SPARROW® | ASCENT

# Sparrow® Ascent Instructions for Use

(tAN®: Transcutaneous Auricular Neurostimulation)

# Table of Contents

**Rx ONLY** **Caution: Rx Only. US Federal Law restricts this device to sale by or on the order of a licensed healthcare provider.**

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

# Indication for Use & Device Description

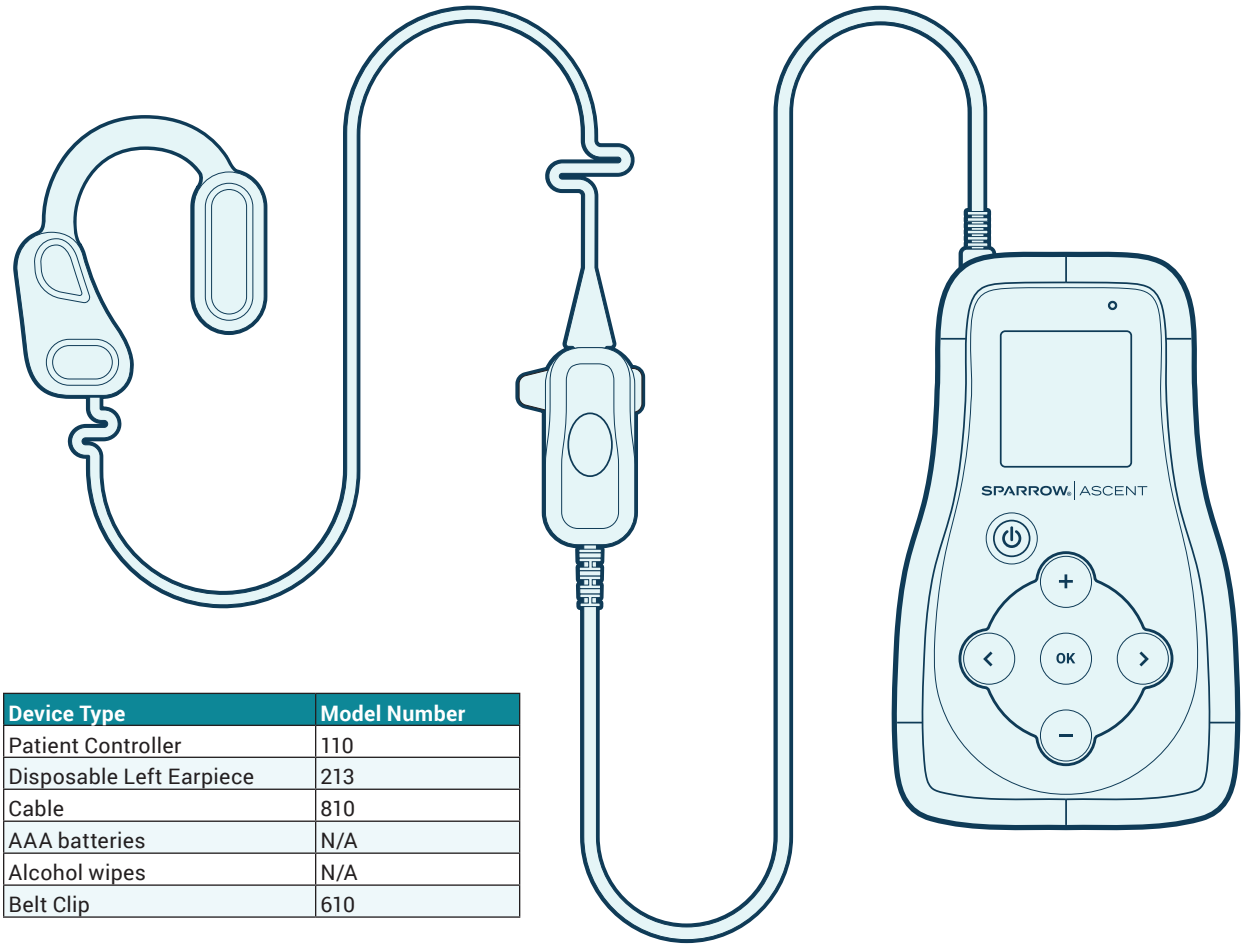
The Sparrow Ascent is a wearable, battery-operated neurostimulation device intended to transcutaneously stimulate nerves on and/or around the ear.

The Sparrow Ascent is intended for prescription use only as an aid to the standard of care. The patient undergoing therapeutic treatment should be under the care of a clinical professional trained in opioid reduction, detoxification, and/or recovery.

**Indication for Use**
The Sparrow Ascent is a transcutaneous nerve field stimulator that is intended to be used in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel.

Sparrow Ascent is designed to be used up to 24 hours a day or as needed for relief of withdrawal symptoms. The disposable Earpiece should be changed daily and the AAA batteries powering the device should be replaced as needed, based on power consumption. The Sparrow Ascent is provided non-sterile and should not be sterilized before use, however routine sanitation of the Patient Controller and Cable is recommended as needed.

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




| Device Type | Model Number |
|---|---|
| Patient Controller | 110 |
| Disposable Left Earpiece | 213 |
| Cable | 810 |
| AAA batteries | N/A |
| Alcohol wipes | N/A |
| Belt Clip | 610 |

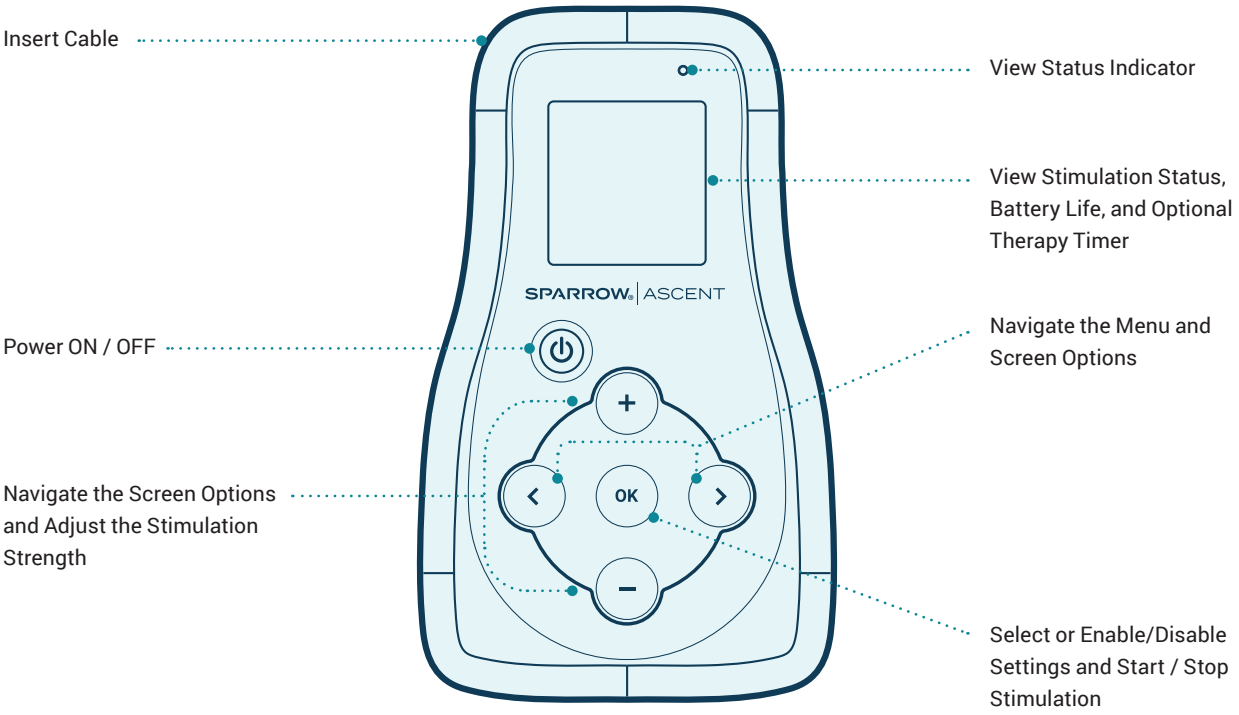
## Contraindications

Use of Sparrow Ascent is contraindicated for history of seizures, epilepsy, neurological diseases, traumatic brain injury, active ear infection, and presence of Active Implanted Medical Device (AIMDs) such as cochlear implant, pacemaker, and/or neuro-stimulator.

## Sparrow Ascent Patient Controller – Model 110

The Sparrow Ascent Patient Controller is a hand-held, battery-powered device designed to be carried with the patient during therapy. Patients can safely use the Sparrow Ascent in the comfort of their own home and during most daily activities. The Patient Controller delivers stimulation to the Sparrow Ascent Earpiece via a removable Cable. The Patient Controller is powered by three standard Alkaline AAA batteries.

The Patient Controller has a physical user interface comprised of a 6-button keypad with a 1.5" LCD screen display. The Patient Controller allows users to:




The Patient Controller also indicates to the user:

- Alerts and notifications
- Earpiece errors
- Cable disconnections

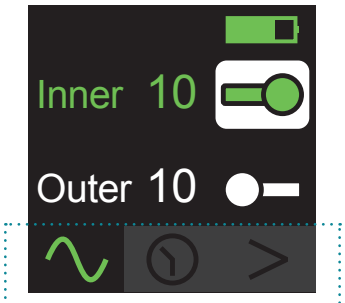
## Menu Options

The Patient Controller has a menu bar located at the bottom of the screen.

Use the menu bar to navigate Patient Controller 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 Patient Controller. There are 4 screen options to which the user can navigate:

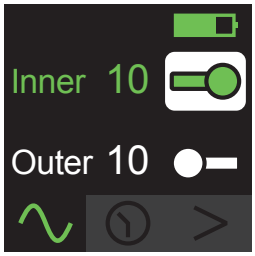
- Stimulation status
- Therapy timer
- Bluetooth connectivity
- Device information



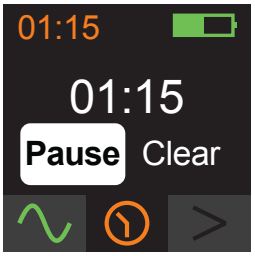

**Menu Bar**

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

**Stimulation Status**




**Therapy Timer**




**Bluetooth Connectivity**


**Device Information**

## 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. 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 Patient Controller. 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 Patient Controller 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 slowly ramp to the pre-set strength (0-50). When stimulation is toggled OFF, stimulation will ramp down in 3 seconds.

## 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.

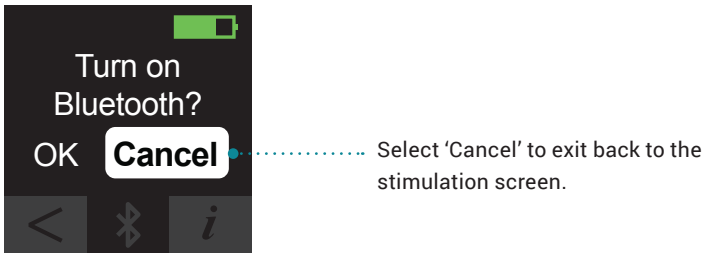
**Pause / Resume Timer** – To pause or resume the timer, navigate to the timer screen and highlight the 'Pause' or 'Resume' option and press OK. The timer will automatically pause when stimulation is turned OFF and resume when stimulation is turned ON up to 24 hours.

**Timer Icon** – Turns orange when the timer is active.

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

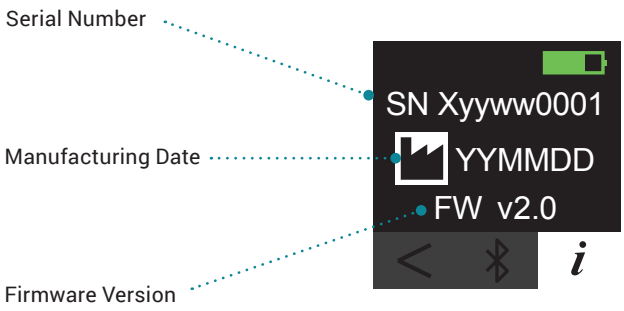
### Bluetooth Connectivity

Bluetooth capability is currently intended to support system diagnostics performed by the Clinician or manufacturer.




### Device Information

The Device Information screen displays Patient Controller specifications. Use this screen to view Patient Controller serial number, manufacturing date, and firmware version.

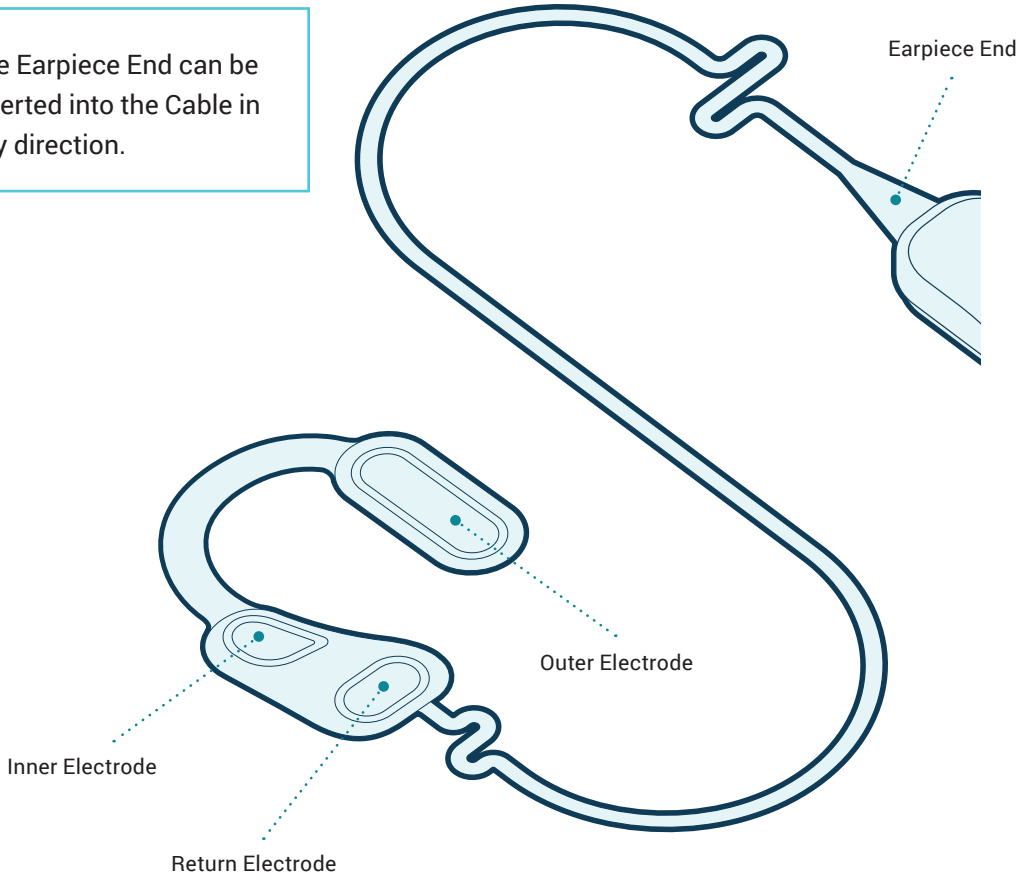


## Sparrow Ascent Earpiece — Model 213

The Sparrow Ascent contains Earpieces designed to deliver mild stimulation around the left ear. Each Earpiece connects to the Cable to receive electrical inputs from the Patient Controller.

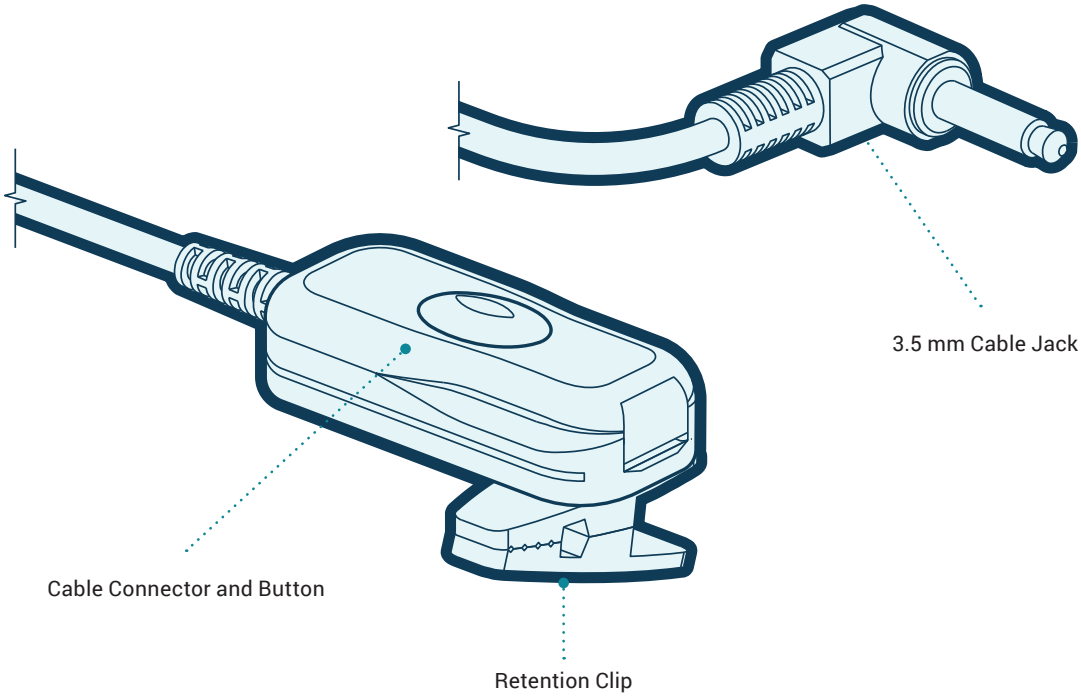
The Earpiece is a disposable component of the Sparrow Ascent and is designed to stay adhered to the skin for up to 24 hours. The Inner Electrode interfaces with the Vagus nerve and the Outer Electrode interfaces with the Trigeminal nerve. The Return Electrode is shared by both the Inner and Outer Electrodes.

The Earpiece End can be inserted into the Cable in any direction.



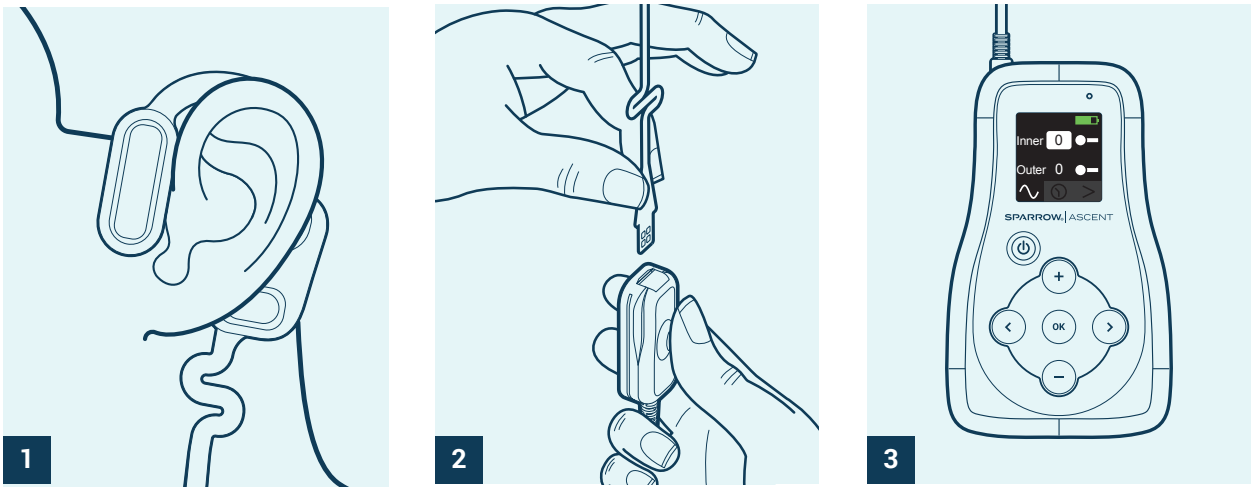
## Sparrow Ascent Cable – Model 810

The Sparrow Ascent Cable is 37 inches long and connects the Patient Controller to the Earpiece. The Cable length is designed to allow the user to carry the Patient Controller 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 Ascent in 3 easy steps:.




## Step 1:

**Apply the Earpiece**

Prepare the skin, 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 however that only one Electrode be applied at a time.

1. Gently clean in and around the ear with one of the provided alcohol wipes. 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 1**).

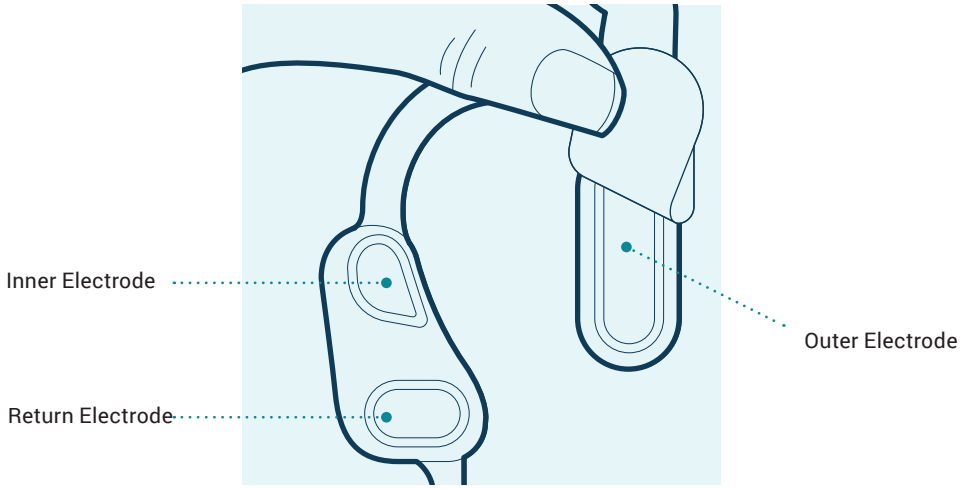



**Figure 1**

2. Place the Earpiece on the ear with the Outer Electrode in front of the ear. Next, remove the adhesive liner covering the Inner/Return Electrode. Press firmly to ensure the Inner/Return Electrodes are adhered to the skin.

   **NOTE:** Try not to touch the hydrogels/adhesive surface during the Earpiece application.

3. Next, remove the adhesive liner covering the Outer Electrode. Press firmly to ensure the entire Outer Electrode is adhered to the skin. See **Figure 2** for correct Earpiece placement.

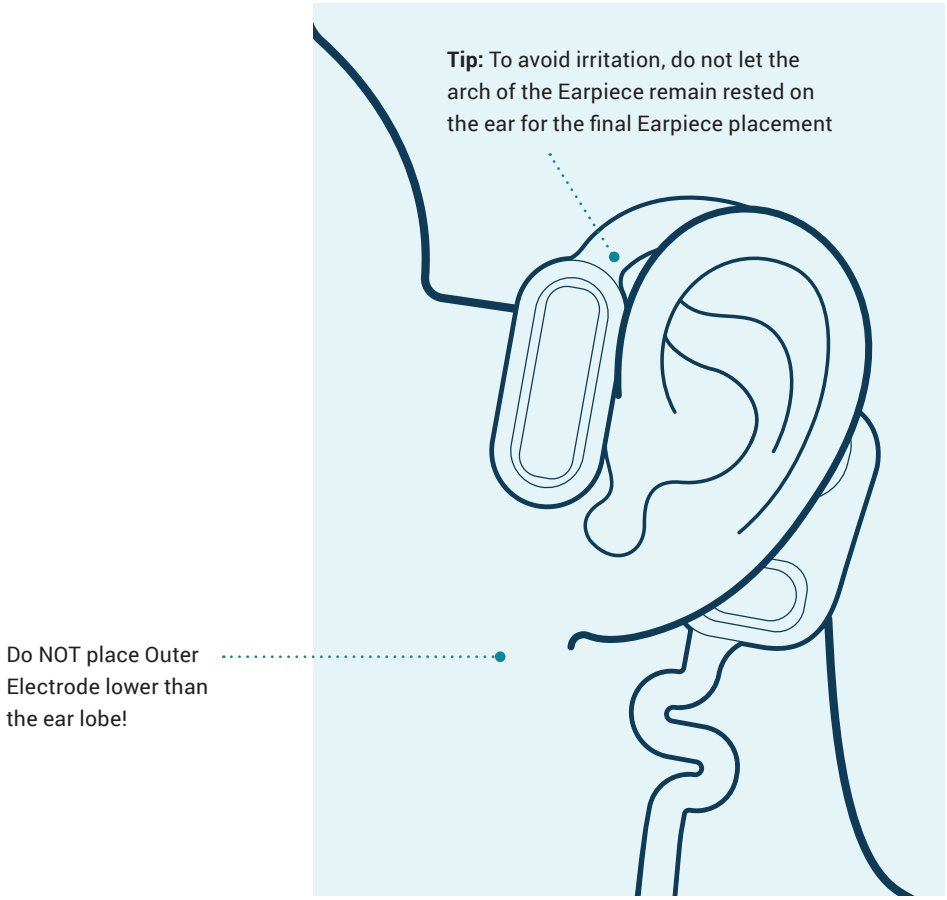



**Figure 2:** Earpiece placed correctly

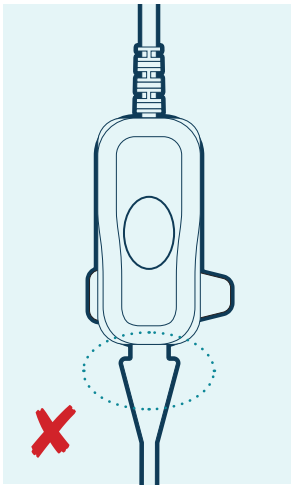
## Step 2:

**Connect the Cable**

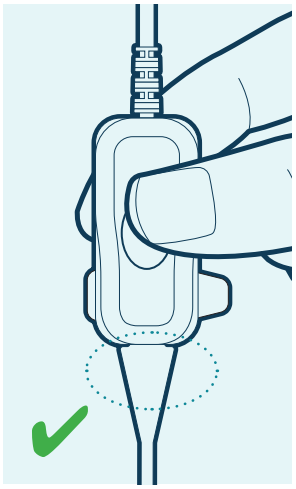
Connect the Earpiece to the Cable, then connect the Cable to the Patient Controller.

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 connecter. 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.



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



Earpiece fully inserted

2. Insert the Cable jack into the Patient Controller (**Figure 3**)

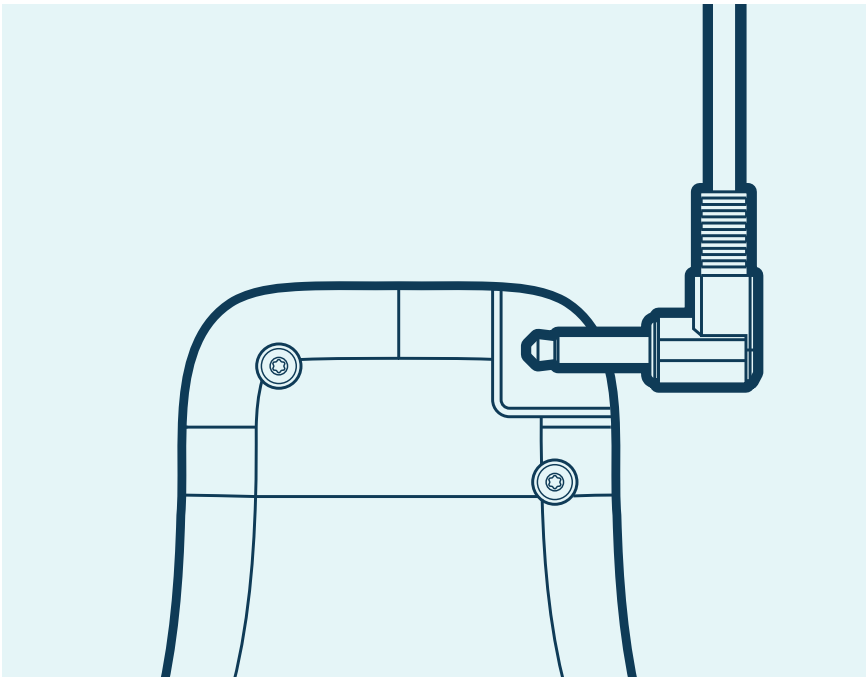


**Figure 3:** Insert Cable jack into Patient Controller

## Step 3:

**Start Stimulation**

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

1. Power ON the Patient Controller

    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: If the output level is set to 0, toggle the output to ON before adjusting stimulation in order to feel the stimulation strength as the setting is adjusted.

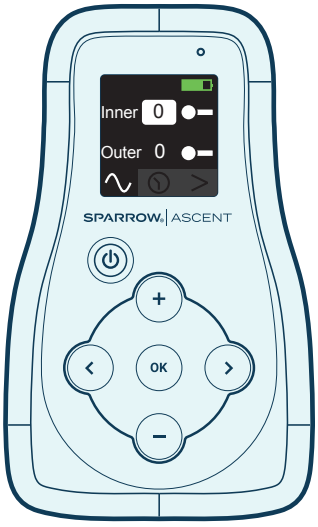



**Figure 4:** The Inner strength is highlighted

3. Use the directional buttons to highlight the Inner or Outer strength (**Figure 4**). 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). Stimulation may be felt behind the ear at the Inner and Return Electrodes or in front of the ear at the Outer Electrode. Initial stimulation programming should be set at a strength that is both perceptible and comfortable. 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 controller 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 Patient Controller

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

**Understanding Stimulation**
It is typical to experience reduced or lost sensation of stimulation after prolonged use, however this does not mean the therapy will be less effective. A 5-minute ON / 10-second OFF duty cycle is a default feature of all stimulation output by the Patient Controller. This means that every 5 minutes, stimulation will ramp down and turn OFF for 10 seconds, then ramp back ON to the target stimulation strength.

When stimulation is turned ON to a preset strength, stimulation ramping will occur over 0- 50 seconds depending on the target strength. While ramping, the strength displayed will increment from the current strength to the target strength. The user may halt ramping by pressing the OK button while the ramping strength is selected.

**NOTE:** In order to stop stimulation quickly, unplug the Cable.

The Patient Controller will automatically lower stimulation strength when high impedance is detected. High impedance can be caused by an improperly cleaned ear, soiled Earpiece, re-used Earpiece, improperly fitted Earpiece, or unplugging the Cable while in use. See troubleshooting on page 19 to resolve.

# 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 the Sparrow Ascent components while in use.
- Do not make any modifications to the Sparrow Ascent components.
- Only connect the Sparrow Ascent to approved components listed in this manual.
- The Sparrow Ascent Cable model 810 may cause strangulation. Don't allow children to use or play with the Sparrow Ascent.
- Do not use the Sparrow Ascent with High Frequency surgical equipment.
- Do not use the Sparrow Ascent near shortwave or microwave equipment.
- Do not use the Sparrow Ascent in an explosive atmosphere or in the presence of flammable gas mixtures.
- Do not apply the Sparrow Earpiece model 213 on/near the thorax as it may increase the risk of fibrillation.
- Do not apply/use the Sparrow Ascent Earpiece model 213 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 the Sparrow Ascent Earpiece model 213 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 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 Ascent Patient Controller model 110, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## Cautions

- Do not use the Sparrow Ascent Patient Controller model 110 in wet environments. Always keep the controller dry.
- Do not use the Sparrow Ascent Cable model 810 in wet environments. Always keep the Cable and Cable connecters dry.
- Do not use contaminated, dirty, or previously used Sparrow Earpieces.
- Do not use other transcutaneous (e.g., TENS) or implanted neurostimulators while using the Sparrow Ascent.
- Do not use the Sparrow Ascent if any of the components are cracked, dented, or appear to be damaged.
- Do not use the Sparrow Ascent Earpiece model 213 if it has passed its expiration date indicated on the Earpiece Pouch.
- Do not use the Sparrow Ascent Earpiece model 213 if the protective covering is tampered with, damaged, or missing.
- Do not use the Sparrow Ascent if the Sparrow Ascent Cable model 810 is damaged.
- Do not clean the Sparrow Ascent Earpiece model 213. Replace the Sparrow Ascent Earpiece if it is soiled.
- Do not use corrosive substances to clean the Sparrow Ascent Patient Controller model 110 or Sparrow Ascent Cable model 810.
- Do not use soap, hand sanitizer, detergents, or abrasive cleaning agents when cleaning the Sparrow Ascent Patient Controller model 110 or Sparrow Ascent Cable model 810. These may damage the equipment surfaces.
- Do not use the Sparrow Ascent for greater than 6 hours continuously in high ambient temperatures (100° F). The Patient Controller device may reach temperatures or 43° C (109.4° F) which can be uncomfortable to touch.
- Aggressive cleaning of the Ear with Alcohol wipe may lead to skin irritation.

# Patient Safety

The Sparrow Ascent 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 Ascent 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 Ascent.
- The safety and effectiveness of the subject device was not evaluated in females who are pregnant or lactating.

## 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**<br>"Low Battery! Replace to resume therapy." | The battery life is insufficient to continue therapy. | Power OFF the Patient Controller and replace the batteries with 3 new AAA batteries. Power ON the Patient Controller and resume therapy. | See Changing Batteries in the Maintenance section for more information. |
| **Alert Message**<br>"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**<br>"The Cable or Earpiece is disconnected." | The system has lost connection with the Earpiece or Patient Controller. | Check the Cable jack connection at the Patient Controller 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.<br>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 Patient Controller 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.<br>To resolve skin irritation:<br>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<br>Discontinue use of Alcohol wipes and use a gentle cleansing wipe instead to prep the skin for Earpiece application.<br>Apply Dermatologist recommended ointment for sensitive skin in between daily Earpiece applications |

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 Patient Controller as needed. The battery icon in the upper right-hand side of the Patient Controller screen will turn red when the batteries are low. To change the batteries, press and hold the power button until the Patient Controller 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 5)**, then close the cover. Turn the device back ON and resume therapy.

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

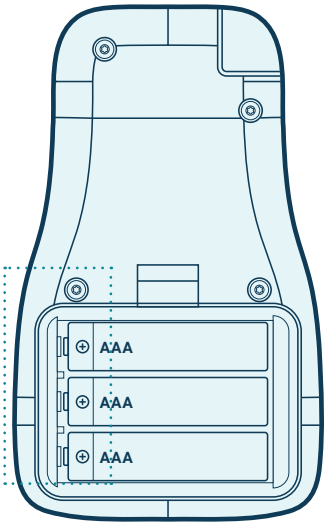



**Figure 5:** Battery Orientation

### Cleaning

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

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

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

To clean the Patient Controller:

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.
4. (Optional) Place the Patient Controller in a UV sanitizer box and follow the manufacturer's instructions for UV cycle time.

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 Patient Controller 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 Patient Controller.

**NOTE:** Follow your internal guidelines for sanitizing the Patient Controller and Cable before each user. The Sparrow Ascent is non-sterile. Do not attempt to sterilize any portion of the Sparrow Ascent.

### Factory Reset

A factory reset should be performed on the Patient Controller only at the recommendation of the manufacturer. NOTE: Performing a factory reset erases customized therapy settings and all device logs.

To perform a factory reset:

1. Power ON the Patient Controller and navigate to the Device Information screen.
2. While on the device information screen, press and hold the + and – buttons on the Patient Controller at the same time until the factory reset alert appears.
3. Move the cursor to select OK on the factory reset alert. The Patient Controller will reboot to the stimulation status screen when the factory reset is complete. Do not power OFF the Patient Controller 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 Ascent produces an electrical signal consisting of a rectangular, symmetrical shaped waveform with 100 µs 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 Ascent Patient Controller for long term storage.
- The Sparrow Ascent 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 the Sparrow Ascent is 3 years.

# Technical Details

## Sparrow Patient Controller Device 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 µs – 750 µs |
| Impedance Range | 500 – 19,000 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 <= 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 Patient Controller 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<br>Implements Gaussian Frequency Shift Keying (GFSK).<br>Bandwidth of each of the 40 possible frequency channels does not exceed 2MHz.<br>Transmitter effective radiated power will not exceed 0 dBm. |

## BLE Use

The Sparrow Ascent Patient Controller Device offers wireless diagnostic using Bluetooth Low Energy (BLE) from a mobile device. This interface, when used with an internal diagnostic tool, can export Sparrow Ascent Patient Controller history, erase history, and reset to default factory settings.

## EMC Declarations

The Sparrow Patient Controller Device 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 Patient Controller Device 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)<br>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. |
| 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 Vrmsc3 V/mc | Portable and mobile RF communications equipment should be used no closer to any part of the Sparrow Patient Controller Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>d = 1.2 √P<br>d = 1.2 √P 80 M Hz – 800 M Hz<br>d = 2.3 √P 800 M Hz – 2.5 G Hz<br>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).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey:<br>A) should be less than the compliance level in each frequency range.<br>Interference may occur in the vicinity of RF communications equipment |

| Immunity test | IEC 60601 test level | Compliance level | Compliance level |
|---|---|---|---|
| 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. | | | |
| 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 the Sparrow Ascent is used exceeds the applicable RF compliance level above, then the Sparrow Ascent should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sparrow Ascent.<br>b Over the frequency range 150 k Hz to 80 M Hz, field strengths should be less than 3 V/m.<br>c Amplitude modulated at 80% with a modulation frequency of 1K Hz per EN 60601-1-2. | | | |

## Recommended Separation Distances

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

The Sparrow Ascent is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Sparrow Ascent can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sparrow Ascent 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.<br>Note1: At 80 M Hz and 800 M Hz, the separation distance for the higher frequency range applies.<br>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 |
| Rx ONLY | Prescription Only |
|  | 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

| | |
|---|---|
| **Customer Success:**<br>Email: customersupport@sparkbiomedical.com<br><br>Spark Biomedical, Inc.<br>7535 W Grand Parkway South<br>Richmond, TX 77407<br>Telephone: (844) 654-SPRK (7775) | **Manufacturer:**<br>Email: customersupport@sparkbiomedical.com<br><br>Spark Biomedical, Inc.<br>7535 W Grand Parkway South<br>Richmond, TX 77407<br>Telephone: (844) 654-SPRK (7775) |
| **Product Complaint Reports and/or related issues may be submitted directly to Spark Biomedical:**<br>Telephone: (844) 654-SPRK (7775)<br>Email: customersupport@sparkbiomedical.com | |

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