

IBI Therapy™ Dual-8™ Ablation Catheter

CAUTION:

- United States law restricts this device to sale by or on order of a physician.
- Read directions prior to use.

DESCRIPTION:

The IBI Therapy™ Dual 8™ Ablation Catheter is a sterile, single use catheter with one 8 mm ablation electrode at the tip and three 2 mm diagnostic electrodes. The catheter includes two temperature sensors in the tip electrode for temperature monitoring and the handle is equipped with a steering mechanism to deflect the distal tip of the catheter. The catheter is available in various distal curve configurations.

INDICATIONS:

The IBI Therapy™ Dual 8™ Ablation Catheter is intended to be used with the IBI-1500T6 (USA) 100 watt generator at a maximum of 100 watts. The catheter is intended for creating long, linear endocardial lesions during cardiac ablation procedures (mapping, stimulation and ablation) for the treatment of typical atrial flutter.

The IBI-1500T6 (USA) Generator is intended for use with temperature controlled compatible ablation catheters for creating endocardial lesions. The generator may be used with the IBI Therapy™ Dual-8™, the IBI Therapy™ Catheter. The generator is internally limited to 50 watts when used with the IBI Therapy™ catheters.

CONTRAINDICATIONS:

Do not use the IBI Therapy™ Dual-8™ Ablation Catheter:

- In patients with active systemic infection
- If the patient has intracardiac mural thrombus or has 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.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as 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 the use of this catheter 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.
- Vascular perforation is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or

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tamponade. Catheter advancement should be done under fluoroscopic guidance. Do not force the catheter to advance or withdraw when resistance is encountered.

- Pacemakers and implantable cardioverter/defibrillators can adversely be affected by RF signals. It is important to: a) have temporary external sources of pacing and defibrillation available during ablation, b) deactivate 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 analysis on all patients after ablation.
- The long term risks of RF ablation lesions have not been established, particularly with respect to lesions placed in proximity to the specialized conduction system.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- Do not attempt to use the device before completely reading and understanding the applicable directions for use.
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- When using an 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 patient injury and /or the communication of infectious disease(s) from one patient to another.
- Failure of RF Ablation Generator could result in an unintended power output increase. In case of system malfunction, attempt to shut power off using the generator's STOP button, release the footswitch or turn the power switch to the off position. If none of the previous attempts turn off the power, disconnect the power cord.

PRECAUTIONS:

- To maintain optimal patient safety and electrode catheter integrity, do not wipe this catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Standard grounding procedures should be followed if electro surgical instruments are used.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- Needle monitoring electrodes are not recommended.
- Two DIP return electrodes must be used to minimize the potential for skin burns
- Read and follow the Dispersive Indifferent Patch (DIP) electrode manufacturer's instructions for use.
- Position connecting cables such that contact with patient or other leads is avoided.
- The catheter impedance display of the Cardiac Ablation Generator should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed and

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the distal tip of the catheter carefully cleaned with a sterile gauze pad dampened with sterile saline to eliminate any coagulum.

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

POTENTIAL ADVERSE EVENTS:

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

- | | |
|--|---|
| • Adult Respiratory Distress Syndrome (ARDS) | • Myocardial infarction |
| • Air embolism | • Obstruction or perforation or damage to the vascular system |
| • Anemia | • Pericardial effusion |
| • Anesthesia reaction | • Pericarditis |
| • Arrhythmias | • Phrenic nerve damage |
| • AV fistula | • Pleural effusion |
| • Cardiac perforation/tamponade | • Pneumonia |
| • Cardiac thromboembolism | • Pneumothorax |
| • Cerebrovascular accident (CVA) | • Pseudoaneurysm |
| • Chest pain/discomfort | • Pulmonary edema |
| • Complete heart block | • Pulmonary embolism |
| • Component damage to ICD or implantable pacemaker | • Radiation injury |
| • Congestive heart failure | • Respiratory Depression |
| • Coronary artery spasm | • Seizure |
| • Death | • Skin burns |
| • Dislodgement of implantable cardioverter defibrillator or permanent pacing leads | • Temporary complete heart block |
| • Endocarditis | • 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 |
| • Increased phosphokinase level | • Vascular bleeding |
| • Infections | • Vasovagal reactions |
| • Laceration | • Ventricular tachycardia |
| • Leakage of air or blood into the lungs or other organs due to perforation | • Worsening chronic obstructive pulmonary disease |
| • Local hematomas/ecchymosis | |

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SUMMARY OF CLINICAL STUDIES:

Objectives

A prospective, multicenter study of RF ablation was conducted to demonstrate the Safety and Effectiveness of the IBI Therapy™ Dual 8™ Ablation Catheter used in conjunction with the IBI Cardiac Ablation Generator.

Study Design

The Device was evaluated in a prospective, non-randomized, multi-center clinical study for the treatment of isthmus dependent atrial flutter (typical AFL).

The objective of the clinical study was to demonstrate the safety and effectiveness of the Device for the treatment of AFL. Interpretation of the results was based primarily on objective performance criteria (OPC) regarding acute procedural success and rate of Major Complications. The OPC are defined below:

- **Safety:** major adverse events within 7 days of the procedure occur at a rate of 2.7% or less with a 7% one-sided 95% confidence bound;
- **Acute success:** 88% with an 80% one-sided 95% confidence bound.

Effectiveness:

"Acute success" was defined as the creation of bi-directional conduction block across the IVC/TA isthmus (confirmed 45 to 60 minutes after the last ablation treatment) and non-inducibility of atrial flutter using only the study catheter. Due to the strong correlation of acute bi-directional conduction block with chronic success, and in consideration of FDA's current practices, the acute endpoint of bi-directional conduction block also serves as a surrogate measure of chronic success.

"Chronic success", a secondary endpoint, was defined as the absence of recurrence of the target arrhythmia over a 3-month period following an acute success. "Conditional chronic success" was defined as freedom from recurrence among acute procedural successes. "Conditional chronic success free of antiarrhythmic drug changes" refers to any Class Ia, Ic, or III antiarrhythmic that is newly introduced following the index procedure or whose dosage is increased compared to the pre-ablation dosage.

Safety:

"Major Complication" was defined as any occurrence of death, cardiac tamponade, myocardial infarction, stroke, perforation, valvular damage (new mitral or tricuspid damage), inadvertent AV block, coronary artery injury, arterial thrombosis, pulmonary embolism, thromboembolic event (stroke or TIA), peripheral venous thrombosis, endocarditis, hemothorax, pneumothorax, sepsis, catheter insertion site hematoma or AV fistula requiring a blood transfusion and/or surgical repair or any other "serious" cardiovascular adverse event within one week of the study ablation.

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“Serious” was defined as any event that was:

- Life threatening; or
- Resulted in permanent impairment of a body function or permanent damage to a body structure; or
- Necessitated significant intervention, such a major surgery, to prevent permanent impairment of a body function or permanent damage to a body structure; or
- Required hospitalization or an extended hospital stay; or
- Resulted in moderate transient damage to a body structure; or
- Required intervention to prevent permanent impairment of a body function or damage to a body structure.

“Minor Complication” was defined as any non-serious cardiovascular adverse event within one week of the study ablation. A non-serious event was any reported sign, symptom or diagnosis that did not satisfy any of the criteria for “serious” described above.

Data collection included basic demographics, presenting signs and symptoms, characteristics of the index arrhythmia, procedural parameters (ablation duration, impedance, power and temperature), cardiac medications, treatment outcome, adverse events and assessments for recurrence of the treated arrhythmia. Patients were evaluated one and three months after the initial ablation procedure.

Subjects Studied

| Status | Number of Patients |
|---|--------------------|
| Screened | 168 |
| Discontinued | 18 |
| Non-protocol arrhythmia (2 mapped with IBI catheter) | 9 |
| Other Screen Failure | 5 |
| Withdrew Consent | 2 |
| MD Consent | 1 |
| Equipment Not Available | 1 |
| Treated | 150 |

Demographics

Of the 150 patients undergoing RF ablation, 27 (18.0%) were female and 123 (82.0%) were male. The average age (\pm SD) of all treated patients was 65.6 (\pm 10.2) (range 33-88). All of the patients had arrhythmia symptomatic at the time of ablation. The most commonly reported symptoms were dyspnea (55.3%), fatigue (53.3%) and palpitations (52%).

Overall, 42.0% of patients were receiving anti-arrhythmic medications.

The enrolled patients had an average of four co-morbid conditions each and only 2.7% (4/150) were free of baseline co-morbidities.

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Procedural Data

Energy was applied a total of 1,818 times with an average of 12.4 (± 11.5) applications per patient (range 1-60). The mean duration of energy delivery per application was 93.0 (± 58.4) seconds (range 1-200) at an average temperature of 51.4 (± 6.8) degrees (range 20-85). The vast majority of applications were directed to the region between the tricuspid annulus and the inferior vena cava.

Mean fluoroscopy time was 24.0 (± 18.4) minutes (range 0.9-106) and mean procedure time (treatment phase with the study catheter) was 59.3 (± 36.2) minutes (range 7-191). Procedure time was defined as the number of minutes from the first ablation attempt until the last ablation attempt with the Device. Average study time (procedure time plus waiting time) was 106.6 (± 39.9) minutes (range 20-255).

Two patients received ablation therapy during the index ablation procedure for concomitant arrhythmias.

| Parameter | n | mean \pm SD | Range |
|---|-----|-------------------------------|--------------------------|
| # RF applications per procedure | 147 | 12.4 \pm 11.5 | 1-60 |
| RF time (min) per procedure | 147 | 19.2 \pm 16.7 | 0.12-108.3 |
| Fluoroscopy time (min) per procedure | 145 | 24.0 \pm 18.4 | 0.9-106 |
| RF usage time [#] (min) | 147 | 38.3 \pm 37.6 | 0-197 |
| Procedure time [*] (min) per patient | 122 | 59.3 \pm 36.2 ^x | 7-191 |
| Study time ^b | 123 | 106.6 \pm 39.9 ^x | 20-255 |
| | | | |
| RF time (sec) per application | | 93.0 \pm 58.4 | 1-200 |
| Temperature ($^{\circ}$ C) per application | | 51.4 \pm 6.8 | 20 ^{&} -85 |
| Power (Watts) per application | | 47.7 \pm 19.0 | 1 ^{&} -100 |
| Impedance (Ohms) per application | | 82.6 \pm 13.1 | 39 ^{&} -150 |

* Procedure time is defined as the time mapping started until the time of last ablation

^x These values do not include 25 cases because the mapping time was not recorded

[#] RF usage time is defined as the time from the first ablation to the last ablation

^b Study time is the time mapping starts until the time of last catheter withdrawal

[&] Reported values are lower than actual expected minimum values but reflect documented parameters.

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Results

Effectiveness

| ENDPOINT | N | Successes | PERCENT | 95% CL |
|---|-----|-----------|---------|--------|
| ACUTE PROCEDURAL SUCCESS | 150 | 140 | 93.3% | 89.3% |
| CONDITIONAL CHRONIC SUCCESS | 140 | 137 | 97.8 | 94.9% |
| CONDITIONAL CHRONIC SUCCESS FREE OF ANTIARRHYTHMIC DRUG CHANGES | 140 | 118 | 84.3 | 78.4% |
| OBJECTIVE PERFORMANCE CRITERIA (OPC) | -- | -- | 88.0 | 80.0% |

Safety

| EVENT DESCRIPTION | N | Patients With Event(s) | PERCENT | 95% CL |
|---|------|---------------------------|---------|--------|
| ALL MAJOR COMPLICATION | 152* | 17 | 11.2 | 16.0% |
| OBJECTIVE PERFORMANCE CRITERIA (OPC) | -- | -- | 2.7 | 7.0% |

* 2 patients had the IBI device inserted into the vasculature, but were not ablated

Observed Adverse Events

Among the 150 study subjects who underwent RF ablation, 18 major complications in 17 subjects were observed within 7 days of the procedure. See table below. There were no unanticipated, serious device-related adverse events.

| Type of adverse event within 7 days | Number of patients |
|--|--------------------|
| Acute myocardial infarction | 1 |
| Atrial fibrillation episode post ablation | 2 |
| Ectopic atrial tachycardia post ablation | 1 |
| Pulmonary emboli | 1 |
| Abnormal echocardiogram post ablation (wall motion abnormalities and decreased EF) | 1 |
| Skin burn | 2 |
| Hematoma | 1 |
| Sedation related | 3 |
| UTI | 1 |
| Treatment of pre-existing condition | 3 |
| Diagnostic hospitalization | 1 |

There was one death during the clinical study. The patient was a 42 year old woman with a history of asthma, mild CHF and atrial flutter. Her ablation procedure was described as

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uneventful and acutely successful. She had recurrence of her atrial flutter 6 weeks post ablation and developed a cerebral embolus after cardioversion. She died of respiratory complications during the resulting hospitalization.

Comparison of OPC and results from clinical study of Therapy™ Dual 8™ show that the OPC for effectiveness was met but the safety OPC was not. An overall risk benefit evaluation of these adverse events was performed and a detailed review of each adverse event was completed. The adverse event rate described above was assessed to be specifically correlated to the increased number of co-morbid conditions present in the subject population enrolled relative to patient population from which the OPC's were derived.

PATIENT SELECTION AND TREATMENT RECOMMENDATIONS:

The patient should be prepared for the ablation procedure in accordance with standard clinical practice, for example:

- A baseline electrophysiological study documenting the presence of the arrhythmia,
- Discontinuation of antiarrhythmic drugs prior to the ablation procedure, and
- Anticoagulation therapy such as heparin.

The safety and effectiveness of the Therapy™ Dual-8™ Ablation Catheter has not been studied in asymptomatic or pregnant patients.

DIRECTIONS:

1. Inspect the package prior to use. Do not use if the package is open or damaged.
2. Remove the catheter from its package. Inspect the electrodes and catheter carefully for integrity, and overall condition.
3. Insert the catheter by using a standard percutaneous catheter introducer. Make sure the thumb control is pulled downward completely before insertion.
4. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy.
5. The catheter has a built in cable connector and must be used with the appropriate interface cable for electrogram recording and radiofrequency ablation. Refer to the cable and/or RF generator Operator's Manual for details.
6. Connect the appropriate interface cable to the catheter.
7. Observe the polarity of the proximal end connector pins of the cable when connecting to an EP recording system.
8. Use care to isolate any unused connector pins. This will reduce the chances of developing accidental current pathways to the heart.
9. To manipulate the tip portion of the catheter, push or pull the thumb control located at the distal end of the handle.
10. Always use fluoroscopy when manipulating the tip of catheter.
11. Always straighten the catheter tip by pulling the thumb control downward completely, before removing the catheter from the patient.

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CONNECTION TO OTHER EQUIPMENT:

This device may be connected to a commercially available EP recording system and/or a compatible radio frequency generator using a connection cable with a Redel 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. The maximum power to be delivered through this catheter is limited to 100 Watts.

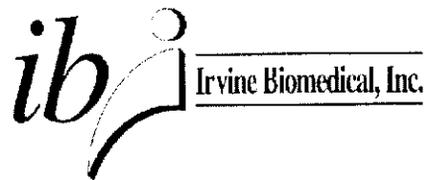
| IBI Catheter | IBI Cables | RF Generator |
|--|------------|-------------------------------------|
| Therapy™ Ablation Catheter (4 mm Tip) | 1641 | IBI 1500T6 RF Ablation Generator |
| Therapy™ Dual 8™ Ablation Catheter (8 mm Tip) | 1641 | IBI 1500T6 RF Ablation Generator |

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 package until time of use. Contents are sterile if 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:

Irvine Biomedical, Inc. warrants that its products shall be free from defects in material and workmanship under normal use and service. 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. IBI disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. IBI'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. IBI 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. IBI 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 IBI warranty policy available from IBI (1-949-851-3053) or on the back of an IBI invoice.



Operator's Manual

**CARDIAC ABLATION GENERATOR
WITH TEMPERATURE CONTROL**

Model No. IBI- 1500T6 (USA)

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CAUTION

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

DO NOT attempt to operate the IBI-1500T6 (USA) 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 IBI-1500T6 (USA) 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

GENERATOR DESCRIPTION

The IBI-1500T6 (USA) Cardiac Ablation Generator (“The Generator”) supplies RF energy through an ablation catheter that incorporates a compatible temperature sensor. For proper system operation, the use of IBI recommended accessories is required. These accessories are listed in Section 10 of this manual. .

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. The catheter delivers the RF power from the generator in a monopolar mode between its distal electrode (tip electrode) or other ablating electrodes and the large indifferent electrodes (dispersive pads).

The generator is a temperature controlled system, where temperature measured by the temperature sensor in the Therapy™ Ablation Catheter is monitored and the power delivered by the generator adjusts within the selected limits until the desired temperature is achieved. The generator’s thermocouple temperature control circuitry is based on a Type T thermocouple.

The front panel displays the actual power output, impedance, and measured temperature. The amount and duration of RF power delivery is user selectable. The desired 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 Generator has four (4) independent channels for monitoring the tissue temperature simultaneously using Thermocouple sensor and (1) channel (Thermistor) for catheters using a thermistor sensor. The desired tissue temperature is user selectable when using a Catheter with a temperature sensor. 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 5°C 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 Generator operates in Temperature Control mode only and is compatible with an IBI Therapy™ or IBI Therapy™ Dual 8™ Catheter.

The maximum amount of power to be delivered by the Catheter is determined by the Temperature Control mode. Desired tissue temperature may not be achieved with an insufficient power setting.

SECTION 2

INDICATIONS FOR USE / CONTRAINDICATIONS

2.1 Indications for Use

The IBI Therapy™ Dual 8™ Ablation Catheter is intended to be used with the IBI-1500T6 (USA) 100 watt generator at a maximum of 100 watts. The catheter is intended for creating long, linear endocardial lesions during cardiac ablation procedures (mapping, stimulation and ablation) for the treatment of typical atrial flutter.

The IBI-1500T6 (USA) Generator is intended for use with temperature controlled compatible ablation catheters for creating endocardial lesions. The generator may be used with the IBI Therapy™ Dual 8™, the IBI Therapy™ Catheter. The generator is internally limited to 50 watts when used with the IBI Therapy™ catheters.

2.2 Contraindications

The use of this device with the IBI Therapy™ ablation catheter is contraindicated:

- In patients with active systemic infection.
- If the patient has intracardiac mural thrombus or has had a ventriculotomy or atriectomy within the preceding four weeks.

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.
- 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 adversely be affected by RF signals. It is important to: a) have temporary external sources of pacing and defibrillation available during ablation, b) deactivate ICD's as they could discharge and injure the patient or 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.
- The long-term risks of RF ablation lesions have not been established, particularly with respect to lesions placed in proximity to the specialized conduction system.
- When using an 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, attempt to shut power off using the front control panel's STOP/RESET button, release the footswitch or turn the rear panel's rocker switch to the off position. If none of the previous attempts turn off the power, disconnect the power cord.

3.2 Precautions

- The catheter impedance display of the Cardiac Ablation Generator should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed and the distal tip of the catheter cleaned 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 adversely 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.
- Read and follow the Dispersive Indifferent Patch (DIP) electrode manufacturer's instructions for use.
- Two DIP electrodes must be used with the Therapy™ Dual 8™ catheter to minimize the potential for skin burns.
- Standard grounding procedures should be followed if electrosurgical instruments are used.
- The IBI 1500T6 (USA) Cardiac Ablation Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and DIP electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces. This can be achieved by placing a non-conductive material between the patient and the grounded metal surfaces. DIP electrode attachments are to be as close to the operating field as possible.
- Position connecting cables such that contact with patient or other leads 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 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, misapplication, or poor connections.
- 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 agents for cleaning the generator surfaces; a low lint cloth/pad dampened with soap and water is recommended.
- This equipment has been tested and found to comply with the limits for medical devices in 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 radio frequency 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. Consult the manufacturer for help.
- Regularly inspect and test re-usable cables and accessories.
- Output power selected is to be as low as possible for intended purpose.
- Do not connect items, which are not specified as part of system.
- Follow the system installation to achieve optimal use.

3.3 Potential Adverse Events:

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

- | | |
|---|--|
| <ul style="list-style-type: none">• Adult Respiratory Distress Syndrome (ARDS)• Air embolism• Anemia• Anesthesia reaction• Arrhythmias• AV fistula• Cardiac perforation/tamponade• Cardiac thromboembolism• Cerebrovascular accident (CVA)• Chest pain/discomfort• Complete heart block• Component damage to ICD or implantable pacemaker• Congestive heart failure• Coronary artery spasm• Death• Dislodgement of implantable cardioverter defibrillator or permanent pacing leads• Endocarditis• Exacerbation of pre-existing atrial fibrillation• Expressive aphasia• Heart Failure• Hemothorax• Increased phosphokinase level• Infections• Laceration• Leakage of air or blood into the lungs or other organs due to perforation• Local hematomas/ecchymosis | <ul style="list-style-type: none">• Myocardial infarction• Obstruction or perforation or damage to the vascular system• Pericardial effusion• Pericarditis• Phrenic nerve damage• Pleural effusion• Pneumonia• Pneumothorax• Pseudoaneurysm• Pulmonary edema• Pulmonary embolism• Radiation injury• Respiratory Depression• Seizure• Skin burns• Temporary complete heart block• Thrombi• Thromboembolism• Transient ischemic attack (TIA)• Unintended (in)complete AV, sinus node or other heart block or damage• Valvular damage/insufficiency• Vascular bleeding• Vasovagal reactions• Ventricular tachycardia• Worsening chronic obstructive pulmonary disease |
|---|--|

SECTION 4

CONTROLS, AND INDICATORS

IBI 1500T6 (USA) Front Panel

4.1 Stop/Reset Button

The Stop/Reset button is illuminated when the power is first turned on, and after passing the self-test routine. To stop RF energy output during ablation, firmly press the Stop/Reset button until it is illuminated. Firmly press the Stop/Reset button until the display of the set parameters are posted. The system is then ready to start the next ablation cycle.

4.2 Start Button

Firmly press the Start button to begin the RF output cycle. RF output will continue until one of the following occur: timer expires, the temperature exceeds the preset temperature, the impedance falls below 50 Ohms, or exceeds maximum limit of 300 Ohms or exceeds the operator set impedance, the Stop button is depressed or the Footswitch is released.

4.3 Setup/Test Button

When the generator is turned ON, the system goes into the Self-Test mode. The Setup/Test button light is illuminated during Self-Test mode. This test will result in the delivery of RF power from the RF circuit to an internal 100-Ohm resistance load. Firmly press the Setup/Test button to activate the Monitor Mode. Firmly press this button again to activate the PID selection mode (refer to section 5.10). Firmly press this button a third time to return the system to Ready Mode.

4.4 Clear Button

The Clear button resets the generator to the default values. After the ablation cycle ends and final average readings are displayed, the buttons on the front panel will not operate until the Clear button or Stop/Reset is firmly pressed and held again until default settings are displayed. Firmly press this button a second time to reset the power, temperature, and time entries to their default values and allow new parameters to be set.

This Button becomes illuminated (Flashing Red with Audible noise) in red to indicate an error has occurred.

The clear button is also used to clear a displayed error message (See section 5.18). An error message occurs when the system detects a temperature or impedance outside the set limit.

4.5 Time Up Button

Depress and/or hold the Time Up button to increase the maximum duration for each RF power delivery. Each time the button is depressed the timer is increased by one second, until a maximum of 200 seconds is reached. Holding the button depressed will cause the set point to scroll up rapidly.

4.6 Time Down Button

Depress and/or hold the Time Down button to decrease the maximum duration for each RF power delivery. Each time the button is depressed the timer is decreased by one second, until a minimum of 1 second is reached. Holding the button depressed will cause the set point to scroll down rapidly.

4.7 Temperature Up Button

Depress and/or hold the Temperature Up button to increase the temperature set point by 1 degree Celsius. The temperature selection range is from 15 to 80 degrees Celsius in 1 degree increment. The generator, however, cannot achieve a temperature less than the ambient blood temperature. Holding the button depressed will cause the set point to scroll up rapidly.

When the desired temperature is shown, release the button. The temperature value shown in the TEMPERATURE display window is the target tissue temperature that the Generator will attempt to achieve, within the user selected power limit.

4.8 Temperature Down Button

Depress and/or hold the Temperature Down button to decrease the temperature set point by 1 degree Celsius. Holding the button depressed will cause the temperature set point to scroll down rapidly.

When the desired temperature is shown, release the button. The temperature value shown in the TEMPERATURE display window is the target tissue temperature that the Generator will attempt to achieve, within the user selected power limit.

4.9 Impedance Up Button

Depress and/or hold the Impedance Up button to increase the maximum impedance limit set point by 1 Ohm. The maximum impedance selection range is from 50 to 300 Ohms in increments of 1 Ohm. User is unable to make adjustments lower than 50 Ohms or higher than 300 Ohms. Holding the button depressed will cause the set point to scroll up rapidly.

4.10 Impedance Down Button

The impedance LED display window will indicate a default of 150 Ohms when the generator is initially powered ON. Depress and/or hold the Impedance Down button once to decrease the maximum impedance limit set point by 1 Ohm. Holding the button depressed will cause the set point to scroll down rapidly.

4.11 Power Up Button

Power LED display window will indicate 30 Watts when the generator is initially powered ON. Depress and/or hold the Power Up button to increase the power set point by 1 Watt. The power selection range is from 1 to 100 Watts in increments of 1 Watt. Holding the Power Up button depressed will cause the power set point to scroll up rapidly.

4.12 Power Down Button

Depress and/or hold the Power Down Button once to decrease the power set point by 1 Watt. The Watts value displayed represents the maximum RF power that will be delivered to the tissue. Holding the button depressed will cause the set point to scroll down rapidly.

4.13 Patient Isolated Connector

The patient isolated connector is a fourteen-pin Redel connector for connecting the Catheter to the Generator.

4.14 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.

4.15 Indifferent Electrode Connectors

F

Neutral Electrode "Floating Output" is isolated from the earth potential. The indifferent electrode connectors are a 2-pin connector for connecting the generator to the Indifferent/Dispersive Electrode Pad(s).

IBI 1500T6 (USA) Rear Panel

4.16 Main Power Switch

Turn the generator ON by depressing the rocker switch to the "I" position. Returning the rocker switch to the "0" position will turn the generators main power supply OFF.

4.17 Serial Port

Provided for computer interface is an RS-232 cable port.

4.18 Footswitch Cable Connector

Provided for connecting the footswitch to the generator. The footswitch may be used to start or stop the delivery of RF power instead of the start and stop buttons on the front panel of the generator.

4.19 Power Entry Module and Fuses

Two modes of power supply 100V, 120V, and fuses are available to select the proper power line voltage and fuse rating.

4.20 Equipotential Ground

Provided for connecting the generator ground to the EP monitoring device's ground.

SECTION 5

OPERATIONAL SEQUENCE

Initial Installation

- 5.1 Position the Generator so that its front panel displays are easily accessible.
- 5.2 Connect the Generator Power Cord plug into a properly grounded AC electrical outlet. To ensure proper grounding, the Power Cord plugs must be installed at an AC electrical wall outlet designated "Hospital Grade" or "Hospital Only." **Never use an outlet without a grounding connection.** Position the Generator so that its front panel displays are easily accessible.
- 5.3 Connect an IBI-1641 Ablation Catheter 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.
- 5.4 Use an IBI-1804-S Cable to connect from the EGM output on the front panel to the junction box of the EP monitoring system for recording intracardiac signals. **Note:** The IBI-1500T6 (USA) 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.
- 5.5 Install one (1) or two (2) DIP electrode into the INDIFFERENT ELECTRODE I and II connectors on the front panel of the RF ablation generator. Two DIP electrodes must be utilized with the Therapy Dual 8 catheter. Gently push the DIP electrode-fitting straight in until it is firmly in place. To unplug, grasp the DIP electrode fitting and gently pull it out of the receptacle.

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

Turn Generator "ON"

- 5.6 Turn the Generator "ON" by pressing the rocker switch located on the rear panel of the Generator to the "I" position. Software version "1", "250" (1.250) will be displayed momentarily and the generator will automatically start a self-test procedure, which is indicated by having all front panel displays lit. If no system failure is detected, the Generator will be in "READY/EDIT" mode and default values will be displayed.

| PARAMETER | Units | Power up Default |
|-------------|---------|------------------|
| Power | Watts | 30 |
| Temperature | °C | 65 |
| Impedance | Ohms | 150 |
| Time | Seconds | 60 |

READY/ EDIT Mode

5.7 This mode is used to set the desired parameters for the delivery of RF power.

Monitor Mode

5.8 Firmly Press <Set Up/Test> button to enter Monitor Mode. This mode is used to monitor the impedance and temperature of the catheter after it has been connected to the Generator. In this mode:

- Time display flashes “P1” (Tip Electrode), display changes every 3 seconds.
- Temperature and Impedance from the tip electrode updated continuously.

PID Select Mode

5.9 PID value is the rate of power rise with “1” being the slowest and “7” being the fastest.

Firmly Press < Set Up/Test > button again to enter the PID select mode.

- Impedance field displays PID.

This indicates the PID select mode.

- Time field displays number from 1 to 7 (default is 4).

PID value is the rate of power rise with “1” being the slowest and “7” being the fastest.

To exit and return to preset settings, firmly press <Setup/Test> button a third time.

Select Power Level Parameter

5.10 To deliver RF power, it is necessary to select a Generator power level. To select the desired RF power, press the POWER ▲ Button. One actuation increases RF power set point by one watt; holding the button depressed causes the RF power set point to increase rapidly until the button is released. When the POWER display window shows the appropriate RF power set point, release the POWER ▲ Button. The RF power setting can be increased or decreased in the “READY” mode or the “POWER Control” mode by actuating the POWER ▲ or POWER ▼ Button, respectively.

Note: The power level can be adjusted up or down during the ablation in both modes.

Select Desired Temperature Parameter

- 5.11** If a Catheter with a temperature sensor is connected to the Generator, a desired value of tissue temperature (temperature set point) can be selected. The Generator will automatically adjust power, within a user selected power limit, to achieve the desired tissue temperature. Actuating the TEMPERATURE ▲ Button increases the temperature that the Generator will attempt to achieve during RF power delivery. Firmly pressing the TEMPERATURE ▲ Button once increases the temperature set point by 1°C. Holding the TEMPERATURE ▲ Button down firmly will cause the temperature set point to scroll up rapidly. When the desired temperature set point is shown, release the button. The temperature value shown in the TEMPERATURE display window will be the tissue temperature that the Generator will attempt to achieve within the user selected power limit. The tissue temperature selection range is 15° - 80°C in increments of 1°C, although the Generator cannot achieve a temperature that is less than the ambient blood temperature. Once an initial temperature set point has been selected, the value can be reduced by actuating the TEMPERATURE ▼ Button. Firmly pressing the TEMPERATURE ▼ Button once decreases the temperature set point by 1°C. Holding the button depressed will cause the temperature set point display to scroll down rapidly. When the desired temperature set point is shown, release the button.

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

Set Time Duration Parameter

- 5.12** The TIME display window and the TIME ▲/▼ Buttons allow the user to select the duration (in seconds) that RF power will be delivered to the Catheter. When the Generator is first powered "ON", the green LED's in the TIME display window will read 60 seconds. Firmly depressing the TIME ▲ Button selects the maximum RF power output duration to a maximum of 200 seconds. The value can be changed at any time during the "READY" mode by depressing the TIME ▲ Button (increase) or TIME ▼ Button (decrease).

RF Power Delivery Parameter

- 5.13** To deliver RF power to the Catheter, be sure that all connections are made properly and that all the aforementioned selections have been made. RF power is delivered by firmly pressing the START Button once or continuously depressing the Footswitch. When RF power is delivered to the Catheter, the display function is as follows:

RF POWER START BUTTON Light: This light illuminates and an audio tone generates to indicate the RF Power is being delivered. It will remain lit until RF power delivery is discontinued by any of the following methods:

- Reaching the user selected time duration.
- Firmly pressing the STOP/RESET Button.
- Releasing the Footswitch.

- Exceeding the preset limits of tissue impedance.
- Exceeding the selected limits of tissue temperature.

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

TEMPERATURE Display: When using a Catheter with a temperature sensor with the Generator in the Temperature Control mode, this display will continuously show measured tissue temperature during the RF Power delivery. When using a catheter with more than one temperature sensor in the Temperature Control mode, this display however will continuously show the highest measured temperature from any temperature sensor during the RF delivery.

IMPEDANCE Display: This display will show measured impedance in the range of 50 to 300 Ohms. Values shown will be approximately 80 - 150 Ohms when the Catheter ablating electrode is in stable contact with cardiac tissue. The displayed readings may fluctuate slightly due to variation in the stability of electrode/tissue contact as the heart beats. If the measured value demonstrates significant fluctuation, the Catheter should be repositioned. Alternatively, slight pressure on the Catheter shaft may minimize Catheter motion. If an excessively high impedance value is detected during delivery of RF power, check that the Catheter is correctly connected to the Generator. Always check for proper Connections first. If this is not the cause of the high impedance value, then a build-up of coagulum on the Catheter tip may be the cause, and RF power should be disconnected. If the impedance value exceeds 300 Ohms, the Generator will automatically turn RF power "OFF". An excessively low value (less than 50 Ohms) will also cause the Generator to automatically turn RF power "OFF" and the message "LO" will be shown in the IMPEDANCE display window.

TIME Display: When the RF Power START Button is firmly pressed or the Footswitch is depressed, this display will change 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 Button is pressed during delivery of RF power or the Footswitch is released, the RF power output will immediately turn "OFF". The remaining elapsed time in seconds will be on the TIME Display.

ERRORS AND INFORMATION DISPLAYS

The following displays may be seen at various times:

5.14HELP" Display on Power Window

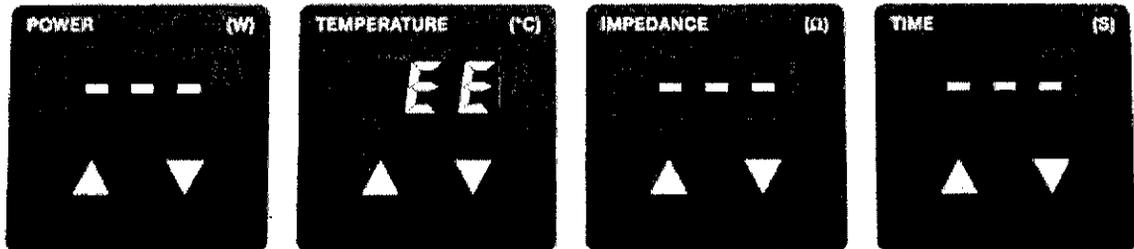
The instrument has failed its own internal self-test routines EPROM, RAM, and 100Ω internal load resistor.

5.15 "EE"

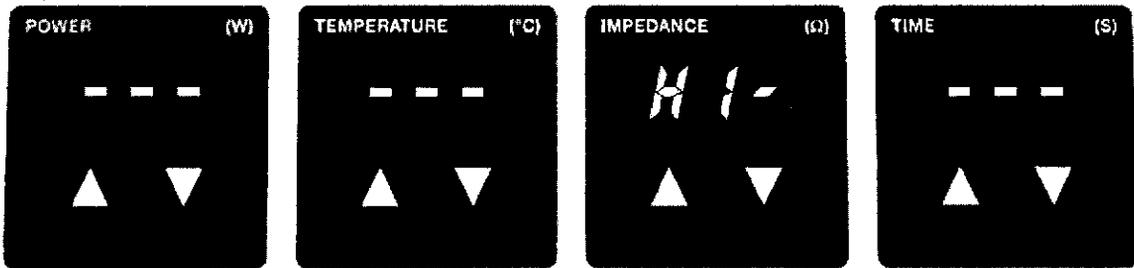
Flashing temperature value, and alternating with "EE" display on temperature window. The temperature has gone out of the range during and ablation session. Power delivery was terminated. Press the "CLEAR" key to advance to edit Mode.

“HI”, “LO” display on Impedance window.

Out of range Impedance measurements are measured during ablation. Detectable Impedance measurements are higher than 50 Ω and less than the user specified maximum. Power delivery was terminated. Press the “CLEAR” key to advance to edit mode.



In the event of a malfunction of the thermocouple, the generator will display an error message and RF energy delivery will not be allowed. The flashing “--- EE ---” message will appear in the Temperature window if the temperature readings are out of the range of 15° Celsius to 80° Celsius. If the impedance readings are out of the range of 50 Ω to 300 Ω then the flashing error message is “--- EE ---”. To correct the error, press the “Mode” clear button to reset the system to default settings.

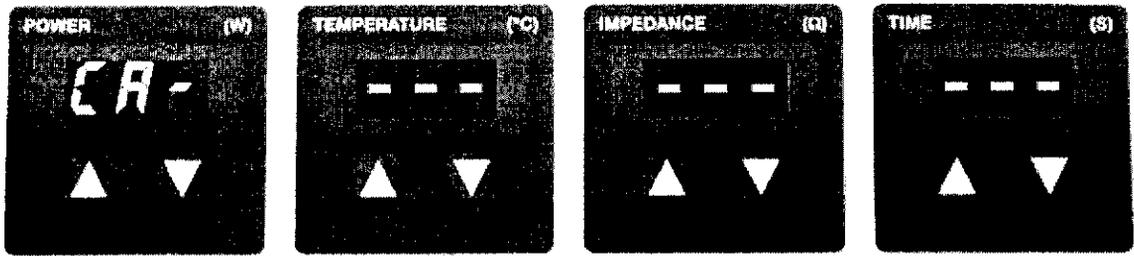


This display will appear if the catheter has inadequate tissue contact during ablation. To return to the default settings, press the “CLEAR” button twice.

5.16 “CA”

The catheter was disconnected from the cable, which caused a display of “CA” in the power window.

Reconnect the catheter to the cable. Press the “Clear” button twice to return to the default settings.



This display will appear if the generator does not recognize the catheter connected. If this occurs try exchanging the original catheter with a new catheter. For the Dual 8, press the "CLEAR" button and the setup button to achieve default settings.

SECTION 6

TECHNICAL DATA

Supply voltage 100-120VAC, 60 Hz (U.S.A. and North America)

Current rating/ 2.5A

Fuse rating T3.0A/250V (100-120VAC)

Operating duration **Stand by:** Continues until start button or footswitch is activated.
Ablation: Continues from 1-200 second maximum and minimum of 60 –second stand by (not Ablation) before next ablation cycle.

Safety class Class I. Type CF, 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

Operating Parameters Values are digitally displayed on the generator front panel.

| PARAMETER | Units | Min | Max | Adjustment steps | Accuracy |
|-----------------|---------|-----|-----------------------|------------------|----------------|
| RF Output Power | Watts | 1 | 100 (into 50-200 Ohm) | 1 | ± 20% (1-4W) |
| | | | | | ± 10% (5-100W) |
| Temperature | °C | 15 | 80 | 1 | ± 3°C |
| Impedance | Ohms | 50 | 300 | 1 | ± 10% |
| Time | Seconds | 1 | 200 | 1 | Internal clock |

Temperature Monitoring 4-channel independent and simultaneous display

Operating modes Temperature Control mode

Input / Output

- 14 pin socket for the isolated patient connector
- Socket for the footswitch
- RS.232 serial interface port
- Temperature analog output BNC connector
- 8-pin socket for EGM out
- Indifferent electrode connector

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

Weight 8.6 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: $+0^{\circ}\text{C}$ to $+40^{\circ}\text{C}$
- Relative humidity: 30% to 75%, non-condensing
- Atmospheric pressure: 700 to 1060 millibar

SECTION 7

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. If a second failure occurs, notify Irvine Biomedical for service. The Generator contains no user-serviceable parts; disassembly and attempted repair by unqualified personnel may create a hazardous condition and will void the warranty.

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

7.1 Cleaning

Turn off/or unplug the generator before cleaning it.

If cleaning is required, user may clean the outer surfaces of generator with damp cloth using 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.

7.2 Replacing the Fuses

A. Disconnect main power cord from the Generator.

B. Main Fuses.

Replace the fuse with another of the same type and rating. Refer to the rear panel label and Section 6 of this manual. Pull the fuse holder out of the power entry module. Use a slotted screwdriver to assist in removing the fuse holder. Insert the new fuse in the fuse holder and reinsert it in the power entry module. **When replacing the fuse holder, ensure that the fuse holder is inserted in the correct orientation for the operational voltage level.**

C. If there appears to be a problem with the Generator, please contact IBI for instructions on returning the Generator to Irvine Biomedical for service.

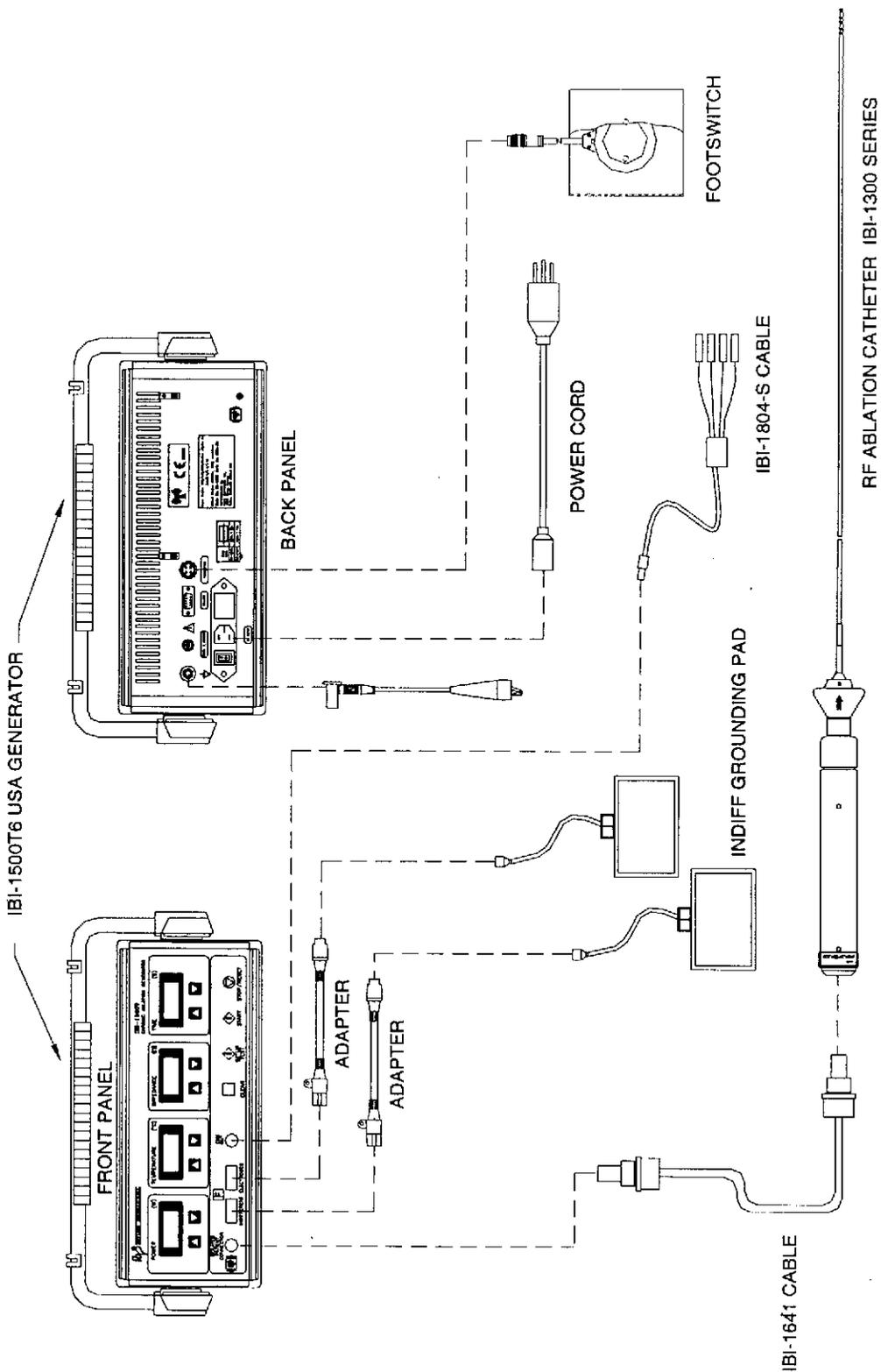
7.3 Connecting Cable Inspection

A. Visually inspect the cables for integrity (cut, broken or loosen pins) and overall condition.

Refer to **IBI Electrophysiology Cable's Instruction for Use (P/N XXXXXX)**.

SECTION 8

SYSTEM SET UP DIAGRAM



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SECTION 9

LABELING SYMBOLS

| | |
|--|-----|
| Power ON | |
| Power OFF | ○ |
| Alternating current | ~ |
| Increase | ▲ |
| Decrease | ▼ |
| Protective earth ground | ⊕ |
| Defibrillator-proof type Applied Part Symbol | ⊠♥⊠ |
| Mains Input | — — |
| Clock: time switch: timer | ⌚ |
| Start (of action) symbol | ◊↓ |
| Stop (of action) symbol | ◊↑ |
| Type CF (Cardiac Floating) Applied Part Symbol | ⊠♥⊠ |
| Attentions, consult accompanying documents | ⚠ |
| Equipotentiality symbol | ⚡ |
| Foot switch symbol | ⚡ |
| Neutral Electrode (Floating Ground) | ⊠F⊠ |
| Non-Ionizing Radiation (RF) | Ⓜ |

SECTION 10

ACCESSORIES

| IBI Generator Accessories | | |
|---------------------------|----------|---|
| Item# | Catalog# | Description |
| 85452 | 1452 | Footswitch with cover |
| 85710 | 1710 | Grounding Cable for IBI generator-2.5 m |
| 85731 | N/A | Indifferent grounding pad (3M, 1149C) |
| 85732 | N/A | Indifferent grounding pad, Adapter (3M, 1172C) |
| 85641 | 1641 | Connecting cable from IBI 1500T6 Ablation generator to IBI catheter |
| 85809 | 1804-S | Connecting cable from IBI 1500T6 Ablation generator to EP monitor |
| 85756 | 1756 | Hospital grade Power Cord (UL Listed) |

SECTION 11

LIMITED IBI WARRANTY AND GENERAL SERVICE POLICIES

Initial Warranty Period

Irvine Biomedical, Inc. ("IBI" or "we") 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 IBI.

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. Our address is 2382 Morse Ave., Irvine, California 92614, USA, Telephone: +1-949-851-3053 (or such other address as IBI may specify when the RGA number is obtained).

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.

IBI 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 IBI'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. IBI will provide a written report to the distributor or customer listing the repairs made.

If IBI 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

IBI'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. IBI disclaims any responsibility and liability for the use of its catheter products and RF Ablation Devices in a manner that has not been authorized or approved.

IBI 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. IBI 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 IBI'S LIABILITY EXCEED THE PURCHASE PRICE PAID FOR THE DEFECTIVE PRODUCT. Further, this limited warranty shall not apply to, and IBI shall not be responsible for, any loss arising in connection with the purchase or use of any IBI product that has been repaired by anyone other than IBI or altered in any way that might, in IBI'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 IBI. 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 IBI's part and IBI neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with IBI's products. **The foregoing shall not relieve IBI 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.**

RF Ablation Device Maintenance Service Policies

Maintenance Service Arrangement

IBI may establish an annual Maintenance Service arrangement for the customer for the RF Ablation Device. IBI's current, standard rate for a Maintenance Service arrangement is \$800.00 per year. The Maintenance Service arrangement includes an annual inspection of the RF Ablation Device, complete testing of its functionality, and repairs (Parts and Labor to be paid by customer), or replacement, as necessary and as determined by IBI in its sole discretion, provided that the RF Ablation Device has not been abused and has been used solely in the authorized manner and as part of an approved method, all as set forth in the related "Directions/Instructions for Use" that accompany each RF Ablation Device. Upon the completion of inspection, testing, and repair or replacement of an RF Ablation Device subject to a Maintenance Service arrangement, IBI will return it to the customer, freight collect. Loss or damage in shipment to the distributor or customer shall be at the distributor's or customer's risk. IBI reserves the right, subject to sixty (60) days' prior written notice, to modify its current, standard rates and terms for annual Maintenance Service arrangements.

Requests under the Maintenance Service arrangement 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, if any, the conditions under which the problem was noticed, and the name of a contact person and a phone number should we have questions.

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, IBI 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, IBI 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. IBI 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, IBI 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, IBI reserves the right to vary its then-current, standard rates and terms on any specific out-of-warranty repairs.

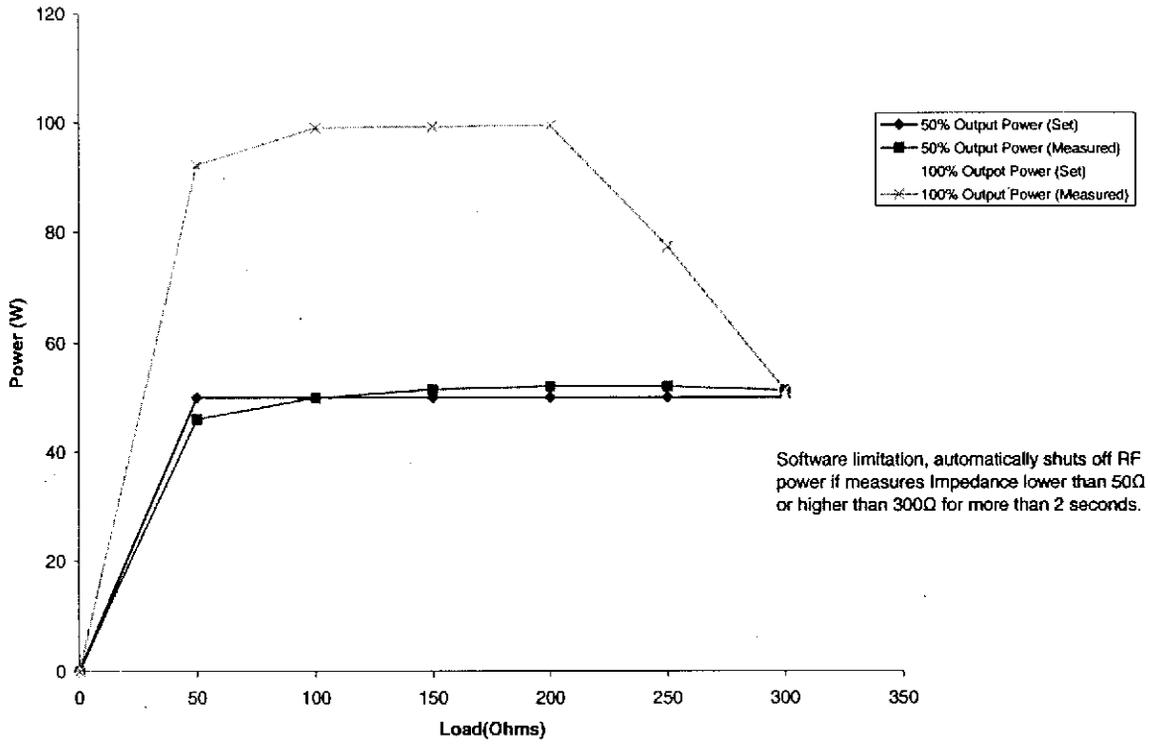
The terms of IBI's repair limited warranty shall apply to the repaired portion of the RF Ablation Device except that the duration of such repair limited warranty is ninety (90) days, or the balance of the Initial Warranty Period or applicable agreement period, whichever is greater.

Loaner RF Ablation Devices

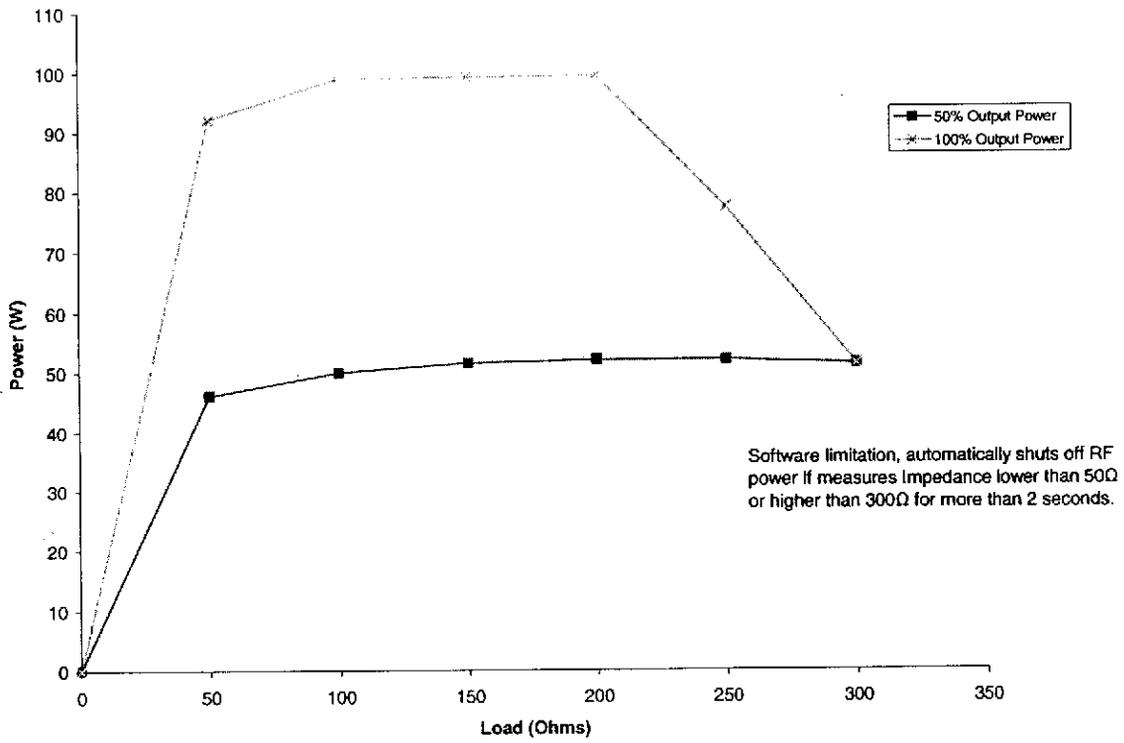
Subject to availability, if requested by a customer, a loaner RF Ablation Device may be made available for use by the customer during the time the RF Ablation Device is being serviced and/or repaired by IBI. IBI will invoice the customer for the loaner RF Ablation Device at the then-current list price 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 IBI. 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. IBI will not charge any rental fee to a customer whose RF Ablation Device is being repaired by IBI under this limited warranty, provided that, 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.

SECTION 12

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



Output power vs. Load Resistance



MaximumOutput Voltage Peak Value (Set) vs. Output Voltage Peak Value (Measured) vs. Load Resistance

