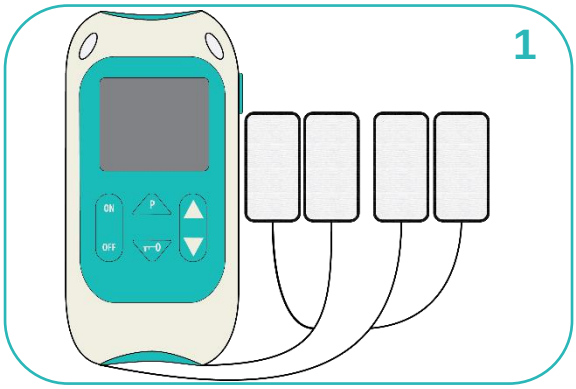
perfect mamaTENS

INSTRUCTIONS FOR USE

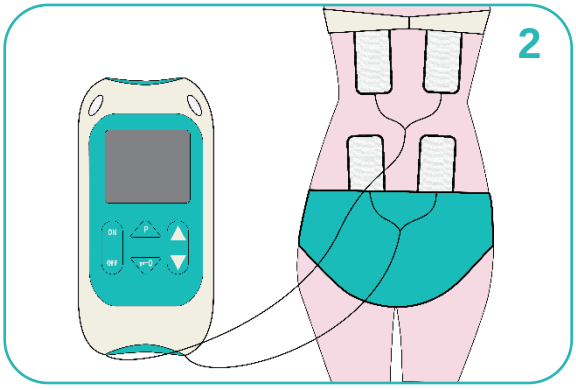
READ CAREFULLY BEFORE USE

TensCare™

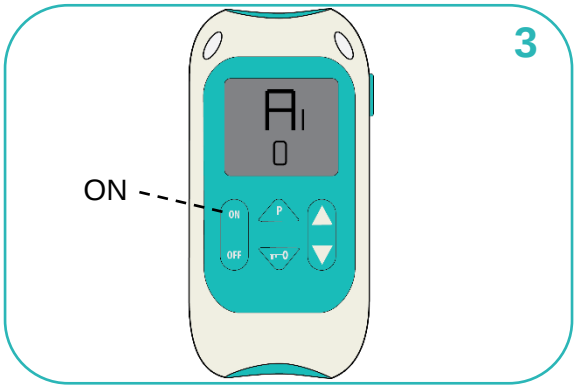
QUICKSTART GUIDE



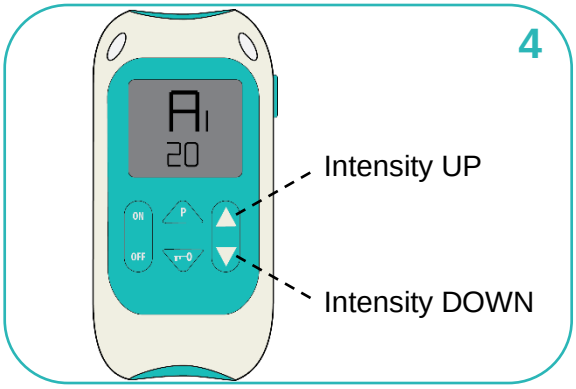
Connect the unit to the electrode pads



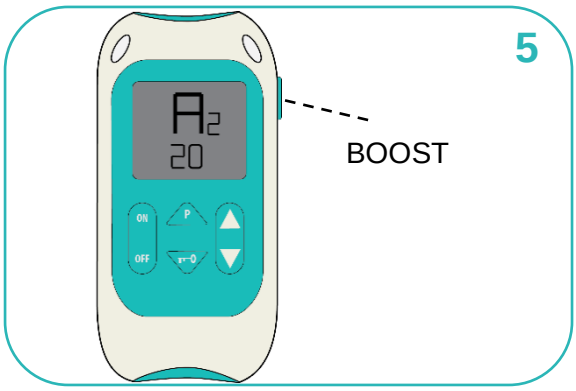
Place the electrode pads as indicated in section 11.3.



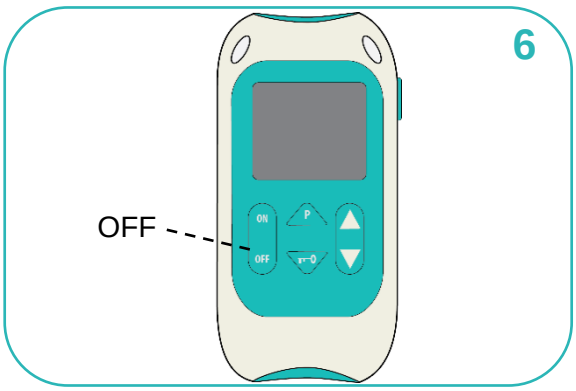
Press and hold the ON button to switch the device on



Regulate the output intensity with ▲ and ▼



During a contraction press the BOOST button



Press and hold the OFF button to switch the device off

Note

We strongly recommend trying the unit before the onset of labour, so to better understand the device during childbirth.

Dear Customer,

Thank you for choosing **Perfect mamaTENS**. TensCare stands for high-quality, thoroughly tested products for the applications in the areas of gentle electrotherapy, muscle toning, continence management and pain relief during labour.

Please read these instructions for use carefully and keep them for later use, be sure to make them accessible to other users and observe the information they contain.

Best regards,

Your TensCare Team

CONTENTS

SYMBOLS USED

	TYPE BF APPLIED PART: Equipment providing a degree of protection against electric shock, with isolated applied part. Indicates that this device has conductive contact with the end user.
	This symbol on the unit means “Refer to instructions for use”.
	Temperature Limitation: indicates the temperature limits to which the medical device can be safely exposed.
	Lot Number: indicates the manufacturer’s batch code so that the batch or lot can be identified.
	Humidity Limitation: indicates the humidity limits to which the medical device can be safely exposed.
	Serial Number: indicates the manufacturer’s serial number so that a specific medical device can be identified.
	Do not dispose in household waste.
	Catalogue Number: indicates the manufacturer’s catalogue number so that the device can be identified.
	Atmospheric Pressure: indicates the atmospheric limits to which the medical device can be safely exposed.
	Manufacturer Symbol
	Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the device (usually on the back of the device), either as “E/Year/Number” (YY/123456) or “E/Month/Year/Number” (MM/YY/123456).
	CE Mark
	Medical Device
	This medical device is indicated for home use.
	Importer Symbol
IP22	This medical device is not water resistant and should be protected from liquids. **The first number 2:** Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mm ø, 80 mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5 mm ø and greater. **The second number 2:** Protected against vertically falling water drops when enclosure is 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.

1. INTRODUCTION

Device Description & Principles of Design

The **Perfect mamaTENS** machine is safe and effective to use from the onset of labour providing mums-to-be with **pain relief** in the comfort of their own home.

The unit also enables the mother to remain mobile and upright, which can aid **descent and dilatation.**

TENS could also be used to relieve **back pain** in the last 3 weeks of pregnancy and to ease post-operative pain following **perineal tear** or **episiotomy**.

Note: Whilst some expectant mothers will achieve sufficient pain relief using just the **Perfect mamaTENS**, others may require additional pain relief. **Perfect mamaTENS** can be used with other pain relief options such as gas and air however, due to the electrical nature it cannot be used for water births.

2. INTENDED USE

Perfect mamaTENS is a medical device designed to be used in the home healthcare and hospital environments to provide symptomatic relief and management of acute pain in the perinatal* and postpartum period and is suitable for use by all who can control the device and understand the instructions.

Do not use the device for any purpose other than this intended use.

* **Perinatal:** Pertaining to the period immediately before and after birth. The perinatal period is defined in diverse ways. Depending on the definition, it starts at the 20th to 28th week of gestation and ends 1 to 4 weeks after birth.

3. PERFECT MAMATENS FEATURES

- **Dual Channel**

Two channels with four electrode pads and a single intensity control for ease of use during labour.

- **Comfortable Stimulation**

Gentle stimulation with 50 steps of intensity in programme A and B, and 60 steps in programme C maximizes the comfort level.

- **3 Preset Programmes**

Specifically designed to counter labour pain at every stage. Integrated Boost button provides constant stimulation during contractions.

- **Large Backlit Screen**

Makes the screen easy to read under all conditions as well as clearly shows the programme and intensity being used.

- **Large Electrode Pads**

Rectangular electrode pads with integrated leads adhere to the body during treatment.

- **Open Circuit Detection**

Intensity returns to zero if the electrode pads come loose. Zeros will flash on the

screen until connection is re-established.

- **Keypad Lock**

Enables the user to manually lock the controls to prevent any accidental changes in settings.

- **Belt Clip and Neck Cord**

A belt clip and a neck strap allow you to attach the unit to your clothing or your neck; neck cord has a quick-release system for safety if pulled.

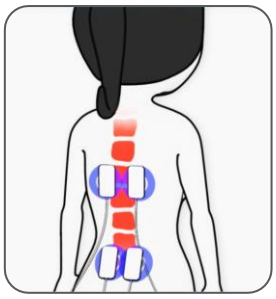
Note: The electrode pads need to be applied directly to the skin before the intensity increase buttons will operate. If the **Perfect mamaTENS** detects the unit is not properly connected to you (for example if the electrode pads or leads come loose) then the unit switches the intensity to zero. This safety feature prevents any unpleasant changes in output.

4. HOW "TENS" WORKS

T.E.N.S. stands for Transcutaneous Electrical Nerve Stimulation. T.E.N.S. stimulates your body's own natural defences against pain, namely the release of endorphins. TENS has been used successfully by thousands of pain sufferers.

TENS sends a gentle stimulation through the skin which works in TWO ways:

Pain Gate

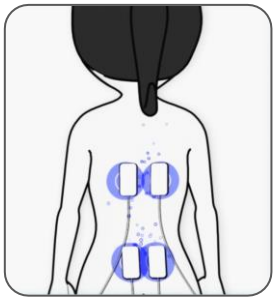


It stimulates the sensory nerves, which carry touch and temperature signals. These nerves go to the same connections in the spine as the nerves carrying pain. A strong sensory signal will block the pain signal travelling up the spine to the brain. This is known as closing the "Pain Gate" and takes effect quite quickly after the unit is switched on. When the gate is open, pain messages get through to the brain and we feel pain. When the gate is closed, these pain messages are blocked and we do not feel pain.

Evidence suggests that TENS produce pain relief in a similar way to 'rubbing the pain better'. The pain gate can be closed by activation of mechanoreceptors through 'rubbing the skin'.

Scientifically, the pain gate works by release of chemical in the synapse at spinal level that inhibits transmission of pain signal.

Endorphin Release



At low frequency settings, and slightly stronger outputs, TENS drives the motor nerves to produce a small repetitive muscle contraction. This is seen by the brain as exercise, and this promotes the release of endorphins - your body's own natural pain killer.

5. CONTRAINDICATIONS, WARNINGS & CAUTIONS

In this manual:

A **Contraindication** is used when a device should not be used because the risk of use clearly outweighs any foreseeable benefits and may result in serious injury or death.

A **Warning** is used when failure to follow the instructions may result in serious injury or death.

A **Caution** is used when failure to follow the instructions may result in a minor or moderate injury, or damage to the device or other property.

Notes are used to provide clarification or recommendation.

CONTRAINDICATIONS:

Do NOT use if you have a pacemaker (or if you have a heart rhythm problem) or with any electronic medical devices. *Using this unit with electronic medical devices may cause erroneous operation of the device. Stimulation in the direct vicinity of an implanted device may affect some models.*

Do NOT use during the first three months of pregnancy. *It is not known whether TENS may affect foetal development.*

Do NOT use on the abdomen in the later stages of pregnancy. *Stop using immediately if you experience unexpected contractions.*

Do NOT use with electrical stimulation in patients with a history of carcinoma at the site of stimulation.

WARNINGS:

Do NOT use when driving, operating machinery, or similar actions needing muscular control. *Loose electrode pads, damaged leads, or sudden changes in contact may cause brief involuntary muscle movements.*

Do NOT use to mask or relieve undiagnosed pain. *This may delay diagnosis of a progressive condition.*

Do NOT use if you have, in the area being treated: active or suspected cancer or undiagnosed pain with a history of cancer. *Stimulation directly through a confirmed or suspected malignancy should be avoided as it may stimulate growth and promote spread of cancer cells.*

Do NOT use electrodes on the front of the neck. Stimulation on the front of the neck can affect your heart rate or cause contraction of the throat.

Do NOT use electrodes across the chest as this may increase the risk of cardiac fibrillation. Very strong stimulation across the chest may cause an extra heartbeat and/or rhythm disturbances to your heart, which could be lethal.

Do NOT use Perfect mamaTENS while simultaneously connected to high frequency surgical equipment as it may result in burns at the site of stimulator electrodes and possible damage to the stimulator.

Do NOT use Perfect mamaTENS in close proximity (e.g. 1 m) to a shortwave or microwave as this may produce instability in the stimulator output.

CAUTIONS:

Caution should be used if you have a bleeding disorder as stimulation may increase blood flow to the stimulated region.

Caution should be used if you have suspected or diagnosed epilepsy as electrical stimulation may affect seizure threshold.

Caution should be observed when using the device at the same time as being connected to monitoring equipment with body worn electrode pads.

TENS machines may affect ECG based foetal heart rate monitors, causing them to give a very high reading. Please advise hospital staff that you are using a TENS device.

Caution should be used following recent surgical procedures. Stimulation may disrupt the healing process.

Caution Not intended for use in an oxygen rich environment.

Caution Not intended for use in conjunction with flammable anaesthetics or flammable agents.

Caution The patient is an intended operator.

Caution Do not service and maintain the device while in use.

Caution Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.

If necessary, we will provide circuit diagrams, component part lists or other information that will assist authorized service personnel to repair the device.

Caution The operator should not touch the patient at the same time when touching the battery output.

Caution Keep away from pets and pests

Caution Do not permit use by persons unable to understand the instructions such as those with cognitive disabilities, i.e.; Alzheimer's disease or dementia.

Caution Keep away from children under 5 years of age. *Long cord - risk of strangulation in infants*.

Caution should be observed when using the Perfect mamaTENS at high strength settings. Perfect mamaTENS has Yellow LED lights on output sockets which means the output will exceed 10 mA (R.M.S) or 10 V (R.M.S) averaged over any period of 1 sec. Prolonged use at high settings may cause muscle injury or tissue inflammation.

DO NOT PLACE ELECTRODE PADS:

- On skin, which does not have normal sensation. *If the skin is numb too great a strength may be used, which could result in skin inflammation.*
- On broken skin. *The electrode pads could encourage infection.*
- On the front of the neck. *This could cause the airway to close, giving breathing problems. May cause sudden drop in blood pressure (vasovagal response).*
- Over the eyes. *May affect eyesight or cause headaches.*

- Across the front of the head. *Effect on patients who have had strokes or seizures is not known. May affect your sense of balance. The effects of stimulation on the brain are unknown.*

ELECTRODE PADS CAUTION:

Caution: Do not ignore any allergic reaction to the electrode pads: *If a skin irritation develops, stop using TENS, as this type of electrodes may not be suitable for you. Alternative electrode pads specially made for sensitive skin are available.*

Caution: Do not use this device with leads or electrode pads other than those recommended by the manufacturer. *Performance may vary from specification. Electrodes with smaller surface area may cause tissue irritation.*

Caution: Do not use high intensity settings if electrodes are smaller than 50x50mm.

Note: Electrode pads supplied have no measurable latex content.

TO KEEP YOUR DEVICE IN GOOD WORKING ORDER, OBSERVE THE FOLLOWING ADDITIONAL CAUTIONS:

Caution: Do not immerse your device in water or place it close to excessive heat such as a fireplace or radiant heater or sources of high humidity such as a nebulizer or kettle as this may cause it to cease to operate correctly.

Caution: Keep the device away from sunlight, as long-term exposure to sunlight may affect the rubber causing it to become less elastic and crack.

Caution: Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the sockets or cause the battery connector to develop a bad contact.

Caution: Temperature & Relative Humidity of operating: 5°C to +40°C, 15% to 93% R.H. Temperature & Relative Humidity of storage: -25°C to +70°C, up to 93% R.H.

Caution: There are no serviceable user parts. Do not attempt to open or modify the TENS unit. *This may affect the safe operation of the unit and will invalidate the warranty.*

Note: There are no known side effect to TENS use and long-term TENS use is not harmful.

6. INFORMATION ABOUT THE PROGRAMME SETTINGS

Each programme has its own combination of Frequency and Pulse Width settings which allow for different sensations through the electrode pads and suppress pain in different ways.

- **Frequency (measured in Hz - pulses per second)**

PAIN GATE: A high frequency of 110 Hz is good at blocking pain signals.

- **Pulse Width (measured in µs - millionths of a second)**

The **Perfect mamaTENS** unit has pulse widths of 150 to 250 µs. Generally

speaking, the higher the pulse width, the more "aggressive" the stimulation feels, and eventually, if the pulse width is set high enough, it will usually elicit a muscle contraction, which is typically not the desired result with a TENS unit. However, if the pulse width is too low, the patient may not perceive the stimulation. Pulse Rate is important because different frequency settings target different nerve groups and the setting will determine if the "Gate Theory" or "Endorphin Theory" of TENS will be used.

- **Constant and Burst Modes**

Constant mode is when the sensation is continuous versus Burst mode when the sensation, as its name implies, is one of on and off. Constant mode is often used for acute pain via Pain Gate Effect whereas Burst mode is useful in chronic pain relief. Burst gives a combination of Pain Gate and Endorphin Release, but the squeezing feeling may not be as comfortable. The stimulation intensity will need to be relatively high. In Constant mode, the sensation is continuous and is more of a tingling pins and needles type.

- **Active Power Ramp Mode**

When pressing the **BOOST** button in programme **C**, the power or level of intensity during the final contractions ramps up to give additional short-term pain relief through a third mechanism called “Brief intense”.

7. PROGRAMMES

Programme	Frequency Hz	Pulse Width µs	Mode
A1	80	150	Burst
A2 Boost	80	150	Constant
B1	150	150	Burst
B2 Boost	150	150	Constant
C	80	250	Ramp

7.1. PROGRAMME A

You can start using **Perfect mamaTENS** as soon your contractions start to become regular.

When you switch the machine on, it automatically selects programme **A**. The LCD screen will display **A1**. This programme is designed to provide a pulsing sensation that triggers the release of endorphins, relaxing you and relieving you from pain. This programme has 50 small steps of intensity, so you have fine control of the strength of stimulation.

There are two modes, **A1** and **A2**.

Mode **A1** is for use between contractions and mode **A2** is for use during contractions. You can switch between the two modes at any time by pressing the **BOOST** button.

The **Perfect mamaTENS** will start at zero intensity. Increase the intensity until you feel a pulsing on-off-on-off sensation. When the next contraction starts press the **BOOST** button once and the mode will change to mode **A2**,

at the same intensity level as it was when in mode **A1**. Mode **A2** feels like a constant strong tingling. At the end of the contraction, press the **BOOST** button to return to mode **A1**. Repeat this each time a contraction starts. As the contractions become stronger simply increase the intensity.

7.2. PROGRAMME B

You should stay in programme **A** as long as possible, but when your contractions intensify and become more frequent you can progress to programme **B**.

Do this by pressing the programme button **P**. The LCD screen will display **B1**. To avoid discomfort with the change in programme, the set intensity will drop by half. This programme has 50 small steps of intensity, so you have fine control of the strength of stimulation. Press and release the ▲ button until you reach a comfortable intensity setting.

Programme **B** provides you with a stimulation pattern which is set to block the heightened pain which you may suffer.

You will feel that the stimulation in the higher set of pads CH1 (left channel) which have been placed just below your bra line is stronger than the lower set of pads CH2 (right channel) at the bottom of your back - this is intentional and part of the therapy. As the contractions become more intense and closer together, increase the intensity.

Note: If the lower electrode pads feel stronger then the upper ones then the leads have probably been incorrectly inserted into the **Perfect mamaTENS**. To correct this, change over the leads as per section 6, and reset the intensity.

Again, there are two modes, **B1** and **B2**.

The second mode **B2** is triggered by pressing the **BOOST** button when you experience a strong contraction. This mode provides a constant tingling sensation. When the contraction passes, press the **BOOST** button once more and your **Perfect mamaTENS** unit will change back to mode **B1**.

7.3. PROGRAMME C

If you find programs **A** and **B** do not meet your needs for pain relief there is a third program **C**, which provides a higher level of pain relief.

Press the programme button **P** again and this will take you to programme **C** which will be displayed on the screen as **C**. To avoid discomfort with the change in programme, the set intensity will drop by half. This programme has 60 steps of intensity. Press and release the ▲ button until you reach a comfortable intensity setting. This is a very natural way for you to control your pain as you rapidly increase and decrease the intensity to match the strength of your contractions.

Again, there are two modes, **C** and **C UP** (Active Power Ramp mode).

However, this time mode **C** is constant. Pressing the **BOOST** button starts the **Active Power Ramp** mode which ramps the power or level of intensity

during the final contractions to give the additional “Brief intense” pain relief.

In between contractions use the ▲ and ▼ buttons until you reach a comfortable level. When you experience a contraction just press the **BOOST** button down and HOLD IT.

The intensity will increase until you release the **BOOST** button because the intensity may become too much to bear. When you release, the intensity will drop rapidly and return to the background setting you pre-selected.

As it falls, you can press and hold the **BOOST** button again to keep the intensity at a fixed level to the end of your contraction.

When instructed to start ‘pushing’ you can use the programme button **P** to switch **Perfect mamaTENS** back to programme **A**.

Just remember the three programmes **A**, **B** and **C** which you can choose at any time as your labour progresses, and when you need a boost, just press the **BOOST** button.

TENS can be used for as long as it is necessary. Continuous treatment is fine, but, except during labour, the electrode pads should be repositioned regularly (about every 12 hours) to allow the skin to be exposed to the air.

8. ELECTRODE PADS

The electrode pads must always be used in pairs (two electrode pads on each channel), so that the signal can flow in a circuit.

The electrode pads need to be placed over the junctions of the nerves joining the womb and birth canal to the spinal cord. Correct positioning of the pads will give maximum pain relief so please study the images in section 11 and then follow these instructions.

Always check that the unit is OFF before attaching or removing electrode pads.

Perfect mamaTENS resets strength to zero if the pad or lead is disconnected from your body. This is to prevent sudden changes in sensation when the pad is re-connected.

ELECTRODE PADS ADVICE:

- The electrode pads supplied are reusable but for single patient use. The adhesive is a peelable hydrogel (water based).
- In order to obtain the best conductivity through the electrode pads always ensure that they are in good condition and tacky.
- Before use make sure your skin is clean and dry.
- Peel the electrode pads from their protective plastic shield by holding and lifting one corner of the pad and pulling. **Do not** pull on the pigtail wire of the pad.
- After use always replace the electrode pads on the plastic liner

and replace them in the re-sealable plastic bag.

If using before or after labour:

- If the electrode pads dry out, then it is best to buy a replacement pack. In an emergency, it may be possible to restore some of the tackiness of the pad by adding a tiny drop of water on each pad and spreading around. If too much water is added, the electrode pad will become too soft. If that happens then it is suggested in order to try and re-establish some adhesiveness, to place them sticky side up in a refrigerator for a few hours.
- In very hot weather the gel on the electrode pads may become soft. In such cases place them, still on their plastic liners and in their pouch into a fridge until they return to their normal condition.
- The electrode pads provided are latex-free.
- Replace the electrode pads when they lose their stickiness.
  Poor connection may cause discomfort and skin irritation.

Storage life of an unopened pack of electrode pads is 2 years. This may be affected by very high temperatures or very low humidity.

9. CONTENT

The pack contains:

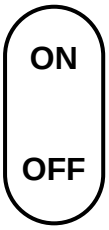
- 1 x **Perfect mamaTENS** unit, pain relief during labour
- 4 x 50x100 mm electrode pads with integrated leads (E-CM50100-PM)
- 2 x AA 1.5V alkaline batteries
- 1 x Detachable belt clip
- 1 x Neck cord
- 1 x Storage pouch
- 1 x Manual instruction

10. UNIT INFORMATION

10.1. CONTROLS & DISPLAY

10.2. OPERATING INSTRUCTIONS

ON/OFF



To turn the unit **ON**, press the **ON** button and hold for 3 to 5 seconds until the display shows.

To turn the unit **OFF**, press the **OFF** button and hold for 3 to 5 seconds until the display stops.

The unit will turn **OFF** automatically if it is left at zero strength for more than 5 minutes.

When switching the unit on, the display shows that the unit is automatically set in programme **A** at zero strength.

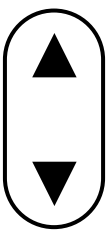
Note: Always check unit is OFF before applying or removing electrode pads.

The backlight will turn off 10 seconds after the last button press.

On the front of the unit there are six buttons:

STRENGTH CONTROLS

The buttons marked ▲ and ▼ are the strength controls.



To increase strength in steps of 1, press and release the ▲ button.

The strength level is shown on the LCD.

The strength control buttons will not operate until the unit is properly connected to you. Perfect mamaTENS detects a disconnection and automatically returns the strength to zero.

The unit has 50 levels of strength in programme **A** & **B**, and 60 levels in programme **C**. If you hold down the button for 3 to 5 seconds, the strength will start scrolling.

You may feel nothing over the first few presses. Continue pressing until the sensation is strong but comfortable. Further increases during use may be necessary if your body becomes used to the sensation.

To decrease the strength, press and release the lower part of the button marked ▼.

The yellow LED on the output socket indicates that there is an active output. The display will remain on for 5 seconds after the plug is removed.

PROGRAMME CONTROL

The button marked **P** is the programme control. The **Perfect mamaTENS** has 3 different preset programmes lettered **A**, **B** and **C**.

Each time you press and release the **P** button, the programme changes and the letter is shown on the LCD.

Each time the programme changes the intensity of stimulation is automatically reduced by 50%.

KEYPAD LOCK

The button marked is the **LOCK** button, it can be used to lock the keypad. This is to avoid accidental changes in setting. To lock the controls, press and hold the **LOCK** button down for 3 seconds. will appear on the LCD screen and none of the controls will be working except for the ▼ button. Press and hold to unlock.

BOOST BUTTON

On the side of the unit there is a **BOOST** button. Its action depends upon the programme selected and is detailed within the section 7.

LOW BATTERY

An empty battery symbol will show when you need to change the batteries. The unit will shut down about 2 minutes after this.

OPEN CIRCUIT CUTOUT

If the **Perfect mamaTENS** is not correctly connected to your body, the strength will automatically reset to zero. This is to prevent sudden changes if a broken connection is re-made.

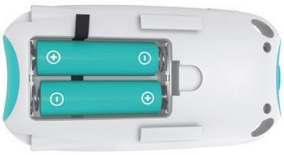
11. SETTING UP AND USING THE PERFECT MAMATENS

11.1. INSTALLATION OF BATTERIES

1) Remove belt clip by sliding down.

2) Remove battery cover by pulling on tag.

3) Insert batteries.



Ensure that the batteries are inserted the right way as shown in battery compartment and that the ribbon is behind them.

4) Replace battery cover and belt clip.

When the batteries are running low, a low battery indicator will show on the screen and it is important to change the batteries as soon as possible.

Rechargeable batteries

Do not use rechargeable batteries. *They have a lower voltage and may activate the low battery cut-out.*

Caution: Remove batteries from your **Perfect mamaTENS** if the unit is unlikely to be used for a long period. *Some types of batteries may leak corrosive fluid.*

Battery Life

Batteries should last at least 30 hours (Programme A, both channels 40mA).

Unused batteries have a nominal shelf life of 3 years, but will usually last longer than this.

Battery Warnings

Do NOT pierce, open, disassemble, or use in a humid and/or corrosive environment.

Do NOT expose to temperatures over 60°C(140F).

Do NOT put, store or leave near sources of heat, in direct strong sunlight, in a high temperature location, in a pressurized container or in a microwave oven.

Do NOT immerse in water or sea water, or get wet.

Do NOT short-circuit.

Do NOT connect the device unless the battery cover is in place.

If battery leakage occurs and comes in contact with the skin or eyes, wash thoroughly with lots of water and immediately seek medical attention.

Warning: Keep batteries out of the reach of children to prevent them from swallowing them by mistake. If swallowed by child, contact doctor immediately.

Caution NEVER attempt to recharge an alkaline battery. *Risk of explosion.*

Caution Do not mix old, new or different types of batteries as this may lead to battery leakage or low battery indication.

Disposal: *Always dispose of batteries and device responsibly according to local government guidelines. Do not throw batteries onto a fire. Risk of explosion.*

11.2. CONNECTING LEAD WIRES

Connect the lead wires to each channel as shown on the image.

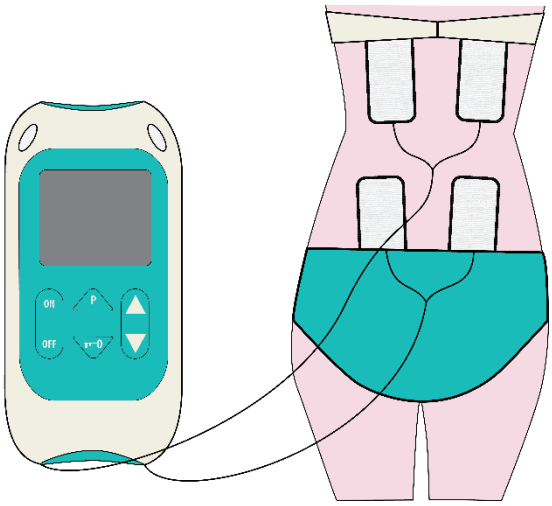
Insert the lead wire for the pads to be used under the bra line into Channel 1 at the base of the machine.

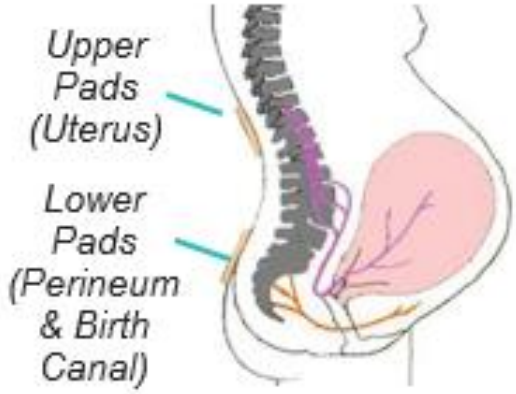
The lead wire for the pads which will be used on your lower back should then be inserted into Channel 2.

The lead wires may be damaged by rough handling, and should be treated with care.

11.3. PREPARING FOR SESSION

1) After the lead wires are securely connected you will need to ask your birthing partner to place the electrode pads into the correct position on your back. To ensure good adhesion of pads, the area of skin they are going to be applied to needs to be clean, dry, and free from grease or powder.
2) For contraction, episiotomy pain or perineal tear, place the top pair of pads (connected to CH1) either side of the spinal column 2 inches (50 mm) apart from each other and about 3 inches (75 mm) below the bottom of the shoulder blades (close to vertebrae T10, T11, T12 and L1). This is just below the bra line.
3) Place the lower pair of pads (connected to CH2) either side of the spine about 4 inches (100 mm) apart and about 1 inch (25 mm) above the dimples at the base of the spine, just above the buttocks (close to vertebrae S2, S3 and S4).





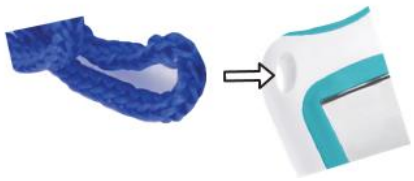
Warning: Ensure the **Perfect mamaTENS** is switched OFF before applying the electrode pads on the skin.

4) You can safely lean on the electrode pads. The sensation might change.
5) With the electrodes pads in place you can choose to use the belt clip or the neck cord, whichever you are most comfortable with, so you are able to remain as mobile as possible.

   A belt clip is provided to allow you to attach the unit to your clothing. It can be inserted either way up. Slide the clip along the base of the unit until it locks in position.

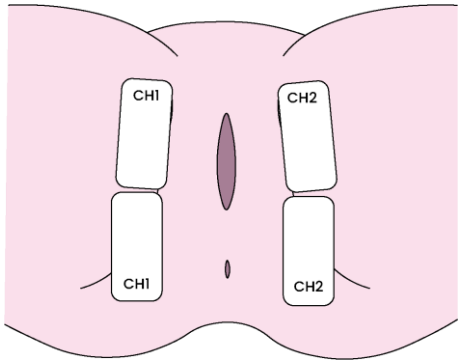
   You can also hang the unit from your neck with the neck cord using the holes on each shoulder of the unit. The neck cord is designed to open for safety if pulled.

   Feed a loop of the neck cord through the hole in the shoulder of the unit and pull through. Feed cord through the loop and pull tight towards the unit.



Warning: Do not use other cords than the one provided.

Pad placement for episiotomy



11.4. TREATMENT SESSION

1) Press and hold the **ON** button on the control unit for 3 to 5 seconds to switch the control unit on.

   The LCD display will appear as **A1 00** indicating that the unit has set itself into Labour Pain Phase A and Mode 1 at Zero intensity (00 mA).

2) You can now adjust the intensity of the stimulation with the buttons ▲ and ▼ until you reach a comfortable level. The LCD display shows the strength of intensity.
3) Just remember the three programmes **A**, **B** and **C** which you can choose at any time as your labour progresses, and when you need a boost, just press the **BOOST** button (see section 7).

Note: If the sensation becomes uncomfortable, reduce the intensity.

Note: If the user is able to turn the device on, increase and decrease the intensity, switch between all three programmes and activate Boost mode in all programmes, this confirms the device will perform as intended by the manufacturer.

11.5. AFTER YOUR TREATMENT SESSION

After use, press and hold the **OFF** button on the control unit for 3 to 5 seconds to switch the control unit off

1) Once the unit off, remove the electrode pads from your skin by holding the pad itself and gently pulling.
2) Replace the electrode pads to their protective plastic shield and return them to the re-sealable plastic bag.

Note: When removing the electrode pads, DO NOT PULL ON LEAD WIRES.

Before the birth, you can use your **Perfect mamaTENS** to help with back pain, and after with post birth pain.

Perfect mamaTENS programme A1 stimulation can be used with the breast electrode pads* (see E-CMR60130) to help initiate lactation. However, it is not intended to treat any medical issues and your first step in deciding appropriate therapy should be to consult your professional medical advisor.

If you plan to put your **Perfect mamaTENS** into storage for your next baby then do the following:

- Remove batteries

- Clean as instructed in section 12
- Store or throw away the electrode pads with integrated leads
- Remember to buy new electrode pads and batteries before you need to use your **Perfect mamaTENS** again.

12. CLEANING & STORAGE

Clean the case and lead wires after each use by wiping with a damp cloth and a solution of mild soap and water. Wipe dry.

- **Do not** immerse your TENS machine in water.
- **Do not** use any other cleaning solution than soap and water.

Storage life

- Storage life of an unopened pack of self-adhesive electrode pads is 2 years. This may be affected by very high temperatures or very low humidity.
- The unit has no fixed shelf life.

13. EMC

Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment.

(Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m).

Note: For hospital use, full EMC advice tables are available on request.

14. DISPOSAL OF WASTE ELECTRICAL AND ELECTRONIC PRODUCTS (WEEE)

One of the provisions of the European Directive 2002/96/CE is that anything electrical or electronic should not be treated as domestic waste and simply thrown away. To remind you of this Directive all affected products are now being marked with a crossed-out wheelie bin symbol, as depicted below.

To comply with the Directive, you can return your old electro-therapy unit to us for disposal. Simply print a postage-paid PACKETPOST RETURNS label from our website www.tenscare.co.uk, attach this to an envelope or padded bag with the unit enclosed, and post it back to us. Upon receipt, we will process your old device for components recovery and recycling to help conserve the world's resources and minimise adverse effects on the environment.

15. ACCESSORIES

Expected Service Life

- The machine will often last for more than 5 years, but is warrantied for 2

years. Accessories (electrode pads, neck cord, belt clip and batteries) are not covered by the warranty.

- Electrode pads should last 12 to 20 applications, depending on skin condition and humidity.
- Batteries should last at least 15 hours at 50 mA, 300 µs, 50 Hz.

Replacement electrode pads, new batteries and separate lead wires are available from your supplier or distributor (see back cover for contact details), by mail order from TensCare, by telephone using a credit or debit card, or through the TensCare website.

The following replacement parts may be ordered from TensCare at www.tenscare.co.uk or +44(0) 1372 723434.

E-CM50100-PM	Pack of 4 50x100 mm electrode pads with integrated leads
E-CMR60130	Breast electrode pads Pack of 4 (2 pairs)
L-CPT	Separate lead wire
B-AA	1.5V AA batteries
X- BC-PT	Replacement belt clip
X-NC-MR	Replacement neck cord
X- BL-PTT	Replacement battery cover

16. WARRANTY

This warranty refers to the unit only. It does not cover electrode pads or battery.

PRODUCT WARRANTY INFORMATION

This product is warranted to be free from manufacturing defects for 2 years from date of purchase.

This warranty is void if the product is modified or altered, is subject to misuse or abuse; damaged in transit; lack of responsible care; is dropped; if incorrect battery has been fitted; if the unit has been immersed in water; if damage occurs by reason of failure to follow the written instructions for use booklet enclosed; or if product repairs are carried out without authority from TensCare Ltd.

We will repair, or at our option replace free of charge, any parts necessary to correct material or workmanship, or replace the entire unit and return to you during the period of the warranty. Otherwise, we will quote for any repair which will be carried out on acceptance of our quotation. The benefits conferred by this warranty are in addition to all other rights and remedies in respect of the product, which the consumer has under the Consumer Protection Act 1987.

Our goods come with warrantees that cannot be excluded under the UK consumer Law. You are entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality.

Before you send your unit for service

Before sending in your unit for service, please take a few minutes to do the following:

Read your manual and make sure you follow all the instructions for use.

Returning your unit for service

Should repair be needed within the warranty period, enclose the tear off section of the warranty card (see page 35) and your proof of purchase receipt. Please ensure all relevant details are completed before sending your unit in for service. Please ensure your contact details are still current and include a brief description of the problem you are experiencing together with your purchase receipt.

For hygiene reasons, please do not include used electrode pads. Send only the unit.

Please return the unit and warranty card (see page 35) at your cost to:

TensCare Ltd

PainAway House,
9 Blenheim Road,
Longmead Business Park,

Epsom, Surrey
KT19 9BE, UK

Should you require any further information please do not hesitate to contact us by calling our number:

+44 (0) 1372 723 434.

17. TROUBLESHOOTING

If your TENS machine is not working properly, please check the following:

Problem	Possible causes	Solution
No display	Flat batteries.	Replace batteries.
	Batteries inserted incorrectly.	Remove plastic wrap. Check + / - .
	Damaged springs in battery compartment.	Contact supplier.
Low battery display	Low batteries.	Replace batteries.
No sensation	Incorrect connection.	Check that you have applied the 4 electrode pads to ensure a complete circuit.
	Intensity is not strong enough.	Increase strength. Most users will feel something at a setting below 10.
	Open circuit cut-out operating.	Ensure machine is attached to your body correctly.

Output will not increase above zero	Lead not connected to body or faulty/damaged.	Try using the second lead wire. Purchase replacement if necessary.
	(Lead wires can break at the bend where they leave the machine giving no, or intermittent, output).	
Sudden change in sensation	If you disconnect and re-connect a few minutes later, the signal will feel quite a lot stronger.	Always return strength to zero after disconnecting the leads or electrode pads.

If the above review has failed to resolve your problem, or to report unexpected operation or events, or to provide feedback call TensCare or your local supplier or distributor (address on back cover) for advice.

Contact TensCare customer service on +44 (0) 1372 723 434. Our staff are trained to assist you with most issues you may have experienced, without the need to send your product in for service.

European Medical Device Regulation requires that any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority in your country. This can be found at:

https://ec.europa.eu/docsroom/documents/36683/attachments/1/translations/en/renditions/pdf

18. RESIDUAL RISKS

The user should be aware of the residual risks associated with using the device.

Risk Category	Foreseeable sequence of events	Hazardous situation	Harm
Energy Hazards			
Thermal Energy	Resistance to Heat: Mechanical Characteristics will be impacted by the heat, which result in distorion of case	Device stored in hot place.	Device does not function correctly. No Essential Performance, so no harm to the patient, other than delay in pain relief
		Parts could come loose while in use, exposing sharp edges.	Minor cuts, abrasions. Loose parts stuck in orifice.
Hyperthermic Effects	Electrode surface area too small to safely carry maximim output from stimulator	inappropriate electrode supplied	Once the power density that delivers to the skin is over 0.25W/ cm² can produce a

			burn. Thus small contact area of electrode may cause high power density and burn.
	High current output causes burns	User not aware that high setting can be dangerous	At high settings devices with high outputs can cause both thermal and chemical burns
	Inadequate supply of power or coolant	None. No coolant. No Essential Performance	None
	Restriction of cooling. Device overheats while battery is charging.	Battery explodes	Unquantified Injury
Hypothermic Effects	Material could become brittle when exposed to extreme cold	Material could crack if subjected to impact, creqating sharp edges. Device fails to function	At high settings devices with high outputs can cause both thermal and chemical burns
Acoustic Energy	Acoustic Pressure, The sound Pressure is too loud	Device held near to ear when adjusting intensity	Causes hearing damage
Electrical Energy	Design input or output error. Software or hardware failure	High energy output- High energy deliver to the user could lead to serious hazards.	Burn, electric shock
	Electricity Excessive leakage current to the user; Electric shock to the user, caused by the internal inadequate output, or the external interference and electrostatic charge.		
Electromagnetic energy	Channel isolation	no issue- only one channel	
	Electromagnetic field There may be electro-magnetic fields that might affect the user.	High EMF emitted.	Affect brain fuction. Induce seizures/loss of balance?
	Electromagnetic interference and susceptibility	The electromagnetic wave may affect the patients and interfere of other	May cause malfunction of life support or monitoring devices.

		devices in hospital. The device may not work normally as was impacted on surrounding electromagnetic environment.	
	Electromagnetic interference and susceptibility	External interference may cause this device to malfunction and go to maximum output	Burn, muscle contraction.
	Delivered stimulation excessive	High energy output- High energy deliver to the user could lead to serious hazards.	Burn, electric shock
Static Discharge	Static in clothes discharges through device.	Device damaged and fails to operate correctly	For excessive, see rows 9, 10, 15, 16 &20 . For ineffective- no Essential Performance
Leakage Current	Defibrillator or mains current conducted through device	High current goes through electrodes	Burn, electric shock
Enclosure Leakage	Touch current. Possibility of a current flowing from an accessible conductive part of the device and the applied part.	Output current from device goes through third party, or an unsafe part of the body (heart, eyes, pacemaker)	Burn, electric shock
Magnetic fields(e.g. MRI)	Not intended for use in MRI. Domestic appliance causes device to malfunction. Emissions from device cause another medical device to malfunction	- Device switches to max output. Life support Device fails	- Burn Death
Radiation Energy Ionizing radiation	No ionising radiation emitted		
	Non-ionizing radiation might affect other devices or user	see EMC above	
Mechanical Energy			
Mechanical Force Inadequate mechanical strength	Inadequate design strength. Component may break.	breaks in use, producing sharp	Minor cuts, abrasions. Loose parts stuck in

		edges and stopping function.	orifice. Patient does not benefit from this treatment session. May affect future compliance.
Vibrating Parts	Connection might come loose.	Treatment would stop	Patient does not benefit from this treatment session. May affect future compliance
Potential Energy			
Suspended masses	Not present		
Patient support device failure	Not present		
Pressure(vessel rupture)	Not present		
Software failure. May cause electric shock, etc.	Software fails, goes to maximum output	High energy output- High energy deliver to the user could lead to serious hazards.	Burn, electric shock
Unintended output pulses		High energy output- High energy deliver to the user could lead to serious hazards.	Burn, electric shock
Parameters adjustable during use	User has not read instructions	Sets intensity too high or too low. Intensity too high when Programme changed.	Pain/discomfort. Treatment ineffective. Burn, electric shock
Controller or display failure	May cause the display of intensity to be incorrect. Too large output set by user	High energy output- High energy deliver to the user could lead to serious hazards.	Burn, electric shock
B. Biological hazards, chemical hazards, biocompatibility			
Viruses, Toxins, Prions, Parasites, Fungi, Bacteria	Device not cleaned adequately after/before use	Infection multiplies on	Seriousness depends on infection. Increased risk

		device between uses.	over daily living uncertain
Bio-burden	Device is contaminated and transfers infection to user	User does not clean before first use	Not sterilized. Normal level of cleanliness required in production.
Bio-contamination	Device is contaminated in use	user shares with another person and spreads infection	Seriousness depends on infection.
Bio-incompatibility	Poor selection of materials for electrode gel , probe and other parts in contact with skin. Lack of control in production allows change of materials or contamination	Device is used for 60 mins daily. The material of gel may be toxic to skin and human body. The material of Enclosure may be toxic to skin or human body.	Poisoning
Incorrect formulation (chemical composition). The material of gel may cause incompatibility to skin	Poor selection of materials for electrode gel , probe and other parts in contact with skin. Lack of control in production allows change of materials or contamination. Allergen such as latex included in gel.	Device is used for 60 mins daily. The material of gel may be toxic to skin and human body. Patient may be allergic to materials in the gel.	Poisoning. Allergic reaction
Toxicity gel material may have some toxicity to human skin	Poor selection of materials for electrode gel and other parts in contact with skin. Lack of control in production allows change of materials or contamination. Allergen such as latex included in gel.	Device is used for 60 mins daily. The material of gel may be toxic to skin and human body. Patient may be allergic to materials in the gel.	Poisoning. Allergic reaction
Cleaning method	User doesn't clean the device as instructed.	Build-up of dirt allows bacteria to colonise	Broken skin becomes infected
Contact injuries Skin irritation; potential allergic reactions	User is sensitive to a chemical component of the gel. Approx 0.36% of users will have adverse reaction to electrode gel. (See CER)	User continues use after skin becomes inflamed	Broken skin becomes infected
Irritants			

Cleaning Residues	Inadequate cleaning in production. User does not clean before first use.	Irritants from moulding release agents left on surface of device.	Infection, poisoning, allergic reaction
Performance-related Hazards			
Software failure	Product goes out of control while in use	User unable to control output. Delays in removing device from skin	May cause electric shock, etc.
Unintended output pulses	Product goes out of control while in use	User unable to control output. Delays in removing device from skin	May cause electric shock, etc.
Error in adjusting output intensity during use.	failure of keypad causes the output to increase suddenly.	User unable to control output. Forced to remove device from skin to stop stimulation	skin burn or discomfort
Controller or display failure	component failure. Display of intensity is not correct,	Output set too high. First feedback is skin sensation - display is only a backup.	electrical shock or skin burn
Degraded component.	Self-adhesive electrodes are loose. Electrodes will not stick.	Gel eroded. Small contact surface area creates higher current density or tunneling, Minor “pinprick” burns.	Electrodes may be less effective. No treatment given. Sharp pain or skin burn
Functionality			
Ingress of water	Device dropped in water. Water spilled over it	Fails to operate, or goes to max output	burn, electric shock
Interruption of power supply	Internal battery operation. Lose charging cable. Unable to charge	No ESSENTIAL PERFORMANCE	Loss of benefit while battery not charged.
Incompatibility with other devices	Not intended to work with other devices. Accidentally connect lead from other device into charging socket.	Other device uses USB connector but delivers higher voltage.	battery overheats, catches fire/explodes

Other mechanical hazards	Long lead causes strangulation	Small child wraps lead wires around neck	Death
Diagnostic Information			
Inadequate specification of: — design parameters	Device ineffective	No essential performance	delay in relief of symptoms
— operating parameters	Device ineffective		
— performance requirements	Device ineffective		
Lack of, or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	No maintenance other than cleaning required. See B06 above		No essential performance. The device is not used for diagnosing or life- supporting. Loss/ deterioration of function will not lead to hazard.
Lack of adequate determination of end of device life Deterioration may cause hazardous output	Device is used for many years. Material starts to disintegrate	component malfunction Particles/parts/ sharp edges appear.	See A30, A31 above No essential performance. User receives minor cut/abrasion to vaginal wall. Electrode plate detaches inside of vagina.
Cleaning, disinfection and sterilization			
Disposal and scrapping	toxic materials in device released to environment.	device placed in general waste	poisoning of environment/water supply
	Device incinerated	Battery explodes	injury to bystander
Usability			
Confusing or missing instructions for use Complex or confusing control system Poor mapping of controls to actions, or of displayed information to actual state	User applies to wrong part of the body.	Stimulates unwanted response.	High output of ES can cause heart problems etc
	Uses wrong setting	No effect	no essential performance

Insufficient warning of side effects	User ignores or does not notice side effects.	Side effects become worse	no significant side effects reported in CER
Effects of dust, lint, pet hair on operation	household dirt gets into device and prevents proper function	Up button jams in on position. High energy output- High energy deliver to the user could lead to serious hazards.	Burn, electric shock
		Gel will not stick	Benefit of treatment not received.
Use over cancerous tissue	It is not known whether electrical stimulation may increase malignant growth.	device placed over malignant tissue	worsening of condition, death.
Use on chest	User places device on chest	Very strong stimulation across the chest may cause an extra heartbeat and/or rhythm disturbances	death
Use on other parts of body	User places device on eyes, mouth, front of neck	stimulating these areas could cause eye damage, restriction of airways, change in heart rate. Very unlikely as TENS has a built-in control -it usuallly causes pain before harm.	Injury or death.
Use late into pregnancy	User applies stimulation on the abdomen in the later stages of pregnancy	Stimulation could cause unexpected contractions	Injury or death to baby.
Use during first three months of pregnancy	User applies stimulation during the first three months of pregnancy	Stimulation could affect foetal development.	Injury or death, impact on foetal development

19. GENERAL SPECIFICATION

Waveform	Symmetrical Bi-Phasic Rectangular
Amplitude (over 500 Ohm load)	75.0 mA zero to peak, 50 steps in A & B, 60 steps in C +/- 10%
Output plug	Fully shielded: touch proof
Channels	Dual channel
Batteries	2 x AA alkaline (two AA batteries)
Weight	75 g without batteries
Dimensions	120 x 60 x 20 mm
Safety Classification	Internal power source. Designed for continuous use. No special moisture protection.
Environmental specifications:	
Operating: Storage:	Temperature range: 5 to 40ºC Humidity: 15 to 93% RH non-condensing Atmospheric pressure: 700hPa to 1060hPa Temperature range: -25 to +70ºC Humidity: Up to 93% RH non-condensing
TYPE BF APPLIED PART 	Equipment providing a degree of protection against electric shock, with isolated applied part.
	This symbol on the unit means “Refer to Instructions for use”.
IP22	The unit is not water resistant, and should be protected from liquids.
	Complies with EU WEEE regulations

Note: The electrical specifications are nominal and subject to variation from the listed values due to normal production tolerances of at least 5%.

Note: At least 30min required for the device to warm / cool from the minimum / maximum storage temperature between uses until it is ready for intended use

PLEASE RETAIN THIS WARRANTY CARD.

RETURN THIS PORTION ONLY WHEN YOU RETURN YOUR PRODUCT FOR REPAIR UNDER WARRANTY.

NAME: _____

ADDRESS: _____

_____

POSTCODE: _____

DAYTIME TELEPHONE: _____

E-MAIL: _____

MODEL: _____

DATE OF PURCHASE: _____

ATTACH PROOF OF PURCHASE

DO NOT RETURN ELECTRODE PADS OR LEADS

RETAILERS NAME: _____

RETAILERS ADDRESS: _____

_____

RETAILERS POSTCODE: _____

BRIEF DESCRIPTION OF PROBLEM YOU ARE EXPERIENCING: _____

_____

_____

_____

WARRANTY IS VOID UNLESS THE ABOVE INFORMATION IS COMPLETED AND CORRECT.

TensCare aim to give you the best possible product and service. We listen to your suggestions and are constantly trying to improve our products. We also want to learn about the way our products are used, and the benefits they give. If you have anything you would like to share with us, please get in touch.

www.tenscare.co.uk

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CE
2797

EC Declaration of Conformity

Tenscare Ltd herewith declare that the product meets the provisions of REGULATION (EU) 2017/745 which apply to it. The medical device has been assigned to class IIa according to Annex IV of the REGULATION (EU) 2017/745. The product concerned has been designed and manufactured under a quality management system according to Annex IX, of REGULATION (EU) 2017/745. This EU declaration of conformity is issued under the sole responsibility of the manufacturer. No “Common Specification” is applicable.

Distributed by:

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EC REP

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