



# MEDERI RF Generator

## MDRF1



## stretta®

For use with Stretta Disposable Catheter.



# MEDERI RF Generator Operator's Manual

## MDRF1 GENERATOR KIT CONTENTS

177-5150 MDRF1 Generator  
175-5252 MDRF1 Accessory Kit

## ACCESSORY KIT CONTENTS

155-06038 MDRF1 IFU CD  
174-5447 Set Up/Troubleshooting Guide  
143-5255 MDRF1 Main Power Cord  
145-5241 Connecting Cable  
145-5541 RFT3 Connecting Cable  
143-5245 Foot Pedal

**CAUTION:** Federal law restricts this system to sale by or on the order of a physician.

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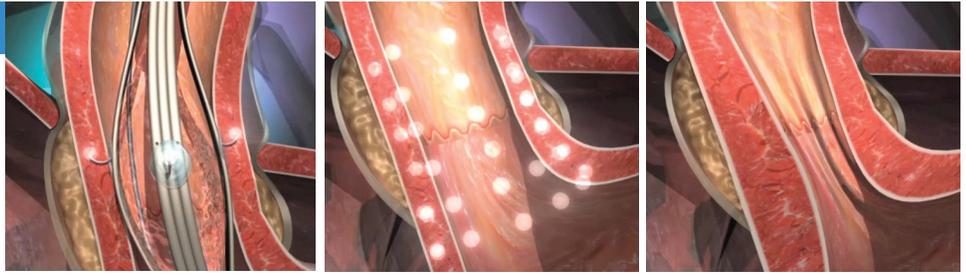
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U.S. Patents 6,273,886; 7,122,031; 6,783,523; 6,440,128; 6,056,744; 6,846,312; 6,971,395; 6,712,814; 6,009,877; 6,613,047; 6,044,846; 6,749,607; 6,092,528; 7,462,179; 6,254,598; 6,673,070; 7,125,407; 6,197,022; 9,310,956, 9,292,152 and other patents pending.

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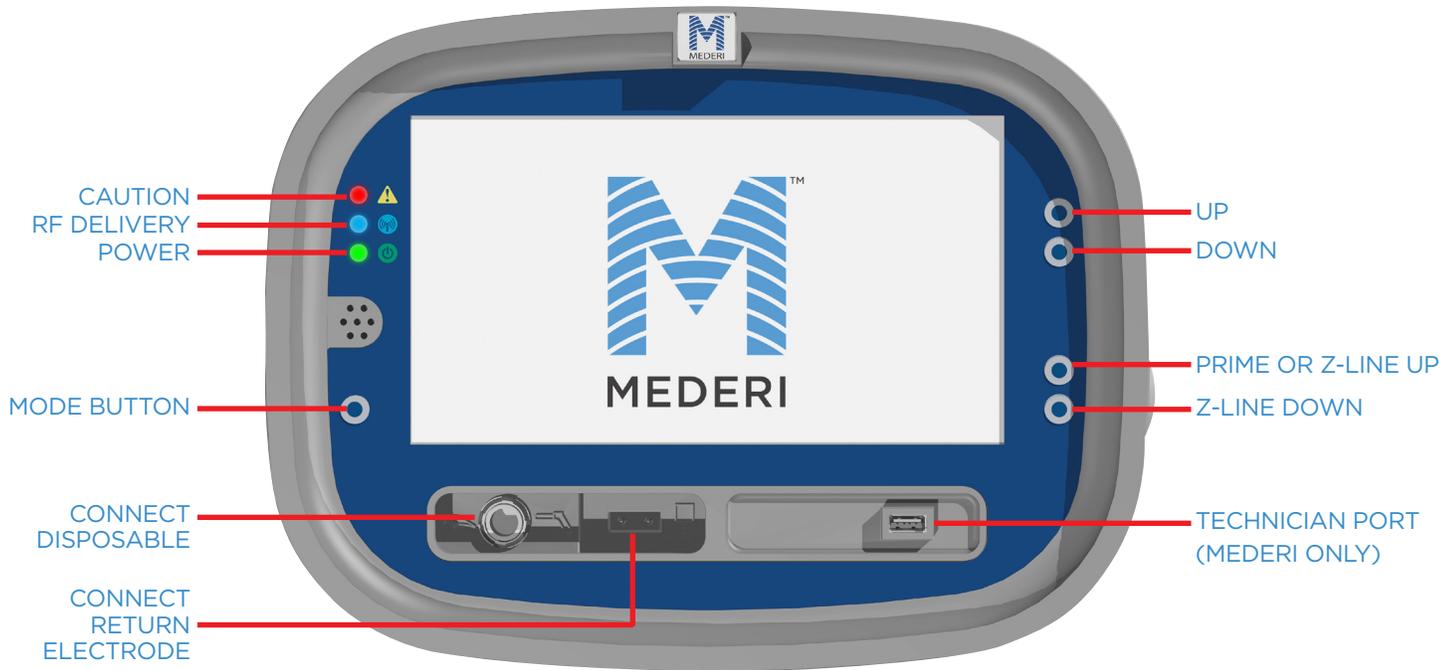
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### STRETTA SYSTEM OVERVIEW

Stretta therapy is a minimally invasive, outpatient treatment for GERD. The procedure is performed in an outpatient setting. The procedure takes less than one hour and patients typically return to normal activity the following day.

The Stretta System consists of the Stretta Catheter, a single-use flexible device with needle electrodes, and the Mederi RF Generator. The Stretta Procedure typically is performed in an endoscopy unit or ambulatory surgery. In the hands of a physician Stretta is used to deliver radiofrequency (RF) energy in the muscle of the lower esophageal sphincter (LES) and gastric cardia for the treatment of GERD. The Stretta Catheter is positioned at the junction of the esophagus and stomach (GE junction). The integrated balloon is inflated and needle electrodes are then extended from the device into the target tissue. Precisely controlled low power, low temperature radiofrequency (RF) energy is delivered via the needles to the muscularis propria. This significantly reduces tissue compliance and transient LES relaxations without fibrosis.



### MEDERI RF GENERATOR - STRETTA THERAPY

The Mederi RF Generator, a multi-channel electrosurgical generator, produces low power, radiofrequency (RF) energy using a sinusoidal waveform of 460 kHz. For Stretta Therapy the Mederi RF Generator can deliver up to 5 watts of power to each of its four independent RF channels.

Needle tip and surface tissue temperatures are measured during treatment by thermocouples located at the tip and base of the needle, respectively. The electrode tip temperature measurement regulates the output power in a closed-loop fashion to maintain the target temperature, while monitoring of the surface tissue temperature prevents overheating.

## INDICATIONS FOR USE

The Mederi Therapeutics RF Generator is intended for general use in the electrosurgical coagulation of tissue, specifically:

- The Mederi RF Generator when used with the Stretta Disposable Catheter is intended for the treatment of gastroesophageal reflux disease (GERD).
- The Mederi RF Generator when used with the Secca Disposable Handpiece is intended for the treatment of bowel incontinence in patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.

## CONTRAINDICATIONS

There are no known absolute contraindications to the use of radiofrequency in humans. The use of the Stretta System is contraindicated when, in the judgment of the physician, radiofrequency surgical procedures would be contrary to the best interests of the patient.

The following is a list of patient groups in whom the use of the Stretta System for the treatment of GERD may be contraindicated.

1. Subjects under the age of 18
2. Pregnant women
3. Patients without a diagnosis of GERD
4. Hiatal hernia > 2 cm
5. Achalasia or incomplete LES relaxation in response to swallow
6. Poor surgical candidate, ASA IV classification

## WARNINGS

**For the Stretta System, only the Mederi RF Generator can be used with the Stretta Disposable Catheter.**

**Carefully read all instructions for use for Stretta Catheter and Mederi RF Generator.**

As with any procedure, use of sedation or general anesthesia for patients with airway or cardiopulmonary compromise (such as obesity, airway abnormality and sleep apnea) may result in increased risk of complications.

**This product must be disposed of according to local laws and regulations.**

## WARNINGS RELATED TO THE USE OF ELECTROSURGERY

- Use of electrosurgery for patients with internal or external pacemakers or ICDs, neural stimulators, implantable drug delivery systems, or any other electrical implantable devices and monitoring equipment may require special consideration. The appropriate physician and/or manufacturer should be consulted prior to surgery.
- This electrosurgical equipment is intended for use only by qualified medical personnel trained in the use of the Stretta System.
- Burns to the physician's hands are possible if the electrode comes into contact with a metal instrument or surface.
- Interference produced by the operation of high-frequency surgical equipment may adversely influence the operation of other electronic medical equipment such as monitors and imaging systems.
- Do not stack equipment on top of the Mederi MDRF1 Generator or place the generator on top of or adjacent to electrical equipment. This may block access to the unit and not allow for proper ventilation.
- Provide as much distance as possible between the Mederi MDRF1 Generator and other electronic equipment (such as monitors). An activated generator may cause interference with them.

- If it is necessary to locate the Mederi MDRF1 Generator adjacent to or stacked with other equipment, then observe the generator and other equipment for proper operation.
- Do not position the Generator so that is difficult to disconnect the power cords.
- Dispose of Stretta disposable Catheter and accessories in an environmentally safe manner according to local regulations.
- CAUTION: Electrical shock hazard. Do not remove the cover of the Mederi RF Generator. Refer servicing to Mederi Therapeutics qualified personnel. There are no user serviceable parts inside the Generator.
- CAUTION: No unauthorized modification to this device is allowed.
- CAUTION: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not perform the procedure if flammable or explosive media are present, such as flammable anesthetics, skin preparation agents, or bio-intestinal gases.
- DANGER: Risk of explosion if used in the presence of flammable anesthetics.
- WARNING: The risk of igniting flammable gases or other materials is inherent in the application of RF power. These substances may come in the form of anesthetics, oxygen, cleaning or disinfection agents, adhesive solvents, endogenous gases, surgical drapes, etc. and should be removed from the area of RF energy delivery. Non-flammable agents should be used for cleaning and disinfection wherever possible as a means to reduce the possibility of ignition. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of RF power to reduce the chance of ignition.
- WARNING: Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of RF surgery.
- WARNING: There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before RF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of RF surgical equipment.
- **Stimulation of nerves and muscles.** A known risk of high-frequency surgery is the unintentional electric stimulation of the patient's nerves and muscles. This stimulation can result from low-frequency electrical currents that are caused either by low-frequency current sources or due to electrical arcs between an active electrode and the patient's tissue. Electric alternating current with a frequency above 300 kHz is unable to stimulate nerves and muscles. Note that the electric alternating current used by this generator is 460kHz. During controlled application of radiofrequency to muscles in the GI tract, the unavoidable electric arcs between an active electrode and the tissue nevertheless have the effect that a portion of the high-frequency alternating current is rectified, from which more or less strongly modulated, low-frequency current components result which stimulate electrically stimuable structures such as nerves and muscles.

This can result in more or less strong spasms or muscle contractions. **WARNING:** When using high-frequency energy on electrically stimu- lable structures, contractions of the affected muscles must be taken into account. This can occur, for example, during endoscopic opera- tions in the area of the lower esophageal sphincter or the internal anal sphincter muscles.

**WARNINGS RELATED TO THIS SPECIFIC PROCEDURE**

- Inspect all components prior to use for any obvious signs of damage that may have occurred during transit and/or storage. In particular, the electrode cable should be checked prior to use.
- Ensure adequate volume of irrigation fluid is available prior to start of procedure.
- Do not attach suction tube until the electrode catheter is positioned in the tissue.
- Be sure that the reusable cable has been cleaned prior to use.
- Do not attempt to re-sterilize and/or reuse the electrode catheter.
- Reuse of Mederi single-use items is contraindicated in all patients. Like all single-use items, use on more than one patient may result in diseases of cross-contamination and possible transmission of blood borne pathogens.
- Balloon must be in the deflated state during insertion, treatment lo- cation adjustment, and removal of the catheter from target organs.
- Pressure relief valve should be used for antegrade lesions only. Do not use for pull-back treatments.
- If pressure relief valve malfunctions in use, remove it and replace.
- Needle electrodes must be in the retracted position during in- sertion, treatment location adjustment, and removal of the catheter from target organs.
- **WARNING:** To avoid overlap of treatment sites, ensure that treatment sites are spaced a minimum of 5mm apart in all directions.
- **WARNING:** Failure to follow proper shutdown sequence could cause damage to the Generator.

**CAUTION:** Use of accessories not outlined in this Operator's Manual could affect the safety of the Stretta System. Use only power cord supplied by Mederi.

**CAUTION:** "Spring-tipped" guidewires are not recommended.

**CAUTION:** Due to elastic properties of the Irrigation Tubing material, excessive longitudinal force may result in stretching (flat tube on the pump rotor) and as a result, reduction of the irrigation flow.

**CAUTION:** Failure to achieve good skin contact by the entire adhesive surface of the return electrode may result in a burn or poor electrical performance. Excessive hair, moist skin, lotions, creams or skin creases, may result in inadequate electrical contact.

**CAUTION:** Do not use steam or heat sterilization on the Mederi Gen- erator. Do not soak in glutaraldehyde or other disinfectant. Do not al- low any liquid to pass into any electrical connections or into the interior of the Generator.

When conducting periodic inspections of the Mederi Generator, refer to the chapter, Care & Maintenance, if testing reveals a defect that could harm the patient, employees, or third parties, immediately notify your Mederi representative. The device should not be used until it has been properly repaired/serviced by an authorized Mederi technician or representative.

The following is a list of patient groups who have not been specifi- cally studied using the Stretta System for the treatment of GERD. The performance characteristics of the device for the following groups of patients have not been established.

- Patient has an implant near the LES that could be conductive with RF energy
- Normal 24-hour pH study
- ALL GERD symptoms completely unresponsive to properly dose-escalated anti-secretory medication
- Barrett's metaplasia
- Poor surgical candidate
- Presence of dysphagia, esophageal bleeding, or gas bloat
- Active esophagitis grades III or IV by Savary criteria
- Endocarditis risk (mitral valve prolapse, heart valve replacement, etc.)
- Untreated or unstable hypertension, diabetes mellitus, heart disease, collagen vascular disease, steroid use, immunosuppressed state, or cardiac pacemaker
- Abnormal blood coagulation or use of anticoagulant or platelet anti- aggregation therapy.

These complications are rarely seen but could potentially occur with the use of electrosurgery for the treatment of GERD (alphabetical order).

- Bleeding - transient
- Bloating
- Chest pain - transient
- Difficulty belching - transient
- Dysphagia - transient
- Epigastric discomfort - transient
- Esophageal mucosal laceration
- Fever - transient
- Injury to esophageal mucosa
- Perforation
- Pharyngitis
- Vomiting - transient with potential for bleeding or Esophageal injury.

**If any vomiting occurs, contact your treating physician imme- diately. Excessive vomiting may result in perforation and more serious injury resulting in death.**

The following complications have not been seen, but could possibly occur infrequently (alphabetical order).

- Achalasia
- Delayed gastric emptying - transient
- Dental injury
- Dyspnea
- Infection
- Larynx injury
- Worsened GERD

**WARNING:** Use only chilled, sterile, plain water as irrigation flu- id for this device. Do not use saline or other conductive/ionic/ volatile solution, as this may lead to improper device perform- ance. Do not expand balloon to more than 15 psi or 30 ml of air.

**PRECAUTIONS RELATED TO THE USE OF ELECTROSURGERY**

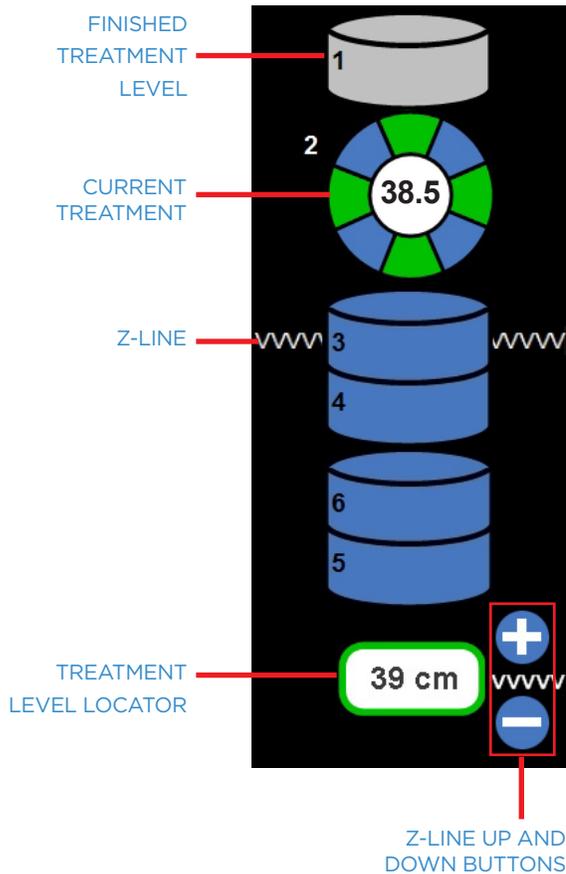
- Safe use of monopolar electrosurgery demands proper grounding of the patient. Follow the manufacturer's directions for the placement of the dispersive electrode and for proper insulation between the patient and any metal surfaces.
- Maintain safe handling techniques when Catheter is in use due to electrical field and potentially hot needle electrodes.
- Do not touch the tip of the needle electrode and the dispersive electrode at the same time - especially while operating the Mederi RF Generator. Superficial skin burns could occur.
- Ensure that the dispersive electrode pad achieves complete contact with cleaned and hairless patient skin.
- Activation of an electrosurgical device when not in contact with target tissue or in a position to deliver energy to target tissue, but when in close approximation to a metal object, may result in capacitive coupling which could result in shock or discharge.
- Simultaneous use of electrosurgical electrodes with conductive irrigation fluid (such as saline) may alter the path of electrical energy away from target tissue. Do not operate the Stretta Disposable Catheter in the presence of saline or other conductive irrigation fluid.
- This Mederi RF Generator is in compliance with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other equipment. As a precaution, avoid use of the Mederi RF Generator in close proximity to other equipment.
- Interference from other electrical equipment may cause interference in the operation of the Mederi MDRF1. Also, Interference to other electrical equipment may be caused by the Mederi MDRF1 Generator. If interference occurs, increase the physical separation distance between the Mederi RF Generator and other electrical equipment. Avoid the overlap of cables from the Mederi MDRF1 Generator with cables from other electrical equipment.
- Power Cords: Do not wrap power cords around metal objects. This may induce currents that could lead to shock, fire, or other injury to the patient or user. All power cords should be positioned in a way to avoid contact with the patient or other cables.
- Emissions produced by the operation of the Mederi RF Generator together with the Stretta Disposable Catheter may adversely influence the operation of other electronic medical equipment such as monitors and imaging systems.
- The immunity of the Mederi RF Generator to interference by other equipment may be decreased when the Stretta Disposable Catheter is used together with the Mederi RF Generator.
- When conducting periodic inspections of the Mederi RF Generator, refer to the Care and Maintenance section in this Operator's Manual, if testing reveals a defect that could harm the patient, employees, or third parties, immediately notify your Mederi representative. The device should not be used until it has been properly repaired/serviced by an authorized Mederi Therapeutics technician.
- Do not operate the RF Generator when the ambient temperature is below 15° C.
- The entire area of the neutral electrode should be reliably attached to the patient's body and as close to the operating field as possible.
- The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.
- Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
- When HF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating high frequency current limiting devices are recommended.
- The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored in a location that is isolated from the patient.
- Non-flammable agents should be used for cleaning and disinfection wherever possible (see Care and Maintenance). Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF energy.
- Failure of HF surgical equipment could result in an unintended increase of output power.

**STRETTA SUGGESTED TREATMENT GUIDES**

The diagram on the right side of the screen will help to direct and track your Stretta treatments. (Please refer to the "Procedure" section of the Stretta Catheter Instructions for Use for the treatment recommendations.) The disks represent treatment levels, and the segments of the disks represent treatment target sites.

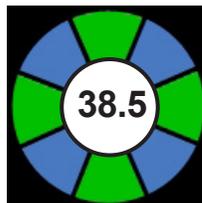
**The disks and the segments are color coded:**

- Untreated target sites are indicated in blue
- Green indicates currently treated target site and site to be treated next
- Previously treated target sites are indicated in grey
- A treatment level locator allows you to enter the Z-line measurement using the up and down buttons on the bottom right of the generator
- Once the Z-line is entered, the measurement for each treatment level will appear in the white circle in the disk for the current treatment level
- This number corresponds to the markings on the shaft of the Stretta catheter

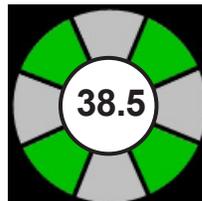


**TREATMENT POSITION INDICATORS**

**ANTEGRADE LEVELS 1-4**



First treatment at this level is in progress



Turn 45° - Second treatment at this level is in progress



Always use Pressure Relief Valve (PRV) for all levels 1-4 only

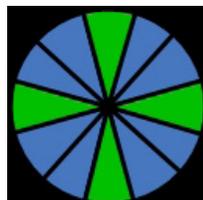


For Level 5, inflate balloon to 25 ml

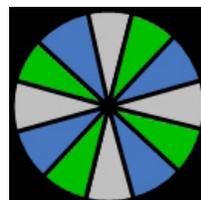


For Level 6, deflate balloon to 22 ml

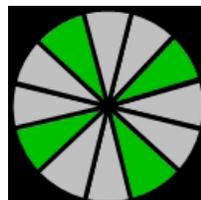
**CARDIA PULL-BACK TREATMENTS LEVELS 5-6**



First treatment at this level is in progress

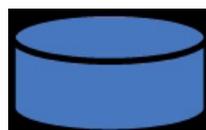


Turn 30° from center  
Second treatment at this level is in progress



Turn -30° from center  
Third treatment at this level is in progress

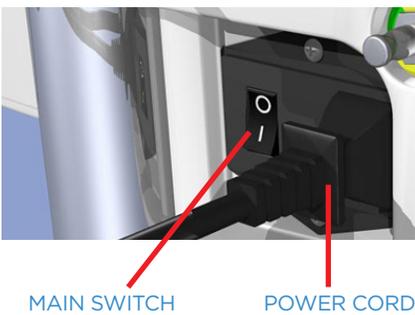
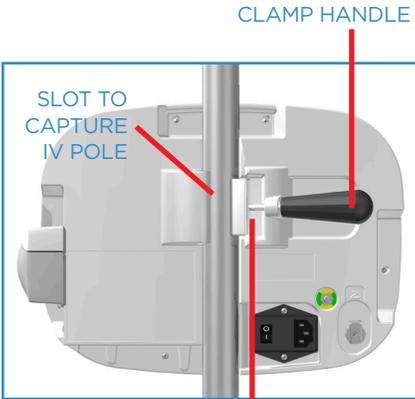
**OTHER TREATMENT INDICATORS**



Stretta Level Untreated



Stretta Level Completely Treated

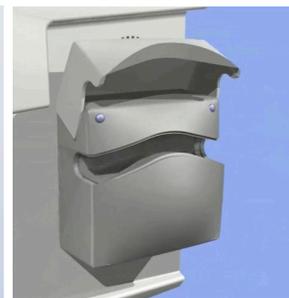


**INSTALLATION**

The Mederi RF Generator is designed to be mounted to an IV pole with a diameter of 1" to 1.5" (2.5 to 3.8 cm).

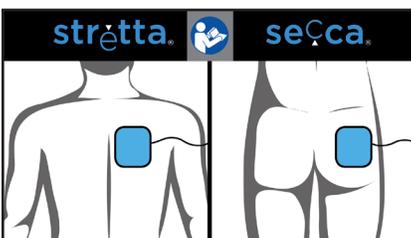
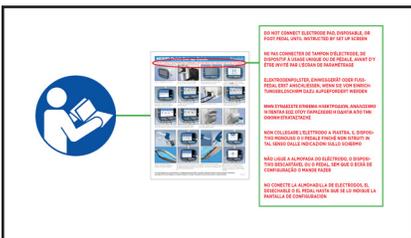
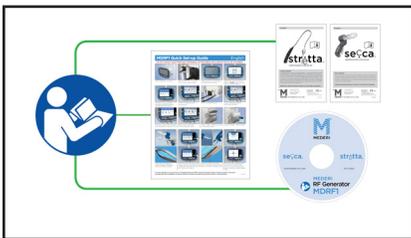
CAUTION: To prevent tipping, clamp the Generator to the IV pole at a height that provides stability. It is recommended that the RF Generator be clamped no higher than 48" (122 cm) from the floor on an IV pole having five legs and a minimum of 22" (56 cm) diameter wheelbase. Failure to do so may result in IV pole tipping and patient injury.

1. Unpackage the Mederi RF Generator - note that the generator will not operate below 10°C.
2. Note pole clamp is on the back of the generator
3. Turn handle to loosen clamp, backing all the way out to the loosest adjustment available without removing it from the generator.
4. Insert the pole into the clamp and tighten against the pole.
5. Attach the power cord to the generator.



NOTE: Irrigation Pump door should be open and Irrigation Tubing should NOT be inside the pump during Power Up of Generator.

**REMINDER SCREENS**



**POWER UP**

If any of these steps fails to automatically perform during the power up procedure - check troubleshooting section in this manual.

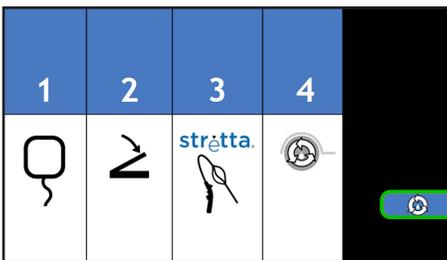
**DO NOT CONNECT THE ELECTRODE PAD, DISPOSABLE OR FOOT PEDAL UNTIL INSTRUCTED BY THE SET UP SCREEN**

1. Plug power cord into a suitable wall outlet.
2. Turn on the Generator's main switch on the back of the unit.
3. Self test automatically performs. The red, green and blue LED lights are active.
4. Several screens appear during the self test. These are reminders to:
  - Review the instructions for use that come with the generator and the disposable.
  - Carefully follow the set up instructions for the generator, do not connect the electrode pad, disposable or foot pedal until instructed by the set up screen.
  - Place the electrode pad correctly on the patient to ensure complete contact.
5. The Generator will "beep" during self test, testing both Generator and Irrigation Pump.
6. When the Generator has completed its power up process, it will automatically advance to the Set Up screen.

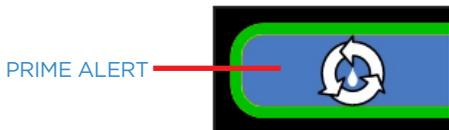
SET UP SCREEN



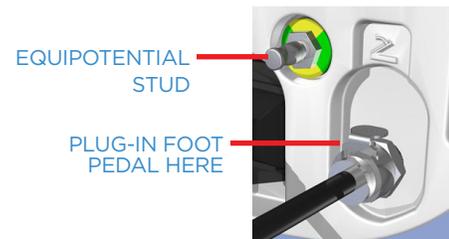
BEFORE CATHETER ATTACHED



AFTER CATHETER ATTACHED

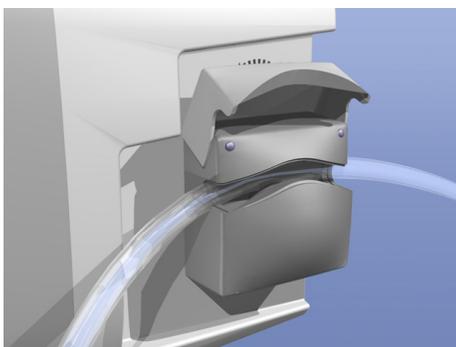


PRIME ALERT



EQUIPOTENTIAL STUD

PLUG-IN FOOT PEDAL HERE



IRRIGATION PUMP SET UP  
USE WATER ONLY - NOT SALINE

SET UP PROCEDURE

1. Follow Power Up procedure on previous page.
  2. Unpackage Stretta Catheter and accessories. Use appropriate aseptic technique.
  3. Use return lectrode pad provided with disposable device kit.
  4. Place return electrode pad on patient's right mid scapular area off the mid line area (roll it on). To ensure proper electrical contact with patient skin, area must be clean and hairless.
  5. Follow instructions on Set Up screen for connections
    - Connect return electrode pad
    - Plug-in foot pedal to back of Generator
    - Attach Connecting Cable to Stretta Catheter and plug in to Generator
  6. Connect Irrigation Tubing to pump on right side of Generator, connect to chilled bag of sterile WATER **CAUTION: Use water only, DO NOT USE SALINE.** WARNING: Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the irrigation tubing in the pump head while pump head rotor is turning. Prevent fingers or loose clothing from being caught in the pump head rotors.
  7. Inspect Catheter for basket integrity and symmetric needle extension, extend/retract needles to ensure proper working.
  8. Insert the Pressure Relief Valve (PRV) with syringe into the balloon inflation port.
  9. Inflate the Stretta Catheter with 25 ml of air through the PRV.
  10. Extend and retract the needles, check for needle extendment angle and that needles fully retract.
  11. Connect Irrigation Tubing to bottom of Stretta Catheter.
  12. Push Prime button on bottom right of generator to prime Catheter to ensure water flows through the device near the base of each needle.
  13. Push Prime button again to stop prime cycle.
  14. Retract needles on Catheter and deflate balloon. Make sure needles are retracted before insertion into patient and always retracted and balloon deflated before moving Catheter during procedure.
  15. Set wall suction to 100-160 CM H2O.
- NOTE:** Do not connect suction to Catheter until after insertion of Catheter.
16. Push the Mode button on the left front panel to advance to the Ready mode. Note that mode will not advance until priming has occurred.

**NOTE:** Catheter is usable for 3 hours from first treatment cycle.

Follow procedure instructions provided with Stretta Catheter, for further information consult Stretta Training module.



CONNECTIONS TO CATHETER

**NOTE:** To disconnect the Connecting Cable from the Stretta Catheter or the RF Generator, pull on the movable outer ring (marked in red) not on the cable itself.

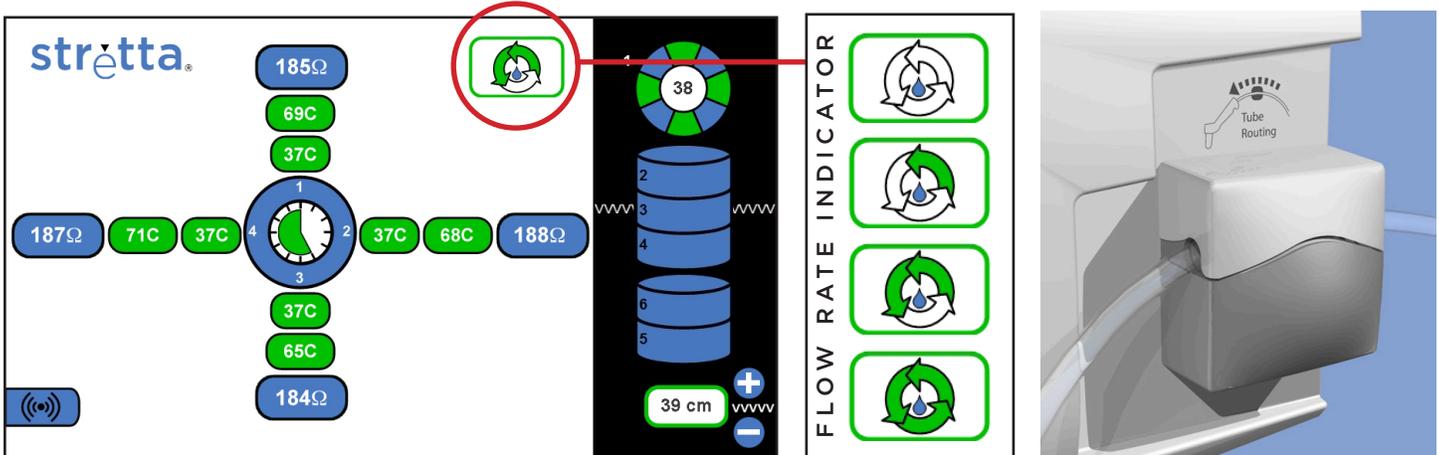
SUCTION

IRRIGATION

CONNECTING CABLE

### IRRIGATION FLUID PUMP/FLOW RATE CONTROL

An integrated peristaltic pump located on the right side of the Generator connects with Irrigation Tubing to deliver irrigation fluid to surrounding tissue adjacent to the needle electrode(s). This irrigation method helps preserve mucosal integrity.



**Priming the Irrigation pump** - Pump priming is performed in the Set Up mode by pressing the circular key adjacent to the Priming icon. Once activated, priming will continue until the priming button is pressed again. Be sure to open up clamp on irrigation line to ensure proper flow is never cut off.

**Irrigation flow rate** - Flow rate of irrigation during the procedure is automatically controlled by the generator.



### UP AND DOWN BUTTONS

The physician may choose to manually skip individual treatment sites using the “down” button on top right of generator. To skip forward one treatment, depress the “down” button once, to go backward one level, depress the “up” button once.

### GENERATOR SHUT DOWN

Once all treatments are complete, follow these shut down instructions:

1. Shut off the main switch on the back of the unit.
3. Disconnect all equipment.
4. Dispose of Stretta Catheter and single use accessories.
5. Clean all cables and Generator per instructions in Care and Maintenance chapter.

The generator operates in three modes:

1. READY
2. RF ON
3. DELAY

33C SURFACE TEMPERATURE

37C NEEDLE TIP TEMPERATURE

140Ω IMPEDANCE

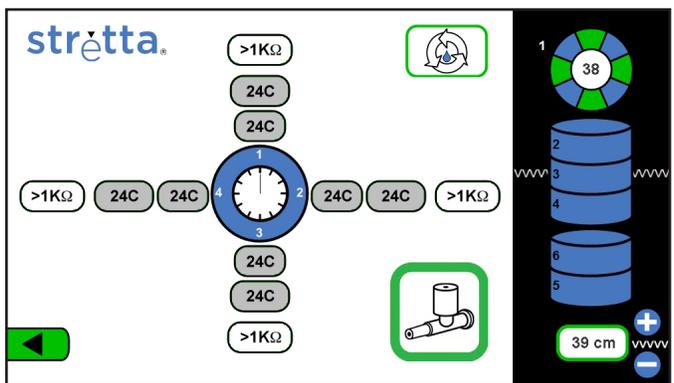
**OPERATION SCREENS AND MODES**

The below information outlines normal operation – review Troubleshooting section in this manual for explanation of indicators out of temperature or impedance range.

**READY**

The Ready screen becomes accessible from the Set Up screen by depression of the Mode button. The Generator also returns to this screen automatically after the Delay Screen.

In the Ready Mode, prior to extending needles in tissue, surface and tip temperature will display room temperatures and impedance readings will be high (>1KΩ) until needles are extended in tissue.



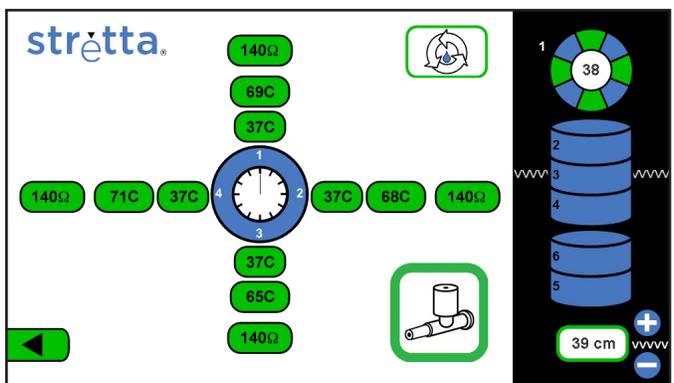
IN READY MODE BEFORE EXTENDING NEEDLES IN TISSUE

While in the Ready mode, the RF On Indicator blinks intermittently indicating low energy bursts of RF. These bursts will not deliver treatment levels of RF, but are used for impedance measurement only after needles have been extended in tissue. Electrode and surface temperature readings display body temperature along with impedance values for each of the activated electrodes. All ovals should be green, if not consult Troubleshooting.

REMINDER TO USE PRESSURE RELIEF VALVE

LEVEL 5 REMINDER 25ml INFLATION

LEVEL 6 REMINDER 22ml INFLATION



IN READY MODE AFTER EXTENDING NEEDLES IN TISSUE

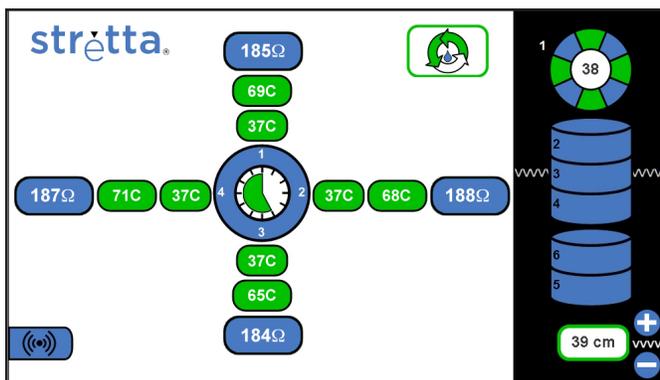
During the Ready Mode in the Antegrade treatment levels, a green highlighted PRV indicator flashes to remind the user to always use the Pressure Relief Valve during these treatment levels.

During the Ready Mode in the Cardia Pull-Back Treatments, a green highlighted balloon indicator flashes to remind the user to adjust the balloon inflation after dropping back into the stomach. Prior to treatment level 5 balloon should be inflated to 25 ml and prior to treatment level 6 balloon should be deflated down to 22 ml.

	Working	Optimal	Shut-off
<b>Surface</b>	10-50	20-45	>50
<b>Tip</b>	10-100	20-84	>100
• <i>Tip after 30 seconds</i>			<65
<b>Impedance</b>	50-1000	100-250	>1000

- High impedance (>250) indicates poor needle contact
  - Reposition needles by slightly increasing retraction tension or slightly extending the needles to seat needles deeper.
- Low impedance (<50) indicates guidewire/needle contact, reposition guidewire.
- Slow rising surface temperature is optimal. Rapid rise requires attention: remove a small amount of balloon inflation to allow irrigation free-flow to cool surface, and/or increase flow rate.
- Low temperatures (unable to reach optimal) indicate insufficient needle penetration, and may be due to inadequate balloon inflation, irrigation too high or due to specific patient anatomy.
- Note that if after 30 seconds of RF energy delivery, tip temperature drops to 65°C or below, the channel will shut-off for the remainder of that 60 second treatment cycle.

### RF ON



WHEN IN RF ON MODE, THIS SCREEN APPEARS

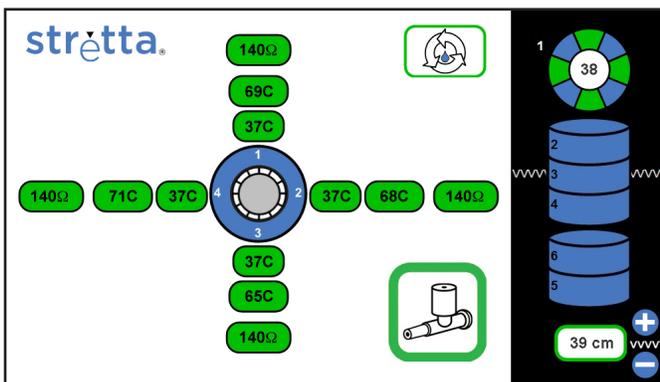


From the Ready Screen (after needle extension), the Foot Pedal is depressed to initiate treatment. The RF ON Screen appears immediately with the blue RF ON indicator. This signifies that RF energy treatment is in progress; the fluid pump activates simultaneously. The screen continues to exhibit temperatures and impedance values.

Green indicates temperatures are within optimal parameters, consult troubleshooting if color changes. The timer indicates elapsed procedure time of one-minute. At the end of this one-minute treatment cycle, the Generator advances to the Delay mode, where the RF energy output is automatically stopped and the blue RF On indicator is no longer displayed.

If the cycle ceases before a one-minute treatment is complete, refer to troubleshooting. You may manually stop the RF On treatment cycle by depressing the Foot Pedal or the Mode button.

### DELAY



WHEN IN DELAY MODE, THIS SCREEN APPEARS

When the RF On mode ends, the Delay screen appears, and all temperature/impedance indicators are frozen from the previous treatment. The running clock turns grey when target duration is attained.

When RF On (RF delivery) ends, the Generator goes into Delay mode due to any of the following reasons (note that these are not Errors, but normal operation).

1. Automatically when target duration is attained,
2. Manually when the Foot Pedal is depressed,
3. Manually when the Mode button is depressed, or
4. Automatically when all four channels exhibit an error condition and have shut off (e.g. temperature or impedance values out of range).

When the Generator is in Delay mode due to either 1, 2 or 4 conditions above - it will automatically go into the Ready mode after approximately 8 seconds.

If the Generator is in Delay mode due to number 3 above - it will automatically go into the Setup mode after approximately 8 seconds.

# Symbols and Icons

 RETURN ELECTRODE

 FOOT PEDAL

 STRETTA DISPOSABLE CATHETER

 CONNECT IRRIGATION TUBING

 DO NOT REUSE

 ALARM GRAPHIC

 PRIMING IN PROGRESS

 FLOW RATE INDICATOR

 CONSULT INSTRUCTIONS FOR USE

 Follow Operator's Manual and INSTRUCTIONS FOR USE

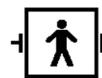
 RF ON INDICATOR

 ON

 OFF

 DANGER - Explosion risk if used with flammable anesthetics.

 Mederi RF Generator output is floating (isolated with respect to ground).

 Defibrillator-proof type BF equipment

 EQUIPOTENTIAL SYMBOL - The connection for the Potential Equalization Conductor terminates at this point.

 DANGEROUS VOLTAGE - To reduce the risk of electric shock, do not remove cover; there are no user serviceable parts. Refer any servicing to Mederi Therapeutics Customer Service.

 DO NOT DISCARD IN TRASH - Electronic equipment should be disposed of in an appropriate manner. EU product to be disposed of in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive. Contact Mederi Therapeutics for product return and collection information.

**LED LIGHTS**

 CAUTION

 RF DELIVERY  
This equipment intentionally supplies non-ionizing RF energy for physiologic effect

 POWER

**REF** CATALOG NUMBER

 The Mederi MDRF1 Generator System meets Intertek's safety requirements.

 0473 Complies with the Council Directive 93/42/EEC.

# Troubleshooting

## COMMON ERRORS AND REMEDIES



### CONNECTION ERRORS

When the screen on the left appears, there is a problem with the connection of the RF circuit. This can occur at multiple points of contact as illustrated in the graphic. Check connections to components listed below, then complete the remaining steps in the setup procedure.

- Connecting cable or return electrode pad connections to the front of the generator
- The connection of the return electrode pad on the patient
- Needle contact with muscle tissue
- Connecting cable to disposable



### DISPOSABLE ERROR

The screen on the left indicates an error from the disposable Stretta device. Disconnect the disposable handle from the connecting cable, wait 5 seconds and then reconnect. Be sure disposable is an “authentic” Mederi disposable. If this problem continues, replace with new Stretta device.



### DO NOT REUSE SYMBOL APPEARS ON SCREEN

This is a used or unauthorized device, dispose of properly and connect new unused Stretta disposable device.

### FOOT PEDAL UNRESPONSIVE

- Check Foot Pedal connection and check line for signs of bends and kinks.
- Review temperature levels and adjust - temperatures out of range (possibly caused by hot or cold storage temperatures of RF Generator or disposable) can also prevent start of a treatment.



### UNIT ENTERS SAFE MODE

- DISPLAY FROZEN WITH RED LED (SAFE MODE)
- ALARM GRAPHIC IS DISPLAYED

This indicates a system failure. An audible alarm signal will also occur. Restart the system using these steps to clear the failure error:

1. Remove the Stretta Catheter from the patient (make sure needles are retracted).
2. Disconnect the Connecting Cable from the Generator.
3. Disconnect the Return Electrode cable from the RF Generator.
4. Power down using main switch on back of unit.
5. Wait 30 seconds.
6. Restart following proper power up procedure.

**NOTE: IF ANY OF THESE ERRORS OCCUR DURING RF DELIVERY MODE, MAKE SURE TO RETRACT NEEDLES AND REMOVE THE STRETTA DEVICE FROM THE PATIENT BEFORE PERFORMING TROUBLESHOOTING.**

### CAUTION: Disconnect return electrode and connecting cable, and open irrigation pump prior to restart.

If unit continues to exhibit failure, or repeats same failure during procedure, please contact Mederi Customer Service.

# Troubleshooting

## POWER UP DOES NOT PERFORM AUTOMATICALLY

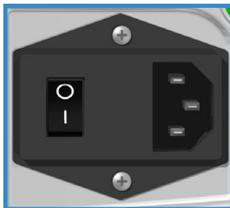
1. Power down using main switch on back of unit
2. Wait 30 seconds
3. Restart following proper power up procedure

If unit continues to exhibit this problem, please contact Mederi Customer Service.

## TURN MACHINE ON (MAIN SWITCH ON BACK) AND NOTHING HAPPENS (LED LIGHTS DO NOT ACTIVATE)

### CHECK POWER CORD AND CONNECTION TO WALL RECEPTACLE

- Use power cord shipped with the Mederi RF Generator.
- Install power cord into a functioning wall receptacle.
- Ensure power cord is full inserted into back of RF Generator and wall receptacle.
- Ensure power cord is plugged into an appropriate wall outlet (for example, not protected against ground fault, etc.)



### REPLACE FUSES

There are two fuses located in the fuse door (see image on left) on the back panel of the Mederi RF Generator.

For AC MAIN power entry voltages of 100-120V AC, the fuses must both be of the type listed in table below for the 100-120V AC table entry.

For AC MAIN power entry voltages of 200-240V AC, the fuses must both be of the type listed in table below for the 200-240V AC table entry.

#### To replace the fuses use the following procedure:

1. Unplug the AC power cord from the wall receptacle.
2. Disconnect the AC power cord from the rear panel of the Generator.
3. Open the fuse door using a flat blade screwdriver (or equivalent tool) at the fuse door latch located left of the on/off switch.
4. Remove the existing two fuses from the fuse door.
5. Insert two new fuses of the type listed in the fuse replacement specification table according to the AC MAINS voltage to which the AC power cord of the Generator will be connected. Then close the fuse door.
6. Reconnect the AC power cord into the power entry receptacle on the back panel of the Generator enclosure.



### FUSE REPLACEMENT SPECIFICATIONS

AC MAINS Voltage	Minimum Certification Marking	Fuse Type
100-120 VAC	UL/CSA	4A 250V SB (slow-blow)
200-240 VAC	IEC	2A 250V T

### ENSURE ROUTINE PERIODIC MAINTENANCE HAS BEEN PERFORMED

- See ROUTINE PERIODIC MAINTENANCE section of this manual.

# Troubleshooting

READY	Working	Optimal
Surface	10-50	NA
Tip	10-50	NA
Impedance	50-1000	<1000

	Working	Optimal	Shut-off
Surface	10-50	20-45	>50
Tip	10-100	20-84	>100
• Tip after 30 seconds			<65
Impedance	50-1000	100-250	>1000

**NOTE: Temperature and impedance shutoffs are NOT normally a sign of trouble with the MDRF1 Stretta system but are designed to provide optimal and safe RF delivery.**

## WORKING WITH TEMPERATURE AND IMPEDANCE

### READY MODE

- <10C** • If ovals are not Gray in Ready mode or are yellow with <10 indicated, the room temperature is too low for equipment operation.
- For optimal needle performance ambient temperature of >15°C is recommended

### READY MODE AND RF ON MODE

Review the chart to the left for working and optimal ranges as well as shut-off limits for temperatures and impedance.

- <50Ω** • Low impedance (<50Ω) indicates guidewire/needle contact, reposition guidewire.
- 300Ω** • High impedance (>250Ω) indicates poor needle contact with tissue (>1K shutoff) and may be corrected by
  - Reposition needles by slightly increasing retraction tension.
  - Slightly extending the needles to seat deeper in tissue.
  - Check that balloon is properly inflated, and that the electrode pad is placed on patient properly.
  - Ensure that all connections are secure.
- >1KΩ**

### RF ON MODE

- 47C** • When oval color changes to yellow - this is a warning that surface temperature levels are nearing shut-off limits (>50°C).
- <65C** • Low temperatures (<65°C) indicate insufficient needle penetration, and may be due to inadequate balloon inflation, or due to specific patient anatomy.
  - Note that if after 30 seconds of RF energy delivery, tip temperature drops to 65°C or below, the channel will shut-off for the remainder of that 60 second treatment cycle.

## REPEATED SURFACE TEMPERATURE SHUT-OFFS

Flush irrigation port of Catheter with sterile water using a syringe. Ensure that PRECAUTIONS are taken to avoid inadvertent activation of RF energy when flushing.

- Check irrigation lines for kinks, and loose connections, and for possible occlusion by other equipment or instruments.
- Check proper loading and orientation of silastic section of tubing into peristaltic pump.
- Reprime disposable device, make sure irrigation flows at base of all 4 needles.
- Reconnect irrigation tubing and resume procedure.

## REPEATED HIGH IMPEDANCE SHUT-OFFS

- Check that return electrode pad is placed on patient properly and plugged into the RF generator securely.
- Check that Connecting Cable is securely connected to Generator and Catheter.
- Replace the Connecting Cable if there are frayed edges, cracks, exposed wires or damaged connectors.

## CARE AND MAINTENANCE

### Cleaning the Mederi RF Generator

1. Disconnect the Generator from the wall plug before cleaning.
2. Wipe the exterior surface and the foot pedal with 70-90% isopropyl alcohol.

CAUTION: Do not use steam or heat sterilization on the Generator. Do not soak in glutaraldehyde or other disinfectant. Do not allow any liquid to pass into any electrical connections or into the interior of the Module.

3. Allow the surfaces to dry thoroughly before plugging in the Mederi RF Generator.
4. Gently wipe down the external surfaces of the Connecting Cable with a 70% isopropyl alcohol prep pad.

### STORAGE

Keep the Mederi RF Generator attached to the IV pole and stored in a secure temperature controlled area.

### ROUTINE PERIODIC MAINTENANCE

**WARNING: Electric Shock Hazard.** Do not remove the RF Generator cover. Removal of the cover voids any warranty. Contact authorized personnel for service.

The Mederi RF Generator should be serviced according to your hospital's equipment servicing guidelines. Mederi Therapeutics recommends that the RF Generator be checked for RF output level and undergo a safety check by a qualified service technician (e.g., hospital biomedical engineer) on an annual basis.

Check the power cord and RF Connecting Cable each time you use the RF Generator or at the intervals recommended by your institution. Replace the Power Cord and/or Connecting Cable (used in connecting the Stretta Disposable Catheter to the RF Generator) if you find exposed wires, cracks, frayed edges, or a damaged connector. Replacement power cords and Connecting Cables are available for sale from Mederi Therapeutics. Contact Mederi Therapeutics Customer Service at 1-866-982-2595 to obtain a replacement.

## TECHNICAL SPECIFICATIONS

### PERFORMANCE CHARACTERISTICS

#### General

Output Configuration	Isolated output
Cooling	Internal fan, natural convection on chassis
Display	LCD screen, LED Alarm and Event Indicators
Mounting	Integral Clamp for IV pole mounting

#### Dimensions and Weight

Width	13.5" (34.29 cm)
Depth	8.17" (20.75 cm)
Height	9.75" (24.76 cm)
Approximate Weight	12.25 lbs (5.5 kg), 6 kg maximum

#### RF Output Power

Watts (Secca)	Max 8 Watts ( $\pm 20\%$ ) x 4 Channels
Watts (Stretta)	Max 5 Watts ( $\pm 20\%$ ) x 4 Channels
Frequency	460 KHz

#### Operating Parameters

Ambient temperature range	59° to 104° F (15° to 40° C)
Relative humidity	20% to 90%, non-condensing
Air pressure	70 kPa to 106 kPa (Altitude: +7,877 ft to -1287 ft)

#### Transport and Storage

Ambient temperature range	-4° to +140° F (-20° to 60°C)
Relative humidity range	10% to 90% (non-condensing)
Air pressure (altitude) range	50 kPa to 106 kPa (Altitude: +15,308 ft to -1287 ft)

#### Audio Volume

The audio volume level and frequencies of the activation tone and alarm tones meet the requirements of IEC 60601-2-2:2009.

#### Leakage Currents

The Mederi RF Generator meets the Leakage Current limits of IEC 60601-1:2005, ES60601-1:2005 and CAN/CSA-C22.2 No. 60601-08 for Type BF, Defibrillator-Proof Equipment.

#### Electromagnetic Compatibility

The Mederi RF Generator meets the electromagnetic compatibility requirements of IEC 60601-1-2:2007, EN 60601-1-2:2007.

### STANDARDS COMPLIANCE

#### General Standards

ANSI/AAMI ES60601-1:2005  
 IEC 60601-1:2005 + CORR1:2006 + CORR2:2007  
 CAN/CSA-C22.2 No. 60601-1-08  
 EN 60601-1:2006

#### Collateral Standards

IEC 60601-1-2:2007, EN 60601-1-2:2007  
 IEC 60601-1-6:2010  
 IEC 62366:2007

#### Particular Standards

IEC 60601-2-2:2009

**TECHNICAL SPECIFICATIONS**

ACCESSORIES

**Mederi MDRF1 Power Cords**

In the U.S.A., the Mederi power cord has a voltage rating of 125V and is 6ft 7in. (2.0m) in length.

Outside the U.S.A. Mederi power cords are available in a range of plug designs and cord lengths. Voltage ratings range from 125V to 250V. Please contact Mederi Therapeutics or your local distributor for the specific power cord suitable for your regional power requirements.

**Mederi Stretta System Interface Accessories**

TYPE	LENGTH
Connecting Cable	6 feet
Irrigation Tubing	127 inches
Stretta Catheter	39.9 inches
Guidewire for Stretta Catheter	260 cm

**PATIENT AND EQUIPMENT SAFETY**

It is important that the operating instructions supplied with this or any electrical equipment be read, understood, and followed.

The Mederi MDRF1 is for use only by qualified medical personnel properly trained in the use of electrosurgical equipment, technology, and techniques.

Personnel should fully understand the nature and use of RF before performing electrosurgical procedures to avoid the risks of shock and burn hazards to both the patient and the operator and damage to the instrumentation.

It is recommended that physicians utilize pre-clinical training, review of pertinent literature, and other appropriate educational tools before attempting newer medical procedures.

**Safety during Equipment Setup**

PRECAUTION:

Read the instructions, warnings, precautions, and instructions for the use of Mederi disposable devices before using.

Inspect each disposable device and cord for breaks, cracks, nicks, or other damage before every use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team.

WARNINGS:

**Electric Shock Hazard** Ensure that the device is correctly connected. Connect the Mederi MDRF1 Generator power cord directly to a properly grounded receptacle which provides the appropriate electrical voltage and current. Otherwise, product damage may result.

**Fire Hazard** Do not use extension cords.

## PATIENT AND EQUIPMENT SAFETY

### Patient Safety

Use the Mederi MDRF1 Generator only if the self-test has been successfully completed as described in the section entitled "Setting Up the Generator." Inaccurate power outputs may result if the unit is operated prior to completion of the self-test.

Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the irrigation tubing in the pump head while the pump head rotor is turning. Fingers or loose clothing could be caught in the pump rollers.

If required by your institution or applicable regulations, connect the generator's equipotential lug connector to earth ground using a suitable cable.

Priming is required to avoid RF power activation without sterile water irrigation fluid. The Mederi disposable device is primed when irrigation fluid drips from the outlet ports of the disposable device. Failure to prime the disposable device may result in RF power activation without irrigation fluid. Activation without irrigation fluid may result in charring or damage to the electrodes.

### Safety during Treatment

WARNINGS IN THE USE OF THE MEDERI DISPOSABLE DEVICES:

- Contact between the active electrodes and any metal will greatly increase current flow and can result in unintended, catastrophic burn injury.
- Fire Hazard Do not place a disposable device near or in contact with flammable materials. Electrosurgical devices that are activated can cause a fire. When not using the disposable device, place it in clean, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- Mederi disposable devices are for use only with the Mederi MDRF1 Generator. Use of these disposable devices with other electrosurgical generators could result in injury to the patient or user, or cause damage to the disposable device and/or the generator.

PRECAUTIONS IN THE USE OF THE MEDERI DISPOSABLE DEVICES:

- Use of improper suction techniques while the device is activated may remove irrigation fluid flow that is needed for proper device function and result in activation without sufficient irrigation fluid, which may char or damage the instrument.

### Safety after Treatment

WARNINGS

- Electrical Shock Hazard Always turn off and unplug the Mederi MDRF1 Generator before cleaning.

PRECAUTIONS

- Do not clean the Mederi MDRF1 Generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the unit. Use a mild cleaning solution or disinfectant with a damp cloth.

**IEC 60601-1-2:2007 INFORMATION**

**ELECTROMAGNETIC EMISSIONS:**

This equipment has been tested and found to comply with the applicable EMC emission limits for medical devices in IEC/EN 60601-1-2:2007. This testing shows the device provides reasonable protection against causing harmful interference in a typical medical installation.

**PRECAUTION:** Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service with adherence to the Warnings and Precautions of emissions and immunity in this Operator’s Manual.

Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the Mederi equipment.

**ESSENTIAL PERFORMANCE:**

The Mederi RF Generator when used with the Stretta or Secca Disposable Catheter was determined to have no essential performance.

**ELECTROMAGNETIC EMISSIONS & IMMUNITY (EMC) NOTES**

<b>Table A-1 Guidance and manufacturer’s declaration – electromagnetic emissions</b>		
The Mederi RF Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the Mederi RF Generator should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 2	The [EQUIPMENT or SYSTEM] must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected..
RF emissions CISPR 11	Class A	The Mederi RF Generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this Operator’s Manual.		

<b>Table A-2 Guidance and manufacturer’s declaration – electromagnetic immunity</b>			
The Mederi RF Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the Mederi RF Generator should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% $U_t$ (>95% dip in $U_t$ ) for 0.5 cycle 40% $U_t$ (60% dip in $U_t$ ) for 5 cycles 70% $U_t$ (30% dip in $U_t$ ) for 25 cycles <5% $U_t$ (>95% dip in $U_t$ ) for 5 seconds	<5% $U_t$ (>95% dip in $U_t$ ) for 0.5 cycle 40% $U_t$ (60% dip in $U_t$ ) for 5 cycles 70% $U_t$ (30% dip in $U_t$ ) for 25 cycles <5% $U_t$ (>95% dip in $U_t$ ) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment.  At less than 5% $U_t$ for 5 seconds the Mederi RF Generator will enter the Safe State. Procedures to recover from the Safe State are provided in Section 7 of this manual.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_t$ is the a.c. mains voltage prior to application of the test level.			

Table A-3 Guidance and manufacturer's declaration – electromagnetic immunity			
The Mederi RF Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the Mederi RF Generator should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Mederi RF Generator System. Including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b>  <math>d = 1.2\sqrt{P}</math></p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m)</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p><math>d = 1.2\sqrt{P}</math> 80 MHz to 800 MHz  <math>d = 2.3\sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radiobroadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Mederi RF Generator is used exceeds the applicable RF compliance level above, the Mederi RF Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Mederi RF Generator.</p> <p><sup>b</sup> Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Table A-4 Recommended separation distance between Portable and mobile RF communications equipment and the Mederi RF Generator**

The Mederi RF Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mederi RF Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mederi RF Generator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

## WARRANTY

### Limited Express One Year Warranty

For one (1) year from the date of shipment from Mederi Therapeutics, Inc., if a Mederi RF Generator is found, to Mederi's satisfaction, to be inoperable during normal and proper use in accordance with applicable instructions, Mederi will repair or replace the product, at its sole option, provided the product is returned, freight prepaid, in accordance with all return packaging and shipping instructions. A product repaired or replaced under this warranty will be warranted for the remainder of the original warranty period.

MEDERI THERAPEUTICS, INC. MAKES NO OTHER WARRANTIES WITH RESPECT TO THE PRODUCT AND EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER. IN NO EVENT SHALL MEDERI THERAPEUTICS, INC. BE LIABLE FOR ANY CONSEQUENTIAL DAMAGES.

THE ABOVE WARRANTY IS VOID ON ANY PRODUCT WHICH HAS BEEN MODIFIED OR REPAIRED OTHER THAN BY MEDERI OR AN AUTHORIZED REPRESENTATIVE, IMPROPERLY INSTALLED, USED, MAINTAINED, OR STORED, OR SUBJECT TO ABUSE, MISUSE, NEGLIGENCE, OR ACCIDENT. MEDERI IS NOT RESPONSIBLE FOR DAMAGE OR ANY OTHER LOSS DURING RETURN SHIPMENT.

### EXTENDED WARRANTY

Mederi offers extended warranties, including a 2-Year Limited Service Warranty with a Preventive Maintenance (PM) or a 3-Year Limited Service Warranty with a Preventive Maintenance (PM) service. Extended warranty options are only available at the time of initial purchase. These programs cover all components, labor, and expenses incurred in the normal service of your Mederi RF Generator during the period. Mederi performs the preventive maintenance service close to the anniversary date of purchase.

Damages caused by misuse are not covered.

### RETURN OF PRODUCTS UNDER WARRANTY

To return a System or Component that fails to conform to the limited warranty set forth above, You shall first obtain a Return Material Authorization (RMA) number from Mederi Therapeutics Inc. by calling Mederi Customer Service at 1.866.982.2595. If any System or Component is returned without an RMA number, Mederi reserves the right to refuse to accept such System or Component. Within seven (7) days of receipt of the RMA number, You will return to Mederi Therapeutics, Inc. the System or Components in its original shipping carton, or other approved crating, with the RMA number displayed visibly on the outside of the carton, freight and insurance prepaid. Systems or Components should be returned to Mederi Therapeutics, Inc. - 392 Gallatin Park Drive, Unit 102 - Bozeman, MT 59715, USA, or such other location as Mederi may designate. Mederi will reimburse you for shipment charges for return of nonconforming System or Components.

### CUSTOMER SERVICE

Contact your representative or Mederi Therapeutics Inc. via the following:

### CUSTOMER SERVICE CENTER

392 Gallatin Park Drive, Unit 102  
Bozeman, MT 59715 USA  
PHONE 406.522.3121  
FAX 406-556-1322  
TOLL FREE 1.866.982.2595  
info@mederi-inc.com

### CORPORATE OFFICE

Mederi Therapeutics Inc.  
800 Connecticut Ave.  
Norwalk, CT 06854 USA  
PHONE 203.930.9900  
info@mederi-inc.com

### INTERNATIONAL CUSTOMERS

Please contact your local distributor.



stretta-therapy.com  
800 Connecticut Ave.  
Norwalk, CT 06854 USA  
203 930 9900  
mederi-inc.com



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