

SPARROW® | LINK

Sparrow® Link Instructions for Use

(tAN®: Transcutaneous Auricular Neurostimulation)




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

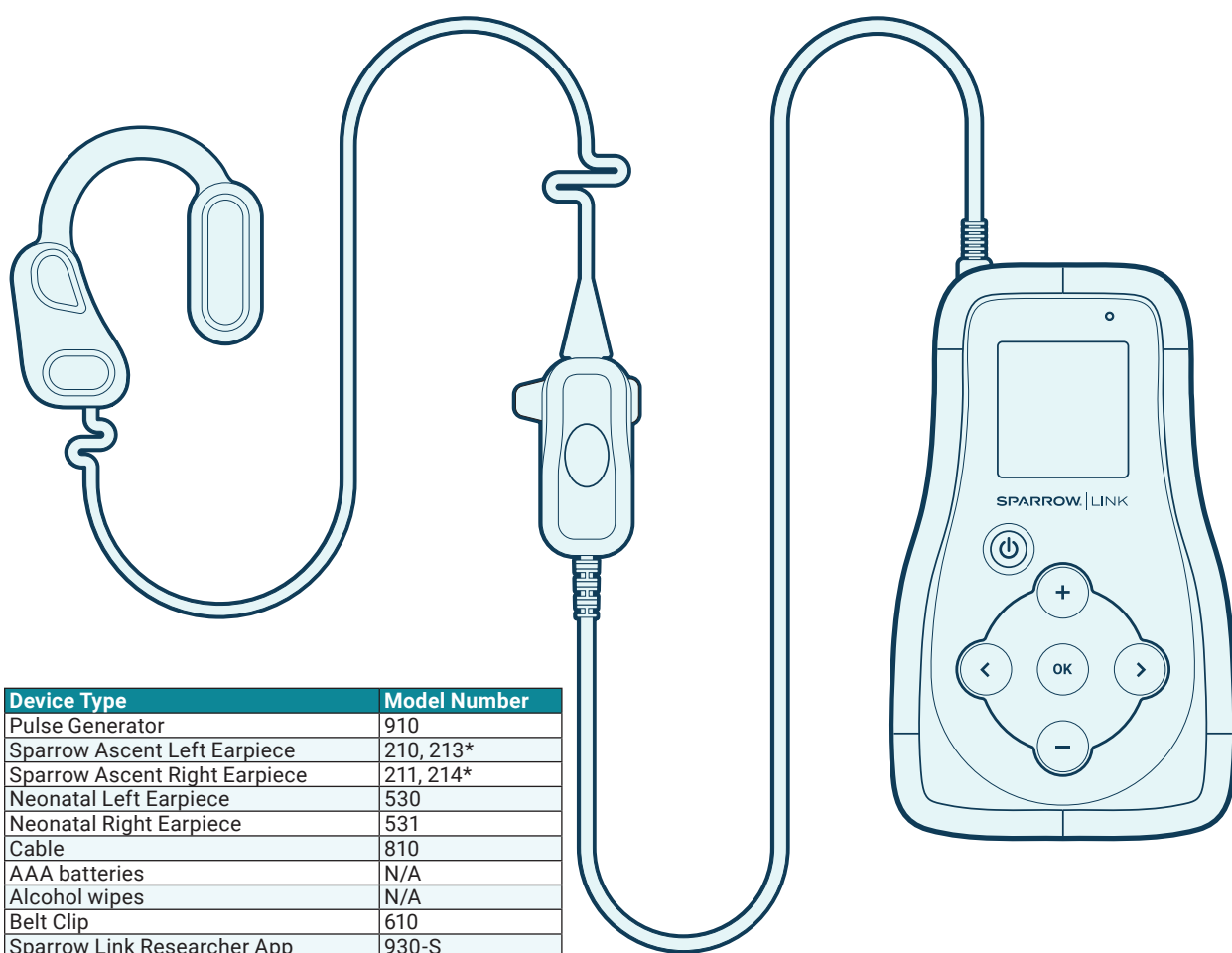

 If you have any other questions or concerns, please contact Spark Biomedical, Inc at (844) 654-SPRK (7775). For more detailed instructions, visit Sparrow Link resources at sparkbiomedical.com/research/sparrow-link.

Indication for Use & Device Description

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.

The Sparrow Link Platform is comprised of the Sparrow Link Pulse Generator, Sparrow Link Researcher App, Sparrow Link Hub, and Sparrow Link Application Programming Interface (API). Researchers may customize the Sparrow Link Pulse Generator's device settings and stimulation output parameters by using the Sparrow Link Researcher Application or Sparrow Link Hub with the Sparrow Link API developed by Spark Biomedical, Inc.

Sparrow Link is designed to be used only with the accessories described below:



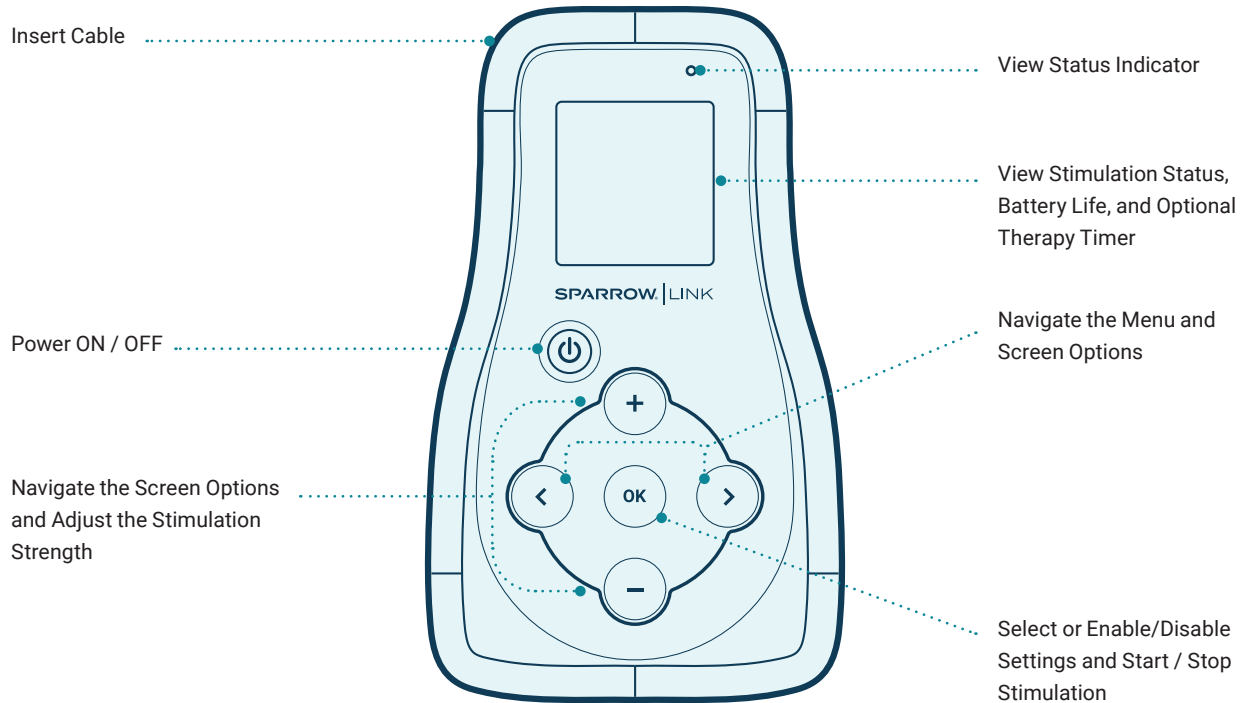
Device Type	Model Number
Pulse Generator	910
Sparrow Ascent Left Earpiece	210, 213*
Sparrow Ascent Right Earpiece	211, 214*
Neonatal Left Earpiece	530
Neonatal Right Earpiece	531
Cable	810
AAA batteries	N/A
Alcohol wipes	N/A
Belt Clip	610
Sparrow Link Researcher App	930-S
Sparrow Link Hub	940

*Sparrow Earpiece Models 510 / 511 (labeled for investigational use) follow the same compatibilities and electrode configurations as Sparrow Ascent Earpiece Models 213 and 214.

Sparrow Link Pulse Generator – Model 910

The Sparrow Link Pulse Generator is a hand-held, battery-powered, biphasic pulse generator designed to be carried while receiving tAN® therapy. The Sparrow Link Pulse Generator is compatible with Sparrow Ascent components and accessories. The Pulse Generator delivers adjustable stimulation to the Earpiece via the Sparrow Ascent Cable. The Pulse Generator has a physical user interface comprising a 6-button keypad with a 1.5" LCD screen display and is powered by three standard Alkaline AAA batteries.

The Pulse Generator allows users to:



The Pulse Generator also indicates to the user:


- Alerts and notifications
- Earpiece errors
- Cable disconnections

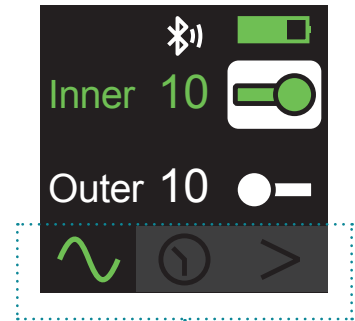
Menu Options

The Pulse Generator has a menu bar located at the bottom of the screen.

Use the menu bar to navigate Pulse Generator features.

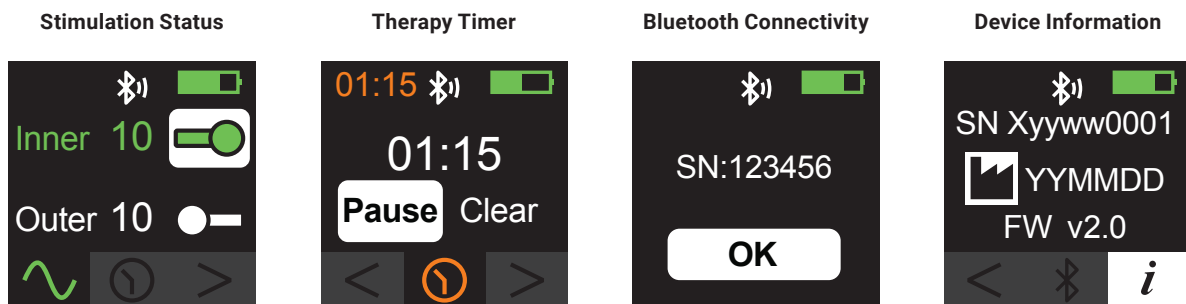
Use the directional buttons to place the cursor over an icon in the menu bar. The cursor selection will appear highlighted. Select the highlighted screen option by pressing the OK button on the Pulse Generator controls. There are 4 screen options to which the user can navigate:

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



Menu Bar

Tip: Select the < or > icons to view more screen options




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 Status

The stimulation status screen allows the user to turn stimulation ON / OFF or adjust stimulation strength.

BATTERY LIFE

Change batteries when the battery icon turns red. 

ADJUST STIMULATION

Enable Adjustments – First, use the directional buttons to highlight stimulation strength (0-50) for the Inner or Outer Electrode or Front and Back Electrodes for Earpiece Model 213 / 214. Press OK to enable adjustments. The strength will flash when adjustments are enabled.

Increase / Decrease Stimulation –

Next, press the + and - buttons to adjust the strength from 0-50. Press OK to save your settings and disable adjustments.

Stimulation Icon – Turns green when stimulation is ON.

POWER BUTTON

Turn ON – Press and hold the power button until the Spark Logo appears on screen.

Turn OFF – Press and hold the power button. When prompted, select OK to turn the device OFF.

Wake / Unlock – Click the power button to wake the Pulse Generator. Then press OK to unlock.

Return to Sleep Mode – Click the power button.



NOTIFICATIONS

ERR – A minor system error is detected. Check the Cable connection and press firmly against the Earpiece at the Electrodes to ensure full contact with the ear. See Troubleshooting section to resolve.

Top Light – The top LED will periodically flash to indicate stimulation status.

- Green: Stimulation is ON.
- Red: System error. Unlock the Pulse Generator to view alert. See Troubleshooting section to resolve.

TURN ON / OFF STIMULATION

Toggle Stim ON / OFF – Use the directional buttons to highlight a toggle bar. Press OK to flip the toggle switch. Green toggle bar(s) indicate stimulation is ON for that Electrode. Grey toggle bar(s) indicate stimulation is OFF for that Electrode.

Ramping Stimulation – When stimulation is toggled ON, stimulation will ramp to the pre-set strength (0-50). When stimulation is toggled OFF, stimulation will ramp down.

Pulse Generator Output

The Pulse Generator has default settings consistent with the therapeutic settings on the FDA-cleared Sparrow Ascent Patient Controller. Using the Sparrow Link Researcher App or Sparrow Link Hub with API, you can modify the parameters of the biphasic waveform output by the Pulse Generator for the Inner and Outer channels. See **Table 1.0** below for the list of default settings and ranges of waveform modifications.

Table 1.0: Sparrow Link Pulse Generator Outputs

Settings	Default		Range	Step Size or Values
	Inner	Outer	Inner and Outer	Inner and Outer
Amplitude*	0.0 mA	0.0 mA	0 mA – 5.0 mA	0.1 mA
Pulse Width**	350 μ s	250 μ s	50 μ s – 750 μ s	50, 100, 150, 250, 350, 500, 750 μ s
Frequency***	30 Hz	100 Hz	1 Hz – 150 Hz	1, 5, 10, 15, 20, 25, 30, 40, 50, 75, 100, 125, 150 Hz
Cycle Time	On 5 minutes Off 10 seconds		On 102 ms – 24 hours Off 0 ms – 24 hours	1 sec, 1 min, 1 hour
Ramping Time****	Up 1 second per 0.1 mA Down 3 seconds		Up 50 ms – 60 sec Down 50 ms – 3 sec	N/A
Intra Phase PW	125 +/- 25 μ s		N/A	N/A
Max. Voltage	95 V		N/A	N/A

Unless otherwise specified, outputs shall be within a tolerance of +/- 15%.

*For Amplitude, the tolerance shall be +/- 15% or 0.1mA, whichever is greater.

** For Pulse Width, the tolerance shall be +/- 15% or 15 μ s, whichever is greater.

*** For Frequency, the tolerance shall be +/- 15% or 15 Hz, whichever is greater.

****For default ramping mode and custom ramping mode, the minimum cycle ON time must be equal to or greater than the ramping-up duration plus the ramping-down duration.

**Table 1.1: Sparrow Link Pulse Generator
Unsupported Frequency Combinations**

Certain frequency combinations output waveforms in which the frequency settings exceed the +/- 15% tolerance. The Sparrow Link Researcher App will not have the unsupported frequencies available to select and attempts to set unsupported frequencies using the Sparrow Link Hub and API will return false. The Sparrow Link platform does not support the combinations listed on the right in **Table 1.1**.

High Frequency Setting (Hz)	Low Frequency Setting (Hz)
15	10
20	15
25	10, 15
30	20, 25
40	25, 30
50	20, 30, 40
75	20, 30, 50
100	40, 75
125	50, 75, 100
150	100, 125, 150

Certain frequency combinations output waveforms in which the frequency settings do not exceed the +/- 15% tolerance; however, the nominal output of the lowest frequency exceeds +/- 1%. The Sparrow Link Researcher App will have the following frequencies available to select and attempts to set the following frequencies using the Sparrow Link Hub and API will return true. The Sparrow Link platform will support the combinations with nominal output listed below in **Table 1.2**.

Table 1.2: Sparrow Link Pulse Generator

High Frequency Setting (Hz)	Low Frequency Setting (Hz)	Nominal Low-Frequency Output (Hz)
40	15	13.33333
50	15	16.66667
75	10	10.72099
75	20	18.76173
75	40	37.52345
100	15	14.28571
100	30	33.33333
125	10	10.41667
125	15	15.625
125	20	20.83333
125	30	31.25
125	40	41.66667
150	1	1.005454
150	5	4.993757
150	10	10.70090
150	15	14.98127
150	20	18.72659
150	25	24.96878
150	30	29.96254
150	40	37.45318
150	50	49.93757
150	75	74.90636

Therapy Timer

The therapy timer is an **optional** feature that controls the amount of time stimulation is delivered. When the timer is used, stimulation will remain ON for the timer duration set by the user OR until the user stops stimulation for both Inner and Outer Electrodes.

SET TIMER DURATION

Enable Adjustments – Use the directional buttons to highlight the hours (HH) or minutes (MM). Press OK to enable adjustments. The selection will flash when adjustments are enabled.

Increase / Decrease Duration – Enable Adjustments then press the + and - buttons to adjust the hours (0-24 Hrs.) or minutes (0, 5, 10, 15, 30, or 45 Min). Press OK to save each setting.

Clear Timer Duration – To clear the timer duration, navigate to the timer screen and highlight the 'Clear' option and press OK.

! Time remaining displays in the upper left corner when enabled.



TURN TIMER ON / OFF

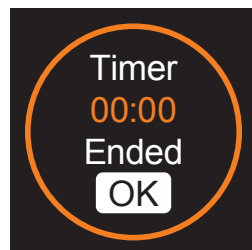
Start Timer – Set a timer duration from 5 minutes up to 24 hours. Highlight the 'Start' option and press OK to begin the timer. The timer icon will turn orange while a timer is activated and the time remaining will appear in the upper left corner.

Pause / Resume Timer – To pause or resume the timer, navigate to the timer screen and highlight the 'Pause' or 'Resume' option and press OK. The timer will automatically pause when stimulation is turned OFF and resume when stimulation is turned ON up to 24 hours.

Timer Icon – Turns orange when the timer is active.



A pop up message will appear on screen when your timer is finished.



Bluetooth Connectivity

The Sparrow Link Pulse Generator pairs with Sparrow Link Researcher Application or the Sparrow Link Hub via Bluetooth Low Energy (BLE) to receive custom modifications to the default stimulation settings.

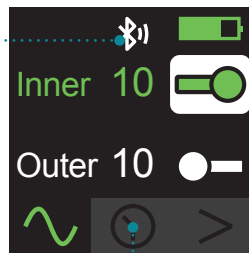
Complete the following steps to pair the Sparrow Link Pulse Generator to a Sparrow Link Researcher Application on an Android tablet or mobile device.

1. Enable Bluetooth, WiFi, and location sharing on your tablet or mobile device.
2. Launch the app and log in using the Username and Password provided to your institution.
3. Next, on the Sparrow Link Pulse Generator, navigate to the BLE screen to view the 6-digit serial number (**Figure 1**).
4. Enter the 6-digit serial number displayed on the Sparrow Link Pulse Generator into the field on the app and press CONNECT.
5. If the connection fails, repeat steps 1-4. After a factory reset, the Pulse Generator may initially require two attempts to connect to an app or the Hub.



Figure 1: Sparrow Link Pulse Generator BLE screen

BLE icon indicates the Pulse Generator is advertising or paired.

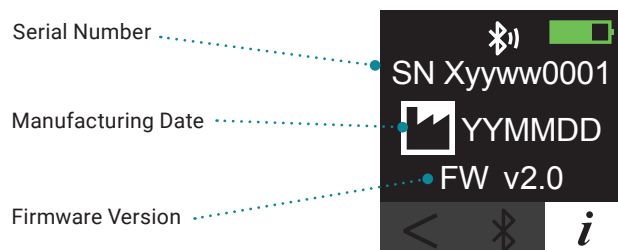


Select 'Ok' to exit back to the stimulation screen.

For information on pairing the Sparrow Link Pulse Generator to the Sparrow Link Hub, see the Sparrow Link Hub Instructions for Use.

Device Information

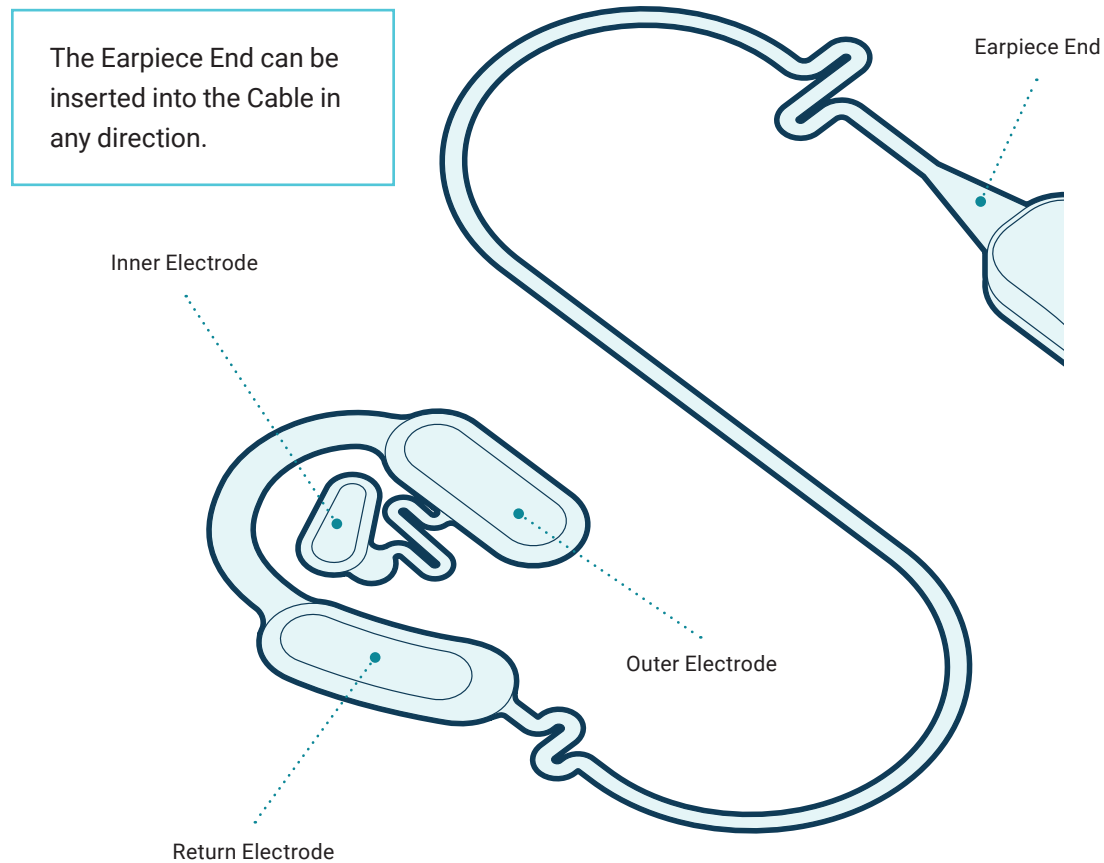
The Device Information screen displays Pulse Generator specifications. Use this screen to view the Pulse Generator serial number, manufacturing date, and firmware version.



Sparrow Ascent Earpiece – Model 210 / 211

The Sparrow Link Pulse Generator requires Sparrow Earpieces and Cable. Sparrow Ascent Earpieces are available for either the left or right ear. The Earpiece connects to the Cable to receive electrical inputs from the Pulse Generator. The Earpiece must be connected and applied properly to the ear, or suitable substitute such as a load board, before attempting to program the Pulse Generator.

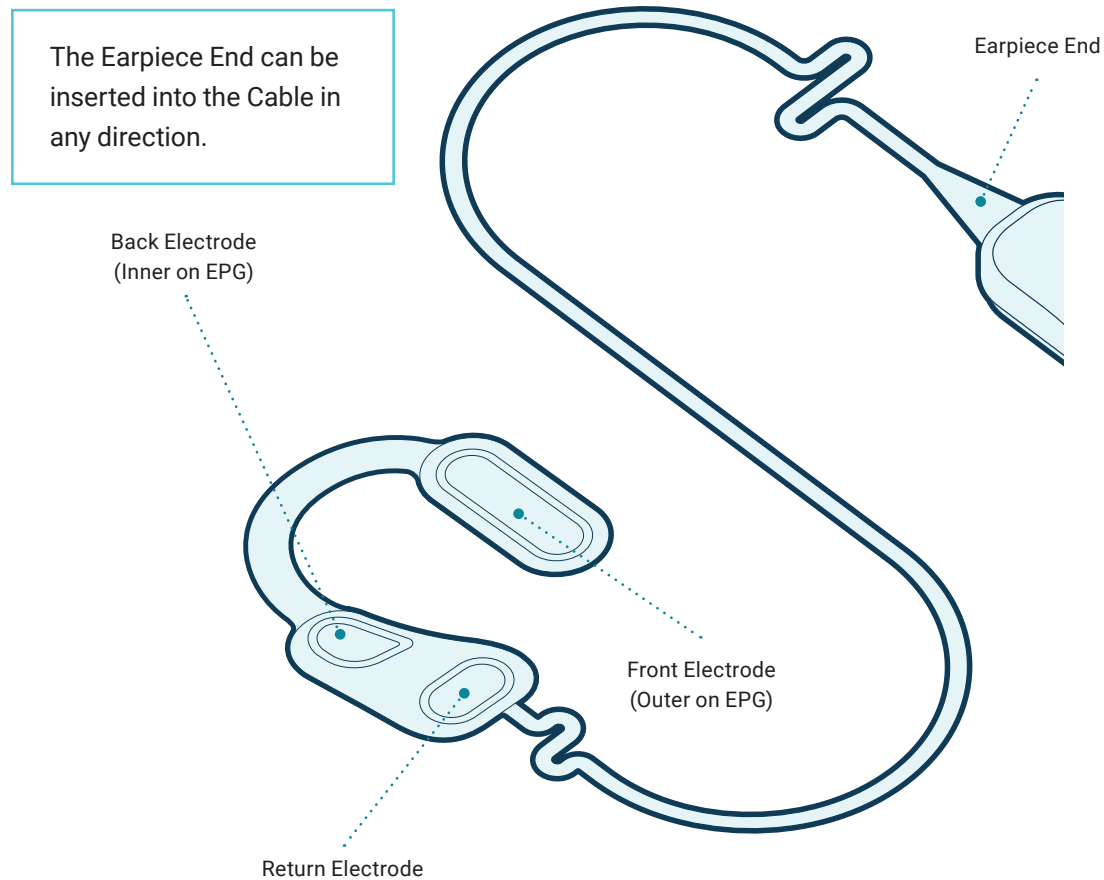
The Earpiece is a single-use disposable component of the Sparrow Link and is designed to stay adhered to the skin of the left or right ear for up to 24 hours of electrical connectivity. The Inner Electrode interfaces with the vagus nerve that surfaces in the cymba concha area of the ear and the Outer Electrode interfaces with the trigeminal nerve. The Return Electrode is shared by both the Inner and Outer Electrodes.



Sparrow Ascent Earpiece – Model 213 / 214

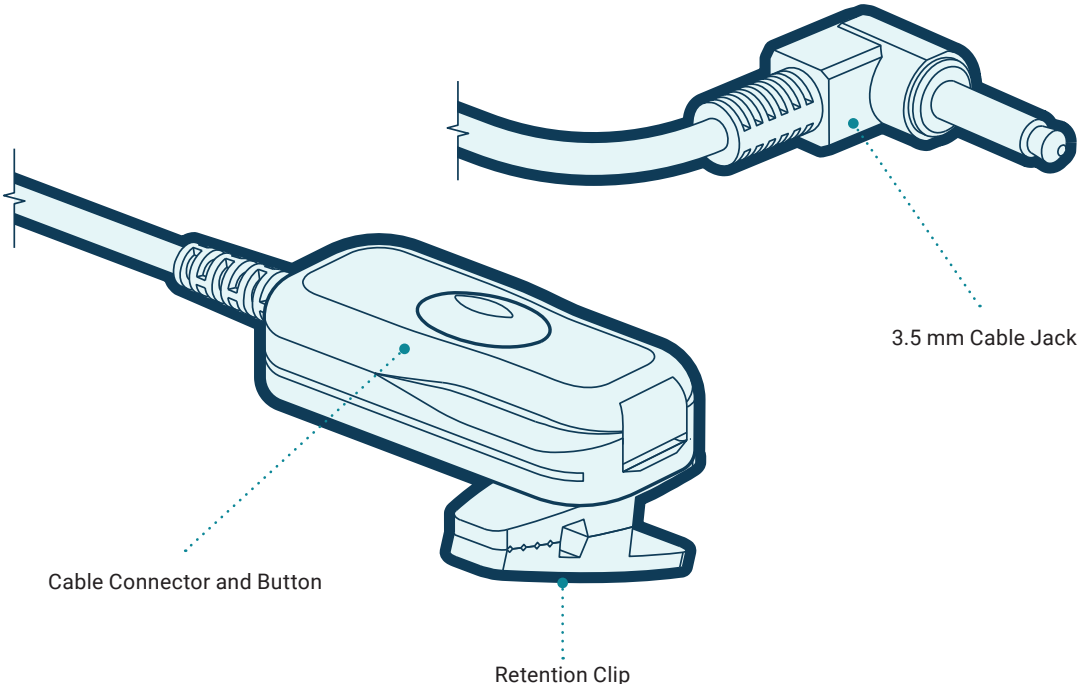
The Sparrow Link Pulse Generator requires Sparrow Earpieces and Cable. Sparrow Earpieces Model 213 / 214 are available for the left or right ear. The Earpiece connects to the Cable to receive electrical inputs from the Pulse Generator. The Earpiece must be connected and applied properly to the ear, or subtable substitute such as a load board, before attempting to program the Pulse Generator.

The Earpiece is a single-use disposable component of the Sparrow Link and is designed to stay adhered to the ear for up to 24 hours of electrical connectivity. The Front Electrode interfaces with the trigeminal nerve. The Back Electrode interfaces with the auricular branch of the vagus nerve. The Return Electrode is the return electrode for both the Front and Back Electrodes.



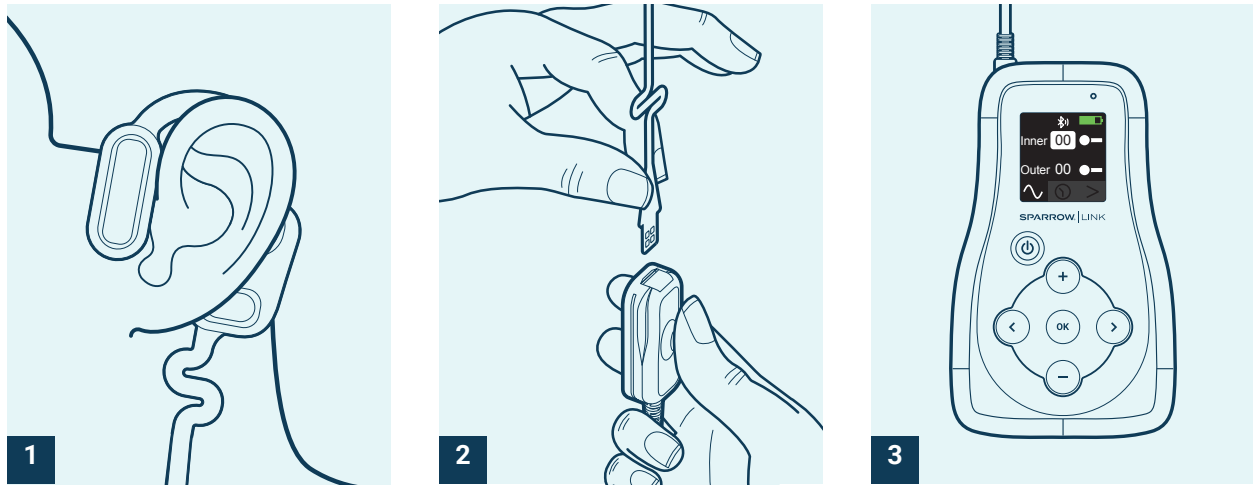
Sparrow Ascent Cable – Model 810

The Sparrow Ascent Cable is 37 inches long and connects the Pulse Generator to the Earpiece. The Cable length is designed to allow the user to carry the Pulse Generator in a pocket or worn in the Belt Clip (model 610) without constricting mobility. A built-in retention clip allows the user to clip the Cable to their clothing to relieve cable strain.



Directions for Use

Get started with Sparrow Link in 3 easy steps:.



Step 1:

Apply the Earpiece

Prepare the skin and unpackage the Earpiece. Apply the Earpiece in front of a mirror when applying to yourself. Application of the electrodes may be completed in any order. It is recommended that only one electrode be applied at a time.

1. Gently clean in and around the ear with an alcohol wipe. Remove any jewelry on the ear. Allow the skin on and around the ear to dry before applying the Earpiece.

NOTE: It may be necessary to shave any hair prohibiting the Earpiece electrodes from making full contact with the skin (see **Figure 2.1** or **2.2**).

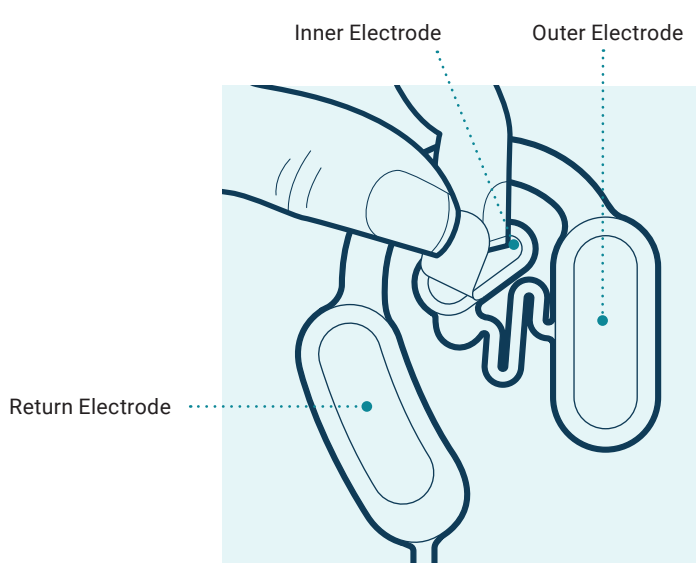


Figure 2.1

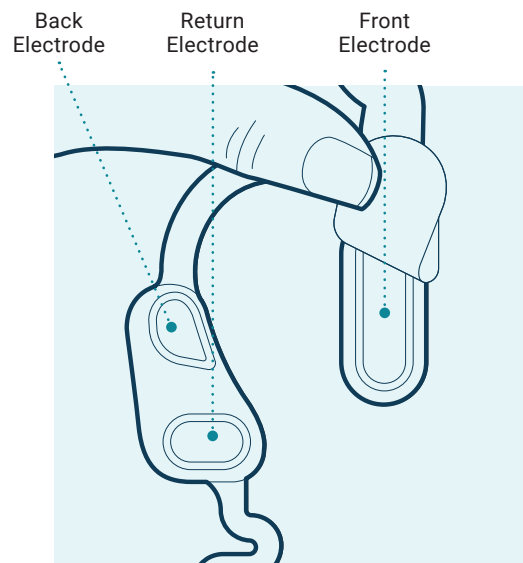


Figure 2.2

2. Place the Earpiece on the ear with the Outer Electrode (or Front Electrode for Models 213 / 214) in front of the ear. Next, remove the adhesive liner covering the Inner Electrode as needed.
- NOTE:** Try not to touch the hydrogels/adhesive surface during the Earpiece application.
3. For earpieces that have an Inner Electrode, insert the Inner Electrode into the hollow area of the ear, just above the ear canal. Press firmly to ensure the entire Inner Electrode is adhered to the skin.
 4. Next, remove the adhesive liner covering the Outer Electrode (or Front Electrode for Models 213 / 214). Press firmly to ensure the entire Electrode is adhered to the skin.
 5. Next, remove the adhesive liner covering the Return Electrode (or Back and Return Electrodes for Models 213 / 214). Press firmly to ensure the entire Back Electrode is adhered to the skin. See **Figure 3.1** or **3.2** for correct Earpiece placement.

Tip: Check your Earpiece label to determine whether the Earpiece is intended for the left or right ear.

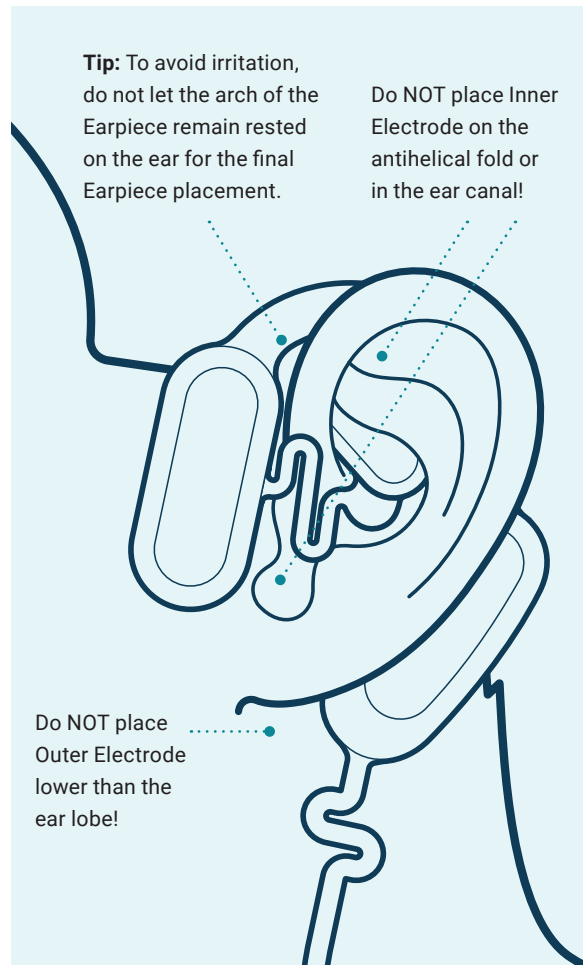


Figure 3.1: Earpiece Model 210 / 211 placed correctly

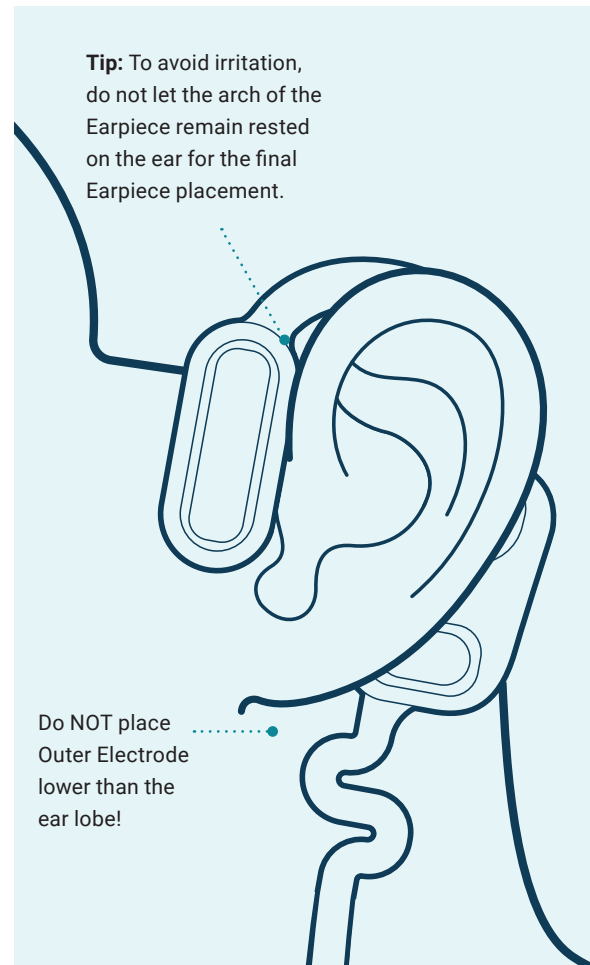


Figure 3.2: Earpiece Model 213 / 214 placed correctly

Step 2:

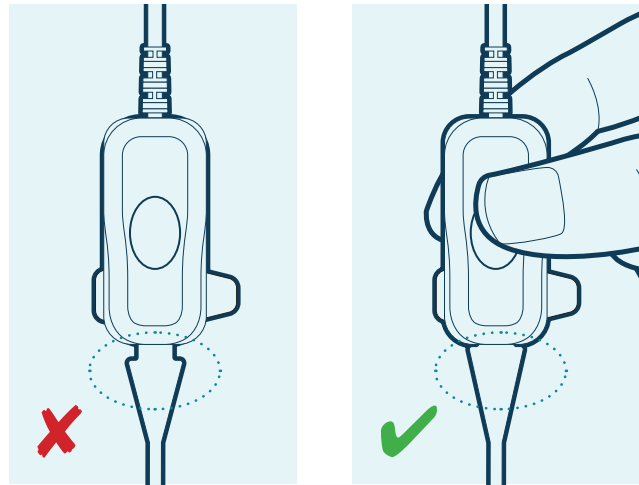
Connect the Cable

Connect the Earpiece to the Cable, then connect the Cable to the Pulse Generator.

1. Press down fully on the grey Cable button and insert the end of the Earpiece into the Cable Connector until the wide part of the Earpiece end is flush against the connector. The Earpiece end should easily insert in the connector slot and can be inserted in either direction. If there is resistance, increase pressure to the grey Cable button and try again.

NOTE: Failure to fully insert the Earpiece may reduce stimulation output.

2. Insert the Cable jack into the Pulse Generator (**Figure 4**)



Wide part of Earpiece **NOT** flush against the connector

Earpiece fully inserted

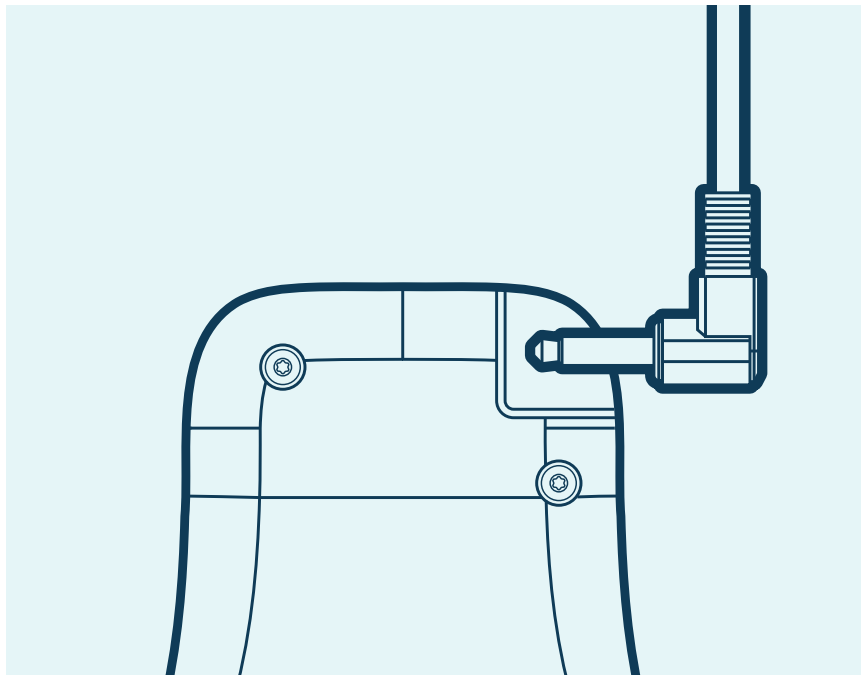


Figure 4: Insert Cable jack into Pulse Generator

Step 3:

Start Stimulation

Turn the stimulation ON/OFF and adjust the stimulation strength.

1. Power ON the Pulse Generator
 - a. Press and hold the power button until the Spark logo appears on screen
2. Toggle Stimulation ON
 - a. Once the Stimulation Status screen is displayed, use the directional buttons to highlight the Inner or Outer toggle bars. Press OK while the toggle bar is highlighted to turn ON or OFF stimulation output.

NOTE: For Model 213 / 214 Earpieces, Outer = the Front electrode and Inner = the Back electrode.

NOTE: If the output level is set to 0, toggle the output to ON before adjusting stimulation.

3. Use the directional buttons to highlight the Inner or Outer strength (**Figure 5**). Once highlighted, press the OK button to enable adjustments. The cursor will flash when adjustments are enabled.
4. Once adjustments are enabled, press the plus or minus button to increase or decrease stimulation strength for the Inner or Outer Electrode(s). Lower stimulation strength if stimulation is uncomfortable. Press OK again to save the stimulation setting. The setting is saved when the cursor is no longer flashing.

NOTE: The default Pulse Generator interface will dim after 15 seconds and lock after 30 seconds of inactivity, but stimulation will continue. Press the power button once to wake the device.

5. Power OFF the Pulse Generator

- a. Press and hold the power button. When prompted, select OK to turn the device OFF.

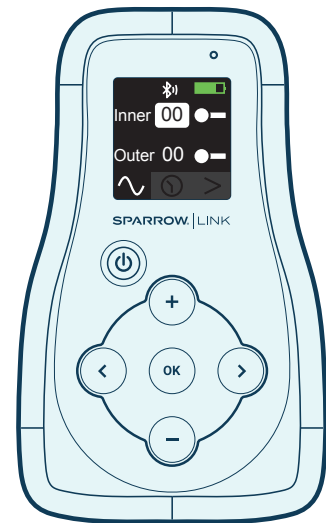


Figure 5: The Inner strength is highlighted

General Warnings and Cautions

General Warnings or Cautions in this User Manual are listed below and displayed in this document with the following WARNING or CAUTION symbols.

Example:



WARNING: Failure to follow instructions may result in serious injury or death to the patient or user.



CAUTION: Failure to follow instructions may result in damage to the equipment or degradation in the quality of treatment



Warnings

- Do not service Sparrow Link or Sparrow Ascent components while in use.
- Do not make any unauthorized modifications to Sparrow Link or Sparrow Ascent components.
- Only connect Sparrow Link to approved components listed in this manual.
- The Sparrow Ascent Cable model 810 may cause strangulation. Do not allow children to use or play with the Sparrow Ascent.
- Do not use Sparrow Link or Sparrow Ascent components with High Frequency surgical equipment.
- Do not use Sparrow Link or Sparrow Ascent components near shortwave or microwave equipment.
- Do not use Sparrow Link or Sparrow Ascent components in an explosive atmosphere or in the presence of flammable gas mixtures.
- Do not apply any Sparrow Earpiece on/near the thorax as it may increase the risk of fibrillation.
- Do not apply/use any Sparrow Earpiece in the presence of a wound, rash, swelling, cut, sore, drug patch, or surgical scar. This may result in discomfort, inadequate/inappropriate treatment, or decreased therapeutic response.
- Excessive hair around the ear may interfere with the ability of a Sparrow Earpiece to adhere to the skin and deliver therapy. Ensure the site is prepared in accordance with the directions in this manual for best results.
- Always keep the AAA batteries away from heat sources and fires.
- Stop using the product if you experience an allergic reaction while using the Earpiece and contact your physician.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the

manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sparrow Link Pulse Generator model 910, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



Cautions

- Do not use the Sparrow Link Pulse Generator model 910 in wet environments. Always keep the Pulse Generator dry.
- Do not use the Sparrow Ascent Cable model 810 in wet environments. Always keep the Cable and Cable connectors dry.
- Do not use contaminated, dirty, or previously used Sparrow Earpieces.
- Do not use other transcutaneous (e.g., TENS) or implanted neurostimulators while using Sparrow Link.
- Do not use Sparrow Link if any of the components are cracked, dented, or appear to be damaged.
- Do not use any Sparrow Earpiece if it has passed its expiration date indicated on the Earpiece Pouch.
- Do not use any Sparrow Earpiece if the protective covering is tampered with, damaged, or missing.
- Do not use Sparrow Link if the Sparrow Ascent Cable model 810 is damaged.
- Do not clean any Sparrow Earpiece. Replace the Sparrow Earpiece if it is soiled.
- Do not use corrosive substances to clean the Sparrow Link Pulse Generator model 910, Sparrow Link Hub model 940, or Sparrow Ascent Cable model 810.
- Do not use soap, hand sanitizer, detergents, or abrasive cleaning agents when cleaning the Sparrow Link Pulse Generator model 910, Sparrow Link Hub model 940, or Sparrow Ascent Cable model 810. These may damage the equipment surfaces.
- Do not use the Sparrow Link Pulse Generator for more than 6 hours continuously in high ambient temperatures (100° F). The Generator may reach temperatures of 43° C (109.4° F) which can be uncomfortable to touch.
- Aggressive cleaning of the ear with alcohol wipe may lead to skin irritation.

User Safety

Sparrow Link meets the essential requirements of the European Medical Device Directive for General Product Safety and complies with the applicable U.S., Canadian and other medical safety standards where Sparrow Link is registered to be sold.



Warnings

- Do not use the device beyond the safe limits of environmental conditions of temperature and humidity (see “Environmental Specifications” on page 24).
- Do not use the device in an MR environment.



Cautions

- **RF Interference**—The device conforms to ANSI/AAMI/EN/IEC 60601-1-2:2014; however, avoid environments with high levels of RF noise.
- **Other Interference**—The presence of an electrocautery device, infrared energy, or defibrillator may impact the operation of this device.
- Do not use the device in unintended areas.
- Do not use other devices in/on the ear at the same time as Sparrow Link.



Note

- **Electromagnetic interference**—This device conforms to ANSI/AAMI/EN/IEC 60601-1-2:2014.
- **Biocompatibility**—All materials that come into contact with the user or patient are of the type commonly used in a clinical environment.

Troubleshooting

Problem	Cause	Solution	Comments
Alert Message “Low Battery! Replace to resume therapy.”	The battery life is insufficient to continue therapy.	Power OFF the Pulse Generator and replace the batteries with 3 new AAA batteries. Power ON the Pulse Generator and resume therapy.	See Changing Batteries in the Maintenance section for more information.
Alert Message “Loose Earpiece. Check connection at ear and cable.”	The Earpiece may not be making connection with the skin, or the Earpiece hydrogels are worn out.	The output level of the loose Electrode will automatically decrease. Gently press the Earpiece to the skin to improve adherence at the Electrodes. Once resolved, you may increase stimulation to the previous strength.	If this does not fix the problem, or only fixes the problem temporarily, you may need to change the Earpiece.
Alert Message “The Cable or Earpiece is disconnected.”	The system has lost connection with the Earpiece or Pulse Generator.	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. Re-insert the Earpiece end into the Cable connector if the Alert appears after turning stimulation back ON.	Stimulation will automatically be turned OFF when the Cable is disconnected, or the Earpiece is removed. Stimulation will need to be manually turned back ON once the problem is resolved. This alert may appear if the Earpiece is loose and only one Electrode, Inner or Outer, is turned ON.
What does “ERR” at the top of the screen mean?	A mild impedance error or slight system disconnection is detected.	Ensure all 3 Electrodes on the Earpiece are making full contact with the skin. Ensure the Earpiece end is inserted fully into the Cable connector.	Once resolved, the error notification will clear when stimulation is resumed.

Continued on next page.

Problem	Cause	Solution	Comments
I changed the batteries and now the Pulse Generator will not turn ON or shows low battery level.	The batteries inserted are depleted or not inserted correctly.	Verify that the three AAA batteries are inserted as indicated in the battery compartment. Be sure to use new AAA batteries.	
Skin irritation around the ear	Abrasive cleaning of the ear with Alcohol wipes may cause skin irritation on dry sensitive skin.	Discontinue use of the Earpiece until skin irritation has resolved. To resolve skin irritation: Apply 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.	To resume therapy after skin irritation is resolved Discontinue use of Alcohol wipes and use a gentle cleansing wipe instead to prep the skin for Earpiece application. Apply Dermatologist recommended ointment for sensitive skin in between daily Earpiece applications
The Pulse Generator won't turn on or the screen stays black.	The batteries are depleted.	Insert 3 new AAA batteries in the battery compartment as indicated.	Be sure to power OFF the Pulse Generator when not in use. A Pulse Generator left in sleep mode will slowly drain the batteries.



If you have any other questions or concerns, please contact Spark Biomedical, Inc at (844) 654-SPRK (7775)

Maintenance, Cleaning, and Disposal

Maintenance

Changing the Earpiece

Earpieces are daily disposable and should be changed out every 24 hours. Earpieces are not intended to be cleaned or reused. Prolonged use may cause damage to skin. To change the earpiece, first stop simulation. Next, remove the Earpiece end from the Cable Connector and gently peel the Earpiece away from the ear. Applying a warm compress for 30 seconds loosens Earpiece adhesive, making removal easier. Always unplug the Earpiece from the Cable before using the warm compress. Apply the new Earpiece following the steps on page 12.

Changing Batteries

Change the batteries in the Pulse Generator as needed. The battery icon in the upper right-hand side of the Pulse Generator screen will turn red when the batteries are low. To change the batteries, press and hold the power button until the Pulse Generator fully turns OFF. Remove the battery cover on the back of the device, **replace with new batteries as noted on the inside the case (Figure 6)**, then close the cover. Turn the device back ON and resume therapy.

NOTE: Changing the batteries does not affect the configured stimulation settings.

Cleaning

The Pulse Generator and Cable may be cleaned and sanitized as needed and should be sanitized between each user. Do not use corrosive substances such as bleach to clean any part of Sparrow Link. Do not use the Pulse Generator or Cable if the devices appear damaged.

If a dampened cloth with water is not effective at removing debris from the Pulse Generator or Cable, you may use a cloth dampened with 91% isopropyl alcohol. To sanitize the Pulse Generator or Cable, use a quaternary ammonium based product such as a Lysol disinfecting wipe.

Be sure the Pulse Generator has been turned OFF, the Cable is unplugged, and the batteries have been removed before you start the cleaning.

To clean the Pulse Generator:

1. Wipe the outer case with a clean dampened cloth, following with a disinfecting wipe to sanitize.
2. Dry with a clean cloth or paper towel.
3. Inspect the outer case for remaining debris and repeat steps 1-2 as needed until visually clean.

Ensure the outer case is fully dry before reconnecting components and powering ON the device.

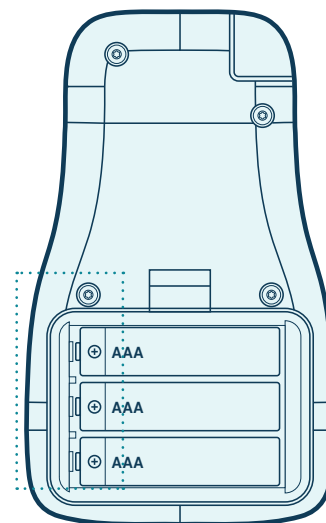


Figure 6: Battery Orientation

Be sure the Cable is unplugged from the Earpiece and Pulse Generator before you start cleaning the Cable.

To clean the Cable:

1. Wipe the Cable connector and Cable wire with a clean dampened cloth, following with a disinfecting wipe to sanitize.
2. Dry with a clean cloth or paper towel.
3. Inspect the Cable connector and Cable wire for remaining debris and repeat steps 1-2 as needed until visually clean.

Ensure the Cable connector and Cable wire are fully dry before reconnecting components and powering ON the Pulse Generator.

NOTE: Follow your internal guidelines for sanitizing the Pulse Generator and Cable before each user. Sparrow Link is non-sterile. Do not attempt to sterilize any portion of Sparrow Link or Sparrow Ascent components.

Factory Reset

NOTE: Performing a factory reset erases customized therapy settings and all device logs.

To perform a factory reset:

1. Power ON the Pulse Generator and navigate to the Device Information screen.
2. While on the device information screen, press and hold the + and – buttons on the Pulse Generator at the same time until the factory reset alert appears.
3. Move the cursor to select OK on the factory reset alert. The Pulse Generator will reboot to the stimulation status screen when the factory reset is complete. Do not power OFF the Pulse Generator during a factory reset.



Cautions

- Do not clean earpiece. Replace if soiled.
- Do not submerge the device in water; it is not water resistant.
- Do not use soap, hand sanitizer, detergents, or other cleansers when cleaning the device.

Product Handling

Operating Conditions

- Range: 4° to 38°C (40° to 100° F)
- Humidity: 10% - 90%
- Barometric Pressure: less than 80 kPa
- Max Output Voltage: 95V
- Sparrow Link produces an electrical signal consisting of a rectangular, symmetrical shaped waveform with 100 μ s between phases. The waveform of the system pulse is biphasic.

Storage/Transport Conditions

- Make sure the device is turned OFF before storing. Remove the 3 AAA batteries from the Sparrow Link Pulse Generator for long term storage.
- Sparrow Link should be stored at room temperature away from moisture.
- Range: 4° to 38°C (40° to 100°F)
- Humidity: 10% - 90%
- Barometric Pressure: less than 80 kPa
- Store device in such a way (e.g., drawer or shelf) so that the device components are not damaged.
- Do not store the device in places where it could be subjected to vibrations or sudden impacts.

Service Life

The service life of Sparrow Link is 3 years. See the Sparrow Ascent Instructions for Use for the service life of Sparrow Ascent components and accessories.

Technical Details

Sparrow Link Pulse Generator Specifications

Specification	Description
Dimensions (H X W X D)	111mm x 66mm x 24mm (HxWxD)
Weight	111.4g including battery
Disposal	According to WEEE: Directive 2012/19/EU - Device, accessories, and packaging waste must be disposed of properly after each usage. Follow Local Ordinances and Regulations for disposal.
Service Life	3 yr.

Sparrow Earpiece Specifications

Specification	Description
Shelf Life	18 mo.
Weight	1.6g (28.9g with cable)
Disposal	According to WEEE: Directive 2012/19/EU - Device, accessories, and packaging waste must be disposed of properly after each usage. Follow Local Ordinances and Regulations for disposal.

Electrical Specifications

Specification	Description
Power Supply	
Voltage	3 AAA Alkaline Batteries (provided) in series, max 4.5 V
Battery (new battery with a full charge)	
Capacity	Approximately 24 hours of normal use.

Environmental Specifications

Specification	Description
Temperature	
Operating	40°F to 100°F
Storage	40°F to 100°F
Fluid Rating	IP22 – protected against soft falling water, non-pressurized.

Stimulation Outputs

Amplitude, pulse width, and frequency meet or exceed IEC 60601-2-10:2016 requirements. The amplitude range specified is selectable for either channel with any frequency and pulse width combination. However, certain frequency and pulse width combinations within the specified ranges are unsupported when defining stimulation parameters other than the default settings.

Amplitude Range	0 mA – 5.0 mA
Frequency Range	1 Hz – 150 Hz
Pulse Width Range	50 μ s – 750 μ s
Impedance Range	500 – 75,000 Ω

Configuration

Specification	Description
BLE Use Environment	The BLE wireless interface is intended to be used in medical office, industrial park, hospital, and home settings.
BLE QoS	BLE should perform with ≤ 2 s latency. If you experience slower communication performance, use the troubleshooting section to resolve. Contact Spark Biomedical if you are unable to resolve the BLE communication performance issues.
BLE Distance	Sparrow Link Pulse Generator can safely be used around other wireless and cellular equipment. Standard BLE distances and line of site requirements apply – direct line of site max distance is 10m, obscured line of site max distance is 3m.
BLE Radio Frequency	SM frequency band 2400 - 2483.5 MHz Implements Gaussian Frequency Shift Keying (GFSK). Bandwidth of each of the 40 possible frequency channels does not exceed 2MHz. Transmitter effective radiated power will not exceed 0 dBm.

BLE Use

The Sparrow Link Pulse Generator offers wireless configuration using Bluetooth Low Energy (BLE). This interface, when used with the Sparrow Link Researcher App or Sparrow Link Hub, can export Sparrow Link Pulse Generator history, erase history, reset to default factory settings, and configure custom stimulation parameters and Pulse Generator settings. See the Sparrow Link Researcher Application Instructions for Use or the Sparrow Link Hub Instructions for Use for more information.

EMC Declarations

The Sparrow Link Pulse Generator is intended for use in the electromagnetic environment specified below, which is representative of medical office, industrial park, hospital, and home settings.

Electromagnetic Emissions

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Sparrow Link Pulse Generator is suitable for use in commercial, hospital, and typical home use environments.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A – primary cell powered	

Electronic Immunity

Immunity test	IEC 60601 test level	Compliance level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric Field Radiated IEC 61000-4-3	3 V/m from 80 MHz to 2700 MHz, 80% AM modulated, 1kHz 9-28 V/m at Table 9 Frequencies	3 V/m from 80 MHz to 2700 MHz, 80% AM modulated, 1kHz 9-28 V/m at Table 9 Frequencies	Angles and Sides: four angles (front, back, left and right) Antenna Distance: 3 meters (< 1 GHz); 1 meter (> 1 GHz)
Electrical fast transient/burst IEC 6100-4-4	---	---	N/A – primary cell powered
Surge IEC 61000-4-5	---	---	N/A – primary cell powered
Conducted Immunity IEC 61000-4-6	AC and SIP/ SOP: 3 Vrms (6 Vrms in ISM Bands), 80% AM modulated, 1kHz, from 0.15-80MHz	AC and SIP/ SOP: 3 Vrms (6 Vrms in ISM Bands), 80% AM modulated, 1kHz, from 0.15-80MHz	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	---	---	N/A – primary cell powered
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home use environment.

Immunity test	IEC 60601 test level	Compliance level	Compliance level
Conducted RF IEC 6100-4-6 Radiated RF IEC 6100-4-3	3 Vrms150 k Hz 80M Hz3 V/m80 M Hz 2.7 G Hz	3 Vrms3 V/mc	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Sparrow Link Pulse Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 M Hz – 800 M Hz}$ $d = 2.3 \sqrt{P} \text{ 800 M Hz – 2.5 G Hz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey:</p> <p>A) should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of RF communications equipment</p>
<p>Note 1: the voltage is the main supply voltage, and the degradation is based on nominal voltage prior to the application of the test level. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p>A Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Sparrow Link is used exceeds the applicable RF compliance level above, then Sparrow Link should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Sparrow Link.</p> <p>b Over the frequency range 150 k Hz to 80 M Hz, field strengths should be less than 3 V/m.</p> <p>c Amplitude modulated at 80% with a modulation frequency of 1K Hz per EN 60601-1-2.</p>			

Recommended Separation Distances

Refer to the following table for recommended separation distances between the Sparrow Link and portable and mobile RF communication equipment.

Sparrow Link is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of Sparrow Link can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Sparrow Link as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter W	Separation distance according to the frequency of the transmitter		
	150 k Hz – 80 M Hz $d = 1.2 \sqrt{P}$	80 M Hz – 800 M Hz $d = 1.2 \sqrt{P}$	800 M Hz – 2.5 G Hz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23


















For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

Note1: At 80 M Hz and 800 M Hz, the separation distance for the higher frequency range applies.


Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

System Information

Symbols and Nomenclature Description

	Device Model Number and Name		Disposal
	Manufacture Date		Caution
	Manufacturer		Warning
	Serial #		Applied Part
	FCC Symbol and ID		Note
	Expiration Date		Single-Use
	Follow Instructions for Use		Keep Dry
	Lot #		IP Rating
	Storage Temperature		

Contact Information

	
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<p>Product Complaint Reports and/or related issues may be submitted directly to Spark Biomedical: Telephone: (844) 654-SPRK (7775) Email: customersupport@sparkbiomedical.com</p>	

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Version: LBL-072 Rev 4

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