PRESCRIBING INFORMATION

FOREWORD



Read this manual carefully before using your StimTec NEO unit.

The manufacturer strongly recommends carefully reading the "Warnings and Cautions", and subsequent chapters of this manual.

WARNINGS AND CAUTIONS

Prescription labeling:

Federal law restricts this device to sale or use by or on the order of a practitioner appropriately licensed by the state or province.

Contraindications:

- Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
- Do not use this device on patients whose pain syndromes are undiagnosed.

WARNINGS

 Do not apply stimulation over the patient's neck or mouth 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.

- Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
- 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).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- 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.
- 6. Do not apply stimulation when the patient is in the bath or shower.
- 7. Do not apply stimulation while the patient is sleeping.
- Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.
- Consult with the patient's physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
- 10. Apply stimulation only to normal, intact, clean, healthy skin.

- TENS is not effective for pain of central origin, including headache.
- TENS is not a substitute for pain medications and other pain management therapies.
- 3. TENS devices have no curative value.
- 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.
- 6. The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- 8. The safety of electrical stimulation during pregnancy has not been established.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- 11. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.

- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture.
- Use caution following recent surgical procedures when stimulation may disrupt the patient's 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 with less than normal sensitivity.
- 16. Keep this device out of the reach of children.
- 17. Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
- 18. Use this device only under the continued supervision of a Professional Healthcare Provider.

ADVERSE REACTIONS

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

GENERAL WARNINGS

- 1. Do not immerse any part of the unit in water.
- 2. Do not place the unit close to excessive heat.
- Do not use any electrodes which are less than 50mm X 50mm.
- 4. Do not use the unit while asleep.
- Keep the unit away from sources of high magnetic fields such as TV'S, microwave ovens, and hi-fi speakers, as these may affect the LCD screen.
- 6. Environmental Condition:

Operating Temperature: +5° C to +40° C Operating Humidity: 15% RH to 90% RH Operating Atmospheric Pressure: 700 hPa to 1060 hPa Storage/Transport Temperature: -10° C to +60° C Storage/Transport Humidity: 15% to 75% R.H Storage/Transport Atmospheric Pressure: 700 hPa to 1060 hPa

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OPERATING INSTRUCTIONS FOR HEALTHCARE PROVIDER

INTENDED USE

The StimTec NEO combines the treatment capabilities of a TENS device, an EMS or NMES device, a MIC stimulator, and an IFT stimulator all in one unit.

TENS stands for Transcutaneous Electrical Nerve Stimulation. The TENS settings are used to provide symptomatic pain relief for chronic, acute or post-operative pain.

EMS stands for Electrical Neuromuscular Stimulation. The EMS settings are used to provide a muscular training for localized regeneration and muscular hypertrophy.

MIC stands for MicroCurrent Stimulation. The MIC settings are used to provide symptomatic pain relief for chronic, acute or post-operative pain.

IFT stands for Interferential Stimulation. The IFT settings are indicated for symptomatic relief of chronic intractable pain.

How does TENS/EMS/MIC/IFT work?

For the TENS treatment:

Transcutaneous Electrical Nerve Stimulation (TENS) is believed to work by stimulating your body's own natural defenses against pain. The unit produces a gentle stimulus that is communicated through electrodes normally placed over the area of pain. This stimulus helps the body to produce natural pain relievers called endorphins.

The correct positioning of the electrodes is important and we recommend correct placement through

experimentation. Some people feel immediate benefit from EMS/TENS, however some may only achieve benefit after repeated treatment sessions and over an extended period of time.

For EMS treatment:

Electrical Neuromuscular Stimulation (EMS) is believed to work by stimulating the muscles with electrical impulses. When the muscle receives impulses, it contracts as if the brain has sent the signal itself. As the pulse strength increases, the muscle flexes as in physical exercise. Then when the pulse ceases, the muscle relaxes and the cycle is repeated.

For MIC treatment:

MicroCurrent Stimulation (MIC) is a type of therapy where very low current is sent into the cells of the body. MIC is a very faint current that is so small it is measured in millionths of an amp (Microamps). Human cells generate a current that is in the micro amp range which is why some can't feel it – the current is so low it doesn't stimulate the sensory nerves.

MIC is a physiological electric modality that increases ATP (energy) production in the cells of your body. This dramatically increases the tissue's healing rate. The immediate response to the correct MIC frequency suggests that other mechanisms are involved as well. The exact effects or changes in the tissue can be noticeable; scars can suddenly soften; trigger points often become less painful when the "correct" frequency is applied. In many situations the changes can be long lasting and even permanent in some cases.

For IFT treatment:

Interferential Stimulation (IFT) is an anti-inflammatory based treatment modality characterized by two

alternating-current sine waves or square waves of differing frequencies that "work" together to produce an IFT current that is also known as a beat pulse or alternating modulation frequency. One of the two currents is usually held at 4,000 Hz, and the other can be held constant or varied over a range of 4,004 to 4,160 Hz. Because of the interference between the two frequencies. IFT waves create low impedance when crossing the skin into soft tissues. The IFT currents can stimulate sensory. motor, and pain fibers. These large impulse fibers interfere with the transmission of pain messages at the spinal cord level. This deep tissue penetration stimulates parasympathetic nerve fibers for increased blood flow and edema reduction. It utilizes the low electric-current to stimulate muscle nerves to achieve the symptomatic relief of chronic intractable pain, post-traumatic pain, and post-surgical pain.

INSTRUCTIONS FOR USE

Your StimTec NEO has been designed to be simple and easy to use.

CONTENT IN THE PACK

Your StimTec NEO pack should contain the following:

- 1 × StimTec NEO Unit
- 2 × Leads
- 4 × Self Adhesive Electrodes with Connectors (Size: 50mm × 50mm)
- 1 × AC Power adapter and USB cord
- 1 × User Manual

HOW TO ASSEMBLE YOUR UNIT

Assembly of the StimTec NEO Unit is very simple and requires only four steps.

STEP 1 LEADS

If only using one lead, insert into one jack. If using two leads, insert into both jacks.



- A: Insert the lead wires
- **B**: Turn the plug on the lead wire 90° to lock it between the main body and handle of the unit. This prevents accidental disconnection during treatment.

STEP 2 ELECTRODES

Remove electrodes from the bag and connect to the leads.







STEP 3 PLACEMENT OF ELECTRODES

Ensure wherever you intend to place the electrodes, the skin is clean and thoroughly dry. Remove the electrodes from the clear plastic shield and position on your body as required.

Please note: Attempting to increase intensity without electrodes connected and placed on the treatment area is not possible. The symbol on the display will notify you if this occurs.





STEP 4 READING

Read "Operation of the StimTec NEO Unit" on page 15, and decide how to use the unit for the treatment.

NOTE: AFTER USE

Always ensure that the unit is switched OFF before removing the electrodes. After use, return the electrodes to the clear plastic shields. There is no need to separate the lead wires from the electrodes.





Life of the electrodes: When the electrodes initially lose their adhesive quality, it is possible to reactivate their adhesiveness by applying a fine spray of water. Replace the electrodes when they lose their adhesive quality in order not to affect the efficiency of the unit.

CHARGING THE BATTERY

The StimTec NEO is powered by a built-in rechargeable polymer battery or directly from the power adaptor. Separate power adaptor is included in the kit.

When the battery is running low, the battery symbol on the screen is empty and keep flashing. It is time to charge the battery. Turn off the unit and connect with the adaptor to start charging.

Please make sure the unit is off during charging. Because when the unit is on, it would recognize to operate with the power adaptor directly, the bulit-in battery would be disconnected accordingly and could not be charged.

When charging is in progress, the battery indicator bar cycles from zero to the max. When the battery charging has completed, the bar stops cycling and remains at maximum to indicate full capacity. Remove the adapter from the device when charging is completed.

NOTE

- 1. When the battery is running low, it has to be charged with the power adaptor.
- 2. Use only the provided power supply adapter that certified to IEC 60601-1 and IEC 60601-1-11.
- 3. Only factory provided cords are approved for use.



USE OF OTHER ACCESSORIES OR OTHTER TYPE OF CHARGER COULD BE HAZARDOUS

OPERATION OF THE STIMTEC NEO UNIT

StimTec NEO Unit is easy to operate using the keys shown in the following diagram.



WHAT DOES EACH KEY DO

▲ This key switches the unit on or off. Press once and the unit is on, the LCD display located at the front of the unit will light up, there will be no feeling from either lead at this point as the intensity always starts at zero. Press this key again and the unit will switch off.

(Frog) There are four stimulation types available with the StimTec NEO (TENS, EMS, MicroCurrent and Interferential stimulation).

Press and hold the "Prog" key at least 3 seconds, to switch between TENS – EMS – MICRO – IFT. The symbol "TENS", "EMS", "MICRO" and "IFT" will display on the LCD accordingly.

Once the stimulation type is selected, press the "Prog" key to select the related programs.

There are a total of 40 programs available:

For TENS treatment: Program 0-13 --- TENS Preset programs Program 14-21 --- TENS Manual programs

For EMS treatment: Program 22-31 --- EMS Preset programs Program 32, 33 --- EMS Manual programs

In EMS preset modes (Prog 22- Prog 31) the treatment status symbols below will be displayed.

	WARM-UP	•	FORCE 1
A	AEROBIC EXERCISE	¥.	FORCE 2
X	TONING	R	FAST FORCE
え	HARDENING	7	EXPLOSIVE FORCE
ħ	RESISTING FORCE		PROGRESSIVE RECUPERATION

For MIC treatment: Program 34 --- Micro Preset programs Program 35 --- Micro Manual programs

For IFT treatment: Program 36-39 --- IFT Manual program

(NENU) Press this key to select the following parameters one by one:

TENS Preset Mode(P0-P13) : Treatment Timer (min) TENS Manual Mode(P14-P21) : FREQUENCY (Hz) PULSE WIDTH (us) Waveform Treatment Timer (min) EMS Manual Mode(P32-P33) : FREQUENCY (Hz) PULSE WIDTH (µs) Waveform Treatment Timer (min) SYNCHRONOUS/ALTERNATING ON TIME (sec) OFF TIME (sec) RAMP UP TIME (sec) RAMP DOWN TIME (sec) MicroCurrent Mode : FREQUENCY (Hz) (P35) Treatment Timer (min) (P34,P35) IFT Mode (P36-P39) : FREQUENCY (Hz)

Treatment Timer (min)

 (\mathbf{P})

Press these keys to increase or decrease the value of the parameter, which has been selected by MENU key.



Press these keys to adjust the intensity of channel 1 and channel 2. Left side is for channel 1; right side is for channel 2.



Pause key: Press this key to make the unit pause; to continue treatment, press and hold down this key again.

For TENS preset modes (Prog 2- Prog 13), if a preset mode is working, press this key to skip a phase (sub-programs (A) (B) (C)). For EMS preset and manual modes (Prog 22- Prog 33), if a preset mode is working, press this key to choose the treatment area.

Press and hold this key for at least 3 seconds to LOCK or UNLOCK parameters. When the unit is locked, only intensity and treatment timer can be adjusted. The symbol displayed on the LCD screen indicates that the unit is locked.

Press this key to enable or disable the backlight of the device. When the backlight is enabling, each time when a key is pressed, the backlight is lighted and last 8 seconds.

SPECIFICATIONS			
Model:	StimTec NEO		
Channel	Dual, isolated		
TENS:			
Intensity	0-100mA zero to peak at 500ohm load		
Frequency	1-150 Hz		
Pulse width	50, 60, 70, 80, 90, 100, 110, 120, 130,		
	140, 150, 160, 170, 180, 190, 200, 210,		
	220, 230, 240, 250µs		
Waveform	Symmetrical bi-phase rectangular,		
	Asymmetrical bi-phase rectangular,		
	Mono-phase rectangular		
Treatment timer	Continuous, 15, 30, 45, 60, 90min		

The PRESET program apply a sequence of 3 sub-programs (A) (B) (C), optimized to treat the specific pain situation. The characters (A), (B) or (C) will flash, showing the phase in use or will be ON to show the completed phase.

Mode Constant A – Both Pulse Rate and Pulse Width are adjustable. Default values are PR=3Hz and PW=250µs characterized by a decontracturating effect. Use this program if you want to relax the painful area. The stimulation level must be set to produce a gentle muscular contraction.

Mode Constant B – Both Pulse Rate and Pulse Width are adjustable. Default values are PR=10Hz and PW=150µs characterized by an endorphins stimulating effect. Use this program if you want produce endorphins at the painful area. The stimulation may reach the muscular contraction level. If the Pulse Rate will be increased, the stimulation level must be set to avoid the muscular contraction.

Mode Constant C – Both Pulse Rate and Pulse Width are adjustable. Default values are PR=70Hz and PW=50µs characterized by an endorphins stimulating effect through the Gate-control mechanism. Use this program in case of ACUTE PAIN. The stimulation level must be set to avoid the muscular contraction.

Mode MODulation SW (A) – Pulse Rate SWeep modulation. Pulse Rate is automatically modulated within F1=50Hz and F2=80Hz (adjustable); each frequency step will last 1 sec. F2 can be changed only if the intensity level of both channels are set to 0. The Pulse Width is 200µs (adjustable from 50µS to 250µS).

Mode MODulation 2F (B) – Pulse Rate Dual Frequencies modulation. Pulse Rate is automatically changed every 5 seconds, between F1=70Hz (adjustable) and F2=5Hz. F1 can be changed only if the intensity level of both channels are set to 0. The Pulse Width is 50µs (adjustable from 50µS to 250µS).

Mode Burst A – 3 second Burst sequence = 1s on, 2s off. Both Pulse Rate and Pulse Width are adjustable. Default values are PR=30Hz and PW=250 μ s. The stimulation level must be set to produce a gentle muscular contraction.

Mode Burst B – 1.5 second Burst sequence = 0.5s on, 1s off. Both Pulse Rate and Pulse Width are adjustable. Default values are PR=50Hz and PW=200 μ s. The stimulation level must be set to produce a gentle muscular contraction. Mode Burst C - 0.75 second Burst sequence = 0.25s on, 0.5s off. Both Pulse Rate and Pulse Width are adjustable. Default values are PR=100Hz and PW=150µs. The stimulation level must be set to produce a gentle muscular contraction.

EMS:	
Intensity	0-100mA zero to peak at 500ohm load
Frequency	1-120 Hz
Pulse width	Positive phase: 50-400µs, in steps of
	50µs
Waveform	Symmetrical Bi-Phasic rectangular,
	Alternated Bi-Phasic rectangular
Ramp up time	0-8s in steps of 1s
Ramp down time	0-8s in steps of 1s
On time	1-60s in steps of 1s
Off time	0-60s in steps of 1s
Treatment timer	Continuous, 10, 20, 30, 45, 60, 90min

Program 32&33 (manual) – When using <u>ALTERNATIING</u> <u>Frequency</u>, ensure that the "Ramp Up Time", "On Time", and "Ramp Down Time" equals "Off Time".

Ramp Up + On Time + Ramp Down = Off Time



The N will appear on your screen if this formula is not followed in EMS manual mode.

Micro Current:

Frequency	94Hz fixed (A)/ 0.5, 8, 80Hz(B)		
Pulse width	250uS fixed (A), 2ms fixed (B)		
Wave form	Mono-Phase rectangular,		
	Symmetrical Bi-Phasic rectangular		
Treatment timer	Continuous, 10, 20, 30, 45, 60, 90min		

Interferential (IFT):

Carrier Frequency4000Hz fixed (CH1)Modulating Frequency4004-4160Hz,
in steps of 4Hz (CH2)Pulse width125µsWave formSymmetrical balanced Sine waveTreatment timerContinuous, 10, 20, 30, 45, 60,
90min

Programs:

1) P0-P21 TENS programs

Program 0-13 --- TENS Preset programs Program 14-21 --- TENS Manual programs 2) P22-P33: EMS Modes Program 22-31 --- EMS Preset programs Program 32,33 --- EMS Manual programs 3) P34-P35: MicroCurrent Modes Program 34 --- Micro Preset programs Program 35 --- Micro Manual programs 4) P36-P39: Interferential(IFT) Modes Program 36-39 --- IFT Manual program

OTHER FEATURES

- When the unit is turned on, if any of the keys are not pressed within 5 minutes, it will automatically shut off.
- When the treatment timer has been set, it begins to count down one minute by one minute and is displayed on the LCD. Once it counts down to zero, the device automatically shuts off.
- 3. The treatment time will be accumulatively recorded when the output level is above zero, by pressing "CH1▼" key and "Prog" key for 3 seconds, the accumulative treatment time in minutes can be displayed, or return back to the previous normal display in toggle; by pressing "CH2▼" key and "Prog" key for 3 seconds will clear the treatment time to zero.
- 4. When the program changes, the output level will go down to zero immediately.
- When the unit is turned on, it will automatically enter the mode that the unit had worked in before the unit was turned off.
- When the battery is low, the battery icon will flash indicating that the batteries should be recharged.
- When one or both of the electrodes are not placed firmly on the skin, the output level goes immediately to zero.

Waveform Information

There are 5 types of waveforms:

(1). Symmetrical Bi-Phasic rectangular waveform

Amplitude



(2). Asymmetrical Bi-Phasic rectangular waveform

Amplitude



(3). Mono-Phasic waveform Amplitude



(4). Alternated Bi-Phasic rectangular waveform Amplitude



(5). Symmetrical balanced Sine waveform Amplitude



ELECTRODES PLACEMENT

Please study the body maps in this guide, which illustrate placement of the electrodes depending on your symptoms.

Note: 1B =Channel 1 black / 1R =Channel 1 red

2B =Channel 2 black / 2R =Channel 2 red

Examples of electrodes placement for TENS: 0 & 1 – HANDS & FEET

These modes require the use of special electrode garments not included. These program modes should only be used under the direct care and supervision of your Professional Healthcare Provider.

Note to Professional Healthcare Provider: Should you choose to source electrode garments and prescribe these treatment modes, please ensure that the garment selected is designed to function in accordance with the following instructions for use, and with the output specifications of this device.

Using a single channel, connect one lead to the garment, and connect the other lead to an electrode which is placed on the lower arm or lower leg.



2 – NECK PAIN

Using both leads, place the electrodes at the back of the neck and over the top of your shoulders.

Note: Do not place electrodes on the side or front of the neck.



3 – TORTICOLLIS

Using a single channel, place the electrodes, over the area of maximum pain.



4 - LOW BACK PAIN

Using both leads, place electrodes on either side of the spine, crossing the channels, at the site of pain.



5 – SCIATICA

Using both leads, take the first lead and place the electrode with the black adapter on your lower back on one side of your spine, and the second electrode with the red adapter at the top of the back of your leg. With the second lead, place the other two electrodes lower down as illustrated.



6 - EPICONDYLITIS

Using both leads, place electrodes on either side of the elbow.



7 - WRIST PAIN

Using a single channel, place the electrodes over the area of maximum pain on each side of the wrist.



8 - KNEE PAIN (CHRONIC)

Using both leads, place electrodes over the top and base of the knee. Avoid placing directly on the kneecap. Below are two common application techniques.



9 – ANKLE SPRAIN

Using both leads, place an electrode from one lead on either side of the leg, and the other electrode on your ankle. The electrodes from the other lead will be placed along the affected nerve.



10 - KNEE PAIN (ACUTE)

Using both leads, place electrodes over the top and base of the knee. Avoid placing directly on the kneecap. Below are two common application techniques.



11 - HIP PAIN (COXALGIA)

Using both lead wires, place one electrode from each lead wire on your lower back on the side of the spine related to the affected hip. The remaining electrodes must be placed on the area of pain, on your hip.



12 - MENSTRUAL PAIN

Using both lead wires, place electrodes over the tummy area as shown.



13 - MIGRAINE

Using only 2 electrodes, place each on the back of the neck.

Note: Do not place electrodes on the side or front of the neck.



MIGRAINE (ADDITIONAL POSITION)

Using only 2 electrodes, place one on the left temple, and the other on the back of your right hand between your thumb and first finger.



Note: If only 2 electrodes are being used, connect both electrodes to the 2-lead single-channel lead wire.

Examples of electrodes placement for EMS:

Please Note: In EMS mode, electrode placement is not determined by the program mode selected. Simply select your program mode, then place electrodes on the required treatment area according to the following diagrams.

TRICEPS



LATISSIMUS DORSI



SPINALIS MUSCLE (BACK)



GLUTEUS



HAMSTRINGS



CALVES



BREAST



ABDOMEN



ABDOMEN + WAIST



QUADRICEPS



THIGHS



NOTE: When the using MicroCurrent or Interferential stimulation, please consult your doctor for directions on electrode placement.

ELECTRODES

The electrodes that are supplied with your STIMTEC NEO Unit are self-adhesive and can be used several times. Skin must be allowed to breathe, so the electrodes should be removed periodically. When not in use, the electrodes should be placed onto the clear plastic shield.

The condition of the electrodes has a direct effect on conductivity, and therefore the effectiveness of the treatment. When the electrodes start to lose their adhesive quality, it is possible to reactivate their adhesiveness by applying a fine spray of water to the gel side of the electrode. In time, this technique will not work, the gel will not reactivate, and new electrodes should be used.

WARNINGS

Do not use any electrodes less than 50mm X 50mm.

Allergic reactions to the self-adhesive electrodes can occur even though they are hypoallergenic.

- Do not apply to broken skin.
- Do not apply electrodes to areas with less than normal sensitivity. This could lead to setting intensities at higher levels than intended.

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