



CRYOCOR™ CARDIAC CRYOABLATION SYSTEM

Instructions for Use Manual



CAUTION: Investigation Device. Limited by Federal (USA) law to investigational use.

IMPORTANT:

Save This Manual

Includes:

- Operating Instructions
- Safety Warnings
- Technical Specifications
- Customer Service

NOTICE:

Before operating the CryoCor Cardiac Cryoablation System, please read all instructions in this manual carefully.

If you have any questions, please contact:

CryoCor, Inc.
 9717 Pacific Heights Blvd.
 San Diego, CA 92121
 1-858-909-2200
 1-858-909-2300 (Fax)

TABLE OF CONTENTS:

DEVICE DESCRIPTION AND PRINCIPLE OF OPERATION:.....	3
INDICATIONS AND CONTRAINDICATIONS:	3
WARNINGS:	4
PRECAUTIONS:.....	5
RISKS AND POTENTIAL ADVERSE EVENTS:	5
CRYOCOR CARDIAC CRYOABLATION SYSTEM COMPONENTS:	6
REFRIGERANT SUPPLY:	11
COMPATIBLE CATHETERS:	13
NORMAL SETUP AND OPERATION:	13
OPTIONS MENU:	18
DEVICE SETUP (ADJUST CLOCK):	20
VALUE SETUP (ERASE PROCEDURE LOGS):	22
WARNING AND ERROR MESSAGES	23
SYSTEM SHUT DOWN:	32
CLEANING AND DISINFECTION:.....	33
STORAGE CONDITIONS:.....	33
OPERATING CONDITIONS:	33
SERVICE:	34
FUSE REPLACEMENT:	34
MAINTENANCE:.....	35
SHIPPING CRATE AND PACKING MATERIALS:.....	35

Device Description and Principle of Operation:

The CryoCor Cardiac Cryoablation System is intended for the ablation of cardiac tissue through localized application of extreme cold. The system consists of a console, an articulating arm housing a precooler, and a disposable catheter intended for the ablation of cardiac tissue. The disposable sterile catheter is supplied separately. A replenishable refrigerant supply is housed in the console, from which coolant circulation is controlled and monitored.

The system's operation is based on a microprocessor controlled two-stage cooling process initiated by activation of the system's freeze cycle. The system delivers refrigerant to the first-stage precooler located at the end of the attached articulating arm. The precooler reduces refrigerant temperature and supplies a steady flow of liquid refrigerant to the tip of the connected catheter. In the second stage, liquid refrigerant at the catheter tip changes to its gas phase causing a rapid additional reduction in temperature allowing for ablation of cardiac tissue. The refrigerant gas is then returned from the catheter through the console to an outlet.

Deactivation of the freeze cycle stops refrigerant flow to the catheter, ending cooling.

Indications and Contraindications:

For indications and contraindications, refer to the specific catheter's Instructions For Use.

Warnings:

Failure to follow any instructions or to heed any warnings or precautions could result in patient or operator injury or prevent normal operation of the console.

- The CryoCor Cardiac Cryoablation System is capable of delivering significant cryoablation therapy. When operating, do not touch the catheter tip because operator injury may occur.
- Use only **isolated Type CF** EKG amplifiers with the CryoCor Cardiac Cryoablation System. These amplifiers must be defibrillation proof. Leakage current from a connected device to the patient must not exceed 10 microamps (μA).
- The CryoCor Cardiac Cryoablation System can not be used at altitudes that are greater than 3600 feet.
- Spark generation possible: DO NOT use the system in a (flammable) anesthesia-rich environment.
- This equipment has been tested and found to comply with the limits for medical devices to the EN60601-1-2: Edition 2 (Circulated 2001-05-11), Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - a. Reorient or relocate the receiving device.
 - b. Increase the separation between the equipment.
 - c. Connect the equipment into a grounded outlet on a circuit different from that to which the other device(s) are connected.

Precautions:

- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of catheter ablation in a fully equipped electrophysiology laboratory.
- Do not attempt to operate the CryoCor Cardiac Cryoablation System before completely reading and understanding the applicable Instructions For Use.
- The CryoCor Cardiac Cryoablation Console is intended to be used with CryoCor Cardiac Cryoablation Catheters and accessories only. The safety of use with other electrophysiology catheters and accessories has not been assessed.
- Refer to the catheter Instructions For Use Manual for information on handling and operation of the catheter.
- The LCD display on the console should be monitored during therapy delivery.
- The CryoCor Cardiac Cryoablation System is incompatible with magnetic resonance imaging (MRI) equipment.
- **DO NOT remove Luer fitting during ablations.**
- Clean and disinfect the articulating arm according to instructions under “Cleaning and Disinfection” in this Instruction For Use Manual.
- Do not attempt to disassemble the Console, Articulating Arm or Catheter.
- Do not allow ventilation holes on Console to become obstructed as overheating may result.
- Do not allow liquids to contact EKG electrical connections, or distorted signals may result.
- Precooler assembly at end of the Articulating Arm may feel cold to hand contact.
- Although the system has integrated refrigerant leak detection, immediately shut down system if an audible leak is observed, and notify service personnel.

Risks and Potential Adverse Events:

- For risks and potential adverse events, refer to the Instructions for Use for the specific catheter.

CryoCor Cardiac Cryoablation System Components:

- The console - contains the refrigerant delivery-and-return system, LCD display panel and microprocessor control system.
- The articulating arm – houses the precooler, the EKG output connectors, the catheter in/out refrigerant connection, the pressure gauge connection, and the sensor cable connection.
- The sterile, disposable catheter – provides delivery of therapy to the cardiac tissue. Returns the spent refrigerant through the console to an outlet and provides electrical connection to the console.
- The console cannot be operated without the CryoCor Cardiac Cryoablation Catheter attached.

Console:

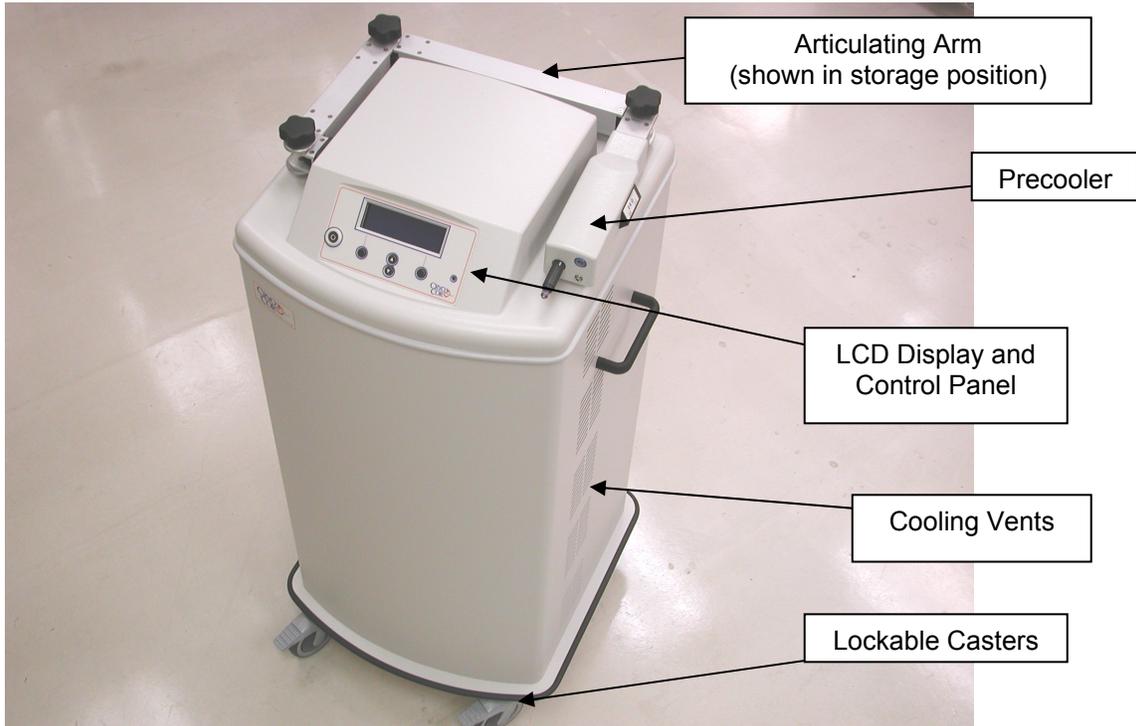
The console plugs into a standard grounded electrical outlet. The system's controls and LCD display panel are mounted on the front of the console. The console wheels have four (4) locking casters that allow for easy portability and maneuverability. The console has the following indicators and controls:

Indicator/Control	Function
Rocker Switch	Controls main power (at rear of Console).
Green LED	Illuminates when power is on.
Control Panel Power Switch	Controls power for LCD display and command buttons.
LCD Display Panel	Displays information relating to the status of the system.
Control Panel Command Buttons (Left and Right)	Enters the corresponding commands which are displayed on the LCD display panel.
Control Panel Up/Down Arrow Buttons	Moves cursor through menu items on the LCD display panel.

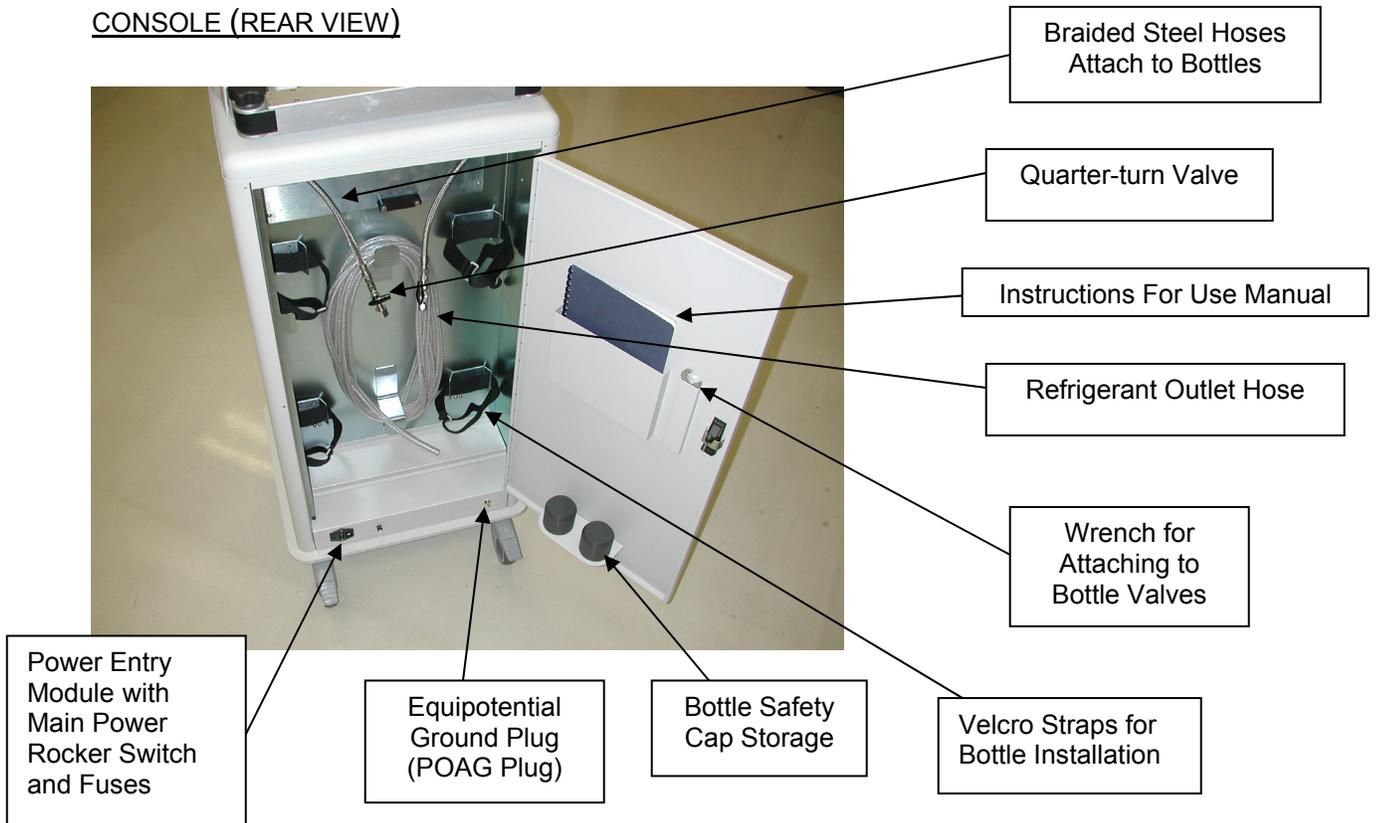
Articulating Arm:

The articulating arm is mounted to the console and houses the precooler and the connection points for the refrigeration lines and electrical connections of the catheter. The articulating arm pivots to allow for optimal positioning of the console and catheter or for storage when not in use.

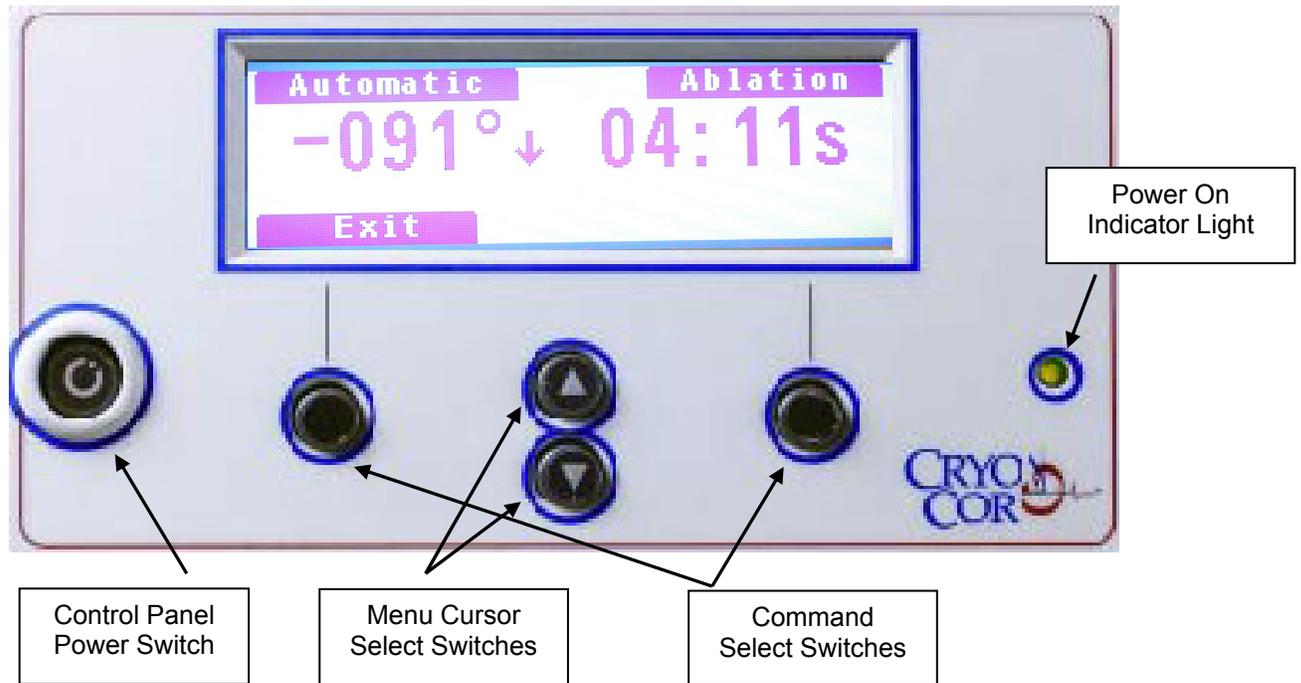
CONSOLE (FRONT VIEW) AND ARTICULATING ARM



CONSOLE (REAR VIEW)



LCD DISPLAY AND CONTROL PANEL



ARTICULATING ARM SHOWING CATHETER AND EKG ATTACH POINTS

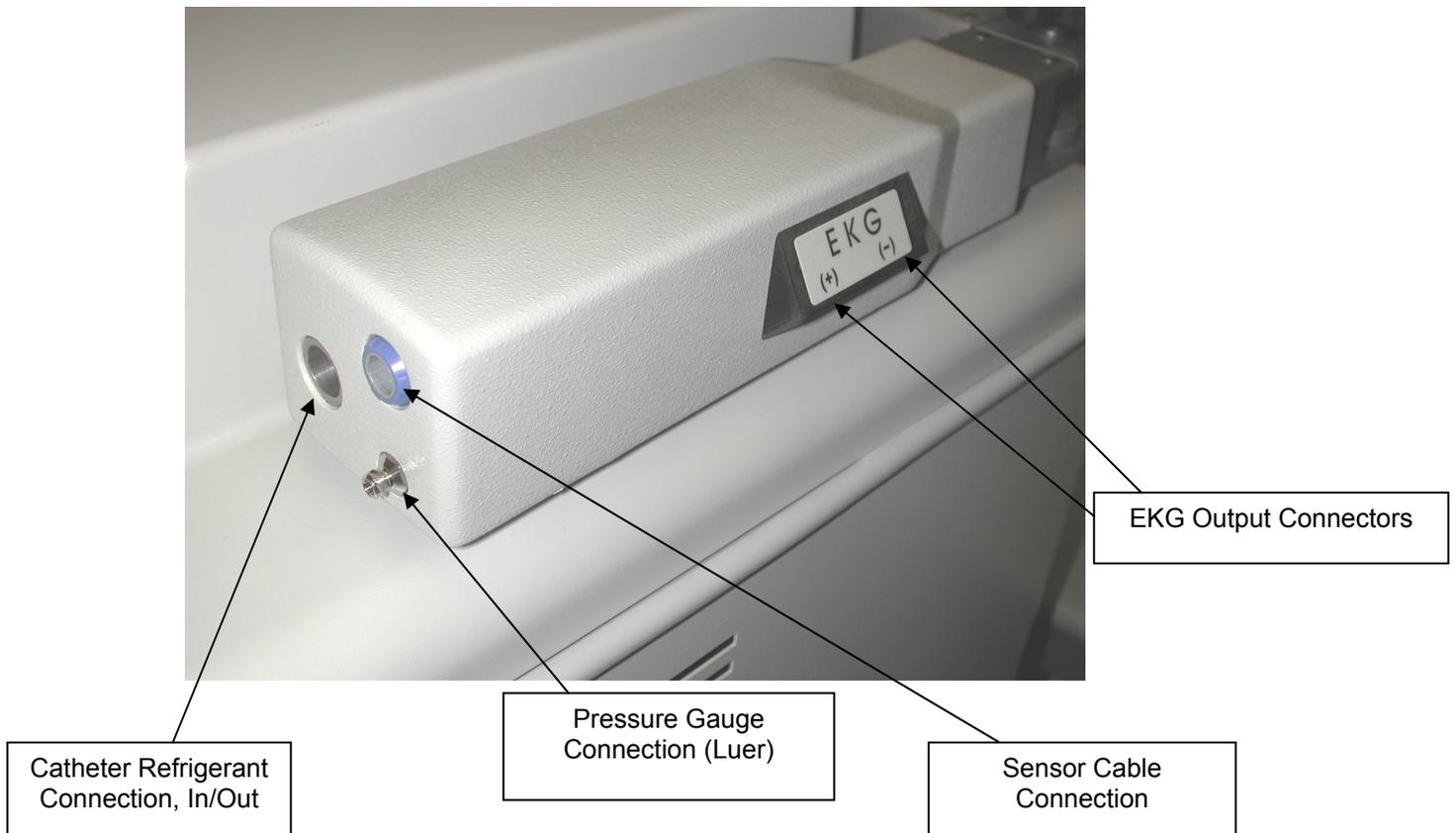


Table I - Technical Specifications for the CryoCor Cryoablation System, Model 2020

CRYOCOR CARDIAC CRYOABLATION SYSTEM	MODEL 2020
Weight (without refrigerant bottles)	127 kg (280 lbs.)
Dimensions (H x W x D)	137x 64x 64 cm (54 x 25 x 25 inches)
Refrigerant Bottle	DOT Approved ⁽¹⁾ , 16 Liter, CGA 326 Valve
Operating Temperature Range	15 - 30 °C (59 – 86 °F)
Configuration	Air Cooled
Noise	<70 dBA at 1 Meter
Input Power	120 V, 7 A, 60 Hz
Type of Protection against Electric Shock	Class 1: Protective Earth Ground
Degree of Protection against Electric Shock	Category CF: Cardiovascular Floating, Defibrillator-proof
Fluid Ingress Protection	Ordinary Construction
Mode of Operation	Continuous
Temperature Display	
Accuracy	± 5 °C
Precision	1 °C
Time Display	
Accuracy	± 2 Seconds
Precision	1 Second
Pressure Display	
Accuracy	± 2%
Precision	1 PSI or 6.9 kPa

- (1) Nitrous Oxide (N₂O) shall be Grade 4.5 or 5.0 and supplied in DOT Approved cylinders only.

Table II - Symbols Key for CryoCor Cryoablation System, Model 2020 and Catheter

	Attention: See Instructions for Use
	Lot number
REF	Catalog number
	Do not reuse
	Sterilized by radiation. Do not use if package is opened or damaged.
	Use by date
	CE mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42 EEC.
	Off (power: disconnection from the mains)
	On (power: connection to the mains)
	Standby
	Up arrow
	Down arrow
	Equipotentiality
	Alternating current
	Type CF Equipment, Defibrillator-proof
	TUV NRTL mark. The product meets the requirements of UL 2601-1: 1997, & CAN/CSA-C22-601.1-M90 excluding sub-clauses 48 and software part of 52.

Refrigerant Supply:

The CryoCor Cardiac Cryoablation System requires periodic replenishment of refrigerant, which is High Purity Grade N₂O. This refrigerant is supplied in “bottles” (metal cylinders with a valve and knob at top), which are accessible through the door at the rear of the console.

WARNING:

Use only High Purity Grade N₂O, with a moisture content of less than 3 ppm. Use of “hospital” or “commercial” grade N₂O is NOT ACCEPTABLE. The moisture content of these grades is too high; this moisture will freeze inside the narrow passages of the catheter, causing blockage; operation of the system will cease.

The console is designed to hold up to two 16-liter refrigerant bottles. Each full bottle is capable of providing approximately 1000 minutes of ablation time (e.g., 330 3-minute freezes). A 16-liter bottle of N₂O contains approximately 12 kg of refrigerant. Before the refrigerant is exhausted, the display will indicate a low bottle pressure. When the low pressure indicator is displayed, sufficient refrigeration for approximately 10 to 15 3-minute freezes will remain per refrigerant bottle in use. Empty bottles should be replaced with full ones at the earliest opportunity (see instructions below for proper bottle installation and removal procedure).

If two bottles are installed, it is recommended that only a single bottle be used at a time. When it is necessary to change to the second bottle, the first should be closed prior to opening the second, thus preventing transfer of refrigerant from the full bottle into the empty bottle.

CAUTION:

Improper technique in changing of refrigerant bottles may result in freeze-burn to the operator. Use of safety glasses and protective gloves is recommended.

CAUTION:

Refrigerant bottles are heavy and are unstable standing up; take care when handling to avoid injury.

CAUTION:

Refrigerant bottles (even “empty” ones) contain high-pressure gas. Always keep Safety Cap on bottle when outside of the console. Avoid standing bottle upright where it might accidentally get knocked over while exchanging bottles; instead, lay the bottle on its side in a safe, out of the way location. For long term storage, use a bottle rack with safety chain intended for storage of high pressure gas bottles of this size and type.

Installation of the refrigerant supply bottles is as follows:

1. Open rear door. Open the 2 Velcro straps on the side being serviced.
2. Remove the safety cap from the bottle by unscrewing; store the safety cap on the gray cylindrical holder at the bottom/center of the rear door. Position the refrigerant bottle inside the console, oriented so that the valve is aligned with the refrigerant fitting. The braided steel hoses should cross each other to the opposite side.
3. Prior to connecting the braided steel hose, briefly “crack” open the bottle valve; this will release a small amount of refrigerant and purge any contaminants from the valve.
4. Insert the braided hose fitting into the bottle valve and hand-tighten the threaded nut.
5. Using the wrench supplied, tighten the fitting to the cylinder valve while restraining the body of the ¼-turn valve from rotating. (An adjustable wrench works well for restraining the valve from rotating.)
6. Fasten the 2 Velcro straps securely, so that the bottle is held firmly.
7. Open the ¼-turn valve (black knob), so that the knob is parallel with the braided steel hose.
8. Open the bottle valve, by rotating round knob at top counter-clockwise, 2 turns. Listen for any leak at connection; tighten the fitting to stop leak.

Removal of the refrigerant supply bottles is as follows:

1. Close the bottle valve, by rotating the round knob at the top clockwise until tight.
2. Close the ¼-turn valve (black knob), so that the knob is perpendicular with the braided steel hose.
3. Using the wrench supplied, loosen the fitting that attaches to the bottle valve; there will be a brief hiss of escaping gas as it vents. By hand, loosen this fitting, so that it can be withdrawn from the bottle. Open the 2 Velcro straps so that the bottle is free to be removed.
4. Carefully tilt and remove the bottle from the console. Immediately replace the safety cap on top of the bottle. The safety cap must be fully threaded onto the collar attached to the bottle.
5. Store the bottle with safety cap in a safe and secure area.

Compatible Catheters:

- The CryoCor Cardiac Cryoablation Catheters

Normal Setup and Operation:

Console Setup:

- Attach the hospital's equipotential ground line to the POAG plug (identified with green/yellow washer and equipotential ground symbol) on the rear of the console. Attach the power cord to the connector at the rear of the console. (The Power Cord can be secured with the c-clamp and plastic thumbscrew nearby to strain-relief the cord to prevent accidental removal.) Plug the power cord into a grounded outlet. Turn the main power rocker switch (located at the rear of the console) to ON. The green LED on the front panel of the Console will illuminate.
- Position the Console into the desired location adjacent to the patient; depress the lever on each caster to lock the wheels. Unfurl the refrigerant outlet hose (stored inside the rear door) and connect to a regulated hospital scavenge line connection (200 mmHg max vacuum); if no connection is available, extra length can be added to the hose, and the refrigerant can be exhausted to the outdoors.
- Open the refrigerant bottles. Rotate the valve on the top of the bottle counter clockwise until it is fully open. Rotate the ¼-turn valve so that its handle is parallel to the refrigerant supply line.

Articulating Arm Setup

- The articulating arm may be draped prior to its placement over the sterile field. To drape the articulating arm, rotate the arm's black knobs counter-clockwise and pivot it into a desirable draping position. After draping and positioning the arm, lock it in place by rotating the black knobs clockwise until hand tight.

Catheter Setup and Connection To Console

- Refer to the catheter's Instructions For Use for the steps to be followed in its preparation.
- **Note: The articulating arm mounted to the console is non-sterile. Ensure that care is taken to avoid contact when making or breaking connections with the catheter.**
- Twist and remove the black plastic end cap from the main refrigerant connector on the proximal end of the catheter and let it hang by the metal chain.

- Remove the black protective plug at the catheter refrigerant connection on the end of the articulating arm and set it aside for later use in a location free from contaminants.
- Attach the catheter to the end of the articulating arm. Three connections need to be made.
 1. Align the catheter refrigerant connector with the mating receptacle on the articulating arm (non-sterile) and push the refrigerant connector in until it latches indicating it is firmly seated. Note: this connection is not keyed and can rotate freely.
 2. Locate the Luer at the proximal end of the catheter and align it with the mating pressure gauge connection at the end of the articulating arm. Grasp the body of the Luer and twist until a snug connection has been made.
 3. Locate the sensor cable connector at the proximal end of the catheter and align the key on this connector with the key indicator on the sensor cable receptacle at the end of the articulating arm. Attach the connector to the receptacle by pushing them together until the connector latches indicating it is firmly seated.
- The EKG signal output on the side of the articulating arm can be connected directly to an EKG amplifier through the bi-polar connectors identified as such.
- Advance the catheter to the desired location.
- Appropriate catheter tip deflection is achieved using finger adjustment of the steering knob. As desired, the steering knob can be secured using the brake.
- Verify catheter placement through imaging and/or appropriate EKG signal from the catheter.

System Operation

1) Depress the **Control Panel Power Switch** (front of the console). During power-up the system will go through a series of internal checks and a cycling of the system control devices. This will take approximately 15 seconds. The console will automatically begin a 120 second chilling of the pre-cooler.

Automatic	05-02-04 06:05p
PCC DELAY TIME REMAINING	
108	
Exit	PCC=158

2) After the compressor meets start-up requirements, the system automatically gives the option of exiting the pre-cooler chilling sequence. Normally, allow the chilling sequence to continue to completion.

Automatic	05-02-04 06:06p
PCC DELAY TIME REMAINING	
105	
Exit	PCC=158

3) At the end of the pre-cooler chilling sequence, the following display will appear if the sensor cable is not yet attached.

Start Up	05-02-04 06:06p
TC NOT CONNECTED	
Options	Start

- 4) When the thermocouple connection is made, the “TC CONNECTION VERIFIED” message appears. Choose “Start” to continue.

Start Up	05-02-04 06:07p
036°	
TC CONNECTION VERIFIED	
Options	Start

- 5) When initially installed, the system has a preset freeze time of 5 minutes. Use the up/down arrows to increase or decrease this freeze time: 10 minutes is the maximum, 30 seconds is the minimum. For subsequent freezes, the system will automatically default to the last freeze time input. Once the desired freeze time is displayed, press “Proceed” to initiate the ablation.

Automatic	05-02-04 06:07p
Set Freeze Time	
5:00	
Exit	Proceed

- 6) The freeze sequence now begins; the catheter tip temperature and the ablation freeze time are displayed. After a brief period the temperature will start dropping. **Note: The “Exit” button is active during all ablation conditions and can be used to terminate an ablation at anytime.**

Automatic		
036° ↓ 05:00s		
Exit		

- 7) When the tip temperature has reached -30°C , the freeze time clock begins counting down. **WARNING: Because the catheter tip adheres to tissue during freezing, reposition or remove the catheter only when the catheter tip moves freely.**

Automatic	Ablation
-046° ↓ 04:57s	
<div style="background-color: black; color: white; display: inline-block; padding: 5px 20px; margin: 5px;">Exit</div>	

- 8) At the end of the freeze “Continue?” will be displayed, choose “Yes” to begin another freeze of the same duration.

Automatic	05-02-04 06:07p
-091° ↓ 00:00s	
Dur 02:30 Avg. -088 Low -093	
<div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="background-color: black; color: white; display: inline-block; padding: 5px 15px;">No</div> <div style="background-color: black; color: white; display: inline-block; padding: 5px 15px;">Continue?</div> <div style="background-color: black; color: white; display: inline-block; padding: 5px 15px;">Yes</div> </div>	

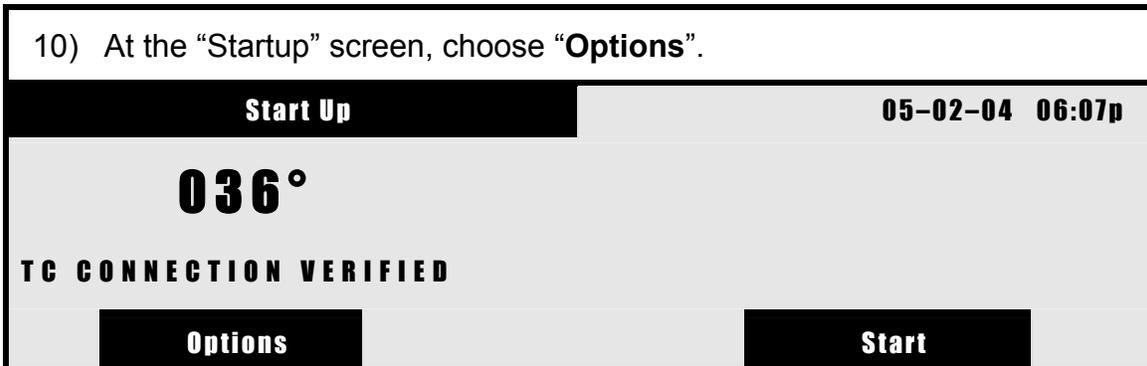
- 9) If “No” is chosen, the display returns to the beginning of the sequence. See Step #4.

Start Up	05-02-04 06:07p
036$^{\circ}$	
TC CONNECTION VERIFIED	
<div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="background-color: black; color: white; display: inline-block; padding: 5px 15px;">Options</div> <div style="background-color: black; color: white; display: inline-block; padding: 5px 15px;">Start</div> </div>	

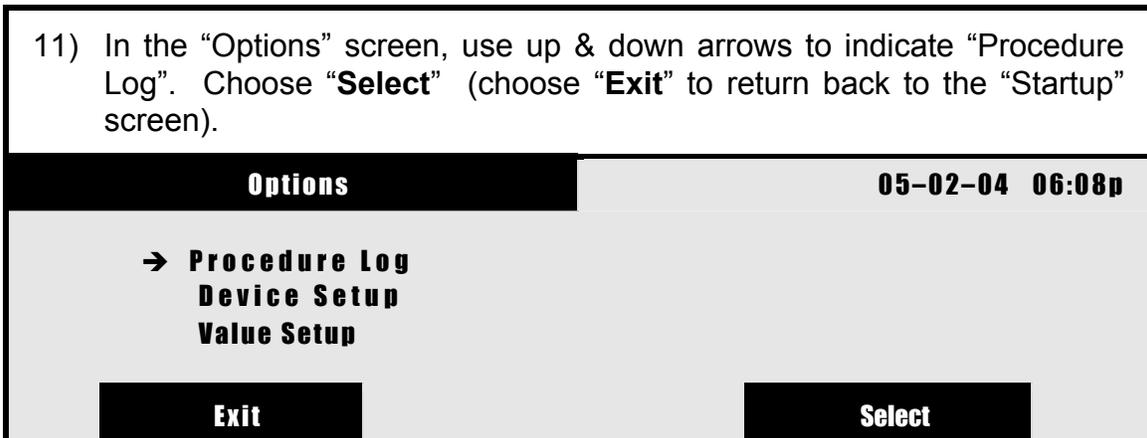
Options Menu:

Each procedure is logged according to date and time. If desired, specific ablation information may be viewed by following steps 10 through 13.

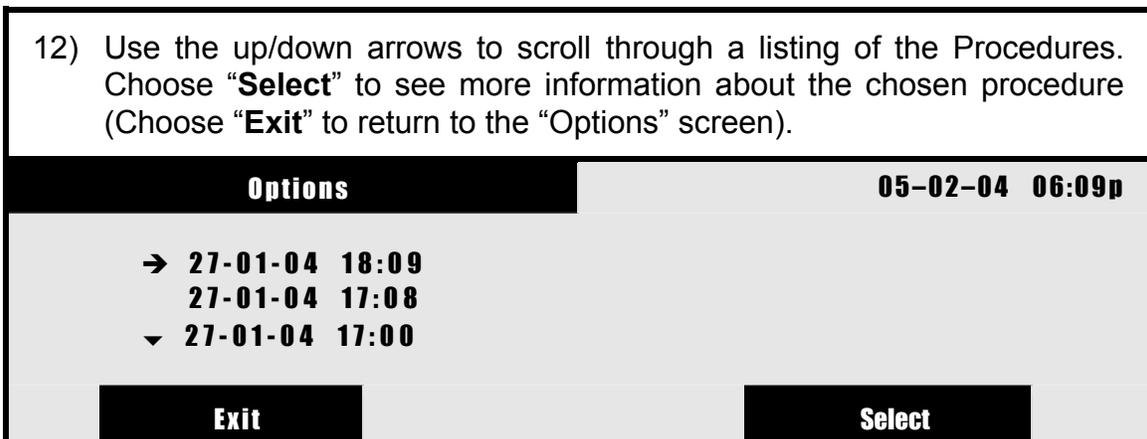
10) At the “Startup” screen, choose “Options”.



11) In the “Options” screen, use up & down arrows to indicate “Procedure Log”. Choose “Select” (choose “Exit” to return back to the “Startup” screen).



12) Use the up/down arrows to scroll through a listing of the Procedures. Choose “Select” to see more information about the chosen procedure (Choose “Exit” to return to the “Options” screen).

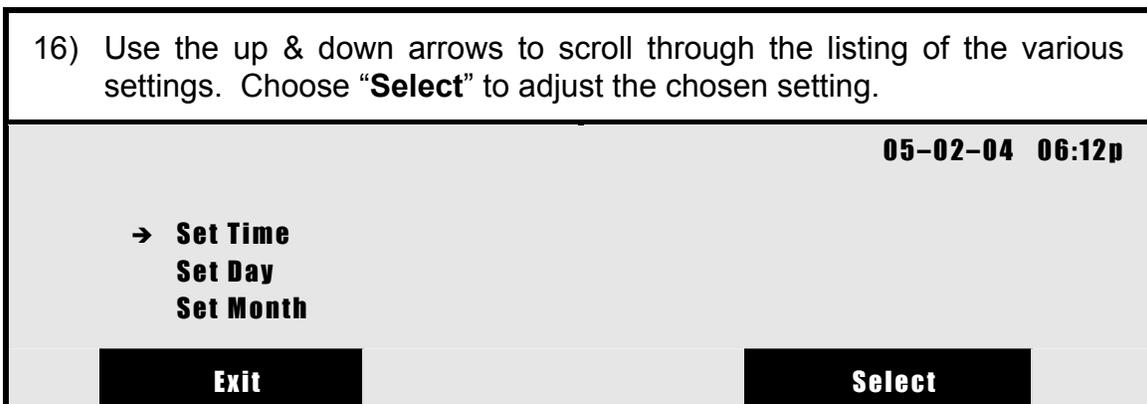
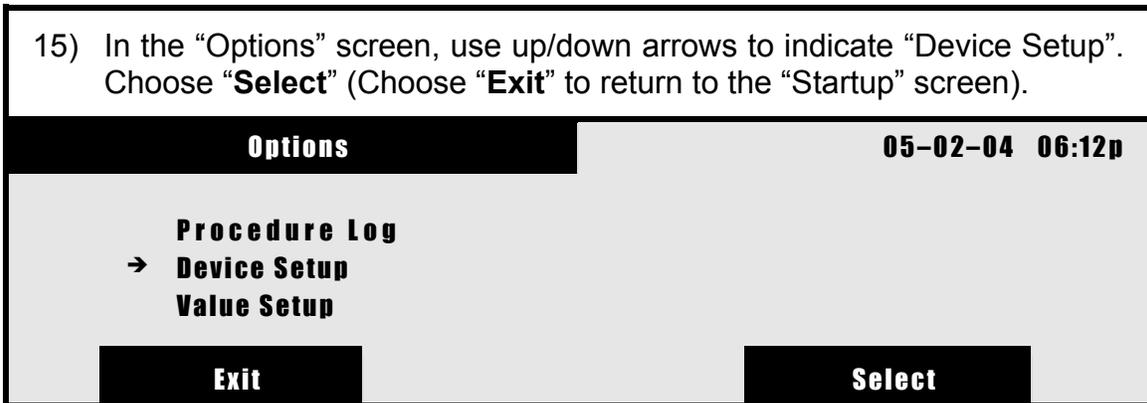
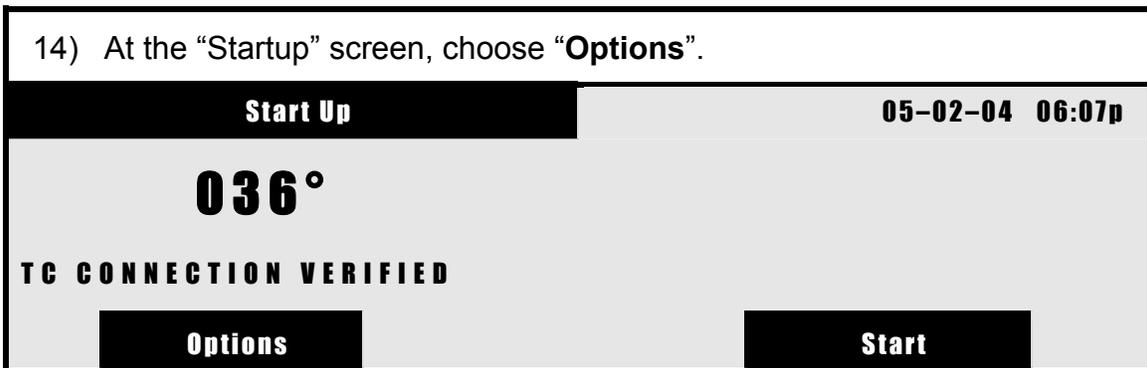


- 13) When a specific procedure is selected, the display shows parameters of the chosen procedure. Choose “**Exit**” to go back to the listing of logs in the Procedure Log.

Options		05-02-04 06:10p
Freeze Duration	02:30	
Avg. Temperature	-088	
Low Temperature	-093	
Exit		

Device Setup:

Clock settings may be changed following steps 14 through 17.



- 17) Adjust the setting using the up & down arrows; the “time” setting is shown as an example. Be sure to enter time in the 24-hour clock format (0:00 to 24:00 hours). When the correct time is displayed, press “**Select**” to set the time. The “Day”, “Month” and “Year” settings are adjusted in a similar manner.



Value Setup:

Value Setup allows for the erasure of the procedure logs by following steps 18 through 20.

- 18) In the “Options” screen, use up & down arrows to indicate “Value Setup”. Choose “**Select**”. (Choose “**Exit**” to return back to the “Startup” screen).



- 19) If “Value Setup” is selected, this screen appears.



- 20) If “Data Log Reset” is selected, the “Reset The Data Log?” screen appears. Choosing “Yes” will delete all previously stored procedure logs. Choose “No” to return to the previous screen without deleting data.



Warning and Error Messages

During system operation a variety of conditions may occur that cause the software to interrupt normal operation. For each of these conditions the console will display a message that will provide certain information, possibly allowing the user to correct the condition and continue with normal operation.

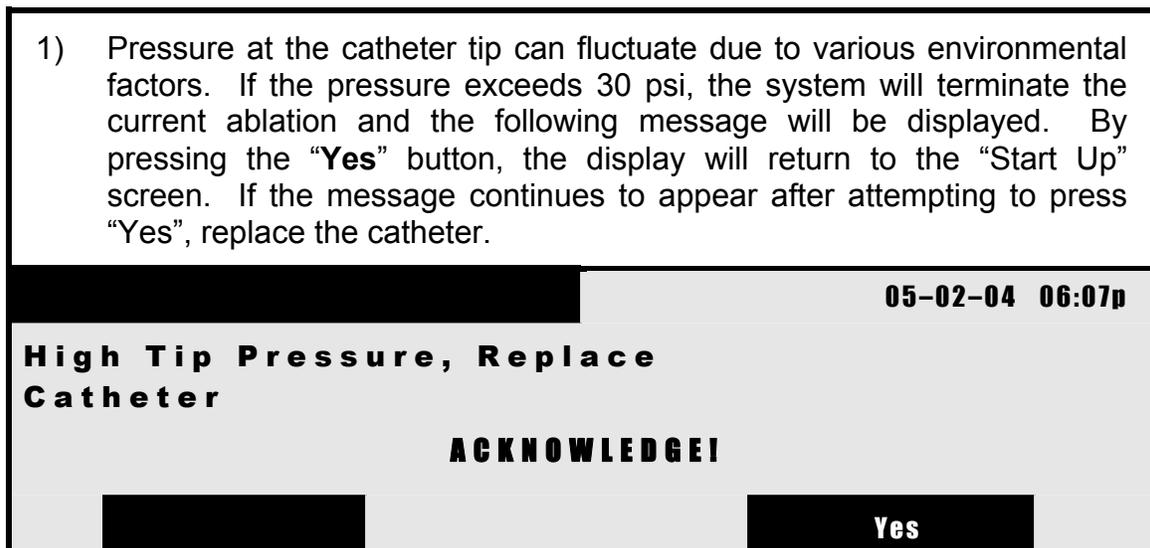
Warnings: Warning messages are displayed if conditions occur that may prevent continued safe operation of the system. The condition may, in some cases, cause the system to abort the current ablation (for instance, when catheter tip pressure rises too high) or the ablation may continue but a message will be placed on the screen (for instance, when the supply pressure is low).

Most warnings will require that the user make an acknowledgement before normal operation resumes.

Errors: Error messages are displayed if conditions exist that may prevent proper or safe operation. In the event of an Error, the display will alternately show the error message followed by a data display that provides information that may allow CryoCor personnel to more rapidly resolve the error. In the event of an error the Control Panel Power Switch will need to be cycled Off and then On to attempt to resume operation.

The following are the Warning messages and their meanings:

1) Pressure at the catheter tip can fluctuate due to various environmental factors. If the pressure exceeds 30 psi, the system will terminate the current ablation and the following message will be displayed. By pressing the “**Yes**” button, the display will return to the “Start Up” screen. If the message continues to appear after attempting to press “**Yes**”, replace the catheter.

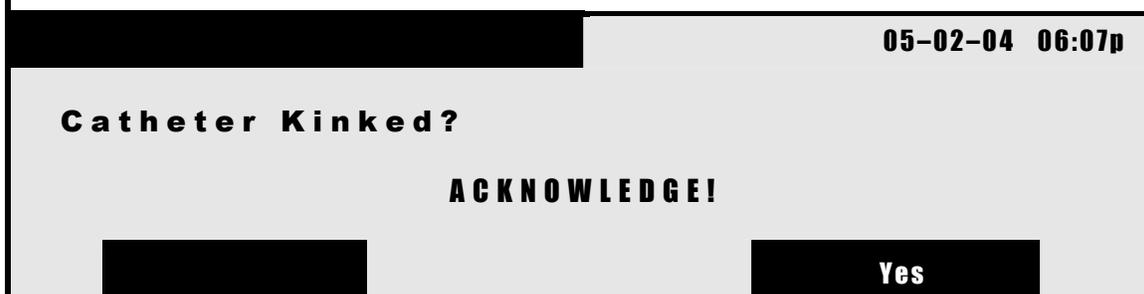


The screenshot shows a console display with a warning message. At the top right, the date and time are displayed as '05-02-04 06:07p'. The main message is 'High Tip Pressure, Replace Catheter' in bold. Below this, the word 'ACKNOWLEDGE!' is displayed in bold. At the bottom right, there is a button labeled 'Yes'.

- 2) At the “Start Up” screen, the number “1” will be displayed in the upper right corner indicating the high tip pressure condition. The ablation process can be resumed by pressing “Start”.



- 3) At the beginning of an ablation, the gas pressure at the tip of the catheter is carefully monitored to ensure that it does not rise too rapidly. If it does, the system will terminate the current ablation and the message below will be displayed indicating that the catheter lines should be inspected to ensure that refrigerant flow is not being inhibited due to kinks. By pressing the “Yes” button, the display will return to the “Start Up” screen, and the ablation may be restarted. If the message continues to appear, replace the catheter.



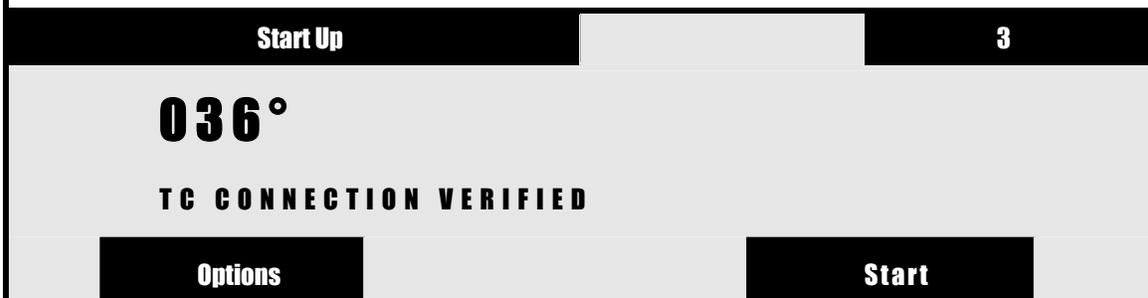
- 4) At the “Start Up” screen, the number “2” will be displayed in the upper right corner indicating a rapid increase in tip pressure. The catheter should be inspected to insure that there are no kinks along the blue corrugated tubing or along the shaft distal to the handle before attempting to resume an ablation.



- 5) At the beginning of all ablations, the first action performed by the system is the evacuation of the refrigerant lines as a means to leak check the system and ensure the catheter is connected properly. If the Luer fitting has not been connected or if there is ingress of ambient air into the system, this step will fail and the message below will be displayed. Check all three catheter connections (Refrigerant Coax connection, the Luer Fitting, and the sensor cable) before continuing. By pressing the “**Yes**” button, the display will return to the “Start Up” screen, and another ablation may be started.



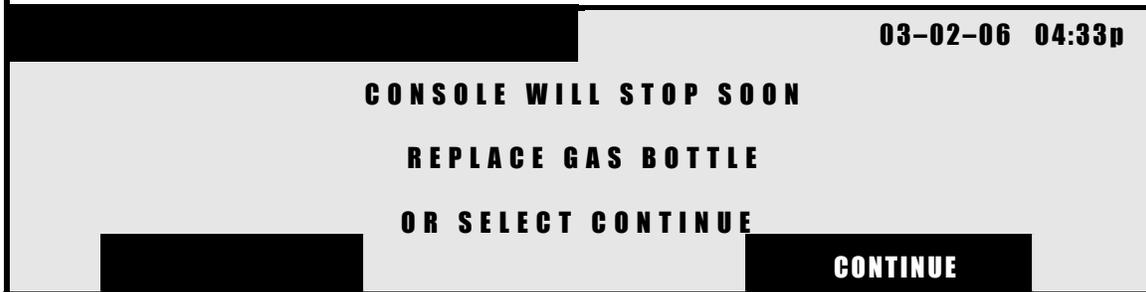
- 6) At the “Start Up” screen, the number “3” will be displayed in the upper right corner indicating the inability to properly evacuate ambient air before the start of an ablation. The connections between the catheter and the articulating arm should be checked before attempting to re-initiate an ablation.



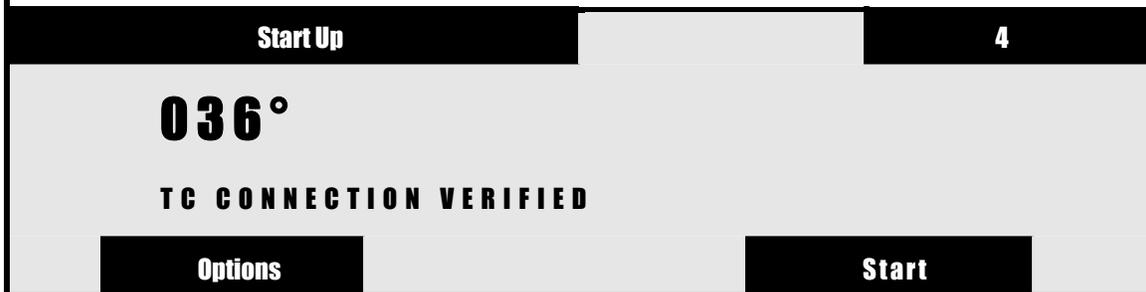
- 7) If the supply pressure is low (below 600 psia) while the “Start Up” screen is displayed, the message ‘Replace Gas Bottle’ will be alternated with the message ‘TC Connection Verified’. This is to alert the user that the supply cylinder will need to be replaced soon. If the supply pressure drops below 600 psia during an ablation, this message will also be displayed below the temperature. The following display shows the warning message for the low supply pressure. Check that the supply valves are fully open before continuing.



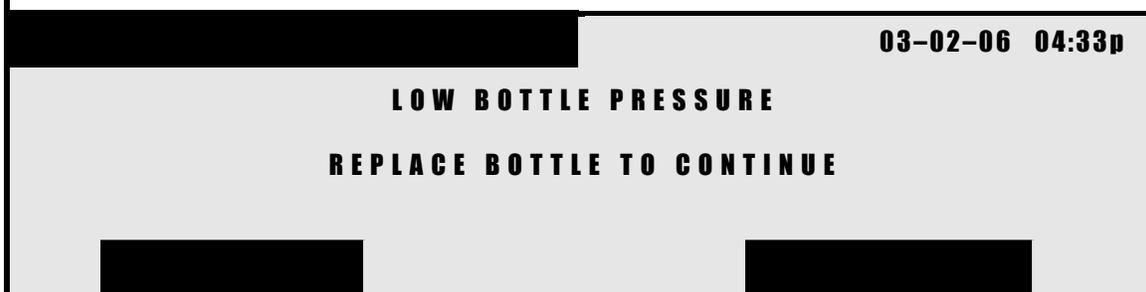
- 8) The screen below occurs during Start Up and at the end of an ablation when the bottle pressure is below 525 psia, indicating that insufficient refrigerant is present in the bottle. Degradation in performance may be observed if the pressure drops below 500. **The refrigerant bottle of N₂O should be replaced before continuing.** By pressing the **“CONTINUE”** button, the display will return to the “Start Up” screen and allow the user to perform an ablation.



- 9) At the “Start Up” screen. The number “4” will be displayed in the upper right corner indicating that insufficient refrigerant may be present to perform an ablation. **If not already replaced as noted above, the refrigerant bottle of N₂O should be replenished before continuing.**



- 10) The screen below occurs during Start Up and at the end of an ablation when the bottle pressure is below 490 psia, indicating that insufficient refrigerant is present in the bottle. Degradation in performance may be observed if the pressure drops below 500. **The refrigerant bottle of N₂O must be replaced before continuing.**



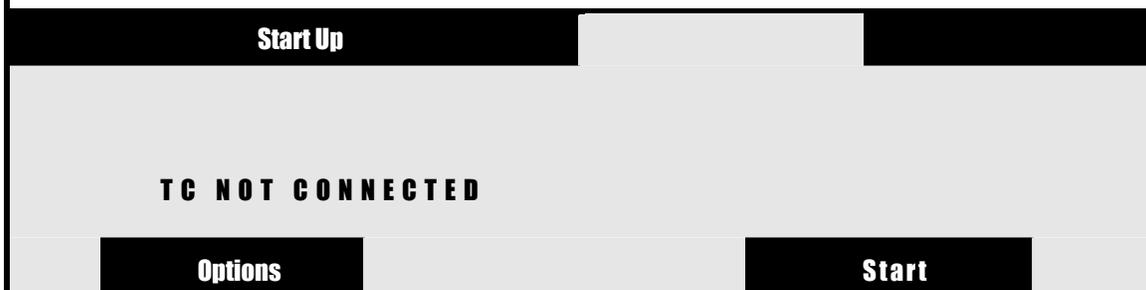
- 11) If the coaxial refrigerant connector is not fully connected, refrigerant will not flow from the articulating arm into the catheter. The system will detect this condition and display the message below shortly after an ablation has been initiated. Please check the coaxial connector for proper connection. By pressing the “Yes” button, the display will return to the “Start Up” screen, at which point the user may start another ablation. If this message continues, replace the catheter.



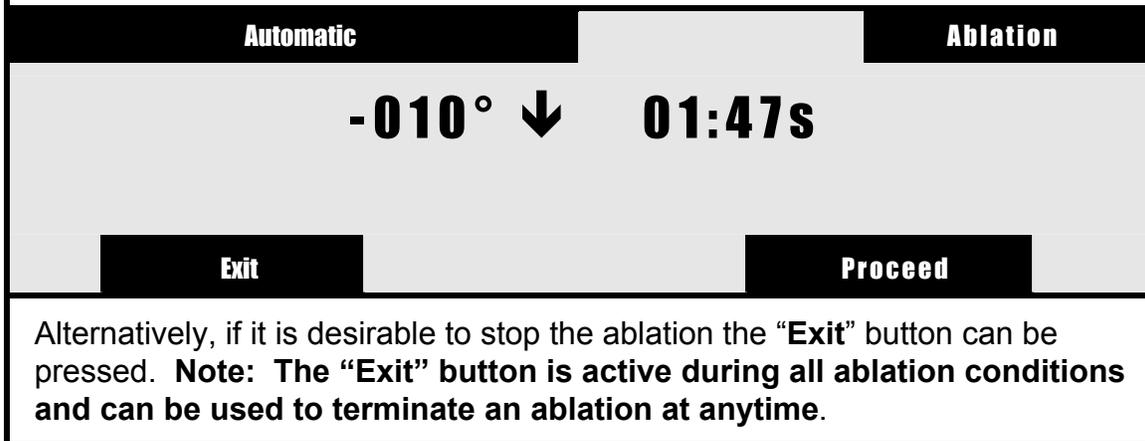
- 12) At the “Start Up” screen. The number “4” will be displayed in the upper right corner indicating the improper coax connection.



- 13) At the “Start Up” screen, if the sensor cable is not connected the following screen will be displayed. Follow instructions for connecting the catheter. If the console still displays, “TC NOT CONNECTED”, replace the catheter.



- 14) During the ablation process the tip of the catheter will be extremely cold and will adhere to any tissue it is in contact with. If for any reason the catheter should warm during the ablation period, it may be possible for the catheter tip to move away from where it was originally placed. The system monitors temperature and, once an ablation has begun, an alarm will sound if the temperature warms to a point that may allow the tip to move. The ablation will continue. The alarm can be turned off by pressing the “**Proceed**” button when it appears on the display as shown.



- 15) In the event of an Error or power interruption, when the console is restarted the internal pressures may not have had the opportunity to equilibrate with the ambient environment. In this situation the display will provide the message that the Luer Fitting (part of the catheter) be removed - when done, press “Yes” to acknowledge its removal.

05-02-04 04:33p

Remove Luer fitting

ACKNOWLEDGE!

Yes

The system will then go through a series of internal checks and a cycling of system control devices. This will take approximately 15 seconds. When the “Start Up” screen is displayed, reattach the Luer Fitting. Ablations are now able to be performed. If the message is displayed again, replace the catheter.

- 16) The following message may appear either during self-tests when the console is first started, or during operation. This message indicates a parameter did not meet its specified conditions. If the following screen appears, with XX representing the error code number, please record the error number and contact CryoCor service. Electronic Hardware Errors are not user serviceable.

05-02-04 04:35p

Electronic Hardware Error XX

- 17) Following any error conditions the display will alternate between the error message and a screen that displays a variety of sensor information. The sensor information and error number should be noted and relayed to the CryoCor representative. It will assist in the initial trouble-shooting of the console failure.

				05-02-04 04:35p	
PA = 19	PB = 258	P1 = 734		P3 = 15	
P4 = 0	P5 = 13	P6 = 497		T = 33	
Vt=+	By=+	Sp=+	PCC=+	Rec=+	

System Shut Down:

1. After the catheter is removed from the patient, depress the **Control Panel Power Switch** on the front of the console. The system will shut down.
2. Turn the main power (located at the rear of the console) to **Off**. The green LED on the front panel of the console will go out.
3. Remove the CryoCor disposable catheter from the three connectors at the end of the articulating arm (refrigerant connector, sensor cable connector, and Luer fitting).
4. **Immediately following removal of the catheter, insert the black protective plug** (supplied with the system) into the refrigerant connector at the end of the articulating arm. This is necessary to prevent condensation from forming on the interior of the orifice which could freeze and block the refrigerant lines of the system during the next ablation. Return the black plastic end cap to the proximal catheter refrigerant connector to avoid contamination within the sterile field.
5. Turn off the refrigerant supply by shutting the valve on the top of the bottle(s) used. Also rotate the ¼-turn valve (the valve with the black handle next to each bottle) so that the handle is perpendicular to the refrigerant supply line.
6. Clean and disinfect the articulating arm and console exterior according to instructions in this user manual under “Cleaning and Disinfection.” After cleaning, pivot the articulating arm and store behind the top cover; tighten the locking knobs.

WARNING:

If, when removing the catheter from the articulating arm connections, there is any sign of blood in the connectors, the entire system must be considered blood contaminated; blood may have entered the refrigeration system. Notify CryoCor immediately.

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

NOTE:

After each procedure, the system should be turned off (by depressing the control panel power switch) and the refrigerant bottle valve and the supply line ¼-turn valve should be closed.

Cleaning and Disinfection:

The exterior of the console and the articulating arm can be cleaned and with a towel or cloth soaked in 70% isopropyl alcohol.

WARNING:

When cleaning, do not allow liquid of any kind to enter the catheter refrigerant connection on the end of the articulating arm; this liquid could freeze and block refrigerant flow through the catheter.

Storage Conditions:

Temperature: -20 °C (-4 °F) to +60 °C (+140 °F)

Relative Humidity: 10% – 95%

Allow console to remain at Operating Conditions (shown below) for at least 5 hours prior to use.

Operating Conditions:

Temperature: +15 °C (+59 °F) to +30 °C (+86 °F)

Relative Humidity: 15% – 75%

Max. Elevation 3600 ft

Service:

If the CryoCor Cardiac Cryoablation System is determined to be inoperable, please contact CryoCor at **858-909-2200** for assistance. If field service is not possible, instructions for cleaning and repackaging the Console for return to CryoCor for repair or service will be provided.

CryoCor, Inc.
 9717 Pacific Heights Blvd.
 San Diego, CA 92121
 1-858-909-2200
 1-858-909-2300 (Fax)

Caution to Service Personnel:

Removal of the access panel or exterior cowling will expose personnel to dangerous high voltages.

Fuse Replacement:

The console has two fuses, both located in the input power module at the bottom rear of the console. To access, use a blade screwdriver to gently pry open the fuseholder door; swing open the door, and use the screwdriver to pry the sides of the red fuseholder to lift it out of the module.

Within the fuseholder are the two fuses; one or both may be blown and will require replacement. Pry out the fuse(s) from the fuseholder, and inspect for integrity.

Fully insert the replacement fuse(s) into the metal contacts in the fuseholder. Orient the fuseholder so that the correct voltage listed (115 V) will show through the window in the fuseholder door. Insert the fuseholder into its compartment, until it is fully seated. Swing the fuseholder door closed, and snap shut.

IMPORTANT:

Verify that the correct voltage is indicated in the window of the fuseholder door.

Replacement fuses are as follows:

Fuse Type	Vendor & Part Number	CryoCor Part Number
10 A, 250 VAC, Time Delay	Panel Components Corporation (Interpower Corporation) 1 641 673-5000 P/N 813MDA-10	090-04018-003

Maintenance:

All system maintenance must be performed by CryoCor personnel.

Please do not attempt to perform service to the system. Refrigerant bottle replacement and fuse replacement, as described in this manual, are the only user serviceable components.

Shipping Crate and Packing Materials:

The supplied shipping crate and foam packing materials are intended for re-use in the event that the system must be returned for service. Retain these materials; do not discard after uncrating the system.

CryoCor, Inc.
9717 Pacific Heights Blvd.
San Diego, CA 92121
1-858-909-2200
1-858-909-2300 (Fax)

