Flexistim IF

Instructions For Use

Please read carefully

TensCare™

Contents

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 **Contraindication** is used when a device should not be used because the risk of use clearly outweighs any foreseeable benefits and may result in serious injury or death.
	A **Warning** is used when failure to follow the instructions may result in serious injury or death.
	A **Caution** is used when failure to follow the instructions may result in a minor or moderate injury, or damage to the device or other property.
	**Notes** are used to provide clarification or recommendation.

1.0 Introduction

Intended Use

IF stands for Interferential Stimulation. IF is indicated for symptomatic relief of chronic intractable pain.

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

Flexistim IF provides interferential therapy to treat conditions where inflammation is a problem such as Back Pain, Osteoarthritis, Rheumatoid Arthritis, Muscular Pain / Strain, and Sports injuries, or where deep penetration of low frequency stimulation isrequired.

Flexistim IF produces a low frequency current treatment that uses two medium frequency currents, which "interfere" with each other to produce a beat frequency that the body recognizes as a low frequency energy source.

The aim is to overcome the problems caused by low-frequency currents, while maintaining their claimed therapeutic effect. Unlike TENS, which delivers intermittent pulses to stimulate surface nerves and block the pain signal, Interferential Current Therapy delivers continuous stimulation deep into the affected tissue.

The actual stimulation is produced by crossing two alternating currents with medium frequencies simultaneously to a targeted body region. As a result, these two currents will superimpose to form a new low frequency current deep within the tissue.

Flexistim IF Features

Flexistim IF includes many of the features of a professional desk-top unit in a compact, portable, battery operated device.

1. **Power Supply**

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

2. **Output**

60mA Peak to Peak pure sinusoidal carrier wave with constant energy (modified constant

current) control and 40mA safety override for home use.

3. Flexible Programmes

3 preset and 3 adjustable programmes give a wide selection of treatment options.

4. Memory

Flexistim IF allows you to save and recall a particular programme setting and has a Usage Timer to record the time it has been used.

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 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 IF at high strength settings. Flexistim IF 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.
- 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.
- 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.

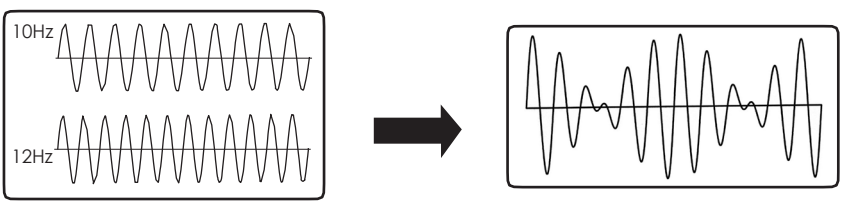
- Temperature & Relative Humidity of storage: -25°C–+70°C, 10%--93% R.H.
- Temperature & Relative Humidity of transportation: -25°C–+70°C, 10%--93% R.H.

3.0 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.



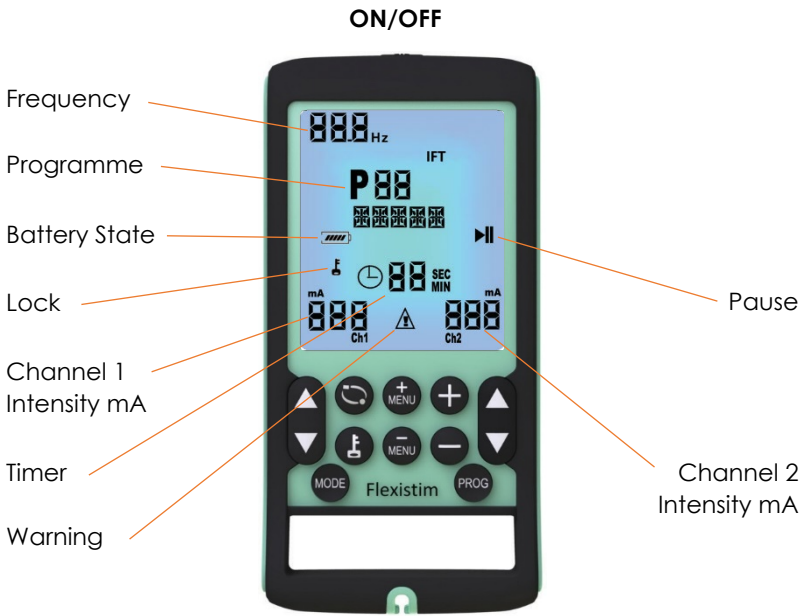
The range of this **beat frequency** in the Flexistim IF is 1 to 160Hz.

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.

4.0 Keypad and Display



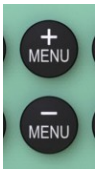
Keys

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.

Programme Selection

Press the "Prog" key to select the programme you require (see section 8)



Parameter Menu Selection

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

Programme P1:

Treatment Timer (min)

FREQUENCY (Hz)

Programmes P2-P4:

Treatment Timer (min)

Programmes P5-P6:

Sweep is between High Frequency and Low Frequency over the set cycle time in seconds

HIGH FREQUENCY (Hz)

LOW FREQUENCY (Hz)

CYCLE TIME (Sec)

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 either left or right hand keys to adjust the intensity

I.F. signals penetrate deep into the tissue. Positioning pads across the chest or head could be dangerous - see section 9

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.

Note that the two channels ADD intensity, so that **max effective IF intensity is 120mA.**

Memory Mode

Pressing the MODE button enters Memory Mode

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

Press Mode key 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.

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.

SKIP Key

High intensity I.F. can be harmful if electrodes are placed so that the current goes directly through the chest or across the head. For your safety, when intensity reaches 40mA, the warning triangle flashes, and intensity cannot be increased.

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.

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.

Power Supply

The ***Flexistim IF*** may be operated from the re-chargeable battery, or directly from the power adaptor. When the adaptor is plugged in to the ***Flexistim IF***, 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.

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.

5.0 Contents

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

- 1 × ***Flexistim IF*** 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

6.0 How to Assemble Your Unit

Your ***Flexistim IF*** has been designed to be simple and easy to use. Assembly of the ***Flexistim IF*** 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 27.

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.

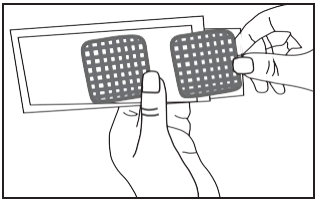
A: Insert the lead wires

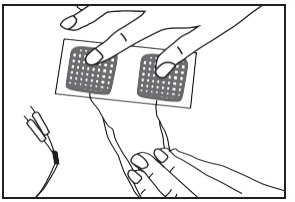
B: Turn the plug on the lead wire 90° to lock it between the main body and handle of the unit.

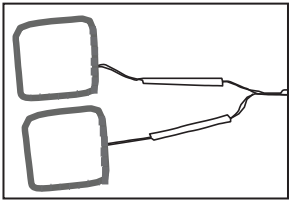
This prevents accidental disconnection during treatment.

STEP 3: Electrodes

Remove electrodes from the bag and connect to the leads.

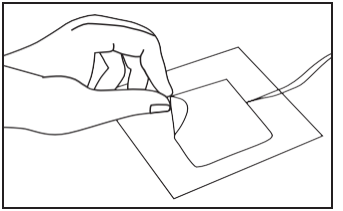


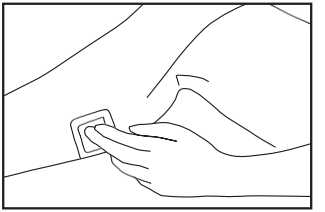




STEP 4: Placement of electrodes

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.



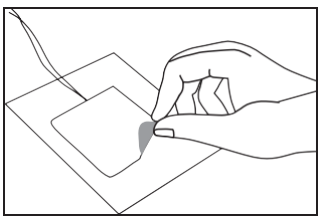


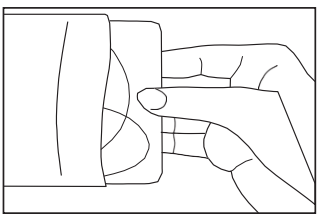
STEP 5: Reading

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.

7.0 Operation

After assembling and connecting the device:

7.1 Turn on the device

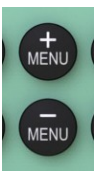
Press **ON/OFF KEY**.

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.*

7.2 Select a Programme

Use **Programme Selection Key** to choose a desirable programme from P1 to P6.
The output intensity resets to zero when you change a treatment program.



7.3 Set Treatment Timer

The Treatment Timer defaults to 20 minutes.
To set a Treatment Time, press either of the Parameter Selection keys.
The Timer symbol will flash

Use the Parameter Adjustment Controls **+/-** to select your desired treatment period ranging from 1 to 90 minutes. You can also select C Continuous operation but should use this setting with caution.

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.

7.4 Attach the Electrode Pads

Attach the leads as shown in section 6 and position the electrode pads as shown in section 9.

7.5 Adjust the Intensity

The output from both leads is linked.

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.

Warning: Observe caution when using Flexistim IF at high strength settings. Prolonged use at high settings may cause muscle injury or tissue inflammation. Flexistim IF 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.

7.6 Adjust the Parameters

In programmes 1, 5 & 6 you can adjust other parameters.

Press **MENU +** key.

In Prog 1, there are only two parameters - Hz and Timer – to adjust.

Hz display at top left will start flashing.

In Progs 5 & 6 there are 4 parameters to adjust:

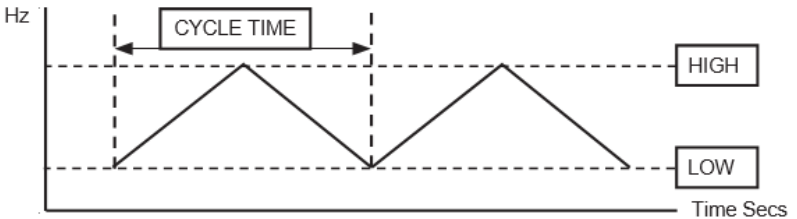
HIGH, LOW, CYCLE, and Timer.

When you first press **MENU+** key, HIGH will be shown in the centre, and the Hz display at the top left will start flashing.

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

The interference beat frequency moves between the set HIGH and LOW frequencies over the CYCLE time set.

Default is 80-130Hz in 6 seconds.



7.7 Lock and Unlock Your Own Programme

To lock programme settings in Programmes 1,5 & 6, first adjust the intensity to zero, then press & hold the LOCK KEY for 3 seconds. You cannot adjust settings while the key symbol is displayed. 3 seconds is a long time, but you will want to avoid accidental activation of this key.

To unlock the programme, take the same step. i.e. Press **INTENSITY ▼** till it reaches zero, then press & hold the LOCK key for 3 seconds.

7.8 Memory Mode

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

To enter MEMORY MODE and view the Usage Timer, set intensity to zero, then press and hold the **MODE** key 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 **MODE** key again to return to the previous normal display. To reset the Usage Timer to zero, press the **CH2▼** key and **MODE** key together for 3 seconds.

8.0 Programmes

Programme table:	
P1	Constant. The pulse frequency is selectable. 2-16-Hz
P2	2-100 Hz sweep over cycle time
P3	2-100 Hz sweep over cycle time
P4	80-150 Hz sweep over cycle time
P5	The pulse frequency varies set LOW frequency to set HIGH frequency over Cycle Time and back. The transition is ramping (triangular wave function).
P6	The pulse frequency varies from set LOW frequency to set HIGH frequency over Cycle Time and back. The transition is abrupt (square wave function).

8.1 Choosing 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 IF*** page on **www.tenscare.co.uk** for some published clinical protocols for IFT.

9.0 Electrode Pad Placement

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

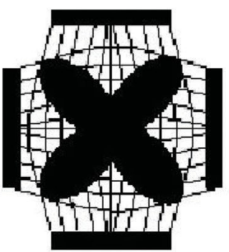
Rotate the body of the plug to lock the lead in place. Plug the lead pins into the sockets in the pad pigtails.

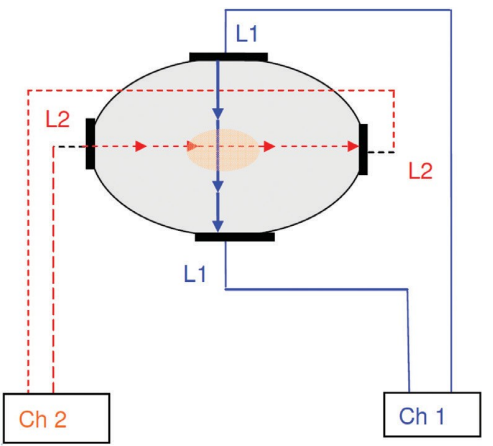
Warning: To avoid damage, remember to rotate the plug to unlock it before removing the lead.

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

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.

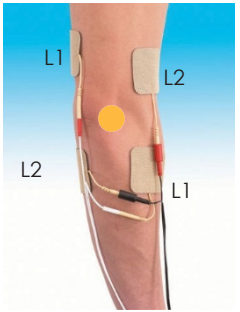




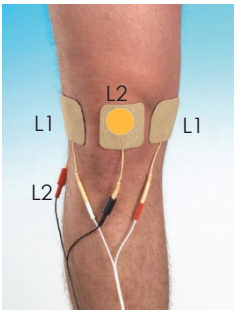
The diagrams on the following pages shows how pads can be placed in various body areas.

They all follow the same principles.

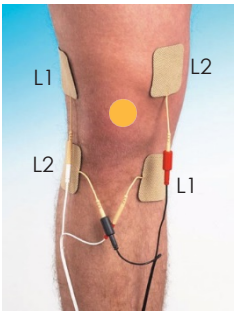
Elbow



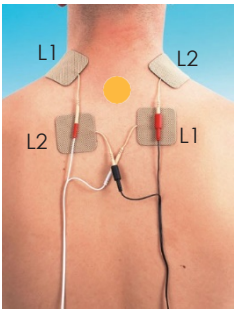
Knee



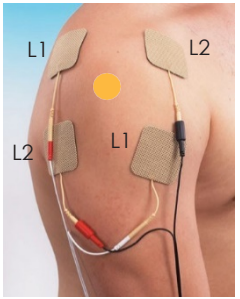
Alternative Knee



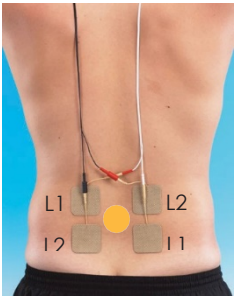
Neck



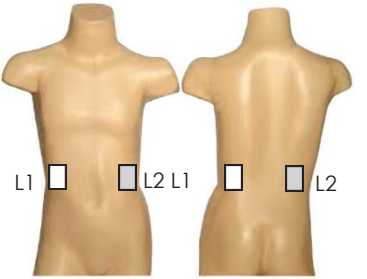
Shoulder



Lower Back



Constipation in Children



10.0 Further Clinical Information and Treatment Protocols

For further information and clinical references go to **www.tenscare.co.uk** and look on the ***Flexistim IF*** product page.

11.0 Care of Electrodes

The electrodes that are supplied with your ***Flexistim IF*** 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.

- In very hot weather the gel on the pads may become soft. In such cases place the pads, still on their plastic liners and in their bag, into a fridge until they return to their normal condition.

Warnings

Do not use high intensity settings if electrodes are smaller than 50x50mm.

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.

12.0 Charging the Battery

The ***Flexistim IF*** 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 will only last about one hour's use at 30mA.

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

Note: Remove the battery from your ***Flexistim IF*** 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 IF*** 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.
- Do not disassemble the battery.
- Do not incinerate or heat the battery.
- Do not use or leave battery near a fire stove or heated place.
- Only use the charger provided and observe charging instructions.

Disposal

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

13.0 Troubleshooting

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

Problem:	
No display/won't turn on:	BATTERY: i) Is it fitted? ii) Is it charged?
Controls don't work	i) Press Ch1 or Ch2 ▼button to unlock the keypad ii) If 🔋 is not showing on the display. Ensure battery is charged.
No impulse output from electrodes	A circuit is not being made. i) Have you applied both electrode pads (per lead wire) to ensure a complete circuit? ii) Are the lead wires properly connected at both ends? iii) Is the lead damaged? (Try using the other lead - if this works, then the original lead is faulty)
Warning triangle flashing, cannot increase intensity.	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.
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.	

14.0 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 IF*** in water.
- Do not use any other cleaning solution than soap and water.

15.0 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.

16.0 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 IF*** dealer. Note: only our authorised service agents should carry out repairs of the ***Flexistim IF*** 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.

17.0 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.

18.0 Specifications

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 µs
Waveform:	Symmetrical balanced sine wave
Treatment Timer:	Continuous, 10-90 mins

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	Humidity: 15% to 93% RH
Specifications:	Temperature: 5°C to 40°C
	Pressure: 700 hPa to 1060 hPa
Storage and	Humidity: 15% to 93% RH
Transport Specifications:	Temperature: -25 to 70°C
	Pressure: 700 hPa to 1060 hPa
Typical Operation Time:	No less than 1 week (@50%AMP)
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.

19.0 EMC Precautions

Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be 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.

RETURN THIS PORTION ONLY WHEN YOU RETURN YOUR PRODUCT FOR REPAIR UNDER WARRANTY.

Name: _____

Address: _____

_____

Postcode: _____

Daytime telephone: _____

E-mail: _____

Model: _____

Date of purchase: _____

ATTACH PROOF OF PURCHASE

DO NOT SEND IN LEADS OR ELECTRODE PADS

Retailer's name: _____

Retailer's address: _____

_____

Retailer's postcode: _____

Brief description of problem you are experiencing: _____

_____

_____

_____

WARRANTY IS VOID UNLESS THE ABOVE INFORMATION IS COMPLETED AND CORRECT

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

CE
0197

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

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