

Quick Start Guide



Table of Contents

| | |
|--------------------------------------|----|
| Introducing Sparrow Link | 1 |
| Get Started With Sparrow Link | 2 |
| Apply the Earpiece | 2 |
| Connect the Cable | 4 |
| Turn ON the Pulse Generator | 6 |
| Toggle ON/OFF and Adjust Stimulation | 6 |
| Turn OFF the Pulse Generator | 7 |
| Menu Options | 8 |
| Pulse Generator Screens | 8 |
| Stimulation Tips | 9 |
| Notifications | 10 |
| Troubleshooting | 12 |

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.

Indication for Use

Sparrow Link is an investigational platform that allows researchers to customize the stimulation parameters output by the Sparrow Link Pulse Generator for use in studies requiring non-invasive transcutaneous auricular neurostimulation (tAN®) therapy.

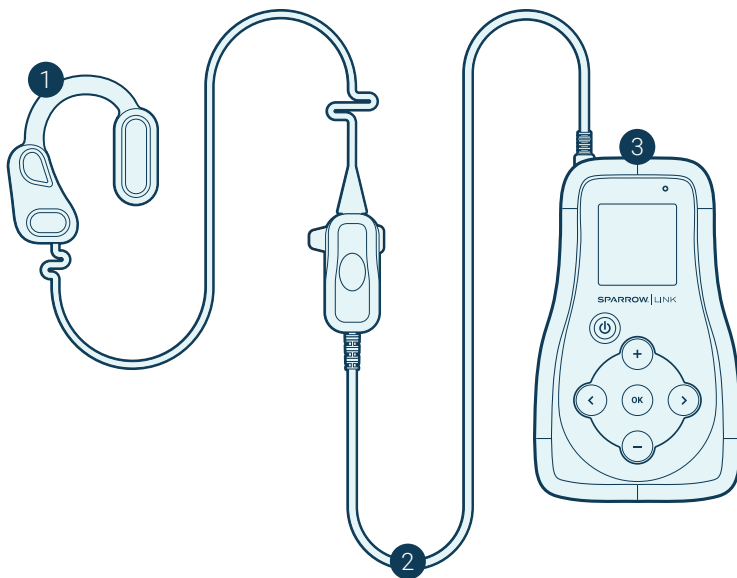
Introducing Sparrow Link

Sparrow Link is an extension of the FDA-Cleared Sparrow® Ascent wearable neurostimulation device.

Sparrow Link is an investigational platform that allows researchers to customize the stimulation parameters output by the Sparrow Link Pulse Generator for use in studies requiring non-invasive transcutaneous auricular neurostimulation (tAN®) therapy.

Parts Included

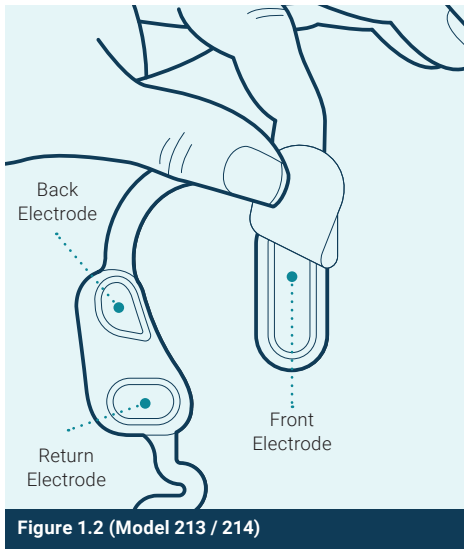
1. Earpiece
2. Cable
3. Pulse Generator
4. AAA Batteries
5. Alcohol Wipes



Get Started With Sparrow Link

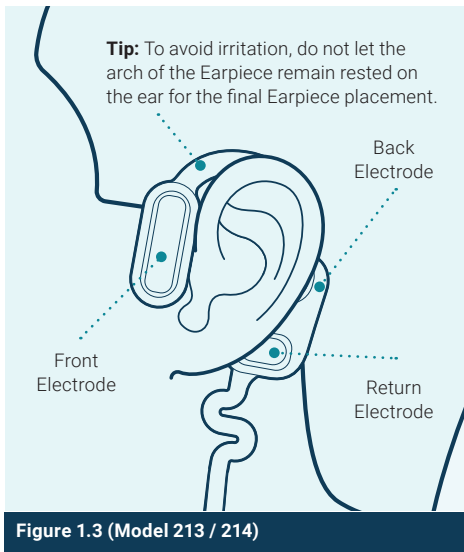
1) Apply the Earpiece

- 1.1 Apply the earpiece while in front of a mirror when applying to yourself. Be sure all hair is pulled back, and the areas in and around where the earpiece will be placed are clear of hair or jewelry. This may require trimming or shaving hair in small areas in front of or behind the ear. Gently clean around the ear with one of the provided alcohol wipes. Allow the ear to dry before proceeding to the next step.
- 1.2 Open an earpiece pouch. Then, open the earpiece tray and gently remove the earpiece. Next, place the earpiece over the ear so the Outer or Front Electrode is in front of the ear.



- 1.3 Remove the adhesive liner from the Front Electrode and press to apply, as shown in **Figure 1.3**. Press firmly and hold to ensure the entire Front Electrode adheres to the skin. Repeat with the Back/Return Electrodes. Once in place, press down and hold for 30 seconds to secure it.

NOTE: For Model 213 / 214 earpieces, the Outer channel controls the stimulation at the Front Electrode and the Inner Channel controls the stimulation at the Back Electrode.

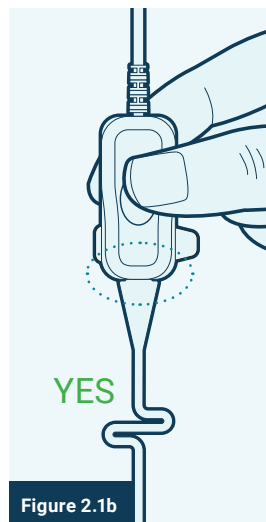
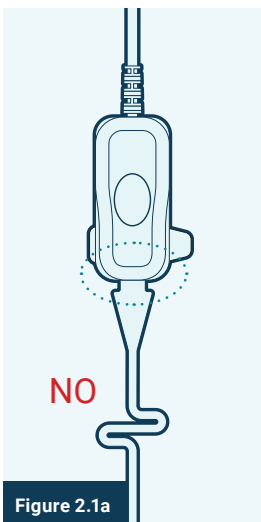
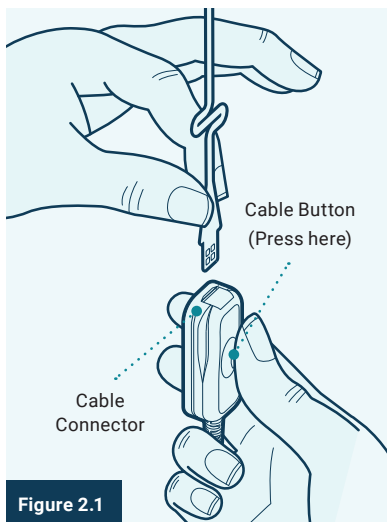


2) Connect the Cable

2.1 Locate the cable and find the end with the button. This is the Cable Connector. Press down fully on the Cable Button and insert the earpiece end (**Figure 2.1**) into the Cable Connector slot until the earpiece end is flush against the Cable Connector (**Figures 2.1a and 2.1b**), then release the button. The earpiece end can be inserted either direction.

Tip: The earpiece end should easily insert into the Connector slot. If there is resistance, increase pressure to the Cable Button and try again.

2.2 Next, clip the Cable Connector to your shirt near or at the neckline. Then, insert the Cable Jack into the Pulse Generator, as shown in **Figure 2.2**.



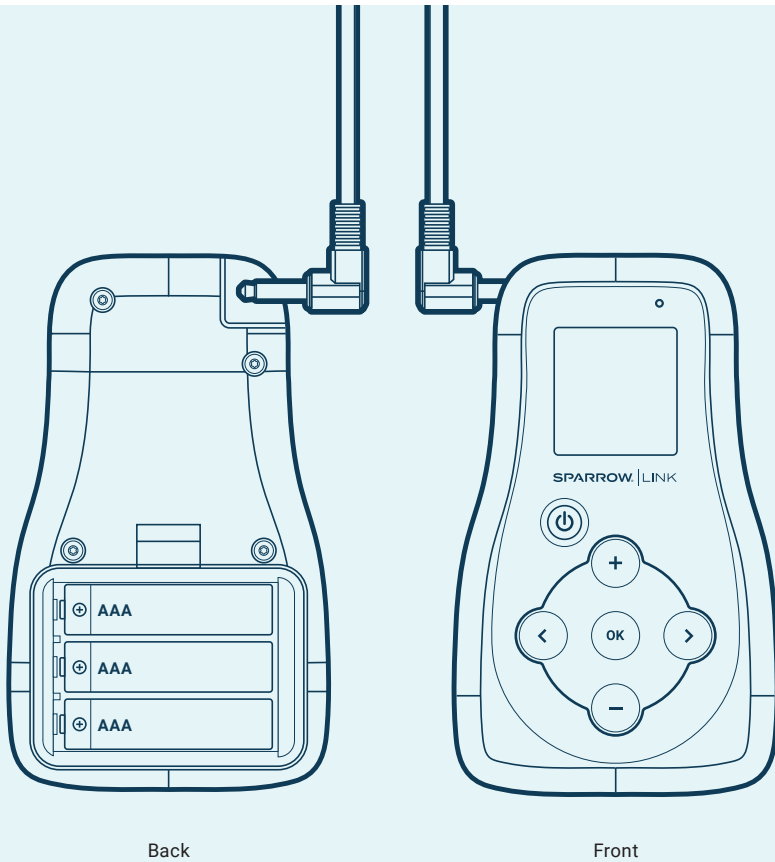


Figure 2.2

3) Turn ON the Pulse Generator

- 3.1 Press and hold the power button located just below the word “Sparrow,” for one to three seconds. You’ve successfully turned the device ON when the Spark logo appears on screen.

4) Toggle ON/OFF and Adjust Simulation

- 4.1 Press either arrow to move the cursor on the screen until you highlight the toggle bar for the Inner or Outer Electrodes. The Inner or Back Electrode is the small electrode placed in the hollow of your ear just above your ear canal (Model 210 / 211) or just behind the ear (Model 213 / 214), depending on your model of earpiece. The Outer or Front Electrode is the electrode in front of your ear.
- 4.2 Press OK to activate stimulation. Stimulation is ON when the toggle bar is green. Grey toggle bar(s) indicate stimulation is OFF for the designated electrode(s).
- 4.3 Next, use either arrow to move the cursor and highlight the stimulation strength (0–50). Press OK to enable stimulation strength adjustments. **NOTE:** The stimulation strength will flash when adjustments are enabled.

Press the + or - buttons to increase (+) or decrease (-) the stimulation strength from 0 to 50. Press OK to save your settings.

5) Turn OFF The Pulse Generator





Press and hold the power button for two to four seconds. When prompted, select OK to turn the device OFF.

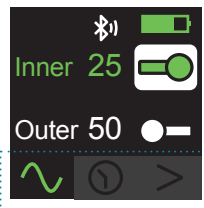


NOTE: Quickly tap the Power button to wake the device then click OK to unlock the Pulse Generator. The interface will dim after 15 seconds and lock after 30 seconds of inactivity, but stimulation will continue. You can also lock the device by quickly tapping the Power button.

Menu Options

The Pulse Generator has a menu bar located at the bottom of the screen. Use the arrow buttons to highlight an icon in the menu bar. Select the highlighted icon by pressing the OK button on the Pulse Generator. There are four screens to select:

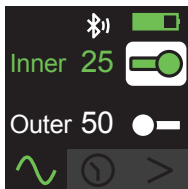
-  Stimulation status
-  Therapy timer
-  Bluetooth connectivity
-  Device Information



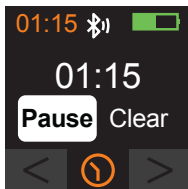
Menu Bar

Pulse Generator Screens

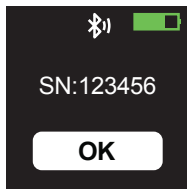
Stimulation
Status



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Bluetooth
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Information



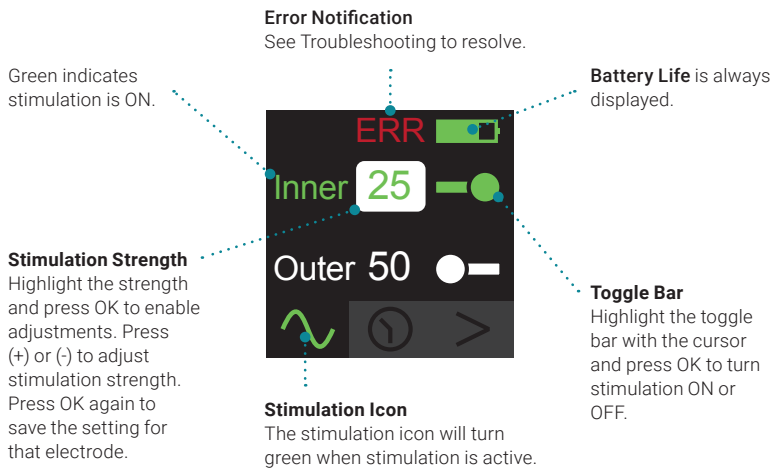
NOTE: For Model 213 / 214 earpieces, the Outer channel controls the stimulation at the Front Electrode and the Inner Channel controls the stimulation at the Back Electrode.

Stimulation Tips

Turn stimulation ON or OFF by using the toggle bars for the Inner and Outer Electrode(s).

When therapy is toggled ON, stimulation will slowly increase to the preset stimulation strength (0–50). When therapy is toggled OFF, stimulation will quickly decrease over three seconds. Lower the stimulation strength if stimulation is uncomfortable. If you notice any muscle spasms in your face or neck, you may need to slightly reposition the earpiece (**Figure 1.3**).

When stimulation is active, it will cycle ON and OFF automatically – ON for five minutes and OFF for 10 seconds.



Notifications

Top Light – The top LED will flash periodically to indicate stimulation status while the Pulse Generator is locked.

- Green Light – A green flashing light means stimulation is active, and no errors are detected.
- Red Light – A red flashing light indicates an error. Unlock the Pulse Generator by tapping the power button to wake the device then press OK. You should then see an error notification on screen. See the troubleshooting section to resolve the error.

ERR – A minor system error is detected. See the Troubleshooting section on pages 12–13 for help resolving error notifications.

Low Battery Icon – Power OFF the Pulse Generator and replace the batteries with three new AAA batteries. Power ON the Pulse Generator and resume therapy. Expected battery life is 2–3 days, depending on use.



Troubleshooting

What does “ERR” at the top of the screen mean?

A low battery, mild impedance error, or slight system disconnection is detected. Check battery level and ensure all three electrodes on the earpiece are making full contact with the skin. While troubleshooting, stimulation must complete ramping before the ERR alert will clear.

Loose Earpiece. Check connection at ear and cable.

Gently press each electrode to the skin to improve adherence. If doing so does not fix the error, disconnect the earpiece from the cable, then reinsert. Resume therapy and allow stimulation to complete ramping.

The Cable or Earpiece is disconnected.

Check the Cable Jack connection at the Pulse Generator end. Ensure the earpiece end is inserted fully into the Cable Connector and that each electrode is adhered to the skin. If doing so does not fix the error, disconnect the earpiece from the cable, then reinsert. Stimulation will be turned OFF automatically when the cable or earpiece is disconnected. Resume therapy and allow stimulation to complete ramping. Re-insert the earpiece end into the Cable Connector if the alert reappears after turning stimulation back ON.

Skin irritation around the ear

The Sparrow Earpiece is latex free; however, if you experience any skin irritation from use, please discontinue use of the earpiece until skin irritation has resolved. Apply a dermatologist-recommended ointment for sensitive skin, such as Aquaphor healing ointment. Medicated ointments are not recommended. If irritation does not improve within 24 hours, contact your physician.

Cleaning

Earpieces are daily disposable. You should change the earpiece every 24 hours, or sooner if needed. Earpieces are not intended to be cleaned or reused. To clean the Pulse Generator or cable, wipe the outer case with a clean, damp cloth and then dry with a clean cloth or paper towel.

App Connection

If you are instructed to connect your Sparrow Link Pulse Generator to the Sparrow Link Participant App, use the arrow buttons to highlight the Bluetooth icon in the menu bar and press OK. Enter the code displayed on the Pulse Generator into the App to pair the devices.



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