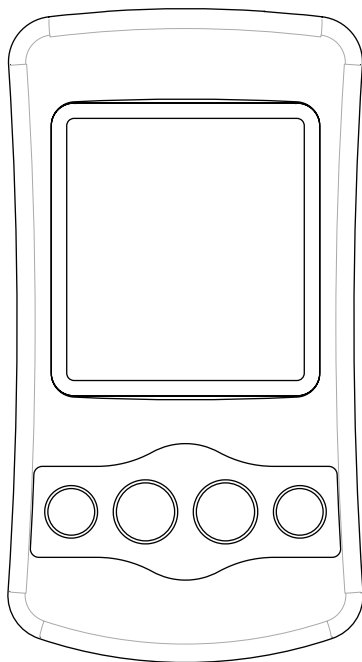


TOP TENS™

(DT6030)

Instruction Manual



Please keep this instruction manual safe for future use.

TABLE OF CONTENTS

INDICATIONS AND CONTRAINDICATIONS.....	1
WARNINGS AND PRECAUTIONS.....	2
PACKAGE CONTENTS.....	7
ABOUT the TOP TENS™	7
STEP BY STEP OPERATION GUIDE FOR TREATMENT.....	8
Preparing the Skin for Treatment	8
Inserting 3 AAA Batteries.....	8
Connecting the Lead Wires to the TOP TENS™	9
Turning ON the TOP TENS™	9
Setting Treatment Program, Time and Intensity Level.....	9
Turning OFF the TOP TENS™	10
Special Notes.....	10
SPECIAL FEATURES.....	11
CARE AND MAINTENANCE.....	12
TROUBLE SHOOTING.....	13
TECHNICAL SPECIFICATIONS / PROGRAM DETAILS.....	14
WARRANTY.....	15

INDICATIONS AND CONTRAINDICATIONS

Read the operation manual before using.

Read instruction manual before using. Be sure to comply with all “CAUTIONS” and “WARNINGS” in the manual. Failure to follow instructions can cause harm to the user or the TOP TENS™ unit.

INDICATIONS FOR USE

This device is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities due to strain from exercise or normal household and work activities.

CONTRAINDICATIONS:

Heart Disease – Use caution prior to using the TOP TENS™ if you or your Physician suspect you have heart disease.

Cardiac pacemakers – Do not use the TOP TENS™ if you have a demand-type cardiac pacemaker or any implanted defibrillator.

Trans cerebral stimulation – Do not apply electrical stimulation trans cerebrally (through the head).

Epilepsy – Use caution when using the TOP TENS™ if you suspect you have or have been diagnosed with epilepsy.

Carotid sinus – Do not apply electrical stimulation to carotid sinus region of the neck.

Unknown etiology – Do not use the TOP TENS™ if pain symptoms are undiagnosed. Use only after the origin/cause of pain has been determined by your physician.

Hemorrhages – Use caution when there is a tendency to hemorrhage, such as following acute trauma or fracture.

Post-surgical use – Use caution following recent surgical procedures when muscle contraction may disrupt the healing process.

Uterus – Do not use electrical stimulation during menstruation.

Sensory loss – Do not use electrical stimulation where sensory nerve damage is present, and when there is a loss of normal skin sensation.

Skin irritation – If you experience skin irritation, due to electrical stimulation, stop using the TOP TENS™ device and consult your Physician. Irritation may be reduced by an alternative conductive medium or an alternative electrode placement. Isolated cases of skin irritation may occur at the site of electrode placement following long term application.

Adverse reactions – in addition to skin irritation, inflammation and burns beneath the electrodes are potential adverse reactions. Follow directions carefully to avoid any adverse reactions.

WARNINGS AND PRECAUTIONS

Warnings

- If you are under the care of a Physician, consult with your Physician before using the TOP TENS™.
- The long-term effects of the TOP TENS™ are not known.
- Do not place the electrodes on or close to your heart.
- Do not place the electrodes around or close to your neck. Do not apply stimulation over 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 have an adverse effect on hearing or blood pressure.
- Do not apply stimulation 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 the electrodes on or around your head. The effects of stimulation of the brain are unknown.
- Do not use the electrodes over or close to sores.
- Do not place the electrodes on the front or sides of the neck, across or through the heart (one electrode on the front of the chest and one on the back), in the genital region, or on the head, because of the risk of stimulating inappropriate muscles and organs.
- Do not place the electrodes over any recent scars, broken or inflamed areas of infection or susceptibility to acne, thrombosis or other vascular problems (e.g. varicose veins), or any part of the body where feeling is limited.
- Do not place the electrodes over areas of injury or restricted movement (e.g. fractures or sprains).
- Do not use the TOP TENS™ while sleeping.
- Do not use if you feel numbness.
- Do not use the TOP TENS™ in or close to water.
- Do not use the electrodes over or close to cancerous lesions.
- Use the electrodes only on normal, healthy, clean and dry skin. Do not use the electrodes on open wounds or rashes, or over swollen, red, infected or inflamed skin.
- If you have ever had back surgery, consult your Physician before using the TOP TENS™.
- Electronic monitoring equipment (such as ECG and ECG alarms) may not operate properly when electrical stimulation is in use.
- You must position the electrodes and operate the TOP TENS™ ONLY as indicated in this manual.
- Avoid areas of injury or restricted movement (e.g. fractures or sprains).
- Avoid placing the pads over metal implants.
- Avoid using different size electrodes together, doing so can cause skin irritation or increased

stimulation intensity under the smaller electrode. Some programs may require the use of different sized electrodes for treatment.

- Do not use in the bath or shower, or in an environment of elevated humidity (e.g. sauna, hydrotherapy, etc).
- Operation in close proximity, such as 3 feet (1 meter), to shortwave or microwave therapy equipment may produce instability in the TOP TENS™ output and may shut the TOP TENS™ off.
- Do not use the TOP TENS™ in an environment where flammable or explosive fumes may exist.
- Patient should never operate potentially dangerous machinery such as power saws, automobiles, etc. during electrical stimulation.

Wait before using next until:

- At least 6 weeks after the birth of your baby (you must consult your physician before use).
- One month after an IUD contraceptive device (e.g. coil) has been fitted (you must consult your physician before use).
- At least 3 months after having a caesarean section (you must consult your physician before use).
- The heavy days of your period have finished, because vigorous abdominal exercise is not recommended during this time.

Precautions

- Read User Manual before using the TOP TENS™ for the first time.
- Keep this manual available whenever you use your TOP TENS™.
- The TOP TENS™ is intended for personal use on healthy adult muscle only.
- The safety of using the TOP TENS™ neuromuscular stimulation during pregnancy or birth has not been established.
- The effectiveness of the TOP TENS™ depends greatly on a person's individual physical condition. It may not always be effective for every user.
- Use caution when/if:
 - Sensory nerve damage is present by a loss of normal skin sensation.
 - Use caution prior to using the TOP TENS™ on patients suspected of having heart disease.
 - Use caution for patients with suspected or diagnosed epilepsy when using this device.
 - Use caution following recent surgical procedures when muscle contraction may disrupt the healing process.
 - Use caution when there is a tendency to hemorrhage, such as following acute trauma or fracture.

- A menstruating or pregnant uterus.
 - Patient experiences skin irritation due to electrical stimulation or the electrical conductive medium used, turn off the TOP TENS™ device to discontinue stimulation, remove the electrodes, and consult your physician. Irritation may be reduced by an alternative conductive medium or an alternative electrode placement. Isolated cases of skin irritation may occur at the site of electrode placement following long term application.
- Place electrodes in accordance with illustrations in the User Manual.
 - The TOP TENS™ should not be used while driving, operating machinery or during any activity in which involuntary muscle contractions may place the user at undue risk of injury.
 - Some users may experience skin irritation or hypersensitivity due to the electrical stimulation or the conductive medium.
 - Keep the TOP TENS™ out of the reach of children. If the patient is a child, make sure he/she is properly supervised during electrical stimulation.
 - Application of moderate heat (thermal wrap) to muscles as well as moistening skin prior to treatment improves treatment efficacy; use of cold packs on treated muscles after treatment is also recommended.
 - The TOP TENS™ should only be used with the leads, electrodes and accessories provided by the manufacturer.
 - The TOP TENS™ is not intended for medical use, for the treatment of any medical condition or for any permanent physical changes.
 - Contact an authorized dealer if your TOP TENS™ is not working correctly. Do not use in the meantime.
 - An effective session should not cause discomfort.
 - For first time users, muscle stimulation can be an unusual sensation. We recommend that you begin in a seated position with low stimulation intensity settings to familiarize yourself with the sensation before progressing to higher intensity settings.
 - The lead wires and electrodes must not be connected to any other objects.
 - Do not over exert yourself while using muscle stimulation. Any workout should be at a comfortable level for you.
 - Do not place electrodes over jewelry or body piercings.



Use Caution and consult your Physician before using TOP TENS™ if any of the following conditions apply to you :

- You have any serious illness or injury not mentioned in this guide.
- You have recently undergone a surgical procedure.

- You take insulin for diabetes.
- You use the TOP TENS™ as part of a rehabilitation program.
- If you have suspected or diagnosed heart problem.
- 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.
- During menstruation or during pregnancy.
- Some people may feel skin irritation or experience a very sensitive feeling in the skin due to electrical stimulation. If this occurs, stop using your TOP TENS™ and consult your physician.
- If skin under one of more electrodes 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 as 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 the TOP TENS™ if the stimulation feels unpleasant or does not provide pain relief.
- Keep your TOP TENS™ out of the reach of children.
- Use your TOP TENS™ only with the electrodes, lead wires, snap cables, and accessories recommended by the manufacturer.
- Do not use this TOP TENS™ when driving, operating machinery or when swimming.
- Before removing the electrodes, be sure to power off the TOP TENS™ to avoid unpleasant stimulation.

After strenuous exercises or exertion:

Always use lower intensity to avoid muscle fatigue.

Important :

- Do not use your TOP TENS™ unit at the same time as any other device, which transfers an electrical current into the body (e.g. another muscle stimulator).
- Cease using your unit if you are feeling light headed or faint. Consult your physician if this happens.
- Do not touch the electrodes or metal studs while the unit is switched on.
- Do not use the TOP TENS™ if you are wearing a belly button ring. Remove ring before session.
- Use the TOP TENS™ with only the leads and electrodes provided for use by the manufacturer

with your TOP TENS™. Any others may not be compatible with your unit and could degrade the minimum safety levels. Use only the electrode placements and stimulation settings prescribed by your Healthcare Practitioner.

- This TOP TENS™ is for external use only.

Note: If you are in any doubt about using TOP TENS™ for any reason, please consult your Healthcare Provider.

Electrode Precautions

- To reposition the electrodes during a session, always pause the program currently running, reposition the electrodes and then restart the program again.
- The electrodes are for single person use only.
- Do not immerse the electrodes into water.
- Do not apply solvents of any kind to the electrodes.
- Always ensure the unit is OFF before removing the electrodes.
- Apply the whole surface of the electrodes firmly to the skin. Do not use electrodes, which do not adhere properly to the skin.
- If your skin is red under the electrodes after a session, do not start another session in the same area until your redness has completely disappeared.

Adverse Reactions

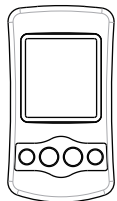
- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.
- You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face.
- You should stop using the TOP TENS™ and should consult with your Healthcare Provider if you experience adverse reactions from the TOP TENS™.

Conditions that may affect your TOP TENS™ system

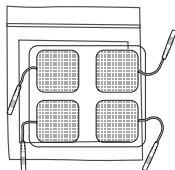
Since the TOP TENS™ is a battery-operated electronic system, its output performance and safety may be affected greatly in extreme humidity. Therefore, it is very important to keep the stimulator dry to ensure the safety and performance of the TOP TENS™.

PACKAGE CONTENTS

1. DT6030 TOP TENS™ Device
2. 1 pack of 4 Electrodes
3. 3 AAA batteries
4. 2 lead wires
5. Instruction Manual.
6. Quick Start Guide



TOP TENS™ device



4pcs of Electrodes



2 lead wires

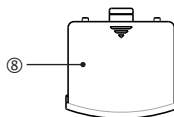
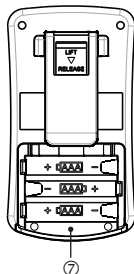
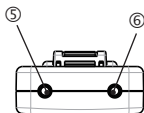
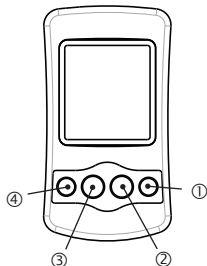


3 of AAA batteries



Instruction Manual

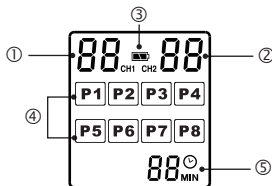
ABOUT THE TOP TENS™



1. On / + key: Power on / adjust / increase setting key
2. Off / - key: Power off / adjust / decrease setting key
3. Mode key: Therapy Mode (Program) / Timer selection Key
4. CH key: select CH1 / CH2
5. Connection Socket CH1
6. Connection Socket CH2
7. Batter compartment
8. Battery cover

The LCD Display:

1. Intensity level for CH1
2. Intensity level for CH2
3. Low battery indicator
4. Program number
5. Timer



STEP BY STEP OPERATION GUIDE FOR TREATMENT

Preparing the Skin for Treatment

Proper preparation of the skin covered by the electrodes allows more stimulation to reach targeted tissues, prolongs electrode life, and reduces the risk of skin irritation. After connecting the lead wire(s) to the stimulator, use the following steps to prepare your skin at the electrode placement sites:

1. Determine the placement sites for the electrodes.
2. Wash the area with mild soap and water (do not use alcohol). Rinse and dry thoroughly.
3. Trim excess body hair from the area with scissors (do not shave).
4. Optionally, apply skin prep to the area to form a protective barrier on your skin. Apply, let dry, and apply electrode as directed. This will both reduce the chance of skin irritation and extend the life of your electrodes.
5. When removing electrodes, always remove by pulling in the direction of hair growth.
6. It may be helpful to apply skin lotion on electrode placement area when not wearing electrodes.

Inserting the Batteries

Your device operates with 3 AAA batteries. Please install batteries with polarities as indicated on the TOP TENS™ unit. Make sure the battery strip is placed below the batteries.

CAUTION: Never force a battery into the battery compartment. A battery that does not fit can damage the stimulator. This device requires 3 AAA batteries, never attempt to use any other battery type.

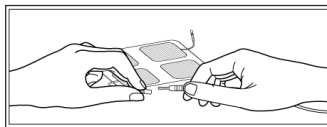
▲ Note : For important precautions regarding the batteries:

- Always use only 3x1.5V(AAA) batteries.
- Keep away from children.
- Do not recharge.
- Do not short-circuit.
- Do not throw into a fire.
- Please recycle. Do not dispose of old batteries with your household waste; dispose of them safely at your recycling center or at the business where the batteries were purchased.

Connecting the Lead Wires to the TOP TENS™

Hold the insulated portion of the electrode connector and push the plug end of the lead wire into the electrode connector. Repeat for all 4 electrodes. After connecting each electrode, plug the other end of the lead wire into the TOP TENS™.

Caution: The TOP TENS™ should be OFF before connecting the lead wire to the TOP TENS™.



Note: Use care when you plug and unplug the wires. Pulling on the lead wire instead of its insulated connector may cause wire breakage.

Caution: Never insert the plug of the lead wire into an AC power supply or other equipment not specified as safe for the lead wires.

Turning on the TOP TENS™

- Turn on TOP TENS™ device by pressing the On/+ button.

Setting Treatment Program, Time and Intensity Level

- Press the Mode button once to select treatment program, default P1 will flash on the screen
 - Press the On/+ (increase) or Off/- (decrease) button to scroll through treatment programs P1 thru P8 (see page 14 for treatment program details).
 - Press the Mode button to lock in the selected treatment program and to open up treatment time selection. Treatment program will stop blinking on the screen, and the default treatment time of 30 minutes will blink on the screen.
 - While treatment time is blinking press the On/+ (increase) or Off/- (decrease) button to scroll through treatment time in 5 minute increments from 5 to 60 minutes and C (continuous). Once you reach 60 and press the On/+ button one more time, C (continuous time) will appear.
 - Press mode button to lock in treatment time.
- Press the CH button to set the Channel (lead wire connection) Intensity. Channel 1 (left side of screen) is the set default and will be blinking.
- Press the On/+ (increase) or Off/- (decrease) button to adjust stimulation intensity for channel 1.
- Press the CH button again to set Channel 2 (lead wire connection) Intensity. Channel 2 (right side of

screen) will blink, while blinking press the On/+ (increase) or Off/- (decrease) button to adjust stimulation intensity for Channel 2. *If using only one channel, you can simply leave Channel 2 at zero.*

- Press CH again to lock in treatment intensity.

Note: You will feel intensity increase or decrease as you select the intensity level. You can use this as a guide to select a level that is most comfortable for you.

- Treatment will proceed and continue until either the timer runs down, or if in C (continuous time mode) until you manually power the device off.

Turning OFF the TOP TENS™

- You can terminate treatment at any time by:
 - Pressing the Mode button to reset the channels to “0” – this will not power off the device but allow you to change treatment options, or
 - By pressing and holding the Off/- button (approximately 10 seconds) until the screen shuts down – this will completely power off the device.
 - If any part of the device has a setting that is blinking on the screen, you need to lock in the setting by pressing either the Mode or CH buttons before the device will allow you to power off.

Special Notes:

- The TOP TENS device allows you approximately 30 seconds to make selections while the Channel Intensity is blinking and while the Treatment Time is blinking. If no selection is made, the treatment will operate under the default selection of channel 1 and 30 seconds.
- If you fail to press the Mode button to lock in a selection for the Channel Intensity and the Treatment Time after making your desired selection, the device will lock it in automatically after approximately 30 seconds.
- If you change the Therapy Selection (P1-P8) at any time during the therapy session, the intensity level will reset to “0” as shown on the screen, for your safety.
- The TOP TENS device is programmed to shut off automatically during the following situations:
 1. Program timer reaches zero, or
 2. If no treatment program has been set after approximately 60 seconds.

SPECIAL FEATURES

Treatment Time

The TOP TENS™ offers 12 preset times: 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60 minutes and C (continuous).

Count down minutes is shown on the display.

- The TOP TENS™ turns off automatically when the therapy time has elapsed.
- If you alter the program mode during your therapy, the treatment time will not restart, unless you reset the therapy time.

Automatic Shut off

- If no button is pushed for 60 seconds when in programming mode, the TOP TENS™ will automatically turn off.
- The TOP TENS™ automatically turns off when the time for your therapy session has elapsed.

Intensity Level set at “0”

For your safety, when the TOP TENS™ is in use and the MODE button is pushed, the intensity levels will change to “0”.

Low Battery Status Indicator

The low battery indicator will display whenever the battery is low. The batteries will need to be changed.

CARE AND MAINTENANCE

The TOP TENS™ unit

The TOP TENS™ may be wiped clean with a small amount of soapy water on a clean cloth. Do not submerge the TOP TENS™ in liquids or expose it to large amounts of water.

- Never use aggressive cleaning products or stiff brushes to clean the TOP TENS™.
- Remove the batteries before cleaning the TOP TENS™.
- Do not use the TOP TENS™ again until it is completely dry.
- Do not expose the TOP TENS™ to direct sunlight and protect it from dirt and moisture.

Lead Wires

- Disconnect the lead wires from the TOP TENS™ and electrodes.
- Do not pull on the lead wires, but on the connectors attached to the ends of the lead wires.
- Store the TOP TENS™ with the lead wires in a clean, dry place.

Electrodes

The electrodes are disposable and use an adhesive that will dry after prolonged usage or storage. Electrodes should be replaced when they lose their adhesive quality, or you sense a change in stimulation sensation.

If you are in doubt about the integrity of the electrodes, replacements can be ordered by your authorized TOP TENS™ dealer.

How to Store Your TOP TENS™

1. Store your TOP TENS™ at room temperature in a dry place, out of the reach of children.
2. If the TOP TENS™ will not be used for more than a week, remove the batteries from the TOP TENS™.

Trouble Shooting

Always check the TOP TENS™ and accessories before use to prevent damage and defects; these are some of the simple checks:

1. Make sure the battery has sufficient charge and is in proper condition.
2. Make sure the lead wires fit tightly into the connection sockets of the TOP TENS™. The table below shows some common defects. If you cannot remedy the defects as described, contact your TOP TENS™ unit provider if it is not possible to remedy in the manner described.

Defect	Cause	Remedy
The TOP TENS™ does not turn on	No battery or bad battery	Replace battery
The TOP TENS™ turns on and then off again	Battery not inserted properly	Insert battery again Replace battery
	Battery life expired	Replace battery
The TOP TENS™ turns on, but does not generate electric pulses	Lead wires faulty	Replace lead wires
	Lead wire not connected properly	Connect lead wire properly
	Treatment time has expired	Switch unit to the OFF position and switch back on.

Note: If there is any other problem, please contact your authorized TOP TENS™ distributor.

Technical Specifications

Channel : Dual, isolated between channels

Pulse Intensity : Adjustable 0 – 100mA peak into 500 Ω load each channel

Pulse Rate : 2 - 60Hz

Pulse Width : 156 – 260uS

Timer : 5-60 min (optional, 5-minute increments) and C (continuous)

Wave Form : Symmetrical Bi-Phasic square pulse

Power Source : 3 x AAA / 4.5 Volt batteries

*All electrical specifications are $\pm 20\%$ at 500 Ω load.

PROGRAM DETAILS

Program	Intensity Max.	Pulse Width	Pulse Rate	Mode
P1	100 mA	260uS	15 Hz	C (Constant)
P2	100 mA	260uS	60Hz	B (Burst)
P3	100 mA	260uS	60Hz	C (Constant)
P4	100 mA	260~156uS	2~60Hz	M (Modulated)
P5	100 mA	260~156uS	60Hz	M (Modulated)
P6	100 mA	260uS	7~60Hz	SDR
P7	100 mA	260~156uS	60Hz	SDW
P8	100 mA	P1~P7		Sequential

Warranty

This TOP TENS™ device carries a one-year warranty from the date of purchase.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alterations or disassembly by unauthorized individuals.

The warranty applies to the main device and necessary parts and labor relating thereto. Batteries, lead wires, electrodes, and other accessories are warranted to be free from defects in workmanship and materials at the time of delivery.

For warranty claims, please contact your authorized TOP TENS™ dealer.

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www.roscoemedical.com

Model No. WL-2407
IM-24-036 RevA12
FDA-2407