proactive™
Physiotherapy • Physiothérapie

pulse™

TENS Electro-Stimulator

Model: 715-420

Instructions

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

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INTRODUCTION

The Proactive™ Pulse™ Tens is intended to be used by adults for the temporary relief of muscle and joint pain by applying electrical nerve stimulation to the surface of the skin near the site requiring therapy.

This device provides two independent, controllable output channels. A pair of electrodes which can be connected to each output channel and the current's parameters and intensity level can be adjusted according to your needs.

1. What is pain?

Pain warns our body of injury to prevent additional damage. This sensation is important because without it, vital parts of our bodies might be injured without our knowledge. However, long-lasting, persistent (chronic) pain, once diagnosed serves no apparent purpose and reduces quality of life.

2. How does TENS work?

TENS (Transcutaneous Electrical Nerve Stimulation) refers to the transmission of small electrical pulses through the skin to the underlying peripheral nerves. The theory of TENS suggests two different modes of operation:

In **conventional (high frequency)** TENS, continuous mild electrical activity may block the pain signal traveling to the brain. If the pain signal does not get through to the brain, the pain is not “felt”.

In **low frequency** TENS, short bursts of electrical activity may stimulate the release of endorphins, the body's own pain-control substance. Ask your physician or therapist for more details. No matter what pain theory is used, TENS has been proven useful in pain management for many patients in helping to make their lives better.

SAFETY INFORMATION

1. 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.

2. 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 or 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.

WARNING

For external use only. The long-term effects of frequent electrical stimulation are unknown. This device should be used only under the continued supervision of a licensed medical practitioner.
Do not apply stimulation over the thyroid or carotid sinus regions, as this could disrupt breathing, cardiac frequency or blood pressure. Do not use while connected to high-frequency surgical equipment or near shortwave or microwave therapy equipment.
Never use in environments with high humidity (ex.: bathroom).
Never place the electrodes anywhere on the front of the thorax or transthoracically as it can increase the risk of ventricular fibrillation, cause cardiac arrhythmia and lead to cardiac arrest. Never place the electrodes in a way that would cause the current to go through the head. Never use near the eyes, the genitals, the heart or on areas which lack normal sensation. This stimulator should never be used by patients who are noncompliant or are emotionally, cognitively or mentally impaired. Keep the stimulator out of reach of children.

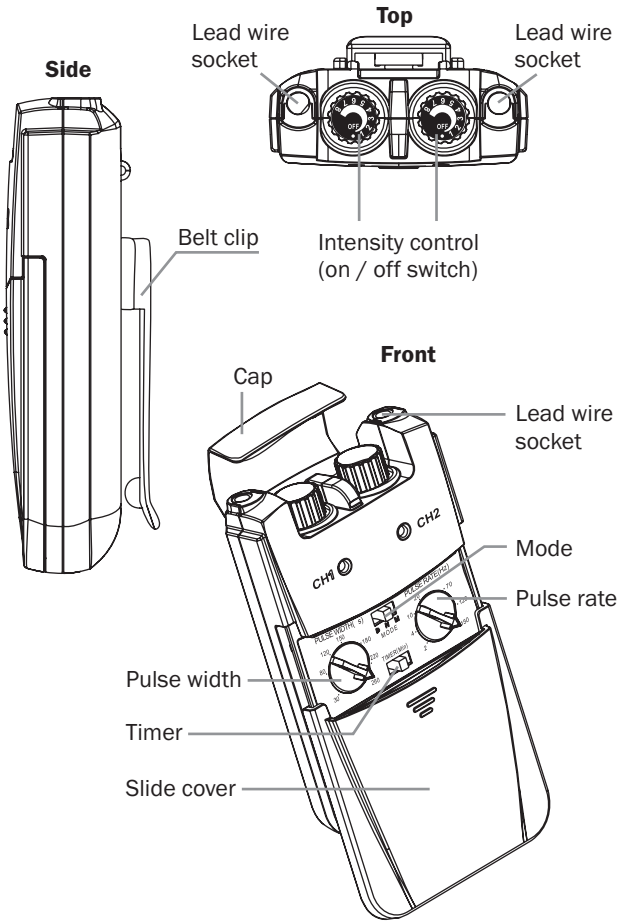
4. Precautions

- Do not adjust controls while operating machinery or vehicles.
- Turn the stimulator off before applying or removing electrodes.
- Only use with ProActive™ lead wires and electrodes.
- Long-term stimulation at the same electrode site may cause skin irritation. Use only as prescribed by a physician.
- 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.
- Apply the electrodes to clean, dry, and unbroken skin only.
- Keep electrodes separate during treatment. Electrodes coming in contact with each other could result in improper stimulation or skin burns.
- Should the treatment become unpleasant, discontinue the use of this device until its use has been reassessed by a physician or therapist.

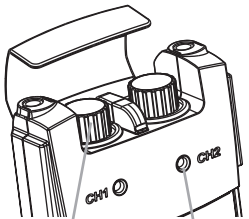
5. Possible adverse reactions

Skin irritation or electrode burn under the electrodes.
Allergic skin reaction to electrode gel may also occur.

DEVICE OVERVIEW



DEVICE OVERVIEW – DETAILS

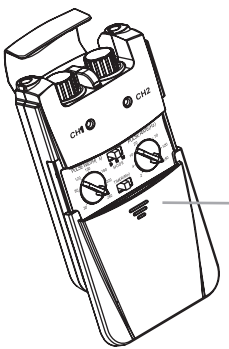


On / off switch and intensity controls:

When both controls are in the OFF position, the device is turned off. Turning the controls clockwise turns on the corresponding channel according to the chosen settings. Turn clockwise to augment intensity and counterclockwise to reduce the intensity, or all the way to the OFF position to stop the treatment.

Display LED

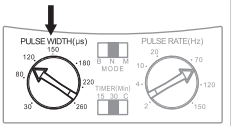
Lights up when a current pulse is sent through the corresponding channel. At frequencies above 30 Hz, the LED appears to be constantly lit.



Slide cover

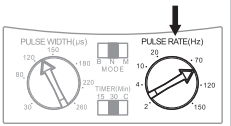
Reveals the controls for pulse width, pulse rate, mode selector and modulation, as well as the battery. Your medical professional may wish to set these controls for you and request that you leave the cover in place.

Pulse duration (width)



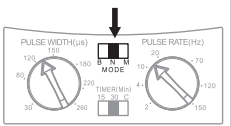
A wider pulse will deliver stronger stimulation. Using a combination of intensity and pulse duration can stimulate different nerve groups. Pulse duration is partially dependent on the treatment mode and protocol.

Pulse rate



The pulse rate (hz or pulses / second) is set depending on electrode placement. For contiguous and dermatome electrode placements (i.e. stimulating the pain site directly), a quick pulse rate (over 80 Hz) is desired. You should not perceive individual pulses but rather have the sensation of steady, continuous stimulation.

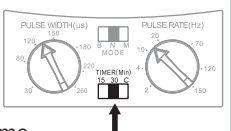
Treatment modes



N - Normal (or conventional) TENS offers complete control of the various parameters.
B - Burst mode provides a combination of conventional and low-frequency TENS by replacing the individual pulses by short “bursts” of 7 - 10 pulses. In this mode, the treatment frequency cannot be adjusted.

M - Modulated mode attempts to prevent nerve accommodation by continuously cycling the treatment intensity. In this mode, increase the intensity only when at the cycle’s maximum intensity.

Time

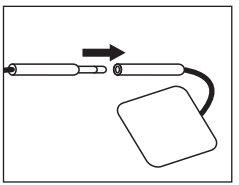


Pain relief should begin shortly after the onset of treatment. However, in some cases, it may take as long as 30 minutes to achieve. TENS units are typically operated for long periods of time, with a minimum of 20 - 30 minutes and in some post-operation protocols, as long as 36 hours. In general, pain relief will diminish within 30 minutes of the cessation of stimulation.

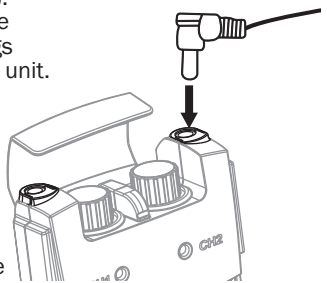
INSTRUCTIONS FOR USE

1. Insert the battery
Slide the cover completely to uncover the battery cavity. Insert a 9V battery (included), matching the positive and negative ends of the battery to the markings, then close.

2. Connect electrodes to lead wires
Insert the lead wire connector into the electrode connectors, ensuring that no bare metal remains exposed.



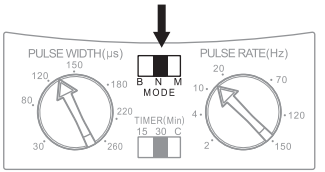
3. Connect lead wires to the device
This device has 2 output channels, which can be used simultaneously (with 2 electrode pairs) or individually (1 channel with 1 electrode pair). After making sure that the device is turned off, insert the wire plugs into the sockets at the top of the unit.
Caution: Always use the lead wires supplied with this unit.



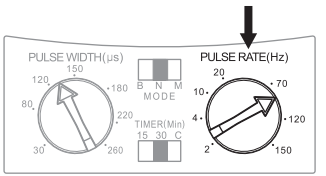
4. Place electrodes on skin
Ensure that the skin surface where the electrodes will be placed is clean and dry.
Apply electrodes to the exact site indicated by your physician.
The electrodes should be placed firmly and evenly on the skin to ensure good contact.

Caution:
Always wash and dry the treatment area before applying the electrodes. Do not turn the device on when the electrodes are not applied to the treatment area. Never adjust, reposition, or remove the electrodes while the device is still on. Always use this device with 4cm x 4cm self-adhesive square electrodes, or larger. The electrodes are for single-patient use only and should be discarded when they no longer adhere properly.

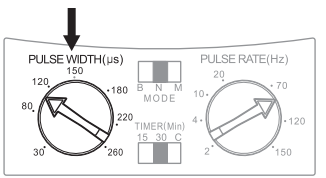
5. Select a treatment mode
Expose the controls by sliding front cover down from top of unit. This switch has 3 positions: B for burst stimulation, N for constant stimulation, and M for modulation stimulation. Push the mode selector until engaged in position desired.



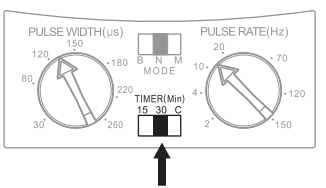
6. Set the pulse rate
Turn the pulse rate dial to the setting recommended by your doctor or therapist. Unless otherwise instructed, the pulse rate control should be set in the 70 -120 Hz range.



7. Set the pulse width
Turn the pulse width dial to the setting recommended by your doctor or therapist. Unless otherwise instructed, the pulse width control should be set in the 70 -120 μs range.

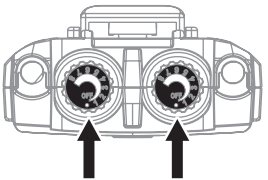


8. Set the timer
Select the appropriate treatment time (15 minutes, 30 minutes or continuous) as recommended by your doctor or therapist.



9. Set the intensity and begin treatment

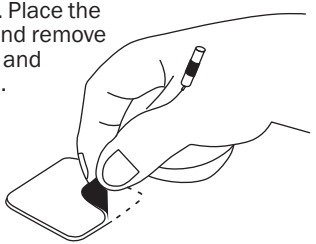
Slowly turn the intensity control dials clockwise. This will turn the corresponding channels on and begin treatment. To further increase the intensity, turn the dials clockwise. To decrease the intensity or turn the device off, rotate the dials counterclockwise to the desired setting or to the "OFF" position.



10. After treatment is finished

Once the treatment time has elapsed, turn the intensity control dials counterclockwise to the "OFF" position. Unplug the lead wires from the device.

To remove the electrodes, lift one edge and gently peel (do not pull on the lead wires because it may damage the electrodes). Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.



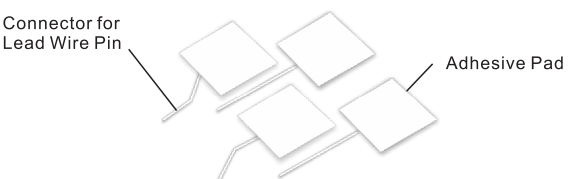
CLEANING AND MAINTENANCE

1. Stimulator

Remove the battery before cleaning. Wipe the stimulator with a soft, slightly moistened cloth. If a more thorough cleaning is needed, you can also moisten the cloth with mild soapy water. Do not submerge the stimulator or expose it to a large amount of water. Do not use any chemical cleaners or abrasive agents to clean this device. After use, store the stimulator in the storage pouch to protect it from shock and dust. If you plan not to use it for a prolonged period, remove the battery from the unit and store in a cool, dry place.

2. Electrodes

- Use the device only with the leads and electrodes provided with this device or sold under the ProActive brand, following the placements and settings prescribed by your practitioner.
- It is recommended to use at minimum 4cm x 4cm self-adhesive, square electrodes.
- Inspect your electrodes before every use and replace as needed. Reusing electrodes too many times may cause slight skin irritation, low adhesion, or ineffective stimulation.
- Between uses, store the electrodes in the resealed bag in a cool dry place. It may be helpful, between applications, to moisten their adhesive surface with a few drops of water (be careful not to over-saturate) and then let them air-dry to help them last longer.



Reusable, self-adhesive electrodes

3. Cleaning the electrode cords

Clean the electrode cords by wiping them with a damp cloth. Coating them lightly with talcum powder will reduce tangles and help them last longer.

4. Maintenance

- Do not attempt any repairs to the device or any of its accessories. Contact us at 1-800-363-2381 for repair information.
- The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- Check the device before each use for signs of wear and/or damage. Replace worn items (electrodes, lead wires) as required.

TROUBLESHOOTING

Should any malfunction occur while using this device:

- Verify that the controls are set to the appropriate therapy settings and adjust accordingly.
- Verify that the lead wires are correctly connected to the device. They should be inserted completely into the sockets.
- Verify whether the LEDs light up when the unit is in use. If necessary, insert a new battery.
- Inspect the lead wires for damage and replace if necessary.
- Verify that the electrodes are properly applied to the skin in a position that promotes proper functioning of the device. See the notes on electrode positioning on the next page for more details.
- If the above fails, do not attempt any repairs to the device or any of its accessories. Contact us at 1-800-363-2381 for repair information.

ELECTRODE POSITIONING

Electrode positioning can be one of the most important parameters in achieving success with TENS therapy. Of utmost importance is the willingness of the clinician to try the various styles of electrode placement to find which method best fits the needs of each individual patient.

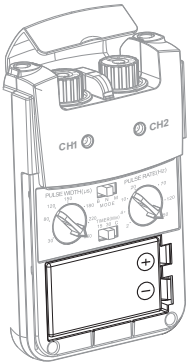
Everyone responds to electrical stimulation differently and, accordingly, their needs may vary from the conventional settings suggested here. If the inital results are not positive, feel free to experiment. Once an effective positioning has been achieved, mark down the electrode sites and the settings at the end of this manual so that it can easily be replicated at home.

Contiguous placement is the most common technique. It involves placing the electrodes alongside the site of localized pain, in such a way as to direct the flow of current through or around the pain site. In a single channel application, this would involve placing the electrodes on either side of the pain site in the case of limb or deep tissue pain. Electrode placement on the posterior and anterior aspects of the affected limb will allow the current to flow completely through the limb, and thus through the endogenous pain site. With a two channels application, the clinician may either direct the current flow to cross through the pain site or, in what is called the “bracket” method allows the current flow on either side of the painful area, generally through the nerve branches that feed into the pain site.

CHECK / REPLACE THE BATTERY

Over time, in order to ensure the functional safety of this device, changing the battery is necessary.

1. Make sure that both intensity controls are switched to the off position.
2. Slide the battery compartment cover and remove.
3. Remove the battery from the compartment.
4. Insert the battery into the compartment. Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and slide to close.



TECHNICAL SPECIFICATIONS

Mechanism	Technical description
Channel	Dual, isolated between channels
Pulse amplitude	Adjustable, 0 - 80 mA at 500 ohm load each channel
Pulse rate	Adjustable, from 2 to 150 Hz
Pulse width	Adjustable, from 30 to 260 microseconds
Modulation mode	Pulse rate is automatically varied in a cyclic pattern over an interval of nominally 10 seconds (in max 150 Hz). Pulse rate decreases linearly over a period of 4 seconds from the control setting value to a value which is 40% less. The lower pulse rate will continue for 1 second. Then increase linearly over a 4 seconds period to its original value. The original pulse rate will continue for 1 second. The cycle is then repeated.
Burst mode	Bursts occur twice every second. Pulse width (adjustable), frequency: 100 Hz
Wave form	Asymmetrical bi-phasic square pulse
Timer	15, 30 minutes or continuous
Voltage	0 to 40 V (load: 500 ohm)
Max charge per pulse	20 micro-coulombs
Power supply	One 9 V battery (alkaline or nickel-cadminum rechargeable)
Battery life	Approximately 50 hours at nominal settings
Size	95 mm (H) x 65 mm (W) x 23.5 mm (T)
Weight	115 grams (battery included)
Operating Conditions	5 °C ~ 40 °C; 30% RH ~ 75% RH
Storage Conditions	-10 °C ~ 55 °C; 10% RH ~ 90% RH

LIMITED WARRANTY

A.M.G. Medical Inc. warrants the stimulator 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 5:00 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 parties.
  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.