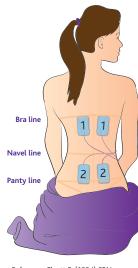
Suggested Electrode Placement Chart

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. Ensure unit remains switched off. 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. Ensure that you increase the intensity slowly.
- c) Repeat the previous step with the CH2+ key. You will now feel a sensation in both sets of pads.

 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

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. Mode 2 can be operated in the same way as mode 1.

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.



EFFELENZ



Q When shall I start using my Elle TENS?

Frequently Asked Questions

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

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

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

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.

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. Switch the unit off, and then try the unit again.
- 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 0333 121 9737.

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.
- The pads can be used several times. Replace the pads when they stop sticking to the skin.
 Replacement pads are available from www.babycaretens.com
- 4. Always ensure that the unit is switched off before you remove all the leads and pads. Do not pull the wires. ALWAYS remove the jack plug from its socket by holding the plug between the forefinger and thumb and pulling gently.
- 5. 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 caesarean section.
 Please seek medical advice first.

Post-Natal Pad Placement Diagrams

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

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

to combat the pain during

a continuous sensation.

extra surge of power required

contractions. This will feel like

pain-killing chemicals known as

'endorphins' and 'encephalins'.

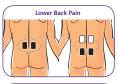
KEY

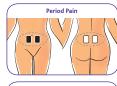
■ = first pair of electrodes

of labour.

= 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.







Elle TENS Technical Data

Display	TN type LCD			
Operation Mode	4 treatment modes: Burst 1, Burst 2, Boo	eatment modes: t 1, Burst 2, Boost 1, Boost 2		
	Pulse (Hz) Frequency	Pulse Width (μs)	Description	
Burst 1	16	150*	1 Burst/sec and 8 pulses per burst	
Burst 2	32	150*	2 Burst/sec and 8 pulses per burst	
Boost 1	80	150*	Constant	
Boost 2	100	150*	Constant	
	- Output Voltage: 0 – 55V zero to peak at 500Ω load - Output Waveform: Symmetrical biphasic rectangular			
Automatic Power Off	5 Minutes			
Output Channel	Two Channel			
Output Voltage	$0-55V$ (zero-to-peak) across a 500Ω load; adjustable in 15 steps			
Output Intensity	$0-110$ mA (max.) into a 500Ω load			
Output Waveform	Symmetrical bi-phasic rectangle			
Output Jacks	CE Touch-proof jacks			
Load Detector	Contact detection between the device and human skin (This feature is activated from Level 2 and up)			
Battery	2 x 1.5V AA Battery			
Battery Low Detect	2.2V ±0.2V			
Tolerances	All output parameters are subjected to a ±20% tolerance unless other specified.			
Weight	75g			
Size	60 x 120 x 35mm			

* Default pulse width after mode changed (pulse width is <u>NOT</u> changed when switched between BURST and BOOST mode) 5 selectable pulse widths in all modes: 50, 100, 150, 200, 250.

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.

Guarantee

Your ElleTENS machine is guaranteed for a period of 2 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. Applies to purchases only.

Date of purchase:

Invoice number:

Babycare TENS

Body Clock Health Care Ltd

108 George Lane, South Woodford, London E18 1AD

Tel (+44) (0)20 8532 9595 Fax (+44) (0)20 8532 9551 www.babycaretens.com e-mail customercare@babycaretens.com

> Babycare TENS is part of the Body Clock group of companies



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This manual is recyclable

11

Ouick 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 pages 1 and 2.

- 1. Ensure the Elle TENS unit is switched off.
- 2. Insert 2 x AA batteries in the compartment at the back of the unit (see figs 1 and 2, page 6).
- 3. Insert the leadwire plugs into the top of the unit (see fig 3, page 6).
- 4. 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).

Controls For The Elle TENS

Opti-max Kev -

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

Mode Key

Intensity Keys

The Elle TENS is very simple to use. However, it is advisable to read these

precautions have been read thoroughly. See page 2.

instructions to obtain the most out of the unit. Please ensure that all of the

- 5. Position the electrode pads on the body as indicated on page. A pair of electrodes must be connected to each lead wire in order for you to feel any sensation. The electrode pads must be peeled away from their backing and placed directly on your body for you to feel any sensation.
- 6. 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).
- 7. Press the (0) (on/off) to turn the unit on.
- 8. Now push the (CH1+) key until you feel a pulsating sensation
- 9. Repeat the same with the (CH2+) key.
- 10. At the onset of a contraction press the # 'boost' button for the additional surge of power needed to combat the pain.
- 11. Release the 'boost' button once the contraction has passed and continue in the BURST 1 mode as before.

Leadwire Jack

Plug Socket

Connectors

User Display

Boost Button -

used for extra

surge during

contractions

On/Off Button

Right Channel

Intensity Keys

Hoop for attaching neck

cord used for portability

during labour

Contents

Elle TENS Quick Reference Guide How Will The Elle TENS Help Your Pain?......1 Introduction To The Elle TENS 1 General Precautions..... Controls For The Elle TENS...... Display Symbols and their Meanings...... 4 Setting Up Your Elle TENS5 Useful Diagrams..... Suggested Electrode Placement Chart....... 7 Using Your Elle TENS Frequently Asked Questions...... 10 Troubleshoooting Questions...... 10 Useful Information..... Technical Specifications...... 12

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 pages 1-2 of these instructions.

This symbol indicates the SN serial number of the device and includes the year of manufacture. The serial number can be found in the battery compartment of

this device.

Please keep device away

IP22 The first number 2:

from sprays of water or rain.

Protected against access to

and the jointed test finger

of 12 mmΦ, 80 mm length,

clearance from hazardous

parts, and protected against

solid foreign objects of 12.5

Protected against vertically

falling water drops when

enclosure tilted up to 15°.

have no harmful effects

Vertically falling drops shall

when the enclosure is tilted

at any angle up to 15° on

either side of the vertical

Denotes a product which

must be disposed of safely.

shall have adequate

mmΦ and greater.

The second number 2:

hazardous parts with a finger,

This unit needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENT.

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 2: 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 BLIRST 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 us

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

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' and 'encephalins'.

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 uses a state-ofthe-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.

Setting Up Your Elle TENS

Check the following contents:

1 x Pack of 4 self adhesive

· 1 x Easy-release neck cord

1 x Instruction manual

The Assembly Stage

1, page 6).

b) Release the battery

· 1 x EMC documentation

a) Press and rotate the belt clip

at the back of the Elle TENS in

either direction to reveal the

battery compartment (see fig

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. Ensure the

leadwires and insert each of

unit is switched off.

c) Take two of the purple

electrodes (40mm x 100mm)

1 x FIIe TFNS unit

· 2 x Leadwires

2 x AA batteries

· 1 x Carrying pouch

Precautions and Contraindications

- 1. TENS must NOT be used before the 37th week of pregnancy.
- 2. If you are pregnant, do NOT place the electrodes over your abdomen.
- 3. Do <u>NOT</u> use if you have a pacemaker or any other implanted electrical device.
- 4. Check with your healthcare professional before using if you suffer from a heart condition. epilepsy, undiagnosed pain, have any metal implants, or any doubts whatsoever.
- 5. Do NOT use if you experience an allergic reaction to the electrodes.
- 6. Never use TENS to mask undiagnosed pain since this could require urgent treatment.

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).

other end of the leadwires) into

sticky electrodes. Fach leadwire

has two pins, ensure each pin

Do not remove the electrodes

from the backing at this stage

is attached to an electrode.

NB. Each leadwire has a

red and black pin. It makes

NO difference whatsoever

which electrode they are

easy-release neck cord which

enables you to hang the Elle

TENS from your neck whilst

in labour (see fig 5, page 6).

Now place your electrodes

NB. The unit should be wiped

bacterial wipes or a very slightly

dampened cloth. A mild soap

may be used but DO NOT apply

clean periodically using

medically approved anti-

(see fig 4, page 6).

attached to!

(see page 7).

solvents

e) If you wish, attach the

the sockets attached to the

d) Now insert the pins (at the

General Precautions

- 1. Do NOT use this unit without first reading these instructions.
- 2. Do NOT immerse the Elle TENS in any liquid. Do not use in the bath or the shower.
- 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 Elle TENS.
- 6. Only use specified batteries and electrodes
- 7. If damaged, do not use. Return to supplier.
- 8. Remove the batteries when not
- 9. Do NOT use while driving or operating potentially dangerous machinery or while using a microwave.

- 10. Keep out of the reach of children.
- 11. Do NOT place electrodes on or near the eyes, in the mouth, over the front or sides of the neck or across the head or the heart.
- 12. Do NOT place the electrodes on varicose veins or recent scarring or on any 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, 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.

Useful Diagrams



Inserting the battery

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



compartment and

Release the battery insert the batteries.

Connecting the leads Insert both black iack plugs into the sockets.



Electrode Pads

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.

Connecting the

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