Boston Scientific

90892169-01

2016-02
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Blazer® Open Irrigated

Ablation Catheter

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℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Carefully read all ancillary device instructions prior to use including the Maestro 4000™ Controller Operator's Manual, MetriQ™ Pump Operator's Manual, and MetriQ Irrigation Tubing Set directions for use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications.

DEVICE DESCRIPTION

The Blazer Open-Irrigated Ablation Catheter (henceforth referred to as the Blazer OI Catheter) is a 7.5F (2.5 mm) quadrapolar open-irrigated ablation catheter designed to deliver radiofrequency (RF) energy to the 4 mm catheter tip electrode for cardiac ablation.

The Blazer OI Catheter is to be used with the Boston Scientific Corporation (BSC) Open-Irrigated System, which consists of: Maestro 4000 Controller, Maestro 4000 100 W Pod (limited to 50 W for the Blazer OI Catheter), MetriQ Pump, MetriQ Irrigation Tubing Set and BSC M0046710 Cable.

The Blazer OI Catheter incorporates an open-irrigated cooling mechanism through a tip that is partitioned into two chambers. The proximal chamber circulates normal saline (0.9 %) within the tip to cool the proximal electrode and mitigate overheating while the distal chamber allows the fluid to flow through six irrigation holes into the patient's vasculature, thereby cooling the tip/tissue interface. A luer connection at the proximal end of the handle connects the catheter to the MetriQ Irrigation Tubing Set, allowing the MetriQ Pump to generate the flow of saline to the catheter.

The electrode segment is comprised of a tip electrode and three ring electrodes. The tip electrode has an embedded temperature sensor and delivers RF energy for cardiac ablation. The ring electrodes record Electrogram (EGM) signals for mapping and deliver stimulus for pacing. The Blazer OI Catheter interfaces with standard recording equipment. The handle includes the electrical connector for the cable connection to the Maestro 4000 Pod and one luer fitting used to connect the catheter to the MetriQ Irrigation Tubing Set.

The Blazer OI Catheter offers a choice of three curve configurations: standard, large, and asymmetric. All curves come in a 110cm shaft length. Additionally, there is a 115cm length available in the large curve configuration.

The Blazer OI Catheter is shown in Figure 1. A system connectivity diagram (Figure 2) shows how the catheter connects to the Maestro 4000 Cardiac Ablation System.

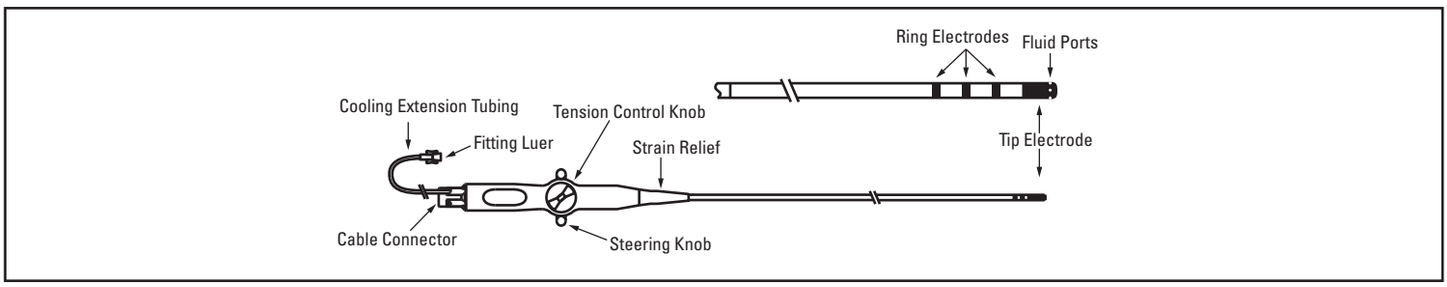

Figure 1. Blazer Open-Irrigated Ablation Catheter

User Information

The Blazer® OI Catheter is a component of the Open-Irrigated System and is to be used only by physicians fully trained in cardiac electrophysiology procedures. Assistance to prepare and load the MetriQ™ Irrigation Tubing Set, operate the MetriQ Pump and Maestro 4000™ Controller may only be provided by trained electrophysiology laboratory staff.

Contents

- One (1) Sterile Blazer Open-Irrigated Ablation Catheter

INTENDED USE / INDICATIONS FOR USE

The Blazer Open-Irrigated Ablation Catheter, when used with a Maestro 4000 Radiofrequency (RF) Controller and MetriQ Irrigation Pump, is indicated for:

- cardiac electrophysiological mapping
- delivering diagnostic pacing stimuli
- RF ablation of sustained or recurrent type I atrial flutter in patients age 18 years or older

CONTRAINDICATIONS

The Blazer Open-Irrigated Ablation Catheter is contraindicated for use in patients:

- with active systemic infection;
- with a mechanical prosthetic heart valve through which the catheter must pass;
- unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation;
- who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach;
- who are hemodynamically unstable;
- who have myxoma or an intracardiac thrombus;
- who have had a ventriculotomy or atriotomy within the preceding eight weeks.

WARNINGS

- Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology and in the techniques of open-irrigated RF powered catheter mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab.
- Carefully read all ancillary device instructions prior to use, including the Maestro 4000 Controller Operator's Manual, the MetriQ Pump Operator's Manual and the MetriQ Irrigation Tubing Set directions for use. Observe all contraindications, warnings, and precautions noted in these directions. Failure to do so may result in patient complications.

  Note: The Blazer OI Catheter is not designed to be compatible with the Maestro 3000™ Cardiac Ablation System.

- Before using, inspect the Blazer OI Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that may cause patient and/or user injury if the catheter is used. Do not use defective or damaged devices. Replace damaged device(s) if necessary.
- No modification of this equipment is allowed.
- Contents are supplied **STERILE** using an EO process and should be used by the "Use By" date on the device package. Do not use the device if past the "Use By" date. Do not use if sterile barrier is damaged as use of non-sterile devices may result in patient injury. If damage is found, call your BSC representative.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for this use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in prepubescent children.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Start the initial RF application at low power and carefully follow the power titration and the correlating flow rate procedures as specified in the instructions for use. A drop in impedance may be an indicator of lesion creation. Too rapid an increase in power during ablation, increasing power with a decrease in impedance, ablating at high power (>30 W) or insufficient flow rate may lead to perforation caused by steam pop, arrhythmias, damage to adjacent structures, and/or embolism. Collateral tissue damage is a possibility when using the catheter at the upper power setting (50 W) or durations longer than 60 seconds or with a decrease in impedance without moving the catheter tip. Power should be increased to >30 W only if lower energies do not achieve the intended result.
- Patients undergoing an atrial flutter ablation are at risk for complete AV block which requires the implantation of a temporary and or permanent pacemaker.
- There are no data to support the safety and effectiveness of this device in the pediatric population.
- Because the long term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children.
- Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism.
- During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces to minimize the potential for electrical shock.
- Electrodes and stimulating devices can provide paths of high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes as far away as possible from the ablation site and the dispersive pad. Protective impedances may reduce the risk of burns and permit continuous monitoring of the electrocardiogram during energy delivery.
- Before use, ensure irrigation ports are patent by infusing heparinized normal saline through the catheter tubing. Patency of irrigation ports is important to maintain cooling function and minimize risks of coagulum and char that may result in embolism as well as perforation caused by steam pop.
- Due to the design of the Blazer OI Catheter tip, the velocity of fluid exiting the irrigation ports may change based on rate and pressure of flushing. As long as there is fluid exiting each port, regardless of the velocity, the catheter is functioning as designed and may be used. However, if any irrigation port has no flow (or extremely low flow compared to adjacent ports) despite attempts to flush the irrigation port, do not insert the catheter in the patient as there may be potential risk of embolism.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
- Electrical recording or stimulation equipment must be isolated. Current leakage from any electrical equipment that is connected to the patient must not exceed 10 microamps for intracardiac electrodes. Care must be taken to ensure that any equipment used in connection with the BSC catheters be type CF, be defibrillation proof, and meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use to reduce the potential risk of inadvertent electrical shock.
- Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.
- Maximum catheter Rated Voltage: 93.5 Vrms (132 Vpk).
- Stimulation of cardiac tissues caused by pacing stimulus and/or RF energy may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns.
- Warnings for patients with implantable pacemakers and implantable cardioverter/defibrillators (ICDs):
  - Temporarily adjust tachytherapy settings of an ICD per the manufacturer guidelines during RF ablation as the device could reset or deliver inappropriate defibrillation therapy resulting in patient injury. The ICD could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reactivate the ICD's pre-operative pacing, sensing, and therapy parameters after the ablation procedure.
  - Temporarily reprogram the pacemaker per the manufacturer guidelines during RF ablation to a non-tracking pacing mode if pacing is likely to be required during the ablation. The pacemaker 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.
  - Have temporary external sources of pacing and defibrillation available.
  - Do not apply RF energy directly to a lead or to tissue immediately in contact with a lead because it could potentially damage the lead or lead function.
  - Perform a complete analysis of the implanted device function after ablation.
  - Fluoroscopic guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgment.
  - Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function.
  - During RF ablation, care must be taken not to deliver RF energy on or near the coronary artery even on the right side of the heart, as the resulting myocardial injury can be fatal.
  - Ablation in contact with any other electrodes alters the function of the catheter and can lead to thrombus, coagulum, or char formation that may result in embolism.
  - At no time should a Blazer OI Catheter be advanced or withdrawn when resistance is felt, without determining the cause. Valve damage, vascular and/or cardiac perforation is a risk with any intracardiac catheter.
  - Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is overtorqued and/or positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage.
  - Significant radiation exposure can result in acute radiation injury as well as dose-related risk for somatic and genetic effects. Take all appropriate measures to minimize radiation exposure to both patients and clinical staff.
- In the event of a suspected failure of the integrity of fluid flow through the Blazer OI Catheter or if there is a rapid temperature rise of greater than 15 degrees C noted on the Maestro 4000 Controller, the procedure should be stopped, and the Blazer OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the Blazer OI Catheter and the MetriQ Irrigation Tubing Set should be replaced. The replacement catheter and tubing set must be primed outside the body prior to insertion to reduce the risk of air embolism.
- Prior to the procedure, always identify the patient's risk of volume overload. Monitor the patient's fluid balance throughout the procedure and after the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.
- Excessive curves or kinking of the Blazer OI Catheter may damage internal wires and components, including the cooling lumen. This damage may affect steering performance and may cause patient injury.
- Manual bending and/or twisting of the distal curve can damage the steering mechanism and cooling lumens and may cause Blazer OI Catheter failure and patient injury.
- Do not scrub the tip electrode as this may result in irrigation port(s) occlusion and may lead to Blazer OI Catheter failure and/or patient injury.
- Use both fluoroscopy and electrograms to monitor the advancement of the Blazer OI Catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade.
- Do not deliver RF energy with the Blazer OI Catheter outside the target site. The Maestro 4000 Controller can deliver significant electrical energy and may cause patient injury.
- In the event of Maestro 4000 Controller cut-off (impedance or temperature), the Blazer OI Catheter must be withdrawn and the tip electrode cleaned of coagulum before RF energy is reapplied. Ensure that all of the irrigation holes are patent prior to reuse to reduce the risk of embolism and/or perforation.
- Verify effective contact between the patient and the dispersive pad whenever the patient is repositioned as patient movement may disrupt dispersive pad contact resulting in patient injury and/or extended procedure times.
- Inspect irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism.
- Always verify that the MetriQ Irrigation Tubing Set, Blazer OI Catheter and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing and Blazer OI Catheter can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system.
- Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution.
- This Blazer OI Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death.
- The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown.
- If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the atrial flutter procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of mural thrombus and/or thrombus in the left atrial appendage.
- Guiding catheters and/or long introducer sheaths present the potential for thromboembolic events. Pre-flush and maintain lumen patency with heparinized intravenous infusion.
- Do not wipe the Blazer OI Catheter with organic solvents such as alcohol, or immerse the handle cable connector in fluids. This may result in electrical or mechanical catheter failures. It may also result in an allergic reaction from the patient.
- Use only sterile saline and gauze pad to clean the tip.
- Irrigation flow during RF ablation may distort distal tip electrogram recordings due to the signal conductivity of the external cooling solution. Careful monitoring of additional intracardiac electrograms during RF application is recommended to reduce the possibility of inadvertent injury to adjacent structures if appropriate. Higher power coupled with higher flow rates may exacerbate the distortion of the EGM signal recordings.

PRECAUTIONS

- The Blazer® OI Catheter is designed for use with the Boston Scientific M0046710 Cable, the Maestro 4000™ Cardiac Ablation Controller the MetriQ™ Pump, and the MetriQ Irrigation Tubing Set.
- Do not use the temperature sensor to monitor tissue temperature. The temperature sensor located within the electrode will not reflect either electrode-tissue interface or tissue temperature due to the cooling effects of the saline irrigation of the electrode.
- Electromagnetic interference (EMI) produced by the Blazer OI Catheter when used in conjunction with the Maestro 4000 Controller during normal operation may adversely affect the performance of other equipment.
- The Blazer OI Catheter is not intended to be used with a RF generator output setting exceeding 50 W or 200 Volts peak.
- When used with The Blazer OI Catheter, the Maestro 4000 Controller must only be used in power control mode. (Temperature control mode may be affected by the cooling effects of the saline irrigation of the electrode).
- Do not use the Blazer OI Catheter in the proximity of magnetic resonance imaging (MRI) equipment because the MRI equipment may adversely impact the function of the Maestro 4000 Controller and the Maestro 4000 Cardiac Ablation System may adversely impact the MRI equipment's image quality.
- Use only dispersive pads which meet or exceed IEC 60601-1/IEC 60601-2-2 requirements and follow the dispersive pad manufacturer's instructions for use. The use of dispersive pads which meet ANSI/AAMI requirements (HF18) is recommended.
- Apparent low power output, high impedance reading or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive pad or failure of an electrical lead.
- The Blazer OI Catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. Do not rotate the handle and catheter shaft more than one and one-half (1 ½) full rotations (540°). If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall, before resuming rotation of the handle and catheter shaft.
- Do not insert or withdraw the catheter without straightening the catheter tip (returning the steering lever to neutral position).
- Electrophysiology catheters and systems are intended for use only in radiation shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines.
- Ensure that the cable /catheter connection remains dry throughout the procedure.
- The Blazer OI Catheter contains Bis (2-ethyhexyl) phthalate (DEHP). BSC has assessed the residual patient risk associated with phthalates in this device to be minimal; however, BSC has not assessed the residual patient risk associated with phthalates which may be contained in non-BSC ancillary devices required for use in conjunction with the Blazer OI Catheter.
- The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical suite.
- Patients undergoing a long irrigated ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely.
- Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the dilator or catheter.

POTENTIAL ADVERSE EVENTS

Potential adverse events which may be associated with catheterization and ablation include:

- allergic reaction (including anaphylaxis)
- angina
- arrhythmias (new or exacerbation of existing arrhythmias)
- arterial-venous fistula
- cardiac perforation
- cardiac/respiratory arrest
- catheter entrapment
- cerebrovascular accident (CVA)
- chest discomfort
- conduction pathway injury
- complete heart block (transient/permanent)
- complications of sedative agents/anesthesia
- congestive heart failure
- death
- effusion (pericardial/pleural)
- embolism (venous/arterial) (i.e., air embolism, cerebrovascular accident, myocardial infarction, pulmonary embolism)
- fluid volume overload
- hematoma
- hemorrhage
- hypertension
- hypotension
- infection
- lead dislodgement
- myocardial infarction
- nerve injury (phrenic/vagus)
- pericarditis
- pleuritis
- pneumothorax
- pseudoaneurysm
- pulmonary/pedal edema
- radiation exposure
- renal insufficiency/failure
- skin burns (radiation/defibrillator/cardiovertor)
- tamponade
- transient ischemic attack (TIA)
- thrombosis
- valvular damage
- vasospasm
- vasovagal reactions
- vessel trauma (perforation/dissection/rupture)

CLINICAL STUDIES

Boston Scientific conducted a clinical study (BLOCk-CTI) to establish a reasonable assurance of safety and effectiveness of radiofrequency cardiac ablation using the Blazer OI Catheter in the treatment of type I Atrial Flutter (AFL). The clinical study was conducted using a surrogate system consisting of the Stockert 70 Radiofrequency Generator and the CoolFlow® Irrigation Pump and Tubing Set. However, on the basis of the engineering testing and animal studies, the results of the BLOCk-CTI study may be extrapolated to the use of Blazer OI Catheter with the Maestro 4000 Generator and MetriQ Pump. These data from the clinical study are summarized below.

Objective

A multi-center clinical study was conducted using the Blazer OI Catheter. The purpose of the clinical study was to demonstrate that the Blazer Open-irrigated Investigational Catheter is non-inferior to that of the Control Catheters when used to ablate the cavo-tricuspid isthmus for the treatment of sustained or recurrent type I atrial flutter.

Study Design

BLOCk-CTI (Blazer Open-Irrigated Radiofrequency Catheter for the Treatment of Type I Atrial Flutter) was a prospective, randomized, controlled, single-blinded, multi-center U.S. investigation. A roll-in Cohort was introduced into the study for investigators to use the Blazer OI Catheter and a Control Catheter but these subjects were not part of the endpoint analyses. In this study, the Control devices were open-irrigated radiofrequency (RF) ablation catheters that received FDA market-approval for the treatment of type I atrial flutter and the Investigational device was the Blazer OI Catheter.

Patients were treated between January 17, 2011 and January 15, 2014. The database for this PMA reflected data collected through January 15, 2014 and included 302 patients. There were 24 investigational sites.

All adverse events and deaths reported in this study were reviewed and adjudicated by a Clinical Events Committee (CEC). The CEC was comprised of independent physicians, and its decisions were based upon independent physician review of data.

Study Endpoints

Primary Safety Endpoint

The Primary Safety Endpoint was the procedure-related complication- free rate at 7 days post-procedure. Procedure-related complications were defined as adverse events that are related to the ablation procedure or catheter and result in death, life threatening complication, or a persistent or significant disability/incapacity or required intervention to prevent impairment of a body function or damage to a body structure. The difference in procedure-related complication free rates between the randomized groups was calculated and compared against a 10% non-inferiority margin.

Primary Effectiveness Endpoint

The Primary Effectiveness Endpoint was Acute Success. Acute Success was defined as demonstration of bi-directional cavo-tricuspid isthmus (CTI) block 30 minutes following the last RF application in the CTI with the sole use of the randomized Investigational or selected Control Catheter only. Acute Success was evaluated for each randomized group and the difference between the two groups was compared against a 10% non-inferiority margin.

Secondary Effectiveness Endpoints

The Secondary Effectiveness Endpoint for the study was Chronic Success, evaluated separately for All Treated subjects (all subjects that had an ablation procedure) and Acute Success subjects (defined by the Primary Effectiveness Endpoints). Chronic Success was defined as freedom from recurrence of type I atrial flutter at 3 months post procedure. Subjects who were prescribed anti-arrhythmic drugs (AADs) for the treatment of type I AFL during the follow-up period were considered chronic failures. Chronic Success was evaluated in two secondary endpoints: Chronic Success in Acute Successes and Chronic Success in All Treated Subjects. The difference in chronic success rates between the randomized groups was compared against a 10 % non-inferiority margin.

Tertiary Objectives

The following was evaluated for differences between the Investigational and Control groups as tertiary objectives:

- Total procedure time (first catheter inserted to last catheter removed)
  - Procedure time for patients without concomitant arrhythmias ablated
  - Procedure time for patients with concomitant arrhythmias ablated
- Fluoroscopy time
  - Fluoroscopy time for patients without concomitant arrhythmias ablated
  - Fluoroscopy time for patients with concomitant arrhythmias ablated
- Total number of RF applications per patient
- Cumulative RF time per patient
- Frequency and severity of arrhythmia-related symptoms at 3 months post-procedure as compared to baseline

Patient Accountability

All subjects who signed the Informed Consent form were considered enrolled in the study and counted towards the enrollment ceiling. Subjects were classified as either part of the Roll-in cohort or the Randomized cohort.

Roll-in - To facilitate the investigator's familiarity with the Blazer OI Catheter and the EGMs, the study included a cohort of subjects considered to be "Roll-in" Subjects. Investigational sites without previous experience with the Blazer OI Catheter or the Control Catheter were required to utilize one Roll-in subject for each treatment arm. Roll-in requirements could be waived for investigational sites that had previous experience.

Randomized - Once the roll-in requirements were met at an investigational site, the subsequent enrolled subjects were part of the randomized cohort, and were randomized 1:1 to receive treatment with either the Control Catheter or the Investigational Catheter.

Enrolled subjects were further classified into the subject statuses described below.

Intent - A subject who had been enrolled but then withdrawn from the study and did not undergo the protocol-required ablation procedure.

Attempt - A subject who had been enrolled and had anesthesia or sedation administered in preparation for the ablation procedure but did not receive ablation therapy with the treatment or Control Catheter per protocol.

Treatment subject – A subject who had an ablation procedure and received ablation therapy with the Investigational or Control Catheter.

Each Primary Endpoint was analyzed based on Modified Intention-to-Treat, Per-Protocol, and As Treated Populations. The Modified Intention-to-Treat analysis included all Randomized Treatment subjects in their randomized group, regardless of compliance to the assigned treatment. The Per-Protocol analysis included subjects who were treated with the randomized catheter, had complete endpoint data, and had no major protocol violations. The As Treated analysis was done for each Primary Endpoint to account for one subject where the subject was randomized to the Investigational catheter but mistakenly treated with the Control Catheter. The As Treated analysis included subjects in the group for which they received treatment, regardless of randomization.

Table 1 shows the disposition of subjects in the BLOCk-CTI study. There were five subjects enrolled and classified as part of the Randomized cohort, but who withdrew prior to being randomized. Subjects that were randomized and underwent an ablation procedure were referred to as Randomized Treatment subjects, and these were the subjects eligible for endpoint analyses. Among the Randomized Cohort, there were 30 Randomized subjects classified as Intents (20 subjects) or Attempts (10 subjects). Since these subjects did not have an ablation procedure, they were not eligible for any endpoint analyses.

Subjects classified as Roll-ins, Not Randomized, Randomized Intents and Randomized Attempts were not included in endpoint analyses. Table 1 also summarizes the accountability of the Randomized Treatment subjects for inclusion in each endpoint analysis for each analysis type.

Table 1: Subject Disposition and Accountability for Endpoint Analysis

	Control	Investigational	Total
Enrolled subjects			302
Roll-In Cohort	17	30	47
Not Randomized	N/A	N/A	5
Randomized Cohort	125	125	250
Intents	10	10	20
Subject did not meet eligibility criteria	4	4	8
Subject refused testing/follow-up	1	1	2
Subject withdrawn by physician	2	3	5
Insurance issues	2	1	3
Lab equipment issues	1	1	2
Attempts	4	6	10
Subject did not meet eligibility criteria	3	3	6
Lab equipment issues	1	2	3
Subject anatomical issues	0	1	1
Treatment subjects (eligible for endpoint analysis)	111	109	220
3-Month Follow-Up Visit Completed	106	104	210
3-Month Follow-Up Visit Not Completed	5	5	10
Death	0	1	1
Withdrawals	1	3	4
Additional missed 3-month follow-ups	4	1	5
Endpoint Accountability for Randomized Treatment Subjects (n=220)			
Primary Safety: 7 Day Procedure-related Complications			
Modified Intention-to-treat	111	109	220
Per Protocol	111	107	218
Excluded due to randomization error *	0	1	1
Excluded due to withdrawal within 7 days	0	1	1
As Treated*	112	108	220
Primary Effectiveness: Acute Success			
Modified Intention-to-treat	111	109	220
Per Protocol	111	108	219
Excluded due to randomization error *	0	1	1
As Treated*	112	108	220
Secondary Effectiveness: Chronic Success in All Treated Subjects			
Modified Intention-to-treat	111	109	220
Secondary Effectiveness: Chronic Success in Acute Success Subjects			
Modified Intention-to-treat (Acute Success subjects only)	99	95	194

*One subject randomized to Investigational group was treated with the Control Catheter only.

There were four Randomized Treatment subjects that withdrew from the study. A summary of withdrawal reasons for these subjects is included in Table 2.

Table 2: Randomized Subjects Withdrawal Summary

Reason	Control	Investigational
Subject refused testing/follow-up	0	2
Subject "lost to follow-up"	1	1
Total	1	3

Study Population Demographics and Baseline Parameters

The average age of the subjects was 66 ± 10 years for the Control Group and 65 ± 11 years for the Investigational Group.

For both treatment groups, the majority of subjects were male. The Control Group enrolled 96 male subjects (76.8 %) and the Investigational Group enrolled 102 male subjects (81.6 %). There were 29 females enrolled in the Control Group, (23.2 %) and 23 female subjects enrolled in the Investigational Group, (18.4 %). The demographics of the study population are typical for an atrial flutter ablation study performed in the US.

Overall, there were no imbalances in baseline characteristics between the two treatment groups as shown in Table 3.

Table 3: Baseline Characteristics (Randomized Cohort N=250)

Characteristic	Measurement or Category	Control (N=125)	Investigational (N=125)	P-value
Age (years)	N	125	125	0.66
	Mean ± SD	66 ± 10	65 ± 11	
	Range	35 - 85	25 - 91	
Gender [N (%)]	Female	29 (23.2)	23 (18.4)	0.35
	Male	96 (76.8)	102 (81.6)	
Cardiac and cardiovascular disease history	Hypertrophic Cardiomyopathy [N (%)]	1 (0.8)	2 (1.6)	0.56
	Ischemic Cardiomyopathy [N (%)]	12 (9.6)	9 (7.2)	0.49
	Non-ischemic Cardiomyopathy [N (%)]	2 (1.6)	3 (2.4)	0.65
	Congestive Heart Failure (CHF) [N (%)]	22 (17.6)	17 (13.6)	0.38
	Coronary Artery Disease [N (%)]	44 (35.2)	44 (35.2)	1.00
	Hypertension [N (%)]	88 (70.4)	81 (64.8)	0.34
	Prior Myocardial Infarction [N (%)]	20 (16.0)	23 (18.4)	0.62
	Valvular Disease [N (%)]	22 (17.6)	27 (21.6)	0.43
Cardiac intervention/surgery history	Angiography/Angioplasty [N (%)]	13 (10.4)	12 (9.6)	0.83
	Stent [N (%)]	20 (16.0)	10 (8.0)	0.05
	CABG [N (%)]	25 (20.0)	24 (19.2)	0.87
	Device Implant (CRT) [N (%)]	1 (0.8)	0 (0)	0.32
	Device Implant (ICD) [N (%)]	8 (6.4)	5 (4.0)	0.39
	Pacemaker Implant [N (%)]	3 (2.4)	10 (8.0)	0.05
	Heart valve repair/ replacement [N (%)]	5 (4.0)	12 (9.6)	0.08
Significant non-cardiovascular disease history	Type II Diabetes [N (%)]	35 (28.0)	30 (24.0)	0.47
	Hyperlipidemia [N (%)]	75 (60.0)	77 (61.6)	0.80
Conduction disorder	1st Degree AV Block [N (%)]	13 (10.4)	17 (13.6)	0.44
	2nd Degree AV Block (Mobitz I) [N (%)]	2 (1.6)	9 (7.2)	0.03
	2nd Degree AV Block (Mobitz II) [N (%)]	2 (1.6)	0 (0)	0.16
History of Non-Type I AFL atrial arrhythmias	Atrial Fibrillation [N (%)]	57 (45.6)	72 (57.6)	0.08
	Atypical Atrial Flutter [N (%)]	2 (1.6)	2 (1.6)	1.00
	Sick Sinus Syndrome [N (%)]	9 (7.2)	7 (5.6)	0.61

RESULTS

Procedural Data

The goal of the ablation procedure was to produce bi-directional conduction block between the tricuspid annulus and inferior vena cava at the CTI. Subjects with type I atrial flutter were randomized to be treated with either the Investigational device or the Control device in the ablation procedure.

Three subjects were ablated for a concomitant arrhythmia, two subjects for atrial tachycardia and one subject for atrial fibrillation and atypical flutter, during the index procedure for type I atrial flutter.

Control Catheters Used

Investigators used a total of 112 Control Catheters as the initial catheter in the ablation procedure for 111 Randomized Control subjects and one (1) randomized to the Investigation group. The ThermoCool Open-Irrigated catheter (Biosense Webster) was the most frequently used catheter in the Control group (66/112), followed by the ThermoCool OI Nav catheters (32/112) and the St. Jude Medical Cool Path, Therapy Cool Path, and Safire BLU Duo Ablation catheters (14/112).

Ablation Parameters

The ablation parameters to achieve bidirectional block are shown in Table 4 for the Control and Investigational Catheters.

Table 4: Ablation Parameters*

Procedure Parameter	Measurement	Control N=111	Investigational N=109
RF Applications with randomized catheter	N	1262	1313
	Mean ± SD	14 ± 12	15 ± 10
	Range	1 - 71	1 - 67
Ablation Duration (seconds)	N	1260	1313
	Mean ± SD	96 ± 91	91 ± 78
	Range	0 - 999	0 - 742
Starting Power	N	1260	1306
	Mean ± SD	20 ± 2	19 ± 2
	Range	0 - 35	0 - 30
Max Power (W)	N	1259	1308
	Mean ± SD	36 ± 7	37 ± 9
	Range	0 - 50	0 - 50
Average Power (W)	N	1255	1301
	Mean ± SD	31 ± 7	32 ± 8
	Range	0 - 48	0 - 49
Max Temperature (°C)	N	1259	1300
	Mean ± SD	38 ± 5	33 ± 3
	Range	23 - 63	0 - 72
Average Temperature (°C)	N	1255	1301
	Mean ± SD	34 ± 4	29 ± 2
	Range	23 - 51	21 - 46
Max Impedance (Ω)	N	1254	1299
	Mean ± SD	141 ± 51	155 ± 46
	Range	62 - 999	0 - 940
Average Impedance (Ω)	N	1255	1300
	Mean ± SD	119 ± 30	132 ± 34
	Range	35 - 380	33 - 230

*Only includes data from randomized catheters.

Fluids Received During the Procedure

Procedural fluids administered via the Open-irrigated catheters and non-catheter sources were recorded as shown in Table 5. The investigational catheter used more fluid than the Control Catheter. Patients randomized to the Control Group received an ablation using any open irrigated RF ablation catheter with FDA market approval for the treatment of type I AFL, when used in conjunction with the catheter's corresponding market-approved generator and pump. Fluid infusion rates for the Control Catheter pump(s) were programmed per the manufacturer's instructions for use and some had lower flow rates than the Investigational Catheter. The choice of the Control Catheter used during the procedure was left up to the discretion of the Investigator.

Table 5: Fluid and Flow Rates Recorded During the Ablation Procedure

Fluid infusion	Measurement	Control	Investigational
Primary flow rate for RF applications <= 30 W	N	110	109
	Mean ± SD	18 ± 7	20 ± 6
	Range	8 - 30	15 - 30
Primary flow rate for RF applications > 30 W	N	110	107
	Mean ± SD	25 ± 7	30 ± 1
	Range	13 - 30	15 - 30
Total fluid infused through ablation catheter (mL)	N	108	108
	Mean ± SD	611 ± 433	699 ± 386
	Range	20 - 2346	50 - 1881
Total fluid infused through non-catheter sources (mL)	N	109	109
	Mean ± SD	449 ± 337	544 ± 416
	Range	0 - 1900	0 - 2000
Total fluid output from the patient (mL)	N	110	109
	Mean ± SD	113 ± 304	133 ± 393
	Range	0 - 1300	0 - 2200

Primary Safety Endpoint

The objective of the Primary Safety Endpoint was to demonstrate that the proportion of subjects free from procedure-related complications in the Investigational group is non-inferior to that in the Control group. The safety of the Blazer® OI Catheter was evaluated by the Procedure-related Complication-Free Rate at 7-days Post-procedure. The Primary Safety Endpoint was determined after all adverse events that occurred within seven (7) days of the procedure were adjudicated by an independent Clinical Event Committee.

The Primary Safety Endpoint analysis includes all Randomized Treatment subjects (111 Control and 109 Investigational). Based on the Modified Intention-to-Treat analysis (mITT), the 7 day Procedure-related Complication-free rate was 98.2 % in the Control group and 93.6 % in the Investigational group. The difference in the 7-day Procedure-related Complication-free rate between the Control and the Investigational groups was 4.6 %. The upper 95 % confidence bound of 9.78 % was less than the non-inferiority margin of 10 %, demonstrating non-inferiority between the two groups. The results of the Primary Safety Endpoint are shown in Table 6. The Primary Safety Endpoint results were consistent across three analysis cohorts (i.e. mITT, PP and AT) and supported the safety of the Blazer OI Catheter for the treatment of type I atrial flutter.

Table 6: Primary Safety Endpoint Results (Randomized Treatment Subjects N=220)

Analysis Cohort	Study Group	Subjects Event-Free	Treatment Subjects	Procedure-Related Complication-Free Rate	Difference (One-Sided Upper 95% Bound)	Endpoint Result
Modified Intention-to-Treat	Control	109	111	98.2%	4.6% (9.78%)	Pass
	Investigational	102	109	93.6%		
Per-Protocol	Control	109	111	98.2%	4.7% (9.98%)	Pass
	Investigational	100	107	93.5%		
As Treated	Control	110	112	98.2%	4.7% (9.89%)	Pass
	Investigational	101	108	93.5%		

Of the 220 Randomized Treatment subjects, 9 subjects (7 investigational and 2 Control) had procedure-related complications that are detailed in Table 7.

Table 7: Primary Safety Endpoint Events by Group (Randomized Treatment Subjects N=220)

Primary Safety Events	Investigational Group N = 109	Control Group n = 111
Cardiovascular Accident (CVA) Resulting in Death	1 (0.9%)	0
Congestive Heart Failure	0	1 (0.9%)
Hypotension	2 (1.8%)	0
Vasovagal Reaction	1 (0.9%)	0
Junctional Rhythm Requiring Pacemaker Implantation	1 (0.9%)	0
Pseudoaneurysm with Hematoma	0	1 (0.9%)
Pseudoaneurysm	1 (0.9%)	0
Urinary Tract Infection	1 (0.9%)	0
Total	**7* (6.4%)**	**2 (1.8%)**

*None of the primary safety events in the Investigational group was adjudicated by the Clinical Events Committee as related to the Blazer OI Catheter.

There were no device-related complications reported in the Randomized Treatment subjects.

There was one death reported during the course of the clinical study that was adjudicated by the Clinical Events Committee as procedure-related event. The subject was a 64 year old male with a medical history of coronary artery disease (CAD), hypertension, and myocardial infarction (MI) with coronary artery bypass graft surgery. The subject also had a history of chronic obstructive pulmonary disease (COPD), hyperlipidemia and asthma. There was no prior history of embolic phenomena and the subject was Class 1 for the New York Heart Association Functional Classification. The subject was on ASA (325mg.QD) for 21 days pre-procedure and Accupril for persistent type I atrial flutter. No anticoagulation therapy was administered prior to, during or after the ablation procedure. No transesophageal echocardiogram (TEE) was performed to exclude left atrial thrombus prior to the ablation procedure. The subject underwent CTI ablation using the Investigational Catheter and acute success was achieved without immediate complications. On day three post procedure, the subject presented to the Emergency Department with left sided weakness, facial droop, aphasia and dysarthria. Head CT was negative for acute intracranial hemorrhage. The diagnosis of ischemic stroke (right MCA distribution) was made. Shortly after thrombolysis therapy with IV tPA administrated within two hours of symptom onset, the subject deteriorated. Repeat head CT showed massive parenchymal hemorrhagic transformation of the infarct with massive effect and midline shift. The subject passed away on day four post procedure. The cause of the death was massive cerebral hemorrhage status post tPA for embolic stroke. The ischemic stroke could be attributed to inadequate peri-procedure anticoagulation and lack of pre-procedure TEE for exclusion of left atrial thrombus. Not performing a TEE prior to the ablation procedure in this subject with persistent AFL who was not anticoagulated pre-procedure was also a study protocol violation.

Primary Effectiveness Endpoint: Acute Success

The objective of the Primary Effectiveness Endpoint was to demonstrate that the proportion of subjects with Acute Success in the Investigational group was non-inferior to that in the Control group. Acute Success was defined as demonstration of bi-directional CTI block 30 minutes following the last RF application in the CTI, with the sole use of the randomized Investigational or selected Control Catheter.

The Primary Effectiveness Endpoint analysis includes all 220 Randomized Treatment subjects (111 Control and 109 Investigational). Based on the Modified Intention-to-Treat analysis, the Acute Success rate was 89.2 % in the Control group and 87.2 % in the Investigational group, respectively, as shown in Table 8. The difference in the Acute Success rates between the Control and the Investigational Groups was 2.0 %. The upper 95 % confidence bound of 9.4 % was less than the non-inferiority margin of 10 %, demonstrating non-inferiority between the two groups.. The results of the Per-Protocol and As Treated analyses were consistent with the mITT analysis and supported the effectiveness of the Blazer® Open-Irrigated Ablation Catheter for the treatment of type I atrial flutter.

Table 8: Primary Effectiveness Endpoint Results: Acute Success (Randomized Treatment Subjects N=220)

Analysis Cohort	Study Group	Successful Procedures	Total Procedures	% Success	Difference (One-Sided Upper 95% Bound)	Endpoint Result
Modified Intention-to-Treat	Control	99	111	89.2%	2.03% (9.37%)	Pass
	Investigational	95	109	87.2%		
Per-Protocol	Control	99	111	89.2%	2.15% (9.53%)	Pass
	Investigational	94	108	87.0%		
As Treated	Control	100	112	89.3%	2.25% (9.61%)	Pass
	Investigational	94	108	87.0%		

Secondary Effectiveness-Chronic Success

The objective of each of the Secondary Effectiveness Endpoints was to demonstrate that the proportion of subjects with Chronic Success in the Investigational group was non-inferior to that in the Control group. Chronic Success was evaluated for All Treated subjects and randomized subjects who had Acute Success separately.

Subjects that were followed through 3 months or had an ECG documented recurrence of type I atrial flutter with less than 3 months of follow-up were considered to have complete data. Subjects that withdrew or died with no arrhythmia recurrence or did not follow the protocol with regards to follow-up requirements were considered to have incomplete data. These subjects with incomplete data were reviewed to determine if there was sufficient data to determine Chronic Success. Subjects with insufficient data to determine Chronic Success were included in the analysis, but could not be considered as Chronic Successes, and therefore counted against the endpoint.

Among the 220 Randomized Treatment subjects, 19 (ten control and nine investigational) had incomplete data due to death (n = 1, one investigational), request to be withdrawn (n = 4, one control and three investigational), or missing follow-up ECG/visit (n = 14, nine control and five investigational).

Six subjects in the Investigational group (five acute successes and one acute failure) had ECG documented type I AFL recurrence during the 3 month follow-up period and thus were classified as chronic failures; no subjects from the Control group were classified chronic failures due to ECG documented type I AFL recurrence or on AADs for type I AFL during follow-up.

Chronic Success in Acute Successes

The analysis of this secondary endpoint was performed in the Modified Intention-to-Treat cohort and included only Randomized Treatment subjects who had Acute Success (99 Control and 95 Investigational). The Chronic Success rate was 89.9 % in the Control group and 85.3 % in the Investigational group, respectively. The difference in the Chronic Success rates between the Control and the Investigational groups was 4.64 %. The upper 95 % confidence bound of 12.64 % was greater than the non-inferiority margin of 10 %, resulting in failure to demonstrate non-inferiority between the two groups. The results of this secondary endpoint analysis are shown in Table 9.

Table 9: Chronic Success in Acute Successes (Randomized Treatment Subjects with Acute Success N=194)

Analysis Cohort	Study Group	Chronic Success	Total Acute Subjects	% Success	Difference (One-Sided Upper 95% Bound)	Endpoint Result
Modified Intention-to-Treat	Control	89	99	89.9%	4.64% (12.64%)	Fail
	Investigational	81	95	85.3%		

Chronic Success in All Treated Subjects

The analysis of this secondary endpoint was performed in the Modified Intention-to-Treat cohort and included all 220 Randomized Treatment subjects (111 Control and 109 Investigational). In this analysis, all acute failures were classified as chronic failures.

The Chronic Success rate was 80.2 % in the Control Group and 74.3 % in the Investigational group, respectively. The difference in the Chronic Success rates between the Control and the Investigational groups was 5.87 %. The upper 95 % confidence bound of 15.08 % was greater than the non-inferiority margin of 10 %, resulting in failure to demonstrate non-inferiority between the two groups. The results of this secondary endpoint are shown in Table 10.

Table 10: Chronic Success in All Treated Subjects (Randomized Treatment Subjects N=220)

Analysis Cohort	Study Group	Chronic Success	Total Treatment Subjects	% Success	Difference (One-Sided Upper 95% Bound)	Endpoint Result
Modified Intention-to-Treat	Control	89	111	80.2%	5.87% (15.08%)	Fail
	Investigational	81	109	74.3%		

The clinical study failed to statistically demonstrate non-inferiority in chronic success, a secondary effectiveness endpoint of the study. However, it should be noted that the study was not powered to test the non-inferiority hypothesis for chronic success. The observed difference in chronic success between the two study groups (about 5 %) is not considered clinically meaningful. The vast majority of the acute successes in the Investigational group with complete follow-up data had no type I atrial flutter recurrence during follow-up, supporting the effectiveness of the Blazer Open-Irrigated Ablation Catheter for the treatment of type I atrial flutter.

Data Summary on Tertiary Objectives

The tertiary objectives included procedure time, fluoroscopy time, number of RF applications, RF time, and changes in frequency and severity of arrhythmia-related symptoms. These data are summarized in Table 11.

Table 11: Tertiary Objectives Summary (Randomized Treatment Subjects N=220)

Tertiary Objective	Measurement	Control (N=111)	Investigational (N=109)
Total procedure time for subjects without concomitant arrhythmias ablated (minutes)	N	108	109
	Mean ± SD	94 ± 41	98 ± 34
	Minimum - Maximum	44 - 250	33 - 190
	Median	83	93
Total procedure time for subjects with concomitant arrhythmias ablated (minutes)	N	3	0
	Mean ± SD	153 ± 86	N/A
	Minimum - Maximum	84 - 249	N/A
	Median	127	N/A
Fluoroscopy time for subjects without concomitant arrhythmias ablated (minutes)	N	108	109
	Mean ± SD	14 ± 15	17 ± 10
	Minimum - Maximum	0 - 83	2 - 46
	Median	10	15
Fluoroscopy time for subjects with concomitant arrhythmias ablated (minutes)	N	3	0
	Mean ± SD	53 ± 65	N/A
	Minimum - Maximum	11 - 127	N/A
	Median	20	N/A
Total number of RF applications per patient	N	111	108
	RF applications per patient	12.4	13.6
Cumulative RF time per patient (seconds)	N	110	108
	Mean ± SD	1170 ± 976	1199 ± 842
	Minimum - Maximum	180 - 4739	159 - 4452
	Median	856	992
Change in frequency of arrhythmia-related symptoms (3 months-baseline)	N	106	104
	Mean ± SD	-6.9 ± 7.4	-7.8 ± 7.4
	Minimum, Maximum	-25, 15	-35, 11
	Median	-5	-6
Change in severity of arrhythmia-related symptoms (3 months-baseline)	N	106	104
	Mean ± SD	-5.3 ± 6.8	-5.9 ± 6.2
	Minimum, Maximum	-28, 11	-26, 7
	Median	-4	-4.5

STUDY CONCLUSION

The clinical study met its predefined success criterion by meeting both primary safety and effectiveness endpoints. There were no device related complications in the Investigational group.

The clinical study demonstrated non-inferiority of the Blazer OI Catheter to the control catheters in acute success (defined as the achievement of bidirectional cavo-tricuspid isthmus block), an accepted surrogate effectiveness endpoint for RF catheter ablation of type I atrial flutter (AFL). The clinical study failed to statistically demonstrate non-inferiority in chronic success, which was a secondary effectiveness endpoint of the study. However, it should be noted that the study was not powered to test the non-inferiority hypothesis for chronic success. Consistent with the results of other AFL ablation studies for similar technologies, approximately 95% of the subjects in the investigational group who had acute success and complete follow-up data were free of type I AFL recurrence during 3-month follow-up, the study's definition of chronic success. Moreover, the observed difference in chronic success between the two study groups (about 5%) is not considered clinically meaningful.

Taken together, the study results support a reasonable assurance of safety and effectiveness of the Blazer OI Catheter when used in accordance with the Indications for Use.

HOW SUPPLIED

The Blazer OI Catheter is supplied sterile using an ethylene oxide (EO) process. Peel-off labels for device and accessories can be used for device traceability. In addition to the Blazer OI Catheter, please refer to the Materials Required section below for a detailed list of other materials typically required in an Electrophysiology (EP) procedure.

- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.
- Do not use the device if past the "Use By" date.

MATERIALS REQUIRED

Intracardiac electrophysiology and cardiac ablation procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access. In addition to the Boston Scientific Blazer OI Catheter, the following materials, devices, and equipment will be required:

- Maestro 4000™ Controller (M00440000)
- Maestro 4000 Pod 100 Watt (M00440100)
- MetriQ™ Pump (M00441000)
- Blazer OI to Maestro 4000 Pod Cable (M0046710)
- MetriQ Irrigation Tubing Set (M0041170)
- Cable, Generator to Pump or Remote (20, 50 and 75 ft. length) (M0046610)

Accessories:

- Commercially available disposable dispersive pads that meet or exceed IEC 60601-1/IEC 60601-2-2 requirements (M0043540)
- Sterile, normal (0.9 %), heparinized (1 u heparin/ml) saline (commercially available)
- 8F (2.67 mm) Venous Introducer Sheath

Optional Equipment for the Maestro 4000™ Controller / MetriQ™ Pump System:

- Maestro 4000 Remote (M00440200)
- Maestro Footswitch (M004218500)
- MetriQ Pump Footswitch (M0044105F0)

Handling and Storage

Operating Environment

Ambient Temperature: 10 °C to 40 °C

Relative Humidity: 30 % to 75 %

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29 °C to 60 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

Storage Environment

Temperature: 15 °C to 30 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

SETUP AND OPERATIONAL INSTRUCTIONS

Caution: Before use, inspect the packaging for any violation of the sterile barrier and inspect the Blazer® OI Catheter for any defects. Do not use potentially contaminated or defective equipment.

Please refer to the Operator's Manuals for the MetriQ Pump, Maestro 4000 Controller and the MetriQ Irrigation Tubing Set for instructions on connecting and operating these systems in conjunction with the Blazer OI Catheter. Use appropriate Maestro 4000 Cardiac Ablation System accessory cables to connect the Blazer OI Catheter to the appropriate accessory equipment.

1. Attach the dispersive pad to the patient and Maestro 4000 Cardiac Ablation System per the manufacturer's operator's manual(s).
2. Connect the patient to an ECG recording system to facilitate arrhythmia monitoring per the standard operating procedure of the electrophysiology lab or manufacturer's operator's manual.

   Note: This should be done prior to introducing any intracardiac catheters.

3. Open the Blazer OI Catheter and Cable packages and the MetriQ Irrigation Tubing Set package. Carefully transfer the package contents into the sterile field, maintaining sterile technique.
4. Obtain vascular access via a vein (e.g. a femoral vein) by placing an 8F (2.67 mm) venous introducer sheath using a standard percutaneous technique under aseptic conditions.
5. Connect the Maestro 4000 Controller to the MetriQ Pump using the appropriate interface cable (M0046610). Note: the serial terminal that connects to the MetriQ Pump is labeled. Power on the MetriQ Pump but leave the Maestro 4000 Controller turned OFF.
6. Connect the Maestro 4000 Controller to a recording system with the appropriate interface cables according to the operators' manuals.

   Note: Make sure that the MetriQ Pump is in Automatic mode (displayed on the screen) and that the following flowrates are set on the pump: 2 ml/min (Standby), 17 ml/min (Low Ablation Flow - 30 W or less), 30 ml/min (High Ablation Flow - Above 30 W). Refer to the MetriQ Pump Operator's Manual for instructions on how to adjust the pump settings if required.

7. Connect the Blazer OI Catheter to the Maestro 4000 Controller via the Maestro 4000 Pod using the appropriate interface cables (M0046710 cable). The end of the cable with the red band should be inserted into the Maestro 4000 Pod while the end with all grey coloring inserts into the Blazer OI Catheter. Refer to Figure 2. Ensure that the cable / catheter connection remains dry throughout the procedure.

   Note: If a three-dimensional (3-D) catheter navigation and mapping system is going to be used, please follow the standard operating procedure of the electrophysiology lab or the directions for use contained in the manufacturer's operator's manual.

8. Ensure Power Control mode is enabled on the Maestro 4000 Controller.
9. The Controller's default temperature limit is 50°C, but can be set lower at physician discretion.
10. Refer to either the MetriQ Tubing Set or MetriQ Pump DFU for instructions to connect the MetriQ Irrigation Tubing Set to irrigation fluid and install into the MetriQ Pump.
11. Connect the Blazer OI Catheter to the MetriQ Irrigation Tubing Set via the luer fitting at the proximal end of the catheter handle. Care must be taken to ensure all luer fittings are secure to prevent leaking.
12. Purge the Blazer OI Catheter and MetriQ Irrigation Tubing Set using the triple arrow purge button on the MetriQ Pump. Fluid should exit all six (6) irrigation ports during the flushing process. Assure that no air remains within the MetriQ Irrigation Tubing Set or lumen and all irrigation ports are patent.
13. Check the catheter steering by articulating the steering knob prior to inserting the catheter in the sheath.
14. Before placing the Blazer OI Catheter in the sheath, begin continuous irrigation at a flow rate of 2ml/min, i.e. standby flow. Check for any leaks at the tip of the Blazer OI Catheter (other than normal saline flowing out of the distal ports), at the Blazer OI Catheter handle, and at the luer connections and tubing joints.
15. Under fluoroscopic guidance, insert the Blazer OI Catheter into the sheath and advance through the vasculature into the heart.
16. The degree of tip deflection of the Blazer OI Catheter is controlled by the Steering Knob on the Blazer OI Catheter handle (See Figure 1). If the Steering Knob is turned in a clockwise direction from its neutral position, the tip will curve proportionately up to a maximum of 270 degrees in one direction depending upon the curve option selected. Turning the Steering Knob in the counter- clockwise direction will cause the tip to deflect in the opposite direction. To prevent overstressing the tip, the Steering Knob movement is limited by the handle design. The tension adjust knob may be used when the desired catheter placement is achieved.
17. Determine the area of interest for ablation.
18. Set the initial power level to 15 W - 20 W.
19. Increase the irrigation flow rate to 17 ml/min up to 5 seconds before the onset of RF energy delivery and maintain this higher flow rate until 5 seconds after termination of the energy application. Then return the flow rate to 2 ml/min.

    Note: Confirm the increased irrigation flow rate prior to onset of RF energy by observation of a decrease in tip electrode temperature of at least a 2 °C. If it is necessary to ablate with power levels of 31 W - 50 W, irrigation flow rate should be increased to 30 ml/min starting 5 seconds before onset and ending 5 seconds after RF energy delivery. Then return the flow rate to 2 ml/min.

20. Start the procedure at 15 W - 20 W. Power may be increased by 5 W - 10 W increments as needed to create a transmural lesion. A greater than 80 % reduction in unipolar electrogram amplitude or emergence of double potentials of equal and low amplitude may be indicators of a transmural lesion.

    Note: Too rapid an increase in power during ablation, ablating at high power (>30 W) or insufficient flow rate may lead to perforation caused by steam pop, arrhythmias, damage to adjacent structures, and/or embolism.

21. Do not ablate for greater than 60 seconds in duration without moving the tip of the Blazer OI Catheter.
22. RF current may be reapplied to the same or alternate sites using the same catheter.

End of Procedure

1. Prior to removing the Blazer OI Catheter, straighten the distal end of the Blazer OI Catheter completely.
2. Withdraw the Blazer OI Catheter when the procedure is finished.
3. Turn off Maestro 4000 Controller and MetriQ Pump.
4. Carefully monitor patient while in recovery to ensure hemostasis is achieved and any complications are immediately treated.

Troubleshooting

Problems	Possible Cause	Corrective Action Procedure
Temperature not displayed	Poor catheter/cable connections	1. Verify that the M0046710 Cable is plugged into both the Maestro 4000 Pod and Blazer OI Catheter. 2. Replace cable and/or catheter. 3. If the Maestro 4000 still does not display temperature, there may be a malfunction in the temperature sensing system. 4. Consult the user manual and correct this malfunction prior to reapplying RF energy.
• Impedance cutoff • Temperature cutoff	Char/coagulum on tip electrode	1. Discontinue RF delivery. 2. Straighten the distal end and withdraw Blazer OI Catheter. 3. Inspect tip electrode for any char/coagulum. 4. If present, gently wipe the tip section with a sterile gauze dampened with sterile saline (do not scrub or twist the tip electrode as damage to the tip electrode bond may occur and loosen the tip electrode). 5. Prior to reinsertion, ensure the irrigations ports are patent. If irrigation port occlusion occurs: a. Ensure Blazer OI Catheter is removed from the patient. b. Fill a 1 ml or 2 ml syringe with sterile saline and attach to the stop-cock sidearm of the Blazer OI Catheter. c. Carefully inject the saline from the syringe into the Blazer OI Catheter. Fluid should exit all six (6) irrigation ports during the flushing process. d. Repeat steps b and c, if necessary. e. If the irrigation ports are cleared, the Blazer OI Catheter can be reintroduced into the patient. WARNING: Do not continue to use the Blazer OI Catheter if still occluded.
Suspected failure of fluid flow integrity	Leak in catheter and/or irrigation tubing set Irrigation pump out of calibration	1. Discontinue RF delivery. 2. Straightening the distal end and withdraw catheter. 3. Replace Blazer OI Catheter and Irrigation tubing set, prime outside of the patient. 4. Replace Blazer OI Catheter and/or Irrigation tubing set if parameters do not appear normal or if there is any abnormality of the integrity of fluid flow. 5. Refer to the MetriQ Irrigation Pump user manual to verify fluid flow is accurate. 6. Contact BSC representative to replace Irrigation pump.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

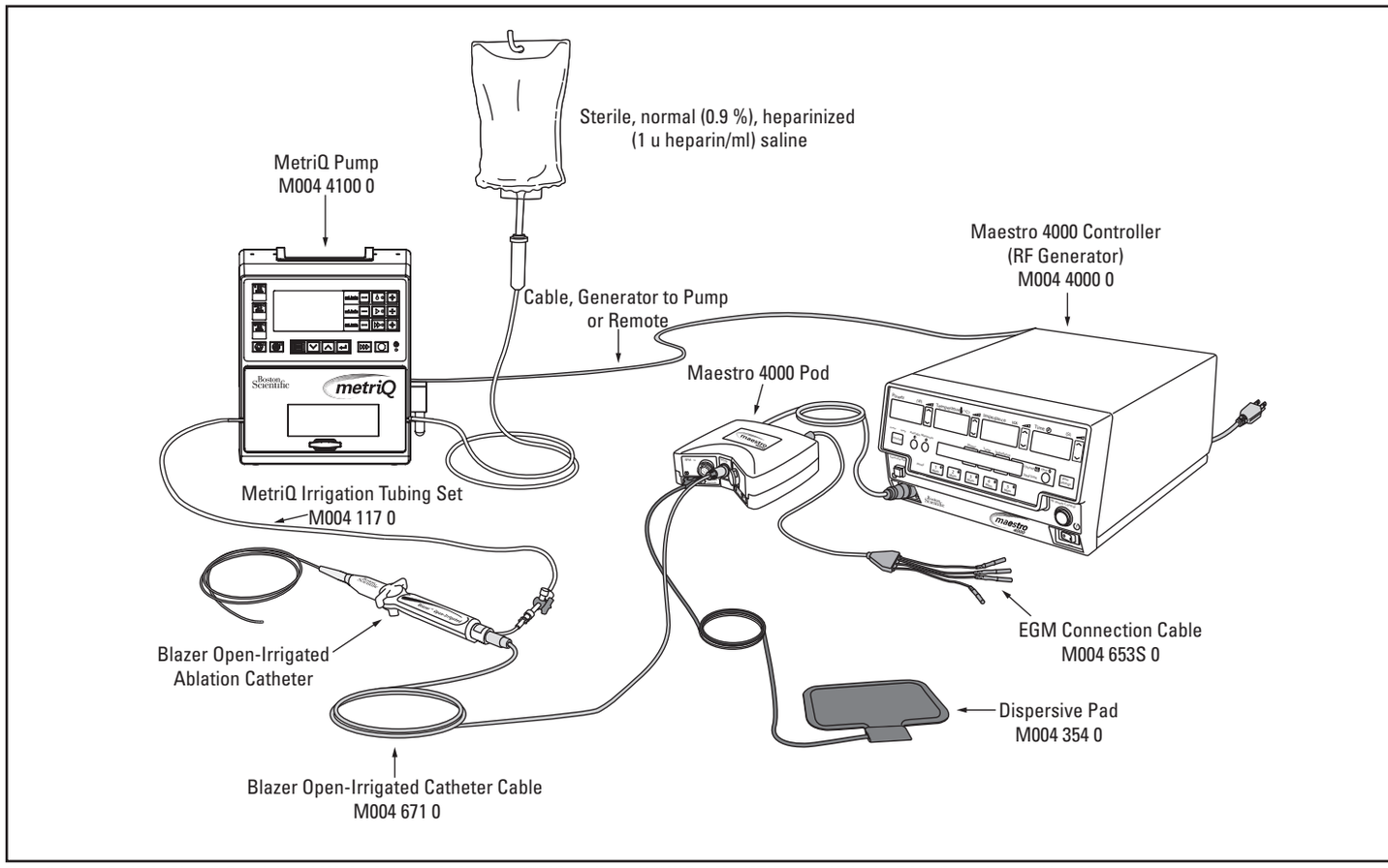

Figure 2. System Set Up for Blazer® Open-Irrigated Ablation Catheter with Maestro 4000™ Controller and 100 W Pod, MetriQ™ Pump and Irrigation Tubing Set, and compatible cables

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

Boston Scientific (Master Brand DFU Template 8.2677in x 11.6929in A4, 90105918AR), eDFU, MB, Blazer Open-Irrigated, en, 90892169-01B

SPINE WIDTH

This artwork is not ready for release until this note is removed. Engineer must verify spine width. Remove note after layout has been adjusted.

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TUR **Turkey Local Contact**

Boston Scientific Tıp Gereçleri Ltd. Şti.
Altunizade Mah. Ord. Prof. Fahrettin Kerim Gökay Cad. 45/1
Üsküdar 34662, Istanbul
Tel +90 216 544 47 00
Faks +90 216 544 47 01

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Made in USA:
560 Cottonwood Drive
Milpitas, CA 95035
USA

Do not use if package is damaged.

Recyclable Package

CE 0344

Component	Model
Maestro 4000™ Controller	M00440000
Maestro 4000™ Pod 100 W	M00440100
Maestro 4000™ Pod 150 W	M004EPT40100
Maestro 4000™ Remote Control	M00440200
Maestro Foot Switch	M004218500

YYYY-MM

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Maestro 4000™ Cardiac Ablation System Operator's Manual

Boston Scientific

Maestro 4000™ Cardiac Ablation System

Operator's Manual

91081869-01A

Boston Scientific \Master Brand User's Manual Cover + Spine\Templates 17in + 1.15in lip\mil = 18.15in x 11in Global 91006969(AB)_MANUAL_USERS_Maestro 4000_MB_16-lang_91081869-01A_pretrans

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TABLE OF CONTENTS

WARNING: Do not attempt to operate the Maestro 4000™ Cardiac Ablation System prior to reading this entire Operator's Manual. All instructions should be understood, and followed carefully. For future reference, keep this manual in a convenient, readily accessible place.

℞ ONLY

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

DEVICE DESCRIPTION

Maestro 4000 Cardiac Ablation System

The Maestro 4000 Cardiac Ablation System is a non-sterile product that supplies radiofrequency energy to catheters during ablation procedures. The System is compatible with all BSC cardiac ablation catheters including BSC open-irrigated catheters used in conjunction with the MetriQ™ Pump and MetriQ Irrigation Tubing Set.

Note: Throughout this manual, the term "System" refers to the Maestro 4000 Cardiac Ablation System.

Maestro 4000 Controller

The Maestro 4000 Controller is an RF Generator specifically designed for cardiac ablation. It produces user-selectable power-controlled or temperature-controlled RF power output in the range of 0 watts to 150 watts into a nominal tissue impedance of 100 ohms. It delivers RF power via a monopolar method driving current between a single active electrode at the tip of the ablation catheter and one or two dispersive pads applied on the skin. When used with BSC open-irrigated catheters, the RF Generator communicates with the MetriQ Pump to coordinate delivery of RF energy with irrigation flow to the catheter tip.

Note: Throughout this manual, the term RF Generator, or Generator, refers to the Maestro 4000 Controller.

Maestro 4000 Pod

The Pod, which is connected to the RF Generator, allows connection to all BSC catheters and provides connections for dispersive pad(s) to complete the RF circuit. The Pod also connects to EP recording systems and provides RF filtering to allow continuous electrogram recording during RF delivery. The Pod model varies by operating territory and determines the maximum power setting allowed by the RF Generator.

Maestro 4000 Remote Control

The optional Remote allows the user to control the RF Generator with up to 75 feet (22.9 meters) between the user interface and the sterile field.

Maestro Foot Switch

The optional Foot Switch provides hands-free control to start/stop RF delivery.

Dispersive Pads

A Dispersive Pad provides external patient contact to complete the RF circuit. It disperses current over a large area to minimize damage due to heating of skin and underlying tissue. It is also known as the DIP (dispersive indifferent pad), ground pad, or return pad.

User Profile

The Maestro 4000™ Cardiac Ablation System should be used only by physicians fully trained in cardiac electrophysiology. EP lab staff members may prepare the Maestro 4000 Cardiac Ablation System for use and assist with operation of the RF Generator.

Contents

The RF Generator and Pod are packaged separately as:

- (1) Maestro 4000 Controller (M00440000)
- (1) Maestro 4000 Pod, 100 W (M00440100) or (1) Maestro Pod, 150 W (M004EPT40100)

Optional Accessories

The MetriQ™ Pump, Maestro 4000 Remote Control, Maestro 4000 Foot Switch, and communication cables required for optional equipment such as the MetriQ Pump, Maestro 4000 Remote Control, or connection to an EP recording system are packaged and sold separately.

- MetriQ Pump (M00441000)
- Maestro 4000 Remote Control (M00440200)
- Maestro 4000 Foot Switch (M004218500)
- Cable, Generator to Pump or Remote
  - 20 ft (M0046610)
  - 25 ft (M0046620)
  - 50 ft (M0046630)
  - 75 ft (M0046640)
- Pod to EGM Cable (M004653S0)

INTENDED USE/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. 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 4000 Cardiac Ablation System.

CONTRAINDICATIONS

There are no specific contraindications for use of the Maestro 4000 Cardiac Ablation System 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. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each catheter, prior to use of the catheter with the Maestro 4000 Cardiac Ablation System.

ADVERSE EVENTS

Users should also 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 use of 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 Attack (TIA)
- Vasospasm
- Vessel Occlusion
- Vessel Trauma

HOW SUPPLIED

The Maestro 4000 Cardiac Ablation System components are supplied as non-sterile in corrugated boxes. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Operating Environment

Ambient Temperature: 10 °C to 40 °C
Relative Humidity: 30% to 75%
Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29 °C to 60 °C
Relative Humidity: Uncontrolled
Atmospheric Pressure: Uncontrolled

Storage Environment

Temperature: 15 °C to 30 °C
Relative Humidity: Uncontrolled
Atmospheric Pressure: Uncontrolled

SYSTEM CONTROLS, DISPLAYS AND INDICATORS

The controls and displays for the Maestro 4000™ Cardiac Ablation System are located on the front panel of the RF Generator and are duplicated on the front panel of the optional Remote. These two control panels are identical except that the RF Generator's front panel also has an Isolated Patient Connection for the System's Pod. Since the front panels are the same, only the RF Generator front panel is illustrated in Figure 1.

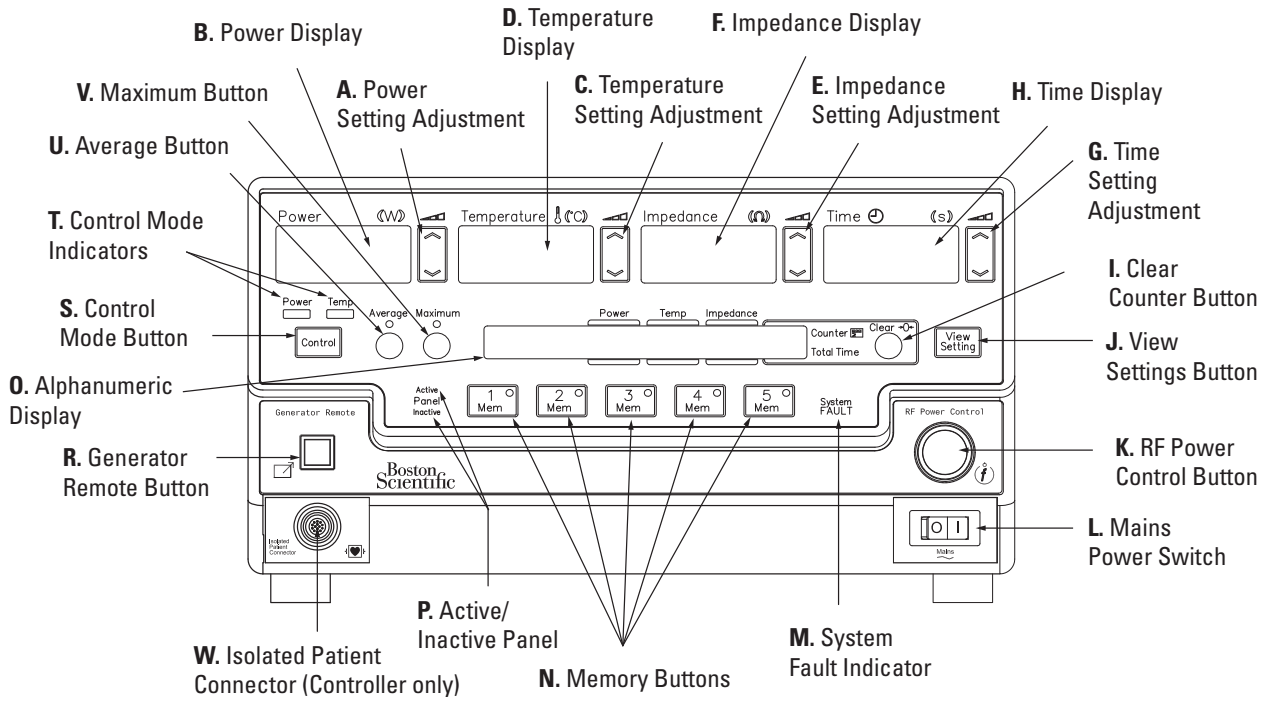

Figure 1. RF Generator Front Panel

Power Setting Adjustment

- A single press of a Power Setting Adjustment Button (▲/▼) will increase or decrease the RF power setting in 1-watt increments in both STANDBY and DELIVER states.
- Pressing and holding the Power Setting Adjustment Buttons (▲/▼) allows rapid scrolling of the RF power setting in STANDBY state only.
- The adjustment range varies by catheter/pod type (See Table 1 Adjustment Ranges for Power and Temperature).

Power Display

- In STANDBY state, the RF Power setting is displayed.
- In DELIVER state, the measured RF Power is displayed.
- Temperature Setting Adjustment: A single press of the Temperature Setting Adjustment Button (▲/▼) will increase or decrease the catheter tip temperature setting by 1 °C increments in both STANDBY and DELIVER states.
- Pressing and holding the Temperature Setting Adjustment Buttons (▲/▼) allows rapid scrolling of the catheter tip temperature setting in STANDBY state only.
- The adjustment range varies by catheter/pod type and the control mode selected (See Table 1 Adjustment Ranges for Power and Temperature).

Temperature Display

- In STANDBY state, the temperature setting is displayed.
- In DELIVER state:
  - Measured catheter tip temperature is displayed (between 15 °C and 95 °C).
  - Three dashes (---) will be displayed when the measured temperature is below 15 °C and above 95 °C.

Impedance Upper Limit Adjustment

- A single press of the Impedance Setting Adjustment Button (▲/▼) will increase or decrease the impedance upper limit setting by 1 Ω increments in both STANDBY and DELIVER states.
- Pressing and holding the Impedance Setting Adjustment Buttons (▲/▼) allows rapid scrolling of the impedance upper limit setting in STANDBY state only.
- The adjustment range for the impedance upper limit is 150 Ω to 300 Ω.

Impedance Display

- In STANDBY state, the impedance upper limit setting is displayed.
- In DELIVER state, the measured impedance is displayed.
- The impedance display will flash “HI” and RF power will shut off if the measured impedance rises above the upper limit during RF delivery.
- The impedance display will flash “LO” and RF power will shut off if the measured impedance falls below the low impedance limit for the catheter during RF delivery.
  - The low impedance limit for high-power catheters is 25 Ω.
  - The low impedance limit for non-high-power catheters is 50 Ω.

Time Setting Adjustment

- The Time Setting Adjustment Button increases or decreases the maximum duration for RF power delivery in one-second increments during STANDBY state only.
- A single press of the Time Setting Adjustment Button (▲/▼) will increase or decrease the time by 1 second.
- Pressing and holding the Time Adjust Buttons (▲/▼) allows rapid scrolling of the time setting.
- The range for the maximum duration setting varies by catheter type.
  - The range for open-irrigated catheters is 0 seconds – 999 seconds.
  - The range for all other catheter types is 0 seconds – 120 seconds.

  Note: The maximum duration must be set to at least 4 seconds to start RF delivery.

Time Display

- In STANDBY state, the setting for maximum duration of RF power is displayed.
- In DELIVER state, the display changes to zero seconds at the onset of RF delivery, and then counts up to the maximum duration (unless delivery is manually terminated).

Clear Counter Button

- The Clear Counter Button resets the count of valid RF deliveries to zero and resets the total RF delivery time to zero.
- This button is inactive during RF delivery.

View Settings Button

- During RF delivery, pressing and holding the View Settings Button temporarily displays the settings for Power, Temperature, Impedance, and Time instead of the measured values.

RF Power Control Button

- Press to start RF delivery while in STANDBY state.
- Press to stop RF delivery while in DELIVER state.
- Press to clear a DIAGNOSTIC message and exit DIAGNOSTIC state.

Mains Power Switch

- The Mains Power Switch turns the unit ON and OFF.

Memory Buttons

- Memory Buttons - allow RF delivery settings to be stored and recalled.
  - Select the desired Control Mode, Power, Temperature, Impedance, Time, and status of the Maximum and Average Buttons (ON or OFF)
  - To store these values, press and hold a Memory button for at least two seconds until audible tone confirms that settings have been saved.
  - To recall the settings, press and release the appropriate Memory button.
- The Memory buttons are inactive during RF power delivery.

Alphanumeric Display

In STANDBY state

- Measured temperature is displayed between 15 °C – 95 °C (Outside this range, the display reads "D06-TEMP OUT OF RANGE [15C-95C]").
- Measured impedance is displayed between 0 Ω-300 Ω (Over 300 Ω, the display reads "HI").
- Operational messages (M06 to M10) alert the operator to special conditions (without entering DIAGNOSTIC state). See OPERATIONAL MESSAGES Section for additional information.

In DELIVER state

- Operational messages (M02 to M05 and M11) alert the operator to special conditions affecting the delivery of RF (without entering DIAGNOSTIC state). See OPERATIONAL MESSAGES Section for additional information.

In Both STANDBY and DELIVER states

- The count of valid RF deliveries and total RF delivery time are displayed.
  - A valid delivery is defined as an RF application greater than 4 seconds.
  - After 999 deliveries, the counter will roll over to zero.
  - The total RF delivery time is displayed in MM:SS format.
- The counter should be cleared between patients.
  - Upon initial power ON, the counter clears automatically
  - Reconnecting a catheter within 20 minutes will not reset the counter. If a catheter is reconnected after 20 minutes, the counter will be reset.
- Average and maximum values for power, temperature, and impedance are displayed if the feature is selected.
- Diagnostic codes (D01 – D12) alert the operator to a diagnostic condition. See DIAGNOSTIC MESSAGES Section for additional information.

Generator-Remote Button

- The Generator-Remote buttons toggle the Generator and Remote Control panels between active and inactive states.
- All controls are functional on the active panel.
- The following controls remain fully or partially functional on the "inactive" panel:
  - The RF Power Control button can be used to stop RF power.
  - The Generator-Remote and View Settings buttons are fully functional.
- The Generator-Remote Button is inactive during RF power delivery.

Control-Mode Button

- Pressing the Control-Mode Button toggles the unit between the Power-Control and Temperature-Control modes of operation.
- The button is inactive during RF power delivery.

Average Button

- When the Average Button is pressed in STANDBY state, the average values of power, temperature and impedance for the previous ablation are shown in the alphanumeric display.
- When the Average Button is pressed in DELIVER state, the average values of power, temperature and impedance for the current ablation are shown in the alphanumeric display.

Maximum Button

- When the Maximum Button is pressed in STANDBY state, the maximum values of power, temperature and impedance for the previous ablation are shown in the alphanumeric display.
- When the Maximum Button is pressed in DELIVER state, the maximum values of power, temperature and impedance for the current ablation are displayed in the alphanumeric display.

Isolated Patient Connector

Provides for connection of the Pod to the RF Generator.

Front Panel Indicators

The front panel indicators include the following:

System Fault	Red	Indicates a System Fault has occurred.
Temperature Mode	Green	Indicates System is in Temperature-Control Mode
Power Mode	Green	Indicates System is in Power-Control Mode
RF Power Control	Flashing Amber	Indicates System is in STANDBY state
RF Power Control	Solid Amber	Indicates System is in RF DELIVER state
Memory	Green	Indicates settings are loaded from memory
Panel Active	Green	Indicates the Control Panel is active
Panel Inactive	Yellow	Indicates the Control Panel is inactive
Average	Green	Indicates the Average feature is active
Maximum	Green	Indicates the Maximum feature is active

Remote (Optional Accessory)

The Remote allows an operator access to all controls, displays, and indicators while at a distance from the RF Generator. The Remote can be connected to the RF Generator with cables of various lengths. All controls, displays, and indicators on the Remote have the same appearance and function as those on the RF Generator.

Foot Switch (Optional Accessory)

A Foot Switch with a 10 foot cable can be connected to the RF Generator. The Foot Switch provides hands-free control to start/stop RF delivery. The Foot Switch functions similarly to the RF Power Control button except that the operator must continuously hold the Foot Switch down for RF power to be delivered. RF power delivery is immediately terminated when the operator's foot is lifted off the Foot Switch.

Pressing and releasing the Foot Switch can also be used to clear diagnostic messages and exit diagnostic state.

SYSTEM INSTALLATION

This section provides installation instructions for the Maestro 4000™ Cardiac Ablation System.

- **WARNING:** No modification of this equipment is allowed other than the specified fuses, as this may result in electrical shock and/or other unexpected consequences.
- **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- **WARNING:** A Hospital Grade power cord (such as those supplied with the Maestro) must be used to connect the RF Generator or Remote Mains Power Inlet to an AC wall outlet designated as "Hospital Grade" or "Hospital Only."
- **WARNING:** 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.
- **WARNING:** Equipment connected to the analog and digital interfaces of the System 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 (or 60601-1 3rd edition). Any user who connects additional equipment to the signal input ports or signal output ports configures a medical system, and is therefore responsible for the compliance of that system with the requirements of the system standard IEC 60601-1-1 (or 60601-1 3rd edition).
- **WARNING:** Electromagnetic interference (EMI) produced by the RF Generator 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. The use of accessories, transducers and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the System. EMC installation and service information is provided in the Maestro 4000 Cardiac Ablation System Safety Specifications section.
- **WARNING:** Components of the Maestro 4000 Cardiac Ablation System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Maestro 4000 Cardiac Ablation System should be observed to verify normal operation in the configuration in which it will be used.
- **WARNING:** 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.
- **WARNING:** 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.
- **WARNING:** 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.). The use of antistatic sheeting is recommended.
- **WARNING:** Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
- **WARNING:** There is a possibility of skin burns to the patient during ablation therapy. The use of dispersive pads, which meet or exceed IEC 60601-2-2 requirements, is required. The entire area of the dispersive pad should be reliably attached to the patient's body as close to operating field as possible. Refer to the manufacturer's directions for use for proper application. When using BSC high-power catheters, it is required that two dispersive pads be used.

- **WARNING:** The Pod cable is permanently attached to the Pod. Do not attempt to loosen or remove this cable from the Pod. Do not attempt to rotate or twist the connector itself.

- **Caution:** 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 4000™ Cardiac Ablation System receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.
- **Caution:** Portable and mobile RF communications equipment can affect the Maestro 4000 Cardiac Ablation System. It is advised not to use this equipment in proximity to the Maestro 4000 Cardiac Ablation System.
- **Caution:** Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications.

- **Note:** The RF Generator, Pod, and if used, the Remote Control and Foot Switch, are intended for installation within the Patient Environment.

  Note: The Patient Environment is described per IEC 60601-1 as any volume in which intentional or unintentional contact can occur between Patients and parts of the System, or between Patient and other persons touching parts of the System.

RF Generator Rear Panel

This section describes the connections and controls on the rear panel of the cardiac RF Generator shown in Figure 2.

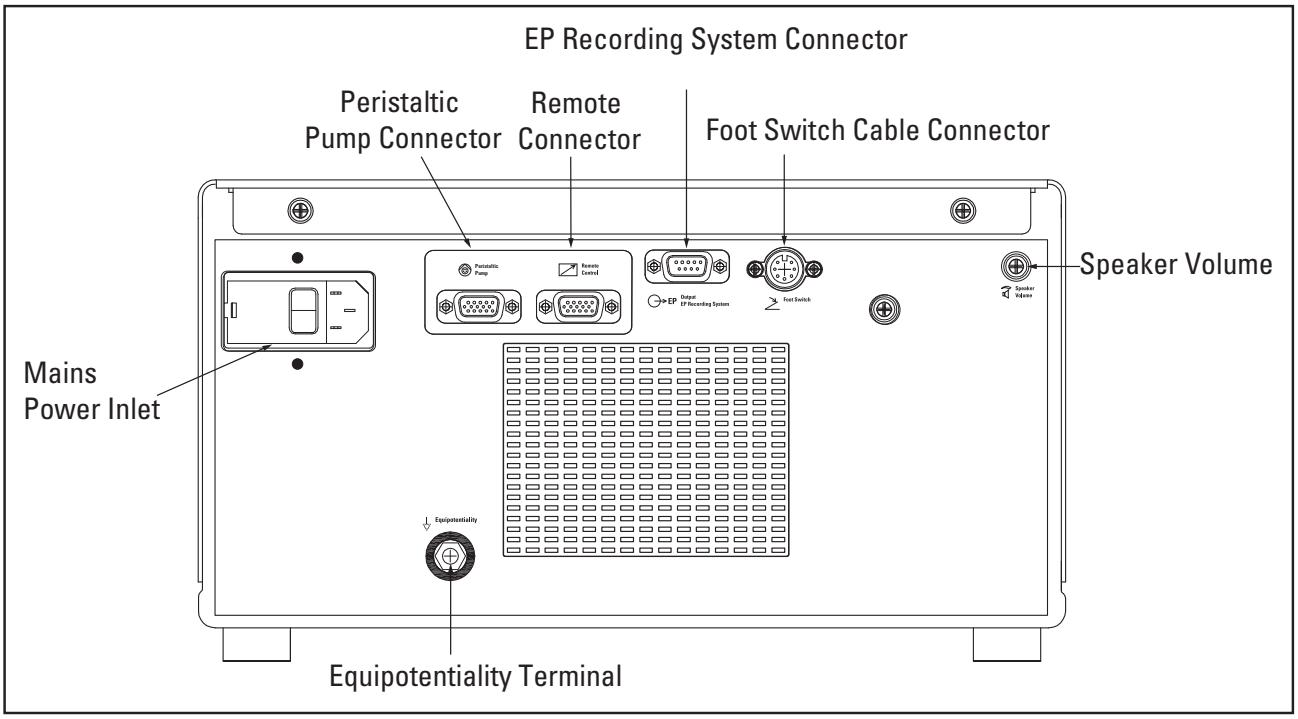

Figure 2. RF Generator Rear Panel

Mains Power Inlet

The Mains Power Inlet connects to an AC wall outlet designated as “Hospital Grade” or “Hospital Only” using a “Hospital Grade” power cord.

Potential Equalization Terminal

- This terminal can be used to verify compliance with 60601-1.
- This terminal is used for connecting dedicated ground leads.

Foot Switch Connector

This connector is used for the optional Foot Switch.

Peristaltic Pump Connector

This connector can be used to communicate with the optional MetriQ™ Pump.

Remote Connector

This connector can be used to communicate with the optional Remote.

EP Recording System Connector

This connector allows the RF Generator to communicate the ablation parameters to the EP Recording System.

Speaker Volume Knob

This knob adjusts the volume of the RF Generator audio speaker.

Remote Rear Panel

This section describes the connections and controls on the rear panel of the Remote shown in Figure 3.

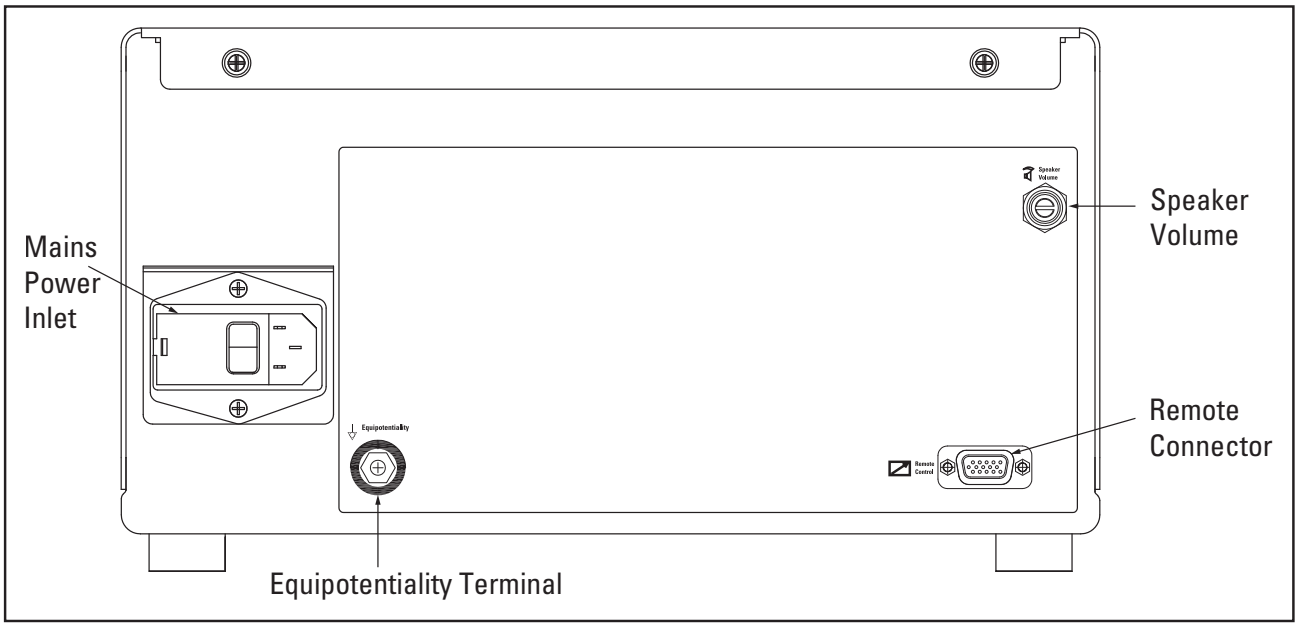

Figure 3. Remote Rear Panel

Mains Power Inlet

The Mains Power Inlet must be connected to an AC wall outlet designated as “Hospital Grade” or “Hospital Only” using a “Hospital Grade” power cord.

Potential Equalization Terminal

- This terminal can be used to verify compliance with 60601-1.
- This terminal is used for connecting dedicated ground leads.

Remote Control Connector

Provides an interface between the Remote and the RF Generator.

Speaker Volume Knob

This knob adjusts the volume of the Remote audio speaker.

Pod Connections

This section describes the connectors on the Pod shown in Figure 4.

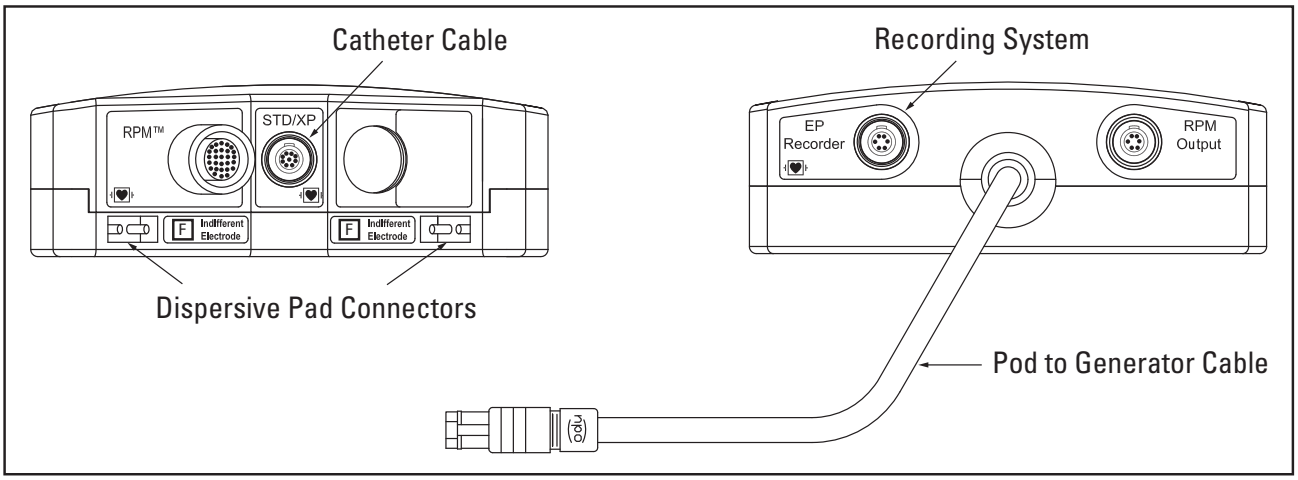

Figure 4. Pod Connections

Standard/High-Power Catheter Connector

One nine-pin receptacle labeled "STD/XP" is provided for connection to catheters.

Dispersive Pad Connectors

- Two male two-pin receptacles are provided for connection to dispersive pads (also known as the dispersive indifferent pads, ground pads, or return pads).
- Dispersive pads complete the electrical circuit, allowing RF power to be delivered to the patient.
- Connect (2) dispersive pads to the Pod when using high-power catheters.
- A single dispersive pad is sufficient when using non-high-power catheters.
- The RF Generator will cease RF output to the patient if the current through a dispersive pad exceeds 1.1 amps.
- Read the manufacturer's instructions before installing dispersive pads.

EP Recorder Connector

Connects the Pod to the EGM pins of the EP Recording System using a BSC M004653S0 cable.

Pod-to-Generator Cable

The Pod-to-Generator cable is used to connect the Pod to the "Isolated Patient Connector" on the front panel of the RF Generator.

Compatible Catheters

- **WARNING:** Refer to the Directions for Use (DFU) provided with individual catheters to determine if the catheters are compatible with the Maestro 4000™ Cardiac Ablation System. Carefully review the specific indications, contraindications, warnings, precautions and adverse events included in a catheter's DFU prior to using the catheter with the Maestro 4000 Cardiac Ablation System.

Catheters tested for compatibility for use with the Maestro 4000 Cardiac Ablation System include the BSC Models listed below.

Note: some catheters may not be available in all geographic areas.

Standard Catheters:

- Blazer II™
- Blazer II HTD™
- Blazer Prime™ HTD

High-Power Catheters:

- Blazer II XP™
- Blazer Prime™ XP
- IntellaTip MiFi XP

Closed-Irrigation Catheters:

- Chilli II Cooled Ablation Catheter

Open-Irrigated Catheters:

- Blazer Open-Irrigated Ablation Catheter

The RF Generator recognizes the catheter/pod combination and automatically adjusts the ranges of power and temperature settings available for the selected control mode.

Table 1. Adjustment Ranges for Power and Temperature

Catheter Type	Pod Type	Temperature Range Temp-Control Mode	Temperature Range Power-Control Mode	Power Range
Standard	100 W	30 °C – 90 °C	30 °C – 95 °C	0 W - 50 W
Standard	150 W	30 °C – 90 °C	30 °C – 95 °C	0 W - 100 W
High-Power	100 W	30 °C – 80 °C	30 °C – 85 °C	0 W - 100 W
High-Power	150 W	30 °C – 90 °C	30 °C – 95 °C	0 W - 150 W
Closed-Irrigation	100 W	30 °C – 90 °C	30 °C – 95 °C	0 W - 50 W
Closed-Irrigation	150 W	30 °C – 90 °C	30 °C – 95 °C	0 W - 50 W
Open-Irrigated	100 W	30 °C – 50 °C	30 °C – 50 °C	0 W - 50 W
Open-Irrigated	150 W	30 °C – 50 °C	30 °C – 50 °C	0 W - 50 W

Catheter Cable Configurations and System Interconnections

Refer to the Directions for Use (DFU) provided with individual catheters to determine the cable configurations for connecting catheters to the Pod.

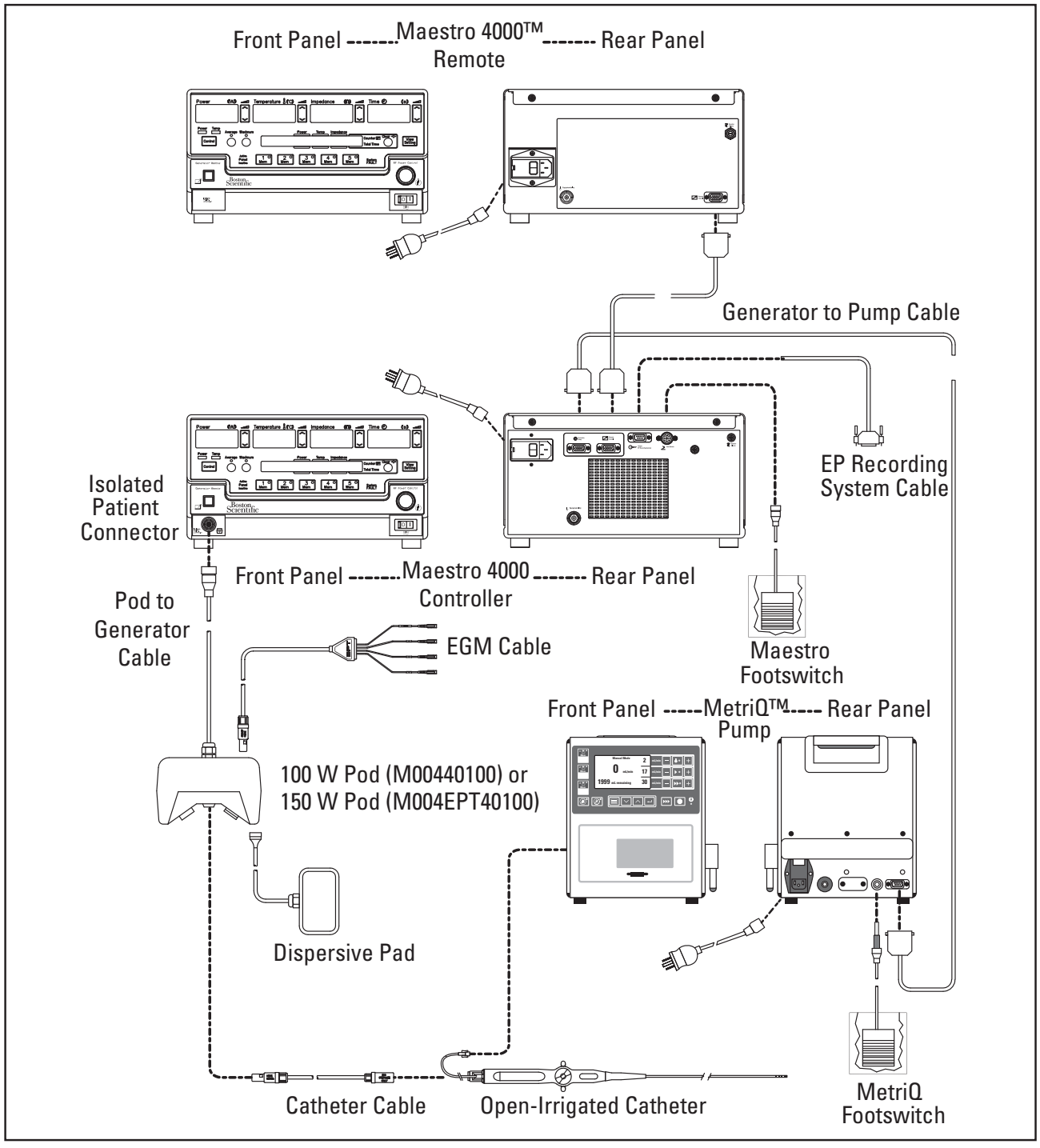

Figure 5. Maestro 4000 Cardiac Ablation System Connection Guide illustrates optional components. Example includes optional Remote Control, footswitches, MetriQ Pump and typical Open-Irrigated Catheter

Read the MetriQ Pump Operators Manual before attempting to operate the MetriQ Pump.

OPERATION

- **WARNING:** Pacemakers, implantable cardioverter/defibrillators, and leads can be adversely affected by radiofrequency energy. It is important to refer to the manufacturer's instruction for use prior to performing ablation procedures.
- **WARNING:** The impedance display of the RF Generator should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, RF power delivery should be discontinued.
- **WARNING:** Failure of the RF Generator could result in an unintended increase of output power.
- **WARNING:** The risk of igniting flammable gases or other materials is inherent in the application of RF power and precautions must be taken accordingly. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the HF surgical equipment.

  Note: Boston Scientific relies on the physician to determine, assess and communicate to the individual patient all foreseeable risks of the cardiac ablation procedure.

This section provides basic operation instructions for the Maestro 4000™ Cardiac Ablation System.

Start-Up

Turn the RF Generator ON by toggling the Mains Power Switch on the front panel to the "I" position.

If a Remote is connected to the RF Generator:

- Turn the Remote ON by toggling its Mains Power Switch to the "I" position.
- Press the Generator Remote button to activate the Remote Control Panel.

The RF Generator and Remote (if applicable) will initiate a self-test.

- "SELF TEST" appears on the alphanumeric display, a continuous audio tone is generated for approximately two seconds, and all front panel displays/indicators are lit.
- The Pod and a Catheter must be connected to complete the self-test.
- If no System malfunction is detected, the RF Control Button will flash to indicate the RF Generator has entered STANDBY state.
- If a System malfunction is detected, the RF Generator or Remote (if applicable) will not operate. The red SYSTEM FAULT indicator will be lit. The displays for Power, Temp, Impedance and Time will all read 888.

Standby State

STANDBY state initiates automatically after System start-up and whenever Deliver state is terminated. Power, Temperature, Impedance, and Time settings may be viewed and adjusted in this state.

When STANDBY state is initiated after System start-up:

- The default settings shown in Table 2 will appear in the Power, Temperature, Impedance, and Time displays.

Table 2. Default Setting for Power, Temperature, Impedance, Time

Catheter Type	Power	Temperature	Impedance	Time
Standard, High-Power, Closed-Irrigation	0 Watts	30 °C	300 Ω	0 Seconds
Open-Irrigated	0 Watts	50 °C	250 Ω	0 Seconds

- Measured impedance and temperature values appear in the alphanumeric display.
- Ablation count and total time (also in the alphanumeric display) will be reset to zero.

Select RF Delivery Settings

Use one of the methods below to select RF Delivery settings for a procedure.

- Recall RF Delivery settings stored with the Memory Buttons.
- Manually set the RF Delivery settings as described below.

Control-Mode Selection

- **WARNING:** With non-irrigated catheters, start with a low temperature setting in temperature-control mode, and then slowly titrate the temperature setting up to achieve the desired effect. With irrigated catheters, select power-control mode with a temperature setting intended to ensure that adequate fluid is irrigating the tip of the catheter.

The mode of operation can be toggled between Power-Control Mode and Temperature-Control Mode by pressing the Control Mode Button while the unit is in STANDBY mode (The control mode button is inactive during RF power delivery).

The control-mode selection determines the effect of the Power and Temperature settings.

- In Power-Control Mode:
  - The amount of RF power delivered will equal the power setting unless the measured temperature exceeds the temperature setting.
  - The temperature setting is a limit for catheter tip temperature. If the limit is exceeded, power will be reduced or halted to lower the measured temperature below this limit.

  Note: When power is reduced or halted, an operational message or diagnostic code will appear in the front panel display. See OPERATIONAL MESSAGES Section, or DIAGNOSTIC MESSAGES Section for additional information.
- In Temperature-Control Mode:
  - The power setting is a limit. The RF Generator is allowed to adjust RF power delivery up to this limit to achieve the target temperature.
  - The temperature setting is the target temperature.

  Note: The target temperature may not be reached if the power setting (limit) is reached.

The default control modes for BSC Catheters are listed in Table 3. When a catheter is initially connected, the RF Generator automatically switches to the default control mode for that catheter. However, the user may switch control modes by pressing the control-mode button.

Table 3. Catheter Default Control Modes

Catheter Types	Default Control Mode
High-Power and Standard Power	Temperature Control
Open-Irrigated and Closed-Irrigated	Power Control

Power Setting

- **WARNING:** To minimize the potential for thrombus formation, inadvertent damage to cardiac tissues, and collateral damage to adjacent tissue not intended for ablation, begin by using a low power setting and gradually increase the power output if necessary, especially in areas where low blood flow and correspondingly low convective cooling may be present.

Temperature Setting

- **WARNING:** To minimize the potential for thrombus formation, inadvertent damage to cardiac tissues, and collateral damage to adjacent tissue not intended for ablation, begin by using a low temperature setting and gradually increase the power output if necessary, especially in areas where high blood flow and correspondingly high convective cooling may be present.
- **WARNING:** The displayed temperature is not the maximum tissue temperature. The measured temperature may be influenced by the degree of tissue contact and variations in blood flow. The difference between the max tissue temperature and the displayed temperature increases when using irrigated catheters, and the correlation with lesion formation is greatly reduced. The temperature displayed with irrigated catheters is not intended to guide lesion formation. The temperature displayed with irrigated catheters is intended to verify that the tip is being sufficiently irrigated. This behavior will minimize the potential for thrombus formation and/or inadvertent damage to nearby tissue.

Impedance Setting

The impedance upper limit may be adjusted between 150 Ω to 300 Ω.

Time Setting

Set the timer for the maximum duration of RF Power delivery.

Selecting Average and Maximum Display

Press the “Maximum” and/or “Average” Buttons, if those values are to be displayed.

RF Power Delivery with Open-Irrigated BSC Catheters

Use of the RF Generator with BSC open-irrigated catheters requires proper set-up and preparation of the MetriQ™ Pump and the MetriQ Irrigation Tubing Set. The MetriQ Pump Operator’s Manual provides complete instructions for set-up and operation of the MetriQ Pump and MetriQ Irrigation Tubing Set .

Starting RF Power Delivery:

- Press the RF Power Control button once, or hold down the Foot Switch pedal.
- The MetriQ Pump will switch from standby flow to ablation flow.
- Delivery of RF Power will start when the Pre-RF Delay is complete.
- The RF Power Control button will illuminate and remain lit until RF power delivery stops.
- RF Power will stop automatically when the setting for maximum duration of RF Power Delivery is reached.
- The Pump will switch to standby flow when the Post-RF Delay is complete.

Stopping RF Power Delivery:

- To stop delivery of RF Power before reaching the setting for maximum duration, press the RF Power Control Button, or release the Foot Switch pedal.
- The RF Power Control button will flash to indicate the RF Generator is in STANDBY state.
- The Pump will switch to standby flow when the Post-RF Delay is complete.

RF Power Delivery with all other Catheters

Starting RF Power Delivery:

- Press the RF Power Control button once, or hold down the Foot Switch pedal.
- Delivery of RF Power will start immediately.
- The RF Power Control button will illuminate and remain lit until RF power delivery stops.
- RF Power will stop automatically when the setting for maximum duration of RF Power Delivery is reached.

Stopping RF Power Delivery:

- To stop delivery of RF Power before reaching the setting for maximum duration, press the RF Power Control Button, or release the Foot Switch pedal.
- The RF Power Control button will flash to indicate that the RF Generator is in STANDBY state.

SERVICE AND MAINTENANCE

Preventative Inspection

- **WARNING:** Damage such as frayed cords or cables and cracks or dents on the equipment may result in electrical shock.
- **Caution:** BSC recommends that the RF Generator and Remote be powered off at the end of each procedure in order to ensure that the self-test is performed before the next procedure.

During the useful life of the equipment, maintain close watch for damage such as frayed cords or cables and cracks or dents on the equipment. If damage is identified, take the equipment out of service and contact Boston Scientific Corporation for service requirements.

Functional Self-Test

System does not require periodic preventative maintenance and calibration. Upon start up, the unit performs self-test per OPERATION Start-up Section of this manual. For further details refer to that section.

System Servicing

None of the System components are user-serviceable. Contact Boston Scientific Corporation for all service requirements.

Cleaning/Disinfecting

- **WARNING:** Do not immerse the Generator, the Remote, or accessories in any liquid.
- **WARNING:** Use of non-flammable cleaning and disinfection agents is recommended. If used, flammable agents or solvents should be allowed to evaporate before high-frequency surgery. There is a risk of pooling of flammable solutions under the PATIENT or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF SURGICAL EQUIPMENT is used.

- **Caution:** The Generator, Pod, Remote, Footswitch, power cords, and communication cables are not intended to be sterilized and should remain outside of the sterile field.

The outer surfaces of the Generator, the Pod, the Remote and their accessories may be wiped clean with a mild soapy solution. Isopropyl alcohol may be used to clean the outer surfaces. Avoid caustic or abrasive cleaners.

ESD Training and Precautionary Procedures

Prior to assembly, installation, or interconnection of the Maestro 4000™ Cardiac Ablation System, it is recommended that any staff (i.e. clinical/biomedical engineers and health care staff) that could touch connectors identified with the ESD warning symbol undergo ESD training. At minimum, ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice, and the damage that can be done to electronic components if they are touched by an operator who is electrostatically charged. Further, an explanation should be given of methods to prevent build-up of electrostatic charge, and how and why to discharge one's body to earth or to the frame of the equipment or System, or bond oneself by means of a wrist strap to the equipment or System or to earth prior to making a connection. Finally, staff must be made aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a hand-held tool unless proper precautionary procedures have been followed. ESD precautionary procedures should include:

- Methods to prevent build-up of electrostatic charge (e.g. air conditioning, humidification, conductive floor coverings, non-synthetic clothing);
- Discharging one's body to the frame of the equipment or System or to earth or a large metal object;
- Bonding oneself by means of a wrist strap to the equipment or System or to earth.

End of Useful Life

When the equipment reaches the end of its useful life, dispose of the Generator, Remote and all accessories in accordance with hospital, administrative and, local government policy. Contact your BSC representative or BSC field service engineer (1.800.949.6708 in the US) prior to disposal.

The Maestro 4000 Controller components are expected to have a useful life up to 7 years.

PRODUCT SPECIFICATIONS

General Specifications

Description	Specification
Power Specifications	
Line Power	
• RF Generator	100 V_{AC}-120 V_{AC}/220 V_{AC}-240 V_{AC}, 50/60 Hz, 300 VA
• Remote	100 V_{AC}-120 V_{AC}/220 V_{AC}-240 V_{AC}, 50/60 Hz, 25 VA
Current Rating	
• RF Generator	4 A @120 V_{AC}
• Remote	1 A @120 V_{AC}
Fuses	
• RF Generator	T4AL250V
• Remote	T1AL250V
Power Cord	
Length	10 feet (3.0 meters)
Foot Switch (Cable)	
Length	10 feet (3.0 meters)

Description	Specification
Pod to RF Generator Cable	
Length	15 feet (4.6 meters)
Connector	14-pin Quick Connector
Pod	
Dimensions (excluding cable)	
• Height	2.3 in (5.8 cm)
• Width	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	Standard male 2-pin for commercial pads - Type CF-Defibrillation-Proof
Pod Recorder Filters	
• Low Pass Filters	Referenced to the Indifferent Electrode
• Low Frequency Cutoff	–3 dB at 5 kHz ± 1 kHz
High-Current Shutoff Mechanism	RF output ceases to the patient if more than 1.1 Amp flows in either Dispersive Pad

RF Generator Power Output @ 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
	• Maximum RF power setting based on catheter type used and Control Mode
	• Use catheters that have a rated voltage higher than the RF Generator maximum output voltage rating.

Impedance	In STANDBY Mode: The impedance is measured in the 0 Ω-300 Ω range In DELIVER Mode: High-power catheters display measured impedance in the 25 Ω-300 Ω range and display “LO” or “HI” outside that range. Non-high-power catheters display measured impedance in the 50 Ω-300 Ω range and displays “LO” or “HI” outside that range.

Description	Specification
Temperature	
In Temperature-Control Mode	The catheter tip temperature (temperature set point) can be selected within the ranges listed in Table 1.
In Power-Control Mode	The catheter tip temperature (upper limit for continued RF power delivery at the power set point) can be selected (within the ranges listed in Table 1).
In either control mode:	The RF Generator measures and displays temperature in the 15 °C to 95 °C range and displays “LO” or “HI” outside that range.
RF Generator 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)
Time	For open-irrigated catheters, the time can be set between 0 seconds – 999 seconds in increments of 1 second. For all other catheters, the time can be set between 0 seconds – 120 seconds in increments of 1 second.
Counter	0 to 999 RF power deliveries
Generator Sound Output	
• Power Up – Sign On Tone	500 Hz – 1.5 kHz – 2.5 kHz Square Wave
• Keyboard Key Click	1 kHz Square Wave
• RF Delivery	500 Hz Square Wave
• Three Tone Beep	300 Hz Square Wave
Remote Dimensions	
• Height	13.0 inches (33.1 cm)
• Width	7.3 inches (18.6 cm)
• Depth	7.5 inches deep (19.1 cm)
• Weight	11 lb (5 kg)

Maestro 4000™ Cardiac Ablation System Safety Specifications

Device Description
Class I, Defibrillation proof Type CF Equipment, IPX0, not AP/APG
Mode of Operation: Continuous
EMC Emissions and Susceptibility: The Maestro 4000 Cardiac Ablation System has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This System generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instruction given below, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.
TUV Rheinland of North America Certified. IEC 60601-1 -1-1, -1-2, -1-4 -2-2

Electrical Isolation
Leakage current conforms to IEC 60601-1
Dielectric withstand conforms to IEC 60601-1

Guidance and manufacturer's declaration – electromagnetic emissions

The Maestro 4000 Cardiac Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Maestro 4000 Cardiac Ablation System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Maestro 4000 Cardiac Ablation System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Maestro 4000 Cardiac Ablation System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The Maestro 4000 Cardiac Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Maestro 4000 Cardiac Ablation System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Maestro 4000™ Controller requires continued operation during electrical disturbances on the power mains, it is recommended that the MetriQ™ Pump be connected to an uninterruptible power supply with surge and electrical fast transient-suppression filtering/device embedded or connected in series.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Maestro 4000 Controller requires continued operation during electrical disturbances on the power mains, it is recommended that the MetriQ Pump be connected to an uninterruptible power supply with surge and electrical fast transient-suppression filtering/device embedded or connected in series.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Maestro 4000 RF Generator requires continued operation during electrical disturbances on the power mains, it is recommended that the MetriQ Pump be connected to an uninterruptible power supply with surge and electrical fast transient-suppression filtering/device embedded or connected in series.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Maestro 4000™ Cardiac Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Maestro 4000 Cardiac Ablation System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Maestro 4000 Cardiac Ablation System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.17\sqrt{P}$ 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Maestro 4000 Cardiac Ablation System or any of its components are used exceeds the applicable RF compliance level above, the Maestro 4000 Cardiac Ablation System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating components or the entire Maestro 4000 Cardiac Ablation System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Guidance and Manufacturer's Declaration – electromagnetic immunity			
The Maestro 4000™ Cardiac Ablation System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Maestro 4000 Cardiac Ablation System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Maestro 4000 Cardiac Ablation System as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter M**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Power Delivery

Refer to Table 1 for maximum power settings. In the event of unusually high or low tissue impedance, the System limits the maximum power. Figure 6 through Figure 9 depict the maximum output power of the System (as a function of tissue impedance) as measured at the output of the catheter for each catheter-pod configuration. Figure 10 depicts the nominal, minimum, and maximum output power of the Generator as a function of the control setting at nominal impedance of 100 Ω.

Note: Due to the inductive and capacitive loads presented by each Catheter configuration, the power delivered at the Catheter tip may be less than the power on the System display.

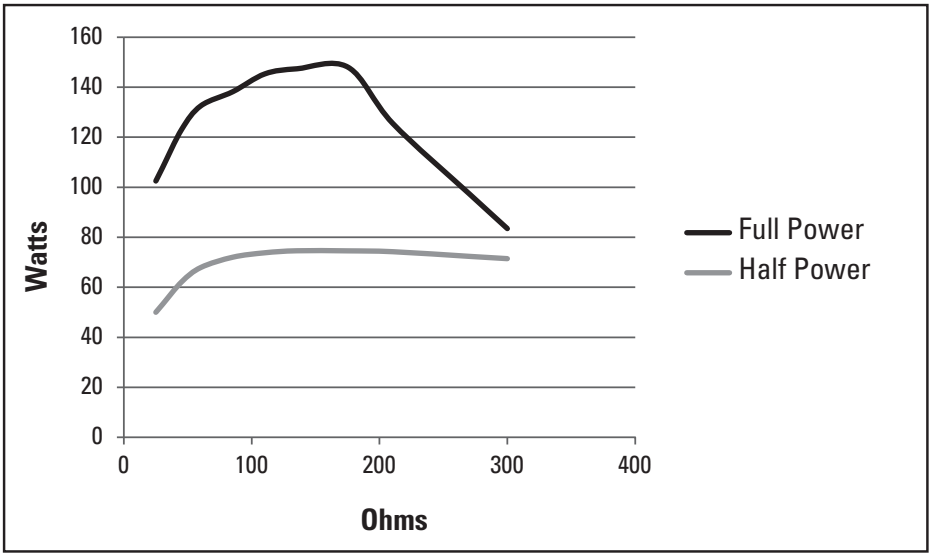

Figure 6. Power Output for High-Power Catheters with 150-W Pods

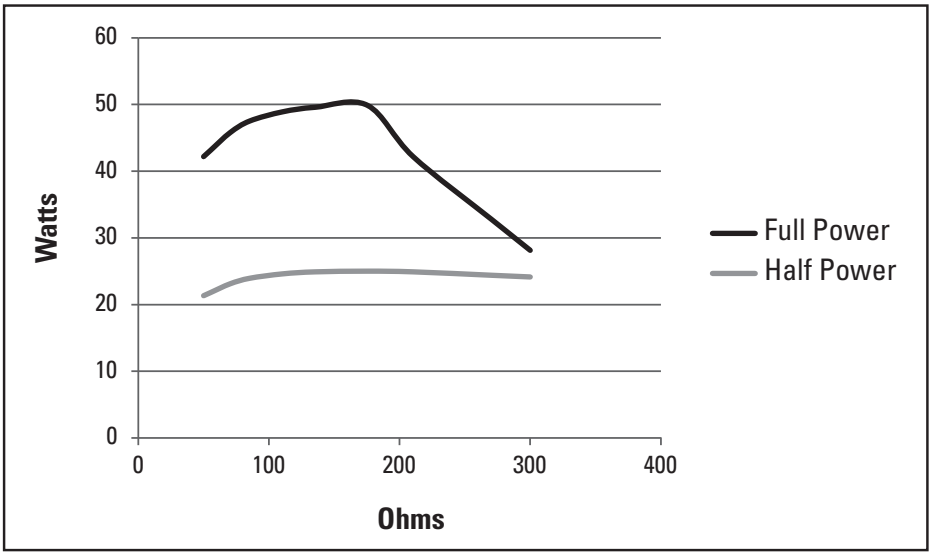

Figure 7. Power Output for OI/Chilli II Catheters with 100-W and 150-W Pods and for Standard Catheters with 100-W Pods

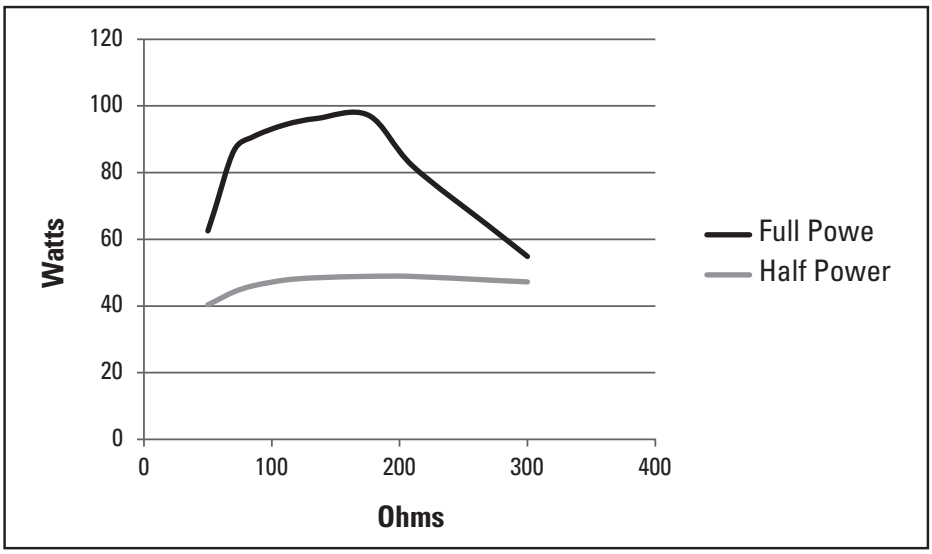

Figure 8. Power Output for Standard Catheters with 150-W Pods.

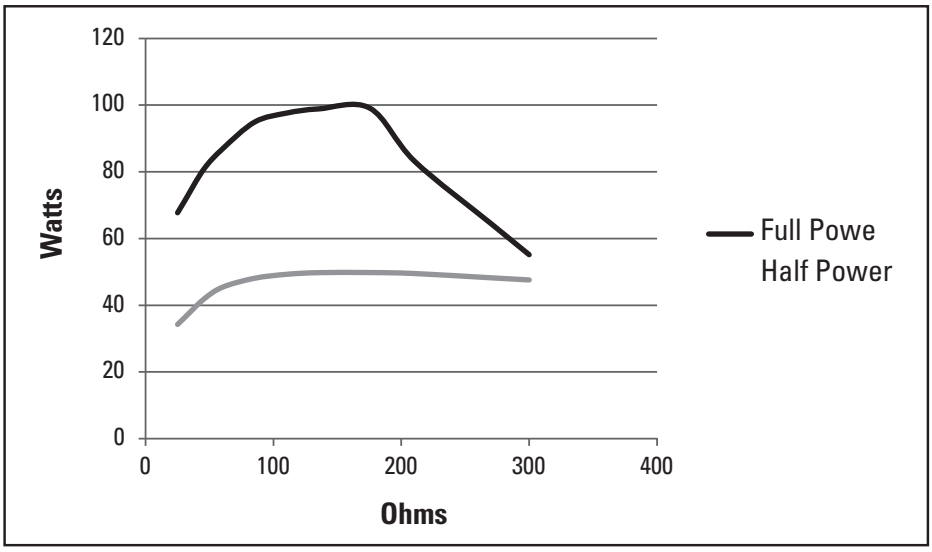

Figure 9. Power Output for High-Power Catheters with 100-W Pods

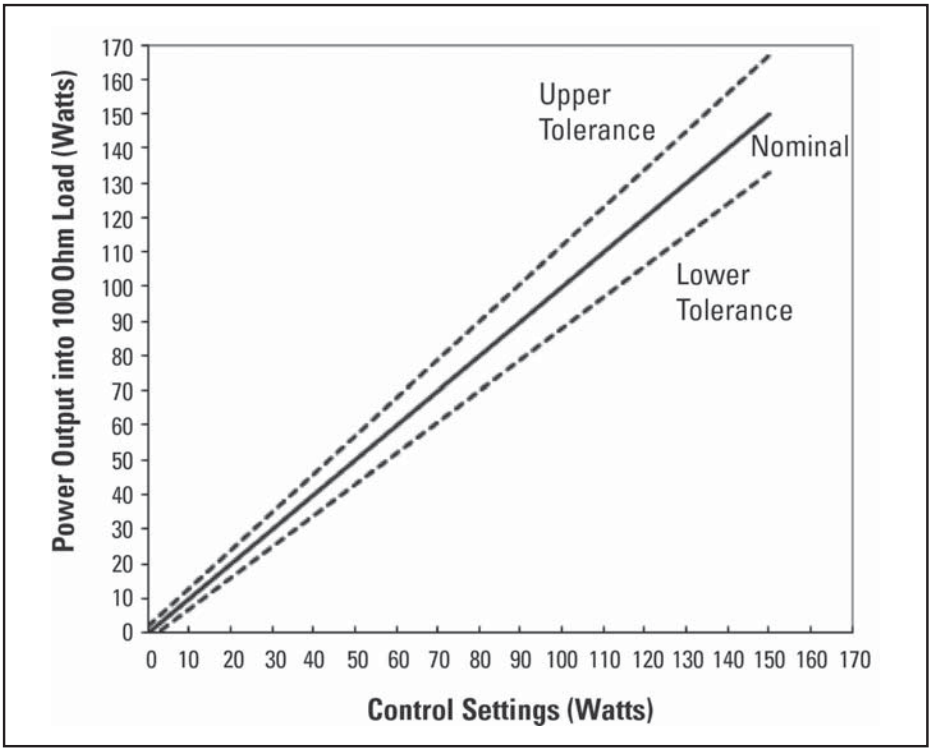

Figure 10. Maestro 4000™ Controller (RF Generator) Power Output Versus Power Setting

OPERATIONAL MESSAGES

Table 4. Operational Messages

Code	Display	Description	Action
M02	POWER LIMITED, POWER SETTING	This message is displayed as long as the power setting is reached in temperature-control mode.	Reduce temperature setting or increase power setting, as appropriate.
M03	POWER LIMITED, LOW IMPEDANCE	This message is displayed as long as the power is limited due to reaching the current limit due to low impedance.	See power curves in RF delivery section of this document.
M04	POWER LIMITED, HIGH IMPEDANCE	This message is displayed as long as the power is limited due to reaching the voltage limit due to high impedance.	**WARNING**: Apparent low power output or higher than typical impedance measurements may be indicative of faulty dispersive pad application or failure of an electrical lead. Check the application of the dispersive pad and all electrical connections before continuing or selecting higher power outputs. See power curves in RF delivery section of this document.
M05	WAIT FOR PUMP	This message is displayed during pre-RF and post-RF delay.	Wait for MetriQ™ Pump to complete pre-RF delay or post-RF delay (or adjust the delay duration, and minimum temperature drop setting on MetriQ Pump, as appropriate). See the MetriQ Pump Operator's Manual for additional information on pre-RF delay.
M06	CLOSE PUMP MENU	This message is displayed when RF is requested but the MetriQ Pump's menu is open (with an OI catheter connected and Maestro 4000™ Controller is operating with MetriQ Pump in Automatic mode).	Close the MetriQ Pump's menu prior to requesting RF delivery.
M07	SET TIME	This message is displayed when RF is requested but the time setting is still 0 seconds.	Adjust time setting appropriately.
M08	SET POWER	This message is displayed when RF is requested but the power setting is still 0 Watts.	Adjust power setting appropriately.
M09	SET TEMPERATURE	This message is displayed when RF is requested but the temperature setting is still 30 degrees.	Adjust temperature setting appropriately.

Code	Display	Description	Action
M10	RECONNECT PUMP	This message is displayed when communication is lost between the Maestro 4000™ Controller and MetriQ™ Pump.	Reconnect Pump and tighten connector thumb screws if the Pump was accidentally disconnected. Inspect generator-to-pump cable and/or connectors for damage.
M11	RF REDUCED 50%, MAX TEMP REACHED	This message is displayed when a non-OI catheter is used and the Maestro 4000 Controller measured temperature exceeds the temperature setting in power-control mode (and the power setting is automatically reduced by 50% to facilitate continued lesion formation).	Verify that the power-control mode is the desired mode of operation. Decrease the power setting and/or increase the temperature setting, as appropriate.

DIAGNOSTIC MESSAGES

The Maestro will stop/prevent RF delivery in association with each of the following diagnostic messages.

Table 5. Diagnostic Messages and Corresponding Corrective Actions

Code	Display	Description	Action
D01	LOW IMPEDANCE	Measured impedance below the low impedance threshold of 25 Ω when using a high power catheter and 50 Ω for all other catheters.	Inspect generator-to-pod cable and connections and replace components which may appear damaged. If error recurs, replace Pod. If error recurs, replace the Generator.
D02	HIGH IMPEDANCE	Measured impedance above the impedance setting (150 Ω – 300 Ω).	Check application of dispersive pad and abide to all recommendations in the dispersive pad DFU/IFU.
D03	LIMIT EXCEEDED	$V > 1.1 \times V_{max}$ or $I > 1.1 \times I_{max}$ or $P > 1.2 \times P_{max}$	Do not disconnect catheter, catheter cable, dispersive pad(s), or pull catheter back into sheath during RF delivery. If error recurs, restart Generator. Adding a second dispersive pad may help (especially if also experiencing M03 operational message). If error recurs, replace Pod. If error recurs, replace the Generator.
D04	TEMP ABOVE SET POINT	Measured temperature is greater than set point by at least 5 °C for more than four seconds.	Check temperature setting. If error recurs, restart the Generator. If error recurs, replace the Generator.

Code	Display	Description	Action
D05	EXCESSIVE TEMPERATURE	Measured temperature greater than 95 °C for more than one second or measured temperature exceeds setting in Power Control mode.	Check temperature and power settings. Check control-mode setting. Check cables and connectors in the RF pathway for possible damage or loose connection. Verify that temperature in standby is appropriate and doesn't change with agitating connectors/cables in the RF pathway. If temperature changes with agitation, replace suspected components one at a time. If error recurs, replace catheter cable. If error recurs, replace Pod. If error recurs, replace the Generator.
D06	TEMP OUT OF RANGE [15C-95C]	Measured temperature <15 °C or >95 °C	This condition may have been caused by switching catheters during a procedure. Check cables and connectors in the RF pathway for possible damage or loose connection. Verify that temperature in standby is appropriate and doesn't change with agitating connectors/cables in the RF pathway. If temperature changes with agitation, replace suspected components one at a time. If error recurs, replace catheter cable. If error recurs, replace catheter. If error recurs, replace Pod. If error recurs, replace the Generator.
D07	TEMPERATURE TOO HIGH	An attempt to RF delivery with a measured temperature > 43 °C or greater than the temperature setting within 30 seconds of the previous RF delivery.	Check temperature setting. Check cables and connectors in the RF pathway for possible damage or loose connection. Verify that temperature in standby is appropriate and doesn't change with agitating connectors/cables in the RF pathway. If temperature changes with agitation, replace suspected components one at a time. If error recurs, replace catheter cable. If error recurs, replace Pod. If error recurs, replace the Generator.
D08	CHECK POD	Generator detects a pod failure or an issue with the generator-to-pod connection.	Check generator-to-pod connection. If error recurs, replace pod.
D09	N/A	Invalid Code	Contact BSC

Code	Display	Description	Action
D10	INVALID CATHETER ID	Invalid catheter ID	Check catheter cable for damage. If error recurs, replace catheter cable. If error recurs, replace catheter. If error recurs, replace catheter Pod.
D11	CHECK REMOTE	There is a communications problem between the Remote and the Generator or the Remote was disconnected or connected during RF.	Do not disconnect or connect the Remote during RF. Check cable and connections between the Generator and remote, tightening the thumb screws on the connectors, or replacing component if damage is suspected.
D12	CHECK PUMP	There is a communication error with the MetriQ™ Pump or there is a diagnostic condition at the Pump.	Clear diagnostic condition at Pump. Check cable and connections between the Generator and Pump, tightening the thumb screws on the connectors, or replacing component if damage is suspected.
N/A	SYSTEM FAULT	An unrecoverable error has occurred on the Generator/ Remote (as indicated by which unit displayed the "SYSTEM FAULT" LED). The Generator/ Remote enters SAFE mode and will not allow any operations.	Power off the Generator/Remote and restart. If error recurs, contact BSC field service for further assistance.

LIMITED WARRANTY AND DISCLAIMER

Limited Warranties

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this System. When maintained in such conditions as specified by BSC, it will be free from defects in material and workmanship at buyer's location for 12 months from the date of deliver. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, and cleaning of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the System and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Service is limited to exchanging faulty System components. No in-field repairs will be performed. For service, contact the BSC authorized service representative. The user must pay all freight charges for all parts returned to BSC. BSC will pay freight for shipping the repaired or replaced parts back to the user. BSC extends, to the registered user, all warranties offered by third party software upon which the System depends.

Extended warranties that include both the hardware and software can be purchased any time after the current warranty period has expired. If the System falls under the initial 12 month manufacturer's warranty, then an extended warranty can be purchased anytime during the first year (12 months) or after the manufacturer's warranty expires. Contact BSC for more information.

All catheters used with the System are for single use only. Do not reuse, reprocess, or re-sterilize. Re-use, reprocessing, or re-sterilization may compromise the structural integrity of the catheter and/or lead to device failure, which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the catheter and/or cause patient infection or cross-infection including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. BSC assumes no liability with respect to single use instruments that are reused, reprocessed, or re-sterilized and makes no warranties, express or implied, including, but not limited to the warranties of merchantability or fitness for intended use with respect to such instrument.

Disclaimer and Exclusion of Other Warranties

There are no warranties of any kind that extend beyond the description of the warranties above. Boston Scientific Corporation disclaims and excludes all warranties, whether express or implied, of merchantability of fitness for a particular use or purpose.

Limitation of Liability for Damages

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Boston Scientific Corporation shall not be liable for damages for loss of profits or revenues, loss of use of the product, loss of facilities or services, any downtime costs, or for claims of buyer's customers for any such damages. Boston Scientific Corporation's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Boston Scientific Corporation to buyer which give rise to the claim for liability. The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

REF

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Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
カタログ番号
Katalognummer
Αριθμός καταλόγου
Referência
Katalognummer
Katalógusszám
Katalogové číslo
Numer katalogowy
Katalognummer
目录编号
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내용물
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Conteúdo
Sisältö
Conținut
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EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
EU認定代理店
Autoriseret repræsentant i EU
Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ
Representante Autorizado na U.E.
Auktoriserad EU-representant
Hivatalos képviselet az EU-ban
Autorizovaný zástupce pro EU
Autoryzowany przedstawiciel w UE
Autorisert representant i EU
欧盟授权代表
EU 공인 대리점
AB Yetkili Temsilcisi
Representante Autorizado na UE
EU-valtuutettu edustaja
Reprezentantul Autorizat UE
Уполномоченный представитель в ЕС
Autorizovaný zástupca pre EÚ

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
法定製造元
Lovmæssig producent
Νόμιμος κατασκευαστής
Fabricante Legal
Laglig tillverkare
Hivatalos gyártó
Oprávněný výrobce
Producent uprawniony
Lovmessig produsent
合法制造商
법적 제조사
Yasal Üretici
Fabricante Legal
Laillinen valmistaja
Producător legal
Законный изготовитель
Výrobca

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
リサイクル可能包装
Genanvendelig pakning
Ανακυκλώσιμη συσκευασία
Embalagem Reciclável
Återvinningsbar förpackning
Újrahasznosítható csomagolás
Recyklovatelný obal
Opakowanie przeznaczone do recyklingu
Emballasjen kan resirkuleres
可回收再利用包装
재활용 포장재
Geri Dönüşümlü Ambalaj
Embalagem Reciclável
Kierrätettävä pakkaus
Ambalaj reciclabil
Упаковка, подлежащая вторичной переработке
Recyklovateľný obal

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
オーストラリア認定代理店住所
Australsk sponsoradresse
Διεύθυνση χορηγού στην Αυστραλία
Endereço do Patrocinador Australiano
Adress till australisk sponsor
Az ausztrál szponzor címe
Adresa australského zadavatele
Adres sponsora australijskiego
Australsk sponsors adresse
澳大利亚赞助商地址
호주 후원인 주소
Avustralyalı Sponsor Adresi
Endereço do Patrocinador Australiano
Australialaisen toimeksiantajan osoite
Adresa sponsorului australian
Адрес австралийского спонсора
Adresa austrálskeho zadávateľa

ARG

Argentina Local Contact
Contacto local en Argentina
Contact local en Argentine
Lokaler Kontakt Argentinien
Contatto locale per l'Argentina
Contactpersoon Argentinië
アルゼンチン現地連絡先
Lokal kontakt i Argentina
Υπεύθυνος επικοινωνίας στην Αργεντινή
Contacto local na Argentina
Lokal kontakt, Argentina
Helyi kapcsolattartó (Argentína)
Místní kontaktní osoba v Argentině
Miejscowy przedstawiciel w Argentynie
Lokal kontakt for Argentina
阿根廷当地联络人
아르헨티나 현지 문의처
Arjantin Yerel İletişim
Contato local na Argentina
Argentiina – paikalliset yhteystiedot
Reprezentant local Argentina
Представительство в Аргентине
Miestny zástupca v Argentíne

BRA

Brazil Local Contact
Contacto local en Brasil
Contact local au Brésil
Lokaler Kontakt Brasilien
Contatto locale per il Brasile
Contactpersoon Brazilië
ブラジル現地連絡先
Lokal kontakt i Brasilien
Υπεύθυνος επικοινωνίας στη Βραζιλία
Contacto local no Brasil
Lokal kontakt, Brasilien
Helyi kapcsolattartó (Brazília)
Místní kontaktní osoba v Brazílii
Miejscowy przedstawiciel w Brazylii
Lokal kontakt for Brasil
巴西当地联络人
브라질 현지 문의처
Brezilya Yerel İletişim
Contato local no Brasil
Brasilia – paikalliset yhteystiedot
Reprezentant local Brazilia
Представительство в Бразилии
Miestny zástupca v Brazílii

TUR

Turkey Local Contact
Contacto local en Turquía
Contact local en Turquie
Lokaler Kontakt Türkei
Contatto locale per la Turchia
Contactpersoon Turkije
トルコ現地連絡先
Lokal kontakt i Tyrkiet
Υπεύθυνος επικοινωνίας στην Τουρκία
Contacto local na Turquia
Lokal kontakt, Turkiet
Helyi kapcsolattartó (Törökország)
Místní kontaktní osoba v Turecku
Miejscowy przedstawiciel w Turcji
Lokal kontakt for Tyrkia
土耳其当地联络人
터키 현지 문의처
Türkiye Yerel İletişim
Contato local na Turquia
Turkki – paikalliset yhteystiedot
Reprezentant local Turcia
Представительство в Турции
Miestny zástupca v Turecku

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
包装が破損している場合は使用しないこと。
Må ikke anvendes, hvis pakken er beskadiget.
Μη χρησιμοποιείτε αν η συσκευασία έχει υποστεί ζημιά.
Não utilize se a embalagem estiver danificada.
Använd inte om förpackningen är skadad.
Ne használja, ha a csomagolás sérült.
Nepoužívejte, pokud je obal poškozen.
Nie używać, jeśli opakowanie jest uszkodzone.
Skal ikke brukes hvis emballasjen er skadet.
包装如有损坏，请勿使用。
패키지가 손상된 경우 사용하지 마십시오.
Eğer paket zarar görmüşse kullanmayın.
Não utilize se a embalagem estiver danificada.
Ei saa käyttää, jos pakkaus on vaurioitunut.
A nu se utiliza dacă ambalajul este deteriorat.
Не использовать, если упаковка повреждена.
Nepoužívajte, ak je balenie poškodené.

Defibrillation-Proof Type CF Applied Part
Pieza de tipo CF aplicada compatible con desfibrilación
Pièce appliquée de type CF protégée contre les chocs de défibrillation
Defibrillationssicher, angelegtes Teil vom Typ CF
Parte applicata di tipo CF protetta da scarica di defibrillazione
Defibrillatiebestendig toegepast onderdeel van type CF
耐除細動CFタイプ装着部
Defibrilleringssikker type CF anvendt del
Εφαρμοζόμενο εξάρτημα τύπου CF με προστασία από απινίδωση
Peça Aplicada de Tipo CF à Prova de Desfibrilhação
Defibrilleringssäker applicerad del, typ CF
Defibrillálás-biztos, CF típusú alkalmazott rész
Aplikovaná část typu CF odolná vůči defibrilaci
Część aplikacyjna typu CF odporna na defibrylację
Defibrilleringssikker, anvendt del av type CF
防除颤 CF 类应用部件
제세동 방지 유형 CF 적용 부품
Defibrilasyona dayanıklı, CF Tipi Uygulanan Parça
Peça aplicada tipo CF à prova de desfibrilação
Defibrillaation kestävä tyypin CF sovellettu osa
Piesă aplicată de tip CF protejată împotriva şocurilor de defibrilaţie
Рабочая часть для дефибриллятора типа CF
Aplikovaná časť typu CF odolná voči defibrilácii

2X T 4A 250V

Fuse
Fusible
Fusible
Sicherung
Fusibile
Zekering
ヒューズ
Sikring
Ασφάλεια
Fusível
Säkring
Biztosíték
Pojistka
Bezpiecznik
Sikring
保险丝
퓨즈
Sigorta
Fusível
Sulake
Siguranţă fuzibilă
Предохранитель
Poistka

Foot Switch
Pedal
Pédale
Fußschalter
Interruttore a pedale
Voetschakelaar
フットスイッチ
Fodpedal
Ποδοδιακόπτης
Pedal Interruptor
Fotbrytare
Lábkapcsoló
Nožní spínač
Przełącznik nożny
Fotbryter
脚踏开关
발 스위치
Ayak Pedalı
Pedal
Jalkakytkin
Pedală
Ножная педаль
Nožný spínač

Equipotentiality
Equipotencialidad
Équipotentialité
Potenzialgleichheit
Equipotenzialità
Equipotentialiteit
等電位
Ækvipotentiale
Ισοδυναμικότητα
Equipotencialidade
Ekvipotentialitet
Ekvipotenciális felület
Ekvipotencialita
Ekwipotencjalność
Ekvipotensialitet
等电位
등위성
Eşpotansiyellilik
Equipotencialidade
Tasapainopotentiaalisuus
Echipotenţialitate
Эквипотенциальность
Ekvipotenciál

Date of Manufacture
Fecha de fabricación
Date de fabrication
Herstellungsdatum
Data di fabbricazione
Fabricagedatum
製造日
Fremstillingsdato
Ημερομηνία κατασκευής
Data de Fabrico
Tillverkningsdatum
A gyártás időpontja
Datum výroby
Data produkcji
Produksjonsdato
生产日期
제조일
Üretim Tarihi
Data de Fabricação
Valmistuspäivämäärä
Data fabricaţiei
Дата изготовления
Dátum výroby

SN

Serial Number
Número de serie
Numéro de série
Seriennummer
Numero di serie
Serienummer
シリアル番号
Serienummer
Σειριακός αριθμός
Número de série
Serienummer
Gyári szám
Sériové číslo
Numer seryjny
Serienummer
序列号
일련 번호
Seri Numarası
Número serial
Sarjanumero
Număr de serie
Серийный номер
Sériové číslo

Non-Sterile
No estéril
Non stérile
Nicht steril
Non sterile
Niet-steriel
未滅菌
Ikke-steril
Μη αποστειρωμένο
Não esterilizado
Icke-steril
Nem steril
Nesterilní
Niejałowy
Ikke-steril
非无菌
비멸균
Steril Değildir
Não estéril
Epästeriili
Non-steril
Не стерильно
Nesterilný

Input / Ouput
Entrada/Salida
Entrée / Sortie
Eingang / Ausgang
Ingresso / Uscita
Ingang/uitgang
入力 / 出力
Indgang / udgang
Είσοδος / Έξοδος
Entrada/Saída
Ingång/utgång
Bemenet/Kimenet
Vstup/výstup
Wejście/wyjście
Inngang/utgang
输入/输出
입력/출력
Giriş / Çıkış
Entrada/Saída
Sisääntulo/Ulostulo
Intrare/Ieşire
Ввод / вывод
Vstup / výstup

cTUVus Mark indicates compliance to UL 60601-1 and CAN/CSA 22.2 601.1 M90 covering electrical safety requirements for the US and Canada.
El símbolo cTUVus indica cumplimiento con las regulaciones UL 60601-1 y CAN/CSA 22.2 601.1 M90 correspondientes a los requisitos de seguridad eléctrica en los Estados Unidos y Canadá.
La marque cTUVus indique le respect des normes de sécurité électrique UL 60601-1 et CAN/CSA 22.2 601.1 M90 pour les États-Unis et le Canada.
Das cTUVus-Kennzeichen bedeutet die Übereinstimmung mit UL 60601-1 und CAN/CSA 22.2 601.1 M90, wodurch die Anforderungen für elektrische Sicherheit in den USA und Kanada abgedeckt sind.
Il marchio cTUVus indica la conformità del prodotto ai requisiti elettrici di sicurezza UL 60601-1 e CAN/CSA 22.2 601.1 M90 per gli Stati Uniti e il Canada.
Het cTUVus-keurmerk geeft aan dat het product voldoet aan UL 60601-1 en CAN/CSA 22.2 601.1 M90 aangaande de vereisten betreffende elektrische veiligheid voor de VS en Canada.
cTUVusマークは、米国およびカナダ向け電気安全要件を包含するUL 60601-1および
CAN/CSA 22.2 601.1 M90へ適合していることを示す。
cTUVus-mærket betyder, at produktet overholder UL 60601-1 og
CAN/CSA 22.2 601.1 M90 vedr. sikkerhedskrav til elektrisk udstyr for USA og Canada.
Το σήμα cTUVus δείχνει συμμόρφωση με τα πρότυπα UL 60601-1 και
CAN/CSA 22.2 601.1 M90, που καλύπτουν τις απαιτήσεις ηλεκτρικής ασφαλείας στις Η.Π.Α. και τον Καναδά.
A marca cTUVus indica conformidade com as normas UL 60601-1 e
CAN/CSA 22.2 601.1 M90 que cobrem os requisitos de segurança eléctrica para os EUA e o Canadá.
cTUVus-märkningen anger uppfyllelse av UL 60601-1 och CAN/CSA 22.2 601.1 M90 som behandlar elektriska säkerhetskrav i USA och Kanada.
A cTUVus jel az USA és Kanada területén érvényes UL 60601-1. és a
CAN/CSA 22.2 601.1 M90. számú elektromos biztonsági követelményeknek való megfelelőséget jelzi.
Označení cTUVus značí soulad s elektrickými bezpečnostními předpisy UL 60601-1 a CAN/CSA 22.2 601.1 M90 pro Spojené státy a Kanadu.
Znak cTUVus jest potwierdzeniem zgodności z normami UL 60601-1 i CAN/CSA 22.2 601.1 M90 określającymi wymagania dotyczące bezpieczeństwa instalacji elektrycznych w USA i Kanadzie.
cTUVus-merket viser samsvar med UL 60601-1 og CAN/CSA 22.2 601.1 M90 som dekker elektriske sikkerhetskrav for USA og Canada.
cTUVus 标记表示符合美国及加拿大关于电气安全要求的 UL 60601-1 和
CAN/CSA 22.2 601.1 M90
标准的规定。
cTUVus 마크는 미국 및 캐나다의 전기 안전 요건을 포괄하는 UL 60601-1 및
CAN/CSA 22.2 601.1 M90의 규격을 준수함을 나타냅니다.
cTUVus İşareti, ABD ve Kanada için elektrik güvenliği gereklerini kapsayan UL 60601-1 ve CAN/CSA 22.2 601.1 M90 normlarına uygunluğu gösterir.
A marca cTUVus indica conformidade com as normas UL 60601-1 e CAN/CSA 22.2 601.1 M90 que abrangem os requisitos de segurança elétrica para os EUA e o Canadá.
cTUVus-merkki osoittaa, että laite on yhdenmukainen standardien UL 60601-1 ja CAN/CSA 22.2 601.1 M90 kanssa, jotka kattavat sähköturvallisuusvaatimukset USA:ssa ja Kanadassa.
Marca cTUVus atestă conformitatea cu UL 60601-1 şi CAN/CSA 22.2 601.1 M90 privind cerinţele de siguranţă pentru echipamentele electrice în SUA şi Canada.
Знак cTUVus указывает на соответствие требованиям UL 60601-1 и CAN/CSA 22.2 601.1 M90 охватывает требования по электрической безопасности в США и Канаде.
Označenie cTUVus predstavuje súlad s požiadavkami na elektrickú bezpečnosť podľa normy UL 60601-1 a CAN/CSA 22.2 601.1 M90 pre USA a Kanadu.

F

HF Isolated Patient Circuit
Circuito del paciente aislado de HF
Circuit patient isolé HF
HF-isolierter Patientenkreis
Circuito paziente isolato HF
HF-geïsoleerd patiëntcircuit
HF患者用絶縁回路
HF-isoleret patientkredsløb
Απομονωμένο κύκλωμα ασθενούς HF
Circuito do Paciente Isolado contra HF
HF-isolerad patientkrets
HF szigetelt pácienskör
Izolovaný okruh pacienta HF
Izolowany obwód HF pacjenta
HF-isolert pasientkrets
HF 绝缘患者回路
HF 절연 환자 회로
HF Yalıtımlı Hasta Devresi
Circuito do paciente isolado contra HF
HF-eristetty potilaspiiri
Circuit pacient izolat HF
Контур пациента изолирован от ВЧ
Izolovaný okruh pacienta HF

Electrostatic Sensitive Device
Dispositivo sensible a la electrostática
Dispositif sensible aux décharges électrostatiques
Elektrostatisch empfindliches Gerät
Dispositivo sensibile all'energia elettrostatica
Voor elektrostatische energie gevoelig hulpmiddel
静電気に敏感なデバイス
Instrument, der er følsomt over for statisk elektricitet
Συσκευή ευαίσθητη στην ηλεκτροστατική ενέργεια
Dispositivo Sensível a Descarga Electrostática
Utrustning känslig för statisk elektricitet
Elektrosztatikus kisülésre érzékeny eszköz
Zařízení citlivé na elektrický náboj
Urządzenie wrażliwe na wyładowania elektrostatyczne
Enhet som er følsom overfor statisk elektrisitet
静电敏感设备
정전기 감지 장치
Elektrostatik Duyarlılık Cihazı
Dispositivo sensível a descarga eletrostática
Sähköstaattisuudelle herkkä laite
Dispozitiv sensibil la descărcări electrostatice
Устройство, чувствительное к электростатике
Zariadenie citlivé na elektrický náboj

Non-Ionizing Electromagnetic Radiation
Radiación electromagnética no ionizante
Rayonnement électromagnétique non ionisant
Nichtionisierende elektromagnetische Strahlung
Radiazione elettromagnetica non ionizzante
Niet-ioniserende elektromagnetische straling
非電離性電磁放射線
Ikke-ioniserende elektromagnetisk stråling
Μη ιονίζουσα ηλεκτρομαγνητική ακτινοβολία
Radiação Electromagnética Não Ionizante
Icke-joniserande elektromagnetisk strålning
Nem ionizáló elektromágneses sugárzás
Neionizující elektromagnetické záření
Promieniowanie elektromagnetyczne niejonizujące
Ikke-ioniserende elektromagnetisk stråling
非电离电磁辐射
비이온화 전자기 방사선
İyonlaşmayan Elektromanyetik Radyasyon
Radiação eletromagnética não ionizante
Ei-ionisoiva sähkömagneettinen säteily
Radiaţie electromagnetică non-ionizantă
Неионизирующее электромагнитное излучение
Neionizujúce magnetické žiarenie

EP

Output EP Recording System
Salida del sistema de grabación de EF
Sortie vers système d'enregistrement EP
Ausgang EP-Aufzeichnungssystem
Uscita a sistema di registrazione EP
Uitgang EF-registratiesysteem
EP記録システムへの出力
Udgang til EP-registreringssystem
Σύστημα καταγραφής εξόδου EP
Saída do Sistema de registo de EP
Utgång till registreringssystem för EP
EP-rögzítőrendszer kimenet
Systém pro záznam výstupu evokovaných potenciálů
Wyjście do systemu rejestracji parametrów elektrofizjologicznych
Utgang til elektrofysiologisk registreringssystem
输出电生理记录系统
출력 EP 기록 시스템
Çıkış EP Kayıt Sistemi
Sistema de gravação EP de saída
Elektrofysiologiatutkimustietojen tallennusjärjestelmä
Sistem de înregistrare Output EP
Регистрационная система Output EP
Výstupný záznamový systém EP

Remote Control
Control remoto
Commande à distance
Fernbedienung
Telecomando
Afstandsbediening
リモート・コントロール
Fjernbetjening
Μονάδα τηλεχειρισμού
Controlo Remoto
Fjärrkontroll
Távirányító
Dálkový ovladač
Zdalne sterowanie
Fjernkontroll
遥控器
리모컨
Uzaktan Kumanda
Controle remoto
Kauko-ohjain
Telecomandă
Дистанционное управление
Diaľkový ovládač

Speaker Volume
Volumen del altavoz
Volume du haut-parleur
Lautsprechereinstellung
Volume altoparlante
Luidsprekervolume
スピーカー音量
Højttalerstyrke
Ένταση ηχείου
Volume do Altifalante
Högtalarvolym
A hangszóró hangereje
Hlasitost reproduktoru
Głośność głośnika
Høyttalervolum
扬声器音量
스피커 볼륨
Hoparlör Ses Düzeyi
Volume do alto-falante
Kaiuttimen äänenvoimakkuus
Volum difuzor
Громкость динамика
Hlasitosť reproduktora

Power On
Encender
Mettre sous tension
Netz EIN
Accendere
Voeding aan
電源オン
Tænder
Ενεργοποίηση
Ligar
Ström på
Bekapcsolás
Zapnout
Zasilanie Wł.
Slå på
打开电源
전원 켜기
Aç
Ligar
Virta päälle
Pornire
Включение питания
Zapnúť

Power Off
Apagar
Mettre hors tension
Netz AUS
Spegnere
Voeding uit
電源オフ
Slukker
Απενεργοποίηση
Desligar
Ström av
Kikapcsolás
Vypnout
Zasilanie Wył.
Slå av
关闭电源
전원 끄기
Kapat
Desligar
Virta pois päältä
Oprire
Выключение питания
Vypnúť

Temperature at Distal Electrode
Temperatura en el electrodo distal
Température de l'électrode distale
Temperatur an distaler Elektrode
Temperatura presso elettrodo distale
Temperatuur bij distale elektrode
遠位側電極温度
Temperatur ved distal elektrode
Θερμοκρασία στο περιφερικό ηλεκτρόδιο
Temperatura no Elétrodo Distal
Temperatur vid distal elektrod
A disztális elektródánál mért hőmérséklet
Teplota na distální elektrodě
Temperatura na elektrodzie dystalnej
Temperatur ved distal elektrode
远端电极上的温度
원위부 전극 온도
Uzak Elektrottaki Sıcaklık
Temperatura no eletrodo distal
Distaalielektrodin lämpötila
Temperatura la electrodul distal
Температура дистального электрода
Teplota na distálnej elektróde

Mains
Alternating Current
Corriente alterna
Courant alternatif
Wechselstrom
Corrente alternata
Wisselstroom
交流
Vekselstrøm
Εναλλασσόμενο ρεύμα
Corrente Alternada
Växelström (AC)
Váltakozó áram
Střídavý proud
Prąd przemienny
Vekselstrøm
交流电
교류
Alternatif Akım
Corrente alternada
Vaihtovirta
Curent alternativ
Переменный ток
Striedavý prúd

Clock: Time Switch
Reloj: interruptor de tiempos
Horloge : commutation de temps
Uhr: Zeitschalter
Orologio: interruttore di durata
Klok: tijdschakelaar
クロック：時間切替え
Ur: Tidskontakt
Ρολόι: Χρονομετρητής
Relógio: Interruptor de Tempo
Klocka: Tidsbrytare
Óra: időkapcsoló
Hodiny: Přepnutí času
Zegar: przełącznik czasu
Klokke: tidsbryter
时钟：时间开关
시계: 타임 스위치
Saat: Saat Anahtarı
Relógio: temporizador
Kello: aikakytkin
Ceas: comutator cronometru
Часы: программируемый выключатель
Hodiny: časový spínač

Increase
Aumentar
Augmenter
Erhöhen
Aumento
Verhogen
增加
Øg
Αύξηση
Aumentar
Öka
Növelés
Zvýšit
Zwiększ
Øk
升高
증가
Arttır
Aumentar
Lisää
Creştere
Увеличить
Zvýšenie

Decrease
Disminuir
Diminuer
Verringern
Diminuzione
Verlagen
減少
Reducer
Μείωση
Diminuir
Minska
Csökkentés
Znížiť
Zmniejsz
Reduser
降低
감소
Azalt
Diminuir
Vähennä
Reducere
Уменьшить
Znížením

Variability in Steps
Variabilidad en etapas
Variabilité par pas
Variabilität in Schritten
Variabilità a incrementi
Variabiliteit in stappen
段階変動
Skift i trin
Βηματική μεταβολή
Variabilidade em Etapas
Stegvis justering
Lépésvariációk
Velikost kroků
Zmienność skokowa
Trinnvis regulering
逐步变化
단계 변동
Adımlardaki Çeşitlilik
Variabilidade em etapas
Portaallinen säätö
Variabilitate în trepte
Изменение значения (дискретно)
Variabilita krokov

Counter
Contador
Compteur
Zähler
Contatore
Teller
カウンタ
Tæller
Μετρητής
Contador
Räkneverk
Számláló
Počítadlo
Licznik
Teller
计数器
카운터
Sayaç
Contador
Laskuri
Contor
Счетчик
Počítadlo

Zero-Point Adjustment
Ajuste del punto cero
Ajustement à zéro
Nullpunkteinstellung
Regolazione su zero
Instelling nulpunt
ゼロポイント調整
Nulpunktsindstilling
Προσαρμογή σημείου μηδέν
Ajuste de Ponto Zero
Nollpunktsjustering
Nullára állítás
Nastavení nulového bodu
Zerowanie
Nullstilling
零点调节
영점 조정
Sıfır Noktası Ayarı
Ajuste zero
Nollaus
Revenire la zero
Установка нуля
Nastavenie nulového bodu

Radio-Frequency Power (On/Off)
Potencia de radiofrecuencia (activada/desactivada)
Puissance de radiofréquence (marche/arrêt)
Hochfrequenzleistung (Ein/Aus)
Energia a radiofrequenza (attivazione/disattivazione)
Radiofrequentievermogen (aan/uit)
高周波（RF）エネルギー（On/Off）
Radiofrekvens (tænd/sluk)
Ισχύς ραδιοσυχνοτήτων (Ενεργοποίηση/απενεργοποίηση)
Potência de Radiofrequência (Ligar/Desligar)
Radiofrekvensenergi (på/av)
Rádiófrekvencia (be/ki)
Radiofrekvenční výkon (zap/vyp)
Moc częstotliwości radiowej (wł./wył.)
Radiofrekvensenergi (på/av)
射频功率（开/关）
무선 주파수 전원(켬/끔)
Radyo Frekans Gücü (Açık/Kapalı)
Radiofrequência (Liga/Desliga)
Radiotaajuusteho (päällä/pois)
Alimentare radiofrecvență (Pornire/Oprire)
ВЧ-энергия (вкл./выкл.)
Spínač rádiovej frekvencie (Zap./Vyp.)

Explosion Hazard
Peligro de explosión
Risque d'explosion
Explosionsgefahr
Rischio di esplosione
Explosiegevaar
爆発の危険性あり
Eksplosionsfare
Κίνδυνος έκρηξης
Risco de Explosão
Explosionsrisk
Robbanásveszély
Nebezpečí výbuchu
Niebezpieczeństwo wybuchu
Eksplosjonsfare
爆炸危险
폭발 위험
Patlama Tehlikesi
Perigo de explosão
Räjähdysvaara
Pericol de explozie
Взрывоопасно
Nebezpečenstvo výbuchu

Boston Scientific

Maestro Foot Switch

RF Ablation Foot Switch

Directions for Use **2**

90993049-01A

2014-10

TABLE OF CONTENTS

Maestro Foot Switch

RF Ablation Foot Switch

℞ ONLY

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

WARNING

Contents supplied NON-STERILE. If damage is found, call your Boston Scientific representative. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Foot Switch is an accessory available for use with the Boston Scientific Corporation Maestro Cardiac Ablation Controllers.

A Foot Switch can be used to provide ON/OFF control of the RF power delivery. The connecting cable's 10-foot length allows the user to stand at the catheterization table near the patient without requiring another person for starting/stopping RF power delivery.

User Profile

The Foot Switch is an optional accessory of the Maestro Cardiac Ablation Controller and is to be used only by physicians fully trained in cardiac electrophysiology procedures. Assistance to connect the cables, operate the Irrigation pump and Radiofrequency (RF) controller may only be provided by fully trained electrophysiology laboratory staff.

Contents

- One (1) Foot Switch

INTENDED USE / INDICATIONS FOR USE

The Maestro Cardiac Ablation Controller and Foot Switch are indicated for use in cardiac ablation procedures with Boston Scientific cardiac ablation catheters.

Note: Refer to the individual Directions for Use for catheter compatibility to the Cardiac Ablation. 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 Cardiac Ablation.

Note: Refer to the Cardiac Ablation System Operator's Manual for specific indications, contraindications, warnings, precautions and adverse events, prior to use of Cardiac Ablation System.

CONTRAINDICATIONS

There are no known contraindications for the Maestro Foot Switch.

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

WARNINGS

Before operating the System, carefully review these warnings:

- 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. Additional equipment connected to the signal input ports or signal output ports configures a medical system. Ensure that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical services department or your local BSC representative.
- The use of accessories, transducers and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Cardiac Ablation System.
- No modification of the equipment is allowed.

PRECAUTIONS

Review the following precautions before using the System:

- Do not attempt to operate the Cardiac Ablation System or Foot Switch before thoroughly reading this Operator's Manual.
- 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 Foot Switch 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 high-frequency surgery.
- Regularly inspect re-usable cables and accessories. In particular, cables and accessories should be checked for possible damage to the insulation.

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, contra-indications, warnings, precautions, and adverse events included with each catheter and the Cardiac Ablation System, prior to use of the catheter and System with the Foot Switch.

HOW SUPPLIED

- One (1) Foot Switch, supplied non-sterile.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Handling And Storage

Operating Environment

Ambient Temperature: 10 °C to 40 °C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29 °C to 60 °C

Relative Humidity: 30% to 85%

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 20 °C to 30 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

OPERATIONAL INSTRUCTIONS

- The Foot Switch is intended for installation within the Patient Environment.

Note: The Patient Environment is described per IEC 60601-1 as any volume in which intentional or unintentional contact can occur between Patients and parts of the System, or between Patient and other persons touching parts of the system.

- If using the Foot Switch, install its cable connector into the "Foot Switch" Cable Connector on the Controller rear panel. The Foot Switch functions similarly to the RF POWER CONTROL Button except that the user must continuously hold the Foot Switch down for RF power to be delivered. RF power delivery is immediately terminated when the user's foot is lifted off the Foot Switch.

SERVICE AND MAINTENANCE

Preventative Inspection

During the useful life of the equipment, maintain close watch for damage such as frayed cords or cables and cracks or dents on the equipment. If damage is identified, take the equipment out of service and contact Boston Scientific Corporation for service requirements.

System Servicing

None of the System components are user-serviceable. Contact Boston Scientific Corporation for all service requirements.

Cleaning/Disinfecting

The outer surfaces of the Foot Switch may be wiped clean with a mild soapy solution. If disinfecting is required, isopropyl alcohol may be used to clean the outer surfaces.

Precaution: Do not immerse the Foot Switch, cable and connector in any liquid. Avoid caustic or abrasive cleaners.

Precaution: 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 high-frequency surgery.

End of Useful Life

When the equipment reaches the end of its useful life, dispose of the Foot Switch in accordance with hospital, administrative and/or local government policy.

Note: Contact your BSC representative or BSC field service engineer (1.800.949.6708 in the US) prior to disposal.

LIMITED WARRANTY AND DISCLAIMER

Limited Warranties

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this system. When maintained in such conditions as specified by BSC, it will be free from defects in material and workmanship at buyer's location for 12 months from the date of deliver. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, and cleaning of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the system and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Service is limited to exchanging faulty system components. No in-field repairs will be performed. For service, contact the BSC authorized service representative. You must pay all freight charges for all parts returned to BSC. BSC will pay freight for shipping the repaired or replaced parts back to you. BSC extends, to the registered user, all warranties offered by third party software upon which the System depends.

Software, Hardware and Support Service Contracts may be purchased at any time after the warranty expires. Contact BSC for more information.

Disclaimer and Exclusion of Other Warranties

There are no warranties of any kind that extend beyond the description of the warranties above. Boston Scientific Corporation disclaims and excludes all warranties, whether express or implied, of merchantability of fitness for a particular use or purpose.

Limitation of Liability for Damages

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Boston Scientific Corporation shall not be liable for damages for loss of profits or revenues, loss of use of the product, loss of facilities or services, any downtime costs, or for claims of buyer's customers for any such damages. Boston Scientific Corporation's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Boston Scientific Corporation to buyer which give rise to the claim for liability. The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

REF

Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência

Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
Conteúdo

EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

UPN

Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

[blue safety sign]
Follow Instructions For Use
[símbolo azul de seguridad]
Seguir las instrucciones de uso
[symbole de sécurité bleu]
Suivre les instructions du mode d'emploi
[blaues Sicherheitszeichen]
Gebrauchsanweisung befolgen
[simbolo di sicurezza blu]
Attenersi alle Istruzioni per l'uso
[blauw veiligheidsteken]
Volg de instructies voor gebruik
[sinal de segurança azul]
Siga as Instruções de Utilização

SN

Serial Number
Número de serie
Numéro de série
Seriennummer
Numero di serie
Serienummer
Número de série

Non-Sterile
No estéril
Non stérile
Nicht steril
Non sterile
Niet-steriel
Não esterilizado

Separate Collection
Recogida independiente
Élimination séparée
Sonderabfall
Raccolta differenziata
Gescheiden inzameling
Recolha Separada

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

Date of Manufacture
Fecha de fabricación
Date de fabrication
Herstellungsdatum
Data di fabbricazione
Fabricagedatum
Data de Fabrico

CAUTION. Attention: Consult ACCOMPANYING DOCUMENTS.
PRECAUCIÓN. Atención: consulte los DOCUMENTOS ADJUNTOS.
AVERTISSEMENT. Attention : Lire les documents joints.
VORSICHT. Achtung: BEGLEITDOKUMENTE beachten.
ATTENZIONE. Attenzione: consultare i DOCUMENTI ALLEGATI.
LET OP. Attentie: Raadpleeg BIJGAANDE DOCUMENTEN.
CUIDADO. Atenção: Consulte os DOCUMENTOS INCLUSOS.

cTUVus Mark indicates compliance to UL 60601-1 and CAN/CSA 22.2 601.1 M90 covering electrical safety requirements for the US and Canada.
El símbolo cTUVus indica cumplimiento con las regulaciones UL 60601-1 y CAN/CSA 22.2 601.1 M90 correspondientes a los requisitos de seguridad eléctrica en los Estados Unidos y Canadá.
La marque cTUVus indique le respect des normes de sécurité électrique UL 60601-1 et CAN/CSA 22.2 601.1 M90 pour les États-Unis et le Canada.
Das cTUVus-Kennzeichen bedeutet die Übereinstimmung mit UL 60601-1 und CAN/CSA 22.2 601.1 M90, wodurch die Anforderungen für elektrische Sicherheit in den USA und Kanada abgedeckt sind.
Il marchio cTUVus indica la conformità del prodotto ai requisiti elettrici di sicurezza UL 60601-1 e CAN/CSA 22.2 601.1 M90 per gli Stati Uniti e il Canada.
Het cTUVus-keurmerk geeft aan dat het product voldoet aan UL 60601-1 en CAN/CSA 22.2 601.1 M90 aangaande de vereisten betreffende elektrische veiligheid voor de VS en Canada.
A marca cTUVus indica conformidade com as normas UL 60601-1 e CAN/CSA 22.2 601.1 M90 que cobrem os requisitos de segurança eléctrica para os EUA e o Canadá.

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Made in USA:
29 Plaine Hill Road
Woodstock, CT, 06281
USA

Do not use if package is damaged.

Recyclable Package

CE

SPINE WIDTH

This artwork is not ready for release until this note is removed. Engineer must verify spine width. Remove note after layout has been adjusted.

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

BRA **Brazil Local Contact**

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TUR **Turkey Local Contact**

Boston Scientific Tıp Gereçleri Ltd. Şti.
Altunizade Mah. Ord. Prof. Fahrettin Kerim Gökay Cad. 45/1
Üsküdar 34662, Istanbul
Tel +90 216 544 47 00
Faks +90 216 544 47 01

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Made in USA:
47215 Lakeview Blvd
Fremont, CA 94538
USA

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2015-09

91081756-01

MetriQ™ Pump Operator's Manual

Boston Scientific

MetriQ™ Pump

Operator's Manual

MetriQ Pump (M00441000)
91081756-01A

TABLE OF CONTENTS

WARNING: Do not attempt to install or operate the MetriQ™ Pump before thoroughly reading this 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. For future reference, keep this manual in a convenient, readily accessible place.

℞ ONLY

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

DEVICE DESCRIPTION

The MetriQ Pump is a peristaltic pump used during RF Cardiac Ablation interventional procedures. Its purpose is to irrigate BSC open-irrigated ablation catheter tip electrodes with saline solution by providing a single channel of continuous flow. The pump will be used in conjunction with the MetriQ Irrigation Tubing Set, the BSC Maestro 4000 Cardiac Ablation System, and BSC open-irrigated ablation catheters.

When used in automatic mode, the Maestro 4000 Cardiac Ablation System and the MetriQ Pump communicate to coordinate delivery of RF energy and irrigation flow to the catheter tip.

Note: Throughout this Manual, the term "System" refers to the Maestro 4000 Cardiac Ablation System and the terms "RF Generator", or "Generator", refer to the "Maestro 4000 Controller.

User Profile

The MetriQ Pump should be used only by physicians fully trained in cardiac electrophysiology. EP lab staff members prepare the Pump for use and assist with operation of the Pump.

Contents

- (1) MetriQ Pump (M00441000)
- (1) Intravenous (IV) Pole Mount
- (1) MetriQ Pump Operator's Manual

Accessories

- MetriQ Irrigation Tubing Set (M0041170)
- Foot Switch (M0044105F0)
- Cable, Generator to Pump or Remote
  - 20 ft (M0046610)
  - 25 ft (M0046620)
  - 50 ft (M0046630)
  - 75 ft (M0046640)

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 the specific indications, contraindications, warnings, and precautions included with any open-irrigated cardiac ablation catheter used in conjunction with the pump.

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

HOW SUPPLIED

The MetriQ Pump, MetriQ Pump Operator's Manual, and an IV pole clamp are supplied as non-sterile devices in a corrugated box.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Operating Environment

Ambient Temperature: 10 °C to 40 °C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 kPa to 106 kPa

Storage Environment

Temperature: 15 °C to 30 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

Transport Environment

Temperature: -29 °C to 60 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

CONTROLS, DISPLAYS AND INDICATORS

Note: The use of all components and accessories of the MetriQ™ Pump and MetriQ Irrigation Tubing Set are described in this manual with the exceptions of the Maestro 4000™ Cardiac Ablation System and the BSC open-irrigated catheters which are compatible with the pump. Instructions for use of the Maestro 4000 Cardiac Ablation System are included in the Operator's Manual provided with the System. Instructions for use of the BSC open-irrigated catheters are included in the Directions for Use (DFU) provided with the individual catheters. This manual provides a description of the pump, the Pump controls and displays, and the Pump operation. Other important information has also been supplied for user convenience and safety.

Rear Panel Features/Connections

The following features and connectors are illustrated in Figure 1.

- Mains Power Switch — the Mains Power Switch turns the unit ON and OFF.
- IV Pole Mounting Bracket — the pump can be mounted to an IV pole using this bracket.
- Fuse Panel — this panel contains the pump's electrical fuses.
- Mains Power Inlet — the pump's AC power cord connects to this receptacle.
- Potential Equalization Terminal — this terminal can be used to verify compliance with 60601-1. This terminal is used for connecting dedicated ground leads.
- Service Port — the service port is used by BSC qualified personnel to service the pump. Users should not attempt to access this port.
- Foot Switch Receptacle — the pump's foot switch cable plugs into this receptacle.
- Receptacle — the Generator to Pump cable connects to this receptacle.
    - The pump is shipped with a removable cover on this receptacle. Remove the cover to connect the Generator to Pump cable.

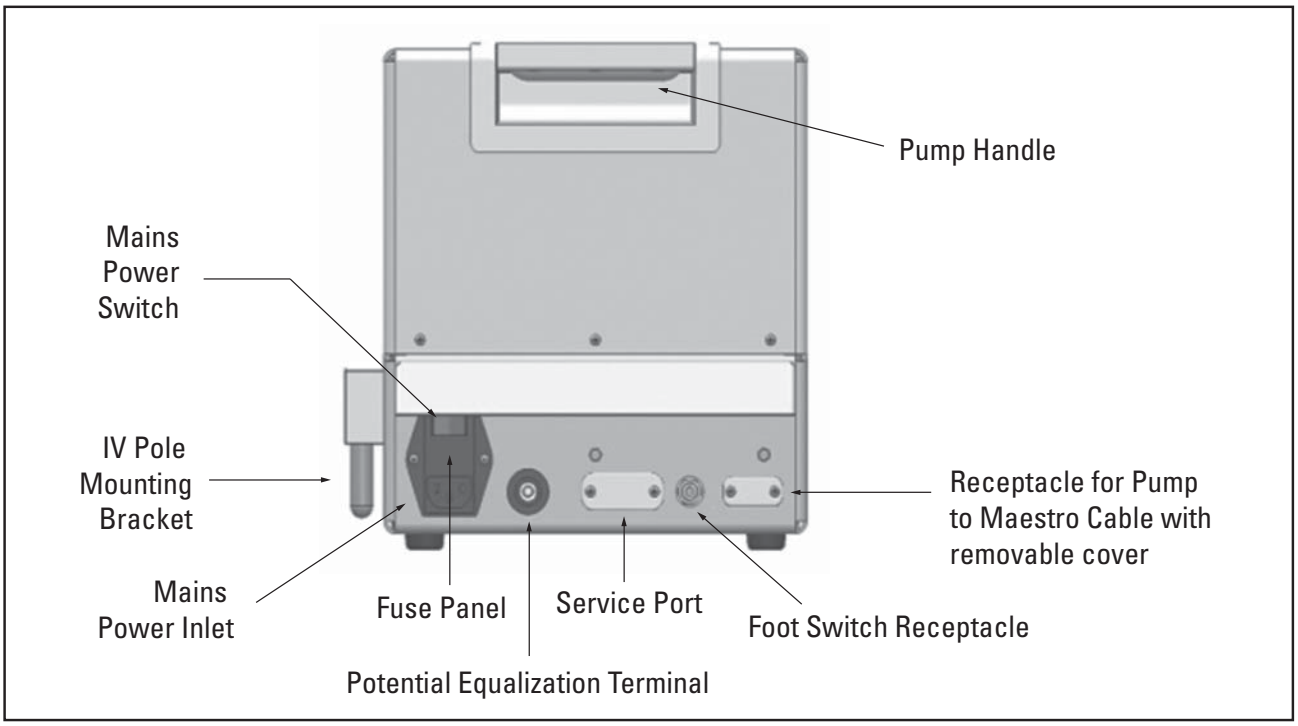


Figure 1. MetriQ Pump Rear Panel

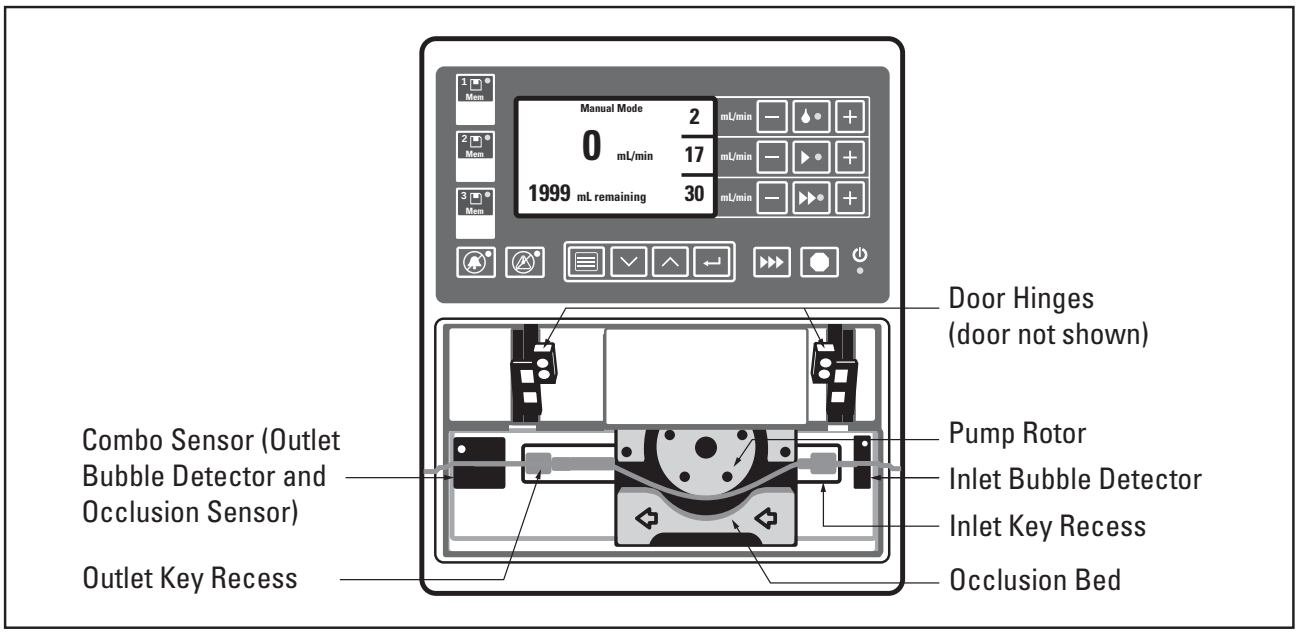


Figure 2. MetriQ™ Pump Front Panel

Front Panel Features and Controls

The pump's display screen and the control button groups are illustrated in Figure 3.

- Buttons in the FLOW CONTROL group are used to set flow rates and to start irrigation flow manually.
- Buttons in the PURGE/STOP group are used to purge the tubing set and manually stop irrigation flow.
- Buttons in the MENU NAVIGATION group are used to navigate the menu screens that control other operating parameters.
- Buttons in the MEMORY group are used to save the flow rate settings and the parameters that can be changed through the menu screens.
- Buttons in the ALARMS section are used to silence audible alarms or clear the diagnostic message associated with the alarm.

Each group of control buttons listed above is explained in greater detail in the following pages.

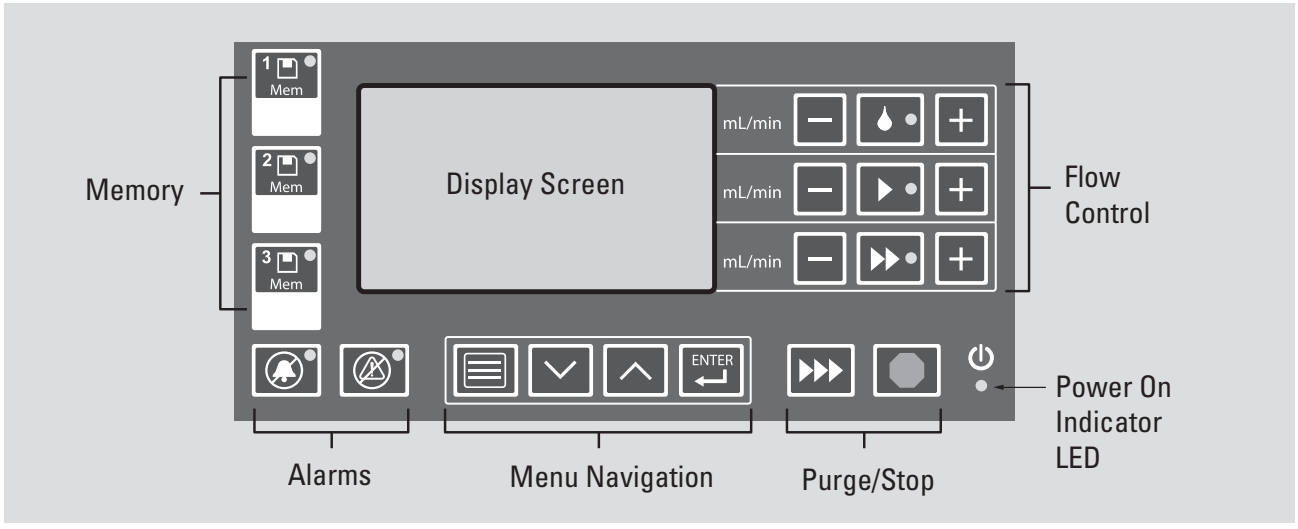


Figure 3. MetriQ Pump Front Panel Controls

Flow Control Buttons

Pump flow rates that can be preset by the user include a STANDBY FLOW rate plus LOW ABLATION FLOW and HIGH ABLATION FLOW rates. The minimum and maximum settings for each flow rate and the icon representing that flow rate are listed in Table 1.

Table 1. Pump Flow Rate Icons and Ranges

Pump Flow Rates	Icon	Minimum	Maximum
Standby Flow		2 mL per minute	5 mL per minute
Low Ablation Flow		6 mL per minute	29 mL per minute
High Ablation Flow		7 mL per minute	30 mL per minute

As shown in Figure 4, each flow rate has three control buttons arranged in a row. The center button of each row is marked with the icon for the flow rate controlled by that row. The center button also has a small LED that lights when the pump is running at that flow rate. The flow rate settings are displayed on the display screen to the left of the flow control buttons. The setting for each flow rate can be decreased or increased in 1 mL increments by pressing the minus (-) or plus (+) buttons for that flow rate.

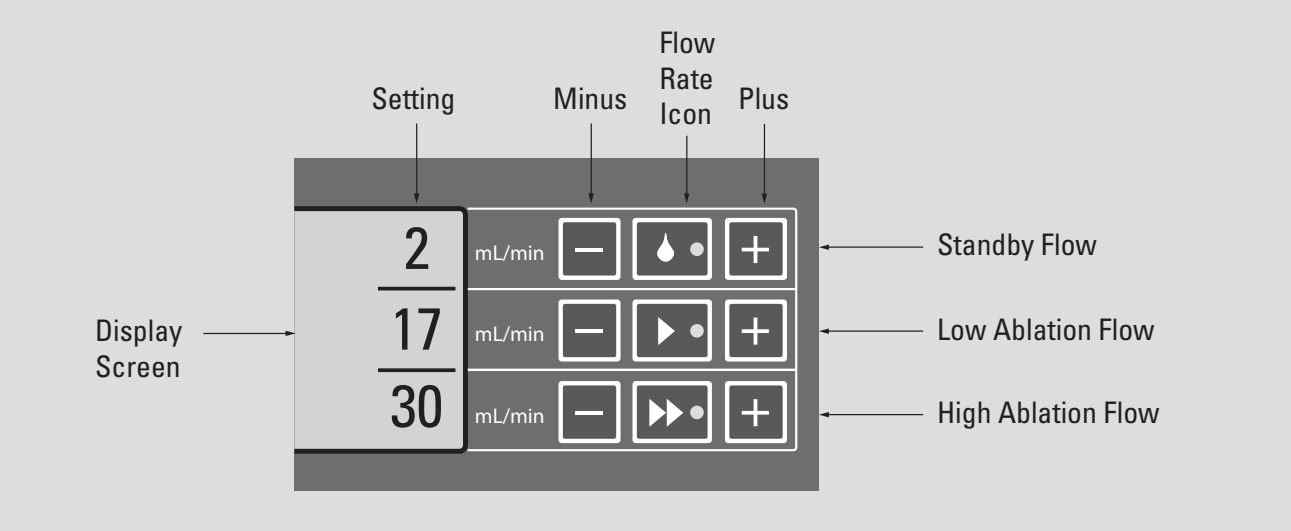


Figure 4. Flow Rate Control Buttons

Note: The HIGH FLOW rate must be at least 1mL greater than the LOW FLOW rate. When there is only 1 mL difference between the HIGH FLOW and LOW FLOW rates:

- Pressing the LOW FLOW plus (+) button will increase both LOW FLOW and HIGH FLOW rates
- Pressing the HIGH FLOW minus (-) button will decrease both LOW FLOW and HIGH FLOW rates

The PURGE button is provided to purge air from the tubing set and catheter while the catheter is not in the patient. When the purge button is pressed and held, bubble detection is bypassed and the pump runs at a rate of 60 mL/min. Purge flow stops when the button is released.

The purge function is disabled and the pump displays the message "PURGE NOT ALLOWED…"

- when Standby or Ablation flow is active
- when the menu is open
- when the Maestro indicates the catheter is in the patient

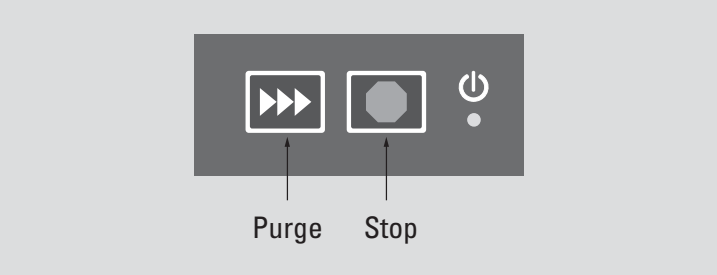


Figure 5. Purge Flow and Stop Flow Control Buttons

The STOP button instantly stops all flow by stopping the pump rotor. The user will hear a single beep as the pump stops.

Menu Navigation Buttons

The menu navigation buttons shown in Figure 6 are used to access and navigate menu screens that allow the user to set the operating parameters described in the following section.

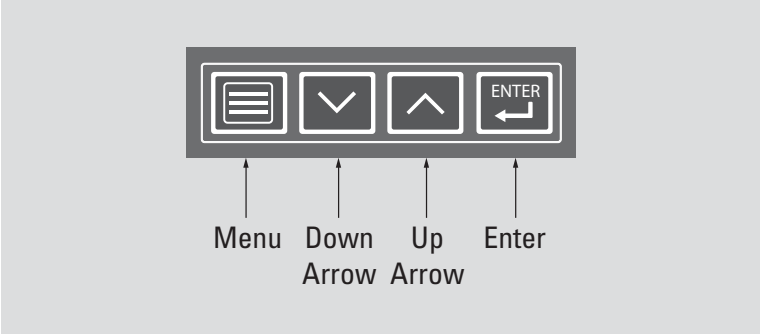


Figure 6. Menu Navigation Buttons

Follow the sequence below to access the menu and choose a new value for a parameter.

- Press the MENU button to display the menu on the display screen.
- Press the ARROW buttons to highlight the desired parameter.
- Press the ENTER button to select the highlighted parameter.
  Note: The current value for the selected parameter will flash
- Press the ARROW buttons to choose a new value.
- Press the ENTER button to save the new value.

The MENU button can also be used to deselect a parameter or to exit the menu.

Operating Parameters

Volume Remaining, Volume Infused, and Volume Dispensed are the first parameters listed in the menu.

- **Volume Remaining** is calculated by subtracting the Volume Dispensed from the Saline Bag Size.
- **Volume Infused** (only accumulates in automatic mode) — indicates how much fluid has been pumped only while the catheter is inside the patient (This does not include purge volumes).
- **Volume Dispensed** — shows the total volume of fluid dispensed regardless of whether catheter is in/out of patient and/or IV bag changes (This does include purge volumes).

Volume Infused and Volume Dispensed are recorded measurements that may be reset by starting a new case or procedure.

Parameters that Apply in both Manual and Automatic Mode

New Saline Bag? NO/YES — Selecting YES will reset the Volume Remaining to the value currently entered for Saline Bag Size.

New Procedure? NO/YES — Selecting YES will reset the dispensed and infused irrigation fluid volumes to zero.

Saline Bag Size? — Select the size of the saline bag (500 mL, 1000 mL, 1500 mL or 2000 mL).

Low Fluid Warning — Select the fluid level (Volume Remaining) that will trigger the Low Fluid Warning.

Fluid Vol. Display — Select the volume parameter to be displayed during pump operation (Volume Remaining, Volume Infused or Volume Dispensed).

Note: The Volume Infused can only be displayed in automatic mode. If Volume Infused is selected while the pump is in manual mode, the Volume Dispensed will be displayed instead.

Loudness — Select the volume level for audible alarms and tones (1 low/5 high).

Parameters that Apply in Automatic Mode Only

Pre-RF Delay — Select the amount of time (1 second to 15 seconds) the pump runs at the ablation flow rate before the RF Generator delivers RF energy.

Post-RF Delay — Select the amount of time (0 seconds to 15 seconds) the pump runs at the ablation flow rate after the RF Generator stops delivery of RF energy.

Min. Temperature Drop — Select the drop in catheter tip temperature (0 °C to 5 °C) that must be measured by the RF Generator during the Pre-RF Delay to allow delivery of RF Energy.

Note: This is a safety feature to ensure the pump is properly cooling the catheter tip. Delivery of RF energy will be prevented and the RF Generator will display the message "NO TEMP DROP" if the temperature does not drop by at least this amount during the Pre-RF Delay.

To Trigger Hi Flow — Select the RF Generator power setting that will trigger the pump to switch from LOW ABLATION FLOW rate to HIGH ABLATION FLOW rate.

Note: During Pre-RF delay, Ablation, or Post-RF delay, the pump will:

- Operate at the preset LOW ABLATION FLOW rate when the RF Generator power is below the trigger value.
- Operate at the preset HIGH ABLATION FLOW rate when the RF Generator power is at or above the trigger value.

Memory Buttons

The MEMORY buttons shown in Figure 7 allow the user to save a set of pump settings which include the (Standby, Low, and High) flow rates plus settings the user can change using the menu. A MEMORY button may be designated to store a commonly used set of pump settings or a set of pump settings associated with a specific procedure. A white space for labeling is provided on each MEMORY button.

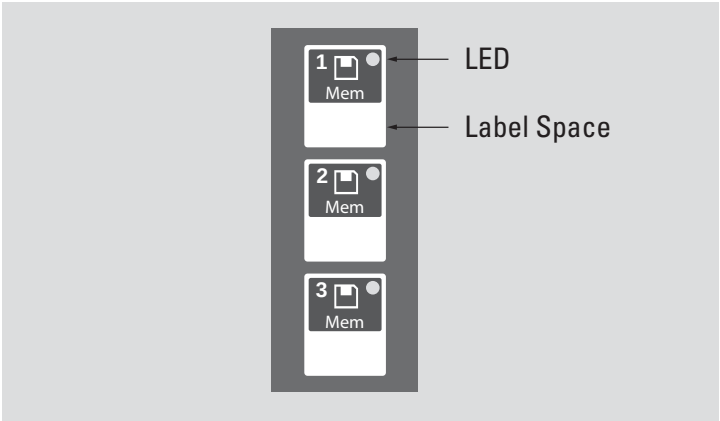


Figure 7. Memory Buttons

Pressing and holding a MEMORY button will save the current pump settings to that MEMORY button. The LED on the MEMORY button will darken momentarily and a short beep will sound, indicating that the settings have been saved. After saving, the LED will remain lit to indicate the settings stored by the MEMORY button are currently active.

Pressing and releasing a MEMORY button will replace the current pump settings with the settings stored by that MEMORY button. The MEMORY button's LED will be lit to indicate the pump is currently using the settings stored by that MEMORY button.

The MEMORY buttons are only functional when the pump is in STANDBY FLOW or STOPPED. If a MEMORY button is pressed during LOW FLOW or HIGH FLOW, the message "MEMORY BUTTON NOT ALLOWED" will appear.

Alarm Buttons

The SILENCE ALARM button and the CLEAR MESSAGE button are shown in Figure 8.

Figure 8. Silence Alarm and Clear Message Buttons

When a fault occurs during operation, an alarm sounds and a diagnostic message is displayed on the display screen. The SILENCE ALARM button and the CLEAR MESSAGE button each have an LED that will flash in sync with the audible alarm.

Pressing the SILENCE ALARM button will silence the alarm for two minutes in manual mode, or five minutes in automatic mode. Once the audible alarm is silenced, take the appropriate action to correct the cause of the fault (See Diagnostic Messages for corrective actions).

After the cause of the fault is corrected, press the CLEAR MESSAGE button to clear the diagnostic message.

Note: The alarm will sound again after the alarm silence period ends if the cause of the fault is not corrected and the diagnostic message is not cleared.

Display Screen Fields

The fields of the Display Screen are shown in Figure 9 below.

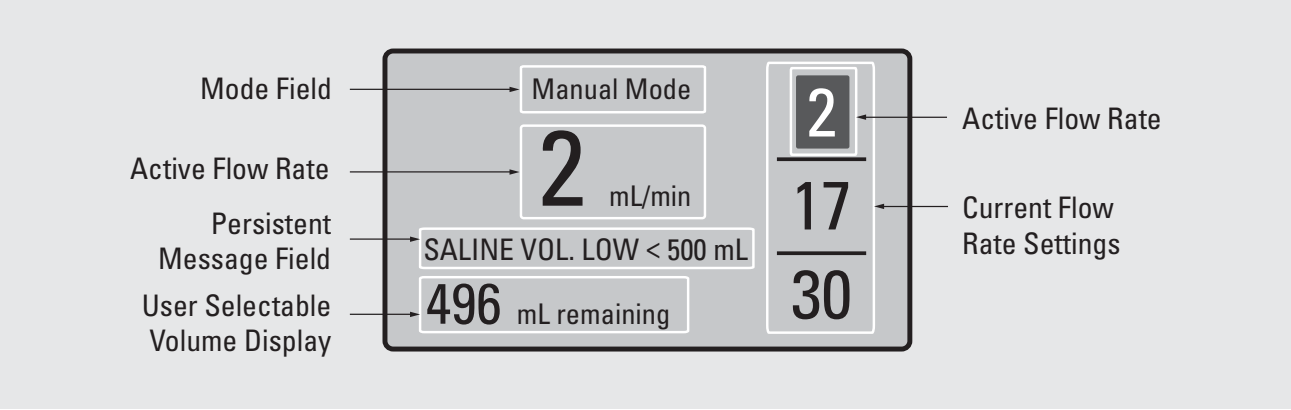


Figure 9. Fields of the Display Screen

- The Mode field indicates the current operating mode (manual or automatic).
- The Active Flow Rate field displays the current flow volume.
- The Low Saline field prompts the user to change the saline bag.
- The Volume Display field displays Infused, Dispensed, or Remaining Volume.

PUMP SETUP

- **WARNING:** No modification of this equipment is allowed other than the specified fuses, as this may result in electrical shock and/or other unexpected consequences.
- **WARNING:** To avoid the risk of explosion, do not use the pump in the presence of flammable anesthetics or in an oxygen rich environment.
- **WARNING:** If not installed and used in accordance with the instructions, this equipment may cause harmful interference to other devices in the vicinity. Even though this equipment has been tested and found to comply with the limits for medical devices, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to devices, which can be determined by turning the equipment off and on, 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 the manufacturer for help.
- **WARNING:** 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.
- **WARNING:** The pump should not be used adjacent to, or stacked with, other equipment that is sensitive to moisture.
- **WARNING:** Do not place any items on top of the pump when mounted to IV pole.
- **WARNING:** 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.

Inspection

Thoroughly inspect the outside of all shipping containers for indications of damage. Contact the shipping firm as necessary to resolve shipping damages.

Carefully remove components from shipping cartons and packing material and inspect all components to make certain they have not been damaged in shipment. Contact Boston Scientific using the phone numbers listed on the back cover of this manual with any questions or concerns.

The following items are required for use and are included in the shipping carton:

- MetriQ™ Pump
- MetriQ Pump Operator's Manual
- IV pole Mounting Clamp

The following additional items are needed for use and are available separately:

- MetriQ Irrigation Tubing Set (single-use only)
- BSC Open Irrigated Catheter (single-use only)
- Power Cord (country/region-specific)
- Generator to Pump Cable

Operating the MetriQ Pump in automatic mode in conjunction with the Maestro 4000™ Cardiac Ablation System requires a Generator to Pump Cable.

IV Pole Mount

The pump can be mounted on a standard IV pole or horizontal mounting rail using the IV pole mounting clamp. The pump can also be operated while sitting on a level surface such as a table top.

- Firmly fasten the mounting clamp onto the IV pole or mounting rail near the patient.
- Slide the pump mounting bracket pin into the hole in the mounting clamp.
- Compatible width of the IV pole: 0.875 inches to 1.375 inches (2.22 cm to 3.49 cm)

It is recommended to:

- Use a five or six-legged hospital grade IV pole with a minimum base diameter of 25 inches (63.5 cm).
- Attach the mounting clamp to the IV pole no more than 5 feet (1.5 m) above the ground.
- Attach the IV bag to the IV pole on the side opposite the pump.
- Position the hook for the IV bag no more than 7 feet (2.1 m) above the ground.

Footswitch

The foot switch is an optional accessory used only in Manual Mode to switch between the existing flow rate and the HIGH ABLATION FLOW rate. The pump foot switch will not function when the pump is in Automatic Mode. Plug the foot switch cable into the foot switch receptacle on the pump's rear panel. The foot switch is immediately ready for use upon connection. Press either the STANDBY FLOW or the LOW ABLATION FLOW button on the front panel to manually start irrigation flow. Press and hold down the foot switch pedal to switch to the HIGH ABLATION FLOW rate. When the pedal is released, the pump will revert to the previous flow rate.

Connections

- **WARNING:** A Hospital Grade power cord (such as those available for the MetriQ™ Pump) must be used to connect the MetriQ Pump's Mains Power Inlet to an AC wall outlet designated as "Hospital Grade" or "Hospital Only."
- **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- **WARNING:** Equipment connected to the analog and digital interfaces of the System 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 (or 60601-1 3rd edition). Any user who connects additional equipment to the signal input ports or signal output ports configures a medical system, and is therefore responsible for the compliance of that system with the requirements of the system standard IEC 60601-1-1 (or 60601-1 3rd edition).

Note: Connect the RF Generator and the MetriQ Pump using the Generator to Pump Cable to operate in Automatic Mode. Otherwise, the pump will operate in Manual Mode.

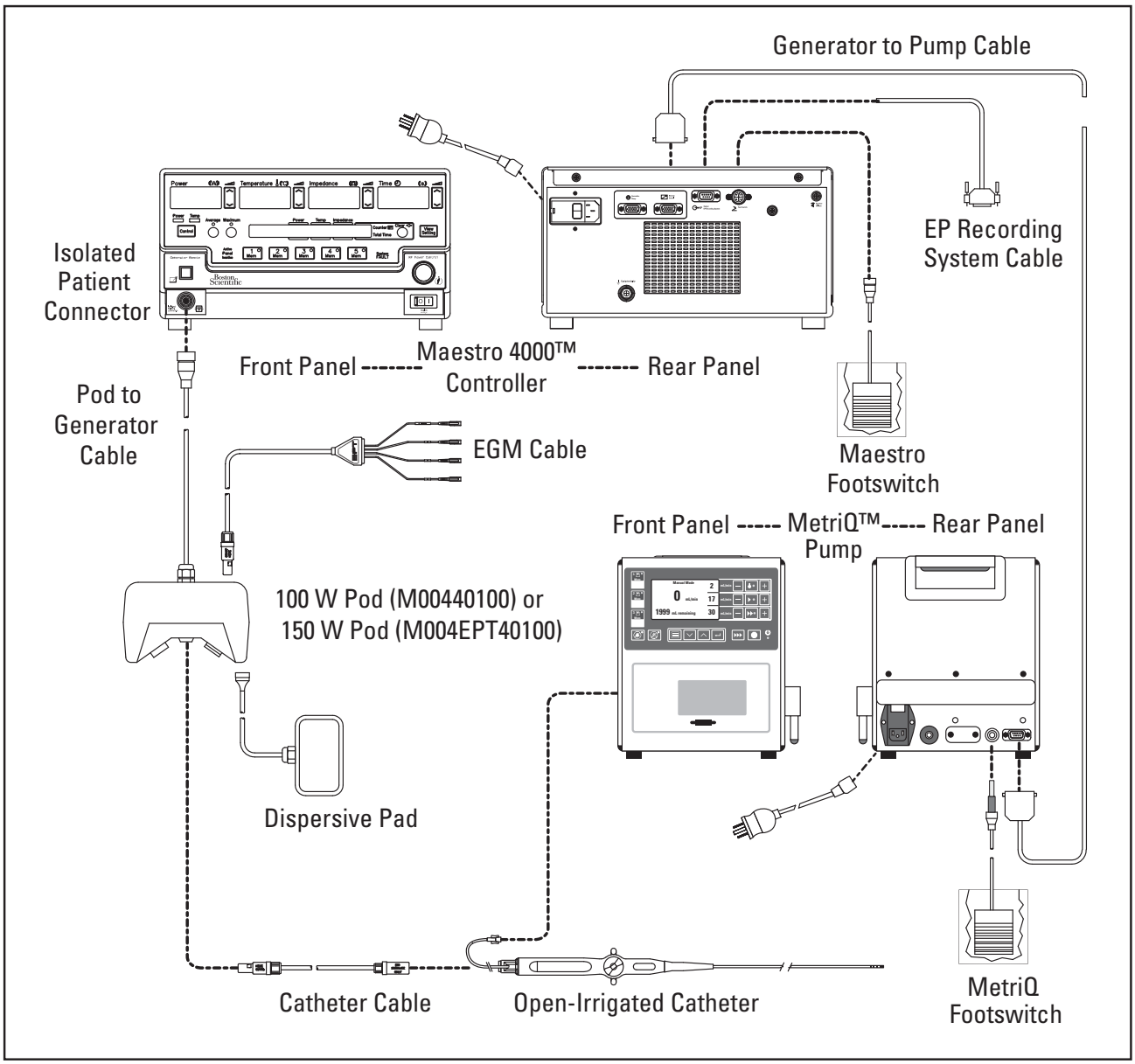


Figure 10. Diagram of Maestro 4000 Cardiac Ablation System with Optional MetriQ Pump

OPERATION

- **WARNING:** Intentional misuse of the pump may cause serious injuries to operator and/or patient.
- **WARNING:** 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.
- **WARNING:** 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.

- **WARNING:** 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.
- **WARNING:** During use, monitor tubing set for visible bubbles and stop the pump if air bubbles are observed to prevent possible occurrence of embolism.
- **WARNING:** Do not press the purge button while catheter is in the patient or embolism may occur. The bubble detector is necessarily disabled during purging.
- **WARNING:** 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.

Start-Up

The MAINS POWER SWITCH is located on the pump's rear panel near the MAINS POWER INLET (See Figure 1). The Power ON Indicator LED located on the front panel (See Figure 3) will light when power is engaged.

When power is switched ON, the pump runs a self-test to verify functionality. When the test passes, the message "Ready" appears briefly on the screen indicating the pump is ready for use.

After the self-test, the user is prompted to retain or reset pump-volume measurements by choosing one of the two options listed below. Use the ARROW keys to highlight the desired option, and then press the ENTER button.

- The **Continue Previous Case** option will retain the values currently recorded for dispensed and infused irrigation fluid volume.
- The **Start New Case** option will reset the dispensed and infused irrigation fluid volumes to zero.

Loading the Tubing Set

- **WARNING:** 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.
- **WARNING:** 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.
- **WARNING:** 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.
- **WARNING:** The tubing set must be properly loaded into the pump before inserting the catheter into the patient.

The features of the MetriQ Irrigation Tubing Set are identified in Figure 11.

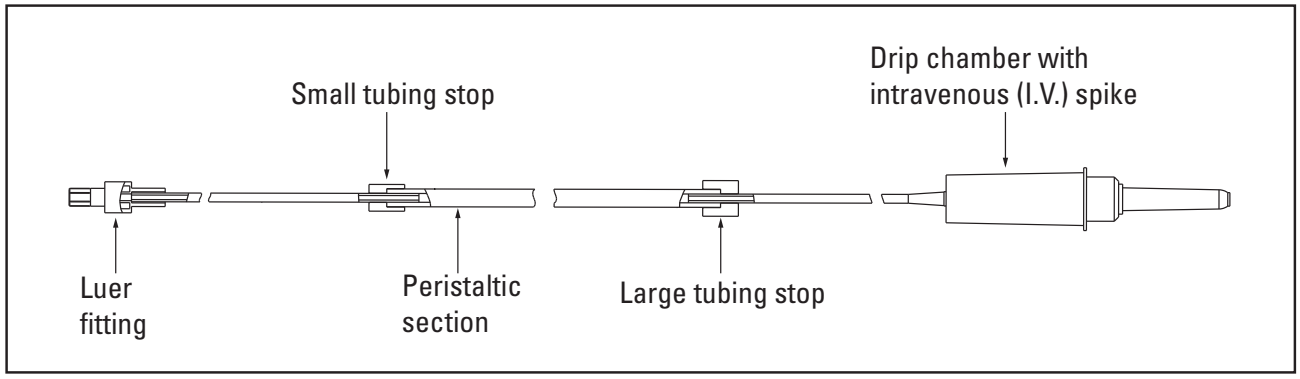


Figure 11. MetriQ Irrigation Tubing Set

1. Open the MetriQ™ Irrigation Tubing Set package. Carefully transfer the package contents into the sterile field, maintaining sterile technique.
2. While in the sterile field remove the two (2) tie clips from the tubing by gently twisting the heads of the clips. Ensure the outer surface of the tubing set is dry.
3. Connect the stopcock to the luer lock on the tubing set and ensure it is closed.
4. Connect the Tubing Set to the irrigation source. Hang the irrigation source near the pump and fill the drip chamber about two-thirds full.

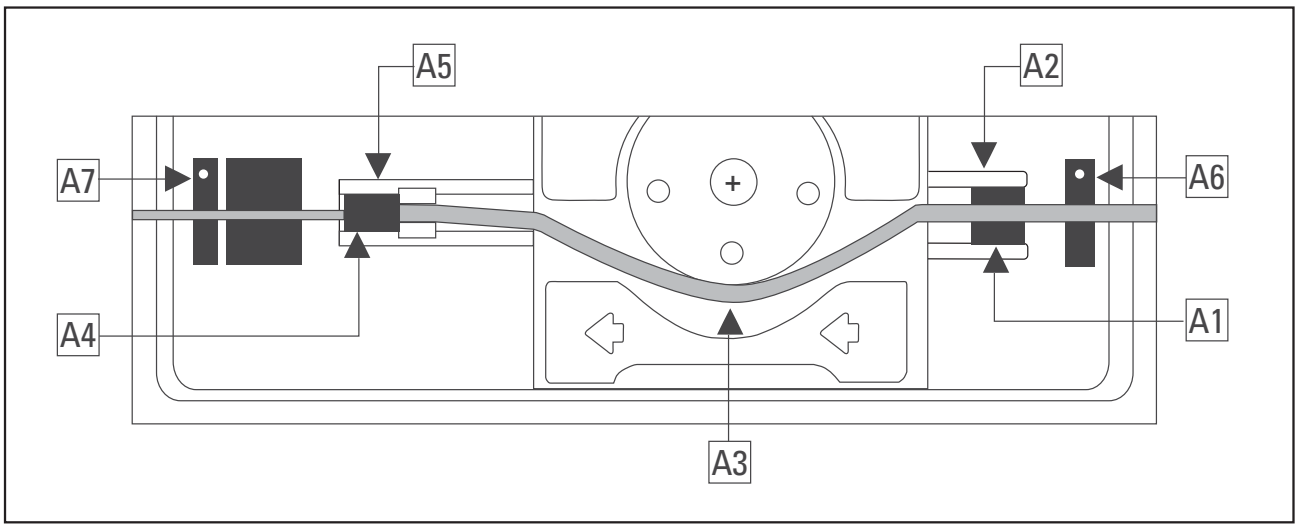


Figure 12. MetriQ Irrigation Tubing Set Installed on MetriQ Pump

5. Open the door on the MetriQ Pump by turning the black handle counter-clockwise.
6. Install the large tubing stop (A1) of the tubing set into the retainer on the right side (A2).
7. Lay the peristaltic section under the rollers in the middle of the MetriQ Pump (A3).
8. Gently stretch the tubing and place the small tubing stop (A4) into the retainer on the left side of the rotor (A5). Make sure the tubing is not twisted.
9. Ensure the MetriQ Irrigation Tubing Set is stretched and set into each Air-In-Line Detector (A6 and A7). To ensure proper operation of the Air-In-Line Detectors, the outer surface of the tubing must be dry.
10. Close the door of the MetriQ Pump and turn the black handle clockwise. The pressure plate will automatically close.
11. To prepare for irrigation, open the stopcock on the end of the MetriQ Irrigation Tubing Set.
12. Press and hold the Purge button on the MetriQ Pump until all visible air bubbles are evacuated.
13. Securely connect the stopcock to the Boston Scientific Open-Irrigated Catheter luer lock then press and hold the Purge button on the MetriQ Pump until all air bubbles are evacuated and saline is flowing through the catheter.

Pump Self Calibration

Whenever the pump's main power switch is cycled, the pump must self-calibrate before flow can be started. This calibration routinely occurs when the pump door is closed after loading the tubing set. During the calibration, the message "PLEASE WAIT CALIBRATION IN PROGRESS" is displayed. If the pump's main power switch is cycled without opening and closing the door to replace the tubing set, the message "OPEN DOOR FULLY AND RE-CLOSE BEFORE CONTINUING" will appear to facilitate calibration.

Set Flow Rates and Operating Parameters

Use one of the methods below to set flow rates and operating parameters for the procedure.

- Refer to the sections on Flow Control Buttons and Operating Parameters to manually select the flow rates and operating parameters.
- Refer to the section on Memory Buttons to recall flow rates and operating parameters using the memory buttons.

Standby Flow Operation

- To start STANDBY FLOW when the pump is stopped, press the STANDBY FLOW button.
- To completely stop pump flow, press the STOP button.

Ablation Flow Operation

Automatic Mode

When the RF Power Control button on the Maestro 4000™ Controller (RF Generator) is pressed, the following sequence of events will occur:

- The pump will start LOW ABLATION FLOW or HIGH ABLATION FLOW based on the "To Trigger Hi Flow" setting.
- If the minimum temperature drop is measured at the catheter tip, the RF Generator will begin RF delivery after the Pre-RF Delay is completed.
- The pump will continue at the ablation flow rate during RF delivery and the Post-RF Delay.
- The pump will return to STANDBY FLOW after the Post-RF Delay is completed.
- RF will automatically stop if any diagnostic condition is detected, as identified in the 'DIAGNOSTIC MESSAGES' section.

Manual Mode

In this mode, the user controls the pump flow rates by manually pressing the LOW ABLATION FLOW/ HIGH ABLATION FLOW and STANDBY FLOW buttons on the pump's front panel.

- Press the LOW/HIGH ABLATION FLOW button based on the RF Power setting as indicated in the catheter DFU.
- Allow the pump to run at the ablation flow rate for 1 second to 15 seconds while observing the temperature display on the RF Generator to confirm the minimum temperature drop.
- Press the RF Control button on the RF Generator to begin RF delivery.
- Allow the pump to run at the ablation flow rate throughout RF delivery and for 0 seconds to 15 seconds after RF delivery is stopped.
- Press the STANDBY FLOW button to return to the STANDBY FLOW rate.

Note: In manual mode, an optional footswitch may be used to toggle between the existing flow rate and the High ablation flow rate (See Footswitch in Figure 10).

SERVICE AND MAINTENANCE

Preventative Inspection

WARNING: Damage such as frayed cords or cables and cracks or dents on the equipment may result in electrical shock.

During the useful life of the equipment, maintain close watch for damage such as frayed cords or cables and cracks or dents on the equipment. If damage is identified, take the equipment out of service and contact Boston Scientific Corporation for service requirements.

Calibrations and Adjustments

There are no user serviceable components or subsystems in the pump. The pump is calibrated by the manufacturer. Improper operation or damage to the pump can occur if altered by unauthorized personnel. If flow rate accuracy is in question, any adjustment or service is to be performed only by trained service personnel.

Cleaning/Disinfecting

Turn off and unplug the pump before cleaning it.

The pump head should be wiped clean after each use with a damp lint free cloth.

If cleaning is required, the user may clean the outer surfaces of the pump with a damp cloth using mild detergent. Or one of the following chemicals or their equivalents:

- Mild dishwashing detergent
- Isopropyl alcohol (70% solution)
- Bleach (10% solution)
- Window cleaning solution (with Isopropyl alcohol and ammonia)
- Hydrogen peroxide (3% solution)
- **WARNING:** Never immerse the pump or its accessories in any liquid. Avoid caustic or abrasive cleaners. Do not use flammable cleaning or disinfection agents. Do not expose the pump to steam autoclave or ethylene oxide (EtO) sterilization.
- **CAUTION:** The Pump, Footswitch, power cords, and communication cables are not intended to be sterilized and should remain outside of the sterile field.

End of Useful Life

When the equipment reaches the end of its useful life, dispose of the MetriQ™ Pump and all accessories in accordance with hospital, administrative and, local government policy. Contact your BSC representative or BSC field service engineer (1.800.949.6708 in the US) prior to disposal.

The MetriQ Pump non-sterilizable components are expected to have a useful life up to 5 years.

ESD TRAINING AND PRECAUTIONARY PROCEDURES

Prior to assembly, installation, or interconnection of the MetriQ™ Pump, it is recommended that any staff (i.e. clinical/biomedical engineers and health care staff) that could touch connectors identified with the ESD warning symbol undergo ESD training. At minimum, ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice, and the damage that can be done to electronic components if they are touched by an operator who is electrostatically charged. Further, an explanation should be given of methods to prevent build-up of electrostatic charge, and how and why to discharge one's body to earth or to the frame of the equipment or System, or bond oneself by means of a wrist strap to the equipment or System or to earth prior to making a connection. Finally, staff must be made aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a hand-held tool unless proper precautionary procedures have been followed. ESD precautionary procedures should include:

- Methods to prevent build-up of electrostatic charge (e.g. air conditioning, humidification, conductive floor coverings, non-synthetic clothing);
- Discharging one's body to the frame of the equipment or System or to earth or a large metal object;
- Bonding oneself by means of a wrist strap to the equipment or System or to earth.

PRODUCT SPECIFICATIONS

Electrical Specifications	
Supply Voltage/AC Power Requirements	100 V_{AC}-120 V_{AC} / 220 V_{AC}-240 V_{AC}, 50/60 Hz, 65 VA
Current Rating	5A @120V_{AC}
Fuses	F5AL250V

Electrical Isolation
Leakage current conforms to IEC 60601-1
Dielectric withstand conforms to IEC 60601-1

Technical Specifications	
Maximum Operating Back Pressure	35 psi (standby and ablation) 60 psi (purge)
Maximum Pressure Generated	150 psi
Flow Rate Accuracy	-5% +15% (6 mL/min-30 mL/min) -10% +20% (2 mL/min-5 mL/min) ±20 mL/min (60 mL/min)
Minimum Detectable Bubble Size	2 µL

Physical Dimensions	
Height	25.5 cm (excluding the handle)
Width	24.5 cm (without the pole clamp attached)
Depth	20.5 cm including the pump head
Weight	4.50 lbs
Power Cord	3 m

DIAGNOSTIC MESSAGES

Diagnostic Messages, Corresponding Conditions, and Corrective Actions		
Diagnostic Message	**Condition**	**Correction**
P01 - BUBBLE DETECTED	This message indicates that a bubble ≥ 2 µL has been detected in the tubing. Flow will stop.	Remove the catheter from the patient if applicable. Check saline bag level, and replace if necessary. Check drip chamber level, and adjust if necessary. Position the catheter tip where waste saline may be dispensed. Press and hold the purge button until air bubbles have been purged from the system. Press the CLEAR MESSAGE button. Press the STANDBY FLOW button to resume pump operation. Return the catheter to the patient and resume the procedure.
P02 - OCCLUSION DETECTED	This message indicates pressure > 50 psi in the tubing during non-purge flow or pressure > 70 psi in the tubing during purge flow, both of which would indicate a blockage in the tubing. Flow will stop.	If catheter is in patient and the occlusion cannot be corrected external to the patient, remove the catheter from patient. Replace catheter. Press and hold purge button until air has been purged from the new catheter. Press the CLEAR MESSAGE button. Press the STANDBY FLOW button to resume pump operation. Return the catheter to the patient (if appropriate) and resume the procedure.
P03 – NO TEMP DROP	This diagnostic error indicates that there has been no temperature drop (or too little of a temperature drop) based on the Minimum Temp Drop setting detected at the catheter's tip during the pre-RF delay period. Flow rate will revert to Standby flow.	Check minimum temperature drop pre-RF delay, and flow settings, and adjust as appropriate. If the flow rate does not change a substantial level for a substantial duration, the minimum temperature drop setting may not be achieved. Check tubing set, extension tube, and catheter fluid connections for improper connections or leaks, correct connections, as appropriate; otherwise, replace catheter or tubing set if still leaking. Check drip chamber for indication of flow. If no flow, but no leaks, and the pump is turning, then replace catheter and have pump occlusion detector serviced. Once problem is found and repaired, press the CLEAR MESSAGE button. Press the STANDBY FLOW button to resume pump operation. Return the catheter to the patient (if appropriate) and resume the procedure.

Diagnostic Messages, Corresponding Conditions, and Corrective Actions		
Diagnostic Message	**Condition**	**Correction**
P04 - COVER OPEN	This diagnostic error indicates that the pump door has come unlatched during flow, or substantial force is being applied trying to open the door during flow. Flow will stop.	Do not try to open the door during flow. Close and latch the cover that protects the pump head, tubing and sensors. Press the CLEAR MESSAGE button. Press the STANDBY FLOW button to resume pump operation. Return the catheter to the patient (if appropriate) and resume the procedure.
P05 - CHECK STANDBY FLOW	If the RF Generator detects that the catheter is in the patient and the pump is not running at least in STANDBY, the pump will issue a CHECK STANDBY FLOW error.	Press the STANDBY FLOW button to begin pump operation. Press the CLEAR MESSAGE button. Resume the procedure.
P06 - COMM ERROR	This diagnostic error indicates that the pump has lost communication with the RF Generator or catheter during ablation flow.	Check the Pump to RF Generator Cable. Reconnect the catheter connections at the Pod. Press the CLEAR MESSAGE button.
P07 - PUMP SPEED ERROR	This diagnostic error indicates that the measured pump speed is ≤ 85% or ≥ 120% of the calculated nominal speed based on the flow rate setting during Standby or Ablation flow. Flow will stop.	Open the door and inspect the tubing set. Especially look to see if the tubing has slipped out of the keyed fittings on either side of the rotor. Reinstall the tubing set in the pump. Install a new tubing set if the set appears damaged or defective. Press the CLEAR MESSAGE button.

OPERATIONAL MESSAGES

Display	Description	Action
PURGE NOT ALLOWED	Purge is not allowed with the catheter in the patient, or if Standby, low or high flow is active.	Do not attempt to purge with the catheter in the patient. If the catheter is not in the patient click the pump stop button to exit current state, then click purge button again.
GENERATOR DISCONNECTED	Pump lost communication with the RF Generator. This could occur if the communications cable is not securely attached to both devices. It will also occur if the RF Generator has a Safe state error.	Check the RF Generator for errors. Refer to the Maestro 4000™ Cardiac Ablation System Operator's Manual to resolve Generator errors. If there are no errors on the Generator, check the cable connections.
OI CATHETER DISCONNECTED	Pump received information from RF Generator that an Open-Irrigated catheter is disconnected from Pod.	Informational message. It should only occur when an Open-Irrigated catheter is disconnected from the RF Generator. When this occurs, the RF Generator will stop communicating with the pump and the pump will exit from Automatic mode into Manual mode.
PUMP NOT READY	Pump menu is open when RF Generator sends a command to the pump to start an ablation sequence. The pump will not start the ablation sequence while the menu is open.	Close the pump menu and restart the ablation on the RF Generator.
CHECK GENERATOR	This message has two possible causes. 1. Pump received message from RF Generator that the RF Generator has a diagnostic error. 2. Pump lost communication with RF Generator during RF delivery.	Check the RF Generator for a diagnostic error and resolve the error according to the Maestro 4000 Cardiac Ablation System Operator's Manual. If there is no error and RF Generator is delivering RF energy when this message is displayed, check the communications cable connections to both devices.
CONTACT BSC FOR NON-CRITICAL SERVICING	The message indicates that an internal chip needs to be replaced in order to properly time-stamp internal code logging.	Call service to replace chip.
COVER OPEN	The pump door is open and a Standby, Low, High or Purge flow button was pressed.	Close the door, and then press the desired flow button.
SALINE VOL. LOW < xxx mL	The saline is below the user's setting of "Low Fluid Warning".	Check bag to ensure that saline volume is low. User error may cause a discrepancy between actual and counted. If low, press the stop button to stop flow. Change the saline bag, and then go to menu and set the parameter "New Saline Bag" to Yes.

Display	Description	Action
Automatic Mode	Pump is under control of the RF Generator. Automatic mode is entered when the RF Generator and pump are powered on and connected, and an Open-Irrigated catheter is connected to the Maestro 4000 Cardiac Ablation System. RF will automatically stop if any diagnostic condition is detected, as identified in the 'DIAGNOSTIC MESSAGES' section.	If you intend to operate the pump in automatic mode, but the pump shows "Manual Mode", check to make sure the Open-Irrigated catheter and pod are securely connected, and the communications cable between the RF Generator and MetriQ™ Pump is secure at both ends.
Manual Mode	This message is displayed if the Pump is not under control of a RF Generator. This message is also displayed if the Pump and RF Generator are connected, but an Open-Irrigated catheter is not connected to the Maestro 4000™ Cardiac Ablation System. In Manual mode the MetriQ Pump can be operated manually using the flow buttons, or a footswitch. If an ablation is attempted when the Pump is in this mode the RF Generator will not wait for the Pump to start before it delivers RF Energy.	If you intend to operate the Pump in automatic mode, but the MetriQ Pump shows "Manual Mode", check to make sure the RF Generator is powered on, the Pump and pod are securely connected, and the communications cable between the RF Generator and MetriQ Pump is secure at both ends.
TUBING NOT LOADED	The MetriQ Irrigation Tubing Set is not loaded correctly.	Open the Pump door. Check if the tubing set is properly loaded, and then close the door.
FOOTSWITCH NOT ALLOWED	The footswitch can only be used in Manual mode. Users can't use footswitch in Automatic mode.	Do not use the footswitch in Automatic mode.
OPEN DOOR FULLY AND RE-CLOSE BEFORE CONTINUING	The Pump detects that the occlusion sensor reading is out of range and the door must be opened to calibrate the occlusion sensor.	Follow the instructions. Open the door completely then close and latch the door.
PLEASE WAIT CALIBRATION IN PROGRESS	The Pump is calibrating the occlusion sensor. The door is locked while calibration is in process.	Wait for the calibration to complete. Within a few seconds the message will disappear and the door will unlock.
Start New Case vs. Continue Previous Case	After the power on self-test, the Pump will prompt the user to select "Start New Case" or "Continue Previous Case".	Select "Continue Previous Case" to keep the previous dispensed and infused volume levels. Select "Start New Case" to reset the dispensed and infused volume levels to zero.

Display	Description	Action
SELF TEST	Immediately after the Pump is powered on it goes through a power on self-test. The LCD shows “SELF-TEST” during this stage.	If Pump passes self-test, “SELF-TEST” will disappear and the LCD will show “READY”.
READY	After completion of the self-test, if there is no system error, the Pump LCD will display “READY” and the Pump firmware version number.	Informational message. The Pump is operating normally.
SYSTEM FAULT	An unrecoverable error has occurred on the Pump. The Pump enters SAFE mode and will not allow any operations.	Power off the Pump and restart. If error recurs, contact BSC field service for further assistance.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

The MetriQ™ Pump complies with the requirements for electromagnetic compatibility (EMC) for medical devices as defined in IEC 60601-1-2. To help the user ensure optimum operation, the following tables indicate the acceptable electromagnetic environment for operating the MetriQ Pump.

Use of accessories other than those specified may result in increased emissions or decreased immunity of the equipment. Use only accessories approved for use with the MetriQ Pump.

Electromagnetic Emissions

Electromagnetic Emissions		
Emissions test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The MetriQ Pump is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker Emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The MetriQ Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MetriQ Pump should assure that it is used in such an environment.

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MetriQ™ Pump requires continued operation during electrical disturbances on the power mains, it is recommended that the MetriQ Pump be connected to an uninterruptible power supply with surge and electrical fast transient-suppression filtering/device embedded or connected in series.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MetriQ Pump requires continued operation during electrical disturbances on the power mains, it is recommended that the MetriQ Pump be connected to an uninterruptible power supply with surge and electrical fast transient-suppression filtering/device embedded or connected in series.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MetriQ Pump requires continued operation during electrical disturbances on the power mains, it is recommended that the MetriQ Pump be connected to an uninterruptible power supply with surge and electrical fast transient-suppression filtering/device embedded or connected in series.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level. The MetriQ Pump was tested at 100 V_{AC} and 230 V_{AC}.			

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.5 GHz	10 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the MetriQ™ Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 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,[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MetriQ Pump is used exceeds the applicable RF compliance level above, the MetriQ Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MetriQ Pump.			
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances

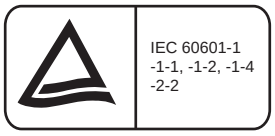
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and The MetriQ™ Pump

The MetriQ Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MetriQ Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MetriQ Pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
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

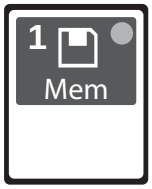
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

MetriQ Pump Safety Specifications

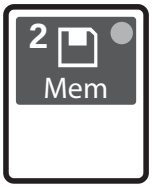
Device Description
Class I, Defibrillation proof Type CF Equipment, IPX0, not AP/APG
Mode of Operation: Continuous
EMC Emissions and Susceptibility: The MetriQ Pump has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation.
TUV Rheinland of North America Certified. 

Electrical Isolation
Leakage current conforms to IEC 60601-1
Dielectric withstand conforms to IEC 60601-1

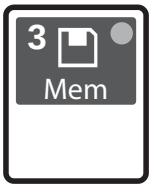
SYMBOLS



Memory 1 Button



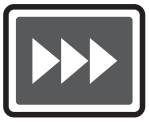
Memory 2 Button



Memory 3 Button

Silence Alarm Button

Clear Diagnostic Message Button



Purge Button

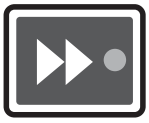
Pump Stop Button

Menu Navigation Buttons

Menu Button

Select Button

Standby Flow Button



HIGH Flow Button

LOW Flow Button

Flow Rate Adjustment Buttons

LIMITED WARRANTY AND DISCLAIMER

Limited Warranties

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this system. When maintained in such conditions as specified by BSC, it will be free from defects in material and workmanship at buyer's location for 12 months from the date of deliver. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, and cleaning of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the system and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Service is limited to exchanging faulty system components. No in-field repairs will be performed. For service, contact the BSC authorized service representative. The user must pay all freight charges for all parts returned to BSC. BSC will pay freight for shipping the repaired or replaced parts back to the user. BSC extends, to the registered user, all warranties offered by third party software upon which the System depends.

Software, Hardware and Support Service Contracts may be purchased at any time after the warranty expires. Contact BSC for more information.

All catheters used with the System are for single use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the catheter and/or lead to device failure, which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the catheter and/or cause patient infection or cross-infection including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. BSC assumes no liability with respect to single use instruments that are reused, reprocessed, or re-sterilized and makes no warranties, express or implied, including, but not limited to the warranties of merchantability or fitness for intended use with respect to such instrument.

Disclaimer and Exclusion of Other Warranties

There are no warranties of any kind that extend beyond the description of the warranties above. Boston Scientific Corporation disclaims and excludes all warranties, whether express or implied, of merchantability of fitness for a particular use or purpose.

Limitation of Liability for Damages

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Boston Scientific Corporation shall not be liable for damages for loss of profits or revenues, loss of use of the product, loss of facilities or services, any downtime costs, or for claims of buyer's customers for any such damages. Boston Scientific Corporation's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Boston Scientific Corporation to buyer which give rise to the claim for liability. The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

REF

Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Katalogusnummer
カタログ番号
Katalognummer
Αριθμός καταλόγου
Referência
Katalognummer
Katalógusszám
Katalogové číslo
Numer katalogowy
Katalognummer
目录编号
카탈로그 번호
Katalog Numarası
Número de catálogo
Kataloginumero
Număr de catalog
Номер по каталогу
Katalógové číslo

Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
内容物
Indhold
Περιεχόμενα
Conteúdo
Innehåll
Tartalom
Obsah
Zawartość
Innhold
包装内容
내용물
İçindekiler
Conteúdo
Sisältö
Conținut
Состав
Obsah

EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
EU認定代理店
Autoriseret repræsentant i EU
Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ
Representante Autorizado na U.E.
Auktoriserad EU-representant
Hivatalos képviselet az EU-ban
Autorizovaný zástupce pro EU
Autoryzowany przedstawiciel w UE
Autorisert representant i EU
欧盟授权代表
EU 공인 대리점
AB Yetkili Temsilcisi
Representante Autorizado na UE
EU-valtuutettu edustaja
Reprezentantul Autorizat UE
Уполномоченный представитель в ЕС
Autorizovaný zástupca pre EÚ

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
法定製造元
Lovmæssig producent
Νόμιμος κατασκευαστής
Fabricante Legal
Laglig tillverkare
Hivatalos gyártó
Oprávněný výrobce
Producent uprawniony
Lovmessig produsent
合法制造商
법적 제조사
Yasal Üretici
Fabricante Legal
Laillinen valmistaja
Producător legal
Законный изготовитель
Výrobca

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
リサイクル可能包装
Genanvendelig pakning
Ανακυκλώσιμη συσκευασία
Embalagem Reciclável
Återvinningsbar förpackning
Újrahasznosítható csomagolás
Recyklovatelný obal
Opakowanie przeznaczone do recyklingu
Emballasjen kan resirkuleres
可回收再利用包装
재활용 포장재
Geri Dönüşümlü Ambalaj
Embalagem Reciclável
Kierrätettävä pakkaus
Ambalaj reciclabil
Упаковка, подлежащая вторичной переработке
Recyklovateľný obal

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
オーストラリア認定代理店住所
Australsk sponsoradresse
Διεύθυνση χορηγού στην Αυστραλία
Endereço do Patrocinador Australiano
Adress till australisk sponsor
Az ausztrál szponzor címe
Adresa australského zadavatele
Adres sponsora australijskiego
Australsk sponsors adresse
澳大利亚赞助商地址
호주 후원인 주소
Avustralyalı Sponsor Adresi
Endereço do Patrocinador Australiano
Australialaisen toimeksiantajan osoite
Adresa sponsorului australian
Адрес австралийского спонсора
Adresa austrálskeho zadávateľa

ARG

Argentina Local Contact
Contacto local en Argentina
Contact local en Argentine
Lokaler Kontakt Argentinien
Contatto locale per l'Argentina
Contactpersoon Argentinië
アルゼンチン現地連絡先
Lokal kontakt i Argentina
Υπεύθυνος επικοινωνίας στην Αργεντινή
Contacto local na Argentina
Lokal kontakt, Argentina
Helyi kapcsolattartó (Argentína)
Místní kontaktní osoba v Argentině
Miejscowy przedstawiciel w Argentynie
Lokal kontakt for Argentina
阿根廷当地联络人
아르헨티나 현지 문의처
Arjantin Yerel İletişim
Contato local na Argentina
Argentiina – paikalliset yhteystiedot
Reprezentant local Argentina
Представительство в Аргентине
Miestny zástupca v Argentíne

BRA

Brazil Local Contact
Contacto local en Brasil
Contact local au Brésil
Lokaler Kontakt Brasilien
Contatto locale per il Brasile
Contactpersoon Brazilië
ブラジル現地連絡先
Lokal kontakt i Brasilien
Υπεύθυνος επικοινωνίας στη Βραζιλία
Contacto local no Brasil
Lokal kontakt, Brasilien
Helyi kapcsolattartó (Brazília)
Místní kontaktní osoba v Brazílii
Miejscowy przedstawiciel w Brazylii
Lokal kontakt for Brasil
巴西当地联络人
브라질 현지 문의처
Brezilya Yerel İletişim
Contato local no Brasil
Brasilia – paikalliset yhteystiedot
Reprezentant local Brazilia
Представительство в Бразилии
Miestny zástupca v Brazílii

TUR

Turkey Local Contact
Contacto local en Turquía
Contact local en Turquie
Lokaler Kontakt Türkei
Contatto locale per la Turchia
Contactpersoon Turkije
トルコ現地連絡先
Lokal kontakt i Tyrkiet
Υπεύθυνος επικοινωνίας στην Τουρκία
Contacto local na Turquia
Lokal kontakt, Turkiet
Helyi kapcsolattartó (Törökország)
Místní kontaktní osoba v Turecku
Miejscowy przedstawiciel w Turcji
Lokal kontakt for Tyrkia
土耳其当地联络人
터키 현지 문의처
Türkiye Yerel İletişim
Contato local na Turquia
Turkki – paikalliset yhteystiedot
Reprezentant local Turcia
Представительство в Турции
Miestny zástupca v Turecku

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
包装が破損している場合は使用しないこと。
Må ikke anvendes, hvis pakken er beskadiget.
Μη χρησιμοποιείτε αν η συσκευασία έχει υποστεί ζημιά.
Não utilize se a embalagem estiver danificada.
Använd inte om förpackningen är skadad.
Ne használja, ha a csomagolás sérült.
Nepoužívejte, pokud je obal poškozen.
Nie używać, jeśli opakowanie jest uszkodzone.
Skal ikke brukes hvis emballasjen er skadet.
包装如有损坏，请勿使用。
패키지가 손상된 경우 사용하지 마십시오.
Eğer paket zarar görmüşse kullanmayın.
Não utilize se a embalagem estiver danificada.
Ei saa käyttää, jos pakkaus on vaurioitunut.
A nu se utiliza dacă ambalajul este deteriorat.
Не использовать, если упаковка повреждена.
Nepoužívajte, ak je balenie poškodené.

Defibrillation-Proof Type CF Applied Part
Pieza de tipo CF aplicada compatible con desfibrilación
Pièce appliquée de type CF protégée contre les chocs de défibrillation
Defibrillationssicher, angelegtes Teil vom Typ CF
Parte applicata di tipo CF protetta da scarica di defibrillazione
Defibrillatiebestendig toegepast onderdeel van type CF
耐除細動CFタイプ装着部
Defibrilleringssikker type CF anvendt del
Εφαρμοζόμενο εξάρτημα τύπου CF με προστασία από απινίδωση
Peça Aplicada de Tipo CF à Prova de Desfibrilhação
Defibrilleringssäker applicerad del, typ CF
Defibrillálás-biztos, CF típusú alkalmazott rész
Aplikovaná část typu CF odolná vůči defibrilaci
Część aplikacyjna typu CF odporna na defibrylację
Defibrilleringssikker, anvendt del av type CF
防除顫 CF 类应用部件
제세동 방지 유형 CF 적용 부품
Defibrilasyona dayanıklı, CF Tipi Uygulanan Parça
Peça aplicada tipo CF à prova de desfibrilação
Defibrillaation kestävä tyypin CF sovellettu osa
Piesă aplicată de tip CF protejată împotriva şocurilor de defibrilaţie
Рабочая часть для дефибриллятора типа CF
Aplikovaná časť typu CF odolná voči defibrilácii

Fuse
Fusible
Fusible
Sicherung
Fusibile
Zekering
ヒューズ
Sikring
Ασφάλεια
Fusível
Säkring
Biztosíték
Pojistka
Bezpiecznik
Sikring
保险丝
퓨즈
Sigorta
Fusível
Sulake
Siguranță fuzibilă
Предохранитель
Poistka

Foot Switch
Pedal
Pédale
Fußschalter
Interruttore a pedale
Voetschakelaar
フットスイッチ
Fodpedal
Ποδοδιακόπτης
Pedal Interruptor
Fotbrytare
Lábkapcsoló
Nožní spínač
Przełącznik nożny
Fotbryter
脚踏开关
발 스위치
Ayak Pedalı
Pedal
Jalkakytkin
Pedală
Ножная педаль
Nožný spínač

Equipotentiality
Equipotencialidad
Équipotentialité
Potenzialgleichheit
Equipotenzialità
Equipotentialiteit
等電位
Ækvipotentiale
Ισοδυναμικότητα
Equipotencialidade
Ekvipotentialitet
Ekvipotenciális felület
Ekvipotencialita
Ekwipotencjalność
Ekvipotensialitet
等电位
등위성
Eşpotansiyellilik
Equipotencialidade
Tasapainopotentiaalisuus
Echipotențialitate
Эквипотенциальность
Ekvipotenciál

Peristaltic Pump
Bomba peristáltica
Pompe péristaltique
Peristaltikpumpe
Pompa peristaltica
Peristaltische pomp
蠕動ポンプ
Peristaltisk Pumpe
Περισταλτική αντλία
Bomba Peristáltica
Peristaltisk pump
Perisztaltikus pumpa
Peristaltická pumpa
Pompa perystaltyczna
Peristaltisk pumpe
蠕动泵
연동 펌프
Peristaltik Pompa
Bomba peristáltica
Peristalttinen pumppu
Pompă peristaltică
Перистальтический насос
Peristaltická pumpa

Date of Manufacture
Fecha de fabricación
Date de fabrication
Herstellungsdatum
Data di fabbricazione
Fabricagedatum
製造日
Fremstillingsdato
Ημερομηνία κατασκευής
Data de Fabrico
Tillverkningsdatum
A gyártás időpontja
Datum výroby
Data produkcji
Produksjonsdato
生产日期
제조일
Üretim Tarihi
Data de Fabricação
Valmistuspäivämäärä
Data fabricației
Дата изготовления
Dátum výroby

Serial Number
Número de serie
Numéro de série
Seriennummer
Numero di serie
Serienummer
シリアル番号
Serienummer
Σειριακός αριθμός
Número de série
Serienummer
Gyári szám
Sériové číslo
Numer seryjny
Serienummer
序列号
일련 번호
Seri Numarası
Número serial
Sarjanumero
Număr de serie
Серийный номер
Sériové číslo

Non-Sterile
No estéril
Non stérile
Nicht steril
Non sterile
Niet-steriel
未滅菌
Ikke-steril
Μη αποστειρωμένο
Não esterilizado
Icke-steril
Nem steril
Nesterilní
Niejałowy
Ikke-steril
非无菌
비멸균
Steril Değildir
Não estéril
Epästeriili
Non-steril
Не стерильно
Nesterilný

Separate Collection
Recogida independiente
Élimination séparée
Sonderabfall
Raccolta differenziata
Gescheiden inzameling
別途回収
Indsamles separat
Ξεχωριστή συλλογή
Recolha Separada
Separat avfallshantering
Elkülönített gyűjtés
Shromažďovat oddělně
Usuwać do odpadów segregowanych
Spesialavfall
分类回收
분리 수집
Ayrılması Gereken Atık
Coleta separada
Erilliskerays
Colectare separată
Раздельный сбор
Separovaný zber

CAUTION. Attention: Consult ACCOMPANYING DOCUMENTS.
PRECAUCIÓN. Atención: consulte los DOCUMENTOS ADJUNTOS.
AVERTISSEMENT. Attention : Lire les documents joints.
VORSICHT. Achtung: BEGLEITDOKUMENTE beachten.
ATTENZIONE. Attenzione: consultare i DOCUMENTI ALLEGATI.
LET OP. Attentie: Raadpleeg BIJGAANDE DOCUMENTEN.
注意，注意：附属の説明書を参照のこと。
FORSIGTIG. Obs! Se MEDFØLGENDE DOKUMENTER.
ΠΡΟΣΟΧΗ. Προσοχή: Συμβουλευτείτε τα ΣΥΝΟΔΕΥΤΙΚΑ ΕΓΓΡΑΦΑ.
CUIDADO. Atenção: Consulte os DOCUMENTOS INCLUSOS.
FÖRSIKTIGHETSÅTGÄRD. Obs! Se MEDFÖLJANDE DOKUMENTATION.
FIGYELEM! Figyelem! Nézze át a KÍSÉRŐ DOKUMENTUMOKAT.
UPOZORNĚNÍ. Upozornění: Nahlédněte DO PŘILOŽENÝCH DOKUMENTŮ.
OSTRZEŻENIE. Uwaga: proszę zapoznać się z ZAŁĄCZONĄ DOKUMENTACJĄ.
FORSIKTIG. Viktig! Les MEDFØLGENDE DOKUMENTER.
警示。注意：请参阅随附文档。
조심. 주의: 관련 문서를 참조하십시오.
İKAZ. Dikkat: BİRLİKTE VERİLEN BELGELERE başvurun.
CUIDADO. Atenção: Consulte os DOCUMENTOS INCLUSOS.
VAROITUS. Huomio: tutustu OHEISIIN ASIAKIRJOIHIN.
AVERTIZARE. Atenție: Consultați DOCUMENTAȚIA ÎNSOȚITOARE.
ПРЕДОСТЕРЕЖЕНИЕ. Внимание! Обратитесь к СОПРОВОДИТЕЛЬНОЙ ДОКУМЕНТАЦИИ.
UPOZORNENIE. Pozor: Pozri SPRIEVODNÉ DOKUMENTY.

[blue safety sign]
Follow Instructions For Use
[símbolo azul de seguridad]
Seguir las instrucciones de uso
[symbole de sécurité bleu]
Suivre les instructions du mode d'emploi
[blaues Sicherheitszeichen]
Gebrauchsanweisung befolgen
[simbolo di sicurezza blu]
Attenersi alle Istruzioni per l'uso
[blauw veiligheidsteken]
Volg de instructies voor gebruik
[青の安全標識]
取扱説明書に従うこと。
[blåt sikkerhedsskilt]
Følg brugsanvisningen
[μπλε σήμα ασφαλείας]
Ακολουθήστε τις οδηγίες χρήσης
[sinal de segurança azul]
Siga as Instruções de Utilização
[blå säkerhetssymbol]
Följ bruksanvisningen
[kék biztonsági jel]
Használat során az utasításoknak megfelelően járjon el
[modrý bezpečnostní symbol]
Dodržujte návod k použití.
[niebieski znak bezpieczeństwa]
Postępować zgodnie z instrukcją obsługi
[blått sikkerhetssymbol]
Følg bruksanvisningen
[蓝色安全标志]
请遵照使用说明
[청색 안전 표지]
사용 지침을 따르십시오
[mavi güvenlik işareti]
Kullanım Talimatlarını İzleyin
[símbolo de segurança azul]
Siga as instruções de uso
[sininen turvallisuusmerkintä]
Noudata käyttöohjeita
[simbol de siguranță albastru]
Urmați instrucțiunile de utilizare
[синий знак безопасности]
Соблюдайте инструкции по применению
[modré bezpečnostné označenie]
Dodržiavajte pokyny na používanie

cTUVus Mark indicates compliance to UL 60601-1 and CAN/CSA 22.2 601.1 M90 covering electrical safety requirements for the US and Canada.
El símbolo cTUVus indica cumplimiento con las regulaciones UL 60601-1 y CAN/CSA 22.2 601.1 M90 correspondientes a los requisitos de seguridad eléctrica en los Estados Unidos y Canadá.
La marque cTUVus indique le respect des normes de sécurité électrique UL 60601-1 et CAN/CSA 22.2 601.1 M90 pour les États-Unis et le Canada.
Das cTUVus-Kennzeichen bedeutet die Übereinstimmung mit UL 60601-1 und CAN/CSA 22.2 601.1 M90, wodurch die Anforderungen für elektrische Sicherheit in den USA und Kanada abgedeckt sind.
Il marchio cTUVus indica la conformità del prodotto ai requisiti elettrici di sicurezza UL 60601-1 e CAN/CSA 22.2 601.1 M90 per gli Stati Uniti e il Canada.
Het cTUVus-keurmerk geeft aan dat het product voldoet aan UL 60601-1 en CAN/CSA 22.2 601.1 M90 aangaande de vereisten betreffende elektrische veiligheid voor de VS en Canada.
cTUVusマークは、米国およびカナダ向け電気安全要件を包含するUL 60601-1および
CAN/CSA 22.2 601.1 M90へ適合していることを示す。
cTUVus-mærket betyder, at produktet overholder UL 60601-1 og CAN/CSA 22.2 601.1 M90 vedr. sikkerhedskrav til elektrisk udstyr for USA og Canada.
Το σήμα cTUVus δείχνει συμμόρφωση με τα πρότυπα UL 60601-1 και CAN/CSA 22.2 601.1 M90, που καλύπτουν τις απαιτήσεις ηλεκτρικής ασφαλείας στις Η.Π.Α. και τον Καναδά.
A marca cTUVus indica conformidade com as normas UL 60601-1 e CAN/CSA 22.2 601.1 M90 que cobrem os requisitos de segurança eléctrica para os EUA e o Canadá.
cTUVus-märkningen anger uppfyllelse av UL 60601-1 och CAN/CSA 22.2 601.1 M90 som behandlar elektriska säkerhetskrav i USA och Kanada.
A cTUVus jel az USA és Kanada területén érvényes UL 60601-1. és a CAN/CSA 22.2 601.1 M90. számú elektromos biztonsági követelményeknek való megfelelőséget jelzi.
Označení cTUVus značí soulad s elektrickými bezpečnostními předpisy UL 60601-1 a CAN/CSA 22.2 601.1 M90 pro Spojené státy a Kanadu.
Znak cTUVus jest potwierdzeniem zgodności z normami UL 60601-1 i CAN/CSA 22.2 601.1 M90 określającymi wymagania dotyczące bezpieczeństwa instalacji elektrycznych w USA i Kanadzie.
cTUVus-merket viser samsvar med UL 60601-1 og CAN/CSA 22.2 601.1 M90 som dekker elektriske sikkerhetskrav for USA og Canada.
cTUVus 标记表示符合美国及加拿大关于电气安全要求的 UL 60601-1 和 CAN/CSA 22.2 601.1 M90 标准的规定。
cTUVus 마크는 미국 및 캐나다의 전기 안전 요건을 포괄하는 UL 60601-1 및
CAN/CSA 22.2 601.1 M90의 규격을 준수함을 나타냅니다.
cTUVus İşareti, ABD ve Kanada için elektrik güvenliği gereklerini kapsayan UL 60601-1 ve CAN/CSA 22.2 601.1 M90 normlarına uygunluğu gösterir.
A marca cTUVus indica conformidade com as normas UL 60601-1 e CAN/CSA 22.2 601.1 M90 que abrangem os requisitos de segurança elétrica para os EUA e o Canadá.
cTUVus-merkki osoittaa, että laite on yhdenmukainen standardien UL 60601-1 ja CAN/CSA 22.2 601.1 M90 kanssa, jotka kattavat sähköturvallisuusvaatimukset USA:ssa ja Kanadassa.
Marca cTUVus atestă conformitatea cu UL 60601-1 şi CAN/CSA 22.2 601.1 M90 privind cerinţele de siguranţă pentru echipamentele electrice în SUA şi Canada.
Знак cTUVus указывает на соответствие требованиям UL 60601-1 и CAN/CSA 22.2 601.1 M90 охватывает требования по электрической безопасности в США и Канаде.
Označenie cTUVus predstavuje súlad s požiadavkami na elektrickú bezpečnosť podľa normy UL 60601-1 a CAN/CSA 22.2 601.1 M90 pre USA a Kanadu.

Boston Scientific

MetriQ™ Foot Switch

Irrigation Pump Foot Switch

90993366-01

2014-10

TABLE OF CONTENTS

MetriQ™ Foot Switch

Irrigation Pump Foot Switch

℞ ONLY

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

WARNING

Contents supplied NON-STERILE. If damage is found, call your Boston Scientific representative. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The MetriQ Foot Switch is an accessory available for use with the Boston Scientific Corporation (BSC) MetriQ Irrigation Pump.

The Foot Switch can be used to provide irrigation fluid flow rate control of the RF power delivery when in manual mode. The connecting cable's 10-foot length allows the user to stand at the catheterization table near the patient without requiring another person for starting/stopping ablation flow.

User Profile

The Foot Switch is a component of the Open-Irrigated System and is to be used only by physicians fully trained in cardiac electrophysiology procedures. Assistance to connect the cables, operate the Irrigation pump and Radiofrequency (RF) controller may only be provided by fully trained electrophysiology laboratory staff.

Contents

- One (1) Foot Switch

INTENDED USE / INDICATIONS FOR USE

The MetriQ Irrigation Pump and Foot Switch, in conjunction with the Maestro Controller are indicated for use in cardiac ablation procedures with Boston Scientific cardiac ablation catheters.

Note: Refer to the MetriQ Irrigation Pump Operator's Manual for specific indications, contraindications, warnings, precautions and adverse events, prior to use of the system.

CONTRAINDICATIONS

There are no known contraindications for the MetriQ Foot Switch.

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

Note: The following warnings and precautions apply to the MetriQ Foot Switch. Refer to the appropriate catheter Direction for Use and MetriQ Irrigation Pump Operator's Manual for specifc Warnings, Precautions, and Adverse Events related to the MetriQ Irrigation Pump.

WARNINGS

Before operating the System, carefully review these warnings:

- 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. Additional equipment connected to the signal input ports or signal output ports configures a medical system. Ensure that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical services department or your local BSC representative.
- The use of accessories, transducers and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Cardiac Ablation System.
- No modification of the equipment is allowed.

PRECAUTIONS

Review the following precautions before using the System:

- Do not attempt to operate the MetriQ™ Irrigation Pump or Foot Switch before thoroughly reading this Operator's Manual.
- 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 Foot Switch in any liquid. Avoid caustic or abrasive cleaners.
- Flammable agents or solvents used for cleaning and disinfection should be allowed to evaporate before high-frequency surgery.
- Regularly inspect re-usable cables and accessories. In particular, cables and accessories should be checked for possible damage to the insulation.

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, contra-indications, warnings, precautions, and adverse events included with each catheter and the MetriQ Irrigation Pump, prior to use of the catheter and System with the MetriQ Irrigation Pump and Foot Switch.

HOW SUPPLIED

- One (1) Foot Switch, supplied non-sterile.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Handling And Storage

Operating Environment

Ambient Temperature: 10 °C to 40 °C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29 °C to 60 °C

Relative Humidity: 30% to 85%

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 20 °C to 30 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

OPERATIONAL INSTRUCTIONS

- The Foot Switch is intended for installation within the Patient Environment.

Note: The Patient Environment is described per IEC 60601-1 as any volume in which intentional or unintentional contact can occur between Patients and parts of the System, or between Patient and other persons touching parts of the system.

- If using the Foot Switch, install its cable connector into the "Foot Switch" Cable Connector on the MetriQ™ Irrigation Pump rear panel. The Foot Switch functions similarly to the flow control buttons on the MetriQ Irrigation Pump. When pressed, the pump provides high ablation flow and when released, the pump returns to the prior flow rate.

SERVICE AND MAINTENANCE

Preventative Inspection

During the useful life of the equipment, maintain close watch for damage such as frayed cords or cables and cracks or dents on the equipment. If damage is identified, take the equipment out of service and contact Boston Scientific Corporation for service requirements.

System Servicing

None of the System components are user-serviceable. Contact Boston Scientific Corporation for all service requirements.

Cleaning/Disinfecting

The outer surfaces of the Foot Switch may be wiped clean with a mild soapy solution. If disinfecting is required, isopropyl alcohol may be used to clean the outer surfaces.

Precaution: Do not immerse the Foot Switch, cable and connector in any liquid. Avoid caustic or abrasive cleaners.

Precaution: 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 high-frequency surgery.

End of Useful Life

When the equipment reaches the end of its useful life, dispose of the Foot Switch in accordance with hospital, administrative and/or local government policy.

Note: Contact your BSC representative or BSC field service engineer (1.800.949.6708 in the US) prior to disposal.

LIMITED WARRANTY AND DISCLAIMER

Limited Warranties

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this system. When maintained in such conditions as specified by BSC, it will be free from defects in material and workmanship at buyer's location for 12 months from the date of deliver. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, and cleaning of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the system and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss,

damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Service is limited to exchanging faulty system components. No in-field repairs will be performed. For service, contact the BSC authorized service representative. You must pay all freight charges for all parts returned to BSC. BSC will pay freight for shipping the repaired or replaced parts back to you. BSC extends, to the registered user, all warranties offered by third party software upon which the System depends.

Software, Hardware and Support Service Contracts may be purchased at any time after the warranty expires. Contact BSC for more information.

Disclaimer and Exclusion of Other Warranties

There are no warranties of any kind that extend beyond the description of the warranties above. Boston Scientific Corporation disclaims and excludes all warranties, whether express or implied, of merchantability of fitness for a particular use or purpose.

Limitation of Liability for Damages

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Boston Scientific Corporation shall not be liable for damages for loss of profits or revenues, loss of use of the product, loss of facilities or services, any downtime costs, or for claims of buyer's customers for any such damages. Boston Scientific Corporation's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Boston Scientific Corporation to buyer which give rise to the claim for liability. The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

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Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

UPN

Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

[blue safety sign]
Follow Instructions For Use
[símbolo azul de seguridad]
Seguir las instrucciones de uso
[symbole de sécurité bleu]
Suivre les instructions du mode d'emploi
[blaues Sicherheitszeichen]
Gebrauchsanweisung befolgen
[simbolo di sicurezza blu]
Attenersi alle Istruzioni per l'uso
[blauw veiligheidsteken]
Volg de instructies voor gebruik
[sinal de segurança azul]
Siga as Instruções de Utilização

SN

Serial Number
Número de serie
Numéro de série
Seriennummer
Numero di serie
Serienummer
Número de série

Non-Sterile
No estéril
Non stérile
Nicht steril
Non sterile
Niet-steriel
Não esterilizado

Separate Collection
Recogida independiente
Élimination séparée
Sonderabfall
Raccolta differenziata
Gescheiden inzameling
Recolha Separada

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

Date of Manufacture
Fecha de fabricación
Date de fabrication
Herstellungsdatum
Data di fabbricazione
Fabricagedatum
Data de Fabrico

CAUTION. Attention: Consult ACCOMPANYING DOCUMENTS.
PRECAUCIÓN. Atención: consulte los DOCUMENTOS ADJUNTOS.
AVERTISSEMENT. Attention : Lire les documents joints.
VORSICHT. Achtung: BEGLEITDOKUMENTE beachten.
ATTENZIONE. Attenzione: consultare i DOCUMENTI ALLEGATI.
LET OP. Attentie: Raadpleeg BIJGAANDE DOCUMENTEN.
CUIDADO. Atenção: Consulte os DOCUMENTOS INCLUSOS.

cTUVus Mark indicates compliance to UL 60601-1 and CAN/CSA 22.2 601.1 M90 covering electrical safety requirements for the US and Canada.
El símbolo cTUVus indica cumplimiento con las regulaciones UL 60601-1 y CAN/CSA 22.2 601.1 M90 correspondientes a los requisitos de seguridad eléctrica en los Estados Unidos y Canadá.
La marque cTUVus indique le respect des normes de sécurité électrique UL 60601-1 et CAN/CSA 22.2 601.1 M90 pour les États-Unis et le Canada.
Das cTUVus-Kennzeichen bedeutet die Übereinstimmung mit UL 60601-1 und CAN/CSA 22.2 601.1 M90, wodurch die Anforderungen für elektrische Sicherheit in den USA und Kanada abgedeckt sind.
Il marchio cTUVus indica la conformità del prodotto ai requisiti elettrici di sicurezza UL 60601-1 e CAN/CSA 22.2 601.1 M90 per gli Stati Uniti e il Canada.
Het cTUVus-keurmerk geeft aan dat het product voldoet aan UL 60601-1 en CAN/CSA 22.2 601.1 M90 aangaande de vereisten betreffende elektrische veiligheid voor de VS en Canada.
A marca cTUVus indica conformidade com as normas UL 60601-1 e CAN/CSA 22.2 601.1 M90 que cobrem os requisitos de segurança eléctrica para os EUA e o Canadá.

EU Authorized Representative

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Argentina Local Contact

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Made in USA:
29 Plaine Hill Road
Woodstock, CT, 06281
USA

Do not use if package is damaged.

Recyclable Package

Boston Scientific (Master Brand DFUTemplate 3in x 9in Global, 90106040AL), DFU, MB, MetriQ Foot Switch, Global

Boston Scientific

MetriQ™ Irrigation Tubing Set

Open-Irrigation Tubing Set

Directions for Use **2**

91020928-01

2014-01

Boston Scientific (Master Brand DFU Template 3in x 9in Global, 90106040AL), DFU, MB, MetriQ Tubing Set, Global

Black (K) ΔE ≤5.0

MetriQ™ Irrigation Tubing Set

Open-Irrigation Tubing Set

℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

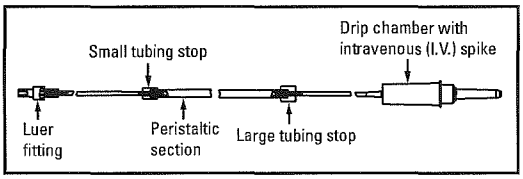

Figure 1. Boston Scientific Corporation (BSC) MetriQ Tubing Set

DEVICE DESCRIPTION

The MetriQ Tubing Set is a sterile, disposable tubing assembly which consists of a drip chamber with intravenous (I.V.) spike for connection to the irrigation source, a peristaltic section that is loaded around the pump head, and a standard luer fitting for connection to the Boston Scientific Blazer Open-Irrigated Catheter. The tubing set is designed to operate with the MetriQ Irrigation Pump. A four-way stopcock is included.

User Profile

The MetriQ Tubing Set is a component of the Open-Irrigated System and is to be used only by physicians fully trained in cardiac electrophysiology procedures. Assistance to prepare and load the tubing set, operate the Irrigation pump and Radiofrequency (RF) controller may only be provided by fully trained electrophysiology laboratory staff.

Contents

- One (1) MetriQ Irrigation Tubing Set
- One (1) four-way stopcock

INTENDED USE

The MetriQ Tubing Set is intended for use with the Boston Scientific MetriQ Pump, for use in the administration of irrigation solution into the patient through a Boston Scientific Blazer Open-Irrigated Ablation Catheter.

INDICATIONS FOR USE

The MetriQ™ Tubing Set is indicated for use with the Boston Scientific Blazer Open-Irrigated Ablation Catheter, which is indicated for use in catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation.

CONTRAINDICATIONS

This tubing set is contraindicated for use in patients who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation. Refer also to the Contraindications section in the associated Boston Scientific Blazer Open-Irrigated Catheter Directions for Use.

WARNINGS

- Carefully read all instructions prior to use including the Directions for Use for the associated Boston Scientific Blazer Open-Irrigated Catheter. Observe all indications, contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications.
- Before using, inspect the tubing set for any defects or physical damage that, if used, may cause patient and/or user injury. Replace damaged tubing; do not use defective or damaged tubing. Replace damaged equipment.
- Contents are supplied STERILE using an ethylene oxide (EO) process and should be used by the "Use By" date on the device package. Do not use the device if past the "Use By" date. Do not use if sterile barrier is damaged as use of non-sterile devices may result in patient injury. If damage is found, call your BSC representative.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
- In the event of a suspected failure of the integrity of fluid flow through the catheter or the tubing set or if there is a rapid temperature rise of >15°C noted on the generator, the procedure should be stopped, and the catheter withdrawn to reduce the risk of steam pop that could result in adverse events including perforation, embolism or injury to adjacent structures. Both the catheter and the tubing set should be replaced, primed outside the body to reduce risk of air embolism and then reinserted.
- Always verify that the tubing, catheter and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing and catheter can potentially cause injury or cardiac arrest. The operator is responsible for removing all air from the system.
- Inspect irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism.

PRECAUTIONS

- Do not use the tubing set after the expiration date because the device performance may no longer be acceptable and/or the device may no longer be sterile.
- Care must be taken to ensure all luer fittings and the I.V. spike placement into irrigation source are secure to prevent leaking.
- Also refer to the Precautions section in the associated Boston Scientific Blazer Open-Irrigated Catheter Directions for Use.
- Avoid creating kinks in the tubing set throughout the procedure.

ADVERSE EVENTS

Refer to the Adverse Events Section in the associated Boston Scientific Blazer Open-Irrigated Catheter Directions for Use.

HOW SUPPLIED

- One (1) tubing set, supplied sterile.
- One (1) four-way stopcock, supplied sterile.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

MATERIALS REQUIRED

MetriQ™ Pump

Sterile, normal (0.9%), heparinized (1 u heparin/ml) saline (commercially available)

Refer to the associated compatible Boston Scientific Blazer Open-Irrigated Catheter Directions for Use.

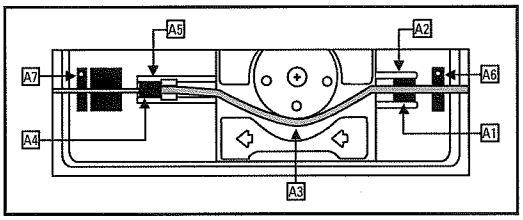

Figure 2. MetriQ Tubing Set installed on MetriQ Irrigation Pump

OPERATIONAL INSTRUCTIONS

1. Open the MetriQ Tubing Set package. Carefully transfer the package contents into the sterile field, maintaining sterile technique.
2. While in the sterile field remove the two (2) tie clips from the tubing by gently twisting the heads of the clips. Ensure the outer surface of the tubing set is dry.
3. Connect the stopcock to the luer lock on the tubing set and ensure it is closed.
4. Connect the Tubing Set to the irrigation source. Hang the irrigation source near the pump and fill the drip chamber about two-thirds full.
5. Open the door on the MetriQ pump by turning the black handle counter-clockwise.
6. Install the large tubing stop (A1) of the tubing set into the retainer on the right side (A2).
7. Lay the peristaltic section under the rollers in the middle of the MetriQ pump (A3).
8. Gently stretch the tubing and place the small tubing stop (A4) into the retainer on the left side of the rotor (A5). Make sure the tubing is not twisted.
9. Ensure the MetriQ Tubing Set is stretched and set into each Air-In-Line Detector (A6 and A7). To ensure proper operation of the Air-In-Line Detectors, the outer surface of the tubing must be dry.
10. Close the door of the MetriQ pump and turn the black handle clockwise. The pressure plate inside will automatically close.
11. To prepare for irrigation, open the stopcock on the end of the MetriQ tubing set.
12. Press and hold the Purge button on the MetriQ pump until all visible air bubbles are evacuated.
13. Securely connect the stopcock to the Boston Scientific Blazer Open-Irrigated Catheter luer lock then press and hold the Purge button on the MetriQ pump until all air bubbles are evacuated and saline is flowing through the catheter.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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Número de catálogo
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Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização

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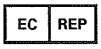

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Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
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Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

Lot
Lote
Lot
Charge
Lotto
Partij
Lote

Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.

Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

Includes Stopcock
Incluye llave de paso
Inclut un robinet
Einschließlich Absperrhahn
Include rubinetto di arresto
Bevat afsluiter
Inclui a Válvula Reguladora

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Made in Mexico:
Av. Paseo Reforma No 8950
Interior G1
La Mesa, Tijuana
C.P. 22116
Mexico

Do not use if package is damaged.

Recyclable Package

CE 0344

Boston Scientific

Cable, Maestro 4000™

Sterile Cable

Directions for Use **2**

90968696-01

2014-10

Cable, Maestro 4000™

Sterile Cable

℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

Sterile cable is used to connect Boston Scientific Blazer™ Open-Irrigated Ablation Catheters to the Maestro 4000™ Radiofrequency Controller.

User Profile

The Sterile Cable is a component of the Open-Irrigated System and is to be used only by physicians fully trained in cardiac electrophysiology procedures. Assistance to connect the cable, operate the Irrigation pump and Radiofrequency (RF) controller may only be provided by fully trained electrophysiology laboratory staff.

Contents

- One (1) Sterile Cable

INTENDED USE

The Intended Use of this cable is to connect Boston Scientific Blazer Open-Irrigated Ablation Catheters to the Maestro 4000 Radiofrequency Controller during Electrophysiology procedures.

INDICATION FOR USE

This cable is intended to be used with the Boston Scientific Blazer Open-Irrigated Ablation Catheter which is indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a radio frequency controller, for cardiac ablation.

CONTRAINDICATIONS

Refer to the Contraindications section in the Blazer Open-Irrigated Ablation Catheter Directions for Use.

WARNINGS

- Carefully read all instructions prior to use including the Directions for Use for the associated Blazer Open-Irrigated Ablation Catheter. Observe all indications, contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications.
- Before using, inspect for physical damage, including electrical insulation. Replace damaged equipment.
- No Modification of this equipment is allowed.
- For Rated Voltage, refer the associated Blazer Open-Irrigated Ablation Catheter Directions for Use.

PRECAUTIONS

- Do not use the cable after the expiration date because the device performance may no longer be acceptable and/or the device may no longer be sterile.
- Ensure that the cable/catheter connection remains dry throughout the procedure.
- Also refer to the Precautions section in the associated Blazer™ Open-Irrigated Ablation Catheter Directions for Use.

ADVERSE EVENTS

Refer to the Adverse Events Section in the Boston Scientific Blazer Open-Irrigated Catheter Directions for Use.

HOW SUPPLIED

- One (1) cable, supplied sterile.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Handling and Storage

Operating Environment

Ambient Temperature: 10°C to 40°C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29°C to 60°C

Relative Humidity: 30% to 85%

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 20°C to 30°C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

MATERIALS REQUIRED

Refer to the compatible Boston Scientific Blazer Open-Irrigated Catheter Directions for Use.

SETUP AND OPERATION

Refer to the Blazer Open-Irrigated Ablation Catheter Directions for Use.

OPERATIONAL INSTRUCTIONS (REPROCESSING)

Cable Maintenance and Re-sterilization

1. Boston Scientific Sterile Cables are expected to perform within their specifications after exposure to sterilization using typical hospital cycles specified in this document up to 10x within the shelf-life of the device.
2. Prior to each use, it is recommended that the connector contacts be visually inspected. Contamination and corrosion will cause inaccurate readings.
3. Prior to cleaning, visually examine each cable. Contaminated contacts or cavities of any connector cannot be reliably cleaned, sterilized, or used. Such a cable should be discarded.
4. The following cleaning and sterilization methods are recommendations to clean, disinfect, and sterilize the cable. It is the user's responsibility to qualify any deviations from these processing methods.
5. The cable must be cleaned, disinfected, and sterilized prior to each use.

Cleaning and Disinfection

1. Visually examine the cable prior to cleaning. Contaminated contacts or cavities of any connector cannot be reliably cleaned, sterilized, or used. Such a cable should be discarded.

2. Prepare the Manu-Klenz® (cleaning) Solution as recommended by the manufacturer (1/4 ounce/gallon using lukewarm tap water). Obtain a soft clean towel and soak in the Manu-Klenz Solution.
3. Ensure that the ends of the connectors are protected with parafilm prior to cleaning with the Manu-Klenz Solution and subsequent rinsing.
4. Wipe the cable and the external surfaces of the connectors with a soft towel dipped into the Manu-Klenz Solution to visually clean the external surfaces.
5. Thoroughly rinse the cable under lukewarm, running tap water for a minimum of one minute.
6. Prepare the Klenzyme® (cleaning) Solution as recommended by the manufacturer (1 ounce/gallon using lukewarm tap water).
7. Ensure that the connectors and remote handles are protected with parafilm prior to soaking the cable in the Klenzyme Solution. Connector protection (parafilm) should remain in place until rinsing complete.
8. Allow the cable to soak a minimum of two (2) minutes in the Klenzyme Solution and rinse thoroughly in lukewarm running tap water making sure that the connector cavities of the cable are protected from splashes or spills.
9. After rinsing, immerse the cable back into the prepared Klenzyme Solution and, using a soft bristle brush, gently clean the cable while immersed in the Klenzyme Solution. Pay particular attention to crevices and other hard-to-clean areas until all visible soil has been removed.
10. Remove the cable from the cleaning solution and thoroughly rinse the device using reverse osmosis/ de-ionized (RO/DI) water for a minimum of one minute. Dry the cable off using a clean lint-free cloth. Pressurized air (20 psi) can be used to assist in drying.
11. Prepare the Cidex® Solution per the "High Level Disinfection" as described in the manufacturer's directions.
12. Ensure that the connectors are protected with parafilm prior to cleaning with the Cidex Solution and subsequent rinsing.
13. Immerse and soak the cable in the Cidex Solution for 45 minutes making sure that the connector cavities and contacts are protected from splashes or spills.
14. Rinse by immersing the cables thoroughly in reverse RO/ DI water for one (1) minute. Repeat this step two (2) more times, each time using RO/DI water, while protecting the connector cavities and contacts.
15. Dry the device with a sterile clean, soft cloth.

Sterilization

1. Boston Scientific Cables can be reprocessed by using Ethylene Oxide Sterilization (EO) and Steam by exposure to typical hospital cycles to a maximum number stated on the package labeling and within the specified shelf-life.
2. Insert cable into the pouch and seal the pouch prior to sterilization.
3. Use a Tyvek® pouch for EO method of sterilization.

Ethylene Oxide (EO) Sterilization

1. Package the cable per the health care facility's standard practice for EO sterilization.
2. Sterilize by EO cycle with biological indicators.
3. The following typical hospital EO cycle was validated for this application.
   a. Conditioning: 131˚F (55˚C), 50-80% Relative Humidity (RH), 30 minutes, vacuum setpoint of 1.3 psia.
   b. EO Exposure: 131˚F (55˚C), 50-80% Relative Humidity (RH), 60 minutes, 100% EO, 725 mg/L EO.

A Post Exposure time of 12 hours or greater at 131˚F (55˚C) is recommended.

Steam Sterilization

A. Gravity Cycle

1. Package the cable per the health care facility's standard practice for steam sterilization.
2. The following typical hospital gravity steam cycles were validated for this application.
   a. Exposure: 132° C (270°F), 15 minutes
      Dry Time: 30 minutes minimum
   b. Exposure: 135° C (275°F), 10 minutes
      Dry Time: 30 minutes minimum

B. Pre-Vacuum Cycle

1. Package the cable per the health care facility's standard practice.
2. The following typical hospital pre-vacuum steam cycles were validated for this application.
   a. Exposure: 132°C, 4 minutes
      Dry Time: 30 minutes minimum
      Preconditioning Pulses: 3
   b. Exposure: 135°C, 3 minutes
      Dry Time: 16 minutes
      Preconditioning Pulses: 3

Hospital Equipment Qualification

The health care facility should qualify these procedures using their equipment. The effectiveness of sterilization should be validated and monitored using biological indicators. Cycle and aeration times may vary depending on the characteristics of the aeration system employed, the sterilization system, the size and arrangement of the package, etc. Handle per the health care facility's procedures to ensure that sterility is not compromised.

Health care facility may reprocess the cable up to 10x within the shelf-life of the device.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

REF

Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização

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EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

LOT

Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN

Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

STERILE Σ

Allowable Resterilizations
Reesterilizaciones permitidas
Restérilisations autorisées
Zulässige Resterilisationen
Risterilizzazioni consentite
Toegestane hersterilisaties
Reesterilizações Permitidas

STERILE EO

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

CE 0344

Boston Scientific (Master Brand DFU Template 3in x 9in Global, 90106040AL), DFU, MB, CABLE, MAESTRO 4000, Global

Black (K) ΔE ≤5.0

Boston Scientific

Cable Maintenance and Sterilization

90979286-01

2014-08

Cable Maintenance and Sterilization

℞ ONLY

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

WARNING

Contents supplied NON-STERILE. If damage is found, call your Boston Scientific representative.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

INDICATIONS FOR USE/INTENDED USE

The Boston Scientific (BSC) cables are indicated for use with BSC catheters or capital equipment in cardiac ablation procedures. Refer to the individual Directions for Use for the associated BSC catheters or capital equipment. It is important to carefully review the specific indications included with the associated catheters and or capital equipment prior to use.

CONTRAINDICATIONS

For the BSC cables, it is important to carefully review the specific contraindications with the associated BSC catheters or capital equipment prior to use.

WARNINGS

For the BSC cables, it is important to carefully review the specific warnings included with the associated BSC catheters or capital equipment prior to use.

No modification of this equipment is allowed.

For Rated Voltage, see associated compatible BSC catheter Directions for Use.

PRECAUTIONS

For the BSC cables, it is important to carefully review the specific precautions included with the associated BSC catheters or capital equipment prior to use.

ADVERSE EVENTS

For the BSC cables, it is important to carefully review the specific adverse events included with the associated BSC catheters or capital equipment prior to use.

CONFORMANCE TO STANDARDS

Non-sterile Cable output conforms to:

- EN 60601-1 Medical electrical equipment - Part 1: General requirements for Basic Safety and Essential Performance
- EN 60601-1-1 General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems
- EN 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

HOW SUPPLIED

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

Handling and Storage

Operating Environment:

Ambient Temperature: 10°C to 40°C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment:

Temperature: -29°C to 60°C

Relative Humidity: 30% to 85%

Atmospheric Pressure: Uncontrolled

Storage Environment:

Ambient Temperature: 20°C to 30°C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

MATERIALS REQUIRED

Refer to the associated compatible BSC Electrophysiology Catheter Directions for Use.

SETUP AND OPERATION

Refer to the associated compatible BSC catheter Directions for Use and to the capital equipment Operator Manuals.

CABLE MAINTENANCE

Boston Scientific EP cables are expected to perform within electrical specification after exposure to a maximum of 10 typical hospital ethylene oxide (EO) sterilization cycles.

Prior to each use it is recommended that connector contacts be visually inspected. Contamination and corrosion will cause inaccurate readings.

CLEANING AND EO STERILIZATION

Visually examine each cable prior to cleaning. Contaminated contacts or cavities of any connector cannot be reliably cleaned, sterilized, or used. Such cables should be discarded. The following method is recommended to clean, disinfect, and sterilize cables. It is the user's responsibility to qualify any deviations from these processing methods.

1. Protect connectors from contact with all cleaning agents and water during processing.
2. Follow manufacturer's recommendations for cleaning using an enzymatic presoak. Follow with a detergent cleaning agent using a soft bristle brush after soaking. Rinse completely.
3. Disinfect in CIDEX® (Activated Dialdehyde solution), or equivalent, according to manufacturer's instructions. Rinse. Dry thoroughly. Place Cable/Connector in a packaging system appropriate for EO sterilization.
4. Sterilize by EO exposure cycle using biological indicators. The following typical hospital EO cycle was validated for this application.

Conditioning:	125-145°F, 55-75% RH, 1.9-3.9 PSIA, 30-46 minutes.
Exposure:	125-145°F, 100% EO, 600 +/- 50 mg/L, 4 hours.
Post Exposure:	Two evacuations at 1.9-3.9 PSIA, followed by 11-12 hours aeration at 120-145°F.

HOSPITAL EQUIPMENT QUALIFICATION

The health care facility should qualify these procedures using their equipment. The effectiveness of sterilization should be validated and monitored using biological indicators. Cycle and aeration times may vary depending on the characteristics of the aeration system employed, the sterilization system, the size and arrangement of the package, etc. Handle per the health care

facility's procedures to ensure that sterility is not compromised.

Health care facility may reprocess the cable up to the maximum number of specified times within the shelf-life of the device.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.

Cable Maintenance and Sterilization

℞ ONLY

Precaución: las leyes federales de los Estados Unidos sólo permiten la venta de este dispositivo bajo prescripción facultativa.

ADVERTENCIA

El contenido se suministra SIN ESTERILIZAR. Si se encuentran daños, llamar al representante de Boston Scientific.

Después de su uso, desechar el producto y su envase de acuerdo a las normas del hospital, administrativas y/o de las autoridades locales.

INDICACIONES DE USO/USO INDICADO

El uso de los cables de Boston Scientific (BSC) está indicado con catéteres BSC o con equipos en ablaciones cardíacas. Consulte las Instrucciones de uso individuales de los catéteres BSC o de los equipos asociados. Es importante revisar detenidamente las indicaciones específicas incluidas con los catéteres o los equipos asociados antes de utilizarlos.

CONTRAINDICACIONES

Para los cables BSC, es importante revisar detenidamente las contraindicaciones específicas respecto a los catéteres BSC o a los equipos asociados antes de utilizarlos.

ADVERTENCIAS

Para los cables BSC, es importante revisar detenidamente las advertencias específicas incluidas con los catéteres BSC o los equipos asociados antes de utilizarlos.

No se permite realizar ninguna modificación en el equipo.

Para obtener información sobre la tensión nominal, consulte las Instrucciones de uso del catéter de BSC compatible asociado.

PRECAUCIONES

Para los cables BSC, es importante revisar detenidamente las precauciones específicas incluidas con los catéteres BSC o los equipos asociados antes de utilizarlos.

EPISODIOS ADVERSOS

Para los cables BSC, es importante revisar detenidamente los episodios adversos específicos incluidos con los catéteres BSC o los equipos asociados antes de utilizarlos.

CONFORMIDAD NORMATIVA

La salida del cable no estéril cumple las siguientes normativas:

- EN 60601-1 Equipos electromédicos - Parte 1: requisitos generales para la seguridad básica y el funcionamiento esencial
- EN 60601-1-1 Requisitos generales de seguridad - Norma colateral: requisitos de seguridad para sistemas electromédicos
- EN 60601-2-2 Equipos electromédicos - Parte 2-2: requisitos particulares para la seguridad básica y el funcionamiento esencial de los equipos quirúrgicos de alta frecuencia y de los accesorios quirúrgicos de alta frecuencia

PRESENTACIÓN

- No utilizar si el envase está abierto o dañado.
- No utilizar si la etiqueta está incompleta o ilegible.

Manipulación y almacenamiento

Entorno de funcionamiento:

Temperatura ambiente: 10 °C a 40 °C

Humedad relativa: 30% a 75%

Presión atmosférica: 70 kPa a 106 kPa

Entorno de transporte:

Temperatura: -29 °C a 60 °C

Humedad relativa: 30% a 85%

Presión atmosférica: no controlada

Entorno de almacenamiento:

Temperatura ambiente: 20 °C a 30 °C

Humedad relativa: no controlada

Presión atmosférica: no controlada

MATERIALES NECESARIOS

Consulte las Instrucciones de uso del catéter de electrofisiología de BSC compatible asociado.

CONFIGURACIÓN Y UTILIZACIÓN

Consulte las Instrucciones de uso del catéter de BSC compatible asociado y los Manuales del operador de los equipos asociados.

MANTENIMIENTO DEL CABLE

Los cables EP de Boston Scientific deben funcionar conforme a la especificación eléctrica tras su exposición a un máximo de 10 ciclos típicos de esterilización en hospital con óxido de etileno (OE).

Antes de cada uso se recomienda inspeccionar visualmente los contactos del conector. La contaminación y la corrosión ocasionan lecturas imprecisas.

LIMPIEZA Y ESTERILIZACIÓN CON OE

Examine visualmente cada cable antes de la limpieza. Los contactos o las cavidades de los conectores que se hayan contaminado no pueden limpiarse, esterilizarse ni utilizarse de forma fiable. Dichos cables deben desecharse. Se recomienda el siguiente método para limpiar, desinfectar y esterilizar los cables. El usuario es responsable de decidir sobre la conveniencia de variar estos métodos.

1. Evite el contacto de los conectores con los productos de limpieza y el agua durante el proceso.
2. Observe las recomendaciones del fabricante para utilizar un limpiador enzimático de remojo previo. Complete la limpieza con un detergente, utilizando un cepillo de cerdas blandas después del remojo. Enjuague a fondo.
3. Desinfecte con CIDEX® (solución de dialdehído activado) o equivalente, según las instrucciones del fabricante. Aclare. Seque completamente. Coloque el cable/conector en un sistema de envasado apropiado para la esterilización mediante OE.
4. Esterilice por ciclo de exposición al OE con indicadores biológicos. Para esta aplicación se ha validado el siguiente ciclo típico de esterilización en hospital con OE.

Acondicionamiento:	125-145 °F, 55-75% HR, 1,9-3,9 PSIA, 30-46 minutos.
Exposición:	125-145 ºF, 100% OE, 600 ± 50 mg/l, 4 horas.
Exposición posterior:	Dos evacuaciones a 1,9-3,9 PSIA, seguidas de 11-12 horas de aireación a 120-145 °F.

CALIFICACIÓN DE EQUIPO HOSPITALARIO

El centro de asistencia sanitaria debe habilitar estos procedimientos usando su equipo. La eficacia de la esterilización debe validarse y controlarse mediante indicadores biológicos. El ciclo y los tiempos de aireación pueden variar en función de las características del sistema de aireación empleado, el sistema de esterilización, el tamaño y la distribución del paquete, etc. Manipule el dispositivo según los procedimientos del centro sanitario para no comprometer la esterilidad.

El centro sanitario puede reprocesar el cable el número de veces máximo especificado dentro del período de vida útil de almacenamiento del dispositivo.

GARANTÍA

Boston Scientific Corporation (BSC) garantiza que se ha puesto un cuidado razonable en el diseño y la fabricación de este instrumento. **Esta garantía sustituye a cualquier otra que no se mencione expresamente en este documento, ya sea de forma explícita o implícita por ley o de otro modo, incluida, entre otras, cualquier garantía implícita de comerciabilidad o de adecuación para un fin concreto.** La manipulación, el almacenamiento, la limpieza y la esterilización de este instrumento, así como otros aspectos relacionados con el paciente, el diagnóstico, el tratamiento, las intervenciones quirúrgicas y cualquier otro aspecto ajeno al control de BSC afectan directamente a este instrumento y a los resultados que puedan obtenerse de su uso. La responsabilidad de BSC en virtud de esta garantía se limita a la reparación o sustitución de este instrumento y BSC no asumirá responsabilidad alguna por pérdidas accidentales o consecuentes, por daños ni por gastos directos o indirectos que pueda ocasionar el uso de este instrumento. BSC tampoco asume ninguna otra obligación o responsabilidad relacionada con este instrumento ni autoriza a ninguna persona a que lo haga en su nombre. **BSC rechaza cualquier responsabilidad con respecto a instrumentos reutilizados, reprocesados o reesterilizados y, respecto a los mismos, no ofrece garantía alguna, ya sea explícita o implícita, incluyendo entre otras la de comerciabilidad y adecuación para un fin concreto.**

Cable Maintenance and Sterilization

℞ ONLY

Avertissement : Selon la loi fédérale américaine, ce dispositif ne peut être vendu que sur prescription d'un médecin.

MISE EN GARDE

Contenu NON STÉRILISÉ. Si le produit est endommagé, contacter le représentant de Boston Scientific.

Après utilisation, éliminer le produit et l'emballage conformément au règlement de l'établissement, de l'administration et/ou du gouvernement local.

INDICATIONS/UTILISATION

Les câbles de Boston Scientific (BSC) sont destinés à être utilisés avec les cathéters ou les biens d'équipement de BSC utilisés lors des procédures d'ablation cardiaque. Consulter le mode d'emploi spécifique à chaque cathéter ou bien d'équipement de BSC associé. Il est important de revoir avec soin les indications spécifiques incluses avec les cathéters ou les biens d'équipement associés avant l'utilisation.

CONTRE-INDICATIONS

Pour les câbles de BSC, il est important de revoir avec soin les contre-indications spécifiques relatives à l'utilisation de cathéters ou de biens d'équipement de BSC associés avant l'utilisation.

MISES EN GARDE

Pour les câbles de BSC, il est important de revoir avec soin les mises en garde spécifiques relatives à l'utilisation de cathéters ou de biens d'équipement de BSC associés avant l'utilisation.

Aucune modification de cet équipement n'est autorisée.

Pour connaître la tension nominale, consulter le mode d'emploi du cathéter BSC compatible associé.

PRÉCAUTIONS

Pour les câbles de BSC, il est important de revoir avec soin les précautions spécifiques relatives à l'utilisation de cathéters ou de biens d'équipement de BSC associés avant l'utilisation.

ÉVÉNEMENTS INDÉSIRABLES

Pour les câbles de BSC, il est important de revoir avec soin les événements indésirables spécifiques relatifs à l'utilisation de cathéters ou de biens d'équipement de BSC associés avant l'utilisation.

CONFORMITÉ AUX NORMES

Sortie de câble non stérile conforme à :

- EN 60601-1 Appareils électromédicaux - Partie 1 : exigences générales pour la sécurité de base et des performances essentielles
- EN 60601-1-1 Règles générales de sécurité - Norme collatérale : règles de sécurité pour systèmes électromédicaux
- EN 60601-2-2 Appareils électromédicaux - Partie 2-2 : exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence

PRÉSENTATION

- Ne pas utiliser si l'emballage est ouvert ou endommagé.
- Ne pas utiliser si l'étiquetage est incomplet ou illisible.

Manipulation et stockage

Environnement de fonctionnement:
Température ambiante : 10 à 40 °C
Humidité relative : 30 à 75 %
Pression atmosphérique : 70 à 106 kPa

Environnement de transport:
Température : -29 à 60 °C
Humidité relative : 30 à 85 %
Pression atmosphérique : non contrôlée

Environnement de stockage:
Température ambiante : 20 à 30 °C
Humidité relative : non contrôlée
Pression atmosphérique : non contrôlée

MATÉRIEL REQUIS

Consulter le mode d'emploi du cathéter d'électrophysiologie de BSC compatible associé.

CONFIGURATION ET FONCTIONNEMENT

Consulter le mode d'emploi des cathéters et les manuels de l'opérateur des biens d'équipement de BSC associés compatibles.

ENTRETIEN DES CÂBLES

La performance des câbles EP de Boston Scientific doit correspondre aux spécifications électriques après exposition à un maximum de 10 cycles de stérilisation à l'oxyde d'éthylène (OE) généralement pratiquée dans les milieux hospitaliers.

Avant chaque utilisation, il est recommandé d'inspecter visuellement les contacts de connecteur. La contamination et la corrosion des contacts peuvent entraîner des mesures inexactes.

NETTOYAGE ET STÉRILISATION À L'OE

Avant de procéder au nettoyage, examiner visuellement chaque câble. Si les cavités ou les contacts d'un quelconque connecteur sont contaminés, il est impossible de les nettoyer, de les stériliser ou de les utiliser de manière fiable. De tels câbles doivent être éliminés. La méthode suivante est recommandée pour nettoyer, désinfecter et stériliser les câbles. Il incombe à l'utilisateur de justifier toute dérogation à ces méthodes de traitement.

1. Protéger les connecteurs pour éviter tout contact avec les produits de nettoyage et l'eau au cours du traitement.
2. Suivre les recommandations du fabricant pour effectuer le nettoyage avec un produit de prétrempage enzymatique. Après quoi, appliquer un détergent à l'aide d'une brosse à soies souples. Rincer complètement.
3. Désinfecter dans du CIDEX® (solution de dialdéhyde activé) ou un équivalent selon les instructions du fabricant. Rincer. Sécher intégralement. Placer le câble/connecteur dans un emballage approprié à la stérilisation à l'OE.
4. Stériliser par cycle d'exposition à l'OE avec des indicateurs biologiques. Le cycle hospitalier typique d'exposition à l'OE décrit ci-dessous a été validé pour cette application.

Conditionnement :	125-145 °F, 55-75 % HR, 1,9-3,9 PSIA, 30-46 minutes.
Exposition :	125-145 °F, 100 % OE, 600 ± 50 mg/l, 4 heures.
Exposition postérieure :	Deux évacuations à 1,9-3,9 PSIA, suivies d'une aération de 11-12 heures à 120-145 °F.

VALIDATION DE L'ÉQUIPEMENT HOSPITALIER

L'établissement de soins doit valider ces procédures en utilisant ses équipements. L'efficacité de la stérilisation doit être validée et contrôlée à l'aide d'indicateurs biologiques. Les durées de cycle et d'aération peuvent varier en fonction des caractéristiques du système d'aération utilisé, du système de stérilisation, de la taille et de la disposition de l'emballage, etc. Manipuler en respectant les procédures de l'établissement de soins pour assurer que la stérilité n'est pas compromise.

L'établissement de soins peut retraiter le câble pour le nombre de fois maximum spécifié et dans les limites de la durée de conservation du dispositif.

GARANTIE

Boston Scientific Corporation (BSC) garantit que cet instrument a été conçu et fabriqué avec un soin raisonnable. **Cette garantie remplace et exclut toute autre garantie non expressément formulée dans le présent document, qu'elle soit explicite ou implicite en vertu de la loi ou de toute autre manière, y compris notamment toute garantie implicite de qualité marchande ou d'adaptation à un usage particulier.** La manipulation, le stockage, le nettoyage et la stérilisation de cet instrument ainsi que les facteurs relatifs au patient, au diagnostic, au traitement, aux procédures chirurgicales et autres domaines hors du contrôle de BSC, affectent directement l'instrument et les résultats obtenus par son utilisation. Les obligations de BSC selon les termes de cette garantie sont limitées à la réparation ou au remplacement de cet instrument. BSC ne sera en aucun cas responsable des pertes, dommages ou frais accessoires ou indirects découlant de l'utilisation de cet instrument. BSC n'assume, ni n'autorise aucune tierce personne à assumer en son nom, aucune autre responsabilité ou obligation supplémentaire liée à cet instrument. **BSC ne peut être tenu responsable en cas de réutilisation, de retraitement ou de restérilisation des instruments et n'assume aucune garantie, explicite ou implicite, y compris notamment toute garantie de qualité marchande ou d'adaptation à un usage particulier concernant ces instruments.**

Cidex est une marque commerciale de Johnson & Johnson Corporation.

Cable Maintenance and Sterilization

℞ ONLY

Vorsicht: Laut Bundesgesetz der USA darf diese Vorrichtung ausschließlich an einen Arzt oder auf dessen Anordnung verkauft werden.

WARNHINWEIS

Der Inhalt wurde NICHT STERILISIERT. Im Falle von Beschädigungen Kontakt mit einem Vertreter von Boston Scientific aufnehmen.

Nach dem Gebrauch das Produkt und die Verpackung gemäß den Bestimmungen des Krankenhauses, administrativen und/oder örtlichen Regelungen entsorgen.

INDIKATIONEN/VERWENDUNGSZWECK

Die Boston Scientific (BSC) Kabel sind für die Verwendung mit BSC Kathetern oder anderen Vorrichtungen bei Herzablationsverfahren bestimmt. Die jeweiligen Gebrauchsanweisungen der entsprechenden BSC Katheter oder anderen Vorrichtungen beachten. Vor dem Gebrauch müssen die speziellen, im Lieferumfang der entsprechenden BSC Katheter oder anderen Vorrichtungen enthaltenen Indikationen sorgfältig gelesen werden.

KONTRAINDIKATIONEN

Vor dem Gebrauch der BSC Kabel müssen die im Lieferumfang der entsprechenden BSC Katheter oder anderen Vorrichtungen enthaltenen speziellen Informationen über Kontraindikationen sorgfältig gelesen werden.

WARNHINWEISE

Vor dem Gebrauch der BSC Kabel müssen die im Lieferumfang der entsprechenden BSC Katheter oder anderen Vorrichtungen enthaltenen speziellen Warnhinweise sorgfältig gelesen werden.

Es dürfen keine Veränderungen an dieser Ausrüstung vorgenommen werden.

Informationen zur Nennspannung sind in der Gebrauchsanweisung des entsprechenden kompatiblen BSC Katheters zu finden.

VORSICHTSMASSNAHMEN

Vor dem Gebrauch der BSC Kabel müssen die im Lieferumfang der entsprechenden BSC Katheter oder anderen Vorrichtungen enthaltenen Informationen über spezielle Vorsichtsmaßnahmen sorgfältig gelesen werden.

UNERWÜNSCHTE EREIGNISSE

Vor dem Gebrauch der BSC Kabel müssen die im Lieferumfang der entsprechenden BSC Katheter oder anderen Vorrichtungen enthaltenen Informationen über spezielle unerwünschte Ereignisse sorgfältig gelesen werden.

NORMENKONFORMITÄT

Die Ausgangsleistung des nicht sterilen Kabels ist konform mit:

- EN 60601-1 Medizinische elektrische Geräte, Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale
- EN 60601-1-1 Allgemeine Festlegungen für die Sicherheit – Ergänzungsnorm: Festlegungen für die Sicherheit von medizinischen elektrischen Systemen
- EN 60601-2-2 Medizinische elektrische Geräte, Teil 2-2: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hochfrequenz-Chirurgiegeräten und HF-chirurgischem Zubehör

LIEFERFORM

- Bei geöffneter oder beschädigter Verpackung nicht verwenden.
- Bei unvollständigem oder unleserlichem Etikett nicht verwenden.

Handhabung und Lagerung

Betriebsbedingungen:

Umgebungstemperatur: 10 °C bis 40 °C

Relative Luftfeuchtigkeit: 30 % bis 75 %

Luftdruck: 70 kPa bis 106 kPa

Umgebungsbedingungen für den Transport:

Temperatur: -29 °C bis 60 °C

Relative Luftfeuchtigkeit: 30 % bis 85 %

Luftdruck: Unkontrolliert

Lagerungsbedingungen:

Umgebungstemperatur: 20 °C bis 30 °C

Relative Luftfeuchtigkeit: Unkontrolliert

Luftdruck: Unkontrolliert

ERFORDERLICHE MATERIALIEN

Siehe Gebrauchsanweisung des entsprechenden kompatiblen BSC Elektrophysiologiekatheters.

EINRICHTUNG UND BETRIEB

Weitere Informationen sind in den Gebrauchsanweisungen der zugehörigen kompatiblen Katheter von BSC und in den Betriebsanleitungen der medizinischen Vorrichtungen zu finden.

WARTUNG DES KABELS

Die Leistung von durch Boston Scientific EP hergestellten Kabeln sollte nach 10 typischen Klinik-Sterilisationszyklen mit Ethylenoxid immer noch innerhalb der vorgegebenen elektrischen Nennwerte liegen.

Vor jedem Gebrauch wird die visuelle Prüfung der Steckverbinderstifte empfohlen. Kontamination und Korrosion führen zu ungenauen Messwerten.

REINIGUNG UND EO-STERILISATION

Jedes Kabel vor der Reinigung visuell prüfen. Kontaminierte Anschlusskontakte oder Steckeröffnungen können nicht zuverlässig gereinigt, sterilisiert oder verwendet werden. Solche Kabel müssen entsorgt werden. Die folgende Methode wird für das Reinigen, Desinfizieren und Sterilisieren der Kabel empfohlen. Es liegt in der Verantwortung des Benutzers, wenn von diesen Aufbereitungsmethoden abgewichen werden soll.

1. Die Steckverbinder während der Aufbereitung vor Reinigungsmittel und Wasser schützen.
2. Die Herstelleranweisungen zur Reinigung mit einer enzymatischen Vorspülung befolgen. Anschließend in ein Reinigungsmittel tauchen und mit einer weichen Bürste reinigen. Gut abspülen.
3. In CIDEX® (aktivierte Dialdehydlösung) oder einer ähnlichen Lösung gemäß Herstelleranweisungen desinfizieren. Abspülen und gründlich trocknen. Das Kabel/den Steckverbinder in eine Verpackung legen, die sich zur Sterilisation mit Ethylenoxid eignet.
4. Durch Ethylenoxid-Sterilisationsverfahren mit Bioindikatoren sterilisieren. Folgender typischer Krankenhaus-EO-Zyklus wurde für die Anwendung validiert.

Vorbehandlung:	125–145 °F, 55–75 % relative Luftfeuchtigkeit, 1,9–3,9 PSIA, 30-46 Minuten.
Behandlungsdauer:	125–145 °F, 100 % EO, 600 ± 50 mg/L, 4 Stunden.
Nachbehandlung:	Zwei Entleerungen bei 1,9–3,9 PSIA, gefolgt von 11–12 Stunden Lüftung bei 120–145 °F.

KRANKENHAUSAUSSTATTUNG

Die Gesundheitseinrichtung sollte in der Lage sein, diese Verfahren ordnungsgemäß mit den verfügbaren Geräten durchzuführen. Die Wirksamkeit der Sterilisation sollte mithilfe biologischer Indikatoren überprüft und überwacht werden. Die Zyklus- und Lüftungszeiten können in Abhängigkeit von den Eigenschaften des verwendeten Lüftungssystems, des Sterilisationssystems sowie der Größe und Anordnung der Verpackung usw. unterschiedlich lang ausfallen. Die Zeiten gemäß Verfahren der Gesundheitseinrichtung gestalten, um sicherzustellen, dass die Sterilität nicht beeinträchtigt wird.

Die Gesundheitseinrichtung kann das Kabel bis zur maximalen Anzahl der angegebenen zulässigen Resterilisationen innerhalb der Lagerbeständigkeit der Vorrichtung aufbereiten.

GARANTIE

Boston Scientific Corporation (BSC) garantiert, dass bei der Konstruktion und Herstellung dieses Instruments mit angemessener Sorgfalt vorgegangen wurde. **Diese Garantie ersetzt alle anderen ausdrücklichen oder stillschweigenden gesetzlichen oder anderweitig implizierten Garantien, die hier nicht ausdrücklich erwähnt werden, und schließt diese aus, einschließlich, aber nicht beschränkt auf, jegliche implizierten Zusicherungen in Bezug auf marktgängige Qualität oder Eignung für einen bestimmten Zweck.** Die Handhabung, Aufbewahrung, Reinigung und Sterilisation dieses Instruments sowie andere Faktoren, die sich auf den Patienten, die Diagnose, die Behandlung, chirurgische Verfahren und andere Umstände beziehen, die außerhalb der Kontrolle von BSC liegen, haben direkten Einfluss auf das Instrument und die Resultate aus seinem Einsatz. Die Verpflichtung von BSC im Rahmen dieser Garantie beschränkt sich auf die Reparatur oder den Ersatz des betreffenden Instruments; BSC ist nicht haftbar für beiläufige bzw. Folgeverluste, Schäden oder Kosten, die sich direkt oder indirekt aus der Verwendung dieses Instruments ergeben. BSC übernimmt keine weitere Haftung oder Verantwortung im Zusammenhang mit diesem Instrument und bevollmächtigt dazu auch keine anderen Personen. **BSC übernimmt keine Haftung, weder ausdrücklich noch stillschweigend, für wiederverwendete, wiederaufbereitete oder resterilisierte Instrumente, einschließlich, aber nicht beschränkt auf, Garantien bezüglich ihrer marktgängigen Qualität oder ihrer Eignung für einen bestimmten Zweck.**

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Attenzione: la legge federale degli Stati Uniti autorizza la vendita di questo prodotto esclusivamente su prescrizione medica.

AVVERTENZA

Contenuto fornito NON STERILE. In caso si rilevino danni, rivolgersi al rappresentante Boston Scientific.

Dopo l'uso, eliminare il prodotto e la confezione in conformità ai protocolli ospedalieri, alle normative amministrative e/o alle leggi locali vigenti.

INDICAZIONI PER L'USO/USO PREVISTO

I cavi Boston Scientific (BSC) sono indicati per l'uso con i cateteri o l'apparecchiatura principale BSC nelle procedure di ablazione cardiaca. Fare riferimento alle rispettive Istruzioni per l'uso dei cateteri o dell'apparecchiatura principale BSC associati. Prima dell'uso è importate esaminare con cura le indicazioni specifiche relative ai cateteri o all'apparecchiatura principale BSC associati.

CONTROINDICAZIONI

Per i cavi BSC, prima dell'uso è importante esaminare con cura le controindicazioni specifiche relative ai cateteri o all'apparecchiatura principale BSC associati.

AVVERTENZE

Per i cavi BSC, prima dell'uso è importante esaminare con cura le avvertenze specifiche relative ai cateteri o all'apparecchiatura principale BSC associati.

Non è consentita alcuna modifica a questa apparecchiatura.

Per la tensione nominale, fare riferimento alle Istruzioni per l'uso del catetere BSC compatibile associato.

PRECAUZIONI

Per i cavi BSC, prima dell'uso è importante esaminare con cura le precauzioni specifiche relative ai cateteri o all'apparecchiatura principale BSC associati.

EFFETTI INDESIDERATI

Per i cavi BSC, prima dell'uso è importante esaminare con cura gli specifici effetti indesiderati relativi ai cateteri o all'apparecchiatura principale BSC associati.

CONFORMITÀ AGLI STANDARD

L'uscita del cavo non sterile è conforme a:

- EN 60601-1 Apparecchi elettromedicali - Parte 1: requisiti generali per la sicurezza e prestazioni essenziali (Medical electrical equipment - Part 1: General requirements for Basic Safety and Essential Performance)
- EN 60601-1-1 Requisiti generali per la sicurezza - Standard collaterale: requisiti per la sicurezza dei sistemi elettromedicali (General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems)
- EN 60601-2-2 Apparecchi elettromedicali - Parte 2-2: requisiti particolari per la sicurezza e le prestazioni essenziali di apparecchi e accessori chirurgici ad alta frequenza (Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories)

MODALITÀ DI FORNITURA

- Non usare il prodotto se la confezione è danneggiata o aperta.
- Non usare il prodotto se le etichette sono incomplete o illeggibili.

Trattamento e conservazione

Condizioni ambientali operative:
Temperatura ambiente: da 10 °C a 40 °C
Umidità relativa: dal 30% al 75%
Pressione atmosferica: da 70 kPa a 106 kPa

Condizioni ambientali per il trasporto:
Temperatura: da -29 °C a 60 °C
Umidità relativa: dal 30% all'85%
Pressione atmosferica: non controllata

Condizioni ambientali per la conservazione:
Temperatura ambiente: da 20 °C a 30 °C
Umidità relativa: non controllata
Pressione atmosferica: non controllata

ATTREZZATURA NECESSARIA

Fare riferimento alle Istruzioni per l'uso dei cateteri per elettrofisiologia BSC compatibili associati.

IMPOSTAZIONE E USO

Fare riferimento alle Istruzioni per l'uso dei cateteri BSC compatibili associati e ai manuali dell'operatore dell'apparecchiatura principale.

MANUTENZIONE DEI CAVI

È previsto che i cavi EP Boston Scientific funzionino entro le specifiche elettriche dopo l'esposizione ad un massimo di 10 cicli di sterilizzazione ospedalieri tipici con ossido di etilene (EO).

Prima dell'uso, si consiglia di esaminare i contatti del connettore. La contaminazione e la corrosione causano un rilevamento non accurato dei valori.

PULIZIA E STERILIZZAZIONE CON OSSIDO DI ETILENE

Prima della pulizia, esaminare attentamente ciascun cavo. Non è possibile pulire, sterilizzare o utilizzare in modo affidabile i connettori che presentano contatti o cavità contaminati. Tali cavi devono essere eliminati. Per la pulizia, disinfezione e sterilizzazione, attenersi alla procedura indicata di seguito. La responsabilità di eventuali modifiche alla procedura di pulizia e sterilizzazione ricade sull'utente.

1. Proteggere i connettori dal contatto con gli agenti di pulizia e l'acqua, usati durante la procedura.
2. Per la pulizia a base di un bagno enzimatico, attenersi alle istruzioni del produttore. Ultimato il bagno, far seguire da un lavaggio con un detergente, utilizzando una spazzola morbida. Sciacquare a fondo.
3. Disinfettare il cavo con una soluzione di dialdeide attivata, come CIDEX®, o con un prodotto equivalente, in base alle istruzioni del produttore, quindi sciacquarlo ed asciugarlo completamente. Porre il cavo e il connettore in un sacchetto adatto alla sterilizzazione con ossido di etilene.
4. Sterilizzare il cavo tramite ciclo di esposizione ad ossido di etilene con indicatori biologici. Per questa applicazione è stato convalidato il seguente ciclo ospedaliero tipico EO.

Condizionamento:	125-145 °F, 55-75% di umidità relativa, 1,9-3,9 PSIA, 30-46 minuti.
Esposizione:	125-145 °F, 100% ossido di etilene, 600 ± 50 mg/L, 4 ore.
Fase successiva all'esposizione:	due evacuazioni a 1,9-3,9 PSIA, seguite da 11-12 ore di aerazione a 120-145 °F.

QUALIFICAZIONE DELLE APPARECCHIATURE OSPEDALIERE

È compito della struttura ospedaliera verificare le procedure qui descritte utilizzando le apparecchiature a disposizione. L'efficacia della sterilizzazione deve essere convalidata e monitorata mediante indicatori biologici. La durata del ciclo e dell'aerazione può variare, a seconda delle caratteristiche del sistema di aerazione e di sterilizzazione utilizzati, delle dimensioni e della disposizione dell'imballo dei cavi e così via. Per garantire che la sterilità non venga compromessa, maneggiare i componenti attenendosi alle procedure ospedaliere standard.

Il cavo può essere ritrattato fino al numero massimo di volte specificato entro la data di scadenza del dispositivo.

GARANZIA

Boston Scientific Corporation (BSC) garantisce che questo strumento è stato progettato e costruito con cura ragionevole. **La presente garanzia sostituisce ed esclude tutte le altre garanzie non espressamente stabilite nella presente, siano esse esplicite o implicite ai sensi di legge o altrimenti, compresa, in modo non esclusivo, qualsiasi garanzia implicita di commerciabilità o idoneità a uno scopo particolare.** Le condizioni di trattamento, conservazione, pulizia e sterilizzazione di questo strumento, nonché altri fattori relativi al paziente, alla diagnosi, al trattamento, agli interventi chirurgici e altri elementi al di là del controllo di BSC, influiscono direttamente sullo strumento stesso e sui risultati del suo impiego. L'obbligo di BSC in base alla presente garanzia è limitato alla riparazione o sostituzione di questo strumento. BSC non potrà essere ritenuta responsabile di perdite, spese o danni diretti o indiretti, derivanti direttamente o indirettamente dall'uso di questo strumento. BSC non si assume, né autorizza alcuno ad assumersi a suo nome, alcun altro tipo di obbligo o responsabilità in relazione a questo strumento. **BSC non si assume alcuna responsabilità per strumenti riutilizzati, ritrattati o risterilizzati e non offre alcuna garanzia, né implicita né esplicita, inclusa, in modo non limitativo, ogni garanzia di commerciabilità o di idoneità a scopo particolare, per tali strumenti.**

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Let op: De Amerikaanse federale wetgeving bepaalt dat dit hulpmiddel slechts door of namens een arts kan worden gekocht.

WAARSCHUWING

De inhoud wordt NIET-STERIEL geleverd. Neem contact op met uw Boston Scientific-vertegenwoordiger als er schade wordt aangetroffen.

Werp dit product en het verpakkingsmateriaal na gebruik weg volgens het hiervoor geldende beleid van de instelling en de overheid.

INDICATIES VOOR GEBRUIK/BEOOGD GEBRUIK

De kabels van Boston Scientific (BSC) zijn bedoeld voor gebruik met katheters of basisuitrusting van BSC bij hartablatieprocedures. Raadpleeg de afzonderlijke gebruiksaanwijzing voor de bijbehorende katheters of basisuitrusting van BSC. Het is belangrijk om vóór gebruik de specifieke indicaties van de bijbehorende kathethers en/of basisuitrusting door te lezen.

CONTRA-INDICATIES

Voor de BSC-kabels is het belangrijk om vóór gebruik de specifieke contra-indicaties van de bijbehorende katheters of basisuitrusting van BSC door te lezen.

WAARSCHUWINGEN

Voor de BSC-kabels is het belangrijk om vóór gebruik de specifieke waarschuwingen voor de bijbehorende katheters of basisuitrusting van BSC door te lezen.

Deze apparatuur mag op geen enkele wijze worden gewijzigd.

De nominale spanning staat vermeld in de gebruiksaanwijzing van de bijbehorende compatibele BSC-katheter.

VOORZORGSMAATREGELEN

Voor de BSC-kabels is het belangrijk om vóór gebruik de specifieke voorzorgsmaatregelen voor de bijbehorende katheters of basisuitrusting van BSC door te lezen.

COMPLICATIES

Voor de BSC-kabels is het belangrijk om vóór gebruik de specifieke complicaties voor de bijbehorende katheters of basisuitrusting van BSC door te lezen.

NALEVING VAN NORMEN

De uitgang van de niet-steriele kabel voldoet aan:

- EN 60601-1 Medische elektrische toestellen - Deel 1: Algemene eisen voor basisveiligheid en essentiële prestaties
- EN 60601-1-1 Algemene veiligheidsvereisten - Secundaire norm: Veiligheidseisen voor medische elektrische systemen
- EN 60601-2-2 Medische elektrische toestellen - Deel 2-2: Bijzondere eisen voor de veiligheid en essentiële prestatie van hoogfrequent chirurgische toestellen en toebehoren

LEVERING

- Niet gebruiken als de verpakking open of beschadigd is.
- Niet gebruiken als de etikettering onvolledig of onleesbaar is.

Hantering en opslag

Gebruiksomgeving:
Omgevingstemperatuur: 10 °C tot 40 °C
Relatieve luchtvochtigheid: 30% tot 75%
Atmosferische druk: 70 kPa tot 106 kPa

Transportomgeving:
Temperatuur: -29 °C tot 60 °C
Relatieve luchtvochtigheid: 30% tot 85%
Atmosferische druk: niet gereguleerd

Opslagomgeving:
Omgevingstemperatuur: 20 °C tot 30 °C
Relatieve luchtvochtigheid: niet gereguleerd
Atmosferische druk: niet gereguleerd

BENODIGDHEDEN

Raadpleeg de gebruiksaanwijzing van de bijbehorende compatibele elektrofysiologiekatheter van BSC.

INSTALLATIE EN GEBRUIK

Raadpleeg de gebruiksaanwijzing van de bijbehorende compatibele BSC-katheter en de gebruiksaanwijzingen van de basisuitrusting.

KABELONDERHOUD

De EP-kabels van Boston Scientific worden verondersteld binnen de elektriciteitsspecificaties te functioneren na blootstelling aan maximaal 10 voor ziekenhuizen typische sterilisatiecycli met ethyleenoxide (EO).

Visuele inspectie van de contactpunten van de connector vóór gebruik wordt aanbevolen. Verontreiniging en corrosie leiden tot onnauwkeurige metingen.

REINIGING EN STERILISATIE MET GEBRUIK VAN EO

Controleer elke kabel op het oog voordat u deze gaat reinigen. Geen enkele connector met verontreinigde contactpunten of holten kan op betrouwbare wijze worden gereinigd, gesteriliseerd of gebruikt. Dergelijke kabels moeten worden weggegooid. De volgende methode wordt aanbevolen voor het reinigen, desinfecteren en steriliseren van kabels. Het kwalificeren van afwijkingen van deze methoden valt onder de verantwoordelijkheid van de gebruiker.

1. Bescherm de connectoren zo dat ze tijdens de verwerking niet in aanraking komen met reinigingsmiddelen en water.
2. Volg de aanbevelingen van de fabrikant om de kabels vóór reiniging eerst in een enzymenweek te zetten. Maak na het weken de kabel verder schoon met reinigingsmiddel en een zachte borstel. Volledig afspoelen.
3. Desinfecteren in CIDEX® (een geactiveerde dialdehydeoplossing) of het equivalent daarvan, volgens de instructies van de fabrikant. Spoelen. Grondig drogen. Gebruik voor de kabel/connector een verpakkingssysteem dat geschikt is voor EO-sterilisatie.
4. Steriliseren door middel van de EO-blootstellingscyclus met biologische indicatoren. De volgende gangbare EO-ziekenhuiscyclus is voor deze toepassing gevalideerd.

Conditionering:	125-145 °F, 55-75% rel. luchtvochtigheid, 1,9-3,9 PSIA, 30-46 minuten.
Blootstelling:	125-145 °F, 100% EO, 600 ± 50 mg/L, 4 uur.
Na blootstelling:	Twee evacuaties bij 1,9-3,9 PSIA, gevolgd door 11-12 uur ventilatie bij 120-145 °F.

KWALIFICATIE VAN ZIEKENHUISAPPARATUUR

De zorginstelling moet deze procedures voor de eigen apparatuur valideren. De effectiviteit van de sterilisatie moet worden gevalideerd en bewaakt met biologische indicatoren. Cyclus- en ventilatietijden kunnen afwijken afhankelijk van de kenmerken van het gebruikte ventilatiesysteem, het sterilisatiesysteem, de grootte en opstelling van het pakket enz. Hanteer deze volgens de procedures van de zorginstelling om te waarborgen dat de steriliteit niet in gevaar wordt gebracht.

De zorginstelling mag de kabel binnen de houdbaarheidsduur van het hulpmiddel het aangegeven maximum aantal keren herverwerken.

GARANTIE

Boston Scientific Corporation (BSC) garandeert dat er redelijke zorg is betracht bij het ontwerpen en vervaardigen van dit instrument. **Deze garantie vervangt en ontkracht alle andere garanties die hier niet worden vermeld, hetzij uitdrukkelijk, hetzij impliciet door de werking van de wet of anderszins, met inbegrip van, maar niet beperkt tot, geïmpliceerde garanties van verkoopbaarheid of geschiktheid voor een bepaald doel.** Hanteren, opslag, schoonmaken en sterilisatie van dit instrument alsmede andere factoren in verband met de patiënt, diagnose, behandeling, chirurgische ingrepen en andere zaken die buiten de macht van BSC vallen, zijn direct van invloed op het instrument en de resultaten die ermee worden verkregen. De aansprakelijkheid van BSC volgens deze garantievoorwaarden is beperkt tot het repareren of vervangen van dit instrument; BSC aanvaardt geen aansprakelijkheid voor incidentele of bijkomende schade die direct dan wel indirect voortvloeit uit gebruik van dit instrument. BSC aanvaardt geen, en geeft niemand de bevoegdheid tot het in naam van BSC aanvaarden van, andere of aanvullende aansprakelijkheid of verantwoordelijkheid in verband met dit instrument. **BSC aanvaardt geen aansprakelijkheid voor instrumenten die opnieuw zijn gebruikt, verwerkt of gesteriliseerd en biedt geen uitdrukkelijke dan wel impliciete garanties in verband met zulke instrumenten, met inbegrip van, maar niet beperkt tot, garanties van verkoopbaarheid of geschiktheid voor een bepaald doel.**

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Cuidado: A lei federal (EUA) só permite a venda deste dispositivo sob receita médica.

ADVERTÊNCIA

O conteúdo é fornecido NÃO ESTERILIZADO. Se verificar a presença de quaisquer danos no produto, contacte o seu representante da Boston Scientific.

Depois de utilizar, deite fora o produto e a embalagem de acordo com a política do hospital, administrativa e/ou do governo local.

INDICAÇÕES DE UTILIZAÇÃO/UTILIZAÇÃO PREVISTA

Os cabos da Boston Scientific (BSC) destinam-se a ser utilizados com cateteres da BSC ou outros equipamentos compatíveis em procedimentos de ablação cardíaca. Consulte as Instruções de Utilização individuais para obter informações relativas aos cateteres da BSC ou outros equipamentos compatíveis associados. É importante que reveja cuidadosamente as indicações específicas incluídas com os cateteres e/ou outros equipamentos compatíveis associados antes de utilizar.

CONTRA-INDICAÇÕES

Para os cabos da BSC, é importante que reveja cuidadosamente as contra-indicações específicas dos cateteres da BSC ou outros equipamentos compatíveis associados antes de utilizar.

ADVERTÊNCIAS

Para os cabos da BSC, é importante que reveja cuidadosamente as advertências específicas dos cateteres da BSC ou outros equipamentos compatíveis associados antes de utilizar.

Não é permitido modificar este equipamento.

Para conhecer a tensão nominal, consulte as Instruções de Utilização do cateter da BSC compatível associado.

PRECAUÇÕES

Para os cabos da BSC, é importante que reveja cuidadosamente as precauções específicas dos cateteres da BSC ou outros equipamentos associados antes de utilizar.

EFEITOS INDESEJÁVEIS

Para os cabos da BSC, é importante que reveja cuidadosamente os efeitos indesejáveis específicos dos cateteres da BSC ou outros equipamentos compatíveis associados antes de utilizar.

CONFORMIDADE COM AS NORMAS

A potência do cabo não esterilizado está em conformidade com:

- Norma EN 60601-1 Equipamentos eléctricos médicos - Parte 1: Requisitos gerais de segurança básica e desempenho essencial
- Norma EN 60601-1-1 Requisitos gerais de segurança - Norma colateral: Requisitos de segurança para sistemas eléctricos médicos
- Norma EN 60601-2-2 Equipamentos eléctricos médicos - Parte 2-2: Requisitos particulares para a segurança básica e desempenho essencial de equipamento cirúrgico de alta frequência e acessórios cirúrgicos de alta frequência

FORMA DE APRESENTAÇÃO DO PRODUTO

- Não utilize se a embalagem estiver aberta ou danificada.
- Não utilize se a etiquetagem estiver incompleta ou ilegível.

Manuseio e Armazenamento

Ambiente de Funcionamento:
Temperatura ambiente: 10°C a 40°C
Humidade relativa: 30% a 75%
Pressão atmosférica: 70 kPa a 106 kPa

Ambiente de Transporte:
Temperatura: -29°C a 60°C
Humidade relativa: 30% a 85%
Pressão atmosférica: não controlada

Ambiente de Armazenamento:
Temperatura ambiente: 20°C a 30°C
Humidade relativa: não controlada
Pressão atmosférica: não controlada

MATERIAIS NECESSÁRIOS

Consulte as Instruções de Utilização do Cateter de Electrofisiologia da BSC compatível associado.

CONFIGURAÇÃO E FUNCIONAMENTO

Consulte as Instruções de Utilização do cateter da BSC compatível associado ou os Manuais do Operador dos outros equipamentos.

MANUTENÇÃO DO CABO

Os cabos de electrofisiologia (EP) da Boston Scientific devem funcionar dentro das especificações eléctricas depois da exposição a um número máximo de 10 ciclos de esterilização por óxido de etileno (EO) hospitalares típicos.

Antes de cada utilização, recomenda-se que os contactos do conector sejam inspeccionados visualmente. A contaminação e a corrosão resultarão em leituras imprecisas.

LIMPEZA E ESTERILIZAÇÃO POR ÓXIDO DE ETILENO (EO)

Examine visualmente cada cabo antes da limpeza. Os contactos ou cavidades contaminados de qualquer conector não podem ser bem limpos, esterilizados nem usados com segurança. Estes cabos devem ser descartados. O método seguinte é o recomendado para limpar, desinfectar e esterilizar cabos. Quaisquer alterações efectuadas a estes métodos de processamento são da responsabilidade do utilizador.

1. Proteja os conectores contra o contacto com quaisquer agentes de limpeza ou água durante o processamento.
2. Siga as recomendações do fabricante relativas à limpeza com uma solução enzimática. Em seguida, use um agente de limpeza detergente com uma escova de cerdas macias depois da lavagem. Passe por água completamente.
3. Desinfecte em CIDEX® (solução de dialdeídos activados), ou com uma solução equivalente, de acordo com as instruções do fabricante. Passe por água. Seque completamente. Coloque o Cabo/Conector num sistema de embalagem adequado para esterilização por óxido de etileno (EO).
4. Esterilize por ciclo de exposição a óxido de etileno (EO) usando indicadores biológicos. O seguinte ciclo de óxido de etileno (EO) hospitalar típico foi validado para esta aplicação.

Preparação:	125-145°F, 55-75% de HR, 1,9-3,9 PSIA, 30-46 minutos.
Exposição:	125-145°F, 100% de EO, 600 ± 50 mg/l, 4 horas.
Após a Exposição:	Duas evacuações a 1,9-3,9 PSIA, seguidas de um arejamento de 11-12 horas a 120-145°F.

QUALIFICAÇÃO DO EQUIPAMENTO HOSPITALAR

A unidade de cuidados médicos deve qualificar estes procedimentos usando o respectivo equipamento. A eficácia da esterilização deve ser validada e monitorizada usando indicadores biológicos. Os tempos de ciclo e arejamento podem variar, dependendo das características do sistema de arejamento utilizado, do sistema de esterilização, do tamanho e disposição da embalagem, etc. Manuseie de acordo com os procedimentos da unidade de cuidados médicos para que a esterilidade não seja comprometida.

A unidade de cuidados médicos pode voltar a processar o cabo até ao número máximo de vezes especificado, dentro do prazo de vida útil do dispositivo.

GARANTIA

A Boston Scientific Corporation (BSC) garante que foram tomados todos os cuidados devidos na concepção e fabrico deste instrumento. **Esta garantia substitui e exclui todas as outras aqui não expressamente mencionadas, explícitas ou implícitas por força de lei, ou de qualquer outra forma, incluindo, mas não se limitando a, quaisquer garantias implícitas de comercialização ou adequação para fins específicos.** O manuseio, o armazenamento, a limpeza e a esterilização deste instrumento, bem como os factores relacionados com o paciente, diagnóstico, tratamento, procedimentos cirúrgicos e outros assuntos fora do controlo da BSC afectam directamente o instrumento e os resultados obtidos pela sua utilização. A responsabilidade da BSC, de acordo com esta garantia, limita-se à reparação ou substituição deste instrumento e a BSC não se responsabiliza por quaisquer perdas, danos ou despesas incidentais ou consequenciais resultantes, directa ou indirectamente, da utilização deste instrumento. A BSC não assume, nem autoriza qualquer outra pessoa a assumir em seu nome, qualquer outra obrigação ou responsabilidade adicional em relação a este instrumento. **A BSC não assume nenhuma responsabilidade relativamente a instrumentos reutilizados, reprocessados ou reesterilizados e não estabelece quaisquer garantias, explícitas ou implícitas, incluindo mas não se limitando à comercialização ou adequação para fins específicos, em relação a estes instrumentos.**

REF

Catalog Number
Número de catálogo
Numéro de catalogue
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Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização

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Codice prodotto
Productnummer
Número do Produto

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ARG

Argentina Local Contact
Contacto local en Argentina
Contact local en Argentine
Lokaler Kontakt Argentinien
Contatto locale per l'Argentina
Contactpersoon Argentinië
Contacto local na Argentina

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Non-Sterile
No estéril
Non stérile
Nicht steril
Non sterile
Niet-steriel
Não esterilizado

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Zulässige Resterilisationen
Risterilizzazioni consentite
Toegestane hersterilisaties
Reesterilizações Permitidas

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BRA **Brazil Local Contact**

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Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
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