ROSCOE MEDICAL
Better Living™

InTENSity™ Twin Stim IV

INSTRUCTION MANUAL

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This manual is valid for the Twin Stim IV

This instruction manual is published by Roscoe Medical Inc.

Roscoe Medical Inc. reserves the right to improve and amend it at any time without prior notice. Amendments may however be published in new editions of this manual.

United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner

Conformity to safety standards

Roscoe Medical Inc. declares that the device complies with following normative documents:

IEC60601-1, IEC60601-1-2, I EC60601-2-10, IEC62366, IEC60601-1-11, ISO10993-5, ISO10993-10, ISO10993-1, ISO7010

Table of Contents

1. INTRODUCTION

1.1 General

The InTENSity Twin Stim IV is a portable electrotherapy device featuring two therapeutic modes: Transcutaneous Electrical Nerve Stimulator (TENS) and Neuromuscular Electrical Stimulation (NMES), which are used for pain relief and electrical muscle stimulation. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. The parameters of device are controlled by the buttons on the front panel. The intensity level is adjustable according to the needs of patients.

1.2 Medical Background

Explanation of pain

Pain is an unpleasant sensation that can serve a useful purpose by alerting us to a possible injury or disease. When the body is functioning normally, pain serves as a warning system that something is not right. Without pain a person would not know when to avoid danger or seek medical help. Pain becomes a problem when it continues after treatment has started or long after an injury is healed.

There are two types of pain:

Acute — Limited in duration. Examples include but are not limited to:

- Sprains
- Incisional pain
- Muscle strain

Chronic — Long-lasting, persistent pain that ceases to serve as a warning system and becomes a problem. Examples include but are not limited to:

- Low back pain
- Pinched Nerves
- Bursitis
- Joint Pain

The Twin Stim IV was developed to help relieve some types of chronic and acute pain.

How does TENS work?

There is nothing “magic” about Transcutaneous Electrical Nerve Stimulation (TENS). TENS is intended to help relieve pain. The TENS unit sends comfortable impulses through the skin to stimulate the nerve (or nerves) in the treatment area. In many cases, this stimulation will greatly reduce or eliminate the pain sensation the patient feels. Pain relief varies by individual patients, mode selected for therapy, and the type of pain. In many patients, the reduction or elimination of pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, pain is only modified while stimulation actually occurs. You may discuss this with your physician or therapist.

How NMES works

Neuromuscular Electrical Stimulation (NMES) is an internationally accepted and proven way of treating muscular injuries. It works by sending electronic pulses to the muscle needing treatment; this causes the muscle to exercise passively. This device is low frequency and in conjunction with the square wave pattern allows the stimulation to work directly on the muscle groups. This is being widely used in hospitals and sports clinics for the treatment of muscular injuries and for the re-education of paralyzed muscles, to prevent atrophy in affected muscles and improving muscle tone and blood circulation.

The goal of electrical muscle stimulation is to achieve contractions or vibrations in the muscles. Normal muscular activity is controlled by the central and peripheral nervous systems, which transmit electrical signals to the muscles. NMES works similarly but uses an external source (the stimulator) with electrodes attached to the skin for transmitting electrical pulses into the body. The pulses stimulate the nerves to send signals to a specifically targeted muscle, which reacts by contracting, just as it does with normal muscular activity

1.3 Indication for Use

Twin Stim IV Stimulator may be used for the following conditions:

1) Symptomatic relief of chronic intractable pain.
2) Post traumatic pain.
3) Post surgical pain.

For Neuromuscular Electrical Stimulation Therapeutic Mode (NMES):

1) Relaxation of muscle spasm.
2) Increase of blood flow circulation.
3) Prevention of disuse atrophy.
4) Muscle re-education.
5) Maintaining or increasing range of motion.
6) Immediate post-surgical stimulation of lower leg muscles to prevent venous thrombosis.

2. IMPORTANT SAFETY PRECAUTIONS AND WARNINGS

It is important that you read all the warning and precautions included in this manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the device.

SAFETY SYMBOLS USED IN THIS MANUAL	
DANGER	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device or other property.

DANGER

This stimulator must not be used in combination with the following medical devices:

- Internally transplanted electronic medical devices, such as a pacemaker.
- Electronic life support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs.

Using this stimulator with other electronic medical devices may cause erroneous operation of those devices.

WARNING

DO NOT USE THIS DEVICE UNDER THESE CONDITIONS

- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances in certain susceptible individuals.
- 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.
- Together with a life-supporting medical electronic device such as an artificial heart or lung or respirator.
- 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.
- On open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); or on top of, or in proximity to, cancerous lesions.
- Over areas of skin that lack normal sensation.
- On the opposite sides of your head since the effects of stimulation of the brain are unknown.

DO NOT USE ON THESE INDIVIDUALS

- Pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
- Children or infants, because the device has not been evaluated for pediatric use.
- Persons incapable of expressing their thoughts or intentions.

⚠ WARNING (CONTINUED)

DO NOT USE THIS DEVICE DURING THESE ACTIVITIES

- When in the bath or shower
- While sleeping

While driving, operating machinery, or during any activity in which electrical stimulation can put you at risk for injury.

PAIN MANAGEMENT WARNINGS

- If you have had medical or physical treatment for your pain, consult with your physician before using this device.
- If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician.
- The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this TENS Stimulator.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

- Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
- If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

NEVER APPLY THE PADS TO:

- The head or any area of the face.

- Any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

-
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

⚠ CAUTION

WARNINGS AND PRECAUTIONS REGARDING THE PADS

- United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner
- Do not bend or fold because the pad may not function properly. Place the pads onto the plastic film and then store into the sealed package when not in use.
- Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
- The pads are already pre-gelled and will adhere to your skin.
- To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic film provided.
- Place the pads at least 1 inch apart on your skin. The pads should never touch each other.
- Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

- Pads should not touch each other when placed onto your skin.
- Do not place on your spine or backbone.
- Pad should not touch any metal object, such as a belt buckle or necklace.
- Pads should not be placed simultaneously on the soles of both feet.
- Pads should not be placed simultaneously on the calves of both legs.
- Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
- Do not place or relocate the pads while the device is on.
- Always turn the power off before removing or changing the pad location.
- Do not leave pads attached to the skin after treatment.

⚠CAUTION (CONTINUED)

CAUTION WHILE USING THE STIMULATOR

- If the stimulator is not functioning properly or you feel discomfort, immediately stop using the device.
- Do not use for any other purpose except for what it is intended for.
- Do not insert the electrode plug into any place other than the jack on the main unit.
- Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
- Do not pull on the electrode cord during treatment.
- Do not use the device while wearing electronic devices such as watches as this may damage the device.
- Do not use near a cell phone as this may cause the stimulator to malfunction.
- Do not bend or pull the end of the cord.
- When pulling out the cord from the device, hold the plug and pull.
- Replace the cord when broken or damaged.
- Do not throw the batteries into a fire. The batteries may explode.
- Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
- The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
- Using pads that are too small or incorrectly applied, could result in discomfort or skin burns.

GENERAL PRECAUTIONS

- The long-term effects of electrical stimulation are unknown.
- Apply stimulation to only normal, intact, clean, dry, and healthy skin.
- TENS is not effective in treating the original source or cause of the pain, including headache.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices do not cure disease or injuries.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- Use caution if stimulation is applied over the menstruating or pregnant uterus.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- **Keep unit away from young children**. The unit contains small pieces that may be swallowed. The electrode cord can cause strangulation. Immediately contact your physician should any of these things occur.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
- **Keep unit out of the reach of young children**.

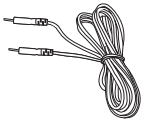
POSSIBLE ADVERSE REACTIONS

- Do not use to treat one region for extended periods of time (more than 30 minutes a session, up to 2 times/day) or muscles in that region may become exhausted and sore.
- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.
- You should stop using the device and consult with your physician if you experience adverse reactions from the device.

Note: Always use electrodes that are legally marked and sold in the United States under 510K guidelines.

3. PACKAGE CONTENTS

Twin Stim IV Unit



2 × Lead wires

4 × Electrode pads
(2" x 2")

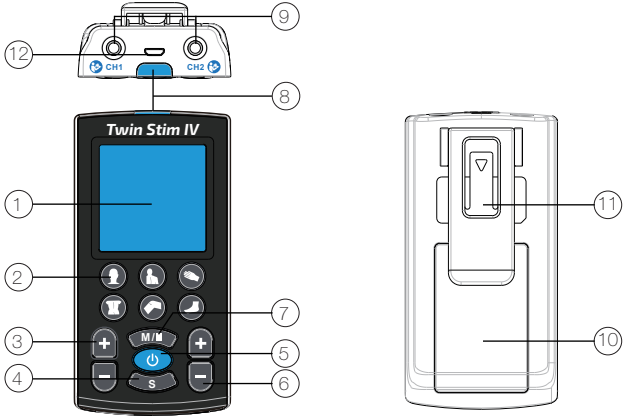
1 x Instruction Manual

1 × LI rechargeable
Battery Pack

1 × USB Cable
and Wall Charger

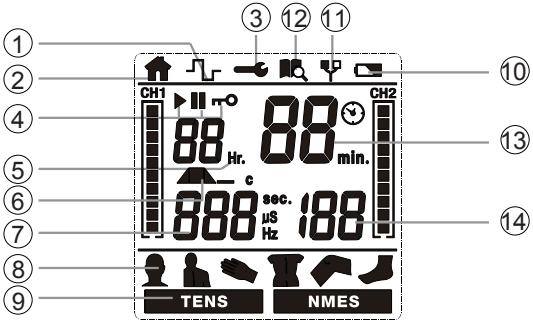
1 x Quick Start Guide

3.1 Front and Rear Panel



1) LCD Display: Operating state of the device
2) Body Part Buttons: Select body part or treatment program
3) Channel 1 Intensity Buttons: Increase or decrease the output intensity of channel 1.
4) Set button: Press this button to enter the setting status
5) Power Button: Press once to turn on. Press and hold for 3 seconds to turn off.
6) Channel 2 Intensity Buttons: Increase or decrease the output intensity of channel 2.
7) Pause/Mode Button: Press this button to change treatment modes (TENS or NMES). Press button again to pause active treatment status
8) LED: Charging indicator light.
9) Output Sockets: Lead wire output sockets
10) Battery compartment cover.
11) Belt Clip.
12) USB charging port.

3.2 LCD Display



1) Displays waveform mode.
2) Displays home screen
3) Displays set mode
4) Displays output state: start, pause, lock
5) Hour Indicator
6) Contraction, Relaxation & Ramp
7) Displays output intensity of channel 1 , pulse width and pulse rate
8) Displays therapeutic body part: hand, foot, shoulder, arm, leg and back
9) Displays therapeutic mode: TENS, NMES
10) Low-battery indicator
11) Load indicator
12) Indicates compliance meter mode
13) Displays the treatment time
14) Display output intensity of channel 2

4. SPECIFICATIONS

4.1 Technical Information

Channel	Dual, isolated between channels
Power Supply	3.7V LI rechargeable battery pack Charger output: 5.0V DC, 300mA (optional)
Operating Conditions	5°C to 40°C (41°F to 104°F) with a relative humidity of 30% – 75%,atmospheric pressure from 700 to 1,060 Hpa
Storage and Transport Conditions	-10°C to 55°C (14°F to 131°F) with a relative humidity of 10%-90%,atmospheric pressure from 700 to 1,060 Hpa
Dimensions	11.7 × 6 × 2.1 cm (L*W*H)
Weight	3.5 oz. (Without battery)
Electrode Detection Function	The amplitude level will be reset to 0mA when the amplitude level is 10mA or greater and an open circuit at either channel is detected.

Technical Specifications (TENS & NMES)

Waveform	TENS: Symmetrical bi-phase rectangular wave NMES: Biphasic rectangular
Pulse Amplitude	TENS/NMES: Adjustable, 0 to 100mA at 1,000 ohm Load each channel, 1mA/Step
Pulse Width	TENS: From 50 to 400us microseconds NMES: From 200 to 400us (microseconds)
Pulse Rate	TENS: From 1 to 150Hz NMES: From 1 to 100Hz
Treatment Time	5 to 90 minutes

Technical Specifications (NMES ONLY)

Contraction Time	5 to 30 seconds
Relaxation Time	5 to 60 seconds
Ramp Up/Down Time	1 to 9 seconds
Treatment Time	5 to 90 minutes

4.2 Program Parameters

TENS

Body Part	Program	Treatment Time	Pulse Rate	Pulse Width	Cycle Time
 Neck	P1	20 Min.	80 – 100Hz	100 – 120µs	10 Sec
	P2	20 Min.	4Hz	150 – 200µs	20 Sec
 Shoulder	P1	20 Min.	80 – 100Hz	100µs	10 Sec
	P2	20 Min.	10Hz	220 – 260µs	20 Sec
 Hand	P1	20 Min.	100Hz	100µs	Fixed
	P2	20 Min.	1 – 10Hz	200µs	20 Sec
 Low back	P1	20 Min.	80 – 100Hz	100µs	10 Sec
	P2	20 Min.	4Hz	200 – 260µs	20 Sec
 Knee	P1	20 Min.	120Hz	100 – 120µs	10 Sec
	P2	20 Min.	1 – 10Hz	150 – 200µs	20 Sec
 Foot	P1	20 Min.	80 – 120Hz	100 – 120µs	10 Sec
	P2	20 Min.	1 – 10Hz	200µs	20 Sec

Body Part	Program	Treatment Time	Pulse Rate	Pulse Width
All Therapeutic Parts	U1	Adjustable 5 – 90 mins	Adjustable 1 – 150 Hz	Adjustable 50 – 400µs

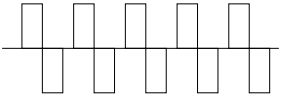
4.2 Program (Continued)

NMES

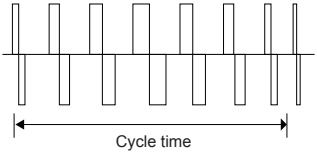
Body Part	Program	Treatment Time	Pulse Rate	Pulse Width	Contract Time	Relax Time	Ramp Up/Down
 **Neck**	P1	20 Min.	40Hz	300µs	12 Sec	20 Sec	2 Sec
	P2	20 Min.	50Hz	300µs	12 Sec	30 Sec	2 Sec
 **Shoulder**	P1	20 Min.	45Hz	300µs	12 Sec	20 Sec	2 Sec
	P2	20 Min.	55Hz	300µs	12 Sec	35 Sec	2 Sec
 **Hand**	P1	20 Min.	10Hz	300µs	12 Sec	20 Sec	2 Sec
	P2	20 Min.	5Hz	300µs	12 Sec	30 Sec	2 Sec
 **Low back**	P1	20 Min.	60Hz	300µs	12 Sec	20 Sec	2 Sec
	P2	20 Min.	70Hz	300µs	12 Sec	30 Sec	2 Sec
 **Knee**	P1	20 Min.	20Hz	300µs	12 Sec	30 Sec	2 Sec
	P2	20 Min.	25Hz	300µs	12 Sec	50 Sec	2 Sec
 **Foot**	P1	20 Min.	30Hz	300µs	12 Sec	20 Sec	2 Sec
	P2	20 Min.	5Hz	300µs	12 Sec	30 Sec	2 Sec
All Body Parts	U1	Min: 5 - 90, Step: 5min Default: 20Min	1 - 100Hz Step: 1Hz Default: 40Hz	200 - 400µs Step: 5 Default: 300uS	5 - 30s Step:1s Default: 12s	5 - 60s Step: 1s Default: 20s	1 - 9s Step: 1s Default: 2s

4.3 Waveform Information — TENS

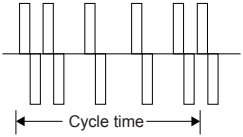
Continuous



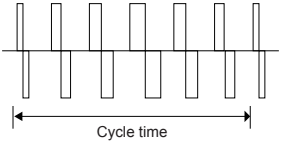
Pulse Width Modulation



Pulse Rate Modulation

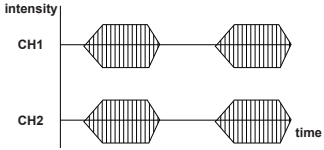


Modulation (Pulse rate and width modulation)



Waveform Information — NMES

Synchronous

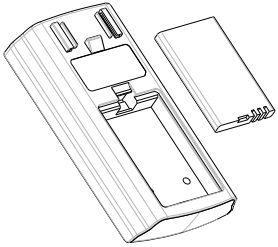


5. INSTRUCTIONS FOR USE

5.1 Battery

Installation of Battery

Push down on the belt clip to release it. Remove the battery cover and insert the battery, as shown on the diagram. Replace the battery cover and belt clip. For battery charging instructions, please see page 29.



Disposal of Battery

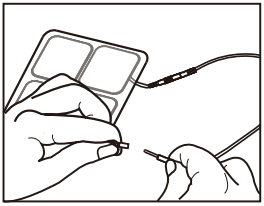
Depleted batteries do not belong in the household waste. Dispose of the batteries according to the your federal, state and local regulations. As a consumer, you are obligated by law to return depleted batteries.

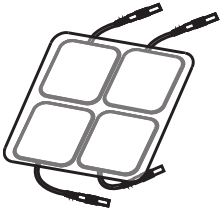
⚠ CAUTION

1) Keep the battery and the product out of the range of children.
2) Battery may not be dismantled, thrown into fire or short-circuited.
3) Protect battery from excess heat; Take the battery out of the product if the product is not used for a long period of time.
4) Always replace with the same type of battery.

5.2 Connecting Electrodes

Take the pads out of the sealed package; insert the pin of the lead wire into the electrodes pigtail. Make sure there is no bare metal exposed.



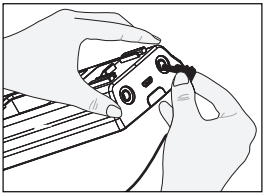


⚠ CAUTION

Always use electrodes with CE mark, or which are legally marketed in the US under 510(K) procedure.

5.3 Connecting Lead Wires

1) Before proceeding to this step, be sure the device is completely turned OFF.
2) Insert the lead wires into the output sockets located on the top of the device.
3) Holding the insulated portion of the connector, push the plug end of the wire into one of the sockets (see drawing); one or two sets of wires may be used.
4) This device has two output receptacles controlled by Channel 1 and Channel 2 at the top of the unit. You may choose to use one channel with one pair of lead wires or both channels with two pairs of lead wires. Using both channels gives the user the advantage of stimulating two different areas at the same time.



Note: If you use only one Channel, only plug in 1 lead wire at the top of the unit

5.4 Turn on The Device

Press the [⏻] button to turn on the device.

⚠ CAUTION

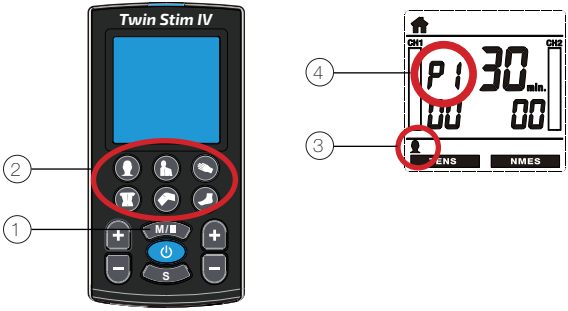
Before using the device for the first time, you are strongly advised to take careful note of the contraindications and safety measures detailed at the beginning of this manual (Safety information), as this powerful equipment is neither a toy nor a gadget!

5.5 Setting a New Program

There are 6 therapeutic body part buttons available — neck, shoulder, hand, low back, knee and foot. Each therapeutic part has 3 programs – P1, P2 and U1 for a total of 36 programs.

1. Press [M/⏸] button to select the treatment mode (TENS or NMES).

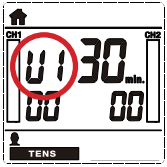
2. Select a body part on the device and press it.
3. The body part will display on the LCD screen.
4. Press the same button again to select one of the 3 programs (such as P1, P2 or U1).



Manual TENS Program — U1

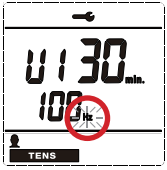
A. Select Body Part

Press the "**M/II"** button to choose TENS mode. Then select the body part which you want to treat. Press the body part button until the LCD displays program **"U1"**



B. Set Pulse Rate

Press [**S**] button to enter the pulse rate and the "Hz" will flash.
Press [**+**] or [**−**] button to adjust pulse rate.



C. Set Pulse Width

Press [**S**] button to enter the pulse width and the "μs" will flash. Then press [**+**] or [**−**] button to adjust the pulse width.

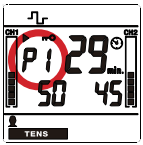
D. Set Treatment Time

Press [**S**] button to enter treatment time and the "min." will flash. Then press [**+**] or [**–**] button to adjust the treatment time.

Set Preset TENS Programs — P1 and P2

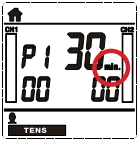
A. Select Body Part

Press the "**M/II"** button to choose TENS mode. Then select the body part which you want to treat. Press the body part button until the LCD displays program **"P1"** or **"P2"**



B. Set Treatment Time

Press [**S**] button to enter the treatment time and the "Min" will flash. Press [**+**] or [**–**] button to adjust treatment time. After you finished settings, press the [**S**] or [⏻]button to confirm, the device will go back to the home screen.



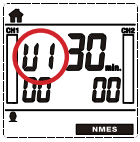
C. Start Treatment

Press [**CH1+**] or [**CH2+**] to increase the output intensity of channel 1 and/or channel 2. Press [**CH1–**] or [**CH2–**] to decrease the output intensity of channel 1 and/or channel 2.

Manual NMES Program — U1

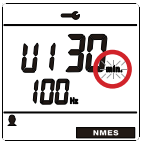
A. Select Body Part

Select the body part which you want to treat. Then press the body part button until the LCD displays program **"U1"** like the following:



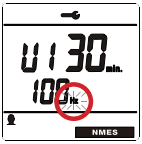
B. Set Treatment Time

Press [**S**] button to enter treatment time and the "min." will flash. Then press [**+**] or [**−**] button to adjust the treatment time.



C. Set Pulse Rate

Press [**S**] button to enter the pulse rate and the "Hz" will flash. Press [**+**] or [**−**] button to adjust pulse rate.



D. Set Pulse Width

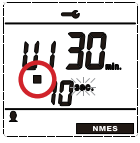
Press [**S**] button to enter the pulse width and the "μs" will flash. Then press [**+**] or [**−**] button to adjust the pulse width.

E. Set Ramp Up Time

Press [**S**] button to set the ramp up and down time and the “sec.” will flash and you will see the below image circled in red on the screen. Then press [**+**] or [**−**] button to adjust the treatment time.

F. Set Contraction Time

Press [**S**] button to set the contraction time and the “sec.” will flash along with the symbol circled in red below. Then press [**+**] or [**−**] button to adjust the time.



G. Set Relaxation Time

Press [**S**] button again to set the relaxation time and the “sec.” will flash along with the picture circled in red below. Then press [**+**] or [**−**] button to adjust the time.

After you have finished settings, press [⏻] button to confirm, the device will go back to the home screen.

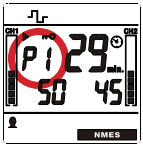
H. Start Treatment

Press [**CH1+**] or [**CH2+**] to increase the output intensity of channel 1 and/or channel 2. Press [**CH1–**] or [**CH2–**] to decrease the output intensity of channel 1 and/or channel 2.

Set Preset NMES Programs — P1 and P2

A. Select Body Part

Press the "**M/II"** button to choose NMES mode. Then select the body part which you want to treat. Press the body part button until the LCD displays program **"P1"** or **"P2"**



B. Set Treatment Time

Press [**S**] button to enter the treatment time and the "Min" will flash. Press [**+**] or [**–**] button to adjust treatment time. After you finished settings, press the [**S**] or [⏻]button to confirm, the device will go back to the home screen.

C. Start Treatment

Press [**CH1+**] or [**CH2+**] to increase the output intensity of channel 1 and/or channel 2. Press [**CH1–**] or [**CH2–**] to decrease the output intensity of channel 1 and/or channel 2.

⚠CAUTION

1) If the electrodes are not placed firmly on skin or the device has not connected with the electrodes or lead wires securely, and the output intensity level is equal to or greater than 10mA, the intensity will stop automatically.
2) If the stimulation levels become uncomfortable, reduce the intensity to a comfortable level. Contact your medical practitioner if the problems persist.

D. Pause or Stop Treatment

If there is an immediate need to pause treatment, press the [M/**II**] button and the "**II**" will display on the LCD. Press it again to continue treatment or press [⏻] button to stop treatment and the device will return to the home screen.

5.7 Turn OFF Device

Press and hold [⏻] button until the device turns off.

⚠CAUTION

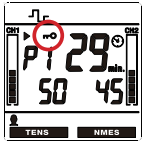
If there is no operation in the panel for 3 minutes in the standby status, the device will shut off automatically and you will hear a beep sound.

5.10 Other Important Functions

Safety Lock Feature

The lock function automatically activates after there is no operation in the panel for 20 seconds while in treatment status. The indicator "⚷" will display on the LCD .

This is a safety feature to prevent accidental changes to your settings and to prevent accidentally increasing the output intensity level. Press [**CH1–**] or [**CH2–**] button to unlock.



Low Battery Indicator

When the low power indicator "  " displays on the LCD, stop the device and charge the battery.

Charging the Battery

NOTE: Battery comes pre-charged.
Proceed as follows to recharge the battery:

- This device cannot be used while charging.
- Make sure that the device has been switched off.
- Make sure that the device is no longer connected to the patient (the output cables and electrodes must be disconnected).
- Connect the USB cable to the charging port on the top of device.
- Connect the USB cable to the wall outlet or USB port.
- When the device is charging, the indicator light will be red.
- It could take up to 6 hours to reach a full charge.
- When charging is completed, the indicator light will be green.

After the battery has been recharged, disconnect the cable from the wall outlet or USB port and the device is ready to be used again.

The life of a rechargeable battery depends on the number of recharging/ rundown cycles it undergoes and how these cycles are performed. The following suggestions will help prolong the life of the battery:

- Whenever the device is not used frequently, charge the battery once a month.
- For longer battery life, discharge the battery as much as possible.

⚠ CAUTION

1) Please use the standard charger provided by the manufacturer or agent.
2) **Do not use the device for treatment when in charging status as it will not work. When you are using the device, never connect it to the charger. If you do, the device will turn off automatically as a safety precaution and you will not be able to turn it back on until you disconnect the charger from the device.**
3) When charging is complete, you are strongly advised to disconnect the charger

5.9 Patient Compliance Meter

You can store 60 sets of treatment records and a total treatment time of up to 100 hours on this device.

A. Check and Delete Individual Records

In standby, press [M/**II**] button and hold for 3 seconds to enter the compliance meter records. The LCD will show the number of records and treatment time (as shown in the below picture). Press [**+**] or [**−**] buttons to check each record. To delete a record, press [**S**] button and hold for 3 seconds.

B. Check and Delete Accumulative Records

Individual records menu, press [**II**] button to switch to accumulative records menu. Press [**S**] button holding for 3 seconds and all of records will be deleted followed by a beeping sound.

⚠CAUTION

The records will be permanently deleted and can be not restored if you follow the delete records method mentioned above.

6. CLEANING AND STORAGE

6.1 Cleaning the Unit

1) Turn unit off and disconnect the lead wires from the unit.
2) Clean the device after use with a soft, slightly moistened cloth and wipe gently.
   - Do not use chemicals (like thinner, benzene).
   - Do not let water get into the internal area.

Note:

➢ This device and accessories (including the electrodes) do not require sterilization.

6.2 Cleaning the Electrode Pads

1) Turn the power off and remove the lead wires from the electrodes.
2) Wash the electrodes when the adhesive surface becomes dirty and/or the electrodes are difficult to attach.
   - To “wash” the pads, place a small drop of water on your clean fingertip and rub the water across the entire gel part. Place the adhesive part face up and let it air dry until the water is absorbed and has been reconstituted. Do not wipe with a tissue paper or cloth. If the electrode still does not stick properly, replace them with new electrodes.

⚠ CAUTION

1) The life of electrodes may vary by the frequency of washing, skin condition, and storage state.
2) If the electrodes no longer stick to your skin or the electrodes are broken, you should replace new electrodes.
3) Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
4) Do not turn on the device when the electrodes are not positioned on the body.
5) Never remove the self-adhesive electrodes from the skin while the device is still turned on.
6) If replacement electrodes are necessary, use only electrodes that are the same size (2" x 2") as the electrodes provided with the Twin Stim IV.
7) Use of larger electrodes may reduce the effect of the stimulation. Use of electrodes that are much smaller than the electrodes provided with the Twin Stim IV may increase the chance of skin irritation or electrode burns occurring under the electrodes.
8) Always use electrodes that have been cleared for marketing in the USA by the FDA.

6.3 Storing The Electrode Pads and Lead Wires

1) Turn the device off and remove the lead wires from the unit.
2) Remove the electrodes from your body and disconnect the lead wires from the electrodes.
3) Place the electrodes onto the plastic film and then store into the sealed package.
4) Wrap the lead wires and store into the sealed package.

6.4 Storing the Unit

1) Place the unit, electrodes, lead wires and manual back into the carrying case. Store the box in a cool, dry place, -10ºC ~ 55ºC; 10% ~ 90% relative humidity.
2) Do not keep in places that can be easily reached by children
3) When not in use for a long period, remove the battery before storage.

7. TROUBLESHOOTING

Problem	Possible Causes	Possible Solution
The unit cannot power on	Are the batteries exhausted?	Charge or replace the batteries.
	Are the batteries installed correctly?	Insert the batteries observing polarity.
Stimulation weak or cannot feel any stimulation	Electrodes dried out or contaminated	Replace with new electrodes
	Electrodes are not securely attached to the skin.	Reconnect the electrodes
	Lead wires Old/worn/damaged	Replace with new lead wires
Stimulation is uncomfortable	Intensity is too high	Decrease intensity.
	Electrodes are too close together	Reposition the electrodes at least 1-1⁄2" apart.
	Electrode active area size is too small.	Replace electrodes with ones that have an active area no less than 25.0cm^2 (5cm*5cm).
	May not be operating the device according to the manual.	Please check the manual before use
Intermittent output	Lead wires	Verify connection is secure.
		Turn down the intensity.
		Rotate lead wires in socket 90°. If still intermittent, replace lead wire.
		If still intermittent after replacing lead wire, a component may have failed. Call the repair department.

7. TROUBLESHOOTING (Continued)

Problem	Possible Causes	Possible Solution
Stimulation is ineffective.	Improper electrode placement	Reposition the electrodes at least 1-1⁄2" apart.
	Unknown	Contact clinician.
The skin becomes red and/or you feel a stabbing pain	Using the electrodes on the same site every time.	Re-position the electrodes. If at any time you feel pain or discomfort stop use immediately.
	The electrodes aren't stuck onto the skin properly	Ensure the electrodes are stuck securely on the skin.
	The electrodes are dirty.	Clean the electrodes according to description in this manual or replace with new electrodes.
	The surface of the electrode was scratched.	Replace with a new electrode.
Output current stops during therapy	The electrodes come off the skin.	Turn off the device and place the electrodes again.
	The lead wires are disconnected	Turn off the device and reconnect the lead wires.
	The power of the batteries has been exhausted.	Charge or replace the batteries.
Li rechargeable battery pack doesn't last or life is short	Brand new or stored batteries	This is normal operation. Please charge and use in device. You must do this 3 – 5 times before full capacity is reached.
	Used Li rechargeable battery has reached end of life	Charge the battery. If this does not work, replace the battery.

8. 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. You are under legal obligation to dispose of batteries correctly.

Please dispose of the device in accordance with the legal obligation.

9. GLOSSARY OF SYMBOLS

Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.

Type BF Applied Part

Please refer to instruction manual because of the higher levels of output.

10. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Information for accompanying documents in the scope of IEC60601-1-2:2007

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect 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 (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured for Roscoe Medical Inc. conform to this EN60601-1-2:2007 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by Roscoe Medical, with the exception of cables sold by Roscoe Medical as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

Guidance and manufacturer's declaration — electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF emissions CISPR 11	Group 1	The device 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 CISPR11	Class B	The device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance And Manufacturer's Declaration — Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	**EC 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	Not applicable	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4- 11	Not applicable	Not applicable	Not applicable
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance And Manufacturer's Declaration — Electromagnetic Immunity (Continued)			
Immunity Test	**EC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment — Guidance**
Conducted RF IEC 61000-4-6	Not applicable		Portable and mobile RF communications equipment should be used no closer to any part of the Electrical Stimulator including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to he 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, (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with he following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Guidance And Manufacturer's Declaration — Electromagnetic Immunity (Continued)
Note1: At 80 MHz and 800 MHz, the higher frequency range applies. Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 site survey should be considered. If the measured field strength in the location in which the Electrical Stimulator are used exceeds the applicable RF compliance level above, the Electrical Stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Electrical Stimulator. b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the Electrical Stimulator

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

Output Power of Transmitter in Watt	Separation distance according to frequency of transmitter in meter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.78
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 estimated using 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.

Note: At 80MHz and 800MHz, the separation distance for the higher pole frequency range applies

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Note: EMC tests conducted including attached electrode cord of 1.5 m length.

11. WARRANTY

Please contact your dealer or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

1) The warranty period for device is one year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2) Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.
3) The following is excluded under the warranty:
   - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
   - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
   - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
   - Accessories which are subject to normal wear and tear.
4) Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

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