CIONIC

Neural Sleeve

NS-200

Instructions

For Use

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Patents Pending
Aspects of the Neural Sleeve are covered by patents and patent applications.

How it Works
The Cionic Neural Sleeve uses a combination of continuous motion analysis and Functional Electrical Stimulation (FES). Sophisticated sensors continuously monitor movement in real-time to evaluate muscle firing and limb position, and personalized algorithms deliver FES to activate the necessary muscles precisely coordinated to the gait cycle.

Disclaimer
CIONIC Inc. and its affiliates shall not be liable for any injury or damage suffered by any person, either directly or indirectly, as a result of the unauthorized use or attempted repair of the Neural Sleeve and all of its components. CIONIC does not accept any responsibility for any damage caused by the Neural Sleeve, either directly or indirectly, as a result of use and/or repair by unauthorized personnel.

Environmental Policy
Users are advised that when changing electrode pads on the Neural Sleeve, care should be taken to dispose of the old electrodes and plastic packaging from the new electrodes in the correct manner, where applicable, parts should be recycled. For more detailed information regarding the recommended procedures, please contact CIONIC Inc. CIONIC Inc. is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing practices.

Warranty
The Cionic Neural Sleeve and the Control Unit carry a one-year warranty, starting at the date of delivery. The warranty covers any defects in materials and workmanship when used normally in accordance with CIONIC's published guidelines. CIONIC's published guidelines include but are not limited to information contained in technical specifications, user manuals, and service communications.

CIONIC does not warrant that the operation of the Cionic Neural Sleeve will be uninterrupted or error-free. CIONIC is not responsible for damage arising from failure to follow instructions relating to the Cionic Neural Sleeve's use.

This Warranty does not apply:

- to consumable parts, such as batteries or protective coatings that are designed to diminish over time, unless failure has occurred due to a defect in materials or workmanship
- to cosmetic damage, including but not limited to tears, scratches, dents and broken plastic on ports unless failure has occurred due to a defect in materials or workmanship
- to damage caused by use with a third party garment, component or product
- to damage caused by accident, abuse, misuse, neglect, fire, liquid contact, earthquake or other

external cause
- to damage caused by corrosive substances or exposure to harsh environments
- to damage caused by operating the Cionic Neural Sleeve outside CIONIC's published guidelines
- to damage caused by service (including upgrades and expansions) performed by anyone who is not a representative of CIONIC
- to a Cionic Neural Sleeve that has been modified to alter functionality or capability without the written permission of CIONIC
- to defects caused by normal wear and tear or otherwise due to the normal aging of the Cionic Neural Sleeve

Visit **cionic.com/legal/terms** for additional warranty terms and for how to obtain warranty service.

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CHAPTER 1 | Introduction to Your Neural Sleeve

CIONIC
Neural Sleeve

The Neural Sleeve is a platform for the measurement and augmentation of mobility composed of the leg-worn Neural Sleeve, a battery-powered Control Unit and a mobile application (the CIONIC App). It addresses mobility limitations to support both rehabilitation and functional improvement. The Neural Sleeve includes up to 24 electrodes that wrap around your upper and lower leg. The Neural Sleeve System consists of the fabric sleeve (available in various sizes), a Neural Sleeve Control Unit, a charging cable and up to 4 packets of 12 electrode pads. To operate the Neural Sleeve, you will need to download the CIONIC App which can be accessed through most Apple (iOS) and Android smartphones or tablets.

To get started, go to **cionic.com/app** where you'll be able to download and access the app, and register and authenticate the mobile device.

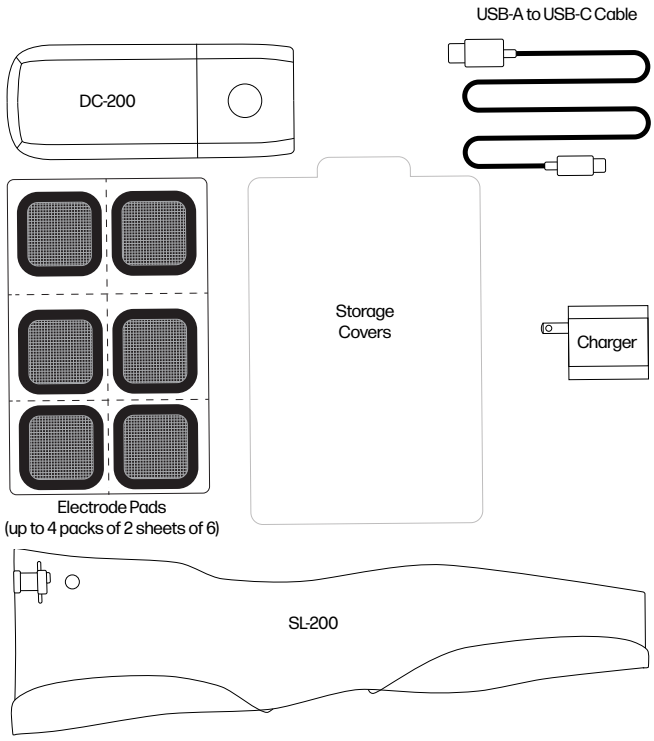


Figure 1 | Neural Sleeve System

Cionic Neural Sleeve System NS-200:

- **Sleeve SL-200** consists of up to 24 electrodes that wrap around the lower and upper leg. Sensors within the sleeve provide precise real-time 3-dimensional orientation, calibrated acceleration, and angular velocity using an inertial measurement unit (IMU) and electromyography (EMG) sensing.
- **Control Unit DC-200:** A portable electronic device worn within the sleeve that provides sensing and stimulation capabilities. It is removable and powered by a rechargeable lithium polymer battery.
- **Mobile Application:** The Control Unit is enabled through the CIONIC App that can run on iOS and Android devices.

CAUTION: It is recommended that you read the Instructions for Use carefully before using your Neural Sleeve. ⚠

Neural Sleeve User Manual

This document includes:

- How to set up and operate your Neural Sleeve
- Important safety information
- How to clean and maintain the Neural Sleeve
- Troubleshooting tips

Indications for Use

The Cionic Neural Sleeve NS-200 is intended to provide ankle dorsiflexion and/or plantarflexion in adult individuals with foot drop and/or to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g. stroke, damage to pathways to the spinal cord). The Cionic Neural Sleeve NS-200 electrically stimulates muscles in the affected leg to provide ankle dorsiflexion and/or plantarflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The Cionic Neural Sleeve NS-200 may also:

- Facilitate muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

Please read the precautions with symbols to ensure that your device is in the proper condition and you are safe to use it. ⚠

Environment of Use

The Cionic Neural Sleeve NS-200 is intended to be used in a clinical or home use setting.

Contraindications

- Individuals with implanted demand-type cardiac pacemaker or defibrillators should not use the Neural Sleeve.
- The Neural Sleeve should not be used over malignant tumors.
- The Neural Sleeve should not be placed over any areas where existing thrombosis is present.
- The Neural Sleeve should not be used on an area of the leg where a regional disorder, such as a fracture or dislocation, could be adversely affected by motion from stimulation.

Warnings ⚠

- The long-term effects of chronic electrical stimulation are unknown.
- The Neural Sleeve System components are non-sterile.
- The Neural Sleeve should not be worn over swollen, infected, or inflamed areas or skin eruptions, such as phlebitis, thrombophlebitis and varicose veins.
- When in doubt about correct operation or if you feel discomfort or pain, turn off the stimulation and remove the Neural Sleeve. If the stimulation does not turn off for any reason, remove the Neural Sleeve.
- Simultaneous connection of the Neural Sleeve to the user and high-frequency surgical equipment may result in skin burns where the stimulator electrodes touch and damage to the Control Unit.
- Do not use the Neural Sleeve within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the Control Unit's output.
- The Neural Sleeve NS-200 may be interfered with by other equipment, even if that other equipment complies with International Special Committee on Radio Interference, International Electrotechnical Commission (CISPR) emission requirements.

Precautions

- Use the Neural Sleeve with caution if you have a suspected or diagnosed heart condition, have a tendency to hemorrhage following trauma or fracture, have had a recent surgery or procedure in which muscle contractions may disrupt the healing process, have an epilepsy diagnosis or suspected diagnosis of epilepsy/seizures, or have need for application of the Neural Sleeve over areas of the skin that lack normal sensation.
- The Neural Sleeve may cause some users to experience skin irritation, an allergic reaction, or hypersensitivity to the fabric, electrical stimulation or a similar electrically conductive medium. Do not wear the Neural Sleeve during any diagnostic or therapeutic medical procedure such as an x-ray, ultrasound, MRI, EMG, etc.
- Replacement electrode pads for the Neural Sleeve should only be provided by CIONIC.

- Do not use the Neural Sleeve System in an oxygen rich environment.
- The Control Unit should be unplugged from the Neural Sleeve before removing the sleeve and before removing or replacing any electrode pads.
- Safe use of the Neural Sleeve during pregnancy has not yet been established.
- Existing skin conditions on the legs may be aggravated or irritated if occuring in the area where the Neural Sleeve is worn.
- Never use the Neural Sleeve with worn-out electrode pads or exposed, frayed or broken wires.
- Users with significantly limited mobility and coordination should seek assistance while using the Neural Sleeve.
- The Neural Sleeve, Control Unit and all associated components should be protected from any exposure to water.
- The Neural Sleeve and Control Unit should not be stored where temperatures may exceed -4˚F to +140˚F (-20˚C to +45˚C). Turn the Control Unit off should it be exposed to these temperature extremes.
- If the device has been stored in a cold or hot environment, allow it at least 5 minutes to acclimate to room temperature before operating.
- Do not modify or attempt to repair the Neural Sleeve or Control Unit yourself. Contact CIONIC if you experience any problems not covered in this document.
- The Neural Sleeve is only intended to be used on the leg of the user who has obtained a prescription for use and has received a properly fitting sleeve. It should never be worn by anyone else or used on any other part of the body.
- The Neural Sleeve should not be worn while driving, operating machinery or performing any activity in which involuntary muscle contractions could lead to injury.
- The Neural Sleeve should not be operated in the presence of liquids or flammable substances.

Adverse Reactions

Skin irritations and burns beneath the electrode pads can occur with the use of surface electrical stimulation devices. While it is normal to see reddened areas under the electrode pads, they should disappear within a few hours. NEVER continue stimulation over irritated skin or open wounds. If the conditions persist after you discontinue use of the Neural Sleeve, consult with an authorized CIONIC Mobility Specialist, or your physician or therapist.

In the unlikely event that any of the following occurs while using the Neural Sleeve, stop use immediately and consult with your physician or therapist;

- Feeling of stress to the heart or unusual shortness of breath
- Significant increase in muscle spasticity
- Sudden and noticeable swelling of the leg, knee, ankle or foot
- Any pain or other unanticipated and concerning reaction

Proper Use

Both the safety and efficacy of the Neural Sleeve depend on the proper use and handling of the system. Improper use of the device and its components can result in failure of the device or injury. Steps can be taken to ensure the Neural Sleeve is operating properly and safely, which include:

- Make sure the Control Unit is fully charged before initial use, before daily use, and after any extended storage. Charging instructions can be found in Chapter 8: Maintenance and Cleaning.
- Regularly check the Neural Sleeve and Control Unit for wear and tear.
- Be sure to firmly secure the electrode pads to the skin.
- Never use the Neural Sleeve if it appears in any way to be malfunctioning, or if you notice any change in its normal operation.
- The Neural Sleeve is only intended for use on the legs only. Do not apply the Neural Sleeve to any other part of the body.

- Using a wet washcloth, clean the area of the skin to be covered by the Neural Sleeve, removing any oils or lotions. Allow skin to dry before putting on the Neural Sleeve.
- Excessive hair on the legs can reduce sensor and electrode pad contact with the skin. If necessary, trim excessive hair. Don't shave immediately before use.
- Replace the electrode pads every two to four weeks, or sooner if the condition or effectiveness of the electrode pads has diminished.
- Always cover the electrode pads with the storage covers after each use.
- Effective current densities above 2 mA/cm2 require increased attentiveness of the user for all electrode surfaces.

CHAPTER 3 | Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information

The Neural Sleeve Control Unit communicates via radio communication and have been tested and found to comply with the limits for a Class B device, pursuant to Part 15 (RF Devices) of the Federal Communications Commission (FCC) Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

The antenna of the transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. Portable and mobile RF communications equipment may affect the Neural Sleeve NS-200.

Conformity Certification

This device may not cause harmful interference, and it will accept any interference received, including interference that may cause undesired operation. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

Travel and Airport Security

The Neural Sleeve charger is compatible with voltages 110/220 V

Turn off your Control Unit before going through airport security. It is advised to carry a copy of your Neural Sleeve prescription and a description of the product, which can be useful when passing through customs as well. To request a copy of your prescription or the product description, please email the Cionic Care team at support@CIONIC.com. Please use the subject heading, "Travel Request."

NOTE: The Neural Sleeve contains radio transmitters. The Federal Aviation Administration (FAA) rules require that all radio-transmitting devices be turned off during flight.

CIONIC Neural Sleeve

Control Unit

The Neural Sleeve Control Unit is the computer that interfaces with the CIONIC App via Bluetooth to control the Neural Sleeve. It is also used to turn the system on and off. The Control Unit is powered by a single rechargeable ion battery.

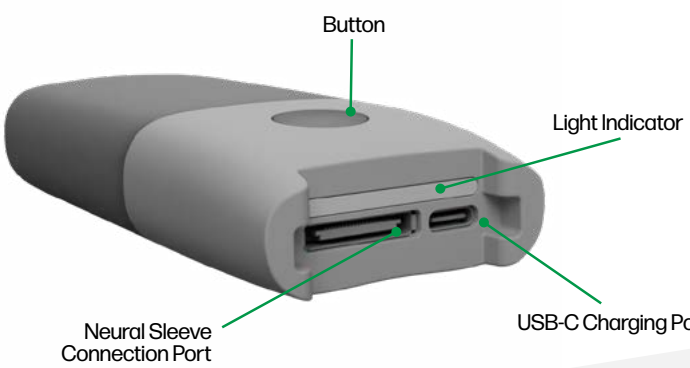
- To turn the Control Unit on, press the button once.
- To turn the Control Unit off, press and hold the button. The light indicator will turn orange and fade out.

CAUTION: Inspect the Control Unit for damage to the plastic enclosure prior to use. Contact CIONIC should you observe any damage.

Table 1 | Control Unit Visual Indicators

LIGHT DISPLAY	DISPLAY PATTERN	DESCRIPTION
	Solid white	Control Unit initializing after turning on or restarting
	Blinks green	Activity in progress
	Solid yellow	Stimulation active >10mA
	Pulses orange	Battery charging
	Solid green	Battery fully charged. Disconnect from charger
	Pulses green	Unit on
	Pulses red	Battery low <10%. Charge Control Unit
	Blinks red 2x	Battery low <5%. Stop use and charge Control Unit.
	Red to yellow 3x	Critical hardware error. Refer to Chapter 9 Troubleshooting
	Blinks green 3xs	Sleeve was plugged in
	Blinks blue	Bluetooth® pairing mode active
	Solid blue for 3 seconds	Bluetooth® pairing complete
	Blinks orange 3x	Bluetooth® pairing failed. Retry pairing
	Orange to fade out	Powering off
	Pulses purple	Button pressed and stimulation paused
	Blinks red	Factory reset mode active (see Chapter 9)
	Solid red	Factory reset complete

Figure 2 | Control Unit



Control Unit Button

The Control Unit contains a button used for multiple purposes.

Table 2 | Control Unit button operations

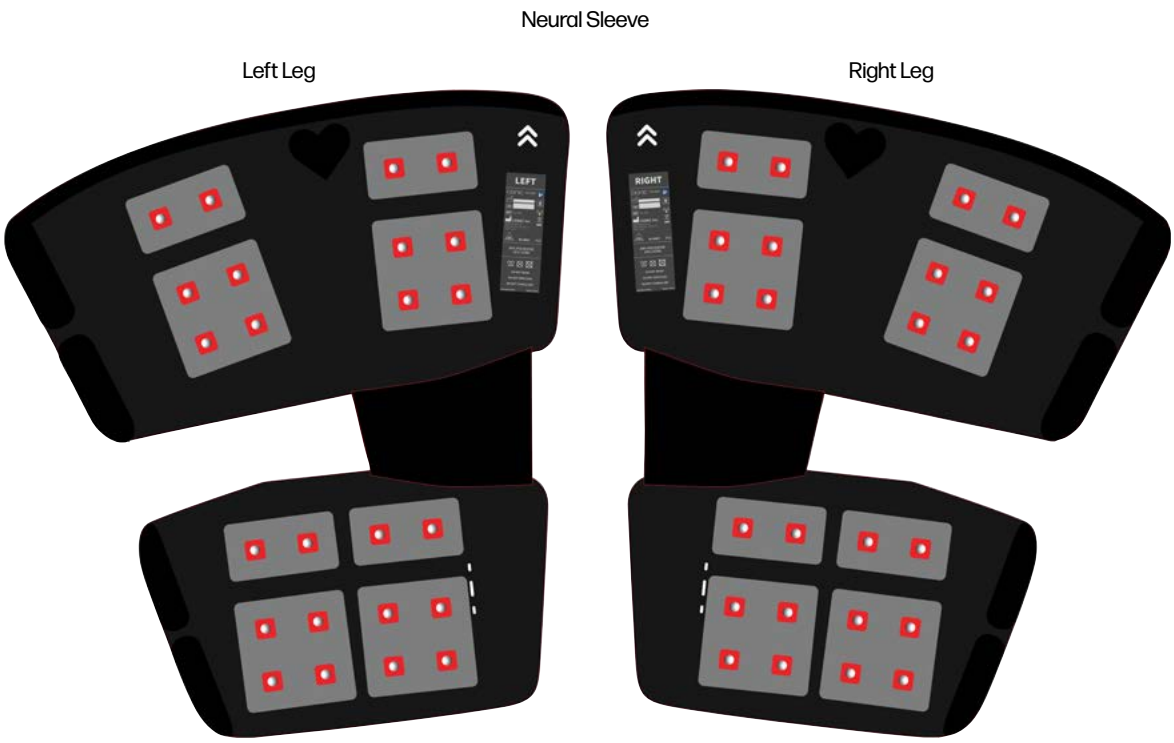
DESIRED ACTION	BUTTON OPERATION
Turn Control Unit On	Press the button
Turn Control Unit Off	Press and hold the button for 5 seconds
Pause and Resume Stimulation	Press button while stimulation is on
Factory Reset	Troubleshooting; See Chapter 9

Neural Sleeve

The Neural Sleeve is a wearable fabric sleeve that fits the leg. It is available in right or left leg configurations (Figure 3), offered in multiple sizes. The Neural Sleeve is designed to facilitate movement of the foot, lower leg, and upper leg, depending on the programming.

The Neural Sleeve has four Velcro® panels to hold the sleeve firmly in place. The pocket at the top of the Neural Sleeve holds the Control Unit.

Figure 3 | Cionic Neural Sleeve Left and Right



Neural Sleeve Electrodes & Electrode Pads

The Neural Sleeve contains up to 24 electrodes. Each metal disc requires an electrode pad containing a conductive film that provides current control. They are reusable (up to four weeks), self-adhering, and serve as an interface between the user's skin and the Neural Sleeve metal discs. (Figure 4)

Figure 4 | Applying Electrode Pads to Metal Discs

WARNING: Only the electrode pads provided by CIONIC should be used with the Neural Sleeve. To reorder electrode pads please visit CIONIC.com/support

WARNING: The electrode pads carry an expiration date which is printed on the packaging. Verify that the expiration date is at least two weeks in the future prior to use.

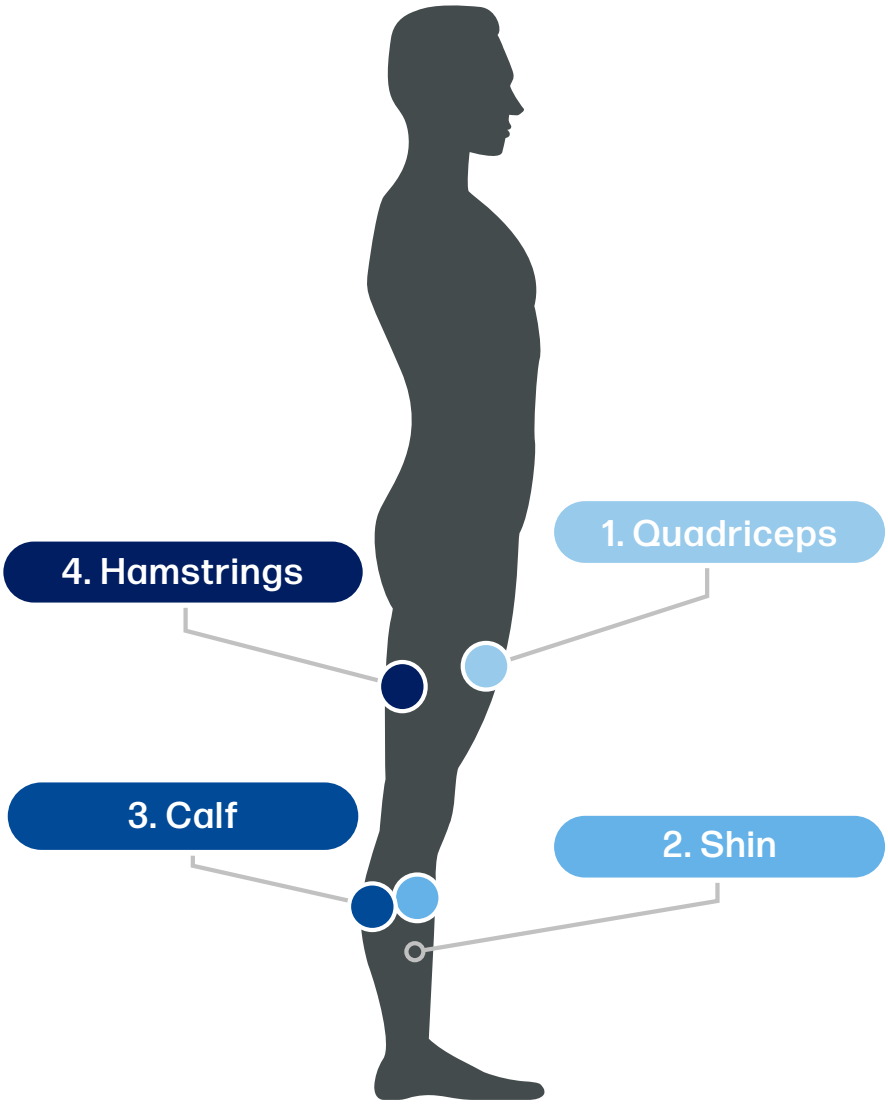
Control Unit Charger

The Control Unit includes a 3-foot long (1m) USB Type A to Type C charging cable, as well as a removable power adapter.

Figure 5 | Control Unit and Charger

WARNING: Only use the Control Unit charging cable and power adapter that was included with your Neural Sleeve. Using any other charger could cause damage to the unit.

Figure 6 | Major Leg Muscle Groups



Downloading the Mobile App

The CIONIC App is a required application that must be downloaded onto a mobile device (smartphone or tablet) in order to operate the Neural Sleeve. All the set-up instructions detailed in the following pages are available in a step-by-step process within the CIONIC App. It will also act as the only interface needed to operate the Neural Sleeve. Use your smartphone or tablet to visit cionic.com/app to access the app. The CIONIC App communicates with the Control Unit through Bluetooth® Low Energy.

Applying Electrode Pads to the Neural Sleeve

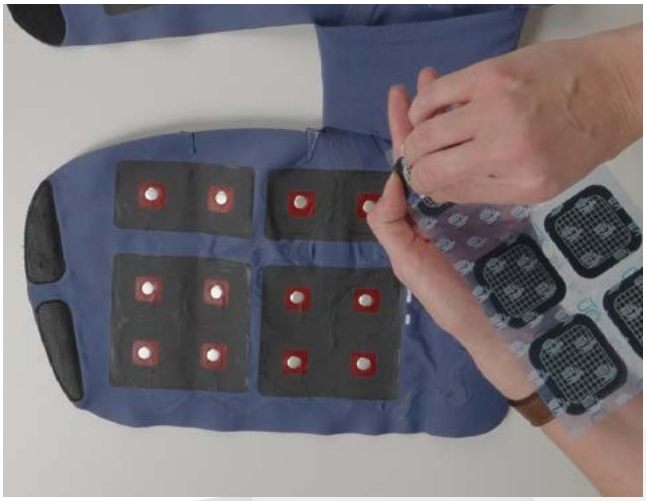
In order to use your Neural Sleeve, you must attach the sheets of electrode pads onto the metal discs on the inside of your Neural Sleeve (Figure 7). Open the sleeve and place it on a flat, solid surface. There are four groups of metal discs which correspond to muscles on your leg.

Figure 7 | Electrode Pad Application Stages

Sleeve Without Electrode Pads | Sleeve With Electrode Pads | Sleeve With Electrode Storage Covers

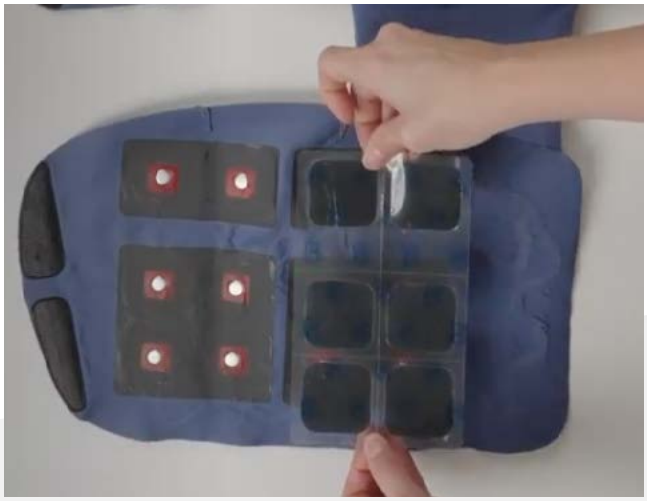
Step 1

Starting with one of the top panels of the Neural Sleeve, select one sheet of electrode pads. Carefully remove the clear protective film from the grid side of the electrode pads. Protective film can be discarded.



Step 2

Carefully place the sheet of electrode pads, grid side down, in accordance with the panel of metal discs. The electrode pads must be centered on the metal discs, so you should not see any of the red square.



Step 3

Firmly press each electrode pad onto the metal discs on the sleeve fabric. Leave the clear film on the pads.

Step 4

Repeat this process for each panel of electrode pads until all metal discs are covered.

Step 5

When complete, carefully remove the clear plastic film cover from the top of each panel of electrode pads. Discard the clear plastic film. Then cover each section with the corresponding storage cover. Note that the lower section of the Neural Sleeve uses the larger cover and the top two panels use the smaller storage covers. **The shiny side of the cover should be in contact with the electrode pads.**

CAUTION: Before each use, it's important to inspect the Neural Sleeve and Control Unit for obvious damage, including tears in the fabric, broken electrical connections or damage to the housing of the Control Unit. If damage is suspected, contact CIONIC technical support.

WARNING: Before applying the electrodes to your Neural Sleeve for the first time, make sure that you have verified that the sleeve fits properly by watching the instructions in the CIONIC App.

Depending on your Cionic Neural Sleeve model, the configuration of the metal disks might be different from what is shown in the pictures.

Lycra has a tendency to stretch over time, especially during the initial wear. This stretching is not a sign of wear and tear; rather, it is a result of the fabric's inherent elasticity. The fibers, when subjected to consistent use and movement, gradually loosen up, allowing the sleeve to expand and contract.

CIONIC
Neural Sleeve

Prior to using your Neural Sleeve for the first time, you will have a consultation with a CIONIC technician using the CIONIC App. This will provide an opportunity to review the Neural Sleeve System and CIONIC App prior to use. You can view tutorial videos by going to CIONIC.com/tutorials

Putting on the Neural Sleeve

- While seated, remove your shoe from the side on which you will be using the sleeve.
- Pick up the Neural Sleeve.
- Unfold the sleeve and place it over your leg so that the connector is facing up and the wings of the sleeves are facing outward (Image 1).
- Turn over the sleeve, ensure all the electrodes are covered, and observe the opening in which you will be sliding your foot through (Image 2).
- Turn the sleeve back over, and slide your foot through the opening (Image 3).
- Pull the sleeve up your leg until the middle of the sleeve is aligned with your knee cap (Image 4).

Apply Sleeve to the Quadriceps

- Pull the top of the sleeve down over your knee and rest it on the shin with the storage cover facing up (Images 5 & 6).

Image 1

Image 2

Image 3

Image 4

Image 5

Image 6

Image 7

Image 8

Image 9

Image 10

Image 11

Image 12

- Remove the storage cover exposing the six electrode pads, making sure that all electrode pads are still attached to the sleeve (Image 7). Set the storage cover to the side.
- If needed, adjust your clothing to ensure electrode pads will only come in contact with the skin of your quadriceps.
- Pull the section of the sleeve back up over your knee (Image 8), placing the electrode pads on the skin of your quadriceps.
- Press down firmly on the sleeve to ensure electrode pads adhere flat and securely to the skin (Image 9).

Apply Sleeve to the Hamstrings

- Adjust yourself toward the front of your chair.
- Reach behind the back of your upper leg and grab the top wing of the sleeve (Image 10). Guide the sleeve up and over, resting the sleeve on your quadriceps with the storage cover facing up (Image 11).
- Remove the storage cover exposing the six electrode pads, making sure that all electrode pads are still attached to the sleeve (Image 12).
- Set the storage cover to the side.

Apply Sleeve to the Hamstrings (cont.)

- If needed, adjust your clothing to ensure electrode pads only come in contact with the skin of your hamstrings
- Pull the exposed panel of the sleeve back under the hamstrings, pulling across tightly to secure the Velcro connection points while ensuring the electrode pads are in contact with the skin of your hamstrings (Images 13 & 14).
- Press down firmly on the sleeve to ensure electrode pads adhere flat and securely to your skin.

Image 13

Image 14

Apply Sleeve to the Shin

- Reach down and grip the bottom of the sleeve by the ankle (Image 15).
- Pull the sleeve up and over your knee and rest the sleeve on your quadriceps (Image 16).
- Carefully remove the storage cover exposing the 12 electrode pads of the lower sleeve, making sure that all pads are still attached to the sleeve (Image 17).
- Set the storage cover to the side.
- Pull the panel of the sleeve back down over the knee (Image 18).

Image 15

Image 16

Image 17

Image 18

Image 19

Image 20

- Use the markings on the interior of the sleeve to align to the shin bone, making sure to place the top, inside gel pad on the muscle just below and lateral to the knee with the two electrode pads below close to the shin bone, but not touching it (Images 19 & 20).
- Press down firmly on the sleeve to ensure electrode pads adhere flat and securely to your skin (Image 21).

Apply Sleeve to the Calf

Image 21

Image 22

- Reach behind the back of the lower leg and grab the bottom wing of the sleeve.
- Pull the exposed panel of the sleeve back under your calf, pulling across tightly to secure the Velcro connection points while ensuring the electrode pads are in contact with the skin of your calf (Image 22).
- Press down firmly on the sleeve to ensure electrode pads adhere flat and securely to your skin (Image 23).

Image 23

To remove the Neural Sleeve, simply follow these steps in reverse, starting by pulling down on the sleeve.

You can access tutorial videos on how to correctly put on, align, and take off the sleeve by visiting the app or by going to **cionic.com/tutorials**

Plugging the Neural Sleeve into the Control Unit

- Pick up the Control Unit.
- Press the button, and ensure you see a pulsing green light (Image 24).
- With the port connector facing up and the power button facing out, slide the Control Unit into the Neural Sleeve pocket (Image 25).
- Gently plug the Control Unit into the Neural Sleeve connector cable, and ensure it is secure (Image 26).
- You may now put your shoe back on, stand up, and adjust your clothing over the Neural Sleeve.

Image 24

Image 25

Image 26

CAUTION: if you have decreased mobility and dexterity in one or both hands, please place the Control Unit in the pocket of the sleeve and plug it in before putting the sleeve on your leg. This will help protect the cable that connects your device to the sleeve.

The CIONIC App allows you to control the Neural Sleeve. The CIONIC App communicates with the Control Unit over a Bluetooth® connection. The CIONIC App connects to the internet through either a wireless or cellular signal. This allows you to log into the app, upload data, and receive programs.

CIONIC App Settings

The CIONIC App resides on your smart device and requests permissions of functions commonly used by apps. Table 3 outlines the settings required for operation of the CIONIC App.

Table 3 | Settings For The CIONIC App

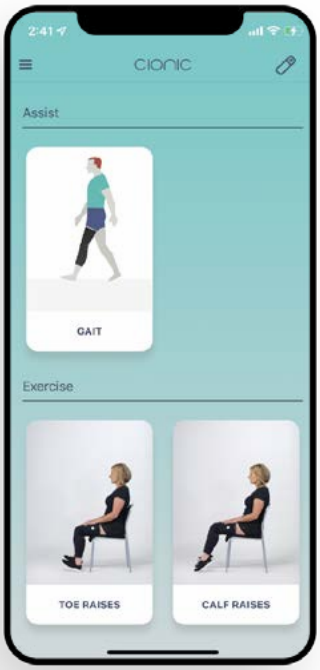
SETTING	REQUIRED	DESCRIPTION
Location	Yes	Required by the Operating System to communicate with CIONIC technical support
Bluetooth®	Yes	Required to communicate with the Control Unit
Local Network	No	Not applicable to CIONIC App
Microphone	Yes	Communicate with CIONIC technical support
Camera	Yes	Communicate with CIONIC technical support
Siri & Search	No	Not applicable to CIONIC App, only relevant for iOS
Notifications	Yes for Android devices Recommended for iOS devices	The CIONIC App will provide notifications while you are using your Neural Sleeve and in case there are updates available.
Cellular Data	Optional	Allows the CIONIC App to utilize your cellular network data to upload activity data. If this is not enabled, the app will hold your recordings until you are connected to WiFi

Video Onboarding to Set Up Your Neural Sleeve

Prior to using your Neural Sleeve you will have an onboarding session with a CIONIC Mobility Specialist using the CIONIC App. This video conference will provide an opportunity to review the Neural Sleeve System, customize your settings, and become familiar with the mobile app prior to use. Once you receive your Neural Sleeve, you will receive instructions for how to schedule your appointment via the CIONIC App. To reschedule at any time, contact support@cionic.com.

Complete these steps prior to your Video Onboarding:

- ☐ Install the CIONIC App onto your device
- ☐ Record and upload the walking video
- ☐ Try on your Neural Sleeve to verify it fits comfortably
- ☐ Apply electrode pads to your Neural Sleeve
- ☐ Charge your Control Unit
- ☐ Charge your mobile device
- ☐ Wear shorts or a skirt so your full leg is visible, with shoes and an assistive device (if needed) on hand
- ☐ Be seated in a comfortable chair near a space where you can walk back and forth safely
- ☐ Put on the Neural Sleeve



At the time of your appointment, open the CIONIC App. You will see an option to join the setup session from the home screen and confirm you are prepared with all devices. You will meet your CIONIC Mobility Specialist virtually and begin the setup process.

Table 4 | Remote Consultation Menu

CIONIC App Remote Consultation SYMBOLS	
	Your microphone is on. Press to mute yourself.
	Your microphone is off. Press to unmute yourself.
	Camera is on. Press to turn off.
	Camera is off. Press to turn on.
	Changes the camera view between the front-facing and rear-facing camera.
	Switch between your camera view and the technician camera view.
	Ends remote session.
	Toggles between video chat and app view.

Navigation

The CIONIC App includes four primary sections to navigate.

Home Screen

The app Home Screen (Figure 8) contains a list of programs available for use. The programs available to you may vary depending on your Mobility Specialist's instructions. These programs may change over time.

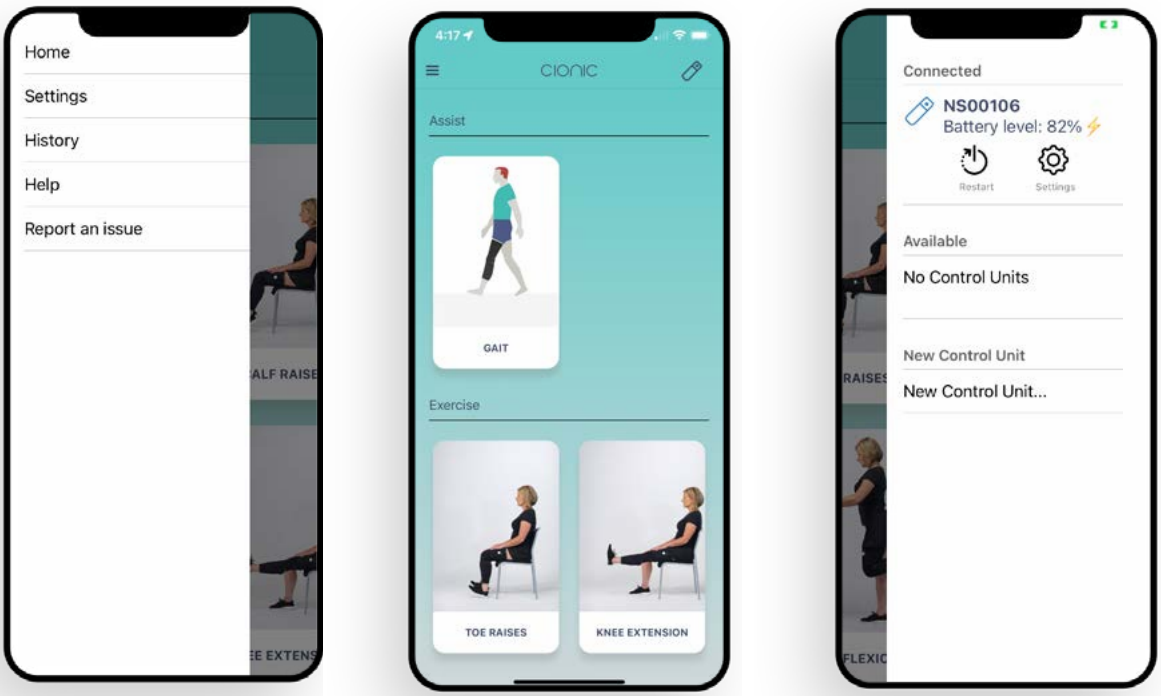
To view all programs, scroll down. To open a program or exercise, select the image for the desired item.

Figure 8 | CIONIC App Main Screen

Opens the Main Menu

Home Screen

Opens the Device Menu



Settings

The Settings screen contains options for the CIONIC App (Figure 9). Toggling the selector switch to the right enables the setting.

Create/upload recordings

The Control Unit receives data from the Neural Sleeve and uses it temporarily to operate your device. If this option is selected, data will be recorded in the Control Unit's memory and used to improve our algorithms.

Location tracking

If this is selected, your distance and elevation will be included with any recordings. Only relative location is tracked, and this data is only collected to improve our Algorithms. For Android devices, this option needs to be enabled in order to connect to technical support.

Allow cellular uploads

If data is recorded, recordings can be uploaded using the user's cellular data plan. Disable this if you only want recordings uploaded when you are connected to Wi-Fi.

Advanced FES Settings

If this is selected, you may access additional stimulation parameters, including frequency and pulse width when configuring FES.

Metric

Toggling the selector will switch between imperial (feet and inches) and metric (meters and millimeters) measurements.

Reset

- Reset help/tutorials - some instructional videos are only shown one time. This selection will restore the ability to watch the videos.
- Clear FES settings - this will remove all saved settings.

Sign out

Will immediately sign you out of the CIONIC App. You will not need to sign out of the app unless instructed by CIONIC.

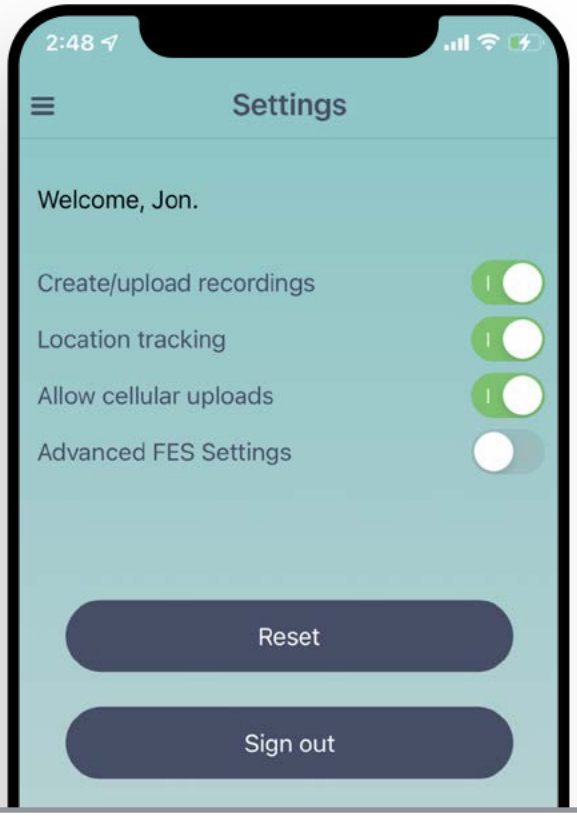


Figure 9 | Settings Menu

History Screen

The History screen lists all trends and activities (Figure 10).

The summary at the top shows how your main metrics (Daily Activity Time; Gait Speed; Stride Length) are trending during the last 7 days or the last 30 days.

The summary at the top shows how your main metrics (Daily Activity Time; Gait Speed; Stride Length) are trending during the 7 days or the last 30 days. Below the summary you can find a list of all the activities. Each entry lists the program that was executed, the number of steps/repetitions done, and the duration.

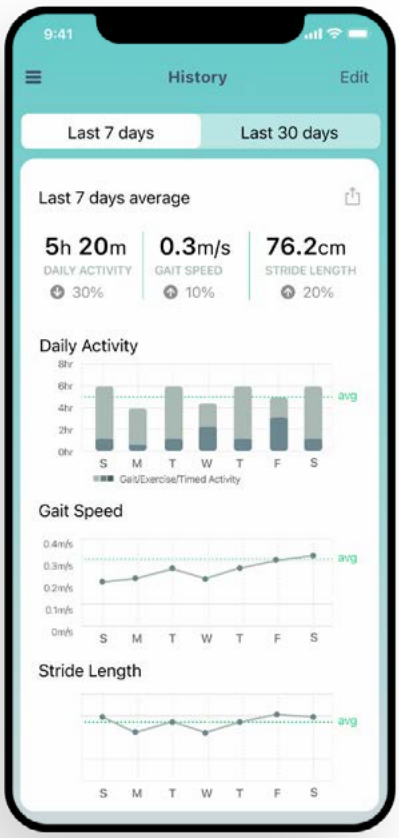


Figure 10 | History Screen

Help Screen

The Help screen allows you to perform multiple actions like reorder electrodes, account and billing changes and gives you access to support content, user manual and a library of instructional videos that you can reference at any time. Select the image to play a video. Videos include audio narration. Increase speaker volume as needed.

Report An Issue Screen

The "Report an Issue" screen on your device provides a straightforward method to notify our support team about any problems you encounter while using the device. This feature allows you to submit detailed information, including descriptions, screenshots, and logs, which helps our engineers diagnose and resolve issues more effectively. When reporting an issue please make sure that the Control unit is on and it is connected to the phone in order to retrieve the device logs.

Connecting the CIONIC App to the Control Unit for the first time

Communication between the CIONIC App and the Control Unit is managed under the Device Menu. The app and Control Unit communicate using Bluetooth® communications. Your Control Unit must be charged and within 5 feet of your mobile device. The device should be ON, as indicated by a slowly pulsing green indicator. If the device is not on, press the button once.

- With the Control Unit on, press the button.
- Observe the indicator blinking blue.
- Open the Device Menu.
- Select "New Control Unit".
- Follow the on-screen instructions to complete the connection process.

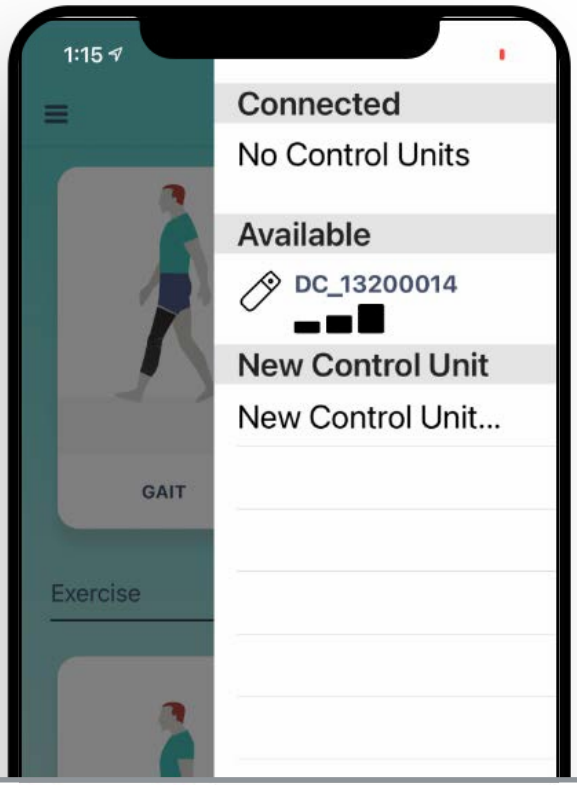


Figure 11 | Control Unit Connection Screen

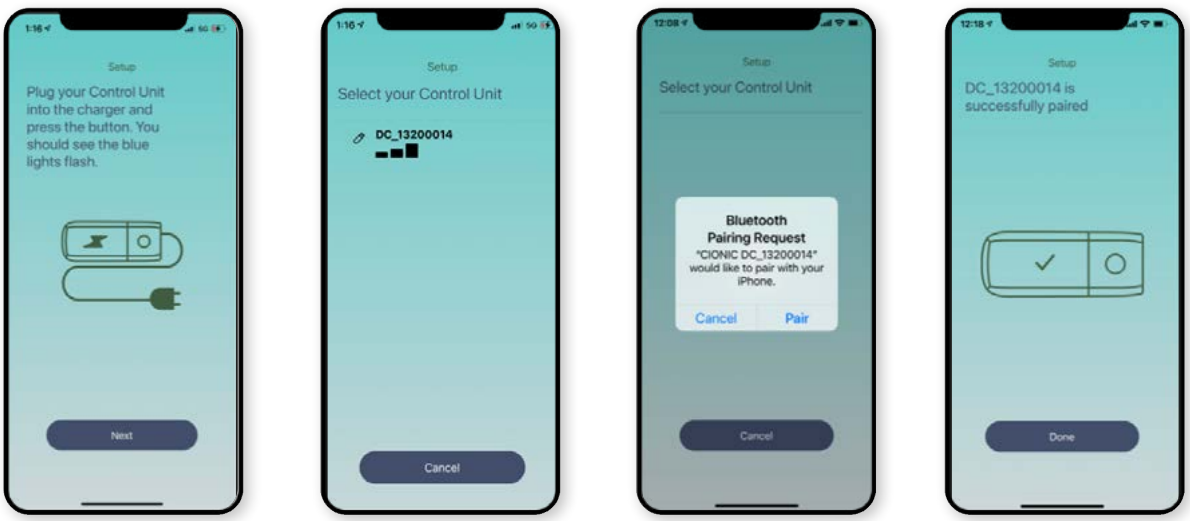
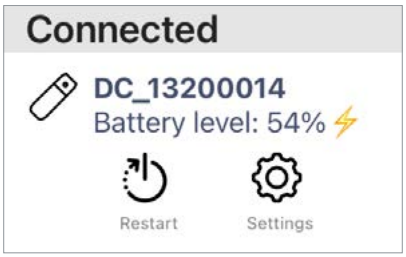


Figure 12 | Pairing The Control Unit

Once your device is connected, the following symbols apply:



SYMBOLS	
	Control Unit charging
	Control Unit connected
	Control Unit connected but running low on battery
	Control Unit detected
	Control Unit cannot be connected. See Chapter 9 Troubleshooting
	Control Unit is acceptably close to your mobile device
	Control Unit is acceptably close to your mobile device
	Control Unit is detected but out of reliable connection range
	Restart Control Unit
	Control Unit settings **Change Control Unit Name** To customize the name of your device **Unpair Control Unit** To end Bluetooth® pairing from your mobile device. This would be done only if you wish to pair your Control Unit to a different mobile device. **Start Firmware Upgrade...** You will receive a notification when updated firmware for your Control Unit is available. Select this option to initiate the upgrade. **Get FIrmware Info** Learn more about the current version of firmware running on the Control Unit. **Disconnect from Control Unit** To disconnect the Control Unit from the phone (use this option only if instructed by CIONIC)

CAUTION:
If you have multiple Control Units, be sure to select the proper one or your system will not work properly.

The Cionic Neural Sleeve is intended to help improve your mobility through a combination of exercise and functional assistance.

Exercise programs are intended to help you strengthen specific muscle groups that contribute to walking. Exercises can be performed with or without muscle stimulation. Exercises are intended to be performed sitting or standing while holding onto a secure surface when applicable.

Assist Programs are functional augmentation programs designed to assist and support your movements by providing stimulation. Assist programs are intended to be used while walking or performing other movements such as stationary exercise cycling.

Calibration

Sensors in the Neural Sleeve measure leg muscle activity and leg movement, as well as verify the electrode pads are working and are in contact with the skin. These sensors must be calibrated specifically to your body at least once every time you wear your Neural Sleeve. Follow the on-screen instructions to complete the calibration process (Figure 8). If calibration has been completed previously you may press the Skip button to proceed to FES configuration.

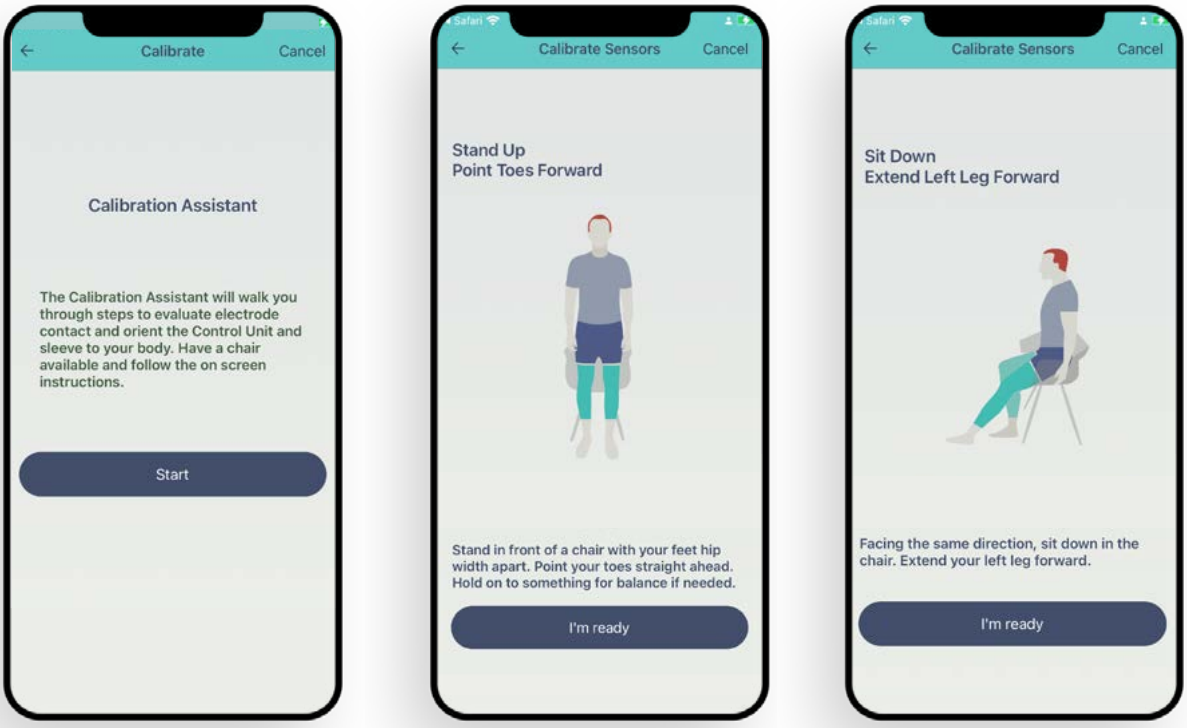


Figure 13 | Neural Sleeve Calibration Process

Operating Modes

Assist Modes

Multiple programs may exist under the Assist section of the Home Screen. These programs will vary depending on your mobility needs and goals. Use of the Gait Assist Programs are described in the following pages.

Exercise Modes

Multiple programs may exist under the Exercise section of the Home Screen. These programs will vary depending on your mobility needs and goals. Programs can be added and removed throughout your use of the Neural Sleeve System. Exercises are designed to help you strengthen your muscles and increase your tolerance of electrical stimulation.

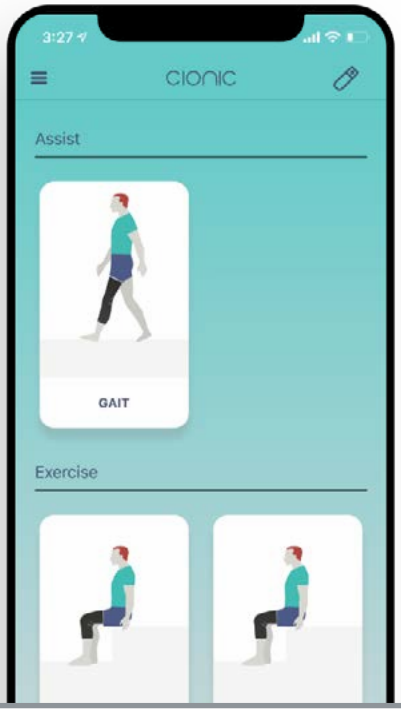


Figure 14 | Assist and Exercise Mode Screen

Configuring Stimulation

The procedure for programming stimulation is identical for all Assist and Exercise programs. Stimulation is customized for the muscle(s) involved in the program.

Stimulation Parameters

The Neural Sleeve delivers small pulses of electrical energy from the electrode pads. Three parameters are controlled to optimize the stimulation delivered to your body.

Frequency
Stimulation is delivered in pulses that are measured in Hertz (Hz), or number of pulses per second.

Pulse Width
Each individual stimulation pulse turns on and off within a very short time and is measured in microseconds.

Intensity
Each individual stimulation pulse has a magnitude or strength, measured in milliamps (mA).

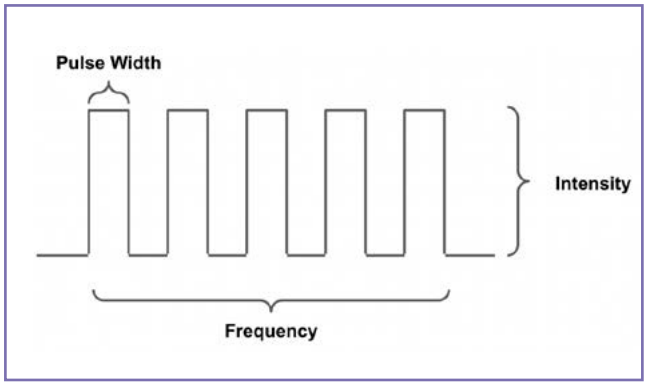


Figure 15 | Graphical Illustration of Stimulation Waveforms

PARAMETER	RANGE	INCREMENTS	IMPACT
Frequency	5 - 100 Hz	5 Hz	Comfort and effectiveness
Pulse Width	100 - 400 microseconds	100 microseconds	Strength of muscle contraction
Intensity	0 - 100 mA	5 mA	Strength of muscle contraction

Stimulation is fully customizable for your comfort and to produce the desired muscle reaction. There are two levels of programming: Basic and Advanced. Advanced Mode is available only when enabling Advanced FES Settings (see Chapter 6).

Basic FES Configuration Mode

In Basic Mode, the programming screen includes:

- An illustration of a leg showing orange and blue squares that represent the electrode pads within the Neural Sleeve
- An enlarged view of the electrode pads that can be adjusted
- Slider control for the level of current (mA) delivered
- Option to adjust electrode percentage (press and hold on an electrode)
- Option to enter Advanced Mode (if setting enabled)
- Adjust intensity by pressing and holding the slider control and moving your finger left and right. You may also tap the left or right of the circle to increase or decrease

Press the lightning bolt to deliver a short burst of stimulation. This is used to evaluate your comfort with the stimulation as well as the strength of the muscle contraction produced. Press the "Next" button to advance through the individual muscles if more than one muscle is enabled and the "Done" button when you have finalized your stimulation parameters.

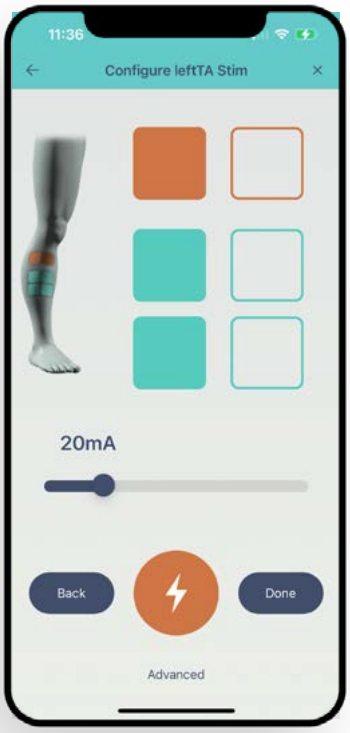


Figure 16 | Basic Mode FES Configuration

Advanced FES Configuration Mode

In Advanced Mode, the programming screen includes:

- An illustration of a leg showing orange and blue squares that represent the electrode pads within the Neural Sleeve.
- An enlarged view of the electrode pads that can be adjusted
- Control for Frequency
- Control for Pulse Width
- Control for Intensity
- Option to enter Basic Mode
- Option to adjust electrode percentage (press and hold on an electrode)

To adjust any parameter, press and hold the number wheel below the desired parameter and slide your finger up to increase or down to decrease. You may also tap above or below the number to increase or decrease. Each parameter is adjusted separately.

Press the lightning bolt to deliver a short burst of stimulation. This is used to evaluate your comfort with the stimulation as well as the strength of the muscle contraction produced. Press the "Done" button when you have finalized your stimulation parameters.

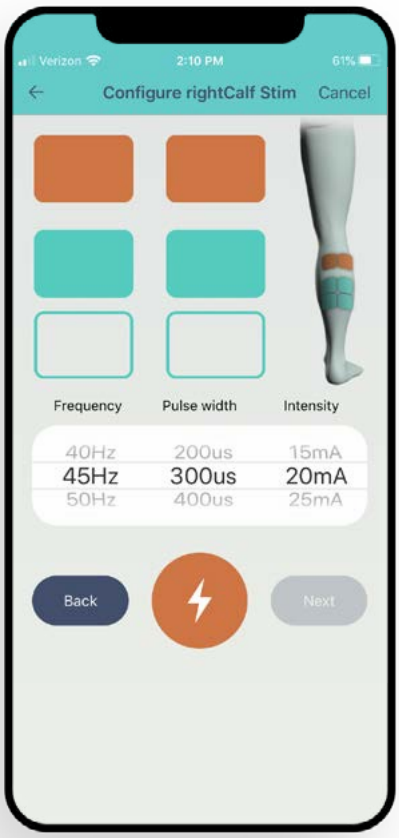


Figure 17 | Advanced Mode FES Configuration

WARNING: for safety reasons, you will have to press the "test" button after each 10mA increase in order to continue increasing intensity

Adjusting Stimulation

You will be able to program stimulation for up to four muscle groups. Available muscles may be added or removed during the course of your use of the Neural Sleeve. Follow the FES programming instructions to determine the strength and direction of each muscle movement.

- Shin - lifts your foot up, pulling your toes away from the ground
- Calf - presses your foot down, pointing your toes towards the ground
- Quadriceps - straightens your lower leg at the knee
- Hamstrings - flexes your lower leg at the knee

Using Gait Assist for Mobility

When you have programmed each available muscle to your satisfaction, initiate walking. The animation will reflect the movement of your leg and symbols next to the animation will turn on and off at the same time that stimulation is delivered to each muscle group.

- To activate stimulation, start walking.
- To stop stimulation, press the Pause button.
- To exit Gait Assist, press the Stop button after pausing.
- To adjust the intensity of all muscles at the same time, press and hold the horizontal slider and move it left (lower) and right (higher).
- To change the parameters of a specific muscle group after stimulation has been activated, select the muscle at the bottom of the screen and adjust accordingly.

Figure 18 | Gait Assist Mode

WARNING: during the calibration and setup process, the slider intensity is always set at 100%

Using Exercise Programs

Exercise programs are designed to help improve your walking by conditioning one or more muscles in your leg. The Neural Sleeve delivers electrical stimulation in a coordinated pattern using parameters you have defined. To start, select one of the programs to exercise.

Follow the instructions in the app to program the strength of stimulation.
Finally, choose the example to perform and follow the on-screen instructions. Observe that the number under the right arrow button counts down from 3 during the movement and relax phases.

If you leave the CIONIC App during a program, stimulation will continue. When returning to the CIONIC App, the on-screen instructions will refresh when you proceed to the next repetition.

EXERCISE MODE	STIMULATION USED?	DESCRIPTION
Muscle Activated Stimulation	Yes	This exercise uses stimulation to reinforce muscle activity.
Timer Activated Stimulation	Yes	This exercise provides timed stimulation to increase strength.
Biofeedback	No	This exercise measures muscle activity without stimulation. An activity meter displays the strength of each contraction.

Figure 19 | Toe Raise Exercise Example

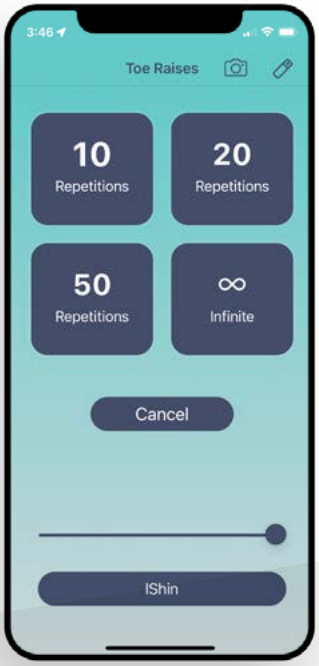


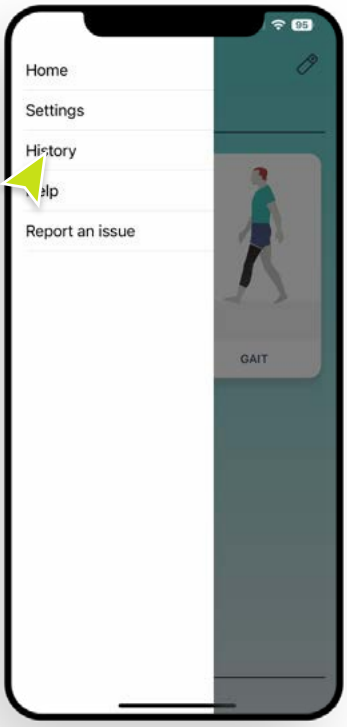
Figure 20 | Change Exercise Repetitions

Restore FES Settings from a Past Activity

The CIONIC App allows you to restore Functional Electrical Stimulation (FES) settings for activities you have performed, in the past 30 days, both for Assist or Exercise programs. This feature lets you replicate optimal settings for specific activities based on your past experiences. Follow the steps below to restore FES settings for a desired activity:

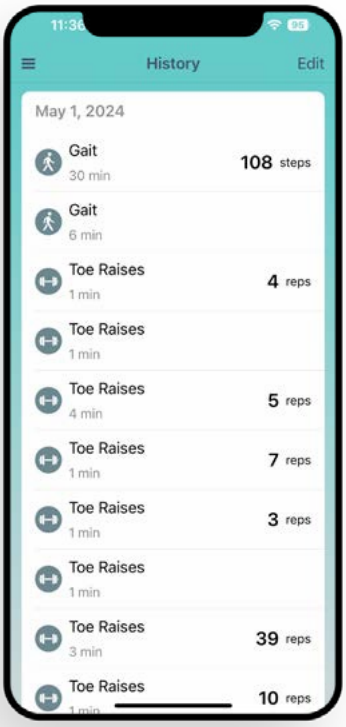
Step 1

Navigate to the History Screen: Begin by accessing the History screen in the app by tapping on the History item from the main menu.



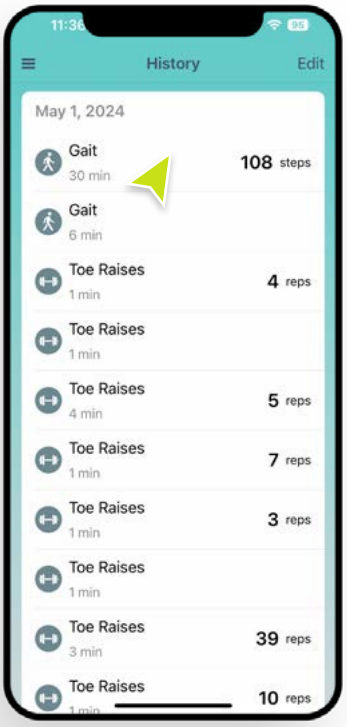
Step 2

Scroll to Activity Details: In the History screen, scroll through the list of recorded activities under the graphs.



Step 3

Scroll to the Desired Activity: Identify the activity from which you wish to restore FES settings. Tap on this activity to open its detailed view.



Step 4

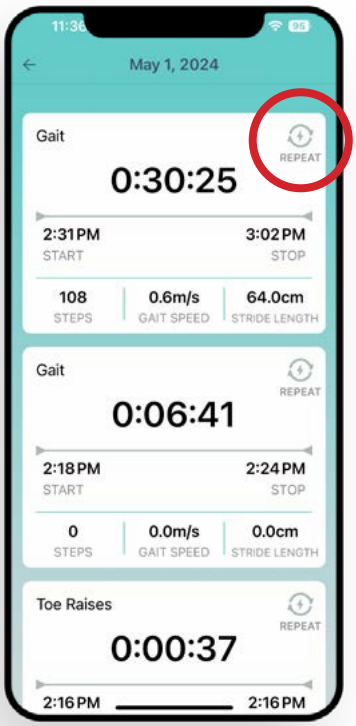
Restore Specific Settings:
To restore the FES settings for this activity, locate the "Repeat" button in the top right corner of the Activity Details screen.

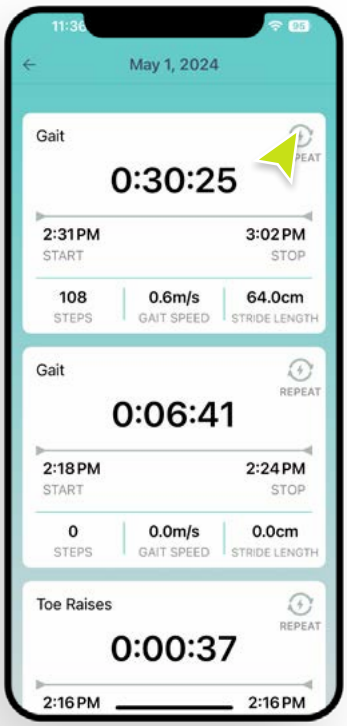
Step 5

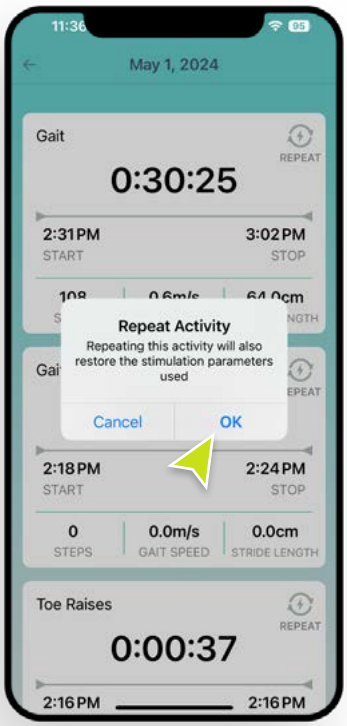
Tap the "Repeat" Button:
Tap on the "Repeat" button. This action prompts a dialog box to appear, confirming your intention to restore the settings.

Step 6

Confirm Restoration:
In the dialog box that appears, confirm that you wish to restore the FES settings by tapping the appropriate confirmation button.







After confirming, the Cionic Neural Sleeve will apply the saved FES parameters from the selected activity to your next session.

By following these steps, you can easily restore FES settings from past activities to optimize your experience with the Cionic Neural Sleeve for various assist programs and exercises. This feature ensures consistent and tailored stimulation based on your preferred parameters.

Daily Maintenance and Storage

- Carefully examine each electrode pad and each additional component for wear or damage.
- Always replace any electrode pad that appears to be old, worn, lacking adequate adhesive or damaged.
- Be sure that the storage covers are fully covering all electrode pads on all the corresponding sections of the Neural Sleeve.
- Make sure the Control Unit is detached when the Neural Sleeve is not in use.
- When not in use, store the Neural Sleeve in the plastic bag provided.
- After each use, be sure the Neural Sleeve Control Unit is not plugged in to the sleeve.
- Fully charge the Control Unit between each use.
- In case you don't have the plastic bag provided with the sleeve, you can store the sleeve, when not in use, in a regular ziploc bag. This will prevent the electrode pads from drying out prematurely.

Charging

In order to work properly, it is important to ensure the Neural Sleeve is fully charged before each use.

- Connect the charging cord (provided) to the small plug at the end of the Control Unit.
- Confirm the light is pulsing orange to confirm it is charging. The Neural Sleeve is fully charged when the indicator light has a solid green display and/or the CIONIC App's Device Menu shows a battery level of 100% when connected to the Control Unit.

Replacing the Neural Sleeve Electrode Pads

For regular daily Neural Sleeve at-home users, the electrode pads should be replaced at least every four weeks.

The electrode pads need to be removed to clean the Neural Sleeve. It is recommended that you clean your Neural Sleeve whenever you change electrode pads.

To reorder electrode pads please visit the Help section in the CIONIC App.

CAUTION: Use only the Neural Sleeve electrode pads supplied by CIONIC.

The Control Unit should be unplugged from the Neural Sleeve before putting on or removing the sleeve and before removing or replacing any electrode pads.

Never use Neural Sleeve without electrode pads.

Verify electrode pads are not expired prior to use.

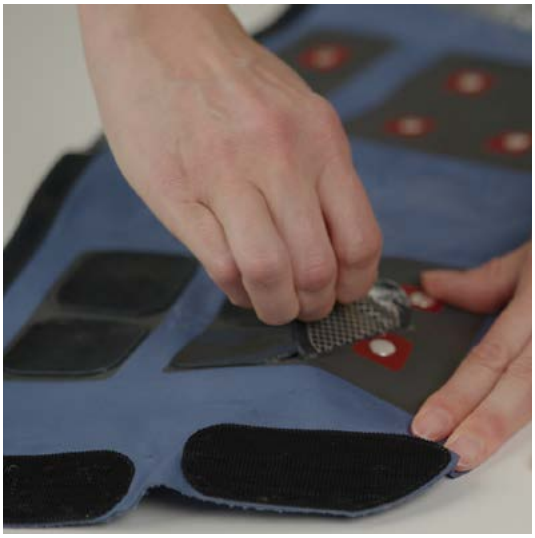
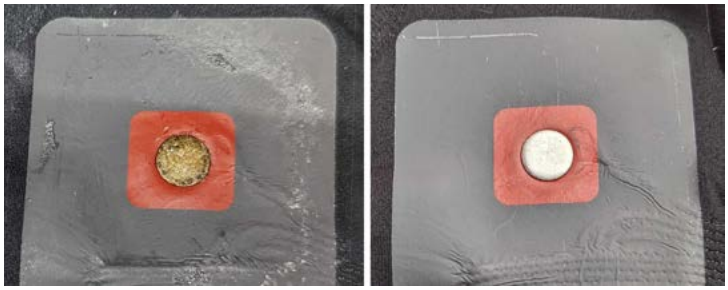


Figure 21 | Change Electrode Pads

- Control Unit should be unplugged from the Neural Sleeve.
- Gently pull off and discard all 24 electrode pads, or only those that have been identified as worn or damaged. Ensure the electrode metal discs are not removed and fabric is not torn (Figure 21).
- If cleaning is necessary, refer to cleaning instructions below.
- Refer to the section, "Apply Electrode Pads to the Neural Sleeve" for instructions on how to replace electrode pads.



Gel Buildup

CAUTION: you may notice a dark orange buildup on the buttons. This is caused by the gel that sticks on the button and might reduce effectiveness. In order to remove the buildup, you can wipe the buttons with cleaning disinfecting wipes. If you experience difficulties trying to remove the gel buildup from the button, try to dampen the button and leave it for a few minutes before trying to wipe it again.

This operation can be done even without replacing the electrode pad by just carefully removing the pad and reapplying it after cleaning the buildup.

WARNING: never use abrasive tools or chemicals to clean the buttons as they might remove the metal protective coating and cause the button to rust.

Cleaning the Neural Sleeve

It is recommended you clean your Neural Sleeve every time the electrode pads are replaced.

- Make sure to remove all electrode pads from the Neural Sleeve.
- Verify that the Control Unit is unplugged and removed from the pocket of the Neural Sleeve.
- Place the Neural Sleeve on a table with the flaps open so that the metal discs are visible.
- If there is any gel residue, try to remove it by carefully dabbing the surface with a clean, damp cloth.
- Spray the Neural Sleeve surface with an antibacterial fabric spray, making sure to cover the whole surface of the sleeve. Let stand for 5 minutes. Allow to air dry.
- Turn the Neural Sleeve on the opposite side and repeat the spraying process. Let stand for 5 minutes. Allow to air dry.

CAUTION: Avoid spraying the cable connector. If the connector gets wet, use a clean, dry cloth to wipe the moisture off until fully dried.

CAUTION: Do not use flammable liquids or solvents to clean the Neural Sleeve or Control Unit.

Taking Care of Your Skin

Taking care of your skin is key to preventing skin irritation and breakdown as well as extending the life of your hydrogel electrode pads. In the evening, once you have finished using your sleeve for the day, please cleanse your skin with a gentle cleanser and pat dry. Immediately following, moisturize your skin with lotion and leave the lotion to absorb into your skin overnight. There is no need to cleanse your skin of the lotion in the morning unless there is excess on the surface of your skin. In addition to this daily routine, please gently exfoliate your skin 2–3 times a week, also removing any excess hair. Please do not exfoliate or shave immediately before using the sleeve—these steps are best completed during the cleansing process and before applying lotion to your skin.

If you notice any skin irritation, please discontinue use of the sleeve until your skin has healed. You may need to decrease overall wear time to prevent further skin irritation. If you continue to have skin breakdown or a rash with use of the sleeve, please consult your Physician for possible treatment options.

Upgrade Your Neural Sleeve Firmware

Before you start:
Make sure the latest version of the CIONIC App is installed on your phone. If you are not sure, you can open the App Store app on your phone and search for "CIONIC". Once you are on the CIONIC App page, the button next to the icon should say "OPEN". If the button instead reads "UPDATE" tap on the button to update to the latest version.

CAUTION: In order to proceed with the upgrade, your Control Unit needs to be plugged in to your Neural Sleeve. ⚠

CAUTION: Make sure your Control Unit has at least 30% battery before starting the upgrade process. ⚠

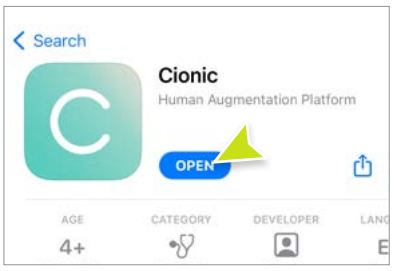


Figure 22 | iOS App Store

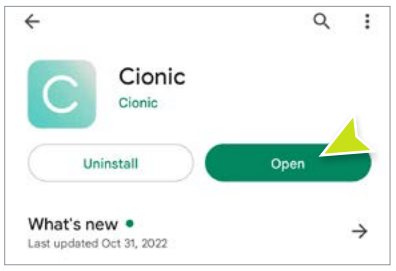
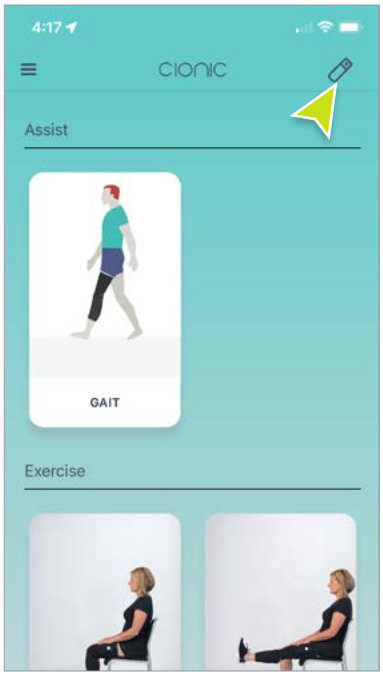


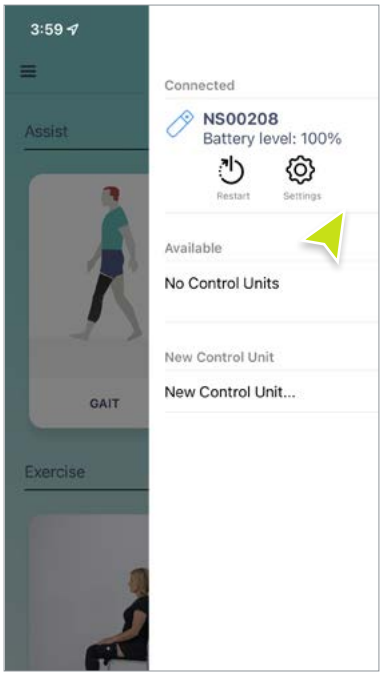
Figure 23 | Google Play Store

In order to upgrade your Neural Sleeve with the latest firmware available follow the instructions below:

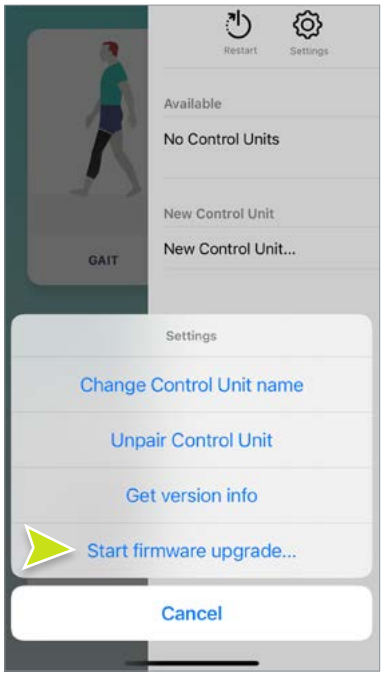
Step 1
From the Home screen in the CIONIC App, tap the Control Unit icon at the top right.



Step 2
Tap on the "Settings" icon of your Control Unit.



Step 3
Tap on "Start Firmware Upgrade" from the menu at the bottom of the screen.



Step 4

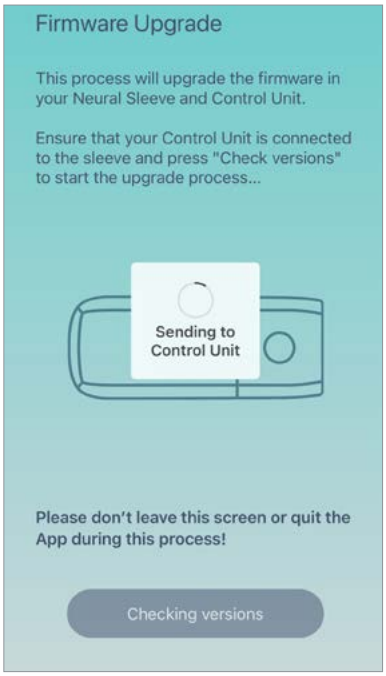
Tap on the “Check versions” button to verify if a firmware upgrade is needed.

Step 5

If new firmware is available, the app will download it to your phone...

Step 6

...and then transfer the firmware from the phone to the Control Unit.

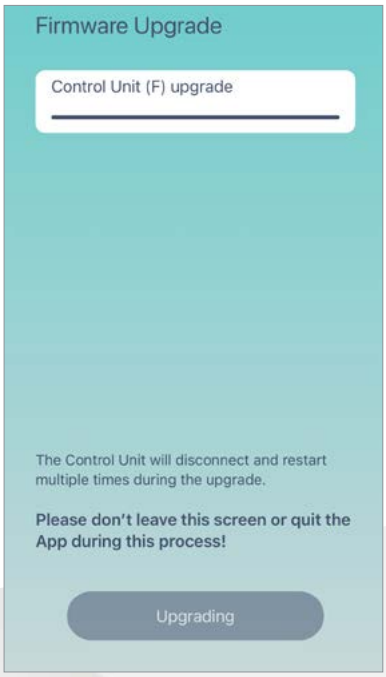


Step 7

You are now ready to start by tapping on the “Start Upgrade” button.

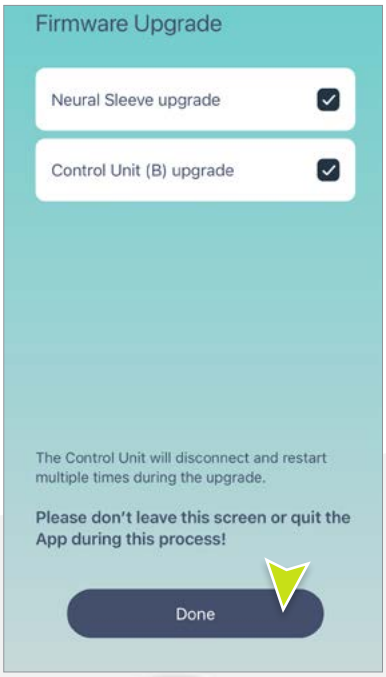
Step 8

Wait for the app to upgrade all the components of the Neural Sleeve...



Step 9

...until you see the “Done” button at the bottom of the screen. Tap on “Done” to exit.



If Your Neural Sleeve Doesn't Need to be Upgraded

If your Neural Sleeve firmware is already up to date, you will be notified with a dialog box after step 4 of the upgrade process. In that case just tap on the "OK" button and then on the "Done" button at the bottom of the screen to exit the process.

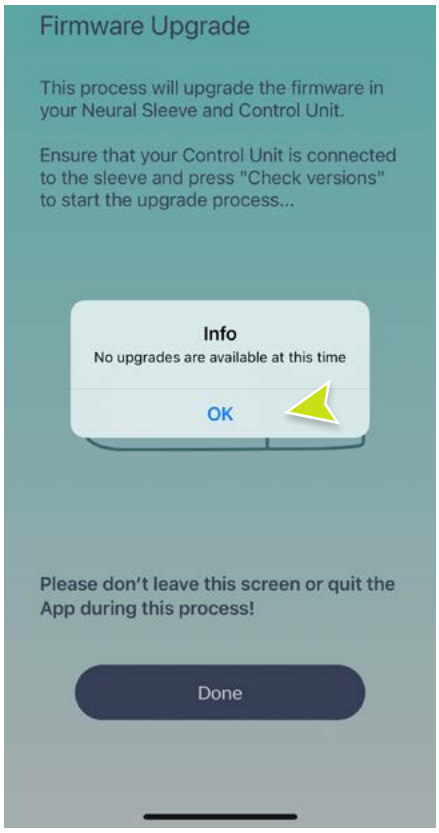


Figure 24 | No Upgrade Needed

Errors While Upgrading

During the firmware upgrade process you might encounter some errors, in that case please be sure to do the following:

- Make sure your Control Unit is plugged in to the Neural Sleeve.
- Make sure your Control Unit has at least 30% battery.
- Restart the upgrade process by following the instructions in the "Upgrade Your Neural Sleeve Firmware" section above.
- If the error persists, take note of the error message and use the contact button in the Help screen to notify CIONIC.

Verify Your Firmware Version

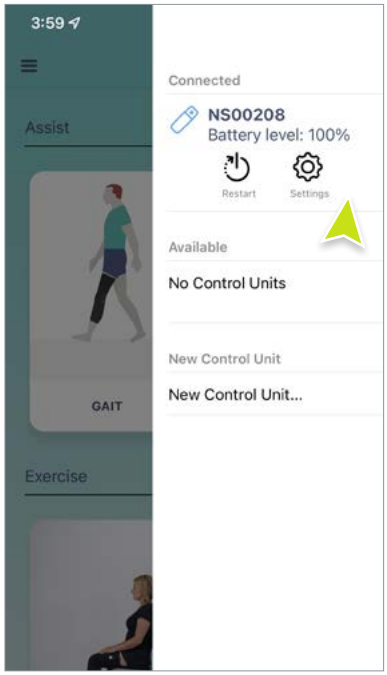
In order to verify the firmware version installed on your Neural Sleeve, follow the instructions below:

Step 1

From the Home screen in the CIONIC App, tap the Control Unit icon at the top right.

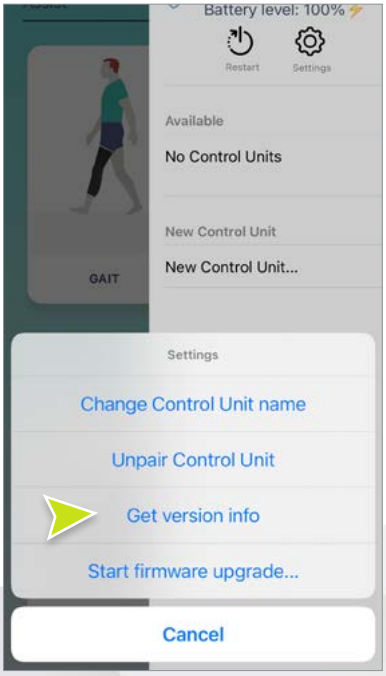
Step 2

Tap on the "Settings" icon of your Control Unit.



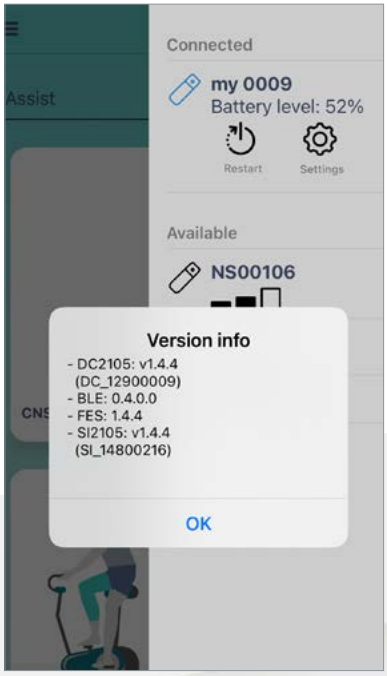
Step 3

Tap on "Get version info" from the menu at the bottom of the screen.



Step 4

The Firmware version installed will be visualized in a dialog box. Press OK to dismiss.



If you have any questions or concerns about your Neural Sleeve System, contact CIONIC at support@cionic.com

Control Unit fails Adherence Check

Check and make sure all electrodes are applied correctly to your sleeve. Check and make sure that all electrode pads are fully adhered to your skin.

Control Unit is Not Visible in Your CIONIC App

Make sure the device is charged and turned on. Make sure your Control Unit is within range of your mobile device. If you were instructed to operate a factory reset, make sure to press the button on the Control Unit to start pairing mode. See Connecting the CIONIC App to the Control Unit for the first time.

Control Unit is Unable to Pair with Your CIONIC App

Go into settings under Bluetooth®, identify your Control Unit serial number and "forget" the device. Reattempt pairing process in the CIONIC App. See Factory Reset.

If You Feel a Sharp, Uncomfortable Pain

Check to see that each electrode is fully flat so that the entire surface is on your skin. Verify that the skin under the electrodes is not irritated or has open wounds

Stimulation Feels Uncomfortable

Enter FES settings in the Exercise or Assist mode and adjust stimulation parameters.

Factory Reset

In rare cases, and only when instructed by a CIONIC technician, it may be necessary to reset your Control Unit to the original factory settings. To perform a factory reset, plug your Control Unit to the charger and wait for the LED indicator to start blinking.

With the Control Unit on, press and hold the button for 10 seconds. When the LED indicator starts flashing red, press the button again to start the factory reset process.

After performing a factory reset on your device, you will need to pair the control unit with your phone again to ensure proper functionality. Refer to the section "Connecting the CIONIC App to the Control Unit for the first time" in CHAPTER 6 of this manual to know how.

Control Unit Battery Maintenance Disposal

The Control Unit has a rechargeable battery that is not removable. Do not attempt to replace the battery. Maintain a routine of daily charging if using the system regularly, and at minimum, once monthly if your system is in storage. Avoid leaving your Control Unit uncharged indefinitely to minimize the risk of decreased battery longevity. Refer to the technical specifications section in this document for appropriate operating and storage conditions. The Control Unit battery can be expected to last several years when maintained accordingly. For support with your device contact support@cionic.com or under "report an issue" in the CIONIC App.

Disposal

Disposal of the Control Unit, which contains a Lithium Polymer battery, must be performed in accordance with local regulations. Improper disposal presents a hazard to the environment.

Classification	Internally powered, continuous operation with Type BF applied parts
Power Source(s)	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh
Controls	Single button
Indicators	Single LED indicator
Operating Modes	Exercise & Assist
Number of Output Channels	1 stimulator channel with 8 virtual Positive output channels and 15 virtual Negative output channels
Number of EMG (input) Channels	8
EMG Sampling Rate	2kHz
EMG detection (Bipolar/Monopolar)	Bipolar
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed Monophasic with hybrid stimulation
Regulated Current or Regulated Voltage	Regulated Current
Charging System	Medical Class II Power Adapter Input: 100-240V ~ 50/60Hz Output: 5V 2A using USB-C cable
Weight	Control Unit (DC-200): 145 g Sleeve (SL-200): S2 230 g, S4 240 g, S6 250g
Dimensions [W x H]	Control Unit (DC-200) 137 x 53 x 24 mm Sleeve (SL-200) S2 52x61cm, S4 58x63cm, S6 69x68cm
Waveform	Pulsed Monophasic with hybrid stimulation
Shape	Rectangular
Maximum Output Voltage	135 V
Maximum Output Current	100 mA @ 500 Ω , 65 mA @ 2 kΩ , 13 mA @ 10 kΩ
Current	0 to 100 mA at 5 mA increments
Pulse Width	100 to 400 μs at 100 μs increments
Frequency	5 – 100 Hz at 5 Hz increments
Maximum Intensity	24.6 mA (rms)
Maximum Load	Maximum load: 300 Ω
Minimum Load	Minimum load: 22 kΩ
Sizes	S2, S4, S6
Materials	Control Unit (DC-200): Injection Molded Plastic (medical grade polycarbonate (Makrolon)) with encased electrical components Sleeve (SL-200) : 84% Polyester 16% Lycra® Sleeve (SL-200) Sensors: Injection Molded Plastic (medical grade polycarbonate (Makrolon)) with encased electrical components
Environmental Ranges	Transport and storage temperature: -4°F to +140°F (-20°C to +45°C) Operating conditions temperature: 41°F to 104°F (5°C to 40°C) Charging temperature: 41°F to 104°F (5°C to 40°C) Relative humidity: 10% to 75% Operating humidity: 15% to 93% Shipping pressure: 20 kPa to 106 kPa Operating pressure: 70 kPa to 106 kPa

REF	Product part number
	Caution, Warning, Danger, Important. Refer to accompanying Instructions for Use
SN	Serial Number
	Type BF Applied Part
	Date of manufacture
	Manufacturer
	This product must not be disposed of with other household waste
	Non-ionizing radiation
NON STERILE	Product is non-sterile
Rx ONLY	This product is available by prescription only
FC	FCC Registered Product
IP22	Degree of Ingress Protection
	Do not wash
	Do not dry clean
	Do not tumble dry
	Follow Instructions for Use
	This product needs to be protected from moisture
	Range of humidity to which the medical device can be safely exposed
	Indicates the temperature limits to which the product can be safely exposed
	Range of atmospheric pressure to which the medical device can be safely exposed
	Double Insulated (Equivalent to Class II of IEC 61140)
2	Single Patient Use - To Prevent Cross Contamination

Description	Industry-standard Bluetooth® Low Energy (BLE) 5.0 communication protocol
FCC ID Number	To Be Assigned
Operating Frequency Band	2.4 Ghz, ISM band (2.402-2.480 GHz)
Type of Modulation	FSK
Type of Modulating Signal	Binary data message
Data Rate [=Frequency of Modulating Signal]	1 Mbps
Effective Radiated Power	<10 dBm
Receiver Bandwidth	2.4 Ghz, ISM band (2.402-2.480 GHz)
EMC Testing	Complies with FCC 15.2473 (for U.S.) regulations Complies with IEC 60601-1-2 Complies with IEC 60601-2-10

Wireless Quality of Service (QoS): The Cionic Neural Sleeve NS-200 System was designed and tested to have an average response rate of 30-150 ms latency depending on system configuration.

Wireless Interference: The Neural Sleeve NS-200 System was designed and tested to not have interference from other RF devices (including other Neural Sleeve NS-200 Systems, WiFi networks, Cellular Devices, Microwaves and other Bluetooth® devices).

The Neural Sleeve NS-200 System is not susceptible to the wide range of expected EMI emitters, such as Electronic Article Surveillance Systems (EAS), Radio Frequency Identification Systems (RFID), Tag Deactivators, and Metal Detectors. However, there is no guarantee that interference will not occur in a particular situation.

Caution: If performance of the Neural Sleeve NS-200 System is affected by other equipment, the user should turn the Neural Sleeve NS-200 System off, and move away from the interfering equipment.

Electromagnetic Compatibility (EMC) Information

Guidance and Manufacturer's Declaration—Electromagnetic Emissions
The Neural Sleeve NS-200 System is intended for use in the electromagnetic environment specified below. The user of the Neural Sleeve NS-200 System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Neural Sleeve NS-200 System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Neural Sleeve NS-200 System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissionsIEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration– Electromagnetic Immunity for All Equipment and Systems
The Neural Sleeve NS-200 System is intended for use in the electromagnetic environment specified below. The customer or the user of the Neural Sleeve NS-200 System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment– Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 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%.
Electrical fast transient/ burst IEC 61000-4-4	+/-2 kV for power supply lines +/- 1 kV for Input/ output lines	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line to line +/-2 kV line to earth	+/-1 kV line to line +/-2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Neural Sleeve NS-200 System requires continued operation during power mains inter-ruptions, it is recommended that the equipment be powered from an uninterrupted power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration—Electromagnetic Immunity
The Neural Sleeve NS-200 System is intended for use in the electromagnetic environment specified below. The customer or the user of the Neural Sleeve NS-200 System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Neural Sleeve NS-200 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and Amateur Radio Bands	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and Amateur Radio Bands	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz Proximity Fields per 60601-1-2 4th edition	[E1] = 10 V/m in 26 MHz to 2.7 GHz Proximity Fields per 60601-1-2 4th edition	Recommended separation distance: $d = 0.4\sqrt{P}$, 80–800 MHz range $d = 0.7\sqrt{P}$, 800-2700 MHz range

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
Note 3: 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).
Note 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,should be less than the compliance level in each frequency range.
Note 5: Interference may occur in the vicinity of equipment marked with the following symbol:
a) Field strengths 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 Neural Sleeve NS-200 System is used exceeds the applicable RF compliance level above, the Neural Sleeve NS-200 System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Neural Sleeve NS-200 System.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Neural Sleeve NS-200 System

This device can be used under the environment that radiated RF disturbances are controlled. User should maintain a minimum distance between portable and mobile RF communications equipment to prevent electromagnetic interference. Following recommended distance is calculated according to the maximum output power of the communication equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter		
	150 kHz to 80 MHz Outside ISM Bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12m	0.04 m	0.07 m
0.1	0.38 m	0.13 m	0.22 m
1	1.2 m	0.4 m	0.7 m
10	3.8 m	1.3 m	2.2 m
100	12 m	4 m	7 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance "d" in meters (m) can be determined 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.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Notes

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