Boston Scientific

SMARTFREEZE™

Cryoablation System Console

User's Manual **2**

Boston Scientific (Master Brand DFUTemplate 8.5in x 11in Global, 92238515B), IFU, SMARTFREEZE 4.2, EN, 51288687-01A

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℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or use by on the order of a physician.

WARNING: Sterile accessories (balloon catheters, mapping catheters, sterile sheaths, and connection cables) are for single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

Carefully read all ancillary device instructions prior to use.

Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications.

1. DEVICE DESCRIPTION

The SMARTFREEZE™ Cryo-Console (henceforth referred to as SMARTFREEZE Console) is a component of the Boston Scientific Cryoablation System (henceforth referred to as System). The System is intended for the electrical mapping and cryoablation performed during pulmonary vein isolation (PVI) treatment for atrial fibrillation. Using its accessories and compatible proprietary catheters, the SMARTFREEZE Console employs N_2O (nitrous oxide) to cool tissues to the point of necrosis.

During a therapy session, pressurized liquid N_2O (the refrigerant) is delivered to the Boston Scientific POLARx™ Cryoablation Balloon Catheter (henceforth referred to as POLARx Catheter) from a tank stored in the SMARTFREEZE Console. Since the refrigerant cools as it expands within the POLARx Catheter's cryo-balloon, it absorbs the heat from the surrounding tissue and kills the cells within that tissue. The SMARTFREEZE Console keeps the cryo-balloon under constant vacuum in order to remove the spent refrigerant, which it then exhausts to the hospital scavenging system (active or passive transfer).

Figure 1. SMARTFREEZE Cryo-Console

The complete Boston Scientific Cryoablation System consists of the following system components and sterile, single-use, patient-contact accessories:

1.1 System Components

Component	Model	Description
SMARTFREEZE Console	M004CRBS4000	Controls overall ablation process.
Console Power Cord	M004CRBS6240 M004CRBS6210 M004CRBS6270 M004CRBS6260 M004CRBS6220 M004CRBS6230 M004CRBS6250 M004CRBS6280 M004CRBS6290 M004CRBS62100 M004CRBS62110 M004CRBS62120 M004CRBS62130	Power cord used to connect AC mains to the SMARTFREEZE Console.
Inter-Connection Box (ICB)	M004CRBS4110	Interconnect device used to connect the POLARx Catheter, Diaphragm Movement Sensor (DMS) and Esophageal Temperature Sensor (ETS) cable (M004CRBS6310) to the SMARTFREEZE Console.
Inter-Connection Box with Remote Control and Occlusion Pressure Sensor Option	M004CRBS4130	Interconnect device used to connect the POLARx Catheter, Diaphragm Movement Sensor (DMS), Esophageal Temperature Sensor cable (M004CRBS6320) or Esophageal Temperature Sensor Cable (CIRCA) (M004CRBS6340), Occlusion Pressure Sensor Cable, and Remote Control to the SMARTFREEZE Console.
Cryo-Console Foot Switch	M004CRBS4200	When connected to the SMARTFREEZE Console, used to allow starting and stopping of cryo-energy to the POLARx Cryoablation Balloon Catheter.
Diaphragm Movement Sensor (DMS)	M004CRBS6110	Sensor used to monitor the patient response to the pacing signal. (Applied Part)
Esophageal Temperature Sensor (ETS) Cable	M004CRBS6310	Extension cable used to connect a commercially available temperature sensor to the SMARTFREEZE Cryo-Console. (Applied Part) Compatible with ICB M004CRBS4110.
Esophageal Temperature Sensor (ETS) Cable	M004CRBS6320	Extension cable used to connect a commercially available temperature sensor to the SMARTFREEZE Cryo-Console. (Applied Part) Compatible with ICB M004CRBS4130.
Esophageal Temperature Sensor (ETS) Cable (CIRCA)	M004CRBS6340	Extension cable used to connect a commercially available CIRCA S-CATH™ Esophageal Temperature Probe to the SMARTFREEZE Cryo-Console. (Applied Part) Compatible with ICB M004CRBS4130.

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Component	Model	Description
Scavenging Hose	M004CRBS4310 (Yellow) M004CRBS4320 (Purple)	When connected to the SMARTFREEZE Cryo-Console, the scavenging hose exhausts the N_2O from the SMARTFREEZE Console to the hospital evacuation system.
Wrench	M004CRBS6400	Wrench used to tighten and loosen the refrigerant tank connection to the SMARTFREEZE Console.
Remote Control	M004CRBS6500	Remote control device used to change the ablation site, increase/decrease the ablation time and to allow starting and stopping of cryo-energy to the POLARx Cryoablation Balloon Catheter from within the sterile field when fitted with a sterile sleeve.
Occlusion Pressure Sensor Cable	M004CRBS6600	Extension cable used to connect a commercially available pressure sensor to the SMARTFREEZE Cryo-Console. (Applied Part) Compatible with ICB M004CRBS4130.

1.2 Sterile, single-use accessories

Accessory	Model	Description
POLARx Cryoablation Balloon Catheter	M004CRBS2000	Cryo-ablation catheter (Short tip, 28mm) (Applied Part)
POLARx Cryoablation Balloon Catheter	M004CRBS2100	Cryo-ablation catheter (Long tip, 28mm) (Applied Part)
POLARMAP™ Circular Mapping Catheter	M004CRBS7200	Mapping catheter used to confirm electrical isolation before and after cryo-ablation procedures (20mm). (Applied Part)
POLARSHEATH™ Steerable Sheath	M004CRBS3050	Conduit used to provide a path for the POLARx Cryoablation Balloon Catheter to the heart. (Applied Part)
SMARTFREEZE Cryo-Cable	M004CRBS5200	Refrigerant path between the SMARTFREEZE Console and the balloon catheter
SMARTFREEZE Catheter Extension Cable	M004CRBS5100	Extension cable used to connect the balloon catheter to the Inter-Connection Box (ICB)
EP Electrical Cable	M004CRBS6200	Cable used to connect the POLARMAP Circular Mapping Catheter to a hospital EP recording system.

1.3 Operating Priniciple

The SMARTFREEZE Console delivers pressurized liquid nitrous oxide (N_2O) to the Boston Scientific POLARx Cryoablation Balloon Catheter (POLARx Catheter) thru the SMARTFREEZE Cryo-Cable from a tank stored in the SMARTFREEZE Console. The N_2O (the refrigerant) is delivered to the injection coil of the POLARx Catheter, which directs the flow of refrigerant toward the interior, distal surface of the balloon segment of the catheter. The SMARTFREEZE Console monitors the inner balloon temperature during in ablation via the balloon catheter thermocouple in the distal balloon segment. Since the refrigerant cools as it expands within the POLARx Catheter's cryo-balloon, it absorbs the heat from the surrounding tissue creating lesions. The SMARTFREEZE Console keeps the cryoballoon under constant vacuum in order to remove the spent refrigerant, which it then exhausts to the hospital scavenging system (active or passive transfer).

The SMARTFREEZE Console controls the injection pressure, injection flow as well as the inner balloon pressure throughout the ablation. It provides means to inflate/deflate the cryo-balloon as well as to start and stop ablations.

The SMARTFREEZE Console automatically records procedure data and stores this information in non-volatile memory allowing users to review the data locally or export the data on a USB key for review on a separate computer.

1.4 User Information

The SMARTFREEZE Console is to be used only by, or under the supervision of, physicians fully trained in cardiac electrophysiology procedures, in properly equipped facilities. Assistance to prepare and run the system may only be provided by appropriately trained personnel.

2. INTENDED USE/INDICATIONS FOR USE

The SMARTFREEZE Cryo-Console is intended to be used with POLARx cryoablation balloon catheters only.

The Boston Scientific Cryoablation Catheter System is intended for cryoablation and electrical mapping of the pulmonary veins for pulmonary vein isolation (PVI) in the ablation treatment of paroxysmal atrial fibrillation.

3. CLINICAL BENEFIT STATEMENT

The benefit of the POLARx Cryoablation System is the ability to sense cardiac electrograms and achieve pulmonary vein isolation (PVI) through delivery of cryoablation energy in a "single shot" manner. The potential clinical benefits include complete or partial elimination of symptoms related to atrial fibrillation (AF) via PVI with confirmation of conduction block.

The benefit of the SMARTFREEZE Console and system components is to provide the user interface for controlling and monitoring cryoablation delivery, and, protections to ensure safe delivery and removal of nitrous oxide.

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4. CONTRAINDICATIONS

Use of the Boston Scientific Cryoablation Catheter System is contraindicated as follows:

- In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis.
- In patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolic event.
- In the ventricle of the heart where the device may become entrapped in the valve or chordae structures.
- In patients with a prosthetic heart valve (mechanical or tissue).
- In patients with a recent ventriculotomy or atriotomy because this may increase the risk of cardiac perforation or embolic event.
- In patients with pulmonary vein stents as the catheter may dislodge or damage the stent.
- In patients with cryoglobulinemia as the application of cryogenic energy may lead to vascular injury.
- In conditions where insertion into or manipulation in the atria is unsafe as this may increase the risk of perforation or systemic embolic event.
- In patients with an interatrial baffle or patch as the transseptal puncture could fail to close.
- In patients with hyper-coagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure.
- In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe.

5. WARNINGS

- To avoid the risk of electric shock, the SMARTFREEZE Console must always be connected to a supply mains with protective earth.
- This Console must only be used with Boston Scientific equipment and accessories listed in this manual or patient injury or death may occur.
- Do not modify the SMARTFREEZE Console in any way. Doing so may affect performance and/ or patient safety.
- The Equipotential ground provides a direct connection between the chassis of the SMARTFREEZE Console and the equalization bus of the electrical installation. It is not a protective earth connection point.
- The SMARTFREEZE Console must be installed by a qualified/ trained Boston Scientific representative. For assistance with installation, please contact your local Boston Scientific representative or Technical Support.
- There are no user serviceable parts in the SMARTFREEZE Console. Do not attempt to service the SMARTFREEZE Console while in use with a patient.
- Do not touch the SMARTFREEZE Console and the patient simultaneously as this may cause patient harm.

- Standard of care methods for evaluating phrenic nerve function and determining when intervention is needed should always be applied during right pulmonary vein ablations. The DMS is not intended as a substitute for such standard of care methods.
- Read and follow IFUs for POLARx Catheter and cryoablation system components prior to use. Observe all contraindications, warnings, and precautions. Failure to do so may result in patient harm or device malfunction.
- Cryoablation therapy applied with the balloon positioned within the pulmonary veins may cause PV stenosis and injury to adjacent tissues resulting in patient complications, including death. If using pressure measurement to assess PV occlusion, verify the balloon is properly positioned using fluoroscopy or other appropriate visualization technique.

6. PRECAUTIONS

- Electrophysiology procedures, including ablation, may introduce arrhythmias.
- It is the user's responsibility to ensure that the equipment used with the system meets all local applicable electrical safety standards.
- Perform cryoablation procedures only within environmental parameters as outlined in Section 14.1.1.
- Cryoablation procedures should only be performed in a fully equipped facility.
- Use only isolated equipment (IEC 60601-1 Type CF equipment or equivalent) with this equipment and accessories.
- Use of accessories, transducers and cables other than those specified or provided by Boston Scientific could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not connect any device to the Ethernet port.
- Only connect an external monitor that is compliant to IEC 60601-1:2012 or any local equivalent standards. Do not use a power bar or extension cord. When connecting an external monitor to the SMARTFREEZE Console, an evaluation of IEC 60601-1:2012 requirements should be performed.
- Use of this equipment adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 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 re-orienting the equipment.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12in) to any part of the SMARTFREEZE Console, including cables specified by Boston Scientific. Otherwise, degradation of the performance of this equipment could result.
- Only connect portable flash drives to USB ports for extraction of procedural data. Connection of a USB flash drive could result in previously unidentified risks to Patient, Operators or third

parties. It is the hospital's responsibility to identify, analyze, evaluate and control these risks. IEC 80001-1:2010 provides guidance on this matter.

- Properly scavenge and dispose of the N_2O with appropriate hospital systems. Do not outgas in the operating room.
- Only physicians thoroughly trained in electrophysiology procedures should operate the System.
- Do not use a power bar or extension cord when connecting the SMARTFREEZE Console to the hospital AC source (wall outlet).

7. ADVERSE EVENTS

Any potential clinical complications are in large part expected to be related to the accessories and/or therapeutic catheter that are used with the system, rather than the system itself. In order to identify potential adverse events, the user is instructed to read the pertinent instructions for use associated with the catheters and accessories that will be employed during the ablation procedure. As with other ablation systems, the SMARTFREEZE Console can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures. Potential adverse events associated with the use of the system include, but are not limited to, the following:

- Procedural related side effects
  - Allergic reaction (including anaphylaxis)
  - Genitourinary complication
  - Side effects related to medication and/or anesthesia
  - Radiation injury/tissue burn
  - Renal failure/insufficiency
  - Vasovagal response
- Arrhythmia (new or exacerbated)
  - Conduction pathway injury (Heart block, nodal injury, etc.)
- Nerve injury, for example:
  - Phrenic nerve injury
  - Vagal nerve injury
- Injury due to embolism/thromboembolism/air embolism/gas embolism/foreign body embolism
  - Cerebrovascular accident (CVA)/stroke
  - Transient ischemic attack (TIA)
  - Myocardial infarction
  - Neurological impairment and its symptoms, for example:
    - Cognitive changes, visual disturbances, headaches, motor impairment, sensory impairment, and speech impairment
  - Pulmonary embolism
  - Asymptomatic cerebral embolism
- Electric shock
- Injury related to tissue damage and/or adjacent structures, for example:
  - Esophageal injury
  - Pulmonary injury
  - Catheter entrapment
  - Physical trauma
- Cardiac trauma, for example:
  - Cardiac perforation/cardiac tamponade/pericardial effusion
  - Valvular damage
  - Stiff left atrial syndrome

8. HOW SUPPLIED

The System is provided as individually packaged non-sterile components as listed in Section 1.1.

8.1 Device Details

Do not use if any packages are damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

Do not use the device if past the "Use By" date.

8.2 Handling and Storage

Operating Environment

- Ambient Temperature: 15°C to 30°C
- Relative Humidity: 30 to 75% non-condensing
- Atmospheric Pressure: 75.3 kPa to 106 kPa, 10.92 psia to 15.40 psia / -2m to 2438.4m (-6.56 feet to 8000 feet) above sea level

Transport Environment

- Temperature: -40°C to 55°C (-40°F to 131°F)
- Relative Humidity: Uncontrolled
- Atmospheric Pressure: Uncontrolled

Storage Environment

- Ambient Temperature: -40°C to 55°C (-40°F to 131°F)
- Relative Humidity: 30%-93% non-condensing
- Atmospheric Pressure: Uncontrolled

9. INSTRUCTIONS FOR USE

9.1 Additional Items for Safe Use

- BSC approved N_2O tank
- BSC approved Non-Medical Grade nitrous oxide (N_2O)
- Optional:
  - General Purpose Temperature Sensor (Series 400)
  - Pressure Transducer (e.g. Edwards Lifesciences TruWave disposable pressure transducer)
  - CIRCA S-CATH™ Esophageal Temperature Sensor
  - Remote Sterile Sleeve
  - Pressure Sensor Cable Sterile Sleeve
  - LABSYSTEM PRO – SMARTFREEZE Connection Cable

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9.2 Console setup

WARNING: This Console must only be used with Boston Scientific equipment and accessories listed in this manual or patient injury or death may occur.

WARNING: Do not touch the SMARTFREEZE Console and the patient simultaneously as this may cause patient harm.

CAUTION: Only physicians thoroughly trained in electrophysiology procedures should operate the System.

9.2.1 Console placement

1. Position the SMARTFREEZE Console in the EP lab, ensuring that the main power switch, AC power cord, scavenging hose and foot switch remain accessible.
2. The SMARTFREEZE Console can be directed and locked in position using the red and green control pedals on the SMARTFREEZE Console:
   - Pressing the red pedal (left) locks the wheels and immobilizes the SMARTFREEZE Console.
   - The SMARTFREEZE Console is fully maneuverable when the green pedal (right) is pressed.
3. Adjust the screen height and angle to the desired setting using the screen handle.

9.2.2 Refrigerant tank preparation

Note: If the SMARTFREEZE Console or tank have been stored in a location where the temperature is outside the recommended operating temperature, the SMARTFREEZE Console may need more time to prepare for the procedure.

1. Pull open the SMARTFREEZE Console door at the rear of the SMARTFREEZE Console to expose the refrigerant tank.
2. Make sure that the tank is centered on the tank support.
3. Turn the refrigerant tank knob counter-clockwise to open the tank valve.
4. Close the SMARTFREEZE Console door.

9.2.3 Connection of non-sterile components

1. If the scavenging hose is not already connected to the SMARTFREEZE Console, connect one end to the SMARTFREEZE Console scavenging port connector, securing it finger-tight. Connect the other end of the scavenging hose to the hospital evacuation system. The SMARTFREEZE Console is supplied with a standard scavenging hose. An adapter might be necessary if the hospital does not use the same standard.
2. If not already connected to the SMARTFREEZE Console, connect the foot switch to the SMARTFREEZE Console foot switch connector (optional).

Note: Locate the foot switch to minimize the risk of inadvertently starting or stopping a therapy session. The foot switch may also be temporarily disabled during a treatment session, if desired (see section 15.2 on page 57).

3. Connect the Inter-Connection Box (ICB) to the SMARTFREEZE Console front panel connector. Note that a safety lock system prevents the connector from being inadvertently disconnected.
4. Optional Diaphragm Movement Sensor (DMS): See *Diaphragm Movement Sensor (DMS)* on page 66 for complete operating instructions.
    - Install and secure the DMS on the patient.
    - Connect the DMS to the ICB.
5. Optional Esophagus Temperature Sensor (ETS)
    - Insert and secure the ETS sensor on the patient.
    - Connect the ETS cable to the ICB.
    - Connect the ETS sensor to the ETS cable.
6. Optional CIRCA S-CATH™ Esophagus Temperature Probe.
    - Insert and secure the CIRCA S-CATH™ Esophagus Temperature Probe on the patient.
    - Connect the ETS Cable (CIRCA) to the ICB.
    - Connect the CIRCA S-CATH™ Esophagus Temperature Probe to the ETS Cable (CIRCA).
7. Optional Potential Equalization Conductor:
    - The SMARTFREEZE Console is equipped with a potential equalization conductor. If needed, connect as per hospital standard procedures. Consult IEC 60601-1 for ME Systems.
8. Optional Remote Control
    - Connect the Remote Control to the ICB.
9. Optional Pressure Sensor Cable
    - Connect the Pressure Sensor Cable to the ICB.

    Note: The Pressure Sensor Cable is a non-sterile cable that connects to an off the shelf pressure sensor that may be within the sterile field. If used in the sterile field, use a sterile sleeve to cover the Pressure Sensor Cable.
10. Optional LABSYSTEM PRO Connection

    Note: Ensure that LABSYSTEM PRO is powered off prior to connecting.
    - Connect the USB to serial cable to the left most (facing the rear of the SMARTFREEZE Console) USB port on the rear of the SMARTFREEZE Console.
    - Connect the USB to serial cable to the COM port of the LABSYSTEM PRO. Refer to the LABSYSTEM PRO IFU for details on port connection.

9.2.4 Console power-on procedure

Note: It is important to power-on the SMARTFREEZE Console at least five (5) minutes prior to commencing a procedure.

Note: To disconnect the SMARTFREEZE Console from the AC mains, unplug the AC power cord from the wall outlet.

1. If the AC power cord is not already connected to the SMARTFREEZE Console, connect it to the SMARTFREEZE Console power inlet.
2. Connect the AC power cord to the hospital AC mains (wall outlet).

   CAUTION: Do not use a power bar or extension cord when connecting the SMARTFREEZE Console to the hospital AC source (wall outlet).

3. Turn on the main power switch located on the rear of the SMARTFREEZE Console. The SMARTFREEZE Console will perform a self-test to assure that it is working properly.

   Note: If the SMARTFREEZE Console does not start up normally or if there is a system message displayed during the start-up process, refer to *Troubleshooting* on page 53.

4. The home screen will be displayed once the SMARTFREEZE Console has completed the boot-up procedure (Figure 2).
5. Press the **Cryo Therapy** icon to access the Login screen. Enter your user name and password on the Login screen. Press the **OK** button on the Login screen.

Figure 2. Home screen

9.3 Cryo-therapy procedure

9.3.1 Patient setup

1. Press the **Cyro Therapy** button on the home screen.

Note: If the **Cryo Therapy** button is not in the center forefront, pressing the button a second time will activate it.

The Patient Information screen is displayed (Figure 3).

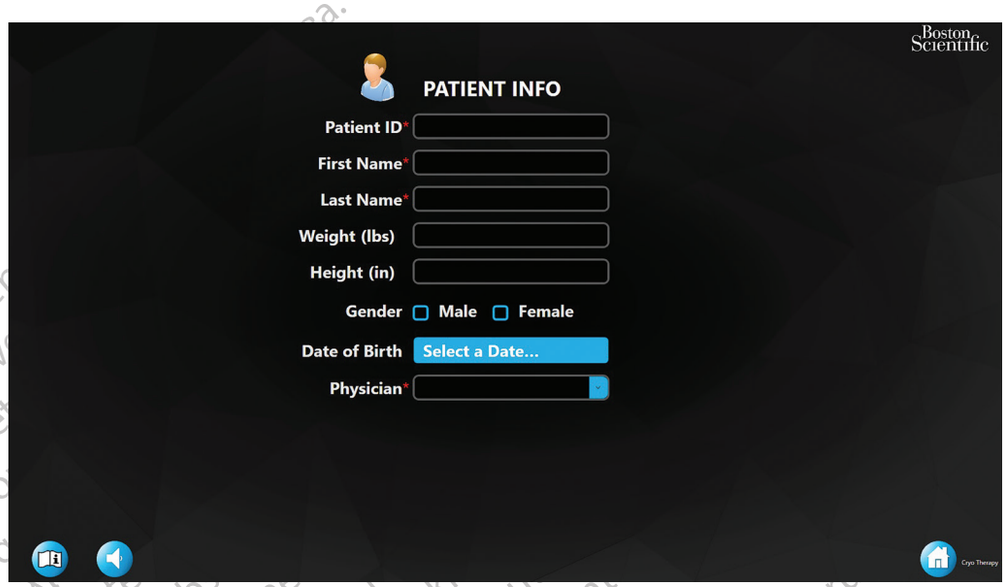

Figure 3. Patient information screen

2. Press the **Patient ID** box.
3. Enter the **Patient ID** using the on-screen keyboard.
4. If this is the first time the patient is being treated with the SMARTFREEZE Console, use the on-screen keyboard to fill in the patient information fields.

Note: If the Patient ID is already in the SMARTFREEZE Console database, pressing anywhere else on the screen will automatically populate the remaining patient information fields.

5. A list of attending physicians is presented when the **Physician** field is chosen. Select the patient's physician from the drop-down list.

Note: System administrators add physicians that are not present in the current physician list by using the **Manage Users -> New Doctor** routines found on the Settings screen. See Section 10: User Profiles.

6. Press the **Next** button, which appears once the patient information input is completed. Screen Data is required for Patient ID, First Name, Last Name, and Physician fields.
7. The Therapy screen will be displayed (Figure 4).

Note: After navigating to the Therapy screen for the first time after boot up, if the user returns to the Home screen, the next time the user navigates to the Patient Info screen, a **Load Previous Patient** button is displayed. Pressing the **Load Previous Patient** button auto populates the patient information screen. Pressing the **Next** button will load the previous patient procedure (if any treatments were performed, the procedure will continue as if the physician had not left the procedure).

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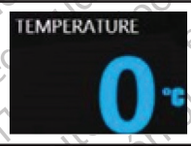
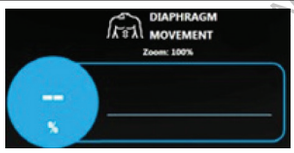
8. If using the LABSYSTEM PRO, power on the LABSYSTEM PRO and follow its IFU for setup instructions. If communication with the SMARTFREEZE Console is not established, press the **Settings** button on the Therapy screen. Once on the Settings window, press the **Reconnect LABSYSTEM PRO** button and then the **OK** button on the Settings window.

Figure 4. Therapy Screen–idle state

Key elements of the Therapy Screen are highlighted in the table below:

	Indicates the current system status (**IDLE**, **READY**, **INFLATION**, **ABLATION**, **THAWING**). The active state will be highlighted (the system state should indicate **IDLE** as shown in Figure 4).
	Opens settings window for timers, notifications and system settings.
	Indicates the electrical status of the catheter. A red dot indicates that it is not electrically connected; a green dot indicates that it is electrically connected and recognized.
	Indicates the mechanical status of the cryo-cable. A red dot indicates the cryo-cable connection has not been completed and the vacuum enabled. A green dot indicates that the cable is mechanically connected, that the vacuum is enabled, and that the return plumbing is not leaking.
	Indicates operation status of the foot switch. A red dot indicates that the foot switch is disabled; a green dot indicates that the foot switch is enabled.
	Indicates temperature inside the cryo-balloon in °C.
	Esophageal temperature (if connected).
	Diaphragm Movement Sensor (DMS) waveform with amplitude in percentage of the reference value (if connected).
	Indicates the approximate amount of N_2O gas that is in the refrigerant tank in lbs or kg (or minutes, if so selected in the settings).

9.3.2 Pre-Ablation

Prepare the POLARx Catheter and other sterile components in accordance with their Instructions for Use.

WARNING: Read and follow IFUs for POLARx Catheter and cryoablation system components prior to use. Observe all contraindications, warnings, and precautions. Failure to do so may result in patient harm or device malfunction.

Figure 5. Therapy Screen–IDLE state–valid catheter connected

1. Follow the instructions in the POLARx Catheter IFU for connecting the components to the SMARTFREEZE Console.
2. Optional pressure sensor.
   - Refer to the off-the-shelf pressure sensor IFU for information on unpacking.
   - Connect the off-the-shelf pressure sensor to the POLARx Catheter guidewire lumen (or Y adapter connected to the POLARx Catheter guidewire lumen).
   - Connect the off-the-shelf pressure to the Pressure Sensor Cable.

   Note: Before introducing the Remote Control and/or Pressure Sensor Cable into a sterile environment, insert the device(s) into sterile sleeve(s).
3. Press the **VACUUM ON** button on the Therapy screen (Figure 5).

   Note: A system message is displayed if the Cryo-Cable is not properly connected to both the POLARx Catheter and the SMARTFREEZE Console. If this message is displayed, verify the connections of the Cryo-Cable and press the **OK** button on the message window to automatically retry enabling the Vacuum. Press **Cancel** to close the window without enabling the vacuum.

4. The system status should indicate **READY** and the **INFLATE** button on the Therapy screen should appear (Figure 6). In addition, the START pushbutton on the SMARTFREEZE Console front panel and the indicator on the Remote Control, if used, should be illuminated green.

Note: To disengage the vacuum on the catheter, press the **VACUUM OFF** button on the Therapy screen or press the Stop button on the Remote Control. It is only possible to disengage the vacuum from the **READY** state.

Figure 6. Therapy screen–READY state

Note: If a fault is detected, a system message will be displayed with detailed information of the failure. See *Troubleshooting* on page 53 for troubleshooting steps.

5. Verify that the refrigerant tank gauge indicates that there is sufficient refrigerant to perform the treatment procedure. Change the tank if necessary by following instructions in section 9.2.2.

9.3.3 Ablation

WARNING: Read and follow IFUs for POLARx Catheter and cryoablation system components prior to use. Observe all contraindications, warnings, and precautions. Failure to do so may result in patient harm or device malfunction.

9.3.3.1 User Selectable Settings

Prior to the start of a procedure, review the ablation settings, timers and preferences by pressing the **Settings** button on the Therapy screen. The Settings window is displayed (Figure 7). To change numeric parameters, press the numeric value then adjust using the up / down arrows. To change toggled parameters, touch the toggle button next to each parameter.

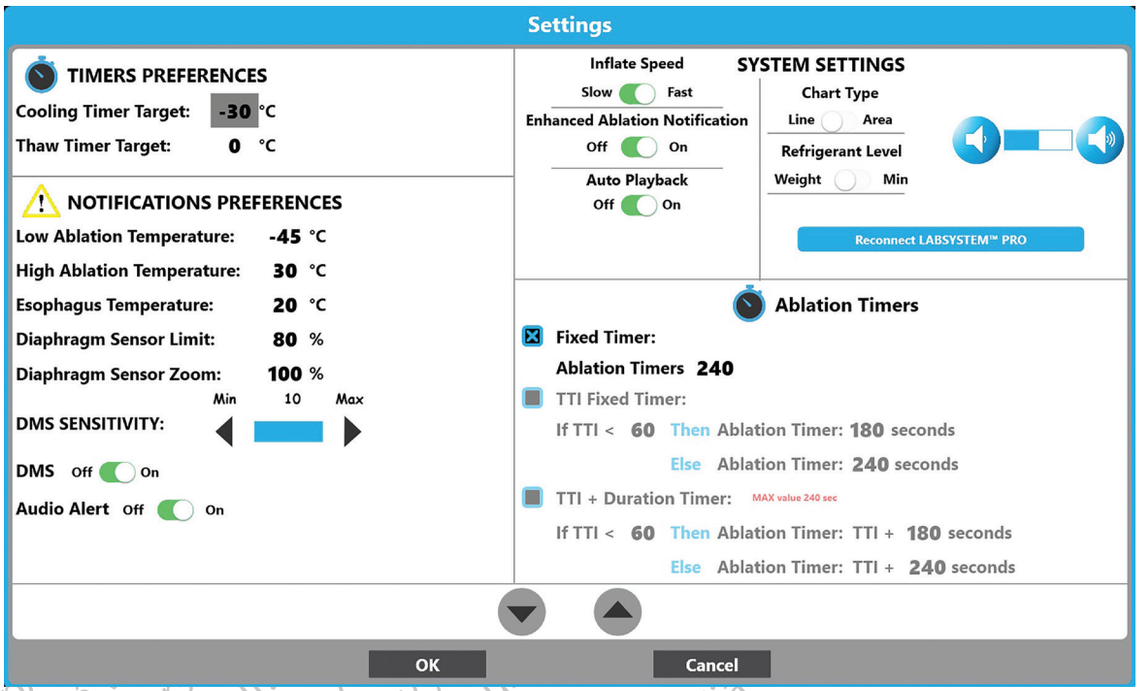


Figure 7. Settings window

- Select the numeric value next to **Cooling Timer Target.** Set the **Cooling Timer Target** to the desired temperature using the up/down arrows on the Settings window. The **Cooling Time** timer on the Therapy screen will stop when the temperature reaches this preset.
- Select the numeric value next to the **Thaw Timer Target.** Set the **Thaw Timer Target** to the desired temperature using the up/down arrows on the Settings window. The **Thaw Time** timer on the Therapy screen will stop when the temperature reaches the set point chosen in this field.
- Select the numeric value next to the **Low Ablation Temperature.** Set the L**ow Ablation Temperature** to the desired temperature using the up/down arrows. The **Temperature** graph data line on the Therapy screen will change from blue to red during the ablation state when the temperature reaches the set point chosen in this field.
- Select the numeric value next to the **High Ablation Temperature.** Set the **High Ablation Temperature** to the desired temperature using the up/down arrows. The **Temperature** graph data line on the Therapy screen will change from blue to red during the ablation state when the temperature reaches the set point chosen in this field.
- Select the numeric value next to the **Esophagus Temperature.** Set the **Esophagus Temperature** to the desired temperature using the up/down arrows. When the temperature reaches the set point chosen in this field, the **ESOPHAGUS TEMPERATURE** reading on the Therapy screen will turn red and flash, a red border around the screen will flash and the Temperature graph title bar will flash red with an audible notification (Figure 8). The alert may be displayed during **INFLATION**, **ABLATION**, and **THAWING** phases.

Figure 8. Esophagus temperature alert

- If using a CIRCA™ S-CATH Esophageal Temperature Probe, with or without a series 400 temperature probe, an image of the CIRCA™ S-CATH Esophageal Temperature Probe will automatically be displayed (Figure 9). A typical CIRCA™ S-CATH Esophageal Temperature Probe has 12 sensors with some models including a proximal sensor.

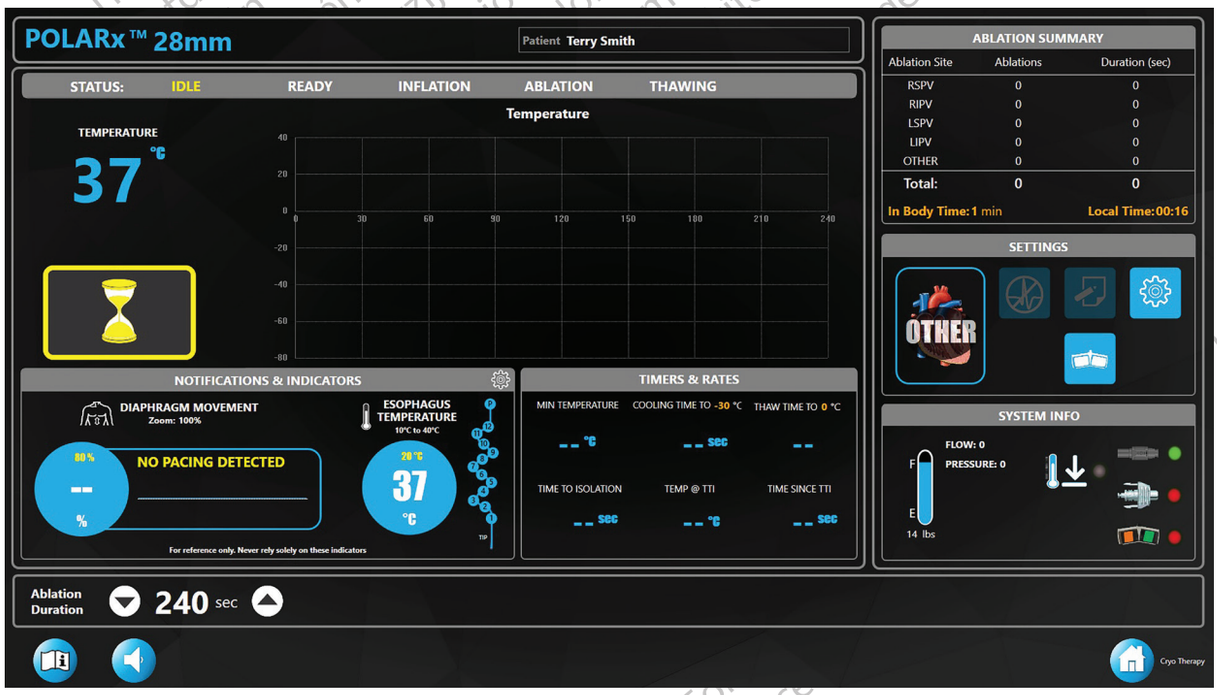


Figure 9. CIRCA™ S-CATH Esophageal Temperature Probe

- The displayed **Esophagus Temperature** will always be the lowest temperature measured of all of the sensors. The sensor with the lowest temperature will also be highlighted in blue. As the temperature drops in affected areas, only the sensors with the lowest temperature will be highlighted (see Figure 10). Note that it is possible for more than one sensor to have the same temperature as in Figure 9.

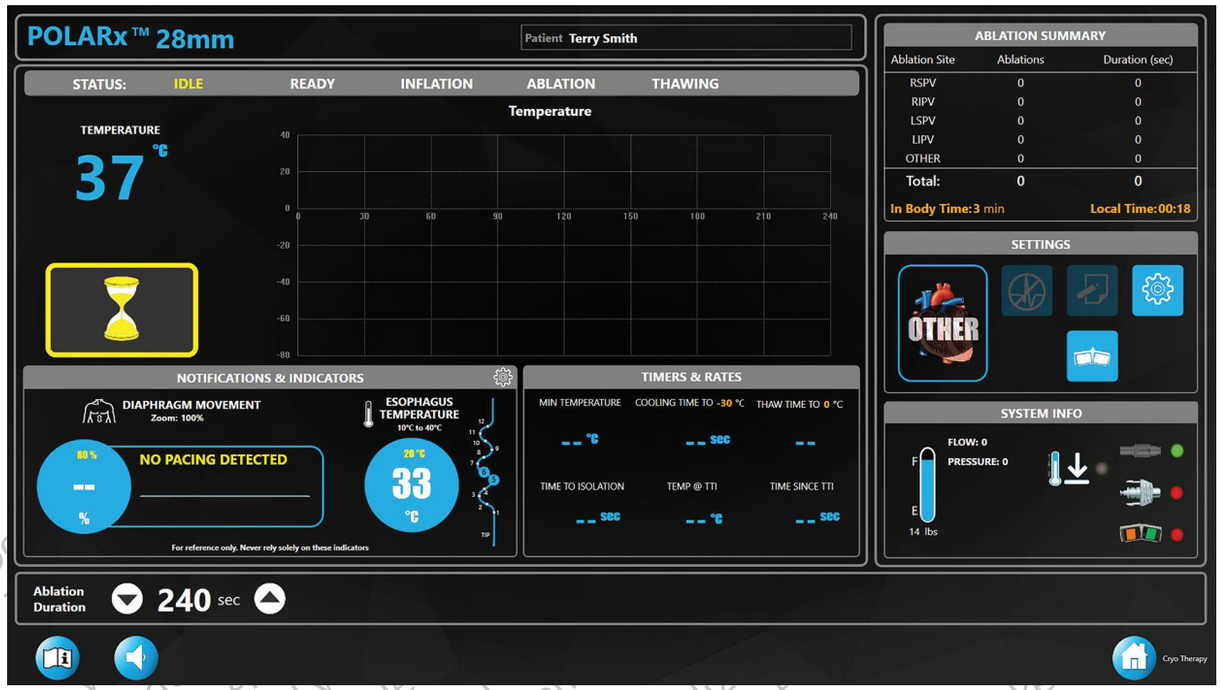


Figure 10. CIRCA™ S-CATH Esophageal Temperature Probe - Low Temperatures Selected

- If any of the sensors are not functional, they will be highlighted in red (see Figure 11).

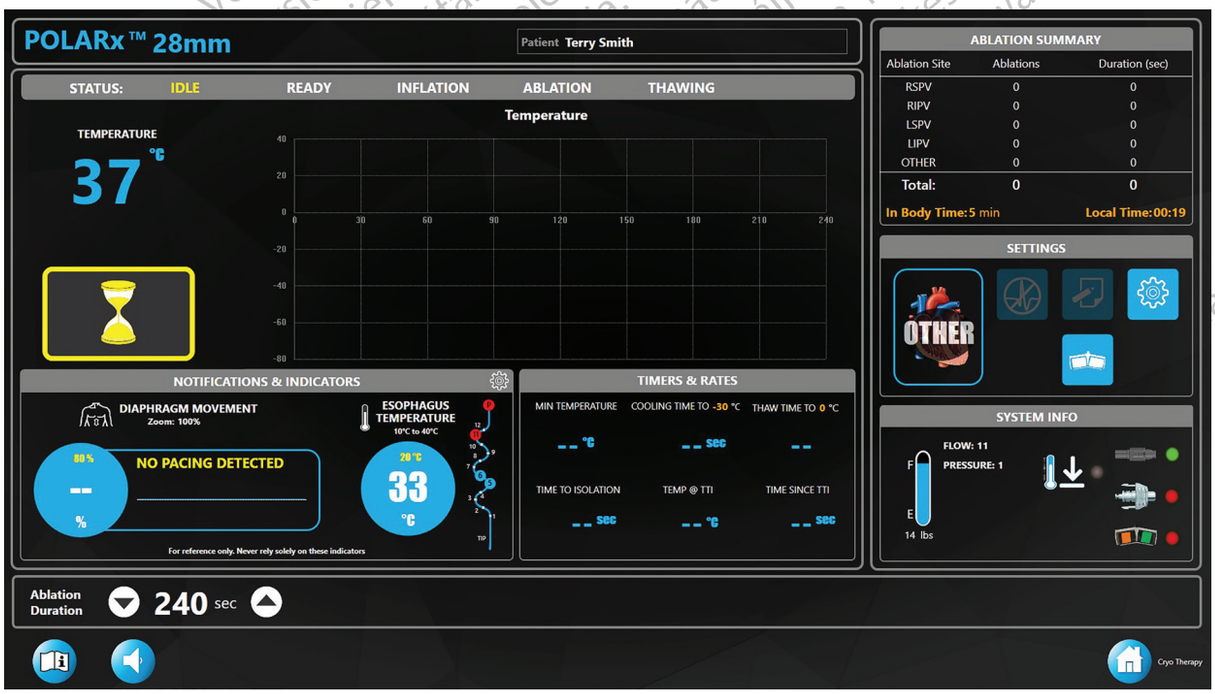


Figure 11. CIRCA™ S-CATH Esophageal Temperature Probe - Non-functioning sensors

- Select the numeric value next to the **Diaphragm Sensor Limit.** Set the **Diaphragm Sensor Limit** to the desired percentage using the up/down arrows. When the percentage reaches the set point chosen in this field, the **DIAPHRAGM MOVEMENT** Sensor reading on the Therapy screen will turn red and flash, a red border around the screen will flash, and the Temperature graph title bar will flash red with the audible notification when the percentage reaches the set point chosen in this field (Figure 12). The alert may be displayed during the ablation phase.

Figure 12. **Diaphragm Movement** sensor alert

- Select the numeric value next to the **Diaphragm Sensor Zoom.** Set the **Diaphragm Sensor Zoom** to the desired percentage. The **DIAPHRAGM MOVEMENT** graph on the Therapy screen will zoom into the set percentage (used to see smaller signal responses).
- Set the **DMS SENSITIVITY** to the desired level using the low and high arrows. (Used to set the DMS detection threshold. Lower settings require stronger DMS signals in order to be registered, and higher settings allow weaker DMS signals to be registered).
- Optional: Slide the **DMS** to the **Off** position to disable the **DMS** on the Therapy screen. (Typically used when ablating veins that do not affect the phrenic nerve).
- Optional: Slide the **Audio Alert** to the **Off** position to disable the audible notification if the **DMS Sensor Limit** and **Esophagus Temperature** notifications are triggered.
- Optional: Set the inflation speed to slow by sliding the **Inflate Speed** slider to **Slow**. The default is set to **Fast**.
- Optional: Set the Cryo-balloon Temperature chart on the Therapy screen to display a filled in area graph by sliding the **Chart Type** slider to **Area**. The default is set to **Line**.
- Optional: Set the N_2O Tank level meter on the Therapy screen to display in lbs by sliding the **Refrigerant Level** slider to **Weight**. The default is set to **Min** (minutes).

- Optional: Set the alert volume level to the desired setting by pressing the button to lower the volume or the button to raise it. The default is set to mid-range.
- Optional: Slide the **Auto Playback** to the **Off** position to disable the automatic display of Playback Mode upon exiting the Thawing state. The default state is set to On.
- Optional: **Enhanced Ablation Notification** will cause a solid blue screen border to appear when in the Inflation and Thawing states (refer to Figure 14) as well as a flashing blue border in the Ablation state. Additionally upon entering and exiting the Ablation state, a distinct audible sound will be made. Slide the **Enhanced Ablation Notification** to the Off position to disable the enhanced ablation notifications. The default state is set to On.
- Select the desired Ablation Timers setting from the three options:
  - **Fixed Timer**

    Set the **Fixed Timer** to the desired time using the up/down arrows on the Settings window. The ablation will stop when the **Ablation Time** reaches the set point chosen in this field. The **Ablation Time** may also be set directly on the Therapy screen using the white up/down arrows.
  - **TTI Fixed Timer**

    This timer option allows the user to predetermine the total amount of ablation time based on the time to vein isolation.

    This option requires three (3) user settings: Time To Isolation (**TTI**), shorter duration (**Then**), and longer duration (**Else**).

    If the vein is isolated sooner than the user-set TTI time, the total ablation time will be the shorter duration. If the vein is isolated at or later than the user-set TTI time, the total ablation time will be the longer duration. The three set points are adjusted by selecting the desired setting and using the up/down arrows.

    The TTI set point is adjustable in 10 second increments beginning with 30 seconds up to a maximum of 10 seconds less than the shorter duration setting. (For example, the TTI can be adjusted from 30 to 170 if the shorter duration is set to 180 seconds).

    The shorter duration is adjustable in 30 second increments beginning with 60 seconds (if the TTI user setting is set to 50 seconds or less) to a maximum of 30 seconds less than the longer duration (maximum of 210 seconds).

    The longer duration is adjustable in 30 second increments beginning with 90 seconds (if the shorter duration user setting is set to 60 seconds) to 240 seconds.

If **TTI Fixed Timer** option is chosen, the ablation duration on the Therapy screen will display the longer ablation time setting. If the user indicates that the vein is isolated prior to the set point, the **Ablation Duration** will change to the shorter ablation time and flash for a few seconds. Each time the ablation duration is changed automatically by the SMARTFREEZE Console, the ablation duration flashes.

– **TTI + Duration Timer**

This timer option allows the user to predetermine the amount of additional ablation time based on the time to vein isolation.

This option requires three (3) user settings: Time To Isolation (**TTI**), Shorter Additional Time (**Then**), and Longer Additional Time (**Else**).

If the vein is isolated sooner than the user set TTI time, the ablation will last the shorter additional time from the TTI time. If the vein is isolated at or later than the user set TTI time, then the total ablation will last the longer additional time from the TTI time. The three set points are adjusted by selecting the desired setting and using the up/down arrows.

The TTI set point is adjustable in 10 second increments from 30 seconds to 210 seconds.

The shorter additional time is adjustable in 30 second increments beginning with 60 seconds (if the TTI user setting is set to 50 seconds or less) to a maximum of 30 seconds less than the longer duration (maximum of 210 seconds).

The longer additional time is adjustable in 30 second increments beginning with 60 seconds (if the shorter duration user setting is set to 60 seconds) to 240 seconds.

If this option is chosen, the ablation duration will display 240 seconds regardless of the set points on the settings screen. If the user indicates that the vein is isolated before the set point, the ablation duration will display the current ablation time plus the shorter time. If the user indicates that the vein is isolated after this set point, the ablation duration will display the current ablation time plus the longer time setting. Each time the ablation duration is changed automatically by the SMARTFREEZE Console, the ablation duration flashes. Note that the maximum ablation time is always 240 seconds.

Note: During an ablation, if the ablation duration is manually changed, this change will only be effective on the current ablation. Subsequent ablations will revert to the initial user preference setting.

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9.3.3.2 Beginning Cryoablation Procedure

The ablation procedure for the isolation of pulmonary veins follows the following algorithm:

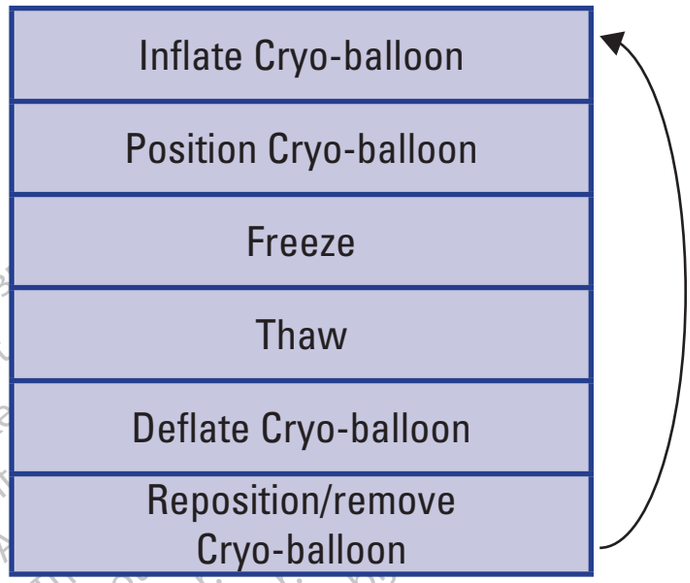

Figure 13. Ablation procedure algorithm

Note: At any point during the process, the ablation site can be set by pressing the ablation site button on the Therapy screen or by using the left and right arrows on the Remote Control. The available ablation sites are: Other, RSPV, RIPV, LSPV, LIPV.

1. Inflate the cryo-balloon when desired using one of the following methods:
   - Press the START pushbutton on the SMARTFREEZE Console front panel.
   - Press the START foot switch pedal (right pedal, green).
   - Press the **INFLATE** button on the therapy screen.
   - Press the START button on the Remote Control.

When the cryo-balloon has reached the inflated state, the following indicators will be visible in the Therapy screen (Figure 14). The STATUS bar will indicate **INFLATION**; the catheter illustration will depict an inflated balloon; the **STOP** and **ABLATE** buttons will appear; the diaphragm movement data will be plotted on the **DIAPHRAGM MOVEMENT** graph and the esophagus temperature will be displayed under **ESOPHAGUS TEMPERATURE**.

Additionally, the START pushbutton on the SMARTFREEZE Console front panel and the indicator on the Remote Control, if used, will be illuminated blue and the STOP pushbutton on the SMARTFREEZE Console front panel will be illuminated white.

Figure 14. Therapy screen – inflation state with solid blue border when enhanced notifications are enabled

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Note: If necessary, the cryo-balloon can be deflated from the **INFLATION** state using one of the following methods:

- Pressing the STOP pushbutton ▽ on the SMARTFREEZE Console front panel.
- Pressing the STOP foot switch pedal (left pedal, orange).
- Pressing the **STOP** button on the Therapy screen.
- Press the STOP button ▽ on the Remote Control.

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2. Position the inflated cryo-balloon per standard clinical practice and verify that the vein is properly occluded.

3. If the optional Pressure Sensor Cable and pressure sensor are used, the Therapy screen will display the pressure reading along with the balloon temperature and a graph of the pressure vs time instead of the balloon temperature graph (refer to Figure 15). Use this graph to help determine vein occlusion.

Note: This feature may not be available in all countries

Figure 15. Therapy screen – Inflation state with pressure graph

4. Start the cryoablation treatment using one of the following methods:

- Press the START pushbutton on the SMARTFREEZE Console front panel.
- Press the START foot switch pedal (right pedal, green).
- Press the **ABLATE** button on the therapy screen.
- Press the START button on the Remote Control.

Note: If necessary while in the **ABLATION** state, the injection can be stopped and the cryo-balloon can be deflated by one of the following methods:

- Press the STOP push button on the SMARTFREEZE Console front panel to stop injection. Press the STOP button again to deflate the cryo-balloon.
- Press the STOP foot switch pedal (left pedal, orange) to stop injection. Press the STOP foot switch pedal again to deflate the cryo-balloon.
- Press the **STOP** button on the Therapy Screen to stop injection. Press the **STOP** button again to deflate the cryo-balloon.
- Press the STOP button on the Remote Control to stop injection. Press the STOP button again to deflate the cryo-balloon.

Figure 16. Therapy screen–ablation state

5. When the system is in the **ABLATION** state, the following indicators will be visible in the Therapy screen (Figure 16):
   - The **STATUS** bar will indicate **ABLATION**
   - The **ABLATE** button will be replaced with a **STOP** button
   - The cryo-balloon temperature is plotted on the Cryoballoon **Temperature** graph.
   - The Temperature reading begins to drop.
   - The catheter illustration will change to the ablation timer and the **Ablation Time** timer begins to increment.
   - A flashing snowflake will appear above the ablation timer.
   - If the Enhanced Ablation Notifications are enabled, a blue border around the screen will flash.
   - The **MINIMUM TEMPERATURE** displays the lowest temperature recorded.
   - The **TREATMENT NOTES** option becomes available.
     - Press the **TREATMENT NOTES** button on the Therapy screen to add observations and other relevant information to the treatment file (Figure 17).
     - Press the white space in the **TREATMENT NOTES** window.
     - Press the **OK** button to save the added notes or **Cancel** to close the **TREATMENT NOTES** window without saving them.

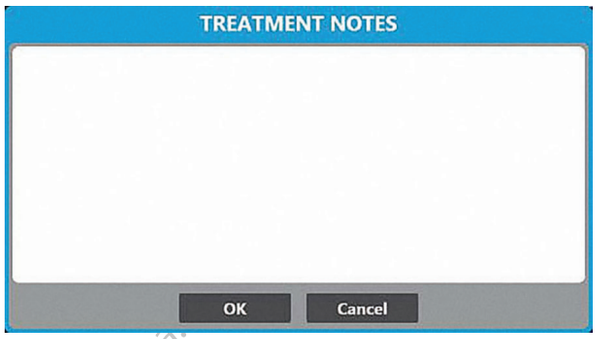

Figure 17. **TREATMENT NOTES** window

- The Low Flow button 

becomes available.
  - Press the Low Flow button to reduce the flow to the catheter by 10% if desired. When Low Flow is activated a **Low Flow** indicator underneath the balloon **TEMPERATURE** will be displayed and the Low Flow button will disappear (see Figure 18).

Note: The Low Flow button is visible only in the ablation state.

Note: This feature may not be available in all countries

Figure 18. Low Flow is activated

Note: If a fault is detected, a system message will be displayed with detailed information of the failure (see Figure 19).

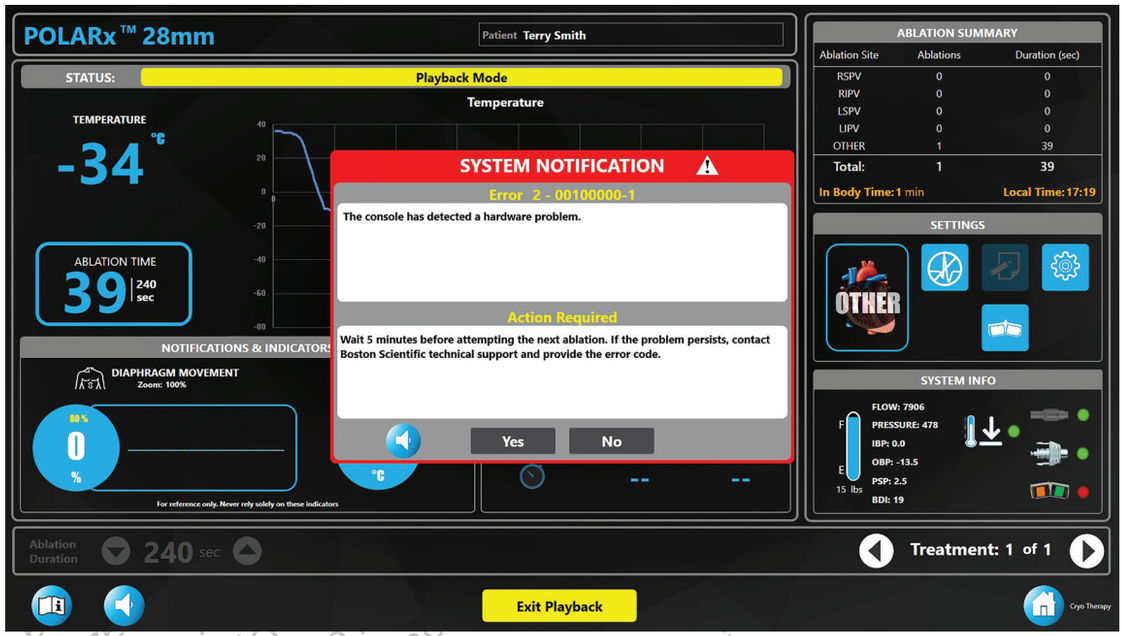

Figure 19. System Error Message

- Press the **Mute** button on the system notification window to temporarily mute the alert sound.
- Press **Yes** to attempt to reset the system and press no to hide close the system notification window without clearing the error.
- After pressing **No**, the System Messages indicator will be displayed on the Therapy screen.

Figure 20. Playback Error

- Press the red triangle at the bottom of the screen to open the system messages window (see Figure 20 and Figure 21).

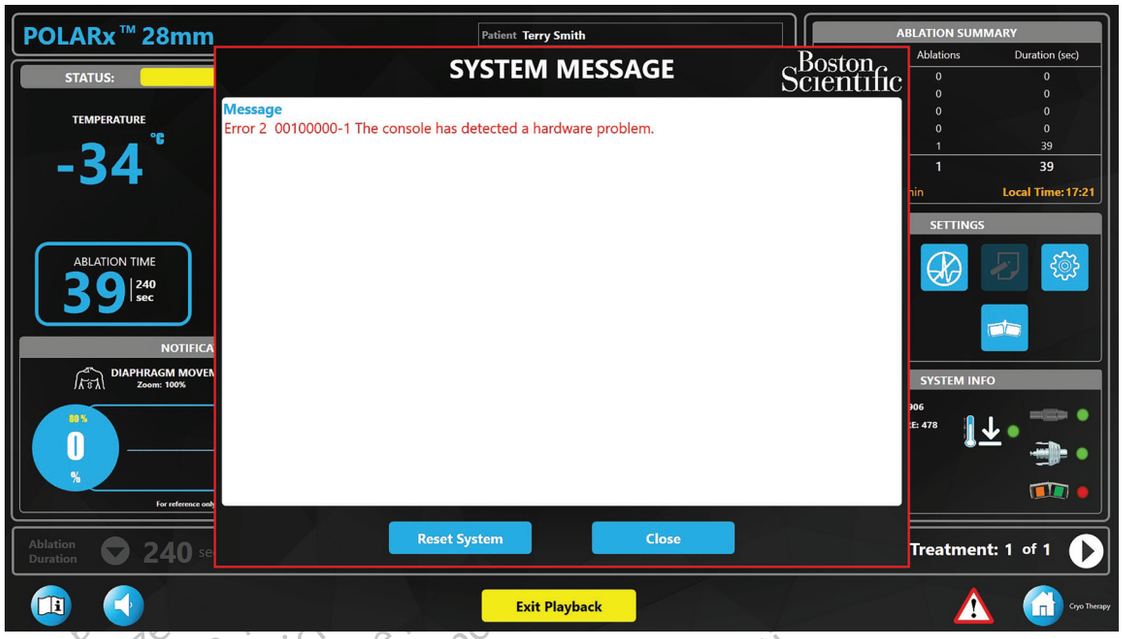

Figure 21. System Messages Window

- Press the **Reset System** button to clear all active messages (see Figure 22).

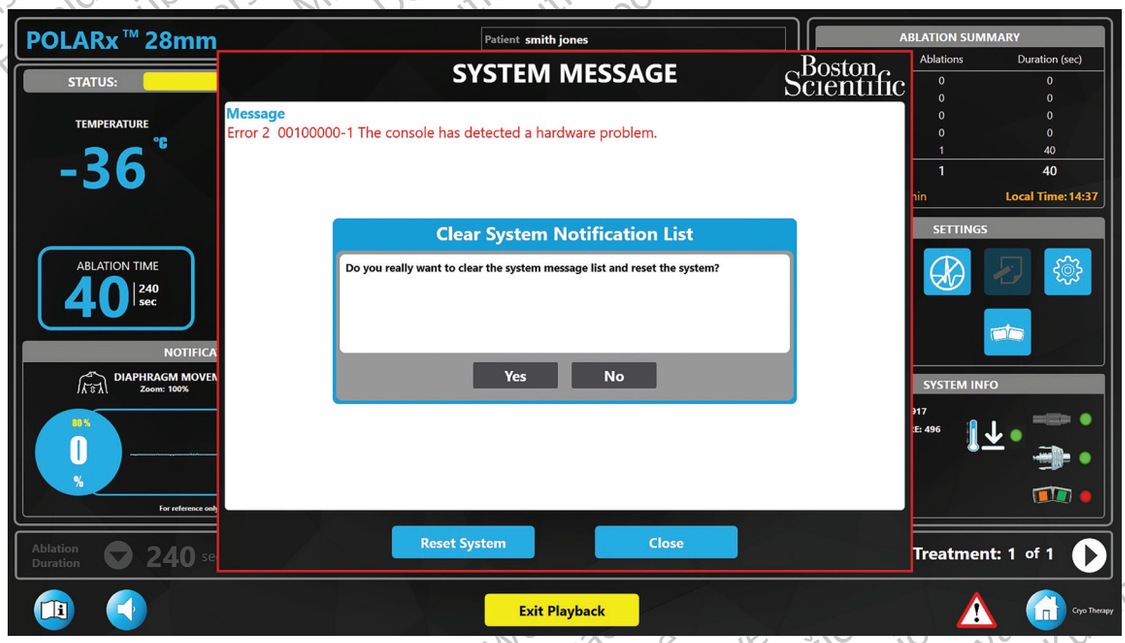

Figure 22. Clear System Notifications List Window

- Press the **Close** button to close the **System Message** window (see Figure 23).

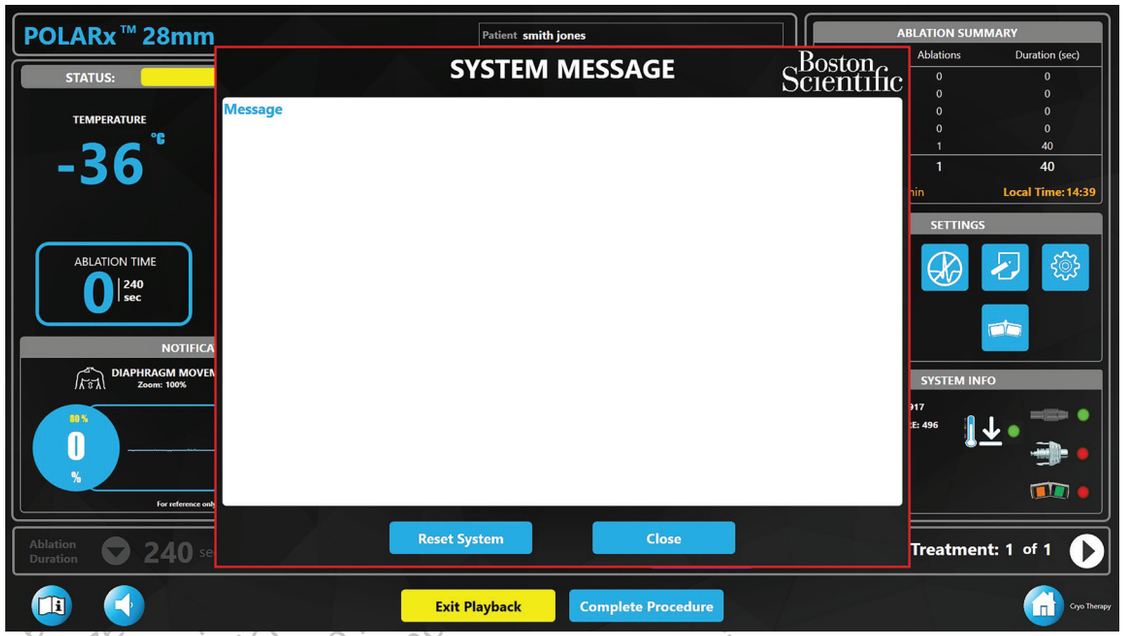

Figure 23. Cleared System Message

- The diaphragm movement data will be plotted on the **DIAPHRAGM MOVEMENT** graph and the current amplitude will be displayed as percent. The percentage is based on the measured response at the start of the ablation phase and will decrease as the patient's response to the pacing signal decreases. If the percentage reaches the setpoint, the current diaphragm movement percentage will be displayed in a red circle and flash, a red border around the screen will flash and the **Temperature** graph title bar will flash red with the audible notification (Figure 12). The alert is present during the ablation phase.
  - Press on the **NOTIFICATIONS & INDICATORS** header bar to display the DMS and ETS Quick Menu to adjust settings (refer to Figure 24).
    - Press the **Reset Baseline** button on the Quick Menu to reset the DMS threshold.
    - Press the DMS enable/disable the DMS functionality.
    - Press the Audio Alert button to disable DMS and ETS audio alerts for the procedure.
    - Press the on the DMS and ETS Quick Menu to mute the DMS and ETS audible alerts for the current treatment.
    - Press the **Save & Close** button to save changes made on the DMS and ETS Quick Menu to the doctor's preferences.

If the DMS reading is less than the DMS sensitivity setting, the DMS graph will indicate **No Pacing Detected**. The DMS graph has a white line that adjusts to the average DMS value seen.

Note: Never rely solely on this indicator. It is for reference only.

Figure 24. Therapy screen–DMS and ETS Quick Menu

- The current esophageal temperature data will be displayed in °C. If the temperature reaches the setpoint, the current temperature will be displayed in a red circle and flash, a red border around the screen will flash and the **Temperature** graph title bar will flash red with the audible notification (Figure 8). The alert is present during **INFLATION**, **ABLATION**, and **THAWING** phases. Press on the **NOTIFICATIONS & INDICATORS** header bar to display the DMS and ETS Quick Menu to adjust settings.

Note: Never rely solely on this indicator. It is for reference only.

- When the temperature reaches the Cooling Timer temperature setpoint, the measured time is displayed.

Note: During the ablation phase, the SMARTFREEZE Console will periodically emit an audible sound. To adjust the volume level, press the button to lower the volume and the button to raise the volume.

- When the vein is determined to be isolated, use one of the following methods to indicate this:
  - Press the button on the Therapy screen;
  - Press and hold the green foot switch pedal for two seconds
  - Press the button on the Remote Control.
  - Once pressed, the Time to Effect will display the time in seconds since the ablation began.

Note: A green dot is displayed on the **Temperature** graph at the vein isolated point. The vein isolated point can be updated by pressing the vein isolated button again or by pressing and holding the green foot switch pedal for three seconds. If updated, the green dot will be displaced to the new isolation point, the **Temperature at Isolation** will be updated and the **Time Since Isolation** counter will reset.

- When the vein isolation point is identified, the Therapy screen will display the temperature at the vein isolation point and the Time Since Isolation counter will begin to increment. The **Time Since Isolation** will continue to count until the system enters the Thawing state.
- Additionally, the START pushbutton on the SMARTFREEZE Console front panel and if used, the indicator on the Remote Control will be flashing blue and the STOP pushbutton on the SMARTFREEZE Console front panel will be illuminated white.

6. During an ablation, pressing the ⚙ on the **NOTIFICATIONS & INDICATORS** header bar will display the DMS and ETS Quick Menu. This menu offers the same sensor adjustments described in the DMS and ETS bullets in section 9.3.3.2.
7. Wait for the ablation timer to end.

Note: Once the timer reaches the ablation set time, the ablation treatment automatically stops and the thawing phase begins. The system state will indicate **THAWING** (Figure 25), the **STOP** button is displayed on the Therapy screen, and the stop pushbutton will be illuminated white. When the thaw temperature (20°C) is reached, the **ABLATE** button is displayed on the Therapy screen. In addition, the START pushbutton on the SMARTFREEZE Console front panel and the indicator on the Remote Control, if used, will be illuminated blue.

Figure 25. Therapy screen–THAWING state

When the system is in the **THAWING** state, the following indicators can be observed on the Therapy screen:

- The cryo-balloon temperature continues to be plotted on the balloon **Temperature** graph.
- The Temperature reading begins to rise.
- The Ablation Time timer is stopped and changes to an illustration of the inflated catheter.
- The Minimum Temperature displays the lowest temperature recorded.
- When the temperature reaches the Thaw Timer temperature setpoint, the measured time is displayed.
- The Time Since Isolation counter stops incrementing.
- When the Temperature reaches 20°C, the cryo-balloon will automatically deflate.

Note: Extending the Deflation Switch on the catheter handle elongates the cryo-balloon to its maximum length and allows it to wrap uniformly. To elongate the balloon during deflation, press forward on the POLARx Catheter slider extension switch before the system reaches 20°C. If necessary, re-inflate the balloon and press forward on the POLARx Catheter slider extension switch.

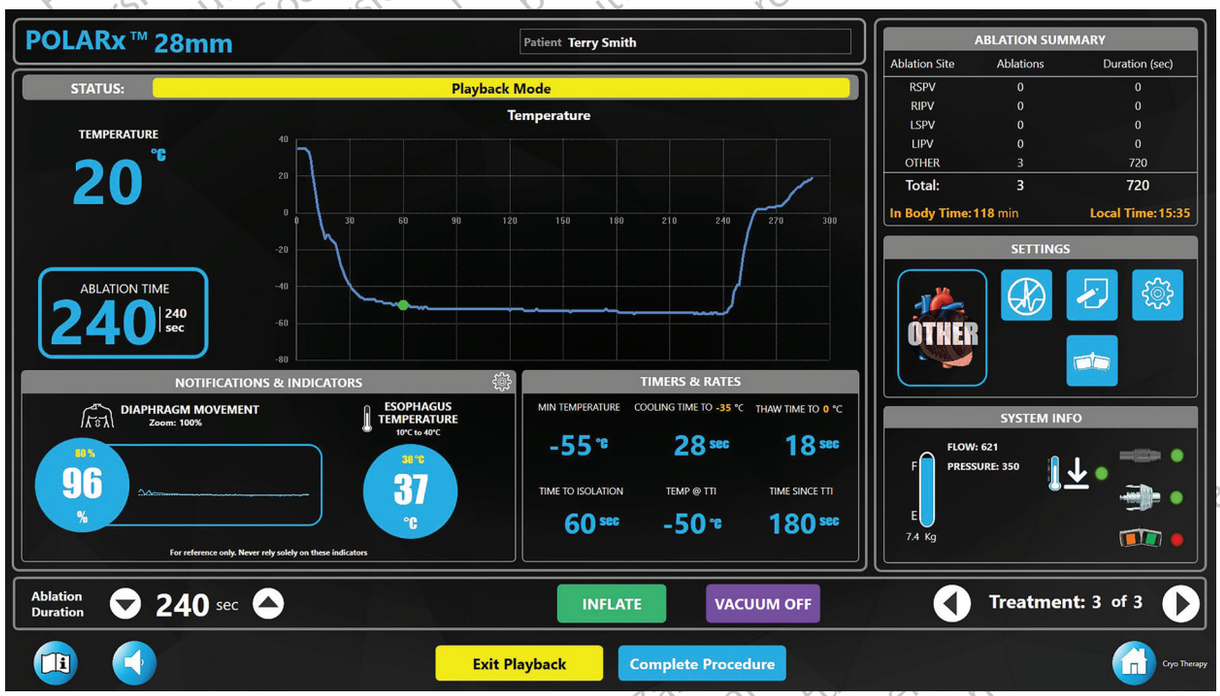

Figure 26. **Playback Mode**

8. The following activity can be observed on the Therapy screen when moving from the **THAWING** state to the **READY** state:

    a. The system will display the **Playback Mode** automatically.

        - The status indicator is replaced with a **Playback Mode** indication.
        - The **Exit Playback** button appears. Pressing this button allows real time data to be displayed.
        - To disable automatic **Playback Mode** after **THAWING**, press the Settings button on the Therapy screen. Set the **Playback Mode** slider to the Off position and press **OK** on the Settings window.

    b. The START pushbutton on the SMARTFREEZE Console front panel will be illuminated green when in the **READY** state.

    c. The **STOP** button on the Therapy screen disappears in **IDLE** state and the **INFLATE** button appears in the **READY** state.

    d. The **Complete Procedure** button appears.

    e. If the **Exit Playback** button is pressed immediately, the system state will first indicate **IDLE** and then indicate **READY** as the system evacuates remaining refrigerant from the injection line.

    f. If the **Exit Playback** button is pressed, the **PLAYBACK** button appears. Pressing the **PLAYBACK** button allows data from the previous ablations to be reviewed. Press the **PLAYBACK** button to enter the **Playback Mode**, shown in Figure 26.

    Note: The system automatically exits **Playback Mode** if a new inflation is started.

9. Select a point on the cryo-balloon **Temperature** graph. The corresponding recorded information from that moment will be displayed.

    - Use the **Treatment** arrows (Figure 26) to display data from previous treatments within the current procedure.
    - In **Playback Mode**:
        - The ablation site for each treatment may be updated by pressing the ablation site button and selecting the desired ablation site from the dropdown menu.
        - The vein isolation point may be updated by pressing the button on the Therapy screen and entering a new time in seconds. The entered time must be before the thawing period began. The system will automatically update the **Temperature at Isolation** and **Time Since Isolation** to match the new isolation point.
        - The treatment notes may be added/updated by pressing the button on the Therapy screen.

10. If an error occurred during an ablation, press the red triangle on the temperature graph to display the error message (see Figure 27).

Figure 27. Playback Mode After an Error

Figure 28. Error Message Displayed in Playback Mode

- Press the **Exit Playback** button on the Therapy screen to manually exit **Playback Mode** (see Figure 28).

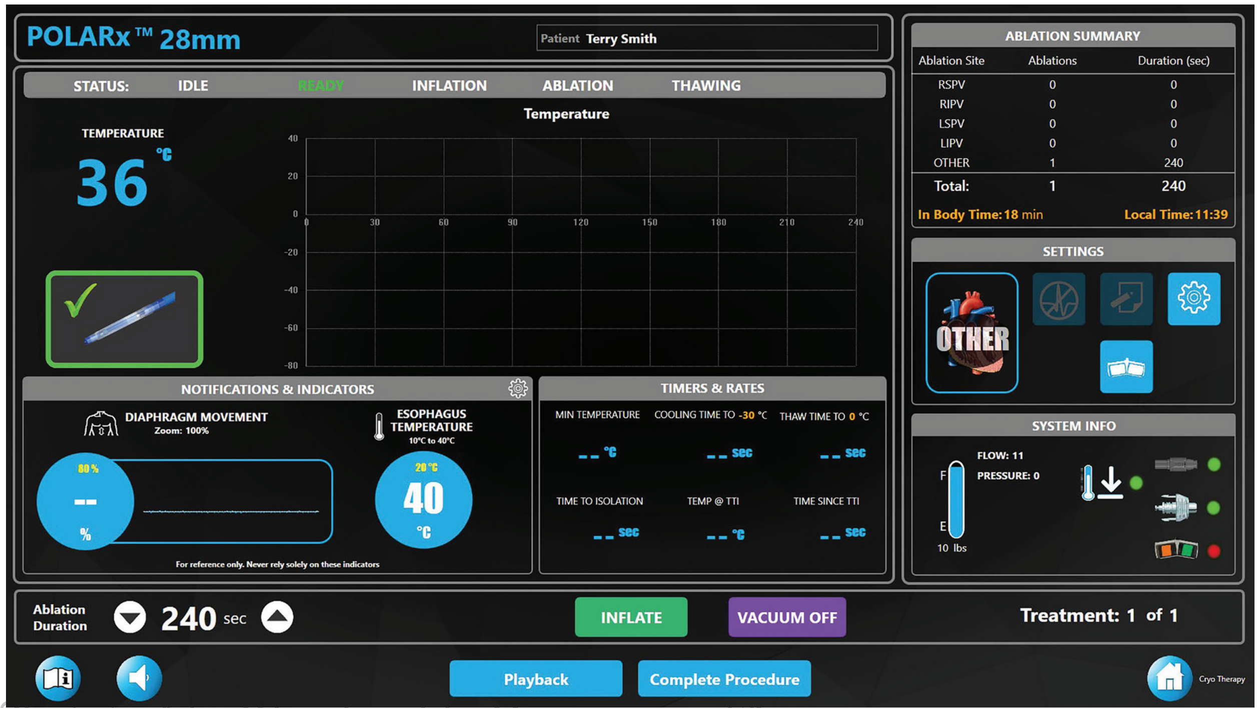

Figure 29. **READY** state after an ablation

11. To start a new treatment, follow this procedure from step 4 on page 28.
12. If additional treatment is not necessary, ensure the balloon is deflated then retract the cryo-balloon into the sheath and remove the catheter from the patient.

Note: Extending the Deflation Switch on the catheter handle elongates the cryo-balloon to its maximum length and allows it to wrap uniformly. To elongate the balloon during deflation, press forward on the POLARx Catheter slider extension switch before the system reaches 20°C. If necessary, re-inflate the balloon and press forward on the POLARx Catheter slider extension switch.

Note: It is possible—though it is not recommended—to manually deflate the cryo-balloon before the cryo-balloon reaches 20°C by one of the following methods:

- Pressing the Stop pushbutton on the SMARTFREEZE Console front panel.
- Pressing the Stop foot switch pedal (left pedal, orange).
- Pressing the Stop button on the Therapy screen.
- Pressing the Stop button on the Remote Control.

9.3.4 Procedure termination

1. When treatment is completed, press the **Complete Procedure** button on the Therapy screen (Figure 26 or Figure 29).

   The Summary Report screen is presented (Figure 30).

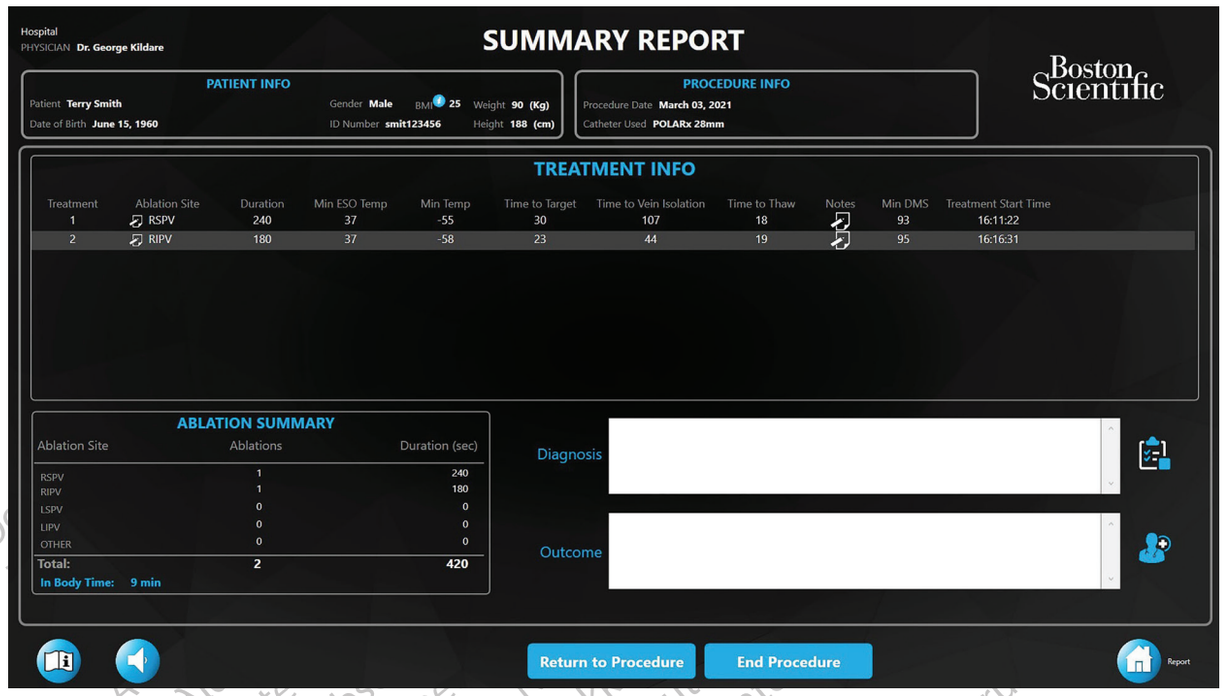

Figure 30. Summary report

Screen activity: The following can be observed on the Summary Report Screen:

- The **Patient ID** number is displayed at the top left of the screen. If the logged-in user is the doctor that performed the procedure, all patient information will be displayed. Note that the patient information also includes a calculated BMI based on the entered patient weight and height. If the is pressed, the BMI chart is displayed (see Figure 31).

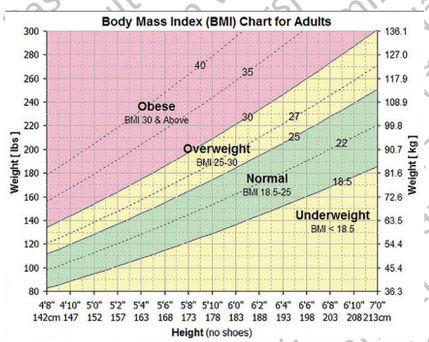

Figure 31. BMI Chart

- The Procedure configuration information is displayed at the top right of the screen.

- Each of the treatments that were performed during the procedure are individually entered in the **TREATMENT INFO** table. The ablation site, duration, minimum ESO temperature, temperature rate, lowest temperature achieved, time to ablation temperature, minimum DMS value and time to thaw temperature as well as any notes that were added per treatment can be seen.
- The ablation site for each treatment may be updated by pressing the clipboard icon in the ablation site column next to each treatment.
- The ablation summary displayed on the Therapy screen is repeated on the Summary Report screen on the bottom left of the screen.

2. Click on the clipboard icon in the **Notes** column to add/edit the treatment notes.
3. Click on the check-marked clipboard icon to add/edit an overall patient diagnosis. The Diagnosis window is displayed.
4. Press the **OK** button to save the patient diagnosis and close the Diagnosis window or the **Cancel** button to close the window without saving.
5. Click on the  icon to add/edit an overall procedure outcome. The Outcome window is displayed.
6. Press the **OK** button to save the procedure outcome and close the Outcome window or **Cancel** to close the window without saving.
7. Press the **Return to Procedure** button to return to the Therapy screen if additional treatments are required.
8. Press the **End Procedure** button to end the procedure and return to the Home screen.

Note: Once the procedure is ended, it is possible to continue treatment without creating a new procedure record if the Load Previous Patient button is pressed. Once the Therapy screen is accessed with new patient information, it is no longer possible to continue a previous patient's treatment.

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9. To review the patient records, see section *Review and Export Treatment Records* on page 48.

10. SYSTEM SHUTDOWN

1. Press the **Shutdown** button on the home screen.

Note: If the **Shutdown** button is not in the center forefront, pressing the button a second time will be necessary.

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2. Press the **YES** button on the message window.

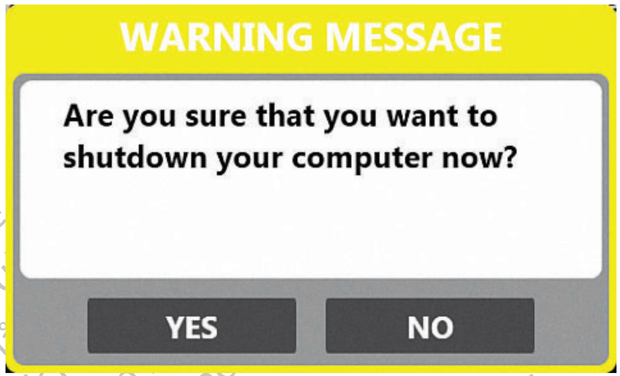

Figure 32. Shutdown message

Note: When the system shutdown is complete, the screen will briefly display **Entering Sleep Mode** and then will go black.

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3. After shutdown is complete, turn off the main power switch located on the rear of the SMARTFREEZE Console.
4. Pull open the SMARTFREEZE Console door at the rear of the SMARTFREEZE Console to expose the refrigerant tank.
5. Turn the refrigerant tank knob clockwise to close the tank valve.
6. Disconnect the AC power cord from the hospital AC source (wall outlet).
7. Disconnect the scavenging hose from the hospital evacuation system.
8. If using the DMS:
   - Remove the Diaphragm Movement Sensor from the patient.
   - Disconnect the Diaphragm Movement Sensor from the ICB.
9. If using a series 400 temperature sensor:
   - Remove the Esophagus Temperature Sensor from the patient.
   - Disconnect the Esophagus Temperature Sensor from the ETS Cable.
   - Disconnect ETS Cable from the ICB.
10. If using the CIRCA S-CATH™ Esophageal Temperature Probe:
    - Remove the CIRCA S-CATH™ Esophageal Temperature Probe from the patient.
    - Disconnect the CIRCA S-CATH™ Esophageal Temperature Probe from the ETS Cable (CIRCA).
    - Disconnect the ETS Cable (CIRCA) from the ICB.

11. If using a pressure sensor:
    - Disconnect the off-the-shelf pressure sensor from the POLARx Catheter.
    - Disconnect the off-the-shelf pressure sensor from the Pressure Sensor Cable.
    - Disconnect the Pressure Sensor Cable from the ICB.
12. If using a Remote Control, disconnect the Remote Control from the ICB.
13. Disconnect the Catheter Extension harness from the ICB.
14. Disconnect the ICB from the SMARTFREEZE Console.
15. Disconnect the Cryo-Cable from the SMARTFREEZE Console.
16. Dispose of all single-use items according to standard hospital procedures.
17. Store the reusable items in the SMARTFREEZE Console as follows:
    a. Clean items according to standard hospital procedures.
    b. Wrap the AC Power cord around the designated hooks on the SMARTFREEZE Console door.
    c. Wrap the scavenging hose around the designated scavenging hose hooks on the side of the SMARTFREEZE Console.
    d. Wrap the ICB harness in a loop and store in the designated location on the side of the SMARTFREEZE Console.
    e. Wrap the DMS in a loop and store with the ICB or in the tank storage area.
    f. Wrap the ETS Cable in a loop and store with the ICB or in the tank storage area.
    g. Wrap the ETS Cable (CIRCA) in a loop and store with the ICB or in the tank storage area.
    h. Wrap the Pressure Cable in a loop and store with the ICB or in the tank storage area.
18. Close the SMARTFREEZE Console door.

10.1 Post Procedure

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

11. USER PROFILES

The system employs three types of user profiles (User, Administrator, and Doctor) to control access to five system functions (Cryotherapy, Records, Settings, Change Tank, and Shut Down). User profiles are separate and distinct from patient profiles.

	Cryo Therapy	Records	Settings	Change Tank	Shut Down
User	•			•	•
Administrator	•		•	•	•
Doctor	•	•		•	•

Figure 33. User access capability matrix

Users are prompted to login if a session is not already in progress. Active sessions are indicated by the presence of a user icon at the bottom center of the home screen (Figure 2). Permission to proceed will be denied if the logged in user profile does not support a given function (Figure 3).

Tap the user icon at the bottom center of the screen to log out of a session.

11.1 Creating and editing user profiles

Note: Only administrator profiles have access to the Settings screen.

All user profile creation and maintenance must be performed by an administrator via the settings option on the home screen.

11.2 Creating and Managing Users

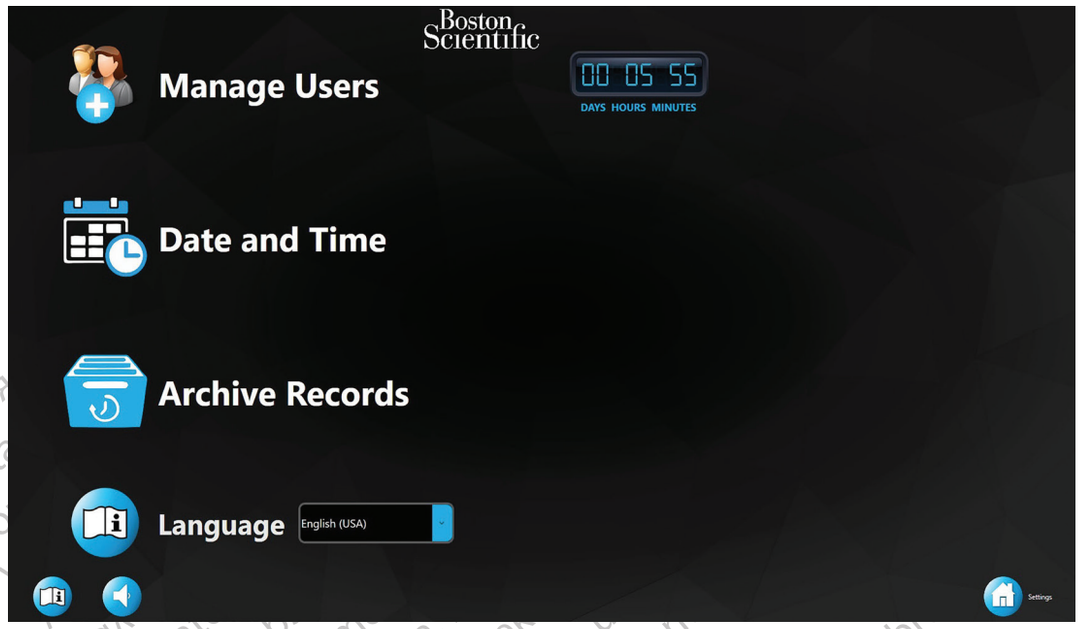

Figure 34. System settings

The system settings screen (Figure 34) contains the **Manage Users** , Date and Time, Archive Records, User's Manual language setting icons and a software timer that indicates the amount of time the SMARTFREEZE Console software has been in operation. Click the **Manage Users** icon to begin.

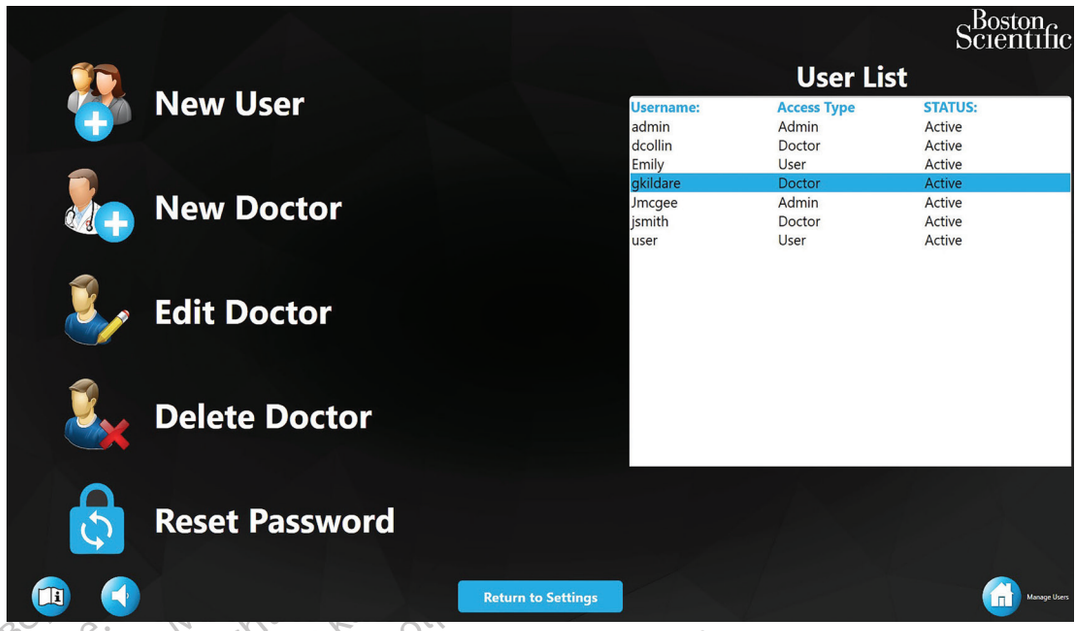

Figure 35. Manage users home screen

The Manage Users home screen (Figure 35) provides services to add new users and new doctors, edit users/doctors, delete users/doctors, and reset passwords.

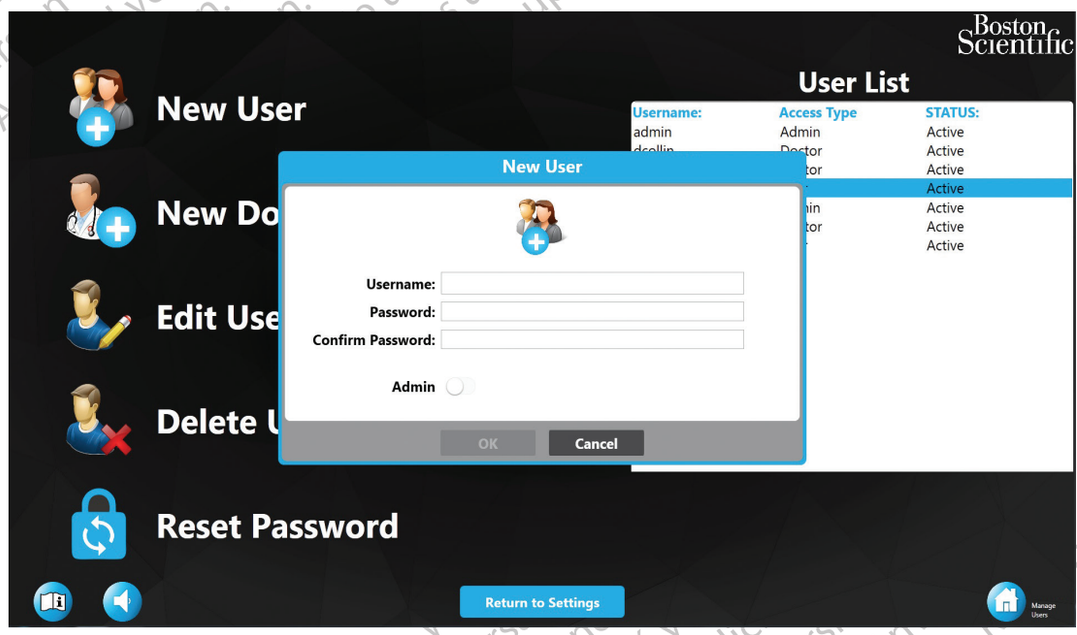

Figure 36. Creating a new user

New users are created by entering the **Username**, **Password**, and password confirmation. The Admin slider switch determines whether or not the user is placed in the administrators group (Figure 36).

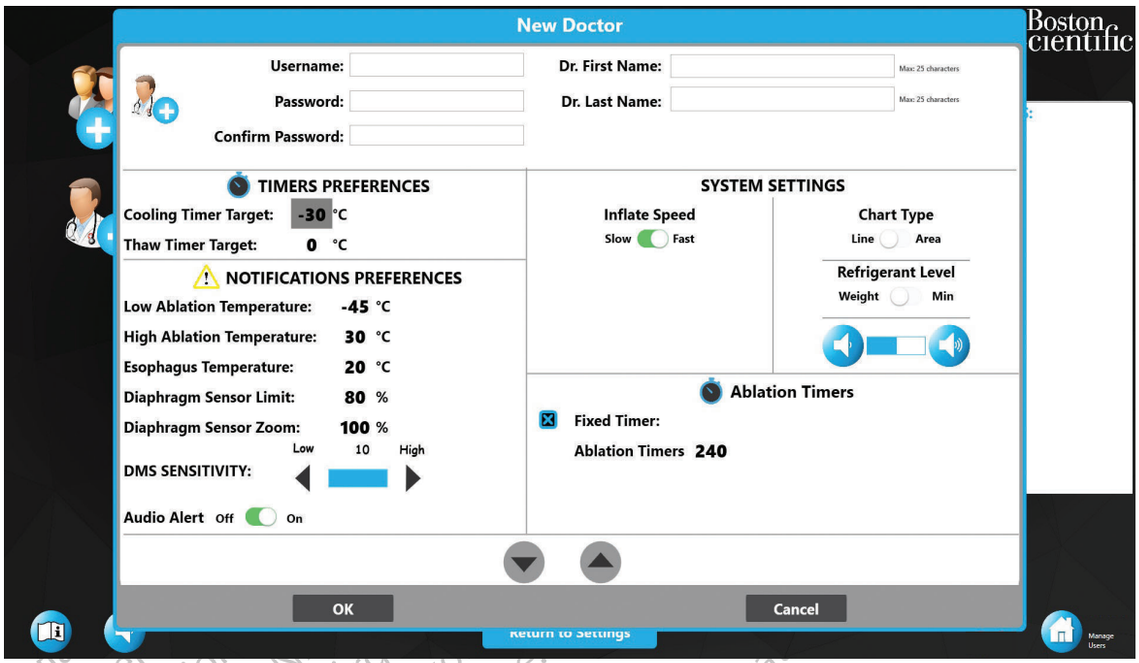

Figure 37. New doctor setup

The New Doctor screen (Figure 37) allows a doctor's individual procedure settings and preferences to be preset and then loaded whenever that physician is selected at the beginning of a procedure.

To edit a user or a doctor, select the subject from the user list and tap the Edit icon. For users, only user names and access levels can be edited. In the case of doctors, the doctor's name and individual settings/preferences can be edited.

To delete a user, select the user from the list and tap the Delete icon.

To reset a user/doctor password, select the subject and press the Reset Password icon.

Note: The logged-in administrator must enter their own password first.

11.3 Adjusting the Clock for Daylight Savings Time

Press the **Date and Time** button on the Settings screen.

Press the **Daylight Savings** button on the Date and Time screen to enable/disable daylight savings time (see Figure 38).

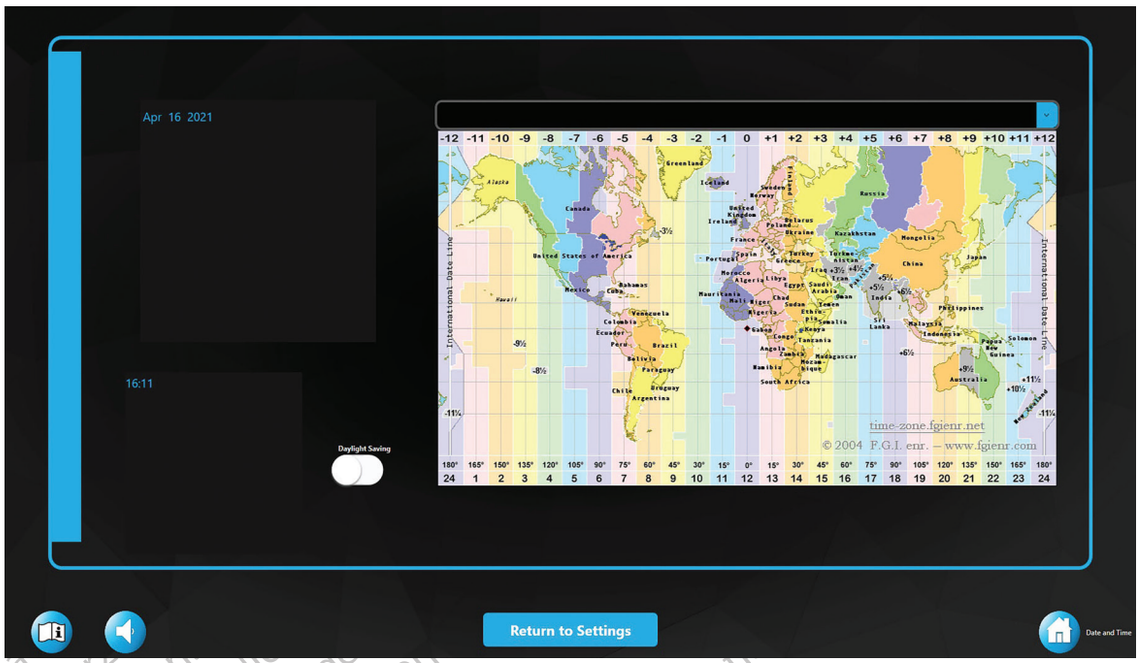

Figure 38. Daylight Savings Time Settings

11.4 Archiving Records

Archiving records allows the system to continue to be used when the available hard drive space is too low.

1. Press the **Archive Records** button on the Settings screen.

Note: Once archived, the records are not viewable on the SMARTFREEZE Console.

2. Press **Yes** to archive the patient records on the SMARTFREEZE Console. Press **No** to cancel the archiving process.
3. After the archiving procedure is complete, press **OK** to close the window.

Note: The SMARTFREEZE Console will shutdown after pressing **OK**.

Figure 39. Archive Confirmation

11.5 User's Manual

The SMARTFREEZE Console user's manual can be found on every user screen.

Press the button to display the user's manual.

Note: The user's manual is not available for display when N_2O is flowing in and out of the SMARTFREEZE Console.

To change the language of the user's manual to another supported language, press the drop-down arrow next to the Language setting on the Settings screen and select the desired language.

12. REVIEW AND EXPORT TREATMENT RECORDS

Note: Only doctor profiles have access to treatment records. Moreover, only the doctor profile (attending physician) associated with a given patient treatment file is permitted to review and/or export records from that file. The doctor must be logged in to review treatment records.

12.1 Review Treatment Records

1. Press the **Records** button on the Home screen (Figure 40).

Figure 40. Home screen

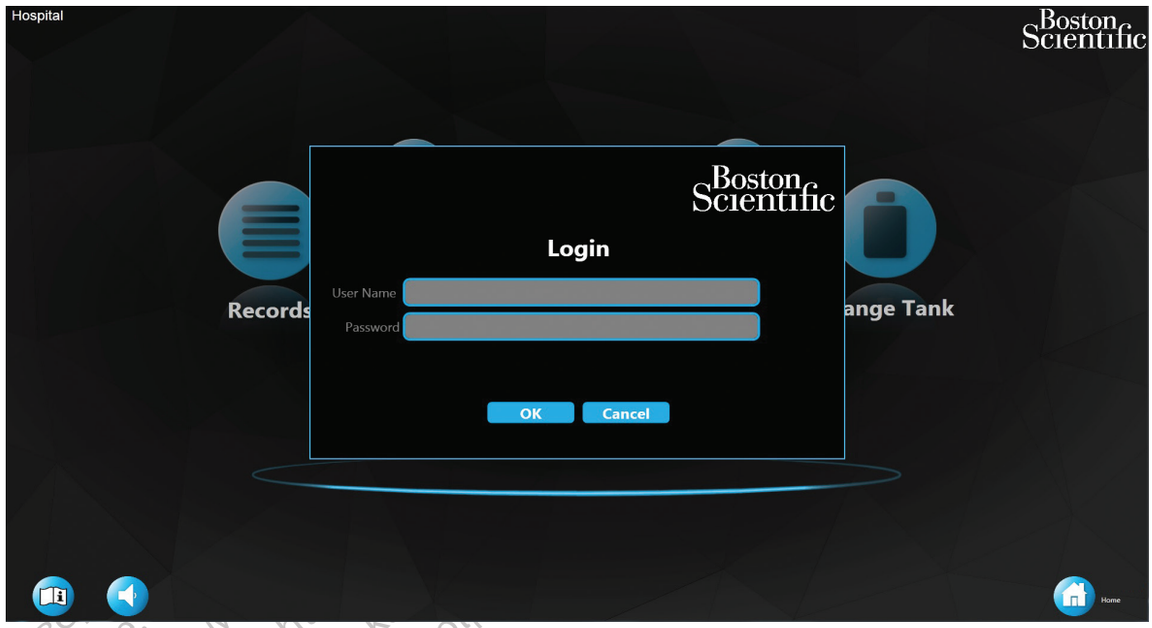

Figure 41. Login screen

2. Enter physician's user name and password.
3. Press the **OK** button on the login screen

   If the entered user name and password have the necessary rights, the Treatment Records screen is displayed (Figure 42).

Figure 42. Treatment Records screen

The following can be observed on the Treatment Records screen:

- The **PROCEDURE RECORDS** list is displayed on the right of the screen. The list can be sorted by patient first name, last name, or by case date. To sort from A to Z by one of these categories, press on the **First Name, Last Name** or **Case Date** column titles. Press a second time to sort from Z to A.
- The Patient Information is displayed on the top left of the screen.
- The Procedure configuration information is displayed at the top right of the screen.
- The recorded procedure data is displayed on the left of the screen.

4. Select a procedure record from the list. The corresponding recorded data is displayed.
5. Select a point on the graph to display the corresponding data from that moment during the treatment.
6. If more than one treatment was performed during the selected case, use the Treatment arrows (Figure 42) to display data from the different treatments performed.
7. Press the **Summary Report** button on the Treatment Records screen to display the summary of all treatments from the selected case (Figure 43).

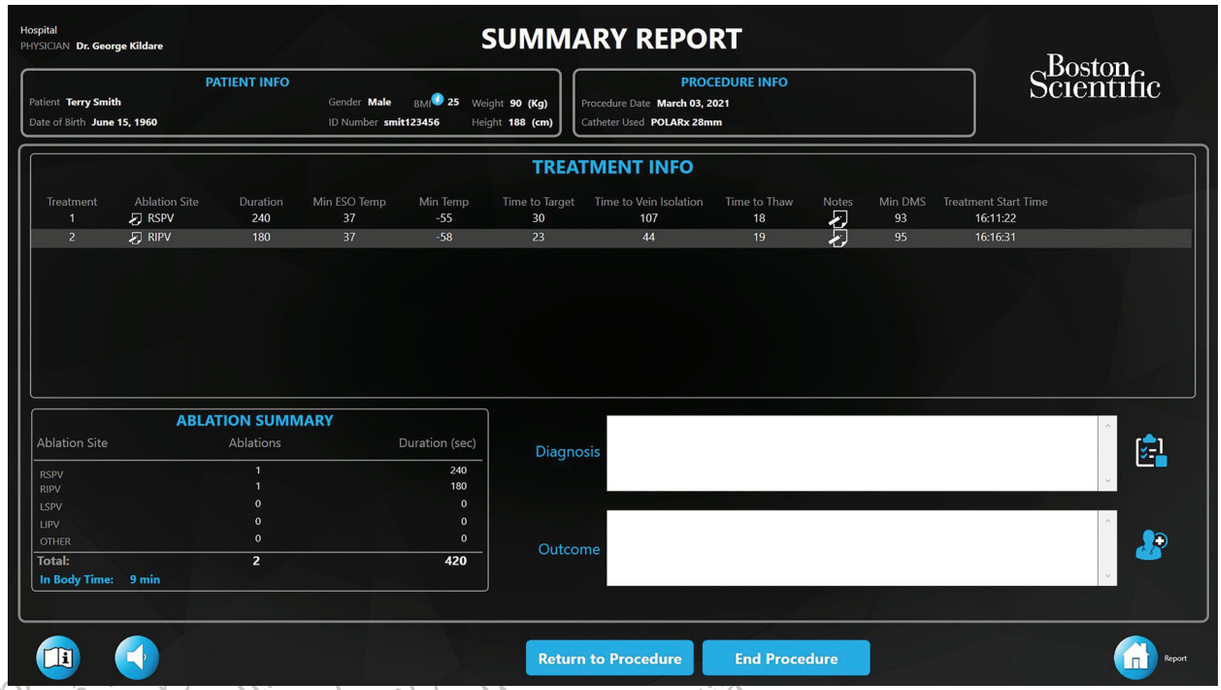

Figure 43. Summary Report Screen

The following can be observed on the Summary Report screen:

- The Patient Information is displayed on the top left of the screen.
- The Procedure configuration information is displayed at the top right of the screen.
- The  button appears when any of the of data fields on this screen have been edited and shows the edit history.
- Each of the treatments that were performed during the procedure are individually entered in the **TREATMENT INFO** table. The ablation site, duration, temperature rate, lowest temperature achieved, time to ablation temperature and time to thaw temperature as well as any notes that were added per treatment can be seen.
- The ablation site for each treatment may be updated by pressing the clipboard icon in the ablation site column next to each treatment.
- The **ABLATION SUMMARY** is displayed on the Summary Report screen.

8. Click on the  icon next to each treatment to see the treatment notes. The **TREATMENT NOTES** window is displayed.
9. Press the **OK** button to close the Treatment Notes window.
10. Click on the  icon next to the Diagnosis field to see the overall patient diagnosis. The Diagnosis window is displayed.
11. Press the **OK** button to close the Diagnosis window.

12. Click on the  icon to see the overall procedure outcome.
    The Outcome window is displayed.
13. Press the **OK** button to close the Outcome window.
14. Press the **Back To Treatment Record** button to return to the Treatment Records screen.

12.2 Export Treatment Records

1. Insert a USB drive into the USB slot on the front panel.
2. Select the procedure record that will be exported from the list of procedure records.
3. Press on the **Save to USB** button on the Treatment Records screen.

Note: The **Save to USB** button on the Treatment Records screen is not available until the SMARTFREEZE Console has successfully recognized the USB drive.

The **SAVE TO USB DRIVE** window will be displayed (Figure 44).

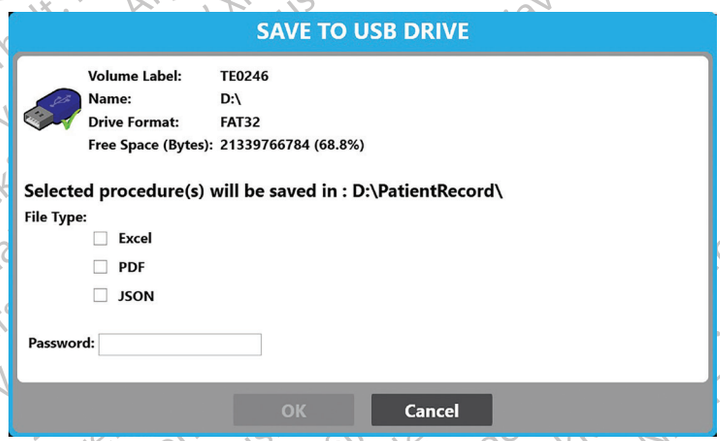

Figure 44. **Save to USB Drive** window

4. Select the desired file type(s).
5. Press the **OK** button on the **SAVE TO USB DRIVE** window or **CANCEL** to return to the Treatment Records screen without saving.

Note: Once the file has successfully been exported to the USB drive, the **Procedure Saved Successfully** window will be displayed (Figure 45).

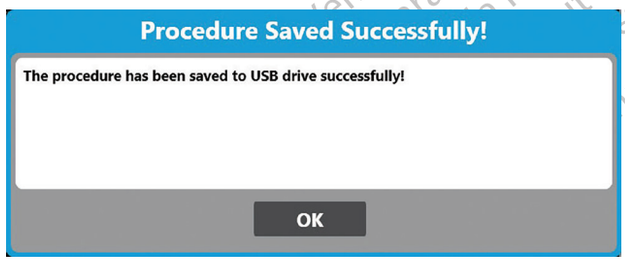

Figure 45. Procedure Saved Successfully window

6. Press the **OK** button on the **Procedure Saved Successfully** window.
7. Remove the USB drive from the USB slot on the SMARTFREEZE Console front panel.

Note: It is recommended that dedicated USB drives be used to store Console procedure records to ensure the security of patient health information.

Note: The exported information contains all the recorded information from the selected case. Recorded information begins from **ABLATION** state of the procedure and ends after the **THAWING** state.

12.3 Report Printing

If a BSC supplied printer is connected to one of the SMARTFREEZE Console USB ports, the PDF report may be printed.

Press the **Print Report** button on the Records screen.

13. TROUBLESHOOTING

System Notice Number	Problem	Action
00000020-1	Low refrigerant level in the tank.	Consider replacing the refrigerant tank soon.
00000200-1	The tank pressure is too low.	Ensure that the refrigerant tank valve is open. If the problem persists, replace the tank. If the problem persists, contact Boston Scientific technical support and provide the message code.
00040000-1	The subcooler temperature is too high.	Wait 5 minutes before attempting the next ablation. If the problem persists, contact Boston Scientific technical support and provide the message code.
00200000-1	The system has detected a stuck command.	One of the Start/Stop commands (Pushbuttons, Foot Switch or Screen input) is defective. If one of the Start commands is stuck, the case may be completed using one of the other Start commands. If one of the Stop commands is stuck, the case cannot be continued. Contact Boston Scientific technical support and provide the message code.
1 - 00000004-2	The inner balloon pressure is too high.	Try another ablation. If the problem persists, replace the cryocable then the catheter. If the problem persists, contact Boston Scientific technical support and provide the error code.
1 - 00000008-2	The inner balloon pressure is too low.	Repeat the inflation, if the problem persists replace the catheter.
1 - 00000020-2	The outer balloon pressure is too high.	Disconnect and reconnect the cryocable from the SMARTFREEZE Console and catheter. If the problem persists, replace the catheter and cryocable. If the problem persists, contact Boston Scientific technical support and provide the error code.
1 - 00001000-2	The balloon temperature is too low. The catheter might be too deep in the vein.	Reposition the catheter and try another ablation.
1 - 00004000-2	The SMARTFREEZE Console detected blood in the catheter.	Replace the catheter. Do not attempt any more inflations or ablations with this catheter.

System Notice Number	Problem	Action
1 - 00008000-2	The SMARTFREEZE Console detected a problem with the blood detection circuit in the catheter.	Replace the catheter. Do not attempt any more inflations or ablations with this catheter.
2 - 00000001-1	The SMARTFREEZE Console has detected a hardware problem.	Disconnect the ICB from the SMARTFREEZE Console and reboot the SMARTFREEZE Console. Once the SMARTFREEZE Console finishes rebooting, connect the ICB to the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00000002-1	The SMARTFREEZE Console has detected a hardware problem.	Disconnect the ICB from the SMARTFREEZE Console and reboot the SMARTFREEZE Console. Once the SMARTFREEZE Console finishes rebooting, connect the ICB to the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00000002-2	The SMARTFREEZE Console has failed the self test.	Reboot the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00000004-1	High refrigerant flow detected.	Disconnect and reconnect cryocable and try another ablation. If the problem persists, replace the cryocable then the catheter. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00000008-1	Refrigerant flow obstruction detected.	Disconnect and reconnect the cryocable and try another ablation. If the problem persists, replace the cryocable then the catheter. If problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00000010-1	The SMARTFREEZE Console detected that the catheter was electrically disconnected during treatment.	Make sure that the catheter is properly connected to the ICB, and that the ICB is properly connected to the SMARTFREEZE Console. If the problem persists, disconnect and re-connect the ICB from the SMARTFREEZE Console. If the problem persists, disconnect and re-connect the catheter electrical cable from the ICB and then the catheter. Apply vacuum to continue. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00000040-1	Insufficient refrigerant level in tank to perform a procedure.	Replace the refrigerant tank.
2 - 00000080-1	The SMARTFREEZE Console detected that the vacuum was disabled unexpectedly.	Make sure that the cryocable is properly connected to both the SMARTFREEZE Console and the catheter. If problem persists, change the cryocable, then the catheter. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00000400-1	The tank pressure is too high.	Make sure the SMARTFREEZE Console fans are working. Open the tank door and shut down the SMARTFREEZE Console. If the SMARTFREEZE Console fans were working, wait at least 10 minutes before restarting. Otherwise, or if the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00000800-1	The SMARTFREEZE Console has detected a software problem.	Disconnect the ICB from the SMARTFREEZE Console and reboot the SMARTFREEZE Console. Once the SMARTFREEZE Console finishes rebooting, connect the ICB to the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.

System Notice Number	Problem	Action
2 - 00001000-1	The injection pressure is too high.	Replace cryocable and try another ablation. If problem persists, replace the catheter. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00002000-1	The SMARTFREEZE Console has detected a hardware problem.	Contact Boston Scientific technical support and provide the error code.
2 - 00004000-1	Flow obstruction detected.	Disconnect and reconnect the cryocable. If problem persists, replace the catheter. If problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00008000-1	The SMARTFREEZE Console has detected a hardware problem.	Disconnect the ICB from the SMARTFREEZE Console and reboot the SMARTFREEZE Console. Once the SMARTFREEZE Console finishes rebooting, connect the ICB to the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00010000-1	Flow obstruction detected.	Try another ablation. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00020000-1	The SMARTFREEZE Console has detected a hardware problem.	Disconnect the ICB from the SMARTFREEZE Console and reboot the SMARTFREEZE Console. Once the SMARTFREEZE Console finishes rebooting, connect the ICB to the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00100000-1	The SMARTFREEZE Console has detected a hardware problem.	Wait 5 minutes before attempting the next ablation. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 00400000-1	The scavenging line pressure is too high.	Ensure hospital scavenging system is turned on and the scavenging hose is securely attached. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 04000000-1	The SMARTFREEZE Console has failed the self test.	Reboot the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 0003FB12	The system has detected a problem with the communication system.	Disconnect the ICB from the SMARTFREEZE Console and reboot the SMARTFREEZE Console. Once the SMARTFREEZE Console finishes rebooting, connect the ICB to the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.
2 - 0003FB13	The system has detected a problem with the communication system.	Disconnect the ICB from the SMARTFREEZE Console and reboot the SMARTFREEZE Console. Once the SMARTFREEZE Console finishes rebooting, connect the ICB to the SMARTFREEZE Console. If the problem persists, contact Boston Scientific technical support and provide the error code.
0003FB1B	This system is running low on disk space.	Consider downloading case data and archiving the files.
0003FB19	This system is running critically low on disk space.	Download case data and archive the files to continue using the system.

14. MAINTENANCE

14.1 Change tank procedure

Note: The scavenging hose must be attached to both the SMARTFREEZE Console and to the hospital scavenging system before this procedure is started.

1. Press the **Change Tank** button on the home screen.

   Note: If the **Change Tank** button is not in the center forefront, pressing the **Change Tank** button a second time is necessary.

2. Follow the on-screen instructions.
   a. Close the tank valve by rotating the valve clockwise.
   b. Press the **Next** button on the Change Tank screen. The system will purge the N_2O gas within the SMARTFREEZE Console via the scavenging hose.
   c. When the green indicator is displayed, disconnect the tank using the SMARTFREEZE Console wrench.
   d. Remove the tank from the SMARTFREEZE Console.
   e. Place the new tank in the SMARTFREEZE Console and connect the SMARTFREEZE Console tank hose to the tank, securing with the SMARTFREEZE Console wrench.

      Note: Hold the SMARTFREEZE Console tank hose such that the tubing remains vertical when tightening to ensure that the SMARTFREEZE Console door will close.

   f. Choose the tank size.
   g. Open the tank valve by rotating the valve counter-clockwise.
   h. Press the **Finish** button on the Change Tank screen.

14.2 Cleaning

Wipe the SMARTFREEZE Console with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. For the screen, use a standard screen cleaner.

Cleaning should be performed at the end of each case at a minimum.

Never clean and reuse components that are sterile or that are intended for single use.

14.3 Preventative maintenance

The SMARTFREEZE Console and its components must undergo annual preventative maintenance. Contact your local Boston Scientific representative to schedule this service.

15. SMARTFREEZE COMPONENTS

15.1 Console

15.1.1 Specifications

Voltage	100 – 240V, 50/60Hz, 10 - 5A
External Fuses	2 x 10A, 250V delay fuses, 0.250" Diameter x 1.252" L (6.35mm x 31.80mm), Breaking Capacity 1500A @ 250V
Internal Fuses	7.5A, 250V delay fuse, 0.250" Diameter x 1.250" L (6.35mm x 31.75mm), Breaking Capacity 10000A @ 125V
Power Cord	See section 15.5 on page 61.
IEC Compliance	IEC 60601-1 3.1 2012-08, Class I type CF defibrillation proof
Mode of Operation	Continuous
Weight	117Kg (258 lbs)
Console Pressure Measurement Accuracy (Essential performance)	±2% of measurement span
Flow Measurement Accuracy (Essential performance)	+2% S.P. 35-100%, +0.35% F.S. 2-35%
Catheter Pressure Measurement Accuracy (Essential performance)	±1% of measurement span
Temperature Measurement Accuracy (Essential performance)	±1°C

15.1.2 Disposal

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products that are at their end of service life.

Dispose of all single use devices per standard hospital procedures.

15.2 Foot Switch

15.2.1 Intended Use

The Cryo-Console Foot Switch (model M004CRBS4200) is designed for use with the SMARTFREEZE Console.

15.2.2 Description

The foot switch is an optional device that is supplied with the SMARTFREEZE Console. It allows the user to start (green pedal) and stop (orange pedal) the flow of refrigerant for both the inflation and ablation phases of the procedure.

If the foot switch is not connected to the SMARTFREEZE Console or if it is simply not used, the procedure may be started and stopped using the pushbuttons on the SMARTFREEZE Console or the buttons on the touch screen.

The foot switch consists of the following:

- Dual foot switch assembly (green and orange) used to start or stop refrigerant flow;
- Permanently attached connection cable that connects to the foot switch connector on the SMARTFREEZE Console.

15.2.3 Instructions for Use

1. If not already connected, connect the foot switch to the foot switch connector on the SMARTFREEZE Console. The foot switch may remain permanently connected to the SMARTFREEZE Console after the procedure is complete.
2. Position the foot switch in the desired location, ensuring that there are no tripping hazards.
3. Enable the foot switch by pressing the  button on the therapy screen or by pressing and holding the orange foot pedal for three seconds in the **IDLE** or **READY** states.
4. To inflate the cryo-balloon, press and release the green foot pedal.
5. To deflate the cryo-balloon from the inflated state, press and release the orange foot pedal.
6. To begin an ablation from the inflated state, press and release the green foot pedal.
7. To stop an ablation and begin thawing the cryo-balloon, press and release the orange foot pedal.
8. To deflate the cryo-balloon from the thawing state, press and release the orange foot pedal.
9. The foot switch may be temporarily disabled when the SMARTFREEZE Console is in the **IDLE** or the **READY** state by holding the orange pedal down for three seconds. Repeat this action to unlock the foot switch.
10. The foot switch can also be enabled/disabled in any state by using the foot switch enable/disable button on the therapy screen.
11. The system will sense stuck pedals and take appropriate action. If the green pedal (start) becomes stuck, the SMARTFREEZE Console will issue a warning but will continue cryoablation processes already in progress. Should the orange pedal (stop) become stuck, the SMARTFREEZE Console will issue a warning and disable all cryogenic start functionality.

15.2.4 Cleaning and Storage

Wipe the foot switch with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water.

Dry thoroughly before storing it in its designated location on the side of the SMARTFREEZE Console.

Always keep the foot switch stored in its designated location on the side of the SMARTFREEZE Console when not in use.

15.2.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product. Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.2.6 Physical Characteristics

Overall length	19.7cm (7.75in)
Overall width	34cm (13.4in)
Cable length	5m (15ft)

15.3 Refrigerant Tank

15.3.1 Intended Use

The refrigerant tank is designed for use with the SMARTFREEZE Console.

15.3.2 Description

The refrigerant tank supplies nitrous oxide (N_2O) to the SMARTFREEZE Console in liquid form. The tank stores up to 6.8kg (15lbs) of N_2O.

The refrigerant tank consists of the following:

- N_2O reservoir to store the N_2O;
- Control knob used to open or close the tank valve allowing or stopping the flow of refrigerant to the SMARTFREEZE Console.

Note: Tanks may be refilled by an approved gas supplier.

15.3.3 Instructions for Use

1. Pull open the SMARTFREEZE Console door at the rear of the SMARTFREEZE Console to expose the refrigerant tank.
2. Make sure that the tank is centered on the tank support.
3. Turn the refrigerant tank knob counter-clockwise to open the tank valve.
4. Close the SMARTFREEZE Console door during Console use.
5. After the ablation procedure is complete, pull open the SMARTFREEZE Console door at the rear of the SMARTFREEZE Console to expose the refrigerant tank.
6. Turn the refrigerant tank knob clockwise to close the tank valve.

Note: Do not open the tank valve when the tank is not connected to the SMARTFREEZE Console as user injury may occur.

15.3.4 Cleaning and Storage

Wipe the refrigerant tank with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water.

Dry thoroughly before storing the tank in its designated location in the SMARTFREEZE Console. In-use refrigerant tanks are usually stored connected to the SMARTFREEZE Console plumbing with a closed tank valve.

Secure the refrigerant tank to the SMARTFREEZE Console for proper and safe transport of the SMARTFREEZE Console.

Spare refrigerant tanks should be stored upright and in temperatures between 15°C and 30°C.

15.3.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.3.6 Physical characteristics

Net N_2O weight when full (excluding tank weight)	6.8kg (15lbs)
Gross tank weight when full (including tank weight)	European Union: 22.4kg (49lbs)
	North America: 15.4kg (34lbs)
N_2O Purity:	≥99.5% with humidity level <50 ppm

15.4 Scavenging Hose

15.4.1 Intended Use

The scavenging hose (models M004CRBS4310 and M004CRBS4320) is designed for use with the SMARTFREEZE Console.

15.4.2 Description

The scavenging hose connects the SMARTFREEZE Console to the hospital evacuation system for transportation of the refrigerant exhaust from the SMARTFREEZE Console. The scavenging hose is required during ablation procedures.

One end of the scavenging hose connects to the designated connector on the SMARTFREEZE Console. The other end connects to the hospital evacuation system (usually a wall receptacle). An adapter (available from Boston Scientific) may be required to connect the scavenging hose to the hospital system.

15.4.3 Instructions for Use

If not already connected, connect the scavenging hose to the SMARTFREEZE Console and to the hospital evacuation system prior to powering up the SMARTFREEZE Console. Tighten the connections until they are finger-tight. When the procedure is complete, disconnect the scavenging hose from the hospital evacuation system.

15.4.4 Cleaning and Storage

Wipe the scavenging hose with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the scavenging hose in its designated location on the SMARTFREEZE Console by wrapping it around the hooks on the side of the SMARTFREEZE Console.

15.4.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.4.6 Physical Characteristics

Overall Length	12m (40ft)

15.5 AC Power Cord

15.5.1 Intended Use

The SMARTFREEZE Console Power Cord (models M004CRBS6210, M004CRBS62100, M004CRBS62110, M004CRBS62120, M004CRBS62130, M004CRBS6220, M004CRBS6230, M004CRBS6240, M004CRBS6250, M004CRBS6260, M004CRBS6270, M004CRBS6280, M004CRBS6290) is designed for use with the SMARTFREEZE Console.

15.5.2 Description

The SMARTFREEZE Console Power Cord supplies AC electricity to the SMARTFREEZE Console. It is required for Console operation.

The SMARTFREEZE Console Power Cord connects to the SMARTFREEZE Console at the designated inlet on the bottom rear of the SMARTFREEZE Console. The other end connects to a standard source of line power (wall outlet).

15.5.3 Instructions for Use

1. If not already connected, connect the power cord to the SMARTFREEZE Console and to the hospital wall outlet prior to powering up the SMARTFREEZE Console.
2. Press the SMARTFREEZE Console cord retention clip over the power cord to secure power cord in position.
3. After shutting down the SMARTFREEZE Console (see *System shutdown* on page 42), disconnect the power cord from the hospital wall outlet.

15.5.4 Cleaning and Storage

Wipe the power cord with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the power cord in its designated location on the SMARTFREEZE Console by wrapping it around the hooks on the rear of the SMARTFREEZE Console.

15.5.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.5.6 Physical Characteristics

Model Number	Geography	Overall Length
M004CRBS6240	North America	3m (10ft)
M004CRBS6210	Continental Europe	2.5m (8ft)
M004CRBS6270	UK and Ireland	2.5m (8ft)
M004CRBS6260	Switzerland	2.5m (8ft)
M004CRBS6220	Italy	2.5m (8ft)
M004CRBS6230	Australia and New Zealand	2.5m (8ft)
M004CRBS6250	Japan	2.5m (8ft)
M004CRBS6280	China	2.5m (8ft)
M004CRBS6290	Argentina	2.5m (8ft)
M004CRBS62100	Brazil	2.5m (8ft)
M004CRBS62110	Denmark	2.5m (8ft)
M004CRBS62120	Israel	2.5m (8ft)
M004CRBS62130	South Africa	2.5m (8ft)

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CMYK | Black (K) ΔE ≤5.0

15.6 Inter-Connection Box (ICB)

15.6.1 Intended Use/Indications for Use

The Inter-Connection Box (ICB) (model M004CRBS4110 or M004CRBS4130) is designed for use with the SMARTFREEZE Console.

15.6.2 Description

The ICB (model M004CRBS4110) is used to connect the SMARTFREEZE Console to the POLARx Catheter as well as to the optional Diaphragm Movement Sensor (DMS), optional Esophageal Temperature (ETS) Cable, general purpose series 400 temperature sensor. The ICB connects to the front panel connector of the SMARTFREEZE Console. It provides connection points for the Catheter Extension Cable (blue connector), the Diaphragm Movement Sensor (DMS) (white connector), the Esophageal Temperature Sensor (ETS) Cable (orange connector).

The ICB (model M004CRBS4130) is used to connect the SMARTFREEZE Console to the POLARx Catheter as well as to the optional Diaphragm Movement Sensor (DMS), optional Esophageal Temperature (ETS) Cable, general purpose series 400 temperature sensor, the optional Pressure Sensor Cable, off-the-shelf pressure sensor, and optional Remote Control. The ICB connects to the front panel connector of the SMARTFREEZE Console. It provides connection points for the Catheter Extension Cable (blue connector), the Diaphragm Movement Sensor (DMS) (white connector), the Esophageal Temperature Sensor (ETS) Cable or ETS Cable (CIRCA) (orange connector), the Pressure Sensor Cable (yellow connector) and the Remote Control (grey connector).

An ICB is required during ablation procedures.

15.6.3 Instructions for Use

1. If not already connected, connect the Inter-Connection Box (ICB) to the SMARTFREEZE Console front panel connector.
2. Connect one end of the Catheter Extension Cable to the ICB Catheter connector (blue connector).
3. If not already ON, power ON the SMARTFREEZE Console and wait for the boot-up process to complete.
4. Connect the other end of the Catheter Extension Cable to the POLARx Catheter.

Note: If the POLARx Catheter is expired, the SMARTFREEZE Console will display a message indicating that the catheter cannot be used.

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5. If the DMS is being used:
   - Connect the DMS to the ICB Accelerometer connector (white connector).
   - Install and secure the DMS on the patient.
6. If a general purpose series 400 temperature sensor is being used:

Note: The ETS Cable must be used with the compatible ICB. Refer to section 1.1 System Components for compatibility information.

   - Connect the Esophageal Temperature Sensor (ETS) Cable to the ICB Esophagus connector (orange connector).
   - Connect the general purpose series 400 temperature sensor to the ETS Cable.
   - Install and secure the general purpose series 400 temperature sensor on the patient.
7. If a ETS Cable (CIRCA) is being used:

Note: The ETS Cable (CIRCA) must be used with the compatible ICB. Refer to section 1.1 System Components for compatibility information.

- Connect the ETS Cable (CIRCA) to the ICB Esophagus connector (orange connector).
- Install and secure the CIRCA S-CATH™ Esophageal Temperature Probe on the patient.
- Connect the CIRCA S-CATH™ Esophageal Temperature Probe to the ETS Cable (CIRCA).

8. If a pressure sensor is being used:

Note: The Pressure Sensor Cable must be used with the compatible ICB. Refer to section 1.1 System Components for compatibility information.

- Connect the Pressure Sensor Cable to the ICB Pressure Sensor connector (yellow connector) (for model M004CRBS4130 only).
- Place a sterile sleeve over the Pressure Sensor Cable to be able to use it in the sterile field.
- Install the pressure sensor on the POLARx Catheter.
- Connect the pressure sensor to the Pressure Sensor Cable.

9. If the Remote Control is being used:
   - Connect the Remote Control to the ICB (model M004CRBS4130 only).
   - Place a sterile sleeve over the Remote Control to be able to use it in the sterile field.
10. Perform procedural steps as per Console and catheter documentation.
11. After procedure completion, remove the Catheter Extension Cable from the POLARx Catheter.
12. Remove the Catheter Extension Cable from the ICB.
13. If used, remove the DMS from the patient and disconnect the DMS from the ICB.
14. If used, remove the general purpose series 400 temperature sensor from the patient.
15. Disconnect the ETS Cable from the ICB.
16. Disconnect the ICB from the SMARTFREEZE Console.

15.6.4 Cleaning and Storage

Wipe the ICB with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the ICB in its designated location on the SMARTFREEZE Console and placing it in the ICB receptacle.

15.6.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.6.6 Physical Characteristics

Cable Length	2.6m (8.5ft)
Length	9cm (3.6in)
Width	17cm (6.8in)
Height	4cm (1.6in)

15.7 Catheter Extension Cable

15.7.1 Intended Use

The Catheter Extension Cable (model M004CRBS5100) is designed for use with the SMARTFREEZE Console and the POLARx Catheter. **This component is a sterile component (using an ethylene oxide [EO] procedure) intended for single use only.**

15.7.2 Description

The Catheter Extension Cable is a cable that provides an electrical connection between the POLARx Catheter and the SMARTFREEZE Console (via the ICB). It is required during ablation procedures.

The Catheter Extension Cable connects the non-sterile ICB to the sterile POLARx Catheter. Both the ICB and POLARx Catheter have socket connectors that allow the Catheter Extension Cable to be reversible.

15.7.3 Instructions for Use

1. Unpack the Catheter Extension Cable.
2. Connect one end of the Catheter Extension Cable to the ICB Catheter connector (blue connector).
3. Connect the other end of the Catheter Extension Cable to the POLARx Catheter.
4. After procedure completion, disconnect the Catheter Extension Cable from the POLARx Catheter.
5. Disconnect the Catheter Extension Cable from the ICB.

15.7.4 Cleaning and Storage

The Catheter Extension Cable is a sterile, single use component. Do not attempt to clean it.

Prior to removal from packaging, store the Catheter Extension Cable in the same conditions as the SMARTFREEZE Console (see section *How Supplied* on page 11).

15.7.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Discard all sterile single use components as per standard hospital procedures.

15.7.6 Physical Characteristics

Overall Length	107cm (42in)

15.8 Cryo-Cable

15.8.1 Intended Use

The Cryo-Cable (model M004CRBS5200) is designed for use with the SMARTFREEZE Console and the POLARx Catheter. **This component is a sterile component intended for single use only.**

15.8.2 Description

The Cryo-Cable provides a mechanical connection between the POLARx Catheter and the SMARTFREEZE Console. It allows for the flow of N_2O from the SMARTFREEZE Console to the POLARx Catheter and returns the exhaust from the catheter to the SMARTFREEZE Console. It is required during ablation procedures.

15.8.3 Instructions for Use

1. Unpack the Cryo-Cable.
2. Connect one end of the Cryo-Cable to the mechanical connector on the SMARTFREEZE Console.
3. Connect the other end of the Cryo-Cable to the POLARx Catheter handle.
4. After procedure completion, disconnect the Cryo-Cable from the POLARx Catheter handle.
5. Disconnect the Cryo-Cable from the SMARTFREEZE Console.

15.8.4 Cleaning and Storage

The Cryo-Cable is a sterile, single use component. Do not attempt to clean it.

Prior to removal from packaging, store the Cryo-Cable in the same conditions as the SMARTFREEZE Console (see section *How Supplied* on page 11).

15.8.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Discard all sterile single use components as per standard hospital procedures.

15.8.6 Physical Characteristics

Overall Length	190cm (75in)

15.9 EP Electrical Cable

15.9.1 Intended Use

The EP Electrical Cable (model M004CRBS6200) is designed for use with the POLARMAP Mapping Catheter and the hospital EP recording system. **This component is a sterile component intended for single use only.**

15.9.2 Description

The EP Electrical Cable connects the POLARMAP Mapping Catheter to the hospital EP recording system. Its use is optional during ablation procedures.

The EP Electrical Cable has ten (10) 2mm connection points that connect to the hospital EP recording system and one (1) connector that connects directly to the POLARMAP Mapping Catheter.

15.9.3 Instructions for Use

1. Connect the EP Electrical Cable to the POLARMAP Mapping Catheter.
2. Connect the eight (8) connection points to the hospital EP recording system.

Note: Pins 9 and 10 are not used when connecting this catheter.

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3. After procedure completion, disconnect the EP Electrical Cable from the POLARMAP Mapping Catheter.
4. Disconnect the eight (8) connection points from the hospital EP recording system.

15.9.4 Cleaning and Storage

The EP Electrical Cable is a sterile, single use component. Do not attempt to clean it.

Prior to removal from packaging, store the Cryo-Cable in the same conditions as the SMARTFREEZE Console (see section *How Supplied* on page 11).

15.9.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Discard all sterile single use components as per standard hospital procedures.

15.9.6 Physical Characteristics

Overall Length	183cm (72in)

15.10 Diaphragm Movement Sensor (DMS)

15.10.1 Intended Use

The Diaphragm Movement Sensor (DMS) (model M004CRBS6110) is designed for use with the SMARTFREEZE Console.

15.10.2 Description

The Diaphragm Movement Sensor (DMS) is an adjunctive sensor designed to monitor a phrenic nerve pacing response.

WARNING: Standard of care methods for evaluating phrenic nerve function and determining when intervention is needed should always be applied during right pulmonary vein ablations. The DMS is not intended as a substitute for such standard of care methods.

15.10.3 Instructions for use

1. Connect the DMS to the ICB.
2. Place a disposable ECG electrode just below the right side costal cartilage.
3. Snap the DMS onto the electrode.
4. Ask the patient to cough and verify that signal is visible on the SMARTFREEZE Console screen. Adjust the position of the electrode if necessary.
5. Prior to performing the ablation, pace the phrenic nerve with a focal or circular catheter positioned superior to the ablation location (e.g. superior vena cava) . Adjust the pacing settings and catheter location as necessary to attain phrenic nerve capture. Typically, high output at 20 mA and 800 – 1000 ms may be needed.

   Note: Avoid or minimize use of paralytics if general anesthesia is used as paralytics may interfere with pacing capture of the phrenic nerve.

6. While pacing the phrenic nerve, adjust the DMS gain and sensitivity levels within the Settings screen to maximize the DMS signal level in the display window. Reduce the gain if the DMS signal appears saturated. Stop pacing until needed for the ablation.
7. Set the DMS threshold (within the Settings screen) at which the DMS notification will be displayed.
   - The movement amplitude measured by the DMS at the initiation of cryoablation is used as the baseline value and is displayed as 100%.

- If the phrenic nerve pacing response decreases during cryoablation, the DMS amplitude will correspondingly decrease. The SMARTFREEZE Console will display the DMS amplitude as a percentage of the baseline value. For example, 80% displayed on the SMARTFREEZE Console indicates the DMS amplitude is 80% of the baseline value and that movement amplitude is reduced by 20%.

8. In case of a DMS notification, continue to closely monitor phrenic nerve activity and pacing capture, and consider immediately interrupting cryoablation.
9. After procedure completion, remove the DMS from the electrode.
10. Disconnect the DMS from the ICB.

15.10.4 Cleaning and Storage

Wipe the DMS with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the DMS with the ICB or in the tank storage area at the rear of the SMARTFREEZE Console.

15.10.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.10.6 Physical Characteristics

Overall Length	3m (9.8ft)

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15.11 ETS Cable (CIRCA)

15.11.1 Intended Use/Indications for Use

The ETS Cable (CIRCA) (model M004CRBS6340) is designed for use with the SMARTFREEZE Console and the CIRCA S-CATH™ Esophageal Temperature Probe.

15.11.2 Description

The ETS Cable (CIRCA) is used to connect the CIRCA S-CATH™ Esophageal Temperature Probe to the ICB. The CIRCA S-CATH™ Esophageal Temperature Probe is used to measure the patient's esophageal temperature during ablation procedures to monitor for esophagus damage. Its use is optional during ablation procedures.

15.11.3 Instructions for Use

1. Insert and secure the CIRCA S-CATH™ Esophagus Temperature Probe on the patient.
2. Connect the ETS Cable (CIRCA) to the ICB.
3. Connect the CIRCA S-CATH™ Esophagus Temperature Probe to the ETS Cable (CIRCA).
4. After procedure completion, remove the CIRCA S-CATH™ Esophageal Temperature Probe from the patient.
5. Disconnect the CIRCA S-CATH™ Esophageal Temperature Probe from the ETS Cable (CIRCA).
6. Disconnect the ETS Cable (CIRCA) from the ICB.

15.11.4 Cleaning and Storage

Wipe the ETS Cable (CIRCA) with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the ETS Cable (CIRCA) with the ICB or in the tank storage area at the rear of the SMARTFREEZE Console.

15.11.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.11.6 Physical Characteristics

Overall Length	3m (9.8ft)

15.12 Esophageal Temperature Sensor (ETS) Cable

15.12.1 Intended Use/Indications for Use

The Esophageal Temperature Sensor (ETS) Cable (model M004CRBS6310 or M004CRBS6320) is designed for use with the SMARTFREEZE Console and a general purpose series 400 temperature sensor.

15.12.2 Description

The ETS Cable is used to connect a general purpose series 400 temperature sensor to the ICB. The general purpose series 400 temperature sensor is used to measure the patient's esophageal temperature during ablation procedures to monitor for esophagus damage. Its use is optional during ablation procedures.

15.12.3 Instructions for Use

1. Install and secure the general purpose series 400 temperature sensor on the patient.
2. Connect the ETS Cable to the ICB.

Note: The ETS Cable must be used with the compatible ICB. Refer to section 1.1 System Components for compatibility information.

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3. Connect the ETS Cable to the general purpose series 400 temperature sensor.
4. After procedure completion, remove the general purpose series 400 temperature sensor from the patient.
5. Disconnect the general purpose series 400 temperature sensor from the ETS Cable.
6. Disconnect the ETS Cable from the ICB.

15.12.4 Cleaning and Storage

Wipe the ETS Cable with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the ETS Cable with the ICB or in the tank storage area at the rear of the SMARTFREEZE Console.

15.12.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.12.6 Physical Characteristics

Overall Length	3m (9.8ft)

15.13 Wrench

15.13.1 Intended Use

The Wrench (model M004CRBS6400) is intended for use with the SMARTFREEZE Console.

15.13.2 Description

The Wrench is a 1-1/8” open-end wrench used while changing a refrigerant tank to tighten and loosen the SMARTFREEZE Console connection to the tank.

15.13.3 Instructions for Use

1. When using the Wrench to loosen the tank connection for removal, make sure that the tank valve is completely closed to avoid injury.
2. Place the Wrench over the nut securing the SMARTFREEZE Console plumbing to the tank and rotate counter- clockwise to loosen.
3. When using the Wrench to tighten the tank connection for installation, first place the SMARTFREEZE Console plumbing nut over the tank port and tighten by hand.
4. Place the Wrench over the nut and rotate clockwise to tighten.

15.13.4 Cleaning and Storage

Wipe the Wrench with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the Wrench in the tank storage location at the rear of the SMARTFREEZE Console.

15.13.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.13.6 Physical Characteristics

Open-end width	1 1/8”

15.14 Remote Control

15.14.1 Intended Use

The Remote Control (model M004CRBS6500) is intended for use with the SMARTFREEZE Console.

15.14.2 Description

The Remote Control is used to change the ablation site, increase/decrease the ablation time, enable/disable vacuum and indicate vein isolation, and to allow starting/stopping of cryo-energy to the POLARx Cryoablation Balloon Catheter.

15.14.3 Instructions for Use

1. Connect the Remote Control to the ICB (model M004CRBS4130).
2. If applicable, place a sterile sleeve over the Remote Control prior to introducing it to the sterile field.

Note: The Remote Control is not a sterile product.

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3. If necessary, press the plus/minus buttons associated with the ⏱ to increase/decrease the Ablation Duration prior to or during an ablation.

Note: This feature only works with the Fixed ablation timer method.

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4. If necessary, press the left/right pointing arrows associated with the 📍 to toggle between ablation sites.
5. In the Idle state, press the ◇ button on the Remote Control to enable the vacuum.
6. In the Ready state, press the ▽ button on the Remote Control to disable the vacuum.
7. Press the ◇ to inflate/ablate, depending on the system state (see above for ablation procedure).
8. During ablation, press the ◇ button on the Remote Control to indicate vein isolation.
9. Press the ▽ to stop the ablation/deflate the balloon (see above for ablation procedure).
10. The Remote Control indicates the state of the system:
    - Off: Idle
    - Green: **READY**
    - Solid Blue: **INFLATION** / **THAWING**
    - Flashing Blue: **ABLATION**
    - Red: Fault

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15.14.4 Cleaning and Storage

Wipe the Remote Control with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the Remote Control with the ICB on the side of the SMARTFREEZE Console in the ICB receptacle or in the tank storage area.

15.14.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Follow local regulations to dispose of this product.

Contact your local Boston Scientific service representative for disposal instructions for Boston Scientific products.

15.14.6 Physical Characteristics

Cable Length	3m (9.6ft)
Remote Control Length	15cm (5.7in)
Remote Control Width	4cm (1.7in)
Remote Control Height	2cm (0.63in)

15.15 Pressure Sensor Cable

15.15.1 Intended Use

The Pressure Sensor Cable (model M004CRBS6600) is designed for use with the SMARTFREEZE Console and the POLARx Catheter. This component is a non-sterile component that may be used in the sterile field when inserted into a sterile sleeve.

WARNING: Cryoablation therapy applied with the balloon positioned within the pulmonary veins may cause PV stenosis and injury to adjacent tissues resulting in patient complications, including death. If using pressure measurement to assess PV occlusion, verify the balloon is properly positioned using fluoroscopy or other appropriate visualization technique.

Note: The occlusion pressure measurement is intended to provide supplemental information for assessing pulmonary vein occlusion. Pressure measurement is not intended to be a substitute for fluoroscopy or other visualization methods used for confirming pulmonary vein occlusion and ensuring that the balloon is properly positioned prior to therapy delivery, as recommended in the POLARx Cryoablation Balloon Catheter Instructions for Use.

15.15.2 Description

The Pressure Sensor Cable is used to connect an off-the-shelf pressure sensor to the ICB. The pressure sensor is used to measure the ventricular pressure during ablation procedures to aid in determining vein occlusion. Its use is optional during ablation procedures.

15.15.3 Instructions for Use

1. Connect the Pressure Sensor Cable to the ICB Pressure Sensor connector (yellow connector).
2. If applicable, place a sterile sleeve over the Pressure Sensor Cable to prior to introducing the sterile field.
3. Install the pressure sensor on the POLARx Catheter.
4. Connect the pressure sensor to the Pressure Sensor Cable.
5. After procedure completion, disconnect the off-the-shelf pressure sensor from the POLARx Catheter.
6. Disconnect the off-the-shelf pressure sensor from the Pressure Sensor Cable.
7. If applicable, remove sterile sleeve.
8. Disconnect the Pressure Sensor Cable from the ICB.

15.15.4 Cleaning and Storage

Wipe the Pressure Sensor Cable with a damp cloth. If necessary, use a mild detergent solution or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the Pressure Sensor Cable with the ICB or in the tank storage area at the rear of the SMARTFREEZE Console.

15.15.5 Disposal

Do not dispose of this product in the unsorted municipal waste system. Discard all sterile single use components as per standard hospital procedures.

15.15.6 Physical Characteristics

Overall Length 200cm (79in)

16. EMC OPERATING CONDITIONS

EMC SPECIFICATIONS & LABELING

SMARTFREEZE™ Cryoablation System Console Electromagnetic Emissions

The SMARTFREEZE Cryoablation System Console is intended for use in the electromagnetic environment specified below. The customer or the user of the SMARTFREEZE Cryoablation System Console should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic Environment
RF Emissions EN 55011/CISPR 11	Group 1	The SMARTFREEZE Cryoablation System Console uses RF energy only for its interval function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The SMARTFREEZE Cryoablation System Console is suitable for use in all establishments other than domestic, and may be used connected to the public low voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING**: The SMARTFREEZE Cryoablation System Console is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measure such as re-orientating or relocating the SMARTFREEZE Cryoablation System Console or shielding the location.
RF Emissions EN 55011/CISPR 11	Class A	
Harmonic Emission EN 61000-3-2	Class A	
Voltage Fluctuations/ flicker Emission EN 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

Electromagnetic Immunity

The SMARTFREEZE Cryoablation System Console is intended for use in the electromagnetic environment specified below. The customer or the user of the SMARTFREEZE Cryoablation System Console should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2 JIS C61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4 JIS C61000-4-4	±2 kV for power supply lines	±2 kV AC power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC 61000-4-5 JIS C61000-4-5	±0.5 kV, ±1 kV Line to Line ±0.5 kV, ±1 kV, ±2 kV Line to Ground	±0.5 kV, ±1 kV Line to Line ±0.5 kV, ±1 kV, ±2 kV Line to Ground	Mains and power quality should be that of a typical commercial or hospital environment.

Table 2 Electromagnetic immunity (*continued*)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 JIS C61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T)for 5 sec.	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T)for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SMARTFREEZE™ Cryoablation System Console requires continued operation during power mains interruptions, it is recommended that the SMARTFREEZE Cryoablation System Console be powered rom an uninterruptable power supply (UPS) or a battery.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8 JIS C61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 JIS C61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands inside 105 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands inside 105 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the SMARTFREEZE Cryoablation System Console, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

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Table 2 Electromagnetic immunity (*continued*)

Radiated RF IEC 61000-4-3 JIS C61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m 80 MHz to 2,7 GHz	Recommended separation distance:	
			$d = 1,2\sqrt{P}$	150 kHz to 80 MHz
	RF communication equipment inside 80 MHz to 6 GHz	RF communication equipment inside 80 MHz to 6 GHz	$d = 1,2\sqrt{P}$	80 MHz to 800 MHz
			$d = 2,3\sqrt{P}$	800 MHz to 6 GHz
			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b].	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartFreeze™ Console is used exceeds the applicable RF compliance level above, the SmartFreeze™ Console should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SmartFreeze™ Console.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 3 Separation distances

Recommended separation distances between portable and mobile RF communications equipment and the SMARTFREEZE™ Cryoablation System Console

The SMARTFREEZE Cryoablation System Console is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SMARTFREEZE Cryoablation System Console can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SMARTFREEZE Cryoablation System Console as recommended below, according to the maximum output power of the communications equipment.

Radiated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d = 1{,}2\sqrt{P}$	**80MHZ to 800MHz** $d = 1{,}2\sqrt{P}$	**800MHZ to 2.5GHz** $d = 2{,}3\sqrt{P}$
0.001	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people).

Note 3: Known sources of electromagnetic disturbance such as diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors may interfere with the operation of this device. Avoid operating this device in the presence of such other devices or take other actions to minimize interference such as relocating the devices further apart from this device.

17. WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

EU Importer: Boston Scientific International B.V., Vestastraat 6, 6468 EX Kerkrade, The Netherlands

The SMARTFREEZE cyroablation Console is designed for use with CIRCA S-CATH™ esophageal temperature probe manufactured and distributed by CIRCA Scientific, Inc. CIRCA Scientific, Inc. is independent of and not affiliated with Boston Scientific.

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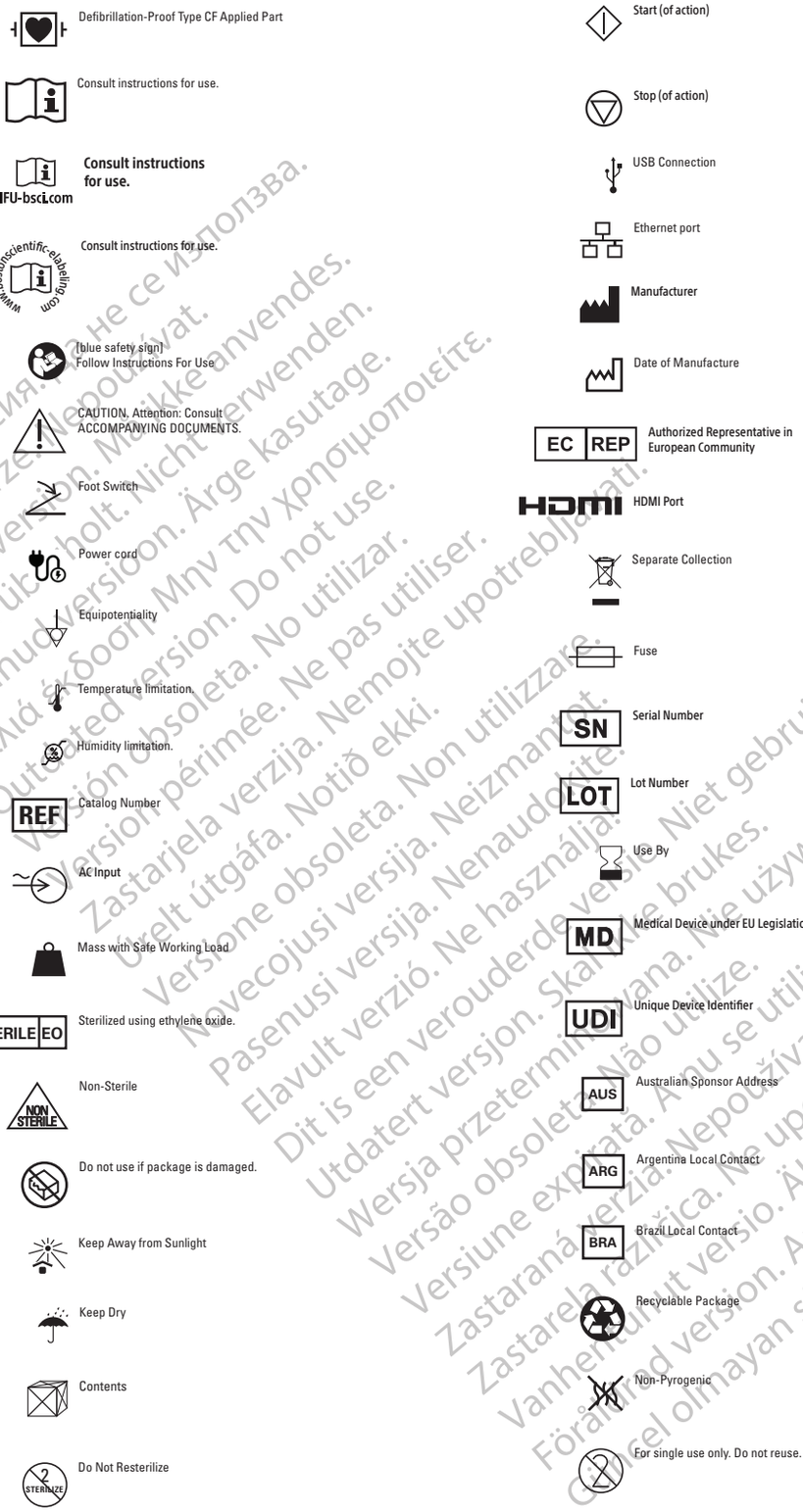
18. SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary. Additional symbols are defined at the end of this document.



Symbol	Title	ISO 15223-1 Reference Number	Description
SN	Serial Number	5.1.7.	Indicates the manufacturer's serial number so that a specific medical device can be identified.
LOT	Lot Number	5.1.5.	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalog Number	5.1.6.	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Date of Manufacture	5.1.3.	Indicates the date when the medical device was manufactured.

EC REP **EU Authorized Representative**

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ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

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Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

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2021-06

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