

METRIQ™ Pump

ExpertCare Service Program

Working together to maximize productivity and patient care

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EssentialCare

Detail	Benefit
100% parts, labor and replacement coverage	Predictable spending
24-hour access to technicians via phone	First line of help for improved uptime



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Technical Assistance Center 1-800-949-6708

For more information please contact your **Boston Scientific Electrophysiology Sales Representative**.

For full terms and conditions of these plans, please see the plan service agreement.

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)

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.

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