

KURA TENS - 6 PROGRAMMES

Use and maintenance book

REF AD-2126 (GIMA 28431)



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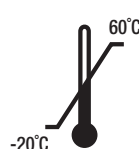
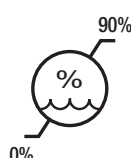
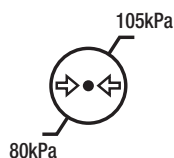


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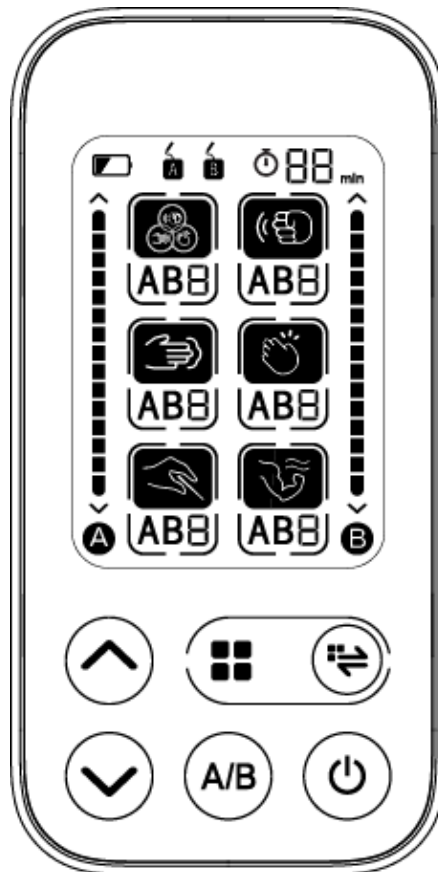
IP22



USER MANUAL

Transcutaneous Electrical Nerve Stimulators (TENS device)

Model:AD-2126



Please read this user manual carefully before using the product

Thank you for purchasing AD-2126 TENS device.

Transcutaneous Electrical Nerve Stimulators (TENS device) is effective in relieving pain. Before using, please read the instructions carefully, so that you can use it correctly. Please keep this user manual properly.

MODEL AD-2126

TENS device

(Transcutaneous Electrical Nerve Stimulators)

OPERATION GUIDE

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INTENDED USE

The TENS device is intended to provide temporary relief of muscle soreness caused by exercise, normal household or work activities, as well as to alleviate chronic, intractable pain and pain associated with arthritis. It is important to apply the electrode pads only on intact skin and avoid placing them directly on the head, upper neck, chest, upper back near the heart, spine, and private areas. The TENS device is suitable for adult users, including lay persons and professionals.

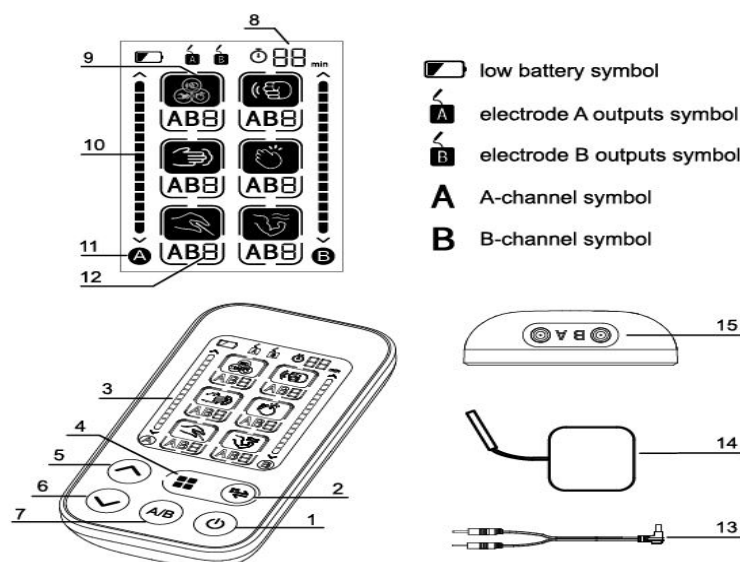
CONTRAINDICATION

Patients with implanted electronic devices such as pacemakers, life-sustaining medical devices such as artificial heart or lung, and medical devices such as electrocardiograph.

OPERATION PRINCIPLE

TENS lessens pain by sending electrical impulses (Output pulse frequency: 0-100Hz; Output voltage: max. 120 Vpp (500 ohm); Output pulse width: 20~100 μ s) through electronic core and self adhesive pads placed on the skin. The electrical signal then passes to the nerves under the skin. These nerves take messages to the brain about what they feel, such as thump, vibrate, press and knead. TENS signals can interfere the message of pain on these nerves with a tingling sensation, which changes the feel of the pain. Further more, low frequency vibrations can promote circulation of blood and relieve pain.

CONTENTS AND DISPLAY INDICATORS




Note: The pictures in the manual are for reference only.

- | | |
|-----------------------------------|---------------------------------|
| 1 ON/OFF button | 9 Out-of-group mode |
| 2 Intra-group mode switch button | 10 Treatment of strength |
| 3 LCD screen | 11 Currently adjustable channel |
| 4 Out-of-group mode switch button | 12 Intra-group mode |
| 5 Increase setting button | 13 Wire |
| 6 Decrease setting button | 14 Electrode Pads |
| 7 Channel selection button | 15 Output Pin |
| 8 Remaining message time display | |

PACKAGE CONTENTS

- 1 TENS device
- 1 User Manual
- 2 Electrode wires
- 4 Electrode Pads

SPECIFICATIONS

1. Product name: Transcutaneous Electrical Nerve Stimulators (TENS device)
2. Model: AD-2126
3. Classification: Internally powered, Type BF applied part, IP22, No AP or APG, Continuous operation
4. Machine size: Approx. 120.3mm × 60.3mm × 20.6mm (4 3/4 " x 2 3/8 " x 13/16 ")
5. Weight: Approx. 73g (2 9/16 oz.) (exclude batteries)
6. Electrode Pads: Approx. 50mm × 50mm (1 31/32 " x 1 31/32 "), Applicable to all treatment modalities. **Electrode Pads model: EP505020W**
7. Wire: Approx. 1200mm (47 1/4 ") .Wire model: 23507-2.0-1200
8. Output channel: 2 (A and B)
9. Number of treatment program: 24 sub-mode in 6 main modes (COMPOSITE(Default), THUMP, PRESS, SLAP, ACUPUNCTURE, RELAX)
10. Number of treatment strength: 15 strength levels
11. Output pulse frequency: 0-100Hz
12. Output voltage: max. **120 Vpp (500 ohm)**
13. Output pulse width: 20~100 **μs**
14. Large LCD with blue backlight
15. 15 minutes countdown time for running, also can set times by yourself
16. Batteries: 4 × 1.5V  SIZE AAA
17. Environmental temperature for operation: 5°C ~ 40°C
18. Environmental humidity for operation: ≤ 80% **RH**
19. Environmental temperature for storage and transport: -20°C ~ 55°C
20. Environmental humidity for storage and transport: ≤ 90% **RH**
21. Environmental pressure: 80kPa-105kPa
22. Device life: 3 years
23. Battery life: Approx. 2 months with alkaline batteries and 15-min. usage per day.

NOTICE

1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
2. ⚠️ This TENS device is designed for adults and never should be used on infants or young children. Consult your physician or other health care professionals before use on older children.
3. ⚠️ The device must never be used near to the heart, such as chest or the upper back. The stimulation electrodes must not be placed on any part of the front ribcage (where the ribs and breastbone are located), especially not on the two large pectorals. this can increase the risk of ventricular fibrillation and induce cardiac arrest.
4. ⚠️ The device should not be applied across or through the head, directly on the eyes ,covering the mouth.on the front of the neck,(especially the carotid sinus) , or from electrodes placed on the chest and the upper back or crossing over the heart.
5. ⚠️ The device must never be used on both feet simultaneously or on the spine.And never be used on private parts or skin disease parts
6. The therapy time should not be more than 30 minutes in each session if the electrode pads are on the same part of the body.
7. When you feel unwell or your skin is abnormal in using the TENS device, please stop using it immediately and ask for and follow the advice form the doctor.
8. Before you are to shift the electrode pad to the other position in using the apparatus, you must turn off the power first.
9. Do not make any sharp kinks in the connecting leads or electrodes.
10. Observe caution when using the device in the immediate vicinity of cellular phones that are switched on.
11. ⚠️ Please do not let children or persons who are incapable of expressing their own will use the TENS device; Keep the product at a place inaccessible to children to prevent children from swallowing the batteries or small parts.or it may lead to incident or make one feel unwell.
12. Please do not use the TENS device in bathroom or other place in high humidity . Otherwise one may receive fierce stimulation.
13. Please do not use it when driving , Otherwise it may lead to incident.
14. Please do not use it in sleep.
15. In the process of stimulating and therapy, please do not get the metal part of leather belt, wristwatch or necklace touch the leaf electrode pads.
16. Please do not use it for other purpose than treatment.
17. The device might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
18. ⚠️ User who with implanted electronic equipment, such as pacemakers and intracardiac defibrillators has not got the doctor's advice must not use the device. Pregnant women should not use the device during the first trimester, and should always consult a doctor, midwife or physiotherapist prior to use.

19. ⚠ 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.
20. ⚠ Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy EQUIPMENT may produce instability in the STIMULATOR output.
21. ⚠ Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
22. Please do not knock down, repair, and rebuild it privately. if you have any problem, please contact the service center.
23. Please do not use the electrode pads and wire other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in uncomfortable feeling.
24. Please do not share the electrode pads with other infective person to avoid cross-infection.
25. The output wave parameters are not be influence by load resistance, except output voltage.
26. Information regarding potential electromagnetic or other interference between the electrical muscle stimulator and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the unit be kept at least 30 cm away from other wireless devices, such as WLAN unit, microwave oven, etc. It can't be used near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
27. Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
28. If you are allergic to the device's material, please don't use this device.
29. The patient is an intended operator.
30. For Hospitals and Clinics, in the presence of or when attached to the body, electronic monitoring equipment (e.g. cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.

SETUP AND OPERATING PROCEDURES

1. BATTERY LOADING


- a. Open battery cover at the back of the monitor.
- b. Load four "AAA" size batteries. Make sure the batteries are inserted according to the positive and negative marks ("+" and "-") printed in the battery housing.
- c. Close the battery cover.


When LCD shows battery symbol  , replace all batteries with new ones.

Rechargeable batteries are not suitable for this monitor.

Remove the batteries if the monitor will not be used for a month or more to avoid relevant damage of battery leakage.

⚠ Avoid getting battery fluids in your eyes, if it happens, immediately rinse with plenty of clean water and contact a physician.

 The negative terminal of the battery needs to be compressed into the battery compartment properly after horizontal compression of the negative electrode. The battery is in contact with the spring.


 Make sure the battery cover is intact and not damaged before installing the battery.




The monitor, the batteries the electrode pad, and the wire must be disposed of according to local regulations at the end of their usage.

2. PREPARE THE ADHESIVE GEL PADS

- a. Connect the output cable to the electrode pads. Connect the output cable to the output plug socket on the main unit.
- b. Each adhesive gel pad is protected by a layer of transparent film. Remove the layer of film before stick the pads to the skin. Press the pads to ensure adhesion.





 Please use clear water to wash or use wet cloth (instead of facial tissue) to gently wipe up the electrodes when cleaning them. Do not use brush or fingernail to do it lest that the surface of the electrodes should get scratched.

 Wires stay away from babies and children, prevent the winding neck causing suffocation and death.

note:

- 1) Clean the intended skin area before stick the pads.
- 2) You should hold the plug when pulling it out. Please do not pull the wire.
- 3) Never stick two adhesive gel pads to each other ,Gel pads have to fit precisely inside the conductive surface.
- 4) If the pads are not stuck in the exact position, remove the pads and attach them again.
- 5) Keep the adhesive gel pads clean and do not expose to heat or direct sunlight
- 6) If the gel pads do not attach or are dirty, wipe with a wet cloth or replace with new ones. Do not clean the pad or adhesive gels with any chemical. Please contact the sale server of the TENS device to get replaced electrode Pads.
- 7) The electrode pad has a service life and is generally not recommended to be used for a long time. It is recommended to use the electrode less than 20 times. The specific number of times depends on the use and storage conditions.
- 8) Place the electrodes on intact skin only. Do not place on cuts or damaged skin.

3. TREATMENT TIME ADJUSTMENT

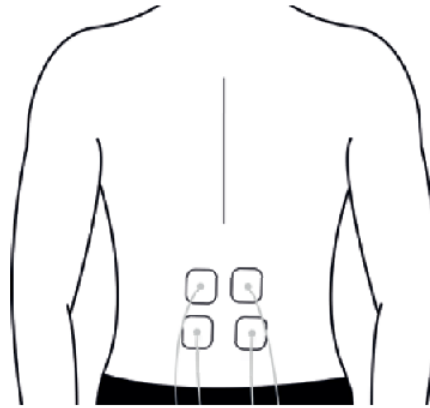
- 1) Long press  button to enter the treatment time setting when the device is power on.
- 2) When treatment time flickers on the LCD(The default value is 15 minutes), Press  or  button to adjust the treatment time.Short press  button to finish the treatment time setting.

4. APPLYING THE ADHESIVE GEL PADS

The Transcutaneous Electrical Nerve Stimulators (TENS device) can treat many different types of pain. On the next page are diagrams of where to place the electrodes for the most common forms of pain. For other areas of pain, place the electrodes on either side of the area of pain.

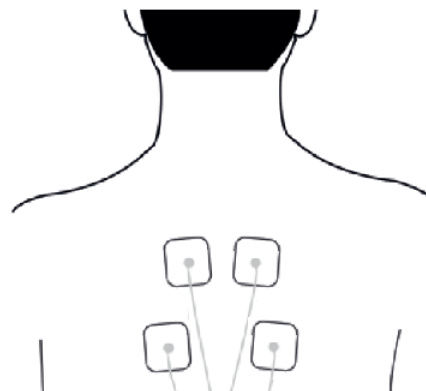
◎ **Waist**

● Sticking Diagram



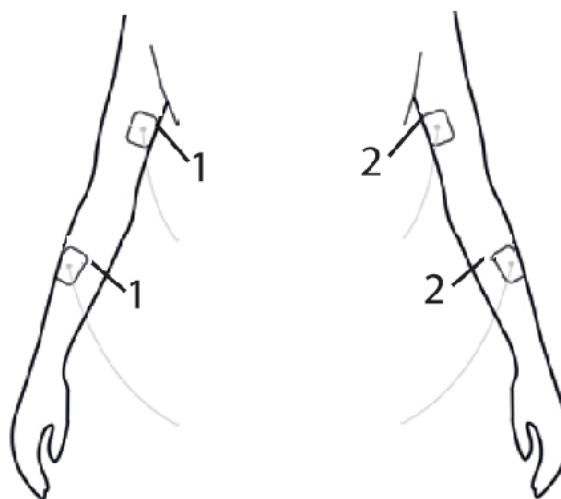
◎ **Back**

● Sticking Diagram



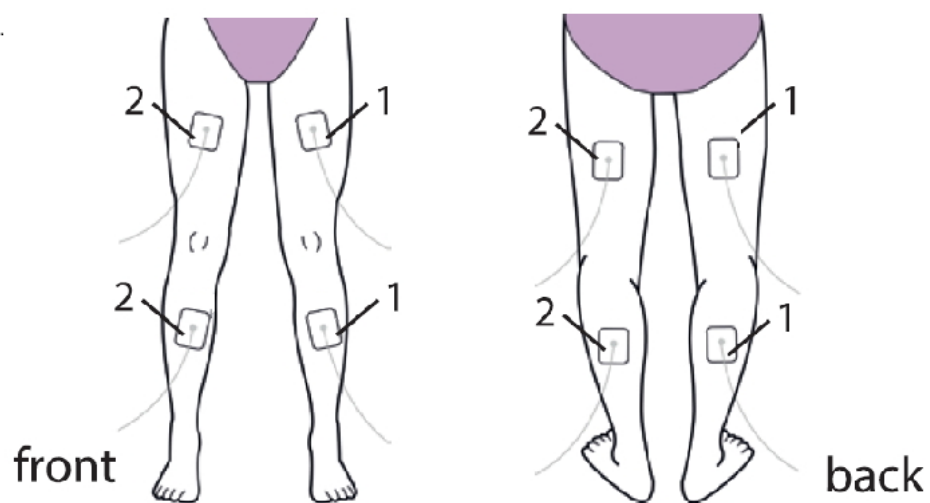
◎ Arm

● Sticking Diagram



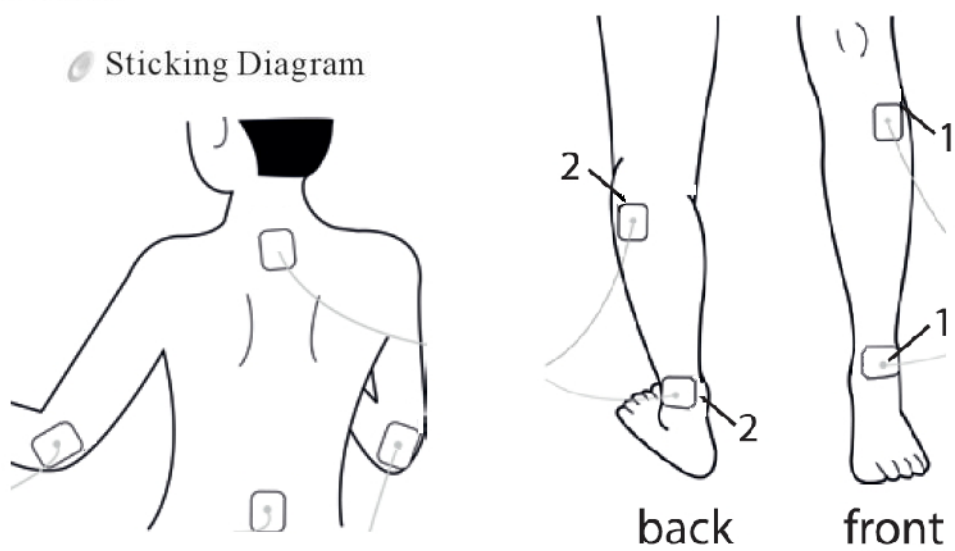
◎ Leg

● Sticking Diagram



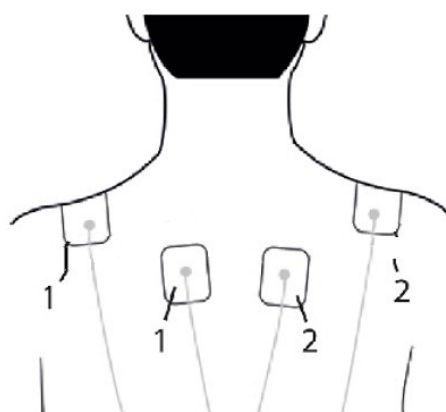
◎ Joint

● Sticking Diagram



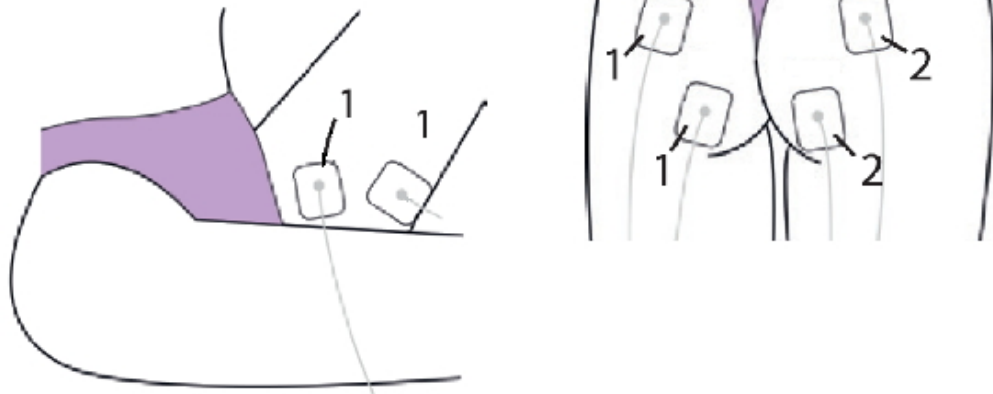
◎ Shoulder

● Sticking Diagram



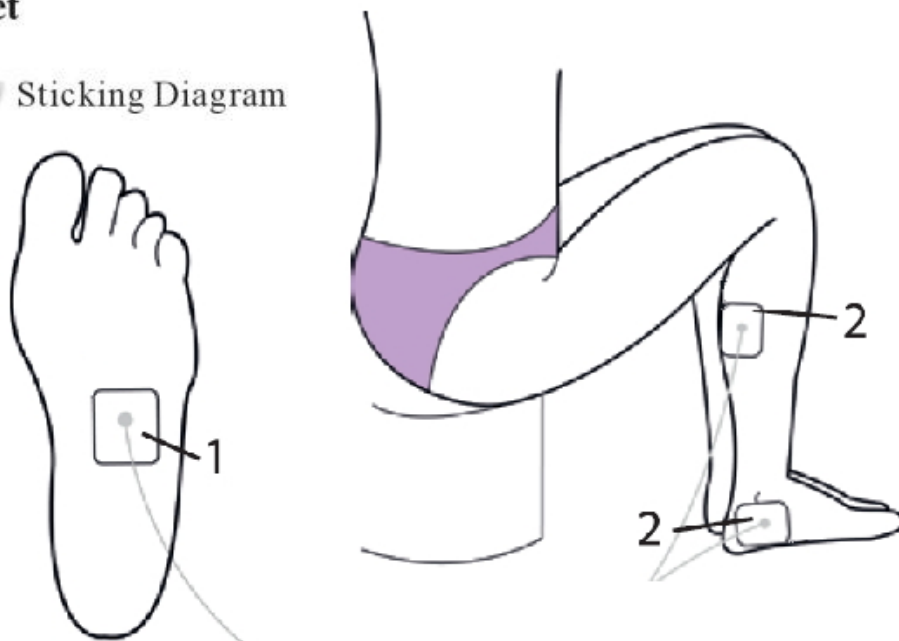
◎ Adductor and Gluteus

● Sticking Diagram



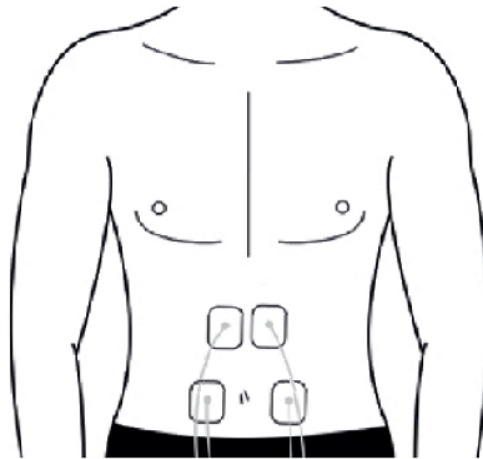
◎ Feet

● Sticking Diagram







◎ Belly











● Sticking Diagram















5. USING YOUR TENS device




- Attach the adhesive gel pads around the area of pain.
- Press the ON/OFF (⏻) button for one second to turn on the device.
Note: you can press the “ON/OFF” button for one second in anytime to turn off the monitor manually when the unit is working .
- Press the **A/B** button to select current channel (channel A) or (channel B).
- Press the  button to select outside the group mode.
- Press the  button to select intra-group mode.

Mode	Display on the LCD	Your feeling	Parameters of wave
1		Composite(1)	Output pulse frequency = 2~33.33Hz; Output pulse width = 20~100μs;
2		Composite(2)	Output pulse frequency = 2~20Hz; Output pulse width = 20~100μs;

3		Composite(3)	Output pulse frequency = 1~33.33Hz; Output pulse width = 20~100μs;
4		Composite(4)	Output pulse frequency = 20~50Hz; Output pulse width = 20~100μs;
5		Thump(1)	Output pulse frequency = 1~16.67Hz ; Output pulse width = 20~100μs; Continue output
6		Thump(2)	Output pulse frequency = 1~16.67Hz; Output pulse width = 20~100μs; Intermittent
7		Thump(3)	Output pulse frequency = 1~6.67Hz; Output pulse width = 20~100μs;
8		Thump(4)	Output pulse frequency = 1~6.67Hz; Output pulse width = 20~100μs;
9		Press(1)	Output pulse frequency = 50Hz; Output pulse width = 20~100μs;
10		Press(2)	Output pulse frequency = 33.33Hz; Output pulse width = 20~100μs;
11		Press(3)	Output pulse frequency = 50Hz; Output pulse width = 20~100μs;
12		Press(4)	Output pulse frequency = 33.33Hz; Output pulse width = 20~100μs;

13		Slap(1)	Output pulse frequency = 5~20Hz; Output pulse width = 20~100μs;
14		Slap(2)	Output pulse frequency = 2.5~10Hz; Output pulse width = 20~100μs;
15		Slap(3)	Output pulse frequency = 3.33~5Hz; Output pulse width = 20~100μs;
16		Slap(4)	Output pulse frequency = 3.33~10Hz; Output pulse width = 20~100μs;
17		Acupuncture(1)	Output pulse frequency = 2.5~100Hz; Output pulse width = 20~100μs;
18		Acupuncture(2)	Output pulse frequency = 50~100Hz; Output pulse width = 20~100μs;
19		Acupuncture(3)	Output pulse frequency = 11.11~100Hz; Output pulse width = 20~100μs;
20		Acupuncture(4)	Output pulse frequency = 16.67~100Hz; Output pulse width = 20~100μs;
21		Muscular Relaxation(1)	Output pulse frequency = 1~10Hz; Output pulse width = 20~100μs;
22		Muscular Relaxation(2)	Output pulse frequency = 1~50Hz; Output pulse width = 20~100μs;
23		Muscular Relaxation(3)	Output pulse frequency = 1~50Hz; Output pulse width = 20~100μs;

24		Muscular Relaxation(4)	Output pulse frequency = 16.67~100Hz; Output pulse width =20~100μs;
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- f. Press  or  button to adjust output intensity of selected channel.
- g. When the output intensity is at 1~15 other 0, the treatment starts and the time setting counts down with a flashing time sign on the LCD display.
- h. The defaulted treatment time is 15 minutes. During the treatment, the time will not be changed if the program or the intensity is changed.
- i. After treatment or channel A and B intensity are at 0, the device will be shut off automatically in 20s if no operation.
- j. If you want to end the treatment, press the ON/OFF () button to switch off the device.

6. TROUBLESHOOTING




Problem	Cause	Solution
You have no feeling of stimulus.	<ol style="list-style-type: none"> Are the batteries exhausted? Are the batteries properly loaded? Is the wire properly connected? Have you torn off the transparent protection film over the electrode pad? 	<ol style="list-style-type: none"> Replace the batteries. Correctly load the batteries. Firmly connect the wire. Tear off the protection.
Stimulus is weak.	<ol style="list-style-type: none"> Do the electrode pads closely stick to the skin? Are the electrode pads overlapped? Are the electrode pads dirty? Is intensity too weak? Are the electrode pads position pro-per? 	<ol style="list-style-type: none"> Closely stick the electrode pad to the skin. Separate the electrode pad and stick them to the skin gain. Please clean the electrode pad. Change intensity according to Part 5. Change the position of the electrode pad.
The skin becomes red.	<ol style="list-style-type: none"> Is the therapeutic time too long? Are the electrode pads too dry? Do the electrode pad closely stick to the skin? Are the electrode pads dirty? Are the surface of the electrode pads scratched? 	<ol style="list-style-type: none"> Control it within 10~15 minutes a time. Please gently wipe them up with wet cloth and then use them again. Please closely stick the electrodepad to the skin. Please clean the electrode pad. Please replace them with new electrode pad.
Power source is cut	<ol style="list-style-type: none"> Have the electrode pads come off the skin? 	<ol style="list-style-type: none"> Turn off the power and stick the electrode pad firmly to the skin.













off in the therapeutic process.	2. Are the wire disconnected? 3. Have the batteries been exhausted?	2. Turn off the power and connect the wire. 3. Please replace them with new ones.
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MAINTENANCE

1.  Do not drop this monitor or subject it to strong impact.
2.  Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
3. If this monitor is stored near freezing, allow it to acclimate to room temperature before use.
4. If you do not use the monitor for a long time, please remove the batteries.
5.  Do not attempt to disassemble this monitor.
6. Be sure not to move the electrode pads to another part of your body without turning off the power first.
7. Avoid contact of the electrode pads with anything made of metal, such as belts or necklaces.
8. After using the device, please remove plug out of output socket and re-attach the pads to the protective transparent film.
9. Do not twist or pull the output cables.
10. Please do not use any chemical to clean the main unit or electrode pads. In case you need to clean them, please wipe with a damp cloth, and suggested to clean the electrode pads after every use.
11. No component can be maintained by user in the monitor. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied.
12. The apparatus can maintain the safety and performance characteristics three years.
13. The monitor requires 6 hours to warm from the minimum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
14. The monitor requires 6 hours to cool from the maximum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
15. No servicing/maintenance while the monitor is in use.

EXPLANATION OF SYMBOLS ON UNIT

	Imported by
	Caution: read instructions (warnings) carefully
	Type CF applied part, with defibrillation-proof function

	Serial number
	Manufacturer
	Date of manufacture
	Lot number
	Atmospheric pressure limit
	Temperature limit
	Humidity limit
	Medical Device compliant with Directive 93/42/EEC
	Authorized representative in the European community
	Follow instructions for use
	Product code
IP22	Covering Protection rate
	WEEE disposal

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1 - Emission limits per environment

Phenomenon	Compliance	Electromagnetic environment
Conducted and radiated RF emissions	CISPR 11 Group 1, Class B	The device is intended to be used in home healthcare environment
Harmonic distortion	IEC 61000-3-2 NA	The device is powered by battery
Voltage fluctuations and flicker	IEC 61000-3-3 NA	The device is powered by battery

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV,

		$\pm 15\text{kV}$ air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 - Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, $\pm 5\text{kHz}$ deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 - PATIENT coupling PORT

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	$\pm 8\text{ kV}$ contact $\pm 2\text{kV}$, $\pm 4\text{kV}$, $\pm 8\text{kV}$, $\pm 15\text{kV}$ air
Conducted disturbances induced by RF fields a)	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur

		radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
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Table 5 - Signal input/output parts PORT

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transients / bursts	IEC 61000-4-4 NA	The device is powered by battery
Surges Line-to-ground	IEC 61000-4-5 NA	The device is powered by battery
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz



Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.