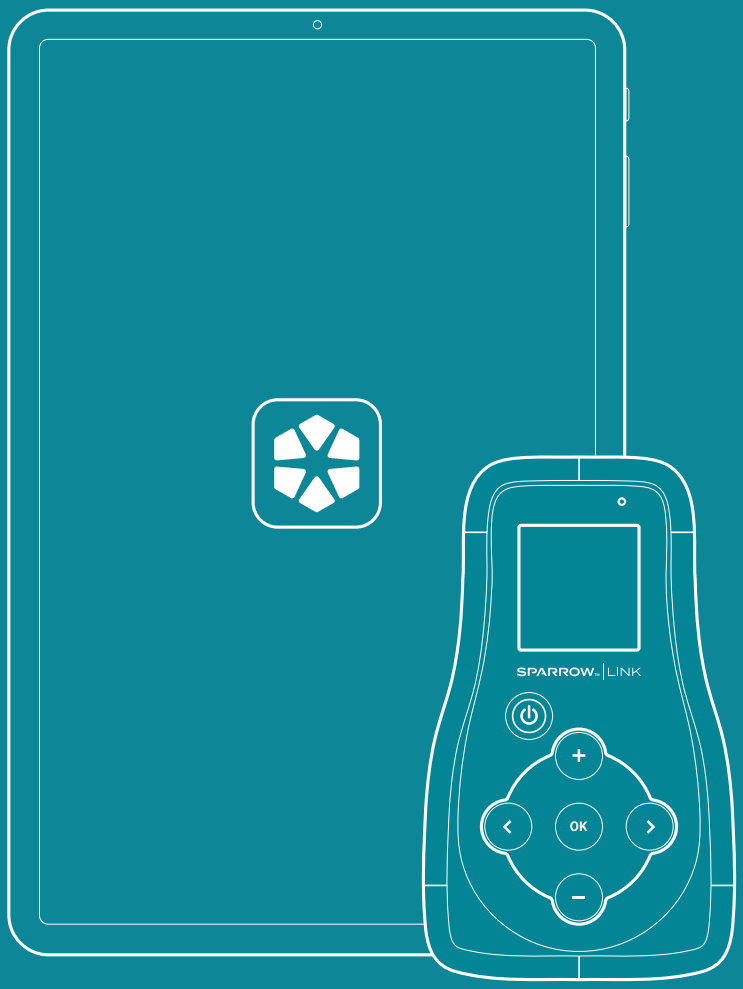
SPARROW® | LINK

Sparrow® Link Researcher Application Instructions for Use



Sparrow Link Researcher Application Instructions for Use

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**.

App Description

The Sparrow Link Researcher Application (model 930-S) can be used to connect with a Sparrow Link Pulse Generator ("controller") to view or modify device behavior and stimulation parameters. The Sparrow Link Researcher Application is only available for Android platforms and is compatible with the Sparrow Link Pulse Generator (model 910).

For information about the Sparrow Link Pulse Generator and other products, please see the Sparrow Link Instructions for Use.

Instructions for Use

App Installation Instructions

The Sparrow Link Researcher Application will install on any tablet with an Android platform; however, an operating system of Android 11 or higher and Bluetooth Low Energy (BLE) hardware of 4.2 or higher is required. Spark Biomedical has installed and validated the Sparrow Link Researcher Application performance on a limited amount of Android tablets. Installation on tablets or mobile phones not in the validated list below may result in poor app performance.

Validated Tablets for using Sparrow Link Researcher Application:

Manufacturer	Model/Name	Screen Size
Samsung	Galaxy Tab A7 & A7 Lite	10.1” (A7) & 8.7" (A7 Lite)
Samsung	Galaxy Tab A9+	11”

To access Sparrow Link user manuals and downloads, create a Researcher account with Spark Biomedical at **https://www.sparkbiomedical.com/accounts/sign-up**. Once the account is created, you can login and access Sparrow Link documentation and downloads. Access Sparrow Link downloads from your tablet to download the Sparrow Link Researcher Application installation file (apk). After downloading, navigate to installation files in the system settings on your tablet and tap to begin the installation of the app.

Tablet Settings

The following settings must be enabled to use the app.

- Bluetooth
- Location services
- Wi-Fi

Login Instructions

The login credentials cannot be changed within the app. Sparrow Link Pulse Generator users should use the following login credentials.

Username: tANresearch
Password: guest

Contact Spark Biomedical to retrieve a lost username and password or if your institution requires alternative credentials. When prompted, select "Allow while in use" for Location Services and Media Access permissions.

Pairing the App to your Pulse Generator

Complete the following steps to pair your Pulse Generator to the app.

1. Enable Bluetooth, Wi-Fi, and location services on your tablet.
2. Launch the app and log in using the username and password provided to your institution.
3. Next, on the Pulse Generator, navigate to the BLE screen to view the 6-digit serial number.
4. Enter the 6-digit serial number on the Pulse Generator into the field on the app and press CONNECT.
5. Ignore any system popups requesting you to reenter the serial number; the number will automatically be applied, and the app will transition to the Information screen once the pairing process is complete.
6. If the connection fails, repeat steps 1-5. After a factory reset, Pulse Generators may initially require two attempts to connect to the app.

Information Screen

The Information screen displays the Pulse Generator hardware specifications and current settings.

Note: If any of the current settings are empty or incorrect, the pairing is unstable and changes made within the app will not be applied to the Pulse Generator. Disconnect the Pulse Generator from the app and try again.

Default Configurations and Stimulation Settings:

A factory reset or firmware update of the Pulse Generator will return all settings to the preset manufacturing configuration. Unless the default settings of the Pulse Generator were customized in manufacturing, the device will default to the following settings:

Parameter	Inner Channel	Outer Channel
Stimulation Amplitude	0 mA	0 mA
Pulse Width	350 µS	250 µS
Frequency	30 Hz	100 Hz
Sham	OFF	OFF
Configurations		
Duty Cycle	Cycle Time ON: 5 Minutes Cycle Time OFF: 10 Seconds	
Error Notifications	ON	

Configuration Screen

The Configuration screen allows you to update firmware, perform a factory reset on the paired Pulse Generator, and enable or disable the following features for the paired Pulse Generator: Screen Lock, Auto-off, Autodecrement, Error Notifications, and Sham the stimulation output of the Inner Electrode and Outer Electrode by the Pulse Generator.

Update Firmware

A firmware update will modify the paired Pulse Generator to the most recent firmware version.
NOTE: Confirm all device use logs are shared prior to updating firmware.

1. Press UPDATE FIRMWARE on the configuration screen.
2. A notification titled 'Select Firmware' will appear. Press UPDATE to continue.
3. Select the appropriate firmware file in your files application to begin installation.
4. Once installation is complete, the Pulse Generator screen will turn blue. Power OFF the Pulse Generator.
5. Power the Pulse Generator ON to complete the firmware update. Next, perform a factory reset on the Pulse Generator by simultaneously holding the UP and DOWN arrows on the Pulse Generator. When prompted, press YES to perform the Factory Reset. The Pulse Generator will revert stimulation settings back to the manufactured settings, modify the settings again as needed.

Factory Reset

A factory reset will delete:

- All controller logs
- Any modifications made to the controller settings
- Internal clock settings (date/time) on the controller

To avoid accidental deletion of logs, downloading the logs before a factory reset is recommended. A factory reset is recommended between each user to keep the logs limited to each user's history.

> ! Note: Following a factory reset, immediately pair the Pulse Generator with the app or Sparrow Link Hub to automatically reset the internal clock on the Pulse Generator.

Screen Lock

The Pulse Generator screen will automatically time out after 30 seconds of inactivity. This default feature can be disabled or extended.

Auto-off

The Pulse Generator screen will automatically shutdown after 30 minutes of inactivity. Note that stimulation being ON prevents the Pulse Generator from an automatic shutdown. This default feature can be disabled for the Pulse Generator to remain ON until a manual shutdown is prompted by the user or the batteries are depleted.

Autodecrement

The Pulse Generator screen will automatically ramp down if high impedance is detected. This default feature can be disabled for stimulation to remain ON at its set intensity despite high impedance.

Error Notifications

Disabling the Error Notifications can help unify the Pulse Generator user interface behavior across active and sham groups. The user will continue to receive low battery alerts and notifications, such as a timer ending, but will not be notified if the Cable or Earpiece loses connectivity.

Sham

Enabling Sham on a Pulse Generator will turn off the delivery of any stimulation but it will appear that users can increase or decrease the strength settings, toggle stimulation ON / OFF, and set a stimulation timer. However, because the stimulation output on a shamed device is 0 mA, there will be no Error Notifications on the Pulse Generator if the Cable or Earpiece loses connectivity.

Single channel sham capabilities are available for the Sparrow Link devices. Variations in stimulation can be applied to the Inner Channel and Outer Channel separately.

Share Logs Screen

The Share Logs screen allows you to name and download the Pulse Generator logs to the tablet's or mobile phone's internal storage running this app. A timestamp of when the logs are downloaded will be automatically appended to the end of your filename. Enter a filename and press the SHARE LOG button to begin the download of logs from the Pulse Generator.

Locating Logs for Sharing

Retrieve the downloaded logs from the tablet's or mobile phone's internal storage running this app. Open the documents folder in your system storage and look for a Spark Folder.

The logs will download as both a zip file and a .CSV file of the logs. Share logs from this location using email or other messaging applications.

The exact location of logs may vary depending on the operating system. If the file path is not created or a documents folder does not exist, update the operating system software and try again.

Advanced Settings Screen

Modify the default waveform parameters here. All changes will occur with no more than a 2-second latency. You can confirm the changes in most settings by viewing the information screen. Some pulse width and frequency combinations are not supported. The best practice for navigating pulse width and frequency combination changes is to set the pulse width for both channels first. Next, set the highest frequency desired, then the lowest frequency. Unsupported combinations will be grayed out. Some frequency combinations are supported but the nominal value of the lower frequency selected may be up to +/- 15%. See the Sparrow Link Instructions for Use for the full list of unsupported or nominal frequency combinations.

Parameter	Action	Description
Inner Channel Power	Toggle ON / OFF	Toggle the stimulation for this channel ON / OFF just as you would from the stimulation screen on the Pulse Generator.
Outer Channel Power	Toggle ON / OFF	Toggle the stimulation for this channel ON / OFF just as you would from the stimulation screen on the Pulse Generator.
Inner Strength	Set Strength	Set the target strength for this channel just as you would from the stimulation screen on the Pulse Generator. Caution: When stimulation is ON, changing the amplitude from this screen will immediately update the stimulation strength with no ramping period.
Outer Strength	Set Strength	Set the target strength for this channel just as you would from the stimulation screen on the Pulse Generator. Caution: When stimulation is ON, changing the amplitude from this screen will immediately update the stimulation strength with no ramping period.
Inner Channel Pulse Width	Set Pulse Width	Set the pulse width for this channel to 50, 100, 150, 250, 350, 500, or 750 µs
Inner Channel Frequency	Set Frequency	Set the frequency for this channel to 1, 5, 10, 15, 20, 25, 30, 40, 50, 75, 100, 125, or 150 Hz
Outer Channel Pulse Width	Set Pulse Width	Set the pulse width for this channel to 50, 100, 150, 250, 350, 500, or 750 µs
Outer Channel Frequency	Set Frequency	Set the frequency for this channel to 1, 5, 10, 15, 20, 25, 30, 40, 50, 75, 100, 125, or 150 Hz
Cycle Time ON	Set Time	Enter the duration of the ON portion of the duty cycle in milliseconds. 53 – 86,400 miliseconds.
Cycle Time OFF	Set Time	Enter the duration of the OFF portion of the duty cycle in milliseconds. 1 – 86,400 milliseconds.
Inner Channel Impedance	Get Impedance	Press to view the current impedance (Ω) for this channel.
Outer Channel Impedance	Get Impedance	Press to view the current impedance (Ω) for this channel.
Step Type Action	Set Step Type	Set the step type to Default or Fixed Time to modify the ramping rate of the desired stimulation settings.
Ramp Up Time Action	Set Time	Enter the duration of the upward ramping of stimulation in milliseconds. 50 - 60,000 milliseconds. Caution: Ramping quickly at perceptible stimulation levels may result in discomfort.
Ramp Down Time Action	Set Time	Enter the duration of downward ramping of stimulation in milliseconds. 50 - 3,000 milliseconds.

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, researchers can modify the parameters of the biphasic waveform output by the Pulse Generator for the Inner and Outer channels. See **Table 1.0** 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 µs	250 µs	50 µs - 750 µs	50, 100, 150, 250, 350, 500, 750 µs
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 µs		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 µs, 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.*

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 to the right in **Table 1.1**.

Table 1.1: Sparrow Link Pulse Generator Unsupported Frequency Combinations

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

Reading the Logs

The Pulse Generator log history can be downloaded and saved as a .CSV file type.

Log History		
Record Name: Description	**Parameter Recorded**	**Record Details**
Bluetooth: Describes the Bluetooth (BT) status of the Pulse Generator.	Old Value / New Value	Disconnected, Advertising, or Connected
Cable Disconnect: A cable disconnection was detected, and an alert was shown or cleared by the user.	Value	Cleared or Shown
Cycle Off: Describes a change to the off portion of the duty cycle.	Source	BT
	Old Value / New Value	Time in milliseconds
Cycle On: Describes a change to the on portion of the duty cycle.	Source	BT
	Old Value / New Value	Time in milliseconds
Dim Time: The duration of inactivity required before the screen dims.	Old Value / New Value	Time in milliseconds
Earpiece Disconnect: A loose Earpiece was detected, and an alert was shown or cleared by the user.	Channel	Inner or Outer
	Value	Cleared or Shown
Error Notification: This indicates when Error Notifications are disabled (Off) / enabled (On).	Old Value / New Value	On or Off
Fault: The Pulse Generator failed. This error can typically be resolved with new batteries, a power cycle, or a factory reset.	N/A	N/A
Fixed Ramp Up: The duration stim will ramp up to the set amplitude.	Old Value / New Value	Time in milliseconds
Frequency: Describes a change made to the frequency of a channel.	Source	BT
	Channel	Inner or Outer
	Old Value / New Value	1, 5, 10, 15, 20, 30, 40, 50, 75, 100, 125, 150 Hz
Impedance: Impedance is logged every ten minutes while stimulation is turned ON. An impedance ≥ 75K will trigger a connectivity alert. Note that a channel left ON but set to a strength of 0 mA may have impedance logged as 0 or 65535000. This includes channels that have sham enabled.	Channel	Inner or Outer
	Value	0-65535000 ohms
Lock Time: The duration of inactivity required before the screen locks.	Old Value / New Value	Time in milliseconds
Log Reset: This indicates the previous logs have been erased.	N/A	N/A
Power: Describes when one or more channels have been turned on or when both channels have been turned off.	Old Value / New Value	On or Off

Log History		
Record Name: Description	**Parameter Recorded**	**Record Details**
Pulse Width: Describes a change made to the pulse width of a channel.	Source	BT
	Channel	Inner or Outer
	Old Value / New Value	50, 100, 150, 250, 350, 500, 750 µs
Ramp Down: The duration in which stimulation will ramp down.	Old Value / New Value	Time in milliseconds
Ramp Type: The type of ramping stimulation will follow.	Old Value / New Value	Default or Fixed Time
Sham: Describes when the Sham state is enabled or disabled. When impedance is logged, shammed channels will show an impedance of 0.	Old Value / New Value	On or Off
Shutdown: Describes when the Pulse Generator has been turned off.	N/A	N/A
Sleep: Describes when the Pulse Generator screen has locked (off) or unlocked (on).	Old Value / New Value	On or Off
Stimulation: Describes if the stimulation on a channel was toggled On or Off and the strength setting the channel was at.	Source	BT or EPG
	Channel	Inner or Outer
	Old Value / New Value	On or Off
	Strength	Set Strength (0-50)
Strength: Describes the increase or decrease of the set strength for a channel. Note: The stimulation does not need to be on for the user to change the set strength. When stimulation is on, the strength slowly decreases to 0 when the Earpiece comes loose.	Source	BT or EPG
	Channel	Inner or Outer
	Old Value / New Value	Strength (0-50)
Strength Programming: Describes when the user has enabled or disabled strength adjustments on the Pulse Generator.	Channel	Inner or Outer
	Old Value / New Value	On or Off
System Startup: This indicates the Pulse Generator has been turned on.	Serial	6 characters, may be numbers and letters
	Firmware	#.#.##
	Hardware	#.#.#
Time Set: Describes the state of the clock on board the Pulse Generator. Clock settings are automatically synced with the date and time of the device on which the app is installed.	Old Time Stamp / New Time Stamp	mmm-dd-yyyy HH:MM:SS AM or PM
Trigger: Describes when one or both channels have been triggered.	Old Value / New Value	(A or B) On or Off
	Impedance	0-65535000 ohms
Trigger Mode: Describes when Trigger Mode has been enabled for one or both channels.	Old Value / New Value	Inner, Outer, or Both Triggers Enabled
User Timer: Describes the state of the timer when enabled.	Source	EPG
	Old Value / New Value	Off, Paused, or Running

Troubleshooting

Need help with the Sparrow Link Pulse Generator, Sparrow Earpiece, or Cable? Additional information and troubleshooting for these components can be found in the Sparrow Link Instructions for Use.

Issue	Solution
I can't find the Spark folder because there is no documents folder on my tablet.	Update the operating system on the tablet or mobile device to the latest software.
Logs appear to download, but the log isn't in the Spark folder.	Disconnect the Pulse Generator from the app. Reconnect the Pulse Generator to the app and try again to download the logs.
"Bad CRC" appears in the logs.	The Pulse Generator has corrupted log memory. The log can not be recovered. The safety or efficacy of the Pulse Generator is not affected. To fix the memory issue, factory reset the Pulse Generator, then retrieve a log and confirm Bad CRC is not shown. If shown, perform a second factory reset.
The Pulse Generator settings are not updated when I send a command.	Disconnect the Pulse Generator from the app. Reconnect the Pulse Generator to the app and try again.
The connection crashes immediately after pairing the app to the Pulse Generator.	This issue is observed immediately following a factory reset. Reconnect the Pulse Generator to the app. Confirm the connection is stable by viewing the Pulse Generator screen. The pairing is stable if the current device settings on the screen are complete and correct.
I can't connect my Sparrow Ascent Patient Controller to the app.	The Sparrow Ascent Patient Controller (Model 110) is not compatible with the current version of the Sparrow Link Researcher Application. Users on app versions prior to 1.1.15 may still be able to connect the Sparrow Ascent Patient Controller. If you are experiencing connection issues with an earlier app version, please contact Spark Biomedical.
The app crashes after selecting the Advanced Settings icon.	Close and then reopen the application and reconnect the Pulse Generator to the app. Be sure to press the 'Connect' only once. The Pulse Generator screen will read 'Paired' immediately when successful, however the app may take several seconds to finish loading the Information screen.
Other	For all other issues, ensure the tablet used is from the validated list of supported tablets. If available, update the tablet operating software. Then uninstall the app, restart the tablet, and reinstall the app. Ensure the tablet has BLE and Location services turned on and is connected to a secure Wi-Fi network before using the app.

BLE performance issues:

To resolve BLE performance issues:

1. First, close the app and ensure that the tablet running the app has a secure Wi-Fi connection with BLE and location services enabled.
2. Next, forget the Pulse Generator (EPG) in your system's paired devices. To determine the correct device to forget, match up the last six digits of the EPG's serial number to the list of paired devices.
3. Relaunch the app, log in, and connect to the Pulse Generator.

Technical Details

Stimulation Outputs

Amplitude, frequency, and pulse width meet or exceed IEC 60601-2-10:2016 requirements.

Parameter	Output Range
Amplitude Range	0 mA – 5.0 mA
Frequency Range	1 Hz – 150 Hz
Pulse Width Range	50 µs – 750 µs
Impedance Range	0 Ω – 75,000 Ω

Configuration

Specification	Description
Bluetooth Low Energy (BLE)	
BLE QoS	BLE for stimulation programming 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	The Sparrow Link Pulse Generator can safely be used around other wireless and cellular equipment. Standard BLE distances and line of sight requirements apply – direct line of sight max distance is 10m, obscured line of sight max distance is 3m.

BLE Use

The Sparrow Link Pulse Generator offers wireless stimulation programming using Bluetooth Low Energy (BLE) from an Android tablet. This interface may be used to update firmware, perform a factory reset, retrieve Pulse Generator history, set the amplitude, pulse width, frequency, and cycle settings, enable or disable error notifications and sham, and modify auto-off and autodecrement using the Sparrow Link Researcher Application, model 930-S.

Potential Issue with BLE Stimulation Programming

Though unlikely, delayed stimulation settings are possible under extreme conditions. The BLE transport protocol typically resolves these issues automatically without software or end-user action. If you experience delays or disruptions to programming performance, use the troubleshooting section to resolve them. Contact Spark Biomedical if you are unable to resolve the BLE communication performance issues.

EMC Declarations

Please see the Sparrow Link Instructions for Use for detailed information regarding EMC compliance.

Contact Information

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Product Complaint Reports and / or related issues may be submitted directly to Spark Biomedical:

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