

Trim and Tone

Electronic Pulse Stimulator (EMS) and LED Light 660nm



Operating Manual

TT-75R515
Edition V1.1



Consult instructions for use

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Introduction

TT-75R515 delivers electric pulses and LED Light 660nm generated to the user's skin through the electrodes and the light wave. The portable and compact device has multiple modes of different pulse frequencies, Electrical Muscle Stimulation (EMS). It includes operating elements of POWER-ON/OFF button, intensity increase button, intensity decrease button, mode button, timer button, and LED Light button, and can be attached and detached to the electrode through the four magnetic connectors.

Indications for Use

EMS: To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

LED Light 660nm: To help promote skin improvement and body contouring by supporting cellular function and assist with general health and wellness goals. Intended to treat areas of the abdomen, hips or thighs. Not intended to cure or diagnose any medical conditions or diseases.

Safety Warning

Contraindications

- Do not use this device on patients 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 patients whose pain syndromes are undiagnosed.

Warnings

- Do not apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or 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.
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation when the patient is in the bath or shower.
- If you have one of the following conditions, please consult with your physician before purchasing or using this device:
 - Acute disease, malignant tumor, infective disease, pregnant, heart disease, high fever, abnormal blood pressure, lack of skin sensation or an abnormal skin condition, any condition requiring the active supervision of a physician.
- Simultaneous connection of a PATIENT to a high frequency surgical ME EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME EQUIPMENT may result in device malfunction due to electronic interference.

Precautions

Do not use this device while driving.

Do not use this device while sleeping.

Do not use this device in high humidity areas such as a bathroom.

Keep the device away from wet, high temperature and direct-sunlight place.

Keep this device out of reach of children.

Stop using this device at once if you feel pain, discomfort, dizziness or nausea and consult your physician.

Do not attempt to move the electrode pads while the device is operating.

Do not use the device around the heart, on the head, mouth, pudendum or blemished skin areas.

Do not apply stimulation of this device in the following conditions:

- (1) across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal;
- (2) over painful areas. Please consult with your physician before using this device if you have painful areas;
- (3) over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins). Apply stimulation only to normal, intact, clean, healthy skin;
- (4) in the presence of electronic monitoring equipment (e.g. cardiac monitors, ECG alarms). The electronic stimulator may not operate properly when the electrical stimulation device is in use;
- (5) on children.

Be aware of the following.

- (1) to consult with your physician before using this device. The simulation with the device may:
 - i. cause lethal rhythm disturbances to the heart in susceptible individuals;
 - ii. disrupt the healing process after a recent surgical procedure;
- (2) that the device is not effective for pain of central origin, including headache;
- (3) that the device is not a substitute for pain medications and other pain management therapies;
- (4) that the device has no curative value;
- (5) that the device is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
- (6) that the long-term effects of electrical stimulation are unknown;
- (7) that the user may experience skin irritation, burns or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);
- (8) if the user has suspected or diagnosed epilepsy, the user should follow precautions recommended by his or her physician;
- (9) to use caution if the user has a tendency to bleed internally, such as following an injury or fracture;
- (10) use caution if stimulation is applied over the menstruating uterus;
- (11) use caution if stimulation is applied over areas of skin that lack normal sensation;
- (12) stop using the device if the device does not provide pain relief;
- (13) use this device only with the leads, electrodes, and accessories that the manufacturer recommends.
- (14) Do not share the use of the electrode pads with others.
- (15) Do not use the device while it's charging.
- (16) The device contains the lithium battery. If overheating of the device occurred during the charging, stop the charging or operation immediately and report to the seller.
- (17) Dispose of the battery-containing device according to the local, state, or federal laws.
- (18) The USB port used for charging needs to be securely isolated from the power grid, such as the security isolation adapter or power source with IEC60950 or IEC62368 or iec60601-1, the power adapter and product constitute the medical system when charging, and the risk of leakage of current should be paid attention to.

- The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy has not been established.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (silicon pads).
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- Use caution if stimulation is applied over the menstruating or pregnant uterus.

Adverse Reactions

Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin; Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.











Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

Environmental condition for normal working, transport and storage

- Normal working ambient temperature: 5~40°C
- Normal working ambient humidity: 15~90%
- Store and transport ambient temperature: -25 ~70°C
- Store and transport ambient humidity: 0~90%
- Atmospheric pressure: 70~106kPa

Symbol interpretation

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
IP22	IP code of the device
	Unrecyclable
	This way up
	Date of manufacture
	Batch code
	Serial number
	Type BF applied part
	CAUTION, Avoid injury. Read and understand owner's manual before operating this product.
	Fragile, handle with care
	Keep the product in the dry place Away from water and rain.
	Product packaging is able to be recycled

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
- IEC60601-1-2: 2014/EN60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-10:2012/EN 60601-2-10:2000+A1:2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- EN 1041 Information supplied by the manufacturer with medical devices
- IEC/60601-1-6/ EN 60601-1-6 Medical electrical equipment – Part1-6: 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
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk

Electromagnetic Compatibility and FCC Compliance Statement

- 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 manufacturer'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 emissions IEC 61000-3-3	Complies	

Guidance and manufacturer'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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacturer'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 $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ 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 meters (m).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

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.

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.

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	10	10	23

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.

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

- (1) This device may not cause harmful interference.
- (2) This device must accept any interference received, including interference that may cause undesired operation.

The subject device 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.

The product generates, uses, and can radiate radio frequency energy and, if not installed and used accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that the interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on or off, the user is encouraged to try to correct the interference by one or more of the following measures:

- a) Reorient or relocate the receiving antenna;
- b) Increase the separation between the product and the receiver;
- c) Consult the dealer or an experienced radio / TV technician for help.
- d) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

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

Product Specifications

Accessories included in the package.

- (1). EMS and LED Light unit controller * 1pc
- (2). Waist belt * 1pc
- (3). Extension Belt * 1pc
- (4). Manual * 1pc
- (5). USB cable * 1pc

Technical Information

Model/type	PL-029K13A	Weight	90g
Power supply	Powered by internal 3.7V li-ion battery	Automatic shutoff	20 minutes
Waveform and wave shape	Biphasic rectangular wave pulse	Degree of protection against electric shock	Type BF applied part
Pulse duration	100 μ s \pm 15 μ s	Type of protection against electric shock	Internally powered equipment
Pulse frequency	1-50HZ (Hz=vibration per second)	Grade of waterproof	IP22
Output Voltage	Max. 45Vpp \pm 20%(at 500ohm load)	Product life	1 year
Treatment time	10,20,30,40,50,60 minutes	Lifetime for electrode	Storage for 2 years (no use) , Times of reusable: 30 times
Output intensity	0 to 20 levels, adjustable	Mode of operation	Continuous operation
Modes	1 combined EMS mode + 1 heating mode	Software version	A0
Typical operation time of Battery	If to use at level 20, the same setting with the light function, the battery can be used for about 150 minutes after fully charged.	The time required for me equipment to warm from the minimum storage temperature between uses until it is ready for intended use	30 minutes

Technical Information Continued

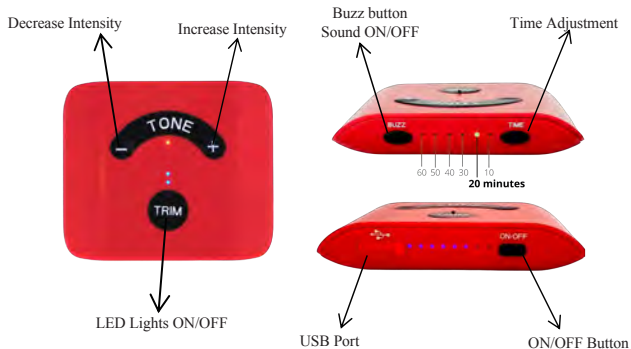
Behaviour of me equipment while the rechargeable internal electrical power source is charging:	The eight LED light flashes by turns during charging, and become solid when the device is charged fully.	The time required for me equipment to cool from the maximum storage temperature between uses	15 minutes
Typical service life of Battery	300 times of recharging	Adapter for charging	Please use output DCSV and output current 1.0-2.0A adapter for charging
Note: Not intended to be sterilized.			
Not for use in an OXYGEN RICH ENVIRONMENT			

Product EMS Programs



Program name	Time min.	Frequency (Hz)	Pulse Width (μ s)
Warm up	2	5	100 μ s
Sport	(setting time-4)/4	40	100 μ s
	(setting time-4)/4	30	100 μ s
	(setting time-4)/4	50	100 μ s
	(setting time-4)/4	20-50	100 μ s
Relax	2	3	100 μ s




Operating Instructions





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



Instructions for Use

<p>Step 1 – Check the battery power of the device</p> <p>Before use, please check if the device can be turned on. If it can't be turned on, please charge the device with the received USB cable before using it. While charging, the 8 battery indicator lights (blue lights) next to the ON/OFF button will flash one by one.</p>	
<p>Step 2 - fasten the device to the belt wrap</p> <p>Fasten the magnetic fastener on the device and ensure that all four magnetic buckles are fastened.</p>	

<p>Step 3 - Wear the belt wrap with the device on the waist</p> <p>Note: If the belt is not long enough, use the matching extension belt; the waist wrap should be in close contact with the body skin.</p>	
<p>Step 4 - Press the ON/OFF button to turn on the power</p> <p>After the preparation project is completed, press the ON/OFF button for 0.2 second. The buzzer will sound once and the front LED indicator (orange) will light up. The default state is: intensity 0, heat 0 , working time is 20 minutes.</p>	
<p>Step 5 – Adjust the stimulation intensity</p> <p>Press and release the + or – button to increase or decrease the intensity by one level (up to 20 levels), indicated by the front orange LED flashing once and beeping once ; After increasing to the highest level, press the “+” button again(or after decreasing to the lowest level, press the “-”button again), the buzzer will sound twice, and the orange indicator will flash twice, indicating that it has reached the highest level (or lowest level) and cannot increase(or decrease) any more.</p>	

<p>Step 6 – Choose the stimulation time</p> <p>The device defaults with 20 minutes, 10-60 minutes can be adjusted (10 minutes / level, total of 6 levels), press the TIME button to adjust, the first indicator light (next to the TIME button) represents 10 minutes, and the second light represents 20 minutes and so on. When turn to 10 minutes, the buzzer will sound once; when turn to 20 minutes, the buzzer will sound twice and so on. The device will turned off automatically after the countdown ends.</p>	 <p>A red, rectangular electronic device with a control panel. A red button labeled 'TIME' is circled in white. To its left is a 'TONE' dial and a 'TRIM' button. A small indicator light is visible next to the TIME button.</p>
<p>Step 7– Press TRIM button to turn on the infrared function.</p> <p>Press TRIM button to turn on the infrared function. The 2 blue light above the TRIM button light on and the buzzer sound once.</p>	 <p>A close-up of the red device's control panel. A finger is shown pressing the 'TRIM' button. Above the TRIM button is a small blue indicator light. A 'TONE' dial is visible above the TRIM button.</p>
<p>Step 8– Hold the ON/OFF button again to turn off the device</p> <p>When the countdown timer is up, the device will turn off automatically. If you need to continue using it, please turn it on. If you need to stop during using, turn off the device manually .</p>	 <p>An hourglass is shown above the red device. The device's control panel is visible, with the 'ON/OFF' button circled in white. The device is shown from a slightly elevated angle.</p>
<p>Step 10</p> <p>After use, remove the belt wrap, separate the device from the wrap and store them separately.</p>	 <p>A hand is shown pulling the red device out of a dark grey or black fabric wrap. The wrap has a label that reads 'TRIM TONE' with a small 'W' logo below it.</p>

Recommended Practice:

- (1). Duration suggested time is 20 minutes, 3 to 5 times per week.
- (2). Start on the lowest intensity and gradually adjust to a comfortable level on a scale level from 1 to 20.
- (3). Be sure the area to be treated is free of perspiration, dirt and abrasions.
- (4). Good skin care is important for comfortable use of device. Be sure the treatment site is clean of dirt and body lotion, and wipe with an alcohol pad if needed.
- (5). If the LED light becomes blurry and/or the stimulation intensity becomes weaker, it means the battery power is running low. It is time to recharge the device. After fully charged, the 8 battery indicator lights (blue lights) next to the ON/OFF button will light on and stop flashing.

Use Direction

1. Clean skin thoroughly prior to each application of electrodes, which will not stick well if any lotion, make-up, or dirt is left on the body skin.
2. Ensure the device is off before applying the electrode to it.
3. Wear the belt wrap firmly to the waist or thighs, in direct contact with skin.

Removal and Storage

1. Turn the device off before removing the belt wrap.

Cleaning and Maintenance

Please use a damp cloth of water or neutral detergent to clean the device first, and then use a dry cloth to wipe it dry.

If not using on a regular basis, please charge the unit device every 3 months to maintain proper functions.

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.

Problem	Possible Cause	Possible Solution
One pad feels more intense than the other.	This is normal. Different area of your body will react differently	Nothing needs to be done. Make sure the belt wrap silicon pads are moist and making good contact with skin.
The EMS intensity is not felt on lower intensity levels.	Belt wrap not attached to the body firmly	Wear the belt wrap firmly to the skin
	The intensity setting is getting weak	Increase the intensity level
	The battery capacity is low	Charge the battery
	The therapy time is too long or the intensity is set too low	Reduce the application time or increase the warm-up intensity
	The battery capacity is depleted	Charge the battery

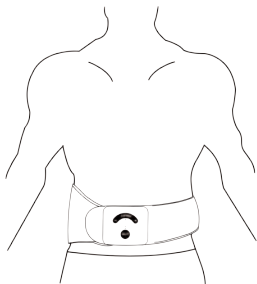
Warranty

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 distributor.

Recommended Use Positions



Contact Information

Distributor:

Trim and Tone USA.

Address: 4409 N Hesperides St, Tampa, FL 33614

Info@trimandtone.net