

TTM-6/0740 Low-Frequency Therapy Instrument



Instruction Manual

Please read all instructions carefully and retain for future use

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Know your Device

Indications for Use

The Low-Frequency Therapy Instrument is a product that adopts modern electronic science and technology to produce low-frequency electrical pulse and transmit that through the skin to the underlying peripheral nerves by electrodes, in order to reach the therapeutic aim.

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

Medical Disclaimer

- This device and manual are not meant to be a substitute for advice provided by doctors or other medical professionals.
- Contact your physician for interpretation of measurements, or if you have or suspect you have a medical issue.
- Do not use this product on pregnant women, children or people without ability to express their own consciousness.
- Do not use it on patients with cardiac demand pacemaker, defibrillator or implanted metallic or electronic device.

A Precautions

- 1.Do not move the instrument while using, or when the user wishes to change treated area, first be sure to turn off the instrument then use it, or it might cause strong stimulation.
- 2. If the user doesn't feel well due to instrument anomaly, please stop using at once and consult a doctor.
- 3. If the instrument is not to be used in a long time, please take out the battery to avoid leakage which may damage the instrument.
- 4.Do not use this instrument under circumstances that are beyond the range of application.
- 5. Do not use or contact with the product for a long time.

Important Safety Information

- 1. Never use this product along with other medical electronic instruments, such as cardiac pacemaker, artificial heart-lung which are used to maintain life, and electrocardiograph. Otherwise it may cause danger.
- 2. If the user is using high frequency surgical equipment and this therapy instrument at the same time, then there might be burn in the place where the electrode patch is pasted to or damage to the instrument; If this instrument is used in the vicinity (1m) of short wave or microwave therapy instrument, then the output of this instrument might not be stable.
- 3. Do not use this product near the heart, over the head, neck, mouth cavity, private parts, parts with skin disease and so on.
- People with abnormally sensitive skin, heart disease, abnormal blood pressure, malignant tumor, serious cerebrovascular disease, acute disease, epilepsy or currently under doctor's treatment, should consult a doctor before use this product.
- 5. Do not use this product in places where there are high heat, inflammables and electromagnetic radiation.
- 6. Do not use this product while bathing or sleeping.
- 7. Do not use this product while driving or operating machinery or during any activity in which involuntary stimulation may put the user at undue risk of injury.
- 8. Do not modify the product, or else electric shock might occur.
- 9. Do not inhale or swallow small parts, which might lead to lifethreatening condition.
- 10. The long-term effects of chronic electrical stimulation are unknown.
- 11. Stimulation should not be applied:
- 12. over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex;

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- 13. transthoracically and transcerebrally;
- 14. over swollen, infected, or inflamed areas or skin eruptions;
- 15. over, or in proximity to, cancerous lesions.
- 16. Do not arbitrarily disassemble, repair and reform this instrument, otherwise it might cause malfunction or electric shock accidents.
- 17. Stimulation should not be applied over the 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.
- 18. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- 19. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

Technical description is contained in the instruction manual.

BATTERY WARNING:

- Do not mix alkaline, stand (carbon-zinc) and rechargeable batteries (nickel hydride).
- Do not mix old and new batteries.
- Non-rechargeable batteries are not to be recharged.
- Rechargeable batteries are to be removed from the unit being charged (if removable).
- Rechargeable batteries are only to be charged under adult supervision (if removable).
- Exhausted batteries are to be removed.
- The supply terminals are not to be short-circuited.
- Only batteries of the same or equivalent type as recommended are to be used.
- Batteries are to be inserted with the correct polarity (see diagram).

Preparation

Package Content

Low-Frequency Therapy Instrument Machine Pair of Electrode Pads Connecting Cable Storage Pouch 2 AAA Batteries (Included)

Parts



About Therapy Machine

Therapy Machine

User can select appropriate treatment mode and other parameters, such as intensity, through function buttons (shown below) on the host and know about the current status through LCD at any time.

Treatment Mode

5 Full-automatic treatment mode and 5 manual treatment mode which satisfy to different demands.

Electrode Pad

To be attached to bare skin to perform stimulation.

Connecting Cable

To be used to make the connection between the machine and electrode pads.

Set Up Your Device

- Open battery cover and insert 2 AAA batteries into the battery compartment according to polarity.
 Caution: When the intensity stimulation is very weak, it means the battery is low and a new battery should be replaced.
- 2. Insert one end of two-core connecting cable to machine socket and connect the other to electrode pad.

Caution: The connecting line can only be used to connect electrode patch and the host; it is prohibited to be used for other purposes. Do not put the connecting line around the neck in case of strangulation.

Getting Start

Tear off the protective films on electrode pads, and then paste the electrode pads onto painful areas. Relax your body completely. Push the power switch on the right of the host to "on" position, and press "On/+" button to power on and start treatment. It's recommended to use the instrument twice a day, 15 minutes each time.

Caution:

Only use electrode pads equipped with the product.

Do not dispose the electrode patch casually. Please follow the local environmental requirements.

Make sure well connection between electrode pad and machine, or else it might affect the function of the product.

Pair of electrode pads can only be used by one person.

After Used

Suggested to paste those pads into the storage plate and keep in dry, ventilated place for next use.

Set Up Your Device

Instruction for Use

- Press "On/+" button to power on and start working procedure, the instrument enters into automatic combination mode 5 (intensity is 1st level, timing for 15 minutes), LCD displays corresponding contents.
- 2. Press **"On/+"** button after the instrument has been powered on to enhance intensity which is divided into 9 levels. Intensity is initially set to 1st level (the weakest) by default, LCD will display corresponding contents.
- 3. Press **"Off/-"** button to weaken the intensity which is divided into 9 levels. When the intensity is set to 1st level (the weakest), one more press of the "Off/-" button will shut down the instrument.
- 4. Press "Auto" button to choose from 5 automatic combination modes which can automatically and circularly operate 3 manual treatment modes. Choose different combination treatment modes according to different treated areas, which are (1) waist, (2) leg and foot and (5) shoulder.

5 automatic combination modes include (i) Cycles of Mode $1 \rightarrow$ Mode $2 \rightarrow$ Mode 4 (ii) Cycles of Mode $2 \rightarrow$ Mode $4 \rightarrow$ Mode 5 (iii) Cycles of Mode $1 \rightarrow$ Mode $2 \rightarrow$ Mode 5 (iv) Cycles of Mode $2 \rightarrow$ Mode $1 \rightarrow$ Mode 4 and (v) Cycles of Mode $5 \rightarrow$ Mode $1 \rightarrow$ Mode 4, that each Mode will work for 30 seconds within each cycle.

Default setting as Mode 1. After each conversion of treatment mode, the intensity will be back to 1st level.

- 5. Press **"Manual"** button to choose from 5 manual treatment modes which included Mode 1 to Mode 5. After each conversion of treatment mode, the intensity will be back to 1st level.
- 6. Press **"Speed+"** button to accelerate the speed which is divided into 5 levels and the LCD will display a corresponding number. When the LCD displays "5", it means the speed is the fastest. Under this situation, it's no use pressing the "Speed+" button again
- 7. Press **"Speed-"** button to reduce the speed which is divided into 5 levels and the LCD will display a corresponding number. When the LCD displays "1", it means the speed is the slowest. Under this situation, it's no use pressing the "Speed-" button again.
- 8. When under automatic mode, press "Repeat" button once to lock the currently running treatment mode and stop the cycle operation of this automatic combination mode, and the LCD displays "Repeat"; If press the "Repeat" button again, the circulation mode restarts and the LCD does not display "Repeat".

For regular maintenance, this device only needs to be wiped gently with a soft, dry cloth. Never immerse this device or any components in water.

- Do not carry out repairs of any kind yourself. If a defect occurs, please contact your local authorized distributor. Use only authorized parts and accessories.
- Keep the surface of electrode patches clean, or else the viscidity of electrode pad will be lower. When the surface of electrode patch is dirty, use damp cloth to clean it and dry it before using it again.
- Do not calibrate or maintain the instrument, and is prohibited from opening, disassembling and maintaining the instrument arbitrarily.
- Keep the instrument out of children's reach.
- Please store the therapy set in dry and ventilated places.

Troubleshooting

No display in LCD

Reason: No battery \underline{OR} detach fails may cause by foreign object inside the compartment.

Solution: Check/remove batteries, re-install batteries according to polarity. LCD Display well but no stimulation

Reason: Two-core connecting cable not connected well \underline{OR} is there any protective film left on the pad.

Solution: Detach two-core connecting cable again <u>OR</u> remove protective film. **Solution:** Change the location of electrode pads for Mild allergy user, or shorten the treatment time.

*Stop to use this device and do physical check for allergy before the next use Stimulation is weak

Reason: Pads overlapped to each other.

Solution: Separate them and re-attach to the location again.

Reason: Electrode pads get dirt / electrode pads getting loose.

Solution: Use damp cloth to clean / re-attach the pads closely to the skin

Sense of Piercing pain and skin is red

Reason: Treatment time may be too long.

Solution: Suggested treatment time is about 15 minutes.

Reason: Treatment intensity maybe too high.

Solution: Take rest for 5 mins and turn down the intensity level.

Reason: Skin allergic to electrode pads.

EMC Statement

This device needs special precautions regarding EMC and need to be installed and put into service according to the EMC information provided in the accompanying document.

Portable and mobile RF communications equipment can affect this device.

Warning:

- The use of accessories, transducers and cables other than those specified with the exception of transducers and cables sold by the manufacturer of this device as replacement parts for internal components, may result in increased emissions or decreased immunity of this model.
- This device should not be used adjacent to or stacked with other equipment Guidance and Manufacturer's declaration can be seen in the attachment.

EMC Declaration

Guidance and Manufacturer's Declaration - Electromagnetic Immunity this device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should ensure that it is used in such an environment.

Immunity Test	Compliance	Electromagnetic
		Environment - Guidance
RF emissions CISPR11	Group 1	This device used 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 CISPR11	Class B	This device is suitable for use in all establishments other
Harmonic emmissions IEC 61000-3-2	Not applicable	than domestic and those directly connected to the
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	public low voltage power supply network that supplies buildings used for domestic purposes.

EMC Declaration

Immunity Test Electrostatic discharge (ESD) IEC 61000-4-2	IEC 60601 Test Level <u>+</u> 8 kV contact <u>+</u> 2 kV, <u>+</u> 4 kV, <u>+</u> 8 kV, <u>+</u> 15 kV air	Compliance Level ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Electromagnetic Environment - Guidance Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electric fast transient/brust IEC 61000-4-4 Surge	<u>+</u> 2 kV for power supply lines <u>+</u> 1 kV for input/output lines <u>+</u> 1 kV line to line	Not applicable	
IEC 61000-4-5	<u>+</u> 2 kV line to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC610004-11	< 5% UT (>95% dip in UT.) for 0.5 cycle 40% UT (60% dip in UT.) for 5 cycle 70% UT (30% dip in UT.) for 25, cyce < 5% UT (>95% dip in UT.) for 5 sec	Not applicable	Main power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m .c. mains voltage prior t	30 A/m	Magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

EMC Declaration

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V/m 150kHz to 80MHz 6 Vrms in ISM 10 V/m 80MHz to 2.7GHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the models including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
	10 V/m 80MHz to 2.7GHz	Not applicable	Recommended separation distance
Radiated RF IEC 61000-4-6	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10V/m 80MHz to 2.7GHz	d=[3,5/V ₁]×P ^{1/2} d=1.2×P ^{1/2} 80 MHz to 800MHz d=2.3×P ^{1/2} 800 MHz to 2.7GHz
		385MHz-5785MHz	Where P is the maximum output
		Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	Field strengths from fixed RF 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 of this device is used exceeds the applicable RF compliance level above, the models KTR-201, KTR-202, KTR-203 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Model	TTM-6/0740	
Dimensions – Therapy Machine	147mm (L) x 59mm (W) x 27.5mm (D)	
Dimensions – Electrode Pads	83mm x 59mm x 6mm	
Dimensions – Connecting Cable	Cable Length: 1.2m	
Weight – Therapy Machine	2.7oz	
Power	2 AAA (Included)	
Number of Channels / Modes	1/10	
Safety category	Type BF	
Output Specification		
Output Intensity Level	9 Levels	
Waveform and Shape	Pulsed symmetric, Biphasic, Square wave	
Maximum Output Voltage (±10%)	36.5V @ 500 Ω / 54.5V @ 2k Ω / 56.5V @ 10k Ω	
Maximum Output Current (±10%)	73mA @ 500 Ω / 27mA @ 2k Ω / 5.7mA @ 10k Ω	
Net Charge (per pulse)	0μC @ 500 Ω	
Maximum Phase Charge	11.7μC @ 500 Ω	
Maximum Average Current	7.4mA @ 500 Ω	
Maximum Current Density	0.15mA/ cm ² @ 500 Ω	
Maximum Power Density	0.00056W/ cm² @ 500 Ω	
Pulse Duration	20µs-220µs	
Frequency	1 Hz-330Hz	
Default Treatment Time	15min	
Environment		
Operations	Temperature: About 5°Cto 40°C	
	Humidity: About 15% to 93%RH	
Storage	Temperature: About -25°C to +70°C	
	Humidity: About 0 to 93%RH	
Transport	Temperature: About -10°C to 40°C	
	Humidity: About 15% to 93%RH	

To improve performance, these specifications are subject to change without notice. Disposal of the device, accessories and packaging shall be carried out in accordance with national and local regulations for proper handling of waste.

Calibration and Service

The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life. It is generally recommended to have this device inspected and calibrated every 2 years to ensure correct functioning and accuracy. Please consult you authorized distributor.

WARRANTY DURATION: All materials and workmanship are warranted to the original consumer purchaser for a period of ninety (90) days from the original purchase date.

WARRANTY COVERAGE: This product is warranted against defective materials or workmanship. This warranty is void if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, commercial use, repairs by unauthorized personnel or other causes not arising out of defects in materials or workmanship. This warranty does not cover the following which may be supplied with product, including but not limited to; LCD Screens, glass parts, lenses, bulbs etc. This warranty is effective only if the product is purchased and operated in USA, and does not extend to any units which have been used in violation of written instructions furnished by manufacturer or to units which have been altered or modified or, to damaged products or parts thereof which have had the serial number removed, altered, defaced or rendered illegible.

WARRANTY PERFORMANCE: During the above 90 day warranty period, a product with a defect will be either repaired or replaced with a reconditioned comparable model (at manufacturer's option). The repaired or replacement product will be in warranty for the balance of the 90 day warranty period and an additional one-month period. No charge will be applicable for such repair or replacement. **SERVICE AND REPAIR:** If service is required for this product, you should first contact Nuvomed Inc. Customer Service at <u>info@nuvomed.us</u> or by calling Toll-Free Number 1 (866) 815-4714, Monday to Friday 10am to 6pm EST.

NOTE: Manufacturer cannot assume responsibility for loss or damage during incoming shipment. As a precautionary measure, carefully package the product for shipment, and insure it with the carrier. Be sure to enclose the following details with the product: your full name, return address and daytime phone number, a note describing the problem you experienced, a copy of your sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.

This manufacturer's product warranty extends to the original consumer purchaser of the product. Neither the retailer nor any other company involved in the sale or promotion of this product is a co-warrantor of this manufacturer warranty.

WARRANTY DISCLAIMERS: This warranty is in lieu of all warranties expressed or implied and no representative or person is authorized to assume for manufacturer any other liability in connection with the sale of our products. There shall be no claims for defects or failure under any theory of tort, contractor commercial law including but not limited to, negligence, gross negligence, strict liability, breach of warranty and breach of contract. Under no circumstances will Manufacturer's / Distributor's maximum liability exceed the retail value of the product.