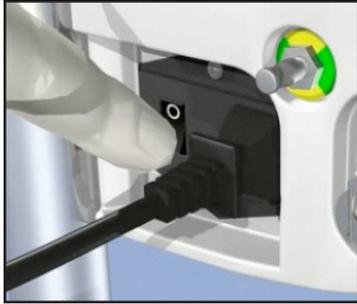


**POWER UP DO NOT CONNECT ELECTRODE PAD, STRETTA, OR FOOT PEDAL UNTIL INSTRUCTED BY SET UP**



Attach power cord and plug in. Turn on main switch on back. Keep irrigation pump open.



**REMINDER SCREENS**

Refer to IFUs      Follow set-up screen      Electrode pad placement

The Generator runs a self-test that takes approximately 2.5 minutes. It will then automatically advance to the Set Up screen.

**SET UP SCREEN**

1	2	3	4
		secca strætta	

**CONNECT**

1	2	3	4
<p><b>Connect provided Return Electrode Pad.</b></p>	<p><b>Plug in Foot Pedal to back of the Generator.</b></p>	<p><b>Attach Connecting Cable to Stretta Catheter and plug other end into Generator.</b></p>	<p><b>Place Irrigation Tubing in pump and connect to base of Stretta Catheter handle.</b></p>
		<p>Generator automatically recognizes Stretta. Usable for 3-hours from first treatment.</p>	

**PRIMING**



- Connect to chilled bag of sterile WATER (**H2O only, DO NOT USE SALINE**).
- Inflate Balloon, extend and retract needles.
- Push Prime to activate pump and ensure that water flows through device near base of each needle.
- Set wall suction to 100-160 CM H2O but do not connect to catheter until after inserting into patient.

**TREATMENT**



Push the Mode button to advance to the Ready Mode.

Step on the Foot Pedal to begin RF treatment.

For more detailed set up instructions or Troubleshooting see MDRF1 Generator Operators Manual. Follow procedure instructions provided with Secca Handpiece or Stretta Catheter, for further information consult Secca/Stretta Training modules.

# MDRF1 Troubleshooting Guide - Stretta

## COMMON ERRORS AND REMEDIES



### CONNECTION ERRORS

Problems with connections along the RF circuit can occur at multiple connection points.

Check connections:

1. Connecting cable or return electrode pad connections to generator
2. Connecting cable to disposable
3. Return electrode pad on the patient
4. Needle contact with muscle tissue



### STRETTA DISPOSABLE ERROR

- Disconnect, wait 5 seconds then reconnect.
- Be sure disposable is "authentic".
- If problem continues, replace with new Stretta catheter.

### DO NOT REUSE SYMBOL

Signifies a used or unauthorized device.



### FOOT PEDAL UNRESPONSIVE

- Check Foot Pedal connection and cord
- Temperatures out of range (equipment storage) can also prevent start of a treatment.



### UNIT ENTERS SAFE MODE

- **DISPLAY FROZEN/RED LED (SAFE MODE)**
  - **ALARM GRAPHIC**
- System failure: An alarm signal will also occur.
- Shut down and restart the system.
  - Consult Operators Manual.

**CAUTION: Disconnect return electrode and Connecting Cable, and open irrigation pump prior to restart.**

### POWER UP DOES NOT PERFORM AUTOMATICALLY

- Power down and restart.

*If problems continue, contact Mederi Customer Service.*

*For more detailed troubleshooting, see MDRF1 Operators Manual.*

**Always deflate balloon, retract needles, and remove the device from the patient before performing troubleshooting.**

## WORKING WITH TEMPERATURES AND IMPEDANCE

**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.**

RF ON	Working	Optimal	Shut-off
Surface	10-42	20-45	>50
Tip	10-100	20-84	>100
	• Tip after 30 seconds		<65
Impedance	50-1000	<250	>1000

### READY MODE

- <10C** • If ovals are not Gray or are yellow with <10 indicated, room temperature is too low.
- Ambient temperature of >15°C recommended

### READY MODE AND RF ON MODE

- <50Ω** • Low impedance (<50Ω) indicates guidewire/needle contact, reposition guidewire.
- 300Ω** • High impedance (>250Ω) indicates poor needle to tissue contact (>1K Ω shutoff)
  - Reposition needles with retraction or extension
  - Check balloon inflation and electrode pad placement.
  - Ensure that all connections are secure.
- >1KΩ**

### RF ON MODE

- 47C** • Yellow oval (46-50) warns surface temperatures are nearing shut-off limits >50°C
- <65C** • <65°C low tip temperatures can indicate insufficient needle penetration
  - Inadequate balloon inflation, or specific patient anatomy.
  - If tip temperature <65°C after 30 seconds channel will shut-off

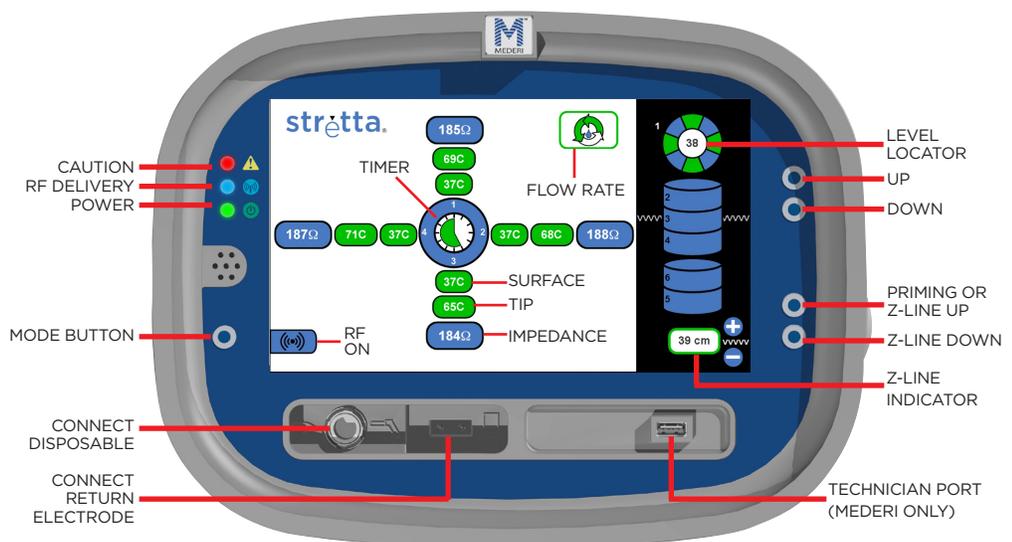
### REPEATED SURFACE TEMPERATURE SHUT-OFFS

Flush irrigation port of Catheter with sterile water using a syringe. Take PRECAUTIONS 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 return electrode pad placement and connection to Generator.
- Check that Connecting Cable is securely connected to Generator and Catheter.
- Replace the Connecting Cable if damaged.



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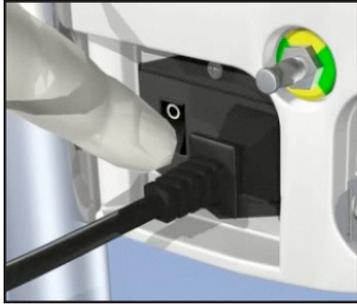
**MEDERI THERAPEUTICS INC**

**EC REP CE 0473**

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174-5447-01C

**POWER UP** DO NOT CONNECT ELECTRODE PAD, SECCA, OR FOOT PEDAL UNTIL INSTRUCTED BY SET UP SCREEN.



Attach power cord and plug in. Turn on main switch on back. Keep irrigation pump open.



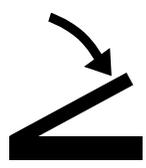
**REMINDER SCREENS**

Refer to IFUs      Follow set-up screen      Electrode pad placement

The Generator runs a self-test that takes approximately 2.5 minutes. It will then automatically advance to the Set Up screen.

SET UP SCREEN			
1	2	3	4
		secca stratta	

**CONNECT**

<h2>1</h2> <p>Connect provided Return Electrode Pad.</p> 	<h2>2</h2> <p>Plug in Foot Pedal to back of the Generator.</p> 	<h2>3</h2> <p>Attach Connecting Cable to Secca Handpiece and plug other end into Generator.</p> <p>Generator automatically recognizes Secca.</p> <p>Usable for 3-hours from first treatment.</p> 	<h2>4</h2> <p>Place Irrigation Tubing in pump and connect to base of Secca Handpiece handle.</p> 
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**PRIMING**

- Connect to chilled bag of sterile WATER (**H2O only, DO NOT USE SALINE**).
- Extend and retract needles.
- Push Prime to activate pump and ensure that water flows through device near base of each needle.
- Set wall suction to 100-160 CM H2O and connect to Secca handpiece.

**TREATMENT**

Push the Mode button to advance to the Ready Mode.

Step on the Foot Pedal to begin RF treatment.

For more detailed set up instructions or Troubleshooting see MDRF1 Generator Operators Manual. Follow procedure instructions provided with Secca Handpiece or Stretta Catheter, for further information consult Secca/Stretta Training modules.

# MDRF1 Troubleshooting Guide - Secca

## COMMON ERRORS AND REMEDIES



### CONNECTION ERRORS

Problems with connections along the RF circuit can occur at multiple connection points.

Check connections:

1. Connecting cable or return electrode pad connections to generator
2. Connecting cable to disposable
3. Return electrode pad on the patient
4. Needle contact with muscle tissue



### SECCA DISPOSABLE ERROR

- Disconnect, wait 5 seconds then reconnect.
- Be sure disposable is "authentic".
- If problem continues, replace with new Secca Handpiece.

### DO NOT REUSE SYMBOL

Signifies a used or unauthorized device.



### FOOT PEDAL UNRESPONSIVE

- Check Foot Pedal connection and cord
- Temperatures out of range (equipment storage) can also prevent start of a treatment.



### UNIT ENTERS SAFE MODE

- **DISPLAY FROZEN/RED LED (SAFE MODE)**
  - **ALARM GRAPHIC**
- System failure: An alarm signal will also occur.
- Shut down and restart the system.
  - Consult Operators Manual.

**CAUTION: Disconnect return electrode and Connecting Cable, and open irrigation pump prior to restart.**

### POWER UP DOES NOT PERFORM AUTOMATICALLY

- Power down and restart.

*If problems continue, contact Mederi Customer Service.*

*For more detailed troubleshooting, see MDRF1 Operators Manual.*

*Always deflate balloon, retract needles, and remove the device from the patient before performing troubleshooting.*

## WORKING WITH TEMPERATURES AND IMPEDANCE

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

RF ON	Working	Optimal	Shut-off
Surface	10-42	20-39	>42
Tip	10-95	20-84	>95
	• Tip after 30 seconds		<65
Impedance	50-500	<200	>500

### READY MODE

- <10C** • If ovals are not Gray or are yellow with <10 indicated, room temperature is too low.
- To achieve optimal impedance readings, reposition needles and increase or decrease Secca barrel pressure on rectal wall - apply pressure on buttocks for better contact
- Ambient temperature of >15°C is recommended.

### RF ON MODE

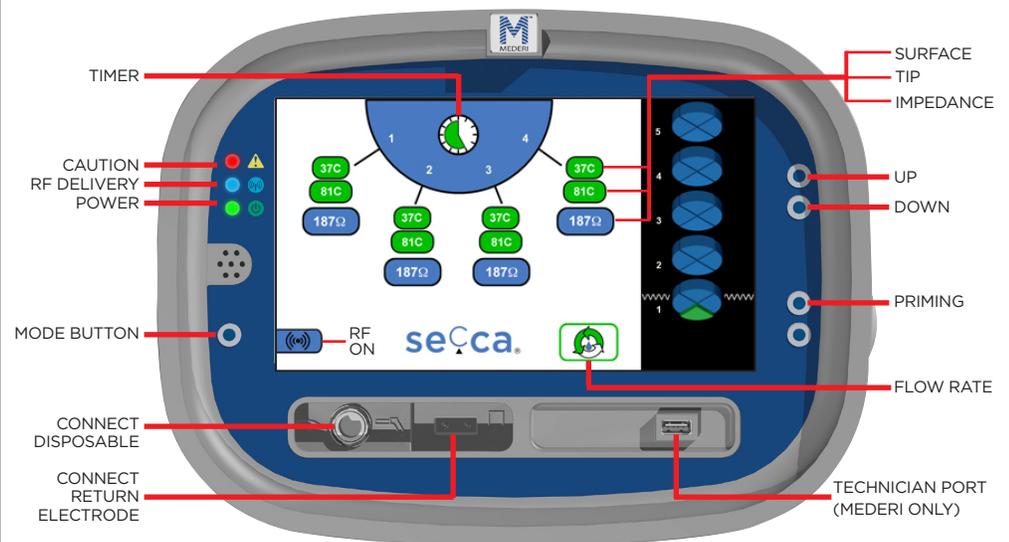
- 40C** • Yellow oval (40-42) warns surface temperatures are nearing shut-off limits (>42°C).
- 420Ω** • High or rising impedance (>400Ω) indicates poor needle contact (>500Ω shutoff) and may be corrected by:
  - Adjusting barrel pressure, or slightly extending needles by squeezing Secca handle
  - Apply pressure on buttocks in lateral or posterior quadrant treatments
  - Ensure that all connections are secure
- >500Ω** • Slow rising surface temperature is optimal. If rising rapidly, reduce barrel pressure.
- <65C** • If tip temperature <65°C after 30 seconds channel will shut-off

### REPEATED SURFACE TEMPERATURE SHUT-OFFS

- Flush irrigation port of Handpiece with sterile water using a syringe. Take PRECAUTIONS to avoid inadvertent activation of RF energy when flushing.
- Check irrigation lines for air bubbles, 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

- Attempt massaging the tissue after needle extension to achieve better tissue contact.
- Check proper placement of return electrode pad and connection to generator.
- Check that Connecting Cable is securely connected to RF Generator and Secca Handpiece.
- Replace the Connecting Cable if damaged.



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