

Distributed by:



TensCare™

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ova♀

Period Pain Reliever

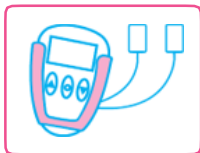


INSTRUCTIONS FOR USE

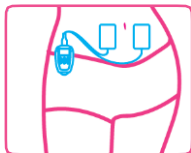


READ CAREFULLY BEFORE STARTING USE

TensCare™



Connect the main unit with electrodes using the Y-cable



Place two electrodes on each side of your lower tummy, distance between the electrodes should be over 3cm



Turn on the device by pressing and holding the "▲" button for 3 seconds



Select the programme which works best for you by pressing and holding the "PROGRAMME SELECTOR" button



Regulate the output intensity by pressing the "▲", or "▼" buttons



Keep pressing and holding the "▼" button for 3 seconds to turn off the device

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1. INTRODUCTION

Period Pain (Dysmenorrhoea) is a widespread problem which affects 40-90% of women. Period pain can have a real impact on quality of life, leading to absences from work and school.

The “Ova +” Period Pain Reliever offers drug-free relief from period pain. If you are unsure of the cause of the pain then you should seek medical advice to establish the cause and identify the correct treatment.

The “Ova+” is a non-invasive small and convenient unit that can be worn all day under clothing to provide safe, continuous, drug-free period pain relief whilst maintaining a normal, active lifestyle.

2. INTENDED USE



This device has been designed to be used in the home healthcare environment to treat symptoms of primary menstrual pain (dysmenorrhoea).

The “Ova+” may also help to relieve the pain of secondary menstrual pain due to conditions such as endometriosis, fibroids or pelvic inflammatory disease.

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

3. PERIOD PAIN

Painful periods are common in teenagers and young adults.

Most women have some pain during periods. The pain is often mild but, in about 5 in 10 women, the pain is severe enough to affect day-to-day activities. The pain can be so severe that they are unable to go to school or work.

Period pain generally falls into two categories: **primary dysmenorrhoea** and **secondary dysmenorrhoea**.

Primary dysmenorrhoea has no specific cause yet is the most common type of painful periods affecting 9 out of 10 women. It occurs where there is no underlying problem of the womb (uterus) or pelvis. The main symptom is a cramping type of pain in the lower tummy (abdomen); it may in some cases spread to the lower back, or to the top of the legs. Pains are generally worst in the first few years after starting your period, with symptoms tending to improve with age or after childbirth.

Secondary dysmenorrhoea is less common, and is more likely to occur in women in their 30s and 40s. It is caused by a specific underlying condition such as *endometriosis* (when cells that normally line the uterus are found at other sites in the body – usually the ovaries and fallopian tubes). Again, the main symptom is cramping pain in the lower tummy during your periods. In some women with secondary dysmenorrhoea the pain starts several days before the period begins, and lasts all the way through the period. (This is uncommon with primary dysmenorrhoea). With secondary dysmenorrhoea it is likely to have other symptoms - for example:

- Irregular periods.
- Bleeding between periods.
- Pains between periods.
- The bleeding becomes heavier than previously.
- Vaginal discharge.
- Pain during sex.
- Pain in your back passage (rectum).

Secondary dysmenorrhoea may occur as a result of:

- Endometriosis/adenomyosis.
- Pelvic inflammatory disease.

- Fibroids when it is often associated with heavy menstrual bleeding.
- Adhesions.
- Developmental abnormalities.

Consult your healthcare professional if you are experiencing any of the above symptoms.

4. ADVANTAGES OF “OVA+”

The “Ova+” can be an option for women who prefer not to use medication.

The “Ova+” causes muscles in the uterine area to relax with a calming analgesic effect.

By reducing menstrual pain, the “Ova+” can help improve sense of wellbeing and allows everyday activity to resume while it is worn.

The “Ova+” is non-invasive and drug-free, therefore the risk of side effects is considered to be low, and can be worn comfortably while engaging in everyday activities.

The “Ova+” is easy to use and very discreet. Its small size makes it convenient to wear all

day and this allows you to get on with your everyday life, without period pain.

5. HOW IT WORKS

The “Ova+” uses T.E.N.S. to relieve pain. T.E.N.S. stands for Transcutaneous Electrical Nerve Stimulation. The “Ova+” machine delivers small electrical pulses to the body via electrode patches placed on the lower abdomen. It works in three ways:

- It blocks pain signals from reaching the brain through a mechanism called the ‘Pain Gate’.
- It stimulates the natural production of endorphins which raise the threshold for pain perception.
- Finally, it helps to relax the contracted muscles.

It is important to allow the “Ova+” time to work. Each time a new programme or position for the pads is selected allow the “Ova+” to run for thirty minutes. If after that time the relief is not sufficient, then try another programme or pad position. Even if you obtain excellent relief it is still useful to try other settings.

6. CONTRAINDICATIONS, CAUTIONS & WARNINGS

In this manual:

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.

CONTRAINDICATIONS:

Do NOT use if you have a pacemaker (or 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. Stimulation on the front of the neck can affect your heart rate. Very strong stimulation across the chest may cause an extra heartbeat.*

Do NOT use if you are or may be pregnant; or in the first 6-8 weeks after childbirth. *It is not known whether TENS may affect foetal development.*

WARNINGS:



Do NOT use when driving, operating machinery, or similar actions needing muscular control. *Loose 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 poor sensation in the pelvic region. *You may not be able to control the intensity of stimulation safely.*



Do NOT use if you have, in the area being treated: active or suspected cancer; or have 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.*

CAUTIONS:

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 “Ova+” at the same time as being connected to monitoring equipment with body worn electrode pads. It may interfere with the signals being monitored.

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

Caution. Simultaneous connection to high frequency surgical equipment may result in burns and damage to the stimulator.

Caution. Strong electromagnetic fields (electro-surgery/ microwave cookers/ mobile phones) may affect the correct operation of this unit. If it appears to behave unusually, move it away from these devices.

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

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 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 of the brain are unknown.*

- 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. You may need to contact your healthcare professional to discuss other suitable options.*

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. Do not attempt to open up or modify the TENS unit. *This may affect the safe operation of the unit and will invalidate the warranty.*

Caution. Do not use this device with electrodes other than those recommended by the manufacturer. *Performance may vary from specification.*

7. PAIN RELIEF PROGRAMMES

The "Ova+" offers four preset clinically tested programmes which are displayed on the screen as Mode 0, Mode 1, Mode 2, Mode 3. Each programme relieves pain in a different way. It is important to try all four programmes to find which suits you the best. It is also sensible to change from one programme to another regularly in order to prevent your body unduly accommodating to one particular programme.

Mode 0 has a constant output that produces a tingling sensation, activating the Pain Gate. It is the programme that is likely to result in the greatest pain relief.

Mode 1 also has a constant output but, due to a different pulse width, it will feel less strong than Mode 1.

Mode 2 contains a burst signal thus the feeling will be one of pulsing. This programme can have the advantage of achieving, for a time, ongoing residual pain relief after the "Ova+" has been switched off.

Mode 3 is a fast tapping/vibrating sensation. This setting uses the Endorphin Release mechanism, and has been shown to soothe over-excited nerves.

GENERAL POINTS

i) A microprocessor inside the device offers user-friendly controls and gentle outputs.

ii) Most users feel a warm, relaxing sensation and pain relief across the lower tummy during treatments. These results are the favourable effects produced by the electrical output from the device which copies natural nerve impulses.

iii) A large LCD screen clearly shows the operation of the unit.

iv) A small clip on the back of the plastic holder of the main unit helps to attach the device to your underwear, skirt, trousers or pockets.

v) 4 programmes cover typical types of individual nerve differences.

vi) Output current automatically returns to zero when switching programmes.

vii) The unit has a built-in Li-ion rechargeable battery & a micro USB port. To charge the device, use a phone or tablet charger, or the USB port of a computer.

viii) When the device is switched ON, it will resume in the mode previously used.

ix) When the battery is low, the battery symbol on the LCD screen will flash.

x) Use the highest intensity setting that is still comfortable.

xi) You will find that you grow accustomed to the stimulation (this is known as accommodation), and need to increase the intensity to keep feeling a strong sensation.


xii) TENS can be used as long as it gives relief. If the effect wears off, turn off the unit for an hour to allow your nerves to re-set.

xiii) Do not use while sleeping.



Warning. Turn off the device before disconnecting leads or removing the electrodes from the skin.

8. BATTERY

1. A fully charged battery should run for at least 5 hours.
2. When the battery symbol on the LCD screen flashes, it is time to charge the battery. 
3. Connect the USB cable to a mobile phone or tablet charger, or to a PC USB port.



4. The battery indicator bar cycles from zero to the max when charging is in progress.
5. Charging should take about 40 minutes.

6. When the battery charging has completed, the bar stops cycling and remains at maximum to indicate full capacity.
7. Remove the charging cable and adaptor from the device when charging is completed.

WARNING:

This product is equipped with a Lithium-ion battery. Failure to follow these instructions could cause the lithium-ion battery to leak acid, become hot, explode or ignite and cause injury and/or damage:



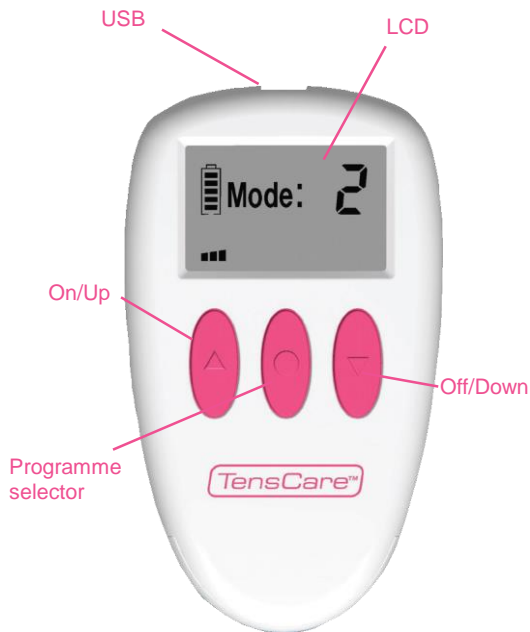
Do NOT expose to temperatures over 60°C (140F)



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

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

9. CONTROLS AND DISPLAY



Left button (▲):

Press and hold this key for 2 seconds to **turn ON** the device. When the device is ON, repeatedly press it to **increase the strength** of the electrical signal. Turn the strength up slowly, wait after each press to feel the effect.

Central button (●):


Every time the unit is switched ON, the **programme** used in the last session is automatically loaded. To change it, press and hold the button for 2 seconds. This allows the selection one of the 4 preset programmes. When a different programme is selected, the stimulation strength is automatically reset to 0.

Right button (▼):

Repeatedly press this key to **decrease the strength**. To **switch OFF** the device, press and hold it for 2 seconds.

The micro **USB** port provides a connection to the electrodes, or to charge the battery inside.

The **LCD** display shows the selected Mode (through a number from 0 to 3) and the level and status of stimulation output (through a 20 segment bar graph).

When the battery is low, a blinking symbol is displayed to warn it should be recharged. 

10. CONTENTS OF PACK

The Ova+ packaging should include the following parts:

- “Ova+” unit
- Pack of 2 self adhesive electrodes, 50x90 mm with 2.1 mm “pigtail” connection
- USB charging cable
- Lead wire (Y- cable)
- Belt clip support to be attached to clothing
- User guide
- Storage pouch



11. SETTING UP

11.1 PREPARING THE “OVA+” UNIT

1. To test that the battery is charged (see section 8) and that the unit is working press and hold the “▲” button for at least **three seconds**.

The display should appear and an audible “Beep” will be heard.

Press and hold the “▼” button to turn off the unit.

2. Connect the Y-cable to the unit.



Y-cable

3. Connect the electrode pad “pigtail” connections to the Y-cable.



4. After the wires are securely connected, separate the electrodes from the backing and apply as described in sections 12 & 13.

Caution: Ensure the device is OFF before connecting/disconnecting the leads or applying/removing the electrodes from the skin.

11.2 USING THE “OVA+”

1. Once the electrode pads are in place, press and hold the “▲” button on the control unit for at least 3 seconds to switch the control unit on.
2. When switched on for the first time, the “Ova+” will automatically select the Mode 0. After that it will automatically select the programme you were using the last time it was switched off.
3. You can select from the four preset programmes. Details in section 7 will help you identify the best programme to suit you.
4. With the required programme selected, you can adjust the intensity of the stimulation until you reach a comfortable level.

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

12. PLACEMENT OF PADS

In order to obtain the best relief, the pads need to be placed over the dermatomes T10, T11 and T12, which are the nerve roots that supply the sensory fibres to the uterus. These dermatomes wrap around the body, but do not quite meet up at the front. They run from around waist height at the back down to the groin area at the front.

As each person's body is different, the “Ova+” is supplied with pads which are large enough to be effective even if not located exactly over all three dermatomes. When the pads are placed correctly the “Ova+” will work very well. Therefore if after thirty minutes considerable relief has not been achieved, either move the pads slightly or try one of the other pad positioning areas.

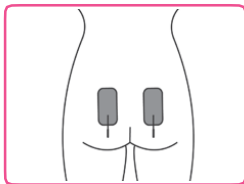
There are THREE positions where the pads can be placed for maximum benefit. It is recommended that the positions are tried in the following order until maximum relief is obtained:

- On the lower back
- On the front, in a vertical format
- On the front, in a diagonal format

Please refer to the diagrams below:

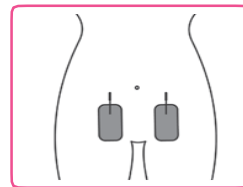
On the lower back:

Place the pads vertically either side of the spine, approximately 10cms (4 inches) apart, with the bottom of the electrodes no higher than the top of your buttocks. The “pigtails” should hang down from the pads.



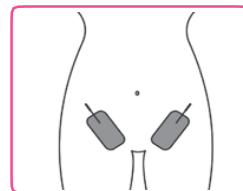
On the front, in a vertical format:

In the vicinity of your groin, place the pads vertically, about 10cms (4 inches) apart. The “pigtails” should be uppermost.



On the front, in a diagonal format:

In the vicinity of your groin, place the pads in a V-shape, narrowing to about 10cms (4 inches) apart at the lower end of the pads. The “pigtails” should be uppermost.



Caution: The self-adhesive pads supplied are intended for multi-use by one person only. Do not lend used pads to others, nor use someone else's used pads yourself.

13. APPLICATION OF PADS

To apply the pads simply peel off the clear film liner and the pads will adhere to the skin automatically.

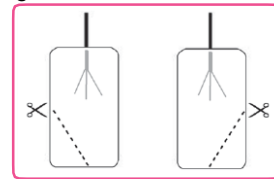
Return the plastic film liner into the bag, as the pads will need to be replaced onto the film after use.

Points to note when applying the pads:

- Make sure the “Ova+” is switched off before applying or removing the pads.
- Ensure that the skin is clean and thoroughly dry before attaching the pads, as they will not adhere well if the skin is wet or greasy.
- Do not worry if a small part of each pad covers the pubic hair. After use the pads can be removed gently without pulling out the hair.
- If a large part of the pad area is covered with hair the stimulation may be less effective. If hair needs to be removed, wait 48 hours after shaving, waxing or using depilatory cream before applying the pads, to avoid irritating the skin.

- Remove the pads from the skin or from the liner by peeling them back from the edge of the pad. Do not remove by pulling on the pad’s “pigtail” wire.
- If you find that a small part of the pad overlaps the top of your thigh, and that this is uncomfortable, then it is possible to cut off this part using scissors. Before cutting make sure that you are cutting from the opposite end to the lead wire and that you are not cutting through any of the wires which run through the pad. *Do not cut off more than a small triangular piece, with sides no more than 20mm long and an area no greater than 200 sq.mm.*

See diagram.



Ensure that the leadwire is slack at all times when the “Ova+” is in use. Excessive force applied to the leadwire could cause a “pigtail” to separate from its pad.

Care of Electrode Pads

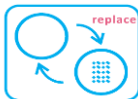
The electrode pads supplied with your “Ova+” unit are self-adhesive and can be used several times. Skin must be allowed to breathe, so the pads should be removed periodically.

When not in use, the pads should be placed onto the plastic film liner and sealed in the bag.

- When the pads initially lose their adhesive quality, it is possible to reactivate their adhesiveness by applying a fine mist of water.



- Replace pads when they lose their stickiness.



Note: Poor connection may cause discomfort and skin irritation.

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

- The pads provided are latex-free.

14. CLEANING

Clean the case and lead wires at least once a week either with an alcohol-free antibacterial wipe or by wiping with a damp lint-free 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.

Expected Service life

- The machine will often last for more than 5 years, but is guaranteed for 2 years. Damage to the leads or electrode pads is not covered by the warranty.
- Lead life depends greatly on use. Always handle the lead with care.
- Pads should last 12-20 applications, depending on skin condition and humidity.
- Fully charged battery should last about 5 hours continuous use.
- Battery should last approximately 400 charge cycles.

15. ACCESSORIES

REF Part number:

E-CM5090-2 - pack of 2 electrodes

L-OVA+ - Y electrode cable

X-OVA-USB - USB cable

Further information on purchasing accessories can be obtained from TensCare Ltd:

Telephone: +44 (0) 1372 723 434

Web: www.tenscare.co.uk

16. DISPOSAL

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 wheellie bin symbol, as depicted below.

To comply with the Directive you can return your old electrotherapy 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 send your old device for components recovery and recycling to help to conserve the world's resources and minimise any adverse effects on the environment.




17. EMC PRECAUTIONS

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.

NB: 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 use in hospitals, full EMC tables are available on request.

18. TECHNICAL SPECIFICATIONS

Output	Single channel
Output current	Max. 52 mA across 500 Ohm
Wave shape	Symmetrical Bi-Polar rectangular
Display	14 mm x 24 mm LCD
Battery	Rechargeable Li-ion 3.7V
Power supply	5V DC 1A
Dimensions	38x65.3x9.6 mm
Type BF 	Degree of protection against electrical shock
Equipment	shock
Water resistance	IP22. No special moisture protection

Contact Duration At least 10 minutes

Environmental Specifications

Operating:	 Temperature range:	5 to 40 C
	 Humidity:	15 to 93%RH non condensing
Storage:	 Temperature range:	-25 to +70 C
	 Humidity:	93%RH non condensing

NB The electrical specifications are nominal and subject to variation from the listed values due to normal production tolerances.

Mode	Description	Rate Hz	Pulse duration μ s
0	Constant Output	110	100
1	Constant Output	110	50
2	Burst Output 2Hz	100	150
3	Constant Output	10	200

19. TROUBLESHOOTING

Problem	Possible causes	Solution
No display	Flat batteries	Charge battery
Low battery display	Low batteries	Charge battery
No sensation	Incorrect connection	Have you applied both electrode pads to the Y-cable to ensure a complete circuit?
	Not strong enough	Increase strength. Most users will feel something at a setting below 5.
	Lead faulty/damaged	Replace lead

SYMBOLS USED



Attention! Please follow the instruction in the Instruction Manual.



TYPE BF EQUIPMENT: 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 Instruction Manual”



Temperature Limitation: Indicates the temperature limits to which the medical device can be safely exposed.



Humidity Limitation: indicates the humidity limits to which the medical device can be safely exposed.



Do not dispose in household waste.



This medical device is not water resistant and should be protected from liquids.



Serial Number: indicates the manufacturer's serial number so that a specific medical device can be identified.



Atmospheric Pressure: indicates the atmospheric limits to which the medical device can be safely exposed.



Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the device (usually in the battery compartment), “E/Month/Year/Number” (MM/YY/123456).



This medical device is indicated for home use.



Catalogue Number: indicates the manufacturer's catalogue number so that the device can be identified.

20. WARRANTY

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

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 instruction 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 guarantees 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 and the failure does not amount to a major failure.

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.

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.

Returning your unit for service

Should repair be needed within the warranty period, enclose the tear off section of this warranty card and your proof of purchase receipt. Please ensure all relevant details are completed and 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.

Please return the unit and warranty card 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

**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

RETAILERS NAME: _____

RETAILERS ADDRESS: _____

RETAILERS POSTCODE: _____

BRIEF DESCRIPTION OF PROBLEM YOU ARE
EXPERIENCING: _____

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

NOTES:

FEEDBACK

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 contact:



www.tenscare.co.uk



Tenscare Ltd



TensCare Ltd (@TensCareLtd)



Tenscare Ltd –
<http://uk.pinterest.com/TensCareLtd/>



TensCare Ltd –
<http://tenscareltd.wordpress.com/>



Tenscare Ltd –
<https://www.youtube.com/user/TenscareLtd>

