



PROCLAIM™ XR SCS SYSTEM AND
PROCLAIM™ DRG THERAPY

PATIENT CONTROLLER APP **USER GUIDE**

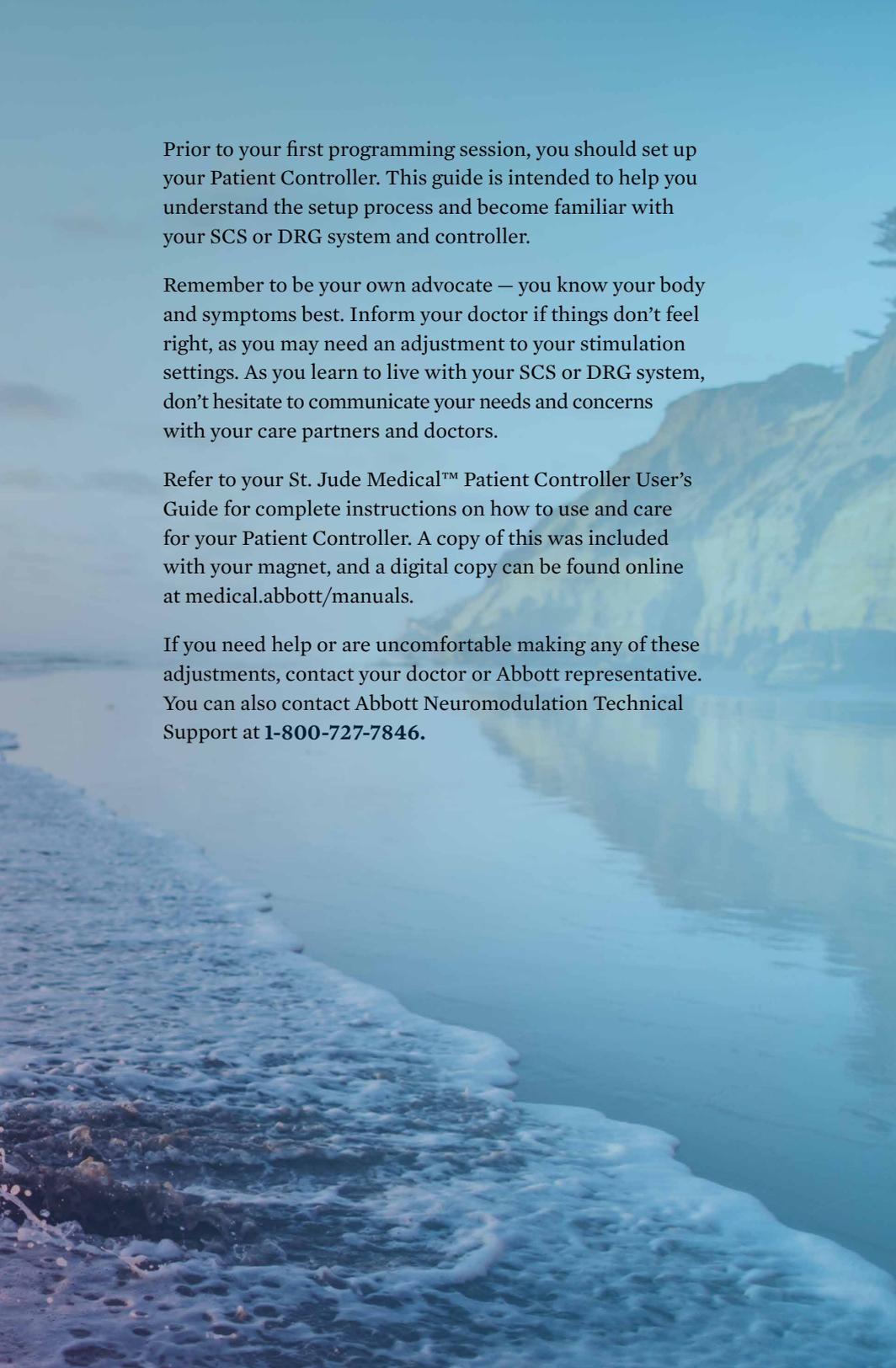
Your Connection. Your Care.

NEUROSPHERE™ DIGITAL CARE

THE WEEKS AND MONTHS FOLLOWING YOUR SPINAL CORD STIMULATION (SCS) OR DORSAL ROOT GANGLION (DRG) SURGERY CAN BE AN EXCITING TIME AS YOU BECOME FAMILIAR WITH YOUR NEW SYSTEM.

Over the course of the next few months, you should gain more control over your pain, although individual results may vary. With an increase in activity and a reduction in noticeable symptoms, many people feel more confident and experience the freedom to live their best life.





Prior to your first programming session, you should set up your Patient Controller. This guide is intended to help you understand the setup process and become familiar with your SCS or DRG system and controller.

Remember to be your own advocate — you know your body and symptoms best. Inform your doctor if things don't feel right, as you may need an adjustment to your stimulation settings. As you learn to live with your SCS or DRG system, don't hesitate to communicate your needs and concerns with your care partners and doctors.

Refer to your St. Jude Medical™ Patient Controller User's Guide for complete instructions on how to use and care for your Patient Controller. A copy of this was included with your magnet, and a digital copy can be found online at medical.abbott/manuals.

If you need help or are uncomfortable making any of these adjustments, contact your doctor or Abbott representative. You can also contact Abbott Neuromodulation Technical Support at **1-800-727-7846**.

COMPATIBLE DEVICES

The St. Jude Medical™ Patient Controller app from Abbott is available for download on certain personal Apple® iOS® mobile digital devices. If you own a compatible personal Apple® mobile digital device, it can be used in place of the Abbott-provided Apple® iPod touch® mobile digital device as your Patient Controller. To find out whether your personal Apple mobile digital device is compatible with Abbott's St. Jude Medical Patient Controller app, visit www.NMmobiledevicesync.com/cp.



APPLE® ID SETUP

To use the Patient Controller app on your Abbott-provided iPod touch mobile digital device or personal Apple mobile digital device,* you will need to have an Apple® ID. If you do not have an Apple ID or an email address, it is recommended that you have a friend or family member help you through the setup process for both. We ask that you create your Apple ID before you arrive for your final procedure. You will be required to use the Apple ID to download the app that controls your stimulation and to perform any app software updates that may come in the future. **Please do not lose your Apple ID and password.**

TO CREATE AN APPLE⁺ ID, PLEASE FOLLOW THESE STEPS:

Use your existing personal email address OR create a new email address. (A free email account can be created — for example, go to <https://accounts.google.com/SignUp>)

Email address

Create an Apple⁺ ID using your email address at the following website:
<https://appleid.apple.com/account>

Apple ID

NOTE: A credit card is not needed to set up an Apple ID.

Feel free to write down your preferred (6-digit) passcode to access the Apple⁺ mobile digital device — and keep it in a safe place. Do not share with others or allow other users to access the mobile device.

IF YOU NEED HELP, PLEASE CONTACT:

Apple Support (United States)

1-800-275-2273

Abbott Neuromodulation Technical Support
NMDTechnicalSupport@abbott.com

1-800-727-7846

When creating your Apple⁺ ID, use a password that you will remember. If you are concerned you will forget it, you may write it down below.

You will need your log-in credentials for future updates. Your credentials should be stored and maintained in a safe place. Do not share with others or allow other users to access the mobile device.

Name

First Name _____

Middle Name (optional) _____

Last Name _____

Apple ID and Password

Apple ID _____

Your Apple ID is the email address you used to create your Apple ID account.

Password _____

Security Questions

Security Question 1 _____

Answer _____

Security Question 2 _____

Answer _____

Security Question 3 _____

Answer _____

Date of Birth _____

Rescue Email Address

This is the email address where a link can be sent to confirm your identity and will let you reset your information should any security issues arise.

Rescue Email Address (optional) _____

Mailing Address

Country/Institution _____

Address Line 1 _____

Address Line 2 (optional) _____

Town/City _____

State/Province _____

ZIP Code _____

If you lose your Apple ID, contact Apple Support at 1-800-275-2273.

DOWNLOADING THE PATIENT CONTROLLER APP

The St. Jude Medical™ Patient Controller app is compatible with select personal Apple+ mobile digital devices running iOS+ software 12.2 or later.

A current list of compatible devices can be found at www.NMmobiledevicesync.com/cp.

As Apple releases new or upgraded operating systems (OSs), **it is important that you DO NOT upgrade the OS on the device until instructed to do so by Abbott.**

To minimize therapy interruption, Abbott needs to check every iOS software upgrade to ensure security and compatibility with the Patient Controller app.

Before turning on your device, you will download the Patient Controller app and set up your Apple[®] mobile digital device. You will use the Patient Controller app to control your therapy within the parameters your doctor sets. Should you need to download the Patient Controller app again, follow these steps. If you have any questions or concerns about the Patient Controller app or Abbott-provided iPod touch[®] mobile digital device, contact technical services or your Abbott representative.

Before you begin, make sure the device has a strong connection to the internet (full bars on Wi-Fi[®]) and you have ample time to complete the steps (Figure 1).

Download the Patient Controller app using your Apple[®] ID.

a. Sign in by going to **Settings** and then **iTunes & App Store[®]**.

b. Enter your **Apple ID** and **password** (Figure 2). If you do not already have an Apple ID, refer to the Apple ID Setup section.

c. Tap this icon to open the **App Store**. Search for Patient Controller.

d. Tap **GET** to download the app (Figure 3).

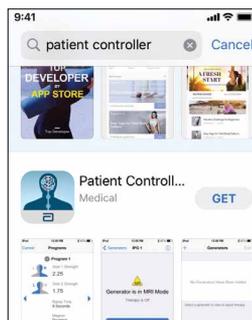
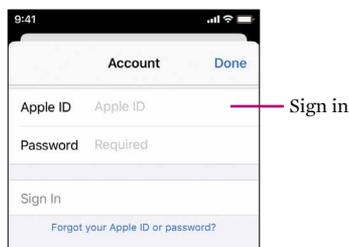
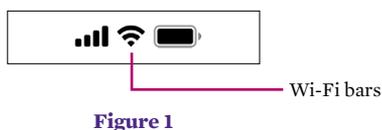


Figure 3

e. Pair the Patient Controller app to your implantable pulse generator (IPG).
To do so, remove the keeper bar on the magnet and hold the magnet over your IPG for 10 seconds.

f. **Remove the magnet.**

g. Open the **Patient Controller app** on the Apple[®] mobile digital device.

h. Touch the + button (Figure 4).

i. The serial number of the IPG you just held the magnet over will appear. Select it. Only IPGs that have had the magnet placed over them for 10 seconds will appear in this list.

j. A number code appears on the screen of your Patient Controller app. Enter that number and touch **Pair** (Figure 5).

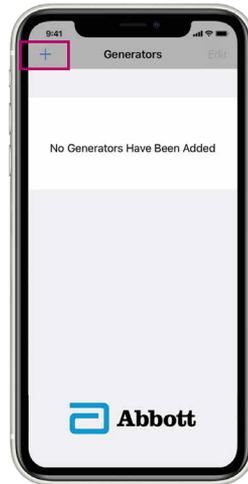


Figure 4

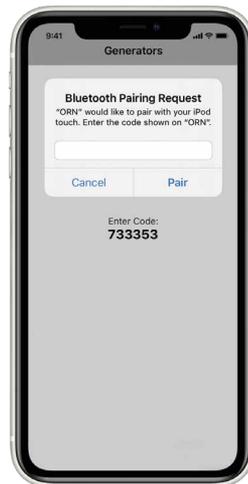


Figure 5

UPDATING YOUR PATIENT CONTROLLER APP

The St. Jude Medical™ Patient Controller app is compatible with select personal Apple® mobile digital devices running iOS® software 12.2 or later.

A current list of compatible devices can be found at www.NMmobiledevicesync.com/cp.

As Apple releases new or upgraded OSs, **it is important that you DO NOT upgrade the OS on the device until instructed to do so by Abbott.**

To minimize therapy interruption, Abbott needs to check every iOS software upgrade to ensure security and compatibility with the app.

UPDATING YOUR IOS⁺ SOFTWARE

- Go to **Settings**.
- Make sure you are connected to Wi-Fi[†]
- Go to the **General** tab under **Settings** (Figure 6).



Figure 6

- Tap **Software Update** (Figure 7).

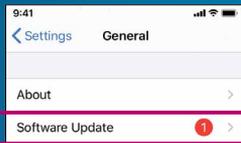


Figure 7

- If an update is available, **Download and Install** will appear. Tap this (Figure 8).
- Enter your passcode and agree to the **Terms and Conditions**.



Figure 8

Example iOS update screen

- Wait for the update to finish loading (Figure 9).

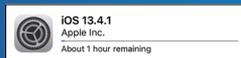


Figure 9

- Tap **Install Now** (Figure 10).



Figure 10

Example iOS update screen

UPDATING YOUR PATIENT CONTROLLER APP

As Abbott releases new versions of the St. Jude Medical™ Patient Controller app, you will receive an alert from the app informing you a new update is available. To update your Patient Controller app:

a. Tap on the **App Store**.[†]



b. Select the **Updates** button to view available app updates (Figure 11).

c. If an update is shown, tap it to update the Patient Controller app.

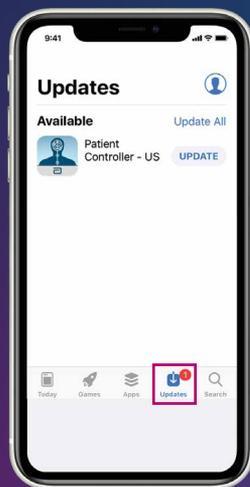


Figure 11

USING YOUR PATIENT CONTROLLER APP

This section provides an overview of your St. Jude Medical™ Patient Controller app. It shows you how to start, stop and adjust your therapy. Refer to your User's Guide for complete instructions on how to use and care for your Abbott Patient Controller.

A copy of this was included with your magnet, and a digital copy can be found online at medical.abbott/manuals.



BEFORE CONNECTING TO YOUR PATIENT CONTROLLER APP

- a. Make sure that Bluetooth® wireless technology is enabled on the device. You can turn Bluetooth® wireless technology settings on/off in the **Settings** (Figure 12).

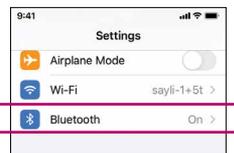


Figure 12

CONNECTING TO YOUR STIMULATION DEVICE

- a. Tap the **Patient Controller** icon on your device screen to launch the app (Figure 13). Your St. Jude Medical™ Patient Controller app will automatically connect to your generator.



Figure 13

- b. If you have two generators, select the generator you want to connect with from the list (Figure 14).

When selecting icons on an Apple[†] mobile digital device, please use a short, light touch. Pressing on an app for longer than 1 second can result in moving or possibly deleting the app.

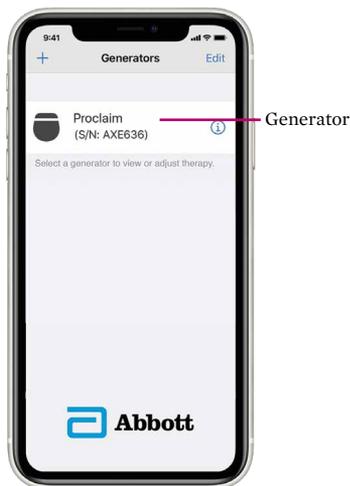


Figure 14

STARTING AND STOPPING STIMULATION

- a. Start and stop stimulation by tapping on the **Therapy is ON** or **Therapy is OFF** button on the Therapy screen (Figure 15).

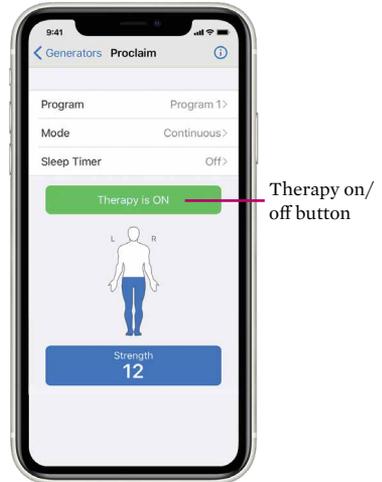


Figure 15

VIEWING AND SELECTING A PROGRAM

Tap the **Program Name** on the Therapy screen to open the Programs screen. On the Programs screen, you can view and select any of the saved programs (Figure 16). To switch between the saved programs:

- a. Either swipe the screen right or left, or tap the right or left arrows.
- b. When you locate the program you want to activate, tap **Select This Program**.

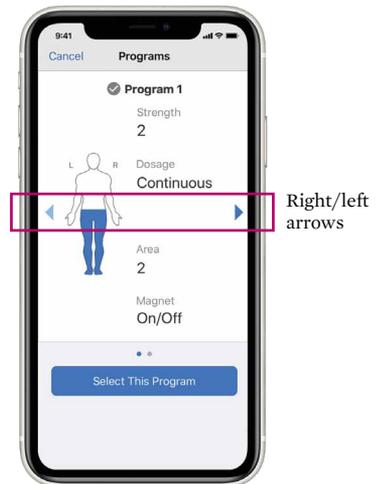


Figure 16

ADJUSTING STRENGTH

- a. The **Strength** button shows the current stimulation strength level. Tap the **Strength** button to adjust the stimulation level.
- b. Tap **Strength** on the Therapy screen to open the Strength screen. On the Strength screen, you can adjust the program strength (Figure 17).



Figure 17

- c. Tap on the - or + buttons to increase or decrease strength levels until you feel a comfortable level of stimulation (Figure 18).

The number and green bar will increase or decrease as you increase or decrease strength (Figure 18).



Figure 18

TURNING OFF YOUR PATIENT CONTROLLER APP

When you are finished adjusting your therapy, you can exit the Patient Controller app. Your Patient Controller app can be reactivated quickly if you want to make changes to the program.

If you power off your Apple⁺ mobile digital device, the system will continue delivering the therapy you've selected until you reopen your Patient Controller app and make changes.

To turn off an Abbott-provided Apple⁺ iPod touch⁺ mobile digital device, press and hold the **Power** button (Figure 19) until the **Slide to Power Off** bar appears, and then slide the bar to the right.



Power button (location of button may vary)

Figure 19

PATIENT CONTROLLER APP ALERTS

APP UPGRADE AVAILABLE

The St. Jude Medical[™] Patient Controller app will show an alert when a new version of the app is available in the App Store[‡] online store. You can refer to the earlier instructions in this user guide for how to upgrade your Patient Controller app.

SECURITY ALERT

The St. Jude Medical Patient Controller app includes enhanced cybersecurity measures to protect your data privacy and security. If you receive an alert indicating that your device is not secure, access to your app for therapy adjustments will be temporarily disabled. If you need help with this alert, you should contact your Abbott representative or Abbott Neuromodulation Technical Support at **1-800-727-7846**.

ACCESSING TEMPORARY MOBILE DEVICE MODES

Your system has temporary device modes that help reduce the possibility the system will interact with external factors.

These temporary modes include:

- Airplane Ready Mode
- Surgery Mode
- MRI Mode

This section will discuss when and how to place your device in Airplane Ready, Surgery or MRI Mode.

AIRPLANE READY MODE

In some environments, the use of wireless functions (e.g., Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes.

If you need to set your system to Airplane Ready Mode, tap **Mode** from the Therapy screen to open the Mode screen. From this screen, you may place your system in Airplane Ready, Surgery or MRI Mode (when applicable). Tap **Airplane Ready** to view the Airplane Ready screen. Follow the instructions on the screen to turn Airplane Ready Mode on or off.

BEFORE YOUR FLIGHT

- a. Switch Airplane Ready option to ON.
- b. Hold a magnet over the generator for 5 seconds to disable Bluetooth® wireless technology.

AFTER YOUR FLIGHT

- a. Hold a magnet over the generator for 5 seconds to re-enable Bluetooth® wireless technology.
- b. Switch Airplane Ready option to OFF.

SURGERY MODE AND MRI MODE

Your SCS or DRG system is an active electronic device that can interact with external factors such as those sometimes seen during surgery or magnetic resonance imaging (MRI) scans.

Surgery Mode and MRI Mode are features that can help reduce the possibility of these interactions.

Both can be activated directly from your Patient Controller app. These features do not completely eliminate the possibility of your system being affected during surgery or an MRI scan.

THE FOLLOWING STEPS EXPLAIN HOW TO TURN THESE MODES ON AND OFF.

If you feel uncomfortable completing the steps, contact your Abbott representative before your surgery or MRI scan. Contact your doctor before your surgery or MRI scan to learn about any risks.

THIS GUIDE SHOULD BE USED IN ADDITION TO THE INSTRUCTIONS FOR USE FOR THE ST. JUDE MEDICAL™ PATIENT CONTROLLER APP. YOU CAN FIND A COPY OF THIS AT [MEDICAL.ABBOTT/MANUALS](https://www.medicalexpress.com/medical/ABBOTT/MANUALS).

PLACING YOUR SCS OR DRG SYSTEM IN SURGERY MODE

Place your device in Surgery Mode
before your procedure.

Turning on Surgery Mode turns
off your stimulation.



To Turn On Surgery Mode

- a. From the Therapy screen, tap **Mode** to display the Mode screen (Figure 20).

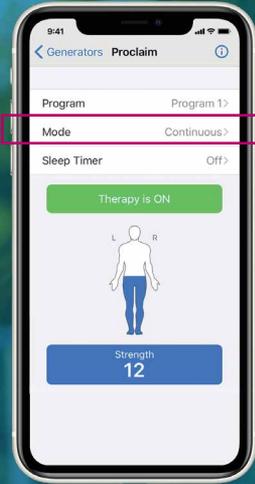


Figure 20

- b. Tap **Surgery Mode** to view the Surgery Mode screen (Figure 21).



Figure 21

- c. Tap the **Surgery Mode** toggle button (Figure 22).

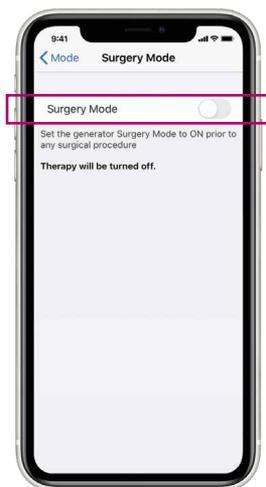


Figure 22

To Turn Off Surgery Mode

- a. Launch the Patient Controller app and connect with your generator. The “Generator Is in Surgery Mode” message appears.
- b. Tap **Exit Surgery Mode** to turn off Surgery Mode (Figure 23).

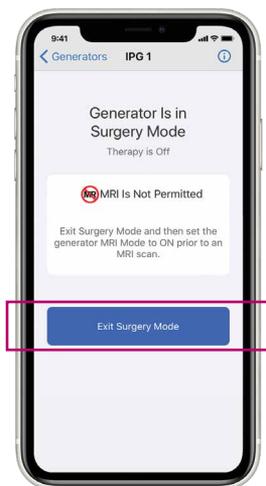


Figure 23

- c. The Therapy screen appears, showing that stimulation therapy is off.
- d. Tap **Therapy is OFF** to start stimulation (Figure 24).

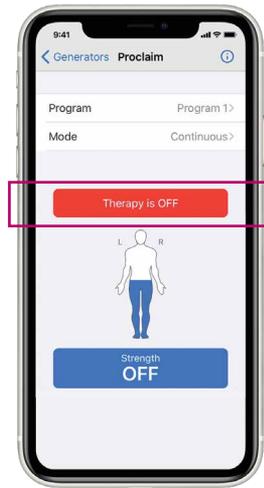


Figure 24

PLACING YOUR SCS OR DRG SYSTEM IN MRI MODE

If your device is MR Conditional, place your device in MRI Mode before entering the magnetic resonance (MR) environment. Turning on MRI Mode turns off your stimulation.

To Turn On MRI Mode

- a. From the Therapy screen, tap **Mode** to display the Mode screen (Figure 25).

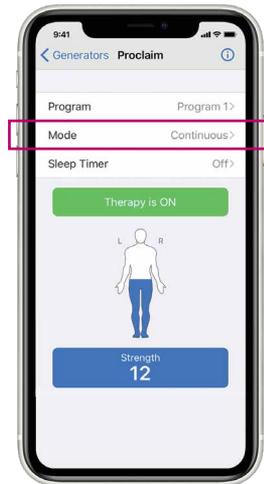


Figure 25

b. Tap **MRI Mode** to view the MRI Mode screen (Figure 26).



Figure 26

c. Tap the **MRI Mode** toggle button (Figure 27).



Figure 27

d. When the “Set Generator to MRI Mode?” message appears, tap **Continue** (Figure 28). Stimulation stops, and the Patient Controller app checks the system for any issues.

e. If the checks are successful, the “Proceed with MRI” message appears and MRI mode is turned on. Tap **OK**.

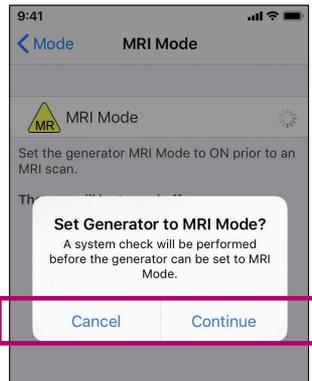


Figure 28

To Turn Off MRI Mode

- a. Launch the Patient Controller app and connect with your generator. The “Generator Is in MRI Mode” message appears. Tap **Exit MRI Mode** to turn off MRI Mode (Figure 29).
- b. The Therapy screen appears, showing that stimulation therapy is off.

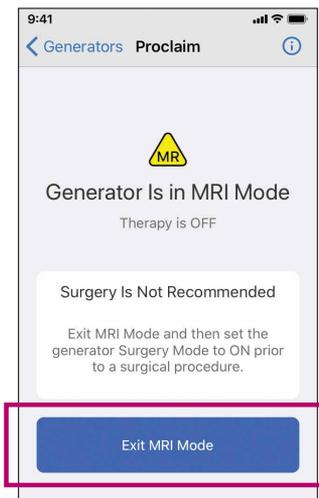


Figure 29

- c. Tap **Therapy is OFF** to start stimulation (Figure 30).

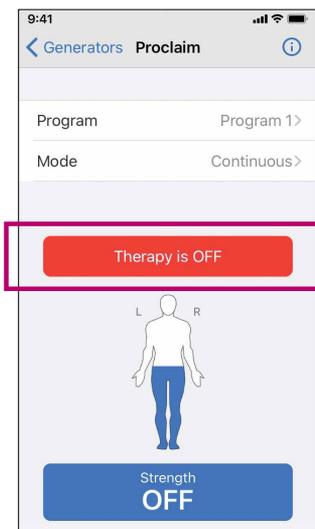


Figure 30

IMPORTANT ITEMS TO REMEMBER

Surgery Mode or MRI Mode should be turned on before you enter the room where your surgery or MRI scan will be performed. Otherwise, the potential for uncomfortable, unintended stimulation or damage to the neurostimulator is increased. Refer to the Instructions for Use for more information.



FOR SURGERY MODE

Turning off Surgery Mode before the completion of your surgery may cause unintended effects like unintended stimulation or damage to your SCS or DRG system. Refer to the Instructions for Use for more information.

FOR MRI MODE

Do not bring your Patient Controller into the room where your MRI will be performed. Your neurostimulator may be MR Conditional, but your Patient Controller is not. Exposing it to the MRI magnet can present a projectile hazard.

PREPARING FOR YOUR SURGERY OR MRI SCAN

Before you undergo a surgery or have an MRI scan, follow these steps:

- a. Tell the physician who is performing your surgery or MRI scan that you have an implanted Abbott neurostimulation system.
- b. Contact your doctor to discuss your upcoming procedure or MRI scan and the possible effects it may have on your implanted device.
- c. Schedule your surgery or scan. When scheduling, provide the model numbers and locations of your implanted neurostimulation system parts and your doctor's contact information. This information is located on your Abbott Patient ID Card.
- d. Fully charge your Patient Controller before arriving for the procedure.

BRING THE FOLLOWING ITEMS TO YOUR SURGICAL APPOINTMENT OR MRI SCAN:

- Abbott Patient ID Card**
- Patient Controller**



If you need help accessing Surgery or MRI Mode on your Patient Controller app, contact Abbott Neuromodulation Technical Support at **1-800-727-7846**.

*Available on eligible Apple® mobile digital devices. To find out whether your personal Apple mobile digital device is compatible with Abbott's St. Jude Medical™ Patient Controller app, visit www.NMmobiledevicesync.com/cp.

Abbott

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Neuromodulation.Abbott

Rx Only

Brief Summary: Prior to using these devices, please review the User's Guide for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

DRG Indications for Use: Spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable* pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.**

*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.

**Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively. CRPS II (causalgia) is defined as a painful condition arising from damage to a nerve. Nerve damage may result from traumatic or surgical nerve injury. Changes secondary to neuropathic pain seen in CRPS I (RSD) may be present, but are not a diagnostic requirement for CRPS II (causalgia).

Contraindications: Patients who are unable to operate the system, who are poor surgical risks. Patients who have failed to receive effective pain relief during trial stimulation.

Warnings/Precautions: Diathermy therapy, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), computed tomography (CT), electrosurgery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery, equipment and vehicles, pregnancy, and case damage.

Adverse Effects: Unpleasant sensations, changes in stimulation, stimulation in unwanted places, lead or implant migration, epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space, cerebrospinal fluid leakage, tissue damage or nerve damage, paralysis, weakness, clumsiness, numbness, sensory loss, or pain below the level of the implant, pain where needle was inserted or at the electrode site or at IPG site, seroma at implant site, headache, allergic or rejection response, battery failure and/or leakage. User's Guide must be reviewed for detailed disclosure.

SCS Indications for Use: Spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

Contraindications: Patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

Warnings/Precautions: Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery, equipment and vehicles, postural changes, pediatric use, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Effects: Unpleasant sensations, changes in stimulation, stimulation in unwanted places, lead or implant migration, epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space, cerebrospinal fluid leakage, paralysis, weakness, clumsiness, numbness, sensory loss, or pain below the level of the implant, pain at the electrode or IPG site, seroma at IPG site, allergic or rejection response, battery failure. User's Guide must be reviewed for detailed disclosure.

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