Prepare for Procedure

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Introduction

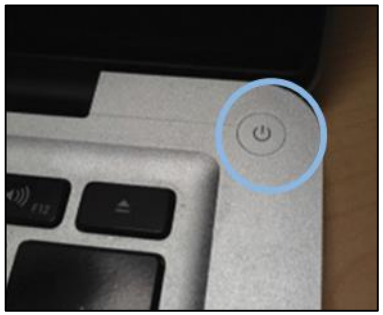
To prepare for the procedure, you must:

- Power on the System.
- Log in to the System.
- Open the Case Kit to access components.
- Prepare the System Components.
- Connect the System Components.

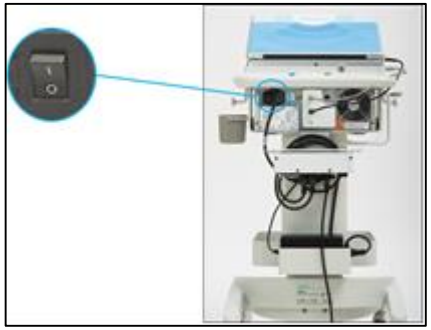
Power on the System

1. Open the Ultrasound Console (laptop).

2. Press the **Power ON** button on the top-right of Ultrasound Console (laptop) keyboard.



3. Power ON the RF Generator using the **Power** switch on the back of the RF Generator. When the switch is pressed ON, an audible tone is heard, and the LED display on the front of the Generator is lit.

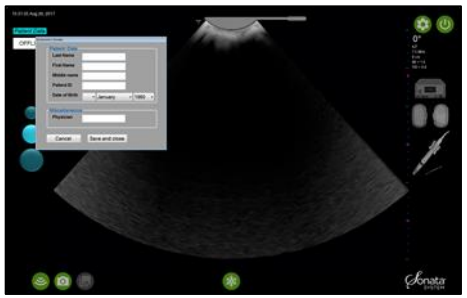


4. Connect the Footswitch to the front of RF Generator. The footswitch is pneumatic. Verify that the connection is secure .

Log in to the System

1. Log in to the system. The **Patient Data** window is displayed upon login.

2. Enter the patient data and click **Save and close**.



3. To create a new patient file (after the initial patient data entry):
    a. Click the **Patient Name** e.g., Jane Doe.
    b. Select **New Patient**. The patient data entry menu is displayed.
    c. Enter the data and click **Save and close**.

Prepare the Case Kit

1. Check the expiration dates of the Case Kit and its contents.

2. Open and remove the contents of the Case Kit –
    - RFA Handpiece in sterile packaging.
    - Two Dispersive Electrode pouches which are not sterile.

3. Apply the Dispersive Electrodes prior to draping. Note the Dispersive Electrodes are **not** sterile.
    a. Apply a Dispersive Electrode to each thigh. The thigh should be clean, dry.
    b. Position one Dispersive electrode **across** each thigh.
    c. Ensure the cable is directed towards the knee.
    d. Confirm the Dispersive Electrode is fully adhered to each thigh.
    e. Route the cables below the table to connect to the RF Generator. Note the cables are **not** sterile.

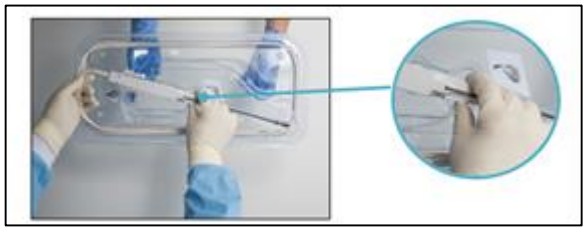
Prepare the System Components

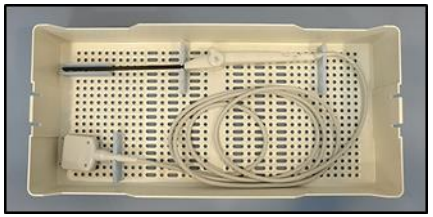
1. Prepare sterile table with required supplies:
    a. 250 cc Hypotonic fluid including sterile water, Glycine, Sorbitol, or Mannitol.
        - Do Not use normal saline or Lactated Ringer's Solution.
    b. (2) 60 cc syringes filled with hypotonic solution.
    c. Dilation and curettage (D & C) Kit including:
        - Dilators to 27 Fr / 9mm
        - Fenestrated speculum
        - Tenaculum
    d. New RFA Handpiece
    e. Sterile IUUS Probe

2. Sterile transfer of the RFA Handpiece:
    a. Inspect packaging for expiration date and tear or breach in seal.

b. Support Staff (not sterile) holds from the bottom of the plastic tray and opens the cover completely, making sure tip is not encumbered. Physician or Sterile Support Staff removes the RFA Handpiece by grasping the device from the center. There is a label indicating the proper place to grab the device for removal. The device should not be removed by the shaft. This may cause damage.
c. Pull to remove from tray and place on the RFA Handpiece on the sterile table.

3. Sterile IUUS Probe:
   a. Verify the IUUS Probe has been reprocessed (cleaned and sterilized).
   b. The Physician or Sterile Support Staff removes the IUUS Probe from the sterile tray and places it on the sterile table.





4. Inspect the IUUS Probe Tip:
    a. Inspect IUUS Probe Tip:
        - Imaging Surface
        - Hinge Mechanism
        - Hinge Cover

For more information, refer to the ***Sonata Operator's Manual*** *or the* ***Sterile Prep*** section in the ***Quick Reference Guide***.

Connect the System Components

1. Connect the dispersive electrode cables:
    a. Connect each Dispersive Electrode cable to the port on the front of the RF Generator. Either port supports either cable. There is no left or right cable port.
    b. Avoid bundling cables (including RFA Handpiece and IUUS Probe).

2. Connect the RFA Handpiece cable:
    a. The Physician or Sterile Support Staff hands the RFA Handpiece connector at the end of the cable to the non-sterile staff, while maintaining the sterility of the cable. The non-sterile staff takes hold of the connector without touching the cable.
    b. Direct the black dot marker on the connector up and align with the mark on the RF Generator port. The connector is plugged into the port on the front of the RF Generator with the dot marker facing up .

3. Connect the IUUS Probe to the Ultrasound Console:
    a. The Physician or Sterile Support Staff hands the connector of the IUUS Probe to the non-sterile staff, without contaminating the sterile field or the IUUS Probe cable.
    b. Insert the connector into the port on the right side of the ultrasound console. The Post (nub) on the connector faces up.
    c. Lock by sliding latch to the right.

4. Confirm the component connections. If a component is not connected, the screen displays an image of that component. The image will be blinking. For e.g., if the RF Generator is not connected or powered ON, an image of the generator is displayed on the ultrasound display. If the Component Connection Indicator icons are blinking, check if the:
    a. Dispersive Electrodes are connected and adhered.
    b. RF Generator is connected and there is communication to ultrasound.
    c. RF Generator is powered ON.
    d. RFA Handpiece is connected.