



Med-Fit

Wireless 2 Channel TENS Machine



CE 0413

Patient Instructions & User Manual

Instrucciones para el paciente y manual de usuario

Patientenanweisungen und Benutzerhandbuch

Instructions pour les patients et manuel d'utilisation

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www.tensmachineuk.com

IMPORTANT INFORMATION

Información importante | Wichtige Informationen | Une information important

Instructions for operating with the remote control.

Step 1 - Turn on your module, a green LED will show and a single beep.

Step 2 - Turn on your remote control. Two beeps indicate control is now paired with the module and is ready for use.

Instructions for operating without the remote control.

Step 1 - Turn off the remote control.

Step 2 - Turn on the Painless TENS modules. Press the + or - button to adjust the intensity. The module will automatically turn off your treatment session of 60 minutes.

Anleitung zur Bedienung mit der Fernbedienung.

Schritt 1 - Schalten Sie Ihr Modul ein, eine grüne LED leuchtet auf und es ertönt ein einzelner Piepton.

Schritt 2 - Schalten Sie Ihre Fernbedienung ein. Zwei Pieptöne zeigen an, dass die Steuerung jetzt mit dem Modul gekoppelt und einsatzbereit ist

Anleitung zum Betrieb ohne Fernbedienung.

Schritt 1 - Schalten Sie die Fernbedienung aus.

Schritt 2 - Schalten Sie die Painless TENS-Module ein. Drücken Sie die + oder - Taste, um die Intensität einzustellen. Das Modul schaltet automatisch Ihre Behandlungssitzung von 60 Minuten ab.

Instrucciones para operar con el control remoto.

Paso 1: encienda su módulo, se mostrará un LED verde y un solo pitido.

Paso 2: enciende tu control remoto. Dos pitidos indican que el control ahora está emparejado con el módulo y está listo para usar.

Instrucciones para operar sin el control remoto.

Paso 1: apague el control remoto.

Paso 2: encienda los módulos Painless TENS. Presione el botón + o - para ajustar la intensidad. El módulo apagará automáticamente su sesión de tratamiento de 60 minutos.

Instructions d'utilisation avec la télécommande.

Étape 1 - Allumez votre module, une LED verte s'affichera et un seul bip.

Étape 2 - Allumez votre télécommande. Deux bips indiquent que la commande est maintenant jumelée avec le module et est prête à l'emploi.

Instructions pour le fonctionnement sans la télécommande.

Étape 1 - Éteignez la télécommande.

Étape 2 - Allumez les modules TENS indolores. Appuyez sur le bouton + ou - pour régler l'intensité. Le module éteindra automatiquement votre séance de traitement de 60 minutes.

Electrodes available on Amazon | Electrodos disponibles en Amazon | Elektroden bei Amazon erhältlich | Électrodes disponibles sur Amazon

RC340 - Butterfly - SA360 Round | RC340 - Mariposa - SA360 Redondo | RC340 - Schmetterling - SA360 Rund | RC340 - Papillon - SA360 Rond

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4 GENERAL DESCRIPTION

The Painless TENS is a battery operated single channel electronic nerve stimulator.

The wireless painless TENS is a single channel transcutaneous electrical nerve stimulator (TENS). The device generates small pulses of electrical current and delivers the pulse to the user through self-adhesive electrodes such that the underlying nerves are activated and the pain associated with sore and aching muscles is relieved. The painless TENS is portable, compact, rechargeable and stylish in design. It may help relieve pain in various areas of the body, such as lower back, shoulders, arms and legs.

The device generates small pulses of electrical current and delivers the pulse to the user's skin through adhesive gel electrode pads such that the underlying nerves are activated and the pain associated with sore and aching muscles is relieved.

The PAINLESS TENS is portable, compact, rechargeable and stylish in design. It may help to relieve pain in various areas of the body, such as the lower back, shoulders, arms and legs.

INTENDED USE

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg and foot, due to strain from exercise or normal household and work activities.

CAUTIONS

CONTRAINDICATIONS

1. Patients with pacemakers and cardiovascular problems should not use the device.
2. The device should not be administered over the abdomen or pelvis during pregnancy.
3. Patients with epilepsy should not apply the electrodes to the neck or head.
4. Patients with heart disease, cancer or any other health conditions should not use the device, unless recommended by a medical practitioner.
5. Patients who have suffered acute trauma or surgical procedures in the past six months.
6. Patients with undiagnosed pain syndromes should not use the device, unless recommended by a medical practitioner.

PRECAUTIONS

1. Do not apply the electrodes on inappropriate sites, such as over chest, the head, anterior neck, eyes, mouth and the front of throat.
2. Do not apply the electrodes on areas of broken or damaged skin, such as open wounds.
3. Do not apply the electrodes on the swollen, infected or inflamed areas or skin eruptions.
4. Do not apply the electrodes on the skin with diminished sensation because nerve damage is likely to diminish the effectiveness and the patient maybe unaware that high-intensity currents are causing skin irritation.
5. Patients should not use the device in water or when operating hazardous machinery such as driving.
6. Do not use the device near monitoring equipment.
7. Do not use the device close to transdermal drug delivery system.

1. PATIENT with an implanted electronic device (such as a cardiac pacemaker) should not use the device unless specialist medical opinion has first been obtained.
2. Simultaneous connection of a PATIENT to a high frequency surgical ME EQUIPMENT may results in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
3. Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.
4. Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
5. Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.
6. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the cartid sinus reflex.
7. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
8. Stimulation should not be applied transcerebrally.
9. Never use the device while driving, operating machinery or during activities in which involuntary muscle contractions may endanger the user or others.
10. Do not use the device in the bath or shower.
11. Never use the device while sleeping.
12. Never immerse the device in any liquid.
13. No service and no maintenance shall be done while in use with a patient.

WARNINGS

14. Do not modify the device without authorization of the manufacturer.
15. Keep unit out of the reach of young children.
16. Apply the whole surface of the electrodes firmly to the skin. Do not use electrodes that do not stick properly to the skin or only partially stick to the skin.
17. The electrodes should be discarded when they are no longer adhering.
18. Only use the electrodes provided by the manufacturer, do not use other kinds of electrodes. Otherwise, it will cause skin irritation if the current density is more than $2\text{mA}/\text{cm}^2$
19. Over long application may cause harm to the patient.
20. Stimulation should not be done in conjunction with OXYGEN RICH ENVIRONMENTS.

ADVERSE REACTIONS

1. You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin;
2. You should stop using the device and should consult with your healthcare advisor if you experience adverse reactions from the unit.

8 INTRODUCTION TO TENS

What is TENS?

Transcutaneous electrical nerve stimulation is a pain control treatment. It is often called TENS for short.

A TENS unit is a portable, pocket-sized, battery-powered device.

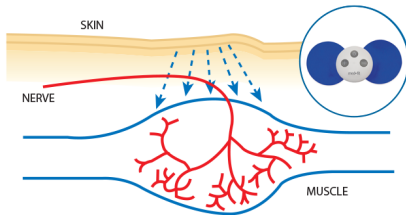
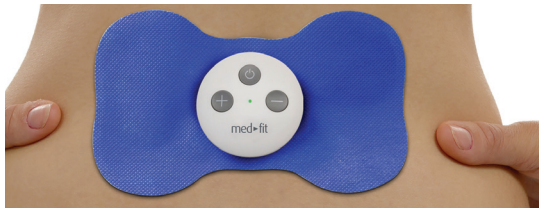
The TENS unit uses mild, safe electrical signals to help control pain and delivers the electrical signal to the body through self-adhesive conductive electrodes.

How does TENS work?

The most common TENS programmes use high-frequency stimulation, which is the first choice for both acute and chronic pain. High-frequency stimulation sends impulses to the nervous system's own pain-inhibiting mechanisms, which block the pain. You can use it as often and as long as you like, but each treatment should last at least 1 hour.

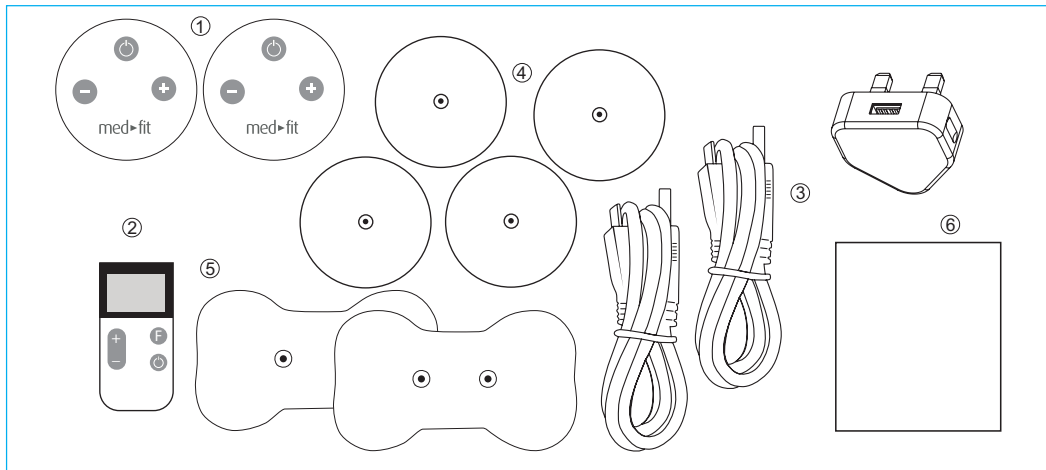
Another type of TENS is low-frequency stimulation. Low-frequency TENS treatment can alleviate pain by stimulating muscles to release the body's own morphine-like substances, endorphins.

Place the electrodes on a muscle in the painful area so that a visible contraction occurs.



CONTENTS & GENERAL INFORMATION

Please check carefully the contents of the Painless wireless TENS TENS Device and Electrode Pads



1. Painless TENS module x2

2. Remote control x1

3. AC adaptor and charging lead x2

4. Self adhesive electrodes x4

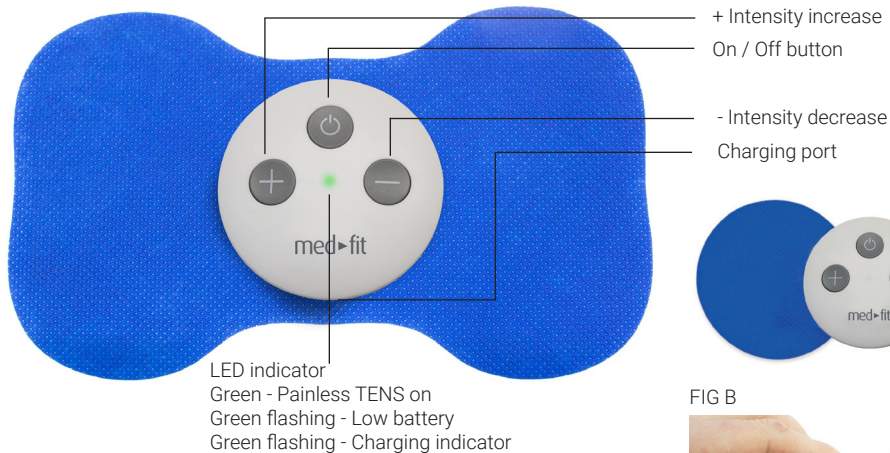
5. Large butterfly electrode x2

6. Instruction & User Manual x1

**** In case of any discrepancy between the physical and picture, refer to the actual product.***

OPERATING INSTRUCTIONS

Painless TENS connected to the butterfly electrode



When the TENS is switched on and not in use, it will automatically turn off after approximately one minute, to conserve battery life.

Please note when using the small round shaped electrodes (see Fig B) you must connect 2 electrodes one to each connection point.

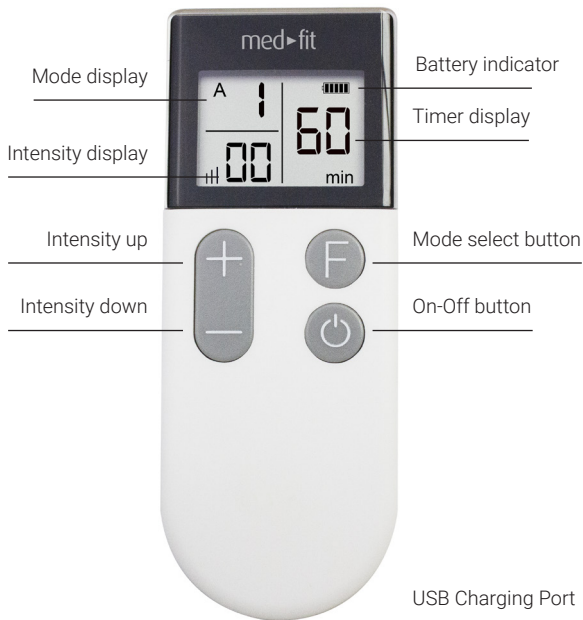


FIG B



OPERATING INSTRUCTIONS

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Mode A has 6 programmes

Single press

Mode M has 9 programmes



12 USING YOUR REMOTE CONTROL

Before using your painless TENS we highly recommend you familiarise yourself with the features available.

The intensity has 16 levels available. Pressing the +/- buttons increases and decreases between 1 -16



Remote control modes

The remote control has two modes

A mode and M mode

A mode is modulation mode

M mode is a continuous mode

To change between M mode and A mode press and hold the F button for approx 3 seconds.

Once you have chosen the desired mode a single press on the F button changes the programme.

Please note the time is always set at 60 minutes turning off you're remote will always re-set the time at 60 minutes.

CHARGING THE REMOTE CONTROL

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It is always recommended that you charge your remote control before using it for the first time.

Charging indicator flashes when charging.

There are two methods of charging your painless TENS remote control.

To charge from a mains outlet socket, simply connect the USB cable to the mains charging adaptor and the other end to the Painless TENS remote control. Please do not force the USB cable into the sockets as they are designed to fit one way only see Fig C

Charging the Painless TENS via a computer USB port.

You may charge your Painless TENS remote control through a computer by using the USB cable port see Fig D



USB Charging Port

Fig C



Fig D



INSTRUCTIONS FOR USE

Once you are familiar with the features and general operating instructions,

Please follow the steps below.

1. Make sure both inputs of the Painless TENS unit are connected into the snap-pin connectors of the gel electrode pad or pads.
2. Peel off the plastic film from the opposite side of the butterfly or standard gel electrodes supplied.
3. Place the Painless TENS attached to the gel electrode pad onto the treatment areas. Press down firmly and ensure a full and firm contact is made with the skin.
4. Press the On/Off power button to turn on the TENS module as indicated by the LED light being green.
5. Turn on your remote control you should hear two beeps this indicates the remote and tens modules are responding. We recommend starting with M1 as this is ideal for first-time use.
6. Once you have set M1, increase the intensity slowly by pressing the + button. Set a level that is a pleasant sensation and not too strong.
7. To turn off your remote by pressing the ON./OFF button, this will also turn off the intensity of the TENS module the green light on the TENS module will stay on. This feature allows you to turn on your TENS module again if required. If your remote is not activated again within one minute your TENS module will turn off automatically.

Pairing the Modules to the Remote Control.

The TENS Modules must be switched on before the remote control is switched on, this is to ensure that the modules pair to your remote control.

A double beep will indicate pairing was successful. You can use either one or two TENS modules at the same time for the best pain relief.

For example, you would always use both TENS modules to treat sciatica. As one module would be placed directly over the lower back (L5 = Lumbar Vertebrae 5).

PAINLESS TENS PROGRAMMES

Below is the table of programmes available:

A MODE - PROGRAMMES A1 TO A6

Programme A1 - is a set frequency programme of 80Hz this is the most common setting used by N.H.S pain clinics for chronic pain-relief.

Programmes A2 - A6 are modulated frequency programmes 20Hz - 100Hz.with a set pulse width of 120 microseconds.

Modulated TENS is ideal for long-term use varying the frequency during treatment reduces the factor of TENS accommodation.

Try each programme A1 - A6 to see which helps with the best pain relief.

M MODE - PROGRAMMES M1 TO M9

The M programmes are set frequencies with 120-microsecond pulse width.

Each programme has 3 modes again reduces the accommodation factor.

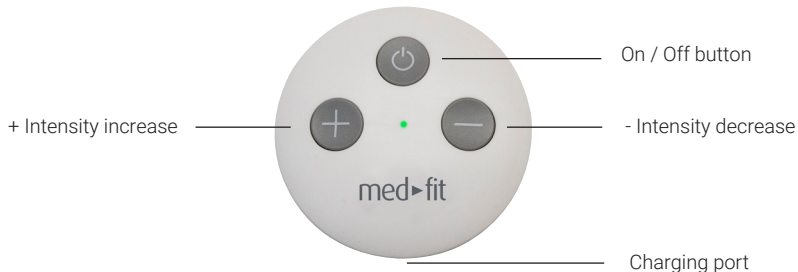
Try each programme M1 - M9 to see which helps with the best pain relief.

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USING YOUR MODULE INDEPENDENTLY

You may use the TENS Module in a standalone mode without the use of the remote control. To do this follow the simple steps below.

1. Turn on your TENS module by pressing the On-Off button once your TENS module shows a solid green light.
2. Connect one large pad or 2 smaller pads and place on the treatment area.
3. To increase the intensity press the + button to the desired level each press increases the intensity allowing approximately 10 to 15 seconds for the intensity to reach the desired level.
4. Your TENS module has 3 available programmes in stand-alone mode to change the programmes hold down the button for 3 seconds, then increase the intensity as already described. The treatment time in stand-alone mode is set at 60 minutes.



CHARGING THE PAINLESS TENS

It is always recommended that you charge your TENS module prior to using it for the first time.

There are two methods of charging your painless TENS.

To charge from a mains outlet socket, simply connect the USB cable to the mains charging adaptor and the other end to the Painless TENS. Please do not force the USB cable into the sockets as they are designed to fit one way only see Fig C

Charging the Painless TENS via a computer USB port.

You may charge your Painless TENS through a computer by using the USB cable port see Fig D

How long should I charge the Painless TENS.

Once connected the charging light will flash green a fully charged battery is indicated by a continuous green LED.

Auto shut down mode.

To save battery life the painless TENS will automatically shut down once switched on but is not being used.

Fig C



Fig D



ELECTRODE INSTRUCTIONS FOR USE

Turn Stimulator OFF before applying or removing electrodes

Application of the self-adhesive pads & aftercare

The electrode pads have a maximum usage of 25-30 applications to keep your pads in good condition apply a small amount of water to the gel side of the pad every 4th application (do not over wet). Do not apply any gels or creams to the pads as this will destroy the hydro-gel on the electrode pad.

Application

1. Skin site must be very clean and dry, dirty, flaky or oily skin will prevent electrodes from adhering to the skin. If necessary, trim excess hair with scissors. If skin is oily wipe down with an alcohol or electrode skin prep prior to application. Be sure to wash hands before handling electrodes.
2. Remove electrodes from bag and reseal bag to protect remaining electrodes.
3. Insert the stud electrode on to the back of the device.
4. Grasping a tiny edge of the electrode, peel and remove electrode from the protective plastic liner. Save liner for electrode storage.
5. Place electrode onto skin treatment site (as recommended by your clinician) by firmly applying from the center of the electrode to the outer edges. Adhesion improves when electrodes reach skin temperature.
6. If gel appears over-saturated with excessive moisture or perspiration, allow the electrode to air dry in a refrigerator with the gel side facing up until the gel regains its tack. If the gel appears dry, try adding a few drops of water to the gel and allow to rest in a dust-free environment until the gel regains its tack.

ELECTRODE INSTRUCTIONS FOR USE

Removal and storage

1. Lift a corner of the electrode and slowly peel the electrode off the skin, touching the adhesive gel as little as possible.
2. Place the electrodes back onto the saved protective plastic liner.
3. Return the electrodes back into the storage bag and reseal tightly to prevent dry-out.
4. Store at room or cool temperature and keep out of direct sunlight.
5. The life of the electrode varies depending on skin conditions, amount of use, storage and climate. Electrode life may be extended by carefully following the application, removal, and storage instructions.

Caution

1. DO NOT place electrodes on broken skin. If skin irritation develops discontinue use. Consult physician. Replace electrodes when they do not adhere or when treatment becomes uncomfortable.
2. DO NOT use unit while driving or operating machinery
3. DO NOT wear electrodes when showering, bathing or swimming
4. DO NOT apply electrodes across the head or across the heart or on the front neck.
5. Keep electrodes separated during treatment
6. DO NOT exceed 0.1 watts/cm²
7. Using stimulation electrodes that are small or incorrectly applied could result in discomfort or skin burns.

Latex Free

When the TENS is switched on, pushing the + button, if the device emits 1 bleep and the green light flashes once, but you feel no sensation through the electrode pads this may be due to the following conditions:

1. The TENS Pads are not securely fastened to the skin.
 2. The area being treated is too dry please remove your pads and rub warm water into the treatment area and reapply the pads.
 3. The electrode pads need replacing.
- * Please note self-adhesive pads need replacing after 20-30 applications. To increase the life of your pads smear small amount of water onto the pad every 4th application.

If your device is not operating properly please check for common problems and suggested solutions. If the recommended action does not solve the problem, please contact the seller.

Stimulation is weak or non-existent

- Be sure skin is clean and gel electrode pads are firmly attached to the skin.
- The battery is low and needs to be charged.
- The gel electrode pad needs to be replaced.

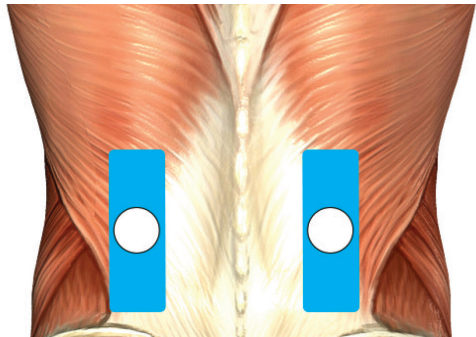
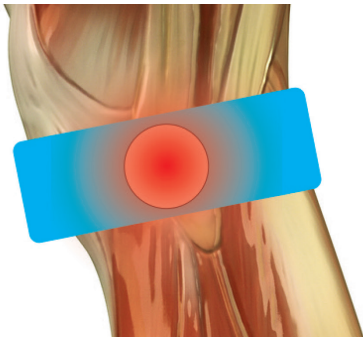
1. Turn off the device before cleaning.
2. The electrode pad of the device can be cleaned with a soft and wet cloth.
3. Never use excessive water or cleaning agents to clean the device.
4. The gel electrode pad can remain on the control unit between uses, and are covered by the plastic film to avoid getting dirty and dry.
5. Avoid exposure to extreme moisture or temperature.

Once you have familiarised yourself with the controls and features of your TENS device, it is important to place the TENS electrodes in a position which gives the most pain relief. This may take 3 or 4 attempts to find the most suitable position, for maximum pain relief.

If you are using two electrodes, place the electrodes directly onto the painful area at a position where you feel the pain starts and where it finishes. You may now position the electrodes around the painful area to locate the most suitable position for maximum pain relief.

The alternative method is to use four electrodes surrounding the painful area see examples below

The complete area between the electrodes will now be treated when positioning the electrodes as shown.



CONFORMITY TO SAFETY STANDARDS

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Statement of EMC

IEC 60601-1-2:2014, EN 60601-1-2:2015, IEC 60601-1-11:2015 clause 12, EN 60601-1-11:2015 clause 12,
IEC 60601-2-10:2012 + A1:2016 clause 201.17 & 202, EN 60601-2-10:2015 + A1:2016 clause 201.17 & 202

Conformity to MDD Requirements

IEC 60601-1:2005+A1:2012, EN 60601-1:2006+A1:2013, ANSI/AAMI ES60601-1:2005+A1:2012, C1:2009 and A2:2010,
IEC 60601-1-11:2010, EN 60601-1-11:2010, IEC 60601-2-10:2012, EN 60601-2-10:2015

TECHNICAL SPECIFICATIONS

Transcutaneous Electrical Nerve Stimulators: KTR-2492

Operating condition Temperature: +5°C+40°C

Relative humidity: 15% - 93%RH

Atmospheric pressure: 700hPa-1060hPa

Environment for storage

Temperature: -25°C+70°C

Humidity: 0-93%RH

Barometric pressure: 700hPa - 1060hPa



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|  | Authorized Representative in the European Community |
|  | CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC. |
|  | Class II equipment |
|  | Date of manufacture |
|  | Manufacturer |
|  | Specifies serial number |
|  | Type BF applied part |
|  | DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary. |
|  | Follow instructions for use. |
| IP22 | The first number 2: Protected against solid foreign objects of 12.5 mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure is tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical. |



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