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REV2.4.9.15



User manual

English

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GENERAL DESCRIPTION

The **drive** Wireless TENS/EMS System is a battery operated wireless pulse generator that sends electrical impulses from a REMOTE(A) control to RECEIVER(B) (round) with ELECTRODE(S), that are placed on the body to stimulate the nerves causing pain. When this happens, the nerves feel gentle electrical sensations instead of the pain.

The Wireless REMOTE controls the ON/OFF of the system, the INTENSITY and the MODE functions of the RECEIVER(S). The RECEIVER(S) with the electrode attached adheres easily and firmly to the skin.

Because the System is Wireless - Needing No Lead Wires - you must use only DRIVE SNAP PIN Electrodes. Lead wire electrodes will not work with this Wireless system.

INTENDED USE

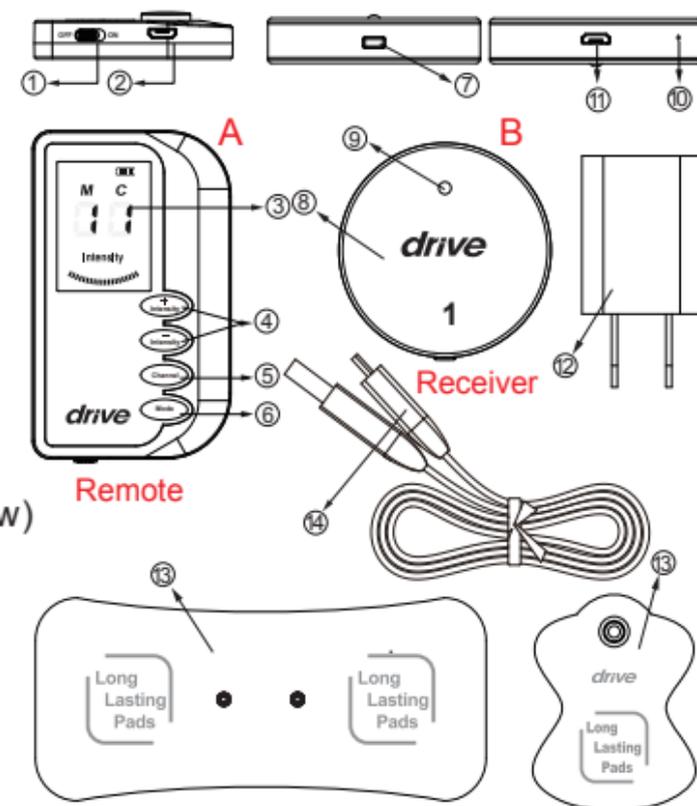
To be used for the temporary relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

To be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

INCLUDED IN THIS PACKAGE

- 1 REMOTE Control
- 2 RECEIVERS - Numbered 1 and 2
- LARGE LONG-LASTING BACK ELECTRODE, 1/ea.
- 2"x3" LONG-LASTING ELECTRODES, 2/ea.
- AC Adapter
- USB Cable for Recharging
- Instruction Booklet

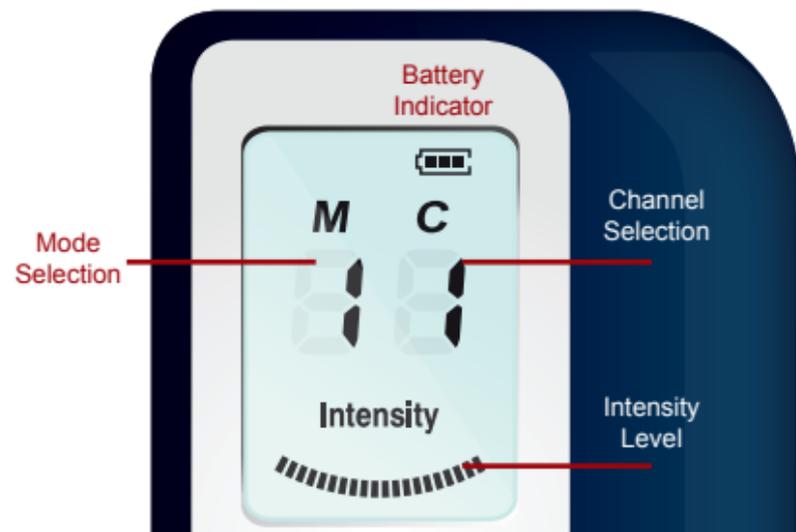
- | | |
|-----------------------|--|
| 1. ON/OFF | 9. Working Indicator Light(Green)
/Charging Indicator Light(Yellow) |
| 2. USB Port | 10. Reset Button |
| 3. LCD Screen | 11. USB Port |
| 4. Intensity Adjustor | 12. AC Adapter |
| 5. Channel Switch | 13. Electrode Pad |
| 6. Mode Selector | 14. USB Cable |
| 7. Power Switch | |
| 8. Receiver | |



INSTRUCTIONS FOR USE

The REMOTE control has an LCD display, Intensity Up(+) and Down(-) and C button for choosing which RECEIVER you plan to adjust. Channel 1 controls RECEIVER 1, while Channel 2 controls RECEIVER 2.

The M button is to control the MODE functions of the 2 RECEIVERS.



REMOTE CONTROL

The slide SWITCH(1) on the bottom of the REMOTE is to turn the unit "ON" and "OFF". Its LCD display lights up when the REMOTE is "ON". If the LCD display is blank or the REMOTE does not turn on, the REMOTE needs to be recharged.

The default setting time of REMOTE is 45 minutes. The REMOTE will shut off automatically after that time, or you can manually turn off.

RECEIVER(S) CONTROL

Push and hold the power button on each RECEIVER until you can see the green light. Push again, and the RECEIVER turns off. If the green light becomes red, the RECEIVER needs to be recharged.

INTENSITY



INTENSITY adjusting on the REMOTE is just below the LCD Screen figured as + and -. The more you push + the HIGHER "UP" the Intensity level of the Channel shown in the LCD display goes.

The more you push - the LOWER "DOWN" the Intensity level of the Channel shown in the LCD display goes.

CHANNEL and RECEIVER CONTROLS

Channel

There are 2 RECEIVERS labeled 1 and 2.

**RECEIVER 1 is Channel 1 and RECEIVER 2 is Channel 2.*

Both Channels/Receivers are controlled by the REMOTE. To use Channel 1 push the 'C' button on the REMOTE until you see 1 under the 'C' in the LCD display. Then set the MODE, by pushing 'M' on the REMOTE to see 1, 2, 3, 4 in the LCD display. To use Channel 2 push the 'C' button on the REMOTE until you see 2 under the 'C' in the LCD display. Then set the MODE for it by pushing 'M' on the REMOTE to see 1, 2, 3, 4 in the LCD display.

****Note: Receiver must be connected to either 1 large or 2 small electrodes to function. Using only 1 small electrode will result in non-function.***

MODES - PRE-PROGRAMMED MODE FUNCTIONS

Mode

Once the correct Channel/Receiver is chosen by pushing 'C' and seeing 1 or 2 appear in the LCD display, push the 'M' button on the REMOTE to change the selected Channel from Mode 1, to Mode 2, to Mode 3 or to Mode 4.

Suggested MODE Uses for Treatment

Mode 1: Legs, Arms, Hands, Feet, Knees, Lower Back, Hips, Stomach, Shoulders, Upper Back, Neck

Mode 2: Lower Back, Shoulders, Upper Back, Neck

Mode 3: Legs, Arms, Hands, Feet, Knees, Lower Back, Hips, Stomach, Shoulders, Upper Back, Neck

Mode 4: Combination Wave Mode, a mixture of Modes 1, 2 & 3.

APPLICATION DURATION

2-3 treatments per day, 45 minutes treatment times, over 10 days for one course.

ELECTRODE PLACEMENT

The placement of electrodes can be one of the most important parameters in achieving success with TENS therapy. Of utmost importance is the willingness of the user to try the various styles of electrode placement to find which method best fits his or her needs. Every user responds to electrical stimulation differently and their needs may vary from the conventional settings suggested here. If the initial results are not positive,

feel free to experiment.

- The user should position the electrodes on the buttons of the RECEIVER(S) before placement.
- Both of the smaller electrodes need to be used at the same time in order for the unit to work.
- Do NOT peel the paper covering at the middle of large back electrode.
- Keep the clear electrode covering close by for protecting electrode sticky surface after removal.

TIPS FOR SKIN CARE

To avoid skin irritation, especially if you have sensitive skin, follow these suggestions:

1. Wash the area of skin where you will be placing the electrodes, using mild soap and water before applying electrodes, and after taking them off. Be sure to rinse soap off thoroughly and dry skin well.
2. Excess hair may be clipped with scissors; do not shave stimulation area.
3. Wipe the area with the skin preparation your clinician has recommended. Let this dry. Apply electrodes as directed.
4. Many skin problems arise from the 'pulling stress' from adhesive patches that are excessively stretched across the skin during application. To prevent this, apply electrodes from center outward; avoid stretching over the skin.
5. When removing electrodes, always remove by pulling in the direction of hair growth.

6. It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
7. Never apply electrodes over irritated or broken skin.

CONTRAINDICATIONS

DO NOT use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

WARNINGS

1. If you are in the care of a physician, consult with your physician before using this device.
2. If you have had medical or physical treatment for your pain, consult with your physician before using this device.
3. If your pain does not improve, becomes more than mild, or continues for more than five days, stop using the device and consult with your physician.
4. **Do not** apply stimulation over your throat. This could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
5. **Do not** apply stimulation across your chest. The introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.

6. **Do not** apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
7. **Do not** apply stimulation over, or in proximity to, cancerous lesions.
8. **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.
9. **Do not** apply stimulation when in the bath or shower or around any other water source.
10. **Do not** apply stimulation while sleeping.
11. **Do not** apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
12. **Do not** use the device on children, if it has not been evaluated for pediatric use.
13. Consult with your physician before using this device. The device may cause lethal rhythm disturbances to the heart in susceptible individuals.
14. Apply stimulation only to normal, intact, clean, healthy skin.

PRECAUTIONS

1. TENS is not effective for pain of central origin, including headache.
2. TENS is not a substitute for pain medications and other pain management therapies.
3. TENS devices have no curative value.

4. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
5. Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
6. The long-term effects of electrical stimulation are unknown.
7. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head.
8. The safety of electrical stimulation during pregnancy has not been established, consult with your physician.
9. You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
10. If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
11. If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
12. Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
13. Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.

14. Use caution if stimulation is applied over the menstruating or pregnant uterus.
15. Use caution if stimulation is applied over areas of skin that lack normal sensation. The user manual should advise users of the following:
 - Keep this device out of the reach of children.
 - Use this device only with the leads, electrodes and accessories recommended by the manufacturer.
16. Do not use TENS anywhere on the head or face (unless instructed by your therapist for TMJ), front of the neck, internally, or on genitals.

ADVERSE REACTIONS

You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin. You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face; and you should stop using the device.

TROUBLESHOOTINGS

1. The REMOTE is not turning on or I can't see anything on the screen.
 - Make sure the REMOTE has been fully charged.

2. The indicator light of RECEIVER becomes red.
 - Charge the RECEIVER soon or it will turn off automatically.
3. The REMOTE and/or RECEIVER do(es) not seem to be charging.
 - Ensure the USB cable is firmly in the REMOTE/RECEIVER on one side and plugged into the AC adapter into the electrical socket on the other side - Isolate whether there is a problem with the AC adapter by plugging the USB cable from the REMOTE/RECEIVER into a computer.
4. Adhesive electrode pads do not stick to skin even after cleaning and moistening their surface.
 - Replace the adhesive gel pads. Pads can be purchased from your distributor or from www.drivemedical.com.
5. During use the skin feels a painful burning sensation or the stimulation becomes weakened.
 - Apply a few drops of water to adhesive surface of the pads and make sure the pads are pressed firmly to the skin during application.
6. When pressing 'M' (Mode) and (+) (-) (Intensity adjustor) of the REMOTE, there is no any reaction.
 - Make sure both REMOTE and RECEIVERS are turned on, and the Channel number matches the RECEIVER number correctly.
7. The REMOTE can't control the RECEIVER well.
 - Make sure the distance between the REMOTE and RECEIVER is less than 10 meters under the open environment.

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

Drive PainAway Model# RTLAGF-900 Tens Conforms to EMC Standards

As the number of electronic devices such as computers and cellular mobile telephones increases, medical devices in use may be at risk to electromagnetic interference from other devices.

Electromagnetic interference may result in faulty operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices. In order to regulate the requirements for EMC or Electromagnetic Compatibility with the goal to prevent unsafe product use, the EC60601-1-2 standard was implemented.

This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.