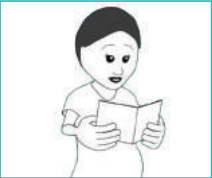







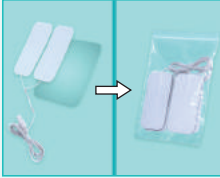



MAMATM
tens



INSTRUCTIONS FOR USE
READ CAREFULLY BEFORE USE

mamaTENS QUICKSTART GUIDE

<p>1. Read instruction book carefully</p> 	<p>2. Check contents</p> 	<p>3. Press ON/OFF button to check that the unit is working (LCD will be activated) then switch OFF</p> 	<p>7. Put everything back into the pouch until labour begins</p> 	<p>8. As soon as labour begins, set up, attach, and use the unit as per instructions</p> 	<p>9. After the birth, dispose of electrodes and leads</p> 
<p>4. Attach leads to the unit</p> 	<p>5. Attach the electrodes to your back and try out the unit to see how it feels</p> 	<p>6. Replace electrodes onto their liners and seal them in the re-sealable bag</p> 	<p>10. Place unit, belt clip, and neck cord back into the pouch</p> 	<p>mamaTENS Helpline</p> <p>mama[™] <i>tens</i></p> <p>Helpline 01372 723434</p>	

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1. INTRODUCTION

The **mamaTENS** is a TENS machine specially designed to help counter Labour Pain.

The pain during birth might start with the first contraction or when the cervix starts to dilate. The pain then increases progressively until the cervix is completely dilated. During this period you will experience pain of different types and intensities but due to the innovative technology which has been incorporated into your **mamaTENS**, you will be able to help counter this. The **mamaTENS** achieves this by delivering a variety of signals dependent upon the stage of your labour.

Please note that whilst some expectant mothers will achieve sufficient pain relief using just the **mamaTENS**, others may require additional pain relief. **MamaTENS** can be used with other pain relief options such as gas and air but as you might expect should be removed if having a water birth.

2. WHAT IS TENS AND HOW DOES IT WORK?

Midwives recommend maternity TENS machines for their benefits, particularly in early labour, as they enable mums to remain mobile and upright. This aids descent and dilatation and provides a completely drug free and natural form of pain relief which is safe for both you and your baby. Maternity TENS machines can be used in conjunction with other forms of pain relief.

However, as you might expect, it can't be used in a birthing pool.

TENS stands for **Transcutaneous Electrical Nerve Stimulation**.

Transcutaneous simply means 'across the skin'.

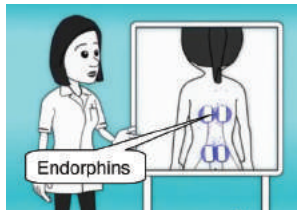
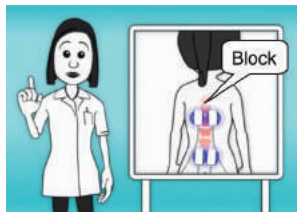
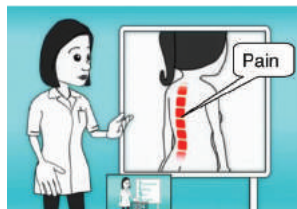
We feel pain when signals reach the brain from the affected area.

TENS works by stimulating the nerve endings to reduce the pain message.

It also stimulates your body into generating endorphins, the body's own natural pain relievers.

This is why pain relief can continue even when the machine is switched off.

Your TensCare maternity TENS machine allows you complete control over the strength of the pain relief it provides so that you can manage your pain as labour progresses.



3. WHAT'S IN THE BOX?

When you open the box your **mamaTENS** and its accessories are contained within a white leatherette pouch, ideal for putting into your hospital bag.



3.1 CONTENTS

Inside the pouch you will find:

- Your **mamaTENS** unit
- Two sets of batteries (Rental units will have one set already inserted)
- Neck cord
- Handy belt clip
- Electrode pads designed specifically for use with your **mamaTENS**
- This instruction manual



Before using your mamaTENS, please read this manual thoroughly, especially the safety notes and precautions.

3.2 TRIAL RUN

We recommend that all mums-to-be familiarise themselves with the unit prior to the due date for added peace of mind.

4. SETTING UP AND USING YOUR mamaTENS

The curved green button to the left of the machine is clearly marked 'on' and 'off' whilst the curved green button to the right of the machine is marked with arrows to increase or decrease the intensity as desired.

Intensity cannot be adjusted unless the electrode pads are properly attached.



In the centre of the panel are two yellow buttons.

The top button says 'Prog' and is used to select from three preset programmes, one for each stage of labour.



The bottom button says 'Lock'. Holding this button down for three seconds when intensity is more than zero locks the controls: this avoids any accidental changes of intensity.

On the side of the unit is the green 'Boost' button. Its action depends upon the programme selected.



4.1 ASSEMBLY

Before use, you will first need to assemble your mamaTENS.

Insert the lead wire for the pads to be used under the bra line into channel one 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 two.

Once you have done this you will need to ask your birthing partner to place the electrode pads into the correct position on your back.

To ensure 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.

Peel off the clear plastic covers and attach the pads to your back as shown in section 9. Please keep the bag and clear film liners for preserving the pads after use.

Place the pads which are wired to channel one under the bra line and the pads wired to channel two just below the knicker line.



With the 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.



This neck cord is specially designed to pull apart if you snag it or the machine. Do not use other things like string that might not break.



4.2 WHEN TO START USING YOUR mamaTENS

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

4.3 PROGRAMME A

When you switch the machine on it automatically selects Labour Programme A.

The LCD screen will display 'A01'.

This programme is designed to provide a pulsing sensation that triggers the release of endorphins, relaxing you and relieving you from pain.

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 **mamaTENS** will start at zero intensity. Increase the intensity until you feel a pulsing on-off-on-off sensation. **mamaTENS** has 50 small steps of intensity, so you have fine control of the strength of stimulation.

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.



If a lead wire becomes detached from its socket the unit will automatically reset intensity to zero.



4.4 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 'Prog' button. The LCD screen will display 'B01'.

To avoid discomfort with the change in programme, the set intensity will drop by half. Press and release the INTENSITY ▲ BUTTON until you reach a comfortable intensity setting.

Again there are two modes.

The second mode 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 **mamaTENS** unit will change back to mode B1.

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 (which have been placed just below your bra line) is stronger than the lower set of pads (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.



If the lower electrodes feel stronger than the upper ones then the leads have probably been incorrectly inserted into the **mamaTENS**. To correct this, change over the leads, and reset the intensity.



4.5 PROGRAMME C

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

Press the 'Prog' button again and this will take you to programme C which will be displayed on the screen as 'C01'.

To avoid discomfort with the change in programme, the set intensity will drop by half. Press and release the INTENSITY ▲ BUTTON until you reach a comfortable intensity setting.

Again there are two modes.

However this time mode C1 is continuous. Mode C2 ramps the power or level of intensity during the final contractions.

In between contractions use the INTENSITY ▲ & ▼ 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 became too much to bear, at which point 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.

In MODE C2 RAMP the intensity goes up to 60.

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.

When instructed to start “pushing” you can use the ‘Prog’ button to switch the TENS unit back to programme A.

And that’s all there is to it. It’s quite simple really.

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.

5. AFTER USE

Always ensure that the **mamaTENS** is switched OFF before removing the electrodes.

After use, return the electrodes onto the clear plastic covers and store in the resealable bag(s). The electrodes are water-based, and will dry out if left out in the open.

After the birth, you can use your **mamaTENS** to help with post-episiotomy pain.

- If you are re-using the unit, be sure to replace pads when they lose their stickiness. Poor connection may cause discomfort and skin irritation.

If you purchased, rather than rented, and plan to put your **mamaTENS** into storage for your next baby then do the following:

- Clean as instructed
- Remove batteries
- Throw away the electrode pads and leads (You will need to buy a new set for the next use)
- Storage life of an unopened pack of electrodes is 2 years. This may be affected by very high temperatures or very low humidity.



6. CLEANING

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.

7. CAUTIONS & WARNINGS

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 heartbeat.
- If you have epilepsy.
TENS may affect seizure threshold. You should consult your doctor prior to using the mamaTENS unit.
- 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 immediately 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.
TENS may delay diagnosis of progressive condition.

Caution:

- Observe caution when using the **mamaTENS** 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 17. 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).
- 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 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.
Alternative pads specially made for sensitive skin are available, see section 16.

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.
- Mix old, new or different types of batteries.
- Use this device with leads, electrodes, and accessories other than those recommended by the manufacturer.
Performance may vary from specification.

IF IN DOUBT CONSULT YOUR MEDICAL PRACTITIONER, MIDWIFE OR OBSTETRIC PHYSIOTHERAPIST

8. CONTROLS

The **mamaTENS** has four coloured buttons on the front and one on the side.



The left curved GREEN BUTTON marked "ON/OFF" is the ON and OFF Switch.

Press ON and hold for 2 seconds to turn ON. (This delay avoids turning ON accidentally). The LCD display will appear as "A01 00" indicating that the unit has automatically set itself into Labour Programme A and mode 1 at zero intensity (00). Press OFF to turn the unit off.

The right curved GREEN BUTTON marked ▼ & ▲ is the intensity control.



Each time the ▲ is pressed and then released, the **mamaTENS** will increase in intensity by one level. The **mamaTENS** has 50 levels of intensity in Programmes A and B and 60 in Programme C.

Each time the ▼ is pressed, the intensity will decrease by one level. Hold down the ▼ or ▲ button to scroll intensity.

As you increase the intensity you will experience a gentle tingling feeling. You may feel little or no sensation from the **mamaTENS** at its lower levels, but keep pressing and releasing the green button until the sensation is strong but comfortable. To maintain the effect as your body becomes accustomed to the signal you will probably need to steadily increase the stimulation by raising the intensity one level at a time: this is perfectly normal.

SAFETY FEATURE - If the pads or leads become disconnected, the intensity will automatically reset to zero. If the **mamaTENS** is accidentally switched on it will switch off automatically if the intensity is not pressed within 5 minutes.





The UPWARD POINTING TRIANGULAR YELLOW BUTTON marked 'Prog' is used to select from three programmes, one for each phase of labour.

Each time the 'Prog' button is pressed the programme changes and intensity is reduced by 50%.

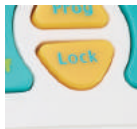
The programme selected is displayed on the LCD screen.

Programme A, for Phase 1 is shown as A 01

Programme B, for Phase 2 is shown as B 01

Programme C, for Phase 3 is shown as C 01

The programmes are explained in detail in section 4 "Setting up and Using Your **mamaTENS**".



The DOWNWARD POINTING TRIANGULAR BUTTON marked 'Lock' is the lock switch.

Holding this button down for 3 seconds locks the controls. A key symbol appears in the LCD and none of the controls will operate. This function avoids accidental changes in programme and intensity.

Hold down the 'Lock' button for 3 seconds to remove the lock.



On the SIDE of the unit is a BOOST button. Its action depends upon the programme selected and is detailed within the section "Setting up and Using Your **mamaTENS**".

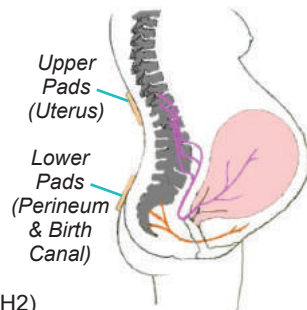
9. POSITIONING OF PADS

The 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 diagram and then follow these instructions:

1. Carefully peel the pads off their plastic covers. Do not pull on the lead wire.

2. Place the top pair of pads (connected to CH1) either side of the spinal column 2 inches (50mm) apart from each other and about 3 inches (75mm) below the bottom of the shoulder blades (close to vertebrae T10, T11, T12 and L1). This is just below the bra line.

3. The lower pair of pads (connected to CH2) are placed either side of the spine about 4 inches (100mm) apart and about 1 inch (25mm) above the dimples at the base of the spine, just above the buttocks (close to vertebrae S2, S3 and S4).

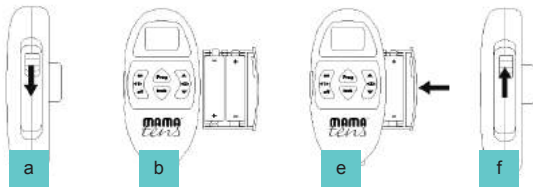


10. BATTERIES

10.1 LOW BATTERY DISPLAY

If the batteries begin to lose their power a battery symbol will appear on the LCD. Change both batteries at this stage using spare batteries supplied. See instructions below as to how to change the batteries.

10.2 CHANGING THE BATTERIES



- Unlock the battery holder by sliding the knob downwards.
- Pull out the battery holder.
- Remove the existing batteries.
- Using the diagram on the battery holder as a guide, insert the new AA (LR6) batteries.
- With the batteries uppermost, slide the battery holder back into place.
- Lock the battery holder by sliding the knob upwards.

To check that the batteries have been correctly fitted, press and hold the ON for 2 seconds and the LCD screen will display 'A 01'.

Warnings

- The **mamaTENS** will not function if the batteries are inserted incorrectly and damage to the unit could occur.
- If the battery holder cannot be fully inserted it is upside down. Do not force the battery holder into place.
- Replace only with the AA(LR6) battery type indicated.
- Replace both batteries at the same time.
- Do not dispose of the batteries in a fire.
- Keep batteries out of the reach of children.

11. RETURNING YOUR RENTAL UNIT

If you rented your **mamaTENS** your machine should have been sent to you three weeks before your due date.

The rental period is for five weeks, but if you need more time just call us before the end of the rental period and we'll arrange an additional two weeks absolutely free of charge.

Sending your maternity TENS machine back at the end of the rental period is very easy.

- You'll have received a pre-paid envelope with your machine so simply put the unit back in the box - no need to include the lead wires and pads - pop the box into the envelope and drop it in at the post office.
- You'll need to ask for a proof of posting certificate at the post office but it's all free of charge and very straightforward.
- If you rented by purchasing a **voucher or DVD**, do NOT return the unit to the shop where you made the purchase. It should only be returned in the envelope provided.
- If you collected your unit at a **Tesco Pharmacy**, please return it to the same place.

12. GUARANTEE

(Refers only to **mamaTENS** units that have been purchased).

Your unit is guaranteed for two years from the date of purchase.

If a fault develops, return the unit to **mamaTENS** at the address on the back cover, together with a copy of your invoice and details of the problem. The guarantee does not cover the batteries, electrode pads or mono leadwire.

Please note that the guarantee is invalidated if:

- i) incorrect batteries have been fitted.
- ii) the unit has been immersed in water, maltreated or tampered with.
- iii) the unit has not been used with genuine **mamaTENS** or TensCare electrode pads.

13. 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	Check
	Damaged battery contacts	Contact supplier
Low battery display	Low batteries	Replace batteries
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 10
Intensity will not go above zero	Open circuit cutout	Ensure machine is attached to your body correctly.
	Lead faulty/damaged	Purchase replacement if necessary.

If the above review has failed to resolve your problem, call TensCare or your local dealer (address on back cover) for advice.

Or if you have any questions or need more information you can contact TensCare at anytime via our website, www.tenscare.co.uk or by phoning 01372 723 434.

14. CONSUMABLES AND SERVICING

(Refers only to **mamaTENS** that have been purchased)

To ensure reliability and hygiene, use only genuine rectangular electrodes with integral leads:

For units after 1330000, we are using part number E-CM50100-MTNEW



For units before 1330000, we are using part number E-CM50100-MT



Please note: these are the part numbers according to the TensCare website.

These are available from either your supplier or by ringing 01372 723434 or by going to www.tenscare.co.uk. Please ensure that you order the correct pads.

Batteries can also be purchased in the same way or on the high street. They are AA 1.5v alkaline batteries.

For servicing please return the unit to: TensCare Ltd, 9 Blenheim Road, Longmead Business Park, Epsom, Surrey KT19 9BE. Please ensure that you enclose your name, address and contact telephone number so that you can be contacted and informed about any problem and any costs involved.

Expected Service Life

- The machine will often last for more than 5 years, but is guaranteed for 2 years. Accessories (leads, pads, and batteries) are not covered by the guarantee.
- Lead life depends greatly on use. Always handle the leads with care.
- Pads should last 12-20 applications, depending on skin condition and humidity.
- AA alkaline batteries should last about 48 hours continuous use.

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




(Refers only to **mamaTENS** that have been purchased)

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 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. TECHNICAL INFORMATION

Waveform	Symmetrical Bi-Phasic Rectangular
Amplitude (over 500 Ohm)	75 mA zero to peak 50 steps in A&B, 60 steps in C
Channels	Dual channel
Weight	96 gms
Dimensions	120x52x22mm
Batteries	2 x 1.5V AA Alkaline LR6
Environmental: Specifications Operating Storage	Temperature range: 5 to 40C Humidity: 15 to 93% RH non-condensing Temperature range: -25-+70C RH 93% non condensing
Contact Duration:	at least 10 minutes
Safety classification	Internal power source. Designed for continuous use.
 TYPE BF EQUIPMENT	Equipment providing a degree of protection against electric shock, with isolated applied part.
	This symbol on the unit means "Refer to Instructions for Use"
	The unit is not water resistant, and should be protected from liquids.
NB The electrical specifications are nominal and subject to variation from the listed values due to normal production tolerances.	

Programme Settings

Display	Mode	Frequency/Pulse Width
A1	Burst	80Hz 150us
A1 Boost	Continuous	80Hz 150us
B2	Burst	150Hz 150us
B2 Boost	Continuous	150Hz 150us
C3	Ramp	80Hz 250us

17. EMC PRECAUTIONS

Use special precautions regarding EMC according to the information provided below.

Guidance and manufacturer's declaration - electromagnetic emissions		
<p>The mamaTENS is intended for use in the electromagnetic environment specified below. The customer or the user of the mamaTENS should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The mamaTENS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The mamaTENS is suitable for use in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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 18 may affect EMC performance.

The mamaTENS is intended for use in the electromagnetic environment specified below. The customer or the user of the mamaTENS should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile
If floors are covered with synthetic material, the relative humidity should be at least 30%.			
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for Input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U _r (>95 % dip in U _r) for 0,5 cycle 40 % U _r (60 % dip in U _r) for 5 cycles 70 % U _r (30 % dip in U _r) for 25 cycles <5 % U _r (>95 % dip in U _r) For 5s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE U _r is the a.c. mains voltage prior to application of the test level.			

The mamaTENS is intended for use in the electromagnetic environment specified below. The customer or the user of the mamaTENS should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the mamaTENS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance 3V $d = 1.2\sqrt{P}$ 80 MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol on the left of this box

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the mamaTENS is used exceeds the applicable RF compliance level above, the mamaTENS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the mamaTENS.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the mamaTENS.

The mamaTENS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the mamaTENS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the mamaTENS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

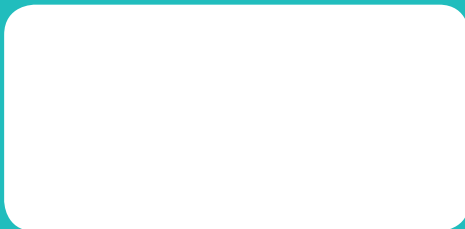


EC Declaration of Conformity

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 0088 marking on this product.



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