

1st Choice™ and 1st Choice Plus™

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.



Contents

Technical Data	1
-----------------------------	---

Introduction to

Patient and Professional	3
---------------------------------------	---

What is TENS and How Does it Work? ..	3
---------------------------------------	---

Accessories	4
-------------------	---

How to Place Electrodes	4
-------------------------------	---

Lead Wires.....	5
-----------------	---

How to Use the Body Clock

First Choice and First Choice Plus	6
---	---

Continuous Mode	7
-----------------------	---

Burst Mode	7
------------------	---

Modulation Mode	7
-----------------------	---

Contraindications	8
-------------------------	---

Warnings	8
----------------	---

Precautions	9
-------------------	---

Adverse Reactions	9
-------------------------	---

Maintenance and Care	10
-----------------------------------	----

Guidelines for Optimum	
------------------------	--

Performance:	10
--------------------	----

General Precautions:.....	10
---------------------------	----

Checking System Performance:	10
------------------------------------	----

Device Failures	11
-----------------------	----

Dials and Controls	12
--------------------------	----

Guarantee	13
-----------------	----

Technical Data

Equipment Type:	Dual Channel TENS
Waveform:	Asymmetrical Bi-phasic Rectangular
Output Modes:	Continuous (C), Burst (B), Modulation (M)
Output Intensity:	0-100mA (500-ohm load)
Output Voltage:	50V (500-ohm load)
Pulse Rate:	1-200Hz Adjustable
Pulse Width - 1st Choice:	250 microseconds fixed
1st Choice Plus:	50 - 250 microseconds adjustable
Burst mode:	1 per second. Pulses within each burst adjustable by pulse rate control

Modulation mode:	Pulse width automatically varies from the rate set by user, down 90% and back. Ramp up 2.5.secs, ramp down 2.5.secs
Power source:	9v PP3 battery
Output Jacks:	CE Touch-proof jacks
Unit size:	63mm x 85mm x 23mm (2 1/2" x 35/16" x 7/8")
Unit weight:	100g

Classification:

This unit is fully compliant with EEC Directive 93/42/EEC, classified as internally powered equipment type BF. It is intended for continuous operation.

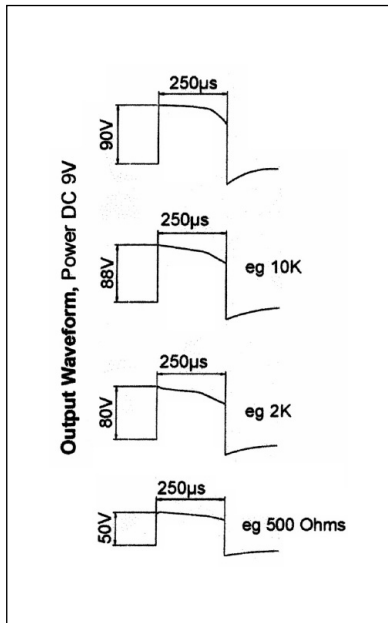
Explanation of symbols:



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. this user manual).



Introduction to Patient and Professional

The Body Clock first Choice and First Choice Plus are 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 Libra TENS is supplied with the following accessories:

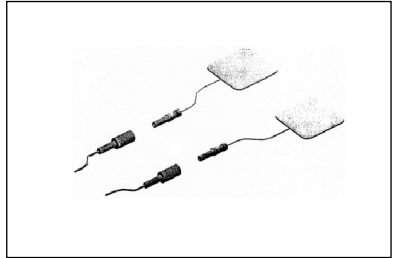
1. 1 pack of 4 50mm x 50mm self adhesive electrodes;
2. 1 9v PP3 battery;
3. 2 lead wires;
4. 1 manual; and
5. 1 carrying pouch.

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.

How to Use the Body Clock First Choice and First Choice Plus

1. **Battery Placement:** Slide the front cover down by gently pressing on the ribbed section with your thumb and move downward until battery compartment is visible. Insert battery, ensuring the positive (+) and negative (-) terminals are correctly positioned. Slide front cover up.
2. **Leadwire Connection:** Insert the pin ends of the leadwires into the self-adhesive electrodes.
3. **Electrodes:** If using self-adhesive electrodes, there is no need to use gel and tape. Please read the instructions provided with the electrodes. If using carbon rubber electrodes and gel, spread a small amount of the gel on each electrode and keep in place with permeable non-woven surgical adhesive tape.
4. **Before Beginning Stimulation:** Set the pulse rate dial to “1”. Turn the Output intensity (Amp) dials to the “0” position. Set the pulse width to “100”. Set the mode selector to switch “C”. Insert the leadwire plugs into the jack plug sockets at the top of the unit. You are now ready to commence stimulation.
5. **Stimulation:** Slowly turn the Output intensity (Amp) dials clockwise until they click to the “ON” position and the power indicator is lit. Continue to turn the dials slowly until a mild pricking sensation is felt.
6. **Pulse Rate:** By turning the pulse rate control dial slowly to the upper end of the pulse rate range (approx. 80Hz) you will feel a tingling sensation. This is based upon the Gate Control Theory. Effective pain relief may also be achieved at the lower end of the pulse rate range

(approx. 2Hz). After setting your unit to this level, you will feel a sensation like a heart beat.

7. **1st Choice Plus ONLY - Pulse Width**

Adjustment: provides extra versatility. Increasing or decreasing the setting increases or decreases the width of the pulse. Initially set the pulse width to 100 μ s and then adjust as desired.

8. **Mode Selector Switch:** This selector switch enables you to choose the different types of modes available:

Continuous mode

This mode provides a steady uninterrupted (constant) signal.

Burst mode

This mode emits a train of pulses turning on and off once per second in regular bursts. This feels like a tapping sensation.

Modulation mode

This mode provides a signal automatically decreases and then increases in regular cycles. After 5 seconds, the cycle starts over again. This can be very soothing.

Varying the modes helps your body avoid becoming used to one particular setting. Your medical adviser will be pleased to assist you to find the best settings for your particular problem. Continue stimulating for as long as necessary but preferably for no less than 30-50 minutes, unless you experience discomfort. Some people achieve pain relief after a short period of time, while others may require the use of the TENS unit for a lot longer.

- 9. Electrode Care:** If you stimulate for a number of hours, check that the self-adhesive electrodes have not dried out. If this is the case, they may be moistened with a drop of water. If using carbon rubber electrodes, check that you still have sufficient gel on them. If electrodes are allowed to dry out, this can cause minor skin irritation.
- 10. After Stimulation:** Turn the Output intensity (Amp) dials to the “o” position. Ensure that the unit is switched off before removing the leads. Do not pull out the leadwires. Always remove the jack plugs from their sockets by holding the plugs between the forefinger and thumb.
- 11. Belt Clip:** To remove belt clip, push downward with thumb. To re-attach clip, reposition it so that side flanges fit under the brackets. Slide upward until it clicks into place.

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 transcranially (through the head).
4. The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.

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.
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.
8. The First Choice and First Choice Plus are capable of delivering a pulse of 25 microcoulombs (μc). This stimulus may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax as it may cause a cardiac arrhythmia.

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:

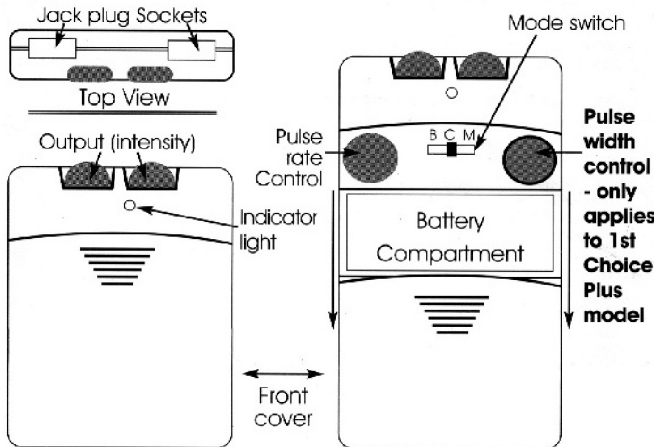
- If your unit does not appear to be operating properly, first change the battery. Replacing the battery can eliminate most operational problems.
- Ensure that the leadwire attachment is properly fixed to the unit.
- Check the electrodes are firmly attached to the pins of the leadwire.
- Make sure that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

Dials and Controls

1st Choice and 1st Choice Plus



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: 1st Choice / 1st Choice Plus

Date of purchase: _____

Invoice number: _____



Medical Devices Directive 93/42/EEC Annex V

Body Clock Health Care Limited

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



November 2006 (1)