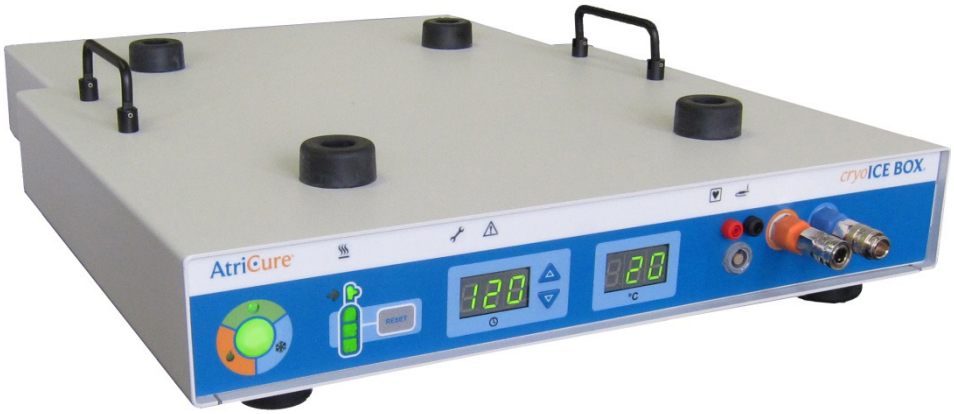
AtriCure®

® *cryo*ICE BOX




# Version 6

## USER'S MANUAL

***AtriCure cryo*ICE BOX, model ACM1 – 115 (100-120)VAC, 4A, 50/60 Hz**

***AtriCure cryo*ICE BOX, model ACM2 – 230 (220-240)VAC, 2A, 50/60 Hz**

EC REP

European Representative:
AtriCure Europe B.V.
De entree 260
1101 EE Amsterdam
NL
+31 20 7005560
ear@atricure.com

Manufacturer:
AtriCure, Inc.
7555 Innovation Way,
Mason, Ohio 45040 USA
+1 866 349 2342 (toll free)
+1 513 755 4100 (phone)

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CE 2797

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## FOREWORD

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. The AtriCure *cryo*ICE BOX also referred to as the AtriCure Cryo Module (ACM) consisting of two model units: ACM1 and ACM2.

## ⚠ CAUTION

Federal (US) 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 including patient and caregiver harm.

## IMPORTANT

This user manual is designed to provide instructions for use of the AtriCure *cryo*ICE BOX (A000896-3 & A000897-3 assembly/A000898-3 & A000899-3 packaged assembly) with the AtriCure *cryo*ICE probes and AtriCure Detachable and Accessory Devices (See page 22 of this manual for specific part numbers information.) This user manual is not a reference to surgical technique.

## INDICATIONS FOR USE/INTENDED PURPOSE

The AtriCure *cryo*ICE BOX is a non-sterile, reusable device which delivers cryogenic energy, namely nitrous oxide, to AtriCure's cryo-ablation probes.

The intended purpose of the ACM Exhaust Hose Connector is an optional accessory of the AtriCure cryoICE BOX, providing a method to connect the AtriCure cryoICE BOX exhaust to a hospital medical vacuum or waste anesthesia gas disposal (WAGD) system. It is intended only to be used together with the AtriCure cryoICE BOX to enable meeting its intended purpose.

The ACM footswitch is used to activate the AtriCure cryoICE BOX as an alternative to using the Activation Button on the front panel of the generator.

The AtriCure *cryo*ICE BOX unit is an electro-mechanical cryogenic surgical unit that delivers a cryogenic Nitrous Oxide ($N_2O$) energy source to a *cryo*ICE probe to create lines of ablation through tissue. The AtriCure *cryo*ICE BOX is part of a system which includes the $N_2O$ gas cylinder, $N_2O$ gas line hose, $N_2O$ exhaust hose, cylinder heater band, an optional footswitch, and single-use *cryo*ICE probes. The system provides controlled lesion forming temperatures below -40°C, with typical operating ranges between -50°C to -70°C.

The AtriCure *cryo*ICE BOX is designed to operate only with AtriCure designed and developed *cryo*ICE probes. The AtriCure *cryo*ICE probe will be referred in this User's Manual as the "*cryo*ICE probe".

This User's Manual provides a description of the AtriCure *cryo*ICE BOX, its controls, displays, indicators, and a sequence for its operation with the *cryo*ICE probe. This User's Manual also supplies other information of importance to the user. For information about the *cryo*ICE probes, please refer to the *cryo*ICE probe Instructions for Use.

Do not operate the AtriCure *cryo*ICE BOX before thoroughly reading this manual.

## PATENT INFORMATION

May be covered by one or more patents.

## WARNINGS AND CAUTIONS

The safe and effective use of the cryo device and equipment 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 AtriCure *cryo*ICE BOX unit be read, understood, and followed before use.

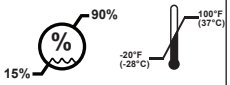
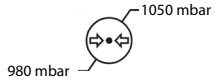
## ⚠ WARNINGS

- Do not operate the *cryo*ICE BOX unit before thoroughly reading this manual.
- Do not use cryo surgical equipment unless properly trained 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.
- **Fire Hazard**: Do not use extension cords.
- **Trip Hazard**: Standard care should be used to reduce the risk of tripping on the Footswitch cable, as well as the $N_2O$ exhaust hose.
- No modification of this equipment is allowed.
- The voltage selector is factory set and should not be changed by the user. The voltage setting and the fuse rating must be appropriate as identified to prevent *cryo*ICE BOX malfunction and potential instrument damage.
- **Electric Shock Hazard**: Connect the *cryo*ICE BOX 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 *cryo*ICE probe is correctly connected to the *cryo*ICE BOX and that no thermocouple wires are exposed from the cable, connector, or the *cryo*ICE probe.
- Use of accessories, transducers and cables other than those specified or provided by AtriCure could result in increased electromagnetic emissions or decreased electromagnetic immunity of the *cryo*ICE BOX and result in improper operation
- Use of the *cryo*ICE BOX adjacent to or stacked with other equipment should be avoided because it could result in improper operation
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the *cryo*ICE BOX, including cables specified by the AtriCure. Otherwise, degradation of the performance of this equipment could result.
- The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.
- The ACM Exhaust Hose connector requires a dedicated Vacuum or WAGD port to prevent back pressure into the patient's breathing line, which may result in Pneumothorax.

## ⚠ CAUTIONS

- Use only with the *cryo*ICE probes intended for use with the *cryo*ICE BOX.
- Do not transition into FREEZE mode until the *cryo*ICE probe is properly positioned at the ablation site.
- The system status indicators and displays are important safety features. Do not obstruct either the ablation or the system status indicators.
- Do not remove the *cryo*ICE BOX cover as there is a potential for electrical shock. Refer to authorized personnel for service.
- The Power Cord of the *cryo*ICE BOX must be connected to a properly grounded receptacle. Extension cords and/or adapter plugs must not be used.
- Do not contact *cryo*ICE probes with a RF device.
- Compressed Air Hazard: Do not operate $N_2O$ cylinders with a pressure greater than 1000 PSIG (6900 kPa).
- Nitrous Oxide connections should only be unplugged when the *cryo*ICE BOX is in the READY mode and properly vented.

## *Meanings of Symbols on AtriCure cryoICE BOX*

| | | | |
|---|---|---|---|
| Power Off |  | Cylinder Valve On/Off |  |
| Caution |  | $N_2O$ Gas Gauge Reset |  |
| Alternating Current |  | Gas Exhaust |  |
| Equipotential Terminal |  | Maintenance Needed |  |
| Type CF Applied Part (cryoICE Probe) |  | Cylinder Heater Band |  |
| READY |  | Footswitch |  |
| FREEZE |  | Maximum Pressure |  |
| DEFROST |  | Gas Inlet |  |
| $N_2O$ Gas Gauge |  | Gas Outlet |  |
| Timer |  | Non-Sterile |  |
| Timer Increase Button |  | Manufacturer |  |
| Timer Decrease Button |  | Catalog Number |  |
| cryoICE Probe Temperature |  | Serial Number |  |
| Thermocouple/Probe |  | Caution: Federal Law (US) restricts this device to sale by or on the order of a physician |  |
| Humidity and Temperature Storage, Transit, and Operational Limits |  | Conforms to the requirements of the European Directives and Regulations |  |
| Operational & Storage Pressure Limits |  | Follow Instructions for Use |  |
| Medical Device |  | Consult Instructions for Use |  |
| Contains hazardous substances |  | Waste Electrical and Electronic Equipment (WEEE) |  |
| Date of Manufacture |  | Model Number |  |
| Not made with dry natural rubber or natural rubber latex |  | Does not contain phthalates |  |

## Classification in accordance with IEC, EN, ANSI/AAMI, CSA 60601-1

**SAFETY INFORMATION**

**E509985**

**MEDICAL — GENERAL MEDICAL EQUIPMENT**
**AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY**
**IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)**
**CAN/CSA C22.2 No. 60601-1 (2014) E509985**

Cryogenic Ablation Device, Model AtriCure Cryo Module, ACM1 & ACM2, cord connected/ appliance coupler / transportable, rated: 115/230Vac, 4/2A, 50/60 Hz

1. Type of protection against electric shock: Class I

2. Degree of protection against electric shock: Type CF

3. Degree of protection against ingress of water: IPX0

4. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

5. Mode of operation: Continuous

6. Environmental Conditions: Normal: 10-40°C (50°F-104°F), 15-90% rH, 980-1050mb

# 1. SYSTEM OVERVIEW

## The AtriCure *cryo*ICE BOX

This section provides a detailed description of the *cryo*ICE BOX including its function and operating features.

- The cryoICE BOX unit is an electro-mechanical cryogenic surgical unit that delivers a Nitrous Oxide (N2O) cryogenic energy source to a cryoICE probe to create lines of ablation through tissue. The cryoICE BOX is part of a system which includes the N2O cylinder, N2O gas line hose, N2O exhaust hose, cylinder heater band, an optional footswitch, and single-use cryoICE probes. The system provides controlled lesion forming temperature that is below -40°C, with typical operating ranges between -50°C to -70°C.
- Along with the Activation Button on the front panel of the cryoICE BOX, an optional Footswitch can also be used to activate and terminate the cryo ablation cycle.
- The cryoICE BOX is designed to operate only with AtriCure cryoICE probes. Refer to the cryoICE probe Instruction for Use for complete description and indications for use of these devices.

## AtriCure *cryo*ICE BOX Front and Rear Panels – Illustrations and Nomenclature

Illustrations of the *cryo*ICE BOX front panel (Figure 1) and rear panel (Figure 2) are shown below.

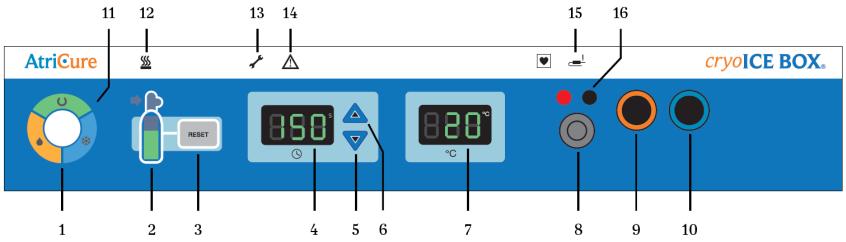
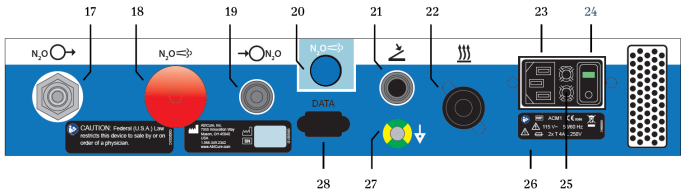
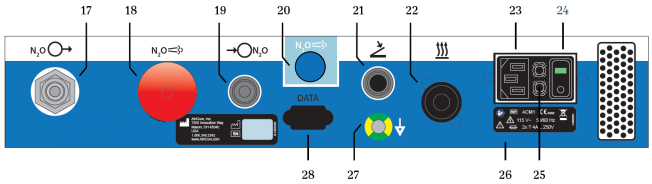



*Figure 1:* AtriCure *cryoICE BOX Front Panel*

1. Activation Button
2. $N_2O$ Gas Gauge Indicator Display
3. $N_2O$ Gas Gauge Indicator Display Reset
4. Ablation Timer Display
5. Ablation Timer Decrement
6. Ablation Timer Increment
7. *cryo*ICE Probe Temperature
8. Future Probe Connection
9. *cryo*ICE Probe Gas Outlet Port
10. *cryo*ICE Probe Gas Inlet Port
11. Ablation Status Indicator
12. Cylindexr Heater Band Indicator
13. Maintenance Needed Indicator
14. System Fault Indicator
15. Thermocouple Open Indicator
16. *cryo*ICE Probe Thermocouple Ports




*Domestic*




*International*

*Figure 2:* AtriCure *cryoICE BOX Rear Panel*

17. $N_2O$ Exhaust Port
18. $N_2O$ Manual Exhaust Knob
19. $N_2O$ Inlet Port
20. $N_2O$ Exhaust Switch
21. Activation Footswitch Connection Port
22. Heater Band Cord Receptacle
23. Power Plug Receptacle
24. Power Switch
25. Mains Fuse Location
26. *cryo*ICE BOX Voltage Rating Label
27. Equipotential Terminal
28. RS232 Data Connection

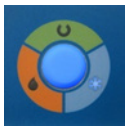
## Operating Modes

The *cryo*ICE BOX operates in one of three modes: READY, FREEZE, and DEFROST. These modes are identified by the system status indicator LEDs and the ablation status indicator LEDs located on the front of the *cryo*ICE BOX unit.

### READY Mode

This mode is entered automatically upon successful execution of Power-on-self -test when the unit is first turned on or following DEFROST Mode upon the *cryo*ICE probe reaching approximately 10°C and automatically venting. This indicates that the system is ready for the next cryo ablation run.

### FREEZE Mode



This Mode is entered from the READY Mode when the user initiates the cryo ablation cycle by pressing and releasing the Activation Switch or the Footswitch. In this mode, the $N_2O$ gas is allowed to cycle through the *cryo*ICE probe causing a temperature drop to take place at the *cryo*ICE probe.

### DEFROST Mode

This Mode is entered automatically from FREEZE Mode upon expiration of the ablation timer, or manually by the operator when the Activation Switch or the Footswitch is actuated while in the FREEZE Mode. In this mode, the *cryo*ICE probe temperature is actively forced towards the ambient temperature.

Once the *cryo*ICE probe temperature is above approximately 10°C, the *cryo*ICE BOX unit will transition back to the READY Mode.

**Note:** *cryo*ICE BOX does allow early transition out from the DEFROST Mode into either the READY Mode or the FREEZE Mode by pressing the Activation Button.

**Note:** *cryo*ICE probe temperature may drop temporarily upon transition from DEFROST to READY state.

### FAULT Condition

This is entered upon detection of any unrecoverable error condition during any Mode. The system is inoperable in this Mode until the unit is first power cycled, and only if the fault condition no longer exists or has been remedied.

# 2. TECHNICAL SPECIFICATIONS

## Mechanical Specifications

Size: 17.5 in *(44.5 cm)* - (W) × 27.0 in *(68.6 cm)* - (D) × 4.5 in *(11.4 cm)* - (H) maximum

Weight: 45 lb. *(20.4 kg)* absolute maximum

## Environmental Specifications

| | Temperature | Humidity | Atmospheric pressure |
|---|---|---|---|
| Operational Temperature | +10°C to +40°C<br>+50°F to +104°F | 15% to 90% relative humidity | 980mb to 1050mb |
| Storage | -28°C to +37°C<br>-20°F to +100°F | 15% to 90% relative humidity | 980mb to 1050mb |
| Transit | -28°C to +37°C<br>-20°F to +100°F | 30% to 85% relative humidity | |

### Electrical Specifications

*AtriCure cryo*ICE BOX*, model ACM1 – 115 (100-120)VAC*, 4A, 50/60 Hz
*AtriCure cryoICE BOX, model ACM2 – 230 (220-240)VAC*, 2A, 50/60 Hz

### Mains Fuses

*AtriCure cryo*ICE BOX*, model ACM1 – 115 (100-120)VAC,* 4A, 50/60 Hz
Replace fuses as marked: 4.0A/250V, T-lag, 5 × 20 mm, UL Recognized, IEC Approved
*AtriCure cryo*ICE BOX*, model ACM2 – 230 (220-240)VAC,* 2A, 50/60 Hz
Replace fuses as marked: 2.0A/250V, T-lag, 5 × 20 mm, UL Recognized, IEC Approved

### cryoICE Probe Temperature Display Accuracy (see figure 1 item 7)

Resolution: 1°C (increments)
Temperature > or = -40°C Accuracy of +3°C/-6°C
Temperatures<-40°C Accuracy of +5°C/-8°C

### Footswitch Specifications

Moisture protection rating: IP68

### Equipment Type / Classification

Class 1 Equipment

## 3. AtriCure *cryo*ICE BOX, DETACHABLES, AND ACCESSORIES

As shown in Figure 3, the system is comprised of the following:
A: AtriCure *cryo*ICE BOX Cylinder Heater Band (CMH15 or CMH22) - Detachable
B: AtriCure ***cryo***ICE BOX Tank Hose Assembly, without Canister Set, Standard - Detachable
C: AtriCure ***cryo***ICE BOX $N_2O$ Exhaust Hose - Detachable
D: AtriCure cryoICE BOX Exhaust Hose Connector - Detachable
E: AtriCure ***cryo***ICE BOX Tank Hose Assembly, with Filter Canister Set (Optional) -Detachable
F: AtriCure ***cryo***ICE BOX
G: AtriCure *cryo*ICE BOX Footswitch (Optional – not shown) - Accessory
H: AtriCure *cryo*ICE BOX Power Cord (not shown) - Detachable
I: AtriCure *cryo*ICE probe with integral tube set (not shown) - Type CF Applied Part
J: AtriCure *cryo*ICE BOX Heater Band Extension Spring (not shown) – Detachable

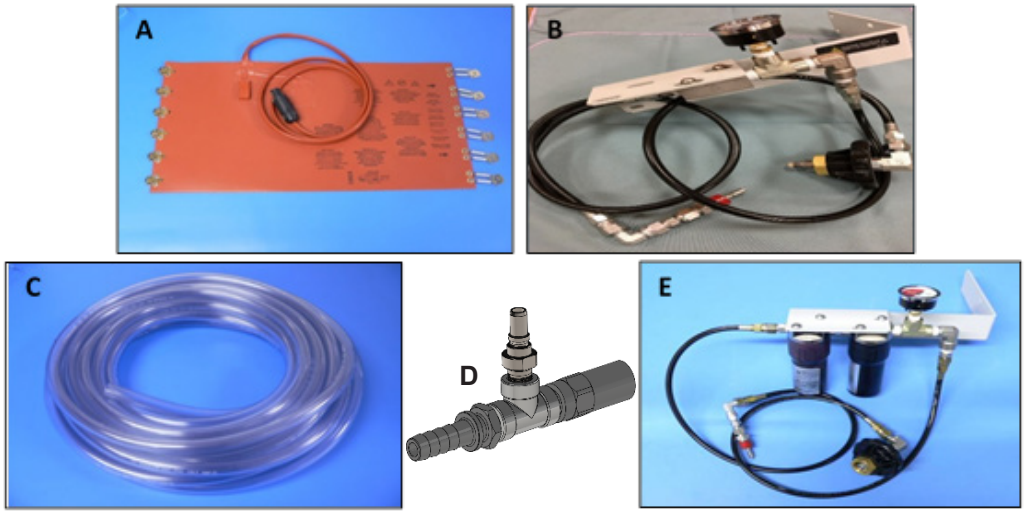



*Figure 3: AtriCure cryoICE BOX, Detachables, and Accessories*

## AtriCure cryoICE BOX Set-Up and Preparation

This section will outline the preliminary set-up for the *cryo*ICE BOX, including cylinder installation, heater band installation, turning on the *cryo*ICE BOX, and resetting the cylinder gauge on the *cryo*ICE BOX user interface. **Note:** The *cryo*ICE BOX should be set up at least 15-minutes prior to the procedure to allow time for the heater to warm the $N_2O$ cylinder to operating temperature.

## $N_2O$ Cylinder Installation

- Use only nitrous oxide gas with a water content not exceeding 3 ppm. Automotive grade nitrous oxide should not be used due to the inclusion of hydrogen sulfide.
- The *cryo*ICE BOX is designed to use 20-pound (9-kg.) cylinders.
- Always install a completely full cylinder so the cylinder volume can be indicated correctly.
- To install a new $N_2O$ cylinder, first find the $N_2O$ gas line receptacle on the rear panel and connect this end into the corresponding end of the $N_2O$ gas line. Insert and push in the connector until you hear it "click" in place and the connection is fully seated and secured from unlatching as seen below in Figure 4.

*Figure 4: $N_2O$ Inlet Connection*

- Next, match the opposite black knob end of the N2O gas line with the threaded connection port of a new N2O gas cylinder.
- Screw the cryoICE BOX gas line into place by hand tightening the knob as shown in Figure 5. Over tightening this fitting with a wrench may cause damage, allowing N2O gas to leak.
- To open gas cylinder valve, slowly turn the knob on the top of the cylinder counter-clockwise as seen in Figure 6.

*Figure 5: Attach Black Knob to Threaded Connection*

*Figure 6: Turn Valve Counter-Clockwise to Open*

- Listen for leaks. If a leak is detected, tighten the black knob with a wrench if needed.
- If the Low-Pressure indicator, as seen in Figure 7, illuminate's amber this indicates that the cryoICE BOX is not detecting proper pressure. Check to ensure that the gas cylinder valve is open fully and that the cylinder you have attached is not empty.

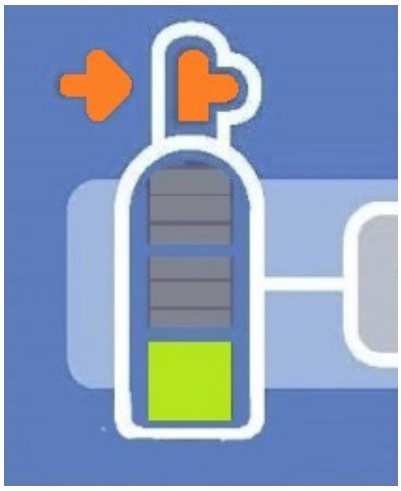


*Figure 7: Low Pressure Indicator*

## Exhaust Tubing

**Note**: Ensure the Exhaust tubing (hose) is firmly attached to the *cryo*ICE BOX $N_2O$ exhaust port, see Figure 2 item 17.

- Be sure to route the $N_2O$ vent tubing to a safe area prior to use.
- If a scavenger system is used, it must be able to accommodate a continuous flow of 60-liters per minute.

## Heater Band Installation

- Ensure the cryoICE BOX is properly connected to an N2O gas cylinder.
- Place heater band with the cord facing upward.
- Secure all tensioning spring retainers around the gas cylinder, starting with the very bottom and very top retainers and then proceed to secure the middle retainers as shown in Figure 8.
- The Heater band must be positioned less than 2-inches (5-cm) from bottom of the cylinder to ensure that the N2O is heated efficiently.
- Plug heater band cord into the appropriate indicated receptacle located on the rear panel of the cryoICE BOX unit as shown in Figure 9.
- Verify that the Cylinder Heater Band Icon on the front of the unit is not illuminated.

*Figure 8: Secure All Tensioning Spring Retainers*

*Figure 9: Plug Heater Band Cord into Receptacle*

## Turning On the AtriCure *cryo*ICE BOX

- Plug in the cryoICE BOX unit into an approved hospital outlet.
- Turn-On the cryoICE BOX unit with the switch located on the back as seen in Figure 10. The power switch is used to connect mains power (Turn-On) or disconnect mains power (Turn-Off) to the cryoICE BOX unit.
- After powering up, the Activation Button on the front of the cryoICE BOX interface will be illuminated. If no light is observed, check for proper power cord connection and switch position

*Figure 10: Turn-On AtriCure cryoICE BOX with Switch*

## Resetting the $N_2O$ Gas Gauge

- Only reset the gauge when a new full cylinder has been installed.
- Ensure *cryo*ICE BOX is powered on.
- Ensure the unit is in READY mode.
- Find the gas cylinder display on the front of the *cryo*ICE BOX and note the RESET button to the right of this display, see Figure 11.
- Press and hold the RESET button for one second.

**Note:** Once the $N_2O$ gas gauge is reset, the display can take up to several minutes to display the remaining volume in the tank.

- The gauge can only be reset to full after a system power cycle or following a cylinder swap out. If RESET button is pressed following usage the gauge will reset to the estimated cylinder volume.

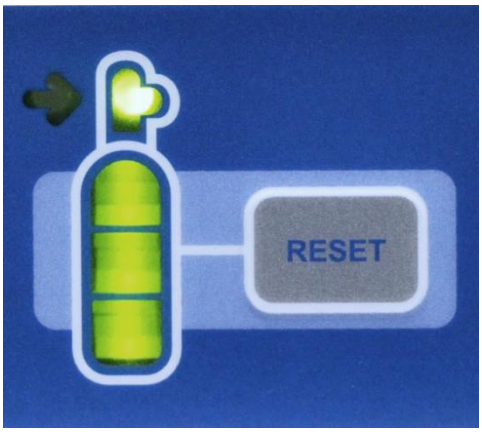



*Figure 11: $N_2O$ Gas Gauge RESET Button*

- Meaning of gas gauge indicators seen in Figure 12

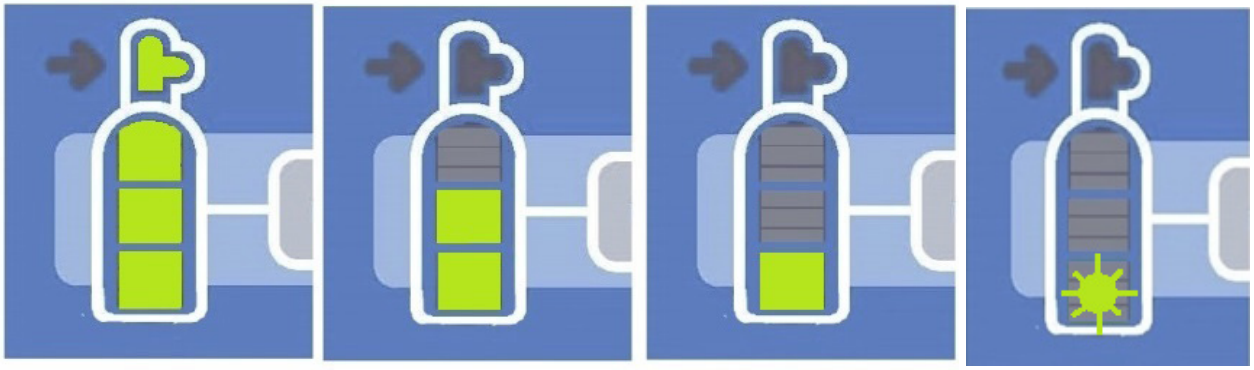


*Figure 12: $N_2O$ Gauge Indicators*

3-Segments On = Approximately 20-40 minutes remaining

2-Segments On = Approximately 15-20 minutes remaining

1-Segment On = Approximately 5-10 minutes remaining

1-Segment Flashing = Approximately 5 minutes or less remaining – **CHANGE TANK**

### System Check

- Verify neither the Maintenance Needed or System Fault icons are illuminated.

## 4. DEVICE USE

### Install AtriCure *cryo*ICE Probe

1. Ensure cryoICE BOX is properly connected to a N2O gas cylinder.
2. The cryoICE probe may be connected before the cryoICE BOX has been turned on, while the cryoICE BOX is being turned on, or when the cryoICE BOX unit is on and in READY mode.
3. Insert the corresponding connections on the pneumatic connectors as shown below in Figure 13. The sliding ring will need to be manually pushed-in on the orange connector.

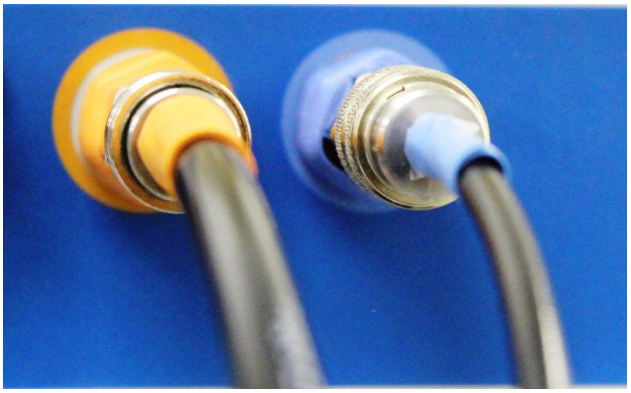


*Figure 13: Color Coded Pneumatic Connectors*

4. Ensure each pneumatic connection is fully seated by listening for an audible “click” as each connector engages its receptacle. Gently tug on each tube to ensure proper engagement with connector.
5. Insert the corresponding red and black colored connections into the thermocouple connectors, see Figure 15.

*Figure 14*

*Figure 15*

6. The cryoICE probe icon, seen above in Figure 14, will extinguish if the cryoICE probe is functioning properly and the approximate room temperature will be displayed on the temperature display (typically 10 to 25° C). An example of this is shown in Figure 16.


*Figure 16: Probe Temperature Display*

7. A test run is advised to ensure the cryoICE probe and system is working properly prior to the case.
8. Pneumatic connectors should only be unplugged when the cryoICE BOX is in the READY mode.

### Set Ablation Time

1. The time of ablation is displayed in the middle of the interface of the cryoICE BOX and is indicated by a clock underneath the display. The display shows the time of ablation in seconds, see Figure 17.

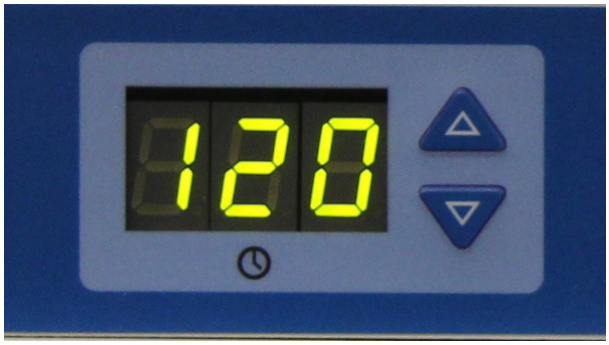



*Figure 17: Ablation Time Display*

2. To change the duration of the ablation, press either of the up or down arrows to the right of the time display. The display will change in increments of ten seconds. The timer will reset to the default setting after a single cycle has been run.

### Start Ablation

1. Ensure cryoICE BOX is powered on and the cryoICE probe and N2O is connected properly.
2. Check that desired ablation time is displayed, change if needed.
3. Press and release the Activation Button at the left of the device to begin the ablation.
4. The temperature display on the front panel displays the cryoICE probe temperature. A double-beep will indicate that the therapeutic temperature has been reached (typically -40°C), and the ablation timer will begin to count down. A short beep will sound every 30 seconds. A series of beeps will indicate the last 5-seconds of the Ablation cycle.
5. At the conclusion of the Ablation cycle, the cryoICE BOX will automatically transition into the DEFROST mode. The DEFROST indicator will illuminate indicating probe warming until it has reached the transition temperature which ends DEFROST, then the unit will automatically transition into READY and vent the probe. During the DEFROST cycle, a triple-beep will alert the user that the temperature of the probe has transitioned above 0°C degrees.

## 5. SPECIAL CASES

### Abort FREEZE

To stop ablation during a FREEZE cycle, press and release the Activation Button during the ablation. The system will then transition into DEFROST mode.

### Change Ablation Time during Ablation

To change the current ablation time, the up and down arrows can be used to add or decrease time in 10 second increments.

### Emergency Stop

To stop ablation and depressurize the cryoICE probe during a FREEZE or DEFROST push the Activation Button to vent cryoICE probe until the cryoICE BOX system has sequenced into READY mode.

The unit can also be stopped by turning off power in the back of the unit or unplugging it from the AC power outlet. The flow of N2O will stop, however gas will be trapped within the cryoICE probe and the cryoICE BOX. This gas will be vented the next time the cryoICE BOX is powered on.

### Set Default Ablation Time

1. Ensure *cryo*ICE BOX is powered on.
2. Press and hold both up and down arrows simultaneously for one second to initiate the mode that allows a change to the default ablation time.

3. The time display will flash and the default time can now be changed by using the up or down arrows. The time will change in increments of 10 seconds. The time cannot be set lower than 20 seconds, nor higher than 270 seconds.
4. To save the set default time, the display will stop flashing after 5 seconds and the new default will be set.

### Operate Without Temperature Reading

If the cryoICE BOX does not display a temperature and the cryoICE probe is properly plugged in (red and black connectors) the cryoICE probe should not be used. If the Activation Button is pressed with this condition, the cryoICE BOX will flash and beep for 5-seconds. If the Activation Button is pressed again within 5-seconds, the cryoICE BOX will sequence into FREEZE mode and the counter will start the countdown immediately. This should only be done at the discretion of a physician as there will not be temperature feedback.

## 6. SYSTEM DISASSEMBLY AFTER USE

Check to see that the service icon is not illuminated. If so, notify AtriCure service to correct the problem.

### Disconnecting the AtriCure *cryo*ICE Probe

1. The cryoICE probe can only be removed in the READY mode.
2. Remove the cryoICE probes pneumatic connections by pushing in the sliding ring on the receptacle while pulling out the cryoICE probe side of the connector.
3. Remove the black and red connections for the thermocouples.

### $N_2O$ Cylinder Removal

1. Turn-Off the N2O cylinder by turning the knob clockwise.
2. Purge the N2O from the system by pressing and holding the N2O Exhaust Switch in the back of the unit. Watch the pressure gauge on the cylinder to see that all the pressure has been released. If the cryoICE BOX is powered off, pull and hold the N2O Manual Exhaust Knob until the pressure is relieved.
3. Disconnect the gas cylinder inlet fitting on the back of the cryoICE BOX by sliding the collar back.
4. Disconnect the hose from the N2O cylinder by unscrewing the black knob.
5. Turn-Off power and unplug the cryoICE BOX.

## 7. PREVENTIVE MAINTENANCE AND CLEANING OF THE AtriCure *cryo*ICE BOX

### Cleaning and Disinfecting Instructions

**Note**: Do not spray or pour liquids directly on the unit.
**Note**: The unit and/or accessories cannot be sterilized.

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

⚠ **CAUTION**: Avoid caustic or abrasive cleaners to avoid damage to ACM chassis.

### Guidelines

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

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

## Preventive Maintenance

AtriCure service representatives or the hospital biomed personnel shall conduct annual preventative maintenance procedures to ensure all cryoICE BOX 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
- Any front panel display damage including switches, numeric displays and indicator lights.
- cryoICE probe electronic interface connector damage, cracking or inability to insert and latch cryoICE probe connector.
- cryoICE probe pneumatic interface connector damage or inability to insert and latch cryoICE probe pneumatic connector.
- Carrying handle damage or inability to fold.
- Rubber feet damage, cracking or inability for the cryoICE BOX to remain stable on a flat surface.
- Rubber alignment cup damage, cracking or inability for the ASB/ASU to remain stable atop cryoICE BOX and within the alignment cup.
- Listen for leaks when pressurized.
- Other medical equipment that may be used simultaneously with the cryoICE BOX should also be inspected for damage. Specifically, check for insulation damage of electrical cables and associated connectors.

The cryoICE BOX does not have any customer serviceable parts aside from mains fuses and gas line desiccant filter for cryoICE BOX units so equipped. For servicing issues, contact AtriCure, Inc. at:

### AtriCure Address / Toll Free Telephone Number

AtriCure, Inc.
7555 Innovation Way,
Mason, Ohio 45040 USA
1.866.349.2342

### Corporate Website

www.atricure.com

### Customer Service/ Product Inquiries

Telephone: 513-755-4100
866-349-2342 Toll Free
Fax: 513-755-4567

### Replacement of AC Line Fuses

Tools and Parts

• Needle Nose Pliers

***Fuses***

| AtriCure *cryo*ICE BOX Model | Fuse Type | Manufacturer | Part Number |
|---|---|---|---|
| ACM1 | T 4A L 250V | Schurter | 0034.5049 |
| ACM2 | T 2A L 250V | Schurter | 0034.5046 |

The cryoICE BOX unit has been pre-set at the factory to a nominal voltage of 115V (ACM1) or 230V (ACM2). The Rating Label below the Power Entry Module on the back panel of the cryoICE BOX indicates the selected Input Voltage for this unit. This setting should only be adjusted by the manufacturer or by an authorized AtriCure technical service representative.

**Note:** *cryo*ICE BOX unit should be powered off and unplugged before continuing with the fuse replacement procedure.

### Procedure to Replace AC Mains Fuses

1. Determine the fuse type by looking at the *cryo*ICE BOX Model Number or the *cryo*ICE BOX Rating Label.

2. Using the needle nose pliers, carefully extract the fuse box from the power entry module by squeezing down on the fuse box tabs in the slots as shown in Figure 18.

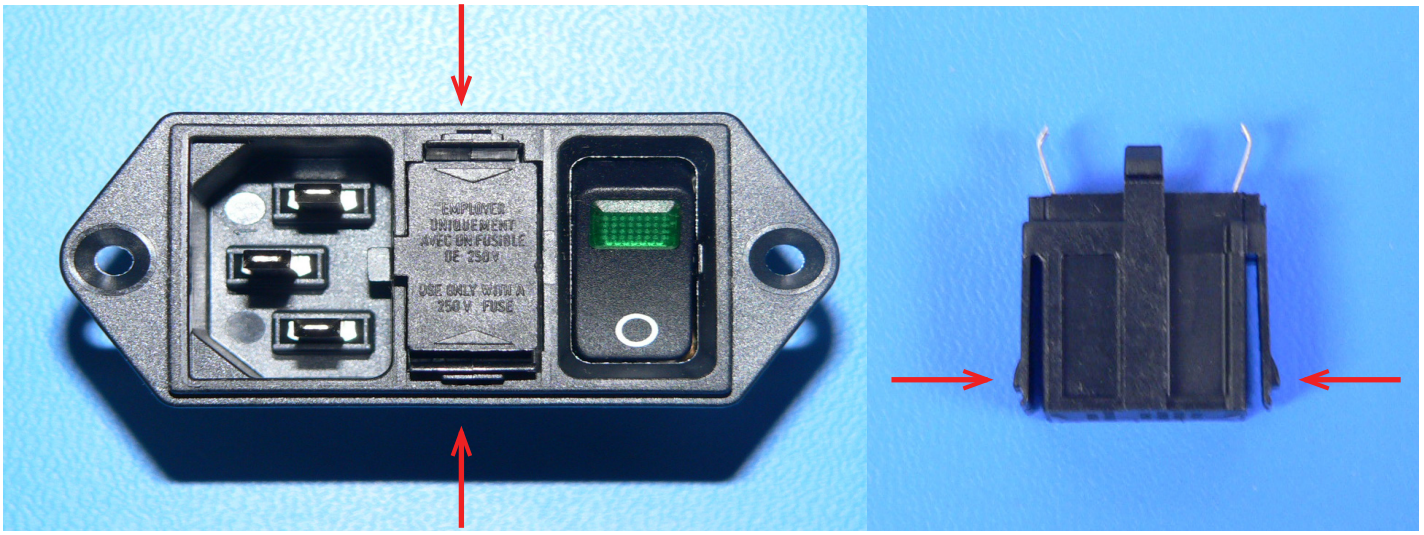


*Figure 18: Fuse Box Tabs*

3. Replace the (2) two fuses located in the fuse box. Make sure the fuses are aligned properly.

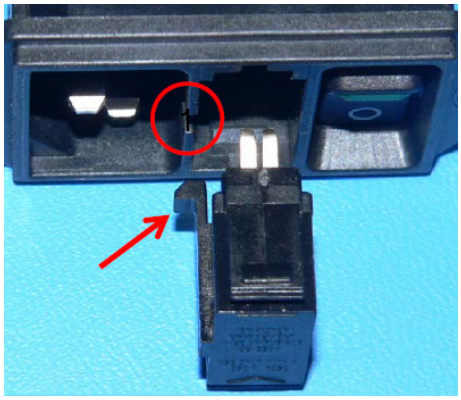


*Figure 19: Guide Tab Location*

4. Align the fuse cartridge so the guide tab is towards the power entry side.
5. Return the fuse box to the power entry module and push in firmly.
6. Confirm operational status by plugging in the *cryo*ICE BOX and turning power on. Ensure that the self-test is completed without errors.

## Tank Hose Assembly without canisters – Standard

### *New AtriCure cryoICE BOX Installation*

| | |
|---|---|
| A001053 | Packaged, ACM Accessories- Domestic |
| A001054 | Packaged, ACM Accessories- International |

### *Existing AtriCure cryoICE BOX Upgrade*

| | |
|---|---|
| A001056 | Packaged, Gas Line Hose Module Assembly- Domestic |
| A001055 | Packaged, Tank Hose Assembly- International |

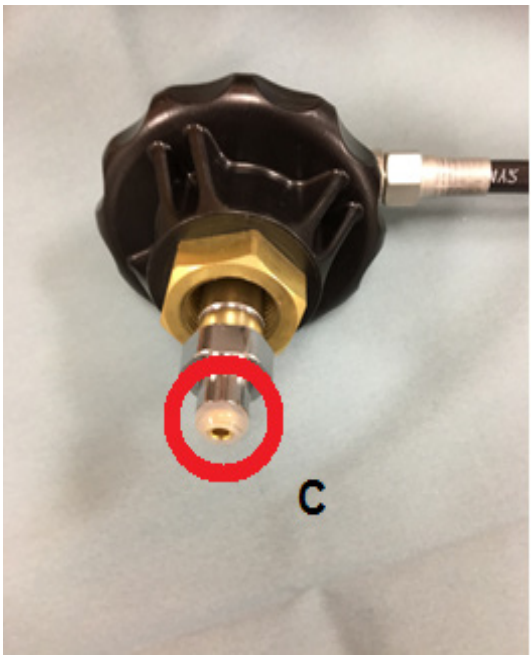



*Figure 20: $N_2O$ Cylinder Interface*

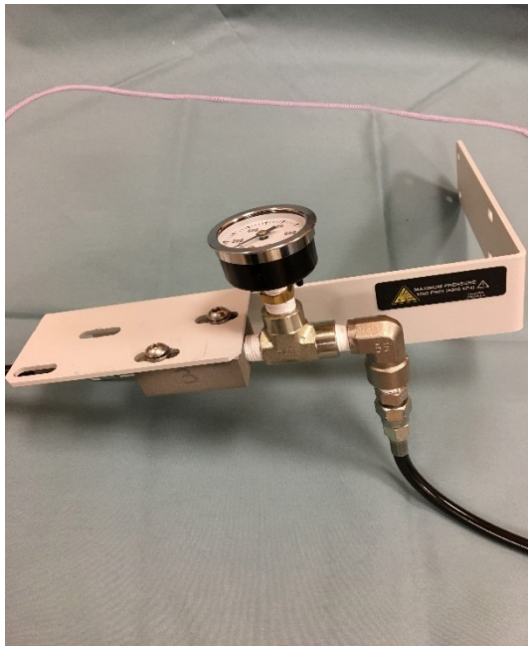


*Figure 21: AtriCure cryoICE BOX Tank Hose Assembly without canisters*

***Replacement Part***

| | | | |
|---|---|---|---|
| Component "C" | Tip Washer | AtriCure | F021837 |

## Tank Hose Assembly with canisters – Alternate (Replacement of Desiccant Filter)

This section only applies to *cryo*ICE Box Systems equipped with the Tank Hose Assembly which contains the canister set.

***Tank Hose Assembly with Canisters Replacement Parts***

| Item | Supplied By | Part Number |
|---|---|---|
| Filter Cartridge | AtriCure | F021720 |
| Filter O-ring | AtriCure | F010924 |
| Tip Washer | AtriCure | F021837 |
| O-Ring Lubricant | AtriCure | C002502 |

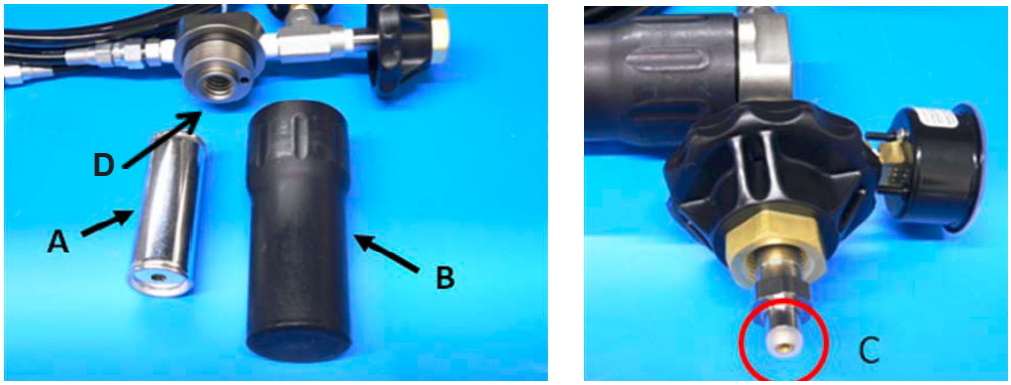



*Figure 22: Gas Line Components*

- Desiccant Filter Cartridge **(A)**

**Note:** Replace desiccant filter cartridge every time the $N_2O$ tank is replaced.

- Filter Housing **(B)**
- Tip Washer **(C)**
- Filter O-Ring **(D)**

**Note:** Replace filter O-Ring with replacement of the desiccant filter cartridge.

## Procedure

1. Prior to changing the Desiccant Filter Cartridge, assure that the *cryo*ICE probe is disconnected from the patient and the *cryo*ICE Box is turned off.
2. Unscrew the filter cartridge housing by rotating it counter-clockwise. Refer to Figure 23 below.

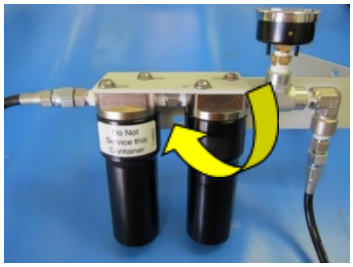


*Figure 23: Filter Housing Removal*

3. Remove the desiccant filter cartridge by rotating it counter-clockwise using hand force only. Refer to Figure 24 below.

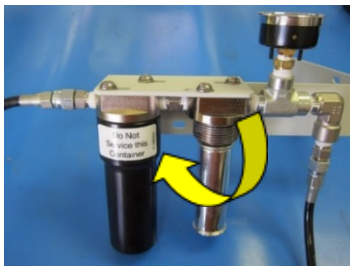


*Figure 24: Desiccant Filter Cartridge Removal*

4. Remove the old black O-ring from the top of the filter housing fixture.
5. Slide the new O-ring onto the filter housing fixture, making sure that it is fully seated in the groove at the top.
6. Apply a thin film of O-Ring Lubricant around the new O-Ring.
7. Replace the desiccant filter cartridge with the new cartridge.
8. Replace the filter housing by screwing on clockwise using hand force only.
9. Remove the old Tip Washer and replace it with the new washer.

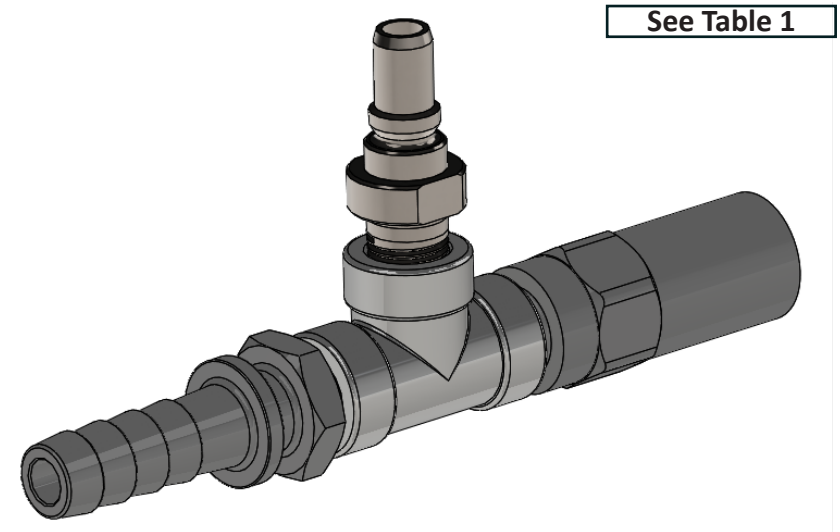



*Figure 25: Exhaust Hose Connector Assembly – A001150*

## Table 1 – Region Specific Vacuum/WAGD Connectors

| Connector | Part Description | Region |
|---|---|---|
| A001150-1 | Medical Vacuum Connector DISS by 1/4” MNPT | ***US*** |
| A001150-2 | Medical Vacuum Connector Chemetron by 1/4” MNPT | ***US*** |
| A001150-3 | Medical Vacuum Connector PB by 1/4” MNPT | ***US*** |
| A001150-4 | Medical Vacuum Connector Ohmeda by 1/4” MNPT | ***US*** |
| A001150-5 | WAGD Connector DISS by 1/4” MNPT | ***US*** |
| A001150-6 | WAGD Connector Chemetron by 1/4” MNPT | ***US*** |
| A001150-7 | WAGD Connector PB by 1/4” MNPT | ***US*** |
| A001150-8 | WAGD Connector Ohmeda by 1/4” MNPT | ***US*** |
| A001150-9 | Japanese Type K Coupler to .250-18 NPT | ***JPN*** |
| A001150-10 | Japanese Type C Coupler to .250-18 NPT | ***JPN*** |
| A001150-13 | AGSS Type 1L Coupler to .250-18 NPT | ***EU*** |
| A001150-14 | AGSS Alternate Coupler Assembly | ***EU*** |

## Other Detachable and Accessory Devices

| Item | Supplied By | USA Part Number | International Part Number |
|---|---|---|---|
| ACM Footswitch | AtriCure | A000708 | A000708 |
| Tank Hose Assembly with canisters | AtriCure | A000837 | A000838 |
| Tank Hose Assembly without canisters | AtriCure | A001056 | A001055 |
| Heater Band Extension Springs (Qty. 6) | AtriCure | A000836 | A000836 |
| $N_2O$ Exhaust Hose (50ft./15.2m.) | AtriCure | C002051 | C002051 |
| Cylinder Heater Band (CMH15) | AtriCure | A000728 | A000728 |
| **International** | Watlow | 120150509 or SK025877-DWG7 | 120150509 or SK025877-DWG7 |
| Cylinder Heater Band (CMH22) | AtriCure | A000727 | A000727 |
| **Domestic** | Watlow | 120220507 or SK025877-DWG10 | 120220507 or SK025877-DWG10 |
| AC Power Cord | AtriCure | C000262<br>125 VAC, 10A. (10ft./3.3m.) | C002090<br>250 VAC, 10A. (11.5ft./3.5m.) |

## Disposal

The *cryo*ICE BOX does not contain hazardous substances. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. The used *cryo*ICE probe is considered bio-hazardous. Follow facility procedures for disposal.

# 8. TROUBLESHOOTING

| Problem | Possible Cause | Action |
|---|---|---|
| Front displays not lit. | • No power.<br><br><br><br>• *cryo*ICE BOX electrical failure. | • Check power switch on back of *cryo*ICE BOX.<br>• Check plug connection on back of *cryo*ICE BOX.<br>• Check AC plug in wall socket.<br>• Ensure power is available at wall socket.<br>• Call AtriCure Service. |
| Cylinder Heater Band Icon Illuminated.<br>  | • Heater not plugged in.<br>• $N_2O$ cylinder valve closed.<br>• Empty $N_2O$ cylinder.<br>• Extremely cold $N_2O$ cylinder.<br>• Heater not attached to $N_2O$ cylinder.<br>• Heater malfunctioning. | • Check connection on back of unit.<br>• Ensure $N_2O$ valve is open.<br>• Replace $N_2O$ cylinder.<br>• Allow 15 minutes to warm up.<br>• Attach Heater Band to cylinder.<br>• Call AtriCure Service. |
| Temperature Not Displayed.<br>  | • *cryo*ICE probe not plugged in.<br><br>• Malfunctioning *cryo*ICE probe.<br>• *cryo*ICE BOX malfunctioning. | • Ensure *cryo*ICE probe thermocouple leads are firmly seated within their receptacles.<br>• Replace *cryo*ICE probe.<br>• Call AtriCure Service. |
| *cryo*ICE BOX has power but will not go into FREEZE mode. | • *cryo*ICE probe not plugged in.<br>• $N_2O$ cylinder empty.<br>• $N_2O$ cylinder valve closed.<br>• Inlet Gas Connection not secure. | • Plug in *cryo*ICE probe.<br>• Replace $N_2O$ Cylinder.<br>• Open cylinder valve.<br>• Ensure Inlet Gas Connection is completely seated. |

| Problem | Possible Cause | Action |
|---|---|---|
| *cryo*ICE probe not getting cold enough. | • Heater Band not properly installed.<br>• $N_2O$ cylinder low or out of gas.<br>• Exhaust filter is clogged. | • Check heater installation and heater icon.<br>• Replace $N_2O$ cylinder.<br>• Exhaust connector (orange) is frosting/ freezing ice (liquid condensate is not uncommon) call AtriCure Service. |
| Temperature Display indicates incorrect values. | • *cryo*ICE probe plugged in incorrectly.<br>• Malfunctioning *cryo*ICE probe.<br>• Electromagnetic interference<br>• *cryo*ICE BOX malfunctioning. | • Ensure *cryo*ICE probe black and red plugs are in correct receptacles.<br>• Replace *cryo*ICE probe.<br>• Relocate or Reorient cryoICE BOX<br>• Call AtriCure Service. |
| Bottom segment on $N_2O$ icon flashing.  | • $N_2O$ cylinder empty.<br>• $N_2O$ cylinder cold.<br>• Indicator not reset when cylinder was replaced. | • Replace with full cylinder.<br>• Make sure heater blanket is installed and working. Allow time for the cylinder to warm up if it is cold.<br>• Press Reset when cylinder is replaced. |
| $N_2O$ Gas Gauge flashing.  | • $N_2O$ cylinder pressure is below 650psi.<br>• $N_2O$ cylinder empty. | • Make sure heater blanket is installed and working. Allow time for the cylinder to warm up if it is cold.<br>• Replace with full cylinder. |
| Amber Low Pressure Indicator on $N_2O$ icon flashing.  | • $N_2O$ cylinder not turned on. | • Ensure the $N_2O$ cylinder is fully turned on. |
| Difficulty connecting a *cryo*ICE probe to the *cryo*ICE BOX.  | • Trapped $N_2O$ within the system.<br>• Quick connector out of sequence, sleeve on blue connector is forward.<br>• Quick connector O-ring dried out and/or swelling. | • Power-On the *cryo*ICE BOX which clears trapped gas exerting pressure on the connector.<br>• Push the sleeve toward the *cryo*ICE BOX until it locks back. (usually clicks)<br>• Lubricate the connector inside with silicon-based O-ring. lubrication such as AtriCure Part No. C002502. |

| Problem | Possible Cause | Action |
|---|---|---|
| Wrench Icon flashing and clicking heard inside *cryo*ICE BOX, may also include display flashing.  | • Heater band over temperature due to empty $N_2O$ Cylinder.<br>• Heater band over temperature due to loose fit on $N_2O$ cylinder. | • Unplug heater band if clicking stops and/ or display flashing stops, check if tank is warm to the touch – If so, tank is likely empty, replace tank with full tank. Power-off, then Power-on *cryo*ICE BOX to reset wrench Icon.<br>• Heater band is to be tight and positioned at bottom of tank, cord at top edge. If problem is not corrected by above two actions, return *cryo*ICE BOX and heater band to AtriCure. |
| *cryo*ICE probe getting colder than -75°C and not defrosting. | • The *cryo*ICE BOX and probe system are flooded with liquid $N_2O$. | • If probe does not reach desired defrost temperature, apply warm sterile saline to the tissue and probe area as necessary.<br>• Replace the Tank Hose Assembly which has canister set with Tank Hose Assembly without canister set.<br>A001056 – Domestic Tank Hose Assembly without canisters<br>A001055 – International Tank Hose Assembly without canisters<br>• Power-On *cryo*ICE BOX within a few minutes of *cryo*ICE probe use to minimize $N_2O$ condensing in system. |
| | • The $N_2O$ quality is not adequate to be used as a refrigerant. | • Medical grade nitrous oxide, 3ppm water maximum, is preferred for use with AtriCure cryogenic Devices. |
| | • $N_2O$ cylinder contains a siphon tube or a dip tube. | • Verify the $N_2O$ cylinder does not contain a siphon tube or dip tube. Cylinder valve body should be blank (no mark of: S, DT, or D.) |

## AtriCure *cryo*ICE BOX Error Codes

If an error condition should occur, the Maintenance Needed Indicator or the System Fault Indicator will illuminate. The probe Temperature display on the front panel will temporarily display one of the following error codes during the power-up sequence. Contact AtriCure Service if one of these conditions occurs.

| Error ID | Error | Likely Cause |
|---|---|---|
| **001** | No 24 VDC | Fuse (F2) |
| **002** | Cylinder Over Temperature | Heater blanket |
| **003** | probe Overpressure | Pressure regulator |
| **004** | Unwanted probe Pressure | Leaky inlet valve |
| **005** | No 230 VAC | Fuse (F1) |
| **008** | Cylinder Over Pressure/Temperature | Overheated Cylinder |
| **PPP** | Power On Self-Test Error | Activation Button/Footswitch Pressed during power up |

# 9. ELECTROMAGNETIC COMPATABILITY TABLES

### Electromagnetic Emissions

| **Guidance and manufacturer's declaration – Electromagnetic Emissions** | |
|---|---|
| The **AtriCure *cryo*ICE BOX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AtriCure *cryo*ICE BOX** unit should assure that it is used in such an environment. | |
| **Phenomenon** | **Professional healthcare facility environment [a)]** |
| Conducted and radiated RF EMISSIONS | CISPR 11 (Group 1, Class A) |
| Harmonic distortion | See IEC 61000-3-2 [b)] (Class A) |
| Voltage fluctuations and flicker | IEC 61000-3-3 [b)] |
| a) Professional healthcare facility environment.<br>b) This test is not applicable in this environment unless the AtriCure *cryo*ICE BOX used there will be connected to the PUBLIC MAINS NETWORK and the power input Is otherwise within the scope of the Basic EMC standard. | |

### Electromagnetic Immunity – Enclosure Port

| **Guidance and manufacturer's declaration – Enclosure Port Immunity** | | |
|---|---|---|
| The **AtriCure *cryo*ICE BOX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AtriCure *cryo*ICE BOX** unit should assure that it is used in such an environment. | | |
| **Phenomenon** | **Basic EMC standard or test method** | **Immunity Test Levels**<br>**Professional healthcare facility environment** |
| ELECTROSTATIC DISCHARGE | IEC 61000-4-2 | ± 8 kV contact<br>± 2kV, ± 4kV, ± 8kV, ± 15 kV air |
| Radiated RF EM fields [a)] | IEC 61000-4-3 | 3 V/m [f)]<br>80 MHz – 2.7 GHz [b)]<br>80% AM at 1kHz [c)] |
| Proximity fields from RF wireless communications equipment | IEC 61000-4-3 | Refer to Table 9 in IEC 60601-1-2:2014 – Test specification for Enclosure Port Immunity to RF wireless communication equipment |
| Rated power frequency magnetic fields [d) e)] | IEC 61000-4-8 | 30 A/m [g)]<br>50 Hz or 60 Hz |
| a) The interface between the PATIENT physiological signal simulation, if used, and the AtriCure *cryo*ICE BOX shall be located within 0.1 m of the vertical plane or the uniform field area in one orientation of the AtriCure *cryo*ICE BOX.<br>b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for its operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.<br>c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.<br>d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.<br>e) During the test, the AtriCure *cryo*ICE BOX may be powered at any NOMINAL input voltage, but with the same frequency as the test signal.<br>f) Before modulation is applied.<br>g) This test level assumes a minimum distance between the AtriCure *cryo*ICE BOX and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the AtriCure *cryo*ICE BOX will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance. | | |

## Electromagnetic Immunity – Input A.C. Power Port

| **Guidance and manufacturer's declaration – Input A.C Power Port Immunity** | | |
|---|---|---|
| The **AtriCure *cryo*ICE BOX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AtriCure *cryo*ICE BOX** unit should assure that it is used in such an environment. | | |
| **Phenomenon** | **Basic EMC standard or test method** | **Immunity Test Levels** |
| | | **Professional healthcare facility environment** |
| Electrical fast transients / bursts [a) l) o)] | IEC 61000-4-4 | ± 2 kV<br>100 kHz repetition frequency |
| Surges [a) b) j) o)]<br>Line-to-line | IEC 61000-4-5 | ± 0.5 kV,-± 1 kV |
| Surges [a) b) j) k) o)]<br>Line-to-ground | IEC 61000-4-5 | ± 0.5 kV, ± 1 kV, ± 2 kV |
| Conducted disturbances Induced by RF fields [c) d) o)] | IEC 61000-4-6 | 3 V/m [m)]<br>0.15 MHz - 80 MHz<br>6 V/m [m)] in ISM bands between 0.15 MHz and 80 MHz [n)]<br>80% AM at 1kHz [e)] |
| Voltage dips [f) p) r)] | IEC 61000-4-11 | 0% $U_T$; 0.5 cycle [g)]<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)] |
| | | 0% $U_T$: 1 cycle<br>And<br>70% $U_T$: 25/30 cycles [h)]<br>Single phase: at 0° |
| Voltage interruptions [f) i) o) r)] | IEC 61000-4-11 | 0% $U_T$: 250/300 cycle [h)] |

a) The test may be performed at any one power input voltage within the AtriCure *cryo*ICE BOX's RATED voltage range. If the AtriCure *cryo*ICE BOX is tested at one power input voltage, It Is not necessary to re-test al additional voltages.

b) All AtriCure *cryo*ICE BOX cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used In the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a D.C. power input intended for use with A.C.-to-D.C. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the A.C. power input of the converter.

g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase A.C. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED Input current greater than 16 A/phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line{s) to earth and ± 1 kV line(s) to line(s).

k) Not applicable to CLASS 11 ME EQUIPMENT and ME SYSTEMS.

l) Direct coupling shall be used.

m) R.M.S., before modulation Is applied.

n) The ISM (Industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz lo 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A/phase and ME EQUIPMENT and ME SYSTEMS with RATED Input current greater than 16 A/phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED Input current less than or equal to 16 A/ phase.

q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power Input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the AtriCure *cryo*ICE BOX shall provide BASIC SAFETY during and after the test.

r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shell be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range.

## Electromagnetic Immunity – Input D.C. Power Port – Not Applicable

## Electromagnetic Immunity – Patient Coupling Port

| **Guidance and manufacturer's declaration – Patient Coupling Port Immunity** | | |
|---|---|---|
| The **AtriCure *cryo*ICE BOX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AtriCure *cryo*ICE BOX** unit should assure that it is used in such an environment. | | |
| **Phenomenon** | **Basic EMC standard or test method** | **Immunity Test Levels** |
| | | **Professional healthcare facility environment** |
| ELECTROSTATIC DISCHARGE [c)] | IEC 61000-4-2 | ± 8 kV contact<br><br>± 2kV, ± 4kV, ± 8kV, ± 15 kV air |
| Conducted disturbances induced by RF fields [a)] | IEC 61000-4-6 | 3 V [b)]<br>0.15 MHz - 80 MHz<br>6V [b)] in ISM bands between<br>0.15 MHz and 80 MHz<br>80% AM at 1 kHz |

a) The following apply:
- All PATIENT-COUPLED cables shalt be tested, either Individually or bundled
- PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shalt be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids end intended to be connected to a PATIENT shalt be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used In the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (Industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz: 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz lo 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b) R.M.S., before modulation Is applied

c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

# 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 *cryo*ICE BOX Unit ..... One (1) Year

AtriCure Cylinder Heater Band ..... One (1) Year

AtriCure Gas Line Hose Assembly..... ..... One (1) Year

Grounded Electrical Cord ..... One (1) Year

AtriCure Cryo Footswitch ..... One (1) Year

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ATRICURE, INC. AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ATRICURE, INC. BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL.

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# Disclaimer

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

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