FARAPULSE

FARASTAR™

Recording System Module

REF M004PFCE61M550, M004PFCE61M407

BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, MB, FARASTAR RSM, en, 51625759-01A

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FARASTAR™

Recording System Module

℞ ONLY

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

Note: The equipment documented in the Contents section (Recording System Module, cables, and input/output modules) 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)
One (1) FARASTAR RSM Catheter Pin Cable
One (1) FARASTAR RSM EGM Input Module
One (1) FARASTAR RSM ECG Output Module
One (1) FARASTAR RSM ECG Trunk Cable

1.2. FARASTAR RSM Specifications

Voltage	100V/50Hz–240V/60Hz, 1.5A–0.5A
External Fuses	250VAC, 1.6A, 215 Series Ceramic Fuse, Timelag, Cartridge, 5 mm diameter x 20 mm length
Power Supply Cord	See Section 12.1
IEC Compliance	IEC 60601-1 3.1 2012-08, Class I type CF defibrillation proof
Mode of Operation	Continuous
Weight	17 lbs/7.7 kg

System has no essential performance specifications.

1.3. System Components

The basic connection scheme is shown below:

BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, MB, FARASTAR RSM, en, 51625759-01A

MB Drawing 50573138
Black (K) ΔE ≤5.0 / CMYK

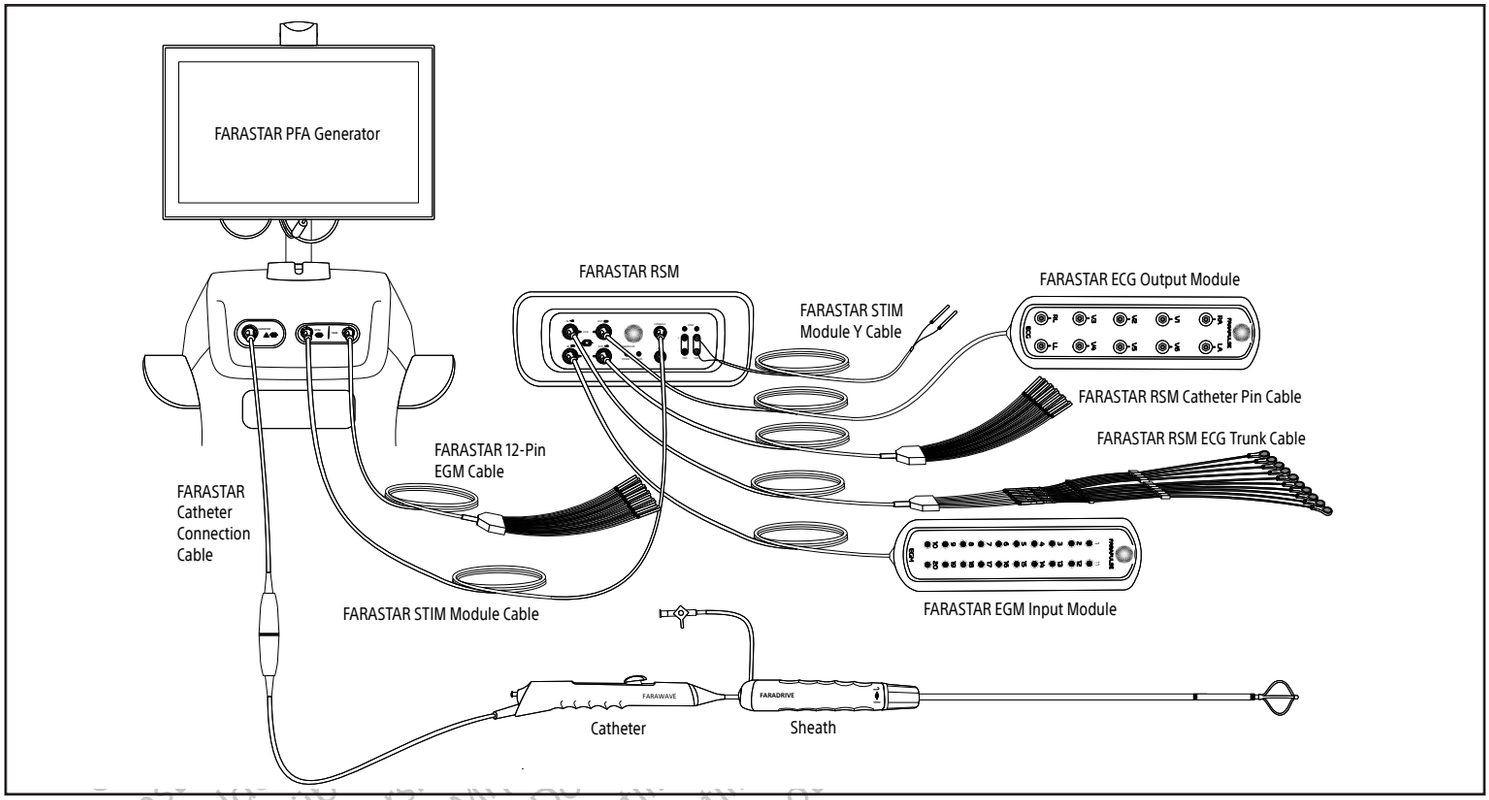


Figure 2. Recording System Module Connection Diagram

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
- Includes replaceable ECG Snap Leads (DIN Style) (applied part, type CF defibrillation proof), Cables & Sensors
- FARASTAR Recording System Module ECG Output Module
- 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

The internal operation of the FARASTAR RSM is shown as follows, for reference:

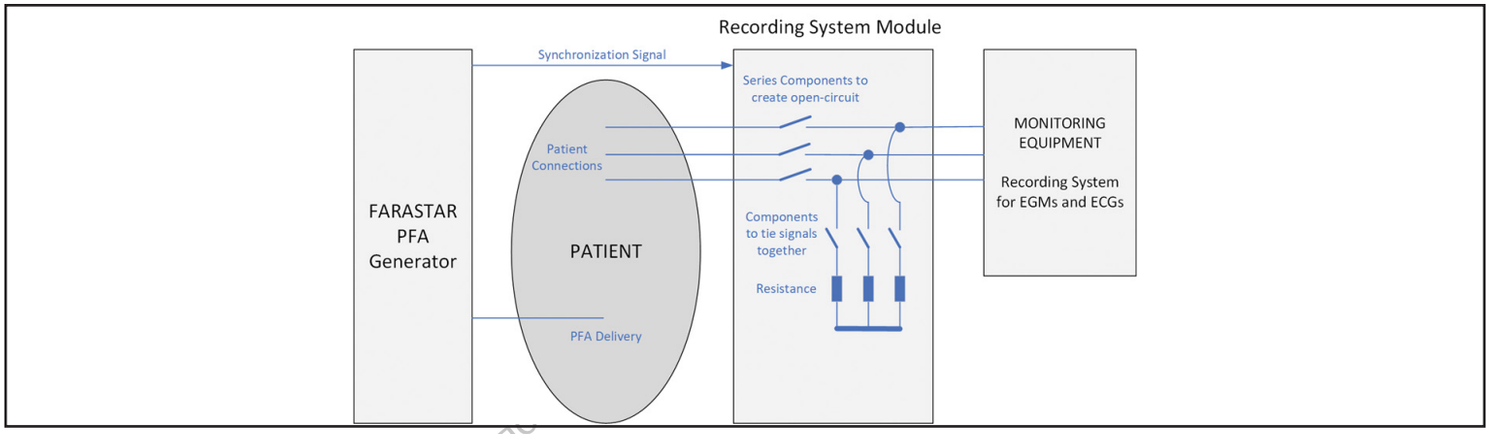


Figure 3. Basic treatment of signals through the FARASTAR RSM. Patient connections here include ECG and EGM signals.

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

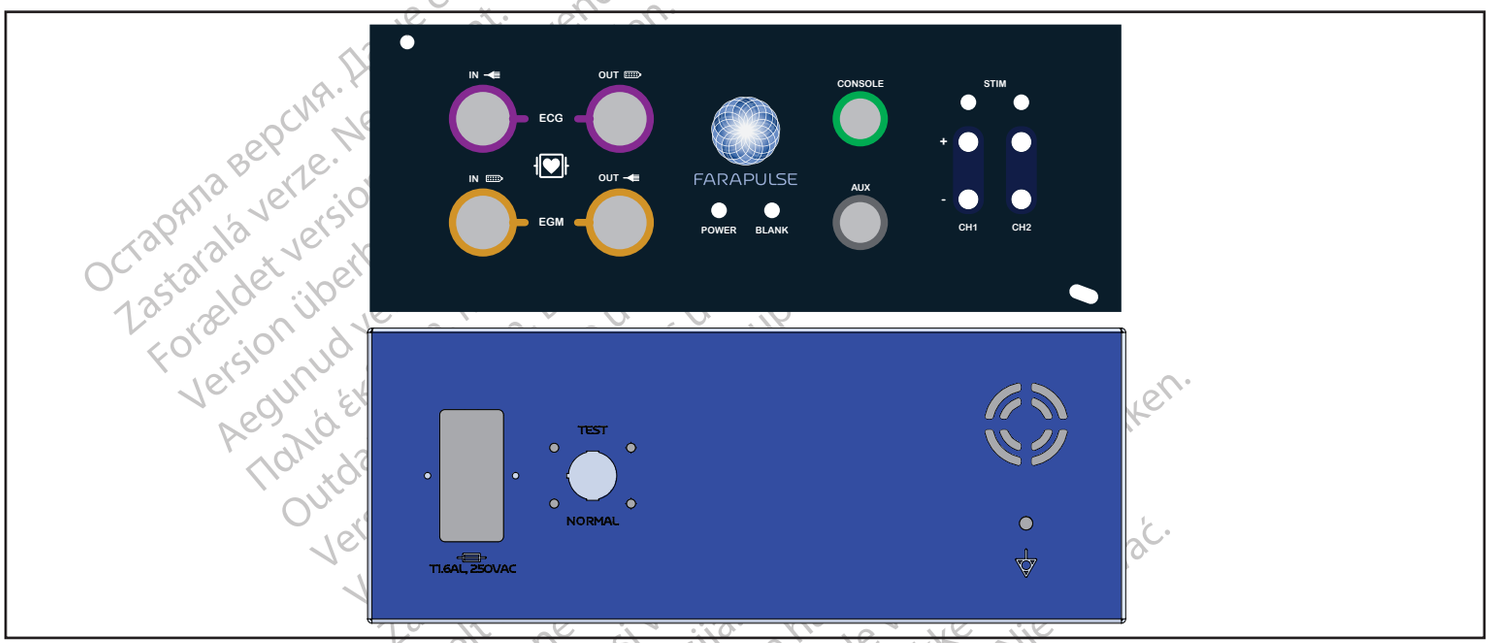


Figure 4. FARASTAR RSM External Panel Interfaces

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 the manufacturer.

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 use in adult (18 ≤ age ≤ 75 years) cardiac arrhythmia patients, excluding pregnant or nursing patients, as there are no studies to support the use of the FARAPULSE PFA System in patients who are pregnant, nursing, < 18 years of age, or > 75 years of age.

5. CLINICAL BENEFIT STATEMENT

The FARASTAR RSM is part of the FARAPULSE PFA System. Refer to the FARAWAVE PFA Catheter Instructions for Use for the Clinical Benefits of the FARAPULSE PFA System.

6. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (EUDAMED) website:

https://ec.europa.eu/tools/eudamed

7. 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.

8. 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 the manufacturer. 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 strip 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 100V/50Hz—240V/60Hz.

9. PRECAUTIONS

- This equipment is intended for use in hospitals except near active High Frequency (HF) surgical 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.
- 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 11.1.
- 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.
- 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 with a towel damped with water only.
- 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.

10. 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.

11. HOW SUPPLIED

The FARASTAR RSM and components are packaged together and provided as listed in the Contents section.

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

11.1. 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%

Transport and Storage Conditions

Temperature: -30 °C to 60 °C

Relative Humidity: 15% to 90%

11.2. Service Life

The expected service life of this equipment is 3 years.

12. OPERATIONAL INSTRUCTIONS

12.1. 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 models are designed for use with the FARASTAR RSM.

Model Number	Geography	Overall Length
M004FP6210	European Union (EU)	2.5 m
M004FP6220	Italy	2.5 m
M004FP6230	Australia / New Zealand	2.5 m
M004FP6240	North America	3.05 m
M004FP6250	Japan	2.5 m
M004FP6260	Switzerland	2.5 m
M004FP6270	United Kingdom (UK) / Ireland	2.5 m
M004FP6280	China	2.5 m
M004FP6290	Argentina	2.5 m
M004FP62100	Brazil	2.5 m
M004FP62110	Denmark	2.5 m
M004FP62120	Israel	2.5 m
M004FP62130	South Africa	2.5 m
M004FP62140	India	2.5 m
M004FP62150	Korea	2.5 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.

Disposal — Power Supply Cord

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

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

12.2. 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 included 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.

12.3. 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.

13. 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.

13.1. 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.

13.2. 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.

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic 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: ((ı)) 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.

For Users in the European Union

If you wish to discard this product(s), please contact your distributor or supplier for further information.

For Disposal in Countries Outside of the European Union

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

15. MAINTENANCE

- The FARASTAR RSM does not require any user periodic maintenance/calibration.
- Only trained and certified personnel may perform service or maintenance on the FARAPULSE PFA System. Contact your local Boston Scientific representative for service and technical support.
- 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 the manufacturer for evaluation.

16. 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.

17. CLEANING

- As needed, use a damp, non-abrasive cloth to clean the outer surfaces of the FARASTAR RSM, Power Supply Cord, and Cables.
- Do not use abrasive cleaners.
- 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.

18. CYBERSECURITY

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

19. 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 competent authority of the Member State in which the user and/or patient is established.

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

19.1. 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

20. 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.
- 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.

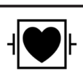
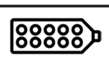
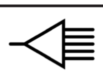
21. WARRANTY

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

22. SYMBOL DEFINITIONS

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

The following symbols appear on the FARASTAR RSM:

Symbol	Meaning	Location
	OFF (power) When a mains switch is moved to the position marked by this symbol, the FARASTAR RSM is OFF.	On the Power Switch.
	ON (power) When a mains switch is moved to the position marked by this symbol, the FARASTAR RSM is ON.	On the Power Switch.
	Defibrillation-proof type CF applied part	On patient side ECG and EGM connections and printed on label.
	Equipotentiality	On the Equipotential Ground Post on the unit.
	Fuse	On the rear, adjacent to the power supply cord inlet.
	ECG/EGM Module	On Patient side ECG and EGM Connections.
	ECG/EGM Cable	On Patient side ECG and EGM Connections.
	Non-ionizing electromagnetic radiation	This symbol does not appear on the device. The symbol is referenced by Section 13.2.

BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, MB, FARASTAR RSM, en, 51625759-01A

Black (K) ΔE ≤5.0 / CMYK
MB Drawing 50573138

Contents

Separate Collection

BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, MB, FARASTAR RSM, en, 51625759-01A

MB Drawing 50573138

Black (K) ΔE ≤5.0 / CMYK

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