

### Pre-Procedure

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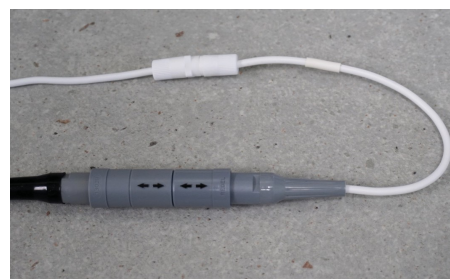
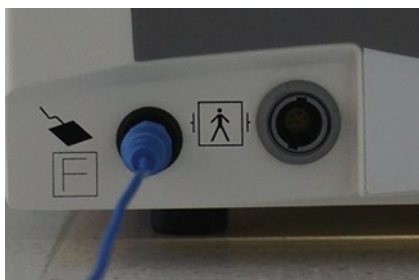
1. Prior to use review Instructions for Use (User Manual) shipped with your Thermi® products.
2. Review patient history.
3. Confirm signed consent form.
4. Take photos of the treatment areas per office photography protocol.
5. Remove make up and lotions from treatment area.
6. Mark treatment area based on office protocol.
7. Apply grounding pad close to area being treated, avoid boney prominences and ensure full contact with the skin.
8. Position patient in anatomical position for body area treated.
9. Nerve mapping device (Optional): Once positioned use the external nerve mapping device, such as the Xavant STIMPOD device, to map the nerves located in the area of treatment.
  - Place ink marks on the skin to outline the path of the nerve.
  - When treating the neck, consider marginal mandibular nerve and buccal nerve.
10. Set up sterile treatment tray or area for procedure.
  - See InjectableRF® Recommended Supply List for reference.
11. Prep the procedure area using sterile technique per office protocol (example: betadine, hibiclens, chlorhexidine).

### Procedure Set-Up

1. System: Position the system in a convenient location, so that the procedure screen and monitor are visible to the operator. Turn on the black power switch on the back of the console. You will hear a beep, the blue light on the upper left of the machine will flash and the display will show procedure settings. Position FLIR® camera with the treatment area centered on the monitor and visualization beyond the treatment zone.

### Connections

- A. Grounding Pad: Connect the Disposable Grounding Pad cord (blue) to the black neutral electrode connection port at the bottom left.
- B. Connect SJM-AC-PN-ADAP Black Extension Cable: Ensure that the arrows are at the 12 o'clock position before connecting to the Thermi® Radiofrequency generator. DO NOT twist the connector.
- C. Connect the gray end of the AC-SN-DUS adapter cable to the gray end of the extension cable. The black arrows should meet at each connection. DO NOT twist.



2. Once the desired electrode has been selected, screw black textured handle to back of electrode to close opening. Connect white plug end of cable to free end of AC-SN-DUS, See Above (pic 3)



### Settings

- A. Press the white button in the lower right corner that corresponds with the "Start" on the front display panel. (the blue light on the upper left corner will illuminate and flash).
- B. The display will have three options ThermiTight®, ThermiRase®, and ThermiSmooth®. Press the corresponding button below for the Thermi® treatment you are performing.
- C. Using the middle set of arrows, increase the Set Temp to desired starting subdermal temperature (Fig. A | Pg. 3)



### Selecting a temperature for anatomical area to be treated:

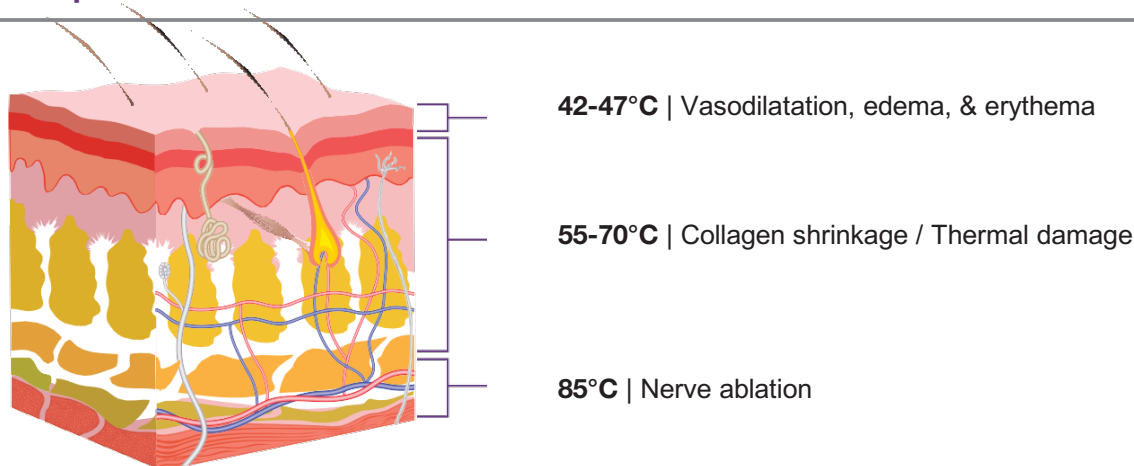
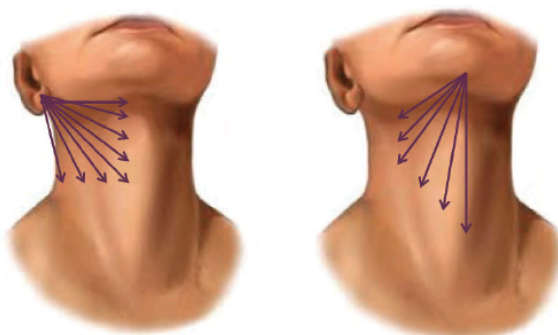


Figure A. Skin Anatomy (iStock, 2015)

### Procedure Guidelines and Techniques

1. Divide treatment area into sections. For example, a neck is divided into 3 sections.
2. Inject local anesthesia into skin at the RF Electrode insertion site.
  - Recommend 1% Lidocaine with epinephrine
3. Use 18 Gauge needle or physician preferred needle to create an opening at the electrode insertion site.
4. Infuse infiltration fluid per clinic standard practice. Recommend 30- 40 cc of infiltration fluid per 8x 8 cm square body area using a blunt standard infiltration cannula. Fluid should be warmed to 40°-45°C just before infiltration.
5. With energy off insert the Injectable RF electrode to the distal portion of first pass.
6. Press foot pedal (or Start Button) to start radiofrequency emission
  - The blue light on the upper left of the display will become solid and the device will give an audible beep every five seconds to indicate RF energy is on and being delivered through the active tip of the Injectable RR electrode.
7. When the ACTUAL sub dermal tissue temperature displayed on the Thermi<sup>®</sup> Generator Screen reaches physician selected SET temperature slowly begin withdrawing the electrode.
  - Withdraw the electrode, ½ to 1cm and again allow ACTUAL temp to reach SET temp.
  - Continue withdrawing in this manner until entire pass has reached physician selected SET temperature.
  - The goal is to keep the actual temp within 3 degrees of set temp as you withdraw.
  - Repeat with a fanning technique until entire area has been treated and reaches the recommended treatment parameters.



### Recommended Treatment Parameters

1. Visualized via the FLIR<sup>®</sup> camera and monitor: The surface skin temperature should reach between 42°-47°C across the entire treatment area.  
**Important:** The cursor must follow each sub-dermal pass and the surface temperatures should maintain the 42°-47°C range throughout.
2. Visualized via the FLIR<sup>®</sup> camera and monitor: The entire area treated should appear an even uniform color.  
**Important:** If you are treating the superficial subdermal plane, the color change will graduate to bright white as the surface temperatures reach 42°-47°C.  
When treating a deeper subdermal plane, color change will likely be orange to light yellow and surface skin temperature should remain less than 40°C.
3. Displayed on the Thermi<sup>®</sup> Generator Screen: The Actual (ACT) temperature (Subdermal) should be maintained within 3 degrees of the (SET) temperature as you withdraw your pass.

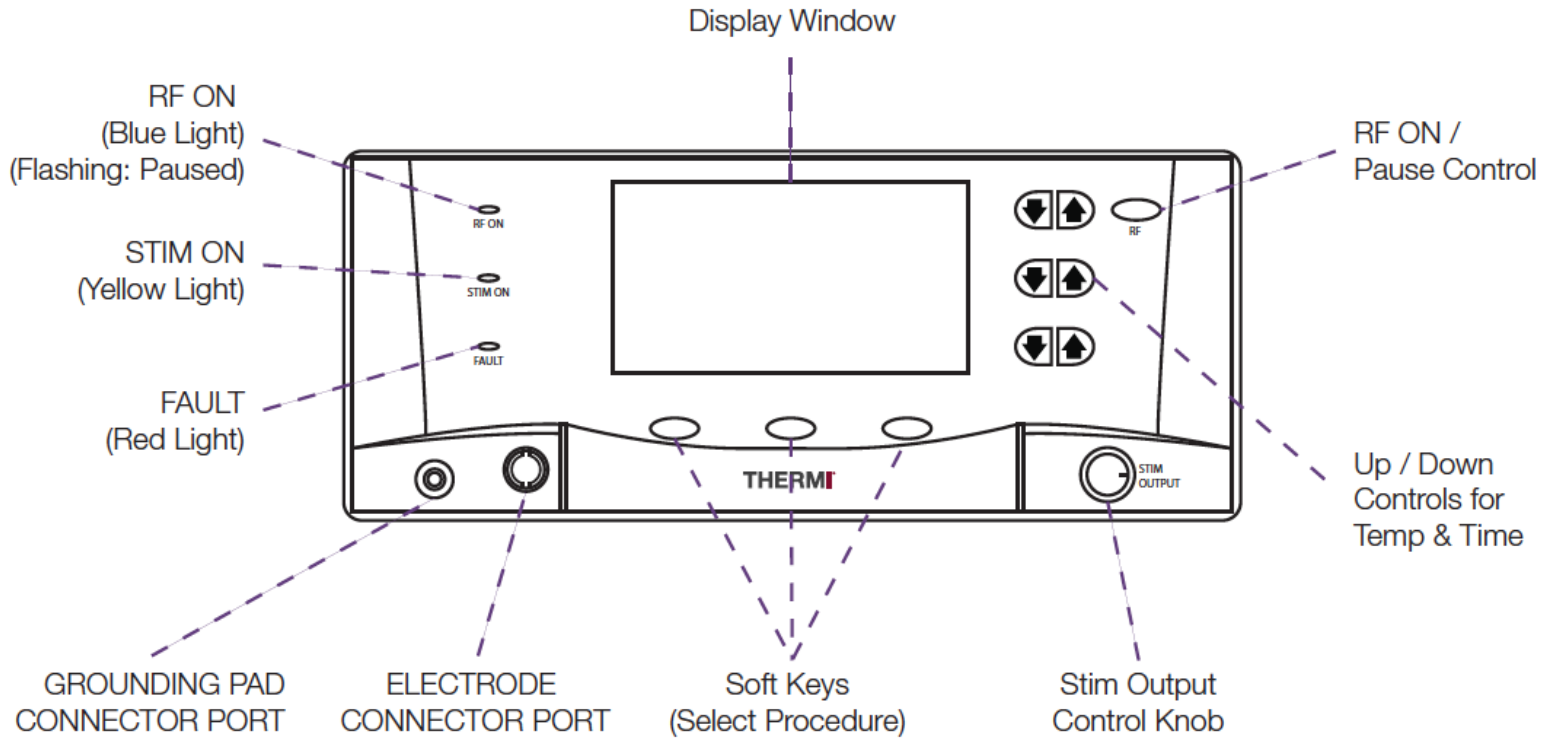
### Pearls

- If surface tissue temperature of the skin does not reach 42-47°C place your passes closer together or slightly overlap them or consider adjusting your subdermal plane more superficially.
- If surface tissue temperatures of the skin reach 47°C, dab with cold compress, and space your passes further apart, consider a lower set temperature, or adjust your electrode to a deeper subdermal plane.
- The RF Generator MUST be in the OFF or PAUSED mode when the InjectableRF<sup>®</sup> Electrode is entering and exiting the entry point.
- Avoid tenting the skin.
- Avoid catching the dermis with the InjectableRF<sup>®</sup> electrode (appears as a pucker in the skin).
- Avoid hitting the distal skin with the tip of the InjectableRF<sup>®</sup> electrode.
- Verify by viewing the monitor, that the FLIR<sup>®</sup> camera has complete visualization of the area being treated before starting each new area.
- Always be aware of surface skin temperature on the monitor (Max in the upper left corner).
- Recommend having cool saline soaked 4x4 gauze available for dabbing a “hot spot” when the skin temp reaches 47°C.
- Avoiding nerve injuries:
  - Map nerves such as the marginal mandibular nerve with an external nerve mapping device such as the Xavant STIMPOD.
  - Infuse additional infiltrate over and around the nerve area to create a cushion from the deeper structures.
  - Consider a lower sub-dermal set temperature in the area (Example: 55°C).
  - Consider staying > 5mm away from the mapped nerve.

### Post-Procedure

- Entry sites may be cleaned and dressed if necessary.
- Compression garments can be used at physician's discretion.
- For head and neck procedures, elevate head while sleeping for the first 72 hours post procedure to minimize swelling.
- Treatment area may experience minor swelling immediately post-procedure.

## ThermiRF Generator



### References

iStock (2015). Skin Anatomy vector. Retrieved from <http://www.istockphoto.com/vector/skin-anatomy-gm483754169-25580031>