DYONICS° RF System
Glossary of Symbols

See Instructions for Use

Caution, Consult accompanying documents / Caution

Manufacturer

Authorized representative in the European Community

Date of Manufacture

Coagulation

Ablation

RF Probe connected

Foot Pedal Connected

Defibrillator–Proof Type BF Equipment

Fuse Rating

Non-ionizing Electromagnetic Radiation

UL Classified Mark

Equipotential Ground

Tone Volume Control

Fragile, Handle with Care

Temperature Limitations

Keep Dry

Do not dispose in waste container

Humidity Range: 10% - 85% R.H., Non-condensing

CE mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive (93/42/EEC).

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Lot Number

Catalogue Number

Serial Number

Final Assembly Number
## Preface

This equipment has been tested and found to comply with the limits for medical devices to IEC/EN 60601-1-2:2001. 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. If this equipment does cause harmful interference to other devices, which can be verified by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the affected equipment and the generator
- Connect the affected equipment to an outlet or circuit different from that to which the generator is connected
- Consult the manufacturer or field service technician for help


## Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preface</td>
<td>4</td>
</tr>
<tr>
<td>Description</td>
<td>5</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>5</td>
</tr>
<tr>
<td>Contraindications</td>
<td>5</td>
</tr>
<tr>
<td>Principle of Operation</td>
<td>6</td>
</tr>
<tr>
<td>Warnings</td>
<td>6</td>
</tr>
<tr>
<td>Precautions</td>
<td>7</td>
</tr>
<tr>
<td>Adverse Reactions</td>
<td>8</td>
</tr>
<tr>
<td>Unpacking</td>
<td>8</td>
</tr>
<tr>
<td>Assembly and System Check</td>
<td>8</td>
</tr>
<tr>
<td>System Overview</td>
<td>9</td>
</tr>
<tr>
<td>Front Panel Layout</td>
<td>10</td>
</tr>
<tr>
<td>Rear Panel Layout</td>
<td>11</td>
</tr>
<tr>
<td>Instructions for Use</td>
<td>12</td>
</tr>
<tr>
<td>Operator Training Requirements</td>
<td>12</td>
</tr>
<tr>
<td>General System Operation</td>
<td>12</td>
</tr>
<tr>
<td>Voltage Outputs</td>
<td>12</td>
</tr>
<tr>
<td>System Preparation and Care</td>
<td>12</td>
</tr>
<tr>
<td>System Preparation</td>
<td>12</td>
</tr>
<tr>
<td>RF Probe Selection</td>
<td>13</td>
</tr>
<tr>
<td>System Shut Down</td>
<td>13</td>
</tr>
<tr>
<td>Cleaning and Sterilization</td>
<td>13</td>
</tr>
<tr>
<td>Surface Cleaning &amp; Disinfection of Generator and Foot Pedal</td>
<td>13</td>
</tr>
<tr>
<td>DYONICS RF Probe</td>
<td>13</td>
</tr>
<tr>
<td>Maintenance and Troubleshooting</td>
<td>13</td>
</tr>
<tr>
<td>Maintenance</td>
<td>13</td>
</tr>
<tr>
<td>Fuse Replacement</td>
<td>13</td>
</tr>
<tr>
<td>Alarms</td>
<td>13</td>
</tr>
<tr>
<td>Troubleshooting Guide</td>
<td>14</td>
</tr>
<tr>
<td>Error and Fault Messages</td>
<td>15</td>
</tr>
<tr>
<td>Product Specifications</td>
<td>15</td>
</tr>
<tr>
<td>Technical Specifications</td>
<td>15</td>
</tr>
<tr>
<td>Input Power Requirements</td>
<td>15</td>
</tr>
<tr>
<td>Output Power</td>
<td>15</td>
</tr>
<tr>
<td>Generator Dimensions</td>
<td>15</td>
</tr>
<tr>
<td>Foot Pedal</td>
<td>15</td>
</tr>
<tr>
<td>Environmental Conditions</td>
<td>15</td>
</tr>
<tr>
<td>Generator Output Graphs</td>
<td>16</td>
</tr>
<tr>
<td>Generator Classification and Safety Verification</td>
<td>19</td>
</tr>
<tr>
<td>Classification</td>
<td>19</td>
</tr>
<tr>
<td>Safety Verification</td>
<td>19</td>
</tr>
<tr>
<td>Parts List</td>
<td>19</td>
</tr>
<tr>
<td>Warranty</td>
<td>20</td>
</tr>
<tr>
<td>Service Replacement Units Warranty</td>
<td>20</td>
</tr>
<tr>
<td>Service Replacement Program</td>
<td>20</td>
</tr>
<tr>
<td>Repair Service Program</td>
<td>20</td>
</tr>
</tbody>
</table>
**Description**

The Smith & Nephew DYONICS™ RF System is a bipolar, radiofrequency (RF) electrosurgical system designed for use in arthroscopic and orthopedic procedures. The DYONICS RF System consists of the following components:

1) a bipolar radiofrequency generator
2) a reusable, non-sterile power cord
3) a reusable, non-sterile foot pedal
4) a disposable, sterile RF probe

The generator is the voltage source that delivers RF energy to the treatment site via a DYONICS RF Probe with an integrated cable. The generator is activated by the foot pedal. The disposable DYONICS RF Probe is available in various single or multi-electrode configurations and is supplied separately.

**Indications for Use**

The Smith & Nephew DYONICS RF System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures.

<table>
<thead>
<tr>
<th>Arthroscopic and Orthopedic Procedures</th>
<th>Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ablation and Debridement</strong></td>
<td></td>
</tr>
<tr>
<td>• ACL/PCL</td>
<td>Knee</td>
</tr>
<tr>
<td>• Acromioplasty</td>
<td>Shoulder</td>
</tr>
<tr>
<td>• Articular Cartilage</td>
<td>All Joints</td>
</tr>
<tr>
<td>• Bursectomy</td>
<td>All Joints</td>
</tr>
<tr>
<td>• Chondroplasty</td>
<td>All Joints</td>
</tr>
<tr>
<td>• Fascia</td>
<td>All Joints</td>
</tr>
<tr>
<td>• Ligament</td>
<td>All Joints</td>
</tr>
<tr>
<td>• Notchplasty</td>
<td>Knee</td>
</tr>
<tr>
<td>• Scar Tissue</td>
<td>All Joints</td>
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<tr>
<td>• Soft Tissue</td>
<td>All Joints</td>
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<td>• Subacromial Decompression</td>
<td>Shoulder</td>
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<td>• Synovectomy</td>
<td>All Joints</td>
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<tr>
<td>• Tendon</td>
<td>All Joints</td>
</tr>
<tr>
<td><strong>Excision and Resection</strong></td>
<td></td>
</tr>
<tr>
<td>• Acetabular Labrum</td>
<td>Hip</td>
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<tr>
<td>• Articular Labrum</td>
<td>All Joints</td>
</tr>
<tr>
<td>• Capsule</td>
<td>All Joints</td>
</tr>
<tr>
<td>• Capsular Release</td>
<td>Knee</td>
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<tr>
<td>• Cartilage flaps</td>
<td>Knee</td>
</tr>
</tbody>
</table>

**Contraindications**

The Smith & Nephew DYONICS RF System is contraindicated in any procedures where a conductive solution is not used. The System is also contraindicated for patients who have cardiac pacemakers or other electronic implants without specific instructions from the manufacturer of the cardiac pacemaker or implant. Refer to the DYONICS RF Probes with Integrated Cables Instructions for Use for a more comprehensive list of contraindications regarding specific procedures. The generator is not intended to be used with a neutral electrode (split grounding pad).
Principle of Operation

The Smith & Nephew DYONICS™ RF System is designed to deliver RF energy to the electrode elements located at the distal end of the sterile single-use DYONICS RF Probe. Current flows between the active electrode element and the return electrode element located on the DYONICS RF Probe in a bipolar configuration, providing a localized energy field. The result of this arrangement is controlled energy delivery with minimal collateral tissue damage.

The DYONICS RF System passes RF energy through a conductive solution. The conductive solution forms a thin layer between the active and return electrode elements. In the ablation mode, the conductive solution is converted into an RF energy field containing energized charged particles. When the high-energy charged particles come in contact with tissue, they cause its disintegration through molecular dissociation.

This mode of operation results in limited collateral thermal damage to the surrounding untreated tissue.

The system can also function when a lower voltage is applied between the active and return electrodes. In this case, the electrical field is below the threshold required to create an energy field and resistive tissue heating occurs. This mode is useful when a greater thermal effect is needed (e.g., for coagulation of blood vessels). The appropriate voltage setting depends on the design of the DYONICS RF Probe used, tissue type, and desired tissue effect.

⚠️ Warnings

- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions completely prior to use.
- The DYONICS RF System is intended for use by healthcare professionals only. The DYONICS RF System may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the DYONICS RF System or shielding the location.
- Failure to follow all applicable instructions may result in serious surgical consequences.
- Explosion Hazard: The following substances will contribute to increased fire and explosion hazards in the operating room: flammable substances (such as alcohol-based skin prepping agents and tinctures), flammable anesthetics, naturally occurring flammable gases which may accumulate in body cavities such as the bowel, oxygen enriched atmospheres, and oxidizing agents such as nitrous oxide (N2O) atmospheres.
- Fire Hazard: Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes).
- Electrosurgical accessories, which are activated or hot from use, can cause a fire.
- Accessory tips may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of DYONICS RF probes outside the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrosurgical current carried through other instruments and conductive objects.
- Electrosurgical current may be generated in conductive objects by direct contact with the active electrode or by the active or return electrode being in close proximity to a conductive object.
- If excessive heating or physical forces cause damage to the DYONICS RF Probe tip, foreign body fragments may result, possibly requiring extended surgery for removal.
- Do not use the Smith & Nephew DYONICS RF System with non-conductive media (e.g. sterile water, dextrose, air, gas, glycine, etc.). Use only conductive media such as normal saline or Ringer's lactate.
- Electric Shock Hazard: Do not connect wet accessories to the generator.
- Generator failure could result in an unintended increase in output power.
- Do not use metal cannulas as they may create an alternate current path resulting in unintended patient burn.
- If used for laparoscopic procedures, gas embolism due to insufflation of gas in the abdomen may result.
Precautions

Rx only  U.S. Federal law restricts this device to sale by or on the order of a physician.

• Prior to initial use, ensure that all package inserts, warnings, precautions, and Instructions for Use are read and understood.
• Safe and effective electrosurgery is dependent not only on equipment design, but also, to a large extent, on factors under the user’s control. Only persons having adequate training and familiarity with orthopedic surgery should perform procedures with the Smith & Nephew DYONICS® RF System.
• Consult medical literature relative to techniques, complications, and hazards prior to performance of any procedure.
• Evaluate patients for predisposing medical problems that may be aggravated by the stress of surgery.
• A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or generator grounding is not compromised.
• When instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
• When not in use, remove the DYONICS RF Probe from the surgical site and place away from metallic objects. RF probes should remain separated from other electrosurgical equipment to avoid inadvertent electrical coupling between devices. Inadvertent activation may cause injury to patient and/or user or equipment damage.
• Do not wrap cables around metal objects. Wrapping cords around metal objects may induce currents that could lead to shocks, fires, or injury to the patient or surgical personnel.
• Use caution when using DYONICS RF Probe tips to probe or manipulate tissue. Forceful contact between DYONICS RF Probe tips and tissue or other instruments may result in damage to the instrument.
• Do not use the DYONICS RF Probe as a lever to enlarge surgical site or gain access to tissue.
• Do not allow fluid to contact any electrical connectors on the RF probes, generator, or cables during use.
• To avoid risk of shock, do not allow patient contact with grounded conductive objects, such as a surgical table frame or an instrument table. Grounding pads should not be used.
• Do not contact metal objects with an activated DYONICS RF Probe.
• Observe fire precautions at all times. Sparking and heating associated with electrosurgery may be an ignition source.
• Do not use flammable agents for cleaning and disinfection of the generator or cables.
• As with other electrosurgical units, electrodes and cables can provide paths for high frequency current. Position the cables to avoid contact with the patient or other electrical leads.
• High frequency (HF) electrosurgical equipment such as the Smith & Nephew DYONICS RF System may adversely affect the operation of other electronic equipment.
• Electrodes should remain separated from other electrosurgical equipment to avoid inadvertent electrical coupling between devices.
• Monitoring electrodes (e.g., electrocardiography (ECG)) should be positioned as far as possible from the surgical electrodes when HF surgical equipment and physiological monitoring equipment are used simultaneously on a patient. Monitoring needle electrodes (e.g., electromyography (EMG)) are not recommended.
• Monitoring equipment incorporating high frequency current-limiting devices is recommended.
• Do not remove the cover of the generator. Refer servicing to qualified personnel.
• Do not obstruct the exhaust fan (located at rear of generator).
• Do not touch the generator’s fan and/or speaker while touching the patient.
• Before each use, check that all generator indicator lights and audio signals are functional. Make sure that the power cable plug is properly connected to the generator receptacle.
• To avoid risk of fire, only replace the generator fuses with the same type and rating.
• Controller failure could result in an unintended increase in output power.
Adverse Reactions

As a consequence of electrosurgery, damage to surrounding tissue through iatrogenic injury could occur.

Unpacking

Verify that all items have been received and are not damaged. Report damage immediately to Customer Service. Save all containers and packaging material; they are required if it is necessary to return the equipment.

Assembly and System Check

1. Connect the power cord to the receptacle on the rear panel of the generator. Connect the other end of the power cord to the electrical outlet.
   
   Note: If a power cord other than the DYONICS power cord is used, ensure that the power cord meets local requirements and complies with the voltage and current rating listed on the back panel of the generator.

2. Turn the power switch on the front of the generator to the “ON” position. The system performs a Power-On Self-Test routine. A series of digits identifies the software version.

3. Attach the foot pedal receiver to the tan receptacle (black outline) on the front of the generator. The Foot Pedal Connected Indicator on the front of the generator illuminates.

4. Depress the Ablation function on the foot pedal. The red Warning Indicator on the front of the generator illuminates and the generator emits an intermittent monotone alarm. The yellow Ablation Activation Indicator on the front panel is off.

   Note: Use only the foot pedal authorized by Smith & Nephew for use with the DYONICS RF System.

5. Attach the DYONICS RF Probe to the cable receptacle (orange outline). The green RF Probe Indicator illuminates. The DYONICS RF System defaults to a recommended power setting for each DYONICS RF Probe style to serve as a guide for safe and effective operation.

   Note: Initial and maximum settings are suggested settings. Proper activation of the DYONICS RF Probe should always be confirmed.

   In order to adjust the settings, the DYONICS RF Probe cable must be connected to the generator.

   ! WARNING: Electrosurgical accessories which are activated or hot from use can cause a fire.

   ! WARNING: Accessory tips may remain hot enough to cause burns after the electrosurgical current is deactivated.

   ! WARNING: Localized burns to the patient or physician may result from electrosurgical current carried through other instruments and conductive objects.

   CAUTION: Do not contact metal objects with an activated RF probe.

   CAUTION: Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes).

6. Taking care not to touch the DYONICS RF Probe end, depress the Ablation (yellow) foot pedal. The yellow Ablation Activation Indicator illuminates. DO NOT use the generator if the alarms during system check are not audible. If the generator does not function as described above, do not use. Please contact Customer Service immediately.
System Overview

1. Generator
2. Power cord
3. Foot pedal
4. Ablation pedal
5. Coagulation pedal
6. Setting Adjustment button
7. Foot control connector
8. Cable connector with orange plug
9. DYONICS® RF Probe with Integrated Cable
10. Shaft (DYONICS RF Probe)
11. Return electrode (DYONICS RF Probe)
12. Active electrode tip (DYONICS RF Probe)
13. Suction tube (depending on DYONICS RF Probe style)
Front Panel Layout

Cable Receptacle
Accepts Smith & Nephew DYONICS® RF Probes with orange mating ends.

RF Probe Connected Indicator
Illuminates when the DYONICS RF Probe is properly connected.

Symbol for Defibrillator-Proof Type BF Equipment
Indicates that this equipment provides a degree of protection against electric shock to TYPE BF applied parts as defined in IEC/EN 60601-1. It also has an F type applied part capable of withstanding the effects of defibrillator discharge.

LED Display Window
Indicates the setting output level.

Setting Adjustment
Increment (arrow up) and decrement (arrow down) arrow buttons control the power setting. The power output adjustment is only enabled on DYONICS RF Probes for which this feature is allowed. The output level can also be adjusted from the Setting Adjustment function on the foot pedal. See “Voltage Outputs” for the voltage levels corresponding to each setting.

Warning Indicator
Illuminates and alarms when a generator-specific failure or malfunction occurs.

Ablation Activation Indicator
Illuminates when the foot pedal Ablation function is depressed with a DYONICS RF Probe attached.

Coagulation Activation Indicator
Illuminates when the foot pedal Coagulation function is depressed with a DYONICS RF Probe attached.

Foot Pedal Connected Indicator
Illuminates when the foot pedal is properly connected.

Foot Pedal
Plugs into the tan receptacle (black outline) on the front of the generator.

On/Off Switch
Turns the AC power on and off. When the switch is on, the LED display on the generator is active. May remain active for up to 5 seconds following power turn-off.

Figure 1. Generator front panel
Rear Panel Layout

Rear Panel Layout

Figure 2. Generator rear panel

12 **Power Cord Receptacle / Fuse Holder**
Accepts the generator power cord. The fuse holder is behind the receptacle.

13 **Serial Communication Port**
Allows the DYONICS® RF system to communicate with remote accessory devices that use the RS-232 serial communication protocol.

14 **Tone Volume Control**
Regulates tone volume. To increase volume, turn the knob clockwise. To reduce volume, turn the knob counterclockwise.

15 **Equipotential Ground Symbol**
Identifies the conductor used to bond the equipment to earth ground.

16 **Non-Ionizing Radiation Symbol**
Indicates that this equipment emits RF energy during activation.

17 **Fuse Rating Symbol**
Indicates that only fuses with the appropriate rating should be used. Check the generator rear label for the appropriate fuse rating. See “Maintenance and Troubleshooting” for fuse replacement instructions.

18 **TÜV Nord Classified Mark**
Indicates compliance with applicable international IEC 60601 series safety standards.

19 **Attention Symbol**
Alerts the user to read and understand this manual and accompanying instructions before operating the equipment.

20 **No Disposal Symbol**
Indicates that this equipment should not be discarded in any waste container.

21 **CE Mark - European Certification Symbol**
Indicates compliance with the European Commission Medical Device Directive (93/42/EEC).

22 **UL Classified Mark**
Indicates compliance with applicable safety standards for the United States and Canada by Underwriters Laboratories, Inc. (UL).
Instructions for Use / System Preparation and Care

Instructions for Use

Operator Training Requirements
The operator should be experienced in electrosurgical techniques. It is recommended that the user remain current with advances in orthopedic procedures. Additional training on the use of the Smith & Nephew DYONICS® RF System from a Smith & Nephew representative is available.

General System Operation
DYONICS RF Probes are activated by the foot pedal. The foot pedal has three functions as described below:

Ablation Activation
The Ablation Activation function (yellow pedal) operates the generator’s normal ablation mode and activates the DYONICS RF probe.

Coagulation Activation
The Coagulation Activation function (blue pedal) operates the generator’s preset coagulation mode and activates the DYONICS RF Probe for hemostasis of blood vessels.

Setting Adjustment
The Setting Adjustment function adjusts the voltage level on the generator. Each press of the Setting Adjustment function increases the voltage by one level up to the maximum setting for each DYONICS RF Probe style. Once the maximum level for the connected DYONICS RF Probe has been reached, the system cycles back to setting 1.

Voltage Outputs
The voltage outputs correspond to the Ablation or Coagulation Settings as listed in the table below.

<table>
<thead>
<tr>
<th>Patient Cable Receptacle</th>
<th>Display</th>
<th>Output Voltage (Vrms ±10%)</th>
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<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
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<td>300</td>
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<td></td>
<td>C</td>
<td>65</td>
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</table>

When the generator is powered on it runs through a series of self tests. If a DYONICS RF Probe is attached at power-up, the generator displays the default setting on the LED display. Otherwise, the generator displays 0 until a DYONICS RF Probe is attached, at which time the default setting is displayed. Default settings usually provide the best results in most situations.

Note: If a setting outside of the default range (between the initial setting and maximum setting) is selected, confirm proper activation of the DYONICS RF Probe.

Once a DYONICS RF Probe is properly connected, the setting can be adjusted by pressing the adjustment buttons on the front panel. The setting can also be adjusted by pressing the Setting Adjustment function on the foot pedal. In general, higher settings result in more aggressive tissue ablation, and lower settings (e.g., 1 or 2) cause the DYONICS RF Probe to maintain a resistive heating mode.

System Preparation and Care

System Preparation
1. Prior to each use, inspect the Smith & Nephew DYONICS RF System for possible damage to the generator casing, accessories, and cables.
2. Insert the receptacle end of the power cord into the power cord receptacle at the rear of the generator. Insert the plug end of the power cord into an appropriately grounded electrical outlet. Position the generator so that the exhaust fan in the rear of the generator is unobstructed and directed away from the patient.
3. Press the On/Off switch on the front panel of the Generator to the “On” (I) position.
4. Connect the foot pedal to the foot pedal receptacle on the front of the generator. The Foot Pedal Connected Indicator (green) on the generator front panel illuminates.
5. Connect the DYONICS RF Probe with Integrated Cable to the probe cable receptacle (18 pin, orange outline) on the front of the generator.

Note: Refer to the DYONICS RF Probe with Integrated Cables Instructions for Use (REF 10600464) for specific instructions regarding surgical preparation and procedures.
6. Use Setting Adjustment arrow buttons to obtain desired effects.
RF Probe Selection
Select the DYONICS® RF Probe most appropriate for the procedure. The DYONICS RF System generator defaults to a recommended power setting for each DYONICS RF Probe as a guide for safe and effective operation.

Note: Initial and maximum settings are suggested settings. Always confirm proper activation of the DYONICS RF Probe.

In order to adjust the settings, the DYONICS RF Probe cable must be connected to the generator.

System Shut Down
1. Turn the power switch to the “OFF” position. Within four seconds, all lights on the generator and the Setting display go off.
2. Disconnect the suction tubing if appropriate.
3. If using the DYONICS RF Probe with Integrated Cable, disconnect the DYONICS RF Probe cable connector from the generator. Do not attempt to separate the DYONICS RF Probe from the cable component. Discard the DYONICS RF Probe with Integrated Cable.

Cleaning and Sterilization
Surface Cleaning & Disinfection of Generator and Foot Pedal
Do not sterilize or immerse in liquid. Wipe clean with a soft cloth and mild detergent as needed.

Clean with detergents and disinfectants according to standard practices. Disinfect with liquid chemical disinfectants such as chlorine solutions, iodophors, glutaraldehydes and hydrogen peroxides. Follow manufacturer guidelines for concentration and length of exposure.

DYONICS RF Probe
The DYONICS RF Probe is supplied sterile and is intended for single use only. Do not clean, resterilize, or reuse the DYONICS RF Probe as this may result in product malfunction, failure, or patient injury, which may also expose the patient to the risk of transmitting infectious diseases. Please refer to the Instructions for Use packaged with the DYONICS RF Probe for specific information concerning DYONICS RF Probe use.

Maintenance and Troubleshooting
Maintenance
Other than fuse replacement, the generator has no user-serviceable parts. It is designed to provide consistent output levels and is calibrated by clock crystals, voltage references, and fixed resistors. There are no internal adjustments in the instrument and, due to the calibration methods, no annual maintenance check is required. If any component malfunctions, call Customer Service for a return authorization.

Fuse Replacement
The fuse holder is located on the back of the generator. To replace a fuse, turn off the power to the generator and unplug the power cord from the power receptacle at the rear of the generator. After waiting at least 10 seconds for internal circuitry to discharge, use a screwdriver or similar tool to remove the fuse holder by depressing the locking tabs. Replace both fuses with the same type and rating as specified on the rear panel of the generator. Reinsert the fuse holder until the locking tabs snap into place. Reconnect the Power Cord and restore power to the generator. If a fuse fails again, disconnect all power to the generator and contact Customer Service.

Alarms

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<thead>
<tr>
<th>Alarm</th>
<th>Possible Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent dual tone</td>
<td>Power limit alarm or overload</td>
</tr>
<tr>
<td>Intermittent monotone</td>
<td>Connection fault alarm (DYONICS RF Probe, Over Temperature Condition, Over Power Condition)</td>
</tr>
</tbody>
</table>
**Troubleshooting Guide**

If you are experiencing problems with the Smith & Nephew DYONICS® RF System, use the following troubleshooting guide to help identify or eliminate the problem before contacting Customer Service.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Possible Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>System does not power up after the power switch is pressed.</td>
<td>Check that the power cord is properly connected to the generator and plugged into an appropriately grounded outlet. If the unit is plugged in properly, check if the fuses have blown. To change the fuses, see “Fuse Replacement.”</td>
</tr>
<tr>
<td>System powers up and generator is unresponsive.</td>
<td>The generator performs self-tests immediately after the power is applied to the unit and prior to the initialization of the user interfaces. If one of these self tests fails, the generator may go into idle mode without displaying an error message or emitting an alarm. If this occurs, turn the generator off and then on again and check for proper operation. If the problem persists, return the system for service.</td>
</tr>
<tr>
<td>Green Foot Pedal Connected Indicator light does not illuminate</td>
<td>Check that the foot pedal is properly connected to the generator and that the cord is not nicked, cut, or frayed. Do not use the foot pedal if the cord has been damaged. If the problem persists, change the foot pedal. If the Foot Pedal Connected Indicator light is still not illuminated, return the system for service.</td>
</tr>
<tr>
<td>Green RF Probe Connected Indicator light does not illuminate when a DYONICS RF Probe is connected.</td>
<td>Make sure that the DYONICS RF Probe is properly connected to the generator. If the problem persists, first change the DYONICS RF Probe. If the RF probe indicator light is still not illuminated, return the system for service.</td>
</tr>
<tr>
<td>Nothing happens when one of the device activation functions on the foot pedal is depressed.</td>
<td>Verify that both the Foot Pedal Connected Indicator light and the RF Probe Connected Indicator light are illuminated when the foot pedal is depressed. Check if the setting has been adjusted to a level appropriate for operation (usually 1 or greater). Confirm that the DYONICS RF Probe tip and shaft are covered by a conductive irrigant. Make sure that the DYONICS RF Probe is properly connected to the generator. If the problem persists, replace the DYONICS RF Probe. If the system still fails to operate, return the system for service.</td>
</tr>
<tr>
<td>The DYONICS RF Probe does not activate, an intermittent monotone alarm sounds, and a red warning light illuminates.</td>
<td>Generally indicates that the DYONICS RF Probe is not properly connected to the generator. Check all connections. If the alarm continues to sound when the foot pedal is depressed, replace the DYONICS RF Probe. If the problem continues, return the system for service.</td>
</tr>
<tr>
<td>A dual tone alarm sounds and a red warning light illuminates when the DYONICS RF Probe is activated.</td>
<td>This is a safety feature of the Smith &amp; Nephew DYONICS RF System and may occur if the DYONICS RF Probe is activated for an extended time without contacting tissue. To reset the unit, step off the foot pedal. Make sure that the DYONICS RF Probe is close to or in contact with the target tissue and depress the foot pedal again. If the alarm continues, replace the DYONICS RF Probe. If the problem persists, return the system for service.</td>
</tr>
</tbody>
</table>
Error and Fault Messages

When the system encounters an error, the generator first displays "E" and then the digit identifying the error. When the system encounters a fault, the generator first displays "F" and then the digit identifying the fault.

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>LED Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error</td>
<td>Both CUT/COAG buttons pressed simultaneously</td>
<td>E/1</td>
</tr>
<tr>
<td>Error</td>
<td>DYONICS® RF Probe disconnected while RF active</td>
<td>E/2</td>
</tr>
<tr>
<td>Error</td>
<td>Use-limiting time expired</td>
<td>E/3</td>
</tr>
<tr>
<td>Error</td>
<td>Shorted DYONICS RF Probe</td>
<td>E/4</td>
</tr>
<tr>
<td>Error</td>
<td>Re-used DYONICS RF Probe detected</td>
<td>E/5</td>
</tr>
<tr>
<td>Fault</td>
<td>Integrity of stored program compromised (calculated CRC differs from loaded value)</td>
<td>F/1</td>
</tr>
<tr>
<td>Fault</td>
<td>Integrity of RAM space compromised (RAM test failed)</td>
<td>No LED message can be displayed</td>
</tr>
<tr>
<td>Fault</td>
<td>COP watchdog timer not strobed</td>
<td>F/3</td>
</tr>
<tr>
<td>Fault</td>
<td>Output of the DC-DC converter out of specification</td>
<td>F/4</td>
</tr>
<tr>
<td>Fault</td>
<td>Analog measurement failure (measured value out of specification)</td>
<td>F/5</td>
</tr>
<tr>
<td>Fault</td>
<td>Foot pedal or front panel switch pressed during power on</td>
<td>F/6</td>
</tr>
<tr>
<td>Fault</td>
<td>Over temperature of internal electronics</td>
<td>F/7</td>
</tr>
</tbody>
</table>

Product Specifications

Technical Specifications

Input Power Requirements
Voltage: 100 –120/220–240 V~
Frequency: 50/60 Hz
Input Current: 8/4 A
Fuse Rating: T8 A /250V

Output Power
Fundamental Frequency: 100 kHz
Voltage Range: 0–300 Vrms @100 kHz
Max. Output Power: 325 W @ 250 Ω
Operating Temperature: 10° C to 40° C

Generator Dimensions
Weight (max): < 5 kg (< 11 lbs)
Height: 10.2 cm (4.0 inches)
Width: 30.4 cm (12.0 inches)
Length: 40.2 cm (15.8 inches)

Foot Pedal
Foot pedal cable length: 4.7 m (15 ft.)

Environmental Conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Transport and/or Storage</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>-40°–70° C (-40°–158° F)</td>
<td>10°–40° C (50°–104° F)</td>
</tr>
<tr>
<td>Humidity</td>
<td>10–85% (no condensation allowed)</td>
<td>10–85%</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>500–1060 hPa (7.2 psi–15.3 psi)</td>
<td>700–1060 hPa (10.1 psi–15.3 psi)</td>
</tr>
</tbody>
</table>
Generator Output Graphs

The graph below shows the output power at each specified setting of the instrument. The used load was 250 Ohms for all settings (per IEC/EN 60601-2-2, subclause 6.8.3).

Output Power vs. Setting at 250 Ohms Resistive Load
The graph below shows the output power (at full and half settings) versus load resistance (per IEC/EN 60601-2-2, subclause 6.8.3).

Output Power vs. Load Resistance
The following graph illustrates the relationship between instrument settings and output RMS voltage.

Output Voltage vs. Setting
Generator Classification and Safety Verification

Classification

According to IEC/EN 60601-2-2, Specification for High Frequency Surgical Equipment, the generator is classified as follows:

- **Type of protection against electrical shock:**
  - Class I equipment.

- **Degree of protection against electrical shock:**
  - Defibrillation proof, type BF (Isolating/floating).

- **Degree of protection against harmful ingress of water:**
  - Generator is classified as 1PX0.
  - Foot pedal meets requirements of IEC/EN 60601-2-2, subclause 44.6, watertight construction (IPX8).

- **Equipment not suitable for use in the presence of a flammable anesthetic mixture.**

- **Mode of operation:** capable of continuous operation.

Safety Verification

The Smith & Nephew DYONICS™ RF System meets the requirements of IEC/EN 60601-1, IEC/EN 60601-1-2, IEC/EN 60601-1-4, IEC/EN 60601-2-2, CSA 22.2 No. 6011, and IEC/EN 60601-2-18. It is recommended that the biomedical engineering department test the system to ensure that it meets the following leakage levels:

- **Leakage current ≤100μA at 100-120/220-240 V~, 50/60 Hz isolated patient connections**
- **Leakage current ≤500μA at 100-120/220-240 V~, 50/60 Hz non-patient applied parts**

If the system fails to meet the specifications listed above, please contact Smith & Nephew Customer Service for a return merchandise authorization.

Parts List

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>72202149</td>
<td>DYONICS RF System</td>
</tr>
<tr>
<td>72202491</td>
<td>DYONICS RF Power Cable, US</td>
</tr>
<tr>
<td>72202492</td>
<td>DYONICS RF Power Cable, International</td>
</tr>
<tr>
<td>72202151</td>
<td>DYONICS RF Foot Pedal</td>
</tr>
<tr>
<td>72202138</td>
<td>DYONICS RF-S DYNAMO 90° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202139</td>
<td>DYONICS RF-S WHIRLWIND 90° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202140</td>
<td>DYONICS RF-S CROSS 50° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202141</td>
<td>DYONICS RF ABLATION 90° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202144</td>
<td>DYONICS RF HEDGEHOG Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202143</td>
<td>DYONICS RF CURVE 45° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202145</td>
<td>DYONICS RF HOOK 30° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202142</td>
<td>DYONICS RF BROADNOSE 90° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202146</td>
<td>DYONICS RF SLICE 20° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202147</td>
<td>DYONICS RF CONTRACT 30° Probe with Integrated Cable</td>
</tr>
<tr>
<td>72202148</td>
<td>DYONICS RF ROUND 60° Probe with Integrated Cable</td>
</tr>
</tbody>
</table>
Warranty

Smith & Nephew products are guaranteed to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

This limited warranty is restricted to repair or replacement by Smith & Nephew, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Smith & Nephew be liable for any anticipated profits, consequential damages, or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

Service Replacement Units Warranty

Smith & Nephew service replacement units are warranted to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

Service Replacement Program

Smith & Nephew offers a Service Replacement Program for its products to minimize downtime in your operating room.** For a Return Authorization (RA) number or for additional information on this program, call Customer Service at +1-800-343-5717 in the U.S., or contact your authorized representative.

**Service Replacement Program may not be offered in all countries.

Repair Service Program

For devices no longer under warranty, repairs can be made by Smith & Nephew or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully disinfected, repackaged, marked with the Return Authorization (RA) number, and returned postpaid to the appropriate Smith & Nephew Service Center. Smith & Nephew Customer Service or your local authorized representative can provide shipping information.

For customer service please contact Smith & Nephew.

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The Smith & Nephew DYONICS RF System is covered by the following U.S. Patents: 5,697,909; 5,697,281; 5,697,536; 5,697,882; 5,683,366; 5,681,282; 5,766,153; 5,810,764; 5,843,019; 5,871,469. Additional patents issued and pending.