

Babycare TENS[®]



ELLE TENS²

Instructions for use

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. The Elle TENS 2 contains all of the award winning features of its predecessor, the Elle TENS, plus a built-in contraction timer, updated user interface and backlight. The Elle TENS 2 is ready for all of your labour and post-natal needs.

The instructions in this manual are designed to cover most operational issues. If you have any questions concerning setting up, using or maintaining this device which are not covered by these instructions or any other concerns please do not hesitate to contact Babycare TENS at help@babycaretens.com alternatively, you can call 0333 1219 737 during our office hours.

TENS is recognised as a safe and highly effective method of pain relief and is regularly recommended by medical professionals.

TENS is drug-free, with no known side effects. It 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 an F type (floating) applied part.



Warning -
Please read these instructions before use particularly pages 17-18.



Denotes a product which must be disposed of safely.



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.

What is TENS?

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.

What can the Elle TENS 2 be used for?

1. The Elle TENS 2 provides pain relief during labour. However some people may find that other analgesics are also needed during the later stages of labour.
2. The Elle TENS 2 can be used for many chronic and acute pain conditions such as back pain, shoulder pain, arthritis, sciatica, sports injuries, migraine, period pain and post-operative pain.



Please also refer to your
'Women's guide to drug free
pain relief'*.

**A women's guide to
drug free pain relief**

*Before, during, and
after the birth*

**A simple and
essential guide to
acupressure,
acupuncture without
needles, and TENS
techniques.**

**Includes
guide for
birthing
partners**

By Dr Gordon Gadsby

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Babycare TENS has become the most popular choice for mums-to-be as it is specifically designed to combat pain during childbirth. This is a safe, effective drug-free method of pain relief, which still allows you to use other analgesics, such as pethidine or gas-and-air if you wish.

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Controls on your 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.



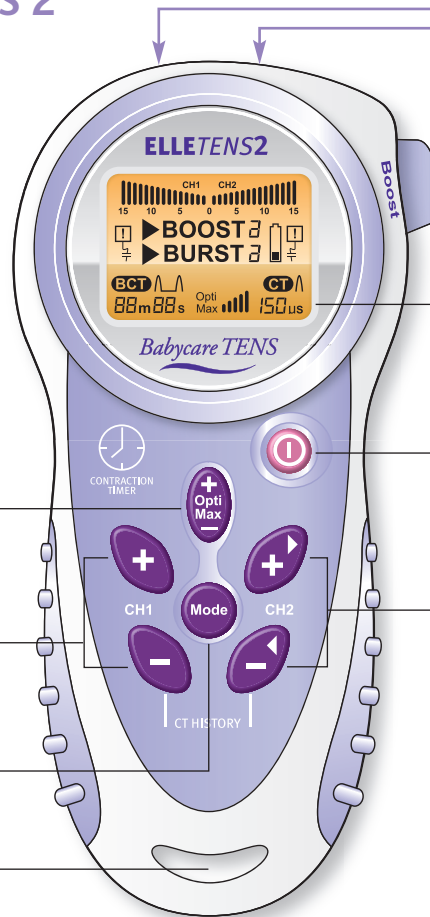
Please ensure that all of the contraindications and precautions have been read thoroughly. See pages 17-18.

Opti-Max Key
Adjusts depth of the pulses:
Refer to p14 for more details.

Channel 1 Intensity Adjustment Keys

Mode Button
Selects modes.

Space to attach neck cord



Leadwire Jack Plug Sockets

Boost/Timer Button

Used for an extra surge of power during contractions and also activates Contraction Timer.

LCD automatically lit by backlight

On/Off Button

Channel 2 Intensity Adjustment Keys

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

This function 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 13).

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 13).

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 7 for instructions.

Power Bar

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

Contraction Timer

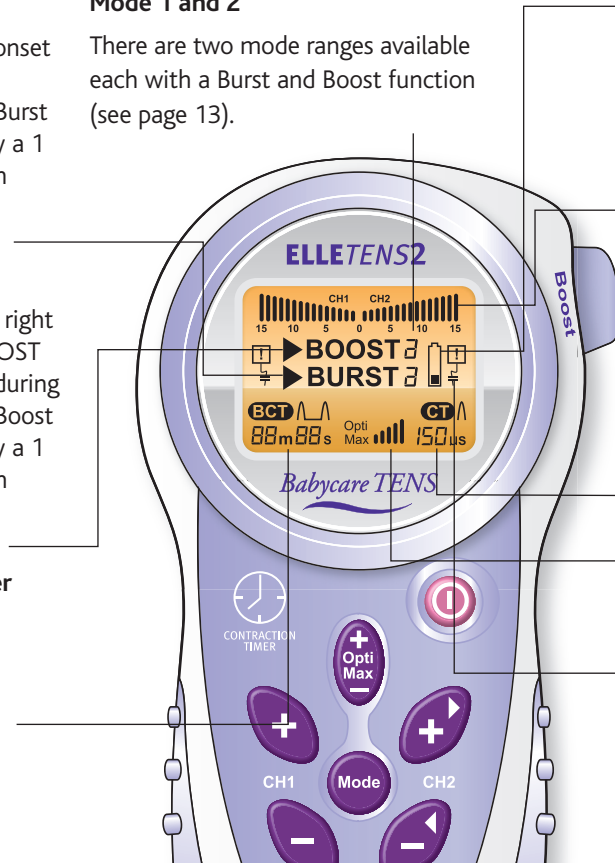
Starts by pressing the Boost Button. This automatically records the duration of your contractions.

Opti-Max

Indicates the Opti-Max output. Refer to page 14 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

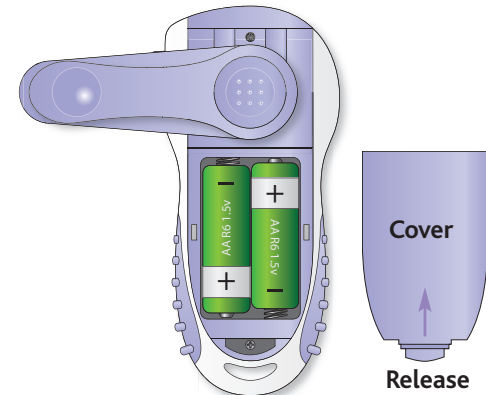
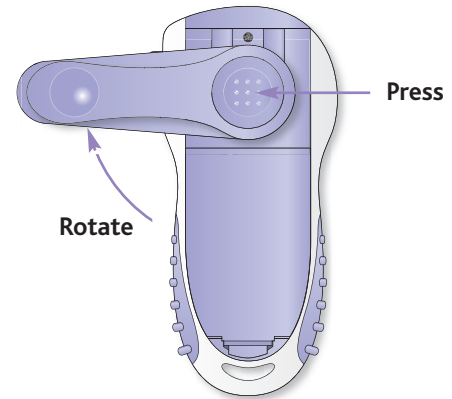
Check the following contents:

- 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 Quick Start Guide
- 1 x Women's Guide*

*(only if you have purchased this unit)

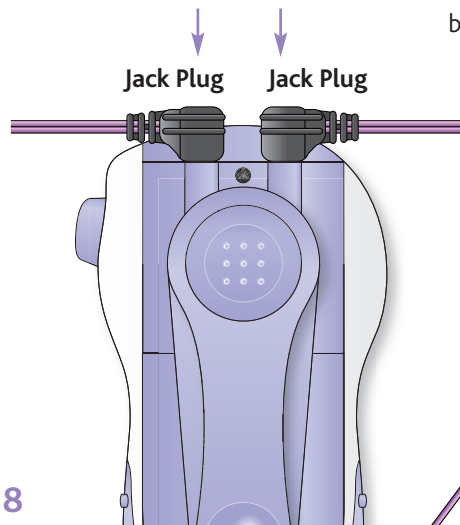
The Assembly Stage

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

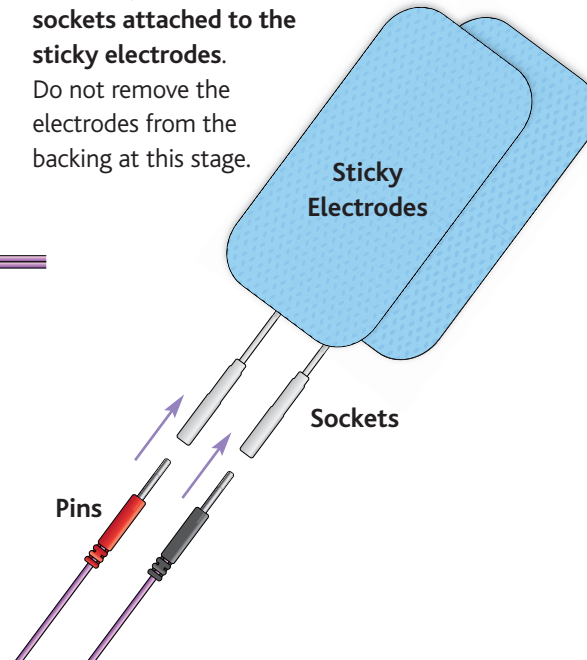


Setting up your Elle TENS 2

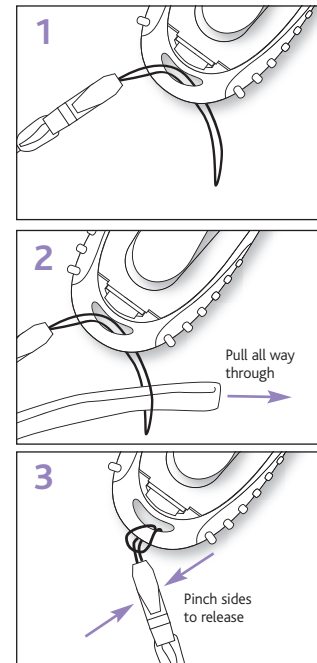
- c) Take two of the purple **leadwires** and insert each of the black jack plugs **into the sockets at the top of the Elle TENS 2 unit.**



- 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.



If you wish, attach the easy-release neck cord:



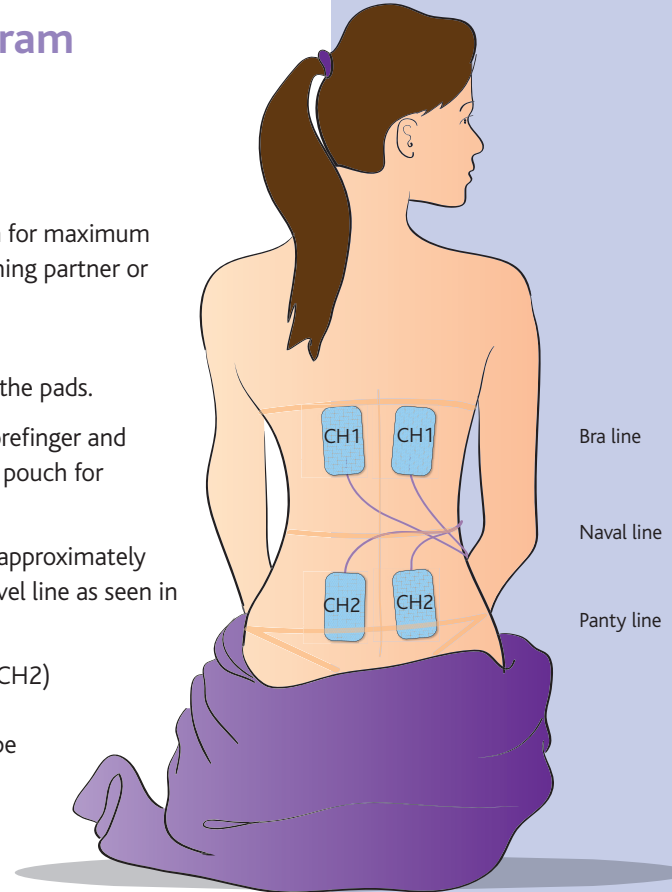
Suggested electrode placement diagram

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. Clean the skin thoroughly and allow skin to dry before applying the pads.
2. Carefully **peel the pads from the plastic backing** using your forefinger and thumb. Do not pull on the lead wires. Retain plastic backing and pouch for storage after use.
3. **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.
4. **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.

For general pain relief, see pad placement diagrams in the 'A Women's Guide to Drug Free Pain Relief' booklet.



Using the Elle TENS 2

Press



Turn your Elle TENS 2 on

Press the on/off button to power up the unit. The unit is in BURST 1 mode.

Adjusting intensity for pain relief during labour

Begin by pressing the **CH1+** key. Each time this key is pressed, 'columns' at the top of the screen will appear on the screen increasing in number and size as the intensity is increased. You will begin to feel a pulsating sensation.

Press **CH1-** and the columns will decrease in number should you wish to reduce the intensity.

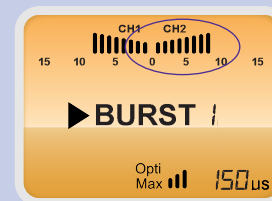
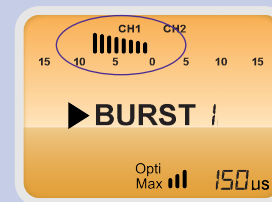
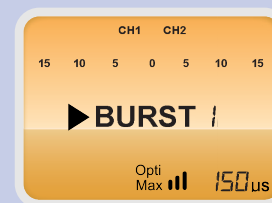
Repeat the previous step with the **CH2+** and **CH2-** keys. You will now feel a sensation in both sets of pads.



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Babycare TENS

Display



Using the Elle TENS 2

Burst 1 (use between contractions*)

This is the first mode that you will use. It feels like a pulsing, 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'.

Boost 1 (use during contractions*)

When experiencing a contraction, simply press the **Boost** Button once and release. This is the big button located at the top right of the unit. Your Elle TENS 2 will then switch automatically into the BOOST mode for that extra surge of power required to combat pain during contractions. This will feel like a continuous sensation. You do not need to hold the button in.

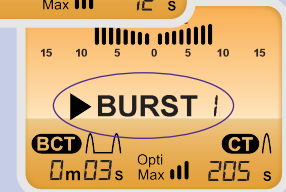
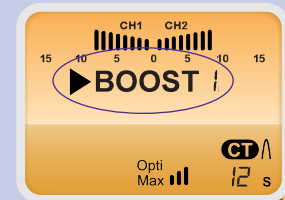
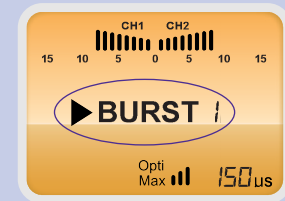
Once the contraction has passed, release the **Boost** Button by lightly pressing it. The Elle TENS 2 will return to the original BURST 1 mode. Continue this cycle during the early stages of labour.

*See page 13 for additional BURST and BOOST information.



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Display



Using the Elle TENS 2



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.

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.

Babycare TENS

Display



Using the Elle TENS 2



To return back to the original mode screen, (which will have continued counting the contraction times 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

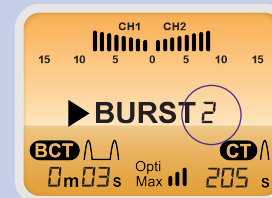
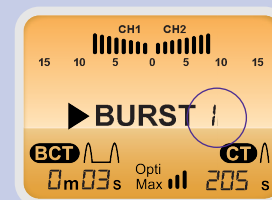


Press the **Mode** Button to switch between mode ranges. You will see from the User Display, that the number on the centre right of the display will change from 1 to 2 (and vice-versa).

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

Babycare TENS®

Display



Using the Elle TENS 2

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.

Press



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 250 μ s (microseconds). The unit will always start up at Opti-Max 150 μ s, which is exactly half way between the highest and lowest setting.

N.B. **1.** The Opti-Max Key can be used according to your preference and not necessarily for the stage of labour you are in. **2.** When operating the Opti-Max Key the CT information temporarily disappears, but reappears in 1 second automatically.

Press

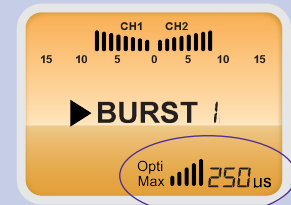


When you have finished

Press the **On/Off** Button to turn the unit off before removing the wires. Remove the jack plugs from sockets holding the plugs between the forefinger and thumb. Remove electrodes returning them to the plastic backing and pouch as supplied.

Babycare TENS[®]

Display



Useful Tips

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.

Questions, answers and troubleshooting

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, using one leadwire, place 2 pads on your forearm to feel the different pulse sensations following the instructions on page 10 for CH1 and CH2.

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.

Q Is TENS safe?

A Yes, TENS is used widely for pain relief and is recommended by medical professionals.

Q Can I use it with other medications?

A Yes. TENS is drug-free so you can use it with any other medication including paracetamol.

Q What conditions can TENS be used to treat?

A TENS can be used to treat numerous pain conditions such as back pain, neck pain, period pain and arthritic pain etc.

If you are unsure about using TENS please consult your medical adviser or contact Babycare TENS at help@babycaretens.com.

Troubleshooting Questions

Q Why does the pulse sensation 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 acclimatised to a lower setting.

Q Why does the pulse sensation feel strong but ineffective?

A You may need to reposition the electrode pads (don't forget to switch the Elle TENS 2 off before doing so).

Q What should I do if I can not feel any or little sensation even on a high intensity setting?

A Check that the leadwires are properly connected and the pads are fixed to the skin. Also check batteries.

Specifications

General

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 \pm 0.2v
Battery	2 x 1.5v AA Battery (Type LR6)
Operating Environment	Temperature 0-40°C Air humidity 30-75% Air pressure 700 hPa-1060 hPa
Storage and Transport Environment	Temperature 0-40°C Air humidity 30-90% Air pressure 700 hPa-1060 hPa

Technical Specifications

Programme	Display	Output Frequency / Duration
Burst	Burst 1	Pulse Frequency (16Hz) Pulse Width (150 μ s) 1 burst per second, 8 pulses per burst*
Burst	Burst 2	Pulse Frequency (32Hz) Pulse Width (150 μ s) 2 bursts per second, 8 pulses per burst*
Boost	Boost 1	Pulse Frequency (80Hz) Pulse Width (150 μ s) continuous*
Boost 2	Boost 2	Pulse Frequency (100Hz) Pulse Width (150 μ s) continuous*
Output Channel		Dual Channel
Output Waveform		Symmetrical bi-phasic rectangular
Output Voltage		0 - 55v zero to peak adjustable in 15 steps at 500 Ω load
Output Intensity		0 - 110mA adjustable in 15 steps at 500 Ω 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 150 μ s. There are 5 adjustable pulse widths selectable in all modes: 50, 100, 150, 200 and 250 μ s.



Contraindications

1. Do NOT use TENS before 37 weeks of pregnancy unless under medical supervision.
2. Electrodes should only be positioned as recommended for childbirth (see page 9), 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 a heart condition, epilepsy, undiagnosed pain, have any metal implants, or any doubts whatsoever, consult your medical adviser.
6. Never use TENS to mask undiagnosed pain as this could require urgent treatment.



General Precautions & Adverse Reactions

1. Do NOT use this unit without first reading these instructions.
2. Do NOT immerse the Elle TENS 2 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 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.
10. Do NOT use in close proximity (e.g. 1m) to shortwave or microwave therapy equipment to avoid instability in the stimulator output.
11. Do NOT use adjacent to or stacked with other equipment.
12. Keep out of the reach of children.
13. Do NOT place electrodes on varicose veins, across or through the head, directly or near the eyes, covering the mouth, on the front or sides of the neck (especially the carotid sinus), on the chest and upper back so as to cross over the heart, directly over your heart or an area of broken, inflamed, infected or numb skin.
14. Do NOT use in the presence of tuberculosis, malignant tumors, very high or very low blood pressure, high fever or acute inflammatory disease unless under medical supervision.
15. Electrodes should only be applied to skin with normal sensation unless under medical supervision as skin irritation may occur following long term application.

16. This is an internally powered medical electrical equipment. Do not use battery or power sources other than those specified in these instructions.
17. No modification of this equipment is allowed.



Warnings

1. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS is in use. Portable and mobile RF communications equipment can affect medical electrical equipment. Operation of the equipment or system below this amplitude or value may cause inaccurate results.
2. Mild temporary skin irritation can occur following long term application. Simultaneous connection by the user to a high frequency surgical medical electrical equipment may result in burns at the site of the electrodes and equipment. Users should seek advice from their medical advisors when use of this equipment is required.
3. Keep out of the reach of children and babies at all times. Children and babies may be at risk of strangulation by entanglement in leadwires or choking by swallowing small parts or accessories. Ensure that from the device and all accessories are stored away safely out of the reach of children and babies at all times.
4. It is unsafe to use accessories, detachable parts and materials not described in these instructions for use. Please see www.bodyclock.co.uk for suitable accessories or contact us if you require any spare parts on +44 (0)20 853 9595.
5. Do not interconnect this device with any other equipment not described in these instructions for use.
6. Do not modify this equipment in any way.
7. The device shall not be serviced or maintained while in use with a patient.
8. The Elle TENS 2 is not user repairable and must be returned to the manufacturer if it requires repair.
9. 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 Electromagnetic Information document on page 19.

If you have any concerns please do not hesitate to contact Babycare TENS at help@babycaretens.com.

Checking system performance and troubleshooting

1. Check if the unit is turned on and if so, turn it off before taking any further steps.
2. Then replace the batteries and turn the device on. If it does not function at all, return the device for repair.
3. If your unit does not appear to be operating properly or there are changes in the performance of your equipment, first replace the batteries following the instructions for doing so in this manual. Replacing the battery can eliminate most operational problems. If the device still does not appear to function properly or the changes to the performance still continue, turn off the unit and double check that your skin is prepared as instructed above. Finally, replace your electrodes with new ones. If your device still does not appear to function properly or the performance is still changed return the device for repair to the manufacturer.
4. Where there are any unexpected operational issues or events when using this device, turn off the unit and contact the manufacturer for advice and assistance.

Maintenance and Care (Guidelines for optimum performance):

1. Remove the batteries if this device is not likely to be used for some time.
2. Change the batteries regularly when regularly using this device.
3. The unit must be switched off when changing the batteries. Check if the unit is turned on and if so, turn it off before taking any further steps.
4. The unit should be wiped clean periodically using a very slightly dampened cloth. A mild soap may be used but DO NOT apply solvents.
5. Follow instructions supplied with your electrodes and take note of their intended number of uses and replace them when needed.
6. Do not attempt to open or dismantle this device at any time to undertake any other repairs or maintenance.
7. Please see troubleshooting section found on page 15 for further information.

Battery Replacement Please refer to page 7.

Materials The Elle TENS 2 casing is made from ABS plastic. Electrodes consist of fibre, conductive carbon mesh and conductive hydro gel.

Applied Parts The self adhesive electrodes and lead wires.

Device failures

1. Please do not attempt to repair damaged devices yourself.
2. In case of further inquiries, always state the model of your device (as this device should only be repaired by the manufacturer's qualified technical personnel).
3. This unit is guaranteed for a period of 2 years (the service life of this unit) against manufacturer's defects excluding consumables. Consumables include leadwires, batteries and self-adhesive electrodes. The expected service life will depend on how often the device is used but the average service life is expected to be 3 months for leadwires, 20 hours for batteries and 10-20 applications for self-adhesive electrodes depending on skin type.
4. **Note:** the guarantee is null and void if any attempt is made to open or modify the unit by unauthorized personnel.
5. 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.co.uk

Recycling **Recycling of batteries, electrical and electronic equipment (WEEE)**

When you decide to dispose of used batteries or if you ever choose to dispose of your device, please do so safely using official recycling facilities. To find your nearest recycling sites for waste electrical and electronic products, contact your local council, or visit www.recycle-more.co.uk and type your postcode into the recycling bank locator.

Latex Warning

The Elle TENS 2 and applied parts are NOT made with latex. Please check carefully before choosing to use any other third party accessories other than those provided by the manufacturer.

Natural rubber latex or its synthetic derivative is used in numerous medical products. Repeated exposure can result in sensitivity to natural rubber latex proteins, with symptoms ranging from skin redness, rash, hives or itching to difficulty breathing and wheezing. Rarely, shock and even death can occur. Learn to recognize the symptoms of a natural rubber latex allergy, seek medical advice and take all steps recommended by your medical advisors.

EMC Information


This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

*Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation! This machine should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Manufacturer's declaration – electromagnetic emission		
This unit is intended for use in the electromagnetic environment specified below. The customer of the user of this unit should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	This unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	This unit is suitable for use in all establishments other than those directly connected to the public low-voltage power supply network that in some cases requires buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration – electromagnetic immunity		
This unit is intended for use in the electromagnetic environment specified below. The user of this unit should ensure that it is used in such an environment.		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	not applicable
Surge IEC 61000-4-5	± 1 kV (line(s) to line(s))	not applicable
Voltage dips, short interruptions and voltage fluctuations on power supply input lines IEC 61000-4-11	<5% UT (0-95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles 95% UT (5% dip in UT) for 5 sec	Not applicable (INTERNALLY POWERED MEDICAL EQUIPMENT)
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration – electromagnetic immunity		
This unit is intended for use in the electromagnetic environment specified below. The user of this unit should ensure that it is used in such an environment.		
Immunity test	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 150 kHz to 80 MHz	not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the unit than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: not applicable $d = 1.67 \sqrt{P}$ $d = 2.33 \sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Radiated RF IEC 61000-4-3 80 MHz to 2.5 GHz	3 V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m), the recommended separation distance should be determined by an electromagnetic site survey. (a) should be less than the compliance level in each frequency range (b). Interference may occur in the frequency range (b). (c) should be less than the compliance level with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a). Field strengths from fixed transmitters, such as base stations (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be conducted. If the measured field strength in the frequency range of interest is found to exceed the guideline for a particular application, remedial measures may be necessary, such as reorienting or relocating the unit.

b). Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this unit		
This unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of this unit can help prevent electromagnetic interference by maintaining a minimum distance from portable and mobile RF communications equipment (transmitters) and this unit as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	150 kHz to 80 MHz $d = 1.16 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.17	0.233
0.1	0.369	0.738
1	not applicable	1.67
10		3.689
100		11.667

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guarantee

The Elle TENS 2 is guaranteed for 2 years against manufacturer's defects excluding consumables such as leads, electrodes and batteries.

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