Boston Scientific

POLARx™

Cryoablation Balloon Catheter

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BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324F), eIFU, MB, POLARx, US, 51594698-01A

℞ **ONLY**

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

WARNING:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Carefully read all ancillary device instructions prior to use, including the SMARTFREEZE™ Cryoablation System Console (henceforth referred to as SMARTFREEZE Console) User's Manual.

Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications and/or failure of the device to perform as intended.

DEVICE DESCRIPTION

The POLARx™ Cryoablation Balloon Catheter (henceforth referred to as POLARx Catheter) is a component of the Boston Scientific Cardiac Cryoablation System (System) and is a single-use, flexible, over-the-wire balloon catheter used to ablate cardiac tissue. The POLARx Catheter is used in conjunction with the SMARTFREEZE Console to induce thermal injury and endocardial tissue necrosis when the POLARx Catheter balloon is in contact with cardiac tissue and reaches cryoablation temperatures created by a nitrous oxide refrigerant (N_2O) injected from the SMARTFREEZE Console into the balloon segment of the POLARx Catheter. The POLARx Catheter connects to the SMARTFREEZE Console with a SMARTFREEZE Cryo-Cable (for N_2O delivery and removal) and a SMARTFREEZE Catheter Extension Cable (for electrical connection via the Inter-Connection Box). The POLARx Catheter is designed to be used with a POLARMAP™ Circular Mapping Catheter (henceforth referred to as POLARMAP Mapping Catheter) deployed within the guidewire lumen during ablation procedures.

During an electrophysiology (EP) ablation procedure, the POLARx Catheter (including the POLARMAP Mapping Catheter) is inserted through a POLARSHEATH™ Steerable Sheath (henceforth referred to as POLARSHEATH Sheath) into the venous system, directed into the left atrium (LA) and towards the ostium of the target pulmonary vein (PV). Once positioning that occludes the PV has been verified, refrigerant is delivered through the Cryo-Cable to the POLARx Catheter injection coil, which directs the flow of refrigerant toward the interior distal surface of the POLARx Catheter balloon. This results in a cooled region at the POLARx Catheter balloon tissue interface, which adheres to the endocardial surface. The low temperature and pressure gradient allows the POLARx Catheter balloon to thermally create transmural, circumferential tissue necrosis (lesions) and interrupt electrical conduction.

The POLARx Catheter is comprised of the following major components, distal to proximal:

- Atraumatic tip
- Double layer balloon system
- Guide wire lumen
- Internal balloon thermocouple
- Injection coil delivery of the refrigerant; liquid nitrous oxide (N_2O)
- Catheter shaft; to retrieve the expanded N_2O gas
- Catheter handle
- Distal handle connections

Contents

One (1) POLARx Cryoablation Balloon Catheter.

Operating Principle

The POLARx Catheter is designed to be an over-the-wire occlusive balloon catheter to deliver cryoablation therapy to the pulmonary veins (PV) for electrical isolation of the PVs. Nitrous oxide refrigerant (N_2O) is delivered from the SMARTFREEZE Console to the distal hemisphere of the inflated balloon via the SMARTFREEZE Cryo-Cable and the POLARx catheter's injection coil. The catheter includes a guidewire lumen for the passage of a POLARMAP Mapping Catheter to provide an atraumatic supportive rail during catheter manipulation and to provide real-time electrograms for assessment of conduction block. Positioning of the POLARx balloon uses guidance from the POLARSHEATH Sheath towards the PV, tracking along the POLARMAP Mapping Catheter, and POLARx catheter tip deflection using a bi-wing steering feature in the catheter handle. The PV occlusion verification may be performed using fluoroscopy and/or other appropriate visualization/assessment techniques. The catheter includes a pressure sensor to enable control of inner balloon pressure during operation. The cryogenic temperature is monitored with a thermocouple inside of the POLARx balloon measuring the temperature of the returning N_2O gas.

Non-pyrogenic

This device meets pyrogen limits specifications for all patient-contacting parts.

User Information

The POLARx Catheter 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.

INTENDED USE

The Boston Scientific Cardiac Cryoablation 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.

The POLARx Cryoablation Balloon Catheter is a single use, flexible, over-the-wire balloon catheter intended to ablate cardiac tissue.

INDICATIONS FOR USE

The Boston Scientific Cardiac Cryoablation System using the POLARx Cryoablation Balloon Catheter is indicated for the treatment of patients with drug refractory, recurrent symptomatic paroxysmal atrial fibrillation (PAF).

CONTRAINDICATIONS

Use of the POLARx Catheter 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 patients with a prosthetic heart valve (mechanical or tissue).
- In the ventricle of the heart where the device may become entrapped in a valve or chordae structures.
- In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event.
- In patients with pulmonary vein stents as the POLARx Catheter may dislodge or damage the stent.
- In patients with cryoglobulinemia as the cryoablation application may lead to vascular injury.
- In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event.
- In patients with intra-atrial septal patch or any other surgical intervention in or adjacent to the intra-atrial septum.
- In patients with an interatrial baffle or path as the transseptal puncture could fail to close.
- In patients with hypercoagulopathy 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.
- In patients previously implanted with a percutaneous Left Atrial Appendage Occlusion device.

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WARNINGS

- Introducing catheters and sheaths into the circulatory system increases the risk of air emboli. Always advance/retract components slowly and use proper flushing techniques to minimize risk of air embolism.
- Avoid proximity to all heart valves whenever possible. Manipulation of the POLARx Catheter across a heart valve structure may result in entanglement and damage to the valve.
- Use of N_2O as a refrigerant during the cryoablation procedure increases the risk of a gas embolism if the integrity of the POLARx Catheter balloon is disrupted. Replace the POLARx Catheter if there is any concern the POLARx Catheter balloon has been damaged.
- Do not use the POLARx Catheter without a POLARMAP Mapping Catheter fully inserted into the guidewire lumen, past the POLARx Catheter balloon. An absent or partially inserted POLARMAP Mapping Catheter may not provide sufficient mechanical support for POLARx Catheter balloon inflation and cryoablation operations and may result in POLARx Catheter damage and N_2O leakage.
- Administer appropriate peri-procedural anticoagulation therapy per standard of care for patients undergoing cardiac cryoablation procedures. Administer anticoagulation therapy during and post-procedure according to local institution standards to minimize bleeding and thrombotic complications.
- Electrophysiology procedures, including ablation, may introduce arrhythmias.
- Always deflate the POLARx Catheter and retract into the POLARSHEATH Sheath before pulling back across the septum. Crossing the septum with the POLARx Catheter balloon exposed, inflated or inflating within the septum may cause endocardial damage.
- Do not use the POLARx Catheter if it is not working properly. A POLARx Catheter failing to function properly should be removed and replaced before continuing with the procedure.
- Do not inflate the balloon while housed in the POLARSHEATH Sheath. Always verify that the POLARx Catheter balloon is outside the POLARSHEATH Sheath before inflation to prevent POLARx Catheter damage.
- Do not inflate the balloon while the POLARx Catheter is positioned inside the PV. Always inflate the POLARx Catheter balloon while the POLARx Catheter is positioned in the LA and then position it in the PV ostium. Inflating the POLARx Catheter balloon in the PV may result in vascular injury.
- Always deflate and extend the POLARx Catheter balloon prior to retraction of the balloon back into the POLARSHEATH Sheath.
- Do not use the POLARx Catheter if any part of the POLARx Catheter shaft appears to be kinked or damaged. If the POLARx Catheter shaft appears kinked while in the body, remove the POLARx Catheter and replace with a new POLARx Catheter before continuing with the procedure.
- When using the POLARx Catheter, catheter manipulation must be carefully performed in order to avoid cardiac damage, perforation, or tamponade. Do not advance the POLARx Catheter with an exposed lumen; always advance the POLARx Catheter over the POLARMAP Mapping Catheter, with the POLARMAP Mapping Catheter distal to the POLARx Catheter balloon. Do not use excessive force to advance or withdraw the POLARx Catheter when resistance is encountered.
- The steerability feature of the POLARx Catheter is designed to operate in a single plane of motion. Attempts to deflect the distal section in other planes (e.g., perpendicular to normal steering plane) may result in damage to the steering mechanism and impaired ability to position the POLARx Catheter as desired by the operator.
- Do not pull or move the POLARx Catheter, POLARSHEATH Sheath, attached cables, or SMARTFREEZE Console while the POLARx Catheter balloon is frozen as this may lead to tissue damage.
- Catheter ablation procedures near or in the PV may cause narrowing or stenosis. Avoid ablation in the tubular portion of the PV.
- Implantable pacemaker (PM) and cardioverter/defibrillator (ICDs) leads may be displaced during an EP procedure. See PM/ICD technical manual for additional instructions.
- To prevent occlusion of the refrigerant line, over-pressurization and potential POLARx Catheter failure when using the POLARx Catheter in combination with the POLARSHEATH Sheath, avoid applying simultaneous high torque (twisting) and tensile stress (pulling) on the POLARx Catheter while the catheter is engaged in the POLARSHEATH Sheath and the POLARx Catheter is deflected.

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- Cryoablations may cause collateral injury to the esophagus and in rare instances atrio-esophageal fistulas. Temperature monitoring with a probe placed within the esophagus may mitigate this risk.
- Cryoablations may cause collateral phrenic nerve injury. Stop cryoablation immediately if phrenic nerve impairment is observed. Continuous phrenic nerve pacing and diaphragm movement monitoring should be performed to mitigate this risk.
- The POLARx Catheter contains pressurized gas during operation. Failure of the POLARx Catheter balloon to operate properly may result in a release of gas into the circulatory system and potential gas emboli.
- Use caution when manipulating the POLARx Catheter around other intracardiac devices. Entanglement may prevent removing the devices from the cardiac chamber and require surgical intervention.
- Significant x-ray exposure during an electrophysiology procedure may result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure and steps taken to minimize this exposure.

PRECAUTIONS

- Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the POLARx Catheter and SMARTFREEZE Console.
- The POLARx Catheter shall only be used with the SMARTFREEZE Console.
- Use only the POLARMAP Mapping Catheter with the POLARx Catheter.
- Use only the POLARSHEATH Sheath with the POLARx Catheter.
- If necessary, use only 0.081 cm (0.032 in.) or 0.089 cm (0.035 in.) guidewires with the POLARx Catheter. Use of other guidewire sizes may damage the POLARx Catheter.
- It is the user's responsibility to ensure that the equipment used with the POLARx Catheter meets all local applicable electrical safety requirements.
- Perform cryoablation procedures only within environmental parameters as outlined in Section 11.8, Specifications.
- Do not immerse the POLARx Catheter handle or Cryo-Cable in fluids; electrical performance could be affected.
- Do not change the equipment configuration or modify the equipment or applied parts in any way. Doing so may cause the system to behave unreliably and affect the patient adversely.
- Always straighten the POLARx Catheter prior to insertion or withdrawal from the body.
- Flush the guidewire lumen initially and then frequently throughout the cryoablation procedure to prevent coagulum formation. If contrast is used, flush the lumen thoroughly after each contrast injection.
- Do not physically scrub or twist the POLARx Catheter balloon surface as damage to the POLARx Catheter balloon may impact balloon shape or integrity.
- Do not apply excessive torque to the POLARx Catheter during the procedure as it may adversely affect the cryoablation function.
- Do not apply excessive torque to the steering lever as doing so may damage the POLARx Catheter deflection mechanism.
- Do not apply excessive force to the POLARx Catheter extension slider switch (slider switch) during cryoablation or while the POLARx Catheter balloon temperature is below freezing as doing so may damage the catheter.
- Properly scavenge and dispose of the N_2O with appropriate hospital systems. Do not outgas in the operating room.
- Dispose of the POLARx Catheter per local regulatory and biohazard standards.

ADVERSE EVENTS

Potential adverse events associated with manipulation of the POLARx Catheter within the left atrium and pulmonary veins may include the following conditions:

- Arrhythmia (new or exacerbated)
  - Conduction pathway injury
- Cardiac arrest
- Cardiac trauma, for example:
  - Cardiac perforation/tamponade/effusion
  - Valvular damage
  - Stiff left atrial syndrome
- Death
- Edema/heart failure/pleural effusion
- GI disorders
- Hypertension
- Hypotension
- Infection/inflammation/exposure to biohazardous material
- Injury related to tissue damage and/or adjacent structures, for example:
  - Esophageal injury
  - Pulmonary injury
  - Catheter entrapment
  - Physical trauma
- Injury due to embolism/thromboembolism/air embolism/foreign body embolism:
  - CVA/stroke
  - TIA
  - MI
  - Neurological impairment and its symptoms, for example:
    - Cognitive changes
    - Visual disturbances
    - Headache
    - Motor impairment
    - Sensory impairment
    - Speech impairment
  - Pulmonary embolism
  - Asymptomatic cerebral embolism
- Nerve injury, for example:
  - Phrenic nerve injury
  - Vagal nerve Injury
- Pain or discomfort, for example:
  - Angina
  - Chest pain
  - Non-cardiovascular pain

- Procedural related side effects, for example:
  - Allergic reaction (including anaphylaxis)
  - GU complications
  - Side effects related to medication or anesthesia
  - Radiation injury/tissue burn
  - Renal failure/insufficiency
  - Vasovagal response
- PV Stenosis and its symptoms, for example:
  - Cough
  - SOB
  - Fatigue
  - Hemoptysis
- Respiratory distress/insufficiency/dyspnea
- Surgical and access complications, for example:
  - Hematoma/seroma
  - AV Fistula
  - Bleeding
  - Pseudoaneurysm
  - Pneumothorax
  - Residual atrial septal defect
- Thrombus/thrombosis
- Vessel Trauma, including:
  - Perforation
  - Dissection
  - Coronary artery injury
  - Vasospasm
  - Occlusion
  - Hemothorax

HOW SUPPLIED

One (1) POLARx Catheter is supplied sterile using an Ethylene Oxide (EO) process and is individually packaged within a pouch. Package contents are listed on the carton and pouch labels.

Device Details

Do not use if package is 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.

Report any serious incident that occurs in relation to this device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.

Handling and Storage

Operating Environment

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

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

Transport Environment

Temperature: -30 °C to 60 °C (-22 °F to 140 °F)

Relative Humidity: 15% to 90%

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 15 °C to 25 °C (59 °F to 77 °F)

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

INSTRUCTIONS FOR USE

Carefully read all instructions prior to use and observe all contraindications, warnings, and precautions. Failure to do so may result in patient harm or device malfunction.

Additional Items For Safe Use

The POLARx Catheter has been tested and verified for use with the POLARSHEATH Sheath, the POLARMAP Mapping Catheter, the SMARTFREEZE Console and its accessories.

Device Compatibility

The POLARx Catheter is compatible for use with the Boston Scientific Cardiac Cryoablation System.

Preparation

Refer to these Instructions for Use and the SMARTFREEZE Console User's Manual when using the POLARx Catheter.

1. Inspect the POLARx Catheter sterile packaging for any breach that may cause contamination of the components.
2. Check the expiration date. Do not use POLARx Catheter devices after the expiration date shown on the POLARx Catheter package label.
3. Remove the POLARx Catheter from the packaging following sterile technique.
4. Inspect the integrity of the POLARx Catheter to verify that there is no damage to the device.
5. Connect the Cryo-Cable and the SMARTFREEZE Catheter Extension Cable to the handle of the POLARx Catheter while maintaining sterility of the POLARx Catheter.
   NOTE: The end of the connections should remain dry.
   NOTE: Connecting the Cryo-Cable and SMARTFREEZE Catheter Extension Cable to the SMARTFREEZE Console should be performed by personnel outside the sterile field (refer to the SMARTFREEZE Console User's Manual).
6. Attach a Y adapter with a Tuohy Borst valve (or equivalent) to the flush port of the POLARx Catheter handle.
7. Flush the POLARx Catheter guidewire lumen and Y adapter with heparinized saline.
8. Prepare and insert a POLARMAP Mapping Catheter into the POLARx Catheter guidewire lumen (refer to POLARMAP Mapping Catheter Instructions for Use).
9. Submerge the POLARx Catheter balloon tip with the protective sleeve in sterile heparinized saline and agitate to remove all air bubbles.
   NOTE: Pulling the sleeve over the POLARx Catheter shaft and back on the POLARx Catheter balloon under saline may remove additional trapped air.
10. Pull the protective sleeve proximally over the shaft to expose the balloon. While submerged in saline, inflate the balloon (refer to SMARTFREEZE Console User's Manual) and remove all air bubbles.
11. Press forward on the extension slide on the POLARx Catheter handle to deflate the balloon. While submerged in saline, pull the protective sleeve back over the balloon.

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Catheter Handle Operation

The POLARx Catheter handle has three controls: the balloon extension slider switch (slider switch) on the top, the steering lever on the left side, and the steering tension knob on the right side.

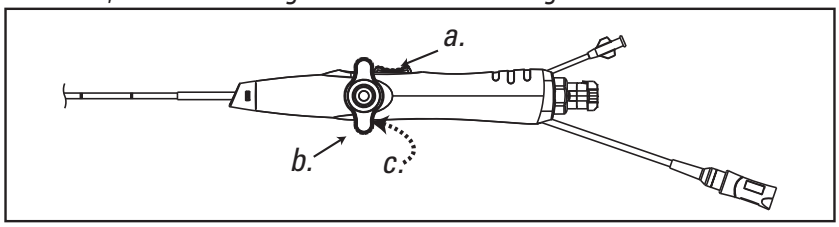

Figure 1. Catheter Handle

a. Slider Switch: Advancing the balloon extension slider switch forward deflates and extends (elongates) the balloon for re-sheathing. Deflation will not occur if the balloon temperature is less than +20°C.
b. Steering lever (left side): From the 12 o'clock (center) position, counterclockwise rotation deflects the POLARx Catheter tip downward; clockwise rotation deflects it upward.
c. Tension knob (right side): Applies tension to the steering lever operation.

The slider switch houses a color-keyed indicator LED which indicates the status of the procedure as follows:

Indicator Color	Procedure Status
Off	Idle
Green	Ready
Solid blue	Inflation / Thaw
Flashing blue	Ablation
Red	Fault –refer to error message on SMARTFREEZE Console screen.

Procedure

To use the POLARx Catheter for a cryoablation procedure, follow these steps: (For more detailed instructions on the use of the SMARTFREEZE Console, refer to its User's Manual.)

1. Create the required vascular access in a large central vein (e.g., femoral vein).
2. Complete a transseptal puncture to access the LA.
3. Place guidewire across the septum to provide sufficient support.
4. Prepare and place a POLARSHEATH Sheath into the LA. (Refer to the POLARSHEATH Sheath Instructions for Use.)
5. Prepare the POLARx Catheter as instructed in the Preparation section.
6. Load the POLARx Catheter with POLARMAP Mapping Catheter across the POLARSHEATH Sheath hemostasis valve while flushing through the POLARx Catheter. Gently insert the introducer sleeve into the handle of the POLARSHEATH Sheath to facilitate loading the POLARx Catheter. DO NOT push the introducer sleeve through the hemostasis valve.
7. Advance the POLARMAP Mapping Catheter and POLARx Catheter to the distal end of the POLARSHEATH Sheath. When the distal end of the POLARx Catheter is at the distal end of the POLARSHEATH Sheath, the first marker band on the POLARx Catheter will align with the end of the handle of the POLARSHEATH Sheath.

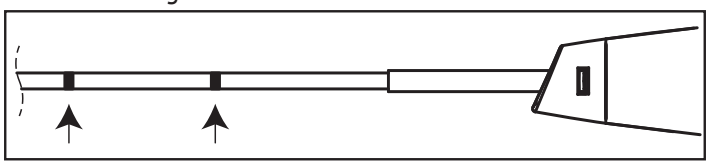

Figure 2. Marker bands

8. Advance the POLARMAP Mapping Catheter into the target PV.
   NOTE: Carefully positioning the POLARMAP Mapping Catheter distally in the target PV may improve POLARx Catheter support and balloon positioning.

9. Advance the POLARx Catheter over the POLARMAP Mapping Catheter into the LA.
10. Verify the POLARx Catheter balloon is completely out of the POLARSHEATH Sheath. This may be performed by confirming the second marker band on the POLARx Catheter is at or past the end of the handle of the POLARSHEATH Sheath.
11. Verify the balloon is at an appropriate position for inflation (e.g., within the left atrium). This may be performed using imaging such as fluoroscopy or echocardiography.
12. Inflate the POLARx Catheter balloon (Refer to the SMARTFREEZE Console User's Manual) in the LA while remaining outside the target PV.
13. Advance the inflated POLARx Catheter balloon, as necessary, to occlude blood flow to the targeted PV, but remain in the atrium outside the tubular portion of the PV. For best results, maneuver the POLARx Catheter and / or POLARSHEATH Sheath to position the distal half of the balloon at the PV ostium.
14. Verify PV occlusion. Verification may be performed with fluoroscopy and 50/50 contrast/saline injection into the guidewire lumen port or with other appropriate visualization / assessment techniques. If the balloon needs to be deflated for repositioning, use the slider switch on the POLARx Catheter handle to simultaneously deflate and extend the balloon.
    NOTE: When using an auto injector for contrast delivery, ensure that the pressure limit does not exceed 500 psig.
    NOTE: If a stable occlusion cannot be achieved, the POLARMAP Mapping Catheter may be exchanged and a guidewire used to provide increased mechanical support. The POLARx Catheter should be removed from the body prior to any POLARMAP Mapping Catheter / guidewire exchange. Proper flushing and air bubble management should be repeated with each exchange.
15. Positioning the POLARMAP Mapping Catheter to visualize pulmonary vein electrograms may improve ablation dosing.
16. Perform the cryoablation. (Refer to the SMARTFREEZE Console User's Manual for setup, settings, and use.)
17. At the completion of the cryoablation application, wait for the thawing phase to complete before any POLARx Catheter balloon manipulation.
    NOTE: Determination of an effective lesion is achieved by verifying electrical isolation of the PV from the LA after the cryoablation has been completed.
    NOTE: As needed, perform additional cryoablation(s) in the same PV, adjusting the position of the POLARx Catheter balloon if necessary.
18. Deflate the POLARx Catheter balloon (Refer to the SMARTFREEZE Console User's Manual).
    NOTE: The POLARx Catheter balloon will automatically deflate once the cryoablation is complete and the balloon temperature has reached +20°C.
    NOTE: Before resheathing, ensure the balloon has been extended by inflating the balloon and deflating using the slider switch on the POLARx Catheter handle.
19. Retract the POLARx Catheter and POLARMAP Mapping Catheter into the POLARSHEATH Sheath.
20. Return to step 8 to position the POLARx Catheter balloon at the ostium of the next targeted PV and repeat steps for positioning, cryoablation application and thawing.
21. After cryoablation treatments of all targeted PVs have been completed and when the POLARx Catheter balloon is completely deflated, extend the POLARx Catheter balloon and retract the POLARx Catheter/POLARMAP Mapping Catheter into the POLARSHEATH Sheath.
22. Remove POLARx Catheter, POLARMAP Mapping Catheter, and POLARSHEATH Sheath from the patient.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

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

Specifications

Catheter Shaft Size	11.8 Fr (4.0 mm)	
Catheter Overall Length	134 cm	
Catheter Tip Outer Diameter (OD)	9 Fr (3 mm)	
Compatible Introducer Sheath	Compatible with POLARSHEATH 12F Steerable Sheath	
Guidewire Lumen Inner Diameter (ID)	Compatible with POLARMAP Mapping Catheter and guidewires ≤ 0.035" (0.89 mm)	
Inflated Balloon Dimensions	Diameter	28 mm
	Catheter Effective Length	99 cm
Tip Length	Short Tip	5 mm
	Long Tip	12 mm
Thermocouples	Internal to Balloon	

PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of the catheter in association with the Electrophysiological cardiac interventional procedure:

- Discuss the risks and benefits including review of potential adverse events listed in this document.
- Discuss post procedure instructions, including any lifestyle changes, medications, when to call the Healthcare Provider (HCP) and any post procedure follow-up that might be needed.

CUSTOMER SERVICE

Boston Scientific team members are dedicated to serving customers and are available to provide training and technical consultation on the use of the BSC Cardiac Cryoablation System to qualified hospital personnel. Please contact your local Boston Scientific representative for more information.

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.

WARRANTY

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

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FROZEN-AF CLINICAL STUDY

Study title	FROzEN-AF study: Safety and Effectiveness IDE trial for Boston Scientific's Cryoballoon in the Treatment of Symptomatic Drug Refractory Paroxysmal Atrial Fibrillation
Number of centers	44 total sites including the United States (30), Europe (6), Canada (4), and Asia-Pacific (4)
Number of subjects	385 subjects treated with the Boston Scientific Cardiac Cryoablation System (including 60 roll-in subjects)

Objective

The objective of the clinical study was to evaluate the safety and effectiveness of the Boston Scientific Cardiac Cryoablation System for the treatment of drug refractory, recurrent symptomatic paroxysmal atrial fibrillation.

FROzEN-AF Study Design, Scope and Methods

The FROzEN-AF study was a multi-center, open label, prospective, single arm study conducted at 44 sites including the United States (30), Europe (6), Canada (4), and Asia-Pacific (4). A total of 404 subjects enrolled in the study, and a total of 385 subjects were treated with the Boston Scientific Cardiac Cryoablation System. All subjects who met the enrollment criteria, signed the consent, and underwent the index procedure with the study devices were followed for twelve (12) months after the index procedure.

Endpoints

Primary Safety Endpoint: Safety event-free rate at 12 months post procedure. Primary safety events consisted of a composite of the following procedure-related and device-related adverse events.

- Acute primary safety endpoint events, occurring up to 7 days post index or hospital discharge, whichever was later, included:
  - Death
  - Myocardial infarction
  - Transient ischemic attack (TIA)
  - Stroke/ Cerebrovascular accident (CVA)
  - Vascular access complications
  - Mitral or tricuspid valvular damage
  - Thromboembolism/ Air embolism leading to a life-threatening event such as a ventricular arrhythmia, stroke, pulmonary embolism, or myocardial infarction, and thromboembolic events that result in permanent injury, require intervention for treatment or prolongs or require hospitalization for more than 48 hours
  - Gastroparesis/ injury to vagus nerve
  - Pneumothorax
  - Pulmonary edema/ heart failure
  - Atrioventricular (AV) block
- Cardiac tamponade/perforation, occurring up to 30 days post index procedure.
- Chronic primary safety endpoint events, events occurring through 12 months post procedure, included:
  - Atrial esophageal fistula
  - Severe pulmonary vein (PV) stenosis (≥ 70% reduction in the diameter of the PV or PV branch from baseline)
  - Persistent phrenic nerve palsy (a non-recovered phrenic nerve palsy at 12 months post index procedure)
- Hypothesis for primary safety endpoint:
  - Ho: The primary safety endpoint event-free rate at 12 months post procedure ≤89%
  - Ha: The primary safety endpoint event-free rate at 12 months post procedure >89%

Primary Effectiveness Endpoint: Failure-free rate at 12 months post procedure. Failure was defined as follows:

- Failure to achieve acute procedural success in the index procedure or repeat procedure during the blanking period
- Use of amiodarone post index procedure
- Surgical treatment for atrial fibrillation (AF), atrial flutter (AFL), or atrial tachycardia (AT) post index procedure
- Use of a non-study ablation catheter for AF targets in the index procedure or repeat procedure during the blanking period

- More than one repeat procedure with the POLARx Catheter during the blanking period (90 days post index procedure)
- Documented atrial fibrillation, or new onset of atrial flutter or atrial tachycardia event (≥ 30 seconds in duration from the study-specific event monitor, Holter Monitor, or from a 10 second 12-lead ECG) between 91 and 365 days post index procedure
- Any of the following interventions for atrial fibrillation, or new onset of atrial flutter or atrial tachycardia between 91 and 365 days post procedure:
  - Repeat procedure
  - Electrical and/or pharmacological cardioversion for AF/AFL/AT
  - Prescribed any anti-arrhythmic drug (AAD) (all Class I/III and any Class II/IV medications taken for control of AF/AT/AFL recurrence)
- Hypothesis for primary effectiveness endpoint:
  - Ho: The 12-month failure-free rate ≤50%
  - Ha: The 12-month failure-free rate >50%

  The performance goal of 50% is based on the minimum chronic acceptable success rate for paroxysmal AF at 12 months follow-up defined in the 2017 HRS Consensus document.

Study Success Criteria

As this study was designed to address the safety and effectiveness of the Boston Scientific Cardiac Cryoablation System, there is both primary safety endpoint and primary effectiveness endpoint. Both primary endpoints must pass in order for study success to be achieved.

Subject Accountability

All subjects who signed and dated the Informed Consent Form were considered enrolled in the study.

All Treatment subjects were counted against the enrollment ceiling of 325 subjects. Subjects were classified as either part of the Roll-In cohort or the Non Roll-In cohort:

Roll-In Subject – To help facilitate investigators' familiarity with the new investigational system and avoid learning curve bias, Roll-in subjects were enrolled at each study site. Each ablating physician needed to treat one Roll-in subject with the Cryoablation System. Data from Roll-In subjects are not included in endpoint analyses.

Non Roll-In Subject – After the Roll-In subject criteria or case review was satisfied (documentation of waiver) for the treating physician, non Roll-in subjects could be enrolled.

Roll-in and non roll-in subjects were further classified as Intent, Attempt, and Treatment as described below.

Intent - Refers to a subject who was enrolled but did not have any study investigational devices inserted into the body.

Attempt - Refers to a subject who was enrolled and had any study device inserted into the body but did not receive any Cryoablation application.

Treatment - Refers to all enrolled subjects who had the study device inserted into the body and received at least one Cryoablation application.

Figure 3 shows the subject disposition for all Roll-In and Non Roll-In subjects in the FROzEN-AF study.

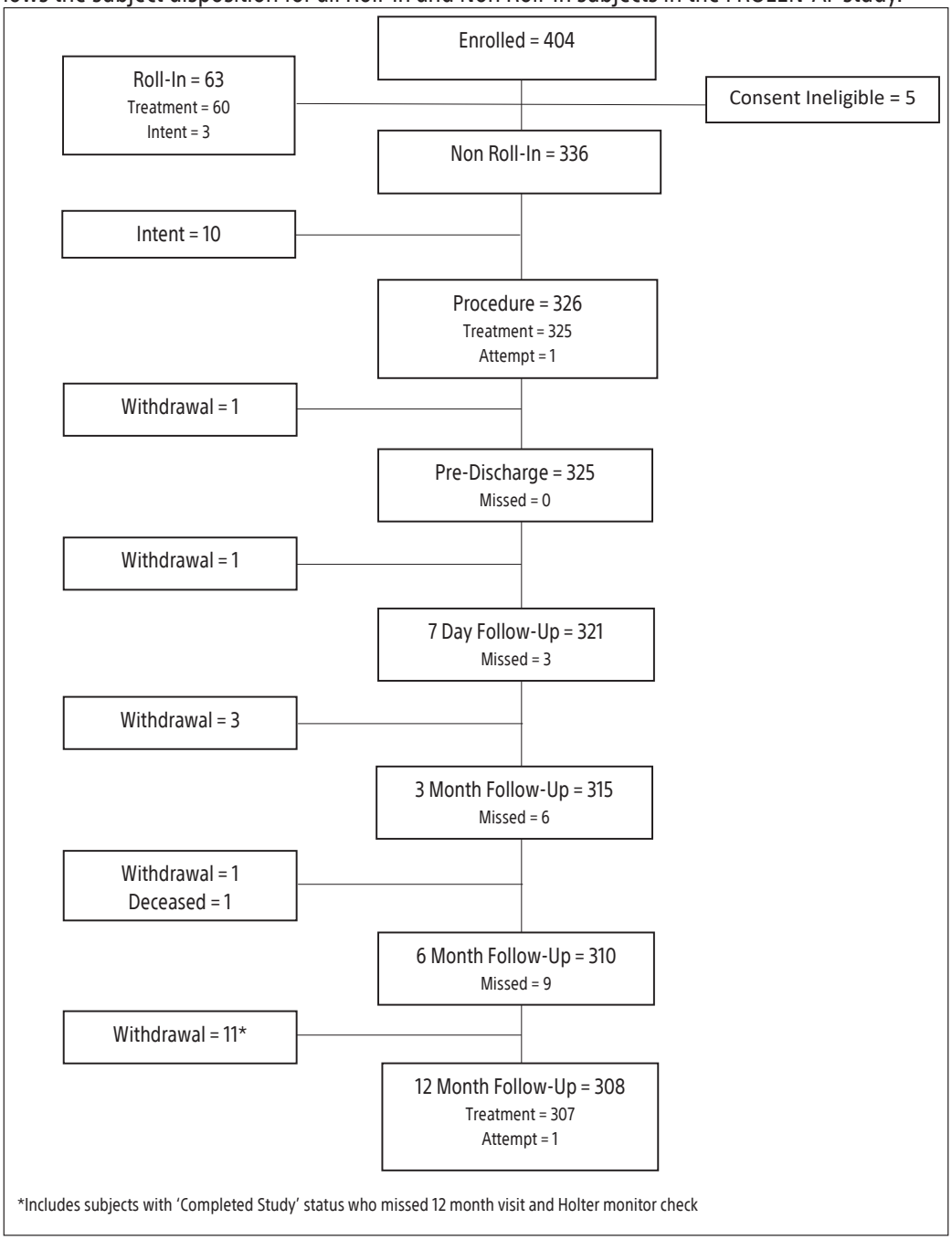

Figure 3. Subject Disposition and Accountability for Endpoint Analysis in FROzEN-AF Study

Study Population Demographics and Baseline Parameters

This section includes data from all Non Roll-In Treatment subjects (cohort for endpoint analysis) in the FROzEN-AF study (N= 325). The average age of the subjects in the FROZEN AF study was 62. The average time between first diagnosis and subject enrollment for the Non Roll-In Treatment subjects was 1.0 years (IQR:0.3 – 3.8 years).

Table 1 presents the demographics and physical assessment data for all Non Roll-In Treatment subjects.The gender and race characteristics in the patient population in the FROzEN-AF Study are consistent with previous clinical studies on PAF ablation.

Table 1. Subject Demographics and Physical Assessment Data

Characteristic	Measurement	Result
Age at Enrollment (years)	Mean +/- SD	62 +/- 11
	Min - Max	23 - 83
Gender [N (%)]	Female	124 (38.2)
	Male	201 (61.8)
Race* [N (%)]	Hispanic or Latino	5 (1.6)
	Native American	1 (0.3)
	Asian	35 (11.2)
	Black	4 (1.3)
	Pacific Islander	0 (0.0)
	White	274 (87.5)
	Other	1 (0.3)
	Race Undisclosed	12 (3.7)
Height (cm)	Mean +/- SD	174 +/- 10
	Min - Max	147 - 196
Weight (kg)	Mean +/- SD	86 +/- 19
	Min - Max	45 - 154
BMI	Mean +/- SD	29 +/- 6
	Min - Max	16 - 60
Pulse	Mean +/- SD	67 +/- 14
	Min - Max	40 - 130
Systolic BP	Mean +/- SD	133 +/- 18
	Min - Max	90 - 202
Diastolic BP	Mean +/- SD	79 +/- 11
	Min - Max	35 - 118
CHA2DS2-VASc Score [N (%)]	0	63 (19)
	1	82 (25)
	2	92 (28)
	3	59 (18)
	4	21 (6)
	5	8 (2)
*Subjects may contribute to more than one category		

Results

Primary Safety Endpoint

The results of the main analysis for the primary safety endpoint including data from all Non Roll-In Treatment/Attempt subjects (N=326) are presented in Figure 4.

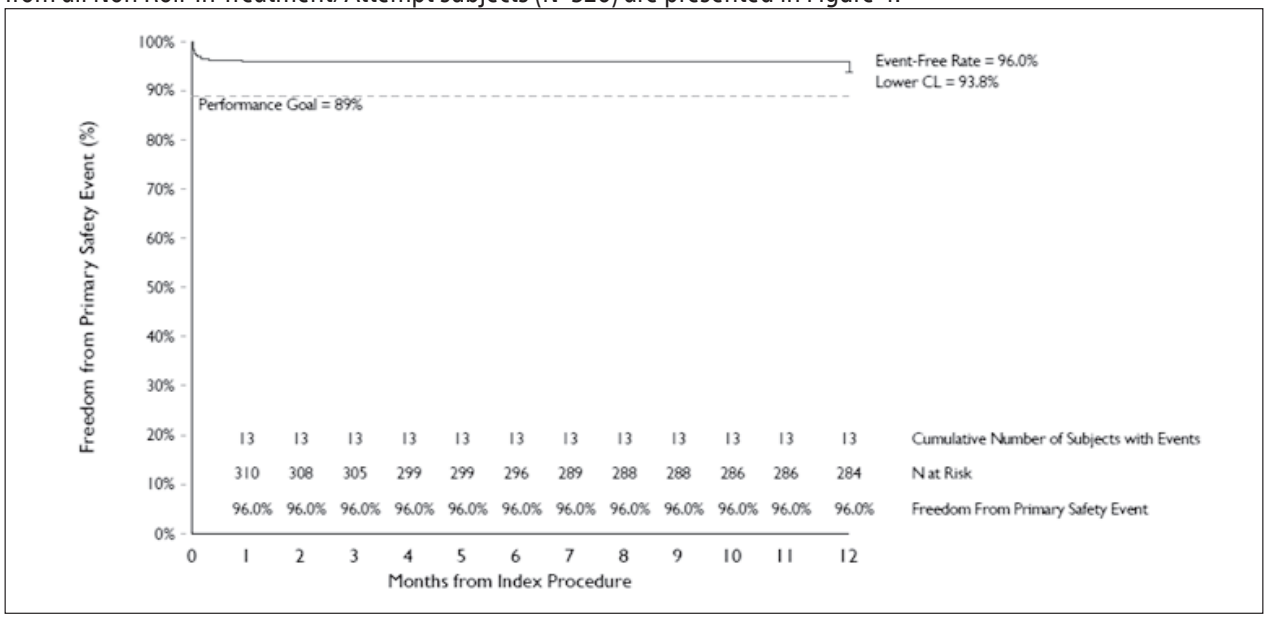

Figure 4. Primary Safety Endpoint Main Analysis

The observed event-free rate at 12 months follow-up was 96.0% with a one-sided 95% lower confidence limit of 93.8%. The lower confidence limit was greater than the performance goal of 89%, resulting in a rejection of the null hypothesis and the primary safety endpoint was passed.

Thirteen (13) subjects out of the 326 subjects in the primary safety endpoint analysis experienced a primary safety endpoint event prior to 12 months follow-up, as detailed in Table 2.

Table 2. Summary of Primary Safety Events in Non Roll-In Subjects

Endpoint Event	N (% Subjects)
MI	1 (0.3)
Pulmonary edema / heart failure	1 (0.3)
Thromboembolism/Air embolism	1 (0.3)
Cardiac Tamponade/Perforation	2 (0.6)
Gastroparesis / Injury to vagus nerve	3 (0.9)
Vascular Access Complication	5 (1.5)
Total	**13 (4)**

Additional Safety Information

Serious Adverse Events

A total of 100 serious adverse events (SAEs) in 73 study subjects were reported by Investigators during the first 12 months of study follow-up: 79 SAEs occurred in 60 Non Roll-In subjects and 21 SAEs occurred in 13 Roll-In subjects. The overall proportion of Non Roll-In subjects with SAEs was 17.9% and for the Roll-In subjects 20.6%. There were no confirmed PV stenosis events. No persistent phrenic nerve palsies were reported. No Atrioesophageal Fistulas were reported.

The SAEs occurring in Non Roll-In and Roll-In subjects are listed in the following tables. SAEs were further classified between serious adverse events and serious adverse device effects (SADE) per ISO classification.

Table 3. Serious Adverse Events in Non Roll-In Subjects

ISO Classification						
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Total Adverse Events	**41**	**33 (9.8)**	**38**	**32 (9.5)**	**79**	**60 (17.9)**
Ablation Related (N=326)	**0**	**0 (0)**	**38**	**32 (9.8)**	**38**	**32 (9.8)**
Ablation induced arrhythmia	0	0 (0)	2	2 (0.6)	2	2 (0.6)
Angina/Chest pain	0	0 (0)	3	3 (0.9)	3	3 (0.9)
Atrial Fibrillation (AF)	0	0 (0)	3	3 (0.9)	3	3 (0.9)
Atrial flutter, not specified	0	0 (0)	2	2 (0.6)	2	2 (0.6)
Edema	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Embolism – Air	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Esophagitis	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Gastroparesis	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Hematoma	0	0 (0)	4	4 (1.2)	4	4 (1.2)
Myocardial infarction	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Myocardial perforation with tamponade	0	0 (0)	2	2 (0.6)	2	2 (0.6)
Oozing/Bleeding	0	0 (0)	4	4 (1.2)	4	4 (1.2)
Pericarditis	0	0 (0)	4	4 (1.2)	4	4 (1.2)
Phrenic nerve injury temporary	0	0 (0)	4	4 (1.2)	4	4 (1.2)
Post procedure infection/ Sepsis	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Procedure related Hypertension	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Procedure related Neurological (Non-TIA, non-stroke, dysphagia, speech disturbance/dysarthria)	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Procedure related Pulmonary (including cough, hemoptysis)	0	0 (0)	2	2 (0.6)	2	2 (0.6)
Cardiovascular (N=336)	**22**	**19 (5.7)**	**0**	**0 (0)**	**22**	**19 (5.7)**
1st degree AV block	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Atrial Fibrillation (AF)	6	6 (1.8)	0	0 (0)	6	6 (1.8)
Atrial flutter	2	2 (0.6)	0	0 (0)	2	2 (0.6)
Atypical (Type II) atrial flutter	2	1 (0.3)	0	0 (0)	2	1 (0.3)
Chest pain - Other	2	1 (0.3)	0	0 (0)	2	1 (0.3)

ISO Classification						
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Hypertension/Hypertensive crisis	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Palpitations	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Peripheral vascular disease	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Sinus bradycardia	3	3 (0.9)	0	0 (0)	3	3 (0.9)
Syncope	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Ventricular Tachycardia (VT)/Monomorphic VT	2	2 (0.6)	0	0 (0)	2	2 (0.6)
Non-Cardiovascular (N=336)	**19**	**15 (4.5)**	**0**	**0 (0)**	**19**	**15 (4.5)**
COPD Exacerbation	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Cancer	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Death	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Gastrointestinal	5	3 (0.9)	0	0 (0)	5	3 (0.9)
Genitourinary	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Hematological	4	4 (1.2)	0	0 (0)	4	4 (1.2)
Musculoskeletal	2	2 (0.6)	0	0 (0)	2	2 (0.6)
Neurological	2	2 (0.6)	0	0 (0)	2	2 (0.6)
Physical trauma	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Vasovagal reaction	1	1 (0.3)	0	0 (0)	1	1 (0.3)

Table 4. Serious Adverse Events in Roll-In Subjects

ISO Classification						
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Total Adverse Events	**16**	**10 (15.9)**	**5**	**5 (7.9)**	**21**	**13 (20.6)**
Ablation Related (N=60)	**0**	**0 (0)**	**5**	**5 (8.3)**	**5**	**5 (8.3)**
Ablation induced arrhythmia	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Atrial Fibrillation (AF)	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Atrial tachycardia/Other SVT (e.g., AVRT, AVNRT, EAT)	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Pulmonary edema	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Right atrial (Type I) atrial flutter	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Cardiovascular (N=63)	**4**	**4 (6.3)**	**0**	**0 (0)**	**4**	**4 (6.3)**

ISO Classification						
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Atrial tachycardia/Other SVT (e.g., AVRT, AVNRT, EAT)	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Chest pain - Other	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Multiple symptoms	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Peripheral vascular disease	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Non-Cardiovascular (N=63)	**12**	**8 (12.7)**	**0**	**0 (0)**	**12**	**8 (12.7)**
Abnormal laboratory values	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Cancer	2	2 (3.2)	0	0 (0)	2	2 (3.2)
Fever and/or virus	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Gastrointestinal	2	2 (3.2)	0	0 (0)	2	2 (3.2)
Hematological	2	2 (3.2)	0	0 (0)	2	2 (3.2)
Musculoskeletal	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Physical trauma	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Pulmonary	2	1 (1.6)	0	0 (0)	2	1 (1.6)

Summary of Clinical Trial Adverse Events

There was a total of 226 adverse events (AEs), inclusive of serious and non-serious events, reported in 145 study subjects (119 Non Roll-In and 26 Roll-In) during the 12 month period of study follow-up:

- 92 subjects (78 Non Roll-In and 14 Roll-In) experienced at least one procedure-related AE.
- 46 subjects (40 Non Roll-In and 6 Roll-In) experienced at least one device-related AE.

The most frequently reported procedure-related AEs were hematoma (13 events), temporary phrenic nerve injury (13 events), and pericarditis (14 events). The most frequently reported device-related AEs were hematoma (8 events), temporary phrenic nerve injury (13 events), and pericarditis (7 events).

Two hundred fifty-four (254) study subjects (217 non Roll-In and 37 Roll-In) had no AEs reported.

Two (2) patients died during the course of the study. The deaths were classified by the Clinical Events Committee (CEC) as unrelated to the ablation procedure or to the investigational devices.

Primary Effectiveness Endpoint

The observed event-free rate at 12 months follow-up was 59.9% with a one-sided 95% lower confidence limit of 55.2%. The lower confidence limit was greater than the performance goal of 50%, resulting in a rejection of the null hypothesis and the primary effectiveness endpoint was passed.

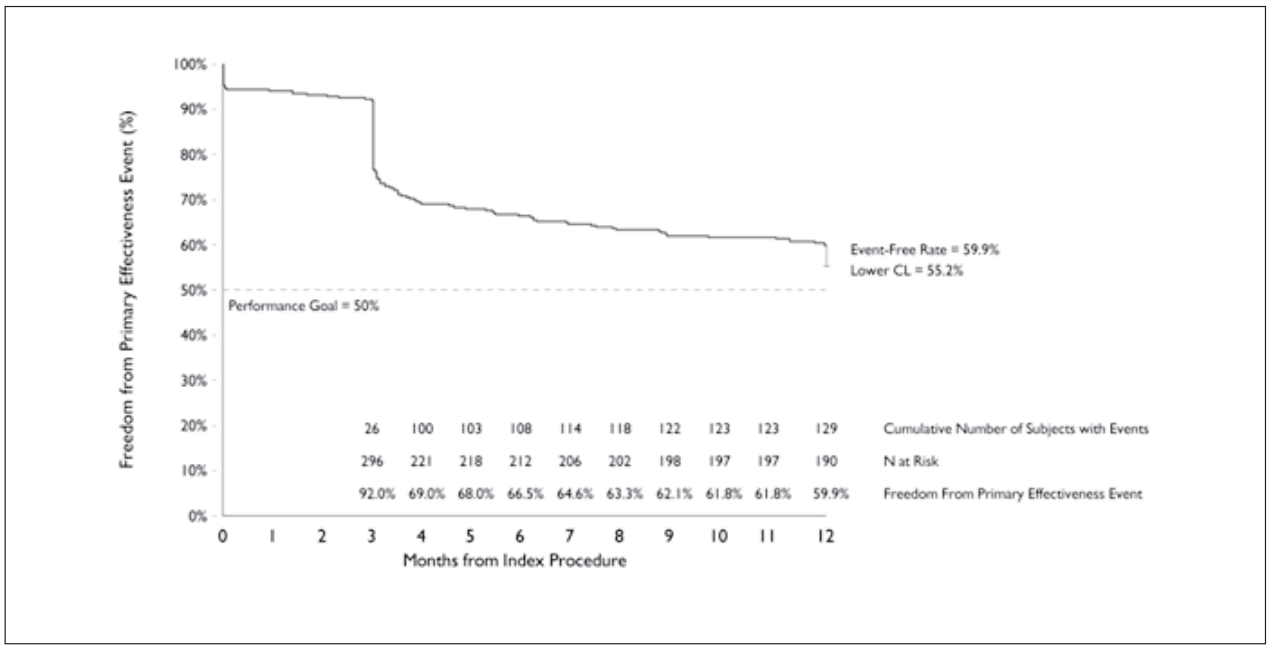

Figure 5. Primary Effectiveness Endpoint Main Analysis

One hundred twenty-nine (129) subjects out of the 325 subjects in the primary effectiveness endpoint analysis experienced an endpoint event prior to 12 months follow-up. The primary effectiveness events are shown in Table 5.

Table 5. Summary of Primary Effectiveness Events

Failure Component	**N (%)**
Overall Event-Free Rate at 12 Months	**59.9%**
Amiodarone/AAD Failure	86 (26.5)
Event Monitor Failure	58 (17.8)
Acute Failure	14 (4.3)
Repeat Procedure Failure	14 (4.3)
Holter Failure	11 (3.4)
Cardioversion Failure	9 (2.8)
ECG Failure	7 (2.2)
Non-study catheter for AF target at Repeat Procedure	6 (1.8)
Non-study catheter for AF target at Index Procedure	4 (1.2)
Surgical Treatment for AF/AFL/AT Failure	0 (0.0)
*Subjects may contribute to more than one category if multiple failure types were observed	

The primary effectiveness endpoint was assessed using the 2017 HRS expert consensus definition of "freedom from AF/AFL/AT after removal from antiarrhythmic drug therapy as assessed from the end of the 3 month blanking period to 12 months following the ablation procedure" and the recommended Objective Performance Criteria (OPC) of freedom from AF at 12 months in 50% of subjects.

In other studies reported in the medical literature, continuation of a pre-ablation antiarrhythmic drug therapy at stable or lower doses was allowed and subjects were only counted as effectiveness failures if a new AAD or higher dose of an existing AAD was started after ablation. Excluding continuation of pre-ablation AADs at the same or lower dose, the number of primary effectiveness AAD Failures decreased from 86 to 48. Figure 6 shows Primary Effectiveness results when subjects were counted as failures only if they took a new AAD or a higher dose of an already prescribed AAD (excluding amiodarone). All other endpoint components, including Amiodarone use, were unchanged in this analysis. The observed event-free rate increased to 71.6% (lower confidence limit of 67.2%).

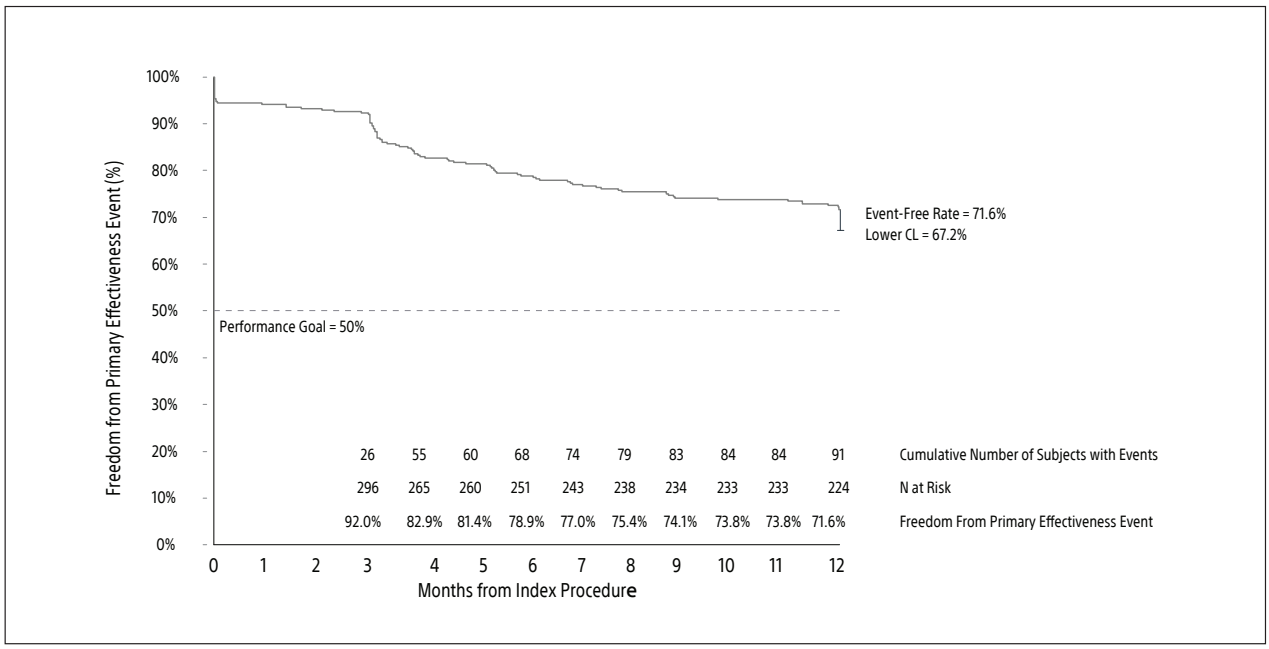

Figure 6. Sensitivity Analysis - Primary Effectiveness Endpoint Event Free Rate Allowing Previously Prescribed AADs

Freedom from arrythmia recurrence is clinically important. Figure 7 shows the recurrence free rate of individual atrial arrhythmia types as documented on a rhythm monitoring device post- blanking period. Other protocol defined primary effectiveness failures (e.g., AAD failures, acute procedural failure) were not considered in this analysis. Overall, the freedom from documented arrhythmia recurrence, including atrial fibrillation (AF), atrial flutter (AFL), and atrial tachycardia (AT), was 79.9%. Atrial Fibrillation was the most common documented arrythmia recurrence with an AF recurrence free rate of 82.7%.

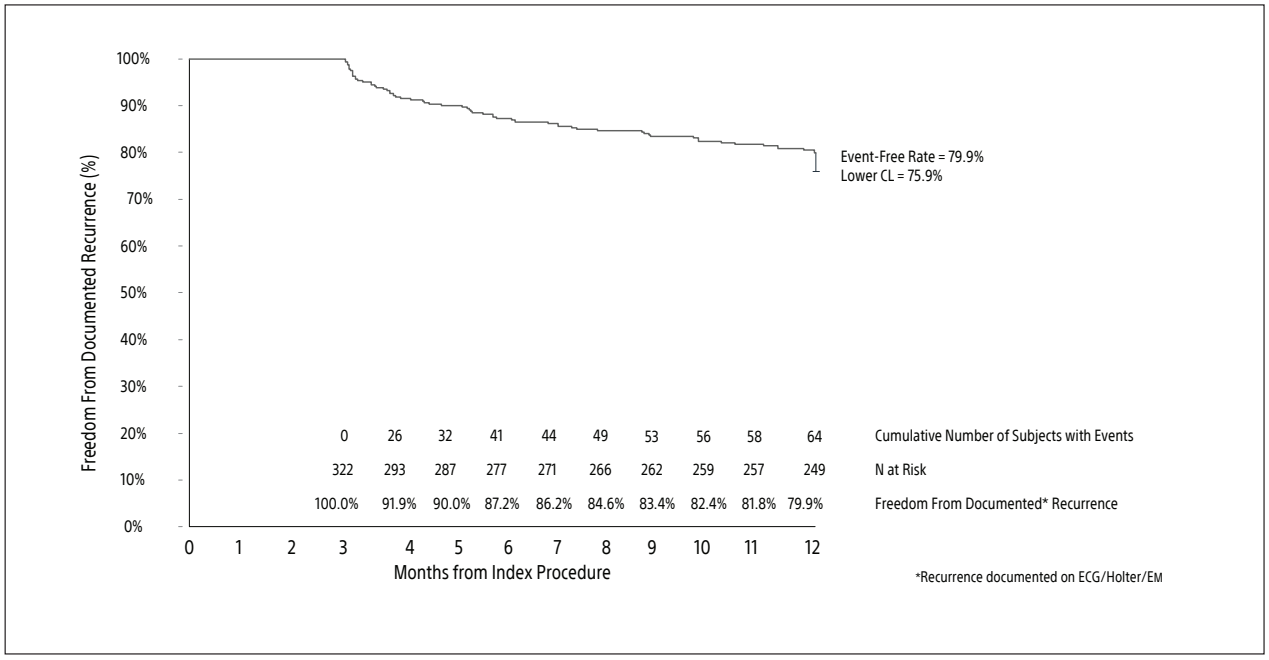

Figure 7. Freedom from Documented Recurrence

Rhythm Monitoring Compliance

Compliance to required endpoint assessment rhythm monitoring is outlined in Table 6 below. Total compliance to 12-lead ECG required throughout the course of the trial was 95.2%, and compliance to 24-Hour Holter at the 12 month follow-up visit was 88.3%. Subjects were compliant at a rate of 61.1% (Table 6) with the required event monitor transmission schedule of at least 2 transmissions per month for months four through nine (18 total transmissions). Subjects were considered partially compliant with respect to event monitors for each 30-day window post-blanking period where at minimum one event monitor recording was submitted.

Table 6. Rhythm Monitoring Compliance

(Non Roll-In Treatment Subjects N=325)

Monitor	Compliance % (N Obs/N Expected)
ECG Compliance	95.2% (885/930)
Holter Compliance	88.3% (272/308)
Event Monitor Compliance	61.1% (1723/2820)
Event Monitor Compliance (partial)	73.5% (2082/2833)

An additional analysis was conducted using an >80% compliance rate to assess for differences in the Primary Safety and Primary Effectiveness Endpoints shown in the table below.

Table 7. Event Monitor Compliance Subgroup Analysis (80% Compliance Cutoff)

Endpoint	Subgroup	N	Rate (Lower Confidence Limit)	P Value
Primary Safety Endpoint	Subject TTM Compliance < 80%	211	96.7% (93.9%)	0.3438
	Subject TTM Compliance ≥80%	108	94.4% (89.3%)	
Primary Effectiveness Endpoint	Subject TTM Compliance < 80%	211	61.6% (55.8%)	0.4681
	Subject TTM Compliance ≥ 80%	130	56.9% (49.3%)	

Although a lower event monitoring compliance could overestimate the efficacy of the system, no significant difference exists between highly compliant (>80%) and less compliant (<80%) subjects in terms of the Primary Safety Endpoint (p=0.3438) and Primary Effectiveness Endpoint (p=0.4681).

Acute Procedural Success

The secondary effectiveness endpoint was the rate of acute procedural success, defined as achievement of electrical isolation of all PVs by using the POLARx Cryoablation System only, where electrical isolation of PVs is demonstrated by entrance and exit block. The acute procedural success results are shown in Table 8 below. Six (6) of the 14 subjects who were deemed acute procedural failures were due to entrance/exit block testing performed not according to protocol requirements.

Table 8. Acute Procedural Success

N Total	N Success	Acute Success Rate (%)	95% Confidence Interval
325	311	95.69	(92.88, 97.63)

Study Conclusion

The FROzEN-AF study demonstrated there is a reasonable assurance of safety and effectiveness to support use of the Boston Scientific Cardiac Cryoablation System in treatment of patients with drug refractory, recurrent symptomatic paroxysmal atrial fibrillation.

Contents

Store between 15°C – 25°C (59°F – 77°F);
excursions permitted to -30°C – 60°C
(-22°F – 140°F)

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300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

www.bostonscientific.com

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BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324F), eIFU, MB, POLARx, US, 51594698-01A

Boston Scientific

POLARx™ FIT

Cryoablation Balloon Catheter

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BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324F), eIFU, MB, POLARx FIT, US, 51594697-01A

℞ **ONLY**

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

WARNING:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Carefully read all ancillary device instructions prior to use, including the SMARTFREEZE™ Cryoablation System Console (henceforth referred to as SMARTFREEZE Console) User's Manual.

Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications and/or failure of the device to perform as intended.

DEVICE DESCRIPTION

The POLARx™ FIT Cryoablation Balloon Catheter (henceforth referred to as POLARx FIT Catheter) is a component of the Boston Scientific Cardiac Cryoablation System (System) and is a single-use, flexible, over-the-wire balloon catheter used to ablate cardiac tissue. The balloon diameter of POLARx FIT Catheter is adjustable to 28 or 31 mm. The POLARx FIT Catheter is used in conjunction with the SMARTFREEZE Console to induce thermal injury and endocardial tissue necrosis when the POLARx FIT Catheter balloon is in contact with cardiac tissue and reaches cryoablation temperatures created by a nitrous oxide refrigerant (N_2O) injected from the SMARTFREEZE Console into the balloon segment of the POLARx FIT Catheter. The POLARx FIT Catheter connects to the SMARTFREEZE Console with a SMARTFREEZE Cryo-Cable (for N_2O delivery and removal) and a SMARTFREEZE Catheter Extension Cable (for electrical connection via the Inter-Connection Box).

The POLARx FIT Catheter is designed to be used with a POLARMAP™ Circular Mapping Catheter (henceforth referred to as POLARMAP Mapping Catheter) deployed within the guidewire lumen during ablation procedures.

During an electrophysiology (EP) ablation procedure, the POLARx FIT Catheter (including the POLARMAP Mapping Catheter) is inserted through a POLARSHEATH™ Steerable Sheath (henceforth referred to as POLARSHEATH Sheath) into the venous system, directed into the left atrium (LA) and towards the ostium of the target pulmonary vein (PV). The appropriate diameter is selected based on clinical need and physician discretion. Once positioning that occludes the PV has been verified, refrigerant is delivered through the Cryo-Cable to the POLARx FIT Catheter injection coil, which directs the flow of refrigerant toward the interior distal surface of the POLARx FIT Catheter balloon. This results in a cooled region at the POLARx FIT Catheter balloon tissue interface, which adheres to the endocardial surface. The low temperature and pressure gradient allows the POLARx FIT Catheter balloon to thermally create transmural, circumferential tissue necrosis (lesions) and interrupt electrical conduction.

The POLARx FIT Catheter is comprised of the following major components, distal to proximal:

- Atraumatic tip
- Double layer balloon system
- Guide wire lumen
- Internal balloon thermocouple
- Injection coil delivery of the refrigerant; liquid nitrous oxide (N_2O)
- Catheter shaft; to retrieve the expanded N_2O gas
- Catheter handle
- Distal handle connections

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 9252A324F), eIFU, MB, POLARx FIT, US, 51594697-01A

Contents

One (1) POLARx FIT Cryoablation Balloon Catheter.

Operating Principle

The POLARx FIT Catheter is designed to be an over-the-wire occlusive balloon catheter to deliver cryoablation therapy to the pulmonary veins (PV) for electrical isolation of the PVs. Nitrous oxide refrigerant (N_2O) is delivered from the SMARTFREEZE Console to the distal hemisphere of the inflated balloon via the SMARTFREEZE Cryo-Cable and the POLARx FIT Catheter's injection coil. The catheter includes a guidewire lumen for the passage of a POLARMAP Mapping Catheter to provide an atraumatic supportive rail during catheter manipulation and to provide real-time electrograms for assessment of conduction block. Positioning of the POLARx FIT balloon uses guidance from the POLARSHEATH Sheath towards the PV, tracking along the POLARMAP Mapping Catheter, and POLARx FIT Catheter tip deflection using a bi-wing steering feature in the catheter handle. The PV occlusion verification may be performed using fluoroscopy and/or other appropriate visualization/assessment techniques. The POLARx FIT Catheter balloon diameter is adjustable to either 28 or 31 mm to support treatment of a wide range of PVs. The catheter includes a pressure sensor to enable control of inner balloon pressure during operation. The cryogenic temperature is monitored with a thermocouple inside of the POLARx FIT balloon measuring the temperature of the returning N_2O gas.

Non-pyrogenic

This device meets pyrogen limits specifications for all patient-contacting parts.

User Information

The POLARx FIT Catheter 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.

INTENDED USE

The Boston Scientific Cardiac Cryoablation 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.

The POLARx FIT Cryoablation Balloon Catheter is a single use, flexible, over-the-wire balloon catheter intended to ablate cardiac tissue.

INDICATIONS FOR USE

The Boston Scientific Cardiac Cryoablation System using the POLARx FIT Cryoablation Balloon Catheter is indicated for the treatment of patients with drug refractory, recurrent symptomatic paroxysmal atrial fibrillation (PAF).

CONTRAINDICATIONS

Use of the POLARx FIT Catheter 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 patients with a prosthetic heart valve (mechanical or tissue).
- In the ventricle of the heart where the device may become entrapped in a valve or chordae structures.
- In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event.
- In patients with pulmonary vein stents as the POLARx FIT Catheter may dislodge or damage the stent.
- In patients with cryoglobulinemia as the cryoablation application may lead to vascular injury.
- In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event.
- In patients with intra-atrial septal patch or any other surgical intervention in or adjacent to the intra-atrial septum.
- In patients with an interatrial baffle or path as the transseptal puncture could fail to close.
- In patients with hypercoagulopathy 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.
- In patients previously implanted with a percutaneous Left Atrial Appendage Occlusion device.

WARNINGS

- Introducing catheters and sheaths into the circulatory system increases the risk of air emboli. Always advance/retract components slowly and use proper flushing techniques to minimize risk of air embolism.
- Avoid proximity to all heart valves whenever possible. Manipulation of the POLARx FIT Catheter across a heart valve structure may result in entanglement and damage to the valve.
- Use of N_2O as a refrigerant during the cryoablation procedure increases the risk of a gas embolism if the integrity of the POLARx FIT Catheter balloon is disrupted. Replace the POLARx FIT Catheter if there is any concern the POLARx FIT Catheter balloon has been damaged.
- Do not use the POLARx FIT Catheter without a POLARMAP Mapping Catheter fully inserted into the guidewire lumen, past the POLARx FIT Catheter balloon. An absent or partially inserted POLARMAP Mapping Catheter may not provide sufficient mechanical support for POLARx FIT Catheter balloon inflation and cryoablation operations and may result in POLARx FIT Catheter damage and N_2O leakage.
- Administer appropriate peri-procedural anticoagulation therapy per standard of care for patients undergoing cardiac cryoablation procedures. Administer anticoagulation therapy during and post-procedure according to local institution standards to minimize bleeding and thrombotic complications.
- Electrophysiology procedures, including ablation, may introduce arrhythmias.
- Always deflate the POLARx FIT Catheter and retract into the POLARSHEATH Sheath before pulling back across the septum. Crossing the septum with the POLARx FIT Catheter balloon exposed, inflated or inflating within the septum may cause endocardial damage.
- Do not use the POLARx FIT Catheter if it is not working properly. A POLARx FIT Catheter failing to function properly should be removed and replaced before continuing with the procedure.
- Do not inflate the balloon while housed in the POLARSHEATH Sheath. Always verify that the POLARx FIT Catheter balloon is outside the POLARSHEATH Sheath before inflation to prevent POLARx FIT Catheter damage.
- Do not inflate the balloon while the POLARx FIT Catheter is positioned inside the PV. Always inflate the POLARx FIT Catheter balloon while the POLARx FIT Catheter is positioned in the LA and then position it in the PV ostium. Inflating the POLARx FIT Catheter balloon in the PV may result in vascular injury.
- Always deflate and extend the POLARx FIT Catheter balloon prior to retraction of the balloon back into the POLARSHEATH Sheath.
- Do not use the POLARx FIT Catheter if any part of the POLARx FIT Catheter shaft appears to be kinked or damaged. If the POLARx FIT Catheter shaft appears kinked while in the body, remove the POLARx FIT Catheter and replace with a new POLARx FIT Catheter before continuing with the procedure.
- When using the POLARx FIT Catheter, catheter manipulation must be carefully performed in order to avoid cardiac damage, perforation, or tamponade. Do not advance the POLARx FIT Catheter with an exposed lumen; always advance the POLARx FIT Catheter over the POLARMAP Mapping Catheter, with the POLARMAP Mapping Catheter distal to the POLARx FIT Catheter balloon. Do not use excessive force to advance or withdraw the POLARx FIT Catheter when resistance is encountered.
- The steerability feature of the POLARx FIT Catheter is designed to operate in a single plane of motion. Attempts to deflect the distal section in other planes (e.g. perpendicular to normal steering plane, etc.) may result in damage to the steering mechanism and impaired ability to position the POLARx FIT Catheter as desired by the operator.
- Do not pull or move the POLARx FIT Catheter, POLARSHEATH Sheath, attached cables, or SMARTFREEZE Console while the POLARx FIT Catheter balloon is frozen as this may lead to tissue damage.
- Catheter ablation procedures near or in the PV may cause narrowing or stenosis. Avoid ablation in the tubular portion of the PV.
- Implantable pacemaker (PM) and cardioverter/defibrillator (ICDs) leads may be displaced during an EP procedure. See PM/ICD technical manual for additional instructions.

- To prevent occlusion of the refrigerant line, over-pressurization and potential POLARx FIT Catheter failure when using the POLARx FIT Catheter in combination with the POLARSHEATH Sheath, avoid applying simultaneous high torque (twisting) and tensile stress (pulling) on the POLARx FIT Catheter while the catheter is engaged in the POLARSHEATH Sheath and the POLARx FIT Catheter is deflected.
- Cryoablations may cause collateral injury to the esophagus and in rare instances atrio-esophageal fistulas. Temperature monitoring with a probe placed within the esophagus may mitigate this risk.
- Cryoablations may cause collateral phrenic nerve injury. Stop cryoablation immediately if phrenic nerve impairment is observed. Continuous phrenic nerve pacing and diaphragm movement monitoring should be performed to mitigate this risk.
- The POLARx FIT Catheter contains pressurized gas during operation. Failure of the POLARx FIT Catheter balloon to operate properly may result in a release of gas into the circulatory system and potential gas emboli.
- Use caution when manipulating the POLARx FIT Catheter around other intracardiac devices. Entanglement may prevent removing the devices from the cardiac chamber and require surgical intervention.
- Significant x-ray exposure during an electrophysiology procedure may result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure and steps taken to minimize this exposure.

PRECAUTIONS

- Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the POLARx FIT Catheter and SMARTFREEZE Console.
- The POLARx FIT Catheter shall only be used with the SMARTFREEZE Console.
- Use only the POLARMAP Mapping Catheter with the POLARx FIT Catheter.
- Use only the POLARSHEATH Sheath with the POLARx FIT Catheter.
- If necessary, use only 0.081 cm (0.032 in.) or 0.089 cm (0.035 in.) guidewires with the POLARx FIT Catheter. Use of other guidewire sizes may damage the POLARx FIT Catheter.
- It is the user's responsibility to ensure that the equipment used with the POLARx FIT Catheter meets all local applicable electrical safety requirements.
- Perform cryoablation procedures only within environmental parameters as outlined in Section 11.8, Specifications.
- Do not immerse the POLARx FIT Catheter handle or Cryo-Cable in fluids; electrical performance could be affected.
- Do not change the equipment configuration or modify the equipment or applied parts in any way. Doing so may cause the system to behave unreliably and affect the patient adversely.
- Always straighten the POLARx FIT Catheter prior to insertion or withdrawal from the body.
- Flush the guidewire lumen initially and then frequently throughout the cryoablation procedure to prevent coagulum formation. If contrast is used, flush the lumen thoroughly after each contrast injection.
- Do not physically scrub or twist the POLARx FIT Catheter balloon surface as damage to the POLARx FIT Catheter balloon may impact balloon shape or integrity.
- Do not apply excessive torque to the POLARx FIT Catheter during the procedure as it may adversely affect the cryoablation function.
- Do not apply excessive torque to the steering lever as doing so may damage the POLARx FIT Catheter deflection mechanism.
- Do not apply excessive force to the POLARx FIT Catheter extension slider switch (slider switch) during cryoablation or while the POLARx FIT Catheter balloon temperature is below freezing as doing so may damage the catheter.
- Properly scavenge and dispose of the N_2O with appropriate hospital systems. Do not outgas in the operating room.
- Dispose of the POLARx FIT Catheter per local regulatory and biohazard standards.

ADVERSE EVENTS

Potential adverse events associated with manipulation of the POLARx FIT Catheter within the left atrium and pulmonary veins may include the following conditions:

- Arrhythmia (new or exacerbated)
  - Conduction pathway injury
- Cardiac arrest
- Cardiac trauma, for example:
  - Cardiac perforation/tamponade/effusion
  - Valvular damage
  - Stiff left atrial syndrome
- Death
- Edema/heart failure/pleural effusion
- GI disorders
- Hypertension
- Hypotension
- Infection/inflammation/exposure to biohazardous material
- Injury related to tissue damage and/or adjacent structures, for example:
  - Esophageal injury
  - Pulmonary injury
  - Catheter entrapment
  - Physical trauma
- Injury due to embolism/thromboembolism/air embolism/foreign body embolism:
  - CVA/stroke
  - TIA
  - MI
  - Neurological impairment and its symptoms, for example:
    - Cognitive changes
    - Visual disturbances
    - Headache
    - Motor impairment
    - Sensory impairment
    - Speech impairment
  - Pulmonary embolism
  - Asymptomatic cerebral embolism
- Nerve injury, for example:
  - Phrenic nerve injury
  - Vagal nerve Injury
- Pain or discomfort, for example:
  - Angina
  - Chest pain
  - Non-cardiovascular pain

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- Procedural related side effects, for example:
  - Allergic reaction (including anaphylaxis)
  - GU complications
  - Side effects related to medication or anesthesia
  - Radiation injury/tissue burn
  - Renal failure/insufficiency
  - Vasovagal response
- PV Stenosis and its symptoms, for example:
  - Cough
  - SOB
  - Fatigue
  - Hemoptysis
- Respiratory distress/insufficiency/dyspnea
- Surgical and access complications, for example:
  - Hematoma/seroma
  - AV Fistula
  - Bleeding
  - Pseudoaneurysm
  - Pneumothorax
  - Residual atrial septal defect
- Thrombus/thrombosis
- Vessel Trauma, including:
  - Perforation
  - Dissection
  - Coronary artery injury
  - Vasospasm
  - Occlusion
  - Hemothorax

HOW SUPPLIED

One (1) POLARx FIT Catheter is supplied sterile using an Ethylene Oxide (EO) process and is individually packaged within a pouch. Package contents are listed on the carton and pouch labels.

Device Details

Do not use if package is 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.

Report any serious incident that occurs in relation to this device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.

Handling and Storage

Operating Environment

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

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

Transport Environment

Temperature: -30 °C to 60 °C (-22 °F to 140 °F)

Relative Humidity: 15% to 90%

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 15 °C to 25 °C (59 °F to 77 °F)

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

INSTRUCTIONS FOR USE

Carefully read all instructions prior to use and observe all contraindications, warnings, and precautions. Failure to do so may result in patient harm or device malfunction.

Additional Items For Safe Use

The POLARx FIT Catheter has been tested and verified for use with the POLARSHEATH Sheath, the POLARMAP Mapping Catheter, the SMARTFREEZE Console and its accessories.

Device Compatibility

The POLARx FIT Catheter is compatible for use with the Boston Scientific Cardiac Cryoablation System.

Preparation

Refer to these Instructions for Use and the SMARTFREEZE Console User's Manual when using the POLARx FIT Catheter.

1. Inspect the POLARx FIT Catheter sterile packaging for any breach that may cause contamination of the components.
2. Check the expiration date. Do not use POLARx FIT Catheter devices after the expiration date shown on the POLARx FIT Catheter package label.
3. Remove the POLARx FIT Catheter from the packaging following sterile technique.
4. Inspect the integrity of the POLARx FIT Catheter to verify that there is no damage to the device.
5. Connect the Cryo-Cable and the SMARTFREEZE Catheter Extension Cable to the handle of the POLARx FIT Catheter while maintaining sterility of the POLARx FIT Catheter.
   NOTE: The end of the connections should remain dry.
   NOTE: Connecting the Cryo-Cable and SMARTFREEZE Catheter Extension Cable to the SMARTFREEZE Console should be performed by personnel outside the sterile field (refer to the SMARTFREEZE Console User's Manual).
6. Attach a Y adapter with a Tuohy Borst valve (or equivalent) to the flush port of the POLARx FIT Catheter handle.
7. Flush the POLARx FIT Catheter guidewire lumen and Y adapter with heparinized saline.
8. Prepare and insert a POLARMAP Mapping Catheter into the POLARx FIT Catheter guidewire lumen (refer to POLARMAP Mapping Catheter Instructions for Use).
9. Submerge the POLARx FIT Catheter balloon tip with the protective sleeve in sterile heparinized saline and agitate to remove all air bubbles.
   NOTE: Pulling the sleeve over the POLARx FIT Catheter shaft and back on the POLARx FIT Catheter balloon under saline may remove additional trapped air.
10. Pull the protective sleeve proximally over the shaft to expose the balloon. While submerged in saline, inflate the balloon (refer to SMARTFREEZE Console User's Manual) and remove all air bubbles.
11. Press forward on the extension slide on the POLARx FIT Catheter handle to deflate the balloon. While submerged in saline, pull the protective sleeve back over the balloon.

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Catheter Handle Operation

The POLARx FIT Catheter handle has three controls: the balloon extension slider switch (slider switch) on the top, the steering lever on the left side, and the steering tension knob on the right side.

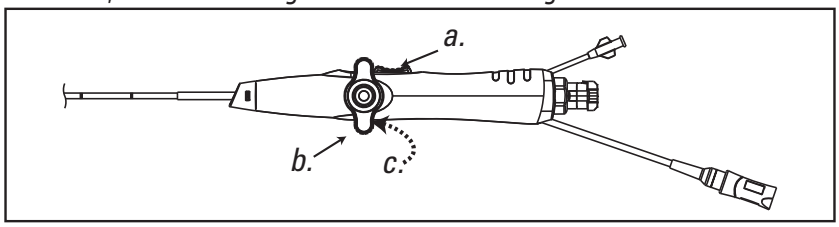

Figure 1. Catheter Handle

a. Slider Switch: Advancing the balloon extension slider switch forward deflates and extends (elongates) the balloon for re-sheathing. Deflation will not occur if the balloon temperature is less than +20°C.
b. Steering lever (left side): From the 12 o'clock (center) position, counterclockwise rotation deflects the POLARx FIT Catheter tip downward; clockwise rotation deflects it upward.
c. Tension knob (right side): Applies tension to the steering lever operation.

The slider switch houses a color-keyed indicator LED which indicates the status of the procedure as follows:

Indicator Color	Procedure Status
Off	Idle
Green	Ready
Solid blue	Inflation / Thaw
Flashing blue	Ablation
Red	Fault –refer to error message on SMARTFREEZE Console screen.

Procedure

To use the POLARx FIT Catheter for a cryoablation procedure, follow these steps: (For more detailed instructions on the use of the SMARTFREEZE Console, refer to its User's Manual.)

1. Create the required vascular access in a large central vein (e.g. femoral vein).
2. Complete a transseptal puncture to access the LA.
3. Place guidewire across the septum to provide sufficient support.
4. Prepare and place a POLARSHEATH Sheath into the LA. (Refer to the POLARSHEATH Sheath Instructions for Use.)
5. Prepare the POLARx FIT Catheter as instructed in the Preparation section.
6. Load the POLARx FIT Catheter with POLARMAP Mapping Catheter across the POLARSHEATH Sheath hemostasis valve while flushing through the POLARx FIT Catheter. Gently insert the introducer sleeve into the handle of the POLARSHEATH Sheath to facilitate loading the POLARx FIT Catheter. DO NOT push the introducer sleeve through the hemostasis valve.
7. Advance the POLARMAP Mapping Catheter and POLARx FIT Catheter to the distal end of the POLARSHEATH Sheath. When the distal end of the POLARx FIT Catheter is at the distal end of the POLARSHEATH Sheath, the first marker band on the POLARx FIT Catheter will align with the end of the handle of the POLARSHEATH Sheath.

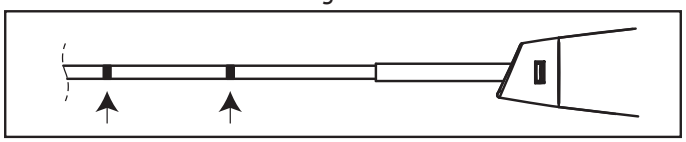

Figure 2. Marker bands

8. Advance the POLARMAP Mapping Catheter into the target PV.
   NOTE: Carefully positioning the POLARMAP Mapping Catheter distally in the target PV may improve POLARx FIT Catheter support and balloon positioning.

9. Advance the POLARx FIT Catheter over the POLARMAP Mapping Catheter into the LA.
10. Verify the POLARx FIT Catheter balloon is completely out of the POLARSHEATH Sheath. This may be performed by confirming the second marker band on the POLARx FIT Catheter is at or past the end of the handle of the POLARSHEATH Sheath.
11. Verify the balloon is at an appropriate position for inflation (e.g. within the left atrium). This may be performed using imaging such as fluoroscopy or echocardiography.
12. Inflate the POLARx FIT Catheter balloon (Refer to the SMARTFREEZE Console User's Manual) in the LA while remaining outside the target PV. The initial inflation of POLARx FIT Catheter will be at 28 mm balloon diameter. Once inflated, the balloon is able to be expanded to a 31mm diameter with the SMARTFREEZE Console based on clinical judgement. To downsize from 31 mm to 28 mm, the balloon must be first deflated and then reinflated.
13. Advance the inflated POLARx FIT Catheter balloon, as necessary, to occlude blood flow to the targeted PV, but remain in the atrium outside the tubular portion of the PV. For best results, maneuver the POLARx FIT Catheter and / or POLARSHEATH Sheath to position the distal half of the balloon at the PV ostium.
14. Verify PV occlusion. Verification may be performed with fluoroscopy and 50/50 contrast/saline injection into the guidewire lumen port or with other appropriate visualization / assessment techniques. If the balloon needs to be deflated for repositioning, use the slider switch on the POLARx FIT Catheter handle to simultaneously deflate and extend the balloon.
    NOTE: When using an auto injector for contrast delivery, ensure that the pressure limit does not exceed 500 psig.
    NOTE: If a stable occlusion cannot be achieved, the POLARMAP Mapping Catheter may be exchanged and a guidewire used to provide increased mechanical support. The POLARx FIT Catheter should be removed from the body prior to any POLARMAP Mapping Catheter / guidewire exchange. Proper flushing and air bubble management should be repeated with each exchange.
15. Positioning the POLARMAP Mapping Catheter to visualize pulmonary vein electrograms may improve ablation dosing.
16. Perform the cryoablation. (Refer to the SMARTFREEZE Console User's Manual for setup, settings, and use.)
17. At the completion of the cryoablation application, wait for the thawing phase to complete before any POLARx FIT Catheter balloon manipulation.
    NOTE: Determination of an effective lesion is achieved by verifying electrical isolation of the PV from the LA after the cryoablation has been completed.
    NOTE: As needed, perform additional cryoablation(s) in the same PV, adjusting the position of the POLARx FIT Catheter balloon if necessary.
18. Deflate the POLARx FIT Catheter balloon (Refer to the SMARTFREEZE Console User's Manual).
    NOTE: The POLARx FIT Catheter balloon will automatically deflate once the cryoablation is complete and the balloon temperature has reached +20°C.
    NOTE: Before resheathing, ensure the balloon has been extended by inflating the balloon and deflating using the slider switch on the POLARx FIT Catheter handle.
19. Retract the POLARx FIT Catheter and POLARMAP Mapping Catheter into the POLARSHEATH Sheath.
20. Return to step 8 to position the POLARx FIT Catheter balloon at the ostium of the next targeted PV and repeat steps for positioning, cryoablation application, and thawing.
21. After cryoablation treatments of all targeted PVs have been completed and when the POLARx FIT Catheter balloon is completely deflated, extend the POLARx FIT Catheter balloon and retract the POLARx FIT Catheter/ POLARMAP Mapping Catheter into the POLARSHEATH Sheath.
22. Remove POLARx FIT Catheter, POLARMAP Mapping Catheter, and POLARSHEATH Sheath from the patient.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

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

Specifications

Catheter Shaft Size	11.8 Fr (4.0 mm)	
Catheter Overall Length	134 cm	
Catheter Tip Outer Diameter (OD)	9 Fr (3 mm)	
Compatible Introducer Sheath	Compatible with POLARSHEATH 12F Steerable Sheath	
Guidewire Lumen Inner Diameter (ID)	Compatible with POLARMAP Mapping Catheter and guidewires ≤ 0.035" (0.89 mm)	
Inflated Balloon Dimensions	Diameter	28/31 mm
	Catheter Effective Length	99 cm
Tip Length	Short Tip	5 mm
	Long Tip	12 mm
Thermocouples	Internal to Balloon	

PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of the VIKING and VIKING SOFT TIP Catheter in association with the Electrophysiological cardiac interventional procedure:

- Discuss the risks and benefits including review of potential adverse events listed in this document.
- Discuss post procedure instructions, including any lifestyle changes, medications, when to call the Healthcare Provider (HCP) and any post procedure follow-up that might be needed.

CUSTOMER SERVICE

Boston Scientific team members are dedicated to serving customers and are available to provide training and technical consultation on the use of the BSC Cardiac Cryoablation System to qualified hospital personnel. Please contact your local Boston Scientific representative for more information.

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.

WARRANTY

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

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FROZEN-AF CLINICAL STUDY

Study title	FROzEN-AF study: Safety and Effectiveness IDE trial for Boston Scientific's Cryoballoon in the Treatment of Symptomatic Drug Refractory Paroxysmal Atrial Fibrillation
Number of centers	44 total sites including the United States (30), Europe (6), Canada (4), and Asia-Pacific (4)
Number of subjects	385 subjects treated with the Boston Scientific Cardiac Cryoablation System (including 60 roll-in subjects)

Objective

The objective of the clinical study was to evaluate the safety and effectiveness of the Boston Scientific Cardiac Cryoablation System for the treatment of drug refractory, recurrent symptomatic paroxysmal atrial fibrillation.

FROzEN-AF Study Design, Scope and Methods

The FROzEN-AF study was a multi-center, open label, prospective, single arm study conducted at 44 sites including the United States (30), Europe (6), Canada (4), and Asia-Pacific (4). A total of 404 subjects enrolled in the study, and a total of 385 subjects were treated with the Boston Scientific Cardiac Cryoablation System. All subjects who met the enrollment criteria, signed the consent, and underwent the index procedure with the study devices were followed for twelve (12) months after the index procedure.

Endpoints

Primary Safety Endpoint: Safety event-free rate at 12 months post procedure. Primary safety events consisted of a composite of the following procedure-related and device-related adverse events.

- Acute primary safety endpoint events, occurring up to 7 days post index or hospital discharge, whichever was later, included:
  - Death
  - Myocardial infarction
  - Transient ischemic attack (TIA)
  - Stroke/ Cerebrovascular accident (CVA)
  - Vascular access complications
  - Mitral or tricuspid valvular damage
  - Thromboembolism/ Air embolism leading to a life-threatening event such as a ventricular arrhythmia, stroke, pulmonary embolism, or myocardial infarction, and thromboembolic events that result in permanent injury, require intervention for treatment or prolongs or require hospitalization for more than 48 hours
  - Gastroparesis/ injury to vagus nerve
  - Pneumothorax
  - Pulmonary edema/ heart failure
  - Atrioventricular (AV) block
- Cardiac tamponade/perforation, occurring up to 30 days post index procedure.
- Chronic primary safety endpoint events, events occurring through 12 months post procedure, included:
  - Atrial esophageal fistula
  - Severe pulmonary vein (PV) stenosis (≥ 70% reduction in the diameter of the PV or PV branch from baseline)
  - Persistent phrenic nerve palsy (a non-recovered phrenic nerve palsy at 12 months post index procedure)
- Hypothesis for primary safety endpoint:
  - Ho: The primary safety endpoint event-free rate at 12 months post procedure ≤89%
  - Ha: The primary safety endpoint event-free rate at 12 months post procedure >89%

Primary Effectiveness Endpoint: Failure-free rate at 12 months post procedure. Failure was defined as follows:

- Failure to achieve acute procedural success in the index procedure or repeat procedure during the blanking period
- Use of amiodarone post index procedure
- Surgical treatment for atrial fibrillation (AF), atrial flutter (AFL), or atrial tachycardia (AT) post index procedure
- Use of a non-study ablation catheter for AF targets in the index procedure or repeat procedure during the blanking period

- More than one repeat procedure with the POLARx Catheter during the blanking period (90 days post index procedure)
- Documented atrial fibrillation, or new onset of atrial flutter or atrial tachycardia event (≥ 30 seconds in duration from the study-specific event monitor, Holter Monitor, or from a 10 second 12-lead ECG) between 91 and 365 days post index procedure
- Any of the following interventions for atrial fibrillation, or new onset of atrial flutter or atrial tachycardia between 91 and 365 days post procedure:
  - Repeat procedure
  - Electrical and/or pharmacological cardioversion for AF/AFL/AT
  - Prescribed any anti-arrhythmic drug (AAD) (all Class I/III and any Class II/IV medications taken for control of AF/AT/AFL recurrence)
- Hypothesis for primary effectiveness endpoint:
  - Ho: The 12-month failure-free rate ≤50%
  - Ha: The 12-month failure-free rate >50%

  The performance goal of 50% is based on the minimum chronic acceptable success rate for paroxysmal AF at 12 months follow-up defined in the 2017 HRS Consensus document.

Study Success Criteria

As this study was designed to address the safety and effectiveness of the Boston Scientific Cardiac Cryoablation System, there is both primary safety endpoint and primary effectiveness endpoint. Both primary endpoints must pass in order for study success to be achieved.

Subject Accountability

All subjects who signed and dated the Informed Consent Form were considered enrolled in the study.

All Treatment subjects were counted against the enrollment ceiling of 325 subjects. Subjects were classified as either part of the Roll-In cohort or the Non Roll-In cohort:

Roll-In Subject – To help facilitate investigators' familiarity with the new investigational system and avoid learning curve bias, Roll-in subjects were enrolled at each study site. Each ablating physician needed to treat one Roll-in subject with the Cryoablation System. Data from Roll-In subjects are not included in endpoint analyses.

Non Roll-In Subject – After the Roll-In subject criteria or case review was satisfied (documentation of waiver) for the treating physician, non Roll-in subjects could be enrolled.

Roll-in and non roll-in subjects were further classified as Intent, Attempt, and Treatment as described below.

Intent - Refers to a subject who was enrolled but did not have any study investigational devices inserted into the body.

Attempt - Refers to a subject who was enrolled and had any study device inserted into the body but did not receive any Cryoablation application.

Treatment - Refers to all enrolled subjects who had the study device inserted into the body and received at least one Cryoablation application.

Figure 3 shows the subject disposition for all Roll-In and Non Roll-In subjects in the FROzEN-AF study.

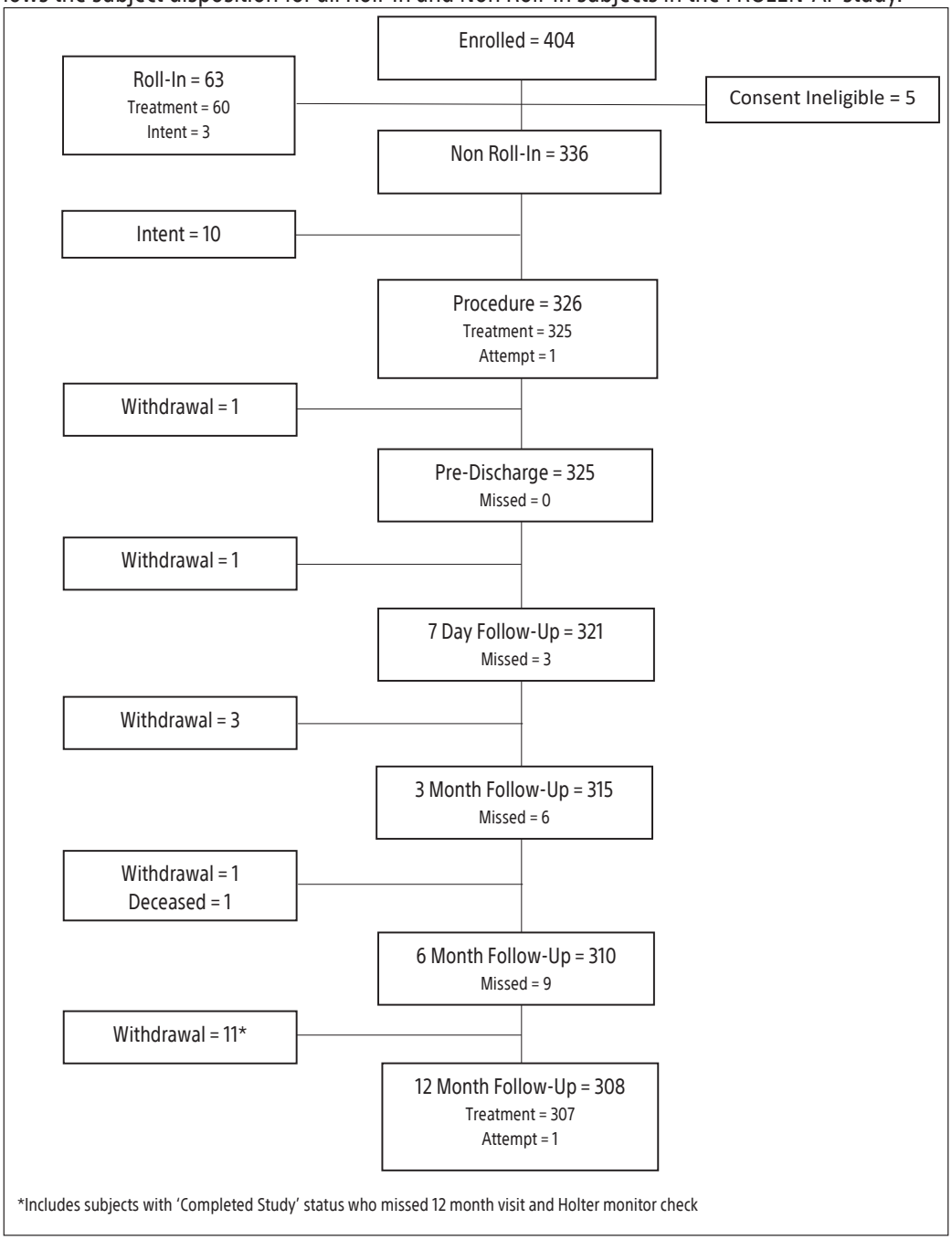

Figure 3. Subject Disposition and Accountability for Endpoint Analysis in FROzEN-AF Study

Study Population Demographics and Baseline Parameters

This section includes data from all Non Roll-In Treatment subjects (cohort for endpoint analysis) in the FROzEN-AF study (N= 325). The average age of the subjects in the FROZEN AF study was 62. The average time between first diagnosis and subject enrollment for the Non Roll-In Treatment subjects was 1.0 years (IQR:0.3 – 3.8 years).

Table 1 presents the demographics and physical assessment data for all Non Roll-In Treatment subjects.The gender and race characteristics in the patient population in the FROzEN-AF Study are consistent with previous clinical studies on PAF ablation.

Table 1. Subject Demographics and Physical Assessment Data

Characteristic	Measurement	Result
Age at Enrollment (years)	Mean +/- SD	62 +/- 11
	Min - Max	23 - 83
Gender [N (%)]	Female	124 (38.2)
	Male	201 (61.8)
Race* [N (%)]	Hispanic or Latino	5 (1.6)
	Native American	1 (0.3)
	Asian	35 (11.2)
	Black	4 (1.3)
	Pacific Islander	0 (0.0)
	White	274 (87.5)
	Other	1 (0.3)
	Race Undisclosed	12 (3.7)
Height (cm)	Mean +/- SD	174 +/- 10
	Min - Max	147 - 196
Weight (kg)	Mean +/- SD	86 +/- 19
	Min - Max	45 - 154
BMI	Mean +/- SD	29 +/- 6
	Min - Max	16 - 60
Pulse	Mean +/- SD	67 +/- 14
	Min - Max	40 - 130
Systolic BP	Mean +/- SD	133 +/- 18
	Min - Max	90 - 202
Diastolic BP	Mean +/- SD	79 +/- 11
	Min - Max	35 - 118
CHA2DS2-VASc Score [N (%)]	0	63 (19)
	1	82 (25)
	2	92 (28)
	3	59 (18)
	4	21 (6)
	5	8 (2)
*Subjects may contribute to more than one category		

Results

Primary Safety Endpoint

The results of the main analysis for the primary safety endpoint including data from all Non Roll-In Treatment/Attempt subjects (N=326) are presented in Figure 4.

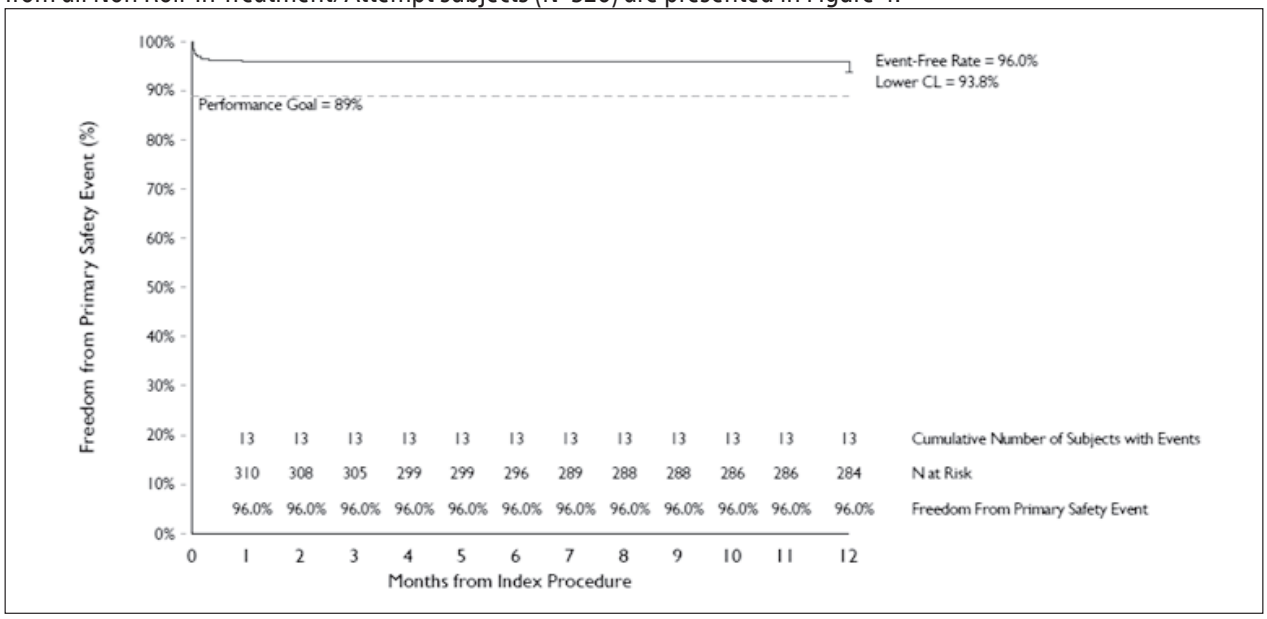

Figure 4. Primary Safety Endpoint Main Analysis

The observed event-free rate at 12 months follow-up was 96.0% with a one-sided 95% lower confidence limit of 93.8%. The lower confidence limit was greater than the performance goal of 89%, resulting in a rejection of the null hypothesis and the primary safety endpoint was passed.

Thirteen (13) subjects out of the 326 subjects in the primary safety endpoint analysis experienced a primary safety endpoint event prior to 12 months follow-up, as detailed in Table 2.

Table 2. Summary of Primary Safety Events in Non Roll-In Subjects

Endpoint Event	N (% Subjects)
MI	1 (0.3)
Pulmonary edema / heart failure	1 (0.3)
Thromboembolism/Air embolism	1 (0.3)
Cardiac Tamponade/Perforation	2 (0.6)
Gastroparesis / Injury to vagus nerve	3 (0.9)
Vascular Access Complication	5 (1.5)
Total	**13 (4)**

Additional Safety Information

Serious Adverse Events

A total of 100 serious adverse events (SAEs) in 73 study subjects were reported by Investigators during the first 12 months of study follow-up: 79 SAEs occurred in 60 Non Roll-In subjects and 21 SAEs occurred in 13 Roll-In subjects. The overall proportion of Non Roll-In subjects with SAEs was 17.9% and for the Roll-In subjects 20.6%. There were no confirmed PV stenosis events. No persistent phrenic nerve palsies were reported. No Atrioesophageal Fistulas were reported.

The SAEs occurring in Non Roll-In and Roll-In subjects are listed in the following tables. SAEs were further classified between serious adverse events and serious adverse device effects (SADE) per ISO classification.

Table 3. Serious Adverse Events in Non Roll-In Subjects

ISO Classification						
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Total Adverse Events	**41**	**33 (9.8)**	**38**	**32 (9.5)**	**79**	**60 (17.9)**
Ablation Related (N=326)	**0**	**0 (0)**	**38**	**32 (9.8)**	**38**	**32 (9.8)**
Ablation induced arrhythmia	0	0 (0)	2	2 (0.6)	2	2 (0.6)
Angina/Chest pain	0	0 (0)	3	3 (0.9)	3	3 (0.9)
Atrial Fibrillation (AF)	0	0 (0)	3	3 (0.9)	3	3 (0.9)
Atrial flutter, not specified	0	0 (0)	2	2 (0.6)	2	2 (0.6)
Edema	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Embolism – Air	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Esophagitis	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Gastroparesis	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Hematoma	0	0 (0)	4	4 (1.2)	4	4 (1.2)
Myocardial infarction	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Myocardial perforation with tamponade	0	0 (0)	2	2 (0.6)	2	2 (0.6)
Oozing/Bleeding	0	0 (0)	4	4 (1.2)	4	4 (1.2)
Pericarditis	0	0 (0)	4	4 (1.2)	4	4 (1.2)
Phrenic nerve injury temporary	0	0 (0)	4	4 (1.2)	4	4 (1.2)
Post procedure infection/ Sepsis	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Procedure related Hypertension	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Procedure related Neurological (Non-TIA, non-stroke, dysphagia, speech disturbance/dysarthria)	0	0 (0)	1	1 (0.3)	1	1 (0.3)
Procedure related Pulmonary (including cough, hemoptysis)	0	0 (0)	2	2 (0.6)	2	2 (0.6)
Cardiovascular (N=336)	**22**	**19 (5.7)**	**0**	**0 (0)**	**22**	**19 (5.7)**
1st degree AV block	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Atrial Fibrillation (AF)	6	6 (1.8)	0	0 (0)	6	6 (1.8)
Atrial flutter	2	2 (0.6)	0	0 (0)	2	2 (0.6)
Atypical (Type II) atrial flutter	2	1 (0.3)	0	0 (0)	2	1 (0.3)
Chest pain - Other	2	1 (0.3)	0	0 (0)	2	1 (0.3)

ISO Classification						
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Hypertension/Hypertensive crisis	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Palpitations	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Peripheral vascular disease	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Sinus bradycardia	3	3 (0.9)	0	0 (0)	3	3 (0.9)
Syncope	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Ventricular Tachycardia (VT)/Monomorphic VT	2	2 (0.6)	0	0 (0)	2	2 (0.6)
Non-Cardiovascular (N=336)	**19**	**15 (4.5)**	**0**	**0 (0)**	**19**	**15 (4.5)**
COPD Exacerbation	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Cancer	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Death	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Gastrointestinal	5	3 (0.9)	0	0 (0)	5	3 (0.9)
Genitourinary	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Hematological	4	4 (1.2)	0	0 (0)	4	4 (1.2)
Musculoskeletal	2	2 (0.6)	0	0 (0)	2	2 (0.6)
Neurological	2	2 (0.6)	0	0 (0)	2	2 (0.6)
Physical trauma	1	1 (0.3)	0	0 (0)	1	1 (0.3)
Vasovagal reaction	1	1 (0.3)	0	0 (0)	1	1 (0.3)

Table 4. Serious Adverse Events in Roll-In Subjects

ISO Classification						
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Total Adverse Events	**16**	**10 (15.9)**	**5**	**5 (7.9)**	**21**	**13 (20.6)**
Ablation Related (N=60)	**0**	**0 (0)**	**5**	**5 (8.3)**	**5**	**5 (8.3)**
Ablation induced arrhythmia	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Atrial Fibrillation (AF)	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Atrial tachycardia/Other SVT (e.g., AVRT, AVNRT, EAT)	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Pulmonary edema	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Right atrial (Type I) atrial flutter	0	0 (0)	1	1 (1.7)	1	1 (1.7)
Cardiovascular (N=63)	**4**	**4 (6.3)**	**0**	**0 (0)**	**4**	**4 (6.3)**

ISO Classification						
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Atrial tachycardia/Other SVT (e.g., AVRT, AVNRT, EAT)	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Chest pain - Other	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Multiple symptoms	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Peripheral vascular disease	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Non-Cardiovascular (N=63)	**12**	**8 (12.7)**	**0**	**0 (0)**	**12**	**8 (12.7)**
Abnormal laboratory values	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Cancer	2	2 (3.2)	0	0 (0)	2	2 (3.2)
Fever and/or virus	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Gastrointestinal	2	2 (3.2)	0	0 (0)	2	2 (3.2)
Hematological	2	2 (3.2)	0	0 (0)	2	2 (3.2)
Musculoskeletal	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Physical trauma	1	1 (1.6)	0	0 (0)	1	1 (1.6)
Pulmonary	2	1 (1.6)	0	0 (0)	2	1 (1.6)

Summary of Clinical Trial Adverse Events

There was a total of 226 adverse events (AEs), inclusive of serious and non-serious events, reported in 145 study subjects (119 Non Roll-In and 26 Roll-In) during the 12 month period of study follow-up:

- 92 subjects (78 Non Roll-In and 14 Roll-In) experienced at least one procedure-related AE.
- 46 subjects (40 Non Roll-In and 6 Roll-In) experienced at least one device-related AE.

The most frequently reported procedure-related AEs were hematoma (13 events), temporary phrenic nerve injury (13 events), and pericarditis (14 events). The most frequently reported device-related AEs were hematoma (8 events), temporary phrenic nerve injury (13 events), and pericarditis (7 events).

Two hundred fifty-four (254) study subjects (217 non Roll-In and 37 Roll-In) had no AEs reported.

Two (2) patients died during the course of the study. The deaths were classified by the Clinical Events Committee (CEC) as unrelated to the ablation procedure or to the investigational devices.

Primary Effectiveness Endpoint

The observed event-free rate at 12 months follow-up was 59.9% with a one-sided 95% lower confidence limit of 55.2%. The lower confidence limit was greater than the performance goal of 50%, resulting in a rejection of the null hypothesis and the primary effectiveness endpoint was passed.

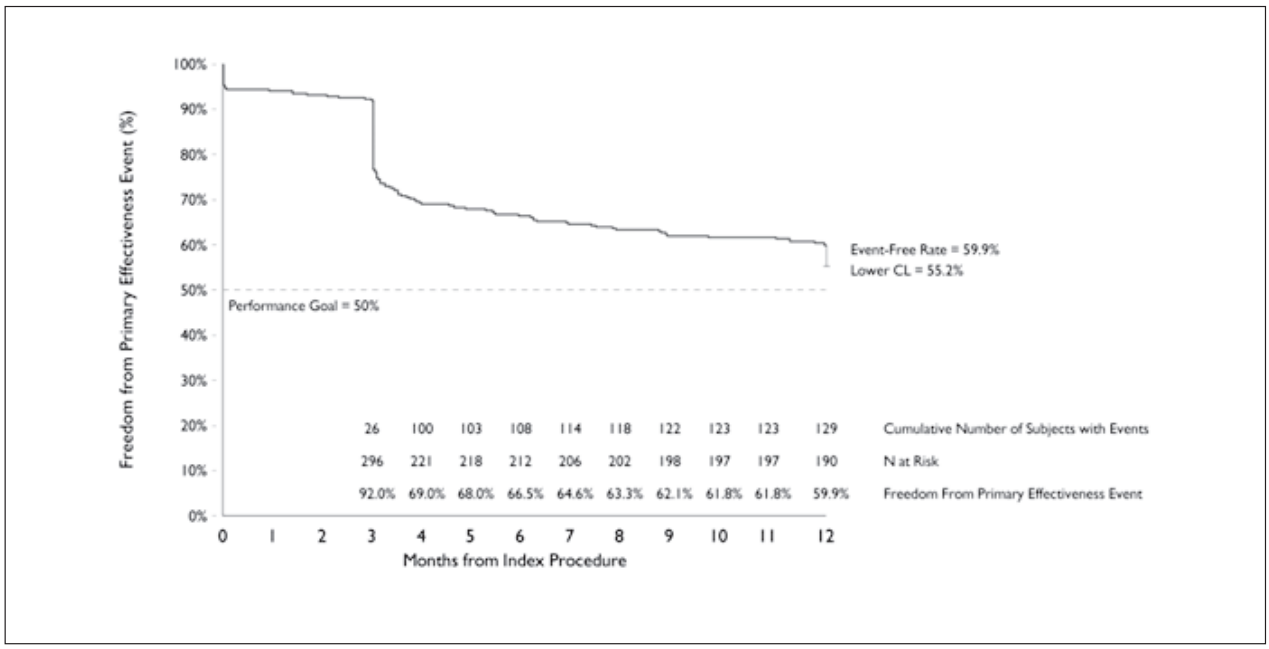

Figure 5. Primary Effectiveness Endpoint Main Analysis

One hundred twenty-nine (129) subjects out of the 325 subjects in the primary effectiveness endpoint analysis experienced an endpoint event prior to 12 months follow-up. The primary effectiveness events are shown in Table 5.

Table 5. Summary of Primary Effectiveness Events

Failure Component	**N (%)**
Overall Event-Free Rate at 12 Months	**59.9%**
Amiodarone/AAD Failure	86 (26.5)
Event Monitor Failure	58 (17.8)
Acute Failure	14 (4.3)
Repeat Procedure Failure	14 (4.3)
Holter Failure	11 (3.4)
Cardioversion Failure	9 (2.8)
ECG Failure	7 (2.2)
Non-study catheter for AF target at Repeat Procedure	6 (1.8)
Non-study catheter for AF target at Index Procedure	4 (1.2)
Surgical Treatment for AF/AFL/AT Failure	0 (0.0)
*Subjects may contribute to more than one category if multiple failure types were observed	

The primary effectiveness endpoint was assessed using the 2017 HRS expert consensus definition of "freedom from AF/AFL/AT after removal from antiarrhythmic drug therapy as assessed from the end of the 3 month blanking period to 12 months following the ablation procedure" and the recommended Objective Performance Criteria (OPC) of freedom from AF at 12 months in 50% of subjects.

In other studies reported in the medical literature, continuation of a pre-ablation antiarrhythmic drug therapy at stable or lower doses was allowed and subjects were only counted as effectiveness failures if a new AAD or higher dose of an existing AAD was started after ablation. Excluding continuation of pre-ablation AADs at the same or lower dose, the number of primary effectiveness AAD Failures decreased from 86 to 48. Figure 6 shows Primary Effectiveness results when subjects were counted as failures only if they took a new AAD or a higher dose of an already prescribed AAD (excluding amiodarone). All other endpoint components, including Amiodarone use, were unchanged in this analysis. The observed event-free rate increased to 71.6% (lower confidence limit of 67.2%).

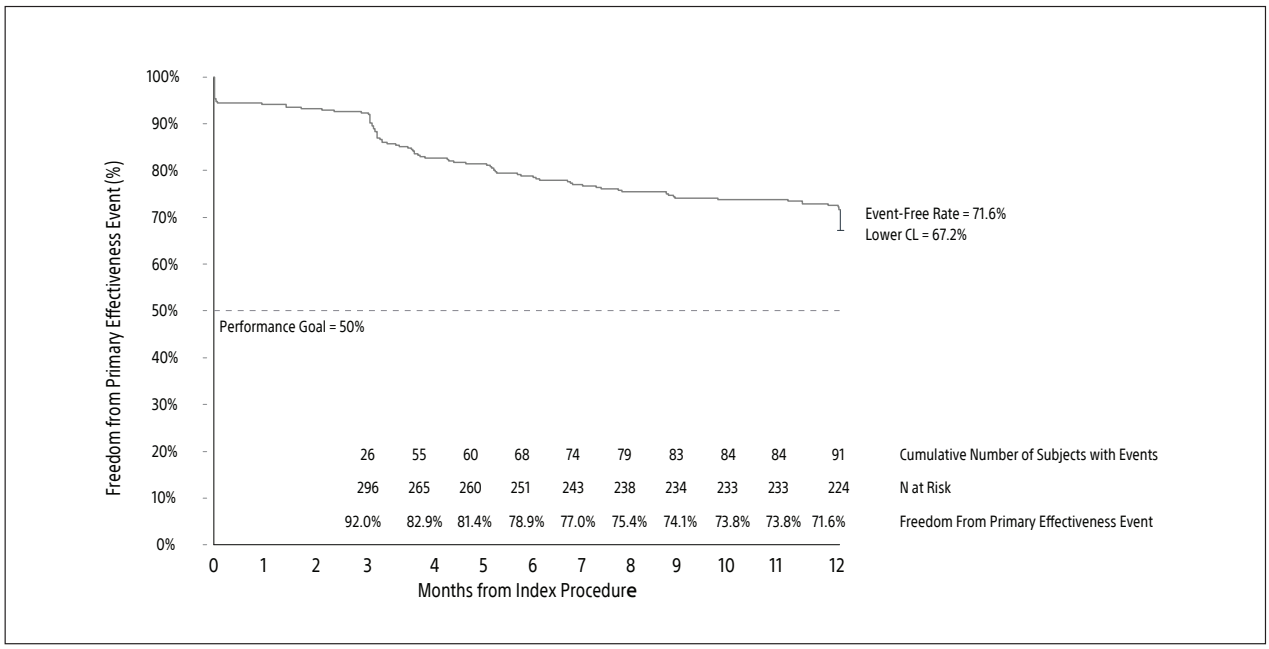

Figure 6. Sensitivity Analysis - Primary Effectiveness Endpoint Event Free Rate Allowing Previously Prescribed AADs

Freedom from arrythmia recurrence is clinically important. Figure 7 shows the recurrence free rate of individual atrial arrhythmia types as documented on a rhythm monitoring device post- blanking period. Other protocol defined primary effectiveness failures (e.g., AAD failures, acute procedural failure) were not considered in this analysis. Overall, the freedom from documented arrhythmia recurrence, including atrial fibrillation (AF), atrial flutter (AFL), and atrial tachycardia (AT), was 79.9%. Atrial Fibrillation was the most common documented arrythmia recurrence with an AF recurrence free rate of 82.7%.

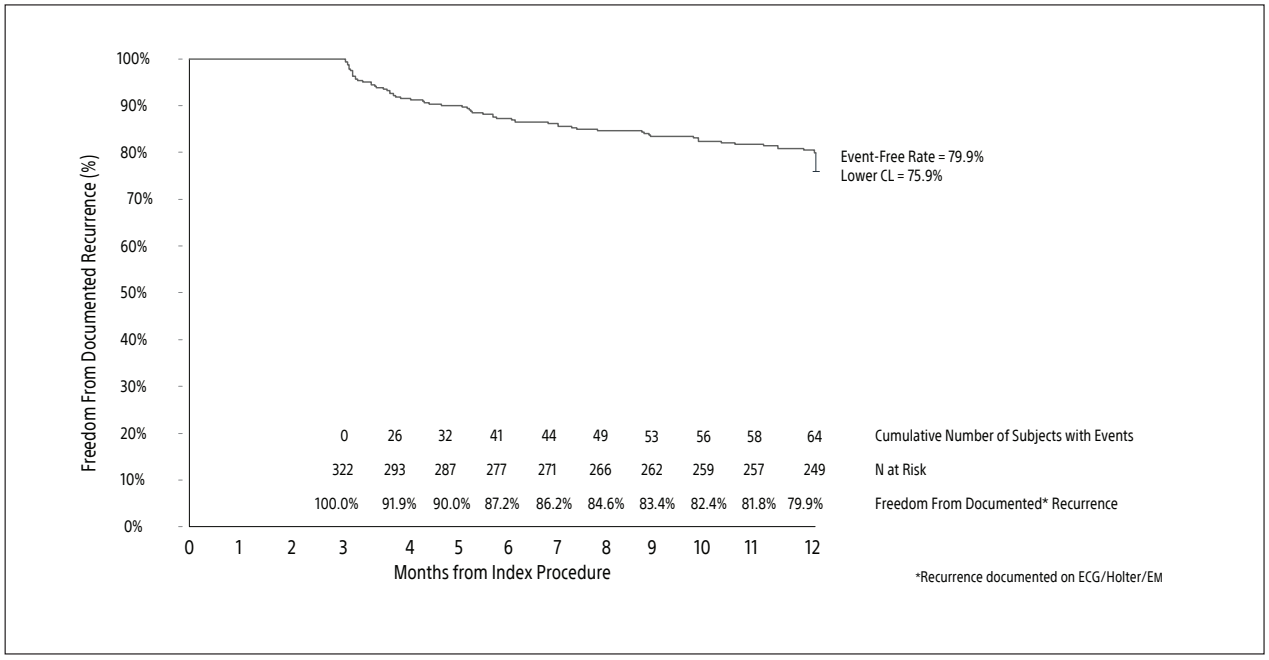

Figure 7. Freedom from Documented Recurrence

Rhythm Monitoring Compliance

Compliance to required endpoint assessment rhythm monitoring is outlined in Table 6 below. Total compliance to 12-lead ECG required throughout the course of the trial was 95.2%, and compliance to 24-Hour Holter at the 12 month follow-up visit was 88.3%. Subjects were compliant at a rate of 61.1% (Table 6) with the required event monitor transmission schedule of at least 2 transmissions per month for months four through nine (18 total transmissions).

Subjects were considered partially compliant with respect to event monitors for each 30-day window post-blanking period where at minimum one event monitor recording was submitted.

Table 6. Rhythm Monitoring Compliance

(Non Roll-In Treatment Subjects N=325)

Monitor	Compliance % (N Obs/N Expected)
ECG Compliance	95.2% (885/930)
Holter Compliance	88.3% (272/308)
Event Monitor Compliance	61.1% (1723/2820)
Event Monitor Compliance (partial)	73.5% (2082/2833)

An additional analysis was conducted using an >80% compliance rate to assess for differences in the Primary Safety and Primary Effectiveness Endpoints shown in the table below.

Table 7. Event Monitor Compliance Subgroup Analysis (80% Compliance Cutoff)

Endpoint	Subgroup	N	Rate (Lower Confidence Limit)	P Value
Primary Safety Endpoint	Subject TTM Compliance < 80%	211	96.7% (93.9%)	0.3438
	Subject TTM Compliance ≥80%	108	94.4% (89.3%)	
Primary Effectiveness Endpoint	Subject TTM Compliance < 80%	211	61.6% (55.8%)	0.4681
	Subject TTM Compliance ≥ 80%	130	56.9% (49.3%)	

Although a lower event monitoring compliance could overestimate the efficacy of the system, no significant difference exists between highly compliant (>80%) and less compliant (<80%) subjects in terms of the Primary Safety Endpoint (p=0.3438) and Primary Effectiveness Endpoint (p=0.4681).

Acute Procedural Success

The secondary effectiveness endpoint was the rate of acute procedural success, defined as achievement of electrical isolation of all PVs by using the POLARx Cryoablation System only, where electrical isolation of PVs is demonstrated by entrance and exit block. The acute procedural success results are shown in Table 8 below. Six (6) of the 14 subjects who were deemed acute procedural failures were due to entrance/exit block testing performed not according to protocol requirements.

Table 8. Acute Procedural Success

N Total	N Success	Acute Success Rate (%)	95% Confidence Interval
325	311	95.69	(92.88, 97.63)

POLARx FIT: FROzEN-AF Extension Clinical Study

Additional subjects were enrolled in an extension to the FROzEN-AF Study to establish a reasonable assurance of safety and effectiveness of catheter ablation with the POLARx FIT Catheter models for the treatment of drug refractory, recurrent symptomatic paroxysmal atrial fibrillation in patients age 18 or older. The POLARx FIT Extension study was a multi-center, open label, prospective investigation conducted at 11 sites in the United States. A total of 54 subjects were enrolled in the study and fifty (50) subjects received treatment with the 31mm POLARx FIT balloon configuration.

Study Endpoints

Primary Safety Endpoint: Primary safety event free rate at 3 months post procedure. Primary safety events consisted of the same composite of procedure-related and device-related adverse events that were used inthe FROzEN-AF main study but analyzed at 3 months post procedure.

Primary Effectiveness Endpoint: Rate of acute procedural success defined as the achievement of electrical isolation of all PVs when using the POLARx Cardiac Cryoablation System with the POLARx FIT cryoablation balloon catheter models (with ablation performed using the 28 mm or 31 mm balloon size per physician discretion). Isolatin was demonstrated by entrance and exit block.

Study Success Criteria: Statistical considerations were not utilized in the design of this extension study and no statistical hypothesis was defined.

The subject disposition for all subjects in the POLARx FIT Extension Study is provided in the figure below. Data from the 50 Treatment subjects are included in endpoint analyses.

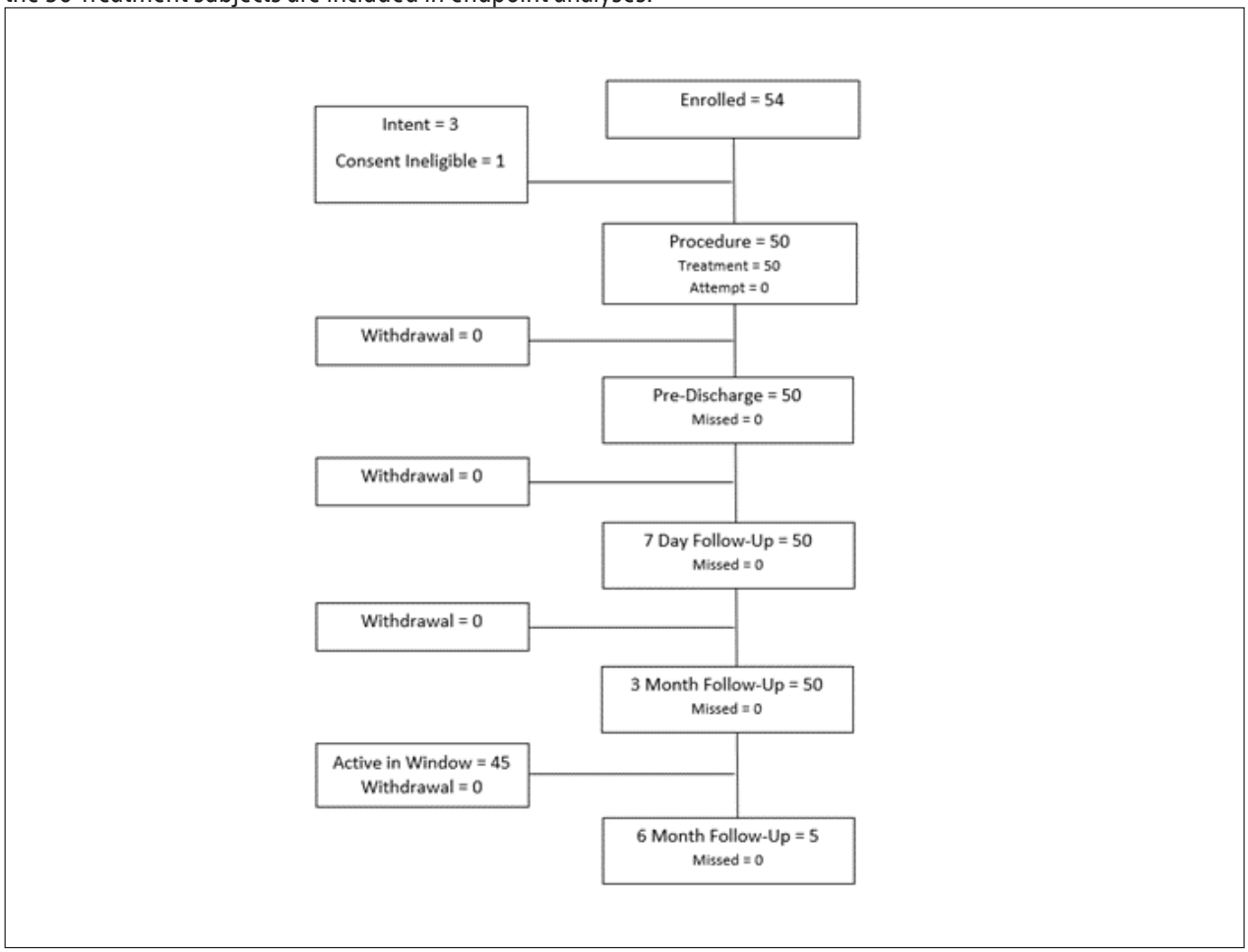

Figure 8. Disposition of Study Subjects in the POLARx FIT Extension Study

POLARx FIT Extension Study Population Demographics and Baseline Parameters

This section includes data from all Treatment subjects in the POLARx FIT Extension Study (N=50). The demographics were similar to the FROzEN-AF main study although the POLARx FIT Extension Study had a larger representation of female subjects (46%).

Table 9. POLARx FIT Extension Study Subject Demographics and Physical Assessment Data

Characteristic	Measurement	Result
	Native American	0 (0.0)
	Asian	0 (0.0)
	Black	1 (2.0)
	Pacific Islander	0 (0.0)
	White	49 (98.0)
	Other	0 (0.0)
	Race Undisclosed	0 (0.0)
Height (cm)	Mean +/- SD	173 +/- 10
	Min - Max	149 - 198
Weight (kg)	Mean +/- SD	93 +/- 22
	Min - Max	49 - 159
BMI	Mean +/- SD	31 +/- 7
	Min - Max	19 - 50
Pulse	Mean +/- SD	66 +/- 13
	Min - Max	50 - 118
Systolic BP	Mean +/- SD	134 +/- 16
	Min - Max	106 - 185
Diastolic BP	Mean +/- SD	76 +/- 9
	Min - Max	56 - 106
CHA2DS2-VASc Score [N (%)]	0	3 (6)
	1	15 (30)
	2	16 (32)
	3	5 (10)
	4	6 (12)
	5	4 (8)

Results

Primary Safety Endpoint

The results of the main analysis for the primary safety endpoint of the safety event free rate at 3 months post procedure are presented in the figure below.

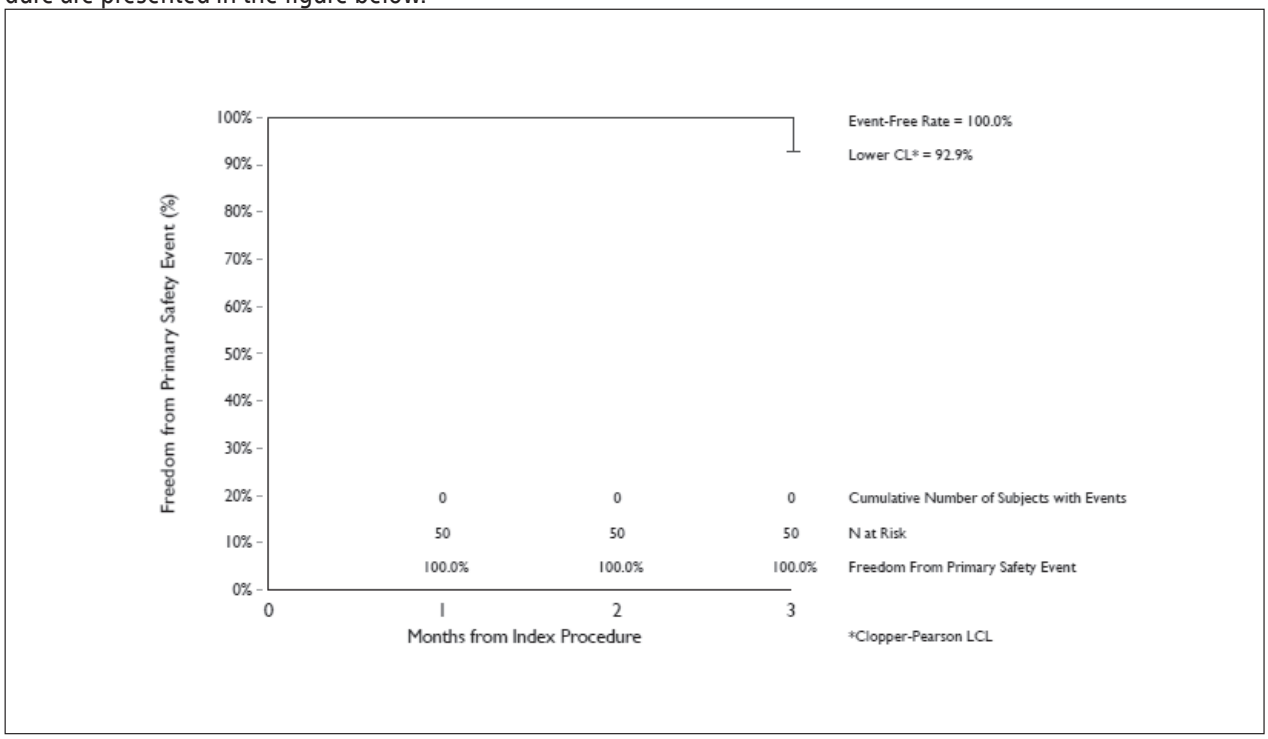

Figure 9. Primary Safety Endpoint Main Analysis

The observed event-free rate at 3 months follow-up was 100% with a one-sided 95% lower confidence limit of 92.9%. None of the subjects in the primary safety endpoint analysis experienced a safety endpoint event prior to 3 months follow-up.

Summary of Clinical Trial Adverse Events

A total of 7 serious adverse events (SAEs) in 6 study subjects were reported by Investigators during the first 3 months of study follow-up. Of these, there were five ablation related events in 4 subjects.

- There were no confirmed PV stenosis events.
- No persistent phrenic nerve palsies were reported.
- No Atrioesophageal Fistulas were reported.
- There were no patient deaths during the study.

Table 10. Serious Adverse Events in POLARx FIT Extension Study Subjects

	ISO Classification					
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	N events	N subjects (%)	N events	N subjects (%)	N events	N subjects (%)
Total Adverse Events	2	2 (3.8)	5	4 (7.5)	7	6 (11.3)
Ablation Related (N=50)	0	0 (0)	5	4 (8)	5	4 (8)
Angina/Chest pain	0	0 (0)	1	1 (2)	1	1 (2)

	ISO Classification					
	Serious Adverse Event		Serious Adverse Device Effect		Total	
Adverse Event	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**	**N events**	**N subjects (%)**
Oozing/Bleeding	0	0 (0)	1	1 (2)	1	1 (2)
Phrenic nerve injury temporary	0	0 (0)	1	1 (2)	1	1 (2)
Procedure related Pulmonary (including cough, hemoptysis)	0	0 (0)	1	1 (2)	1	1 (2)
Pulmonary edema	0	0 (0)	1	1 (2)	1	1 (2)
Cardiovascular (N=53)	**1**	**1 (1.9)**	**0**	**0 (0)**	**1**	**1 (1.9)**
Sinus bradycardia	1	1 (1.9)	0	0 (0)	1	1 (1.9)
Non-Cardiovascular (N=53)	**1**	**1 (1.9)**	**0**	**0 (0)**	**1**	**1 (1.9)**
Integumentary	1	1 (1.9)	0	0 (0)	1	1 (1.9)

Primary Effectiveness Endpoint

All subjects in the primary effectiveness endpoint analysis were acute procedural successes. The observed acute success rate was 100% with a one-sided 95% lower confidence limit of 92.9 %.

Table 11. Primary Effectiveness: Acute Procedural Success

N Total	N Success	Acute Success Rate (%)	95% Confidence Interval
50	50	100	(92.9, 100)

Utilization of the 31mm POLARx FIT Balloon Size

Selection of balloon size for ablation was based on medical judgment considering anatomical factors including PV size, geometry, and LA size, as well as other procedural factors that could affect balloon placement, occlusion quality, and tissue contact.

- The 31mm balloon size was used for at least one PV ablation in all 50 treatment subjects. Twleve (12) of the 50 (24%) subjects were treated exclusively using the 31mm size.
- Of the 191 PVs in the 50 subjects, 113/191 (59.2%) were treated exclusively with the 31mm size.

Study Conclusion

The FROzEN-AF study demonstrated there is a reasonable assurance of safety and effectiveness to support use of the Boston Scientific Cardiac Cryoablation System in treatment of patients with drug refractory, recurrent symptomatic paroxysmal atrial fibrillation. Additionally, the POLARx FIT Extension Study demonstrates a similar safety and acute effectiveness profile of the POLARx FIT Catheter compared to the POLARx Catheter.

Contents

Store between 15°C – 25°C (59°F – 77°F);
excursions permitted to -30°C – 60°C
(-22°F – 140°F)

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Boston Scientific

SMARTFREEZE™

Cryoablation System Console

User's Manual **2**

TABLE OF CONTENTS

℞ 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 Cardiac 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™ or POLARx FIT Cryoablation Balloon Catheter (henceforth referred to as cryoablation balloon catheter) from a tank stored in the SMARTFREEZE Console. Since the refrigerant cools as it expands within the cryoablation balloon catheter's cryo-balloon, it absorbs the heat from the surrounding tissue and kills the cells within that tissue. The SMARTFREEZE Console removes 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 Cardiac 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 Cryoablation balloon catheter, Diaphragm Movement Sensor (DMS) and Esophageal Temperature Sensor (ETS) cable (M004CRBS6310) to the SMARTFREEZE Console.
Inter-Connection Box with Remote Control Option	M004CRBS4130	Interconnect device used to connect the cryoablation balloon catheter, Diaphragm Movement Sensor (DMS), Esophageal Temperature Sensor cable (M004CRBS6320) or Esophageal Temperature Sensor Cable (CIRCA) (M004CRBS6340), 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.

Component	Model	Description
Scavenging Hose	M004CRBS4310 (Yellow) M004CRBS4320 (Purple) M004CRBS4300 (White)	When connected to the SMARTFREEZE Cryo-Console, the scavenging hose exhausts the N_2O from the SMARTFREEZE Console to the hospital gas removal 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.
USB to Serial Cable	M004CRBS62860	USB to Serial Cable used to connect the SMARTFREEZE Console to a hospital recording system.

1.2 Sterile, Single-Use Accessories

Accessory	Model	Description
POLARx Cryoablation Balloon Catheter	M004CRBS2050	Cryo-ablation catheter (Short tip, 28mm) (Applied Part)
POLARx Cryoablation Balloon Catheter	M004CRBS2150	Cryo-ablation catheter (Long tip, 28mm) (Applied Part)
POLARx™ FIT Cryoablation Balloon Catheter	M004CRBS2060	Cryo-ablation catheter (Short tip, 28mm - 31mm) (Applied Part)
POLARx FIT Cryoablation Balloon Catheter	M004CRBS2160	Cryo-ablation catheter (Long tip, 28mm - 31mm) (Applied Part)
POLARMAP™ Circular Mapping Catheter	M004CRBS7210	Mapping catheter used to confirm electrical isolation before and after cryo-ablation procedures (20mm). (Applied Part)
POLARSHEATH™ Steerable Sheath	M004CRBS3150	Conduit used to provide a path for the POLARx Cryoablation Balloon Catheter to the heart. (Applied Part)
SMARTFREEZE Cryo-Cable	M004CRBS5210	Refrigerant path between the SMARTFREEZE Console and the balloon catheter
SMARTFREEZE Catheter Extension Cable	M004CRBS5110	Extension cable used to connect the balloon catheter to the Inter-Connection Box (ICB)
EP Electrical Cable	M004CRBS62000	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 cryoablation balloon catheter through 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 cryoablation balloon 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 ablation via the balloon catheter thermocouple in the distal balloon segment.
Since the refrigerant cools as it expands within the cryoablation balloon catheter's cryo-balloon, it absorbs the heat from the surrounding tissue creating lesions. The SMARTFREEZE Console removes 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 Boston Scientific Cardiac Cryoablation System is intended for cryoablation and electrical mapping of the pulmonary veins for pulmonary vein isolation (PVI) in the ablation treatment of patients with drug refractory recurrent symptomatic paroxysmal atrial fibrillation (PAF). The SMARTFREEZE Console is intended to be used with POLARx Cryoablation Balloon Catheters only.

2.1 Intended Use Environment

The SMARTFREEZE Console is intended to be used in facilities equipped for interventional cardiac electrophysiology procedures.

3. CONTRAINDICATIONS

Use of the Boston Scientific Cardiac Cryoablation 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 intra-atrial septal patch or any other surgical intervention in or adjacent to the intra-atrial septum.
- 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.
- In patients previously implanted with a percutaneous Left Atrial Appendage Occlusion device.

4. 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, POLARx FIT 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.

5. 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).
- In order to maintain the device cybersecurity, firmware, and software (including off the shelf applications) of the SMARTFREEZE Console and accessories cannot be updated by the user.

Contact your local Boston Scientific representative to schedule approved updates including security patches.

- In order to maintain the device cybersecurity, do not attempt to connect the SMARTFREEZE Console to the internet or hospital network in any way.
- Post installation, there are no specific security actions that the user or user facility are expected to take/implement to ensure secure use of this device.
- Patient data is stored on the console and should be purged prior to system decommissioning. Contact your local Boston Scientific representative to schedule this service.

6. 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

7. HOW SUPPLIED

The components in section 1.1 are provided as individually packaged non-sterile components. The components in section 1.2 are provided as individually packaged sterile components.

7.1 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.

7.2 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%-90% non-condensing
- Atmospheric Pressure: Uncontrolled

7.3 Wired Electronic Interface Specifications

The SMARTFREEZE Console includes the following wired electrical interfaces:

- HDMI port: intended to allow mirroring of the console screen on an external monitor (see precautions).
- Ethernet port: disabled.
- Three (3) USB ports: intended to allow exporting of procedure data (see precautions), printing of procedure reports, and EP recording system communication.

These connections are not intended to control the operation of another medical device or accessory.

8. INSTRUCTIONS FOR USE

8.1 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)
  - CIRCA S-CATH™ Esophageal Temperature Sensor
  - Remote Sterile Sleeve

8.2 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.

8.2.1 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.

8.2.2 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. Connect the refrigerant tank to the SMARTFREEZE Console using the tank to process plate hose and the supplied wrench.
4. Turn the refrigerant tank knob counter-clockwise to open the tank valve.
5. Close the SMARTFREEZE Console door.

8.2.3 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 gas removal 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 63).

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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 72 for complete operating instructions.
    - Connect the DMS to the ICB.
    - Place a disposable ECG electrode just below the right side costal cartilage.
    - Snap the DMS onto the electrode.
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 LABSYSTEM PRO Connection

Note: Ensure that LABSYSTEM PRO is powered off prior to connecting.

Note: The SMARTFREEZE Cryoablation Console is designed to function with LABSYSTEM PRO Recording System. The SMARTFREEZE Cryoablation Console may be compatible with other recording systems.

- Connect the USB to serial cable (M004CRBS62860) 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 (M004CRBS62860) to the COM port of the LABSYSTEM PRO. Refer to the LABSYSTEM PRO IFU for details on port connection.

8.2.4 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 58.

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

8.3 Cryo-therapy procedure

8.3.1 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.

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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.

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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.

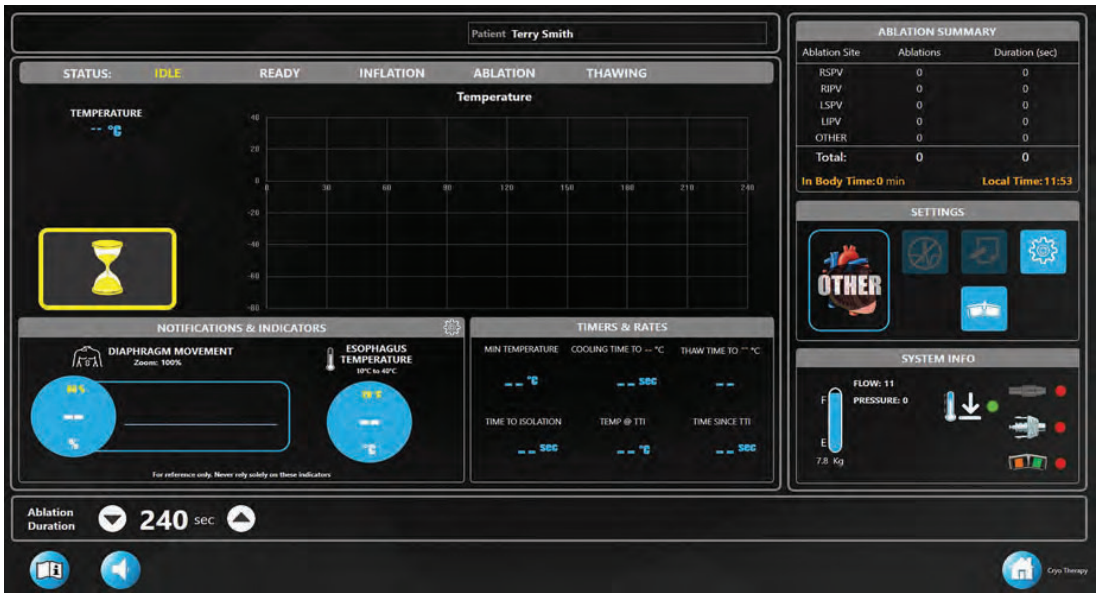


Figure 4. Therapy Screen–idle state

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).

8.3.2 Pre-Ablation

Prepare the cryoablation balloon catheter and other sterile components in accordance with their Instructions for Use.

WARNING: Read and follow IFUs for POLARx Catheter, POLARx FIT 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 cryoablation balloon catheter's IFU for connecting the components to the SMARTFREEZE Console.
2. 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 cryoablation balloon 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.

3. 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 58 for troubleshooting steps.

4. 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 8.2.2.

8.3.3 Ablation

WARNING: Read and follow IFUs for POLARx Catheter, POLARx FIT 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.

8.3.3.1 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.

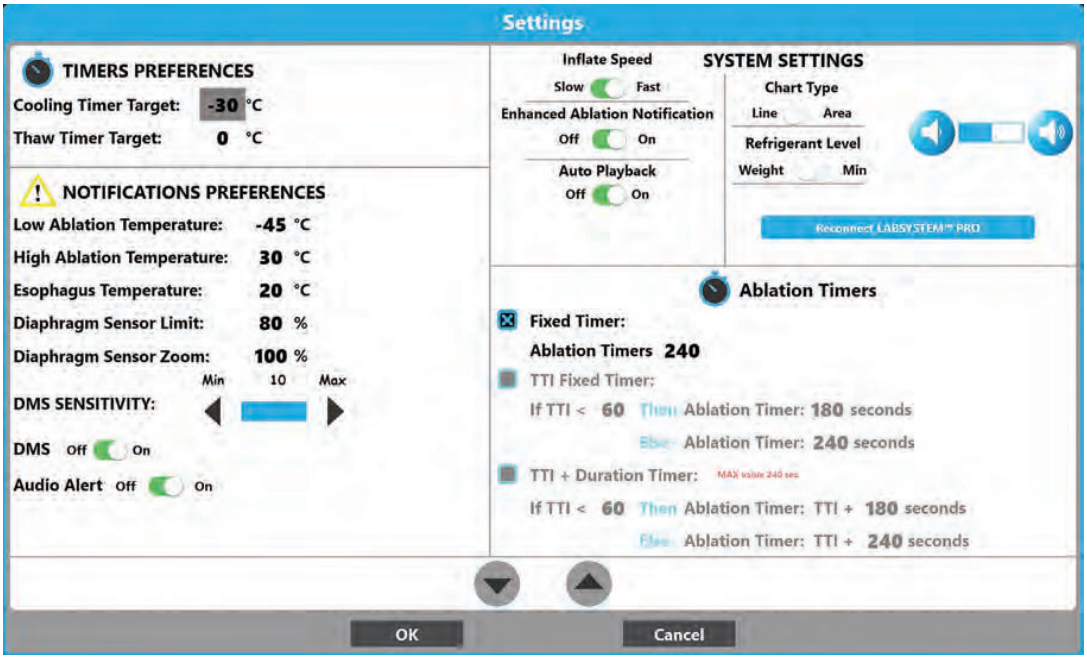


Figure 7. Settings window

- 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.

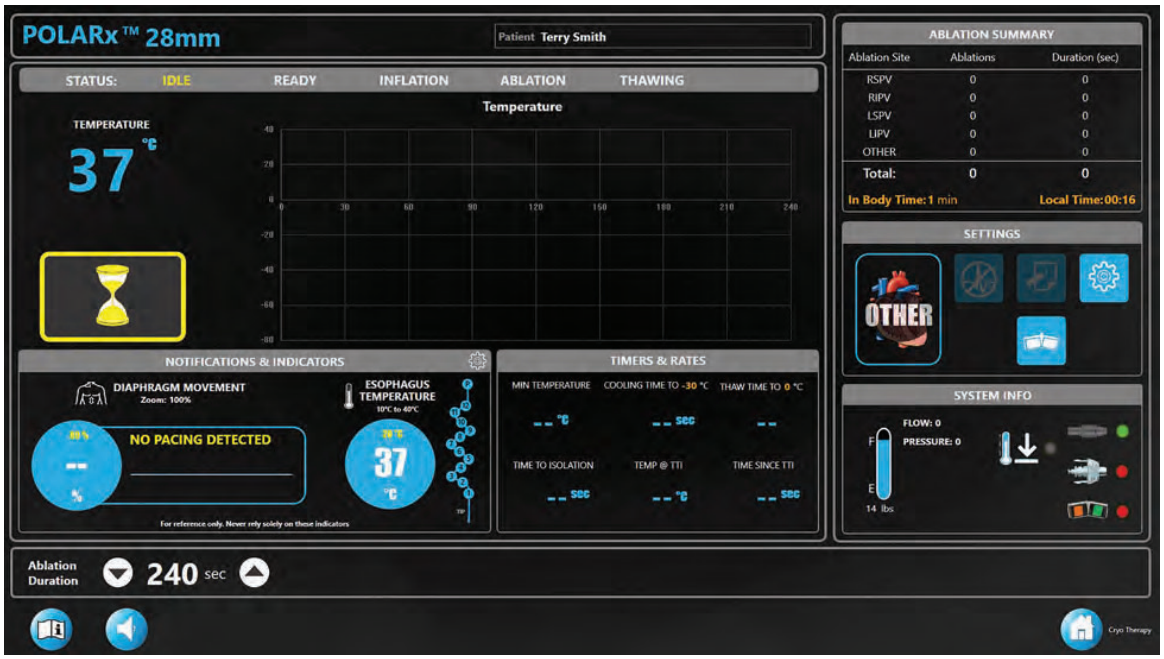


Figure 9. CIRCA™ S-CATH Esophageal Temperature Probe

- 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

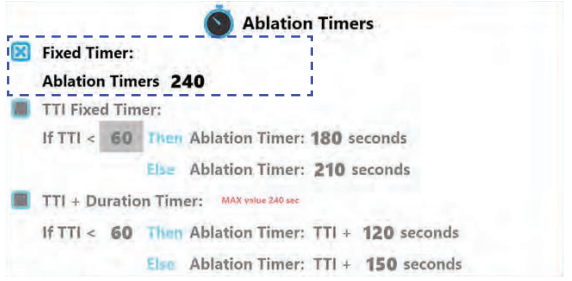
- Select the numeric value next to the **Diaphragm Sensor Limit.** Set the **Diaphragm Sensor Limit** to the desired percentage using the up/down arrows. When the percentage reaches the set point chosen in this field, the **DIAPHRAGM MOVEMENT** Sensor reading on the Therapy screen will turn red and flash, 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 mode from the three options:
  - **Fixed Timer**

    In this mode, the ablation duration is fixed at a defined value. Set the **Ablation Timers** value to the desired duration using the up/down arrows on the Settings window. All ablations will stop when the **Ablation Time** reaches the set value. For example, a user can use this mode to set the ablation duration to 240 seconds regardless of when TTI is marked, as illustrated below.

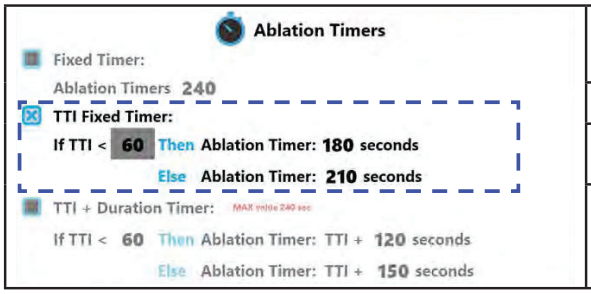


Time that TTI was marked	Final Ablation Duration
59 sec	240 sec
TTI was not marked	240 sec

  - **TTI Fixed Timer**

    In this mode, the ablation duration is set to a fixed value based upon a time-to-isolation (TTI) criterion. With this option the console will automatically change the ablation duration based on when TTI is marked on the console. The ablation duration will be a defined length when TTI is shorter than a certain threshold and a different length when TTI is longer than the threshold. For example, a user can use this mode to set the ablation duration to 180 seconds if TTI is less than 60 seconds and to 210

seconds if TTI is longer than 60 seconds , as illustrated below.



Time that TTI was marked	Final Ablation Duration
59 sec	180 sec
65 sec	210 sec
TTI was not marked	210 sec

This option requires the user to input the TTI threshold ("**TTI <**" value), the shorter duration ("**Then Ablation Timer**" value), and the longer duration ("**Else Ablation Timer**" value). The user defined values are adjusted by selecting the desired setting and using the up/down arrows.

The TTI threshold is adjustable in 10 second increments, with a minimum of 30 seconds.

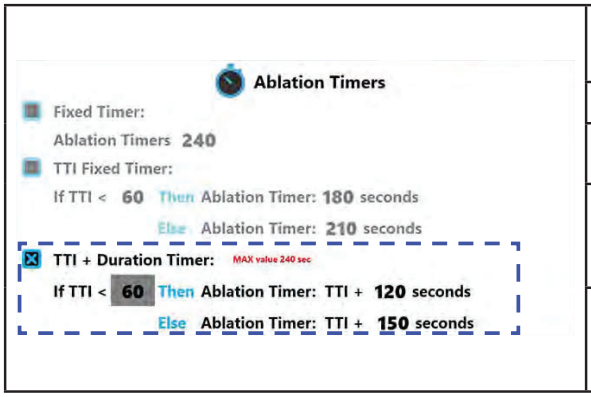
The shorter duration is adjustable in 30 second increments beginning with 60 seconds. The shorter duration cannot be shorter than the TTI threshold and must be shorter than the longer duration.

The longer duration is adjustable in 30 second increments beginning with 90 seconds. The longer duration must be longer than the shorter duration and cannot exceed 240 seconds.

If **TTI Fixed Timer** option is chosen, the ablation duration on the Therapy screen will initially display the longer duration setting. If TTI is marked prior to the TTI threshold value, the **Ablation Duration** will automatically change to the shorter duration and flash for a few seconds.

– **TTI + Duration Timer**

In this mode, the console will automatically add a fixed amount of time based on when TTI is marked on the console. For example, a user can use this mode to add 120 seconds if TTI is less than 60 seconds and to add 150 seconds if TTI is longer than 60 seconds, as illustrated below. The additional duration is not allowed to extend the ablation duration beyond the system limit of 240 seconds. If TTI is not marked, the ablation duration will be set at 240 seconds.



Time that TTI was marked	Final Ablation Duration
59 sec	179 sec
65 sec	215 sec
120 sec	240 sec (system limit)
TTI was not marked	240 sec

This option requires the user to input the TTI threshold ("**TTI <**" value), the shorter Additional Time ("**Then Ablation Timer**" value), and longer

Additional Time (“**Else Ablation Timer**” value).

The TTI threshold is adjustable in 10 seconds increments from 30 seconds to 210 sec.

The shorter Additional Time is adjustable in 30 seconds increments beginning with 30 seconds. The shorter Additional Time must be shorter than the longer Additional Time.

The longer Additional Time is adjustable in 30 seconds increments from 60 seconds. The longer Additional Time must be longer than the shorter Additional Time and cannot exceed 240 seconds.

If this option is chosen, the ablation duration will initially display 240 seconds. If TTI is marked earlier than the TTI threshold value, the ablation duration will increase by the shorter Additional Time. If TTI is marked later than the TTI threshold value, the ablation duration will increase by the longer Additional Time. The ablation duration will not be set greater than 240 seconds.

Note: During any ablation, the ablation duration can be manually changed, using the up/down arrows on the Therapy Screen. If the ablation duration is manually changed, the change will apply only to the current ablation. The ablation duration of subsequent ablations will revert back to the settings defined by the user selected Ablation Timers mode.

8.3.3.2 Beginning Cryoablation Procedure

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

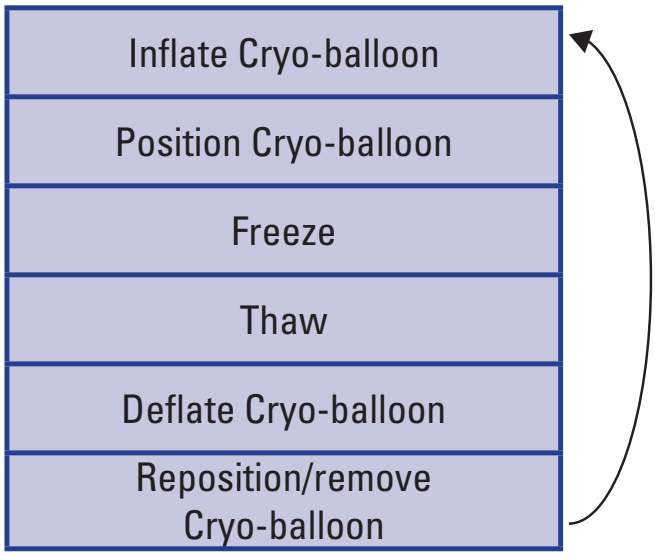


Figure 13. Ablation procedure algorithm

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

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.

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

Note: Prior to starting a cryoablation treatment, confirm that the ablation duration is set to the expected value and that all procedure settings are as expected. Adjust the values if necessary.

3. 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 cryoablation treatment 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 the cryoablation treatment. Press the STOP button a second time to deflate the cryo-balloon.
- Press the STOP foot switch pedal (left pedal, orange) to stop the cryoablation treatment. Press the STOP foot switch pedal a second time to deflate the cryo-balloon.
- Press the **STOP** button on the Therapy Screen to stop the cryoablation treatment. Press the **STOP** button a second time to deflate the cryo-balloon.
- Press the STOP button  on the Remote Control to stop the cryoablation treatment. Press the STOP button a second time to deflate the cryo-balloon.

Figure 15. Therapy screen–ablation state

4. When the system is in the **ABLATION** state, the following indicators will be visible in the Therapy screen (Figure 15):
    - 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 16).
        - 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.

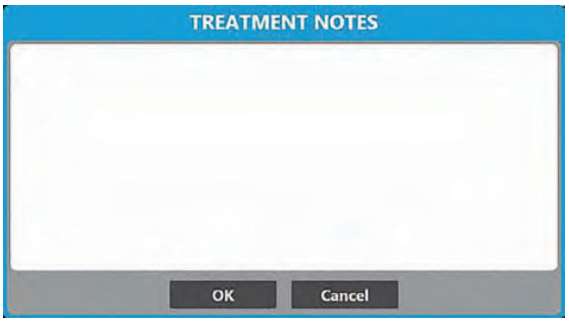


Figure 16. **TREATMENT NOTES** window

- 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 17).

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

Note: This feature may not be available in all countries

Figure 17. Low Flow is activated

Note: If a fault is detected, a system message will be displayed with detailed information of the failure (see Figure 18).

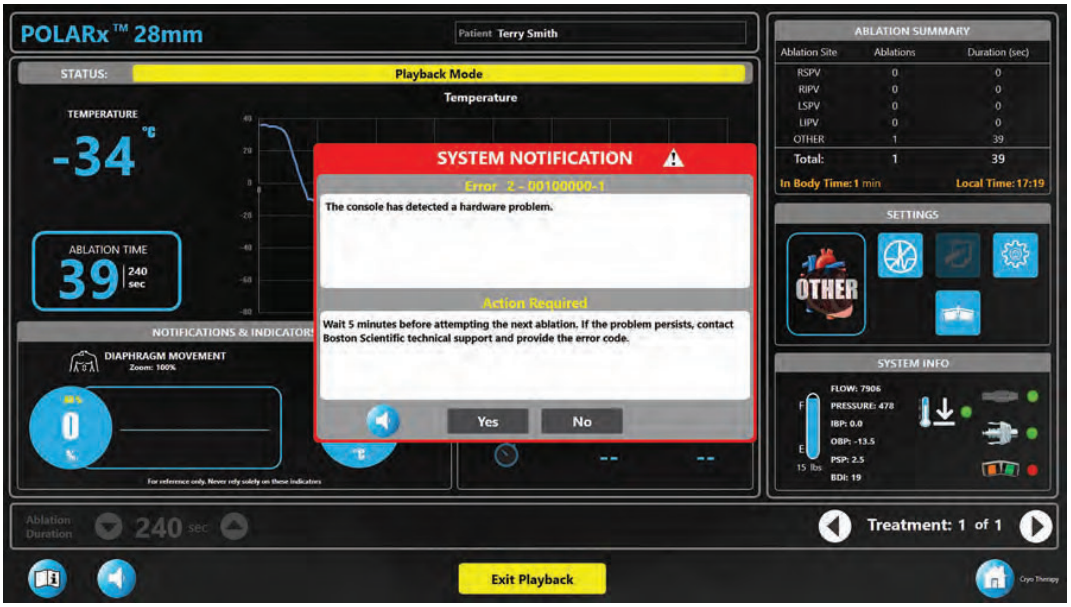


Figure 18. System Error Message

- 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 19. Playback Error

- Press the red triangle at the bottom of the screen to open the system messages window (see Figure 19 and Figure 20).

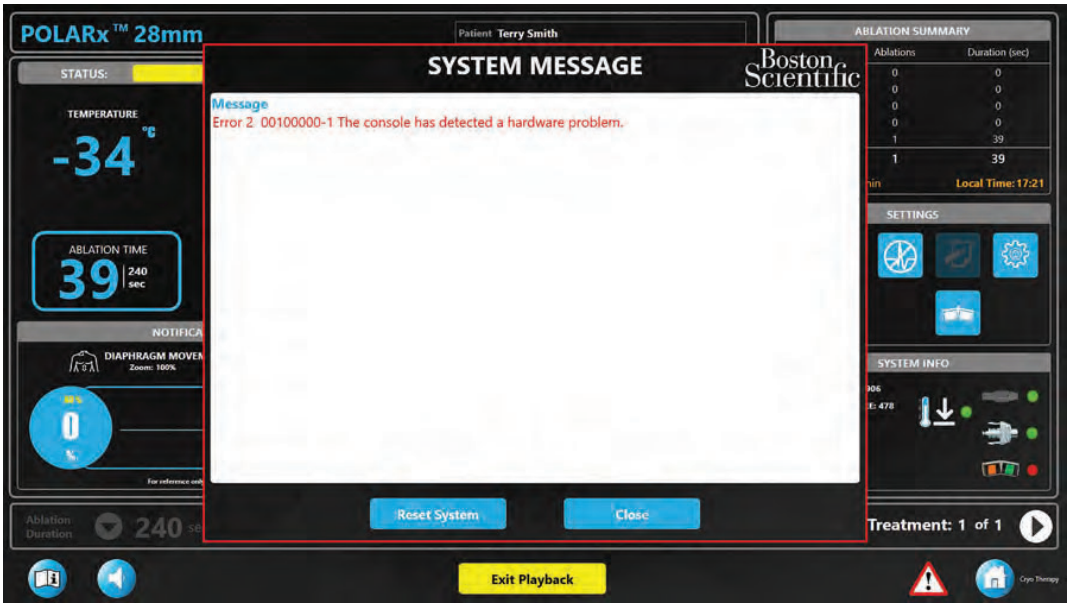


Figure 20. System Messages Window

- Press the **Reset System** button to clear all active messages (see Figure 21).

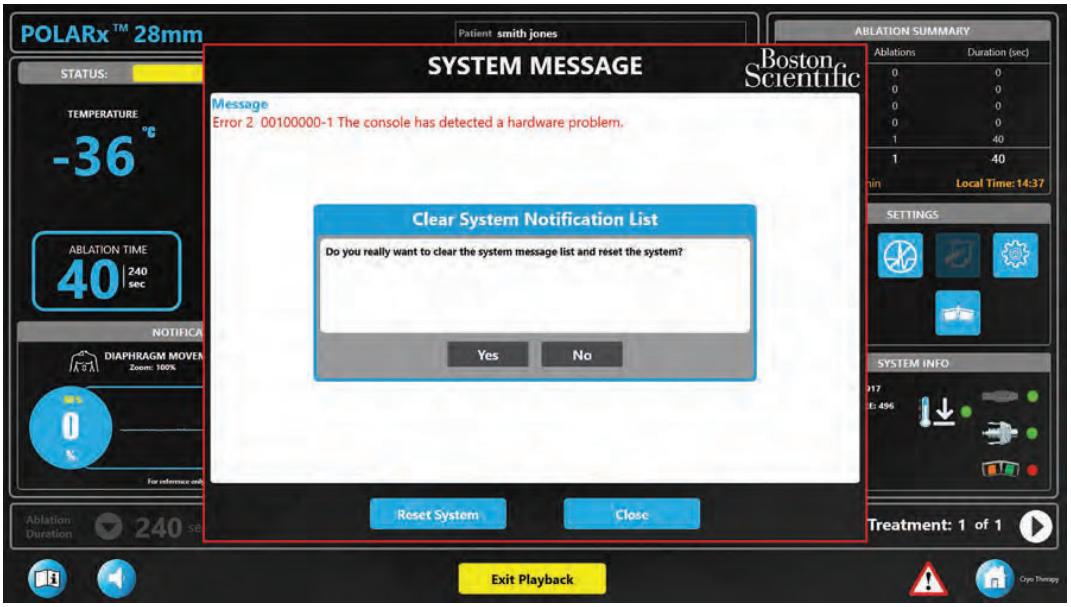


Figure 21. Clear System Notifications List Window

- Press the **Close** button to close the **System Message** window (see Figure 22).

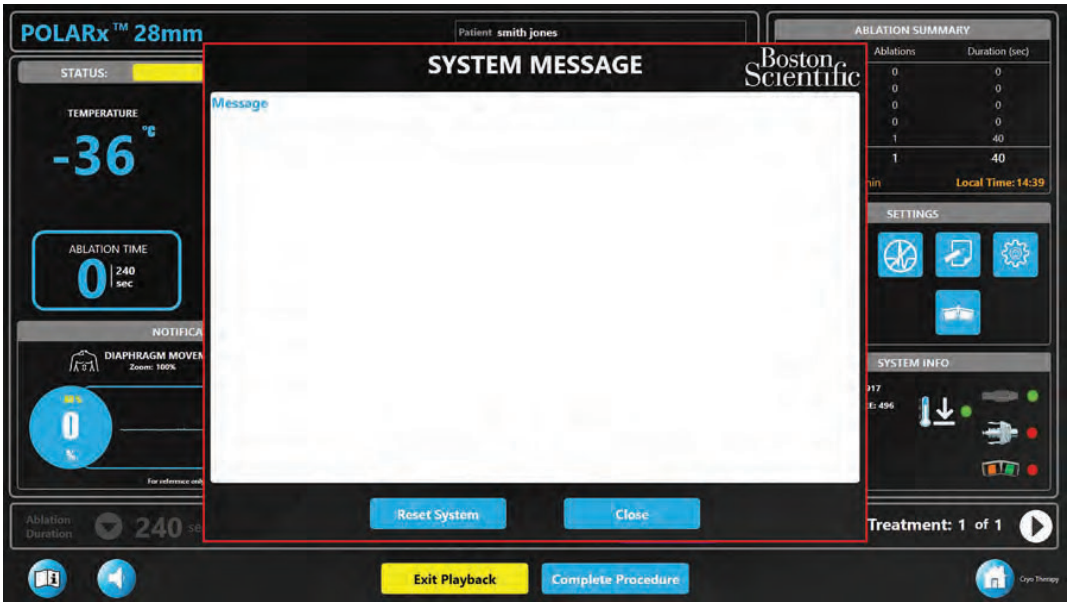


Figure 22. Cleared System Message

- 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 23).
  - 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 23. 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.

5. 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 8.3.3.2.
6. 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 24), 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 24. 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 cryoablation balloon catheter slider extension switch before the system reaches 20°C. If necessary, re-inflate the balloon and press forward on the cryoablation balloon catheter slider extension switch.

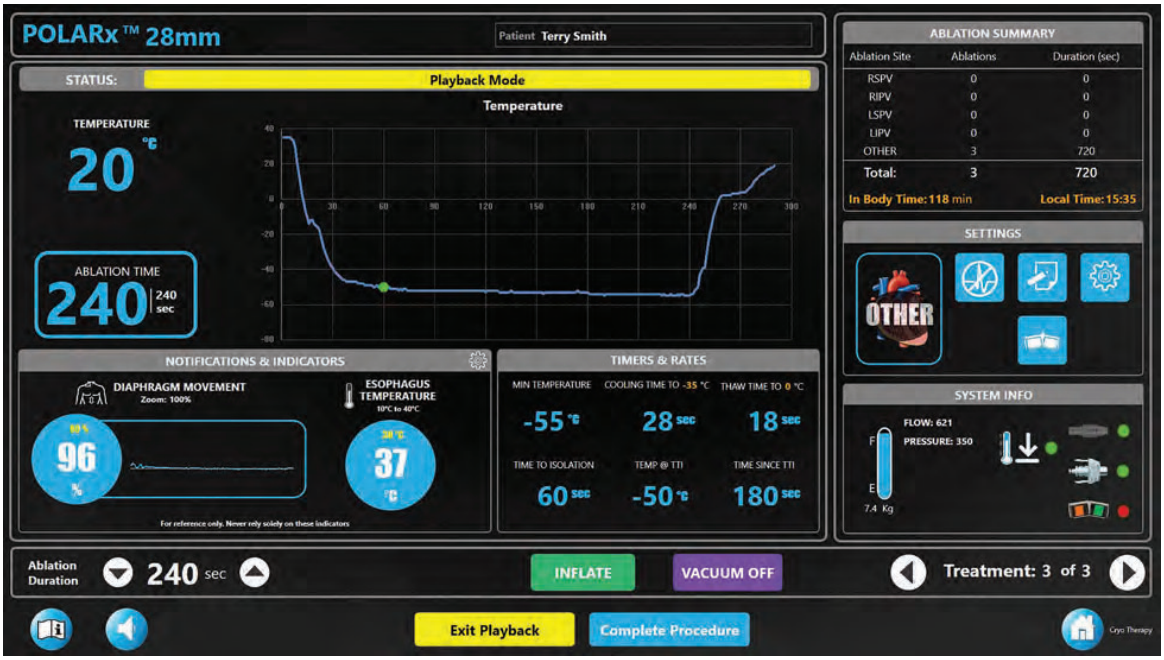


Figure 25. **Playback Mode**

7. 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 25.

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

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8. Select a point on the cryo-balloon **Temperature** graph. The corresponding recorded information from that moment will be displayed.
    - Use the **Treatment** arrows (Figure 25) 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.
9. If an error occurred during an ablation, press the red triangle on the temperature graph to display the error message (see Figure 26).

Figure 26. Playback Mode After an Error

Figure 27. Error Message Displayed in Playback Mode

- Press the **Exit Playback** button on the Therapy screen to manually exit **Playback Mode** (see Figure 27).

Figure 28. **READY** state after an ablation

10. To start a new treatment, follow this procedure from step 3 on page 29.
11. 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 cryoablation balloon catheter slider extension switch before the system reaches 20°C. If necessary, re-inflate the balloon and press forward on the cryoablation balloon 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.

8.3.4 Procedure termination

1. When treatment is completed, press the **Complete Procedure** button on the Therapy screen (Figure 25 or Figure 28).

   The Summary Report screen is presented (Figure 29).

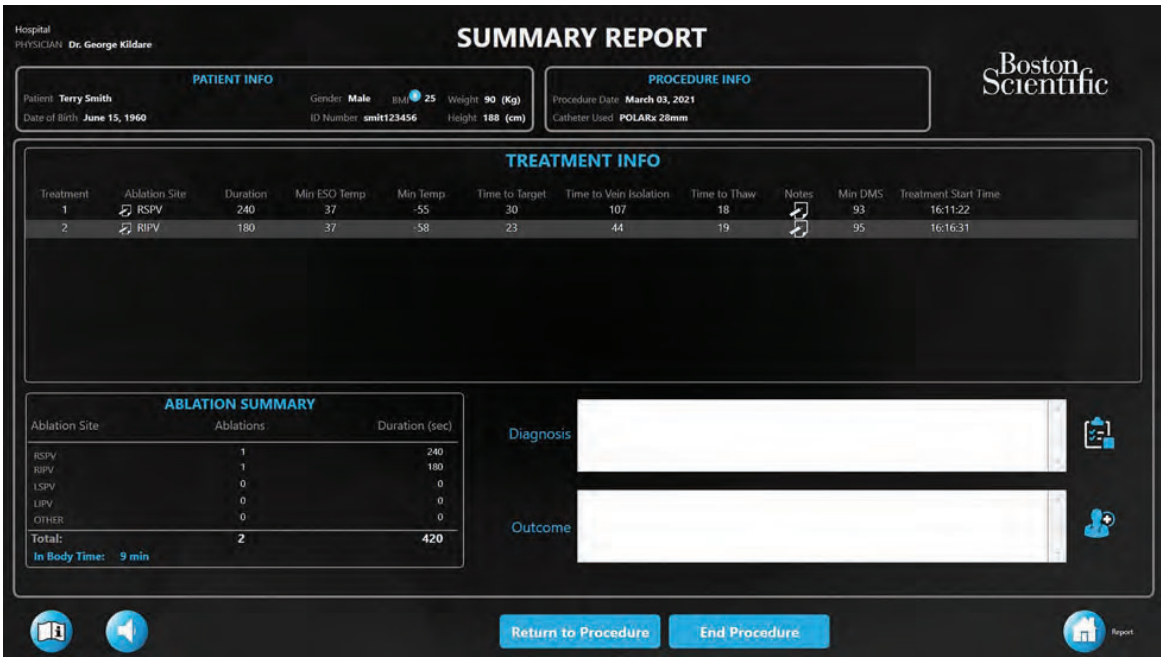

Figure 29. Summary report

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 30).

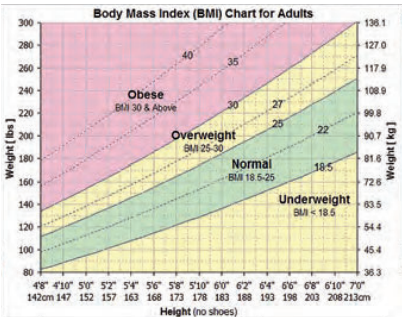

Figure 30. BMI Chart

- 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 52.

9. POLARx FIT CATHETER

The SMARTFREEZE Console behaves the same with the POLARx FIT Catheter as with the POLARx Catheter with the following exceptions:

- Upon connection of a POLARx FIT Catheter to the System, the  will appear in the **SYSTEM INFO** section of the Therapy screen (see Figure 31).

- Upon inflating the cryoballoon, the  button is displayed on the Therapy screen (see Figure 31). If this button is not pressed, the system controls the remainder of the process as with the POLARx Catheter.

Figure 31. Therapy Screen - **INFLATION** state with POLARx FIT Catheter

- To increase the balloon size press the  button on the Therapy screen or press the "plus" (+) button over the  icon on the Remote Control. The Therapy screen will display an hourglass until the cryoballoon has reached the new size. A plus (+) sign will be displayed next to the image of the balloon when it is inflated to a larger size during the inflation and thawing states (see Figure 32) and the POLARx FIT Catheter indicator in the **SYSTEM INFO** section of the Therapy screen will be lit green in all states.

Note: The POLARx FIT Catheter and POLARx Catheter have the same initial cryoballoon inflation sizes.

Figure 32. POLARx FIT Catheter inflated to larger size

- See Figure 33 for an example of an **ABLATION** state with the larger cryoballoon.

Note: Flow rates are higher when using larger balloon size (refer to Figure 33).

Figure 33. Therapy Screen - **ABLATION** state with larger cryoballoon

- See Figure 34 for an example of an **ABLATION** state low flow with the larger cryoballoon.

Figure 34. Therapy Screen - **ABLATION** state in low flow with larger cryoballoon

- See Figure 35 for an example of the **THAWING** state with the larger cryoballoon.

Figure 35. **THAWING** State FIT

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.

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

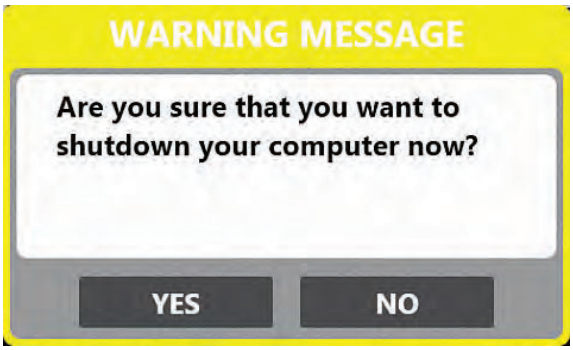

Figure 36. Shutdown message

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

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 gas removal 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 Remote Control, disconnect the Remote Control from the ICB.
12. Disconnect the Catheter Extension harness from the ICB.
13. Disconnect the ICB from the SMARTFREEZE Console.
14. Disconnect the Cryo-Cable from the SMARTFREEZE Console.
15. Dispose of all single-use items according to standard hospital procedures.
16. 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.
17. 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 37. 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

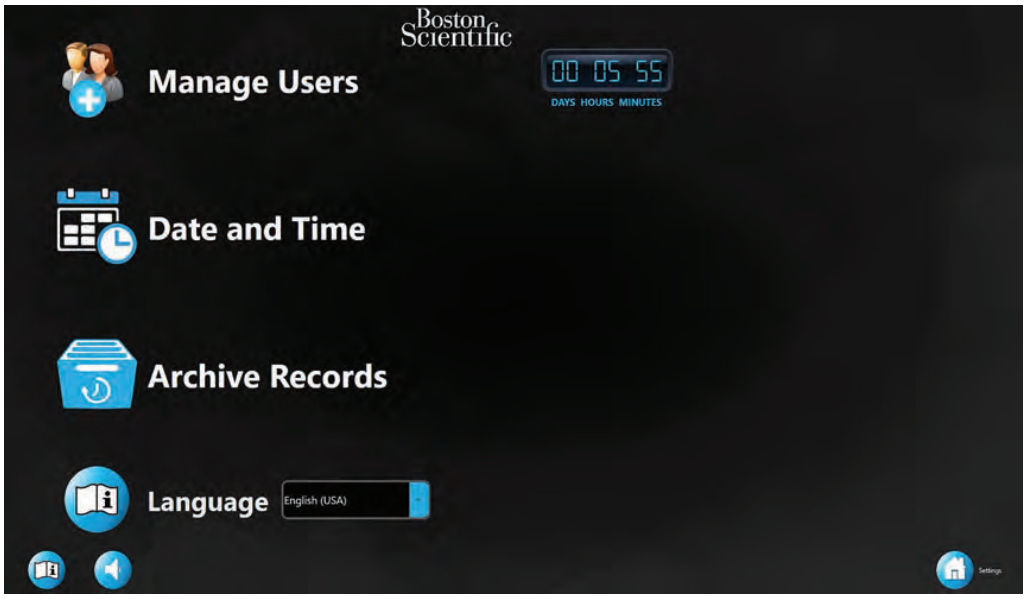

Figure 38. System settings

The system settings screen (Figure 38) 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.

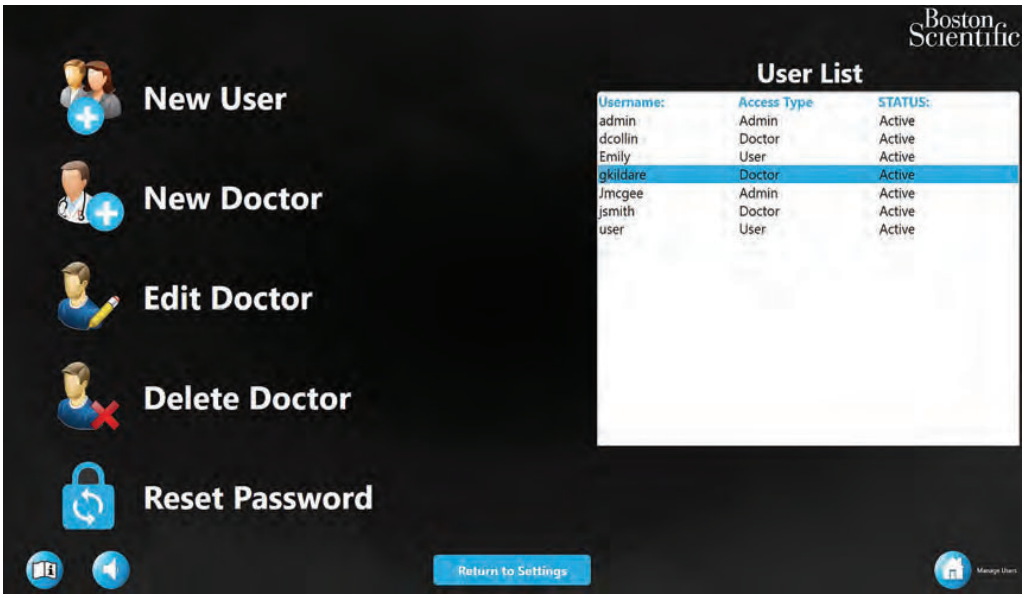

Figure 39. Manage users home screen

The Manage Users home screen (Figure 39) provides services to add new users and new doctors, edit users/doctors, delete users/doctors, and reset passwords.

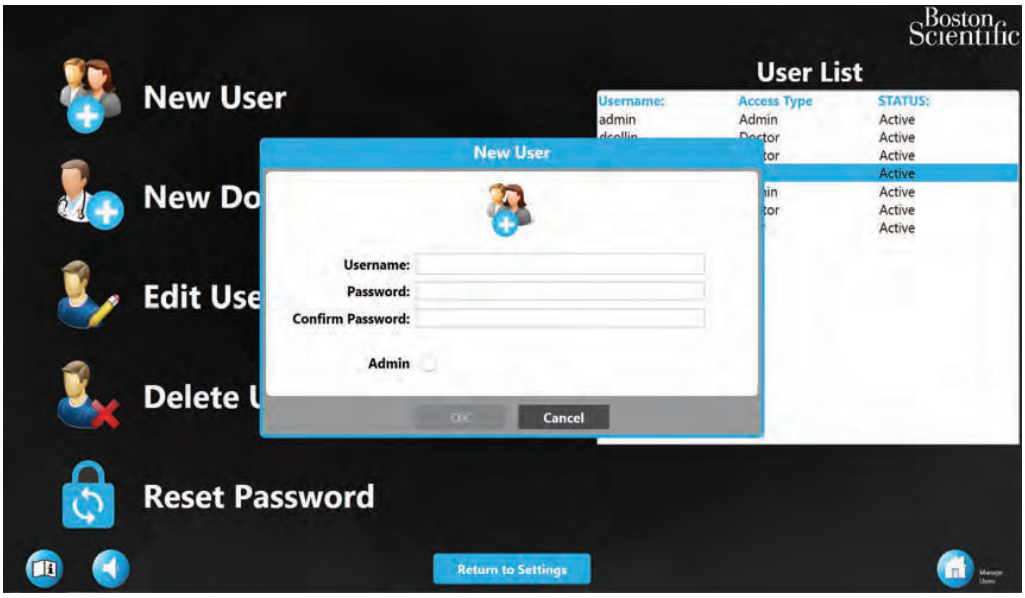

Figure 40. Creating a new user

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 40).

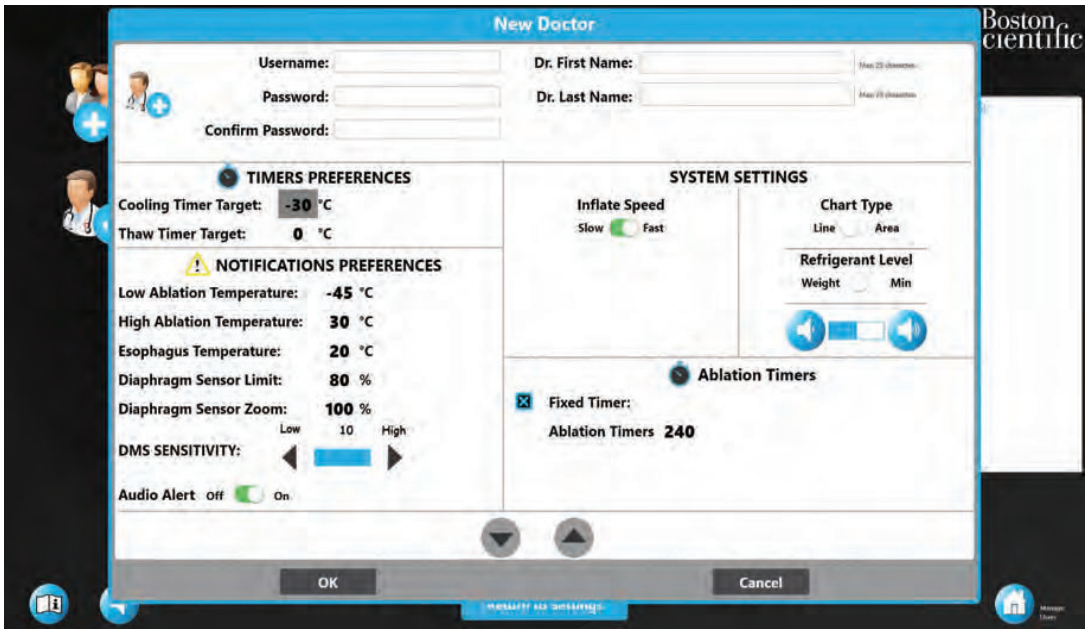

Figure 41. New doctor setup

The New Doctor screen (Figure 41) 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 42).

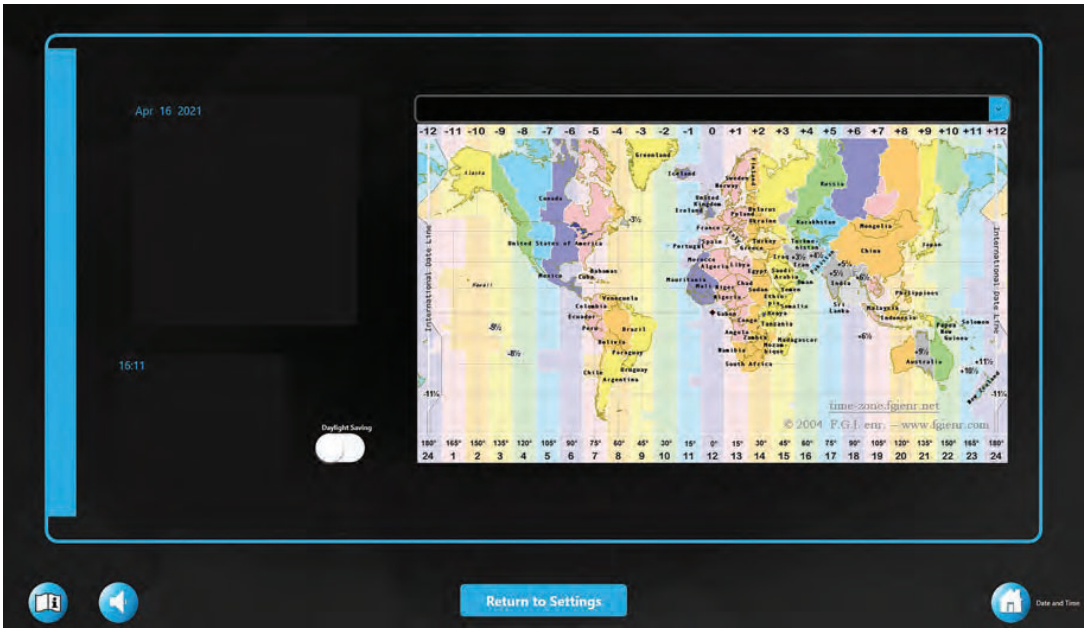

Figure 42. Daylight Savings Time Settings

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**.

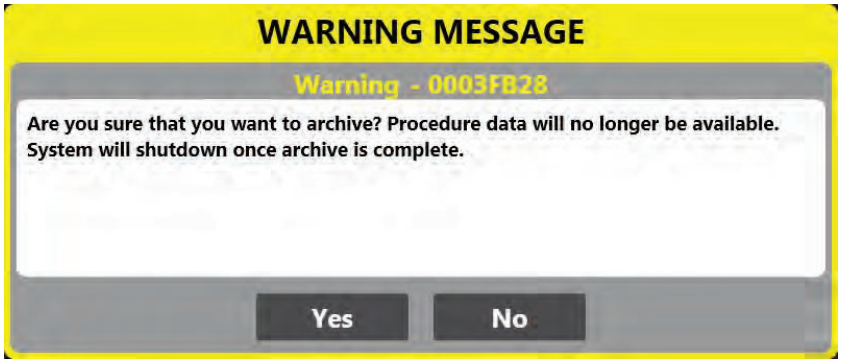

Figure 43. Archive Confirmation

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 44).

Figure 44. Home screen

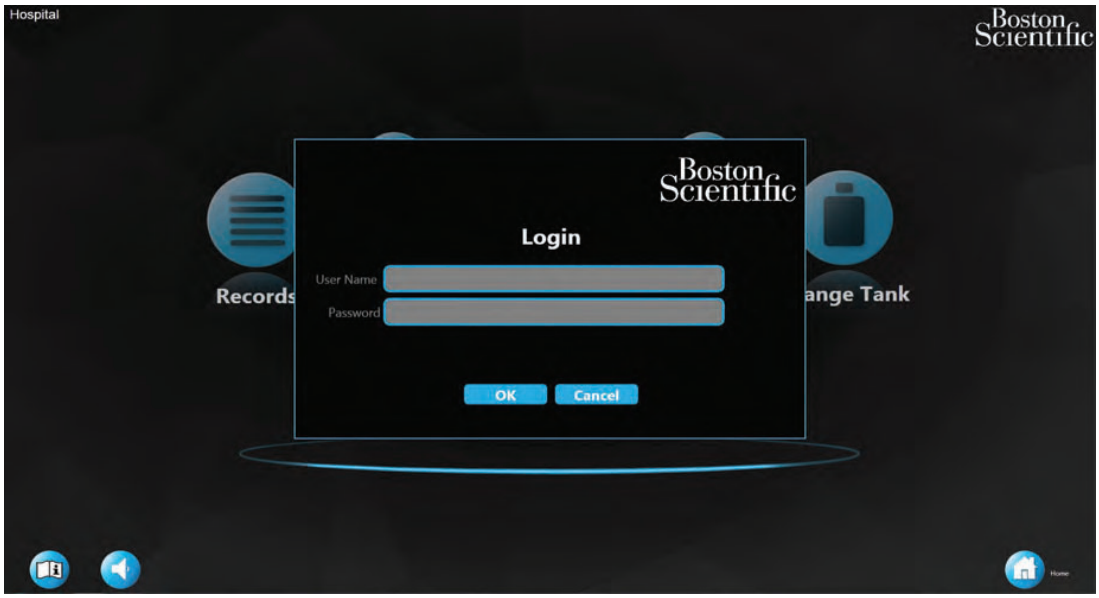

Figure 45. Login screen

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 46).

Figure 46. 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 46) 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 47).

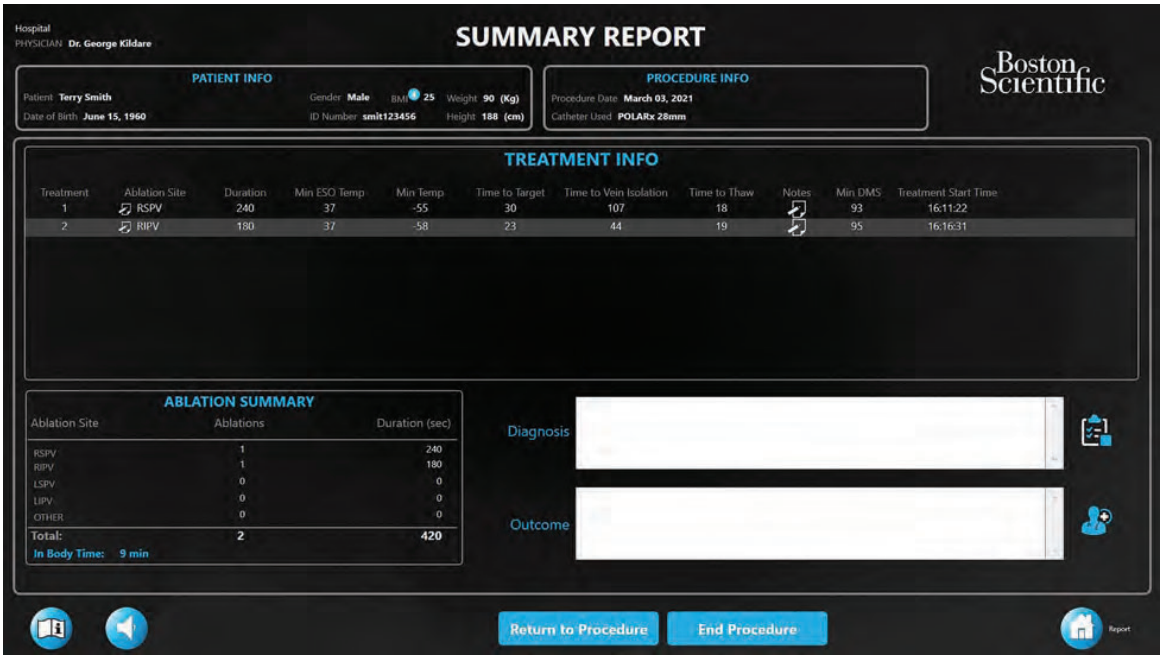

Figure 47. Summary Report Screen

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 48).

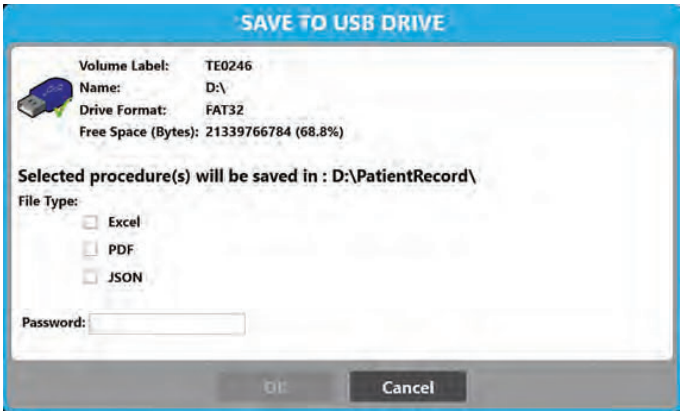

Figure 48. **Save to USB Drive** window

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 49).

Figure 49. 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

Note: If the SMARTFREEZE application freezes or the TOUCH SCREEN is not responsive, power off the console, then restart the console.

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.
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.

System Notice Number	Problem	Action
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.
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.

System Notice Number	Problem	Action
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 (not containing enzymes, abrasives, bleach, or alkali) 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 67.
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.

15.1.3 Physical Characteristics

Length	65.8cm (25.9in)
Width	53.3cm (21in)
Height	1.7m (67in)

15.2 Foot Switch

15.2.1 Intended Use

The Cryo-Console Foot Switch (model M004CRBS4200) is designed for use with the SMARTFREEZE Console. The foot switch enables the user to control certain SMARTFREEZE Console functions remotely. Use of the foot switch is optional.

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 (not containing enzymes, abrasives, bleach, or alkali) 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. The refrigerant tank supplies nitrous oxide (N_2O) to the SMARTFREEZE Console in liquid form needed for the cryo-ablation procedure. Use of the refrigerant tank is required.

15.3.2 Description

The standard Boston Scientific 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. Connect the refrigerant tank to the SMARTFREEZE Console using the tank to process plate hose and the supplied wrench.
4. Turn the refrigerant tank knob counter-clockwise to open the tank valve.
5. Close the SMARTFREEZE Console door during Console use.

6. After the ablation procedure is complete, pull open the SMARTFREEZE Console door at the rear of the SMARTFREEZE Console to expose the refrigerant tank.
7. 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 (not containing enzymes, abrasives, bleach, or alkali) 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 M004CRBS4300, M004CRBS4310, and M004CRBS4320) is designed for use with the SMARTFREEZE Console. The scavenging hose connects the SMARTFREEZE Console to the hospital gas removal system for transportation of the refrigerant exhaust from the SMARTFREEZE Console. Use of the scavenging hose is required.

15.4.2 Description

One end of the scavenging hose connects to the designated connector on the SMARTFREEZE Console. The other end connects to the hospital gas removal 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 gas removal 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 gas removal system.

15.4.4 Cleaning and Storage

Wipe the scavenging hose with a damp cloth. If necessary, use a mild detergent solution (not containing enzymes, abrasives, bleach, or alkali) 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, M004CRBS62140, M004CRBS62150) is designed for use with the SMARTFREEZE Console. The power cord supplies AC electricity to the SMARTFREEZE Console. Use of the AC Power Cord is required.

15.5.2 Description

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 46), 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 (not containing enzymes, abrasives, bleach, or alkali) 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)

15.6 Inter-Connection Box (ICB)

15.6.1 Intended Use

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

The ICB (model M004CRBS4110) is used to connect the SMARTFREEZE Console to the cryoablation balloon catheter as well as to the optional Diaphragm Movement Sensor (DMS), and optional Esophageal Temperature (ETS) Cable with general purpose series 400 temperature sensor.

The ICB (model M004CRBS4130) is used to connect the SMARTFREEZE Console to the cryoablation balloon catheter as well as to the optional Diaphragm Movement Sensor (DMS), optional Esophageal Temperature (ETS) Cable with general purpose series 400 temperature probe or Esophageal Temperature (ETS) CIRCA Cable with S-CATH series temperature probe, and optional Remote Control.

Use of an ICB is required.

15.6.2 Description

The ICB (model M004CRBS4110) 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) 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), and the Remote Control (grey connector).

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 cryoablation balloon catheter.

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

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 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.
9. Perform procedural steps as per Console and catheter documentation.
10. After procedure completion, remove the Catheter Extension Cable from the cryoablation balloon catheter.
11. Remove the Catheter Extension Cable from the ICB.
12. If used, remove the DMS from the patient and disconnect the DMS from the ICB.
13. If used, remove the general purpose series 400 temperature sensor from the patient.
14. Disconnect the ETS Cable from the ICB.
15. 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 (not containing enzymes, abrasives, bleach, or alkali) 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 on the side of 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 cryoablation balloon catheter. The Catheter Extension Cable provides an electrical connection between the cryoablation balloon catheter and the SMARTFREEZE Console (via the ICB). Use of the Catheter Extension Cable is required.

15.7.2 Description

The Catheter Extension Cable connects the non-sterile ICB to the sterile cryoablation balloon catheter. Both the ICB and cryoablation balloon catheter have socket connectors that allow the Catheter Extension Cable to be reversible. **This component is a sterile component (using an ethylene oxide [EO] procedure) intended for single use only.**

15.7.3 Non-pyrogenic

This device meets pyrogen limits specifications.

15.7.4 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 cryoablation balloon catheter.
4. After procedure completion, disconnect the Catheter Extension Cable from the cryoablation balloon catheter.
5. Disconnect the Catheter Extension Cable from the ICB.

15.7.5 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).

15.7.6 Disposal

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

15.7.7 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 cryoablation balloon catheter. The Cryo-Cable provides a mechanical connection between the cryoablation balloon catheter and the SMARTFREEZE Console to allow flow of N_2O from the SMARTFREEZE Console to the Catheter and returns the exhaust from the catheter to the SMARTFREEZE Console. Use of the Cryo-Cable is required.

15.8.2 Description

The Cryo-Cable is a triaxial cable that provides a means to supply liquid N_20 from the SMARTFREEZE Console to the cryoablation balloon catheter, a means to return the N_2O exhaust from the cryoablation balloon catheter to the SMARTFREEZE Console and a path to allow the SMARTFREEZE Console to pull vacuum between the inner and outer balloons of the cryoablation balloon catheter. **This component is a sterile component (using an ethylene oxide [EO] procedure) intended for single use only.**

15.8.3 Non-pyrogenic

This device meets pyrogen limits specifications.

15.8.4 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 cryoablation balloon catheter handle.
4. After procedure completion, disconnect the Cryo-Cable from the cryoablation balloon catheter handle.
5. Disconnect the Cryo-Cable from the SMARTFREEZE Console.

15.8.5 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).

15.8.6 Disposal

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

15.8.7 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. The EP Electrical Cable connects the POLARMAP Mapping Catheter to the hospital EP recording system. Use of the EP Electrical Cable is optional.

15.9.2 Description

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. **This component is a sterile component (using an ethylene oxide [EO] procedure) intended for single use only.**

15.9.3 Non-pyrogenic

This device meets pyrogen limits specifications.

15.9.4 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.

15.9.5 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).

15.9.6 Disposal

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

15.9.7 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. The DMS is an adjunctive sensor designed to monitor a phrenic nerve pacing response. Use of the DMS is optional.

15.10.2 Description

The DMS, when properly positioned, measures the patient's response to pacing.

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 (not containing enzymes, abrasives, bleach, or alkali) 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)

15.11 ETS Cable (CIRCA)

15.11.1 Intended Use

The ETS Cable (CIRCA) (model M004CRBS6340) is designed for use with the SMARTFREEZE Console and the CIRCA S-CATH™ Esophageal Temperature Probe. The ETS Cable (CIRCA) is used to connect the CIRCA S-CATH™ Esophageal Temperature Probe to the ICB (Model M004CRBS4130 only). Use of the ETS Cable (CIRCA) is optional.

Note: The role of esophageal temperature monitoring using this device in reducing the risk of cardiac cryoablation-related esophageal injury has not been established. The performance of the SMARTFREEZE ETS Cables and compatible temperature probe in detecting esophageal temperature changes as a result of energy delivery during cardiac cryoablation procedures has not been evaluated.

15.11.2 Description

The ETS Cable (CIRCA) connects the CIRCA S-CATH™ Esophageal Temperature Probe to the ICB (Model M004CRBS4130 only).

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 (not containing enzymes, abrasives, bleach, or alkali) 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

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. The ETS Cable is used to connect a general purpose series 400 temperature sensor to the ICB. Use of the ETS Cable is optional.

Note: The role of esophageal temperature monitoring using this device in reducing the risk of cardiac cryoablation-related esophageal injury has not been established. The performance of the SMARTFREEZE ETS Cables and compatible temperature probe in detecting esophageal temperature changes as a result of energy delivery during cardiac cryoablation procedures has not been evaluated.

15.12.2 Description

The ETS Cable connects a general purpose series 400 temperature sensor to the ICB.

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 (not containing enzymes, abrasives, bleach, or alkali) 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. The wrench is used to tighten and/or loosen the SMARTFREEZE Console connection to the refrigerant tank.

15.13.2 Description

The Wrench is a 1-1/8" open-end wrench used while changing a refrigerant 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 (not containing enzymes, abrasives, bleach, or alkali) 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. The Remote Control enables the user to control certain SMARTFREEZE Console functions remotely. Use of the Remote Control is optional.

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. The Remote Control can also be used to increase the balloon size with the POLARx FIT 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.

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.

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

15.14.4 Cleaning and Storage

Wipe the Remote Control with a damp cloth. If necessary, use a mild detergent solution (not containing enzymes, abrasives, bleach, or alkali) 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 USB to Serial Cable

15.15.1 Intended Use

The USB to Serial Cable (M004CRBS62860) is used to connect the SMARTFREEZE Console to a hospital recording system. Use of the USB to Serial Cable is optional.

15.15.2 Description

The USB to Serial cable is a null model device used to connect the SMARTFREEZE Console to a hospital recording system.

15.15.3 Instructions for Use

Note: Ensure that LABSYSTEM PRO is powered off prior to connecting.

Note: The SMARTFREEZE Cryoablation Console is designed to function with LABSYSTEM PRO Recording System. The SMARTFREEZE Cryoablation Console may be compatible with other recording systems.

1. Connect the USB to serial cable (M004CRBS62860) to the left most (facing the rear of the SMARTFREEZE Console) USB port on the rear of the SMARTFREEZE Console.
2. Connect the USB to serial cable (M004CRBS62860) to the COM port of the LABSYSTEM PRO. Refer to the LABSYSTEM PRO IFU for details on port connection.

15.15.4 Cleaning and Storage

Wipe the USB to Serial Cable with a damp cloth. If necessary, use a mild detergent solution (not containing enzymes, abrasives, bleach, or alkali) or isopropyl alcohol. Do not immerse in water. Dry thoroughly.

While not in use, store the USB to Serial 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. Follow local regulations to dispose of this product.

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

15.15.6 Physical Characteristics

Overall length: 1.7m (67in)

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.
Radiated RF IEC 61000-4-3 JIS C61000-4-3	3 V/m 80 MHz to 2,7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 V/m 80 MHz to 2,7 GHz RF communication equipment inside 80 MHz to 6 GHz	Recommended separation distance: $d = 1,2\sqrt{P}$ — 150 kHz to 80 MHz $d = 1,2\sqrt{P}$ — 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].

Table 2 Electromagnetic immunity (*continued*)

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. SOFTWARE LICENSE AND USE RESTRICTIONS

The SMARTFREEZE Console includes Boston Scientific software and software licensed to Boston Scientific by third parties (hereinafter referred to as, the Software), and the SMARTFREEZE Console is subject to certain limitations and restrictions.

17.1 Grant of License

The Software is licensed only to the original purchaser of the SMARTFREEZE Console and not sold. Boston Scientific hereby grants the original purchaser a revocable, non-transferable, non-sublicensable, non-exclusive, fully paid-up license to use the object code of the Software for the sole purpose of diagnosis and treatment of patients.

17.2 Restrictions

Users may not (i) copy, alter, enhance or otherwise modify or create derivative works of the Software or SMARTFREEZE Console; (ii) decompile, disassemble, or otherwise reverse engineer the Software or SMARTFREEZE Console; (iii) remove or destroy any proprietary markings, warning notices, confidential legends or any trademarks, trade names or brand names of Boston Scientific or its suppliers placed upon or contained within the SMARTFREEZE Console or embedded in the Software; (iv) allow use of or access to the SMARTFREEZE Console, or sublicense, lease, transfer or assign its rights to access and use the SMARTFREEZE Console, in whole or in part, to a third party; (v) operate the SMARTFREEZE Console for any activity other than diagnosing and treating patients; (vi) post or transmit into the SMARTFREEZE Console any information or software which contains a virus, Trojan horse, worm or other harmful component.

17.3 Sale or Transfer

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17.5 Limitation of Liability

To the maximum extent permitted by law, in no event shall Boston Scientific be liable for any special, incidental, consequential, punitive, or indirect damages, which shall include without limitation, damages for lost profits, lost data, and business interruption, arising out of the use or inability to use the SMARTFREEZE Console.

18. PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of the SMARTFREEZE Console and accessories in association with the Electrophysiological cardiac interventional procedure:

- Discuss the risks and benefits including review of potential adverse events listed in this document.
- Discuss post procedure instructions, including any lifestyle changes, medications, when to call the Healthcare Provider (HCP) and any post procedure follow-up that might be needed.

19. CUSTOMER SERVICE

Boston Scientific team members are dedicated to serving customers and are available to provide training and technical consultation on the use of the BSC Cardiac Cryoablation System to qualified hospital personnel. Please contact your local Boston Scientific representative for more information.

20. WARRANTY

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

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.

21. 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.

Consult instructions for use.


Foot Switch


Power cord


AC Input


Mass with Safe Working Load


Contents


Fuse


Start (of action)


Stop (of action)

USB Connection


Ethernet port

HDMI Port


Separate Collection

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

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