PowerDot PD-02 Muscle Stimulator

Operator’s Instructions For Use

INTENDED USE

PowerDot PD-02 uses electrical muscle stimulation (EMS) (also known as neuromuscular electrical stimulation or NMES) and transcutaneous electrical nerve stimulation (TENS) technologies to stimulate your muscles and nerves for therapeutic purposes.

For your convenience, you can operate PowerDot PD-02 wirelessly using PowerDot Doctor mobile application running from your iPad. Additionally, you can also prescribe/schedule certain stimulation programs for your patients to be executed by them in their home environment using PowerDot Patient mobile application from their iOS or Android mobile devices.

Indications for Use

PowerDot PD-02 stimulator is a prescription device which is intended to be used following the directions of a healthcare provider. The device can be either used by the therapist in healthcare facility setting (when operated from PowerDot Doctor mobile application) or by patient/lay operator in a home environment (when operated from PowerDot Patient mobile application).

PowerDot PD-02 has the following indications for use:

NMES

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasms
- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Stimulation of healthy muscles in order to improve or facilitate muscle performance

TENS

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical and post-trauma acute pain
- Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities

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.

Safety Guidelines

1. Counter-indications

Do NOT use PowerDot PD-02 for the patients with the following conditions:

- Cardiac stimulator (pacemaker), implanted defibrillator or other implanted electronic device. Such use could cause electric shock, burns, electrical interference or death.
- Body-worn electro mechanical medical devices, i.e. insulin pump.
- Serious arterial circulation problems in lower limbs.
- Abdominal or inguinal hernia
- Symptomatic local pain relief unless etiology is established or pain syndrome has been diagnosed
- Cardiac arrhythmia (do not use on chest)

2. Additional Precautions

- Use caution for patients with suspected or diagnosed heart problems
- Use caution for patients with suspected or diagnosed epilepsy
- Use caution in the presence of the following:

    - when there is a tendency to hemorrhage following acute trauma or fracture
    - following recent surgical procedure when muscle contraction may disrupt the healing process
    - over a menstruating or pregnant uterus
    - over the skin areas which lack normal sensation

- Depending on the judgement of the responsible physician, the device may only be applied under supervision and with the parameters defined by the responsible physician. Otherwise the exercise may be too strenuous for the patients with:

    - hypertension (> stage 2), ischemic heart disease and cerebrovascular diseases
    - cardiovascular diseases
    - pregnancy. Safety of powered muscle stimulators for use during pregnancy has not been established.
    - under 16 years of age

- Proceed with caution after recent surgery

- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement

3. Adverse Effects

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.
- Potential adverse effects with TENS are skin irritation and electrode burns.

4. General Safety Measures

- Read all instructions for operation before treating a patient.

- The long-term effects of chronic electrical stimulation are unknown.

- TENS is not effective for pain of central origin (including headache).

- TENS waveforms have no curative value.
- TENS is a symptomatic treatment, and as such, suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- Stop treatment immediately if patient experiences discomfort or pain.
- The choice of the therapy parameters to program, of the stimulation programs and electrode placement is restricted to the responsible physician or therapist. It is the physician's or therapist's decision whether or not to use the device on a specific patient.
- Do not apply stimulation if you patient has progressive cancer or near any cancerous tumour. The increased metabolism, caused by certain modes of stimulation, is likely to encourage cancer cells to spread.
- Proceed with caution if stimulation is applied to areas of the skin whose level of sensation is lower than normal.
- Do not apply stimulation to a person who cannot express themselves.
- Stimulators should be kept out of the reach of children

5. Device Operating Safety Measures

- Do not charge PowerDot PD-02 device while the device remains placed on/attached to any part of the patient's body.
- The patient must be familiar with the ways to terminate their stimulation session, if needed. Patients unable to operate the emergency stop function (either by pressing button on the device or by unplugging lead cables from the device), e.g. paralytic patients, must never be left unattended during therapy.
- During the muscular contraction phase it is recommended to hold the extremities of the stimulated limbs to avoid any shortening of the muscle during contraction, which could cause cramps.
- Never begin an initial stimulation session on a person who is standing. The first five minutes of stimulation must always be performed on a person who is sitting or lying down. In rare instances, people of a nervous disposition may experience a vasovagal reaction. This is of psychological origin and is connected with a fear of the muscle stimulation as well as surprise at seeing one of their muscles contract without having intentionally contracted it themselves. A vasovagal reaction causes heart to slow down and blood pressure to drop, which produces a feeling weakness and a tendency towards fainting. If this does occur, all that is required is to stop the stimulation and for the person to lie down with the legs raised until the feeling of weakness disappears (5 to 10 minutes).
- Do not wind cables around the neck. Tangled cables can cause strangulation.
- Do not apply stimulation during sleep.
- Do not use PowerDot PD-02 while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the patient at undue risk of injury.

6. Co-existence and Environmental Safety Measures

- Do not use PowerDot PD-02 in the areas where an explosion hazard may occur. An explosion hazard may result from the use of flammable anesthetics, skin cleansing agents and disinfectants as well as in the oxygen-rich environments.
- Do not use device in water or in a humid atmosphere (sauna, bath, shower etc.) that would cause electrical failure.
- Do not use PowerDot PD-02 at altitudes of over 9,800 feet.

- Do not use PowerDot PD-02 if patient is connected to a high-frequency surgical instrument as this could cause skin irritations or burns under the electrodes.

- Do not use PowerDot PD-02 in the close proximity of medical devices such as MRI, CT, diathermy, X-Ray as well as RFID equipment (e.g. electromagnetic security systems) as those could alter the current generated by PowerDot PD-02, cause tissue damage, and can result in severe injury or death. If you have any doubts when using PowerDot PD-02 device in close proximity to another medical device, please contact the device manufacturer.

- Do not use the PowerDot PD-02 within 3 feet of short wave or microwave devices as this could alter the currents generated by the stimulator. If you are in any doubt as to the use of the stimulator in close proximity to another medical device, seek advice from the manufacturer.

- Do not apply stimulation with PowerDot PD-02 near the area of an implant, such as cochlear implants, pacemakers, skeletal anchorage or electric implants. This could cause an electrical shock, burns, electrical interference or death.

- Do not apply stimulation with PowerDot PD-02 close to metal. Remove jewelry, piercings, belt buckles or any other metallic product or device in the area of stimulation.

- Disconnect the electrode pads from the device before using electrosurgical equipment, or a defibrillator, to avoid cutaneous burns from the electrodes and destroying the device.

- Apply caution when using PowerDot PD-02 near electronic surveillance equipment (e.g. cardiac monitors, ECG alarms), as there is a risk they may not work properly whilst the electrical stimulation device is being used.

- Do not use PowerDot PD-02 in areas in which unprotected devices are used to emit electromagnetic radiation. Portable communications equipment can interfere with the device.

7. Electrode Pads Placements Safety

NEVER attach electrodes:

- Transcerebrally, or on the eyes

- On the front and sides of the patient's neck or mouth because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure

- Stimulation should not be applied over the carotid sinus nerve particularly in patients with a known sensitivity to the carotid sinus reflex.

- Counter-laterally, i.e. one stimulator should not be applied on opposite sides of the body.

- Transthoratically, to the patient's front torso (i.e. chest or abs) and back torso (i.e. upper back, lower back) *simultaneously.* Introduction of electrical current into the heart may cause cardiac arrhythmia.

- Over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins)

- Over, or in proximity to, cancerous lesions

8. General Electrode Pads Safety Measures

- Always use electrode pads supplied by the manufacturer. Other electrodes may have electrical properties that are unsuitable for or may cause damage.

- For best results, wash and clean the skin of any oil and dry it before attaching the electrode pads.

- For reasons of hygiene, each patient must have their own set of electrode pads. Do not use the same electrodes on different patients.
- Contaminated electrode pads or hydrogel can lead to infection.
- Use of electrode pads with degraded hydrogel can result in burns to the skin.
- Do not place the electrode pads in water.
- Do not apply solvents of any kind to the electrode pads.
- Always stop the stimulation before moving or removing any electrode pads during a session, to avoid electrical shock to the patient.
- Attach the electrode pads in such a way that their entire surface is in contact with the skin.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode pad placement. If redness of the skin is observed under the electrode pad, do not start another stimulation session on the same area if the redness is still visible.
- Electrode pads usage and storage instructions are provided on the mylar bag with electrodes.

PowerDot PD-02 Device & Accessories

1) Power/Stimulation indicator

2) Multifunction button

3) Micro USB connector (dual function: connects either leads or charging cable)

4) Charging indicator

5) Female magnetic pad connector

6) Lead cable with two female magnetic connectors

Power/Stimulation Indicator (1):

Can be either WHITE (when the PowerDot is on or on standby mode) or ORANGE (when it's being used for stimulation).

Multifunction Button (2) Modes:

Multifunction Button carries out these PowerDot functions:

Multi-function Button Action	**PowerDot Initial State**	**PowerDot Resulting State**
Hold for ~1 second	PowerDot is OFF (no lights)	PowerDot is now ON (white light is on)
Hold for ~1 second	PowerDot is ON (white light is on)	PowerDot is now OFF (no lights)
Quick Click	PowerDot is in Stimulation (orange light is on)	Stimulation stops (orange light is ON)
Hold for 5 seconds	Device is ON	Full Factory Reset: activation lock is released, , Power LED turns OFF, after few seconds turns ON again, blinks several times and the PowerDot becomes OFF
Hold for 3 seconds	Device is OFF	Soft Reset: Activation lock is released, Power LED blinks several times

Micro-USB Connector (3):

PowerDot uses the same high voltage micro-USB connector (3) for lead cable connection and for charging.

If the device is being used for stimulation, it will immediately stop once the lead cables are disconnected from the micro-USB connector.

Charging Indicator (4):

While the device is still charging, you will see the ORANGE Charging Indicator (4) next to the micro-USB charging connector. Refer to the **Recharging PowerDot** section below for more information on PowerDot charging.

Snap Connector (5):

Used to attach and hold the PowerDot device in place on the rectangular pad.

Lead Cable (6):

For an easier, more comfortable PowerDot stimulation, two lead cables of different lengths (10 cm and 30 cm) (6) are provided with each PowerDot. These give you the option to choose the right cable to reach the muscle group you're targeting, depending on your physical measurements.

Electrode Pads (7,8):

PowerDot supports 3 types of electrode pads – 5.5 cm (2.2”) diameter round pads, 4.5 cm (1.8”) diameter round pads and 9x5 cm (3.5”x2”) rectangular pads.

PowerDot pads use unique skin biocompatible hydrogel with superb conductive qualities and adhesiveness.

The lifetime of PowerDot pads depends a lot on your individual skin properties, level of hairlessness and the quality of maintenance. On average, each pad lasts for around 20 stimulation sessions. After that, adhesiveness and conductive properties of the pads may start deteriorating.

Store the pads on the safety film, in a dry environment (either in the original zipper plastic bag or inside the PowerDot carry case). Make sure you attach the pads to clean and dry skin!

Directions For Use

1. Installing/Launching PowerDot Doctor App

1) Make sure you iPad runs iOS 9.0 or later.

2) Launch Apple App Store application, search for “PowerDot Doctor” Mobile Application and install it.

3) Launch the installed PowerDot Doctor application, create your profile and then follow instructions to locate and activate your PowerDot (or PowerDots) for the first use.

2. Turning PowerDot ON/OFF

To turn on your PowerDot PD-02 unit, hold the Multifunction Button for approximately 1 second, until you see the power light turn on. When PowerDot is not in stimulation, you can turn it off by holding the Multifunction Button again for approximately 1 second.

When a stimulation is ongoing, click on the Multifunction Button once to stop the stimulation and then hold the Multifunction Button to turn off the PowerDot.

3. Activating PowerDot

Before PowerDot PD-02 can be used for muscle stimulation, it must be activated from within your PowerDot Doctor App.

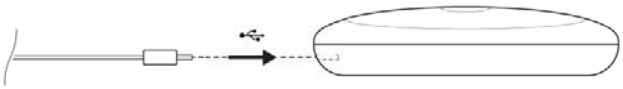
When PowerDot is activated, it gets paired with your mobile phone securely. Neither you nor anyone else will be able to connect and use your PowerDot from any other mobile device.

Follow the App’s onscreen advice to scan for and activate your PowerDots. Make sure your PowerDot (or PowerDots) is turned on before you start scanning.

Use the Devices screen (available from the PowerDot Doctor App menu) to activate another or additional PowerDot devices or to deactivate previously activated ones. You can activate and use up to 32 PowerDots from your PowerDot Doctor app.

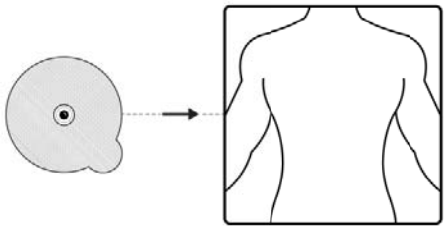
4. Preparing and Placing PowerDot

1) Plug the lead cable you intend to use into the USB Type C connector on your PowerDot PD-02 device.



2) Detach both round pads, rectangular pad from their safety film and stick them to the targeted part of your body, according to the pad placement visual guidelines provided by PowerDot Doctor App or in this manual. Based on your experience and understanding of the principles of electrical muscle stimulation, you

may try to introduce some variations to the offered pad placement set ups for better efficiency. Make sure you create and store photos of the new setups once they prove efficient. PowerDot Doctor app provides you with the functionality to store and display custom pad placement photos for your patients.



3) Attach female magnetic round pad connectors on the lead cable to the male snaps on the round pads. Attach PowerDot PD-02 device female magnetic connector to the male snap on the rectangular pad;

4) Make sure that the entire surface of the round and rectangle pads are completely and securely attached to your body;

5) It's a good time to turn on your PowerDot (or PowerDots), if you haven't done it yet.

Always thoroughly inspect the lead cable and PowerDot unit itself for any signs of damage BEFORE every stimulation session. Do not use damaged accessories or devices For your safety, you are strongly advised to replace them before using again.

5. Starting a Stimulation

PowerDot Doctor App offers multiple ways to initiate a stimulation session:

1) Initiate ad hoc stimulation session, which is not attributed to any specific patient.

   You will be asked first to select stimulation program, relevant muscle groups or body areas and adjust stimulation parameters and optionally select number of PowerDot PD-02 devices to be used before launching your session.

   We generally recommend using this option for testing or demo purposes.

2) Initiate ad hoc stimulation session for selected patient.

   - First, the relevant patient is looked up and selected on the Patients screen.
   - Secondly, you will be asked first to select stimulation program, relevant muscle groups or body areas and optionally adjust stimulation parameters before launching your session.
   - Thirdly, if relevant, you will be asked to select number of PowerDot PD-02 devices you want to engage in the current session (one or two).
   - Once this stimulation session is completed, relevant session statistics will be recorded on the patient's Sessions History screen.

   We generally recommend using this option for casual/one off sessions or when testing patient for the tolerance and/or reaction to electrical stimulation.

3) Initiate scheduled stimulation session for the selected patient.

   - First, you look up and select relevant patient from the Patients screen.

- Secondly, you will be asked to look up and select stimulation program, up to 3 relevant muscle groups or body areas and optionally select number of PowerDot devices to be used.
- Thirdly, you will be asked to select scheduling parameters, such as total duration of the program (in days), periodization of the sessions, starting date, notifications settings (about missing or late stimulation sessions).
- Fourthly, you can optionally mark stimulation sessions to be accessible for the Remote (home use) stimulation from Patient Mobile App.

Be careful when confirming stimulation sessions for remote execution by the patient!

First, you have to make sure that your patients or their caregivers are prepared for and capable of running unsupervised electrical stimulation sessions.

Specifically, they should be aware on to assemble, apply and control PowerDot PD-02, are able to follow stimulation pad placements and stimulation positions recommendations and are able to adjust their stimulation intensities in the controlled manner.

They should be also aware of the product counter-indications, basic troubleshooting and maintenance guidelines. Remote stimulation sessions are not for everyone!

- Finally, you will be asked to adjust stimulation parameters for the session (in the relevant ranges only).

Use scheduled sessions functionality whenever a stimulation course is required for the specific patient. Scheduled sessions' parameters, listed above, can be always changed/re-adjusted if required.

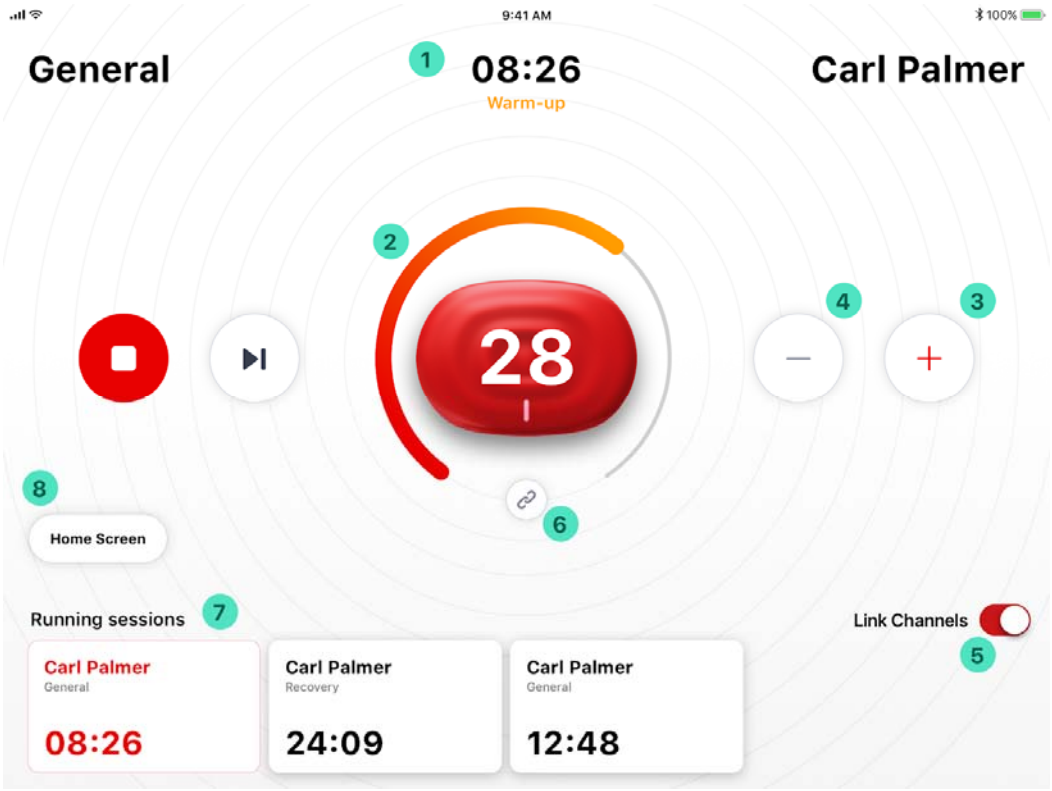
Before commencing the stimulation, PowerDot Doctor App will be asking to turn on PowerDot PD-02 device (or devices) which you are planning to use for the current stimulation session (please make sure the device has been previously activated via Devices screen). Doctor App will automatically detect turned on devices, connect to them, check for activation, display serial numbers and blink Power LED to confirm that right PowerDot PD-02 device has been selected and associated with the session.

In addition, PowerDot Doctor App will automatically check for remaining battery level and lead cable connection status for all the PowerDot PD-02 devices associated with the current session.

After the checks, Get Started button will appear, which means you can already launch the stimulation session.

6. Controlling A Stimulation

Using the PowerDot Doctor App, you can control your stimulation session from the Stimulation Dashboard, which has the following controls available:



Header Indicator (1) displays the remaining time for the total stimulation session, current stimulation phase (if applicable), name of the stimulation program and stimulation phase (if applicable), and name of the patient (if applicable).

Contraction/Rest Indicator (2) – for the stimulation programs (and individual phases) involving muscle contractions, helps to understand time between and during contraction and rest intervals.

Intensity Adjustment controls – Tap on Intensity Increase (or "+") *(3)* and Intensity Decrease (or "-") *(4)* buttons an accurate adjustment, or hold either button down for a faster adjustment.

Device-level Intensities Lock (6) and *Channel-level Intensities Lock* controls *(5)* synchronize intensity changes either a) between PowerDot PD-02 devices (this applies only to the two-device Duo stimulation mode) or (b) between two stimulation channels of individual PowerDot PD-02 device.

Both controls are enabled by default and can be used to fine-tune the intensity of your current stimulation session. However, it's best to use them only when you really need them (e.g. to address muscle imbalance).

Use *Stop, Pause, Resume, Skip Phase* controls to control the flow of the stimulation session. Skip Phase control is only applicable to stimulation programs which are comprised of multiple and skippable stimulation phases (e.g. such as Performance *Strength* program).

Switch Session Control (7) - allows you to switch between actively running stimulation sessions (on a different patients). When switching between sessions, your iPad will be disconnecting from PowerDot PD-02(s) used in currently active session and re-connecting to PowerDot(s) being used in the newly selected session.

Home Screen Control (8) – helps you to navigate back to PowerDot Doctor App Main Menu screen, so you could select another patient and initiate a new stimulation session.

When applying Switch Session and Home Screen Controls, you will be leaving current stimulation session and disconnecting from currently used PowerDot PD-02 devices. Although the devices will be continuing maintaining your stimulation session parameters, you won't be able to control them programmatically (e.g. adjust intensities or stop/resume session using App controls) until your select your original stimulation session and re-connect to your devices again. Re-connection is not immediate and it can take up to 10 seconds, therefore, in all emergency situations, we strongly advice to get yourself familiar and follow manual Terminating Stimulation protocols 2 and 3, as provided below.

If your patient experiences major discomfort or pain – PAUSE your stimulation session and/or DECREASE intensities. For your patient's safety, after a PAUSE, your stimulation session will resume at only 80% of the previous intensity values.

7. Terminating Stimulation

It's important to know the quick ways to stop the stimulation session when something unexpected happens (e.g. pads get detached or partially detached; patient starts feeling pain; the stimulation area gets wet, etc.).

There are 3 main ways to immediately terminate stimulation:

1) The recommended/most commonly used option: Tap Pause or Stop on the Stimulation Dashboard

2) *Alternatively* press the Multifunctional Button on the PowerDot device

3) *Or:* quickly unplug the lead cable from PowerDot device

8. Carrying & Storing PowerDot

PowerDot PD-02 carry case is specifically designed for carrying and storing up to 2 PowerDot devices, their lead cables and electrode pads.

To keep electrode pads clean and make them last longer, always re-attach them to the safety film in between use, then store them in your carrying case pocket. You can use both sides of a single safety film to attach one set of PowerDot electrode pads (one side for the rectangular pad and the other for the two round pads).

In multi-patient environment, it is always a good idea to mark patient pads with the patient name or initials on the top surface or on the pads film, e.g. using resistant marker pen.

9. Deactivating PowerDot

PowerDots can be deactivated from your Doctor App either from within the Patient or or by manually resetting the PowerDot device.

For manual deactivation: when PowerDot is OFF, press and hold Multi-function button for 3 seconds until you see the power indicator blinking. Now you can activate your PowerDot.

Deactivation from the PowerDot Doctor App is performed from the Devices screen as per on-screen instructions.

Upon successful deactivation, the power indicator will blink several times.

Intensity Adjustment Guidelines

For TENS programs or less demanding NMES programs, you are generally required to progressively increase the stimulation intensities until you see muscle twitches or feel comfortable sensation.

For the majority of NMES stimulation programs, that use powerful muscle contractions, the efficacy of the treatment can be proportional to the maximum number of fibers being recruited, and, therefore, it is often required to adjust your stimulation intensity to the maximum levels the patient can comfortably endure.

Keep in mind that the maximum intensity levels may vary, not only from one stimulation session to another, but also within the course of a single stimulation session. It's possible that patient's muscles will adapt to stimulation at a certain intensity level reasonably quickly. Various conditions, such as differences in skin's dampness or sweat level, or the rate of the electrode pad deterioration, may affect the intensity of stimulation.

During stimulation, it is important to maintain feedback with the patient to make sure that his/her stimulation intensity settings are always in balance with the level of comfort on one side and efficiency of stimulation on the other.

For efficiency in NMES and Performance sessions, based on patient feedback and feelings, try increasing slowly intensities during the course of the session.

Charging PowerDot

PowerDot PD-02 device can be recharged from any reliable USB connection (e.g. laptop, mobile phone charger, wall USB charger, etc.). It takes around 60 minutes for the device to go from zero level to full charge.

NEVER charge PowerDot when it is attached to the patient's body.

Always use an original charging cable provided with PowerDot.

NEVER charge PowerDot from unreliable or problematic sources.

When using 3rd party party USB AC chargers, we recommend unplugging the AC plug from the wall before contacting PowerDot device.

PowerDot PD-02 uses UL 1642 and UN 38.3 certified built-in Lithium Polymer battery, which requires recharging after approximately 5-6 hours of continuous usage. The battery will last for at least 500 charging cycles.

If you plan to store PowerDot PD-02, unused, for longer than six months, charge it to at least 50% every six months.

In the PowerDot Doctor App, the current battery charge level is displayed at the Stimulation and is also available on the Devices screen.

When you see the ORANGE charging light next to micro-USB connector, this means PowerDot is currently charging.

Once PowerDot is fully charged, the ORANGE light will turn off.

Stimulation Protocols

Stimulation protocols, accessible to doctors from PowerDot Doctor App, based on their intended use, can be divided into 3 main groups:

1. NMES Rehabilitation Protocols

Disuse Atrophy

Protocol Name				*Indication For Use*		
Disuse Atrophy*				Retarding disuse atrophy		
Description						
Targeting slow twitch (Type I) muscle fibers to facilitate increases in muscle volume after long periods of immobilization or diminished movement.						
Contraction, sec (allowed range)	*Contraction, Hz (allowed range)*	*Rest, sec (allowed range)*	*Rest, Hz (allowed range)*	*Ramp Up/Down, sec (allowed range)*	*Pulse Width, uS (allowed range)*	*Duration, min (allowed range)*
5 (3-8)	40 (30-50)	5 (3-8)	4 (0-6)	2/0.5 (0.5-3)	208 (160-320)	25 (15-30)
Reinforcement Post Disuse Atrophy*				Stimulation of healthy muscles in order to improve or facilitate muscle performance		
To be used on previously atrophied muscles that have gained the volume. Increases strength and stability by targeting fast twitch (type II) muscle fibers.						
4 (3-6)	80 (60-100)	8 (5-12)	4 (0-6)	1.5/0.75 (0.5-3)	320 (208-432)	20 (15-30)
Reinforcement Post Disuse Atrophy (Agonist/Antagonist)				Stimulation of healthy muscles in order to improve or facilitate muscle performance		
To be used on previously atrophied muscles that have gained the volume. Increases strength and stability by targeting fast twitch (type II) muscle fibers. Agonist/Antagonist sequencing.						
4 (3-6)	70 (60-100)	4 (3-6)	4 (0-6)	1.5/0.75 (0.5-3)	320 (208-432)	15 (10-20)
Prevention of Disuse Atrophy*				Preventing disuse atrophy		
Reproduces a series of slow twitch (Type I) targeted contractions comparable to the normal level of activity during a day. To be used on the immobilized limb after surgery or bone fracture.						
5 (3-8)	35 (30-50)	12 (9-18)	4 (0-6)	2/0.5 (0.5-3)	320 (208-432)	45 (30-60)
Prevention of Disuse Atrophy (Agonist/Antagonist)				Preventing disuse atrophy		
Reproduces a series of slow twitch (type I) targeted contractions comparable to the normal level of activity during a day. To be used on the immobilized limb after surgery or bone fracture. Agonist/Antagonist sequencing.						
6 (4-8)	35 (30-50)	6 (4-8)	4 (0-6)	2/0.5 (0.5-3)	320 (208-432)	20 (15-30)

Muscle Re-education and Increasing Range of Motion

Protocol Name				*Indication For Use*		
Muscle Re-education, Level 1 (Slow Twitch)*				Muscle re-education		
Description						
Targets re-education and muscle function improvements of slow twitch (Type I) muscle fibers.						
Contraction, sec (allowed range)	*Contraction, Hz (allowed range)*	*Rest, sec (allowed range)*	*Rest, Hz (allowed range)*	*Ramp Up/Down, sec (allowed range)*	*Pulse Width, uS (allowed range)*	*Duration, min (allowed range)*
5 (3-8)	40 (30-50)	5 (3-8)	4 (0-6)	2/0.5 (0.5-3)	208 (160-320)	25 (15-30)
Muscle Re-education, Level 2 (Fast Twitch)*				Muscle re-education		
Targets re-education and muscle function improvements of fast twitch (Type II) muscle fibers. Apply/schedule after at least 2 weeks of usage of Level 1 program.						
4 (3-6)	80 (50-100)	8 (5-12)	4 (0-6)	1.5/0.75 (0.5-3)	320 (208-432)	20 (15-30)
Neuro Rehab*				Muscle re-education		
Targets facilitation and re-learning of motor skills for stroke patients.						

5 (3-8)	40 (30-50)	15 (9-24)	0	4/2 (1.5-6)	208 (160-320)	20 (15-30)
Increase Range of Motion*				Maintaining or increasing range of motion		
Targets increase in range of motion by creating contraction and movement in the antagonist muscle, thus causing maximum stretch of the problematic muscle.						
5 (3-8)	40 (30-50)	10 (6-16)	4 (0-6)	2/0.5 (0.5-3)	208 (160-320)	20 (15-30)
Spasticity Treatment*				Maintaining or increasing range of motion		
Targets reduction of spasticity by inhibition of motor neurons of the spastic muscle via the reciprocal inhibition reflex. To be used on the antagonist of the spastic muscle with the intensity sufficient to create movement to the maximum range of motion.						
5 (3-8)	40 (30-50)	10 (6-16)	4 (0-6)	2/0.5 (0.5-3)	208 (160-320)	20 (15-30)

Specific Rehabilitation

Protocol Name				*Indication For Use*		
Hip Prosthesis, Level 1				Retarding disuse atrophy		
Description						
Targets improving stability and strength of Gluteus Maximus and Medius muscles following the orthopedic surgery of hip. Level 1 is targeting slow twitch (Type I) muscle fibers.						
Contraction, sec (allowed range)	*Contraction, Hz (allowed range)*	*Rest, sec (allowed range)*	*Rest, Hz (allowed range)*	*Ramp Up/Down, sec (allowed range)*	*Pulse Width, uS (allowed range)*	*Duration, min (allowed range)*
6 (4-8)	40 (30-50)	6 (4-8)	0	1.5/0.75 (0.5-3)	208 (160-320)	30 (20-40)
Hip Prosthesis, Level 2				Retarding disuse atrophy		
Targets improving stability and strength of Gluteus Maximus and Medius muscles following the orthopedic surgery of hip. Level 1 is targeting fast twitch (Type II) muscle fibers. Use/schedule Level 2 at least 2 weeks after using Level 1 program.						
4 (3-6)	80 (60-100)	10 (7-15)	0	1.5/0.75 (0.5-3)	208 (160-320)	15 (10-20)
Patellar Syndrome, Level 1				Retarding disuse atrophy		
Targets increase of the stability of the knee and retardation of the disuse atrophy in Medial Vastus and larger Quadriceps muscle. Level 1 is targeting slow twitch (Type I) muscle fibers.						
6 (4-8)	40 (30-50)	6 (4-8)	0	1.5/0.75 (0.5-3)	208 (160-320)	30 (20-40)
Patellar Syndrome, Level 2				Retarding disuse atrophy		
Targets increase of the stability of the knee and retardation of the disuse atrophy in Medial Vastus and larger Quadriceps muscle. Level 2 is targeting fast twitch (Type II) muscle fibers. Use/schedule Level 2 at least 2 weeks after using Level 1 program.						
4 (3-6)	80 (60-100)	10 (7-15)	0	1.5/0.75 (0.5-3)	208 (160-320)	15 (10-20)
Hemiplegia*				Maintaining or increasing range of motion		
Targets re-learning of motor skills and reduction of spasticity. Features long ramp up time o the contraction and a long rest phase. Can be used to complement traditional physiotherapy after a stroke.						
10 (6-15)	45 (30-50)	20 (12-30)	0	4/2 (1.5-6)	208 (160-320)	20 (15-30)
Rotator Cuff, Level 1				Muscle re-education		
Targets increase of the muscular function and neuro motor re-education of the rotator cuff. Use to treat disturbed range of motion, shoulder tendopathies and pain around the shoulder. Training can be combined with active movements.						
6 (6-15)	40 (30-50)	6 (4-8)	4 (0-6)	1.5/0.75 (0.5-3)	208 (160-320)	20 (15-30)
Rotator Cuff, Level 2				Muscle re-education		
Targets increase of the muscular function and neuro motor re-education of the rotator cuff. Use to treat disturbed range of motion, shoulder tendopathies and pain around the shoulder. Training can be combined with active movements. Apply/schedule after at least 2 weeks of using Level 1 program.						
4 (3-6)	80 (60-100)	10 (7-15)	4 (0-6)	1.5/0.75 (0.5-3)	208 (160-320)	15 (10-20)
Post-ACL Treatment (Agonist/Antagonist)				Muscle re-education		
Targeting improving active stability of the knee joint after rupture of the ACL. This is a contraction offset session: stimulation starts on Hamstrings and then continues on the Quadriceps, preventing the risk of the anterior drawer.						
3+6	40	8	4	1.5+3/0+0.75	320	25

	(30-50)				(240-432)	
Shoulder Subluxation				Prevention and retardation of atrophy		
Targets stimulation of Deltoid and Supraspinatus muscles as prevention and treatment for atrophy of the sub-dislocated shoulder.						
8 (6-10)	40 (30-50)	8 (6-10)	0	3/1.5 (1-5)	208 (160-320)	25 (20-30)
Back-Trunk Stabilization*				Muscle re-education		
Targets stabilization of trunk and back muscles by stimulating abdominal or lumbar muscle groups. Suits patients with insufficiency in the bank and trunk due to long term pain or neurological disorder. This program can be also combined with active movements.						
6 (3-8)	40 (30-50)	12 (6-16)	4 (0-6)	2/1 (0.5-3)	208 (160-320)	30 (20-40)

Circulation, Relaxation of Muscle Spasms, Vascular

Protocol Name				*Indication For Use*		
Heavy Legs				Increasing local blood circulation Relaxation of muscle spasms		
Description						
For use when swelling of the feet and ankle occurs together with a feeling of the legs being very heavy. Muscle contractions will compress the deep veins of the legs and eject venous blood upwards. The stimulation will also help to overcome the tension and tendency to cramp. To be used on calf muscles (Gastrocnemius).						
Contraction, sec (allowed range)	*Contraction, Hz (allowed range)*	*Rest, sec (allowed range)*	*Rest, Hz (allowed range)*	*Ramp Up/Down, sec (allowed range)*	*Pulse Width, uS (allowed range)*	*Duration, min (allowed range)*
continuous	7/5/3 (7/7/7 min)	0	0	1/0.5	208 (160-320)	21 (15-30)
Capillarization				Increasing local blood circulation		
Helps to make muscle fibers more resistant to fatigue. Capillarization decreases the amount of lactic acid being produced and creates a larger area of exchange and distribution of oxygen and metabolites.						
continuous	8 (5-10)	0	0	1/0.5	208 (160-320)	25 (20-30)
De-contraction				Relaxation of muscle spasms Post-surgical and post-trauma acute pain		
Targets reduction of muscular tension by using very low stimulation frequency.						
continuous	1	0	0	1/0.5	208 (160-320)	20 (10-40)
Arterial Insufficiency				Increasing local blood circulation		
Targets arterial insufficiency of the lower limbs. Low frequency stimulation increases the capacity of the fibers to use the oxygen, improves the tolerance while avoiding the tetanization and considerable fatigue. Electrodes are placed on the calf muscles (Gastrocnemius) and popliteal nerve.						
15 (10-20)	10 (7-12)	15 (10-20)	3 (0-6)	1/1 (0.5-1.5)	208 (160-320)	15 (10-20)
Prevention of Venous Thrombosis				Prevention of venous thrombosis		
Targets achieving maximum drainage of the veins and combats the stasis. Uses short tetanic contractions separated by long active pauses to increase the blood flow. Electrodes are placed on the calf muscles (Gastrocnemius) and popliteal nerve.						
4 (3-5)	50 (40-60)	20 (15-25)	8 (6-10)	1.5/1.5 (1-2)	208 (160-320)	20 (15-30)
Cramp Prevention				Increasing local blood circulation Relaxation of muscle spasms		
Targeting cramps at calves. First sequence increases local blood circulation, second sequence provides relaxation to muscle tone. Each sequence repeats 4 times.						
continuous	8/3 x 4 (8 min/2 min) (2-10)	0	0	1/0.5	208 (160-320)	40

2. TENS Pain Management Protocols

By Type of Pain

Protocol Name		*Indication For Use*	
Acute Pain		Post-surgical and post-trauma acute pain	
Description			
High frequency TENS is a popular choice for the management of acute pains. Adjust pulse width to patient pain sensitivity level.			
Frequency, Hz (allowed range)	*Burst Parameters (allowed range)*	*Pulse Width, uS (allowed range)*	*Duration, min (allowed range)*
100 (80-150)	N/A	208 (32-320)	30 (15-60)
Fracture Pain		Post-surgical and post-trauma acute pain	
Medium frequency/medium pulse width TENS is a good choice for treating sensitive fracture pains. Pain management helps to prevent various complications such as pulmonary complications or thrombosis.			
75 (60-80)	N/A	160 (128-240)	30 (15-60)
Chronic Pain		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
Chronic pains are handled well with low frequency Endorphinic TENS stimulation. Low frequency stimulation alleviates pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation.			
5 (1-8)	N/A	240 (160-320)	30 (15-60)
Radiating Pain **Projected Pain**		Symptomatic relief and management of chronic, intractable pain	
Burst TENS is effective in managing various kinds of radiating (projected) pains such as mononeuropathy, central pain as well as for deep muscular pains. High frequency pulses packaged into low frequency bursts alleviate pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation.			
80 (80-150)	5 pulses per burst, 2 bursts/sec (5-10 ppb, 2-4 bursts/sec)	208 (160-320)	20 (10-40)

By Body Part

Protocol Name		*Indication For Use*	
Cervical Pain **Neck Pain**		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
Description			
For treating neck pain resulting from chronically contracted of Levator scapulae and/or superior Trapezius muscles. Low frequency stimulation alleviates pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation.			
Frequency, Hz (allowed range)	*Burst Parameters (allowed range)*	*Pulse Width, uS (allowed range)*	*Duration, min (allowed range)*
5 (1-8)	N/A	240 (160-320)	30 (15-60)
Lower Back Pain		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	

For treating lower back pain resulting from chronically contracted lumbar paravertebral muscles. Low frequency stimulation alleviates pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation.			
5 (1-8)	N/A	240 (160-320)	30 (15-60)
Lumbosciatica **Sciatica**		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating lumbar pain originating from chronic contractions of the paravertebral muscles. Electrodes are placed over the sciatic nerve root exit sites and on the lower part of the buttock/posterior face of the thigh. Low frequency stimulation alleviates pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation.			
5 (1-8)	N/A	240 (160-320)	30 (15-60)
Mononeuropathy **Central Pain** **Deep Muscular Pain** **Rhizopathy**		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
Burst TENS is usually effective in managing various kinds of radiating (projected) pains, for conditions with reduced or changed sensory of touch as well as for deep muscular pains. High frequency pulses packaged into low frequency bursts alleviate pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation.			
80 (80-150)	5 pulses per burst, 2 bursts/sec (5-10 ppb, 2-4 bursts/sec)	208 (160-320)	20 (10-40)
Arthralgia		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating arthralgia pain: pain in or affecting a joint, caused by either degenerative or destructive processes. To avoid adaptation, this protocol uses continuous variation of stimulation frequency at very short pulses.			
50-150 Hz at 2 sec (50-150 Hz at 2-5 sec)	N/A	48 (32-160)	20 (10-40)
Epicondylitis		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating epicondylitis pain. Epicondylitis is a tendinopathy which may result from repetitive gripping of the objects. To avoid adaptation, this protocol uses continuous variation of stimulation frequency with short width pulses.			
50-150 Hz at 2 sec (50-150 Hz at 2-5 sec)	N/A	48 (32-160)	20 (10-40)
Lower Back Muscle Pain		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating lower back muscle pain. This protocol is recommended to shorten recovery and/or as symptomatic therapy. To avoid adaptation, this protocol uses variation of stimulation frequency in medium range with medium width pulses.			
40-100 Hz at 3 sec (20-100 Hz at 2-5 sec)	N/A	240 (160-320)	30 (15-60)

Muscle Pain		Symptomatic relief and management of chronic, intractable pain Post-surgical and post-trauma acute pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating all kinds of muscle pains. This protocol uses pulse width modulation, which creates undulating sensation and is generally more comfortable than constant pulse width stimulation.			
80 Hz at 2 sec (60-150 Hz at 2-5 sec)	N/A	64-320 (32-432)	30 (15-60)
Knee Pain		Symptomatic relief and management of chronic, intractable pain Post-surgical and post-trauma acute pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating knee pain caused by the injury or by underlying medical conditions such as osteoarthritis, rheumatoid arthritis or chondromalacia. This protocol uses pulse width modulation, which creates undulating sensation and is generally more comfortable than constant pulse width stimulation.			
80 Hz at 2 sec (60-150 Hz at 2-5 sec)	N/A	64-320 (32-432)	30 (15-60)
Shoulder Pain		Symptomatic relief and management of chronic, intractable pain Post-surgical and post-trauma acute pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating shoulder pain resulting from heavy repetitive lifting, sports injuries or underlying medical conditions such as arthritis, tendinopathy and impingement. This protocol uses pulse width modulation, which creates undulating sensation and is generally more comfortable than constant pulse width stimulation.			
80 Hz at 2 sec (60-150 Hz at 2-5 sec)	N/A	64-320 (32-432)	30 (15-60)
Joint Pain		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating various kinds of joint pains, especially in shoulders and knees. This protocol uses pulse width modulation, which creates undulating sensation and is generally more comfortable than constant pulse width stimulation.			
60 Hz at 2 sec (50-100 Hz at 2-5 sec)	N/A	48-160 (32-240)	30 (15-60)
Lumbago		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating lumbago pain, the result of sharp and intense contractions of lower back muscle. This protocol produces very low frequency stimulation twitches to reduce muscle tension during rest of the stimulated muscles.			
1	N/A	208 (160-320)	20 (10-40)
Torticollis		Symptomatic relief and management of chronic, intractable pain	

		Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
For treating torticollis pain: a sharp pain in the neck, often accompanies by considerable reduction of the mobility of the cervical region. This protocol produces very low frequency stimulation twitches to reduce muscle tension during rest of the stimulated muscles.			
1	N/A	208 (160-320)	20 (10-40)

By Type Of TENS

Protocol Name		*Indication For Use*	
Conventional TENS, High Frequency		Post-surgical and post-trauma acute pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
Description			
High frequency TENS is a popular choice for the management of acute pains. Adjust pulse width to patient pain sensitivity level in the treatment area. Can be altered with more comfortable Mixed Frequency TENS/Hans Stimulation and Medium Frequency TENS protocols.			
Frequency, Hz (allowed range)	*Burst Parameters (allowed range)*	*Pulse Width, uS (allowed range)*	*Duration, min (allowed range)*
100 (80-150)	N/A	208 (32-320)	30 (15-60)
Conventional TENS, Medium Frequency		Post-surgical and post-trauma acute pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
Medium frequency TENS can be used as a more comfortable alternative to High Frequency TENS.			
75 (60-80)	N/A	160 (128-240)	30 (15-60)
Acupuncture TENS **Endorphin TENS** **Low Frequency TENS**		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
This low frequency TENS protocol is generally used to manage chronic pains, can be varied with or accompanied by more comfortable Burst TENS or less adaptive Low Range Frequency Modulated TENS protocols. Low frequency pulses alleviate pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation.			
5 (1-8)	N/A	240 (160-320)	30 (15-60)
Conventional TENS, High Frequency/Short Pulse		Post-surgical and post-trauma acute pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
High frequency TENS is a popular choice for the management of acute pains. Short pulse version should be used for the patients with very sensitive treated areas. Can be also varied with Mixed Frequency TENS/Hans Stimulation protocol.			
100 (80-150)	N/A	48 (32-160)	20 (10-40)
Frequency Modulated TENS, High Range		Post-surgical and post-trauma acute pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
This protocol can for treatment of various chronic pain conditions such as arthralgia, epicondilitis, lower back muscle pains etc. Modulation of frequencies helps to avoid adaptation. Adjust pulse width to patient pain sensitivity level in the treatment area.			

50-150 Hz at 2 sec (50-150 Hz at 2-5 sec)	N/A	48 (32-160)	20 (10-40)
Frequency Modulated TENS, Medium Range		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
This protocol can be used for treatment of various chronic pain conditions such as arthralgia, epicondilitis, lower back muscle pains etc. Modulation of frequencies helps to avoid adaptation. Medium range modulation provides more comfortable stimulation than high range option.			
40-100 Hz at 3 sec (20-100 Hz at 2-5 sec)	N/A	240 (160-320)	30 (15-60)
Frequency Modulated TENS, Low Range		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
This protocol is a more effective version of Low Frequency TENS and Burst TENS protocols for the long-term treatments as it avoids adaptation via frequency modulation. Low frequency pulses alleviate pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation.			
1-8 Hz at 5 sec (1-15 Hz at 3-10 sec)	N/A	240 (160-320)	30 (15-60)
Pulse Modulated TENS, High Range		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
This protocol can used for treating of chronic pain conditions requiring higher levels of comfort such as muscle pain, sharp knee and shoulder pains. It also creates massage like effect on certain muscle groups (such as Trapezius).			
80 Hz at 2 sec (60-150 Hz at 2-5 sec)	N/A	64-320 (32-432)	30 (15-60)
Pulse Modulated TENS, Low Range		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
This protocol can used for treating of chronic pain conditions requiring higher levels of comfort. Low Range provides even more pleasant/comfortable stimulation when comparing to High Range option, more suitable for treating of the joint pains.			
60 Hz at 2 sec (50-100 Hz at 2-5 sec)	N/A	48-160 (32-240)	30 (15-60)
Burst TENS		Symptomatic relief and management of chronic, intractable pain Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
Burst TENS is usually effective against radiating pain in the arms or legs (rhizopathy), for conditions with reduced or changed sensory of touch, for deep muscular pain or when the post-treatment of TENS is too short. High frequency pulses packaged into low frequency bursts alleviate pain by stimulating muscles to release the endorphins. In addition, muscle twitches also increase local blood circulation. Burst TENS can be effectively altered with more aggressive Low Frequency/Endorphin TENS and less adaptable Low Range Frequency Modulated TENS protocols.			
80 (80-150)	5 pulses per burst, 2 bursts/sec (5-10 ppb, 2-4 bursts/sec)	208 (160-320)	20 (10-40)
Mixed Frequency TENS **Hans Stimulation**		Post-surgical and post-trauma acute pain	

		Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities	
Mixed Frequency TENS is more comfortable and convenient form of High Frequency Conventional TENS. Also commonly referred as Hans Stimulation. Can be altered with more aggressive High Frequency Conventional TENS protocol.			
80/2, 3 sec each	N/A	208 (32-320)	30 (15-60)
1 Hz TENS		Post-surgical and post-trauma acute pain Relaxation of muscle spasms	
Targets reduction of muscular tension by using very low stimulation frequency.			
1	N/A	208 (160-320)	20 (10-40)

3. NMES Performance and Massage Programs

Protocol Name				*Indication For Use*		
Muscle Endurance*				Stimulation of healthy muscles in order to improve or facilitate muscle performance		
Description						
Targets improvements of muscle endurance and fatigue resistance through activation of slow twitch (Type I) muscle fibers.						
Contraction, sec (allowed range)	*Contraction, Hz (allowed range)*	*Rest, sec (allowed range)*	*Rest, Hz (allowed range)*	*Ramp Up/Down, sec (allowed range)*	*Pulse Width, uS (allowed range)*	*Duration, min (allowed range)*
8 (6-10)	15 (30-25)	4 (3-5)	3 (0-6)	1/0.5 (0.5-2)	208 (160-432)	45 (35-60)
Strength Endurance*				Stimulation of healthy muscles in order to improve or facilitate muscle performance		
Targets improvements of muscle capacity (strength endurance), ability to resist intense and prolonged effort, muscle tone and definition. Works through activation of slow twitch (Type I) and some fast twitch oxidative (Type IIa) muscle fibers at medium stimulation frequencies.						
7 (5-10)	40 (30-50)	7 (5-10)	3 (0-6)	1.5/0.75 (0.5-3)	240 (160-432)	35 (25-45)
Resistance *				Stimulation of healthy muscles in order to improve or facilitate muscle performance		
Targets improvements of muscle ability to resist intense and prolonged effort, muscle hypertrophy. Works through activation of fast twitch oxidative (Type IIa) muscle fibers at medium stimulation frequencies.						
7 (5-10)	55 (45-65)	7 (5-10)	3 (0-6)	2/1 (0.5-3)	320 (160-432)	25 (20-30)
Strength*				Stimulation of healthy muscles in order to improve or facilitate muscle performance		
Targets improvements of muscle strength. Works through activation of fast twitch oxidative (Type IIa) muscle fibers at high stimulation frequencies.						
4 (3-8)	80 (70-100)	20 (15-40)	3 (0-6)	2/1 (0.5-3)	352 (160-432)	20 (15-30)
Explosive Strength*				Stimulation of healthy muscles in order to improve or facilitate muscle performance		
Targets improvements of explosive strength and power. Works through activation of fast twitch glycolic (Type IIb) muscle fibers at very high stimulation frequencies.						
3 (2-8)	120 (100-150)	30 (20-80)	3 (0-6)	2/1 (0.5-3)	400 (160-432)	15 (10-20)
Active Recovery				Increasing local blood circulation Relaxation of muscle spasms		
Targets acceleration of muscle recovery after intensive exercise. Increases local blood circulation, releases endorphins, provides muscle relaxation.						
210 (for each phase) (120-360)	10, 8, 5, 3, 2, 1 (1-10)	N/A	N/A	1/1	208 (160-432)	18 (12-36)
Relaxation Massage				Increasing local blood circulation Relaxation of muscle spasms		

Targets decrease in muscular tension. Provides effect of wellbeing and relaxation.						
420 (for each phase) (300-720)	7,5,3 (1-10)	N/A	N/A	1/1	208 (160-432)	21 (15-36)
Circulation Massage				Increasing local blood circulation		
Helps to get rid of heaviness sensation and uncomfortable body tensions via increasing blood circulation in the target areas.						
120 (for each phase) (90-240)	1,3,5,7,5,3,1, 1-7@5 sec (1-10)	N/A	N/A	1/1	208 (160-432)	16 (12-32)
De-contraction Massage				Increasing local blood circulation Relaxation of muscle spasms		
Enables de-contraction of the muscles through the comfortable low frequency vibrations that increase the blood circulation in the treated region and improve oxygenation.						
60, 60, 60, (30, 30, 30)x5, (60,30,60,30)x2, 30	3,2,1,(1-5@5, 1-3@5, 1)x5, (1-5@5, 1, 1-3@5, 1)x2,1	N/A	N/A	1/1	208	17
Dual Wave Massage				Increasing local blood circulation Symptomatic relief and management of chronic, intractable pain		
Helps to get rid of heaviness sensation and uncomfortable body tensions via increasing blood circulation in the target areas. Combines massage with TENS pain relief. Delivers a pleasant wave-like effect by isolating stimulation sequences between the devices in Duo mode.						
60, 60, (30x4, 30x4)x5	5, 100, (1-8x4, 100x4)x5	N/A	N/A	1/1	208	22

* Marked programs are preceded with 2 minutes Warm Up phase at 5-10 Hz stimulation and 3 minutes of Recovery at 5-1 Hz stimulation using 208 uS pulses.

For each stimulation program, you can adjust stimulation parameters within allowed ranges. Contraction/rest duty cycles can be only adjusted proportionally to the proposed default values.

Adjusted stimulation programs will be saved and always available from the Sessions History screen (for ad hoc sessions) or from the Scheduled Sessions screen (if the session has been previously scheduled).

To identify stimulation parameters for recommended intended use, manufacturer has used stimulation parameters and programs from the number of substantially equivalent NMES and TENS devices, available on the market.

Basic Troubleshooting

DEVICE DOESN'T TURN ON

PowerDot PD-02 is probably very low on the battery. Charge your PowerDot for a few hours.

DURING PRE-STIMULATON SET UP, POWERDOT(S) CANNOT BE FOUND (OR ARE NOT CONNECTED) .

*C*heck out Devices screen and make sure that PowerDot device you're trying to use is in the list of active devices.

Make sure your PowerDot is turned on (the white light is on in the device).

In some rare cases, you would be required to forget (remove) relevant PowerDot device from Bluetooth Settings (use device serial number to identify the right one).

STIMULATION DOES NOT PRODUCE THE USUAL SENSATION

Check that your electrode pads are firmly attached to your body and are correctly positioned (as advised on the Pre-Stimulation screen). Put the stimulation on pause, re-attach or reposition pads, then resume the stimulation.

THE STIMULATION CAUSES DISCOMFORT OR A BURNING FEELING

If you're using your standard intensity modes, than most probably your pads are worn out and and/or losing their bonding strength. Pause the stimulation and re-attach your pads firmly, then resume stimulation. If the same sensation continues, pause the stimulation again and replace your pads.

ELECTRODE PADS DON'T STICK TO THE BODY OR STIMULATION IS SURPRISINGLY WEAK EVEN ON HIGHER INTENSITIES

Replace your electrode pads. Most probably they're worn out. If it doesn't work, check your lead cable for physical damage. If there is any damage, replace the lead cable.

CAN'T ACTIVATE POWERDOT DEVICE OR IPAD STOPPED CONNECTING TO THE POWERDOT

- Remove relevant PowerDot(s) from Devices menu (use serial number to identify the right one(s)).
- Perform manual factory reset of your PowerDot (or PowerDots) by turning the device off and then holding the button on the device for around 5 seconds, until you see power light blinking several times.
- Go to Bluetooth Settings and remove/forget relevant PowerDot(s) using device's serial number.
- Terminate PowerDot Doctor App using Task Manager.
- Launch PowerDot Doctor App again and try to activate your device again.
- If after all steps above, you still experience connectivity problem, please send us your phone model, OS version and the list of actions you have performed to service@powerdot.com. We will respond within 24 hours.

PowerDot Maintenance

PowerDot PD-02 device, together with its accessories, should be kept in PowerDot carry case and carefully stored on a secure surface and protected conditions listed in the Warnings above.

Keep replacing your electrode pads after 20 uses as recommended. Deteriorated & worn out pads can cause major discomfort during stimulation, affect the effectiveness and even lead to minor injury.

Cleaning: only clean PowerDot device using a dry soft cloth.

Keep PowerDot device and electrode pads away from water. Store them in a dry place, in protective packaging or in the PowerDot carry case.

PowerDot PD-02 devices do not require calibration or verification of performance parameters. The characteristics are systemically verified and validated for each device manufactured. Those characteristics are stable and do not vary when used under normal conditions.

The manufacturer states that PowerDot cannot be repaired by personnel external to the company. Any work of this nature carried out by personnel not authorized by the manufacturer will be classified as tampering with the unit, releasing the manufacturer from any responsibility with regards to the warranty and hazards that the operator or user may be exposed to.

PowerDot Warranty

PowerDot PD-02 is covered by a worldwide warranty of 2 years, which comes into effect on the date of purchase of the device (proof of purchase is required).

The warranty does not apply to the electrode pads and carry cases. Within the warranty period, manufacturer will replace your faulty PowerDot or accessories at no charge (except shipping & handling fees in some cases), provided that the product:

- Has been used for the intended purpose and in the manner described in this manual
- Has not been connected to an unsuitable power source
- Has not been subjected to misuse or neglect
- Has not been modified or repaired
- Has not been damaged further by shock

Legal rights are not affected by this warranty.

Technical Specifications

All electrical specifications are given for an impedance of 1000 Ω per channel.

Battery: 2x Lithium Polymer (LiPo) rechargeable 3.7 V, 210 mAh

Charging Input: 5V through USB Type C connection (custom USB charging cable is provided as part of the package), I/P rating: 5Vdc ⎓ 1-2.1A

Stimulation Channels: 2 independent, optically isolated

Stimulation Waveform: Bi-phasic rectangular with zero mean (under load)

Supported Stimulation Frequency Range: 1-150 Hz

Supported Stimulation Pulse Width: 32-416 µs (for main/positive phase)

Maximum output voltage/amperage: 130 V/130 mA (+-5%)

Bluetooth: Built-in Bluetooth Low Energy 4.0

Electro-compatibility (EMC): ETSI EN 301 489-1/EN 301 489-17/EN 50385/EN 55011/IEC 60601-1-2

C RF Data:

- Operating Frequency Range: 2402 MHz-2480 MHz (ISM range)
- Modulation Type: GFSK with AFH
- Peak Transmit Power: -15.86dBm (0.026 mW)
- Channel Spacing/Number of Channels: 2 MHz, 40 channels (3 for advertising, 37 for data)
- Antenna Type: PCB Antenna, 2 dBi (1.58 mW) gain

Mobile Application Compatibility:

- Android 5.0 Lollipop (or later) powered smart phone with Bluetooth Smart Ready compatibility and High Definition (or better) touch screen
- Apple iPhone 4S/iPod 5th Gen/iPad 3rd Gen or newer smart phone/tablet powered by iOS 9.0 (or later)

Device Dimensions: 55x55x13.6 mm

Device Weight: 30 g

Environment Specifications:

- **Operating/Storage/Transport:** Temperature from 0 C to +40 C
- **Humidity:** 10-90% RH
- **Atmospheric pressure:** from 700 hPa to 1060 hPa

Product Expected Lifetime: 5 years

Housing: ABS & TPU

Limitations: product is not suitable for use in the environments with a high concentration of oxygen and/or flammable liquids and/or flammable gas; do not use with equipment for electro surgery or short-wave or microwave therapy; the device may be interfered by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

PowerDot PD-01 has been tested to the compliance with the following Emission and Immunity standards:

Emission:

STANDARD	**ITEM**	**REMARKS**
CISPR 11: 2011	Conducted	Class B
	Radiated	Class B
IEC 61000-3-2:2014	Harmonic current emissions	
IEC 61000-3-3:2013	Voltage fluctuations & flicker	

IMMUNITY:

STANDARD	**ITEM**	**IEC 60601-1-2 Test Levels for Home Healthcare Environment**	**PowerDot PD-01 Test Levels**	**REMARKS**
IEC 61000-4-2:2008	ESD	± 8 kV contact; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±2 kV, ± 4 kV, ± 8 kV contact; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	No performance degradation observed.
IEC 61000-4-3:2010	RS	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 5.785 GHz 80% AM at 1 kHz	No performance degradation observed.
IEC 61000-4-4:2012	EFT	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	No performance degradation observed.
IEC 61000-4-5:2014	Surge	± 0.5 kV, ± 1 kV	± 0.5 kV, ± 1 kV	No performance degradation observed.
IEC 61000-4-6:2013	CS	3V 0.15 MHz – 80 MHz 6V in ISM and amateur bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	10V 0.15 MHz – 80 MHz 80% AM at 1 kHz	No performance degradation observed.
IEC 61000-4-8:2009	PFMF	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	No performance degradation observed.
IEC 61000-4-11:2004	Voltage dips & voltage variations	**Voltage Dips:** 1) 0% U_T; 0,5 cycle at 0º. 45º, 90º, 135º, 225º, 270º, 315º 2) 0% U_T; 1 cycle; Single phase at 0º 3) 70% U_T; 25/30 cycles; Single phase at 0º	As on the previous column	**Voltage Dips:** 1) No performance degradation observed 2) No performance degradation observed

		Voltage Interruptions: 0% U_T; 250/300 cycle;		3) No performance degradation observed **Voltage Interruptions:** Performance degradation (device stopped charging) has been observed only during voltage interruption testing, but no degradation observed after the testing

Bluetooth Connectivity

The unique feature of PowerDot system is that PowerDot stimulators are controlled through Bluetooth Low Energy wireless radio interface.

PowerDot PD-02 is specifically designed to be used together with PowerDot Doctor App, which is supported for the selected Apple iPad devices.

Secure Pairing

Your PowerDot is paired with your iPad using secure 8 digit numeric code which, by design, prohibits any other mobile phones or wireless devices to connect to your PowerDot. Secure pairing takes place during PowerDot activation process (see *Activating PowerDot* above) and, once your PowerDot becomes active, numeric activation code is written into PowerDot's flash memory and gets verified by your PowerDot Doctor App after every PowerDot restart.

All Bluetooth commands sent from your mobile phone to PowerDot device are securely encrypted using Bluetooth AES-128 encryption protocol.

Disconnections and Quality of Service

PowerDot Doctor App and PowerDot PD-02 Bluetooth communication interface are specifically designed to accommodate temporarily and permanent Bluetooth disconnections during a stimulation session.

PowerDot PD-02 device is capable of independent execution of a pre-loaded stimulation program with the latest intensity values as well as implements automatic Bluetooth re-connections.

In this regard, temporary radio frequency interference (e.g. caused by co-existence of multiple Bluetooth and/or Wi-Fi devices in your range) should not affect the overall efficiency and safety of your stimulation session.

Due to hardware-level emergency stop mechanisms (see *Directions For Use*), Bluetooth disconnections of more permanent nature should not affect the safety of stimulation, and can only cause temporary inconvenience by forcing you to postpone your planned stimulation session until a more favorable Bluetooth connectivity environment is established.

Like any wireless device, PowerDot PD-02 emits very low levels in the radio frequency (RF) interval, and, is therefore not likely to cause any interference with nearby electronic equipment (e.g. radios, computers, telephones, etc.).

PowerDot PD-02 is designed to withstand foreseeable disturbances originating from electrostatic discharges, mains supply magnetic fields, or radio frequency transmitters.

Despite this, it is not possible to guarantee that the stimulator will not be affected by strong RF (radio frequency) fields emitting from other sources (such as in the proximity of working microwave oven).

Try not to use PowerDot closer than 1.5 meters to the working microwave oven as radio interference from microwave is likely to cause disconnection between PowerDot and your mobile phone.

Troubleshooting Wireless Connectivity

If you run into issues with Bluetooth wireless connectivity (e.g. your PowerDot PD-02 device becomes unresponsive to PowerDot Doctor App commands during stimulation session or you were not able to connect to your PowerDot and initiate stimulation), do not panic and consider terminating your stimulation session manually by shortly pressing Power button on your PowerDot device.

PowerDot Doctor App has built-in re-connection and disconnection detection mechanism and, in most cases, it will re-connect back to your PowerDot shortly and allow you to resume your stimulation using Resume button on the stimulation screen.

If you fail to re-connect and resume stimulation after several attempts, consider stopping your stimulation session using Stop button on the Stimulation Screen and postponing it for later.

Used Symbols

SN	Serial Number
	Stand by
	Attention
	Direct Current (DC)

IMPORTANT NOTE : (For Portable Device Configuration)

FCC Radiation Exposure Statement:

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment for body-worn configuration in direct contact to the phantom.

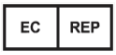
The device complies with Part 15 of FCC. Operation is subject to the following conditions:

a. This device may not cause harmful interference, and

b. This device must accept any interference received, including interference that may cause undesired operation.

FCC ID: 2AC2KPD001201400SMT

EU Only Symbols:

CE 0197	This symbol on your PowerDot unit is to indicate conformity with the requirements of the Medical Device Directive (94/42/EEC)
	Manufacturer
	EU Authorized representative
	Internally powered device Class II with Type BF applied parts
	Product subject to WEEE regulations concerning separate waste collection
	Read the instructions for use carefully before using this device
IP22	IP Rating IP22

Manufacturer & After-Sale Service:

Smartmissmo Technologies Pte Ltd

4 Shenton Way, #28-01 SGX Centre II

Singapore 068807

E-Mail: service@powerdot.com

Phone: +1-844-479-7368

Contact for any assistance in setting up, using, maintaining, or reporting unexpected operation or events.

EU AUTHORISED REPRESENTATIVE:

Medical Technology Promedt Consulting GbmH,

Altenhostrasse 80, 66386, St. Ingbert, Germany

Electromagnetic Compatibility (EMC)

PowerDot PD-02 is designed to be used in home healthcare environments in accordance with the EMC safety standard IEC 60601-1-2 (4th Edition) and with limitations, defined by the warnings and precautions in this manual (e.g. operation near RFID emitters, working microwave ovens, etc.).

Examples of home healthcare environment include restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), vehicles (cars, buses, trains, boats, planes, helicopters), train stations, bus stations, airports, hotels, hostels, pensions, museums, theatres.

PowerDot PD-02 is designed to support anticipated disturbance originating from electrostatic discharge, magnetic fields for the power supply or radiofrequency emitters.

However, the performance of PowerDot PD-02 device can still affected by radio frequency fields originating from other sources.

For more information about EMC emissions and immunity, contact the manufacturer.

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

The use of accessories, transducers and cables others than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PowerDot PD-02, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

PowerDot PD-02 battery charging performance might degrade in the environments

with frequent voltage interruptions (when charging from the wall adapter). To support consistent and reliable charging, the usage of uninterrupted power supply (UPS) is highly recommended, if operating in such environments.

The following device function is considered essential to the safety of the user: ability to maintain consistent stimulation intensity (amplitude), pulse frequency and pulse waveform (both shape and width).

In case if the essential performance is lost or degraded due to electromagnetic disturbances, stimulation safety and effectiveness can be compromised. Whenever the patient realizes unexpected change in any of stimulation parameters, it's is advised to terminate the stimulation session immediately by using one of the methods provided in the Terminating Stimulation section.