

Elle TENS +TM

Instructions for use



The Elle TENS+™ is a 3-in-1 state-of-the art, 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+ contains a powerful TENS unit to combat labour pain with a built in contraction timer, a TENS unit for general pain relief and a Pelvic Floor Stimulator (PFS) for treating post-natal incontinence.

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.

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.



Denotes a product which must be disposed of safely.

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+ be used for?

1. The Elle TENS+ 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+ 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.
3. The Elle TENS+ can also be used for treating incontinence. (**NOT** to be used during the 12 weeks following childbirth).

Section ***1 Using your Elle TENS+ in BIRTH mode:***

1

See page 4

Section ***2 Using your Elle TENS+ in PAIN mode:***

2

See page 16

Section ***3 Using your Elle TENS+ in PELVIC mode:***

3

See page 24

Section 1

For more information

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



BIRTH mode

Waiting for that big day to finally arrive is exciting, but it is perfectly natural to feel a little apprehensive. You will be thinking about how to make giving birth as easy as possible - preparation is essential.

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.

Contents for BIRTH mode

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Controls on your Elle TENS+ in BIRTH mode

The Elle TENS+ 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 34 and 35.

Opti-Max Key

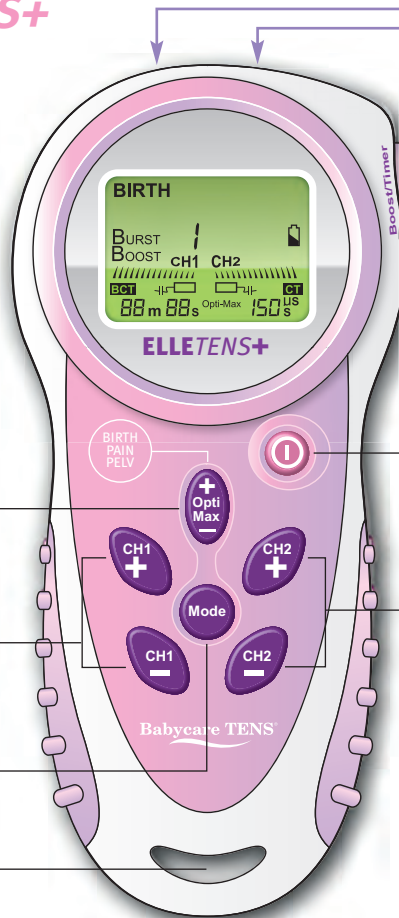
Adjusts depth of the pulses:
Refer to p14 for more details.

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.

On/Off Button

Channel 2 Intensity Adjustment Keys

N.B. Automatic Power Off

When the intensity levels are zero, and the Elle TENS+ has not been in use for 5 minutes, it will shut off automatically.

Display symbols and their meanings in BIRTH mode

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 11).

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

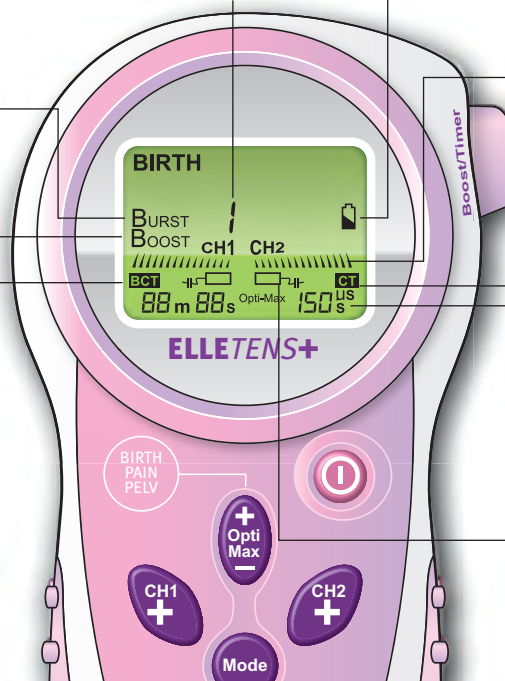
Starts by pressing the Boost Button, this automatically records the duration of your contractions.

Opti-Max

Indicates the Opti-Max output. Refer to p14 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+ for BIRTH

Check the following contents:

- 1 x Elle TENS+ 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*
- 1 x Electrode Placement Chart*
- 1 x Lubricant Gel Sachet

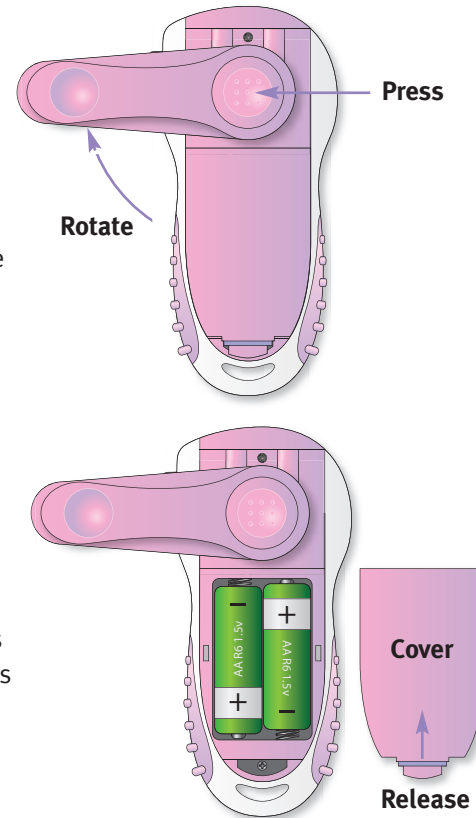


1 x vaginal probe
(NOT to be used until at least 12 weeks after childbirth. See contraindications and precautions on pages 34 and 35. For use only in the PELVIC mode - see p24).

* (only if you have purchased this unit)

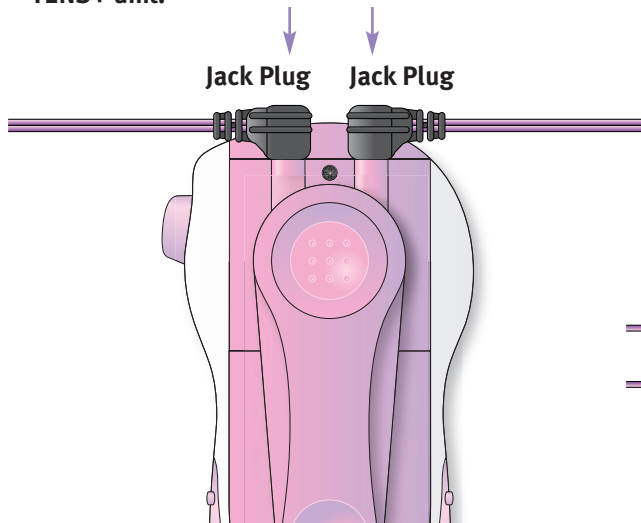
The Assembly Stage

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



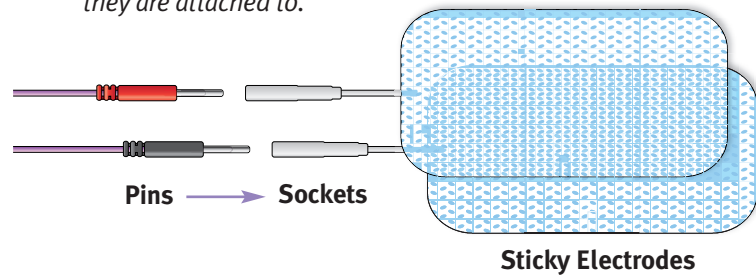
Setting up your Elle TENS+ for BIRTH

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

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



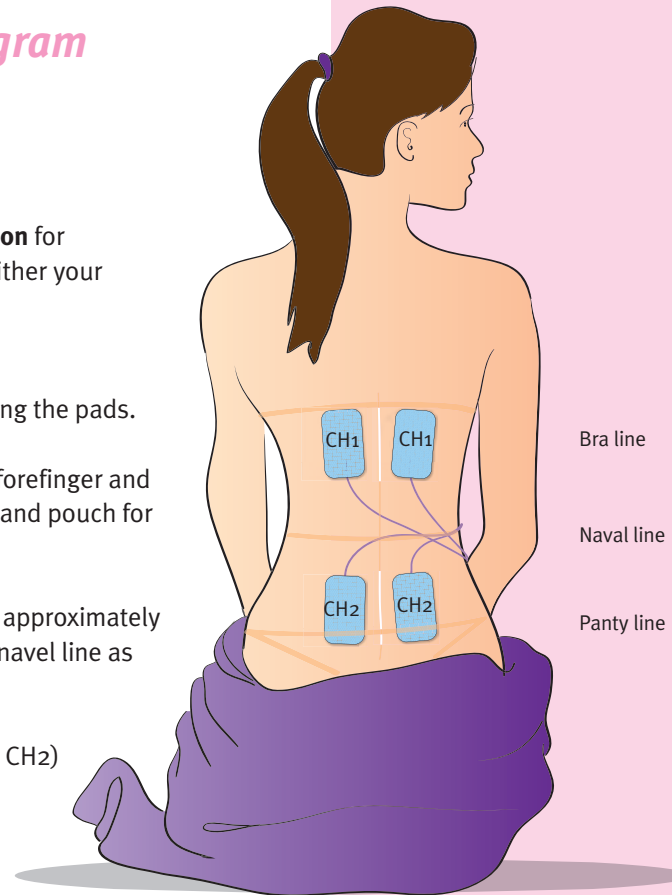
If you wish, attach the easy-release neck cord which enables you to hang the Elle TENS+ from your neck.

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.



Using the Elle TENS+ in BIRTH mode

Press



Entering BIRTH mode

- You are now ready to use your Elle TENS+. Ensure that the **Boost** Button located at the top right of the unit is **not** pressed in. Switch the unit **ON** by pressing the **On/Off** Button. You will see 'BIRTH' flashing in the top left corner of the display.
- Press **Mode** to confirm 'BIRTH' mode, otherwise your Elle TENS+ will automatically enter the BIRTH mode after a few seconds.
- If the unit does not already display 'BIRTH' (i.e. PAIN or PELVIC is flashing), use the **Opti-Max** Key to cycle through the modes, until 'BIRTH' is flashing.

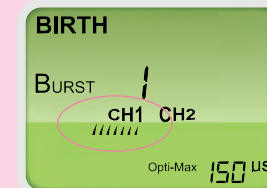
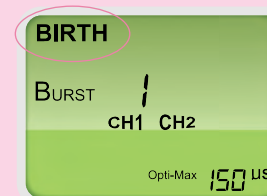
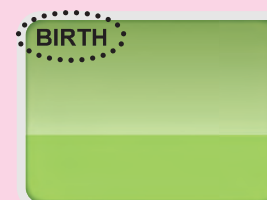
N.B. Your Elle TENS+ always starts up in the mode used previously.
To select another mode you must first turn off the unit and follow the instructions as above.

Adjusting intensity for pain relief during labour

Begin by pressing the **CH1+** key. Each time this key is pressed, 'half-moons' will appear on the screen increasing in number and size as the intensity is

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Using the Elle TENS+ in BIRTH mode

increased. You will begin to feel a pulsating sensation. The unit is in BURST mode. Press **CH1-** 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.

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'.

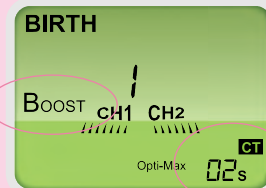
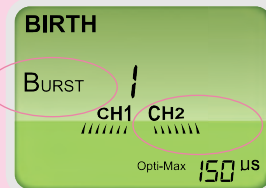
Boost 1 (use during contractions*)

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+ 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.

*See page 13 for additional BURST and BOOST information.

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Using the Elle TENS+ in BIRTH mode



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

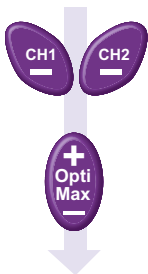
Using the contraction timer

The first time you press the **Boost** Button, the Elle TENS+ 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 the **Opti-Max -** Key to go back to previous sets (eg, -2, -3, -4, -5) or forward again by pressing the **Opti-Max +** 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.

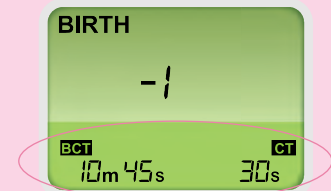
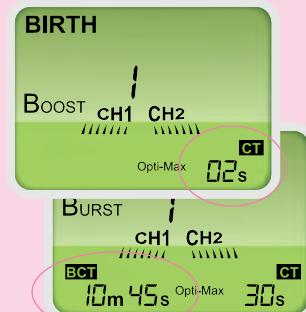
Press



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Using the Elle TENS+ in BIRTH mode



To return back to the original BIRTH mode screen, press the **CH1-** and **CH2-** buttons together again.

The Mode Button

There are two mode ranges 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) usually used when your labour advances and your contractions become more frequent.

Press

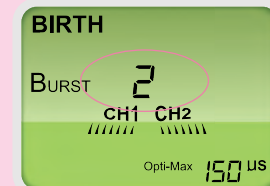
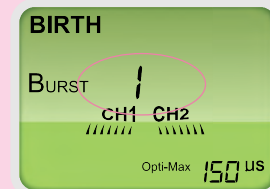


Press the **Mode** Button to switch between mode ranges. You will see from the User Display, that the number in the centre of the display will change from 1 to 2 and vice-versa.

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

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Using the Elle TENS+ in BIRTH mode

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.

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 in the BIRTH mode: 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.

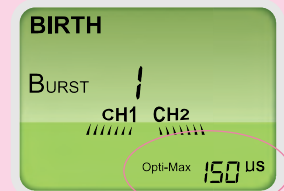
N.B. 1. The Opti-Max Key can be used according to your preference and not necessarily for the stage of labour you are in. **2.** When operating the Opti-Max Key the CT information will temporarily be replaced but will return automatically.

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.

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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+?

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, using one leadwire, place 2 pads on your forearm to feel the different pulse sensations following the instructions on page 9.

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.

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+ 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+ off before doing so).

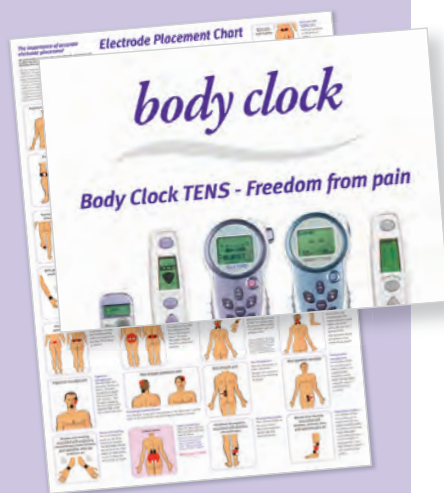
Q What should I do if I can not feel any or little sensation even on a high intensity setting?

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

Section 2

Pad Placement

For help with placement of pads please refer to diagrams found in your 'Electrode Placement Chart'.



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PAIN mode

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

TENS 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.

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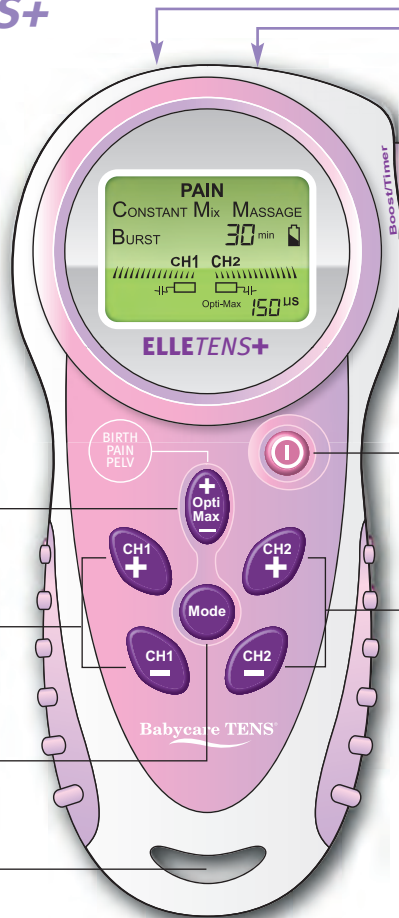
Controls on your Elle TENS+ in PAIN mode

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 contraindications and precautions have been read thoroughly. See pages 34 and 35.

- Opti-Max Key**
Adjusts depth of the pulses
Refer to p22 for more details.
- Channel 1 Intensity Adjustment Keys**
- Mode Button**
Selects one of four different modes:
Refer to p19 for more details.
- Space to attach neck cord**



Leadwire Jack Plug Sockets

Timer Button

On/Off Button

Channel 2 Intensity Adjustment Keys

N.B. Automatic Power Off

When the intensity levels are zero, and the Elle TENS+ has not been in use for 5 minutes, it will shut off automatically.

Display symbols and their meanings in PAIN mode

The diagram shows the ELLE TENS+ device with its LCD screen displaying the following information in PAIN mode:

- Mode:** PAIN
- Program:** CONSTANT Mix MASSAGE
- Intensity:** BURST
- Timer:** 30 min
- Channels:** CH1 and CH2
- Opti-Max:** 150 US
- Power Bar:** A bar with 15 segments, approximately 70% filled.
- Low Battery Indicator:** A battery icon with a lightning bolt.
- Pad Contact Warning:** A symbol consisting of two horizontal lines with a gap in the middle.

Callouts from the text blocks point to these specific elements on the device's screen and controls.

Timer
Shows your selected length of treatment.

Mode Indicator
indicates mode currently in use. For more information on the modes available see opposite page.

Pad contact warning (safety cut-out)
This symbol will appear if any of your pads are not attached securely to the skin.

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 channels. Each segment represents approximately 7% of the total output.

Opti-Max
Indicates the Opti-Max output in numerals.

Setting up your Elle TENS+ in PAIN mode



First set up unit as described on page 7. Please contact Body Clock Health Care should you require a **new set of electrode pads** for using your Elle TENS+ in the PAIN mode. www.bodyclock.co.uk Tel +44 (0)20 8532 9595.

About the modes

The Elle TENS+ has **4 TENS modes**. Each has been designed to provide a different sensation. You can use **any** of the TENS modes to treat your pain.

CONSTANT

Pulses are continuous and feel like a tingly sensation. This mode is generally used for acute pain conditions.

BURST

Pulses are off and on in a regular cycle and will feel like a heartbeat sensation. This mode is generally used for chronic pain conditions.

MASSAGE

The pulses decrease and then increase in regular cycles creating a massaging sensation.

MIXED (Dense Disperse or Han Stimulation*)

3 seconds of Constant and 3 seconds of Burst as described above.

* Professor Han suggests that switching between low and high-frequency stimulation for three seconds each i.e. 2/100 stimulation produces a simultaneous activation of the of the enkephalin and dynorphin systems which creates a more potent analgesic effect to combat pain. *Published in the January issue of 2003 of 'Trends in Neuroscience' (26:17-22).*

Using the Elle TENS+ in PAIN mode

Press



Entering PAIN mode

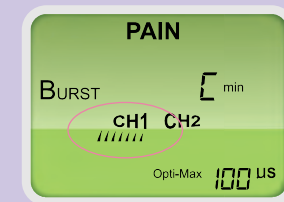
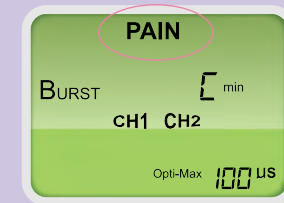
- Switch the unit **ON** by pressing the **On/Off** Button. Note that your Elle TENS+ will always start up in perviously used mode. You need to select 'PAIN'.
- If the unit does not already display 'PAIN' press the **Opti-Max** Key to cycle through the 3 available modes, (BIRTH, PAIN, PELVIC) until 'PAIN' flashes at the top of the display as shown in the diagram.
- Press the **Mode** Button to confirm 'PAIN' mode, otherwise your Elle TENS+ will automatically enter PAIN mode after a few seconds. To select another mode you must first turn off the unit and follow instructions as in a) above.

Adjusting intensity for pain relief

Begin by pressing the **CH1+** key. Each time this key is pressed, 'half-moons' will appear on the screen increasing in number and size as the intensity is increased. You will begin to feel a tingling sensation. Press **CH1-** should you wish to reduce the intensity.

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Using the Elle TENS+ in PAIN mode



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

Please note that you do not need to use both channels. Either one will work on its own.

Mode selection

The Elle TENS+ has 4 modes as described on page 19.

Press



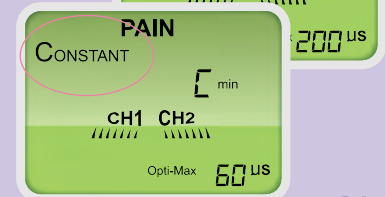
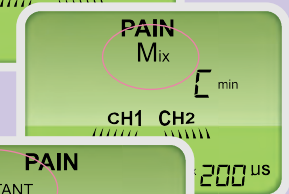
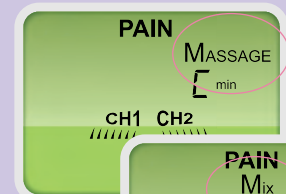
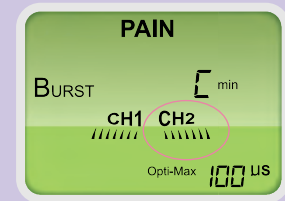
These modes are selected by pressing the **Mode** Button. This allows you to select whichever mode you find to be the most comfortable.

Select from: **CONSTANT**, **BURST**, **MASSAGE** and **MIX**.

Varying the modes helps to avoid or delay your body becoming used to any particular setting. You will note that the Opti-Max value for each mode changes and is generally set at half way between the highest and lowest setting. **N.B.** *The intensity will drop to zero when changing mode. This is safety feature.*

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Using the Elle TENS+ in PAIN mode

Opti-Max (pulse width) adjustment

Press



An added facility giving extra versatility to your Elle TENS+. Increasing or decreasing the pulse width heightens or lessens the sensation at the site of the electrodes. This is fully adjustable between $20\mu\text{s}$ and $250\mu\text{s}$ in steps of $10\mu\text{s}$.

Using the timer

Press



The **timer** allows you to set your **length of treatment**. There are 5 settings: Continuous (C), **15 mins**, **30 mins**, **45 mins** and **60 mins**.

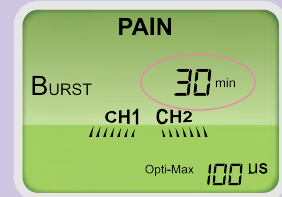
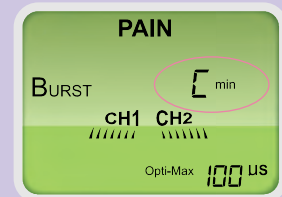
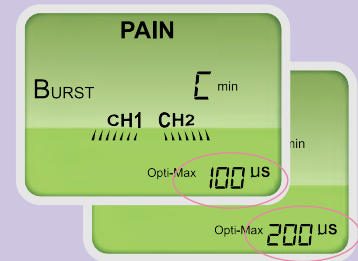
In any mode press the **Timer** Button to cycle through the 5 available time periods. The default setting is Continuous (C). The programme's **remaining time** is shown in the display.

Length of treatment

Continue stimulating for as long as necessary but preferably for no less than 30 minutes, unless you experience discomfort. Some people achieve pain relief after short periods of time. Others may require to use their TENS for a lot

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Display



Using the Elle TENS+ in PAIN mode

longer. If you continue to stimulate for a number of hours, temporarily turn off your unit and check to make sure your self-adhesive electrodes have not dried out. If this is the case, dampen them slightly. If electrodes are allowed to dry out this can cause minor skin irritation.

When you have finished

Press



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.

Questions, answers and troubleshooting

Refer to page 15.

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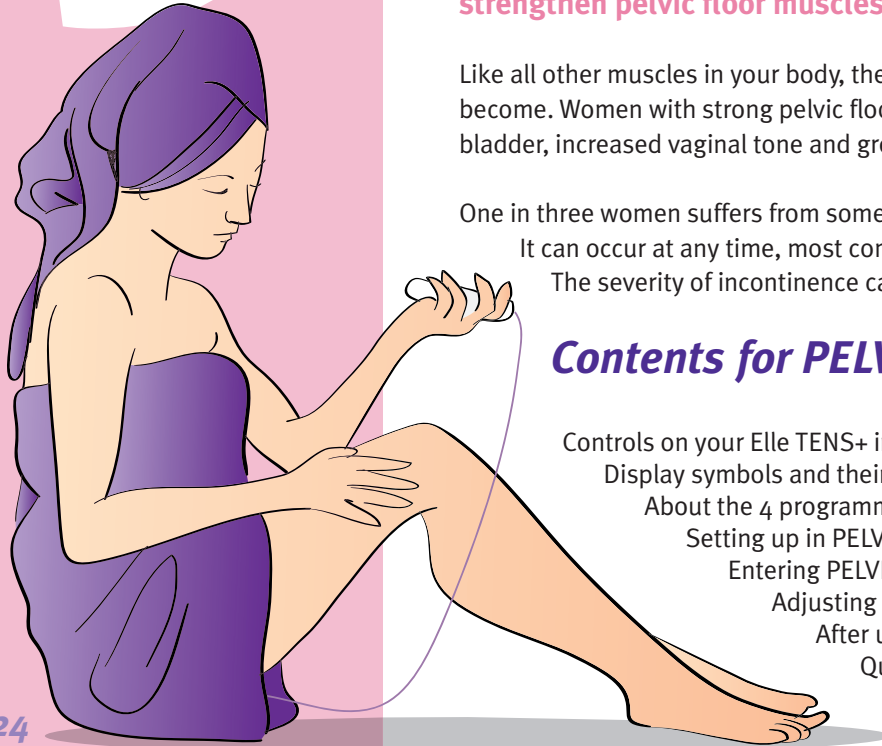
Useful Tips

Remember to refer to Electrode Placement Chart for pad placement information.



Section

3



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PELVIC mode



NOT to be used until at least 12 weeks after childbirth.
Check the appropriate time with your medical advisor.

The PELVIC mode is an ultra simple, yet powerful digital Pelvic Floor Stimulator (PFS). It is designed for use by women of all ages to help strengthen pelvic floor muscles and to treat incontinence.

Like all other muscles in your body, the more you stimulate them, the stronger they become. Women with strong pelvic floor muscles enjoy greater control over their bladder, increased vaginal tone and greater sensation during intercourse.

One in three women suffers from some form of incontinence during her life.
It can occur at any time, most commonly after childbirth.
The severity of incontinence can vary.

Contents for PELVIC mode

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Controls on your Elle TENS+ in PELVIC mode

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 contraindications and precautions have been read thoroughly. See pages 34 and 35.



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

Display symbols and their meanings in PELVIC mode

The diagram shows the front panel of the ElleTENS+ device. The central LCD screen displays the following information: 'PELVIC' in the top right corner; 'PROG' followed by a vertical bar and '30 min' in the center; 'CH1' and 'CH2' with corresponding bar graphs below; and 'Opti-Max 150 US' at the bottom. A battery icon is visible in the top right of the screen. Below the screen, there are several buttons: 'BIRTH PAIN PELV' (circular), 'Opti Max' (with a plus sign), 'CH1' (with a plus sign), 'CH2' (with a plus sign), and 'Mode'. A 'Boost/Timer' button is located on the right side of the device. A power bar is located below the screen, and a low battery indicator is located to the right of the screen.

Timer
Shows your length of treatment which is preset in the PELVIC mode.

Mode Indicator
indicates mode currently in use. For more information on the modes available see opposite page.

Probe contact warning (safety cut-out)
This symbol will appear if the probe is not inserted correctly or insufficient gel has been used.

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.

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

Opti-Max
Preset for use in the PELVIC mode.

Setting up your Elle TENS+ in PELVIC mode

About the 4 programmes

Your Elle TENS+ has four preset programmes:

PROG 1 - For Urge Incontinence

Occurs with a strong, sudden and uncontrollable urge to urinate.

PROG 2 - For Stress Incontinence

Occurs when sneezing, coughing, laughing, lifting or during exercise and causes a small amount of urine to leak.

PROG 3 - For Mixed Incontinence

A combination of urge and stress incontinence.

PROG 4 - After Care

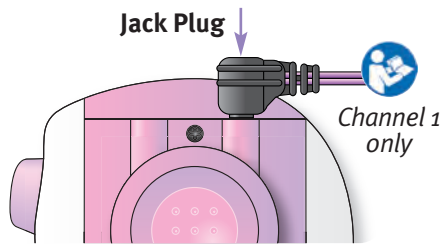
This is an optional mode and can be used directly after treatment:-

- Provided you are not experiencing any muscle fatigue or as a maintenance mode.
- After you have been using the unit on a regular basis and have experienced an improvement in your condition.

Setting up your Elle TENS+ for PELVIC mode

Setting up in PELVIC mode

1. Remove the **Vaginal Probe** from its packaging. **Wash hands** in soap and warm running water. Liberally **wash the probe** using the same method but do not soak. Rinse all soap and residue from hands and probe. Dry your hands and the probe with a clean cloth/paper towel and allow to air dry.
2. Take one of the **leadwires** and insert the black jack plug **into the channel 1 (only) socket at the top of**

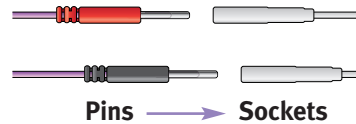


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the Elle TENS+ unit

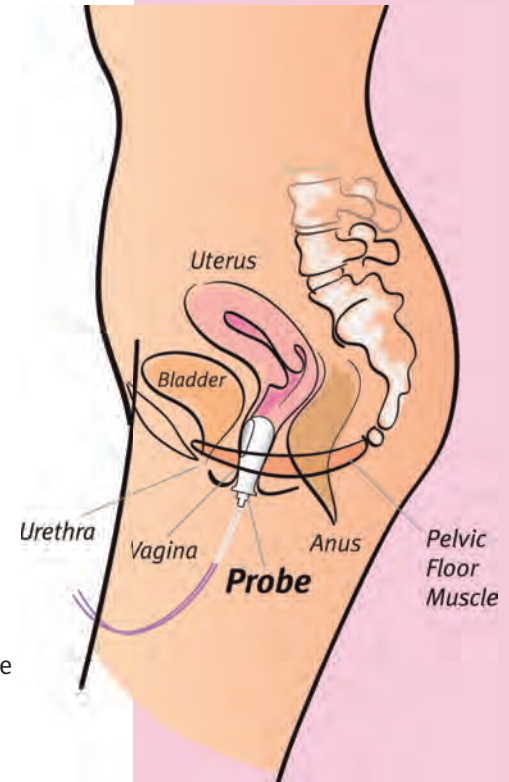
(the socket to the right when viewed from the back).

3. Now insert the **pins** (at the other end of the leadwire) **into the sockets attached to the Vaginal Probe**.



4. Apply a thin coating of lubricating gel to the probe.
5. Insert the probe until the flange at the base of the probe is sited between the labia as shown in the diagram. There is no need for precise orientation.

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Using the Elle TENS+ in PELVIC mode

Press



Entering PELVIC mode

- Switch the unit **ON** by pressing the **On/Off** Button. Note that your Elle TENS+ will always start up in last previously used mode. You need to select 'PELVIC'.
- If the unit does not already display 'PELVIC' press the **Opti-Max** Key to cycle through the 3 available modes, (BIRTH, PAIN, PELVIC) until 'PELVIC' flashes at the top of the display as shown in the diagram.
- Press the **Mode** Button to confirm 'PELVIC' mode, otherwise your Elle TENS+ will automatically enter PELVIC mode after a few seconds. To select another mode you must first turn off the unit and follow instructions from a) above.

Select the **Programme** most appropriate for your type of incontinence by pressing the **Mode** Button (refer to page 27 for Programme descriptions).

Programme	Duration	How often?
PROG 1	30 mins	Once or twice a day
PROG 2	30 mins	Once a day or every other day depending on severity
PROG 3	45 mins	Complete the programme once a day
PROG 4	45 mins	At your discretion

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Display



Using the Elle TENS+ in PELVIC mode

Do not exceed treatment times unless advised by a medical professional.

Adjusting your intensity level

Begin by pressing the **CH1+** key. Each time you press this key, you will see the intensity level increase on the LCD.

Carefully continue to press **CH1+** key until you comfortably feel your muscles contracting. If the sensation feels too strong, simply press the **CH1-** key to minimise the intensity.

The programme's **remaining time** is shown in the display.

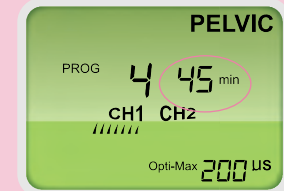
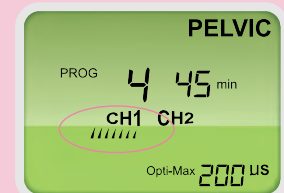
After use

Your Elle TENS+ will automatically switch off once the programme is complete. After use, always remember to ensure that the Elle TENS+ is switched **off**. Remove the Elle TENS+ probe from your body and disconnect the leads. Clean the probe with warm running water but do not soak. Rinse all soap and residue from probe. Dry with a clean cloth/paper towel and allow to air dry.



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Display



Important

- The Vaginal Probe is **single patient** use only. Additional probes and gel can only be purchased from Body Clock.
- Probes may be re-used by the **same patient** only.
- Wash probe as instructed before each use.
- Do **NOT** use the probe if the pack is open or damaged.

Questions and answers in PELVIC mode

Q How long will it take to see results?

A The amount of time varies from woman to woman. It is also dependent on the type of incontinence from which you are suffering.

STRESS Incontinence -

improvement comes slowly with the building of muscle fibre and nerve sensitivity. This can take up to 2 months.

URGE Incontinence -

improvements are made by reducing the false signals sent by the bladder to the brain. Results can be seen in as little as 14 days

MIXED Incontinence -

improvements are made by building the muscle fibre and nerve sensitivity as well as reducing the false signals being sent to the brain. This can take slightly longer, but you should be able to notice a difference within 21 days.

Q What does it feel like?

A All three PFS programmes feel slightly different. In general, the feeling is that of a pleasant, tingly, squeezing sensation that contracts and relaxes the pelvic floor muscles.

Q Is it suitable for use by all women?

A Yes, all women can use it provided none of the contraindications apply.

Q Can I use it in PELVIC mode whilst I'm pregnant?



A No, not until at least 12 weeks after childbirth. Check the appropriate time with your medical advisor

Q Are there any side effects?

A No, it is totally drug free. There are no known side effects.

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 ± 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

BIRTH mode

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-phasic rectangular
Output Voltage		0 - 55v zero to peak adjustable in 15 steps at 500q load
Output Intensity		0 - 110mA adjustable in 15 steps at 500q 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.

PAIN mode

Programme	Display	Output Frequency / Duration
Contstant	CON-STANT	Pulse Frequency 100Hz Pulse Width 20-250µs
Burst	BURST	32Hz-2 bursts per second, 14 pulses per burst Pulse Frequency 2Hz (each Hz = 14 pulses per burst) Pulse Width 20-250µs
Massage	MAS-SAGE	Pulse Frequency 100Hz fixed frequency modulating on pulse width Pulse Width 20-250µs
Mixed	MIX	3 seconds in mode 1, 3 seconds in mode 2, repeat Pulse Frequency 2Hz (each Hz = 16 pulses per burst) and 100Hz (repeated) Pulse Width 20-250µs
Timer	min	(C) Continuous, 15 Minutes, 30 Minutes 45 Minutes and 60 Minutes
Output Channel	Dual Channel	
Output Waveform	Asymmetrical bi-phasic rectangular	
Output Voltage	0-60V adjustable in 15 steps (500Ω load, peak to 0)	
Output Intensity	0 - 120mA adjustable in 15 steps (500Ω load). Intensity level will drop back to 0 after mode changes	

PELVIC mode

Programme	Display	Output Frequency / Duration
Urge	PROG 1	5Hz / 3 mins 10Hz / 5 mins 15Hz / 5 mins 20Hz / 5--Hz / 5 mins 10Hz / 5 mins 5Hz / 2 mins Total time = 30 mins*
Stress	PROG 2	10Hz / 5 mins 35Hz / 5 mins 50Hz / 10 mins 35Hz / 5 mins 10Hz / 5 mins Total time = 30 mins*
Mixed	PROG 3	10Hz / 5 mins 20Hz / 5 mins 30Hz / 5 mins 40Hz / 5 mins 50Hz / 5 mins 40Hz / 5 mins 30Hz / 5 mins 20Hz / 5 mins 10Hz / 5 mins Total time = 45 mins*
After Care	PROG 4	Frequency Modulation Frequency increases from 2 Hz to 10 Hz in 4 secs. and then back to 2Hz in another 4 secs. Total cycle = 8 secs Total time = 45 mins*
Pulse Duration		Pulse width fixed at 200µs for all programmes
Output Channel		Single Channel
Output Waveform		Bi-phasic rectangular
Output Voltage		0-40V adjustable in 14 steps across a 500 ohm load
Output Intensity		0-80mA adjustable in 14 steps across a 500 ohm load

* Timer countdown displayed on screen.



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 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 or any undiagnosed pain, have any metal plates or any doubts whatsoever consult your medical adviser.
6. Never use TENS to mask undiagnosed pain as this could require urgent treatment.
7. The unit MUST NOT be used for Pelvic Floor Stimulation in any mode or with the Vaginal Probe during pregnancy.
8. You can only use the unit for Pelvic Floor Stimulation from at least 12 weeks after childbirth. Check the appropriate time with your medical advisor.
9. Do NOT use the Elle TENS+ for Pelvic Floor Stimulation with the Vaginal Probe if you are suffering from any urinary or vaginal infection, or at the same time as using a barrier contraceptive device such as a diaphragm or cervical cap, or during your menstrual period.



General Precautions & Adverse Reactions

1. Do NOT use this unit without first reading these instructions.
2. Do NOT immerse the Elle 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 Elle TENS+.
6. Only use specified batteries, electrodes and probe.
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 or vaginal probe 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. Electrodes should only be applied to skin with normal sensation unless under medical supervision as skin irritation may occur following long term application.
15. This is an internally powered medical electrical equipment. Do not use battery or power sources other than those specified in these instructions
16. 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+ is not user repairable and must be returned to the manufacturer if it requires repair.

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+ casing is made from ABS plastic and the material used for the vaginal probe is ABS plastic and stainless steel metal. Electrodes consist of fibre, conductive carbon mesh and conductive hydro gel.

Applied Parts The self adhesive electrodes and the vaginal probe.

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, a vaginal probe 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, 3 months for the vaginal probe 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+ 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.

Guarantee: The Elle TENS+ is guaranteed for 2 years against manufacturer's defects excluding consumables.

www.babycaretens.com

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.bodyclock.co.uk

e-mail customercare@bodyclock.co.uk

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



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