History Screen

The History screen lists all recordings (Figure 6). This page will be empty if you have not enabled recordings. Each entry lists the program that was recorded, the time and date of completion, and the save status. Some conditions, such as absence of a cellular or WiFi connection, can lead to upload errors. If an error is presented, change your network connection status and tap the record. To delete records, select "Edit" and press the icon.

Help Screen

The Help screen contains 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.

The "Contact" button allows you to:

- Rejoin a technical support call should one end unexpectedly.
- Send an email message directly to Cionic with any thoughts or concerns.

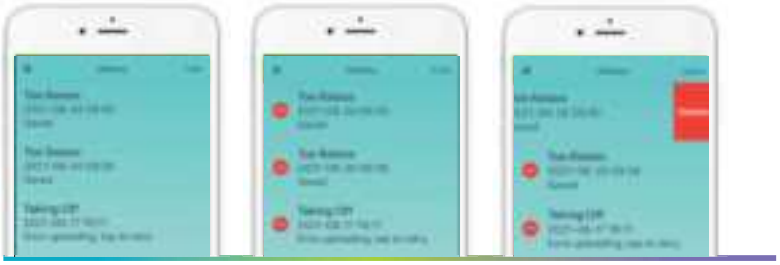


Figure 6 | Managing recordings in history

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 and find the device number under the "Available" section accompanied by the icon"
- Select "New Control Unit".
- Follow the on-screen instructions to complete the connection process.

Once your device is connected, the following symbols apply:

	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
	Disconnect from Control Unit
	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...** To update the software that runs your Control Unit. You will be contacted by Cionic when this is required.

⚠ **Caution: If you have multiple devices, be sure to select the proper device or your system will not work properly.**

CHAPTER 7 | Using Programs and Exercises

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.
- **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.

The Cionic App will include all programs and exercises that have been recommended by your physician.

Calibration

Sensors in the Neural Sleeve measure leg muscle activity and leg movement. These sensors must be calibrated specifically to your body at least once every time you wear your Neural Sleeve. On any Assist or Exercise program screen, you can find the Calibration icon as a set of concentric circles.

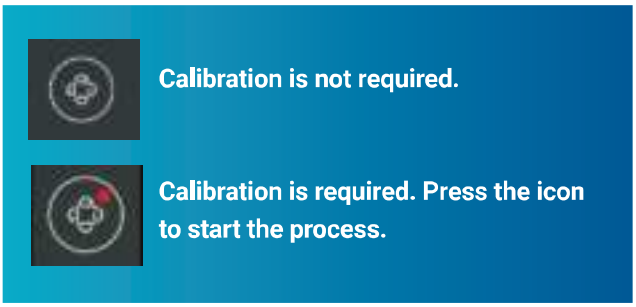
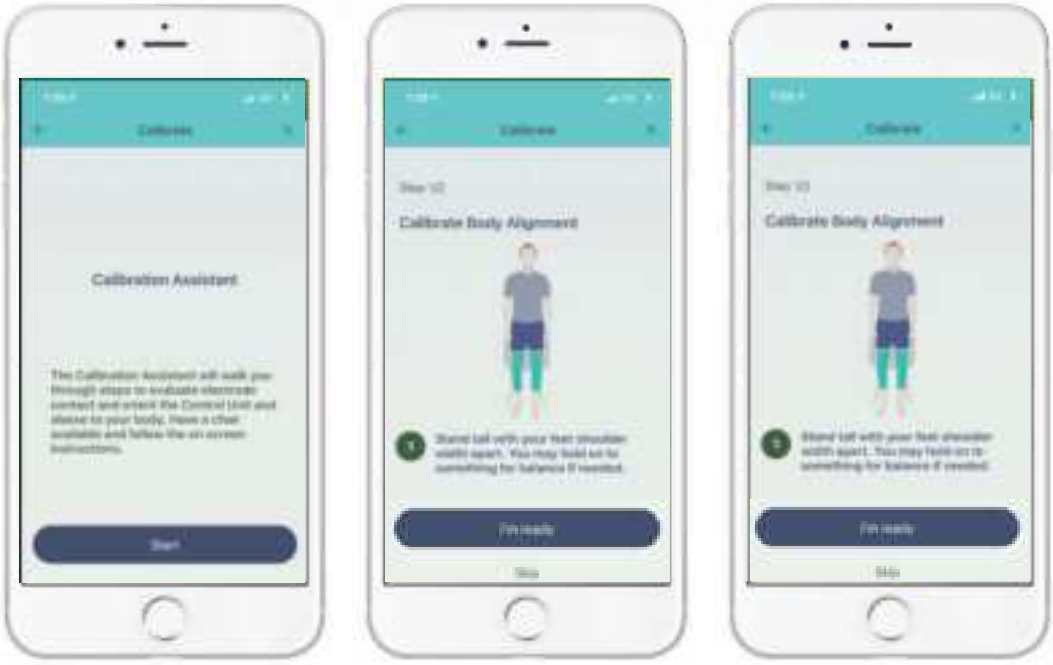


Figure 7 | Calibration is needed (Left) and not needed (Right)

Follow on-screen instructions to complete the calibration process (Figure 7).

Figure 8 | Neural Sleeve calibration process



Operating Modes

Ready Mode

No Neural Sleeve programs are active. Functions in the Settings, History, Help and the Device Menus are enabled. A menu of programs is available to you on the Home Screen.

Assist Modes

Multiple programs may exist under the Assist section of the Home Screen. These programs will vary depending on the instructions of your physician. Use of the Gait Assist and Cycle 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 the instructions of your physician or therapist. 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.

Exercises can be performed with or without electrical stimulation. When used with electrical stimulation, your muscles will be stimulated in support of your performance of the exercise. When used without stimulation, your muscles will not be stimulated and you will perform the movement on your own. Some exercises such as Hip Abduction and Mini Squats do not offer stimulation.

Programming 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.

- Exercise programs will only involve stimulation of one muscle
- Assist programs will involve one or more muscles, depending on the direction of your physician or therapist.

Press the ⚡ button to initiate stimulation programming.

Adjusting the Stimulation Parameters

You are able to control the level of stimulation delivered to your muscles for Assist or Exercise programs. The level of electrical stimulation provided to your muscles is controlled using three parameters and by selecting which electrodes will be used.

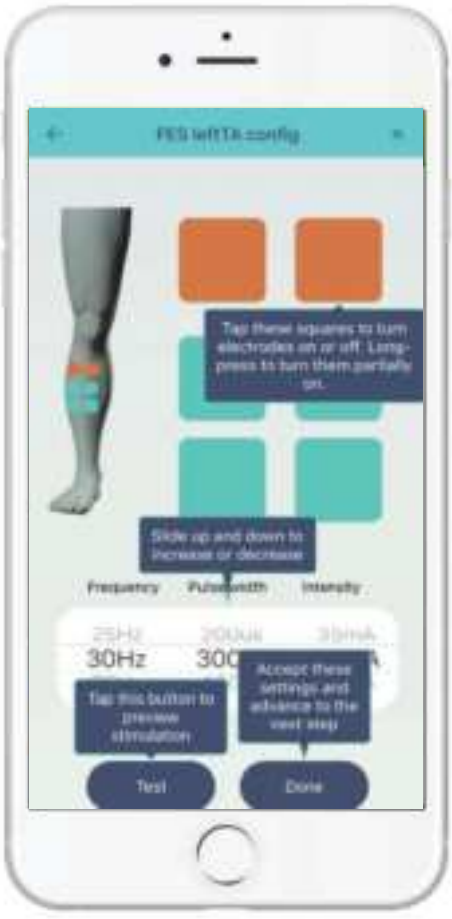
The programming screen includes:

- 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 turned on and off
- Three stimulation parameters that you will customize for your stimulation.

The first time you program stimulation, dialogue boxes will appear, explaining each control and parameter. Tap these dialogue boxes to make them disappear.

⚠ **Caution: If you have multiple devices, be sure to select the proper device or your system will not work properly.**

Figure 9 | Stimulation Programming Screen with explanatory dialogue boxes



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)

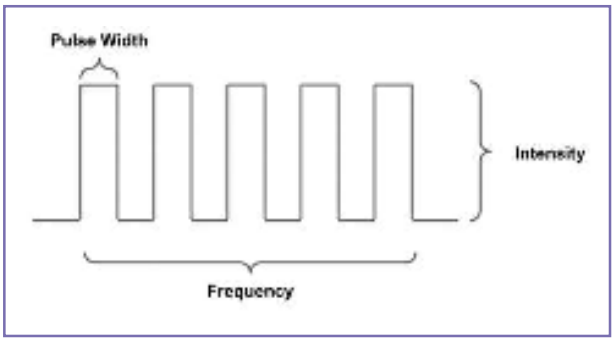


Figure 10 | Graphical illustration of stimulation waveforms

PARAMETER	RANGE	INCREMENTS	IMPACT
Frequency	5 - 125 Hz	5 Hz	Sensation
Pulse Width	100 - 400 microseconds	100 microseconds	Strength of muscle contraction
Intensity	5 - 100 mA	5 mA	Strength of muscle contraction

Stimulation is fully customizable for your comfort and to produce the desired muscle reaction. 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 "Test" to deliver a 2 second 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 and wish to store them for future use.

⚠ **Caution: Always test stimulation before selecting "Done" in order to confirm the stimulation parameters. Skipping test stimulation may result in ineffective muscle contraction. Skipping test stimulation may result in a painful sensation or a stronger muscle contraction than desired.**
The User should set the stimulation parameters trying to minimize the amount of current delivered to the body. Such amount of current shall be set to strictly match the intended medical need.

Adjusting the Electrode Array

Stimulation activates muscles by directing electrical current through your skin and into your muscle. Electrical current flows between the electrodes. You are able to program which electrodes are involved in the flow of electrical current. Choosing electrodes allows you to direct the current to different places in your muscle to optimize the type of contraction desired.

The stimulation configuration screen includes an illustration of a leg with orange and blue squares representing the electrodes in your Neural Sleeve. The large orange and blue squares are used to turn electrodes "on" or "off". Electrodes that are on will be involved in the flow of stimulation. Electrodes that are off will not be involved in the flow of stimulation. At least one upper and one lower electrode must be turned on.

1. A single tap on an electrode where active percent > 0 will set its active percent to 0
2. A single tap on an electrode where active percent = 0 will set its active percent to 100
3. A long press on an electrode puts the electrode into advanced edit mode (see below)
4. In advanced edit mode, moving the slider will modify the percent active.
5. Advanced edit mode can be exited by tapping the dismiss 'x'

Press "Done" when you are satisfied with the parameters you have programmed. These parameters are now saved and will be used by the Neural Sleeve when you perform your Exercise or Assist program.

Figure 11 | Electrodes fully active (left) or partially active (right)

Gait Assist Program

The Gait Assist program is designed to help improve your walking by stimulating one or more muscles in your leg at the same time you are moving them. The Neural Sleeve delivers electrical stimulation in a coordinated pattern using electrical stimulation parameters you have defined. The timing of the stimulation is determined automatically using measurements from the sensors in the Neural Sleeve.

Adjusting Stimulation

You will be able to program stimulation for up to four muscles. The muscles available to you have been selected by your physician. 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.

- **Tibialis Anterior*** (Shin) - lifts your foot up, pulling your toes away from the ground
- **Gastrocnemius** (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

Select the icon to enter the stimulation programming mode.

Using Gait Assist for Mobility

When you have programmed each available muscle to your satisfaction, select "Start". 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.

- To activate stimulation press the Start button.
- To stop stimulation press the Stop button
- 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).

⚠ **WARNING: When you stop walking, a pattern of stimulation may continue. Press the Stop button to end stimulation.**

Figure 12 | Calibration of stimulation

Using Cycle Assist for Stationary Exercise

Cycle assist mode allows you to operate a stationary exercise bike with electrical stimulation to your leg muscles. Cycle Assist mode provides stimulation to your quadriceps and hamstrings in a coordinated manner to add to the power you provide. To use Cycle Assist mode, program your preferred electrical stimulation parameters using the Programming Stimulation procedure. Position yourself on a stationary exercise cycle.

- To activate stimulation press the **Start** button.
- To stop stimulation press the **Stop** button
- 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).

⚠ CAUTION: Cycle Assist is for use only with a stationary exercise bike. Do not use Cycle Assist when cycling.

You must initiate movement in order to start electrical stimulation. Stimulation will be timed automatically to stimulate the quadriceps for knee extension and your hamstrings for knee flexion.

⚠ CAUTION: When you stop operating the pedals, a pattern of stimulation may continue. Press the STOP button to end stimulation.

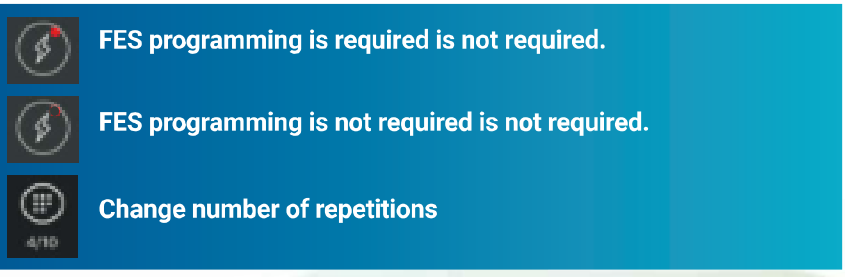
Using Exercise Programs

Exercise programs are designed to help improve your walking by 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 under Programming Stimulation to program the strength of stimulation.
Finally, choose the example to perform and follow the online instructions.

Determine whether or not calibration is required by noting the calibration icon.

EXERCISE MODE	STIMULATION USED?	DESCRIPTION
EMG-Triggered	Yes	EMG exercise uses stimulation to add to your own muscle movement
Timed	Yes	Timed exercise uses stimulation in a pattern with or without your own muscle movement.
Unassisted	No	Unassisted exercise is performed by you without stimulation as you would without a Neural Sleeve system.



CHAPTER 8 | Maintenance and Cleaning

Daily Maintenance and Storage

- Carefully examine each hydrogel electrode and each additional component for wear or damage.
- Always replace any hyprogel that appears to be old, worn, lacking adequate adhesive or damaged.
- Be sure that the protective cover is covering all 24 hydrogel electrodes on all four (4) sections of the Neural Sleeve.
- Make sure the Neural Sleeve control unit is detached when the Neural Sleeve is not in use.
- Allow the Neural Sleeve to air dry when not in use.
- After each use, be sure the Neural Sleeve control unit is turned off.
- Fully charge the Neural Sleeve control unit between each use.

Charging

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

- Ensure the Neural Sleeve control unit is turned off by pressing and holding the button for 5 seconds.
- Connect the charging cord (provided) to the small connector at the end of the Neural Sleeve Control Unit.
- Confirm the Yellow Light is blinking on the Neural Sleeve control unit to confirm it is charging
- Allow to charge for at least 3-4 hours. The Neural Sleeve is fully charged when the indicator light has a solid green display

Replacing the Neural Sleeve

Hydrogel Electrodes

For regular daily Neural Sleeve at-home users, the hydrogel electrodes should be replaced at least every two weeks.

The hydrogel electrodes need to be removed to clean the Neural Sleeve. It is recommended that you perform cleaning and replacement of the hydrogel electrodes at the same time.

⚠ CAUTION: Use only the Neural Sleeve hydrogels electrodes supplied by Cionic.

⚠ CAUTION: The Neural Sleeve must be turned off before putting on or removing the sleeve and before removing or replacing any electrodes.

⚠ CAUTION: Never use Neural Sleeve without hydrogel electrodes.

Replacing the Neural Sleeve Hydrogel Electrodes (cont.)

- Control unit should be turned off and disconnected from the Neural Sleeve.
- Gently pull off and discard all 26 hydrogel electrodes, or only those that have been identified as worn or damaged. Ensure the electrode metal buttons are not removed and fabric is not torn.
- If cleaning is necessary, refer to cleaning instructions below.
- The new hydrogel electrodes arrive with two (2) attached. Separate the two (2) electrodes along the perforation.
- Remove the plastic cover from the hydrogel electrode from the grid side.
- Attach the grid side to one of the electrode metal button bases, making sure the metal base button is fully positioned within the grid.
- Press firmly to make sure hydrogel electrodes are secure.
- Repeat until all electrodes are in place.
- Remove the covers from all the electrodes during next used, replacing them with the four (4) protective films.

Cleaning the Neural Sleeve

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

- Make sure to remove all hydrogel electrodes from the Neural Sleeve.
- Verify that the Control Unit is disconnected and removed from the pocket of the Neural Sleeve.
- Place the Neural Sleeve on a table with the flaps open so that the electrode metal buttons are visible.
- If there are gel residues, try to remove them by carefully detaching them.
- 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.**

Control Unit Firmware Upgrade

You may be contacted by Cionic and directed to update the firmware on your Control Unit. This will be requested, for example, when improvements to the Neural Sleeve system are available. You will only perform this update when directed to by Cionic. The following steps describe the process for upgrading your device firmware.

STEP 1 Download the new firmware

- Log in to cionic.com
- If your Control Unit and Neural Sleeve need a firmware upgrade, a box that says Firmware Upgrade will appear.
- Look for the box that says Firmware Upgrade. Click Download.

STEP 2 Copy the Firmware to your Control Unit

- Find the apollo_img.cionic file that you just downloaded in your file system.
  - If you're using a Chrome browser, click on the little arrow at the top of the file and click Show in Finder:
  - If you're using a Safari browser, click on the downward facing arrow that appears in the upper right side of the screen. Then click Show in Finder.

- Plug your Control Unit into your computer using the provided USB cable with your charger.
- Double check that your Control Unit appears as a mounted drive

Important Note: ***Do not modify the filename!*** If, for example, you've downloaded multiple copies of the file, you must restore its original name for the upgrade to work correctly. It should be called **apollo_img.cionic**

- Move the .cionic file into the CIONIC mounted drive
- Eject your Control Hub from your computer

STEP 3 Navigate to Control Unit settings in your Cionic App

- Click on the Hub icon in the upper right corner

- Click on Start Firmware Upgrade

- Connect to your Control Unit and click on Settings

STEP 4 Follow the directions in the Cionic App

- Connect your Control Unit to your Neural Sleeve
- Make sure your Control Unit has at least 50% battery
- Click Check Versions to start the firmware upgrade process

FAQ

What happens if my Neural Sleeve unplugs during the upgrade?

- The firmware upgrade will fail and your Neural Sleeve will temporarily be in an unresponsive state. To fix this, go through the upgrade process again.

CHAPTER 9 | Troubleshooting

If you have any questions or concerns about your Neural Sleeve system, contact Cionic at 1-800-555-5555 or visit cionic.com.

Control Unit Fails Calibration

Check and make sure all electrodes are installed correctly in your sleeve. Check and make sure that all electrodes 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.

Control Unit is Unable to Pair with Your Cionic App

Go into iOS settings under Bluetooth, identify your Control Unit serial number and "forget" the device. Reattempt pairing process in the Cionic app.

If You Feel a Sharp, Uncomfortable Pain

Check to see that each electrode is fully unfolded so that the entire surface is on your skin.

Control Unit is Malfunctioning

Attempt a factory reset as outlined below.

Stimulation Feels Uncomfortable

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

Factory Reset

In rare cases it may be necessary to reset your Control Unit to the original factory settings. To perform a factory reset, plug your Control Unit into a computer using the USB-C connector on the Control Unit and a USB port on a computer. 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. Be aware that the Factory Reset process will erase your collection history and reset all of your device settings, including stimulation parameters.

> ⚠ **CAUTION: Factory reset process will reset stimulation parameters to default settings. Prior to performing any Exercise or Assist programs, follow the stimulation programming process to ensure your desired parameters are utilized.**

Control Unit Battery Maintenance

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 manual 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 Cionic at 1-800-555-5555 or visit cionic.com

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.

Cionic Neural Sleeve (NS-100)	
Classification	Internally powered, continuous operation with Type BF applied parts
Power Source(s)	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh
Controls	Single multifunction button
Indicators	Single LED indicator
Operating Modes	Exercise & Assist
Number of Output Modes	Single mode with discrete stimulation settings.
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 mono-phasic, 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-100): 145 g Sleeve (SL-100): 100 g
Dimensions [W x H x D]	Control unit (DC-100) 137 x 53 x 24 mm Sleeve (SL-100) Small 596x560 mm Medium 613 x 602 mm
Waveform	Pulsed Monophasic with hybrid stimulation
Shape	Rectangular
Maximum Output Voltage	50 V @ 500 Ω , 130V @ 2 kΩ , 130V @ 10 kΩ
Maximum Output Current	100 mA @ 500 Ω , 65 mA @ 2 kΩ , 13 mA @ 10 kΩ
Current [mA]	0 to 100 [mA] at 5 mA increments
Pulse Width [µs]	100 to 400 [µs] at 100 µs increments
Frequency [Hz]	5 – 125 [Hz] at 5 Hz increments
Sizes	Small, Medium.
Materials	Liner: 85% poly, 9% spandex, 6% nylon Shell: 92% poly, 8% spandex
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

CHAPTER 11 | Wireless Information

Frequency Band	2.4 GHz, ISM band
Transmission Power	Complies with FEC 15.247

CHAPTER 12 | List of Symbols

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
	Product is non-sterile
Rx ONLY	This product is available by prescription only
	FCC Registered Product
IP22	Degree of Ingress Protection
	Do not wash
	Do not dry clean
	Do not tumble dry
	The instruction manual / booklet must be read
	This product needs to be protected from moisture
	Indicates the range of humidity to which the product can be safely exposed
	Indicates the temperature limits to which the product can be safely exposed
	Indicates the range of atmospheric pressure to which the product can be safely exposed