

TheraHeat |||





Instructions

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

Packaging Content

Please ensure you have all of the following components before using your tens device



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Introduction

Tens Therapy

TENS technology (Transcutaneous Electrical Nerve Stimulation) stimulates nerve endings producing the body's natural painkillers while improving circulation and muscle tone. Helps relieve sore, aching muscles and joints throughout the body naturally, without drugs or medication.

Heat Therapy

Heat is associated with comfort and relaxation; targeted heat therapy goes a step further, stimulating blood flow and soothing sore muscles during treatment. Heat therapy works by dilating the blood vessels within the muscles, increasing the flow of oxygen and nutrients, helping to promote healing of damaged tissues. Penetrating heat application at an injury site can help stretch tissue, relax muscles, promote flexibility and reduce stiffness.

Indications For Use

TENS (Modes 1, 2, 4, 5, 6, 8)

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

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

EMS (Modes 1, 3, 7)

To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.



NOTE: Read all instructions and inserts included with this device carefully before use. The following basic precautions are needed when using an electrical product.

CAUTION: Failure to read and observe all precautions could result in injury or equipment damage.

Improper care or use of your device may result in injury, damage to the unit or ineffective treatment. Following these instructions will ensure the device's efficacy and long life.

CONTRAINDICATIONS:

- Do not use this device if you have a cardiac pacemaker, implanted defibrillator or other implanted metal or electronic device.
- Do not use this device to treat undiagnosed chronic pain.
- Do not use this device if you have a suspected or diagnosed heart condition.
- Do not use this device if you have suspected or diagnosed epilepsy.
- Do not use this device if you have a tendency to bleed internally following an injury.
- · Do not use this device during pregnancy.



GENERAL WARNINGS PRIOR TO USE

- If you are under the care of a physician, consult with your physician before using this device.
- · Long-term effects of this device are not known.
- Do not place the device on or close to your heart.
- Take care when applying device close to the neck; do not place
 this device on the front or sides of the neck. Severe spasm of the
 muscles may occur and the contractions may be strong enough
 to close the airway or cause difficulty in breathing. Stimulation
 over the neck could also affect hearing or blood pressure.
- Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause cardiac rhythm disturbances.
- Do not place the device on or around your head.
 The effects of stimulation of the brain are unknown.
- · Do not use this device while sleeping.
- · Do not use if you feel numbness.
- · Do not use this device in or close to water.



GENERAL WARNINGS PRIOR TO USE (Cont'd)

- Use only on normal, healthy, clean skin. Do not use on or close to open wounds or rashes, or over swollen, red, infected or inflamed skin.
- Do not apply stimulation over, or in proximity to cancerous lesions.
- Do not use the device on children or incapacitated persons.
- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.

GENERAL CAUTIONS PRIOR TO USE

- Read this manual before using this device for the first time.
- · Keep this manual available whenever you use this device.
- This device is intended for individual personal use only.
- This device is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This device is for pain caused by muscle soreness, and should be placed only around muscles where pain originates.



- The pain may indicate that you have some other health problem.
 You should know the reason and source of your pain before using this device.
- The safety of using this device during pregnancy has not been established.
- The effectiveness of this device depends greatly on a person's individual physical condition. It may not always be effective for every user.
- If you have had medical or physical treatment for your muscle pain, consult with your treatment provider before using this device. You should contact your physician prior to using this device following recent surgical procedures. Stimulation may disrupt the healing process.



OPERATING WARNINGS & CAUTIONS

CONSULT WITH YOU PHYSICIAN IF YOU HAVE ANY OF THE FOLLOWING:

- · If you have a suspected or diagnosed heart condition.
- · If you have suspected or diagnosed epilepsy.
- If you have a tendency to bleed internally following an injury.
- If you recently had surgery, or have ever had surgery on your back.
- If areas of skin lack normal sensations, such as skin that tingles or is numb.
- The unit is intended for the temporary relief of pain caused by muscle soreness. The source or cause of the pain should be addressed by a healthcare professional. Pain could indicate an injury or condition that requires treatment.
- Skin irritation or experience a very sensitive feeling in the skin due to electrical stimulation. If this occurs, stop using the device and consult your physician.
- If skin under the pad feels irritated after using the stimulator for a long period of time, use the stimulator for a shorter period of time.



- Minor redness at stimulation placement is a normal skin reaction.
 It is not considered a skin irritation, and it will normally disappear within 30 minutes after the electrodes are removed.
 - If the redness does not disappear after 30 minutes from the removal of electrodes, do not use the stimulator again until after the excessive redness has disappeared.
- Turn off your device if the stimulation feels unpleasant or does not provide pain relief.
- Use this device only with the pads and accessories recommended by the manufacturer.
- Do not use this device when driving, operating machinery or when swimming.
- Before removing the Electrode Pad, be sure to turn it OFF, avoiding unpleasant stimulation.
- TENS is not a substitute for pain medications or other pain management therapies.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- · Do not use the unit while sleeping.



- After each use, clean any adhesive residue left on the skin with soap and water.
- The effectiveness of therapy varies from person to person.
 It may not be an effective treatment for all users.
- · The long-term effects of stimulus therapy are unknown.

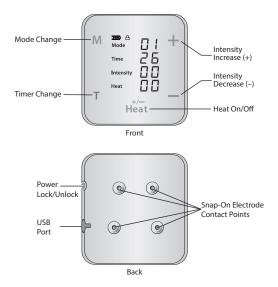


STORAGE WARNINGS & CAUTIONS

- Storage outside of stated storage temperature may result in measurement error or device malfunction; storage environment temperature is: 14°F – 122°F (-10°C – 50°C); humidity: 30 – 90% RH.
- · Keep the unit out of reach of small children.
- Do not store the device in direct sunlight, dusty or humid environments, or extreme temperatures. Exact figures for appropriate use and storage can be found in the Product Specifications Section of this manual.

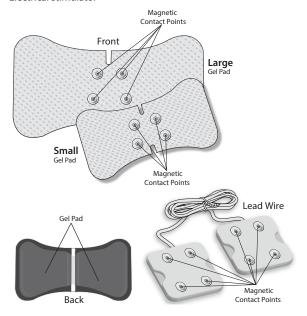
Product Features

Electrical stimulator



Product Features

Electrical stimulator



Charging the Device

This device includes an internal rechargeable battery within the electrical stimulator unit and USB cable.

A USB wall charger/adapter is required for charging; not included.

Before first use, the device should be fully charged. Charging time may vary depending on the wall adapter used; 3–6 hours from depleted battery to full charge.

- 1. Connect the wide end of the USB cable to a wall adapter.
- 2. Connect the smaller mini USB to the TENS stimulator.
- 3. During charging the battery symbol on the stimulator will flash. When the device is fully charged, the battery symbol will be solid green.
- Unplug the charger and stimulator when fully charged; never operate the unit while charging.



Charging the Device

NOTE:

The TENS + Heat device offers 3 user modes, 8 pulse modes and 20 levels of intensity. As such, the power usage and rechargeable battery life will vary depending on the users specific settings during treatment.

For example, a fully charged device utilizing mid-range intensity and only the TENS setting battery life may extend to 20 hours of use. The same setting with the heat function activated may only extend to approximately 3 hours of use.

For maximum effectiveness, monitor the battery life symbol and charge the device when the battery level graphic is depleted.

Preparing Your Device

It is necessary to prepare and assemble your device prior to treatment.

- While the stimulator device is OFF (the display is NOT illuminated) carefully attach the electrode pads to the control unit via the magnetic connection points.
- For lead wire application, carefully attach one end of the lead wire to the electrodepad and the other end to the device via the magnetic connection points. (Refer to page 35 for details)
- 3. Pull gently to ensure the electrode pad is firmly attached.
- 4. Carefully remove the plastic film from the electrode pad.
- 5. You are ready to apply the pad to the affected treatment area.

Do not turn the power ON until the device is in place on the user's skin as indicated in the 'Instructions for Use' section of this manual.







- NOTE: (1) Lead wire application should be used on hard to reach sites including the lower back or shoulder, so the device is accessible during your TENS treatment.
 - (2) Save the plastic film for storage after treatment to protect the pads from dirt & debris.

Placement & Treatment

Read all warnings and cautions completely before use.

The electrode pads are applied directly to the skin. Clothing may be worn over the device; clothing should not constrict the device and should allow access to the control unit buttons.

Targeted treatment areas may include:

- · shoulder
- elbow
- thigh
- knee
- calf
- ankle
- · back of neck
- upper back
- lower back
- feet

Never place device over the heart, on the front or sides of the neck or face.



Pulse Program Descriptions

	Pulse Rate	Description	Benefit
P1	Combination of the below	Combination of the below	All kinds of pain relief
P2	69	Pulse on for 3.4 seconds and off for 1.6 seconds	Mild gate pain relief
Р3	12.5–55.5	Pulse on for 2 0 seconds and off for 1 second	Muscle performance improvement with variable pulse rate
P4	1.2	Pulse on every 0.85 seconds	Slow endorphin pain relief
P5	100	Pulse on for 10 seconds and off for 2.5 seconds	Quick gate pain relief
P6	100	Pulse on for 20 seconds and off for 1 second	Quick gate pain relief and strong pulse amplitude
P7	20	Pulse on for 5 seconds and off for 1 second	Muscle performance improvement
P8	160	Pulse on for 10 seconds and off for 2 seconds	Quick and deep gate pain relief

Pulse Program Descriptions

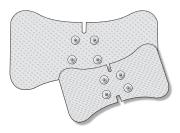
The programs are not specific to treatment at a certain body location or to treat a specific ailment or pain.

The sensations may include—massage, acupuncture, tapping, scraping or a combination of the sensations at variable durations and cycles.

Select the program that provides the best relief for your particular ache and pain.

Selecting Your Gel Pad

This device includes two sizes of gel electrode pads. There is no functional difference in the pad. Select the size for use most appropriate to the size of the treatment area.



Read all warnings and cautions completely before use.
Recommended treatment time is 30-minutes; consult your healthcare professional for a treatment cycle that best suits your injury. Discontinue use immediately if treatment is uncomfortable or painful.

- Treatment area should be clean before applying the control unit. Note that excessive skin lotion or soap residue may reduce the adhesiveness of the pad. Only use on HEALTHY skin areas with no cuts, sores or wounds.
- Apply the pad to the desired treatment area, taking care to ensure the controller is comfortably within reach of your hand for safety and control during treatment.
- **3.** The electrode pad should be smoothly applied and the gel adhesive should hold the pad firmly in place on the skin.
- 4. After the device is applied to the desired treatment area or is connected to the lead wire, press and hold the **Φ POWER** button for 2-seconds; the display will illuminate.
- 5. The TENS unit will begin to operate at the lowest intensity level setting for program 1. The HEAT feature will default to off when the unit is first powered on. The default TIMER setting is 30 minutes.

- Until you are familiar with use of the unit, begin with the lower intensity levels and gradually progress to more advanced levels as you feel comfortable.
- INTENSITY SETTING Press and release the '4' button to find your desired therapy sensation level. This device offers 20 intensity levels. Press and release the '-' button to reduce the intensity level.
- 8. MODE SETTING To change the mode, while the unit is on/operating, press and release the 'M'; the mode will switch to the next in the sequence of 8 pulse types. See page 18 for a detailed description of each pulse type. When changing modes, the intensity will revert to level 0 (lowest sensation).



- HEAT SETTING To activate the HEAT setting, press the (+/- HEAT).
 The HEAT sensation has two levels, press and release the (+/- HEAT) to scroll through the settings: 00–0FF; 01–level 1; 02–level 2.
- 10. TIMER SETTING Press and release the 'T' to adjust the therapy time in 10-minute increments; the unit will automatically shut off when the timer is done.

- 11. The sensation should be strong but comfortable; press the + or button at any time during the treatment to change the intensity as desired.
- **12.** Press and hold the **OPOWER** button for 2 seconds to turn the device off at any time during treatment.
- 13. Be sure the device is OFF (no sensation is felt) before removing the device from your skin. Take care during removal to best protect the adhesive and preserve the life of the electrode pad.
- **14.** Place the plastic cover over the gel side of the pad to prevent them from drying out.
- **15.** To conserve the battery and prevent shock, the device will automatically power off when not in use.

NOTF:

You may wish to clean the treatment site after use to remove any adhesive residue from the electrode pad.

DISPLAY LOCK FEATURE:

The display may be locked to prevent the user from accidently pressing the touch-sensitive buttons.

- 1. While the device is active, press and release the **O POWER** button.
- 2. A LOCK symbol will appear on the upper left of the display.
- 3. To release the LOCK, press and release the **O POWER** button again. The modes/timer/intensity can now be adjusted.



Caring For The Electrode Pads

Gel Electrode Pads

- The electrode pads can be reused as long as they retain their adhesion. Cover the pads with the included film pieces when not in use to prevent them from drying out.
- Storing the pads in a plastic zip bag will help prevent the gel pads from drying out prematurely.
- Properly cared for, the electrode pads may last up to 50 uses; the life of the electrode pad is largely dependent upon proper care and the condition of the skin as applied for use.
- To help prolong the life of the electrode pad, between uses, moisten the gel side of the pad with a drop of water and allow to dry; replace the film for storage.
- If you notice that the pads have become dry, no longer adhere well to the skin, or begin to irritate the skin, they are in need of replacement.

Replacement pads are sold separately.

Cleaning and Storage

Cleaning

- · Unsnap the electrode pad before cleaning the device.
- The Electrical Stimulator can be cleaned with a soft, dry cloth.
- Never use cleaning agents or excessive water to clean any part of the unit. Do not submerge any part of the unit or let it get wet.
- · Never disassemble the unit or attempt to repair the control unit.

Storage

- Always use the included plastic film to protect the gel electrode from dust and debris
- If the device will not be used for several days or longer, place the film cover over the electrode pads to prevent from drying out.
- Store all components in the included bag while not in use.
- Storing the pads in a plastic zip bag will help prevent the gel pads from drying out prematurely.
- · Protect the unit from mechanical shock or heavy impact.
- · Avoid exposure to extreme temperatures.

Troubleshooting

Problem	Solution
Display does not illuminate/ is weak / Control unit will not turn on	Recharge the batteries.
Intensity output is low / no stimulation is occurring	Electrode pad may be dirty; clean and attempt again. Confirm that the electrode snaps are firmly connected to the control unit. Battery power is low, recharge the battery. Device may not be applied properly; ensure the gel pad is making complete contact with the skin.
Electrode pads are not adhering to the skin	Review the 'Caring for Electrode Pads' section of this manual; pads may need to be replaced.

Device & Label Symbols

These symbols may appear on your device, instructions or packaging and may vary by make and model.

Symbol	Meaning	
<u>l</u> i	Read this Manual/Consult Instructions Before Use	
<u></u>	Caution/Consult Accompanying Documents Before Use	
\subseteq	Use by Date	
\sim	Date of Manufacture	
LOT	Batch Code	
REF	Catalogue Number	
SN	Serial Number	

Meaning	
Manufacturer	
Temperature Limitation	
Humidity Limitation	
Non-sterile	
Fragile, Handle with Care	
Keep Device Dry	
Product Packaging is Recyclable	

Table 1 - For all MEDICAL ELECTRICAL EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emissions

This monitor is intended for use in the electromagnetic environment specified below.

The customer or the user of this monitor should assure that it is used in such an environment.

Emmission Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	This monitor 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	This monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply
Harmonic emissions IEC 61000-3-2	Class A	network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 - For all MEDICAL ELECTRICAL EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity

This monitor is intended for use in the electromagnetic environment specified below. The customer or the user of this monitor 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%.
Electrical fast transient/burst IEC 61000-4-4	± 6 kV contact ± 8 kV air	± 2 kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
RF emissions CISPR 11		Class B	This monitor 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.

Table 3 - For all MEDICAL ELECTRICAL EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity

This monitor is intended for use in the electromagnetic environment specified below.

The customer or the user of this monitor 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this monitor, including cables, than the recommended separation distance calculated from 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 and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,** should be less than the compliance level in each frequency range.*** Interference may occur in the vicinity of equiument marked with the following symbol: ((c))

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.

[&]quot;Field strengths from fixed transmitters, such as base stations for radio (collusia recidens) releptonees and and mobile radios, antiture 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 lest survey should be considered. If the measure field strength in the location in which this monitor is used exceeds the applicable RF compliance level above, this monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be recessary, such as or exceiming or relocation the innoister. "Over the frequency range 150 MR br. field strengths should be less than 3Vm.

Table 4 - For all MEDICAL ELECTRICAL EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and this monitor

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

Rated maximum		ion distance according to frequency of transmitter m		
output power of transmitter W	150 kHz to 80 MHz d = 1.2	80 MHz to 800 MHz d = 1.2	800 MHz to 2,5 GHz d = 2.3	
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 waits (W) according to the transmitter in waits (W) according to the transmitter in waits (W) according to the transmitter of maximum and curren.

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.

Product Specifications

Name	Proactive TheraHeat Tens
Model Number	715-440
Number Of Modes	8 Modes
Timer Range	10 – 60 (Minutes)
Heat Setting Levels	Level 1: 105.8°F (41°C); Level 2: 109.4°F (43°C)
Waveform	Biphasic
Shape	Rectangular
Channel S	Single Channel
Maximum Output Voltage	64V@500Ω
Maximum Output Current	128Ma@500Ω
Pulse Duration	100Msec
Maximum Frequency	160Hz
Pulse Intensity	0~84Ma +/- 20%; 0~20 Stages Adjustable
Automatic Shut-Off	After Completion Of Set Therapy Treatment Time; 10–60 Minutes Maximum
Power Source	3.7V Battery
Operation Environment	Temperature 50°F - 104°F (10°C - 40°C); Humidity 30% - 90%
Storage Environment	Temperature 14°F - 122°F (-10°C - 50°C); Humidity 30% - 90%
Device Dimensions	(3.5 X 3.03 X 0.70 po) 8.89 X 7.62 X 1.778 cm

Product Specifications

Weight	Device weight 1.3 oz	
Included	Electrical stimulator, large gel pad, small gel pa USB cable, lead wire, instruction manual	
Available Separately	Replacement Gel pads — 2 per pack, 715-732 (Large Size) and 715-734 (Small Size)	
Lead Wires - Length	59 inch (1.5m) - 6% acceptable error	
Lead Wires - Weight	2.2oz (62.3g)	
Connectors Diameter:	0.4 inch (12mm) - Magnetic	

Specifications are subject to change without notice.

LIMITED WARRANTY

A.M.G. Medical Inc. warrants TheraHeat[™] 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. Carefully package the product to avoid any damage that may occur while in transit; shipping insurance with returned receipt is recommended. At our discretion, the Warrantor will repair or replace the unit found to be defective in materials or workmanship under normal consumer usage. The purchaser will be notified of any additional repairs required prior to completing.

Lead Wire Instructions

Use Lead Wire with TheraHeat™ on hard to reach sites (ie: lower back, shoulder) ensuring the unit is close to your hands during TENS treatment.

APPLICATION:

- While the device is OFF (the display is NOT illuminated) carefully attach one end of the lead wire to the electrode pad and the other end to the control unit via the magnetic connection points
- 2. Pull gently to ensure the electrode pad is firmly attached.
- 3. Carefully remove the plastic film from the electrode pad.
- 4. You are ready to apply the pad to the treatment area.

Note: Do not turn the power ON until the device is in place on the user's skin.





Notes

Notes



For any other comments or questions contact our customer service at:



A.M.G. Medical Inc.
Montréal, QC H4T 1V5 • 1-800-363-2381
West Chazy, NY 12992 • 1-888-412-4992
www.amgmedical.com