

# **POLARx**<sup>™</sup> Cryoablation System

# Troubleshooting Guide

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information not intended for use or distribution in France



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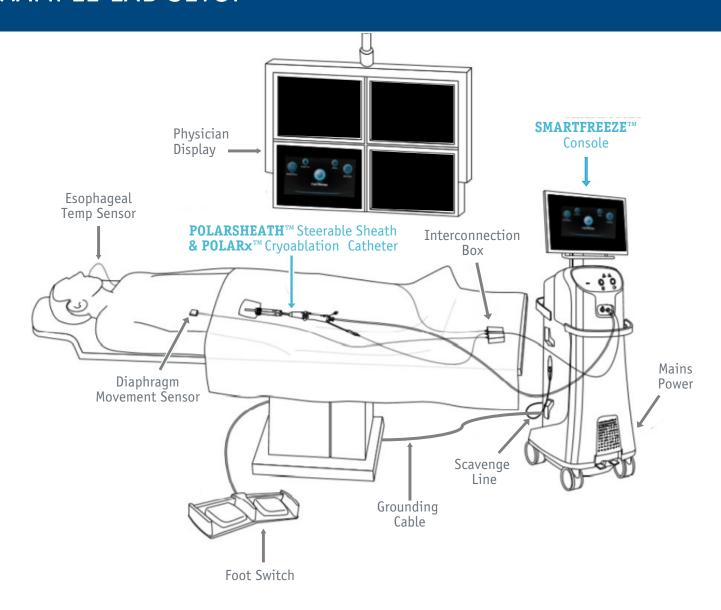
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### **EXAMPLE LAB SETUP**



## POLARx<sup>™</sup> Cryoablation System **Troubleshooting Guide**



ERROR 1-00004000-2 OR ERROR 1-00008000-2

### CONSOLE DETECTED BLOOD IN THE CATHETER

### WHAT

Error 1-00004000-2 The console detected blood in the catheter.

#### 0R

Error 1-00008000-2 The console detected a problem with the blood detection circuit of the catheter. Blood detection wires are open.

#### **Possible Causes:**

- · Blood detection sensor wires short circuit
- Inner or outer balloon breach
- Guidewire lumen breach

### **Potential Procedural Impact:**

Requires catheter exchange.

- 1. Avoid re-inflating the balloon after blood detection error.
- 2. Write down error code.
- 3. Clear error if system allows.
- 4. Do not attempt to reapply vacuum.
- 5. Elongate balloon by extending the slider switch and re-sheath balloon for removal.
- 6. Disconnect cryo-cable (gas) from console.
- 7. Replace balloon catheter AND cryo-cable.
- 8. Retain catheter and cryo-cable for return/error analysis.
- 9. If case done independently, notify BSC Sales Rep of occurrence details.



ERROR - GENERAL

### CATHETER INSERTION DIFFICULTY

### **WHAT**

Difficulty inserting the POLARx™ Cryoablation Catheter into the POLARSHEATH™ Steerable Sheath.

#### **Possible Causes:**

- Balloon Catheter not deflated with slider switch
- Insertion Tool not fully engaged in valve well
- Catheter/sheath diameter misfit

#### **Potential Procedural Impact:**

May require catheter and/or sheath replacement.

- 1. Ensure insertion tool is engaged in valve well but doesn't penetrate valve itself.
- 2. Reattempt insertion.
- 3. If problem persists, re-prep the balloon and deflate by pushing the slider switch fully forward to elongate and wrap the balloon.
- 4. Re-sheath in Insertion Tool and attempt insertion again.
- 5. If no success, exchange catheter first, then sheath if not resolved.



Insertion Tool



ERROR 1-00000020-2

### OUTER BALLOON PRESSURE IS TOO HIGH

### **WHAT**

Error 1-0000020-2 Outer Balloon Pressure (OBP) is too high.

#### **Possible Causes:**

- Cryo-cable (gas) misconnection
- Cryo-cable (gas) leak
- Outer balloon breach
- Console hardware issue

### **Potential Procedural Impact:**

May require cryo-cable replacement or catheter exchange if error not resolved.

- 1. Disconnect and reconnect the cryo-cable (gas) at the console and the catheter. Ensure well aligned connection to console with audible click.
- 2. If problem persists, replace the cryo-cable (gas).
- 3. If problem persists, replace the catheter.
- 4. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pq 29)



Cryo-cable (gas)



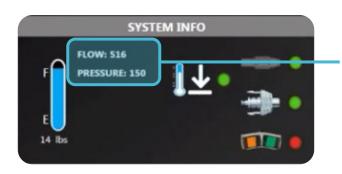
### FLOW OSTRUCTION ERRORS

### **BACKGROUND INFORMATION**

- The catheter delivers N<sub>2</sub>0 during inflation and ablation.
- At inflation, the catheter delivers low pressure, low flow N<sub>2</sub>O to inflate the balloon without creating a therapeutic effect.
- During ablation, the catheter switches to a flow-controlled mode in which it increases and modulates pressure to meet the flow rate necessary for ablation (~7800sccm).
- The point at which the console switches to flow-controlled mode is called transition and occurs when flow is >4500sccm.
- This usually occurs 15 ± 5 seconds after starting ablation and is noted by an audible beep from the console.

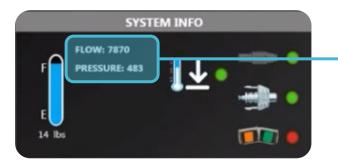
To help diagnose the cause of the error, it is important to monitor Flow/Pressure history during the procedure from the System Info section in the bottom right of the Therapy Screen.

There are 5 Separate Flow Obstruction Error Codes: Write down specific error.



During inflation, Pressure should be 150psig ± 5

Flow rate varies, but if <700, as shown here, indicates poor system performance



During ablation,  $N_2O$  flow rate should be  $7800 \pm 400$ 

Pressure varies, but if >550 and increases with successive ablations, may indicate poor catheter performance

See next page for N<sub>2</sub>O Delivery Reference Values =



### N<sub>2</sub>0 DELIVERY REFERENCE VALUES

| System State      |                        | INFLATION              | ABLATION                        |  |
|-------------------|------------------------|------------------------|---------------------------------|--|
| Control Parameter |                        | Pressure<br>@ 150 psig | Flow<br>@ 7800 sccm             |  |
| FLOW              | "Good" Clinical Range  | > 750                  | 7,800 ± 400<br>~3,000 (dynamic) |  |
| (sccm)            | Error – Low Threshold  | 0                      |                                 |  |
|                   | Error – High Threshold | 5,000                  | 10,000                          |  |
| PRESSURE          | "Good" Clinical Range  | 150 ± 5                | <525                            |  |
| (psig)            | Error – Low Threshold  | N/A                    | N/A                             |  |
|                   | Error – High Threshold | 250                    | 680                             |  |

Transition Time = 15s +/- 5s

In the **INFLATION state**, abnormal PRESSURE is indicative of a potential console valve or subcooler issue. Conversely, low FLOW is indicative of a cryo cable or catheter obstruction.

In the **ABLATION state**, high PRESSURE is indicative of a cryo cable or catheter obstruction. Conversely, abnormal FLOW is indicative of a potential console valve or controller issue.



FLOW OBSTRUCTION ERROR 2-00001000-1

### INJECTION PRESSURE IS TOO HIGH

### **WHAT**

Error 2-00001000-1 The injection pressure is too high.

#### **Possible Causes:**

- Console valve issue (if triggered at inflation)
- Catheter or Cryo-cable (gas) obstruction (if triggered during ablation)

### **Potential Procedural Impact:**

May require cryo-cable (gas) exchange or catheter replacement.

### WHAT TO DO

#### Action if error occurs DURING INFLATION:

- 1. Disconnect and reconnect the cryo-cable (gas).
- 2. Attempt another inflation.
- 3. If persistent replace cable first, then the catheter, if not resolved.

#### Action if error occurs DURING ABLATION:

- 1. Disconnect and reconnect the cryo-cable (gas).
- 2. Replace cryo-cable (gas).
- 3. Attempt another ablation.
- 4. If problem persists, replace the catheter.
- 5. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pq 29)



Cryo-cable (gas)



FLOW OBSTRUCTION ERROR 2-00000008-1

### REFRIGERANT FLOW OBSTRUCTION DETECTED

### **WHAT**

Error 2-00000008-1 Refrigerant flow obstruction detected. This error code occurs during Ablation.

#### **Possible Causes:**

- Catheter cryo-cable (gas) disconnected
- Flow obstruction in cryo-cable (gas)
- Flow obstruction in the catheter
- Flow obstruction in the console

### **Potential Procedural Impact:**

May require cryo-cable (gas) exchange, catheter exchange or minor prolongation (5min) of procedure time if console shut down required.

- 1. Disconnect and reconnect the cryo-cable (gas) at catheter and console.
- 2. Attempt another ablation.
- 3. If problem persists, replace the cryo-cable (gas).
- 4. If problem persists, replace the catheter.
- 5. If problem persists, turn off unit and let sit for 5 minutes. Then try again.
- 6. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pq 29)



Cryo-cable (gas)



FLOW OBSTRUCTION ERROR 2-00004000-1

### RETURN LINE PRESSURE IS TOO HIGH

### **WHAT**

Error 2-00004000-1 Flow obstruction detected. The return line pressure is too high. This error can occur during Inflation, Transition, Ablation, or Thawing.

### **Possible Causes:**

- Cryo-cable (gas) disconnected
- Obstruction in cryo-cable
- Obstruction in catheter

### **Potential Procedural Impact:**

May require cryo-cable or catheter exchange.

- 1. Disconnect and reconnect the cryo-cable.
- 2. If problem persists, replace the cryo-cable.
- 3. If problem persists, replace the catheter.
- If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707.
   (See full list of TAC Numbers by Country on Pg 29)



Cryo-cable (gas)



FLOW OBSTRUCTION ERROR 2-00400000-1

### SCAVENGING LINE PRESSURE IS TOO HIGH

### **WHAT**

Error 2-00400000-1 Scavenging line pressure is too high. This error can occur in any state: Idle, Ready, Inflation, Ablation, Thawing.

#### **Possible Causes:**

- Misconnection of the scavenging hose
- Hospital scavenging system not active or wall inlet valve not open
- · Kink in scavenging hose

### **Potential Procedural Impact:**

Potential for postponement of procedure if unable to resolve.

### WHAT TO DO

- 1. Ensure scavenging hose is securely attached at console and wall adapter.
- 2. Ensure hospital scavenging system is working properly.
- 3. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pq 29)



Scavenging Line



FLOW OBSTRUCTION ERROR 2-0001000-1

### VACUUM LINE PRESSURE IS TOO HIGH

### **WHAT**

Error 2-0001000-1 Flow obstruction detected. Vacuum line pressure is too high. This error can occur during Idle, Ready, Inflation, Ablation, or Thawing.

#### **Possible Causes:**

- Insertion of scavenging hose to hospital exhaust system (transient, self-resolving error)
- Failed vacuum pump in console
- Obstruction in return gas line of console

### **Potential Procedural Impact:**

Potential for postponement of procedure if unable to resolve.

- 1. Clear the error.
- 2. Attempt another ablation.
- 3. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pg 29)



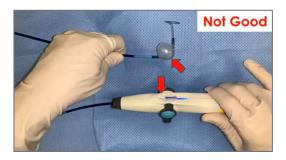
### GUIDEWIRE LUMEN BUCKLING

### **GENERAL INFORMATION**

- The guidewire lumen is a sheath within the sheath. At the proximal end, it is connected to the slider switch and ends distally at the tip of the catheter.
- When the balloon inflates, the lumen shortens and pushes the slider switch back to a neutral position on handle.
- On occasion, the slider switch may meet resistance in the shaft and does not move back completely.
- If it doesn't move back into its resting slot in the neutral position, the guidewire lumen may bend or buckle.











### GUIDEWIRE LUMEN BUCKLING

### **PREVENTION**

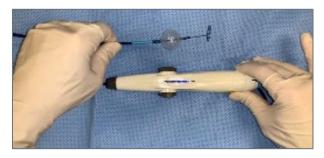
During inflation at preparation:

- Ensure balloon shaft not tightly looped (adds resistance to guidewire lumen ability to move to appropriate position).
- Advance POLARMAP™ Circular Mapping Catheter well beyond tip of balloon during prep to provide support over stiffer wire portion of catheter.

Note: Prevention of buckling during prep helps prevent recurrence during inflation in vivo.

### **Best Practice to prevent buckling during catheter preparation:**

"Standard" Prep (mapping catheter more proximal)



"More Support" Prep (mapping catheter more distal)





### GUIDEWIRE LUMEN BUCKLING

### IN VIVO: WHAT TO DO

Guidewire lumen buckling during procedure.

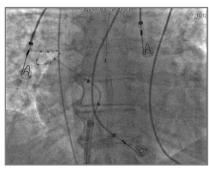
#### **Possible Causes:**

Slider switch not retracted to neutral position

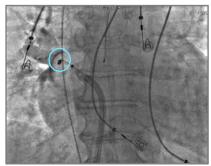
### **Potential Procedural Impact:**

If persistent, may require catheter replacement. Do not ablate with buckled guidewire lumen as it may result in:

- Altered temperature readings (displaced thermocouple)
- Kinking of injection tube
- Guidewire lumen damage
- 1. Do not push slider switch forward.
- 2. Manually pull slider switch back as far as possible.
- 3. Observe catheter under fluoroscopy to make sure guidewire lumen is straightened.
- 4. If corrected, proceed with procedure.
- 5. If not corrected, deflate the catheter using the slider switch to reposition.



Example 1: Guidewire lumen buckling (lumen displaced from center)



Example 2: Guidewire lumen buckling

Catheter should be repositioned prior to ablation



### **RE-SHEATHING DIFFICULTY**

### **WHAT**

Difficulty re-sheathing the POLARx™ Cryoablation Catheter into the POLARSHEATH™ Steerable Sheath.

#### **Possible Causes:**

- Possible bunching of balloon
- Catheter not deflated using slider switch

### **Potential Procedural Impact:**

May require catheter and/or sheath removal or replacement.

### WHAT TO DO

Emphasize that the POLARx Catheter should retract smoothly into the sheath. If it does not, advise the following:

- 1. Inflate and use the slider switch to deflate and extend the balloon.
- 2. Check fluoro or other imaging modality to identify if, and where, there is a possible obstruction (see image).
- 3. Perform another inflation and deflation cycle maintaining strong forward pressure on the slider switch while attempting to re-sheath.
- 4. If difficulty persists and access to the LA is still needed, exchange the POLARMAP™ Circular Mapping Catheter for a guidewire (>220cm) and advise physician to remove POLARSHEATH Introducer Sheath and POLARx Catheter together from the groin.



Possible distal "bunching"



### MONITOR BLANK ON POWER UP

### **WHAT**

SMARTFREEZE™ Console monitor blank on console power up.

#### **Possible Causes:**

- Possible power supply issue
- Possible monitor failure
- Possible computer issue

#### **Potential Procedural Impact:**

Depends on root cause.

- 1. Power down and reboot the SMARTFREEZE Console.
- Check monitor for loose cable connections on the back/ underneath side of the monitor.
- 3. Power on the console.
- 4. Ensure the green power light is illuminated.
  - If not, touch the small rectangular power button on the bottom right corner of the monitor.
- 5. Reboot system.
- If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pq 29)



Cable Connections/Back of Monitor







### MONITOR NOT RECOGNIZED (EXTERNAL)

### **WHAT**

SMARTFREEZE™ monitor is not shared to external monitor as expected.

#### **Possible Causes:**

- Incorrect power up sequence

  The video cabling must be connected to the external monitor, and the external monitor powered on before the console is powered up
- Faulty HDMI cable or adapter

### **Potential Procedural Impact:**

None

- 1. Power down the SMARTFREEZE console.
- 2. Make the appropriate connection to the external monitor from the HDMI port on the back of the console.
  - If used, ensure the HDMI to DVI adapter is fully seated in the console HDMI port.
  - If adapter is being used and it requires power, ensure adapter is powered on appropriately.
    - If using the fiber optic cables and adapter, ensure the transceiver module's green lights are on to indicate it is receiving power.
    - Ensure same fiber optic pair is being used at both ends. Also try using the other pair.
- 3. Power on the external monitor.
- 4. Power on the console.
- 5. Check source 'input' selection on external monitor and choose the input that the cable is physically connected to.
- 6. Ensure resolution of monitor accommodates 16:9 format.
- 7. If problem persists, change HDMI cable, then adapter.
- 8. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pg 29)



HDMI Cable



**DVI** Adapters



ERROR 2-00000200-1

### TANK PRESSURE IS TOO LOW

### **WHAT**

Error 2-00000200-1: The tank pressure is too low.

#### **Possible Causes:**

- Tank valve partially open
- Tank too cold
- Tank empty and scale is displaying inaccurate weight

#### **Potential Procedural Impact:**

Need for Change Tank process.

- 1. Open back of console and ensure tank valve is completely open.
- 2. Turn on console, change tank, close door, and let tank warm.
  - Enter 'Change Task' and observe tank pressure. Pressure should be greater than 680psig.
- 3. If insufficient pressure once tanks is warm, change tank.
- 4. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pg 29)





ERROR 2-0000400-1

### TANK PRESSURE IS TOO HIGH

### **WHAT**

Error 2-0000400-1: The tank pressure is too high.

#### **Possible Causes:**

- Warm temperatures within the tank compartment may cause the gas within the tank to expand, triggering the error
- Tank compartment cooling fans not running
- Tank may be overfull

### **Potential Procedural Impact:**

None

- 1. Open back of console to allow cooling of the compartment (may take several minutes).
- 2. Ensure the fans are running.
- 3. If problem persists, reboot console.
- 4. If the alarm happens when a new tank is installed, the tank may be overfull. Install the tank as normal and follow the Change Tank procedure twice. This will siphon off some of the gas in the tank.
- 5. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pq 29)





Tank compartment door



FRROR - GENERAL

### TANK WEIGHT INACCURATE

### **WHAT**

Tank weight weighs more or less than expected value at time of change out or upon bootup.

#### **Possible Causes:**

- Tank used does not match tank selected in console
- Tank scale not calibrated appropriately
- Items resting on top of tank
- Console tank hose not appropriately looped

### **Potential Procedural Impact:**

None

- 1. Open back of console and slightly reposition the tank on the scale.
  - Reevaluate tank weight reading to see if it was corrected.
- 2. Ensure unwarranted items (lab supplies) are not resting on top of the tank or scale, or that console door is not impinging the console tank hose.
- 3. Ensure the console tank hose is not exerting any additional weight on the tank.
- 4. Ensure the tank selected in the software matches the tank being used. If this is incorrect, the new weight must be entered, system rebooted, and the on-screen tank change process completed for the system to accept the changes.
- 5. If problem persists, contact BSC Europe Technical Assistance Center at 00800 5555 7707. (See full list of TAC Numbers by Country on Pq 29)



Tank Scale



Appropriate console tank hose looping



Inappropriate console tank hose looping may exert additional weight on the tank scale



ERROR - GENERAL

### SHUT DOWN (UNEXPECTED)

### **WHAT**

Reported shutdown of a console in the middle of a procedure. In some instances, patient procedural information in the console is not available.

#### **Possible Causes:**

- Power cord disconnected or not firmly seated at wall or console inlet
- Software issue
- Hardware issue Single Board Computer (SBC)

### **Potential Procedural Impact:**

Low risk; balloon automatically deflates and N2O delivery stops. Procedure may continue once system reboots and session continues.

- 1. Check power cord connection at wall power outlet and back of console.
- 2. Reboot the console.
  - Reboot to the main screen can take up to 2.5 minutes.
- 3. Try to Reload Previous Patient from the patient information screen.
  - If unable to reload, create a new patient identifier and resume procedure; i.e., same patient name with a #2 suffix on the patient identifier number.
- 4. Verify balloon position on imaging.
- 5. If re-sheathing is necessary, inflate and deflate balloon with slider switch.
- 6. Proceed with procedure.





### DMS NOT DETECTING SIGNAL

### **WHAT**

Diaphragm Movement Sensor (DMS) not detecting pacing well.

#### **Possible Causes:**

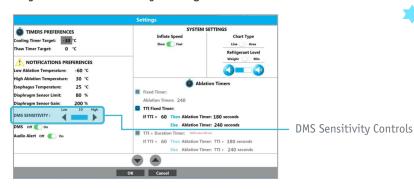
- Insufficient capture from the pacing catheter
- DMS sensor not paced in optimal position
- Dampening of signal by palpation over the DMS sensor
- DMS Sensitivity needs to be increased

### **Potential Procedural Impact:**

Inability to use DMS sensor during procedure for adjunctive monitoring.

### WHAT TO DO

- 1. Ensure stable pacing location with sufficient output to capture phrenic nerve consider wider spaced bipole or increasing output (mA).
- 2. Ensure palpation not directly on top of the sensor.
- 3. Pace at faster rate (range 600-1000ms).
- 4. Adjust DMS sensitivity to higher number.



Central Tendon (insertion)

Sub-xiphoid

Place DMS sensor 2-4cm subxiphoid or right subcostal (blue area) where max inhalation/exhalation breathing pattern is noted or max movement when patient instructed to cough.

5. Reposition sensor.



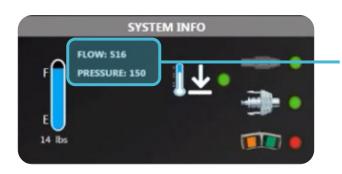
### FLOW OSTRUCTION ERRORS

### BACKGROUND INFORMATION

- The catheter delivers N<sub>2</sub>0 during inflation and ablation.
- At inflation, the catheter delivers low pressure, low flow N<sub>2</sub>O to inflate the balloon without creating a therapeutic effect.
- During ablation, the catheter switches to a flow-controlled mode in which it increases and modulates pressure to meet the flow rate necessary for ablation (~7800sccm).
- The point at which the console switches to flow-controlled mode is called transition and occurs when flow is >4500sccm.
- This usually occurs 15 ± 5 seconds after starting ablation and is noted by an audible beep from the console.

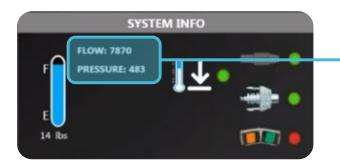
To help diagnose the cause of the error, it is important to monitor Flow/Pressure history during the procedure from the System Info section in the bottom right of the Therapy Screen.

There are 5 Separate Flow Obstruction Error Codes: Write down specific error.



During inflation, Pressure should be 150psig ± 5

Flow rate varies, but if <700, as shown here, indicates poor system performance



During ablation,  $N_2O$  flow rate should be  $7800 \pm 400$ 

Pressure varies, but if >550 and increases with successive ablations, may indicate poor catheter performance



### N<sub>2</sub>0 DELIVERY REFERENCE VALUES

| System State      |                        | INFLATION              | ABLATION            |  |  |
|-------------------|------------------------|------------------------|---------------------|--|--|
| Control Parameter |                        | Pressure<br>@ 150 psig | Flow<br>@ 7800 sccm |  |  |
| FLOW              | "Good" Clinical Range  | > 750                  | 7,800 ± 400         |  |  |
| (sccm)            | Error – Low Threshold  | 0                      | ~3,000 (dynamic)    |  |  |
|                   | Error – High Threshold | 5,000                  | 10,000              |  |  |
| PRESSURE          | "Good" Clinical Range  | 150 ± 5                | <525                |  |  |
| (psig)            | Error – Low Threshold  | N/A                    | N/A                 |  |  |
|                   | Error – High Threshold | 250                    | 680                 |  |  |

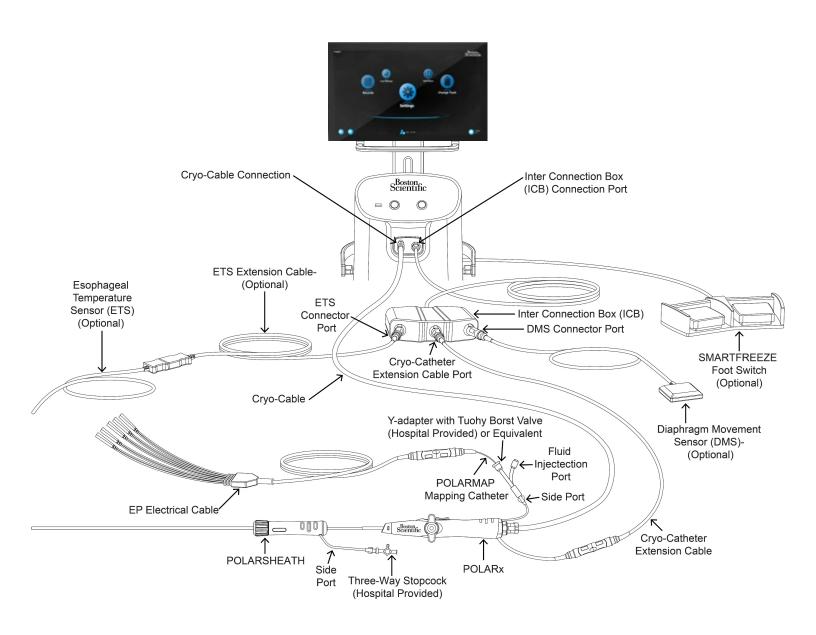
Transition Time = 15s +/- 5s

In the **INFLATION state**, abnormal PRESSURE is indicative of a potential console valve or subcooler issue. Conversely, low FLOW is indicative of a cryo cable or catheter obstruction.

In the **ABLATION state**, high PRESSURE is indicative of a cryo cable or catheter obstruction. Conversely, abnormal FLOW is indicative of a potential console valve or controller issue.



### POLARx™ CRYOABLATION SYSTEM CONNECTION DIAGRAM



### **POLARx**™ Cryoablation System



### SMARTFREEZE™ CONSOLE ERROR CODES & STATES

| Error #        | Error Description  | IDLE | READY | INFLATION | ABLATION | THAWING | Engineering Message   |
|----------------|--|------|-------|-----------|----------|---------|---|
| 00000020-1     | Low refrigerant level in the tank.   | Х    | Х     | Х         | Х        | Х       | Warning - 00000020-1 Low refrigerant level in the tank. (LC1)   |
| 00000200-1     | The tank pressure is too low.  | Х    | Х     | Х         | Х        | Х       | Warning - 00000200-1 Tank pressure is too low. (PT1)  |
| 00040000-1     | The subcooler temperature is too high.   | Х    | Х     | Х         | Х        | Х       | Warning - 00040000-1 Subcooler temperature is too high. (TS1)   |
| 00200000-1     | The system has detected a stuck command.   | Х    | Х     | Х         | Х        | Х       | Warning - 00200000-1 The system has detected a stuck command (start/stop pushbuttons or foot switch or GPIO). |
| 1 - 00000004-2 | The inner balloon pressure is too high.  | Х    | Х     | Х         | Х        | Х       | Error 1 - 00000004-2 Inner balloon pressure is too high. (IBP)  |
| 1 - 00000008-2 | The inner balloon pressure is too low.   |      |       |           | Х        | Х       | Error 1 - 00000008-2 Inner balloon pressure is too low. (IBP)   |
| 1 - 00000020-2 | The outer balloon pressure is too high.  | Х    | Х     | Х         | Х        | Х       | Error 1 - 00000020-2 Outer balloon pressure is too high. (OBP)  |
| 1 - 00001000-2 | The balloon temperature is too low. The catheter might be too deep in the vein.        | X    | X     | Х         | Х        | Х       | Error 1 - 00001000-2 Balloon Temperature Too Low  |
| 1 - 00004000-2 | The console detected blood in the catheter.  | Х    | Х     | Х         | Х        | Х       | Error 1 - 00004000-2 Blood was detected in the catheter.  |
| 1 - 00008000-2 | The console detected a problem with the blood detection circuit in the catheter.       | X    | X     | Х         | Х        | Х       | Error 1 - 00008000-2 Blood detection wires are open.  |
| 2 - 00000001-1 | The console has detected a hardware problem.   | Х    | Х     | Х         | Х        | Χ       | Error 2 - 00000001-1 CPLD Watch Dog timer error.  |
| 2 - 00000002-1 | The console has detected a hardware problem.   | Х    | Х     | Х         | Х        | Х       | Error 2 - 00000002-1 CMCU two multiplex readings do not match.  |
| 2 - 00000002-2 | The console has failed the self test.  | Х    | Х     | Х         | Х        | Х       | Error 2 - 00000002-2 Patient microcontroller failed the self test.  |
| 2 - 00000004-1 | High refrigerant flow detected.  | Х    | Х     | Х         | Х        | Χ       | Error 2 - 00000004-1 High refrigerant flow detected. (FM1)  |
| 2 - 00000008-1 | Refrigerant flow obstruction detected.   |      |       |           | Х        |         | Error 2 - 00000008-1 Refrigerant flow obstruction detected. (FM1)   |
| 2 - 00000010-1 | The console detected that the catheter was electrically disconnected during treatment. |      |       | Х         | Х        | Х       | Error 2 - 00000010-1 The Catheter connected signal from the PMCU was lost when vacuum was applied.            |
| 2 - 00000040-1 | Insufficient refrigerant level in tank to perform a procedure.                         | X    | Х     | Х         | Х        | Х       | Error 2 - 00000040-1 Insufficient refrigerant level in the tank. (LC1) $$                                     |
| 2 - 00000080-1 | The console detected that the vacuum was disabled unexpectedly.                        |      |       | Х         | Х        | X       | Error 2 - 00000080-1 The injection enable or vacuum enable signal(s) were lost when vacuum was applied.       |
| 2 - 00000400-1 | The tank pressure is too high.   | X    | Х     | Х         | Χ        | Χ       | Error 2 - 00000400-1 Tank pressure is too high. (PT1)   |
| 2 - 00000800-1 | The console has detected a software problem.   | Х    | Х     | Х         | Х        | Χ       | Error 2 - 00000800-1 GUI Watchdog timeout.  |
| 2 - 00001000-1 | The injection pressure is too high.  | Х    | Х     | Х         | Х        | Χ       | Error 2 - 00001000-1 Injection line pressure is too high. (PT2)   |
| 2 - 00002000-1 | The console has detected a hardware problem.   | X    | Х     | X         | Х        | X       | Error 2 - 00002000-1 CPLD state does not match the expected state.  |
| 2 - 00004000-1 | Flow obstruction detected.   |      | х     | Х         | Х        | Х       | Error 2 - 00004000-1 Return line pressure too high. (PT3)   |
| 2 - 00008000-1 | The console has detected a hardware problem.   | Х    | Х     | Х         | Х        | Х       | Error 2 - 00008000-1 Control microcontroller watchdog timeout.  |
| 2 - 00010000-1 | Flow obstruction detected.   | Х    | Х     | Х         | Х        | Х       | Error 2 - 00010000-1 Vacuum line pressure is too high. (PT4)  |
| 2 - 00020000-1 | The console has detected a hardware problem.   | Х    | Х     | Х         | Χ        | Х       | Error 2 - 00020000-1 Patient microcontroller watchdog timeout.  |
| 2 - 00100000-1 | The console has detected a hardware problem.   |      | Х     | Х         | Х        | Х       | Error 2 - 00100000-1 Venting line error detected. (PS1)   |
| 2 - 00400000-1 | The scavenging line pressure is too high.  | Х    | Х     | Х         | Х        | Χ       | Error 2 - 00400000-1 Scavenging line pressure is too high. (PT5)  |
| 2 - 04000000-1 | The console has failed the self test.  | Х    | Х     | Х         | Х        | Х       | Error 2 - 04000000-1 Control microcontroller failed the self test.  |
| 2 - 0003FB12   | The system has detected a problem with the communication system.                       | X    | X     | Х         | Х        | Х       | Error 2 - 0003FB12 CAN1 Communication   |
| 2 - 0003FB13   | The system has detected a problem with the communication system.                       | Х    | Х     | Х         | Х        | Х       | Error 2 - 0003FB13 CAN2 Communication   |
| 0003FB1B       | This system is running low on disk space.  | Х    |       |           |          |         | Consider downloading case data and archiving the files.   |
| 0003FB19       | This system is running critically low on disk space.                                   | X    |       |           |          |         | Download case data and archive the files to continue using the system.  |



### TECHNICAL ASSISTANCE CENTER CONTACT NUMBERS

### For Email Support <a href="mailto:CEtechsupportEMEA@bsci.com">CEtechsupportEMEA@bsci.com</a>

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