

# Flexistim



## Instructions For Use

Please read carefully





















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## Symbols Used

	TYPE BF APPLIED PART: Equipment providing a degree of protection against electric shock, with isolated applied part. Indicates that this device has conductive contact with the end user.
	This symbol on the unit means "Refer to instructions for use".
	Temperature Limitation: indicates the temperature limits to which the medical device can be safely exposed.
	Lot Number: indicates the manufacturer's batch code so that the batch or lot can be identified.
	Humidity Limitation: indicates the humidity limits to which the medical device can be safely exposed.
	Serial Number: indicates the manufacturer's serial number so that a specific medical device can be identified.
	Do not dispose in household waste.
	Catalogue Number: indicates the manufacturer's catalogue number so that the device can be identified.

	Atmospheric Pressure: indicates the atmospheric limits to which the medical device can be safely exposed.
	Manufacturer Symbol
	Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the device (usually on the back of the device), either as "E/Year/Number" (YY/123456) or "E/Month/Year/Number" (MM/YY/123456).
	CE Mark
	Medical Device
	This medical device is indicated for home use.
	A <b>Contraindication</b> 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 <b>Warning</b> is used when failure to follow the instructions may result in serious injury or death.
	A <b>Caution</b> is used when failure to follow the instructions may result in a minor or moderate injury, or damage to the device or other property.
	<b>Notes</b> are used to provide clarification or recommendation.

# 1.0 Introduction

## Intended Use

The **Flexistim** combines the treatment capabilities of a TENS device, an EMS or NMES device, a MIC stimulator, and an IFT stimulator all in one unit.

TENS stands for Transcutaneous Electrical Nerve Stimulation. The TENS settings are used to provide symptomatic pain relief for chronic, acute or post-operative pain.

EMS stands for Electrical Muscular Stimulation. The EMS settings are used to provide a muscular training for localised regeneration and muscular hypertrophy.

MIC stands for Microcurrent Stimulation. The MIC settings are used to provide symptomatic pain relief for chronic pain, and the DC setting is used for wound healing.

IFT stands for Interferential Stimulation. The IFT settings are indicated for symptomatic relief of chronic intractable pain.

The **Flexistim** is intended for use in both the Hospital and Home Healthcare Environments.

## Flexistim Features

### 1) Multiple Functions

10 TENS programmes, 2 manual TENS programmes, 27 EMS programmes, 4 IFT Programmes, 4 Microcurrent Programmes and 6 user defined EMS programmes enabling you to experiment and save your favourite settings - unrivalled performance for a product of this size and price.

### 2) Output

99 mA TENS and EMS

60mA Peak to Peak pure sinusoidal carrier wave with constant energy (modified constant current) control and 40 mA safety override for home use.

700  $\mu$ A Microcurrent with DC option.

### 3) Memory

**Flexistim** allows you to save and recall a particular programme setting and has a Usage

Timer to record the time it has been used.

#### 4) Power Supply

Removeable, rechargeable Li-ion battery, with option of operation through external mains power adaptor.

## 2.0 Contraindications, Warnings and Cautions



### Contraindications

- **Do NOT use** this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted electronic devices, because this may cause electric shock, burns, electrical interference, or death.
- **Do NOT use** this device on patients whose pain syndromes are undiagnosed.
- **Do NOT apply** stimulation over the pregnant uterus.



### Warnings

- **Do NOT** apply stimulation over the neck or mouth because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- **Do NOT** apply stimulation across the chest, because IFT currents penetrate deep into the tissue and the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
- **Do NOT** apply stimulation, other than microcurrent, over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins).
- **Do NOT** apply stimulation over, or in proximity to, cancerous lesions.
- **Do NOT** apply stimulation in the presence of electronic monitoring equipment (e.g. cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- **Do NOT** apply stimulation when in the bath or shower.
- **Do NOT** apply stimulation while driving, operating machinery, or during any activity

in which electrical stimulation can put the patient at risk of injury.

- **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 near the thorax because the introduction of electrical current may increase the risk of cardiac fibrillation.
- Stimulation should not be applied across or through the head, 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.
- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Apply stimulation only to normal, intact, clean, healthy skin.
- Using the device directly over metallic implants could cause the currents to focus over a small area, causing tissue burns. If you have metal implants, do not place the pads near, or across the implant, and adjust the intensity with care.
- Caution should be observed when using the Flexistim at high strength settings. Flexistim has a Yellow LED light on output socket which means Flexistim is capable of delivering outputs >10 mA (RMS) averaged over 1s.
- Prolonged use at high settings may cause muscle injury or tissue inflammation.
- There are no user serviceable parts. No modification of this equipment is allowed.



## Cautions

- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head and electrodes should not be placed on opposite sides of the head, unless you are in Microcurrent mode.
- The safety of electrical stimulation during pregnancy has not been established.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium (gel).
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- Patients with suspected or diagnosed epilepsy should follow precautions

recommended by their physicians.

- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture.
- Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process.
- Use caution if stimulation is applied over areas of skin with less than normal sensitivity.
- Keep this device out of the reach of children. Long cord - risk of strangulation in infants.
- Do not permit use by children unable to understand the instructions or persons with cognitive disabilities, i.e.: Alzheimer's disease or dementia.
- **Caution** Not intended for use in an oxygen rich environment.
- **Caution** Not intended for use in conjunction with flammable anaesthetics or flammable agents.
- **Caution** The patient is an intended operator.
- **Caution** Do not service and maintain the device while in use with a patient.
- **Caution** Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- **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.
- If necessary, we will provide circuit diagrams, component part lists or other information that will assist authorized service personnel to repair the device.
- Keep away from pets and pests.

## **Adverse Reactions**

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physicians if they



experience adverse reactions from the device.

## **General Warnings**

- Do not immerse any part of the unit in water
- Do not place the unit close to excessive heat.
- Do not use any electrodes which are less than 50 mm x 50 mm.
- Use only the specified battery: 1 x 3.7 volt rechargeable lithium battery. The use of any other battery could damage the unit.
- Remove battery if unit is not used for a long period of time.
- Do not use the unit while asleep.
- Do not put the lead wire on, or wrapped around the neck.
- Use this device only with the leads, electrodes and accessories recommended by the manufacturer. Use of other parts materials supplied by the manufacturer can degrade minimum safety and invalidate the warranty.
- After inserting plugs into both CH1 and CH2 sockets, please do not remove the plugs when the unit is working. Ensure that the unit is switched OFF before removing the plugs.
- Keep the unit away from sources of high magnetic fields such as TV'S, microwave ovens and hi-fi speakers, as these may affect the LCD screen.
- Keep the device away from a fireplace or radiant heater, as the heat may affect the device.
- Keep the device away from nebulizer or steam kettle, as the moisture may affect the device.
- Keep the device away from sunlight, as long-term exposure to sunlight may affect the rubber causing it to become less elastic and crack.
- Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the sockets or cause the battery connector to develop a bad contact.
- Temperature & Relative Humidity of storage: -25°C--+70°C, 10%--93% R.H.
- Temperature & Relative Humidity of transportation: -25°C--+70°C, 10%--93% R.H.

## **3.0 How TENS Works**

TENS stands for Transcutaneous Electrical Nerve Stimulation. TENS stimulates your body's own natural defences against pain. It is totally safe and has been used successfully by thousands of pain sufferers.

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

### **Pain Gate**

Stimulating the sensory nerves, which carry touch and temperature signals. These nerves go to the same connections in the spine as the nerves carrying pain. A strong sensory signal will block the pain signal travelling up the spine to the brain. This is known as closing the "Pain Gate" and takes effect quite quickly after the unit is switched on. You can use TENS several times a day, for as long as you like.

### **Endorphin Release**

At low frequency settings, and slightly stronger output, TENS drives the motor nerves to produce a small repetitive muscle contraction. This is seen by the brain as exercise and this promotes release of Endorphins – your body's own natural pain killer. The relief builds up and normally takes about 40 minutes to reach a maximum level which can last for hours after the machine is switched off.

By using TENS, you can expect to achieve a significant reduction in pain if not complete pain relief.

### **Side Effects**

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

### **Positioning the electrodes for TENS**

The TENS effect is confined to the nerves entering a single vertebra in the spine. To be effective, you therefore need to stimulate a sensory nerve entering the spine at the same level as the nerve carrying the pain. For this reason, electrodes are usually first placed

where the greatest pain is felt. Nerves follow the curve of the ribs and spiral around the limbs, so you will need to try different positions until you find the best for you. Try moving the electrodes short distances to establish the positions that are most effective for you.

TENS is clinically tested and approved for many applications including:

- Back pain and lumbar and cervical spine problems
- Joint pain (e.g. knee joint, hip joint, shoulder)
- Neuralgia • Headaches • Women's period pains
- Pain after injuries to musculoskeletal system
- Pain with circulatory problems
- Chronic pain through various causes

## **4.0 EMS: What It Is and How It Works**

EMS stands for Electrical Muscle Stimulation and is a widespread and generally recognised method which has been used for years in sports and rehabilitation medicine. In the sports and fitness field, one of the uses of EMS is as a supplement to conventional muscle training, in order to increase the efficiency of muscle groups and adapt physical proportions to the desired aesthetic results.

EMS has two main applications. Firstly, a targeted strengthening of musculature can be produced (Activating application) and secondly a relaxing, resting effect can also be achieved (Relaxing application).

Typical uses are:

- Muscle training to improve endurance performance
- Muscle training to support the strengthening of certain muscles or muscle groups in order to achieve desired changes to body proportions
- Sports training, covering - warm-up, strength, speed, power, resistance, endurance and recovery
- Rehabilitation in relation to sports injury

The effect on muscle tone of electrical stimulation (EMS) is generally only noticeable after regularly repeated application. Electrical stimulation does not replace regular exercising

of the muscle but is able to reasonably supplement it.

Muscle wastage: EMS is used in the treatment of medical conditions involving muscle wastage including: Neuromuscular facilitation - Muscle re-education - Muscle training - Prevention/slowing of atrophy/hypotrophy - Preventing postoperative muscle weakness - Reduction of spasticity - Maintaining or increasing range of motion - Training of partial peripheral nerve damage with signs of re-innervation - Treatment of scoliosis.

#### **4.1 Mode of Operation**

EMS uses external electrical impulses that act through the skin to stimulate the nerves supplying a specific muscle group.

The muscle reacts in different ways depending on the strength of current and duration and frequency of the electrical impulse.

Muscles are made up of two different types of fibre:

Red fibre is slower contracting and aerobic working.

White fibre is faster acting and capable of anaerobic working.

The proportions of red and white fibres depend on the way the muscle is used.

Fibre can be converted from one type to the other, depending on the signals it receives. This is known as the Trophic effect.

Different frequencies have different effects: Low (1-10 Hz) frequencies coupled with long impulse times have a purifying and relaxing effect through individual contractions, whereby the circulation in the treated muscle is simultaneously improved and removal of metabolic end products is supported (lymphatic drainage). The oxygen supply to the muscle is improved.

In contrast, medium (20-50 Hz) frequencies can put a high level of strain on the muscle, thus promoting the muscular structure.

Very high frequencies (60-90 Hz) can be used to promote muscle definition and bulk. The body maps at the back of this guide show pad positioning in order to stimulate specific muscle groups.

## **4.2 Treatment time and treatment interval**

Treatment by EMS can vary between 15–60 minutes stimulation twice a week to treatment several times per day.

## **4.3 Choosing the right strength**

The object of EMS treatment is to produce powerful muscle contractions.

The strength of the current should be increased to about three times the level at which you can first feel the tingling, or to as high as you can stand without causing pain. You will probably feel that electrical contraction is being more powerful than a voluntary contraction, because the current also stimulates your sensory nerves. The signals have a pain-relieving effect.

You may find the sensation uncomfortable to start with, therefore you may not get up to therapeutic strength at the start of treatment. The strength can be increased during the course of the treatment, as you become accustomed to the sensation. Voluntary muscular activity is more effective than stimulation, and it may improve progress if you combine voluntary contraction with stimulation.

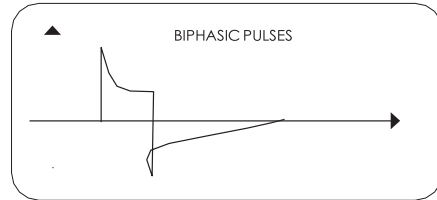
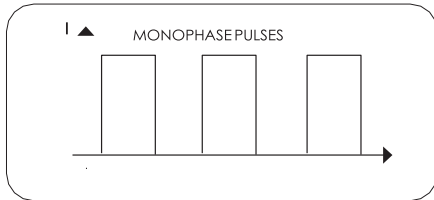
The powerful muscle contractions caused by electrical stimulation give rise to training aches, which usually disappear within a week.

After treatment tingling sensations may continue or your skin may feel numb. This is normal.

## 5.0 TENS and EMS Stimulation Parameters

The effect of electrical stimulation on the body depends on the following current settings:

### 5.1 Pulse Waveform



This describes the time function of the excitation current which may be either monophasic or biphasic.

With monophasic pulse trains, the current flows in one direction. With biphasic pulses, the excitation current alternates its direction.

The **Flexistim** uses only biphasic pulse trains, as they reduce the strain on the muscle, leading to less muscle fatigue as well as safer application and reduce the risk of skin irritation under the electrode.

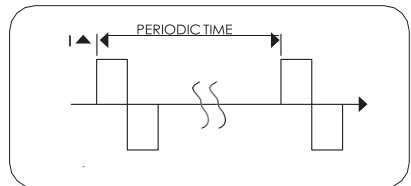
### 5.2 Pulse Frequency

Frequency indicates the number of individual pulses per second and is indicated in Hz (Hertz = pulses per second). It can be calculated by working out the inverse value of the periodic time.

Different types of muscle fibres react preferentially to different frequencies:

Slow-response fibres tend to react to lower pulse frequencies up to 15Hz, while fast-response fibres only respond to frequencies over approx. 35Hz.

With pulses of approx. 45~70Hz, there is permanent tension in the muscle (tetany)



combined with premature muscle fatigue. Higher pulse frequencies can therefore preferably be used for elasticity and maximum strength training.

For TENS:

A frequency of 110 Hz is good at blocking pain signals.

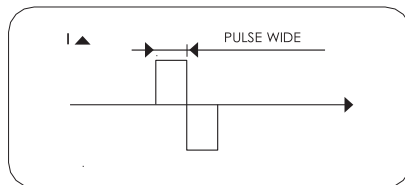
A low frequency of 4 or 10 Hz allows for the release of endorphins, the body's natural morphine-like substances.

### 5.3 Pulse Width

Pulse width is used to indicate the duration of an individual pulse in microseconds (millionths of a second). Pulse width also determines the penetration depth of the current. In general, a greater muscle mass requires a greater pulse width. A higher pulse width is also more likely to activate pain nerves, so there is a fine balance between maximum muscle stimulation and tolerable sensation.

EMS 50-400 depending on frequency

TENS 50 to 250  $\mu$ s.



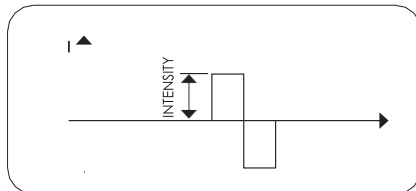
### 5.4 Pulse Intensity

Setting the degree of intensity is dependent on the subjective feeling of each individual user and is determined by a number of parameters such as application site, skin circulation, skin thickness as well as quality of electrode contact. The actual setting

should be effective but should never produce any unpleasant sensation such as pain at the site of application.

In TENS programmes, while a slight tingling sensation indicates sufficient stimulation energy, any setting which leads to pain must be avoided.

In EMS programmes, the intensity needs to be as high as possible for maximum benefit



– so set just below the pain threshold.

With prolonged application, you may need to increase intensity as nerves get used to the stimulation and become less sensitive (known as accommodation).

## 5.5 WORK

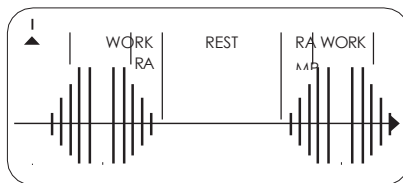
Work is the time in seconds that muscle is stimulated (not including Ramp time). The Flexistim offers a range of work periods from 1-40 sec.

## 5.6 REST

Rest is the time in seconds at zero strength in between stimulation. The Flexistim offers a range of rest periods from 1-40 sec. The EMS programmes use an active rest - low frequency pulses help to clear metabolites in-between work periods.

## 5.7 RAMP

Ramp is the time in seconds taken to move up and down between zero and the set stimulation strength. The Flexistim has a fixed ramp time of 1.5 up and 0.75 down.



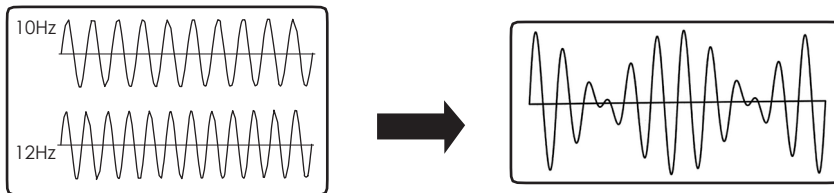
## 6.0 IFT: What It Is and How It Works

Many users will be familiar with TENS, which delivers intermittent pulses to stimulate surface nerves and block the pain signal. Unlike TENS, Interferential Therapy delivers a continuous stimulation deep into the affected tissue.

IFT achieves this deep penetration by using a 4000 Hz carrier wave to overcome the skin impedance. TENS signals travel around the top 1cm of the skin surface. IFT signals travel almost directly between the electrodes.

Interferential Therapy uses two medium frequency 4000 Hz currents that 'interfere' with each other to produce a **beat frequency** that the body recognises as a low frequency energy source.





The range of this **beat frequency** in the Flexistim is 1 to 160Hz.

Unlike TENS, which delivers intermittent pulses to stimulate surface nerves and block the pain signal, IFT delivers continuous stimulation deep into the affected tissue. In addition to providing pain relief by the same mechanism that TENS uses, most physiotherapists consider that IFT's major role is to accelerate the inflammatory or healing rate.

IFT is believed to work by stimulating parasympathetic nerve fibres to give increased blood flow and oedema reduction and by passing currents across cell membranes; these currents vary depending upon the tissue involved. By using particular frequencies in the range, different systems within the body can be stimulated or used to increase the blood supply, which in turn hastens the healing rate. IFT is used to treat almost any condition where inflammation is a problem. For example, sports injuries; arthritic conditions; bruising and swellings, back pain, arthritis and muscular pain.

Many practitioners use a "Sweep" treatment which uses constantly changing interference pulse frequency. Practical clinical experience suggests therapeutic benefits for these sweeps in addition to those of conventional nerve stimulation.

## 7.0 Microcurrent

**Microcurrent Stimulation (MIC)** is a type of therapy where very low current is sent into the cells of the body. MIC is a very faint current that is so small it is measured in millionths of an amp (microamps). Human cells generate a current that is in the micro amp range which is why some can't feel it - the current is so low it doesn't stimulate the sensory nerves.

MIC is a physiological electric modality that increases ATP (energy) production in the cells of your body. This dramatically increases the tissue's healing rate. The immediate response to the correct MIC frequency suggests that other mechanisms are involved as well. The exact effects or changes in the tissue can be noticeable; scars can suddenly soften; trigger points often become less painful when the "correct" frequency is applied. In many situations the changes can be long lasting and even permanent in some cases.

Microcurrent has been shown to give very effective pain relief. In patient surveys over 90% of patients reported significant improvement.

The results of MIC can be seen after only a minute or so of treatment in most people.

## 8.0 Keypad and Display

ON/OFF

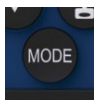


## Keys



### **ON/OFF Key** (On top of unit)

This key switches the unit on or off. Press once for 2 sec and the unit is on, the LCD display located at the front of the unit will light up. There will be no feeling from either lead at this point as the intensity always starts at zero. Press this key again and the unit will switch off.



### **Mode Selection Key**

Press this key to select the therapy Mode:

TENS, EMS I, II and III (small, medium and large muscles), IFT or Microcurrent.

When a programme is running, this key also acts a PAUSE button. The PAUSE symbol **II** will be displayed and the programme timer will stop. Pressing again resumes the programme and the intensity gradually returns to the set value.



### **Programme Selection**

Press the "Prog" key to select the programme you require (see section 15)



### **Parameter Menu Selection**

Press these keys to select the following parameters one by one:

#### **TENS Preset Mode (P1-P10):**

Treatment Timer (min)

#### **TENS Manual Mode (P11-P12):**

FREQUENCY (Hz)

PULSE WIDTH ( $\mu$ s)

Treatment Timer (min)

#### **EMS Preset Mode (P1-P09):**

Treatment Timer (min)

#### **EMS Manual Mode (P10-P11):**

FREQUENCY (Hz)

PULSE WIDTH ( $\mu$ s)

SYNCHRONOUS/ALTERNATING - SYNCH/ALT in display WORK TIME (sec)

REST TIME (sec)

RAMP UP/DOWN TIME (sec)

Treatment Timer (min)

### **IFT Mode**

#### **IFT Preset (P1-P3)**

Treatment Timer (min)

IFT Manual (P4)

FREQUENCY (Hz) (P1-P3)

Treatment Timer (min)

#### **Microcurrent Mode:**

#### **Preset (P1, P2 and P4) Manual (P3)**

WAVEFORM - Const /Square/Ramp FREQUENCY (Hz)

PULSE WIDTH ms

Treatment Timer (min)



#### **Parameter Adjustment Controls**

Press these keys to increase or decrease the value of the parameter which you have selected with the MENU keys.




#### **Intensity Controls**

Press the keys on the left to adjust the intensity in Ch1 and on the right to adjust the intensity in Ch2

#### **IF MODE:**

I.F. signals penetrate deep into the tissue. Positioning pads across the chest or head could be dangerous - see section 16.3.

 For your safety, when intensity reaches 40 mA, the warning triangle flashes and intensity cannot be increased.

Check electrode pad position. If you are certain that the pads are positioned safely, press the SKIP key to override. The triangle will stop flashing and intensity can be increased to 60 mA.



### **SKIP Key**

The EMS programmes have three phases: Warm/ Train/ Cool.

You can jump to the next phase by pressing the Skip key.

In IF MODE, use this key to override limit and set intensity at > 40 mA.



### **Manual Programme Lock**

When "Manual" is showing, you can protect the manual settings by pressing and holding this key for 3 seconds.

The key symbol will flash and you will be unable to change the manual settings.

Press and hold for 3 seconds to unlock programme.

### **Automatic keypad lock**



There is an automatic keypad lock if no button is used for 10 seconds. Key symbol appears. Press the Intensity Down button for either channel to unlock.

### **Lead Fault Detector**



In TENS and EMS modes, when one or both of the electrodes are not placed firmly on the skin, or the leads are not properly connected and the intensity is >10, the output level goes immediately to zero and a lead fault icon flashes.

### **Treatment Timer**

When the Treatment Timer has been set, it begins to count down in minutes and the time remaining is displayed on the LCD. When it reaches zero, the device automatically shuts off.

## Memory

There is a usage memory for each Mode.

Pressing the **MODE** and **CH1 ▼** button together for 3 seconds enters Memory.

The Usage time will be accumulatively recorded when the output level is above zero. The accumulative treatment time in minutes is displayed.

Press the same keys again to return back to the previous normal display.

Pressing **CH2 ▼** key and **MODE** key together for 3 seconds will clear the treatment time to zero.

## Power Supply



The **Flexistim** may be operated from the re-chargeable battery, or directly from the power adaptor. When the adaptor is plugged in to the Flexistim, the internal battery is automatically disconnected. The battery cannot be charged while in the unit, only in the charging cradle supplied.

The rechargeable battery will give about 1 hours use at 50% intensity in IFT Mode, and much longer in other Modes.

If you need to make more than one treatment you may either:

- a) Purchase and recharge additional batteries
- b) Connect to mains power using the mains adaptor



**Warning:** The power adaptor supplied has special medical grade isolation. Use of any mains adaptor other than the one supplied with the device could compromise electrical safety.

## Other Features

- The LCD is backlit. To save energy the back light will switch off if the keypad is not used for 30 secs. Pressing any key will re-activate it.
- When the unit is turned on, if you do not press any of the keys, or intensity is set to

zero, for > 5 mins it will automatically shut off.

- When you turn the unit on, it will automatically enter the mode that you used last.
- When you change Programme, the output level will reset to zero immediately.
- When the battery is low, the battery icon will flash indicating that the batteries should be recharged.

## 9.0 Contents

Your **Flexistim** pack should contain the following:

- 1 × **Flexistim** Unit
- 2 × Leads
- 4 × Self-Adhesive Electrodes with Connectors (Size: 50mm × 50mm)
- 1 × 3.7V Rechargeable Lithium Battery (BL-6F)
- 1 × AC Power Cord
- 1 × Battery Charging Cradle
- 1 x Detachable belt clip
- 1 x Storage pouch
- 1 x Instructions for use

## 10.0 How to Assemble Your Unit

Your **Flexistim** has been designed to be simple and easy to use. Assembly of the **Flexistim** unit is very simple and requires only five steps.

### STEP 1: Battery

Slide belt clip down to access battery cover.

Remove the battery cover and insert the battery (as shown on the diagram) inside



the battery compartment. Replace the battery cover.



**Note:** Fully charge battery before initial use. See “Charging the Battery” on page 51.



**Caution:** There is a risk of explosion if the battery is fitted incorrectly. Replace only with the correct 3.7 volt lithium battery. Do not dispose of the battery in a fire and keep it out of reach of children. The battery must be removed from the unit if unit is not used for a long period of time.

## STEP 2: Leads

If only using one lead, insert into one socket. If using two leads, insert into both sockets.

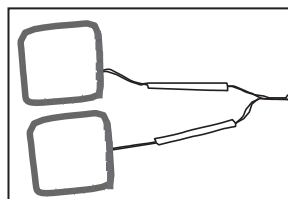
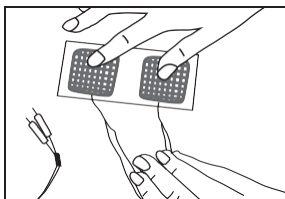
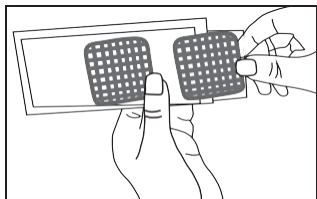
**A:** Insert the lead wires

**B:** Turn the plug on the lead wire 90° to lock it between the main body and handle of the unit.

This prevents accidental disconnection during treatment.

## STEP 3: Electrodes

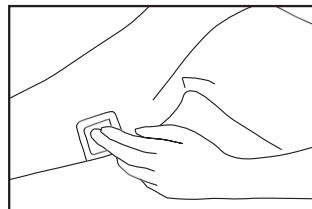
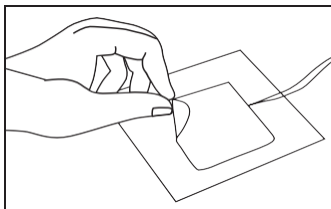
Remove electrodes from the bag and connect to the leads.





## STEP 4: Placement of electrodes

Ensure wherever you intend to place the electrodes, the skin is clean and thoroughly dry. Remove the electrodes from the clear plastic shield and position on your body as required.

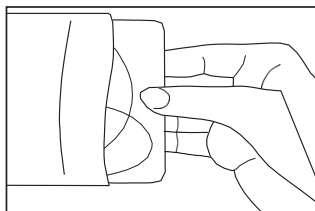
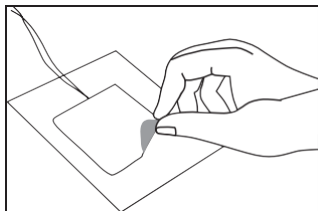


## STEP 5: Reading

Read sections 11 to 16 and decide how to use the unit for the treatment.

### Note: After Use

Always ensure that the unit is switched OFF before removing the electrodes. After use, return the electrodes to the clear plastic shields and seal them in the PVC bag. There is no need to separate the lead wires from the electrodes.



### Life of the electrodes:

The electrodes are water based and can dry out if left outside of the PVC storage bag. If the electrodes lose their adhesive quality in this way, it is possible to reactivate

their adhesiveness by applying a fine spray of water.

Replace the electrodes when they stop sticking well. This can affect the efficiency of the unit and may lead to skin irritation.

## 11.0 Operation

After assembling and connecting the device:

### 11.1 Turn on the device

Press **ON/OFF KEY**.

LCD displays when the device is on. The LCD is backlit. To save energy the back light will switch off if the keypad is not used for 30 seconds. Pressing any key will re-activate it. *Always switch the device off before removing electrodes from the skin.*

### 11.2 Select Mode

Use **MODE** key to select:

- TENS
- EMS I, II, and III (small, medium and large muscles)
- IFT
- Microcurrent

When a programme is running the **MODE** key acts as a **PAUSE** button.

The **PAUSE** symbol **II** is displayed and the Timer stops. When you press again to resume the programme, the intensity slowly increases to the set level.

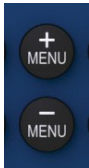
### 11.3 Select a Programme

Use **Programme Selection Key** to choose a desirable program (See section 15 Programmes).

The output intensity resets to zero when you change a treatment program.

## 11.4 Set Treatment Timer

The Treatment Timer defaults to Continuous (C) for some TENS programmes and a safe standard treatment time for others. If you wish to adjust the Treatment Timer proceed as follows;



To set a Treatment Time, press either of the Parameter Selection keys:

MENU +/-

The Timer symbol will flash



Use the Parameter Adjustment Controls +/- to select your desired treatment period ranging from 1 to 90 minutes.

Press any intensity key or wait 10 seconds to return to the main screen

The Treatment Timer starts counting as soon as you increase the intensity above zero. At this point, the display begins to count down from its preset value.

When the preset treatment period is elapsed, the device switches off its output.

## 11.5 Attach the Electrode Pads


Attach the leads as shown in section 10 and position the electrode pads as shown in section 16.

## 11.6 Adjust the Intensity



Use the left-hand keys to adjust the intensity in the left-hand lead (Ch1) and the right-hand keys to adjust the intensity in the right-hand lead (Ch2).

In IFT MODE both channels are linked and there is only one intensity adjustment. You can adjust a desired intensity by pressing either of the intensity controls.

For your safety, when intensity reaches 40 mA, the warning triangle  flashes and intensity cannot be increased.

Check electrode pad position. If you are certain that the pads are positioned safely - not through the chest, head or neck - press the **SKIP** key to override.

The triangle will stop flashing and intensity can be increased to 60 mA.



**Warning:** Observe caution when using Flexistim at high strength settings. Prolonged use at high settings may cause muscle injury or tissue inflammation. Flexistim is capable of delivering outputs >10 mA (RMS) averaged over 1s.

### **Automatic keypad lock**

There is an automatic keypad lock if no button is used for 10 seconds. Key symbol appears. Press the Intensity Down button for either channel to unlock.

### **11.7 Skip Function**

The EMS programmes have three phases:



- Warm
- Train
- Cool

You can jump to the next phase by pressing the SKIP key.

## **12.0 Adjusting Manual Programmes**

Press **PROG** to select one of the manual programmes

Press **MENU+** key to cycle through the available parameters (see list below)

Use the Parameter Adjustment controls to select the required value, then press **MENU+** or **MENU-** to move to the next parameter.

## 12.1 TENS

Press **MODE** button until TENS is selected  
P1 appears

Press **PROG** to Select P11 MANUAL Press  
**MENU+**: Hz flashes

Menu steps:

FREQUENCY (Hz)

PULSE WIDTH ( $\mu$ s)

Treatment Timer (min) Press **+/-** to adjust  
Parameter

Press **MENU +/-** to save and advance to next Parameter. Press any intensity button or wait 10 sec to exit setting menu.



## 12.2 EMS

Press **MODE** button until EMS I, II, or III selected.

I, II and III are for small, medium, and large muscles and use different Pulse Width settings  
P1 appears

Press **PROG** to Select P10 or 11 MANUAL Press **MENU +**: Hz flashes

Menu steps:

FREQUENCY (Hz)

PULSE WIDTH ( $\mu$ s)

SYNCHRONOUS/ALTERNATING



(SYNCH/ALT in display) WORK TIME (sec) REST TIME  
(sec)


RAMP UP/DOWN TIME (sec)

Treatment Timer (min) Press **+/-** to adjust the setting

Press **MENU +/-** to save and advance to next Parameter.



A warning triangle  will be displayed when the Rest period is less than Rest Time = Work Time X (Work Hz-16.66)/16.66 seconds. You will not be able to increase the intensity above zero. When setting the Rest time, you can over-ride this by pressing the LOCK key , but be aware that using settings outside of this ratio may cause muscle fatigue. The triangle will continue to flash while you are outside recommended settings.

When using ALTERNATING, ensure that the "Ramp Up Time", "Work Time", and "Ramp Down Time" equals "Rest Time". The  will appear on your screen if this formula is not followed in EMS manual mode.

If the warning triangle appears at any other time, see "Troubleshooting". Adjust intensity above zero to start an EMS programme.

The EMS programmes have three phases: Warm / Train / Cool. You can jump to the next phase by pressing the SKIP key.

### 12.3 IFT

Press **MODE** button until IFT is selected. P1 appears

Press **PROG** to Select P4 MANUAL Press **MENU +**: Hz flashes,

Menu steps:


FREQUENCY (Hz)

Treatment Timer (min)


Press **+/-** to adjust the setting. Press **MENU +/-** to save and advance to next Parameter.

Adjust intensity above zero to start the programme.

In IFT MODE both channels are linked and there is only one intensity adjustment. You can adjust a desired intensity by pressing either of the intensity controls.

For your safety, when intensity reaches 40mA, the warning triangle  flashes and intensity cannot be increased.



Check electrode pad position. If you are certain that the pads are positioned safely, press the SKIP  key to override. The triangle will stop flashing and intensity can be increased to 60mA.

## 12.4 Microcurrent

Press **MODE** button until MICRO is selected. P1 appears  
Press **PROG** to Select P3 MANUAL Press **MENU +**: Hz flashes

Menu steps:

FREQUENCY (Hz)

PULSE WIDTH ms (milliseconds) WAVEFORM - SQUARE/SAW/DC

Treatment Timer (min)

Press +/- to adjust the setting.



## 13.0 Lock and Unlock Your Own Programme

To lock a programme, first adjust the intensity to zero, then press & hold the LOCK key for 3 seconds. When you turn on the device again, this programme will load automatically.

To unlock the programme, reduce the intensity to zero, then press and hold LOCK key for 2 seconds.

## 14.0 Memory Mode

Once you set intensity >5 in TENS and EMS and >0 in IF and Micro, the Usage Timer automatically and accumulatively counts your total usage up to 999 hours 59 minutes.

There is a memory for each MODE.

To enter MEMORY and view the Usage Timer, set intensity to zero,



select the MODE, then press & hold the **PROG** and **CH1 ▼** keys for 3 seconds.

- The number at bottom left shows the number HOURS, and at bottom right the number of MINUTES.
- The number at the top left shows the numbers of uses.

Press the same keys to return to the previous normal display. To reset the Usage Timer to zero, press the **CH2 ▼** key and **PROG** key together for 3 seconds.

## 15.0 Programmes

### 15.1 TENS Programmes

Prog	Hz	Pulse width	Mode	Time		EFFECT Pain Gate / Endorphin Release
1	110	50	Const	C	PRESET	PG
2	80	150	Const	C	PRESET	PG
3	110	200	Const	C	PRESET	PG
4	2	250	Const	30	PRESET	ER
5	4	200	Const	30	PRESET	ER
6	100	150	Burst	30	PRESET	PG+ER
7	150	200	Burst	30	PRESET	PG+ER
8	10/100	250	FM	C	PRESET	PG+ER
9	2/120	200/100	PFM	C	PRESET	PG +ER
10	2/100	200/150	Han	30	PRESET	PG+ER
11	2-150	50-300	Const	5-90/C	MANUAL	
12	2-150	50-300	Burst 2Hz	5-90/C	MANUAL	

#### Using the TENS Programmes

Your nervous system is different to everyone else's. Only you know how the stimulation feels for you. The best way to use TENS is to try the programmes, and see which ones work best for you. There are some general guidelines:



## Programmes with high frequency (Pain Gate)

Programmes 1, 2, 3, 8, 9, 10

- These programmes use the Pain Gate to block the signals travelling along the pain nerves.
- The sensation will fade after 5 or 10 minutes. Keep increasing the intensity so that you can always feel the stimulation clearly.
- You can use these programmes as long as you like. The pain relief may wear off after a few hours. In which case, you can take a break and try again later.
- Programmes 8 and 9 keep changing the sensation, which some users find will extend the effective pain relief.
- Programme 1 is the gentlest stimulation. If you have not used TENS before, start with this until you are comfortable with the feeling.
- Programmes 2 and 3 are similar to 1 but feel stronger and deeper.

## Programmes with low frequency (Endorphin release) elements

Programmes 4, 5, 6, 7, 12

- These programmes encourage production of your natural endorphins by inducing very small, repetitive muscle twitches. All but programmes 4 & 5 combine this with a higher frequency to combine the pain relief mechanisms but may be a little less comfortable.
- To be effective, you need to keep the intensity high enough to induce small muscle movements. This limits the time you can use these programmes - if you use them for more than about 40 minutes, you may have aching muscles later.

## 15.2 EMS Programmes

Prog			FreqHz	Work				Active Rest				Total time mins	
				Pulsewidthµs	Sec	Amp %	Hz	µs	Time s	Amp %			
											I		II
1	PRESET	Warm	6	200	280	340	300	100					5
		Train	10	200	280	340	9	80	4	200	2	50	41
		Cool	3	200	280	340	600	70					10
2	PRESET	Warm	6	200	280	340	120	100					2

		Train	22	200	280	340	7	80	4	200	11	70	18
		Cool	3	200	280	340	180	70					3
3	PRESET	Warm	6	200	280	340	120	100					2
		Train	25	200	280	340	7	80	4	200	11	50	21
		Cool	3	200	280	340	180	70					3
4	PRESET	Warm	6	200	280	340	120	100					2
		Train	40	200	280	340	7	80	4	200	11	50	18
		Cool	3	200	280	340	180	70					3
5	PRESET	Warm	6	200	280	340	120	100					2
		Train	55	200	280	340	5	80	4	235	11	50	27
		Cool	3	200	280	340	180	70					3
6	PRESET	Warm	5	200	280	340	300	100					5
		Train	60	200	280	340	4	80	5	20	10	50	41
		Cool	3	200	280	340	600	70					10
7	PRESET	Warm	5	200	280	340	300	100					5
		Train	65	200	280	340	4	80	4	200	11	25	20
		Cool	3	200	280	340	600	70					10
8	PRESET	Warm	6	200	280	340	120	100					
		Train	75	200	280	340	4	80	4	200	14	50	25
		Cool	3	200	280	340	180	70					
9	PRESET	Warm	5	200	280	340	300	100					
		Train	100	200	280	340	6	80	4	200	36	25	28
		Cool	3	200	280	340	600	70					
10	MANUAL	Warm	6	200	280	340	120	100					
		Train	10-120	100-350			1-30	80			1-60*		1-90
		Cool	3	200	280	340	180	70					
10	DEFAULT		35		280		5				9		20
11	MANUAL	Warm	6	200	280	340	120	100					
		Train	10-120	100-350			1-30	80			1-60*		1-90
		Cool	3	200	280	340	180	70					
11	DEFAULT		50		300		5						

All EMS programmes include a WARM Up, TRAIN, and COOL Down phase.

During the TRAIN phase stimulation alternates between Work - when the muscles are contracted - and Active Rest, with low frequency stimulation to promote metabolite clearance and delay fatigue.

Each Work contraction starts and finishes with a gradual change in intensity - called a Ramp

- All preset TRAIN phases have Ramp up 1.5 s, Ramp Down 0.75 s
- All WARM phases are 6 Hz at same PW as Work phase
- All COOL phases are 3 Hz at same PW as Work phase
- All Active Rest phases have Ramp up 0.5 s, Ramp down 0.5 s
- All Active Rest phases are at 4 Hz, 200  $\mu$ s
- Press SKIP key to move to next phase

### **Manual Settings:**

All WARM phases are 6 Hz at same PW as set Work PW

All COOL phases are 3 Hz at same PW as set Work PW

At first use of a Manual programme the default values are shown.

The Warning triangle is displayed if Rest period is less than Rest Time=Work Time X (WorkHz-16.66)/16.66 seconds.

This is because muscle fibres can only activate a limited number of times a minute (about 1000) without becoming fatigued.

### **Using the EMS Programmes**

EMS can be used for a wide range of sports and medical applications, and the application can get very complicated. The Flexistim programmes have been designed to simplify this as much as possible. You can use the manual programmes if you want to modify the settings, or to experiment with completely different ones. Here are some of the ways you can use the programmes:

#### **Programme 1 Muscle Calming**

Aims to relax the muscles as much as possible. Encourages production of the body's natural endorphins to promote pain relief and improves the blood circulation which supplies oxygen to the muscle.

#### **Programme 2 Resume Training 1**

To promote growth of the slow twitch fibres. This builds muscle strength and helps reduce muscle atrophy, keeping muscles ready for when you want to resume training.

Used for all type of **sports**.

### **Programme 3 Resume Training 2**

Progress from 2 as tolerance increases.

### **Programme 4 Resistance 1**

Improving and increasing the capacity to develop very high level of muscle force over a long period of time. Improving the efficacy of the oxygen consumption at the muscle level and the capacity to withstand toxin build up, such as lactic acid. Used for sports activities that require very high levels of prolonged muscle activity: Rowing, Cycling, Middle distance running.

### **Programme 5 Resistance 2**

Improving oxygen consumption at muscular level and increasing the capacity to withstand build-up of toxins. Used with sports activities requiring prolonged and high levels of muscle force: Cycling, Rowing, Middle distance running.

Alternative application: Lipolysis. Increasing the circulation and modifying the metabolism of the lipocytes. Helps stimulate the subcutaneous deposits of fat. Helps to reduce or eliminate the - Orange Peel effect of the skin surface.

### **Programme 6 Maximum Muscle Contraction**

To increase muscle bulk and volume and to improve muscle force. Searching for muscular hypertrophy.

### **Programme 7 Muscle Toning 1**

Strengthening the muscles, improving blood circulation and capillary bed density. Ideal for applying to the Thigh, Legs, Bottom and Abdomen.

### **Programme 8 Muscle Toning 2**

Similar to 7 but adding bulk in preference to endurance.

### **Programme 9 Force Output**

Anaerobic activity - increasing the muscle capacity to a level of instantaneous maximum muscle force, changing muscle force into explosive action. Used for all activities requiring maximum muscle output in a very short space of time, such as

Judo, short distance sprinting, throwing the discus or shot-put.

### 15.3 IFT Programmes

Programme table:	
P1	2-10 Hz Sweep over 6 s
P2	2-100 Hz sweep over 6 s
P3	80-150 Hz sweep over 6 s
P4	The pulse frequency varies from -30% to +60% of the set pulse frequency over 6 secs. The transition is ramping (triangular wave function).

In IFT MODE both channels are linked and there is only one intensity adjustment. You can adjust a desired intensity by pressing either of the intensity controls.

For your safety, when intensity reaches 40 mA, the warning triangle flashes and intensity cannot be increased.

Check electrode pad position. If you are certain that the pads are positioned safely, press the SKIP key to override. The triangle will stop flashing and intensity can be increased to 60 mA.

### Choosing IFT Settings

IFT works in the same way a TENS but penetrates much deeper into the body. So, you can use IFT with the same settings as the TENS programmes.

Many therapists believe, however, that IFT has additional effects, and can be used to reduce swelling and muscle tension. One of the leading textbooks says:

2Hz      Around this frequency the metencephalins are stimulated which will result in short term pain relief.

10Hz     This frequency has a beneficial effect on the immune system and tends to make patients wakeful yet relaxed.

130Hz    This frequency stimulates the production of endorphins and results in longer term pain relief and some local anaesthesia.

1-100Hz This frequency sweep will increase the inflammatory rate.

45-90Hz This frequency sweep will depress the sympathetic nervous system so allowing increased activity of the parasympathetic system and increase the blood supply.

See the **Flexistim** page on [www.tenscare.co.uk](http://www.tenscare.co.uk) for some published clinical protocols for IFT.

## 15.4 Microcurrent Programmes

Prog	Waveform	Hz	PW ms	Treatment default mins
1	Square	0.5	998	20
2	Saw	30	10	20
3	Manual	0.5-50	10-998	20
4	DC max 99 µA Ch1 only	/	/	20

Frequency: 0.5Hz 1Hz 1.5Hz 2Hz 3Hz 4Hz 5Hz to 50Hz Pulse Width: 0.01-1 SECOND = 10-999 ms

Manual settings:

- Frequency: 0.5Hz 1Hz 1.5Hz 2Hz 3Hz 4Hz 5Hz to 50Hz
- Pulse Width: 0.01-1 SECOND = 10-999 ms

In Programmes 1, 2 & 3:  $PW \leq 1/2 \times \text{Frequency}$

Treatment Time: 20 mins default

Intensity: 0-700 µA in 10 µA steps (Chen: Less than 750 µA promotes ATP)

### Choosing MIC Settings

For most conditions, use a low frequency 1-10 Hz, starting at 0.5Hz in programme P1. A higher frequency up to 100 Hz may give faster results when treating inflammatory problems (e.g. arthritis, tendonitis, etc.).

However, you should always follow this up with a short treatment at low frequency.

Set the current intensity level at the highest comfortable position. This is usually 500 to

600  $\mu$ A, which most people can barely feel.

If you have a very sensitive condition like neuralgia, you can start with a very low current unlike TENS there is no lower threshold.

## **Preparing for Microcurrent Treatment**

To gain the best results make sure that you are in a relaxed position for the treatment. Make sure you do not have tense muscles.

## **How Long Should Each Session Last?**

Start with 10 minutes, then pause to re-evaluate your pain. Stop treatment when the pain is completely gone or when there is no further improvement. This could take an hour or more. However, continuing to treat after the pain has gone may cause it to return. More is not necessarily better when using microcurrent to relieve pain.

## **Follow-Up**

Although results will usually be seen immediately, in some people the effects will be delayed, continuing to improve from several hours to over a day or two after the treatment. In others, it may take several treatments before you start to see noticeable improvement. The effects of microcurrent therapy are cumulative.

Use daily for 1-2 weeks, then switch to every other day.

## **Problems**

While microcurrent therapy can provide a noticeable improvement on more than 90% of users, it will not work for everyone. Where there appear to be no effects, try the following:

- Increase your fluid intake. If you are dehydrated you may not respond well.
- Some people who have had a significant exposure to strong electrical current may be poor candidates for microcurrent therapy. If you have had a severe electric shock in the past, or have used TENS for a long time, microcurrent may not work as quickly for you. You may need prolonged treatment to gain results.

- Microcurrent electrical therapy works through very small electrical flows in the body. These can be affected by earlier surgical scars and traumatic injuries some distance from the present pain. It is possible to clear the body of these “blocks”. Try covering the scar with the electrodes or, on larger scars, putting one electrode at each end, and treating for 10 minutes four days in a row. As this treatment “unblocks” your body’s electrical flow, you may feel increased energy and the pain may also temporarily increase. After treating the scar, allow time to treat the painful area as well.
- Try using a lower current setting of 100  $\mu\text{A}$  for longer - an hour or more.

See the **Flexistim** page on [www.tenscare.co.uk](http://www.tenscare.co.uk) for some published references for Microcurrent.

## 16.0 Electrode Pad Placement



**Warning:** Ensure that intensity is zero before connecting electrodes. Insert connection lead(s) into the sockets below the handle.

Rotate the body of the plug to lock the lead in place. Plug the lead pins into the sockets in the pad pigtails.



**Warning:** To avoid damage, remember to rotate the plug to unlock it before removing the lead.

Only pull the lead by holding the body of the plug.

### 16.1 Electrode Pad Placement for TENS

The placement of electrodes is one of the most important parameters in achieving effective pain relief using TENS. You may need to try various positions before you find the most effective positioning. There are several positioning methods:

#### **Across the painful area**

This is the simplest method. Placing one pad over, or slightly further away from the spine than, the source of the pain. Place the other pad closer to the spine so that the



stimulation travels through the area of pain

### **Dermatomes**

TENS only works at the level of one vertebra of the spine. The nerves carrying pain and the TENS stimulation into each vertebra cover an area of the body called a Dermatome. Each nerve root serves a known area of the skin. You can stimulate the sensory nerves anywhere in this area to reduce the transmission in the pain nerves. The nerves wrap around the trunk and limbs in a spiral, so the dermatomes can give you a better idea of where to place the pads. You can download a dermatome diagram from our website [www.tenscare.co.uk](http://www.tenscare.co.uk).

### **Trigger or Acupuncture Points**

You can use low frequency TENS to stimulate therapy points. Accurately locating these points can be difficult, so you may want to seek professional advice.

## Example TENS Electrode Pad Positions

**Low Back Pain**



**Neck and  
Shoulder Tension**



**Sciatica**



**Shoulder Pain**



**Knee Pain**



**Elbow Pain**



**Ankle Pain**



**Wrist Pain**



**Leg Pain**



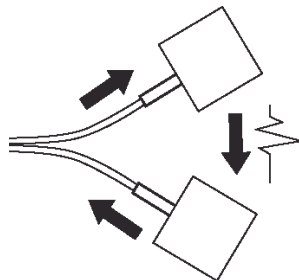
Where only two pads are shown on the arm, shoulder, and leg, use the other two pads either on the opposite limb or place all four pads on the same limb in a square pattern with each pad being about 4 inches apart.

## 16.2 Electrode Pad Placement for EMS

Electrode placement for electrical muscle stimulation is very important for obtaining the best results. Place two electrodes over the bulk of the muscle, with one electrode over the muscle's motor point. The motor point is the area on the skin that is located closest to the motor nerve's entry into the muscle - about 1/3 of the way down the muscle from the spine. Here it is easiest to trigger a contraction by electrical stimulation. Experiment by moving the electrode across the skin until you locate the point over the muscle that gives the cleanest contraction.

Large muscle groups may require stimulation with two channels, that is, four electrodes simultaneously.

The electrode pads must always be used in pairs, so that the signal can flow in a circuit.



**Note:** Always check the unit is OFF before attaching or removing pads.

When exercising smaller muscles, take care to adjust the intensity slowly as the motor nerves may be more sensitive.

## Example EMS Electrode Pad Positions

### Eye care

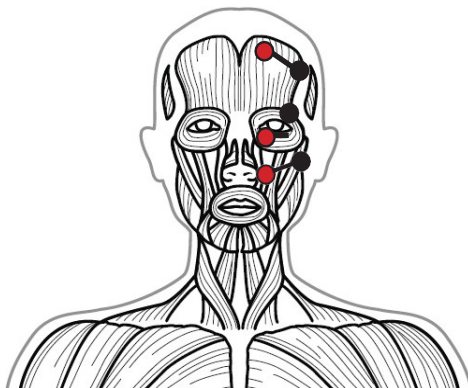
We all are familiar with it. The ever-increasing set of little wrinkles around the eyes. At first, they're accepted as laugh-lines and seen as a symbol of maturity. But, when the eyes also start to swell up, deep wrinkles plough their way through the skin and puffy lids appear, the time has come to do something about it.

You can use Programme 7 to stimulate the muscles around the eyes. You will notice the muscles working straight away from the slight twitching. The activation of the muscles stimulates the circulation. This relaxing

skin care also contributes to an increase in well-being, making you appear more awake and content.

Use small 25mm round electrodes. In order to prevent triggering unpleasant sensations, you should increase the current strength very carefully.

- Do not attach electrodes from one side of the head to the other
- Do not attach electrodes to the front of the neck



### Stomach / Hips

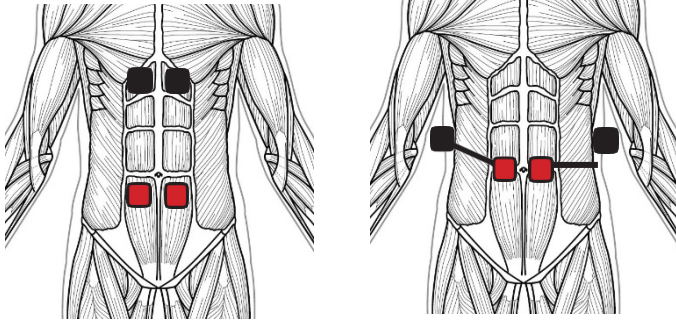
#### Muscle training and fighting the fat

The stomach, that tiresome subject - you can't wish it away.

Weight reduction is usually the magic word. Weight reduction is effectively aided by training the stomach muscles. With **Flexistim** you can single out muscles for direct stimulation.

The stomach contains several different individual muscles.

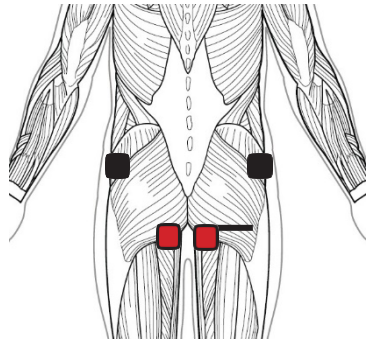
The central stomach muscle is responsible for giving you a slim stomach and a good upper body posture.



### Bottom

The bottom is equipped with a very strong set of muscles.

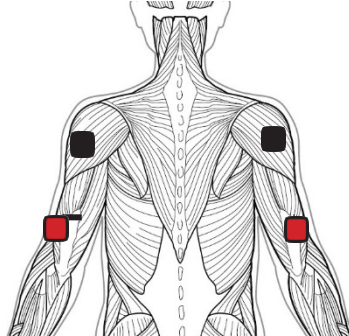
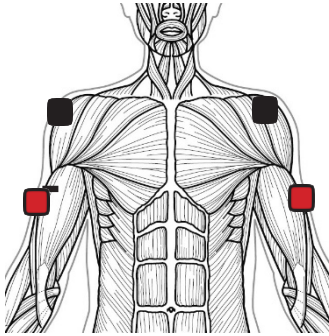
Unfortunately, unwanted fat and cellulite zones are often to be found in this area and are very difficult to combat. Muscular training is one way of improving shape. The picture shows the possible electrode positions for building muscles.



### Upper Arms

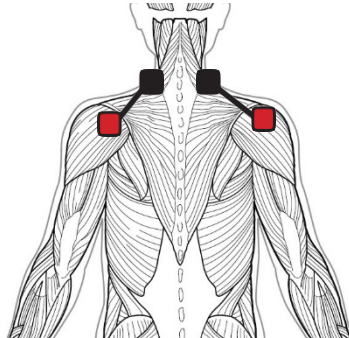
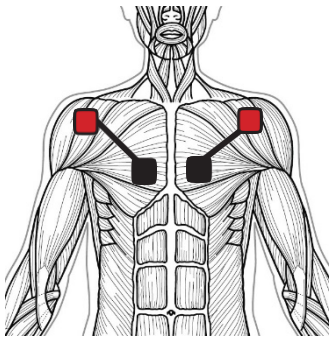
Our upper arms often have little shape and flabby, coarse skin. The cause is usually a lack of movement and muscular work. The **Flexistim** can be used to carry out muscle training.

In this case too, it is all about stimulation of the circulation of blood. You have the option of treating the front side or the reverse side of both upper arms depending on where the need is greatest.



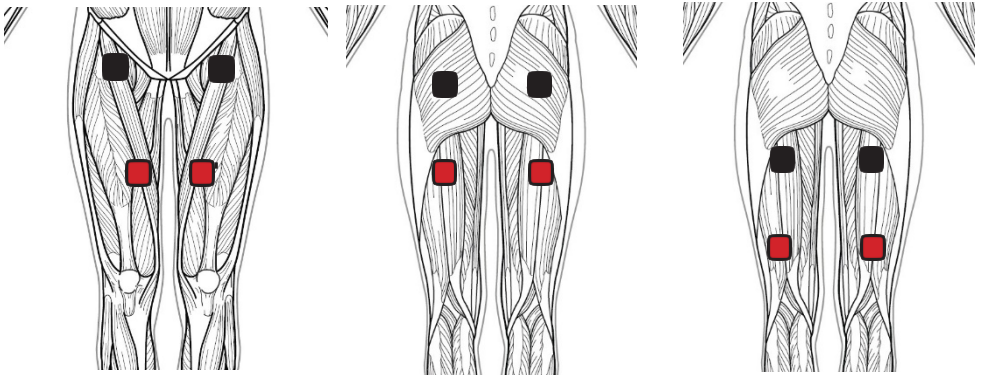
## Chest and Shoulders

Building chest muscle affects posture and movement in the upper body as a whole.



## Legs - Thighs and Calves

It is usually a lack of trained muscles in the legs which disturbs us most, particularly in conjunction with areas of cellulite in the thigh area. Targeted muscle training for the front and back of the thigh and calves is very simple to perform.



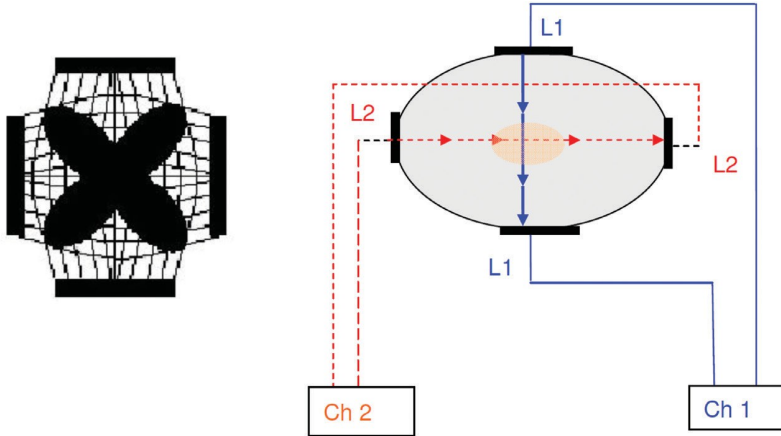
### 16.3 Electrode Pad Placement for IFT

The diagrams on the following pages shows how pads can be placed in various body areas.

They all follow the same principles.

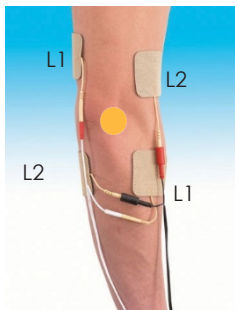
The interferential electrical signal is created by the interaction of the signals from all four pads (i.e. between the pads of each channel). So, the pads need to apply in positions so that the signals from each channel cross over the point to be treated.

The two channels add and subtract to create an interference pattern. In theory this looks like the cross shaped diagram. In real tissue the pattern is difficult to predict and you may need to adjust the pad positions until you can sense the stimulation in the correct area.

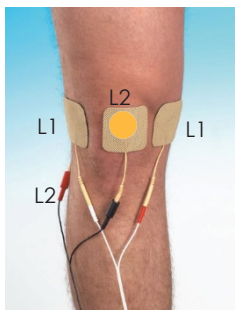




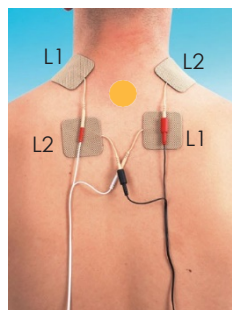
**Elbow**



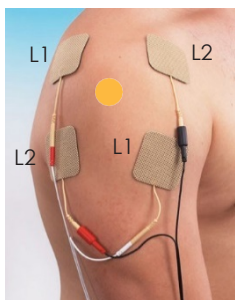
**Knee**



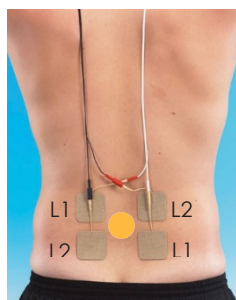
**Neck**



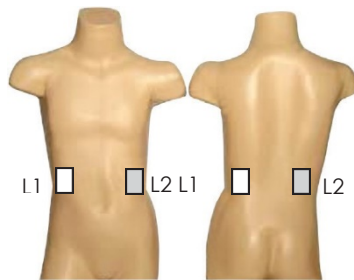
**Shoulder**



**Lower Back**



**Constipation in Children**

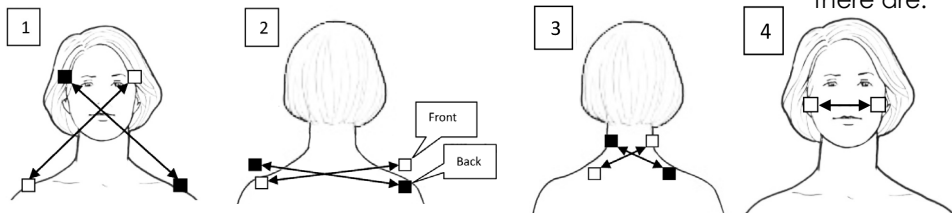


## 16.4 Electrode Pad Placement for Microcurrent

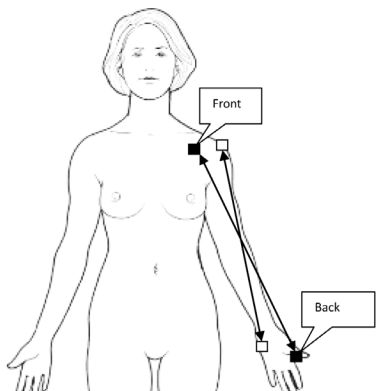
Pad positioning is NOT like TENS and is closer to Interferential.

The pads should be placed so that a straight line between them passes through the problem area. This is different to TENS, where the aim is to stimulate the correct sensory and motor nerves.

Since the body is three dimensional, this often means going from front to back, and side to side. The four alternatives for headache below show how many possibilities there are:



There is no single correct placement, and the best position may vary from day to day. **Warning:** Positions 1 & 4 on the head must NOT be used in other MODES  
One position for treatment of arm pain:



Microcurrent seems to work better if you also treat the OPPOSITE side of the body to where the pain is felt (with the second pair of pads). Also try connecting both sides of the body by placing one pad at the site of the pain, and the other on the opposite side (i.e. left hand to right hand), for 10 mins.

## 17.0 Further Clinical Information and Treatment Protocols

For further information and clinical references go to [www.tenscare.co.uk](http://www.tenscare.co.uk) and look on the **Flexistim** product page.

## 18.0 Care of Electrodes

The electrodes that are supplied with your **Flexistim** are self-adhesive and can be used several times. Skin must be allowed to breathe, so the electrodes should be removed periodically. When not in use, the electrodes should be placed onto the clear plastic shield.

The condition of the electrodes has a direct effect on conductivity, and therefore the effectiveness of the treatment. When the electrodes start to lose their adhesive quality, it is possible to reactivate their adhesiveness by applying a fine spray of water to the gel side of the electrode. In time, this technique will not work, the gel will not reactivate and new electrodes should be used.

### General Pad Advice

- The electrode pads supplied are reusable but are for single patient use. The adhesive is a peel- able hydrogel (water based).
- In order to obtain the best conductivity through the pads always ensure that they are in good condition and tacky.
- Before use make sure your skin is clean and dry.
- Peel the electrode pads from their protective plastic shield by holding and lifting one corner of the pad and pulling. Do not pull on the pigtail wire of the pad.
- After use always replace the pads on the plastic liner and replace in the re-sealable plastic bag.
- If the pads dry out, then it is best to buy a replacement pack of electrodes. In an emergency it may be possible to restore some of the tackiness of the pad by adding a tiny drop of water on each pad and spreading around. If too much

water is added the pads will become too soft, then it is suggested in order to try to re-establish some adhesiveness to place them sticky side up in a refrigerator for a few hours.



## Warnings

Do not use high intensity settings if electrodes are smaller than 50x50mm. However, 25mm x 25mm electrodes can be used for the microcurrent treatment.

Allergic reactions to the self-adhesive electrodes can occur even though they are hypoallergenic.

- Do not apply to broken skin.
- Do not apply electrodes to areas with less than normal sensitivity. This could lead to setting intensities at higher levels than intended.

## 19.0 Charging the Battery

The **Flexistim** is powered by a type BL-6F rechargeable Li-ion battery.

The battery cannot be charged while it is in the unit. A separate charging cradle and power adaptor are included in the kit.

The battery should need charging about once a week unless you are using IF, in which case the battery may only last about one hour.

A battery state indicator on the screen shows how much charge is in the battery. When it gets low, this will start to flash.

NB: Remove the battery from your **Flexistim** if the unit is unlikely to be used for a long period.

When the battery is charged, the indicator light on the cradle will change from red to



green. For a replacement battery, contact Tenscare or your local distributor.

**Use only the power adaptor and charging cradle supplied.**

The *Flexistim* can also be operated directly from the charger.

Just plug it directly into the socket in the side of the unit. This automatically disconnects the battery.



**WARNING: USE OF OTHER CHARGERS COULD BE HAZARDOUS AND WILL NEGATE THE GUARANTEE**

**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** pierce, open, disassemble it, or use it in a humid and/or corrosive environment.
- **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.
- **Do NOT** immerse the battery in water or sea water, or get it wet
- **Do NOT** short-circuit the battery
- The operator should not touch the patient when touching the battery output

**Disposal**

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

## 20.0 Troubleshooting

If your **Flexistim** is not working properly please check the following:

Problem:	
No display/won't turn on:	<p>BATTERY:</p> <ul style="list-style-type: none"> <li>i) Is it fitted?</li> <li>ii) Is it charged?</li> </ul>
Controls don't work	<ul style="list-style-type: none"> <li>i) Press Ch1 or Ch2 ▼ button to unlock the keypad</li> <li>ii) No  showing. Ensure battery is charged.</li> </ul>
No impulse output from electrodes	<p>A circuit is not being made.</p> <ul style="list-style-type: none"> <li>i) Have you applied both electrode pads (per lead wire) to ensure a complete circuit?</li> <li>ii) Are the lead wires properly connected at both ends?</li> <li>iii) Is the lead damaged? (Try using the other lead - if this works, then the original lead is faulty)</li> </ul>
Warning triangle flashing, cannot increase intensity.	<p>You are in EMS Manual Programme 10 or 11. When using ALTERNATING, ensure that the "Ramp Up Time", "Work Time", and "Ramp Down Time" equals "Rest Time". These will appear on your screen if this formula is not followed in EMS manual mode.</p> <p>In EMS Manual programmes 10 or 11 a Warning triangle will be displayed if the Rest period is less than <math>\text{Rest Time} = \text{Work Time} \times (\text{WorkHz} - 16.66) / 16.66</math> seconds.</p> <p>In IF MODE when intensity reaches 40mA, the warning triangle flashes, and intensity cannot be increased.</p> <p>Check electrode pad position. If you are certain that the pads are positioned safely, press the SKIP key to override. The triangle will stop flashing and intensity can be increased to 60mA.</p>
<p>If the above review has failed to resolve your problem, or to report unexpected operation or events or provide feedback call our UK distributor, Tenscare, for advice. Contact our customer service on +44(0) 1372 723434.</p>	

## 21.0 Cleaning

- Clean your device before use.
- Remove the battery from the device every time when you clean the device.
- The case and lead wires can be cleaned by wiping with a damp cloth and a solution of mild soap and water. Wipe dry.
- Do not immerse your **Flexistim** in water.
- Do not use any other cleaning solution than soap and water.

## 22.0 Consumables and Servicing

### Original Accessory

The unit must be used only with the original accessories, supplied by the manufacturer. Replacement electrode pads, new batteries and lead wires are available from your supplier or distributor (see back cover for contact details), by mail order from TensCare, by telephone using a credit or debit card, or through our website.

### Part Number

L-ST2	Replacement lead 1.25m
E-CM5050	Electrode pads 50x50mm for external use. Pack of 4
B-BL6F	Li-Ion battery type BL-6F 3.7V 1100mAh
X-FLEX-CR	Charging Cradle 5V
X-MDA534627-1000	Power adaptor with UK and EU plugs X-MULTIPA-USA Plug for USA

Apart from these items, there are no user-serviceable parts or calibration.

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

- The user must not attempt any repairs to the device or accessories. Please contact the retailer for repair.
- Opening of the equipment by unauthorised agencies is not allowed and will terminate any claim to warranty.
- Check the unit before each use for signs of wear and/or damage. Replace worn items as required.

## 23.0 Warranty

In addition to your statutory rights, the manufacturer agrees that if any defect in materials or workmanship appears in this product within two years after the original date of consumer purchase, it will repair or at its option, replace the product in question free of charge. This applies only if the product has been used for domestic purposes and has not been damaged through misuse, accident or neglect and has not been modified or repaired by anyone other than the manufacturer or its authorised agents.

If a defect appears, please make sure that the unit is being used in accordance with the instructions, if so, return it with this warranty and the proof of purchase to your nearest **Flexistim** dealer. Note: only our authorised service agents should carry out repairs of the **Flexistim** units.

Exclusions: The batteries, lead wires and electrode pads are not considered covered by this warranty.

The supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.



## 24.0 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. New products are now being marked with the symbol to remind you. Your local council or retailer will be able to tell you where your nearest facility is. The collection facilities will send items for treatment, recovery and recycling, so by using them you'll help to save resources and minimise the effects on the environment.



## 25.0 Specifications

### TENS & EMS

Output:	99 mA zero to peak Constant current 500-1500 Ohm Constant voltage > 1500 Ohm
Max Pulse Energy:	Total output limited to 25 $\mu\text{C}$ per pulse
Channels:	Dual Channel
Waveform:	Asymmetrical rectangular bi-phasic
TENS:	2-150 Hz in steps of 1, 50-250 $\mu\text{s}$ in steps of 10
Modes:	Burst/Continuous
EMS:	10-120 Hz, 50-350 $\mu\text{s}$ in steps of 10
Ramp Up/Down Time:	1-8 s, in steps of 1 s

Work Time: 2-30 s, in steps of 1 s  
Rest Time: 1-60 s, in steps of 1 s  
Modes: Synchronous (S) Alternating (A)

## **IFT**

Intensity: 60 steps, 0-60 mA peak to peak at 500 Ohm load  
Carrier Frequency: 4000 Hz fixed (CH1)  
Modulating Frequency: 4004-4160 Hz, in steps of 4 Hz (CH2)  
Pulse Width: 125  $\mu$ s  
Mode: 4 pole  
Waveform: Symmetrical balanced sine wave Continuous  
Treatment Timer: 1-90 mins

## **Microcurrent**

Frequency: 0.5 Hz, 1 Hz, 1.5 Hz, 2 Hz, 3 Hz, 4 Hz, 5 Hz to 50 Hz  
Pulse Width: 10-999 ms  
Waveforms: A continuous, B square unipolar, C sawtooth unipolar  
Treatment Time: 20 mins default  
Intensity: 0-700  $\mu$ A in 10  $\mu$ A steps

## **General**

Output Plugs: Fully shielded: touch proof  
Dimensions: 61 x 123 x 22mm (exclude belt clip)  
Weight: 160g (including battery)  
Power Supply: BL-6F Li-Ion battery 3.7V 1100mAh  
Mains adaptor (Class II, IEC60601-1) with charging cradle  
Input 100-240 V  
Output DC 5V 1000 mA

Safety Classification: Type BF Designed for continuous use  
IP22

Applied Part: Self-adhesive skin electrode

## **Environmental**

Operating Specifications: Humidity: 15% to 93% RH  
Temperature: 5°C to 40°C  
Pressure: 700 hPa to 1060 hPa

Storage and Transport Specifications: Humidity: 15% to 93% RH  
Temperature: -25 to 70°C  
Pressure: 700 hPa to 1060 hPa

Typical Operation Time: No less than 1 week (@50%AMP, 4 hours per day, in TENS/EMS/MIC Mode)

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.  
Li-Ion battery should last about 300 charge cycles.

Storage Life: Unopened pack of electrodes: 2 years, may be affected by very high temperatures or very low humidity.  
Battery: 3 years. Unit and probe have no fixed shelf life.

## **26.0 EMS 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 used no closer than 30 cm (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). For use in hospitals, full EMC tables are available on request.

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>



### **EC Declaration of Conformity**

Easymed 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 0197 marking on this product.

Distributed by:



*TensCare's Trade Partner*

**Easymed Instruments Co., Ltd.**

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Germany

**I-FLEXM-UK Rev 2.0 12/20**

