PROFESSIONAL MEDICAL PRODUCTS

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TENS 9 PROGRAMMI - 2 CANALI
TENS 9 PROGRAMMES - 2 CHANNELS
TENS 9 PROGRAMMES - 2 CANAUX
TENS 9 PROGRAMAS - 2 CANALES
TENS 9 PROGRAMAS - 2 CANAIS
TENS 9 PROGRAMME - 2 KANÄLE
TENS 9 PROGRAMÓW - 2 KANAŁY
ΠΡΟΓΡΑΜΜΑΤΑ TENS 9 - 2 ΚΑΝΑΛΙΑ

Manuale d'uso - User manual - Manuel de l'utilisateur
Guía de Uso - Guia para utilização - Gebrauchsanweisung
Instrukcja obsługi - Οδηγίες χρήσης

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefeully read and completely understand the present manual before using the product.*
AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*
ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*
ATENÇÃO: *Os operadores devem ler e entender completamente este manual antes de usar o produto.*
ACHTUNG*: Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.*
UWAGA*: przed rozpoczęciem użytkowania wyrobu operatorzy muszą przeczytać podręcznik i upewnić się, iż wszystko to, co jest w nim napisane jest dla nich jasne i zrozumiałe.*
ΠΡΟΣΟΧΗ*: Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.*

REF **28342 / AD-2026**

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M-28342-I-GB-F-E-P-D-PL-GR-Rev.1.02.16

INDEX

INTRODUCTION OF TENS 17
1. Theory of therapy 17
2. Why consider digital pain relief? 17
3. How does the Digital Pain Relief (TENS) work? 18
CONTENTS AND DISPLAY INDICATORS 18
INTENDED USE 20
CONTRAINDICATION 20
PRODUCT DESCRIPTION 20
SPECIFICATIONS 21
NOTICE 21
SETUP AND OPERATING PROCEDURES 22
1. Battery loading 22
2. Attachment of electrode lead wires 23
3. Operating instructions 23
TROUBLESHOOTING 24
MAINTENANCE 25
EXPLANATION OF SYMBOLS ON UNIT 25
ELECTROMAGNETIC COMPATIBILITY INFORMATION 26
WARRANTY INFORMATION 29

INTRODUCTION OF TENS

1. Theory of therapy

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive technique in which a low-voltage electrical current is delivered through wires from a small power unit to electrodes located on the skin. Electrodes are temporarily attached with paste in various patterns, depending on the specific condition and treatment goals. TENS is often used to treat pain, as an alternative or addition to pain medications. Therapy sessions may last from minutes to hours. The use of electrical stimulus for pain relief was popularized in the 19th century and became widespread in the 1960s and 1970s using battery power.

Transcutaneous electrical nerve stimulation (TENS) was first introduced into current clinical practice following Melzack and Wall's gate control theory of pain in 1965. Davis (1993) and Lewith (1984) explain the gate control theory of pain as follows. An area of the dorsal horn of the spinal cord, known as the substantia gelatinosa, acts as a gate to nociceptive impulses.

It receives myelinated nerve fibres (A fibres), the largest being A fibres, and small non-myelinated nerve fibres (C fibres).
If pain impulses pass along A (finemyelinated) fibres and C fibres rather than along A fibres, the gate is opened, and the patient perceives pain. If A fibre transmission of impulses is greater, the gate may be closed.

There is also evidence that the TENS machine enhances the production of the body's own natural pain killing substances: endorphins and encephalins. Human body produces endorphins and encephalins, which are opiate-like substances to counter the pain. Low frequency stimulation causes the release of the endorphins and encephalins.

2. Why consider digital pain relief?

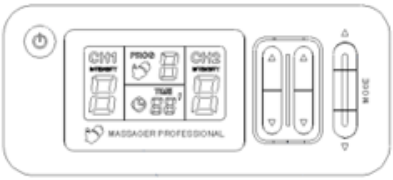
Pain is a warning signal – we need these signals to tell us that something may be wrong with our body. Without it, we may do not know that part of our body might be damaged, thereby damaging them further. However, once we have identified damage, pain serves little purpose. In the case of chronic, regular pain it can significantly interfere with daily activities and the quality of life.

3. How does the Digital Pain Relief (TENS) work?

Digital Pain Relief (TENS) works by passing harmless electrical signals into the body from its pads. This relieves pain in two ways:

- Firstly, it blocks the body's pain signals. These are normally transmitted from the area of damage through the nerve fibers to the brain, TENS interrupts these pain signals.
- Secondly, TENS stimulates the body's production of endorphins-its own natural painkillers.

CONTENTS AND DISPLAY INDICATORS

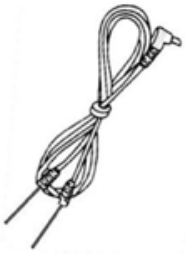


1 Mainframe

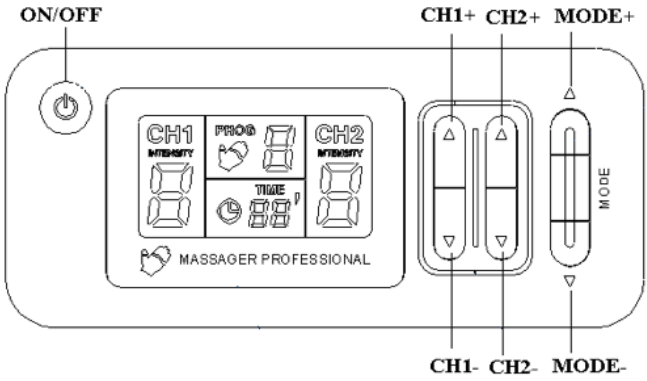
2 Battery

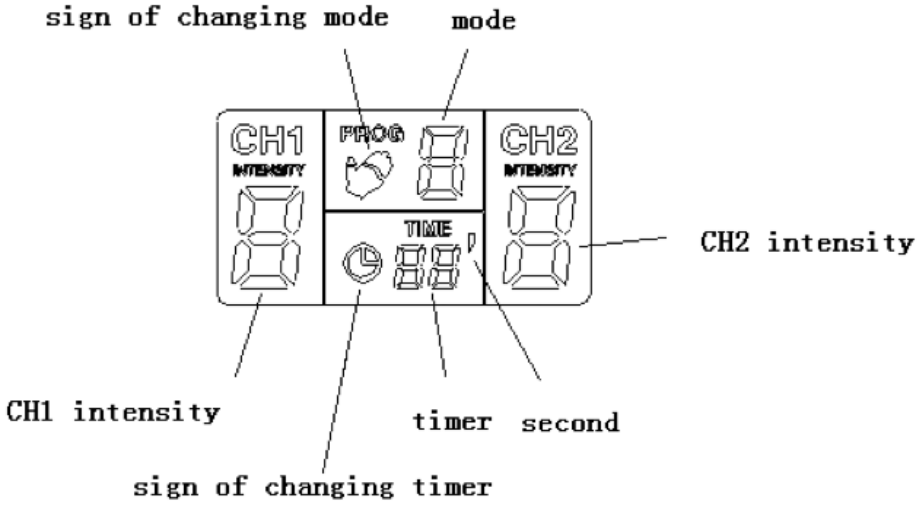
3 Instruction book

4 Electrode Pads (two pairs)



5 wire(two)





ON/OFF: Press the “ON/OFF” button to turn on/turn off the unit.

CH1+: Press the “CH1+”button to increase the CH1’s intensity from 0 to 9.

CH1-: Press the “CH1-”button to decrease the CH1’s intensity from 9 to 0.

CH2+: Press the “CH2+”button to increase the CH2’s intensity from 0 to 9.

CH2-: Press the “CH2-”button to decrease the CH2’s intensity from 9 to 0.

MODE Press the MODE button to changing-timer mode or changing-mode mode .Then use “MODE+” or “MODE-” button to adjust current mode. CH1’s mode will be adjusted when CH1 was selected, CH2’s mode will be adjusted when CH2 was selected.

INTENDED USE

AD-2026 is a dual channels TENS device which is effective in relieving pain.

Treatment effect

- Relieving lower-back pain
- Stimulate muscles
- Promoting blood circulation
- Eliminate tiredness

CONTRAINDICATION

The device is safe for all people, with the following exceptions or the people who are receiving physiotherapy.

1 People with acute disease
2 Cancer patients
3 People with infectious skin wounds
4 People who are in menstrual period or expectant mother
5 People with heart disease
6 People with high fever
7 People with abnormal blood pressure
8 People who have no feeling about their skins or people with abnormal skins
9 People with abnormal feeling of their body except the above cases.

PRODUCT DESCRIPTION

The AD-2026 is a battery operated pulse generator that sends electrical impulses through electrodes to the body and reaches the underlying nerves or muscle group. The device is provided with two controllable output channels, each independent of each other. An electrode pair can be connected to each output channel.
The electronics of the AD-2026 Digital create electrical impulses whose Intensity, Pulse Width, Pulse Rate may be altered according to the program. Press buttons are very easy to use and the panel cover prevents changes in the setting.

The AD-2026 corresponds to the below standards:

IEC 60601-1:2005/EN 60601-1:2006/AC:2010 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance).
EN 60601-1-2:2007 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance) - Collateral standard: Electromagnetic compatibility - Requirements and tests.

SPECIFICATIONS

1. Product name: TENS Device
2. Model: AD-2026
3. Number of treatment program: 9
4. Range of pulse frequency: 2-80Hz
5. Range of output voltage: 30V±20% (500)
6. Classification: Internally powered, Type BF applied part, IPX0, No AP or APG,Continuous operation
7. Machine size: Approx.128mm × 56mm × 16mm
8. Weight: Approx.67.4g (exclude batteries)
9. Power source: batteries: 2 ×1.5V ⎓ SIZE AAA
10. Environmental temperature for operation: 5°C~40°C
11. Environmental humidity for operation: ≤80%
12. Environmental temperature for storage and transport: -20°C~55°C
13. Environmental humidity for storage and transport: ≤95%
14. Environmental pressure: 80KPa~105KPa
15. Battery life: Approx.2 months with alkaline batteries and 30-min. usage per day.

Note: These specifications are subject to change without notice.

NOTICE

1. If you feel uncomfortable or abnormal of skin, please stop using. Consult with doctors and follow doctor's advice.
2. Please don't use it in the bathroom or other place with high humidity.
3. Please don't use it when driving or sleeping.
4. Do not make any sharp kinks in the connecting leads or electrodes.
5. Please don't use it for other purposes except treatment.
6. Please do not throw battery into fire.
7. Do not use the device if you are connected to, or in the vicinity of, high-frequency surgical or industrial equipment. This may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
8. Observe caution when using the device in the immediate vicinity of cellular phones that are switched on.
9. Do not use the device in the direct vicinity of short-wave or microwave equipment, since this may affect the output power of the stimulator.
10. This TENS Device is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
11. 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.

12. Remove the batteries if the device will not be used for a month or more to avoid damage of battery leakage.
13. Please do not use it at the heart, private parts or skin disease parts.
14. 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.
15. Simultaneous connection of a PATIENT to a h.f. surgical EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
16. Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy EQUIPMENT may produce instability in the STIMULATOR output.
17. Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
18. Please do not knock down, repair, and rebuild it privately.
19. Please do not use the electrode pads other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
20. Please do not share the electrode pads with other infective person to avoid cross-infection.

SETUP AND OPERATING PROCEDURES

1. Battery loading

a. Open battery cover at the back of the device.
b. Load two "AAA" size batteries. Please pay attention to polarity.
c. Close the battery cover.

⚠ Rechargeable batteries are not suitable for this device.

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

⚠ Please do not mix use new and old batteries or different type of batteries.

⚠ Please do not throw battery into fire.

The device and the batteries, must be disposed of according to local regulations at the end of their usage.

2. Attachment of electrode lead wires

a. The wires provided with the AD-2026 insert into the jack sockets located on top of the device. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks; one or two sets of wires may be used.
b. After connecting the wires to the stimulator, attach each wire to an electrode.
Use care when you plug and unplug the wires. Jerking the wire instead of holding the insulated connector body may cause wire breakage.
c. Place the electrode on your body as directed by your physician.

⚠ Clean the wires by wiping with a damp cloth.

⚠ Coating them lightly with talcum powder will reduce tangling and prolong life.

3. Operating instructions

a. Press the “ON/OFF” button, the device will be put on, the LCD light all display for 1 second, then the device go into standby mode and wait for your settings.
b. First, set the time of therapy. Press the MODE button to changing-timer mode which is ‘clock’ sign in LCD. Then press the MODE+ button to increase the therapy time or press the MODE- button to decrease the therapy time.
The timer can be change from 1 minute to 30 minutes, defaulted time is 15 minutes.
c. Second, select the mode of therapy. Press the MODE button to changing-mode mode which is ‘hand’ sign in LCD, then like changing of timer, press the MODE+ button or MODE- button to select an expected mode.
9 modes can be selected from 1 to 9 and return to mode 1.
d. As followed, set the intensity and the device start to treat.
Note: different person need different intensity, so you must increase the intensity from 0 to 9 slowly and carefully, stop to increase when you feel comfortable.
e. In treating, the ‘second’ sign in LCD flashes until the time of therapy is exhausted.
f. After treatment, the device will be shut off automatically.
g. You should hold the plug when pulling it out. Please do not pull the wire.
h. 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.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
You have no feeling of stimulus.	Are the batteries exhausted?	Replace the batteries.
	Are the batteries properly loaded?	Correctly load the batteries.
	Is the wire properly connected?	Firmly connect the wire.
	Have you turned off the transparent protection film over the electrode pad?	Tear off the protection.
Stimulus is weak.	Do the electrode pads closely stick to the skin?	Closely stick the electrode pad to the skin.
	Are the electrode pads overlapped?	Separate the electrode pad and stick them to the skin gain.
	Are the electrode pads dirty?	Please clean the electrode pad.
	Is intensity too weak?	Turn the intensity regulation dial to regulate it.
	Are the electrode pads position proper?	Change the position of the electrode pad.
The skin becomes red.	Is the therapeutic time too long?	Control it within 10~15 minutes a time.
	Are the electrode pads too dry?	Please gently wipe them up with wet cloth and then use them again.
	Do the electrode pad closely stick to the skin?	Please closely stick the electrode pad to the skin.
	Are the electrode pads dirty?	Please clean the electrode pad.
	Are the surface of the electrode pads scratched?	Please replace them with new electrode pad.
Power sources cut off in the therapeutic process.	Have the electrode pads come off the skin?	Turn off the power and stick the electrode pad firmly to the skin.
	Are the wire disconnected?	Turn off the power and connect the wire.
	Have the batteries been exhausted?	Please replace them with new ones.

MAINTENANCE

1. Do not drop this device subject it to strong impact.
2. Avoid high temperature and solarization. Do not immerse the device in water as this will result in damage to it.
3. If this device is stored near freezing, allow it to acclimate to room temperature before use.
4. Do not attempt to disassemble this device.
5. If you do not use the device for a long time, please remove the batteries.
6. If the device becomes dirty, please clear it with a soft dry cloth. Do not use any abrasive or volatile cleaners.
7. No component can be maintained by user in the device. 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 by us.
8. In order to ensure that the electrodes adhere as long as possible, they should be cleaned carefully with a damp, lint-free cloth.
9. After use, stick the electrodes onto the backing film.
10. Electrode Pads is consumptive, so when the electrodes still not adhere firmly, you must buy a new pair of electrode-pad.

EXPLANATION OF SYMBOLS ON UNIT


Symbol for "THE OPERATION GUIDE MUST BE READ"
(The sign background colour: blue. The sign graphical symbol: white)


Symbol for "WARNING"(The sign background colour: yellow)


Symbol for "TYPE BF APPLIED PARTS"


Symbol for "ENVIRONMENT PROTECTION
Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice".


Symbol for "KEEP AWAY FROM SUNLIGHT"


Symbol for "KEEP DRY"


Symbol for "MANUFACTURER"

CE 0197 Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"


Symbol for "DATE OF MANUFACTURE"

SN Symbol for "SERIAL NUMBER"

Symbol for "EUROPEAN REPRESENTATION"

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration - electromagnetic emissions		
The AD-2026 is intended for use in the electromagnetic environment specified below. The customer or the user of the AD-2026 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The AD-2026 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 emissions CISPR 11	Class B	The AD-2026 is suitable for use in all establishments other than domestic 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	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 2

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The AD-2026 is intended for use in the electromagnetic environment specified below. The customer or the user of the AD-2026 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) 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: U_T is the a.c. mains voltage prior to application of the test level.

Table 3
For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity

The AD-2026 is intended for use in the electromagnetic environment specified below. The customer or the user of the AD-2026 should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the AD-2026, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ 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 meters (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: 

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 AD-2026 is used exceeds the applicable RF compliance level above, the AD-2026 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AD-2026.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 4

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the AD-2026

The AD-2026 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AD-2026 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AD-2026 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 $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined 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.

***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. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product.This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.
Labor costs and personnel traveling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devicesor software due to outside agents such as: voltage changes, electro-magnetic elds, radio interferences, etc.
The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

Functions

Mode	Parameters	function
1	f=2Hz, pw=240us, continuous outputting.	Tapping
2	f=10Hz, pw=200us, continuous outputting.	Vibrate(slow)
3	f=20Hz, pw=160us, continuous outputting.	Vibrate(fast)
4	f=50Hz, pw=135us, intermittent outputting.	Massage
5	f=80Hz, pw=135us, intermittent outputting.	Massage
6	f=60Hz, pw=135us, continuous outputting.	Knead
7	f=30Hz, pw=135us, intermittent outputting.	Massage
8	f=50Hz, pw=135us, intermittent outputting.	Massage
9	Combined by press& knead &vibrate &thump	Auto