INSTRUCTION MANUAL

INTERFERENTIAL DEVICE

CARE IFC™ Sport

CARE REHAB®
And Orthopaedic Products, Inc.

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Contents

Letter to the Patient

Your physician or therapist has prescribed the CARE IFC SPORT™ System to help control your pain. Please read this operations manual carefully before using your CARE IFC SPORT™. The instructions on the following pages will show you how to use and care for your CARE IFC SPORT™ in a general manner.

IMPORTANT NOTE: Please read the prescription information and precautions in this manual before using the CARE IFC SPORT™.

You should always consult your physician or therapist if you have specific questions or problems regarding the use of your stimulator.

Your physician or therapist possesses technical knowledge about the CARE IFC SPORT™ and is familiar with your specific condition and requirements. In addition, always follow the instructions of your physician or therapist to gain the most benefit from your CARE IFC SPORT™.

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a licensed physician. This device should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

How the CARE IFC SPORT™ Works

Your CARE IFC SPORT™ is a battery-powered device that generates small pulses of electrical current. These small pulses of electrical current are delivered through lead wires to electrodes placed on your skin. These electrical pulses pass through your skin, and activate underlying nerves. The relief from chronic and/or acute pain that the CARE IFC SPORT™ can provide, results from this electrical stimulation.

At lower levels of stimulation, the CARE IFC SPORT™ stimulates sensory nerves, producing a tingling sensation. Higher levels of stimulation activate motor nerves, resulting in muscle contractions. Your practitioner or therapist will instruct you on the correct amount of stimulation for your particular condition.

The CARE IFC SPORT™ has two channels, allowing it to operate two pairs of electrodes. And can also deliver four different stimulation patterns.

Your practitioner or therapist will provide you with directions on the proper mode of operation for your condition. Interferential stimulation differs from conventional neuromuscular stimulation (NMS) and transcutaneous electrical nerve stimulation (TENS), which deliver most stimulation to the surface of the skin directly under the electrode. Interfential stimulation, on the other hand, concentrates the stimulation deep in the affected tissue.

It is important to realize that pain is a symptom of an underlying condition, and the CARE IFC SPORT™ has no curative effect on the cause of your pain. Therefore, Interferential Stimulation is not a substitute for proper medical evaluation and treatment.

In relieving chronic and acute pain, Interferential Stimulation can often be used in place of surgical procedures or drug therapy. It poses none of the risks of addiction or side effects associated with narcotic pain-killing drugs.

The CARE IFC™ SPORT System Components

The CARE IFC SPORT™ System is provided with:

1 CARE IFC SPORT™ Stimulator
1 Package of Electrodes (non-sterile, 1.8" X 1.8")
2 Lead Wires (1 red, 1 black)
1 Package of 4 AA Alkaline Batteries
1 Carrying Case
1 Operations Manual
1 Optional AC Adapter, Output: 6.0 V D.C. 1.2A

USE ONLY CARE IFC SPORT™ MANUFACTURED REPLACEMENT PARTS. ORDER FROM CARE REHAB, INC.

The CARE IFC SPORT™ Operations Controls / Features

1. **Amplitude Control:** This control adjusts the strength of the electrical stimulation delivered through both channels. The "OFF" position indicates that power to the device is turned off. No stimulation is delivered at the "OFF" setting. Always set the amplitude control dial to the "OFF" position before conducting a treatment, and/or inserting the lead wires and removing or replacing batteries. The numeric values on the control dial correspond to output stimulation in milliamps. Slowly turn the amplitude control dial clockwise until you achieve the amount of stimulation recommended by your practitioner or therapist.

2. **Frequency Control:** Adjust the switch to select the frequency directed by your practitioner or therapist.

3. **Lead Wire Sockets (Out 1 and Out 2):** The lead wires with electrodes should be plugged into these sockets. When using CARE IFC SPORT use both sets of lead wires, and both sockets.

4. **Mode Shifting Switch:** This switch automatically adjusts your device to various patterns of frequency, shifting in a rhythmic manner. Your practitioner or therapist will instruct you on where to set this switch.

6. **In Use Light:** This light will glow when the CARE IFC SPORT™ is operational and will pulsate according to the selected frequency. Above a frequency setting of 50, this light will appear to glow constantly, due to the higher frequency.

7. **Low Battery Light (LOW BATT):** This indicator light remains off when the CARE IFC SPORT™ is operational and the batteries are sufficient to run the device for normal operations. The light will glow when the batteries need replacement. When the CARE IFC SPORT™ is turned on or off, this indicator light will flash, which will indicate normal operation of this light.

8. **Battery Compartment:** This device requires 4 AA alkaline batteries to operate. Please insert the batteries according to the instructions within the device, and replace the cover to fit tightly. This device will not operate properly with rechargeable (nickel-cadmium) batteries (see illustration on page 10).

9. **AC Adaptor Outlet:** As an alternative power source to batteries, use the UL listed AC adaptor with an output of 6.0V DC 1.2A provided (optional). See page 13 for more information.

Electrodes

Reusable / Self-adhering electrodes: To use your electrodes, first attach them to your lead wire. (Note that the "pin" on the electrode wire is protected by a plastic sheath.) Then, grasp the electrode by the corner, and gently peel away the electrode from the plastic sheet it is provided with. Finally, apply the electrodes to the skin area (your physician or therapist will show you the approximate area for treatment) by firmly pressing the electrode against the skin.

When your therapy session is completed, grasp the corner of the electrode **(NEVER REMOVE THE ELECTRODE BY PULLING ON THE LEAD WIRE, AS THIS MAY DAMAGE YOUR ELECTRODES)** and gently remove it from your skin, and place it on the plastic sheet it originally was adhered to. Another important note in the care of your electrodes is to replace the electrodes in the resealable pouch provided with your electrodes.
If your electrodes dry out, you can place a few drops of water on them to re-moisten them for continued use.

After repeated usage, reusable electrodes begin to lose their adhesion, deliver less stimulation and shorten battery life. **Replace reusable electrodes as needed.**

We recommend using 1.8" x 1.8" electrodes from Care Rehab.

Proper Skin Care

By properly caring for skin covered by electrodes, you will:

- Allow more stimulation to reach the targeted nerves.
- Prolong the life of your electrodes.
- Reduce the chance that any skin irritation will develop.

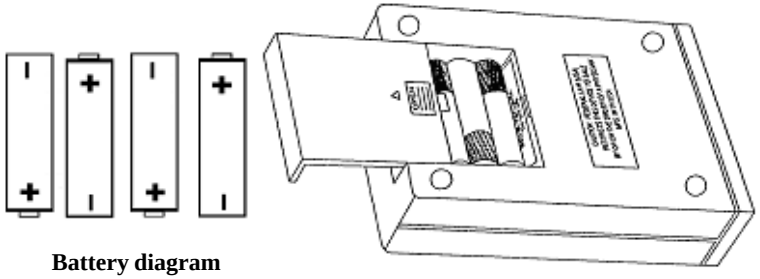
The following directions for proper skin care will reduce the risk of skin irritation. However, if skin irritation develops, remove the electrodes, discontinue using your CARE TENS™, and consult your physician or therapist.

1. Wash all electrode sites with mild soap and water before applying the electrodes.
2. Dry your skin thoroughly before electrode application.
3. Trim excess body hair from electrode sites with scissors.
4. Do not place electrodes on cut, broken or irritated skin
5. Change electrode sites whenever possible, but first consult with your physician or therapist about doing this.

Using the CARE IFC SPORT™

TO BEGIN - Set the "AMPLITUDE" dial to the "OFF" position

1. Inspect device, lead wires, electrodes and batteries, (or AC adaptor if applicable) for damage before using.



Battery diagram

2. Insert 4 AA alkaline batteries into the battery compartment as shown on the diagram in the compartment. Then replace the battery cover.

3. Wash the electrode application sites with mild soap and water and dry your skin thoroughly. Also remove any excess body hair with a pair of scissors, being careful not to cut your skin.

4. Connect the lead wires to the electrodes. Do not use unnecessary force in connecting the electrodes to the lead wires. If they do not fit, use a different set of electrodes, and return the unusable electrodes to your practitioner or therapist.

5. Place the electrodes on the sites prescribed by your practitioner or therapist, and press them firmly onto the skin.

6. Insert the plugs at the end of the lead wires into the CARE IFC SPORT™ Output sockets, checking to see that the plug is fully inserted. When applying only one pair of electrodes, use the Output socket market "OUT2". With the amplitude set in the "OFF" position, set the "ELECTRODES" switch in the "2" position. When applying two pairs of electrodes, use both sockets and lead wires. With the amplitude off, set the "ELECTRODES" switch in the "4" position.

DO NOT CHANGE THE "ELECTRODES" SWITCH DURING A TREATMENT, UNLESS THE AMPLITUDE CONTROL IS TURNED OFF.

7. Now set the “FREQUENCY” control dial. Turn the dial to the frequency prescribed by your clinician.

8. Next, set the “MODE” Shifting switch to the position prescribed by your practitioner.

9. Then, slowly turn the “AMPLITUDE” control dial clockwise until you achieve the amount of stimulation prescribed by your clinician. Low amplitude settings will cause a mild tingling sensation; high amplitude settings will cause strong muscle contractions.

10. Always operate the CARE IFC SPORT™ at the prescribed settings for the amount of time directed by your practitioner or therapist. The CARE IFC SPORT™ has a timer mechanism that will automatically end your treatment after 20 minutes.

IF STIMULATOR IS ACCIDENTALLY DISCONNECTED DURING TREATMENT, SET THE AMPLITUDE CONTROL TO “OFF” AND WAIT 5 SECONDS BEFORE RESETTING AMPLITUDE.

When your treatment session is completed, remember to do the following:

1. Turn the Amplitude control dial to the “OFF” setting.

2. Unplug the lead wires by the plug ends, not the cord from the CARE IFC SPORT™ .

3. Disconnect the lead wires from the electrodes, and properly store your electrodes for your next treatment session, as prescribed by your practitioner or therapist.

4. Unplug the AC adaptor (if using) from the wall outlet and the device.

DO NOT LEAVE BATTERIES IN DEVICE FOR LONG PERIODS OF TIME, THE BATTERIES CAN DEGRADE AND LEAK INTO THE COMPARTMENT DAMAGING THE DEVICE.

Care of your CARE IFC SPORT™

NEVER IMMERSE YOUR STIMULATOR OR BATTERIES IN WATER, ALCOHOL OR OTHER FLUIDS, SINCE THIS COULD SERIOUSLY DAMAGE THE INTERNAL ELECTRONICS.

Maintenance, care and cleaning of your CARE IFC SPORT™ are quick and easy procedures when these instructions are followed. When it is not in use, store your CARE IFC SPORT™ in its carry case to prevent inadvertent damage.

Cleaning: Clean the outside of the CARE IFC SPORT™ case as needed with a damp cloth and mild soap. Avoid using cleaning fluids or solvents to remove stains or dirt, because such liquids may damage the case. Lead wires need to be cleaned only if they become dirty. They should never be immersed in water or other fluids.

Battery Care: Remove all batteries during storage to prevent damage caused by battery leakage or corrosion.

CARE IFC SPORTS™ Battery Information

Since the CARE IFC SPORT™ requires extensive battery power, normal usage will require new AA batteries every 4 to 6 treatments. Replace the AA batteries when the low battery light is on.

CONTINUED USE OF THE CARE IFC SPORT™ WITH THE LOW BATTERY LIGHT ON, WILL CAUSE THE BATTERIES TO BECOME HOT AND POSSIBLY BURST, DAMAGING THE DEVICE.

DO NOT USE RECHARGEABLE BATTERIES WITH THIS DEVICE, AS IT WILL NOT OPERATE TO ITS MAXIMUM POTENTIAL.

WHENEVER REMOVING OR REPLACING BATTERIES FROM YOUR CARE IFC SPORT , ALWAYS REMEMBER TO TURN THE AMPLITUDE CONTROL DIAL TO THE "OFF" POSITION.

NEVER ATTEMPT TO RECHARGE AN ALKALINE BATTERY, AS THIS MAY RESULT IN AN EXPLOSION.

NEVER MIX ALKALINE WITH NICKEL-CADMIUM BATTERIES. ALWAYS USE FOUR ALKALINE BATTERIES WHEN OPERATING YOUR CARE IFC SPORT .

CARE IFC SPORT™
AC Adaptor Information

An alternative source of power for the CARE IFC SPORT™ , is a UL listed AC Adaptor with an output of 6.0 volts DC, 1.2 A. Other types of adaptors may have different specifications. Use of an adaptor other than the one supplied may cause malfunction, electrical shock or fire. Any damage to the CARE IFC SPORT™ due to the use of the incorrect AC adaptor will null and void any warranties.

SAFETY PRECAUTIONS FOR AC ADAPTOR

NEVER USE ANY AC ADAPTOR OTHER THAN THE ONE SUPPLIED.

DISCONNECT THE AC ADAPTOR WHEN NOT IN USE, FAILURE TO DO SO MAY RESULT IN FIRE.

NEVER REMOVE CONNECTIONS BY PULLING ON CORD. WHEN DISCONNECTING AC ADAPTOR, HOLD THE PLUG PART NOT THE CORD. NEVER PLACE HEAVY ITEMS ON THE CORD.

NEVER BREAK OR PINCH CORD. NEVER ALTER AC ADAPTOR CORD OR PLUG. NEVER USE AN EXTENSION CORD. FAILURE TO ADHERE TO THESE WARNINGS CAN RESULT IN MALFUNCTION, ELECTRICAL SHOCK OR FIRE.

DISCONNECT THE AC ADAPTOR IN THE EVENT OF DROPPING AND/OR DAMAGING DEVICE. IF DEVICE EXHIBITS ANY ABNORMAL OR MARKED CHANGE IN PERFORMANCE, PULL OUT THE AC ADAPTOR FROM THE AC OUTLET, AND CONSULT CARE IFC SPORT SERVICE AGENTS. IF USED IN THIS CONDITION, IT MAY RESULT IN FIRE OR ELECTRICAL SHOCK.

NEVER USE THE CARE IFC SPORT™ IN OR AROUND WATER/LIQUID, ESPECIALLY WITH THE AC ADAPTOR. IF NOT, INJURY, ELECTRICAL SHOCK OR FIRE CAN OCCUR.

CARE IFC SPORT™ Lead Wires

Use only the set of lead wires provided with the CARE IFC SPORT™ . When connecting and disconnecting the lead wires, do so by using the plugs, not the cords .**DO NOT USE LEAD WIRES THAT ARE DAMAGED AND/OR BARE WIRE IS EXPOSED.**

DO NOT PLUG THE METAL ENDS OF THE LEAD WIRES INTO ANYTHING OTHER THAN ELECTRODES; IT MAY RESULT IN DAMAGE TO THE DEVICE.

Important Prescription Information

Please read the following prescription information carefully before using your CARE IFC SPORT™ . If you have any questions on this information, consult with your practitioner or therapist before proceeding.

WHEN USED FOR PAIN CONTROL

Indications:
Interferential stimulation is used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment in the management of post surgical and posttraumatic acute pain. The CARE IFC SPORT™ provides symptomatic pain relief only and has no curative value. The CARE IFC SPORT™ is not effective in treating pain of central origin and should be used only in conjunction with continued medical supervision. The effectiveness of interferential stimulation depends directly upon each patient carefully following procedures and schedule set up by their practitioner or therapist.

Contraindications:
Do not use your CARE IFC SPORT™ with demand type cardiac pacemaker, over the carotid sinus, transcerebrally, over the eyes, neck or mouth, on patients diagnosed with cancer, or in undiagnosised pain syndromes until etiology has been established.

Warnings:
Consult your practitioner or therapist if you have any questions in regard to any of the statements listed below, prior to the use of your CARE IFC SPORT™ .

* The long term effects of chronic electrical stimulation are unknown.

* Adequate precautions should be taken in the case of a person with suspected heart problems.

* Adequate precautions should be taken in the case of a person with suspected or diagnosed epilepsy.

* The CARE IFC SPORT™ can mask pain and impair detection and/or diagnosis of disease. The CARE IFC SPORT™ is not a substitute for proper medical evaluation and treatment. Careful evaluation by a practitioner should precede the use of interferential stimulation in patients with myocardial disease, including arrhythmias.

* Interferential stimulation may interfere with electrocardiographic (ECG) monitoring and alarm system.

* Do not use the CARE IFC SPORT™ to stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex.

* Severe spasm of the laryngeal and pharyngeal muscles may occur when electrodes are positioned over the neck or mouth. The contradictions may be strong enough to close the airway or cause difficulty in breathing.

* Keep the CARE IFC SPORT™ away from children.

* Safety during pregnancy, labor, and delivery has not been established for either mothers or fetus.

Observe precautions in the presence of the following:

* Following recent surgical procedures when muscle contraction may disrupt the healing process.

* When there is a tendency to hemorrhage following acute trauma or fracture.

* Over the menstruating uterus.

* When sensory nerve damage is present by a loss of normal skin sensation.

* When skin irritation develops. Skin irritation may occur under electrodes in isolated cases following long-term application. Consult your practitioner or therapist if skin irritation develops.

Adverse Reactions:

* Persistent use of interferential stimulation in the presence of skin irritation may result in electrode burns.

* Operating the CARE IFC SPORT™ at other than the prescribed settings or for longer than the amount of time directed by your practitioner or therapist may cause injury.

Instructions for your Physician or Therapist

Interferential stimulation differs from conventional neuromuscular stimulation (NMS) and transcutaneous electrical nerve stimulation (TENS). Both NMS and TENS use discrete electrical impulses delivered at low frequencies of 2-120 pulses per second.

Interferential stimulation depends upon the interaction or interference of two medium-frequency electrical outputs that differ slightly in frequency.

The CARE IFC SPORT uses a fixed carrier frequency of 4000Hz and an adjustable frequency of 4001-4150Hz (nominal values). When the two frequencies mix inside tissue, they "interfere", producing an "interference frequency" equal to the difference between them.

The frequency switch controls the adjustable frequency and is labeled 1-150 to indicate the interference frequency produced when changing the adjustable frequency. For example, when set at "20" the adjustable output delivers 40 20Hz, and the patient will feel a low frequency tingling of 120beats per second on the skin.

Four-Electrode Operation

True interferential stimulation requires the use of four electrodes, with the "ELECTRODES" switch in the "4" position (four-electrode). Each pair of electrodes creates a current flow between them. When two pairs of electrodes are used, the current flows intersect within the tissue. By making the frequencies for the two channels of stimulation slightly different, an interference or "beat" frequency is established at the point of intersection. This "quadrapolar" interferential effect provides a greater amount of stimulation deeper within the tissue than non-interferential modes of electrotherapy.

Technical Specifications

Carrier Frequency**:**

- 4000Hz nominal, fixed

Adjustable Frequency:

- Continuous Mode 4001-4150Hz nominal, adjustable
- Frequency Shift Mode 4001-4240Hz nominal, adjustable

Interference Frequency:

- Continuous Mode: 1-150Hz, equal to difference frequency between Carrier an adjustable frequency. Determined by Frequency dial, which controls Adjustable Frequency.

Output Configurations:

- Quadra polar (4-electrodes).

Quadra polar:

- Output channel #1 delivers Carrier frequency.
- Output channel #2 delivers Adjustable frequency.
- Interference occurs within tissue, maximal at point of intersection among four electrodes.

Waveform:

- Symmetric Biphasic Square with zero net DC.

Duty Cycle:

- Interferential stimulation has a 100 % duty cycle, since stimulation is always being delivered.

Channel Isolation:

- Channel isolation depends upon the use of two independent transformers.

Electrode Size:

- Maximum electrical densities were determined using 1976 sq. mm. (1.75" x 1.75") electrodes.

Electrical Current as a Function of Amplitude Dial Setting:

- 500-ohm load was used.

AMPLITUDE Dial Setting	**OUTPUT** (Milliamps)*
0	0
10	10
20	20
30	30
40	40
50	50

Pulse Width:

* 125 microseconds for each phase

Output Current:

* 0-50 milliamps, adjustable

Output Voltage:

* 0-25 volts (50 volts peak-to-peak), adjustable

Maximum Charge per Cycle:

* 12.5 microculombs (one biphasic pulse)

Maximum Current Density at Electrodes:

* 25 micro amps per square millimeter

Maximum Power Density at Electrodes:

* 630 microwatts per square millimeter

Output Regulation:

* Voltage is invariable from 500 to 1500 ohms (±10%).
* Voltage output does not change as a function of battery voltage until the low battery light comes on. At this point, voltage follows battery voltage.
* Constant voltage is not a feature regulated by feedback circuitry, but depends upon the use of a low impedance transformer.

In Use Light:
* Shows unit is operating. Blinks at Interference frequency

Low Battery:
* Indicates when batteries become discharged

Power Source:
* Four (4) alkaline AA batteries (1.5v)
* AC Adaptor, 6.0V DC, 1.2A

Size:
* 3.7" X 6.2" X 1.25"

Weight:
* 16oz (including batteries)

Tolerances:
* All electrical specifications are ± 10% into 500 ohm resistive load.

Warranty
This unit has a one year limited warranty from the date of purchase.

Waveforms

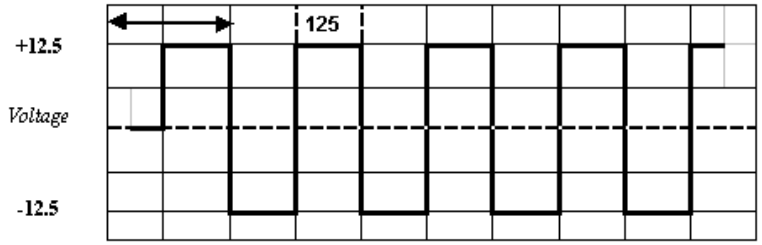


Figure 1: Electrical output of carrier frequency on 500-ohm resistive load with amplitude set at 50% maximum.

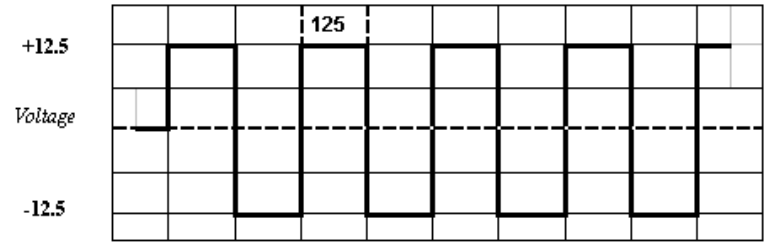


Figure 2: Electrical output of carrier frequency on 500-ohm resistive load with amplitude set at 50% maximum. Note consistency of voltage relative to Figure 1.

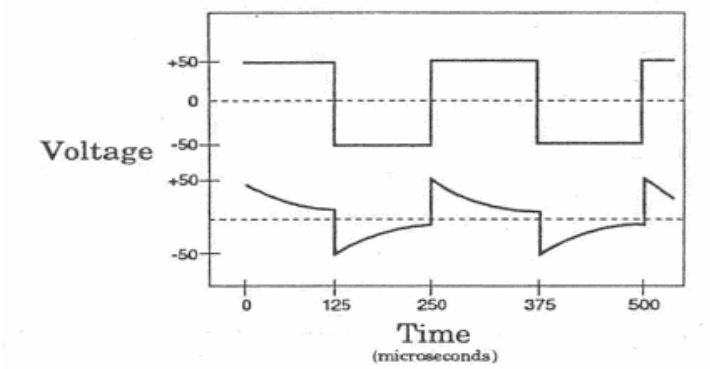


Figure 3: Voltage (top) and current (bottom) outputs of carrier frequency AAMI load (mimicking skin impedance.)

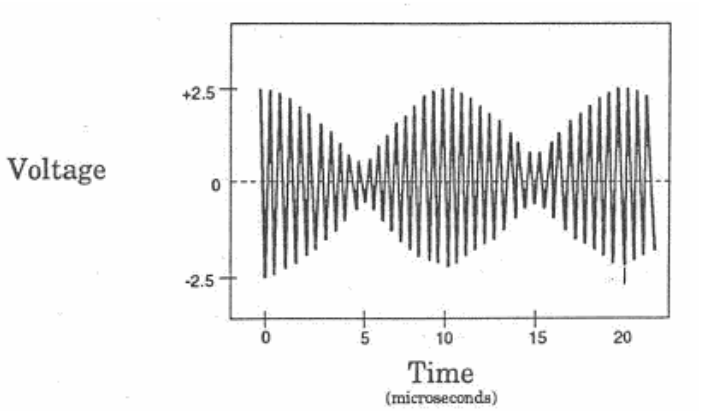


Figure 4: Electrical output during bipolar (2-electrode) stimulation across the capacitive element of the AAMI load. This shows the interaction of the carrier frequency and adjustable frequency which takes place internal to the device. The interferential frequency is evident as an "envelope" of stimulation occurring at Hz. This figure is provided to illustrate interferential stimulation, but does not correspond exactly to the output which an oscilloscope would record with a skin load.

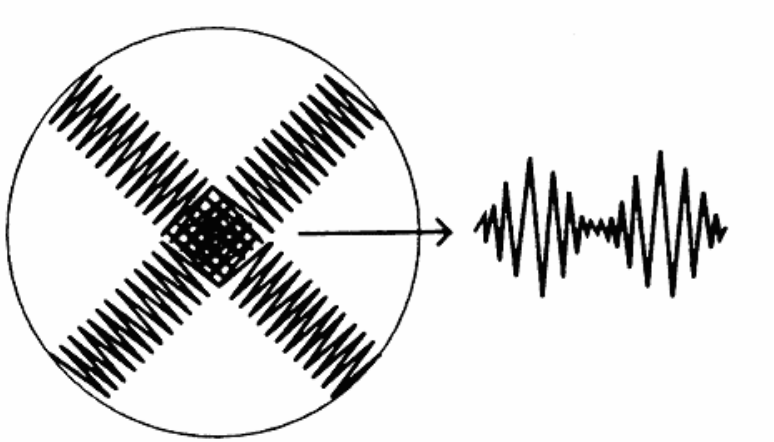


Figure 5: A conceptual diagram of quadrapolar (4-electrode) stimulation with interference taking place within tissue.

Warranty Information

Care Rehab warrants your CARE IFC SPORT™ to be free from electrical circuit defects in workmanship and materials for a period of three (3) years from the date of shipment from the factory. Care Rehab will repair or replace, at its factory, any stimulators found to have become defective within the warranty period.

This warranty does not apply to accessories, specifically lead wires, electrodes, batteries, tapes, gel, carry case, AC adaptor, nor does it apply to stimulators which have been damaged due to misuse, or repaired or altered other than by Care Rehab at its factory.

This warranty is in lieu of any other warranties expressed or implied. No person or entity is authorized to bind Care Rehab to any representation of warranty other than those specifically set forth herein.

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