

mynd manual

Dear Customer,

Thank you for choosing **Mynd**. 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

1.	INTENDED USE	5
2.	CONTRAINDICATIONS, WARNINGS & CAUTIONS	5
3.	PROGRAMMES	12
3.1.	PROGRAMME SETTINGS ...	12
3.2.	GEL PAD ADVICE.....	13
4.	CONTENT.....	14
5.	UNIT INFORMATION.....	14
5.1.	CONTROLS.....	14
5.2.	OPERATING INSTRUCTIONS 15	
6.	SETTING UP AND USING MYND ...	17
6.1.	CHARGING THE BATTERY .	17
6.2.	PREPARING FOR SESSION	21
6.3.	TREATMENT SESSION	23
6.4.	AFTER YOUR TREATMENT SESSION	24
7.	CLEANING & STORAGE	24
8.	EMC	25
9.	DISPOSAL OF WASTE ELECTRICAL AND ELECTRONIC PRODUCTS (WEEE)...	25
10.	ACCESSORIES	26
11.	WARRANTY	27
12.	TROUBLESHOOTING.....	30
13.	GENERAL SPECIFICATION	31

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.
	Medical Device

	Manufacturer Symbol
	Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the travel case, either as "E/Year/Number" (YY/123456) or "E/Month/Year/Number" (MM/YY/123456).
	CE Mark
	This medical device is indicated for home use.
IP22	<p>This medical device is not water resistant and should be protected from liquids.</p> <p>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.</p> <p>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.</p>

1. INTENDED USE



MYND is a medical device designed to be used in the home healthcare environment for the treatment and prevention of frequent episodic and chronic migraine headaches.

It is suitable for use by all who can control the device and understand the instructions. It may be used by a child from the age of 8 if supervised by an adult, but there is currently no evidence of effectiveness for users under the age of 18.

2. 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 unresolved brain or facial injuries.

Do not use MYND on any other areas apart from the forehead. Use on the chest or neck may affect heart or implanted devices and may affect epileptic seizure threshold. May also affect body worn monitoring devices.

Do not use MYND if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

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.



WARNINGS:

After a **MYND** session, wait an hour before undertaking an activity that requires

concentration. *You may experience drowsiness or lack of concentration.*

Do not place electrode pads on broken skin. *The electrode pads could encourage infection.*

Do not use **MYND** in close proximity (less than 1 meter) to short wave or microwave therapy equipment as it may produce instability in **MYND** output.

It can be dangerous to connect **MYND** with devices not described in this user manual.

WARNING: Do not modify this equipment without authorization of the manufacturer.

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

Do not use simultaneously with high frequency hospital diagnostic/therapeutic equipment. Doing so may result in burns at the site of the electrodes and possible damage to device.

Do not apply **MYND** near the thorax because the introduction of electrical current may increase the risk of cardiac fibrillation.

Stimulation should not be applied directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or from electrodes placed on the upper back or crossing over the heart.

Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.

This device is only used for forehead surface skin. Do not use the device for any purpose other than this intended use.



CAUTIONS:

Do not ignore any allergic reaction to the electrode pads: *If a skin irritation develops, stop using MYND, as a small number of users may have an adverse reaction to the gel*

Trigeminal neuralgia and Ophthalmic shingles make facial nerves hypersensitive, so use of **MYND** could be painful.

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

Not intended for use in an oxygen rich environment.

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

The patient is an intended operator.

Do not service and maintain the device while in use with a patient.

Changing the gel is the only maintenance the patient should perform.

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.

Degraded gel pads can negatively impact performance or cause other problems.

Keep this device out of the reach of children pets and pests.

Do not put the lead wire on or wrapped around the neck.

SIDE EFFECTS

- Intolerance to the paresthesia caused by electrical stimulation
- Intolerance to the strong pressure on dental, forehead, cervical pains and tension-type headache
- Arousal and sleep changes
- Vomiting and nausea at the end of stimulation
- Increased tinnitus during the session
- Mild pain over one eyebrow, numbness at the back of the head, feeling of abrupt electrical variation.

**Discomfort during treatment:**

A small portion of users may find the stimulation to be very uncomfortable. This feeling usually goes away as you become used to it. However, for some patients this discomfort remains. If so the patient should reduce the intensity.

**Headache after Programme 2:**

Very rarely you may experience a headache after using Programme 2. This is short-lived but may make use of Programme 2 difficult for some users.

**Neck pain:**

At the start of treatment you may tense your neck muscles when you are using MYND, and this can lead to an aching neck. If this happens, try resting your head on a pillow during treatment.



Note: Electrode pads supplied have no measurable latex content.

IF ANY OF THE SIDE EFFECTS BECOME UNACCEPTABLE, PLEASE STOP USING THE DEVICE IMMEDIATELY.

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 socket

Caution: Temperature & Relative Humidity of storage: -10°C to +60°C, 15% to 75% R.H. Temperature & Relative Humidity of transportation: -10°C to +60°C, 15% to 75% R.H.

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

Caution: Silicone and backside gels on the surface of the device may come into contact with the patient or operator. If allergic to these materials, avoid contact and discontinue use.

3. PROGRAMMES

3.1. PROGRAMME SETTINGS

Programme 1 - Treatment

Maximum intensity (across a load resistance of 500 Ω)	20 mA (Peak)
Pulse frequency	110 Hz
Pulse width	200 μ s
Pulse duration	200 μ s
Session duration	60 minutes

Programme 1 is designed to treat migraine attacks and has a duration of 60 minutes. It should be applied when the migraine is already present or, preferably, when the first signs of the next migraine attack are felt.



Note: Some migraine patients develop Allodynia with their migraine attacks. This makes any skin stimulation, including **MYND**, feel painful.

Programme 2 - Prevention

Maximum intensity (across a load resistance of 500 Ω)	20 mA (Peak)
Pulse frequency	55 Hz
Pulse width	200 μ s
Pulse duration	200 μ s
Session duration	20 minutes

Programme 2 is designed to prevent migraines and will last for 20 minutes. This programme should be used once a day. Regular use helps to reduce the frequency of migraine attacks.

3.2. GEL PAD ADVICE

- Gel pads are reusable but for single patient use.
- In order to get the best conductivity through the gel pads, always make sure they are in good condition and sticky.
- Make sure you clean the forehead before use.
- After use, always replace the clear plastic liner on top of the gel pads on the device. Keep the device and gel pads in the travel case.
- Replace the gel pads when they lose their adhesion.
- A bad connection can cause discomfort and irritation of the skin.
- The shelf life of an unopened packet of gel pads is 2 years. This can be affected by very high temperatures or very low humidity.

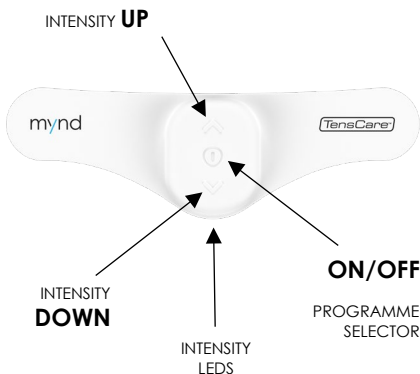
4. CONTENT

The pack contains:

- 1 x **MYND** unit
- 3 x Reusable gel pads
- 1 x Charging cable
- 1 x Travel case
- 1 x Mirror
- 1 x Instruction manual
- 1 x Quickstart guide

5. UNIT INFORMATION

5.1. CONTROLS



5.2. OPERATING INSTRUCTIONS

ON/OFF



To turn the unit **ON**, press the **ON/OFF** button of the unit and hold for 1 second. You will hear a long beep and the white LED lights will switch on.

The unit will turn **OFF** automatically when the session is complete (60 minutes in programme 1 and 20 minutes in programme 2). A long beep will indicate the end of the session, the intensity will gradually decrease and the device switches off.

If you wish to manually turn the unit **OFF**, press and hold the **ON/OFF** button for 3 seconds. You will hear a long beep (1 second) and the white LEDs light will switch off.



Note: Always check unit is **OFF** before applying or removing the **MYND** device from the forehead.



Note: Always clean the forehead before using the device.

PROGRAMME CONTROL

The **ON/OFF** button is also the programme select button. **MYND** has two pre-set programmes.

Every time the unit is switched on, the programme 1 is automatically selected. If you wish to change to programme 2 press and release the **ON/OFF** button. Programme 2 selection will be indicated by two short beeps.

To change back to programme 1, press and release the **ON/OFF** button. A single beep will indicate programme 1 has been selected.

Every time a new programme is selected, the strength level is reverted to zero. This is a safety feature to alleviate any sudden feeling of a surge, as each programme gives a different sensation.

STRENGTH CONTROLS

The buttons marked **▲**, **▼** are the strength controls.

To increase the intensity in steps of 0.5 mA press and release the **▲** button. To increase automatically, press and hold the **▲** button (fast increase in steps of 0.5 mA). To decrease the intensity in steps of 0.5 mA press and release the **▼** button. To decrease automatically, press and hold the **▼** button (fast decrease in steps of 0.5 mA).

A short beep will be heard with each press of the strength controls.

When using the strength controls, reaching maximum or minimum intensity will be indicated by three quick beeps.

You may feel nothing over the first few stages of increase. Continue pressing until the sensation is strong but comfortable. Further increases during use may be necessary if your body becomes used to the sensation. Note that the maximum intensity of 20mA is sufficient to have a therapeutic effect, even if you feel like this intensity has become tolerated.

INTENSITY LEDS

The unit has 40 levels of strength. The strength level will be indicated by the three LEDs on the bottom of the device. Each LED gets brighter as the intensity increases. The minimum and maximum intensities are as follows:

Minimum intensity – one dim LED

Maximum intensity – three bright LEDS

6. SETTING UP AND USING MYND

6.1. CHARGING THE BATTERY

MYND is powered by a built-in rechargeable Li-ion battery. A separate charging cable with universal USB plug is included in the kit.

When the battery is low, the central LED will flash white. This would start about 4 hours before the battery is empty (4 hours on stand-by).



Warning: Use only the charging cable supplied. Use of other chargers could be hazardous and will negate the warranty.

To charge the battery:

Connect the USB cable to a mobile phone or tablet charging socket or PC USB port.

Whilst the battery is charging, the central LED light will flash white slowly and repeatedly.

The device will take approximately 2-2.5 hours to charge.

When the battery is fully charged, the white LED light will stop flashing and remain turned on.



Note: To minimise the reduction in battery capacity the device should be recharged yearly, regardless of usage.



Note: The device cannot be used while being charged.



Note: Charging voltage: DC 5V, charging current: 60mA.



Note: Use adapters of the following specifications.

- Output: DC 5 V; 1A

- Rated input voltage shall not exceed 250 V
- Classification of protection against electric shock: Class II
- IP classification: at least IP21
- The adapter need to comply with IEC 60601-1 or IEC 60950-1

Battery Life

The battery life will last approximately 22 hours at 50% maximum output intensity.



Battery Warnings

This product is equipped with a Lithium-ion battery. Battery is fixed inside the device and so device warnings also apply to the 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 pierce, open, disassemble or use in a humid and / or corrosive environment.

Do not expose to temperatures above 60 ° C (140F).

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

Do not immerse in water or seawater and do not apply to wet skin.

Do not short circuit.

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

Do not replace with your own batteries. Changing lithium batteries or fuel cells incorrectly can lead to unacceptable risks.

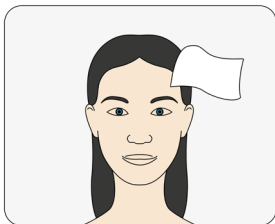
Do not replace the battery without adequately trained personnel, otherwise it will cause danger (such as overtemperature, fire or explosion).

Do not position the equipment during charging such that it is difficult to use the charging adapter. The provided charging adapter is used to isolate the equipment circuits from the mains power supply.

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

6.2. PREPARING FOR SESSION

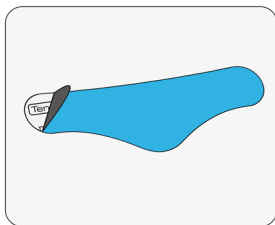
1) Before use ensure to clean your skin with a damp cloth and soapy water. Leaving your forehead slightly damp may allow for better adhesion and stimulation from the device.



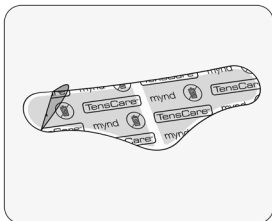
Note: Do not use make-up removal products to clean your forehead as these leave a greasy film on the skin.

2) For first use, remove one of the gel pads from its foil packaging.

3) Remove the blue plastic liner from the gel pads and apply to the rear of the MYND device.

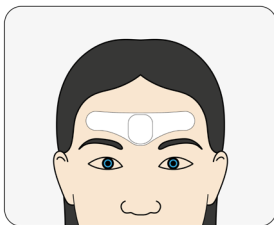


4) Remove the clear plastic liner from the rear of the device. Be careful to ensure the gel pads remain stuck to the device.



5) Place the clear plastic liner back in the travel case. The blue liner can be disposed of.

6) Place the device in the centre of your forehead, roughly 1 cm above the eyebrows.



The gel pads are reusable. However, over time they will become less adhesive. When this happens remove the gel pads currently on the device and apply new gel pad.



Note: The number of applications for each gel pad will vary depending on the user's skin condition.



Note: Gel pads are for single patient use. The gel is a peelable hydrogel (water based).



Warning: Ensure that **MYND** is switched **OFF** before applying and removing the device.

6.3. TREATMENT SESSION

1) Press and hold the **ON/OFF** button on the device for 1 second to switch the unit on.

2) Select the desired programme. Programme 1 will always be the default programme once powering on the device. If you wish to change to programme 2 press and release the **ON/OFF** button. You will hear two short beeps.

3) To increase the intensity in steps of 0.5 mA press and release the **▲** button. To increase automatically, press and hold the **▲** button (fast increase in steps of 0.5 mA).



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

6.4. AFTER YOUR TREATMENT SESSION

The unit will turn off automatically when treatment session is complete.

- 1) To check that the unit is **OFF**, use the mirror provided and ensure the white LED light is switched off. If it is not, hold down the **ON/OFF** button to switch off. Remove the device from your forehead by gently peeling the device by the outer edges.
- 2) Re-apply the clear plastic liner on the gel pads and store the device in the travel case. This will help retain the stickiness of the gel.

When not being used, the device must **ALWAYS** be kept in the travel case.

7. CLEANING & STORAGE

Clean the device at least once a week by wiping with a damp cloth and a solution of mild soap and water. Be careful to avoid contact with silver electrodes. Wipe dry.

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

Storage life

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

8. 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 used no closer than 30cm (12 inches) to any part of the device.

(Note. As indicated in 5.2.1.1(f) of IEC 60601-1-2:2014 for ME EQUIPMENT).



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

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

One of the provisions of the European Directive 2012/19/EU 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 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.



10. ACCESSORIES

Expected Service Life

- The machine will often last for more than 5 years but is warrantied for 2 years. Accessories (charging cable, gel pads, travel case, and mirror) are not covered by the warranty.
- The number of applications for each gel pad will vary depending on the user's skin condition and humidity.

Replacement gel pads and charging lead 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-MYND Pack of 3 MYND gel pads

11. WARRANTY

This warranty refers to the unit only. It does not cover gel pads, charging cable, travel case or mirror.

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 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 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.

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

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.

Returning your unit for service

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 gel pads or charging cable. Send only the **MYND** unit.

Please return the unit with the following details:

- Name:
- Address:
- Postcode:
- Telephone:
- Email:
- Model:
- Date of purchase:
- **Attach proof of purchase**
- Retailers name:
- Retailers address:
- Retailers postcode:
- Brief description of problem you are experiencing:

Returns should be sent 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.

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

12. TROUBLESHOOTING

If your **MYND** device is not working properly, please check the following:

Problem	Possible causes	Solution
The white LEDs do not turn on	Flat battery.	Charge battery. See section 6.1.
No sensation	Intensity is not strong enough.	Increase strength.
Sudden change in sensation	If you remove the device and reapply a few minutes later, the signal should feel a lot stronger.	Always return strength to zero or turn the device off before removing the device from the forehead.

If the above review has failed to resolve your problem, or to report unexpected operation or events, or provide feedback call TensCare or your local dealer (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>

13. GENERAL SPECIFICATION

Waveform	Alternated mono-phasic rectangular
Amplitude (across a load resistance of 500Ω)	20 mA (Peak) zero to peak +ve in 40 steps. +/- 10%
Batteries	Built-in lithium-ion battery Model: WEL 302025 Manufacturer: Ganzhou WeAction New energy Co., Ltd. Ratings: 110mAh, 0.407Wh, 3.7V
Weight	15g
Dimensions	120 x 38 x 11 mm
Safety Classification	Internal power source. Designed for continuous use. No special moisture protection.
Software version	R5
Applied Part	Gel

Environmental specifications:	
Operating:	Temperature: 5°C to 40°C Humidity: 15 % to 90 %, non-condensing Atmospheric pressure: 700hPa to 1060hPa
Storage:	Temperature: -10°C to 60°C Humidity: 15 % to 75% Atmospheric pressure: 700hPa to 1060hPa Battery storage temperature: -10°C ~+60°C (≤ 1 month) -10°C ~+45°C (≤ 3 month) -10°C ~+28°C (≤ 1 year) Humidity: 45% ~75% RH

 **Note:** The electrical specifications are nominal and subject to variation from the listed values due to normal production.

 **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.

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

Follow us:



TensCare Ltd



@TensCareLtd



TensCare Limited



@tenscareLtd



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 organization to use the CE 2797 marking on this product.



TensCare Ltd.

9 Blenheim Road, Epsom
Surrey, KT19 9BE, UK
+44 (0) 1372 723434



Advena Ltd.

Tower Business Centre
2nd Flr, Tower Street
Swatar, BKR 4013, Malta



TensCare Europe BV

Juliana van Stolbergstraat 52
1723LD Noord-Scharwoude
Netherlands