

THERMIsmooth[®] face Recommended Transdermal RF Procedural Guidelines

Pre-Procedure Recommendations:

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. Ensure hair on treatment area has been removed prior to treatment.
 - Shaving should be completed one day prior to treatment.
 - Waxing or laser hair removal should be completed 5 - 7 days prior to treatment.
5. Take photos of treatment area based on office protocol.
6. Ensure you have all supplies needed including clear, ultrasonic water-based gel (i.e. Parker Labs Aquasonic Gel or equivalent).
 - Do not use gel containing color or glycerin.
7. Cleanse treatment area by removing makeup and wiping with alcohol pads before beginning treatment.
8. Position patient in recumbent position. Ensure that the position allows you to apply the electrode to the surface of skin with firm, even pressure.

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Procedure Set-Up: ARVATI™

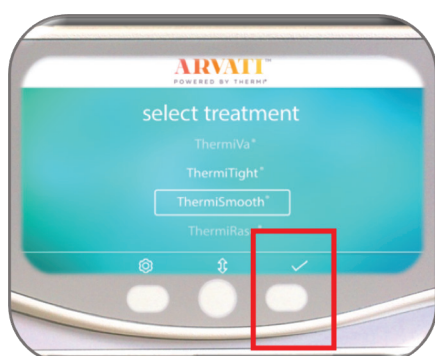
1. Position the system in a convenient location so that the procedure screen is visible to the operator. Turn on the black power switch on the back of the console. You will hear a beep; indicator lights will illuminate, and the display will go through a 10 second boot-up process from the *logo screen* 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 desired size reusable transcutaneous electrode.
 - RFE-10-D-G2
 - RFE-15-D-G2
4. With the Thermi® logo facing up (12 o'clock position), connect the reusable 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.



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Recommended Procedure Guidelines and Techniques

1. Apply moderate amount of warmed water based ultrasonic gel to treatment area.
2. Select desired 'set' temperature and 'set' treatment time.
 - Recommend starting 'set' temperature range between 36°- 38° C.
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.
 - The flashing blue light on the upper right of the display will become solid and the device will give an audible beep every five seconds to indicate that the energy is on and being delivered through the active tip of the electrode.
 - 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 left soft key.
5. Increase temperature in increments of 1 - 2°C per patient tolerance, up to 45°C.
6. Apply RF energy according to facial map recommendations. {Fig.1 Pg. 4}
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 40°-45°C.
3. Erythema should be visualized on tissue.
4. Actual temperature should be maintained within 3 degrees of (SET) temperature.
 - This is managed by controlled slow movement of the electrode.

Pearls

- Request patient feedback on temperature tolerance and comfort.
- Always keep electrode moving.
- Maintain consistent, firm pressure and keep electrode in full contact with tissue at all times.
- Avoid withdrawing electrode from contact with tissue while the energy is on.
- When treating around eyes avoid treatment over the globe.
- 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.

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Average total treatment times, excluding warm up:

- Treatment times for reference only and should be confirmed by treating physician.
- When treating larger areas consider using the 15 mm electrode.

