

Therapy Cool Path Duo™ Ablation Catheter

Instructions for Use (IFU)



Manufacturer:

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CAUTION:

- Federal Law (U.S.A.) restricts the use of this device to sale by or on the order of a physician.
- Read all instructions, warnings, and precautions prior to the use of this device..

DESCRIPTION:

The Therapy Cool Path Duo™ Ablation Catheter is a sterile, single use 7F catheter that is constructed of thermoplastic elastomer material and four noble metal electrodes. This catheter has a through-lumen connected to open conduits at the 4mm tip electrode for heparinized saline irrigation during the ablation procedure. The tip curvature may be manipulated by the thumb control mechanism located on the handle at the proximal end of the catheter. The catheter manipulation is uni-directional. The catheter is available in four distal curve configurations: M, L, L1 and XL. The curve is indicated on the catheter label.

The catheter connects to the 1500T9-CP RF Generator via a 1641 connecting cable and also connects to the Cool Point Irrigation Pump. Refer to the Operator's Manual packaged with the generator and the pump for a description of the generator and pump operations and related accessories.

INDICATIONS FOR USE:

The Therapy Cool Path Duo™ Ablation Catheter is intended for use with the compatible Irrigation pump and 1500T9-CP Radiofrequency (RF) Generator at a maximum of 50 watts. The catheter is intended for creating endocardial lesions during cardiac ablation procedures (mapping, stimulation and ablation) for the treatment of typical atrial flutter.

CONTRAINDICATIONS:

The Therapy Cool Path Duo™ ablation catheter is contraindicated for:

- Patients with active systemic infection;
- Patients with intracardiac mural thrombus or those who have had a ventriculotomy or atriotomy within the preceding four weeks.

WARNINGS:

- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency catheter ablation in a fully equipped electrophysiology laboratory.
- The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for this use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in prepubescent children.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to: a) have temporary external sources of pacing and defibrillation available during ablation, b) deactivate Intracardiac Defibrillators (ICDs) as they could discharge and injure the patient or be damaged by the ablation procedure, c) exercise extreme caution during ablation when in close proximity to permanent pacing or defibrillation leads, and d) perform complete implantable device system analysis on all patients after ablation.
- Caution should be taken when placing lesions in the proximity of the specialized conduction system.
- Ablation within and in close proximity to the coronary arterial vasculature has been associated with myocardial infarction and death.
- In accordance with your hospital's protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid overload.
- Always verify that the tubing and the catheter have been properly cleared of air prior to inserting the catheter into the vasculature. Entrapped air can cause potential injury or fatality.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.
- Do not use force to advance or withdraw catheter when resistance is encountered.
- When using an electrophysiology (EP) recording system, the equipment must be front-end isolated, or have an isolated patient cable.
- This device is intended for one time use only. Do not reprocess or reuse. Reuse can cause device failure, patient injury and /or the communication of infectious disease(s) from one patient to another.

PRECAUTIONS:

- If the irrigation pump alarm sounds, RF energy will be terminated. Evaluate air flow and communication between the irrigation pump and the RF Generator. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. Remove the catheter from the patient and inspect the catheter and the electrodes. If necessary, clean the electrodes with a sterile saline saturated gauze pad. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion.
- Continuously monitor the impedance display on the RF Generator during RF power delivery. If a sudden rise in impedance is noted that does not exceed the preset limit, or a steam pop is observed, manually discontinue power delivery. Clinically assess the situation. If necessary, remove the catheter from the patient and clean the distal tip of the catheter to eliminate any coagulum. If the catheter has defects, exchange it for a new one. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion. Relocate the catheter and attempt another RF application.
- There is a possibility of higher incidences of steam pops at power levels of 40 W and higher. Increase power to these levels only if lower energies do not achieve the intended result.
- Catheter advancement must be performed under fluoroscopic guidance in conjunction with internal electrograms and impedance monitoring to minimize the risk of cardiac damage, perforation or tamponade.

- Always straighten the catheter before insertion or withdrawal by completely retracting the thumb control knob bringing the catheter to its neutral (straight) position.
- Always maintain constant irrigation to prevent coagulation within and around electrodes.
- Do not use if catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if any of the irrigation ports are blocked.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can damage the steering mechanism and may cause patient injury.
- Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Care should be taken when ablating near electrically vulnerable, thin-walled tissue or arterial structures.
- Adequate filtering of mapping and recording system signals must be used to allow continuous monitoring of the surface or intracardiac electrocardiograms during radiofrequency power applications. Monitoring systems which incorporate high frequency current-limiting devices are recommended.
- Needle monitoring electrodes are not recommended.
- Do not immerse the proximal handle or cable connectors in fluids; electrical performance could be affected.
- Position connecting cables such that contact with the patient and other electrical leads is avoided.
- If irrigation flow is interrupted, immediately remove the catheter from the patient. Inspect the irrigation ports and the catheter. Re-flush the catheter outside of the patient. Reestablish irrigation flow prior to placing catheter in the body.
- Do not attempt ablation without using the Cool Point Irrigation Pump.
- Do not twist or pull at distal electrode. Excessive force may loosen the electrode from the catheter shaft.
- After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
- Do not expose the catheter to organic solvents such as alcohol.

POTENTIAL ADVERSE EVENTS

Potential adverse events that may be associated with cardiac catheterization and/or cardiac ablation include:

| | |
|--|--|
| <ul style="list-style-type: none"> • Arrhythmia • Angina • Atypical flutter • Cardiac tamponade • Congestive heart failure (CHF) exacerbation • Component damage to ICD or implantable pacemaker • Coronary artery dissection • Death • Dislodgement of implantable cardioverter defibrillator or permanent pacing lead • Endocarditis • Exacerbation of pre-existing atrial fibrillation as evidence by hospitalization, cardioversion, or worsening of AF Symptoms • Hypotension • Inadvertent AV block • Myocardial infarction/MI | <ul style="list-style-type: none"> • Abnormal vision • Anaphlaxis • Anemia • Arterial/venous thrombus • AV fistula • Catheter insertion site hematoma • Chest Pain (non-specific) • Dizziness • Exacerbation of chronic obstructive pulmonary disease (COPD) • Hemothorax • Hypoxia • Infection • Neck pain / back pain / groin pain related to the procedure. • Peripheral venous thrombosis • Phrenic nerve damage • Pleural effusion • Pneumonia |
|--|--|

| | |
|--|---|
| <ul style="list-style-type: none"> • Palpitations • Perforation (cardiac) • Pericardial effusion • Pericarditis • Pulmonary edema • Pulmonary embolism. • Stroke / Cerebrovascular accident • Syncope • Transient ischemic attack (TIA) • Ventricular arrhythmia requiring defibrillation • Vessel wall/valvular damage or insufficiency (i.e. new tricuspid regurgitation) | <ul style="list-style-type: none"> • Pneumothorax • Pseudoaneurysm • Radiation injury resulting in dermatitis (inflammation of the skin), erythema (redness), etc. • Respiratory failure • Seizure • Sepsis • Thromboembolic event • Vasovagal reaction |
|--|---|

SUMMARY OF CLINICAL STUDY

Objective

A multi-center clinical study was conducted using the Therapy Cool Path Duo™ cardiac ablation system. The purpose of the clinical study was to demonstrate the safety and effectiveness of the use of the Therapy Cool Path Duo™ cardiac ablation system for the treatment of typical atrial flutter (cavotricuspid isthmus dependent).

Study Design

This was a prospective, multi-center and non-randomized study. The subjects who signed informed consent and were verified to meet the inclusion/exclusion criteria received ablation therapy for typical atrial flutter using the Therapy Cool Path Duo™ Cardiac Ablation System.

Raw data from PMA P060019 (Therapy Cool Path™ Catheter Ablation System study) was used for control comparisons in this study. The study was designed to demonstrate that safety and effectiveness of the Therapy Cool Path Duo™ Cardiac Ablation System was equivalent (not inferior) to that of the Therapy Cool Path™ catheter ablation system (legally marketed ablation catheter approved for the treatment of typical atrial flutter).

Clinical Endpoints

Primary safety was defined as the incidence of composite, serious adverse events within 7 days post-procedure, regardless of whether a determination can be made regarding device relatedness.

Primary efficacy or acute success was defined as the achievement of bidirectional block in the cavo-tricuspid isthmus and non-inducibility of typical atrial flutter at least 30 minutes following the last RF application with the Therapy Cool Path Duo™ cardiac ablation system.

Secondary efficacy or chronic success was defined as freedom from recurrence of typical atrial flutter up to three months post ablation. Repeat ablations and new or increased dosage of existing class I / III anti-arrhythmic medication for typical atrial flutter during the three month follow-up were considered chronic failures.

Subjects Studied

| | |
|---|-----|
| Consented subjects | 206 |
| Withdrawn prior to introduction of the investigational device | 18 |
| Late screen failure (typical AFL could not be confirmed) | 17 |
| Patient / family request | 1 |
| Treated with the investigational device | 188 |
| Acute failures | 7 |

| | |
|--------------------------------|-----|
| Acute success, chronic failure | 3 |
| Lost to follow up | 4 |
| Death | 1 |
| Chronic success | 173 |

Demographics

A total of 206 subjects were consented at 22 investigational sites (20 in the US and 2 in Canada). Eighteen (18) subjects were withdrawn prior to the use of the investigational system.

Of the 188 subjects treated with the investigational system, 160 subjects (85.1%) were male and 28 subjects (14.9%) were female. The mean age of treated subjects was approximately 67.0 years and the mean weight was 212.8 pounds.

Cardiac history of treated subjects is summarized in Table 2. The most common cardiac history was Hypertension (77.7%), Atrial Fibrillation (34.6%) and Coronary Artery Disease (28.2%).

| CARDIAC CONDITION | THERAPY COOL PATH DUO™ (N=188) |
|------------------------------|-----------------------------------|
| CORONARY ARTERY DISEASE | 28.19% (n=53) |
| ATRIAL FIBRILLATION | 34.57% (n=65) |
| CORONARY ARTERY INTERVENTION | 19.15% (n=36) |
| PACEMAKER/ICD IMPLANT | 10.64% (n=20) |
| ATYPICAL ATRIAL FLUTTER | 3.19% (n=6) |
| CONGESTIVE HEART FAILURE | 13.83% (n=26) |
| HYPERTENSION | 77.66% (n=146) |
| MYOCARDIAL INFARCTION | 9.04% (n=17) |
| PERICARDITIS | 1.06% (n=2) |
| STROKE/TIA | 6.91% (n=13) |
| VALVE DISEASE | 14.36% (n=27) |
| VALVE SURGERY | 10.64% (n=20) |
| VENTRICULAR TACHYCARDIA | 3.72% (n=7) |

Procedural Data

| PARAMETER | N | MEAN ± SD |
|---|--------------------|-----------------|
| # OF APPLICATION PER PROCEDURE | 188 | 14.49 ± 12.05 |
| RF TIME (Min.) PER PROCEDURE | 188 | 18.18 ± 11.65 |
| PROCEDURE TIME (Min.) PER PATIENT | 188 | 105.79 ± 45.50 |
| TOTAL FLUID ADMINISTERED PER PATIENT (ml) | 185 [†] | 851.16 ± 458.00 |
| TOTAL PUMP SALINE PER PATIENT (ml) | 186 [†] | 408.45 ± 194.63 |
| RF TIME (Sec.) PER APPLICATION* | 2,713 [†] | 75.58 ± 68.64 |
| TEMPERATURE (°C) PER APPLICATION | 2,715 [†] | 34.64 ± 2.27 |
| MEAN POWER (Watts) PER APPLICATION | 2,717 [†] | 32.69 ± 7.62 |
| IMPEDANCE (Ohms) PER APPLICATION | 2,714 [†] | 96.89 ± 15.04 |

| PARAMETER | N | MEAN ± SD |
|--|---|-----------|
| <p>† A total of 2,725 RF applications were delivered, however the procedural data could not be collected by the site on some RF applications. The percentage of such instances is less than 0.5%.</p> <p>*188 subjects were treated with the investigational system, however the total fluid administered or total pump saline administered could not be collected for some subjects. The percentage of such instances is less than 0.4%.</p> <p>* The maximum RF application time for a drag lesion was 689 seconds. The Inter Quartile Range was 36.00 to 89.00 seconds.</p> | | |

Procedural and Ablation Comparison

| Parameter | Therapy CoolPath Duo™ Ablation System (n=188) | Control (n=174) |
|-----------------------------------|--|--|
| Steam Pop | 7.45% (14/188) | 6.32% (11/174) |
| Charring | 0.00% (0/188) | 0.00% (0/174) |
| Coagulum Formation | 0.00% (0/188) | 0.00% (0/174) |
| Change in Catheter Appearance | 0.53% (1/188) | 4.02% (7/174) |
| Mean Temperature (°C) per Patient | 34.74 ± 1.52 (n=188) (30.25-39.63) ¹ | 37.21 ± 2.07 (n=173) (31.05-43.43) ¹ |
| Mean Power (Watts) per Patient | 33.81 ± 5.87 (n=188) (19.00-47.50) ¹ | 29.69 ± 5.18 (n=173) (17.48-40.13) ¹ |
| Mean Impedance (Ohms) per Patient | 95.69 ± 11.79 (n=188) (69.75-139.24) ¹ | 93.47 ± 12.66 (n=173) (68.94-138.14) ¹ |
| Total Fluid Administered (ml) | 851.16 ± 458.00 (n=185) (236.00-3776.0) ¹ | 1021.6 ± 561.82 (n=172) (254.00-2950.0) ¹ |
| Total Pump Saline (ml) | 408.45 ± 194.63 (n=186) (100.00-1150.0) ¹ | 459.92 ± 291.15 (n=173) (27.00-1850.0) ¹ |
| ¹ Range (min to max) | | |

Results

Safety:

Out of 188 subjects treated with the investigational system, 12 subjects had composite serious adverse events within 7 days of the procedure. No unanticipated adverse device effects (UADE) were reported.

| NUMBER OF SUBJECTS | EVENT | DAYS POST PROCEDURE |
|--------------------|---|---------------------|
| 3 | HYPOTENSION | 0 |
| 1 | ARRHYTHMIA | 0 |
| 1 | ARRHYTHMIA | 1 |
| 1 | ARRHYTHMIA | 6 |
| 1 | VENTRICULAR ARRHYTHMIA REQUIRING DEFIBRILLATION | 6 |
| 1 | CONGESTIVE HEART FAILURE (CHF) EXACERBATION | 1 |

| NUMBER OF SUBJECTS | EVENT | DAYS POST PROCEDURE |
|--------------------|---|---------------------|
| 1 | CONGESTIVE HEART FAILURE (CHF) EXACERBATION | 5 |
| 1 | PERICARDITIS | 1 |
| 1 | SYNCOPE | 3 |
| 1 | CORONARY ARTERY DISEASE | 0 |

There was 1 death reported during the course of the clinical study, the causality of which was attributed to the subject's underlying disease by the clinical events committee. Below is the description of this event:

The subject was a 65 year old male with a history of congestive heart failure, GI bleed, hypertension and peripheral vascular disease. The subject was successfully treated for the study arrhythmia with the investigational system on March 25, 2010. The procedure was completed without event and the subject was discharged the following day. Thirty (30) days post procedure, he presented to the emergency room with episodes of vomiting, seizure in his left arm, and decreased responsiveness and consciousness. In the ER, head CT was performed which revealed a large intracerebral hemorrhage with associated intra ventricular hemorrhage. A conversation was entered into with the physician and the family regarding possible external ventricular drain placement. The family at that time did not want to pursue external vein drain placement. Three (3) days later, the subject passed away peacefully. In the opinion of the CEC, this event was not device related, but was related to the subject's underlying disease condition.

The rate of composite serious adverse events was 6.38% (12/188). The 95% confidence limit (CL) for the difference between the treatment group (Therapy Cool Path Duo™ catheter) and the control (Therapy Cool Path™ catheter) was 5.49%. The CL was less than the pre-specified non inferiority margin of 8%. Thus, based on the quantitative assessment, the pivotal study demonstrated that the Therapy Cool Path Duo™ Cardiac Ablation system was equivalent (non-inferior) to the market approved Therapy Cool Path™ Catheter System (control) with respect to safety for its intended use.

Effectiveness

Out of 188 subjects treated with the investigational system, 7 subjects were acute failures. The acute procedural success rate in this study was 96.28% (181/188). The 95% confidence limit (CL) for the difference between the treatment group (Therapy Cool Path Duo™ catheter) and the control (Therapy Cool Path™ catheter) was 0.24%. The CL was less than the pre-specified non inferiority margin of 7.5%. Thus based on a quantitative assessment, the pivotal study demonstrated that the Therapy Cool Path Duo™ Cardiac Ablation system was equivalent (non-inferior) to the market approved Therapy Cool Path™ Catheter System (control) with respect to acute efficacy for its intended use.

Of 181 subjects who were acutely successful 4 were lost to follow up and 1 died. 173 subjects had neither recurrence of typical atrial flutter nor increase / new Class I / Class III AAD for typical atrial flutter up to 3 month follow up. Three (3) subjects had recurrence of typical atrial flutter.

A total of 149 out of the 176 subjects (84.66%) had neither recurrence of typical atrial flutter nor increase / new Class I / Class III AAD (for any arrhythmia) up to 3 month follow. The 95% confidence limit (CL) for the difference between the treatment group (Therapy Cool Path Duo™ catheter) and the control (Therapy Cool Path™ catheter) was 0.98%. The CL was less than the pre-specified non inferiority margin of 12%. Thus based on a quantitative assessment, the pivotal study demonstrated that the Therapy Cool Path Duo™ Cardiac Ablation system was equivalent (non-inferior) to the market approved Therapy Cool Path™ Catheter System (control) with respect to chronic efficacy for its intended use.

PATIENT SELECTION AND TREATMENT RECOMMENDATION

The patient should be prepared for ablation procedure in accordance with standard clinical practice. The safety and effectiveness of Therapy Cool Path Duo™ Cardiac Ablation Catheter has not been studied in pregnant patients.

DIRECTIONS

1. Verify the generator and related accessories are set up per the diagram in the RF generator Operator's Manual. Do not connect the 1641 cable until after the catheter is connected and prepared, as indicated in step 7. Use care to isolate any unused connector pins of the 1804-S electrogram cable. This will reduce the chances of developing accidental current pathways to the heart.

2. Inspect the catheter package prior to use. Do not use if the package is open, damaged or expired.
3. Remove the catheter from its package. Inspect the electrodes and catheter carefully for integrity and overall condition.
4. Connect a sterile luer lock syringe filled with saline mix to the luer connection of the catheter. Push the contents of the syringe into the catheter to confirm all irrigation ports are open.
5. Connect the catheter to the irrigation system using standard luer fittings.
6. Make sure to purge the tubing and catheter of air bubbles. Flush the catheter using a high flow pump setting. Add heparin to the saline infusion medium according to the patient's anticoagulant condition.
7. Connect the 1641 cable to the Therapy Cool Path Duo™ catheter. Observe connector polarity; do not force connectors or pin damage can occur. Then connect the 1641 cable to the socket labeled ISOLATED PATIENT CONNECTOR on the generator front panel.
8. Power ON the generator and initialize the pump. Refer to the Operational Sequence Section of the RF generator Operator's Manual for a complete description of generator and pump set-up and communication between the two instruments.
9. Prior to entering ablation parameters in the generator, ensure the indifferent electrode is appropriately placed on the patient's body.
10. Set the initial power level at 20 watts.
11. Set the initial temperature at 40°C.
NOTE: Temperature represents the tip electrode temperature only and does not reflect tissue temperature.
12. Set the target duration. While total RF application time can be set up to 420 seconds to allow for drag lesions, the maximum duration at each ablation site shall be no more than 60 seconds.
13. Make sure the catheter is in the neutral (straight) position before insertion. An 8F minimum introducer sheath may be used to aid in insertion. To avoid occlusion of the irrigation conduits, THE CATHETER MUST BE CONTINUOUSLY IRRIGATED WHEN WITHIN THE VASCULATURE. Irrigation should only be stopped after removal of the catheter from the body.
14. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy.
15. To adjust the curve of the distal tip, push or pull the thumb control located on the handle.
16. The pump flow rates and RF generator settings are as follows:

| Pump Setting | Basal | During RF application |
|--------------|----------|-----------------------|
| Flow rate | 2 ml/min | 13 ml/min |

| RF Generator Setting | Initial Setting | Maximum Setting |
|----------------------|--|-----------------|
| Power | 20 W | 50 W |
| Temperature | 40°C | 45°C |
| Duration | While total ablation time can be set up to 420 seconds to allow for drag lesions, the maximum duration at each ablation site shall be no more than 60 seconds. | |

17. Monitor the impedance display on the RF generator, before, during, and after RF power delivery. If a sudden rise in impedance is noted during RF delivery that does not exceed the preset limit, manually discontinue the power delivery. Clinically assess the situation. If necessary, remove the catheter and clean the distal tip of the catheter cleaned to eliminate any coagulum if present.
18. Press the START key on the generator to begin RF therapy (ablation). The pump will automatically increase from basal flow rate to high flow rate.
19. If creating a drag lesion, move the catheter in a linear fashion remaining at no more than 60 seconds per site.
20. From the initial power set at 20 watts, power may be increased as needed (50W maximum) to create an effective lesion. Intracardiac electrogram and impedance should be assessed prior to changing power setting. Since there is a possibility of higher

incidences of steam pops at power levels of 40W and higher, power should be increased to these levels only if lower energies do not achieve the intended results.

21. If initial temperature of 40°C is reached but the preset power output is not, it is permissible to increase the temperature setting to a maximum of 45°C. Intracardiac electrogram and impedance should be assessed prior to changing temperature settings.

22. In case of a steam pop or automatic shut off, discontinue RF. Remove the catheter for visual inspection and check for coagulum, charring, or other catheter defects. Flush the ports prior to reinsertion in the subject. If the catheter has defects, exchange it for a new one. Relocate the catheter and attempt another RF application.

23. If the pump alarms and stops the irrigation, immediately remove the catheter from the patient and inspect and re-flush the catheter (see Generator Operator's Manual and Pump Operator's Manual). At the end of each ablation period, the pump will automatically return to the baseline flow rate based on programmed delay.

24. When the procedure is finished, make sure to pull the thumb control downward completely to bring the catheter to its neutral position (straight) before removing the catheter from the patient.

CONNECTION TO OTHER EQUIPMENT:

This device may be connected to a commercially available EP recording system using a connection cable with connector in the pin configuration corresponding to this catheter. The use of cables with shrouded pins is recommended and is required in some countries such as the United States. Such equipment must be "patient isolated", or have an isolated patient cable. Current leakage from the connected EP recording system must not exceed 10 micro amps for intracardiac electrodes.

PACKAGING AND SHELF-LIFE:

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the products remain in the unopened inner package until time of use. Contents are sterile if the inner package is unopened and undamaged. Do not resterilize. The expiration date is marked on the outside of the package. The product should be stored in a cool, dry location.

WARRANTY:

St. Jude Medical warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products are set forth in the related "Instructions for Use" that accompany each product. St. Jude Medical disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. St. Jude Medical's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. St. Jude Medical disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. St. Jude Medical neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete St. Jude Medical warranty policy available from St. Jude Medical (1-949-769-5000) or on the back of a St. Jude Medical invoice.

| | | | | | | | |
|----------------|-------------------------------------|-------------------------------|--|------------|---------|------------|--------------|
| | | | | LOT | | REF | |
| English | Sterilized with Ethylene Oxide Gas. | Read directions prior to use. | This product is single use only; do not reuse or resterilize | Lot number | Use by: | Item no. | Manufacturer |

| | | | | | | | | |
|----------------|-------------------|------------|---------|----------------------|----------|-------------------------|---------------------|----------------------|
| | | | | | | | FG # | Non-Pyrogenic |
| English | Recommended Cable | Electrodes | Spacing | Package Contain item | Keep dry | Keep Away From Sunlight | Finish Goods Number | Non-pyrogenic |

Therapy Cool Path Duo™, ST. JUDE MEDICAL, the stylized SJM, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered or unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. Other names may be trademarks of their respective owners and may be registered. © 2011 St. Jude Medical. All Rights Reserved.

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Safire BLU Duo™ Ablation Catheter

Instructions for Use (IFU)



Manufacturer:

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- Read all instructions, warnings, and precautions prior to the use of this device.

DESCRIPTION:

The Safire BLU Duo™ Ablation Catheter is a sterile, single use 7F catheter that is constructed of thermoplastic elastomer material and four noble metal electrodes. This catheter has a through-lumen connected to open conduits at the 4mm tip electrode for heparinized saline irrigation during the ablation procedure. The tip curvature may be manipulated by the thumb and forefinger control mechanism located on the handle at the proximal end of the catheter. The catheter manipulation is bi-directional. The catheter is available in four distal curve configurations: M, and L. The curve is indicated on the catheter label.

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The catheter connects to the 1500T9 CP - RF Generator via a 1641 connecting cable and also connects to the Cool Point irrigation Pump. Refer to the Operator's Manual packaged with the generator and the pump for a description of the generator and pump operations and related accessories.

INDICATIONS FOR USE:

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CONTRAINDICATIONS:

The Safire BLU Duo™ ablation catheter is contraindicated for:

- Patients with active systemic infection;
- Patients with intracardiac mural thrombus or those who have had a ventriculotomy or atriotomy within the preceding four weeks.

WARNINGS:

- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency catheter ablation in a fully equipped electrophysiology laboratory.
- The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for this use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in prepubescent children.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to: a) have temporary external sources of pacing and defibrillation available during ablation, b) deactivate Intracardiac Defibrillators (ICDs) as they could discharge and injure the patient or be damaged by the ablation procedure, c) exercise extreme caution during ablation when in close proximity to permanent pacing or defibrillation leads, and d) perform complete implantable device system analysis on all patients after ablation.
- Caution should be taken when placing lesions in the proximity to the specialized conduction system. Ablation within and in close proximity to the coronary arterial vasculature has been associated with myocardial infarction and death.
- In accordance with your hospital's protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid overload.
- Always verify that the tubing and the catheter have been properly cleared of air prior to inserting the catheter into the vasculature. Entrapped air can cause potential injury or fatality.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.
- Do not use force to advance or withdraw catheter when resistance is encountered.
- When using an electrophysiology (EP) recording system, the equipment must be front-end isolated, or have an isolated patient cable.
- This device is intended for one time use only. Do not reprocess or reuse. Reuse can cause device failure, patient injury and /or the communication of infectious disease(s) from one patient to another.

PRECAUTIONS:

- If the irrigation pump alarm sounds, RF energy will be terminated. Evaluate air flow and communication between the irrigation pump and the RF Generator. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. Remove the catheter from the patient and inspect the catheter and the electrodes. If necessary, clean the electrodes with a sterile saline saturated gauze pad. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion.
- Continuously monitor the impedance display on the RF Generator during RF power delivery. If a sudden rise in impedance is noted that does not exceed the preset limit, or a steam pop is observed, manually discontinue power delivery. Clinically assess the situation. If necessary, remove the catheter from the patient and clean the distal tip of the catheter to eliminate any coagulum. If the catheter has defects, exchange it for a new one. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion. Relocate the catheter and attempt another RF application.
- There is a possibility of higher incidences of steam pops at power levels of 40 W and higher. Increase power to these levels only if lower energies do not achieve the intended result.

- Catheter advancement must be performed under fluoroscopic guidance in conjunction with internal electrograms and impedance monitoring to minimize the risk of cardiac damage, perforation or tamponade.
- Always straighten the catheter before insertion or withdrawal by completely retracting the thumb control knob bringing the catheter to its neutral (straight) position.
- Always maintain constant irrigation to prevent coagulation within and around electrodes.
- Do not use if catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if any of the irrigation ports are blocked.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can damage the steering mechanism and may cause patient injury.
- Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Care should be taken when ablating near electrically vulnerable, thin-walled tissue or arterial structures.
- Adequate filtering of mapping and recording system signals must be used to allow continuous monitoring of the surface or intracardiac electrocardiograms during radiofrequency power applications. Monitoring systems which incorporate high frequency current-limiting devices are recommended.
- Needle monitoring electrodes are not recommended.
- Do not immerse the proximal handle or cable connectors in fluids; electrical performance could be affected.
- Position connecting cables such that contact with the patient and other electrical leads is avoided.
- If irrigation flow is interrupted, immediately remove the catheter from the patient. Inspect the irrigation ports and the catheter. Re-flush the catheter outside of the patient. Reestablish irrigation flow prior to placing catheter in the body.
- Do not attempt ablation without using the Cool Point Irrigation Pump.
- Do not twist or pull at distal electrode. Excessive force may loosen the electrode from the catheter shaft.
- After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
- Do not expose the catheter to organic solvents such as alcohol.

POTENTIAL ADVERSE EVENTS

Potential adverse events that may be associated with cardiac catheterization and /or cardiac ablation include:

| | |
|---|--|
| <ul style="list-style-type: none"> • Arrhythmia • Angina • Atypical flutter • Cardiac tamponade • Congestive heart failure (CHF) exacerbation • Component damage to ICD or implantable pacemaker • Coronary artery dissection • Death • Dislodgement of implantable cardioverter defibrillator or permanent pacing lead • Endocarditis • Exacerbation of pre-existing atrial fibrillation as evidence by hospitalization, cardioversion, or worsening of AF Symptoms • Hypotension • Inadvertent AV block • Myocardial infarction/MI • Palpitations • Perforation (cardiac) • Pericardial effusion • Pericarditis • Pulmonary edema • Pulmonary embolism • Stroke / Cerebrovascular accident • Syncope • Transient ischemic attack (TIA) • Ventricular arrhythmia requiring defibrillation • Vessel wall/valvular damage or insufficiency (i.e. new tricuspid regurgitation) | <ul style="list-style-type: none"> • Abnormal vision • Anaphlaxis • Anemia • Arterial/venous thrombus • AV fistula • Catheter insertion site hematoma • Chest Pain (non-specific) • Dizziness • Exacerbation of chronic obstructive pulmonary disease (COPD) • Hemothorax • Hypoxia • Infection • Neck pain / back pain / groin pain related to the procedure • Peripheral venous thrombosis • Phrenic nerve damage • Pleural effusion • Pneumonia • Pneumothorax • Pseudoaneurysm • Radiation injury resulting in dermatitis (inflammation of the skin), erythema (redness), etc. • Respiratory failure • Seizure • Sepsis • Thromboembolic event • Vasovagal reaction |
|---|--|

SUMMARY OF CLINICAL STUDY

The Safire BLU Duo™ ablation catheter is supported by the clinical study under the Therapy Cool Path Duo™ ablation catheter.

Objective

A multi-center clinical study was conducted using the Therapy Cool Path Duo™ cardiac ablation system. The purpose of the clinical study was to demonstrate the safety and effectiveness of the use of the Therapy Cool Path Duo™ cardiac ablation system for the treatment of typical atrial flutter (cavotricuspid isthmus dependent).

Study Design

This was a prospective, multi-center and non-randomized study. The subjects who signed informed consent and were verified to meet the inclusion/exclusion criteria received ablation therapy for typical atrial flutter using the Therapy Cool Path Duo™ Cardiac Ablation System.

Raw data from PMA P060019 (Therapy Cool Path™ Catheter Ablation System study) was used for control comparisons in this study. The study was designed to demonstrate that safety and effectiveness of the Therapy Cool Path Duo™ Cardiac Ablation System was equivalent (not inferior) to that of the Therapy Cool Path™ catheter ablation system (legally marketed ablation catheter approved for the treatment of typical atrial flutter).

Clinical Endpoints

Primary safety was defined as the incidence of composite, serious adverse events within 7 days post-procedure, regardless of whether a determination can be made regarding device relatedness.

Primary efficacy or acute success was defined as the achievement of bidirectional block in the cavo-tricuspid isthmus and non-inducibility of typical atrial flutter at least 30 minutes following the last RF application with the Therapy Cool Path Duo™ cardiac ablation system.

Secondary efficacy or chronic success was defined as freedom from recurrence of typical atrial flutter up to three months post ablation. Repeat ablations and new or increased dosage of existing class I / III anti-arrhythmic medication for typical atrial flutter during the three month follow-up were considered chronic failures.

Subjects Studied

| | |
|---|-----|
| Consented subjects | 206 |
| Withdrawn prior to introduction of the investigational device | 18 |
| Late screen failure (typical AFL could not be confirmed) | 17 |
| Patient / family request | 1 |
| Treated with the investigational device | 188 |
| Acute failures | 7 |
| Acute success, chronic failure | 3 |
| Lost to follow up | 4 |
| Death | 1 |
| Chronic success | 173 |

Demographics

A total of 206 subjects were consented at 22 investigational sites (20 in the US and 2 in Canada). Eighteen (18) subjects were withdrawn prior to the use of the investigational system.

Of the 188 subjects treated with the investigational system, 160 subjects (85.1%) were male and 28 subjects (14.9%) were female. The mean age of treated subjects was approximately 67.0 years and the mean weight was 212.8 pounds.

Cardiac history of treated subjects is summarized in Table 2. The most common cardiac history was Hypertension (77.7%), Atrial Fibrillation (34.6%) and Coronary Artery Disease (28.2%).

| CARDIAC CONDITION | THERAPY COOL PATH DUO™ (N=188) |
|------------------------------|-----------------------------------|
| CORONARY ARTERY DISEASE | 28.19% (n=53) |
| ATRIAL FIBRILLATION | 34.57% (n=65) |
| CORONARY ARTERY INTERVENTION | 19.15% (n=36) |

| CARDIAC CONDITION | THERAPY COOL PATH DUO™ (N=188) |
|--------------------------|-----------------------------------|
| PACEMAKER/ICD IMPLANT | 10.64% (n=20) |
| ATYPICAL ATRIAL FLUTTER | 3.19% (n=6) |
| CONGESTIVE HEART FAILURE | 13.83% (n=26) |
| HYPERTENSION | 77.66% (n=146) |
| MYOCARDIAL INFARCTION | 9.04% (n=17) |
| PERICARDITIS | 1.06% (n=2) |
| STROKE/TIA | 6.91% (n=13) |
| VALVE DISEASE | 14.36% (n=27) |
| VALVE SURGERY | 10.64% (n=20) |
| VENTRICULAR TACHYCARDIA | 3.72% (n=7) |

Procedural Data

| PARAMETER | N | MEAN ± SD |
|---|--------------------|-----------------|
| # OF APPLICATION PER PROCEDURE | 188 | 14.49 ± 12.05 |
| RF TIME (Min.) PER PROCEDURE | 188 | 18.18 ± 11.65 |
| PROCEDURE TIME (Min.) PER PATIENT | 188 | 105.79 ± 45.50 |
| TOTAL FLUID ADMINISTERED PER PATIENT (ml) | 185 [‡] | 851.16 ± 458.00 |
| TOTAL PUMP SALINE PER PATIENT (ml) | 186 [‡] | 408.45 ± 194.63 |
| RF TIME (Sec.) PER APPLICATION* | 2,713 [†] | 75.58 ± 68.64 |
| TEMPERATURE (°C) PER APPLICATION | 2,715 [†] | 34.64 ± 2.27 |
| MEAN POWER (Watts) PER APPLICATION | 2,717 [†] | 32.69 ± 7.62 |
| IMPEDANCE (Ohms) PER APPLICATION | 2,714 [†] | 96.89 ± 15.04 |

† A total of 2,725 RF applications were delivered, however the procedural data could not be collected by the site on some RF applications. The percentage of such instances is less than 0.5%.

‡ 188 subjects were treated with the investigational system, however the total fluid administered or total pump saline administered could not be collected for some subjects. The percentage of such instances is less than 0.4%.

* The maximum RF application time for a drag lesion was 689 seconds. The Inter Quartile Range was 36.00 to 89.00 seconds.

Procedural and Ablation Comparison

| Parameter | Therapy CoolPath Duo™ Ablation System (n=188) | Control (n=174) |
|-------------------------------|--|--------------------|
| Steam Pop | 7.45% (14/188) | 6.32% (11/174) |
| Charring | 0.00% (0/188) | 0.00% (0/174) |
| Coagulum Formation | 0.00% (0/188) | 0.00% (0/174) |
| Change in Catheter Appearance | 0.53% (1/188) | 4.02% (7/174) |

| Parameter | Therapy CoolPath Duo™ Ablation System (n=188) | Control (n=174) |
|-----------------------------------|--|--|
| Mean Temperature (°C) per Patient | 34.74 ± 1.52 (n=188) (30.25-39.63) ¹ | 37.21 ± 2.07 (n=173) (31.05-43.43) ¹ |
| Mean Power (Watts) per Patient | 33.81 ± 5.87 (n=188) (19.00-47.50) ¹ | 29.69 ± 5.18 (n=173) (17.48-40.13) ¹ |
| Mean Impedance (Ohms) per Patient | 95.69 ± 11.79 (n=188) (69.75-139.24) ¹ | 93.47 ± 12.66 (n=173) (68.94-138.14) ¹ |
| Total Fluid Administered (ml) | 851.16 ± 458.00 (n=185) (236.00-3776.0) ¹ | 1021.6 ± 561.82 (n=172) (254.00-2950.0) ¹ |
| Total Pump Saline (ml) | 408.45 ± 194.63 (n=186) (100.00-1150.0) ¹ | 459.92 ± 291.15 (n=173) (27.00-1850.0) ¹ |
| ¹ Range (min to max) | | |

Results

Safety:

Out of 188 subjects treated with the investigational system, 12 subjects had composite serious adverse events within 7 days of the procedure. No unanticipated adverse device effects (UADE) were reported.

| NUMBER OF SUBJECTS | EVENT | DAYS POST PROCEDURE |
|--------------------|---|---------------------|
| 3 | HYPOTENSION | 0 |
| 1 | ARRHYTHMIA | 0 |
| 1 | ARRHYTHMIA | 1 |
| 1 | ARRHYTHMIA | 6 |
| 1 | VENTRICULAR ARRHYTHMIA REQUIRING DEFIBRILLATION | 6 |
| 1 | CONGESTIVE HEART FAILURE (CHF) EXACERBATION | 1 |
| 1 | CONGESTIVE HEART FAILURE (CHF) EXACERBATION | 5 |
| 1 | PERICARDITIS | 1 |
| 1 | SYNCOPE | 3 |
| 1 | CORONARY ARTERY DISEASE | 0 |

There was 1 death reported during the course of the clinical study, the causality of which was attributed to the subject's underlying disease by the clinical events committee. Below is the description of this event:

The subject was a 65 year old male with a history of congestive heart failure, GI bleed, hypertension and peripheral vascular disease. The subject was successfully treated for the study arrhythmia with the investigational system on March 25, 2010. The procedure was completed without event and the subject was discharged the following day. Thirty (30) days post procedure, he presented to the emergency room with episodes of vomiting, seizure in his left arm, and decreased responsiveness and consciousness. In the ER, head CT was performed which revealed a large intracerebral hemorrhage with associated intra ventricular hemorrhage. A conversation was entered into with the physician and the family regarding possible external ventricular drain placement. The family at that time did not want to pursue external vein drain placement. Three (3) days later,

the subject passed away peacefully. In the opinion of the CEC, this event was not device related, but was related to the subject's underlying disease condition.

The rate of composite serious adverse events was 6.38% (12/188). The 95% confidence limit (CL) for the difference between the treatment group (Therapy Cool Path Duo™ catheter) and the control (Therapy Cool Path™ catheter) was 5.49%. The CL was less than the pre-specified non inferiority margin of 8%. Thus, based on the quantitative assessment, the pivotal study demonstrated that the Therapy Cool Path Duo™ Cardiac Ablation system was equivalent (non-inferior) to the market approved Therapy Cool Path™ Catheter System (control) with respect to safety for its intended use.

Effectiveness

Out of 188 subjects treated with the investigational system, 7 subjects were acute failures. The acute procedural success rate in this study was 96.28% (181/188). The 95% confidence limit (CL) for the difference between the treatment group (Therapy Cool Path Duo™ catheter) and the control (Therapy Cool Path™ catheter) was 0.24%. The CL was less than the pre-specified non inferiority margin of 7.5%. Thus based on a quantitative assessment, the pivotal study demonstrated that the Therapy Cool Path Duo™ Cardiac Ablation system was equivalent (non-inferior) to the market approved Therapy Cool Path Catheter System (control) with respect to acute efficacy for its intended use.

Of 181 subjects who were acutely successful 4 were lost to follow up and 1 died. 173 subjects had neither recurrence of typical atrial flutter nor increase / new Class I / Class III AAD for typical atrial flutter up to 3 month follow up. Three (3) subjects had recurrence of typical atrial flutter.

A total of 149 out of the 176 subjects (84.66%) had neither recurrence of typical atrial flutter nor increase / new Class I / Class III AAD (for any arrhythmia) up to 3 month follow. The 95% confidence limit (CL) for the difference between the treatment group (Therapy Cool Path Duo™ catheter) and the control (Therapy Cool Path™ catheter) was 0.98%. The CL was less than the pre-specified non inferiority margin of 12%. Thus based on a quantitative assessment, the pivotal study demonstrated that the Therapy Cool Path Duo™ Cardiac Ablation system was equivalent (non-inferior) to the market approved Therapy Cool Path™ Catheter System (control) with respect to chronic efficacy for its intended use.

PATIENT SELECTION AND TREATMENT RECOMMENDATION

The patient should be prepared for ablation procedure in accordance with standard clinical practice. The safety and effectiveness of Therapy Cool Path Duo™ Cardiac Ablation Catheter has not been studied in pregnant patients.

DIRECTIONS

1. Verify the generator and related accessories are set up per the diagram in the RF generator Operator's Manual. Do not connect the 1641 cable until after the catheter is connected and prepared, as indicated in step 7. Use care to isolate any unused connector pins of the 1804-S electrogram cable. This will reduce the chances of developing accidental current pathways to the heart.
2. Inspect the catheter package prior to use. Do not use if the package is open, damaged or expired.
3. Remove the catheter from its package. Inspect the electrodes and catheter carefully for integrity and overall condition.
4. Connect a sterile luer lock syringe filled with saline mix to the luer connection of the catheter. Push the contents of the syringe into the catheter to confirm all irrigation ports are open.
5. Connect the catheter to the irrigation system using standard luer fittings.
6. Make sure to purge the tubing and catheter of air bubbles. Flush the catheter using a high flow pump setting. Add heparin to the saline infusion medium according to the patient's anticoagulant condition.
7. Connect the 1641 cable to the Therapy Cool Path Duo™ catheter. Observe connector polarity; do not force connectors or pin damage can occur. Then connect the 1641 cable to the socket labeled ISOLATED PATIENT CONNECTOR on the generator front panel.
8. Power ON the generator and initialize the pump. Refer to the Operational Sequence Section of the RF generator Operator's Manual for a complete description of generator and pump set-up and communication between the two instruments.
9. Prior to entering ablation parameters in the generator, ensure the indifferent electrode is appropriately placed on the patient's body.

10. Set the initial power level at 20 watts.
11. Set the initial temperature at 40°C.
NOTE: Temperature represents the tip electrode temperature only and does not reflect tissue temperature.
12. Set the target duration. While total RF application time can be set up to 420 seconds to allow for drag lesions, the maximum duration at each ablation site shall be no more than 60 seconds.
13. Make sure the catheter is in the neutral (straight) position before insertion. An 8F minimum introducer sheath may be used to aid in insertion. To avoid occlusion of the irrigation conduits, THE CATHETER MUST BE CONTINUOUSLY IRRIGATED WHEN WITHIN THE VASCULATURE. Irrigation should only be stopped after removal of the catheter from the body.
14. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy.
15. To adjust the curve of the distal tip, push or pull the thumb control located on the handle.
16. The pump flow rates and RF generator settings are as follows:

| Pump Setting | Basal | During RF application |
|--------------|----------|-----------------------|
| Flow rate | 2 ml/min | 13 ml/min |

| RF Generator Setting | Initial Setting | Maximum Setting |
|----------------------|--|-----------------|
| Power | 20 W | 50 W |
| Temperature | 40°C | 45°C |
| Duration | While total ablation time can be set up to 420 seconds to allow for drag lesions, the maximum duration at each ablation site shall be no more than 60 seconds. | |

17. Monitor the impedance display on the RF generator, before, during, and after RF power delivery. If a sudden rise in impedance is noted during RF delivery that does not exceed the preset limit, manually discontinue the power delivery. Clinically assess the situation. If necessary, remove the catheter and clean the distal tip of the catheter to eliminate any coagulum if present.
18. Press the START key on the generator to begin RF therapy (ablation). The pump will automatically increase from basal flow rate to high flow rate.
19. If creating a drag lesion, move the catheter in a linear fashion remaining at no more than 60 seconds per site.
20. From the initial power set at 20 watts, power may be increased as needed (50W maximum) to create an effective lesion. Intracardiac electrogram and impedance should be assessed prior to changing power setting. Since there is a possibility of higher incidences of steam pops at power levels of 40W and higher, power should be increased to these levels only if lower energies do not achieve the intended results.
21. If initial temperature of 40°C is reached but the preset power output is not, it is permissible to increase the temperature setting to a maximum of 45°C. Intracardiac electrogram and impedance should be assessed prior to changing temperature settings.
22. In case of a steam pop or automatic shut off, discontinue RF. Remove the catheter for visual inspection and check for coagulum, charring, or other catheter defects. Flush the ports prior to reinsertion in the subject. If the catheter has defects, exchange it for a new one. Relocate the catheter and attempt another RF application.
23. If the pump alarms and stops the irrigation, immediately remove the catheter from the patient and inspect and re-flush the catheter (see Generator Operator's Manual and Pump Operator's Manual). At the end of each ablation period, the pump will automatically return to the baseline flow rate based on programmed delay.
24. When the procedure is finished, make sure to pull the thumb control downward completely to bring the catheter to its neutral position (straight) before removing the catheter from the patient.

CONNECTION TO OTHER EQUIPMENT:

This device may be connected to a commercially available EP recording system using a connection cable with connector in the pin configuration corresponding to this catheter. The use of cables with shrouded pins is recommended and is required in some countries

such as the United States. Such equipment must be "patient isolated", or have an isolated patient cable. Current leakage from the connected EP recording system must not exceed 10 micro amps for intracardiac electrodes.

PACKAGING AND SHELF-LIFE:

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the products remain in the unopened inner package until time of use. Contents are sterile if the inner package is unopened and undamaged. Do not resterilize. The expiration date is marked on the outside of the package. The product should be stored in a cool, dry location.

WARRANTY:

St. Jude Medical warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products are set forth in the related "Instructions for Use" that accompany each product. St. Jude Medical disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. St. Jude Medical's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. St. Jude Medical disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. St. Jude Medical neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete St. Jude Medical warranty policy available from St. Jude Medical (1-949-769-5000) or on the back of a St. Jude Medical invoice.

| | | | | | | | |
|----------------|-------------------------------------|-------------------------------|--|------------|---------|------------|--------------|
| | | | | LOT | | REF | |
| English | Sterilized with Ethylene Oxide Gas. | Read directions prior to use. | This product is single use only; do not reuse or resterilize | Lot number | Use by: | Item no. | Manufacturer |

| | | | | | | | | |
|----------------|-------------------|------------|---------|----------------------|----------|-------------------------|---------------------|----------------------|
| | | | | | | | FG # | Non-Pyrogenic |
| English | Recommended Cable | Electrodes | Spacing | Package Contain item | Keep dry | Keep Away From Sunlight | Finish Goods Number | Non-pyrogenic |

Safire BLU Duo™, Therapy Cool Path Duo™, ST. JUDE MEDICAL, the stylized SJM, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered or unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. Other names may be trademarks of their respective owners and may be registered. © 2011 St. Jude Medical. All Rights Reserved.

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Operator's Manual

CARDIAC ABLATION GENERATOR With Temperature Control

Model No. 1500T9-CP v.1.6
(Software Version v.1.6)



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Table of Contents

| | |
|---|-----------|
| SECTION 1. System Description | 5 |
| SECTION 2. Indications for use / Contraindications | 6 |
| SECTION 3. Warnings, Precautions, Adverse Reactions | 7 |
| SECTION 4. Operating States, Controls and Indicators | 12 |
| SECTION 5. Operational Sequence..... | 20 |
| Operating with Non-Irrigated Catheter: | 22 |
| Operating with Irrigated Catheter and the Cool Point™ Irrigation Pump:..... | 26 |
| SECTION 6. 1500T Extender Module (Optional)..... | 39 |
| SECTION 7. TECHNICAL SPECIFICATIONS..... | 40 |
| SECTION 8. SERVICE AND MAINTENANCE..... | 42 |
| SECTION 9. LABELING SYMBOLS..... | 45 |
| SECTION 10. ACCESSORIES..... | 46 |
| SECTION 11. GRAPHS..... | 47 |
| Appendix A: State Transitions | 49 |
| Appendix B: Limited Warranty and General Service Policies | 53 |

CAUTION

United States Law restricts this device to sale by or on the order of a physician.

DO NOT attempt to operate the 1500T9-CP v.1.6 Cardiac Ablation Generator before thoroughly reading this Operator's Manual and the catheter's IFU. Operating instructions should be read, understood, and followed carefully. For future reference, keep this Manual in a convenient, readily accessible place.

PREFACE

The use of all components and accessories of the 1500T9-CP v.1.6 Cardiac Ablation Generator is described in this Manual with the exception of the catheter. Instructions For Use (IFU) for the catheter accompany the catheter. This manual provides a description of the generator, its controls and displays, and a sequence for its operation. Other important information has also been supplied for the user's convenience.

SECTION 1. System Description

The Therapy™ Cardiac Ablation System consists of the 1500T9-CP v.1.6 Cardiac Ablation Generator (“the generator”), the Cool Point™ Irrigation Pump (“the pump”), the Therapy™ 1300 Series Steerable Ablation Catheters with temperature measuring capability, the SAFIRE™ TX Ablation Catheters (“the catheter”), the Therapy™ Cool Path™ Ablation Catheters, the SAFIRE BLU™ Catheters, Therapy™ Cool Path™ Duo Catheters, SAFIRE BLU™ Duo Catheters (“the irrigated catheter”), and accessories as defined in Section 11 of this manual.

For proper system operation, the use of recommended accessories is required.

The generator is a microprocessor-controlled device that produces a continuous unmodulated radiofrequency (RF) output of 485 kHz. The generator has a maximum power output of 100 Watts (W). The catheter delivers the RF power from the generator in a monopolar mode between its distal electrode (tip electrode) and a large Disposable Indifferent Patch (“DIP”) electrode (s).

The generator operates in Temperature Control mode only. The generator is a temperature controlled system, where temperature measured by the temperature sensor in the compatible catheters is monitored and the power delivered by the generator adjusts within the selected limits until the desired temperature is achieved.

The front panel displays the actual real-time power output, impedance, duration, and measured tip electrode temperature. The amount and duration of RF power delivery is user-selectable. The desired catheter tip electrode temperature is also user selectable. A low pass filter is enabled during ablation to permit recording of intracardiac electrograms and alternately disables the filter during stimulation (pacing).

The output power of the generator will shut off if the measured temperature exceeds 80oC or if the measured temperature exceeds the user-selected temperature set point by more than 5oC for more than 3 seconds. The generator has built-in safety features, which include a self-test at power up and automatic RF power shut off if the measured tissue impedance falls below 50 Ohms or exceeds 300 Ohms or the preset impedance value for more than 2 seconds.

The 1500T9-CP v.1.6 Cardiac Ablation Generator is only compatible with Cool Point Irrigation Pump.

SECTION 2.

Indications for use / Contraindications

2.1. Indications for Use

The 1500T9-CP v.1.6 Cardiac Ablation Generator is intended for use with compatible St. Jude Medical temperature controlled ablation catheters for creating endocardial lesions to treat arrhythmias. It is currently approved to be used with the following ablation catheters:

- Therapy™: The generator is internally limited to 50 watts when used with 4mm Therapy™ catheters
- Therapy™ Dual 8™: The generator is limited to 100 watts when used with the Therapy™ Dual 8™ catheters.
- SAFIRE™ TX: The generator is limited to 100 watts when used with the SAFIRE™ TX catheters.
- Therapy™ Cool Path™: The generator is internally limited to 50 watts when used with Therapy™ Cool Path™ catheters. A compatible external Irrigation pump must be connected when used with Therapy™ Cool Path™ catheters.
- SAFIRE BLU™: The generator is internally limited to 50 watts when used with SAFIRE BLU™ catheters. A compatible external irrigation pump must be connected when used with SAFIRE BLU™ catheters.
- Therapy™ Cool Path™ Duo: The generator is internally limited to 50 watts when used with Therapy™ Cool Path™ Duo catheters. A compatible external irrigation pump must be connected when used with Therapy™ Cool Path™ Duo catheters.
- SAFIRE BLU™ Duo: The generator is internally limited to 50 watts when used with SAFIRE BLU™ Duo catheters. A compatible external irrigation pump must be connected when used with SAFIRE BLU™ Duo catheters.

2.2. Contraindications

The use of this device with a St. Jude Medical temperature controlled ablation catheter family is contraindicated:

- In patients with active systemic infection.
- If the patients with intracardiac mural thrombus or who have had a ventriculotomy or atriotomy within the preceding four weeks.
- Please refer to appropriate catheter IFU for additional list of contraindications.

SECTION 3. Warnings, Precautions, Adverse Reactions

3.1. Warnings

- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency catheter ablation in a fully equipped electrophysiology laboratory.
- Cardiac ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Cardiac ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for this use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in prepubescent children.
- Pacemakers and implantable cardioverter/defibrillators can adversely be affected by Radiofrequency (RF) signals. It is important to: a) have temporary external sources of pacing and defibrillation available during ablation, b) deactivate implantable cardioverter defibrillators (ICD's) as they could discharge and injure the patient or be damaged by the ablation procedure, c) exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads, and d) perform complete pacing system analysis on all patients after ablation.
- RF Ablation within and in close proximity to the coronary arterial vasculature has been associated with myocardial infarction and death.
- When using an electrophysiology (EP) recording system, the equipment must be front-end isolated, or have an isolated patient cable.
- Failure of RF ablation generator could result in an unintended power output increase. In case of system malfunction, shut off RF power delivery by turning the rocker switch to the off position or disconnect the power cord.
- Please refer to appropriate catheter IFU for additional list of warnings.

Warnings Specific to The Irrigated Catheter:

- When the generator is used with an irrigated catheter, the temperature shown on the front panel temperature display is not the temperature of the tissue being ablated. It is the temperature of the irrigated tip electrode only.
- When the Cool Point Irrigation pump is initialized, during ablation the flow rate is 13mL/min and during non-ablation basal flow rate is 2mL/min. If the pump rate is set by using the pump key pad (pump manual operation), the generator will not control the flow rates. To establish generator control, initialize the pump by following the set-up procedure.
- Do not perform ablation without sufficient irrigation when using the generator with the irrigated catheter.

3.2. Precautions

- Peri-procedural anticoagulation therapy is recommended for patients in persistent or chronic atrial flutter and those undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- The catheter impedance display on the cardiac ablation generator should be continuously monitored during RF power delivery. If a sudden increase in impedance is noted, power delivery should be discontinued. The catheter should be removed and inspected. Clean the distal tip of the catheter with a sterile gauze pad dampened with sterile saline to eliminate any coagulum.
- Do not immerse the cable connector in fluids; electrical performance could be affected.
- Adequate filtering must be used to allow continuous monitoring of the electrogram (EGM) during Radiofrequency power applications. Monitoring systems incorporating high frequency current-limiting devices are recommended.
- Desired ablation parameters must be set by the user; otherwise, the default values will be used.
- Caution should be taken when placing lesions in the proximity to the specialized conduction system. Refer to the instructions for use of the manufacturer's Dispersive Indifferent Patch (DIP). Refer to section 10, Accessories, for recommended DIP electrode(s).
- Standard grounding procedures should be followed.
- The cardiac ablation generator is capable of delivering significant electrical energy. Patient or operator injury can result from improper handling of the catheter and DIP electrode(s), particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces. This can be achieved by placing a non-conductive material between the patient and the

grounded metal surfaces. DIP electrode(s) attachments are to be as close to operating field as possible.

- Position connecting cables such that contact with patient or other catheter, cables or connections is avoided.
- To minimize the possible hazard caused by the summation of leakage currents when several equipments are interconnected, this generator must be connected to the recommended power distribution system.
- Accessory equipment connected to the analog and digital interfaces must comply with the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Additional equipment connected to the signal input or signal output connections comprise a medical system and therefore, must comply with the requirements of IEC 60601-1-1.
- Apparent low power output, high impedance or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrode(s) or failure of an electrical lead. Do not increase the power before checking for obvious defects or improper setup.
- 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 or oxidizing gasses from the surgical site and near the patient.
- Use non-flammable, non-corrosive, gentle cleaning agents for cleaning and disinfection of the generator and accessories.
- This equipment has been tested and found to comply with the limits for medical devices as defined by IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.
- This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 1. Reorient or relocate the receiving device.
 2. Increase the separation between the equipment.
 3. Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
 4. Contact your Biomedical Engineer for help.
 5. Consult the manufacturer for help.

- Inspect reusable cables and accessories regularly and to ensure that they are functional.
- Select lowest possible output power for intended purpose.
- Do not connect items which are not specified as part of the system.
- Follow the system installation to achieve optimal use.

Precautions Specific to the Therapy™ 8mm or SAFIRE™ TX Ablation catheters:

- Two Dispersive Pad electrodes must be used when power levels exceed 50 watts to minimize the potential of skin burns.

Precautions Specific to the Irrigated Catheter:

- When using the irrigated catheter, assess any pump alarms before continuing the procedure. If the Cool Point Irrigation pump alarm sounds (when used with the irrigated catheter), irrigation and RF energy delivery will stop. Communication and flow must be evaluated. Remove and inspect the catheter for damage. Inspect the electrodes for coagulum. If necessary, clean the electrodes with a sterile saline and gauze pad. Ensure that all irrigation ports are patent and that flow is continuous. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. If during this inspection the flow through the catheter is interrupted for any amount of time during the inspection, repeat the initial preparation of catheter and pump by purging the fluid through the catheter and irrigation tubing per standard technique.
- When using the irrigated catheter, inspect the IV tubing for air bubbles and ensure sufficient continuous flow prior to its use in the procedure. Air bubbles may cause emboli. Non-continuous flow may lead to coagulation within and around the distal electrode resulting in blockage of irrigation ports.
- When using Cool Point Irrigation pump with the 1500T9-CP v.1.6 generator, use the recommended interface cables and connectors (refer to Section 10).
- Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Care should be taken when ablating near electrically vulnerable, thin walled tissue or arterial structures.
- Please refer to appropriate catheter IFU for additional precautions to be taken while operating this system.

3.3. Potential Adverse Reactions

Potential adverse events that maybe associated with catheterization and/or cardiac ablation include the following:

- | | |
|--|---|
| • Abnormal vision | • Local hematomas/ecchymosis |
| • Adult Respiratory Distress Syndrome (ARDS) | • Myocardial infarction |
| • Air embolism | • Neck/pain/groin pain |
| • Anaphylaxis | • Obstruction or perforation or damage to the vascular system |
| • Anemia | • Palpitations |
| • Allergic reaction (anesthesia) | • Pericardial effusion |
| • Arrhythmias | • Pericarditis |
| • AV fistula | • Phrenic nerve damage |
| • Cardiac perforation/tamponade | • Pleural effusion |
| • Cardiac thromboembolism | • Pneumonia |
| • Cerebrovascular accident (CVA) | • Pneumothorax |
| • Chest pain/discomfort | • Pseudoaneurysm |
| • Complete heart block | • Pulmonary edema |
| • Component damage to ICD or implantable pacemaker | • Pulmonary embolism |
| • Congestive heart failure/exacerbation | • Radiation injury |
| • Coronary artery spasm | • Respiratory Depression |
| • Death | • Seizure |
| • Dislodgement of implantable cardioverter defibrillator or permanent pacing leads | • Skin burns |
| • Dizziness | • Syncope/near syncope |
| • Endocarditis | • Temporary complete heart block |
| • Esophageal injury (fistula) | • Thrombi |
| • Exacerbation of pre-existing atrial fibrillation | • Thromboembolism |
| • Expressive aphasia | • Transient ischemic attack (TIA) |
| • Heart Failure | • Unintended (in)complete AV, sinus node or other heart block or damage |
| • Hemothorax | • Valvular damage/insufficiency |
| • Hypoxia/shortness of breath | • Vascular bleeding |
| • Increased phosphokinase level | • Vasovagal reactions |
| • Infections/sepsis | • Ventricular tachycardia |
| • Laceration | • Worsening chronic obstructive pulmonary disease |

Please refer to appropriate catheter IFU for additional adverse reactions while operating this system.

SECTION 4. Operating States, Controls and Indicators

4.1. Operating States

Please refer to Appendix A for State Transitions Table.

4.1.1. Edit State

The EDIT state allows the user to change the power level, the temperature set point, the impedance high limit, and the ablation time. The new values are displayed and retained internally while the generator power is on. Refer to Table 1 for operating parameters. With the Cool Point™ Irrigation Pump connected, the CLEAR/PUMP START key initializes the communication between the pump and the generator.

In EDIT state press the START key, start the RF delivery (ABLATION state).

4.1.2. Monitor State

The MONITOR state continuously displays the current temperature and impedance measurements. The Time displays the code "P1", while the Power display window displays dashes (power not activated). While in the MONITOR state the PID setting can be accessed. When the SETUP/TEST key is pressed, a PID setting is displayed. The PID is the temperature control algorithm using Proportional (P), Integral (I), and Derivative (D) values between measured and target temperatures. The PID setting (1-7) will adjust the ramp time for reaching the target temperature (1 being slowest and 7 being fastest). Refer to Table 1 for PID setting and the default value for a respective catheter. Pressing SETUP/TEST key again will return the generator to the EDIT state.

4.1.3. Ablation State

The ABLATION state is the state where RF energy is delivered. The power level, temperature measurement, impedance measurement, and ablation time are displayed. Press and hold the CLEAR/PUMP START key or STOP/RESET key to stop the ablation.

If the Cool Point™ Irrigation Pump is connected and initialized, pressing the START key in the EDIT state starts a programmed countdown and the pump flow rate changes from 2mL/min to 13 mL/min. The countdown is displayed on the Time display and Impedance and Temperature continue to be monitored and displayed. Pressing and holding the CLEAR/PUMP START key or STOP/RESET key during the countdown aborts the cycle prior to ablation and no energy is delivered. If the keys are not pressed during the countdown, the generator enters the ABLATION state. When ablation is stopped, the pump returns to basal rate (2 mL/min) after programmed delay and the RESULTS state will display average readings of measurement. The generator continues to monitor Impedance and Temperature during the countdown.

Refer to Table 1 for more information regarding the programmed delay.

4.1.4. Results State

The RESULTS state is entered automatically when the ABLATION state is exited without error or when the STOP/RESET or the CLEAR/PUMP START key is pressed. While the Cool Point™ Irrigation Pump is connected and after a programmed countdown on the Time display, the pump flow rate changes from 13mL/min to 2 mL/min and the generator enters the RESULTS state. The RESULTS state displays the average power delivered, the average temperature attained, the average impedance measured, and the total ablation time.

4.1.5. Error State

The ERROR state is entered whenever any measured generator parameter (impedance, temperature, power) crosses its respective minimum or maximum operating range. When an error occurs the RF energy delivery (ablation) stops. The error message is displayed alternating with the error value flashing with an audible tone. The CLEAR/PUMP START key also flashes red.

While the Cool Point™ Irrigation Pump is connected, the error message displays non-flashing simultaneously with a programmed countdown displayed on the Time display and an audible tone. The pump flow rate changes from 13mL/min to 2 mL/min and the generator enters the ERROR state. The error message will then be displayed alternating with the error value flashing with an audible tone. The CLEAR/PUMP START key will also be flashing in red.

CONTROLS AND INDICATORS

4.2. 1500T9-CP v.1.6 Generator Front Panel

Please refer to Appendix A for State transitions table.

The front panel controls provide the ability to change operating states, select parameter values, start and stop the delivery of RF energy, clear the error message and initialize communication with the Cool Point™ Irrigation Pump (if connected).

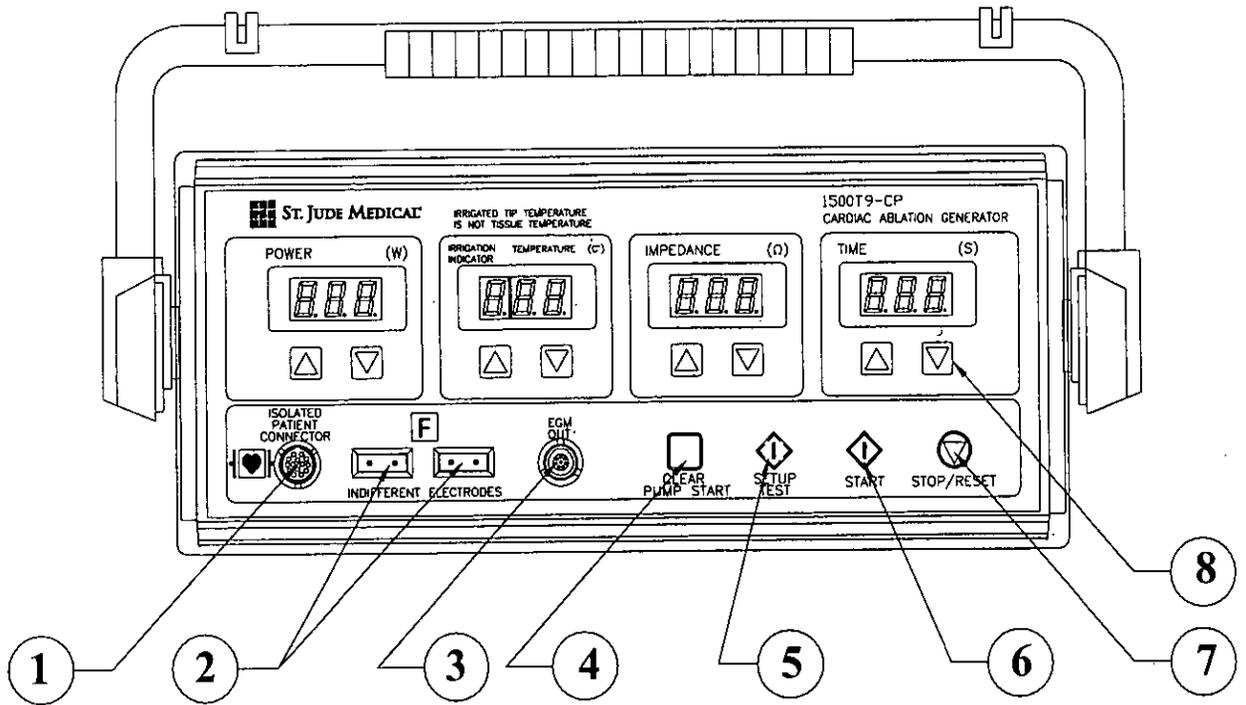


Figure 1: Front View of the 1500T9-CP v.1.6 RF Generator

1. Patient Isolated Connector
2. Indifferent Electrode Connectors
3. EGM output Connector
4. Clear/ Pump Start Key
5. Setup/test Key
6. Start Key
7. Stop/reset Key
8. Up and Down Keys

4.2.1. Clear/Pump Start Key

The operation of this key is dependent on the operating state as shown in Appendix A. If the key is pressed while the generator is in EDIT state, “P-P” is shown in the Time display, indicating the generator is looking for a Cool Point™ Irrigation Pump. Once the Cool Point™ Irrigation Pump is detected, communication between pump and generator is initialized.

If the key is pressed while in ABLATION state, the ablation session is ended. The programmed countdown is displayed on the Time display window. The pump flow rate changes from 13mL/min to 2 mL/min. Temperature and impedance are monitored and the generator enters the RESULTS state.

If the key is pressed while in the RESULTS state the generator enters the EDIT and displays the user selected settings. If pressed while in the ERROR state the generator enters the RESULTS state.

4.2.2. Setup/Test Key

The operation of this key is dependent on the operating state as shown in Appendix A.

4.2.3. Start Key

The operation of this key is dependent on the operating state as shown in Appendix A. Pressing the key initiates the delivery of RF energy.

4.2.4. Stop/Reset Key

The operation of this key is dependent on the operating state as shown in Appendix A. Pressing the Stop/Reset key allows the delivery of RF energy to be stopped. Pressing this key during ablation stops power output even if the footswitch is depressed. If the key or footswitch is pressed again, the generator enters the EDIT state and displays user selected settings. Pressing and holding the Stop/Reset key while the Cool Point™ Irrigation Pump is connected during the programmed countdown causes the RESULTS screen to display briefly. The generator then enters the EDIT state.

4.2.5. Arrow keys ▲/▼

Arrow keys allow the user to adjust the value of the specified parameter up and down. The parameters that can be adjusted by the user are:

- Power (Watts)
- Temperature (°C)
- Impedance (Ω)
- Time (Seconds)
- PID
- Flow delay (Seconds)

The minimum and maximum possible values for each parameter, along with incremental values, are shown in the table 2.

Each time the selected arrow key is depressed the displayed value changes by one incremental value. Pressing and holding the selected key changes displayed value until the key is released or the limit (minimum or maximum) is reached.

4.2.6. Temperature Display

Temperature is displayed in degrees Celsius. The output power of the generator will shut off if the measured temperature exceeds 80°C or if the measured temperature exceeds the user-selected temperature set point by more than 5°C for more than 3 seconds, an “EE” error message displays and RF delivery shuts down. When a Cool Point™ Irrigation Pump is connected and the “EE” error message occurs (non flashing), a programmed delay on the Time display, an audible tone is initiated and the pump flow rate changes from 13mL/min to 2 mL/min. The “EE” message alternates with the value causing the error, displayed flashing and with a faster rate audible tone. The light of CLEAR/PUMP START key will also be flashing in red.

4.2.7. Power Display

Power will be displayed in Watts. Power level can be changed in 1 Watt increments. If the power exceeds the maximum selected limit a “PE” error message is displayed (non flashing) and power delivery is terminated. When a pump is connected and the error occurs, a programmed delay begins on the Time display, an audible tone is initiated and the pump flow rate changes from 13mL/min to 2 mL/min. The “PE” error message alternates with the value causing the error, displayed flashing and with a faster rate audible tone. The light of CLEAR/PUMP START key will also be flashing in red.

4.2.8. Impedance Display

Impedance is displayed in Ohms. Impedance level can be changed in increment of 1 Ohm. If the impedance exceeds the maximum limit or drops below the minimum limit or exceeds the user selected limit, an error message shall be displayed. “HI” is displayed if the upper limit is exceeded and “LO” for the lower limit. The error message (“HI” or “LO”) is displayed (non flashing) and power is terminated. When a pump is connected and the error occurs, a programmed delay begins on the Time display, an audible tone is initiated and the pump flow rate changes from 13mL/min to 2 mL/min. The displayed error message will then alternate with the value causing the error, displayed flashing and with a faster rate audible tone. The light of CLEAR/PUMP START key will also be flashing in red.

4.2.9. Time Display

Time is displayed in seconds. Time can be changed in 1-second increments.

4.2.10. Patient Isolated Connector

The patient isolated connector is a fourteen-pin Redel connector for connecting the catheter to the generator.

4.2.11. EGM Output Connector

The EGM output connector is an eight-pin dual key Redel connector for connecting to EP monitoring system to display the intracardiac signal.

4.2.12. Indifferent Electrode Connectors

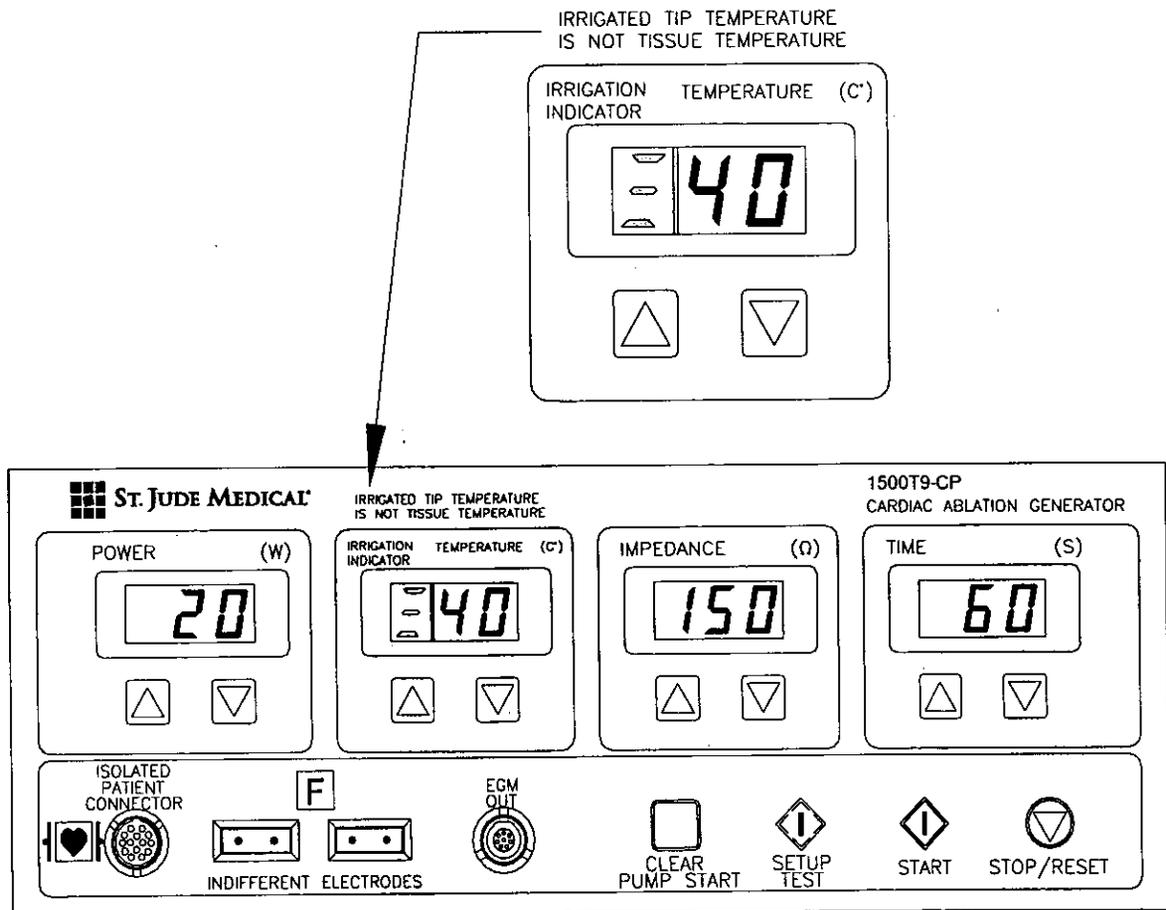
Neutral Electrode “Floating Output” is isolated from earth potential. The indifferent electrode connectors are 2-pin connectors for connecting the generator to the DIP electrode(s).

NOTE: Two pads must be used for power setting greater than 50 watts. Power setting greater than 50 Watts is allowed only with specific catheters as indicated in Table 1.

4.2.13. Irrigation Indicator

When the irrigated catheter is attached to the generator, temperature will be displayed preceded by yellow “≡”. When the communication between the generator and Cool Point™ Irrigation Pump is initiated by pressing CLEAR/PUMP START key then temperature will be displayed preceded by flashing yellow “≡”.

Note: The temperature shown on the generator’s temperature display is not the temperature of the tissue being ablated. It is the temperature of the cooled electrode only and does not represent tissue temperature.



4.3. 1500T9-CP v.1.6 Rear Panel

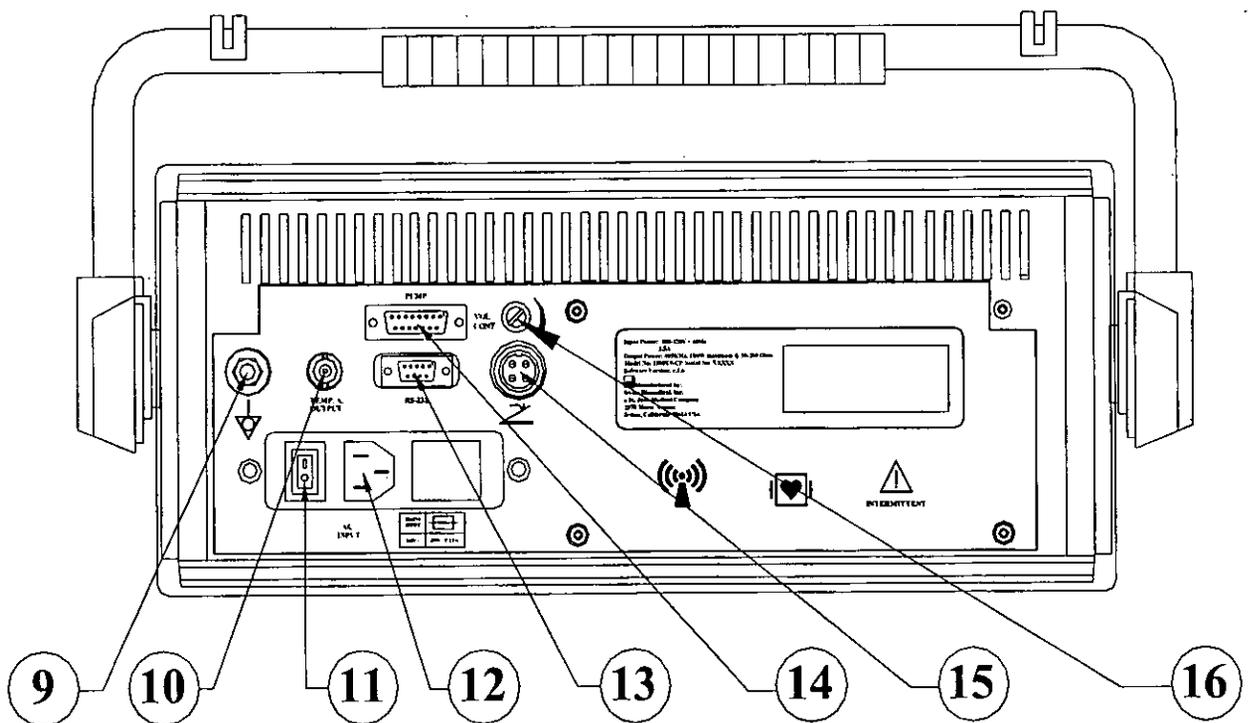


Figure 2: Back View of the 1500T9-CP v.1.6 RF Generator

- 9. Equipotential Ground Stud
- 10. BNC Connector , Temperature Analog Output
- 11. Power Switch
- 12. AC Power Inlet
- 13. EP Recording Monitor Connector
- 14. Pump Communication Connector
- 15. Footswitch Connector
- 16. External Volume Control Knob

4.3.1. Main Power Switch

Turn the generator On by depressing the rocker switch to the “|” position. Returning the rocker switch to the “O” position will turn the main power supply Off.

4.3.2. Serial Port (RS-232)

A serial port is provided for computer interface for an RS-232 cable port connection (DB9 Female Connector). Refer to **Initial Installation** in Section 5.5

4.3.3. Serial Port (PUMP)

A serial port is provided for pump interface to serve as a serial port cable connection (DB15 Female Connector). Refer to **Initial Installation** in Section 5.7.

4.3.4. Footswitch Cable Connector

This connector connects the footswitch to the generator. The footswitch controls start and stop of the generator in the same manner as the front panel controls.

When the footswitch is pressed and **held down**, it will initiate the delivery of RF energy for ablation.

When the Cool Point™ Irrigation Pump is connected to the generator and the footswitch is utilized, a programmed countdown is displayed in the Time display window before RF delivery begins and after RF delivery is completed. The pump flow rate changes from 13mL/min to 2 mL/min, temperature and impedance are monitored, and the generator enters the RESULTS State. If the footswitch is pressed and released during RESULTS State, the generator enters the EDIT State with user selected settings displayed.

4.3.5. Power Entry Module and Fuses

Power entry module is a factory set at 120VAC with 2.5Amp slow Blow Fuses. See Section 8 for further information.

4.3.6. Equipotential Ground

Provided for connecting the generator's ground via grounding cable catalog # 1710 to the EP monitor's ground.

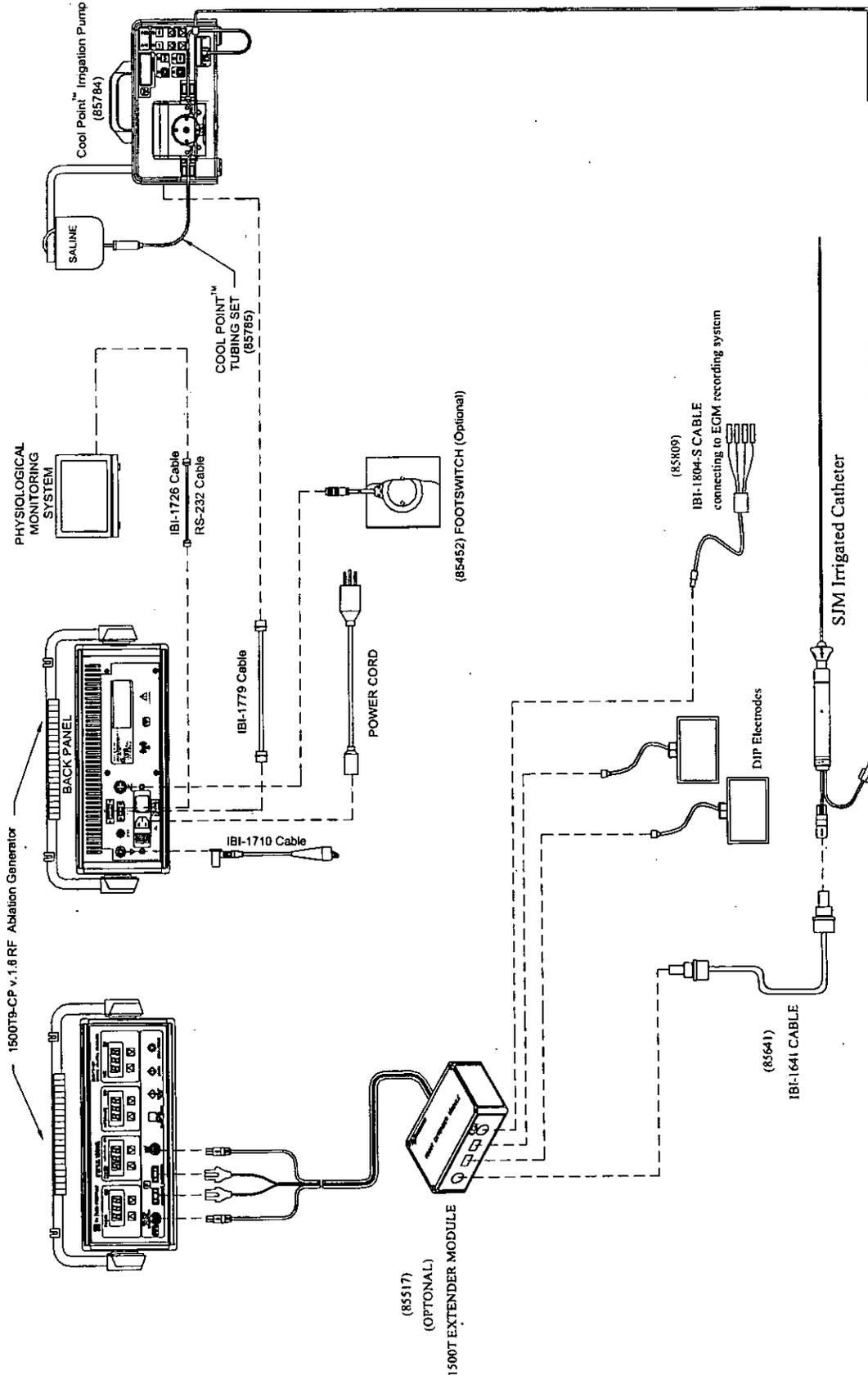
4.3.7. Temperature Analog Output

Provides direct connection to an electrically isolated general purpose recorder or monitor that complies with the requirements of IEC standards (i.e. 60950 for data processing equipment and IEC 60601-1 and 60601-1-1 for medical equipment), using a standard BNC connector to facilitate recording of the catheter measured temperature during delivery of RF power or MONITOR state.

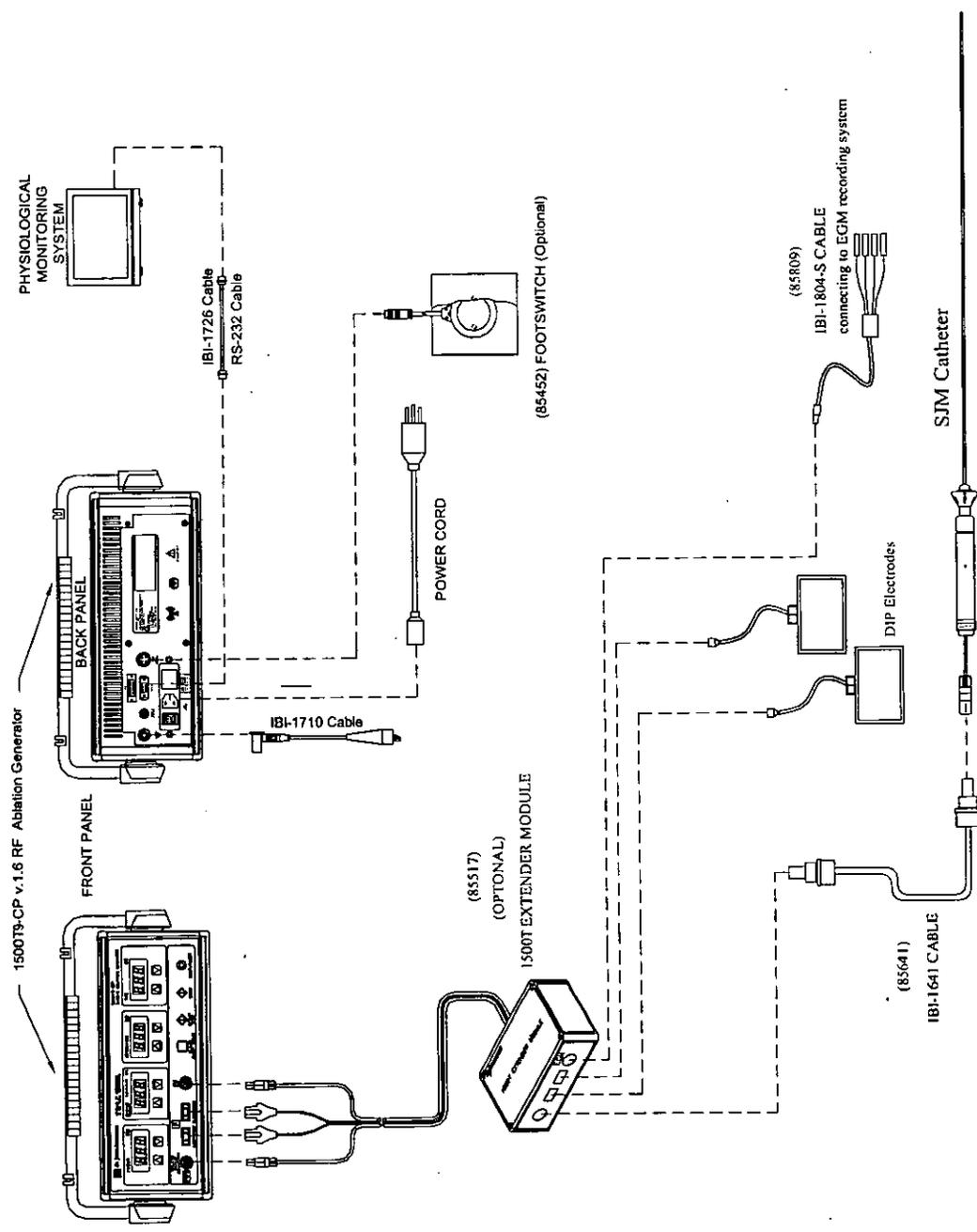
4.3.8. Volume control

This provides the user with volume control for the audible signal that accompanies RF power delivery. To reduce the volumes to minimum level turn the shaft all the way counter-clockwise. To increase the volume, turn the shaft clockwise.

SECTION 5. Operational Sequence Set-up Diagram for Initial Installation/Power Cord & Cable Connection with Irrigated Catheter



Set-up Diagram for Initial Installation/Power Cord & Cable Connection with Non-Irrigated Catheter



Initial Installation of 1500T9-CP v.1.6 Generator and Accessories

- 5.1. Position the generator so that the front display and back panel are easily accessible with special consideration to the physician being able to view the front panel display.
- 5.2. Connect the generator power cord plug into a properly grounded AC electrical outlet. To ensure proper grounding, the Power Cord must be installed to an AC electrical wall outlet designated "Hospital Grade" or "Hospital only."

Never use an outlet without a grounding connection or a power strip.

- 5.3. Use an 1804-S electrogram (EGM) cable to connect from the EGM output on the front panel to an EGM junction box for recording intracardiac signals. Note: The 1500T9-CP v.1.6 Cardiac Ablation System may only be connected to recording systems providing patient electrical isolation in accordance with IEC-60601-2-25. It is necessary that defibrillation protection be provided in the recording system.
- 5.4. Install DIP electrode connector(s) (based upon maximum power for the procedure) into the INDIFFERENT ELECTRODE I and/or II receptacles on the front panel of the RF ablation generator. Gently push the DIP electrode-fitting straight in until it is firmly in place. To unplug, grasp the DIP electrode(s) fitting and gently pull it out of the receptacle. Refer to accessory list for the recommended DIP electrode(s).

Caution: Do not disconnect the DIP Electrode(s) Connector by pulling on its cable.

- 5.5. If desired, connect the generator to a PC compatible computer through the Serial Port by an RS-232 (DB9) cable. Secure the RS-232 cable to the generator port with the connector thumb screws.
- 5.6. **Operation of 1500T9-CP v.1.6 Generator with either Therapy™ or Therapy™ Dual 8™ Catheter or SAFIRE™ TX Catheter:**

Remove the catheter from its packaging using standard practice and inspect catheter integrity. Connect the catheter to the 1641 connecting cable and the cable to the socket labeled ISOLATED PATIENT CONNECTOR on the generator front panel by matching the color-coded connectors. Gently line up the connector pins with the socket and push in until the connector fits firmly into the socket.

Turns the generator power switch located on the back panel to On and allow it to run through the self-check mode. The generator briefly displays the software version before the self-test. There is a delay of approximately 6 seconds before the generator panel displays the default settings, after which the system automatically enters the EDIT State. Default settings are 20 W, 50 degrees Celsius, 150 ohms and 60 seconds. Enter the desired ablation parameters before proceeding; otherwise the default settings will be used.

Table 1 Operating Parameters

| Ablation Catheter | Ablation Power (W) | | Ablation Time (SEC) | | Flow rate (mL/min) | Program Delay (Sec) | | PID setting | | Temperature (°C) | | Impedance (Ω) | |
|--|--------------------|---------|---------------------|---------|----------------------|---------------------|---------------|---------------|---------------|------------------|---------|---------------|---------|
| | Maximum | Default | Maximum | Default | | Range | Default | Range | Default | Maximum | Default | Maximum | Default |
| Therapy™ Dual 8™ and SAFIRE™ TX | 100 | 20 | 200 | 60 | N/A | N/A | N/A | 1-7 | 4 | 80 | 50 | 300 | 150 |
| Therapy™ 4mm | 50 | 20 | 200 | 60 | N/A | N/A | N/A | 1-7 | 4 | 80 | 50 | 300 | 150 |
| Therapy™ 4mm with thermistors | 50 | 20 | 200 | 60 | N/A | N/A | N/A | 1-7 | 4 | 80 | 50 | 300 | 150 |
| Therapy™ Cool Path™ and SAFIRE™ BLU™ | 50 | 20 | 120 | 60 | 2 mL/min 13mL/min | Fixed value 3 | Fixed value 4 | Fixed value 4 | Fixed value 4 | 50 | 50 | 300 | 150 |
| Therapy™ Cool Path™ Duo and SAFIRE™ BLU™ Duo | 50 | 20 | 420 | 60 | 2 mL/min 13mL/min | 1-3 | 3 | Fixed value 7 | Fixed value 7 | 45 | 40 | 300 | 150 |

5.6.1. Preparing the Generator for Ablation

5.6.1.1. Select Power Level Parameter

The default limit for power is set at 20 Watts. The power may be set from 1 to 100 Watts (depending on the catheter in use). Refer to Table 1 for additional information. Use the POWER ▲/▼ Keys to select the desired power setting.

Note: The power level can also be adjusted up or down during the ablation.

POWER Display: This display continuously shows the RF power delivered during ablation.

5.6.1.2. Select Temperature Parameter

The default temperature is set at 50°C. The temperature may be set from 15 °C to 80 °C. Use the TEMPERATURE ▲/▼ Keys to select the desired temperature setting.

Note: The desired target temperature can also be adjusted up or down during the ablation.

TEMPERATURE Display: This display will continuously show the measured temperature.

5.6.1.3. Select Impedance Parameter

The default upper limit for Impedance is set at 150 Ohms. The impedance may be set from 50 to 300 Ohms. Use the IMPEDANCE ▲/▼ Keys to select the desired impedance upper limit.

IMPEDANCE Display: This display will show the measured impedance. If a sudden increase of impedance is detected, stop ablation and remove catheter from patient. Check catheter electrodes for coagulum.

Note: If the impedance value exceeds 300 Ohms or the user selected setting, the generator automatically terminates RF power and the message “HI” is shown in the IMPEDANCE display window, alternating with the high value (maximum of 330 ohms). An impedance value less than 50 Ohms also cause the generator to automatically terminate RF power and the message “LO” is shown in the IMPEDANCE display window, alternating with the low value.

5.6.1.4. Select Time/Duration Parameter

The default duration is set at 60 seconds. The time may be set from 1 second to 200 seconds. Use the TIME ▲/▼ Keys to select the desired duration.

TIME Display: When the START Key is firmly pressed or the Footswitch is depressed and held down, this display changes from the user pre-set time limit to 0 second and begin to count up to the user selected value. When the preset duration has elapsed, the RF power will automatically shut “OFF”. If the STOP Key is pressed during delivery of RF power or the Footswitch is released, the RF power output will immediately turn “OFF”. The elapsed time in seconds will appear flashing on the TIME Display.

Note: Holding the $\blacktriangle/\blacktriangledown$ Key down will cause the set point to scroll up rapidly. When scrolling Time up or down for non-irrigated catheters, the values will increment by 1 when it is between 1 and 59 seconds, and increment by 10 when it is above 59 seconds. When the desired set point is shown, release the key.

5.6.1.5. PID SELECT

Regardless of the catheter type used, the PID SELECT is entered by pressing the SETUP/TEST key while in the Monitor state. Additional control shall adjust the responsiveness of the PID temperature control algorithm, refer to Table 1. The PID setting (1-7) will adjust ramp time for reaching the target temperature. The Time field displays a number from 1 to 7. This value is the ramp with “1” being the slowest and “7” being the fastest. To adjust the PID setting use up and down ($\blacktriangle/\blacktriangledown$) arrow keys on the time display.

Pressing START or the footswitch will transfer to Ablation State.

5.6.1.6. Catheter Positioning

Place the catheter in the target area within the patient and set the generator to the desired therapeutic settings on the front panel by pressing the arrow keys under displays.

NOTE: Press “SETUP/TEST” key to enter monitor mode and check the real-time impedance value to ensure it is at a desired level prior to RF delivery

5.6.2. Initiating Ablation

To ablate, press the “Start” key on the generator or press and hold footswitch. The START KEY is illuminated and an audible tone will sound to indicate the RF Power is being delivered. It remains illuminated until RF power delivery is discontinued.

5.6.3. RF Power Termination

RF power is terminated by any of the following:

- Reaching the user selected time duration
- Firmly pressing the STOP/RESET Key or releasing the footswitch.

- Turning off the generator via the rocker switch and/or dislodging the power cord.
- Disconnection of the patient cable or indifferent electrode connection.
- Exceeding the preset impedance limit or dropping below 50 ohms.
- Exceeding the selected limit of target temperature by more than 5°C for more than 3 seconds.
- Temperature below 15° C or above 80° C.

5.7. Operating the 1500T9-CP v.1.6 Generator with the Irrigated Catheter and the Cool Point™ Irrigation Pump:

Connect the generator to Cool point Irrigation pump through the interface cables (IBI P/N 1779) refer to system setup diagram section 5.

Caution: Secure the cable to the generator and pump with the connector thumbscrews to prevent loss of communication during use.

5.7.1. Catheter Preparation / Pump Set-up/Priming

- 5.7.1.1. Remove the catheter from its packaging using standard practice and inspect catheter integrity.

CAUTION: *Prior to inserting the catheter into the patient, purge all the air through the IV tubing and the catheter lumen. Entrapped air bubbles may cause emboli. Patient should be closely monitored during the post-ablation period for clinical manifestations of infarction and stroke.*

- 5.7.1.2. Attach pump tubing to saline bag.
- 5.7.1.3. Fill and vent the irrigation tubing set.
- 5.7.1.4. Feed tubing through the pump as instructed by Cool Point Irrigation pump operator's manual.
- 5.7.1.5. Attach the Irrigated Catheter to the tubing. ***(Do not insert the catheter into the patient.)*** It is recommended that the pump tubing be connected to the irrigated catheter for full-tubing priming.
- 5.7.1.6. Turn on the power to the pump.
- 5.7.1.7. Press the prime key on the pump twice in less than two seconds. Priming will begin. Visual inspection is required to ensure all air bubbles are purged from the line and irrigation fluid is dripping from the distal end of the irrigated catheter. Continue priming if it's needed.
- 5.7.1.8. Press the pump LOW FLOW key after priming ends. Pump starts irrigation at a flow rate of 2mL/min.
- 5.7.1.9. **Connect the Catheter and Turn Generator "On".**

Connect the catheter to the generator via appropriate connecting cable. Connect the cable to the socket labeled ISOLATED PATIENT CONNECTOR on the generator front panel by matching the color-coded connectors. Line up the connector pins with the socket and gently push in until the connector fits firmly into the socket.

Turn On the generator power switch (which is located on the back panel) and allow it to run through the self-check mode. The generator will briefly display the software version before the self-test. There will be approximately a 6 second delay before the generator panel displays the default settings after which the system automatically enters the EDIT State. Default settings are 20 watts, 50 or 40 degrees Celsius based on the catheter's type (refer to Table 1), 150 ohms and 60 seconds. The "≡" LED (IRRIGATION INDICATOR LED) will be displayed to indicate an irrigated catheter is connected. Enter the desired ablation parameters before proceeding; otherwise the default settings will be used.

- 5.7.1.10. Press "Clear/Pump Start" key on the front panel of the generator.

If "Clear/Pump Start" is pressed while in EDIT State, "P-P" is shown for 3 seconds in the Time display, indicating the generator is looking for a Cool Point™ Irrigation pump. With the Cool Point™ Irrigation pump connected, turned on and primed, the communication green LED on the pump will light up and the irrigation indicator "≡" LED will illuminate and flash on the generator's front panel. The pump LED displays "2 mL/min". This indicates that the initial communication has taken place. In the generator temperature display window, the desired set temperature or default temperature value is preceded by a flashing "≡". Verify flow through the distal tip.

Note: If communication LED does not light up on the pump display, turn off the generator and pump. Check ALL connections between the generator and the pump then repeat steps 5.7.1.1 through 5.7.1.10.

5.7.2. Preparing the Generator for Ablation

- 5.7.2.1. Select Power Level Parameter

The default setting for power is set at 20 Watts. The power may be set from 1 to 50 Watts based on the catheter's type (refer to Table 1). Use the POWER ▲/▼ Keys to select the desired power setting.

Note: The power level can also be adjusted up or down during the ablation.

POWER Display: This display continuously shows the RF power delivered during ablation.

- 5.7.2.2. Select Temperature Parameter

The default temperature is set at 40°C or 50°C based on the Catheter's type (refer to Table 1). For example the temperature may be set from 15°C

to 50 °C, when using the Therapy™ Cool Path™ and the Cool Point Irrigation pump. Use the TEMPERATURE ▲/▼ Keys to select the desired temperature setting.

Note: The desired target temperature can also be adjusted up or down during the ablation.

If the Cool Point Irrigation pump is connected and initialized, the temperature is displayed preceded by “≡”. The temperature shown on the generator’s temperature display is the irrigated catheter tip temperature.

TEMPERATURE Display: This display will continuously show the measured temperature.

5.7.2.3. Select Impedance Parameter

The default upper limit for Impedance is set at 150 Ohms. The impedance may be set from 50 to 300 Ohms. Use the IMPEDANCE ▲/▼ Keys to select the desired impedance upper limit.

IMPEDANCE Display: This display shows the measured impedance. If a sudden increase of impedance is detected, stop ablation and remove the catheter from patient. Check catheter electrodes for coagulum.

If the impedance value exceeds 300 Ohms or the user selected setting, the generator automatically terminates RF power and the message “HI” is shown in the IMPEDANCE display window alternating with the high value (maximum of 330 Ohms). An impedance value less than 50 Ohms also causes the generator to automatically terminate RF power and the message “LO” is shown in the IMPEDANCE display window alternating with the low value.

5.7.2.4. Select Time/Duration Parameter

The default duration is set at 60 seconds regardless of the catheter’s type. The time may be set from 1 to 420 seconds, with a maximum of 60 seconds at any single site. Refer to Table .1 for the maximum allowable set duration for respected catheters. During ablation with the irrigated catheter, the generator sounds a long beep (approx. 0.5 seconds) every 60 seconds to indicate that the catheter should be relocated to a new site. Use the TIME ▲/▼ Keys to select the desired duration.

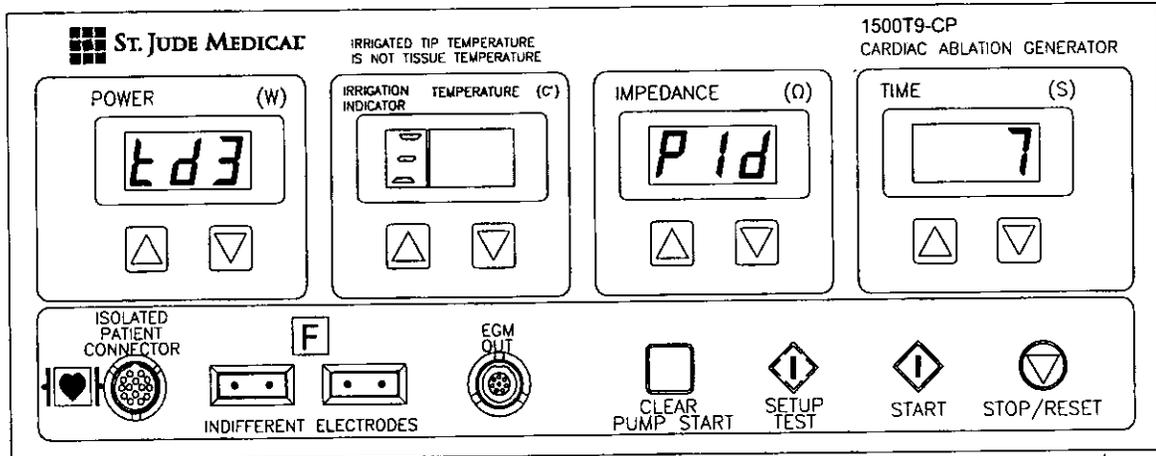
TIME Display: When the START Key is firmly pressed or the Footswitch is depressed and held down, this display changes from the user pre-set time limit to 0 seconds and begins to count up to the user selected value. When the preset duration elapses, the RF power automatically shuts OFF. If the STOP Key is pressed during delivery of RF power or the Footswitch is released, the RF power output immediately turns OFF. The elapsed time in seconds will appear flashing on the TIME Display.

Note: Holding the ▲/▼ Key down causes the set point to scroll up rapidly. When scrolling Time up or down for Therapy™ Cool Path Duo™

Ablation Catheter, or the SAFIRE BLU™ Duo Catheter, the values will increment by 5 from 1 to 29 seconds and by 10 when it is between 30 and 59 seconds. The value will increment by 30 from 60 seconds and above. When the desired set point is shown, release the key.

5.7.2.5. PID and Time Delay Adjustment

PID SELECT is entered by pressing the SETUP/TEST key while in the Monitor state. Following front panel picture shows the PID Display for Therapy™ Cool Path Duo™ Ablation Catheter, or the SAFIRE BLU™ Duo Catheter.



PID is fixed at 7 while Therapy™ Cool Path™ Duo Ablation Catheters or SAFIRE BLU™ Duo Catheters is utilized. The ablation delay is set at 3 seconds default (td3), and can be selected from 1 (td1), 2 (td2), or 3(3d3) seconds. To adjust ablation delay setting use up and down ($\wedge/\blacktriangledown$) arrow keys on the POWER display.

PID is fixed at 4 while Therapy™ Cool Path™ Ablation Catheters or SAFIRE BLU™ Catheters is utilized and ablation delay is fixed at 3 seconds.

NOTE: Ablation Delay adjustments accessible only if Therapy™ Cool Path™ Duo Ablation Catheter or SAFIRE BLU™ Duo Catheter is utilized.

Pressing START or the footswitch will transfer to Ablation State.

5.7.3. RF Application

Place the catheter in the target area within the patient and set the generator to the desired therapeutic settings on the front panel by pressing the arrow keys under displays.

Note: Press the SETUP/TEST key to enter the monitor mode and check the real-time impedance value to ensure it is at a desired level prior to RF delivery.

- 5.7.3.1. To ablate, press the START key on the generator or press and hold footswitch.
- 5.7.3.2. The pump will automatically deliver saline at a rate of 13mL/min for programmed delay (refer to Table 1) before the ablation therapy begins. The real-time temperature and impedance are displayed during the programmed countdown prior to RF delivery. Upon completion of the countdown, the START key is illuminated and an audible tone sounds to indicate the RF Power is being delivered. The START key remains illuminated until RF power delivery is terminated.
- 5.7.3.3. Ablation at any single site shall be limited to a maximum of 60 seconds and catheter repositioning is required if the duration is set to longer than 60 seconds.
- 5.7.3.4. When the energy delivery is terminated the pump continues to deliver saline at 13 mL/min for the programmed delay. The generator displays real-time temperature and impedance, and a new programmed countdown is displayed. After the programmed countdown is complete, the pump returns to the baseline flow rate of 2mL/min. The generator displays average values of power, temperature, and impedance.

5.7.4. RF Power Termination

RF power is terminated by any of the following:

- Reaching the user selected time duration
- Firmly pressing the STOP/RESET Key or releasing the footswitch.
- Turning off the generator via the rocker switch and/or dislodging the power cord.
- Disconnecting the patient cable or indifferent electrode connection.
- Exceeding the preset impedance limit or dropping below 50 ohms.
- Exceeding the selected limit of target temperature by more than 5°C for more than 3 seconds.
- Reaching a temperature below 15° C or above 80° C.
- Triggering a pump alarm (PAL)

5.8. Catheter Type

Compatible Catheters

The generator recognizes the catheters in the list below:

- Therapy™ Dual 8™ Catheter
- SAFIRE™ TX
- Therapy™ 4 mm
- Therapy™ Cool Path™
- SAFIRE BLU™
- Therapy™ Cool Path™ Duo
- SAFIRE BLU™ Duo

The generator will not operate if a catheter without temperature sensor(s) is connected to the generator. If a temperature sensor catheter is not connected, or the temperature sensor(s) is not recognized, “CA” will be displayed flashing, and the generator will not respond to user commands.

A catheter must be connected and recognized by the generator to resolve the “CA” message. If the “CA” condition occurs during ablation, ablation will stop.

If a catheter is not recognized during ablation and the Cool Point Irrigation pump is at 13 mL/min, the pump flow rate is reduced to 2 mL/min after a programmed countdown. Simultaneously with countdown, a no flashing “HI” impedance or “EE” temperature error message is displayed, depending on which characteristic the generator is detected at time of disconnection. After the countdown, “CA” is displayed flashing in the Power window.

5.9. Changing Catheter Type

- Once a catheter has been connected, any change in catheter (including disconnection and reconnection of the same catheter) results in the following conditions:
- When the same type of catheter is used, the generator retains the most recent settings (power, temperature, impedance and time).
- When one type of catheter is disconnected and a new type of catheter is connected, the generator returns to the power-up default settings (refer to Table 1 for default settings).
- When an irrigated catheter is initially connected, the “≡” LED illuminates. If an irrigated catheter is removed and replaced by a non-irrigated catheter, the generator returns to the power -up default setting.

- Once the generator is powered off the generator returns to power-up default settings.

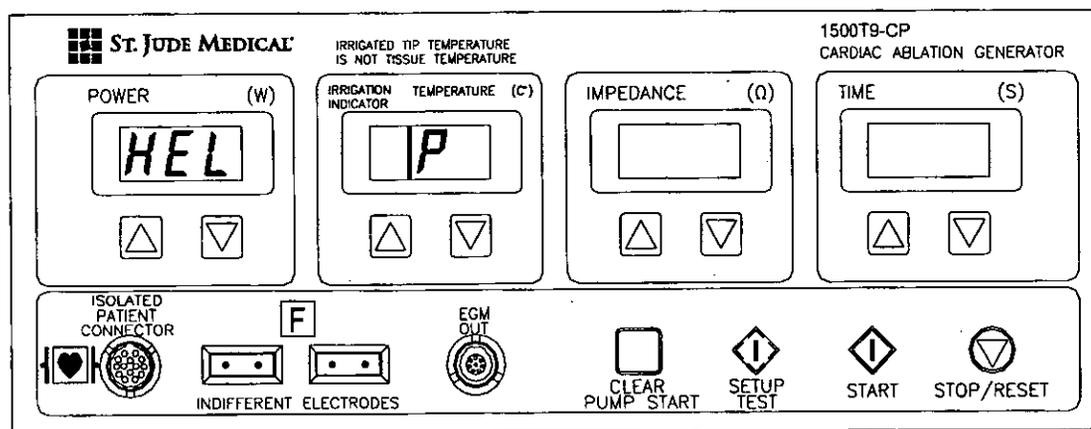
Table 2 Generator Limits by Catheter Type

| Ablation Catheter type | Maximum Power (Watts) | Maximum Temperature Setting (°C) | Maximum Time Setting (Seconds) | Maximum Impedance Setting (Ohms) |
|-------------------------|-----------------------|----------------------------------|--------------------------------|----------------------------------|
| Therapy™ 4 mm | 50 | 80 | 200 | 300 |
| Therapy™ Dual 8™ | 100 | 80 | 200 | 300 |
| SAFIRE™ TX | 100 | 80 | 200 | 300 |
| Therapy™ Cool Path™ | 50 | 50 | 120 | 300 |
| SAFIRE BLU™ | 50 | 50 | 120 | 300 |
| Therapy™ Cool Path™ Duo | 50 | 45 | 420 | 300 |
| SAFIRE BLU™ Duo | 50 | 45 | 420 | 300 |

5.10. ERRORS AND INFORMATION DISPLAYS

5.10.1. Generator display “HELP” on Power and Temperature Window

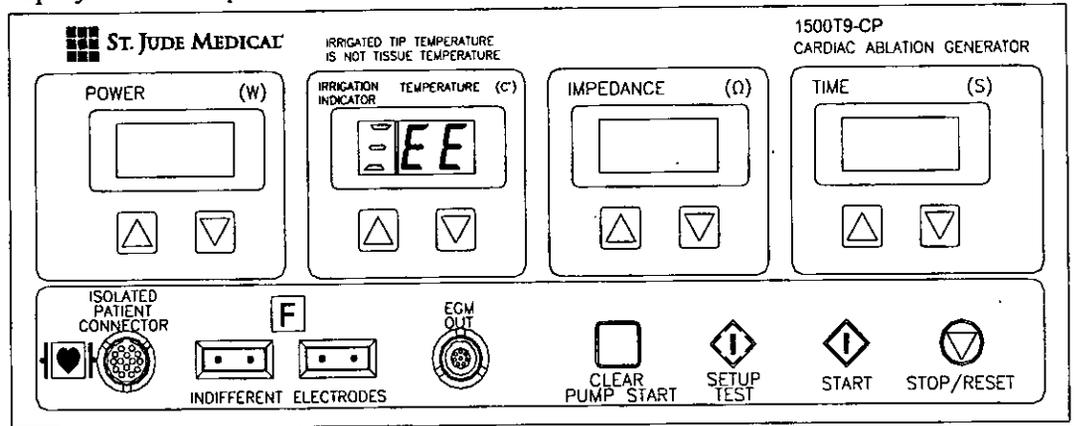
The generator has failed its own internal self-test routines. When this occurs, turn off the generator via the power (rocker switch) and then turn on power (rocker switch). If “Help” display remains contact the manufacturer.



5.10.2. Generator display “EE” on Temperature Window

When a flashing temperature value alternating with “EE” is displayed in temperature window, the temperature has gone out of range during an ablation session. Power delivery is terminated. To correct the error message press the “CLEAR/PUMP START” key twice to advance to the EDIT State. The system displays the user-defined settings. If the “EE” remains, replace the connecting cable and/or catheter. If the “EE” is

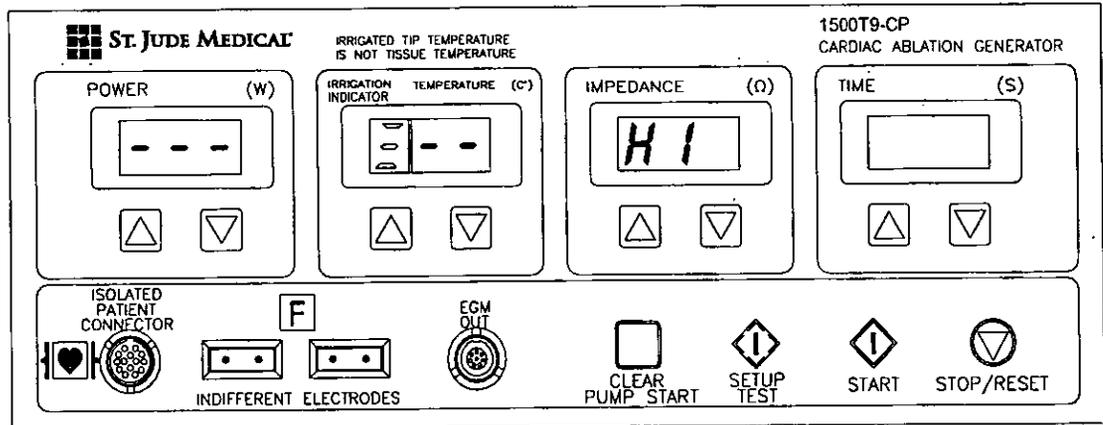
displayed after replacement, contact the manufacturer.

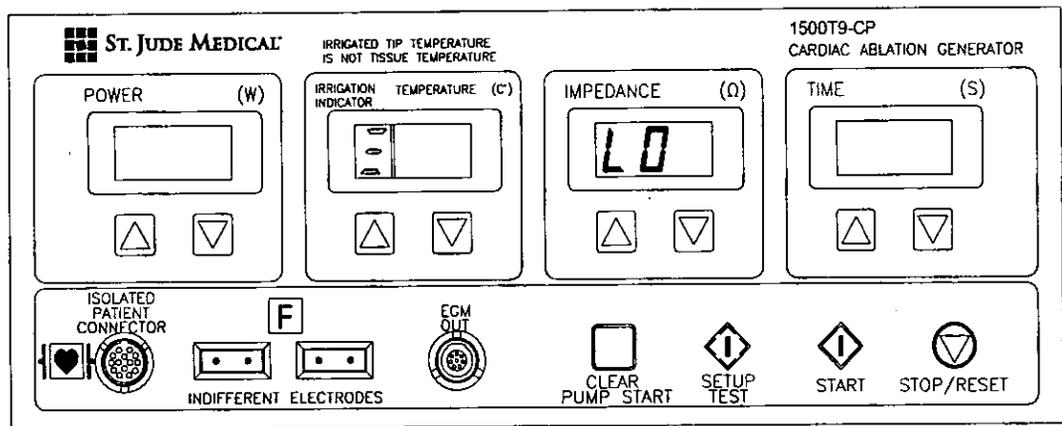


When the Cool Point Irrigation Pump is connected, and the “EE” error message is displayed (non flashing) simultaneously with a programmed countdown on the Time display window, the generator sounds an audible tone and the pump flow rate changes from 13 mL/min to 2 mL/min. The “EE” message alternates with the value causing the error, displayed flashing and with a faster rate audible tone. In addition, the CLEAR/PUMP START key light will also be flashing red.

5.10.3. Generator display “HI” or “LO” on Impedance Window

Impedance is continuously measured during ablation. If the measured impedance is below 50Ω or above the user’s set maximum, a “LO” or “HI” error message is displayed in the impedance window and power delivery is terminated. To correct the error message press the “CLEAR/PUMP START” key twice to advance to EDIT State. Confirm the connection between the DIP electrode(s)/generator and/or the DIP electrode(s)/patient. When error is cleared the generator displays the user previous setting.



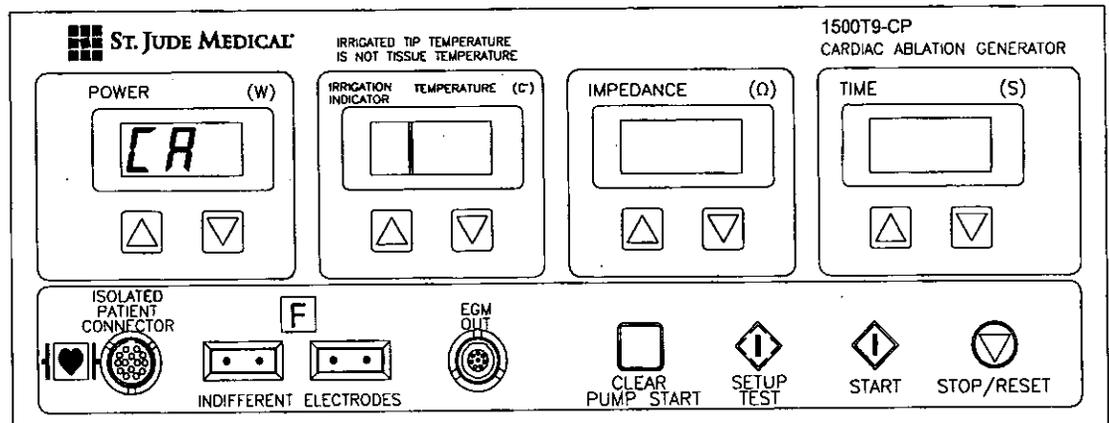


When the Cool Point Irrigation pump is connected and the “HI or LO” error message is displayed (non flashing) simultaneously with a programmed countdown on the Time display window. The generator sounds an audible tone and the pump flow rate is changed from 13 mL/min to 2 mL/min. The “HI or LO” message alternates with the value causing the error, which is displayed flashing and with an audible tone. The CLEAR/PUMP START key light flashes red. To correct the error message press the “CLEAR/PUMP START” key twice to advance to EDIT State. Confirm the connection between the DIP electrode(s)/generator and/or the DIP electrode(s)/patient. When the error is cleared the generator displays the previous user setting.

5.10.4. Generator display “CA” on Power Window

If the catheter is disconnected or the interconnect cable is faulty, a “CA” display appears in the power window.

Reconnecting the catheter and/or replacing the cable return the generator to the EDIT state and display the user previous setting.



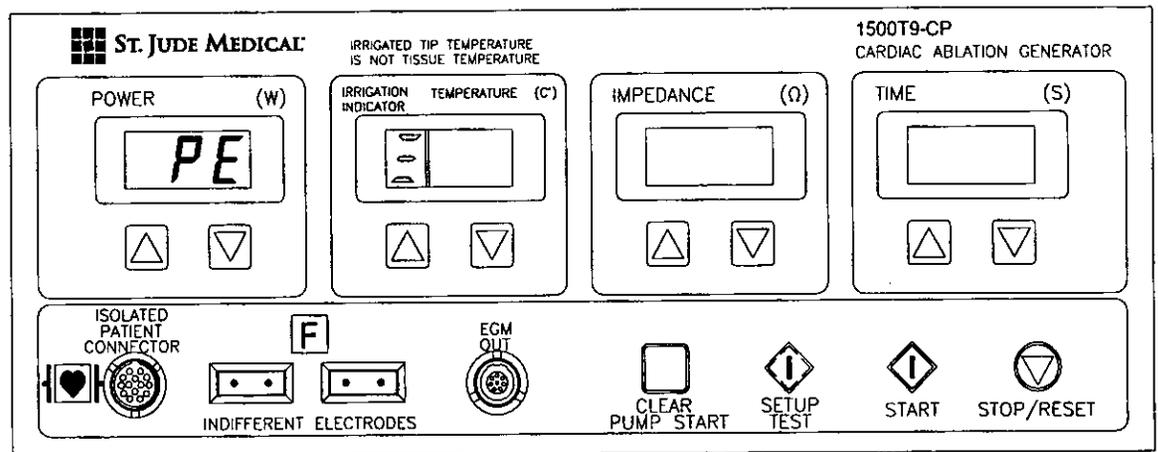
The generator will not operate if a catheter without a temperature sensor is connected to the generator. If a temperature sensor catheter is not connected, or if the temperature sensor is not recognized, “CA” is displayed flashing, and the generator does not respond to user commands. If this occurs, check that all catheter connections are secure. If “CA” is still displayed, replace the catheter.

If the "CA" condition occurs during ablation, RF energy is terminated.

If a catheter is not recognized during ablation and the Cool Point Irrigation pump is at 13 mL/min, the pump flow rate is reduced to 2 mL/min after a programmed countdown. Simultaneously, the generator either displays no flashing "HI" impedance or an "EE" temperature error message, depending on the error detected at time of disconnection. After the programmed countdown, a flashing "CA" message is displayed in the Power window.

5.10.5. Generator display "PE" on Power Window

When a malfunction occurs in the power control circuit, the "PE" error message is displayed and RF delivery is terminated. Contact the manufacturer for service.

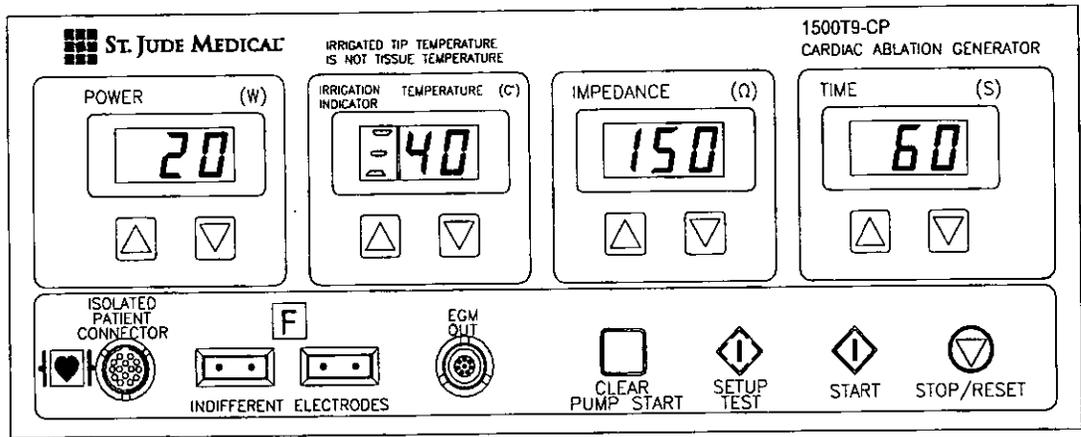


When the Cool Point Irrigation pump is connected, the "PE" error message is displayed (non flashing) simultaneously with a programmed countdown on the Time display with an audible tone and the pump flow rate will be changed from 13 mL/min to 2mL/min. The "PE" message will then alternate with the value causing the error, displayed flashing and with audible tone. The CLEAR/PUMP START light key will also be flashing red. Contact the manufacturer.

5.10.6. Generator Display Irrigation Indicator on Temperature Window

When an irrigated catheter is attached to the generator, temperature is displayed preceded by yellow "≡". After the Cool Point Irrigation pump communication with the generator is initiated (by pressing CLEAR/PUMP START key) temperature will be displayed preceded by flashing yellow "≡".

Note: The temperature shown on the generator's temperature display is not the temperature of the tissue being ablated. It is the temperature of the cooled electrode only and does not represent tissue temperature.

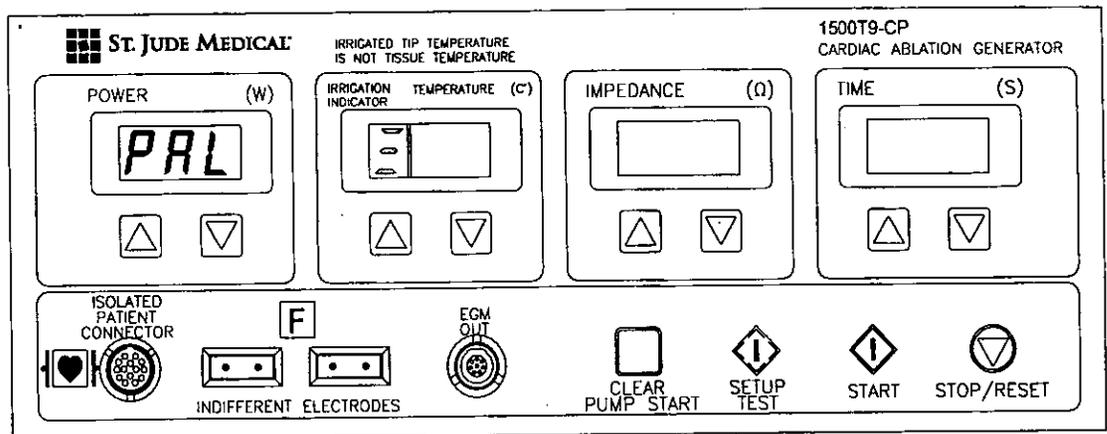


5.10.7. Generator display “PAL” on Power Window

The generator maintains 2-way communication with the pump and receives alarm conditions from the pump. When the Cool Point Irrigation pump is operated in generator controlled mode, a pump alarm condition will occur whenever:

- 1-There is a communication loss between the pump and the generator, or
- 2-When the manual STOP key on the Cool Point Irrigation Pump is depressed, or
- 3-When a pump alarm condition occurs, the generator will stop ablation and display “PAL” And no countdown or pump flow rate change will be performed as the pump alarm triggers the pump to stop the flow.

Pressing the CLEAR/PUMP START key once will put the generator into RESULTS State. Pressing the CLEAR/PUMP START key a second time will put the generator into the EDIT State. If the CLEAR/PUMP START key is pressed a third time, the generator will seek to reestablish communication with the pump. If communication is reestablished, the pump is initialized at the basal rate. If the user clears the pump status message on the generator without resolving the pump alarm, when the START key is pressed, the generator will display “PAL” and will not enter the ABLATION State.



NOTE: If “PAL” is displayed, remove and inspect the catheter. If the flow through the catheter has been interrupted, repeat the initial

preparation of catheter and pump by purging the fluid in the catheter and irrigation tubing using standard technique. Common pump alarms are described below. For other pump alarms refer to the Cool Point Irrigation Pump Instructions for Use.

5.10.8. Cool Point Irrigation Pump displays “OCCL” to indicate downstream occlusion and sounds an alarm

This fault occurs when the pump is running and back pressure is detected. The pump will stop and the generator will display “PAL” on the POWER window and RF energy delivery will stop. Press the silence alarm key then clear key on the pump. Inspect the downstream tubing for kinks and correct, if necessary. Inspect the 3-way stopcock is in open position. Inspect for blockage. Inspect the attached catheter for kinking and follow the catheter’s IFU. To correct the “PAL”, please refer to Section 5.10.7.

If necessary, clean the electrodes with sterile saline and gauze. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. Ensure that the all irrigation ports are patent and that flow is continuous.

5.10.9. Cool Point Irrigation pump displays “Conn” to indicate communication lost with the generator and sounds an alarm

This error will occur when the communication between pump and generator is disrupted. The pump will stop and the generator will display “PAL” on the POWER window and RF energy delivery will stop. Press silence alarm key then clear key on the pump. Inspect the communication cable between Pump and the external device. Make sure that connecting cable (P/N: 1779) thumbscrews are connected securely to the pump and the generator. To correct the “PAL”, please refer to Section 5.10.7

5.10.10. Cool Point Irrigation pump displays “bubd” to indicate an air bubble detected and sounds an alarm

This error occurs when the pump is running in Normal Flow Mode and the sensor detects a bubble. This fault will not occur during priming or when the pump is stopped. Air must be removed from the irrigation tubing. Should this event occur while RF energy is being delivered, the generator will display “PAL” and RF energy delivery will stop. Correct the “PAL”, please refer to Section 5.10.7.

Press SILENCE ALARM key then CLEAR key on the pump. Remove the catheter, reset the alarm. Replace the empty IV bag with a new IV bag, if required, and restart the setup procedure in the PUMP SET-UP/PRIMING section 5.7 by priming the catheter and tubing outside the patient. If necessary, clean the electrodes with a sterile saline and gauze. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. Ensure that the 6 irrigation holes are patent and that flow is continuous.

5.10.11. Cool Point Irrigation pump displays “bubF” to indicate a Bubble Detector Failure error and sounds an alarm

This error occurs if the periodic bubble detector self test detects a failure. Press the SILENCE ALARM key then the CLEAR key on the pump.

Turn the pump power off and on again. If the fault occurs again, contact your local St. Jude Medical Inc. Sales or Customer Service representative. To correct the "PAL", please refer to Section 5.10.7.

5.10.12. Cool Point Irrigation pump displays "door" to indicate a pump door error has been detected and sounds an alarm

This error occurs when the pump is running and the door is opened or the pump is not running, the door is open and the user attempts to run the pump by pressing the PRIME key, the LOW FLOW Rate key or the HIGH FLOW Rate key. Press the SILENCE ALARM key then CLEAR key on the pump.

Verify the transparent pump head door is fully closed. To correct the "PAL", please refer to Section 5.10.7.

5.10.13. Cool Point Irrigation pump displays "SPEE" to indicate a Speed error detected and sounds an alarm

This error indicates the pump is not moving within the tolerance of the commanded rate. Press the SILENCE ALARM key then CLEAR key on the pump.

Verify the tubing is loaded properly into the pump. Refer to the Cool Point Irrigation pump operator's manual for the proper tubing set loading instructions. To correct the "PAL", please refer to Section 5.10.7.

5.10.14. Cool Point Irrigation pump displays "PrES" to indicate the Pressure Sensor is not Connected and sounds an alarm

This error occurs when 1) the pump is running and the pressure sensor has been unplugged or 2) the pressure sensor is not plugged in, the pump is not running and the user attempts to run the pump by pressing the PRIME key, the LOW FLOW Rate key or the HIGH FLOW Rate key. This indicates the tubing set may not have been installed. Press the SILENCE ALARM key then the CLEAR key on the pump. Inspect the pressure sensor plug is inserted securely into the receptacle in the pump front panel. To correct the "PAL", please refer to Section 5.10.7.

SECTION 6.

1500T Extender Module (Optional)

The IBI 1500T Extender Module is an optional accessory for 1500T9-CP RF generator system. The IBI 1500T Extender Module provides 20-foot extension connector capability for:

- Isolated Patient Connector
- Two Indifferent Electrode Connectors
- EGM out Connector

The connecting 1641 cable, 1804-S cables, and indifferent electrode pads can be connected to the generator via the IBI 1500T Extender Module 20 feet away from the generator. This provides more flexibility for the generator location in specific EP labs.

NOTE: The IBI 1500T Extender Module adds approximately 10 Ohms to the overall system impedance while it's being utilized.

Installation

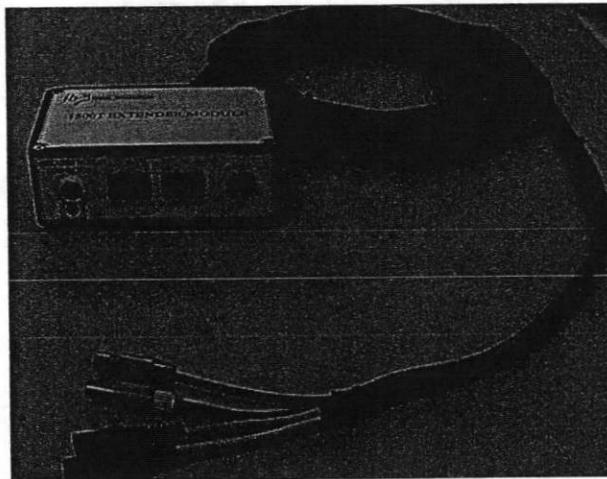
Position the generator so that the front panel displays are easily accessible.

The 1500T Extender Module must be placed on a table ONLY. Connect the yellow connector from the 1500T Extender Module to the socket labeled ISOLATED PATIENT CONNECTOR on the generator front panel. Both the connector and sockets are color-coded yellow. Gently line up the connector pins with the socket and push in until the connector fits firmly into the socket. Refer to Section 5.6 for additional information.

Connect the green connector from the 1500T Extender Module to the socket labeled EGM OUT on the generator front panel. Both the connector and sockets are color-coded green. Gently line up the connector pins with the socket and push in until the connector fits firmly into the socket. Refer to Section 5.3 for additional information.

Connect the two pin connectors from the 1500T Extender Module into the sockets labeled INDIFFERENT ELECTRODE I and II on the front panel of the generator. (Refer to Section 5.4)

Continue the installation beginning at section 5.3 using the 1500T Extender Module front panel in lieu of the generator.



SECTION 7.

TECHNICAL SPECIFICATIONS for 1500T9-CP v.1.6 Generator

| | |
|----------------------|---|
| Supply voltage | 100-120VAC, 60 Hz (U.S.A. and North America) |
| Current rating/ | 2.5A |
| Fuse rating | T2.5A/250V (100-120VAC) (Time Lag) |
| Operating duration | Stand by: Continues until start key or footswitch is activated. Ablation: Continues from 1-420 second maximum and minimum of 30-second standby (no Ablation) before next ablation cycle. |
| Safety class | Class I. defibrillator-Proof Type CF Applied part, IPX0, according to: IEC 60601-1, UL 60601-1, CSA C22.2. No.601.1 IEC 60601-2-2 and CSA C22.2.No.601.2.2 |
| Operating frequency | 485 kHz Maximum peak output voltage is 200V. |
| Operating Parameters | Values are digitally displayed on the generator front panel. Note: Parameters may be further limited by the type of catheter connected (see section 5.12) |

| PARAMETER | Units | Power up Default | Operating Range | Adjustment steps | Accuracy |
|-------------|---------|--------------------|-------------------------|------------------|--------------------------------|
| Time | Seconds | 60 | 1 – (Refer to Table 1) | 1 second | Internal clock |
| Temperature | °C | (Refer to Table 1) | 15 – (Refer to Table 1) | 1°C | ± 3°C* |
| Power | Watts | 20 | 1-1(Refer to Table 1) | 1 Watt | ± 20% (1-4W) ± 10% (5-100W) |
| Impedance | Ohms | 150 | 50 - 300 | 1 Ohm | ± 10% |

* When the generator is used with an irrigated catheter, the temperature shown on the front panel temperature display is not the temperature of the tissue being ablated. It is the temperature of the irrigated tip electrode only.

Temperature monitoring 4-channel independent and simultaneous display

Operating modes Temperature Control mode

Input / Output

- 4 pin circular Socket for the footswitch
- RS-232 serial interface port (DB9)
- RS-232 Pump interface port (DB15)
- Temperature analog output BNC connector
- 14 pin socket for the isolated patient connector
- 8-pin socket for EGM out

- Indifferent electrode connectors
- Alternating current (AC) entry module
- Indifferent equipotential stud

Dimensions 354 mm x 153 mm x 264 mm (W x H x D without handle)

Weight 9.75 kg.

Environmental specifications

Storage:

- Temperature: -40°C to 55°C
- 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

SECTION 8. SERVICE AND MAINTENANCE

The generator requires no routine service or maintenance. If the generator fails to operate when plugged into a proper AC power receptacle and the POWER Switch is turned "ON", check the fuse.

DO NOT REMOVE THE COVER OF THE GENERATOR. REMOVING THE COVER MAY RESULT IN PERSONAL INJURY AND/OR DAMAGE TO THE GENERATOR.

8.1. Cleaning

Generator:

Turn off or unplug the generator before cleaning it.

If cleaning is required, user may clean the outer surfaces of the generator with a damp cloth and mild detergent. NEVER immerse the generator or its accessories in any liquid. Avoid caustic or abrasive cleaners. Do not use flammable agents for cleaning or disinfection.

1500T Extender Module

Unplug the extender module from the generator before cleaning it.

If cleaning is required, user may clean the outer surfaces of the case with a damp cloth and mild detergent. NEVER immerse the 1500T Extender Module or its cables in any liquid. Avoid caustic or abrasive cleaners. Do not use flammable agents for cleaning or disinfection.

8.2. Replacing the Fuses

8.2.1. Turn the pump off and remove the power cord.

8.2.2. Using a small flat screwdriver, open the fuse cover on the AC Power Inlet Module on the back of the generator as shown in Figure 1.

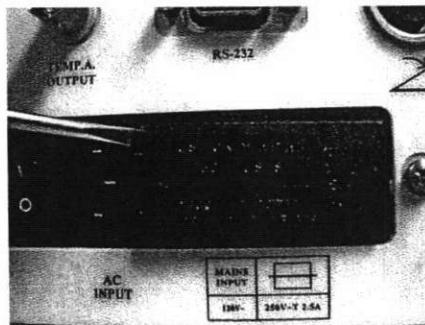


Figure 1

8.2.3. Remove the fuse holder as shown in Figure 2 and 3.

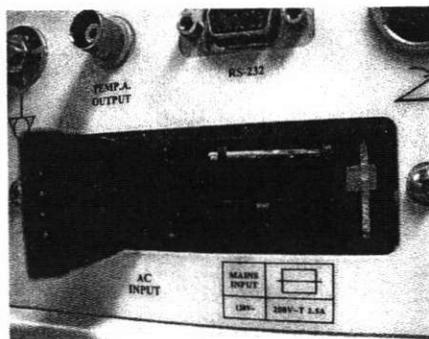


Figure 2

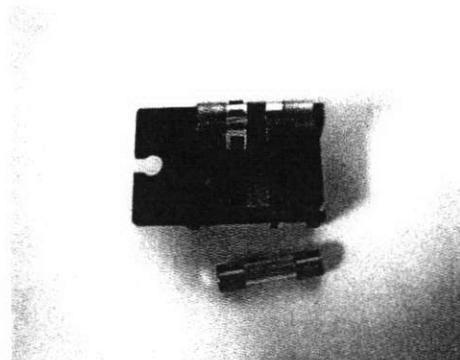


Figure 3

8.2.4. Replace the blown fuse(s) in the holder as show in Figure 4. The replacement fuse must be the value and type identified in the Section 7, Technical Data.

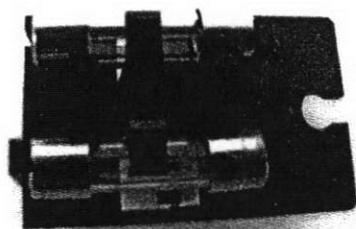


Figure 4

8.2.5. Place the fuse holder containing the new fuse(s) back in to the AC Power Inlet Module as seen in Figure 5.

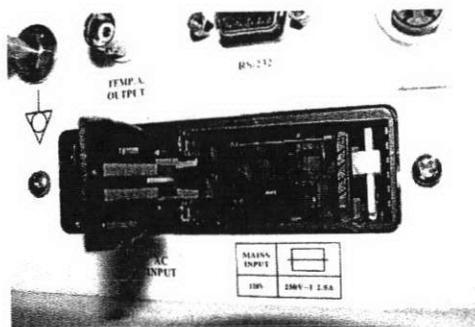


Figure5

8.2.6. Close the fuse cover and plug the power cord into the pump as seen in Figure 6.

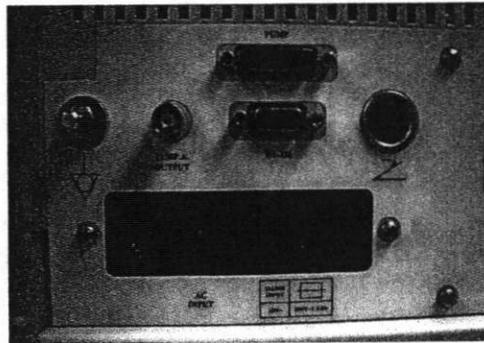


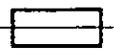
Figure 6

- For repair, contact your St. Jude Medical representative for instructions on returning the generator.

8.3. Connecting Cable Inspection

Visually inspect the cables for integrity (cut, broken or loosen pins) and overall condition. Refer to Electrophysiology Cable's Instruction for Use.

SECTION 9. LABELING SYMBOLS

| | |
|---|---|
| Power ON | |
| Power OFF |  |
| Alternating current |  |
| Increase |  |
| Decrease |  |
| Variability |  |
| Defibrillation-proof type CF applied part |  |
| Mains Input |  |
| Clock; Time switch; Timer |  |
| Start (of action) symbol |  |
| Stop (of action) symbol |  |
| Type CF (Cardiac Floating) applied part |  |
| Attentions, consult accompanying documents |  Intermittent |
| Equipotentiality symbol |  |
| Foot switch symbol |  |
| Neutral Electrode (Floating Ground) |  |
| Non-Ionizing electromagnetic radiation (RF) |  |
| Protective earth ground |  |
| Manufacturer |  |

**SECTION 10.
ACCESSORIES**

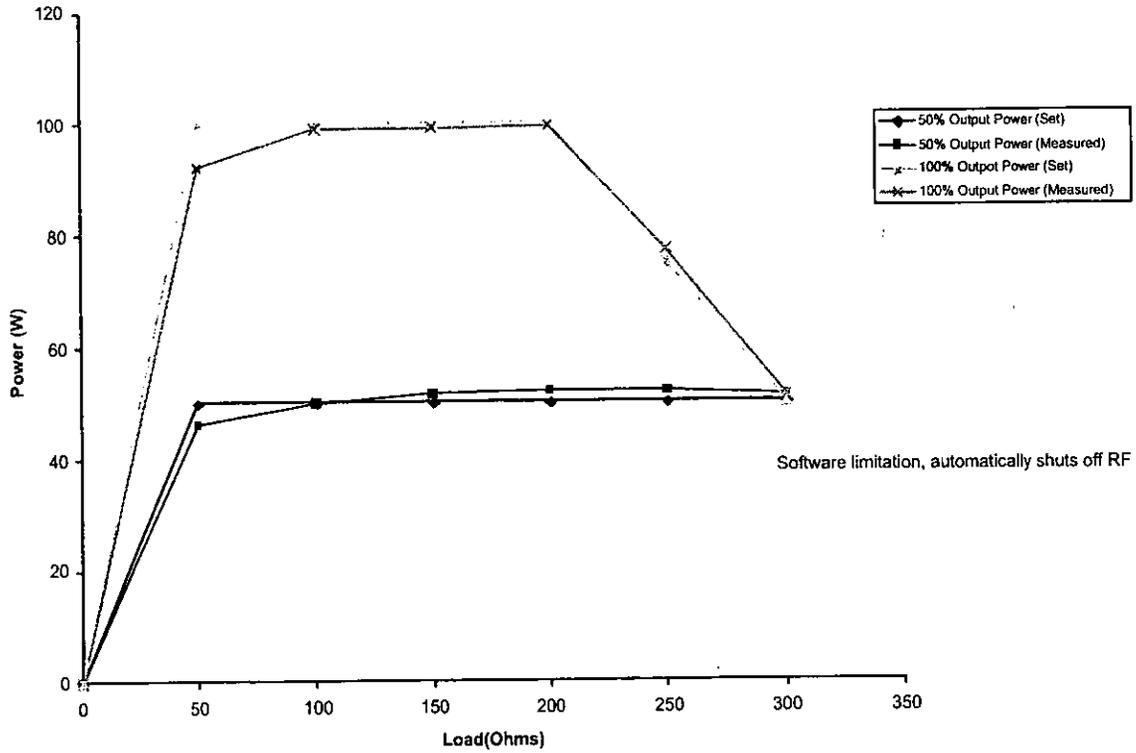
| Generator Accessories | | |
|------------------------------|-----------------|--|
| Item# | Catalog# | Description |
| 85452 | 1452 | Footswitch with cover (Optional) |
| 85710 | 1710 | Grounding Cable for generator-2.5 m |
| 85731 | N/A | (DIP Electrode) Electrosurgical Patient Plate with Cord (3M, 1149C-LP) |
| 85722 | 1722 | (DIP electrode) Patient Return Electrode (PolyHesive E7506 by Valleylab) |
| 85641 | 1641 | Connecting cable from 1500T9-CP Ablation Generator to Ablation Catheters |
| 85809 | 1804-S | Connecting cable from 1500T9-CP Ablation Generator to EP monitor |
| 85756 | 1756 | Hospital grade Power Cord (UL Listed) |
| 85726 | 1726 | RS232 Cable for EP Recording Monitor |
| 85517 | N/A | IBI 1500T Extender Module (Optional) |

| Cool Point Irrigation Pump's Accessories | | |
|---|---------------------|---|
| Item# | Mfg Catalog# | Description |
| 85784 | N/A | Cool Point™ Irrigation Pump |
| 85785 | N/A | Cool Point™ Tubing Set |
| 85780 | 50P136 | Sterile Extension Pressure Tubing with Male/Female Connector (Optional) |
| 85786 | 1779 | Adapter Cable (Pump) DB15M/DB9M (20 Ft) |

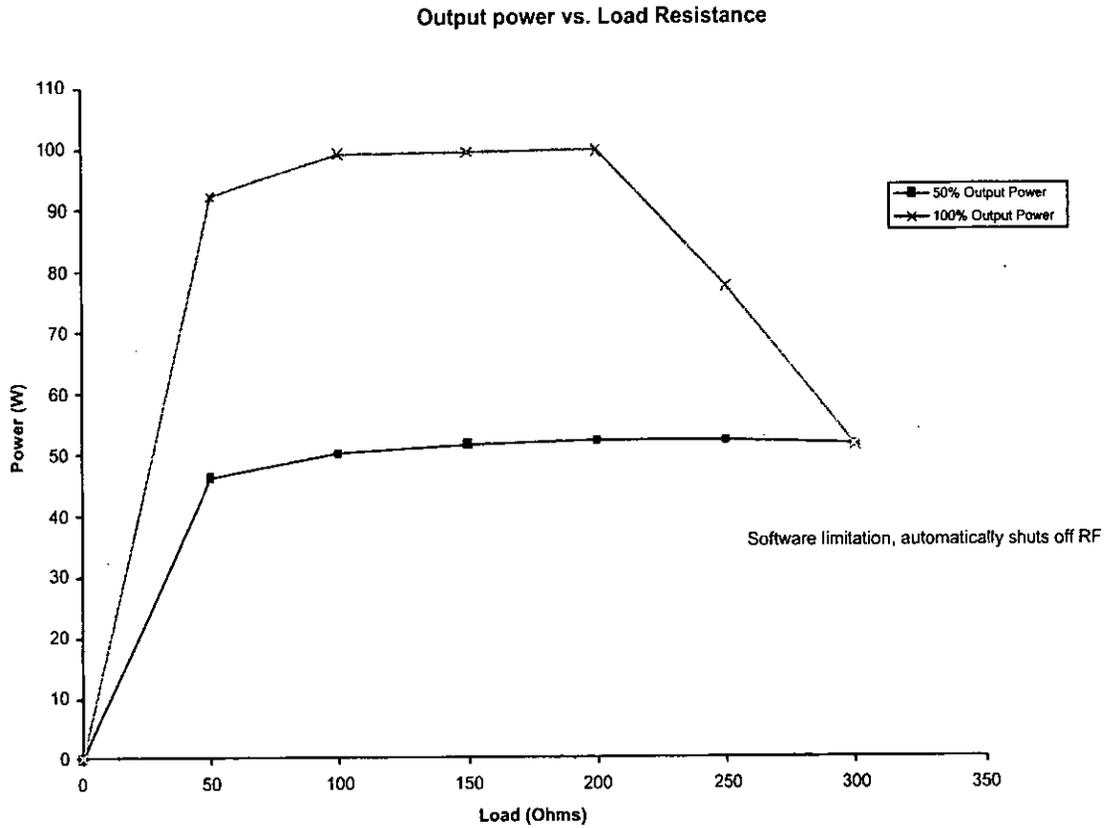
SECTION 11. GRAPHS

1) Diagram shows power output setting versus actual measured power output at load resistance of 50 to 300 Ω .

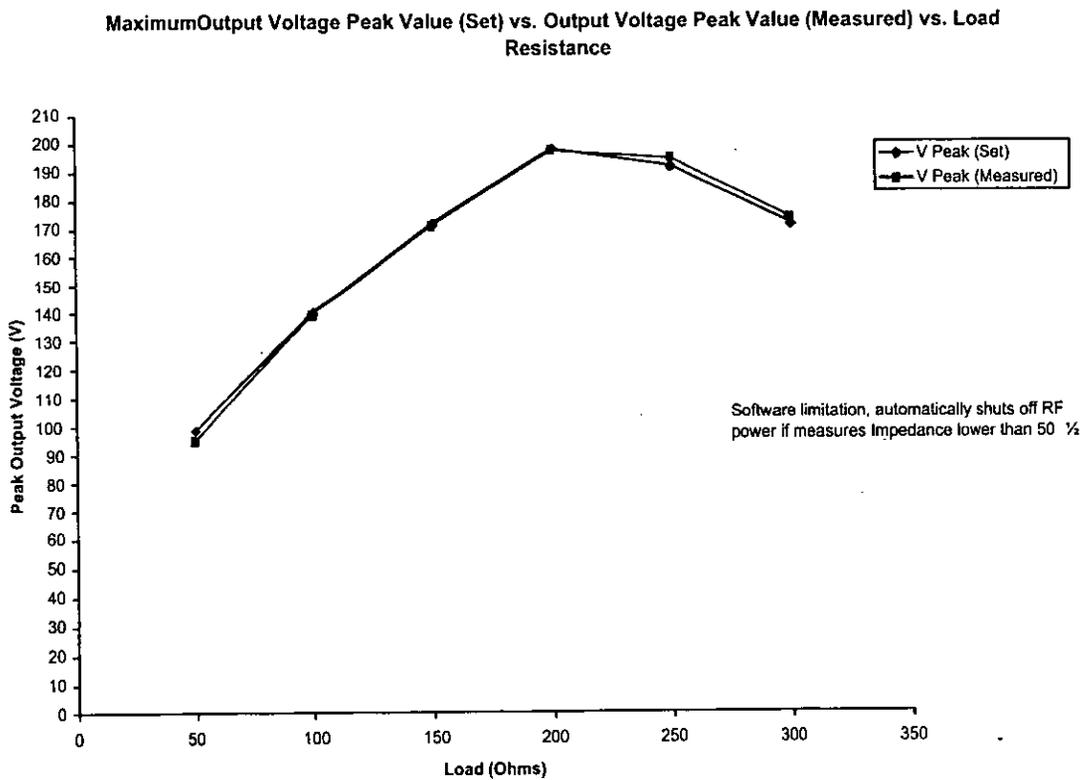
Output power vs. Load Resistance (Set) vs. (Measured)



2) Diagrams show power output at 100% and 50% settings at load resistance of 50 to 300 Ω .



3) Diagram shows maximum possible peak output voltage versus the output control setting



Appendix A: State Transitions

This table shows the action that will be taken and the state that will result based on pressing the respective key.

| KEY STATE | Clear/ Pump Start | Setup/Test | Start | Stop/Reset | Arrow |
|-----------|--|-------------------------|--|------------|-----------------|
| Banner | No effect | No effect | No effect | No effect | No effect |
| Test | No effect | No effect | No effect | No effect | No effect |
| Edit | <p>"P-P" is shown for 3 seconds in Time display indicating that the generator is searching for a pump.</p> <p>When a Cool Path™ or SAFIRE BLU™ irrigated catheter is connected, the maximum power is 50 watts, the max set temperature is 50°C, default temperature is set to 50 °C. If Cool Point™ pump connected, the pump is initialized at flow rate of 2 mL/min and the temperature display is preceded by a flashing "≡" LED symbol.</p> | Change to Monitor State | <p>If NOT an irrigated catheter that is connected, change to Ablation State.</p> <p>If Cool Point™ pump and a Cool Path™ or SAFIRE BLU™ irrigated catheter connected and initialized, the temperature display is preceded by a flashing "≡" LED symbol, the pump flow is changed from 2 mL/min to 13 mL/min. A 3-second timer starts counting, followed by Ablation State.</p> | No effect | Value selection |

| KEY STATE | Clear/ Pump Start | Setup/Test | Start | Stop/Reset | Arrow |
|-----------|--|-------------------------|---|------------|-----------------|
| Edit | When a Cool Path™ Duo or SAFIRE BLU™ Duo irrigated catheter is connected, the maximum power is 50 watts, the max set temperature is 45°C, default temperature is set to 40 °C. If Cool Point™ pump connected, the pump is initialized at flow rate of 2 mL/min and the temperature display is preceded by a flashing "≡" LED symbol. | Change to Monitor State | If Cool Point™ pump and a Cool Path™ Duo or SAFIRE BLU™ Duo irrigated catheter connected and initialized, the temperature display is preceded by a flashing "≡" LED symbol, the pump flow is changed from 2 mL/min to 13 mL/min. A programmable flow delay timer starts counting, followed by Ablation State. | No effect | Value selection |

| KEY STATE | Clear/ Pump Start | Setup/Test | Start | Stop/Reset | Arrow |
|-----------|-------------------|---|---|------------|-----------|
| Monitor | No effect | <p>First time: Change to PID setup.</p> <p>If a Cool Path™ Duo or SAFIRE BLU™ Duo irrigated catheter is connected, a flow delay counter setup will displayed.</p> <p>(Flow delay for Cool Path™ or SAFIRE BLU™ irrigated catheter is not adjustable)</p> <p>Second time: Change to Edit State</p> | <p>If NOT an irrigated catheter that is connected, change to Ablation State.</p> <p>If Cool Point™ pump and Cool Path™ Duo or SAFIRE BLU™ Duo irrigated catheter are connected and initialized, the temperature display is proceeded by a flashing "≡" LED symbol, the pump flow is changed from 2 mL/min to 13 mL/min. A programmed flow delay timer starts counting, followed by Ablation State.</p> <p>If Cool Point™ pump and Cool Path™ or SAFIRE BLU™ irrigated catheter are connected and initialized, the temperature display is proceeded by a flashing "≡" LED symbol, the pump flow is changed from 2 mL/min to 13 mL/min. A 3 second timer starts counting, followed by Ablation State.</p> | No effect | No effect |

| KEY STATE | Clear/ Pump Start | Setup/Test | Start | Stop/Reset | Arrow |
|-----------------|--|------------|-----------|--|--------------------------------------|
| Ablation | <p>If NOT an irrigated catheter that is connected, change to Results State.</p> <p>If Cool Point™ pump and Cool Path™ Duo or SAFIRE BLU™ Duo irrigated catheters are connected and initialized, the temperature display is proceeded by a flashing "≡" LED symbol, a programmed flow delay countdown starts, pump flow changed from 13 mL/min to 2 mL/min, followed by Results State.</p> <p>If Cool Point™ pump and Cool Path™ or SAFIRE BLU™ irrigated catheters are connected and initialized, the temperature display is proceeded by a flashing "≡" LED symbol, a 3-second countdown starts, pump flow changed from 13 mL/min to 2 mL/min, followed by Results State.</p> | No effect | No effect | <p>If NOT an irrigated catheter that is connected, change to Results State.</p> <p>If Cool Point™ pump and Cool Path™ Duo or SAFIRE BLU™ Duo irrigated catheters are connected and initialized, the temperature display is proceeded by a flashing "≡" LED symbol, a programmed flow delay countdown starts, pump flow changed from 13 mL/min to 2 mL/min, followed by Results State.</p> <p>If Cool Point™ pump and Cool Path™ or SAFIRE BLU™ irrigated catheters are connected and initialized, the temperature display is proceeded by a flashing "≡" LED symbol, a 3-second countdown starts, pump flow changed from 13 mL/min to 2 mL/min, followed by Results State.</p> | Edit power and temperature set point |
| Results | Change to Edit State to user defined setting | No effect | No effect | Change to Edit State to user defined setting | No effect |
| Error | Change to Results State | No effect | No effect | No effect | No effect |

Appendix B: Limited Warranty and General Service Policies

Initial Warranty Period

St. Jude Medical (SJM) warrants that its catheter products and 1500T Series Radio-Frequency Ablation Device footswitch and device accessories, shall be free from defects in materials and workmanship under normal use and service for a period of twelve (12) months from the date of our shipment or our distributor's shipment to the customer or fifteen (15) months from the date of our shipment to our distributor shipment (whichever is shorter), but, with respect to sterile products, not beyond the "Expiration" date stated on any product labeling and only if the original packaging is intact (collectively, the "Initial Warranty Period").

Notification; RGA Number; and Return of Defective Products (Warranty and Out-of-Warranty)

Upon our distributor or customer discovering a defect in one of our catheter products or our RF Ablation Device, whether or not the discovery occurs during the Initial Warranty Period and whether or not the catheter products or the RF Ablation Device is subject to this limited warranty or a Maintenance Service arrangement, our distributor or customer should promptly advise our customer service department of the scope and nature of the problem, the conditions under which the problem was noticed, and request a "Returned Goods Authorization" ("RGA") number. The RGA number can only be provided by SJM.

Promptly following the receipt of the RGA number, the distributor or customer should return such product to us for inspection, carefully packaged and postage prepaid. The outside of the shipping carton should prominently display the RGA number. Shipments arriving without an RGA number will not be accepted, and will be returned to the sender. Inside of the package should be a note explaining the scope and nature of the problem, the conditions under which the problem was noticed, and the name of a contact person and a phone number, should we have questions.

Loss or damage in shipment to us shall be at the distributor's or customer's risk.

Warranty Repairs

In addition to the information to be included with the defective product, as set forth above, claims for warranty repairs must also be accompanied by a copy of the original invoice as proof of the date of purchase.

SJM will evaluate the product that is returned to us with an RGA number, and (i) if subject to the terms and conditions of this limited warranty or any other applicable agreement, at SJM's expense, replace or repair (at its sole discretion) any product that proves to be defective and (ii) return it to the customer, freight pre-paid. Loss or damage in shipment to the distributor or customer shall be at the distributor's or customer's risk. SJM will provide a written report to the distributor or customer listing the repairs made.

If SJM determines that the product is not defective, that no repair of the product is required, or that it is not covered by this limited warranty or any other applicable agreement, it will be returned to the customer, freight collect including customs duties. Loss or damage in shipment to the distributor or customer shall be at the distributor's or customer's risk.

No User Serviceable Components

There are no user serviceable components within our products. Do not attempt to perform any repair work, nor attempt to open the RF Ablation Device or footswitch enclosures. This limited warranty is null and void if the product is misused, abused, modified, or tampered with in any way.

Disclaimers

SJM's catheter products are designed as single-use devices and are not intended for re-use. Further, the authorized uses and approved methods of use of each of our catheter products and RF Ablation Devices are set forth in the related "Directions/Instructions for Use" that accompany each of our catheter products and RF Ablation Devices. SJM disclaims any responsibility for the use of its catheter products and RF Ablation Devices in a manner that has not been authorized or approved.

SJM HEREBY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY, OTHER THAN AS EXPRESSLY SET FORTH HEREIN OR IN THE PRODUCT LABELING, INCLUDING THE APPLICABLE USER DIRECTIONS/INFORMATION. SJM WILL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR OTHER DAMAGES OF ANY TYPE ARISING OUT OF THE USE OF THE PRODUCT BY THE CUSTOMER. IN NO EVENT SHALL SJM'S LIABILITY EXCEED THE PURCHASE PRICE PAID FOR THE DEFECTIVE PRODUCT. Further, this limited warranty shall not apply to, and SJM shall not be responsible for, any loss arising in connection with the purchase or use of any SJM product that has been repaired by anyone other than SJM or altered in any way that might, in SJM's sole judgment, affect its stability or reliability, or that has been subject to misuse, negligence, or accident, or that has been used otherwise than in accordance with the directions/instructions for use furnished by SJM. This is a limited warranty and is exclusive and in lieu of all other warranties, express or implied, and of all other obligations or liabilities on SJM's part and SJM neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with SJM's products. **The foregoing shall not relieve SJM from strict tort liability, if otherwise applicable under governing law, for damages for personal injury caused by a product defect that made the product unreasonably dangerous at the time it was sold or placed.**

Out-of-Warranty Service and Repairs

Requests for out-of-warranty service also require an RGA number, which shall be prominently displayed on the outside of the shipping carton. Shipments arriving without an RGA number will not be accepted, and will be returned to the sender. Inside of the package should be a note explaining the scope and nature of the problem, the conditions under which the problem was noticed, and the name of a contact person and a phone number should we have questions.

If a customer requests service for an RF Ablation Device that is not subject to a Maintenance Service arrangement or this limited warranty or another applicable agreement, and returns the RF Ablation Device with an RGA number, SJM will use reasonable efforts to effect repair at its current, standard rates for Maintenance Service Repair are \$220.00 per hour for the first three (3) hours and \$150.00 per hour for subsequent hours, plus parts and out-of-pocket costs. A minimum charge of \$220 will be applied. Upon request by the customer prior to the commencement of service and repair, SJM will provide a non-binding cost estimate and will not proceed with service or repair until it has received the customer's written authorization to proceed. If the customer does not so request and estimated repair costs are expected to exceed \$500, the customer will be notified before repairs are made. Otherwise, customer agrees to pay for service and repairs less than or equal to \$500 without our notification. SJM will provide a written report to the distributor or customer listing the repairs made and will return the RF Ablation Device to the distributor or customer, freight collect, plus any applicable customs charges and taxes. Loss or damage in shipment to the distributor or customer shall be at the distributor's or customer's risk. Current, standard testing and repair time for the RF Ablation Device is approximately two (2) weeks, plus including shipping time.

Notwithstanding the above, SJM reserves the right not to repair any RF Ablation Device that, in its sole discretion, it deems is beyond reasonable repair. Further, on a project-by-project basis and subject to notice prior to the commencement of repair services, SJM reserves the right to vary its then-current, standard rates and terms on any specific out-of-warranty repairs.

The terms of SJM's repair limited warranty shall apply to the repaired portion of the RF Ablation Device except that the duration of such repair limited warranty is ninety (90) days, or the balance of the Initial Warranty Period or applicable agreement period, whichever is greater.

Loaner RF Ablation Devices

Subject to availability, if requested by a customer, a loaner RF Ablation Device may be made available for use by the customer during the time the RF Ablation Device is being serviced and/or repaired by SJM. SJM will invoice the customer for the loaner RF Ablation Device at the then-current list price and will provide a credit to the customer upon the return of the loaner RF Ablation Device, provided that, upon its return, the condition of the loaner RF Ablation Device is equivalent to its condition upon being sent to the customer by SJM. Loaner RF Ablation Devices will be assessed a rental fee of \$300.00 per week, to a maximum of four weeks in excess of the service or repair period plus shipping time. Thereafter, the customer shall not be entitled to return the loaner RF Ablation Device for credit and will be expected to pay the full amount of the invoice. SJM will not charge any rental fee to a customer whose RF Ablation Device is being repaired by SJM under this limited warranty; however, if the customer does not return the loaner device, the rental fee will commence one week after the repaired RF Ablation Device has been shipped to the customer. In all events, all shipping charges for the loaner RF Ablation Device will be invoiced to the customer.