

Flexi TENS™

Instructions for use

Caution: Federal Law restricts this device to sale or use by or on the order of a practitioner so licensed by the State.



The Flexi TENS is an ultra-simple, yet powerful digital TENS unit - flexible because it can be used for one or two pain areas - ideal for numerous acute and chronic pain conditions.

TENS is recognised as a safe and highly effective method of pain relief and is regularly recommended by medical professionals.

TENS is a drug free method of pain relief, with no known side effects. It can also be used in conjunction with any additional medication if required.

Explanation of Symbols on Unit



Equipment providing a particular degree of protection against electric shock particularly regarding allowable leakage currents having an F type (floating) applied part.



Warning – refer to accompanying documents i.e. these instructions.



Denotes a product which must be disposed of safely.

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Introduction to Patient and Professional

The Body Clock Flexi TENS is designed for the treatment of symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

The instructions in this manual are designed to cover most operational issues. However if you have any questions about your particular condition or if problems arise, please seek advice from your physician or therapist.

What is TENS and how does it work?

TENS stands for Transcutaneous Electrical Nerve Stimulation.

The treatment consists of passing mild electrical impulses through your skin into the nerve fibers that lie below. Contact is made with your skin via electrodes. TENS electrodes are placed around or over the painful area.

In 1965, researchers Melzack and Wall presented their concept of a “gate” theory for pain control. This theory says that a “T” cell transmits signals to the dorsal horn, and that the stimulation of large nerve fibers may result in the blocking of pain transmission. The TENS message is carried to the spinal chord faster than a pain message and closes a hypothetical gate, inhibiting the pain message to the brain. This applies when the pulse rate is set at a higher frequency of 60-80 pulses per second or more.

TENS can also work by stimulating the body to release endorphins, the body’s own pain killing substances. This applies

when the Pulse Rate is set below 4 pulses per second – usually at 2 pulses per second. This lower frequency treatment produces slight muscle twitching (tapping). Patients find this treatment takes longer, at least 20-30 minutes to be effective, but the resulting pain relief can last for a longer period.

Accessories

The Flexi TENS is a dual channel TENS unit, supplied with the following accessories:

1. 1 pack of 4 50mm x 50mm self adhesive electrodes;
2. 2 x AAA battery;
3. 1 single lead wire;
4. 1 dual lead wire;
5. 1 manual;
6. 1 carrying pouch; and
7. 1 neck cord.

How to place electrodes

Body Clock TENS units are supplied with 2 x 2 (50mm x 50mm) self-adhesive rectangular electrodes. These are consumable items that can be re-ordered from Body Clock.

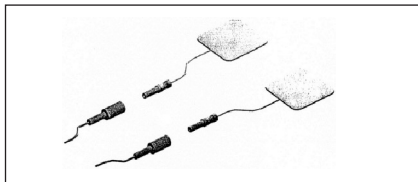
- Store electrodes in packaging provided in a cool dry place.
- A key to successful use of the stimulator is finding the best placement for the electrodes. You may need to try several electrode locations before you find the best one to intercept your pain.
- Before placing the electrodes on your skin, wash the area with mild soap and water and then thoroughly rinse and dry.
- Trim excess body hair, which could interfere with smooth electrode contact with the skin, but do not shave it.
- Do not place electrodes on cut, broken or irritated skin.
- Moisturizing cream may be applied after

treatment, but not before.

- Never place or remove the electrodes, test or wet them while the system is turned on and connected to the electrodes. Failure to comply can result in a sudden unpleasant sensation on your fingertips.

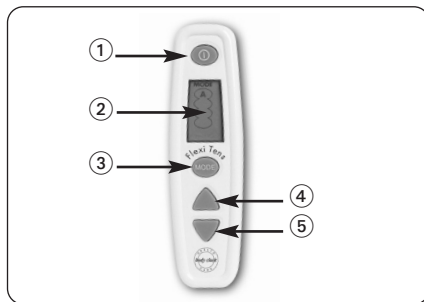
Lead Wires

The lead wires are made of high quality shielded wiring. They are made from fine wire to be flexible and lightweight and if treated gently are designed for long life. The pin ends of the leadwires are inserted into the electrodes.



Controls on the Flexi TENS

- ① **POWER** Key – Turns the Flexi TENS On and Off.
- ② **User display** – Indicates the mode in use and the intensity level. (also see diagram below).
- ③ **MODE** Key – Changes the mode in use.
- ④ **Intensity UP** – Increases the intensity of the pulses.
- ⑤ **Intensity Down** – Decreases the intensity of the pulses.



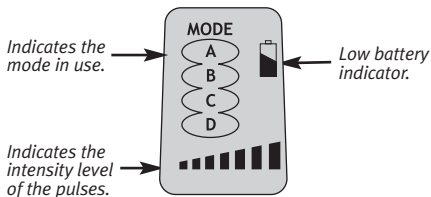
Additional Functions

Load Detector - If an electrode becomes detached from the skin, the intensity will drop back to zero.

Low Battery Indicator - A flashing battery symbol will be shown on the display.

Automatic Power Off - When the unit intensity levels are zero, and the Flexi TENS has not been in use for about 5 minutes, the unit will shut off automatically.

User Display



The assembly stage

1. Slide open the battery cover on the back of the unit to expose the battery compartment.
2. Insert the batteries according to the diagram found in the battery compartment. Replace the cover.
3. Select the leadwire that you wish to use for your treatment:
 - a). The single leadwire can be used to treat one pain area OR
 - b). The dual leadwire can be used to treat two pain areas, or a large pain area such as your back.
4. Insert the plug end of the leadwire into the jack plug socket at the bottom of the Flexi TENS.
5. Connect the electrodes to the pin ends of the leadwire (see diagram right).

Insert a red and black pin (at the end of the lead wire) into each pair of electrodes.





Before first use of the Flexi TENS, please familiarise yourself with the warnings and contraindications contained on page 10.

Using your Flexi TENS

The Flexi TENS has 4 TENS modes. Each has been designed to provide a different sensation.

You can use any of the TENS modes to treat your pain. The table below sets out a brief description of the sensation each mode provides:

Mode A	<i>Tapping</i>
Mode B	<i>Massage</i>
Mode C	<i>Tapping massage</i>
Mode D	<i>Extended burst</i>

To commence treatment

Carefully peel the electrodes from the plastic backing, using your forefinger and thumb. Then position the electrodes in accordance with the instructions provided with your electrodes or preferably from your medical advisor.

Once the electrodes are positioned correctly, switch the unit on. MODE A will start to flash on the screen.

Select the mode that you wish to use by pressing the MODE key. Once you have selected your mode, gradually increase the intensity using the arrow UP key, until the sensation is comfortable. Intensity can be reduced by using the arrow DOWN key.

Contraindications

1. Any electrode placement that applies current to the carotid sinus (neck) region.
2. Any use of TENS on patients who have a demand-type cardiac pacemaker.
3. Any electrode placement that causes current to flow transcerebrally (through the head).
4. The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.
5. TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
6. The user must keep this device out of the reach of children.
7. Electronic monitoring equipment (such as ECG monitors and ECG alarms may not operate properly when TENS stimulation is in use.

Warnings

1. The safety of TENS devices for use during pregnancy or birth has not been established.
2. TENS is not effective for pain of central origin (This includes headache).
3. TENS devices should be used only under the continued supervision of a physician.
4. TENS devices have no curative value.

Precautions

1. Isolated cases of skin irritation may occur at the site of electrode placement following long term application.
2. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

Adverse Reactions

Skin Irritation and electrode burns are potential adverse reactions.

Maintenance and Care

Guidelines for Optimum Performance:

- Change the battery regularly.
- The unit must be switched off when changing the battery.
- The unit should be wiped clean periodically using a very slightly dampened cloth. A mild soap may be used but DO NOT apply solvents.

General Precautions:

- Do not yank or twist the leadwires – treat them gently for long life. They are made from fine wire to be flexible and lightweight.
- Do not immerse your TENS in water or any other liquid
- Do not place it close to any source of excess heat
- Do not operate your unit in the presence of flammable gases

- Do not attempt to open the TENS unit
- Do not use battery or power sources other than those specified
- Do not drop this unit onto a hard surface

Checking system performance:

- If your unit does not appear to be operating properly, first change the battery. Replacing the battery can eliminate most operational problems.
- Ensure that the leadwire attachment is properly fixed to the unit.
- Check the electrodes are firmly attached to the pins of the leadwire.
- Make sure that the leadwire is not damaged or broken.

Device Failures

- Please do not attempt to repair damaged devices yourself.

- In case of further inquiries, always state the model of your device (as indicated on the back of the unit).
- Body Clock TENS should be repaired by qualified technical personnel.
- Body Clock TENS units are guaranteed for a period of 5 years against manufacturer's defects.
- Note: the guarantee is null and void if any attempt is made to open the unit by unauthorized personnel.
- In the event of a fault please contact the supplier (address found on the invoice or delivery note) or
Body Clock, 108 George Lane,
South Woodford, E18 1AD.
Tel: +44 20 8532 9595
Fax: +44 20 8532 9551
email: sales@bodyclock.net

TENS - Frequently Asked Questions

Q.Is it safe?

A.Yes, TENS is used widely for pain relief and is recommended by medical professionals.

Q.Can I use it with other medications?

A.Yes. TENS is drug free so you can use it with any other medication including paracetamol.

Q.What conditions can TENS be used to treat?

A.TENS can be used to treat numerous pain conditions. If you are unsure about using TENS please consult your medical adviser or contact Body Clock Health Care.

Technical Data

Display <i>Operation Mode</i>	<i>Four modes</i>			Output Intensity	<i>0 - 140 mA adjustable in 14 steps (500Ω load)</i>
	- A			Output Waveform	<i>Symmetrical multiphase bipolar rectangular</i>
	- B			Output Jacks	<i>CE Touch-proof jacks</i>
A B C D	<i>Pulse Frequency</i>	<i>Pulse Width (us)</i>	<i>Display</i>	Load Detector	<i>Contact detection between the device and human skin</i>
	45	208	A	Battery	<i>2 X1.5V AAA Battery (Type LR6)</i>
	55	100	B	Battery Low Detect	<i>2.2V±0.1V</i>
	44	208	C	Weight / Size	<i>45g / 12 x 3 x 1.5cm</i>
	90	100	D		
Memory	<i>Memorises latest selections when switched on</i>				
Automatic Power Off	<i>5 Minutes</i>				
Output Channel	<i>ONE Channel</i>				
Output Voltage	<i>± 70V adjustable in 14 steps (500Ω load, peak to peak)</i>				

Guarantee

Your TENS machine is guaranteed for a period of 5 years against manufacturer's defects. Please record purchase details in the space provided below for your record purposes.

The guarantee does not include leads, electrodes or battery

Name of product: Flexi TENS

Date of purchase: _____

Invoice number: _____



ISO 9001:2008 ISO 13485:2003
Medical Devices Directive 93/42/EEC Annex V

Body Clock Health Care Ltd

108 George Lane
South Woodford
London E18 1AD
England

Tel (+44) (0)20 8532 9595
Fax (+44) (0)20 8532 9551
www.bodyclock.net
e-mail sales@bodyclock.net



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