Review: 02

Date: 06/2012

Packing Content

Your TANYX® device contains of

TANYX®	01 unit
Conductive Gel	02 units
User's Manual	01 unit

OBS: A disposable product. Should never use any type of cleaning product for reuse.

USER MANUAL

Congratulations on your recent purchase of TANYX®. A Pain Relief System with advanced technology.

Please carefully read the instruction manual to familiarize you with the operational system of this product.

Virtually everyone at some point in life has had some type of a physical work related, sports pain related due to discomfort caused by repetitive motion of muscles and or joints.

By using TANYX® for certain types of arthritis / rheumatoid and other types of musculoskeletal pain, including menstrual cramps (dysmenorrheal) you will achieve temporary pain relief.

In most situations the use of TANYX® eliminates the necessity of taking oral pharmaceutical medications that may have numerous contraindications and side effects.

Tanyx Pain Relief System is based on a TENS device designed as a compact, disposable, wireless, user-friendly version of any current TENS devices in the market today.

TANYX® is a revolutionary electronic system designed to apply electrical stimulation of low intensity directly to the body to provide symptomatic relief of minor muscle aches and pains and mild muscle tension associated with stress.

To ensure the easy use, electrode gel pads are integrated into the device and then used until the battery is depleted, at which time the device is discarded. If the device is left turned on but not in direct contact with the skins surface, the Tanyx device will automatically turn off after 5 minutes to preserve battery life.

ABOUT TENS

Transcutaneous Electrical Nerve Stimulation (TENS) provides a non-invasive and non medicated means of controlling or reducing pain.

Transcutaneous means on or across the surface of the skin without any penetration of the skin. With mild, electrodes apply safe and comfortable electrical waves transcutaneously and alternative means of pain control becomes available to the user.

TENS has been medically used for several decades and there are various explanations on how the application of TENS controls pain.

In simple terminology, TENS is thought to manage or control pain by either interfering with the neural transmission of pain to the brain (Gate Control Theory), and/or enhancing the release of natural chemicals substances that reduces pain which are normally produced by the body (Endorphin Theory), increasing circulation and providing relaxing to the muscles besides causing a local paraesthesy.

There are numerous scientific publications in medical journals that have documented and supported the effectiveness of TENS as an alternative means of pain control.

Pain is a protective mechanism and its suppression may eliminate its value as an indicator of progression of a condition. It is therefore recommended that before the use of your Tanyx System that your pain condition has been diagnosed by a physician.

The user is instructed to contact his physician if its pain does not change or if there is a worsening in the nature of it.

INDICATIONS

TANYX® can be used for temporary pain relief, for the following indications:

Lower Back Pain

Upper extremities (arms)

Lower extremities (legs)

The gel is intended for use only with the product TANYX®. The gel should be placed over the external electrodes for the purpose of reducing the impedance of the electrode-skin interface and to adhere TANYX® to the skin.

Gel ingredients: Glycerol, Water, Allylamine, Potassium Chloride.

CONTRAINDICATIONS

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

WARNINGS

Keep this device out of the reach of children.

The electrode gel is for external use only.

If you are in the care of a physician, consult with your physician before using this device.

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 severe, or continues for more than five days, stop using the device and consult with your physician.

Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your 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); If a skin rash occurs, discontinue use and contact your physician.

Do not apply stimulation over, or in proximity to, cancerous lesions or tumors.

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.

Do not use when operating machines or during any other activity in which the electrical stimulation could cause risk or injuries.

Do not use the product near short wave equipment and/or microwaves, because this can interfere on the product.

Do not immerse in water or use in a wet environment.

Do not apply stimulation when in the bath or shower.

Do not apply stimulation while sleeping.

Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.

Do not use the device on children, if it has not been evaluated for pediatric use.

Do not use simultaneously with surgical equipment of high frequency.

Do not use if you have a metal prosthesis.

Do not use when the symptoms of the pain have not been diagnosed, or the cause of the pain is unknown.

Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.

Device may not work properly when used it over a sweating part of the body during work and exercise.

Apply stimulation only to normal, intact, clean, healthy skin.

Turn the device OFF prior to placement to or removal of the electrodes from your body to avoid minor electrical shock when touching the pads.

The electrical performance characteristics of the electrode gel may affect the safety and effectiveness of electrical stimulation and recording.

The electrode gel should not be taken off, after being applied, to be reused in another product.

PRECAUTIONS

TENS is not effective for pain of central origin, including headache.

TENS is not a substitute for pain medications and other pain management therapies.

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.

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 your head, and electrodes should not be placed on opposite sides of your head.

The safety of electrical stimulation during pregnancy has not been established.

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, bundle branch block or high fever or even acute inflammatory disease you should follow precautions recommended by your physician.

If you have suspected or diagnosed epilepsy or experience convulsions, 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.

Be aware in avoiding any contamination from other users due to possible skin disease or any other transmissible diseases.

Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

ADVERSE REACTIONS

You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin This device is not intended for use on the face, head, or neck. 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 should consult with your physician if you experience adverse reactions from the device. Isolated cases of skin irritation may occur at the site of electrode placement with long-term applications. Electrode burns may occur, by inappropriate use, when the gel pad is removed from the electrode or gets damaged.

INSTRUCTIONS OF USE

Applications of the TANYX®

1º Remove one side of the gel pad electrode protection, written “Protection”

2º Adhesive those onto the TANYX® electrodes, after that, take off the plastic protections written “take off”. Keep the plastic protection aside while using the device and place them back on right after its use, in order to protect the conductive gel to be reused.

3º Clean and dry the skin application site thoroughly. Tanyx gel pads will not adhere well if any lotions, oil, make up, dirt, etc... is on the skin. Tanyx will also not adhere well to areas where abundant body hair is present, shaving the area may be required if necessary. Attach the Tanyx to the site of pain or as close as possible.

4º If electrode gel pad get’s dry, its effectiveness may be improved by slightly damping the gel pad surface with your finger by dipped it in water.

5º Lightly press the two gel areas to assure adhesion to the skin surface.

6º Use your Tanyx by following these next steps. (**TANYX® OPERATION AND ADJUSTMENT)** Normally, each session can last from 20 to 30 minutes, which is a sufficient amount of time to control ones pain, if necessary you can repeat the session for a longer period time, because there is no time restrictions or amount of application that can be made daily.

7º After use, turn the product off.

8º After turning off, carefully remove your Tanyx from the application site, by removing the gel pad carefully from your skin.

9º Replace the plastic gel pad protection and repack your Tanyx unit again in the blister provided.

The life use of the adhesive gel on the electrodes will vary depending upon skin conditions, number of removals from skin surface, type of stimulation, length of stimulation and site of stimulation.

A physician or physiotherapist should be seen if there are any doubts regarding its usage

TANYX® OPERATION AND ADJUSTMENT

To turn on your TANYX®, press and hold the ON/OFF button (⏻) for 3 seconds. The LED light will turn on and continue to blink once every second.

Your TANYX® offers two choices of stimulation modes:

- CONVENTIONAL (produces a continuous tingling sensation), and;
- PULSE (the stimulation is produced in cycles that alternates between on/off every 3 seconds)

Both modes have predefined pulsation pattern and width wave intensity; however it allows an individual control of intensity using the LOW (L), MEDIUM (M) and HIGH (H) patterns. The choice of which mode should be used depends of the pain nature, location and characteristics; as well as the personal comfort and preference.

TANYX® intensity should be controlled by the patient, in order to be comfortable. If the muscle contraction is troubling, the adhesive position should be slightly changed until the uncomfortable contraction consider by the patient disappears, and stays only a tingling sensation. The intensity may be increased by patient criteria from Low to Medium or High, depending on the patient comfort. TANYX® should remain in the pain local, at least, for 20 to 30 minutes, which is a sufficient time to pain control. One or two daily applications are sufficient, but the product can be used as long as desired, because there is no overdoses risk, even if it is used for more than 30 minutes. It also can be used as many times as desired per day. Applied for this time the product can be used for approximately 18 times, since the battery lasts up to 6 hours.

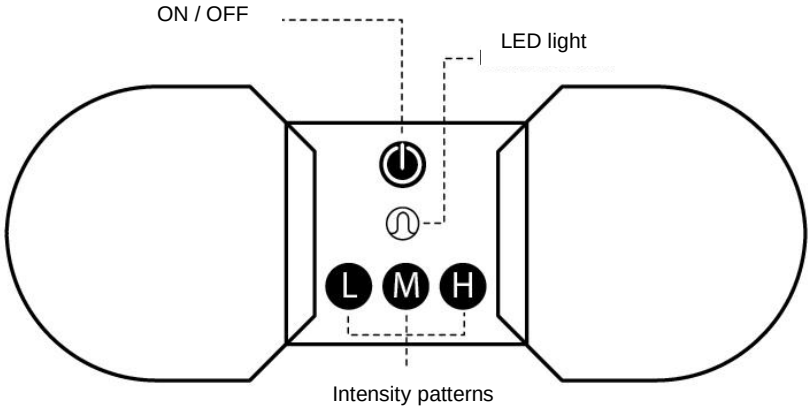
Originally, TANYX® is adjusted for CONVENTIONAL mode in LOW intensity. To change from CONVENTIONAL mode (constant) to PULSE mode (Alternate) or vice versa, press ON button (⏻) for one second and the unit will change from one mode to another.

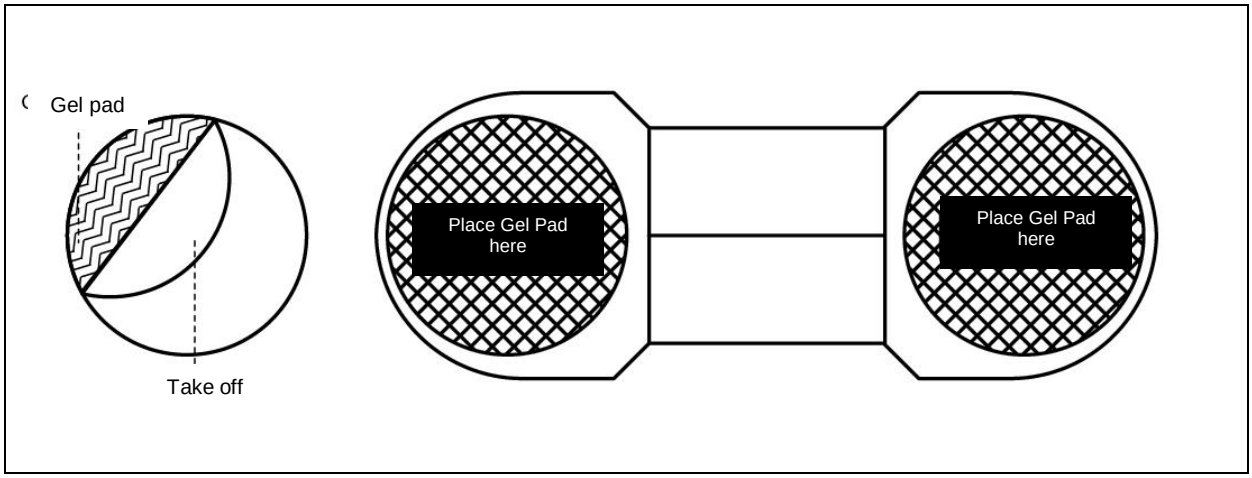
To change the Intensity level, press LOW, MEDIUM or HIGH button for 1 second.

To turn off your TANYX®, press and hold ON/OFF (⏻) button for 3 seconds.

NOTE: If TANYX® is turned ON and not placed in contact with the skin surface it will AUTOMATICALLY turn OFF after 5 minutes to preserve the battery life. TANYX® unit has a predetermined battery life. When the TANYX® battery is within 30 minutes of expiration the LED light will begin to BLINK in a rapid sequence to alert you. The battery is expected to work continuously up to 6 hours depending on how the unit is used and kept.

When the battery has expired the LED light will then go out and the TANYX® unit will stop functioning, at which time the unit should be properly disposed of.





PRODUCT DISPOSAL

Product should be disposal in an appropriate place, according to the local laws.

TECHNICAL SPECIFICATION

The pulse is fixed to a medium value (55 Hz) with the pulse width at a low level (55µs) and an adjustable intensity of 0-30mA.

Product Energy Source: 3 volt CR2025 lithium Cell.

Capacity: 500 ohm.

Intensity Range in mA: (500 ohm load): 0 – 30mA (Peak to Peak)

Low Intensity: 10 mA.

Medium Intensity: 20 mA.

High Intensity: 30 mA.

Range of intensity in Volts (500 ohm of load): 0 – 30 (Peak to Peak).

Modes: Conventional (non-pulse, steady) and Pulsing (or Burst).

Minimum duration: 4 hours – Maximum duration: 6 hours

Protection degree: IPXO

Storage Conditions: Keep in a dry place

Storage Temperature: -20°C ~ 60°C

Operation Temperature: 0°C ~ 60°C

 Protection against electric discharge of the applied part: BF

Product attempts to the biocompatibility criteria of ISO 10993-5:2009

SYMBOLISM

 Warning – see manual

EMC SPREAD SHEET

Norma	Tension	Observations		
CISPR 22	3 Vdc	Preview Measurement Detector 1		Peak detector
		Final Measurement Detector 1		Quasi-Peak Detector (if necessary)
Class	**Distance**	**Polarization**	**Tension**	**Operator**
B	3 m	V / H	3 vdc	Wagner Mello
Obs. The relation between the limits 10m and 3m is established by the formula:E2 = E1 + 20 log [d1 / d2]. Where E is given in dBμV/m and d in meters. Resulting on a variation of 10,5 dB in the limit of the electrical field to d = 3m				

Norma	Tension	Level (kV)		Criterion
IEC 61000-4-2	3 Vdc	Ar:	± 8	A
			± 15	A

Norma	Tension	Polarization	Level	Frequency Range	Modulation	Criterion
IEC 61000-4-3	3 Vdc	H / V	3 V/m	80 MHz a 2,5 GHz	AM, 80%, 1KHz	A
			20 V/m			A
Monitoring: by video camera and functioning verification during the rehearsal with help of one oscilloscope doing some pause during the rehearsals						

Norma	Frequency (Hz)	Level (A/m)	Criterion
IEC 61000-4-8	50 e 60	3	A
		30	A

GUARANTEE: 36 months

PROBLEM SOLVING

1º In case your product does not emit signals: Make sure it is turned on, then check if elected intensity has been chosen.

2º The LED light has stopped flashing: the battery could be depleted or the LED light can be blown out.

3º When the LED light is blinking very quickly: that's an indication the TANYX® battery is ending. That happens when the battery is close to its last 30 minutes of use.

4° The gel pads are not adhering: lightly wet the gel surface by dipping your finger in water. Clean and dry the skin application site thoroughly. The Tanyx gel pads will not adhere well if any lotions, oil, make up, dirt, etc. is on the skin. The Tanyx will also not adhere well to areas where abundant body hair is present, shaving the area may be required if necessary.

5º When turning on the product, an electric shock sensation is felt in the skin: Slightly press the two gel pads onto the skins surface to assure adhesion to the skin.

6º Once battery life is done: Simply dispose your TANYX®, according to the local laws

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