THERM; FitMini®

Recommended Transdermal RF+ Procedural Guidelines

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Pre-Procedure Recommendations

- 1. Prior to use review Instructions for Use and the User Manual shipped with your Thermi[®] device.
- 2. Attend a clinical in-service provided by Thermi.
- 3. **Review patient history.** (avoid treatment of pregnant women, active site infection, patients with implantable electrical devices).
- 4. Confirm signed consent form.
- 5. Ensure hair on treatment area has been significantly reduced or removed prior to treatment.
 - a. Shaving recommendation one day prior to treatment
 - b. Waxing recommendation 5 7 days prior to treatment
 - c. Laser hair removal recommendation 10-14 days prior to treatment
- 6. **Take photos of treatment area** based on office protocol. Pictures of treatment area should be taken before each treatment and 2 weeks after final treatment.
- 7. **Ensure you have all supplies** needed including a clear ultrasonic water-based gel (i.e. Parker Labs Aquasonic Gel or equivalent).

a. Do not use oil, glycerin or gel containing color.

- 8. **Cleanse treatment area** by removing all lotions, skincare products and makeup with antibacterial or antimicrobial cleaners such as Hibiclens, or alcohol pads before beginning treatment.
- 9. Markings: If marking patient, it's best to do so when patient is in standing position. Consider using markings in photos of treatment area
- 10. **Determine Treatment area/zone.** Generally speaking, the treatment area should be 4-6 times the size of the electrode.
- 11. **Position Patient:** Position patient for anatomical area being treated. Ensure that the position allows you to apply the electrode so that it is in full contact with the skin while providing an even amount of moderate pressure.

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Procedure Set-Up: RF+

1.Position the system in a convenient location so that the procedure screen is visible to the operator. Turn on the black power switch on the back of the console. You will her a beep; indicator lights will illuminate, and the display will go through a 10 second boot up process from the logo screen to attach probe screen.

Connections & Settings

2. Select and connect the disposable grounding pad cord (blue) to the black neutral electrode connection port at the bottom left of the device. Place grounding pad on the patient close to the area being treated, avoid bony prominences and ensure full contact with the skin. 3. Select the ThermiFitMini[®] electrode.

4.With the ThermiFitMini[®] logo facing up (12 o'clock position), connect the ThermiFitMini[®] electrode to the port located to the right of the grounding pad.



5.Once the electrode is connected, the ThermiSmooth[®] option will be automatically highlighted 6.Confirm by pressing the button below the check mark. A blue light will begin flashing in the upper right corner of the generator. 7.Using the soft keys to the right, increase the Set Temperature to the desired starting temperature, 37 degrees Celsius

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Recommended Procedure Guidelines and Techniques

- 1. Apply moderate amount of warmed clear water based ultrasonic gel to treatment area.
- 2. Select desired 'set' temperature and 'set' treatment time.
 - a. Recommend starting 'set' temperature 37 degrees Celsius.
- 3. With energy off, place electrode in full contact with the skin and apply a moderate amount of pressure.
- 4. Gently press then release the foot pedal (or RF ON/OFF button) to start radiofrequency emission and begin moving electrode. The running timer starts upon RF emission.
 - a. The flashing blue light on the upper right of the display will become solid and the device will give an audible beep every 5 seconds to indicate that the energy is on and being delivered through the active tip of the electrode.
 - b. To pause RF emission, press and release the foot pedal (or RF ON/OFF button). The blue light will again begin to flash, and the return arrow will appear above the bottom of the soft key.
- 5. Increase temperature in increments of 1-2 degrees Celsius per patient tolerance, up to 42 degrees Celsius on the body (keep below 39 degrees on the lower face)
- 6. Apply RF energy according to treatment area. The treatment area treated should be, on average, 4-6 times the traced size of the electrode.
- 7. Apply additional gel as needed to ensure electrode glides on tissue for patient comfort and adequate conduction.

Recommended Treatment Parameters

- 1. Average total procedure time is based on area, excluding warm-up time.
- 2. Target temperature remains between 39° (face) -42°C (body)
- 3. Erythema should be visualized on tissue.
- 4. Actual temperature should be maintained within 3 degrees of (SET) temperature.
 - a. This is managed by controlled slow movement of the electrode.

Clinical Endpoints

- Temperature is based on patient tolerance and body area treated. The goal is to reach the maximum temperature tolerated by the patient, 39° (face) -42°C (body) being the goal and to maintain this tem- perature for the desired time suggested.
- Target time, 5 minutes face per area/zone, 12-15 minutes body per area/zone unless directed other- wise by Medical Director overseeing procedure.
- Erythema should be present during and at the end of treatment and may be present for hours after treatment.

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Pearls

- All metal objects should be removed from patient prior to treatment, these include all jewelry and piercings. The clinical provider should remove all jewelry prior to providing treatments
- Do not use short wave devices with high frequencies or switched on mobile devices that could interfere with application
- Maintain consistent, moderate pressure with full contact of the electrode
- If patient voices discomfort, increase speed of hand piece movement or decrease temperature to tolerance
- Use water based clear gel applied in a thick layer to area being treated. Apply additional product as needed to ensure patient comfort and adequate conduction
- Request patient feedback on temperature tolerance and comfort
- Always keep electrode moving when the RF energy is on
- Maintain consistent, firm pressure and keep tip of the electrode in full contact with the tissue at all times
- Avoid withdrawing electrode from contact with tissue while the energy is on
- Recommend four treatment sessions separated at one to three-week intervals

Post-Procedure

- Cleanse the skin to remove excess ultrasonic gel
- Patient may experience warmth and mild pink to redness of skin
- Procedure area may experience minor swelling immediately post-procedure
- Patients should avoid exposure to direct sunlight and tanning beds for 24 hours before and after treatments

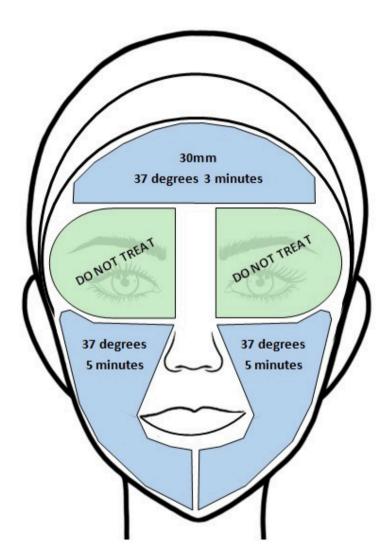




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Facial Map With Suggested Times

ThermiFitMini 30mm FACE 37-39 degrees Celsius 3-5 minutes



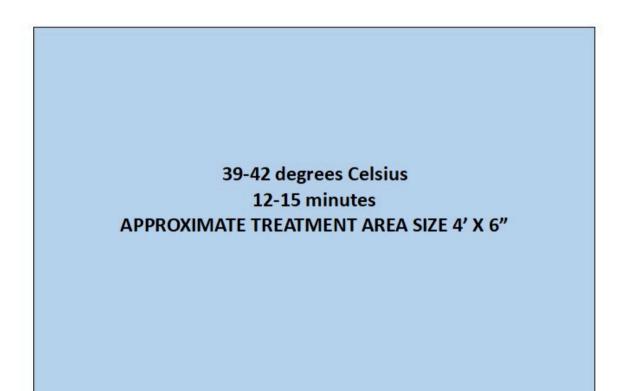




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Treatment Area

ThermiFitMini 30mm BODY 39-42 degrees 12-15 minutes per area



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