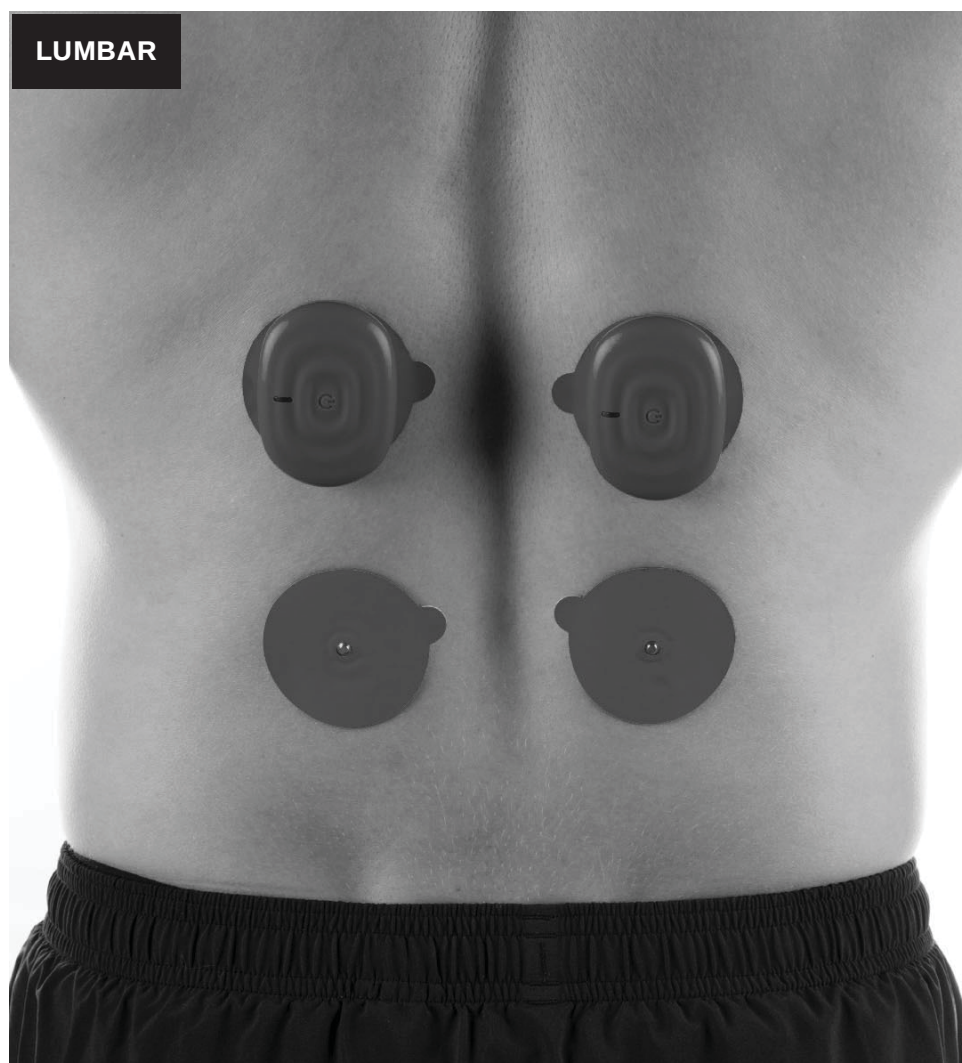






TRAPS



RIBS



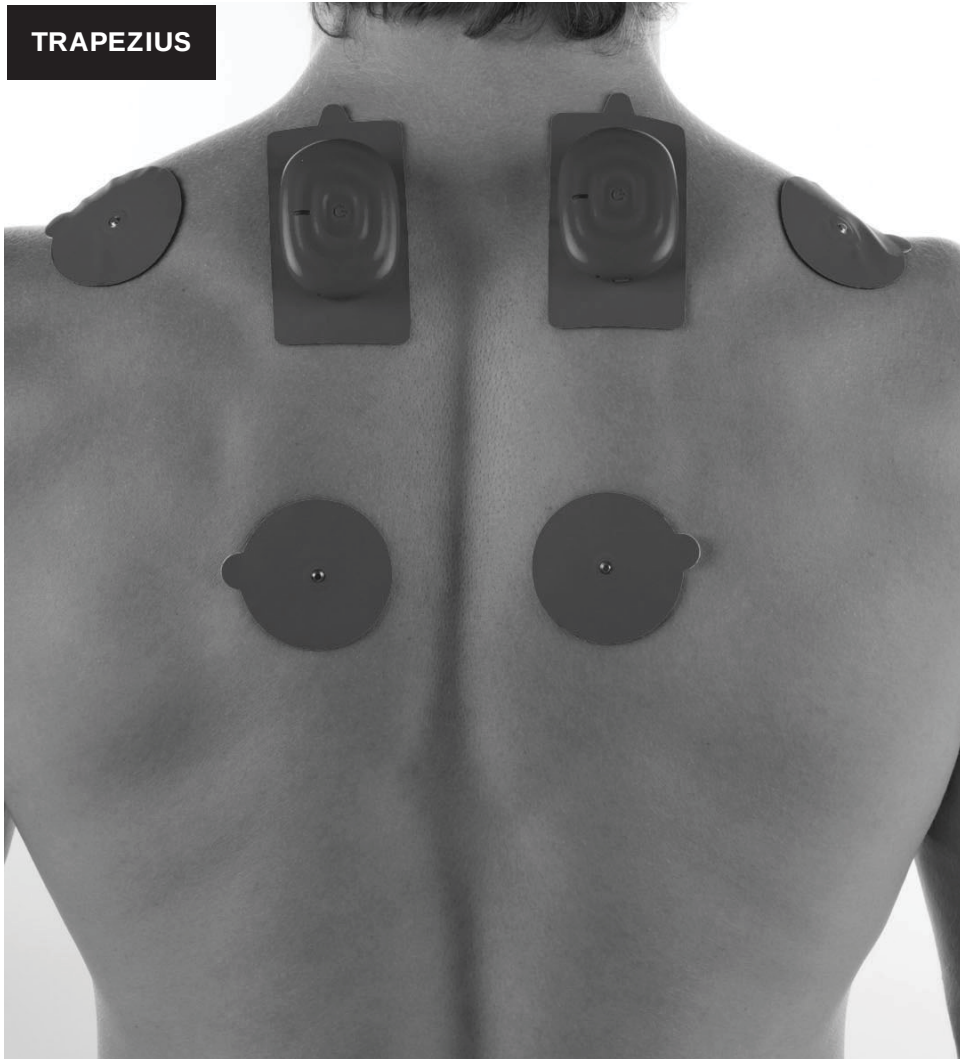
SCIATIC NERVE



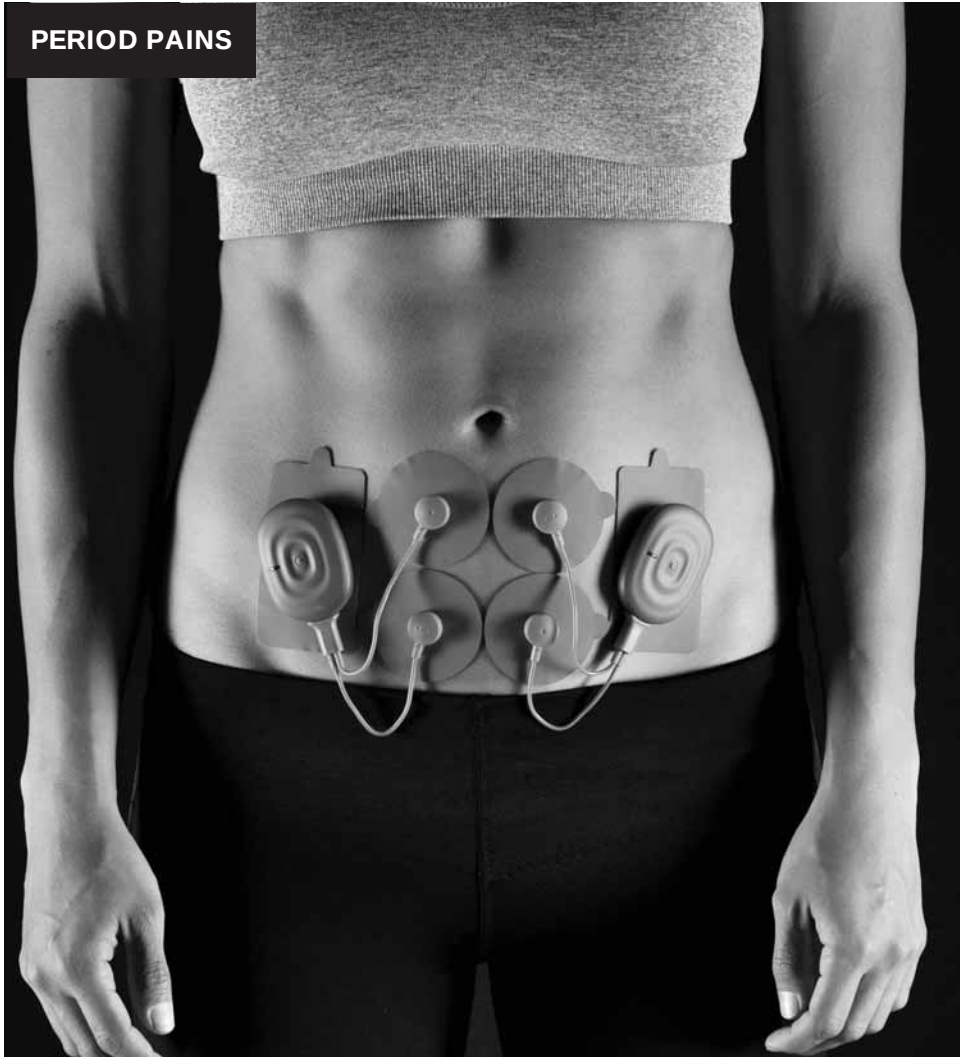
SHOULDER



TRAPEZIUS



PERIOD PAINS



POWERDOT MAINTENANCE

Your PowerDot pod(s) and accessories should be kept in your PowerDot carry case and carefully stored on a secure surface, under the conditions listed in the Warnings above.



Replace your electrode pads after 20 uses as recommended. Deteriorated & worn out pads can cause major discomfort during stimulation, impacting the effectiveness of your PowerDot(s) and even lead to minor injury.



Cleaning: only clean PowerDot device and electrode pads 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 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, thereby 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 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: Lithium Polymer (LiPo) rechargeable 3.7 V, 210 mAh (~5-6 hours of continuous stimulation on average parameters).

Charging Input: 5V through USB 2.0 or 3.0 connections (custom micro-USB to 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 μ s (for main/positive phase)

Maximum output voltage/ampereage: 125 V/125 mA (+/-5%)

Bluetooth: Built-in Bluetooth Low Energy 5.0

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
- Peak Transmit Power: EIRP: 2dBm (1.58mW)
- Channel Spacing/Number of Channels: 2MHz, 40 channels (3 for advertising, 37 for data)
- Antenna Type: PCB Antenna, 1.5 dBi gain

Mobile Application Compatibility:

- Android 6.0 Marshmallow (or later) powered smart phone with Bluetooth Smart Ready compatibility and High Definition (or better) touch screen
- Apple iPhone 4S/iPod 5th Gen or newer smart phone powered by iOS 8.0 (or later)

Device Dimensions: 60.4x43.5x13.6 mm

Device Weight: 25 g

Environment Specifications:

- **Operating/Storage/Transport:**
Temperature from 0°C to +40°C
The maximum temperature of the applied part could be 42.3°C while using in the 40°C environment.
- **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-01M2 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 M2 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% UT; 0,5 cycle at 0°, 45°, 90°, 135°, 225°, 270°, 315° 2) 0% UT; 1 cycle; Single phase at 0° 3) 70% UT; 25/30 cycles; Single phase at 0° Voltage Interruptions: 0% UT; 250/300 cycle;	As on the previous column	Voltage Dips: 1) No performance degradation observed 2) No performance degradation observed 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

PowerDot stimulators are controlled through Bluetooth Low Energy wireless radio interface.

PowerDot is specifically designed to be used together with PowerDot App, which is supported for the selected Android and iOS mobile devices.

SECURE PAIRING

Your PowerDot is paired with your mobile phone 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 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 Mobile App and PowerDot PD-01M2 Bluetooth communication interface are specifically designed to accommodate temporarily and permanent Bluetooth

disconnections during a stimulation session. PowerDot PD-01M2 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-01M2 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-01M2 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 a working microwave oven as radio interference from a 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-01M2 device becomes unresponsive to PowerDot App commands during stimulation session or you were not able to connect to your PowerDot and initiate stimulation), try terminating your stimulation session manually by shortly pressing Power button on your PowerDot device.

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

If you fail to re-connect and resume your session 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)

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

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

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, pursuant to 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 in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

EU ONLY SYMBOLS:

	The symbol on your PowerDot unit is to indicate conformity with the requirements of the MDD (Medical Device Directive 93/42/EEC) & MDR (Medical Device Regulation 2017/745)
	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
IP 22	IP22 IP Rating IP22
	An indication that the device is a medical device
	Unique Device Identification for medical device
	Pads intended for single-user only for hygiene purposes

MANUFACTURER & AFTER-SALE SERVICE

Smartmissmo Technologies Pte Ltd
 4 Shenton Way, #15-01 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 GmbH,
 Altenhostrasse 80, 66386, St. Ingbert, Germany

ELECTROMAGNETIC COMPATIBILITY (EMC)

PowerDot PD-01M2 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-01M2 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-01M2 device can still be 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-01M2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



PowerDot PD-01M2 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.

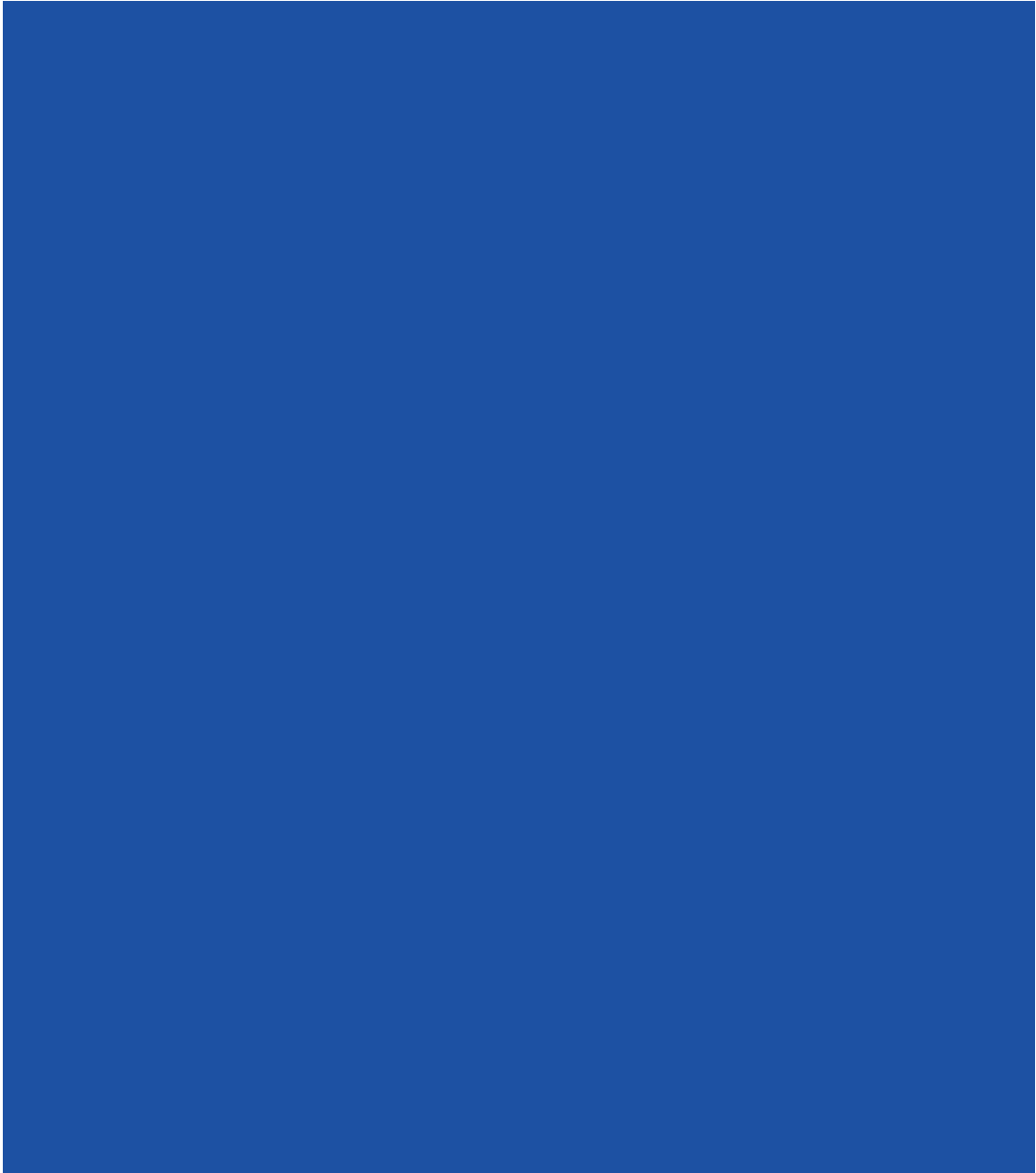
The following device function is considered essential to the safety of the user: ability to maintain consistent stimulation intensity (amplitude), pulse frequency and pulse waveform (both shape and width).

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.

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PowerDot

by Therabody

Born in Los Angeles, CA.
Designed for every*body*.



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