



Neuspera Sacral Neuromodulation System

Patient Manual

Patent information covering this product is available at www.neuspera.com/patent-information/

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Getting to Know Your System

The Neuspera Implantable Sacral Nerve Stimulation System (“Neuspera System”) is intended for stimulation of the sacral nerve to treat urinary urgency incontinence (UUI) symptoms.

Neuspera System Components

The Neuspera System is composed of several components, described below and shown in [Figure 1](#).

- A. A small **neurostimulator** (similar to a wire) is implanted in your lower back by your physician. The neurostimulator delivers pulses of energy to the sacral nerve that helps control the bladder.
- B. A **Wireless Transmitter** (WT) uses Neuspera Medical, Inc. (Neuspera) mid-field powering technology to wirelessly send power to your neurostimulator. Your neurostimulator only works while it receives power from the Wireless Transmitter. Your Wireless Transmitter must be worn in your Neuspera Wearable during stimulation. This device is water-resistant to allow for daily cleaning. The device is powered by a rechargeable battery that is recharged on a wireless charging pad.

- C. The Wireless Transmitter will be provided with a **magnet**, which is used to reset the Wireless Transmitter when the Wireless Transmitter is not charging appropriately or becomes inoperative.
- D. The Neuspera **Wearable (Wearable)** is designed to hold and maintain your Wireless Transmitter (WT) above the implanted neurostimulator for delivery of therapy. The specifically designed pocket will also pad and insulate the Wireless Transmitter against your body to improve comfort. An optional leg loop strap is provided to offer additional support for maintaining vertical positioning. The Wearable is intended to be worn under general clothing (i.e. pants, shirts, and jackets) and over Wearable. It is also compatible with pads and diapers. The Wearable is available in four sizes from Small to Extra Large.
- E. The Wireless Transmitter **charging pad** is used to recharge the Wireless Transmitter between uses.
- F. The Patient Controller Application (**App**) is a software application linked to your Wireless Transmitter to adjust therapy settings to optimize comfort and symptom relief. The App also allows you to monitor battery levels of the Wireless Transmitter and turn communications from your Wireless Transmitter and App on/off. The App will be provided to you on an Apple iPhone.

■ **NOTE:** Your Wireless Transmitter is specific to your neurostimulator and your App. Another person's Wireless Transmitter will not work with your neurostimulator. Another person's App will not work with your Wireless Transmitter.

All parts of the Neuspera system are suitable for use at home. Your system should not be affected by standard household appliances or devices under normal use (for additional information, see [“Home Environment” on page 59](#)).

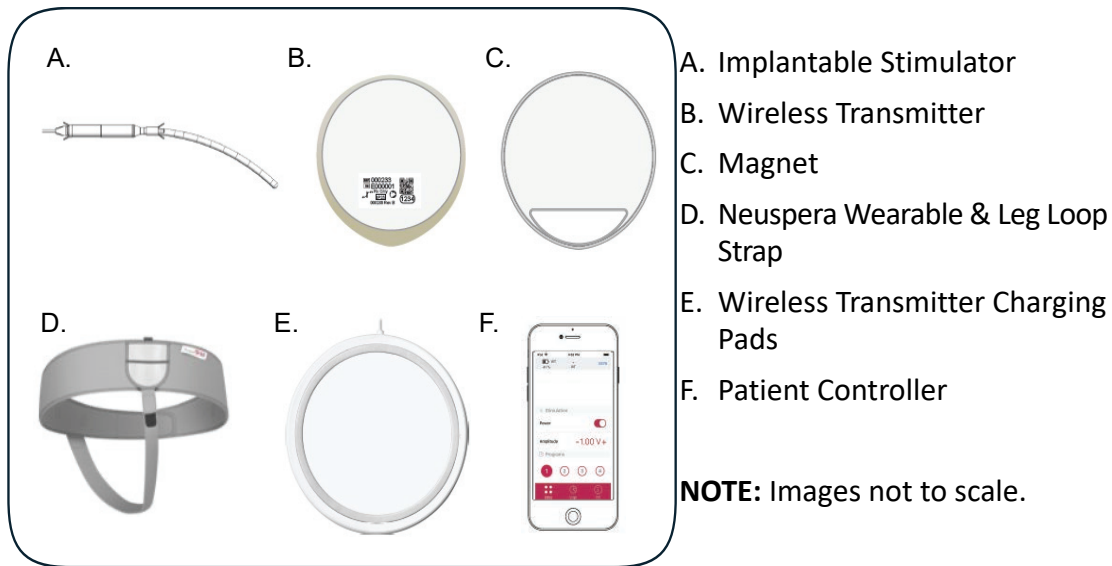


Figure 1. The Neuspera Implantable Sacral Nerve Stimulation System

System Setup

Your system will be set up by your physician or physician's assistant according to your physician's instructions before you leave the hospital or outpatient clinic following the implant of the neurostimulator.

Either a representative of Neuspera or the clinic will explain how each component works. The Neuspera System requires no specialized skills or knowledge for patient use.

If you have any problems using any part of the system, contact your physician/clinic.

Your Patient ID Card

You will receive a patient ID card ([Figure 2](#)) with your Neuspera System. Carry this ID card with you at all times in the event you need medical attention or are passing through a security screening. If you lose your patient ID card, request a new one by contacting your physician/clinic.

Implanted Neurostimulator

neuspera

name: _____

address: _____

city, state: _____

telephone: _____

model number

serial number

implantation date

implanted medical device information

www.neuspera.com

1-408-876-4861

patient has an implanted neurostimulator
in case of emergency, contact:

doctor's name

phone number

This patient has a complete MR Conditional system implanted and may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in patient injury or device malfunction. Full MRI safety information is available in the MRI Safety Information section of the clinician manual which can be obtained by calling 1-408-876-4861.

004071 Rev 01

Figure 2. Patient ID Card

Visiting the Clinic

Please bring your Wireless Transmitter, Charging Pad, magnet and Patient Controller with you to all follow-up visits. Important usage information will be collected. Your physician may also need to modify the programs and/or update the software to improve therapy.

Basic Use/Frequently Performed Tasks

■ **NOTE:** For optimal relief of your symptoms, it is important to follow the described operating use of your Neuspera System.

Before Use

1. Inspect the Wireless Transmitter for cracks, holes, or other damage that may expose the internal circuitry or allow water inside. Do not use if there is any damage.
2. Inspect the Wearable for:
 - a. any tears or holes around the Wireless Transmitter pocket.
 - b. an insulating foam spacer inside the Wireless Transmitter pocket.

Do not use if there are any tears, holes or the insulating foam is not present in the pocket.

■ **NOTE:** If your Wireless Transmitter was stored at very hot or very cold temperatures (such as in your car during cold winters or hot summers), let it reach room temperature prior to use. Depending on the storage temperature, this could take up to 5 hours. Do not use heating or cooling devices to heat or cool your Wireless Transmitter; let it come to room temperature on its own.

Charging the Wireless Transmitter (WT)

The Wireless Transmitter should be charged daily prior to each use. Ensure the charging pad is plugged in and place the Wireless Transmitter on the charging pad as shown in [Figure 3](#). The Wireless Transmitter can only charge if the dotted white side is facing up and the logo/label side is facing down (i.e., device is “upside-down”). You will see a light on the charging pad when charging. Leave the Wireless Transmitter on the charging pad when it is not in use for a therapy/stimulation session. If the charging pad light does not indicate the Wireless Transmitter is charging, refer to *Troubleshooting*.

■ **NOTE:** The Wireless Transmitter is unavailable for use while charging.

A. Make sure charging pad is connected to power and in the correct orientation*.

B. Place Wireless Transmitter on the charging pad with the white dotted side up and the label/Neuspera logo facing down as shown below.



Light on the edge of the charging pad indicates Wireless Transmitter is charging.



Incorrect orientation - Wireless Transmitter will not charge if the label/Neuspera logo is facing up.

C. Confirm charging pad status light* indicates charging has started.

D. If charging has not started or there is an error indicated by the charging pad status light*, refer to the troubleshooting section.

**If needed, refer to instructions for charging pad provided by manufacturer*

Figure 3. Charging the Wireless Transmitter

If the battery is fully drained, it may take up to 5 hours to fully charge your Wireless Transmitter. A fully-charged battery should provide enough power for at least 2 hours of use.

■ **NOTE:** Your Wireless Transmitter will turn on as soon as it is removed from its charging pad. If you are not putting it on immediately, use your App to turn it off (see [“Stopping/Starting Stimulation with the App” on page 31](#)) to ensure that it has enough battery power when you need it.

Putting on the Wireless Transmitter

■ **NOTE:** Your Wireless Transmitter must be worn in the pocket of your Neuspera Wearable. This is to protect you from the heat of the Wireless Transmitter and to position it correctly to power your neurostimulator.

■ **NOTE:** It is normal for the Wireless Transmitter to become warm during use as it is delivering power to your neurostimulator. If it becomes uncomfortably hot, turn it off ([Figure 14 on page 30](#)), take off your Wearable and contact your physician/clinic.



CAUTION: Wearing the Wireless Transmitter against your skin may result in discomfort, irritation, or a burn.



CAUTION: Do not place the Wearable in direct contact with compromised skin such as open or healing wounds. Follow the instructions provided by your physician for post operative wound care after implantation of the Neuspera neurostimulator.

- A. Open the WT Pocket by pulling on the pull tab and disconnecting the Velcro hook and loop. Remove the Wireless Transmitter from the charging pad and insert it into the pocket of your Wearable as shown in **Figure 4**. Be sure to insert the Wireless Transmitter such that the white, dotted side is against your body (against the foam side of the pocket) and the logo/label side is facing out away from your body. The Wearable pocket includes a dotted label, shown in **Figure 4.**, to help place the Wireless Transmitter in the correct direction.

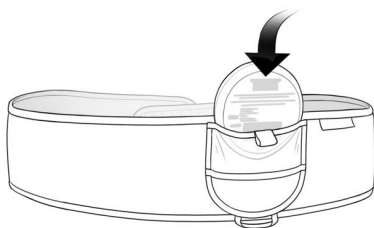


Figure 4. Inserting the Wireless Transmitter into the pocket of the Wearable (Left); Wearable pocket dotted label (Right)

- B. If using the leg loop strap, connect the strap to the leg loop connector below the WT pocket shown in **Figure 5**.

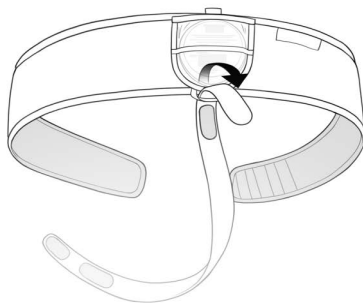


Figure 5. Connect the leg loop strap to the leg loop connector.

- C. Wrap the Wearable around your body as shown in **Figure 6**. The Wireless Transmitter should be on the exterior side of the Wearable and not in direct contact with your skin.

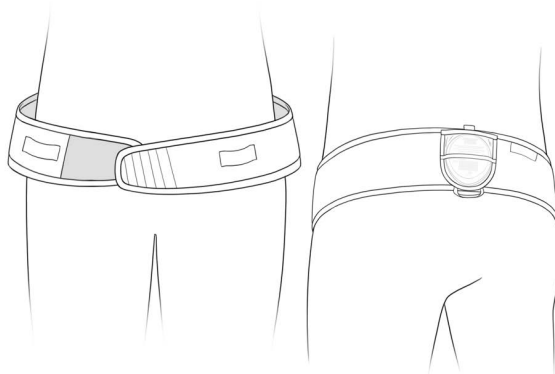


Figure 6. Wrap the Wearable around your body with the Wireless Transmitter on the exterior.

- D. Using both hands, stretch the Wearable to clasp the Velcro hook and loop together in front of your body to the desired level of tightness. Reference **Figure 7.**

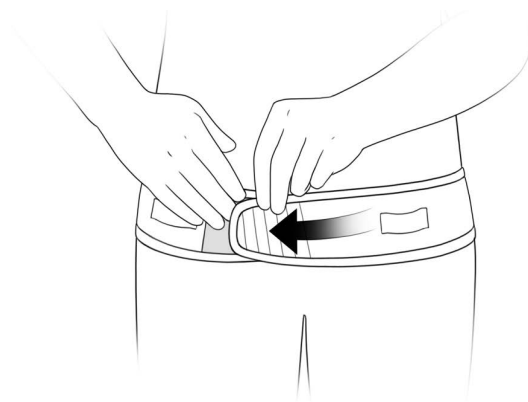


Figure 7. Stretch and clasp the Velcro Hook and loop with both hands.

- E. Horizontally and vertically adjust the Wearable to position the Wireless Transmitter above the implanted neurostimulator (see **Figure 8**). If needed, unclasp the Velcro and reposition the device.

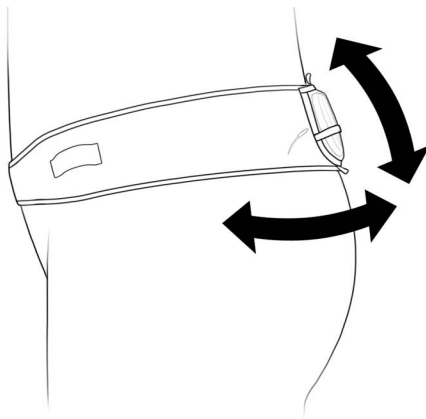


Figure 8. Adjust the Wearable to the position the Wireless Transmitter above the implant.

- F. If using the leg loop strap, pull the strap between your legs and connect it to a leg loop connector on either side (see **Figure 9**). Use whichever leg loop connector feels the most comfortable to you.

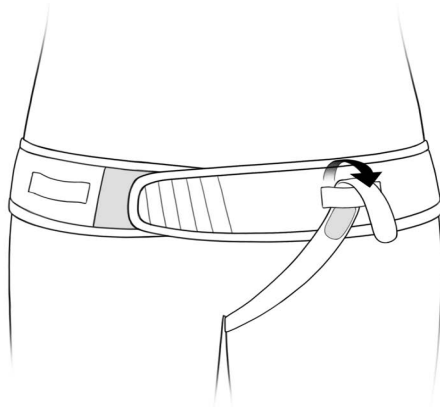


Figure 9. Pull the leg strap between your legs and connect to one of the leg loop connectors.

- G. Wear the Wearable for your prescribed therapy duration. If therapy is lost, try adjusting the Wearable to regain therapy. If therapy cannot be re-achieved, refer to the Neuspera System Patient Manual for troubleshooting the Wireless Transmitter or Patient Controller.

■ **NOTE:** When the Wireless Transmitter is in the correct position, it will connect automatically to the neurostimulator to begin treatment. You should feel a slight “tingling” or “pulling” sensation.

■ **NOTE:** If you do not feel the tingling/pulling, check that the Wireless Transmitter is inserted correctly into the pocket of the Wearable with the dotted white side facing your body.

- a. If you still do not feel the tingling/pulling, increase the stimulation until you can feel it - see [“Changing Stimulation Settings” on page 28](#).
- b. If you still do not feel the tingling/pulling, check your App to confirm that the Wireless Transmitter battery is charged ([Figure 13 on page 28](#)), stimulation is on ([Figure 14 on page 30](#)), and communication is on ([Figure 15 on page 32](#)).

Removing the Wireless Transmitter/Ending a Therapy Session



CAUTION: The Wireless Transmitter will become warm during use. If it is too hot to handle, turn stimulation off to let it cool down or remove the Wireless Transmitter by taking off your Wearable. The Wireless Transmitter may interrupt therapy if an elevated temperature is detected. Programmed therapy will resume after the Wireless Transmitter temperature has sufficiently decreased.

Stimulation stops when the Wireless Transmitter is removed from the area over your neurostimulator. Removing your Wearable and Wireless Transmitter or removing the Wireless Transmitter from the Wearable pocket will stop stimulation. Place the Wireless Transmitter on the charging pad, after removal to ensure it is charged for its next use.

■ **NOTE:** You may also stop therapy from your App - see [“Stopping/Starting Stimulation with the App”](#) on page 31.

Your Patient Controller and Neuspera Application

The Neuspera Application (“App”) is a simple tool you and your doctor can use to adjust your therapy, monitor your Wireless Transmitter battery level, view your program use history, and adjust your Wireless Transmitter for airplane and international travel. The App runs on an iPod Touch, “Patient Controller,” see [Figure 10](#) below).

■ **NOTE:** Keep your Patient Controller at least 10 centimeters (4 inches) away from your Wireless Transmitter when it is in the pocket of your Wearable when you are wearing it. Your Patient Controller may interfere with the communication between your Wireless Transmitter and neurostimulator.

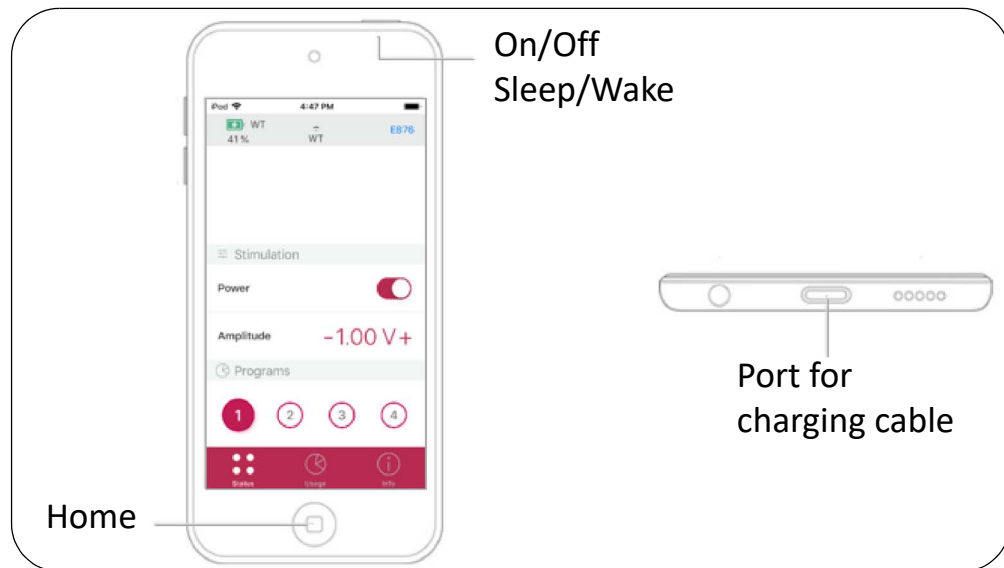


Figure 10. Patient Controller

Charging Your Patient Controller

1. Plug charging cable into a USB outlet.
2. Insert charging cable into the bottom of the Patient Controller.
3. You should see a lightning bolt in the battery icon if the device is charging.

Turning on Your App and Connecting to Your Wireless Transmitter

1. Press the center “Home” button on the Patient Controller to turn on the display. If the Patient Controller is off, press and hold the top button to turn it on (see [Figure 10](#) above).
2. Your App should automatically connect to your Wireless Transmitter when it is within 1 meter (3 feet). When the App is connected to your Wireless Transmitter, the Wireless Transmitter ID will appear in blue in the upper right corner of the App display (see [Figure 11](#) below).

■ **NOTE:** You do not need to turn on the App to connect your Wireless Transmitter to your neurostimulator or to receive therapy.

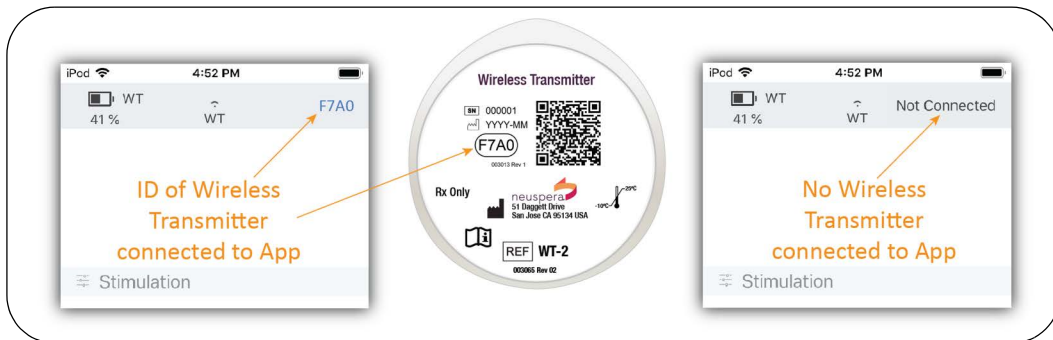


Figure 11. App screen - Connected Wireless Transmitter identification. Your Wireless Transmitter ID is found on the label, under the square barcode. If your App is not connected to any Wireless Transmitter, the ID will display as “Not Connected” (right image).

3. If the App shows that it is connected to a Wireless Transmitter other than the one you are wearing, tap the Wireless Transmitter ID in the upper right corner and select the correct Wireless Transmitter (WT, see [Figure 12](#)).



Figure 12. Choosing a Wireless Transmitter to connect

Checking Wireless Transmitter and Patient Controller Battery Levels

You can check the battery level of your Wireless Transmitter and Patient Controller from any screen on your App. The Wireless Transmitter battery level is in the upper left corner. The Patient Controller battery level is in the upper right corner (see [Figure 13](#)).

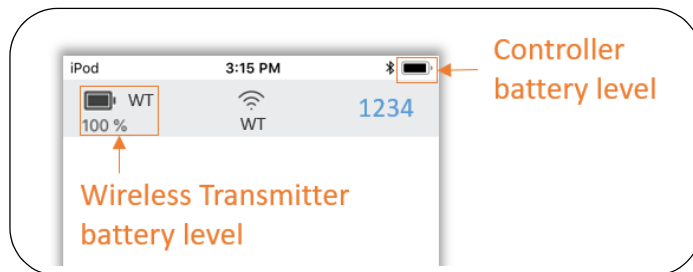


Figure 13. Checking battery levels

Changing Stimulation Settings

From the Status screen on your App, you can adjust your stimulation (see [Figure 14](#)).

1. You should change the stimulation level if:
 - a. Therapy is painful - decrease Amplitude (tap the minus “-”) until it is no longer painful.
 - b. You do not feel any “tingling” - increase Amplitude (tap the plus “+”) until you begin to feel the tingling.

2. You may also switch to a different program that your physician has set up for you. Turn stimulation off (see next section [“Stopping/Starting Stimulation with the App”](#)), select a different program (number), and turn stimulation back on. Consult with your physician for instructions on when to switch programs.

■ **NOTE:** You cannot switch programs when the stimulation is on. You must turn stimulation off before changing programs.

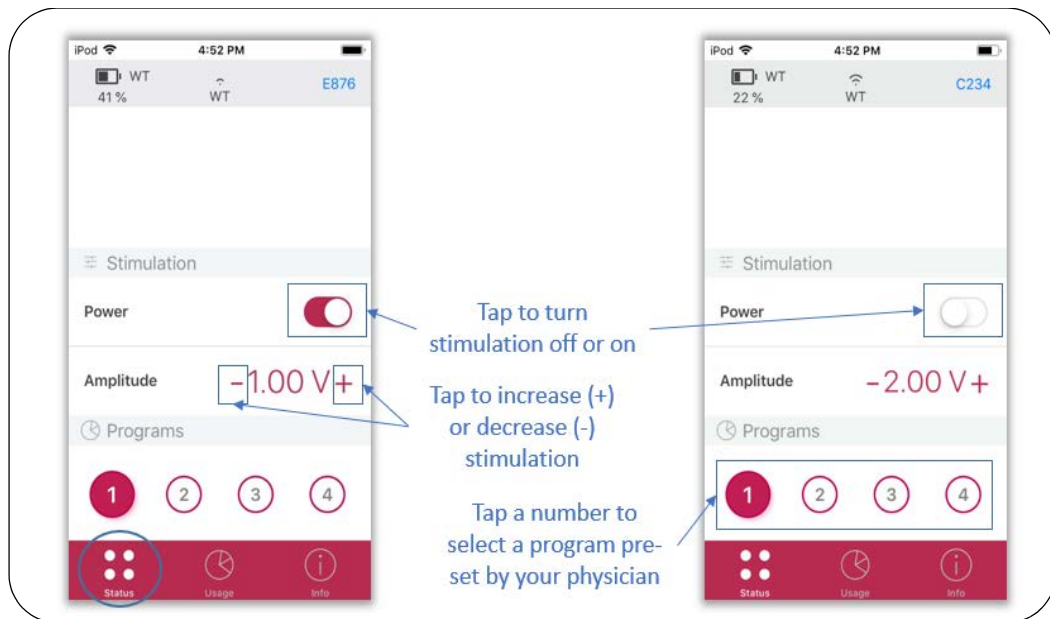


Figure 14. App Status screen - Adjusting stimulation settings and stopping stimulation. Left image: Stimulation on. Right image: Stimulation off.

Stopping/Starting Stimulation with the App

You can stop stimulation on the App by tapping the Power “switch” to move it to the off position (right image, see [Figure 14](#)).

■ **NOTE:** If you turn stimulation off with your App, it will automatically turn back on the next time your Wireless Transmitter is removed from the charging pad.

Adjusting Your Wireless Transmitter and Patient Controller for Travel

■ **NOTE:** See also “[TSA and Other Security Screening](#)” on page 62 for information on going through airport security.

If you are traveling on an airplane or traveling to another continent, you may have to adjust your Wireless Transmitter.

Turning Wireless Communication Off

If your cell phone must be in airplane mode, the communications from your Wireless Transmitter and App should be turned off. Go to the Info screen on your App and tap the Communication “switch” so it is in the off position (see [Figure 15](#)).

■ **NOTE:** When communication is turned off, your Wireless Transmitter will not power your neurostimulator. You must turn communication back on to restart stimulation.

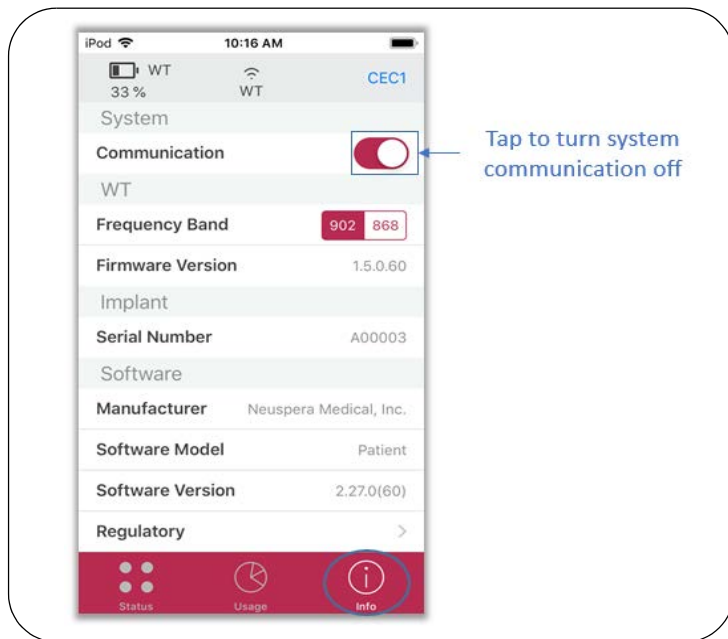


Figure 15. App Info screen – Making adjustments for travel

Viewing Your Program Usage History

From the Usage screen on your App, you can see the relative amount of time that you have used the different programs and a history of your therapy sessions. You can

change the time frame that is displayed by changing the start/end dates or choosing a pre-defined range (see [Figure 16](#) below).

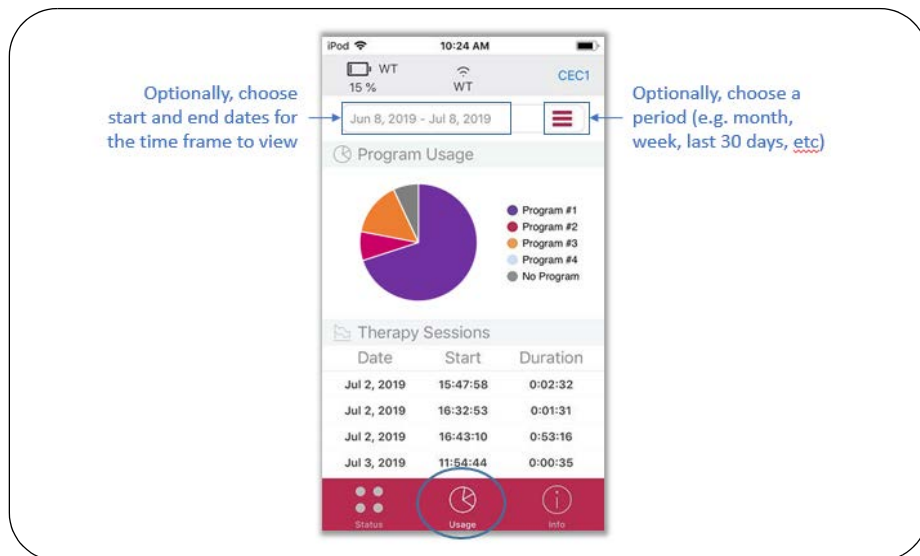


Figure 16. Viewing program and therapy history on the Usage screen

Care of Your System

Cleaning the Wireless Transmitter



CAUTION: The Wireless Transmitter is water-resistant but should not be submerged. Submerging it in water or other cleaning liquids may cause it to malfunction.



CAUTION: Do not use harsh cleaning chemicals to clean the Wireless Transmitter since they may damage the case.

For your safety and hygiene, it is recommended that you inspect your Wireless Transmitter for damage and clean your Wireless Transmitter daily. Look for any signs of damage such as cracking or holes that may expose the internal circuitry or allow water to get inside. To clean your Wireless Transmitter, use a damp cloth and mild soap (such as liquid dish soap).

Cleaning the Neuspera Wearables



CAUTION: Ensure your Wireless Transmitter is removed prior to washing the Wearable.

For proper hygiene, it is recommended that you wash your Wearable once per week between uses. For best results, it is recommended to clasp the Wearable body Velcro

together and machine wash warm followed by tumble dry low. Do not use chlorine bleach or any fabric softener. If ironing, use low heat.

You can request a new Wearable from your clinician if needed.

Cleaning the Magnet, Charging Pad and Patient Controller

Use a soft, dry, lint-free cloth to clean the magnet, charging pad and Patient Controller as needed. Avoid getting liquid in any openings.

Monitoring System Performance

Periodically monitor the activity of the Wireless Transmitter and App. Turn on the App and check for any messages or prompts.

Software Updates

You may receive a notification to update the App software or Wireless Transmitter. These updates may be done at home or during a follow-up visit with your physician.

Troubleshooting

Common problems and their resolutions are listed below. If these actions do not solve the problem, please contact your physician/clinic.

Troubleshooting, Causes, and Resolutions

Problem	Potential Cause	Recommended Action
Wireless Transmitter is not charging (light is not solid and the correct color) *NOTE: The light is dim and may not be visible in bright lighting.	Charging pad is not plugged in	Check that the charging pad cable is plugged into a powered outlet and plugged into the charging pad.
	Charging pad is not placed with the correct side facing up	Check that correct side of charging pad is face up (Wireless Transmitter will be placed on this side of the pad).

Problem	Potential Cause	Recommended Action
<p>(Cont.)</p> <p>Wireless Transmitter is not charging (light is not solid and the correct color)</p>	Wireless Transmitter is not placed with the correct side down on charging pad	Make sure the dotted, white side is facing up and logo/label side is on the bottom (see Figure 3 on page 14).
	Wireless Transmitter is not centered correctly on charging pad	Remove Wireless Transmitter from charging pad and set down in the center of the charging pad.
	Wireless Transmitter was too warm when placed on charging pad.	Remove Wireless Transmitter from the charger and replace it back on the charging pad and confirm charging status indicated in Figure 3 .
	Wireless Transmitter has been damaged (by physical shock, extreme temperatures, and/or water has leaked into device)	Contact your physician for a replacement Wireless Transmitter.

Problem	Potential Cause	Recommended Action
<p>(Cont.)</p> <p>Wireless Transmitter is not charging (light is not solid and the correct color)</p>	<p>Wireless Transmitter has become inoperative.</p>	<p>Wireless Transmitter needs to be reset.</p> <p>Place the Wireless Transmitter correctly on the charging pad (dotted side face up). Place the label side of the magnet (bottom of magnet) against the dotted side of the Wireless Transmitter for 5-10 seconds to perform reset. The teardrop point of the magnet should be aligned with the teardrop point of the Wireless Transmitter (see Figure 17). Ensure that the green light has stopped blinking when the magnet is placed on the Wireless Transmitter. After 5-10 seconds, remove magnet from Wireless Transmitter. Do not leave magnet on Wireless Transmitter while it is charging.</p> <p>Confirm reset was successful by observing the following:</p>

Problem	Potential Cause	Recommended Action
(Cont.) Wireless Transmitter is not charging (light is not solid and the correct color)		1. Confirming the green light on the Wireless Transmitter is blinking. 2. Waiting 30 seconds and observing that the status light of the charging pad has initiated.
Patient Controller is not charging	Charging cable not plugged in	Check that the charging cable is properly plugged into a powered outlet and into the Patient Controller.
Patient Controller display doesn't turn on	Patient Controller is turned off	Turn Patient Controller on by pressing button on top edge of device (see Figure 10 on page 24).
	Patient Controller battery is extremely low	Charge Patient Controller for at least 2 minutes and while still plugged in, turn Patient Controller on by pressing button on top edge of device.

Problem	Potential Cause	Recommended Action
App is not connecting to Wireless Transmitter	Wireless Transmitter and Patient Controller are not close enough	Check that the Wireless Transmitter is within 1 meter (3 feet) of the Patient Controller.
	Patient Controller battery is too low	Check battery level on your App (see Figure 13 on page 28) and charge if needed.
	Wireless Transmitter battery is too low	Charge Wireless Transmitter and try again.
	Wireless Transmitter has been unlinked from your App	Contact your physician/clinic to link your Wireless Transmitter to your App.
App is connected to the wrong Wireless Transmitter	Another Wireless Transmitter is within range of your Patient Controller	If there is another Wireless Transmitter nearby, place the magnet on the unused Wireless Transmitter, click on the Wireless Transmitter "ID" and select the desired Wireless Transmitter (WT; see Figure 12 on page 27).

Problem	Potential Cause	Recommended Action
Wireless Transmitter stops working	Wireless Transmitter battery is not charged or was not fully charged at the start of therapy	Check Wireless Transmitter battery level from the App (see Figure 13 on page 28). Charge Wireless Transmitter if battery level is low. Always leave the Wireless Transmitter on the charging pad when not in use.
	Wireless Transmitter has overheated	Remove the Wireless Transmitter from the Wearable and place it on the charger. This will turn the Wireless transmitter off which will allow it to cool down. Once it has cooled down to room temperature, remove the Wireless Transmitter from the charger and then place it back on the charger. The Wireless Transmitter will then begin charging.

Problem	Potential Cause	Recommended Action
<p><i>(Cont.)</i> Wireless Transmitter stops working</p>	Wireless Transmitter damaged by dropping or water or excessive moisture	Contact your physician/clinic for a new Wireless Transmitter.
	Wireless Transmitter is inoperative.	<p>Wireless Transmitter needs to be reset.</p> <p>Place the Wireless Transmitter correctly on the charging pad (dotted side face up). Place the label side of the magnet (bottom of magnet) against the dotted side of the Wireless Transmitter for 5-10 seconds to perform reset. The teardrop point of the magnet should be aligned with the teardrop point of the Wireless Transmitter (see Figure 17). Ensure that the green light has stopped blinking when the magnet is placed on the Wireless Transmitter. After 5-10 seconds, remove magnet from Wireless Transmitter. Do not leave magnet on Wireless Transmitter while it is charging.</p>

Problem	Potential Cause	Recommended Action
<p>(Cont.)</p> <p>Wireless Transmitter stops working</p>		<p>Confirm reset was successful by observing the following:</p> <ol style="list-style-type: none"> 1. Confirming the green light on the Wireless Transmitter is blinking. 2. Waiting 30 seconds and observing that the status light of the charging pad has initiated.
Wireless Transmitter enclosure is cracked	Wireless Transmitter damaged by dropping or exposure to extremely high or low temperatures or pressure	Discontinue use. Contact your physician/clinic for a new Wireless Transmitter.
Skin irritation develops	Sensitivity to Wearable material	Take off Wearable and discontinue use of system. Contact your physician.

Problem	Potential Cause	Recommended Action
Wearable is uncomfortable	Incorrect size or worn incorrectly	Check that the garment label is on the inside and it is at the back. If the garment is still uncomfortable, contact your physician/clinic for other sizes.
Therapy is uncomfortable	Stimulation too high	Decrease amplitude or change programs (see “Changing Stimulation Settings” on page 28). If this does not resolve your discomfort, contact your physician/clinic.
Therapy is not felt	Stimulation too low	Increase amplitude or change programs (see “Changing Stimulation Settings” on page 28).
	Wireless Transmitter is not connecting to your neurostimulator	See below.

Problem	Potential Cause	Recommended Action
Wireless Transmitter is not connecting to your neurostimulator	Wireless Transmitter is not worn in correct position	Wireless Transmitter must be worn on your lower back in order to connect to your neurostimulator. Ensure the Wireless Transmitter is in the pocket of your Neuspera Wearable. Put on the Wearable so the Wireless Transmitter is positioned over your implanted neurostimulator (see Figure 9 on page 21).

Problem	Potential Cause	Recommended Action
(Cont.) Wireless Transmitter is not connecting to your neurostimulator	Wireless Transmitter is not in Wearable pocket correctly	Check that dotted white side is against your body. The logo/label should be away from your body.
	Wireless Transmitter battery is too low	Check battery level from your App (see Figure 13 on page 28). Charge Wireless Transmitter if battery is low.
	Stimulation has been turned off	Check the Status screen on your App and confirm Stimulation Power is set to “On” (see Figure 14 on page 30). Tap the switch to turn on, if necessary.
	Wireless Transmitter has been damaged (by physical shock, extreme temperatures, and/or water has leaked into device)	Contact your physician/clinic for a replacement Wireless Transmitter.

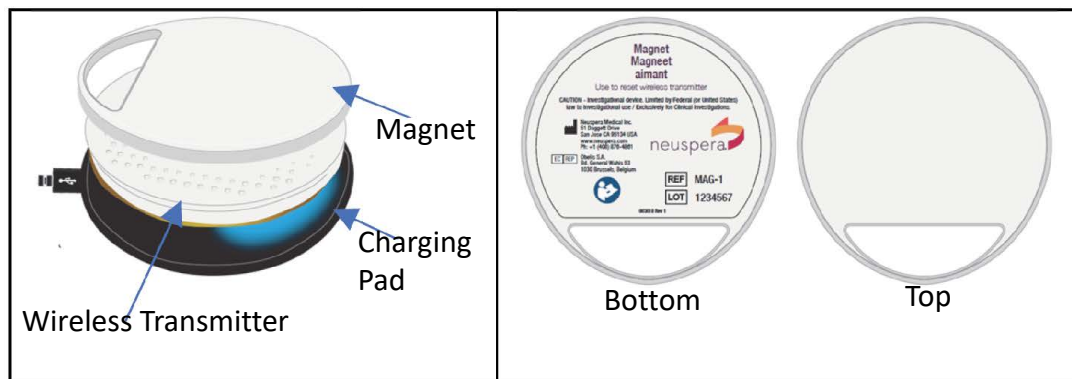



Figure 17. Resetting the Wireless Transmitter. Place the label side of the magnet (bottom of magnet) on the Wireless Transmitter for 5-10 seconds. The top of the magnet is visible during correct placement. Remove magnet after reset is completed. Do not leave magnet on Wireless Transmitter while it is charging.

App Messages, Causes, and Resolutions

System Message	Cause	Resolution
Action Not Available Cannot change settings while Therapy is active OK	User tried to change program while Wireless Transmitter is powering neurostimulator	Tap “OK” to close message. Turn Stimulation Power off, change program, and turn Stimulation Power on (see Figure 14 on page 30).
Therapy Error Please flip over the WT to clear error. OK	User tried to turn on WT Power while communication has been turned off or User tried to turn on WT Power after removing WT from charger without flipping WT over.	Tap “OK” to close message. Go to Info page and turn on Communication. or If the WT was just removed from charger, flip over the WT to turn on WT Power.
WT Alert Battery level below 10% OK	WT battery is getting low	Tap “OK” to close message. Return Wireless Transmitter to the charging pad.

System Message	Cause	Resolution
Connection Failed Connecting to the WT failed, please ensure that the WT is in range and tap yes to try to connect again. No Yes	Patient Controller does not detect Wireless Transmitter signal	Ensure Wireless Transmitter and Patient Controller are within 1 meter (3 feet) of each other. Tap “Yes” to try to connect again. If the issue continues, put Wireless Transmitter on charging pad for a few minutes. Remove Wireless Transmitter from charging pad and try again. If the issue continues, close the App, after a few minutes, restart App and try again.
Connection Failed Please ensure the WT is powered on, Bluetooth advertising, and try again OK	Patient Controller does not detect Wireless Transmitter signal (2nd message if still cannot connect after above message)	Check battery level from your App (see Figure 13 on page 28). Charge Wireless Transmitter if battery is low.

System Message	Cause	Resolution
WT Alert WT temperature algorithm is non-functional OK	Wireless Transmitter temperature control is not working	Tap “OK” to close message. Discontinue use. Contact your physician/clinic for a new Wireless Transmitter.
Disconnected The connection to the WT was lost, would you like to reconnect? No Yes	Wireless Transmitter completely drained, turned off due to contact with a magnet, or moved out of range	Ensure Wireless Transmitter is: <ul style="list-style-type: none"> • Not near a magnet • Charged • Within range (1 meter or 3 feet) of the Patient Controller Click “Yes” to reconnect. If the issue continues, close the App, after a few minutes, restart App and try again.
Retrieval Failure Log file retrieval encountered an error. Data shown may not have been updated. OK	Communication between App and Wireless Transmitter interrupted	Tap “OK” to close message. Ensure App is connected to the Wireless Transmitter. Switch to the Status screen and then switch back to the Usage screen to update data.

System Message	Cause	Resolution
<p>Confirm Delete Are you sure you want to delete all registered WT's?</p> <p>No Yes</p>	User has selected "Delete All Connections"	<p>Tap "No" to exit the message.</p> <p>NOTE: Only your physician or clinic representative, at your physician's direction, should delete the Wireless Transmitter from your App.</p>
	No Wireless Transmitters are linked to your App	Contact your physician/clinic.

Other Information

Patient Activities

Avoid sexual activity during the first week following the implant procedure.

For six weeks following the implant procedures, limit physical activities that may put stress on the neurostimulator. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Examples of such activities include gymnastics, mountain biking, and other sports or equipment that involve the movements described above.

Strenuous physical activity may cause implant fracture or dislodgement which may result in loss of stimulation, intermittent stimulation, or pain at the implant site. Postural changes, and other activities may result in perceiving an increase in stimulation which may be uncomfortable. Some people have described this as a jolting or shocking sensation. Do not wear the Wireless Transmitter to deliver therapy during activities that could be unsafe for yourself or others (e.g., driving or the use of dangerous equipment) if you were to receive an unexpected jolt or shock. Consider movements involved in any planned activity and take precaution to avoid putting undue stress on the implanted system. For example, in activities such as skydiving, when the parachute opens, there can be a sudden jerking motion that occurs. This may cause a neurostimulator dislodgement or fracture. A surgical procedure may be required to reposition or replace the neurostimulator. Inform your physicians about the activities in which you participate and ask the physician if there should be any additional restrictions on your activities.

Component Manipulation

Refrain from receiving any form of spinal or pelvic manipulation in the area of the neurostimulator by chiropractors as this may damage the neurostimulator. This may result in implant fracture or dislodgement which may result in loss of stimulation, intermittent stimulation, or pain at the implant site.

Refrain from manipulating the neurostimulator. Pushing on or rubbing the implant site may cause neurostimulator damage, dislodgement, uncomfortable stimulation or pain at the implant site.

Adverse Events and Risks

Standard risks associated with minor surgery, including side effects from anesthesia and post-procedural pain or discomfort, may occur due to neurostimulator implantation. Other potential risks include:

- Accidental puncture
- Adverse change in bowel or voiding function
- Adverse effects of cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, theft detectors/screening devices on implanted neurostimulator, or adverse effects of the neurostimulator on other implanted devices
- Allergic or immune system response to the implanted materials or Wearable
- Anal discomfort

- Bleeding at implant or incision site
- Joint pain
- Back, leg, or pelvic pain
- Genital or urinary complications
- Implant or incision site pain
- Implant site erosion
- Infection at implant site
- Kidney infection
- Nerve damage
- Neurostimulator device complications, including migration, breakage/fracture, retained lead fragments, or malfunction
- Numbness or tingling sensation (paresthesia)
- Skin reaction
- Surface skin heating with discomfort, irritation, redness, or burn
- Stroke
- Technical difficulties leading to the inability to implant or explant the device
- Undesirable stimulation or sensations, including jolting or shock sensations.
- Urinary tract infection

- Wound Complications: bleeding, bruising, oozing, or swelling at implantation site; Incisional hernia

Contact your physician if any of these events occur. Refer to the clinical study patient informed consent for a detailed list of potential risks.

Precautions

- Do not use your Wireless Transmitter, Patient Controller, charging pad, or charging cables if they are damaged. Using damaged devices and cables may result in fire, electrical shock, injury, or additional damage.
- Ensure the Wireless Transmitter is not punctured or damaged to prevent battery leakage.
- Turn off stimulation or remove the Wireless Transmitter if it becomes uncomfortably hot.
- Avoid taking substances that may impair your ability to feel the Wireless Transmitter getting too hot. This may increase the chance of being injured from the elevated Wireless Transmitter temperature.
- Do not wear the Wireless Transmitter during charging. The Wireless Transmitter may heat up while charging. The Wireless Transmitter cannot stimulate while charging. If the WT needs to be charged, another WT may be worn in the Wearable instead and used to activate the neurostimulator.

- Excessive pressure on the Wireless Transmitter against your body for an extended period of time (such as lying on the Wireless Transmitter) may increase the risk of injuries.
- If rash or other adverse skin reaction do occur, stop using device and contact physician.
- Only wear your Wireless Transmitter in the pocket of the Neuspera Wearable to prevent injury or skin irritation. The Wireless Transmitter is not intended for direct skin contact.
- Consult with your physician prior to wearing your Wireless Transmitter over any skin wounds (blisters, burns, cuts, etc.) or if you are not able to feel hot temperatures.
- Only wear your Wireless Transmitter with Neuspera Wearable to minimize misalignment and loss of therapy.
- Avoid or move away from sources of electromagnetic interference (EMI) to prevent device malfunction (see [“Locations with Electromagnetic Interference \(EMI\)” on page 61](#)).
- Remove the Wireless Transmitter during other medical procedures and treatments to avoid potential interference with other medical equipment. Inform your healthcare professional about your implanted neurostimulator prior to any medical procedure.

- Diathermy (shortwave, microwave, or therapeutic ultrasound) and radiofrequency ablation in the vicinity of the neurostimulator should not be used because these procedures have not been evaluated.
 - Therapeutic ultrasound should not be used in the area of the sacral nerve neurostimulator as the device can inadvertently concentrate the ultrasound field and cause harm.
 - Therapeutic ionizing radiation can damage the electrical components of the neurostimulator and any damage may not be immediately detectable.
- The safety and performance of the Neuspera System has not been evaluated for pregnancy, unborn fetus, or delivery.
- The Neuspera System has not been tested for compatibility with cardiac defibrillation. If you have been defibrillated, contact your physician to check the performance of your Neuspera System.
- Only use items with the Neuspera System that have been specified as part of the system or that have been specified as being compatible with the system.



CAUTION: Do not detach, or disassemble devices or use accessories not described in this manual. The system may not function according to specifications under these conditions.

- Keep all charger cables away from small children or infants for risk of strangulation.
- Keep all components out of reach of children, pets and pests, which may damage the device from rough handling.

MRI Safety Information

Patients with a Neuspera neurostimulator may have an MRI (magnetic resonance imaging) under certain conditions (referred to as “MR Conditional”). Consult with your physician prior to undergoing an MRI.

If you need to undergo an MRI, make sure to inform the relevant MRI medical professionals about your implant when you make the appointment for the MR exam and also upon arrival at the MRI facility for the exam. Make sure to present your Patient ID card and inform your physician or radiologist that the MRI safety information is available in the MRI Safety Information section of the Clinician Manual which can be obtained by calling (888) 846-8332.

You should remove all external system components (the Wearable and Wireless Transmitter) prior to your MR exam and make sure to leave your programmer and WT outside the MR scan room.

Patients with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).

- Maximum spatial field gradient of 2000 G/cm (20 T/m).
- Whole body averaged specific absorption rate (SAR) of 2.0 W/kg.

Radiofrequency (RF) heating

Under the scan conditions defined above, the implanted stimulator is expected to produce a maximum temperature rise less than or equal to 3.0°C after 15 minutes of continuous scanning.

MR Artifact

In non-clinical testing, the image artifact caused by the implanted stimulator extends radially approximately 2.5 cm from the device when imaged in a 3 T MRI system.

Considerations for Locations and Environments

Home Environment



CAUTION: Keep away from lint, dust, or directed sunlight, otherwise Wireless Transmitter may not function as specified.

This Neuspera system has been designed for use in the home environment. Most household appliances and equipment that are working properly and grounded properly will not interfere with your Neuspera System. Metal surfaces (e.g., wall, chair back)

against your Wireless Transmitter may temporarily interrupt therapy (stimulation). If you notice an interruption in therapy move away from the metal surface.

The following equipment is generally safe if you follow these guidelines:

- Radio-frequency sources (AM/FM radios, cellular telephones, cordless and conventional telephones): Keep these items at least 10 centimeters (4 inches) away from the Wireless Transmitter.
- Stereo speakers and radios for the home or car: Do not lift or carry speakers or radios near the Wireless Transmitter.
- Induction range (a glass stovetop with burners under the surface): Keep the Wireless Transmitter away from the burners while they are turned on.
- Power tools: Keep the motors away from the Wireless Transmitter.

The Wireless Transmitter and Patient Controller generate and radiate radio-frequency energy that may, in some instances, interfere with radio communications from other devices. If you suspect that your system is causing interference with other devices, move your Wireless Transmitter and Patient Controller away or turn off system communications using your App (see [Figure 15 on page 32](#)).

Locations with Electromagnetic Interference (EMI)



CAUTION: If your Wireless Transmitter is damaged by EMI, you may experience excessive heating of the device and/or the area of your back near the Wireless Transmitter.



CAUTION: Your Wireless Transmitter, Patient Controller, and charging pad emit EM. Use of these devices near other EM equipment may affect equipment performance. If use of your Neuspera System near EM equipment is necessary, check that both your system and the equipment are operating normally.



CAUTION: Portable radio communications equipment (including accessories such as antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of your Neuspera System when the Wireless Transmitter or Patient Controller are turned on. When used closer, the performance of the radio equipment may be affected.

Equipment that emit large amounts of electromagnetic radiation (EM) may interfere with the proper functioning of your Neuspera System. Examples of such equipment are:

- Switching mode power supplies
- Power substations
- MRI equipment
- Cardiac device

- Defibrillators
- Radiation equipment
- Arc welders
- Strong permanent magnets

Electronic Article Surveillance

Electronic Article Surveillance/Anti-theft systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with your Neuspera System. It is very unlikely that these systems will interact significantly. The most likely effect is a temporary change in stimulation. To minimize the possibility of interaction, however, walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

TSA and Other Security Screening

You should not be screened by a walk-through metal detector if you have an internal medical device.

Inform the security officer that you have an internal medical device and ask to bypass the metal detector. You may need to provide the officer with your patient ID card or the TSA (transportation security administration) notification card* to describe your condition. You may need to undergo a manual (“pat-down”) screening. If you must

walk through the security system, turn off system communications using your App (see [Figure 15 on page 32](#)).

*The TSA notification card template can be found on their website:

https://www.tsa.gov/sites/default/files/disability_notification_card_508.pdf.

It is recommended to fill this out by stating you have an internal medical device.

Bring the card with you to security.

Technical Details

Neurostimulator

The Neuspera Sacral Nerve neurostimulator is an implantable device that is like a short wire with 4 electrodes. Electrical impulses are delivered through these electrodes. The electrical impulses are voltage driven, may vary in amplitude (0.2–4.8 V), pulse width (105–945 μ s), and pulse frequency (5–100 Hz). Your physician will determine the appropriate settings for you.

Wireless Transmitter

The Wireless Transmitter communicates wirelessly with the implanted neurostimulator and the App. The Wireless Transmitter contains two antennae. One antenna connects to the implanted neurostimulator to transmit power using mid-field powering technology developed by Neuspera. This antenna must be directly over (within 3 cm) the neurostimulator to deliver power. The other antenna connects

to the App using Bluetooth® technology. The Wireless Transmitter is powered by a rechargeable lithium ion battery that is recharged on a wireless charging pad.

Battery capacity	2000 mAh
Battery capacity (therapy time)	Minimum 2 hours (will vary with therapy)
Time for full recharge	5 hours
Maximum operating temperature (surface of Wireless Transmitter)	<60°C (140°F)*
Frequency range (implant powering)	902–928 MHz (ISM compliant)
Frequency range (Bluetooth)	2.4–2.5 GHz
Water resistance	IP25 (Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction)
Diameter	8 cm (3.1 inches)
Thickness	15 mm (0.6 inches)
Weight	103 g

**If the Wireless Transmitter reaches 71°C, it will stop stimulation until it cools down.*

Power Transmission Frequency Range

Your Wireless Transmitter communicates best with your neurostimulator in the 902 - 928 MHz industrial, scientific, and medical (ISM) frequency band specifically allocated for use by medical devices in North America.

Wearables

The Neuspera Wearable is specially-designed to hold and position the Wireless Transmitter over the sacrum. The Wireless Transmitter is placed in a padded and insulated pocket sewn into the waistband of the Wearable to hold the Wireless Transmitter against your body comfortably. The Wearables are provided in sizes from small to extra large with an optional leg loop attachment. The Wearables are made from standard garment material (spandex, nylon, polyester, and polyurethane).

Charging pad and Patient Controller

The charging pad and Patient Controller hardware (iPhone) are standard consumer electronics. See manufacturer's manuals for additional information on these devices. Both of these devices may be charged from USB (2.0 or 3.0 ports) or 120V and 240V power mains (standard wall outlet).

The iPhone (“Patient Controller”) has been specially configured to maintain security of the Neuspera patient software application (“App”) used to control your Wireless Transmitter. Your App can only communicate with your Wireless Transmitter.

System Compliance to Standards

Neurostimulator	ISO 14708-3 (active implantable devices - neurostimulators) IEC 60601-1 ISO 10993 (permanent tissue contact)
Wireless Transmitter	IEC 60601-1 IEC 60601-1-2 (Group 2, Class B - Immunity for the home healthcare environment) IEC 60601-1-6 IEC 60601-1-11 IEC 62133-2 (battery)
Patient Controller*	IEC 60950-1
Charging pad*	FCC Part 15 Subpart C 15.209

****NOTE:*** *The charging pad and Patient Controller hardware are standard consumer electronics. These items are not regulated as medical devices.*

Service Life/Ordering Replacements

When used as intended, the estimated service life for your Neuspera System components is as follows:

Component	Service Life	Signs it should be replaced
Neurostimulator	15 years	Does not provide expected stimulation
Wireless Transmitter	1 year	Needs to be charged more frequently/won't hold a charge
Wearable	1 year	Worn out/won't hold Wireless Transmitter in correct position
Patient Controller	3 years	Needs to be charged more frequently/won't hold a charge
Charging pad	3 years	Does not charge device

**To order replacement components, contact your physician/clinic.*

Safe Disposal

All components of your system (Wireless Transmitter, Patient Controller, magnet and charging pad) should be returned to your physician/clinic for disposal. Your data will be extracted for your patient record and all personal information will be erased.

Operating and Storage Conditions

The Wireless Transmitter and Patient Controller both run on lithium ion batteries. These devices are designed to be used and stored in the following temperature ranges:

	Use Temperature Range	Storage Temperature Range
Wireless Transmitter	5°C to 35°C (41°F to 95°F)	–10°C to 25°C (14°F to 77°F)*
Patient Controller	0°C to 35°C (32°F to 95°F)	–20°C to 45°C (–4°F to 113°F)

***NOTE:** The Wireless Transmitter may be exposed to temperatures as low as –30°C (–22°F) for up to 24 hours and may be stored at temperatures as high as 55°C (131°F) for up to one (1) month. Prior to using, the Wireless Transmitter should be allowed to come to room temperature (this may take up to 5 hours).

The devices may be damaged and battery life shortened if used or stored outside these temperature ranges. Avoid exposing the devices to dramatic changes in temperature or humidity. Avoid leaving the Wireless Transmitter or Patient Controller in the car where temperatures can be extreme.

Avoid leaving the Wireless Transmitter and Patient Controller in wet areas (sinks, showers, tubs) or near sources of heat (stove, fireplace, radiant heaters).

The belt, magnet and charging pad do not have restrictions on use or storage temperatures.

Technical Maintenance



CAUTION: No modification of the equipment is allowed. Modifying the equipment may make it unsafe.



CAUTION: Do not attempt to remove or replace the batteries in the Wireless Transmitter or Patient Controller.

No technical maintenance is required on any of the Neuspera System components. See [“Care of Your System” on page 34](#) for general care of the components.

The Neuspera System components are not repairable by service personnel.

Quality of Service and Security for Wireless Technology

Quality of Service

The Neuspera System uses wireless communication between the neurostimulator and Wireless Transmitter, and between the Wireless Transmitter and Apps. The communication's quality of service (QoS) requirements may vary depending on the environment (operating room, recovery room, doctor's office, and home environment). This is similar to your cell phone service.

System Security

After neurostimulator implantation, the Wireless Transmitter will be uniquely paired to your implant and the Clinician and Patient Apps uniquely paired to your Wireless Transmitter (see [Figure 18](#)).

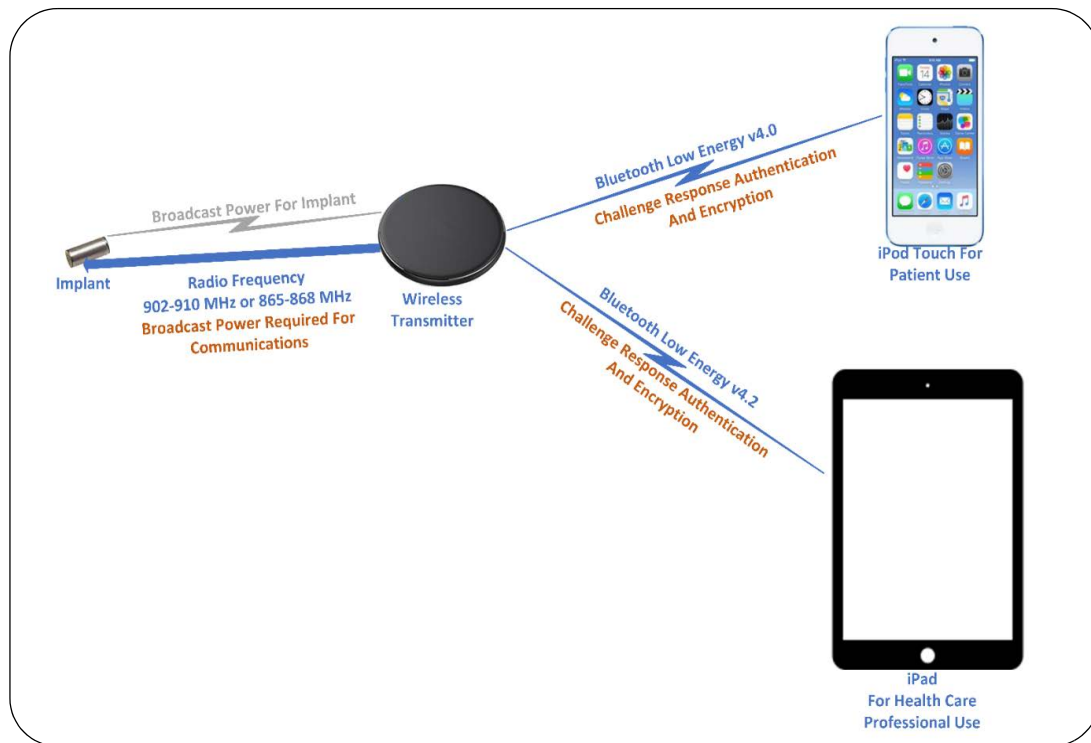


Figure 18. Schematic of authenticated connections/communications

The following measures are in place to enhance the security of the Neuspera System's wireless communications:

- All communications are encrypted or encoded
- An advanced cryptographical secure process is used to uniquely pair a patient's neurostimulator to a patient's Wireless Transmitter and the Wireless Transmitter to the Programmer and Patient Controller App
- The Wireless Transmitter will only communicate with an authenticated paired App
- Data integrity checks are performed by the neurostimulator to ensure it only responds to the paired Wireless Transmitter
- Only a single patient App may be authenticated to link to a Wireless Transmitter
- Only a single Wireless Transmitter may be paired to an App at a time

User Configurable Cybersecurity Controls

There are no installable or user alterable security controls.

Device System Security Features

Your neurostimulator is only powered when energy is being broadcasted from your Wireless Transmitter. When the Wireless Transmitter is removed, power is lost in the

neurostimulator and stops stimulating. Your neurostimulator does not retain any operating configuration or data when power has been removed.

Powering of your neurostimulator is unique and cannot be accomplished with existing off the shelf components. Additionally, the mid-field powering technology used to power your neurostimulator has a limited range of operation (within centimeters), thereby mitigating in a physical manner any unapproved device trying to perform communications to your neurostimulator.

Bluetooth® Low Energy (BLE) communications uses a cryptographically strong method of authentication between the Wireless Transmitter and your Patient Controller and your Clinician's Programmer before either device can perform any operation on the Wireless Transmitter. All cryptographic primitives comply with FIPS 140-2 and utilize a minimum of 128 bits.

Authorization occurs between the Wireless Transmitter and your Patient Controller and your Clinician's Programmer, such that the Neuspera Apps have separate and unique communications and supported functionality.

Supporting Infrastructure Requirements

There are no local infrastructure requirements.

Communication Portals

Bluetooth Low Energy

Updating of Application and Device Firmware

Updates of the Apple mobile device firmware are performed automatically from iOS if/when the devices are connected to the internet. Updates to the Neuspera Apps and Wireless Transmitter firmware are made available to the user from a dedicated server that houses only the Neuspera App and firmware. When your Patient Controller is connected to the internet and an update is available, you will be prompted to update the App. Firmware updates for your Wireless Transmitter can be performed from your clinician's Programmer.

Retention/Recovery of Device Configuration

The neurostimulator does not retain operating parameters when your Wireless Transmitter is removed from use. When your Wireless Transmitter is restored to operation (i.e. within range of the neurostimulator) the neurostimulator will have its operating parameters automatically updated.





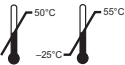


Contact Your Physician/Clinic









- For assistance in setting up, using, or maintaining your Wireless Transmitter or system





- To report unexpected operation or events

Symbols

Explanation of symbols used on product or package labeling.

Symbol	Description
	Reference (Model) number
	Serial number
	Wireless transmitter identification number
	Refer to instruction manual
	Temperature range
	Humidity range
	Type BF Applied Part

Symbol	Description
	Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction.
Rx only	Requires prescription in the United States
	Manufacturer
	Non-ionizing electromagnetic radiation
	Do not dispose of this product in the unsorted municipal waste
	Battery charge level
	Wireless signal strength
	Machine wash warm
	Tumble dry low

Symbol	Description
	Iron low heat
	Non chlorine bleach or fabric softener
	Magnetic Resonance (MR) Conditional
	Magnetic Resonance (MR) Unsafe

Glossary of Terms

Explanation of terms used on product or package labeling.

Acronym/Abbreviation	Term
EM / EMI	Electromagnetic / Electromagnetic Interference
g	Grams
IT	Information Technology

Acronym/Abbreviation	Term
mA / μ A	Milliamperes / Microamperes
MR / MRI	Magnetic Resonance / Magnetic Resonance Imaging
RF / RFID	Radiofrequency / Radiofrequency Identification
SNS	Sacral Nerve Stimulation
UUI	Urinary Urgency Incontinence
USB	Universal Serial Bus
V	Volts
WT	Wireless Transmitter

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Any changes or modifications made to this device that are not expressly approved by Neuspera Medical Inc may void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with FCC radiation exposure limits as set forth for an uncontrolled environment. This device should be installed and operated so that its antenna(s) are not colocated or operating in conjunction with any other antenna or transmitter.

The device has been tested and comply with FCC SAR limits. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. The separation distance is 6.5 mm.



Neuspera Medical, Inc.
51 Daggett Drive
San Jose, CA 95134
(888) 846-8332

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