

Neural Sleeve | Instructions For Use
NS-100



CIONIC

Superpowering the Human Body



RX ONLY | Cionic Neural Sleeve Instructions for Use

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Patents Pending

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

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 electrodes on the Neural Sleeve, care should be taken to dispose of the old electrodes and plastic packaging from the new electrodes in the correct manne, 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

Cionic Neural Sleeve carries a one year warranty, starting at the date of purchase. Cionic will not provide free repair for the malfunctions caused by the following behaviors:

- Disassemble or modify the product without authorization.
- Accidentally drop the product during use or transportation.
- Lack of reasonable maintenance.
- Operate not according to the instructions.
- Repaired by unauthorized repair store.

Only the hydrogel electrodes carry an expiration date, therefore verify the expiration date is outside the two week period before use.

Customer Support

Telephone: (800)555-5555

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CHAPTER 1 | Introduction to Your Neural Sleeve

The Neural Sleeve is a platform of bionic clothing that is a technology-enabled, battery-operated, single-channel neuroelectrical stimulator used to improve your ability to walk. It addresses mobility limitations that support both rehabilitation and functional improvement. The Neural Sleeve includes 24 electrodes that wrap around your upper and lower leg. The Neural Sleeve system consists of the LYCRA® fiber sleeve (available in small, medium, large and extra-large sizes), a Neural Sleeve control unit, unit charging cord and 2 packets of electrode gel replacements. You will need the Neural Sleeve software which can be accessed through most Apple (iOS) or Android devices (smartphone or tablet) by visiting [cionic.com](https://www.cionic.com) to access the app, get registered, authenticated and started.

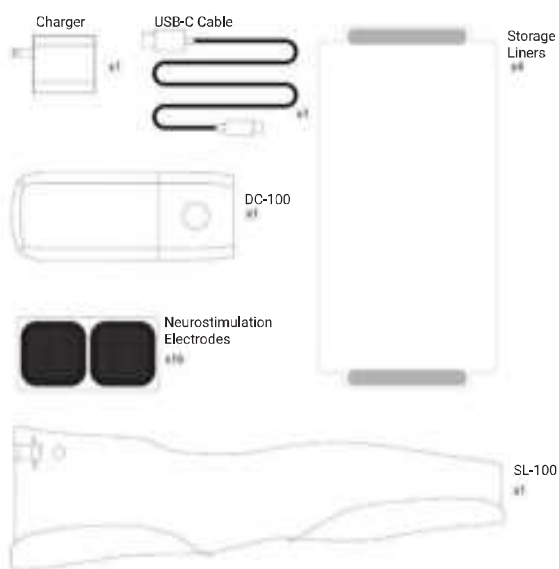


Figure 1 | Neural Sleeve System

⚠ Caution: It is recommended that you read the instruction manual carefully before using your Neural Sleeve.

Cionic Neural Sleeve System (NS-100) Features:

- **Sleeve (SL-100)** consists of 24 electrodes (8 stimulation and 16 shared for sensing and stimulation) that wrap around the lower and upper leg. Sensors within the sleeve include two Inertial Measurement Units (IMUs) and electromyography (EMG) that provides muscle activity data. The IMUs provide precise real-time 3D orientation, heading, calibrated acceleration, and calibrated angular velocity.
- **Control Unit (DC-100):** A portable electronic device is worn within the sleeve. It is removable and powered by a rechargeable lithium polymer battery.
- **Mobile Application:** The Neural Sleeve Control Unit is enabled through the Cionic mobile application that can run on Apple iOS devices.

Neural Sleeve User Manual


The user manual includes:

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

CHAPTER 2 | Safety Information

Indications for Use

The Neural Sleeve 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 or injury. The Neural Sleeve may improve gait, facilitate muscle re-education, prevent or retard disuse atrophy, maintain or increase joint range of motion, and 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.

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 a 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.
- Whenever 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 System

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 System within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the Control Unit output.

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, when using over areas of the skin that lack normal sensation, or if you are diagnosed with or suspect you have epilepsy.
- The Neural Sleeve may cause some users to experience skin irritation, an allergic reaction, or hypersensitivity to the fabric, electrical stimulation or electrically conductive medium. You may be able to remedy this by changing the electrode placement, type of electrodes or stimulation parameters.
- Do not wear the Neural Sleeve during any diagnostic or therapeutic medical procedure like an x-ray, ultrasound, MRI, EMG, etc.
- Replacement electrodes for the Neural Sleeve should only be provided by Cionic.
- Do not use the Neural Sleeve system in an oxygen rich environment.
- The Neural Sleeve must be turned off before putting on or removing the sleeve and before removing or replacing any electrodes.
- 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 in the area where the Neural Sleeve is worn.

CHAPTER 2 | Safety Information (cont.)

- Never use the Neural Sleeve with worn-out gels or exposed, frayed or broken leads.
- 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 user manual.
- 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 electrodes can occur with the use of surface electrical stimulation devices. While it is normal to see reddened areas under the electrodes, 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 Support Advocate, 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 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 or injury. Steps can be taken to ensure the Neural Sleeve is operating properly and safely;

- Make sure the Neural Sleeve control unit is fully charged before initial use, before daily use and after any extended storage. Charging instruction 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 electrodes 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 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 contact with the skin. If necessary, excessive hair can be removed with an electric trimmer or scissors. A straight razor or safety razor is not recommended because it can further irritate the skin.
- Replace the electrodes every two weeks, or sooner if the condition of the electrodes has diminished.
- Always re-cover the hydrogel electrodes with the original plastic 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 FCC (Federal Communications Commission) 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.

Conformity Certification

The Neural Sleeve System complies with Part 15 of the FCC rules. Operation is subject to the device may not cause harmful interference, and must accept any interference received, including interference that may cause undesired operation.

Travel and Airport Security

The Neural Sleeve charger set with interchangeable blades is compatible with U.S. voltage: 110/220 V

Turn off your Neural Sleeve control unit before going through airport security. It is advised to carry a copy of your Neural Sleeve prescription. A prescription can be useful when passing through customs as well.

To request a copy of your prescription, please email Cionic Customer Support, support@cionic.com.

Please use the subject heading, Prescription Copy 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.

CHAPTER 4 | Neural Sleeve Device Description

Control Unit

The Neural Sleeve control unit is the only source of power and is used to turn the system on/off. All the electrode lead wires plug into the power unit from the Neural Sleeve. The power unit does not act as the direct control unit and will not allow you to select operating modes or adjust stimulation intensity. The power unit communicates wirelessly with the user's personal mobile device through the Cionic mobile application. The power unit is powered by a single rechargeable ion battery.

- To turn the Control Unit on, press the multifunction button once.
- To turn the Control Unit off, press and hold the multifunction 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
	Blinks green	Recording in process
	Solid yellow	Stimulation active
	Blinks orange	Battery charging
	Solid green	Battery fully charged. Disconnect from charger
	Blinks green slowly	Unit on
	Blinks red	Unit battery low <20%. Charge Control Unit
	Blinks red 2x	Unit 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 connected
	Blinks blue once	Bluetooth™ pairing mode active
	Blinks blue 3x	Bluetooth pairing complete
	Blinks orange 3x	Bluetooth pairing failed. Retry pairing
	Orange to fade out	Powering off
	Purple pulsating	Button pressed
	Pulse purple to green	Button pressed during FES

Figure 2 | Neural Sleeve System



Control Unit Multifunction Button

The Control Unit contains a button used for multiple purposes.

Table 2 | Multifunction button operations

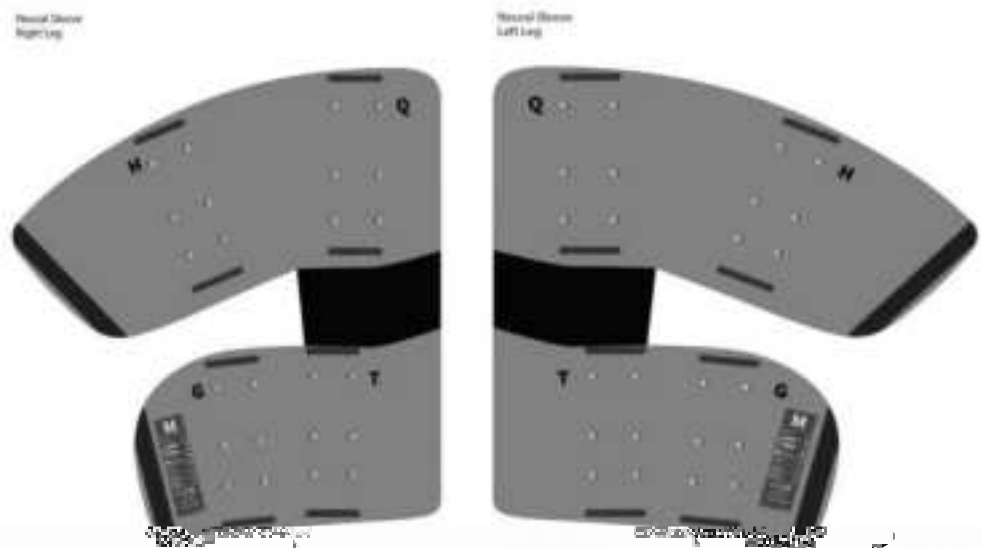
DESIRED ACTION	BUTTON OPERATION
Turn Control Unit on	Press the button
Turn Control Unit off	Press and hold the button for 5 seconds
Pause and Unpause stimulation	Press button while stimulation is on
Factory Reset	Troubleshooting; See Chapter 9

Neural Sleeve

The Neural Sleeve is a wearable fabric sleeve that fits the leg from just above the hamstring to the lower calf muscle. It is available in right or left leg configurations, offered in four sizes (small, medium, large, and -large). The Neural Sleeve is designed to facilitate upward movement of the foot, lower leg and upper leg, depending on the programming.

The Neural Sleeve is a single velcro panel that adjusts to hold the sleeve firmly in place. The upper outward-facing portion of the Neural Sleeve includes a pouch that holds the control unit.

Figure 3 | Cionic Neural Sleeve Left and Right



CHAPTER 4 | Neural Sleeve Device Description (cont.)

Neural Sleeve Electrodes

The Neural Sleeve consists of 24 electrodes. Eight electrodes are used specifically for stimulation and 16 electrodes are used for both sensing and stimulation. Each 2"x2" (5x5cm) electrode contains a conductive film that provides current control. They are reusable (up to two-weeks), self-adhering, and serve as an interface between the user's skin and the Neural Sleeve electrode bases.

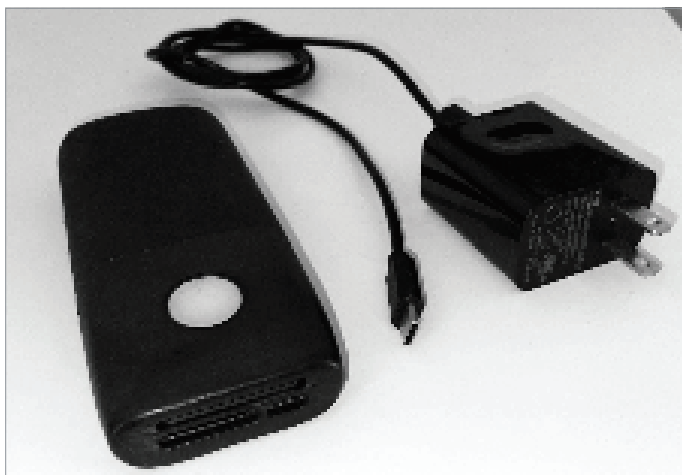


⚠ Warning: Only the neurostimulation electrodes provided by Cionic should be used with the Neural Sleeve

Control Unit Charger

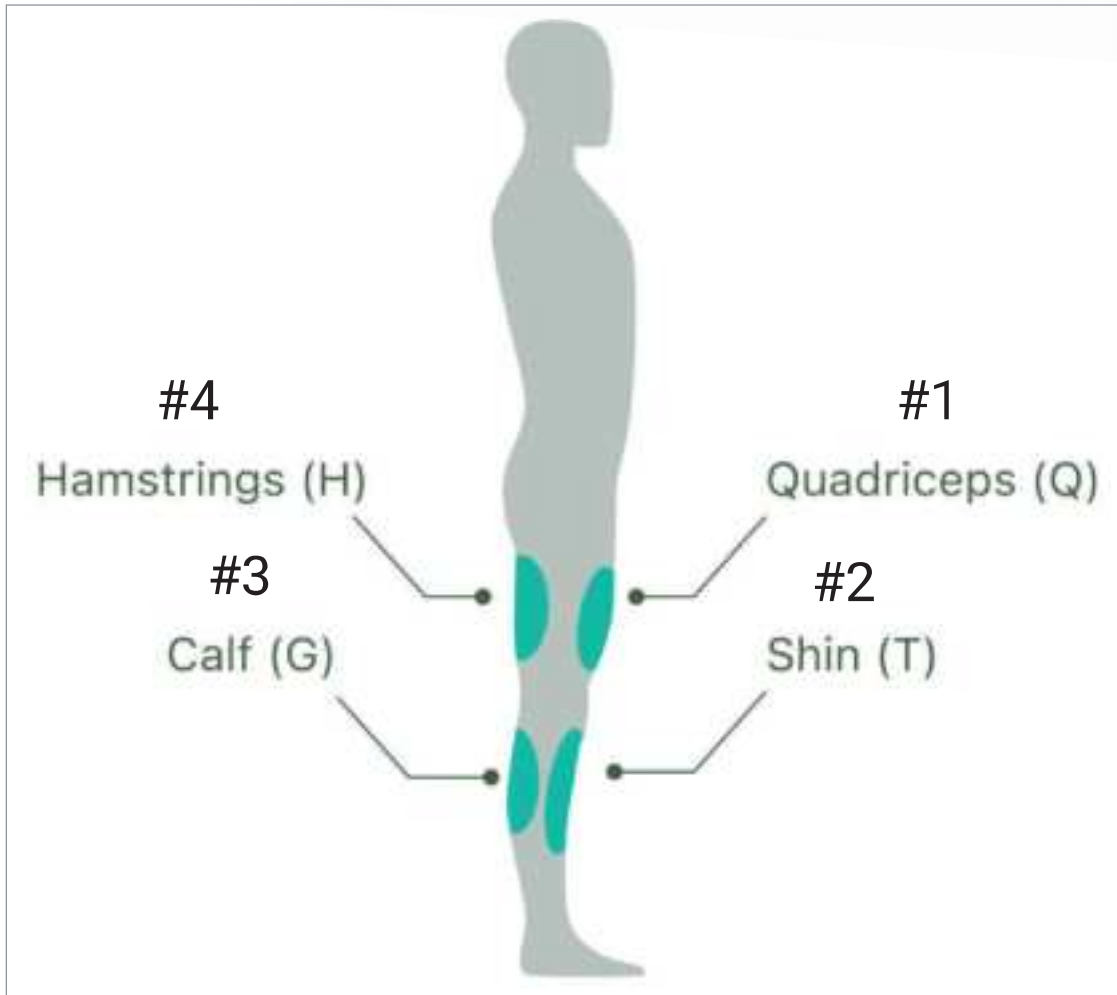
The control unit includes a 3-foot long (1m) USB Type A to Type C charging cable, as well as a removable power adapter.

Figure 4 | Control Unit and Charger



⚠ Caution: Use only the control unit charging cable and power adapter that was included in your Neural Sleeve kit. Using any other charger could cause damage to the unit.

Figure 5 | Major leg muscle groups



Downloading the Mobile App

The Cionic Mobile Application 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 Mobile Application. It will also act as the only interface needed to operate the Neural Sleeve. Use your smartphone or tablet to visit cionic.com to access the app, get registered, authenticated and started. The Cionic App communicates with the Control Unit through Bluetooth™ Low Energy as well as the web-based Cionic server.

CHAPTER 5 | Neural Sleeve (cont.)

Applying Electrode Pads to the Neural Sleeve

In order to use your Neural Sleeve you must attach 24 sticky pads onto the electrodes on the inside of your Neural Sleeve. Open the sleeve and place it on a flat, solid surface. There are six groups of electrodes marked 1, 2, 3 and 4. These groups correspond to muscles on your leg.



Sleeve without electrode pads applied



Sleeve with electrode pads applied



Sleeve with electrode pads and protective covers applied



Step 1

Starting with Section 1 of the electrodes, select one pair of pads. Carefully remove the clear protective film from the grid side of the electrodes. (Protective film can be discarded).



Step 2

Carefully place the pair of pads, grid side down, in a horizontal position onto two metal electrodes. The pads must be centered on the electrode buttons, you should not see any of the red square



Step 3

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



Step 4

Repeat this process for each pair of pads until all electrodes are covered.

Step 5

When complete, carefully remove the clear plastic film cover from the top of each pair of electrodes. Then cover each section of 6 electrodes with the corresponding numbered electrode cover sheet that was provided.



⚠ 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.

CHAPTER 5 | Neural Sleeve (cont.)

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 mobile app prior to use. You can view tutorial videos by going to cionic.com

Putting on the Neural Sleeve

- You will need to be wearing shorts or a skirt in order to use 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)



Image 1



Image 2



Image 3



Image 4



Image 5



Image 6



Image 7



Image 8

Apply Sleeve to the Quadricep

- Pull the top of the sleeve down over your knee and rest it on the shin with the #1 facing up
- Pulling downward, remove the protective liner exposing the six electrodes, making sure that all electrodes are still attached to the sleeve. Set the protective liner to the side.
- If needed, adjust your clothing to ensure electrodes will only come in contact with the skin of your quadricep.
- Pull the #1 section of the sleeve back up over your knee, placing the electrodes on the skin of your quadricep.
- Press down firmly on the sleeve to ensure electrodes adhere flat and securely to the skin.



Image 9



Image 10

Apply Sleeve to the Shin

- With two hands, reach down and grip the bottom of the sleeve by the ankle.
- Pull the sleeve up and over your knee and rest the sleeve on your quadricep with the #2 facing up.



Image 11



Image 12



CHAPTER 5 | Neural Sleeve (cont.)

- Pulling downward, remove the protective liner exposing the six electrodes, making sure that all electrodes are still attached to the sleeve.
- Set the protective liner to the side.
- Pull the #2 section of the sleeve back down over the knee, placing the electrodes on the skin of your shin.
- Press down firmly on the sleeve to ensure electrodes adhere flat and securely to your skin.

Apply the Neural Sleeve to the Calf

- Reach behind the back of the lower leg and grab the bottom wing of the sleeve. Guide it up and over, resting the sleeve on your shin with the #3 facing up.



Image 13



Image 14



Image 15



Image 16



Image 17



Image 18



Image 19



Image 20

- Pulling downward, remove the protective liner exposing the six electrodes. Be sure that all electrodes are still attached to the sleeve.
- Set the protective liner to the side.
- Pull the #3 section of the sleeve back under your calf, pulling across tightly to secure the Velcro connection points while ensuring the electrodes are in contact with the skin of your calf.
- Press down firmly on the sleeve to ensure electrodes adhere flat and securely to your skin.



Image 21



Image 22

Apply the Neural Sleeve to the Hamstring

- Adjust yourself toward the front of your chair.
- Reach behind the back of your upper leg and grab the top wing of the sleeve. Guide the sleeve up and over, resting the sleeve on your quadricep with the #4 facing up.



Image 23



Image 24



CHAPTER 5 | Neural Sleeve (cont.)

- Pulling downward, remove the protective liner exposing the six electrodes. Be sure that all electrodes are still attached to the sleeve.
- Set the protective liner to the side.
- If needed, adjust your clothing to ensure electrodes only come in contact with the skin of your hamstring.
- Pull the #4 section of the sleeve back under the hamstring, pulling across tightly to secure the Velcro connection points while ensuring the electrodes are in contact with the skin of your hamstring.
- Press down firmly on the sleeve to ensure electrodes adhere flat and securely to your skin.



Image 25



Image 26



Image 27



Image 28

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 take off the sleeve by visiting the app or by going to cionic.com



Image 29



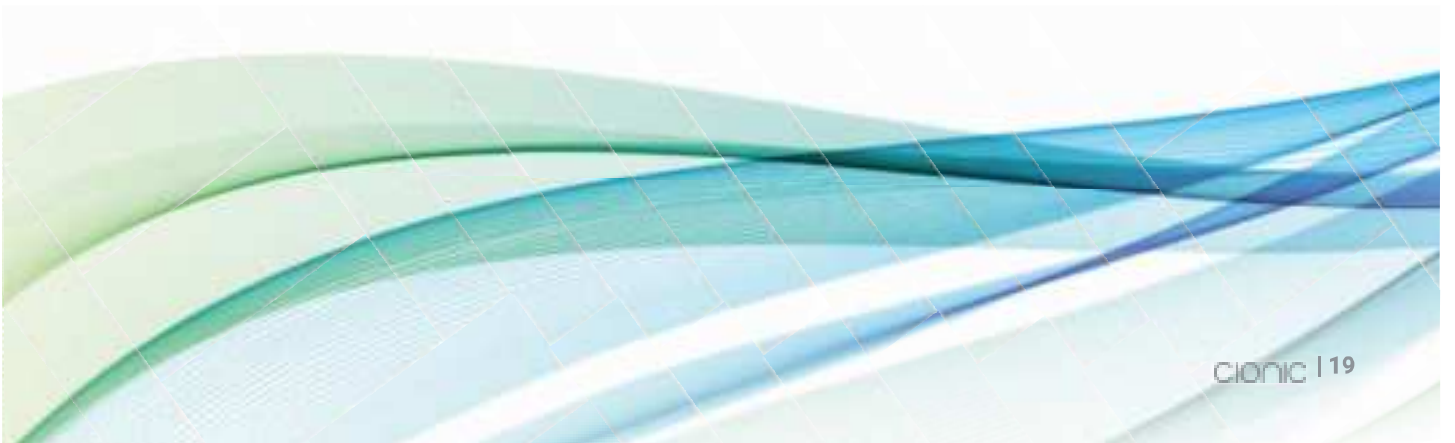
Image 30



Image 31

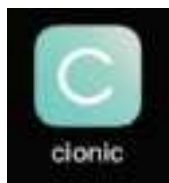
Connecting the Neural Sleeve to the Control Unit

- Pick up the fully charged control unit.
- Press the "On" button, ensuring you see a pulsing green light.
- With the port connector facing up and the power button facing out, slide the control unit into the Neural Sleeve pouch.
- Gently connect the control unit to the Neural Sleeve connector cord, ensuring it is secure.
- You now can put your shoe back on, stand up and adjust your clothing over the Neural Sleeve.



CHAPTER 6 | Cionic Mobile Application

The Cionic Mobile Application (“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 recorded data, and receive programs assigned to you by your physician.



Cionic App Settings | iOS Device

The Cionic app resides on your smart device and makes use of functions commonly used by apps. Table 3 outlines the iOS settings required for operation of the Cionic app.

Table 3 | iOS settings for the Cionic app

SETTING	REQUIRED	DESCRIPTION
Location	No	Record your GPS location with collected data
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
Notifications	Optional	The Cionic app will provide notifications while you are using your Neural Sleeve. Additional notifications controlled in this setting are not required
Cellular Data	Optional	Allows the Cionic app to utilize your cellular network data to upload recordings. If this is not enabled, the app will hold your recordings until you are connected to WiFi

Video Consultation to Set Up Your Neural Sleeve

Prior to using your Neural Sleeve 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 mobile app prior to use. If you have not yet scheduled your video consultation or if you need to reschedule your appointment, contact Cionic at 1-800-555-5555 or go to the Contact Us page at cionic.com.

Complete these steps prior to your Video Consultation:

- Install the Cionic app onto your iOS device.
- Apply electrode pads to your Neural Sleeve.
- Charge your Control Unit.
- Collect all accessories to the Neural Sleeve including the charging cable, extra electrode pads, Quick Start Guide and these instructions.
- Wear shorts or a skirt.
- Be seated in a comfortable chair near a flat surface such as a table.

If you are comfortable putting on the cionic sleeve on your own please feel free to do so.

At the time of your appointment, open the Cionic app. You will see an option to join the setup session and confirm you are prepared with all devices. You will meet your Cionic technician virtually and begin the setup process.



Table 4 | Cionic mobile app symbols during remote consultation

	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.
	Minimizes the camera view.

CHAPTER 6 | Cionic Mobile Application (cont.)

Navigation

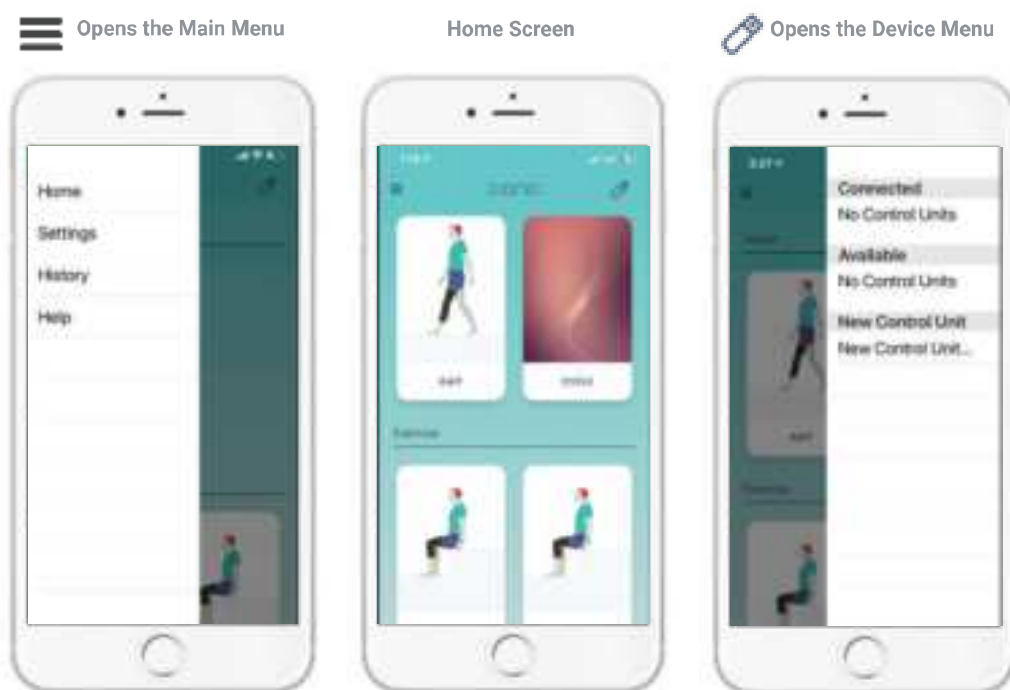
The Cionic Mobile App includes four primary sections to navigate.

Home Screen

The app Home Screen (Figure 5) contains a list of programs available for use. The programs available to you may vary depending on your clinician's instructions at the time of purchase. These programs may change over time as your course of treatment progresses.

To view all programs, press and hold your finger on the main screen and swipe up. To open a program or exercise, select the image for the desired item.

Figure 5 | Cionic App Main Screen



Settings

The Settings screen contains three options. 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 for future use.

Location Tracking

If this is selected, your **distance and elevation** will be included with any recordings. This option is not available if "Create/Upload Recordings" is off.

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 wifi.

Reset

- Reset help/tutorials - some instructional videos are only shown one time. This selection will restore the ability to watch the videos.
- Reset settings - this will return all of the above settings to defaults.

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.

