

Software V6.10

cryoICE BOX[®]

Quick Reference Guide

Commercial Name: AtriCure cryoICE BOX

SOFTWARE UPGRADE V6.10 INCLUDES:

- Audible tone when probe is above 0°C (32°F)
- Gas gauge indicator based on new algorithm, measuring tank temperature and pressure
- Tank pressure reduced from 850psi(5.9MPa) to 800psi(5.5MPa)

SET UP

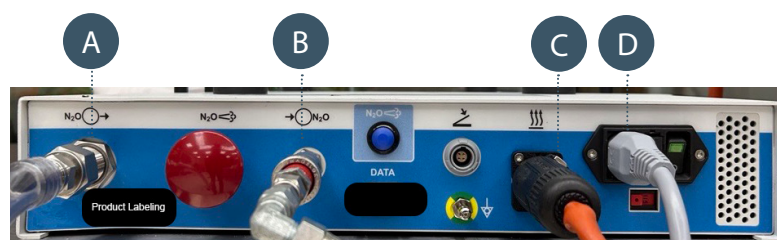
1. Check connections on back of Electrophysiology cryoablation machine

A - Exhaust Hose: connect other side to vent

B - Tank Hose

C - Heater Band

D - Power Cord



2. Open the N₂O tank valve

- Be sure the tank valve is open in order to activate the heater.
- Closing the valve while the unit is on will lead to a heater band error.



3. Turn ON the Electrophysiology cryoablation machine



4. Plug in probe

The probe can be plugged in at any time.

ELECTROPHYSIOLOGY CRYOABLATION MACHINE

FRONT AND REAR PANELS — ILLUSTRATIONS AND NOMENCLATURE

Illustrations of the Electrophysiology cryoablation machine front panel (Figure 1) and rear panel (Figure 2) are shown below.

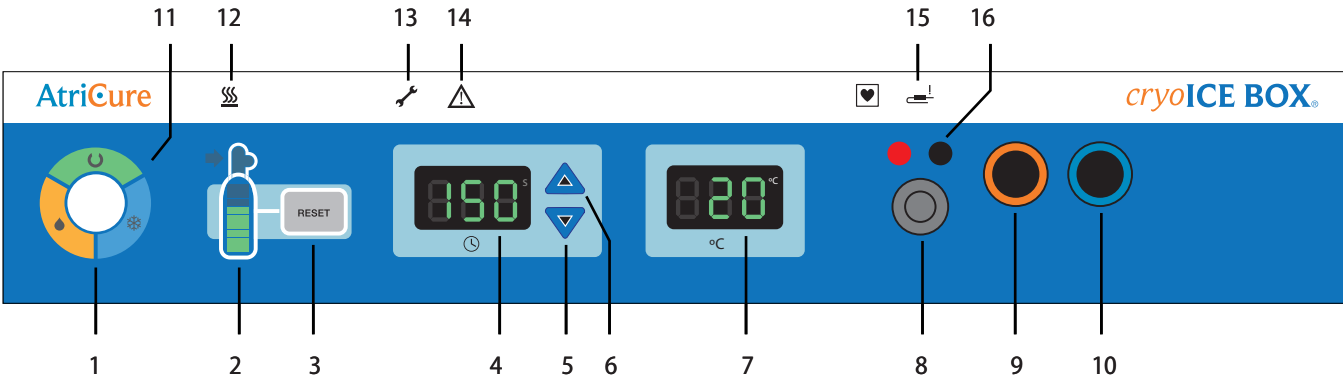


Figure 1: Electrophysiology cryoablation machine Front Panel

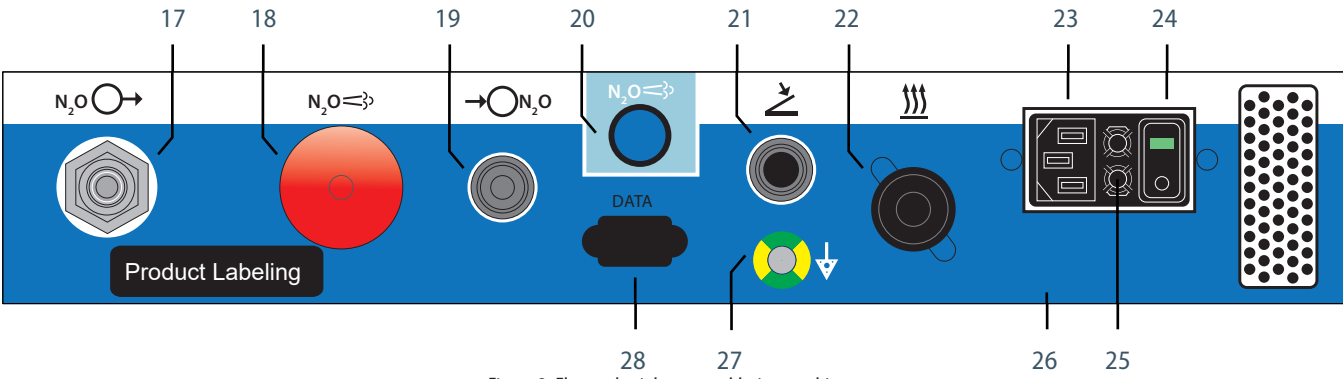


Figure 2: Electrophysiology cryoablation machine Rear Panel

1	Activation Button	11	Ablation Status Indicator	21	Activation Footswitch Connection Port
2	N ₂ O Gas Gauge Indicator Display	12	Cylinder Heater Band Indicator	22	Heater Band Cord Receptacle
3	N ₂ O Gas Gauge Indicator Display Reset	13	Maintenance Needed Indicator	23	Power Plug Receptacle
4	Ablation Timer Display	14	System Fault Indicator	24	Power Switch
5	Ablation Timer Decrement	15	Thermocouple Open Indicator	25	Mains Fuse Location
6	Ablation Timer Increment	16	cryoICE Probe Thermocouple Ports	26	Electrophysiology cryoablation machine Voltage Rating Label
7	cryoICE Probe Temperature	17	N ₂ O Exhaust Port	27	Equipotential Terminal
8	Future Probe Connection	18	N ₂ O Manual Exhaust Knob	28	RS232 Data Connection (To be used by service representatives only. Do not remove the cover.)
9	cryoICE Probe Gas Outlet Port	19	N ₂ O Inlet Port		
10	cryoICE Probe Gas Inlet Port	20	N ₂ O Exhaust Switch		

N₂O = Nitrous Oxide



OPERATING MODES

The Electrophysiology cryoablation machine operates in one of three modes: READY, FREEZE, DEFROST. These modes are identified by the system status indicator LEDs and the ablation status indicator LEDs located on the front of the Electrophysiology cryoablation machine 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 cryoICE probe reaching approximately 10°C(50°F) and automatically venting. This indicates that the system is ready for the next cryoablation run.



FREEZE Mode

This mode is entered from the READY mode when the user initiates the cryoablation cycle by pressing and releasing the Activation Button or the Footswitch. In this mode, the N₂O gas is allowed to cycle through the cryoICE probe causing a temperature drop to take place at the cryoICE 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 Button or the Footswitch is actuated while in the FREEZE mode. In this mode, the cryoICE probe temperature is actively forced towards the ambient temperature. Once the cryoICE probe temperature is approximately 10°C(50°F), the Electrophysiology cryoablation machine unit will transition back to the READY mode.

Note: Electrophysiology cryoablation machine does allow early transition out from the DEFROST mode into either the READY mode or the FREEZE mode by pressing the Activation Button.

Note: cryoICE 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.

GAS GAUGE LEVEL INDICATOR



FULL

20 to 40 minutes remaining¹



TWO SEGMENTS REMAINING

15 to 20 minutes remaining¹



ONE SEGMENT REMAINING

5 to 10 minutes remaining¹



EMPTY

(Flashing)

0 to 5 minutes remaining¹

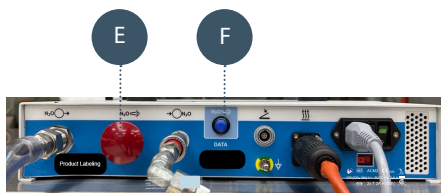
¹ Minutes remaining are based on 20lb(9.1kg) steel tanks with 8"(20cm) diameter.

Time may vary with different style tanks.

SHUT DOWN



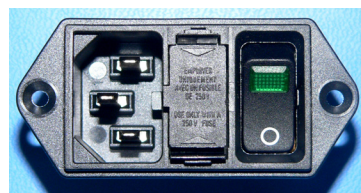
1. Close the N₂O cylinder valve



2. Vent the N₂O from the gas line by:

E - Pulling the red N₂O Manual Exhaust Knob - **or** -

F - Pressing the blue N₂O Exhaust Switch

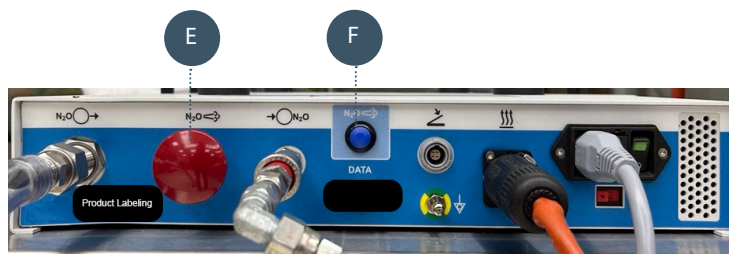


3. Turn OFF the Electrophysiology cryoablation machine

CYLINDER EXCHANGE



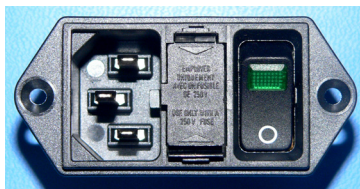
1. Close the N₂O cylinder valve



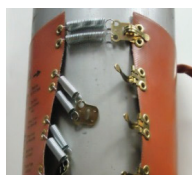
2. Vent the N₂O from the gas line by:

E - Pulling the red N₂O Manual Exhaust Knob - **or** -

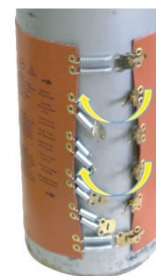
F - Pressing the blue N₂O Exhaust Switch



3. Turn OFF the Electrophysiology cryoablation machine power



4. Remove the heater band from N₂O cylinder



5. Replace with a full cylinder and re-connect the heater band

The band should be located as close to the bottom of the tank as possible

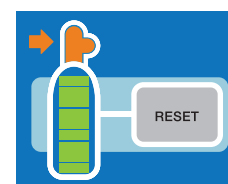
Fasten the outermost buckles first and work toward the center



6. Open the N₂O tank valve



7. Power ON the Electrophysiology cryoablation machine

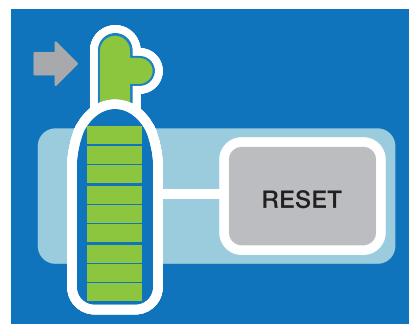


8. Press the RESET button on the front of the Electrophysiology cryoablation machine

Valve icon will be amber and icon will flash if tank valve is closed.

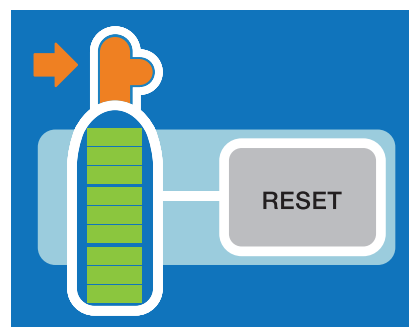
TANK CHANGE TIPS

1. The gas gauge indicator can only be RESET once per Power Cycle or if a tank change has been detected.
 - It is recommended to start with a full N₂O tank.
 - The gas gauge indicator will need to be RESET when a full tank is installed and will not automatically adjust to full without pressing RESET.
2. The Electrophysiology cryoablation machine
3. needs time for the system to warm up in order to estimate the N₂O remaining in the tank.
 - This takes 2 to 5 minutes on average, depending on the initial pressure of the N₂O tank. If the starting pressure is below 725psi(5MPa) due to a cold environment, it could take additional time to estimate the N₂O remaining.
 - The gas gauge indicator requires the heater band to be installed on the N₂O tank for proper functionality.
 - If the gas gauge indicator is RESET prior to the system warming up, it may indicate full until the tank pressure is about 800psi (5.5MPa).



GAS GAUGE INDICATOR FEATURES

1. Tank Closed Indicator
 - The gas gauge indicator arrow and valve portion will flash amber when the Electrophysiology cryoablation machine
 - does not detect any pressure.
 - Check the N₂O tank valve to see if it is closed. If so, open it to turn off the Tank Closed Indicator.
2. Low Pressure Indicator
 - The gas gauge indicator will flash regardless of the gas gauge level indicator if the tank pressure is below 650psi(4.5MPa).
 - This may be due to tanks being stored in a cold environment, and it may take longer than normal for the heater band to bring the system up to pressure.



Tank Closed Indicator

ELECTROPHYSIOLOGY CRYOABLATION MACHINE TROUBLESHOOTING

The Electrophysiology cryoablation machine User Manual has been updated to include additional information in the Troubleshooting sections to assist with maintaining Cryo system performance.

TOPIC #1: CRYO PROBE SLOW TO DEFROST; NO DEFROST

Possible Cause	Action to Take
• Liquid Nitrous Oxide (N ₂ O) flooding system	• Power-On Electrophysiology cryoablation machine no earlier than 15-minutes before use

TOPIC #2: CRYO PROBE NOT GETTING COLD ENOUGH

Possible Cause	Action to Take
• Pressure gauge less than 700psi(4.8MPa) and cylinder warm	• Replace the cylinder with a full one
• Pressure gauge less than 700psi (4.8MPa) and cylinder cold	• Verify heater band is working (warm to touch) • Heater band icon is off, verify heater band connection
• Pressure gauge is above 700psi (4.8MPa) in freeze mode	• Unplug cryolCE PROBE Outlet Connector (Orange) tube, if temperature drops to -65°C(-85°F) the exhaust filter is clogged – return Electrophysiology cryoablation machine • Unplug cryolCE PROBE Outlet Connector (Orange) tube, if temperature doesn't drop to -65°C(-85°F) the Cryo Probe is clogged – replace Probe

TOPIC #3: DIFFICULTY CONNECTING A CRYO PROBE TO THE ACM

Possible Cause	Action to Take
• Trapped N ₂ O within the system	• Power-Off, Power-On Electrophysiology cryoablation machine – vents Probe side N ₂ O
• ACM Blue connector sleeve out of sequence	• Push the Blue connector sleeve toward Electrophysiology cryoablation machine
• Connector O-ring dried out or swelling	• Lubricate the O-ring with AtriCure P/N# C002502

TOPIC #4: FLASHING WRENCH IRON (POSSIBLE ERROR CODE 002)

Possible Cause	Action to Take
• Heater band over temperature due to empty cylinder	• Replace the cylinder with a full one
• Heater band over temperature due to fit being loose	• Verify heater band is at bottom of cylinder and snug
• At Power-On, error code 002 displayed	• Replace N ₂ O cylinder with a known full one
• At Power-On, error code different than 002 displayed	• If no, call AtriCure Technical Support +31 20 700 55 60

TOPIC #5: CRYO PROBE COLDER THAN -70°C(-94°F), NOT DEFROSTING

Possible Cause	Action to Take
• Liquid Nitrous Oxide (N ₂ O) flooding system	• Power-On Electrophysiology cryoablation machine • no earlier than 15-minutes before use
• N ₂ O quality not sufficient to use as a refrigerant	• N ₂ O Supplier to manage water content to 3 ppm max
• N ₂ O cylinder contains a siphon tube or dip tube	• Do not use cylinders containing a siphon or dip tube

For other concerns, consult the Electrophysiology cryoablation machine Instructions for Use or contact the AtriCure Customer Service Hotline at +1 866 349 2342.

For detailed information, please consult the Instructions for Use.



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