Instructions for Use for Lektrafuse® RF Generator

Serial Number
The serial number of this Lektrafuse RF generator is recorded on the label affixed to the back of the RF generator. Note the serial number of this Lektrafuse RF generator in the space provided below, and retain this Instructions for Use (IFU) as a permanent record of your purchase for future communication with Aesculap, Inc.

Serial Number: ____________________________________________
Table of Contents

Glossary of Terms .................................................................................................................................................. 3
1.0 Overview .......................................................................................................................................................... 4
2.0 System Safety Information .......................................................................................................................... 4
2.1 Warnings ....................................................................................................................................................... 4
  2.2 Precautions .................................................................................................................................................. 5
  2.3 Electromagnetic Interference ..................................................................................................................... 6
  2.4 Class I Equipment (IEC 60601-1) ............................................................................................................. 6
  2.5 Type BF Equipment (IEC 60601-1) .......................................................................................................... 6
  2.6 Spillage (IEC 60601-2-2) ....................................................................................................................... 6
  2.7 Duty Cycle ................................................................................................................................................ 6
    2.7.1 Low Frequency (50/60 HZ) Leakage Current .................................................................................... 7
    2.7.2 High Frequency Leakage Current .................................................................................................. 7
  2.8 HF Surgical Equipment (IEC 60601-2-2) ............................................................................................ 7
3.0 Lektrafuse® RF Generator and Accessories ............................................................................................... 8
  3.1 System Components ................................................................................................................................ 8
  3.2 Front Panel ................................................................................................................................................. 8
  3.3 Rear Panel .................................................................................................................................................. 8
4.0 Displays, Symbols and Icons ........................................................................................................................ 9
5.0 Lektrafuse RF Generator: Set-up .................................................................................................................. 9
  5.1 Unpacking and Inspection ....................................................................................................................... 9
  5.2 List of RF Accessories ............................................................................................................................ 9
  5.3 Steps .......................................................................................................................................................... 10
    5.3.1 Step 1: Placing the Lektrafuse RF Generator .................................................................................... 10
    5.3.2 Step 2: Powering the Lektrafuse ....................................................................................................... 10
    5.3.3 Step 3: Connecting the Foot Pedal ................................................................................................... 10
    5.3.4 Step 4: Connecting the Caiman® Instrument .................................................................................... 10
6.0 Care and Storage of the Lektrafuse RF Generator Following Use .............................................................. 11
  6.1 Steps ......................................................................................................................................................... 11
    6.1.1 Step 1: Disconnect the Instrument .................................................................................................. 11
    6.1.2 Step 2: Turn off the Lektrafuse RF Generator ................................................................................. 11
    6.1.3 Step 3: Cleaning the Lektrafuse RF Generator and Accessories .............................................. 11
    6.1.4 Step 4: Storing the Lektrafuse RF Generator ................................................................................ 12
7.0 Additional Information .................................................................................................................................. 12
  7.1 Service ...................................................................................................................................................... 12
  7.2 Technical Assistance ............................................................................................................................... 12
  7.3 Warning, Error, and Fault Conditions .................................................................................................... 12
  7.4 Trouble Shooting ..................................................................................................................................... 15
  7.5 Power Profile .......................................................................................................................................... 15
  7.6 Generator Specifications .......................................................................................................................... 16
  7.7 Accessories ............................................................................................................................................. 16
    7.7.1 Additional Products .......................................................................................................................... 16
Glossary of Terms

**Bipolar Electrosurgery**
Electrosurgery in which current flows between two bipolar electrodes that are positioned around tissue to create a surgical effect (heating, desiccation). Electrical current passes from one electrode through the desired tissue to the second electrode, thus completing the electrical circuit without dispersing through other parts of the patient’s body.

**Bipolar instrument**
An electrosurgical instrument or accessory that incorporates both an active and return electrode. Electrosurgery The directed passage of high frequency electrical current through tissue from an electrode that concentrates the electrical current to a larger electrode (return electrode) that disperses and returns the current to a power supply (RF generator) in order to produce a surgical effect (tissue cutting, tissue coagulation).

**Error**
Condition that requires mitigation by user actions.

**Fault**
Condition that requires power cycling or factory maintenance.

**RF Generator**
The power supply that converts low frequency alternating current to high frequency current used for electrosurgery.

**Hemostasis**
The stopping of bleeding from blood vessels, either spontaneously (with no intervention) or with mechanical and/or electrosurgical instruments and/or pharmaceutical agents.

**Instrument**
The sterile, single use electrosurgical device that, when connected to the RF generator, delivers radiofrequency energy (RF).

**Instrument Cable**
The cord which connects the electrosurgical instrument to the RF generator and delivers radiofrequency energy (RF).

**Regrasp Indicator**
An audible series of tones that indicate the potentially inadequate sealing of the tissue within the instrument jaws (see Regrasp Caution under section 7.5.)

**Radio Frequency**
Frequencies below 550kHz that transmit radio signals; radiofrequency energy (RF) is the high frequency current used in electrosurgery.

**Symbol**
An image or representation printed on the front and/or rear of the RF generator intended to convey information about associated connectors, indicators etc.

**Vessel Sealing**
The electrosurgical fusing of vessel walls to create a permanent seal and prevent blood loss.
1.0 OVERVIEW

Intended Use
The Lektrafuse® RF Generator and Caiman® Instruments are indicated for tissue sealing and division. The instrument can seal vessels up to and including 7mm.

For specific indications, please refer to the individual Caiman Instrument’s Instructions for Use.

This device is not effective for use in tubal sterilization/tubal coagulation for sterilization purposes.

System Description
The Lektrafuse RF System consists of a radiofrequency (RF) energy power supply (RF Generator), RF Instrument (sold separately), and accessories (power cable, RF cable, foot pedal, etc.).

The Lektrafuse RF Generator is an isolated microprocessor-based bipolar electrosurgical power supply which is used for tissue sealing during the performance of open and laparoscopic surgeries. The operation of the Lektrafuse RF Generator is through a closed-loop control, implemented in micro-controlled firmware. Tissue sealing is controlled by internal microprocessor and associated RF generator software.

2.0 SYSTEM SAFETY INFORMATION

2.1 Warnings
The safe and effective use of RF is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained user. It is important that the operating instructions supplied with the Lektrafuse RF Generator be read, understood, and followed before use. Carefully read this IFU and all warnings, cautions, and specifications before using the Lektrafuse RF Generator.

- Electric shock hazard: do not remove RF generator cover. Refer servicing to qualified Aesculap, Inc. technical personnel.

- Use the Lektrafuse RF Generator with caution in the presence of an internal or external pacemaker. Interference produced by electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult with the pacemaker manufacturer or hospital biomedical engineering personnel for further information.

- Use the Lektrafuse RF Generator with caution in the presence of an internal cardiac defibrillator (ICD). Electrosurgery may cause multiple activations of ICDs. Consult with the ICD manufacturer or hospital biomedical engineering personnel for further information when use of electrosurgical application is planned in patients with ICDs.

- Do not use the Lektrafuse RF Generator in the presence of flammable anesthetics or other flammable gases; near flammable fluids, such as skin preparation agents and tinctures; flammable objects; or with oxidizing agents.

- Observe fire precautions at all times. Sparking and heating associated with use of electrosurgical systems such as the Lektrafuse RF Generator can provide an ignition source. When using the Lektrafuse RF Generator, prevent any potentially flammable substances or gases from pooling under surgical drapes or within the area where electrosurgery is performed.

- Fire / Explosion Hazard: do not use the Lektrafuse RF Generator in oxygen enriched atmospheres, nitrous oxide (N2O) atmospheres, or in the presence of other oxidizing agents. Verify that all oxygen circuit connections are leak-free before and during use of the Lektrafuse RF Generator. Verify that endotracheal tubes are leak-free, and that the endotracheal tube cuff is properly sealed to prevent oxygen leakage. Enriched oxygen atmospheres may result in fires and burns to patients or surgical personnel.

- Hazardous Electrical Output: this equipment is for use only by trained users.

- The Lektrafuse RF Generator should not be used in patients in direct contact with grounded metal objects.
• Interference produced by the operation of the Lektrafuse RF Generator may adversely influence the operation of other electronic medical equipment, such as monitors and imaging systems.

• Information in this IFU is provided by Aesculap, Inc. only as a service to trained, licensed physicians and is made available with the understanding that this information does not constitute the rendering of medical advice.

• FAILURE TO FOLLOW ANY INSTRUCTIONS OR FAILURE TO HEED ANY WARNINGS OR CAUTIONS MAY RESULT IN SERIOUS PATIENT INJURY.

• The Lektrafuse® RF Generator accessory cords should never be wrapped around metal objects. Accessory cord wrapping may induce electrical currents that could lead to shock, fire, or injury to the patient or surgical personnel.

• Electric Shock Hazard: do not connect wet accessories to the Lektrafuse RF Generator.

• Connect Lektrafuse RF Generator accessory cords to the proper Lektrafuse RF Generator receptacle or port. Improper accessory cord connection may result in inadvertent accessory activation or other potentially hazardous conditions.

• Electric Shock Hazard: connect the Lektrafuse RF Generator accessory power cord to a properly grounded receptacle. Do not use a power plug adapter.

• THE STERILE CAIMAN® INSTRUMENT IS FOR SINGLE USE ONLY, AND RESTERILIZATION OR REUSE SHOULD NEVER BE ATTEMPTED.

• THE Lektrafuse RF GENERATOR MUST BE USED ONLY IN CONJUNCTION WITH THE CAIMAN INSTRUMENT.

• Studies have shown that smoke generated during electrosurgical procedures may be harmful to surgical personnel. These studies recommend using a surgical mask and adequate ventilation of the smoke by using a surgical smoke evacuator or other means.

• The Lektrafuse RF Generator is meant for use with only the Caiman Instrument or other Caiman Instruments with rating of at least 130Vrms at 460KHz.

• The use of the Lektrafuse RF Generator may produce interference that could adversely influence the operation of other electronic equipment.

2.2 Precautions

• Do not use the Lektrafuse RF Generator if there is any evidence of tampering or damage to the unit.

• Do not attempt to disassemble the Lektrafuse RF Generator.

• Position the Lektrafuse RF Generator to allow adequate ventilation during operation and arrange accessory cords and cables to minimize trip hazard.

• When operating the Lektrafuse RF Generator, do not touch the Caiman Instrument electrodes (on both the upper and lower instrument jaws), as the electrodes may be warm and cause burn or injury.

• To reduce the risk of fire or electrical shock, the Lektrafuse RF Generator should be kept free from dust and moisture.

• Do not use benzene, thinner, or any abrasive powder to clean the Lektrafuse RF Generator. Wipe the RF Generator with a soft, clean cloth dampened with 70-90% isopropyl alcohol.

• Do not allow any liquid to pass into any electrical connections or into the interior of the Lektrafuse RF Generator. Allow all surfaces to dry thoroughly before connecting the RF Generator to a power outlet.

• Prior to use, the Lektrafuse RF Generator, Instrument, accessories, and all packaging should be inspected for signs of damage. Never use a damaged Lektrafuse RF System component or a component from a damaged package.
• Use of accessories not outlined in this IFU could affect the safety of the Lektrafuse RF System.
• Dispose of used Caiman Instruments, Lektrafuse RF Generators, component parts, and any other accessories in accordance with local, state, and national biowaste laws and regulations.
• Read all instructions, warnings, and cautions provided with the Caiman Instruments, Lektrafuse RF Generator, and accessories before use.
• Do not stack equipment on top of the Lektrafuse RF Generator or place the generator on top of electrical equipment. These configurations may be unstable and may not allow for adequate cooling.

2.3 Electromagnetic Interference
The Lektrafuse RF Generator complies with the appropriate IEC 60601-1-2 and IEC 60601-2-2 specifications regarding electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

High levels of interference from other RF transmitting equipment, as well as other sources of electrical noise (such as cellular phones, mobile two-way radios, and electrical appliances) that are in close proximity to the Lektrafuse® RF Generator may result in performance disruption.

The Lektrafuse RF Generator generates, uses, and can radiate RF and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption or interference may be evidenced by erratic readings, cessation of operation, or incorrect functioning.

The user is encouraged to try to correct any interference by one (1) or more of the following measures:
  • Turn equipment in the vicinity of the Lektrafuse RF Generator off and then back on to isolate the offending equipment.
  • Reorient or relocate the device with which the Lektrafuse RF Generator is interfering.
  • Increase the separation between the device and the Lektrafuse RF Generator.

If assistance is required, contact Aesculap, Inc. Customer Service; toll free at (800) 282-9000.

2.4 Class I Equipment (IEC 60601-1)
Accessible conductive parts can not become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor.

2.5 Type BF Equipment (IEC 60601-1)
Lektrafuse RF Generator provides a high degree of protection against electric shock, particularly regarding allowable leakage current. It is type BF, an applied part isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault conditions is not exceeded when a voltage equal to 1.1 times the highest rated mains voltage is applied between the applied part and earth.

2.6 Spillage (IEC 60601-2-2)
The enclosure of the High Frequency (HF) surgical equipment and associated equipment is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which, when wetted, are likely to adversely affect the safety if the HF surgical equipment and associated equipment.

2.7 Duty Cycle
Under maximum power settings and rated load conditions, the Lektrafuse RF Generator is capable of operating a duty cycle of 25%, defined as 10 seconds active and 30 seconds inactive, in any mode for a period of 4 hours.
2.7.1 Low Frequency (50/60 HZ) Leakage Current

<table>
<thead>
<tr>
<th>Source Condition</th>
<th>Leakage Current Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enclosure source current, ground open</td>
<td>&lt;300μA @ 132 Vac</td>
</tr>
<tr>
<td></td>
<td>&lt;500μA @ 264 Vac</td>
</tr>
<tr>
<td>Source current, patient leads, all output</td>
<td>Normal polarity, intact ground: &lt;100μA</td>
</tr>
<tr>
<td></td>
<td>Normal polarity, ground open: &lt;500 μA</td>
</tr>
<tr>
<td></td>
<td>Reverse polarity, ground open: &lt; 500 μA</td>
</tr>
<tr>
<td></td>
<td>Mains voltage on applied part: &lt; 500 μA</td>
</tr>
<tr>
<td>Sink current at high line, all inputs</td>
<td>&lt; 5000 μA</td>
</tr>
</tbody>
</table>

2.7.2 High Frequency Leakage Current

<table>
<thead>
<tr>
<th>Lektrafuse® RF Generator leakage</th>
<th>Measured with leads recommended by Aesculap, Inc.</th>
<th>Measured directly at the energy RF Generator terminals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;21 mA rms</td>
<td>&lt;21 mA rms&lt;100 mA rms</td>
</tr>
</tbody>
</table>

2.8 HF Surgical Equipment (IEC 60601-2-2)

2.8.1 Monitoring electrodes are recommended to be placed as far as possible from surgical electrodes when HF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient. Needle monitoring electrodes are not recommended. Use of monitoring system(s) incorporating high frequency current-limiting device(s) recommended.

2.8.2 Position cables to surgical electrodes to prevent contact with patient or other leads.

2.8.3 Maximum output voltage shall be provided for equipment and active accessory.

2.8.4 A failure of HF surgical equipment could result in an unintended increase of output power.
3.0 LEKTRAFuse® RF GENERATOR AND ACCESSORIES

3.1 System Components

1. Lektrafuse RF Generator
2. AC Power Cord
3. Foot Pedal (optional; available separately)
4. Caiman® Instruments (available separately)

3.2 Front Panel

1. “POWER ON” Indicator
2. Lektrafuse RF Generator Instrument Connector Port
3. Message Display
4. Fault Indicator
5. Regrap Indicator
6. Foot Pedal Connector Port
7. RF Delivery Control Button (center) and RF Delivery Indicator (surrounding ring)

Lektrafuse RF Generator Labeling

3.3 Rear Panel

1. Ventilation
2. Fuse Holder
3. “ON/OFF” Power Switch
4. AC Power Cord Inlet
5. Equipotential Plug
6. Service Port

Manufactured for:
Aesculap, Inc.
Please contact
(800) 282-9000
with any questions.
4.0 DISPLAYS, SYMBOLS AND ICONS

Descriptions of the control buttons, indicators, connector ports, and associated functions and icons are provided in the following table. Please refer to the “Lektrafuse® RF Generator: Front Panel” photograph to locate each button or indicator.

<table>
<thead>
<tr>
<th>Button/Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Delivery Button and Indicator</td>
<td>Lit ring (blue) indicates RF delivery. Each press and release of the RF delivery button initiates or terminates RF delivery.</td>
</tr>
<tr>
<td>“POWER ON” Indicator</td>
<td>Lit indicator (green) indicates that the RF Generator is receiving power and is turned on.</td>
</tr>
<tr>
<td>Regrasp Indicator</td>
<td>Lit indicator (amber) indicates that inadequate or incomplete sealing of the tissue within the Instrument jaws may have occurred. (see Regrasp Caution under section 7.5.).</td>
</tr>
<tr>
<td>Fault Indicator</td>
<td>Lit indicator (red) indicates that a system fault has occurred. Instructions for User action will be presented in the Message Display. User should approach tissue sealing and division as if the Regrasp is also lit (see Regasp Caution under section 7.5.).</td>
</tr>
<tr>
<td>Instrument Connector Port and Indicator</td>
<td>Lit ring (green) indicates correct connection of Instrument within instrument connector port on the front of the Lektrafuse RF Generator.</td>
</tr>
<tr>
<td>Foot pedal Connector Port Icon</td>
<td>Identifies the connector port into which the connector attached to the end of the foot pedal cable is placed. Each press and release of the foot pedal initiates or terminates RF delivery.</td>
</tr>
<tr>
<td>Instrument Connector Port Icon</td>
<td>Identifies the connector port into which the connector attached to the end of the Instrument cable is placed.</td>
</tr>
</tbody>
</table>

5.0 LEKTRAFUSE RF GENERATOR: SET-UP

5.1 Unpacking and Inspection

- If the shipping carton is damaged or if any damage is identified following careful unpacking and inspection of the Lektrafuse RF Generator and Accessories, immediately notify the carrier and Aesculap, Inc.

- Confirm that all Accessories are included (see List of Accessories, below).

- If any Accessories are missing or damaged (without associated packaging damage), contact Aesculap, Inc. Customer Service, toll free at (800) 282-9000.

5.2 List of RF Accessories

(Provided with the Lektrafuse RF Generator)

- AC Power Cord

The Caiman® Instruments (with attached RF cable) and generator foot pedal are available separately.
5.3 Steps

5.3.1 Step 1: Placing the Lektrafuse® RF Generator

Place the Lektrafuse RF Generator on a stable, flat surface (such as a table, platform, or cart). If using a cart, a cart with conductive wheels is recommended. Refer to hospital procedures or local codes for detailed information.

Provide at least four to six inches of space between all sides and the top of the RF Generator to allow for adequate ventilation and cooling (during extended periods of normal RF Generator function, the top, sides, and rear panel of the Lektrafuse RF Generator may become warm).

Do not stack equipment on top of the Lektrafuse RF Generator, and do not place the Lektrafuse RF Generator on top of electrical equipment, as these configurations may be unstable and/or may not allow for adequate RF Generator ventilation and cooling.

Provide as much distance as possible between the Lektrafuse RF Generator and other electrical equipment (such as monitors), as the activated Lektrafuse RF Generator may cause electrical interference.

5.3.2 Step 2: Powering the Lektrafuse RF Generator

Connect the AC Power Cord (provided) to the Lektrafuse RF Generator AC Power Cord Inlet on the rear panel of the RF Generator. Next, plug the AC Power Cord into a standard hospital-grade outlet providing the correct voltage (incorrect voltage may result in product damage).

Electric Shock Hazard: connect the AC Power Cord to a properly grounded, three-pronged wall receptacle.

Turn the “ON/OFF” Power Switch on the rear panel of the generator to the “ON” position. Successful powering of the Lektrafuse RF Generator will illuminate the green “POWER ON” Indicator on the front panel of the RF Generator.

Powering of the Lektrafuse RF Generator automatically initiates an internal Self Test to verify all calibrations and to confirm the operation of the speaker, all visual indicators, and displays. The Message Display will read “Performing Self Test” during this process. When the Self Test is complete, the RF Generator will proceed to Ready Mode, and “Attach Instrument” will appear on the Message Display.

If Self Test fails, an error message will appear on the Message Display. First, restart the RF Generator. If the error persists, contact Aesculap, Inc. Customer Service, toll free at (800) 282-9000.

5.3.3 Step 3: Connecting the Foot Pedal

NOTE: the Foot Pedal (with cord) is a non-sterile device.

Push the connector attached to the end of the Foot Pedal cord directly into the Foot Pedal Connector Port located on the front panel of the RF Generator. No illuminated indicator is associated with successful Foot Pedal cord connection to the RF Generator.

CAUTION: do not continually depress the Foot Pedal during the procedure. RF delivery is initiated and terminated by a press-and-release action using the Foot Pedal.

NOTE: the Foot Pedal allows the user to initiate or terminate RF delivery by a press-and-release action. The user (or other operating room personnel) may also initiate and terminate RF delivery by pressing and releasing the RF Delivery Control Button on the front of the RF Generator; or via the RF button on the handpiece.

5.3.4 Step 4: Connecting the Caiman® Instrument

Place the connector attached to the end of the RF cable on the Caiman Instrument into the Instrument Connector Port on the front of the Lektrafuse RF Generator. Do not force connector. If properly aligned, little to no resistance should be felt. If correctly connected, the green ring encircling the Instrument Connector Port on the front of the RF Generator will illuminate, and the Message Display will read “Instrument Detected” then “Ready to Seal.” If the green ring does NOT illuminate, reconnect the Instrument. If there is still no illumination, connect a new Instrument.
To prepare the Caiman Instrument for use in the surgical procedure, refer to IFU provided with the Caiman Instrument.

During RF sealing, the Message Display will read “Sealing in Progress”. See IFU for further information regarding RF application.

NOTE: if the Lektrafuse RF Generator does not operate as described, refer to the Troubleshooting Section of this IFU. If assistance is required, contact Aesculap, Inc. Customer Service toll free at (800) 282-9000.

6.0 CARE AND STORAGE OF THE LEKTRAFASE® RF GENERATOR FOLLOWING USE

6.1 Steps

6.1.1 Step 1: Disconnect the Instrument

Disconnect the Caiman® Instrument cable from the Instrument Connector Port on the front of the RF Generator. Disconnection of the Instrument will result in the loss of illumination of the green ring encircling the Instrument Connector Port on the RF Generator.

6.1.2 Step 2: Turn off the Lektrafuse RF Generator

Turn the “ON/OFF” Power Switch on the rear panel of the RF Generator to the “OFF” position. Successful power termination of the Lektrafuse RF Generator will result in the loss of illumination of the green “POWER ON” Indicator on the front panel of the RF Generator.

NOTE: the Caiman Instrument(s) (with attached cable and connector) are for single-use and are labeled “DISPOSABLE.” Do not reuse or re-sterilize.

Disconnect the AC Power Cord from the outlet and from the AC Power Inlet on the rear of the RF Generator. The AC Power Cord is a reusable accessory. The AC Power Cord is non-sterile.

Carefully disconnect the Foot Pedal cable from the Foot Pedal Connector Port on the front of the RF Generator. Do not pull on the Foot Pedal cord when disconnecting. The Foot Pedal (with cable) is a reusable accessory. Please store with care. The Foot Pedal (with cable) is non-sterile.

6.1.3 Step 3: Cleaning the Lektrafuse RF Generator and Accessories

CAUTION: the Lektrafuse RF Generator, Caiman Instrument, and related system accessories are not designed to withstand sterilization procedures.

Always unplug the AC Power Cord from the power source prior to cleaning the Lektrafuse RF Generator.

WARNING: Electric Shock Hazard. Always disconnect the Lektrafuse RF Generator from the power source prior to cleaning.

Follow the procedures approved by your institution or use a validated infection control procedure to clean the Lektrafuse RF Generator. Do not clean the Lektrafuse RF Generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the RF Generator. Use a mild cleaning solution or disinfectant on a damp cloth to thoroughly wipe the RF Generator surfaces. Do not allow fluids to enter the RF Generator chassis.

The exterior surface of the RF Generator and the Foot Pedal may be wiped down with a soft, clean cloth and 70% isopropyl alcohol. Do not use benzene, thinner or the like, or any abrasive powder to clean the RF Generator.

NOTE: care must be taken not to allow any liquid to pass into any electrical connector ports or the interior of the RF Generator. Allow all surfaces to dry thoroughly before connecting the RF Generator to a power source.
6.1.4 Step 4: Storing the Lektrafuse RF Generator
The Lektrafuse RF Generator can be stored indefinitely. If you store the RF Generator at a temperature outside of its normal operating range of 50°F - 104°F (10°C - 40°C), allow one hour for the RF Generator to reach room temperature prior to use.

7.0 ADDITIONAL INFORMATION

7.1 Service
WARNING: DO NOT ATTEMPT TO OPEN THE BACK PANEL OF THE LEKTRAFUSE RF GENERATOR, AS THIS MAY CAUSE SERIOUS INJURY TO THE OPERATOR OR DAMAGE TO THE RF GENERATOR AND WILL VOID ALL WARRANTIES.

The Lektrafuse RF Generator requires no routine service other than that mandated by the operator’s institution. A brief “Troubleshooting” section provided in this IFU presents potential Lektrafuse RF Generator and Lektrafuse RF System problems, possible causes, and recommended solutions. Further information can be obtained by calling Aesculap, Inc. Customer Service toll free at (800) 282-9000.

7.2 Technical Assistance
The Troubleshooting section of this IFU presents potential Lektrafuse® RF Generator and Caiman® Instrument problems, possible causes, and recommended solutions. Further information can be obtained by calling Aesculap, Inc. Customer Service toll free at (800) 282-9000.

7.3 Warning, Error, and Fault Conditions
A Warning Condition is indicated by:

1) A unique single tone, separate from that received during an Error or Fault Condition, or normal RF delivery

2) A message on the Message Display on the front of the RF Generator

An Error Condition is indicated by:
1) A unique series of tones, separate from that received during a fault condition or normal RF delivery

2) A message on the Message Display on the front of the RF Generator

Regrasp Indicator Caution:
The Lektrafuse RF System is designed to identify electrical characteristics indicating potentially inadequate sealing of the tissue within the instrument jaws. If such potentially inadequate sealing is identified, a unique and distinctly audible series of tones will immediately sound from the RF Generator following automatic termination of the audible tones associated with tissue sealing. This unique and distinct series of tones is a Regrasp tone and is accompanied by the illumination of the amber Regrasp indicator light on the front of the RF Generator and a Regrasp message on the RF Generator Screen is present.
Regrasp Conditions/Actions

<table>
<thead>
<tr>
<th>User Action</th>
<th>User Action</th>
<th>User Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>REGRASP INDICATOR – OPEN</td>
<td>Jaw are covered with excess tissue, or the tissue bundle grasped is too thin.</td>
<td>Clean jaws with sterile water and a sponge or regasp a thicker tissue bundle.</td>
</tr>
<tr>
<td>Visually check seal – Manually cut</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean jaws</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regrasp thicker tissue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>REGRASP INDICATOR – SHORT</td>
<td>There may be metal (i.e. staples) or other foreign material between the jaws</td>
<td>Open jaws, visually inspect and remove any foreign material or suction excess fluids in surgical field.</td>
</tr>
<tr>
<td>Visually check seal – Manually cut</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check for metal or occlusion in jaw</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove excess fluids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>REGRASP INDICATOR – TIME</td>
<td>The RF Generator reached its maximum seal time of 17.5 seconds without detecting a complete seal or User terminated RF delivery mid-seal</td>
<td>Determine seal quality through visual inspection.</td>
</tr>
<tr>
<td>Visually check seal – Reseal as needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seal cycle interrupted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seal endpoint not reached</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If a Regrasp occurs,
1) Do not divide the tissue with the cutter
2) Open the instrument jaws
3) Visually examine the sealed tissue
4) Manually divide the tissue with surgical scissors

OR
1) Reapply the jaws to the tissue and lock the jaws in place
2) Deliver an additional cycle of RF, which may result in a normal seal process (which can then be followed by routine sealed tissue division, jaw release, and instrument removal)

If a Regrasp reoccurs, the sealed tissue should not be divided, the jaws should be released, and the sealed tissue divided manually with surgical scissors and hemostasis achieved where required.

A single press and release action on either the Foot Pedal, RF Delivery Control Button (on the front of the RF Generator), or the Instrument RF Button will:
1) Automatically terminate the Regrasp tones, amber Regrasp indicator light on the front of the RF Generator, and the Regrasp message on the RF Generator Screen and
2) Setup the System for the next standard tissue sealing and division process.

Error Conditions/Actions

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Error Messages</th>
<th>What it Means</th>
<th>User Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>E001</td>
<td>ERROR E001 Instrument RF-On Button Error</td>
<td>Occurs when the Instrument “RF On” button is pressed while it is being inserted into the generator.</td>
<td>Release the “RF On” button, or remove and reattach the Instrument</td>
</tr>
<tr>
<td></td>
<td>Release instrument RF-ON Button OR Remove and reattach instrument</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E002</td>
<td>ERROR E002 Instrument Error</td>
<td>System can’t detect Instrument or Instrument is defective and needs to be replaced.</td>
<td>Remove and reattach Instrument OR replace with a new Instrument</td>
</tr>
<tr>
<td></td>
<td>Remove and reattach</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Instrument</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
A Fault Condition is indicated by:
1) A distinct series of tones which interrupts the normal tone sounding during RF delivery if the Fault Condition occurs during RF delivery
2) Illumination of the red Fault Indicator on the front panel of the RF Generator
3) A message on the Message Display
4) If the Fault Condition occurs during RF delivery, the user should assume that tissue sealing is potentially incomplete or inadequate. The user should follow the procedure for a Regrasp condition (see Regrasp Indicator Caution under section 7.5) to ensure that hemostasis is adequately achieved during division of the sealed tissue.
5) If fault persists after power cycling twice then call factory

**Fault Codes Conditions/Actions**

<table>
<thead>
<tr>
<th>Fault Code</th>
<th>Fault Conditions</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>F001</td>
<td>System Software Fault</td>
<td>Power cycle (turn system off, wait 5 seconds and turn system on.)</td>
</tr>
<tr>
<td>F002</td>
<td>RF Generator Cover Removed</td>
<td>Check if cover is misaligned or loose. Power off and adjust cover</td>
</tr>
<tr>
<td>F003</td>
<td>Instrument Communications Fault</td>
<td>Remove and reattach Instrument, OR remove and replace Instrument</td>
</tr>
<tr>
<td>F004</td>
<td>System Communications Fault</td>
<td>Power cycle (turn system off, wait 5 seconds and turn system on)</td>
</tr>
<tr>
<td>F005</td>
<td>System Over Temperature Fault</td>
<td>Generator is over 65 C. Turn system off, allow to cool. Check airflow around Generator</td>
</tr>
<tr>
<td>F006</td>
<td>Footswitch/RF On Button Fault</td>
<td>Power system off, unplug and reattach the footswitch OR replace footswitch. Power system on</td>
</tr>
<tr>
<td>F007</td>
<td>RF Power Output Fault</td>
<td>Power cycle (turn system off, wait 5 seconds and turn system on)</td>
</tr>
<tr>
<td>F008</td>
<td>RF Out of Calibration Fault</td>
<td>Power cycle (turn system off, wait 5 seconds and turn system on)</td>
</tr>
<tr>
<td>F009</td>
<td>RF PS Failure Fault</td>
<td>Power cycle (turn system off, wait 5 seconds and turn system on)</td>
</tr>
</tbody>
</table>

NOTE: The Error Condition or Fault Condition instructions provided on the Message Display may instruct the user and operating room personnel to check the RF cable connection; replace the Caiman® Instrument; “Power Off,” then “Power On” the Lektrafuse® RF Generator; contact Aesculap, Inc. Customer Service; etc. The user and operating room personnel should follow the instructions on the Message Display, note the fault code, but not take any action unless specifically instructed to do so by the Message Display or by qualified Aesculap, Inc. personnel.

NOTE: If the Error Condition or Fault Condition is not corrected by following the instructions on the Message Display or as provided by qualified Aesculap, Inc. personnel, the Lektrafuse RF Generator should be turned off. Contact Aesculap, Inc. for further instructions.
7.4 Trouble Shooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Generator will not “Power On”</td>
<td>• Ensure AC Power Cord is correctly connected to the Power Cord Inlet on the rear panel of the RF Generator&lt;br&gt;• Verify that the AC Power Cord is plugged into a functioning power source (outlet)&lt;br&gt;• Verify that Power Switch on the rear panel of the RF Generator is in the “ON” position&lt;br&gt;• Check fuse in fuse compartment*&lt;br&gt;• If above actions fail to rectify the problem, replace AC Power Cord</td>
</tr>
<tr>
<td>Power is “ON,” but no indicators are illuminated and no Self Test occurs</td>
<td>• Power cycle (turn system off, wait 5 seconds and turn system on)&lt;br&gt;• If above actions fail to rectify the problem, call the factory</td>
</tr>
<tr>
<td>RF delivery interferes with operating room monitoring equipment</td>
<td>• Verify that the AC Power Cord from the RF Generator does not physically cross over or under monitoring equipment cables&lt;br&gt;• Alter settings on monitoring equipment (per manufacturer’s recommendation), which may alleviate interference&lt;br&gt;• Reposition patient monitoring equipment and associated cables and electrodes to minimize interference</td>
</tr>
<tr>
<td>RF Generator power is “On” and accessories are connected, but RF is not delivered</td>
<td>• Verify that the Foot Pedal is properly connected (if used)&lt;br&gt;• Verify that CAIMEN Instrument is properly connected (green ring illuminated)&lt;br&gt;• Initiate RF delivery via front panel RF “ON” button&lt;br&gt;• If above actions fail to rectify the problem, replace the CAIMEN Instrument</td>
</tr>
</tbody>
</table>

NOTE: The Troubleshooting information is not intended to cover all possible problems that might occur with the Lektrafuse RF System. If you encounter a problem where the information provided is inadequate or not applicable, please contact Aesculap, Inc. Customer Service toll free at (800) 282-9000.

7.5 Power Profile

Caiman® Instrument Algorithm Power Profile
7.6 Generator Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC Power Range</td>
<td>100-240V, 50-60HZ (8A) universal power supply</td>
</tr>
<tr>
<td>Fuses</td>
<td>Quantity 2: 250 volts, slow-blow, 2x20mm, 8.0A</td>
</tr>
<tr>
<td>Output Power</td>
<td>2 X 150 Watts max, 115Vrms max</td>
</tr>
<tr>
<td>RF Operating Frequency</td>
<td>460 kHz ±1%, Quasi-sinusoidal</td>
</tr>
<tr>
<td>Impedance Operating Range</td>
<td>5-85 Ω</td>
</tr>
<tr>
<td>Dimensions</td>
<td>35.6 cm x 10.2 cm x 40.1 cm (14” x 4” x 15.8”), width x height x depth</td>
</tr>
<tr>
<td>Display</td>
<td>Liquid Crystal Display (LCD)</td>
</tr>
<tr>
<td>Weight</td>
<td>6.8 kg (15 pounds)</td>
</tr>
<tr>
<td>Controls</td>
<td>AC Power Switch, Foot Pedal, RF delivery button</td>
</tr>
<tr>
<td>Audio</td>
<td>Complies with IEC60601-2-2</td>
</tr>
<tr>
<td>Visual Indicators</td>
<td>Green LED, AC Power ON</td>
</tr>
<tr>
<td></td>
<td>Amber LED, Regrasp Indicator</td>
</tr>
<tr>
<td></td>
<td>Red LED, Fault</td>
</tr>
<tr>
<td></td>
<td>Blue, RF On</td>
</tr>
<tr>
<td>Ambient Operating Conditions</td>
<td>Temperature: 10 to 40°C (50 to 104°F)</td>
</tr>
<tr>
<td></td>
<td>Relative Humidity: 15% to 90%, non-condensing</td>
</tr>
<tr>
<td></td>
<td>Atmospheric Pressure: 700 to 1060 millibars</td>
</tr>
<tr>
<td></td>
<td>Warm-up Time: If transported or stored at temperatures outside the operating temperature range, allow one hour for the RF Generator to reach room temperature before using.</td>
</tr>
<tr>
<td>Storage and Transport Conditions</td>
<td>Temperature: -34 to 70°C (-29° to 158°F)</td>
</tr>
<tr>
<td></td>
<td>Relative Humidity: 0% to 95%, non-condensing</td>
</tr>
<tr>
<td></td>
<td>Atmospheric Pressure: 500 to 1060 millibars</td>
</tr>
</tbody>
</table>

7.7 Accessories

<table>
<thead>
<tr>
<th>Product</th>
<th>Maximum Length (typical)</th>
<th>Item #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caiman® Instrument 5mm x 24 cm</td>
<td></td>
<td>PL718SU</td>
</tr>
<tr>
<td>Caiman® Instrument 5 mm x 36 cm</td>
<td></td>
<td>PL720SU</td>
</tr>
<tr>
<td>Caiman® Instrument 5 mm x 44 cm</td>
<td></td>
<td>PL722SU</td>
</tr>
<tr>
<td>Caiman® Instrument 12 mm x 24 cm</td>
<td></td>
<td>PL730SU</td>
</tr>
<tr>
<td>Caiman® Instrument 12 mm x 44 cm</td>
<td></td>
<td>PL731SU</td>
</tr>
<tr>
<td>Foot pedal</td>
<td></td>
<td>GN201</td>
</tr>
<tr>
<td>Foot pedal Cord</td>
<td>8 ft</td>
<td>US072</td>
</tr>
<tr>
<td>AC Power Cord</td>
<td>8 ft</td>
<td>US070</td>
</tr>
</tbody>
</table>

7.7.1 Additional Products

To order additional products, contact Aesculap, Inc. Customer Service toll free at (800) 282-9000.