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Made in India

INFREX PLUS/73/15.6.08

Combining the best clinical & portable therapy for chronic pain.

INFREX Plus

Mode

Instruction Manual

EDFAXX INC

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Precautionary Instructions

The precautionary instructions are found in this section and throughout this manual indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definition of these symbols are as follows;



Text with a "CAUTION" indicator will explain possible Safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.



Text with a "WARNING" indicator will explain possible Safety infractions that will potentially cause serious injury and equipment damage.

NOTE :- Throughout this manual "NOTE" may be found. These Notes are helpful aid in the particular area of function.

- Read, understand and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any electrical stimulation device. Observe the precautionary and operational decals placed on the unit.
- DO NOT operate the unit in an environment of short-wave diathermy use.
- DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel as damage may result.
- This unit should be operated, transported and stored in temperatures between 59°F and 104° (15° C and 40°C), with Relative Humidity ranging from 30%-60%.

A WARNING

- This device should be kept out of the reach of children.
- Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.

TERMINOLOGY

- IFT Interferential Current
- **TNS** Nerve Stimulation Current
- MIN Time in Minute
- W Pulse Width
- R Pulse Rate
- 2P 2 pole application in IFT
- 4P 4 pole application in IFT

Please read this instruction manual carefully before using INFREX plus because it is unsafe to start using the device before reading the whole manual. The instructions on the following pages will show you how to use and care for your INFREX plus in a general manner. You should be particularly familiar with the prescription information and precautions before proceedings.

CAUTION: Federal law restricts this device to sale by, or on the order of a physician, veterinarian, or any practitioner licensed by the law of the state in which he practices, to use or order the use of this device.

1.1 INDICATIONS FOR USE

INFREX plus provides desired stimulating current, which can be chosen by clinicians for the following treatment therapies:

□ Interferential & TENS (Transcutaneous electrical nerve stimulation) Current Stimulation is used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

1.2 CONTRAINDICATIONS

- □ Stimulation is contraindicated for patients using cardiac pacemakers. It shouldn't be used on patients with known myocardial arrhythmia without physician evaluation.
- Stimulation should not be applied transthoracically in any mode.
- Stimulation should not be applied transcerebrally.
- □ Stimulation should not be applied over the carotid sinus nerves, particularly on a patient with a known sensitivity to carotid sinus reflex.
- □ Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, varicose veins, thrombophlebitis etc.

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□ Stimulation should not be applied over or in proximity to, cancerous regions.

1.3 WARNINGS

- For external use only.
- □ Safety of stimulation during pregnancy or delivery has not been yet established.
- Do not stimulate the eye area.
- This therapy is ineffective for pain of central origin.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- □ Stimulation is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
- This device should be kept out of the reach of children.

1.4 PRECAUTIONS

- □ Caution should be used for patients with suspected or diagnosed heart problems and epilepsy.
- □ Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium.
- □ Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- □ This device should be used only with the leads and electrodes recommended for use by the manufacturer.

1.5 ADVERSE REACTIONS

□ Skin irritation and burns under the electrodes are possible adverse reactions.

2. INTRODUCTION

INFREX plus is a Microcomputer controlled digital two channel unit through four pads. It is designed to provide Interferential and Nerve Stimulation current waveforms to manage pains. The unit can be programmed to provide Interferential or Nerve Stimulation through both the channels. Depending upon the mentioned patient's indications, the unit INFREX plus delivers.

TENS & IFT Stimulation

The use of TENS & IFT Stimulation in acute and chronic pain conditions can relieve the pain symptoms. However, it is important to realize that only the pain symptoms are relieved and the underlying conditions are not affected or cured.

What is interferential?

INFREX plus generates medium frequency current of 4000Hz.

When two such currents of slight different frequencies (4001 & 4010Hz / 4080 & 4150Hz), cross over each other, a third frequency current (1-10 / 80-150), created in the deeper tissue known as True Interferential. Carrier frequency of 4000Hz penetrates deeper into the tissues.

2.1 CONDITIONS THAT AFFECT USE

The user needs electric outlet for charging the batteries. The batteries should be fully charged. The unit should not be used in wet environment. Electrodes should be firm contact with body.

3. DESCRIPTION

INFREX plus is a Microcomputer controlled portable electrical stimulator. It allows the treatment specifically tailored to the precise needs of the patient in the clinic and for subsequent treatment off site through one output four pads.

INFREX plus is a portable hand held two channel battery and AC Adaptor operated square wave interferential and TENS device. Unit can be used with AC Adaptor as well as with rechargeable batteries.

The unique feature of this unit is that it is supplied with rechargeable batteries and external charger. The user can charge the batteries using the supplied external charger. This unique system facilitates the user to have charged batteries always available and the treatment can be taken at any time.

The Membrane key panel operation and LCD protocols make the use and programming easy and simple. All the parameters remain in the system control, which can be set by the patient himself. The ergonomic design makes this unit very comfortable to wear and carry.

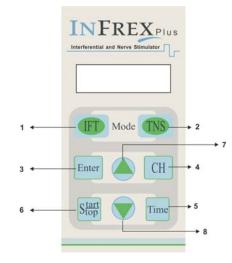
FEATURES: -

- a) INFREX plus uses AC Adaptor & Rechargeable battery operated system.
- b) Micro controller based design and digital display guide through the programming.
- c) It is ABS molded beautiful unit with user friendly Membrane key panel.

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4. CONTROLS & FUNCTIONS

(FRONT VIEW)



1. IFT (Interferential stimulation)

Key to select any of the IFT modes for interferential stimulation, With selectable 2 poles & 4 poles application.

A. IFT LOW- Preset sweep frequency of 1 to 10 bps (Beats per second)

B. IFT HIGH- Preset sweep frequency of 80 to 150 bps (Beats per second)

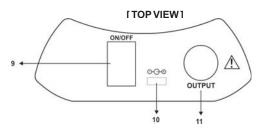
2. TNS (TENS Stimulation)

Key to select any of the TNS modes.

A. TENS Conventional- continuous output with selectable pulse width & pulse rate.

B. TENS Burst- Burst of 7 pulses, with selectable pulse width & pulse rate.

- 3. Enter- Key to select protocol selections & enter the selections.
- 4. CH-Key to select channel 1 or channel 2.
- 5. **Time-**Key to select treatment time during treatment only. Press Enter key to confirm (selectable 15, 30, 45 & continuous)
- 6. Start/Stop-Key to start & stop the power of outputs.
- 7. **INCREMENT**-Key to increase the values of pole, time, pulse width, pulse rate& intensity of output.
- 8. **DECREMENT** Key to decrease the values of pole, time, pulse width, pulse rate& intensity of output.



- 9. **ROCKER SWITCH** Turn the unit ON & OFF.
- **10. DC INPUT**-Insert Adaptor's pin into this socket to operate on Adaptor.
- 11. OUTPUT JACK- The unit is supplied with one 4 pole lead wire, which is inserted into this output socket.

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5. ACCESSORIES

INFREX plus comes complete with all the necessary components to perform Pain Relief. The list of the items included is given below:

1.	INFREX Plus	01
2.	Electrode Cables (4 pole)	01
3.	Self Adhesive Electrodes	04
4.	ACAdaptor	01
5.	Rechargeable batteries AA, Ni-Mh	04
6.	Instruction Manual (Including warranty card)	01
7.	Carry Bag	01
8	External Charger	01

6. TECHNICAL SPECIFICATION

No. of Channel Waveform	:	Dual, Isolated between channels Symmetrical Biphasic Square wave (TENS) & (IFT)
Output Voltage (IFT) Output Voltage (TENS) Modes	:	 40 Vpp@500ohm load 40 Vpp@500ohm load 40 Vpp@500ohm load 1.IFT (Selectable 4 Pole or 2 Pole) * Carrier Frequency: 4000Hz * Selectable Sweep frequency: * IF LOW -1 to 10 Hz * IF HIGH- 80 to 150 Hz 2. TENS (Selectable Conventional or Burst) * Pulse width: Selectable from 50 to 350µs in step of50 µs (Default 100 µs.) * Pulse Rate: Selectable from 1 to 150Hz in step of 1Hz (Default 100 Hz)
Treatment Time (Minutes) IFT & TENS	:	Selectable 15, 30, 45 & Continuous (Selectable During treatment only)
Power Source	:	1.2 Volts * 4Ni-Mh battery & AC Adaptor.

Note: All parameters have ±10% tolerance

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7. OPERATING INSTRUCTIONS

Avoid operating the INFREX plus adjacent to and simultaneously with operating short-wave devices, as it may be susceptible to interference originating from short-wave diathermy units.

Do not use sharp objects to operate the membrane key panel. If the tough outer layer of the membrane key panel is broken, moisture may leak into the switches resulting in switch failure.

7.1 PREPARING ELECTRODES

- □ Use only the leads and electrodes provided with the unit by manufacturer.
- We strongly encourage careful maintenance of the electrodes. This includes the lead wires as well as the pads. Worn cables and/or poor pads (or the wrong sized pads) can have a significant impact upon treatment results.
- □ Make sure that the entire surface of the electrode makes firm contact with the patient.
- Prepare skin prior to electrode application. Cleaning of skin shall eliminate any impairment to current conduction on the patient's skin such as an oily or dry surface, or excessive hair coverage. Shaving may be necessary depending upon the density of hair coverage. Failure to provide for maximum current conduction efficiency could result in skin irritation relating to increase in current density at electrode site.
- □ Reusable electrode should not be used longer than the time specified on the package. This could result in ineffective treatment or skin irritation.

7.2 ELECTRODES PLACEMENT

Electrodes should never be placed in such a manner as to produce current flow through the cardiac area.

The patient should be suitably positioned ensuring maximum

comfort and suitable exposure of the body part to be treated.

- □ The points where electrodes are to be placed should be marked.
- There are four pole electrode cable lead. Lead wire uses two pair of electrode. Place diagonally opposite to form 'X' type placement to cover the pain area while using IFT 4 POLE. For TENS & IFT 2 POLE the electrode pair should be placed in bipolar way.
- The patient should be explained about the subjective sensory motor feeling that he/she will experience. The patient should experience a sensation of deep, sufficiently strong but pleasant vibrations at rhythmical frequencies and a pleasant tingling sensation.
- Patient should describe to therapist or doctor, of any unpleasant sensation or any other discomfort immediately.
- Review precautions, contraindications and side effects or adverse reactions listed above.

7.3 CHECK BATTERY

If the battery is poor, the display will show

LOW BTRY

Indicating that battery is poor, Buzzer will beep every one minute once low battery is detected for 5 minute, after that unit goes into shutdown & low battery icon will glow, No output will be delivered from the unit.

7.4 PROGRAMMING/START TREATMENT

Important- REMOVE THE BATTERY BEFORE USING ADAPTOR.

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Switch ON the unit by using Rocker Switch.

LCD will display Med Faxx followed by Infrex

(A) IFT

Mode IFT LOW:-

Step 1-

Press IFT key. LCD will display IFTLOW

Step 2-

Press Enter key. LCD will display POLE 4 Select desired POLE 4 or POLE 2 by using ▲ or ▼ key.

Step 3-

Press Enter key. LCD will display TIME 30 Select desired treatment time by using ▲ or ▼ key (selectable 15, 30, 45 min. & C)

Step 4-

Press Start/Stop key. LCD will display CH ** (** Intensity)

Mode IFT HIGH:-In case of IFT HIGH follow the procedure given in IFT LOW.

IMPORTANT:-

In case of 2 pole selections in IFT & selections of TENS, by pressing Start/Stop Key. LCD will display $CH1^{**}$ (** Intensity in CH. 1) Increase the intensity in Ch 1 by pressing \blacktriangle key. Now press CH key, LCD will display $CH 2^{**}$ (** Intensity in CH. 2) Increase the intensity in Ch 2 by pressing \blacktriangle key.

(B) TNS

Mode TENS Conventional:-

Step 1-

Press TNS key. LCD will display TN CONVL

Step 2-

Press Enter key. LCD will display TNW 100 Indicating pulse width preset at 100 μ S. Use \blacktriangle or \triangledown key to select desired pulse width (selectable from 50 μ S to 350 μ S in step of 50 μ S)

Step 3-

Press Enter key. LCD will display TN R 100 Indicating pulse rate preset at 100 Hz. Use \blacktriangle or \blacktriangledown key to select desired pulse rate (selectable from 001 Hz to 150 Hz in step of 01Hz)

Step 4-

Press Enter key. LCD will display <u>TIME 30</u> Select desired treatment time by using ▲ or ▼ key (selectable 15, 30, 45 min. & C)

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Step 5-

Press Start/Stop key. LCD will display $\overline{CH1}^{**}$ (** Intensity in CH. 1) Increase the intensity in Ch 1 by pressing \blacktriangle key. Now press CH key. LCD will display $\overline{CH2}^{**}$ (** Intensity in CH. 2) Increase the intensity in Ch 2 by pressing \bigstar key.

Mode TENS Burst:-

In case of TENS Burst follow the procedure given in TENS Conventional.

NOTE:-

Time key will work during treatment only. Press Time key, display will show selected treatment time. Use ▲ or ▼ key to change treatment time. Then press Enter key for confirm.

After the selections is made-

- Insert the electrode cable into output socket.
- Gradually increase intensity by using ▲ key up to the desired strength which your health professional has suggested to you.
- During the treatment display will always indicate selected mode & remaining treatment time.
- When the treatment time is over, the unit will turn off with beep sound and TIME OFF will be displayed on LCD.
- When your prescribed treatment is over. Turn the rocker switch to OFF.
- Then disconnect the lead wires from the unit & remove the electrodes from skin.

8. MAINTENANCE

8.1 CLEANING

- □ The soiled unit should be cleaned with a damp cloth. Follow the care of electrodes as indicated on the package.
- □ For routine cleaning of the electrode cables use soap and water. Thoroughly dry after cleaning.

8.2 WARNING

- Do not pull out electrode cables.
- Electrode wires should be kept loosely winded otherwise breakage may occur.

8.3 STORAGE

- □ Keep the unit properly covered, when not in use. This will help to keep out of dust.
- □ Make special space to keep the unit, after the treatment is over.

8.4 ELECTRODES CARE

There are many kinds of electrodes. Use this device only with the electrodes and accessories that have been included. Don't use any accessories except those recommended by the manufacturer and identified in this manual. The Electrodes are self adhesive and disposable.

These can be reordered from.

MedFaxx, Inc.

P. O. Box 1289

Wake Forest, N. C. 27588 Tel.: 800-937-3993, 919-570-0350 Fax: 919-570-0354 www.medfaxxinc.com

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8.5 SKIN CARE

- Apply electrodes on clean, dry and unbroken skin only.
- Before applying electrodes and after removing -always wash the site with mild soap and water. Then rinse and dry thoroughly.
- Excess body hair in the electrode placement site should be clipped and not shaved.
- □ If clinician recommends skin prep usage-follow instruction as directed.
- U When applying electrodes, do not stretch skin or electrodes.
- □ When removing electrodes always peel back in direction of hair growth, or moisten edges or underside of electrode.
- Applying unflavored Milk of Magnesia over electrode placement sites after removing electrode helps maintain the natural pH of the skin and reduces irritation problems.
- □ If perspiration occurs in the area of the electrodes causing the electrodes to slide out of position, wipe area with unscented antiperspiration pads and allow drying before reapplying electrodes.
- □ If skin irritation arises and persists from the use of this device, discontinue usage immediately and consult your clinician.

9. TROUBLE SHOOTING

Observation	Possible Causes	Remedy
Weak stimulation or No Stimulation even at max.	Poor electrode contact.	Check the electrodes contact
Amplitude setting.	Electrode conduction is	Change electrodes.
	low.	Change electrode
	Lead wire is worn out	wires.
Strong Stimulation	Improper electrode	Check electrode
	placement	Placement
Uncomfortable	Amplitude too high	Reduce
Stimulation or too		
Strong Stimulation		
Skin irritation at	Improper contact	Wet or change the
electrode Placement site		electrode
Sudden high intensity	Increasing amplitude	Increase amplitude
While increasing	too fast	slowly giving time to
Amplitude		patient to his comfort.
Unit doesn't switch	Battery deeply	Charge Battery
ON	discharged	

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If the device still not works Call or Inform MedFaxx, Inc. P. O. Box 1289 Wake Forest, N. C. 27588 Tel.: 800-937-3993, 919-570-0350

10. WARRANTY

Product's warranty extends to the original consumer / purchaser of the product.

WARRANTY DURATION

The product is warranted to the original consumer for a period of one (1) year from the original purchase date.

WARRANTY COVERAGE

The Product is warranted against defective materials or workmanship. This warranty ceases if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, commercial use, and repair by unauthorized personnel or cause not arising out of defect in materials or workmanship. This warranty does not extend to any units which are used in violation furnished by manufacturer, or to units which have been altered or modified, or to damage to products or parts there of which have had the serial number removed, altered or defaced or rendered illegible. The warranty doesn't cover normal wear & tear or replacement of battery, electrode cables, electrodes & other accessories.

WARRANTY DISCLAIMERS

This warranty is in lieu of all warranties expressed or implied and no representative or person is authorized to assume for manufacturer/ any other liable in connection with the sale of our products. There shall be no claims for defects or failure of performance or product failure/ any theory of tort, contract or commercial law including, but not limited in negligence, gross negligence, and strict liability, breach of warranty and breach of contract. Some states do not allow the exclusion or limitation of implied warranties or consequential damages, so the above limitations may not apply to you.

Manufacturer is not responsible or liable for indirect special or consequential damages arising out of or in connection with the use performance of the product or other damage with respect to loss of property or loss of revenues or profit.

LEGAL REMEDIES

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

WARRANTY PERFORMANCE

During the above one-year warranty period, a product with a defect will be repaired or replaced with a reconditioned comparable unit at distributor's option when the product is returned to the distributor. The repaired or replacement product will be in warranty for the balance of the one-year warranty period and an additional one-month period. No charge will be made for such repair or replacement.

CONSUMER SERVICE

For in warranty service for a product covered under the warranty period, no charge is made for service and return postage. Please return the product insured, packed with sufficient protection, postage insurance, prepaid to the address. Customer's duty/brokerage fee, if any, must be paid by the consumer.

OUT OF WARRANTY SERVICE

There will be charges rendered for repairs made to the product after the expiration of the aforesaid one (1) year warranty period, after purchaser is advised appropriately.

The distributor cannot assume responsibility for loss or damage during shipment. For your protection, carefully pack the product for shipment and insure it with the carrier. Ensure that you return the unit and accessories related to your problem and also that your full return address. Also send a copy of sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.

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Please send above warranty information to following address.

MedFaxx, Inc. P. O. Box 1289 Wake Forest, N. C. 27588

Manufacture By Johari Digital Healthcare Limited 582/583 EPIP Boranada, Jodhpur (INDIA)

Model	S. No	Date
Dealer's Name		
Address		
Consumer's Name		
Address		
Dealer's Signature)	Customer's Signature