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### Pre-Procedure Recommendations

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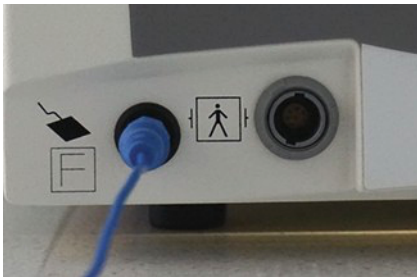
1. Prior to use review Instructions for Use (User Manual) shipped with your Thermi® products
2. Review patient history
  - Current negative pap smear
  - Pelvic exam within 1 year
  - Negative for pregnancy
  - Negative for infection / wounds (including, but not limited to: Herpes Simplex Virus, lesions or abrasions, UTI or Yeast)
3. Confirm signed consent form.
4. Ensure hair on external 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. Have patient empty bladder prior to positioning.
6. Ensure you have all supplies needed including a clear ultrasonic water-based gel (i.e Parker Labs Aquasonic Gel or equivalent).
  - Do not use gel containing color or glycerin.
7. Position patient in lithotomy position. Ensure that the position allows you to apply the electrode to surface of skin with firm, even pressure.
8. Apply grounding pad close to area being treated, avoid boney prominences and ensure full contact with the skin.
9. Take photos of treatment area based on practice protocol.

### Procedure Set-Up

1. System: 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, the blue light on the upper left of the machine will flash and the display will show procedure settings.

### 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 Thermo<sup>®</sup> 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. Select RFDE-VA Disposable RF Electrode and 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 ThermoTight<sup>®</sup>, ThermoRase<sup>®</sup>, and ThermoSmooth<sup>®</sup>. Press the corresponding button below for the Thermo<sup>®</sup> treatment you are performing. The ThermoVa<sup>®</sup> procedure is performed with either the ThermoSmooth<sup>®</sup> or ThermoVa<sup>®</sup> mode, depending on the version of RF Generator.
- C. Using the middle set of arrows, increase the Set Temp to desired temperature.



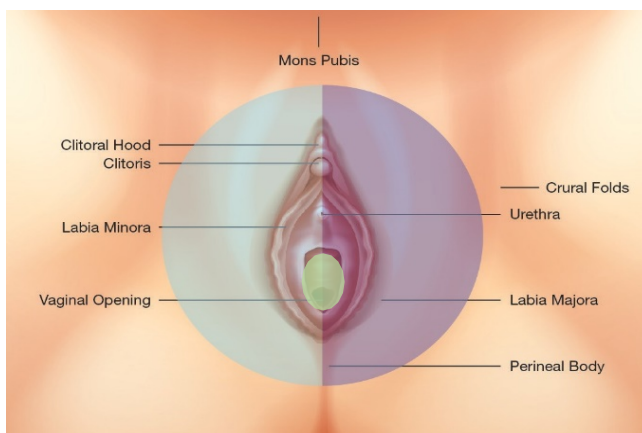
## Recommended Procedure Guidelines and Techniques

### Vaginal Canal

1. Apply moderate amount of warmed water based ultrasonic gel to electrode.
2. With energy off place ThermiVa® RF electrode internally until resistance is met to measure depth of vaginal canal.
3. Note maximum length of vaginal canal, then back out 2 - 3cm from cervix or cuff. This will be your maximum treatment distance.
4. Select desired 'set' temperature
  - Recommend starting 'set' temperature at 45°C.
5. Place electrode in full contact with tissue, apply moderate amount of pressure.
6. Press foot pedal (or Start Button) to start radiofrequency emission; and begin moving electrode.
  - 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 energy is on and being delivered through the active tip of the ThermiVa RF electrode.
7. Increase in increments of 1 - 2°C per patient tolerance. (Max generator temperature 47°C.)
8. Apply RF energy to the entire area needed for desired result.
9. Apply additional gel as needed to ensure electrode glides on tissue for patient comfort and adequate conduction.

### Labia Majora | Labia Minora

1. Apply moderate amount of warmed water based ultrasonic gel to procedure area.
2. Select desired 'set' temperature and treatment time.
  - Recommend starting 'set' temperature at 42°C
3. With energy off place the electrode in full contact with the skin, apply a moderate amount of pressure.
4. Press foot pedal (or Start button) to start radiofrequency emission and begin moving electrode.
  - 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 energy is on.
5. Increase in increments of 1 - 2°C per patient tolerance. (Max generator temperature 47°C)
6. Apply RF energy unilaterally, dividing the left and right side
7. Apply additional gel as needed to ensure electrode glides on tissue for patient comfort and adequate conduction.



Vaginal Canal

Right Labia  
Majora/Minora/

Left Labia  
Majora/Minora/

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### Recommended Treatment Parameters

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#### Vaginal Canal

1. Average total procedure time internally is 12 - 20 minutes, excluding warm-up time.
2. Target temperature is between 45°-47°C.
3. Actual (ACT) temperature should be maintained within 3 degrees of (SET) temperature.
  - This is managed by using controlled slow movement of the electrode.

#### Labia Majora | Labia Minora

1. Average total procedure time externally is 12 - 20 minutes, excluding warm-up time.
2. Target temperature is between 42°-47°C.
3. Erythema visualized on external tissue.
4. Actual (ACT) temperature should be maintained within 3 degrees of (SET) temperature.
  - This is managed by controlled slow movement of the electrode.

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### Pearls

- Request patient feedback on temperature tolerance and comfort.
- Always keep electrode moving.
- Keep active tip of the electrode in full contact with the tissue at all times.
- Avoid withdrawing electrode from contact with tissue with energy on.
- Vary depth and lines, making a different path each time.
- External procedure may require firmer pressure to increase temperature.
- Avoid contact with the cervix during application.
- Avoid applying RF energy near the urethral opening.
- Recommend three treatment sessions separated at one-month intervals.

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### 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.