This manual is valid for the Neo Tek™ Combo Stimulator

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

Declaration of conformity:

TENS PROS declares that the DT8003TP complies with following normative documents:

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1. Safety information

1.1 Product Description

Neo Tek™ Combo Stimulator is a portable electrotherapy device featuring two therapeutic modes: Transcutaneous Electrical Nerve Stimulator (TENS) and Electrical Muscle Stimulation (EMS), which are used for pain relief and electrical muscle stimulation. The stimulator sends gentle electrical current to underlying nerves and muscle groups via electrodes applied to the skin. The parameters of the device are controlled by the buttons on the front panel. The intensity level is adjustable according to the needs of each individual patient.

1.2 Indications for use

The Neo Tek™ Combo Stimulator (TENS and EMS) may be used for the following conditions.

**For TENS mode**
1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

**For EMS mode**
1. Relaxation of muscle spasms
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

1.3 Medical background

**EXPLANATION OF PAIN**

Pain is a warning system and the body's method of telling us that something is wrong. Pain is important; without it abnormal conditions may go
undetected, causing damage or injury to vital parts of our bodies. Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until coded message travels to the brain where it is decoded, analyzed, and then reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is then interpreted, referred back and the pain is felt.

**HOW TENS STIMULATOR FOR PAIN RELIEF WORKS**

**What is it?**
The Neo Tek™ Combo Stimulator is a two output channel TENS machine and highly effective in relieving pain. TENS is now regularly recommended by doctors, physiotherapists and pharmacists throughout the world.

Transcutaneous Electrical Nerve Stimulation (TENS) is a noninvasive, drug free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

**How TENS works?**
Scientific theory suggests that electrical stimulation therapy may work in several ways:

1) The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.

2) The gentle electrical pulses increase the production of the body’s natural pain killer, such as endorphins.

3) Furthermore, it is thought that the electrical stimulation improves blood circulation as well. Muscles contract and relax with the flow of the electrical
stimulation. With repeated contracting and relaxing, the blood flows in and out and the blood circulation is improved.

**HOW EMS STIMULATOR FOR MUSCLE STIMULATION WORK**

**What is it?**
Electrical Muscle Stimulation (EMS) 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. It is a product derived from the square waveform (ladder-shaped). Through the square wave pattern it is able to work directly on muscle motor neurons. This device has low frequency, and this in conjunction with the square wave pattern, allows direct work on muscle groupings. 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.

**How EMS works?**
The EMS unit sends comfortable impulses through the skin that stimulate the nerves in the treatment area. When the muscle receives this signal it contracts as if the brain has sent the signal itself. As the signal strength increases, the muscle flexes as in physical exercise. Then when the pulse ceases, the muscle relaxes and then the cycle is continuously repeated. 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. EMS works similarly but uses an external source (the stimulator) with electrodes attached to the skin for transmitting electrical impulses into the body. The impulses stimulate the nerves to send signals to a specifically targeted muscle, which reacts by contracting, just as it does with normal muscular activity.
1.4 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

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="DANGER" /></td>
<td>Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.</td>
</tr>
<tr>
<td><img src="image" alt="WARNING" /></td>
<td>Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.</td>
</tr>
<tr>
<td><img src="image" alt="CAUTION" /></td>
<td>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.</td>
</tr>
</tbody>
</table>

**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.
- Do not use 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.

- Do not use together with a life-supporting medical electronic device such as an artificial heart or lung or respirator.
- Stimulation should not take place while the user is connected to high-frequency surgical equipment, it may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
- Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
- Do not use 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.
- Do not 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.
- Do not use over areas of skin that lack normal sensation.
- Do not use on the opposite sides of your head since the effects of stimulation of the brain are unknown.

**DO NOT USE ON THE FOLLOWING 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.

**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 REGARDING THE ELECTRODE 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 (e.g. eyes or mouth).

- The neck (especially the carotid sinus) or 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 or upper back simultaneously (lateral or front and back), or across your chest or your heart because the introduction of electrical current may cause rhythm disturbances which could be lethal.

⚠️ CAUTION

PRECAUTIONS REGARDING THE ELECTRODE PADS
- Do not bend or fold because the electrode pad may not function properly. Place the pads onto the plastic film and then store into a sealed package when not in use.
- Do not apply ointment or any solvent to the electrode pads or to your skin because it will disrupt the electrode pads from functioning properly.
- The electrode pads are already pre-gelled and will adhere to your skin.
- To avoid damage to the adhesive surface of the electrode pads, put the electrode pads only on the skin or on the plastic film provided.
- Place the electrode pads at least 1 inch apart on your skin. The electrode pads should never touch each other.
- Always place clean electrode pads on your body according to the user manual or on the advice of your physical therapist.
- Make sure the components are connected well and the electrode pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR ELECTRODE PADS THIS WAY
- The electrode pads should not touch each other when placed onto your skin.
- Do not place the electrode pad on your spine or backbone.
- The electrode pads should not touch any metal object, such as a belt buckle or necklace.
- The electrode pads should not be placed simultaneously on the soles of both feet.
- The electrode pads should not be placed simultaneously on the calves of both legs.
Do not share electrode pads with another person. This may cause skin irritation or infection. Electrode pads are intended for use by one person.

Do not place or relocate the electrode pads while the device is on.

Always turn the power off before removing or changing the electrode pads location.

Do not leave electrode pads attached to the skin after treatment.

**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 electrode pads may affect the safety and effectiveness of electrical stimulation.
- The electrical performance characteristics of electrode pads may affect the safety and effectiveness of electrical stimulation.
- Using electrode 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 a patient’s selection of a practitioner qualified in the management of pain.
- 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 the skin that lack normal sensation.
- Keep unit away from young children. The unit contains small pieces that may be swallowed. If any device piece has been swallowed immediately contact a medical professional for assistance.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
- Keep unit out of the reach of young children. The electrode cord can cause strangulation.
**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 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 device and consult with your physician if you experience adverse reactions from the device.
2. Presentation

2.1 Product structure

1) LED Indicator: Indicates the working status of channel 1
2) LED Indicator: Indicates the working status of channel 2
3) LCD Display: Shows the operating state of the device
4) [P] Button:
   1. Allows user to select a therapeutic program;
   2. Restores the original time setting
5) [CH1+] Button:
   1. Increases the output intensity of channel 1.
   2. Use to select treatment time in the setting mode.
6) [CH1-] Button:
   1. Decreases the output intensity of channel 1.
2. Use to select treatment time in the setting mode.

7) [S] Button: Press the button to enter time setting mode.

8) [CH2+] Button:
   1. Increases the output intensity of channel 2.
   2. Use to select treatment time in the setting mode.

9) [CH2-] Button:
   1. Decreases the output intensity of channel 2.
   2. Use to select treatment time in the setting mode.

10) Output socket for channel 1: electric signal output after connection of the cable with the adhesive electrodes to channel 1.

11) Output socket for channel 2: electric signal output after connection of the cable with the adhesive electrodes to channel 2.

12) [ ] Button:
    1. Turn on or turn off the device.

13) Belt Clip.

14) The battery compartment cover.

### 2.2 LCD display

- **Therapeutic mode**: TENS, EMS
- **Type of waveform**: B, N, M, MM, S, A, D
- **Program number**: 00, 01
- **Timer symbol**: 00 min.
- **Channel 1 output intensity**: 00 mA
- **Channel 2 output intensity**: 00 mA
- **Low-battery indicator**: 
- **Treatment time**: 00 min.
- **Channel 2**
- **Output intensity of channel 2**: 00 mA
- **Lock function indicator**: 

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3. Specification

3.1 Accessories

<table>
<thead>
<tr>
<th>NO</th>
<th>DESCRIPTION</th>
<th>QTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Neo Tek™ Combo</td>
<td>1pc</td>
</tr>
<tr>
<td>2</td>
<td>Lead wires</td>
<td>2pcs</td>
</tr>
<tr>
<td>3</td>
<td>40mm x 40mm Electrodes pads</td>
<td>4pcs</td>
</tr>
<tr>
<td>4</td>
<td>1.5V Battery (AAA)</td>
<td>4pcs</td>
</tr>
<tr>
<td>5</td>
<td>Instruction Manual</td>
<td>1pc</td>
</tr>
</tbody>
</table>

3.2 Technical information

Channel: Two channels
Power supply: DC 6.0V (1.5V x 4AAA)
Waveform: Mono-phasic square waveform
Frequency: 2Hz-125Hz
Pulse width: 100us~400us
Weight: About 102g (Without batteries)
Output amplitude: 0-80V (at 1000Ω Load)
Dimensions: 123mm x 64mm x 34 mm (L x W x H)
Treatment time: 15min, 30min, 60min and continuous
Operating conditions: 5°C to 40°C (41°F to 104°F) with a relative humidity of 30%-80%, atmospheric pressure from 700 to 1060 hPa
-10°C to 55°C (14°F to 131°F) with a relative humidity of 10%-90%, atmospheric pressure from 700 to 1060 hPa
Storage and transportation conditions: The amplitude level will be reset to 0mA when the amplitude level is 12mA or greater and an open circuit at either channel is detected.
Service life of the device: 3 years.
Service life of the batteries: With new battery, approximately 20 days when used for 30 minutes a day in TENS program 01 at 60 level intensity.
4. Instruction for use

4.1 Check/Replace the battery

Over time, in order to ensure the functional safety of the device, changing the battery is necessary.

1. Slide the battery compartment cover to open.
2. Insert the batteries (4x1.5V, type AAA) into the battery compartment.
3. Make sure you are installing the battery properly. Be sure to match the positive and negative ends of the battery to the proper markings in the battery compartment of the device.
4. Press and pull down following the direction of the arrow indicated on the photo.
5. Replace the battery compartment cover and press to close.
6. If replacing the battery, slide the battery compartment cover to open. Pull up the battery following the direction of the arrow indicated on the photo. Insert the battery according to the above step 2 - 5.

CAUTION:
1. Swallowing a battery may be fatal. Therefore, keep the battery and the product out of the reach of children. If a battery is swallowed, consult medical assistance immediately.
2. If a battery has leaked, avoid contact with skin, eyes and mucus membranes. Rinse the affected areas with lots of water immediately and contact medical assistance immediately.
3. Do not charge, dismantle or throw a battery into fire or allow it to short-circuit.
4. Protect battery from excess heat. Remove battery from the device if they are spent or if the device is no longer being used.
5. Always replace with the same type batteries.
4.2 Connect electrodes to lead wires

Insert the lead wire connector into the electrode connector (standard 0.08 inch female connection). Make sure no bare metal of the pins are exposed after connecting.

4.3 Connect lead wires to device
1) Before proceeding to this step, be sure the device is completely turned OFF.
2) The wires provided with the system insert 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 sockets controlled by Channel 1 and Channel 2 at the top of the unit. You may choose to use one or two channels with lead wires. Using both channels gives the user the advantage of stimulating two different areas at the same time.

**CAUTION:**
*Do not insert the plug of the lead wire into any AC power supply socket.*

**4.4 Electrode Placement**

Remove the clear transparent film from the back of the electrode pad. Place electrode pads on clean, dry and healthy skin near or surrounding the area with pain at least 1" apart. Do not let them touch. Make sure there is a linear path between the two electrode pads.

**WARNING:**
Make sure the device is turned off or the intensities are set to 0 before placing the electrodes on the body.

**4.5 Turning on the Device**

Press the power button [ ] to turn on the device, the LCD will illuminate. Before using the device for the first time, it is strongly advised that you take careful note of the contraindications and safety measures detailed at the beginning of this manual (Safety information). This electronic equipment is intended for pain management and muscle stimulation therapy only. This device is not a gadget or toy.
4.6 Selecting the therapeutic program

Press the program button [P] to select the available therapeutic program.

NOTE:
1. The LCD will display the therapeutic mode and program after you selected.
2. Scroll through the therapeutic programs-TENS 01 through EMS 10 by pressing the [P] button. see pages 22-24 for more list details and waveform.

4.7 Set treatment time

Press the set button [S] button to enter time setting mode. The lowercase ‘min’ will flash on the screen. You may select treatment time through the intensity buttons ([CH1+], [CH1-], [CH2+], [CH2-]). To save your selection in this program, press the [S] button again to save.

NOTE:
To restore original settings, press the [P] button while in the setting mode.

4.8 Adjust intensity and start treatment

Press [CH1+] or [CH2+] to increase the output intensity of channel 1 or channel 2, and the treatment time will begin.

Press [CH1-] or [CH2-] to decrease the output intensity of channel 1 or channel 2.
CAUTION:
1. If the stimulation levels are uncomfortable or become uncomfortable, decrease the stimulation intensity to a comfortable level. Contact your medical practitioner if problems continue.
2. If the electrodes are not firmly connected to the skin and the device, and if the stimulator’s output intensity surpasses 12mA, the intensity level will reset to 0 mA automatically.

4.9 Safety Lock Feature

The lock function automatically activates after there is no operation in the panel for 30 seconds, the lock indicator "\(\text{\textbullet} \)" will display on the LCD. This is a safety feature to prevent accidental changes to your settings and to prevent accidental increasing of the output intensity level. Press either the [CH1-] or [CH2-] button to unlock.

4.10 Low battery indicator

When the low power indicator "\(\text{\textbullet} \)" flashes on the LCD, replace the batteries in the device with new batteries as soon as possible.

4.11 Stop treatment

Treatment may be stopped in the following ways:

- Press the [CH1-] or [CH2-] button continuously until the intensity level resets to 0mA.
- The intensity level will reset to 0mA by pressing the [\(\text{\textbullet} \)] button on the upper right side of the device.
4.12 Turn OFF

Press the power button [ ] button and hold for approximately 3 seconds to Turn OFF the device.

**CAUTION:**
If there is no operation in the panel for 3 minutes in the waiting state, the device will turn off automatically.

### 5. Program list and waveform

#### 5.1. EMS PROGRAM

<table>
<thead>
<tr>
<th>Program</th>
<th>Position</th>
<th>Frequency (Hz)</th>
<th>Pulse width (us)</th>
<th>Type of waveform</th>
<th>Treatment time (min)</th>
<th>Description of waveform</th>
<th>Work time(s)</th>
<th>Rest Time(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Neck</td>
<td>75</td>
<td>200</td>
<td>S</td>
<td>30</td>
<td></td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>02</td>
<td>Shoulder</td>
<td>55</td>
<td>280</td>
<td>S</td>
<td>30</td>
<td></td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>03</td>
<td>Back</td>
<td>65</td>
<td>280</td>
<td>S</td>
<td>30</td>
<td></td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>04</td>
<td>Waist</td>
<td>55</td>
<td>300</td>
<td>S</td>
<td>30</td>
<td></td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>05</td>
<td>Buttock</td>
<td>75</td>
<td>380</td>
<td>A</td>
<td>30</td>
<td></td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>06</td>
<td>Knee</td>
<td>75</td>
<td>400</td>
<td>A</td>
<td>30</td>
<td></td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>07</td>
<td>Ankle</td>
<td>75</td>
<td>250</td>
<td>A</td>
<td>30</td>
<td></td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>08</td>
<td>Foot</td>
<td>75</td>
<td>340</td>
<td>D</td>
<td>30</td>
<td></td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>09</td>
<td>Elbow</td>
<td>65</td>
<td>200</td>
<td>D</td>
<td>30</td>
<td></td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>10</td>
<td>Hand</td>
<td>50</td>
<td>200</td>
<td>D</td>
<td>30</td>
<td></td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

Remark:
S: Synchronous, stimulation of both channels occurs synchronously.
A: Alternate, the stimulation of the CH2 will occur after the 1st working of CH1 is completed.
D: Delay, the stimulation of the CH2 will occur after the 1st working of CH1 is started + Delay time.
### 5.2. TENS PROGRAM

<table>
<thead>
<tr>
<th>Program</th>
<th>Position</th>
<th>Frequency (Hz)</th>
<th>Pulse width (us)</th>
<th>Type of waveform</th>
<th>Treatment time (min)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Neck</td>
<td>4/5/6/8</td>
<td>250</td>
<td>M</td>
<td>30</td>
<td>The pulse width is fixed at 250us. The frequency is changes from 4Hz, 5Hz, 6Hz and 8Hz.</td>
</tr>
<tr>
<td>02</td>
<td>Shoulder</td>
<td>2~125</td>
<td>200~100</td>
<td>M1</td>
<td>30</td>
<td>The parameters are automatically varied in 12s cycle time. The frequency and pulse width are decreased from 120Hz/100us to 2Hz/200us, and then increased back to 125Hz/100us.</td>
</tr>
<tr>
<td>03</td>
<td>Back</td>
<td>80</td>
<td>330/200</td>
<td>M</td>
<td>30</td>
<td>The frequency is fixed at 80Hz. The pulse width is changed between 330us and 200us. The cycle time is 1s.</td>
</tr>
<tr>
<td>04</td>
<td>Waist</td>
<td>80/75/10/70/65</td>
<td>250</td>
<td>M</td>
<td>30</td>
<td>The pulse width is fixed at 250us. The frequency changes from 80Hz, 75Hz, 10Hz, 70Hz and 65Hz.</td>
</tr>
<tr>
<td>05</td>
<td>Buttock</td>
<td>100</td>
<td>330/200</td>
<td>M</td>
<td>30</td>
<td>The frequency is fixed at 100Hz. The pulse width changes between 330us and 200us. The cycle time is 1s.</td>
</tr>
<tr>
<td>06</td>
<td>Knee</td>
<td>100</td>
<td>150</td>
<td>B</td>
<td>30</td>
<td>Both channels are operated at the same fixed frequency and pulse width.</td>
</tr>
<tr>
<td>Time</td>
<td>Location</td>
<td>Parameters</td>
<td>Waveform</td>
<td>Duration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>----------</td>
<td>-----------------------------</td>
<td>----------</td>
<td>----------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>Ankle</td>
<td>40/6/50, 250, M, 30</td>
<td>The pulse width is fixed at 250us. The frequency changes from 40Hz, 6Hz, and 50Hz.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>08</td>
<td>Foot</td>
<td>60<del>100, 100</del>160, M1, 30</td>
<td>The parameters are automatically varied in 20s cycle time. The frequency and pulse width increases from 60Hz/100us to 100Hz/160us, and then decreases back to 60Hz/100us.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>09</td>
<td>Elbow</td>
<td>100, 100, N, 30</td>
<td>Both channels are operated at the same fixed frequency and pulse width.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Hand</td>
<td>80, 200, M, 30</td>
<td>The stimulation of one channel will occur 10s later than the other. In this program, the <code>ON' time is equal to </code>OFF' time. ON time = 2s Ramp up + 6s Contraction +2s Ramp down.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Remark:
- N: Normal, parameters of the waveform is fixed.
- M: Modula, one of the parameters of the waveform is varied.
- M1: Modula1, more than one parameters of the waveform is varied.
- B: Burst, the stimulation of both channels will work for 0.5 second, then rest for 0.5 second.
6. Cleaning and Care

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 wipe.
   - Do not use chemicals (like thinner, benzene).
   - Do not allow water to 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 electrode pads.
2) Wash the electrode pads when the adhesive surface becomes dirty and/or the electrode pads are difficult to attach.
   - Wash the electrode pad softly with your fingertips under slow running cold water for several seconds (do not use a sponge/cloth/sharp object like a nail on the adhesive side, do not use detergents, chemicals or soap).
3) To dry the electrode pads, place the pad down on the surface with the adhesive side up to allow the adhesive surface to air-dry completely (do not wipe with tissue paper or cloth).

⚠️ CAUTION:
1) The life of the electrode pads may vary by the frequency of washing, skin condition, and storage state.
2) If the electrode pad no longer sticks to your skin or the electrode pad is damaged, you should replace with new electrode pads.
3) Before applying the self-adhesive electrodes, it is recommended that you wash and degrease the skin, and then allow it to dry completely.
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 (40*40mm) as indicated in this user manual.
7) Use of electrodes that are larger than recommended (40*40mm) may reduce the effect of the stimulation. Use of electrodes that are much smaller than the recommended electrodes (40*40mm) 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 United States 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 electrode pad from your body and pull out the lead wires from the electrode pads.
3) Place the electrode pads onto the plastic film and then store in a sealed package.
4) Wrap the lead wires and store in a sealed package.

6.4 Storing the unit

- Place the unit, electrodes, lead wires and manual back in the device case.
  Store the case in a cool, dry place, -10 °C ~ 55 °C; 10% ~ 90% relative humidity.
- Do not store the device in reach of children.
  Remove the batteries from the device before storing for long periods of time to avoid battery leakage.
7. Troubleshooting

If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the device should be serviced by a certified dealer.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
</table>
| Displays fail to light up      | Battery contact failure                          | 1. Try new batteries.  
2. Ensure batteries are inserted correctly. Check the following contacts:  
   ♦ All contacts are in place  
   ♦ All contacts are not broken |
| Stimulation weak or cannot feel any stimulation | Electrodes  
1. Dried out or contaminated | Replace and re-connect |
|                                | 2. Placement Lead wires old/worn/ damaged        | Replace |
| Stimulation is uncomfortable   | Intensity is too high                           | Decrease intensity |
|                                | Electrodes are too close                        | Reposition the electrodes |
|                                | Damaged or worn electrodes or lead wires        | Replace |
|                                | Electrode active area size is too small.        | Replace electrodes with ones that have an active area no less than 16.0cm² (4cm*4cm). |
|                                | May not be operate the device according to the manual. | Check the manual before use |
| Intermittent output            | Lead wires                                      | 1. Verify connection is secure  
2. Turn down the intensity. Rotate lead wires in socket 90°. If still intermittent, replace lead wire |
<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program is intermittent</td>
<td>The program is designed to treat by intermittent pulse. Refer to the description of programs option in the instruction manual</td>
</tr>
<tr>
<td>Improper electrode placement</td>
<td>Reposition electrode</td>
</tr>
<tr>
<td>Unknown</td>
<td>Contact clinician</td>
</tr>
<tr>
<td>Use the electrodes on the same site every time.</td>
<td>Re-position the electrodes. If at any time you feel pain or discomfort stop using immediately</td>
</tr>
<tr>
<td>The electrodes aren't stuck onto the skin properly.</td>
<td>Ensure the electrode is placed firmly and securely on the skin</td>
</tr>
<tr>
<td>The skin becomes red and/or you feel a stabbing pain</td>
<td>Clean the electrode pads with a damp, lint free cloth or replace with new electrode pads</td>
</tr>
<tr>
<td>The surface of the electrode was scratched.</td>
<td>Replace with new electrode</td>
</tr>
<tr>
<td>The electrode pads come off accidentally</td>
<td>Turn off the device and secure the electrode pad firmly to the skin</td>
</tr>
<tr>
<td>The power of the batteries has been exhausted.</td>
<td>Replace with new batteries</td>
</tr>
<tr>
<td>Output current stops during therapy</td>
<td></td>
</tr>
</tbody>
</table>

3. If still intermittent after replacing lead wire, a component may have failed. Call the repair department
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.

Dispose of the device in accordance with your legal obligation in your local area.

9. Glossary of symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol 1]</td>
<td>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.</td>
</tr>
<tr>
<td>![Symbol 2]</td>
<td>Type BF Applied Part</td>
</tr>
<tr>
<td>![Symbol 3]</td>
<td>Please refer to instruction manual because of the higher levels of output.</td>
</tr>
</tbody>
</table>
10. Important information regarding electromagnetic 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 these 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 IEC60601-1-2 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 TENS PROS conforms to this IEC60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by TENS PROS 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 cases where adjacent or stacked use is necessary, the medical device should be observed in order to verify the normal operation in the configuration in which it will be used.
- Refer to EMC table guidance regarding the EMC environment in which the device should be used.
### Table 1

**Guidance and manufacturer’s declaration - electromagnetic emissions**

*The Neo Tek™ Combo device is intended for use in the electromagnetic environment specified below. The customer or the user of the Neo Tek™ Combo should ensure that it is used in such an environment.*

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>CISPR11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td>Battery</td>
<td>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.</td>
</tr>
<tr>
<td>Voltage fluctuations /</td>
<td>Battery</td>
<td></td>
</tr>
<tr>
<td>flicker emissions</td>
<td>Operated</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td>Device</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2

**Guidance and manufacturer’s declaration - electromagnetic immunity**

*Neo Tek™ Electrical stimulators are intended for use in the electromagnetic environment specified below. The customer or the user of these Electrical stimulators should assure that it is used in such environment.*

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunity test</td>
<td>IEC 60501 test level</td>
<td>Compliance level</td>
<td>Electromagnetic environment - guidance</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>----------------------</td>
<td>------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**Table 3**

**Guidance and manufacturer’s declaration. Electromagnetic immunity**

*Neo Tek™ Combo electrical stimulators are intended for use in the electromagnetic environment specified below. The customers or the users of these Electrical stimulators should assure that it is used in such environment*

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60501 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
</tbody>
</table>
### Recommended separation distance

| Conducted RF IEC 61000-4-6 | Not applicable | d = 1.2√P 
\[ \text{d} = 1.2\sqrt{P}, \text{80MHz to 800MHz} \] 
\[ \text{d} = 2.3\sqrt{P}, \text{800MHz to 2.5GHz} \]  
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol: ![Radio waves](radio_waves.png)  

### Radiated RF IEC 61000-4-3

| 3 V/m  
80 MHz to 2.5 GHz | 3 V/m |  
where P 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 the following symbol: ![Radio waves](radio_waves.png)

---

**NOTE 1** At 80 MHz ends 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur 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 device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device recommended below, according to the maximum output power of the communications equipment.

### Table 6

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

*Note:*
EMC tests conducted included attached electrode cords of 1.5 m length.
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 years 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.

Note:

1) Shelf life is most influenced by several factors: exposure to light and heat, transmission of gases (including humidity), and mechanical stresses. This device and accessories do not require sterilization. The device is approved to be used under non-sterile conditions. Material is not subjected to the degradation phenomenon, also it will not produce a volatile phenomenon. This device has no restricted shelf-life.

2) Stability study display MTBF (mean time between failures) is 9780 hours, according to 90 minute/day use calculation, it can be used approximately 17 years. The expiration date (lifetime) of the product can be defined as 5 years.