



ABBOTT INFINITY™ DBS SYSTEM

DBS PATIENT CONTROLLER APP **USER'S GUIDE**

Your Connection. Your Care.

NEUROSPHERE™ DIGITAL CARE

THE WEEKS AND MONTHS FOLLOWING YOUR DEEP BRAIN STIMULATION (DBS) SURGERY CAN BE AN EXCITING TIME AS YOU BECOME FAMILIAR WITH YOUR DBS SYSTEM.

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

Prior to your first programming session and turning on your device, you should set up your Patient Controller. This user's guide is intended to help you understand the setup process and become familiar with your DBS system and controller.

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

Refer to the NeuroSphere™ Patient Controller User's Guide for complete instructions on how to use and care for your Patient Controller. A copy of this user's guide was included with your magnet, and a digital copy can be found online at manuals.sjm.com.

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

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COMPATIBLE DEVICES

The NeuroSphere™ Patient Controller App from Abbott is available for download on certain personal Apple® mobile digital devices with iOS® software. If you own a compatible personal Apple® mobile digital device, it can be used in place of the Apple® mobile digital device provided by Abbott as your Patient Controller. To find out whether your personal Apple® mobile digital device is compatible with Abbott's NeuroSphere™ Patient Controller, visit NMmobiledevicesync.com/dbs.



APPLE® ID SETUP

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

Do not lose your Apple® ID and password.

TO CREATE AN APPLE⁺ ID, FOLLOW THESE STEPS:

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

Email address

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

Apple⁺ ID

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

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

IF YOU NEED HELP, CONTACT:

Apple⁺ Support (United States)

1-800-275-2273

Abbott Neuromodulation Technical Support
NMDTechnicalSupport@abbott.com

1-800-727-7846

When creating your Apple⁺ ID, use a password that you will remember. If you are concerned you will forget it, you may write it down below. You will need your log-in credentials for future updates. Your credentials should be stored and maintained in a safe place. Do not share your credentials with others or allow other users to access the mobile digital device.

Name

First Name _____

Middle Name (optional) _____

Last Name _____

Apple⁺ ID and Password

Apple⁺ ID _____

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

Password _____

Security Questions

Security Question 1 _____

Answer _____

Security Question 2 _____

Answer _____

Security Question 3 _____

Answer _____

Date of Birth _____

Rescue Email Address

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

Rescue Email Address (optional) _____

Mailing Address

Country/Institution _____

Address Line 1 _____

Address Line 2 (optional) _____

Town/City _____

State/Province _____

ZIP Code _____

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

This is provided for information purposes only. Do not share your Apple⁺ ID with Abbott.

DOWNLOADING YOUR PATIENT CONTROLLER APP

The NeuroSphere™ Patient Controller app is compatible with select personal Apple® mobile digital devices running iOS® software 12.5.7 or later.

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

As Apple® releases new operating system (iOS® software) updates, **it is important that you DO NOT update iOS® software on the device until instructed to do so by Abbott.**

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

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

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

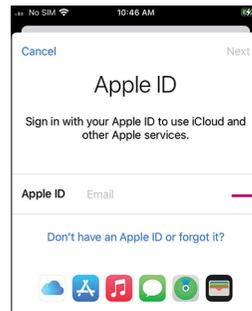
Download your Patient Controller app using your Apple⁺ ID.

- a. Sign in by going to **Settings** and then **Sign In to My Phone**.
- b. Enter your **Apple⁺ ID** and **password** (Figure 2). If you do not already have an Apple⁺ ID, refer to the Apple⁺ ID Setup section (pages 4–6).
- c. Tap this icon to open the **App Store⁺** (Figure 3). Search for Patient Controller NR.
- d. Tap **Get** to download the app (Figure 4).



Wi-Fi⁺ bars

Figure 1



Sign in

Figure 2



Figure 3

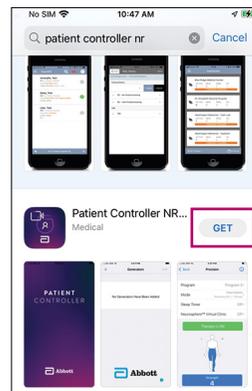


Figure 4

This is provided for information purposes only. Do not share your Apple⁺ ID with Abbott.

- e. Pair your Patient Controller app to the implantable pulse generator (IPG). To do so, remove the keeper bar on the magnet, and hold the magnet over your IPG for 10 seconds.
- f. Remove the magnet.
- g. Open your **Patient Controller app** on the Apple⁺ mobile digital device.
- h. Tap the **+** button (Figure 5).
- i. The serial number of the IPG you just held the magnet over will appear. Tap it. Only IPGs that have had the magnet placed over them for 10 seconds will appear in this list.

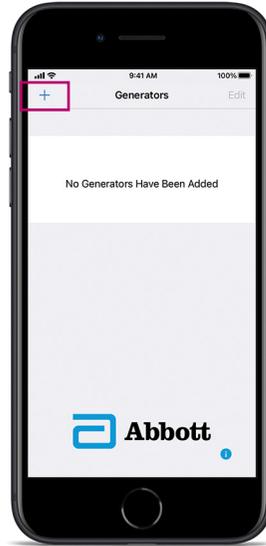


Figure 5

- j. A number code appears on the screen of your Patient Controller app. Enter that number and tap **Pair** (Figure 6).

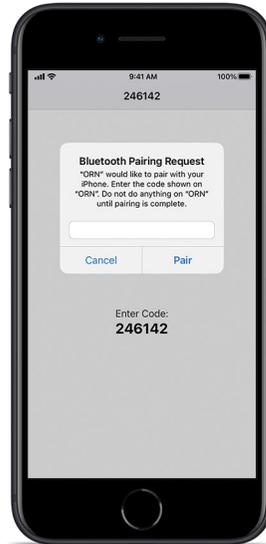


Figure 6

UPDATING YOUR PATIENT CONTROLLER APP

The NeuroSphere™ Patient Controller app is compatible with select personal Apple® mobile digital devices running iOS® software 12.5.7 or later.

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

As Apple® releases new operating system (iOS® software) updates, **it is important that you DO NOT update iOS® software on the device until instructed to do so by Abbott.**

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

UPDATING YOUR iOS⁺ SOFTWARE

- a. Go to **Settings**.
- b. Make sure you are connected to Wi-Fi⁺.
- c. Go to the **General** tab under **Settings** (Figure 7).
- d. Tap **Software Update** (Figure 8).
- e. If an update is needed, **Download and Install** will appear. Tap this (Figure 9).
- f. Enter your passcode and agree to the **Terms and Conditions**.
- g. Wait for the update to finish loading (Figure 10).
- h. Tap **Install Now** (Figure 11).

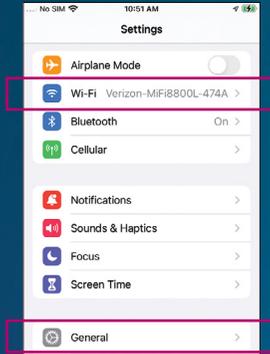


Figure 7

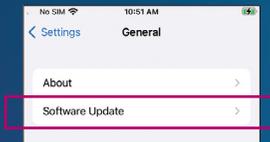


Figure 8



Figure 9



Figure 10



Figure 11

UPDATING YOUR PATIENT CONTROLLER APP

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

- a. Tap on the **App Store**[†].
- b. Search for Patient Controller NR (Figure 12).
- c. If an update is shown, tap it to update your Patient Controller app.



Figure 12

USING YOUR PATIENT CONTROLLER APP

This section provides an overview of your NeuroSphere™ Patient Controller app. It shows you how to start, stop and adjust your therapy. Refer to the NeuroSphere™ Patient Controller User's Guide for complete instructions on how to use and care for your NeuroSphere™ Patient Controller. A copy of this user's guide was included with your magnet, and a digital copy can be found online at manuals.sjm.com.

BEFORE CONNECTING TO YOUR PATIENT CONTROLLER APP

Make sure that Bluetooth® wireless technology is enabled on the device. You can turn Bluetooth® wireless technology settings on and off in the **Settings** (Figure 13).

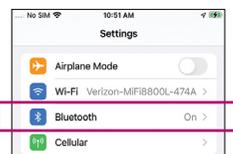


Figure 13

CONNECTING TO YOUR STIMULATION DEVICE

- a. Tap the **Patient Controller** icon on your device screen to launch the app (Figure 14). Your NeuroSphere™ Patient Controller app will automatically connect to your generator.

Note: When tapping icons on an Apple⁺ mobile digital device, use a short, light tap. Pressing on an app for longer than 1 second can result in moving or possibly deleting the app.

- b. If you have two generators, tap the generator in the list that you want to connect (Figure 15).



Figure 14



Figure 15

STARTING AND STOPPING STIMULATION

- a. Start and stop stimulation by tapping on the **Therapy is ON** or **Therapy is OFF** button on the **Therapy** screen (Figure 16).

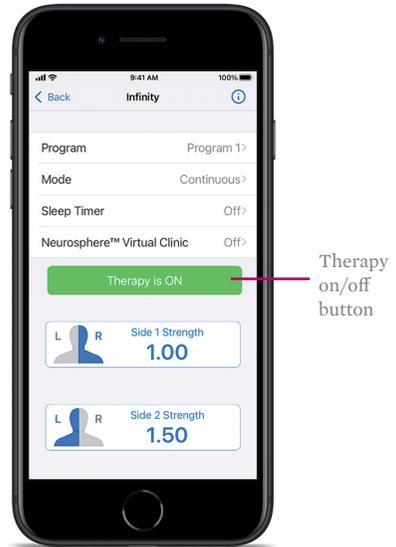


Figure 16

VIEWING AND SELECTING A PROGRAM

Tap **Program Name** on the **Therapy** screen to open the **Programs** screen. On the **Programs** screen, you can view and select any of the saved programs (Figure 17). 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**.

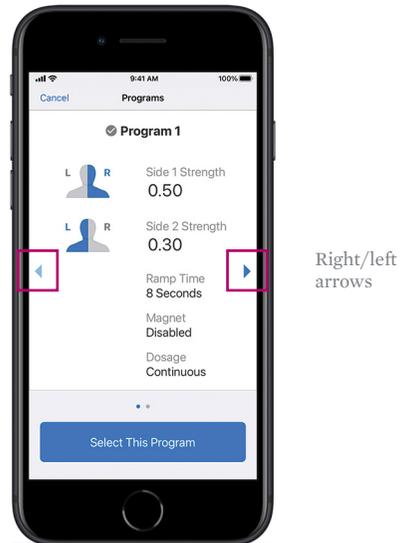


Figure 17

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 (Figure 18).

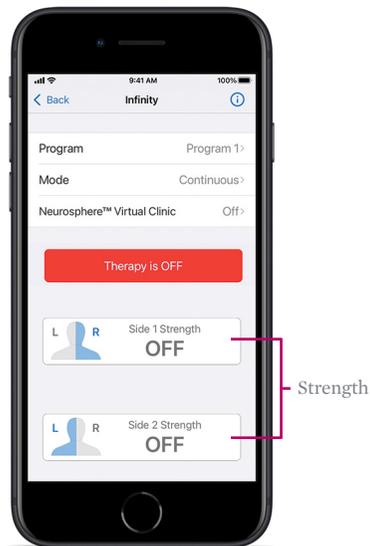


Figure 18

- c. Tap on the **-** or **+** buttons to increase or decrease strength levels until you feel a comfortable level of stimulation (Figure 19).

The number and green bar will increase or decrease as you increase or decrease strength (Figure 19).

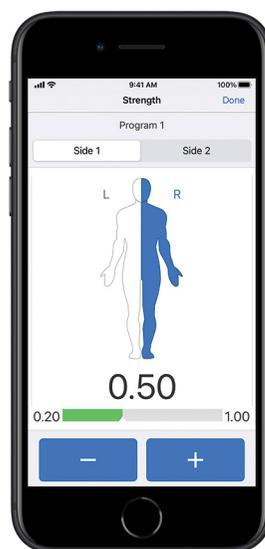


Figure 19

TURNING OFF YOUR PATIENT CONTROLLER APP

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

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

To turn off an Apple[®] mobile digital device provided by Abbott, press and hold the **Power** button (Figure 20) until the **Slide to Power Off** bar appears, and then slide the bar to the right.

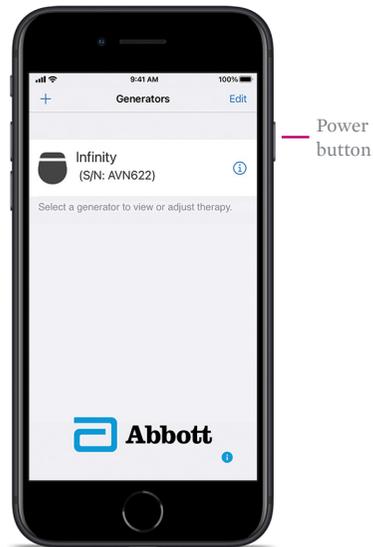


Figure 20

PATIENT CONTROLLER APP ALERTS

APP UPGRADE AVAILABLE

Your NeuroSphere™ Patient Controller app will show an alert when a new version of the app is available in the App Store[®]. You can refer to the earlier instructions in this user's guide for how to upgrade your Patient Controller app.

SECURITY ALERT

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

ACCESSING TEMPORARY MOBILE DIGITAL DEVICE MODES

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

These temporary modes include:

- Airplane-Ready Mode
- Surgery Mode
- MRI Mode

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

AIRPLANE-READY MODE

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

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

BEFORE YOUR FLIGHT

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

AFTER YOUR FLIGHT

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

SURGERY MODE AND MRI MODE

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

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

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

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

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

THIS USER'S GUIDE SHOULD BE USED IN ADDITION TO THE INSTRUCTIONS FOR USE FOR YOUR NEUROSPHERE™ PATIENT CONTROLLER APP. YOU CAN FIND A COPY OF THESE INSTRUCTIONS AT MANUALS.SJM.COM.

PLACING YOUR DBS SYSTEM IN SURGERY MODE

Place your device in Surgery Mode before your procedure.

Turning on Surgery Mode turns off your stimulation.



Turning On Surgery Mode

- a. From the **Therapy** screen, tap **Mode** to display the **Mode** screen (Figure 21).



Figure 21

- b. Tap **Surgery Mode** to view the **Surgery Mode** screen (Figure 22).



Figure 22

- c. Tap the **Surgery Mode** toggle button (Figure 23).



Figure 23

Turning Off Surgery Mode

- a. Launch your Patient Controller app and connect with your generator. The “Generator Is in Surgery Mode” message will appear.
- b. Tap **Exit Surgery Mode** to turn off Surgery Mode (Figure 24).

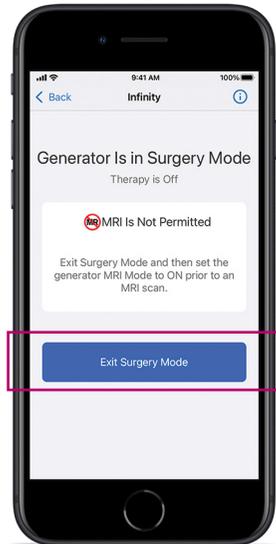


Figure 24

- c. The **Therapy** screen appears, showing that stimulation therapy is off.
- d. Tap **Therapy is OFF** to start stimulation (Figure 25).



Figure 25

PLACING YOUR DBS SYSTEM IN MRI MODE

Place your device in MRI Mode before entering the magnetic resonance (MR) environment. Turning on MRI Mode turns off your stimulation.

Turning On MRI Mode

- a. From the **Therapy** screen, tap **Mode** to display the **Mode** screen (Figure 26).

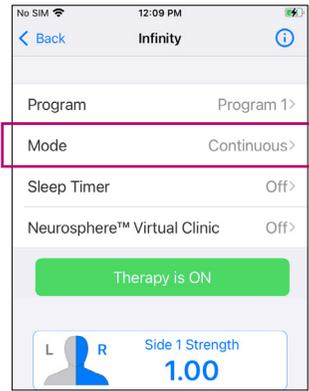


Figure 26

- b. Tap **MRI Mode** to view the **MRI Mode** screen (Figure 27).



Figure 27

- c. Tap the **MRI Mode** toggle button (Figure 28).

CAUTION: Do not delete the paired Bluetooth® wireless connection between the IPG and the patient controller, and do not delete the IPG from the Generators list while the system is in MRI Mode. Doing so will prevent the system from disabling MRI Mode, which may prevent therapy from being turned on again.

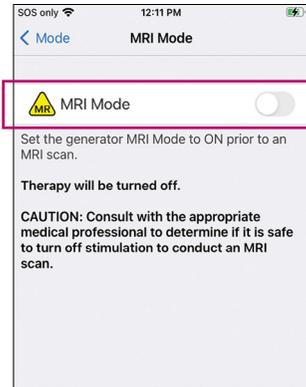


Figure 28

- d. When the “Set Generator to MRI Mode?” message appears, tap **Continue** (Figure 29). Stimulation stops, and your Patient Controller app checks the system for any issues.

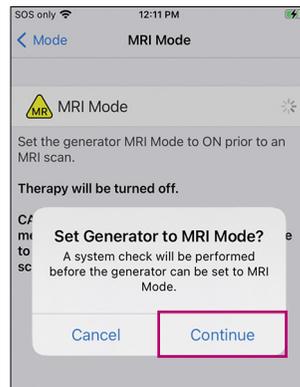


Figure 29

- e. If the checks are successful, the “Proceed With MRI” message will appear, indicating MRI Mode is turned on. Tap **OK**.

Turning Off MRI Mode

- a. Launch your Patient Controller app and connect with your generator. The “Generator Is in MRI Mode” message will appear. Tap **Exit MRI Mode** to turn off MRI Mode (Figure 30).

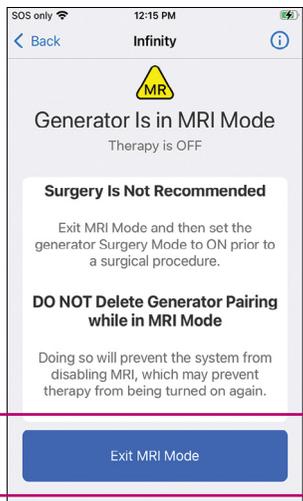


Figure 30

- b. The **Therapy** screen appears, showing that stimulation therapy is off.
- c. Tap **Therapy is OFF** to start stimulation (Figure 31).



Figure 31

CHECKING THE GENERATOR BATTERY STATUS

It is recommended that you connect with your generator to check your generator battery status on a regular basis.

Checking Your Battery Status

- Open your NeuroSphere™ Patient Controller app.
- Connect with your generator.
- Tap the  icon in the top right corner (Figure 32).



Figure 32

When the battery status is good, you will see the  icon displayed (Figure 33).

When the battery status is approaching the end of service, you will see the  icon displayed.



Figure 33

Note: Once your generator is connected to your Patient Controller app, if your generator is approaching the end of service, a warning pops up in your Patient Controller app (Figure 34).

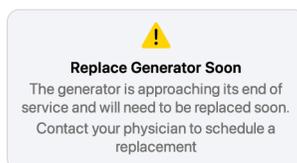


Figure 34

IMPORTANT ITEMS TO REMEMBER

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



FOR SURGERY MODE

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

FOR MRI MODE

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

PREPARING FOR YOUR SURGERY OR MRI SCAN

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

- a. Tell the physician who is performing your surgery or MRI scan that you have an implanted neurostimulation system from Abbott.
- b. Contact your neurologist to discuss your upcoming procedure or MRI scan and the possible effects it may have on your implanted device.
- c. Schedule your surgery or MRI scan. 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 Abbott Patient ID Card.
- d. Fully charge your Patient Controller before arriving for the procedure.

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

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



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

NEUROSPHERE™
VIRTUAL CLINIC
USER'S GUIDE

GETTING STARTED:
**PREPARING FOR YOUR
NEUROSPHERE™ VIRTUAL
CLINIC SESSION**

It is important to find a good environment for your Virtual Clinic session.

- Choose a quiet, well-lit location with the best possible Wi-Fi⁺ and/or cellular signal strength.
- Limit background noise and other distractions like the TV and pets.
- Find an area where you can comfortably lie down for your assessments and programming session conducted during your visit.

TOPICS COVERED IN THIS SECTION

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FOR DETAILED INSTRUCTIONS ON HOW TO USE THE **NEUROSPHERE™ VIRTUAL CLINIC** FEATURE IN YOUR NEUROSPHERE™ PATIENT CONTROLLER APP, REFERENCE THE INSTRUCTIONS FOR USE PROVIDED BY YOUR DOCTOR, OR VISIT **MANUALS.SJM.COM**.

PREPARING FOR A NEUROSPHERE™ VIRTUAL CLINIC SESSION

Before your Virtual Clinic session, it is important to check your mobile digital device.

- a. Prop up your Apple[®] mobile digital device or mobile digital device provided by Abbott for a hands-free session if possible.
- b. Sit so you are within 1-2 meters of your device.
- c. To avoid any interruptions during your session, turn on **Do Not Disturb** (Figure 35).
- d. Make sure your mobile digital device is sufficiently charged (Figure 36).



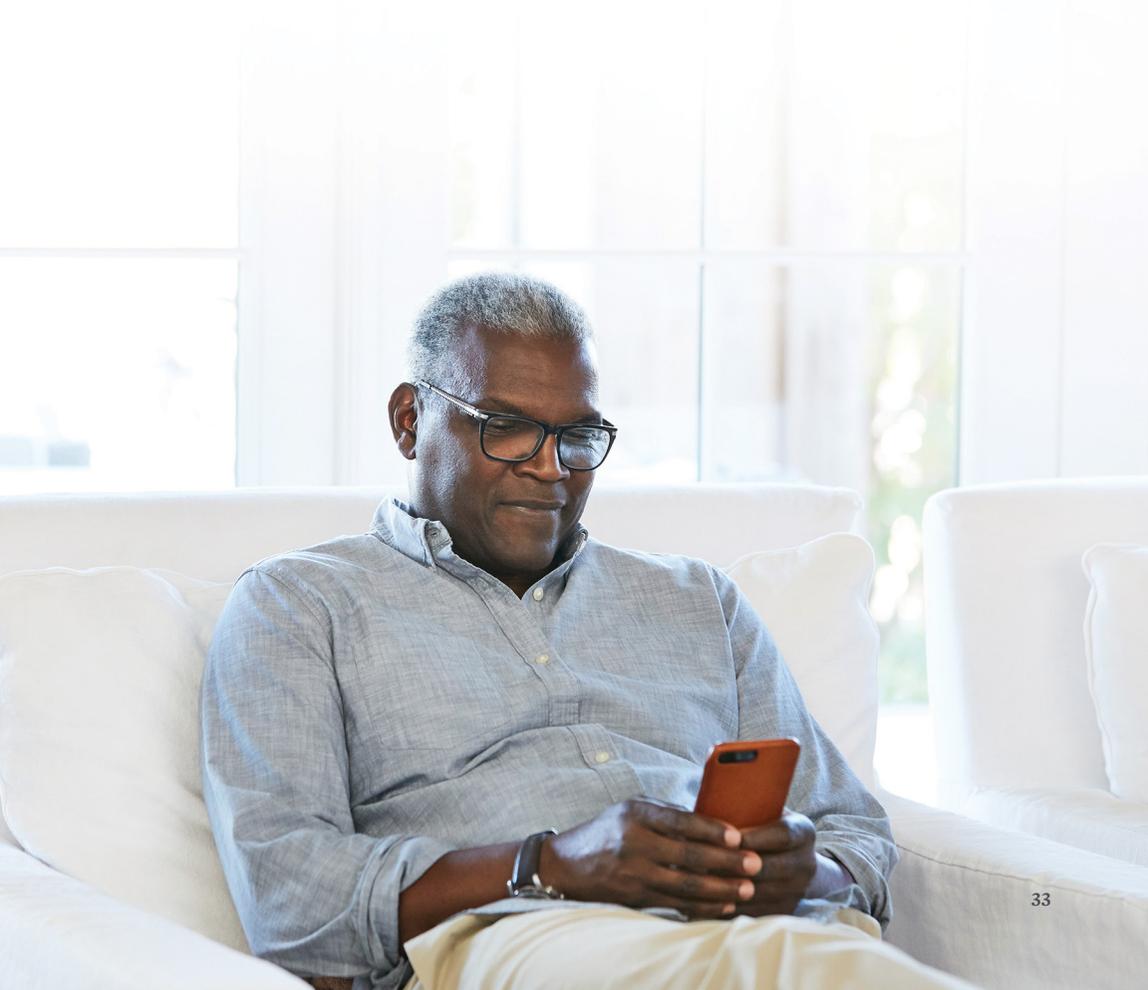
Figure 35



Figure 36

Wireless headphones should not be used during a Virtual Clinic session because they can cause Bluetooth® wireless technology interference with your neurostimulator.

Before your first Virtual Clinic session, your doctor or Abbott representative will help you complete the registration process.



CONNECTING TO A VIRTUAL CLINIC SESSION

- a. Your doctor will call and direct you to Virtual Clinic on your Patient Controller app (Figure 37).



Figure 37

- b. On the **Generators** screen, tap the IPG for your Virtual Clinic session (Figure 38).



Figure 38

- c. On the **Therapy** screen, tap the **NeuroSphere™ Virtual Clinic** option (Figure 39).



Figure 39

- d. Toggle the **NeuroSphere™ Virtual Clinic** switch to **On** (Figure 40), and wait for your doctor to connect.

*Note: Be sure to review the Virtual Clinic session instructions after toggling the NeuroSphere™ Virtual Clinic switch to **ON**.*

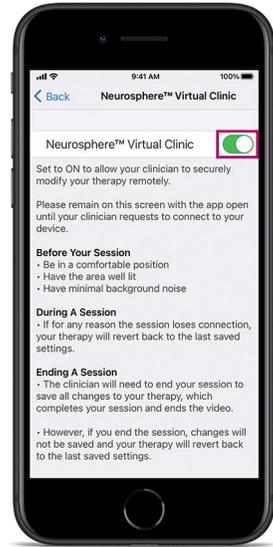


Figure 40

- e. Wait for the “Session Ready to Start” message to appear.
- f. Tap **Start** to begin your Virtual Clinic session (Figure 41).

Note: Your doctor cannot start the session without your permission.

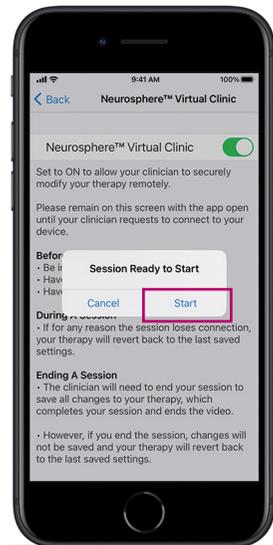


Figure 41

You will see a video of yourself until your doctor is connected.

You will have full control of starting and stopping Virtual Clinic sessions (Figure 42).

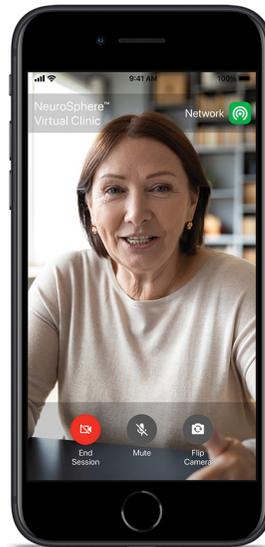


Figure 42

Once your doctor joins, you can talk via video chat (Figure 43).



Figure 43

NAVIGATING THE VIRTUAL CLINIC SCREEN



Figure 44

- 1 Network status indicator
 - 2 Use the **End Session** button only in case of emergencies (for example, if significant connection issues are encountered)
 - 3 The **Mute** button mutes your audio to your doctor
 - 4 Camera reverse
- | | |
|---|--|
|  | GREEN
Good network connection |
|  | YELLOW
Slow network connection |
|  | RED
Very slow network connection |

INTERACTING WITH YOUR DOCTOR **REMOTELY**



WITHIN
1-2 METERS



Always stay within Bluetooth® wireless technology range of your iOS® software device (within 1-2 meters). Bluetooth® wireless technology connection must be maintained to make programming adjustments to your neurostimulator.

TROUBLESHOOTING A VIRTUAL CLINIC SESSION

If you happen to get disconnected during a Virtual Clinic session, here are ways to manage the interruption:

- a. Keep your application open.
- b. Wait for the “Session Ended Unexpectedly” message to appear.
- c. Tap the **Dismiss** button (Figure 45).

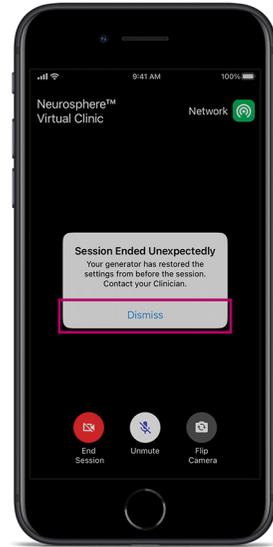


Figure 45

After you dismiss the message, you will be returned to the **Therapy** screen.

Your settings will revert to the last best-known therapy settings stored in your Protected Recovery Program (Figure 46).



Figure 46

FINISHING A VIRTUAL CLINIC SESSION

Your doctor must close the session in order for the adjustments to save.

- a. At the end of your session, wait for the “Session Completed” message to appear (Figure 47).

Do not end your session or close the application until this message appears.

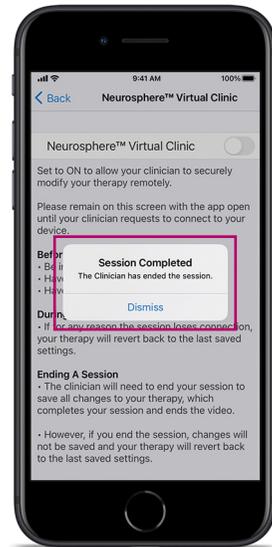


Figure 47

- b. Tap the **Dismiss** button (Figure 48).

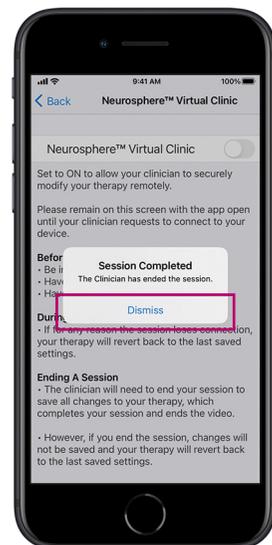


Figure 48

- c. Tap **Generators** to return to the **Therapy** screen.

- d. Confirm your new therapy settings are as you expected based on your Virtual Clinic session (Figure 49).



Figure 49

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

Risk Information: There is no cure for Parkinson's disease (PD) and essential tremor (ET), but there are options available to treat symptoms. The first-line therapy is medication. Surgical treatments are also available. It's important to discuss with your doctor what's right for you along with the risks and side effects of each option, such as motor fluctuations or permanent neurological impairment. As with any surgery or therapy, DBS has risks and complications. Loss of coordination is a potential side effect of DBS therapy. Patients should exercise reasonable caution when participating in activities requiring coordination, including those that were done before receiving therapy (for example, swimming). Patients should also exercise reasonable caution when bathing. New onset or worsening depression, which may be temporary or permanent, is a risk that has been reported with DBS therapy. Suicidal ideation, suicide attempts, and suicide are events that have also been reported. Most side effects of DBS surgery are temporary and correct themselves over time. Some people may experience lasting, stroke-like symptoms, such as weakness, numbness, problems with vision or slurred speech. In the event that the side effects are intolerable or you are not satisfied with the therapy, the DBS system can be turned off or surgically removed. Risks of brain surgery include serious complications such as coma, bleeding inside the brain, paralysis, seizures and infection. Some of these may be fatal.

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

Indications for Use: Bilateral stimulation of the subthalamic nucleus (STN) or the internal globus pallidus (GPI) 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.

Contraindications: 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.

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, case damage, activities requiring excessive twisting or stretching, operation of machinery and equipment, and pregnancy. Loss of coordination is a possible side effect of DBS Therapy, exercise caution when doing activities requiring coordination (for example, swimming), and exercise caution when bathing. 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, 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.

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