Your Galvani System
PATIENT MANUAL

GALVANI
BIOELECTRONICS

YOUR CLINICAL STUDY COORDINATOR _____ IS THERE TO ANSWER ANY OF YOUR QUESTIONS,

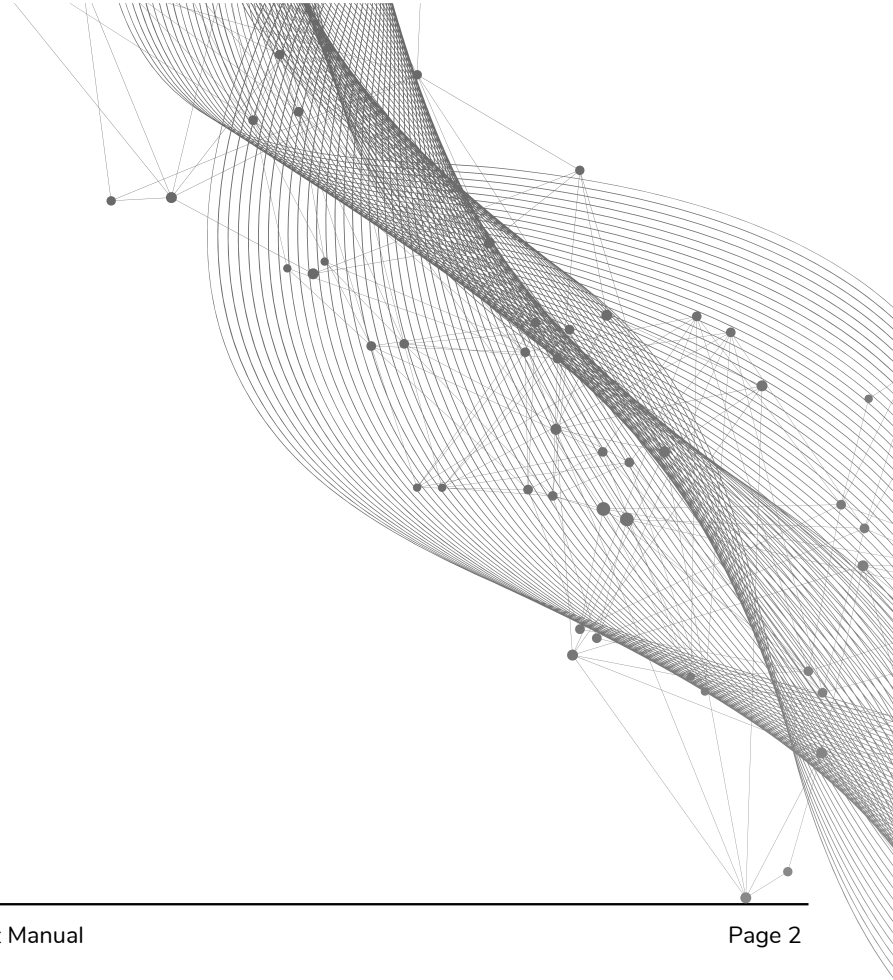CALL _____

YOU CAN ALSO SPEAK TO YOUR DOCTOR, CALL _____

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Packaging Symbol Definitions

Symbol	Definition	Symbol	Definition	Symbol	Definition
R Only	For Prescription Use Only	LOT	Batch Code	(MR)	Magnetic Resonance (MR) Unsafe
⚠	Caution	(Date of Manufacture symbol)	Date of Manufacture	(disposal symbol)	Dispose of properly
(consult symbol)	Consult instructions for use	(factory symbol)	Manufacturer	---	Direct Current
(refer symbol)	Refer to Instruction Manual/Booklet	(hourglass symbol)	Use By Date	(((•)))	Non-ionizing Electromagnetic Radiation
REF	Catalog Number	(thermometer symbol)	Temperature Limit	(person symbol)	Type BF Applied Part
SN	Serial Number	(humidity symbol)	Humidity Limitation	IP22	Protected against solid foreign objects of 12.5 mm diameter and greater. Protected against vertically falling water drops when ENCLOSURE tilted up to 15°.
(sunlight symbol)	Keep Away from Sunlight	FC	Federal Communications Commission	(package symbol)	Do not use if package is damaged

Important Safety Information

About Your Patient Manual

Your doctor or Study Coordinator will provide training on how to use your Galvani System. When at home, this Patient manual will be a good reference for using your Patient Remote and IPG[1] Charger to manage your therapy and charge your Implant. Take some time to read through this manual. If you find you have any questions, you can contact your Study Coordinator using the phone number on the cover of this manual.

The patient components of the Galvani System are intended to be used at home or when traveling away from home. This manual covers the following items:

- Patient Remote (Model 31101)

- IPG Charger[2] (Model 31102) and two items that can be used to hold the Charger while charging:
  - Charging Belt (Model 81101)
  - Adhesive Patch (Model 81102-12)

For details about your Galvani System, see "Chapter 1 Introducing the Galvani System", on page 10.

Indications for Use

Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response, or are intolerant to, two or more biologic Disease Modifying Anti-Rheumatic Drugs (bDMARDs) or targeted synthetic Disease Modifying Anti-Rheumatic Drugs (tsDMARDs), e.g. JAK inhibitor.

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1 Implantable Pulse Generator (IPG) is the clinical name for your Galvani System implant.
2 Refered to in this manul as "the Charger".

Contraindications

Diathermy: You cannot have shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy anywhere on your body. Injury to you or damage to your implanted system can occur during diathermy treatment whether or not your Galvani System is turned ON or OFF.

Warnings

Always inform any healthcare professional who is taking care of you that you have an implanted stimulation system. You should always carry your Patient Identification (ID) card that provides information about your system. This information can help them decide if any new treatments for you are safe.

Magnetic Resonance Imaging (MRI): You cannot have an MRI. The strong electro-magnetic fields generated by MRI scanners may move the implanted system or cause it to stimulate in an unexpected way. Injury to you or damage to your implanted system can occur if you have an MRI even if your system is turned ON or OFF.

- You will not be able to have any MRI scans while the system (any part of it) is implanted. Your healthcare professional may be able to get information about your health from other imaging tests like a CT scan, ultrasound, or X-ray; which will not interfere with your implanted system.

- If an MRI scan is absolutely needed, you will have to have another surgery to remove the implant and lead.

Children: Keep your Patient Remote and Charger away from children. The charging cords can be a strangulation risk.

Significant Discomfort Stop Therapy: If you feel significant discomfort while using the Galvani System such as pain in your abdomen or chest, heart flutters, or feeling lightheaded, especially at times of your scheduled therapy, follow the instructions on page 32 of this Patient Manual to use the Charger to stop therapy. Once you are comfortable, contact your Rheumatologist or your Study Coordinator and tell them you needed to stop your therapy.

Electromagnetic Interference (EMI): Be careful around equipment that generates strong electro-magnetic fields found in airports, medical facilities, and public buildings. (Also avoid welding equipment.) Equipment that generates strong electro-magnetic fields may cause your Galvani System to temporarily stimulate your nerve in an unexpected way. If you need to pass through theft detection or security gates, present your patient ID card which explains that you have an implanted device and request manual screening.

Cardiac Device Interaction: The implanted Galvani System may interfere with other implanted electronic devices such as cardiac pacemakers or defibrillators. Make sure to tell your healthcare professional about your implanted Galvani System and discuss potential options for any currently implanted cardiac devices or possible future devices.

Ablation:[1] Inform your Study Coordinator or current healthcare professional that you have an implanted stimulation system before receiving an ablation. Radiofrequency (RF) or microwave ablation has not been proven safe for patients who have an implanted stimulation system. Electrical ablation currents may heat the implanted system injuring the surrounding tissue.

Electrocautery: Contact your Study Coordinator or current healthcare professional if you plan to have any surgery. Make sure to inform your surgeon that you have an implanted stimulation system. Electrocautery is used during many types of surgery and If used improperly, it may cause severe injury to you or damage to your implanted system.

Unexpected Effects on the Body: The Galvani System stimulation therapy could have unexpected effects on your body such as change in blood pressure, heart arrhythmias, stroke, or immunosuppression. Contact your Study Coordinator or current healthcare professional if you experience any unusual effects while receiving stimulation therapy.

Cautions

Storage, Handling, and Transport: Do not expose your Patient Remote or Charger to excessively hot or cold conditions. For example, do not leave these devices in your car for extended periods of time. The sensitive electronics can be damaged by temperature extremes, especially high heat. If the Patient Remote or Charger is moved from a very warm or very cold environment, wait until the device is at room temperature before using it. Be careful to keep the Patient Remote and Charger away from water and do not drop them. Water and dropping on hard surfaces can damage the devices. Refer to the provided cleaning instructions in this manual.

System Tampering: Do not tamper with your Patient Remote or Charger. Your Galvani System devices do not have any serviceable parts. Only use these devices as described in your Patient manual. Tampering with the Patient Remote or Charger can result in electrical or thermal injury.

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1 Ablation refers to cutting with a laser or electrocautery, including radiofrequency and electrical energy. This process uses heat generated by the electrical current to scar or remove tissue.

Power Adapter: Be careful when removing the power adapter for the Patient Remote or Charger from a power outlet. Use only the certified AC Adapter provided with your Patient Remote and Charger. These adapters have double-reinforced insulation between the input and output circuits and using other AC adapters may result in electrical or thermal injury.

Damaged Devices: Do not use your Patient Remote or Charger if they are damaged. Using damaged devices (for example a damaged IPG Charger) may lead to injury. Contact your Study Coordinator or current healthcare professional if you experience any unexpected operations or events, such as a cracked Patient Remote screen or any slower than usual performance of your Galvani System. Find the contact information for your Study Coordinator on the cover of your Patient manual.

Your Patient ID Card

Always carry your Patient ID Card. This card provides important information in the event that you may need medical care. Show this ID card to any medical professionals when you seek care. You can also show this card to security personnel at airports or other places where security gates are used and ask for manual screening if possible. For more information about security gates, see EMI warning on page 5.

This patient has a complete Galvani Neuromodulation device system implanted, consisting of an Implantable Pulse Generator (IPG) and a Lead.

MRI: Device is MRI UNSAFE. For questions regarding MRI device compatibility, contact Galvani Bioelectronics.

Security Personnel: Magnetic security wands may adversely affect device's function. Do not place wand over implant location. This device may trigger metal detector systems.

Manufactured by:

GALVANI
BIOELECTRONICS

Gunnels Wood Road, Stevenage, Hertfordshire, United Kingdom
Website: *www.galvani.bio*

AW-0522 Rev B

Patient Name: _____

Physician: _____

Physician Contact Number: _____

System Implant Date: _____

IPG Serial Number: _____

IPG Model Number: _____

Lead Serial Number: _____

Lead Model Number: _____

Contact Physician for medical questions or in case of emergency

Figure 1 Patient ID card

Contents

Chapter 1 Introducing the Galvani System

You and your healthcare professional may have tried a range of treatments to help your rheumatoid arthritis (RA) symptoms. For one reason or another, those treatments did not work to keep your symptoms under control. That is why the two of you chose a different path. The Galvani System is a small implant that provides electrical nerve stimulation therapy to treat your RA. Your implant is also referred to as an "Implantable Pulse Generator" or IPG.

You will use all the Galvani System components shown in Figure 2.

Implanted Pulse Generator (IPG): This manual refers to the IPG as your "Implant".

Patient Remote: Use your Patient Remote to monitor your Implant.

IPG Charger: Use the Charger at least 2-3 times a week to charge the internal battery of your Implant. This manual refers to the IPG Charger as "the Charger".

Adhesive patches and charging belt: Use either the adhesive patches or the charging belt to hold the Charger over your implant when charging your implant battery.

Figure 2 The Galvani System Components

Your Implant
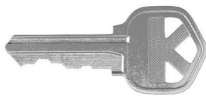
Figure 4
Size of Your Implant

Your Galvani System Implant generates bioelectric therapy. This electrical stimulation is delivered to the nerves in your spleen by your Implant through a thin wire or lead. Your healthcare professional is able to program your Implant for optimal stimulation or therapy.

Your Patient Remote

Your Patient Remote uses wireless Bluetooth® technology to connect to your Implant. Once connected to your Implant, you can use your Patient Remote to:

- Check your Implant battery status (page 28)
- Setup Notifications for your therapy (page 18)
- Delay therapy (page 30)
- Adjust your Patient Remote display settings (page 14)

- Stop therapy if you have significant discomfort[1] (page 31)
- View your next therapy and therapy schedule (page 27)
- View charging instructions (page 28)

For more information about using your Patient Remote, see "Getting Started with Your Patient Remote", on page 13.
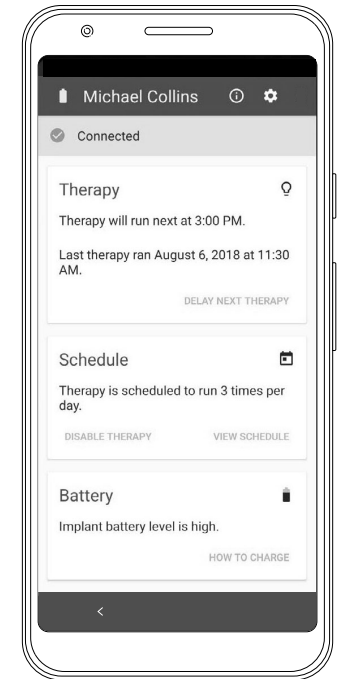
Figure 3 Your Patient Remote

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1 If you stop your therapy, you may need to see your healthcare professional to start your therapy again. For more information, see "Using The Charger to Stop Therapy", on page 32.

The IPG Charger

The IPG Charger is used to charge the internal battery of your Implant. Throughout the rest of this manual, it will be refered to as "the Charger".

You should charge your Implant 2-3 times a week or whenever your Implant battery level is at Medium or Low. For complete information, see "Chapter 5 Using the Charger", on page 34.

Note: You can also use the Charger to quickly stop your therapy if you need to. For more information, see "Using The Charger to Stop Therapy", on page 32.

The Charger package includes:

- A power adapter and charging cord. It is important to only use this cord to charge the Charger because it is customized for the Charger, see Cautions on page 6.

- A Charging belt used to hold the Charger over your implant when charging.

- A set of disposable adhesive patches, also used to hold the Charger over your Implant by sticking the Charger directly to your skin.

Note: You can use either the charging belt or an adhesive patch which ever is more comfortable.

Figure 5 The Charger and AC Adapter

Chapter 2 Getting Started with Your Patient Remote

Your Study Coordinator or healthcare professional will set up your Patient Remote before you use it.[1] You should use your Patient Remote to connect to your Implant at least 2-3 times a week, for more information, see "Connecting to Your Implant", on page 24.

Logging In

1   If your Patient Remote is OFF, press and hold the top button on the side of your Patient Remote for a few seconds to turn it ON. The first screen you see is the Login screen.

2   Unlock your Patient Remote by entering the security passcode provided by your doctor or Study Coordinator. (Figure 6)

3   After entering the passcode, press the check key (√).

4   Select NEARBY IMPLANTS.

5   Keep your Patient Remote close to your Implant while it searches for your Implant. This can take up to 10 seconds.

   Your Patient Remote will automatically connect to your Implant if it has been set-up by your healthcare professional.

6   When your Implant is connected, your Patient Remote displays the Main screen.

   Note   If your Patient Remote remains inactive for 10 minutes, it will go into "sleep'" mode and you will need to re-enter your passcode.

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1 If you need to replace your Patient Remote for some reason, it will need to be registered with your Implant. If you need to do this, see "Appendix A Registering a New Patient Remote", on page 56 for instructions about connecting and registering your Patient Remote to your Implant.

ON / OFF Button

Volume Up and Down Buttons
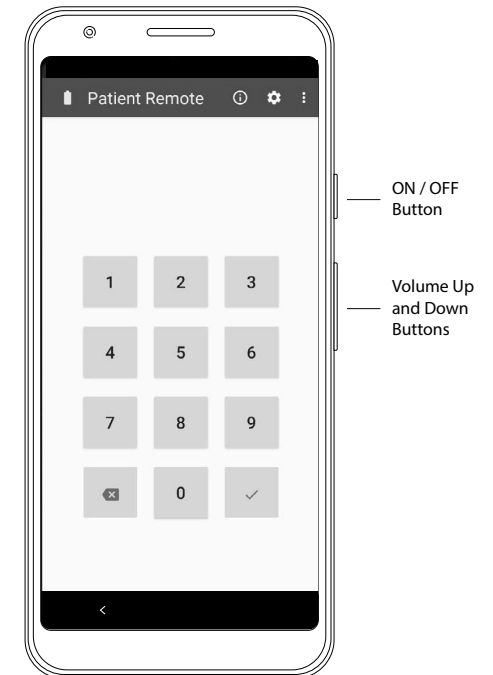
Figure 6 Login Screen

Locking Your Patient Remote

After you are finished using your Patient Remote, select the three dots in the upper right corner of the screen and select Lock Screen. It is important to keep your Patient Remote locked when you are not using it so that programming keys are not accidentally selected and to protect your information on your Patient Remote.

You cannot lock your Patient Remote if it is connected to your Implant. If connected, first select Disconnect from the Settings screen, then when the Nearby Implants screen appears, select Lock Screen. For more information, see "Disconnecting Your Implant from Your Patient Remote", on page 19.

> **Note** If you do not select Lock Screen (when disconnected from your Implant) your Patient Remote automatically locks the screen after 10 minutes of inactivity.

Adjusting Settings

Select the wheel icon (⚙) on the top of the display to adjust the setting options. The Settings screen provides options for both your Patient Remote and for your Implant. (Figure 7)

The Settings screen looks a little different when your Patient Remote is not connected to your Implant. Only the settings available for your Patient Remote are displayed. After your Patient Remote is connected to your Implant, three additional settings are added to the Settings screen.
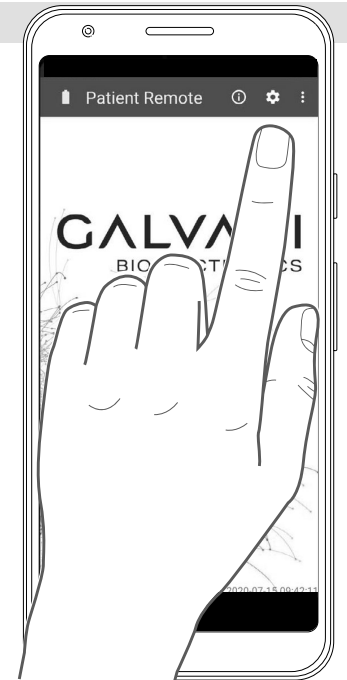
Figure 7 Select Settings

Before your Patient Remote is connected to your Implant, the Settings screen provides three features to adjust for your Patient Remote: (Figure 8)

- **Language[1]:** Select to change the language used by your Patient Remote.
- **Login Passcode:** Select to add a personal login passcode.
- **Screen Brightness:** Select to adjust the screen brightness of your Patient Remote.

After your Patient Remote is connected to your Implant, the Settings screen provides an additional three options. (Figure 9)

- **Notifications:** Select this option to set up reminders about connecting to your Implant or to notify you about an upcoming therapy.
- **Disconnect:** Select to disconnect from your Implant and end your active session.
- **Unpair implant:** This option should only be used if your Study Coordinator or healthcare professional requests you to do this. Selecting this option cancels the auto-connect feature used once your Implant is registered with your Patient Remote. If **Unpair implant** is selected, you will need to pick your Implant from a list of Implants after selecting the Nearby Implants button.[2]

  Note   Only select Unpair implant if your Study Coordinator or healthcare professional asks you to do this.
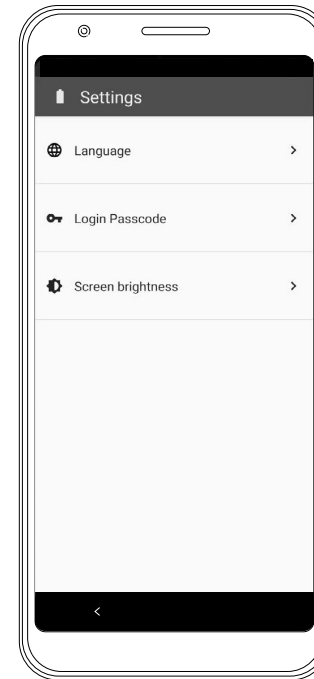
Figure 8 Settings When Not Connected to Your Implant
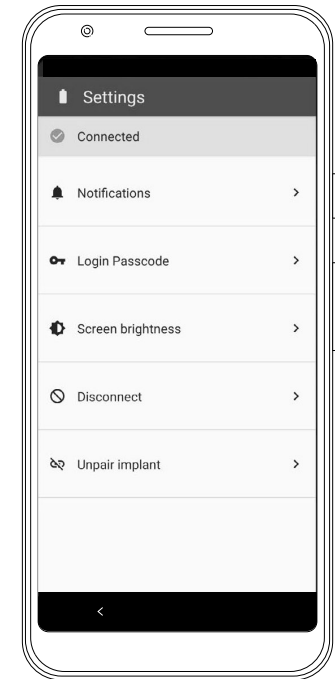
Figure 9 Settings When Connected to Your Implant

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1 The Language setting option is not displayed after your Patient Remote is connected to your Implant.
2 For more information, see "Unpairing Your Implant", on page 20,

Selecting a Language for Your Patient Remote

Note The Language setting is only available when your Patient Remote is not connected to your Implant.

1 From the Settings screen, select **Language**. (Figure 10)

2 Select one of the available languages and select **OK**.

3 Turn your Patient Remote OFF then back ON to enable the selected language setting.

Adding a Personal Passcode

You can add a personal passcode to your Patient Remote if desired. The original passcode remains active.

1 From the Settings screen, select **Login Passcode** to change your personal identification code used to access your Patient Remote. (Figure 11)

The passcode keypad displays. (Figure 12)

2 Enter your new passcode followed by the check key (√).

3 Confirm your new passcode followed by the check key (√).

Note If the passcode numbers appear to be too large to be displayed in the passcode area, restart your Patient Remote.
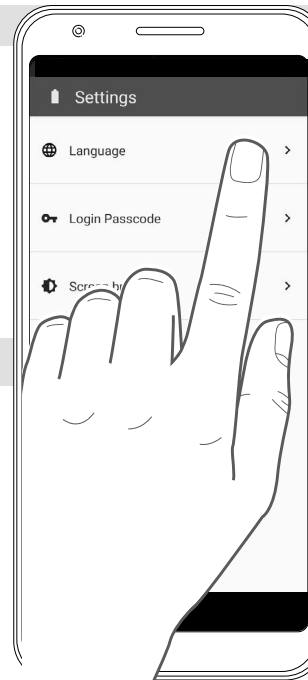
Figure 10 Select Language
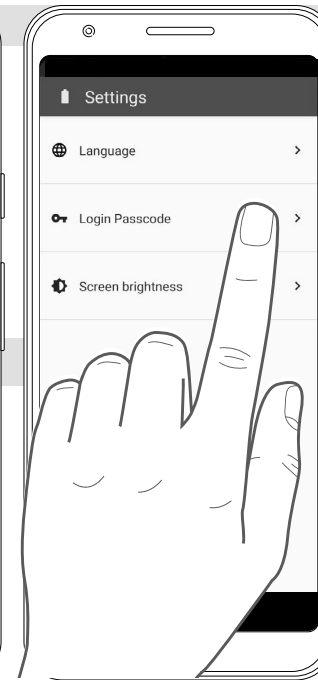
Figure 11 Changing Your Passcode
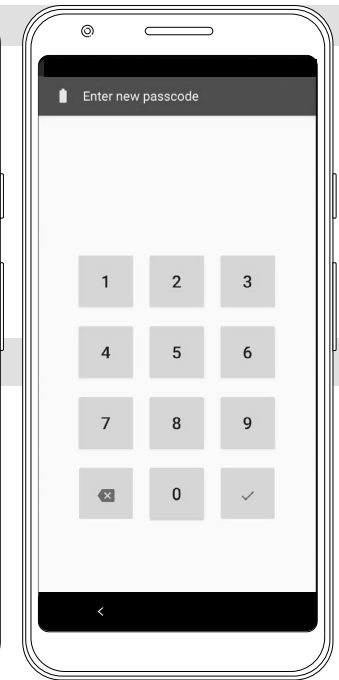
Figure 12 Enter Passcode

Adjusting the Screen Brightness

1 From the Settings screen, select Screen brightness. (Figure 13)

2 Move the slider to the right to increase brightness or left to decrease brightness. (Figure 14)

3 Select Dismiss to set the new brightness level and return to the Settings screen.

Note   Additional setting options appear on the Settings screen when your Patient Remote is connected to your Implant: Notifications, Disconnect, and Unpair. These settings are described on the next few pages.
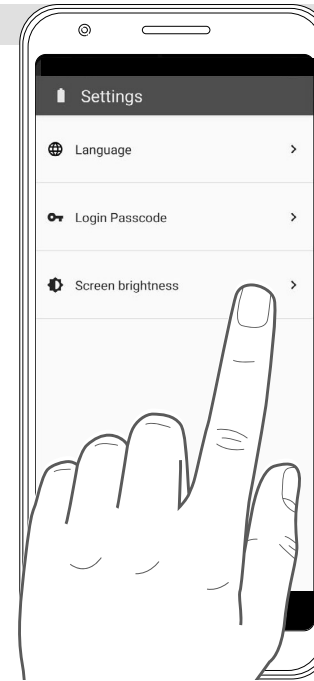
Figure 13 Screen Brightness
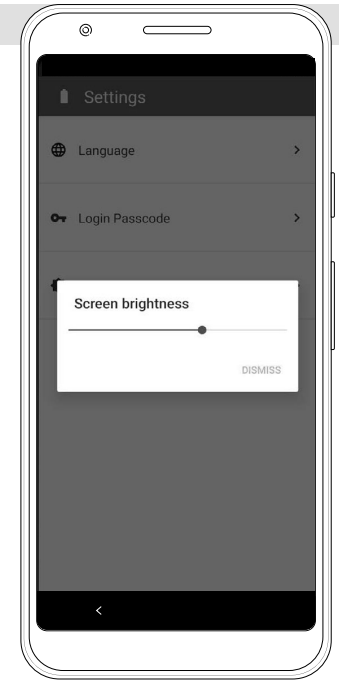
Figure 14 Setting the Screen Brightness

Setting Up Notifications

Your Patient Remote can be set up to send you notifications about your therapy and to remind you if haven't connected to your Implant in over a week.

1   From the Settings screen, select **Notification settings**. (Figure 15)

2   Move the slider button to the right to turn ON any of the three available options: (Figure 16)
    - **Notify me if a week goes by without this remote connecting to the implant**
    - **Notify me before therapy starts**: Set this option and your Patient Remote sends you an alert 10 minutes before your therapy is scheduled to begin.
    - **Notify me when therapy starts**

3   Select the back icon (<) to go back to the Settings screen.

   Note   If you choose to set up Notifications, make sure to connect to your Implant at least once a day to keep these notifications current. For more information, see "Keeping Your Implant and Patient Remote On Time", on page 22.

   If your notifications are not appearing, make sure that you are connecting your Patient Remote to your Implant every day.
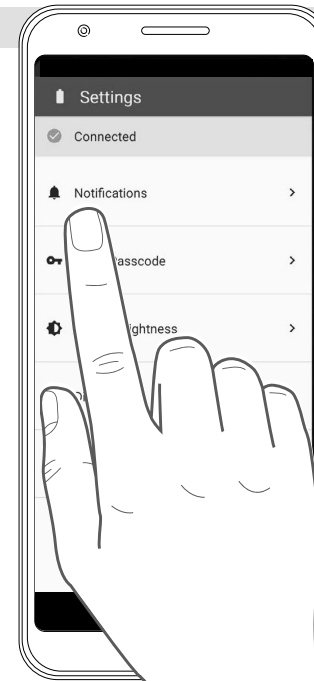
Figure 15 Setting Up Notifications
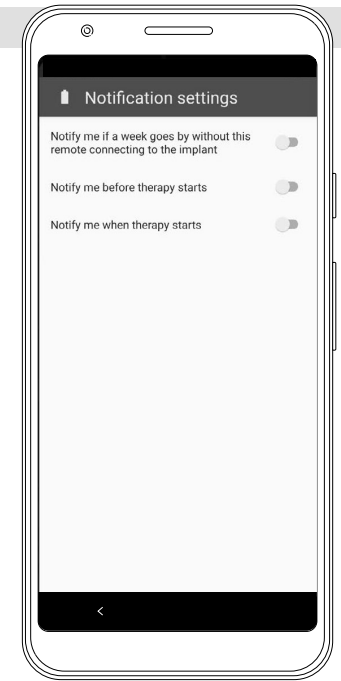
Figure 16 Notification Options

Disconnecting Your Implant from Your Patient Remote

It is a good idea to disconnect your Implant from your Patient Remote when you are finished checking your Implant or adjusting your notifications.

Note Your Patient Remote will automatically disconnect from your Implant after 10 minutes without any activity.

1 From the Settings screen, select Disconnect. (Figure 17)

2 On the confirmation message: (Figure 18)
- Select Cancel to return to the Settings screen without disconnecting from your Implant.
- Select Disconnect to disconnect your Patient Remote from your Implant.

3 Select OK on the second confirmation screen. (Figure 19)

Note If you do not want to disconnect, select Reconnect.

After you disconnect your Implant, you will see the Nearby Implants screen.

4 Click on the 3 dots in the upper right corner of the screen and select Lock Screen.

Note When your Patient Remote is not connected to your Implant, it will automatically lock after 15 minutes without any activity.
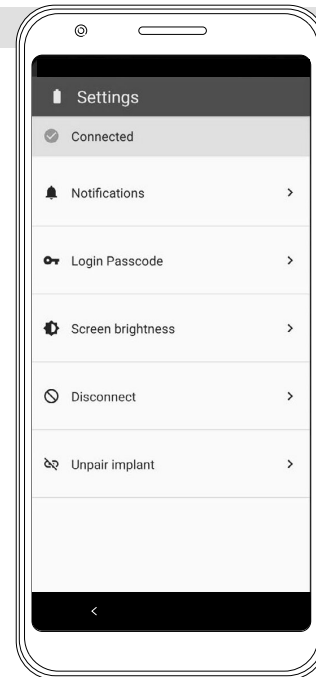
Figure 17 Select Disconnect
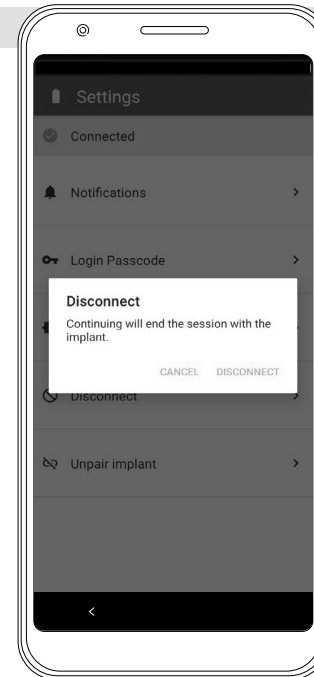
Figure 18 Confirm Disconnect from Implant
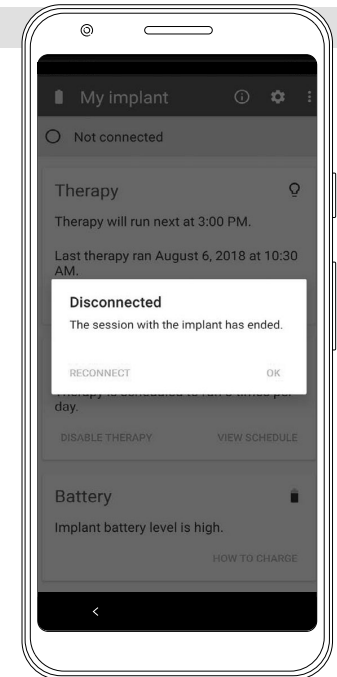
Figure 19 Message When Disconnected

Unpairing Your Implant

<u>This option should not be used under most circumstances.</u> If you want to end a session between your Patient Remote and your Implant, you should select the Disconnect option.

You should only need to use this option if your Study Coordinator or healthcare professional asks you to do so.

> **Note**   If you unpair your Implant, your Patient Remote will not automatically select your implant the next time that you try to connect to it. When you select the Nearby Implants button, you will need to pick your Implant from the displayed list.[1]

1   From the Settings screen, select **Unpair implant**. (Figure 20)

2   On the confirmation message:
- Select **Cancel** to return to the Settings screen without unpairing your Implant.
- Select **Unpair** to unpair your Implant. If you select Unpair, a few confirmation screens are displayed:
  - Select **Reconnect** to your implant.

    or
  - Select **OK** to unpair your implant.

After you unpair your Implant, you will see the Nearby Implants screen.

When your Patient Remote is not connected to your Implant, remember to lock it by selecting the three dots in the upper right corner and selecting **Lock Screen**.
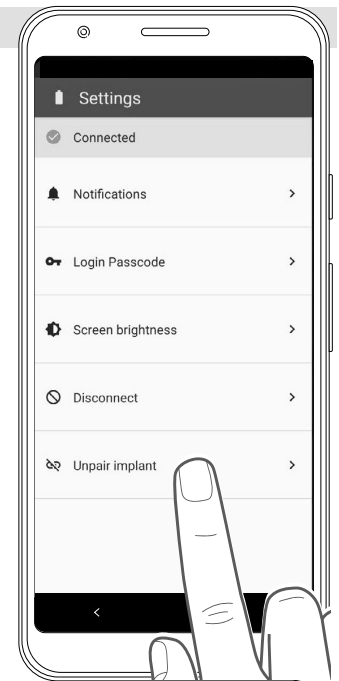
Figure 20 Select Unpair Implant

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1 Because your Patient Remote is registered to your Implant, you are only able to select your specific Implant from any implants listed on your Patient Remote. In the same way, other Patient Remotes cannot connect to your Implant.

Caring for Your Patient Remote

Checking the Battery Status of Your Patient Remote

1   Select the information icon (ⓘ) to display information about your Patient Remote and Implant. (Figure 21)

  The Device Information screen appears. This screen shows information for your Implant and for your Patient Remote.[1] (Figure 22)

2   Check the Battery Level listed under Patient Remote.

  If the battery level is less than 30%, charge your Patient Remote. For instructions, see "Charging Your Patient Remote", on page 22.

3   Select the back icon (<) to go back to the previous screen.
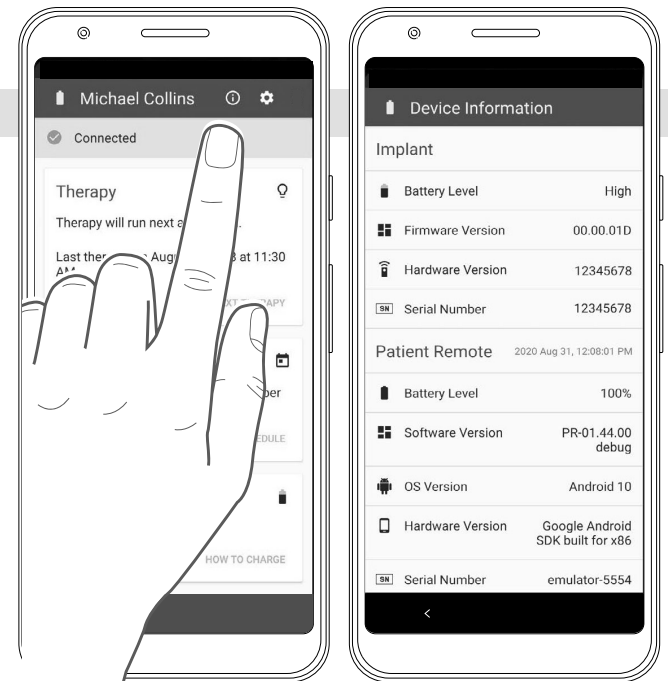
Figure 21 Information Icon

Figure 22 Device Information

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1 The Device and Implant information shown in this manual may not match what is displayed by your Patient Remote.

Charging Your Patient Remote

Select the information icon (ⓘ) on your Patient Remote to review the battery level.

Keep your Patient Remote charged using only the AC power adapter provided with your Patient Remote. Plug the provided AC Adapter power cord into a wall power outlet where you can easily unplug it again after charging. Plug the other end of the cord into USB port on your Patient Remote.

Check the battery status for your Patient Remote and when the battery status is 100%, remove the plug from your Patient Remote and unplug the cord from the power outlet.

> **Caution: Be careful when removing the power adapter for your Patient Remote or Charger from a power outlet. Use only the certified AC Adapter provided with your Patient Remote and Charger. These adapters have double-reinforced insulation between the input and output circuits and using other AC adapters may result in electrical or thermal injury.**

Keeping Your Implant and Patient Remote On Time

Your Implant has an internal clock and when it is connected to your Patient Remote, it confirms the correct time and time zone with the time used by your Patient Remote.

Supporting Notifications by Connecting to Your Implant Every Day

- If you set up Notifications for your Patient Remote, it is important to connect to your Implant every day so that your Patient Remote and Implant can align their internal clocks. If the Patient Remote does not connect and update the internal clock for your Implant every 24 hours, then any Notifications that you've set up will no longer be accurate and they will be disabled.

- After connecting to your Implant, your notifications will automatically resume for the next 24 hours.

Updating Your Patient Remote When Changing Time Zones

If you travel to a different time zone, the time setting for your Patient Remote automatically updates to the local time <u>using local cellular network coverage</u>. The next time you connect to your Implant, your Implant is updated to match the timezone used by your Patient Remote.

It is important that your Implant time uses the local time zone so that you receive your therapy at the correct local time of day. Since your Patient Remote only updates to the correct local time if connected to local cellular network coverage, it will not update to a new time zone if the coverage is not available. For a list of cellular network coverage areas, see "Appendix D Wireless Network Coverage", on page 68.

Bring your Patient Remote into an area with cell phone coverage at least once a week, even if you are not changing time zones, this will ensure that the Implant time remains accurate and consistent.

Cleaning, Handling, and Storing Your Patient Remote

Your Patient Remote is an important part of your Galvani System. It is the only way you are able to connect and communicate with your Implant so it is important to keep it safe.

Cleaning: Clean your Patient Remote with a soft lint-free cloth. Avoid getting moisture into any openings and do not use aerosol sprays, solvents, or abrasives.

Your Patient Remote contains no patient serviceable parts: Do not attempt to open or disassemble your Patient Remote to change the battery, the battery is not designed to be removed. Only use the provided power adapter (and optional international converter if applicable) to recharge the battery.

Handling: If your skin becomes red or irritated from using or handling your Patient Remote, tell your Study Coordinator or healthcare professional.

Storing Your Patient Remote: Do not expose your Patient Remote to extreme temperatures, for example do not leave it in your car where the temperatures could be either be too high or too low. See "Device Specifications for the Patient Remote", on page 60 for the recommended temperature range for your Patient Remote. Keep your Patient Remote away from children and pets. Avoid storing your Patient Remote where it could be exposed to lint, dust, pests, or direct sunlight.

Note   For more important information about caring for your Patient Remote, review the Cautions on page 6.

Chapter 3 View and Monitor Your Implant

When you connect your Patient Remote to your Implant, you can:

- Check the time of your next therapy session and the current therapy schedule.

- Check your Implant battery status.

- Delay or stop your therapy (see "Chapter 4 Delaying or Stopping Your Therapy", on page 30).

Connecting to Your Implant

You should connect to your Implant at least 2-3 times a week to check on your Implant battery level.
If you want to use the Notifications feature, you need to connect to your Implant once a day, for more information about Notifications, see page 18.

1 Select NEARBY IMPLANTS found in the center of the screen. (Figure 23)

Your Patient Remote will search for your Implant.

- **If your Patient Remote has connected to your Implant before**, it will automatically select your Implant and connect.
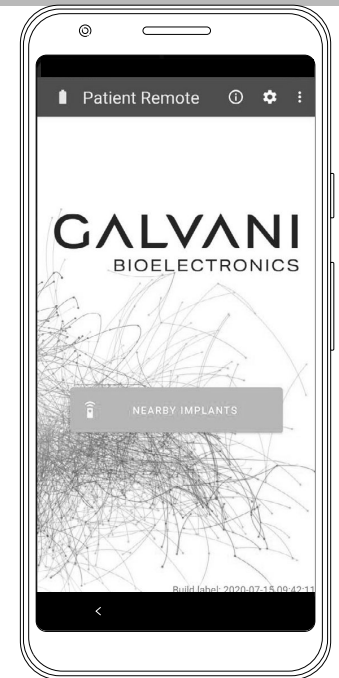
Figure 23 Select Your Implant

- **If your Patient Remote hasn't connected to your Implant before**, your Patient Remote will display a list of nearby implants. Select your Implant using the serial number provided by your Study Coordinator or healthcare professional.

  Note   Because your Implant is registered to your Patient Remote, you are only able to select your specific Implant from any implants listed on your Patient Remote. In the same way, other Patient Remotes cannot connect to your Implant.

- **If you cannot select your Implant**, it may not be registered to your Patient Remote. You need to contact your Study Coordinator or healthcare professional to have your Patient Remote registered with your Implant. This manual provides registration instructions if needed, see page 56.

2   When your Implant is connected, your Patient Remote displays the Main screen. (Figure 24)
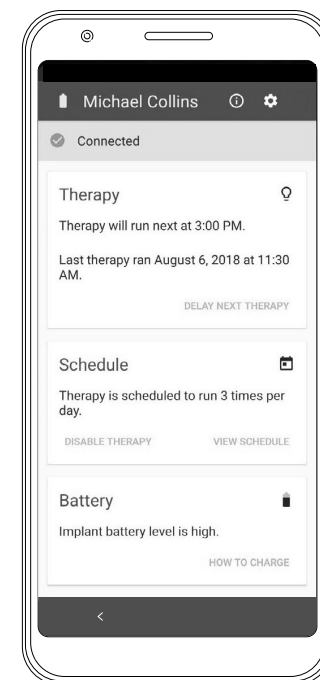
Figure 24 Main Screen

Reviewing the Main Screen

The Main screen of your Patient Remote provides information and options for your therapy and Implant. (Figure 25)

Status Bar

When your Implant is connected to your Patient Remote, the blue Status bar at the top of the Main screen shows Connected with a green check mark. When your Implant is not connected to your Patient Remote, the Main screen is not displayed. The Status bar displays Disconnected when your Patient Remote is not connected to your Implant.

The Status bar also displays other confirmation and status messages such as "Implant Battery is Low".

Therapy

Information: The Therapy section of the Main screen shows you the time for your next therapy and the day and time of your last therapy.

Actions: Select DELAY NEXT THERAPY from the Therapy section to change the time for your next therapy. For instructions about delaying your therapy, see "Delaying Therapy", on page 30. Confirm with your doctor or Study Coordinator that this option is available for you.
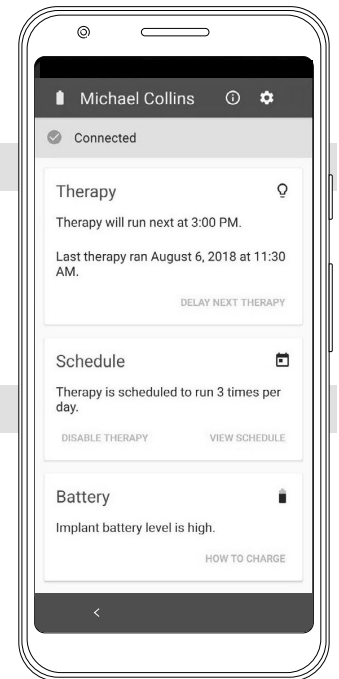
Figure 25 Main Screen

Schedule Therapy

Information: The Schedule section of the Main screen shows how often your therapy is scheduled.

Actions:

- Select DISABLE THERAPY from the Schedule section of the Main screen to turn your therapy OFF. If you turn your therapy OFF, you may need to visit your doctor to turn your therapy back ON. (Figure 26)

  Note   Contact your Study Coordinator or healthcare professional to discuss concerns or symptoms if you intend to disable your therapy.

  If you have significant discomfort due to the therapy, see "Using The Charger to Stop Therapy", on page 32.

- Select VIEW SCHEDULE to see how your doctor has scheduled your therapy. (Figure 27)
  Select DISMISS to return to the Main screen.
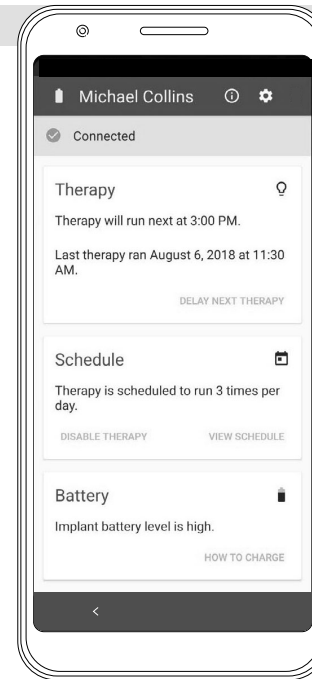
Figure 26 Main Screen
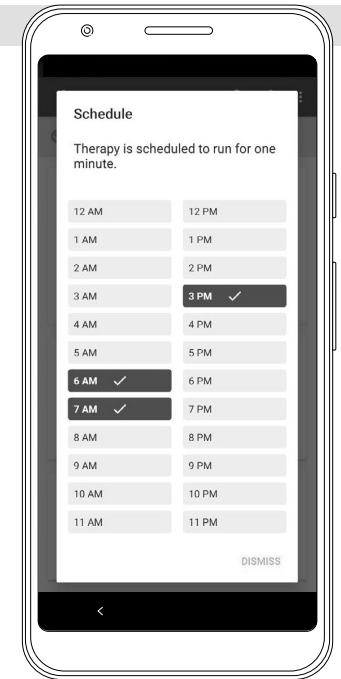
Figure 27 View Schedule

View Implant Battery Status

Information: The Battery section of the Main screen shows the current battery level of your Implant. The battery levels are High, Medium, Low, and Very Low.

Actions: Select HOW TO CHARGE to display instructions on the screen for charging your Implant. (Figure 28 - Figure 31)

For more details, see "Chapter 5 Using the Charger", on page 34.
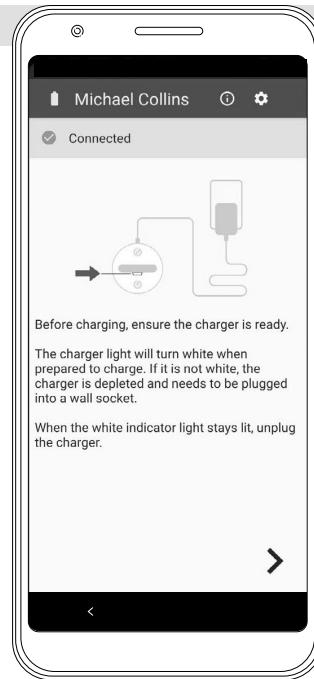
Figure 28 How to charge screen 1
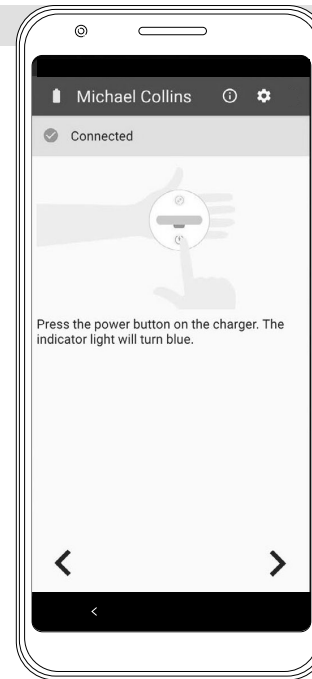
Figure 29 How to charge screen 2
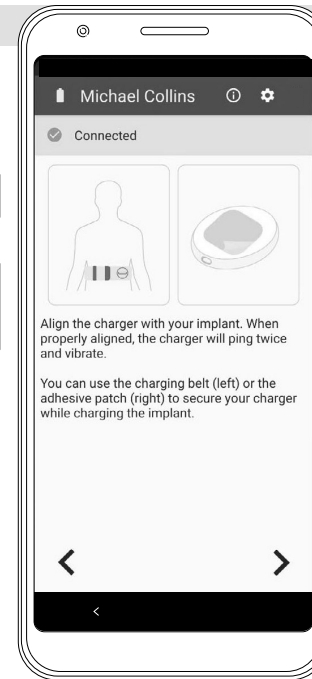
Figure 30 How to charge screen 3
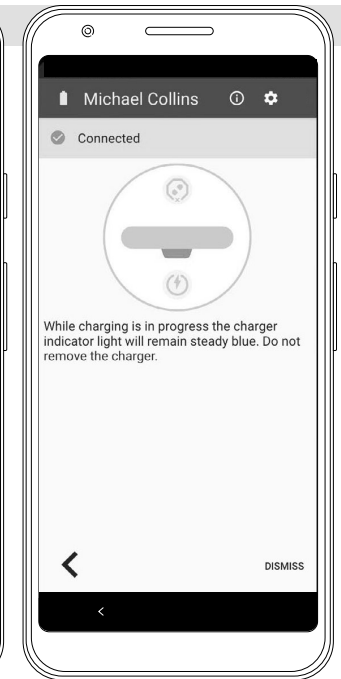
Figure 31 How to charge screen 4

Displaying Implant Device Information

Select the Information icon (ⓘ) at the top of the Main screen to display the Device Information screen. This screen gives you information about your Implant and your Patient Remote. (Figure 32)[1]

If your Patient Remote is not connected to your Implant, the Device Information screen only displays information about your Remote, such as:

- Patient Remote date and time
- Patient Remote Battery Level
- Patient Remote Software Version
- Patient Remote Operating System (OS) Version

- Patient Remote Hardware Version
- Patient Remote Serial Number
- Manufacturer information

After your Patient Remote is connected to your Implant, the screen also displays:

- Implant Battery Level
- Implant Firmware Version
- Implant Operating System (OS) Version

- Implant Hardware Version
- Implant Serial Number
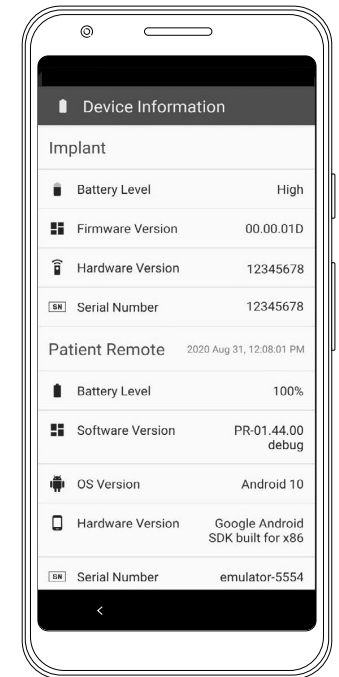
Figure 32 Device Information

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1 The Device and Implant information shown in this manual may not match what is displayed by your Patient Remote.

Chapter 4 Delaying or Stopping Your Therapy

There may be times when you want to delay or stop your therapy. Speak with your Study Coordinator or healthcare professional about whether the Delay Therapy and Stop Therapy options are available for your therapy.

Note If you have significant discomfort due to the therapy, see "Using The Charger to Stop Therapy", on page 32 for instructions.

Delaying Therapy

1 From the Main screen, locate the Therapy section.

2 Select DELAY NEXT THERAPY. (Figure 33)

The Delay Therapy screen shows the next scheduled therapy time.

3 Select the drop-down menu and pick the amount of time you want to delay the therapy. (Figure 34)

After selecting the delay time, the screen shows the adjusted time for your next therapy.

4 Select CONFIRM. (Figure 35)

The Main screen shows the updated time for your next therapy.
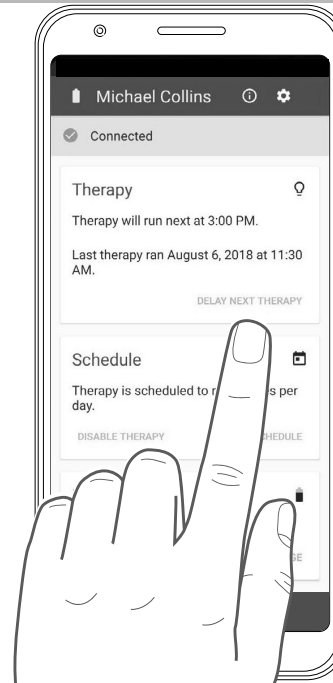
Figure 33 Delay Therapy   *Figure 34 Delay Options*   *Figure 35 Delay Therapy Screen*
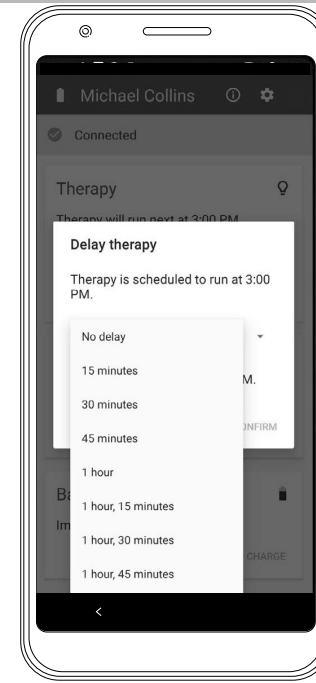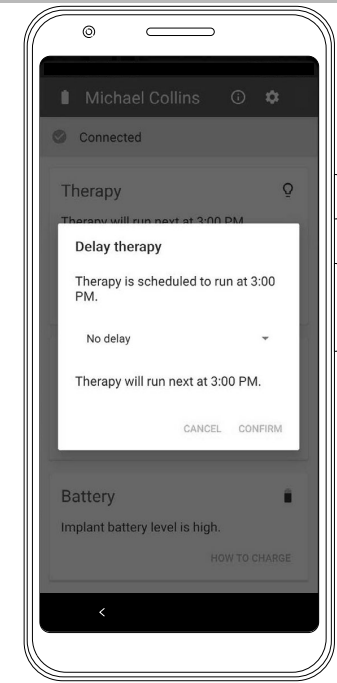
Stopping Therapy

There are two ways to stop your therapy, using your Patient Remote or using the Charger.

Patient Remote: Use your Patient Remote to stop your therapy. Your Patient Remote needs to be connected to your Implant before you can use it to stop your therapy.

Charger: Use the Charger to stop your therapy. For instructions, see "Using The Charger to Stop Therapy", on page 32.

If you disable your therapy, you may not be able to turn it back ON again. Confirm with your Study Coordinator or healthcare professional about whether you can re-enable therapy after stopping it.

Using Your Patient Remote to Stop Therapy

1 From the Main screen, locate the Schedule section in the center of the screen.

2 Select DISABLE THERAPY. (Figure 36)
   - Select CANCEL to continue with the scheduled therapy.
   - Select CONFIRM to stop your therapy.

3 Contact your Study Coordinator or Rheumatologist as soon as possible to tell them that you have stopped your therapy.

   Note   If your therapy is turned OFF, when you charge your Implant you will notice that the Stop Therapy button on the Charger lights up placed over your Implant. This is a reminder that your therapy is OFF.
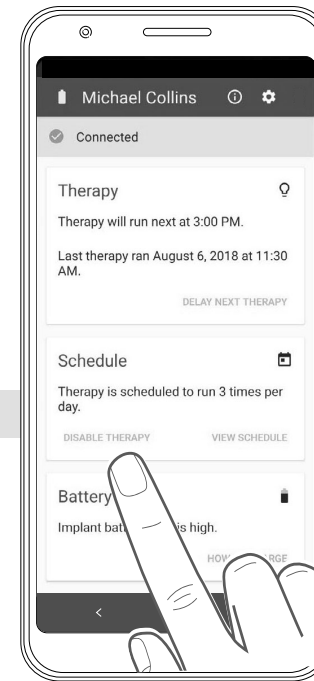
Figure 36 Main Screen
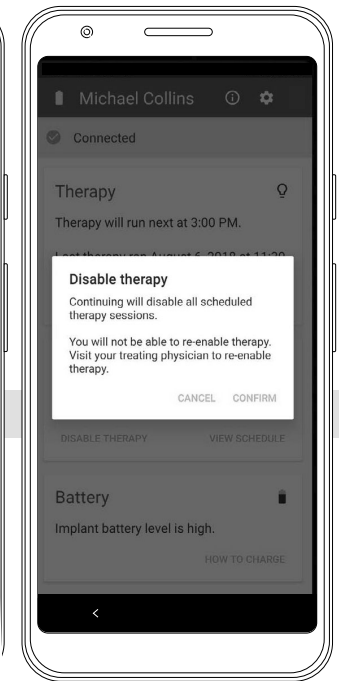
Figure 37 Disable Therapy

Using The Charger to Stop Therapy[1]

1   Start with the Charger in your hand, not over your implant.

2   **Press and hold** the Stop Therapy button for 10 seconds[2]. (Figure 38)

> **Note**   You do not need to turn the Charger ON before pressing Stop Therapy button.

- While you are pressing the button, the Charger Status light turns pink. After 10 seconds the pink light starts quickly flashing.

- You will feel a repeated vibration and hear a long, low tone about every 3 seconds. This means that the Charger is searching for your implant.

3   When you hear the tone, take your finger off the Charger button and place the Charger on your skin over your Implant.
- When the Charger locates your Implant, you will feel 1 vibration and hear 2 pings. (If the Charger battery is too low, you may not be able to feel the vibrations or hear these sounds.)

- The Charger Status light changes to solid White and the Stop Therapy button turns solid White. This shows that your therapy is now OFF.

4   You can remove the Charger from your implant.

5   Contact your Study Coordinator or healthcare professional as soon as possible to tell them that you have stopped your therapy.

> **Note**   If you want to stop your therapy while the Charger is charging your Implant, lift the Charger off your implant and press the Charger Power button to turn the Charger OFF. Then follow the steps above to stop your therapy.

When your therapy is turned OFF, the Stop Therapy button on the Charger will light up when placed over your Implant. This is a reminder that your therapy is OFF.

Figure 38 Charger Stop Therapy Button

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1 Before using the Charger to stop your therapy, make sure that the Charger battery is charged (see "Charging the Charger", on page 46).
2 If there is no initial response on the Charger when you press a button, remove finger from the button for at least 1-2 seconds and press again.

Re-enabling Your Therapy

If you stopped your therapy, you may be able to re-enable it again.

Check with your Study Coordinator or healthcare professional to confirm whether or not you can re-enable your therapy after stopping it.

1   From the Main screen, locate the Schedule section in the center of the screen.

2   Select ENABLE THERAPY. (Figure 39)
   - Select CANCEL to keep your therapy OFF.
   - Select CONFIRM to re-enable your therapy. (Figure 40)
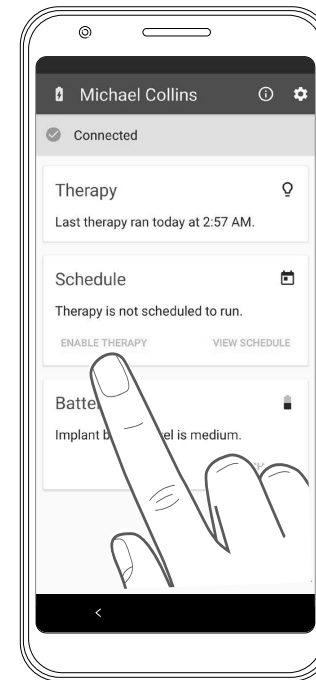
Figure 39 Select ENABLE THERAPY
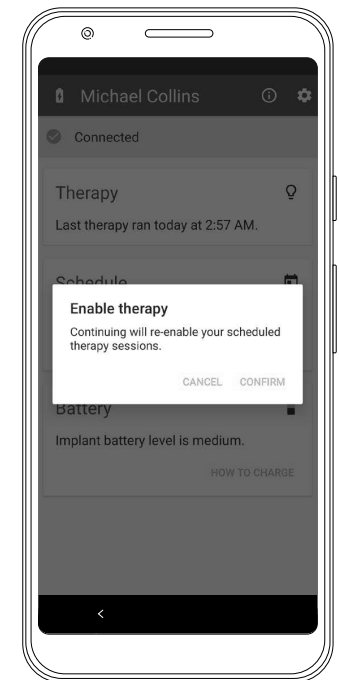
Figure 40 Select CONFIRM

Chapter 5 Using the Charger
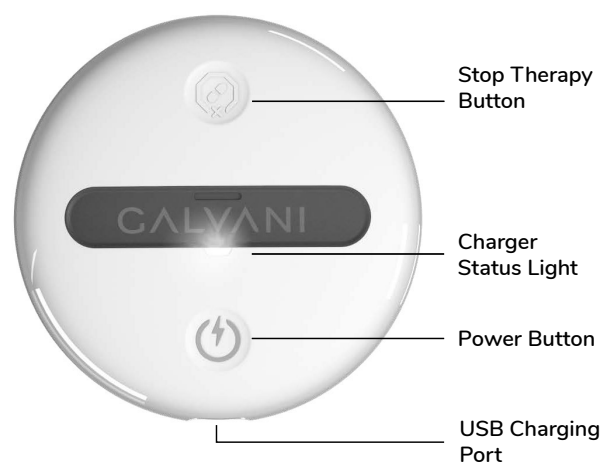
Figure 41 Charger Buttons and Lights

The Charger connects to your Implant using wireless technology to charge the battery of your Implant. It can also be used to stop your therapy. (For more information, see "Using The Charger to Stop Therapy", on page 32.)

Reviewing the Charger

Stop Therapy Button: This button is marked with a capsule inside a circle with an X to indicate "Therapy OFF". You would press this button if your therapy was uncomfortable and you need to turn it OFF. For instructions about turning your therapy OFF, see "Using The Charger to Stop Therapy", on page 32.

Power Button: The Power button is used to turn the Charger ON and OFF.

Charger Status Light: This light is White when the Charger is turned On and battery is fully charged. The light changes to yellow when the battery is low. It also changes color when you are charging your Implant. For detailed information about the Charger lights and sound alerts, see "Understanding the Lights and Sounds of the Charger", on page 47.

USB Charging Port: Plug the provided charging cord into the USB charging port on the Charger and plug the other end into a power outlet to charge the Charger, see "Charging the Charger", on page 46.

Charging Your Implant

You should charge your Implant battery at least 2 to 3 times a week. You can check your Implant battery status from the Main screen of your Patient Remote. When the Implant battery level is medium or low, it is time to charge. When charging, the Charger needs to be placed on your skin over your Implant. You can use either the provided Charging belt or adhesive patches to hold the Charger in place while charging.

Before using the Charger to charge your Implant:

- Make sure that the Charger battery is fully charged, see "Charging the Charger", on page 46.

- Make sure that the Charger is **unplugged** while charging your Implant.[1]

- The Charger must be placed directly on your skin. Make sure you do not place the Charger over any clothing.

- Keep any metal objects, even small objects, at least 6 inches away from the Charger while charging. (For example, belt buckles, rings, metal buttons.)

  Note If you experience any redness or swelling of your skin after charging your implant, you may have a sensitivity to the Charger belt or adhesive patch. Tell your Study Coordinator or healthcare professional.

  Note If you wait longer than three months to recharge your implant, it may not have enough battery to communicate with your Patient Remote. You will still be able to charge your implant using your charger, however if you repeatedly wait to charge your implant longer than three months, your implant battery will need to be charged much more frequently in the future or may even require replacement.

  Warning ! If the Charger becomes uncomfortably warm while charging your implant, immediately remove it from your skin. Wait until the charger cools before starting to charge your Implant again. Contact your study administrator who can help you determine if the Charger is operating correctly.

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1 The buttons on the Charger are disabled when the Charger is plugged into a power outlet.

Monitoring the Implant Battery While Charging

You can use the Patient Remote to monitor the Implant battery level while charging. Connect your Patient Remote to your Implant before starting to charge the Implant battery. Your Patient Remote will display the status of the Implant battery. When the battery level is at High, you can stop charging.

If your Patient Remote becomes diconnected from your Implant while charging. Reconnect to your Implant as you would normally, you do not need to stop charging.

A normal time estimate for Charging is 2 hours, although depending on your therapy and how often you charge your Implant this time can vary.

Using the Adhesive Patch When Charging

1   If this is the first time using the adhesive patch, apply it to the back of the Charger. (Figure 42)

   a   Peel off the paper from the back of the soft fabric patch and apply it to the back of the Charger. This fabric surface attaches to a disposable Velcro® adhesive patch that holds the Charger on your skin while charging.

   b   Press the Velcro® patch against the fabric on the back of the Charger. You will leave this soft patch on the back of the Charger for many uses.

  Note   Do not peel off the backing tape on the sticky side of the patch yet. You first need to locate your Implant.

Figure 42 Apply Adhesive Patch to the Back of the Charger

2   Press the Power button on the Charger. The Charger Status light turns Blue. (Figure 43)

3   Locate your Implant.

    a   Place the Charger against your skin over your Implant.

    b   As the Charger begins searching for your Implant, you will feel a repeated vibration and hear a long, low tone about every 3 seconds.

    c   Slowly move the Charger around the area over your Implant.

    d   When the Charger locates the Implant, it will ping 2 times and vibrate.

    e   Lift the Charger up and place your finger on the location of your Implant.

4   Peel off the backing tape from the sticky side of the disposable patch on the back of the Charger.

5   Firmly press the Charger with the sticky patch against your skin over the spot marked by your finger (where the implant is located).

Note   The Charger must be applied directly to your skin and not over any clothing or fabric. If the adhesive patch does not stick to your skin, remove the patch from the back of the Charger and apply a new patch. The patches are designed for only one use.

When the charger locates the Implant, it will ping 2 times and vibrate. At this point, the Charger is actively charging your Implant.

- If the charger moves out of place during charging, it will alert you with the searching vibrations and a long, low tone about every 3 seconds. Move the Charger back into place and you will again feel 1 vibration and hear 2 pings.

- The time required to charge your Implant depends on how often you charge your Implant. If you charge more frequently, the charge time will be shorter.

6   Check the battery status for your Implant frequently using your Patient Remote. The battery status is displayed on lower part of the Main screen.

Power Button

Figure 43 Charger Power Button

7   Stop charging when your Patient Remote shows Battery: Implant battery level is high.

   Note   It is not recommended that you keep charging your Implant after your Patient Remote shows the Implant battery level is at High. If you continue charging your Implant after the battery is charged to High, it may take considerably more time to reach Full charge and it is not necessary. (When your Implant battery is charged to Full, the Charger Status light changes to solid White and the Charger may vibrate and make a pulsing sound every 6 seconds while it remains over your Implant.)

8   Gently remove the Charger with the adhesive patch from your skin.

   a   Grasp the charger with one hand and with your other hand hold the skin next to the charger.

   b   Slowly tilt the charger away from where you are holding the skin and gently lift it away.

9   Press the Charger Power button to turn it OFF.

10 Remove the adhesive patch from the back of the Charger and discard. Leave the soft fabric patch on the back of the Charger.

   Note   Contact your Study Coordinator for more adhesive patches if needed.

Using the Charging Belt When Charging

1   Place the charging belt around your body with the pocket facing out.

   Note   The charging belt must be placed directly on your skin. Make sure you do not place the charging belt over any clothing.

2   Tighten the charging belt and secure it with the Velcro® flap so that the belt is tight but comfortable.

3   Rotate the charging belt around your body so that the pocket is centered in front, as shown in Figure 44.

4   Press the Power button on the Charger. The Charger Status light turns Blue. (Figure 45).

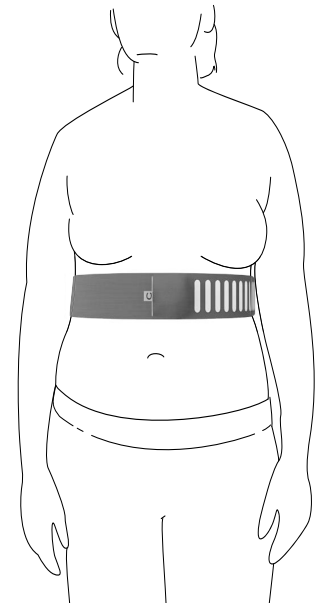Power Button

Figure 45 Charger Power Button

Figure 44 Place the Charging Belt around your body with the pocket facing out.

5   Slide the Charger into the charging belt pocket, as shown in Figure 46, first A then B.

6   The front of the Charger (the side with the light and buttons) should face out.

As the Charger begins searching for the Implant, you will feel a repeated vibration and hear a long, low tone about every 3 seconds.

7   To help the Charger locate your Implant, very slowly rotate the charging belt with the Charger, back and forth around your body, while keeping the Charger over your Implant.

- When the Charger locates the Implant, it will ping 2 times and vibrate.

- While your Implant battery is charging, use your Patient Remote to frequently check the battery status. The battery status is displayed on lower part of the Main screen. (Figure 47)

- If the Charger moves out of place during charging, it alerts you with the searching vibrations and a long, low tone about every 3 seconds. Move the Charger back into place until you feel 1 vibration and hear 2 pings.
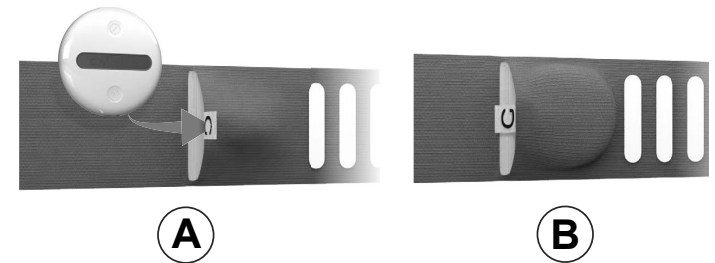

A   B

Figure 46 Slide the Charger into the Charging Belt Pocket

8   Stop charging when your Patient Remote shows Battery: Implant battery level is high.

   Note   The time required to charge your Implant depends on how often you charge your Implant.
   If you charge more frequently, the charge time will be shorter.

9   Remove the Charger from the charging belt.

10 Press the Charger Power button to turn it OFF.

11 Take off the charging belt.

   Note   It is not recommended that you keep charging your Implant after your Patient Remote shows the Implant battery level is at High. If you continue charging your Implant after the battery is charged to High, it may take considerably more time to reach Full charge and it is not necessary. (When your Implant battery is charged to Full, the Charger Status light changes to solid White and the Charger may vibrate and make a pulsing sound every 6 seconds while it remains over your Implant.)
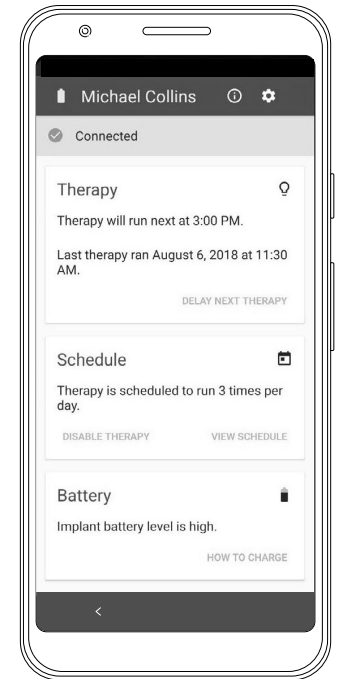

Figure 47 Check Implant Battery Level

Troubleshooting Charging

What happens if my Charger battery runs out while I am charging my Implant?	If the Charger runs out of battery it will vibrate and make a searching sound (long, low tone) about every 6 seconds, and the Charger Status light changes to yellow. If this happens, stop charging your Implant and charge the Charger. **Note** Do not plug in the Charger and try to charge it while you are charging your Implant. The Charger should not be plugged into a power source while you are charging your Implant.
Can I leave my Charger power cord plugged in when I am not using it?	No, you should only have the power cord plugged in while you are charging the charger.
Are there any activities that I should avoid while I am charging my Implant?	Charging your Implant should not be affected by most activities, but do avoid: • Driving a car or operating machinery. • Falling asleep • Charging while the Charger is plugged into a power outlet.

If my Patient Remote displays the following message:	The "Could not connect." message appears when the Charger cannot connect to your Implant after searching for more than 60 seconds.

"Could not connect, The Charger was not aligned over the implant within 60 seconds."	**Why this might happen:**
	
	• The Charger is not centered over your Implant. Try moving the Charger over your Implant until you hear the confirmation sounds and vibration.
	
	• Your Patient Remote is not close enough to your Implant.
	
	    • For example, if another person is holding your Patient Remote while trying to connect and they are not close enough to your implant. If someone else is using your Patient Remote for you, make sure that they are within 3 feet (1 meter) and there are no objects between your Implant and your Patient Remote.
	
	    • Make sure that there are no objects between your Patient Remote and your Implant that may obstruct.
	Action: Start over by pressing the Charger Power button. When the Charger Status light changes to Blue, place it over your Implant. Continue with instructions found in "Chapter 5 Using the Charger", on page 34.
	
	If you cannot connect to your Implant to charge it after following these steps, contact your Study Coordinator or healthcare professional.

What does it mean if my Patient Remote shows this message when I'm trying to charge my Implant: "**Could not connect.** **A connection could not be established with the implant. If you continue experiencing issues, contact your treating physician**"	**Why this might happen:** Your Patient Remote is not close enough to your Implant. For example, if another person is holding your Patient Remote while trying to connect and they are not close enough to your implant. Try moving your Patient Remote closer to your Implant and keep it close while charging. **Action:** Start over by pressing the Charger Power button. When the Charger Status light changes to Blue, place it over your Implant. Continue with instructions found in "Chapter 5 Using the Charger", on page 34. If you continue to have problems connecting to or charging your Implant, contact your Study Coordinator or healthcare professional.
How do I turn OFF my Charger?	Press the Charger Power button to turn it OFF. • The Charger turns OFF automatically if you stop using it for a while. • Remember, turning OFF the Charger does not turn OFF therapy. To turn OFF therapy right away due to significant discomfort, press the Stop Therapy button. Full information about stopping therapy, see "Using The Charger to Stop Therapy", on page 32. Power Button

What if the Charger power button does not turn on the Charger?	If the Charger Power button does not respond, reset the Charger using the following steps.
	1 Plug the USB charging cord into the Charger.
	2 Plug the AC adapter into a power outlet.
	3 Remove the USB charging cord from the Charger.
	4 Press the Power button and the Charger Status light comes ON..
What if I have other questions about charging?	Contact your Study Coordinator or healthcare professional with any other any questions you have.