

Rev3 0116
P/N 861-715425

Questions? Comments?
1-800-363-2381 www.amgmedical.com

AMG Medical Inc.
Montréal, QC H4T 1V5 • 1-800-363-2381
West Chazy, NY 12992 • 1-888-412-4992

proactive™
Physiotherapy • Physiothérapie

ālevia™

2-in-1 Physiotherapy Device



Instructions

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

SPECIFICATIONS



Project: **715-425 TENS instructions EN rev3 0116_corrected_25 feb**

Item No.: **715-425** Part No.: **861-715425**

Flat Size: **24,811 cm x 18,81 cm**

Assembled size: **Folded: 10,5 cm x 15 cm. Open: 21 cm x 15 cm**

Colours: **■ B/W** _CMYK _Spots:

Special Instructions: **This is a double-sided, saddle-stitched instruction booklet.**

Generated by: **Jean--François Perron**

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INTRODUCTION

This device can be used for pain relief and muscle stimulation. It 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.

3. What is EMS and how does it work?

In normal muscular activity, the central and peripheral nervous systems transmit electrical signals to the muscles, making them contract. EMS (Electrical muscle stimulation) uses an external source (the stimulator, via wires and electrodes) to achieve the same effect, creating involuntary muscle contractions. This can help improve and maintain muscle tone without actual physical activity and therefore prevent atrophy.

SAFETY INFORMATION

- 1. This device is recommended for:**
- Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain
 - Improving local blood circulation
 - Relief from muscle spasms
- 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.
 - Epilepsy
 - Serious arterial circulatory problems in the lower limbs
 - Abdominal or inguinal hernia
 - Safety has not been established for use during pregnancy.
 - Electrical stimulation is not effective on pain that is of central origin

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 flow 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.

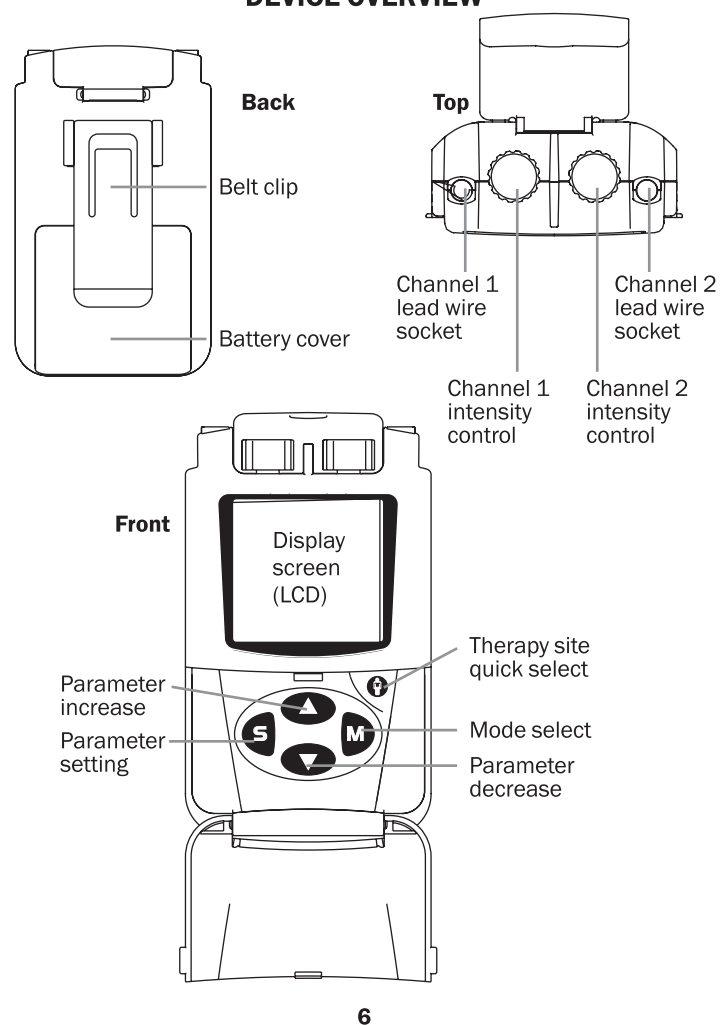
4. Precautions

- Do not adjust controls while operating machinery or vehicles. Never use the stimulator during any activity in which involuntary movement would represent a risk of injury.
- 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.

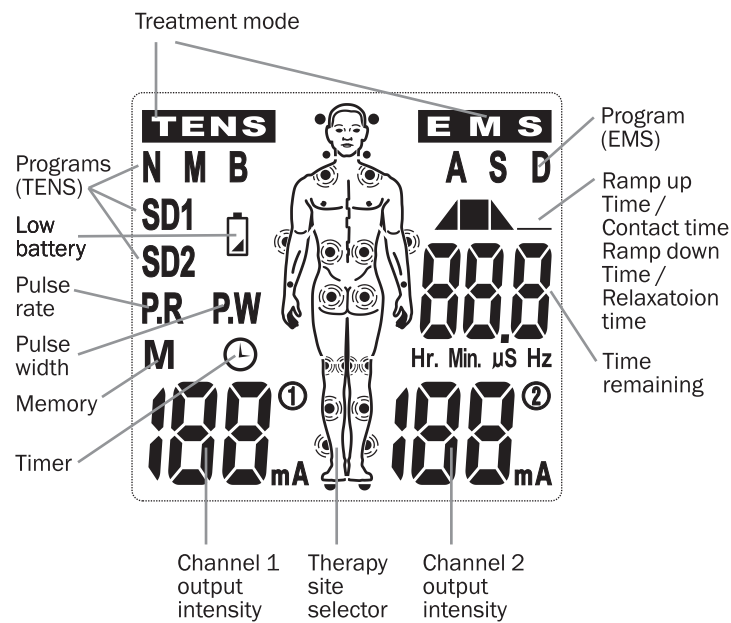
5. Possible adverse reactions

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

DEVICE OVERVIEW



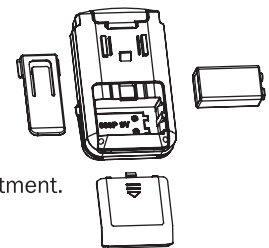
DISPLAY SYMBOLS



INSTRUCTIONS FOR USE

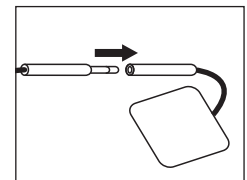
1. Insert the battery

Slide the belt clip off, then the battery compartment cover. Insert a 9V battery (included), matching the positive and negative ends of the battery to the markings, then close the compartment.



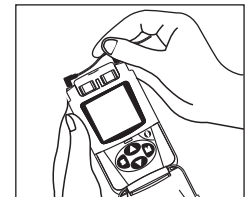
2. Connect electrodes to lead wires

Insert the lead wire connector into the electrodes connector, 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 4 cm self-adhesive electrodes, or larger. If they seem to have lost their adhesive properties, replace with new ProActive™ electrodes.

Important note: Electrode positioning can be one of the most important parameters in achieving success with TENS therapy. Of utmost importance is the willingness of the health care practitioner 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 initial results are not positive, feel free to experiment. Once an effective positioning has been achieved, mark down the electrodes sites and the settings at the end of this manual so that it can easily be replicated at home.

5. Turn the device on

Carefully read the contraindications and safety information in this manual before using for the first time. Turn the intensity control for either channel 1 or 2 clockwise. The device will beep. Continue as described below before increasing output intensity.

6. Select the therapy program (mode) and site

Press **M** until the required mode (EMS or TENS) and body part are selected. The selected therapy mode will then flash on screen.

7. Set the pulse width and rate

Press **S** to enter parameter setting mode, then use the arrow buttons to adjust the pulse width to the value prescribed by your doctor or therapist. Then, press **S** again and use the arrow buttons to adjust the pulse rate to the value prescribed by your doctor or therapist.

8. Set the treatment time

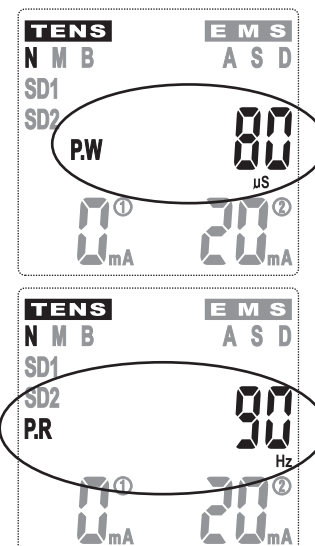
Press **S**, then use the arrow buttons to adjust the treatment time.

9. Set the on time and relaxation time for EMS mode

Press **S**, then use the arrow buttons to first adjust the ramp up time to reach contraction gradually and smoothly. Press **S** again, then use the arrow buttons to secondly adjust the contraction time. Press **S** again, then use the arrow buttons to thirdly adjust the ramp down time to reach relaxation gradually and smoothly. Press **S** again, then use the arrow buttons to lastly adjust the relaxation time to reach relaxation gradually and smoothly. The ranges are adjustable from 1 to 60 seconds depending on the selected therapy.

10. Adjust the intensity for each channel and begin treatment

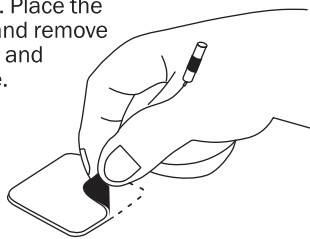
Slowly turn the intensity control dials clockwise until you reach the prescribed setting. To further increase the intensity, turn the dials clockwise. To decrease the intensity or turn the device off, rotate the dials counter-clockwise to the desired setting or to the "OFF" position. If treatment becomes uncomfortable, decrease the intensity to your comfort level and contact your doctor or therapist if the problem persists.



11. After treatment is finished

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

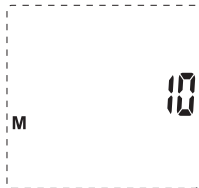
To remove the electrodes, lift one edge and gently peel (do not pull on the lead wires because this may damage the electrodes). Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.



12. To consult the memory

With the unit shut off, press and hold **M** and turn one intensity control knobs to enter memory mode. A **M** will be displayed on the screen.

NOTE: The maximum number of records is 30, after which the oldest record will be deleted.



Use the arrow keys to navigate between records and **S** to switch between data within one record. To clear the memory, press the quick select button.

13. To turn off the device

Rotate both intensity controls to "0".

14. Low battery indicator

When the indicator flashes, replace the batteries as soon as possible. However, the stimulator will continue to operate for several hours. If stimulation seems weaker than usual, replace the battery.

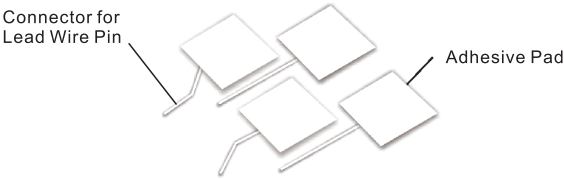
CLEANING AND MAINTENANCE

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 its foam-padded carrying case 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 4 cm self-adhesive 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

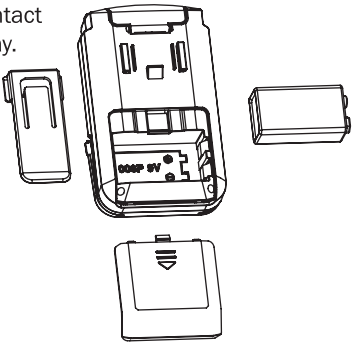
- Do not attempt any repairs to the device or any of its accessories. Contact us at 1-800-363-2381 for repair information.
- The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- Check the device before each use for signs of wear and/or damage.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

5. To replace the battery

To ensure safe and adequate functioning of this device, it is necessary to periodically change the battery. To do so, slide the belt clip off, then the battery compartment cover. Remove the old battery and insert a new one, matching the positive and negative ends of the battery to the markings, then close the compartment.

Caution: If a battery has leaked, avoid any contact with skin, eyes and mucous membranes. Flush any affected skin with water and contact a medical professional right away.

Do not attempt to recharge the battery supplied with this device. If you plan not to use the device for a long time, remove the battery and store appropriately, away from heat.



THERAPY PROGRAMS

Program		Time	Rate	Width	Wave description
TENS	Normal	30	100Hz	200µs	Continuous
	Mod.	30	100Hz	200µs	First 0.5 sec.: pulse width at 50% setting. Next 0.5 sec.: pulse rate at 50% setting and width at 100% setting.
	Burst	30	100Hz	200µs	9 pulses/burst, 2 bursts/sec.
	SD1 (Strength duration 1)	30	100Hz	120 ~ 200µs	Set intensity goes from 100% to 60% then back to 100% while set pulse goes from 60% to 100% and back to 60%, over 10-second cycles.
	SD2 (Strength duration 2)	30	100Hz	60 ~ 200µs	Set intensity goes from 100% to 30% then back to 100% while set pulse goes from 30% to 100% and back to 30%, over 10-second cycles.
	Shoulder	30	2 ~ 125Hz	60 ~ 200µs	12-second cycles, span: 50%. Rate stays in the 2-10Hz range for 1/3 of the cycle time as it modulates down to 2Hz and back up again.
	Neck	30	80Hz	180µs	Continuous
	Lower back	30	100Hz	300/ 200µs	1-second cycles, span: 60%. Modulated amplitude via pulse width 0.5 sec. at 100% of set intensity and 0.5 sec. at 50%.
	Elbow	30	2 ~ 125Hz	100/ 200µs	12-second cycles, span: 50% Rate stays in the 2-10Hz range for 1/3 of the cycle time as it modulates down to 2Hz and back up again.
Knee	30	50Hz	200µs	6-second cycles (1 sec. up / 1 sec. down) then 6 seconds rest.	
EMS	Alternate	30	50Hz	200µs	6-second cycles (1 sec. up / 1 sec. down) then 6 seconds rest.
	synchronous	30	50Hz	200µs	8-second cycles(2 sec. up / 2 sec. down) then 4 seconds rest.
	Delay	30	40Hz	200µs	11-second cycles (4 sec. up / 2 sec. down) then 15 sec. rest (1 sec. delay).

THERAPY PROGRAMS (CONTINUED)

Program	Time	Rate	Width	Wave description	
EMS	Neck	30	20Hz	180μs	Continuous
	Abdomen	30	65Hz	250μs	10-second cycles (2 sec. up / 2 sec. down) then 8 seconds rest.
	Buttocks	30	50Hz	250μs	13-second cycles (1 sec. up / 2 sec. down) then 10 sec. rest.
	Leg	30	40Hz	200μs	13-second cycles (1 sec. up / 2 sec. down) then 10 sec. rest.
	Foot	30	65Hz	200μs	10-second cycles (2 sec. up / 2 sec. down) then 8 seconds rest.

SKIN CARE RECOMMANDATIONS

- Always clean the treatment area using a mild soap, rinse skin thoroughly and dry well before applying the electrodes and after removing them.
- Clip excess hair with scissors – do not shave the treatment area.
- Your doctor or therapist may recommend the use of a skin prep solution. Let it dry thoroughly before applying the electrodes.
- Avoid stretching the electrode over the skin as this could cause "pulling stress". Apply the electrode from the center outward to prevent this from happening.
- When removing the electrodes, pull in the direction of hair growth.
- It may be helpful to apply a skin lotion over the treatment area when not using the electrodes.
- Never apply the electrodes over irritated or broken skin.

 Type BF Applied part.

TROUBLESHOOTING

If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the device should be serviced.

Problem	Possible cause	Solution
Display fails to light up	Battery contact failure	1) Install new batteries
		2) Ensure that the battery is inserted correctly, respecting the polarities, and that battery contacts are in place and in good condition
Weak or no stimulation	Electrodes are dried out or dirty	Replace and re-connect the electrodes
	Electrodes are improperly positioned	Reposition and re-connect the electrodes
	Old / worn / damaged lead wires	Replace the lead wires
Stimulation is uncomfortable	Intensity is too high	Decrease intensity
	Electrodes are too close together	Reposition the electrodes
	Damaged or worn electrodes or lead wires	Replace the lead wires
	Electrode active area is too small	Replace electrodes with ones that are 16 cm ² (4 cm x 4 cm or 1.5" x 1.5") or larger
	The user instructions are not being followed	Please check the manual before use
Intermittent output	Program option in use	Some programs will seem intermittent. This is expected.
	Lead wires	1) Verify connection is secure and firmly in place
		2) Turn down the intensity. Rotate lead wires in socket 90°. If the problem persists, replace lead wire.
		3) If replacing the lead wire does not solve this problem, contact us at: 1-800-363-2381

Problem	Possible cause	Solution
Stimulation is ineffective	Improper electrode placement	Reposition electrode
	Unknown	Contact your doctor
The skin becomes red and / or you feel a stabbing pain	Repetitive use of electrodes on the same site	Reposition the electrodes. If at any time you feel pain or discomfort, stop use immediately
	Electrodes aren't applied on the skin properly	Ensure the electrodes are attached securely to the skin
	The electrodes are dirty	Clean the electrode pads with a damp, lint-free cloth or replace with new electrodes. Clean the electrode cord according to the description in the user manual
Output current stops during therapy	The surface of the electrode is scratched	Replace with a new electrode
	The electrode pads come off the skin	Turn off the device and attach the electrode firmly to the skin
	A cable is disconnected	Turn off the device and connect the cable
	Batteries are low	Replace with new batteries

STORAGE

- Remove the battery if the device is not in use for long periods of time.
- Store the device in a dry place and protect it against heat, sunshine and moisture.
- Never place any heavy objects on the device.

DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer.

Please dispose of the device in accordance with the directive 2012/19/EU WEEE (Waste Electrical and Electronic Equipment). Contact your local distributor for information regarding disposal of the unit and accessories.



LIMITED WARRANTY

AMG 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 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 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.

TECHNICAL INFORMATION

- Channel: Two isolated channels
- Power supply: 1 x 9V battery, type 6F22
- Waveform: Asymmetrical biphasic square waveform
- Pulse duration: adjustable, from 50 to 350µs.
- Pulse frequency: adjustable, from 1 to 150Hz
- Treatment time: 5 to 60min
- Amplitude: 0-40V(Vpp)(Large output 40V±10% at 500ohm load)
- Operating conditions: 0 °C to 40 °C with a relative humidity of 30% - 75%, Atmospheric pressure from 700 hpa to 1060 hpa
- Storage conditions: -10 °C to 55 °C with a relative humidity of 10%~90%, atmospheric pressure from 700 hpa to 1060 hpa
- Dimensions: 110 x 65 x 30.2 mm
- Weight: 139 g (with battery)