Maestro™ 3000 Cardiac Ablation System

To orchestrate even the most complex ablation

Capability

- Maestro 3000 Pod allows connection of standard, high-power or cooled ablation catheters
- RF filtering allows continuous electrogram recording during power delivery

Control

- Real-time impedance monitoring throughout the procedure
- Display of average/maximum values for power, temperature and impedance

Convenience

- Optional Remote Control allows access to all generator functions from a distance up to 75 feet away
- Five programmable memory buttons save frequently used ablation configurations

Ordering Information

System Components

Model Number	Type	Description
M004 21000TC 0	Hardware	Maestro 3000 Controller
M004 21860T 0	Hardware	Maestro 3000 Pod

Cables and Accessories

Model Number	Type	Description	Length
M004 613 0	Cable	Maestro 3000 Pod to standard or high-power Catheter	10 ft.
M004 651 0	Cable	Maestro 3000 Pod to standard or high-power Catheter	3 ft.
M004 681 0	Cable	Maestro 3000 Pod to Chilli II™ Catheter	10 ft.
M004 653S 0	Cable	Maestro 3000 Pod to EGM	3 ft.
M004 21600 0	Cable	Maestro 3000 Pod to PAM	8 ft.
M004 21840 0	Hardware	RF Ablation System Foot Switch	n/a
M004 21880 0	Hardware	Maestro 3000 Remote Control	n/a
M004 SVGA25 0	Cable	Maestro 3000 Controller to Remote Control	25 ft.
M004 SVGA50 0	Cable	Maestro 3000 Controller to Remote Control	50 ft.
M004 SVGA75 0	Cable	Maestro 3000 Controller to Remote Control	75 ft.
M004 21010 0	Manual	Maestro 3000 System Operator's Manual	n/a
M004 21890 0	Software	Graphic User Interface (GUI) Software	n/a
M004 21892 0	Manual	Maestro 3000 System GUI Software Operator's Manual	n/a

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Indications: The Maestro 3000™ Cardiac Ablation System is indicated for use, in cardiac ablation procedures, with standard and high-power BSC cardiac ablation catheters such that the physician is referred to the individual Instructions for Use for catheter compatibility to the Maestro 3000 Cardiac Ablation System. Note Refer to the individual Directions for Use for catheter compatibility to the Maestro 3000 Cardiac Ablation System. It is also important to carefully review the specific indications, contraindications, warnings, precautions and adverse events included with each catheter, prior to use of the catheter with the Maestro 3000 Cardiac Ablation System.

Contraindications: Note: The contraindications listed in the catheter Directions For Use also apply to the use with the Maestro 3000 Cardiac Ablation System. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each catheter, prior to use of the catheter with the Maestro 3000 Cardiac Ablation System.

Warnings: The following warnings and precautions apply only to the Maestro 3000™ Cardiac Ablation Controller and its accessories. Refer to the appropriate catheter Directions for Use for Warnings, Precautions, and Adverse Events related to the catheter. Before operating the System, carefully review these warnings: The displayed temperature is not the maximum tissue temperature. Do not set the maximum temperature higher than 80°C. Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to: Retain temporary external sources of pacing available during ablation. Reprogram the pacing system temporarily to minimum setting or 000 mode to reduce risk of inappropriate pacing. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads. Perform complete pacing system analysis on all patients after ablation. The possibility of skin burns to the patient may exist whenever a high power Catheter is utilized. The use of Catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of components with unprotected male pin connectors must exercise extreme caution during device setup to prevent patient or operator injury. Unused pins should be secured so that they do not inadvertently touch other equipment or surfaces. Never insert pins into MAINS outlets or into any equipment other than systems providing patient electrical isolation in accordance with IEC 60601-1. The Pod output connection labeled “Recorder” must only be connected to a medically isolated recording system. Grounding reliability can only be achieved when the power supply cord is connected to a receptacle marked “Hospital Only” or “Hospital Grade”. Do not use an extension cord with the system and do not connect the system’s power supply cord to an additional multiple portable socket. Do not connect items that are not specified as a part of the system. Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input ports or signal output ports configures a medical system, and it therefore responsible that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical services department or your local BSC representative. If a Booker Box device is used with the system, it should be used with a DIP electrode that is separate from the DIP electrode used by the Controller. Electromagnetic interference (EMI) produced by the Controller during delivery of RF power may adversely affect the performance of other equipment. The user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the receiving device, Increase the separation between the equipment, Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected. Consult your local BSC field service technician for help. Failure of the RF generator could result in an unintended increase of output power. The use of accessories, transducers and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Maestro 3000 Cardiac Ablation System. Components of the Maestro 3000 Cardiac Ablation System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Maestro 3000 Cardiac Ablation System should be observed to verify normal operation in the configuration in which it will be used.

Precautions: Review the following precautions before using the System: Do not attempt to operate the BSC Maestro 3000 Cardiac Ablation System before thoroughly reading this Operator’s Manual. The “Impedance” Display of the Controller should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, RF power delivery should be discontinued. Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications. Read and follow the disposable Dispersive Indifferent Patch (DIP) Electrode manufacturer’s instructions for use. The use of DIP Electrodes, which meet or exceed ANSI/AAMI HF-18 requirements, is required. BSC recommends the use of Valley Labs DIP Electrodes, BSC model number 354. The entire area of the DIP Electrode should be reliably attached to the patient’s body. Placement on the patient’s back is recommended. When using high-power Catheters, it is required that two DIP electrodes be used. Apparent low power output or higher than typical impedance measurements may be indicative of faulty DIP Electrode application or failure of an electrical lead. Check the application of the DIP Electrode and all electrical connections before continuing or selecting higher power outputs. Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze. 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. The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children. Furthermore, the risk/benefit in asymptomatic patients has not been studied. The cables connecting the Catheter to the System should be positioned in such a way that contact with the patient or other leads is avoided. The Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the Catheter and DIP Electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces. The use of antistatic sheeting is recommended. The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the ablation site. Do not immerse the Controller, the Remote or accessories in any liquid. Avoid caustic or abrasive cleaners. Use of non-flammable agents for cleaning and disinfection is recommended. Flammable agents or solvents used for cleaning and disinfection should be allowed to evaporate before highfrequency surgery. Regularly inspect re-usable cables and accessories. In particular, cables and accessories should be checked for possible damage to the insulation. Boston Scientific relies on the physician to determine, assess and communicate to the individual patient all foreseeable risks of the cardiac ablation procedure. The System is designed to be connected to a single ablation catheter at a time. Do not attempt to connect multiple ablation catheters into the Pod, as this will cause unforeseen risks. BSC recommends that the Controller and Remote Control units be powered off at the end of each procedure in order to ensure that the self-test is performed before the next procedure. The power selected should be as low as possible for the intended purpose. The Pod is not intended to be sterilized and should remain outside of the sterile field. The Maestro 3000™ Cardiac Ablation System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Section 7.2. Portable and mobile RF communications equipment can affect the Maestro 3000 Cardiac Ablation System. It is advised not to use this equipment in proximity to the Maestro 3000 Cardiac Ablation System. Pins of connectors identified with the ESD warning symbol should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used. It is recommended that all staff involved in the assembly and/or installation of the Maestro 3000 Cardiac Ablation System receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.

Potential Adverse Effects: Please refer to Section 6.4 for ESD Procedures Adverse Events The potential risks or discomforts that may be associated with electrosurgical procedures can vary greatly in frequency and severity, and may necessitate additional medical intervention, including surgery. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each catheter, prior to use of the catheter with the Maestro 3000 Cardiac Ablation System.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

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