

miracleTENS



Instructions for use

the**miracle**box[®]





The Miracle TENS is an ultra simple yet powerful obstetric TENS unit perfect for drug-free pain relief during labour. It has 2 pre-set modes one for use during contractions, the other for use between contractions.

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, which 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 a BF type (floating) applied part.



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



Denotes a product which must be disposed of safely.





Contents

<i>How will the Miracle TENS Help Your Pain?</i>	<i>3</i>
<i>Precautions and Contraindications</i>	<i>4</i>
<i>The Miracle TENS Controls</i>	<i>5</i>
<i>Additional Functions</i>	<i>5</i>
<i>Setting up your Miracle TENS</i>	<i>6</i>
<i>Suggested Pad Placement Chart.....</i>	<i>7</i>
<i>Using your Miracle TENS</i>	<i>8</i>
<i>Frequently Asked Questions</i>	<i>9</i>
<i>Troubleshooting Questions.....</i>	<i>9</i>
<i>Useful Information.....</i>	<i>10</i>
<i>Post-Natal Pad Placement Diagrams</i>	<i>10</i>
<i>Technical Data</i>	<i>11</i>



How will the Miracle TENS Help Your Pain?



TENS (Transcutaneous Electrical Nerve Stimulation) works by passing mild electrical impulses through the skin, via electrode pads, into the nerve fibres which lie below. The TENS impulses help your body produce its own pain killing chemicals, such as ‘endorphins’.

The level of pain relief obtained from the Miracle TENS varies from person to person. Some find that the Miracle TENS provides all the pain relief required during the whole of labour, whereas others find that other analgesics are also needed during the later stages of labour.





Precautions and contraindications

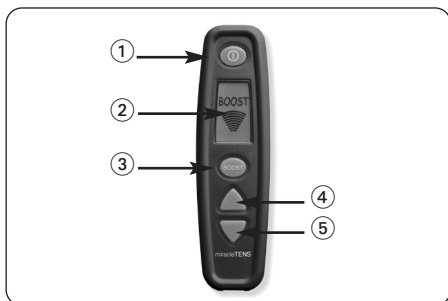
1. Do **NOT** use the Miracle TENS if you have a cardiac pacemaker.
2. Check with your medical adviser before using if you suffer from a heart condition, epilepsy, undiagnosed pain, have any metal implants, or any doubts whatsoever.
3. TENS must **NOT** be used before the 37th week of pregnancy.
4. Never use TENS to mask undiagnosed pain since this could require urgent treatment.
5. If you are pregnant, do **NOT** place the electrodes over your abdomen.

General Precautions

1. Do **NOT** use this unit without first reading these instructions.
2. Do **NOT** immerse the Miracle TENS in any liquid.
3. Do **NOT** place it close to any source of excessive heat or operate it in the presence of flammable gas.
4. Do **NOT** drop this unit onto a hard surface.
5. Do **NOT** attempt to dismantle the Miracle TENS.
7. Only use specified batteries and electrodes.
8. If damaged, do not use. Return to supplier.
9. Remove the batteries when not in use.
10. Do **NOT** use while driving or operating potentially dangerous machinery or while using a microwave.
11. Keep out of the reach of children.
12. Do **NOT** place electrodes on or near the eyes, in the mouth, over the front or sides of the neck, across the head, heart, or an area of broken, inflamed, infected or numb skin. Electrodes should generally only be applied to skin with normal sensation unless under medical supervision.
13. Do **NOT** use in the presence of tuberculosis, malignant tumours, very high or very low blood pressure, epilepsy, high fever or acute inflammatory disease unless under medical supervision.
14. A mild shock may be caused if one electrode is accidentally removed. In the event of this happening the unit should be turned off immediately.



Controls on the Miracle TENS



- ① **POWER** Key – Turns the Miracle TENS On and Off.
- ② **User display** – Indicates the mode in use and the intensity level. (also see diagram below).
- ③ **BOOST** Key –Used for extra surge during contractions.
- ④ **Intensity UP** – Increases the intensity of the pulses.
- ⑤ **Intensity Down** – Decreases the intensity of the pulses.

User Display

BOOST - This mode is used during contractions.

Low Battery indicator.



BURST -

This function is used at the onset of labour and in-between contractions.

Power Bar: This indicates the intensity of the pulses from 0 to 10 for both sets of pads.

Additional Functions

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 Miracle TENS has not been in use for about 5 minutes, the unit will shut off automatically.



Setting up your Miracle TENS

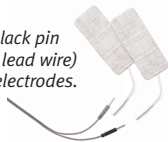
Check you have the following contents:

- 1 x Miracle TENS unit
- 1 x Pack of 4 self adhesive electrodes (40mm x 100mm)
- 1 x Leadwires
- 2 x AAA batteries
- 1 x Carrying pouch
- 1 x Easy-release neck cord
- 1 x Instruction manual

The assembly stage

1. **Slide open the battery cover on the back of the unit to expose the battery compartment.**
2. **Insert 2 x AAA batteries according to the diagram found in the battery compartment. Replace the cover.**
 - a) Take one of the black leadwires and insert the black jack plug at the end of the lead into the socket at the bottom of the Miracle TENS unit.
 - b) Now insert the red and black pins (at the other end of the leadwire) into the sockets attached to the sticky electrodes. You will see that the lead wire is made up of 4 black wires. Do not remove the electrodes from the backing at this stage (see figure below). NB. Each leadwire has a red and black pin at the end. It makes NO difference whatsoever which electrode they are attached to!
 - c) If you wish, attach the easy-release neck cord which enables you to hang the Miracle TENS from your neck whilst in labour.

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

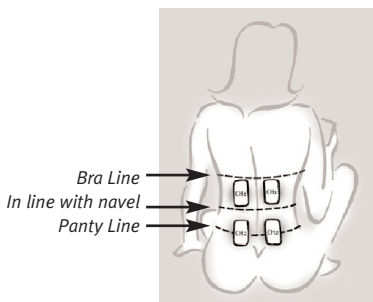




Suggested Electrode Placement Chart

The sticky electrode pads need to be placed in the correct position for maximum pain relief. It is preferable to obtain assistance from either your birthing partner or medical adviser when positioning the pads. Please read the following instructions carefully:

1. Carefully peel the pads from the plastic backing using your forefinger and thumb. Do not pull on the lead wires.
2. Position the top pads (connected to the black coloured leads) approximately 4cm either side of the spine and 4-5cm above the imaginary navel line as seen in the diagram.
3. Position the bottom two pads (connected to the black coloured leads) approximately 4cm either side of the spine and 4-5cm below the imaginary navel line as seen in the diagram. NB. It makes no difference whatsoever which pads are at the top as long as they are in horizontal pairs.



Reference: Cluett E. (1994) SRN RM ADM PGCEA.
Analgesia in Labour: A review of the TENS method.
Professional Care of Mother and Child. Mar;4 (2): 50-2.





Before first use of the Miracle TENS, please familiarise yourself with the precautions and contraindications contained on page 4.

Using your Miracle TENS

- a) You are now ready to start using your Miracle TENS. Switch the unit on by pressing the on/off button. The Miracle TENS will always start up in BURST mode.

- b) Begin by pressing the intensity Up key. Each time you press this key, a small 'half-moon' shape will appear on the screen increasing in number and size as the intensity is increased. You will begin to feel a pulsating sensation which will burst in time with the 'half-moon' shape as shown on the LCD. You will feel this sensation in both sets of pads.

- d) **BURST (use between contractions):** This is the first mode that you will use. It feels like a bursting, tingling sensation i.e. the pulses are off and on periodically. This mode will help to promote those all important natural pain-killing chemicals known as 'endorphins' and 'encephalins'.

- e) **BOOST (use during contractions):** When experiencing a contraction, simply press the 'BOOST' button. The Miracle TENS will then switch automatically into the BOOST mode for that extra surge of power required to combat the pain during contractions. This will feel like a continuous sensation.

- f) Once the contraction has passed, simply press the 'boost' button. The Miracle TENS will return to the original BURST mode. Continue this cycle during your early stages of labour.



Frequently Asked Questions

Q When shall I start using my Miracle TENS?

A Use as early as you can after the onset of labour to allow time for your body's pain-killing chemicals to rise.

Q Can I try the Miracle TENS before going into labour?

A Yes, place 2 pads on your forearm to feel the different pulse sensations following the instructions on page 6.

Q Can I combine the Miracle TENS with other medication?

A Yes, you can still use analgesics such as gas and air (entinox) or pethidine.

Q Can the Miracle TENS be used in hospital?

A Yes. However, a midwife may ask you to switch it off temporarily.

Q Can I use the Miracle TENS if I am considering a water birth?

A Yes, but not in the water itself.

Troubleshooting Questions.

Q Why does the stimulation not appear to be as strong after you have used the Miracle TENS for a while?

A Increase the intensity, you may have become used to a lower setting.

Q Why does the stimulation feel strong but ineffective?

A You may need to reposition the electrode pads.

Q Why does the stimulation not feel sufficiently strong even on a high setting?

A The batteries may need replacing.

Q What do I do if there is no stimulation, intermittent stimulation, or weak stimulation felt even with a new battery?

A Check electrode contact. Check leads. Check batteries. Phone Miracle TENS on 0870 803 3371

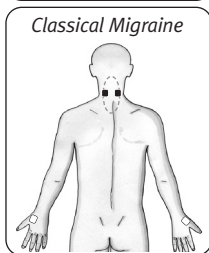
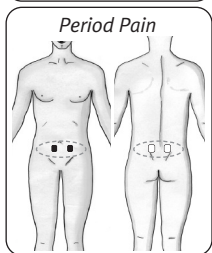
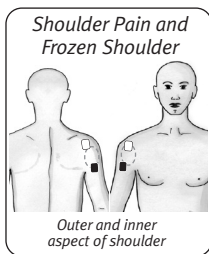
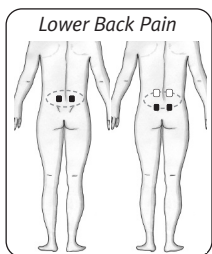


Useful information

1. Continue stimulation for as long as necessary, unless you experience discomfort.
2. If you stimulate for a number of hours ensure the pads do not become dry. If this occurs, switch off the unit, disconnect the electrodes, and apply a small drop of water to them.
3. Always ensure that the unit is switched off before you remove the leads. Do not pull the wires. ALWAYS remove the jack plugs from their sockets by holding the plugs between the forefinger and thumb.
4. The Mirale TENS can also be used as a standard TENS unit for relief of numerous conditions, including after pains and post operative pains. It is worth bearing this in mind if you have a caesarean section. Please seek medical advice first.

KEY: ■ ■ = first pair of electrodes □ □ = second pair of electrodes.

N.B. Electrodes supplied with this unit are all the same colour - the black and white squares show suggested electrode placement only.



Technical Data

Display	The LCD has a total of 13 display segments. The array of Level Bars consists of 10 LCD Level Bar. In addition, 2 individual LCD segments respectively indicate the Modes (i.e. Burst and Boost). The last LCD segment is used to illuminate the low battery indicator.		
Mode	2 operation modes		
	<i>Pulse (Hz) Frequency</i>	<i>Pulse Width (μs)</i>	<i>Pattern</i>
	Burst	32	200
Boost	80	100	2 bursts per second and 8 pulses per burst Constant pulse
Output Channel	ONE Channel		
Output Voltage	0 – 100V (zero-to-peak) across a 500Ω load; adjustable in 10 steps		
Output Intensity	200mA (max.) into a 500Ω load		
Output Waveform	Symmetrical Mono-phasic rectangular		
Output Jacks	CE Touch-proof jacks		
Battery	2 X1.5V AAA Battery (Type LR03)		
Battery Low Detect	2.2V±0.1V		
Tolerances	All output parameters are subjected to a ±10% tolerance unless other specified		



ISO 9001:2008 ISO 13485:2003
EC DIRECTIVE 93/42/EEC Annex V

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June 2009 (2)