Babycare TENS®

ELLE TENS 2™



Instructions for use

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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 pages 1-2 of these instructions.

EC REP EU Representative.

Please keep device away from sprays of water or rain.

IP22 The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mmΦ, 80 mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5 mmΦ and greater. The second number 2: Protected against vertically falling water drops when enclosure tilted up to 15°. Vertically falling drops shall have no harmful effects 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.

SN This symbol indicates the serial number of the device. It can be found in the battery compartment and outer packaging. It includes the year of manufacture (YOM) which appears as two digits after the letters FD e.g. FDXX. The digits following the YOM identify each individual device.

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.

How Will The Elle TENS 2 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 2 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 2

The Elle TENS 2™ is an efficient method of drug-free pain relief. This powerful digital TENS unit is smooth, sophisticated and simple to use. It has been cleverly crafted by Babycare TENS specifically for home use for mums-to-be, for the management of pain for labour and beyond.

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 NOT 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.

General Precautions

1. Do NOT use this unit without first reading these instructions.
2. Do NOT immerse the Elle TENS 2 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 2.
6. Only use specified batteries and electrodes.
7. If damaged, do not use. Return to supplier.
8. Remove the batteries when not in use.
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.

NB. The unit should be wiped clean periodically using medically approved anti-bacterial wipes or a very slightly dampened cloth. A mild soap may be used but DO NOT apply solvents.

Controls For The Elle TENS 2

The Elle TENS 2 is very simple to use. However, it is essential to read these instructions to obtain the most out of the unit.

Please ensure that all of the contraindications and precautions have been read thoroughly. See pages 1 and 2.



N.B. Automatic Power Off
When the intensity levels are zero, and the Elle TENS 2 has not been in use for 5 minutes, it will shut off automatically.

Display Symbols And Their Meanings

▶BURST
BURST is used at the onset of labour and in between contractions. There are two Burst modes available indicated by a 1 or 2. You can switch between them by pressing the Mode Button (see page 9).

▶BOOST
The Boost Button at the top right of the unit activates the BOOST mode. This function is used during contractions. There are two Boost modes available indicated by a 1 or 2. You can switch between them by pressing the Mode Button.

BETWEEN CONTRACTION TIMER
Starts by pressing the Boost Button, this automatically measures the time interval between your contractions.

MODE 1 AND 2
There are two mode ranges available each with a Burst and Boost function (see page 9).

LOW BATTERY INDICATOR
This sign will start flashing if the batteries run low. If this is the case, change both batteries. Please refer to page 5 and 6 for instructions.

POWER BAR
This shows the output from 0 to 15 for both channel 1 and 2.
Each segment represents approx 7% of the total output.

CONTRACTION TIMER
Starts by pressing the Boost Button, this automatically records the duration of your contractions.

OPTI-MAX
Indicates the Opti-Max output. Refer to page 9 for more details.

PAD CONTACT WARNING (safety cut-out)
This symbol will appear if any of your pads are not attached securely to the skin.

Setting Up Your Elle TENS 2

Check the following contents:

- 1 x Elle TENS 2 Unit
- 1 x Pack of 4 Self Adhesive Electrodes (40mm x 100mm)
- 2 x Leadwires and 1 Spare
- 2 x AA Batteries and 2 Spare
- 1 x Carrying Pouch
- 1 x Easy-Release Neck Cord
- 1 x Instruction Manual
- 1 x EMC documentation

The Assembly Stage

Make sure the unit is swiched off.

a) Press and rotate the belt clip at the back of the Elle TENS 2 in either direction to reveal the battery compartment.

b) Release the battery compartment cover and insert 2 x AA batteries 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 into the sockets at the top of the Elle TENS 2 unit.

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.

NB. Each leadwire has a red and black pin. It makes no difference which electrode they are attached to.

e) If you wish, attach the easy-release neck cord which enables you to hang the Elle TENS 2 from your neck.

Using the Neck Cord for mobility during labour
Thread the loop of the neck cord through the space at the top of the unit. Slip the other end of the neck cord through the loop and pull into position.

Useful Diagrams

Figure 1

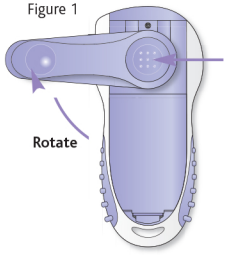


Figure 2

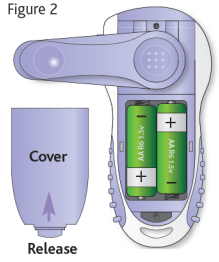


Figure 3

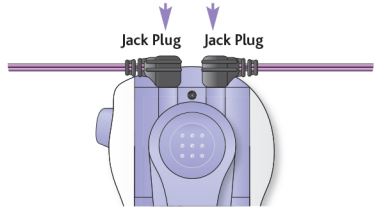
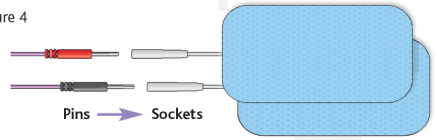


Figure 4



Elle TENS 2
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 2" found on page 5 to obtain the best performance from your unit.

Before using the Elle TENS 2, please read the contraindications and warnings on pages 1 and 2.

1. Ensure the Elle TENS 2 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).
5. Position the electrode pads on the body as indicated on page 7. 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 (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.

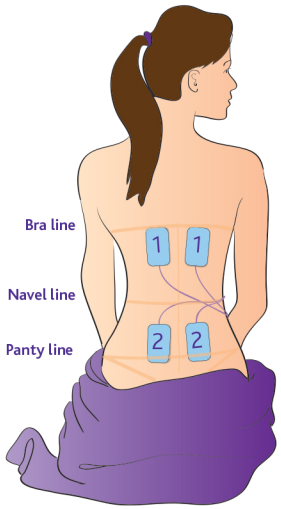
Suggested Electrode Placement Chart

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.



Electrodes can be used several times but the number of uses varies according to the condition of the skin.

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 2

a) You are now ready to start using your Elle TENS 2. 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 2 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.

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 2 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 2 will return to the original BURST 1 mode. Continue this cycle during your early stages of labour.

Using the Contraction Timer

The first time you press the Boost Button, the Elle TENS 2 will automatically trigger the Contraction Timer (CT). This can be seen in the bottom right of the display. This measures the duration of your contractions in seconds. Once the contraction has passed and the Boost Button is released, the unit will trigger the Between Contraction Timer (BCT) which measures the time between contractions. This can be seen in the bottom left of the display.

Recalling your contraction history

To recall a list of your last 5 'Contraction Times' (CT) and 'Between Contraction Times' (BCT) press the CH1- and CH2- buttons simultaneously. The last recorded set of BCT and CT times are shown as 1.

Use CH2+ to go back to previous sets (eg, 2, 3, 4, 5) or forward again by pressing CH2- key. Recalling the contraction history will not interrupt the functionality of the unit. N.B. To avoid losing contraction history, do NOT switch unit off. To return back to the original mode screen, (which will have continued counting in the background) press the CH1- and CH2- buttons together again.

The Mode Button

There are two mode ranges available on the Elle TENS 2, 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) usually used when your labour advances and your contractions become more frequent.

Press the Mode Button to switch between mode ranges. You will see from the User Display, that the number on the centre right of the display will change from 1 to 2 (and vice-versa). N.B. 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 2. 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 Opti-Max 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: 50, 100, 150, 200 and 250μs (microseconds). The unit will always start up at Opti-Max 150μs, which is exactly half way between the highest and lowest setting.
N.B. The Elle TENS 2 starts up in BURST 1. The BCT only appears after one cycle of pressing the Boost button on and off.

Frequently Asked Questions

Q When shall I start using my Elle TENS 2?

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 2 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 8.

Q Can I combine the Elle TENS 2 with other medication?

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

Q Can the Elle TENS 2 be used in hospital?

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

Q Can I use the Elle TENS 2 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 2 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 switch off the unit and 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.
Call our customer careline on +44 (0)20 8532 9595.

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. 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 2 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.

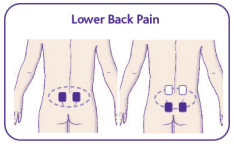
Post-Natal Pad Placement Diagrams

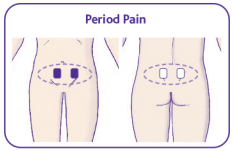
KEY:

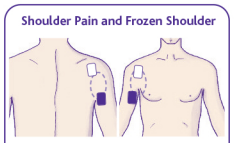
■■ =first pair of electrodes

□□ =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.







Outer and inner aspect of shoulder

Elle TENS 2 Technical Data

Programme	Display	Output Frequency / Duration	
Burst	Burst 1	Pulse Frequency (16Hz) Pulse Width (150µs) 1 burst per second, 8 pulses per burst*	
Burst	Burst 2	Pulse Frequency (32Hz) Pulse Width (150µs) 2 bursts per second, 8 pulses per burst*	
Boost	Boost 1	Pulse Frequency (80Hz) Pulse Width (150µs) continuous*	
Boost 2	Boost 2	Pulse Frequency (100Hz) Pulse Width (150µs) continuous*	
Output Channel		Dual Channel	
Output Waveform		Symmetrical bi-phatic rectangular	
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	

* Pulse width adjustment does not change when switching between Burst and Boost modes. Default pulse width is 150µs. There are 5 adjustable pulse widths selectable in all modes: 50, 100, 150, 200 and 250µs.

Equipment type	Dual Channel Digital TENS
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.
* Default pulse width after mode changed (pulse width not changed when switched between BURST and BOOST mode) 5 selectable pulse widths in all modes: 50, 100, 150, 200, 250	
Unit Size	115mm x 55mm x 30mm
Unit Weight	75 grams
Output Jacks	CE Touch-proof jacks
Display	Digital LCD - 8 seven segment digits and around 95 segments
Automatic Power Off	Will switch off after 5 minutes if not used
Battery Low Detect	2.2v ± 0.2v
Battery	2 x 1.5v AA Battery (Type LR6)
Operating Environment	Temperature 0..40°C Air humidity 20-75% Air pressure 700 hPa-1060 hPa
Storage and Transport Environment	Temperature 0..40 °C Air humidity 30-90% Air pressure 700 hPa-1060 hPa

Guarantee

Your Elle TENS 2 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:

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Cork, Ireland.

Babycare TENS is part of the Body Clock group of companies

CE 1639

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Model: D-BC138T

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This manual is recyclable