

ST. JUDE MEDICAL INFINITY™ DBS SYSTEM

# PATIENT CONTROLLER APP USER GUIDE

Managing your DBS Therapy





**The weeks and months following your DBS surgery can be an exciting time as you become familiar with your DBS system.** Although individual results vary, over the course of the next several months you should gain more control over your symptoms. With an increase in activity, and reduction in noticeable symptoms, many people feel more confident and experience the freedom to live their best life.

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

During your first programming session, your doctor and an Abbott representative will help you set up your Patient Controller and teach you how to use it. This guide is intended to help you understand the set up process and become familiar with your DBS system and controller.

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

# DOWNLOADING THE ST. JUDE MEDICAL™ PATIENT CONTROLLER APP

The minimum system requirements for the Patient Controller app is a 5th generation Apple+ iPod touch+ mobile digital device running iOS+ software 9.3.1 or later. As Apple releases new or upgraded operating systems, it is imperative that you NOT upgrade the device until instructed to do so by Abbott. Abbott must test every iOS software upgrade to ensure security and compatibility with the app.

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

Before you begin, make sure the device has a strong connection to the internet (full bars on Wi-Fi®) (see Figure 1).

Download the Patient Controller app using your Apple ID.

- a. Sign in by going to **Setting, iTunes and App Store**.
- b. Enter your **Apple ID and Password** (see Figure 2). If you do not already have an Apple ID, refer to the Apple ID Setup section.

- c. Tap and open the public **App Store**. Search for Patient Controller.
- d. Tap **Get** to download the App (see Figure 3).



Figure 1

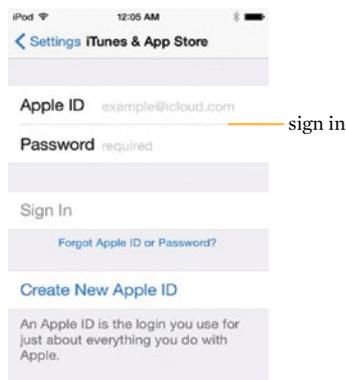


Figure 2

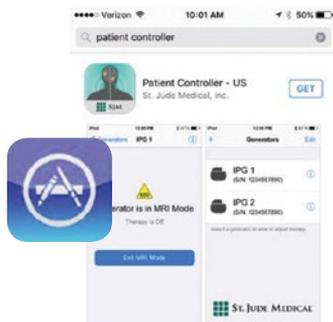


Figure 3

- e. Pair the Patient Controller to the IPG.  
To do so, remove the keeper bar on the magnet and hold the magnet over your IPG for 12–15 seconds only.
- f. Remove the magnet. Leaving the magnet over the IPG for 30 seconds or more will reset the device.
- g. Open the **Patient Controller App** on the iPod<sup>®</sup> mobile digital device.
- h. Touch the + **button** (see Figure 4).
- i. The serial number of the IPG you just held the magnet over will appear. Select it. Only IPGs that have had the magnet placed over them for at least 10 seconds but not more than 30 seconds in the last 5 minutes will appear in this list.
- j. A number code appears on the screen of your Patient Controller. Enter that number and touch **Pair** (see Figure 5).

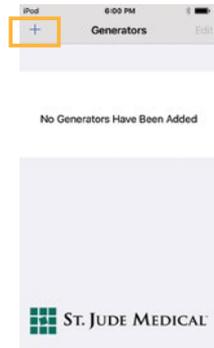


Figure 4



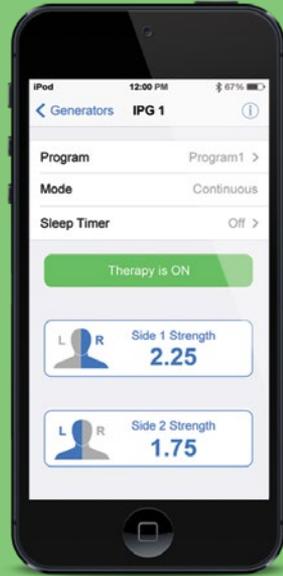
Figure 5

# APPLE<sup>+</sup> ID SETUP

To use the St. Jude Medical™ Patient Controller App on your iPod touch<sup>+</sup> mobile digital device, you will need to have an Apple<sup>+</sup> ID. If you do not have an Apple ID or an email address, it is recommended that you have a friend or family member help you through the setup process for both.

We ask that you create your Apple ID before you arrive for your final procedure.

You will be required to use the Apple ID to download the app that controls your stimulation and to perform any application software updates that may come in the future. Please do not lose your Apple ID and password.



## TO CREATE AN APPLE<sup>®</sup> ID, PLEASE FOLLOW THESE STEPS:

Use your existing personal email address OR create a new email address  
(Free email accounts can be created at the following website:  
*<https://accounts.google.com/signup>*)

**Email address** \_\_\_\_\_

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

**Apple ID** \_\_\_\_\_

FAQs: *<https://support.apple.com/en-us/HT204161>*

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

**Keep a record of the following information used to create your Apple<sup>+</sup> ID in case you need to reference it later:**

**Name**

First Name \_\_\_\_\_

Middle Name (optional) \_\_\_\_\_

Last Name \_\_\_\_\_

**Apple ID and Password**

Apple ID \_\_\_\_\_

Your primary email address for your Apple ID. This will be used as the contact email for your account.

Password \_\_\_\_\_

**Security Questions**

Security Question 1 \_\_\_\_\_

Answer \_\_\_\_\_

Security Question 2 \_\_\_\_\_

Answer \_\_\_\_\_

Security Question 3 \_\_\_\_\_

Answer \_\_\_\_\_

**Date of Birth** \_\_\_\_\_

**Rescue Email Address**

Email address where link can be sent to confirm identity and let you reset your information should any security issues arise. Put after the line for writing this email address.

Rescue Email Address (optional) \_\_\_\_\_

**Mailing Address**

Country/Institution \_\_\_\_\_

Address Line 1 \_\_\_\_\_

Address Line 2 (optional) \_\_\_\_\_

Town/City \_\_\_\_\_

State/Province \_\_\_\_\_

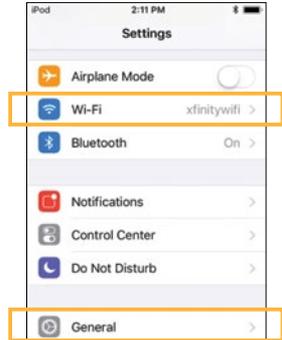
Zip Code \_\_\_\_\_

# UPDATING YOUR PATIENT CONTROLLER

The minimum system requirements for the Patient Controller app is a 5th generation Apple<sup>+</sup> iPod touch<sup>+</sup> mobile digital device running iOS<sup>+</sup> software 9.3.1 or later. As Apple releases new or upgraded operating systems, it is imperative that you NOT upgrade the device until instructed to do so by Abbott. Abbott must test every iOS software upgrade to ensure security and compatibility with the app.

## UPDATING YOUR IOS<sup>+</sup> SOFTWARE

- a. Go to **Settings**
- b. Make sure you are connected to Wi-Fi<sup>+</sup>
- c. Go to the **General** tab under **Settings** (see Figure 6).

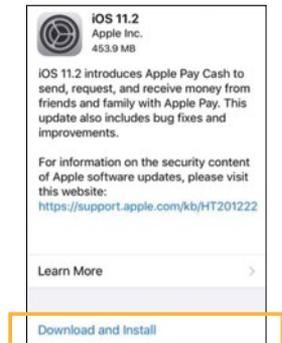


**Figure 6**

- d. Click **Software Update** (see Figure 7).
- e. If there is an update needed **Download and Install** will appear. **Click this** (see Figure 8).
- f. Enter your **Passcode** and **Agree** to the **Terms and Conditions**.

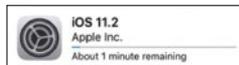


**Figure 7**



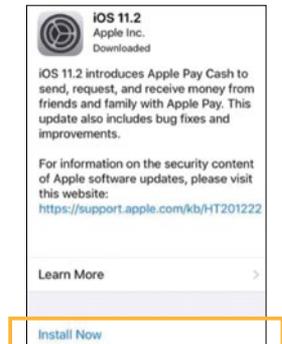
**Figure 8**

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



**Figure 9**

- h. Click **Install Now** (see Figure 10).



**Figure 10**

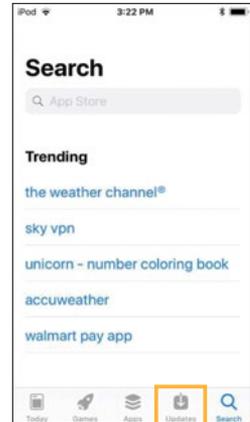
## UPDATING YOUR PATIENT CONTROLLER APP

a. Click on the **App Store**<sup>†</sup>



b. Click on **Updates** at the bottom of the screen (Figure 11).

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



**Figure 11**

# USING THE ST. JUDE MEDICAL™ PATIENT CONTROLLER

This section provides an overview of your St. Jude Medical™ Patient Controller. It shows you how to start, stop and adjust your therapy. Refer to your St. Jude Medical Patient Controller User's Manual for complete instructions on how to use and care for your St. Jude Medical Patient Controller. A copy of this was included with your magnet, and a digital copy can be found online at [manuals.sjm.com](http://manuals.sjm.com).

## TURNING ON YOUR ST. JUDE MEDICAL™ PATIENT CONTROLLER

- To turn your St. Jude Medical™ Patient Controller on, press and hold the **Power** button until the Apple<sup>®</sup> logo appears.
- Slide your finger left to right to unlock the screen.
- If you do not see the screen shown in Figure 12, press the **Home** button to access the Home screen (see Figure 12).
- Make sure that Bluetooth<sup>®</sup> wireless technology is enabled on the device. You can turn Bluetooth<sup>®</sup> settings on/off in the Settings.



Figure 12

## CONNECTING TO YOUR STIMULATION DEVICE

- Tap the **Patient Controller icon** on the Home screen to launch the app (see Figure 12). Your St. Jude Medical Patient Controller app will automatically connect to your generator.
- If you have two generators, select the generator you want to connect with from the list (see Figure 13).

When selecting icons on an Apple<sup>®</sup> mobile digital device, please use a short, light touch. Pressing on an application longer than one second can result in moving or possibly deleting the application.



Figure 13

## STARTING AND STOPPING STIMULATION

- a. Start and stop stimulation by tapping on the **Therapy is ON** or **Therapy is OFF** button on the Therapy screen (see Figure 14).

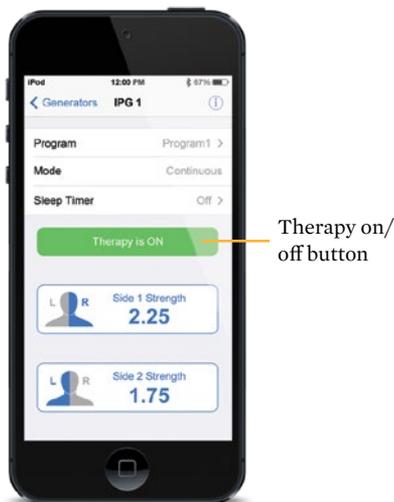


Figure 14

## VIEWING AND SELECTING A PROGRAM

Tap the **Program Name** on the Therapy screen to open the Programs screen. On the Programs screen you can view and select any of the saved programs (see Figure 15). To switch between the saved programs:

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

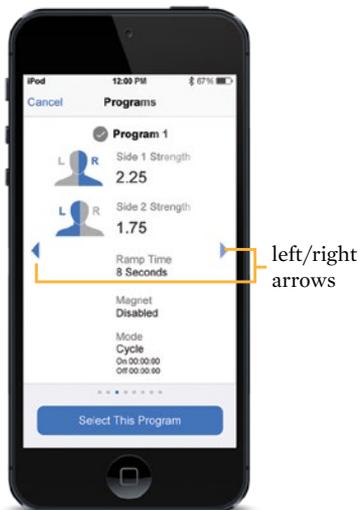


Figure 15

## ADJUSTING STRENGTH

- a. The Strength button shows the current stimulation strength level. Tap the **Strength** button to adjust the stimulation level.
- b. Tap **Strength** on the Therapy screen to open the Strength screen. On the Strength screen you can adjust the strength for the selected side (see Figure 16).

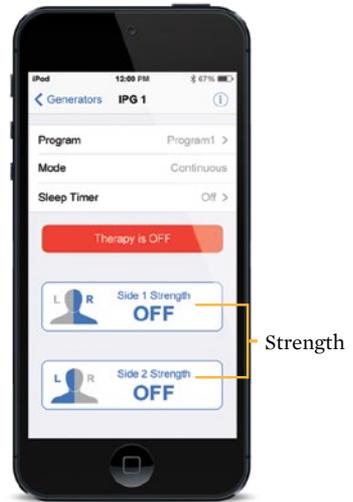


Figure 16

- c. Tap on the - or + buttons to increase or decrease strength levels until you feel a comfortable level of stimulation (see Figure 17).
- d. The number and green bar will increase or decrease as you increase or decrease strength (see Figure 17).



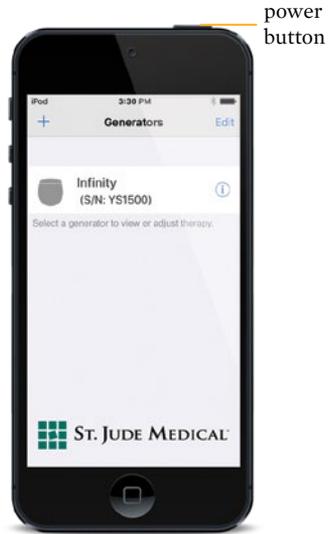
Figure 17

## TURNING OFF YOUR ST. JUDE MEDICAL™ PATIENT CONTROLLER

When you're finished adjusting your therapy, press the **Power** button to close the session. Your St. Jude Medical™ Patient Controller can be reactivated quickly if you want to make changes to the program.

If you press down on the Power button for more than a second, you can turn your controller off completely. The system will continue delivering the therapy you've selected until you turn your controller back on and make changes. Next time you want to use it, it will take a couple of minutes to turn back on.

To turn your St. Jude Medical Patient Controller off, press and hold the **Power** button until the **Slide to Power Off** bar appears and then slide the bar to the right (see Figure 18).



**Figure 18**

# ACCESSING TEMPORARY DEVICE MODES

This section will discuss how and when you should put your system into a temporary device mode to help reduce the possibility of interaction with external factors.

## SURGERY MODE ON YOUR ST. JUDE MEDICAL™ PATIENT CONTROLLER.

Your system has a feature called Surgery Mode that can be turned on to help reduce the possibility for interactions sometimes seen during surgery.

This mode can be turned on directly from your Patient Controller. This feature does not completely eliminate the possibility of the neurostimulator being affected during surgery.

### THE FOLLOWING STEPS EXPLAIN HOW TO TURN ON AND TURN OFF SURGERY MODE.

If you feel uncomfortable completing the steps, contact your Abbott representative before your procedure. Contact your neurologist before your procedure to learn about any risks.

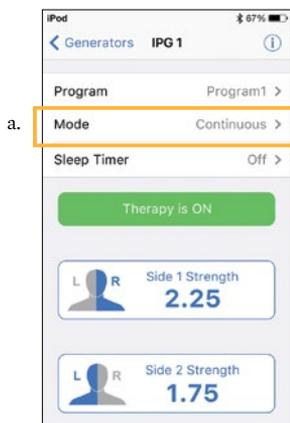
**THIS GUIDE SHOULD BE USED IN ADDITION TO THE USER MANUAL FOR THE ST. JUDE MEDICAL™ PATIENT CONTROLLER. YOU CAN FIND A COPY OF THIS AT [MANUALS.SJM.COM](http://MANUALS.SJM.COM).**

### PLACING YOUR DBS SYSTEM INTO SURGERY MODE

Place your device into Surgery Mode before your procedure. Turning on Surgery Mode turns off your stimulation.

#### To Turn On Surgery Mode

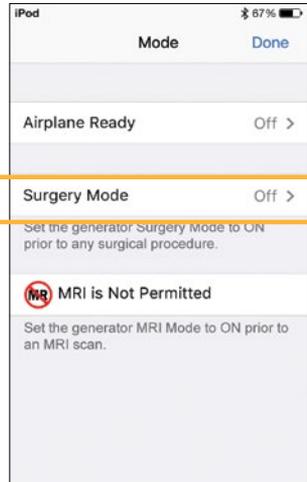
- a. From the Therapy screen, tap **Mode** to display to the Mode screen (see Figure 19).



**Figure 19**

b. Tap **Surgery Mode** to view the Surgery Mode screen. (see Figure 20).

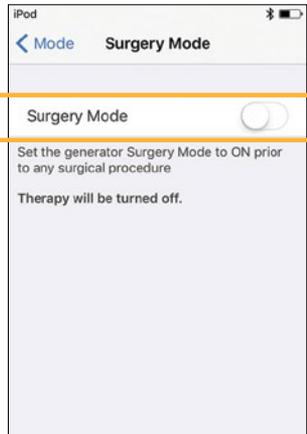
b.



**Figure 20**

c. Tap the **Surgery Mode toggle button**. (see Figure 21).

c.

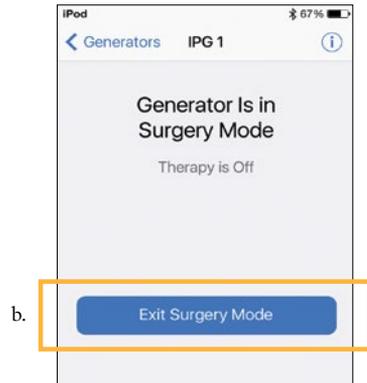


**Figure 21**

## To turn off Surgery Mode

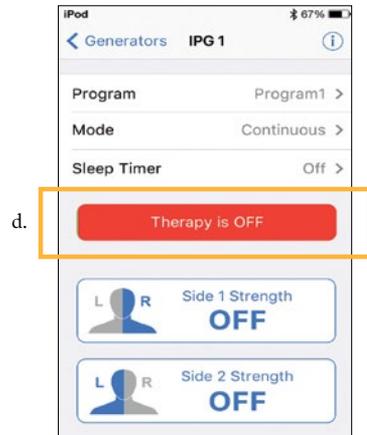
- a. Launch the Patient Controller app and connect with your generator. The “Generator is in Surgery Mode” message appears.

Tap **Exit Surgery Mode** to turn off Surgery Mode.  
(see Figure 22).



**Figure 22**

- b. The Therapy screen appears, showing that stimulation therapy is off.
- c. Tap **Therapy is OFF** to start stimulation.  
(see Figure 23).



**Figure 23**

## PREPARING FOR YOUR SURGERY

Before you undergo a surgical procedure, follow these steps:

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

## BRING THE FOLLOWING ITEMS TO YOUR SURGICAL APPOINTMENT:

- St. Jude Medical™ Patient ID Card
- Patient Controller

## IMPORTANT ITEMS TO REMEMBER

**Surgery Mode** should be activated before entering the room where your procedure will be performed to help reduce the potential for interactions with the neurostimulator.

**TURNING OFF SURGERY MODE BEFORE THE COMPLETION OF YOUR PROCEDURE MAY CAUSE UNINTENDED EFFECTS LIKE UNINTENDED STIMULATION OR DAMAGE TO YOUR NEUROSTIMULATION SYSTEM.**

[Refer to your User Guide for more information.](#)



## Abbott

One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000

SJM.com

St. Jude Medical is now Abbott.

## Rx Only

**Brief Summary:** Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

**US:** Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications, and unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

**International:** Unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease, unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the management of tremor, and unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for the management of intractable, chronic dystonia, including primary and secondary dystonia.

### Contraindications:

**US:** Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Diathermy, electroshock therapy, and transcranial magnetic stimulation (TMS) are contraindicated for patients with a deep brain stimulation system.

**International:** Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Diathermy and magnetic resonance imaging are contraindicated for patients with a deep brain stimulation system.

**Warnings/Precautions:** Return of symptoms due to abrupt cessation of stimulation (rebound effect), excessive or low frequency stimulation, risk of depression and suicide, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), electromagnetic interference (EMI), proximity to electrosurgery devices and high-output ultrasonics and lithotripsy, ultrasonic scanning equipment, external defibrillators, and therapeutic radiation, therapeutic magnets, radiofrequency sources, explosive or flammable gases, theft detectors and metal screening devices, activities requiring excessive twisting or stretching, operation of machinery and equipment, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

**Adverse Effects:** Loss of therapeutic benefit or decreased therapeutic response, painful stimulation, persistent pain around the implanted parts (e.g. along the extension path in the neck), worsening of motor impairment, paresis, dystonia, sensory disturbance or impairment, speech or language impairment, paresis, dystonia, sensory disturbance or impairment, speech or language impairment, and cognitive impairment. Surgical risks include intracranial hemorrhage, stroke, paralysis, and death. Other complications may include seizures and infection. User's Guide must be reviewed for detailed disclosure.

<sup>™</sup> Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

Bluetooth is a registered trademark of Bluetooth SIG, Inc.

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