AtriCure® Synergy Ablation System
Instructions for Use

Rx ONLY

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AtriCure® Synergy Ablation System
Instructions for Use

DESCRIPTION

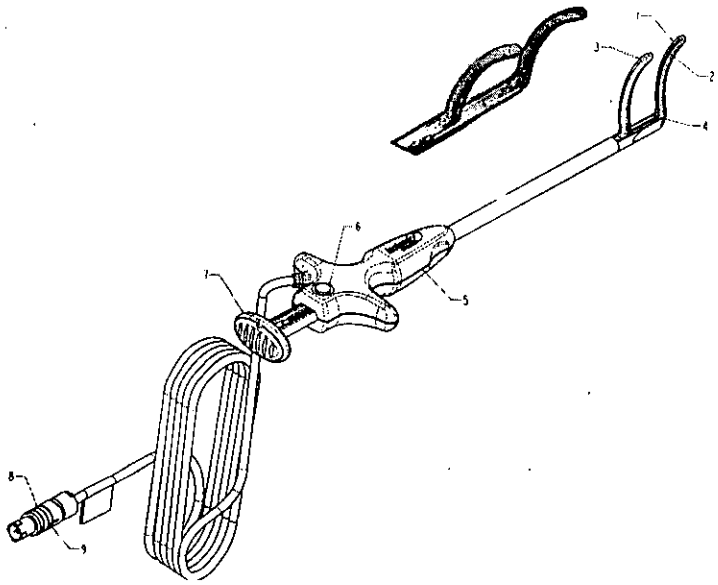
The AtriCure Synergy Ablation System is comprised of the Ablation and Sensing Unit (ASU2), an AtriCure Switch Box (ASB3), an AtriCure Synergy Ablation Clamp, and a footswitch. The AtriCure Synergy Ablation Clamp is a single patient use electrosurgical instrument designed for use only with the ASU2. The Synergy Ablation Clamp is intended to ablate cardiac tissue for the treatment of patients with persistent or longstanding persistent atrial fibrillation who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair. When activated, the ASU2 delivers radiofrequency (RF) energy to the linear electrodes on the insulated jaws of the Synergy Ablation Clamp. The Operator controls the application of this RF energy by pressing the Footswitch.

The Synergy™ Ablation (See Figure 1) Clamps feature two pairs of opposing dual electrodes, an in-line handle with syringe-type actuation and button release mechanisms. The Synergy Ablation Clamp requires the use of the AtriCure Switch Box (ASB3) and Ablation Sensing Unit (ASU2).

NOTE: **Please refer to the AtriCure ASU2 and ASB3 Instructions for Use for information specific to the ASU2 and ASB3.**

AtriCure Synergy Ablation Clamp
ILLUSTRATION AND NOMENCLATURE

(Figure 1)



(AtriCure SYNERGY ABLATION CLAMP)

1. Distal Jaw
2. Electrodes
3. Proximal Jaw
4. Jaw Heel
5. Handle
6. Release Mechanism
7. Closure Lever
8. Connector
9. Connector Alignment Arrow

INDICATION FOR USE

The AtriCure Synergy Ablation System is intended to ablate cardiac tissue for the treatment of persistent atrial fibrillation (sustained beyond seven days, or lasting less than seven days but necessitating pharmacologic or electrical cardioversion) or longstanding persistent atrial fibrillation (continuous atrial fibrillation of greater than one year duration) in patients who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair.

CONTRAINDICATIONS

The AtriCure Synergy Ablation System should not be used for contraceptive coagulation of the fallopian tubes. The device is not designed for safe and effective use for that purpose.

WARNINGS

- Do not touch the electrodes of the Synergy Ablation Clamp while activating the ASU2. Touching the Synergy Ablation Clamp electrodes during ASU2 activation could result in an electrical shock or burn to the operator.
- Do not touch the electrodes of the Synergy Ablation Clamp to metal staples or clips, or to sutures while activating the ASU2. This may damage the Synergy Ablation Clamp or tissue, or result in an incomplete ablation.
- Do not use abrasive cleaners or electrosurgical tip cleaners to clean debris from the Jaws. Use of abrasive cleaners or electrosurgical tip cleaners can damage the electrodes and result in device failure. Use saline-soaked gauze to clean debris off the electrodes.
- Do not immerse any part of the Synergy Ablation Clamp in liquids as this may damage the device.
- Always wear appropriate surgical gloves when using the AtriCure Synergy Ablation System to avoid shock/burn hazards.
- Inspect the product packaging prior to opening to ensure that the sterility barrier is not breached. If the sterility barrier is breached, do not use the Synergy Ablation Clamp to avoid the risk of patient infection.
- 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 use of electrosurgical appliances is planned in patients with cardiac pacemakers.
- The AtriCure Synergy Ablation System has not been studied in the reoperative setting, so safe and effective use can not be assured.
- The full Maze IV procedure cannot be completed with the AtriCure Synergy Ablation System alone. See Table 2 for a description of the devices used in the ABLATE Clinical study.

Potential Complications

The AtriCure Synergy Ablation System is indicated for use as a concomitant procedure with open coronary artery bypass grafting and/or valve replacement or repair. Below is a list of potential adverse effects (e.g., complications) that are associated with this combined procedure:

- Death,
- Excessive bleeding that may require re-intervention,
- Cardiac tamponade,
- Pulmonary vein stenosis,
- Restrictive or constrictive pericarditis,
- Infection that may result in sepsis or endocarditis,
- Myocardial infarction (MI),
- Stroke or transient ischemic attack (TIA),
- Thromboembolism,
- Diaphragmatic (phrenic nerve) paralysis,
- Esophageal-left atrial fistula or esophageal rupture,
- Atrial perforation or rupture,
- Ventricular perforation or rupture,
- Atelectasis,
- Pneumonia,

- Congestive heart failure,
- Cardiac valve injury,
- Persistent pneumothorax,
- Excessive pain and discomfort,
- Deep sternal wound infection (mediastinitis),
- Perioperative atrial or ventricular rhythm/conduction disturbance,
- Pericardial effusion,
- Injury to the great vessels,
- Injury to unintended surrounding tissues, including tears and punctures,
- Extension of cardiopulmonary bypass time or aortic cross clamp time.

PRECAUTIONS

- Read all instructions carefully for the AtriCure Synergy Ablation System, prior to using the device. Failure to properly follow instructions may lead to electrical or thermal injury and may result in improper functioning of the device.

- The use of the AtriCure Synergy Ablation System is limited to physicians with specific training on the procedure and product.

- Use the Synergy Ablation Clamp only as indicated. Variations in specific procedures may occur due to individual physician techniques and patient anatomy.

- Do not drop or throw the Synergy Ablation Clamp as this may damage the device. If the Synergy Ablation Clamp is dropped, do not use. Replace with a new Synergy Ablation Clamp.

- Do not use the Synergy Ablation Clamp in the presence of flammable materials.

- Do not re-sterilize or reuse the Synergy Ablation Clamp.

- Keep the jaws of the Synergy Ablation Clamp clean of debris during surgery to avoid loss of power.

- Do not use of the Synergy Ablation Clamp with another manufacturer's generator to avoid damage to the device, which may result in patient injury. The Synergy Ablation Clamp is only compatible with the AtriCure ASU2 and ASB3.

- Do not ablate tissue greater than 10 mm thick with the Synergy Ablation Clamp. Tissues greater than 10 mm thick may not be fully ablated.

- Do not use the Synergy Ablation Clamp for coagulation or ablation of veins or arteries.

- Inspect the area between the jaws of the Synergy Ablation Clamp for foreign matter before activating the ASU2 or ASB3. Foreign matter captured between the jaws will adversely affect the ablation.

- Do not insert excessive tissue into the jaw heel as it may result in poor ablation at the jaw heel.

- Do not ablate in a pool of blood or other fluids as this may extend the ablation time. Users should suction excess fluids away from the jaws prior to ablation.

- Do not attempt to use a Synergy Ablation Clamp that has reached its time limit expiration. The Synergy Ablation Clamp has an 8-hour useful life that is tracked by the ASU2. The Synergy Ablation Clamp will no longer function after 8 hours of use and the ASU2 will display a message indicating that the Synergy Ablation Clamp must be replaced.

- Do not use the Synergy Ablation Clamp if signs of damaged wire insulation are noted upon inspection of the area around the jaw heel as it may adversely affect ablation performance.

- When the ASU2 (RF generator) and Synergy Ablation Clamp 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 Synergy Ablation Clamp 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 ASU2 (RF generator) and Synergy Ablation Clamp.

- Monitoring systems that incorporate high frequency current-limiting devices are recommended for use with the ASU2 (RF generator) and Synergy Ablation Clamp.

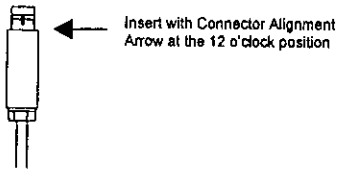
- When the ASU2 (RF generator) is activated in conjunction with the Synergy Ablation Clamp, the conducted and radiated electrical fields may interfere with other electrical medical equipment. Refer to the ASU2 IFU for more information regarding potential electromagnetic or other interference, and advice regarding avoidance of such interference.

INSTRUCTIONS FOR USE

SET UP

1. Examine the packaging of the device to ensure the sterility of the product has not been breached. Remove the sterilized instrument from its package per standard sterile technique.

2. With the Connector Alignment Arrow symbol in the 12 o'clock position, push the connector into the appropriate Synergy Ablation Clamp receptacle on the front of the ASB3. Each Synergy Ablation Clamp has a unique receptacle on the ASB3. To ensure device performance, verify proper connections to the ASB3 by consulting the ASB3 package insert. Verify that the connections between the Synergy Ablation Clamp and the ASB3 are secure. If the connections are loose, do not use the Synergy Ablation Clamp. Inspect the cable and do not use the Synergy Ablation Clamp if the cable is frayed or the insulation is damaged.



ABLATION

3. Place the targeted tissue between the distal and proximal jaws of the Synergy Ablation Clamp.

4. Depress the Closure Lever to close the Jaws. Ensure that no target tissue extends beyond the Indicator Line on either the distal or proximal jaws or into the jaw heel.

5. Activate the ASU2 by depressing the footswitch. When the ASU2 is activated, the ASU2 will emit an audible tone indicating that current is flowing between the jaws of the Synergy Ablation Clamp. When the continuous tone switches to intermittent, release the footswitch.

6. The AtriCure Synergy Ablation System measures tissue impedance and temperature throughout the ablation cycle and uses this information to control the application of energy to the tissue. The amount of energy delivered to the tissue is driven solely by tissue impedance. The System determines the minimum energy delivery required to create a transmural (full thickness) lesion based on tissue impedance and delivers only that amount of energy to the tissue. Energy delivery changes throughout the ablation cycle as tissue impedance changes. The lesion is visible as a white coloration of the tissue. The device is designed such that the lesions will not spread beyond the jaw width.

Note: All of the clamps have been designed to maintain less than 50°C temperature outside of the clamped region.

Note: The time necessary to create a transmural lesion depends on tissue thickness, composition, and the length of tissue captured between the electrodes. The following table describes the average expected time (seconds) and energy delivery (joules) for respective tissue thicknesses. Values are expressed per unit volume of tissue captured between the electrodes. These data were obtained during ablations on ex vivo (excised bovine) tissues and will generally be lower on in vivo (live human) tissues.

Table 1: Average Time vs. Energy Delivery

Tissue Thickness	Time to Transmurality per unit volume (sec/mm^3)		Energy Delivered per Unit Volume (J/mm^3)	
	AVG	STDDEV	AVG	STDDEV
2 mm	0.049	0.007	0.76	0.11
5 mm	0.033	0.006	0.57	0.10
10 mm	0.032	0.009	0.55	0.16

7. To open the jaws, press the Release Mechanism and slowly release the Closure Lever. Do not allow the jaws to spring back. Be aware of any surrounding tissues that could be damaged as the jaws open.

8. Inspect the surgical area to ensure adequate ablation.

9. Between ablations, wipe the jaws clean with a saline-soaked gauze pad. Important: For optimal performance, keep the Synergy Ablation Clamp electrodes clear of coagulum. To ensure the electrodes are clear of coagulum:

   Use a saline soaked gauze pad to clean the electrodes after each ablation. If coagulum is present, it is much easier to remove within the first several seconds after ablation. In a brief period of time, the coagulum could dry out making removal more difficult.

   Check both electrodes before each ablation to ensure that the gold of the electrode is visible and coagulum is removed.

   If the Synergy Ablation Clamp is idle between ablations, clamp the jaws onto a saline soaked gauze pad to prevent any coagulum on the electrodes from drying.

10. Repeat the ablation process as necessary.

REMOVAL AND DISPOSAL

11. Discard the Synergy Ablation Clamp after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

SUMMARY OF CLINICAL STUDIES CONDUCTED FOR ATRIAL FIBRILLATION TREATMENT INDICATION

The ABLATE (AtriCure Synergy Bipolar RF Energy Lesions for Permanent Atrial Fibrillation Treatment during Concomitant On-Pump Endo/Epicardial Cardiac Surgery) clinical study has been performed in demonstration of the AtriCure Synergy Ablation System's safety and effectiveness for the treatment of persistent or longstanding persistent atrial fibrillation (AF) in patients undergoing concomitant coronary artery bypass grafting and/or valve replacement or repair.

A continued registry study (ABLATE AF) was established following ABLATE. The ABLATE AF study had identical inclusion and exclusion criteria as ABLATE, except that ABLATE enrolled patients with "permanent AF" (per 2006 ACC/AHA/ESC Guidelines) and ABLATE AF enrolls patients with "persistent or longstanding persistent AF" (per the 2007 HRS Consensus Statement). Results of both studies are presented.

Study Design
ABLATE was a multi-center, prospective, non-randomized study based on a Bayesian adaptive design that provides high probability of demonstrating safety and effectiveness of the AtriCure Synergy Ablation System for the treatment of permanent atrial fibrillation. The safety and effectiveness of the device was compared to performance goals derived from historical information. The Bayesian adaptive clinical design incorporated interim analyses of the data to determine the point of completion of trial enrollment. Enrollment was targeted to be between 50 and 100 subjects at 20 sites. The study was designed to have an initial assessment of results at the point that 50 subjects were enrolled with a minimum of 20 subjects completing their six-month follow-up visit. Nine investigational sites enrolled 55 subjects.

In the Bayesian setting probabilistic statements are made about parameters given observed data (as compared to the frequentist setting where probabilistic statements are made about the data given an assumed parameter value, e.g. a p-value). Two such Bayesian constructs are the posterior probability and credible interval. A posterior probability conveys the probability that the true but unknown effectiveness rate or MAE rate lies above (effectiveness) or below (safety) the stated threshold. For example "There is a 97.9% chance that the true but unknown effectiveness rate is greater than or equal to 60% in this patient population." Similarly a Bayesian credible interval gives a range for the likely values: a 95% credible interval conveys there is a 95% chance that the true but unknown parameter lies between the interval's lower and upper bounds. For example "given the results of the trial, there is a 95% probability that the chance of success ranges from 60.4% to 82.5%". A narrower interval conveys greater precision in the estimate.

Inclusion and Exclusion criteria
Key Inclusion Criteria included:

- ≥ 18 years of age
- History of permanent AF in which cardioversion (electrical and/or pharmacologic) has failed or has not been attempted (as defined by the 2006 ACC/AHA/ESC Guidelines).
- Scheduled to undergo elective cardiac surgical procedure(s) to be performed on cardiopulmonary bypass
- Left Ventricular Ejection Fraction ≥ 30%

Key Exclusion Criteria included:

- Class IV NYHA heart failure symptoms
- Preoperative need for intra-aortic balloon pump or intravenous inotropes
- Left atrial size ≥ 8cm
- Cerebrovascular accident within the prior 6 months
- Myocardial Infarction within the prior 6 weeks
- Need for emergent cardiac surgery
- Renal failure requiring dialysis or hepatic failure
- Repeat (re-do) cardiac surgical procedure

Maze IV Procedure

Figure 1 and Table 2 below summarize the lesions specified by the ABLATE protocol for completion of the Maze IV lesion set, as well as which lesions were to be performed using the AtriCure Synergy Ablation System or other devices.

Figure 1: Maze IV Procedure Lesion Set

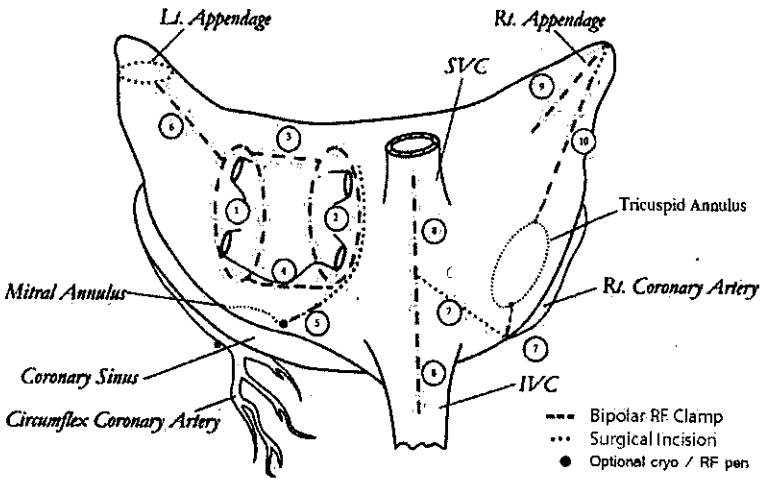


Table 2: Lesions for Maze IV per ABLATE Protocol

Lesion Name	Device to be Used
Pulmonary Vein Lesions	AtriCure Synergy Ablation Clamp
Box Lesion	ROOF and FLOOR lines: AtriCure Synergy Ablation Clamp
Mitral Valve Annulus Lesion	The AtriCure Synergy Ablation clamp is used to start the lesion and the AtriCure Cryoablation System or the AtriCure Bipolar Pen is used to complete the lesion at the annulus of the tricuspid and mitral valve.
LA Appendage Lesion	AtriCure Synergy Ablation Clamp
Tricuspid Valve Lesion	To be performed with the modality of ablation desired by the surgeon.
SVC to IVC Lesion	AtriCure Synergy Ablation Clamp
Right Atrial Free Wall Appendage Lesion	AtriCure Synergy Ablation Clamp
Right Atrial Appendage to Tricuspid Annulus Lesion	The AtriCure Synergy Ablation clamp is used to start the lesion and the AtriCure Cryoablation System or the AtriCure Bipolar Pen is used to complete the lesion at the annulus.

Study Endpoints

The Primary Effectiveness endpoint is the rate of subjects free of AF without the need for Class I and III antiarrhythmic drugs six months after treatment with the system. Freedom from AF is defined as no events of AF longer than 5 minutes and combined events of AF do not exceed 1 hour per 24-hour period assessed by a 24-hour Holter that was reviewed by an independent core laboratory. The effectiveness performance goal was extrapolated from literature to be 60% AF Free and off any AADs at six months.

The Primary Safety endpoint is a composite rate of acute major adverse events within 30 days post procedure or hospital discharge, whichever is later. This composite safety endpoint includes death, stroke (resulting in significant permanent disability), TIA, myocardial infarction, and excessive bleeding (requiring >2 units of blood replacement and surgical intervention). It also included deaths after 30 days if the death was procedure related. The safety performance goal was extrapolated from literature to be 18.95%.

Subject Accountability

Table 3 demonstrates the accountability of subjects enrolled in the ABLATE and ABLATE AF studies.

Table 3: Subject Accountability

Parameter	ABLATE N=55	ABLATE Non-Paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-Paroxysmal N=64
Patients Enrolled [n] [1]	55	51	69	64
Procedure and Follow-up visit data available [% (n/N)]	N=55	N=51	N=69	N=64
Procedure	100.0% (55/55)	100.0% (51/51)	100.0% (69/69)	100.0% (64/64)
Discharge	96.4% (53/55)	96.1% (49/51)	97.1% (67/69)	96.9% (62/64)
30 Day [2]	96.4% (53/55)	96.1% (49/51)	97.1% (67/69)	96.9% (62/64)
3 Month [3]	87.3% (48/55)	86.3% (44/51)	88.4% (61/69)	87.5% (56/64)
6 Month[4]	90.9% (50/55)	90.2% (46/51)	89.9% (62/69)	89.1% (57/64)
12 Months or later [5]	87.3% (48/55)	88.2% (45/51)		
Follow-up Time in Study (Days) [6]				
Mean +/- SD (N)	555.6 +/- 208.1 (55)	555.8 +/- 208.0 (51)	491.9 +/- 227.9 (69)	492.5 +/- 227.5 (64)
Median	554.0	554.0	547.0	547.0
Min, Max	4.0, 743.0	4.0, 743.0	4.0, 743.0	4.0, 743.0

[1] All subjects treated with Ablation procedure.
[2] Two ABLATE subjects expired prior to 30 days. One subject discharged at 35 days. Assessment performed on that day included in both discharge and 30 days summaries.
[3] One ABLATE subject withdrew prior to 3 month assessment, three ABLATE subjects missed the 3 month visit, and one ABLATE subject expired prior to the 3 month assessment.
[4] One ABLATE subject expired prior to 6 months. Subjects in ABLATE AF are shown with completed assessment at 6 months or later. Two ABLATE AF subjects were not evaluated at 6 months or later at the time of this analysis.
[5]] Subjects are shown with completed assessment at 12 months or later. Two ABLATE subjects expired between the 6 month and long-term follow-up assessments.
[6] Study entry to last scheduled follow-up assessment or study exit.

Table 4 demonstrates the population of subjects represented in this dataset. The data are presented for all treated subjects and for the indicated (longstanding persistent and persistent) subjects. In the ABLATE population, there were 4 subjects with paroxysmal AF and 51 subjects with persistent or long-standing persistent AF (hereafter referred to as non-paroxysmal AF). When also including the ABLATE AF registry subjects, there were 5 subjects with paroxysmal AF and 64 subjects with non-paroxysmal AF.

Table 4: AF Classification

	ABLATE	ABLATE AF	ABLATE + ABLATE AF
AF Classification			
Paroxysmal	4	1	5
Persistent	22	2	24
Longstanding Persistent	29	11	40
Indicated Population	**51**	**13**	**64**

Subject Demographics
Table 5 demonstrates subject demographics for all groups.

Table 5: Subject Demographics

Parameter	ABLATE N=55	ABLATE Non-Paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-Paroxysmal N=64
Age [years]				
Mean +/- SD (N)	70.5 +/- 9.3 (55)	70.8 +/- 9.6 (51)	70.4 +/- 9.0 (69)	70.8 +/- 9.2 (64)
Median	72.0	73.0	72.0	72.5
Min, Max	45.0, 88.0	45.0, 88.0	45.0, 88.0	45.0, 88.0
Gender [% (n/N)]				
Male	58.2% (32/55)	60.8% (31/51)	62.3% (43/69)	64.1% (41/64)
Female	41.8% (23/55)	39.2% (20/51)	37.7% (26/69)	35.9% (23/64)
Time since AF onset (months)				
Mean +/- SD (N)	61.2 +/- 49.5 (55)	61.7 +/- 51.1 (51)	67.3 +/- 55.6 (69)	68.4 +/- 57.3 (64)
Median	48.6	48.6	54.8	55.8
Percentile: 25th, 75th	20.1, 96.1	19.5, 98.4	20.5, 98.4	19.8, 99.9
Min, Max	1.78, 188.39	1.78, 188.39	1.78, 247.17	1.78, 247.17
Left Atrial Size (cm)				
Mean +/- SD (N)	5.9 +/- 1.0 (50)	6.0 +/- 1.0 (46)	5.8 +/- 1.1 (64)	5.9 +/- 1.1 (59)
Median	6.0	6.0	5.7	5.8
Min, Max	3.9, 7.7	3.9, 7.7	3.0, 7.7	3.0, 7.7
>= 5 cm	86.0% (43/50)	87.0% (40/46)	81.3% (52/64)	81.4% (48/59)
Surgical Procedure Type(s)				
CABG only	18.2% (10/55)	19.6% (10/51)	21.7% (15/69)	23.4% (15/64)
Valve Surgery	40.0% (22/55)	37.3% (19/51)	34.8% (24/69)	32.8% (21/64)
Mitral Valve Repair/Replacement	18.2% (10/55)	17.6% (9/51)	15.9% (11/69)	15.6% (10/64)
Aortic Valve Repair/Replacement	21.8% (12/55)	19.6% (10/51)	18.8% (13/69)	17.2% (11/64)
Double Valve Surgery	16.4% (9/55)	17.6% (9/51)	14.5% (10/69)	15.6% (10/64)
Aortic & Mitral	7.3% (4/55)	7.8% (4/51)	5.8% (4/69)	6.3% (4/64)
Mitral & Tricuspid	9.1% (5/55)	9.8% (5/51)	8.7% (6/69)	9.4% (6/64)

Parameter	ABLATE N=55	ABLATE Non-Paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-Paroxysmal N=64
CABG and Valve Surgery	16.4% (9/55)	15.7% (8/51)	21.7% (15/69)	20.3% (13/64)
CABG + Mitral Valve Repair/Replacement	10.9% (6/55)	9.8% (5/51)	11.6% (8/69)	10.9% (7/64)
CABG + Aortic Valve Repair/Replacement	5.5% (3/55)	5.9% (3/51)	10.1% (7/69)	9.4% (6/64)
CABG + Double Valve Surgery	9.1% (5/55)	9.8% (5/51)	7.2% (5/69)	7.8% (5/64)
Aortic & Mitral	5.5% (3/55)	5.9% (3/51)	4.3% (3/69)	4.7% (3/64)
Mitral & Tricuspid	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)
Any Mitral Valve Surgery	54.5% (30/55)	54.9% (28/51)	49.3% (34/69)	50.0% (32/64)

Primary Safety Results

The Primary Safety Endpoint for ABLATE has been evaluated in both the treated population and the non-paroxysmal AF study population that were enrolled and treated with the AtriCure Synergy Ablation System. A clinic visit was performed at 30 days to fully assess the patient for potential adverse events. An evaluation of all subjects was available to assess this primary safety endpoint. There were five safety failures in the cohort including two deaths, two excessive bleeds and one stroke, as outlined in Table 6. When tested against the objective performance goal, the upper bound of the Bayesian Credible Interval fell below 0.1895 for the full ABLATE population, but above 0.1895 for the non-paroxysmal subpopulation.

Table 6: Primary Safety Endpoint

Primary Safety Endpoint	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Primary Safety Endpoint	% (n/N) [BCI] [1] PP [2]	% (n/N) [BCI] [1] PP [2]	% (n/N)	% (n/N)
Primary Endpoint (Acute MAE within 30 days post procedure)	9.1% (5/55) [0.00, 0.179] PP = 0.967	9.8% (5/51) [0.00, 0.192] PP = 0.946	7.2% (5/69)	7.8% (5/64)
Death	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)
<=30 days	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)
>30 days, procedure related	0.0% (0/55)	0.0% (0/51)	0.0% (0/69)	0.0% (0/64)
Stroke/TIA	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)
Stroke (with significant permanent disability)	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)
TIA	0.0% (0/55)	0.0% (0/51)	0.0% (0/69)	0.0% (0/64)
MI	0.0% (0/55)	0.0% (0/51)	0.0% (0/69)	0.0% (0/64)
Excessive Bleeding (>2 units blood and surgical intervention)	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)

[1] "BCI" is the 95% one-sided Bayesian Credible Interval. Beta (1,1) prior in accordance with the statistical plan.

[2] "PP" is the posterior probability the safety rate is less than 0.1895, Pr(qT < 0.1895 | Trial Results).

Primary Effectiveness Results

The primary effectiveness endpoint was defined as the rate of subjects that achieved successful obliteration of atrial fibrillation while off of any antiarrhythmic medication (Class I or III) evaluated at six months post procedure via 24 hour Holter monitor assessment (or permanent pacemaker interrogation in the case of those subjects who had a pacemaker implanted). The effectiveness results are presented in Table 7.. When tested against the objective performance goal, the lower bound of the Bayesian Credible Interval exceeded 0.60 for the full ABLATE population, but was below 0.60 in the non-paroxysmal subpopulation. The results for pulmonary vein isolation are presented in Table 8.

Table 7: Primary Effectiveness Endpoint

	ABLATE	ABLATE Non-paroxysmal	ABLATE + ABLATE AF	ABLATE + ABLATE AF Non-paroxysmal
Summary of Effectiveness Endpoints	**% (n/N) [BCI] [1] PP [2]**	**% (n/N) [BCI] [1] PP [2]**	**% (n/N)**	**% (n/N)**
Effectiveness Evaluable at 6 month Follow-up	N=50	N=46	N=62	N=57
Free of AF and off AAD	74.0% (37/50) [0.604, 1.00] PP = 0.978	73.9% (34/46) [0.597, 1.00] PP = 0.972	75.8% (47/62)	75.4% (43/57)
Free of AF	84.0% (42/50)	82.6% (38/46)	85.5% (53/62)	84.2% (48/57)

[1] "BCI" is the 97.5% one-sided Bayesian Credible Interval. Beta (1,1) prior in accordance with the statistical plan.

[2] "PP" is the posterior probability that the effectiveness rate exceeds 0.60, Pr(pT > 0.60 | Trial Results).

Table 8: Pulmonary Vein Isolation Summary

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Both Right & Left Pulmonary Vein Isolation Evaluated [1]	41.8% (23/55)	43.1% (22/51)	47.8% (33/69)	48.4% (31/64)
Both Right & Left Pulmonary Vein Isolation Confirmed [2]	100.0% (23/23)	100.0% (22/22)	100.0% (33/33)	100.0% (31/31)

[1] Includes subjects evaluable on both sides.

[2] Successful pulmonary vein isolation on both left and right side.

Secondary Safety and Effectiveness Results

Table 9 demonstrates primary and secondary effectiveness endpoints, including long-term effectiveness. ABLATE AF subjects had not reached the 12-month follow-up at the time of review.

Table 9: Primary and Secondary Effectiveness Endpoints

	ABLATE	ABLATE Non-paroxysmal	ABLATE + ABLATE AF	ABLATE + ABLATE AF Non-paroxysmal
Summary of Effectiveness Endpoints	% (n/N) [BCI] [1] PP [2]	% (n/N) [BCI] [1] PP [2]	% (n/N)	% (n/N)
Effectiveness Evaluable at 6 month Follow-up	N=50	N=46	N=62	N=57
Free of AF and off AAD	74.0% (37/50) [0.604, 1.00] PP = 0.978	73.9% (34/46) [0.597, 1.00] PP = 0.972	75.8% (47/62)	75.4% (43/57)
Free of AF	84.0% (42/50)	82.6% (38/46)	85.5% (53/62)	84.2% (48/57)
AF Burden [3]				
= 0 min	82.0% (41/50)	82.6% (38/46)	83.9% (52/62)	84.2% (48/57)
<= 5 min	2.0% (1/50)	0.0% (0/46)	1.6% (1/62)	0.0% (0/57)
> 5 min - 1 hr	2.0% (1/50)	2.2% (1/46)	1.6% (1/62)	1.8% (1/57)
> 1 hr	14.0% (7/50)	15.2% (7/46)	12.9% (8/62)	14.0% (8/57)
Effectiveness Evaluable at 12 month Follow-up or greater	N=48	N=45		
Time to Evaluation (days)				
Mean +/- SD (N)	640.9 +/- 147.3	641.7 +/- 151.7		
Min, Max	365.0, 952.0	365.0, 952.0		
Method of Evaluation				
Holter	81.3% (39/48)	82.2% (37/45)		
Pacemaker Interrogation (PMI)	2.1% (1/48)	2.2% (1/45)		
ECG	6.3% (3/48)	4.4% (2/45)		
Other/Telephone Assessment	10.4% (5/48)	11.1% (5/45)		
Free of AF and off AAD (12 month follow-up or greater)	62.5% (30/48)	62.2% (28/45)		
Free of AF (12 month follow-up or greater)	75.0% (36/48)	73.3% (33/45)		
AF Burden (initial 24 hrs or >24 - 48 hrs) [3] [4]				
= 0 min	77.5% (31/40)	76.3% (29/38)		
<= 5 min	0.0% (0/40)	0.0% (0/38)		
> 5 min - 1 hr	0.0% (0/40)	0.0% (0/38)		

	ABLATE	ABLATE Non-paroxysmal	ABLATE + ABLATE AF	ABLATE + ABLATE AF Non-paroxysmal
Summary of Effectiveness Endpoints	% (n/N) [BCI] [1] PP [2]	% (n/N) [BCI] [1] PP [2]	% (n/N)	% (n/N)
> 1 hr	22.5% (9/40)	23.7% (9/38)		

[1] "BCI" is the 97.5% one-sided Bayesian Credible Interval. Beta (1,1) prior in accordance with the statistical plan.

[2] "PP" is the posterior probability that the effectiveness rate exceeds 0.60, Pr(pT > 0.60 | Trial Results).

[3] Patients with Pacemaker Interrogation (PMI) included as 0 min if no Atrial Fibrillation (AFib) on PMI, otherwise included based on equivalent proportion of AFib burden per total pacemaker interrogation period.

[4] Evaluable only in patients with a Holter or Pacemaker Interrogation (PMI)

Table 10 demonstrates the pacemaker implantation rate through 30 days.

Table 10: Pacemaker Implantation Through 30 days

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
	% [n/N]	% [n/N]	% [n/N]	% [n/N]
Pacemaker Pre-procedure	12.7% (7/55)	9.8% (5/51)	14.5% (10/69)	12.5% (8/64)
Post Procedure				
Permanent Pacemaker Implantation, as Adjudicated [1] [2]	25.0% (12/48)	26.1% (12/46)	20.3% (12/59)	21.4% (12/56)
AV node dysfunction	8.3% (4/48)	8.7% (4/46)	6.8% (4/59)	7.1% (4/56)
Sinus node dysfunction	16.7% (8/48)	17.4% (8/46)	13.6% (8/59)	14.3% (8/56)

[1] One subject has both an AV Nodal Block and a Bradycardia event leading to permanent pacemaker implant.
[2] One subject had a single chamber pacemaker present at baseline which was upgraded to dual chamber at follow-up.

The rate of serious device- and ablation procedure-related adverse events through 6 months is demonstrated in Table 11. Table 12 lists the observed serious device- or ablation procedure-related adverse events. There were four subjects with AV node dysfunction who received pacemakers. Using the most conservative approach, these were attributed to the MAZE procedure. However, the need for a pacemaker could be attributed to the primary procedure. Three events occurred during surgical access. They included one case of a pulmonary vein tear when dissecting the vein to place the clamp, one torn IVC during cannulation and one left atrial tear which occurred when lifting the heart for surgical access. The final case of akinesis caused by ischemia was associated with possible coronary injury from an ancillary ablation pen. The event was successfully treated with two bypass grafts.

Table 11: Serious Device- and Ablation Procedure-Related Adverse Events Through 6 Months

	ABLATE N=55		ABLATE Non-Paroxysmal N=51		ABLATE+ABLATE AF N=69		ABLATE+ABLATE AF Non-paroxysmal N=64	
Parameter [1] [2]	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event
Investigational Device	0	0.0% (0/55)	0	0.0% (0/51)	0	0.0% (0/69)	0	0.0% (0/64)
AF Procedure	7	12.7% (7/55)	7	13.7% (7/51)	7	10.1% (7/69)	7	10.9% (7/64)
Ancillary Device	1	1.8% (1/55)	1	2.0% (1/51)	1	1.4% (1/69)	1	1.6% (1/64)

[1] As Adjudicated or site reported if not yet adjudicated.
[2] Relationship presented hierarchally as listed in table.

Table 12: Listing of Observed Serious Device- or Ablation Procedure-Related Serious Adverse Events

Event Name	Relationship	Description
A-V Node Dysfunction	AF Ablation Procedure	AV-Node dysfunction requiring permanent pacemaker implantation. Conservatively attributed to the MAZE procedure, however the need for a pacemaker could be attributed to the primary procedure.
A-V Node Dysfunction	AF Ablation Procedure	AV-Node dysfunction requiring permanent pacemaker implantation. Conservatively attributed to the MAZE procedure, however the need for a pacemaker could be attributed to the primary procedure.
A-V Node Dysfunction	AF Ablation Procedure	AV-Node dysfunction requiring permanent pacemaker implantation. Conservatively attributed to the MAZE procedure, however the need for a pacemaker could be attributed to the primary procedure.
A-V Node Dysfunction	AF Ablation Procedure	AV-Node dysfunction requiring permanent pacemaker implantation. Conservatively attributed to the MAZE procedure, however the need for a pacemaker could be attributed to the primary procedure.
Cardiac Akinesis	Ancillary Device Related	Cardiac akinesis caused by ischemia was associated with possible coronary injury from an ancillary ablation pen. The event was successfully treated with two bypass grafts.
Pulmonary Vein Tear (LPV)	AF Ablation Procedure	Pulmonary vein tear during surgical access when dissecting the vein to place the clamp. The event was successfully treated with a suture to repair the tear.
Torn IVC Cannulation Site	AF Ablation Procedure	During surgical access, the IVC was torn during cannulation. The event was successfully treated with a patch to repair the tear.
Left Atrial Tear	AF Ablation Procedure	A left atrial tear which occurred when lifting the heart for surgical access, prior to use of the AtriCure Synergy Ablation System. The event was successfully treated with epicardial and endocardial sutures.

Table 13 demonstrates a summary of adverse events through 6 months for the ABLATE populations.

Table 13: Summary of Adverse Events by Attribution through 6 Months

	ABLATE N=55		ABLATE Non-paroxysmal N=51	
Parameter [1] [2]	**# of Evts**	**% (n/N) of Pts with Event**	**# of Evts**	**% (n/N) of Pts with Event**
Any Adverse Event	198	90.9% (50/55)	188	94.1% (48/51)
Investigational Device	0	0.0% (0/55)	0	0.0% (0/51)
AF Procedure	8	14.5% (8/55)	8	15.7% (8/51)
Ancillary Device	1	1.8% (1/55)	1	2.0% (1/51)
General Surgical Procedure	144	87.3% (48/55)	138	90.2% (46/51)
Other Relationship	45	41.8% (23/55)	41	43.1% (22/51)
Serious Adverse Event	106	74.5% (41/55)	99	76.5% (39/51)
Investigational Device	0	0.0% (0/55)	0	0.0% (0/51)
AF Procedure	7	12.7% (7/55)	7	13.7% (7/51)
Ancillary Device	1	1.8% (1/55)	1	2.0% (1/51)
General Surgical Procedure	70	61.8% (34/55)	66	62.7% (32/51)
Other Relationship	28	32.7% (18/55)	25	33.3% (17/51)

[1] As Adjudicated or site reported if not yet adjudicated.
[2] Relationship presented hierarchally as listed in table.

Table 14 through Table 18 demonstrate the rates of device use for the Maze IV procedure per subject and per lesion.

Table 14: Ablation Procedure Summary

Parameter	ABLATE N=55 % (n/N)	ABLATE Non-paroxysmal N=51 % (n/N)	ABLATE + ABLATE AF N=69 % (n/N)	ABLATE + ABLATE AF Non-Paroxysmal N=64 % (n/N)
Ablation Procedure Summary				
Complete MAZE Procedure [1]	90.9% (50/55)	92.2% (47/51)	92.8% (64/69)	93.8% (60/64)
Lesion Set Deviations				
Incomplete Lesion Set				
Pulmonary Vein Isolation Only	1.8% (1/55)	0.0% (0/51)	1.4% (1/69)	0.0% (0/64)
Incomplete Right Atrial Ablation Lesion Set	7.3% (4/55)	7.8% (4/51)	5.8% (4/69)	6.3% (4/64)
Right Anterior freewall appendage lesion not done	7.3% (4/55)	7.8% (4/51)	5.8% (4/69)	6.3% (4/64)
Lesion from right atrial appendage to tricuspid annulus not done	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)
Incomplete Left Atrial Ablation Lesion Set	0.0% (0/55)	0.0% (0/51)	0.0% (0/69)	0.0% (0/64)
Required Lesion Completed with Method other than Synergy Ablation Clamp				
Floor Lesion [2]	12.7% (7/55)	13.7% (7/51)	13.0% (9/69)	14.1% (9/64)
LA Appendage [2]	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)
Roof [2]	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)
Mitral Annulus [2]	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)

[1] Complete MAZE IV procedure includes subjects in which required lesions were performed using methods not specified in the protocol.
[2] Alternative methods for ABLATE include Cut & Sew (6 Floor lesions), Cryoablation (2 LA appendage lesions and 1 mitral annulus lesion), and RF pen (One Floor lesion and one roof lesion). Alternative methods for ABLATE AF include Cut & Sew (2 floor lesions).

Table 15: Biatrial Lesion Details - Left Atrial Lesions

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	% (n/N)	% (n/N)	% (n/N)	% (n/N)
Left Sided Lesions [1]				
I. Mitral Valve Connecting Lesion [2]	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	33.3% (18/54)	29.4% (15/51)	35.3% (24/68)	32.8% (21/64)
Cryo	1.9% (1/54)	2.0% (1/51)	22.1% (15/68)	23.4% (15/64)
AtriCure Clamp and AtriCure Pen	27.8% (15/54)	29.4% (15/51)	32.4% (22/68)	32.8% (21/64)
AtriCure Clamp and Cryo	29.6% (16/54)	31.4% (16/51)	8.8% (6/68)	9.4% (6/64)
AtriCure Clamp and Surgical (cut and sew)	7.4% (4/54)	7.8% (4/51)	1.5% (1/68)	1.6% (1/64)
II. Floor Line Lesion	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	87.0% (47/54)	86.3% (44/51)	86.8% (59/68)	85.9% (55/64)
AtriCure Pen	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
Surgical (cut and sew)	11.1% (6/54)	11.8% (6/51)	11.8% (8/68)	12.5% (8/64)
III. Roof Line Lesion	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	98.1% (53/54)	98.0% (50/51)	98.5% (67/68)	98.4% (63/64)
AtriCure Pen	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
IV. LAA Appendage to Pulmonary Vein	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	96.3% (52/54)	96.1% (49/51)	97.1% (66/68)	96.9% (62/64)
Cryo	3.7% (2/54)	3.9% (2/51)	2.9% (2/68)	3.1% (2/64)

[1] One subject did not undergo the Maze IV procedure.

[2] Mitral valve connecting lesion includes the full complement of the mitral valve annular lesion (lesion taken from the atriotomy to the mitral valve annulus and lesion completed on the posterior mitral valve annulus).

Table 16: Biatrial Lesion Details - Right Atrial Lesions

Parameter	ABLATE N=55 % [n/N]	ABLATE Non-paroxysmal N=51 % (n/N)	ABLATE + ABLATE AF N=69 % [n/N]	ABLATE + ABLATE AF Non-paroxysmal N=64 % (n/N)
Right Sided Lesions [1]				
I. Tricuspid Valve Annulus lesion	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	46.3% (25/54)	43.1% (22/51)	50.0% (34/68)	46.9% (30/64)
AtriCure Pen	14.8% (8/54)	15.7% (8/51)	13.2% (9/68)	14.1% (9/64)
Surgical (cut and sew)	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
Cryo	14.8% (8/54)	15.7% (8/51)	17.6% (12/68)	18.8% (12/64)
AtriCure Clamp and AtriCure Pen	9.3% (5/54)	9.8% (5/51)	7.4% (5/68)	7.8% (5/64)
AtriCure Clamp and Cryo	11.1% (6/54)	11.8% (6/51)	8.8% (6/68)	9.4% (6/64)
AtriCure Clamp and Surgical (cut and sew)	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
II. Ablation of SVC / IVC	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
III. Freewall Appendage Lesion	92.6% (50/54)	92.2% (47/51)	94.1% (64/68)	93.8% (60/64)
AtriCure Clamp	100.0% (50/50)	100.0% (47/47)	100.0% (64/64)	100.0% (60/60)
IV. Right Atrial Appendage Lesion	98.1% (53/54)	98.0% (50/51)	98.5% (67/68)	98.4% (63/64)
AtriCure Clamp	54.7% (29/53)	52.0% (26/50)	52.2% (35/67)	50.8% (32/63)
AtriCure Pen	9.4% (5/53)	10.0% (5/50)	9.0% (6/67)	9.5% (6/63)
Cryo	18.9% (10/53)	20.0% (10/50)	22.4% (15/67)	22.2% (14/63)
AtriCure Clamp and AtriCure Pen	7.5% (4/53)	8.0% (4/50)	7.5% (5/67)	7.9% (5/63)
AtriCure Clamp and Cryo	5.7% (3/53)	6.0% (3/50)	6.0% (4/67)	6.3% (4/63)
AtriCure Clamp and Surgical (cut and sew)	1.9% (1/53)	2.0% (1/50)	1.5% (1/67)	1.6% (1/63)
Surgical (cut and sew) and Cryo	1.9% (1/53)	2.0% (1/50)	1.5% (1/67)	1.6% (1/63)
[1] One subject did not undergo the Maze IV procedure.				

Table 17: Biatrial Lesion Details - Optional Procedures

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Right atrial appendage removal [1]	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
Surgical (cut and sew)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
Septal lesion [1]	20.4% (11/54)	21.6% (11/51)	17.6% (12/68)	18.8% (12/64)
AtriCure Clamp	63.6% (7/11)	63.6% (7/11)	66.7% (8/12)	66.7% (8/12)
Cryo	36.4% (4/11)	36.4% (4/11)	33.3% (4/12)	33.3% (4/12)
[1] One subject did not undergo the Maze IV procedure.				

Table 18: Left Atrial Appendage Exclusion

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Left Atrial Appendage [1]				
Excised	88.9% (48/54)	88.2% (45/51)	91.2% (62/68)	90.6% (58/64)
Excluded Only	11.1% (6/54)	11.8% (6/51)	8.8% (6/68)	9.4% (6/64)
[1] One subject did not undergo the Maze IV procedure.				

Additional Data Analysis

Table 19 and Figure 2 present results considering the following factors that affect interpretation of the effectiveness results. First, current definitions for freedom from atrial fibrillation would categorize subjects having any episode of AF, atrial flutter or atrial tachycardia > 30 seconds and/or subjects that were cardioverted after a 3 month blanking period as treatment failures. In addition, one subject had not completed the AAD washout at their 6-month effectiveness evaluation, but was considered to be an effectiveness success based on freedom from AF at later timepoints.

Table 19: Summary of Effectiveness Endpoints for New Definition

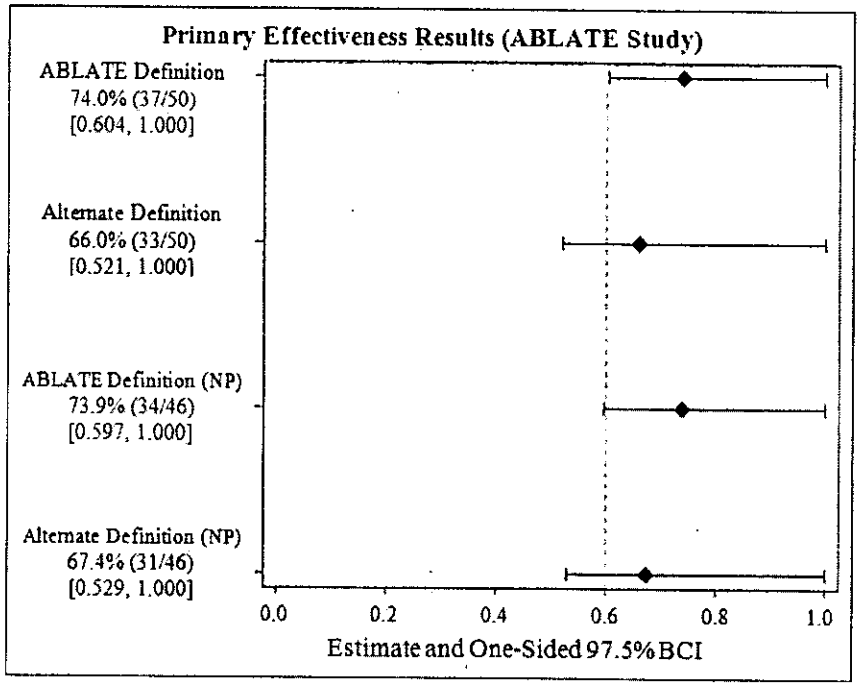
	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Primary Effectiveness through 6 Months	**% (n/N) [BCI] [1]**	**% (n/N) [BCI] [1]**	**% (n/N)**	**% (n/N)**
Effectiveness Evaluable at 6 month Follow-up	N=50	N=46	N=62	N=57
ABLATE Definition (AF Free and Off AADs)	74.0% (37/50) [0.604, 1.00]	73.9% (34/46) [0.597, 1.00]	75.8% (47/62)	75.4% (43/57)
Alternate Definition [2]	66.0% (33/50) [0.521, 1.00]	67.4% (31/46) [0.529, 1.00]	64.5% (40/62)	64.9% (37/57)
Primary Effectiveness Failures by Alternate Definition [3]				
Failure by Rhythm	11	10	13	12
Atrial Fibrillation	(9)	(8)	(10)	(9)
Atrial Flutter	(2)	(2)	(2)	(2)
Atrial Tachycardia	(0)	(0)	(1)	(1)
Failure by AAD	6	5	9	8
Inadequate drug washout	(3)	(3)	(5)	(5)
Failure by CV between 3 and 6 Months	4	4	4	4

[1] 97.5% one-sided Bayesian Credible Interval. Beta (1,1) prior in accordance with the statistical plan.

[2] Alternate definition defined as AF free and off AADs with no Atrial fibrillation, Atrial flutter, or Atrial tachycardia > 30 seconds, AADs washed out and no cardioversion after 3 months.

[3] Overall rate cannot be computed by simple summation of counts for individual failure modes as several subjects failed by more than one mode: Late CV and AAD (1); Rhythm (AFL) and AAD (1); Late CV and Rhythm (AF) (2).

Figure 2: Forest Plot, Primary Effectiveness Success



Additional sources of data corroborate the results observed in ABLATE and ABLATE AF. These sources include the RESTORE clinical trial, the predecessor pivotal trial to ABLATE, and institutional database repositories of consecutively collected procedural and follow up clinical data. RESTORE was a multi-center, prospective, match-controlled clinical trial to evaluate the safety and effectiveness of the AtriCure Ablation System. The Washington University Institutional Database was a prospective single center registry of baseline, procedure, and follow-up data from a repository of information on all AF treated subjects at the institution. The Baylor Plano Institutional Database was a prospective single center registry of baseline, procedure, and follow-up data from a repository of information on all AF treated subjects at the institution. Table 20 and Table 21 demonstrate the data for the non-paroxysmal subjects from these sources.

Table 20: Primary Safety Endpoint, Additional Sources of Data

	ABLATE Non-Paroxysmal (N=51)	ABLATE+ ABLATE AF Non-Paroxysmal (N=64)	RESTORE (N=36)	Wash U. (N=56)	Baylor (N=8)
Primary Safety Endpoint (Acute MAE within 30 days post procedure) Frequentist Observed % (n/N)	9.8% (5/51)	7.8% (5/64)	8.3% (3/36)	14.3% (8/56)	25.0% (2/8)
Death (<= 30 days or > 30 days procedure related)	3.9% (2/51)	3.1% (2/64)	5.6% (2/36)	3.6% (2/56)	12.5% (1/8)
Stroke/TIA	2.0% (1/51)	1.6% (1/64)	0.0% (0/36)	1.8% (1/56)	0.0% (0/8)
MI	0.0% (0/51)	0.0% (0/64)	0.0% (0/36)	0.0% (0/56)	0.0% (0/8)
Excessive Bleeding (>2 units blood and surgical intervention)	3.9% (2/51)	3.1% (2/64)	8.3% (3/36)	8.9% (5/56)	25.0% (2/8)

Table 21: Effectiveness Endpoints

	ABLATE Non-Paroxysmal	ABLATE+ ABLATE AF Non-Paroxysmal	RESTORE	Wash U.	Baylor
6 Month Follow-Up Assessment	N = 46	N = 57	N = 33[1]	N = 47	N = 2
Primary Effectiveness Endpoint 6 mo AF Free and off AADs Frequentist Observed % (n/N)	73.9% (34/46)	75.4% (43/57)	64.3% (18/28)	74.5% (35/47)	0% (0/2)
6 mo AF Free Frequentist Observed % (n/N)	82.6% (38/46)	84.2% (48/57)	81.8% (27/33)	91.5% (43/47)	50.0% (1/2)
12 Month or Greater Follow-Up Assessment	N = 45		N = 24	N = 46	N = 3
12 mo (or greater) AF Free and off AADs Frequentist Observed % (n/N)	62.2% (28/45)		45.8% (11/24)	84.8% (39/46)	0% (0/3)
12 mo (or greater) AF Free Frequentist Observed % (n/N)	73.3% (33/45)		66.7% (16/24)	91.3% (42/46)	0% (0/3)
[1]Subjects off AAD's at 6 months and AF Free but not through the wash-out period are not evaluable.					

Conclusions:
The results demonstrate that there is a reasonable assurance of safety and effectiveness to support the use of the AtriCure Synergy Ablation System for the treatment of persistent or longstanding persistent atrial fibrillation in patients who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair.

HOW SUPPLIED

The Synergy Ablation System is supplied as a STERILE clamp and is for single patient use only. Sterility is guaranteed unless the package is opened or damaged. Do not resterilize.

The other components (ASU2 and ASB3) are not sterile and may be reused

RETURN OF USED PRODUCT

If for any reason these products must be returned to AtriCure, a return goods authorization (RGA) number is required from AtriCure prior to shipping.

If the products have been in contact with blood or body fluids, they must be thoroughly cleaned and disinfected before packing. They should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and they should be properly labeled with an RGA number and an indication of the biologically hazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

CAUTION: It is the responsibility of the health care institution to adequately prepare and identify the products for shipment.

DISCLAIMER STATEMENTS

Users must assume responsibility for approving the condition of these products before they are used. AtriCure, Inc. cannot be held liable for any consequential damage, personal injury or damage to property nor for the misuse of these products.

AtriCure, Inc. will not be liable for any damage caused by the reuse of these products.

This Instruction for Use describes the procedures for proper use of the products. Any deviation from these procedures, which may compromise the function of the products, is the responsibility of the user.

18

Non-Pyrogenic

Sterilized by Ethylene Oxide

Single Use Only

Expiration Date

Lot Number

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

Attention. See Instructions for Use

Manufactured by:
AtriCure© Incorporated
6217 Centre Park Drive
West Chester, Ohio 45069-3866
Customer Service:
1-866-349-2342 (toll free)
513-755-4100

AtriCure

AtriCure Switch Matrix ASB3

Instructions For Use

The AtriCure ASB3 Switch Matrix is a reusable accessory interface module that allows simultaneous connection of AtriCure® Isolator™ Transpolar™ ablative handpiece and pen devices to the ASU RF generator. Devices will be operational only when the ASB3 selector switch is set to the device specific position. Please refer to the applicable handpiece and pen device Instructions For Use. Please refer to the ASU User's Manual for descriptions of RF energy delivery, modes of operation, output power, operating frequency, and approved temporary cardiac pacing and stimulating accessories.

The ASB3 has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The ASB3 generates and can radiate radio frequency 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 in a particular installation. If the ASB3 does cause harmful interference to other devices, which can be determined by turning the ASB3 off and on, the user is encouraged to try to correct the interference by one or more of the following measures; (1) reorient or relocate the receiving device, (2) increase the separation between the ASB3 and the other devices, (3) connect the ASB3 into an outlet on a circuit different from that to which the other device(s) are connected, and (4) contact the AtriCure service representative for assistance.

Inspect the following interface cables for any signs of physical damage to the cable and connectors. If physical damage is found or the interface cables do not perform within specification, notify AtriCure. All returns must have approval from AtriCure. The cables include: (1) A000442-ASB/ASU RF Interface Cable, (2) C001237-ASB/ASU Footswitch Interface Cable, and (3) A000434-ASB3 PSS Interface Cable.

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

Manufactured for:
AtriCure, Inc.
6217 Centre Park Dr.
West Chester, Ohio 45069
Customer Service: 866-349-2342
customerservice@atricure.com
www.atricure.com

European Representative:
Köntges SPRL
Avenue Hellevelt 35
B-1180 Brussels Belgium
Tel: +32 (0) 2 375 51 63
FAX: +32 (0) 2 375 89 06
e-mail: herbert.kontges@skynet.be

Attention: Consult accompanying documents	
Dangerous Voltage	
Type CF Defibrillation-Proof Applied Part Patient Isolated Equipment	
Type CF Applied Part Not Defibrillation-Proof Patient Isolated Equipment	
Alternating Current	
Equipotential	
Footswitch	
Fuses	
Power OFF	O
Power ON	I

Environmental Conditions: (1) operational temperature +10°C to +40°C, (2) storage temperature -35°C to +54°C, and (3) humidity 15% to 90% relative humidity.

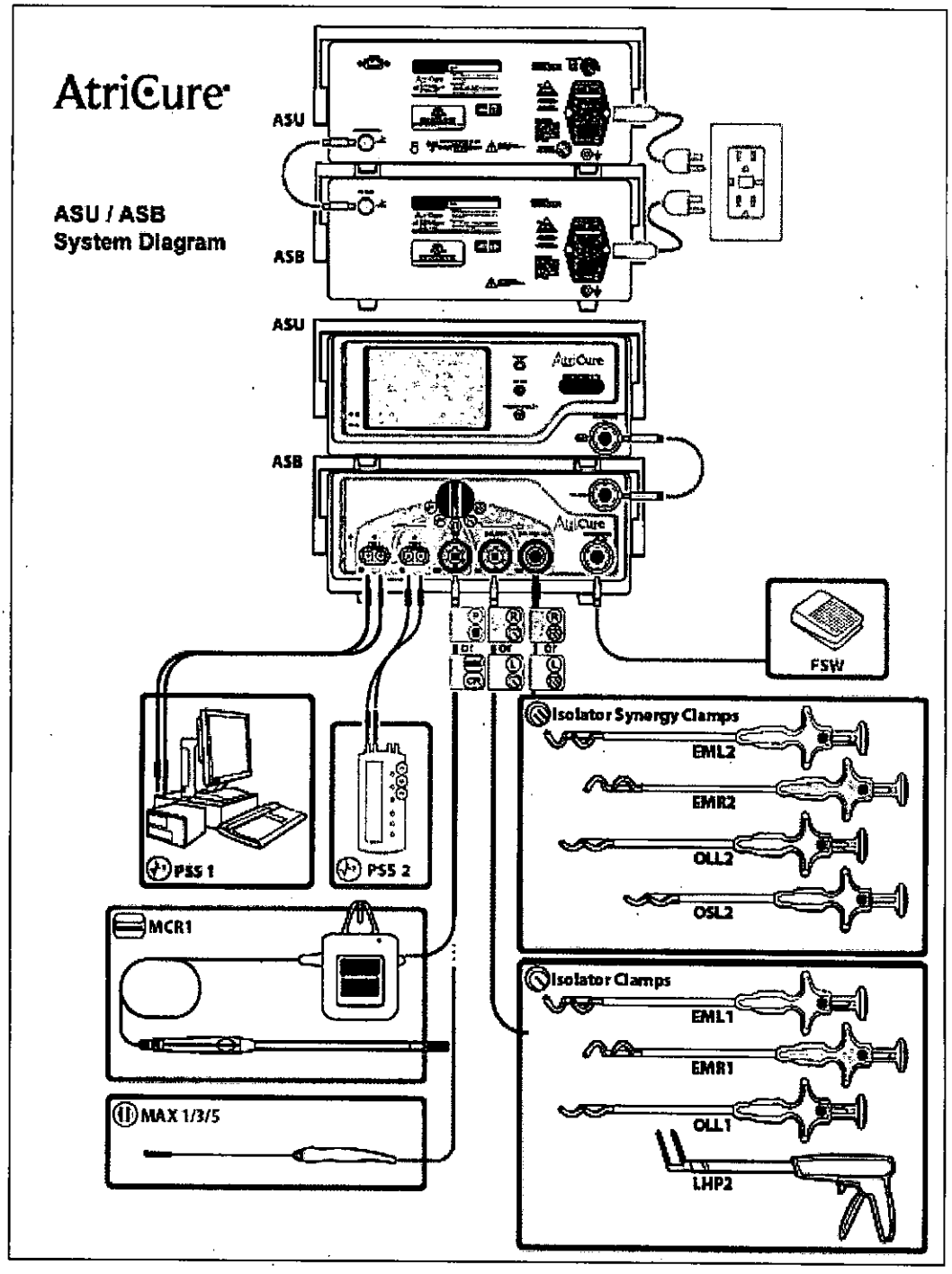
Perform annual preventative maintenance procedures to ensure all ASB3 components are functioning properly, including but not limited to: (1) electrical power cords for fraying, damage, and proper grounding, (2) AC power switch, (3) indicator damage (Power On, Footswitch Present, or Handpiece Select), (4) handpiece connector damage, cracking or inability to insert and latch handpiece plug, (5) carrying handle damage, inability to latch or rotate, (6) rubber feet damage, cracking or inability for the ASB3 to remain stabile on a flat surface, (7) interface cable fraying or damage, and (8) footswitch connector damage cracking or inability to insert and latch footswitch plug.

The ASB3 does not have any serviceable parts. For servicing issues, contact AtriCure, Inc.

The ASB3 Accessory Cleaning and Disinfection Instructions; (1) use a mild detergent (prepared to its specifications) and a damp cloth to clean the exterior of the Switch Matrix, (2) do not submerge or allow fluids to enter the chassis, (3) do not use caustic, corrosive, or abrasive cleaning materials, and (4) the ASB3 and auxiliary device cable cannot be sterilized.

Types and rating of fuses: (1) 100-120V, 220-240V, ~50/60 Hz, and (2) 1.25A/250V, T-lag, 5 x 20mm, UL Recognized, IEC Approved. Replace fuses as marked.

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



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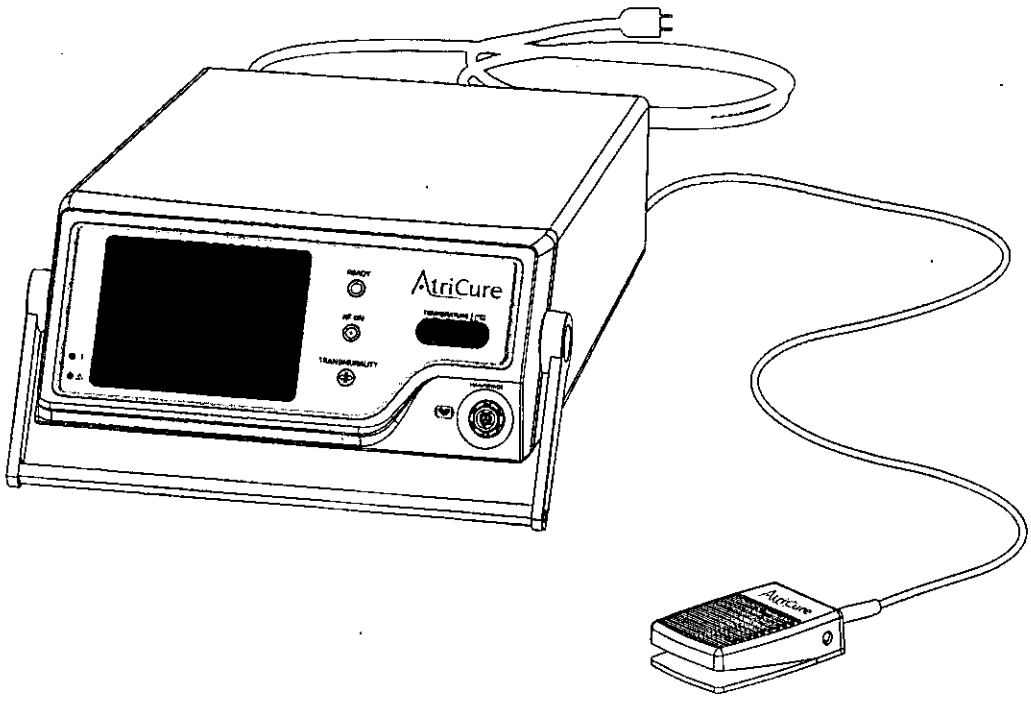
AtriCure®



ABLATION AND SENSING UNIT (ASU)

USER'S MANUAL

Model ASU2-115

Model ASU3-230

AtriCure, Inc.
6217 Centre Park Drive
West Chester, Ohio 45069
USA

P000463 Rev. D

EC REP

European Representative:

Herbert Köntges

Köntges SPRL

Avenue Hellevelt 35

B-1180 Brussels Belgium

Tel: +32 2 375 51 63

FAX: +32 2 375 89 06

email: herbert.kontges@skynet.be

CE 0086

Table of Contents

1. Getting Started

This 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.

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

Please read all information carefully. Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This manual is designed to provide instructions for use of the AtriCure Ablation and Sensing Unit (ASU) with the AtriCure Bipolar Handpiece (Isolator™ Transpolar™ clamp, Isolator™ Transpolar™ pen, or CoolRail™ linear pen) **and AtriCure Accessory Devices (ASB1, ASB 3)**. It is not a reference to surgical technique.

The AtriCure® ASU produces and delivers RF energy, in a bipolar mode, at a frequency of approximately 460 kHz, with a maximum output power ranging from 22.8 Watts up to 28.5 Watts for the Isolator™ Transpolar™ clamps, 12.0 Watts up to 30.0 Watts for the Isolator™ Transpolar™ pen or CoolRail™ linear pen devices depending on the mode of operation The AtriCure® ASU is capable of producing a maximum output power of 32.5 Watts under a 100 Ohm load, although no current AtriCure® Bipolar Handpiece uses power above 30 Watts. The operating mode is a function of the handpieces or pen and is set by the ASU. The AtriCure ASU is designed to operate only with an AtriCure Bipolar Handpiece, AtriCure Isolator Pen, or AtriCure CoolRail™ linear pen. The Footswitch is the input device used to activate RF energy delivery. Please refer to the handpiece and pen Instructions for Use for complete description of the indications and use of these devises.

For the user's convenience, the AtriCure Ablation and Sensing Unit will be referred to in this User's Manual as the "ASU". The AtriCure Bipolar Handpiece will be referred in this User's Manual as the "Handpiece".

This User's Manual provides a description of the ASU, its controls, displays, indicators, tones and a sequence for its operation with the Handpiece. This User's Manual also supplies other information of importance to the user. This manual is intended as a User's Manual only. Do not operate the ASU before thoroughly reading this manual.

1.1. System Description

As shown in Figure 1, the system is comprised of the following:

- AtriCure Bipolar Handpiece with integral cable (not shown)
- AtriCure Ablation and Sensing Unit (ASU)
- Footswitch
- Power cord.

Accessory devices are described in paragraph 10.

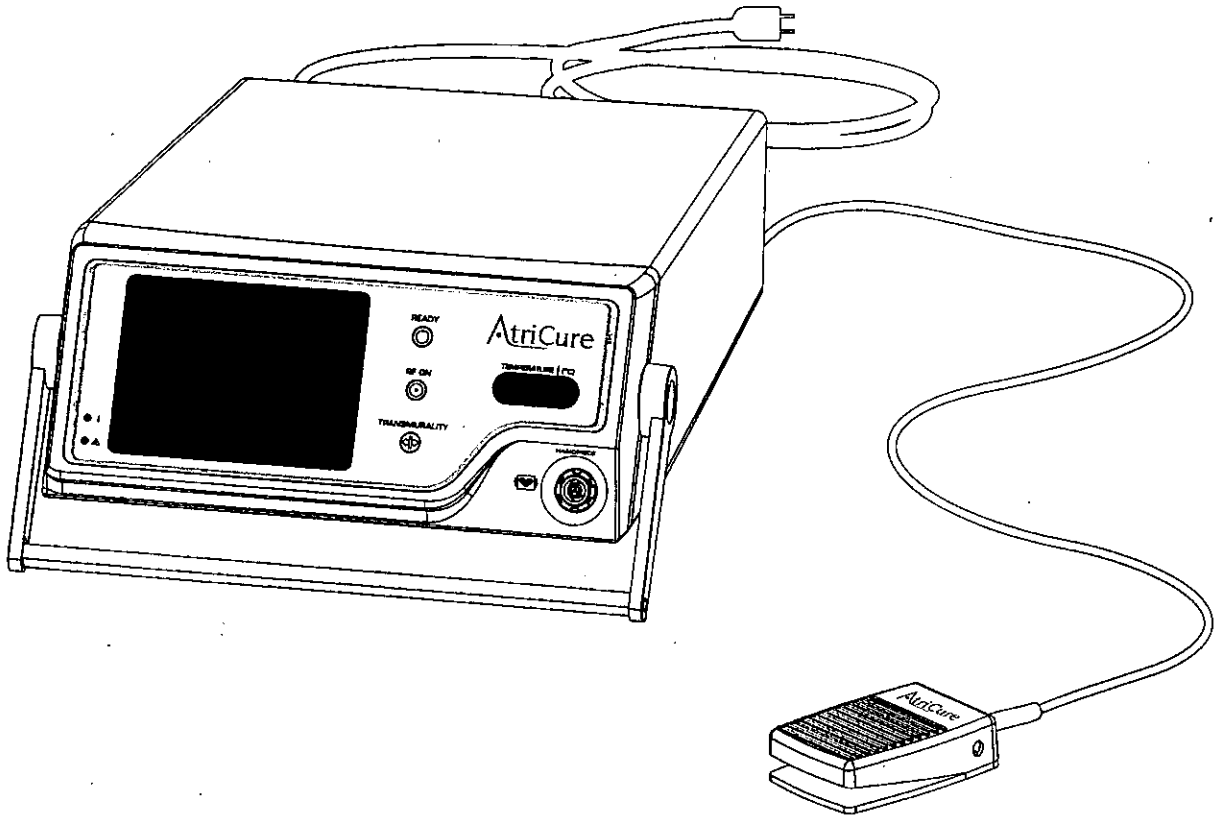


Figure 1 – ASU, Footswitch, and Power Cord

1.2. Unpacking

Lift the ASU, Footswitch, and Power Cord from the box and remove the protective wrapping. It is recommended that the original shipping box and protective wrapping be saved for future storing and/or transporting of the device.

1.3. Warnings and Precautions

The safe and effective use of RF energy is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained operating room staff. It is important that the operating instructions supplied with the ASU be read, understood and followed before use.

1.3.1. WARNINGS

- Do not operate the ASU before thoroughly reading this manual.
- Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. This 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.
- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in oxygen-enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents.
- 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: Do not use extension cords.
- Fire Hazard: To avoid igniting cleaning agents, use only non-flammable agents to clean and disinfect the ASU. If flammable agents are inadvertently used on the ASU, allow these substances to evaporate completely before operating.
- Contact of the Handpiece with any metal (such as hemostats, clamps, staples, etc.) can result in unintended burn injuries.
- When not using the Handpiece, place it in a clean, dry nonconductive, and highly visible area not in contact with the patient. Inadvertent contact by an active Handpiece with the patient may result in burns.
- When the ASU is activated, the conducted and radiated electrical fields may interfere with other electrical medical equipment. Refer to Section 5 for more information regarding potential electromagnetic or other interference, and advice regarding avoidance of such interference.
- 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 use of electrosurgical appliances is planned in patients with cardiac pacemakers.
- Trip Hazard: Standard care should be used to reduce the risk of tripping on the Footswitch cable.

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.

Electric Shock Hazard: Connect the ASU Power Cord to a properly grounded receptacle. Do not use power plug adapters.

Electric Shock Hazard: Do not connect wet accessories to the generator.

Electric Shock Hazard: Ensure that the Handpiece is correctly connected to the ASU and that no wires are exposed from the cable, connector or Handpiece.

1.3.2. PRECAUTIONS

- Use only with the AtriCure Handpieces intended for use with the ASU.
- Do not activate the ASU until the Handpiece is properly positioned in the patient.
- The activation tone and indicator are important safety features. Do not obstruct the activation indicator. Ensure that the activation tone is audible to personnel in the operating room prior to use. The activation tone alerts personnel when the Handpiece is active. Do not disable the audible tone.

Do not remove the cover of the ASU as there is a potential for electrical shock. Refer to authorized personnel for service.

- Use only the Footswitch provided with the ASU.
- The Power Cord of the ASU must be connected to a properly grounded receptacle. Extension cords and/or adapter plugs must not be used.

Do not wrap instrument cable 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 ASU. The use of antistatic sheeting is recommended.

- 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 surgical smoke evacuator or other means.
- When the ASU 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 ASU and Handpiece.
- Monitoring systems that incorporate high frequency current-limiting devices are recommended for use with the ASU and Handpiece.
- Failure of the ASU and Handpiece could result in unintended power output increases.

1.4. EMC Guidance and Manufacturer's Declaration

1.4.1. Electromagnetic Requirements

1.4.1.1. The AtriCure Ablation and Sensing Unit (ASU) has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

1.4.1.2. The ASU can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

1.4.1.3. Portable and mobile RF communications equipment can also affect ASU performance and care should be taken to minimize such interference. However, there is no guarantee that interference will not occur in a particular installation.

1.4.1.4. If the ASU does cause harmful interference to other devices, which can be determined by turning the ASU off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the ASU and the other devices.
- Connect the ASU into an outlet on a circuit different from that to which the other device(s) are connected.
- Contact the AtriCure service representative for help.

1.4.2. Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The AtriCure Ablation and Sensing Unit (ASU) is intended for use in the electromagnetic environment specified below. The customer or the user of the ASU unit should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The ASU unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The ASU unit 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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

1.4.3. Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The AtriCure Ablation and Sensing Unit (ASU) is intended for use in the electromagnetic environment specified below. The customer or the user of the ASU unit 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	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	<5 % U_T (>95 % dip in UT) for 0,5 cycle 40 % U_T (60 % dip in UT) for 5 cycles 70 % U_T (30 % dip in UT) for 25 cycles <5 % U_T (>95 % dip in UT) for 5 s	<5 % U_T (>95 % dip in UT) for 0,5 cycle 40 % U_T (60 % dip in UT) for 5 cycles 70 % U_T (30 % dip in UT) for 25 cycles <5 % U_T (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ASU unit requires continued operation during power mains interruptions, it is recommended that the ASU unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*			

1.4.4. EMC Guidance and Manufacturer's Declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The AtriCure Ablation and Sensing Unit (ASU) is intended for use in the electromagnetic environment specified below. The customer or the user of the ASU should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ASU, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, 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.			
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 is used exceeds the applicable RF compliance level above, the ASU should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ASU. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

1.4.5. Recommended Separation Distance

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

The AtriCure Ablation and Sensing Unit (ASU) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ASU can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ASU 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.

1.5. Responsibility of the Manufacturer

AtriCure is responsible for safety, reliability, and performance of the equipment only if:

- Installation procedures in this manual are followed.
- Persons authorized by AtriCure carry out modifications or repairs.
- The electrical installation of the relevant room complies with local codes and regulatory requirements such as IEC and BSI.
- The equipment is used in accordance with the AtriCure User's Manual.

2. The AtriCure Ablation and Sensing Unit (ASU)

This section provides a detailed description of the ASU including its function and operating features.

2.1. Device Description

The AtriCure® ASU produces and delivers RF energy, in a bipolar mode, at a frequency of approximately 460 kHz, with a maximum output power ranging from 12 Watts up to 30 Watts depending on the operating mode. The AtriCure® ASU is capable of producing a maximum output power of 32.5 Watts under a 100 Ohm load although no current AtriCure® Bipolar Handpiece uses power above 30 Watts. The operating mode is a function of the handpiece and is set by the ASU. The AtriCure ASU is designed to operate with the AtriCure Handpiece. The ASU and Handpiece are designed for use without a neutral electrode. The Footswitch is the input device used to activate RF energy delivery.

2.2. ASU Front Panel – Illustration and Nomenclature

An illustration of the ASU front panel is shown in Figure 2, below.

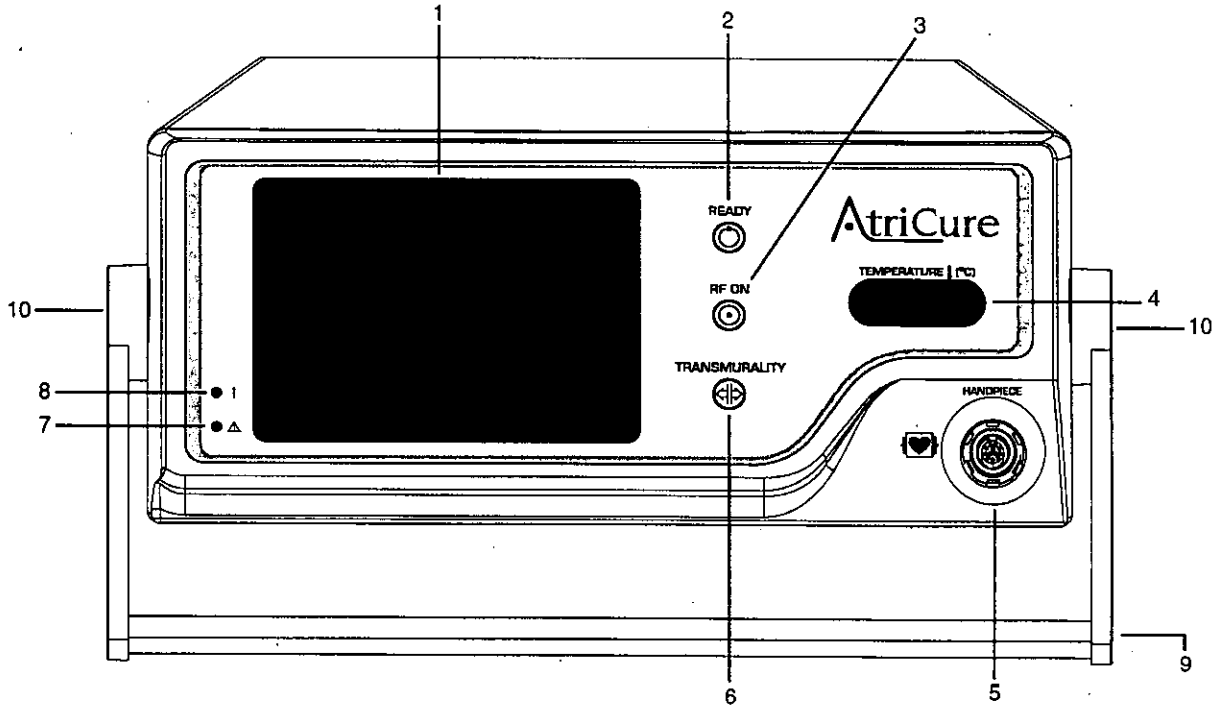
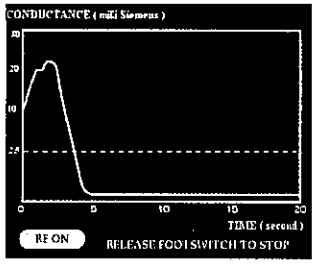
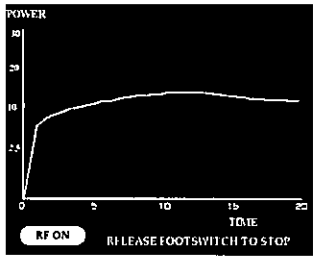
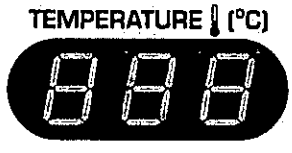


Figure 2 – ASU Front Panel

1. Tissue Conductance/ Power Graph Display
2. Ready Indicator
3. RF ON Indicator
4. Temperature Display
5. Handpiece Receptacle
6. Transmurality Indicator
7. Fault Indicator
8. Power Indicator
9. Handle
10. Handle Adjustment Knobs

2.2.1. Front Panel Displays

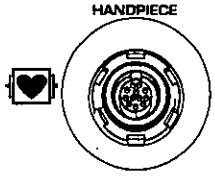
There are two displays on the front panel of the ASU: the Tissue Conductance / Power Graph Display and the Temperature Display. These two displays are described below.

Display	Description
	**Tissue Conductance Graph Display – Isolator™ Transpolar™ clamp (Default):** During the ablation cycle the ASU displays a graph of tissue conductance (Current/Voltage) versus Time. The y-axis is Tissue Conductance and the x-axis is Time. When the Footswitch is disconnected or reconnected, the display of the tissue conductance graph is not affected. Refer to Section 4.4.3.
	**Power Graph Display – Isolator™ Transpolar™ pen or CoolRail™ linear pen:** During the ablation cycle the ASU displays a graph of power (Current × Voltage) versus Time. The y-axis is Power and the x-axis is Time. When the Footswitch is disconnected or reconnected, the display of the power graph is not affected. Refer to Section 4.4.3.
	**Temperature Display** – This 3-digit LED display shows the temperature at the thermocouple, located near the outer edge of the upper jaw 1.3 mm from the electrode. Temperature is measured and displayed in real-time, whenever the Isolator™ Transpolar™ clamp is connected. Functionality can be quickly verified when the handpiece is plugged in by confirming that the temperature reading is of room temperature. When the Isolator™ Transpolar™ clamp or the footswitch is disconnected the temperature display becomes blank. Refer to Section 4.3. If a Handpieces does not have a thermocouple, the temperature display will only show "- - -".

2.2.2. Front Panel Indicators

Indicator	Description
	**POWER Indicator** – A Green LED indicates that the AC power is present and the ASU has been switched on.
	**FAULT Indicator** – This Red lamp indicates that a fault has occurred and requires that the power be cycled.
READY 	**READY Indicator** – This Green lamp indicates that the Footswitch and Handpiece are connected and the ASU is ready for use
RF ON 	**RF ON Indicator** – A Blue LED indicates that RF power is being output to the Handpiece. The RF power output is initiated by pressing the Footswitch.
TRANSMURALITY 	**TRANSMURALITY Indicator** – A Blue flashing LED indicates that the Transmurality Algorithm has been satisfied indicating that the user may terminate the ablation cycle.

2.2.3. Front Panel Receptacle

Receptacle	Description
	**HANDPIECE or ASU Accessory Receptacle** This 12-pin receptacle accepts the AtriCure Handpiece or connection cable to an accessory device. This connection is patient-isolated.

2.3. ASU Rear Panel – Illustration and Nomenclature

An illustration of the ASU rear panel is shown in Figure 3, below.

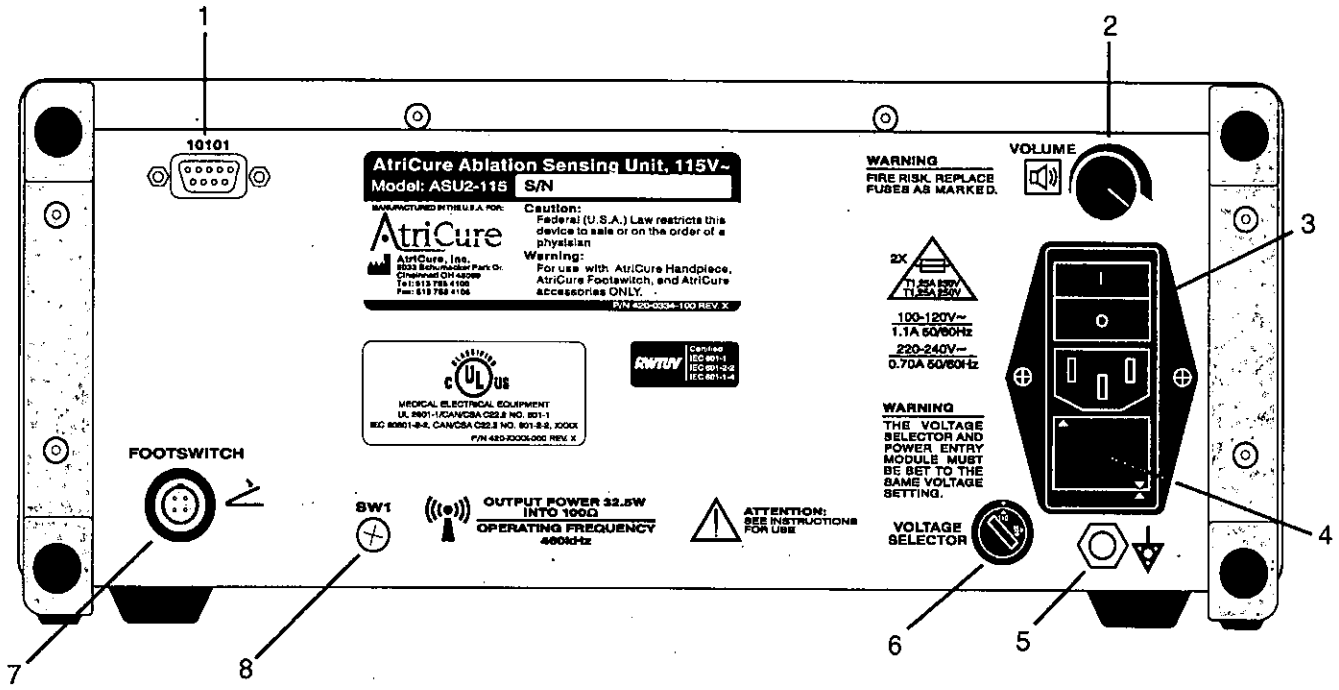
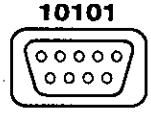
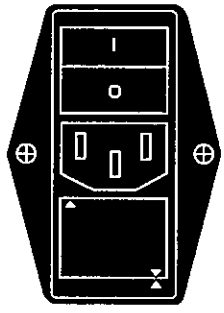
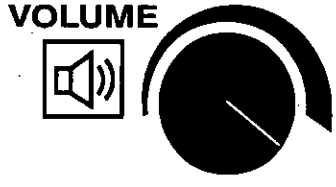
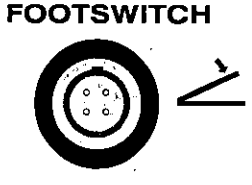


Figure 3 – ASU Rear Panel

1. Data Port
2. Speaker Volume Control
3. Power Entry Module
4. Fuse Box
5. Equipotential Ground Stud
6. Input Voltage Selector Switch
7. Footswitch Receptacle
8. Service Access

2.3.1. Rear Panel Functions

Graphic	Description
	**Equipotential Ground Stud** – Provides a means of securely linking the earth grounds of the AtriCure ASU to other grounded equipment.
	**Data Port** – For manufacturing and test purposes.
	**Power Entry Module** – This module contains both the ON/OFF switch and the fuses. The voltage is selected by the orientation of the fuse drawer as marked. **Fuse Box** – The Fuse Box contains fuses selected for the input voltage. See Technical Specifications in Section 7 of this manual.
	**Input Voltage Selector Switch** – The input voltage selector switch is pre-set at the factory to either 110V or 220V and ***should not*** be adjusted by the operator. This setting should only be adjusted by the manufacturer or by an authorized service representative.
	**Speaker Volume Control** – The audible volume level is adjustable via a rotary dial. The ASU includes a speaker for producing audible feedback to the user.
	**Footswitch Receptacle** – This receptacle accepts the Footswitch connector. The single momentary actuation pedal provides for the activation of RF power output.
	**Service Access** – For manufacturing and test purposes.

3. Installing the ASU

Inspect the ASU for any signs of physical damage to the front panel, chassis or cover.

NOTE: **If any physical damage is found, DO NOT USE THE UNIT. CONTACT AtriCure for a replacement.**

All returns must be approved by AtriCure.

3.1. Transporting the ASU

The handle may be used to carry the ASU. To change the positioning of the handle, depress both handle adjustment knobs simultaneously and move the handle to the desired location. ***Do not*** change the handle position when a Handpiece or Accessory Device is connected to the Handpiece receptacle.

3.2. Adjusting the Viewing Angle

To change the viewing angle of the ASU Conductance Graph Display, adjust the handle position using the directions in Section 3.1., above.

3.3. Preparing the ASU For Use

The ASU may be placed on a mounting cart or on any sturdy table or platform. It is recommended that carts have conductive wheels. Refer to hospital procedures or local codes for detailed information.

Provide at least four to six inches of space around the sides and top of the ASU for convection cooling. Under continuous use for extended periods of time, it is normal for the top and rear panel to be warm.

3.4. Power Cord

The ASU is shipped with an approved hospital grade power cord.

Plug the ASU into a grounded receptacle.

NOTE: Do not use extension cords or three-prong to two-prong adapters. The Power Cord assembly should be periodically checked for damaged insulation or connectors.

3.5. Connecting and Disconnecting the Handpiece

Connect the Handpiece directly to the ASU. Insert the Handpiece cable connector into the receptacle on the front panel of the ASU, ensuring that the arrow symbol on the connector is facing upward and oriented to the arrow symbol on the ASU receptacle.

NOTE: Typically, you will connect the Handpiece to the ASU when the ASU has been powered up and is in STANDBY operating mode (see Section 4.2 regarding the STANDBY mode). However, the Handpiece may be connected when powered up, or prior to powering up the ASU.

NOTE: Once you have connected the Handpiece, it cannot be disconnected from the ASU by pulling on the cable. To disconnect the Handpiece, pull back on the cable connector body and remove it from the ASU receptacle.

NOTE: Refer to the Handpiece instruction sheet for more detailed information about connecting the Handpiece to the ASU in a sterile environment.

3.6. Installing the Footswitch

3.6.1. Inspect the Footswitch

Inspect the Footswitch for any signs of physical damage to the cable and connector. If physical damage is found or the Footswitch does not perform within specification, notify AtriCure. All returns must have approval from AtriCure.

3.6.2. Connecting and Disconnecting the Footswitch

With the connector alignment arrow in the 12 o'clock position, push the Footswitch Connector into the Footswitch Receptacle on the rear panel of the ASU, shown in the Figure 4.

NOTE: Typically, you will connect the Footswitch to the ASU when the ASU has been powered up and is in STANDBY operating mode (see Section 4 regarding the STANDBY mode). However, the Footswitch may be connected when powered up, or prior to powering up the ASU.

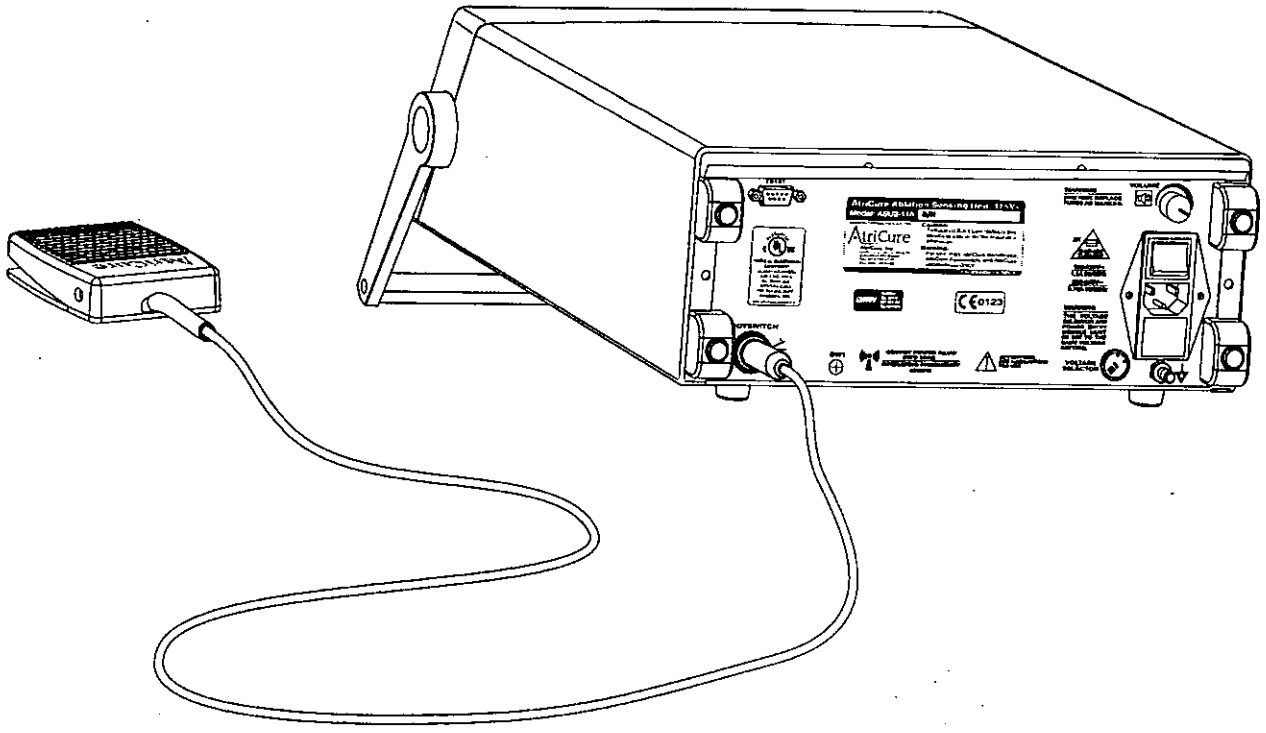


Figure 4 – Connecting the Footswitch to the ASU

3.6.3. Preparing the Footswitch for Use

The Footswitch should be placed on a flat floor. It is recommended that the area near the Footswitch be kept dry to reduce the risk of slippage.

Appropriate precautions should be taken to ensure that the cable connecting the Footswitch to the ASU does not create a hazard in the operating room.

4. Instructions For Use

4.1. Powering Up the ASU

1. Ensure that the ASU has been plugged into a grounded receptacle.

   NOTE: Do not use extension cords or three-prong to two-prong adapters. The power cord assembly should be periodically checked for damaged insulation or connectors.

2. Turn the power on using the ON/OFF switch located on the power entry module on the rear panel. When power is turned on; the system performs the System Self-Tests. See Figure 5. If all Self-Tests pass, the system transitions to the STANDBY mode. If any Self-Test fails, the system transitions to the FAULT mode. The Self-Test generates two quick beeps at startup. The operator must verify that the beeps are generated.

   NOTE: Refer to Section 4.2., below, for a full description of the STANDBY and FAULT modes, as well as all the other operating modes.

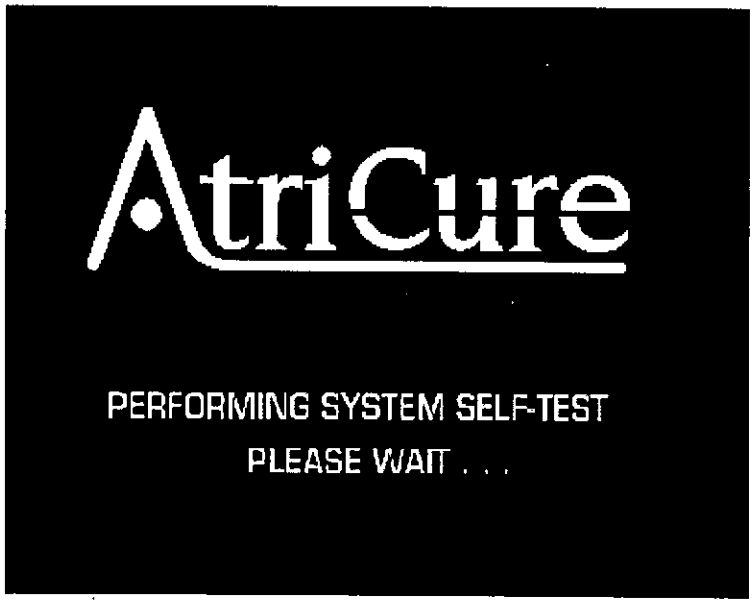


Figure 5 – Display Indicating SELF-TEST

4.2. Operating Modes

The ASU operates in one of five modes: STANDBY, READY, RF ON, ERROR and FAULT modes. These modes are shown on the lower left corner of the Conductance Display Graph. See Figure 6, below.

4.2.1. **STANDBY Mode** – This mode is entered automatically after the ASU is successfully turned on or from READY Mode upon detection of a Handpiece or Footswitch disconnection. The LCD display message indicates the system is in the STANDBY Mode.

4.2.2. **READY Mode** – This Mode is entered upon connecting both Handpiece and Footswitch while 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.

4.2.3. **RF ON Mode** – This Mode is entered when the Footswitch is depressed while in the READY Mode. The system transitions from the RF ON Mode to the READY Mode upon 40-second time expiration or if the Footswitch is released.

4.2.4. **ERROR Mode** – This Mode is entered 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.

4.2.5. **FAULT Mode** – This Mode is entered upon detection of any unrecoverable error condition during any Mode. The system is inoperable in this Mode until the power is cycled off, then on.

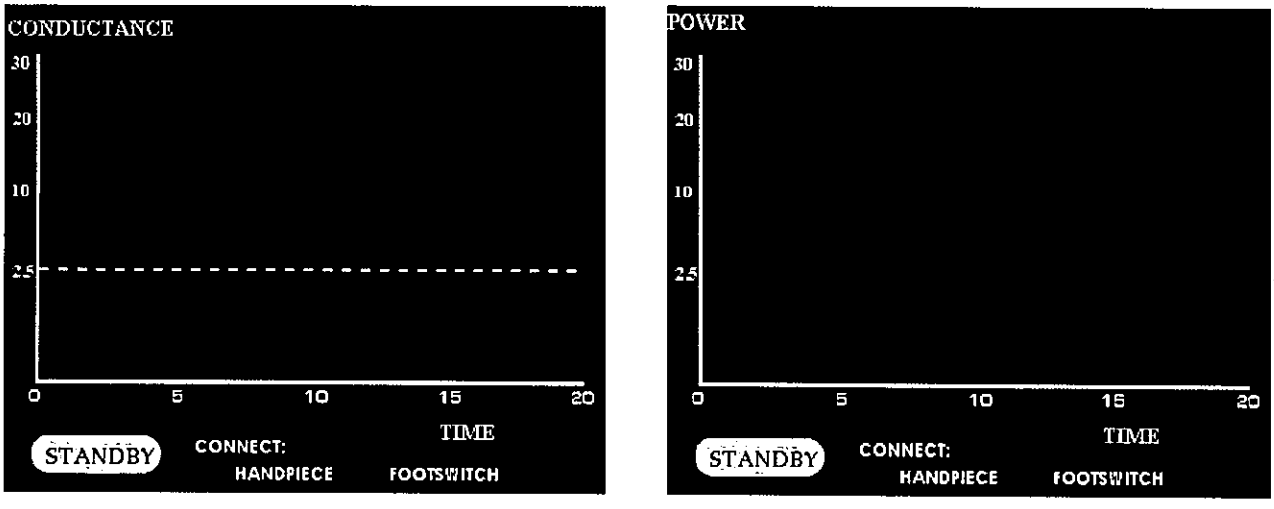


Figure 6 – Conductance and Power Display Graph Indicating STANDBY Mode

4.3. Audio Tones

The ASU uses 7 possible audio tones during its operation: Start Tone, Error Tone, Fault Tone, RF ON Tone, Transmurality Tone, High Temperature RF ON Tone, and the High Temperature Transmurality Tone. You may control the volume of these tones using the Speaker Volume Control on the rear panel of the ASU (See Figure 3). Each of these 7 audio tones is described below.

Tone Name	Tone Description	Meaning for Operator:
Start Tone	Two quick beeps	This tone is generated when the power switch is placed in the "ON" position.
Error Tone	Constant low-pitched tone	This tone occurs while an error is present.
Fault Tone	Rapid succession of low-pitched beeps for 2 seconds duration	This tone occurs upon entering a fault mode.
RF ON Tone	Constant medium-pitched tone	This tone is generated when RF energy is being delivered to the Isolator™ Transpolar™ 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™ Transpolar™ pen. This tone has a higher pitch than the Error tone.
Transmurality Tone	Intermittent medium-pitched tone	This tone is 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 has elapsed. This function is not applicable to the Isolator™ Transpolar™ pen.
High Temperature RF ON	Constant high-pitched tone	This tone is generated while in the RF ON State when a temperature of 70°C or higher is measured by the temperature sensor. The RF energy output is disabled when temperature of 75°C or higher is measured by the thermocouple. This function is not applicable to the Isolator™ Transpolar™ pen and the dual electrode Isolator™ Transpolar™ clamps.
High Temperature Transmurality	Intermittent high-pitched tone	This tone is generated when Transmurality is achieved and when a temperature between 70°C to less than 75°C is measured by the thermocouple. This function is not applicable to the Isolator™ Transpolar™ pen and the dual electrode Isolator™ Transpolar™ clamps.

4.4. Delivering RF Energy

4.4.1. Connect the Handpiece and Footswitch

Connect the Handpiece and Footswitch as described in Sections 3.5. and 3.6., and note the display to ensure connections are made. The display screen and Ready Indicator of the ASU should indicate that the RF generator is in the READY mode. See Figure 7.

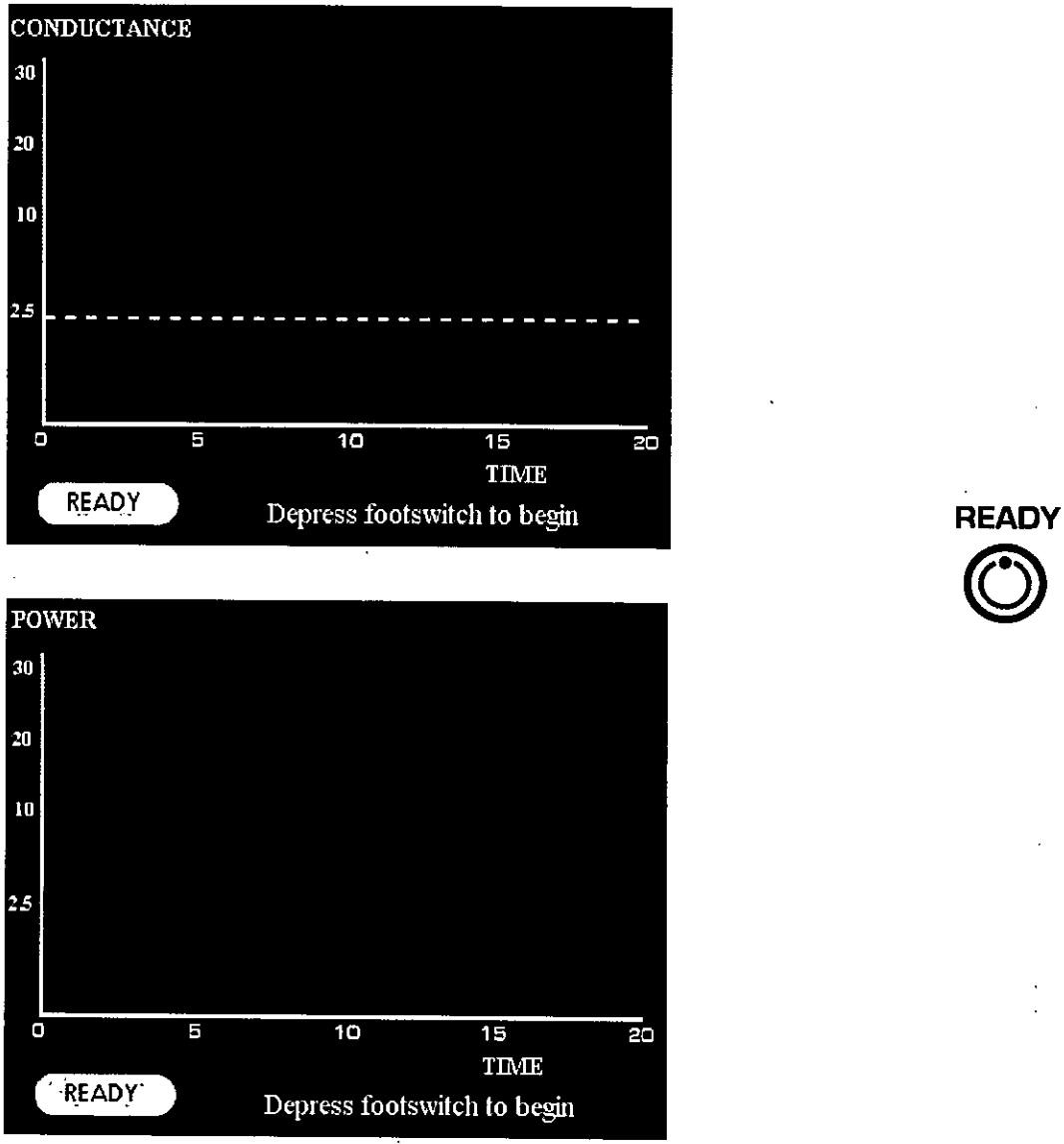


Figure 7 – Tissue Conductance Display Graph Indicating READY Mode for Isolator Handpieces(above) and Power Display Graph for Isolator™ Transpolar™ pen and Coolrail™ linear pen device (below).

NOTE: When the READY mode is entered from the RF ON mode, the previous plot is shown.

4.4.2. Position the Handpiece

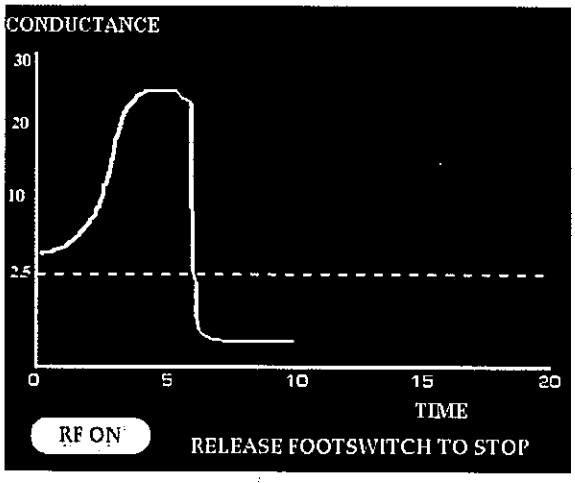
To position the Handpiece, follow the Instructions for Use provided with the Handpiece.

4.4.3. Deliver RF Energy

Press 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. See Figures 8 and 9.

During the Isolator™ Transpolar™ clamp operation, a real-time graph of measured tissue conductance is displayed on the LCD graphics screen, and measured temperature is shown on a numeric display. Using measurements of conductance, the ASU will determine when a transmurality condition has been achieved.

When this condition has been achieved, the Blue Transmurality indicator will flash and the audible tone emitted from the ASU will change from constant to intermittent, thus signaling to you that transmurality has been achieved. If you do not release the Footswitch within 40 seconds, the system will automatically time-out and stop the ablation.



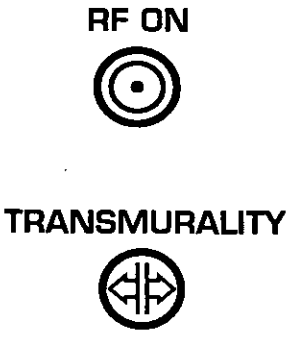
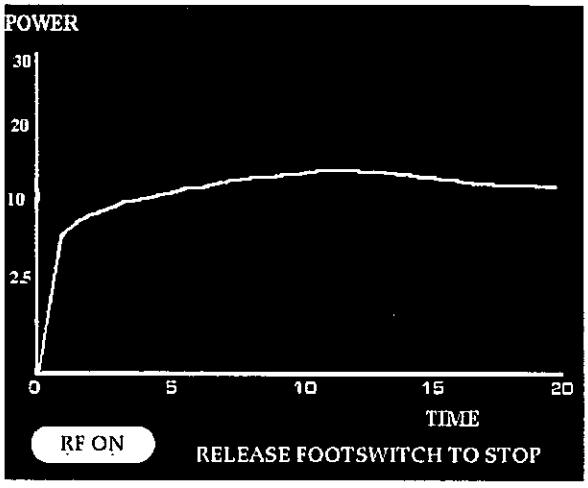


Figure 8 – Conductance Display Graph Indicating RF ON Mode

With the Isolator™ Transpolar™ pen and Coolrail™ linear pen, a real-time graph of measured power delivered to the tissue is displayed on the LCD graphics screen. The ASU will not indicate when a transmurality condition has been achieved in this mode. Furthermore, if you do not release the Footswitch within 40 seconds, the system will automatically time-out and stop the ablation.



RF ON

Figure 9 – Power Display Graph Indicating RF ON Mode

Both the conductance and the power graphs are on a 20-second scale. In some cases, the transmurality condition will not be achieved within the 20 seconds shown on the Tissue Conductance Display Graph (not valid for Isolator™ Transpolar™ pen device or Coolrail™ linear pen). In such cases, the Graph will wrap to a second screen, which will display a continuation of the conductance for a maximum of 20 additional seconds. Figure 10, below, shows an example of this wrapping feature for an ablation requiring more than 20 seconds.

Similarly, for the Isolator™ Transpolar™ pen and Coolrail™ linear pen the power graph will wrap to a second screen for ablations lasting longer than 20 seconds for a maximum of 20 additional seconds.

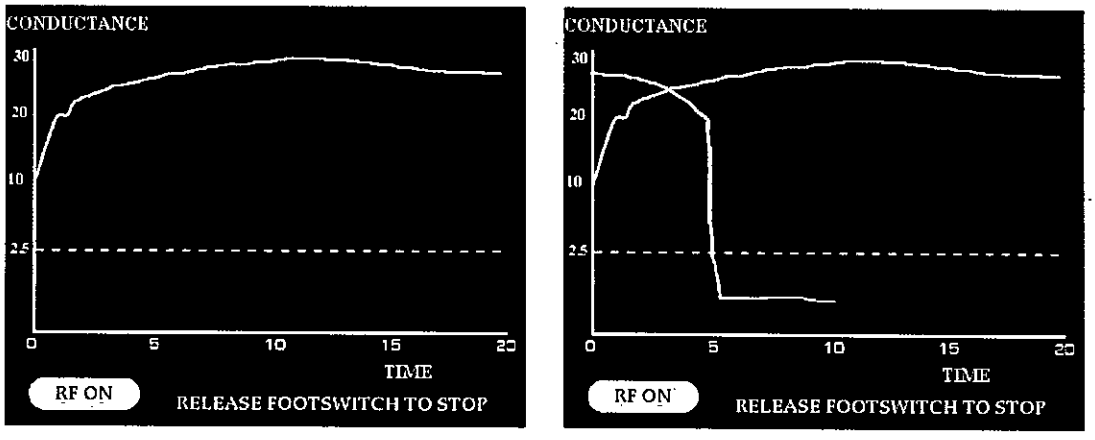


Figure 10 – Display Graph Wraps For An Ablation Lasting More Than 20 Seconds

5. Troubleshooting

Use the following sections to help troubleshoot possible problems with the ASU.

5.1. No RF Power Output

If there is no RF power output, attempt to correct this problem using the checklist below.

Possible Cause	Solution
ASU not turned on	Turn power on
ASU not plugged in	Confirm electrical connections and then turn power on
No Handpiece connected	Connect Handpiece
No Footswitch connected	Connect Footswitch
ASU in FAULT mode	Turn Power off and then on
ASU in STANDBY mode	Ensure that Handpiece and Footswitch are properly connected
Broken Handpiece cable	Replace Handpiece
Fault in Footswitch	Replace Footswitch
Fault in Handpiece	Replace Handpiece
Internal ASU failure	Contact AtriCure Customer Service

If the lack of ASU RF power output persists, contact the AtriCure service representative.

5.2. Error Codes

If a fault condition should occur, the numeric displays on the front panel will display an error code. If an Error Code of E07 through E09, PO1 through P11, or F01 through F14 appears, try turning power off, then on. If the problem persists, contact AtriCure Customer Service.

Use the table below to attempt to resolve the following recoverable application errors.

LCD DISPLAY MESSAGE	DESCRIPTION	SOLUTION
Replace Handpiece H01	Invalid Handpiece Version	Replace Handpiece
Replace Handpiece H02	Time Expired Error: The Handpiece expiration date has been exceeded	Replace Handpiece
Replace Handpiece H03	Handpiece Electrical Problem	Replace Handpiece
Replace Handpiece H04	Invalid Handpiece Version	Replace Handpiece
Check Electrodes E01	Low Impedance Error: Handpiece electrodes are shorted	Check Electrodes or reposition jaws
Close Jaws E02	High Impedance Error: Handpiece jaws are open	Close Handpiece Jaws
Check Electrodes E03	Low Impedance Error: Handpiece electrodes are shorted	Check Electrodes or reposition jaws
Check Electrodes E04	Low Impedance Error: Handpiece electrodes are shorted	Check Electrodes or reposition jaws
Replace Handpiece E05	Open or defective thermocouple	Replace Handpiece

LCD DISPLAY MESSAGE	DESCRIPTION	SOLUTION
Check Footswitch E06	Switch Stuck Test Error: Footswitch closed while connecting	Replace Footswitch
Check Electrodes E10	Handpiece electrodes are shorted	Check electrodes or reposition jaws
Check Footswitch P10	Footswitch closed at power up	Check Footswitch

5.3. Electromagnetic or Other Interference

The ASU has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The ASU generates and can radiate radio frequency 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 in a particular installation. If the ASU does cause harmful interference to other devices, which can be determined by turning the ASU off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the ASU and the other devices.
- Connect the ASU into an outlet on a circuit different from that to which the other device(s) are connected.
- Contact the AtriCure service representative for help.

Use the following sections to troubleshoot specific types of interference, including monitor (display) interference, neuromuscular stimulation, and pacemaker interference.

5.3.1. Monitor (Display) Interference

5.3.1.1. Continuous Interference

1. Check the Power Cord connections for the ASU.
2. Check all other electrical equipment in the operation room 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.

5.3.1.2. Interference Only When ASU is Activated

1. Check all connections to the ASU, and active accessory to look for possible metal-to-metal sparking.
2. If interference continues when the ASU 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 a generator 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 operating room 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, qualified service personnel should check the ASU.

5.3.2. Neuromuscular Stimulation

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

5.3.3. 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.

6. Symbols Used

Alternating Current	
Attention: consult accompanying documents	
Dangerous Voltage	
Type CF Defibrillation-Proof Applied Part	
Type CF Applied Part	
READY	
RF ON	
Transmurality	
Equipotential	
Footswitch	
Fuses	
Non-Ionizing Radiation	
Power OFF	
Power ON	
Speaker	

7. Technical specifications

7.1. RF Output

- Frequency: 460 kHz ±5%, Quasi-sinusoidal
- ASU Maximum Power Output: 32.5 W at 100Ω
- HF Power and Voltage Output:

Device Code	Maximum Output Power	Maximum Output Voltage	Handpiece Type
A	28.5 W at 114Ω	57.0 Vrms	Isolator™ Transpolar™ clamp
B	15.0 W from 20Ω to 400Ω	77.5 Vrms	Isolator™ Transpolar™ pen
C	20.0 W from 31Ω to 300Ω	77.5 Vrms	Isolator™ Transpolar™ pen
D	25.6 W at 127Ω	57.0 Vrms	Isolator™ Transpolar™ clamp
E	22.8 W at 143Ω	57.0 Vrms	Isolator™ Transpolar™ clamp
F	28.5 W at 114Ω	57.0 Vrms	Isolator™ Transpolar™ clamp
G	28.5 W at 114Ω	57.0 Vrms	Isolator™ Transpolar™ clamp
H	28.5 W at 114Ω	57.0 Vrms	Isolator™ Transpolar™ clamp
J	12.0 W from 20Ω to 500Ω	77.5 Vrms	Isolator™ Transpolar™ pen
K	25.0 W from 39Ω to 240Ω	77.5 Vrms	Isolator™ Transpolar™ pen, or Coolrail™ linear pen
L	30.0 W from 47Ω to 200Ω	77.5 Vrms	Isolator™ Transpolar™ pen, or Coolrail™ linear pen

7.2. Mechanical Specifications

- Size: 13″ × 13.75″ × 6″ (32.5 cm × 34.4 cm × 15 cm) maximum.
- Weight: 15 lb. (9 kg) maximum.

7.3. Environmental Specifications

- Operational temperature: 10°C to 40°C
- Storage temperature: –35°C to +54°C

- Humidity: 15 to 90% relative humidity

7.4. Electrical Specifications

- 100-120V ~ 50/60 Hz
- 220-240V ~ 50/60 Hz

7.5. Fuses

- **100 -120V, 220-240V, ~50 / 60 Hz,:** Replace fuses as marked: 1.25A/250V, T-lag, 5 × 20 mm, UL Recognized, IEC Approved

7.6. Footswitch Specifications

- Moisture protection rating: **IPX8**

7.7. Power and Voltage Output Restrictions

- The maximum power output of 28.5 W for the Isolator™ Transpolar™ clamp is available at 114Ω load for devices operating under device code "A, F, G, and H". Lower maximum output powers are available depending on the system operating mode. See Section 7.1.

  The maximum power output of 30.0 W for the Isolator™ Transpolar™ pen is available between 47Ω to 200Ω load for device operating under device code "L". Lower maximum output powers are available depending on the system operating mode. See Section 7.1.

  The maximum power output of 30.0 W for the Coolrail™ linear pen is available between 47Ω to 200Ω load for device operating under device code "L". Lower maximum output powers are available depending on the system operating mode. See Section 7.1.

  At other load impedances, the ASU will reduce the available power to comply with the specified voltage and current limits. See Figure 11 and Figure 12.

  The ASU is capable of producing a maximum output power of 32.5 Watts under a 100 Ohm load although no current AtriCure® Bipolar Handpiece uses power above 30 Watts.

- The maximum output voltage depends on the device code, and can be either 57 Vrms or 77.5 Vrms. See Section 7.1.

7.8. Equipment Type / Classification

- Class 1 Equipment

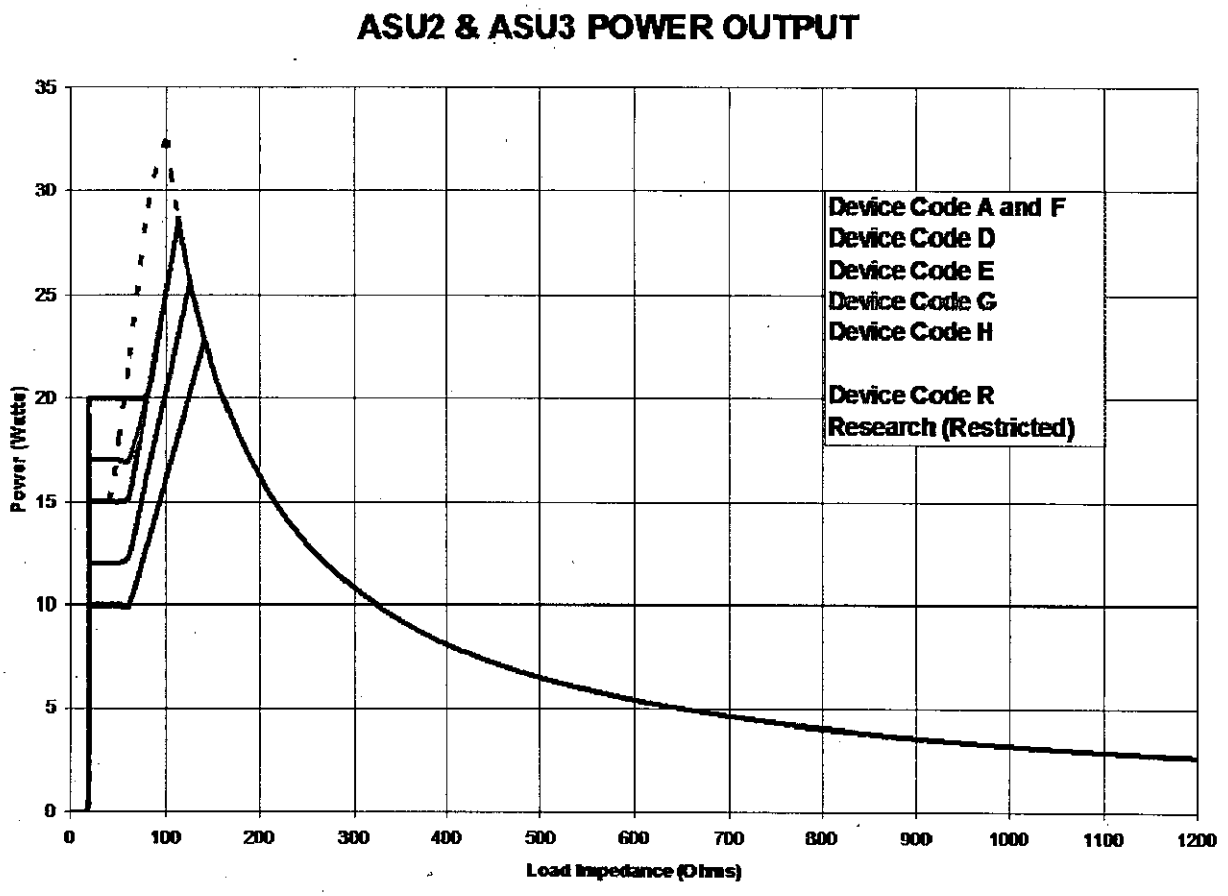


Figure 11 – Power vs. Load (clamp algorithm)

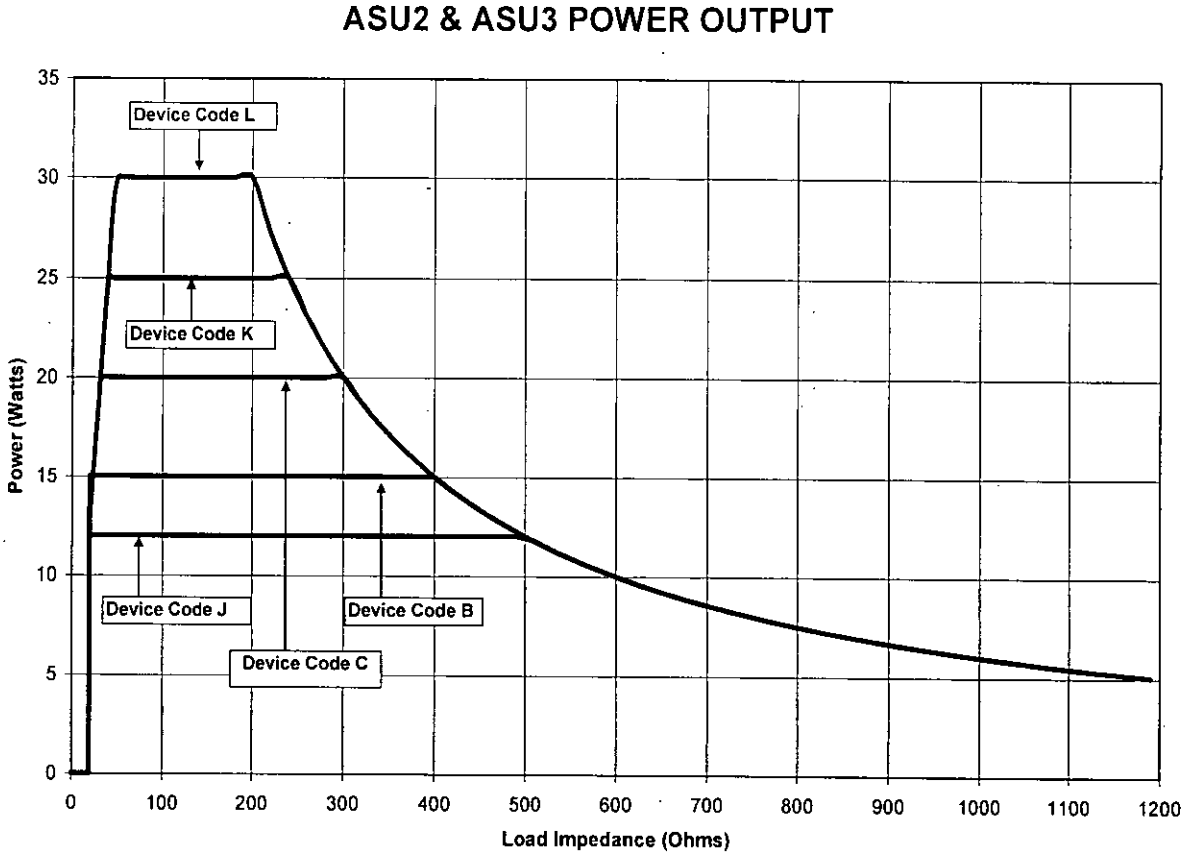


Figure 12 – Power vs. Load (pen algorithm)

8. Preventive Maintenance and Cleaning of ASU

8.1. Preventive Maintenance

Perform annual preventative maintenance procedures to ensure all ASU components are functioning as defined within this manual. Pay particular attention to operational and safety features, including but not limited to:

- Electrical power cords for fraying, damage, and proper grounding
- AC power switch
- Indicator damage (Power On, Fault, Ready, RF ON, Transmurality)
- LCD display damage or loss of graphic information
- Temperature display damage or loss of information
- Handpiece connector damage, cracking or inability to insert and latch Handpiece plug
- Carrying handle damage, inability to latch or rotate
- Rubber feet damage, cracking or inability for the ASU to remain stabile on a flat surface.
- Footswitch cord fraying or damage
- Footswitch connector damage cracking or inability to insert and latch footswitch plug
- Footswitch pedal damage, check activation by pressing and releasing the pedal

Other medical equipment that may be used simultaneously with the ASU should also be inspected for damage. Specifically, check for insulation damage of monitoring electrode cables and endoscopically used accessories.

Visually inspect the footswitch for fluids or other infectious hazards. Clean as necessary using the instructions in Section 8.2.

The ASU does not have any serviceable parts. For servicing issues, contact AtriCure, Inc. at:

6217 Centre Park Drive
West Chester, Ohio 45069
USA
Telephone: 513-755-4100
866-349-2342 Toll Free

8.2. Cleaning and Disinfecting

8.2.1. ASU Cleaning and Disinfection Instructions

Use a mild detergent and damp cloth to clean the ASU cover, front panel, and power cable. The ASU cannot be sterilized. Do not allow fluids to enter the chassis. The ASU may be disinfected using a standard hospital alcohol solution applied with a cloth.

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

WARNING: **To avoid igniting endogenous gases, use only non-flammable agents to clean and disinfect the ASU. If flammable agents are inadvertently used on the ASU, allow these substances to evaporate completely before operating.**

8.2.2. Footswitch Cleaning and Disinfection Instructions

Use a mild detergent (prepared to its specifications) and a damp cloth to clean the exterior of the Footswitch and cord. Do not allow fluids to enter the chassis. Take care not to wet the electrical connector on the cable. Do not use caustic, corrosive, or abrasive cleaning materials. The Footswitch cannot be sterilized. The Footswitch may be disinfected using a standard hospital alcohol solution applied with a cloth.

8.2.3. Source Switch Accessory Cleaning and Disinfection Instructions

Use a mild detergent (prepared to its specifications) and a damp cloth to clean the exterior of the Source Switch and auxiliary device cord. Do not allow fluids to enter the chassis. Take care not to wet the electrical connector on the cable. Do not use caustic, corrosive, or abrasive cleaning materials. The Source Switch and auxiliary device cable cannot be sterilized. The Source Switch may be disinfected using a standard hospital alcohol solution applied with a cloth.

8.2.4. Switch Matrix Accessory Cleaning and Disinfecting Instructions

Use a mild detergent (prepared to its specifications) and a damp cloth to clean the exterior of the Switch Matrix and auxiliary device cord. Do not allow fluids to enter the chassis. Take care not to wet the electrical connector on the cable. Do not use caustic, corrosive, or abrasive cleaning materials. The Switch Matrix and auxiliary device cable cannot be sterilized. The Switch Matrix may be disinfected using a standard hospital alcohol solution applied with a cloth.

9. Disposal

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

10. Accessories

10.1. ASB1, Source Switch Accessory

10.1.1. The Source Switch provides a means of interrupting power to the handpiece and a means of selecting the input to the handpiece electrodes. The input is selected with the Source Switch rocker switch to come either from the ASU or from an auxiliary device. In the auxiliary position the RF power to the handpiece is interrupted. A cable with protected 0.080 inch pin tip plugs is provided to connect the Source Switch to the auxiliary device.

WARNING: Do not connect the ASB1 auxiliary 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.

An auxiliary device (other than those listed in paragraph 10.1.2) may have an adverse effect on nearby radio or TV or medical equipment. There may also be cases when nearby electrical appliances adversely influence the auxiliary device, causing data errors or malfunction.

10.1.2. Auxiliary devices compatible for use with the Source Switch include:

10.1.2.1. OSCOR Model PACE 101H ™

10.1.2.2. OSCOR Model PACE 203H ™

WARNING: Read auxiliary device manual and observe warnings.

10.1.3. Any AtriCure handpiece or pen device may be connected to the Source Switch when the Source Switch is in the ASU position.

10.1.4. The Auxiliary input switch position (AUX) is to be used only with AtriCure Isolator™ Transpolar™ pen devices.

10.1.5. Settings and procedures for the auxiliary device are determined according to the instructions for use provided with the auxiliary device. Set auxiliary pacing device to asynchronous mode (sensing disabled or increased to maximum value).

10.1.6. Source Switch set up is shown in the following figures.

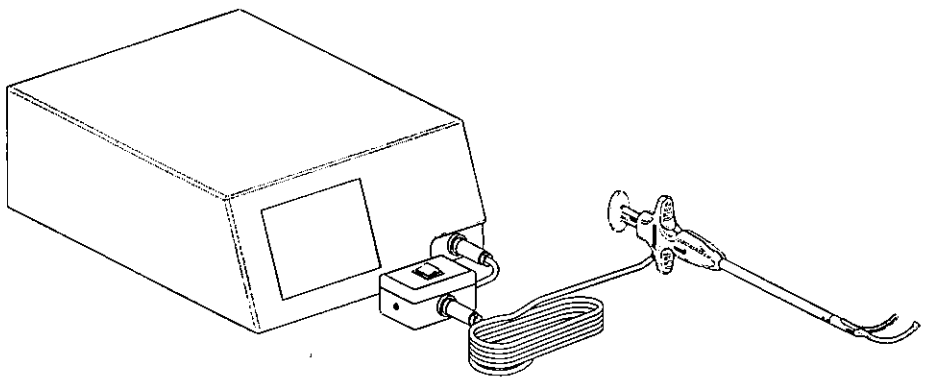


Figure 13

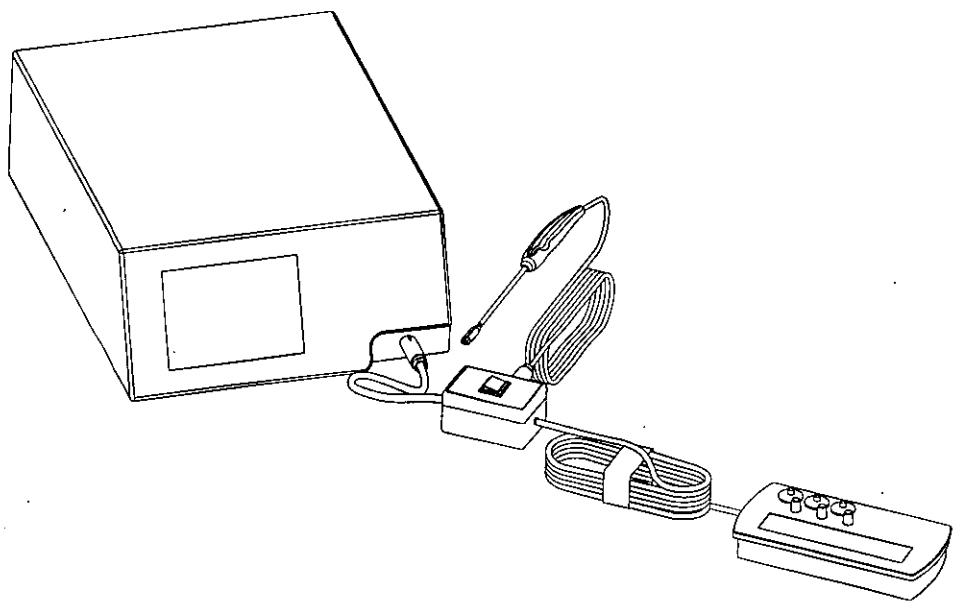


Figure 14

10.2. ASB3, Switch Matrix Accessory

10.2.1. The Switch Matrix provides a means of connecting multiple handpieces to the ASU and a means of selecting the input to the handpiece electrodes. The input is selected with the Switch Matrix knob. A cable with is provided to connect the Switch Matrix to the ASU.

WARNING: Do not connect the ASB3 auxiliary 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.

An auxiliary device (other than those listed in paragraph 10.2.2) may have an adverse effect on nearby radio or TV or medical equipment. There may also be cases when nearby electrical appliances adversely influence the auxiliary device, causing data errors or malfunction.

10.2.2. Auxiliary devices compatible for use with the Switch Matrix include:

10.2.2.1. Any AtriCure Isolator™ Handpiece

10.2.2.2. Any AtriCure Transpolar™ Pen

10.2.2.3. Any AtriCure Coolrail™ linear pen

10.2.2.4. OSCOR Model PACE 101H ™

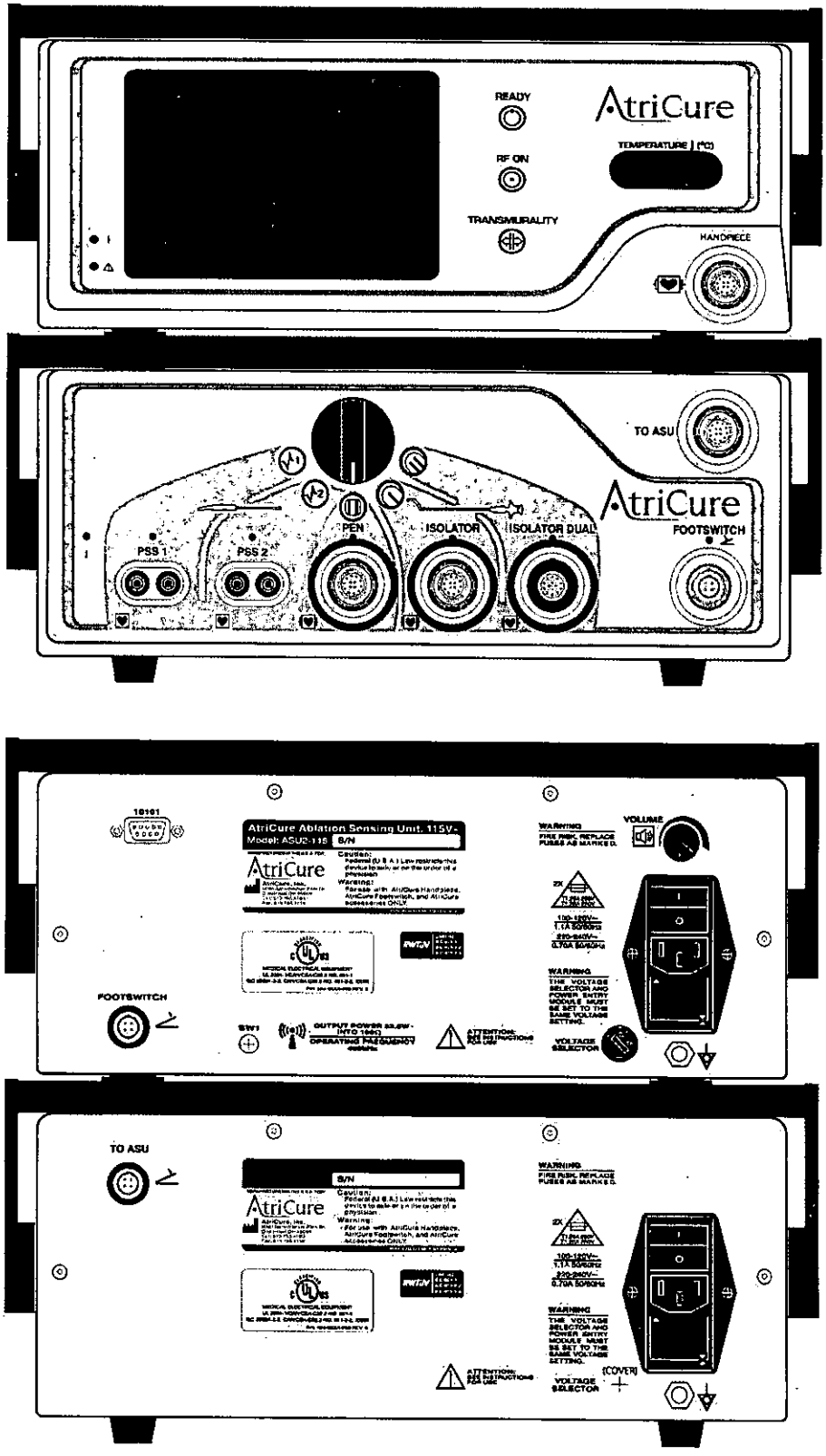
10.2.2.5. OSCOR Model PACE 203H ™

WARNING: Read auxiliary device manual and observe warnings.

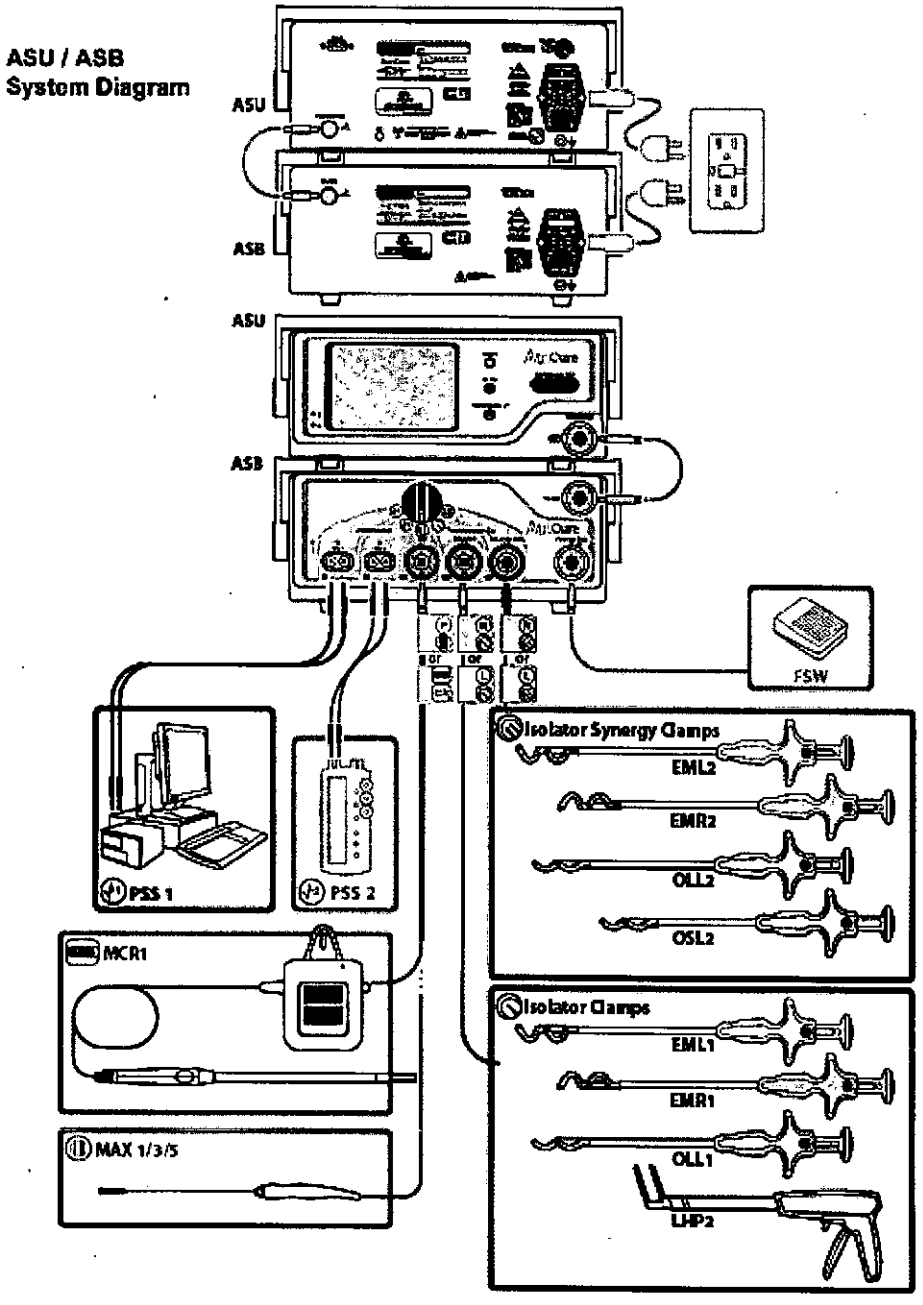
10.2.3. Any AtriCure handpiece or pen device may be connected to the Switch Matrix. AtriCure Devices will be functional when the device is connected to the correct receptacle and the Switch Matrix switch knob is turned to indicate the device for use.

10.2.4. Settings and procedures for the auxiliary device are determined according to the instructions for use provided with the auxiliary device.

10.2.5. ASB3, Switch Matrix Unit is shown below with the ASU.



Switch Matrix set up is shown in the following figures.



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 Source Switch	One (1) Year
AtriCure Footswitch	One (1) Year
Grounded Electrical Cord	One (1) Year

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