

Babycare TENS™



CE
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Medical Devices Directive 93/42/EEC Annex V

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Babycare TENS is part of the Body Clock group of companies





Babycare TENS™


Elle TENS

Instructions
for use



Elle TENS Quick Reference Guide


If you are in labour, please use the quick reference guide set out below. It is however recommended that you read the section entitled “Setting Up Your Elle TENS” found on page 5 to obtain the best performance from your unit.

 Before using the Elle TENS, please read the contraindications and warnings on page 2.


1. Insert 2 x AA batteries in the compartment at the back of the unit (see figs 1 and 2, page 6).
2. Insert the leadwire plugs into the top of the unit (see fig 3, page 6).
3. Insert the pins at the other end of the leadwires into the sockets attached to the electrode pads. Do not remove the electrodes from their backing at this stage (see fig 4, page 6)

4. Position the electrode pads on the body as indicated on page 7.

5. Make sure that the ‘boost’ button at the side of the unit is NOT pressed in. This ensures that the unit will start in the BURST 1 mode (see page 3).

6. Press the  (on/off) to turn the unit on.

7. Now push the  (CH1 +) key until you feel a pulsating sensation.

8. Repeat the same with the  (CH2+) key.

9. At the onset of a contraction press the ‘boost’ button for the additional surge of power needed to combat the pain.

10. Release the ‘boost’ button once the contraction has passed and continue in the BURST 1 mode as before.

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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 page 2 of these instructions.

How will the Elle 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 varies from person to person. Some find that the Elle 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.

Introduction to the Elle TENS

The Elle TENS is the state-of-the-art, efficient method of drug-free pain relief with no known side effects. In order to obtain maximum benefit, it is advised that you seek guidance from your medical adviser as well as reading this instruction guide.

Frequently Asked Questions

Q) When shall I start using my Elle 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 Elle TENS before going into labour?

A) Yes, place 2 pads on your forearm to feel the different pulse sensations following the instructions on page 5.

Q) Can I combine the Elle TENS with other medication?

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

Q) Can the Elle TENS be used in hospital?

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

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

A) Yes, but not in the water itself.

When Should TENS Not Be Used?



Contraindications

1. Do **NOT** use TENS before 37 weeks of pregnancy unless under medical supervision.
2. Electrodes should only be positioned as recommended (see page 7) unless otherwise stated by your midwife or medical adviser.
3. Do **NOT** place electrodes on the abdomen (before birth), the front or side of the neck, or areas on the head, which could cause current to flow transcranially.
4. Do **NOT** use TENS if you have a demand-type cardiac pacemaker.
5. If you suffer from epilepsy, or any undiagnosed pain, consult your medical adviser.



Warnings

1. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.

2. Skin irritation can occur following long term application.

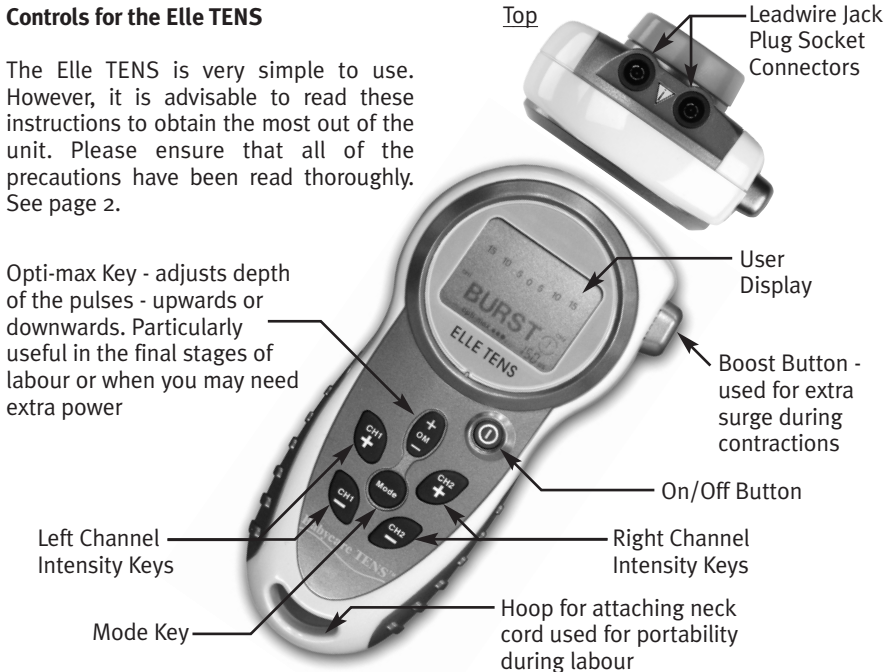
General Precautions

1. Do not use this unit without first reading these instructions.
2. Do not immerse the Elle TENS unit in water or any liquid.
3. Do not place it close to any source of excessive heat.
4. Do not operate this unit in the presence of flammable gas.
5. Do not drop this unit onto a hard surface.
6. Do not attempt to open the Elle TENS unit.
7. Only use the specified batteries and electrodes.
8. If damaged as in precautions 2-5 above, do not use. Return to supplier.
9. Remove the batteries when the Elle TENS unit is not in use.
10. Do not use TENS whilst driving or operating potentially dangerous machinery.

Controls for the Elle TENS

The Elle TENS is very simple to use. However, it is advisable to read these instructions to obtain the most out of the unit. Please ensure that all of the precautions have been read thoroughly. See page 2.

Opti-max Key - adjusts depth of the pulses - upwards or downwards. Particularly useful in the final stages of labour or when you may need extra power



Left Channel Intensity Keys

Right Channel Intensity Keys

Mode Key

Hoop for attaching neck cord used for portability during labour

On/Off Button

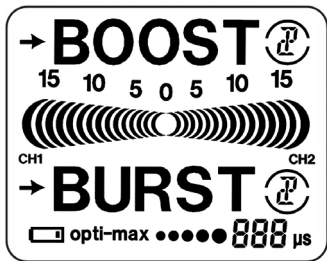
Boost Button - used for extra surge during contractions


User Display


Top

Leadwire Jack Plug Socket Connectors


Display Symbols and Their Meanings




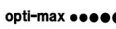
 Power Bar: This shows the output from 0 to 15 for both left and right channels. Each segment represents approximately 7% of the total output.

→ **BOOST** : Pressing the 'Boost' button at the top right of the unit activates the Boost mode. This function is used during contractions. The small arrow to the left of the word Boost will remain on, indicating the unit is in a continuous mode. There are two Boost modes available indicated by a 1 or 2 in a small circle next to the word

BOOST. You can switch between them by pressing the Mode key.

※ **BURST** : This function is used at the onset of labour and in-between contractions. The small arrow to the left of the word Burst will flash in time with the bursting rhythm you feel from the Elle TENS. There are two Burst modes available indicated by a 1 or 2 in a small circle next to the word BURST. You can switch between them by pressing the Mode Key.

 Low Battery Indicator: This sign will start flashing when the batteries are running low. If this is the case, change both batteries. Please refer to page 5 for instructions.

opti-max  **888** μs Opti-max: Indicates the Opti-max output. Each segment represents 20% of total Opti-max power. Please refer to page 8 for more details.

Setting Up Your Elle TENS

Check the following contents:

- 1 x Elle TENS unit
- 1 x Pack of 4 self adhesive electrodes (40mm x 100mm)
- 3 x Leadwires (2 for use and 1 spare)
- 4 x AA batteries (2 for use and 2 spare)
- 1 x Carrying pouch
- 1 x Easy-release neck cord
- 1 x Instruction manual
- 1 x Women's Guide to Drug Free Pain Relief (if you have purchased this unit)

The Assembly Stage

a) Press and rotate the belt clip at the back of the Elle TENS in either direction to reveal the battery compartment (see fig 1, page 6).

b) Release the battery compartment cover and insert 2 x AA batteries (see fig 2, page 6), ensuring the positive (+) and

negative (-) terminals are correctly positioned as marked in the battery compartment. Replace the cover.

c) Take two of the purple leadwires and insert each of the black jack plugs (at one end of each leadwire) into the sockets at the top of the Elle TENS unit (see fig 3, page 6).

d) Now insert the pins (at the other end of the leadwires) into the sockets attached to the sticky electrodes. Do not remove the electrodes from the backing at this stage (see fig 4, page 6).

NB. Each leadwire has a red and black pin. It makes **NO** difference whatsoever which electrode they are attached to!

e) If you wish, attach the easy-release neck cord which enables you to hang the Elle TENS from your neck whilst in labour (see fig 5, page 6).

Useful Diagrams



Inserting the battery

Press and rotate the belt clip to reveal the battery compartment.

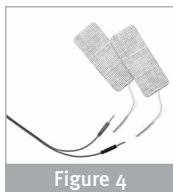


Release the battery compartment and insert the batteries.



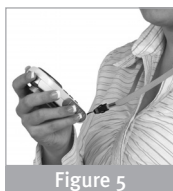
Connecting the leads

Insert both black jack plugs into the sockets.



Connecting the Electrode Pads

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



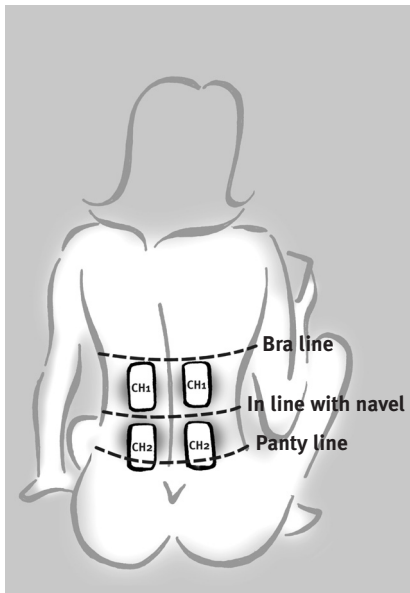
Using the Neck Cord for mobility during labour.

Thread the loop of the neck cord through the space at the base of the unit. Slip the other end of the neck cord through the loop and pull into position.

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 two pads (connected to the left socket CH1) 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 right socket CH2) approximately 4cm either side of the spine and 4-5cm below the imaginary navel line as seen in the diagram.




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.

Using your Elle TENS

a) You are now ready to start using your Elle TENS. Switch the unit on by pressing the  on/off button. Ensure that the 'boost' button located at the top right of the unit is NOT pressed in. The Elle TENS will always start up in BURST 1 mode.

b) Begin by pressing the  CH1+ 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 small arrow flashing on the screen.

c) Repeat the previous step with the  CH2+ key. You will now feel a sensation in both sets of pads.

d) BURST 1 (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 1 (use during contractions):
When experiencing a contraction, simply press the 'boost' button located at the top right of the unit. The Elle TENS will then switch automatically into the BOOST 1 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 release the 'boost' button. The Elle TENS will return to the original BURST 1 mode. Continue this cycle during your early stages of labour.

The Mode Button

There are two modes available on the Elle TENS, each with a Burst and Boost function.

Mode 1 (Burst 1 and Boost 1), which has been described above, is primarily used for the earlier stages of labour.


Mode 2 (Burst 2 and Boost 2) can be used when your labour advances and your contractions become more frequent.

Press the  Mode button to switch between modes. You will see from the User Display, that the number in the small circle next to the BURST or BOOST will change from 1 to 2 and vice-versa.

NB. Both modes are interchangeable and can be used according to your preference, not necessarily for the stage of labour you are in.

The Opti-max Key

This provides extra versatility to your Elle TENS. Increasing or decreasing the Opti-max key will allow you to either heighten or lessen the level of pulse power transmitted to the electrode pads.

Pressing the  OM key either + or - will increase or decrease Opti-max sensation, this is extremely useful for the final stages of labour when you need an extra surge of power.

There are 5 Opti-max levels indicated by 5 dots, enlarging in size as the Opti-max power is increased. The unit will always start up at Opti-max 3, which is exactly half way between the highest and lowest setting.

NB. The Opti-max key can be used according to your preference and not necessarily for the stage of labour you are in.

Useful information

Continue stimulation for as long as necessary, unless you experience discomfort.

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.

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.

N.B. The Elle 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 caesarian section. Please seek medical advice first.

Troubleshooting Questions

Q) Why does the stimulation not appear to be as strong after you have used the Elle 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 Babycare TENS on 0845 230 9737.

Elle TENS - Technical Specifications

| | |
|-----------------------|---|
| Equipment type | Dual Channel Digital TENS |
| Display | Digital LCD - 5 seven segment digits around 42 segments |
| Modes | 2 burst modes and 2 boost modes |

| | Pulse Frequency (Hz) | Pulse Width (μ s) | Description |
|----------------|----------------------|------------------------|--|
| Burst 1 | 16 | 150* | 1 burst per second, 8 pulses per burst |
| Burst 2 | 32 | 150* | 2 bursts per second, 8 pulses per burst |
| Boost 1 | 80 | 150* | Continuous |
| Boost 2 | 100 | 150* | Continuous |

* Default pulse width after mode changed (pulse width is NOT changed when switched between BURST and BOOST mode)

5 selectable pulse widths in all modes:
50, 100, 150, 200, 250

Elle TENS - Technical Specifications Continued

| | |
|------------------------------|--|
| Automatic Power Off | The Elle TENS will switch off after 5 minutes if not used |
| Output Voltage | 0 - 55v zero to peak adjustable in 15 steps at 500Ω load |
| Output Intensity | 0 - 110mA adjustable in 15 steps at 500Ω load Intensity level will drop back to zero after programme changes |
| Output Waveform | Symmetrical bi-phasic rectangular |
| Output Jacks | CE Touch-proof jacks |
| Battery | 2 x 1.5v AA Battery (Type LR6) |
| Unit Size | 115mm x 55mm x 30mm |
| Unit Weight | 75 grams |
| Low Battery Indicator | 2.2V±0.2V |

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.