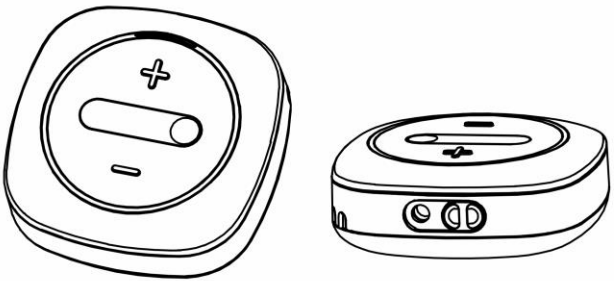
MyndStep

Foot Drop Stimulator

USER MANUAL

800102

MyndStep



Please read this user manual before starting to use the device.

Rx only

www.myndtec.com

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Foreword

*Thank you for purchasing the **MyndStep Foot Drop** System from MyndTec.*

*This manual is intended for the owners and operators of **MyndStep**. It contains general information on the instructions for safety, intended use, working principle, operation, maintenance, troubleshooting, and warranty. In order to maximize the use, efficiency, and working life of your unit, please read this manual thoroughly and become familiar with the controls, as well as the accessories, before operating the unit.*

Specifications put forward in this manual were effective at the time of publication. However, owing to the continually improving policy of MyndTec Inc., any changes to these specifications may be made at any time without obligation on the part of MyndTec Inc.

Before administering any treatment to a patient, the user of this equipment should read, understand, and follow the information contained in this manual for each mode of treatment available, as well as the indications, contraindications, warnings, and precautions.

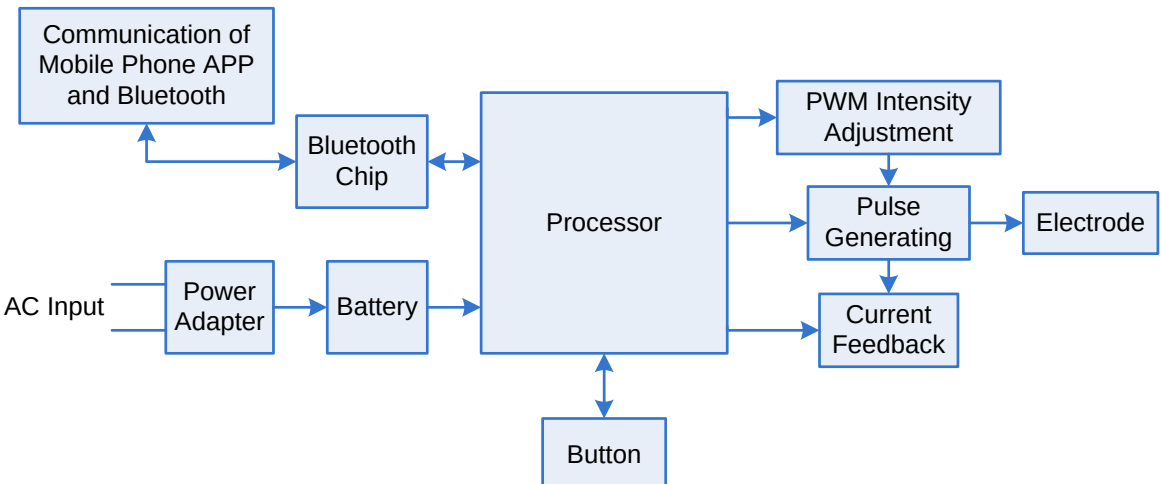
Product Description

MyndStep is a functional electrical stimulation (FES) system indicated for the treatment of foot drop as a consequence of upper motor neuron (UMN) injury to include and not limited to:

- *Stroke*
- *Spinal Cord Injury (SCI)*
- *Traumatic Brain Injury (TBI)*
- *Multiple Sclerosis (MS)*
- *Cerebral Palsy (CP)*

The MyndStep system uses an accelerometer and an inclinometer to signal stimulation of the common peroneal nerve which stimulates the anterior tibialis muscle. The motor output – ankle dorsiflexion - will lift the foot to clear the ground's surface during ambulation; and, manage a step, curb, doorsill and stairs.

Working Principle


Communication of Mobile Phone APP and Bluetooth
Bluetooth Chip
Processor
PWM Intensity Adjustment
Pulse Generating
Electrode
AC Input
Power Adapter
Battery
Current Feedback
Button

Clinical Instructions

A correct examination and diagnosis should be performed before treatment with ***MyndStep.***

Indications for Use

MyndStep *is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. Detect the swing phase of gait and appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function.*

Contraindications

1) *Do not use it on persons with implanted demand-type cardiac pacemakers or defibrillators.*
2) *Do not use it on persons with severe heart failure or arrhythmia.*
3) *Do not use on persons with histories of seizure disorder.*
4) *Do not use it on persons in the acute or critical stage of important organ disease.*

5) *Do not use it on persons who cannot provide sensory feedback for stimulation (unable to express or have difficulty in the communication), such as mental disease.*
6) *Do not place the electrodes on the carotid sinus region.*
7) *Do not place the electrodes over the eyes, pregnant women's waist or abdomen or other specific areas.*
8) *Do not use it on persons whose treatment area with bleeding tendency, metal matter or tuberculous lesions.*
9) *Do not place the electrodes over areas in which symptoms of existing thrombosis or thrombophlebitis are present.*
10) *Do not place the electrodes over areas with acute suppurative inflammation symptoms.*
11) *Do not place the electrodes over areas of skin allergy, infection, rash, wound or scars.*
12) *Do not place the electrodes over malignant tumors.*
13) *Do not place the electrodes over areas of fracture or dislocation.*
14) *Other specific conditions or diseases that doctors deem at risk.*

Adverse Effects

You should stop using the device and consult your doctor if you experience adverse reactions to the device. Possible adverse reactions may include the following:

- *skin irritation beneath the electrodes;*
- *burns beneath the electrodes;*
- *headaches or other painful sensations.*

Safety Instructions

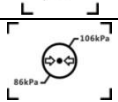
Symbols

1. Medical Device Symbols

Symbols	Explanation
	*Manufacturer*
	*Date of Manufacture*
	*Proper waste disposal for electrical and electronic equipment (WEEE)* *(See disposal for instructions.)*
	*Type BF Applied Part(s)*

IP22	*Protected against solid foreign objects of 12.5 mm (0.5 in) diameter and greater; Protected against vertically falling water drops when the enclosure tilted up to 15°.*
Rx only	*Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.*
	*This device emits non-ionizing radiation.*
	*This symbol indicates that this device is a Class II equipment according to IEC 60601-1 (when charging).*
	*Refer to the instruction manual/ booklet.*
	*ON/OFF Button*

2. Package Symbols

Symbols	*Explanation*
	*This Way Up*
	*Fragile, handle with care*
	*Keep Dry*
	*Temperature Limitation: between -20°C and +55°C*
	*Humidity Limitation: less than 93%*
	*Atmospheric Pressure Limitation: between 86kPa and 106kPa*

Precautionary Definitions

Specific symbols indicate the precautionary instructions in this section and throughout this manual. Understand these symbols and their definitions before operating this equipment. The definitions of these symbols are as follows:

CAUTION

Text with a "CAUTION" indicator will explain possible safety infractions that could potentially cause minor to moderate injury or damage to equipment.

WARNING

Text with a "WARNING" indicator will explain possible safety infractions that will potentially cause serious injury and equipment damage.

Refer to the Instruction Manual/Booklet

NOTE: *Throughout this manual, "NOTE" may be found. These Notes are helpful information to aid in the particular area or function being described.*

 *Type BF applied part (i.e. electrodes) complying with IEC 60601-1.*

Warnings and Cautions

Please carefully read and understand the following warnings and cautions to ensure the safe and correct use of MyndStep and prevent injury.

- *Read, understand and practice the precautionary operating instructions. Know the limitations and hazards associated with using MyndStep. Observe the precautionary and operational decals placed on the unit.*

- *Before using MyndStep, make sure you have read and understood all information provided in this manual. Familiarity with the information included in this manual is an essential requirement to ensure efficient and optimal system use, avoid dangers to persons and the equipment, and obtain good treatment results.*
- *Improper installation, operation, or maintenance of MyndStep may result in malfunctions of this unit or other devices.*
- *Do not use when there is a mixture of the flammable anesthetic gas and air, a mixture of the flammable anesthetic gas and oxygen or nitrous oxide.*
- *In case of device failure or other obvious defects, switch the unit off immediately and notify a certified service technician.*
- *Adjustments or replacement of components may result in the equipment failing to meet the requirements for interference suppression.*
- *The long-term effects of electrical stimulation are unknown.*
- *Do not apply stimulation over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.*
- *Do not apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in the closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.*

- *Do not apply stimulation over or in proximity to cancerous lesions.*
- *Do not apply stimulation across the patient's chest because introducing an electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.*
- *Since the effects of brain stimulation are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.*
- *Do not apply stimulation over swollen, red, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).*
- *Do not apply stimulation when the patient is in the bath or shower.*
- *Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.*
- *Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.*
- *Do not use this unit for purposes other than treatment indicated in this manual.*
- *Do not use MyndStep with high-frequency surgical equipment on the patient. It will cause unstable output when the unit is close to the high-frequency equipment (in the same room and without a shield).*
- *Do not use this device simultaneously with other therapeutic devices (such as microwave or*

shortwave) to avoid misoperation. Operation close (e.g. 1 m) to a shortwave or microwave therapy device may produce instability in the device output.

- *Output current density is related to electrode size. Improper application may result in patient injury. Proceed systematically with caution when the current density is over 2 mA/ cm².*
- *Do not modify this device without the authorization of the manufacturer.*
- *MyndStep contains built-in batteries that the user cannot remove. Do not replace it by yourself to avoid damaging the batteries or device. If necessary, please contact the company or the company authorized maintenance personnel to replace them.*
- *Please dispose of the equipment and other accessories according to local regulations. Do not treat them as household waste. Do not put the device in fire or water. If the batteries are not properly disposed of, it may cause a battery explosion.*
- *Do not use the unit when it is charging.*

CAUTION

- *Always check the device and the electrodes for damage before use.*
- *If the unit is not functioning properly or you feel discomfort, immediately stop using the unit. If you feel any trouble with your body or skin, consult the doctor and follow his/her instructions.*
- *The self-adhesive electrode is limited to the same person to use, do not use in other patients to*

prevent infection.

- *If the electrode loses viscosity, please replace the electrode in order to maintain good electrical properties.*
- *The safety of electrical stimulation during pregnancy has not been established.*
- *Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.*
- *Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process.*
- *Use caution if stimulation is applied over the uterus when menstruating.*
- *Use caution if stimulation is applied over areas of skin that lack normal sensation.*
- *Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.*
- *Keep this device out of the reach of children.*
- *Do not use this unit while sleeping. The main unit may develop trouble, or the pad may move to an unexpected region and cause ill health.*
- *Clean the device using a soft dry cloth. Do not use cleaning solvents or other chemical substances in order to avoid any damage.*
- *Make sure that you end the treatment by switching off the unit or by setting the intensity to 0 mA*

before you remove the unit or the electrodes. If you do not end the treatment, you may experience an unpleasant sensation in your fingers. This sensation is not harmful but can be unpleasant.

- *Handle the unit with care. Do not drop, knock, or shake the unit. Rough handling can damage internal circuit boards.*
- *Use this device only with the charger, cables, electrodes, and accessories recommended by the manufacturer.*
- *Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium (gel).*
- *Always disconnect the power charger from the mains after use.*
- *Please charge the unit at least every three months during long-term storage.*
- *Federal law restricts this device to sale by a practitioner licensed by the law of the State.*
- *Due to a mobile phone system upgrade or cyber-security upgrade, we will update MyndStep Application in time. If the MyndStep Application fails due to a mobile phone system upgrade or other reasons, you can download the latest version of the application from the APP store. Please contact MyndTec Inc. for help if the problem still exists*

FCC

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device under Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used under 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.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

CAUTION

- *This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:*

  1) this device may not cause harmful interference, and

  2) this device must accept any interference received, including interference that may cause undesired operation.

WARNING

- *This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating with any other antenna or transmitter.*

FCC ID: 2ANHPLGT-233

Bluetooth®

The Bluetooth SIG, Inc. owns the Bluetooth® word mark and logos, and any use of such marks by MyndTec Inc. is under license.

Communication between the main unit and the MyndStep Application on the smart phone is via Bluetooth.

Bluetooth Specifications:
Bluetooth Version: 4.0
Frequency Range: 2.402 GHz - 2.4835 GHz
Modulation Type: GFSK
Effective Radiated Power: 0 dBm
Quality of Service (QoS)
Throughput: > 6.4Kb/s
Latency: < 500ms
Packet Error Rate: <10%

EMC Guidance

MyndStep needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. This device has been thoroughly tested and inspected to assure proper performance and operation.

WARNING

- *Keep MyndStep away from active HF surgical equipment, and the RF shielded room of a medical device for magnetic resonance imaging, where the intensity of EM disturbances is high.*
- *Do not place MyndStep adjacent to or stacked with other equipment, or it could result in improper operation. If such use is necessary, all the devices should be observed to verify that they are operating normally.*
- *Portable RF communications equipment (including peripherals such as antenna cables and external antennas) other than the smart phone to be used with MyndStep should be used no closer than 30 cm (12 inches) to any part of MyndStep, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.*
- *Use of accessories, transducers and cables other than those specified or provided by the*

manufacturer of MyndStep could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Accessory Information:

Item	Cable Length	Manufacturer & Part Number
Power cord with adapter	1.0 m	Shenzhen Longxc Power Supply Co., LTD 3/f, B building, Wentao Industrial Park, Yingrenshi Yongxin Road, Shiyan street, Bao'an District, 518108 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Electrode lead wire	0.3 m	MyndTec 800111

Guidance and manufacture's declaration – electromagnetic emission		
MyndStep is intended for use in the electromagnetic environment specified below. The customer of the user of MyndStep should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	MyndStep 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 emission CISPR 11	Class B	MyndStep 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 emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
MyndStep is intended for use in the electromagnetic environment specified below. The customer or the user of MyndStep should ensure 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 ±2,4,8,15 kV air	±8 kV contact ±2,4,8,15 kV air	Floors should be wood, concrete or ceramic tile. If the floor is 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	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage	0% U_T; 0.5 cycle (0°,45°, 90°, 135°, 180°, 225°, 270° and 315°)	0% U_T; 0.5 cycle (0°,45°, 90°, 135°, 180°, 225°, 270° and 315°)	Mains power quality should be that of a typical commercial or hospital environment. If the user of MyndStep requires continued

variations on power supply input lines IEC 61000-4-11	0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	operation during power mains interruptions, it is recommended that MyndStep be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) 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.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity (Continued)			
MyndStep is intended for use in the electromagnetic environment specified below. The customer or the user of MyndStep should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz 6 V rms in ISM bands and amateur radio bands between 150 kHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 150 kHz - 80 MHz 6 V rms in ISM bands and amateur radio bands between 150 kHz and 80 MHz 80 % AM at 1 kHz	N/A
Radiated RF IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	N/A
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment		N/A

Table: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	Band (MHz) [a]	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse Modulation [b]: 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 Hz deviation: 1 kHz sine	2	0.3	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse Modulation [b]: 217 Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b]: 18 Hz	2	0.3	28

1720 1845 1970	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b]: 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n , RFID 2450, LTE Band 7	Pulse Modulation [b]: 217 Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation [b]: 217 Hz	0.2	0.3	9

NOTE: a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.

Inspection of the Goods

1. Unpacking the Unit

The unit is generally delivered with the packaging material supplied by the manufacturer. Proceed as follows:

- *Position the transport packaging so that the arrows are pointing upward.*
- *Remove the transport packaging upward.*
- *Remove the remaining foam material.*

2. Inspections

Immediately upon unpacking the unit, perform the following steps:

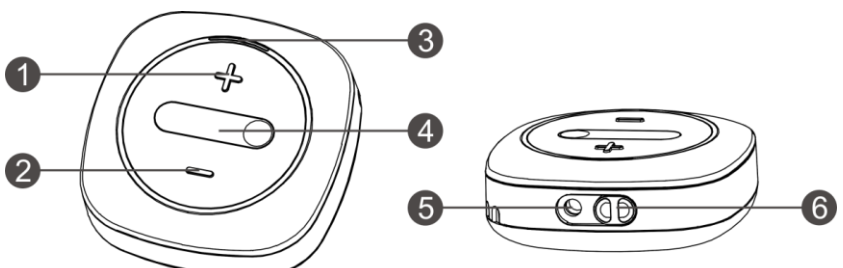
1) *Verify the delivery documents to ensure that the delivery is complete.*
2) *Check the external components and accessories for possible damage due to transport.*
3) *Verify that the packaging contains the following:*

No.	Item Name	Amounts	Unit
1	MyndStep Foot Drop Stimulator (800102)	1	set
2	MyndStep Power Adapter (800114)	1	piece
3	MyndStep Lead Wire (800113)	1	piece
4	MyndStep Self-Adhesive Electrode with Magnetic Connection (800111)	4	pieces
5	MyndStep Foot Drop Brace (800112)	1	piece
6	MyndStep User Manual (800115)	1	piece

*Other parts of **MyndStep** are available as accessories on demand. Visit the website **www.myndtec.com** or call us at 1-888-363-058 to obtain more information.*

Overview of the Unit

1. Nomenclature



1	Increasing intensity button	4	ON/ OFF button
2	Decreasing intensity button	5	Output socket: connect electrode lead hose
3	Indicator light: see table: meaning of indicator light	6	Micro-USB port: connect power adapter. Slide the slider to output sockets when charging.

Table: meaning of indicator light

Status	Indicator color	Way of flashing
Power off	None	None
Bluetooth is connecting	Green	Flash at 3Hz frequency. Flash at 1Hz after successful connection
Ready	Green	Flash at 1Hz frequency
Stimulation on (may be ＞10mA (r.m.s) or 10V (r.m.s))	Yellow*-1	Slight light
Low battery cannot be used	White	Flash at 3Hz frequency for 1s, and then turn off the unit.
Charging	Blue	Flash at 1Hz frequency
Fully charged	Blue	Always bright
Electrodes fall off during treatment	White	Flash at 1Hz frequency

NOTE: The device can deliver an output of more than 10mA (r.m.s) or 10V (r.m.s), when the output intensity is set to more than 10 mA.

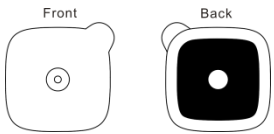
2. Accessories

2.1 Lead Wire

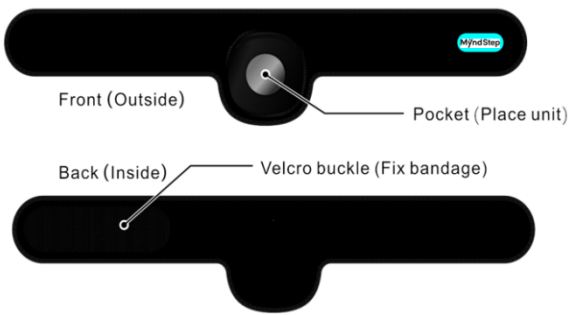
1	The side for connecting device output socket;
2	The side for connecting electrodes.

2.2 Self-adhesive Electrode

The part which contacts the patient is the backside of the electrode, and the material is a conductive hydrogel. When using, place the electrodes on the patient's skin, and connect the snap button of the electrode to the electrode lead hose. Before applying electrodes to the patient skin, you should use alcohol or soapy water to clean the skin first.

No.	Model	Picture	Size	Connector	Remark
1	800111		50mm×50mm (square)	Snap Φ 3.0 mm	Standard

2.3 Foot Drop Brace



MyndStep Application

MyndStep *can only be used with the software provided by MyndTec.*

- ***Name of the software:*** *MyndStep*
- ***Release Version:*** *1.0 (Android & iOS)*
- ***Software operating environment:***

  Android 4.3 or later mobile phone, with 4.0 Bluetooth.

  IOS 8.0 or later iPhone mobile phone, with 4.0 Bluetooth.

1. Download and Install

You can download the MyndStep Application from the APP stores. Download the Android version from Google Play and the IOS version from Apple App Store.

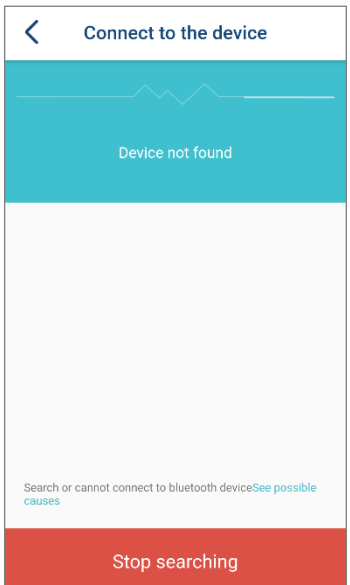
Click the MyndStep Application installation package on your phone, and follow the prompts to install the application.

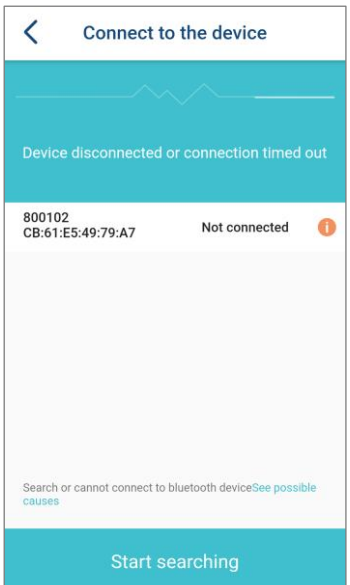
2. Connect the Device

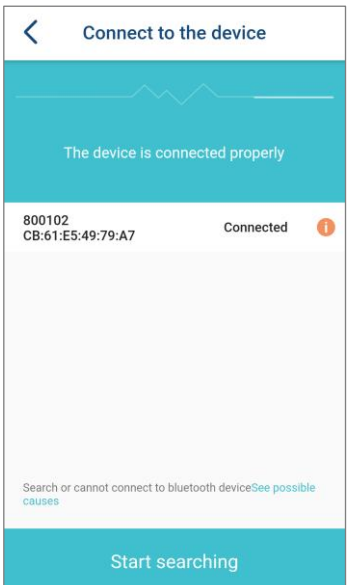
Click “click here to connect the device” at the main interface to connect the MyndStep Application on the phone and the device via Bluetooth.

The APP will search the devices automatically, as shown below. When it searches, the interface will display the device found. Click the device that has searched to connect the device until it becomes “Connected”, which means the device has connected.

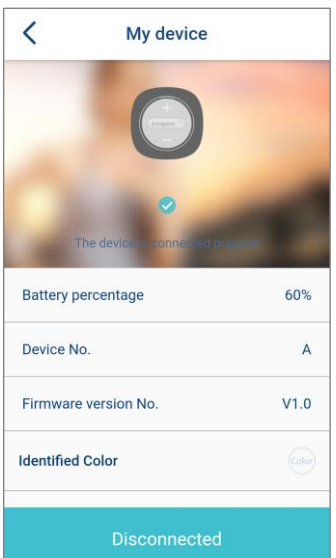
The Bluetooth address of the unit is below the product model. You can paste this Bluetooth address on the unit to distinguish another unit.

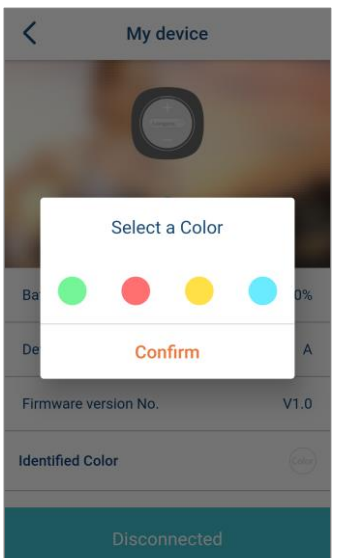

Connect to the device
Device not found
Search or cannot connect to bluetooth deviceSee possible causes
Stop searching

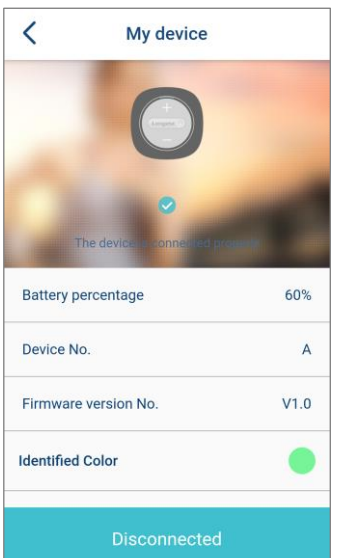

Connect to the device
Device disconnected or connection timed out
800102
CB:61:E5:49:79:A7
Not connected
Search or cannot connect to bluetooth deviceSee possible causes
Start searching

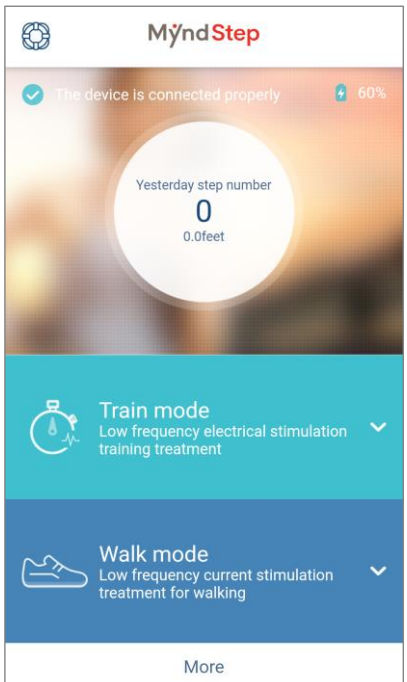

Connect to the device
The device is connected properly
800102
CB:61:E5:49:79:A7
Connected
Search or cannot connect to bluetooth deviceSee possible causes
Start searching

Click  *to view the device information, such as battery percentage, hardware and software version of the device. Also, you can click "Identified Color" to select a color to distinguish other units. Select a color and confirm, then paste the same color label on the unit surface.*









3. Main Interface

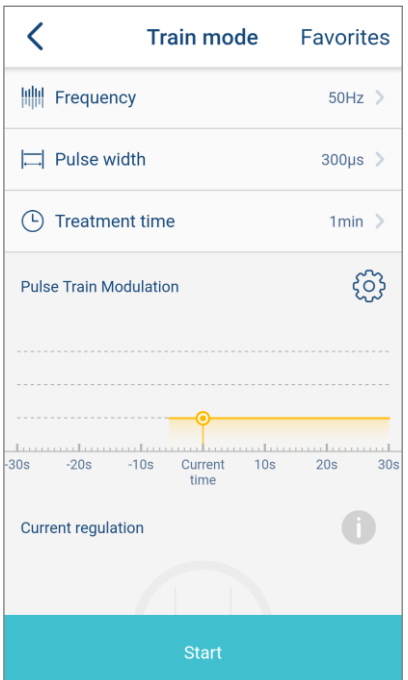
*Open the **MyndStep** APP and you can see the main interface, as shown on the left.*

The software has the power display function; the main interface in the upper right corner shows the main unit's power.

There are two modes on the MyndStep: Train Mode and Walk Mode.

Train mode is suitable for muscle training for patients who need active training to help sit or lie down. It promotes muscle recovery, prevents muscle atrophy, improves joint range of motion, and increases local blood circulation.

Walk mode assists patients in walking with electrical stimulation. It helps patients restore their gait and provide the correct way of walking. In addition, it helps patients rebuild the brain's motor function to restore their walking function.

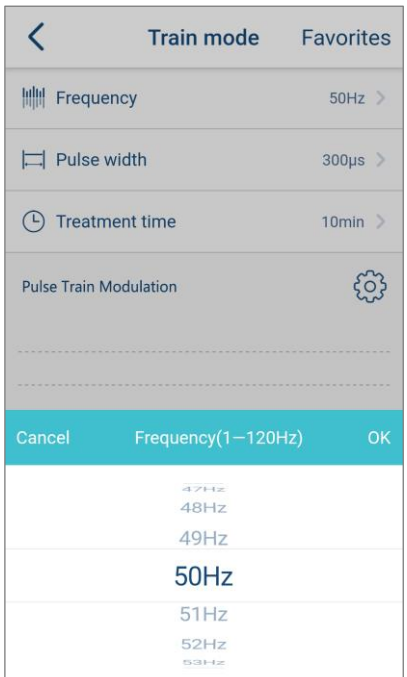


3.1 Train Mode Interface

1) Enter the train mode interface

Click Train Mode at the main interface to enter this interface, as shown on the left.

The current regulation module displays the connection status. The gray circle indicates that the device did not connect. Once it connects, it will become blue, as the following picture shows.



2) Set the parameters

***Frequency**, expressed in Hz, defines the repetition rate of the pulses.*

***Pulse duration** (or pulse width), expressed in μs, defines the length of the pulse.*

Set frequency, pulse width (pulse duration) and treatment time

Take frequency setting as an example. Click the frequency bar, and pop up the frequency setting window, as shown on the left. Swipe up or down to select the desired frequency value (range from 1 Hz to 80 Hz), and then click the OK button. The frequency bar displays the selected frequency value.

Set the Pulse Train Modulation

Click the icon , and enter the Pulse Train Modulation Interface, as shown on the left picture.

Set each parameter under Pulse Train Modulation. The setting method is the same as the frequency setting. After all the settings are complete, click the OK button, and the page jumps to the training mode interface.

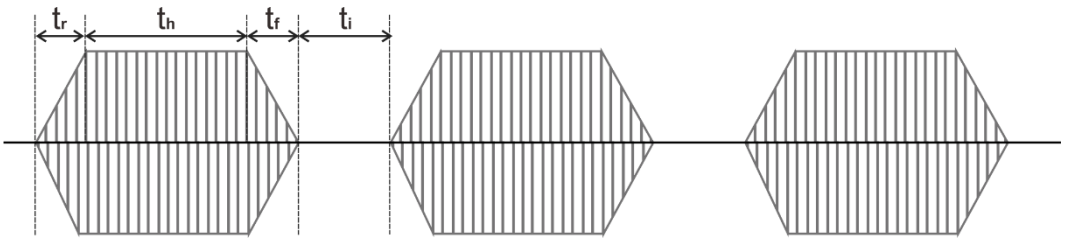
Table: Parameter setting of Train Mode

Parameter Setting	Range	Default	Increment
Frequency Hz	10-80	50	1
Pulse Duration μs	50-500	300	10
Pulse Train Modulation *-1			
Ramp up time s	0.5-5.0	1.0	0.5
Hold time s	1.0-30.0	3.0	1.0
Ramp down time s	0.5-5.0	1.0	0.5
Interval time s	2.0-60.0	10.0	1.0
Treatment time min	1-60	10	1
Output intensity mA*-2	0-100	0	1

-1 Pulse Train Modulation is a type of amplitude modulation program. The Interface is as shown on the left. -- details in the* ***Parameter Description of Pulse Train Modulation**.*

**-2 The output intensity can only be adjusted after starting.*

Parameter Description of Pulse Train Modulation

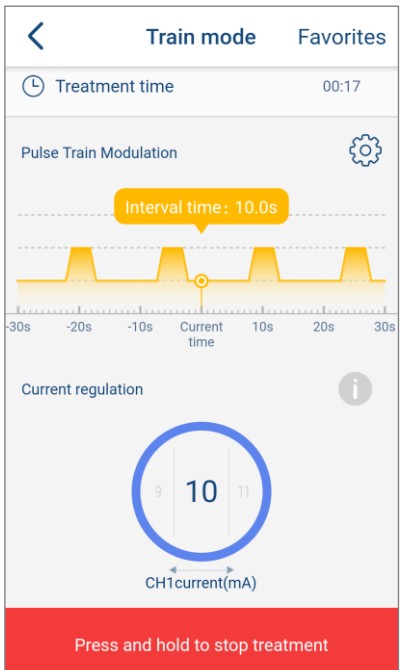


***Ramp up time (t_r)**: the time of the intensity gradually increases from 0 to the set level to avoid a sudden increase in intensity and make the treatment more comfortable.*

***Hold time (t_h)**: the time that the intensity is maintained at the set level, is the time when the electrical stimulation is activated.*

***Ramp down time (t_f)**: the time of the intensity gradually decreases from the set level to 0, in order to avoid a sudden decrease in intensity and to make the treatment feel more comfortable.*

***Interval time (t_i)**: the duration of no intensity output. The interval time avoids muscle fatigue caused by long-term muscle contraction and performs a power-off rest.*



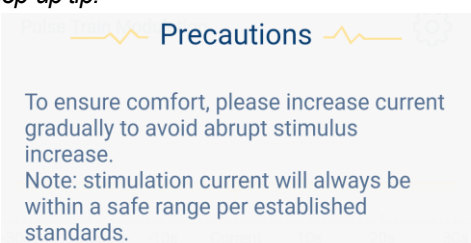
3) *Start treatment*

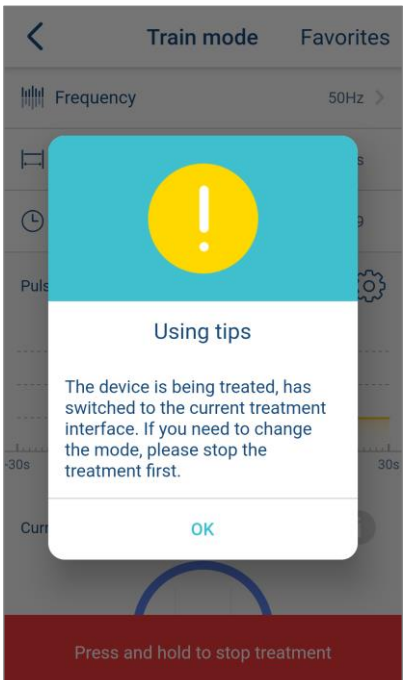
When the parameters are set, click the start button to start the treatment. Meanwhile, the circle will turn blue.

4) *Adjust output intensity*

***Output intensity**, expressed in mA, defines the amplitude of the pulse.*

After clicking the start button, the output intensity can be adjusted. Swipe left or right on the Current regulation circle to select the output intensity. Click the  *button to view the interface pop-up tip:*



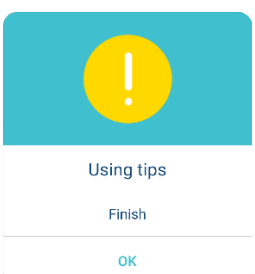


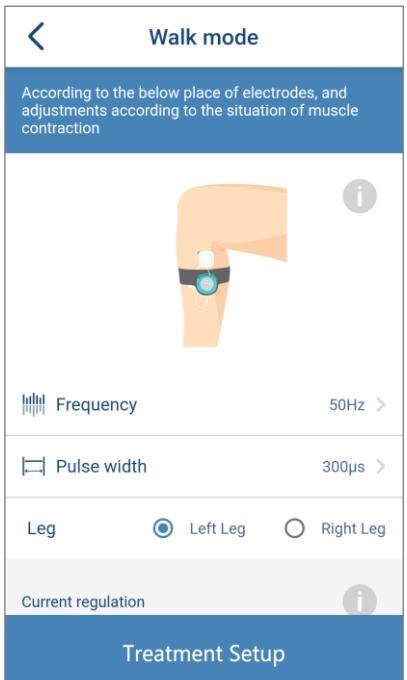
5) Tips to change mode

If you click other modes during the treatment, the interface will automatically go to the current treatment interface and appear as shown on the left. If you want to change the mode, press and hold the stop button to stop the current treatment.

6) End of the treatment

At the end of the treatment, the unit stops output. The indicator is switched from yellow to green and flashes at 1Hz frequency, and the mobile application interface shows "the treatment is finished". Press the OK button to return to the pre-start state.





3.2 Walk Mode Interface

1) Enter the walk mode interface

Click Walk Mode at the main interface to enter this interface, as shown on the left.

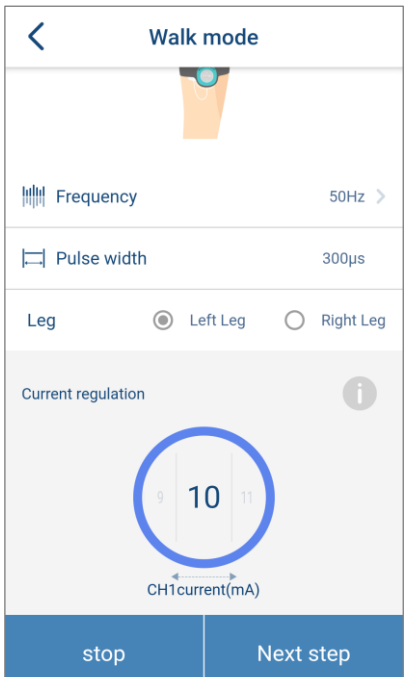
The current regulation module displays the units which had connected. The gray circle indicates that the device did not connect. Once it connects, it will become blue.

2) Electrode Placement Tips

Click *at this interface to view the pop-up prompt box. You can place the electrodes according to this guidance.*

3) Select right or left leg

Select the left or right leg according to the actual situation. This will affect the measurement of the angle.



4) Set the parameters

Table: the parameter setting of Walk Mode

Parameter Setting	Range	Default	Increment
Frequency Hz	10-80	50	1
Pulse duration μs	50-500	300	10
Output intensity mA*[1]	0-100	0	1

*[1] *The output intensity is adjustable only after starting.*

5) Treatment Setup

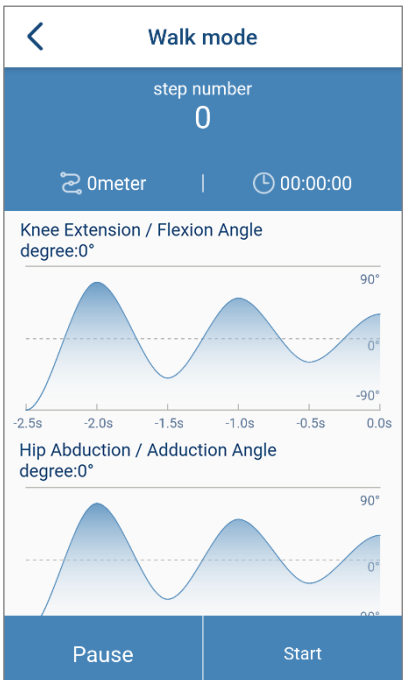
After setting the output frequency and pulse duration, click Setup. Adjust the output current and frequency according to your muscle contraction.

Note: The therapist or patient must ensure the leg side being treated matches with the left or right leg selection on the screen, This will enable the selection of the right current intensity to suit the patient's needs.

6) Calibrating the sensor

After setup click next step to jump to the interface of Sensor calibration.

At this stage, there is no electrical stimulation output. Stand upright according to the figure on the APP and click on "Calibrate" to calibrate the sensor.

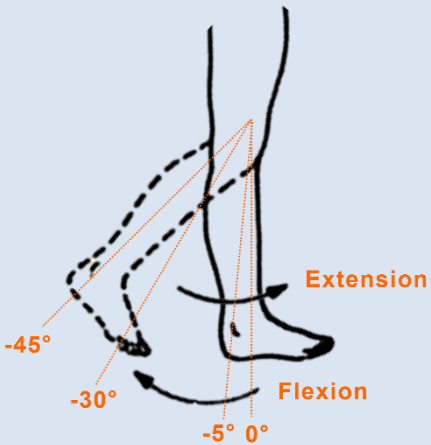
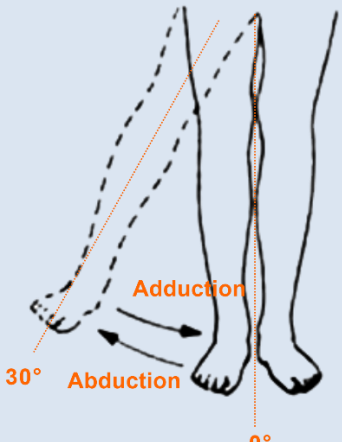


7) Enter the treatment interface of Walking Mode

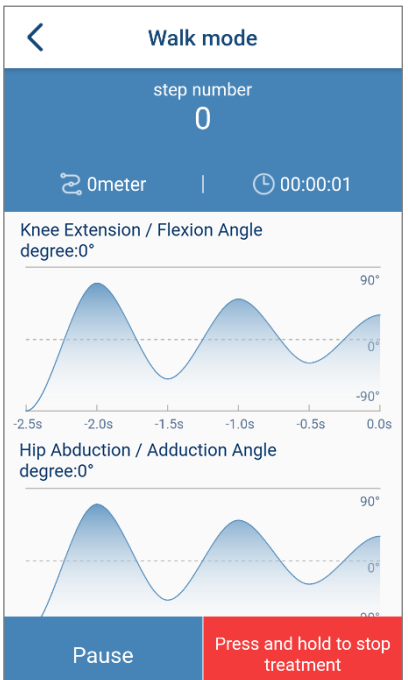
After the calibration is completed, it will automatically enter the walking mode treatment interface.

The following parameters are displayed in real-time after startup:

ITEM	Description
step number 0	*Displays the step numbers you have walking.*
0meter	*Displays the distance you have walked.*
00:00:00	*Displays the time you have spent walking.*

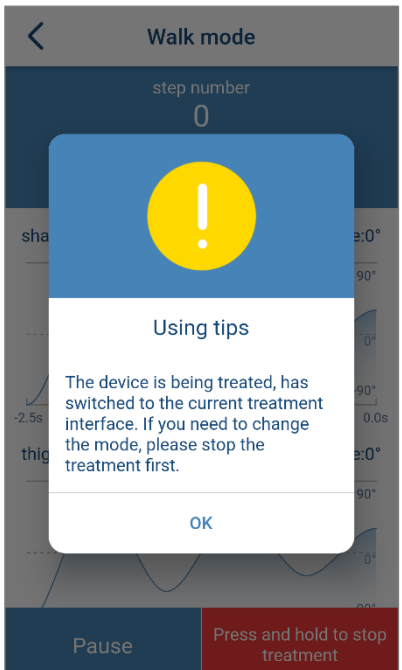
Knee Extension/Flexion Angle	*Hip Abduction/Adduction Angle*
	

NOTE: *The device can trigger electrical stimulation when the patient's knee angle rises to -30°, and it can trigger electrical stimulation. When the patient's knee angle drops to -5°, the device's electrical stimulation output is turned off. The duration of electrical stimulation is 1s-3s.*



8) Start treatment

Click the start button to start the treatment. The output current is the value of the previous–intensity setting. The intensity can be adjusted again at this step if needed.

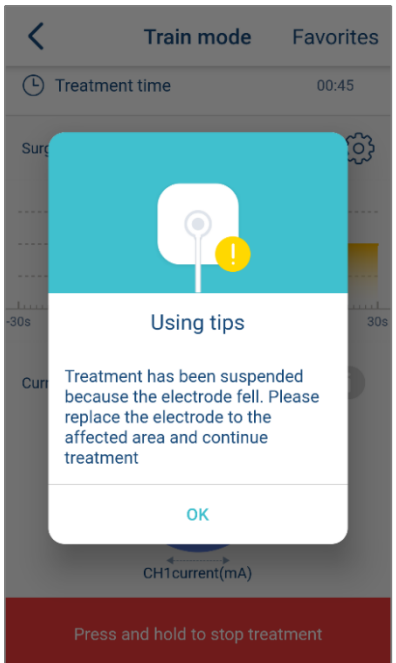


9) Tips for change mode

If you click on other modes during the treatment, the interface will automatically go to the current treatment interface and appear as shown on the left. If you want to change the mode, press and hold the stop button to stop the current treatment.

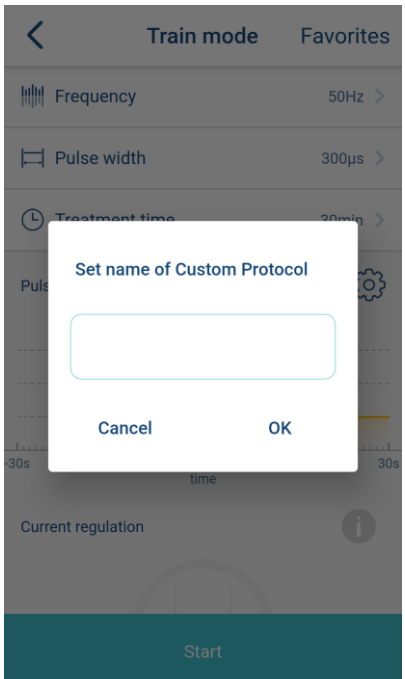
10) End of the treatment

Press and hold the stop button to stop the treatment. The unit stops output and returns to the pre-start state. The indicator is switched from yellow to green and flashes at 1 Hz frequency.



4. Open Circuit Tip

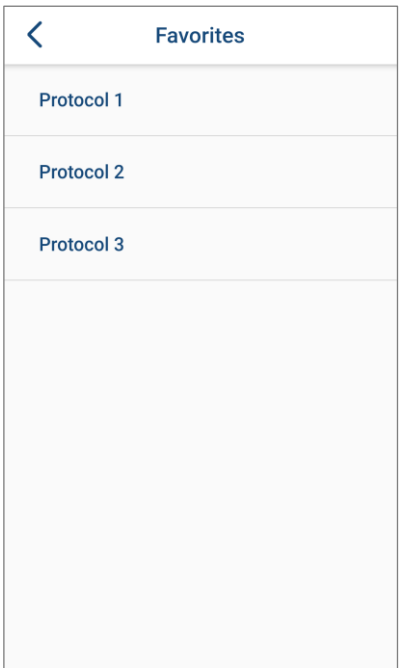
When the output is disconnected during treatment, the indicator on the device will flash white at 1 Hz; the treatment time stops counting down, and the APP displays a pop-up tip. At the same time, the device stops output (i.e., the output intensity is reduced to 0 mA). In this case, check the connection of the electrodes and press the "OK" button, and then restart the treatment.



5. About Favorites

1) Add Custom Protocol

MyndStep can save custom protocols in train mode. Click the train mode at the main interface to enter the interface, and set the frequency, pulse duration, treatment time and pulse train modulation parameters. Click "Favorites" in the upper right corner, then pop up the page as shown on the left, set the name of the custom protocol and click the OK button.



2) Enter treatment from a custom protocol

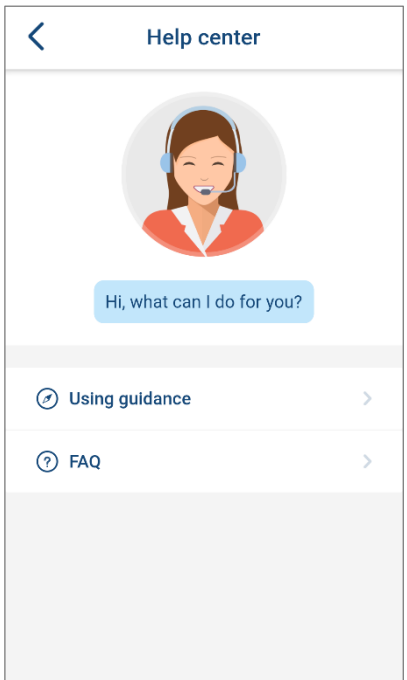
Click the icon  *in the upper right corner of the main interface, or swipe the interface in the main interface to view more. Click the icon*  *to enter the custom protocol.*

Choose one custom protocol you want and click to enter the detail page, which shows the treatment parameters of the custom protocol. Click "Enter Treatment" to enter the treatment.

For details, please refer to clause ***3.1 Train Mode Interface*** *of this chapter.*

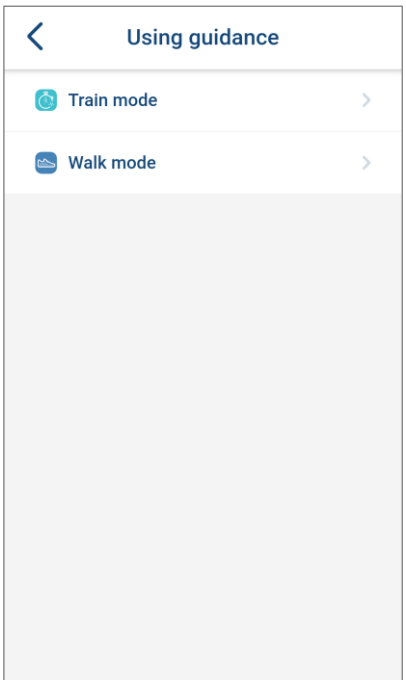
3) Delete custom protocol

Swipe the custom protocol to the left and click "Delete" in the custom protocol interface.



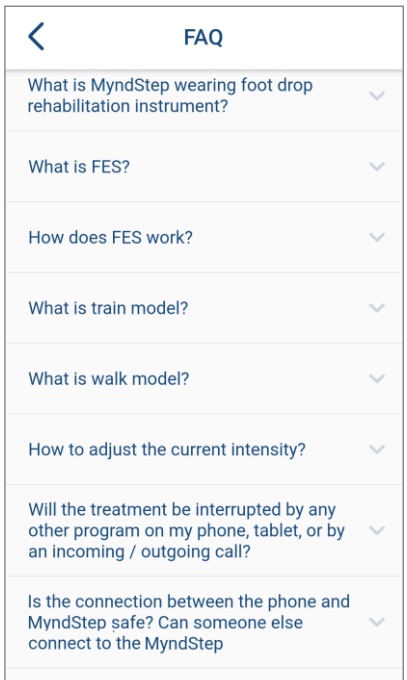
6. Help Center

Click the icon in the upper left corner of the main interface, or press "more" at the bottom of the main interface to see more, click the icon and enter the help center interface.



6.1 Using guidance

*There is some introduction on how to operate **MyndStep** to help you understand the use of the device.*



6.2 FAQ

MyndStep *Application includes a variety of common problems, and you can learn more about* ***MyndStep*** *and treatment.*

Operation Guidance

1. Preparing for Use

1.1 Charging the unit

To use the device, you first have to charge the unit. One side of the power adapter connects with the unit; another side connects with the power socket. The status indicator on the unit flashes blue during charging. The status indicator stops flashing when the battery is fully charged.

NOTE: If the rechargeable battery of the units is not fully charged when you start treatment, the batteries may run out during the treatment. We advise you always fully charge the unit before you start treatment.

NOTE: Always disconnect the power charger from the mains after use.

WARNING

- ***Do not use the unit when it is charging.***

1.2 Turn on the unit

Press the ON/OFF button to turn on the unit to standby.

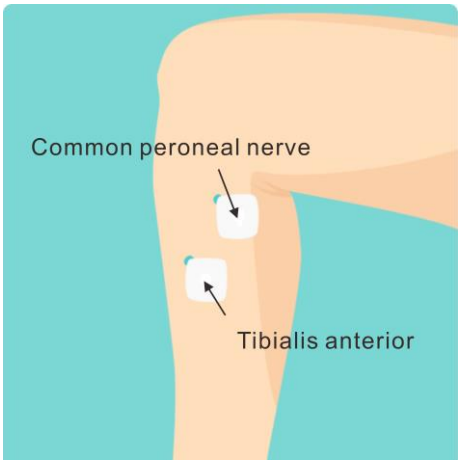
1.3 Open the MyndStep and connect

Turn on the MyndStep Application and connect the unit to your phone via Bluetooth. Two main units can be connected simultaneously, and two units can perform electrical stimulation simultaneously.

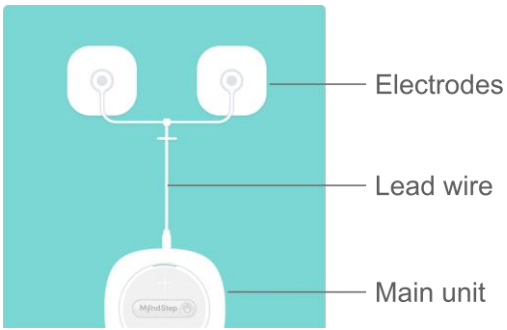
2. Starting a Treatment

- ***Train Mode***

  1) *Clean the skin and pace the electrodes: Use alcohol or soapy water to clean the skin, and remove the grease. After the skin dries, place one electrode on the Common peroneal nerve and the other one at the point of tibialis anterior of the leg (located outside of the calf).*



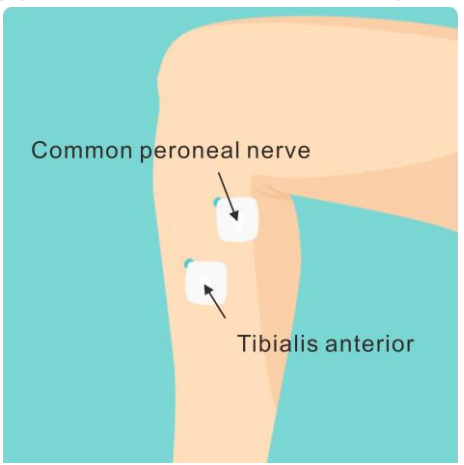
2) *Connect the unit: Connect one end of the electrode lead hose to the electrodes and the other end to the unit.*
3) *Select Train Mode and set parameters: Click Train Mode at the main interface to enter the Train Mode interface, set parameters such as frequency, pulse duration and treatment time according to the actual situation (see Clause 3.1 in chapter MyndStep Application).*
4) *Start Treatment: Click the start button, and the treatment begins.*



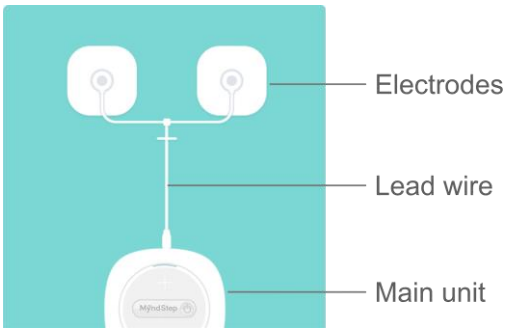
5) *Adjust output intensity: You can adjust the output intensity in the MyndStep interface or through the "+/-" buttons on the unit. The output intensity should be increased slowly from small values to avoid excessive stimulation. Because your body initially adapts to the intensity of the stimulation, you may have to adjust the intensity level after some time to ensure optimal stimulation.*

- ***Walk Mode***

1) *Clean the skin and place the electrodes: Use alcohol or soapy water to clean the skin, remove the grease. After the skin dries, place electrodes according to the schematic of the MyndStep APP. Place one electrode on the Common peroneal nerve and the other one at the point of tibialis anterior of the leg (Located on the outside of the calf).*



2) *Connect the unit: Connect one end of the electrode lead hose to the electrodes and the other end to the unit.*



3) *Select Walk Mode and setup: Click Walk Mode at the main interface to enter the interface, click Treatment Setup, and adjust output intensity.*

4) *Fix Leg Brace: After finishing setup, fix the strap on the calf according to the schematic of the MyndStep APP, and place the unit into the pocket of the Leg Brace.*

5) *Calibrate the sensor: click “next step” at MyndStep APP, Stand according to the schematic of the APP, and click “Adjust”.*
6) *Start treatment: After calibration is completed, it is automatically transferred to the treatment interface. Click the start button, and then you can start your walking training.*
7) *Adjust output intensity: You can adjust the output intensity in the MyndStep interface or through the “+/-" button on the unit. The output intensity should be increased slowly from small values to avoid excessive stimulation. Because your body initially adapts to the intensity of the*

stimulation, you may have to adjust the intensity level after some time to ensure optimal stimulation.

3. The End of Treatment

In Train Mode, the device will stop the treatment automatically after the end of the training, and the MyndStep application interface shows "the treatment is finished". In Walk Mode, you need to stop the treatment manually. Please press and hold the stop button to stop the treatment. The unit stops output. The indicator is switched from yellow to green and flashes at 1 Hz frequency.

Remove the electrodes, electrode lead wire and leg brace from your body. Stick the electrodes back to the plastic film, place them in the storage box along with the main unit, electrode lead wire and leg brace, and store them in a cool and ventilated place, ready for the next use.

Care and Maintenance

1. Cleaning

1) *Turn off the device before cleaning and disinfection;*
2) *For the main unit cleaning, what is recommended are a clean, soft damp cloth for stains, and a clean, soft dry cloth for dust on the surface of the main unit;*
3) *Clean the Leg Brace: Wipe the surface with a damp cloth or antiseptic wipe after use. It can be washed if necessary: moderate amount of neutral detergent, soak for a short time, be careful, gently rinse and dry naturally. Not machine washable; do not use bleach.*

- ***Do not clean the main unit with an organic solvent such as gasoline or diluents; otherwise, it could be deformed, and the paint may peel off.***

2. Routine Maintenance

If it is used under the user manual's instructions, the device does not require particular regular maintenance.

The manufacturer will provide circuit diagrams, component lists, descriptions, and calibration instructions to assist service personnel in parts repair.

Check the unit and accessories at regular intervals.

1) *Check the power line to ensure no distortion, fracture, etc. These circumstances may cause a fire hazard. Please replace a new power line immediately.*
2) *Replace the electrodes if:*
   -- they are damaged or torn.
   -- they are past the use-by date.
   -- they have lost their adhesiveness. Never use plaster or tape to attach them to your skin.
   -- stimulation feels weaker.
   -- when the stimulation is uncomfortable, i.e., you experience an unpleasant stinging or biting sensation.

NOTE: Always replace the electrodes with electrodes recommended for this device by the manufacturer.

WARNING

- ***Never perform unauthorized service work. All service work must be performed only by service technicians whom the manufacturer has authorized.***

3. Disposal

According to EC Directive – WEEE (Waste Electrical and Electronic Equipment), the equipment must not be disposed of as unsorted municipal waste and must be collected separately. Dispose of this product according to local regulations. Contact your local authorities for information regarding the disposal of the unit and accessories.

This symbol indicates that batteries contain substances that may be harmful to humans or the environment. Never dispose of these batteries with household waste. Please take them to an official collection point or a service center to remove the rechargeable battery and follow the local rules for a separate collection of the batteries.

Troubleshooting

*This chapter summarizes the most common problems you could encounter with **MyndStep**. If you are unable to solve the problem with the information below, please call your distributor.*

Issue	Possible causes	Solutions
1. The indicator does not light up at all when pressing the ON/OFF button	The battery of the unit is empty.	Charge the unit (see chapter Preparing for use').
2. The MyndStep APP on the mobile phone could not connect with the unit.	1. The unit is not turned on; 2. Mobile phone Bluetooth is not open or mobile phone Bluetooth problems 3. the distance between the mobile phone and the unit is too far; 4. The unit has connected to another mobile. 5. The unit is asleep, and Bluetooth is stopped; 6. Other reasons.	1. Turn on the unit; 2. Please turn on the Bluetooth on the mobile phone or change to another mobile phone; 3. Please keep the mobile phone near the unit; 4. Disconnect the connected phone or restart the unit; 5. Restart the unit; 6. Turn off the APP background operation, and restart the phone Bluetooth.

Issue	Possible causes	Solutions
3. The status indicator on the unit flashed white, and the unit switched off.	The battery of the unit is empty.	Charge the unit (see chapter Preparing for use).
4. There is no output.	1. Did not press the start button; 2. Did not adjust the output intensity; 3. The electrode lead wire is poorly connected; 4. The electrode lead wire has been damaged.	1. Press the start button; 2. Adjust the output intensity; 3. Re-connect the electrode lead wire; 4. Replace a new electrode lead wire.
5. Stimulation is uncomfortable.	1. The output intensity is too high; 2. Electrodes are too close together; 3. Damaged or worn electrodes or electrode lead wires; 4. Electrode active area size is too small.	1. Decrease the output intensity; 2. Re-position the electrodes; 3. Replace the lead wires; 4. Replace electrodes with ones that have an active area no less than 25.0 cm^2.

Issue	Possible causes	Solutions
6. The MyndStep APP on the mobile phone pop up tips “electrodes fall off”, and the indicator of the unit flashes white.	1. The electrode lead wire is poorly connected; 2. The electrodes are in poor contact with the skin; 3. Electrodes do not stick well.	1. Re-connect the electrode lead wire; 2. Re-connect the electrodes and lead wires; 3. Replace electrodes. Apply electrodes to a clean, dry surface.
7. The unit has output but treatment without sensation.	The output intensity is too low.	Increase the output intensity.

Technical Specifications

1. Stimulator Output Parameters

<table>
<tr><td>Channel:</td><td>Single channel</td></tr>
<tr><td>Output Waveform:</td><td>Symmetrical biphasic pulse</td></tr>
<tr><td>Treatment Mode:</td><td>Train Mode and Walk Mode.</td></tr>
<tr><td>Pulse Duration:</td><td>Adjustable, 50-500μs, increments of 10μs</td></tr>
<tr><td>Pulse Frequency:</td><td>Adjustable, 10-80Hz, increments of 1Hz</td></tr>
<tr><td>Pulse Train Modulation:
(for Train Mode only)</td><td>
<table>
<tr><th>Parameter</th><th>Range</th><th>Stepping</th></tr>
<tr><td>Ramp up time (s)</td><td>0.5–5.0</td><td>0.5</td></tr>
<tr><td>Hold time (s)</td><td>1.0–30.0</td><td>1.0</td></tr>
<tr><td>Ramp down time (s)</td><td>0.5–5.0</td><td>0.5</td></tr>
<tr><td>Interval time (s)</td><td>2.0–60.0</td><td>1.0</td></tr>
</table>
</td></tr>
</table>

Trigger timing and duration of electrical stimulation (for Walk Mode only)	When the patient's extension/flexion rises to -30°, the device can trigger electrical stimulation, and when the patient's extension/flexion drops to -5°, the device's electrical stimulation output is turned off. And the duration of electrical stimulation is 1s-3s.
Timer:	a) Treatment time: 1-60min, increments of 1min; b) Timer tolerance: ±2%; c) When finished, the device can stop output and prompt.
Output Intensity:	Adjustable, 0-100mA, increments of 1mA (at 500Ω load)
Maximum Output Amplitudes (V):	55 V at 500 Ω Load
Maximum Current (r.m.s):	50mA r.m.s.at 500 Ω Load

2. Other Specifications

Product Name	MyndStep Foot Drop Stimulator
Model	800102

<table>
<tr><td>Software Release</td><td>Stimulator (main unit): A
MyndStep Application: 1 (Android & iOS)</td></tr>
<tr><td>Power Supply:</td><td><table>
<tr><td>Adapter model:</td><td>LXCP12X-050200DG (USA)
LXCP12X-050200BG (Europe)</td></tr>
<tr><td>Adapter supply voltage:</td><td>AC100-240V, 50/60Hz</td></tr>
<tr><td>Adapter output:</td><td>DC 5V, 2A.</td></tr>
</table>Battery: 3.7V, 1200 mAh, lithium battery.
Line Current Isolation: Patient disconnected when charging.</td></tr>
<tr><td>Expected Life:</td><td>● The expected useful life of the main unit is 4 years under normal usage (10 min per treatment, 6 treatments per day).
● The expected useful life of the electrode lead wire and leg brace is 12 months under normal usage (10 min per treatment, 6 treatments per day).
● Self-adhesive electrodes:
➢ Shelf life: 24 months
➢ Useful life: The electrodes may be used up to 15 times. These numbers vary depending on the skin and /or climate conditions as well as care of usage and storage.</td></tr>
<tr><td>Rated Power:</td><td>6VA</td></tr>
<tr><td>Dimension:</td><td>59mm (W) × 59mm (L) × 22mm (H)</td></tr>
</table>

Weight:	60g (only main unit)
Classification:	● Classification (IEC 60601-1): Class II, Type BF Applied Part; ● Ingress Protection: IP22; ● Mode of Operation: Continuous.
Environmental conditions of operation:	● Temperature: 5 to 40°C; ● Rel. humidity: 15 to 80%; ● Atmosphere Pressure: 86.0 to 106.0kPa.
Environmental conditions of transport and storage:	● Temperature: -20 to 55°C; ● Rel. humidity: ≤93%; ● Atmosphere Pressure: 86.0 to 106.0kPa.
Environmental conditions of transport and storage between uses:	● Temperature: -25 to 70°C; ● Rel. humidity: ≤90%; ● Atmosphere Pressure: 86.0 to 106.0kPa. NOTE: Except for Self-adhesive electrodes.
Works with:	Requires a smart phone with Bluetooth 4.0, Android 4.3 (or later) or IOS8.0 or later.

Assistance

Any intervention on the device must be performed by the manufacturer. For any assistance intervention and original spare parts, please contact the manufacturer at the following address:

MYNDTEC INC.
1900 Minnesota Court, Suite 122
Mississauga, ON, L5N 3C9

Info@myndtec.com
Tel: 1-888-363-0581
Fax: 1-877-796-4624

Warranty

Any unauthorized modifications or repairs will void this warranty. All repairs to the equipment must be performed by an authorized service center or the manufacturer.

1) Warranty for the main unit

- *This warranty shall remain in effect for two years (24 months) from the product's delivery date to the end customer. If the equipment fails to function during the warranty period due to a defect in material or workmanship, the manufacturer will repair it without charge. The warranty does not extend to wear parts.*
- *To validate the warranty, please complete the Warranty Card and send it with the copy of the original invoice to the email address info@myndtec.com within 7 working days of purchase.*

2) Warranty for the accessories (power adapter, leg brace and lithium battery)

- *The warranty period of the accessories (power adapter, leg brace and lithium battery) is 12 months (1 year) from the date of delivery of the product to the end customer.*
- *If the accessories (power adapter, leg brace and lithium battery) fail to function during the warranty period due to a defect in material or workmanship, at the manufacturer's option, the manufacturer or*

the authorized dealer will repair this product without charge. Damages due to non-adherence to the User Manual are excluded from the warranty.

3) This Warranty Does Not Cover:

- *Replacement parts or labor furnished by anyone other than the manufacturer, the authorized dealer or a certified company service technician.*
- *Defects or damage caused by labor furnished by someone other than the manufacturer, the authorized dealer or a certified company service technician.*
- *Any malfunction or failure in the product caused by product misuse, including, but not limited to, the failure to provide reasonable and necessary maintenance or any use that is inconsistent with the User Manual.*

MyndStep

WARRANTY CARD

www.myndtec.com

Warranty Card

Thank you for purchasing the product from MyndTec Inc In order to provide the best after-sales service with you, please fill the below table out very carefully. Any further assistance please contact your local distributor or our after-sales service.

Model Name/No.	800102 Foot Drop Stimulator	Purchase Date	
Serial Number		Warranty Period	2 years

Repair Record

Date of Repair	Trouble Description	Technician

After-sales line:1-888-363-058

User's Card

Product Name	Foot Drop Stimulator	Model Number	800102
Serial Number		Purchase Date	
User Address		Post Code	
User's Name		Telephone	
Distributor		Post Code	
Distributor Add		Telephone	
Contact Person		Facsimile	

MyndStep

MyndTec Inc.

800116 Rev 1.0