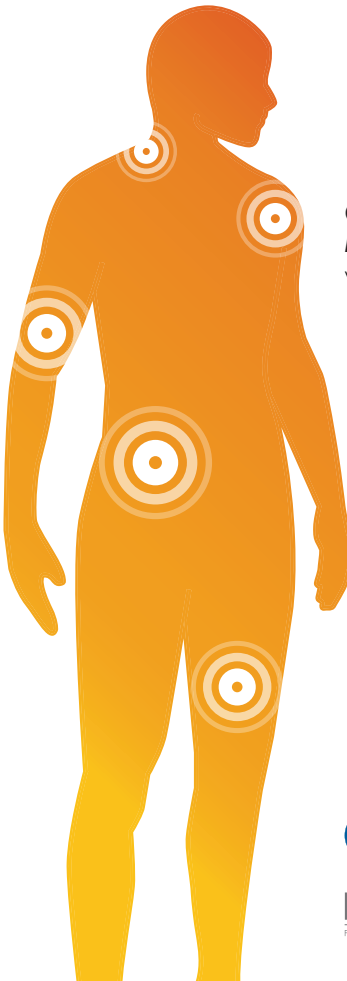
Plus



Operating Manual

Version: V1.0

Consult instructions for use

paingone

Fast, effective pain relief

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Introduction

The device is a hand-held and battery-powered unit of transcutaneous electrical nerve stimulation (TENS) for over-the-counter use. It combines the electrical characteristics of TENS with the point stimulation delivered through the electrodes of a metal contact tip and a metal contact ground on the device. The device has only one TENS mode, and applies a low-frequency (2 Hz) pulse to the body skin.

The device is to generate small pulses of electrical current and delivers the pulses to the user's skin through the metal contact tip such that the underlying nerves and/or muscles are activated.

Indications for Use

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

Accessories included:

1x Paingone Plus
1x User Manual
1x AAA Battery

Safety Warning

Caution, consult accompanying documents

Contraindications

- Do not use this device on persons who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
- Do not use this device on persons whose pain syndromes are undiagnosed.
- Do not modification of equipment

Warnings

- WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous. To reduce the risk of buns, electric shock, and fire, this device must be used in accordance with the instructions.
- Carefully examine the device, and do not use if they show any sign of deterioration.
- Do not tamper with this device in any way. There are no user serviceable parts. If for any reason they do not function satisfactorily, return to the authorized service center at address given.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in persons with a known sensitivity to the carotid sinus reflex. Carotid sinus is located on both sides of the neck.
- Stimulation should not be applied over the front neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation over the neck can also cause adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- The operator shall not touch output of batteries and the patient simultaneously
- On potential hazard from simulteneous connection of a PATIENT to a high frequency surgical ME EQUIPMENT and the STIMULATOR that may result in burns and possible damage to the STIMULATOR

- Operation in close proximity(e.g.1m) to ashortwave or micrrowave therapy ME EQUIPMENT may produce instability in the STIMULATOR output
- The application of lelctrodes near the thorax may increase the risk of cardiac fibrillation
- Do not inhale or swallow the components of the equipment
- Allergies may occur in the contactable parts of equipment

The patient is an intended operrator

WARNING:No servicing/maintenance while the ME equipment is in use

Precautions

- Safety of stimulation use during pregnancy has not been established. Consult with your physician before use during pregnancy.
- Caution should be used for persons with suspected or diagnosed heart problems.
- Caution should be used for persons with suspected or diagnosed epilepsy.
- Caution should be used if you have any of the following:
  - if you have a tendency to bleed internally following an injury;
  - if you recently had surgery, or have ever had surgery on your back;
  - if areas of skin lack normal sensations, such as skin that is numb.
- Consult with your physician before use over the menstrual uterus.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium.
- Do not use this device while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
- Keep this device out of reach of children.
- Do not use this device in high humidity areas such as a bathroom.
- Stop using this device at once if you feel discomfort, dizziness or nausea, and consult your physician.

- Do not apply stimulation of this device in the following conditions:
  - across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal;
  - over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
  - in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms);
  - on children or incapacitated persons.
- Be aware of the following:
  - consult with your physician before using this device;
  - this device is not effective for pain associated with Central Pain Syndromes, such as headaches;
  - this device is not a substitute for pain medications and other pain management therapies;
  - this device is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
  - stop using the device if the device does not provide pain relief;
  - use this device only with the electrodes, and accessories recommended for use by the manufacturer.

- Store the device away from high-temperature and direct-sunlight. Storage outside of stated storage temperature may result in device malfunction.
- Dispose of this battery-containing device according to the local, state, or federal laws.
- Batteries need to be removed when equipment is not used for a period of time

Adverse Reactions

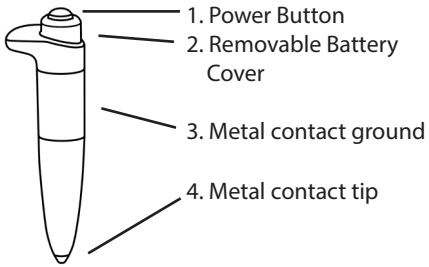
- You may experience skin irritation and burns beneath the stimulation electrodes applied to the skin; check skin under electrodes frequently.
- You should stop using the device and should consult with your physicians if you experience adverse reactions from the device.

Thank You
Thank you and congratulations on your purchase of Plus, the TENS pen for pain relief. This manual will help explain how to correctly use and get the most out of your device.

How the Device Works
Plus is simply applied on the area where you wish to use it. It should be placed directly on skin.

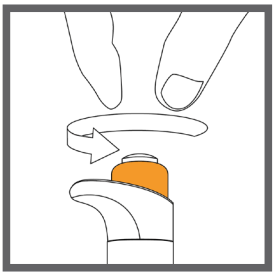
Holding the power button results in the generation of stimulating electrical impulses. These are transferred to the skin, via the electrode of the metal contact tip, in a way that the underlying nerves and/or muscles are activated for pain relief.

Setup and Overview
Unpack the box, taking out the Plus device and the battery. Insert the battery into the device prior to use following the instructions below.



Applied Part: 4 parts
The patient is an intended operator
- the patient can apply the device and change battery under normal circumstances
- the patient can maintain the device according to the user manual

Operating Instructions
The following Operating Instructions are used to guide the operation of the device, and the details about each step are listed in the following table.

1st Step – Insert the battery into the device
The device comes with one AAA battery. Insert the battery into the device prior to use. Locate the removable battery cover, which is the orange section of the device right below the power button. Remove the battery cover by gently twisting it anti-clockwise. It will gradually unscrew from its fixture. Insert the battery with the positive (+) tip going in first. If the battery is inserted incorrectly the device will not work. Replace the battery cover by twisting it gently in a clockwise direction until it is secured. Be careful not to damage the mechanism through excessive force.
Battery placement 

2nd Step – Apply the device

Hold the device in your hand and firmly wrap your fingers around the metal contact ground.

Now place the metal tip of the device directly on the area of the body where you wish to use it. Press and hold the power button for 30 seconds.

The device will emit controlled electrical pulses. You will likely feel these pulses against your skin on the applied area, although some users may not feel anything.

You can treat larger areas by moving the device along the line of pain as it delivers the pulses

Apply the device

3rd Step - Release the power button to turn off the device after use

After 30 seconds, simply release the power button. This will deactivate the device and the electrical pulses will stop. Application is now complete.

You can re-apply the device when necessary, up to 4-5 times a day on each desired body area.

Note: Remove the battery from the device if you are not going to use the device for more than one month. Store the device and battery in a cool place, out of direct sunlight.

Turn off the device

The device includes one AAA battery as its detachable parts, and the battery should be replaced when the device ceases to emit electrical pulses.

Performance Specifications

Power Source	1.5V Battery
Number of Output Modes	1 TENS mode
Dimensions (mm) [L x W x D]	149 x 40 x 40 mm
Output Voltage	7.3V±1.5V@500Ω 30V±6V@2KΩ 128V±25V@10KΩ
Output Current	0-30mA
Wave form	Single rectangular pulse
Pulse Duration	100μSec
Frequency	2Hz
Rated load	500Ωor2KΩor10KΩ
Software version	A0
Hardware version	A0

Time from low temperature storage to suitable temperature: 30 minutes

Time from high temperature storage to suitable temperature: 30 minutes

Life expectancy of equipment: 2 years

Battery life: About 20 days
(30 minutes per day)

Cleaning and Maintenance

To clean, simply wipe with a soft, slightly damp cloth and allow to dry before re-use. No elements of the device require sterilization, and the metal contact tip requires regular cleaning. Although the contact tip is non-invasive, it is recommended alcohol swabs are applied to the tip prior to each usage. This is especially necessary when the device is applied to different people.

Trouble Shooting

If your device is not operating properly, please check below for common problems and suggested solutions. If the recommended action does not solve the problem, please contact the seller.

The device is not emitting any pulse

a) Check that you are holding the device correctly, being sure to make contact with the metal ground.

b) Check that the battery has been inserted the correct way. See the symbol on the reverse of the device for an illustration of the correct polarity.

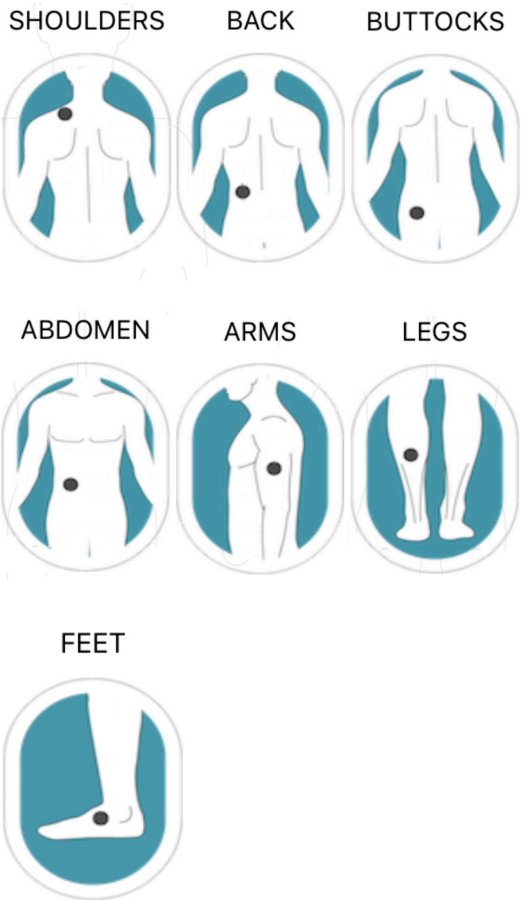
c) Maybe the battery is dead. Replace a new battery.

d) If you believe the device suffers from a manufacturing fault, DO NOT attempt to repair the device. Return it to the location of purchase. Devices with manufacturing faults are covered by a one-year replacement guarantee.

e) If assistance is required in setting up, using, or maintaining the equipment please contact manufacturer.

g) Degraded sensors and electrodes, or loose electrodes, can lead to performance degradation or other problems.

Recommended Use Positions



Never apply electrodes on the throat or both sides of the neck, where the carotid sinus nerves are located.

It is recommended not to stimulate the head, eyes, mouth, anterior neck (especially carotid artery) or upper chest and back, or above the heart.

Symbol and Title

Information essential for proper use shall be indicated by using the corresponding symbols. The following symbols may be seen on the device and labeling.

Symbol	Title
	Consult instructions for use
	Caution, consult accompanying documents
	Use by date
	Unrecyclable
	Date of manufacture
	Batch code
	Catalog number
	Serial number
	Manufacturer
	The type of electric shock protection in the application part:BF
IP22	Ingress Protection Level
	Temperature limitation
	Humidity limitation
	Non-sterile
	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment

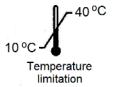
Fragile, handle with care

Keep away from rain

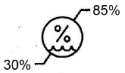
Product packaging is able to be recycled

Environmental Condition for Transport and Storage

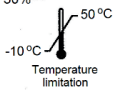
Normal working Atmospheric Pressure :70kPa to 106kPa



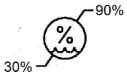
- Normal working ambient temperature: 10~40°C



- Normal working ambient humidity: 30~85%



- Store and transport ambient temperature: -10 ~50°C



- Store and transport ambient humidity: 30~90%

Fragile; handle with care

Keep away from rain

Product packaging is able to be recycled

Non-sterile

Electromagnetic Compatibility

1) This product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile radio frequency (RF) communications equipment.

2) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

4) Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

Guidance and manufacture's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device 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	The device 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 emissionsIEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity.

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure 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 ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are 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	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure 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 to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Safety test standards:

- IEC 60601-1:2005+A1:2012/EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014/EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

- IEC 60601-2-10/EN 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

- EN 980 Symbols for use in the labeling of medical devices

- EN 1041 Information supplied by the manufacturer with medical devices

- IEC 60601-1-6/ EN 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

- IEC 60601-1-11/ EN 60601-1-11 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment

- IEC 62304/ EN 62304 Medical device software - Software life-cycle processes

- IEC 62366/ EN 62366 Medical devices – Application of usability engineering to medical devices

- EN ISO 14971 Medical devices — Application of risk management to medical devices

Warranty

This device carries a limited warranty of one year from the date of delivery. The warranty applies to the device only, and the accessories are not covered by this warranty.

During the warranty period, defective items will be repaired or replaced at no charge. Any evidence of misuse, abuse, alternations, or externally caused damage may have this warranty invalid.

For more information, please contact the manufacturer.

The PCB of the device shall be maintained and checked by the maintenance personnel.

Manufacturer will make available on request circuit diagram, component part lists, description, calibration instructions. Etc., to assist to service personnel in parts repair.

Contact Information
Manufactured for JKH USA, LLC/Medi Direct International Ltd.
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JKH Health Co., Ltd.

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