Premarket Approval (PMA) Package for Dockets Management Branch

PMA Number P020025
Docket # 2003M-0427

Boston Scientific Corporation,
EP Technologies, Inc.
EP Technologies EPT-1000 XP™ RF Ablation System

Includes:

Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling

2003M-0427

AAV 1

APPROVAL ORDER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2003

Dr. Ronald C. Allen, Ph.D.
Manager, Regulatory Affairs
Boston Scientific Corporation
EP Technologies, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Re: P020025
EP Technologies EPT-1000 XP™ RF Ablation System
Filed: August 9, 2002
Amended: August 16, September 9, October 23, November 29, December 6, 2002, January 28 and 30, February 25, May 9, June 27, and August 19, 2003
Procode: LPB

Dear Dr. Allen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the EP Technologies EPT-1000 XP™ RF Ablation System. The Blazer II XP™ Cardiac Ablation Catheter is indicated for use with the EPT-1000 XP Cardiac Ablation Controller and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older. The EPT-1000 XP™ Cardiac Ablation Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act

Expiration dating for this device has been established and approved at 3 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact James Cheng at (301) 443-8517, ext. 164.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Last Modified: 1-31-02

CONDITIONS OF APPROVAL

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e) or (f). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations that require a PMA supplement cannot be briefly summarized; therefore, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report (see below). FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

Alternate submissions permitted under 21 CFR 814.39(f) for manufacturing process changes include the use of a 30-day Notice. The manufacturer may distribute the device 30 days after the date on which the FDA receives the 30-day Notice, unless the FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

1. Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

2. Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

   a. unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

   b. reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

1. A mix-up of the device or its labeling with another article.

2. Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and:

   a. has not been addressed by the device's labeling; or

   b. has been addressed by the device's labeling but is occurring with unexpected severity or frequency.

3. Any significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION.
The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers International and Consumer Assistance (DSMICA) at 301-443-8818.

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

Summary of Safety and Effectiveness Data

I. GENERAL INFORMATION

Device Generic Name:	Diagnostic/Ablation Catheter and Accessories
Device Trade Names:	Blazer II XP™ Cardiac Ablation Catheter EPT-1000 XP™ Cardiac Ablation Controller (with software version 3.12)
Applicant's Name and Address:	Boston Scientific Corporation EP Technologies, Inc. 2710 Orchard Parkway San Jose, CA 95134
Date of Panel Recommendation:	N/A
Premarket Approval Application (PMA) Number:	P020025
Date of Notice of Approval to Applicant:	August 25, 2003

Device and Accessory Model Numbers:

Family Name	Model Number	
Blazer II XP™	4500T	4500THN4
	4500TL	4790TH
	4500TM	4790THM
	4500TK2	4790THK2
	4500TMK2	4790THM2
	4500TMN4	4790THN4
	4500TN4	4770T
	4790T	4770TL
	4790TL	4770TM
	4790TM	4770TK1
	4790TK1	4770TK2
	4790TK2	4770TMK2
	4790TMK2	4770TMN4
	4790TMN4	4770TN4
	4790TN4	4770TH
	4500TH	4770THM
	4500THM	4770THK2
	4500THK2	4770THMK2
	4500THMK2	4770THN4
EPT-1000 XP™ Cardiac Ablation Controller	Model 800XP, with software version 3.12	

Explanation of Model Numbers:

For the Blazer II XP™ catheters, the first four digits of the model number refer to the length and shape of the distal tip electrode. Model 4500 catheters are the 8mm standard tips, model 4790 are the 10mm standard tips, and model 4770 are the 8mm contour tips. The letters located after the first four digits in the model number signify the length and torque of the distal tubing segment, and the type of curve for the catheter. For example, the 4500T has a standard distal tubing length, standard torque, and a standard curve. The 4500TH is the same catheter, but with high torque ("H" signifies high torque). The 4500THK2 is the same as the 4500TH, but with a different curve, K2. Available distal tubing lengths are standard (T), medium (TM), and extended (TL). Available curve types are standard, K2 (large), N4 (asymmetric), and NR1 (asymmetric reach).

Related Pre-Market Applications

The Blazer II XP™ catheter is derived from the Blazer II™ catheter approved under P920047. The major difference is the length of the tip electrode in the present Blazer II XP™ catheter (8 mm and 10mm compared to 4 mm and 5mm in previous devices). Further, the predecessor to the EPT-1000 XP™ controller was also approved under P920047. Relevant design specifications of the previous device were maximum power output of 50W with maximum temperature setpoint of 90°C. For more information on the data that supported the related application, please refer to the summary of safety and effectiveness data available on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written request for this information can also be made to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

II. INDICATIONS FOR USE

The Boston Scientific Corporation Blazer II XP™ Cardiac Ablation Catheter is indicated for use with the EPT-1000 XP Cardiac Ablation Controller and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older.

The EPT-1000 XP™ Cardiac Ablation Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.

III. CONTRAINDICATIONS

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma; and
- via the retrograde approach in patients with aortic valve replacement.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Blazer II XP™ Cardiac Ablation Catheter Directions for Use and the EPT-1000 XP™ Cardiac Ablation Controller & Accessories Operator's Manual.

V. DEVICE DESCRIPTION

The Boston Scientific EPT-1000 XP™ Cardiac Ablation System is used to deliver radiofrequency (RF) energy to selected endocardial sites. As referenced in the above table on Device and Accessory Model Numbers, the system consists of two main components:

A. EPT-1000 XP™ Cardiac Ablation Controller, and

B. Blazer II XP™ Cardiac Ablation Catheters

For catheter ablation procedures, the device components require the use of a High Power Automatic Personality Module (XP APM), accessory cables, an optional footswitch and graphics software previously approved under P920047.

Description

A. EPT-1000 XP Cardiac Ablation Controller (RF Generator) with software 3.12

The EPT-1000 XP™ RF Generator is a modified version of the commercially available EPT-1000™ Cardiac Ablation Generator. Both devices are line-powered RF power generators, which supply and control the RF power output delivered to a cardiac ablation catheter via the appropriate Automatic Personality Module (APM or XP APM).

The EPT-1000 XP™ RF Generator is designed to produce a user selectable constant temperature or constant RF power output to the range of 0 to 50 watts or 0 to 100 watts, depending on catheter type, into a nominal tissue impedance of 100 ohms. The system can deliver up to 100 watts only when the EPT-1000 XP™ is connected to a Blazer II XP™ catheter with its unique, proprietary identification code resistor. One hundred watts is the maximum user selected power that may be delivered.

The RF Generator operates in a monopolar mode between a single active electrode at the tip of the ablation catheter and two large surface area return Dispersive Indifferent Patch (DIP) electrodes applied externally on the skin. The indifferent electrodes may be any standard electrosurgical indifferent electrodes that meet the requirements of ANSI/AAMI Standard HF-18 for Electrosurgical Devices. The RF waveform is sinusoidal at a nominal frequency of 500 kHz.

The EPT-1000 XP™ RF Generator operates in one of two control modes: power control mode or temperature control mode.

B. Blazer II XP™ Cardiac Ablation Catheters

The Blazer II XP™ Cardiac Ablation Catheters (Blazer II XP™) are specifically designed to utilize the maximum power capability (up to 100 watts) of the EPT-1000 XP™ RF Generator. These catheters contain a unique proprietary code which the EPT-1000 XP™ RF Generator must recognize in order to allocate power up to 100W. Note that catheters not containing this unique, proprietary identification code are identified by the EPT-1000 XP™ system as capable of delivering up to 50 watts maximum power only.

The Blazer II XP™ Catheter is a torquable, bi-directionally steerable catheter. The catheter is ethylene oxide sterilized and designed for single-use only

The table below summarizes the basic specifications of the Blazer II XP™ Cardiac Ablation Catheters.

Blazer II XP™ Cardiac Ablation Catheter Specifications

Description	Specification
Electrode Tip	
Straight Tip	8 F/8 mm 8 F/10 mm
Contour Tip	8 F/8 mm
Electrode Spacing	
Tip-to-First-Ring	1.5 – 5.0 mm
Ring-to-Ring	2.5 and 5 mm
Electrode Configuration	Quadripolar (4 Electrodes)
Ring Electrode Width	1.25 mm
Deflection	
Symmetric	Up to 270° in opposite directions
Asymmetric	Up to 180° in one direction, 270° in opposite direction
Curve Configurations	
Symmetric	Standard, K2
Asymmetric	N4, NR1
Catheter Length	60 cm to 130 cm
Distal Tubing	
Length	6.6 cm to 15 cm
Stiffness	Soft, Firm
Catheter Shaft Diameter	6 F, 7 F, and 8 F
Torque Attributes	High Torque

C. XP APM

The XP APM provides RF filtering to allow continuous electrogram recording during RF power delivery via the catheter tip electrode. It passes RF energy (at 500 kHz) from the RF

Generator to the patient via the catheter and two Dispersive Indifferent Patch (DIP) electrodes.

D. EPT Graphics Software

The EPT Graphics Software, version 1.06, allows the user to record data pertinent to an ablation procedure including RF power output, impedance and temperature. The data is stored on the hard drive and can be transferred to a diskette or paper copy record. The software, which is compatible with all models of EPT-1000™ Cardiac Ablation Systems, includes three additional error display codes that are specific to the EPT-1000 XP™ Controller.

E. Footswitch (optional)

A Footswitch is provided for optional control of the RF energy output when the user is not in close proximity to the RF Generator. The 10-foot cable allows the user to stand at the catheterization table near the patient and not require a second person for starting/stopping RF energy.

VI. ALTERNATIVE PRACTICES OR PROCEDURES

Alternative therapy for atrial flutter includes direct surgical ablation, use of drugs for arrhythmia control, antiarrhythmia pacing, and other approved RF ablation catheters.

VII. MARKETING HISTORY

The Boston Scientific/EP Technologies EPT-1000 XP™ Cardiac Ablation System is marketed in Canada, Europe, South America, Africa, and Asia.

The product has not been withdrawn from marketing in any country for any reason related to safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

• air embolism • allergic reaction (including anaphylaxis) • anemia • angina • arrhythmias, including exacerbation of pre-existing atrial fibrillation • arterial or pulmonary embolism • arterial / venous thrombosis	• hemothorax • hypotension • increased phosphokinase level • infection • laceration • myocardial infarction • nerve palsy or weakness • pericarditis

• arterial-venous fistula • atrioventricular node damage (transient/permanent) • atypical flutter • back pain and / or groin pain • cardiac perforation • cardiac or respiratory arrest • cardiac thromboembolism • catheter entrapment • cerebral vascular accident • chest pain / discomfort • complete heart block • complications of sedative agents (e.g. aspiration pneumonia) • congestive heart failure • death • effusion (pericardial / pleural) • endocarditis • hematoma / bruising • hemoptysis • hemorrhage	• phrenic nerve damage/diaphragmatic paralysis • pleural effusion • pleurisy • pneumothorax • pulmonary edema • pseudoaneurysm • radiation exposure • seizure • sinoatrial node damage • skin burn (defibrillator / cardioverter / radiation) • tamponade • temporary complete heart block • thrombi • thromboembolism • transient ischemic attack (TIA) • valvular damage/insufficiency • vascular bleeding • vasovagal reactions • visual blurring • worsening chronic obstructive pulmonary disease

For actual adverse events observed during the clinical study (within 7 days post-ablation), please refer to Table 13 below.

IX. SUMMARY OF PRECLINICAL STUDIES

1. Laboratory Studies – Blazer II XP™ Cardiac Ablation Catheters

Testing can be divided into three categories: 1) Testing performed to ensure product safety (reliability, biocompatibility, and sterilization); 2) Testing performed to ensure adequate performance (electrical and mechanical); and 3) Testing to validate the packaging system for microbial protection (packaging integrity and shelf life).

1a. Reliability

Reliability testing was performed for the Blazer II XP™ catheter. In the tests described below, the catheters were double-sterilized prior to testing.

Table 1 – Reliability Testing of Blazer II XP™

Test	Sample Size	Acceptance Criteria	Results
Pull Test Tip Electrode to Distal Tubing	10	No failure before 5 lbs.	passed*
Pull Test Handle to Catheter Main	29	No failure before 5 lbs.	passed

Body Tubing			
Thermal Response of Tip Electrode	10	Time constant less than 1 second	passed
Thermal Repeatability of Tip Electrode	2	Time constant less than 1 second after 100 RF applications of 150W power	passed
Physico-Chemical Properties	28	Within USP limits after exposure to 100 RF applications of 150W power	passed

*In documenting results, "passed" means that all samples passed.

Tests not conducted

The primary difference between the Blazer II XP™ catheter in the subject PMA and the Blazer II™ catheter approved under P920047 is the length of the tip electrode (8mm and 10mm vs. 4mm and 5mm, respectively). Due to the similarities between the two catheters, the following reliability tests were not repeated in the subject PMA:

- Pull Test Distal Tip Electrode to Steering System
- Pull Test Signal Wire to Ring Electrode
- Pull Test Distal Tubing to Main Body Tubing
- Pull Test Steering Wire to Catheter Handle
- Torque Transmission

1b. Mechanical Performance

Mechanical performance testing was performed for the Blazer II XP™ catheter. In the tests described below, the catheters were double-sterilized prior to testing.

Table 2 – Mechanical Performance Testing of Blazer II XP™

Test	Sample Size	Acceptance Criteria	Results
Buckling Force	29	< 340 g	passed
Steering Mechanism Actuation	22	Angular rotation of steering lever and tension control knob shall be per specifications upon deflection	passed

Tests not conducted

Due to the similarities between the Blazer II XP™ catheter and the approved Blazer II™ catheter, the following mechanical performance tests were not repeated in the subject PMA:

- Twist Test (no mechanical failures after 10 revolutions)
- Steering Life Cycle (no mechanical failures after 100 cycles)
- Bending

1c. Electrical Performance

Electrical performance testing was conducted on Blazer II XP™ catheters that were double-sterilized.

Table 3 – Electrical Performance Testing of Blazer II XP™

Test	Sample Size	Acceptance Criteria	Results
Dielectric	20	Withstand 500V at 60 Hz for 60 seconds without leakage current or electrode circuit failure	passed
Continuity	20	15 – 35 kΩ for thermistor, 10Ω for each electrode circuit at room temperature	passed
RF Leakage (catheter body)	20	< 63 mA_{rms}	passed
RF Leakage (ring electrodes)	20	< 122 mA_{rm}	passed
RF Leakage (tip electrode)	20	nominal	passed
RF Power Transmission Capability (catheter body heating)	2	Temperature of outer surface of catheter body < 44°C in saline and < 55°C in air	passed
RF Power Transmission Capability (multiple RF cycles)	10	No electrical failures after 100 RF applications at 150W for at least 2 minutes each	passed

1d. Biocompatibility of Blazer II XP™

Since the Blazer II XP™ catheter and the Blazer II™ catheter approved under P920047 have the same patient blood contacting materials and there was no change in processing, biocompatibility was not re-validated.

The following table lists the patient blood contacting materials that were tested in accordance with the Tripartite Biocompatibility Guidance for Medical Devices and submitted under P920047. All materials are classified as short duration, direct blood path, and externally communicating per ISO 109993-1.

Table 4 – Patient Blood Contacting Materials of the Blazer II XP™

Component	Material Description
Ring Electrode	90% Platinum, 10% Iridium
Distal Tip (Ablation) Electrode	90% Platinum, 10% Iridium
Distal End Tubing	Polyurethane or Pebax
Main Body Tubing	Coextrusion of Pebax & Stainless Steel Wire Braid
Tube Bonding Adhesive	Cyanoacrylate Ester
Ring Electrode Retaining Adhesive	Urethane Methacrylate, UV Curable

1e. Shelf Life of Blazer II XP™

The Blazer II XP™ catheter sterile packaging is identical to that of the Blazer II™ catheter approved in PMA P920047. The shelf life claim of three years, as demonstrated by physical testing of the Blazer II™ catheters approved under P920047, is acceptable for the Blazer II XP™.

1f. Sterilization of Blazer II XP™

Since the components and the packaging of the Blazer II XP™ are identical to that of the Blazer II™ catheter approved in PMA P920047, the sterilization validation of the Blazer II™ is acceptable for the Blazer II XP™.

As part of the sterilization validation, bioburden was measured after fractional, half, and full cycles of sterilization. The Half and Full cycles were repeated in triplicate. Product sterility test specimens were harvested after a fractional cycle. Product test specimens were gauze sponges and "J" guidewires. Fractional cycle product sterility testing used twenty units each of Trypticase Soy Agar, (TSA) and Fluid Thioglycollate Medium, (FTM) growth media. No indigenous organisms were found to have greater resistance than the biological indicator (BI).

Three repetitions of the Half cycle testing were performed. There was no growth on any of the samples after 7 or 14 days, demonstrating that the sterilization process delivers a minimum six log reduction of the microbial challenge at one-half the gas exposure dwell time.

2. Laboratory Studies – EPT-1000 XP™ Cardiac Ablation Controller & Accessories

Based on the modifications made to the EPT-1000 controller approved in PMA P920047 to create the EPT-1000 XP™ controller, pre-clinical testing included electrical safety,

performance, and software verification and validation related to the increase in RF power output capability to 100 W.

2a. Performance Verification

The following table summarizes the performance testing on the EPT-1000 XP™ with software version 3.12.

Table 5 – Verification Testing of the EPT-1000 XP™ with Software 3.12

Test	Sample Size	Acceptance Criteria	Results
Temperature control	1 generator and 3 catheters	Prevent RF delivery if measured temperature is not within 31°C –41°C	passed
Temperature control	1 generator and 3 catheters	Control measured temperature within ± 3°C	passed
Power shutdown	1 generator and 3 catheters	Shutdown power each time set temperature is exceeded	passed
Low impedance shutdown	1 generator and 3 catheters	Shutdown power if impedance is less than 25Ω or 50 Ω depending on catheter type	passed
High impedance shutdown	1 generator and 3 catheters	Shutdown power if impedance is greater than 300 Ω	passed
Temperature shutdown	1 generator and 3 catheters	Shutdown if measured temperature exceeds setpoint value by 5°C for more than 4 seconds	passed
Temperature shutdown	1 generator and 3 catheters	Shutdown if temperature cutoff is exceeded for more than 1 second	passed
Calibration function	1 generator and 3 catheters	Temperature and impedance settings measured correctly	passed
Chassis, isolation, grounding, and leakage	1 generator	Leakage < 100 µA and > 500 µA for specified conditions	passed
Isolated leakage source current	1 generator	Leakage for distal tip, temperature ports, and indifferent electrode < 10 µA and < 50 µA for specified conditions	passed
Isolated leakage sink current	1 generator	Leakage for distal tip, temperature ports, and indifferent electrode < 50 µA for specified conditions	passed
EMC / EMI	1 generator	Per EN 61000-4 series, EN 55011, EN 1000-4-2	passed

2b. EPT-1000 XP™ Software Verification and Validation

The most significant change in the software for the EPT-1000 XP™ was the power available for ablation. The software was modified to limit the power and temperature settings for the controller to 100 W and 80°C for Blazer II XP™ catheters. Standard temperature-sensing catheters and non-temperature sensing catheters are limited to 50 W

maximum power and 90°C. The software for the EPT-1000 XP™ was verified and validated by safety and performance testing.

3. Animal Studies

In-vivo (animal) testing was performed with the EPT-1000 XP™ Cardiac Ablation System and Blazer II XP™ Catheters to verify that the devices met the basic design and performance criteria as a therapeutic and diagnostic product.

The EPT-1000 XP™ Cardiac Ablation System met its design specifications in terms of signal quality, ability to pace, lesion repeatability, and controlling power to maintain a preset temperature for all test article catheters. The EPT-1000 XP™ Cardiac Ablation System also met the design specifications in an *in vivo* test setup when the catheter distal tip electrode is completely exposed to blood (i.e., no tissue contact) and maximum radiofrequency (RF) power is delivered to the distal tip electrode. The average temperatures for all lesions made with the 8F/8 mm straight, 8F/8 mm contour, and 8F/10 mm straight Blazer II XP™ catheters were less than 50°C, demonstrating sufficient convective cooling of the blood to maintain low electrode temperature despite maximum power levels. No thrombus or coagulum was observed after any radiofrequency (RF) application, whether at 150 Watts or 100 Watts.

X. SUMMARY OF CLINICAL STUDY

1. Objective

The objective of the study was to evaluate the safety and efficacy of the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories for radiofrequency ablation of sustained or recurrent type I atrial flutter.

2. Study Design

The study was a prospective, multi-center, single-arm study using objective performance criteria and historical control data from the medical literature. Clinical efficacy and safety assessments were performed at one, three and six months and at one and two years following the index procedure.

3. Study Endpoints

The primary endpoints for the study were as follows:

Acute Procedural Success – defined as complete bi-directional isthmus block with non-inducible type I atrial flutter with only the use of the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories as assessed at the end of the ablation procedure.

Chronic Effectiveness Success – defined as demonstration of Acute Success and continued absence of targeted type I atrial flutter for the first six months after the ablation procedure.

Procedural Safety – defined by the absence of serious complications associated with the use of the investigational device within seven days of the ablation procedure.

Objective Performance Criteria (OPC):
Objective performance criteria (OPC) were prospectively established for all atrial flutter studies by FDA, based on prior experience with supraventricular tachycardia (SVT) ablation studies and consideration by the FDA Circulatory System Devices Panel. The OPC are defined below:

Table 7 - Objective Performance Criteria for Atrial Flutter Ablation

Endpoint	OPC	
	%	One-sided 95% Confidence Bound[1]
Acute Success	86%	80%
Major Complications	3%	7%
Six-Month Success	86%	80%

[1]Exact binomial using a commercially-available software package.

4. Patient Accountability

The table below documents the accountability of patients throughout the study.

Table 8 – Patient Accountability

Patients enrolled in the study	250
Patients not ablated	0
Patients ablated with EPT-1000 XP™ Cardiac Ablation System	250
Patients ablated only with EPT-1000 XP™ Cardiac Ablation System	243
Patients ablated with EPT-1000 XP™ Cardiac Ablation System and non-investigational catheter*	5
Patients ablated only with non-investigational catheter	2

* Patients were first ablated with the EPT-1000 XP™ Cardiac Ablation System only. If flutter procedure could not be completed, then physicians used another catheter to complete the procedure. These patients were considered acute failures.

5. Patient Demographics

The majority of patients in the study are male (83%, N = 205/243). The average age of the male patients is 60.5 ± 11.1 years. There are 42 (17%) females enrolled in the study, with an average age of 63.4 ± 12.4 years.

6. Results

6a. Intraprocedural Data
The table below describes the intraprocedural data:

Table 9 – Intraprocedural Data (N = 209*)

Description (N)	Mean ± SD	Range
Total # of RF Applications / procedure (N = 209 procedures)	11.5 ± 10.6	1.0 - 86.0
Total Duration of RF Applications (minutes) (N = 209 procedures)	14.6 ± 12.1	2.0 - 74.9
Duration per delivery (seconds) (N = 2405 RF applications)	75.9 ± 37.4	11.0 - 120.0
Maximum Set Power (Watts) (N = 2405 RF applications)	76.9 ± 17.1	30.0 - 100.0
Average delivered power (Watts) (N = 2405 RF applications)	54.3 ± 20.5	6.4 - 96.7
Maximum Set Temperature (°Celsius) (N = 2405 RF applications)	64.2 ± 4.8	45.0 - 80.0
Average delivered temperature (°Celsius) (N = 2405 RF applications)	54.6 ± 6.3	40.5 - 77.9

* Based on RF diskette data received

- RF Application with time set < 6 seconds, temperature set < 6 degrees or duration < 11 seconds are excluded from the analysis
- Maximum power allowed is 100 watts, Maximum temperature allowed is 80° C

The procedure and fluoroscopy times are shown in Table 10.

Table 10 – Fluoroscopy/Procedure Index Times (N = 234)

Description	Number of Procedures	Mean (±SD) Duration	Range
Total Procedure (hours)	234	2.1 (±1.3)	0.3 – 9.8
Ablation Time (hours)	231	0.7 (±0.7)	0.03 – 4.5
Total Fluoroscopy (minutes)	232	28.5 (±20.2)	2.8 – 129.0
Ablation Only Fluoroscopy (minutes)	222	14.8 (±13.8)	0.6 – 102.0

6b. Acute Success

Acute success evaluation was based on 250 patients treated with the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories. The table below describes the information:

Table 11 – Acute Ablation Outcomes (N=250)

	# Success / # Patients Ablated	Percentage (one-sided 95% confidence bound)[1]
Acute Success	235/250	94.0% (91.5%)

[1] Exact binomial using a commercially-available software package.

6c. Freedom from Atrial Flutter Recurrence at Six-Month Follow-Up

Freedom from atrial flutter recurrence was evaluated in patients in whom bi-directional isthmus conduction block (BDB) and non-inducibility of atrial flutter (AFL) post ablation was achieved and were considered evaluable for an assessment of long-term (6-month) success. Based on these criteria, information was available on a total of 151 patients. Results are described in Table 12 below.

Table 12 – Freedom from Atrial Flutter at 6 months

Description	N
Patients ablated **only** with EPT-1000 XP™ System and successful BDB and AFL non-inducibility (Acute Success)	151
Number of patients free from recurrence	145 (96.0%)
Number of patients with recurrence of atrial flutter	6 (4.0%)

The patients were classified as "evaluable at 6 months" and "not evaluable at 6 months." There were also 30 patients of the total 250 patients that had not completed the 6 month follow-up.

Reasons that patients were classified "not evaluable:"

- **Treatment with anti-arrhythmic therapy = 31 patients**
  - **This was defined as treatment with Class 1A, 1C or III at both the one-month and three-month, or at the 6 month follow-up. The rationale was that this treatment might suppress the recurrence of atrial flutter and obscure the actual rate of recurrence.**
- **Implanted defibrillators/pacemakers = 11 patients**
  - **The rationale for not evaluating these patients was that the effect of pacing on atrial flutter is unknown and the presence of pacing might make the assessment of atrial flutter difficult.**
- **Persistent atrial fibrillation = 1 patient**
  - **Persistent atrial fibrillation might essentially "overdrive" the atrial flutter. This one patient developed atrial fibrillation shortly after the procedure and remained in that rhythm for the duration of the study.**
- **Withdrawn consent/lost to follow-up = 6 patients**
  - **These patients were determined to be not evaluable if they were lost to the study prior to 6 month follow-up.**
- **Death = 5 patients prior to the 6 month follow-up**
  - **These patients would have been evaluable if they had a recurrence of atrial flutter and were not on medications that would alter the assessment of that recurrence.**

6d. Adverse Events and Deaths

An adverse event was determined to be any undesirable experience occurring to a subject during the course of the study, whether or not it is related to the device or procedure. A major adverse event was defined as any clinical event (which occurred within the first week) following the use of the investigational device and was life-threatening; or resulted in permanent impairment of a body function or permanent damage to a body structure; necessitated significant intervention, such as major surgery, to prevent permanent impairment of a body function or permanent damage to a body structure; or required hospitalization or an extended hospital stay.

Major Adverse Events

Of the 250 patients treated with the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories, twenty-two (22) major adverse events were reported in twenty (20) patients. The major adverse event rate (number of patients with the major adverse events per the number of patients in the study) was 8 % (20 /250). These events included lower extremity ischemia, cerebral infarct, thrombus (2 events), fractured femur, cerebral emboli, pulmonary embolism, hematoma, pseudoaneurysm (2 events) and AV fistula. Eight patients died during the study. Of the eight deaths, five occurred during the six-month study follow-up period, and all were related to underlying pre-existing conditions.

A detailed review of each adverse event was completed. Several patients had adverse events related to pre-existing non-cardiac disease. Several patients had adverse events related to having an invasive procedure but not relating specifically to the investigational device or ablation procedure. The table below details the major adverse events (AE) information.

Table 13

	Days post ablation	Adverse event
1		Atrial tachycardia
2	1	Pacer implant one day post ablation procedure for junctional rhythm *
3	2	Atrial fib
4	0	Laryngotracheitis due to traumatic intubation
5	0	Left buttock induration
6	3	Groin hematoma
7	0	Pulmonary embolus *
	3	Fractured femur
8	1	Systemic embolus to legs bilaterally, right popliteal and left tibioperoneal
9	1	Pacemaker implantation due to prolonged CSNRT
10	8	DVT
11	1	TIA
12	2	Right groin hematoma, possible thrombosed pseudoaneurysm
13	1	Transection femoral artery with subsequent AV fistula
14	1	Femoral AV fistula repair
15	2	Pseudoaneurysm/hematoma
16	5	Ablation for left atrial tachycardia
	6	CVA, multiple cerebellar infarcts
17	1	Atrial fib
18	4	CVA in patient with pre-existing cerebrovascular disease
19	4	Cholecystitis
20	1	Fever

All the adverse events above can be attributed to the procedure. The adverse events in two patients (*) could possibly be attributed to the use of the device for a rate of 2/250 or 0.8%.

Eight (8) patients died during the course of the study. The deaths were non-temporally related to the ablation procedure. Details regarding patient deaths are summarized below:

Table 14

Days death occurred post ablation	Death summary
345	79 year old man with CHF, s/p CABG 1994, collapse at home in shower, in asystolic arrest when ambulance on scene, autopsy showed AMI and cardiac hypertrophy
53	41 year old man with dilated cardiomyopathy, sudden collapse at work 53 days post ablation, in fine VF was cardioverted to junctional rhythm without perfusion, degenerated to asystole, no autopsy performed
38	71 year old woman with history of a total knee replacement developed a pulmonary embolus 10 hours post a successful ablation procedure which was performed without anticoagulation. This large left pulmonary artery embolus was associated with bilateral pleural effusions and a small pericardial effusion. She was treated with heparin and coumadin. She also fell after the ablation procedure, prior to d/c and sustained a periprosthetic left femur fracture, during treatment and recovery she developed MRSA sepsis from a CVP line, and died from complications
214	73 year old man s/p MI, hypertensive, COPD. Did not have a successful ablation procedure. He had worsening respiratory symptoms 6 months post ablation, and was admitted to a nursing home under hospice care. Death was thought to be due to pre-existing respiratory disease.
59	73 year old woman with hypertension, CHF, on CPAP at night had abrupt onset of severe SOB, chest pain and cough 60 days post ablation. Taken to ER where she rapidly deteriorated to cardiopulmonary arrest 3 hours after onset. No clear reason for death documented.
40	52 year old man with history of PVD, CAD, MI 1990, end stage cardiomyopathy, cardiogenic shock one month prior to ablation. He underwent a successful right atrial ablation for typical atrial flutter on 6/16/00. He continued to have left atrial tachycardia and underwent a second ablation procedure on 6/21/00 during which he had multiple bilateral infarcts in the posterior cerebellum. His neurological exam improved but he was transferred to hospice care because of ongoing CHF. Cause of death was thought to be due to worsening CHF.
15 months	74 year old man developed staphylococcal SBE of the mitral valve more than one year post successful ablation procedure.
30	48 year old woman died after a complicated elective gastric bypass surgery procedure.

6. Statistical Analysis

The table below summarizes the safety and effectiveness of the device when compared to the control group OPC for safety, acute success, and long-term success.

Table 15 – Comparison of Endpoints between EPT-1000 XP™ System Study and OPC

Endpoint	OPC		EPT-1000 XP™ Study	
	%	One-sided 95% Confidence Bound[1]	% (N)	One-sided 95% Confidence Bound[1]
Acute Procedural Success	88%	80%	94.0% (235/250)	91.5% (lower bound)
Major Complications	2.7%	7%	8.0% (20/250)	10.8% (upper bound)
Six-Month Success	88%	80%	96.0% (145/151)	93.4% (lower bound)

[1]Exact binomial using a commercially-available software package.

By comparing the lower bounds of the acute success (91.5% vs. 80%) and six-month success endpoints (93.4% vs. 80%), the results demonstrate that the EPT-1000 XP™ Cardiac Ablation System met the OPC for acute procedural success and six-month success rates. As previously explained, although the device exceeded the upper bound of major complications, review of the specific events revealed that most events were not device-related; accordingly, the adverse event rate was acceptable.

XI. CONCLUSIONS DRAWN FROM THE STUDY

Pre-clinical testing demonstrates that the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories will maintain electrical integrity under the proposed conditions of use. Additionally, biocompatibility testing of the patient-contacting materials demonstrates the devices are biocompatible under the proposed conditions of use.

Clinical testing and statistical analyses demonstrates that the Blazer II XP™ Cardiac Ablation Catheter when used with the EPT-1000 XP™ Cardiac Ablation Controller is safe and effective for the treatment of Type 1 atrial flutter.

XII. PANEL RECOMMENDATION

Pursuant to the provisions of section 515(c)(2) of the Food, Drug, and Cosmetic Act (FD&C) as amended by the Safe Medical Devices Act of 1990 (SMDA 1990), this PMA

application was not referred to the Circulatory System Devices Panel, an FDA advisory panel committee, for review and recommendation because the information in the PMA is similar to information previously reviewed by this panel.

XIII. CDRH DECISION

CDRH issued an approval order on August 25, 2003. The applicant's manufacturing facilities were inspected on May 8, July 10 and 11, 2001, September 26 and November 26, 2002, and June 3, 2003 and found to be in compliance with the device Quality System Regulations (Part 820).

XIV. APPROVAL SPECIFICATIONS

Directions for Use: See Labeling (Information for Use)

Hazards to Health from Use of the Device:
See INDICATIONS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE EVENTS in the labeling (Information for Use).

Post Approval Requirements and Restrictions: See approval order.

LABELING

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

Device Description:

The Blazer II XP™ Cardiac Ablation Catheter is a quadripolar ring electrode cardiac ablation catheter. It is designed to allow for therapeutic ablation, intracardiac diagnostic recordings, and pacing capabilities. The catheter is available with an 8F-diameter tip and 2 electrode tip lengths, 8mm and 10mm. The 8mm tip is available in both a straight and contour shape, while the 10mm tip is only available in a straight shape. The choice of electrode tip configurations (straight or contour) is left to the discretion of the physician. (Figure 1 illustrates the Blazer II XP™ Catheter with available instrument cable.)

The Blazer II XP™ Catheter is capable of accessing high power (100 Watts/2 Amps) from the EPT-1000 XP Cardiac Ablation Controller (henceforth, referred to as the Controller). The catheter connects to the Controller via the High Power Automatic Personality Module (XP APM). The XP APM provides for additional connection to standard hospital electrophysiology recorders/monitors. Boston Scientific Corporation/EP Technologies recommends operating the Controller in Temperature Control mode to access high power (100 Watts/2 Amps).

• **Note:** The Blazer II XP™ catheter can only access high power (100 Watts/2 Amps) when used with the EPT-1000 XP Cardiac Ablation Controller and the XP APM. Attempting to use the Blazer II XP™ with an APM other than the XP APM results in a maximum delivery of 50 Watts/1 Amp.

For all ablation catheters, radiofrequency (RF) power is delivered between the catheter's distal electrode and commercially available external Dispersive Indifferent Patch (DIP) Electrodes. Dispersive Indifferent Patch Electrodes (Valley Lab Model E7506) were tested with the EPT-1000 XP Cardiac Ablation System to meet safety requirements per ANSI/AAMI Standard 18.

A summary of the technical specifications for the Blazer II XP™ Cardiac Ablation Catheters is provided in Table 3, Technical Specifications.

Indication for Use

The Boston Scientific Corporation Blazer II XP™ Cardiac Ablation Catheter is indicated for use with the EPT-1000 XP Cardiac Ablation Controller and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older.

The EPT-1000 XP™ Cardiac Ablation Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.

Contraindications

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma; and
- via the retrograde approach in patients with aortic valve replacement.

Warnings

Before operating the device, read these warnings carefully:

• Peri-procedural anticoagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic anti-coagulation therapy pre- during and postablation to reduce the incidence of major complications.

• 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.

• Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:

a) Retain temporary external sources of pacing available during ablation.

b) Reprogram the pacing system temporarily to minimum output or 000 mode to minimize risk of inappropriate pacing.
c) Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads.
d) Perform complete pacing system analysis on all patients after ablation.

• Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.

• 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 positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue.

• In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.

• 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 thrombus in the left atrial appendage.

• Do not pass the catheter through any prosthetic heart valve (mechanical or tissue), as this may cause entrapment of the catheter and/or damage to the prosthetic heart valve, resulting in valvular insufficiency and/or premature failure of the prosthetic valve.

Precautions

Observe these precautions, before using the device:

• Do not attempt to operate the Controller before thoroughly reading the *EP T-1000 XP Cardiac Ablation Controller & Accessories Operator's Manual*.

• The Blazer II XP ™C ardiac Ablation Catheters are intended for use with the Controller and accessories only.

• Contents are supplied **STERILE** using an ethylene oxide process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

• For single patient 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 diseases(s) from one patient to another. Contamination of the device may lead to injury, illness or death to the patient.

• The Blazer II XP™ Catheter is highly torqueable. 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 times the full rotation (540 degrees).* 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.

• Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance.
***Do not** use excessive force to advance or withdraw the catheter when resistance is encountered.*

• Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.

• Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of RF Powered Catheter Ablation in a fully-equipped electrophysiology laborator y.

• Unlike with conventional catheters, a sudden rise in system impedance is not an indication of coagulum formation. Therefore, to minimize

coagulum, it is recommended that the Catheter periodically be removed and the distal tip cleaned after each line of block.
• Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications.
• When using XP Catheters, it is required that two Dispersive Indifferent Patch (DIP) Electrode Pads satisfying the requirements of ANSI/AAMI Standard HF-18 be used as the ablation return electrodes or skin burns may result. Use of only one DIP electrode will not allow the operator to fully access the higher power capabilities of the Controller.
• Placement of the DIP electrodes on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off .
• During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
• Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrodes or failure of an electrical lead.
• ***Do not*** *increase power before checking for obvious defects or misapplication.*
• Regularly inspect and test re-usable cables and accessories.

Potential Adverse Events

Potential adverse events (in alphabetical order), that may be associated with cardiac catheterization and ablation include, but are not limited to:

- air embolism
- allergic reaction (including anaphylaxis)
- anemia
- angina
- arrhythmias, including exacerbation of pre-existing atrial fibrillation
- arterial or pulmonary embolism
- arterial / venous thrombosis
- arterial-venous fistula
- atrioventricular node damage (transient/permanent)
- atypical flutter
- back pain and / or groin pain
- cardiac perforation
- cardiac or respiratory arrest
- cardiac thromboembolism
- catheter entrapment
- cerebral vascular accident
- chest pain / discomfort
- complete heart block
- complications of sedative agents (e.g. aspiration pneumonia)
- congestive heart failure
- death
- effusion (pericardial / pleural)
- endocarditis
- hematoma / bruising
- hemoptysis
- hemorrhage
- hemothorax
- hypotension
- increased phosphokinase level
- infection
- laceration
- myocardial infarction
- nerve palsy or weakness
- pericarditis
- phrenic nerve damage/diaphragmatic paralysis
- pleural effusion
- pleurisy
- pneumothorax

- pulmonary edema
- pseudoaneurysm
- radiation exposure
- seizure
- sinoatrial node damage
- skin burn (defibrillator / cardioverter / radiation)
- tamponade
- temporary complete heart block
- thrombi
- thromboembolism
- transient ischemic attack (TIA)
- valvular damage/insufficiency
- vascular bleeding
- vasovagal reactions
- visual blurring
- worsening chronic obstructive pulmonary disease

Inspection Prior to Use

Prior to use of the EPT-1000 XP™ Cardiac Ablation System, the individual components including the Blazer II XP™ catheter, the EPT-1000 XP Cardiac Ablation Controller, Quick Connect Instrument Cable, XP Automatic Personality Module and Footswitch should be carefully examined for damage or defects as should all equipment used in the procedure.

***Do not** use defective equipment.*

Equipment 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. Ancillary materials required to perform cardiac ablation are as follows:

• One (1) - 8 French (8F) hemostatic percutaneous catheter introducer and/or a long introducer sheath to match the 8F diameter of the electrode tip.

• Two (2) - DIP Electrodes meeting ANSI standard HF-18 requirements for electro-surgical electrodes.

Setting up the System

Refer to the *EPT-1000 XP™ Cardiac Ablation Controller & Accessories Operator's Manual* for detailed instructions for connecting the system and setting ablation parameters.

Attaching the DIP Electro d e s

Read the manufacturer's manual before installing the DIP Electrode pads

1. Place two DIP electrodes on the patient on a well-vascularized, convex skin surface that is in close proximity to the ablation site (left upper quadrant of the back is suggested unless the patient's scapula is especially prominent or patient is extremely thin). Other possible locations are the upper arm or left flank area.
2. Avoid scar tissue, bony prominence, adipose tissue or distal areas from the heart (thigh), or any areas where fluid may pool. Shave, clean, and dry the application site as needed. Check for wrinkles or folds when applying the pad as these decrease conductivity.
3. Install the two DIP Electrodes connectors into the INDIFFERENT ELECTRODE receptacles located on the XP APM front panel.

Figure 2 illustrates the cable configuration for the Blazer II XP™ Catheter, EPT-1000 XP Cardiac Ablation Controller, and XP APM.

Directions for Use

Prior to insertion of the Blazer II XP™ Cardiac Ablation Catheter, prepare the entry site according to standard aseptic practices.

1. Insert the catheter percutaneously into the appropriate vein by the Seldinger technique, using a 8F hemostatic introducer sheath and/or a long sheath.

2. Once inside the vessel, the catheter tip can be deflected as necessary to facilitate advancement into the selected heart chamber.
3. Connect the XP APM to the ISOLATED PATIENT CONNECTOR located on the Controller's front panel using the attached patient cable. Be sure to carefully follow the instructions in the Operator's Manual to connect the XP APM.
4. Connect the Catheter to the model 613 or 651 instrument cabels and plug the cables into the XP APM.
5. When the ablation site has been accessed and the tip of the catheter is in contact against the endocardial surface, intracardiac electrogram signals may be obtained. Bipolar electrogram recordings can be recorded between the distal tip electrode and any ring electrode, or between any two ring electrodes even during RF ablation.
6. The Blazer II XP™ or a multi-polar catheter can be used to assess bi-directional conduction across the isthmus.
7. Use lower power first- When first delivering RF energy, begin by using a low power setting (i.e., 50W). If the created lesion is unsuccessful or inadequate, incrementally increase the power output with successive ablation attempts to minimize the potential for thrombus formation and/ or inadvertent damage to cardiac tissues.
8. When the targeted site has been located, the same catheter can be used therapeutically in the "Ablate" mode to deliver RF energy. RF power is delivered to the tissue via the distal tip (ablation) electrode which results in thermal necrosis (ablation) of the arrhythmogenic tissue.
9. Ensure that the ablation parameters are set as instructed in the *EPT-1000 XP™ Cardiac Ablation Controller and Accessories Operator's Manual.*
• **N o t e** The Controller automatically adjusts power (up to a maximum of 100 watts), within a user-selected upper power limit, to achieve the desired temperature, in the Temperature Control mode.
10. The catheter tip curve can be straightened completely and deflected in the opposite direction against cardiac tissue, facilitating stability during ablation.
• **N o t e** The EPT-1000 XP™ Cardiac Ablation System is designed so that the temperature set limit cannot exceed 80ₒC in Te m p e r a t u re Contro l M o d e .
11. To begin RF power deliver y, press the RF POWER CONTROL Button on the Controller's front panel once or hold the Footswitch down. The POWER Display shows the RF power delivered to the catheter (in watts).
12. During RF delivery, monitor key parameters and adjust therapy delivery accordingly.
13. If any of the following conditions occur during operation, discontinue RF power delivery and perform corrective action as indicated.
If a problem is encountered during the procedure, first ensure that all connections are secure and correct, then follow the steps in Table 1.

Catheter Removal

1. Prior to removing the Catheter, straighten the distal end of the catheter completely.
2. Withdraw the catheter from the vessel.
3. Remove the introducer and/or long introducer sheath and then follow standard practice for management of the insertion site.

Table 1: Correcting Abnormal Conditions

P ro b l e m s (s)	Possible Cause	Corrective Action Procedure
Lack of	Inadequate contact	1. Discontinue RF delivery.

Temperature Rise	between electrode and tissue.	2. Adjust Catheter position to gain contact and stability. 3. Reinitiate RF delivery.
Low Temperature Fluctuating Temperature Fluctuating Power	Electrode not stable on endocardium.	1. Discontinue RF delivery. 2. Adjust Catheter position to gain contact and stability. 3. Reinitiate RF delivery.
Sudden Drop in Temperature Sudden Rise in Power	Loss of contact or shift in electrode position.	1. Discontinue RF delivery immediately to prevent ablation of nontargeted tissue. 2. Tip position should be assessed using fluoroscopic and electrogram information 3. Reinitiate RF delivery.

SUMMARY OF CLINICAL STUDY

1. Objective

The objective of the study was to evaluate the safety and efficacy of the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories for radiofrequency ablation of sustained or recurrent type I atrial flutter.

2. Study Design

The study was a prospective, multi-center, single-arm study using objective performance criteria and historical control data from the medical literature. Clinical efficacy and safety assessments were performed at one, three and six months and at one and two years following the index procedure.

3. Study Endpoints

The primary endpoints for the study were as follows:

- Acute Procedural Success – defined as the demonstration of bi-directional isthmus block with non-inducible type I atrial flutter with only the use of the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories as assessed at the end of the ablation procedure.

- Six-month Success – defined as demonstration of Acute Success and continued absence of targeted type I atrial flutter for the first six months after the index procedure.

- Complication Rate – refers to major complications experienced by patients exposed to the investigational device which occur within seven days post-procedure.

- Objective Performance Criteria (OPC):
  Objective performance criteria (OPC) were prospectively established for all atrial flutter studies by FDA, based on prior experience with supraventricular tachycardia (SVT) ablation studies and consideration by the FDA Circulatory System Devices Panel. The OPC are defined below:

Objective Performance Criteria for Atrial Flutter Ablation

• **Endpoint**	• **OPC**	
	• %	• One-sided 95% Confidence Bound[1]
• **Acute Success**	• 86%	• 80%
• **Major Complications**	• 3%	• 7%
• **Six-Month Success**	• 86%	• 80%

[1]Exact binomial using a commercially-available software package.

4. Patient Accountability

The table below documents the accountability of patients throughout the study.

Patient Accountability

Patients enrolled in the study	250
Patients not ablated	0
Patients ablated with EPT-1000 XP™ Cardiac Ablation System	250
Patients ablated only with EPT-1000 XP™ Cardiac Ablation System	243
Patients ablated with EPT-1000 XP™ Cardiac Ablation System and non-investigational catheter*	5
Patients ablated only with non-investigational catheter	2

* Patients were first ablated with the EPT-1000 XP™ Cardiac Ablation System only. If flutter procedure could not be completed, then physicians used another catheter to complete the procedure. These patients were considered acute failures.

5. Patient Demographics

The majority of patients in the study are male (83%, N = 205/243). The average age of the male patients is 60.5 ± 11.1 years. There are 42 (17%) females enrolled in the study, with an average age of 63.4 ± 12.4 years.

6. Results

6a. Intraprocedural Data

The table below describes the intraprocedural data:

Intraprocedural Data (N = 209*)

Description (N)	Mean ± SD	Range
Total # of RF Applications / procedure (N = 209 procedures)	11.5 ± 10.6	1.0 - 86.0
Total Duration of RF Applications (minutes) (N = 209 procedures)	14.6 ± 12.1	2.0 - 74.9
Duration per delivery (seconds) (N = 2405 RF applications)	75.9 ± 37.4	11.0 - 120.0
Maximum Set Power (Watts) (N = 2405 RF applications)	76.9 ± 17.1	30.0 - 100.0
Average delivered power (Watts) (N = 2405 RF applications)	**54.3 ± 20.5**	**6.4 - 96.7**
Maximum Set Temperature (°Celsius) (N = 2405 RF applications)	**64.2 ± 4.8**	**45.0 - 80.0**
Average delivered temperature (°Celsius) (N = 2405 RF applications)	**54.6 ± 6.3**	**40.5 - 77.9**

* Based on RF diskette data received

- RF Application with time set < 6 seconds, temperature set < 6 degrees or duration < 11 seconds are excluded from the analysis
- Maximum power allowed is 100 watts, Maximum temperature allowed is 80° C

The index procedure and fluoroscopy times are shown in the table below.

Fluoroscopy/Procedure Index Times (N = 234)

Description	Number of Procedures	Mean (±SD) Duration	Range
Total Procedure (hours)	**234**	**2.1 (±1.3)**	**0.3 – 9.8**
Ablation Time (hours)	**231**	**0.7 (±0.7)**	**0.03 – 4.5**
Total Fluoroscopy (minutes)	**232**	**28.5 (±20.2)**	**2.8 – 129.0**
Ablation Only Fluoroscopy (minutes)	**222**	**14.8 (±13.8)**	**0.6 – 102.0**

6b. Acute Procedural Success (bi-directional isthmus block)

Acute success evaluation was based on 250 patients treated with the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories. The table below describes the information:

Acute Ablation Outcomes (N=250)

	# Success / # Patients Ablated	Percentage (one-sided 95% confidence bound)[1]

Acute Success	235/250	94% (91.5%)

[1]Exact binomial using a commercially-available software package.

6c. Freedom from Atrial Flutter Recurrence at Six-Month Follow-Up

Freedom from atrial flutter recurrence was evaluated in patients in whom bi-directional isthmus conduction block (BDB) and non-inducibility of atrial flutter (AFL) post ablation was achieved and were considered evaluable for an assessment of long-term (6-month) success.

The patients were divided into evaluable at 6 months and not evaluable at 6 months. There were also 30 patients of the total 250 patients that had not completed the 6 month follow-up.

Reasons that patients were classified "not evaluable"

- Treatment with anti-arrhythmic therapy = 31 patients
  - This was defined as treatment with Class 1A, 1C or III at both the one-month and three-month, or at the 6 month follow-up. The rationale was that this treatment might suppress the recurrence of atrial flutter and obscure the actual rate of recurrence.
- Implanted defibrillators/pacemakers = 11 patients
  - The rationale for not evaluating these patients was that the effect of pacing on atrial flutter is unknown and the presence of pacing might make the assessment of atrial flutter difficult.
- Persistent atrial fibrillation = 1 patient
  - Persistent atrial fibrillation might essentially "overdrive" the atrial flutter. This one patient developed atrial fibrillation shortly after the procedure and remained in that rhythm for the duration of the study.
- Withdrawn consent/lost to follow-up = 6 patients
  - These patients were determined to be not evaluable if they were lost to the study prior to 6 month follow-up.
- Death = 5 patients prior to the 6 month follow-up
  - These patients would have been evaluable if they had a recurrence of atrial flutter and were not on medications that would alter the assessment of that recurrence.

Based on these criteria, information was available on a total of 151 patients. Results are described in the table below.

Freedom from Atrial Flutter at 6 months

Description	N
Patients ablated **only** with EPT-1000 XP™ System and successful BDB and AFL non-inducibility (Acute Success)	151
Number of patients free from recurrence	145
Number of patients with recurrence of atrial flutter	6

6d. Adverse Events and Deaths

An adverse event was determined to be any undesirable experience occurring to a subject during the course of the study, whether or not it is related to the device or procedure. A major adverse event was defined as any clinical event which occurred within the first week following the use of the investigational device and was life-threatening; or resulted in permanent impairment of a body function or permanent damage to a body structure; necessitated significant intervention, such as major surgery, to prevent permanent impairment of a body function or permanent damage to a body structure; or required hospitalization or an extended hospital stay.

Twenty-two (22) major adverse events were reported for twenty (20) patients. These events included lower extremity ischemia, cerebral infarct, thrombus (2 events), fractured femur, cerebral emboli, pulmonary embolism, hematoma, pseudoaneurysm (2 events) and AV fistula. Eight patients died during the study. Of the eight deaths, five occurred during the six-month study follow-up period, and all were related to underlying pre-existing conditions.

Major Adverse Events

Of the 250 patients treated with the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories, twenty-two (22) major adverse events were reported in twenty (20) patients. The major adverse event rate (number of patients with the major adverse events per the number of patients in the study) was 8 % (20 /250).

A detailed review of each adverse event was completed. Several patients had adverse events related to pre-existing non-cardiac disease. Several patients had adverse events related to having an invasive procedure but not relating

specifically to the investigational device or ablation procedure. The table below details the major adverse events (AE) information.

	Days post ablation	Adverse event
1		Atrial tachycardia
2	1	Pacer implant one day post ablation procedure for junctional rhythm *
3	2	Atrial fib
4	0	Laryngotracheitis due to traumatic intubation
5	0	Left buttock induration, treated with narcotics
6	3	Groin hematoma
7	0	Pulmonary embolus *
	3	Fractured femur
8	1	Systemic embolus to legs bilaterally, right popliteal and left tibioperoneal
9	1	Pacemaker implantation due to prolonged CSNRT
10	8	DVT
11	1	TIA
12	2	Right groin hematoma
13	1	Transection femoral artery with subsequent AV fistula
14	1	Femoral AV fistula repair
15	2	Pseudoaneurysm/hematoma
16	5	Ablation for left atrial tachycardia
	6	CVA, multiple cerebellar infarcts
17	1	Atrial fib
18	4	CVA in patient with pre-existing cerebrovascular disease
19	4	Cholecystitis
20	1	Fever

All the adverse events above can be attributed to the procedure. The adverse events in two patients (*) could possibly be attributed to the use of the device for a rate of 2/250 or 0.8%.

Eight (8) patients died during the course of the study. The deaths were non-temporally related to the ablation procedure. Details regarding patient deaths are summarized below:

Days post ablation	Death summary
345	79 year old man with CHF, s/p CABG 1994, collapse at home in shower, in asystolic arrest when ambulance on scene, autopsy showed AMI and cardiac hypertrophy
53	41 year old man with dilated cardiomyopathy, sudden collapse at work 53 days post ablation, in fine VF was cardioverted to junctional rhythm without perfusion, degenerated to asystole, no autopsy performed
38	71 year old woman with history of a total knee replacement developed a pulmonary embolus 10 hours post a successful ablation procedure which was performed without anticoagulation. This large left pulmonary artery embolus was associated with bilateral pleural effusions and a small pericardial effusion. She was treated with heparin and coumadin. She also fell after the ablation procedure, prior to d/c and sustained a periprosthetic left femur fracture, during treatment and recovery she developed MRSA sepsis from a CVP line, and died from complications
214	73 year old man s/p MI, hypertensive, COPD. Did not have a successful ablation procedure. He had worsening respiratory symptoms 6 months post ablation, and was admitted to a nursing home under hospice care. Death was thought to be due to pre-existing respiratory disease.
59	73 year old woman with hypertension, CHF, on CPAP at night had abrupt

	onset of severe SOB, chest pain and cough 60 days post ablation. Taken to ER where she rapidly deteriorated to cardiopulmonary arrest 3 hours after onset. No clear reason for death documented.
40	**52 year old man with history of PVD, CAD, MI 1990, end stage cardiomyopathy, cardiogenic shock one month prior to ablation. He underwent a successful right atrial ablation for typical atrial flutter on 6/16/00. He continued to have left atrial tachycardia and underwent a second ablation procedure on 6/21/00 during which he had multiple bilateral infarcts in the posterior cerebellum. His neurological exam improved but he was transferred to hospice care because of ongoing CHF. Cause of death was thought to be due to worsening CHF.**
15 months	**74 year old man developed staphylococcal SBE of the mitral valve more than one year post successful ablation procedure.**
30	**48 year old woman died after a complicated elective gastric bypass surgery procedure.**

6. Statistical Analysis

The table below summarizes the safety and effectiveness of the device when compared to the control group OPC for safety, acute success, and long-term success.

Comparison of Endpoints between EPT-1000 XP™ System Study and OPC

Endpoint	OPC		EPT-1000 XP™ Study	
	%	One-sided 95% Confidence Bound[1]	% (N)	One-sided 95% Confidence Bound[1]
Acute Success	86%	80%	94% (235/250)	91.5% (lower bound)
Major Complications	3%	7%	8% (20/250)	10.8% (upper bound)
Six-Month Success	86%	80%	96% (145/151)	93.4% (lower bound)

[1]Exact binomial using a commercially-available software package.

By comparing the lower bounds of the acute success (91.5% vs. 80%) and six-month success endpoints (93.4% vs. 80%), the results demonstrate that the EPT-1000 XP™ Cardiac Ablation System met the OPC for acute success and six-month success rates. As previously explained, although the device exceeded the upper bound of major complications, review of the specific events revealed that most events were not device-related; accordingly, the adverse event rate was acceptable.

EPT-1000 XP™
Cardiac Ablation Controller & Accessories
110V
Operator's Manual

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

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Natick, MA 01760
Customer Service: 1-800-552-6700
P/N:90067547-01 Rev A (4/03)
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Preface

Manual Conventions

The following naming conventions are used in the *EPT-1000 XP™ Cardiac Ablation Controller & Accessories Manual*:

The EPT-1000 XP™ Cardiac Ablation Controller & Accessories is referred to as the "System." For a complete description of the System's components, refer to Section 1, *System Description.*

- The EPT-1000 XP™ Cardiac Ablation Controller is referred to as the "Controller."
- The Automatic Personality Module is referred to as the "APM."
- The High Power Automatic Personality Module is referred to as the "XP APM."

The Catheters are referred to as follows:

- Steerable Ablation Catheter with temperature measuring capability (thermistor): "Catheter (T°)."
- Steerable Ablation Catheter without temperature measuring capability: "Catheter (Non-T°)."
- Catheter information pertaining to both Catheter styles: "Catheter."

General Information

The use of all components and accessories of the EPT-1000 XP™ Cardiac Ablation System is fully described in this Manual, except for the Steerable Ablation Catheters. This Manual provides a description of the Controller, its controls and displays, and a sequence for its operation. In addition, it provides information relevant to the operation of the appropriate accessories with the The EPT-1000 XP™ only, as well as other information of importance to the user.

■ **Precaution** *Do not attempt to operate the System before thoroughly reading this Operator's Manual. It is important that the equipment's operating instructions be read, understood and followed. For future reference, retain this Manual in a convenient, readily accessible place.*

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List of Tables

1. System Description

The EPT-1000 XP™ Cardiac Ablation System (see Figure 1-1) consists of two principal subsystems:

- BSC Model #800XP Cardiac Ablation Controller (RF Generator)
- Catheter (T°) or Catheter (Non-T°) with Quick Connect Instrument Cables for connection to the EPT Model #822T High Power Automatic Personality Module or BSC Model #821T Automatic Personality Module

☒**Note** Refer to Figure 1-2 for cable configuration.

One optional accessory is provided with the Controller:

- BSC Model 840 Footswitch

For system operation and power level access greater than 50 W/1 A, it is ***mandatory*** to use the XP APM. If accessing up to 100 W/2 A power levels, both an XPAPM and a special high power catheter must be used. The Footswitch usage is optional as the Controller can be operated directly from its front panel controls. The EPT-1000 XP™ Cardiac Ablation System is operated in conjunction with commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrodes, which are in compliance with ANSI/AAMI Standard HF-18.

☒ **Note:** When using special high power catheters with the EPT-1000 XP™ Controller, two DIP Electrodes are required.

The Catheter delivers RF power in a monopolar mode between its distal electrode and the large DIP Electrode(s). Detailed information regarding the Catheter is contained in the appropriate Directions For Use.

System Features

The EPT-1000 XP™ Cardiac Ablation System features the following:

- The Controller produces a continuous unmodulated radio frequency (RF) output at 500 kHz.
- The front panel displays the actual power output, tissue impedance, and if a Catheter (T°) is connected to the Controller, catheter tip temperature.
- The Controller measures RMS (Root Mean Square) voltage, RMS current, and actual power output by taking the average value of the product of voltage and current. (This reflects the effective heating power delivered to the tissue from the Catheter electrode tip. Impedance is calculated as RMS voltage divided by RMS current.)
- The amount and duration of RF power delivery is user-selectable, and if a Catheter

(T°) is connected, the desired tissue temperature or maximum tissue temperature is also user-selectable.

• The number of RF power deliveries is automatically counted for the physician.

• The XP APM provides RF filtering to allow continuous electrogram recording during RF power delivery via the catheter tip electrode.

• The XP APM allows for safe use of either standard or high power BSC ablation catheters.

Safety Features

The System's built-in safety features include automatic shutoff for the following conditions:

• If accessing up to 50 W of RF power and measured tissue impedance is less than 50 Ω.

• If accessing up to 100 W of RF power and measured tissue impedance is less than 25 Ω.

• If measured tissue impedance exceeds 300 Ω.

• If maximum voltage or current limits are exceeded.

• The Controller shuts off if the measured temperature exceeds 85°C for greater than 1 second with high power catheters and 95°C for greater than 1 second with standard catheters, or if measured temperature exceeds the upper temperature limit selected in the Power Control mode. This temperature is not the maximum tissue temperature. The recorded temperature may be up to 15°C different from the maximum tissue temperature. The temperature can be set up to 80°C for high power catheters.

• The Controller shuts off if the measured temperature exceeds the user-selected temperature setpoint by 5°C for greater than 4 seconds. This temperature is not the maximum tissue temperature.

• If greater than 1 A of current is delivered to either of the two DIP Electrodes connected to the XP APM, the Controller shuts off.

Control Modes

The Controller is capable of operating in two "control modes" (Power Control or Temperature Control).

Power Control

The Power Control mode is compatible with all defined Catheter types and allows selection of the quantity of RF power that is delivered by the Catheter. If using a Catheter (T°), the Controller delivers the set power unless the upper temperature limit is exceeded, which results in a reduction in the amount of power delivered.

Temperature Control

The Temperature Control mode is *only* available when using Catheter (T°) and allows selection of a desired tissue temperature.

The maximum amount of power to be delivered by the Catheter must be selected for both control modes (Power Control or Temperature Control).

☒ **Note:** When using the EPT-1000 XP™ Cardiac Ablation Controller in the Temperature Control mode, **ALWAYS** ensure that the TEMP LED on the Control Panel is illuminated.

The following table defines the power delivery protocol for both the Power Control and Temperature Control modes for the Controller with XP APM connected.

Table 1-1: Power Delivery Protocol

Catheter Type	Maximum Power Setting	Maximum Current

(W) (A)
Catheter (Non-T°) 50 1
Catheter (T°) 50 1
High Power Catheter (T°) 100 2

Figure 1-1: System Installation Diagram

Polarity Unimport t an
XP APM/EGM Interconnector
Cable to Junction Box/Recorder
W
ANALOG OUTPUT SPEAKER
PUSES
Front Panel
Isolated
Patient
Connector
Controller
Footswitch
Cable
Connector
Rear Panel
Power
Cord
Patient
Cable
Catheter
DIP Electrode
Quick Connnect
Instrument Cable
CATHETER
RECORDER
ELECTRODES INDIFFERENT
Footswitch
CALIBRATION
MAINS
High Power
Automatic
Personality
Module

Figure 1-2: Cable Configuration for Quick Connect XP APM

2. *Indications/Contraindications*

Indications for Use

The Boston Scientific Corporation Blazer II XP™ Cardiac Ablation Catheter is indicated for use with the EPT-1000 XP Cardiac Ablation Controller and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older.

The EPT-1000 XP™ Cardiac Ablation Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.

Contraindications

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma; and
- via the retrograde approach in patients with aortic valve replacement.

☒ **Note** Refer to individual Directions For Use for the Catheter and ground pads contraindications.

3. Warnings, Precautions, and Adverse Reactions

Warnings for the Controller

Before operating, read these warnings carefully:

• The displayed temperature is not the maximum tissue temperature. Do not set the maximum temperature higher than 80°C .

• Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:

a) Retain temporary external sources of pacing available during ablation.

b) Reprogram the pacing system temporarily to minimum output or 000 mode to reduce risk of inappropriate pacing.

c) Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads.

d) Perform complete pacing system analysis on all patients after ablation.

• Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.

• The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of components with unprotected male pin connectors must exercise extreme caution during device set-up to prevent patient or operator injury.

Unused pins should be secured so that they do not inadvertently touch other equipment or surfaces. Never insert pins into MAINS outlets or into any equipment other than systems providing patient electrical isolation in accordance with EN-60601.

• The APM or XP APM output labeled recorder must only be connected to a medically isolated recorder.

• Grounding reliability can only be achieved when the power supply cord is connected to a receptacle marked Hospital Only or Hospital Grade.

• If a "Booker Box" device is used, it should be used with a DIP electrode that is separate from the DIP electrode used by the Controller.

Precautions

Observe these precautions, before using the System:

• Do not attempt to operate the BSC Cardiac Ablation System before thoroughly reading the EPT-1000 XP™ Cardiac Ablation Controller Operator's Manual.

• When using high power catheters, it is required that two Disposable Indifferent Patch Electrodes be used as the ablation return electrodes or skin burns may result.

• The use of non-EPT approved extension cables may alter the performance of the RF generator and render it out of specification.

• Due to the larger surface area of the catheter's distal tip, coagulum formation may not result in a sudden impedance rise. The catheter should be removed after each line of block and the distal tip of the catheter cleaned to minimize coagulum.

• Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications.

• The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children.
• 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. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
• Read and follow the Disposable Indifferent (Dispersive) Patch (DIP) Electrode manufacturer's instructions for use; the use of DIP Electrodes which meet or exceed ANSI/AAMI HF-18 requirements is required.
• Placement of a DIP electrode on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.
• The Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the Catheter and DIP Electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
• Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP Electrode or failure of an electrical lead. ***Do not*** *increase power before checking for obvious defects or misapplication.*
• 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.
• Electromagnetic interference (EMI) produced by the Controller during the delivery of RF power may adversely affect the performance of other equipment.
• Regularly inspect and test re-usable cables and accessories.

4. Unpacking the Controller

Unpacking

The Controller's shipping carton contains the components identified below:

- ☐ 1 - Controller
- ☐ 2 - EPT-1000 XP™ Cardiac Ablation System Operator's Manuals

The following System components are individually shipped separately:

- ☐ 1 - Footswitch
- ☐ 1 - XP APM with Quick Connect Connectors
- ☐ 1 - Interconnect Cable for XP APM to EGM Equipment
- ☐ 1 - Quick Connect Temperature Instrument Cable
- ☐ 1 - Quick Connect Non-Temperature Instrument Cable
- ☐ 2 - Ground Pads (Disposable Indifferent Patch Electrodes)

To unpack the System, follow these steps:

1. Unpack the Controller and accessories carefully and inspect for damage.

2. Notify the carrier immediately if the shipment carton is damaged.

3. Verify that the items listed above are received.

☎ **Call BSC for Service** If there are any discrepancies, notify BSC. See Section 7, *Service and Maintenance* of the Operator's Manual.

4. Read Section 6, *Operational Sequence* in this Manual very carefully and follow the installation and setup instructions.

Repackaging the Controller

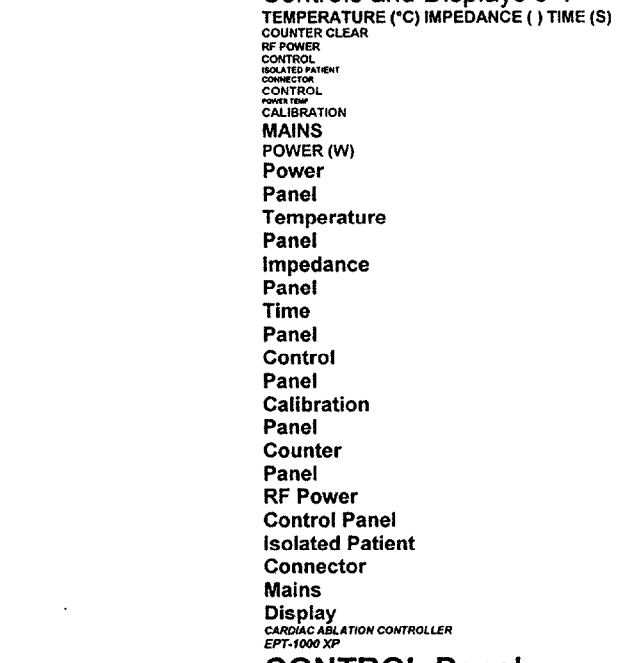
When the Controller requires service or transfer to other location, use the original shipping carton and packing materials to repack and ship the Controller.
For shipping, disconnect the APM or XP APM and Footswitch. Place all the components into the locations reserved for these units in the carton.

5. Controls and Displays

Front Panel

The operator controls for the EPT-1000 XP™ Cardiac Ablation Controller are located on the front panel of the Controller. The buttons on the Controller's front panel allow the user to control the operation of the Controller. The lights/LEDs on the front panel show the Controller's status and/or report error conditions.
This section describes the operator controls on the front panel shown in Figure 5-1.

Figure 5-1: Controller Front Panel



CONTROL Panel

CONTROL Indicator LEDs

The control mode of the Controller is indicated by either of two green LEDs (POWER or TEMP) on the CONTROL Panel (see Figure 5-2). When the Controller is initially powered on, one of the green LEDs displays the control mode which depends on the type of Catheter connected to the Controller.
If a Catheter (T°) is connected, the Controller automatically switches to the Temperature Control mode when initially powered on, as indicated by the flashing green TEMP LED. If it is desirable to operate the Controller in the Power Control mode while using a Catheter (T°), pressing the CONTROL Button (see Figure 5-2) changes the control mode to Power Control, as indicated by the flashing green POWER LED.
If a Catheter (Non-T°) or no Catheter is connected, then the Controller automatically switches to the Power Control mode, when initially powered on, as indicated by the flashing green POWER LED.

☌ **Note** POWER, TIME, and TEMPERATURE setpoints all reset to default values whenever a Catheter (T°) is disconnected and reconnected, or when a switch is made between control modes (Power Control to Temperature Control or vice versa). During RF power delivery, the control mode cannot be changed.

Figure 5-2: CONTROL Panel Indicator LEDs and Button

Control Panel Power LED Temp LED Control Button

CONTROL

POWER TEMP

CONTROL Button

The Controller is capable of operating in Power Control or Temperature Control mode. Press the CONTROL Button to toggle (or change) to a new control mode, as indicated by a flashing LED.

The Power Control mode is compatible with Catheter (T°) and Catheter (Non-T°) and allows selection of the quantity of RF power that is delivered by the Steerable Ablation Catheter (see Table 5-1). It also allows selection of an upper temperature limit from 55°C to 85°C for XP catheters, 95°C for standard catheters (the default value).

The Temperature Control mode is *only* compatible with Catheter (T°) and allows selection of a desired tissue temperature. The maximum amount of power to be delivered by the Catheter, from a value of 0 W to a maximum of either 50 or 100 W depending on catheter type, must also be selected in the Temperature Control mode (see Table 5-1). If insufficient power is selected, the desired tissue temperature may not be achieved.

Catheters are designed to transmit three distinct quantities of RF power, based on their electrode size, internal construction and intended use. The maximum amount of power the Catheters can access is limited by the control mode and catheter type as follows:

✉ **Note:** Access to greater than 50W of power requires the use of appropriately coded (high power) catheters and the XP APM.

Table 5-1: Maximum Amount of Power Output for Catheters

Control Modes			
Catheter Type	**APM Type**	**Power Control (W)**	**Temperature Control (W)**
Catheter (Non-T°)	APM or XPAPM	50	N/A
Catheter (T°)	APM or XPAPM	50	50 High Power)
Catheter (T°)	XP APM	100	100

POWER Panel

POWER Display

The POWER Display (see Figure 5-3) shows the RF power output in Watts. The available power output ranges are dependent on the catheter type and the control mode. Ranges are from a value of 0 Watt to the maximum amount of power output (see Table 5-1).

When the Controller is initially powered on, the POWER Display indicates the default power setpoint of 0 Watt. After the user sets the power setpoint and presses the RF POWER CONTROL Button, the display changes from the setpoint value and begins displaying the actual power output the Catheter delivers to the tissue.

In the Power Control mode, the Controller adjusts its output to maintain the measured power at the power setpoint, and in the Temperature Control mode, the Controller adjusts its output to maintain the measured temperature at the temperature setpoint. In the Temperature Control mode, measured power may be lower than the power setpoint value, depending on the measured tissue temperature and/or tissue impedance. When RF power is discontinued (DONE operational mode), the last measured value of RF power delivered remains on the display, flashing at 1-second intervals.

Figure 5-3: POWER Display and Buttons

Power Panel Power Display Power Increase Button Power Decrease Button POWER (W)

POWER ♉/♉ Buttons

The POWER ♉/♉ (increase/decrease) Buttons select the desired level of delivered RF power for the Power Control mode, or the maximum amount of RF power available for the Temperature Control mode.

For instructions on how to select the level of delivered RF power, see the section *Selecting the Power Output* on page 6-10.

TEMPERATURE Panel

TEMPERATURE Display

The TEMPERATURE Display (see Figure 5-4) shows the temperature setpoint (desired tissue temperature) in degrees Centigrade. *This feature is only available if a Catheter (T°) is connected to the Controller.*

Figure 5-4: TEMPERATURE Display and Buttons

Temperature Panel Temperature Display Temperature Increase Button Temperature Decrease Button (C) TEMPERATURE

Table 5-2 lists all possible temperature display readings under specific operating conditions. Refer to the instructions specified in the table for additional information.

Table 5-2: Summary of TEMPERATURE Display Readings

Catheter Type	Control Mode	TEMPERATURE Display Readings
Catheter (T°)	Temperature Control Mode	• At initial power on, display reading is 30°C. • After setting temperature setpoint per instructions, display indicates desired tissue temperature. (Refer to instructions on page 6-12, *Selecting Temperature When Using the Catheter (T°) in TEMPERATURE Control Mode.)* • In ON or CALIBRATE operational modes, display indicates measured catheter tip temperature. • In ON operational mode: – If the temperature is within 20°C - 120°C range, the measured temperature displays.

– If the measured temperature is below 20°C, the message "LO" displays.
– If the measured temperature is above 120°C, the message "HI" displays.
• In DONE operational mode: When RF power is discontinued, the last measured value of temperature is shown on the display, flashing at 1-second intervals.
Catheter (T°) Power Control • In READY mode, display reading is 85°C for high power Mode catheters and 95°C for standard catheters.
• In ON or CALIBRATE operational modes, display indicates measured catheter tip temperature.
• In ON operational mode:
– If the temperature is within 20°C - 120°C range, the measured temperature displays.
– If the measured temperature is below 20°C, the message "LO" displays.
– If the measured temperature is above 120°C, the message "HI" displays.
• In READY mode, upper temperature limit can be selected.
After setting temperature setpoint per instructions, display indicates desired catheter tip temperature. (Refer to instructions on page 6-13, *Selecting Temperature When Using the Catheter (T°) in POWER Control Mode*.)
• When RF power is discontinued, the last measured value of temperature is shown on the display, flashing at 1-second intervals.
Catheter (Non-T°)* N/A • Display shows three dashes (---)
* Temperature Control is not accessible for this Catheter.

☒ **Note:** In Power Control mode only, when the measured catheter tip temperature decreases to a value that is below the upper temperature limit, the Controller resumes delivery of RF power at a value that is 50% of the power which caused the upper temperature limit to be exceeded. If the upper temperature limit is exceeded a second time, the Controller immediately ceases delivery of RF power and displays an error code indicating that the upper temperature limit has been exceeded a second time. It is recommended that if this error condition arises, the power level should be decreased to prevent the upper temperature limit from being exceeded. T h e Controller can be placed into the READY mode by depressing the RF POWER C O N T R O L Button, which allows adjustment of Controller parameters such as RF p o w e r, upper temperature limit, etc.

TEMPERATURE ⩓/⩔ Buttons

The TEMPERATURE ⩓/⩔ (increase/decrease) Buttons select the temperature that the Controller attempts to achieve during RF power delivery. In Temperature Control mode, the Controller automatically adjusts power, within the user-selected upper power limit, to achieve the desired tissue temperature. In Power Control mode, the Controller automatically decreases RF power to the Catheter if this value of user-selected upper temperature limit is exceeded. For instructions on how to select the temperature setpoint, see the section *Selecting the Desired Tissue Temperature* on page 6-12.

IMPEDANCE Panel

IMPEDANCE Display

The IMPEDANCE Display (see Figure 5-5) shows the measured impedance value in Ω (1 Ω resolution). When the Controller is initially powered on, the display shows three dashes "---", indicating that no measurement is being made. As soon as RF power is delivered by pressing the RF POWER CONTROL Button or the Footswitch, the Controller begins to measure impedance. Because this display reflects the actual tissue impedance, the value shown may fluctuate slightly, depending on the quality of the electrode/tissue interface, but

should remain relatively stable throughout power deliveries. For a summary of the impedance ranges, see Table 6-2 in section *Turning the RF Power Delivery "ON"*.

When RF power is discontinued, the last measured value of impedance remains on the display, flashing at one second intervals. If the Controller is placed into the CALIBRATION mode (by depressing the CALIBRATION Button) and if a Catheter has been positioned within the heart, then the Controller delivers 1 Joule of energy which allows a single measurement of impedance, and continuously displays the value of impedance measured. When either the CALIBRATION or RF POWER CONTROL Buttons are depressed, the Controller returns to the READY mode and the IMPEDANCE Display returns to three dashes "---".

Figure 5-5: IMPEDANCE Display

TIME Panel

TIME Display

The TIME Display (see Figure 5-6) shows the user-selected duration (in seconds) of RF power delivery to the Catheter. When the Controller is initially powered on, the TIME Display reads zero. After the user sets the duration and presses the RF POWER CONTROL Button, the displayed value changes to zero and initiates counting upward at 1-second intervals until the preset time limit is reached (or the RF POWER CONTROL Button is actuated a second time or the Footswitch is released), stopping RF power delivery. If RF power delivery is stopped before the preset maximum duration has been reached, actual duration of RF power delivery is displayed, flashing at 1-second intervals.

TIME ♉/♉ Buttons

The TIME ♉/♉(increase/decrease) Buttons select the maximum duration of each RF power delivery. The range of times available is 1 to 120 seconds in increments of one.

♉ **Note:** These buttons are inoperative during RF power delivery.

For instructions on how to select the duration of RF power delivery, see the section *Setting the Time Control* on page 6-13.

Figure 5-6: TIME Display and Buttons

TIME (S)
Time
Panel
Time
Display
Time
Increase
Button
Time
Button
Decrease

COUNTER Panel

COUNTER Display

The COUNTER Display (see Figure 5-7) automatically counts and displays each delivery of RF power. When the Controller is initially powered on, the display clears and reads zero. The range of values available is 0 to 99 in increments of one.

CLEAR (Counter) Button

The CLEAR Button clears the COUNTER Display (Figure 5-7) to zero and allows the user to keep an accurate count of the number of RF power deliveries to the patient. Press this button before starting initial RF power application on a patient.

Figure 5-7: COUNTER Display and Clear Button

RF POWER CONTROL Panel

RF POWER CONTROL Button/Light

The RF POWER CONTROL Button (see Figure 5-8) controls the three operational modes of the Controller:

- READY mode - This mode allows the ablation parameters to be adjusted.
- ON mode - This mode is the Controllers' state during the delivery of RF power.
- DONE mode - This mode defines the system state after cessation of RF power delivery.

Note: This button can also be used for exiting the CALIBRATION or Error modes and returning the Controller to the READY mode.

When the Controller is initially powered on, the RF POWER CONTROL Light flashes, indicating the Controller is in the READY mode and prepared for RF power delivery. Press the yellow RF POWER CONTROL Button once to place the Controller into the ON mode and allow the Catheter to transfer RF power to the tissue. To alert the user, this button is backlit with a light which is ON during the delivery of RF power (RF Power ON mode), and OFF when RF power delivery stops (DONE mode).

Counter Panel Clear Button Counter Display COUNTER CLEAR

If the Controller is in the Temperature Control mode, a test of the temperature sensor functionality is made prior to delivery of RF power. If a faulty temperature sensor is detected by the Controller, which can be caused by the temperature sensor indicating a temperature outside the operating range of 20°C to 43°C, or a short or open in the temperature measurement circuit, the Controller does not enter the RF Power ON mode. It enters an Error mode, indicating a faulty temperature measuring circuit has been detected or the temperature is outside the operating range. To exit the Error mode, depress the RF POWER CONTROL Button, which returns the Controller to the READY mode.

Figure 5-8: RF POWER CONTROL Panel and Button/Light

CALIBRATION Panel

CALIBRATION Button

Pressing the CALIBRATION Button (see Figure 5-9) places the Controller into the CALIBRATION mode which performs the following functions:

- Approximately 1 Joule of energy is delivered to the tissue which is used to make a single measurement of tissue impedance. This value is continuously displayed on the front panel.
- The catheter tip temperature is continuously monitored and displayed on the front panel. This allows assessment of the temperature measuring function of the Catheter (T°). If this value differs significantly from the normal body temperature of 37°C, the Catheter (T°) should be removed and replaced with another Catheter (T°).
- A zero to one volt square-wave signal representing a minimum-to-full-scale signal is transmitted from each of the rear panel analog outputs (for calibration of an optional recorder). This square-wave calibration signal is transmitted continuously to the rear panel analog output ports.

RF POWER CONTROL RF Power Control

Panel
RF Power
Control
Button/Light

All of the above functions continue to operate as described above until either the CALIBRATION or RF POWER CONTROL Buttons are pressed again. Pressing either of these buttons causes the Controller to return to the READY mode. The minimum-to-full scale values for the individual analog outputs are shown in Table 5-3.

The CALIBRATION LED illuminates when a calibration signal is transmitted to the analog output ports. The calibration signal automatically discontinues if the RF POWER CONTROL Button or the Footswitch is pressed.

Figure 5-9: CALIBRATION Panel and Button/LED

Isolated Patient Connector

The ISOLATED PATIENT CONNECTOR (see Figure 5-1) provides for connection of the APM (either APM or XP APM) to the Controller. The connector has a screw-on/locking mechanism for secure cable installation. The APM Patient Cable must be installed in the ISOLATED PATIENT CONNECTOR before the Controller delivers any RF power. This cable uses a circular connector that is keyed for proper alignment.

MAINS (Power "ON") Display

The MAINS Display (see Figure 5-1) indicates that the power switch (see Figure 5-10) located on the rear panel is ON ("1" position) and the Controller is plugged into an electrical outlet.

CALIBRATION
Calibration
Panel
Calibration
Button
Calibration
LED

Table 5-3: Individual Analog Outputs

Power 0.0 - 1.0 volt corresponds to 0 - 100 W
Impedance 0 - 1.0 volt corresponds to 0 - 300
Temperature 0.0 - 1.0 volt corresponds to 20° - 120°C

Rear Panel

This section describes the output ports and power controls on the rear panel shown in Figure 5-10.

Figure 5-10: Controller Rear Panel

POWER Switch

The power switch (rocker switch) on the rear panel powers the Controller ON ("1" position) or OFF ("0" position).

Analog Outputs

There are 4 analog output ports (see Figure 5-10), which are labeled as follows: RF POWER, IMPEDANCE, TEMPERATURE, and SPARE.

RF POWER
ANALOG OUTPUT SPEAKER
FOOT SWITCH RS-232
MAIN
FUSES
WARNING
RISK OF FIRE.
REPLACE FUSE
AS MARKED.
WARNING
RISK OF FIRE.
REPLACE FUSE
AS MARKED.
OUTPUT POWER 150W

OPERATING FREQUENCY 500KHz
IMPEDANCE TEMPERATURE SPARE VOLUME
CAUTION: DO NOT OPEN
ELECTRICAL SHOCK HAZARD
100-120V
3A 50/60 Hz
220-240V
1.5A 50/60 Hz
AUX
MAINS
100-120V
1A 50/60 Hz
220-240V
500mA 50/60 Hz
Power
Switch
Analog
Outputs
Power
Cord
Mains
Fuse
Holder
Fuse
Holders(2)
Footswitch
Cable
Connector
Volume
Control
Knob
Serial
Port
Auxiliary
Power
Outlet
Ground
Stud
CAUTION: THE TOTAL SYSTEM
CHASSIS RISK CURRENT SHOULD NOT
EXCEED 100«A
ATTENTION: LE COURANT DE TISQUE
TOTAL'ADMISSIBLE AU CHASSIS NE
DOIT PAS DEPASSER 100«A.
AUX
FUSES

Power Analog Output

RF POWER - This output port provides direct connection to an electrically isolated general-purpose recorder or monitor, satisfying the requirements of EN-60601, using a standard BNC connector to facilitate recording of the RF power output during delivery of RF power.

Impedance Analog Output

IMPEDANCE - This output port provides direct connection to an electrically isolated general-purpose recorder or monitor, satisfying the requirements of EN-60601, using a standard BNC connector to facilitate recording of the tissue impedance during delivery of RF power.

Temperature Analog Output

TEMPERATURE - This output port is active only when a Catheter (T°) is in use. It provides direct connection to an electrically isolated general-purpose recorder or monitor, satisfying the requirements of EN-60601, using a standard BNC connector to facilitate recording of the Catheter (T°) measured catheter tip temperature during delivery of RF power.

Spare

SPARE - This output port is not in use at this time.

Power Cord

The Power Cord is "Hospital Grade" and must be installed at an AC electrical wall outlet designated "Hospital Grade" or "Hospital Only."

MAINS Fuse Holder

Housing for AC fuse. (See Controller rear panel for appropriate type of fuse.)

Fuse Holders (2)

Housing for AC fuses. (See Controller rear panel for appropriate type of fuse.)

Footswitch Cable Connector

This connector is polarized for connecting the Footswitch Cable.

Volume Control Knob

This knob provides the user with volume control for the audio signal that accompanies RF power delivery. If no audio tone is heard, check the knob to determine if the volume level has been adjusted too low.

Serial Port

This port is labeled "RS-232." It provides for computer interface to BSC approved accessory computers only.

Auxiliary Power Outlet

This outlet is labeled "Auxiliary Power Outlet." It provides for future optional Boston Scientific approved accessories only.

Ground Stud

Protective Earth Ground stud (chassis ground).

Accessories

Footswitch

An easy-to-use Footswitch (see Figure 1-1) can alternatively be used to provide ON/OFF control of the RF power delivery. The connecting cable's 10-ft length allows the user to stand at the catheterization table near the patient without requiring another person for starting/stopping RF power delivery. The Footswitch functions similarly to the RF POWER CONTROL Button except that the user must continuously hold the Footswitch down for RF power to be delivered. The RF power delivery is immediately terminated when the user's foot is lifted off the Footswitch. Use only the BSC Model 840 Footswitch, which is rated IPX8 (continuous immersion).

High Power Automatic Personality Module (XP APM)

The XP APM provides RF filtering to allow continuous electrogram recording during RF power delivery via the catheter tip electrode. Additionally, the XP APM allows for safe use of either standard or high power EPT ablation catheters. The XP APM passes RF energy (at 500 kHz) from the Controller to the patient via the catheter and one or two DIP Electrodes. The maximum power delivered depends on the configuration of the attached catheter. The XP APM detects the presence of a high power catheter and enables the Controller to deliver RF power up to 100 W. If a standard catheter is detected, the Controller is not able to deliver power greater than 50W.

The Module connections are as follows (see Figure 5-11):

- One 9-pin Quick Connect Connector labeled "CATHETER" for attaching the Quick Connect Instrument Cable to the catheter.
- One 6-pin Recorder Connector labeled "RECORDER" for attaching the XP APM/EGM Interconnect Cable to the recording equipment.
- Two male 2-pin connectors labeled "INDIFFERENT ELECTRODE" for attaching the two DIP Electrodes.

☒**Note:** If greater than 1 A of current is delivered to either of the two DIP Electrodes,the System shuts down.

For additional information on the XP APM, refer to *Table 8-1: System Specifications* in Section 8.

Automatic Personality Module (APM)

The APM (See Figure 5-12) provides automatic switching from electrogram recording to RF power delivery via the catheter tip electrode. The APM has the following connections:

• The Catheter is connected to the APM utilizing the Quick Connect or Instrument Cable. There is a Quick Connect fitting on the front panel of the APM for connection to the Quick Connect Instrument Cable.

• There is a Quick Connect fitting on the side of the APM for connection to the APM/EGM Connector Cable.

☒ **Note:** The Quick Connect Instrument Cable and APM/EGM Connector Cable fittings have different pin patterns to prevent cable assembly error.

• The DIP Electrode is connected to the male 2-pin connector (labeled "INDIFFERENT ELECTRODE") on the APM front panel.

Figure 5-11: High Power Automatic Personality Module with Quick Connect

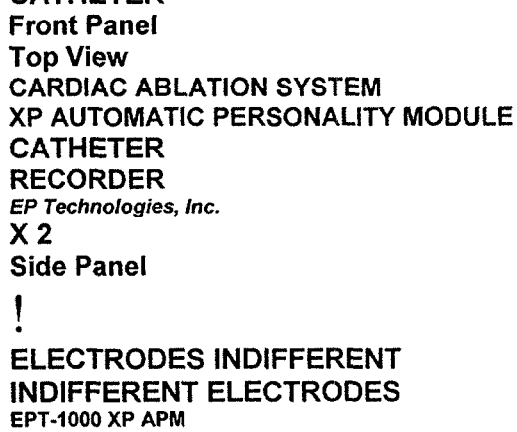


Figure 5-12: Automatic Personality Module with Quick Connect

6. Operational Sequence

Initial Installation

Follow the instructions in this section carefully to prepare the System for operation:

1. Connect the Controller Power Cord plug into a properly grounded AC electrical outlet designated "Hospital Grade" or "Hospital Only."

☋ **Precaution:** Never use an outlet without a grounding connection.

2. Position the Controller for easy viewing of its front panel displays.

3. Install the APM (either APM or XP APM) Patient Cable to the ISOLATED PATIENT CONNECTOR socket on the Controller front panel by carefully lining up the connector pins with the socket. Push the connector firmly into the socket; then secure in place by rotating the locking ring in a clockwise direction.

☋ **Note:** Do not twist the APM Patient Cable connector while inserting or removing it from the Controller ISOLATED PATIENT CONNECTOR socket or the connector pins may be damaged.

Figure 6-1: Connecting the APM to the Controller Front Panel

4. To disconnect the APM (either APM or XP APM) from the Controller, rotate the locking ring counter clockwise to unlock; then grasp the connector and gently pull it out of the socket.

☿ **Note:** Do not twist the APM Patient Cable connector while inserting or removing it from the Controller ISOLATED PATIENT CONNECTOR socket or the connector pins may be damaged.

☿ **Precaution:** Never disconnect the APM by pulling on the cable.

5. For Optional Patient Monitor Equipment Installation only, follow these instructions:

a) Use the APM/EGM Interconnect Cable to connect the APM (either APM or XP APM) to optional recording equipment (see Figure 6-2).

b) Plug in the Quick Connect fitting from the APM/EGM Interconnect Cable into the connector located on the APM side panel labeled "RECORDER" and plug the opposite end of this cable into isolated recorder inputs.

Operational Sequence 6-2

Figure 6-2: Connecting the APM to the Recording Equipment

6. Position the APM (either APM or XP APM) near the table where the procedure is to be performed. The System may only be connected to recording systems providing patient electrical isolation in accordance with EN-60601.

7. Install the Catheter Quick Connect Instrument Cable fitting into the APM (either APM or XP APM) front panel fitting labeled "CATHETER."

6-3 Operational Sequence

Figure 6-3: Connecting the Catheter to the XP APM Front Panel

8. Install one DIP electrode if using an APM or 2 DIP electrodes if using an XP APM and a high power catheter into the INDIFFERENT ELECTRODE receptacle(s) located on the APM front panel (see Figure 6-4) as follows:

a) Read the manufacturer's manual before installing the DIP Electrode pads.

b) Gently push each DIP Electrode fitting straight and firmly into place.

c) To disconnect a DIP Electrode, grasp the DIP Electrode fitting and gently pull it out from the APM Indifferent Electrode receptacle.

☿ **Precaution:** Do not disconnect a DIP Electrode Connector by pulling on its cable.

d) Before use, it is important to check the DIP Electrode(s) for damage to the sealed foil package. Exposure to air, due to a damaged package, could cause the DIP Electrode(s) to become dry and limit their grounding capability.

e) Be sure the pads are moist and sticky to the touch before placing on the patient.

☿ **Precaution:** Do not attempt to relocate the patient grounding pad after initial application. Electrode gel is NOT required and should NOT be used.

f) The DIP Electrode(s) should be placed on a well-vascularized, convex skin surface that is in close proximity to the ablation site (left upper quadrant of the back is suggested unless the patient's scapula is especially prominent or patient is extremely thin). Other possible locations are the upper arm or left flank area. Avoid scar tissue, bony prominence, adipose tissue, or any areas where fluid may pool. Shave, clean, and dry the application site as needed. Check for wrinkles or folds when applying the pad as these decrease conductivity.

Operational Sequence 6-4

CATHETER
X 2
INDIFFERENT ELECTRODES
Quick Connnect
Instrument Cable
Catheter

ϒ **Note** RF output ceases to the patient if more than 1 A flows through either of the DIP Electrodes when the XP APM is connected.

Figure 6-4: Connecting the Disposable Indifferent Patch Electrodes

6-5 Operational Sequence

9. If using the Footswitch, install its cable connector into the FOOTSWITCH Cable Connector on the Controller rear panel (see Figure 6-5). Carefully push the cable connector into the FOOTSWITCH connector until it is seated firmly in place.

ϒ **Note:** Do not twist or bend the FOOTSWITCH connector during insertion as this action might cause damage to the pins.

10. Position the Footswitch to allow easy access by the physician.

Figure 6-5: Connecting the Footswitch to the Controller Rear Panel

11. The System is now ready to record electrograms prior to and during delivery of RF power.

Turning the Controller "ON"

1. Turn the Controller ON by pressing the power switch (to the "1" position) located in the power input module on the Controller rear panel (see Figure 6-6).

The Controller automatically initiates a self-test procedure which is indicated by the illuminated front panel displays and continuous audio tone generated for approximately 2 seconds. If no system malfunction is detected, the Controller changes to the READY Mode.

ϒ **Note:** The connection between the APM (either APM or XP APM) and Controller is not required to complete the initial self-test.

Operational Sequence 6-6

2. If a system malfunction is detected during self-test, all front panel displays remain lit and the Controller does not operate. To clear any malfunctions found during self-test, the Controller must be powered OFF, then back ON. The self-test repeats.

ϒ **Call BSC for Service** Asecond self-test failure is indicative of a Controller malfunction and should be referred to BSC/EPT for service See Section 7, Service and Maintenance of the Operator's Manual. The Controller does NOT operate unless the initial self-test has been successfully completed.

Figure 6-6: Turning the Controller to the ON Position

READY Mode

The Ready mode is designed for setting the desired parameters for RF power delivery. It is automatically initiated after completion of a successful Controller self-test. Ready mode is indicated by a flashing RF POWER CONTROL Button on the Controller front panel;

TEMPERATURE, IMPEDANCE, TIME, and COUNTER Displays are continuously lit. Values displayed when the Controller is first initialized are zero in the POWER, TIME, and COUNTER Displays and dashes (---) in the IMPEDANCE Display. (Refer to Figure 5-1 for the location of displays and buttons.)

Controller in Temperature Control Mode - Catheter (T°) Connected

If a Catheter (T°) is connected, the TEMPERATURE Display shows one of two values depending on the control mode. When the Controller is initially powered on and a Catheter (T°) is connected, the TEMPERATURE Display indicates 30°C, since the Controller is automatically entered into the Temperature Control mode. The user must enter the desired catheter tip temperature, the maximum power that the Controller can deliver to achieve the desired temperature, and the ablation time before RF power delivery.

6-7 Operational Sequence

MAINS
Power Switch
Power Input
Module

Press Power Switch to "1" position.

Controller in Power Control Mode - Catheter (T°) Connected

If the control mode is manually changed to Power Control, by pressing the RF POWER CONTROL Button, the TEMPERATURE Display indicates 85°C with high power catheters, and 95°C with standard catheters during the READY mode of the Controller, indicating the upper temperature limit at which the Controller continues to deliver set power.

Controller in ON or CALIBRATE Operational Modes - Catheter (T°) Connected

When the Controller is in either the ON or CALIBRATE operational modes, the TEMPERATURE Display indicates "LO" if the measured temperature is less than 20°C, "HI" if temperature is greater than 120°C; otherwise, it shows the measured temperature (see Figure 6-7).

Figure 6-7: ON or Calibrate Mode - Catheter (T°) Connected

Catheter (Non-T°) or No Catheter Connected

If a Catheter (Non-T°) or no Catheter is connected, the display shows "---" (Figure 6-8).

Operational Sequence 6-8

Measured
Temperature
Reading
(C) TEMPERATURE

Figure 6-8: Ready Mode, Initialization - Catheter (Non-T°) Connected

Calibrating the Controller Analog Outputs for the Recorder

Each time the Controller is powered on, the analog outputs (see Figure 5-10) should be placed in the CALIBRATION mode to verify that the optional strip chart recorder and/or monitor are calibrated correctly, if used.

To perform calibration of the Controller analog outputs, follow these steps:

1. Check that all connections to the analog outputs are secure.

2. Ensure that the recorder/monitor is powered on and functioning properly.

3. Ensure the recorder satisfies the requirements of EN-60601 prior to connection to Controller analog outputs.

4. To calibrate with the analog outputs, press the CALIBRATION Button (Figure 6-9) at the Controller front panel. This generates a minimum-to-full-scale (0.0 to 1.0 volt) continuous square-wave calibration signal which is sent continuously and simultaneously to each of the

analog outputs (until the CALIBRATION Button is pressed again or until the RF POWER CONTROL Button or footswitch is pressed).

6-9 Operational Sequence

Temperature
Display
(C) TEMPERATURE

Figure 6-9: Calibrating the Controller Analog Outputs

5. With the Controller in the READY mode, analog output calibration can be repeated or checked at any time by repeating the steps identified in steps 1 through 3 above.

6. When RF power is delivered, the analog signals correspond to the Controller's measured power, temperature, and impedance values.

Selecting the Control Mode

The Controller is capable of operating in Power Control or Temperature Control mode. Control mode selection is made via the CONTROL Button. (For complete description of the CONTROL Button, see *CONTROL Panel* in Section 1.)

To select the proper control mode, follow these steps:

1. Ensure that the Controller is in the READY mode.

☞ **Note:** The control mode can only be changed when the Controller is in the READY mode.

2. Press the CONTROL Button to select the appropriate control mode. The CONTROL Indicator LEDs display the selected mode.

Operational Sequence 6-10

Calibration
Button

COUNTER CLEAR
RF POWER CONTROL
CALIBRATION
MAINS

Selecting the Power Output

To deliver RF power, it is necessary to select a Controller power output. This is true for both Temperature Control mode and Power Control mode.

✉ **Note:** Use Lower Power First - Begin by using lower power (50W) when delivering RF energy. Monitor the temperature reading to determine if pre-set temperature is achieved. If not, gradually increase the power output to increase tissue heating. If the created lesion is unsuccessful or inadequate, incrementally increase the power output with successive ablation attempts to minimize the potential for thrombus formation and/or inadvertent damage to cardiac tissues.

Controller in Temperature Control Mode - Catheter (T°) Connected

The Controller is automatically entered into the Temperature Control mode and the RF power setpoint is the maximum amount of power that the Controller can access to achieve the desired catheter tip temperature. If the RF power setpoint is equal to or greater than the amount of power necessary to achieve the desired catheter tip temperature, then the Controller supplies the appropriate amount of power to achieve the temperature setpoint. The Controller only supplies as much RF power as necessary to achieve the desired catheter tip temperature. If the RF power setpoint is less than the amount of power required to achieve the desired catheter tip temperature, then the Controller may not be capable of achieving the desired catheter tip temperature and thus the measured temperature is less than the desired catheter tip temperature.

Controller in Power Control Mode - Catheter (Non-T°) or Catheter (T°) Connected

If a Catheter (Non-T°) or Catheter (T°) is connected, and the Controller is placed into the

Power Control mode, then the RF power setpoint corresponds to the actual amount of power that is delivered to the tissue, unless the upper temperature limit is exceeded, in which case, the Controller reduces and/or ceases delivery of set power.

Controller in Power Control Mode - Catheter (T°) Connected

If using a Catheter (T°) with the Controller in the Power Control mode, the TEMPERATURE Display shows 85°C when the Controller is in the READY mode and displays measured temperature when the Controller is in the ON, CALIBRATE, and DONE operational modes.

Selecting the RF Power Setpoint

To set the RF power setpoint (in W), follow these steps:

1. Press the appropriate POWER (⩓/⩔) Button to increase or decrease the RF power setpoint by 1 W.

2. To scroll rapidly to the desired power setpoint, depress and hold the appropriate POWER (⩓/⩔) Button down.

3. Release the POWER (⩓/⩔) Button when the POWER Display shows the appropriate RF power setpoint.

4. During RF power delivery (RF Power ON mode), the power setpoint can be adjusted in 1-W increments to provide better control during the procedure by pressing the appropriate POWER (⩓/⩔) Button. When the button is released, the POWER Display returns to showing the current value of measured power.

• Holding the POWER ⩓ Button down while RF power is being delivered (RF Power ON mode) does NOT cause the power setpoint to scroll as it does when the Controller is in the READY mode.

• Holding the POWER ⩔ Button down while RF power is being delivered (RF Power ON mode) causes the power setpoint to scroll at a greater rate than it does when the Controller is in the READY mode.

Selecting the Desired Tissue Temperature

For ablation procedures involving automatic temperature control, it is recommended that the operator initially select a lower set temperature range (from 55°C to 70°C). The operator should consider a lower initial set temperature to avoid excessive thermal damage to tissue, or collateral damage to adjacent tissue not intended for ablation, particularly in areas where high blood flow and correspondingly high convective cooling may be present.

☒ **Note:** The displayed tissue temperature may be significantly lower than the maximum tissue temperature, which typically occurs at a depth of a few millimeters. The displayed catheter tip temperature is measured at the electrode-tissue interface and may be influenced by the degree of tissue contact and the convective cooling effects of blood f l o w.

Selecting Temperature When Using the Catheter (T°) in TEMPERATURE Control Mode

If a Catheter (T°) is connected to the Controller, a desired value of catheter tip temperature (temperature setpoint) can be selected. The Controller automatically adjusts power, within a user-selected upper power limit, to achieve the desired catheter tip temperature, in the Temperature Control mode.

To select the temperature setpoint for the Controller, follow these steps:

1. Ensure that the Controller is in READY mode.

2. Press the appropriate TEMPERATURE (⩓/⩔) Button to increase or decrease the temperature setpoint by 1°C.

3. To scroll rapidly to the desired temperature setpoint, depress and hold the appropriate TEMPERATURE (⩓/⩔) Button down.

4. Release the TEMPERATURE (⩓/⩔) Button when the TEMPERATURE Display shows the appropriate temperature setpoint.

For high power catheters, the catheter tip temperature selection range is 30° to 80°C in increments of 1°C while for standard catheters, the catheter tip temperature selection range is 30° to 90°C in increments of 1°C, although the Controller cannot achieve a temperature which is less than the ambient blood temperature (normally 37°C).

5. During RF power delivery (RF Power ON mode), the temperature setpoint can be increased or decreased by pressing the appropriate TEMPERATURE (⩓/⩔) Button. When the TEMPERATURE (⩓/⩔) Button is depressed, the display shows the new temperature setpoint. When the button is released, the display shows the present value of catheter tip temperature. Depressing and holding the TEMPERATURE (⩓/⩔) Button down while RF power is being delivered does NOT cause the temperature setpoint to scroll up, but allows it to scroll down at a slightly greater rate than it does when the Controller is in the READY mode.

Selecting Temperature When Using the Catheter (T°) in POWER Control Mode

If a Catheter (T°) is connected to the Controller, an upper temperature limit can be selected. The Controller automatically decreases RF power to the Catheter if this value of temperature is exceeded in the Power Control mode.

To select the temperature setpoint for the Controller, follow these steps:

1. Ensure that the Controller is in READY mode.

2. Press the appropriate TEMPERATURE (⩓/⩔) Button to increase or decrease the upper temperature limit by 1°C during RF power delivery.

3. To scroll rapidly to the desired temperature setpoint, depress and hold the appropriate TEMPERATURE (⩓/⩔) Button down. (The temperature value shown in the TEMPERATURE Display is the maximum catheter tip temperature at which the Controller attempts to deliver RF power.)

4. Release the TEMPERATURE (⩓/⩔) Button when the TEMPERATURE Display shows the appropriate temperature setpoint.

The catheter tip temperature limit selection range is 55° to 85°C in increments of 1°C for high power catheters; 55° to 95°C in increments of 1°C for standard catheters.

Setting the Time Control

The TIME Display, TIME ⩓ (increase) Button, and TIME ⩔ (decrease) Button allow the user to select the duration (in seconds) that RF power is delivered to the Catheter.

To select the duration for RF power delivery, follow these steps:

1. Ensure that the Controller is in READY mode.

2. Press the appropriate TIME (⩓/⩔) Button to increase or decrease the RF power output duration (up to a maximum of 120 seconds).

3. To scroll rapidly to the desired duration, depress and hold the appropriate TIME (⩓/⩔) Button down.

4. Release the TIME (⩓/⩔) Button when the TIME Display shows the appropriate duration. (When the selected value is programmed into the Controller control circuit.)

Clearing the Counter

☐ **Important:** *Always clear the Counter between patients.*

1. To clear the counter to zero, depress the CLEAR Button.

2. Attempting to set the counter to greater than "99" will cause the counter to reset itself to zero.

Adjusting the Audio Control

The user may adjust the volume of the audio signal when the Controller is initially powered on or during a clinical procedure.

1. Adjust the volume of the audio signal by rotating the Volume Control Knob on the Controller rear panel (see Figure 6-10).

2. If desired during a clinical procedure, the Volume Control Knob may be rotated fully counter-clockwise to its lowest setting

♉ **Note:** At the minimum setting, the tone may NOT be audible during RF power delivery.

Figure 6-10: Adjusting Audio Control

RF POWER
ANALOG OUTPUT SPEAKER
FOOT SWITCH RS-232
IMPEDANCE TEMPERATURE SPARE VOLUME
Volume
Control
Knob
To increase the volume of the audio signal, turn the Volume Control Knob clockwise.
To decrease the volume of the audio signal, turn the Volume Control Knob counter-clockwise.
VOLUME
VOLUME

Turning the RF Power Delivery "ON"

☐ **Important:** *Do not continue with this procedure unless all preceding procedures in this chapter have been completed.*

To deliver RF power to the Catheter, follow these steps:

1. Ensure that all connections are secure and correct.

2. Verify that all aforementioned selections have been made.

3. To begin RF power delivery, press the RF POWER CONTROL Button once or hold the Footswitch down. The POWER Display shows the RF power delivered to the Catheter (in W). *The Audible tone* sounds during RF power delivery.

☒**Note:** If the Controller is in the Temperature Control mode and the measured temperature is outside the range of 20°C to 43°C, the Controller does not deliver RF power and an E07 error code message displays.

When RF power is delivered to the Catheter, the displays function as follows:

RF POWER CONTROL BUTTON/Light

This light illuminates and remains lit until RF power delivery is discontinued. (For instructions on how to discontinue RF power delivery, see the section, *Turning the RF Power Delivery "OFF"* on page 6-20.

POWER Display

This display shows (in W) RF power delivered to the Catheter. The value may fluctuate slightly due to changes in tissue impedance.

Operational Sequence 6-16

TEMPERATURE Display

The readings on this display depend on the current control mode of the Controller (Power Control and Temperature Control), the operational mode, and the type of catheter connected. Table 6-1 summarizes the readings on the display under specified operating conditions.

6-17 Operational Sequence

Table 6-1: TEMPERATURE Display Readings

Catheter Type Control Mode TEMPERATURE Display Readings

Catheter (T°) Temperature • At initial power on, display reading is 30°C.

Control Mode • In READY mode, display shows the temperature setpoint.

• In ON, CALIBRATE, or DONE operational modes, display indicates measured catheter tip temperature.

• If the measured temperature is outside the range of 20°C to 43°C, the Controller does not deliver RF power.

• In ON operational mode:

– If the temperature is within 20°C - 120° C orange, the measured temperature displays.

– If the measured temperature is below 20°C, the message "LO" displays.

– If the measured temperature is above 120°C, the message "HI" displays.

Catheter (T°) Power Control • In READY mode, display reading is 85°C for Mode high power catheters and 95°C for standard catheters.

• In ON, CALIBRATE, or DONE operational modes, display indicates measured catheter tip temperature.

• In ON operational mode:

– If the temperature is within 20°C - 120° C range, the measured temperature displays.

– If the measured temperature is below 20°C, the message "LO" displays.

– If the measured temperature is above 120°C, the message "HI" displays.

Catheter (Non-T°) N/A • Display shows three dashes (---)

IMPEDANCE Display

This display shows measured impedance. The displayed readings may fluctuate slightly due to variation in the stability of electrode/tissue contact as the heart beats. If the measured value demonstrates a significant fluctuation, the Catheter should be repositioned. Alternatively, slight pressure on the Catheter shaft may minimize Catheter motion. Table 6-2 summarizes the readings on the display by impedance range.

Operational Sequence 6-18

Table 6-2: Impedance Display Readings

Impedance Operating Condition Controller Activity Display Values Reading

Typical Impedance Normal operating Normal RF power Display shows condition delivery measured 80 to 150 Ω impedance

Low Impedance[1]

< 50 Ω If accessing up to 50 W Controller automatically Display flashes of RF power shuts off RF power "LO"

< 25 Ω If accessing up to 100 W Controller automatically Display flashes of RF power shuts off RF power "LO"

High Impedance[2] For both 50W or 100W Controller automatically Display flashes power limits shuts off RF power between

> 300 Ω measured impedance and "HI"

1. Low impedance limit depends on type of catheter used in the ablation procedure.
2. High Impedance indicates abnormal operation. This condition also may occur if > 1Ais detected by the XP APM from either DIPElectrode. Refer to the following procedure, *Correcting a High Impedance Condition.*

Correcting a High Impedance Condition

If a high impedance value is detected during RF power delivery, follow these steps:

1. Ensure that the connection between the Catheter and APM (either APM or XPAPM) is correct and secure.

2. Ensure that the connection between each DIP Electrode and APM (either APM or XP APM) is correct and secure.

3. Ensure that each DIP Electrode is properly applied.

4. If an improper cable connection is not the cause of the high impedance value, then a build-up of coagulum on the Catheter tip may be the cause, and RF power output should be discontinued.

5. To discontinue RF power delivery, refer to the instructions in section, *Turning the RF Power Delivery "OFF"* on page 6-20.

TIME Display

This display shows the user-selected value and elapsed time as follows:

• When the RF POWER CONTROL Button is pressed or the Footswitch is depressed, this display changes from the user-selected time limit to 0 seconds and begins to count up to the user-selected value.

• When the preset duration has elapsed, the RF power automatically shuts "OFF." The user-selected value remains flashing on the TIME Display.

• If the RF POWER CONTROL Button is pressed during delivery of RF power or the Footswitch is released, the RF power output immediately turns "OFF." The actual elapsed time in seconds remains flashing on the TIME Display.

COUNTER Display

This display increases by 1 count with each RF power delivery. The value resets to zero at any time when the Controller is in the READY mode. Attempting to set the counter to "99" also will reset the counter to zero.

CONTROL Display

This display indicates the Controller's current control mode (Power Control or Temperature Control). The green LEDs indicate when the Controller is either in the Power Control or Temperature Control modes, respectively.

Directions for Use

Refer to the Blazer II XP™ Cardiac Ablation Catheter Directions For Use for catheter directions for use.

Turning the RF Power Delivery "OFF"

To discontinue RF power delivery during operation (RF Power Done mode), the user may either:

• Press the RF POWER CONTROL Button or

• Release the Footswitch.

✉ **Note** RF power delivery ceases by user intervention or certain operating conditions listed in the next section, Possible Causes of RF Power Delivery Interruption.

Possible Causes of RF Power Delivery Interruption

RF power delivery can cease due to other operating conditions other than user intervention. RF power ceases when:

- User-selected time limit has been reached.
- XP APM detects greater than 1 A in either of the two DIP Electrodes.
- Impedance is less than 50 Ω when accessing up to 50 Wof RF power.
- Impedance is less than 25 Ω when accessing up to 100 W of RF power.
- Impedance is greater than 300 Ω.
- Temperature exceeds setpoint by 5°C for greater than four seconds (Controller in Temperature Control mode).
- Temperature exceeds 85°C for high power catheters or 95°C for standard catheters for greater than one second (Controller in Power Control or Temperature Control mode with a Catheter (T°) connected).
- Temperature is less than 20°C for greater than one second.
- Temperature exceeds temperature setpoint in Power Control mode (e.g., If temperature is set at 60°C and measured temperature exceeds 60°C, RF power shuts off).
- Upper temperature limit is exceeded twice during a single RF power delivery in Power Control mode.
- System operation errors are detected.

Display Readings During Interruption of RF Power Delivery

When RF power delivery ceases for any reason other than an out-of-range impedance value or an error, the last value appearing on each display remains flashing and the RF POWER CONTROL Light turns "OFF."

If RF power delivery ceases due to an out-of-range impedance value, the last measured impedance value remains flashing on the IMPEDANCE Display, alternating with the appropriate "HI" or "LO" message.

If RF power delivery ceases due to an error, the last measured impedance value remains flashing on the IMPEDANCE Display, alternating with the appropriate error code. (See Table 8-3 for a listing of error codes.)

In any of the above cases, when either the RF POWER CONTROL Button or the Footswitch is depressed again, the flashing display values change immediately to the previous user-selected values and the RF POWER CONTROL Light begins flashing. This signals that the Controller is ready for additional RF power deliveries. This is true unless RF power delivery, while in the Power Control mode, is interrupted for exceeding the upper temperature limit a second time. In this case, the set power is 50% of the value of RF power which causes the upper temperature limit to be exceeded.

7. Service and Maintenance

The Controller requires no routine service or maintenance. If the Controller fails to operate when plugged into a proper AC power receptacle and the power switch is turned on, check the fuse (refer to *Replacing the Fuses* in this chapter).

The Controller contains no user-serviceable parts; disassembly and attempted repair by unqualified personnel may create a hazardous condition and voids the warranty.

☎ **Call BSC for Service:** If a second failure occurs, notify BSC for service (Customer Service Telephone Number: 1-800-552-6700)

■ **Precaution:** Do not remove the cover of the Controller. Removing the cover may result in personal injury and/or damage to the Controller.

Cleaning/Disinfecting

The outer surfaces of the Controller and its accessories may be cleaned with a mild soapy solution. If disinfecting is required, isopropyl alcohol may be used to clean the outer surfaces.

■ **Precaution:** Do not immerse the Controller or its accessories in any liquid. Avoid caustic or abrasive cleaners.

Replacing the Fuses

Replacing the MAINS Fuse

1. Before replacing a fuse in the Controller, disconnect the MAINS power cord from the Controller.

2. Replace the fuse with another of the same type and rating. Refer to the fuse label on the rear panel (see Figure 5-10).

3. Pull the fuse holder out of the power entry module.

4. Use a screwdriver to assist in removing the fuse holder.

5. Insert the new fuse in the fuse holder and reinsert it in the power input module.

✉**Note:** When replacing the fuse holder, ensure the fuse holder is inserted in the correct orientation for the operational voltage level.

Auxiliary Power Outlet Fuses

1. Before replacing a fuse in the Controller, disconnect the MAINS power cord from the Controller.

2. Replace the fuse with another of the same type and rating. Refer to the fuse label on the rear panel (see Figure 5-10).

3. Use a screwdriver to rotate the fuse holder counter-clockwise 1/8th of a turn. The fuse holder "pops" out approximately 6 mm (1/4-inch).

4. Remove the fuse holder and the fuse.

5. Insert the new fuse in the fuse holder and reinsert it into the housing.

☎ **Call BSC for Service** If there appears to be a problem with the Controller, please contact BSC for instructions on returning the Controller to Boston Scientific Corporation for repair (Customer Service Telephone Number: 1-800-552-6700)

8. Product Specifications

General Specifications

Table 8-1 lists the specifications for the System (Controller and XPAPM).

Table 8-1: System Specifications

Description	Specification
Power Specifications	
Line Power	100 - 120 VAC (Model #800XP)
Current Rating	
Fuse Rating	3 A, 50/60 Hz (100 - 120 VAC)
Auxiliary Power	100 - 120 VAC (Model #800XP)
Current Rating	
Fuse Rating	1 A, 50/60 Hz (100 - 120 VAC)

Power Length Cord 10 ft

Footswitch

Cable Length 10 ft, Connector (to Controller): Polarized

Patient Cable to Extended

Performance Automatic

Personality Module

Length 10 ft

Connector "Multi-pin" Polarized Connector

High Power Automatic Personality Module

Dimensions

Height 1.8" (4.6 cm)

Width 5.9" (15.0 cm)

Depth 3.1" (7.9 cm)

Weight 2.2 lb (1.0 kg)

Table 8-1: System Specifications, Continued

Description Specification

High Power Automatic Personality Module, Continued

Recorder Connectors Quick Connect Connector

Catheter Connectors Quick Connect Connector

Indifferent Electrode Connectors Standard male 2-pin for commercial pads

Recorder Filters

Low Pass Filters Referenced to the INDIFFERENT ELECTRODE

Low Frequency Cutoff 5 kHz, -3dB at 5 kHz ± 2 kHz

High Power Disconnect Mechanism RF output ceases to the patient if more than 1 A flows in either INDIFFERENT ELECTRODE

Automatic Personality Module

Dimensions

Height 1.5" (3.8 cm)

Width 4.5" (11.4 cm)

Depth 1.8" (4.6 cm)

Weight 16 oz (453.6 g)

Recorder Connectors Quick Connect Connector

Catheter Connectors Quick Connect Connector

Indifferent Electrode Connectors Standard male 2-pin for commercial pads

Controller

RF Power Outputs • 50 W maximum into a minimum impedance of 50 Ω, within a 1 A current limit

• 100 W maximum into a minimum impedance of 25 Ω, within a 2 A current limit

Maximum RF power output based on catheter type used and control mode.

Table 8-1: System Specifications, Continued

Description Specification

Controller, Continued

Impedance • Measures 50 Ω and above, if accessing up to 50 W of RF power

• Measures 25 Ω and above, if accessing up to 100 W of RF power

• Measures up to 999 Ω (Controller automatically shuts off RF power at 300 Ω)

• Displays "LO" or "HI" outside the 25 Ω to 300 Ω range
Temperature
With Catheter (T°) Connected and Allows selection of desired catheter tip
Controller in Temperature Control temperature (temperature setpoint) within
Mode the range of 30° to 80°C for high power catheters and 30° to 90°C for standard catheters
With Catheter (T°) Connected and Allows selection of upper temperature
Controller in Power Control Mode limit or maximum temperature at which the Controller continues to deliver the setpower
Normal Operating Condition: Controller measures 20° to 120°C
With Controller in the Temperature
Control or Power Control Modes
Outside of Normal Operating Range Controller displays "LO" or "HI"
Dimensions
Height 8" (20 cm)
Width 13" (33 cm)
Depth 21" (53 cm)
Weight 23 lb (10.4 kg)
Time 0 to 120 seconds in increments of
1 second
Counter 0 to 99 RF power deliveries

Table 8-1: System Specifications, Continued

Description Specification

Controller, Continued

Low-Frequency Leakage (50/60 Hz);
Source Current, Patient Leads, All Outputs
Tied Together
Normal Polarity, Intact Chassis <10 µA
Ground
Normal Polarity, Ground Open <10 µA
Reverse Polarity, Ground Open <10 µA
Sink Current, at 120 V Applied, All <10 µA
Inputs
Chassis Source Current, Ground Open <100 µA

Calibration Mode

Power Output 0 - 1 volt corresponds to 0 - 100 W, continuous square wave
Impedance 0 - 1 volt corresponds to 0 - 300 Ω, continuous square wave
Temperature 0 - 1 volt corresponds to 20 - 120°C, continuous square wave

Environmental Specifications

Table 8-2 lists the environmental specifications for the System.

Table 8-2: Environmental Specifications

Description Specification

Storage

Temperature -40°C to 70°C
The unit should be gradually returned to the operating temperature range before use and stabilized for one hour before operation.
Relative Humidity 10% to 100%, non-condensing
Atmospheric Pressure 500 to 1060 millibar

Operating

Temperature 10°C to 40°C

Relative Humidity 30% to 75%, non-condensing
Atmospheric Pressure 700 to 1060 millibar

Power Delivery

As an enhanced patient safety feature, the output voltage and current of the System has been limited. Under normal circumstances (normal patient impedances), the maximum output power of the System is either 50 or 100 W, depending on catheter type and control mode. In the event of unusually high or low tissue impedance, the System limits the maximum power. A graph which depicts the maximum output power of the System as a function of tissue impedance is shown in Figure 8-1.

Note: Only the maximum power is affected. If the power setting is less than the maximum power available, the System delivers the set power value.

Figure 8-1: Output Power vs. Tissue Impedance

20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320 340 360
100W, 2A
S/W v2.01 (50 Watt)
P
(Watts)
Z
(Ohms)
10
100
90
80
70
60
50
40
30
20

Error Codes

Table 8-3 defines the error codes for the EP Technologies Cardiac Ablation System.

E01-E03 Error Codes

If error codes E01-E03 are observed, it is recommended that the ablation be attempted again.

Call BSC for Service If the error code displays again, notify BSC for service. See Section 7, *Service and Maintenance* in the Operator's Manual.

E06 Error Code

If an E06 error code message occurs, turn the Controller "OFF." Wait approximately five seconds before turning the Controller "ON."

Call BSC for Service If the Controller does not successfully pass the self-test procedure, or if the E06 error code message occurs again following successful completion of the self-test procedure, notify BSC for service. See Section 7,
Service and Maintenance in the Operator's Manual.

Table 8-3: Error Codes

Code	Description
E01	Apparent power (Vrms * Irms) not greater or equal to real power
E02	Apparent power (Vrms * Irms) measured greater than the setpoint
E03	Limit exceeded: V > Vmax or I > Imax or P > Pmax
E04	Temperature is greater than setpoint by at least 5°C for greater than four seconds
E05	Temperature greater than 85°C for high power catheters, greater than 95°C for standard catheters, or less than 20°C for greater than

1 second
E06 System Operation Error
E07 An attempt to enter RF Power On mode with a measured temperature outside the range of 20°C to 43°C.
E08 Upper temperature limit (cutoff) exceeded for more than 4.0 seconds.
E09 Upper temperature limit (cutoff) exceeded for the second time.

Figure 8-2: Labeling Symbols

8-8 Product Specifications

Power ON Power OFF Temperature at
Distal Electrode
Degree C
Alternating
Current
Increase Decrease Protective
Earth Ground
Defibrillator-Proof
Type Equipment
Variability Clock:
Time Switch:
Timer
Dangerous
Voltage
Attention, Consult
Accompanying
Documents
Non-Ionizing
Radiation
Loudspeaker Fuse Counter
Calibration Clear Indifferent
(Dispersive)
Patch Electrode
Radio Frequency
Power (On/Off)
Equipotentiality
000
M
Explosion
Hazard
AP

9. Limited Warranty and Disclaimer

Warranty and Limitations

Boston Scientific warrants that this product is free from defects in original workmanship and materials. If this product is proved to be defective in original workmanship or original materials, Boston Scientific, in its absolute and sole discretion, will replace or repair it, less charges for transportation and labor costs incidental to inspection, removal or restocking of product.

This limited warranty applies only to original factory delivered products which have been used for their normal and intended uses. Boston Scientific's limited warranty shall NOT apply to Boston Scientific products which were installed or calibrated by persons not authorized by Boston Scientific or which have been repaired, altered, or modified in any way and shall NOT apply to Boston Scientific products which have been improperly stored or improperly installed, operated or maintained contrary to Boston Scientific's instructions.