IonicRF™ Generator

Model RFG-IONIC

Clinician's Manual

Abbott

Contents

Prescription and Safety Information

Intended Use

The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is intended for lesioning of neural tissue in the nervous system as an aid in the management of pain.

Indications for Use

The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is indicated as an aid in the management of pain in the nervous system. Examples include facet denervation, trigeminal rhizotomy, and related functional neurosurgical procedures.

Contraindications

The use of this device is contraindicated in patients with systemic infection or local infection in the area of the procedure.

Warnings

The following warnings apply to this generator.

Instructions for use. Read and understand the instructions for use provided in this clinician's manual before operating the generator.

Hazardous electrical output. The generator is for use only by qualified medical personnel.

Electric shock hazard. This device presents an electric shock hazard under certain conditions. Physicians need to be aware of the following warnings:

- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Only approved medical grade power cords can be used with the generator. Use only the power cord specified for this unit. No modification of this equipment is allowed.
- Do not attempt to service or modify the equipment. For service, contact Abbott Medical.
- Do not under any circumstances perform testing or maintenance on the equipment while it is being used on a patient.
- Replace the power cord or plug immediately if it is cracked, frayed, broken, or otherwise damaged.
- Turn off the equipment and unplug the power cord before cleaning or servicing.
- Do not allow any fluid to enter the ventilation holes or sockets.

Equipment failure. A failure of the equipment could result in an unintended increase of output power. If unexpected parameters are observed that do not correspond to the preset values, halt the procedure immediately by pressing the Emergency Stop button on the top of the generator. Do not operate the equipment again until the source of the problem is identified and corrected.

Explosion hazard. Do not use this equipment in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Fire hazard. This device presents a fire hazard under certain conditions. Physicians need to be aware of the following warnings:

- Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
- Use recommended non-flammable agents for cleaning and disinfection whenever possible. See “Cleaning the Generator” (page 32).
- Flammable agents for cleaning, disinfecting, or as solvents of adhesives must be allowed to evaporate before using radiofrequency (RF) surgery.
- Do not place electrodes near or in contact with flammable materials.

Pooling hazard. Flammable solutions may pool under the patient or in body depressions, such as the umbilicus, and in body cavities, such as the vagina. Remove fluids pooled in body depressions and cavities before using the generator.

Ignition hazard. Be aware of and take care to avoid the danger of ignition of endogenous gasses (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced during normal use of the generator).

Risk of RF burns and unintended stimulation. Do not turn the generator power on while touching any electrodes or probes. Do not place a generator-connected electrode that is not being used in contact with the patient.

Risk of RF burns to patient. This device presents a risk of RF burns to the patient under certain conditions. Physicians need to be aware of the following warnings:

- Ensure the patient does not come into contact with metal parts of the table and its accessories. Antistatic sheeting is recommended.
- Avoid skin-to-skin contact between different parts of patient’s body (for example between the arms and the body of the patient). Use dry gauze if necessary.
- Avoid using physiological monitoring equipment during a procedure. If monitoring is required, place monitoring electrodes as far as possible from the electrode. Monitoring devices that use needle electrodes are not recommended. In all cases, monitoring systems with high-frequency current limiting devices are recommended.
- Connection of a patient to high-frequency surgical equipment and to electromyograph or evoked response equipment simultaneously may result in burns at the site of the electrodes and possible damage to the applied parts.
- Position all cables to the electrode and grounding pad (also known as the return electrode, dispersive electrode, or neutral electrode) to avoid contact with other electrodes and other metal objects.
- Place temporarily unused electrodes connected to the generator in a container or area that is electrically isolated from the patient. Never place a generator-connected electrode that is not being used in contact with the patient.
- When not in use, place accessories in a clean, dry, highly visible area away from patient contact.

- Only use grounding pads listed in the Accessories section of this manual. See “Appendix C: System Components and Accessories” (page 44).
- When positioning the grounding pad, select a well-vascularized muscular site with proximity to the procedure. See "Applying the Grounding Pad" (page 20).
- Place the long side of the grounding pad perpendicular to the direction of the current flow from the operative site. See "Applying the Grounding Pad" (page 20).
- Do not place the grounding pad over scars, bony prominences, prostheses, hair, or EKG electrodes.
- Do not place the grounding pad in a location where fluids may pool.
- If the patient is sedated, place your hand on the backside of the grounding pad, while still leaving it attached to the patient. If the grounding pad is unreasonably hot (a temperature greater than 46°C), stop the procedure by pressing the Emergency Stop button.
- If the patient complains of heating at the grounding pad site, stop the procedure and remove the grounding pad from the patient.
- Before applying power to the electrodes, ensure that the entire area of the grounding pad is firmly adhered to a suitably prepared and appropriate area of the patient’s body as defined in the grounding pad instructions for use.
- If the continuity monitor alarm is triggered, remove and discard the grounding pad. Place a new grounding pad on a fresh patch of skin.
- If unexpected parameter readings are observed that do not correspond to the preset values, halt the procedure immediately by pressing the Emergency Stop button. Do not operate the equipment again until the source of the problem is identified and corrected.

Interference with active implants. Check whether the patient has a cardiac pacemaker or other active implantable device and, if so, obtain qualified advice before using the generator. Operating the generator may interfere with or damage the implanted device.

Redirection of high-frequency currents. Check whether the patient has an electrically conductive implant and, if so, obtain qualified advice before using the generator. Operating the generator may cause concentration or redirection of high-frequency currents.

Interference with other equipment. During RF lesioning procedures, the radiated electrical fields may interfere with other electrical medical equipment. See "Minimizing Electromagnetic Interference" (page 5).

Shortwave or microwave equipment. Operation in close proximity to shortwave or microwave therapy equipment may produce instability in the applied parts.

Apparent low output or failure of equipment. If low output is observed or the equipment does not function correctly at normal operating setting, check the grounding pad and its connections.

Risk of patient injury. Do not use endoscopically. The accessories are not appropriate for endoscopic use.

Proper device use. Do not operate the generator if the alert tones are not audible after the volume is adjusted.

Non-sterile. The generator is non-sterile and should be kept outside of the sterile field.

Accessories. Use only accessories approved by Abbott Medical. See “Appendix C: System Components and Accessories” (page 44).

Continuity monitoring. The generator uses continuity monitoring. Loss of full contact between the neutral electrode and the patient will result in an auditory alarm.

Connection of equipment to rear of machine. Any equipment connected to the rear socket must comply with IEC 60950 and IEC 60601-1.

Precautions

The following precautions apply to this generator.

Inspection. Inspect the generator and reusable accessories before each use. In particular, check the electrode cable insulation for possible damage.

Mechanical damage. If the equipment has suffered any mechanical damage, return it to the supplier for inspection and testing before further use.

Electrode positioning. Do not activate the generator output until the electrodes are correctly positioned in the patient.

Use of fluids. If fluids are being used during a procedure, ensure that they are positioned away from the generator.

Dispersive connections. Ensure that the grounding pad is connected to the patient and to the generator.

Cleaning the generator. When cleaning the outer casing or touchscreen, do not use abrasive agents or solvents. See "Cleaning the Generator" (page 32).

Emergency stop. For safety, always have someone positioned next to the Emergency Stop button during operation. If at any time the device is behaving erratically, press the Emergency Stop button, located on top of the generator, which will return the device to a safe state. For example, if the displayed temperature and graph do not match the desired set temperature.

Adverse Events

Possible adverse events that may result from the use of this device include, but are not limited to, the following:

- As a consequence of electrosurgery, damage to surrounding tissue through iatrogenic injury can occur.
- Nerve injury, including thermal injury, or puncture of the spinal cord or nerve roots, potentially resulting in radiculopathy, paresis, and paralysis.
- Pain, pulmonary embolism, hemothorax or pneumothorax, infection, unintended puncture wound, including vascular puncture and dural tear, hemorrhage, and hematoma.

System Overview

The IonicRF™ Generator system consists of the following components:

- **Generator.** Produces the RF energy that is used for stimulation and neural ablation procedures. Stores a physician and therapy library. Also stores a secure patient library to protect sensitive patient information.
- **Cannula.** Needle that is inserted in the body. Contains a hollow lumen that holds an electrode tip near targeted nerves.

Probe/electrode. A thin, electrically conductive rod that delivers RF energy from the generator into a cannula to treat the targeted nerve. A thermocouple at the end of the electrode tip allows the generator to regulate RF energy to heat the targeted nerve to the desired temperature. Disposable and reusable electrodes are available for use with the generator. See “Appendix C: System Components and Accessories” (page 44).

NOTE: A special multi-electrode RF probe, called the Simplicity™ III Disposable Radiofrequency Electrode (hereafter referred to as the Simplicity™ Probe) can also be used with this generator. The Simplicity Probe contains three evenly spaced, independent electrodes and acts as both a cannula and electrodes.

- **Adapter cable.** Cable that allows a disposable electrode to be connected to the generator.
- **Grounding pad.** Also referred to as the return electrode, dispersive electrode, or neutral electrode. Electrode with a cable on one end that connects to the generator and a broad flat end that is adhered to the body. Functions to receive the RF energy emitted from a monopolar electrode and safely return the electrical current back to the generator.

  NOTE: A grounding pad is not required when a bipolar (dual-electrode) configuration is selected.

This manual provides instructions for using the generator with the accessories and components listed above. For more information about these accessories and components, refer to the instructions for use specific to each accessory or component. For a list of models that are compatible with the generator system, See “Appendix C: System Components and Accessories” (page 44).

Product Description

The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is intended for lesioning of neural tissue in the peripheral nervous system as an aid in the management of pain. The generator is portable and can be placed on a level surface using the countertop stand or mounted to a compatible roll stand using the optional pole mount.

The generator includes sensory and motor stimulation functions to fine-tune electrode placement before procedures are performed. Additionally, the generator can provide therapy to up to four electrode sites simultaneously using Lesion, Pulsed RF, or Pulsed Dose output in a monopolar approach. It is also capable of bipolar (dual-electrode) therapy, using Lesion, Pulsed RF, or Simplicity™ procedure output.

The generator features include a touchscreen monitor that incorporates microprocessor and graphics display technologies for user-interface, self-diagnostic, and record-keeping functions.

Package Contents

The IonicRF™ Generator kit (Model RFG-IONIC) contains the following items:

- Generator with countertop stand
- AC power cords (see “Appendix C: System Components and Accessories” (page 44) for replacement power cord model numbers)
- Clinician's manual
- Quick start guide

Getting Started

The information in this section describes the generator's exterior controls and features and provides steps for setting up the generator.

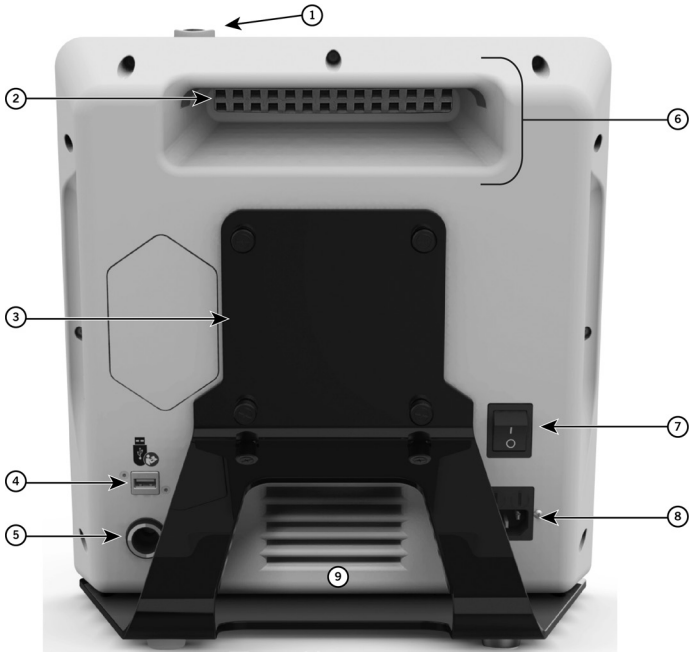
Overview of the Generator

Refer to the following figures for information about the generator features.

Figure 1. Front of the generator

1. Power indicator (lit when powered ON)
2. Touchscreen
3. Sensory/motor intensity dial
4. Emergency Stop button (disable all RF energy)
5. Side USB port (USB drives only)
6. Electrode/adapter cable ports
7. Grounding pad port

Figure 2. Back of the generator



1. Emergency Stop button (disable all RF energy)
2. Handle
3. Countertop stand
4. Rear USB port (USB drives only)
5. Equipotential port
6. Exhaust vent. Do not obstruct.
7. Power switch
8. AC power port
9. Air vent. Do not obstruct.

About the Emergency Stop Button

If you have an emergency during an ablation procedure, such as the touchscreen or sensory/motor intensity dial not responding, you can use the Emergency Stop button to immediately stop all therapy outputs. To use this feature, follow these steps:

1. Press the Emergency Stop button on top of the generator. When the Emergency Stop button is engaged, the generator emits a tone and therapy output stops.
2. When you are ready to use the generator again, press the Emergency Stop button to disengage it. All generator therapy outputs remain stopped.

   NOTE: After using the Emergency Stop button, you will be unable to resume the previous cycle and must start a new session if you want to proceed.

ProbeID™ Intelligent Probe Setup

The IonicRF™ Generator uses ProbeID™ Intelligent Probe Setup to appropriately set up the system. ProbeID Setup allows the generator to detect when electrodes are attached to or removed from the generator and automatically configures the system for use.

ProCharge™ Intelligent Power Algorithm

The IonicRF™ Generator uses the ProCharge™ Intelligent Power Algorithm during lesion therapy. The ProCharge Algorithm allows the generator to intelligently distribute power between electrode channels as needed during temperature ramping.

Minimizing Electromagnetic Interference

Although the generator meets the electromagnetic compatibility requirements for a device of this type, it is good practice to follow certain guidelines to minimize the risk of interference between the generator and other devices.

- Do not twist any of the generator cables or other device cables.
- Avoid putting the generator on top of other operating equipment or putting other operating equipment on top of the generator.
- The generator outputs RF energy at 460 kHz at up to 50 W during the RF lesion treatment phase. If any interference occurs to other equipment, it will be most noticeable under this condition.
- To minimize interference, position the generator as far as possible from the device with which it might interfere.

Setting Up the Generator

To set up the generator, follow these steps.

1. Unpack the contents of the generator kit and inspect them for any physical damage.
2. Place the generator on a level surface and ensure that the vents are not obstructed.

   NOTE: The countertop stand comes attached to the generator. An optional mounting bracket is available to allow you to secure the generator to a compatible roll stand. See “Appendix C: System Components and Accessories” (page 44).for a list of model numbers.

   NOTE: When using the generator, always ensure the attached countertop stand or roll stand is on a level surface.
3. Inspect the four captive thumb screws on the countertop stand, and tighten any that are loose.
4. After selecting the correct AC power cord for your region, insert the AC power cord into the AC power port on the back of the generator, and then plug the AC power cord into a nearby electrical outlet with a ground connection. Ensure access to the power cord is not obstructed so the cord can be easily disconnected.

   NOTE: To minimize movement of the generator, always support the generator when connecting or disconnecting any power cords.
5. If desired, insert a facility-supplied equipotential cable (DIN 42801 compatible) to the equipotential port on the back of the generator.
6. If the generator was stored in an environment that is outside of normal operating temperature, allow it to acclimate to the current environment.
7. Turn on the generator by pressing the power switch on the back of the generator. The power indicator on the front of the generator lights up, a startup screen appears, and then an Add User dialog box appears, prompting you to set the administrator password.

   NOTE: Do not touch the touchscreen during start up because the touchscreen can become unresponsive. If the touchscreen is unresponsive, turn the generator off and then on again without touching the screen.

   NOTE: Passwords must contain at least 8 characters, including one uppercase and lowercase letter, one number, and one special character. For more information about creating passwords, see "Managing User Accounts" (page 7).

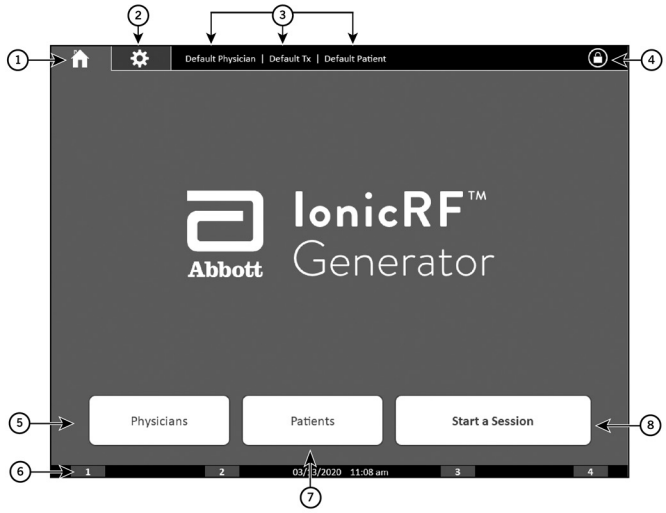
Figure 3. Add User dialog box

8. Tap **Add**.

Navigating the Home Screen

When you turn on the generator after the initial setup, the default Home screen appears. The following figure shows the features of the Home screen.

Figure 4. Features of the Home screen



1. Home
2. Device settings
3. Session selections
4. Sign in
5. Select or manage physicians and therapy settings
6. Electrode connection status
7. Select or manage patients
8. Start a treatment session

The following list describes the features of the Home screen:

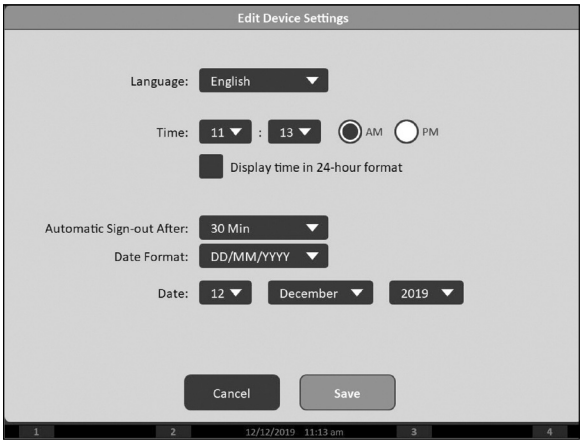
1. **Home.** Shows the Physicians, Patients, and Start a Session buttons. From any screen, tap the Home icon to return to this screen.
2. **Device settings.** Tap to view the Device Settings screen. From this screen you can perform administrative tasks such as set the time, date, and language; manage user accounts and passwords; create and restore backups; and update software.
3. **Session selections.** Shows the physician, therapy, and patient that were selected from the physician and patient libraries. You have the option to select this information before starting a session. If you do not select these options for a session, the generator uses default settings.
4. **Sign in.** Tap to sign in to the generator. The lock icon means that you are not logged in and cannot view custom patient information or manage user accounts.
5. **Physicians.** Tap to select and manage physician and therapy settings.
6. **Electrode connection status.** Shows which electrode ports have an electrode inserted. When the numbered icon is gray, no electrode is inserted. When the numbered icon is green, an electrode is inserted in the electrode port with the corresponding number. When the numbered icon flashes green, power is being delivered to that electrode.
7. **Patients.** Tap to select and manage patient information.
8. **Start a Session.** Tap to start a treatment session (sensory/motor testing or therapy).

Customizing the Device Settings

To customize the device settings, follow these steps:

1. On the Home screen, tap . The Device Settings screen appears.
2. On the Device Settings screen, tap **Set Up Device** to open the Edit Device Settings dialog box.

Figure 5. Edit Device Settings dialog box



3. Under Language, tap the drop-down menu, and then tap the desired language.
4. Under Time, tap the correct hour and minute from the drop-down menus, tap the AM or PM radio button, and tap to select or deselect “Display time in 24-hour format” depending on your preference.
5. Under Automatic Sign-out After, tap the drop-down menu, and then tap the desired amount of time.
6. Under Date Format, tap the drop-down menu, and then tap the desired date format.
7. Under Date, tap each of the drop-down menus and tap to select the current day, month, and year.
8. To save your changes, tap **Save**. Otherwise, tap **Cancel** to close this dialog box without saving your changes.

Managing User Accounts

The generator allows you to create and manage password-protected user accounts. Although you can use the generator and provide therapy without logging into a user account, a user account allows you to do the following:

- Create, view, edit, and delete other user accounts
- Create, edit, and delete custom patient records
- Access the protected health information of any patient stored in the generator's patient library
- Export custom patient data to an encrypted device

  NOTE: The generator can store a maximum of 30 user accounts. Once the maximum number of user accounts is reached, you must delete a user account to add a new one.

Creating User Accounts

When the generator is set up for the first time, it prompts the user to create an administrator-level account (see "Setting Up the Generator" (page 5)). This system administrator can then create accounts for other users and provide them with a username and temporary password. Once authenticated, these users can also create user accounts.

To create a user account, follow these steps:

1. Sign in to your account. See "Signing In to a User Account" (page 8).
2. On the Home screen, tap . The Settings screen appears.
3. On the Settings screen, tap **Manage User Accounts** to open the Manage User Accounts dialog box.
4. Tap to open the Add User dialog box.
5. Using the on-screen keyboard, type a new username and password in the applicable boxes.

   NOTE: Usernames are not case sensitive.

   NOTE: Passwords must contain at least 8 characters, including one uppercase and one lowercase letter, one number, and one special character. For more information about creating passwords, see "Creating Strong Passwords" (page 8).

6. Tap **Add** to create the user account.
7. Provide the user with his or her username and password.

   NOTE: It is recommended that the user change this password when he or she first signs in to the new user account.

Signing In to a User Account

To sign in to a user account, follow these steps:

NOTE: If you are a new user, obtain your account information from your system administrator.

1. Tap in the upper-right corner of the Home screen. The Sign In dialog box appears.

Figure 6. Sign In dialog box

2. Using the on-screen keyboard, type your username and password in the boxes.
3. Tap **Sign In**.

   NOTE: If you enter your password incorrectly five times in a row, the generator will lock you out of your user account for 30 minutes before it will allow you to attempt to log in again.

Signing Out of a User Account

To sign out of a user account, tap in the upper-right corner of the generator screen.

NOTE: The generator will automatically sign you out after a period of inactivity. However, it is good practice to sign out when you are finished using the generator to protect sensitive patient information. For instructions on setting an automatic sign-off time for the generator, see "Customizing the Device Settings" (page 7).

Creating Strong Passwords

Strong passwords can prevent unauthorized access to user accounts and restricted patient information that may be stored on the generator. When creating a password for your user account, follow these guidelines at a minimum:

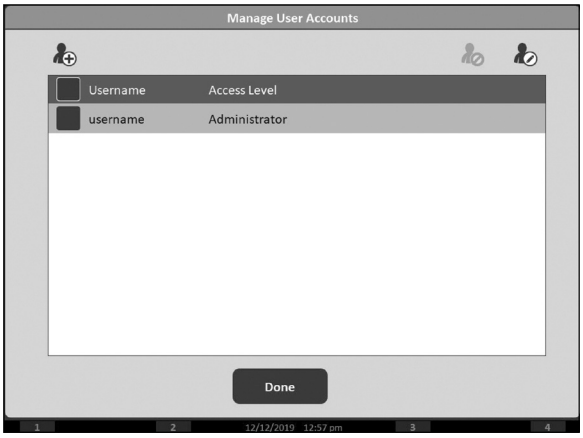
- Minimum of eight characters
- Both upper- and lower-case letters
- At least one numeric and one special character

Changing a Password

You can change the password for a user account at any time. To change a password, follow these steps:

1. If needed, sign in to your account. See "Signing In to a User Account" (page 8).
2. On the Home screen, tap . The Settings screen appears.
3. In the Settings screen, tap **Manage User Accounts** to open the Manage User Accounts dialog box.

Figure 7. Manage User Accounts dialog box



4. Tap the desired username, and then tap to open the Edit User dialog box.
5. Type the new password and confirm the new password in the remaining boxes.
6. To finish changing the password, tap **Update**.

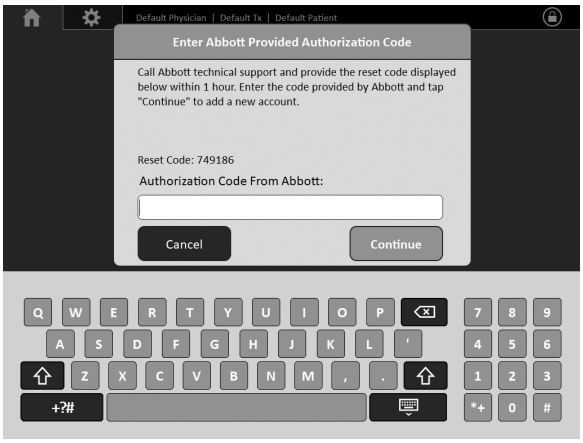
Resetting a Forgotten Password

If you forget the password of your only user account, contact your local system administrator. Your administrator can delete your user account and create a new account for you. See "Creating User Accounts" (page 7). If you forget your password and your local system administrator is not available, follow these steps to reset it:

> NOTE: As an alternative to the following steps, you can reset the generator to factory default settings; however, you will lose the current user environment, including all patient, procedure, and physician data. See "Restoring the Generator to Default Settings" (page 31).

1. On the Home screen, tap . The Sign In dialog box appears.
2. In the Sign In dialog box, tap . The Enter Abbott Provided Authorization Code dialog box appears.

Figure 8. Enter Abbott Provided Authorization Code dialog box



3. Within one hour, call Technical Support and provide the reset code displayed in the dialog box. Technical Support provides you with an authorization code. (See "Technical Support" (page 35) for contact information.)

   > NOTE: If you do not call Technical Support within one hour, you must restart the password recovery process to generate a new reset code. (See the steps above.)

4. Type the received authorization code in the Authorization Code From Abbott box, and then tap **Continue.** The Add User dialog box appears, allowing you to create a new user account.
5. Type a username and password and then confirm the password in the remaining box.
6. Tap **Add**.

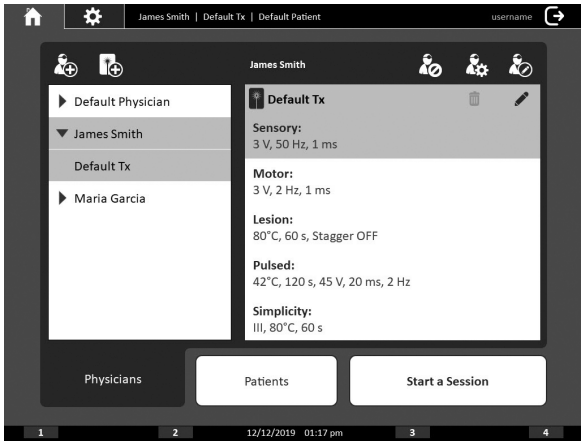
Managing the Physician Library

The generator contains a physician library, which you can use to store and quickly select preferred generator settings and therapy configurations. Additionally, the physician library contains a default physician that can be modified but not deleted. Under each physician in the library, you can store the following information:

- Settings for a default therapy and up to four custom therapies
- Physician preferences, such as screen brightness and audio volume

NOTE: The generator can store a maximum of 150 physicians in the physician library. Once the maximum number of physicians is reached, you must delete a physician in order to add a new one.

Figure 9. Physician Library screen



The following subsections provide instructions for performing tasks in this library.

Adding a Physician

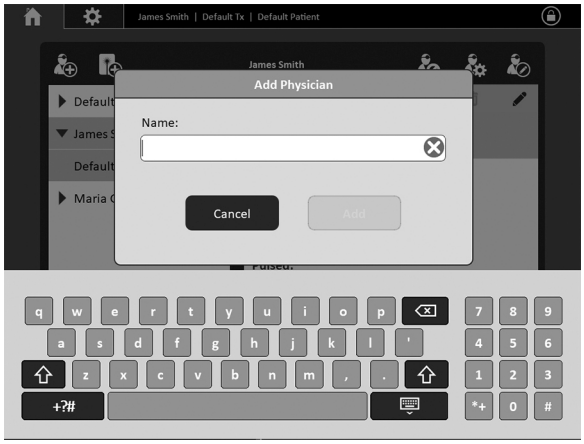
To add a physician to the physician library, follow these steps:

1. On the Home screen, tap **Physicians** to open the physician library.

   NOTE: The physician library contains a default physician record.

2. On the Physician Library screen, tap . The Add Physician dialog box appears.

Figure 10. Add Physician dialog box



3. Using the on-screen keyboard, type the physician's name.
4. Tap **Add**. The new physician appears in the physician list on the left side of the screen with a default therapy.

Editing a Physician

To edit a physician in the physician library, follow these steps:

1. On the Home screen, tap **Physicians** to open the physician library.

2. On the Physician Library screen, tap the physician's name that you want to edit.
3. Tap to open the Edit Physician dialog box.

Figure 11. Edit Physician dialog box

4. Make any changes to the physician's name by typing in the Name box.
5. To save your changes, tap **Update**. Otherwise, tap **Cancel** to close this dialog box without saving your changes.

Deleting a Physician

To delete a physician from the physician library (other than the default physician), follow these steps:

1. On the Home screen, tap **Physicians** to open the physician library.
2. On the Physician Library screen, tap the physician's name you want to delete.
3. Tap .
4. In the Delete Physician Record confirmation message that appears, tap **Delete** to confirm the deletion. Otherwise, tap **Cancel** to close this dialog box and return to the Physician Library screen.

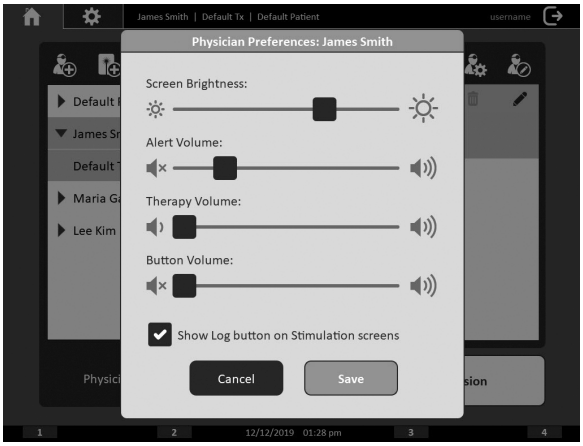
   NOTE: The default physician cannot be deleted.

Setting Physician Preferences

To set audio and display preferences for a physician, follow these steps:

1. On the Home screen, tap **Physicians** to open the physician library.
2. On the Physician Library screen, tap the name of the physician whose preferences you want to update.
3. Tap to open the Physician Preferences dialog box.

Figure 12. Physician Preferences dialog box



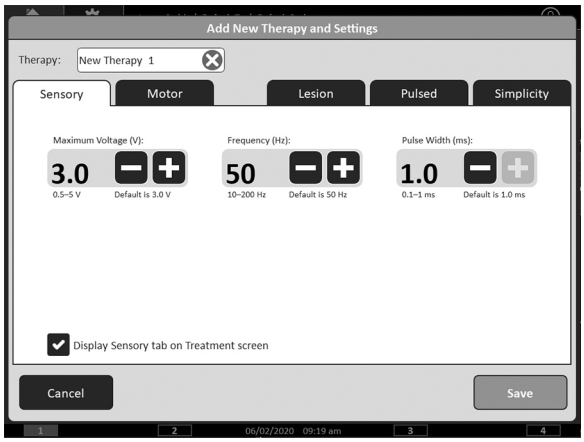
4. Tap and drag the sliders to adjust the following settings. Drag a slider to the left to decrease the value and to the right to increase it.
   - Screen brightness. Adjusts the brightness of the generator screen.
   - Alert volume. Adjusts the volume of the tone that alerts you to messages and warnings that appear on screen.
   - Therapy volume. Adjusts the volume for different activities during a therapy session, such as the beginning of a stimulation test or the end of a lesioning cycle.
   - Button volume. Adjusts the volume when a button is tapped on screen. Drag the slider all the way to the left to mute the button sounds.
5. Tap to select the check box beside "Show Log button on Stimulation screens" to be able to manually log stimulation testing information during a therapy session.
6. After you finish setting preferences, tap **Save**. Otherwise, tap **Cancel** to close this dialog box without saving any changes.

Adding a New Therapy

In addition to a default therapy, you can store up to four custom therapies under a physician's name. To add new therapy settings, follow these steps:

1. On the Home screen, tap **Physicians** to open the physician library.
2. On the Physician Library screen, tap the name of the physician for whom you want to add a therapy. A list of saved therapies appears under the name.
3. On the top left of the Physician Library screen, tap  . The Add New Therapy and Settings dialog box appears.

Figure 13. Add New Therapy and Settings dialog box



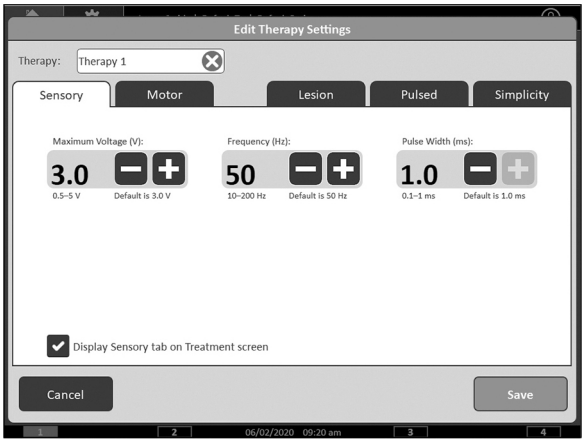
4. In the Add New Therapy and Settings dialog box, use the default name or type a therapy name in the Therapy box.
5. Adjust settings for each type of therapy, noting the following features:
   - Tap the name of the therapy mode to view and change its settings.
   - Tap + to incrementally increase a setting. Tap – to incrementally decrease a setting.
   - Tap and hold + to rapidly increase a setting. Tap and hold – to rapidly decrease a setting.
   - Reference the setting range and default setting value that are displayed below each associated setting.
   - Tap the check box to select if you want the tab for a procedure to appear on the treatment screen during a session. Deselecting this option will simplify what is displayed.
6. To save your changes, tap **Save**. Otherwise, tap **Cancel** to close this dialog box and return to the Physician Library screen without saving your changes.

Editing Therapy Settings

To edit saved therapy settings, follow these steps:

1. On the Home screen, tap **Physicians** to open the physician library.
2. On the Physician Library screen, tap the name of the physician whose therapy settings you want to edit. A list of saved therapies opens under the name.
3. Tap the therapy you want to edit.
4. Tap  to open the Edit Therapy Settings dialog box.
5. Use the keyboard to edit the therapy name in the Therapy field.

Figure 14. Edit Therapy Settings dialog box

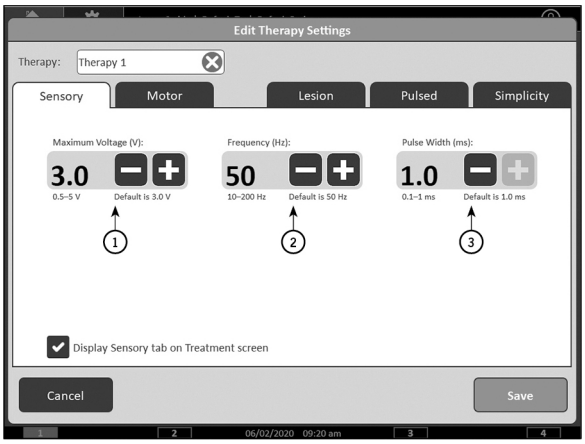


6. Adjust the settings for each type of therapy, noting the following:
   - Tap the name of the therapy mode to view and change its settings.
   - Tap + to incrementally increase a setting. Tap – to incrementally decrease a setting.
   - Tap and hold + to rapidly increase a setting. Tap and hold – to rapidly decrease a setting.
   - Reference the setting range and default setting value that are displayed below each associated setting.
   - Tap the check box to select if you want the tab for a procedure to appear on the treatment screen during a session. Deselecting this option will simplify what is displayed.
7. To save your changes, tap **Save**. Otherwise, tap **Cancel** to close this dialog box and return to the Physician Library screen without saving your changes.

Edit Therapy Settings Dialog Boxes

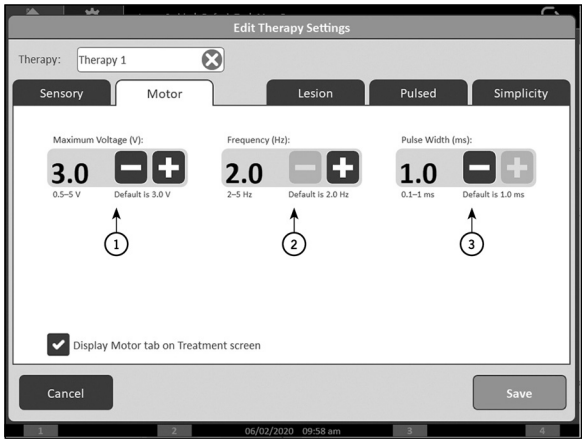
The following figures show the features of each Edit Therapy Settings dialog box.

Figure 15. Edit Therapy Settings dialog box: Sensory tab



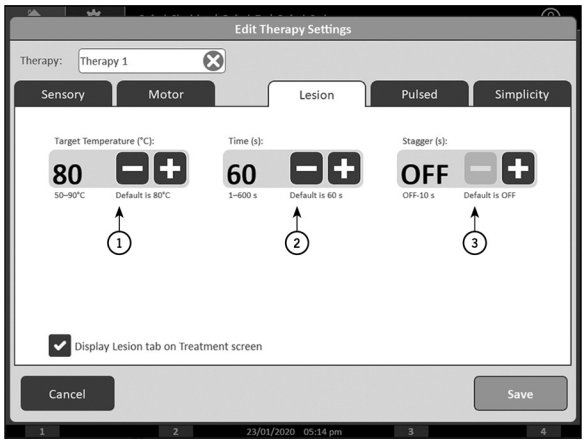
1. Maximum Voltage. Maximum allowable voltage for each pulse.
2. Frequency. The number times per second that a stimulation pulse will be delivered.
3. Pulse Width. The duration of each pulse.

Figure 16. Edit Therapy Settings dialog box: Motor tab



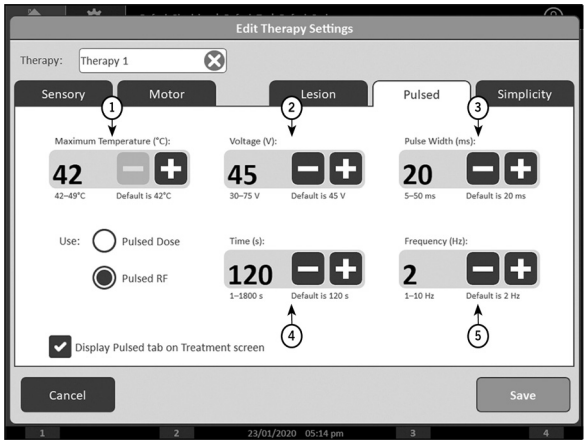
1. Maximum Voltage. Maximum allowable voltage for each pulse.
2. Frequency. The number times per second that a stimulation pulse will be delivered.
3. Pulse Width. The duration of each pulse.

Figure 17. Edit Therapy Settings dialog box: Lesion tab



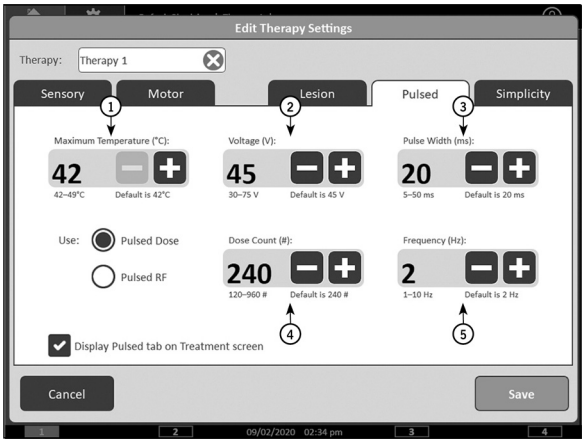
1. Target Temperature. The desired therapy temperature.
2. Time. The duration that the target temperature is held. The countdown starts when the electrode is within 5°C of the target temperature.
3. Stagger. The amount of time that passes after output begins on one electrode before output starts on the next activated electrode for the treatment cycle.

Figure 18. Edit Therapy Settings dialog box: Pulsed RF tab



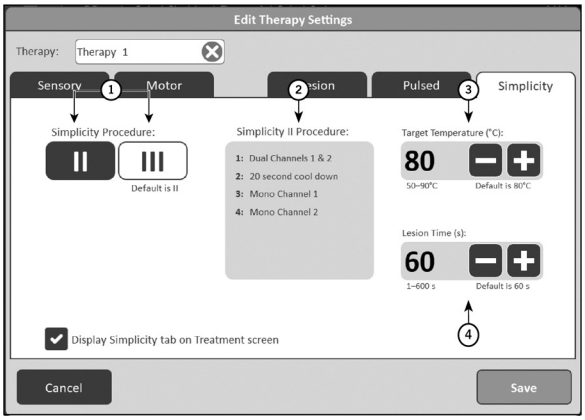
1. Maximum Temperature. The maximum allowable electrode temperature. When the maximum temperature is reached, pulses are disabled until the electrode cools.
2. Voltage. The amplitude of each pulse.
3. Pulse Width. The duration of each pulse.
4. Time. The duration that pulses will delivered.
5. Frequency. The number of times per second that a pulse will be delivered.

Figure 19. Edit Therapy Settings dialog box: Pulsed Dose tab



1. Maximum Temperature. The maximum allowable electrode temperature. When the maximum temperature is reached, pulses are disabled until the electrode cools.
2. Voltage. The amplitude of each pulse.
3. Pulse Width. The duration of each pulse.
4. Dose Count. The number of pulses to be delivered.
5. Frequency. The number of times per second that a pulse will be delivered.

Figure 20. Edit Therapy Settings dialog box: Simplicity™ Procedure tab



1. Simplicity™ Procedure Mode. Simplicity II mode only lesions using the distal and medial electrodes. Simplicity III mode lesions using all electrodes.
2. Simplicity Procedure. The order in which lesions are performed.
3. Target Temperature. The desired therapy temperature.
4. Lesion Time. The duration that the target temperature is held. The countdown starts when the electrode temperature is within 5°C of the target temperature.

Deleting a Therapy

To delete a therapy, follow these steps:

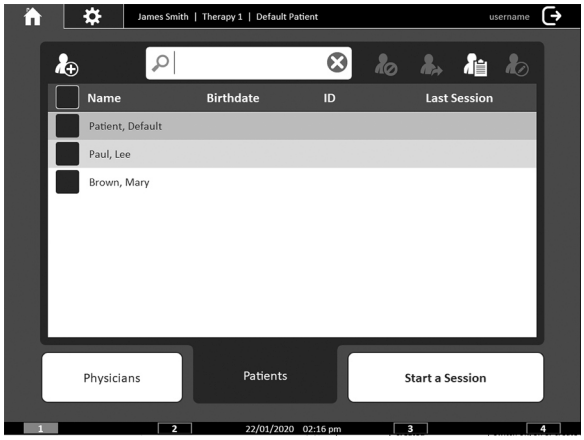
1. On the Home screen, tap **Physicians** to open the physician library.
2. On the Physician Library screen, tap the name of the physician for whom you want to delete a therapy. A list of saved therapies appears under the name.
3. Tap the therapy you want to delete, and then tap .
4. In the Delete Therapy confirmation message that appears, tap **Delete** to confirm the deletion. Otherwise, tap **Cancel** to close this dialog box and return to the Physician Library screen.

   NOTE: Each physician in the library must have at least one therapy.

Managing the Patient Library

The generator contains a patient library, which you can use to store individual therapy sessions for a patient if a patient is selected before starting a therapy session. Additionally, the patient library contains a default patient that can be modified but not deleted. The generator can store a maximum of 499 procedure records across all patients. Once the maximum number is reached, the generator will automatically delete the oldest procedure record.

Figure 21. Patient Library screen



The following subsections provide instructions for performing tasks in this library.

Adding a Patient

To add a patient to the library, follow these steps:

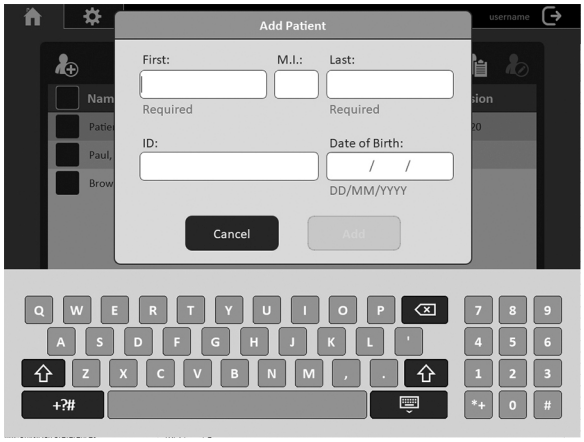
1. If needed, sign in to your account. See "Signing In to a User Account" (page 8).
2. On the Home screen, tap **Patients** to open the patient library.
3. On the Patient Library screen, tap .

   NOTE: If you choose to use a custom patient record, Abbott Medical recommends that you secure the generator from unauthorized access.
4. In the Add Patient dialog box that appears, type the following patient information in the boxes using the on-screen keyboard:
   - First name (required)
   - Middle initial
   - Last name (required)
   - Identification number
   - Date of birth

   NOTE: You must type information in all required boxes. Otherwise, the Add button will remain disabled and you will not be able to save your changes.
5. When you are finished, tap **Add**. The patient's name appears in the list on the Patient Library screen.

   NOTE: If a duplicate name is added, a Patient Name Already Exists message appears. Tap **Update** to return to the Add Patient screen and add the new patient's date of birth or identification number. Otherwise, tap **Cancel** to use the existing patient record.

Figure 22. Add Patient dialog box



Editing a Patient

To edit patient information, follow these steps:

1. If needed, sign in to your account. See "Signing In to a User Account" (page 8).
2. On the Home screen, tap **Patients** to open the patient library.
3. On the Patient Library screen, tap the name of the patient you want to edit.

   NOTE: To find a patient quickly, type the patient's name in the search box above the patient list.
4. Tap to open the Edit Patient dialog box.
5. Using the on-screen keyboard, update the patient information in the boxes as desired.
6. To save your changes, tap **Update**. Otherwise, tap **Cancel** to close this dialog box without saving your changes.

Figure 23. Edit Patient dialog box

Deleting a Patient

If a patient's information is no longer needed, you should delete it from the patient library to provide more space for new patients.

NOTE: To reduce the potential for exposing protected health information, it is good practice to delete patient information that is no longer needed.

1. If needed, sign in to your account. See "Signing In to a User Account" (page 8).
2. On the Home screen, tap **Patients** to open the patient library.
3. On the Patient Library screen, tap to select the check box or boxes beside the patient or patients you want to delete.

   NOTE: To find a patient quickly, type the patient's name in the patient search box above the patient list.
4. Tap . The Delete Patient Record dialog box appears.
5. To confirm the deletion, tap **Delete**. Otherwise, tap **Cancel** to close this dialog box and return to the Patient Library screen.

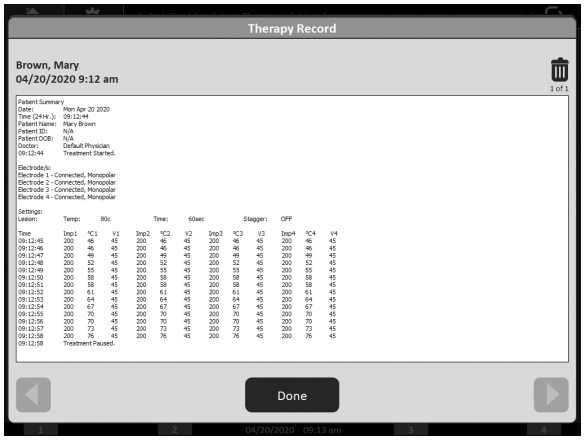
Viewing Treatment History and Patient Therapy Records

During a treatment session, the generator automatically creates a therapy record that summarizes the following information from the session: session date, session start and stop times, electrode configuration, procedure type, impedance, voltage, and temperature. The session information can also be manually logged into the therapy record when performing motor or sensory stimulation. If a patient is selected in the patient library before the treatment session, this therapy record is saved in the patient's treatment history.

To view a patient's treatment history and associated therapy records, follow these steps:

1. If needed, sign in to your account. See "Signing In to a User Account" (page 8).
2. On the Home screen, tap **Patients** to open the patient library.
3. On the Patient Library screen, tap the name of the patient whose history you want to view.
4. Tap . The Therapy History dialog box for that patient appears. For each therapy associated with the patient, the therapy history list shows the patient's name, therapy name, session date, and physician's name.
5. To view the detailed record from a therapy session, tap for that therapy record. The Therapy Record dialog box appears.

Figure 24. Therapy Record dialog box



6. In the Therapy Record dialog box, you can do the following:
   - Tap to view the next therapy record in the therapy history.
   - Tap to view the previous therapy record in the therapy history.
   - Tap and drag the content window of the dialog box to scroll through the record.
   - Tap to delete the therapy record from the patient's therapy history.
     NOTE: You can also delete one or more therapy records in the Therapy History dialog box. To do this, tap to select the check box beside each therapy you want to delete, and then tap .
   - Tap Done to close the Therapy Record dialog box and return to the Therapy History dialog box.
7. When you are finished viewing the therapy history, tap **Done** to close the Therapy Record dialog box.

Exporting Patient Data

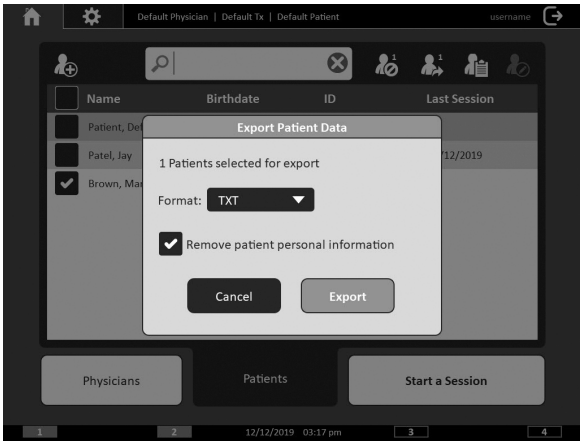
The generator allows you to export patient data from the patient library. It also gives you the option to remove the patient's name, identification number, and date of birth from the record before exporting.

To export all data for one or more patients, follow these steps:

1. Insert a USB drive into the USB port on either the side or the back of the generator.

   NOTE: Only one USB port can be used at a time.
2. If needed, sign in to your account. See "Signing In to a User Account" (page 8).
3. On the Home screen, tap **Patients** to open the patient library.
4. On the Patient Library screen, tap to select the check box beside each patient whose records you want to export.
5. Tap .
6. In the Export Patient Data dialog box that appears
   - Tap the drop-down menu to select your desired file format: TXT or CSV.
   - Keep the check box selected if you want personal patient information to be removed from the file. Otherwise, tap the check box to deselect the check mark and include the personal information.

Figure 25. Export Patient Data dialog box



7. Tap Export. After the Export Is Complete message appears, tap **Dismiss** and remove the USB drive from the USB port.

   NOTE: Confirm that you can open and view the exported files. You can view TXT files using any text editing application, and you can view CSV files using a spreadsheet application. The files are saved using the procedure number.

Selecting Treatment Options

Before starting a therapy session, the physician determines which treatment options will best meet the patient's needs. One important factor in planning the therapy session is whether destructive or non-destructive RF treatment is needed. With this factor in mind, the physician will plan a session using one or more of the following therapy types:

- Lesion
- Pulsed RF/pulsed dose

The following subsections provide information about the different therapy types.

Lesion Therapy

Lesion therapy is used to ablate neural tissue as an aid in the management of pain. Lesion therapy delivers RF energy through compatible cannulae to the targeted nerves, creating focal regions of thermocoagulation. In this way, lesion therapy disrupts the ability of the targeted nerve to deliver pain impulses to the central nervous system.

Lesion therapy can be divided into three steps: cannula placement, sensory and motor stimulation, and lesioning. First, cannulae are inserted into the patient and steered to the targeted nerve using guidance from fluoroscopic imaging. Stimulation is then typically performed to confirm placement. A combination of both sensory and motor stimulation ensures that the cannula is in proximity to the targeted nerve and far from motor nerves. Once proper nerve targeting has been confirmed with stimulation, lesion therapy proceeds. These three steps may be repeated several times to treat multiple nerves.

Lesion size and shape is determined by four parameters: target temperature, dwell time (i.e., the time at the target temperature), cannula size, and electrode configuration. Lesion creation is an equilibrium process in which the RF energy delivered through the electrode is balanced by heat loss to the surrounding tissue. Maintaining a higher electrode tip temperature requires more RF energy and therefore results in a larger lesion. Temperature is continuously measured at the electrode tip and used to titrate RF energy to create a lesion of the desired size. Increasing dwell time will result in a larger lesion, but the lesion size will plateau eventually. A larger diameter cannula or a cannula with a longer exposed tip will produce a larger lesion.

Lesion therapy can be delivered in monopolar, bipolar, Simplicity™ II, or Simplicity™ III electrode configurations. Lesion therapy uses the ProCharge™ Intelligent Power Algorithm to distribute power between channels as needed during temperature ramping.

Pulsed RF and Pulsed Dose Therapy

Pulsed RF and pulsed dose therapy deliver constant voltage pulsed RF energy to expose a nerve to an intense electric field, while also limiting temperature. Electrode temperature is limited by temporarily disabling output when a maximum temperature has been reached. The targeted nerve may be treated in a non-destructive fashion by limiting the electrode temperature to 42°C. Similar to lesion therapy, pulsed RF and pulsed dose therapy has three steps: cannula placement, sensory and motor stimulation, and treatment.

Pulsed RF therapy is typically used on nerve roots that cause radicular pain. Low temperature is used in this case to treat the sensory fibers of the nerve roots, while avoiding damage to the motor fibers nearby. Pulsed RF therapy is also used in the case of combined sensory and motor nerves, which are often found in the peripheral nervous system.

Pulsed RF and pulsed dose therapy are titrated using voltage, pulse rate, and pulse width. Higher parameter values, such as a higher voltage or longer pulse width, are used to create a more intense electric field. More intense electric fields will cause more tissue heating, and the electrode will reach the maximum temperature with fewer pulses.

Pulsed RF and pulsed dose therapy differ only in how the treatment duration is controlled. Pulsed RF therapy continues for a specified duration. Pulsed dose therapy continues until a specific number of pulses has been delivered regardless of the therapy duration.

Pulsed RF therapy can be delivered in the following electrode configurations:

- Monopolar
- Bipolar

Pulsed dose therapy can be delivered only in a monopolar electrode configuration.

The following subsection provides information about the different electrode configurations.

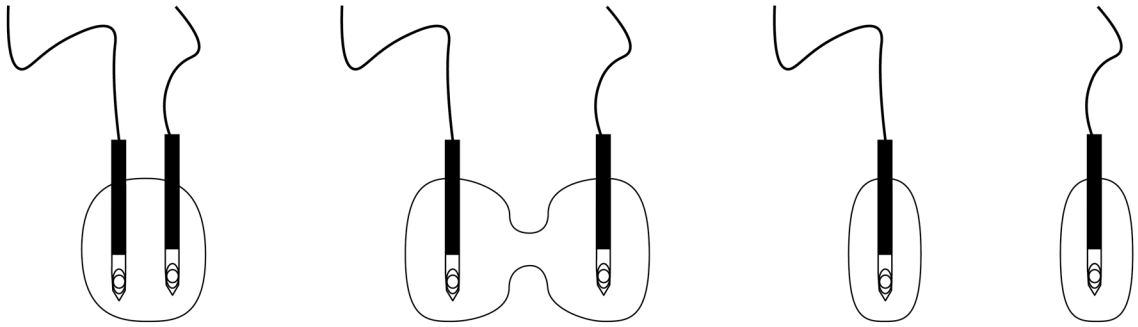
Monopolar Configurations

With a monopolar configuration, RF energy is emitted from an electrode placed at a nerve and conducted to a distant grounding pad. The RF energy can either be used to lesion the nerve or to expose it to a nondestructive, intense electric field. The generator can provide therapy in up to four monopolar electrodes simultaneously.

Bipolar Configurations

With a bipolar configuration, RF energy is emitted from an electrode placed at a nerve and conducted to another nearby electrode. In this configuration, one electrode functions as the active electrode, while the other functions as the return electrode (passive electrode), thereby eliminating the need for a grounding pad. The two cannulae are placed near a nerve, with the tips separated by up to 9 mm.[1] The emitted RF energy flows from the active electrode (channel 1 or 3) to the passive electrode (channel 2 or 4), providing therapy to the area between the cannulae. The generator can provide up to two bipolar therapies simultaneously. The following figure shows how spacing affects lesion shape.

Figure 26. Example of how spacing affects lesion shape



Simplicity™ II and III Procedures

The Simplicity™ II and III procedures use the three-electrode Simplicity™ Probe and a programming algorithm to automatically perform nerve destruction between independent active areas. For detailed instructions for use of the Simplicity Probe, refer to the clinician's manual for the product.

- **Simplicity II procedure (default procedure).** The distal electrode (electrode 1) and the medial electrode (electrode 2) are active at different times during the session, according to the phase sequence. The resulting lesion is a similar, shorter ablation strip than one created from a Simplicity III procedure.
- **Simplicity III procedure.** The distal electrode (electrode 1), the medial electrode (electrode 2), and the proximal electrode (electrode 3) are active at different times during the session, according to the phase sequence. The resulting lesion is an ablation strip.

Preparing for a Treatment Session

This section provides information and instructions about preparing for a treatment session.

NOTE: To minimize movement of the generator, always support the generator when connecting or disconnecting the power cord or cables.

NOTE: When using the generator, always ensure the attached countertop stand or roll stand is on a level surface.

Applying the Grounding Pad

1. Prepare the patient according to facility protocol.

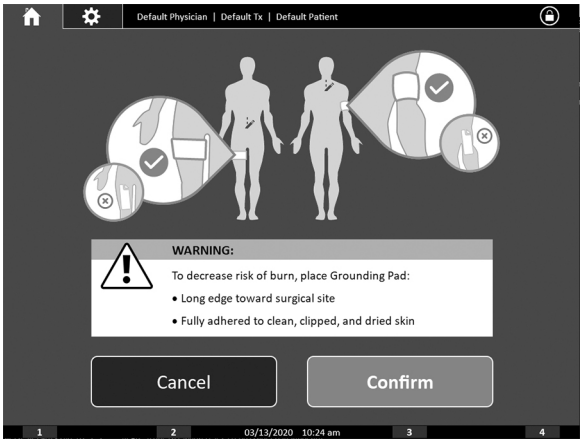
   NOTE: To optimize conduction and reduce the risk of injury, Abbott Medical recommends the following regarding grounding pad placement:

   - The grounding pad should make maximum surface area contact with the patient.
   - The grounding pad should be placed in a well-vascularized muscular site near the procedure that allows full skin-to-pad contact. The grounding pad must not overlap itself when placed on limbs.
   - The grounding pad should not be placed over scars, bony prominences, prostheses, hair, or EKG electrodes.
   - The pad should be placed on clean, dry, hairless skin. If needed, the hair may be clipped and skin oil removed (with alcohol, which must be allowed to dry before application).

[1] Cosman ER, Gonzalez CD. Bipolar radiofrequency lesion geometry: implications for palisade treatment of sacroiliac joint pain. Pain Pract. 2011;11(1):3-22.

2. Place the grounding pad according to the grounding pad instructions for use, ensuring that the wide edge of the grounding pad is perpendicular to the ablation site and the entire grounding pad is adhered fully to the patient's skin.

Figure 27. Example of correct and incorrect grounding pad orientation



3. Connect the grounding pad cable to the grounding pad port on the front of the generator.

Placing the Cannula or Simplicity™ Probe

The process of locating the precise target site for each nerve and electrode placement is generally the same for any of the ablation techniques.

1. Apply local anesthetic to the planned cannula or Simplicity™ Probe insertion site.
2. Using fluoroscopic guidance or standard clinical visualization, insert the cannula or Simplicity Probe into the entry site and advance to the desired target site.
3. Repeat steps 1 and 2 until you have placed all cannulae for the planned procedure.
4. Keep the following details in mind when placing cannulae for bipolar lesioning procedures:
   - Ensure the distance between the cannulae is close enough to produce a single lesion but far enough apart to produce a larger lesion than could be achieved using a monopolar procedure (typically 3 mm to 9 mm [0.12 in to 0.35 in] apart).
   - Ensure that the placement of the cannula will not cause the electrodes to touch during any procedure. If the electrodes touch, the generator will display a low-impedance warning and will not deliver RF output.

   Note the following differences in the targeting procedure for the Simplicity Probe:
   - Simplicity RF ablation is typically performed on nerves in the sacroiliac joint, and the electrode is inserted directly to the target site without using a cannula.
   - Each electrode on the Simplicity Probe is electrically independent; therefore, you can perform distinct stimulation tests from each electrode site to confirm correct electrode placement.

Connecting the Electrodes

To connect the electrodes to the generator, follow these steps:

1. For each reusable electrode, connect the electrode cable to the electrode port on the front of the generator.

   -OR-

   For the Simplicity™ Probe or disposable electrodes, connect a compatible electrode adapter to the electrode port on the front of the generator, and then connect the cable of the Simplicity Probe or disposable electrode to the adapter.

   NOTE: Ensure that the red dot on the electrode cable or adapter aligns with the red dot on the electrode port.
   - For a Simplicity™ II procedure, both electrodes 1 and 2 must be connected to the generator.
   - For a Simplicity™ III procedure, electrodes 1, 2, and 3 must be connected to the generator.
2. If applicable, insert the reusable or disposable electrode into the cannula.

   NOTE: The IonicRF™ Generator uses ProbeID™ Intelligent Probe Setup to detect the attached electrodes and configure the system for use.
3. If applicable, repeat steps 1 and 2 for up to three more electrodes.

Selecting a Physician (Optional)

Users have the option to select a physician from the physician library. When a physician is selected, all of the associated preferences and therapy settings are loaded automatically.

To select a physician, follow these steps:

1. On the Home screen, tap **Physicians** to open the physician library.
2. Tap the name of the physician whose settings you want to use.

   NOTE: If a physician is not selected, the default physician settings will be used to perform the treatment session.
3. If more than one therapy is listed under the physician, tap the name of the therapy you want to use.
4. To start a treatment session immediately using the selected physician settings, tap **Start a Session**.

   -OR-

   If desired, select a patient from the patient library to associate with the selected treatment. See "Selecting a Patient (Optional)" (page 22).

Selecting a Patient (Optional)

When a patient is selected, the treatment session will be associated with this patient.

To select a patient, follow these steps:

1. On the Home screen, tap **Patients** to open the patient library.
2. From the list on the Patient Library screen, tap the patient's name you want to select.

   NOTE: If no patient is selected, the default patient will be associated with the treatment session. You will not be able to reassign an existing treatment session from one patient to another after the treatment session.
3. To start a treatment session immediately using the selected patient, tap **Start a Session**.

   -OR-

   If desired, select a physician from the physician library to associate with the treatment session. See "Selecting a Physician (Optional)" (page 22).

Performing Stimulation Testing

This section provides information about selecting saved therapy settings and performing different stimulation and ablation techniques.

Performing Sensory Stimulation

Sensory stimulation confirms cannula placement using a series of pulses (10 Hz to 200 Hz) to recruit the targeted nerves. If the electrode is in the optimal position, the patient should feel paresthesia localized to the painful area while the stimulation output is low. A low sensory stimulation threshold implies the electrode is close enough to the targeted nerves will be lesioned during the ablation procedure.

To perform sensory stimulation, follow these steps:

1. Set up the desired electrode(s). See "Placing the Cannula or Simplicity™ Probe" (page 21) and "Connecting the Electrodes" (page 21).

   NOTE: Up to four electrodes may be connected to the generator at a time, allowing up to four target sites to be tested during the same sensory stimulation cycle. However. stimulation testing can be performed on only one electrode at a time.
2. Set up the grounding pad. See “Applying the Grounding Pad" (page 20).
3. Verify that the desired physician and patient are selected in the appropriate library. See “Selecting a Physician (Optional)” (page 22) and “Selecting a Patient (Optional)” (page 22). Otherwise, the default settings will be used.

   NOTE: The grounding pad orientation screen will appear and must be acknowledged before you can perform stimulation testing. To acknowledge that the grounding pad has been placed correctly on the patient, tap **Confirm**. Otherwise, tap **Cancel** to return to the previous screen. See “Applying the Grounding Pad” (page 20).
4. On the Treatments screen, tap the Sensory tab to open the Sensory stimulation screen. The Sensory stimulation screen displays the settings selected from the physician library or the default physician.

Figure 28. Features of the Sensory stimulation screen

1. Exit the session and return to the Home screen
2. Voltage values
3. Graphical representation of voltage
4. Edit programmed settings
5. Electrode panel corresponding to each electrode inserted in the electrode ports
6. Programmed settings
7. Manually log parameters
8. Turn off stimulation
9. Increase or decrease voltage step size

5. To edit the stimulation settings, tap . The Edit Sensory Settings dialog box appears so you may adjust stimulation settings before starting the procedure.
   - Tap the + to increase a setting. Tap – to decrease a setting.
   - Tap and hold + to rapidly increase a setting. Tap and hold – to rapidly decrease a setting.
   - To save your changes to the stimulation settings associated with the physician, tap to select the check box beside "Update my saved therapy with these settings."
   - To save your changes and return to the Sensory stimulation screen, tap **Save**. Otherwise, tap **Cancel** to close this dialog box and return to the Sensory stimulation screen without saving your changes.
6. If multiple electrodes are inserted into the generator, tap the electrode panel for the electrode you want to test.

   NOTE: Stimulation can be output on only one electrode channel at a time.
7. Select the desired step size by tapping the step size button any time during stimulation.

   NOTE: The default step size is .10 V. Users can change the step size any time during stimulation.

   CAUTION: Always increase stimulation slowly to minimize patient discomfort and to get an accurate threshold response.
8. To start stimulation, slowly rotate the sensory/motor intensity dial clockwise to increase the stimulation voltage and counterclockwise to decrease stimulation voltage.

   NOTE: When the stimulation output is greater than zero, the numbered icon for the active electrode flashes green, indicating power is being delivered to that electrode, and the generator emits a tone.

   NOTE: If needed, tap **Turn Off** to stop stimulation.

   NOTE: If you have an emergency during a procedure, such as the touchscreen or sensory/motor intensity dial not responding, press the Emergency Stop button on top of the generator.
   - When the Emergency Stop button is engaged, the generator emits a tone, and therapy output stops.
   - When you are ready to use the generator again, press the Emergency Stop button to disengage it. You will be unable to resume the previous session and must start a new session if you want to proceed.
9. If desired, tap to manually log the threshold voltage to the therapy record.
10. If needed, remove the electrode from the cannula, reposition the cannula, reinsert the electrode, and repeat the stimulation test until you confirm all electrodes are optimally placed.

    NOTE: Once the procedure is completed, you can view and export the session records from the Patient tab. See "Viewing Treatment History and Patient Therapy Records" (page 17) and "Exporting Patient Data" (page 18).

Performing Motor Stimulation

Motor stimulation confirms cannula placement using a series of pulses (2 Hz to 5 Hz) to recruit the targeted nerves. If the electrode is in the optimal position, the stimulation should not elicit a motor response in the distal muscles (e.g., legs and arms) until the stimulation intensity is high. A high motor stimulation threshold implies that the electrode site is far enough away from motor nerves that they will not be damaged during the ablation procedures.

To perform motor stimulation, follow these steps:

1. Set up the desired electrode(s). See "Placing the Cannula or Simplicity™ Probe" (page 21) and "Connecting the Electrodes" (page 21).

   NOTE: Up to four electrodes can be connected to the generator at a time, allowing up to four target sites to be tested during the same motor stimulation cycle. However. stimulation testing can be performed on only one electrode at a time.

2. Set up the grounding pad. See “Applying the Grounding Pad" (page 20).

3. Verify that the desired physician and patient have been selected. See “Selecting a Physician (Optional)” (page 22). and “Selecting a Patient (Optional)” (page 22). Otherwise, the default settings will be used.

   NOTE: The grounding pad orientation screen will appear and must be acknowledged before you can perform stimulation testing. To acknowledge that the grounding pad has been placed correctly on the patient, tap **Confirm**. Otherwise, tap **Cancel** to return to the previous screen. See “Applying the Grounding Pad” (page 20).

4. On the Treatments screen, tap the Motor tab to open the Motor stimulation screen. The Motor stimulation screen displays the settings selected from the physician library or the default physician.

Figure 29. Features of the Motor stimulation screen

1. Exit the session and return to the Home screen
2. Voltage values
3. Graphical representation of voltage
4. Edit programmed settings
5. Electrode panel corresponding to each electrode inserted in the electrode ports
6. Programmed settings
7. Manually log parameters
8. Turn off stimulation
9. Increase or decrease voltage step size

5. To edit the stimulation settings, tap  . The Edit Motor Settings dialog box appears to allow you to adjust stimulation settings before starting the procedure.
   - Tap the + to increase a setting. Tap – to decrease a setting.
   - Tap and hold + to rapidly increase a setting. Tap and hold – to rapidly decrease a setting.
   - To save your changes to the stimulation settings associated with the physician, tap to select the check box beside “Update my saved therapy with these settings.” Otherwise, your changes will be in effect only during the current treatment session.
   - To save your changes and return to the Motor stimulation screen, tap **Save**. Otherwise, tap **Cancel** to close this dialog box and return to the Motor stimulation screen without saving your changes.

6. If multiple electrodes are inserted into the generator, tap the number of the electrode you want to test.

   NOTE: Stimulation can be output on only one electrode channel at a time.

7. Select the desired step size.

   NOTE: The default step size is .10. Users can change the step size any time during stimulation.

   CAUTION: Always increase stimulation slowly to minimize patient discomfort and to get an accurate threshold response.

8. To start stimulation, slowly rotate the sensory/motor intensity dial clockwise to increase the stimulation voltage and counterclockwise to decrease stimulation voltage.

   NOTE: When the stimulation output is greater than zero, the numbered icon for the active electrode flashes green, indicating that power is being delivered to that electrode, and the generator emits a tone.

   NOTE: If needed, tap **Turn Off** to stop stimulation.

NOTE: If you have an emergency during a procedure, such as the touchscreen or sensory/motor intensity dial not responding, press the Emergency Stop button on top of the generator.

- When the Emergency Stop button is engaged, the generator emits a tone, and therapy output stops.
- When you are ready to use the generator again, press the Emergency Stop button to disengage it. You will be unable to resume the previous session and must start a new session if you want to proceed.

9. If desired, tap to manually log the threshold voltage to the therapy record.
10. If needed, remove the electrode from the cannula, reposition the cannula, reinsert the electrode, and repeat the stimulation test until you confirm all electrodes are optimally placed.

    NOTE: Once the procedure is completed, you can view and export the session records from the Patient Library screen. See "Viewing Treatment History and Patient Therapy Records" (page 17) and "Exporting Patient Data" (page 18).

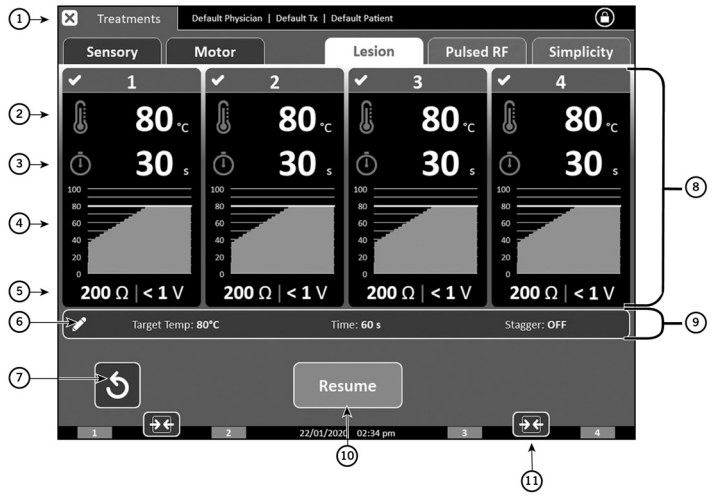
Using Lesion Mode

To use Lesion mode, follow these steps:

1. Set up the desired electrodes. See "Placing the Cannula or Simplicity™ Probe" (page 21) and "Connecting the Electrodes" (page 21).
2. If performing a monopolar procedure, set up the grounding pad. See "Applying the Grounding Pad" (page 20).
3. Verify that the desired physician and patient are selected in the appropriate library. See "Selecting a Physician (Optional)" (page 22) and "Selecting a Patient (Optional)" (page 22). Otherwise, the default settings will be used.

   NOTE: The grounding pad orientation screen will appear and must be acknowledged before you can perform therapy. To acknowledge that the grounding pad has been placed correctly on the patient, tap **Confirm**. Otherwise, tap **Cancel** to return to the previous screen. See "Applying the Grounding Pad" (page 20).
4. On the Treatments screen, tap the Lesion tab to show the Lesion treatment screen. The Lesion treatment screen displays the settings of the therapy selected from the physician library or the default physician.

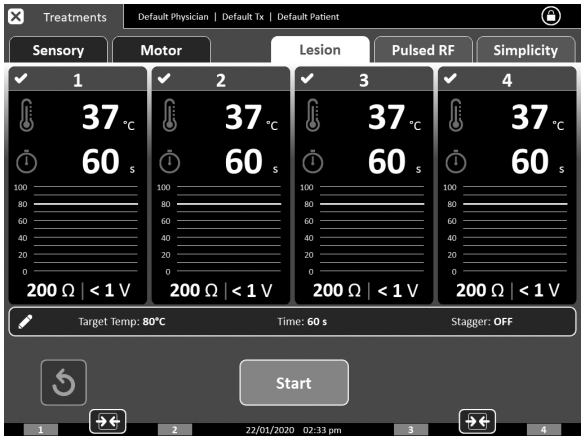
Figure 30. Features of the Lesion treatment screen



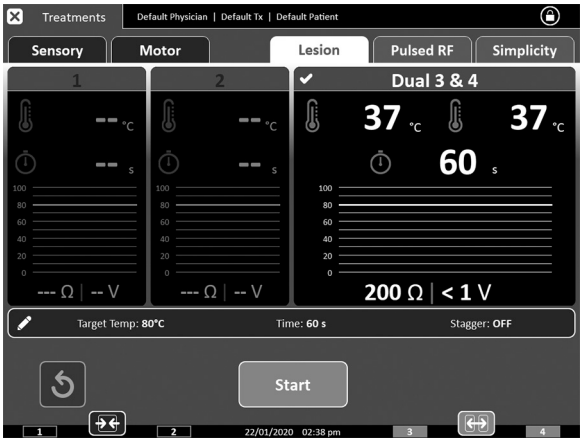
1. Exit the session and return to the Home screen
2. Electrode tip temperature
3. Elapsed time of the procedure
4. Graph of lesion temperature over time
5. Voltage and impedance values
6. Edit programmed settings
7. Start a new therapy cycle
8. Electrode panel corresponding to each electrode inserted in the electrode ports
9. Programmed therapy settings
10. Start the lesion treatment cycle; during treatment, pause and resume the cycle
11. Merge or separate channels

5. If you want to adjust the selected therapy settings, tap to open the Edit Lesion Settings dialog box.
   - Tap + to increase a setting. Tap – to decrease a setting.
   - Tap and hold + to rapidly increase a setting. Tap and hold – to rapidly decrease a setting.
   - To save your changes to the therapy program associated with the selected physician, tap to select the check box beside "Update my saved therapy with these settings."
   - To save your changes and return to the Lesion treatment screen, tap **Save**. Otherwise, tap **Cancel** to close this dialog box and return to the Lesion treatment screen without saving your changes.

Figure 31. Lesion treatment screens



Four simultaneous monopolar lesions



One bipolar lesion

6. If multiple electrodes are inserted, you can tap the electrode panel to deactivate the electrode before starting the treatment cycle.

7. If performing bipolar lesioning, tap to merge the channels for two of the inserted electrodes. The merge icon turns green and the channels merge to show combined values for the new bipolar configuration.

   NOTE: The generator shows individual temperature values at each electrode tip since this value can be different during a procedure. The generator controls the higher of the two temperatures during a session.

8. Tap **Start**. The timer starts when the electrode is within 5°C of the target temperature, and the generator emits a tone while delivering therapy.

   NOTE: If you have an emergency during a procedure, such as the touchscreen or sensory/motor intensity dial not responding, press the Emergency Stop button on top of the generator.

   - When the Emergency Stop button is engaged, the generator emits a tone and therapy output stops.
   - When you are ready to use the generator again, press the Emergency Stop button to disengage it. You will be unable to resume the previous cycle.

   NOTE: To stop RF output without resetting the elapsed lesion time, tap **Pause**. To resume lesioning for the remaining programmed time, tap **Resume**, or tap to start a new cycle.

9. Once the time elapses, RF output stops automatically, the generator emits a tone, and the Therapy Finished message appears. Tap the screen to clear the message.

10. Upon completion of the procedure, start another cycle or tap to exit the current session and return to the Home screen.

    NOTE: Upon completion of a procedure, you can view and export the therapy record from the session, which is accessible from the Patient Library screen. See “Viewing Treatment History and Patient Therapy Records” (page 17) and “Exporting Patient Data" (page 18).

Using Pulsed RF Mode

To use pulsed RF mode, follow these steps:

1. Set up the desired electrodes. See “Placing the Cannula or Simplicity™ Probe" (page 21) and "Connecting the Electrodes" (page 21).

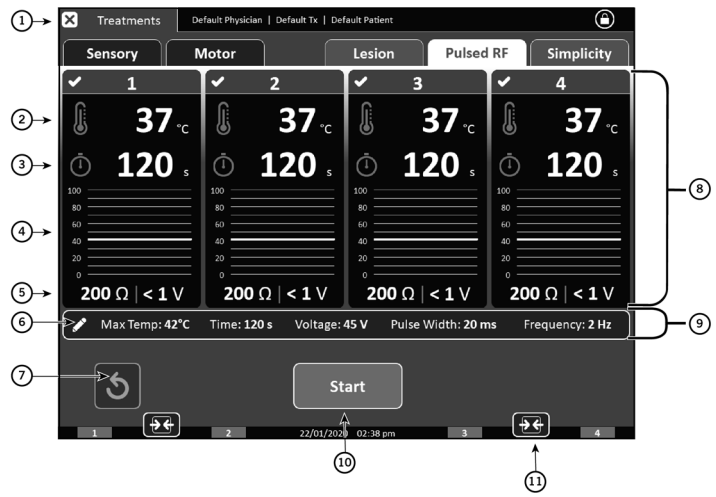
2. If performing a monopolar procedure, set up the grounding pad. See “Applying the Grounding Pad” (page 20).

3. Verify that the desired physician and/or patient has been selected in the appropriate library. See “Selecting a Physician (Optional)” (page 22) and “Selecting a Patient (Optional)” (page 22). Otherwise, the default settings will be used.

   NOTE: The grounding pad orientation screen will appear and must be acknowledged before you can perform therapy. To acknowledge that the grounding pad has been placed correctly on the patient, tap **Confirm**. Otherwise, tap **Cancel** to return to the previous screen. See “Applying the Grounding Pad” (page 20).

4. On the Treatments screen, tap the Pulsed RF tab to show the Pulsed RF treatment screen.

Figure 32. Features of the Pulsed RF treatment screen

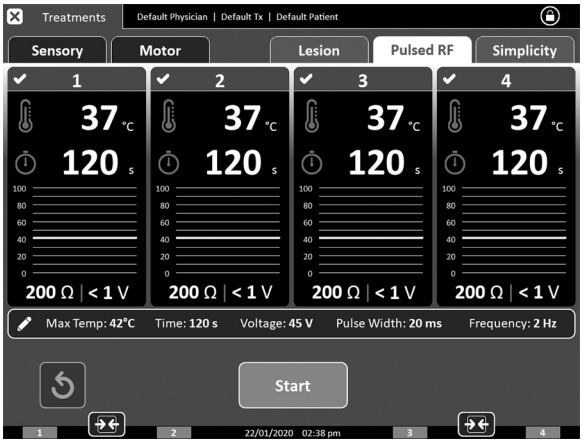


1. Exit the session and return to the Home screen
2. Electrode tip temperature
3. Elapsed time of the procedure
4. Graph of lesion temperature over time
5. Voltage and impedance values
6. Edit programmed settings
7. Reset the therapy settings to the programmed values
8. Electrode panel corresponding to each electrode inserted in the electrode ports
9. Programmed therapy settings
10. Start the pulsed RF treatment cycle; during treatment, pause and resume the cycle
11. Merge or separate channels

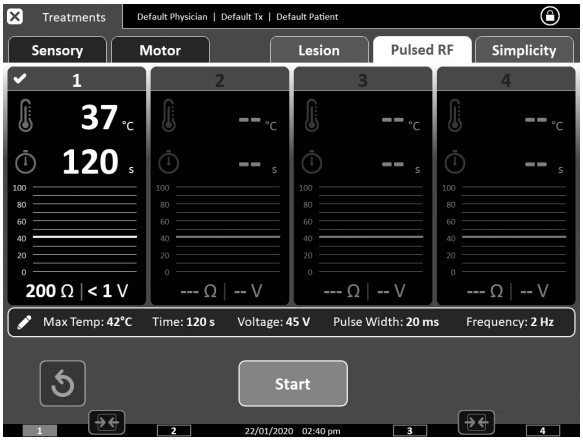
5. If you want to edit the selected therapy settings, tap . The Edit Pulsed Settings dialog box appears.
   - Ensure that the Pulsed RF radio button is selected.
   - Tap + to increase a setting. Tap – to decrease a setting.
   - Tap and hold + to rapidly increase a setting. Tap and hold – to rapidly decrease a setting.
   - To save your changes to the therapy program associated with the physician record, tap to select the check box beside "Update my saved therapy with these settings."
   - To save your changes and return to the Pulsed RF treatment screen, tap **Save**. Otherwise, tap **Cancel** to close this dialog box and return to the Pulsed RF treatment screen without saving your changes.
6. If multiple electrodes are inserted, you can tap the electrode panel to deactivate the electrode before starting the treatment cycle.
7. If performing bipolar pulsed RF, tap to merge the channels for two of the inserted electrodes. The merge icon turns green and the columns merge to show combined values for the new bipolar configuration.

   NOTE: The generator shows individual electrode temperature values since this value can be different during a procedure. The generator controls the higher of the two temperatures during a session.

Figure 33. Monopolar Pulsed RF treatment screens



Four simultaneous monopolar electrodes



Single electrode

8. Tap **Start**. The voltage ramps up, the timer starts, and the generator emits a tone while delivering therapy. When the electrode reaches the maximum temperature setting, the generator stops outputting pulses until the electrode cools.

   NOTE: If you have an emergency during a procedure, such as the touchscreen or sensory/motor intensity dial not responding, press the Emergency Stop button on top of the generator.

   - When the Emergency Stop button is engaged, the generator emits a tone, and therapy output stops.
   - When you are ready to use the generator again, press the Emergency Stop button to disengage it. You will be unable to resume the previous cycle.

   NOTE: To stop RF output without resetting the elapsed lesion time, tap **Pause**. To resume lesioning for the remaining programmed time, tap **Resume**, or tap to start a new cycle.

9. Once the time elapses, RF output automatically stops, the generator emits a tone, and the Therapy Finished message appears. Tap the screen to clear the message.

10. Upon completion of the procedure, tap to exit the current session and return to the Home screen.

    NOTE: Upon completion of a procedure, you can view and export the therapy record from the session, which is accessible from the Patient Library screen. See “Viewing Treatment History and Patient Therapy Records” (page 17) and “Exporting Patient Data” (page 18).

Using Pulsed Dose Mode

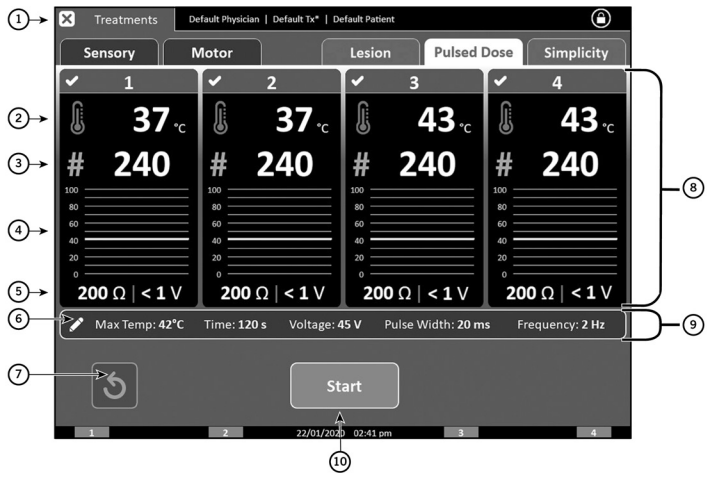
To use pulsed dose RF mode, follow these steps:

1. Set up the desired electrodes. See “Placing the Cannula or Simplicity™ Probe” (page 21) and "Connecting the Electrodes" (page 21).
2. Set up the grounding pad. See “Applying the Grounding Pad” (page 20).
3. Verify that the desired physician, therapy, and patient are selected in the appropriate library. See “Selecting a Physician (Optional)” (page 22) and “Selecting a Patient (Optional)” (page 22). Otherwise, the default settings will be used.

   NOTE: The grounding pad orientation screen will appear and must be acknowledged before you can perform therapy. To acknowledge that the grounding pad has been placed correctly on the patient, tap **Confirm**. Otherwise, tap **Cancel** to return to the previous screen. See “Applying the Grounding Pad” (page 20).

4. On the Treatments screen, tap the Pulsed Dose tab to show the Pulsed Dose treatment screen.
5. If you want to adjust the selected therapy settings, tap to open the Edit Pulsed Settings dialog box.
   - Ensure that the Pulsed Dose radio button is selected.
   - Tap + to increase a setting. Tap – to decrease a setting.
   - Tap and hold + to rapidly increase a setting. Tap and hold – to rapidly decrease a setting.
   - To save your changes to the therapy program associated with the physician, tap to select the check box beside “Update my saved therapy with these settings.”.
   - To save your changes and return to the Pulsed Dose treatment screen, tap **Save**. Otherwise, tap **Cancel** to close this dialog box and returned to the Pulsed Dose treatment screen without saving your changes.
6. If multiple electrodes are inserted, you can tap the electrode panel to deactivate the electrode before starting the treatment cycle.

Figure 34. Pulsed Dose treatment screen



1. Exit the session and return to the Home screen
2. Electrode tip temperature
3. Dose count
4. Graph of lesion temperature over time
5. Voltage and impedance values
6. Edit programmed settings
7. Reset the therapy settings to the programmed values
8. Electrode panel corresponding to each electrode inserted in the electrode ports
9. Programmed therapy settings
10. Start the pulsed RF treatment cycle; during treatment, pause and resume the cycle

7. Tap **Start**. The voltage ramps up, and the generator emits a tone while delivering therapy. When the electrode reaches the maximum temperature setting, the generator stops outputting pulses until the electrode cools.

   NOTE: If you have an emergency during a procedure, such as the touchscreen or sensory/motor intensity dial not responding, press the Emergency Stop button on top of the generator.

   - When the Emergency Stop button is engaged, the generator emits a tone, and therapy output stops.
   - When you are ready to use the generator again, press the Emergency Stop button to disengage it. You will be unable to resume the previous cycle.

   NOTE: To stop RF output without resetting the elapsed lesion time, tap **Pause.** To resume lesioning for the remaining programmed time, tap **Resume**, or tap  to start a new cycle.

8. Once the desired dose count is delivered, the generator emits a tone, RF output automatically stops, and the Therapy Finished message appears. Tap the screen to clear the message.

9. Upon completion of the procedure, tap  to exit the current session and return to the Home screen.

   NOTE: Upon completion of a procedure, you can view and export the therapy record from the session, which is accessible from the Patient Library screen. See “Viewing Treatment History and Patient Therapy Records” (page 17) and “Exporting Patient Data” (page 18).

Performing a Simplicity™ Procedure

A Simplicity™ procedure uses a probe that contains three independent electrodes, which are activated in a predetermined sequence according to the Simplicity™ II or Simplicity™ III procedure programming algorithm. The algorithms combine both monopolar and bipolar lesioning techniques to deliver RF energy in an optimized, phased sequence as shown in the following table.

Table 1. Phased sequence of Simplicity II and III procedure algorithms

Simplicity II Procedure	Phase	Lesion Type	Electrode	Area
	1	Bipolar	1-2	Distal and medial
	2	Cooling (no RF delivery)	--	--
	3	Monopolar	1	Distal
	4	Monopolar	2	Medial
Simplicity III Procedure	**Phase**	**Lesion Type**	**Electrode**	**Area**
	1	Bipolar	1-2	Distal and medial
	2	Cooling (no RF delivery)	--	--
	3	Bipolar	2-3	Medial and proximal
	4	Monopolar	1	Distal
	5	Monopolar	2	Medial
	6	Monopolar	3	Proximal

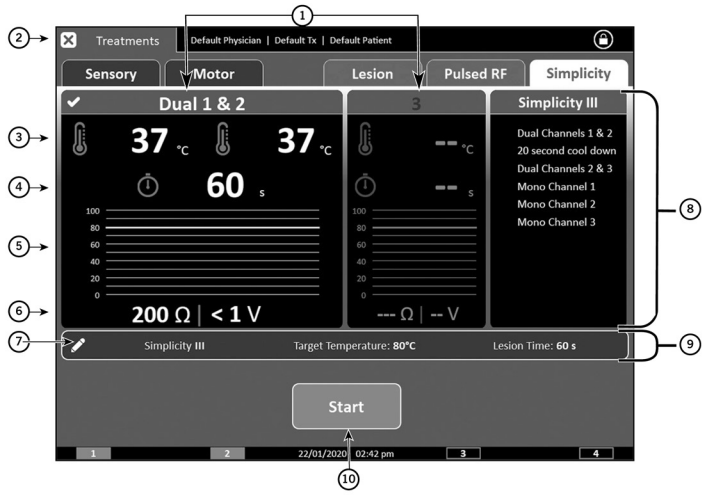
To perform RF ablation using a Simplicity procedure, follow these steps:

1. Verify the electrodes and corresponding adapters are set up correctly for the desired Simplicity II or Simplicity III procedure. See “Placing the Cannula or Simplicity™ Probe” (page 21) and "Connecting the Electrodes" (page 21).
2. Set up the grounding pad. See “Applying the Grounding Pad” (page 20).
3. Verify that the desired physician and patient are selected in the appropriate library. See “Selecting a Physician (Optional)” (page 22) and “Selecting a Patient (Optional)” (page 22). Otherwise, the default settings will be used.

   NOTE: The grounding pad orientation screen will appear and must be acknowledged before you can perform therapy. To acknowledge that the grounding pad has been placed correctly on the patient, tap **Confirm**. Otherwise, tap **Cancel** to return to the previous screen. See “Applying the Grounding Pad” (page 20).

4. On the Treatments screen, tap the Simplicity procedure tab to show the Simplicity procedure screen.

Figure 35. Features of the Simplicity procedure screen



1. Electrode panel
2. Exit the session and return to the Home screen
3. Temperature of each electrode
4. Remaining time of the current phase
5. Graph of lesion temperature over time
6. Voltage and impedance values
7. Edit settings
8. List of phases based on selected therapy
9. Programmed therapy settings
10. Start the Simplicity procedure cycle; during the procedure, stop the cycle

NOTE: Always check operational settings before each procedure.

5. If you want to edit the selected therapy settings, tap . The Edit Simplicity™ Procedure Settings dialog box appears.
   - Ensure the desired Simplicity II or III procedure mode is selected.
   - Tap + to increase a setting. Tap – to decrease a setting.
   - Tap and hold + to rapidly increase a setting. Tap and hold – to rapidly decrease a setting.
   - To save your changes to the therapy program associated with the physician, tap to select the check box beside “Update my saved therapy with these settings.
   - To save your changes and return to the Simplicity procedure screen, tap **Save**. Otherwise, tap **Cancel** to close this dialog box and return to the Simplicity procedure screen.
6. Tap **Start**. The treatment cycle starts.

   NOTE: During the treatment cycle, the active electrode indicator flashes green, indicating power is being delivered to that electrode, and the generator emits a tone while delivering therapy. Additionally, the Simplicity procedure screen shows a sequential list of the phases associated the selected therapy. The active phase is noted with , and a completed phase appears disabled and is noted with .

   NOTE: If you have an emergency during a procedure, such as the touchscreen or sensory/motor intensity dial not responding, press the Emergency Stop button on top of the generator.
   - When the Emergency Stop button is engaged, the generator emits a tone, and therapy output stops.
   - When you are ready to use the generator again, press the Emergency Stop button to disengage it. You will be unable to resume the previous session.
7. During the procedure, monitor the temperature of the grounding pad for excessive heating (e.g., due to a poor connection).
8. Once the time elapses, the generator emits a tone, RF output automatically stops, and the Therapy Finished message appears. Tap the screen to clear the message.
9. Upon completion of the procedure, tap to exit the current session and return to the Home screen.

   NOTE: Upon completion of a procedure, you can view and export the therapy record from the session, which is accessible from the Patient Library screen. See “Viewing Treatment History and Patient Therapy Records” (page 17) and “Exporting Patient Data" (page 18).

Backing Up and Restoring the Generator

This section provides information to help you back up data and settings from your generator and to restore your information from a backup file.

Backing Up the Generator

You should regularly back up all the generator files. In essence, a backup replicates the entire generator user environment, which includes device settings, user accounts and passwords, the physician and patient libraries, and log files. A backup is encrypted and can only be used to restore the generator.

To back up the generator, follow these steps:

1. Insert a USB drive into the USB port on either the side or the back of the generator.

   NOTE: Only one USB port can be used at a time.

2. On the Home screen, tap to open the Device Settings screen.
3. Tap **Back Up or Restore Data**.
4. In the Back Up or Restore Data dialog box that appears, tap **Back Up** and then tap **OK.**

   NOTE: Do not remove the USB drive until the generator says the backup is complete.

   NOTE: Backup files have the following name format: RFGen_backup_[date].backup.
5. When the Backup Is Complete message appears, tap **Dismiss**.
6. Remove the USB drive from the USB port, and store it in a safe place.

Restoring the Generator Using a Backup File

You can restore the generator user environment from the latest backup file. To restore the generator, follow these steps:

1. Insert the USB drive containing the backup file into the USB port on either the side or the back of the generator.

   NOTE: Only one USB port can be used at a time.
2. On the Home screen, tap to open the Device Settings screen.
3. Tap **Back Up or Restore Data**.
4. In the Back Up or Restore Data dialog box that opens, tap the "Restore from backup file" radio button and then tap **OK**. The Restore From Backup confirmation message appears.
5. To confirm the restoration using the file stated in the message, tap **Continue**. Otherwise, tap **Cancel** to close this dialog box and return to the Back Up or Restore Data dialog box.

   NOTE: The most recent backup file on the USB drive is used to restore the generator. If the USB drive contains more than one backup file and the file you want to use is not the most recent, move the file you want to use an empty USB drive; then use that USB drive to perform the restoration.
6. After the generator successfully restores the user environment from the backup file, remove the USB drive from the USB port.

   NOTE: Do not remove the USB drive until the operation is complete.
7. To complete the restoration, restart the generator by turning it off and then on again.

Updating Generator Software

If software updates are available for the generator, Abbott Medical will send them to you on a USB drive. After you receive a software update from Abbott Medical, follow these steps:

1. If desired, back up the generator data. See “Backing Up the Generator” (page 30).
2. Insert the USB drive containing the software update into the USB port on either the side or the back of the generator.

   NOTE: Only one USB port can be used at a time.
3. On the Home screen, tap to open the Device Settings screen.
4. Tap **Update Software**.
5. On the message that appears, tap **Update**. The generator runs the software update from the USB drive.

   CAUTION: Do not turn off the generator during the update.
6. When the Update Is Complete message appears, remove the USB drive from generator, and then restart the generator by turning it off and then on again.

   NOTE: If the update was not successful, the Unable to Upgrade message will appear. Turn the generator off and then on again to revert the software to the previous version. Then retry the update process or contact Technical Support. See "Technical Support" (page 35).

   NOTE: Software updates will not affect your generator user environment. Your saved settings and information will be preserved.
7. To verify the software was updated successfully, wait a few minutes and then open the Device Settings screen by tapping on the Home screen. The latest software versions appear on the Device Settings screen.

Resetting the Generator to Default Settings

To reset the generator to the default settings, follow these steps:

1. On the Home screen, tap . The Device Settings screen appears.
2. On the Device Settings screen, tap **Reset Device to Defaults**. The Reset to Factory Defaults? dialog box appears.

3. To reset the generator to default settings, tap **Reset**. Otherwise, tap **Cancel** to close this dialog box and return to the Device Settings screen without resetting the generator.
4. After the generator resets, turn the generator off and then on again.

   NOTE: After being reset to default settings, the generator will take approximately five minutes to restart the first time it is turned on.

Maintaining the Generator

Although the generator does not require regular maintenance, Abbott Medical recommends that you inspect the generator and power cord periodically for any physical damage. If you experience any software- or hardware-related issues, first see “Troubleshooting” (page 33) for potential solutions. If you cannot resolve the issue, contact Technical Support for assistance or to request and schedule service. See “Technical Support” (page 35).

The generator is not user serviceable. Service is to be performed only by Abbott Medical service technicians. Any attempt to open the generator enclosure or perform repair work will void the warranty.

The following subsections provide instructions for preparing the generator for service, obtaining the troubleshooting logs, and cleaning the generator and accessories.

Preparing the Generator for Service

Once you have a service date scheduled, follow these steps:

1. Insert a USB drive into the USB port on either the side or the back of the generator.

   NOTE: Only one USB port can be used at a time.
2. On the Home screen, tap  to open the Device Settings screen.
3. Back up the generator data. See "Backing Up the Generator" (page 30).
4. Reset the generator to the factory default to remove all patient information. See “Resetting the Generator to Default Settings” (page 31).
5. Disconnect all cables and USB drives from the generator.
6. If you have a service plan with Abbott Medical and receive a loaner (temporary) generator from Abbott Medical, use the packaging from the loaner generator to pack your generator.

   -OR-

   If you do not have a service plan, carefully pack your generator in a suitable shipping carton.
7. Ship your packaged generator to the return address provided by Technical Support.

Exporting Troubleshooting Logs

Each time you turn on the generator, it runs a series of self-diagnostic tests to verify that the generator firmware and hardware are operating according to specifications. The generator saves the test results in a log file. If Technical Support asks you to obtain the troubleshooting logs from the generator, follow these steps:

1. Insert a USB drive into the USB port on either the side or back of the generator.

   NOTE: Only one USB port can be used at a time.
2. On the Home screen, tap  . The Device Settings screen appears.
3. On the Device Settings screen, tap **Export Logs**. The Export Logs? dialog box appears.
4. To export the logs, tap **Export**. Otherwise, tap Cancel to return to the Device Settings screen.

Cleaning the Generator

As needed, clean the outer surfaces of the generator gently with a dry cloth. If disinfection is required, use any of the following to clean the outer surfaces:

- A cotton cloth soaked with 99% isopropyl alcohol
- Sani-Cloth‡ AF3 Germicidal Disposable Wipes

Cleaning the Generator Accessories

For recommended cleaning instructions for the generator accessories, such as the reusable accessories, electrodes, and optional pole mount, refer to the instructions for use for the applicable product.

Reinstalling the Countertop Stand

To reinstall the countertop stand that came with the generator, follow these steps:

1. Ensure that no cables are connected to the generator.

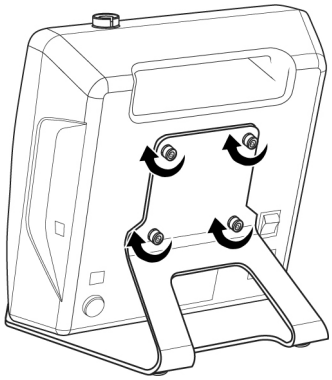
   NOTE: To minimize movement of the generator, always support the generator when connecting or disconnecting any power cords or cables.

2. Place the generator on a stable base, such as a table or counter.

   NOTE: Always place the generator on a level surface when adding or removing the countertop stand.

3. Align the screw holes on the countertop stand with the screw holes on the back of the generator.
4. Place the four captive thumb screws in the screw holes.
5. Using your fingers, tighten each of the four captive thumb screws until the countertop stand is fully secured.

Figure 36. Reinstalling the countertop stand



Disposing of the System

The generator system consists of the generator and its accessories. The generator contains a nonrechargeable CR2032 coin cell battery. When disposing of the generator system, consider these guidelines:

- Dispose of the electrodes and grounding pads using a sharps disposal container or other local biohazard protocol.
- Perform a factory reset of the generator to remove all patient information from device before disposing of it.
- Dispose of the generator according to state and federal laws for disposing of electronic equipment.
- Recycle this clinician manual and any other recyclable paper items.
- Dispose of all other packaging materials as appropriate. Consult local agencies for recycling and disposal options.

Troubleshooting

The following tables show issues you may encounter while using the generator. The first table shows error and warning messages that may appear on the generator screen. The second table shows other issues that may arise. Follow the guidelines under “Possible Solution” to troubleshoot the issue. If the guidelines do not resolve the issue, contact Technical Support for more help. See “Technical Support” (page 35).

Table 2. Error and warning messages

Message	Possible Cause	Possible Solution
High Impedance on Channel [X]	The electrode is not connected properly.	Verify that the electrode is connected to the generator and fully inserted into a cannula.
	The grounding pad is not connected properly.	Verify that the grounding pad is connected to the generator and is fully adhered to the patient.
Low Impedance on Channel [X]	The electrode is not connected properly.	Check the electrode connection.
	The electrodes are touching.	Ensure the electrodes are not touching.
Over Temperature on Channel [X]	The electrode is too warm.	Check the electrode for signs of damage. If damaged, replace the electrode.
		Check the electrode placement location.
		Wait for the electrode to cool before continuing.
Temperature of Channel [X] Is Rising Too Slowly	The electrode is not placed properly.	Check if the electrode is in contact with blood, fluid, or bone.
		Readjust the electrode as needed.
	The grounding pad is not connected properly.	Verify that the electrode is connected to the generator and fully inserted into a cannula.
Target Temperature on Channel [X] Has Not Been Reached	The electrode is not placed properly.	Check if the electrode is in contact with blood, fluid, or bone.

Table 2. Error and warning messages

Message	Possible Cause	Possible Solution
	The electrode is not connected to the generator.	Ensure that all electrode(s) connections are securely connected to their respective electrode port(s).
	The electrode and cannula lengths are mismatched.	Ensure that the electrode and cannulae are the same length.
	The electrode port is damaged.	If available, try using electrode(s) on a different electrode port on the generator.
	The generator is unable to heat multiple cannulae simultaneously or large cannulae (for Lesion mode or a Simplicity™ procedure).	If the procedure is a multiple-electrode procedure, try to perform the procedure using Stagger mode.
	The electrode is damaged.	If the procedure is a multiple electrode procedure, perform the procedure one electrode at a time.
Therapy Was Not Delivered on Channel(s) [x,x,x]	The generator is unable to heat one or more cannula(e) in a multiple electrode procedure.	To retry therapy for the remaining electrodes that did not reach target temperature, tap **Retry.** Otherwise, tap **End Therapy** to end therapy.
	The generator is unable to deliver therapy for Pulsed RF or Pulsed Dose mode.	Lower voltage or pulse width to continue therapy.
	The generator is unable to reach target voltage for configured Pulsed RF or Pulsed Dose therapy.	To retry therapy for the remaining electrodes that did not reach target voltage, tap **Retry**. Otherwise, tap **End Therapy** to end therapy.
Target Voltage on Channel [X] Has Not Been Reached	The electrode is not placed properly.	Check if the electrode is in contact with blood, fluid, or bone.
		Readjust the electrode as needed.
		Verify that the electrode is connected to the generator and fully inserted into a cannula.
Grounding Pad Detached	The grounding pad is not connected properly.	Check the grounding pad connection with the generator, and ensure the pad is adhered fully to the patient's skin.
Output has been stopped until the generator warms up.	The generator is outside of the operating temperature range.	Wait for the generator to warm up and then restart the procedure if desired.
Output has been stopped until the generator cools down.	The generator is outside of the operating temperature range	Wait for the generator to cool and then restart the procedure if desired.
Database Could Not Be Read	A problem has occurred with data storage.	Restart the device by toggling the power switch off and then on.
		Create a new database. NOTE: All saved patient, procedure, and physician data will be lost.
Database Could Not Be Created	The hard drive is full, or a problem occurred during attempted transmission, processing, or storage of the data.	Restart the device by toggling the power switch off and then on.
		Create a new database. NOTE: All saved patient, procedure, and physician data will be lost.
Problem with Disk Drive	The central processing unit (CPU) is busy or a problem exists with the disk drive.	Restart the device by toggling the power switch off and then on.
Procedure Data Cannot Be Saved Because the Disk Drive Is Full	The disk drive is full.	To continue the session without logging, tap **Continue**.
		To continue the session with logging, tap **Cancel**, access the patient library to export and delete old records, and start a new session.
System Problem Found	A system problem exists.	Restart the device by toggling the power switch off and then on.
USB Device Not Found	The generator does not recognize that a USB drive has been inserted.	Leave the USB drive inserted, wait 30 seconds, and then try again.

Table 3. Possible issues

Issue	Possible Cause	Possible Solution
The electrode or adapter cable stops working.	The electrode cable is disconnected from the electrode port on the generator.	Connect the electrode cable to the electrode port on the front of the generator.
	The electrode cable is disconnected from the electrode adapter.	Connect the electrode cable to the electrode adapter.
	The electrode adapter is disconnected from the electrode port on the generator.	Ensure that the electrode adapter is connected to the electrode port on the front of the generator and to the electrode cable.
	The electrode port is malfunctioning.	Connect the electrode cable or adapter to a different electrode port on the front of the generator and try again.
	Multiple electrode ports are malfunctioning.	Contact Technical Support.
	The electrode is damaged.	Replace the electrode with a new one.
	The adapter cable is damaged.	Replace the adapter cable with a new one.
The patient does not respond to sensory/motor stimulation.	The electrode cable or adapter is not connected securely to the electrode port on the front of the generator.	Ensure that each electrode is securely connected to its respective electrode port on the front of the generator.
	The electrode port is damaged.	If available, try using the electrode(s) on a different electrode port.
	The electrode is damaged.	If you are unable to get the electrode(s) working on any port, try using another electrode or electrodes.
The patient complains about heating at the site of the grounding pad.	The grounding pad is not connected properly.	Ensure that the grounding pad connection is securely connected to the grounding pad port on the front panel of the generator.
	The grounding pad is not oriented properly.	Ensure that the grounding pad is fully adhered, with the wide edge oriented towards the electrodes.
	The grounding pad is not placed properly.	Ensure that the grounding pad is placed in a well-vascularized muscular site near the procedure.
		Ensure that the grounding pad is NOT placed over scars, bony prominences, prosthesis, hair, or EKG electrodes and is NOT placed in a location where fluids may pool.
The generator is disabled.	The Emergency Stop button is engaged.	Press the Emergency Stop button on top of the generator to disengage it and to resume generator function.
	The generator is disabled from use because it did not pass one or more of the diagnostic checks during its self-diagnostic test when turned on.	Turn the generator off and then on again.
		If the generator does not function after turning it off and on again, contact Technical Support.
The touchscreen is unresponsive.	The touchscreen was touched while the generator was calibrating during start up.	Turn the generator off and then on again without touching the touchscreen.
A problem is found during the self-diagnostic test.	A possible hardware issue was detected at start up.	Restart the device by toggling the power switch off and then on.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Warranty Information

See product packaging and relevant commercial agreements for specific warranty information.

Appendix A: Technical Specifications

Table 4. Physical characteristics

Input/output	Ports for electrode (4)
	Port for grounding pad (1)
	USB ports (2)
	Equipotential port (1)
LCD size	30.5 cm (12 in)
Power cord	Medical grade power cord; country specific
Cord type	60227 IEC53 (H05VV-F), 3 core, gauge 1.00 mm^2
Total length	2500 mm ± 50 mm
Maximum voltage	250 V
Maximum current	10 A
Dimensions	
Generator only	35.0 cm H x 32.8 cm W x 15.6 cm D (13.8 in H x 12.9 in W x 6.1 in D)
Generator with countertop stand	35.3 cm H x 32.8 cm W x 28.6 cm D (13.9 in H x 12.9 in W x 11.3 in D)
Liquid crystal display (LCD)	30.7 cm (12.1 in)
Weight	
Generator with countertop stand	7.3 kg (16.0 lb)
Expected service life	5 years
Operating modes	Stimulation: Sensory, Motor
	Ablation: Lesion, Pulsed RF, Pulsed Dose, Simplicity™ II or III procedure

Table 5. Environmental specifications

Transportation and storage	Extreme Cold: -30°C (-22ºF); uncontrolled relative humidity
	Desert: 60°C (140ºF); 15% relative humidity
	Tropical: 40°C (104ºF); 90% relative humidity
	Relative humidity: 20%-90%, non-condensing
	Altitude: up to 6096 m (up to 20000 ft)
Operating	Temperature: 10°-35ºC (50º-95ºF)
	Relative humidity: 20%-90% (non-condensing)
	Altitude: up to 3000 m (up to 9843 ft)

Table 6. Power specifications

Voltage input	Europe: 230-240 VAC; 50 Hz; Fused 2.5 amp on live and neutral
	USA/Canada: 120 VAC; 50 Hz/60 Hz; Fused 2.5 amp on live and neutral
	Japan: 100 VAC; 50/60 Hz
Fuse	2.5 amp on live and neutral; slow blow
Fuse rating	2.5 A, 250 VAC, 5x20 mm, 1.4
Input power rating	240 VA
Safety class	Class I. Type BF according to IEC 60601-1. The electrodes and grounding pad are the applied parts connected to the generator.
Maximum total power output	50 W Maximum total power output (the sum of all the RF power entering the patient from all active electrodes) is hardware- and software-limited to 50 W total. This power is distributed as necessary to raise the electrodes to the desired set temperature. Depending on physiological conditions, different electrodes can have different power delivered to them.
Maximum total current output	700 mA
Measuring frequency	460 kHz ± 3%
Impedance	Stimulation: 50-1500 Ω
	Ablation: 47-1500 Ω (prior to RF output) and 31-1500 Ω (during RF output)
Generator temperature accuracy	±2°C
System temperature accuracy	±7°C

Table 7. Sensory stimulation

Electrode	Up to 4 (only one can be active at a time); monopolar
Maximum voltage	0.5-5 V (default 3 V)
Frequency	10, 20, 50, 75, 100, 150, 180, 200 Hz (default 50 Hz)
Pulse width	0.1, 0.2, 0.5, and 1 ms (default 1 ms)
Voltage step size	0.01, 0.10 (default 0.1)
Output voltage and accuracy	0-5 V; ± 5% for voltage ≥1V and ± 50 mV for voltage <1V
Output frequency and accuracy	10-200 Hz ± 3 %
Output pulse width and accuracy	0.10-1 ms ± 15% for impedance >100 Ω and ± 25% for impedance ≤100 Ω

Table 8. Motor stimulation

Electrode	Up to 4 (only one can be active at a time); monopolar
Maximum voltage	0.5-5 V (default 3 V)
Frequency	2 or 5 Hz (default 2 Hz)
Pulse width	0.1, 0.2, 0.5, and 1 ms (default 1 ms)
Voltage step size	0.01, 0.10 (default 0.1)
Output voltage and accuracy	0-5 V; ± 5% for voltage ≥1V and ± 50 mV for voltage <1V
Output frequency and accuracy	2-5 Hz ± 3 %
Output pulse width and accuracy	0.10-1 ms ± 15% for impedance >100 Ω and ± 25% for impedance ≤100 Ω

Table 9. Lesion mode

Electrode	Up to 4; monopolar and bipolar
RF waveform	Sinusoidal
Target temperature	50°-90°C (default 80°C)
Lesion/dwell time (time)	1-600 seconds (default 60 seconds)
Stagger	Off, On: 0-10 seconds (default Off)
Output voltage and accuracy	0-141 V_{RMS} ± 5%

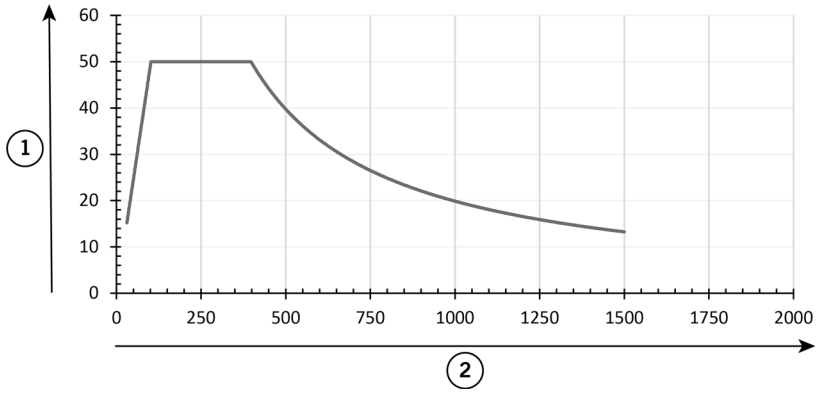
Table 10. Pulsed RF mode

Electrode	Up to 4; monopolar and/or bipolar
RF waveform	Sinusoidal
Maximum temperature	42°-49°C (default 42°C)
Target voltage	30 -75 V_{RMS} (default 45 V_{RMS})
Lesion time (time)	1-1800 seconds (default 120 seconds)
Pulse width	5, 8, 20, or 50 ms (default 20 ms)
Frequency	1, 2, 5, or 10 Hz (default 2 Hz)
Output voltage and accuracy	30 -75 V ± 15%
Maximum output voltage peak value	≤230 Vpk
Output frequency and accuracy	1, 2, 5, 10 Hz ± 5%
Output pulse width and accuracy	5, 8, 20, or 50 ms ± 5%

Table 11. Pulsed Dose mode

Electrode	Up to 4; monopolar
RF waveform	Sinusoidal
Maximum temperature	42°-49°C (default 42°C)
Target voltage	30-75 V_{RMS} (default 45 V_{RMS})
Dose count (doses)	120-960 (default 240)
Pulse width	5, 8, 20, or 50 ms (default 20 ms)
Frequency	1, 2, 5, or 10 Hz (default 2 Hz)
Output voltage and accuracy	30-75 V ± 15%
Maximum output voltage peak value	≤230 Vpk
Output frequency and accuracy	1, 2, 5, 10 Hz ± 5%
Output pulse width and accuracy	5, 8, 20, or 50 ms ± 5%

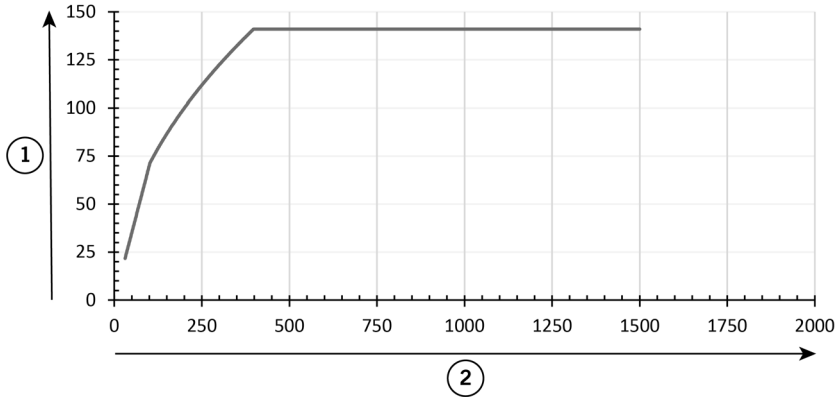
Figure 37. Power output—Lesion mode



Output Power vs. Load Impedance Monopolar and Bipolar Lesion Mode

1. RMS power (W)
2. Impedance (Ω)

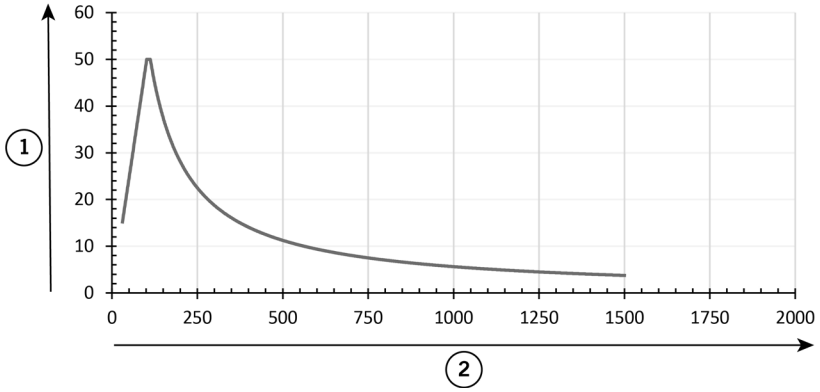
Figure 38. Voltage output—Lesion mode



Output Voltage vs. Load Impedance Monopolar and Bipolar Lesion Mode

1. RMS voltage (V)
2. Impedance (Ω)

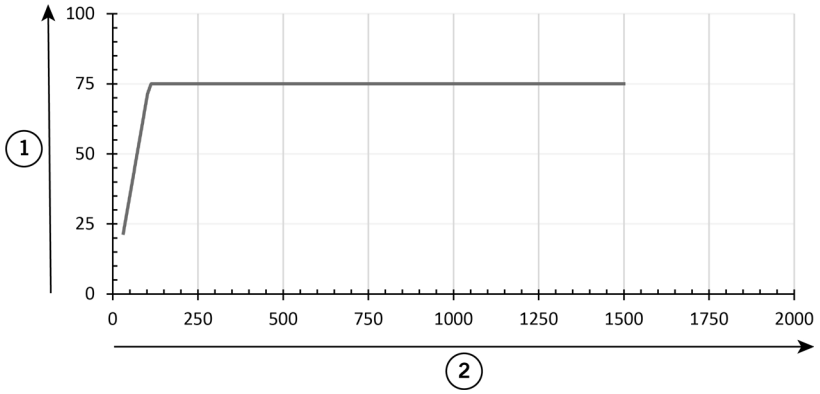
Figure 39. Power output—Pulsed RF and Pulsed Dose modes



Instantaneous Output Power vs. Load Impedance Pulsed RF Mode

1. RMS power (W)
2. Impedance (Ω)

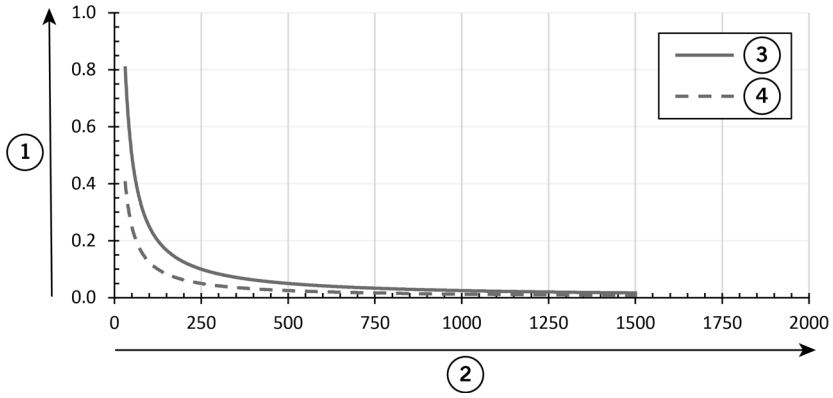
Figure 40. Voltage output—Pulsed RF and Pulsed Dose modes



Instantaneous Output Voltage vs. Load Impedance Pulsed RF Mode

1. RMS voltage (V)
2. Impedance (Ω)

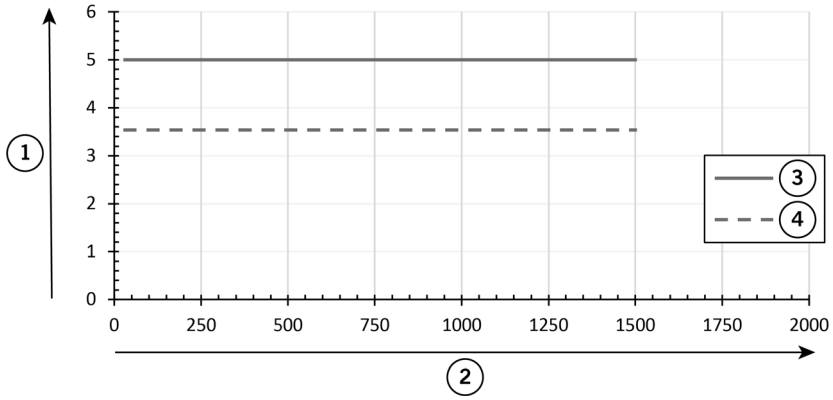
Figure 41. Power output—Stimulation mode



Instantaneous Output Power vs. Load Impedance Sensory and Motor Stimulation Mode

1. RMS power (W)
2. Impedance (Ω)
3. Full power
4. Half power

Figure 42. Voltage output—Stimulation mode



Instantaneous Output Voltage vs. Load Impedance Sensory and Motor Stimulation Mode

1. RMS voltage (V)
2. Impedance (Ω)
3. Full power
4. Half power

Table 12. Ground Leakage

		Normal	Maximum Allowable
1	Enclosure leakage current		
	Normal	45.0 microamps	5000 microamps
	Reverse	44.6 microamps	5000 microamps
	Single fault condition		
	Normal	205.0 microamps	10000 microamps
	Reverse	205.0 microamps	10000 microamps
2	Patient leakage current		
	Normal (AC)	0.2 microamps	100 microamps
	Reverse (AC)	0.2 microamps	100 microamps
	Single fault condition		
	Normal (AC)	2.1 microamps	500 microamps
	Reverse (AC)	2.2 microamps	500 microamps
	Patient leakage current		
3	Normal (DC)	0.0 microamps	10 microamps
	Reverse (DC)	0.0 microamps	10 microamps
	Single fault condition		
	Normal (DC)	0.0 microamps	50 microamps
	Reverse (DC)	0.0 microamps	50 microamps
4	Patient auxiliary current		
	Normal (AC)	0.2 microamps	100 microamps
	Reverse (AC)	0.2 microamps	100 microamps
	Single fault condition		
	Normal (AC)	0.3 microamps	500 microamps
	Reverse (AC)	0.3 microamps	500 microamps
5	Patient auxiliary current		
	Normal (DC)	0.0 microamps	10 microamps
	Reverse (DC)	0.0 microamps	10 microamps
	Single fault condition		
	Normal (DC)	0.0 microamps	50 microamps
	Reverse (DC)	0.0 microamps	50 microamps
6	Patient leakage current with mains of the F-type applied parts (PM)		
	Normal (AC)	10.9 microamps	5000 microamps
	Reverse (AC)	10.9 microamps	5000 microamps
	Single fault condition		
	Normal (AC)	7.3 microamps	5000 microamps
	Reverse (AC)	7.3 microamps	5000 microamps
7	Patient leakage current with mains on the F-type applied parts (PM)		
	Normal (DC)	0.0 microamps	5000 microamps
	Reverse (DC)	0.0 microamps	5000 microamps
	Single fault condition		
	Normal (DC)	0.0 microamps	5000 microamps
	Reverse (DC)	0.0 microamps	5000 microamps

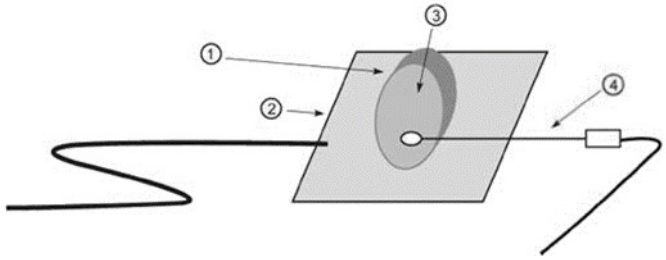
Appendix B: Lesion Size Tables

This section provides physicians a guide on appropriate use conditions by presenting a wide range of expected lesion dimensions from a range of configurations. The testing was done for various common configurations of cannula lengths, cannula tip exposures, target temperature, dwell times, and operational modes in a non-perfused chicken breast at room temperature (20°C +/- 3°C). Ten lesions were measured and the mean dimensions are reported with the standard deviation (SD) in parenthesis. The basic setup is illustrated below, and the results for bipolar, monopolar, and Simplicity™ III procedure lesion testing are provided in the following tables.

NOTE: Lesion measurements reflect the area of tissue raised above 60°C.

WARNING: These results are for reference only. Actual lesion volumes created in human patients will depend on many factors such as tissue resistivity, proximity to bone, and proximity to vascular structures.

Figure 43. Lesion testing setup



1. Chicken breast
2. Grounding pad
3. Lesion
4. Cannula/electrode

Table 13. Bipolar lesions (interelectrode distance = 5 mm)

Cannula Size	Temperature (°C)	Time (s)	Lesion Height (mm) Average (SD)	Lesion Width (mm) Average (SD)
18 gauge, 10 mm tip	80	180	12.5 (0.3)	11.9 (0.2)
20 gauge, 5 mm tip	80	180	7.4 (0.5)	10.4 (0.5)
22 gauge, 10 mm tip	90	240	13.3 (0.4)	12.5 (0.6)

Table 14. Monopolar lesions

Cannula Size	Temperature (°C)	Time (s)	Lesion Height (mm) Average (SD)	Lesion Width (mm) Average (SD)
16 gauge, 10 mm tip	90	90	14.0 (0.4)	8.4 (0.5)
20 gauge, 10 mm tip	80	60	11.0 (0.4)	4.9 (0.4)
22 gauge, 5 mm tip	80	60	6.4 (0.3)	3.8 (0.2)
22 gauge, 2 mm tip	70	60	3.2 (0.3)	2.1 (0.3)

Table 15. Simplicity™ III procedure lesion

Electrode	Temperature (°C)	Time (s)	Lesion Height (mm) Average (SD)	Lesion Width (mm) Average (SD)
RFDE-SI	80	60	71.5 (0.9)	11.4 (0.8)

Appendix C: System Components and Accessories

The following table describes the generator and compatible accessories. For detailed information about an accessory, refer to the instructions for use for the applicable product.

NOTE: Not all models are available in all countries. Contact your local representative for more information.

WARNING: Do not use accessories that are not listed below or competitive accessories as this could compromise safety and will void the warranty.

Table 16. IonicRF™ Generator accessories model list

Component Type	Model Number	Description
Generator	RFG-IONIC	IonicRF™ Generator
Power cords	RF-EPC-NA	External Power Cord, North America
	RF-EPC-EU	External Power Cord, EU
	RF-EPC-UK	External Power Cord, UK
	RF-EPC-AUS	External Power Cord, Australia
	RF-EPC-B	External Power Cord, Brazil
	RF-EPC-I	External Power Adapter, Israel
Pole mount	RF-POLE	IonicRF™ Generator Pole Mount
	RD-0856	Roll Stand
Grounding pad	GPD202D-AC	Cathay Manufacturing Corp. disposable neutral electrode
Adapter cables	AC-SI-III	Adapter cable-Simplicity™ III
	DAC-NT	Adapter cable-NT generator to NT disposable electrode, US
	DACUK-NT	Adapter cable-NT generator to NT disposable electrode, UK
Electrodes, reusable	RF-NE-5	Reusable nitinol RF electrode
	RF-NE-10	Reusable nitinol RF electrode
	RF-NE-15	Reusable nitinol RF electrode
	RF-NE-20	Reusable nitinol RF electrode
	RF-NE-5-CE	Reusable nitinol RF electrode
	RF-NE-10-CE	Reusable nitinol RF electrode
	RF-NE-15-CE	Reusable nitinol RF electrode
	RF-NE-20-CE	Reusable nitinol RF electrode
	RF-SE-5	Reusable stainless steel RF electrode
	RF-SE-10	Reusable stainless steel RF electrode
	RF-SE-15	Reusable stainless steel RF electrode
	RF-SE-20	Reusable stainless steel RF electrode
	RF-SE-5-CE	Reusable stainless steel RF electrode
	RF-SE-10-CE	Reusable stainless steel RF electrode
	RF-SE-15-CE	Reusable stainless steel RF electrode
	RF-SE-20-CE	Reusable stainless steel RF electrode
Electrodes, disposable	RFDE-5	RF disposable electrode, 5 cm, US
	RFDE-10	RF disposable electrode, 10 cm, US
	RFDE-15	RF disposable electrode, 15 cm, US
	RFDE-20	RF disposable electrode, 20 cm, US
	RFDE-SI	Simplicity™ III Disposable Radiofrequency Electrode
	RFDEUK-5	RF disposable electrode, 5 cm, UK
	RFDEUK-10	RF disposable electrode, 10 cm, UK
	RFDEUK-15	RF disposable electrode, 15 cm, UK
	RFDEUK-20	RF disposable electrode, 20 cm, UK
Cannulae	SL-C1010-20	Curved 10 cm length, 10 mm active tip, 20 G
	SL-C1010-18	Curved 10 cm length, 10 mm active tip, 18 G
	SL-C1005-20	Curved 10 cm length, 5 mm active tip, 20 G
	SL-C1005-22	Curved 10 cm length, 5 mm active tip, 22 G
	SL-C1510-18	Curved 15 cm length, 10 mm active tip, 18 G
	SL-C1510-20	Curved 15 cm length, 10 mm active tip, 20 G
	SL-C505-22	Curved 15 cm length, 10 mm active tip, 20 G
	SL-S1005-22	Straight 10 cm length, 5 mm active tip, 22 G

Table 16. IonicRF™ Generator accessories model list

Component Type	Model Number	Description
	SL-S1010-20	Straight 10 cm length, 10 mm active tip, 20 G
	SL-S1505-20	Straight 15 cm length, 5 mm active tip, 20 G
	SL-S1510-20	Straight 15 cm length, 10 mm active tip, 20 G
	SL-C1010-20-R	Curved 10.3 cm length, 10 mm active tip
	SL-C1010-22	Curved 10 cm length, 10 mm active tip, 22 G
	SL-S1005-20	Straight 10 cm length, 5 mm active tip, 20 G
	SL-S1010-22	Straight 10 cm length, 10 mm active tip, 22 G
	SL-S505-22	Straight 5 cm length, 5 mm active tip, 22 G
	C-1005-S-20	Curved 10 cm length, 5 mm tip, 20 G
	C-1010-R	Curved 10 cm length, 10 mm tip, 22 G
	C-1010-R-18	Curved 10 cm length, 10 mm tip, 18 G
	C-1010-R-20	Curved 10 cm length,10 mm tip, 20 G
	C-1010-S	Curved 10 cm length, 10 mm tip, 22 G
	C-1010-S-18	Curved 10 cm length, 10 mm tip, 18 G
	C-510-20	Curved 5.4 cm length, 10 mm tip, 20 G
	S-1005	Straight 10 cm length, 5 mm tip, 22 G
	C-1510-S-18	Curved 14.5 cm length, 10 mm tip, 18 G
	C-510	Curved 5.4 cm length, 10 mm tip, 22 G
	S-1510	Straight 14.5 cm length, 10 mm tip, 20 G
	C-1015-S-20	Curved 10 cm length, 15 mm tip, 20 G
	C-1505-S	Curved 14.5 cm length, 5 mm tip, 20 G
	C-1510-S	Curved 14.5 cm length, 10 mm tip, 20 G
	C-1510-R-22	Curved 14.5 cm length, 10 mm tip, 22 G
	C-1510-R	Curved 14.5 cm length, 10 mm tip, 20 G
	C-505	Curved 5.4 cm length, 5 mm tip, 22 G
	C-1515-S	Curved 15 cm length, 15 mm tip, 20 G SMK
	C-505-20	Curved 5.4 cm length, 5 mm tip, 20 G
	C-1010-16	Curved 10 cm length, 10 mm tip, 16G
	C-1010-S-20	Curved 10 cm length, 10 mm tip, 20 G
	S-1005-20	Straight 10 cm length, 5 mm tip, 20 G
	S-1010	Straight 10 cm length, 10 mm tip, 22 G
	S-1010-18	Straight 10 cm length, 10 mm tip, 18 G
	S-1010-20	Straight 10 cm length, 10 mm tip, 20 G
	S-1505	Straight 14.5 cm length, 5 mm tip, 20 G
	S-2010	Straight 20 cm length, 10 mm tip, 20 G
	S-505	Straight 5.4 cm length, 4.5 mm tip, 22 G
	S-510	Straight 5.4 cm length, 10 mm tip, 22 G
	C-1510-16	Curved 15 cm length, 10 mm tip, 16G
	C-1005-S	Curved 10 cm length, 5 mm tip, 22 G
	SMK-C1005-22	Curved 10 cm length, 5 mm tip, 22 G
	SMK-C1010-18	Curved 10 cm length, 10 mm tip, 18 G
	SMK-C1010-20	Curved 10 cm length, 10 mm tip, 20 G
	SMK-C1010-22	Curved 10 cm length, 10 mm tip, 22 G
	SMK-C1510-20	Curved 15 cm length, 10 mm tip, 20 G
	SMK-S1002-22	Straight 10 cm length, 2 mm tip, 22 G
	SMK-S1005-20	Straight 10 cm length, 5 mm tip, 20 G
	SMK-S1010-20	Straight 10 cm length, 10 mm tip, 20 G
	SMK-S1010-22	Straight 10 cm length, 10 mm tip, 22 G
	SMK-S1510-20	Straight 15 cm length, 10 mm tip, 20 G
	SMK-S505-22	Straight 5 cm length, 5 mm tip, 22 G
	SMK-S1005-22	Straight 10 cm length, 5 mm tip, 22 G
	SMK-S1505-20	Straight 15 cm length, 5 mm tip, 20 G

Appendix D: Electromagnetic Compatibility Guidelines

Standards

This machine complies with the following standards:

IEC 60601-1:2005 Ed.3+A1;C1;C2;CA1

IEC 60601-1-6:2010 Ed.3+A1

IEC 60601-1-9:2007 Ed.1+A1

IEC 60601-2-2:2017 Ed.6

IEC 62366-1:2015 Ed.1

IEC 60601-1-2:2014 Ed.4

JIS T 0601-1-2*AEI Issued:2002/07/25AAMI ES60601-1:2005+AC1;A2

CSA C22.2#60601-1:2014 Ed.3

Table 17. Electromagnetic emissions declaration

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy for its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.**
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 18. Electromagnetic immunity declaration I

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN 61000-4-2 (IEC 1000-4-2)	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4 (IEC 1000-4-4)	±2 kV 100 kHz frequency for power supply lines ±1 kV 100 kHz frequency for input/output lines	±2 kV 100 kHz ±1 kV 100 kHz frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5 (IEC 1000-4-5)	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-11 Voltage dips Maximum and minimum voltages	0% U_T, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase at 0°	0% U_T, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
IEC 61000-4-11 Voltage interruptions	0% U_T; 250/300 cycles	0% U_T; 250/300 cycles	

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

WARNING: The generator is designed to function under a wide range of environmental conditions without compromise to Safety or Essential Performance.

In the event that an environmental artifact (e.g., electrostatic discharge or mains voltage fluctuations) is of sufficient magnitude and/or duration to possibly affect the system's internal communications, or make accessories act haphazardly, the system is designed to automatically recover from these events and continue operation under the settings set prior to the event.

In severe cases, such as if the voltage fluctuation dips below 90 V for an extended period or a full power outage, the system will reboot and re-initialize the software to the default operating state automatically upon the return of stable power.

If this type of condition causes persistent issues, please contact Technical Support. See "Technical Support" (page 35).

Table 19. Electromagnetic immunity declaration II

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms [V_1 = 3]	$d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [1.2]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m [E_1 = 3]	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [1.2]\sqrt{P}$ $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz $d = [2.3]\sqrt{P}$
			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

WARNING: The generator is designed to function under a wide range of environmental conditions without compromise to Safety or Essential Performance.

In the event that an environmental artifact (e.g., electrostatic discharge or mains voltage fluctuations) is of sufficient magnitude and/or duration to possibly affect the system's internal communications, or make accessories act haphazardly, the system is designed to automatically recover from these events and continue operation under the settings set prior to the event.

In severe cases, such as if the voltage fluctuation dips below 90 V for an extended period or a full power outage, the system will reboot and re-initialize the software to the default operating state automatically upon the return of stable power.

If this type of condition causes persistent issues, please contact Technical Support. See "Technical Support" (page 35).

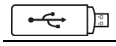
Table 20. Separation distances

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.117	0.117	0.233
0.10	0.369	0.369	0.737
1	1.167	1.167	2.33
10	3.69	3.69	7.37
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix E: Symbols and Definitions

The following symbols may be found on the product or product label:

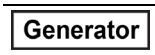
Symbol	Description
	Caution
	Emergency Stop
	Equipotentiality
	Refer to instruction manual/booklet
	Consult instructions for use
	Follow instructions for use on this website
	Type BF equipment
	Keep dry
IPX1	Protection against ingress of vertically dripping water (per IEC 60529)
	Date of manufacture
	Temperature limit
	Humidity limitation
	Do not use if package is damaged
REF	Catalog number
	Manufacturer
	Contents quantity
SN	Serial number
UDI	Unique Device Identification
	Prescription only
EC REP	Authorized Representative in the European Community
	Dispose of hardware in accordance with local law
	European Conformity. Affixed in accordance with European Council Directive 93/42/EEC as amended by 2007/47/EC (NB 2797). Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.
	ETL Listed Conforms to AAMI ES 60601-1 Certified to CSA C 22.2 No. 60601-1
MEDICAL ELECTRICAL EQUIPMENT	Medical Electrical Equipment

Symbol	Description
	Non-ionizing electromagnetic radiation
	USB drive
	Grounding pad - Isolated from earth at high frequency

Additional Symbols for Product Labels

The following table shows additional symbols that may appear on the product labels for parts related to this kit.

Table 21. Additional symbols for product labels

Symbol	Definition
	Generator

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