Ultima IF4160+

Interferential Therapy

Instruction Manual





Introduction

Thank you for choosing **ULTIMA IF4160+** which provides an interferential therapy to treat conditions where inflammation is a problem such as Back Pain, Osteoarthritis, Rheumatoid Arthritis, Muscular Pain / Strain, and Sports injuries.

ULTIMA IF4160 Plus produces the 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 rationale 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.

ULTIMA 4160+ differs from the earlier Ultima 4160 in two ways:-

1 Power Supply

In place of rechargeable internal battery, the IF4160+ has a mains adaptor, for continuous use, and 4 x AA primary replaceable batteries. This arrangement allows longer use in a fixed position. It has shorter portable use, but avoids problems with recharging.

2 Memory

You can set the Ultima IF4160+ to save and recall a particular programme setting. The new model also has a Usage Timer to record the time it has been used.

ULTIMA IF4160 PLUS includes:

- 1 x ULTIMA IF4160 PLUS device
- 2 x Lead Wire
- 4 x Electrodes
- 4 x Battery
- 1x Adaptor
- 1 x AC Plug
- 1 x Belt clip
- 1 x Instruction manual
- 1 x Pouch

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1. Safety Information

USA FDA classifies Interferential devices as TENS, so this description has been used in the following warnings

Contraindications

- 1. Any electrode placement that applies current to the carotid sinus (neck) region.
- 2. Any use of TENS on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
- 3. Any electrode placement that causes current to flow transcerebrally (through the head).
- 4. The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.

Warnings

- 1. The safety of TENS devices for use during pregnancy or birth has not been established.
- 2. TENS is not effective for pain of central origin (This includes headache).
- 3. TENS devices should be used only under the continued supervision of a physician.
- 4. It is recommended that patients consult with their physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
- 5. TENS devices have no curative value.
- 6. TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- 7. The user must keep this device out of the reach of children.
- 8. Electronic monitoring equipment (such as ECG monitors and ECG alarms may not operate properly when TENS stimulation is in use.
- 9. Stimulation should not be applied across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
- 10. Stimulation should not be applied over open wounds or over swollen, infected or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins). Apply stimulation only to normal, intact, clean skin.
- 11. Stimulation should not be applied over, or in proximity to, cancerous lesions.
- 12. Stimulation should not be applied when the patient is in the bath or shower.
- 13. Stimulation should not be applied while the patient is sleeping.
- 14. Stimulation should not be applied while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.



Attention! Read the manual before using the device.

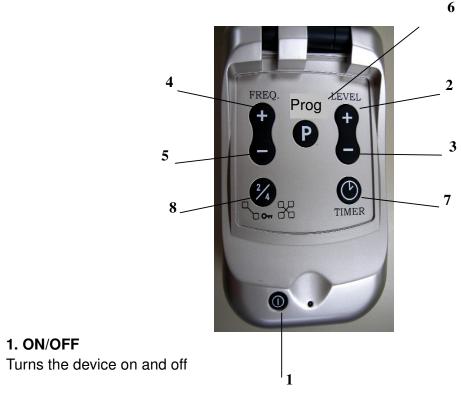
Precautions

- 1. Isolated cases of skin irritation may occur at the site of electrode placement following long term application.
- 2. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
- 3. TENS is not a substitute for pain medications and other pain management therapies.
- 4. The long-term effects of electrical stimulation are unknown.
- 5. Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- 6. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- 7. Caution should be exercised when the patient has a tendency to bleed internally, such as following an injury or fracture.
- 8. Caution should be exercised following recent surgical procedures when stimulation may disrupt the patient's healing process.
- 9. Caution should be exercised when stimulating over areas of skin that lack normal sensation.
- 10. Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

Adverse Reactions

- 1. Skin Irritation and electrode burns are potential adverse reactions.
- 2. Headache and other painful sensations have been reported during or following the application of electrical stimulation near the eyes and to the head and face.

2. Operation keys



2. INCREASE INTENSITY

Press this button to increase amplitude. (intensity of stimulation)

3. DECREASE INTENSITY

Press this button to decrease amplitude. (intensity of stimulation)

4. INCREASE FREQUENCY

Press this button to increase frequency.

5. DECREASE FREQUENCY

Press this button to decrease frequency.

6. PROGRAM

Programs. Select program from P1 to P6.

7. TIMER

Click once to select the next available timer value. i.e. continuous \rightarrow 15 min \rightarrow 30 min \rightarrow 45 min \rightarrow 60 min \rightarrow continuous. If program is locked, TIMER KEY can't work. Press & hold for 2 seconds to display USAGE TIMER DISPLAY stated.

8. 2/4 PAD, KEY LOCK

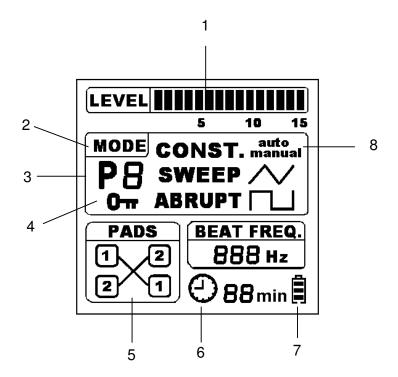
Click once to select for 2 or 4 pads.

Press & hold for 2 seconds to lock or unlock a program.

Click once to select for 2 or 4 pads.

Press & hold for 2 seconds to lock or unlock a program

3. LCD Display



1. LEVEL BAR

Indicates the intensity level, totally 15 levels.

2. MODE

Shows stimulation mode & type of current stimulation.

3. PROGRAM

Displays the current stimulation program, totally 6 programs.

4. LOCK

Displays when program is locked.

5. PAD TYPE

Indicates whether current output is for 2 or 4 pads.

6. TIMER

Shows remaining treatment time.

7. BATTERY LOW

Flashes when battery low.

8. FREQUENCY ADJUSTMENT

"Manual Icon" turns on when frequency can be adjusted.

"Auto Icon" turns on when frequency cannot be adjusted.

4. Operation

i) Attach the electrodes

Connect the electrode to the cable. Place the electrodes on your body. (See section 11)

Connect the cables(s) to the device.

ii) Turn on the device

Press ON/OFF KEY. LED displays when the device is on.

Always switch the device off before removing electrodes from the skin.

iii) Select a program

Use PROG KEY to choose a desirable program from Program 1 to Program 6.

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

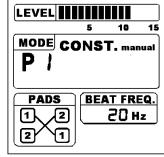
iv) Set your own program

-A practitioner can choose a desirable program, adjust a suitable beat frequency and treatment timer, pad time for his/her patients and then lock the program by following steps mentioned in point iii, and v to viii.

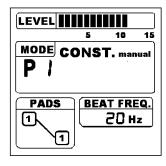
v) 2/4 Pads Mode Button

Press 2/4 KEY to choose either 2-Pads or 4-pads treatment mode. When 2/4 Pads mode is changed, the output intensity resets to zero.

In 4-PADS TREATMENT MODE, 2 sinusoidal outputs with different frequencies will be delivered to Channel 1 and 2 respectively. Channel 1 delivers a fixed 4kHz sine wave while Channel 2 delivers a sine wave with frequency ranges between 4002Hz and 4160Hz.



In 2-PADS TREATMENT MODE, 2 sine waves will be superimposed inside the device to form a new amplitude-modulated waveform. The resulting output is simultaneously delivered to Channel 1 and 2.



vi) Adjust the Intensity

You can adjust a desired intensity by pressing the LEVEL + or LEVEL - accordingly.

vii) Adjust the Beat Frequency

You can also change a frequency by pressing the FREQ. + and FREQ. - when the LCD displays the word "Manual".

The output beat frequency ranges between 2Hz and 160Hz.

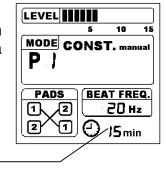
viii) Lock and Unlock your own program

To lock a program, firstly please adjust the "Level" Bar to zero, then press & hold 2/4 KEY for 2 seconds. Whenever you turn on the device again, the program will come up.

To unlock the program, take the same step. i.e. To press the <u>LEVEL - </u> till to zero, then press & hold <u>2/4 KEY</u> for 2 seconds.

ix) Treatment Timer

Press <u>Timer KEY</u> to select your desired treatment period ranging from 15, 30, 45 and 60 minutes. If no timer is set, the device will provide a continuous output, and no "CLOCK" symbol will be displayed.



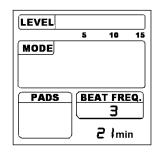
Treatment Timer

Once you fix a treatment timer, the timer starts its calculation only if the output level (Level Bar) is non-zero. When the treatment timer is operated, the output intensity will no longer affect its operation. The treatment timer begins to count down from its preset value. You can notice the timer value from the LCD at every minute interval. When the preset treatment period is elapsed, the device switches off its output.

x) Usage Timer

Once you start the stimulation with output (i.e. non-zero Level Bar), the User Timer automatically and accumulatively counts your total usage up to 999 hours 59 minutes. The User Timer resets to zero when this limit is reached.

To view the Usage Timer, set LEVEL - to zero, then press & hold the TIMER KEY for 2 seconds.



The Usage Timer at the right LCD displays the total usage of 3 hour 21 minutes

To cancel the accumulated Usage Timer, press the TIMER KEY for another 2 seconds and it starts at zero again. After 2 second eclipsed, LCD will show back the ordinary contents.

5. Treatment Programs

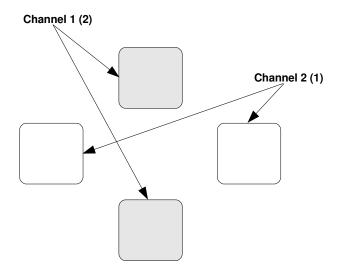
You can choose 6 different treatment programs.

When the treatment program changes, the output intensity and treatment time resets to zero, but changing the treatment program will not alter the choice of the 2-Pads or 4-Pads Treatment.

Program	Туре	I/F	Description	
		frequency adjustable		
1	Constant	Yes	2-160Hz Adjustable	
			2 to 20Hz adjustable in steps of 2 Hz. 20 to 80Hz adjustable in steps of 5Hz.	
			80 to 160Hz adjustable in steps of 10Hz.	
2	Sweep	No	The beat frequency sweeps from 2Hz – 10Hz in 6 seconds, and then back in 6 seconds, total cycle time is 12 seconds.	
3	Sweep	No	The beat frequency sweeps from 2 Hz to 100Hz in 10 seconds, and then back in 10 seconds, total cycle time is 20 seconds.	
4	Sweep	Yes	The beat frequency changes gradually from the set value to +200% of it in 6 seconds, and then back in 6 seconds, total cycle time is 12 seconds. The selectable beat frequency ranges between 5 ~ 80Hz with steps of 5Hz.	
5	Abrupt	Yes	The beat frequency changes abruptly between set value and +200% of it every 1 second. The total cycle repeats in 2 seconds. The selectable beat frequency ranges between 5-80Hz with steps of 5Hz.	
6	Abrupt	Yes	The beat frequency changes abruptly between set value and +200% of it every 6 seconds. The total cycle repeats in 12 seconds. The selectable frequency ranges between 5~80Hz with step of 5Hz.	

6. Placement of Electrodes

- The placement of the electrodes is very important to the success of the treatment, therefore please place electrodes according to the instructions of your treating physician.
- When operating in 4-Pads treatment mode, the electrodes should be placed on the body as described in the diagram below. The arrangement of these 4 electrodes will allow the intersection of the 2 sinusoidal outputs, which will result in the required beat frequency. In 2-Pads treatment mode, 2 separate pairs of electrodes can simultaneously treat two different body regions.



7. Battery replacement

- Slide out the battery holder located at the bottom of the device
- Take the used battery out of the holder and place a new battery
- Check the polarity (+ at the front side)
- Slide the battery holder back to the device
- Check the functions by pressing the keys

8. Maintenance

The life of pads depends on the frequency and time of usage as well as the skin types and storage conditions. You may use a wet cloth for the dried or dirty pads, but the pads with no adherence must be replaced.

The device requires no routine maintenance nor calibration. When needed, for occasional cleaning/disinfecting of the plastic covers, use alcohol wipes.

IMPORTANT. Only use the AC adaptor supplied together with the device. Use of other adaptors may compromise safety.

9. Warranty

Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized dealer or supplier or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.

10. Device failures

DO NOT repair damaged devices yourselves. In the event of a fault, please contact the dealer or supplier for assistance.

Address of Manufacturer

TensCare Ltd 9 Blenheim Road Epsom Surrey KT19 9BE UK www.tenscare.co.uk

11. Trouble shooting

Problem	Check point	Solution
No indication	/ Check the battery:	
No start	-Is battery dead?	-Replace with new battery.
	-Correct polarity?	-Put the battery properly.
Bad contact	ct Check the pads:	
indication	-Firmly placed?	-Press the pads to the skin.
	-Dried or dirty surface?	-Replace with new pads
	Check the snaps to pads:	
	-Firmly connected?	-Connect to the pads
	Check the skin: -Too dry?	
	100 dry .	-Moisturize the skin with a wet towel.
Skin irritation	Check the pads: -Firmly placed? -Dried or dirty?	-Press the pads to the skinReplace to new pads.
	Check the skin: -Scar, cut or damage?	-Avoid the damaged area.
	-Too dry?	-Moisturize the skin with a wet towel
	-Applied chemicals?	-Remove all chemicals or cosmetics from the
	-Applied chemicals:	skin.
	Allorgy:	-Stop using and consult a doctor.

12. Specification

Channel	Dual, isolated between channels
Mode	6 operation programs
Waveform	Symmetrical Balanced Sine Wave
Output Current	Adjustable, 0-33 mA across 500 Ohm load on each channel
Beat Frequency	2-160 Hz
Carrier Frequency	4000Hz (with ±1% tolerance) fixed on Channel 1
Modulating Frequency	4002 — 4160Hz (with ±1% tolerance) adjustable on Channel 2
Power Source	4 x 1.5V AA Size battery OR
	AC/DC adaptor(Input:100~240V AC; Output: 6V, 1A DC)
Low Battery Detection	$4.0V \pm 0.1V$
Treatment Timer	Continuous, 15, 30, 45 or 60 minutes
Usage Timer	Maximum 999 hours, 59 minutes
Automatic Power Off	If the output is continually remained at zero for 5 minutes, the device will then be automatically shut down.
Output Configuration	4-Pads Treatment Conventional Interferential Current Therapy (IFC) with Channel 1 delivers a fixed 4kHz sine wave, while output of Channel 2 can be varied between 4002Hz and 4160Hz. 2-Pads Treatment Pre-modulated Interferential Current Therapy (IFC) in which both Channel 1 and 2 will simultaneously deliver an amplitude-modulated output with beat frequency varies between 2 and 160Hz.
Environment For	Temperature 0-40°C
Storage & Use	Air humidity 30-75%
	Air pressure 700hPa-1060hPa
Expected Service Life	5 years

13. Important symbols



We confirm that the device complies with Directive 93/42/EEC



Attention! Read the manual before using the device.

Device with this symbol is an IEC/EN60601-1 type BF equipment. It provides a high degree of protection against electric shock.



Disposal of the appliance -WEEE

Legislation requires that all electrical and electronic equipment must be collected for reuse and recycling. Electrical and electronic equipment marked with the symbol indicating separate collection of such equipment must be returned to a municipal waste collection point at the end of its service lifetime.

The device is intended for continuous use with no degree of protection against water penetration.

Medical Devices Directive 93/42/EEC

Distributed by:

Manufactured by

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www.tenscare.co.uk



FOR USA MARKET

Caution: Federal Law restricts this device to sale or use by or on the order of a practitioner so licensed by the State.

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