CLINICIAN APP

FOR SACRAL NEUROMODULATION THERAPY

A510

Clinician Programming Guide for the InterStim™ System

! USA Rx only

CE 0123 2018

Medtronic

SYMBOLS

Explanation of symbols in this manual

Refer to the appropriate product for symbols that apply.

Manufacturer

Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive AIMD 90/385/EEC (NB 0123).

Authorized representative in the European community

For USA audiences only

The handset, as configured, does not support voice communication and therefore cannot be used to make any calls (including emergency calls).

Refer to the indications sheet for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to the MRI Guidelines for the InterStim™ system for the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan.

Refer to System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications.

! USA Refer to the clinical summary for information on the clinical study results of the neurostimulation system and individualization of treatment.

TABLE OF CONTENTS

WARNINGS AND CAUTIONS

WARNING: Wound contact — Do not use the communicator on an unhealed wound. The communicator is not sterile, and contact with the wound may cause an infection. Place a sterile bandage or barrier between the wound and device.

WARNING: Sterile field — When using the communicator in a sterile field, place the communicator in a sterile bag. The communicator is not sterile and cannot be sterilized.

△ **CAUTION: Telemetry signal disruption from EMI** — Do not attempt telemetry near equipment that may generate electromagnetic interference (EMI). EMI may cause a disruption in clinician programmer function.

OVERVIEW

The Medtronic Model A510 Clinician application (app) is intended for use with the HH90 Handset and TM90 Communicator to program, adjust, and troubleshoot the Medtronic Models 3023 and 3058 InterStim™ neurostimulators for sacral neuromodulation therapy. The clinician uses the Clinician app to program settings for the patient.

InterStim™ System Components

The InterStim™ system for sacral neuromodulation therapy includes the following components:

- Medtronic Model HH90 Handset and accessories
- Medtronic Model A510 Clinician app loaded on the Medtronic Model HH90 Handset
- Medtronic Model A520 My Therapy app loaded on the Medtronic Model HH90 Handset
- Medtronic Model 3023 or Medtronic Model 3058 InterStim implantable neurostimulator and leads
- Medtronic Model TM90 Communicator

About This Guide

This programming guide contains information a clinician needs to set up, use, and troubleshoot the clinician app on the handset. This guide provides instructions on how to use the A510 Clinician app to program an implanted neurostimulator. This guide is intended to be used for InterStim™ system implantable neurostimulators.

Before using the clinician app for the first time, refer to the Quick Start Guide for initial handset setup. All patient-related instructions on using the patient app on the handset are included in the A520 My Therapy App Patient User Guide for the InterStim system.

QUICK TIPS

See the following information for helpful tips to aid you in using the clinician app, and to help you better understand the contents of this programming guide.

Using the Workflow Navigator

The workflow navigator is displayed at the top of every screen when you are in a workflow and represents the screens/ tasks that can be completed on each screen. A title that is highlighted and underlined in the workflow navigator indicates your position in that workflow. For more information on workflows, see “WORKFLOWS” on page 15.

You can use the workflow navigator in the following ways:

- Swipe to the left or right to view previous or subsequent screens within a workflow.
- Tap on a title to jump to a different screen.

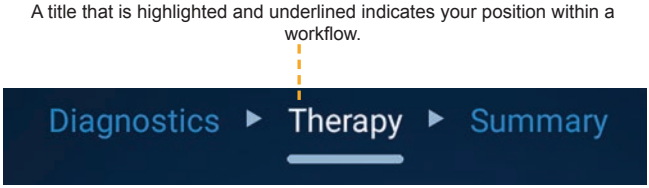


Figure 1. Workflow navigator

Indicators and Icons

The following is a list of the icons found in the clinician app along with their associated descriptions.

Notes:

- The following is not an all-inclusive list of all the icons found in the clinician app, but rather a list of the more

important icons or those that appear most frequently within the app.

- If an icon or button appears gray within the clinician app, that option is not available.

Icon	Icon description
	Tap for additional screen options.
	Indicates that the neurostimulator device has been previously paired.
	Tap to access the About screen, Manage Devices screen, or end a programming session. This icon appears only when in a workflow or on the Home screen.
DEMO:	Indicates that the clinician app is operating in Demo mode.
	Displays the current electrode configurations settings for a program.
	Tap to check battery level.
	Tap to check impedance.
	Tap to exit the current screen and go back to the one you were previously on.
	Indicates the program is enabled for patient use, and is visible to the patient.
	Indicates the program is not enabled for patient use, and is not visible to the patient.
	Tap to end the current programming session and return to the Password screen.

GETTING STARTED

Before using the clinician app to program the neurostimulator, see the following sections for basic information about:

- Accessing the clinician app
- Creating a password
- Using the menu screen
- Operating in Demo mode
- Pairing to the implanted neurostimulator

Accessing the Clinician App

You can access the clinician app by locating the following icon on the main screen of the handset (Figure 2). Tap the icon to open and begin using the clinician app.

Figure 2. Clinician app

Creating a Password

The clinician app requires a password to use the app. A password is required to be entered under the following conditions:

- Upon launch of the app
- After 30 minutes of inactivity

Note: When you launch the clinician app for the first time, you will be asked to enter the default password. Contact Medtronic support for the default password. You will need to obtain the default password before creating your own unique password.

To create a password:

1. Enter the Medtronic default password in the appropriate field. Contact Medtronic support to obtain the default password if you haven't already.
2. Tap **OK** to continue to the next screen.
3. Enter your unique password in the appropriate field.

   Note: The password is case-sensitive and must contain at least six characters.
4. Confirm your new password by entering it for a second time in the appropriate field and tap **CREATE** when finished.

   Note: For information on resetting a forgotten password, see "TROUBLESHOOTING" on page 48.
5. Select your region using the options provided on the handset.
6. Tap **NEXT** to continue on to the Menu screen.

Menu Screen

Upon entering your password, you are taken to the Menu screen. On the Menu screen, you can access Demo mode, connect the communicator and neurostimulator to the handset, or access patient reports.

Demo Mode

Demo mode allows you to simulate using the clinician app without being paired to an actual neurostimulator device. DEMO is displayed next to the screen title when the clinician app is operating in Demo mode.

Pairing the Communicator and the Neurostimulator

All programming functionality takes place within the Connect option on the Menu screen. Tapping this option allows you to

begin the process of pairing the communicator and implanted neurostimulator to the clinician app on the handset.

To pair the communicator and implanted neurostimulator:

1. Press ⏻ on the communicator to turn the communicator on.
2. Navigate to the Menu screen, and tap **CONNECT.**
3. Place the communicator near the handset.
4. Tap . The communicator will attempt to connect to the handset. The blue LED indicator on the communicator will continuously blink to indicate it is on and in discovery mode.
5. If you have previously paired the communicator to the handset, the communicator will automatically attempt to connect to the handset. If the blue LED indicator on the communicator is solid and no longer blinking, the communicator is now connected to the handset, skip to step 8.

   Note: If you are having trouble connecting the communicator to the handset, see ““TROUBLESHOOTING” starting on page 48.
6. If the communicator has not been previously paired to the handset, tap **SWITCH COMMUNICATOR** on the handset**.**
7. Select the appropriate communicator device according to the serial number shown on the Connection screen, and tap **CONTINUE**. The blue LED indicator on the communicator will be solid and no longer blinking. This signifies the communicator is now connected to the handset.

   Note: The serial number, e.g. NPA-xxxxxxx, is located on the back of the communicator, and should match what is listed on the Connection screen.

   △ **CAUTION**: Ensure you are connecting to the proper communicator by confirming the serial number on

the device. Failure to do so could extend the implant procedure or programming session.

8. Ensuring the communicator is on, place the communicator over the implanted neurostimulator site and tap **FIND DEVICE** on the handset.
9. Select the appropriate neurostimulator device according to the serial number and tap **CONTINUE**. If the neurostimulator serial number is not listed on the Connection screen, tap **RETRY**.

   Notes:

   - displayed next to the serial number of the neurostimulator device indicates that the device has been previously paired to the handset.
   - If you are having problems pairing to the neurostimulator, refer to “TROUBLESHOOTING” on page 48.

WORKFLOWS

Workflows are used to assist you in completing programming sessions. Workflows for programming an implanted neurostimulator include:

- Configure implant
- Check impedance
- View MRI status

Starting a Workflow

Starting a workflow allows you to complete tasks for a programming session. You can access workflows on the Home screen.

To start a workflow:

1. Tap the name of a workflow to see an expanded view and description.
2. Tap **START** to proceed with the desired workflow.

Configuring the Implanted Neurostimulator (Configure Implant Workflow)

The Configure Implant workflow allows you to configure the neurostimulator for a patient. The main features of the Configure Implant workflow include:

- Manage patient information
- Configure therapy parameters
- Check therapy and/or electrode impedance
- Check battery status and/or run a battery longevity estimate
- Enable programs for patient use
- Create custom programs
- View a session report

Entering patient information

The Patient screen allows you to enter optional patient information (name, patient ID, gender, and date of birth).

Checking device and system status

The Status screen provides information about the neurostimulator and allows you to check the battery status of the neurostimulator and system impedance. Notice the battery and impedance rows; tap the battery and impedance icons for details. Table 1 displays the device status icons and their associated meaning/descriptions.

Table 1. Neurostimulator device status descriptions

Icon	Description	Meaning
	Orange circle with exclamation point	Status is suspect. Requires further investigation.
	Green circle with check mark	Status is good. No further investigation needed.

Note: A question mark appears in the impedance row if an impedance check has not been performed.

Battery level

Table 2 shows the battery and status display of the models 3023 and 3058 neurostimulators. If the neurostimulator battery level is below 15%, a low battery notification displays on the Home screen. The notification persists until the neurostimulator is replaced; however, you have the ability to dismiss the notification at any time.

To check neurostimulator battery level:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Status** screen, and tap ▭ next to the

battery level to view the current battery status of the neurostimulator.

4. Tap **DONE** to exit the Battery screen when finished.

Longevity estimate

The longevity estimate provides therapy impedance, neurostimulator battery longevity estimate, and program settings for the active program. A longevity estimate for the implanted neurostimulator can be obtained from the Battery screen.

To obtain a neurostimulator battery longevity estimate:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the Status screen, and tap  .
4. Tap **THERAPY MEASUREMENT**.

   Note: Therapy must be turned on to run therapy measurement.
5. Tap **DONE** to return to the Battery screen.
6. Tap **DONE** again to return to the Status screen.

Table 2. Model 3023 and 3058 Neurostimulator battery status descriptions

Approximate Battery Capacity	Model 3023 Neurostimulator	Model 3058 Neurostimulator
More than 15%	**Status**:  **Battery Level**: OK **Longevity**: Estimated number of months of battery longevity (based on new battery).	**Status**:  **Battery Level**: OK **Longevity**: Estimated number of months of battery longevity (based on estimated remaining capacity until LOW).

Approximate Battery Capacity	Model 3023 Neurostimulator	Model 3058 Neurostimulator
5-15%	**Status**:  **Battery Level**: LOW No battery longevity information is displayed.	**Status**:  **Battery Level**: LOW
Less than 5%	**Notification**: End of Service (EOS). Therapy will be stopped and the neurostimulator needs to be replaced. No access to the clinician application beyond this notification.	**Notification**: End of Service (EOS). Therapy will be stopped and the neurostimulator needs to be replaced. No access to the clinician application beyond this notification.

Notes:

- Do not implant the neurostimulator if the battery status displays LOW or EOS prior to implant.
- The longevity measurements are conservative estimates and are not intended to be device replacement indicators. Use LOW and EOS alerts for decisions on device replacement.
- If Cycling or SoftStart/Stop is enabled, longevity measurements may be inaccurate. See “Selecting Cycling feature and time” on page 27 as well as the System Eligibility, Battery Longevity, Specifications Reference Manual for more information.
- Displayed battery longevity is only an estimate, based on estimated battery capacity (Model 3058 only) and program settings. Longevity estimates are intended to reflect the relative effects of different programs on neurostimulator longevity. Actual longevity depends on programmed parameters and patient use. Later changes made to parameter settings, using either the clinician programmer or the patient programmer, will affect subsequent battery

longevity. Also refer to the System Eligibility, Battery Longevity, Specifications Reference Manual for battery longevity calculations.

For the Model 3058 Neurostimulator:

- The Model 3058 neurostimulator should be allowed to stabilize at body temperature for at least one week before conducting Therapy Measurements. The longevity measurements provided prior to this period or prior to implant may be lower than expected.
- If the Model 3058 neurostimulator has experienced a Power on Reset (POR) condition the estimated number of months of battery longevity will be based on a new battery.
- If the estimated battery capacity is greater than 15% of the original capacity, the following additional information is displayed:
  - Number of months of estimated battery longevity is based on remaining estimated battery capacity and program settings.

Impedance measurements

You can check impedance on the Status screen of the Configure Implant workflow, or within the Check Impedance workflow.

Note: Electrodes with impedance measurements outside the nominal impedance range will display an orange icon. See “Table 1. Neurostimulator device status descriptions” on page 16 for details.

To check impedance from the Configure Implant workflow:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Navigate to the **Status** screen.
3. Tap Ω.
4. Tap Ω again to check electrode impedance on the

Impedance screen.

5. Tap **DONE** when finished.

   Notes:

   - Tapping Ω on the status screen will take you to the Impedance screen where you can view the current impedance values of the respective electrode pairs and neurostimulator case.
   - You can tap the status icon on any electrode to view the current impedance values.
   - You have the option to adjust therapy amplitude and/or pulse width temporarily while conducting an impedance check on the Impedance screen. Tap ⚙ in the corner of the screen to temporarily adjust amplitude and adjust pulse width parameters.

Therapy Parameter Settings

You can adjust therapy parameter settings as needed for a program in order to provide optimal therapy. You can access therapy parameter settings by navigating to the **Therapy** screen in the Configure Implant workflow.

During a programming session, the clinician app uses the specified therapy parameters to program the neurostimulator. Table 3 lists the available therapy parameter settings along with their descriptions.

Table 3. Therapy parameter descriptions

Therapy parameter setting	Description
Amplitude	Amplitude is the intensity or strength of the stimulation measured in volts (V). By increasing amplitude, you are increasing the intensity of the stimulation and by decreasing it, you are reducing the intensity. The goal is to use the lowest effective amplitude that will provide optimal patient symptom relief, minimize patient discomfort, and maintain neurostimulator battery life to the best possible extent. A typical setting for amplitude is based on patient comfort which is determined during a programming session by ramping up amplitude gradually and by selecting a default or fine amplitude resolution (increment settings). Available resolution settings are: Default setting (in 0.1 V increments) - For Model 3023 Neurostimulators: 0-10.5 V - For Model 3058 Neurostimulators: 0-8.5 V Fine setting (in 0.05 V increments) - For both models: 0-6.35 V
Pulse Width	Pulse width is the time or duration of the stimulation pulse measured in microseconds (µsec). Increasing pulse width increases pulse duration and decreasing pulse width decreases pulse duration. For example, when a patient feels the stimulation too intensely in one body location, increasing the pulse width spreads the stimulation and makes it less intense in that location. Default setting for pulse width is 210 µsec.
Rate	Rate is the number of times per second a pulse is delivered, measured in pulses per second (pps) or Hertz (Hz). Increasing the rate feels more like a “flutter” or “vibration” and decreasing the rate gives more of a “tapping” or “thumping” sensation. You can use patients’ preferences for the sensation they are most comfortable with, to guide you in selecting an appropriate rate. Default setting for rate is 14 pulses per second.
Optional settings: The following are optional therapy parameters that can be modified if optimal therapy is not provided through default standard programs.	

Therapy parameter setting	Description
Amplitude limit	Selecting an Amplitude Limit sets the boundary for how high the amplitude value can be raised above the programmed therapy amplitude value by the patient. After a programming session, patients can control therapy amplitude using the patient app, but within the programmed Amplitude Limit set by the clinician. When Amplitude Limit is not defined, patients can increase therapy amplitude to the maximum therapy amplitude value allowed.
Cycling	Cycling is a feature used to control how often therapy is running. When the Cycling feature is off, therapy is continuously running. When the Cycling function is turned on, it automatically turns the neurostimulator on and off at clinician-determined intervals (from 0.1 seconds to 24 hours). When Cycling On time is over, therapy turns off and continues to stay off until Cycling Off time ends. When Cycling Off time is over, therapy turns on again and continues to stay on until Cycling On time ends. This process repeats itself until the Cycling feature is disabled or therapy is stopped. By default, the Cycling feature is turned off. **Note**: Due to a carryover effect, the patient may continue to experience symptom suppression during the Cycling Off time.
SoftStart/ Stop™	This feature is intended to increase patient comfort by providing a gentle or “soft” start as stimulation begins and reduces the risk that the patient will be startled by the start of a stimulation cycle. Using the SoftStart/ Stop™ feature helps avoid any unpleasant sensation at the onset of stimulation. Programmable ramp times for this feature (up and down) are 1, 2, 4, 8, 15, or 30 seconds. By default, SoftStart/Stop is turned Off.

Therapy parameter setting	Description
Amplitude resolution	Amplitude resolution is a feature that allows you to change the increments by which amplitude is increased or decreased, and allows you to ramp up or down to the appropriate amplitude setting. The amplitude resolution is provided through two options: • Default • Fine Changing amplitude from default to fine resolution is beneficial if a patient is sensitive to the intensity, measured in Volts (V), of the amplitude being provided. If the default resolution is selected, amplitude increases/decreases by increments of 0.1V. If the fine resolution is selected, amplitude increases/decreases by increments of 0.05V.

Therapy Parameter Settings Instructions For Use

To turn on therapy (set amplitude):

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure (Figure 3).
4. Use the **arrows** to set the amplitude. Holding the Up or Down arrows to adjust the amplitude by increments of 0.5 V.

   Note: If the patient is experiencing discomfort, therapy can be stopped at any time. Tap ⊘ to stop therapy.
5. Tap **DONE** when finished.

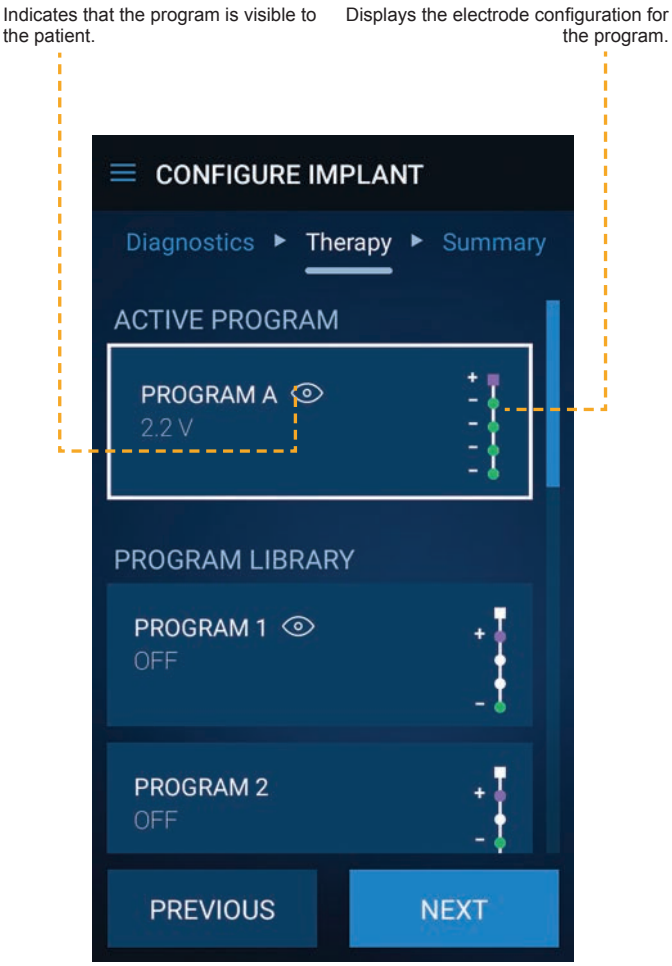


Figure 3. Therapy screen

To set pulse width:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure (Figure 3).
4. Tap ⚙.
5. Select **Pulse Width** from the list of options.
6. Use the **arrows** to set the pulse width.

   △ **CAUTION**: Consider default settings for rate and pulse width when configuring therapy settings. Unsuitable stimulation could result in patient discomfort.
7. Tap **UPDATE**.
8. Tap **DONE** when finished.
9. Tap **DONE** again to return to the Therapy screen.

To set rate:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure (Figure 3).
4. Tap ⚙.
5. Select **Rate** from the list of options.
6. Use the **arrows** to set the rate.

   △ **CAUTION**: Consider default settings for rate and pulse width when configuring therapy settings. Unsuitable stimulation could result in patient discomfort.
7. Tap **UPDATE** when finished.
8. Tap **DONE** when finished.
9. Tap **DONE** again to return to the Therapy screen.

To view electrode settings:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure (Figure 3).
4. Tap ⚙.
5. Select **Electrodes** from the list of options. The Electrode screen displays the current electrode settings for the selected program.
6. Tap **DONE** when finished.

   Notes:

   - Electrode settings for standard programs (1-7) cannot be changed.
   - You can also view electrode settings for programs on the Therapy screen (Figure 3).

To set amplitude limit:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure (Figure 3).
4. Tap ⚙.
5. Select **Amplitude Limit** from the list of options.
6. Tap the **On/Off** switch to enable amplitude limit.

   Note: Tap the **On/Off** switch again to disable.
7. Use the **arrows** to set the amplitude limit.
8. Tap **UPDATE** when finished.
9. Tap **DONE** when finished.
10. Tap **DONE** again to return to the Therapy screen.

Notes:

- When the On/Off switch is turned on, the amplitude limit will default to the current amplitude setting.
- The amplitude limit cannot be set at a value lower than the current amplitude setting for an active program.

Optimizing device settings

The clinician app offers features that you can optionally use to increase patient comfort and ease of use, and when certain parameters are used, extend neurostimulator battery life. These features include:

- Cycling
- SoftStart/Stop™
- Amplitude Resolution

See “Therapy Parameter Settings” on page 20 for more information on setting additional therapy parameters.

Selecting Cycling feature and time

The Cycling feature automatically turns the neurostimulator On and Off at clinician-determined intervals (from 0.1 seconds to 24 hours). Cycling, by default, is disabled. Anytime Cycling is enabled, the battery longevity estimate may not be accurate. If Cycling is being used to improve device battery longevity, the information below should be considered:

- For amplitude settings less than or equal to 1 Volt, Cycling may result in reduced device battery longevity when compared to continuous mode.
- For amplitude settings greater than 1 Volt, the following settings may improve device battery longevity when compared to programming in continuous mode:
  - Set Cycling intervals to greater than or equal to 2 seconds On and greater than or equal to 2 seconds Off (without SoftStart/Stop™ enabled).

OR

- Set Cycling intervals to greater than or equal to 60 seconds On and greater than or equal to 60 seconds Off (with SoftStart/Stop enabled and programmed at greater than or equal to 4 seconds).

Notes:

- Due to carryover effect, the patient may continue to experience symptom suppression during the Cycling Off time.
- When using both SoftStart/Stop and Cycling features, only SoftStart/Stop times that are less than or equal to the Cycling On and Cycling Off times are available for programming.

WARNING: Using some Cycling or SoftStart/Stop therapy settings may cause premature battery depletion, resulting in loss of therapy.

To enable SoftStart/Stop™:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure (Figure 3).
4. Tap ⚙.
5. Tap **SoftStart/Stop** from the list of options.
6. Tap the **On/Off** switch to enable SoftStart/Stop.

   Note: To disable, tap the **On/Off** switch again.
7. Use the **arrows** to configure the SoftStart/Stop time for the implanted neurostimulator.

   Note: The SoftStart/Stop time cannot be more than the Cycling On or Cycling Off time, and/or the Cycling On time and the Cycling Off time cannot be less than the determined SoftStart/Stop time.
8. Tap **UPDATE**.

Note: Enabling Cycling or SoftStart/Stop configurations may reduce device battery longevity.

9. Tap **DONE** when finished.
10. Tap **DONE** again to return to the Therapy screen.

To enable Cycling:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure (Figure 3).
4. Tap ⚙.
5. Tap **Cycling** from the list of options.
6. Tap the **On/Off switch** to enable Cycling.

   Note: Tap the **On/Off** switch again to disable.
7. Use the **arrows** to set the Cycle On time and Cycle Off time for the implanted neurostimulator. The length of Cycle On time and Cycle Off time is measured in seconds.

   Note: Enabling Cycling or SoftStart/Stop configurations may reduce device battery longevity.
8. Tap **UPDATE**.
9. Tap **DONE** when finished.
10. Tap **DONE** again to return to the Therapy screen.

To change amplitude resolution

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure (Figure 3).
4. Tap ⚙.
5. Tap **Resolution** from the list of options.
6. Select the desired amplitude resolution (default or fine)

from the available options.

7. If the amplitude resolution is at the desired setting, tap **DONE**.
8. If you have changed the amplitude resolution, once on the desired setting, tap **UPDATE**.
9. Tap **DONE** when finished.
10. Tap **DONE** again to return to the Therapy screen.

Performing an Integrity Measurement (Check Impedance Workflow)

An impedance measurement can be run to check system integrity when connected to a neurostimulator.

To check impedance from the Check Impedance workflow:

1. Navigate to the **CHECK IMPEDANCE** workflow.
2. Tap **START**.
3. Tap Ω to check electrode impedance (Figure 4).
4. Tap **DONE** when finished.

   Notes:

   - Tapping Ω on the status screen after conducting an impedance check for the first time will take you to the Impedance screen where you can view the current status of the electrodes.
   - You can tap the status icon on any electrode to view the current impedance values.
   - You have the option to adjust therapy amplitude and/or pulse width temporarily while conducting an impedance check on the Impedance screen. Tap ⚙ in the corner of the screen to access temporary adjust amplitude and adjust pulse width options.

Tap to view impedance measurement values for each electrode.

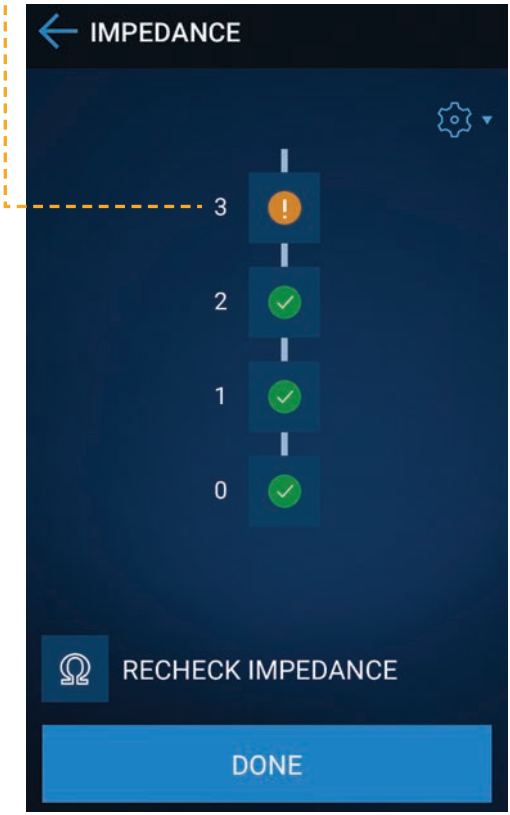


Figure 4. Impedance screen

Electrode polarity

The stimulation pulse is delivered from the neurostimulator to the nerve through the electrodes on the leads. For the stimulation pulse to reach the nerve, you select the electrodes on the lead that best provide the stimulation and assign a negative or a positive polarity. At least one electrode (or the

neurostimulator case) must be designated as positive and at least one electrode must be designated as negative. The negative electrode is called the active electrode; a pulse flows from the active or negative electrode to the positive. Thus, changing an electrode to active changes the location of the stimulation pattern.

Configuring electrodes depends on how the leads and electrodes are placed in relation to the nerve that is being stimulated. Approach configuration systematically, using a variety of electrode configurations and mapping sensory responses to each configuration. The four electrodes on a lead can be configured with or without the neurostimulator case:

- **Unipolar**—Using any combination of electrodes and configuring at least one electrode as negative and configuring the neurostimulator case as positive.
- **Bipolar** —Using one or more electrodes and configuring one or more electrodes as negative and one or more electrodes as positive with the case off.

Notes:

- The neurostimulator case can only be configured as positive. When the case is selected, lead electrodes can only be selected as negative.

- Unipolar configuration depletes the neurostimulator battery at a higher rate. Use bipolar configuration whenever possible to extend battery life.

Checking Neurostimulator MRI Eligibility (View MRI Status Workflow)

The View MRI Status workflow is used to determine neurostimulator eligibility. Medtronic Models 3023 and 3058 InterStim™ neurostimulators may be eligible for a MRI head scan, depending on the serial number. Refer to the MRI

Guidelines for the InterStim system for more information. The MRI screen displays the following information:

- MRI scan eligibility
- Patient information
- Neurostimulator device information

WARNING: Do not conduct an MRI scan on a patient before assessing MRI eligibility. Conducting an MRI scan on a patient who is ineligible for an MRI scan could result in serious patient injury.

To determine MRI eligibility:

1. Navigate to the **VIEW MRI STATUS** workflow.
2. Tap **START**.
3. The app will display the implanted neurostimulator MRI eligibility.

WORKING WITH PROGRAMS

Standard and custom programs are available within the clinician app. These features allow you to provide optimal therapy for the patient. Standard programs provide pre-defined electrode configurations. If default electrode settings from standard programs provide less than optimal therapy, custom programs allow you to manually define electrode settings.

Standard Programs

Programs marked 1-7 under Program Library on the Therapy screen of the Configure Implant workflow signify standard programs with pre-configured electrode settings. The clinician app allows you to switch from one program to another at any time.

Only one program, either standard or custom, can be active at a time. The active program name is displayed at the top of the Therapy screen under **ACTIVE PROGRAM**.

Notes:

- A program is considered active if it is the last program used.
- Upon switching from one active program to another, therapy amplitude automatically resets to zero.

Custom Programs

If the electrode settings for standard programs (1-7) do not provide optimal therapy results, you have the option to create custom programs using custom electrode settings. Programs A-D signify custom programs that you can create using custom electrode configuration settings. You can create up to four custom programs.

To create a custom program:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen.
4. Scroll to the bottom of the screen, and tap +.
5. Tap to configure the electrodes for the custom program.
6. Set the electrode configuration by tapping in the **box** for each electrode you want to configure. Tap once for a positive (+) electrode, tap again for a negative (-) electrode, and once more to clear (Figure 5).

   Notes:

   - Therapy must be off before modifying electrode configuration settings.
   - There must be at least one positive (+) electrode and one negative (-) electrode for a viable electrode configuration.
7. Tap **UPDATE** after the electrode configurations have been set.
8. Tap **DONE** when the update is complete.
9. Tap **DONE** again to return to the Therapy screen.
10. Adjust the parameter settings if necessary. For step by step instructions, see “Therapy Parameter Settings Instructions For Use” on page 23 for more information.

Tap inside the boxes to configure electrodes for custom programs.

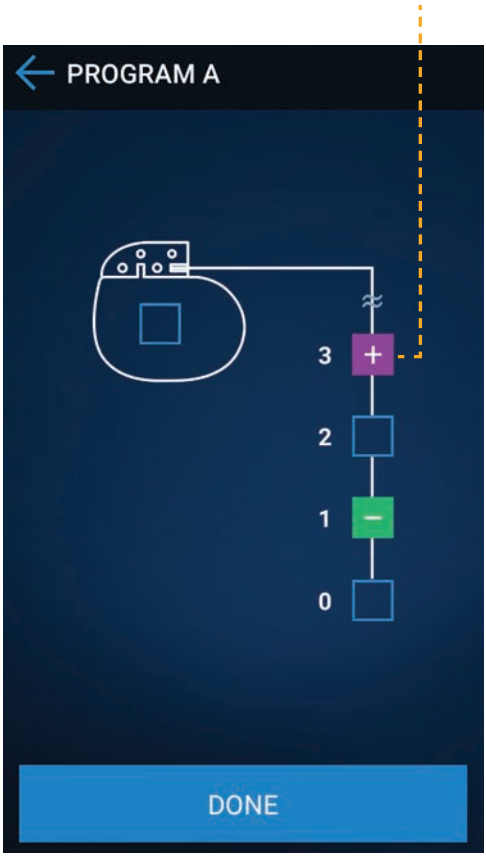


Figure 5. Set electrode setting configurations for custom programs

Deleting a custom program

In the event that a custom program is no longer needed or used, it can be deleted at any time.

To delete a custom program:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the custom program you would like to delete.
4. Scroll to the bottom of the screen, and tap ✕.

   Note: You cannot delete a custom program if the custom program is active.

Enabling programs for patient use

In order for patients to use a program, the program needs to be enabled for patient use.

To enable a program for patient use:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to enable.
4. On the bottom of the screen, tap the **Enable for patient use** switch once to make the program enabled for patient use.

   Note: Tap the **Enable for patient use** switch again to disable the program for patient use.
5. Tap **DONE** when finished. 👁 is displayed next to the program indicating that the program is visible to the patient.

Reviewing a Therapy Programming Session

The last screen in the Configure Implant workflow is the Summary screen. The Summary screen displays the active program setting and a list of patient enabled programs for a programming session.

Note: On the Summary screen, you can also view a session report. For more information, see “REPORTS” on page 44.

Ending a programming session

After completing the necessary programming tasks in a workflow, end the programming session.

WARNING: End programming session — Do not leave a programming session open in the clinician app once therapy has been configured. Not ending a programming session may result in patient access to the clinician app, resulting in the patient being able to configure inappropriate therapy.

To end a programming session:

1. Tap ☰ in the corner of the screen.
2. Tap **End Session**.
3. Confirm that you would like to end the programming session by tapping **END SESSION**.

   Note: Alternatively, you can also tap ⍈ on the **HOME** screen to end a programming session.

After ending a programming session, you will be taken back to the Password screen.

Using the stop therapy feature

The Stop Therapy feature allows you to discontinue therapy at any time while in the Configure Implant workflow.

To stop therapy:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Therapy** screen, and tap the program you would like to configure.
4. Tap ⊘ .
5. Tap **DONE** to return to the Therapy screen.

   Note: For instructions on turning therapy back on, see “To turn on therapy (set amplitude):” on page 23.

DIAGNOSTICS

The clinician app allows you to run the following diagnostics to analyze a patient's therapy:

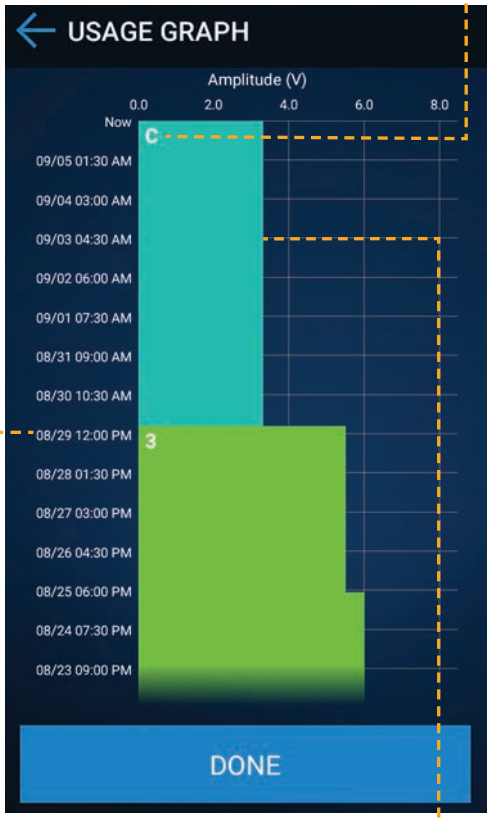
- Usage graph
- Event log
- Usage report

Usage Graph

The usage graph represents daily patient activity while using the therapy (Figure 6). The usage graph displays programs used, the amplitude setting and adjustments, as well as the duration of time each program was used. Each program is represented in the graph through the use of different colors and program numbers.

Time-stamp on the y-axis represents the duration of the program used.

Indicates the program used.



Amplitude values on the x-axis represent the amplitude value each program is set to.

Figure 6. Usage graph

To view the usage graph:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Diagnostics** screen, and tap .

   Notes:

   - Amplitude adjustments are only displayed for amplitude values that have been programmed for 30 minutes or more.
   - The graph displays up to the last 30 days of patient data.

Event Log

The event log provides the following information (Figure 7):

- Date and time of therapy changes
- Amplitude adjustments (if programmed for 30+ minutes)
- Program changes
- Power-on-reset (POR)
- Change in therapy status (ON/OFF)

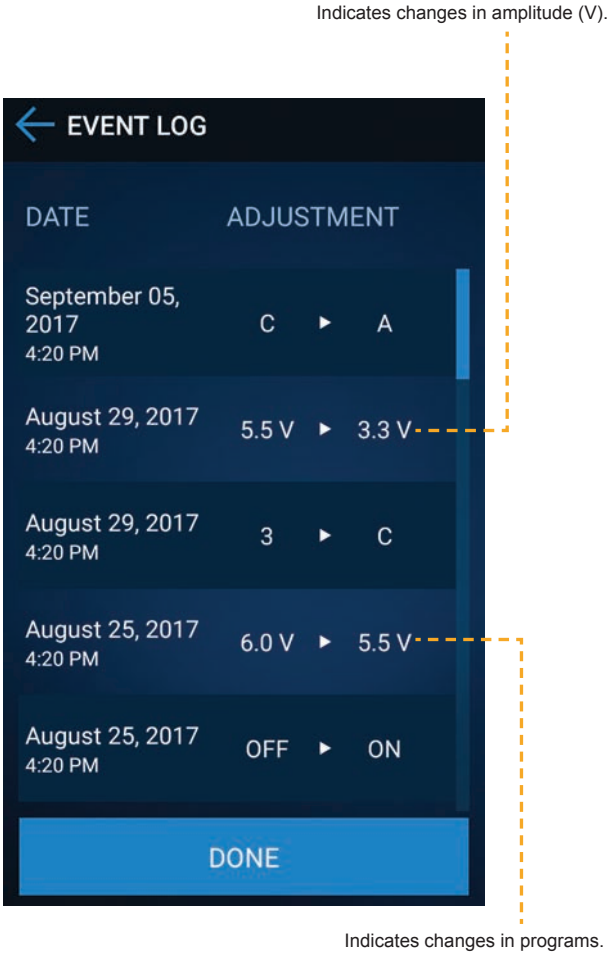


Figure 7. Event log

To view the Event log:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Diagnostics** screen.
4. Tap ☰.

Usage report

The usage report displays data from both the usage graph and event log.

To generate a usage report:

1. Navigate to the **CONFIGURE IMPLANT** workflow.
2. Tap **START.**
3. Navigate to the **Diagnostics** screen.
4. Tap **GENERATE USAGE REPORT**.

   Note: You can access the generated report by navigating to **REPORTS** on the Menu screen.

REPORTS

The clinician app allows you to generate reports that track data once the neurostimulator has been implanted and configured for chronic therapy. You can access a variety of reports by tapping **REPORTS** on the Menu screen.

Table 4. Reports and descriptions

Report	Description
Session report	• Displays the patient's active program settings. • Generates automatically anytime the clinician ends a programming session.
Usage report	• Includes information from the event log and usage graph. • Generated from the Diagnostics screen.
Medtronic data report	• Generated from the Device tab on the About screen. • Used by Medtronic to troubleshoot the system.

To view, download, or delete reports:

1. Navigate to the **Menu** screen and tap **REPORTS**.
2. From the list of options, tap the type of report that you would like to view.
3. Tap the desired report to view a list of options.
   a. Tap to view a report.
   b. Tap to download a report.
   c. Tap to delete a report.

Accessing a Downloaded Report

If you need to download a report, see the following instructions on how to download the report and access it using your computer.

To download and access a report:

1. Navigate to the **Menu** screen and tap **REPORTS**.
2. From the list of options, tap the type of report that you would like to view.
3. Tap the desired report to view a list of options.
4. Tap  to download. A pop-up displays that the report has been saved to the Reports folder.
5. Plug the handset into a computer using the micro USB cable that came with the handset.
6. Navigate to the **Reports** folder from your computer drive. The Reports folder stores the reports that were downloaded from the clinician app.

   Note: Generated reports will remain on the handset for 24 hours before being deleted automatically.

ADDITIONAL FEATURES

See the following sections for information on the additional features of the clinician app.

About Screen

You access the About screen by tapping ☰ in the corner of the screen and selecting **About** from the list of options. The About screen provides the following information:

- Handset and app information such as model numbers, serial number, version numbers, etc.
- Neurostimulator device information such as model number and serial number.
- Communicator information such as firmware version number and serial number.
- General licensing information

Managing Devices

The Manage Devices screen allows you to view, add or remove a neurostimulator device. The Manage Devices screen can be accessed in the following ways:

1. From the Menu screen:
   a. Tap ⚙.
   b. Tap **Manage Devices** from the list of options.
2. After a device has already been connected:
   a. Tap ☰.
   b. Tap **Manage Devices** from the list of options.
3. Tap **DONE** when finished.

   Note: Tap ✕ to remove a device, or + to add a new device. You will be redirected to either the Home screen or Menu screen depending on your selection.

Software Information

The following is important information regarding Medtronic therapy application software.

Data security

Data is protected by application level encryption and encryption provided by the handset. The app does not protect data exported to another destination. Data exported from the app should be handled in accordance with your clinic's security policy for data handling and storage.

To protect patient information, Medtronic recommends you implement the following security measures:

- Use a managed, trusted Wi-Fi connection when network connectivity is needed.
- Consider securing your handset by disabling Wi-Fi connection when using the clinician app.

If you suspect a cybersecurity breach has occurred, stop using the app (if possible) and contact your IT Security or Medtronic Technical Services to document and respond to the suspected incident.

Installation

The clinician app along with supporting software apps are provided pre-installed on the Android platform-based handset and cannot be installed on a personal cellular phone.

Software and firmware updates

Software and firmware updates may be sent to the handset when it connects to a Wi-Fi network.

TROUBLESHOOTING

The clinician app displays notifications you may encounter while using the app. If you are experiencing problems with the handset, check the app screen and follow the instructions to correct the issue. If you experience an issue not described in this section, contact your Medtronic support representative.

Table 5. Clinician app, handset, and communicator scenarios and solutions

Scenario	Explanations and possible solutions
I am unable to pair the communicator to the clinician app and/or implanted neurostimulator	**The communicator is not powered on. You will need to turn on the communicator to communicate with the implanted neurostimulator.** Once the communicator is powered on, follow the connection steps to attempt to reconnect to an existing communicator. See, “Pairing the Communicator and the Neurostimulator” on page 12 for instructions. **Note**: For information on features and functions of the communicator, refer to the TM90 Communicator Instructions For Use. **The communicator is not charged or is in the process of charging. You will need to charge the communicator using the charger provided with the product package.** Once charged, follow the connection steps to attempt to reconnect to an existing communicator. See, “Pairing the Communicator and the Neurostimulator” on page 12 for instructions. **The communicator is out of range. Make sure the communicator is flush with the skin.**

Scenario	Explanations and possible solutions
	Once in range, follow the connection steps to attempt to reconnect to an existing communicator. See, “Pairing the Communicator and the Neurostimulator” on page 12 for instructions. **Note**: The communicator must be paired to the handset first before attempting to connect to the neurostimulator. **You received a replacement communicator. You will need to connect the new communicator to the handset and the implanted device.** 1. Open the clinician app. 2. Make sure the communicator is on. **Note**: For information on features and functions of the communicator, refer to the TM90 Communicator Instructions For Use. 3. A screen will be displayed showing that the communicator is not found. Tap **SWITCH COMMUNICATOR** to connect. 4. Select the communicator you would like to pair to. The serial number of the communicator should match the serial number shown on the screen. 5. If the communicator you would like to connect to is not shown, tap **RETRY**. Follow the remaining instructions on the handset to finish pairing the device. 6. If the issue persists, contact Medtronic support.

Scenario	Explanations and possible solutions
Uncomfortable or intolerable therapy	**The patient is experiencing side effects from the therapy (stimulation).** 1. Turn the therapy (stimulation) down or off. See “Therapy Parameter Settings” on page 20 for instructions. 2. If the issue still persists, call your clinician.
The handset has no power or has lost power	**The handset battery is depleted.** Recharge the battery using the charger. **The handset is damaged or malfunctioning.** Contact Medtronic support.
The handset will not charge	△ **CAUTION:** Use the recommended steps to troubleshoot the clinician app if the clinician app or handset becomes unresponsive. Not following these steps may result in the inability to complete the implant procedure. **The charger is disconnected from the handset.** Connect the charger to the handset. **The wrong charger is connected to the handset.** Connect the appropriate charger to the handset. **Charger is defective**. Contact Medtronic support. The charger will need to be replaced. **The handset is damaged or malfunctioning.** Contact Medtronic support.

Scenario	Explanations and possible solutions
The patient is not receiving therapy	**The therapy might be off.** Turn on the therapy. **The neurostimulator battery may be depleted.** The neurostimulator will need to be replaced. **A lead is damaged or has become disconnected.** Check the impedance on the lead. If impedance is out of range, the lead may be damaged.
I cannot find the clinician app on the handset	**The clinician app may not have downloaded properly.** Contact Medtronic support.
I have forgotten my password	**The password needs to be reset. To reset the password** 1. Tap the “Forgot Password” icon. 2. Take note of the six-character code. You will need to provide this to code to Medtronic support in order to complete the steps to reset your password. **Note**: This code is valid for 24 hours. After 24 hours, you will need to refresh the code. 3. Contact Medtronic support to complete the steps to reset your forgotten password.

Scenario	Explanations and possible solutions
The handset or clinician app is unresponsive	**If the handset or the clinician app is unresponsive:** ⚠ **CAUTION**: Use the recommended steps to troubleshoot the clinician app if the clinician app or handset becomes unresponsive. Not following these steps may result in the inability to complete the implant procedure. 1. Turn the handset Off, then turn the power back On. 2. If that doesn't resolve the issue, use another handset, if available 3. If the issue persists, contact Medtronic support.
I can't find my downloaded report	**Downloaded reports can be found in the Reports folder on the handset.** You can access a downloaded report by navigating to the Reports folder on the handset or by connecting the handset to a PC and navigating to the Reports folder through the PC. See "Accessing a Downloaded Report" on page 44 for more information. **Note**: Generated reports will remain on the handset for 24 hours before disappearing.

Scenario	Explanations and possible solutions
I want to unpair or disconnect the neurostimulator from the apps.	Disconnecting or unpairing a connected neurostimulator is done using the Manage Devices feature. To disconnect: 1. Tap ☰ to open a list of options, and select **Manage Devices**. **Note**: the Manage Devices feature can also be accessed by tapping ⚙ on the Menu screen. 2. Tap ⟲. 3. Tap ✕. 4. Tap **REMOVE DEVICE** to confirm that you want to unpair or disconnect the device from the clinician and patient apps. **Note**: Removing the device from the clinician app will disconnect the device from the My Therapy app. All data will also be erased from the app.

Table 6. Clinician app system notifications and solutions

App notification	Explanations and solutions
System error	**The system has encountered an unexpected problem.** 1. Restart the clinician app. 2. If the problem persists, contact Medtronic support.
Neurostimulator End of Service	**The neurostimulator has reached end of service.** The neurostimulator will no longer be able to provide therapy. You will need to replace the neurostimulator to continue therapy.
Low battery	**The neurostimulator battery is low and therapy will be unavailable soon.** Replace the neurostimulator.

Communicator connection lost	**The communicator may be turned off, out of range, or the battery may be depleted.** 1. Ensure the communicator is on. Move the communicator closer to the handset, and attempt to reconnect following the instructions presented on the screen. **Note**: If you are connecting to the communicator for the first time, see,"Pairing the Communicator and the Neurostimulator" on page 12 for instructions. 2. If the issue persists, the communicator or handset may need to be charged. Recharge the battery using the charger that came with the product. 3. If you are still experiencing issues, contact Medtronic support.
Communicator low battery	**The communicator battery is below 25% and needs to be charged**. The communicator battery LED indicator will be yellow when the battery is low. Charge the communicator using the charger that came in the product package.
Invalid Cycle time - Cycling error	**The clinician app detects you are attempting to set the Cycling time to be shorter than the SoftStart/Stop™ feature time.** Ensure the Cycling time is set to longer than the SoftStart/Stop feature time or tap **CHANGE SOFTSTART/STOP FEATURE TIME** to be shorter than the Cycling time. **The clinician app detects you are attempting to set the Cycling time to one (1) second or less when the SoftStart/ Stop™ feature is enabled.** Ensure the Cycling time is set to greater than one (1) second when SoftStart/ Stop feature is enabled or tap **DISABLE SOFTSTART/STOP FEATURE** to disable the SoftStart/Stop feature.

Invalid SoftStart/ Stop™ Time-SoftStart/Stop Feature Error	**You are attempting to set the SoftStart/ Stop™ time longer than the Cycling time when Cycling is enabled.** Ensure the SoftStart/Stop time is shorter than the Cycling time or tap **CHANGE CYCLING TIME** to change the Cycling On/Off time to the same value as SoftStart/Stop time. Ensure the future settings follow these rules: 1. Cycling On Time must be greater than or equal to SoftStart/Stop Time. 2. Cycling Off Time must be greater than or equal to SoftStart/Stop Time.
An invalid neurostimulator serial number is displayed on the Connection screen (e.g. NJY/ NBV000000)	**You are attempting to connect a neurostimulator that has experienced a Power On Reset (POR).** 1. If the correct serial number is displayed, select the correct serial number, and tap **CONTINUE.** If the correct serial number is not displayed, skip to step 3. 2. Select the correct serial number on the Connection screen, and tap **NEXT** to connect to the neurostimulator. **Note:** If you opt to manually enter the serial number, all stored data on the handset will be deleted. 3. If the correct serial number is not displayed on the Connection screen, select the invalid neurostimulator serial number (e.g. NJY/NBV000000), and tap **CONTINUE**. 4. Enter the serial number of the neurostimulator and tap **NEXT** to connect to the neurostimulator. **Note:** Once the neurostimulator is paired, the entered serial number will be displayed on the Connection screen for all subsequent connections.

Data lost	**The neurostimulator has undergone a Power On Reset (POR). No therapy is available until the information in the neurostimulator is restored.** Restart the clinician app. You will need to reconfigure therapy settings for the neurostimulator.
Therapy state changed	**Therapy output was changed by another programming device. Check therapy output.** Use the same handset and communicator to make adjustments to the neurostimulator.

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