Boston Scientific
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MAESTRO 4000™
CARDIAC ABLATION SYSTEM

Cardiac Ablation System Specifications

MAESTRO 4000 Controller

Physical Dimensions	
Width	13.0 inches (33.1 cm)
Height	7.3 inches (18.6 cm)
Depth	16.5 inches deep (41.9 cm)
Weight	22 lbs. (10 kilograms)
Power Specifications	
Line Power	100-120/220-240VAC, 50/60Hz, 300VA
Current Rating	4 A @120VAC
Fuses	T4AL250V
Cable Lengths	
Power Cord	10 feet (3.0 meters)
Foot Switch Cable	10 feet (3.0 meters)
RF Generator Power Output	
RF Frequency	460 kHz
Maximum Output Power*	100 W for 100-W Pod/ 150 W for 150-W Pod
Maximum Output Voltage	132 Vrms (187 Vpk) with 100-W pod/ 162 Vrms (229 Vpk) with 150-W pod
Maximum Output Current (under normal operation)	1 A per dispersive pad

Pod

Physical Dimensions (Excluding Cable)	
Width	2.3 in. (5.8 cm)
Height	6.8 in. (17.3 cm)
Depth	6.2 in. (15.7 cm)
Weight	2.2 lb. (1.0 kg)
Pod Connectors	
Recorder	Quick Connect Connector
Catheter	9-pin Quick Connect Connector/Type CF/ Defibrillation-Proof
Indifferent Electrodes (Ground pads)	Standard male 2-pin for commercial pads/ Type CF-Defibrillation-Proof
Cable to Controller	
Length	15 feet (4.6 meters)
Connecter	14-pin metal quick connector
Pod Recorder Filters	
Low pass	referenced to the Indifferent electrode
Low Frequency Cutoff	-3 dB at 5 kHz ± 1 kHz

Remote Control Unit

Physical Dimensions	
Width	13.0 inches (33.1 cm)
Height	7.3 inches (18.6 cm)
Depth	7.5 inches deep (19.1 cm)
Weight	11 lb. (5 kg)
Power Specifications	
Line Power	100-120/220-240VAC, 50/60Hz, 25VA
Current Rating	1 A @120 VAC
Fuses	T1AL250V

* Maximum RF power setting is dependent on the catheter type used. Use catheters that have a rated accessory voltage higher than the RF Generator maximum voltage output for that catheter type.

MAESTRO 4000™ CARDIAC ABLATION SYSTEM

METRIQ™ Pump

Physical Dimensions	
Width	10.0 inches (25.5 cm)
Height	9.6 inches (24.5 cm) without pole clamp
Depth	8.0 inches (20.5 cm)
Weight	4.5 lbs. (2.0 kg)
Electrical Specifications	
Supply Voltage/AC Power Requirements	100-120VAC / 220-240VAC, 50/60Hz, 65VA
Current Rating	5A @120VAC
Fusest	F5AL250V
Technical Specifications	
Maximum Operating Back Pressure	35 psi (standby and ablation) 60 psi (purge)
Flow Rate Accuracy	-5%/+15% (6-30mL/min) -10%/+20% (2-5mL/min) +/- 20% (60mL/min)
Minimum Detectable Bubble Size	2µL

Controller Foot Switch

Physical Dimensions	
Width	6.0 inches (15.2 cm)
Height	4.6 inches (11.7 cm)
Depth	6.0 inches (15.2 cm)
Cable Length	10 feet (3.0 meters)

METRIQ Pump

INTENDED USE/INDICATIONS FOR USE

The MetriQ Pump is intended for use in conjunction with a BSC open-irrigated cardiac ablation catheter, MetriQ Irrigation Tubing Set, and Maestro 4000 Cardiac Ablation System to deliver irrigation solution into a patient during cardiac ablation procedures.

CONTRAINDICATIONS

There are no specific contraindications for use of the MetriQ Pump itself. However, users should read and understand specific indications, contraindications, warnings and precautions included with any open-irrigated cardiac ablation catheter used in conjunction with the pump.

WARNINGS

To avoid the risk of explosion, do not use the pump in the presence of flammable anesthetics or in an oxygen rich environment. The MetriQ™ Pump needs special precautions regarding EMC and needs to be installed and put into service according to the Electromagnetic Compatibility Information section of this manual. The pump should not be used adjacent to, or stacked with, other equipment that is sensitive to moisture. Moving parts such as the door, pole clamp and rotating pump head, while designed for safe operation, should be operated with care to prevent injury to the operator. Intentional misuse of the pump may cause serious injuries to operator and/or patient. The flow of irrigation fluid will stop when the alarm is activated due to bubble detection, occlusion detection, wrong pump motor speed, the user attempts to open the door during flow, or a System Fault is detected. To continue irrigation, all alarms must be attended immediately or insufficient irrigation may result. Loss of communication with the Maestro 4000 Controller will NOT stop the flow of irrigation fluid but will automatically switch from a HIGH ABLATION FLOW or LOW ABLATION FLOW rate to STANDBY FLOW. If the pump was STOPPED there will be no change. If the pump was in STANDBY flow it will not change the flow rate. The loss of irrigation flow rate may delay the procedure or require additional intervention. Hospital personnel are responsible for periodically verifying and monitoring the flow rate delivered to prevent improper infusion of irrigation fluid. Flow should be verified visually by noting the drip rate in the drip chamber. During use, monitor tubing set for visible bubbles and stop the pump if air bubbles are observed to prevent possible occurrence of embolism. Do not press the purge button while catheter is in the patient or embolism may occur. The bubble detector is necessarily disabled during purging. In the event of a power loss, the catheter must be withdrawn and all procedural steps must be restarted to reduce the risk of embolism. The MetriQ™ Pump is designed for use with the MetriQ Irrigation Tubing Set, the Maestro 4000™ Controller and the BSC Open-Irrigated catheters. Use of other types of RF controllers, tubing and catheters may cause improper operation of the pump and can result in improper irrigation resulting in serious consequences to the patient. The pump, catheter and tubing set are designed for use with standard irrigation solutions such as normal saline (0.9%). Specified flow rate accuracy MAY NOT BE maintained when used with incompatible fluids or delivery devices. Hospital personnel are responsible for verifying the use of proper irrigation fluid and ensuring the tubing is sufficiently primed to prevent possible occurrence of embolism.

ADVERSE EVENTS

Users should also read and understand the specific indications, contraindications, warnings and precautions included with any catheter used in conjunction with the Maestro 4000 Cardiac Ablation System. Potential adverse events associated with the MetriQ Pump when used with the Maestro 4000 Cardiac Ablation System are, but not limited to, the following: Additional intervention required, Arrhythmia, Burns, Cardiac Arrest, Cardiac Tamponade, Cerebral Vascular Accident (CVA), Complete Heart Block, Conduction Pathway Injury, Congestive Heart Failure, Death, Discomfort, Edema, Embolism, Esophagitis, Fistula, Infection, Injury (Not Otherwise Specified), Myocardial Infarction, Myocardial Trauma, Necrosis, Nerve Injury, Perforation, Pericardial Effusion, Pericarditis, Pleural Effusion, Prolonged Procedure, Renal damage/failure, Swallowing Disorders, Tissue Damage, Transient Ischemic Attack (TIA),Vasospasm, Vessel Occlusion, Vessel Trauma.

(Rev A)

MAESTRO 4000 Cardiac Ablation System

INDICATIONS FOR USE

The Maestro 4000 Cardiac Ablation System is intended for use with BSC cardiac ablation catheters in cardiac ablation procedures. Note: Refer to the individual catheter Directions for Use for catheter compatibility to the Maestro 4000 Cardiac Ablation System.

CONTRAINDICATIONS

There are no specific contraindications for use of the MetriQ Pump itself. However, users should read and understand the specific indications, contraindications, warnings, and precautions included with any cardiac ablation catheter used in conjunction with the System. Note: The contraindications listed in the catheter Directions For Use also apply to the use of the Maestro 4000 Cardiac Ablation System.

WARNINGS

Do not attempt to install or operate the MetriQ Pump before thoroughly reading the Operator's Manual, the Maestro 4000 Cardiac Ablation System Operator's Manual, and the BSC open-irrigated catheter's Directions for Use. All operating instructions should be read, understood, and followed carefully.

ADVERSE EVENTS

Users should read and understand the specific indications, contraindications, warnings, and precautions included with any catheter used in conjunction with the System. Potential adverse events associated with the Maestro 4000 Cardiac Ablation System are, but not limited to, the following: additional intervention required, arrhythmia, burns, cardiac arrest, cardiac tamponade, cerebral vascular accident (CVA), complete heart block, conduction pathway injury, congestive heart failure, death, discomfort, edema, electrical shock, embolism, esophagitis, exposure to biohazardous material, fistula, hematoma, infection, injury (not otherwise specified), laceration, myocardial infarction, myocardial trauma, necrosis, nerve injury, perforation, pericardial effusion, pericarditis, pleural effusion, prolonged procedure, renal damage/failure, respiratory distress/insufficiency, swallowing disorders, tissue damage, transient ischemic attach (TIA), vasospasm, vessel occlusion, vessel trauma.

(Rev A)

CAUTION Federal Law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. Boston Scientific relies on the physician to determine, assess, and communicate to each patient all foreseeable risks of the procedure.

Boston Scientific
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EP-366309-AA MAR2016