AtriCure®

cryoICE® BOX

Instructions for Use

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

 # ACM1

MD

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

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FOREWORD

This Instructions for Use and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. This IFU applies to the AtriCure cryoICE BOX also referred to as the AtriCure cryoICE BOX (ACM). Additionally, cryoICE system probe, cryoICE cryoFORM® probe & cryoSPHERE® probe also referred as the AtriCure PROBE.

⚠ WARNING ⚠

Please read all information carefully. Failure to properly follow the Instructions for Use may lead to serious surgical consequences including patient and caregiver harm.

IMPORTANT

This Instructions for Use is designed to provide instructional guidance for the AtriCure cryoICE BOX (A000896-5 assembly/A000898-5 packaged assembly) with the AtriCure PROBES and AtriCure's Components and Accessories (See Sections 1 and 3 for more information.) This user manual is not a reference to surgical technique.

INDICATIONS FOR USE / INTENDED PURPOSE

The AtriCure cryoICE BOX is a non-sterile, reusable medical 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 an optional accessory used to activate the AtriCure cryoICE BOX as an alternative to using the Activation Button on the front panel of the cryoICE BOX.

PATENT INFORMATION

May be covered by one or more patents.

WARNINGS AND CAUTIONS

The safe and effective use of the ACM, Components and Accessories are 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 Instructions for Use supplied with the AtriCure cryoICE BOX unit be read, understood, and followed before use.

⚠WARNINGS⚠

Do not operate the cryoICE BOX unit before thoroughly reading this manual, as it may result in serious injury to patient or user.

Do not use cryo surgical equipment unless properly trained in the specific procedure being undertaken to prevent risk of serious injury to patient or user. 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.

Care should be exercised in users with suspected or known allergies or hypersensitivity to stainless steel or nickel as they may suffer an allergic reaction as a result of using the cryoICE BOX, and Accessories.

Fire Hazard: The Power Cord of the cryoICE BOX must be connected to a properly grounded receptacle. Extension cords and/or adaptor plugs must not be used to prevent risk of serious injury to patient or user.

No modification of this equipment is allowed to prevent risk of serious injury to patient or user. Equipment malfunction may occur.

Electric Shock Hazard: Connect the cryoICE BOX power cord to a properly grounded receptacle. Do not use power plug adapters to prevent risk of serious injury to patient or user.

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

Electric Shock Hazard: Ensure that the PROBE is correctly connected to the cryoICE BOX and that no thermocouple wires are exposed from the cable, connector, or the cryoICE 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 cryoICE BOX and result in improper operation.

Use of the cryoICE 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 cryoICE BOX, including cables specified by the AtriCure. Otherwise, degradation of the performance of this equipment could result.

The ACM Exhaust Hose connector requires a dedicated Vacuum or WAGD port. Connecting multiple lines to a single WAGD port may result in serious injury to patient.

Do not transition into FREEZE Mode until the cryoICE PROBE is properly positioned at the ablation site to prevent cryoablation of unintended tissue or structures.

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

⚠CAUTIONS

- Do not use the cryoICE BOX and Accessories if visible damage is observed.
- Use only with the cryoICE PROBES intended for use with the cryoICE BOX. Use of other PROBES may result in improper device performance.
- The system status indicators and displays are important safety features. Do not obstruct either the ablation or the system status indicators.
- Do not contact cryoICE PROBES with a RF device to prevent risk of electrical noise/interference with OR equipment.
- Compressed Air Hazard: Do not operate N_2O cylinders with a pressure greater than 1000 PSIG (6900 kPa) to prevent overpressure condition.

- Nitrous Oxide connections should only be unplugged when the cryoICE BOX is in the READY mode and properly vented to prevent gas from being trapped in inlet line and prohibiting handpiece connection.
- Trip Hazard: Standard care should be used to reduce the risk of tripping on the Footswitch cable, Power Cord, as well as the N_2O exhaust hose.
- 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 cryoICE BOX malfunction and potential instrument damage.
- 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.

Meanings of Symbols on AtriCure cryoICE BOX

	Alternating Current		Manufacturer		Caution	NON STERILE	Non-Sterile
	Consult Instructions for Use		Separate collection for Electrical Equipment per WEEE directive		Importer	#	Model Number
US	Country and Date of Manufacture	UDI	Unique Device Identifier	SN	Serial Number	MD	Medical Device
REF	Catalog Number	PHT	Does not contain phthalates	LATEX	Not made with natural latex		Power OFF
10101	Data Port		Footswitch		Equipotential Terminal		Cylinder Heater Band
	Type CF Applied Part (PROBE)		N_2O Gas Gauge		Cylinder Valve ON/OFF	°C	PROBE Temperature
	READY		Timer	RESET	N_2O Gas Gauge Reset		Thermocouple/Probe
	FREEZE		Timer Increase Button		Maintenance Needed	N_2O	Gas Exhaust
	DEFROST		Timer Decrease Button		Contains hazardous substances	N_2O	Gas Inlet
90% 15%	Humidity Limit (Operational and Storage)	85% 30%	Humidity Limit (Transit)	100°F 37°C -20°F -29°C	Temperature Limit (Storage and Transit)	N_2O	Gas Outlet
Rx ONLY	For Prescription Use Only	MAXIMUM PRESSURE 1000 PSIG (6900 kPa) C002423.C	Maximum Pressure	105 kPa 15.2 psi 98 kPa 14.2 psi	Pressure Limit (Operational and Storage)	104°F 40°C 50°F 10°C	Temperature Limit (Operational)
TÜV SÜD C US	TÜV SÜD Mark						

⚠WARNING⚠

This product can expose you to Lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov

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

SAFETY INFORMATION

C US

MEDICAL — GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005/®2012 & A1:2012 & A2:2021

CAN/CSA C22.2 NO. 60601-1:14 + A2:22

Cryogenic Ablation Device, Model AtriCure cryoICE BOX, ACM1, cord connected/ appliance coupler / transportable, rated: 115 VAC, 4A, 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, 98 to 105kPa (14.2 to 15.2 psi)

1. SYSTEM OVERVIEW

System Description

The ACM is designed to operate only with AtriCure designed and developed AtriCure cryoICE system PROBES.

The cryoICE system probe, cryoICE cryoFORM® probe & cryoSPHERE® probe shall be referred as the AtriCure PROBE in this Instruction for Use.

This Instruction for Use provides a description of the ACM, its controls, displays, indicators, and a sequence for its operation with the AtriCure's PROBES. This Instruction for Use also supplies other information of importance to the user. For information about the AtriCure PROBES, please refer to the associated ACM, cryoICE cryoFORM and cryoSPHERE PROBES.

The AtriCure cryoICE BOX (A000898-5) Components include:

- ACM - A000896-5 (See Figure 4)
- ACM Components

Item	Supplied by	Part Number
Power Cord	AtriCure	C000262 (125VAC, 10A)
Tank Hose Assembly with Canisters (see E in Figure 1)	AtriCure	A000837
Tank Hose Assembly without Canisters (see B in Figure 1)	AtriCure	A001056
Heater Band Extension Springs (Qty. 6)	AtriCure	A000836
N_2O Exhaust Hose (50ft/15.2m) (see C in Figure 1)	AtriCure	C002051
Cylinder Heater Band (CMH22) - Domestic (see A in Figure 1)	AtriCure	A000727
Cylinder Heater Band (CMH15) - International (see A in Figure 1)	AtriCure	A000728

The AtriCure cryoICE BOX Accessories include:

- Footswitch: A000708/A001361 (not shown)
- Exhaust Hose Connectors (see D in Figure 1 and refer to Table 1)

The AtriCure cryoICE BOX

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

- The ACM is an electro-mechanical cryogenic surgical system that delivers a Nitrous Oxide (N_2O) cryo-genic energy source to a PROBE to create lines of ablation through tissue. The ACM includes single use PROBES, Component and Accessories. The ACM provides controlled lesion forming temperature that is below -40°C (-40°F).
- In addition of the Activation Button on the front panel of the ACM, an accessory Footswitch can also be used to activate and terminate the cryo ablation cycle.
- The ACM is designed to operate only with AtriCure's PROBES. Refer to the AtriCure's PROBE Instruction for Use for detailed use and description.

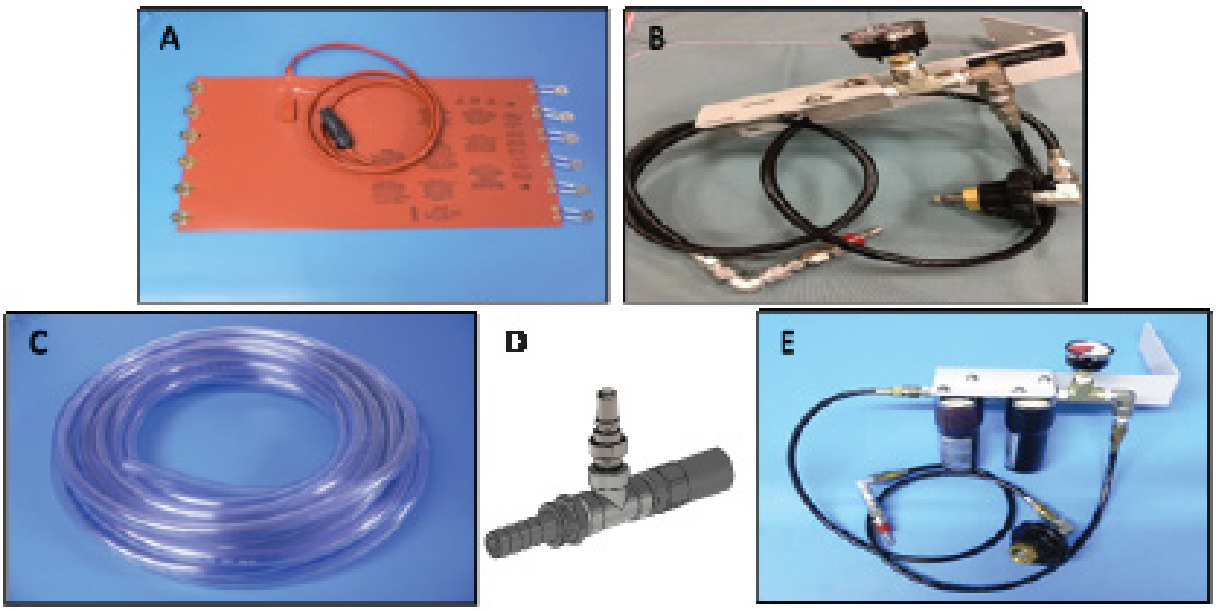

FIGURE 1: ATRICURE CRYOICE BOX, DETACHABLES, AND ACCESSORIES

AtriCure cryoICE BOX Front and Rear Panels – Illustrations and Nomenclature

Illustrations of the cryoICE BOX front panel (Figure 2) and rear panel (Figure 3) are shown below.

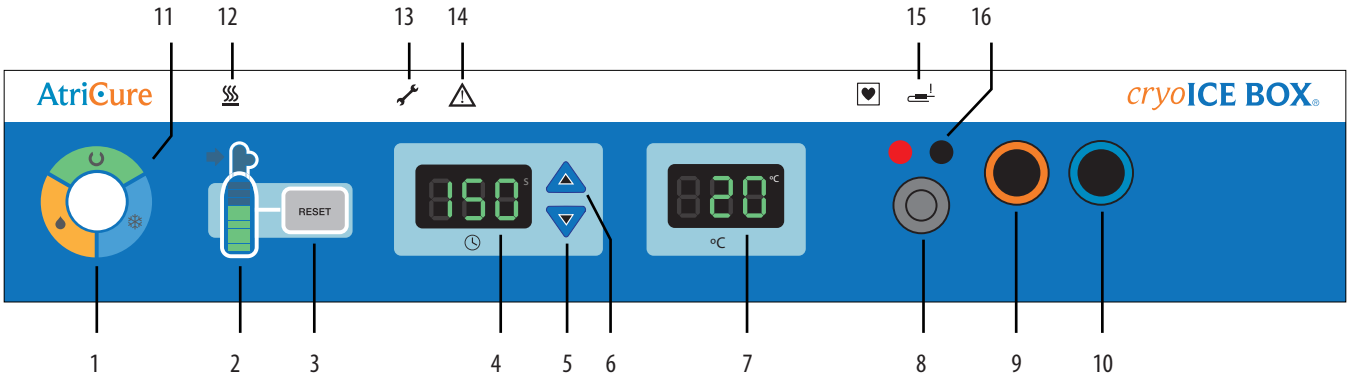

FIGURE 2: ATRICURE cryoICE BOX FRONT PANEL

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. PROBE Temperature Display
8. Future PROBE Connection
9. PROBE Gas Outlet Port
10. PROBE Gas Inlet Port
11. Ablation Status Indicator
12. Cylinder Heater Band Indicator
13. Maintenance Needed Indicator
14. System Fault Indicator
15. Thermocouple Open Indicator
16. PROBE Thermocouple Ports

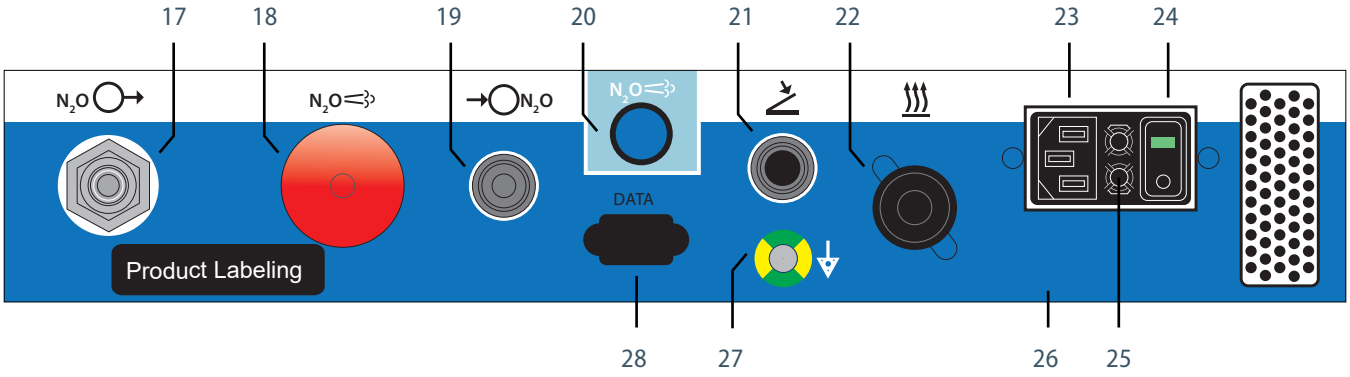

FIGURE 3: ATRICURE cryoICE BOX REAR PANEL

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 (To be used by service representatives only. Do not remove the cover)

Operating Modes

The cryoICE BOX operates in one of three modes: READY, FREEZE, and DEFROST. These modes are identified by the ACM status indicator LEDs and the ablation status indicator LEDs located on the front of the ACM display.

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 PROBE reaching approximately 10°C (50°F) and automatically venting. This indicates that the ACM 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 AtriCure's PROBE causing a temperature drop.

DEFROST Mode

This mode is entered automatically from FREEZE Mode upon expiration of the ablation timer, or manually by actuating the Activation Switch or the Footswitch while in the FREEZE Mode. In this mode, AtriCure's PROBE temperature is actively forced towards the ambient temperature.

Once AtriCure's PROBE temperature is above approximately 10°C (50°F), the cryoICE BOX unit will transition back to the READY Mode.

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

Note: AtriCure's PROBE temperature may drop temporarily upon transition from DEFROST to READY state.

FAULT Condition

This fault condition is entered upon detection of any unrecoverable error during any mode. The ACM is inoperable in this mode until the ACM 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	+10°C to +40°C +50°F to +104°F	15% to 90% relative humidity	98 to 105kPa (14.2 to 15.2 psi)
Storage	-29°C to +37°C -20°F to +100°F	15% to 90% relative humidity	98 to 105kPa (14.2 to 15.2 psi)
Transit	-29°C to +37°C -20°F to +100°F	30% to 85% relative humidity	

Electrical Specifications

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

Software Specification

Software version: 6

Mains Fuses

AtriCure cryoICE 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 cryoICE System Probe Temperature Display Accuracy (see Figure 2 item 7)

Resolution: 1°C (increments)

Temperature > or = -40°C Accuracy of +3°C/-6°C (-40°F Accuracy of +2.4°F/-4.8°F)

Temperatures<-40°C Accuracy of +5°C/-8°C (-40°F Accuracy of +4°F/-6.8°F)

Performance Characteristics

The ACM provides controlled lesion forming temperature that is below -40°C (-40°F).

The ACM defrosts to 0°C (32°F) in under 30 seconds.

Footswitch Specifications

Moisture protection rating: IPX8

Equipment Type / Classification

Class 1 Equipment

FIGURE 4: ATRICURE cryoICE BOX

⚠WARNING⚠

Use gloves when setting up and operating the ACM and associated components.

This section will outline the preliminary set-up for the cryoICE BOX, including N_2O cylinder installation, heater band installation, turning on the cryoICE BOX, and resetting the cylinder gauge on the cryoICE BOX user interface.

Note: The cryoICE BOX should be set up at least 15-minutes prior to the procedure to allow time for the heater band to warm the N_2O cylinder to operating temperature.

N_2O Gas Coupling Installation

- Use Teflon tape (not provided) to wrap around the ¼" (0.635 cm) -18 NPT connector of the N_2O gas coupling.
- Connect the N_2O gas coupling to the Tank Hose Assembly angled connector.
- Secure this connection by hand-tightening as much as possible.

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 cryoICE 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 the tank hose adapter end shown in Figure 5 below into the corresponding end of the N_2O gas line on the ACM. Insert and push in the connector until you hear an audible "click", indicating that the connection is fully seated and secured.

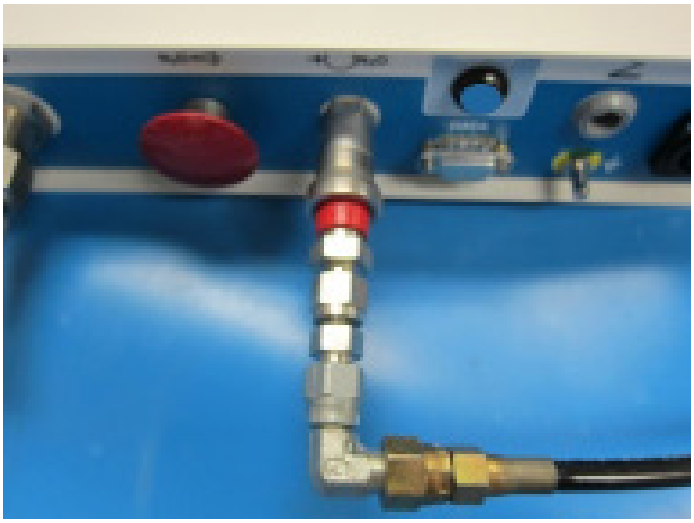

FIGURE 5: N_2O INLET CONNECTION

- Next, match the opposite tank hose connection end of the N_2O gas line with the threaded connection port of a new N_2O gas cylinder.
- Screw the cryoICE BOX gas line into place by hand tightening the knob as shown in Figure 6.
  Over tightening this fitting with a wrench may cause damage, allowing N_2O gas to leak.
- To open gas cylinder valve, slowly turn the knob on the top of the cylinder counter-clockwise as seen in Figure 7.

FIGURE 6: ATTACH BLACK KNOB TO THREADED CONNECTION

FIGURE 7: TURN VALVE COUNTER-CLOCKWISE TO OPEN

- Listen for leaks. If a leak is detected, tighten the N_2O gas coupling with a wrench if needed.
- If Low-Pressure indicator is detected, as seen in Figure 8, the top portion of the indicator will illuminate amber, indicating that the ACM is not detecting proper cylinder pressure. Check to ensure that the gas cylinder valve is open fully and that the connected cylinder is not empty.

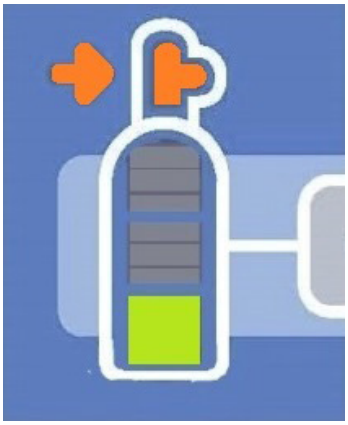

FIGURE 8: LOW PRESSURE INDICATOR

Exhaust Tubing

- Note: Ensure the Exhaust tubing (hose) is firmly attached to the cryoICE BOX N_2O exhaust port, see Figure 3 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 60LPM (16 GPM).

Heater Band Installation

- Ensure the cryoICE BOX is properly connected to an N_2O 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 9.
- The Heater band must be positioned less than 2-inches (5-cm) from bottom of the cylinder to ensure that the N_2O 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 10.
- Verify that the Cylinder Heater Band Icon on the front of the ACM is not illuminated.

FIGURE 9: SECURE ALL TENSIONING SPRING RETAINERS

FIGURE 10: PLUG HEATER BAND CORD INTO RECEPTACLE

Turning On the AtriCure cryoICE 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 11. The power switch is used to connect mains power (Turn-ON) or disconnect mains power (Turn-OFF) to the cryoICE BOX unit.
- After powering ON, the Activation Button on the front of the cryoICE BOX interface will illuminate. If the button does not illuminate, check for proper power cord connection and switch position.

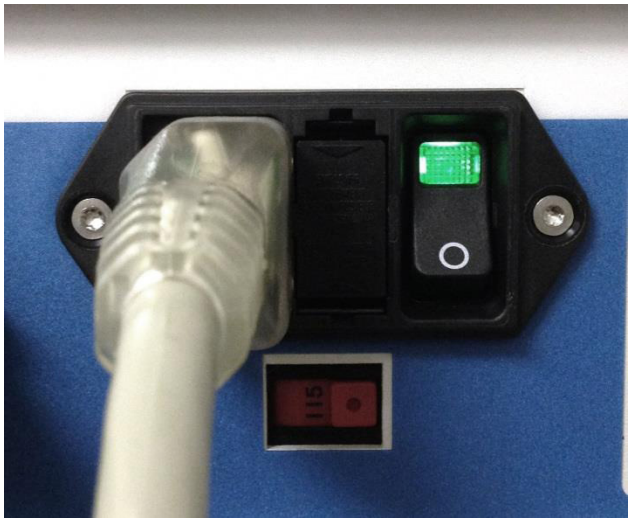

FIGURE 11: TURN-ON ATRICURE cryoICE BOX WITH SWITCH

Resetting the N_2O Gas Gauge

- Only reset the gauge when a new full cylinder has been installed.
- Ensure cryoICE BOX is powered ON.
- Ensure the ACM is in READY mode.
- Find the gas cylinder display on the front of the cryoICE BOX and note the RESET button to the right of this display, see Figure 12.
- 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 update 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 the RESET button is pressed following usage the gauge will reset to the reflect the estimated cylinder volume.

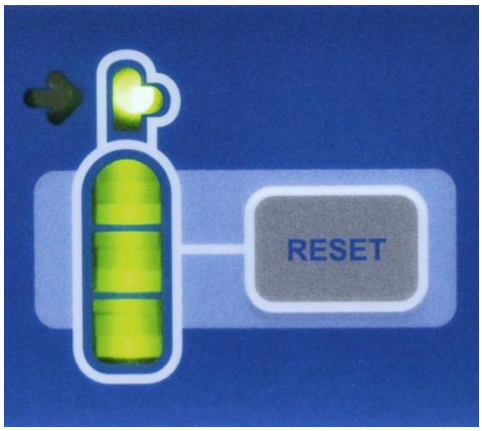

FIGURE 12: N_2O GAS GAUGE RESET BUTTON

- Meaning of gas gauge indicators seen in Figure 13

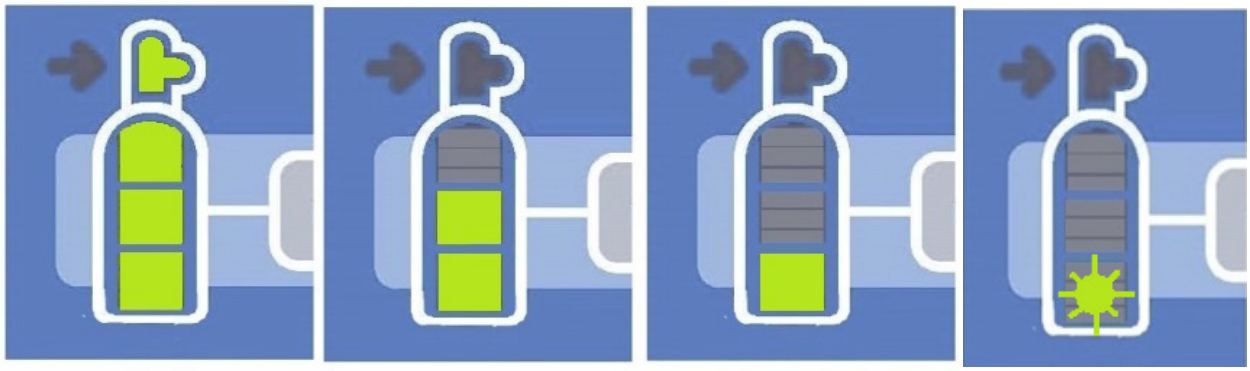

FIGURE 13: N_2O GAUGE INDICATORS

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 cryoICE System Probe

1. Ensure cryoICE BOX is properly connected to a N_2O gas cylinder.
2. The 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 14. The sliding ring will need to be manually pushed-in on the orange connector.

FIGURE 14: 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 16.

FIGURE 15

FIGURE 16

6. The PROBE icon, seen above in Figure 15, will extinguish if the PROBE is functioning properly and the approximate room temperature will be displayed on the temperature display (typically 10° C to 25° C [50° F to 77° F]). An example of this is shown in Figure 17.

FIGURE 17: PROBE TEMPERATURE DISPLAY

7. A test run is advised to ensure the PROBE and ACM are 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 18.

FIGURE 18: 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 confirm the PROBE and N_2O cylinder are properly connected.
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 PROBE temperature. A double-beep will indicate that the therapeutic temperature has been reached (typically -40°C

[-40°F]), 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, VENT the PROBE and automatically transition into READY Mode. During the DEFROST cycle, a triple-beep will alert the user that the temperature of the PROBE has transitioned above 0°C [32°F].

5. SPECIAL CASES

Abort FREEZE

To stop ablation during a FREEZE cycle, press and release the Activation Button during the ablation. The ACM 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 PROBE during a FREEZE or DEFROST, push the Activation Button until the ACM has sequenced into READY Mode.

The ACM can also be stopped by turning OFF power in the back or unplugging it from the AC power outlet. The flow of N_2O will stop, however gas will be trapped within the 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 cryoICE 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 and 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 PROBE is properly plugged in (red and black connectors) the 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, contact your local AtriCure service representative to correct the problem.

Disconnecting the AtriCure cryoICE system Probe

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

N_2O Cylinder Removal

1. Turn-Off the N_2O cylinder by turning the knob clockwise.
2. Purge the N_2O from the ACM by pressing and holding the blue N_2O Exhaust Switch in the back of the ACM. 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 red N_2O 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 N_2O cylinder by unscrewing the N_2O gas coupling.
5. Turn-OFF power and unplug the cryoICE BOX.

7. PREVENTIVE MAINTENANCE AND CLEANING OF THE ATRICURE CRYOICE BOX

Cleaning and Disinfecting Instructions

Note: Do not spray or pour liquids directly on the ACM.

Note: The ACM and/or accessories cannot be sterilized.

⚠**CAUTION:** Ensure Isopropyl Alcohol (IPA) is completely dry before operating the cryoICE system to prevent potential equipment malfunction.

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

Instructions

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

1. Disconnect the ACM or cart from the outlet before cleaning.
2. If the ACM, Components and 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 ACM, Components, Accessories shall be cleaned with a cloth that has been dampened with 70% 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 ACM, Components and 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. Visually inspect the ACM for any signs of degradation.
9. After cleaning is complete, turn the ACM ON to perform Power On Self-Test (POST). If any errors are received, contact AtriCure to begin return process.

Preventive Maintenance

In determining preventive maintenance requirements, AtriCure has taken into consideration internationally recognized standards and guidance's, including IEC 62353

The ACM shall be periodically subject to preventive maintenance, as specified below.

The AtriCure cryoICE BOX Preventive Maintenance comprises of the following activities:

- Visual Inspection and Functional Testing
  - Electrical power cords for fraying, damage, and proper grounding
  - AC Power switch
  - Any front panel display damage, including switches, numeric displays, and indicator lights.
  - PROBE electronic interface connector damage, cracking, or inability to insert and latch PROBE connector.
  - PROBE pneumatic interface connector damage or inability to insert and latch PROBE pneumatic connector.
  - Carrying handle damage or inability to fold.
  - Rubber feet damage, cracking, or inability for the ACM to remain stable on a flat surface.
  - Rubber alignment cup damage, cracking, or inability for the AtriCure RF Generator to remain stable atop ACM and within the alignment cup.
  - Listen for leaks when pressurized.
  - Other medical equipment that may be used simultaneously with the ACM should also be inspected for damage. Specifically, check for insulation damage to electrical cables and associated connectors.
- Electrical Safety Check in accordance with IEC 62353 standard.

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.

7555 Innovation Way,

Mason, Ohio 45040 USA

+ 1 866 349 2342

Corporate Website

www.atricure.com

Customer Service/ Product Inquiries/ Technical Support

Telephone: 513 755 4100

866 349 2342 Toll Free

Email: technical.service@atricure.com

Fax: 513-755-4567

Quick Connect O-Ring Lubricant

Item	Supplied By	Part Number
O-Ring Lubricant	AtriCure	C002502

Replacement of AC Line Fuses

Tools and Parts

- Needle Nose Pliers

Fuses

AtriCure cryoICE BOX Model	Fuse Type	Part Number
ACM1	T 4A L 250V	C002262

The cryoICE BOX unit has been pre-set at the factory to a nominal voltage of 115V (ACM1). 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 service representative.

Note: cryoICE 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 cryoICE BOX Model Number or the cryoICE 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 19.

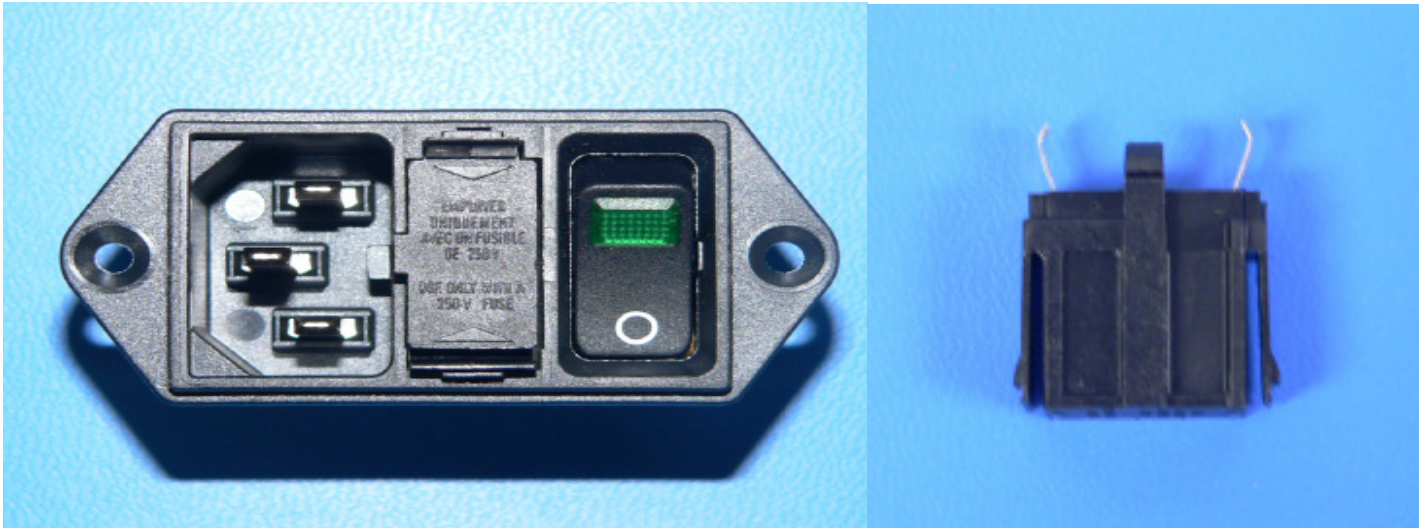

FIGURE 19: FUSE BOX TABS

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

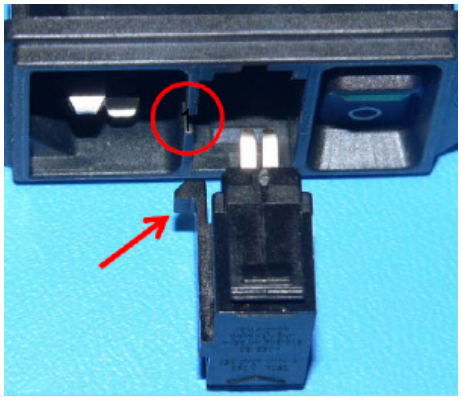

FIGURE 20: GUIDE TAB LOCATION

4. Align the fuse cartridge so the guide tab is towards the power entry side as shown in Figure 20.
5. Return the fuse box to the power entry module and push in firmly.
6. Confirm operational status by plugging in the cryoICE 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

Existing AtriCure cryoICE BOX Upgrade

A001056	Packaged, Tank Hose Assembly- Domestic

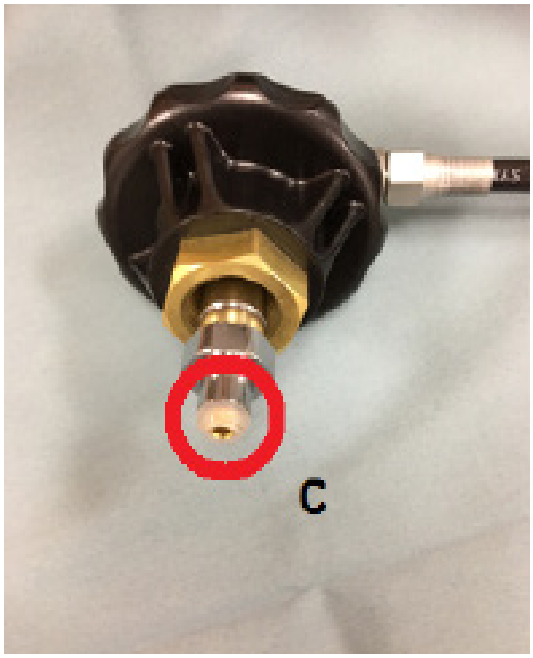

FIGURE 21: N_2O CYLINDER INTERFACE

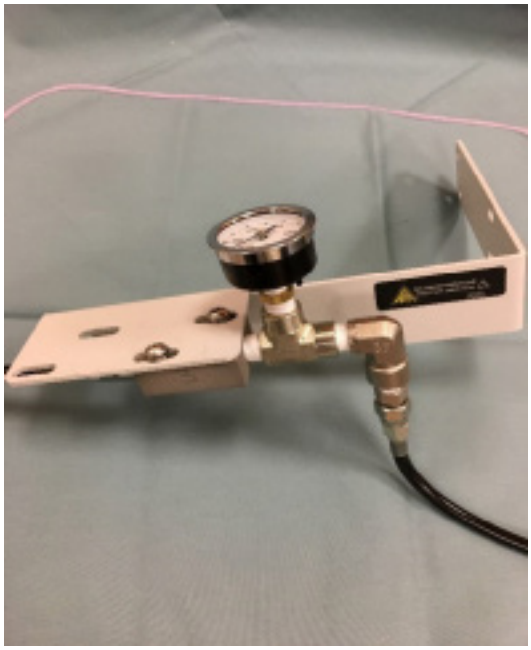

FIGURE 22: ATRICURE CRYOICE BOX TANK HOSE ASSEMBLY WITHOUT CANISTERS

Replacement Part

Component "C"	Tip Washer	AtriCure	F021837

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

This section only applies to cryoICE 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

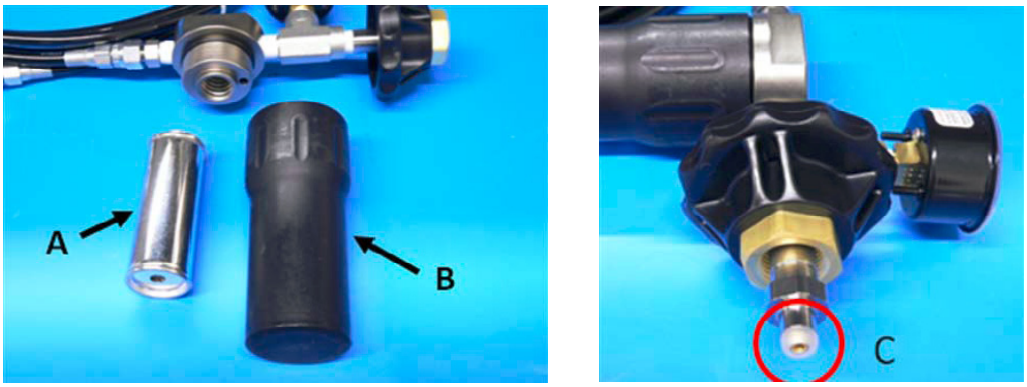

FIGURE 23: GAS LINE COMPONENTS

- 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

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

Procedure

1. Prior to changing the Desiccant Filter Cartridge, assure that the PROBE is disconnected from the patient and the cryoICE Box is turned off.
2. Unscrew the filter cartridge housing by rotating it counter-clockwise. Refer to Figure 24 below.

FIGURE 24: FILTER HOUSING REMOVAL

3. Remove the desiccant filter cartridge by rotating it counter-clockwise using hand force only. Refer to Figure 25 below.

FIGURE 25: 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.

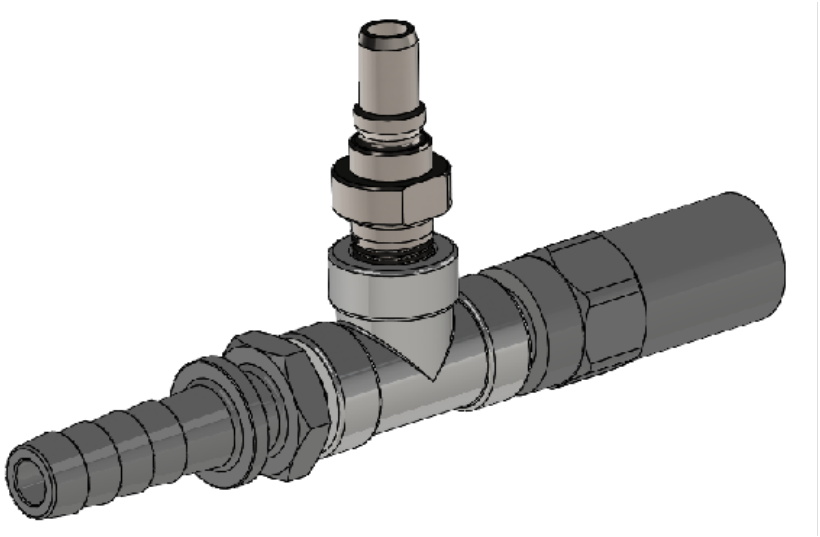

FIGURE 26: EXHAUST HOSE CONNECTOR ASSEMBLY – A001150 (FOR ILLUSTRATION PURPOSES ONLY)

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

Connector	Part Description	Region
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

Disposal

Disconnect PROBE and treat as regulated medical waste requiring decontamination to render safe for further handling and disposal. Follow cleaning and disinfecting steps for the ACM as outlined in IFU Section 7. Contact local medical equipment recycling and disposal service. The used PROBE is considered biohazardous. After use, the PROBE should be treated as medical waste and disposed by following local hospital protocol.

Expected Life Time

The Expected Life Time is the time-period during which the ACM, Components and Accessories are expected to remain suitable for its intended purpose, assuming the responsible organization will follow AtriCure's Instruction for Use for preventive maintenance.

AtriCure has defined the Expected Life Time of the ACM to be 5 years.

For information on preventive maintenance, please see Preventive Maintenance, or contact your local AtriCure representative.

8. TROUBLESHOOTING

Note: If the problem persists and could not be resolved by taking the recommended actions in the tables below, please contact your local AtriCure representative.

Problem	Possible Cause	Action
Front displays not lit.	• No power. • cryoICE BOX electrical failure.	• Check power switch on back of cryoICE BOX. • Check plug connection on back of cryoICE BOX. • Check AC plug in wall socket. • Ensure power is available at wall socket.
Cylinder Heater Band Icon Illuminated. 	• Heater band not plugged in. • N_2O cylinder valve closed. • Empty N_2O cylinder. • Extremely cold N_2O cylinder. • Heater band not attached to N_2O cylinder. • Heater band malfunctioning.	• Check connection on back of cryoICE BOX. • Ensure N_2O valve is open. • Replace N_2O cylinder. • Allow 15 minutes to warm up. • Attach Heater Band to cylinder.
Temperature Not Displayed. 	• PROBE not plugged in. • Malfunctioning PROBE. • cryoICE BOX malfunctioning.	• Ensure the PROBE thermocouple leads are firmly seated within their receptacles. • Replace PROBE.
cryoICE BOX has power but will not go into FREEZE mode.	• PROBE not plugged in. • N_2O cylinder empty. • N_2O cylinder valve closed. • Inlet Gas Connection not secure.	• Plug in PROBE. • Replace N_2O Cylinder. • Open cylinder valve. • Ensure Inlet Gas Connection is completely seated.
PROBE not getting cold enough.	• Heater Band not properly installed. • N_2O cylinder low or out of gas. • Exhaust filter is clogged.	• Check heater installation and heater icon. • Replace N_2O cylinder. • Exhaust connector (orange) is frosting/ freezing ice (liquid condensate is not uncommon).
Temperature Display indicates incorrect values.	• PROBE plugged in incorrectly. • Malfunctioning PROBE. • Electromagnetic interference • cryoICE BOX malfunctioning.	• Ensure PROBE black and red plugs are in correct receptacles. • Replace PROBE. • Relocate or Reorient cryoICE BOX.
Bottom segment on N_2O icon flashing. 	• N_2O cylinder empty. • N_2O cylinder cold. • Indicator not reset when cylinder was replaced.	• Replace with full cylinder. • Make sure heater blanket is installed and working. Allow time for the cylinder to warm up if it is cold. • Press Reset when cylinder is replaced.
N_2O Gas Gauge flashing. 	• N_2O cylinder pressure is below 650psi. • N_2O cylinder empty.	• Make sure heater blanket is installed and working. Allow time for the cylinder to warm up if it is cold. • Replace with full cylinder.

Problem	Possible Cause	Action
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 PROBE to the cryoICE BOX. 	• Trapped N_2O within the cryoICE System..	• Power-ON the cryoICE BOX which clears trapped gas exerting pressure on the connector. • Push the sleeve toward the cryoICE BOX until it locks back. (usually clicks)
	• Quick connector out of sequence, sleeve on blue connector is forward. • Quick connector O-ring dried out and/or swelling.	• Lubricate the connector inside with silicon-based O-ring lubrication such as AtriCure Part No. C002502.
Wrench Icon flashing and clicking heard inside cryoICE BOX, may also include display flashing. 	• Heater band over temperature due to empty 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 cryoICE BOX to reset wrench Icon.
	• Heater band over temperature due to loose fit on N_2O cylinder.	• 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 cryoICE BOX and heater band to AtriCure.
PROBE getting colder than -75°C (-103°F) and not defrosting.	• The system 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. • Replace the Tank Hose Assembly which has canister set with Tank Hose Assembly without canister set. • A001056 – Domestic Tank Hose Assembly without canisters • A001055 – International Tank Hose Assembly without canisters • Power-On cryoICE BOX within a few minutes of PROBE use to minimize N_2O condensing into a liquid within the ACM.
	• 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 PROBES.
	• 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 and should not contain the following markings: S, DT, or D.

AtriCure cryoICE 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 your local AtriCure representative 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-ON

9. ELECTROMAGNETIC COMPATIBILITY TABLES

Electromagnetic Emissions

Guidance and manufacturer's declaration – Electromagnetic Emissions	
The AtriCure cryoICE BOX is intended for use in the electromagnetic environment specified below. The customer or the user of the AtriCure cryoICE 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.

[b)] This test is not applicable in this environment unless the AtriCure cryoICE 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 cryoICE BOX is intended for use in the electromagnetic environment specified below. The customer or the user of the AtriCure cryoICE 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	IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4kV, ± 8kV, ± 15 kV air
Radiated RF EM fields [a)]	IEC 61000-4-3	3 V/m [f)] 80 MHz – 2.7 GHz [b)] 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)] 50 Hz or 60 Hz

[a)] The interface between the PATIENT physiological signal simulation, if used, and the AtriCure cryoICE BOX shall be located within 0.1 m of the vertical plane or the uniform field area in one orientation of the AtriCure cryoICE BOX.

[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.

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

[d)] Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

[e)] During the test, the AtriCure cryoICE BOX may be powered at any NOMINAL input voltage, but with the same frequency as the test signal.

[f)] Before modulation is applied.

[g)] This test level assumes a minimum distance between the AtriCure cryoICE BOX and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the AtriCure cryoICE 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 cryoICE BOX is intended for use in the electromagnetic environment specified below. The customer or the user of the AtriCure cryoICE 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 100 kHz repetition frequency
Surges [a) b) j) o)] Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges [a) b) j) k) o)] 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)] 0.15 MHz - 80 MHz 6 V/m [m)] in ISM bands between 0.15 MHz and 80 MHz [n)] 80% AM at 1kHz [e)]

Guidance and manufacturer's declaration – Input A.C Power Port Immunity		
Voltage dips [f) p) r)]	IEC 61000-4-11	0% UT; 0.5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)]
		0% UT: 1 cycle And 70% UT: 25/30 cycles [h)] Single phase: at 0°
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0% UT: 250/300 cycle [h)]

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

[b)] All AtriCure cryoICE 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 to 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 cryoICE 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 shall 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 cryoICE BOX is intended for use in the electromagnetic environment specified below. The customer or the user of the AtriCure cryoICE 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 ± 2kV, ± 4kV, ± 8kV, ± 15 kV air
Conducted disturbances induced by RF fields [a)]	IEC 61000-4-6	3 V [b)] 0.15 MHz - 80 MHz 6V [b)] in ISM bands between 0.15 MHz and 80 MHz 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 where 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 CRYOICE 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

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Disclaimer

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