ovaq

Period Pain Reliever



Instructions for Use

QUICK START GUIDE

CONTENTS



Connect the main unit with electrodes using the Y-cable



Turn on the device by pressing and holding ON/UP button



Regulate the output intensity by pressing ON/UP, or OFF/DOWN buttons



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



Select the programme which works best for you by pressing and holding the middle button



Keep pressing down the OFF/DOWN button for 2 seconds to turn off the device

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1 INDICATIONS FOR USE

The Ova+ unit is indicated for the relief of simple or primary menstrual pain (dysmenorrhoea).

Ova+ may also help to relieve the pain of secondary menstrual pain due to conditions such as endometriosis, fibroids or pelvic inflammatory disease. However if there is a question as to the reason for the pain then you should seek medical advice to establish the cause and identify the correct treatment.

The Ova+ applies a small electric current through two electrode patches placed on the lower abdomen. This causes muscles in the uterine area to relax and a calming analgesic effect results. By reducing menstrual pain, Ova+ improves the sense of wellbeing and allows normal activity to resume while it is worn.

Ova+ is safe, non-invasive, drug-free, and therefore has no side effects, and can be worn comfortably while engaging in normal activities. The Ova+ 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 muscle.

Clinical trials have shown that the Ova+ is very effective and has none of the side effects, such as nausea and drowsiness, which are commonly associated with drugs used to relieve period pain. 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 normal life, without pain.

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.

3 CAUTIONS & WARNINGS

BEFORE USING PLEASE READ THE WARNINGS AND CONTRAINDICATIONS BELOW

Do not use TENS:

- If you have a heart pacemaker or have a heart rhythm problem TENS in the direct vicinity of a pacemaker may affect some models. If TENS is applied on the front of the neck this can affect your heart rate. Very strong TENS across the chest may cause an extra heartheat
- If you have epilepsy TENS may affect seizure threshold.
- During the first three months of pregnancy It is not known whether TENS may affect foetal development.
- On the abdomen in the later stages of pregnancy Stop use if you experience unexpected contractions.
- When driving, operating machinery, or similar actions needing fine control Loose pads, damaged leads, or sudden changes in contact may cause brief involuntary muscle movements.
- To mask or relieve undiagnosed pain This may delay diagnosis of a progressive condition.

Caution:

- Observe caution 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.
- Strong electromagnetic fields (electrosurgery /microwave cookers/mobile phones) may affect the correct operation of this unit - see section 16. If it appears to behave unusually, move it away from these devices.
- Use caution following recent surgical procedures. Stimulation may disrupt the healing process.

Do not place electrode pads:

- On broken skin The pads could encourage infection.
- 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 the front of the neck Could cause the airway to close, giving breathing problems. May cause sudden drop in blood pressure (vasovagal response).

4 SETTING UP

- 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.
- Near malignant tumours In vitro experiments have shown that electricity can promote cell growth.

Do not:

• Ignore any allergic reaction to the electrode pads: *If a skin irritation develops, stop using TENS and try a different type of electrode.*

Also do not:

- Immerse your TENS unit in water or place it close to excessive heat It may cease to operate correctly.
- Attempt to open up the TENS unit *This will invalidate the guarantee.*
- Use this device with electrodes other than those recommended by the manufacturer *Performance may vary from specification.*

Your Ova+ unit has been designed to be simple and easy to use yet highly effective.

4.1 Overview

- A microprocessor inside the device offers user-friendly controls and gentle outputs.
- 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.
- A large LCD screen clearly shows the operation of the unit.
- 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.
- 4 programmes cover typical types of individual nerve differences.
- Output current automatically returns to zero when switching programmes.

- 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.
- When the device is switched ON, it will resume in the mode previously used.
- When the battery is low, the battery symbol on the LCD screen will flash.

4.2 Contents of Pack

The Ova+ packaging should include the following parts:

- 1 x Ova+ unit
- 1 x Pack of 2 self adhesive electrodes, 50x90 mm with pigtail connection
- 1 x USB charging cable
- 1 x Belt clip support to be attached to clothing
- 1 x User guide (which you are reading)
- 1 x Storage pouch



A charging adaptor is available as an optional accessory. Please contact TensCare or your dealer for more details.



4 SETTING UP

5 PLACEMENT OF PADS

4.3 Preparing the Ova+ unit

- 1. Ensure that the battery is charged see section 10.
- 2. Connect the electrode Y-cable to the unit.
- Connect the electrodes to the wires of the unit.



- 4. Separate the electrodes from the backing.
- 5. Apply the electrodes (See sections 5 & 6).
- 6. Set the unit as described in sections 8 & 9.
- 7. Turn off the device before disconnecting the leads or removing the electrodes from the skin. When not in use the electrode pads should be placed back on the original plastic film liner.

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.

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 so if after thirty minutes considerable relief has not been achieved, either move the pads slightly or try one of the other pad positioning areas.

6 APPLICATION OF PADS

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.

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.

7 CLEANING

Care of Electrode Pads

The electrodes 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. 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.

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



Left button (\blacktriangle):

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 pre-set programmes. When a different programme is selected, the stimulation strength is automatically reset to 0.

Right button ($\mathbf{\nabla}$):

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 program (through a number from 1 to 4) 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.

9 PROGRAMME RECOMMENDATIONS

The Ova+'s four programmes are displayed on the screen as 0, 1, 2, 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.

Programme 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.

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

Programme 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.

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

- Use the highest intensity setting that is still comfortable.
- 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.
- 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.



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

10 **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.

A charger is available as an optional accessory - see section 11

4 The intensity setting indicator bar cycles from zero to max when charging is in progress.



- 5 Charging should take about 40 minutes.
- 6 When the battery charging has completed, the symbol indicates full capacity and stops flashing.
- 7 Remove the charging cable and adaptor from the device when charging is completed.

Warning:

For your safety only use the charging cable provided in the package with the device to charge the built-in Li-Ion rechargeable battery.

11 CONSUMABLES AND SERVICING

Pads, charger, and new units can be obtained either by visiting www.tenscare.co.uk or by calling TensCare on 01372 723434.

Spare part stock codes:

E-CM5090-2	- pack of 2 electrodes
L-OVA+	- Y electrode cable
X-OVA-USB	- USB cable
X-OVA-CHARGE	- Charger with USA, UK, and EU plug adaptors

Expected Service Life

- The machine will often last for more than 5 years, but is guaranteed for 2 years. Damage to the lead is not covered by the guarantee.
- 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.

12 TECHNICAL SPECIFICATIONS

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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	38 x 65.3 x 9.6 mm		
Environmental Speci	fications		
Operating	Temperature range: 5 to 40C Humidity: 15 to 93% RH non-condensing Temperature range: -25-+70C RH 93% non-condensing		
Storage	_		
EQUIPMENT	Equipment providing a degree of protection against electric shock, with isolated applied part.		
Contact Duration	at least 10 minutes		
S	This symbol on the unit means "Refer to Instructions for use"		
Ť	The unit is not water resistant, and should be protected from liquids		
X	Complies with Waste Electrical and Electronic Equipment Directive		
NB The electrical specifications are nominal and subject to variation from the listed values due to normal production tolerances			

Progs.	Description	Rate Hz	Pulse duration µs
0	Constant Output	110	100
1	Constant Output	110	50
2	Burst Output 2Hz	100	
3	Constant Output	10	200

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 (per lead wire) 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

If I have other issues?

Speak to the retailer from whom you purchased the unit or telephone TensCare on +44(0)1372 723434.

14 WARRANTY

The Ova+ is warranted for two years from the date of purchase. This warranty refers to the unit only. It does not cover the electrode pads, lead wire or battery. This warranty applies only if the unit has been used for its intended purpose and has not been damaged through misuse, accident or neglect and has not been modified or repaired by anyone other then TensCare or its authorised agents.

If defect appears return the unit to TensCare or its authorised agents, with your proof of purchase.

15 DISPOSAL OF THE PRODUCT (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.

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.



16 EMC PRECAUTIONS

Other portable and mobile RF communications equipment can affect performance. Do not use when adjacent to or stacked with other electrical equipment. Use of leads or pads other than those listed in section 11 may affect EMC performance.

Full EMC Guidance tables may be downloaded from www.tenscare.co.uk

References

Schiøtz, H. A., Jettestad, M. and Al-Heeti, D. (2007) 'Treatment of dysmenorrhoea with a new TENS device (OVA)', Journal of Obstetrics and Gynaecology, 27:7, 726 - 728

Cochrane Review 2010

Transcutaneous electrical nerve stimulation for primary dysmenorrhoea (Review)

Proctor M, Farquhar C, Stones W, He L, Zhu X, Brown J.



EC Declaration of Conformity

TensCare Ltd hereby declare that an examination of the production quality assurance system has been carried out following the requirements of the UK national legislation according to Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organisation to use the CE 0473 marking on this product.



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