FARAWAVE™

Pulsed Field Ablation Catheter

FARAPULSE

REF M004PF41M401; M004PF41M402

℞ ONLY

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

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REUSE 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 (BSC) 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.

Carefully read all ancillary device instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications.

DEVICE DESCRIPTION

The FARAWAVE Pulsed Field Ablation (PFA) Catheter (henceforth referred to as the FARAWAVE Catheter) is a component of the FARAPULSE PFA System.

The FARAWAVE Catheter is an over-the-wire, multi-electrode catheter designed to deliver PFA energy to the distal section for cardiac ablation. The FARAWAVE Catheter distal section consists of five splines with four electrodes located on each spline, twenty electrodes total.

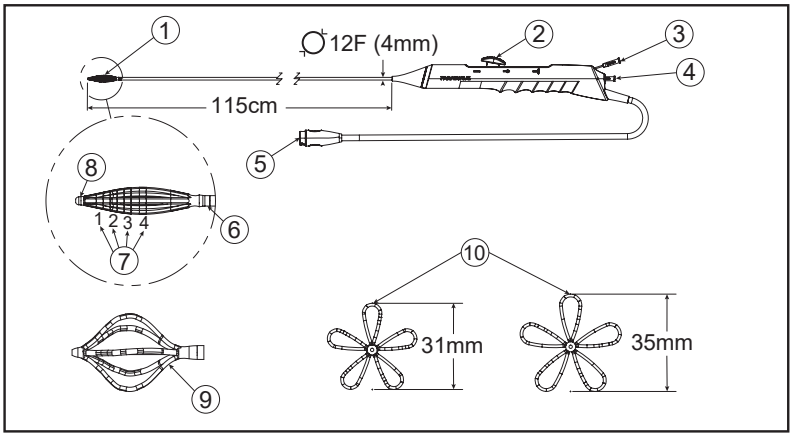


Figure 1. FARAWAVE Catheter

(1) Distal splines (2) Deployment mechanism (3) Flush port (4) Guidewire hub (5) Cable connector (6) Radiopaque marker (7) Four electrodes on five splines (8) Radiopaque tip (9) Partial ("basket") deployment (10) Full ("flower") deployment

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324F), eIFU, FARAWAVE, en, 51654496-01

The FARAWAVE Catheter handle features a deployment mechanism that enables the ability to deploy the distal section into multiple configurations, where the partially deployed configuration is a "basket" shape and the fully deployed configuration is a "flower" shape. The symbols on the FARAWAVE Catheter handle indicate each configuration.

Table 1. FARAWAVE Catheter Configurations

Symbol	Configuration
	Undeployed
	Partially deployed ("basket")
	Fully deployed ("flower")

The FARAWAVE Catheter is a 12F catheter and is compatible with the FARADRIVE Steerable Sheath (henceforth referred to as the FARADRIVE Sheath). The FARAWAVE Catheter is available in two sizes, 31 mm and 35 mm, representative of the fully deployed diameter.

For ablation, the FARAWAVE Catheter is designed to be used with the FARASTAR Catheter Connection Cable and FARASTAR Generator.

Contents

One (1) sterile FARAWAVE Catheter

Materials

Contains Cobalt; CAS No 7440-48-4; EC No. 231-158-0. Defined as a 1B according to the European Commission in a concentration above 0.1% weight by weight.

Note: This device is made with a metal alloy which contains cobalt. Current scientific evidence supports that metal alloys containing cobalt used in medical devices do not cause an increased risk of cancer or adverse reproductive effects.

Non-pyrogenic

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

INTENDED USE

The FARAPULSE Pulsed Field Ablation (PFA) System is intended for the isolation of the pulmonary veins in the treatment of paroxysmal atrial fibrillation by rendering targeted cardiac tissue electrically non-conductive to prevent cardiac arrhythmia initiation or maintenance.

Indications for Use

The FARAWAVE Catheter is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic Paroxysmal Atrial Fibrillation (PAF).

Intended Patient Population

The FARAPULSE PFA System is intended for adult patients who are age 18 or older who have drug-refractory, recurrent, symptomatic PAF.

CONTRAINDICATIONS

The FARAWAVE Catheter is contraindicated for use:

- in patients with active systemic infection;
- in patients with a mechanical prosthetic heart valve through which the catheter must pass;
- in patients with conditions where insertion into or manipulation in the cardiac chambers is unsafe as these conditions (e.g., presence of intracardiac thrombus or myxoma, history of recent cardiac surgery with atriotomy, etc.) may increase the risk of systemic embolism or cardiac perforation;

- in patients with a bleeding disorder, or who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation;
- in patients who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach;
- in patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe, such as but not limited to, a recent previous cardiac surgery (e.g., ventriculotomy or atriotomy, Coronary Artery Bypass Graft [CABG], PTCA/PCI/coronary stent procedure/unstable angina) and/or in patients with congenital heart disease where the underlying abnormality increases the risk of the ablation (e.g. severe rotational anomalies of the heart or great vessels);
- via transseptal approach in patients with an intra-atrial baffle or a foramen ovale patch.

WARNINGS

- If the visibility of the EP catheter is compromised for any reason, the user should stop and not resume ablation therapy until catheter visibility is established in order to prevent patient injuries such as perforation, heart block and injury to adjacent structures.
- Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology, in the techniques of mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab. Device specific physician in-service training is made available by the manufacturer.
- Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures. There is an increased risk of thromboemboli if appropriate anticoagulation levels are not maintained while the transseptal sheath and/or catheter is in the left side of the heart. Administer anticoagulation therapy during and post procedure according to the institution's standards to minimize bleeding and thrombotic complications.
- Carefully read all equipment and ancillary device instructions required for the procedure prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications.
- Do not use the device if past the "Use By" date on the device package. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury.
- Before using, inspect the FARAWAVE Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that, if used, may cause patient and/or user injury. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed.
- Electromagnetic Interference (EMI) from any source during normal operation may adversely affect the visualization and tracking of the catheter during the procedure, which can cause patient injuries such as perforation, heart block and injury to adjacent structures.
- Use of the FARAWAVE Catheter with generators other than a compatible BSC PFA Generator can lead to unexpected energy delivery resulting in either insufficient ablation treatment or over-delivery of energy leading to possible patient hazardous events such as thrombus formation, tissue damage, etc.
- Patients undergoing ablation are at risk for complete AV block which requires the implantation of a temporary and/or permanent pacemaker.
- When the catheter is in the patient, neither the patient nor the catheter connector should be allowed to come in contact with grounded metal surfaces to minimize the potential for electrical shock.
- Ensure that the cable/catheter connection remains dry throughout the procedure in order to prevent electric shock or other patient injuries as well as to prevent loss of device function.
- Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the catheter.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
- Electrical recording or stimulation equipment must be isolated. Current leakage from any electrical equipment that is connected to the patient must not exceed 10 microamps for intracardiac electrodes.

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324F), eIFU, FARAWAVE, en, 51654496-01

- Care must be taken to ensure that any equipment used in connection with the FARAWAVE Catheter be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use to reduce the potential risk of inadvertent electrical shock.
- Do not directly touch the patient when ablation energy is being delivered to prevent the risk of electric shock.
- Stimulation of cardiac tissues caused by pacing stimulus and/or ablation energy may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns.
- Warnings for patients with implantable pacemakers (PPMs) and Implantable Cardioverter Defibrillators (ICDs):
  - PPMs, ICDs, and leads can be adversely affected by ablation energy. It is important to refer to the device manufacturer's instruction for use prior to performing ablation procedures.
  - Do not apply ablation energy directly to a lead or to tissue immediately in contact with a lead because it could potentially damage the lead or lead function.
  - Temporarily reprogram the pacemaker or defibrillator per the manufacturer guidelines during ablation. The device could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reprogram to preoperative sensing and pacing parameters.
  - Program the ICD Tachy therapy to "Off" to prevent inappropriate shock and/or possible damage to the device from the ablation procedure. Remember to turn Tachy Therapy to "On" once ablation is complete.
  - Have temporary external sources of pacing and defibrillation available.
  - Perform a complete analysis of the implanted device function after ablation.
  - Fluoroscopic or appropriate imaging guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgement.
  - Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function.
- Ablation in contact with any other electrodes alters the function of the catheter and can lead to embolism.
- At no time should a FARAWAVE Catheter be advanced, withdrawn, rotated, deployed or undeployed when resistance is felt, without determining the cause. Valve damage, vascular and/or cardiac perforation is a risk with any intracardiac catheter.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is over torqued and/or positioned in the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage.
- Do not use the FARAWAVE Catheter in the proximity of Magnetic Resonance Imaging (MRI) equipment because the MRI equipment may adversely impact the function of a PFA Generator and the ablation system may adversely impact the image quality. This can also lead to loss of visibility during ablation which can cause patient injuries such as perforation, heart block and injury to adjacent structures.
- Catheter ablation procedures present the potential for significant radiation exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the radiation beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Due to radiation exposure during catheter ablation, the safety and effectiveness of this device has not yet been established in pregnant and/or nursing women and pediatric patients.
- There are no data to support the safety and effectiveness of this device in the pediatric population.
- Prior to the procedure, always identify the patient's risk of volume overload. Monitor the patient's fluid balance throughout the procedure and after the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.
- Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism.

- Excessive curves or kinking of the catheter may damage internal wires and components, including the flush lumen. This damage may affect mechanical and electrical performance leading to patient injury.
- Do not attempt to bend, kink, or shape the patient-contact portions or flush lumen of the FARAWAVE Catheter. Doing so could cause electrical or mechanical catheter failure resulting in patient injury. Kinking of the flush lumen may compromise flow through the device leading to potential thrombus formation and embolism.
- Use both fluoroscopy, or other visualization techniques such as echocardiography, and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade.
- The FARAWAVE Catheter tip and guidewire move forward during device undeployment. Device deployment and undeployment should be visualized using fluoroscopy. Failure to do so may result in catheter damage and/or patient injury.
- Do not deliver ablation energy with the catheter outside the target site. Ablation Generators can deliver significant electrical energy and may cause patient injury such as arrhythmia and heart block.
- Always verify that the tubing set, catheter, sheath and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing, catheter or sheath can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system.
- Patients undergoing left-sided ablation procedures should be closely monitored during and post procedure for clinical manifestations of infarction, pulmonary vein injury, nerve damage, and/or embolism.
- Patients undergoing an ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely due to the increased risk for bleeding/ hemorrhage and/or embolism.
- Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution.
- The FARAWAVE Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death.
- Inspect irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism.
- If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the procedure, there should be a low threshold to perform a Transesophageal Echocardiogram (TEE) prior to the procedure to confirm absence of mural thrombus and/or thrombus in the left atrial appendage.
- Guiding catheters and/or long introducer sheaths present the potential for thromboembolic events. Pre-flush and maintain lumen patency with heparinized intravenous infusion.
- Do not wipe this catheter with organic solvents such as alcohol or immerse the handle and/or cable connector in fluids. This may result in electrical or mechanical catheter failures. It may also result in an allergic reaction from the patient.
- Pre-procedural anticoagulation therapy is at the discretion of the physician. However, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy, pre-, during and post-ablation to reduce the incidence of major complications. Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- The safety and/or efficacy of epicardial use of the FARAWAVE Catheter has not been evaluated in a clinical trial.
- Care should be used during multiple sheath/catheter exchanges through the transseptal puncture to avoid causing a residual atrial septal defect that would require repair.
- Do not leave the FARAWAVE Catheter in the patient for more than four (4) hours. Failure to remove the device before four hours after first insertion could result in formation of thrombus with attendant stroke risks.
- Use of the FARAWAVE Catheter with delivery devices other than the FARADRIVE Sheath can result in poor access to endocardial locations, inefficient ablation delivery and inadequate procedural outcomes.
- Cardiac ablation has the potential of causing unintended myocardial injury. Clinical indications of myocardial ischemia should be closely monitored during the procedure (e.g., ECG changes).

- The FARAWAVE Catheter has not been studied clinically in the mitral isthmus or cavotricuspid isthmus areas. Ablations in areas adjacent to coronary arteries may lead to coronary artery spasm and/or injury, and the resulting myocardial injury can be fatal.
- Ensure that the guidewire is properly inserted into the catheter for adequate support during use. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire fully inserted, at or past the FARAWAVE Catheter tip. Failure to do so may result in catheter damage and/or patient injury.
- When positioning on cardiac structures, the guidewire should be retracted to prevent cardiac perforation or tissue damage. Ensure the tip of the device is not against tissue prior to advancing or retracting the guidewire to prevent cardiac perforation or tissue damage.
- The risk of igniting flammable gases or other materials is potential outcome of ablation procedures. Precautions must be taken to restrict flammable materials from the electrosurgical suite.
- Take care when manipulating the guidewire to prevent cardiac or vessel trauma.
- To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue.
- Minimize catheter exchanges and always advance and withdraw components through the valve slowly to minimize the vacuum created during withdrawal and to reduce the risk of air embolism. Follow advancement or withdrawal of catheters with appropriate aspiration and flushing according to institutional standards or consensus statements.
- Instruct users with co-implanted devices to refer to ancillary device labeling as well as the manufacturer of the ancillary device for recommended compatibility and settings.
- Use caution when advancing, retracting or otherwise manipulating system components to avoid damaging tissue or vessels or interfering with previously implanted medical devices.
- When advancing or undeploying the FARAWAVE catheter, do not retract the guidewire simultaneously. If resistance is felt during retraction of the guidewire, do not continue to retract the guidewire until cause of resistance is determined as this may result in cardiac trauma. If resistance is felt, it may be necessary to advance guidewire under imaging guidance before continuing to retract.
- Ensure that the guidewire is not contacting ablation electrodes prior to starting ablation to prevent inappropriate energy delivery.
- Always un-deploy the catheter and withdraw the catheter into the sheath before removing the catheter from the Left Atrium (LA). Deploying the catheter in the septal puncture site or crossing the septum while the catheter is unsheathed or deployed may cause serious atrial septal defects or other cardiac and vessel trauma. Use visualization (such as fluoroscopy) to verify undeployment.
- Avoid deploying the catheter in constrained parts of the anatomy to prevent cardiac trauma or damage to the device.
- Prior to starting ablation verify that the catheter has been positioned and deployed correctly to prevent inappropriate application of ablation energy.
- Do not deploy the catheter while the distal end is inside the sheath as it could lead to catheter damage which may result in patient harm.
- PV potentials recorded from the electrodes on the FARAWAVE Catheter will likely show a significant reduction in amplitude after the first application of PFA. This should not be used as an indication that no further ablation is necessary. The nominal dose of PFA should be delivered in accordance to the parameters listed in the Operational Instructions section, regardless of absence of PV signal.
- Potential biohazard after use. Handle and dispose of in accordance with applicable regulations.

PRECAUTIONS

- Do not attempt to use with devices, including guidewires, larger than the delivery lumen diameter specified on the package label.
- Care must be taken to ensure all luer fittings are secure to prevent leaking.
- It is essential that a cardiac defibrillator with paddles connected is readily available in the procedure room for use if Ventricular Fibrillation is noted subsequent to ablation.
- There is limited data to support the safety and effectiveness of this device in patients older than 75 years.
- Catheter deployment and undeployment should occur under imaging guidance. Catheter may be fully deployed or undeployed even though the slider switch is not fully engaged. Failure to monitor deployment may result in catheter damage and need for catheter exchange.
- Device deployment friction is increased when attempting to deploy the device when the catheter shaft is bent. FARAWAVE Catheter deployment should always occur with the catheter shaft as straight as possible.
- Do not apply excessive force to the deployment mechanism when deploying the catheter as doing so may damage the catheter.
- Avoid allowing the distal end of the catheter to be put into an acute bend, particularly when advancing the catheter beyond the sheath or deploying the catheter. A catheter exchange may be necessary if the catheter deploys improperly.

ADVERSE EVENTS

Potential adverse events associated with use of the FARAWAVE Catheter includes, but are not limited to:

- Pain or discomfort, for example:
  - Angina
  - Chest pain
  - Non-cardiovascular pain
- Cardiac arrest
- Death
- Electric shock
- Hypotension
- Infection/inflammation/exposure to biohazardous material
- Edema/heart failure/pleural effusion
- Renal failure/insufficiency
- Respiratory distress/insufficiency/dyspnea
- Arrhythmia (new or exacerbated)
  - Conduction pathway injury (heart block, nodal injury, etc.)
- Nerve injury, for example:
  - Phrenic nerve injury
  - Vagal nerve injury
- Gastrointestinal disorders
- Vessel trauma, including:
  - Perforation
  - Dissection
  - Coronary artery injury
  - Vasospasm
  - Occlusion
  - Hemothorax
- Cardiac trauma, for example:
  - Cardiac perforation/cardiac tamponade/pericardial effusion
  - Valvular damage

    - Stiff left atrial syndrome
- Injury related to tissue damage and/or adjacent structures, for example:
    - Esophageal injury
    - Pulmonary injury
    - Catheter entrapment
    - Physical trauma
- Fistula, for example:
    - Atrio-esophageal fistula
    - Bronchopericardial fistula
- PV stenosis and its symptoms, for example:
    - Cough
    - Shortness of breath, fatigue
    - Hemoptysis
- Surgical and access complications, for example:
    - Hematoma/seroma
    - AV fistula
    - Bleeding
    - Pseudoaneurysm
    - Pneumothorax
    - Residual atrial septal defect
- Thrombus/thrombosis
- Muscle spasm
- Injury due to embolism/thromboembolism/air 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, headache, motor impairment, sensory impairment, and speech impairment
    - Pulmonary embolism
    - Asymptomatic cerebral embolism
- Hemolysis
- Procedural related side effects, for example:
    - Allergic reaction (including anaphylaxis)
    - Genitourinary complication
    - Side effects related to medication or anesthesia
    - Radiation injury/tissue burn
    - Vasovagal response
    - Fluid volume overload

The potential adverse events may be related to the ablation catheter(s) and/or the interventional procedure. The severity and/or the frequency of these potential adverse events may vary and may result in prolonged procedure time and/or additional medical and/or surgical intervention, implantation of a permanent device such as a pacemaker, and in rare cases, may result in death.

CLINICAL STUDIES

ADVENT Clinical Study

Study Title	The ADVENT Trial – A Prospective Randomized Pivotal Trial of the FARAPULSE Pulsed Field Ablation System Compared with Standard of Care Ablation in Patients with Paroxysmal Atrial Fibrillation
Number of Centers	30 sites in the United States
Number of Subjects	706 enrollments, including 80-roll-in subjects and 626 randomized subjects (313 Pulsed Field and 313 Thermal [171 Radiofrequency (RFA) ablation, 142 Cryoballoon (CBA)]). 19 subjects withdrew prior to the procedure resulting in 607 modified-intent-to-treat (MITT) subjects (305 Pulsed Field and 302 Thermal [167 RF ablation and 135 CBA]).

Objective

The primary objective of the ADVENT Trial was to establish valid scientific evidence that endocardial ablation using the FARAPULSE Pulsed Field Ablation System is both safe and effective for treating patients with drug-resistant, recurrent, symptomatic paroxysmal atrial fibrillation (PAF).

Design, Scope, and Methods

The ADVENT Trial was a prospective, Bayesian adaptive, multi-center, 1:1 randomized, blinded, non-inferiority safety and effectiveness pivotal study comparing the FARAPULSE Pulsed Field Ablation System with thermal ablation (using either force-sensing RFA catheters or CBA catheters) for the treatment of patients with drug-resistant, recurrent, symptomatic PAF. All subjects who met the eligibility criteria, signed the informed consent, and underwent the Index Procedure were followed for 12 months post-ablation with weekly event monitoring beginning on Day 90, and 72-hour Holter monitoring at Months 6 and 12. Clinical follow-up at Days 7, 30, 90, Month 6 and Month 12 were performed to determine any occurrence of adverse events or arrhythmia recurrence.

Endpoints

Primary Safety Endpoint

The primary safety endpoint was the Composite Safety Endpoint (CSE) defined as the proportion of MITT subjects with one or more of the following device- or procedure-related SAEs as adjudicated by the Clinical Events Committee (CEC) according to the protocol-specified definitions.

Early onset

Any of the following with an Onset Date within 7 days of the Index / Rescheduled Index procedure:

- Death
- Myocardial infarction
- Persistent phrenic nerve palsy
- Stroke
- TIA
- Peripheral or organ thromboembolism
- Cardiac tamponade / perforation
- Pericarditis
- Pulmonary edema
- Vascular access complications
- Heart block
- Gastric motility/pyloric spasm disorders

Late onset

Either of the following with an Onset Date any time through the completion of 12-month follow-up visit:

- Pulmonary Vein Stenosis
- Atrio-esophageal fistula

Hypothesis

The analysis of the primary safety endpoint was a test of non-inferiority of the event rate at 12 months using a non-inferiority margin of 8%. The null and alternative hypotheses are presented below for primary safety:

$H_0: Q_T \geq Q_C + 0.08$ versus $H_A: Q_T < Q_C + 0.08$

where QT is the CSE proportion in the Pulsed Field (Treatment) Group and QC is the CSE proportion in the Thermal (Control) Group. The differences in the proportion of subjects with 1 or more CSE events between the Pulsed Field Group and the Thermal Group will be tested with a Bayesian statistical method and the prior distributions for QT and QC in these calculations are Beta (0.5, 0.5), which is the Jeffreys non-informative prior. QT will be deemed to be non-inferior to QC if it can be established that the posterior probability Pr(HA | data) > Ψsaf, where Ψsaf is a pre-specified threshold value that controls the one-sided type I error rate (under simulation) at level 0.05.

Primary Effectiveness Endpoint

The Primary Effectiveness Endpoint was Treatment Success in MITT subjects through the Month 12 Assessment, defined as:

1. Acute Procedural Success, defined as demonstration of isolation of all attempted PVs using the randomized treatment during the first ablation procedure as clinically assessed by entrance block demonstrated ≥ 20 minutes after the last PVI lesion is made with or without adenosine testing and
2. Chronic Success, defined as freedom from:
   a. Use of a non-randomized treatment modality for PVI at the Index Procedure and
   b. After the Blanking Period, occurrence of any detectable atrial fibrillation (AF), atrial flutter (AFL) or atrial tachycardia (AT)[1], any cardioversion for AF, AFL or AT, use of any Type I or Type III antiarrhythmic medication for the treatment of AF, AFL or AT and
   c. At any time, re-ablation for AF, AFL or AT (other than for CTI-dependent flutter) or use of amiodarone, except intra-procedurally to control an arrhythmia

Hypothesis

The primary effectiveness endpoint for this study was Treatment Success, which will be analyzed as a test of non-inferiority of the event rate at 12 months using a non-inferiority margin of 15%. The null and alternative hypotheses are:

$H_0: P_T \leq P_C - 0.15$ versus $H_A: P_T > P_C - 0.15$

where PT is the Treatment Success rate at 12 months in the Pulsed Field Group and PC is the Treatment Success rate at 12 months in the Thermal (Control) Group.

This study was designed using Bayesian statistical techniques and the prior distributions for PT and PC in these calculations are Beta (0.5, 0.5), which is the Jeffreys non-informative prior. PT will be deemed to be non-inferior to PC if it can be established that the posterior probability Pr(HA | data) > Ψeff, where Ψeff is a pre-specified threshold value that controls the one-sided type I error rate (under simulation) at level 0.05.

Subject Accountability

All subjects who signed and dated the Informed Consent Form were considered enrolled in the study. Subjects were classified as either Roll-In or Randomized:

- **Roll-In Subject** – To help facilitate Investigators' familiarity with the new investigational system and avoid learning curve bias, the first 1-3 subjects at each site were enrolled as Roll-In subjects. Data from Roll-In subjects are not included in the endpoint analyses or results presented.
- **Randomized Subject** – Once roll-in requirements were satisfied, all subsequent subjects enrolled were randomized 1:1 to receive either Pulsed Field ablation or Thermal (control) ablation. Thermal control modality (RFA or CBA) was determined at the site level. Subject classification was as follows:
  - **Intent-to-Treat (ITT)** – Enrolled subjects randomized to either the Pulsed Field group or Thermal group.
  - **Modified Intent-to-Treat (MITT)** – ITT subjects who received any energy delivery for pulmonary vein isolation (PVI) with the randomized ablation catheter the Index Procedure.

1 Detectable AF, AFL or AT is an episode of AF, AFL or AT which is permanently recorded for review, contains at least 30 seconds of continuous interpretable signal, includes symptomatic and asymptomatic episodes, and excludes CTI isthmus-dependent AFL when the mechanism is confirmed electrophysiologically

A total of 706 subjects were enrolled in the study, including 80 Roll-In subjects and 626 Randomized subjects, 313 in the Pulsed Field Group and 313 in the Thermal Group (171 RFA, 142 CBA). Nineteen (19) subjects (8 PFA, 11 Thermal) exited the study prior to undergoing the Index Procedure ablation, resulting in 607 Randomized subjects in the MITT cohort (305 Pulsed Field, 302 Thermal [167 RFA and 135 CBA]). Of the 607 MITT subjects, 583 (96.0%) completed the 12-month follow-up (293 PFA subjects and 290 Thermal subjects), with the 24 early exits equally represented across the groups (12 Pulsed Field, 12 Thermal).

Study Population Demographics, Baseline Parameters, and Visit Compliance

Effective randomization was verified by comparing the groups on basic demographic data, assessments of AF status, and multiple cardiovascular parameters. Key baseline comparators for the MITT subjects are presented in Table 2 and Table 3. While there were a few statistical differences between the Pulsed Field and Thermal groups, commonly seen when multiple comparisons are performed, none were clinically significant.

Table 2. Baseline Demographics and Arrhythmia History – MITT Subjects

Baseline Perimeter	Total Subjects % (n / N)	Pulsed Field Subjects % (n / N)	95% BCI[1]	Thermal Subjects % (n / N)	RFA Subjects % (n / N)	CBA Subjects % (n / N)
Female	34.6 (210/607)	33.8 (103/305)	[-9.2, 5.9]	35.4 (107/302)	32.9 (55/167)	38.5 (52/135)
Male	65.4 (397/607)	66.2 (202/305)		64.6 (195/302)	67.1 (112/167)	61.5 (83/135)
Hispanic or Latino	1.8 (11/607)	2.6 (8/305)	[-0.5, 4.0]	1.0 (3/302)	1.2 (2/167)	0.7 (1/135)
White	91.9 (558/607)	93.8 (286/305)	[-0.6, 8.1]	90.1 (272/302)	89.8 (150/167)	90.4 (122/135)
Black/African American	2.5 (15/607)	1.3 (4/305)	[-5.0, 0.1]	3.6 (11/302)	4.2 (7/167)	3.0 (4/135)
Asian	1.8 (11/607)	2.0 (6/305)	[-1.9, 2.6]	1.7 (5/302)	1.2 (2/167)	2.2 (3/135)
American Indian or Alaska Native	0.2 (1/607)	0.0 (0/305)	[-1.4, 0.5]	0.3 (1/302)	0.6 (1/167)	0.0 (0/135)
Native Hawaiian or other Pacific Islander	0.5 (3/607)	0.3 (1/305)	[-1.7, 0.9]	0.7 (2/302)	1.2 (2/167)	0.0 (0/135)
Race Unknown	1.5 (9/607)	0.7 (2/305)	[-3.8, 0.2]	2.3 (7/302)	1.8 (3/167)	3.0 (4/135)
Race Not Specified	1.6 (10/607)	2.0 (6/305)	[-1.5, 2.8]	1.3 (4/302)	1.2 (2/167)	1.5 (2/135)
Typical Atrial Flutter	30.1 (183/607)	27.2 (83/305)	[-13.1, 1.4]	33.1 (100/302)	42.5 (71/167)	21.5 (29/135)
Other SVT	14.0 (85/607)	11.8 (36/305)	[-10.0, 1.1]	16.2 (49/302)	21.0 (35/167)	10.4 (14/135)
Previous RA Ablation	3.9 (22/562)	3.5 (10/283)	[-4.1, 2.5]	4.3 (12/279)	5.0 (8/161)	3.4 (4/118)

Note 1: Bayesian credible interval for the difference in proportions, using Beta (0.5, 0.5) priors.

Table 3. Baseline Demographics and Medical History – MITT Subjects

Baseline Perimeter	Total Subjects Mean (N) Min, Max	Pulsed Field Subjects Mean (N) Min, Max	95% BCI[1]	Thermal Subjects Mean (N) Min, Max	RFA Subjects Mean (N) Min, Max	CBA Subjects Mean (N) Min, Max
Age (years)	62.4 (607) 30, 75	62.4 (305) 36, 75	[-1.5, 1.3]	62.5 (302) 30, 75	62.5 (167) 42, 75	62.4 (135) 30, 75
Height (cm)	175.7 (607) 147, 201	175.9 (305) 147, 198	[-1.0, 2.2]	175.4 (302) 149, 201	176.3 (167) 149, 201	174.2 (135) 149, 196
Weight (kg)	88.7 (607) 45.4, 145.6	87.9 (305) 45.4, 137.9	[-4.5, 1.1]	89.6 (302) 45.6, 145.6	89.0 (167) 45.6, 136	90.3 (135) 47.6, 145.6
BMI	28.7 (607) 15, 47.2	28.3 (305) 15, 41.6	[-1.45, 0.05]	29.0 (302) 17.7, 47.2	28.5 (167) 17.7, 47.2	29.6 (135) 18.6, 40
LVEF (%)	60.1 (600) 40, 78	60.5 (300) 40, 78	[-0.1, 1.9]	59.6 (300) 40, 77	60.6 (167) 40, 77	58.4 (133) 44, 75
Left Atrial Diameter (mm)	39.2 (607) 23, 55	38.8 (305) 23, 55	[-1.6, 0.2]	39.6 (302) 24, 54	39.3 (167) 24, 53	40.0 (135) 25, 54
Years since first AF diagnosis	3.6 (607) 0, 51.55	3.8 (305) 0, 51.55	[-0.4, 1.4]	3.3 (302) 0, 36.19	3.5 (167) 0, 21.65	3.1 (135) 0, 36.19

Baseline Perimeter	Total Subjects % (n / N)	Pulsed Field Subjects % (n / N)	95% BCI[2]	Thermal Subjects % (n / N)	RFA Subjects % (n / N)	CBA Subjects % (n / N)
CAD	13.7 (83/607)	10.5 (32/305)	[-11.9, -0.9]	16.9 (51/302)	17.4 (29/167)	16.3 (22/135)
Diabetes	10.7 (65/607)	10.8 (33/305)	[-4.7, 5.2]	10.6 (32/302)	11.4 (19/167)	9.6 (13/135)
CHF: NYHA Class I or II	19.4 (118/607)	19.3 (59/305)	[-6.5, 6.1]	19.5 (59/302)	18.6 (31/167)	20.7 (28/135)
Sleep Apnea	27.8 (169/607)	26.6 (81/305)	[-9.7, 4.6]	29.1 (88/302)	28.7 (48/167)	29.6 (40/135)
Using CPAP	77.5 (131/169)	71.6 (58/81)	[-23.8, 1.2]	83.0 (73/88)	79.2 (38/48)	87.5 (35/40)
CHA_2DS_2-VASc Score	1.7 (606) 0, 6	1.7 (304) 0, 6	[-0.2, 0.2]	1.7 (302) 0, 6	1.8 (167) 0, 5	1.6 (135) 0, 6

Note 1: Bayesian credible interval for the difference in means, using uniform priors on (μ, log(σ)) scale.
Note 2: Bayesian credible interval for the difference in proportions, using Beta (0.5, 0.5) priors.

Follow-up visit compliance (pre-discharge, Day 7, Day 90, Month 6, and Month 12) was high and similar across both treatment groups with an overall compliance rate of 99.3% in the Pulsed Field group (1800/1813) and 99.3% (1786/1799) in the Thermal group. Post-ablation rhythm monitoring for the MITT cohort included symptomatic and weekly event monitor transmissions during the evaluation period, 12-lead ECGs at Day 90 and 12 months, and 72-Hour Holter monitors at 6-months and 12-months post-Index Procedure. Overall rhythm monitoring compliance across all assessment methods was 70.0% (71.3% Pulsed Field and 68.7% Thermal).

Procedural Durations

The duration of clinically relevant portions of each Index Procedure were recorded and compared descriptively. Procedure time (mean 105.8 versus 123.1 minutes), LA dwell time (mean 59.4 versus 83.7 minutes), total ablation time (mean 29.2 versus 50.0 minutes), and pre-ablation mapping time (mean 3.8 versus 6.2 minutes) were all significantly different and shorter in the Pulsed Field group as compared to the Thermal group. Fluoroscopy time was longer in the Pulsed Field group (mean 21.1 versus 13.9 minutes), as many thermal procedures have shifted to fluoroless procedures, which is further enabled by the integrated mapping system technologies that were used. Procedure times were inclusive of the protocol-required 20-minute wait, CTI ablation time, and any additional ablation, if performed.

Results

Primary Safety Endpoint

The primary safety endpoint was the CSE defined as the proportion of MITT subjects with one or more pre-specified device- or procedure-related SAEs adjudicated by the ADVENT Clinical Events Committee. The endpoint was compared between the MITT subjects in the Pulsed Field and Thermal Groups with a Bayesian test of non-inferiority of the CSE rate at 12 months using a non-inferiority margin of 8%.

In Pulsed Field MITT subjects, six (6) subjects experienced one or more CSE events; the estimated incidence was 2.1% (posterior mean). In Thermal MITT subjects, four (4) subjects experienced one or more CSE events; the estimated incidence was 1.5% (posterior mean).

The ADVENT Trial met the success criterion for the primary safety endpoint. The probability of a Pulsed Field MITT subject having one or more CSE events was non-inferior to the probability of a Thermal MITT subject having one or more CSE events using a non-inferiority margin of 8%: the posterior probability of non-inferiority was >0.999, which exceeded the prespecified threshold of 0.966 (Table 4).

Table 4. Primary Safety Endpoint – MITT Subjects

Primary Safety Endpoint	Subjects with Events (N) Incidence (%) 95% BCI[1]		Difference (%) 95% BCI[2]	Posterior Probability of Non-Inferiority δ = 8%)[3]
	Pulsed Field Group N = 305	Thermal Group N = 302		
MITT Subjects with one or more CSE events	6 2.1 [0.8, 4.0]	4 1.5 [0.4, 3.1]	0.6 [-1.5, 2.8]	> 0.999

Note 1: Point estimate calculated as the mean of the posterior distribution; posterior mean and Bayesian credible interval calculated using Beta (0.5, 0.5) prior, with multiple imputation for incomplete data.
Note 2: Point estimate calculated as the mean of the posterior distribution; posterior mean and Bayesian credible interval for the difference in population proportions calculated using Beta(0.5, 0.5) priors and multiple imputation for incomplete data.
Note 3: Posterior probability using Beta (0.5, 0.5) priors and multiple imputation for incomplete data

The components of the CSE Events were analyzed as separate outcomes in Table 5. Six (6) Pulsed Field subjects experienced a CSE, of the following types: 1 death, 1 TIA, 2 cardiac tamponade/ perforation, 1 pericarditis, 1 pulmonary edema, and 1 vascular access complication. One subject in the Pulsed Field group experienced two events (death and cardiac tamponade/perforation). Four (4) subjects in Thermal group experience a CSE: 1 stroke, 1 pulmonary edema, and 2 vascular access complications. All CSEs in the Thermal group occurred in RFA subjects.

Table 5. Proportion of MITT Subjects with One or More CSE Events by Event Type

MITT Subjects with One or More CSE Events by Event Type	Pulsed Field Group[1] % (n / N)	Thermal Group % (n / N)
Any CSE Event	**2.0 (6/305)**	**1.3 (4/302)**
Death	0.3 (1/305)	0.0 (0/302)
Myocardial infarction	0.0 (0/305)	0.0 (0/302)
Persistent phrenic nerve palsy	0.0 (0/305)	0.0 (0/302)
Stroke	0.0 (0/305)	0.3 (1/302)
TIA	0.3 (1/305)	0.0 (0/302)

MITT Subjects with One or More CSE Events by Event Type	Pulsed Field Group[1] % (n / N)	Thermal Group % (n / N)
Peripheral organ thromboembolism	0.0 (0/305)	0.0 (0/302)
Cardiac tamponade or perforation	0.7 (2/305)	0.0 (0/302)
Pericarditis	0.3 (1/305)	0.0 (0/302)
Pulmonary edema	0.3 (1/305)	0.3 (1/302)
Vascular access complication	0.3 (1/305)	0.7 (2/302)
Heart block	0.0 (0/305)	0.0 (0/302)
Gastric motility/ pyloric spasm	0.0 (0/305)	0.0 (0/302)
Pulmonary vein stenosis	0.0 (0/305)	0.0 (0/302)
Atrio-esophageal fistula	0.0 (0/305)	0.0 (0/302)

Abbreviations: n = number of subjects with event, N = number of evaluable subjects.

Note 1: PFA Subject 109-017 has event meeting the CSE definition for both death and cardiac tamponade/perforation and is included in event counts for both CSE events

Secondary Safety Endpoint

The secondary safety endpoint was Aggregate PV Cross-Sectional Area, defined as the paired difference in the computed Aggregate PV Cross-Sectional Area between baseline and 3 months in MITT subjects. This was compared between randomization groups, regardless of re-ablation with any second energy modality. The within-subject changes in the Aggregate PV Cross-Sectional Area from baseline to Day 90 were tested between the Pulsed Field and Thermal Groups for superiority (less reduction in area) using a Bayesian version of a t-test.

The secondary safety endpoint success criterion for superiority was met. The mean change in PV cross-sectional area in Pulsed Field MITT subject PVs (–0.18 cm2 or -0.9% of baseline value) was statistically less than the change in Thermal MITT subject PVs (–1.18 cm2 or -12.0% of baseline value) with an observed posterior probability of >0.999, exceeding the prespecified threshold value of 0.975 (Table 6).

Examination of the change in Aggregate PV Cross-Sectional Area by ablation modality demonstrated that the difference was driven by the large reduction in RFA subjects, who had a mean reduction of 19.5% in Aggregate PV Cross-Sectional Area. Thermal subjects treated with CBA had a 3.3% reduction.

Table 6. Aggregate PV Cross-Sectional Area by Ablation Modality

Aggregate PV Cross-Sectional Area (cm^2)	Interval	Pulsed Field Subjects Mean (N) Min, Max	Thermal Group		
			All Thermal Subjects Mean (N) Min, Max	RFA Subjects Mean (N) Min, Max	CBA Subjects Mean (N) Min, Max
MITT Subjects	Baseline	8.9 (259) 3.7, 15.3	8.9 (255) 4.0, 17.6	9.1 (137) 5.0, 17.6	8.7 (118) 4.0, 15.7
	Day 90	8.7 (259) 4.2, 15.1	7.8 (255) 3.6, 13.5	7.3 (137) 3.6, 12.4	8.3 (118) 3.7, 13.5
	Percent Change	-0.9 (259) -40.7, 65.5	-12.0 (255) -55.2, 44.3	-19.5 (137) -55.2, 16.8	-3.3 (118) -44.5, 44.3
	Change [95% BCI][1]	-0.18 [-0.37, 0.00]	-1.18 [-1.39, -0.97]	-1.86 [-2.12, -1.59]	-0.39 [-0.67, -0.11]
	Posterior Mean of Difference 95% BCI[2]	1.00 [0.72, 1.28]			
	Posterior Probability of Superiority[3]	>0.999			

Note 1: This change is the paired comparisons of the baseline to Day 90 mean values within each treatment group using a posterior mean and Bayesian credible interval; uniform priors on (μ, log(s)) scale

Note 2: This difference is the comparison of the baseline to Day 90 change in per-subject means between PFA and Thermal group using a posterior mean and Bayesian credible interval; uniform priors on (μ, log(σ)) scale.

Note 3: Posterior probability that the change in baseline to Day 90 mean values is larger (less negative) in the Pulsed Field group than the Thermal group, using a Bayesian version of a t-test; uniform priors on (μ, log(σ)) scale.

Additional Safety Information

There were no Unanticipated Adverse Device Effects (UADEs) in the ADVENT Trial.

Summary of Clinical Trial Adverse Events

The following table summarizes the incidence of all major categories of adverse events, comparing the MITT subjects in the Pulsed Field and the Thermal Groups. There were no statistical differences in any adverse events or SAEs, any procedure- or device-related AEs, between the two groups. There were 20 Pulsed Field subjects with one or more procedure-related SAEs compared with 9 Thermal subjects, a statistical difference presented in the table below. The device-related SAEs are all included within the procedure-related numbers.

Table 7. Overview of Adverse Events – MITT Subjects

Adverse Event	All Subjects (N = 607) n (%) e[1]	Pulsed Field Subjects (N = 305) n (%) e[1]	95% BCI[2]	Thermal Subjects (N = 302) n (%) e[1]	RFA Subjects (N = 167) n (%) e[1]	CBA Subjects N = 135) n (%) e[1]
Any adverse event	390 (64.3%) 1012	189 (62.0%) 487	[-12.2, 3.0]	201 (66.6%) 525	115 (68.9%) 321	86 (63.7%) 204
Any SAE	71 (11.7%) 103	37 (12.1%) 51	[-4.3, 6.0]	34 (11.3%) 52	21 (12.6%) 37	13 (9.6%) 15
Any procedure-related AE	191 (31.5%) 288	97 (31.8%) 147	[-6.7, 8.0]	94 (31.1%) 141	58 (34.7%) 89	36 (26.7%) 52
Any device-related AE	40 (6.6%) 45	21 (6.9%) 22	[-3.4, 4.6]	19 (6.3%) 23	13 (7.8%) 16	6 (4.4%) 7
Any procedure-related SAE	29 (4.8%) 34	20 (6.6%) 23	[0.2, 7.1]	9 (3.0%) 11	7 (4.2%) 9	2 (1.5%) 2
Any device-related SAE	4 (0.7%) 4	4 (1.3%) 4	[0.1, 3.0]	0 (0.0%) 0	0 (0.0%) 0	0 (0.0%) 0

Note 1: N = number of subjects in group, n = number of subjects with one or more events, % = percentage of subjects with one or more events, e = number of events.

Note 2: Bayesian credible interval of the difference in proportions of subjects with one or more events using Beta (0.5, 0.5) priors

Serious Adverse Events

All adverse events reported were screened by the CEC per the protocol requirements and CEC charter. Events reported as serious, and additional events that study monitors or CEC members felt might be serious, were all formally adjudicated by the CEC.

There were 34 device- or procedure-related SAEs reported in 29 subjects (20 Pulsed Field and 9 Thermal). Eleven (11) of the events in ten (10) subjects were the primary safety endpoint events presented previously in the primary safety endpoint results. The remaining 23 events (16 Pulsed Field and 7 Thermal) are summarized in Table 8 below. All of these SAEs were determined to be resolved (21) events or resolving (2 events) by the conclusion of study participation without reported sequelae.

Table 8. Related Serious Adverse Events by Category – MITT Subjects

Adverse Event	All Subjects (N = 607) n (%) e[1]	Pulsed Field Subjects (N = 305) n (%) e[1]	Thermal Subjects (N = 302) n (%) e[1]	95% BCI[2]
Total Device or Procedure Related Serious Adverse Events	**29 (4.8%) 34**	**20 (6.6%) 23**	**9 (3.0%) 11**	**[0.2, 7.1]**
Atrial Flutter	3 (0.5%) 4	2 (0.7%) 3	1 (0.3%) 1	[-1.0, 1.7]
Atypical (Type II) Atrial Flutter	2 (0.3%) 3	1 (0.3%) 2	1 (0.3%) 1	[-1.2, 1.2]
Pseudoaneurysm	3 (0.5%) 3	1 (0.3%) 1	2 (0.7%) 2	[-1.7, 0.9]
Myocardial Perforation With Tamponade	2 (0.3%) 2	2 (0.7%) 2	0 (0.0%) 0	[-0.3, 2.0]
Oozing/Bleeding	2 (0.3%) 2	2 (0.7%) 2	0 (0.0%) 0	[-0.3, 2.0]
Procedure Related Genitourinary	2 (0.3%) 2	1 (0.3%) 1	1 (0.3%) 1	[-1.2, 1.2]
Pulmonary Edema	2 (0.3%) 2	1 (0.3%) 1	1 (0.3%) 1	[-1.2, 1.2]
Abnormal Lab Values	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Access Site Complication	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Atrial Fibrillation	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Atrial Flutter Not Specified	1 (0.2%) 1	0 (0.0%) 0	1 (0.3%) 1	[-1.4, 0.5]
Cerebral Vascular Accident	1 (0.2%) 1	0 (0.0%) 0	1 (0.3%) 1	[-1.4, 0.5]
Conduction Disturbances/Arrhythmia - Other	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
EP/Ablation Other-Multi Organ Failure	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Fistula (Arterial/Venous)	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Intracardiac Thrombus	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Left Atrial (Type II, Atypical) Atrial Flutter	1 (0.2%) 1	0 (0.0%) 0	1 (0.3%) 1	[-1.4, 0.5]
Pain Cardiovascular (Non-Ischemic)	1 (0.2%) 1	0 (0.0%) 0	1 (0.3%) 1	[-1.4, 0.5]
Pericarditis	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Procedure Related Hypertension	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Symptomatic Pericardial Effusion	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]
Systemic Infection	1 (0.2%) 1	0 (0.0%) 0	1 (0.3%) 1	[-1.4, 0.5]
Transient Ischemic Attack	1 (0.2%) 1	1 (0.3%) 1	0 (0.0%) 0	[-0.5, 1.4]

Note 1: N = number of subjects in group, n = number of subjects with one or more events, % = percentage of subjects with one or more events, e = number of events.

Note 2: Bayesian credible interval of the difference in proportions of subjects with one or more events using Beta (0.5, 0.5) priors

Primary Effectiveness Endpoint

The primary effectiveness endpoint was Treatment Success (Acute Procedural Success and Chronic Success). The endpoint was compared between the MITT subjects in the Pulsed Field and Thermal Groups with a test of non-inferiority of the Treatment Success rate at 12 months using a non-inferiority margin of 15%.

In Pulsed Field MITT subjects, 204 subjects were Treatment Successes, while 80 subjects experienced Treatment Failures; the remaining 21 subjects had no known Treatment Failure but did not have an eligible 12-month follow-up visit. The failure-free time for these 21 subjects is included in the estimate of Treatment Success Rate through Bayesian multiple imputation, and the estimated Treatment Success Rate is 73.3% (calculated as the mean of the posterior distribution).

In Thermal MITT subjects, 194 subjects were Treatment Successes, while 85 subjects experienced Treatment Failures; the remaining 23 subjects had no known Treatment Failure but did not have an eligible 12-month follow-up visit. The failure-free time for these 23 subjects is included in the estimate of Treatment Success Rate through Bayesian multiple imputation, and the estimated Treatment Success Rate is 71.3% (calculated as the mean of the posterior distribution).

The ADVENT trial met the success criterion for the primary effectiveness endpoint. The probability of a Pulsed Field

MITT subject having Treatment Success was non-inferior to the probability of a Thermal MITT subject having Treatment Success using a non-inferiority margin of 15%: the posterior probability of non-inferiority is >0.999, which exceeded the prespecified threshold of 0.956.

Table 9. Primary Effectiveness Endpoint – MITT Subjects

Primary Effectiveness Endpoint	Subjects with Treatment Success [Incomplete Subjects without Treatment Failure] Incidence (%) 95% BCI[1]		Difference (%) 95% BCI[2]	Posterior Probability of Non-Inferiority δ = 15%)[3]
	Pulsed Field Group N = 305	Thermal Group N = 302		
MITT Subjects with Treatment Success	204 [21] 73.3 [68.1, 78.1]	194 [23] 71.3 [66.0, 76.3]	2.0 [-5.2, 9.2]	> 0.999

Abbreviations: N = number of subjects included in analysis (including those with incomplete follow-up)

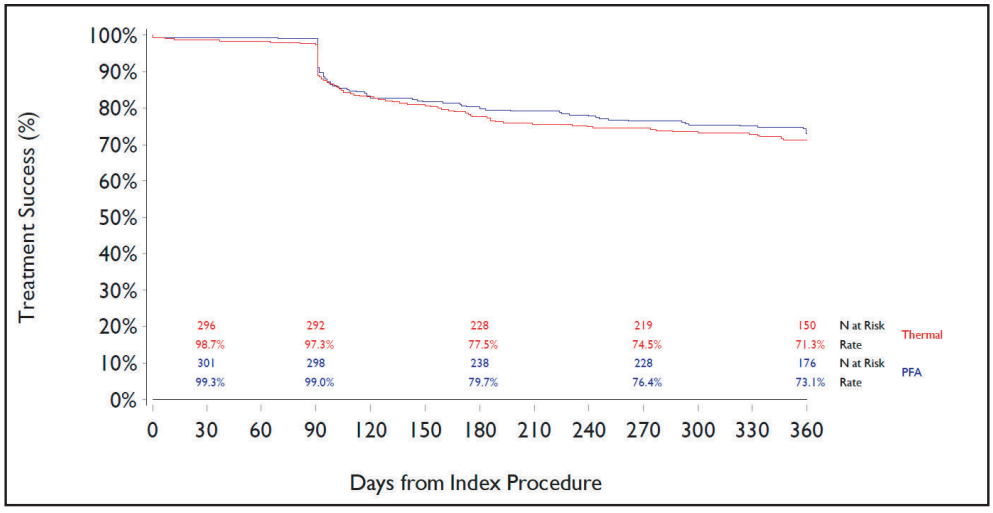
Note 1: Point estimate calculated as the mean of the posterior distribution; posterior mean and Bayesian credible interval calculated using Beta (0.5, 0.5) prior, with multiple imputation for incomplete data.

Note 2: Point estimate calculated as the mean of the posterior distribution; posterior mean and Bayesian credible interval for the difference in population proportions calculated using Beta(0.5, 0.5) priors and multiple imputation for incomplete data.

Note 3: Posterior probability using Beta (0.5, 0.5) priors and multiple imputation for incomplete data

As a sensitivity analysis, the primary effectiveness endpoint was also assessed via Kaplan-Meier estimates, as shown in Figure 2. The Kaplan-Meier estimate of freedom from failures of the primary effectiveness endpoint at 360 days is 73.1% in the Pulsed Field group and 71.3% in the Thermal group. Although freedom from failures at 360 days differs somewhat from the Treatment Success definition in that 12-month follow-up visits and their associated visit windows are not formally considered, the numerical estimates agree closely: 73.3% for Pulsed Field subjects and 71.3% for Thermal subjects from the pre-specified Bayesian model and 73.1% for Pulsed Field subjects and 71.3% for Thermal subjects from the Kaplan-Meier estimates.

Figure 2. Survival Analysis, Primary Effectiveness Endpoint – MITT Subjects



The mode of the earliest failure of the primary effectiveness endpoint for each MITT subject is detailed in the following table. The data show similar distributions of failure modes for the Pulsed Field and Thermal subjects.

Table 10. Earliest Primary Effectiveness Failure Modes – MITT Subjects

Earliest Primary Effectiveness Failure Modes	Pulsed Field Group N = 305 Incidence, %1 (Subjects with event)	Difference 95% BCI[1]	Thermal Group N = 302 Incidence, %[1] (Subjects with event)
Any Primary Effectiveness Failure Mode[2]	**26.7 (80)**	**-2.0 [-9.2, 5.2]**	**28.7 (85)**
Acute Procedural Failure	0.8 (2)	-0.0 [-1.5, 1.5]	0.8 (2)
Post-blanking Detectible AF/AFL/AT	17.2 (51)	0.7 [-5.2, 6.7]	16.4 (48)
Post-blanking Detectible AF	11.2 (33)	1.2 [-3.7, 6.1]	10.0 (29)
Post-blanking Detectible AFL	4.8 (14)	-0.4 [-4.0, 3.1]	5.3 (15)
Post-blanking Detectible AT	1.5 (4)	-0.0 [-2.1, 2.0]	1.5 (4)
Post-blanking cardioversion for AF/AFL/AT	0.5 (1)	0.3 [-0.6, 1.5]	0.2 (0)
Post-blanking use of Type I/III AAD	8.1 (24)	-1.1 [-5.6, 3.4]	9.2 (27)
Re-ablation for AF/AFL/AT	0.5 (1)	-0.0 [-1.2, 1.2]	0.5 (1)
Any non-procedural use of amiodarone	0.5 (1)	-2.0 [-4.2, -0.2]	2.5 (7)

Abbreviations: N = number of subjects included in analysis (including those with incomplete follow-up)

Note 1: Point estimate for incidence and incidence difference calculated as the mean of the relevant posterior distribution; posterior mean and Bayesian credible interval calculated Bayesian credible interval for the difference in proportions, using Beta (0.5, 0.5) priors and multiple imputation for incomplete data.

Note 2: Each subject has only one earliest primary effectiveness failure mode.

Acute Procedural Success

Acute Procedural Success was defined as demonstration of Acute Vein Success in all attempted PVs using the randomized treatment catheter during the Index/Rescheduled Index Procedure, as clinically assessed by entrance block demonstrated ≥ 20 minutes after the last PVI lesion was made, with or without adenosine.

The proportion of Pulsed Field MITT subjects with Acute Procedural Success was 99.3%, and the proportion of Thermal MITT subjects with Acute Procedural Success was 99.3%. There was not a statistical difference between these results [95% BCI -1.5, 1.5]. There were two acute procedural failures in the Pulsed Field group and two in the Thermal group.

Study Conclusion

The ADVENT Trial results constitute valid scientific evidence that gives reasonable assurance of the safety and effectiveness of the FARAPULSE Pulsed Field Ablation System when used in the treatment of patients with drug-resistant, recurrent, symptomatic paroxysmal atrial fibrillation.

Supplemental Clinical Information: FARA-Freedom Post-Market Clinical Follow-Up Study

Study Title	A Prospective Open-Label Single Arm Post Market Clinical Follow-Up Trial of the FARAPULSE Pulsed Field Ablation System in Patients with Paroxysmal Atrial Fibrillation
Number of Centers	14 sites in Europe
Number of Subjects	180 subjects treated with the FARAPULSE Pulsed Field Ablation System

Objective

The primary objective of the FARA-Freedom Study was to provide ongoing post-market demonstration of the safety and performance of the FARAPULSE Pulsed Field Ablation System in the treatment of patients with Paroxysmal Atrial Fibrillation (PAF), when used commercially in Europe.

Design, Scope and Methods

The FARA-Freedom Study was a prospective, open label, post market study conducted at 14 centers in Europe. All treated subjects were followed for 360 days post-ablation with weekly event monitoring beginning on Day 90, and 72-hour Holter monitoring at Days 180 and 360. Clinical follow-up at Days 7, 30, 90, 180 and 360 were performed to determine any occurrence of adverse events or arrhythmia recurrence. The interim study analysis results from this study were provided as supplementary clinical evidence to support the safety and effectiveness of the FARAPULSE PFA System using statistical analyses that are identical or analogous to the methods used for the ADVENT Trial.

Endpoints

The primary safety endpoint was a Composite Safety Endpoint (CSE) defined as the proportion of MITT subjects with one or more of the following device or procedure-related SAEs as adjudicated by the CEC.

Acute Primary safety endpoints were the following with an onset date within 7 days of the Index procedure:

- Death
- Myocardial infarction
- Persistent phrenic nerve palsy
- Stroke
- TIA
- Peripheral or organ thromboembolism
- Cardiac tamponade / perforation
- Pericarditis
- Pulmonary edema
- Vascular access complications
- Heart block
- Gastric motility/pyloric spasm disorders

Late onset primary safety endpoints were the following with an onset date any time through the completion of 12-month follow-up visit:

- Pulmonary Vein Stenosis (PVS)
- Atrio-esophageal fistula

The safety hypotheses are as follows:

$H_0: Q_T \geq PG_{saf}$

$H_A: Q_T < PG_{saf}$,

where QT is the probability of an MITT subject experiencing one or more CSE, and PGsaf is a performance goal of 0.14. The null hypothesis will be rejected and the alternative accepted if the posterior probability Pr(HA | data) > 0.975, corresponding to the upper bound of a 95% central Bayesian credible interval (BCI) being less than PGsaf. The parameter QT is assigned a Beta (0.5, 0.5) prior distribution, which is the Jeffreys non-informative prior. In the absence of missing or incomplete data, the posterior distribution of QT would be a conjugate Beta distribution, but the planned timing of this analysis (before 1 year of follow-up is complete for all subjects) will induce some incomplete data. Therefore, Bayesian multiple imputation of 12-month outcomes was employed in this analysis, using the same approach that is used in the ADVENT Statistical Analysis Plan.

The primary performance endpoint was Treatment Success in MITT subjects through the Month 12 Assessment defined as:

1. Acute Procedural Success AND
2. Chronic Success, defined as freedom from:
    a. At the Index / Rescheduled Index Procedure: Use of a non-PFA treatment modality for PVI
    b. After the Blanking Period, occurrence of any Detectable AF, AFL or AT excluding CTI-dependent AFL confirmed by EP study, any cardioversion for AF, AFL or AT (excluding for CTI-dependent AFL), Use of any Type I or Type III antiarrhythmic medication for the treatment of AF, AFL or AT
    c. At any time re-ablation for AF, AFL or AT (other than for CTI-dependent AFL) or use of amiodarone, except intra-procedurally to control an arrhythmia.

The performance hypotheses are as follows:

$H_0: P_T \leq PG_{perf}$

$H_A: P_T > PG_{perf}$,

where PT is the probability of a subject being a Treatment Success at 12 Months, and PGperf is a pre-specified performance goal of 0.50. The null hypothesis will be rejected and the alternative accepted if the posterior probability Pr(HA | data) > 0.975, corresponding to the lower bound of a 95% central Bayesian credible interval (BCI) being greater than PGperf. PT is assigned a Beta (0.5, 0.5) prior distribution, which is the Jeffreys non-informative prior. In the absence of missing or incomplete data, the posterior distribution of PT would be a conjugate Beta distribution, but the planned timing of this analysis (before 1 year of follow-up is complete for all subjects) will induce some incomplete data. Therefore, Bayesian multiple imputation of 12-month outcomes was employed in this analysis.

Subject Accountability

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

Intent-to-Treat (ITT) Subjects are subjects who met all the following criteria:

- The subject signed the informed consent document
- The subject was determined by the site to meet all pre-procedural study eligibility criteria
- The subject began the Index Procedure

Modified Intent-to-Treat (MITT) Subjects are ITT Subjects who received any energy delivery for PVI with the FARAPULSE Pulsed Field Ablation System at an Index / Rescheduled Index Procedure.

A total of 185 subjects were enrolled in the study and a total of 180 subjects were treated with the FARAPULSE Pulsed Field Ablation System. The ITT, MITT, and Safety analysis sets consist of the same population (N=180), as all subjects received energy delivery for PVI with the FARAPULSE Pulsed Field Ablation System.

Study Population Demographics, Baseline Characteristics, and Visit Compliance

The demographics of the study population represented a typical PAF catheter ablation patient. Mean age was 62.3 years and 61.1% were male. Mean LVEF was 60.8 % and mean LAD was 4.0 cm. The mean CHA2DS2-VASc Score was 1.8. Palpitations were the most prevalent baseline AF symptom reported in subjects (76.7%) with a mean frequency of 11.0 palpitations over the previous two-month period. The most common comorbidities were hypertension (55%) and dyslipidemia (38.9%).

Study subjects were scheduled for assessment at Baseline, Index Procedure, Pre-Discharge, Days 7, 30, 60, 90, 180 and Day 360. Visit compliance for these study assessments was high at 99.3% overall, and 96.8% of visits conducted within protocol window. The overall rhythm monitoring weekly compliance was high, with 89.1% of monitored weeks resulting in an evaluable rhythm monitoring record for study subjects .

Procedural Durations

Ablations were performed using the FARAPULSE Pulsed Field Ablation System, with either the 31mm or 35mm FARAWAVE Pulsed Field Ablation Catheter, using a recommended minimum of 8 applications in each PV at between 1.8 and 2.0 kilovolts (kV).

The duration of clinically relevant portions of each Index Procedure were recorded and compared descriptively.

Overall procedure time averaged 72 minutes; this is inclusive of the protocol-required 20-minute wait time following the last ablation. Longer procedure durations occurred in subjects that had an acute reconnection of the PV requiring

a touch up to be performed thereby adding an additional 20-minute wait period as specified per protocol. Total ablation time averaged 17.8 minutes. Mean LA dwell time was 40.9 minutes, which is inclusive of the 20-minute wait time post-ablation.

Results

Primary Safety Endpoint

Two (2) subjects experienced one or more CSE events therefore the estimated incidence through 12 months is 1.4%, and the upper bound of the 95% BCI is 3.7%. The posterior probability that the incidence is less than the pre-specified performance goal of 14% is >0.999. Since this posterior probability is greater than 0.975, this endpoint met its success criterion.

Table 11. Summary of Subjects with one or more CSE

Safety Subjects with One or More CSE Events by Event Type	Number of Subjects % (n / N) N=180
Any CSE Event	1.1 (2/180)
Death	0.0 (0/180)
Myocardial infarction	0.0 (0/180)
Persistent phrenic nerve palsy	0.0 (0/180)
Stroke	0.0 (0/180)
TIA	0.6 (1/180)
Peripheral organ thromboembolism	0.0 (0/180)
Cardiac tamponade or perforation	0.6 (1/180)
Pericarditis	0.0 (0/180)
Pulmonary edema	0.0 (0/180)
Vascular access complication	0.0 (0/180)
Heart block	0.0 (0/180)
Gastric motility/pyloric spasm	0.0 (0/180)
Pulmonary vein stenosis	0.0 (0/180)
Atrio-esophageal fistula	0.0 (0/180)

Note 1: n = number of subjects with event, N = number of safety subjects.

Abbreviations: CSE = Composite Safety Endpoint, TIA = transient ischemic attack

Additional Safety Information

Overall, 137 adverse events were experienced in 69 subjects. There were no incidences of persistent phrenic nerve palsy, no occurrences of pulmonary vein stenosis, and no atrio-esophageal fistulas occurring at any time during study follow-up.

There were no Unanticipated Adverse Device Effects (UADEs) in the FARA-Freedom Study.

Table 12. Summary of Adverse Events

Adverse Events Categories- MITT	All Subjects (N=180) n (%) e[1]
Any adverse event	69 (38%) 137
Any SAE	20 (11%) 31
Any device-related AE	6 (3%) 6
Any procedure-related AE	26 (14%) 31
Any device-related SAE	1 (1%) 1
Any procedure-related SAE	7 (4%) 9

Note 1: N = number of MITT in group, n = number of subjects with one or more events, % = percentage of subjects with one or more events, e = number of events.

Serious Adverse Events

The following table summarizes the incidence of all SAEs by AE Category. There were 7 device- or procedure-related SAEs reported in 9 subjects. One (1) event of TIA was assessed by the CEC as possibly related to the device and probably related to the procedure. All other events were classified as procedure related only by the CEC. All of these SAEs were determined to be resolved by the without reported sequelae.

Table 13. Related Serious Adverse Events by Category – MITT Subjects

Procedure- or Device-Related Serious Adverse Events	All Subjects (N=180) n (%) e[1]
Procedure- or Device-Related Serious Adverse Events	7 (4%) 9
Atrial flutter	1 (1%) 2
Procedure related Abnormal labs	2 (1%) 2
Angina/Chest Pain - Post EP procedure	1 (1%) 1
Atrial tachycardia/Other SVT	1 (1%) 1
Myocardial Perforation with Tamponade	1 (1%) 1
Pseudoaneurysm	1 (1%) 1
TIA	1 (1%) 1

Note 1: N = number of MITT subjects in group, n = number of subjects with one or more events, % = percentage of subjects with one or more events, e = number of events.

Primary Performance Endpoint

The estimated probability of MITT subjects experiencing Treatment Success was 66.3% (lower bound of the 95% BCI is 59.1, upper bound is 73.1). The posterior probability that this success rate exceeds the pre-specified performance goal of 50% is > 0.999. Since this posterior probability is greater than 0.975, this endpoint met its success criterion.

Table 14. Primary Performance Endpoint – MITT Subjects

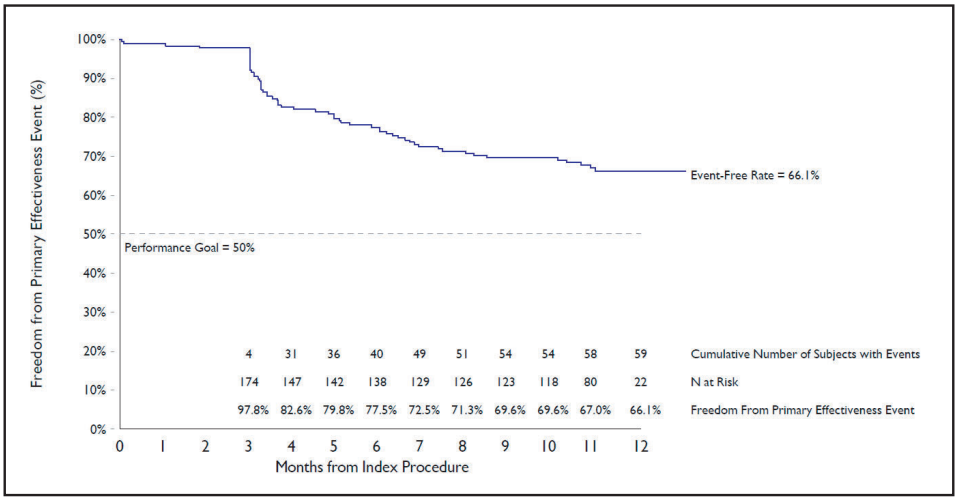
Subjects with Treatment Success [Incomplete Subjects without Treatment Failure] N = 180	Incidence (%)	95% BCI	Posterior Probability of Treatment Success Proportion > 50%
90 [31]	66.3	[59.1, 73.1]	>0.999

Abbreviations: N = number of subjects included in analysis (including those with incomplete follow-up)

Note: Estimated incidence calculated as the mean of the posterior distribution; posterior mean and Bayesian credible interval (BCI) calculated using Beta (0.5, 0.5) prior, with multiple imputation for incomplete data.

An additional analysis of the primary performance endpoint was performed using the Kaplan-Meier method to include incomplete subject data. This is a different statistical technique applied to a slightly different definition of the endpoint (time to failure rather than Treatment Success at the 12-month visit), but the Kaplan-Meier estimate of 66.1% at 360 days agrees closely with the 66.3% estimate produced by the pre-specified Bayesian statistical model. These data are displayed in the following graph.

Figure 3. Survival Analysis, Primary Performance Endpoint



The mode of the earliest failure of the primary effectiveness endpoint for each MITT subject is detailed in the following table.

Table 15. Earliest Primary Effectiveness Failure Modes – MITT Subjects

First Primary Effectiveness Failure Mode	Number of Subjects with Event N = 180	Estimated Incidence (%)[1]	95% BCI[1]
Any Primary Effectiveness Failure Mode[2]	59	33.7	[26.9, 40.9]
Acute Procedural failure	0	0.3	[0.0, 1.4]
PVI performed with non-PFA device	0	0.3	[0.0, 1.4]
Post-blanking Detectable AF/AFL/AT/SVT	41	23.6	[17.6, 30.2]
Post-blanking Detectable AF	31	17.9	[12.6, 23.9]
Post-blanking Detectable AFL	0	0.3	[0.0, 1.6]
Post-blanking Detectable AT	8	4.8	[2.2, 8.4]
Post-blanking Detectable SVT	2	1.5	[0.3, 3.9]
Post-blanking cardioversion for AF/AFL/AT	0	0.3	[0.0, 1.6]
Post-blanking use of Type I/III AAD	12	7.1	[3.8, 11.3]
Any re-ablation for AF/AFL/AT	3	2.0	[0.5, 4.6]
Any non-procedural use of amiodarone	3	2.0	[0.5, 4.5]

Abbreviations: N = number of subjects included in analysis (including those with incomplete follow-up)

Note 1: Estimated incidence calculated as the mean of the posterior distribution; posterior mean and Bayesian credible interval (BCI) calculated using Beta (0.5, 0.5) prior, with multiple imputation for incomplete data.

Note 2: Each subject has only one earliest primary effectiveness failure mode.

Additional Performance Information

Acute Procedure Success was defined as the proportion of all attempted PVs isolated using the FARAWAVE Pulsed Field Ablation Catheter during the Index procedure, as clinically assessed by entrance block demonstrated ≥ 20 minutes after the last PVI lesion is made with or without adenosine testing. All ablated PVs achieved Acute Vein success (100%).

Study Conclusion

The primary safety and performance endpoint analysis from the European FARA-Freedom PMCF Study provides supplemental evidence supporting the safety and performance of the FARAPULSE PFA System in the treatment of patients with PAF.

HOW SUPPLIED

Device Details

One (1) FARAWAVE Catheter is supplied sterile using an Ethylene Oxide (EO) process.

WARNING: Do not use the device if past the "Use By" date on the device package. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury.

Handling and Storage

Store in a cool, dry, dark place, with temperature excursions between -29 °C and 60 °C degrees permitted. Do not use if the FARAWAVE Catheter is exposed to environmental conditions beyond this range.

OPERATIONAL INSTRUCTIONS

Compatible Related Devices

Intracardiac electrophysiology and cardiac ablation procedures should be performed in a fully equipped clinical electrophysiology lab. In addition to the FARAWAVE Catheter, the following devices and materials are intended to be used:

- FARADRIVE Sheath
- Compatible BSC Generator
- Compatible BSC Recording System Module
- Compatible FARASTAR Catheter Connection Cable
- Standard commercially available guidewires up to 0.035"

Preparation

WARNING: Before use, inspect the packaging for any violation of the sterile barrier and inspect the FARAWAVE Catheter for any defects. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire. Do not use potentially contaminated or defective equipment.

WARNING: Ensure that the guidewire is properly inserted into the catheter for adequate support during use. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire fully inserted, at or past the FARAWAVE Catheter tip. Failure to do so may result in catheter damage and/or patient injury.

Please refer to the operator's manuals and Instructions for Use for the compatible BSC Generator, FARASTAR Catheter Connection Cable and the FARADRIVE Sheath for instructions on connecting and operating these systems in conjunction with the FARAWAVE Catheter. Use appropriate accessory cables to connect the catheter to the appropriate accessory equipment.

1. Connect the patient to an ECG recording system to facilitate arrhythmia monitoring per the standard operating procedure of the electrophysiology lab or manufacturer's operator's manual.

   Note: This should be done prior to introducing any intracardiac catheters.

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2. Open the FARAWAVE Catheter package. Carefully transfer the package contents into the sterile field, maintaining aseptic technique.
3. Connect the FARAWAVE Catheter to a compatible BSC PFA Generator using a FARASTAR Catheter Connection Cable, maintaining aseptic technique. Ensure that the cable/catheter connection remains dry throughout the procedure. For connection information, refer to the FARASTAR Catheter Connection Cable IFU for additional connection instructions.

Note: If a three-dimensional (3-D) catheter navigation and mapping system is going to be used, please follow the standard operating procedure of the electrophysiology lab or the instructions for use contained in the manufacturer's operator's manual.

4. Turn on the PFA Generator.
5. Obtain femoral vein access under aseptic conditions. Then place an introducer sheath into the vein using a standard percutaneous technique.
6. Obtain left atrial, transseptal access using standard techniques and commercially available equipment. (Refer to the FARADRIVE Sheath IFU for guidance on transseptal access and placement of the FARADRIVE Sheath.)
7. Flush the guidewire lumen and flush port lumen with sterile saline. Connect the flush port to a continuous flush line with pressurized heparinized saline and purge the catheter and tubing of all air bubbles. Ensure all luer fittings are secure.

WARNING: Always verify that the tubing set, catheter, sheath and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing, catheter or sheath can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system.

8. Insert a standard commercially available 0.035" guidewire through the FARAWAVE Catheter until the tip of the wire is aligned with the tip of the catheter.

Caution: Device deployment friction is increased when attempting to deploy the device when the catheter shaft is bent. FARAWAVE Catheter deployment should always occur with the catheter shaft as straight as possible.

Procedure

Standard procedures for electrophysiology studies will be followed.

WARNING: Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures. There is an increased risk of thromboemboli if appropriate anticoagulation levels are not maintained while the transseptal sheath and/or catheter is in the left side of the heart. Administer anticoagulation therapy during and post procedure according to the institution's standards to minimize bleeding and thrombotic complications.

1. Before placing the FARAWAVE Catheter in the sheath, begin continuous irrigation.

WARNING: Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism.

2. Compress the splines of the FARAWAVE Catheter for insertion and allow flush to fill the compressed spline array prior to inserting the sheath.

WARNING: Use both fluoroscopy, or other visualization technique such as echocardiography, and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade.

3. Advance the FARAWAVE Catheter and the guidewire together into the FARADRIVE Sheath taking care to avoid introducing air into the sheath.
4. Once the distal end of the FARAWAVE Catheter has been fully inserted through the valve, slowly aspirate and flush the FARADRIVE Sheath. Refer to the FARADRIVE Sheath IFU for additional instructions on minimizing air ingress.

5. Under standard imaging guidance (e.g. fluoroscopy or echocardiography), track the guidewire to the target pulmonary vein.
6. Advance the FARAWAVE Catheter over the guidewire into the left atrium. Ensure the tip of the catheter is not bent as it advances beyond the sheath. Ensure the proximal marker band on the catheter is within or beyond the marker band at the tip of the sheath.

CAUTION: Avoid allowing the distal end of the catheter to be put into an acute bend, particularly when advancing the catheter beyond the sheath or deploying the catheter. A catheter exchange may be necessary if the catheter deploys improperly.

7. Check that the distal portion of the FARAWAVE Catheter is free to move. Under standard imaging guidance, carefully deploy the distal splines by pressing down the button and sliding it proximally until the splines deploy into the desired shape. Deployment locks when the button is released.

WARNING: Do not deploy the catheter with any portion of the distal splines located within the sheath as it could lead to catheter damage which may result in patient harm.

WARNING: Ensure that the guidewire is properly inserted into the catheter for adequate support during use. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire fully inserted, at or past the FARAWAVE Catheter tip. Failure to do so may result in catheter damage and/or patient injury.

8. Position the FARAWAVE Catheter at the ostium of the targeted pulmonary vein. Use both standard imaging techniques and intracardiac electrograms to aid in uniform positioning of the catheter splines and electrodes while obtaining good tissue apposition. Ensure a stable position is achieved before delivering PFA.
9. If applicable, apply sedative bolus per site protocol.
10. Follow the recommended ablation parameters in the table below. (Refer to the PFA Generator IFU for detailed instructions.)

Note: The following table details nominal dose parameters for PV isolation with PFA.

Parameter	Nominal Value (Per PV)
Voltage Amplitude	1.8 kV, 1.9 kV or 2.0 kV
Total PFA Applications	8
PFA Applications in Full Deployment	4
PFA Applications in Partial Deployment	4

Note: Some anatomies may restrict the ability to achieve the partial or full deployment state. In these cases, ablations may be performed in the achievable full or partial deployment state. Incomplete or interrupted deliveries should be repeated.

11. Deliver ablation from the PFA Generator at the selected output setting.
12. When ablation is complete, verify that the position of the FARAWAVE Catheter has not changed.
13. Deliver an additional application in the same location. Total number of applications at this site is now two (2).
14. Rotate the FARAWAVE Catheter and reposition at the PV ostium using standard imaging techniques and intracardiac electrograms to aid in uniform positioning of the splines and electrodes while obtaining good tissue apposition. The splines should engage the vein in a different position than the previous two ablations. Ensure a stable position is achieved before delivering PFA.
15. Deliver an additional set of two (2) applications. Total number of applications at this site is now four (4).

16. Retract the FARAWAVE Catheter over the guidewire. Change the deployment shape and re-advance to the target ablation site. The splines should engage the vein in a different position than the previous two positions. Ensure a stable position is achieved before delivering PFA.
17. Deliver an additional set of two (2) applications. Total number of applications at this site is now six (6).
18. Rotate the FARAWAVE Catheter and reposition at the PV ostium using standard imaging techniques and intracardiac electrograms to aid in uniform positioning of the splines and electrodes while obtaining good tissue apposition. The splines should engage the vein in a different position than the previous two ablations. Ensure a stable position is achieved before delivering PFA.
19. Deliver an additional set of two (2) applications. Total number of applications at this site is now eight (8).
20. If needed, perform additional ablations.

Note: After energy delivery, the PFA Generator automatically routes the FARAWAVE Catheter electrodes to the EGM Connector. Signals formed from these electrodes can be viewed on the Recording/Mapping System.

Caution: PV potentials recorded from the electrodes on the FARAWAVE Catheter will likely show a significant reduction in amplitude after the first application of PFA. This should not be used as an indication that no further ablation is necessary. The nominal dose of PFA should be delivered in accordance to the parameters listed in the table above, regardless of absence of PV signal.

End of Procedure

1. Under standard imaging guidance (e.g. fluoroscopy or echocardiography), track the guidewire to any pulmonary vein.
2. Carefully un-deploy the FARAWAVE Catheter and retract the catheter over the guidewire until it is completely inside the FARADRIVE Sheath.

WARNING: The FARAWAVE Catheter tip and guidewire move forward during device undeployment. Device deployment and undeployment should be visualized using fluoroscopy. Failure to do so may result in catheter damage and/or patient injury.

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3. Retract the guidewire into the FARADRIVE Sheath.
4. Carefully withdraw the FARAWAVE Catheter, along with the guidewire, from the body through the FARADRIVE Sheath using caution to avoid introducing air into the sheath upon removal.
5. Carefully withdraw the FARADRIVE Sheath from the left atrium in accordance with its IFU.
6. Turn off the PFA Generator.

Disposal

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

After use, the catheter may contain biohazardous substances. The catheter and packaging should be treated and disposed of as biohazardous waste 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

Carefully monitor patient while in recovery to ensure hemostasis is achieved and any complications are immediately treated.

Complaint Reporting

In the event that a serious incident occurred in relation to the device, including all patient deaths for procedures where the FARAPULSE product was used, the event should be reported to Boston Scientific and the appropriate regulatory agency. ~~competent authority of the Member State in which the user and/or patient is established.~~

Boston Scientific's local contact information may be found at: www.bostonscientific.com

Return any catheter related to a complaint, patient harm, injury, or death to Boston Scientific using a BSC Returned Product Kit.

- Returning products for analysis and providing product performance observations helps drive higher reliability on an ongoing basis.
- Be sure to follow the instructions with regard to packaging and shipping any biohazard devices taking care not to expose the handle or connector to fluid that may compromise the catheter and limit analysis.

PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of the FARAWAVE 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.

WARRANTY

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

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.

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 9252A324F), eIFU, FARAWAVE, en, 51654496-01

Contents

GW Maximum Guidewire OD

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www.bostonscientific.com

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FARAPULSE

FARASTAR™

Catheter Connection Cable

REF M004PF41M424; M004PF41M434; M004PF41M444

TABLE OF CONTENTS

FARASTAR™

Catheter Connection Cable

℞ ONLY

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

REUSE 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 (BSC) 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.

DEVICE DESCRIPTION

The FARASTAR Catheter Connection Cable (henceforth referred to as the FARASTAR Connection Cable) has multi-pin quick-disconnect plugs that connect the FARASTAR Pulsed Field Ablation (PFA) Generator to a FARAPULSE™ Catheter.

Contents

One (1) sterile FARASTAR Connection Cable

User Information

The FARASTAR Connection Cable is a component of the FARAPULSE PFA System and is intended for those physicians who are specialists trained in cardiac ablation procedures to treat cardiac arrhythmias in a fully-equipped electrophysiology laboratory. Assistance to connect the cable and operate the FARASTAR Generator may only be provided by fully trained electrophysiology laboratory staff.

INTENDED USE/INDICATIONS FOR USE

The FARASTAR Connection Cable is intended to be used with a FARAPULSE Catheter during an Electrophysiology procedure for cardiac tissue ablation.

It is important to carefully review the Indications for Use section in the associated compatible FARAPULSE Catheter Instructions for Use prior to use.

The FARASTAR Connection Cable is supplied sterile and for single use only.

Clinical Benefit Statement

When operated by the intended user the clinical benefit of the FARAPULSE PFA System is the elimination of atrial fibrillation by selectively creating durable conduction block at targeted myocardial tissue with low likelihood of damage to adjacent structures. Pulsed field ablation does not rely on thermal effects and thereby incurs low risk of thermal damage such as pulmonary vein stenosis, phrenic nerve injury, or esophageal injury. In addition, pulsed field ablation therapy is less invasive than open-chest surgical interventions.

CONTRAINDICATIONS

It is important to carefully review the Contraindications section of the associated compatible FARAPULSE Catheter Instructions for Use prior to use.

WARNINGS

- Carefully read all instructions prior to use including the Instructions for Use for the associated compatible FARAPULSE Catheter. Observe all indications, contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications.
- Do not use the device if past the "Use By" date on the device package. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury.
- Before using, inspect the cable for any defects or physical damage, including electrical insulation on the cable that may cause patient and/or user injury if the device is used.
- Replace damaged equipment. Do not use defective or damaged devices. No repair or modification of this equipment is allowed as this may result in electrical shock or inducement of arrhythmias.

PRECAUTIONS

- It is important to carefully review the Precautions section in the associated compatible FARAPULSE Catheter Instructions for Use prior to use.
- Use only with the FARASTAR Generator. Consult the FARASTAR Generator User Manual for more information.

- Carefully check the condition of all packaging upon receipt of the cable. The cable is provided sterile. Sterility may be compromised if packaging is damaged (e.g., cut, torn, punctured, or ripped).
- Carefully inspect the cable prior to use. Inspect for physical damage, including electrical insulation, cuts, kinks, nicks, crushed, elongated sections, or bent pins. Do not use damaged equipment.
- Ensure that the cable/catheter connection remains dry throughout the procedure.
- To minimize the risk of damage, do not sharply bend or kink the cable. Do not use excessive force when connecting or disconnecting the cable connections.

ADVERSE EVENTS

It is important to carefully review the Adverse Events section in the associated compatible FARAPULSE Catheter Instructions for Use and FARASTAR PFA Generator User Manual prior to use.

HOW SUPPLIED

Device Details

The FARASTAR Connection Cable is supplied sterile using and Ethylene Oxide (EO) process.

WARNING: Do not use the device if past the "Use By" date on the device package. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury.

Handling and Storage

Store in a cool, dry, dark place, with temperature excursions between -29 °C and 60 °C degrees permitted. Do not use if the FARASTAR Connection Cable is exposed to environmental conditions beyond this range.

OPERATIONAL INSTRUCTIONS

Preparation/Procedure

Prior to use, consult the compatible FARAPULSE PFA Generator and Catheter IFUs.

1. Introduce the cable aseptically into sterile field.
2. In the sterile field, connect either end of the cable to a compatible FARAPULSE Catheter.
3. In the non-sterile field, connect the cable to the FARASTAR PFA Generator.
4. Prior to using the cable, ensure that all cable connectors are securely attached.

Note: To disconnect, rotate the latch ring toward the arrow symbol and pull gently.

Disposal

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

After use, the device may contain biohazardous substances. The cable and packaging should be treated and disposed of as biohazardous waste 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.

Complaint Reporting

In the event that a serious incident occurred in relation to the device, including all patient deaths for procedures where the FARAPULSE product was used, the event should be reported to Boston Scientific and the competent authority of the Member State in which the user and/or patient is established.

Boston Scientific local contact information may be found at: www.bostonscientific.com

Return any device related to a complaint, patient harm, injury, or death to Boston Scientific using a BSC Returned Product Kit.

- Returning products for analysis and providing product performance observations helps drive higher reliability on an ongoing basis.
- Be sure to follow the instructions with regard to packaging and shipping any biohazard devices taking care not to expose the handle or connector to fluid that may compromise the catheter and limit analysis.

WARRANTY

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

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.

Contents

CH REP

Boston Scientific AG
Ritterquai 8
4500 Solothurn
Switzerland

AR REP

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

AU REP

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY NSW 1455 Australia
Free Phone 1800 676 133
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EC REP

Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
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www.bostonscientific.com

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FARAPULSE

FARASTAR™

Pulsed Field Ablation Generator

REF M004PF61M401

en	**User's Manual**	**3**

BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, MB, FARASTAR Generator, en, 51645472-01A

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FARASTAR™

Pulsed Field Ablation Generator

℞ ONLY

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

Note: The equipment documented in the Device Description section (excluding sterile cables and catheters) is supplied non-sterile and cannot be sterilized. The equipment is intended for multi-patient reuse.

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 FARASTAR Pulsed Field Ablation Generator (henceforth referred to as the FARASTAR PFA Generator) is a 12 channel Pulsed Electric Field Generator (PEF) unit that is used with the FARAWAVE Pulsed Field Ablation Catheter (henceforth referred to as the FARAWAVE PFA Catheter) for cardiac tissue ablation. The FARASTAR PFA Generator contains a two channel cardiac stimulator that can be used for optional synchronous energy delivery. Additional cables and components are described in this manual that enable connection of FARAWAVE PFA Catheter electrodes to a Recording or Mapping System and to diagnostic catheters that can be used for cardiac pacing.

1.1. Contents

One (1) FARASTAR Pulsed Field Ablation Generator

1.2. FARASTAR PFA Generator Specifications

Voltage	120V/60Hz, 8.0A
External Fuses	Two 10A, 250V delay fuses, 5 mm diameter x 20 mm length, breaking capacity 100A @ 250V (T10AL)
Power Supply Cord	See Section 11.2
IEC Compliance	IEC 60601-1 3.2 2020, Class I type CF defibrillation proof
Mode of Operation	Continuous
Weight	260 lbs/118 kg

The following essential performance are identified for the FARAPULSE PFA System:

- Output Voltage / Current – The output voltage accuracy shall be maintained during an ablation.
- Pulse Width – The pulse width of the energy shall be maintained during an ablation.

1.3. System Components

The FARASTAR PFA Generator is compatible with the following components:

- FARASTAR Catheter Connection Cable, EGM Cable, and FARAWAVE PFA Catheter
- FARASTAR Recording System Module (henceforth referred to as the FARASTAR RSM) and associated cables/modules
- Cables for system connections to other Electrophysiology (EP) lab equipment for pacing:
  - FARASTAR Stimulation Module Male Cable
  - FARASTAR Stimulation Module Female Cable
  - FARASTAR Stimulation Module Y-Cable, Long
  - FARASTAR Stimulation Module Y-Cable, Short

These components are shown in a system setup in Figure 1 and are summarized in the accompanying table.

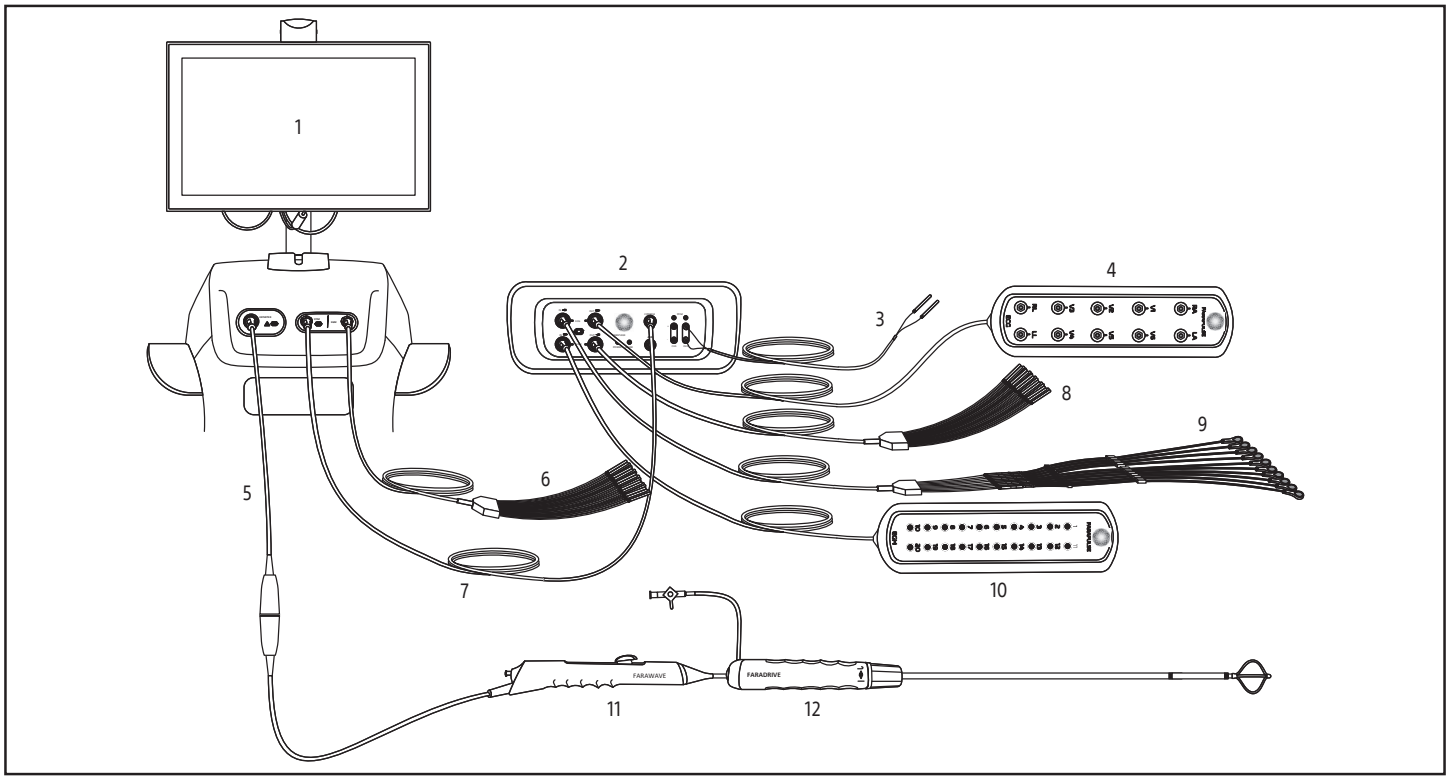

Figure 1. System Setup Diagram (Including Components)

Figure 1 Legend: (1) FARASTAR PFA Generator, (2) FARASTAR RSM, (3) FARASTAR STIM Module Y Cable, (4) FARASTAR ECG Output Module, (5) FARASTAR Catheter Connection Cable, (6) FARASTAR 12-Pin EGM Cable, (7) FARASTAR STIM Module Cable, (8) FARASTAR RSM Catheter Pin Cable, (9) FARASTAR RSM ECG Trunk Cable and Snap Cable, (10) FARASTAR RSM EGM Input Module, (11) Catheter, (12) Sheath

Component Name	Location/Use
FARASTAR PFA Generator	PFA Generator
Catheter Components:	
FARAWAVE PFA Catheter, 31 mm	Ablation Catheter (Applied part, type CF defibrillation proof)
FARAWAVE PFA Catheter, 35 mm	Ablation Catheter (Applied part, type CF defibrillation proof)
FARASTAR Catheter Connection Cable	Ablation Catheter to Generator 'CATH'
FARASTAR EGM Cable	Generator 'EGM' connector to EP Recording System for ablation catheter EGM signals (Applied part, type CF defibrillation proof)
Recording System Module Components:	
FARASTAR RSM	Between patient and EP Recording System
FARASTAR RSM EGM Input Module	EGM input (patient diagnostic catheters)
FARASTAR RSM Catheter Pin Cable	EGM output to EP Recording System
FARASTAR RSM ECG Trunk Cable*	ECG input (patient surface leads, AAMI or IEC available)
Snap Cable R/L*	ECG input (patient surface leads, AAMI or IEC available (Applied part, type CF defibrillation proof))
Snap Cable V Set*	ECG input (patient surface leads, AAMI or IEC available (Applied part, type CF defibrillation proof))
FARASTAR RSM ECG Output Module*	ECG output to EP Recording System (AAMI or IEC available)
FARASTAR Stimulation Module Cable	Generator 'STIM' to RSM 'CONSOLE' conn.
FARASTAR Stimulation Module Male Cable	Connect stimulation signals in Electrophysiology Lab
FARASTAR Stimulation Module Female Cable	Connect stimulation signals in Electrophysiology Lab
FARASTAR Stimulation Module Y-Cable, Long	Connect stimulation signals in Electrophysiology Lab
FARASTAR Stimulation Module Y-Cable, Short	Connect stimulation signals in Electrophysiology Lab

***Note:** To ensure proper connection, the ECG Trunk Cable, Snap Cable, and ECG Output Module must be of the same standard (either AAMI or IEC).

1.4. Intended User

Use of the FARASTAR PFA Generator is intended for those physicians who are specialists trained in cardiac ablation procedures to treat cardiac arrhythmias in a fully-equipped electrophysiology laboratory. Device specific physician in-service training is made available by Boston Scientific Corp. (BSC).

2. INTENDED USE

The FARAPULSE Pulsed Field Ablation (PFA) System is intended for the isolation of the pulmonary veins in the treatment of paroxysmal atrial fibrillation by rendering targeted cardiac tissue electrically non-conductive to prevent cardiac arrhythmia initiation or maintenance. The FARASTAR PFA Generator is part of the FARAPULSE PFA System.

3. INDICATIONS FOR USE

The FARASTAR PFA Generator when used in conjunction with the FARAWAVE PFA Catheter, is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic Paroxysmal Atrial Fibrillation (PAF).

4. INTENDED PATIENT POPULATION

The FARAPULSE PFA System is intended for adult patients who are age 18 or older who have drug-refractory, recurrent, symptomatic paroxysmal atrial fibrillation.

5. SAFETY FEATURES

Features of the FARASTAR PFA Generator that assist with safe use are identified and described below:

Safety Feature	Description
Ablation Start and Stop	A CONFIRM button must be pressed prior to the DELIVER button each ablation, to reduce the chances of inadvertent delivery. The CANCEL button can be pressed on the user interface of the FARASTAR PFA Generator to halt an ongoing ablation or to disable energy delivery.
Emergency Stop button	As an additional safety feature, a mechanical Emergency Stop (E-Stop) button is provided on the generator. Engaging this button terminates energy delivery and displays a dialog box prompting the user to initiate a reset sequence.
Output current restriction	The FARASTAR PFA Generator has a built in safety feature that monitors and limits the maximum amount of current during energy delivery.
Pre-Ablation Pulse	The FARASTAR PFA Generator performs a pre-ablation pulse just prior to the start of an ablation output, to evaluate the deployment of the catheter. If an issue is discovered the ablation is prevented and a warning is displayed to check the catheter position.
Time-Outs	The FARASTAR PFA Generator includes time-out intervals such that if the unit is left unattended, high-voltage present in the system will be discharged.
Self-Tests	The FARASTAR PFA Generator includes a comprehensive power-on-self-test when first powered, as well as internal monitoring and self-tests prior to each ablation.

6. CONTRAINDICATIONS

The FARAPULSE PFA System is contraindicated for use:

- in patients with active systemic infection;
- in patients with a mechanical prosthetic heart valve through which the catheter must pass;
- in patients with conditions where insertion into or manipulation in the cardiac chambers is unsafe as these conditions (e.g., presence of intracardiac thrombus or myxoma, history of recent cardiac surgery with atriotomy, etc.) may increase the risk of systemic embolism or cardiac perforation;
- in patients with a bleeding disorder, or who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation;
- in patients who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach;
- in patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe, such as but not limited to, a recent previous cardiac surgery (e.g., ventriculotomy or atriotomy, Coronary Artery Bypass Graft [CABG], PTCA/PCI/coronary stent procedure/unstable angina) and/or in patients with congenital heart disease where the underlying abnormality increases the risk of the ablation (e.g. severe rotational anomalies of the heart or great vessels);
- via transseptal approach in patients with an intra-atrial baffle or a foramen ovale patch.

7. WARNINGS

- To avoid the risk of electric shock, the FARASTAR PFA Generator must always be connected to a supply mains with protective earth.
- The Equipotential ground provides a direct connection between the chassis of the FARASTAR PFA Generator and the equalization bus of the electrical installation. It is not a protective earth connection point.
- The conductive parts of electrodes and associated connectors for system applied parts, including the neutral electrode, should not come into contact with any other conductive parts including earth ground. Electric shock can occur if this happens.
- The FARASTAR PFA Generator must only be used with equipment and accessories listed in this manual or patient injury or death may occur.
- Use of the FARASTAR PFA Generator with devices other than the FARAWAVE PFA Catheter can lead to unexpected energy delivery resulting in either insufficient ablation treatment or over-delivery of energy leading to possible patient hazardous events such as thrombus formation, tissue damage, etc.
- Use only with equipment and cabling that are listed in this manual or tested during installation of the equipment. Use with untested equipment or cables could result in increased EM emission or decreased EM immunity.
- Before using, inspect the FARASTAR PFA Generator for any defects or physical damage. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed.
- The FARASTAR PFA Generator must be installed by a qualified/trained Boston Scientific representative. For assistance with installation, please contact your local Boston Scientific representative or Technical Support.
- Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology, in the techniques of mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab.
- The FARASTAR PFA Generator User's Manual is a fundamental part of the FARASTAR PFA Generator and should accompany it at all times. Users must refer to this manual for correct and complete information on the use of the FARASTAR PFA Generator.
- The FARASTAR RSM includes its own User's Manual. See this manual for specifics regarding the usage of the FARASTAR RSM.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment, including cables specified by Boston Scientific. Otherwise, degradation of the performance of this equipment could result in patient or user harm.
- The FARASTAR PFA Generator internally produces voltages that are high enough to be potentially fatal. There are no user serviceable parts in the FARASTAR PFA Generator and it should not be opened. Maintenance should only be carried out by trained authorized personnel. Do not attempt to service the FARASTAR PFA Generator while in use with a patient.
- Cardiac ablation has the potential of causing unintended myocardial injury. Clinical indications of myocardial ischemia should be closely monitored during the procedure (e.g., ECG changes).
- The FARAWAVE PFA Catheter has not been studied clinically in the mitral isthmus or cavotricuspid isthmus areas. Ablations in areas adjacent to coronary arteries may lead to coronary artery spasm and/or injury may occur, and the resulting myocardial injury can be fatal.
- Direct patient contact should be avoided during ablation delivery as this may result in a mild electrical sensation and/or electric shock to the user.
- Do not touch the FARASTAR PFA Generator console and the patient simultaneously as this may cause excessive leakage currents on the patient which could lead to arrhythmias.
- Ensure that any additional equipment used with the FARAPULSE PFA System has been certified to IEC 60601-1. Use of non-certified equipment can increase the risk of patient harm due to failure of protective isolation barriers that could place hazardous voltages on the patient or operator or cause excessive leakage currents that may increase the risk of cardiac arrhythmias.
- Do not use a power bar or extension cord when connecting the FARASTAR PFA Generator and accessories (FARASTAR RSM) to the hospital AC source as this could cause an increase in leakage currents.

- Ensure the FARASTAR PFA Generator and FARASTAR RSM are plugged into separate AC mains connections. Do not use a power bar to connect any combination of FARASTAR PFA Generator or FARASTAR RSM together to an AC mains supply as doing this could cause an increase in leakage currents.
- Ensure that equipment is used at 120V/60Hz.
- Ablation with the FARASTAR PFA Generator may result in Ventricular Fibrillation. It is essential that a cardiac defibrillator with paddles or patches connected is readily available in the procedure room for use if Ventricular Fibrillation is noted subsequent to ablation.
- The FARASTAR stimulator outputs are primarily used to synchronize energy delivery and are not meant to replace the functions of the primary cardiac stimulator used by the Electrophysiology Lab, delay in arrhythmia treatment and/or arrhythmia may occur. Always have external sources of pacing and defibrillation available during ablation.
- Catheter electrodes are subjected to potentially harmful electrical energy. During preparation of the system do not deliver energy. If the user comes into contact with the catheter electrodes during delivery, electric shock can occur.
- Warnings for patients with implantable pacemakers (PPMs) and Implantable Cardioverter Defibrillators (ICDs):
  - PPMs, ICDs, and leads can be adversely affected by ablation energy. It is important to refer to the device manufacturer's instruction for use prior to performing ablation procedures.
  - Do not apply ablation energy directly to a lead or to tissue immediately in contact with a lead because it could potentially damage the lead or lead function.
  - Temporarily reprogram the pacemaker or defibrillator per the manufacturer guidelines during ablation. The device could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reprogram to preoperative sensing and pacing parameters.
  - Program the ICD Tachy therapy to "Off" to prevent inappropriate shock and/or possible damage to the device from the ablation procedure. Remember to turn Tachy Therapy to "On" once ablation is complete.
  - Have temporary external sources of pacing and defibrillation available.
  - Perform a complete analysis of the implanted device function after ablation.
  - Fluoroscopic or appropriate imaging guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgement.
  - Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function.

8. PRECAUTIONS

- Ensure prior to use that the FARASTAR PFA Generator is connected to the proper mains power supply.
- This equipment is intended for use in hospitals except near active High Frequency (HF) surgical equipment (including diathermy and electrocautery equipment), or Radiofrequency (RF) shielded room of a Medical Electrical (ME) system for Magnetic Resonance Imaging (MRI) where the intensity of Electromagnetic Interference (EMI) is high.
- Do not use the FARASTAR PFA Generator no closer than 30 cm (12 inches) to any Wireless Power Transfer (WPT) and 5G cellular devices, otherwise electromagnetic interference from those devices could result in degradation of the performance of this equipment.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
- Perform pulsed field ablation procedures only within environmental parameters as outlined in section 10.2.
- It is the user's responsibility to ensure that the equipment used with the system meets all local applicable electrical safety standards.
- 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.
- For purpose of disconnection, the mains connection is on the back of the console.
- Do not connect any device to the fiber optic port.
- Do not use the FARASTAR PFA Generator if a malfunction is suspected. Contact Boston Scientific if a malfunction is suspected.
- Do not use the FARASTAR PFA Generator in oxygen rich environment or in the presence of flammable gases or explosive gas mixtures.
- Ensure that the mains power supply cord is not damaged before plugging it into an electrical mains power supply. Replace the power supply cord if any damage is noticed.
- In the event of an external defibrillation pulse is delivered to the patient, the FARASTAR PFA Generator may become unresponsive and will require a reboot of the system.
- Avoid intentional or accidental liquid spills on the FARASTAR PFA Generator. Do not place cups or containers of liquid on the generator. Do not handle the generator with wet hands or gloves. Do not use the generator near irrigation equipment.
- Store the FARASTAR PFA Generator away from direct sunlight, heat sources or dust. Do not expose the LCD display of the generator to direct sunlight for long time periods.
- Ensure that the vents on the back of the generator are unobstructed.
- Avoid moving the generator when powered on. During transport, avoid jarring the device.
- Do not scratch the LCD display of the FARASTAR PFA Generator.
- Before cleaning the generator, ensure that it is powered OFF and disconnect the mains cord from the device.
- Clean the FARASTAR PFA Generator and the FARASTAR RSM by wiping down surfaces using a non-abrasive cloth with a mild detergent solution (not containing enzymes, abrasives, bleach, or alkali) or isopropyl alcohol. For the screen, use a standard screen cleaner.
- Do not position the FARASTAR PFA Generator in such a manner that it is difficult to access or unplug in the event of an emergency.
- To maintain system isolation, only Classified Medical Electrical Equipment may be connected to the FARAPULSE PFA System.
- The FARASTAR RSM must be used to pass ECG and/or EGM signals to the EP Recording System, during use of the FARAPULSE PFA System, to avoid potentially damaging the EP Recording System components.
- Disconnect all patient inputs from the Mapping System prior to pulsed field ablation. Leaving patient inputs connected during pulsed field ablation delivery may damage the Mapping System.

Note: If available, accessories which automatically disconnect patient inputs prior to pulsed field ablation may be utilized.

9. 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 generator, rather than the generator 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.

Potential adverse events associated with use of the FARASTAR PFA Generator include, but are not limited to:

- Pain or discomfort, for example:
  - Angina
  - Chest pain
  - Non-cardiovascular pain
- Cardiac arrest

- Death
- Electric shock
- Hypotension
- Infection/inflammation/exposure to biohazardous material
- Procedural related side effects, for example:
  - Allergic reaction (including anaphylaxis)
  - Genitourinary complication
  - Side effects related to medication or anesthesia
  - Radiation injury/tissue burn
  - Vasovagal response
  - Fluid volume overload
- Renal failure/insufficiency
- Respiratory distress/insufficiency/dyspnea
- Arrhythmia (new or exacerbated)
  - Conduction pathway injury (heart block, nodal injury, etc.)
- Nerve injury, for example:
  - Phrenic nerve injury
  - Vagal nerve injury
- Gastrointestinal disorders
- Vessel trauma, including:
  - Perforation
  - Dissection
  - Coronary artery injury
  - Vasospasm
  - Occlusion
  - Hemothorax
- Cardiac trauma, for example:
  - Cardiac perforation/cardiac tamponade/pericardial effusion
  - Valvular damage
  - Stiff left atrial syndrome
- Injury related to tissue damage and/or adjacent structures, for example:
  - Esophageal injury
  - Pulmonary injury
  - Catheter entrapment
- Physical trauma/laceration
- Fistula, for example:
  - Atrio-esophageal fistula
  - Bronchopericardial fistula
- PV stenosis and its symptoms, for example:
  - Cough
  - Shortness of breath, fatigue
  - Hemoptysis
- Thrombus/thrombosis
- Muscle spasm
- Injury due to embolism/thromboembolism/air embolism/foreign body embolism
  - Cerebrovascular Accident (CVA)/stroke
  - Transient Ischemia Attack (TIA)
  - Myocardial infarction
  - Neurological impairment and its symptoms, for example:
    - Cognitive changes, visual disturbances, headache, motor impairment, sensory impairment, and speech impairment
  - Pulmonary embolism
  - Asymptomatic cerebral embolism
- Hemolysis

The potential adverse events may be related to the PFA generator, ablation catheter(s), and/or the interventional procedure. The severity and/or the frequency of these potential adverse events may vary and may result in prolonged procedure time and/or additional medical and/or surgical intervention, implantation of a permanent device such as a pacemaker, and in rare cases, may result in death.

10. HOW SUPPLIED

The FARASTAR PFA Generator is packaged and provided per the Contents section.

10.1. Device Details

Do not use if any packages are damaged or unintentionally opened before use. Do not use if labeling is incomplete or illegible.

10.2. Handling and Storage

Do not use if the FARASTAR PFA Generator is exposed to environmental conditions outside of the following ranges:

Operating Conditions

Temperature: 15 °C to 30 °C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 80 kPa to 106 kPa

Transport and Storage Conditions

Temperature: -30 °C to 60 °C

Relative Humidity: 15% to 90%

Atmospheric Pressure: Uncontrolled

10.3. Service Life

3 years.

11. OPERATIONAL INSTRUCTIONS

11.1. System Location

The FARASTAR PFA Generator must be installed and operated in an environment that conforms to the Operating Conditions specified in Section 10.2. It must be placed on a rigid, stable surface that is capable of supporting the FARASTAR PFA Generator's weight.

It is very important that all ventilation outlets on the unit are at least 5 cm from a solid surface. Ensure there are no objects occluding the ventilation outlets while the system is powered on.

Position the FARASTAR PFA Generator in the electrophysiology lab, ensuring that the mains power switch and mains Power Supply Cord remain accessible.

11.2. Power Supply Cord

The FARASTAR PFA Generator Power Supply Cord supplies AC electricity to the FARASTAR PFA Generator. It is required for generator operation.

The Power Supply Cord connects to the FARASTAR PFA Generator at the designated inlet on the rear of the FARASTAR PFA Generator. The other end connects to a standard source of line power (wall outlet).

The following Power Supply Cord model is designed for use with the FARASTAR PFA Generator.

Model Number	Geography	Overall Length
M004FP6240	North America	3.05 m

Instructions for Use — Power Supply Cord

If not already connected, connect the Power Supply Cord to the FARASTAR PFA Generator and to the hospital wall outlet prior to powering up the FARASTAR PFA Generator.

Press the FARASTAR PFA Generator cord retention clip over the power supply cord to secure Power Supply Cord in position.

After shutting down the FARASTAR PFA Generator (see Section 11.9), disconnect the Power Supply Cord from the hospital wall outlet.

Storage — Power Supply Cord

While not in use, store the Power Supply Cord in its designated location on the FARASTAR PFA Generator by wrapping it around the hooks on the rear of the FARASTAR PFA Generator.

11.3. Setup Instructions

Note: The basic system setup is shown in the System Setup Diagram in Section 1.3.

1. Connect the mains Power Supply Cord to the FARASTAR PFA Generator using the IEC 320/13 end of the Power Supply Cord. Also connect the FARASTAR RSM Power Supply Cord.
2. Connect the FARASTAR RSM 'CONSOLE' connector to the FARASTAR PFA Generator 'STIM' connector using the Stimulation Module Cable.

   CAUTION: The FARASTAR RSM must be used to pass ECG and/or EGM signals to the EP Recording System, during use of the FARAPULSE PFA System, to avoid potentially damaging the EP Recording System components.

3. If using Synchronous mode, connect the FARASTAR RSM STIM outputs ('STIM' connections) to the Electrophysiology (EP) Recording System stimulation inputs using cables provided in the cable set (FARASTAR Stimulation Module Male Cable/Female Cable, FARASTAR Stimulation Module Y-Cable (long/short)). Alternatively, the FARASTAR RSM 'STIM' connections may be directly connected to diagnostic catheters. Additional stimulation inputs of the EP Recording System are to be connected to the Electrophysiology Lab Stimulator STIM output channels. If there are more Electrophysiology Lab Stimulator output channels than EP Recording System STIM input channels available, leave any additional Electrophysiology Lab Stimulator outputs disconnected.
4. Connect the FARASTAR EGM Cable from the FARASTAR PFA Generator 'EGM' connector to the EP Recording System Pin Box.

   Note: For the FARAWAVE PFA Catheter, signals 6–10 are the individually wired electrodes of each spline, and signals 1–5 are the combined other electrodes of each spline.

5. Ensure the FARASTAR RSM's TEST/NORMAL switch is in the NORMAL mode. (BLANK LED is not lit.)
6. Connect ECGs from the patient through the FARASTAR RSM en route to the electrophysiology lab's ECG monitoring system. Refer to the FARASTAR RSM User's Manual for specific connections.
7. Connect diagnostic catheter EGMs from the patient through the FARASTAR RSM en route to the EP Recording System Pin Box. Refer to the FARASTAR RSM User's Manual for specific connections.
8. Connect the Catheter Connection Cable to the FARASTAR PFA Generator CATHETER Connector.
9. Ensure the Emergency Stop Button on top of the FARASTAR PFA Generator is disabled before powering on.

11.4. Generator Power-ON Procedure

1. Move the Mains switch located on the back panel of the unit to the Power ON position (See Section 20 to identify the Power ON symbol).
2. The FARASTAR PFA Generator starts its Power On Self Tests (POST). During this time, the splash screen will be displayed that indicates the progress of the POST process. See Figure 2.

Figure 2. Splash Screen with POST Progress Indicator

3. Once POST is complete, the initial password login screen will appear. Enter the login password using the keypad and then press the OK button (see figure 3).

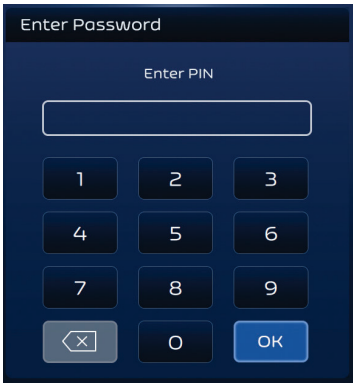

Figure 3. Initial Password Login Screen

4. Upon successful login, the Home Screen will appear, as shown in Figure 4. Press THERAPY to enter the Therapy Screen.

Note: The icon in the upper-right corner of the Home Screen is only used by BSC personnel for Engineering Access. This function is not accessible to the user and is not necessary in using the system as intended.

Figure 4. Home Screen

5. In the Therapy Screen, connect the FARAWAVE PFA Catheter to enable therapy.

Figure 5. Therapy Screen — Asynchronous Mode — Catheter Selection

6. After selecting and connecting a catheter, the Therapy Screen will now reflect the selection (see Figure 6 for an example). Asynchronous Mode is the default energy delivery mode of the FARASTAR PFA Generator.

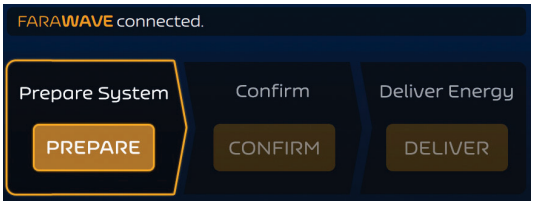

Figure 6. Therapy Screen — Asynchronous Mode — Idle State

11.5. Delivering Therapy in Asynchronous Mode

1. Select the output voltage until the desired level is highlighted.

Note: Selection of ablation voltage setting is at the discretion of the treating physician.

2. After positioning the FARAWAVE PFA Catheter in the desired location, press the PREPARE button to initialize the FARASTAR PFA Generator. Figure 7 shows the User Interface in this mode.

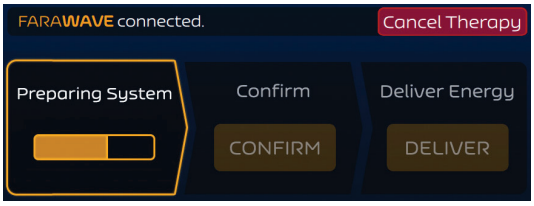

Figure 7. Therapy Screen — Asynchronous Mode — Preparing State

3. Once the PREPARE button is pressed, it will be enabled for approximately four minutes. If this time is exceeded, the FARASTAR PFA Generator will return to the "Idle" state, which will necessitate re-initialization. A countdown timer will appear within 15 seconds of the timeout. The CONTINUE button may be pressed during this countdown to start a second four minute timeout period (see Figure 8). If the second timeout period is exceeded, the FARASTAR PFA Generator will return to the "Idle" state which will necessitate re-initialization.

Figure 8. Timeout Warning Message

4. Upon completion of initialization, the CONFIRM button will be highlighted as shown in Figure 9.

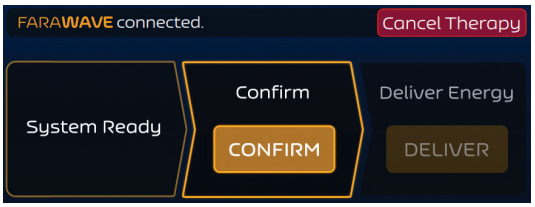

Figure 9. Therapy Screen — Asynchronous Mode — Confirm State

5. Pressing CONFIRM will enable the DELIVER button as shown in Figure 10.

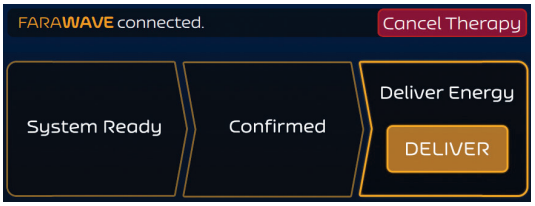

Figure 10. Therapy Screen — Asynchronous Mode — Ready to Deliver State

Note: that the DELIVER button is only enabled for 10 seconds, after which CONFIRM must be pressed again. Also, the CONFIRM button will be enabled for 4 minutes. If this time is exceeded, the FARASTAR PFA Generator will return to the Idle state which will necessitate re-initialization. A countdown timer will appear within 15 seconds of the timeout. The CONTINUE button may be pressed during this countdown to start another four minute timeout period (see Figure 8).

6. Press the DELIVER button to initiate energy delivery. Energy delivery can be canceled by pressing the Cancel Therapy button at any time (see Figure 11), which will return the FARASTAR PFA Generator to the Idle state (see Figure 6).

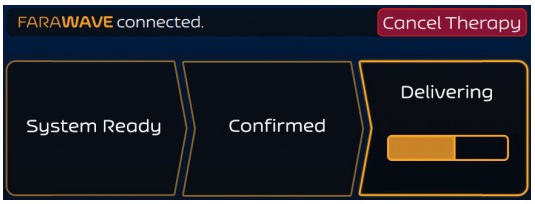

Figure 11. Therapy Screen — Asynchronous Mode — Delivery in Progress

7. When a successful delivery is complete, the FARASTAR PFA Generator will increment the Total Deliveries counter and also record the event in the History Screen. See Figure 12.

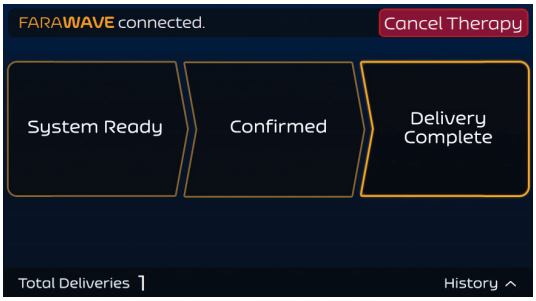

Figure 12. Therapy Screen — Asynchronous Mode — Delivery Complete State

8. The FARASTAR PFA Generator imposes a 10 second delay between deliveries. This is implemented as shown in Figure 13.

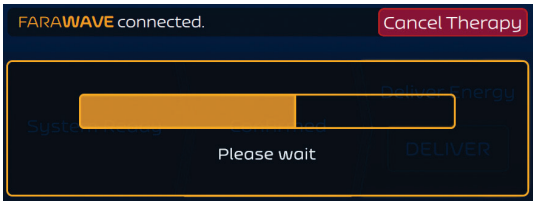

Figure 13. Therapy Screen — Asynchronous Mode — Between Deliveries Countdown State

The FARASTAR PFA Generator will then return to the CONFIRM state as shown in Figure 9.

9. To perform additional deliveries, press CONFIRM and then DELIVER. Energy delivery can be Canceled by pressing the Cancel Therapy button at any time. This will return the FARASTAR PFA Generator to the Idle state as shown in Figure 6.

11.6. Delivering Therapy in Synchronous Mode

1. Select Synchronous Mode by pressing the Sync button in the Pacing Control section of the Therapy Screen. Configure the Pacing System by setting a Cycle Length, selecting which channels are enabled for pacing, and setting the pacing channel output current. See Figure 14.

Figure 14. Therapy Screen — Synchronous Mode — Idle State

2. Check pacing capture by pressing the PACING button to turn on the pacing channel(s) and using the EP Recording System display to confirm. Adjust Cycle Length and Pacing Output Channel current as necessary.
3. Select the ablation output voltage until the desired level is highlighted.

Note: Selection of ablation voltage setting is at the discretion of the treating physician.

4. With pacing on and capture confirmed, press the PREPARE button to initialize the FARASTAR PFA Generator. After preparation is complete, the CONFIRM Pacing Capture button will be enabled (see Figure 15).

CAUTION: Disconnect all patient inputs from the Mapping System prior to pulsed field ablation. Leaving patient inputs connected during pulsed field ablation delivery may damage the Mapping System.

Note: If available, accessories which automatically disconnect patient inputs prior to pulsed field ablation may be utilized.

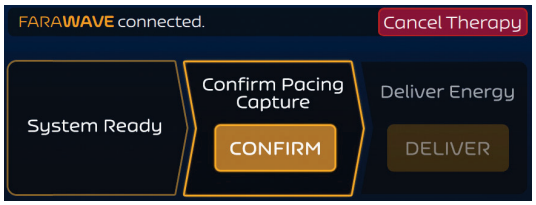

Figure 15. Therapy Screen — Synchronous Mode — Confirm Pacing State

The CONFIRM Pacing Capture button will be enabled for 4 minutes. If this time is exceeded, the FARASTAR PFA Generator will return to the Idle state which will necessitate re-initialization. A countdown timer will appear within 15 seconds of the timeout. The CONTINUE button may be pressed to start another four-minute timeout period.

5. After confirming capture, press the CONFIRM Pacing Capture button to enable the DELIVER button. Note that the DELIVER button is only enabled for 10 seconds, after which CONFIRM Pacing Capture must be pressed again.
6. Press the DELIVER button to initiate energy delivery. After a successful delivery, the FARASTAR PFA Generator will return to the CONFIRM Pacing Capture state. Additional deliveries can be performed by pressing the CONFIRM Capture button and then the DELIVER button. The Total Deliveries counter and History Screen will be updated as described in the Asynchronous Mode section.

11.7. History Screen

At any time during the procedure, the History button can be pressed to see a list of key procedure events (see Figure 16). A scroll bar on the right edge of the screen can be used if the events take up more than one page. Press the History button again to return to the main Therapy Screen.

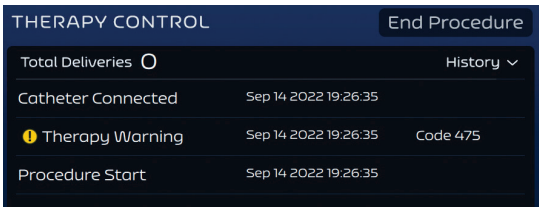

Figure 16. History Screen

11.8. Ending a Procedure

Press the End Procedure button to exit from the Therapy Screen and start a new procedure. A confirmatory dialog box will appear to ensure this is the intended action (see Figure 17).

Note: Ending a procedure will clear the History.

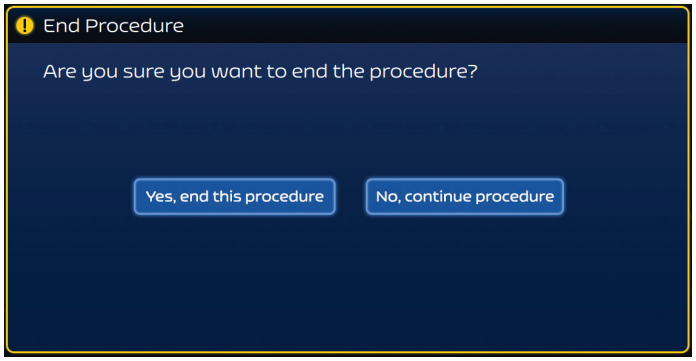

Figure 17. End Procedure Screen

11.9. System Shutdown

Once the End Procedure sequence has completed, the Home Screen (see Figure 4) will once again be showing. System shutdown can be performed by moving the mains switch on the back of the unit to the OFF position.

12. TROUBLESHOOTING

System Notice Types

Fault

A Fault system notice will stop and prevent the system from being used/delivering energy. The message cannot be cleared unless the system is power-cycled or the fault cleared by trained service personnel.

Error

An Error system notice will stop the system from being used/delivering energy. The message can be cleared and the user can attempt to use the system again.

Warning

A Warning system notice is for informational purposes only. System operation is not stopped, and no user action is required.

Problem Category	System Notice Number	System Notice Type	Problem	Message
Calibration	The FARASTAR PFA Generator requires calibration on multiple subsystems. A message is displayed if an issue is detected. To clear the message, power cycle the unit. If this condition persists, contact Boston Scientific.			
	308	Error	Point Calibration Error	Point calibration has encountered an error. Please power-cycle the unit. If this condition persists, please contact customer service.
	323	Error	Power Supply Calibration	Power supply calibration required
Catheter Disconnect	If the FARAWAVE PFA Catheter is disconnected after the FARASTAR PFA Generator has been initialized, a warning message will appear. Re-connect the FARAWAVE PFA Catheter and then press the OK button. The FARASTAR PFA Generator can then be used to continue the procedure.			
	473	Warning	Catheter Disconnected	Please reconnect catheter to enable therapy.
Catheter Verification	The FARASTAR PFA Generator verifies catheters when connected to the system. A message is displayed if an issue is detected. The message can be dismissed. If this condition persists, contact Boston Scientific.			
	306	Error	Catheter Error	Catheter usage has been exceeded.
	372	Error	Catheter Authentication	Catheter Invalid. Please use a new catheter.
	373	Error	Catheter ID	Catheter Invalid. Please use a new catheter.
	374	Error	Catheter Transition	Catheter Invalid. Please use a new catheter.
	375	Error	Catheter Corrupt Data	Catheter Invalid. Please use a new catheter.
Charge Error	The FARASTAR PFA Generator has an internal monitoring circuit that checks the value of the set voltage. If this value is not maintained within a specified tolerance, an error message will appear. Press the OK button and re-initialize the voltage charging circuit by pressing the PREPARE button. If this condition persists, contact Boston Scientific.			
	322	Error	Charge Error	System did not maintain treatment voltage. Re-prepare system. If this condition persists, please contact customer service.
Check Sum	The FARASTAR graphics software implements a Check Sum that is checked on power up. If the software gets corrupted, the check sum calculation will fail, and a message will be displayed. To clear the fault, power cycle the unit. If this condition persists, contact Boston Scientific.			
	272	Fault	Check Sum Fault	Graphics software check sum failed. Please power-cycle the unit. If this fault persists, please contact customer service.
	304	Error	Main Controller Calibration	Main controller calibration required

Problem Category	System Notice Number	System Notice Type	Problem	Message
Communication Fault	The FARASTAR PFA Generator continuously monitors communication channels between the primary micro-controller and the various sub-systems to reduce the risk of inaccurate data transmission. If a fault is detected on any of these channels, an error message will be displayed. To clear the fault, power-cycle the unit. If this condition persists, contact Boston Scientific.			
	202	Fault	Communication Fault	A communication fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	261	Fault	Communication Fault	A communication fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	271	Fault	Communication Fault	A communication fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
Date & Time	The FARASTAR PFA Generator has a system clock. A message is displayed if an issue is detected. The message can be dismissed. If this condition persists, contact Boston Scientific.			
	403	Warning	Date & Time	A preventive maintenance is required for the system. The system can still be used. Please contact customer service.
	404	Warning	Date & Time	A preventive maintenance is required for the system. The system can still be used. Please contact customer service.
Device Placement Error	The FARASTAR PFA Generator monitors the output current delivered to the FARAWAVE PFA Catheter during energy delivery. If the current exceeds a pre-defined limit, an error message will be displayed instructing the user to check the position of the FARAWAVE PFA Catheter splines for uneven distribution and/or contact between electrodes on adjacent splines. If this condition persists, and the catheter splines appear to be as evenly distributed as possible, consider reducing the voltage or replacing the catheter before proceeding with additional energy deliveries.			
	301	Error	Device Placement Error	Reposition the catheter. If this condition persists, replace catheter.
	303	Error	Device Placement Error	Reposition the catheter. If this condition persists, replace catheter.
Emergency Stop	The red "Emergency Stop" button on the top of the FARASTAR PFA Generator enclosure can be pressed to immediately terminate energy delivery. A message will appear. The button can be disengaged by twisting counterclockwise which will release the button to its normal state. The system must be prepared again to continue energy deliveries.			
	302	Error	Emergency Stop Error	The emergency stop button has been pressed. Disengage the emergency stop button to continue therapy.
FARASTAR Recording System Module	If Asynchronous Mode is selected without the FARASTAR RSM attached to the 'STIM' connector, a warning message will appear in the Pacing Control section. Connect the FARASTAR RSM to the FARASTAR PFA Generator front panel labeled "STIM" to remove this message. If Synchronous Mode is selected without the FARASTAR RSM attached to the 'STIM' connector, an error dialog will appear. Press the OK button and then connect the FARASTAR RSM to the FARASTAR PFA Generator front panel labeled "STIM" to continue in Synchronous mode.			
	311	Error	Recording System Module	Sync mode requires a Recording System Module connection for pacing output. Either connect a Recording System Module to the console, or switch to Async mode.
Hard Drive Storage	The FARASTAR PFA Generator has a system hard drive storage. A message is displayed if an issue is detected. The message can be dismissed. If this condition persists, contact Boston Scientific.			
	405	Warning	Memory Space	A preventive maintenance is required for the system. The system can still be used. Please contact customer service.
	406	Warning	Memory Space	A preventive maintenance is required for the system. The system can still be used. Please contact customer service.
Internal System Notification	The FARASTAR PFA Generator continuously monitors its hardware functionality. A message is displayed if an issue is detected. To clear the message, power-cycle the unit. If this condition persists, contact Boston Scientific.			
	262	Fault	Internal System Fault	An internal system fault has occurred. Please power-cycle the unit. If this persists, please contact customer service.
	263	Fault	Internal System Fault	An internal system fault has occurred. Please power-cycle the unit. If this persists, please contact customer service.
	264	Fault	Internal System Fault	An internal system fault has occurred. Please power-cycle the unit. If this persists, please contact customer service.
Pacing System	The FARASTAR PFA Generator continuously monitors the stimulator functions of both channels while in Synchronous Mode. An error message is displayed if a fault is detected. To clear the fault, power-cycle the unit. If this condition persists, contact Boston Scientific.			
	211	Fault	Pacing System Fault	A pacing system fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	212	Fault	Pacing System Fault	A pacing system fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	213	Fault	Pacing System Fault	A pacing system fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	215	Fault	Pacing System Fault	A pacing system fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	312	Error	Internal Stim Error	An internal stimulation error has occurred. Please power-cycle the unit. If the problem persists, please call customer support.

Problem Category	System Notice Number	System Notice Type	Problem	Message
Parameter Failure	A parameter failure message will be displayed if the values saved in the pace function micro-controller do not match those displayed on the user interface. To clear the fault, power-cycle the unit. If this condition persists, contact Boston Scientific.			
	316	Error	Parameter Failure	Stimulator parameters not set internally. Please power-cycle the unit. If this condition persists, please contact customer service.
Power On Self Test Fault	If any of the Power On Self Test checks fail, a fault message will appear. If this fault persists after multiple attempts, power down the unit and contact Boston Scientific.			
	201	Fault	POST Fault	A POST fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
Power Supply Fault	The FARASTAR PFA Generator is continuously monitoring the internal power supply circuits. If a fault is detected, an error message is displayed. To clear the fault, power-cycle the unit. If this condition persists, contact Boston Scientific.			
	221	Fault	Power Supply Fault	A power supply fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	222	Fault	Power Supply Fault	A power supply fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
Relay Fault	The FARASTAR PFA Generator uses internal relays to control the energy delivery to the FARAWAVE PFA Catheter. If a relay fault is detected, an error message is displayed. To clear the fault, power-cycle the unit. If this condition persists, contact Boston Scientific.			
	231	Fault	Relay Fault	A relay fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	232	Fault	Relay Fault	A relay fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	233	Fault	Relay Fault	A relay fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
	234	Fault	Relay Fault	A relay fault occurred. Please power-cycle the unit. If this fault persists, please contact customer service.
Software Version	If the FARASTAR Software detects an incorrect version number a warning message will be displayed. To clear the fault, power-cycle the unit. If this condition persists, contact Boston Scientific.			
	273	Fault	Incorrect Versions	One or more of the version numbers are incorrect. Please power-cycle the unit. If this fault persists, please contact customer service.
	371	Error	System Version Missing	No system version was found on SD card. Check that the SD card is plugged in and contains a version file. Please power-cycle the unit. If this fault persists, please contact customer service.
Testing Notification	The FARASTAR PFA Generator requires successful completion of functional testing prior to use. A message is displayed if an issue is detected. If this condition persists, contact Boston Scientific.			
	307	Error	Stress Test Error	Stress test has encountered an error. Please power-cycle the unit. If this condition persists, please contact customer service.
	475	Warning	Manufacturing Steps Incomplete	"The following manufacturing steps have not been completed:" **Note:** This indicates that some manufacturing steps have not been completed. Contact customer service if this message appears.
	476	Warning	Stress Test Completion	# Cycle Stress Test has completed.
Voltage Tolerance Error	When a voltage is selected by the user and the PREPARE button is pressed, the FARASTAR PFA Generator will charge its internal energy storage components to the set value. If the value measured by internal circuitry is not within a defined tolerance, an error message will be displayed. Press the OK button and re-initialize the voltage charging circuit by pressing the PREPARE button. If this condition persists, contact Boston Scientific.			
	305	Error	Voltage Tolerance Error	System did not reach treatment voltage. Re-prepare system. If this condition persists, please contact customer service.
	321	Error	Voltage Tolerance Error	System did not reach treatment voltage. Re-prepare system. If this condition persists, please contact customer service.

13. ELECTROMAGNETIC COMPATIBILITY (EMC) INFORMATION

The tables below contain FARAPULSE PFA System compliance information on the electromagnetic emissions and immunity. As the equipment user, you have shared responsibility in meeting compliance levels by ensuring that the electromagnetic environment requirements are met.

13.1. EMC Specifications & Labeling

FARAPULSE PFA System Electromagnetic Emissions		
The FARAPULSE PFA System is intended for use in the electromagnetic environment specified below. The customer or the user of the FARAPULSE PFA System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment**
RF Emissions EN 55011 /CISPR 11	Group 1 **Note:** Group 1 Industrial, Scientific and Medical (ISM) Equipment is equipment containing intentionally generated and/or used conductivity coupled radio-frequency that is necessary for the internal functioning of the equipment itself.	The system uses RF energy only for its internal function. Nearby electric equipment may be affected.
RF Emissions EN 55011 /CISPR 11	Class A **Note:** Class A equipment is equipment suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes.	The system 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 system 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 measures, such as re-orientating or relocating the system or shielding the location.

13.2. Electromagnetic Immunity

FARAPULSE PFA System—Electromagnetic Immunity			
The FARAPULSE PFA System is intended for use in the electromagnetic environment specified below. The customer or the user of the FARAPULSE PFA System should assure that it is used in such an environment.			
Immunity Test	**EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic Discharge EN 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	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 EN 61000-4-4	± 2 kV AC mains ± 1 kV I/O lines 5 kHz burst	± 2 kV AC mains ± 1 kV I/O lines 5 kHz burst	Mains power quality should be that of a typical commercial or hospital environment. Sharing mains power lines with large motors and/or noisy equipment must be avoided.
Surge Line to Line (AC Power) EN 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 0.5, 1 kV line to line ± 0.5, 1, 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% dip in Ut .5 cycle 0% dip in Ut 1 cycles 70% dip in Ut 25/30 cycles at 50/60Hz 0% dip in Ut 250/300 cycles at 50/60Hz	0% dip in Ut .5 cycle 0% dip in Ut 1 cycles 70% dip in Ut 25/30 cycles at 50/60Hz 0% dip in Ut 250/300 cycles at 50/60Hz **Note:** The system passed this specific test requirement, however if the loss of power turns off the system, the power switch must be turned OFF and then back ON.	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation of the system during power mains interruptions, use an uninterruptible power supply.
Power Frequency (50/60 Hz) magnetic field EN 61000-4-8	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 EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (3,5 / \sqrt{P})$ 150 KHz to 80 MHz $d = (3,5 / E1) \sqrt{P}$ 80 MHz to 800 MHz $d = (7 / \sqrt{P}) \sqrt{P}$ 800 MHz to 2,5 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: This symbol is labeled on medical equipment that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	6 Vrms in ISM bands between 0.15 MHz and 80 MHz	6 Vrms	
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz And Proximity fields from RF wireless communication equipment per 8.10 of EN 60601-1-2	3 V/m And Per 8.10 of EN 60601-1-2	

13.3. Separation distances

Recommended separation distances between portable and mobile RF communications equipment and the system.			
The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

14. DISPOSAL

It is important to understand and follow all local laws regarding the safe and proper disposal of electrical instrumentation.

The durable portions of the FARAPULSE PFA System shall be disposed of in accordance with local regulations.

This device contains a battery. If you wish to discard this product please contact your local authority or dealer for the correct method of electrical equipment disposal.

15. MAINTENANCE

- The FARASTAR PFA Generator and its components must undergo annual preventative maintenance. Contact your local Boston Scientific representative to schedule this service, or for technical support.
- Only trained and certified personnel may perform service or maintenance on the FARAPULSE PFA System.
- Do not service the FARASTAR PFA Generator or the FARASTAR RSM while the System is in use with a patient.
- Any FARAPULSE PFA System component exposed to excessive shock, vibration, or any mishandling should be returned to Boston Scientific for evaluation.
- Completion of factory test requirements for FARASTAR PFA Generator includes but not limited to: High Voltage (HV) calibration, output calibration, and pre-ablation pulse calibration. Equipment is maintained and calibrated with documented results.

15.1. Cleaning

- As needed, use a non-abrasive cloth with a mild detergent solution (not containing enzymes, abrasives, bleach, or alkali) or isopropyl alcohol to clean the outer surfaces of the FARASTAR Pulsed Field Ablation Generator, Power Supply Cord, and Cables. For the screen, use a standard screen cleaner.
- Cleaning should be performed at the end of each case at a minimum.
- Do not attempt to clean any of the electrical connectors. Do not allow moisture or fluids to enter any of the electrical connectors or vents.
- Never clean and reuse components that are sterile or that are intended for single use.

16. CYBERSECURITY

In order to maintain the device cybersecurity:

- The firmware and software (including off-the-shelf software components) of the FARASTAR PFA Generator and accessories cannot be updated by the user. Software upgrades (including security patches) can only be installed by authorized Boston Scientific personnel.
- Do not attempt to connect the FARASTAR PFA Generator 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.

17. COMPLAINT REPORTING AND REQUESTS FOR INFORMATION

In the event that a serious incident occurred in relation to the device, including all patient deaths for procedures where the BSC product was used, the event should be reported to BSC and the appropriate regulatory agency.

Returning products for analysis and providing product performance observations helps drive higher reliability on an ongoing basis.

17.1. Contacts

For service and support in using this system please contact Boston Scientific Support using the resources given below. Do not send any parts or equipment for service to Boston Scientific without prior authorization.

Technical Support
(North America)
Tel 800 949 6708
Fax 510 624 2493
CETechSupportUSA@bsci.com

Technical Support
(Europe, Middle East, Africa)
Tel 0031 (0)45 5467707
Fax 0031 (0)45 5467805
CETechSupportEMEA@bsci.com

Technical Support (Japan)
Tel +81 03 6853 1000
Fax +81 45 444 2799
japantsc@bsci.com

18. PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of the FARAPULSE PFA System and FARAWAVE PFA Catheter in association with the electrophysiological cardiac interventional procedure:

- Discuss the risks and benefits including review of potential adverse events associated with the system and catheter.
- 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. WARRANTY

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

20. SYMBOL DEFINITIONS

Medical device symbols that appear on the device and/or labeling are defined at the end of this document. Additionally, commonly used medical device symbols are also defined at www.bostonscientific.com/SymbolsGlossary.


AC Input


Atmospheric Pressure Limitation

Catalog Number


Contents


Date of Manufacture


Defibrillation-proof type CF applied part


Do not use if package is damaged.


Equipotentiality

[blue safety sign]
Follow Instructions For Use


Fuse


Humidity limitation.


Laser Warning

Lot Number


Manufacturer


Mass


Non-Ionizing Electromagnetic Radiation


"OFF" (power)

"ON" (power)


Separate Collection

Serial Number


Temperature limitation.

Unique Device Identifier


Warning, electricity

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

www.bostonscientific.com

2024-01 51645472-01

FARAPULSE

FARASTAR™

Recording System Module

REF M004PF61M407

en	**User's Manual**	**3**

BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, MB, FARASTAR RSM, en, 51645473-01A

MB Drawing 50573138

Black (K) ΔE ≤5.0 / CMYK

TABLE OF CONTENTS

FARASTAR™

Recording System Module

℞ ONLY

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

Note: The equipment documented in the Device Description section (excluding sterile cables and catheters) is supplied non-sterile and cannot be sterilized. The equipment is intended for multi-patient reuse.

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

Figure 1. FARASTAR Recording System Module (RSM)

The FARASTAR Recording System Module (henceforth referred to as the FARASTAR RSM) is a filtering/protection unit meant to be placed in between a patient in the electrophysiology lab and other equipment such as a recording system surface-lead signals (Electrocardiograms (ECGs)) and intra-cardiac Electrograms (EGMs).

1.1. Contents

One (1) FARASTAR Recording System Module (RSM)

1.2. FARASTAR RSM Specifications

Voltage	120V/60Hz, 1.5A
External Fuses	Two 10A, 250V delay fuses, 5 mm diameter x 20 mm length, breaking capacity 1500A @ 250V (T1.6AL)
Power Supply Cord	See Section 10.1
IEC Compliance	IEC 60601-1 3.2 2020, Class I type CF defibrillation proof
Mode of Operation	Continuous
Weight	17 lbs/7.7 kg

FARASTAR RSM has no essential performance specifications.

1.3. System Components

The basic connection scheme is shown below:

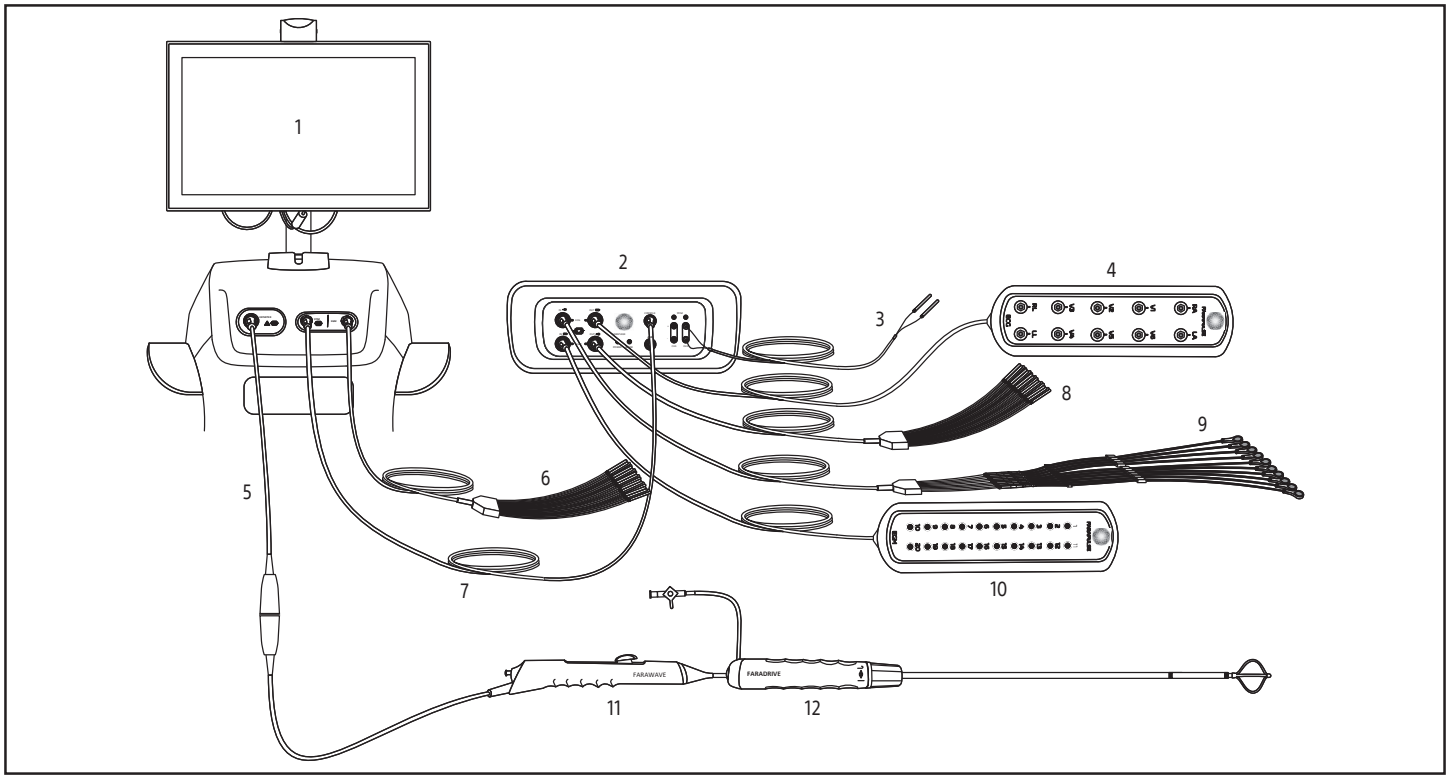

Figure 2. Recording System Module Connection Diagram

Figure 2 Legend: (1) FARASTAR PFA Generator, (2) FARASTAR RSM, (3) FARASTAR STIM Module Y Cable, (4) FARASTAR ECG Output Module, (5) FARASTAR Catheter Connection Cable, (6) FARASTAR 12-Pin EGM Cable, (7) FARASTAR STIM Module Cable, (8) FARASTAR RSM Catheter Pin Cable, (9) FARASTAR RSM ECG Trunk Cable and Snap Cable, (10) FARASTAR RSM EGM Input Module, (11) Catheter, (12) Sheath

The FARASTAR RSM is an accessory component to the FARASTAR Pulsed Field Ablation Generator (henceforth referred to as the FARASTAR PFA Generator). This component's primary function is to disconnect the inputs of the (3rd party) Electrophysiology (EP) Recording System from their connections to the patient during Pulsed Field Ablation (PFA) delivery. The inputs include diagnostic catheter EGMs and surface ECGs. This action reduces the risk of interference with the EP Recording System inputs during an ablation. The secondary function of the FARASTAR RSM component is to provide Stimulation outputs for Synchronous Mode PFA delivery.

The FARASTAR RSM resides between the patient and the EP Recording System. Its functionality is implemented by a set of relay switches that can be open or closed by a synchronization signal ('Blank') coming from the FARASTAR PFA Generator, through the STIM connector on the console. In the default Pass-Through Mode, the FARASTAR RSM closes all internal switches which pass the patient ECG and diagnostic catheter EGM signals through to the EP Recording System. Prior to an application of Pulsed Field Ablation energy, the FARASTAR PFA Generator signals the FARASTAR RSM to enter Blank Mode, which it maintains during any periods of PFA delivery. During Blank Mode, the EGM and ECG signals are disconnected from the patient, and the connections between the FARASTAR RSM and the EP Recording System are electronically tied together to reduce any noise pickup from being injected into the EP Recording System. When ablation is complete, the FARASTAR RSM again returns to Pass-Through Mode.

A manual test switch on the back of the FARASTAR RSM enclosure forces temporary entry into Blank Mode, which is to be used for testing purposes only. If either the generator synchronization signal or the manual test switch instructs the FARASTAR RSM to enter Blank Mode, the mode will be entered. An Auxiliary Connector output is also available on the FARASTAR RSM enclosure to allow for future expansion.

Stimulation outputs from the FARASTAR PFA Generator console are routed to connectors available on the FARASTAR RSM front panel. These may be connected to the EP Recording System STIM Inputs or directly to diagnostic catheters if Sync Mode PFA is desired. Light Emitting Diodes (LEDs) on the FARASTAR RSM light each time stimulation output occurs.

When the FARASTAR RSM is powered off, there is a direct connection between the input and output. This mimics direct connections between the patient and the attached down-stream equipment in order to ensure a safe mode if the FARASTAR RSM is off or mistakenly unpowered. There is an indicator LED on the FARASTAR RSM enclosure showing the power state of the device.

As shown in Figure 2 above, the FARASTAR RSM is meant to be used in conjunction with:

- FARASTAR PFA Generator
- FARASTAR Stimulation Module Cable
- FARASTAR Recording System Module ECG Trunk Cable (AAMI or IEC available)*
- Snap Cable R/L (Applied part, type CF defibrillation proof, AAMI or IEC available)*
- Snap Cable V Set (Applied part, type CF defibrillation proof, AAMI or IEC available)*
- FARASTAR Recording System Module ECG Output Module (AAMI or IEC available)*
- FARASTAR Recording System Module EGM Input Module
- FARASTAR Recording System Module Catheter Pin Cable
- FARASTAR Stimulation Module Male Cable
- FARASTAR Stimulation Module Female Cable
- FARASTAR Stimulation Module Y-Cable, Long
- FARASTAR Stimulation Module Y-Cable, Short

***Note:** To ensure proper connection, the ECG Trunk Cable, Snap Cable, and ECG Output Module must be of the same standard (either AAMI or IEC).

The front and back panel interfaces of the FARASTAR RSM are shown below.

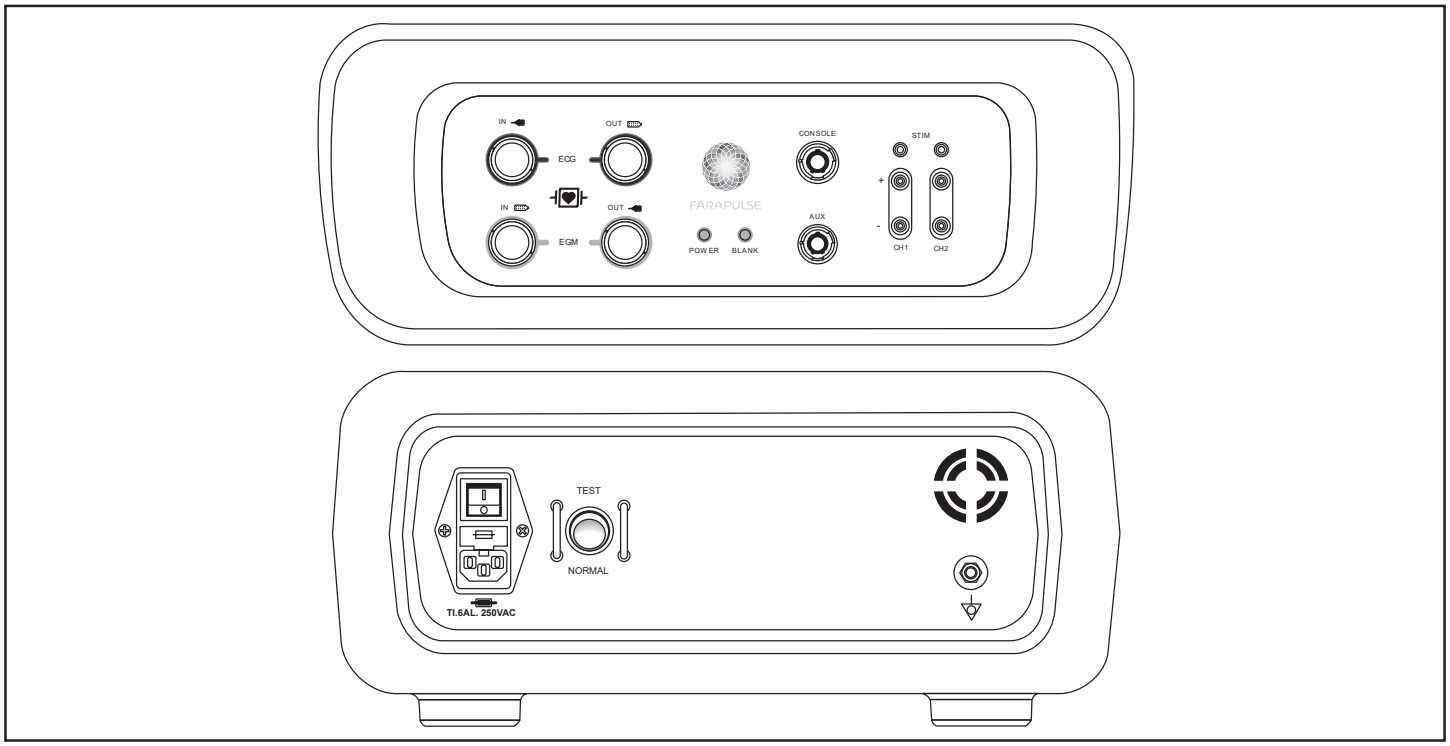

Figure 3. FARASTAR RSM External Panel Interfaces

1.4. Intended User

Use of the FARASTAR RSM is intended for those physicians who are specialists trained in cardiac ablation procedures to treat cardiac arrhythmias in a fully-equipped electrophysiology laboratory. Device specific physician in-service training is made available by Boston Scientific Corp. (BSC).

2. INTENDED USE

The FARAPULSE Pulsed Field Ablation (PFA) System is intended for the isolation of the pulmonary veins in the treatment of paroxysmal atrial fibrillation by rendering targeted cardiac tissue electrically non-conductive to prevent cardiac arrhythmia initiation or maintenance. The FARASTAR RSM is part of the FARAPULSE PFA System.

3. INDICATIONS FOR USE

The FARASTAR Recording System Module (RSM) is indicated for use in an electrophysiology lab environment, as a filtering/protection unit to be connected between the patient and any attached recording systems and/or ECG systems, and as an interface for cardiac stimulation output.

4. INTENDED PATIENT POPULATION

The FARAPULSE PFA System is intended for adult patients who are age 18 or older who have drug-refractory, recurrent, symptomatic paroxysmal atrial fibrillation.

5. CONTRAINDICATIONS

The FARASTAR RSM is contraindicated where such use may present an unacceptable risk to the patient. Refer to the contraindications section in the FARAWAVE PFA Catheter Instructions for Use and FARASTAR PFA Generator User Manual.

6. WARNINGS

- The FARASTAR RSM must be installed by a qualified/trained Boston Scientific representative. For assistance with installation, please contact your local Boston Scientific representative or Technical Support.
- Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology, in the techniques of mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab.
- The FARASTAR PFA Generator User's Manual is a fundamental part of the FARASTAR PFA Generator and should accompany it at all times. Users must refer to this manual for correct and complete information on the use of the FARASTAR PFA Generator.
- To avoid the risk of electric shock, the FARASTAR RSM must always be connected to a supply mains with protective earth.
- There are no user serviceable parts in the FARASTAR RSM and it should not be opened. Maintenance should only be carried out by trained authorized personnel. Do not attempt to service the FARASTAR RSM while in use with a patient.
- The Equipotential ground provides a direct connection between the chassis of the FARASTAR RSM and the equalization bus of the electrical installation. It is not a protective earth connection point.
- Before using, inspect the FARASTAR RSM for any defects or physical damage. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed.
- The FARASTAR RSM must only be used with equipment and accessories listed in this manual or patient injury or death may occur.
- Use only with equipment and cabling that are listed in this manual or tested during installation of the equipment. Use with untested equipment or cables could result in increased EM emissions or decreased EM immunity.
- Portable Radiofrequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment, including cables specified by Boston Scientific. Otherwise, degradation of the performance of this equipment could result in patient or user harm.
- Direct patient contact should be avoided during ablation delivery as this may result in a mild electrical sensation and/or electric shock to the user.
- Do not touch the FARASTAR PFA Generator console and the patient simultaneously as this may cause excessive leakage currents on the patient which could lead to arrhythmias.

- Ensure that any additional equipment used with the FARAPULSE PFA System has been certified to IEC 60601-1. Use of non-certified equipment can increase the risk of patient harm due to failure of protective isolation barriers that could place hazardous voltages on the patient or operator or cause excessive leakage currents that may increase the risk of cardiac arrhythmias.
- Do not use a power bar or extension cord when connecting the FARASTAR PFA Generator and accessories (FARASTAR RSM) to the hospital AC source as this could cause an increase in leakage currents.
- Ensure the FARASTAR PFA Generator and FARASTAR RSM are plugged into separate AC mains connections. Do not use a power bar to connect any combination of FARASTAR PFA Generator or FARASTAR RSM together to an AC mains supply as doing this could cause an increase in leakage currents.
- Ensure that equipment is used at 120V/60Hz.

7. PRECAUTIONS

- This equipment is intended for use in hospitals except near active High Frequency (HF) surgical equipment (including diathermy and electrocautery equipment), or Radiofrequency (RF) shielded room of an Medical Electrical (ME) system for magnetic resonance imaging where the intensity of Electromagnetic Interference (EMI) is high.
- Do not use the FARASTAR RSM no closer than 30 cm (12 inches) to any Wireless Power Transfer (WPT) and 5G cellular devices, otherwise electromagnetic interference from those devices could result in degradation of the performance of this equipment.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
- Perform pulsed field ablation procedures only within environmental parameters as outlined in section 9.1.
- It is the user's responsibility to ensure that the equipment used with the system meets all local applicable electrical safety standards.
- 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.
- Inspect all components before use. Do not use if the package or items therein appear to be damaged or defective.
- Ensure that all devices are connected to their properly labeled connections. Failure to do so can result in inaccurate catheter or ECG recordings, inaccurate pacing locations, and inaccurate rendering on the Navigation System.
- The FARASTAR RSM must be used to pass ECG and/or EGM signals to the EP Recording System, during use of the FARAPULSE PFA System, to avoid potentially damaging the EP Recording System components.
- During the procedure, if unexpected behavior of down-stream equipment is experienced, check the cable connections to the FARASTAR RSM console, confirm the unit is powered on, and ensure the Test switch is set to the Normal mode. Also, if the down-stream equipment includes a pacing stimulator ensure any channel-enable features of the electrophysiology lab stimulator are inactive during PFA deliveries.
- Ensure the electrophysiology lab stimulator is not actively pacing during PFA deliveries. If synchronous PFA is desired Sync Mode may be used in the FARASTAR PFA Generator.
- Test Mode is only meant for temporary use during installation and system checks—do not leave the unit in test mode. Defibrillation of the patient should not be performed when the unit is in Test Mode or during PFA deliveries.
- For purpose of disconnection, the mains connection is on the back side of the device.
- The FARASTAR RSM component should be tested prior to use by installation staff personnel to ensure proper function.
- Avoid intentional or accidental liquid spills on the FARASTAR RSM. Do not place cups or containers of liquid on the module. Do not handle the module with wet hands or gloves. Do not use the module near irrigation equipment.
- Before cleaning the FARASTAR RSM, ensure that it is powered OFF and disconnect the mains cord from the device. Clean the module by wiping down surfaces using a non-abrasive cloth with a mild detergent solution (not containing enzymes, abrasives, bleach, or alkali) or isopropyl alcohol.
- Electromagnetic Interference (EMI) produced by the FARASTAR RSM may adversely affect the performance of other equipment. When EMI is observed on other equipment, contact Boston Scientific Corp. (BSC) personnel for assistance. Avoid placing this equipment adjacent to or stacking on top of other electrical equipment.

8. ADVERSE EVENTS

Any potential clinical complications are in large part expected to be related to the FARASTAR PFA Generator, accessories, and/or catheters 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 generator, catheters and accessories that will be employed during the ablation procedure.

9. HOW SUPPLIED

The FARASTAR RSM is packaged and provided per the Contents section.

Do not use if package is damaged or unintentionally opened before use. Do not use if labeling is incomplete or illegible.

9.1. Handling and Storage

Do not use if the FARASTAR RSM is exposed to environmental conditions outside of the following ranges:

Operating Conditions

Temperature: 15 °C to 30 °C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 80 kPa to 106 kPa

Transport and Storage Conditions

Temperature: -30 °C to 60 °C

Relative Humidity: 15% to 90%

Atmospheric Pressure: Uncontrolled

9.2. Service Life

The expected service life of this equipment is 3 years.

10. OPERATIONAL INSTRUCTIONS

10.1. Power Supply Cord

The FARASTAR RSM Power Supply Cord supplies AC electricity to the FARASTAR RSM. It is required for RSM operation.

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

The following Power Supply Cord model is designed for use with the FARASTAR RSM.

Model Number	Geography	Overall Length
M004FP6240	North America	3.05 m

Instructions for Use — Power Supply Cord

If not already connected, connect the Power Supply Cord to the FARASTAR RSM and to the hospital wall outlet prior to powering up the FARASTAR RSM.

After shutting down the FARASTAR RSM, disconnect the Power Supply Cord from the hospital wall outlet.

10.2. Prior to Procedure

Prior to the procedure, perform the following steps:

1. Ensure the FARASTAR RSM has been tested on site and verified as functional by trained personnel.
2. Prior to the procedure, plug in the FARASTAR RSM and turn on the power switch. Confirm the POWER LED is lit.

Note: Position the FARASTAR RSM in the electrophysiology lab, ensuring that the mains power switch and mains Power Supply Cord remain accessible.

3. Ensure the TEST connector is in the NORMAL position and the BLANK LED is off.
4. Connect two input connectors and two output connectors to the FARASTAR RSM front panel:
   a. ECG IN: Connect the FARASTAR RSM ECG Trunk Cable.
   b. ECG OUT: Connect the FARASTAR RSM ECG Output Module.
   c. EGM IN: Connect the FARASTAR RSM EGM Input Module.
   d. EGM OUT: Connect the FARASTAR RSM Catheter Pin Cable.
5. Connect the FARASTAR RSM ECG Trunk Cable to the 10-lead ECG snap-lead set by connecting the corresponding signal names for each of 10 connectors.
6. Connect the ECG snap-lead set to the patient ECG patches.
7. Connect the Electrophysiology Lab ECG monitoring system to the FARASTAR RSM ECG Output Module.
8. Connect diagnostic catheter signals to the FARASTAR RSM EGM Input Module.
9. Connect the EGM output signals to the EP Recording System using the FARASTAR RSM Catheter Pin Cable.
10. Connect the FARASTAR RSM Console connector to the FARASTAR PFA Generator STIM connector using the FARASTAR Stimulation Module Cable.
11. If Sync Mode is used on the FARASTAR PFA Generator, select appropriate cables for STIM signal connection options, such as FARASTAR Stimulation Module Male Cables, to connect the FARASTAR RSM STIM outputs to the desired pacing location—either directly to a catheter or to stimulation input connectors of an EP Recording System.
12. The AUX connector may be left un-connected. This is reserved for future use.

10.3. Usage during an Electrophysiology Procedure

During the procedure, perform the following steps:

1. Ensure that during use, the FARASTAR RSM is positioned flat with feet side down.
2. Ensure the FARASTAR RSM is powered on throughout the procedure, and is set to NORMAL mode. The POWER LED will be lit and the BLANK LED will be off in this mode.
3. No physical interaction with the FARASTAR RSM is required during the procedure. When PFA exposure is imminent, the FARASTAR PFA Generator will automatically switch the FARASTAR RSM into Blank Mode temporarily, in which case the BLANK LED will light. This may be visually monitored during ablations to confirm operation. If the BLANK LED does not light during ablations, check connections.
4. If any down-stream equipment experiences inappropriate reset or sensed activity, double-check that there are no parallel connections around the FARASTAR RSM which would connect the patient directly to the equipment. Also, confirm power and connections, verify input vs. output cabling is well separated, and check that output cable lengths are minimized/coiled on their way to the down-stream equipment. If the down-stream equipment includes a pacing stimulator, ensure any channel-enable features of the electrophysiology lab stimulator are inactive during PFA deliveries.
5. If issues are encountered with signals unable to reach the down-stream equipment, double-check connections. If that does not resolve the issue, try powering off the FARASTAR RSM which directly connects input to output, in an effort to debug the root of the problem.
6. At the completion of the procedure, power OFF the FARASTAR RSM. Disconnect inputs/outputs and store the unit flat with feet side down.

11. ELECTROMAGNETIC COMPATIBILITY (EMC) INFORMATION

The tables below contain FARASTAR RSM compliance information on the electromagnetic emissions and immunity. As the equipment user, you have shared responsibility in meeting compliance levels by ensuring that the electromagnetic environment requirements are met.

11.1. EMC Specifications & Labeling

FARASTAR RSM Electromagnetic Emissions		
The FARASTAR RSM is intended for use in the electromagnetic environment specified below. The customer or the user of the FARASTAR RSM should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment**
RF Emissions EN 55011 /CISPR 11	Group 1 **Note:** Group 1 Industrial, Scientific and Medical (ISM) Equipment is equipment containing intentionally generated and/or used conductivity coupled radio-frequency that is necessary for the internal functioning of the equipment itself.	The system uses RF energy only for its internal function. Nearby electric equipment may be affected.
RF Emissions EN 55011 /CISPR 11	Class A **Note:** Class A equipment is equipment suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes.	The system 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 system 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 measures, such as re-orientating or relocating the system or shielding the location.

11.2. Electromagnetic Immunity

FARASTAR RSM—Electromagnetic Immunity			
The FARASTAR RSM is intended for use in the electromagnetic environment specified below. The customer or the user of the FARASTAR RSM should assure that it is used in such an environment.			
Immunity Test	**EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic Discharge EN 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	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 EN 61000-4-4	± 2 kV AC mains ± 1 kV I/O lines 5 kHz burst	± 2 kV AC Mains ± 1 kV I/O lines 5 kHz burst	Mains power quality should be that of a typical commercial or hospital environment. Sharing mains power lines with large motors and/or noisy equipment must be avoided.
Surge Line to Line (AC Power) EN 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 0.5, 1 kV line to line ± 0.5, 1, 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% dip in Ut .5 cycle 0% dip in Ut 1 cycles 70% dip in Ut 25/30 cycles at 50/60Hz 0% dip in Ut 250/300 cycles at 50/60Hz	0% dip in Ut .5 cycle 0% dip in Ut 1 cycles 70% dip in Ut 25/30 cycles at 50/60Hz 0% dip in Ut 250/300 cycles at 50/60Hz **Note:** The system passed this specific test requirement, however if the loss of power turns off the system, the power switch must be turned OFF and then back ON.	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation of the system during power mains interruptions, use an uninterruptible power supply.
Power Frequency (50/60 Hz) Magnetic Field EN 61000-4-8	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 EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = (3,5 / $\sqrt{P}$) 150 KHz to 80 MHz d = (3,5 / E1) √P 80 MHz to 800 MHz d = (7 / $\sqrt{P}$) √P 800 MHz to 2,5 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: ((1)) This symbol is labeled on medical equipment that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	6 Vrms in ISM Bands between 0.15 MHz and 80 MHz	6 Vrms	
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz And Proximity fields from RF wireless communication equipment per 8.10 of EN 60601-1-2	3 V/m And Per 8.10 of EN 60601-1-2	

11.3. Separation distances

Recommended separation distances between portable and mobile RF communications equipment and the system.			
The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

12. DISPOSAL

It is important to understand and follow all local laws regarding the safe and proper disposal of electrical instrumentation.

The durable portions of the FARAPULSE PFA System shall be disposed of in accordance with local regulations.

If you wish to discard this product(s) please contact your local authority or dealer for the correct method of electrical equipment disposal.

13. MAINTENANCE

- The FARASTAR RSM and its components must undergo annual preventative maintenance. Contact your local Boston Scientific representative to schedule this service, or for technical support.
- Only trained and certified personnel may perform service or maintenance on the FARAPULSE PFA System.
- Do not service the FARASTAR PFA Generator or the FARASTAR RSM while the System is in use with a patient.
- Any FARAPULSE PFA System component exposed to excessive shock, vibration, or any mishandling should be returned to Boston Scientific for evaluation.

14. INSPECTION

FARASTAR RSM and components should be inspected for damage prior to use. Prior to each use, regularly inspect reusable cables for visual evidence of damage. Replace damaged components.

15. CLEANING

- As needed, use a non-abrasive cloth with a mild detergent solution (not containing enzymes, abrasives, bleach, or alkali) or isopropyl alcohol to clean the outer surfaces of the FARASTAR RSM, Power Supply Cord, and Cables.
- Cleaning should be performed at the end of each case at a minimum.
- Do not attempt to clean any of the electrical connectors. Do not allow moisture or fluids to enter any of the electrical connectors or vents.
- Never clean and reuse components that are sterile or that are intended for single use.

16. CYBERSECURITY

The FARASTAR RSM is not intended to be incorporated into an IT Network.

17. COMPLAINT REPORTING AND REQUESTS FOR INFORMATION

In the event that a serious incident occurred in relation to the device, including all patient deaths for procedures where the BSC product was used, the event should be reported to BSC and the appropriate regulatory agency.

Returning products for analysis and providing product performance observations helps drive higher reliability on an ongoing basis.

17.1. Contacts

For service and support in using this system please contact Boston Scientific Support using the resources given below. Do not send any parts or equipment for service to Boston Scientific without prior authorization.

Technical Support
(North America)
Tel 800 949 6708
Fax 510 624 2493
CETechSupportUSA@bsci.com

Technical Support
(Europe, Middle East, Africa)
Tel 0031 (0)45 5467707
Fax 0031 (0)45 5467805
CETechSupportEMEA@bsci.com

Technical Support (Japan)
Tel +81 03 6853 1000
Fax +81 45 444 2799
japantsc@bsci.com

18. PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of the FARAPULSE PFA System and compatible Boston Scientific PFA Catheters in association with the electrophysiological cardiac interventional procedure:

- Discuss the risks and benefits including review of potential adverse events associated with the system and catheter.
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BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, MB, FARASTAR RSM, en, 51645473-01A

MB Drawing 50573138

Black (K) ΔE ≤5.0 / CMYK


AC Input


Atmospheric Pressure Limitation

Catalog Number


Contents


Date of Manufacture


Defibrillation-proof type CF applied part


Do not use if package is damaged.


ECG/EGM Cable


ECG/EGM Module


Equipotentiality


[blue safety sign]
Follow Instructions For Use
IFU-bsci.com


Fuse


Humidity limitation.

Lot Number


Manufacturer


Non-Ionizing Electromagnetic Radiation


"OFF" (power)

"ON" (power)


Separate Collection

Serial Number


Temperature limitation.

Unique Device Identifier

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

www.bostonscientific.com

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