FARAPULSE

FARASTAR™

Pulsed Field Ablation Generator

REF M004PF61M402, M004PF61M401

BSC (MB IFU Template 8.5 x 11 Global, 92310050P), IFU, MB, FRSTR GENERATOR 1.4 (POINT) US, EN, 52024134-01A

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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 compatible with commercially released Boston Scientific PFA catheters (henceforth referred to as PFA catheter (either navigation-enabled or non-navigation))* as recognized by the FARASTAR Generator 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 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	100VAC-240VAC, 50Hz/60Hz, 10.0A-4.0A
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

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 PFA catheter
- FARASTAR Recording System Module (henceforth referred to as the FARASTAR RSM) and associated cables/modules
- FARASTAR Mapping System Module (henceforth referred to as the FARASTAR MSM), associated components, and cables
- 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.

* The FARASTAR Generator software has safeguards in place to prevent the use of unauthorized catheters and will not recognize unauthorized catheters.

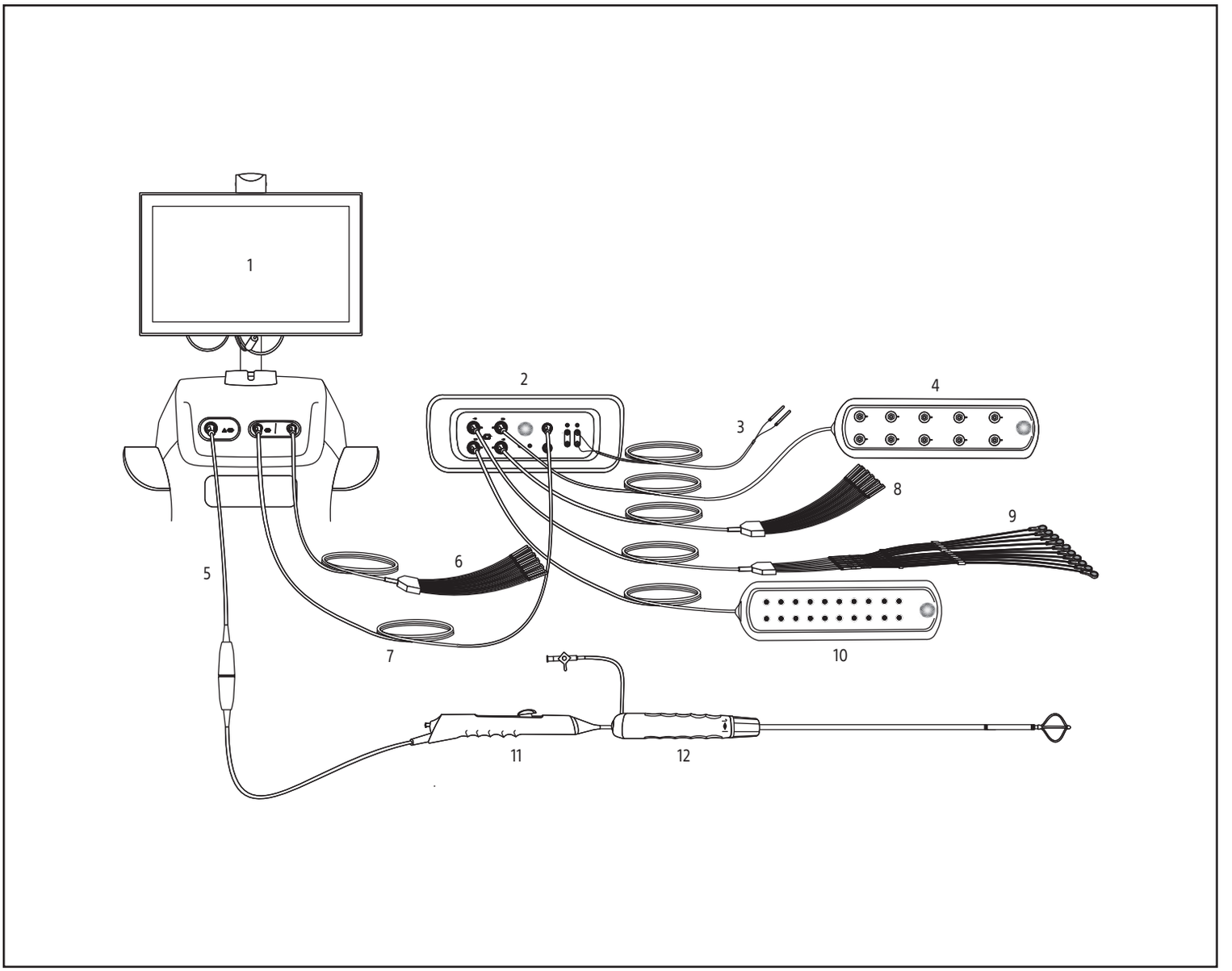

Figure 1a. System Setup Diagram (Including Components) — With Non-Navigation PFA Catheter

Figure 1a 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 — EGM Cable
7 — FARASTAR STIM Module Cable
8 — FARASTAR RSM Catheter Pin Cable
9 — FARASTAR RSM ECG Trunk Cable
10 — FARASTAR RSM EGM Input Module
11 — PFA Catheter
12 — Sheath

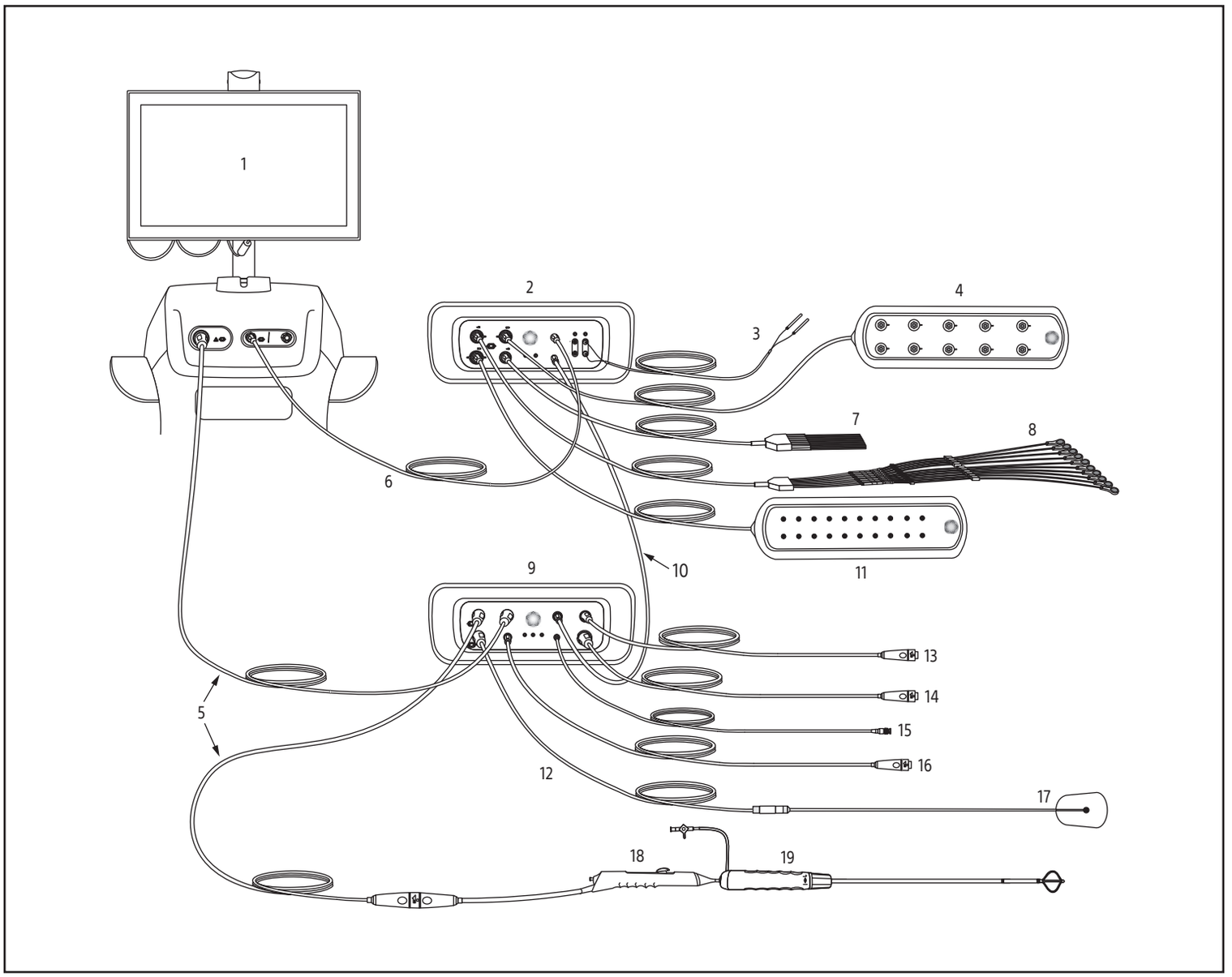

Figure 1b. System Setup Diagram (Including Components) — With Navigation-Enabled PFA Catheter

Figure 1b 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 STIM Module Cable
7 — FARASTAR RSM Catheter Pin Cable
8 — FARASTAR RSM ECG Trunk Cable
9 — FARASTAR MSM
10 — FARASTAR MSM Auxiliary Cable
11 — FARASTAR RSM EGM Input Module
12 — FARASTAR MSM Back Patch Cable
13 — FARASTAR MSM RHYTHMIA ABL Cable
14 — RHYTHMIA Breakout Box Cable
15 — FARASTAR MSM Module BNC-Phono Cable
16 — FARASTAR MSM Back Patch Cable Male
17 — RHYTHMIA Back Patch
18 — PFA Catheter
19 — Sheath

Component Name	Location/Use
FARASTAR PFA Generator	PFA Generator
PFA Catheter Components:	
PFA Catheter (either Navigation Enabled or Non-Navigation)	Ablation Catheter (Applied part, type CF defibrillation proof)
FARASTAR Catheter Connection Cable	Ablation Catheter to Generator 'CATH' (if using a navigation-enabled PFA catheter, see FARASTAR MSM User's Manual for connection with the FARASTAR MSM)
FARASTAR EGM Cable (12-lead cable) FARASTAR EGM to EP Recording System Cable (4-lead cable)	Generator 'EGM' connector to EP Recording System for ablation catheter EGM signals (Applied part, type CF defibrillation proof) Optional cable - Use either the 12-lead or 4-lead cable, depending on the PFA catheter
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 or C 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
Mapping System Module Components:	
FARASTAR MSM Back Patch Cable	FARASTAR MSM 'PATCH (PATIENT)' connector to Back Patch
FARASTAR MSM Back Patch Cable Male	FARASTAR MSM 'PATCH (RHYTHMIA)' connector to RHYTHMIA HDx Mapping System Patch connector
FARASTAR MSM Module BNC-Phono Cable	FARASTAR MSM 'ANALOG OUT (RHYTHMIA)' connector to RHYTHMIA HDx Mapping System Analog Input port
FARASTAR MSM RHYTHMIA ABL Cable	FARASTAR MSM 'RHYTHMIA ABL' connector to RHYTHMIA HDx Mapping System ABL IN port
RHYTHMIA Breakout Box Cable	FARASTAR MSM 'RHYTHMIA M/A/B' connector to RHYTHMIA HDx Mapping System A or B port
FARASTAR MSM Auxiliary Cable	FARASTAR MSM 'AUX IN' connector to FARASTAR RSM 'AUX' connector
FARASTAR RSM EGM Output to RHYTHMIA HDx EGM Input Cable	FARASTAR RSM 'EGM OUT' connector to RHYTHMIA HDx Mapping System 'B' port
FARASTAR RSM ECG Output to RHYTHMIA HDx ECG Input Cable	FARASTAR RSM 'ECG OUT' connector to RHYTHMIA HDx Mapping System 'ECG' input port

***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 FARASTAR PFA Generator is intended for use with a compatible Boston Scientific PFA catheter in cardiac ablation procedures. The FARASTAR PFA Generator is part of the FARAPULSE PFA System.

3. INDICATIONS FOR USE

Carefully review the individual PFA catheter Instructions for Use (IFU) for Indications for Use prior to use of the PFA catheter with the FARASTAR PFA Generator.

4. INTENDED PATIENT POPULATION

Carefully review the individual PFA catheter Instructions for Use (IFU) for Intended Patient Population information prior to use of the PFA catheter with the FARASTAR PFA Generator.

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 FARASTAR PFA Generator is contraindicated where such use may present an unacceptable risk to the patient. Refer to the contraindications section in the respective PFA catheter Instructions for Use.

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 a compatible 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).
- 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. Refer to the individual PFA catheter Instructions for Use (IFU) for specific information regarding use in anatomically sensitive areas, including the cavotricuspid isthmus.
- Do not directly touch the patient or any conductive surface when ablation energy is being delivered to prevent the risk of electric shock. Contact with patient or a conductive surface during energy delivery could result in discomfort.
- 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 to the hospital AC source as this could cause an increase in leakage currents.
- Ensure that each powered component used within the FARAPULSE PFA System are plugged into separate AC mains connections. Do not use a power bar to connect any combination of powered components together to an AC mains supply as doing this could cause an increase in leakage currents.
- During power delivery, the patient should not come into contact with metal parts which are electrically connected to earth ground or which have an appreciable capacitance to earth (such as operating table supports, etc.).
- When physiological monitoring equipment is used on the same patient, any monitoring electrodes should be placed as far as possible from the ablation electrodes. Needle monitoring electrodes are not recommended. Monitoring systems incorporating high frequency current-limiting devices are recommended.
- Ensure that equipment is used at 100VAC-240VAC, 50Hz/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.

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- 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 within 30 cm (12 inches) of 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 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.
- The FARASTAR MSM must be used to pass inputs to the Boston Scientific Mapping System, during use of the FARAPULSE PFA System, to avoid potentially damaging the Boston Scientific Mapping System components.
- If not using a device to automatically disconnect patient inputs, 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. As with other ablation systems, the FARAPULSE PFA System can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures.

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

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 16 and Cybersecurity parameters specififed in Section 16. 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.

	Shorter Power Cord		Longer Power Cord	
Geography	**Model Number**	**Length**	**Model Number**	**Length**
North America	M004FP6240	3.05 m or 3.66 m	M004PF61M63090	7.5 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.

Note: Newer versions of the FARASTAR PFA Generator include a Universal Serial Bus (USB) port on the rear of the unit. The USB port is disabled and non-functional. Do not use the USB port to connect to outside devices or networks.

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.
3. If using a navigation-enabled PFA catheter, connect the FARASTAR MSM as instructed in the FARASTAR MSM User's Manual.

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.

CAUTION: The FARASTAR MSM must be used to pass inputs to the Boston Scientific Mapping System, during use of the FARAPULSE PFA System, to avoid potentially damaging the Boston Scientific Mapping System components.

4. 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.
5. 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.

Note for the FARAPOINT PFA Catheter:
With the 12-lead FARASTAR EGM Cable, signal 1 corresponds to the TIP. Signals 6, 2, and 7 correspond with Ring 1 (R1), Ring 2 (R2) and Ring 3 (R3) electrodes, respectively.

With the 4-lead FARASTAR EGM Cable, signals 1, 2, 3 and 4 correspond to the TIP, Ring 1 (R1), Ring 2 (R2) and Ring 3 (R3) electrodes, respectively.

6. Ensure the FARASTAR RSM's TEST/NORMAL switch is in the NORMAL mode. (BLANK LED is not lit.)
7. 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.
8. 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.
9. Connect the Catheter Connection Cable to the FARASTAR PFA Generator CATHETER Connector.
10. 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 Table 1 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).

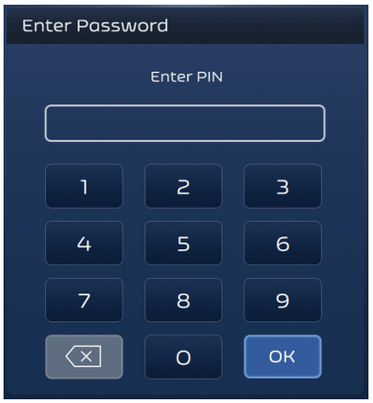

Figure 3. Initial Password Login Screen

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 Boston Scientific 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 a PFA catheter to enable therapy.

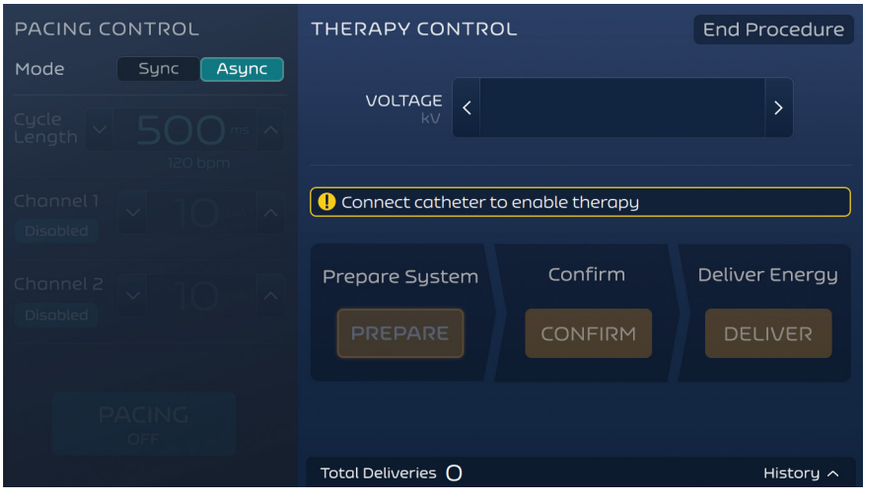

Figure 5. Therapy Screen — Asynchronous Mode — Catheter Selection

6. After selecting and connecting a PFA 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.

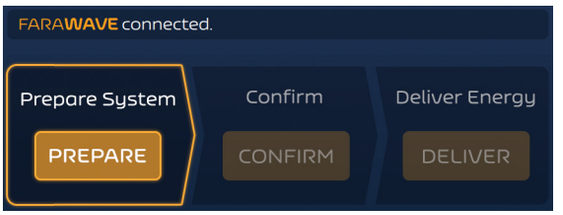

Figure 6. Therapy Screen — Asynchronous Mode — Idle State

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. The output pulse voltage at 2.0kV will have an average output within ± 5% of the voltage setting when applied to a fixed, non-inductive, 70-ohm power resistor.

2. After positioning the 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.

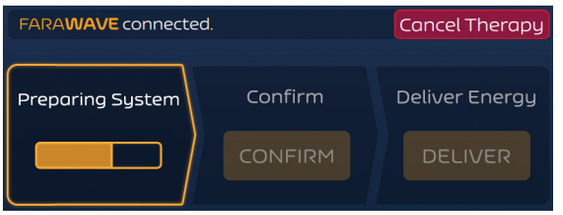

Figure 7. Therapy Screen — Asynchronous Mode — Preparing State

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.

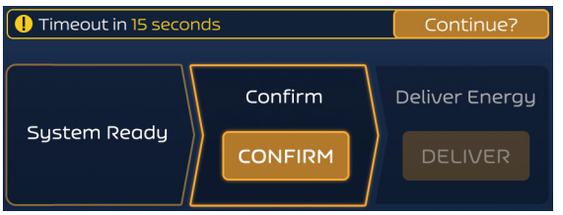

Figure 8. Timeout Warning Message

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

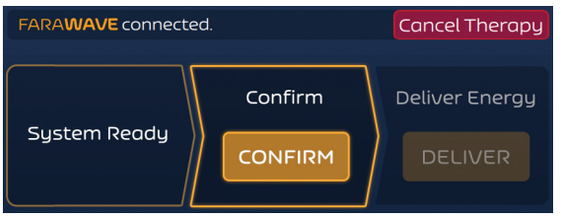

Figure 9. Therapy Screen — Asynchronous Mode — Confirm State

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

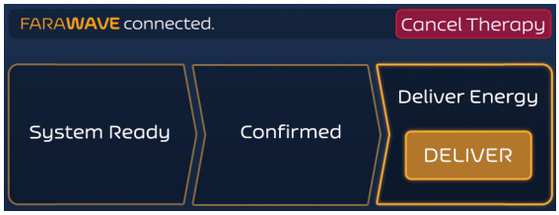

Figure 10. Therapy Screen — Asynchronous Mode — Ready to Deliver State

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).

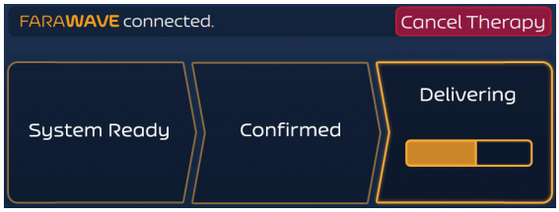

Figure 11. Therapy Screen — Asynchronous Mode — Delivery in Progress

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.

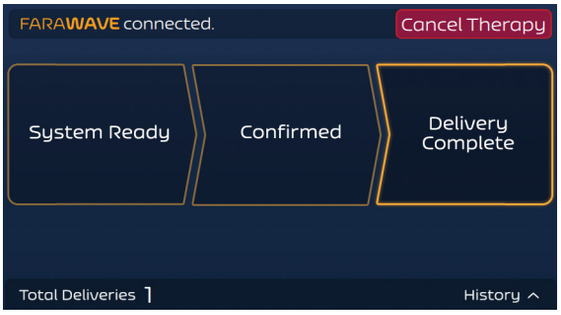

Figure 12. Therapy Screen — Asynchronous Mode — Delivery Complete State

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

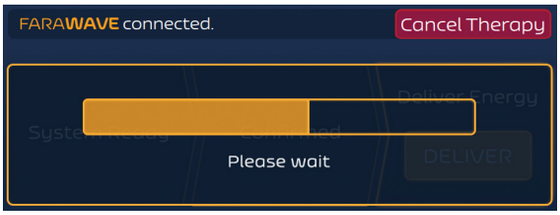

Figure 13. Therapy Screen — Asynchronous Mode — Between Deliveries Countdown State

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: If not using a device to automatically disconnect patient inputs, 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.

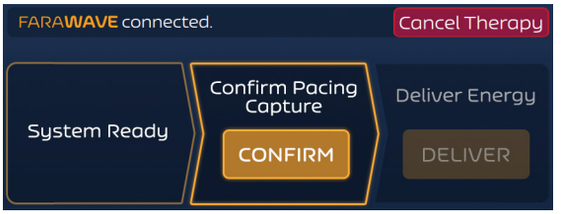

Figure 15. Therapy Screen — Synchronous Mode — Confirm Pacing State

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.

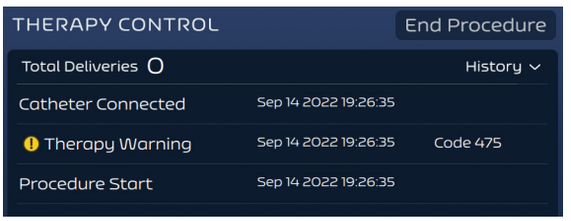

Figure 16. History Screen

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.

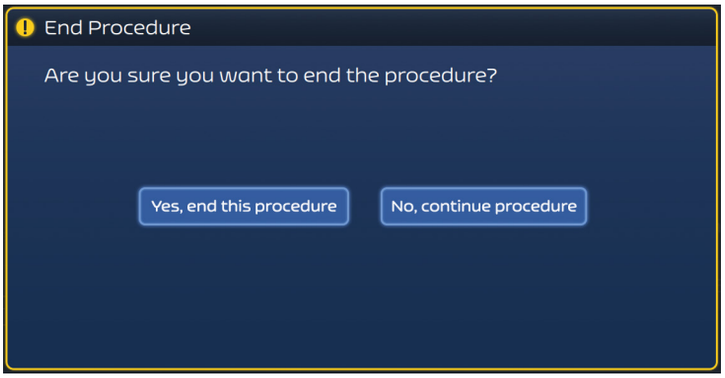

Figure 17. End Procedure Screen

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 PFA catheter is disconnected after the FARASTAR PFA Generator has been initialized, a warning message will appear. Re-connect the 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
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.			

Problem Category	System Notice Number	System Notice Type	Problem	Message
	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 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 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.
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.

Problem Category	System Notice Number	System Notice Type	Problem	Message
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 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.
Treatment Error	The FARASTAR PFA Generator verifies that the system completes the full ablation sequence. A message is displayed if the sequence is incomplete/interrupted. The message can be dismissed. If the condition persists, contact Boston Scientific.			
	309	Error	Treatment Error	Treatment has encountered an error. Please power-cycle the unit. If this condition persists, please contact customer service.
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.

Emissions Test	Compliance	Electromagnetic Environment
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.
Harmonic Emissions EN 61000-3-2	Class A	
Flicker Emissions IEC 61000-3-3	Complies	

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. System Error would indicate any essential performance loss or degradation due to EM disturbances.			
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 100 kHz burst	± 2 kV AC mains ± 1 kV I/O lines 100 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:  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	
Proximity Fields Immunity EN 61000-4-39	65 A/m RMS before modulation is applied, at 134.2 kHz test frequency with a 2.1 kHz pulse modulated square wave at 50% duty cycle. 7.5 A/m RMS before modulation is applied, at 13.56 MHz test frequency with a 50 kHz pulse modulated square wave at 50% duty cycle.	65 A/m RMS before modulation is applied, at 134.2 kHz test frequency with a 2.1 kHz pulse modulated square wave at 50% duty cycle. 7.5 A/m RMS before modulation is applied, at 13.56 MHz test frequency with a 50 kHz pulse modulated square wave at 50% duty cycle.	Close proximity magnetic fields should be that of a typical commercial or hospital environment.

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

13.4. Pass/Fail Criteria Definition

Test Category	Pass/Fail Criteria
Conducted Emissions	Class A – Group 1
Radiated Emissions	Class A – Group 1
Electrostatic Discharge	The system does not change state (charge or start an ablation) or freeze.[1]
Radiated RF EM Field	The system does not change state (charge or start an ablation) or freeze.[1]
Electrical Fast Transients/Bursts	The system does not change state (charge or start an ablation) or freeze.[1]
Surges Immunity	The system does not change state (charge or start an ablation) or freeze.[1]
Conducted Disturbances induced by RF fields	The system does not change state (charge or start an ablation) or freeze.[1]
Rated Power Frequency Magnetic Fields	The system does not change state (charge or start an ablation) or freeze.[1]
Voltage Dips	The system does not change state (charge or start an ablation) or freeze.[1]
Voltage Interruptions	The system does not change state (charge or start an ablation) or freeze.[1]
Proximity Fields Immunity	The system does not change state (charge or start an ablation) or freeze.[1]
Flicker Emissions	The system does not change state (charge or start an ablation) or freeze.[1]
Harmonic Emissions	The system does not change state (charge or start an ablation) or freeze.[1]
[1]Error messages may be displayed and the system may reboot as this does not present an unacceptable risk to the user or patient.	

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 components/accessories 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.
- Newer versions of the FARASTAR PFA Generator include a Universal Serial Bus (USB) port on the rear of the unit. The USB port is disabled and non-functional. Do not use the USB port to connect to outside devices or networks.

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. Please contact your local Boston Scientific representative to access the Software Bill of Materials (SBOM) and/or the Manufacturer Disclosure Statement (MDS2).

17. RISKS OF USING THE DEVICE OUTSIDE OF THE INTENDED USE ENVIRONMENT

Safety and Security risks are disclosed in the Warnings, Precautions, Adverse Events, Contraindications, and Cybersecurity sections. There are no known additional safety or security risks outside of those sections.

18. 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 Boston Scientific product was used, the event should be reported to Boston Scientific and the appropriate regulatory agency.

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

18.1 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

19. PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of the FARAPULSE PFA System and 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.

20. WARRANTY

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

21. 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.

BSC (MB IFU Template 8.5 x 11 Global, 92310050P), IFU, MB, FRSTR GENERATOR 1.4 (POINT) US, EN, 52024134-01A

Black (K) ΔE ≤5.0 | CMYK

MB Drawing 50573138

Table 1. Symbol Definitions

	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
	Universal Serial Bus
	Warning, electricity

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2025-06

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