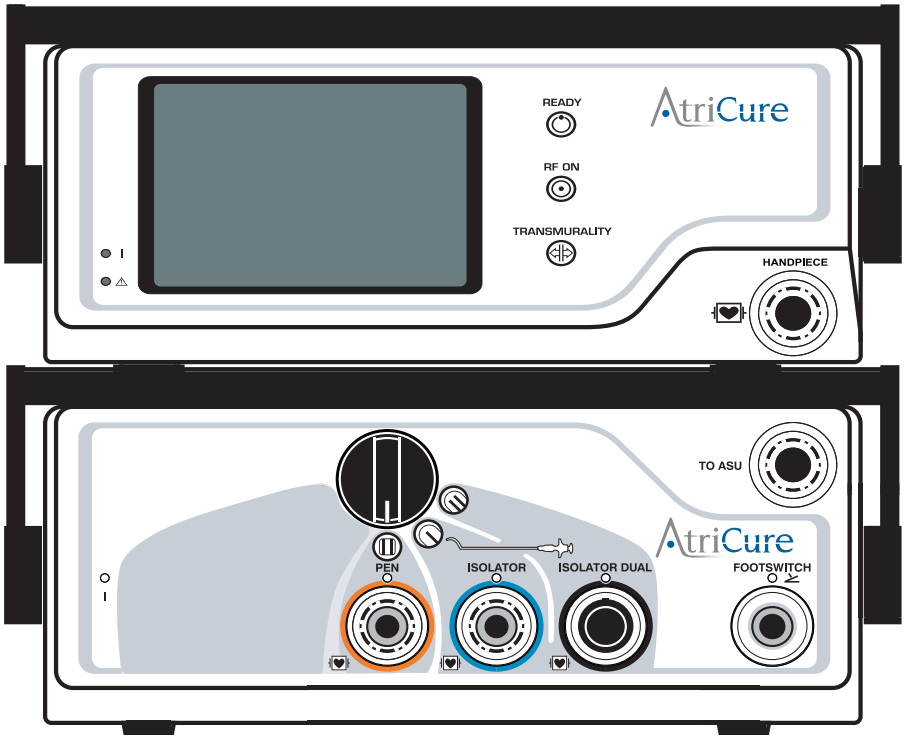
AtriCure®

Ablation and Sensing Unit and AtriCure Switch Matrix RF Generator System

Instructions for Use

ASU2 and ASB3



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DEVICE DESCRIPTION

The AtriCure® Ablation and Sensing Unit Radiofrequency (RF) Generator produces and delivers RF energy, in a bipolar mode, at a frequency of approximately 460 kHz, for localized tissue heating resulting in tissue coagulation.

The AtriCure Switch Matrix provides a means of simultaneously connecting multiple AtriCure Bipolar handpieces to the AtriCure Ablation and Sensing Unit and the means to select the input to the handpiece electrodes using the Switch Matrix knob.

This Instructions for Use (IFU) applies to the Ablation and Sensing Unit (ASU)-AtriCure Switch Matrix (ASB) system. For the user's convenience:

- The AtriCure Ablation and Sensing Unit RF Generator will be referred to in this IFU as **ASU**, and
- The AtriCure Switch Matrix will be referred to in this IFU as **ASB** when referencing the generator controls.
- The AtriCure Bipolar Handpiece will be referred to in this IFU as the **Handpiece**.
- The ASU/ASB system may also be referred to as the **Device** or **Generator**.

The ASU provides a maximum output power ranging from 12.0 Watts (W) up to 30.0 W for the Isolator® Transpolar™ pen or CoolRail™ linear pen devices depending on the mode of operation, and 22.8 W up to 28.5 W for the Isolator Synergy™ clamps or Isolator Synergy Access® clamps when used with the ASB. The ASU can produce a maximum output power of 32.5 W under a 100 Ohm load, although no current AtriCure Bipolar Handpiece uses Power above 30 Watts (W).

The operating mode is a function of the Handpiece and is set by the ASU/ASB system. The ASU/ASB system is designed to operate only with AtriCure Bipolar Handpieces (AtriCure Isolator pens, or AtriCure CoolRail linear pen and Isolator Synergy Clamps). The Footswitch is the input device used to activate and deactivate the RF energy delivery. Please refer to the Handpiece IFU for a complete description of the indications and use of these devices.

This IFU describes the ASU/ASB system, its controls, displays, indicators, tones, and a sequence for its operation with AtriCure Handpiece(s) only. This IFU also supplies other information of importance to the user and is not a reference to surgical techniques.

The AtriCure ASU/ASB and its components are intended to be used in professional healthcare environment only.

INTENDED PURPOSE

The ASU Generator/ASB Switch Matrix system is a non-sterile, reusable medical device intended to transmit radiofrequency (RF) energy to compatible AtriCure ablation handpieces for ablation of cardiac tissue.

INDICATIONS FOR USE

The ASU Generator/ASB Switch Matrix system is indicated to transmit radiofrequency (RF) energy to compatible AtriCure ablation handpieces for treatment of arrhythmias including atrial fibrillation.

INTENDED USER

Licensed medical doctors who perform cardiac and/or thoracic surgical procedures using AtriCure instrumentation.

TARGET PATIENT POPULATION

Adult patients with arrhythmias including atrial fibrillation.

CLINICAL BENEFIT

To achieve the clinical benefit of compatible AtriCure ablation handpieces.

SERIOUS INCIDENT STATEMENT

Any serious incident that has occurred in relation to this device should be reported to AtriCure and the competent authority of the Member State in which the user and/or patient is located.

NON-STERILE

- The ASU/ASB system is provided non-sterile and not intended for use within the sterile field. Do not sterilize the ASU/ASB system with any sterilization method, or the ASU/ASB system may be damaged. Follow cleaning instructions in CHAPTER 3 PREVENTIVE MAINTENANCE AND CLEANING to clean the system and the compatible reusable components.

⚠ WARNINGS ⚠

- Do not operate the ASU/ASB before thoroughly reading this ifu.
- Do not use the ASU/ASB in the presence of flammable anesthetics, other flammable gases, flammable cleaning agents, near flammable fluids such as skin prepping agents and tinctures, flammable objects, or with oxidizing agents. Use near flammable agents may result in fire or explosion. Observe appropriate fire precautions at all times.
- Fire Hazard: Electrosurgical accessories that are activated or hot from use can cause a fire. Do not place them near or in contact with flammable materials (such as gauze or surgical drapes). Avoid igniting endogenous gases.
- Fire Hazard: To avoid igniting cleaning agents, use only non-flammable agents to clean and disinfect the ASU/ASB. If flammable agents are inadvertently used on the Generator, allow these substances to evaporate completely before operating.
- Electrosurgery should be used with caution in the presence of internal or external pacemakers. Interference produced with the use of electrosurgical devices can cause devices such as a pacemaker to enter an asynchronous mode or can block the pacemaker entirely. Consult the pacemaker manufacturer or hospital Cardiology department for further information when the use of electrosurgical appliances is planned in patients with cardiac pacemakers.
- The use of components, transducers, and cables other than those specified in accordance with the instructions or supplied by AtriCure, may result in increased emissions or decreased immunity of the equipment.

- The ASU/ASB should not be used adjacent or stacked with other equipment, except for intended stacking with AtriCure's equipment in accordance with the instructions. The ASU/ASB normal use configuration should be observed to verify normal operation.
- The voltage selector is factory set and should not be changed by the user. The voltage selector and the power entry module must be set to the same voltage setting to prevent ASU malfunction and potential instrument damage.
- The Power cord(s) of the ASU/ASB must be connected to a properly grounded receptacle(s). Extension cords and/or adapter plugs must not be used.
- Electric Shock Hazard: Do not connect wet components to the Generator.
- Electric Shock Hazard: Ensure that the Handpiece is correctly connected to the Generator and that no wires are exposed from the cable, connector, or Handpiece.
- Do not connect the ASU/ASB device cable to supply mains (line voltage) operated equipment without evidence that the safety certification of the Accessory has been performed in accordance to the appropriate EN60601-1 and/or EN60601-1-1 harmonized national standard. Supply mains operated equipment may introduce dangerous leakage currents into the heart. When transporting or handling the ASU/ASB, use caution and care to avoid product damage. Inspect the ASU/ASB and Interface cables for any signs of physical damage before use. If damage is found, the integrity of the product cannot be guaranteed, and the product should not be used.
- Make sure there are no obstructions underneath or near the rear of the ASU/ASB to provide sufficient air flow for cooling.
- Use care when connecting Footswitch, Power cords, or Handpieces. Failure to connect properly may result in product damage.
- The safe and effective use of RF energy is highly dependent upon factors under the control of the operator. The manual, and the equipment it describes, are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is important that the operating instructions supplied with the ASU/ASB be read, understood and followed before use to avoid product damage or patient harm.
- If the ASU powers down, use CHAPTER 5 TROUBLESHOOTING to attempt to correct the problem. If problem persists, contact the AtriCure representative.
- The activation tone and indicator are important safety features. Do not obstruct the activation indicator or disable the audible tone. Ensure that the activation tone is audible to personnel in the Operating Room (OR) prior to use. The activation tone alerts personnel when the Handpiece is active and can help avoid tissue damage.
- Follow the cleaning instructions detailed in CHAPTER 3 PREVENTIVE MAINTENANCE AND CLEANING. Failure to follow these guidelines may result in product damage.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ASU/ASB including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ CAUTIONS

- Use only with the AtriCure Handpieces intended for use with the ASU/ASB.
- Do not activate the Generator until the Handpiece is properly positioned in the patient.
- Electric shock hazard: Do not remove the cover of the ASU/ASB as there is a potential for electric shock. Refer to authorized personnel for service.
- Trip Hazard: Standard care should be used to reduce the risk of tripping on the Footswitch cable.
- Use only the Footswitch provided with the ASU/ASB.
- Do not wrap instrument cables around metal objects. Wrapping cables around metal objects may induce hazardous currents.
- To avoid shock, do not allow patients to come into contact with earth metal parts of the Device. The use of antistatic sheeting is recommended.
- When the ASU/ASB is activated, the conducted and radiated electrical fields may interfere with other electrical medical equipment. Refer to the EMC Guidance and Manufacturer's Declaration section for more information regarding potential electromagnetic or other interference and advice regarding avoidance of such interference.
- Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to surgical personnel. These studies recommend using surgical masks and adequately ventilating the smoke by using a smoke evacuator or other means.
- When the Generator and Handpiece are used on a patient simultaneously with physiological monitoring equipment, ensure that the monitoring electrodes are placed as far as possible from the surgical electrodes. Be sure to position the Handpiece cables so that they do not come in contact with the patient or the other leads.
- Needle monitoring electrodes are not recommended for use when operating the Generator and the Handpiece.
- Monitoring systems that incorporate high-frequency current-limiting devices are recommended for use with the Generator and the Handpiece.
- Failure of the Device and the Handpiece could result in unintended Power output increases.
- Handle the ASU and ASB packaging with care.
- The ASU/ASB, AtriCure Isolator Transpolar Pen, Coolrail Linear Pens, Isolator Synergy Clamps have been tested as a system. Another manufacturer's accessories are not compatible and will not connect to the ASU/ASB.
- The ASU/ASB generates, uses, and can radiate RF energy. Interference produced by the operation of the ASU/ASB may adversely influence the operation of other electronic medical equipment such as monitors and imaging systems.

CLASSIFICATION IN ACCORDANCE WITH EN 60601-1 SAFETY INFORMATION

Radiofrequency Ablation Device:

ASU, rated: 100-120V ~ 50/60 Hz

ASB, rated: 100-240V ~ 50/60 Hz

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: N/A
4. Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
5. Mode of operation: Intermittent

EMC GUIDANCE AND MANUFACTURER'S DECLARATION

ELECTROMAGNETIC REQUIREMENTS

The ASU/ASB system has been tested and found to comply with the limits for medical devices in EN 60601-1-2:2015 + A1:2021 These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This system generates, uses, and can radiate RF energy and, if not installed and used in accordance with the instruction given below, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. The ASU/ASB do not require preventive maintenance with regard to electromagnetic disturbance during the expected service life. If the ASU/ASB does cause harmful interference to other devices, which can be determined by turning the ASU/ASB OFF and ON, the operator is encouraged to try to correct the interference by:

- Relocate or reorient the equipment
- Increase the separation distance between the equipment and the other devices
- Connect the equipment into other outlets different from those to which the other devices are connected
- Consult AtriCure, Inc. representatives for help.

ESSENTIAL PERFORMANCE

The Generator shall not deliver excess energy to the patient.

ELECTROMAGNETIC EMISSIONS

Table A: IEC EMC Specifications (Emissions)		
Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ASU/ASB is intended for use in the electromagnetic environment specified below. The customer or the user of the ASU/ASB System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
Radiated RF emissions CISPR 11	Group 1 Class A	The ASU/ASB must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted RF emissions CISPR 11	Group 1 Class A	The ASU/ASB 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.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage changes / fluctuations / flicker IEC 61000-3-3	Complies	
NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

ELECTROMAGNETIC IMMUNITY

Table B: IEC EMC Specifications (Immunity)			
Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ASU/ASB is intended for use in the electromagnetic environment specified below. The customer or the user of the ASU/ASB System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	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.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips: 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0 % UT; 250/300 cycle	Voltage Dips: 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0 % UT; 1 cycle Single phase: at 0° 70 % UT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ASU System requires continued operation during power mains interruptions, it is recommended that the ASU System be powered from an uninterruptible power supply or 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 typical location in 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.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

EMC GUIDANCE AND MANUFACTURER'S DECLARATION

Table C: IEC EMC Specifications (Immunity from Radiated RF EM Fields)				
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

Table C: IEC EMC Specifications (Immunity from Radiated RF EM Fields)				
Immunity test	**Band (MHz)**	**Wireless Service**	**Immunity Test Level (V/m)**	**Compliance Test Level (V/m)**

Portable and mobile RF communications equipment should be used no closer to any part of the ASU/ASB System including cables, than the recommended separation distance calculated from the equation:

Where:

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

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: 

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/ASB System or any of its components are used exceeds the applicable RF compliance level above, the ASU/ASB 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/ASB System.

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

Table D: Immunity to Proximity Magnetic Fields		
Test Frequency	**Modulation**	**Immunity Test Level (A/m)**
30 kHz [a]	CW	8
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	7,5 [c]

Table D: Immunity to Proximity Magnetic Fields
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s, before modulation is applied.

RECOMMENDED SEPARATION DISTANCE

Recommended separation distances between portable and mobile RF communications equipment and the AtriCure Ablation and Sensing Unit

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

Rated maximum output power of transmitter W	**Separation distance according to the 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.

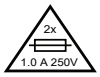
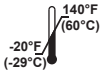
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

COP Timer	Computer Operating Properly Watchdog Timer
CPU	Central Processing Unit
LCD	Liquid-Crystal Display
LED	Light Emitting Diode
MCU	Microcontroller Unit
ROM	Read-Only Memory
RAM	Random Access Memory
OR	Operating Room

SYMBOLS GLOSSARY

	Country and Date of Manufacture		Manufacturer		Keep Upright		Medical Device
	Model Number		Catalog Number		Serial Number		Lot Number
	Unique Device Identifier		Data Port		Service Access		Importer
	Alternating Current		Fuse Information (ASU)		Fuse Information (ASB)		Caution: Electrical Shock Hazard
	Non-ionizing electromagnetic radiation		Footswitch Connection		Non-Sterile		Waste Electrical and Electronic Equipment
	Does not contain phthalates		Not made with natural latex		Defibrillation Proof Type CF Applied Part		Volume Control
	Transit Temperature range		Transit Humidity range		Consult Instructions for Use		Dangerous Voltage
	READY		RF ON		Transmurality		Equipotential Terminal
	Input Voltage Selector Switch		Caution				

CHAPTER 1 INSTRUCTIONS FOR USE

OVERVIEW

The ASU/ASB RF Generator system transmits a high-frequency alternating current through a Handpiece to ablate 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 coagulation device.

As the temperature in the tissue increases, tissue ablation 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 the coagulation device contacting the tissue, and the duration of energy delivery.

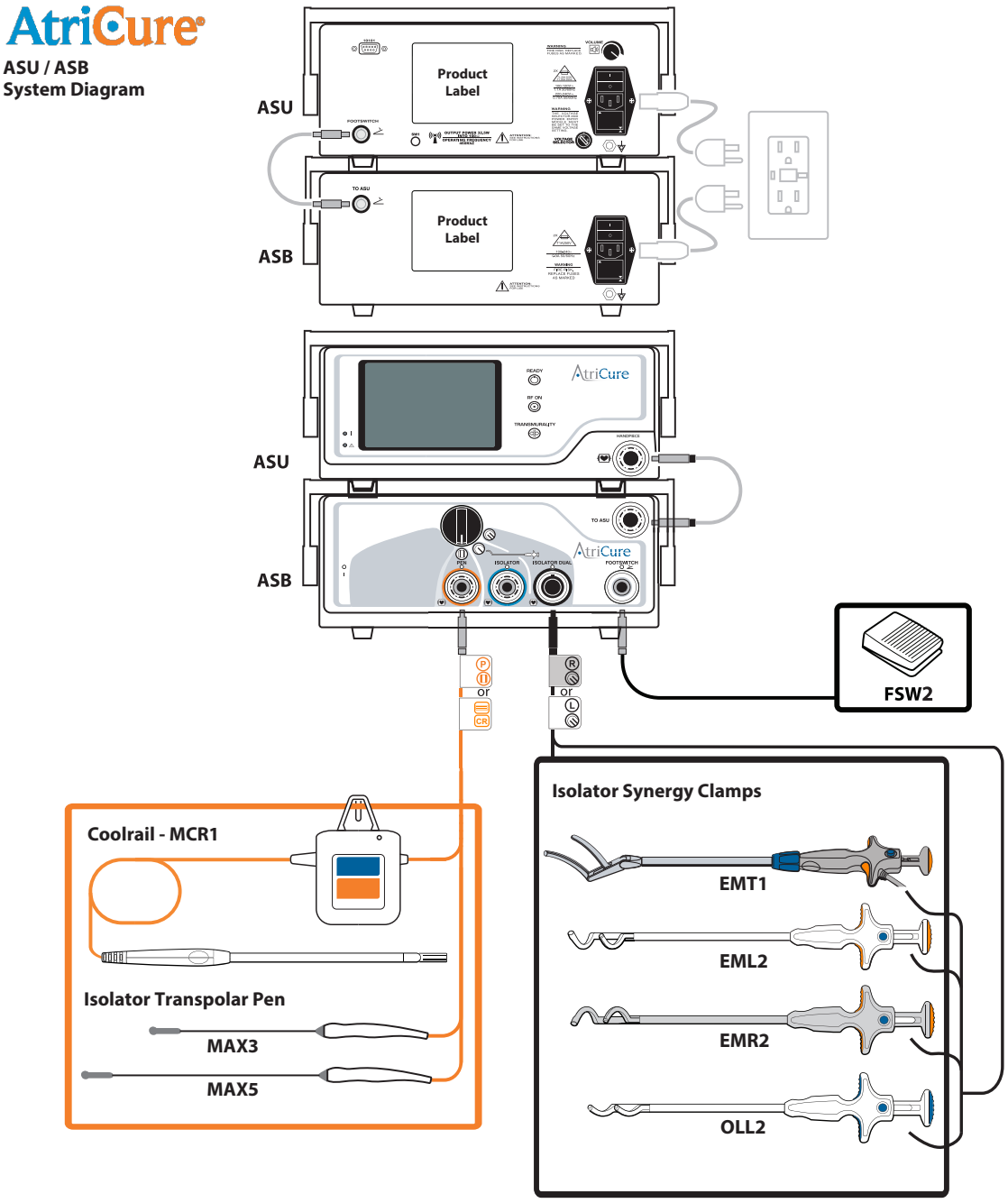


Figure 1: Connections of components and different Handpieces to the ASU/ASB System

SYSTEM OPERATING MODES

The ASU/ASB operates in one of the following five modes. These modes are shown in the lower left corner of the Tissue Conductance/Power Graph Display.

1. STANDBY Mode - The Device automatically enters this mode when successfully turned ON or from READY mode upon detection of a Handpiece or Footswitch disconnection. The LCD display message indicates the system is in STANDBY mode.
2. READY Mode - The Device automatically enters this mode when both the Handpiece and Footswitch are connected in the STANDBY mode or from the ON mode if the Footswitch has been depressed and released. The LCD display message indicates the system is in the READY mode.
3. RF ON Mode - The Device enters this mode when the Footswitch is depressed while in the READY mode. The Device transitions from the RF ON mode to the READY mode upon 40-second time expiration or if the Footswitch is released.
4. ERROR Mode - The Device enters this mode upon detection of any recoverable error conditions during any Mode excluding the FAULT Mode. The system displays the corresponding error message, and upon Footswitch release, transitions to the READY Mode.
5. FAULT Mode - The Device enters this mode upon detection of any non-recoverable error conditions during any Mode. The system is inoperable in this Mode until the cycling of the main power switch, so the Device passes through Self-test.

POWER AND VOLTAGE OUTPUT DIAGRAMS

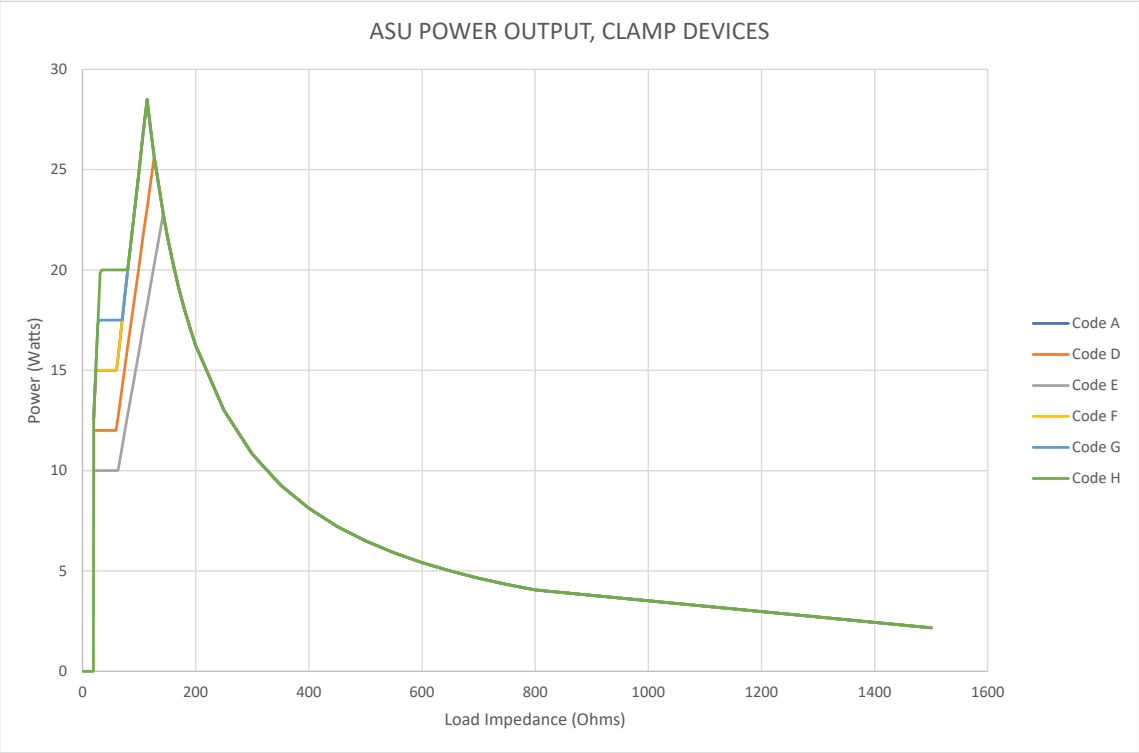


Figure 2: Power vs. Load (Clamp algorithm)

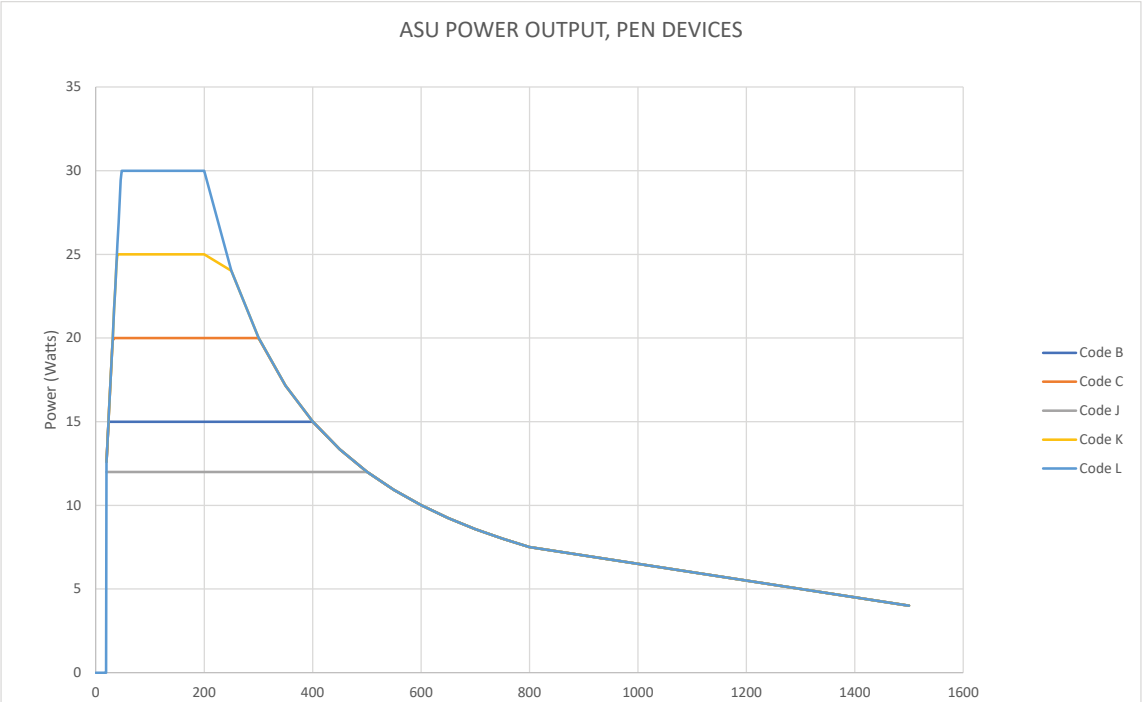


Figure 3: Power vs. Load (Pen algorithm)

SYSTEM OVERVIEW

See **Table 1: ASU RF Generator (A001471) components and configurations** for a complete list of the ASU RF Generator (A001471) components and configurations. All components provided with the ASU are non-sterile and reusable.

Table 1: ASU RF Generator (A001471) components and configurations

Component	AtriCure Part Number	Configuration (Quantity per box)
		A001471
RF Generator	ASU2	1
Footswitch	A000049	1
Instructions for Use	IFU-0435	1
Power Cord - US, Straight 3.0M, 10A, 125V	C000262	1

See **Table 2** for a complete list of the ASB (A000906-6) components and configurations. All components provided with the ASB are non-sterile and reusable.

Table 2: ASB Switch Matrix (A000906-6) components and configurations

Component	AtriCure Part Number	Configuration (Quantity per box)
		A000906-6
Switch Matrix	ASB3	1
Instructions for Use	IFU-0435	1
RF Interface Cable	A000442	1
Footswitch Interface Cable	A000473-1	1
Power Cord - US, Straight 3.0M, 10A, 125V	C000262	1

COMPONENTS NOT SUPPLIED WITH THE ASU/ASB SYSTEM

Sterile components provided separately by AtriCure, Inc. for use with the ASU/ASB system and complying with the limits for medical devices to the IEC 60601-1 standard include:

- Clamps (Refer to the individual Handpiece IFU for operation and disposal)
    - Isolator Synergy Access Clamp
    - Isolator Synergy Clamp(s)
- Pens (Refer to the individual Handpiece IFU for operation and disposal)
    - Isolator Transpolar Pen
    - Coolrail Linear Pen

ASU/ASB SYSTEM USER INTERFACE

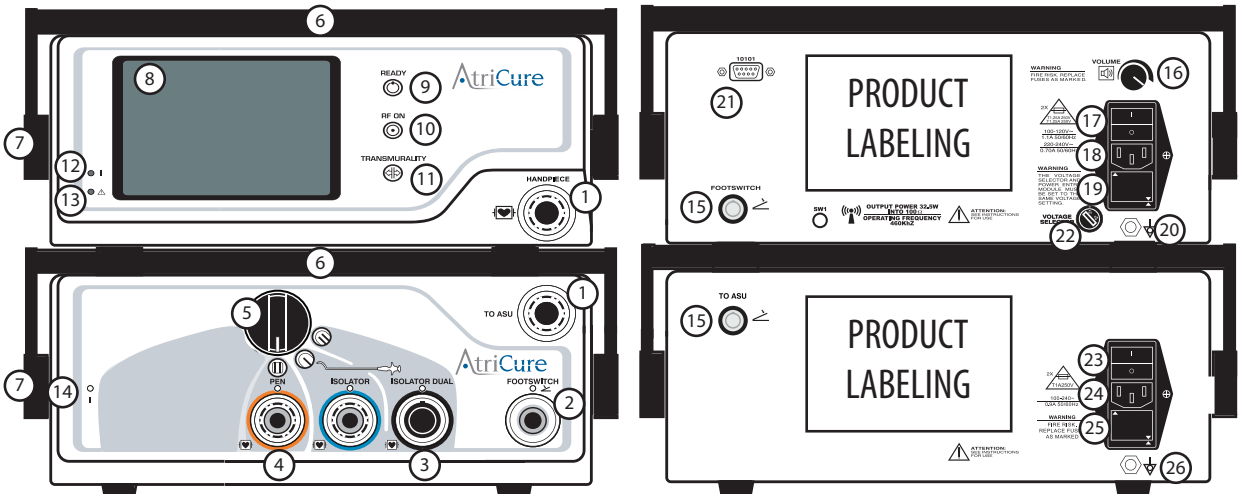
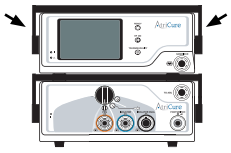
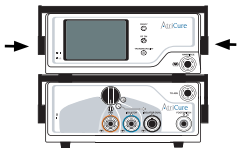
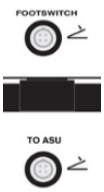


Figure 4: ASU/ASB Front and Back Panel - Key Features

FRONT AND BACK PANEL CONNECTORS/CONTROLS

FRONT PANEL CONNECTORS/CONTROLS			
1		Handpiece Receptacle	The connection of the (Reusable, Non-Sterile) RF Interface Cable (A000442) between the Handpiece Receptacles on the front panel(s) of the ASU and ASB provides RF energy from the ASU to the Sterile Handpiece through the ASB. This 12-pin receptacle is patient-isolated.
2		Footswitch Receptacle and Footswitch Status LED Indicator	The connection of the (Reusable, Non-Sterile) electric Footswitch (A000049) on the front panel of the ASB allows it to act as the input device for activation-deactivation of the RF energy delivery. The Footswitch LED will blink yellow till a Footswitch is connected to the ASB. A solid green LED indicates the Device has a functional Footswitch connected to it.
3		Isolator Synergy Clamp Handpiece Receptacle	This port provides means to connect the (Single Use, Sterile) Synergy Clamp handpiece to the Device.
4		Coolrail Linear Handpiece Receptacle	This port provides means to connect the (Single Use, Sterile) Pen handpiece to the Device.
5		ASB Selector Switch	Setting the selector switch on the ASB allows only the particular handpiece to be operational, even if multiple handpieces are connected simultaneously to the ASB.
6		Handle	The handle may be used to carry or change the positioning of the ASU/ASB.
7		Adjustment Knobs	Simultaneously depressing both the handle adjustment knobs (present on both sides) allows for adjusting the viewing angle of the ASU Tissue Conductance/Power Graph Display. **Note**: The ASU is nested atop the ASB. A change in the viewing angle by lowering the ASU handle may unnest the ASU from the ASB.
8		ASU Graphical Display	During the ablation cycle, the LCD graphical display on the ASU front panel displays a graph of: • Tissue conductance (Current/Voltage) on the y-axis versus Time on the x-axis for Isolator Synergy Clamp handpieces, and • Power (Current x Voltage) on the y-axis versus Time on the x-axis for the Isolator Pen handpieces. Handpiece code is also displayed in the top right corner of this display (see **Table 4** for Device code under CHAPTER 4 TECHNICAL SPECIFICATIONS AND SAFETY INSPECTION. The display of the graphs is not affected when the Footswitch is disconnected or reconnected.
9		READY Indicator	This green LED indicates the Footswitch and the Handpiece(s) are connected, and the ASU is ready for use. Refer to CHAPTER 2 SETUP AND OPERATION *Setting up the Device* section regarding the ASB Selector Switch.
10		RF ON Indicator	This LED indicator, when Blue, indicates that the RF power is being delivered to the Handpiece upon depressing the Footswitch.

11		Transmurality Indicator	This LED indicator, when flashing Blue, indicates that the Transmurality algorithm has been satisfied and that the user may terminate the ablation cycle. **NOTE: This function is applicable only to the Synergy Clamps.**
12		ASU Power LED	A green LED on the ASU front panel indicates the AC power is present, and the ASU has been switched ON.
13		FAULT Indicator LED	A red LED indicates that a FAULT has occurred and requires cycling of the AC power to the ASU.
14		ASB Power LED	A green LED on the ASB front panel indicates the AC power is present, and the ASB has been switched ON.
BACK PANEL CONNECTORS/CONTROLS			
15		Footswitch Receptacle	The connection of the (Reusable, Non-Sterile) Footswitch Interface Cable (A000473-1) between the Footswitch Receptacles on the back panel(s) of the ASU and ASB provides Footswitch signals from the ASB to the ASB Sterile Handpiece through the ASB.
16		Speaker Volume Control	This rotary dial can adjust the volume level of the ASU speaker. The speaker provides audible feedback to the user about the Device status. Rotate the knob clockwise to increase the volume.
17		ASU Power Switch	Switch that powers the ASU ON and OFF.
18		ASU AC Power Connector	Connector for the AC line power cable (Reusable, Non-Sterile) on the ASU.
19		ASU Fuse Box	The Fuse Box contains fuses selected for the input AC voltage. See CHAPTER 4 TECHNICAL SPECIFICATIONS AND SAFETY INSPECTION for additional details.
20		ASU Equipotential Grounding Stud	Provides a means of securely linking the earth grounds of the ASU to other grounded equipment.
21		Data Port	Serial communication connector to a host computer for manufacturing and test purposes only.
22		Input Voltage Selector Switch	The input voltage selector switch is pre-set by the manufacturer and should not be adjusted by the operator. Adjustment of this setting should only be performed by the manufacturer or an authorized AtriCure Service representative.
23		ASB Power Switch	Switch that powers the ASB ON and OFF.
24		ASB AC Power Connector	Connector for the AC line power cable (Reusable, Non-Sterile) on the ASB.
25		ASB Fuse Box	The Fuse Box contains fuses selected for the input AC voltage. See CHAPTER 4 TECHNICAL SPECIFICATIONS AND SAFETY INSPECTION for additional details.
26		ASB Equipotential Grounding Stud	Provides a means of securely linking the earth grounds of the ASB to other grounded equipment.

CHAPTER 2 SETUP AND OPERATION

SETTING UP THE DEVICE

> ⚠ **WARNING** ⚠
>
> Use gloves when setting up and operating the ASU/ASB system and associated components.

1. Place the ASB on a mounting cart or any table or platform capable of supporting the weight of ASU/ASB. Place ASU on top of the ASB, ensuring all four rubber feet nest with the ASB rubber bumpers. It is recommended to provide at least four to six inches of space around the sides and top of the ASU for convection cooling. It is normal for the top and back panels of the Device to be warm when used continuously for extended periods.

> ⚠ **WARNING** ⚠
>
> Ensure there are no obstructions underneath or near the back of the Devices to provide sufficient airflow for cooling.
>
> Connect cables and devices into receptacles with care to avoid damage.

2. Connect the supplied power cord(s) to the back of the ASU and ASB.

⚠ **Caution:** Inspect cord insulation, connector ends, and receptacles for damage before use.

3. Plug the power cord(s) into the grounded outlet(s).

> ⚠ **WARNING** ⚠
>
> Do not use extension cords or three-prong to two-prong adapters. Power cords should be periodically inspected for damages per CHAPTER 3 PREVENTIVE MAINTENANCE AND CLEANING.

4. Connect the Footswitch Interface Cable (A000473-1) between the Footswitch Receptacles on the back panel(s) of the ASU and ASB until a click is audible (refer to **Figure 5: Connecting Footswitch Interface Cable (ASU/ASB back panels)**).

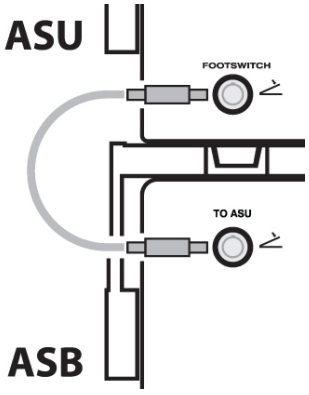


Figure 5: Connecting Footswitch Interface Cable (ASU/ASB back panels)

5. Connect both the connectors into the Handpiece Receptacles on the front panel(s) of the ASU and ASB until a click is audible, the connectors are keyed for alignment (refer to **Figure 6: Connecting RF Interface Cable (ASU/ASB front panels)**).

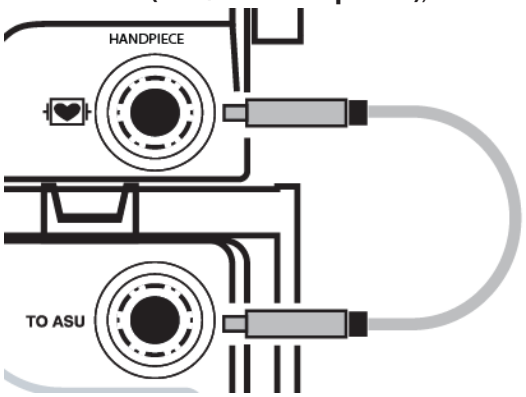


Figure 6: Connecting RF Interface Cable (ASU/ASB front panels)

6. Push the Footswitch connector into the Footswitch receptacle on the ASB front panel, the connector is keyed for alignment. Ensure the Footswitch Status LED Indicator is solid green. Place the Footswitch on a flat floor.

> ⚠ **WARNING** ⚠
>
> Care should be taken to ensure that the footswitch is not unintentionally activated to avoid ablation of unintended tissue or structures.

- **Note:** It is recommended that the area near the Footswitch be kept dry to reduce the risk of slippage.

7. Activate the Power Switches in the back of the ASU and ASB and turn them ON (refer to **Figure 4: ASU/ASB Front and Back Panel - Key Features**).
8. Allow the ASU to perform a Power ON Self-Test (POST) (refer to **Figure 7: Display indicating Power ON Self-Test (POST)**). The Self-Test generates two quick beeps at startup. If the Self-Test fails or any errors are received, the ASU transitions to the FAULT Mode. Refer to CHAPTER 5 TROUBLESHOOTING for possible causes and solutions. If the problem persists, contact AtriCure Customer Service (see CHAPTER 6 CUSTOMER SERVICE/EQUIPMENT SERVICING/ WARRANTY) to begin the return process. If POST is successful, the Device enters STANDBY mode (refer to **Figure 8: Conductance Display Graph (Synergy Clamps) and Power Display Graph (Isolator Pens) indicating STANDBY Mode**). The user must verify that the beeps are generated.

Figure 7: Display indicating Power ON Self-Test (POST)

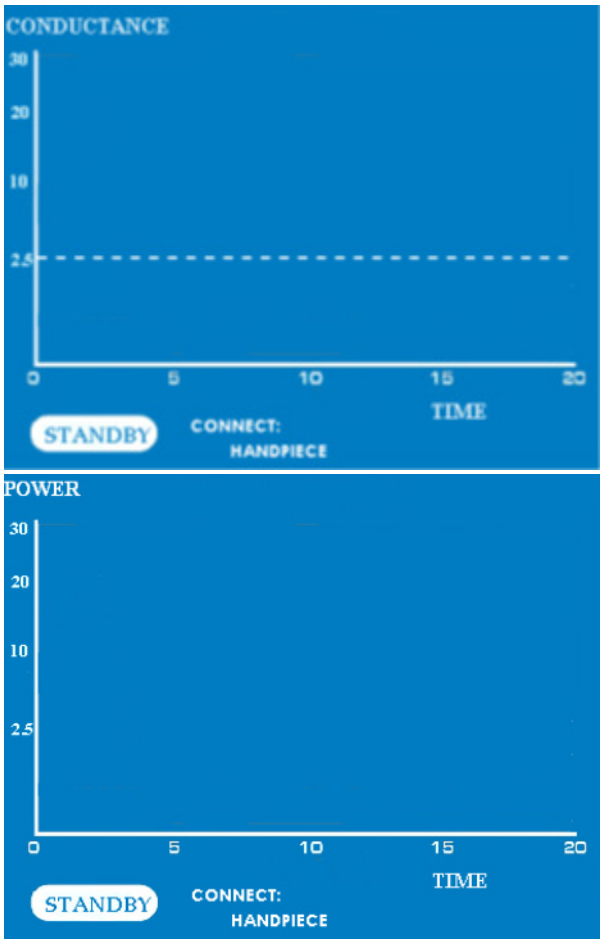


Figure 8: Conductance Display Graph (Synergy Clamps) and Power Display Graph (Isolator Pens) indicating STANDBY Mode

9. Adjust the viewing angle of the ASU if desired by pressing the two Handle Adjustment Knobs simultaneously and turning the handle to the desired location. ***Do not*** change the handle position if the RF Interface Cable is connected between ASU/ASB. Disconnect the RF Interface Cable and the Footswitch Cable before turning the handle(s) and reconnect them to the Device once the desired angle is set.
10. With the arrow symbol on the Handpiece Cable connector facing upward and oriented to the arrow symbol on the ASB receptacle (refer to **Figure 4: ASU/ASB Front and Back Panel - Key Features**), insert the sterile Handpiece(s) (Isolator Synergy Clamp or the Isolator Pen Handpiece) Cable connector(s) into the corresponding receptacle on the ASB Front panel.
    - **Note**: Refer to the Handpiece(s) IFU for more detailed information about connecting the Handpiece(s) to the ASB in a sterile environment.
11. Rotate the ASB Selector Switch to select the desired Handpiece. A green LED above the Handpiece receptacle indicates the Handpiece selected for activation. The Generator will transition to the READY mode (refer to **Figure 9: Tissue Conductance Display Graph (Synergy Clamps) and Power Display Graph (Isolator Pens) indicating READY Mode**). The display screen and the green illuminated READY indicator show the Device is in READY Mode.

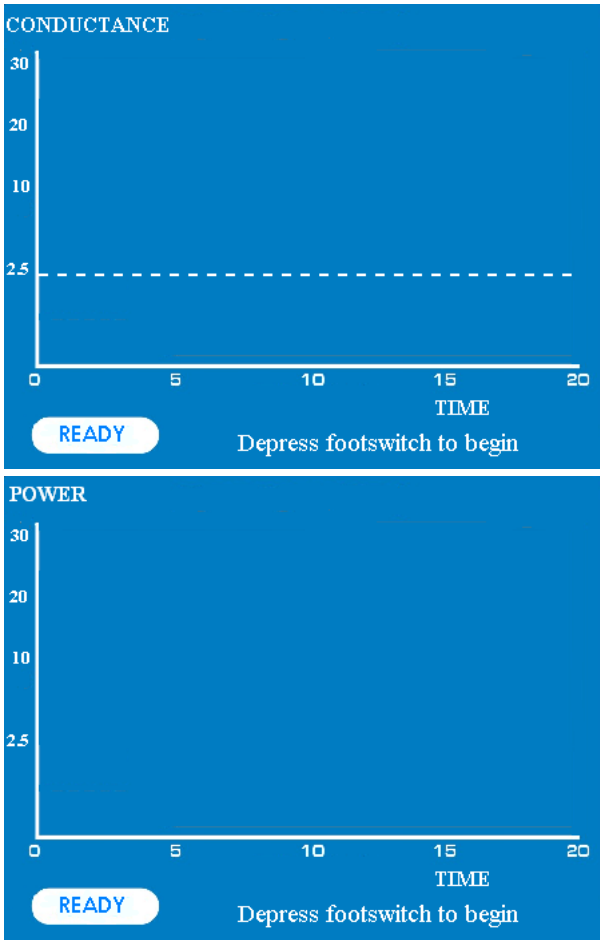


Figure 9: Tissue Conductance Display Graph (Synergy Clamps) and Power Display Graph (Isolator Pens) indicating READY Mode

⚠ **Caution:** Ensure the power cord, Footswitch, and Handpieces are installed into the correct receptacle.

⚠ **Caution**: Ensure the ASB Selector Switch is positioned on the correct Handpiece electrode input.

⚠ **Caution:** Ensure Handpieces and cables are fully and properly installed into the correct receptacle.

DEVICE OPERATION

1. Position the Handpiece per the Handpiece IFU.
2. Press and hold the Footswitch to initiate RF energy output. RF energy output is terminated by releasing the Footswitch or at the end of 40 continuous seconds of energy delivery. The display screen of the ASU will indicate that the generator is in the RF ON Mode (refer to **Figure 10: Wrapped Conductance Display Graph indicating RF ON Mode for Synergy Clamps**). The RF ON indicator on the ASU Front Panel will be with blue illumination.

⚠ **Caution:** Ensure activation footswitch connected to the ASU/ASB is held down only when delivery of RF energy is desired. Release the Footswitch after ablation is completed.

a. Synergy Clamp Operation:

i. The real-time graph of the measured tissue conductance is displayed on the LCD graphics screen with a ±20% tolerance. The Conductance graph is on a 20-second scale. Using measurements of conductance, the Generator will determine when a transmurality condition has been achieved. If the transmurality condition is not achieved within the 20 seconds shown on the Tissue Conductance Display graph, the graph will wrap to a second screen and will display a continuation of the conductance for a maximum of 20 additional seconds (refer to **Figure 10: Wrapped Conductance Display Graph indicating RF ON Mode for Synergy Clamps**).

ii. The Blue Transmurality indicator will flash, and the audible tone emitted from the ASU will change from constant to intermittent when the transmurality condition has been achieved. The system will automatically time out and stop the ablation if the user does not release the Footswitch within 40 seconds.

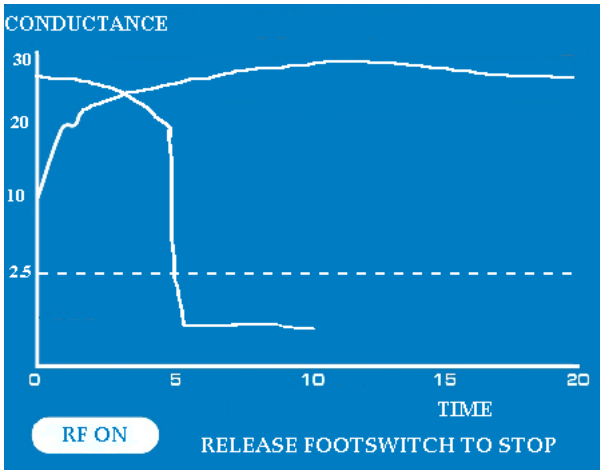


Figure 10: Wrapped Conductance Display Graph indicating RF ON Mode for Synergy Clamps

b. Isolator Pen Operation:

i. The real-time graph of measured Power delivered to the tissue is displayed on the LCD graphics screen with a ±20% tolerance. The Power graph is on a 20-second scale (refer to **Figure 11: Power Display Graph (Isolator Pens) indicating RF ON Mode (wrapping now shown)**).

ii. The system will automatically time out and stop the ablation if the user does not release the Footswitch within 40 seconds (refer to **Figure 11: Power Display Graph (Isolator Pens) indicating RF ON Mode (wrapping now shown)**).

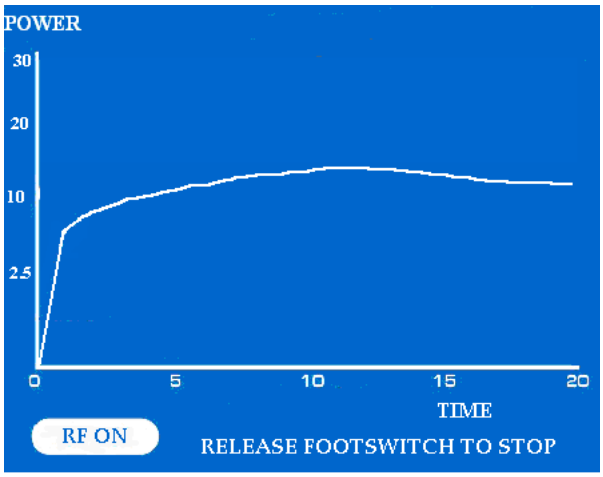


Figure 11: Power Display Graph (Isolator Pens) indicating RF ON Mode (wrapping now shown)

3. The Generator uses five (5) possible audio tones during its operation (refer to **Table 3: Audible Tones from the ASU**). The volume of these tones can be controlled using the Speaker Volume Control on the back panel of the ASU (refer to **Figure 4: ASU/ASB Front and Back Panel - Key Features**).

Table 3: Audible Tones from the ASU

Tone Name	Tone Description	Meaning for the Operator
Start Tone	Two quick beeps	Generated when the ASU is powered ON.
Error Tone	Constant low-pitched tone	Generated while an error is present.
FAULT Tone	A rapid succession of low-pitched beeps for 2 seconds duration	Generated upon entering a FAULT mode.
RF ON Tone	Constant medium-pitched tone	Generated when RF energy is being delivered to Synergy Clamp. This tone has a higher pitch than the Error tone.
	Varying medium-pitched tone	A discrete, decrementing tone in 10-second intervals is generated when RF energy is being delivered to the Isolator Pens. This tone has a higher pitch than the Error tone.
Transmurality Tone	Intermittent medium-pitched tone	Generated in the RF ON Mode when Transmurality is achieved. The Transmurality tone will continue, and RF energy will continue to be applied until the Footswitch is released or until 40 seconds have elapsed. **This function is applicable only to the Synergy Clamps.**

CHAPTER 3 PREVENTIVE MAINTENANCE AND CLEANING

Follow local governing ordinances and recycling plans regarding the disposal or recycling of device components.

ASU/ASB Generator:

> ⚠ **WARNING** ⚠
>
> 70% Isopropyl Alcohol (IPA) alcohol wipes should be used to clean the exterior of the ASU/ASB. Do not submerge or allow fluids to enter the chassis. Do not spill fluid over the ASU/ASB system and ensure IPA is completely dry before operating the units to avoid damage to the equipment or injury to the patient. If the fluid is spilled on the Device, return it to the hospital's Biomedical Engineering Department for evaluation.

⚠ **Caution:** Avoid caustic or abrasive cleaners.

⚠ **Caution:** If the tamper proof seal is broken, the integrity of the ASU/ASB cannot be ensured. Contact AtriCure representative.

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

NOTE: The units or their components cannot be sterilized.

Interface Cables:

> ⚠ **WARNING** ⚠
>
> If necessary, clean the RF Interface Cable and Footswitch Interface Cable with 70% IPA wipes to ensure it does not cause infection.
>
> Inappropriate handling of the Interface cables, including sterilization and immersing the electrical connectors, can result in degradation of system performance, including the inability to initiate or complete an ablation therapy.

⚠ **CAUTIONS**

- Position the cables to surgical electrodes to prevent contact with the patient or other leads.
- Avoid caustic or abrasive cleaners.
- Ensure IPA is completely dry before operating the cables.

NOTE: None of the Interface Cables are intended to be used within the sterile field. Do not sterilize them with any sterilization method.

Disconnecting the Interface Cables:

- To disconnect the Interface cables from the System, grasp the connector and pull back. Do NOT pull on the wire.
- Excess pulling and flexing of the cable may damage it and render it non-functional.
- Store the cables in a safe, dry area until the next use.

NOTE: Disconnect the cables from the System before cleaning.

CLEANING GUIDELINES

The following guidelines are recommended for cleaning the Generator and all reusable components.

1. Disconnect the unit or cart from the outlet before cleaning.
2. If the unit or components 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 or components shall be cleaned with 70% 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 components with a dry, white lint-free cloth.
6. Conduct a final confirmation of the cleaning process by visually inspecting the white cloth for the 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 the Power ON Self-Test (POST). If any errors are received, refer to CHAPTER 5 TROUBLESHOOTING for possible causes and solutions. If the problem still persists, contact AtriCure Customer Service (see CHAPTER 6 CUSTOMER SERVICE/EQUIPMENT SERVICING/WARRANTY) to begin the return process.

⚠ **Caution:** Ensure all Interface cables and Footswitch are adequately cleaned/disinfected.

PREVENTIVE MAINTENANCE PROGRAM

AtriCure has considered internationally recognized standards and guidances in determining preventive maintenance requirements.

The ASU/ASB system has no user-serviceable parts inside. The ASU/ASB system and compatible reusable components shall be periodically subjected to preventive maintenance by:

- Performing Power ON Self-Test (POST)
- Visual Inspection (for damages, fraying, cracked parts, missing items, etc.)

⚠ Caution: If a maintenance message is displayed on the ASU display screen, contact the AtriCure representative for assistance.

Please contact the local AtriCure Service representative for more detailed information about Preventive Maintenance programs.

PERIODIC INSPECTIONS

Periodic safety inspections of the ASU/ASB system and attached components 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 system.

VISUAL INSPECTION

- Instructions for Use (this document) present.
- Labels, cautions, or warnings are placed correctly and in all required locations.
- No apparent external mechanical damage to the ASU/ASB system, connectors, components, or wiring.

OPERATING TEST

- Self-test diagnostic upon startup includes self-calibration of measurement circuitry.
- Footswitch operation.
- Front panel; displays, indicators, and receptacles.
- Back panel; controls and receptacles.

CHAPTER 4 TECHNICAL SPECIFICATIONS AND SAFETY INSPECTION

MECHANICAL SPECIFICATIONS

Size:

ASU: 17.5″ (44.5 cm) D x 13.75″ (35 cm) W x 6″ (15 cm) H maximum.

ASB: 17.5″ (44.5 cm) D x 13.75″ (35 cm) W x 6″ (15 cm) H maximum.

Weight:

ASU: 15 lbs. (6.8 kg) absolute maximum; 20 lbs. (9 kg) including cables

ASB: 15 lbs. (6.8 kg) absolute maximum; 20 lbs. (9 kg) including cables

TECHNICAL SPECIFICATIONS

- Software version: V3.11B

RF OUTPUT

- Frequency: 460 kHz ± 5%, Quasi-sinusoidal
- Maximum Power Output: 32.5W at 100Ω
- Accuracy:
    - Power: ± 20%
    - Time: ± 20%
- RF Power and Voltage Output Restrictions (See **Table 4: RF Power and Voltage Output Restrictions**.)

Table 4: RF Power and Voltage Output Restrictions

Device Code	Maximum Output Power	Maximum Output Voltage	Handpiece Type
A	28.5W at 114Ω	57.0 Vrms	Isolator Clamp
B	15.0W from 20Ω to 400Ω	77.5 Vrms	Isolator Transpolar Pen
C	20.0W from 20Ω to 300Ω	77.5 Vrms	Isolator Transpolar Pen
D	25.6W at 127Ω	57.0 Vrms	Isolator Clamp
E	22.8W at 143Ω	57.0 Vrms	Isolator Clamp
F	28.5W at 114Ω	57.0 Vrms	Isolator Clamp
G	28.5W at 114Ω	57.0 Vrms	Isolator Clamp
H	28.5W at 114Ω	57.0 Vrms	Isolator Clamp
J	12.0W from 20Ω to 500Ω	77.5 Vrms	Isolator Transpolar Pen
K	25.0W from 39Ω to 240Ω	77.5 Vrms	Isolator Transpolar Pen Coolrail Linear Pen
L	30.0W from 20Ω to 200Ω	77.5 Vrms	Isolator Transpolar Pen Coolrail Linear Pen

ELECTRICAL SPECIFICATIONS

- **ASU**, rated: 100-120V ~ 50/60 Hz
- **ASB**, rated: 100-240V ~ 50/60 Hz

ENVIRONMENTAL SPECIFICATIONS

Operating Conditions	
Temperature	10°C to 40°C, 50°F to 104°F
Humidity	15% RH to 90% RH, non-condensing
Atmospheric pressure	80 kPa to 106 kPA, 11.603 psi to 15.374 psi
Storage Conditions	
Temperature	-29°C to 60°C, -20°F to 140°F
Humidity	30% RH to 85% RH, non-condensing
Transit Conditions	
Temperature	-29°C to 60°C, -20°F to 140°F
Humidity	30% RH to 85 % RH, non-condensing

EQUIPMENT TYPE/CLASSIFICATION

- Class I Equipment.

FOOTSWITCH SPECIFICATIONS

- Moisture protection rating: **IPX8**

FUSE SPECIFICATIONS

- **ASU:** LittelFuse 1.25A 250V, T-lag, 5 x 20 mm, UL Recognized, IEC Approved, RoHS
- **ASB:** LittelFuse 1A 250V, T-lag, 5 x 20 mm, UL Recognized, IEC Approved, RoHS

⚠ **Caution:** Do not alter the fuse from factory settings.

EXPECTED LIFETIME

The Expected Lifetime is the time-period during which the ASU/ASB and components are expected to remain suitable for its intended purpose, assuming the responsible organization will follow AtriCure's Instructions for Use for preventive maintenance.

AtriCure has defined the Expected Lifetime of the ASU/ASB system to be 10 years.

For information on preventive maintenance, please see CHAPTER 3 PREVENTIVE MAINTENANCE AND CLEANING, or contact your local AtriCure representative.

CHAPTER 5 TROUBLESHOOTING

Use this section for troubleshooting possible problems with the ASU/ASB system.

⚠ **Caution:** Do not open the back panel of the Devices. This may cause injury and damage to the units. 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.

NO RF POWER OUTPUT

Possible Cause	Action
ASU and/or ASB were not turned ON	Turn power ON for ASU and/or ASB
ASU and/or ASB were not plugged in	Confirm electrical connections for ASU and/or ASB, and then turn the power ON
No handpiece connected to ASB	Connect Handpiece to ASB
Incorrect handpiece selected on ASB	Rotate ASB Selector Switch to the desired handpiece
No Footswitch connected to ASB	Connect the Footswitch to the ASB Front Panel
Footswitch Interface Cable not connected	Connect the Footswitch Interface Cable between ASU and ASB back panels
RF Interface Cable not connected	Connect RF Interface Cable between ASU and ASB front panels
Fault in Footswitch	Replace Footswitch
Internal ASU Failure	Contact AtriCure Customer Service (refer to CHAPTER 6 CUSTOMER SERVICE/ EQUIPMENT SERVICING/WARRANTY)
ASU in FAULT mode	Turn the power OFF and then ON
ASU in STANDBY mode	Ensure that Handpiece and Footswitch are properly connected (no blinking LEDs)
Broken Handpiece	Replace Handpiece
Fault in Handpiece	
Expired Handpiece	

ERROR CODES

If a fault condition should occur, the Power Graph display on the front panel will display an error code.

Recoverable Errors		
LCD DISPLAY MESSAGE	**DESCRIPTION**	**SOLUTION / ACTION**
Code E01	Low Impedance Error: Handpiece electrodes are shorted	Check electrodes or reposition jaws
Code E02	High Impedance Error: Handpiece jaws are open	• Close handpiece jaws • Replace the handpiece or ASU/ ASB RF Interface Cable
Code E03	Low Impedance Error: Handpiece* electrodes are shorted *If the Handpiece is Coolrail Linear Pen, check if the Pump box LED is illuminated.	Check electrodes or reposition jaws. The end effector has overheated, or the cooling system has malfunctioned. Ensure the fluid cable is not kinked or occluded. If the E03 error persists more than 2 minutes, replace the Handpiece.
Code E04		
Code E06	Switch Stuck Test Error: Footswitch closed while connecting	Replace footswitch
Code E10	Handpiece electrodes are shorted	Check electrodes or reposition jaws
Code H01	Invalid Handpiece Error	Replace handpiece or ASU/ ASB RF Interface Cable or ASB
Code H02	Time Expired Error: Handpiece expiration date has been exceeded	Replace Handpiece
Code H03	Handpiece electrical problem	
Code H04	Invalid Handpiece version	
Return ASU for Maintenance	ASU Clock Battery had failed	ASU will continue to operate, but the message and tone will repeat. Return ASU for battery replacement.

POWER ON SELF TEST (POST) Errors detected at start up		
Code P01	Power Generation / Measurement Error	Power the unit OFF, then Power it ON again. Allow the Device to run through normal start-up self-diagnostics. If the device returns to the Error state and the problem persists, contact AtriCure Customer Service (refer to CHAPTER 6 CUSTOMER SERVICE/ EQUIPMENT SERVICING/ WARRANTY) ****For P10:** Deactivate the footswitch and power cycle the Device.
Code P02	Impedance Generation / Measurement Error	
Code P03	Voltage Generation / Measurement Error	
Code P04	Current Generation / Measurement Error	
Code P05	Watchdog Test Error	
Code P06	ROM Test Error	
Code P07	RAM Test Error	
Code P08	Configuration Register Error	
Code P09	MCU COP Timer Error	
Code P10**	Switch Stuck Test Error (Check Footswitch as it was activated during POST)	
Code P12	Reference Voltage Error	

ERRORS during ASU Operation		
Code F01	Illegal CPU Instruction	Cycle power OFF and back ON If the problem persists, replace ASU, and contact AtriCure Customer Service
Code F02	Duplicate Variable Error	
Code F03	Software Error	
Code F05	Reference Voltage Error	
Code F06	Power Limit Error	
Code F07	Voltage Limit Error	
Code F09	Vrms Offset Error	
Code F10	Irms Offset Error	
Code F11	Power Offset Error	
Code F12	System Sync Error	
Code F13	Power Measurement Error	
Code F14	Relay Stuck Closed Error	

MONITOR (DISPLAY) INTERFERENCE

CONTINUOUS INTERFERENCE

1. Check the power cord connections to both the ASU and ASB.
2. Check all other electrical equipment in the OR for defective grounds.
3. If the electrical equipment is grounded to different objects, rather than a common ground, voltage differences can appear between the two grounded objects. The monitor may respond to these voltages. Some types of input amplifiers can be balanced to achieve optimum common mode rejection and may possibly correct the problem.

INTERFERENCE ONLY WHEN ASU/ASB IS ACTIVATED

1. Check all connections to the ASU/ASB, and the active Handpiece to look for possible metal-to-metal sparking.
2. If interference continues when the ASU/ASB is activated and while the electrode is not in contact with the patient, the monitor is responding to radio frequencies. Some manufacturers offer RF choke filters for use in the monitor leads. These filters reduce interference while the ASU/ASB is activated. RF filters minimize the potential for an electrosurgical burn at the site of the monitor electrode.
3. Check that the ground wires in the OR are electrically consistent. All ground wires should go to the same grounded metal with wires that are as short as possible.
4. If the above steps do not remedy the situation, contact AtriCure Customer Service.

NEUROMUSCULAR STIMULATION

1. Stop the surgical procedure.
2. Check all connections to the ASU/ASB and active electrodes to look for a possible metal-to-metal spark.
3. If no problems are found, the ASU/ASB should be checked by qualified AtriCure service personnel for abnormal 50/60 Hz AC leakage current.

PACEMAKER INTERFERENCE

1. Check all connections,
2. Always monitor pacemaker patients during surgery.
3. Always keep a defibrillator available during electrosurgery on patients with pacemakers.
4. Consult the pacemaker manufacturer for specific recommendations.

CHAPTER 6 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 Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
+1 866 349 2342
+1 513 755 4100

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:

AtriCure Ablation and Sensing Unit	**One (1) Year**
AtriCure Switch Matrix	**One (1) Year**
AtriCure Footswitch	**One (1) Year**
Grounded Electrical Cord(s)	**One (1) Year**
RF and Footswitch Interface Cables	**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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