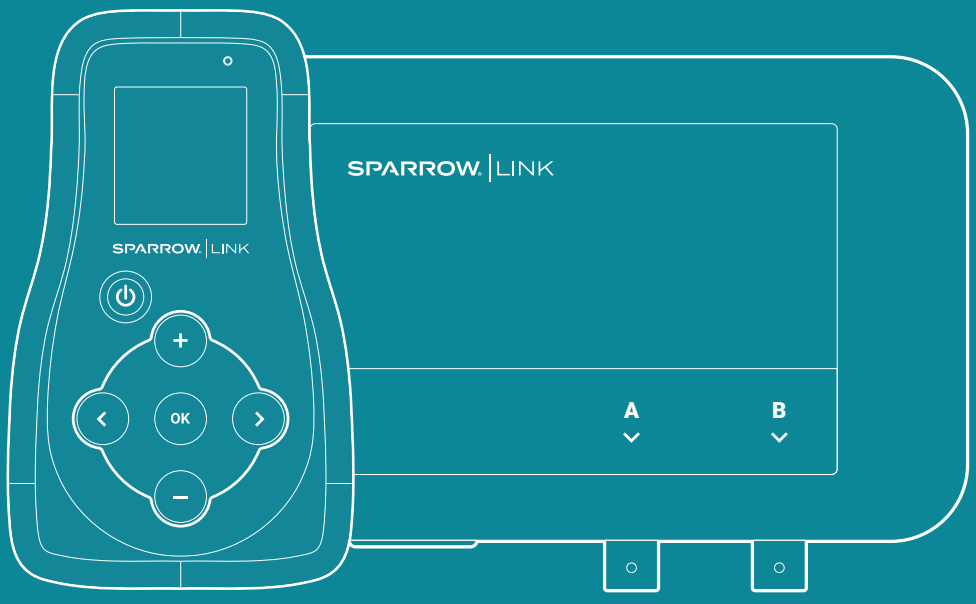
SPARROW | LINK

Sparrow® Link Hub Instructions for Use

(tAN®: Transcutaneous Auricular Neurostimulation)



Contents

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**.

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 non-invasive Transcutaneous Auricular Neurostimulation (tAN®) therapy stimulation parameters output by the Sparrow Link Pulse Generator. The Sparrow Link platform is intended for use in studies approved by the corresponding competent authorities in accordance with all applicable local laws and regulations.

Connect the Sparrow Link Hub to your PC with a USB-C to USB-A cable (not included). Then, using the built-in Bluetooth Low Energy (BLE) communication protocol, send Sparrow Link API commands to the Sparrow Link Pulse Generator via the Hub.

The Sparrow Link Hub pairs with the Sparrow Link Pulse Generator via BLE to:

- Modify stimulation output parameters, including amplitude, pulse width, frequency, duty cycle, and ramping duration
- Enable or disable error notifications on the Sparrow Link Pulse Generator
- Factory reset the Sparrow Link Pulse Generator
- Enable or disable the Sparrow Link Pulse Generator lock screen
- Programmatically modify stimulation output by the Sparrow Link Pulse Generator
- Enable trigger mode, which allows external signal inputs into the Hub to trigger stimulation at the Inner or Outer areas of the Sparrow Ascent Earpiece when paired with the Sparrow Link Pulse Generator.

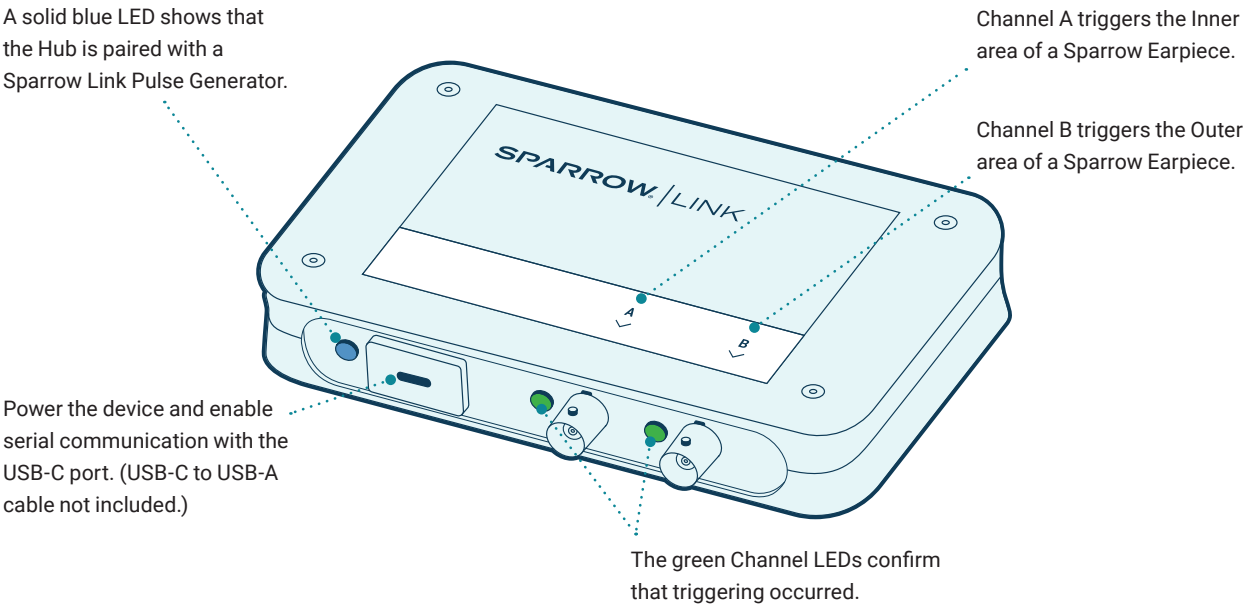
The Sparrow Link Hub is compatible with the following software and components:

Device Type	Model Number
Sparrow Link API	N/A
Sparrow Link Pulse Generator	910
Sparrow Ascent Disposable Left Earpiece	210, 213*
Sparrow Ascent Disposable Right Earpiece	211, 214*
Sparrow Fledgling Disposable Left Earpiece	530
Sparrow Fledgling Disposable Right Earpiece	531
Sparrow Ascent Cable	810

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

Sparrow Link Hub – Model 940

The Sparrow Link Hub has an onboard BLE chip, one USB-C input for serial communication to a PC, and two BNC connections to receive input signals for stimulation triggering. Connect the Hub to your PC, then using the Sparrow Link API, pair the Hub to your Sparrow Link Pulse Generator. Once paired, continue to use the API to modify device or stimulation parameters and enable triggering. To power off the Hub, simply unplug the USB-C to USB-A cable from either the Hub or your PC.



Customize the features of Sparrow Link Pulse Generator output with the Sparrow Link Hub & API.

Features	Options	Description
Stimulation Range	0.0 mA. – 5.0 mA.	Stimulation amplitude for either channel can be increased or decreased in 0.1 mA increments.
Pulse Widths	50, 100, 150, 250, 350, 500, 750 µs	Possible Pulse Widths for either channel.
Frequencies	1, 5, 10, 15, 20, 25, 30, 40, 50, 75, 100, 125, 150 Hz	Possible Frequencies for either channel.
Duty Cycle	OFF 102 mS - 24 hours ON 0 mS - 24 hours	The Duty Cycle sets the stimulation intervals. The OFF portion of the Duty Cycle reduces nerve accommodation.
Ramp Up Duration	Default Ramp or Custom Fixed Duration 50 mS – 60 second	The default ramping increases the stimulation amplitude at 0.1 mA per second. A fixed ramp time will distribute the amplitude increase over the duration applied.
Ramp Down Duration	Custom Range 50 mS – 3 seconds	The default ramping decreases the stimulation amplitude over a three-second duration. A custom ramp-down time distributes the amplitude decrease over the duration applied.
Passive Sham	Inner Channel, Outer Channel, or both Channels	Channels with sham enabled will not deliver stimulation.
Triggering	Inner Channel, Outer Channel, or both Channels simultaneously	Use the API to enable Trigger Mode, then trigger stimulation ON or OFF based on signal voltage input at the BNC connectors.

Connect the Hub

Follow these steps for setting up your Sparrow Link Hub.

1. **Install the drivers for the Hub.** You can find the drivers needed at: **https://www.silabs.com/developers/usb-to-uart-bridge-vcp-drivers?tab=downloads**
2. **Install Python 3.12 (or greater) and required packages**
    a. When installing, you'll want to check the "Add Python to Path" checkbox so it integrates it into the standard command line.
    b. Once Python is installed, go into a Windows CMD terminal, type **pip install pyserial** and press enter.
    c. Once pyserial is installed, type **pip install esptool** then press enter.
3. **Plug in the Hub and view the COM Port**
    a. Plug the Hub into your PC using a USB-C to USB-A cable (not included).
    b. Next, find your COM Port by navigating to your PC's Device Manager control panel. Under “Ports (COM & LPT)” the Sparrow Link Hub will appear as “Silicon Labs CP210x USB to UART Bridge”. Here you will find the name of the COM Port into which the Hub is connected. An example COM Port name is “COM1”.
4. **Import the API and set the COM Port**
    a. Log in to download the latest API file at **sparkbiomedical.com/research/sparrow-link**.
    b. Save the API file, **SparrowLinkHub.pyd**, at the file path where Python is installed, or save the file in your preferred workspace.
    c. Launch the Python console or hold shift and right-click in the folder where the SparrowLinkHub.pyd file is located to open PowerShell or similar.
    d. In the console, type **import SparrowLinkHub**
    e. Next, you can assign a short variable name to the Spark Hub class location. In this documentation, the assigned shortcut variable name used is sl. For example, in the console type **sl = SparrowLinkHub.SparkHub()**
    f. Next, use the SetPort() API command to set the com port associated with the Hub for serial communication. For example, **sl.SetPort(“COM1”)**
    g. Next, open the port for serial communication using the Open() command. For example, **sl.Open()**

5. **Pair the Hub to the Sparrow Link Pulse Generator**

    a. Power on the Sparrow Link Pulse Generator then navigate to and select the BLE icon at the bottom of the screen. Select “OK” to turn on Bluetooth. The 6-digit serial number needed to connect is shown when Bluetooth is advertised on the controller.

    b. Back on the console, enter in the last 6 digits of the serial number to the ConnectSync() command to connect the Hub to the Controller. For example, sd.ConnectSync(“123456”)

    c. Confirm the ConnectSync() command returned ‘True’ and that the Pulse Generator screen now reads “Paired”. You can now modify the Sparrow Link Pulse Generator output as needed. For the full list of commands, see the API documentation in the documentation section at **sparkbiomedical.com/research/sparrow-link**.

Using the API

Follow the steps above to connect the Hub to the Sparrow Link Pulse Generator. Then, using the Sparrow Link API, modify stimulation output parameters, including amplitude, pulse width, frequency, duty cycle, and ramping duration as needed. You may also use API commands to enable the triggering of the Pulse Generator using the external BNC connections on the Hub, or change certain Sparrow Link Pulse Generator user interface characteristics, such as hiding error notifications and lengthening the screen lock-out time.

Frequently Used API Commands

Connecting the Hub

SetPort()		
Parameters	**Input**	**Description**
Port	Enter the name of the COM port the Hub uses as a string. Example: SetPort(“COM1”)	Plug the Hub into your computer and find the COM port number for the device named: “Silicon Labs CP210x USB to UART Bridge” Install any necessary drivers.

Open()		
Parameters	**Input**	**Description**
None	None	Opens the serial port to enable communication with the Hub. Please note that you must use the SetPort() call to set the serial communication port prior to opening the line of communication.

ConnectSync(serial)		
Parameters	**Input**	**Description**
Serial	Enter the 6-digit serial number (SN) displayed on the Sparrow Link Pulse Generator in quotations.	Connects the Sparrow Link Hub to the Sparrow Link Pulse Generator and sets the Sparrow Link Pulse Generator system time to match the date and time of your computer. Steps to connect: 1. Enable Bluetooth Low Energy (BLE) on the Sparrow Link Pulse Generator by navigating to the BLE screen and selecting 'OK' to turn on Bluetooth. 2. After BLE is enabled, enter the 6-digit number shown on the Pulse Generator screen into the ConnectSync() call as shown in the example. Example: ConnectSync("123456") or ConnectSync('123456')

Starting and Stopping Stimulation

StartStimulation(channel)		
Parameters	**Input**	**Description**
Channel	0	Toggles ON stimulation for the **Inner** channel.
	1	Toggles ON stimulation for the **Outer** channel.

StopStimulation(channel)		
Parameters	**Input**	**Description**
Channel	0	Toggles OFF stimulation for the **Inner** channel.
	1	Toggles OFF stimulation for the **Outer** channel.

Amplitude

SetAmplitude(channel,amplitude)		
Parameters	**Input**	**Description**
Channel	0	Sets the amplitude for the **Inner** channel.
	1	Sets the amplitude for the **Outer** channel.
Amplitude	An integer from 0-50.	Sets the amplitude for the given channel. An amplitude input of 0 sets the amplitude to 0.0 mA. An amplitude input of 50 sets the amplitude to 5.0 mA. Note: Changes to the amplitude while stimulation is ON will be instantaneous and will not ramp.

ReadAmplitude(channel)		
Parameters	**Input**	**Description**
Channel	0	Gets the amplitude for the **Inner** channel as shown on the Pulse Generator. Returns an integer from 0-50.
	1	Gets the amplitude for the **Outer** channel as shown on the Pulse Generator. Returns an integer from 0-50.

Frequency

SetFrequency(channel,freq)		
Parameters	**Input**	**Description**
Channel	0	Sets the frequency for the **Inner** channel.
	1	Sets the frequency for the **Outer** channel.
Frequency	1, 5, 10, 15, 20, 25, 30, 40, 50, 75, 100, 125, 150	Sets the frequency for the given channel in **Hz**. Note: Attempts to set unsupported frequency combinations will return false. See the Sparrow Link Instructions for Use for documentation on our frequency combinations that are unsupported or output a nominal value +/-15% of the selected frequencies.

Pulse Width

SetPulseWidth(channel,pw)		
Parameters	**Input**	**Description**
Channel	0	Sets the pulse width for the **Inner** channel.
	1	Sets the pulse width for the **Outer** channel.
pw	50, 100, 150, 250, 350, 500, 750	Sets the pulse width for the given channel in µS.

Triggering

SetTriggerMode(value)		
Parameters	**Input**	**Description**
Value	0	Exit the trigger state.
	1	Enable triggering for the Inner channel via Channel A on the Hub.
	2	Enable triggering for the Outer channel via Channel B on the Hub
	3	Enable triggering for BOTH the Inner and Outer channels via Channel A & B on the Hub.

For the full list of commands, see the Sparrow Link API documentation in the documentation section at **sparkbiomedical.com/research/sparrow-link**.

> **Note:** BLE latency will vary between operating environments but should not exceed 2 seconds. To understand your environment's response rate, characterize response times between the Sparrow Link Hub and the Sparrow Link Pulse Generator.

Triggering

Sparrow Link Hub supports external hardware trigging. Simply connect your signal to the intended channels using the BNC connections on the Hub and set the Pulse Generator into triggering mode with the API commands.

Follow these steps for triggering.

1. **Set your stimulation parameters, such as pulse width, frequency, ramping types, and durations, before entering trigger mode.** Once you enter trigger mode, the Pulse Generator will display a “Trigger mode enabled” screen that prevents the user from viewing or modifying stimulation using the controls on the Pulse Generator.

2. **Enable trigger mode on the paired Pulse Generator using the Hub and API commands.** First, pair the Pulse Generator with the Hub using the Connect the Hub steps above. Once paired, and all parameters are set, use the **SetTriggerMode()** command to enable external triggering.

SetTriggerMode(value)		
Parameters	**Input**	**Description**
Value	0	Exit the trigger state.
	1	Enable triggering for the Inner channel via Channel A on the Hub.
	2	Enable triggering for the Outer channel via Channel B on the Hub
	3	Enable triggering for BOTH the Inner and Outer channels via Channel A & B on the Hub.

3. Connect your signal to the Hub BNC connections. Voltage input of 1.75V or higher will trigger stimulation ON. Voltage input below 1.75V will trigger stimulation OFF. Do not exceed 3.3V input voltage at the BNC connections. The green LEDs for Channels A and B will light when a triggering command is received. However, when external triggering frequencies are higher than 1 Hz, the LED status may not reflect the latest input received, and stimulation changes may not be captured in the device logs.

> ! **Note:** BLE latency will vary between operating environments but should not exceed 2 seconds. To understand your environment's response rate, characterize response times between the Sparrow Link Hub and the Sparrow Link Pulse Generator.

Updating the Hub

When a new firmware version is available, follow these steps to update your Sparrow Link Hub.

1. First, follow steps 1-3 on page 4 to connect the Hub to your PC.

2. Download Firmware Updates to your PC

   Four files contain the firmware needed to update the Hub. You can log in and download Sparrow Link Hub firmware from **sparkbiomedical.com/research/sparrow-link**. Unzip the downloaded files, move them to an easily accessible location, such as the desktop or downloads folder on your computer, then copy the file path.

3. Next, open a Windows CMD terminal and change the directory to the file path where the Sparrow Link Firmware files were saved. To change the CMD directory type:

   cd *then paste the file path*

   then press enter. Confirm the directory has been updated to the correct path name copied from the file explorer.

4. Next, in the same location in the CMD terminal, you'll enter the script to load the firmware files. You can copy and paste the script provided in the Firmware download or type in the following script. Be sure to modify the highlighted selections to match your COM Port and Firmware version:

   esptool --chip esp32 --port "COMX" --baud 921600 --before default_reset --after hard_reset write_flash -z --flash_mode dio --flash_freq 80m --flash_size 4MB 0x1000 "sparkdongle.ino.bootloader.bin" 0x8000 "sparkdongle.ino.partitions.bin" 0xe000 "boot_app0.bin" 0x10000 "SparkHub.0.0.17.bin"

   If an error occurs despite being in the correct directory with the correct com port entered, try changing **esptool** to **esptool.py**.

Troubleshooting

Problem	Cause	Solution	Comments
The Hub commands are returning false.	An unstable pairing, BLE interference, or the command was sent while the buffer of the Pulse Generator was full.	Unplug, replug, and reconnect to the Pulse Generator.	Allow commands sent from the Hub to the Pulse Generator time to apply changes to the Pulse Generator before sending the next command.
I cannot find the Hub listed under COM Ports.	Drivers not installed.	Install drivers for Silicon Labs CP210x USB to UART Bridge.	If drivers are installed, ensure that all devices are shown in the device manager by selecting “view hidden devices.”
The Hub won’t pair or the Pulse Generator times out while BLE searches.	The wrong serial number or connection command was entered.	Ensure the 6-digit number displayed on the Pulse Generator BLE screen matches the number entered into the ConnectSync() command.	

For help with the Sparrow Link Pulse Generator see the Sparrow Link Instructions for Use.

Is the problem not listed here? Contact Spark Biomedical for further assistance at **(844) 654-SPRK (7775)**. For more detailed instructions, visit Sparrow Link resources at **sparkbiomedical.com/research/sparrow-link**.

Maintenance and Cleaning

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 the skin and degrade stimulation performance. 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 the Earpiece adhesive, making removal easier. Always unplug the Earpiece from the Cable before using the warm compress.

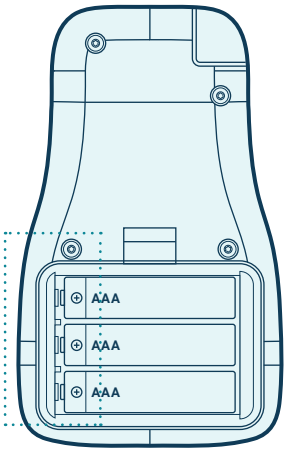


Figure 6: Battery Orientation

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 Hub may be cleaned and sanitized as needed. Do not use corrosive substances such as bleach to clean any part of the Hub. Do not use the Hub if the device appears damaged. If a dampened cloth with water is not effective at removing debris from the Hub, you may use a cloth dampened with 91% isopropyl alcohol. To sanitize the Hub, use a quaternary ammonium-based product such as a Lysol disinfecting wipe.

Be sure any cables connected to the Hub are unplugged before you start the cleaning.

To clean the Hub:

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 cables and powering ON the device.

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.

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 connecter 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.

Product Handling

System Operating Conditions

- Range: 4° to 38°C (40° to 100° F)
- Humidity: 10% - 90%
- Barometric Pressure: less than 80 kPa
- Sparrow Link Pulse Generator Max Output Voltage: 95V
- Sparrow Link Pulse Generator produces a biphasic, rectangular, symmetrical shaped waveform

System Storage/Transport Conditions

- Unplug the Sparrow Link Hub from your PC to power off the device. Remove any cables from the USB-C port and BNC connections for long-term storage.

Make sure the Pulse Generator is turned off before storing it. For long-term storage, remove the 3 AAA batteries from the Sparrow Link Pulse Generator.

- Sparrow Link and Sparrow Ascent products 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 the device in a way (e.g., drawer or shelf) that does not damage the device components.
- 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 Link Instructions for Use for the service life of Sparrow components and accessories.

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 or Sparrow Ascent components 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 a Sparrow 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 Controller model 910, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Cautions

- The researcher is the intended operator of the Sparrow Link Hub. Do not allow unintended operators to use the Hub.
- Ramping durations faster than 0.1 mA per second may cause discomfort or overstimulation of the end user.
- Do not use the Sparrow Link Pulse Generator model 910 in wet environments. Always keep the Pulse Generator dry.
- Do not use the Sparrow Link Hub model 940 in wet environments. Always keep the Hub 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 the 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 the 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

The 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 the 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 16).
- 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.

Technical Details

Sparrow Link Hub Specifications

Specification	Description
Dimensions (H X W X D)	29mm X 101mm X 150mm
Weight	156g
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.

Electrical Specifications

Specification	Description
Power Supply	
USB-C Input Voltage	5V
BNC Input Voltage Range	Max 3.3V

Environmental Specifications

Specification	Description
Temperature	
Operating	40°F to 100°F
Storage	40°F to 100°F

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 <= 2s 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 Hub offers a wireless configuration of the Sparrow Link Pulse Generator using Bluetooth Low Energy (BLE). This interface can trigger stimulation ON or OFF, export Sparrow Link Pulse Generator history, erase history, reset to default factory settings, and configure custom stimulation parameters and Pulse Generator settings. For more information, see the Sparrow Link Researcher Application Instructions for Use or the Sparrow Link Instructions for Use.

Recommended Separation Distances

Response times may vary based on system limitations. Characterize your system setup to determine the minimum response times achievable.

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 √P	80 M Hz – 800 M Hz d = 1.2 √P	800 M Hz – 2.5 G Hz d = 2.3 √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

REF	Device Model Number and Name
	Manufacture Date
	Manufacturer
SN	Serial #
	FCC Symbol and ID
	Expiration Date
	Follow Instructions for Use
LOT	Lot #
	Storage Temperature

	Disposal
	Caution
	Warning
	Applied Part
	Note
	Single-Use
	Keep Dry
IP22	IP Rating

Contact Information

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