RH, non-condensing
Atmospheric pressure	700 to 1060 millibar

Storage & Shipping Conditions

Temperature	-34°C to 60°C, -30°F to 140°F
Humidity	30% RH to 85% RF, non-condensing
Atmospheric pressure	500 to 1060 millibar

NOTE: Gradually return the RF Generator to operational conditions after storage or shipping and stabilize for one hour before use.

Periodic Inspections

Periodic safety inspections of the generator and attached accessories should be performed by persons who, based on their training, knowledge, and practical experience, are capable of adequately testing and assessing the safety and functionality of the generator.

Visual Inspection

1. Instruction manual present.
2. Labels, cautions, or warnings placed correctly and in all required locations
3. No apparent external mechanical damage to the generator, connectors, accessories, or wiring.

Operating Test

1. Self-test diagnostic upon start-up, includes self-calibration of measurement circuitry.
2. Footswitch operation.
3. Front control panel; keys and displays.

⚠ **WARNING**: If testing reveals a defect that could harm the patient, employees, or third parties, the generator should not be used until it has been properly repaired or serviced. The operator must immediately notify the appropriate authorities of the defect.

Chapter 5 Product Specifications

Operational Conditions & Front Panel Displays

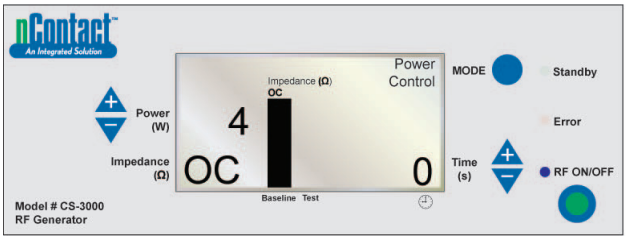
Figure 8. RF Generator Front Panel Display at "Power On"

Turning POWER ON to the generator transitions the generator to "Standby" mode.

Figure 9. RF Generator Front Panel Display at "Standby Mode"

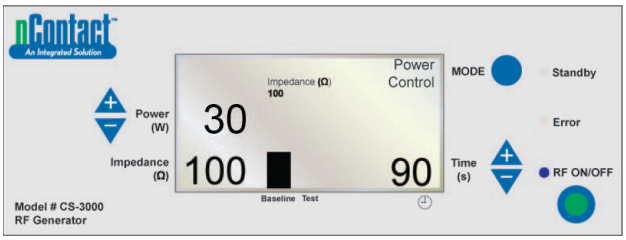
Entering STANDBY MODE activates the "Standby" LED ("Error" LED and "RF ON/OFF" LEDs remain off). The nContact logo & "software version" are displayed.

Figure 10. RF Generator Front Panel Display Entering "Power Control Mode"



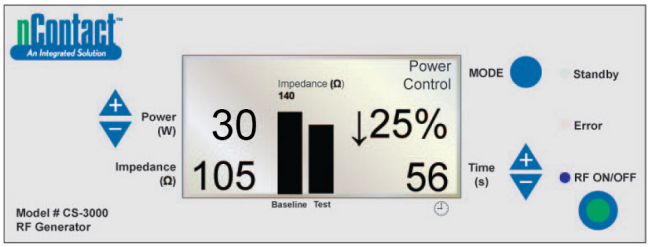
From Standby, when the user presses the "MODE" button, the generator passes a self-test. If the self-diagnostic tests don't detect an Error code, the generator then enters POWER CONTROL MODE (in this mode, the RF ON/OFF LED is blinking). As displayed in the drawing above, the impedance measurement is Open Circuit (OC) because the device and the indifferent electrode is not connected. The generator Power is set to 4 W and Time is set to 0.

Figure 11. RF Generator Front Panel Display in "Power Control \ Ready State"



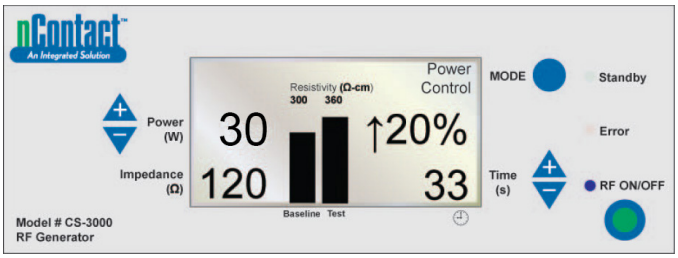
From POWER CONTROL MODE the generator enters a **Ready State.**
Note: An indifferent electrode and coagulation device are connected to the generator and placed on the patient.
"RF ON/OFF" LED is not activated, but will be blinking.
When the user attaches a device, the generator **detects** device type and **presets** information.
Refer to the Instructions for Use of the coagulation devices for the pre-set power and time.

Figure 12. Sample Display in "RF ON" State with a Device Attached



POWER CONTROL \ **RF ON State** for Devices
In this mode, the user presses "**RF ON/OFF**" to activate and transmit RF energy to the coagulation device. The "RF ON/OFF" LED is activated. **Power** is preset for the coagulation devices. The cycle **Time** (e.g. 56 s) is displayed in lower right corner and counts up to the set value.
Impedance is measured and the value displayed in the lower left (e.g. 105 Ω). Impedance is graphed (in the right "Test" bar) against the baseline value measured at initiation of RF. The baseline value is also displayed above the graph and in the left "Baseline" bar.
The percent change in impedance from baseline is displayed on the right (e.g. ↓25%) with an arrow (↑ or↓) to indicate whether the change in value was an increase or a decrease.
During RF application, an audible tone will sound every second for a 200 millisecond pulse.

Figure 13. Front Panel Display in "RF ON" with Resistivity Active

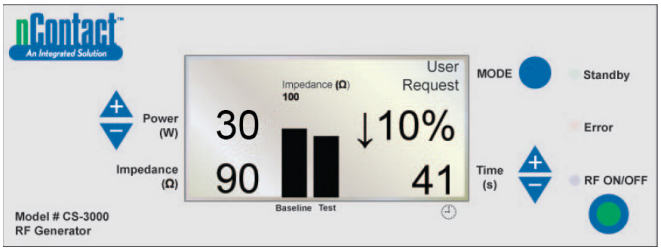


POWER CONTROL \ **RF ON** with **Resistivity Active, Device & Indifferent, Dispersive Electrode Attached**
"RF ON/OFF" is transmitted to the device and the "RF ON/OFF" LED is activated.
Measured impedance is displayed (120) but not graphed.
Resistivity is measured and graphed ("Test") against the "Baseline" value (300 Ω/cm).
Percent change in resistivity is displayed on the right (e.g. ↑ 20%)
Power transmitted at 50 W
Time (33 sec) counts up to set point

Figure 14. RF Generator Cycle Complete, Returns to Power Control "Ready" State

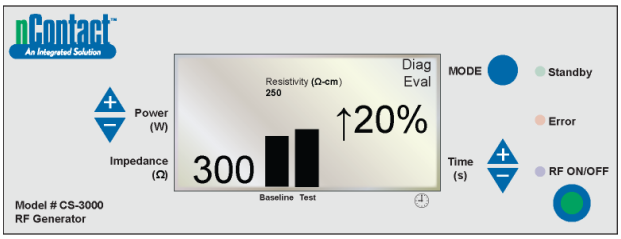
When the RF cycle is complete upon reaching preset time, generator returns to the POWER CONTROL MODE **Ready State.**
"RF ON/OFF" terminates when Time equals set point, and LED turns off.
"Time Limit" message is displayed in the upper right.
Parameters display for 3 seconds, then reset to preset values.
Final Impedance is measured (80 Ω) and displayed in lower left and is graphed against the "baseline" value (100 Ω).
Final Percent change in impedance is displayed (↓ 20%).
Final Power transmitted shown (50W).
Time at Termination of RF energy is displayed (90 s).

Figure 15. User Terminates Energy Cycle – Generator Returns to "User Request" State



When user presses **RF ON/OFF button** to terminate RF transmission, generator returns to the POWER CONTROL MODE **User Request State** and **"RF ON/OFF"** LED turns off.
"User Request" message is displayed in the upper right.
Both device and indifferent, dispersive electrode remain connected.
Parameters display for 3 seconds then reset to preset values.
Final Impedance measured (90 Ω) is displayed and graphed against baseline value (100 Ω).
Final Percent change in impedance is displayed (e.g. ↓ 10%).
Final Power transmitted is shown on the left (50 W).
Time at User Termination of RF energy is displayed (41 s).

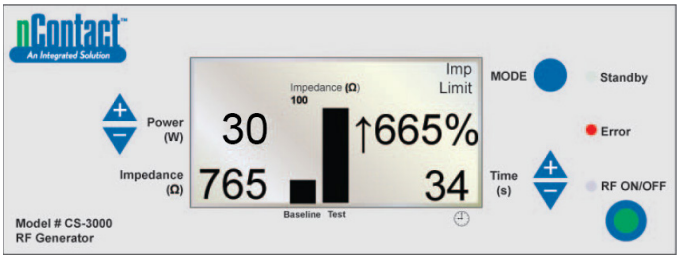
Figure 16. Generator Enters "Diagnostic Evaluation Mode"



To enter the Diagnostic Mode from the POWER CONTROL - Ready State, user presses the MODE button.
RF energy is inactive and the "RF ON/OFF" LED is off.
User connects an accessory device (not yet available), presses "RF ON/OFF" to set the baseline resistivity value.
Measured resistivity (300 Ω/cm) is displayed and graphed against baseline (250 Ω/cm).
Final Percent change in resistivity is displayed (↑ 20% indicating an increase).

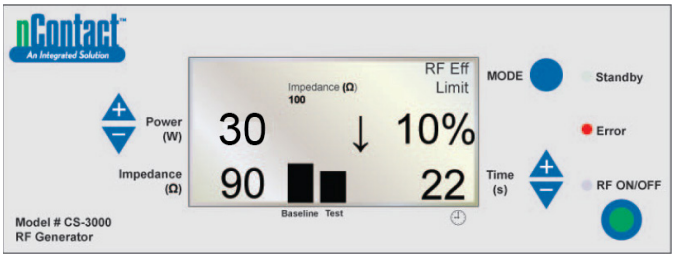
Warning and Fault States – Error Conditions

Figure 17. ERROR "Imp Limit" – Impedance Exceeds Threshold



This error (warning) occurs when **Impedance** exceeds the threshold limit, causing termination of RF energy transmission.
"Imp Limit" message displays in upper right and **Error LED** illuminates.
For warnings, parameters display for 3 seconds or until the warning is corrected.
Once the warning is corrected then the parameters reset to the preset values.
Final Impedance (765 Ω) is displayed and graphed against the baseline (100 Ω).
Final Percent change in impedance is displayed (↑ 665%).
Final Power transmitted shown (50 W).
Time at User Termination of RF energy (34 s) displayed.
When this warning occurs, an audible tone will sound three times for 1.5 seconds with 450 milliseconds between tones

Figure 18. ERROR "RF Eff Limit" – System Error

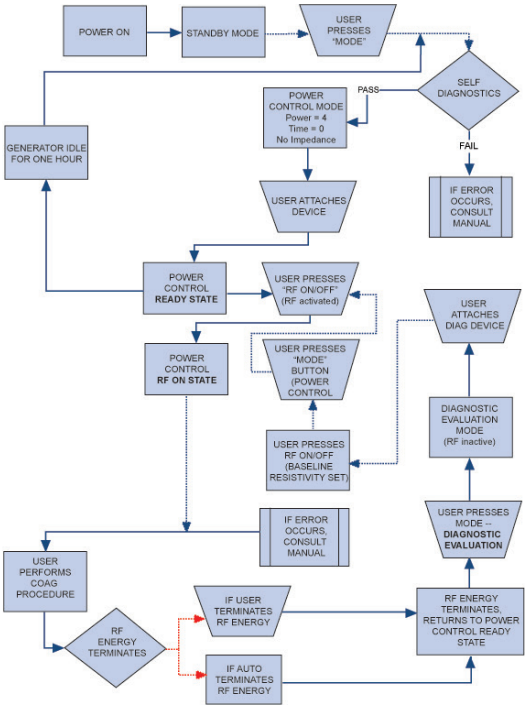


This error (fault) occurs when there is a **conflict with hardware or software**, causing termination of RF energy transmission.
All faults that are not recoverable will be displayed with the appropriate message and will require cycling of the main power switch so the generator passes through self-test.
"RF Eff Limit" message is displayed and the **Error LED** illuminates. (Eff = Efficiency).
Parameters display until the generator is Powered OFF, then Powered ON so that the generator performs its start-up diagnostic self tests.
Final Impedance (90 Ω) displays and is graphed against baseline (100 Ω).
Final Percent change in impedance is displayed (e.g. ↓ 10%).
Final Power transmitted is shown (50 W).
Time at User Termination of RF energy (22 s) is displayed.
When this fault occurs, an audible tone will sound continuously until the generator is turned off.

Chapter 6 Troubleshooting

The following flowchart illustrates a user decision tree to assist in operation of the generator and troubleshooting.

Figure 19. Generator Modes, States and Operational Flow



⚠ **WARNING**: Do not open the back panel of the RF Generator. This may cause serious injury and damage to the unit. It will void the warranty. When problems cannot be resolved by the directions in this troubleshooting section, contact AtriCure, Inc. for additional service and repair information

Table 1 provides a list of symptoms which may occur during routine operation of the RF Generator. If you encounter a problem that is not listed here, contact AtriCure, Inc.

Table 1 – List of Troubleshooting Symptoms & Actions

Symptom	Action
No displays or indicators when the RF Generator is turned on	• Be sure the generator is plugged into a working electrical outlet. • Check power switch on back of generator. • Unplug and check the fuse on the rear panel. Fuses should only be replaced with LittleFuse 2183.15, Time Delay (Slo Blo) rated at 3.15A, 250VAC.
IMP LIMIT warning, indicating impedance out of range	• Check connections to coagulation device and indifferent, dispersive electrode. • Ensure device is properly placed on tissue site. • Check position of indifferent, dispersive electrode on patient's back or thigh. • If problem persists, replace the coagulation device and indifferent, dispersive electrode.
Error LED indicator illuminates and one of the following Fault messages appears in Message window: RF EFF LIMIT ROM CRC FAILURE RAM FAILURE TIMER FAILURE +48 VOLT SUPPLY FAIL -12 VOLT SUPPLY FAIL +12 VOLT SUPPLY FAIL +5 VOLT SUPPLY FAIL IMPEDANCE TEST FAIL RF POWER TOO HIGH WHEN OFF RF POWER TOO HIGH WHEN ON RESISTIVITY FAILED MEASURED POWER CALCULATED POWER FAN FAULT GROUND FLOAT ON A/D CAL VOLTAGE ON A/D AMBIENT TEMP FAIL	• Power unit OFF, then Power ON again. • Allow generator to run through normal start-up self-diagnostics. • If generator returns to Error state and the problem persists, contact your AtriCure, Inc. representative.
Error LED indicator shows a button is stuck and one of the following Fault messages appears: RF ON BUTTON STUCK MODE BUTTON STUCK POWER/TEMP UP BUTTON STUCK POWER/TEMP DOWN BUTTON STUCK TIME UP BUTTON STUCK TIME DOWN BUTTON STUCK	• Depress and release the indicated button to determine if the button remains stuck. • Power unit OFF, then Power ON again. • Allow generator to run through normal start-up self-diagnostics. • If generator returns to Error state and the problem persists, contact your AtriCure, Inc. representative.
RF power does not turn on when footswitch is depressed	• Verify the footswitch is connected to the front panel of the generator • Ensure Time is not set to 0. • Ensure IMP LIMIT error is not detected - impedance should be within 30 – 500Ω. • Ensure a coagulation device is connected to the generator • Ensure the indifferent, dispersive electrode is attached to the patient and connected to the generator • Check the footswitch by unplugging its cable from the generator, placing a thumb over the foot pedal connector then depressing the pedal. If the footswitch is functioning properly, air should be expelled through the connector as the footswitch is depressed.
RF interferes with ultrasound and other equipment	• Ensure the cables from the electrodes do not cross the cables from the ultrasound probe or other equipment. • Changing settings on the ultrasound may alleviate image interference.
Impedance is greater than 500 Ω at the beginning of RF power delivery	• Ensure the indifferent, dispersive electrode is properly attached. • Check all connections. • Clean off any coagulum from the coagulation device. • Ensure device is properly placed on tissue site.
Impedance is less than 30 Ω at the beginning of RF power delivery	• Reposition the coagulating device

Chapter 7 Customer Service / Equipment Servicing/ Warranty

AtriCure, Inc. is dedicated to providing service and support to its customers. If there are any questions concerning the use of the nContact Coagulation system, please contact Customer Service at:

AtriCure Incorporated
7555 Innovation Way
Mason, Ohio 45040 USA
Customer Service:
1-866-349-2342 (toll free)
1-513-755-4100 (phone)

EC REP
AtriCure Europe B.V.
De Entree 260
1101 EE Amsterdam
The Netherlands
+31 20 7005560
ear@atricure.com

WARRANTIES

Limitation on Liability

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.

AtriCure, Inc. warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below. AtriCure'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 AtriCure, Inc. or its Distributor within the applicable time period shown below and which examination disclosed, to AtriCure'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 AtriCure, Inc. (2) repaired or altered outside AtriCure's factory in a way so as to, in AtriCure'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. **AtriCure has no control over the operation, inspection, maintenance or use of its products after sale, lease or transfer, and has no control of the selection of Customer's patients.**

AtriCure's products are warranted for the following periods after shipment to the original purchaser:

nContact RF Generator ..... One (1) Year
Footswitch ..... One (1) Year
Grounded Electrical Cords ..... One (1) Year
Sensing Cable ..... One (1) Year

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ATRICURE, INC., AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ATRICURE, INC. BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL.

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DISCLAIMER

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use. Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse of this product, including any loss, damage, or expense which is related to personal injury or damage to property.