proactive® Elle

Model: 715-432

Instructions

Please read this manual thoroughly before using this device for the first time.

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INTRODUCTION

Thank you for purchasing the Proactive-Elle™ TENS Device. This innovative unit is designed to provide fast and effective relief from period pain, stomach aches, and cramps.

Before using your Proactive-Elle™ unit for the first time, please read through these instructions carefully and save for future reference. If you still have any questions regarding this device, visit the A.M.G. Medical website or contact our Customer Service team at 1-800-363-2381.

INTENDED USE AND INDICATIONS FOR USE

Proactive-Elle™ is designed to be used at home for the temporary relief of menstrual pain and discomfort.

INTENDED USERS

Proactive-Elle™ is ideal for the treatment of painful period camps. It is non-invasive and drug-free. Proactive-Elle™ should be used only by women 16 years old and above.

PRINCIPAL OF OPERATION

Proactive-Elle™ is a TENS (Transcutaneous Electrical Nerve Stimulator) device, which works as a pain treatment system. The unit sends soothing pulses that are sent via the gel pads through the skin and along the nerve fibers. The pulses suppress pain signals to the brain and encourage the body to produce higher levels of its own natural pain relieving chemicals, called endorphins that ease the feeling of pain.

Proactive-Elle™ has 6 modes and 20 intensity levels. Eachprogram is designed with specific pulse frequency and pulse length.

ADDITIONAL BENEFITS OF PROACTIVE-ELLE™

- Proactive-Elle™ relieves menstrual pain and discomfort.
- Proactive-Elle™ increases feelings of well-being.
- Proactive-Elle™ allows you to carry out your daily activities.
- Proactive-Elle™ is easy to apply and to use.
- Proactive-Elle™ is a compact pocket-sized device that you can carry in your handbag when not in use and wear comfortably under your clothes as needed.
- Simply attach Proactive-Elle™ to your stomach area, switch it on and then go about your normal routine.
- Proactive-Elle™ is not a medication and is non-invasive. It is the closest thing to a natural treatment for menstrual pain.

SAFETY INFORMATION

TENS is a symptomatic treatment that suppresses the sensation of pain. It has no curative value and is not effective on pain that is of central origin including headaches.

Contraindications

Do not use in the following situations:

- Undiagnosed pain syndromes (until etiology is established)
- Cancerous lesions that are present in the treatment area
- Swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.)
- Demand type implanted pacemaker, defibrillator, or any metallic implant
- Epilepsy
- Serious arterial circulatory problems in the lower limbs
- Abdominal or inguinal hernia
- Safety has not been established for use during pregnancy

Precautions

- If your pain is not subdued, becomes more mild, or lasts for more than five days, stop using the device and consult with your healthcare practitioner.
- Do not place electrodes over the neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation over the thyroid or carotid sinus regions, as this could disrupt breathing, cardiac frequency or blood pressure.
- Do not place electrodes across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart which could be lethal.

- Do not place electrodes on cranium.
- Gel pads should be applied only to normal, intact, clean, dry and healthy skin.
- Never use it on the areas of the skin which lack normal sensation.
- The size, shape and type of gel pads may affect the safety and effectiveness of electrical stimulation.
- Using gel pads that are too small or incorrectly applied could result in discomfort or burning of the skin.
- Gel pads are intended to be used by one person only and should not be shared to avoid cross contamination and risk of adverse skin reactions and disease transmission.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- TENS is not recommended for patients with heart disease.
- Proactive-Elle™ should not be used for ovulation pain (mid-cycle pain).
- Proactive-Elle™ should not be used while fertility problems are being evaluated, diagnosed, or treated.
- Proactive-Elle™ should not be used during pregnancy, labour or breastfeeding.
- Do not apply stimulation when in bath or shower.
- Do not apply stimulation while sleeping.
- Do not apply stimulation while driving, operating machinery, or during any activity when electrical stimulation can put you at risk of injury.
- Batteries are rechargeable; batteries should not be replaced by unauthorized personnel.
- Keep Proactive-Elle™ dry. Do not expose the device to a wet environment.

- Turn Proactive-Elle™ off before applying or removing gel pad.
- Only use with Proactive-Elle™ gel pad.
- Long-term stimulation at the same site may cause skin irritation. Use only as advised by a healthcare professional.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive material (silica gel).
- Replace gel pad if it no longer sticks firmly to the skin.
- TENS is not a substitute for pain medications and other pain management therapies.
- Use caution following recent surgical procedures. Electrical stimulation may disrupt the healing process.
- Caution if you have a tendency to bleed internally, e.g. following an injury or fracture.
- Never use in rooms where aerosols (sprays) are used or pure oxygen is being administered. Do not use it near highly flammable substances, gases or explosives.
- Do not use sharp objects such as a pencil or ballpoint pen tip to operate the buttons on the TENS device control panel.
- Do not immerse your device in water or place it close to excessive heat as this may cause the device to cease operating correctly.
- Do not attempt to open up the device – there are no serviceable components.

Adverse Reactions

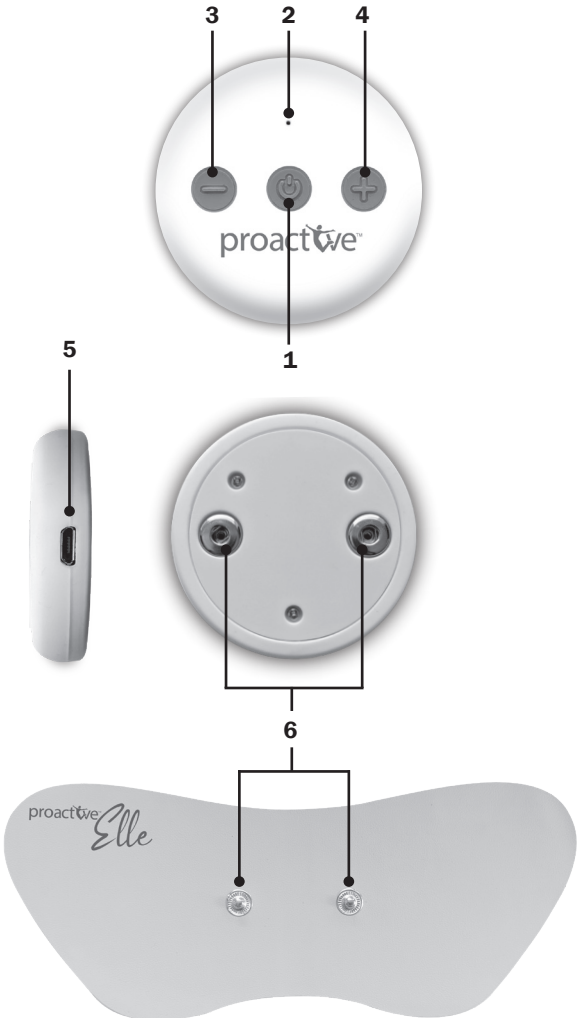
- Skin irritation under the gel pad may occur. Allergic skin reaction to the gel may also occur.
- If the stimulation makes you uncomfortable at any time, discontinue use immediately.

PACKAGE CONTENTS

Your Proactive-Elle™ set includes:

- Proactive-Elle™ device
- Gel pad (Also referred to as electrode)
- USB cable
- User manual

Device Overview



NO.	DESCRIPTION
1	[On/off] button: press the [on/off] button to turn on the device; then quickly press the [on/off] button to select the treatment modes. Once treatment is completed, press the [on/off] button for 5 seconds to turn off the device.
2	Indicator light: red light indicates low power and your Proactive-Elle™ needs to be charged as soon as possible. When your device is charged, the light is blue and ready for use.
3	Button: decreases the intensity of treatment.
4	Button: increases the intensity of treatment.
5	USB Port: plug cable into USB port in order to charge device. It can be plugged into a computer's USB port or into a wall socket using an adaptor (5v 300 mAh adaptor not included).
6	Snaps: connects the gel pad to the TENS device.

GETTING STARTED - USING PROACTIVE-ELLE™

Proactive-Elle™ is as simple to use as it is comforting. Follow these easy steps to get started:

- Prior to first use, charge your Proactive-Elle™ device for approximately 12 hours.
- Turn on Proactive-Elle™ and adjust to the treatment level that is comfortable and start benefiting from soothing pain relief.

INSTRUCTIONS FOR USE

(1) Ensure unit is charged before use

(2) Connect the gel pad to the TENS device

Before proceeding to this step, be sure the device is switched OFF. Connect the gel pad onto the device directly by snapping it into place. Make sure it is properly connected to ensure good performance

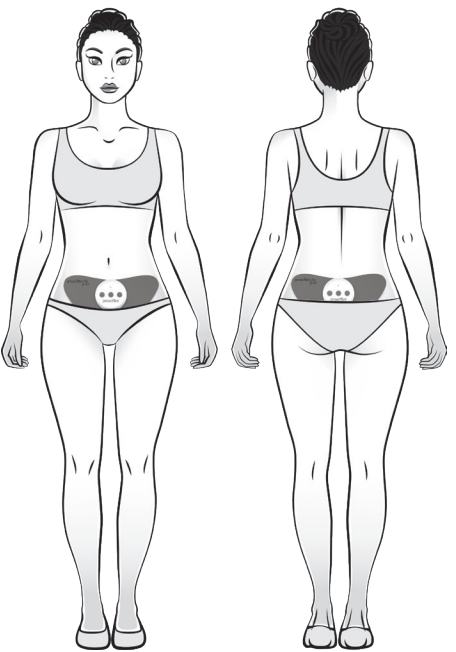
(3) Place gel pad on skin

- Ensure that the skin surface where the gel pad will be placed is clean and dry.
- Peel off the protective film on the gel pad and attach the pad to the center of the lower back or belly. A friend or family member may assist. (Save the protective film to store the gel pad following treatment).
- The gel pad should be placed firmly and evenly on the skin to ensure good contact.

Caution:

- Always wash and dry the treatment area. Do not apply any creams or gels as this may reduce the adhesion of the gel pad.
- Do not turn the device on when the gel pad is not applied to the treatment area. Never adjust, reposition or remove the gel pad while the device is still on.

- Always remove the gel pad from the skin with a moderate pull in order to avoid injury in the event of highly sensitive skin.
- Gel pad should last around 30 applications, but this depends on skin type, oils, and pH levels. If gel pad seems to have lost its adhesive properties, replace with a new Proactive-Elle™ gel pad.
- Use only gel pad supplied with the device or supplied by an authorized Proactive® distributor or purchased at: www.proactive-painmanagement.com



(4) Turn the Device On

Carefully read the contraindications and safety information in this manual before using your device for the first time.

In the center of the front panel of Proactive-Elle™ is the power button, which is easily operated by a light touch of the finger.

Gently press the [ON/OFF] button to turn on the unit to get started. Your device always starts on Mode 1

- Gently press the [ON/OFF] button to switch between modes.
- Press or button to increase or decrease the intensity of the treatment
- Gently press the button several times until you feel a mild tickling sensation in the area where the gel pad is placed.

- Increasing the intensity beyond the level of a tickle may cause muscle twitching and/or contractions. This is completely normal. To decrease the intensity press the button a few times until the twitching and/or contractions cease. Adjust the intensity to where a pleasant sensation is felt.

MODES	
1. SCRAPING	**4. CUPPING**
2. TAPPING	**5. TAI CHI**
3. ACUPUNCTURE	**6. KNEADING**

- Usage time for new users should be no more than 30 minutes a treatment, 2-3 times per day maximum. For subsequent uses, 60 minutes per treatment, 2-3 times per day is recommended.

(5) Turn Off the Device

- Once treatment is completed, press the [ON/OFF] button for 5 seconds to turn off the device.

CHARGING DEVICE

Connect the USB cable into your Proactive-Elle™ device and then connect to a phone or tablet charger, or the USB port of a computer. When charging is completed, the LED light will be blue. Disconnect the USB cable and store it for future use. It is recommended to charge your Proactive-Elle™ for approximately 12 hours prior to first use.

Caution

- Do not charge the device while using it.
- Do not operate the device when gel pad is not connected. Make sure the device is off before removing or connecting the gel pad.

CLEANING AND MAINTENANCE

Device

Wipe the device with a soft, slightly moistened cloth. If a more thorough cleaning is needed, you can also use a disinfectant wipe to clean all external surfaces of the unit. Do not submerge the device or expose it to water. Do not use any chemicals or abrasive agents to clean it. After use, store device in original packaging in a cool, dry place to protect it.

Gel pad (Electrode)

- Inspect your gel pad before every use and replace as needed. Reusing gel pads too many times may cause slight skin irritation, low adhesion or ineffective stimulation.
- Between uses, store the gel pad in a resealable bag in a cool dry place. It may be helpful, between applications, to moisten the adhesive surface with a few drops of water (be careful not to oversaturate) and then let it air-dry to help it last longer.
- If gel pad seems to have lost its adhesiveness, replace with a new Proactive-Elle™ gel pad.

STORAGE

- Fully charge the battery before long-term storage and charge it every 2-3 months to extend the life of the battery.
- Store the device in a cool dry place and protect it against heat, sunshine, and moisture.
- Never place any heavy objects on the device.

Disposal

Please dispose of the device in accordance with the directive 2002/96/EC WEEE (Waste Electrical and Electronic Equipment). Contact your local distributor for information regarding disposal of the unit and accessories.

BASIC TROUBLESHOOTING GUIDE

PROBLEM	CAUSE	SOLUTION
Can't feel any stimulation	The intensity level is not properly adjusted.	Press the ⊕ button until stimulation is felt.
	Gel pad is not firmly attached to the skin.	Attach the gel pad firmly to the skin.
	The adhesive surface of the gel pad is damaged.	Replace it with a new gel pad.
	The adhesive surface of the gel pad is dirty or dusty.	Clean the adhesive surface of the gel pad with a slightly damp lint-free cloth, or replace the gel pad.
Electrical stimulation is too weak	The battery is very low.	Charge the battery.
	The adhesive surface of the gel pad is damaged.	Replace with a new gel pad.
	The adhesive surface of the gel pad is dirty or dusty.	Clean the adhesive surface of the gel pad with a slightly damp lint-free cloth, or replace the gel pad.
Electrical stimulation is too strong	The intensity level is too high or gel pad is not attached correctly.	Press the ⊖ button to decrease intensity.

Troubleshooting Guide (continued)

PROBLEM	CAUSE	SOLUTION
Stimulation stopped unexpectedly	The battery is low.	Charge the battery.
Gel pad won't stay firmly attached to the skin.	The adhesive surface of the gel pad is dirty or dusty.	Clean the adhesive surface of the gel pad with a slightly damp lint-free cloth, or replace the gel pad.
	The adhesive surface of the gel pad is damaged.	Replace it with a new gel pad.
The skin turns red or becomes irritated.	The gel pad is not firmly attached to the skin.	Make sure skin is clean and attach gel pad firmly to skin. (no lotion/oils)
	The adhesive surface of the gel pad is damaged.	Replace it with a new gel pad.

Stop using the device if any problem remains unsolved after trying the suggested solutions.

SYMBOLS

The following table describes the symbols that appear on the system, its components, and packaging.

SYMBOL	MEANING
SN	Serial number
REF	Reference number
	Date of manufacture
	Manufacturer
	Refer to instruction manual
	Dispose of in accordance with EC Regulations on Waste Electrical and Electronic Equipment (WEEE)
	BF-type applied part.

ELECTROMAGNETIC COMPATIBILITY

With the increased number of electronic devices such as PC and mobile (cellular) telephones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, medical devices in use may be susceptible to electromagnetic interference from other device. Electromagnetic interference may result in incorrect operation of the medical devices and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electric Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices.

This unit has been thoroughly tested and inspected to assure proper performance and operation. This product needs special precautions regarding EMC and needs to put into service according to the EMC information provided, the following tables recommend minimum separation distances between portable and mobile RF communications equipment and the TENS unit.

Caution:

With other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.

* Refer to further guidance below regarding the EMC environment in which the device should be used.

There is no guarantee that interference will not occur in a particular installation. Radiated or conducted electromagnetic signals can cause:

1) As to devices:

- Deviation of the values of pulse duration, amplitudes, and repetition frequencies, may impair the unit's essential performance. The device has passed EMC test, and the parameters do not deviate the essential performance requirement.

2) As to patients:

- The sensitivity of stimulation may be weaker or stronger, but it does not produce safety issues.
- It cannot achieve expected effect. If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:
  - If feeling too weak or too strong stimulation, adjust the strength level to an acceptable level.
  - If the device is abnormal, power off and restart the device and check whether it shows properly.
  - Re-orient or relocate the affected device.
  - Increase the separation between the unit and the affected device.
  - Power the equipment from a source other than that of the affected device.

<table>
<tr><th colspan="3">Declaration - Electromagnetic Emission</th></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.</td></tr>
<tr><th>Emmission Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Proactive-Elle™ 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The Proactive-Elle™ 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The Proactive-Elle™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Proactive-Elle™ 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 floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for powe supply lines	± 2 kV 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)	± 1 kV line(s) to line(s)	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 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 0.5 sec	<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 cycle <5% UT (>95% dip in UT) for 0.5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the Proactive-Elle™ be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) 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 Proactive-Elle™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Proactive-Elle™ 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 V rms 150 kHz to 80 MHz	3 V rms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the SProactive-Elle™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.2 √P 150kHz to 80MHz d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic 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 TENS is used exceeds the applicable RF compliance level above, The Proactive-Elle™ TENS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TENS.

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

Recommended separation distances between portable and mobile RF communications equipment and Proactive-Elle™

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

Rated maximum output 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 2.7 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	11.7	11.7	23.3

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 situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

TECHNICAL SPECIFICATIONS

Channel	1 Channel
Power Supply	3.7V/180mAh Polymer rechargeable battery
Suggested Charger	I/P:100-240V~,50/60Hz,0.2A. O/P:5V d.c., 500mA. charging: 5V d.c., 500mA
Waveform	Symmetrical biphasic rectangular
Pulse Duration	Adjustable from 191us ±20%
Pulse Frequency	Adjustable from 1~130Hz ±10%
Device Intensity	20 levels
Battery Duration	About 10-12 cycles
Weight	24 g
Stimulation Modes	6
Charging Voltage	5V
Fully Charged	Approximately 40 minutes
Duration	Approximately 300 minutes
Maximum Output	2.5W
Material	ABS
Dimensions	Length & Width 58 mm, Height 12.5 mm

LIMITED WARRANTY

A.M.G. Medical Inc. warrants the TENS device to be free from defects in material and workmanship for a period of one (1) year, to be proven by means of the sales receipt or invoice. This warranty is valid for the original purchaser only. Any alterations, abuse, misuse or accidental damage voids this warranty. Repairs under warranty do not extend the warranty period. For service under warranty, call us at: 1-800-363-2381, between 8:30 AM and 5 PM EST.

- The following is excluded under the warranty:

  A) All damage which has arisen due to improper treatment, e.g. nonobservance of the user instructions.

  B) All damage which is due to repairs or tampering by the customer or unauthorized third parities.

  C) Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.

  D) Accessories which are subject to normal wear and tear.

- Liability for direct or indirect consequential losses caused by the unit are excluded even if the damage to the unit is accepted as a warranty claim.

Questions? Comments?

1-800-363-2381 • www.proactive-painmanagement.com

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