HF54 Plus • Instructions for Use

Including Instructions for Use for Horizon (HF023) IR Light Probe

Rx ONLY

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PRESCRIPTION USE STATEMENT

Caution: **Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.**

LIMITED WARRANTY

The HF54 is warranted to be free from defects in material and workmanship. A 1 year limited warranty goes into effect from the date of invoice. The warranty covers the generator and applicator(s). All accessory parts have a 90-day warranty.

Hill Laboratories agree to repair, at the point of manufacture, without charge, all parts showing such defects, provided the generator is delivered to us, intact for our examination, with all transportation charges prepaid, and provided such examination discloses in our final judgment that the generator is defective.

The warranty will only be honored if the registration form below is filled out and returned to us within 30 days of purchase by FAX or mail. The FAX number to use is (610) 647-6297.

The warranty is void if the equipment has been subject to misuse, neglect, accident, incorrect wiring (not our own), improper installation, or put to use in violation of instructions furnished by us; has been damaged by excess voltage; has been repaired or altered outside our factory, other than a authorized-factory representative, or has had a serial number altered or removed.

This warranty supersedes all other warranties expressed or implied including the warranties of merchantability and fitness for use and of all other obligations or liabilities on our part, and Hill Laboratories shall not be held liable or responsible for any other liability in connection with the sale or use of this equipment. In no event, shall we be liable for consequential or special damages arising from breach of warranty, breach of contract and negligence. Hill Laboratories makes no warranty whatsoever in respect to accessories or parts not supplied by Hill Laboratories.

REGISTRATION

Copy the registration form below and fill it in. Send either by mail or fax to the mailing address or Fax number given. Keep a copy for your records.

REGISTRATION FORM

Attn: Registration Dept
Hill Laboratories Co.
P O Box 2028
Frazer
PA 19355
USA

Fax to: (610) 647-6297

Facility Name:			
Contact person:			
Street Address:			
City:		State/Province:	
ZIP/Postal Code:		Country:	
HF 54 Serial №:			

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PREFACE

This manual is intended as a guide for the operators of the HF54. It contains precautionary instructions, general instructions for operation and maintenance recommendations. In order to facilitate the proper operation of HF54 and to obtain maximum efficiency and life from the unit, READ AND UNDERSTAND THIS MANUAL THOROUGHLY. Be thoroughly acquainted with the operating procedures, as well as the indications, contraindications, warnings, and precautions before administering any treatment to a patient. Other resources must be referred for additional information regarding the application of therapeutic ultrasound.

1.0 Unpacking and Installing Your HF 54

Unpack all items being especially careful with the handling of the swing arm assembly and the ultrasound generator. These items are sophisticated medical equipment and should be handled accordingly.

Retain the packaging for your HF 54. You will need it in the event you need to return the generator for repair.

1.1 Check the items shipped

The HF 54 Standard Package contain the items in Table 1—1. Use the check boxes provided to record your package items.

Table 1—1 : Standard Package Contents

Description	Part Number	Qty	CHK
HF 54 Generator	HF010	1	☐
72 inch electrode cable	HF001	2	☐
Package 2 inch self adhesive electrode (4 pads)	HF022	1	☐
Package 3 inch self adhesive electrodes (4 pads)	HF002	0	☐
Package 4.75 inch by 2.75 inch self adhesive electrodes	HF003	1	☐
Retainer ring	HF004	1	☐
Stretchable Velcro strap – 24” x 4” (Latex Free)	HF005	1	☐
Aquaflex Gel Pad (2cm x 9cm)	HF007	1	☐
Rolling cart tabletop - Gray	HF018	1	☐
Weight bag	HF008	1	☐
960 kHz ultrasound applicator	HF009	1	☐
Ultrasound Applicator Swing Arm	HF011	1	☐
Cut-off switch	HF012	1	☐
8 oz (240ml) Spray bottle for keeping gel moistened	HF013	1	☐
12” long power cable	HF014	1	☐
Instructions for use	HF015	1	☐
Black post for cart	HF016	1	☐
Utility tray	HF017	1	☐
Velcro strap – 48” x 2”	HF006	1	☐
Cap screws 1/4-20 x 3/4 long	HF018	4	☐
Cart base (5 star – Black)	HF019	1	☐
Cart base caster – Black	HF020	5	☐
1/2” SAE flat washer	HF021	1	☐
Hill Labs Gel Pad	HF023	1	☐
Black Wire Basket	HF024	1	☐

1.2 Cart Assembly Instructions

Now that you have checked the contents of the packaging match the list in Section 1.1, you have all of the parts necessary to assemble the cart.

Step	Instruction	Illustration
1.	Lay the tabletop on floor upside down.	
2.	Place cart post on tabletop with metal bar facing the opposite side of the cord. Line-up the four holes on the cart post with the four holes on the tabletop. Place lock washers on four bolts and screw in bolts using a 7/16 inch wrench.	

Figure 1—1: Caster

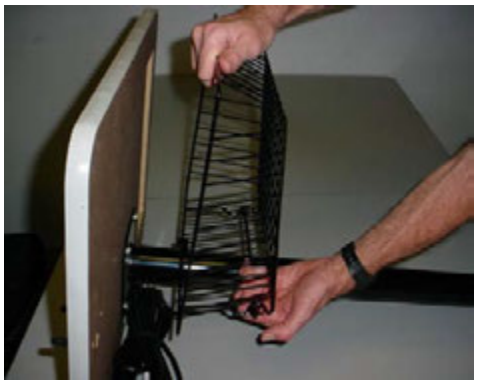
3.	Lay tabletop and post on floor with corded side towards the floor. Hook the upper basket assembly to the cart post. With one hand firmly grab the metal bar that is welded to the post and with the other hand grab the front of the basket. Forcefully connect the metal bar with the basket.	

Figure 1—2: Adding Basket

4.	Insert the casters into the 5 holes in the arms of the base. This can be accomplished easily by hand. Test cart base to determine if casters are seated properly. Place the base – casters downward onto a level surface. If the base is not level, the casters are not seated properly. Do not use excessive force (hammer) or you may crack the caster or the base.	

Figure 1—3: 5-arm Cart Base

5.	Place cart post into cart base. Push down firmly to ensure that the post is properly seated.	

Figure 1—4: Cart Post Inserted Into Base with Casters Fitted

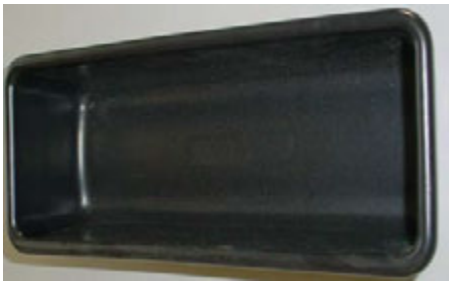
Step	Instruction	Illustration
6.	Turn the table right side up and place the black utility tray into the precut hole in the tabletop (dual soundhead unit will not have black utility tray).	

Figure 1—5: Black Utility Tray

7.	Untape steel washer, which, is taped to tabletop. Place steel washer over existing gray plastic shoulder washer with 2 stop pins located on either side. Do not glue steel washer to plastic shoulder washer, steel washer must float freely.	

Figure 1—6: Steel washer for Swing-Arm

8.	Place HF54 Unit on the tabletop and plug power cord in to a wall receptacle.	

9.	Insert the swing arm into the steel washer and gray plastic shoulder washer. If the generator is facing the assembler, the swing arm should extend out in the opposite direction as pictured. Plug soundhead cord into port 1 on the generator. The HF54 is now ready to operate.	

Figure 1—7: Complete Illustration

DANGER
TO PREVENT ANY LIKELIHOOD OF FIRE AND ELECTRIC SHOCK. DO NOT ALTER THE FACTORY VOLTAGE SETTING OF YOUR HF54 EQUIPMENT. IF YOU SUSPECT THAT THE EQUIPMENT HAS BEEN TAMPERED WITH, CONTACT THE MANUFACTURER IMMEDIATELY.

FOR NORTH AMERICA, THE VOLTAGE SETTING ON THE REAR OF YOUR HF54 SHOULD READ 115V. ANY OTHER VALUE IS NOT SUITABLE FOR CONNECTION TO THE US ELECTIC SUPPLY.

2.0 Warnings, Indications for Use, Contraindications, Cautions and Precautions

Informational symbols used in this manual

Means – Mandatory to read the Instructions. Note the cover page has this symbol meaning that it is a requirement for safety reasons that the manual is read by the operator.

Means – “Warning”

Means – “Caution”

Means = “Precaution”

Means – The subject relates to an electrical hazard or an action that could lead to an electrical hazard

Means – The subject relates to a non-ionizing radiation hazard, e.g. Ultrasound and High Frequency energy.

Means – The subject matter relates to cleaning of the equipment or hazards associated with cleaning the equipment.

2.1 General Warnings & Cautions

2.1.1 Mandatory Instruction

Read these instructions before use or attempting any assembly

Thoroughly read this manual before setting up treatment for the first time. Frequently return to this manual to reacquaint yourself with the correct use of your HF54.

Before treating with the HF54 Ultrasound with Interferential and IR Light Therapy, see Section 2.0 covering the “Contraindications, Warnings, and Precautions”

Retain the packaging for your HF54. You will need it in the event you need to return the generator for repair.

2.1.2 General Warnings

WARNING
To avoid the risk of fire or electric shock, replace fuses only with the same type and rating.

WARNING
To avoid the risk of fire or damage to the device, do not get liquids inside the equipment or its accessories.

WARNING
This Instrument contains dangerous voltages. Refer service to qualified personnel only.

WARNING
Do not use the same power outlet or line with a whirlpool, certain traction machines or other heavy equipment

WARNING
The HF54 should be used only under the continued supervision of a physician.

2.1.3 General Cautions

"CAUTION: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device."

CAUTION
Use of operation control or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

CAUTION
Before cleaning or disinfecting your HF54 or its accessories, always turn off power to the equipment and disconnect the plug from the outlet (prevents accidentally turning the equipment on). Always clean and disinfect in a well ventilated area.

CAUTION
Use a commercially available surge suppressor if power problems are encountered.

CAUTION

In areas which are carpeted and static electricity is present, it may be necessary to use a conductive mat to remove any static charge from the operator (note that there is no danger to the equipment but static build up can be in excess of 50 kilovolts and will discharge to electrodes attached to patients causing discomfort)

CAUTION
Only use the cleaning materials identified in section 12.0. These materials have been tested with the equipment and found to be compatible for repeated application

2.2 Interferential Current and Premodulated Current

2.2.1 Interferential Current and Premodulated Current Indications for use

These are the conditions for which Interferential Current (IFC) or Premodulated Current can be used.

Symptomatic relief of chronic intractable pain and/or management of post-traumatic or post surgical pain.

2.2.2 Interferential Current and Premodulated Current Contraindications for Use

2.2.2.1 Contraindicated Conditions

These are the conditions under which an electrical stimulator should not be used;

- Patients who do not comprehend the physiotherapist's instructions or are unable to co-operate should not be treated
- Powered muscle stimulators should not be used on patients with cardiac demand pacemakers;
- Do not use on patients prone to epileptic seizures
- Do not use on patients that are prone to hemorrhage
- Do not use this device whenever pain syndromes are undiagnosed, until etiology is established;
- Do not use with patients diagnosed with disease processes causing increased local or general metabolism (inferential current)

2.2.2.2 Contraindicated Areas

- Desensitized areas (low volt galvanic stimulation);
- Over the carotid sinus nerves, neck or mouth;
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias;
- Do not apply electrodes such that current flows transcerebrally (through the head);
- Directly over or through a metal implant (low volt galvanic);
- Over moles or warts;
- Directly over abrasions, open wounds or sites of infection;
- Directly over, near or through a recent unhealed fracture site (stimulation of overlying muscle to contraction);
- Directly over or through the heart;
- Directly over or near a pregnant uterus;
- On or near thrombosis;
- Over or in proximity to cancerous lesions;
- Avoid active epiphyseal regions in children.

2.2.3 Interferential Current and Premodulated Current Warnings


1

WARNING
The long term effects of chronic electronic stimulation are unknown


2

WARNING
Do not stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex


3

WARNING
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


4

WARNING
Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias


5

WARNING
Stimulation must not be applied transcerebrally


6

WARNING
Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc


7

WARNING
Stimulation should not be applied over, or in proximity to, cancerous lesions


8

WARNING
Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when stimulation is in use on the same patient


9

WARNING
This device is not effective for pain of central origin (including headache).


10

WARNING
Stimulation delivered by the device may be sufficient to cause electrocution in some patients with a low tolerance to electrical current


11

WARNING
Electronic stimulation should be kept to below 2 mA/cm^2. Burns to tissue may occur quickly if this current density is exceeded.


12

WARNING
Do not operate generator during lightning, thunderstorms or a condition that could have an adverse effect on continuity of power flow to generator


13

WARNING
Never remove or attach electrodes during treatment. Always stop the treatment before applying or removing electrodes


14

WARNING
Never used worn or damaged leads or electrodes


15

WARNING
Do not turn off generator by main power switch while treatment is being given to patient


16

WARNING
Simultaneous connection of a patient to an h.f. surgical equipment may result in burns at the site the stimulator electrodes and possible damage to the stimulator


17

WARNING
Operation in close proximity (e.g. 1 m) to shortwave or microwave therapy equipment may produce instability in the stimulator output


18

WARNING
This device should be used only under the continued supervision of a physician

2.2.4 Interferential Current and Premodulated Current Cautions and Precautions

2.2.4.1 Cautions


1

CAUTION
Safety of powered muscle stimulators for use during pregnancy has not been established


2

Caution should be used for patients with suspected or diagnosed heart problems


3

Caution should be used for patients with suspected or diagnosed epilepsy


4

Caution should be used in the presence of the following:

a. When there is a tendency to hemorrhage following acute trauma or fracture;
b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
c. Over the menstruating or pregnant uterus; and
d. Over areas of the skin which lack normal sensation


5

CAUTION
Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement.


6

CAUTION
Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner


7

CAUTION
The HF54 should be kept out of the reach of children


8

CAUTION

The HF54 should be used only with the leads and electrodes recommended for use by Hill Laboratories


9

CAUTION

The device has no curative value. Current is symptomatic treatment that suppresses the sensation of pain, which would otherwise serve as a protective mechanism

2.2.5 Interferential Current and Premodulated Current Precautions


1

Ensure that the electrodes are not touching each other or within 1 inch (2.5 cm) of each other. Failure to maintain adequate distances may lead to error code 1 being displayed and the need to reset the HF54 and reposition the electrodes;


2

Do not connect stimulator cables to Garments without the electrodes being secured in place;


3

Each electrode must completely cover its metal connection;


4

Disposable electrodes are for single patient use only;


5

Reusable electrodes must be disinfected in accordance with the instructions in this manual prior to use on a patient;


6

Do not apply to broken skin; if a rash appears, discontinue use and consult your medical professional;


7

If there is abnormal skin sensation, electrodes should be positioned in a site other than this area to ensure effective stimulation;


8

Be careful when treating patients who have (marked) abnormal circulation;


9

For patients who have febrile conditions, the outcome of the first treatment should be monitored;


10

Patients who have epilepsy, advanced cardiovascular conditions or cardiac arrhythmias should be treated at the discretion of the physiotherapist in consultation with the appropriate medical practitioner;


11

Caution must be used with treatment which involves placement of electrodes over the anterior chest wall;


12

Isolated cases of skin irritation may occur at the site of electrode placement following long-term application;


13

Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain.

2.2.5.1 Adverse Effects:

- Skin irritation and burns beneath the electrodes have been reported with the use of interferential and premodulated currents. This can be caused by excessive current for the size of electrode being used.

2.2.6 Interferential Current and Premodulated Current Usage Precaution Notes

A patient's tendency to have adverse reactions to electrotherapy is dependent upon several factors. Some of these factors are discussed below. In addition to cautions listed below, read the section in this manual entitled "Contraindications, Warnings, and Precautions."

Electrical stimulation, by its very nature, has the ability to irritate the patient's skin. Certain precautions should be observed to assure maximum safety and comfort for patients. A patient's tendency to have adverse reactions is dependent upon several factors. These factors are:

Current Density – This is the amount of current being delivered to the patient divided by the area through which the current is being delivered (the surface area of the electrodes being used). Example - In a circuit with the smallest electrode equal to 5 cm x 7 cm or 4 inches round, with an applied current of 50 mA, the current density is $\frac{Applied\ Current}{Electrode\ Length \times Width} = \frac{50mA}{5 \times 7cm} = 1.43$ mA/cm^2.

Electrode Condition – Worn or dried out electrodes cause the current to concentrate in small areas of the electrode instead of going into the skin distributed evenly throughout the entire electrode surface. This has the effect of increasing the current density, since the current is being delivered through a smaller area.

Patient Susceptibility – Some patients' skin is more sensitive to electrotherapy currents. This can cause a reaction similar to heat rash.

Electrotherapy treatment can result in a rash, burn, or blister. The tendency to do this is dependent upon the factors listed above and can be minimized by applying the following guidelines:

1. Use only moderate current. It is not always necessary to raise the treatment intensity to just short of the patient's pain threshold to achieve adequate results. For carbon or self adhesive pads slowly increase intensity to patient comfort. Use as large an electrode as is practical for the application. Note that the current density in a 1.25" square electrode is Five Times the current density in a 1.75" x 3.75" electrode for the same intensity setting. Using larger electrodes allows current to be delivered over a larger area of the body, keeping the current density to be as low as possible and minimizing the possibility for adverse reactions. Do not exceed patient tolerance in setting the intensity. Consult published medical literature for more

   The maximum recommended intensity for electrotherapy (interferential and Premod) is 15-20.
2. Ensure that the area on the patient's skin where the electrode is to be placed is clean and free of foreign matter. This includes powders, perfumes, and the like, as well as body oils or dirt and grime. Cleaning with an alcohol wipe should be adequate. Allow the alcohol to fully evaporate before applying the electrodes.
3. Make sure the electrodes being used are in good condition. The self-adhesive electrodes should have good adhesion over the entire surface area of the electrode. The area where the leads attach to the electrode (either through a lead or a snap) should not be damaged such that the connection to the foil backing behind the adhesive is broken. Carbon electrodes should be deep black, and should be free of cracks in the electrode surface.

   *Any electrode which is suspect should be discarded.
4. Some patients tend to be much more sensitive to electrotherapy treatments. On patients with this tendency, treat with reduced intensity and/or shorter treatment times, with possibly more frequent treatments, if required. Most reactions are localized and very short-lived, so limiting the exposure should minimize any potential for adverse reactions.

2.3 Ultrasound Therapy

Ultrasound is used to treat a variety of inflammatory and traumatic conditions. Ultrasonic energy is mechanical vibration identical to that of sound but of a high frequency. It is caused when an electrical signal is applied to the piezoelectric transducer material that converts the electrical energy into mechanical (sound) energy.

2.3.1 Ultrasound Therapy Indications for Use

Ultrasound is indicated for applying therapeutic deep heat within body tissues for the treatment of selected medical conditions such as:

- Relief of pain
- Muscle spasms
- Joint contractures

The use of ultrasonic energy in therapy should not be considered as specific treatment for any disease.

2.3.2 Ultrasound Therapy Contraindications

It is contraindicated to apply therapeutic ultrasound to patients with any of the following conditions:

2.3.2.1 Contraindicated conditions

- Pregnancy
- Acute and sub-acute thrombosis and thrombophlebitis
- Potentially Malignant lesions, tumors malignant or benign
- Areas or lumps that may be suspected as cancerous or precancerous
- Third degree musculo-tendonous lesions
- Cardiac pacemaker
- Implants of any electrical nature
- Skin diseases
- Multiple sclerosis
- Osteomyelitis
- Disturbances in cardiac rhythm
- Tissue or bone with acute sepsis
- Arteriosclerosis or weakened blood vessels
- Hemophilia
- Where sensory nerve damage is present with a loss of normal skin sensation

2.3.2.2 Contraindicated Areas

It is contraindicated to apply ultrasound to any of the following areas:

- Transcerebrally
- To the eye
- To the ear
- Over a carotid sinus
- To the heart
- To major subcutaneous nerves and blood vessels
- To the spinal cord
- Around the bulbar area of the spinal cord
- To reproductive organs
- Over viscera (stomach, spleen, liver)
- Over or near epiphyseal areas of the bones in growing children, or adults until bone growth is complete
- Over stellate ganglion and subcutaneous major nerves
- To tissues previously treated by deep X-ray or other radiation
- Over the joint capsule in acute or sub-acute arthritic conditions
- Over ischemic tissue in patients with vascular disease
- Over a laminectomy site
- Over total joint replacements (the effect of ultrasound on new plastics is unknown)
- Over any internal metal
- Over a healing fracture

2.3.3 Ultrasound Warnings


1

WARNING
Do not use the Ultrasound for underwater treatments. The applicators are not watertight


2

Never operate the instrument at a level where the patient feels pain, and if you have any doubts about the proper level of dosage, select a lower amount


3

WARNING
When using, the applicator must be moved in a circular motion around the treatment site.


4

WARNING
Do not use in general area where high-powered, high frequency transmitting generators are being operated. Short wave diathermy should not be used within 8 feet (2.5 m) of the HF54.


5

WARNING
Avoid unnecessary exposure to ultrasound (patient and therapist)


6

WARNING
Do not turn off generator by main power switch while treatment is being given to patient


7

WARNING
Do not operate generator during lightning, thunderstorms or a condition that could have adverse effects on continuity of power flow to generator

2.3.4 Ultrasound Usage Cautions


1

CAUTION
It is recommended that the Gel Pad part number HF007 is used with the HF54.


2

CAUTION
Ultrasound by its very nature has the ability to irritate the patient's skin. Ultrasound's advantages far outweigh any disadvantages, but certain precautions should be taken to minimize the likelihood of irritation.


3

CAUTION
A patient's tendency to have adverse reactions to ultrasound is dependent upon several factors. Some of these factors are discussed below. In addition to cautions listed below, read the section in this manual entitled "Contraindications, Warnings, and Precautions


4

CAUTION
The ultrasound applicator is not suitable for immersion in water. Immersion will cause damage to the applicator**.**

2.3.5 Ultrasound Precautions


2

Some patients' skin is more sensitive to ultrasound output. This can cause a reaction similar to a heat rash


3

Higher output levels have a greater potential for patient discomfort. Output power may be reduced by simply choosing a lower W/cm^2 setting


4

Do not use ultrasound:

a. Over an area of the spinal cord following a laminectomy, i.e., when major covering tissues have been removed
b. Over anesthetic area
c. On patients with hemorrhagic diathesis

2.3.6 Ultrasound Usage Precaution Notes

2.3.6.1 <u>Potential for Burns</u>

It is possible for a patient to suffer a burn from ultrasound therapy if the therapy is not administered properly. Burns can occur for the following reasons:

- Too high intensity (power).
- Treating an area where sensory nerve damage is present with a loss of normal skin sensation.
- Over bony prominences because they reflect sound waves and increase intensity to the periosteum.
- Desensitized areas can be overheated or burned without the patient realizing it, so extreme care must be taken with these patients, e.g. on areas that are anesthetized.

Burns can be avoided as long as the treatment causes no pain, tingling, excess heat or aching (for patients with normal skin sensation). The gel pad is recommended to ensure sufficient coupling agent. If liquid gel is used, make sure to place an ample amount between the applicator and the patient. Failure to do so may cause skin irritations or surface burns.

2.3.7 Dosage

The dosage received by the patient is primarily a function of the wattage and, to a lesser extent, the length of time. The prescription for ultrasound treatment will usually designate the wattage level at which treatments are to be carried out. At no time must a patient encounter discomfort during ultrasound treatment. A feeling of slight warmth or often a slight tingling sensation is all that should be experienced by the patient.

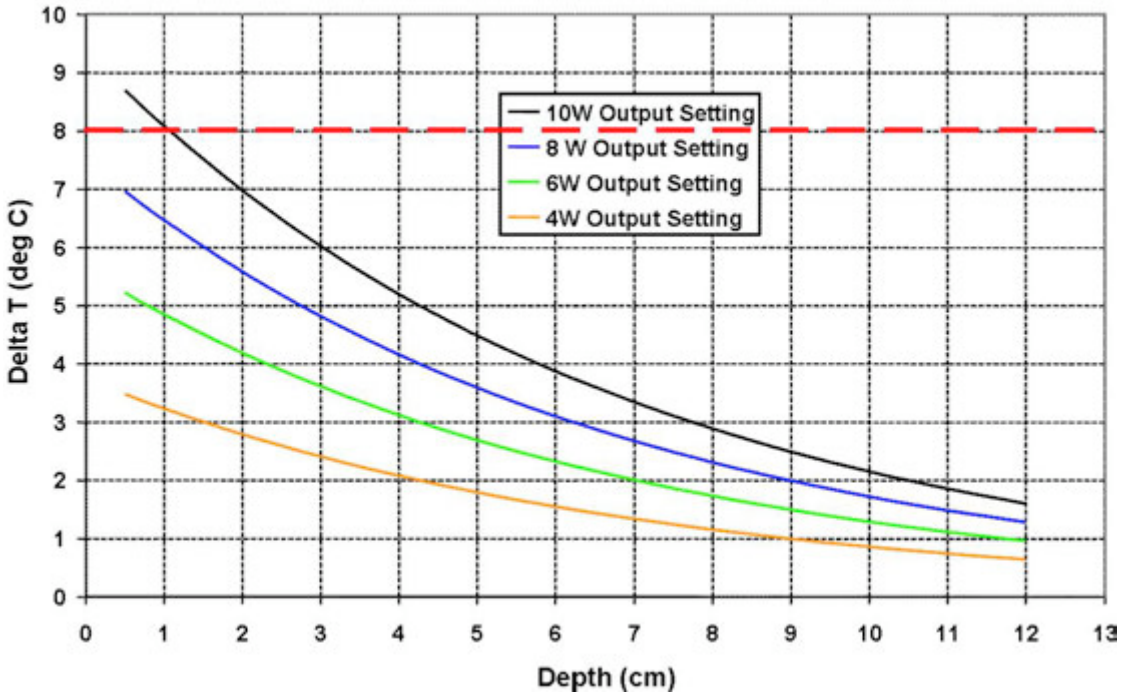


Figure 2—1: Estimated steady-state thermal temperatures in soft tissues rise for different output power settings

The graph above identifies the level of temperature rise between 40 to 45 °C as the temperature level deemed therapeutic by the FDA. Treatments should be done in this therapeutic temperature range to be effective.

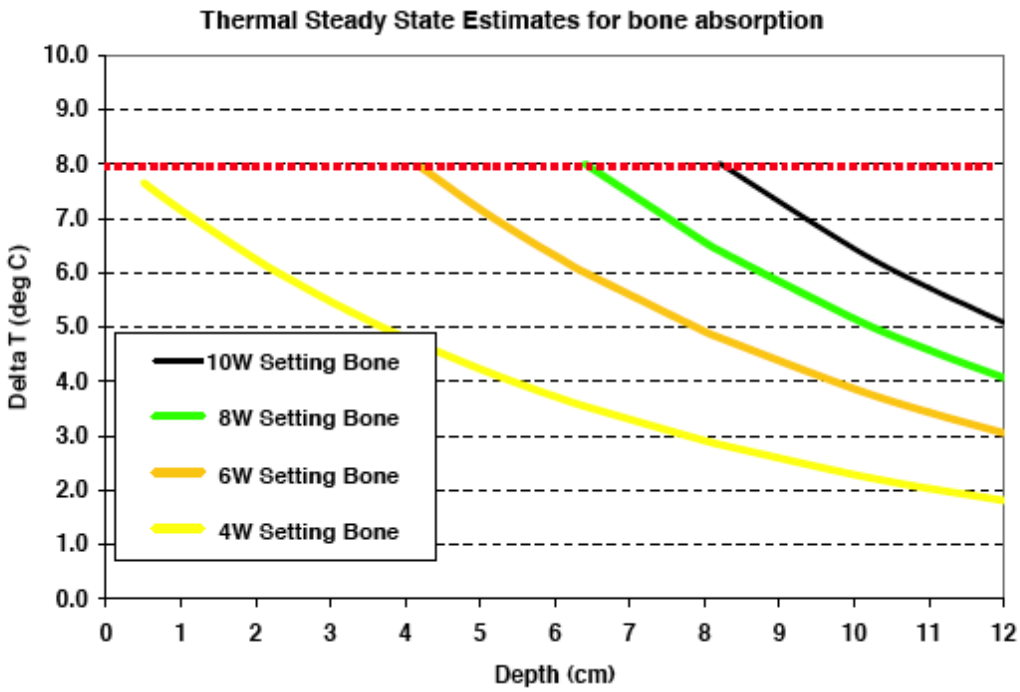


Figure 2—2: Thermal Steady State Estimates for Bone Heating (when using Optional Hands-Free Operation).

2.4 Horizon Infrared Light Therapy

2.4.1 Indications

Application of infrared energy to apply topical heating for the treatment of selected medical conditions such as:

- Temporary increase in local blood circulation
- Temporary relief of minor muscle and joint aches, pains and stiffness
- Relaxation of muscles
- Muscle spasms
- Minor pain and stiffness associated with arthritis

2.4.2 Contraindications

1. Cancer (tumors or cancerous areas)
2. Direct irradiation of eyes
3. Treatment of patients with idiopathic photophobia or abnormally high sensitivity to light. Some medications are known to increase sensitivity to light
4. Patients that have been pre-treated with one or more photosensitizers
5. Direct irradiation over the fetus or the uterus during pregnancy
6. Direct irradiation of the thyroid gland and endocrine glands
7. Patients with pacemakers
8. Growing children (Epiphyseal plates)

2.4.3 Infra Red Therapy Warnings


1

WARNING

The Infra Red Therapy Applicator should not make direct contact with open wounds.


2

WARNING
The unattended use of the infra red therapy applicator by children or incapacitated perons may be dangerous

2.4.4 Infrared Cautions


1

CAUTION
The lens at the front of the applicator is made from glass. If dropped the glass may shatter and cause a hazard. If dropped, handle with care to avoid cuts


2

CAUTION
The Infra Red Applicator has several ventilation holes and slots to aid in effective cooling of the applicator. Do not block the ventilation holes or slots


3

CAUTION
Do not immerse the Infra Red applicator in liquids as this will cause damage to the Infra Red applicator


4

CAUTION
Do not allow liquids to enter the applicator slots or holes when cleaning the applicator. Refer to the cleaning section of this operator's manual for recommended cleaning method and materials

2.5 Combination Treatment

2.5.1 Combination Treatment Indications

The indications of Sections 2.2.1 and 2.3.1 are generally good except where near lesions or wounds. Although not in contact with either cancerous lesions or wounds, this would be contraindicated.

2.5.2 Combination Treatment Contraindications

The contraindications of both Ultrasound and Interferential/Premodulated Current are applied too the device in combination. See sections 2.2.2 and 2.3.2.

Addition – heat in addition to electrical stimulation may lead to bleeding when in close proximity to wounds, sores or cancerous lesions.

2.5.3 Combination Treatment Cautions

CAUTION


1

In some patients, the sensitivity to electrical stimulation increases when used in combination with Ultrasound. The exact mechanism for this increase in sensitivity is not fully understood but sufficient cases have been discussed at scientific meetings to warrant this caution

CAUTION


2

When delivering combination ultrasound and Premod through the applicator, do not exceed patient tolerance in setting the intensity. The maximum recommended intensity for electrotherapy is 15-20 mA used with a 65 cm^2 applicator

2.6 Markings on the outside of the HF54

Rating Label on the rear of the HF54 adjacent to fan

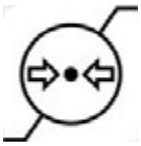
Hill Laboratories, Bacton Hill Rd. Frazer, PA
Serial # 00000
Date: *month/year*

Label on the IR Light Therapy Applicator cable

Type BF Applied Part
(Marked beside the patient outputs)

2.6.1 Markings on protective Packaging

Relative Humidity Range for Transport and Storage (found on shipping label for Europe)



Barometric Pressure Range for Transport and Storage (found on shipping label for Europe)

Keep Dry
Packaging must be protected from excessive humidity and must accordingly be stored under cover

This way up
The package must always be transported, handled and stored in such a way that the arrows always point upwards. Rolling, swinging, severe tipping or tumbling or other such handling must be avoided.

Storage temperature limits

3.0 Introduction to the HF54

3.1 Standard Accessories

The HF54 offers Hands Free Ultrasound, Interferential & Premodulated Current Therapy. The HF54 is supplied with the following standard accessories:

Table 3—1: Standard Accessories

Description	Part Number	Qty	Item #
HF 54 Generator	HF010	1	
72 inch electrode cable	HF001	2	1
Package 2 inch self adhesive electrodes (4 pads)	HF002	1	2
Package 2.75 x 4.75 inch adhesive electrodes	HF003	1	3
Rubber Retainer ring	HF004	1	4
Stretchable Velcro strap – 24” x 4” (Latex Free)	HF005	1	5
Gel Pad (used with ultrasound applicator)	HF007	1	6
Rolling cart tabletop - Gray	HF018	1	7*
Weight bag	HF008	1	8
960 kHz ultrasound applicator (US1)	HF009	1	9
Ultrasound Applicator Swing Arm	HF011	1	10
Cut-off switch	HF012	1	11
8 oz (240ml) Spray bottle for keeping gel moistened	HF013	1	12*
15 ft long power cable	HF014	1	13*
Instructions for use	HF015	1	14*
Black cart post for cart	HF016	1	15*
Utility tray	HF017	1	16*
Velcro strap – 48” x 2”	HF006	1	17
Cap screws 1/4-20 x 3/4 long	HF018	4	18*
Cart base (5 star – Black)	HF019	1	19*
Cart base caster – Black	HF020	5	20*
1/2” SAE flat washer	HF021	1	21*

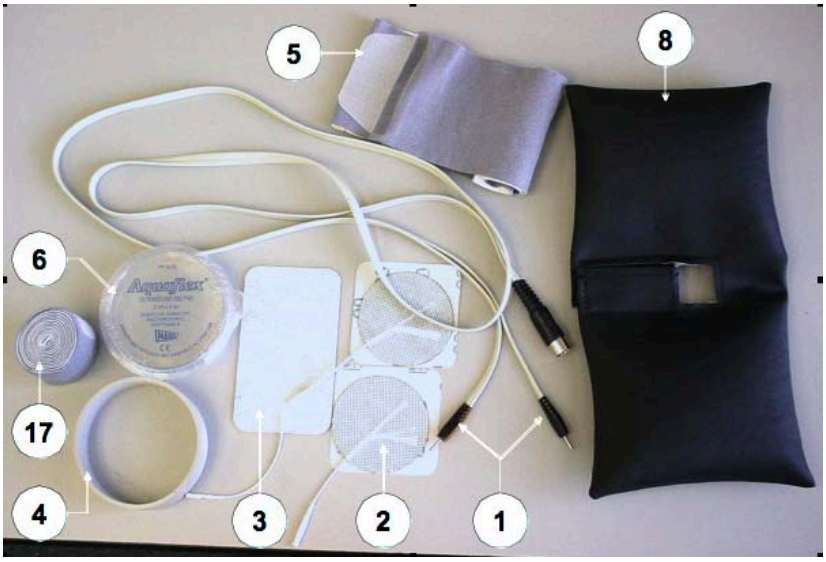


Figure 3—1: Illustration of standard Accessories

3.2 Optional Accessories

Optional Accessories are available for the HF54 and these are identified below:

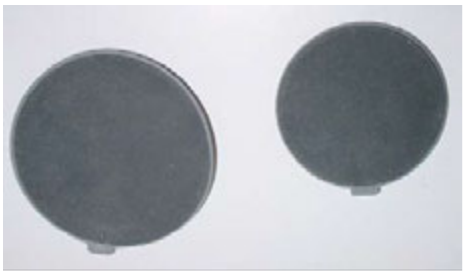
Table 3—2: Optional Accessories

Description	Part Number
Second Ultrasound Applicator	HF022
Infrared Light Therapy Applicator	HF023
Hand-Held Ultrasound Applicator	HF025
Carbon Electrodes	HF024
Separate Power Supply for Standalone IR Therapy	HF030

Figure 3—2: Handheld Ultrasound Applicator

Figure 3—3: Infrared Light Therapy Applicator

Figure 3—4: Carbon Electrodes



3.3 Technical Description

3.3.1 Functional description

The HF54 is a sophisticated Microcomputer controlled device. The heart of the electronics of the HF54 is an 8051 microcontroller running at 22 MHz. The microcontroller contains all of the memory (RAM and Non volatile RAM) counters, timers and other peripheral controllers to make the equipment operate quickly, efficiently and reliably. The embedded software cannot be altered except by a trained engineer and no attempt should be made to do so. There are three main programs running simultaneously:

Main	Executes and maintains the operation of the equipment and is checked several times per second. The LED displays and indicators are maintained and the internal watchdog keeps track of main system functions.
Medium Priority	Makes the timer count down and monitors medium priority functions e.g. whether treatment head or the cut-out switch are still plugged in properly. The numeric displays are refreshed. The medium priority functions are monitored over 200 times per second.
High Priority	Checks the circuit voltages, current level, ultrasound output power levels, whether any buttons are being pressed or whether any values such as time or intensity are being changed. While values are still within adjustable range, compensation will be made for small variations in current due to changing skin resistance (or acoustic coupling in the case of the ultrasound transducer) thereby maintaining the set level. The microcontroller does this 64,000 times per second. If anything goes out of specification internally, the high priority circuit will detect it before any sensation can be felt and turn the outputs off and shut the equipment down in a safe way. The program will now alert you to whatever is causing it a problem.

When you turn on the HF54, the microcontroller waits for a few moments for all of the circuits to settle down. It then forces all of the outputs to turn off and sets all of the intensity controls and timers to zero. It performs an internal check to make sure all of its own circuitry is OK then it will beep to alert you that it is ready to begin therapy whenever the operator is ready.

3.3.2 Therapeutic Ultrasound

Therapeutic ultrasound is a unique form of penetrative energy. Because it is unique, it may be difficult at first to fully understand its application. Ultrasound energy is not electrical, although electricity is used in its generation; it is not chemical energy, although it will accelerate chemical reactions; it is not radiation energy like x-ray or ultraviolet, for it will not penetrate a vacuum; and it is not thermal energy, although absorption of ultrasound in tissue produces heating.

Ultrasound is a mechanical energy. It is a form of sound with a frequency far beyond the maximum that can be detected by the human ear. In the HF54 ultrasound, the frequency is almost one million cycles per second. Therapeutic ultrasound mechanically vibrates tissue at an extremely high frequency but for a very small range of movement. At the cellular level, the molecules are oscillated about a million times a second but for distance of only a few millimicrons. The result is a continuous state of acceleration without displacement.

Ultrasound simultaneously offers good beaming and high depth of penetration. This, combined with high absorption in muscle as compared to fat, makes ultrasound especially suitable for localized deep treatments directed to the painful or affected areas and to the nerve roots supplying the affected part.

Ultrasound is generated by high frequency vibration. In the ultrasound, the vibrations are generated by applying an electrical voltage to crystals, causing them to elongate along one axis. By oscillating correspondingly, the crystals are contained in an applicator, sometimes termed a transducer or applicator, which in turn is connected by a coaxial cable to the device that generates the oscillating voltage.

The acoustic energy generated by the ultrasound is delivered in intermittent pulses, 60 per second, with approximately equal on and off periods. Momentary peak intensities are 5.4 times the average ultrasonic power being generated.

Ultrasound can travel through solids and liquids but cannot penetrate air or a vacuum. When the applicator is applied in direct contact with the body, the gel pad is needed between the body and the applicator for "coupling". The applicator must be coupled to the body at all times during treatment because the slightest layer of air will prevent transmission of energy.

The HF54 has three crystals in the applicator that are calibrated to be in very close frequency with one another. The harmonic vibration that they produce makes the 3 5/8” diameter applicator act as one large crystal. Uniform vibration to the edge of the applicator is easily detected by placing water on the inverted applicator. The crystals pulse in milliseconds 50 percent on and 50 percent off. The applicator is placed on the patient using our special gel pad. The gel pad contours to the patient’s body and eliminates the mess and residue of liquid gel.

3.3.3 Interferential (IFC), Premodulated (Premod) and Russian Therapy

Interferential Therapy is a type of electrical stimulation that uses 4 electrodes to carry medium-frequency alternating currents. The electrodes are aligned on the skin so that the current flowing between each pair intersects at the underlying target, thus maximizing the current permeating the tissues while reducing to a minimum unwanted stimulation of cutaneous nerves. It is theorized that the low frequency of the interferential current causes inhibition or habituation of the nervous system, which results in muscle relaxation, suppression of pain and acceleration of healing.

Premodulated therapy uses a two-electrode application. The current is a composite waveform using two frequencies similar to interferential. Rather than the two frequencies being combined in the patient’s tissues, Premodulated Therapy uses a waveform that is mixed in the generator. Premodulated therapy is used when the application area is smaller and interferential cannot be used.

Russian Stimulation Therapy is mostly used for muscle mass and edema reduction in North America. It is often used to stimulate motor nerves. Its capability of a high frequency allows for deep muscle penetration, stimulation and intense muscle fiber contraction. Russian currents are alternating currents (AC) at a frequency of 2.5 kHz that are burst modulated at a frequency of 50 Hz with a 50% duty cycle.

3.3.4 TENS Therapy

Transcutaneous Electric Nerve Stimulation or TENS. TENS modulates low frequency (125Hz) for controlling pain. It uses the gate control theory that states that if a pain message has already stimulated the nerve fibers of the spinal cord, the gate closes which inhibits the occurrence of another pain message.

3.3.5 Light Therapy

The visible red light is in the range 660 nm, the invisible infrared light is in the range 880 nm. The optional IR light therapy applicator connects directly to the HF54.

3.3.6 Handheld Ultrasound

Handheld therapeutic ultrasound is a mechanical stimulus delivered to the body by a means of an ultrasound beam emitted out of an applicator. It has a frequency range between 1 and 3 megahertz (MHz). Ultrasound at 1 MHz targets tissue 3 to 5 cm deep. Deep tissue requires longer treatment times because the 1 MHZ ultrasound used is absorbed approximately 3 times more slowly than the 3 MHz ultrasound. Conversely, ultrasound at 3 MHz targets tissue less than 2 cm deep and is absorbed 3 times faster. Continuous ultrasound (100% duty cycle) produces greater heating than pulsed at a given intensity because the wave is not interrupted. For optimal effect, stretching needs to be applied during the treatment while the tissue is warm, and continued for approximately 5 minutes after the ultrasound treatment.

3.4 Identification of Wire Connections

3.4.1 HF54 Plus Rear Panel Outputs

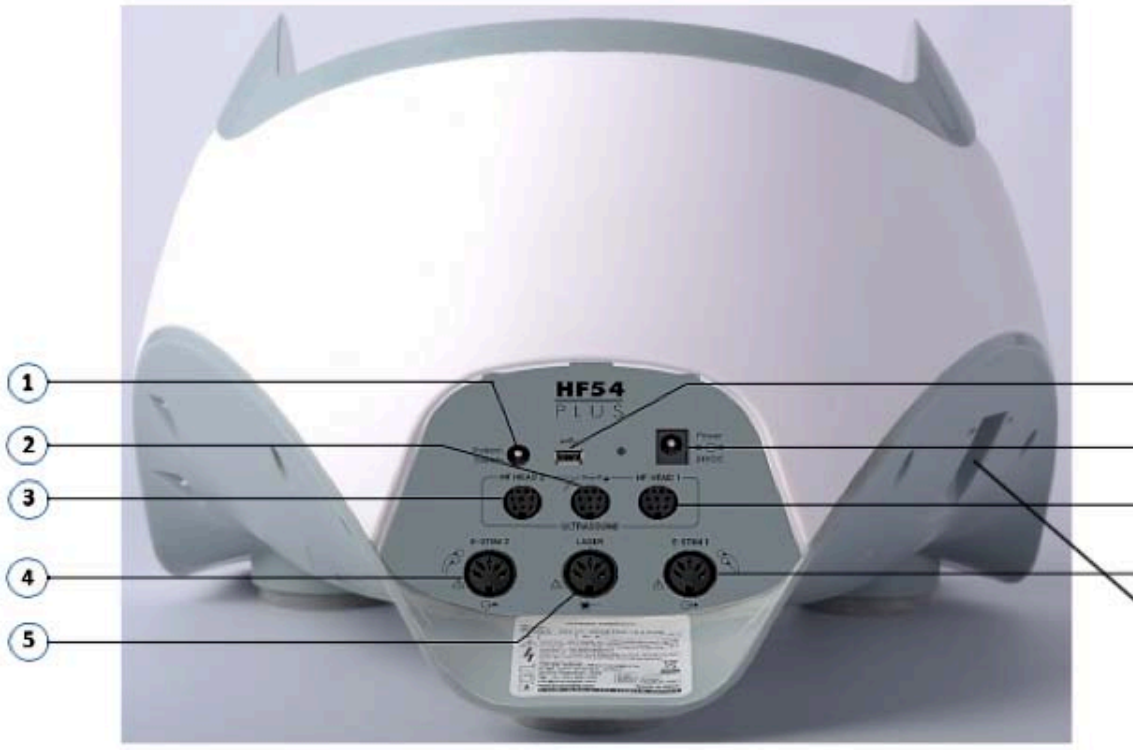


Table 3—3: Rear Panel Items

1	Patient Switch
2	Standard 5 cm. (Handheld)
3	2nd Hands Free Applicator Outlet
4	2nd E-stim Output
5	Laser Output

6	USB Port
7	Power Inlet
8	First Hands Free Applicator Outlet
9	1st E-stim Output
10	ON/OFF Switch

3.4.2 Indicators and Controls

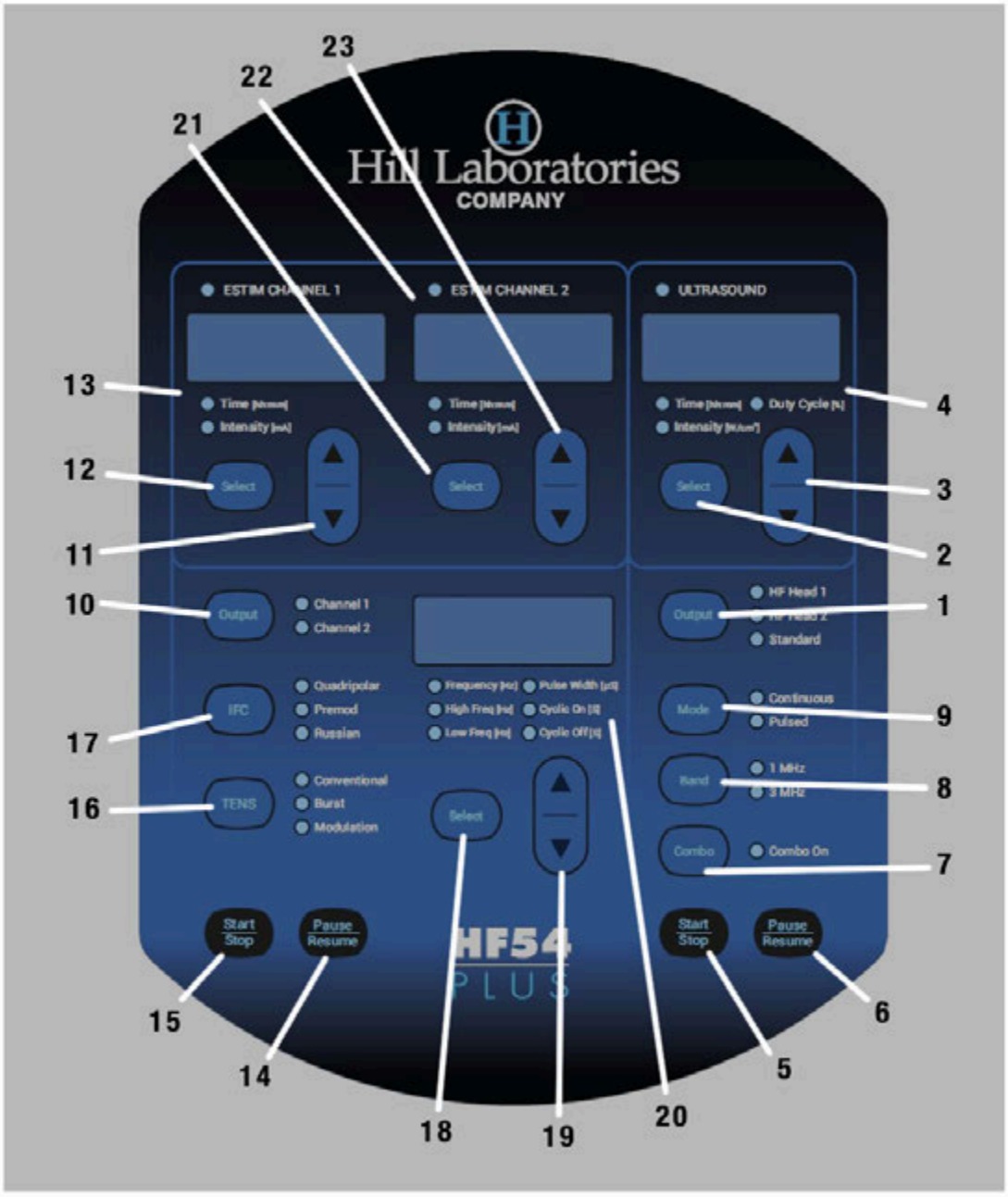


Figure 3—4: Annotated View of Controls and Ports

Table 3—4: List of Controls and Indicators

Item No.	Function
1.	Output Button for soundhead selection
2.	Select button for ultrasound settings
3.	Up and Down arrows for ultrasound
4.	LED indicators and display for ultrasound
5.	Start/Stop button for ultrasound
6.	Pause/Resume button for ultrasound
7.	Combo button for combination therapy
8.	Band button for Hand-held ultrasound
9.	Mode button for Hand-held ultrasound

10.	Output button for channel selection
11.	Up and Down buttons for ESTIM CHANNEL 1
12.	Select button for ESTIM CHANNEL 1
13.	LED indicators and display for ESTIM CHANNEL 1
14.	Pause/Resume button
15.	Start/Stop button
16.	TENS selection button
17.	IFC selection button
18.	Select button for specific settings of chosen treatment
19.	Up and Down buttons for specific settings of chosen treatment
20.	LED indicators and display for specific settings of chosen treatment
21.	Select button for ESTIM CHANNEL 2
22.	Up and Down buttons for ESTIM CHANNEL 2
23.	LED indicators and display for ESTIM CHANNEL 2

4.0 HF54 Ultrasound Setup and Operation

The construction of the Hands-Free 54 consists of a 65 cm^2 applicator with multiple crystals that deliver a large coverage area of ultrasound in a safe and effective manner. The ultrasonic frequency is approximately 1 MHz-60 cycles pulsed at 50% and is amplitude modulated.

4.1 Prior to Using the Ultrasound

MANDATORY INSTRUCTIONS: READ SECTION 2.3 BEFORE SETTING UP THE ULTRASOUND

1. **Always turn main power on before attaching electrodes or soundhead to patient!**

2. Plug the HF54 into the power cord and insert the power cord into an 115V-60HZ grounded wall outlet (note that connecting the HF54 into an outlet strip being used by shortwave diathermy or whirlpool baths is not advised). The ultrasound may be ordered to operate at 220V-50/60HZ if needed.

3. Plug Applicator 1 into the 1st port on the left side of the generator. If the optional second applicator is used, plug it into the 2nd port on the right side of the generator. The 2nd applicator can be purchased with or without the applicator arm.

4. Plug the patient-held cut-off switch into the front port. The cut-off switch will override all of the output functions of the HF54 and turn off the outputs being used on the HF54. The switch provides the patient with a means to prevent undue discomfort and provides a secondary level of safety.

4.2 Patient Set-Up for Ultrasound

1. Slide the rubber retainer ring halfway onto the applicator.

Warning

Gel Pad P/N HF007 must be used with the HF54 when using the Ultrasound or Combination modes.

Failure to do so may cause skin irritations or surface burns.

2. Use alcohol or an alcohol wipe to prepare the treatment site.

3. Place the Gel Pad in the retainer ring against the applicator. Make sure the Gel Pad is always moist. If the Gel Pad is dry it will not conduct ultrasound and may cause skin irritations. Please review the Gel Pad instructions below:

   -Preferred Way:
   To increase suction of gel pad to soundhead and increase transmission of ultrasound, use a small amount of liquid gel on both sides of gel pad. (Make sure there are no air bubbles between head and gel pad) Alcohol can be used to clean the gel pad off.

   -**Alternative Way:**
   A very wet paper towel can be used between the patient and the Gel Pad. Alcohol can be used to clean the gel pad off.

- Always keep the Gel Pad moist. After treatment, spray or add water to both sides of the Gel Pad. Make sure the entire Gel Pad is moist during storage in its protective plastic container. Keeping the Gel Pad moist will prolong its life.

- After treatment, the Gel Pad may become suctioned to the soundhead. To remove the gel pad with minimal damage, push one side of the Retainer Ring towards the coaxial cable. Next, slide the gel pad off of the soundhead while being careful not to puncture the gel pad with your fingernails.

- It is highly recommended that the retainer ring is pulled off of the soundhead and the soundhead is thoroughly cleaned at least once a day. To prevent mineral build up, use distilled or filtered water in the spray bottle.

4. Do not place the weight bag on the coaxial connection (see Figure 4—1. The connection may fail or break if the weight bag is placed on the coaxial connection.

Figure 4—1: Soundhead Cautions

4.2.1 Ultrasound Output Conversion (Based on ERA)

The HF54 Console displays in W/cm^2.

4.2.2 HF54 Handheld Ultrasound: Movement of the Applicator

The sound head should be moved in a circular pattern over the area to be treated overlapping the previous pass only slightly. The head should be held in contact with the surface to be treated firmly but not tightly. Circular or linear patterns are acceptable patterns of administration depending on the area to be treated.

For the handheld applicator, you must use liquid gel on the area you are treating.

When the head does not make contact with the patient (not coupled), the intensity will automatically decrease to the lowest output setting (.1) and the LED light will blink next to “Standard”. These features reduce the possibility of damage or burn-out to the soundhead.

See contraindications and contraindicated areas in section 2.3.2.1 and 2.3.2.2.

4.3 Operating the Ultrasound

IMPORTANT: Before operating the ultrasound, refer to the section on Indications, Contraindications, Warnings Cautions and precautions.

4.3.1 Connecting the patient cut-out switch

Plug the cut-off switch into the front port. The cut-off switch should be used at all times. The patient should be given the cut-off switch and instructed to press the button if he/she feels any pain or discomfort. If the cut-off switch is pressed, the ultrasound and/or stimulation will be shut off and the generator will beep until the operator presses the Start/Stop button.

4.3.2 Applying power to the HF54

Always turn power on before attaching electrodes or soundhead to patient.

Turn on the main power switch located on the left side of the generator.

NOTE: *The generator should be turned off at the end of business hours or when not in use for several hours.*

Figure 4—2: Control Panel

4.3.3 Setting time

Set the duration of the treatment by pressing the “Select” button (see Figure 4—3) below the Time LED.

Figure 4—3: Time selector button

Use the arrow buttons to increase or decrease the time.

4.3.3.1 Adjustment of time after start of treatment

During treatment, you can adjust the time at any point by using the selector arrows (see Figure 4-6). Time can also be adjusted by pressing the Pause/Resume button then using the selector arrows to adjust.

4.3.4 Ultrasound Applicator Selection

Select which applicator to have output by pressing the Output button. The ultrasound selection has 4 available options:

- 1st Applicator: HF Head1 - Standard applicator plugged into the first port (see “8”, page 26)
- 2nd Applicator - Optional HF Head2 - applicator plugged into the second port (see “3”, page 26)
- Both – Enables user to operate both applicators at the same time
- Standard – Activates Handheld Ultrasound Applicator

Note: ***If using two hands-free heads, only one ultrasound intensity can be used while both applicators are operating. Always select an intensity that can be safely used at both treatment areas.***

Figure 4—4: Ultrasound Applicator Selection

4.3.5 Start treatment

Before starting a treatment review the contraindications in Section 2.2

To start treatment, press the Start/Stop button.

The time set in step 4.3.3 will start at the designated level and decrease to zero.

At any time the operator can stop the treatment by pressing the Start/Stop button. The treatment can also be paused by pressing the Pause/Resume button (see **Error! Reference source not found.**).

The timer will automatically turn the instrument off at the end of the treatment time.

Figure 4—5: Start/Stop Selection

4.3.6 Ultrasound Output Intensity

After starting treatment, select “Intensity” of the ultrasound by pressing the Select button.

Use selector arrows (4—3 on page **Error! Bookmark not defined.**) to set the desired intensity level. See below for recommended settings. The factory default display of ultrasound power is expressed in Watts/cm^2.

Figure 4—6: Ultrasound Power Selection

The ultrasound power can also be expressed in Temporal Average Watts/cm^2.

4.3.6.1 Adjustment of Ultrasound Power after Start of Treatment

Intensity can be increased or decreased only during a treatment. Time can be adjusted during treatment or when a treatment is paused.

4.3.7 End of Treatment

After the treatment is finished, take the retainer ring off of the applicator and clean the applicator. Alcohol or soap & water are the recommended cleaning substances. Abrasive cleaners **should not** be used on the applicator or generator. You may damage the ultrasound applicator and damage the finish on the generator.

4.4 Additional Setup for Optional Hands-Free Operation

CAUTION

Operator must remain in the room with the patient at all times during hands-free operation.

Place the weight bag or velcro strap **around** the applicator, as pictured in Figure 4—15, to create good contact between the applicator and the patient. Do not place the weight bag on the coaxial connection (see Figure 4—11). The connection may fail or break if the weight bag is placed on the coaxial connection.

Figure 4—11: Keep off area for weight bag

4.4.1 Maximum Ultrasound Intensity Settings For Hands-Free Operation

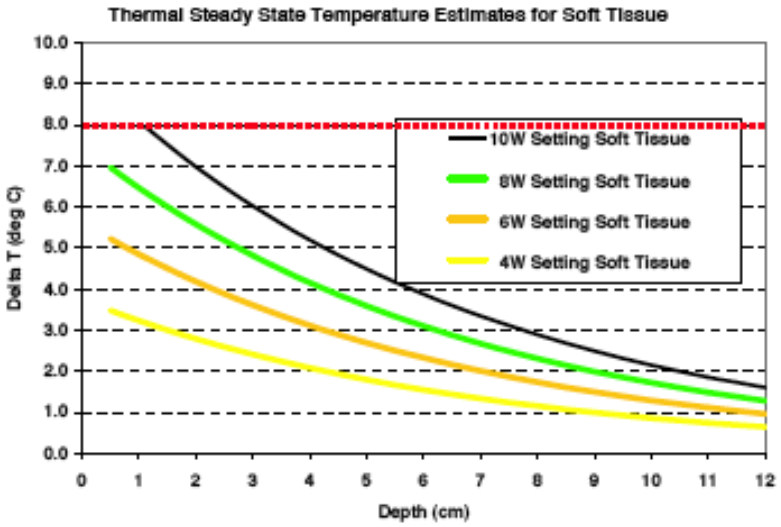


Figure 4—12: Thermal Steady State Estimates for Soft Tissues for Hands-Free Operation
Thermal Steady State Estimates for bone absorption

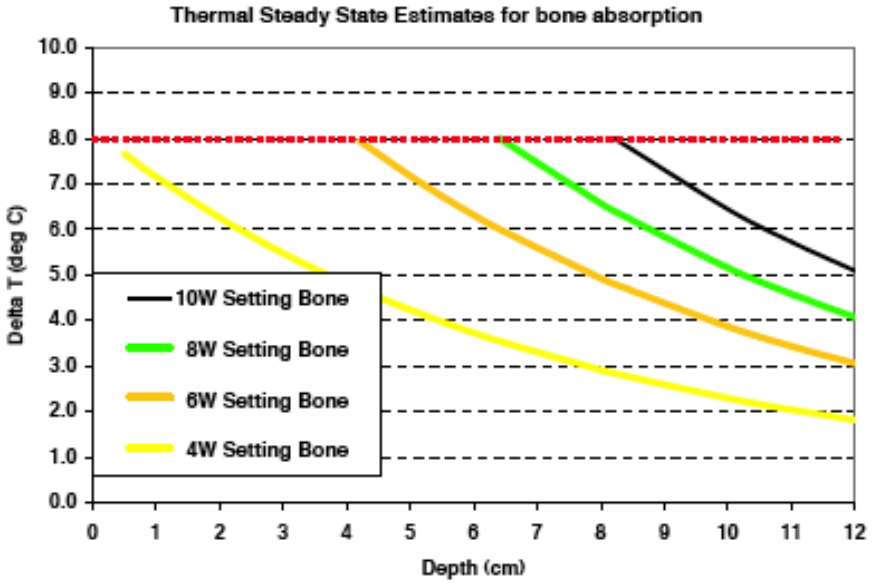


Figure 4—13: Thermal Steady State Estimates for Bone Heating for Hands-Free Operation

4.4.2 Regions of the Body Suitable for Hands-Free Operation

NOTE: Constant attendance is advisable as defined as “verbal, visual or manual” (per ACA, AMA)

Table 4—1: Key to colors in Figure 4—14 below

Color	Output Recommendation	Soft Tissue Depth Over Bone
Black Outline (Buttocks Region only)	Up to 10W or 0.36 W/cm2	Depth Must be Over 8.2cm or 3.25 inches
Green	Up to 8W or 0.25W/cm2	Depth Must be Over 6.4cm or 2.52 inches
Skin Color	Up to 6W or 0.19W/cm2	Depth Must be Over 4.2cm or 1.65 inches
Yellow (Bottom of Foot or Ankle)	Up to 4W or 0.13W/cm2	Depth Must be Over 0.2cm or .08 inches
Red	Can not use the system in stationary (hands-free) mode (see note below)	

NOTE: ***Areas in red have either bone very close to the surface or they are near or over areas such as eye, ear, transcerebrally, carotid sinus, heart, subcutaneous nerves and blood vessels, spinal cord, bulbar area of the spinal cord, reproductive organs, viscera (stomach, spleen, liver) stellate ganglion and subcutaneous major nerves.***

Thus, those regions of the patient's body which may be expected to have at least 8.2cm of soft tissue overlying bone, the system may be used in stationary mode up to the full setting of 10W ($0.31W/cm^2$). For regions of the body where the patient is expected to have at least 6.4cm of soft tissue overlying bone, the system may be used in stationary mode up to a setting of 8W or less (up to $0.25W/cm^2$). Where it is expected to have only 4.2 cm of overlying tissue, the recommendation is to limit the device to 6W ($0.19W/cm^2$). With an output setting of 4W ($0.13W/cm^2$), the system may be used on the bottom of the foot or ankle. The red portions have either bone very close to the surface or other reasons for precluding the use of stationary ultrasound.

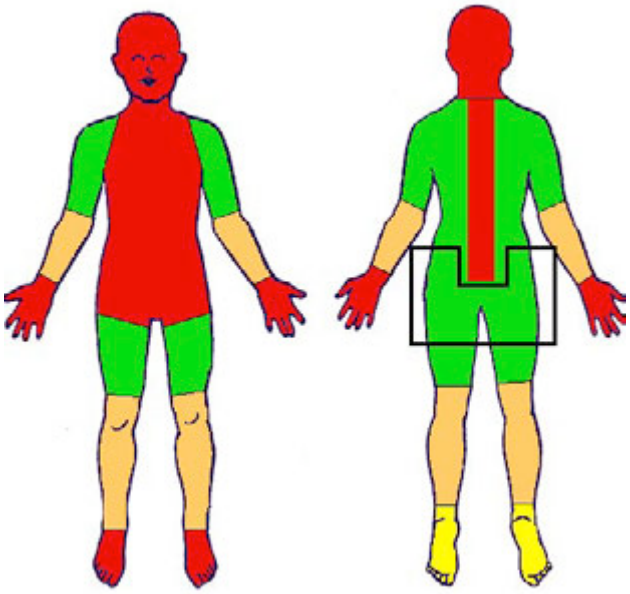


Figure 4—14: Treatment zones when using Optional Hands-free operation. Figure 4—15: Ultrasound Application examples

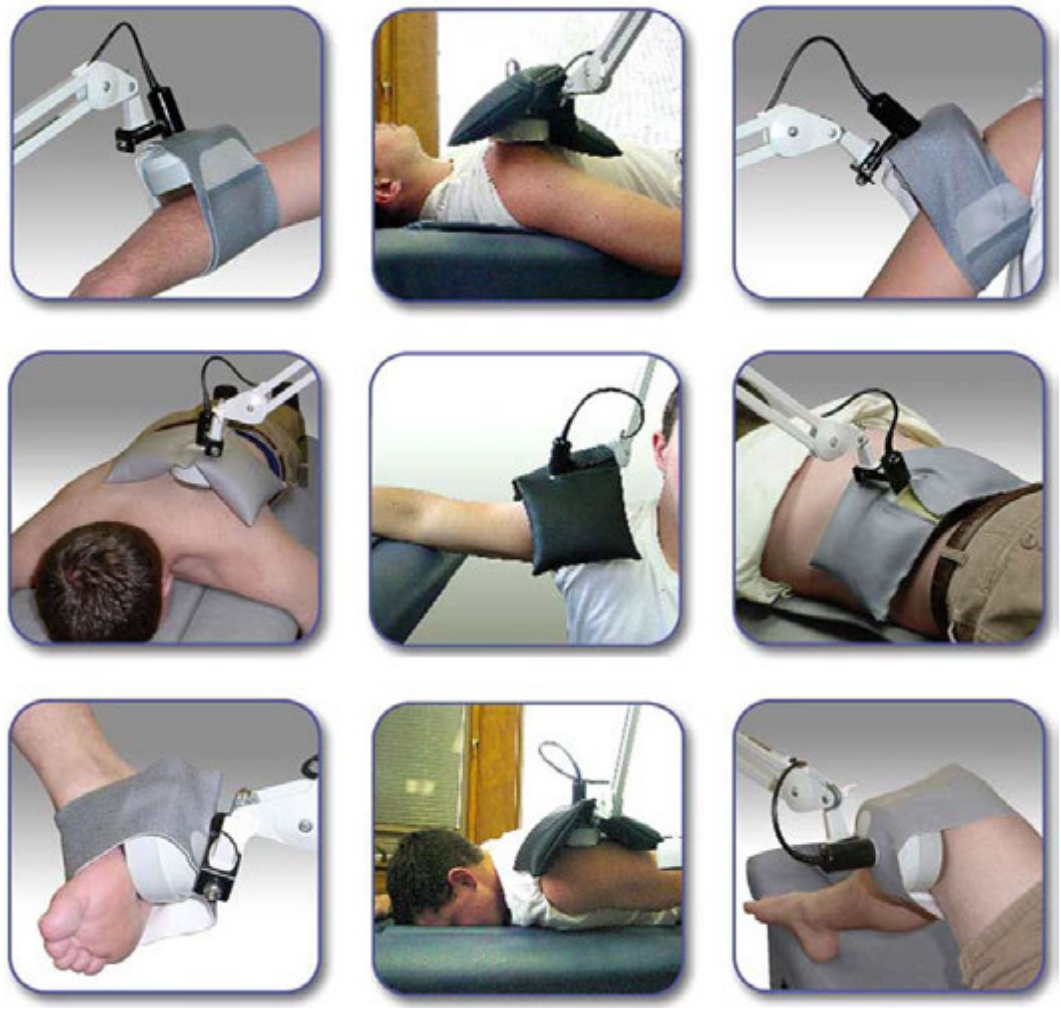


Figure 4—15 Ultrasound Application Examples

5.0 Interferential and Premodulated Treatment

Interferential therapy uses a four-electrode application. These four electrodes deliver two currents. One frequency at a constant 4,000Hz and the other current is a variable frequency of 4,001Hz to 4,150Hz. When these two paths cross they result in a "beat frequency". This "beat frequency" produces a beat which is between 1 and 150Hz which results in a lowered skin resistance (impedance) thus it is more comfortable and a more tolerable penetration into the skin compared to low frequency currents.

Six frequency setting ranges are possible:

- P1: Acute pain - 150 Hz and 80 Hz
- P2: Chronic pain - 50 Hz and 1 Hz
- P3: Edema 1 - 10 Hz and 0 Hz
- P4: Edema 2 - 150 Hz and 1 Hz
- P5: Nerve Block - 250 Hz and 1 Hz
- Custom (Display reads "CUSt"): 1 Hz - 250 Hz

Premodulated therapy uses a two-electrodes. Application can be applied through channel 1, channel 2, or both. The current is a composite waveform using two frequencies similar to interferential. The two frequencies are mixed inside the HF54 and the output waveform is present on two of the electrode leads rather than the four in interferential mode.

Premodulated therapy is used when the application area is smaller and interferential cannot be used.

5.1 Prior to Using Interferential and Premodulated Current Therapy

MANDATORY INSTRUCTIONS: READ SECTION 2.2 BEFORE SETTING UP THE INTERFERENTIAL OR PREMOD THERAPY

5.1.1 Electrodes

It is recommended that the disposable self-adhesive electrodes supplied by Hill Laboratories be used with the HF54. We do not recommend using foil-backed electrodes or rubber electrodes. The metal foil can cause changes in the waveform and the resistance of the rubber electrodes is extremely variable. If the self-adhesive pads lose their adhesive and conductive properties discard the pads and replace them with new electrodes from Hill Laboratories (**available at shop.hilllabs.com**)

The disposable self-adhesive electrodes may be reused by placing them back on the original backing sheet but we advise that the electrodes only be used with the same patient and not for use with different patients. Each patient should have their own electrodes for treatment. This minimizes the likelihood of cross-contamination of patients that may have skin disorders or diseases that are communicable.

5.2 Interferential and Premod Operation

5.2.1 Connect Patient Switch

Plug the Patient Switch into the rear port (see “1” on page 26). The Patient Switch (or “Cut-off” switch) should be used at all times during treatments. The patient should be given the Patient Switch and instructed to press the button if he/she feels any pain or discomfort. If the Patient Switch is pressed, the stimulation will shut off immediately and the generator will emit one long beep. Press the Start/Stop button to restart.

5.2.2 Turning on power to HF54

Turn on the main power switch located left side of the generator (See “10” on page 26

NOTE: ***The generator should be turned off at the end of business hours or when not in use for several hours.***

Figure 5—1: Control Panel

5.2.3 Setting time

Set the duration of the treatment by pressing the “Select” button (see Figure 5—2) below the Time LED.

Figure 5—2: Time selector button

Use arrow buttons to increase or decrease the time.

5.2.3.1 Adjustment of time after start of treatment

During treatment, you can adjust the time at any point by using the selector arrows (see section 5.2.3. Time can also be adjusted by pressing the Pause/Resume button then using the selector arrows to adjust.

5.2.4 Select Interferential or Premodulated Current

Select Quadripolar or Premodulated current by pressing the IFC button. Press the IFC button until the required mode is lit. Both channels (channel 1 and channel 2) are active in any IFC or Premod mode. Only channel 1 is active in combo.

If Interferential (IFC) is selected, both channels on the IFC control area will light up. Similarly, if Premodulated (Premod) current is selected both channels will light up.

5.2.5 Frequency Range Select

5.2.5.1 Default settings for IFC and Premod

- P1: Acute pain - 150 Hz and 80 Hz
- P2: Chronic pain - 50 Hz and 1 Hz
- P3: Edema 1 - 10 Hz and 0 Hz
- P4: Edema 2 - 150 Hz and 1 Hz
- P5: Nerve Block - 250 Hz and 1 Hz
- Custom (Display reads “CUSt”): 1 Hz - 250 Hz
-

5.2.6 Starting IFC or Premod Treatment

To START, press the Start/Stop button. The time will start at the designated level and decrease to zero. No intensity will be felt until the step in 5.2.7 is taken.

Figure 5—3: Start/Stop Selection

5.2.7 Setting IFC or Premod Intensity

Press the Select button and use the selector arrows to increase the intensity to the desired amount.

Note: Intensities can only be changed *during* a treatment.

Figure 5—4: Electrotherapy Intensity

5.2.8 Stopping Treatment

At any time the operator can stop the treatment by pressing the Start/Stop button. The treatment can also be paused by pressing the Pause/Resume button.

The timer will automatically turn the instrument off at the end of the treatment time.

5.2.9 Changing Time, Intensity or Frequencies During Treatment

Intensity can be increased or decreased only during a treatment. Time can be adjusted during treatment or when a treatment is paused.

5.3 Examples of Electrode Placement

5.3.1 Interferential Electrode Placement [1]

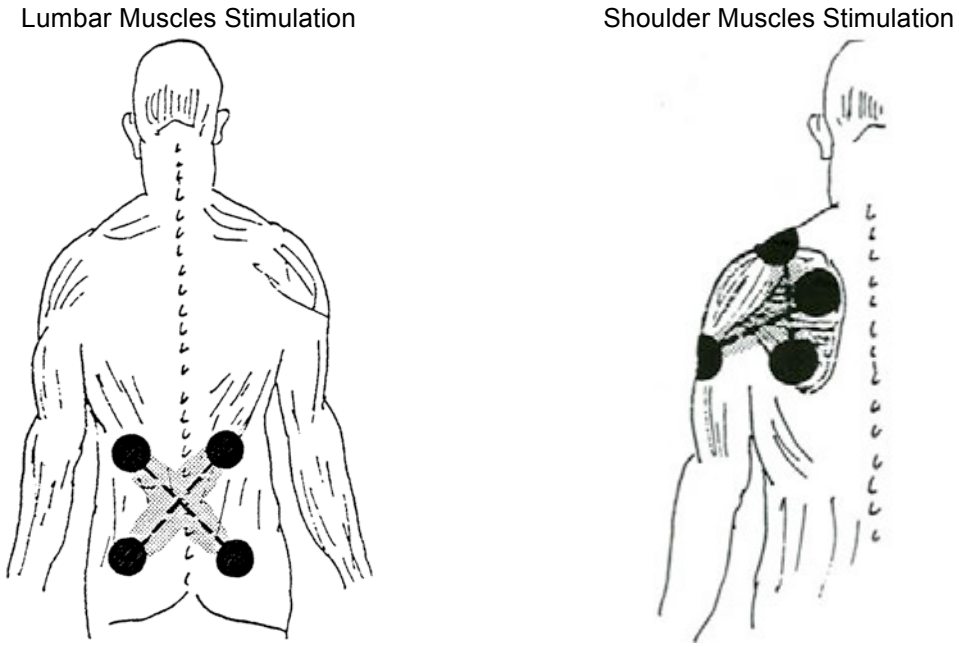


Figure 5—5: Electrode placement for upper body

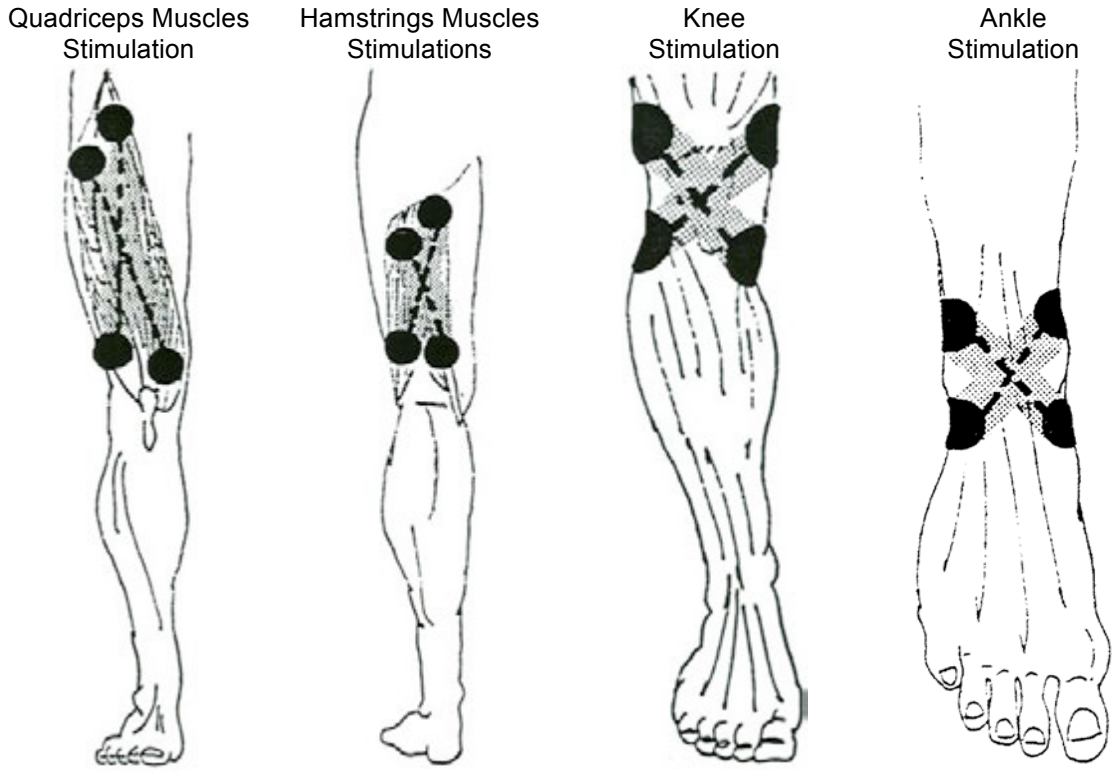


Figure 5—6: Electrode placement for leg and ankle

[1] By permission from LSI International

6.0 Operating Ultrasound and Premod in Combination

MANDATORY INSTRUCTIONS: READ SECTION 2.5 BEFORE SETTING UP COMBINATION THERAPY

The HF54 is designed so that Premod can be used in combination with ultrasound with one, two or both applicators. Premod current can be delivered directly between the applicator and 1 or 2 (with splitter) electrodes connected to channel 1.

Caution

In some patients, the sensitivity to electrical stimulation increases when used in combination with Ultrasound. The exact mechanism for this increase in sensitivity is not fully understood but sufficient cases have been seen to warrant this caution.

6.1 Principle of Combination Therapy

In Combination mode (COMBO 1) using 1, 2 or both soundhead(s), the treatment surface of the ultrasound becomes the return path for the Electrotherapy Current. Only one active channel (channel 1) is available in combination therapy mode. The red lead of the patient is placed opposite (or at an angle) to the ultrasound head. The ultrasound head(s) are secured in place as normal. If both heads are used, the red lead wire on the first channel will be split in two using supplied splitter and 2 electrodes.

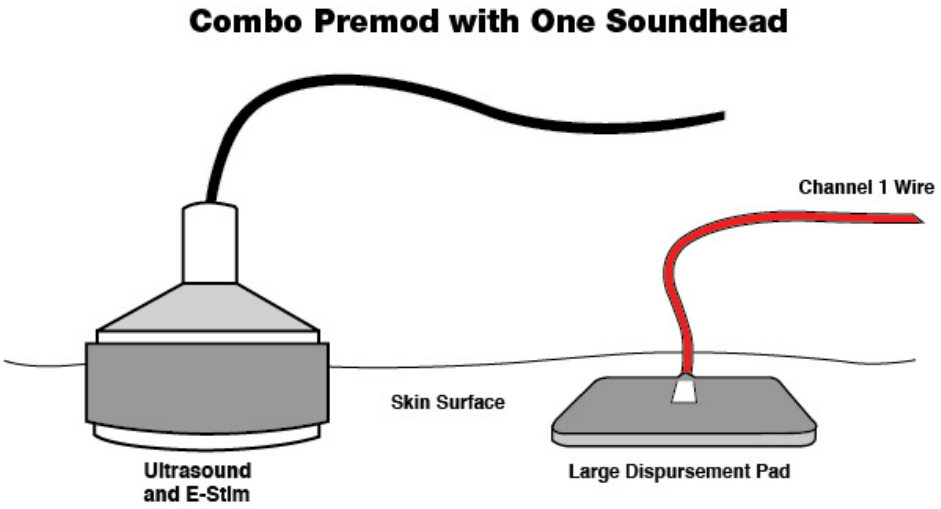


Figure 6—1: Combination Therapy Mode

6.2 Patient Set Up for Single Applicator with Premod – Combo 1

With one applicator , choose HF Head 1. During a regular Premod treatment, 2 pads are required. In Combo 1 with 1 applicator, the soundhead will act as one electrode and the red lead wire with electrode from the first channel will act as the second electrode. Premod output in combo mode is only available on channel 1.

A minimum of 4 inch electrode or optional carbon pad should be used. If a smaller electrode were used, a higher concentration of stimulation would be felt through the pad resulting in a very uncomfortable treatment.

Review of set-up:
***Always turn power on before attaching applicator or electrodes.**

1. Applicator 1 or 2 will be producing Premod and ultrasound.
2. The red lead wire from the first channel is the active (hot) ground pad.
3. 4” or larger pad is required for the red lead wire.

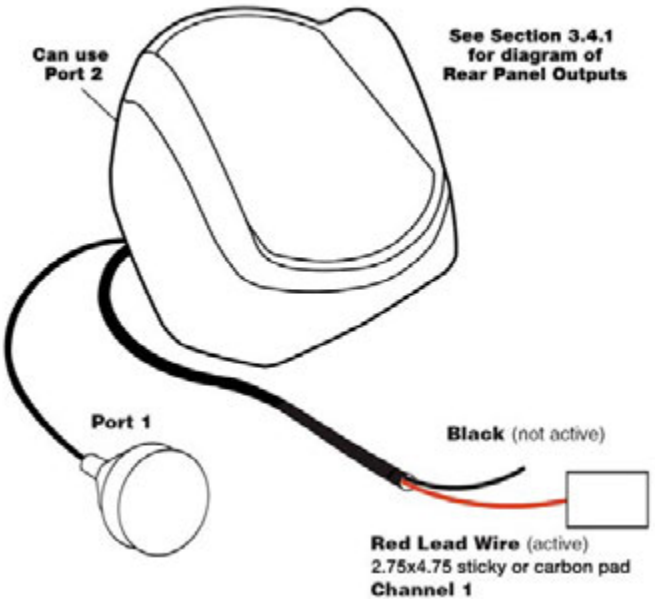


Figure 6—1: Connecting for Combination premod and ultrasound with one applicator

6.2.1 Connect the cut-off switch

Plug the cut-off switch into the back port. The cut-off switch should be used at all times. The patient should be given the cut-off switch and instructed to press the button if he/she feels any pain or discomfort. If the cut-off switch is pressed, the ultrasound and/or stimulation will be shut off and the generator will beep until the operator presses the Start/Stop button.

6.2.2 Turn on the power to the HF54

Turn on the main power switch located on the back of the generator, **NOTE:** ***The generator should be turned off at the end of business hours or when not in use for several hours.***

6.2.3 Setting Time

Set the duration of the treatment by pressing the “Select” button to select the Time LED, then press the arrow buttons to select the desired treatment duration.

Figure 6—2: Setting Time of Combo Treatment

6.2.3.1 Adjustment of time after start of treatment

When time has been started, it can be adjusted during treatment or by pressing the Pause/Resume button then using the arrows to adjust.

6.2.4 Select Single Applicator with Premod Operation – Combo On

1. Select the Combo button
2. Premod will automatically light up.

6.2.5 Starting Combo Treatment

To START, press the Start/Stop button. The time will start at the designated level and decrease to zero.

6.2.6 Setting Ultrasound Intensity

Select the intensity of the ultrasound by pressing the Select button under ULTRASOUND till the Intensity LED is lit. Use the arrows to set Intensity level.

6.2.7 Setting Premod Intensity

Set Premod intensity by pressing the Select button under ESTIM CHANNEL1 till the Intensity LED is lit. Use the arrows to set Intensity level.

6.2.8 Stopping Treatment

At any time the operator can stop the treatment by pressing the Start/Stop button. The treatment can also be paused by pressing the Pause/Resume button.

The timer will automatically turn the instrument off at the end of the treatment time.

6.2.9 End of Treatment

After the treatment is finished, take the retainer ring off of the applicator and clean the applicator. Alcohol, soap & water are the recommended cleaning substances. Abrasive cleaners **should not** be used on the applicator or generator. You may damage the ultrasound applicator and damage the finish on the generator.

6.3 Patient Set Up for Both Applicators with Premod

During a regular Premod treatment, 2 pads are required. In Combo mode with 2 applicators, choose HF Head1 and HF Head2. Both applicators act as one electrode and the spilt off red lead wire with a minimum of 2.75x4.75" electrodes from channel 1 act as the second electrode. Premod output in combo mode is only available on channel 1.

A minimum of a 2.75x4.75" electrode or optional carbon pad should be used. If a smaller electrode were used, a higher concentration of stimulation would be felt through the pad resulting in a very uncomfortable treatment.

NOTE: You cannot change the intensity of the two soundheads to different settings. *Both soundheads I and 2 and the muscle stim will have the same intensities.*

CAUTION

When using both ultrasound applicators in combination 1, the red lead wire from channel one need to use the splitter lead with 2 electrodes 2.75x4.75" electrodes.

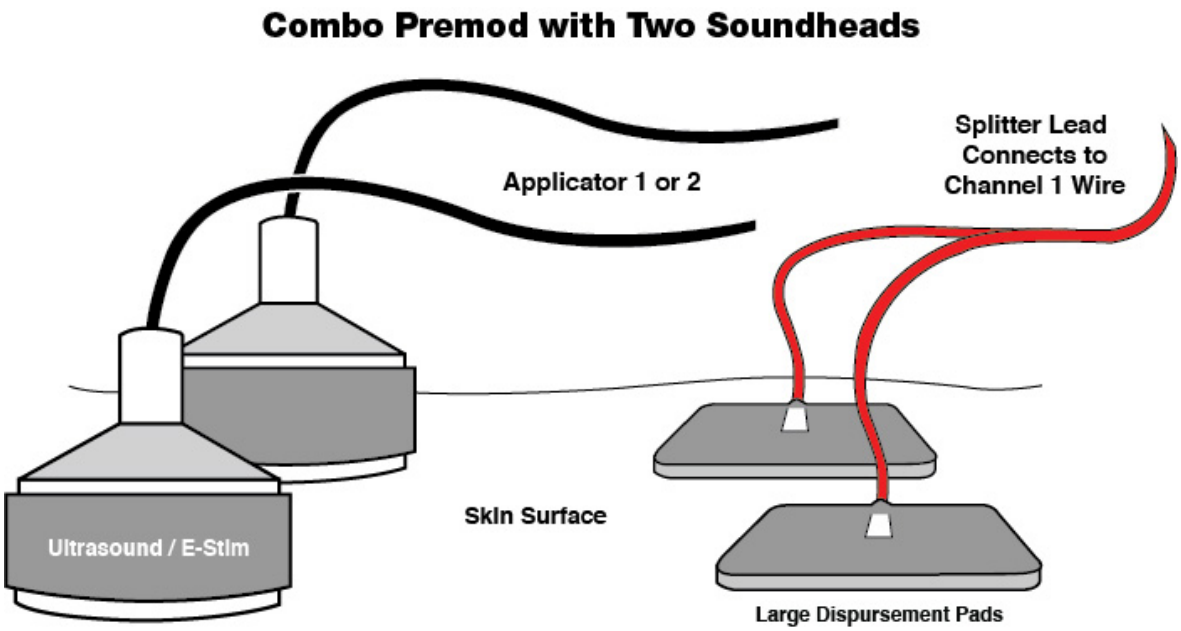


Figure 6—6: Connecting for Combination premod and ultrasound with two applicators

6.3.1 Starting Combo 2 Treatment

To START, press the Start/Stop button. The time will start at the designated level and decrease to zero.

6.3.2 Setting Ultrasound Intesity

Select the intensity of the ultrasound by pressing the Select button under ULTRASOUND till the Intensity LED is lit. Use the arrows to set Intensity level.

6.3.3 Setting Premod Intensity

Set Premod intensity by pressing the Select button under ESTIM CHANNEL1 till the Intensity LED is lit. Use the arrows to set Intensity level.

6.3.4 Stopping Treatment

At any time the operator can stop the treatment by pressing the Start/Stop button. The treatment can also be paused by pressing the Pause/Save button.

The timer will automatically turn the instrument off at the end of the treatment time.

6.3.5 End of Treatment

After the treatment is finished, take the retainer ring off of the applicators and clean the applicators. Alcohol, soap & water are the recommended cleaning substances. Abrasive cleaners **should not** be used on the applicators or generator. You may damage the ultrasound applicators and damage the finish on the generator.

7.0 Operating in PREMOD, RUSSIAN AND TENS

Premod, Russian and TENS can all be administered through Channel 1, Channel 2, or both. To treat one area, select Channel 1 and “Premod” (or Russian or TENS). Using two 2” pads, select Time and then press Start. Increase Intensity to desired setting.

If an additional treatment area is required, select Channel 2; set Time and then press Start. Increase Intensity under Channel 2. Channel 1 and Channel 2, while working simultaneously, may have two different settings for Time and Intensity.

IMPORTANT: To make changes or to stop/pause either treatment, be sure you are in the corresponding channel.

8.0 INFRARED LIGHT THERAPY

	**MANDATORY INSTRUCTIONS: READ SECTION 2.4 BEFORE SETTING UP THE INFRA RED THERAPY**

8.1 Background

The HF023 IR Light Therapy applicator plugs directly into the HF54 Plus Unit

Hill Laboratories HF023 IR Light Therapy is generated by an infrared and red light therapy applicator. It contains 36 Infrared LED’s and 7 Visible Red LED’s. The diameter of the LED cluster is approximately 2 inches.

You cannot see the IR LEDs because they are in the infrared spectrum (880 nm), which is not visible to the human eye. You can see the visible red LEDs which operate at 660 nm which is in the visible light spectrum.

8.2 Patient Setup

8.2.1 When treating an acute or chronic non-wound condition:

1. Use alcohol or an alcohol wipe to prepare the treatment site.
2. Treat with direct contact.

8.2.2 General Setup

1. Turn on the main power switch located on the left side of the HF54 generator.
2. Plug the Light Probe into the back of the HF54 generator port (see “5” on diagram, page 26).
3. The HF023 Light Probe is operated by pushing the buttons on the probe itself and not by the HF54 generator. All of the timing circuitry and on/off control for the output are within the handle of the light probe.

8.3 Operating the HF023 IR Light Probe

8.3.1 Setting Time

1. The probe is operated continuously at one power level and can be set to 4 different time levels: 30, 60, 90 seconds or Continuous (for Continuous, press “Select” four times till all lights are lit). Operator must press Start/Stop to end a Continuous treatment.

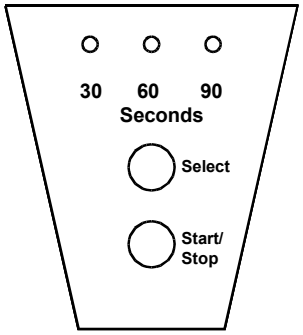


Table 8—1: IR Light Therapy Applicator Controls

2. Use the Select button to select a 30, 60, 90 or continuous treatment.
3. Press the Start/Stop button to begin the treatment.
4. Press the Start/Stop a second time if you want to stop the treatment.
5. Keep the probe in one location at a time. Do not move or “bathe” the treatment area.

   If the treatment area is larger than the probe (2 inches), treat one area at a time until the entire area is covered.
6. After treatment is complete, use an alcohol wipe to clean the glass surface of the LED cluster. Do not use any abrasive cleaning substance. See cleaning instructions.

8.3.2 Timing and Recommended Dose

Dosage: Every 90 Seconds produces slightly less than 4 Joule/cm^2

- Minimum Tissue to Bone Depth: 90 - 270 Seconds per area until entire injury is covered
- Deeper Musculoskeletal: 180 - 360 Seconds per area until entire injury is covered

9.0 Technical Information

9.1 FDA Compliance

The HF54 complies with 21 CFR 1050:

Pursuant to FDA 21CFR 1050.10(f)(1), the uncertainties in magnitude, expressed in percentage error, of the ultrasonic frequency, effective radiating area, and the ratio of the temporal-maximum to temporal-average effective intensity, pulse duration, and pulse repetition rate for the HF54 are as follows:

Table 9—1: F.D.A. Required Information

Ultrasonic Frequency	1 MHz ± 1%
Percent Error of Ultrasonic Frequency	< ± 5%
Percent Error of Effective Radiating Area	< ± 40%
Percent Error of Ratio of Temporal-Maximum to Temporal-Average Effective Intensity	± 3%
Percent Error of Pulse Duration	< 3%
Percent Error in Indication of Radiated Power	< + 20%

The following abbreviations are used on the applicator labels:

Table 9—2: Abbreviations Used on Applicator Labels

GEN	Generator
f	Ultrasonic frequency
AREA	Effective Radiating Area
BNR	Beam Nonuniformity Ratio
Type: COLL	Type of applicator is collimating

9.2 Technical Specifications HF54

9.2.1 Acceptable Operating Conditions:

a) ambient temperature range + 10 °C to + 45 °C.

b) relative humidity range 30 % to 85 %.

c) atmospheric pressure range 700 hPa to 1,070 hPa sea level to 3,000 ft

9.2.2 Transport and Storage Conditions

a) temperature range -10 °C to +55 °C

b) relative humidity range 10 % to 90% non condensing

c) atmospheric pressure range 600 hPa to 1200 hPa -100 feet to 37,000 feet

9.2.3 General and Ultrasound Specifications

Table 9—3: Approximate Dimensions and Weight

	Height	Width	Depth	Weight
HF 54 Generator	6” (15 cm)	12” (30 cm)	10.5” (26 cm)	≤ 8.5 lb (2 kg)
Ultrasound Applicator	2.5” (6.25 cm)	3.625” (9.1 cm)	3.625” (9.1 cm)	≤ 1 lb (0.45 kg)
Infra Red Applicator	8.15” (20.4 cm)	1.25” to 2.128” (3 cm to 5.3 cm)	2.8678” (7.2 cm)	≤ 0.55 lb (0.25 kg)
Cart	31” (77.5 cm)	24” (60 cm)	17” (42.5 cm)	≤ 10 lb (4 kg)

Table 9—4: General and Ultrasound Specifications

Operating Voltage:	115 volts, 60 Hz A.C. single phase (220 volt 50/60 Hz model also available)
Fuse:	F2AL250V
Ultrasonic Frequency:	0.96 MHz ± 100 kHz
Ultrasonic Pulse Rate:	60 Hz
Ultrasound Pulse Duration:	7.6 milliseconds
Ultrasound Wave Form:	Amplitude modulated, sinusoidal
Peak Pulse Intensity:	5.4 times average
BNR:.....	≤ 6 (typical between 4.8 and 5)
ERA:.....	32 cm^2 ± 3 cm^2 (Limits 30 cm^2 to 34 cm^2)

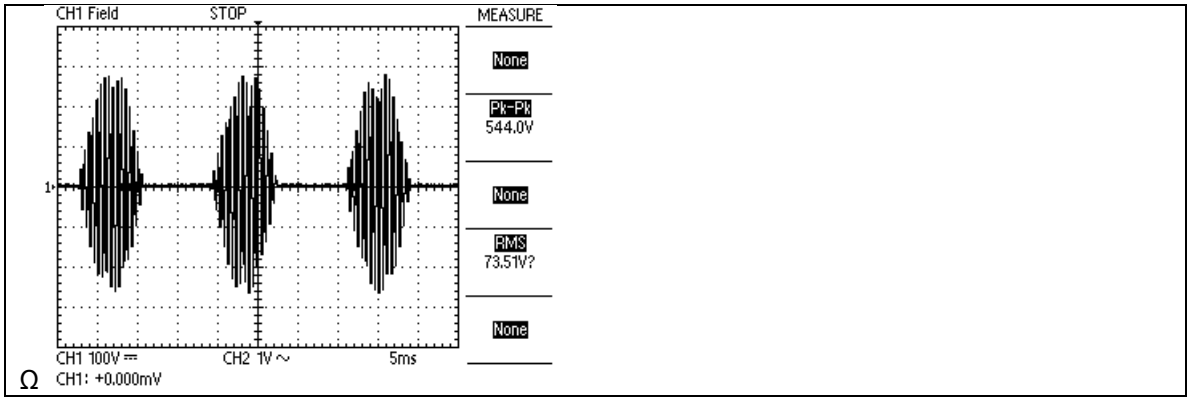


Figure 9—1: Ultrasound Waveform Coupled onto the surface of a water bath (*not immersed*)

The amplitude modulated waveform from the ultrasound looks like the waveform in Figure 9—1. The amplitude will depend on the intensity setting on the HF54 generator. Because of the coupling gel pad that is used with the HF54 Ultrasound Applicator, and the thickness of the transducer surface, there is no discernable difference between the waveform on tissue or off.

9.2.4 Interferential/Premodulated Therapy Specifications:

Table 9—5: Interferential/Premodulated Therapy Specifications

Waveform Type:.....	4000 Hz sine wave frequency modulated by a 4000 to 4150 Hz variable frequency sine wave of equal amplitudes
Frequency Accuracy:	± 1% at any frequency (frequency error governed by microcontroller DAC accuracy – 10 Bit)
Sweep Rate:	1 Hz / 200 mS
Maximum Pk Voltage:	75V (either positive or negative)
Maximum Current into 500 Ω:.....	100 mA RMS, Accuracy ± 5%
Maximum inter-channel difference	≤ 1 mA at max intensity into 500 ohms.

9.2.4.1 Interferential Waveforms

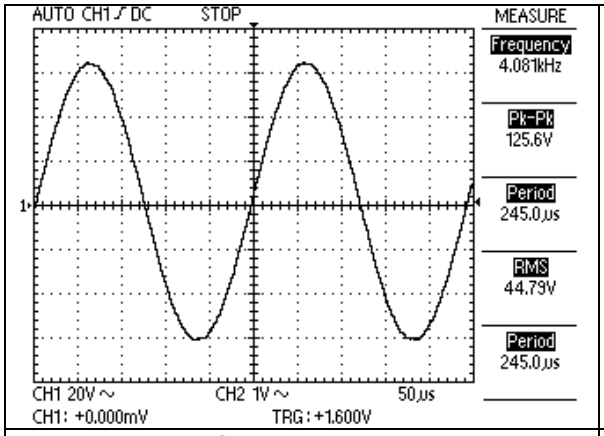


Figure 9—2: Channel 1 output into 500 Ω

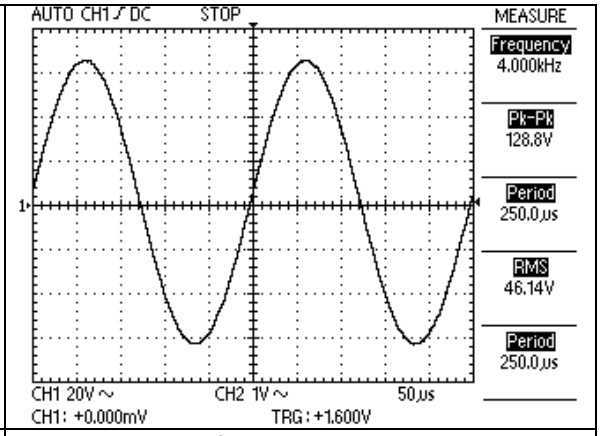


Figure 9—3: Channel 2 output into 500 Ω

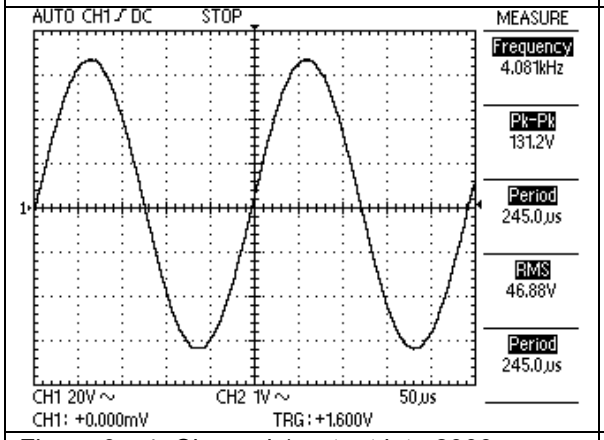


Figure 9—4: Channel 1 output into 2000 Ω

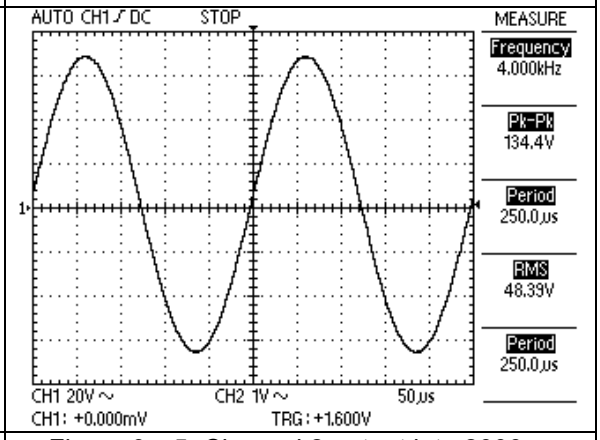


Figure 9—5: Channel 2 output into 2000 Ω

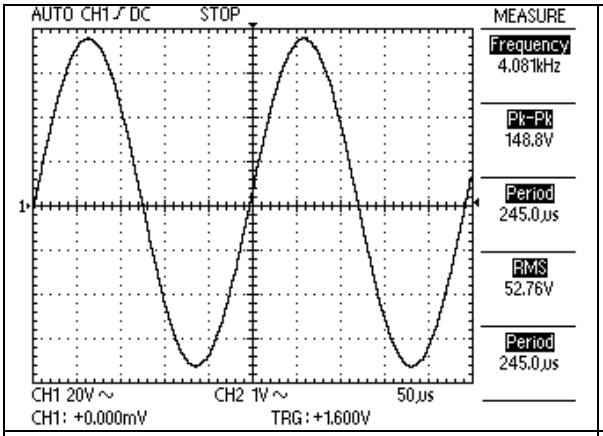


Figure 9—6: Channel 1 output into 10000 Ω

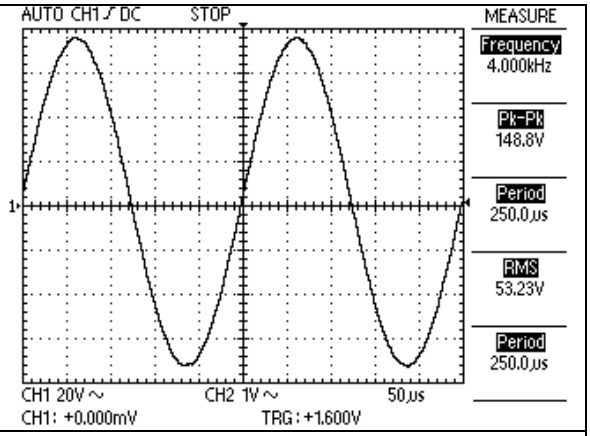


Figure 9—7: Channel 2 Output into 10000 Ω

9.2.4.2 Premodulated Current Waveforms

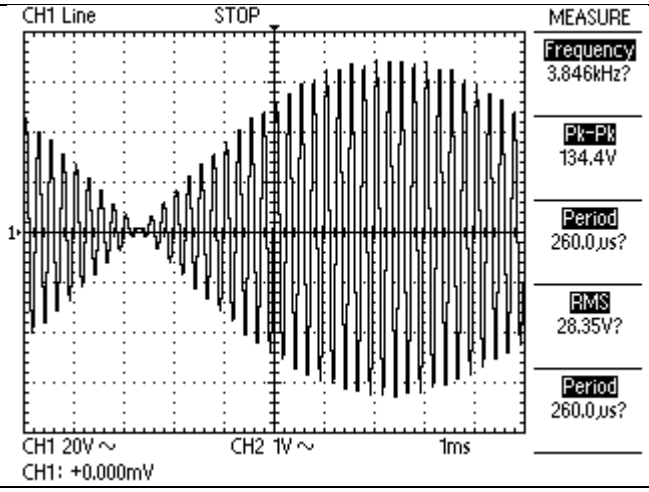


Figure 9—8: Channel 1 output into 500 Ω

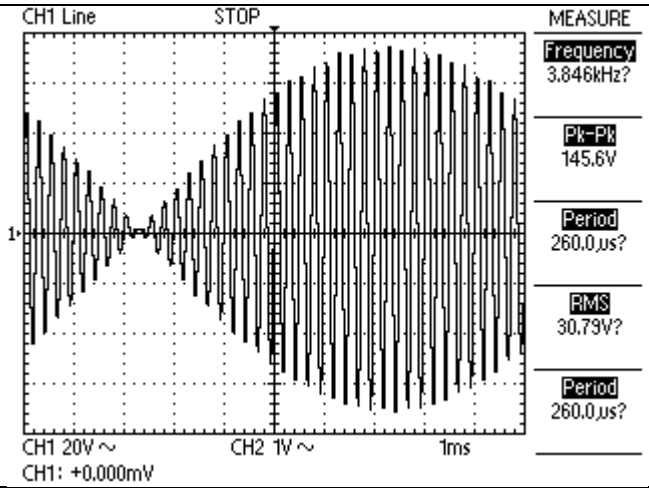


Figure 9—9: Channel 1 output into 2000 Ω

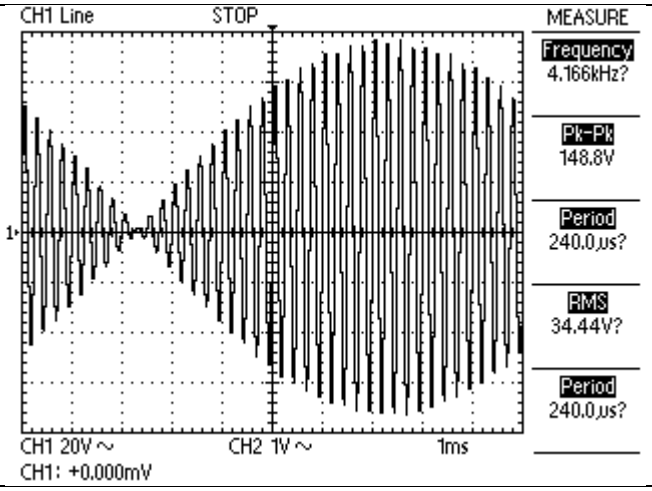


Figure 9—10: Channel 1 output into 10000 Ω

9.2.5 HF 023 IR Light Probe

Table 9—6: IR Light Probe Specifications

Input Voltage:	5 V d.c. (regulated)
Input Voltage Stability:	± 0.1 V
Output Light Energy:	Every second, the cluster's output is 50 mW/cm^2 (50 mJ/cm^2).
Total light output (mW).....	800 mW
Timer:	Continuous, 30, 60 and 90 Seconds
Timer Accuracy:	± 0.001 second
IR LED Wavelength	880 nm
Visible Red LED Wavelength:	660 nm

9.2.6 Compatibility Standards

9.2.6.1 Electromagnetic Compatibility

Table 9—7: Electromagnetic Compatibility Standards Complied With

IEC 60601-1-2: 2001.....	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-2: 2001.....	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

9.2.6.2 Electrical safety

Table 9—8: Electrical Safety Standards Complied With

IEC 60601-1: 1988 +A1, +A2:	Medical Electrical Equipment- Part 1: General Requirements for Safety
UL 60601-1: 2003:	Medical Electrical Equipment- Part 1: General Requirements for Safety
CAN/CSA 22.2 No. 601.1(M90): .	Medical Electrical Equipment- Part 1: General Requirements for Safety
EN 60601-1: 1990 +A1, +A2, +A13:.....	Medical Electrical Equipment- Part 1: General Requirements for Safety

IEC 60601-2-5:.....	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
EN 60601-2-5:.....	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
IEC 60601-2-10:.....	Medical electrical equipment. Part 2: Particular requirements for the safety of nerve and muscle stimulators
EN60601-2-10:.....	Medical electrical equipment. Part 2: Particular requirements for the safety of nerve and muscle stimulators
21 CFR 898:.....	Leadwires

9.3 Audio Tones

9.3.1 Sound Frequency

All the sound frequencies shall be 2.4 kHz. This frequency has been chosen because of the "annoying" characteristics of 2.4 kHz. It is therefore one of the most noticeable frequencies for tones.

9.3.2 Sound Characteristics

9.3.2.1 Key Pressed Sound

When any of the buttons on the keypad are pressed the tone shall be a "beep" lasting 40 ms each time a button is pressed.

9.3.2.2 Error Sound

Error sound shall be 40 ms ON, 40 ms OFF, repeated 3 times

9.3.2.3 Store settings

Store sound shall be a single tone lasting 400 ms.

9.3.2.4 Treatment Timer Timeout (Treatment done)

Treatment done sound is 1400 ms ON, 1400 ms OFF, 3 times

10.0 Equipment Use and Care

10.1 Use and Care of the HF54 Generator

When not in use, and especially at the end of the day, switch the HF54 generator off using the switch on the left side of the Generator.

Do not use the power cord as a means to disconnect power to the HF54 Generator. This will eventually damage the power cord and require replacement. With proper care, the power cord should give many years of service.

There are maintenance tasks that need to be performed at the correct intervals to assure continued safe and proper functioning of the HF54 and its accessories.

10.2 Use and Care of Self-Adhesive Electrodes

Hill Laboratories recommends using a 2" self-adhesive electrode with the HF54 for premod and interferential.

A 2.75x4.75" self- adhesive electrode is recommended when Premod is used in combination with ultrasound.

Hill Laboratories electrodes are intended for multiple usages when used appropriately. Improper use of the electrodes can decrease the life of the electrode and could even result in harm to your

patient. The following instructions will help you achieve maximum usage from your electrodes while ensuring patient safety and comfort during treatment.

1. Make sure the electrode is adhering and making contact with the skin across the entire surface of the electrode. Electrodes will lose their adhesive quality when exposed to air, dust, dry skin, etc. To retain adhesiveness, electrodes should be stored in a tightly sealed pouch until used. The patient's skin should be clean and free from oils or flakiness.

   To restore adhesiveness:

   - **Before a treatment**: Before placing the electrode on the patient, moisten the patient's skin with a damp cloth using plain water, and then apply the electrode to the skin.
   - **After a treatment**: Spray the adhesive side of the electrode with plain water, rub it lightly with fingertips, then reapply the electrode to its plastic backing and seal it tightly in its storage pouch. Do not use an electrolyte spray to remoisten self-adhesive electrodes as this substance can destroy the adhesive.

   With this method of re-hydration, after a couple of hours electrodes can regain up to 90% of their original adhesive quality.

2. **NEVER** use a self-adhesive electrode for more than 15 treatments (maximum).

3. **NEVER** use straps, weights, or other devices to attach self-adhesive electrodes to the skin. If an electrode has lost its adhesive quality, you can use one of the methods given above to re-hydrate the adhesive, or you should discard the electrode. Using straps and weights with self-adhesive electrodes discard the electrode. Using straps and weights with self-adhesive electrodes could have an unpredictable effect on the electrodes and could cause injury.

10.3 Use and Care of Carbon Electrodes

Carbon electrodes provide an economical means of delivering electrotherapy to patients. This type of electrode lasts a long time and can be used again and again. However, if they are not properly cared for, these electrodes can fail to deliver the desired treatment and can present the possibility for injury to the patient.

To ensure greatest safely and effectiveness with your treatments, follow these rules when using carbon electrodes:

1. **Carbon electrodes must be well-moistened prior to treatment setup**. Dry carbon electrodes are very poor conductors of current and should never be used. They may be moistened with either water or an electrolyte spray. Water is adequate for short treatments, but will evaporate too quickly for longer treatments. If water is used for longer treatments, you may need to interrupt the treatment and remoisten the electrodes. A special sponge fabric available with some carbon electrodes may be moistened well and used as a conductive medium (do not use ordinary sponges for this purpose).

   Do not use ultrasound gel as a conductive agent with carbon electrodes.

   If you use an electrolyte spray, this liquid may be diluted with equal amounts of distilled water, if desired. This reduces the amount of build-up on the electrodes yet usually provides adequate moistening of the electrodes.

   Trim (don't shave) body hair where electrodes are going to be applied.

   Clean skin before and after applying electrodes.

   NOTE: ***As you increase the intensity to higher levels during setup, if your patient feels a "biting" sensation or if the patient feels nothing, this indicates you are not getting adequate conductivity – the electrode may be too dry or is not moistened evenly across its entire surface. Stop the setup and correct the problem.***

2. **Carbon electrodes must be free from any build-up**. If electrodes have a buildup from body oils or a moistening agent such as an electrolyte spray, conductivity is greatly impaired. If treatment is allowed to continue, intensity could be inhibited.

When using carbon electrodes with any electrotherapy device, you must make sure conductivity is not impaired due to any type of build-up on the electrodes.

Clean carbon electrodes with soap and water. Daily cleaning is recommended.

3. **Carbon electrodes do eventually wear out**. Do not assume you can safely use carbon electrodes indefinitely. Over time these electrodes will wear and deteriorate; and when worn, the amount of current delivered through the electrode will decrease and will be inconsistent over the surface of the electrode.

   As a general rule, carbon electrodes that are used regularly should be replaced at least every six months.

10.4 Use and Care of Lead Wires

Even with good care, lead wires will eventually develop breaks (open connections) simply from normal usage, and they must be replaced.

Lead wires have a limited lifetime and must be replaced about every six months. Lead wires can be damaged due to jerking or pulling on the wires, excessive bending or tight wrapping of the wires, or running over the wire with a device cart.

When setting up treatments, keep lead wires out of areas where a person could trip on them.

When storing, the lead wires should be loosely wrapped to prevent any kinking in the wire. Do not wind the lead wires tightly. Never use worn or damaged leads to treat a patient. Using faulty leads may result in injury to a patient.

Inspect lead wires daily. Check for corrosion on lead tips. If corrosion is present they should be cleaned with steel wool to remove corrosion. Do not scratch the metal plating off the tip. If tip becomes scratched or shows signs of pitting, replace the lead wires. If the lead wires pass visual inspection and no CODE 1 error occurs during operation, the lead wires are safe to use.

Cleaning leadwires with mild soap and water will prevent them from becoming brittle.

10.5 Use and Care of Ultrasound Applicators

Applicators should be inspected on a daily basis. User should:

- Inspect applicator for cracks, which could allow the ingress of conductive fluid.
- Inspect and applicator for a buildup of dried conductive fluid.
- Clean the applicator after every use.

10.5.1 Calibration and Coupling

Do not allow the applicator to operate for an extended time when it is exposed only to air, as the applicator will become hot. Ultrasound is not easily transmitted through the air and, when exposed only to air, the energy is trapped in the applicator and converted to heat. This heat can make the applicator hot and affect the calibration. Under severe misuse conditions, the applicator can inflict burns on a patient. Always turn off the applicator when not in use.

Improper use of the coupling medium or allowing air between the applicator and the surface being treated can affect the calibration.

Only HF54 applicators provided by Hill Laboratories can be used with the HF54 generator. Two Applicators can be used simultaneously with the HF54. They can be used interchangeably and are self-calibrating to match the unit.

10.6 Use and Care of your HF023 IR Light Probe

The IR Light probe requires no calibration but its light output and lifetime can be negatively affected by dirt or dust build-up on the glass lens of the applicator and dust build up in the ventilation holes in the applicator.

Always place the light therapy applicator gently back into its holder on the back of the cart, when not in use. Never place the applicator onto a surface when it is still running. Press the Start/Stop button to switch off the applicator.

Do not use polishes or waxes on or near the glass lens. These will block the proper transmission of IR light and cause reflection back into the light chamber leading to excessive heating of the applicator.

11.0 Equipment Checks

11.1 Checking the HF54 Generator

Turn on the main power switch located on the left side of the generator.

11.2 Checking Ultrasound Applicators

Check each ultrasound applicator to make sure it is functioning properly. Turn the applicator upside down so it is facing the ceiling. Spray the applicator with a thin coating of water and turn the ultrasound power to its maximum intensity setting. The water on the applicator will show signs of vibration. If no vibration is detected, see troubleshooting section.

11.3 Cut-off switch Checks

Connect the ultrasound applicator No. 1 and power up the HF54 Generator. Spray a little water on the surface of the applicator and then press the patient cut-out switch. The generator should immediately turn off the applicator and sound the alarm. If the equipment does not operate correctly, call for assistance immediately.

11.4 Other Accessory Checks

Ultrasound coaxial cables and IR light therapy cables and connectors must be visually inspected on a daily basis. Damage can be caused by jerking or pulling on the wires, excessive bending or tight wrapping of the wires, or running over the wire with a device cart. When setting up treatments, keep wires out of areas where a person could stand or trip on them. When storing, wires should be loosely wrapped to prevent any kinking in the wire.

12.0 Cleaning and Disinfecting Instructions

12.1 General

It is essential to keep the HF54 and its associated accessories clean and free from dust, dirt and lint. All of these can impair the function of the HF54 or its accessories. For example if the generator is not cleaned regularly, dirt, fungal spores and bacteria can build up or form on the surfaces of the generator meaning that each time you touch the generator and then the accessories, these can be cross contaminated.

Some simple definitions will illustrate the differences between clean and disinfected:

Cleaned	means the absence of visible dirt and contaminants. It does not mean that the equipment is disinfected.
Disinfected	means the reduction of viable organisms on the surfaces of materials to a level that is unlikely to contaminate intact skin or other materials.
Sterilized	means one viable organism in every 100,000,000 ($1{:}10^{-8}$). ***Note that the HF 54 and its accessories cannot be sterilized without causing severe and irreversible damage. It is not necessary to sterilize the equipment or its accessories since the electrodes and ultrasound applicators are for use on intact skin only and the IR Light Therapy applicator is not intended to come into contact with open wounds.***

It is possible to have something that is disinfected but not “Clean”. For example, if a 2% Sodium Hypochlorite Solution is used to clean the surface of the generator, the bleach within it will probably kill most of the bacteria but does not mean that if the surface is covered with dust and grime it will clean it.

CAUTION

Before cleaning or disinfecting your HF54 or its accessories, always turn off power to the equipment and disconnect the plug from the outlet (prevents accidentally turning the equipment on). Always clean or disinfect the HF54 and its accessories in a well ventilated area.

Only use the materials identified in this section. These materials have been tested with the equipment and found to be compatible with long-term use.

12.2 Surface cleaning and disinfection

For cleaning of the surfaces, the following table provides a guide:

Table 12—1: Cleaning Matrix

	General Cleaning Agent	Cleaner for stubborn Stains	Disinfecting Agent
Cart Top	Furniture Polish (e.g. pledge) applied with a dry lint-free cloth	Non-abrasive All purpose surface cleaner	70% Isopropyl Alcohol or Milton Fluid(2)
Cart Base	Furniture Polish (e.g. pledge) applied with a dry lint-free cloth	Non-abrasive All purpose surface cleaner	70% Isopropyl Alcohol or Milton Fluid(2)
HF54 enclosure	Isopropyl Alcohol impregnated wipes	Non-abrasive All purpose surface cleaner(3)	70% Isopropyl Alcohol or denatured alcohol
Flexible Arm for Ultrasound Applicators	Non-abrasive All purpose surface cleaner	Window cleaner with Ammonia D	70% Isopropyl Alcohol
Ultrasound Applicators treatment surface	Window cleaner with Ammonia D(4)	Denatured alcohol	70% Isopropyl Alcohol
Ultrasound Applicators body	Furniture Polish (e.g. pledge) applied with a dry lint-free cloth(5)	Window cleaner with Ammonia D	70% Isopropyl Alcohol or denatured alcohol
Power Cord	PVC Cleaner	Non-abrasive All purpose surface cleaner followed by PVC Cleaner	Denatured alcohol followed by PVC Cleaner
Patient Leads	PVC Cleaner	Non-abrasive All purpose surface cleaner followed by PVC Cleaner	Denatured alcohol followed by PVC Cleaner
Carbon Electrodes	16 oz Water + 1 oz pinesol	Denatured alcohol	70% Isopropyl Alcohol or Milton Fluid(2)
IR Light Therapy Applicator Body	Pledge applied with a lint-free cloth(6)	Non-abrasive All purpose surface cleaner(7)	70% Isopropyl Alcohol

2 Where body fluids have been in contact with the part

3 Do not apply as a spray near or over ventilation openings. Use a lint-free cloth and spray the cleaning fluid onto the cloth. Do not apply such that the cloth is soaked otherwise fluid will enter through ventilation openings or joins in the enclosure.

4 Do not apply such that the cloth is soaked otherwise fluid will enter through openings in the enclosure and attack the seals.

5 Do not get the polish onto the treatment surface of the ultrasound applicator.

6 Do not get the polish onto the glass surface of the IR Therapy applicator.

IR Light Therapy Applicator Glass	Isopropyl Alcohol impregnated wipes	Window cleaner with Ammonia D	70% Isopropyl Alcohol
Spray Bottle	Rinse the inside with Milton fluid	Clean the outside of the bottle with non-abrasive All purpose surface cleaner	70% Isopropyl Alcohol
PVC Tray	PVC Cleaner or furniture Polish (e.g. pledge) applied with a dry lint-free cloth	Non-abrasive All purpose surface cleaner followed by PVC Cleaner	Denatured alcohol followed by PVC Cleaner

Milton fluid Active ingredients: Sodium hypochlorite 2% w/w, Sodium chloride 16.5% w/w., this will make a disinfectant solution added to one pint of water.

Note: ***Heavy dust deposits are best removed with a vacuum cleaner first.***

13.0 Equipment Maintenance

13.1 Daily Maintenance

Keep the generator clean and dry. If there are any spills of liquid onto the generator, wipe the liquid off immediately. Ingress of liquids into the HF54 Generator may cause damage and equipment failure. Clean the generator at the end of each day following the instructions

Moisture-related failure voids the warranty.

The ultrasound applicator should be wiped and cleaned after every patient. Follow the instructions for cleaning the ultrasound applicators.

Empty the spray bottle and follow the cleaning instructions (this prevents mold or bacteria in the water). When refilling the bottle at the beginning of the day, it is good practice to add 15 ml of Milton fluid (see cleaning instructions) to each pint of water. This keeps the water sanitary all day. To ensure that the spray nozzle and tube are disinfected, after refilling the bottle with Milton fluid, pump the spray a few times into a cloth to ensure the bottle contents have passed through the tube and nozzle.

Empty any liquid in the tray on the cart and clean the cart top and the tray in accordance with the cleaning instructions. Ensure that the cart top is dry before replacing the tray (prevents build-up of mold).

Clean the cart base

Untangle any cords or leadwires that may have got wrapped around the cart base and follow the cleaning instructions for the cords. See also care instructions for leadwires in Section 10.4.

13.2 Weekly Maintenance

Inspect the power cord for the HF54 for nicks, cuts and abrasions to the insulation. If you can see the wires through the outer sheath, the power cord has been compromised and requires replacement.

Inspect accessories daily for wear and damage. Examine leadwires and their connectors for any visible sign of wear or damage.

Inspect the air vent in the back of the generator and ensure that it is not blocked.

Replace accessories as needed.

Check the function of the HF54 in accordance with Section 11.1.

13.3 Monthly Maintenance

Check the casters on the base of the cart are not loose and that they rotate freely and are free from dirt and strands of hair, string or other materials that may be wrapped around the hub of the casters.

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7 Do not apply as a spray near or over ventilation openings. Use a lint-free cloth and spray the cleaning fluid onto the cloth. Do not apply such that the cloth is soaked otherwise fluid will enter through ventilation openings or joins in the enclosure.

Failure to check the casters can increase the risk of the cart overbalancing because of extra effort needed to make it move.

Check the ultrasound transducers in accordance with Section 11.2

Replace self-adhesive electrodes after one month or less than 15 uses whichever comes first. Note: self adhesive electrodes pick up dead skin cells, mold spores, hair and dirt and lose their adhesive properties. Failure to replace the electrodes regularly may lead to infection of skin and burns.

Check the cut-off switch in accordance with Section 11.3.

13.4 Quarterly Maintenance

- Replace all used self-adhesive electrodes. The electrode adhesive probably has a high bioburden on them at this point.

Test leads and carbon electrodes.

Turn the generator on and press the ON/OFF switch to see if it cuts off the power.

13.5 Six-Monthly Maintenance

Every 6 months:

Test leadwires and carbon electrodes.

Leadwire resistance should be less than 10% above mean cable resistance. Greater values indicate breakage of strands within the lead and the leads should be replaced.

Frequently used carbon electrodes should be replaced every six months.

13.6 Yearly Maintenance

Every 12 months, maintenance should be performed by an Authorized Service Agent:

Check the calibration of the HF54 and the applicator(s). If the equipment is out of calibration, the applicator and generator should be returned to the factory for recalibration.

Inspect applicator, wire and connector.

Check output voltage and current.

14.0 Service

If the applicator is dropped, sustains damage due to lightning, severe power surge, or submerged in water, it must be examined by the factory or authorized technician.

14.1 User Replaceable Parts

There are no user replaceable parts inside the HF54 Generator or Applicators. Opening the HF54 voids all warranties.

15.0 Troubleshooting Guide

Table 15—1: Troubleshooting matrix

Error Code	*Problem*	*Problem Cause and Action Required*
E010, E015, E016, E022, E023, E024, E025	**General problem with device**	• Restart the device and if the problem is not solved, call for assistance;
E020, E021	**Problem with 24VDC power supply;**	• Check the AC/DC adapter, DC jack contact or use the fresh one; • If the problem is not solved, call for assistance;
E030, E040	**Problem with EEPROM memory**	• Device detected some problem with built-in EEPROM memory and it will be recovered automatically; • If the problem is happening frequently, call for assistance;

E100 … E115	**Problem with ESTIM Channel #1 Generator**	• Device detected some problem with ESTIM Channel #1; • Restart the device in order to the device will try to automatically recover the full functionality of system; • If the problem is happening frequently, call for assistance;
E116, E117	**Extra low or extra high temperature of ESTIM Channel #1 amplifier section**	• Device detected extra low (E116) or extra high (E117) temperature of ESTIM Channel #1 amplifier section; • Switch off the device and take the rest of ~30min in order to device will be adjusted on ambient temperature. • If the problem is not solved or if it is happening frequently, call for assistance;
E120 … E135	**Problem with ESTIM Channel #2 Generator**	• Device detected some problem with ESTIM Channel #2; • Restart the device in order to the device will try to automatically recover the full functionality of system; • If the problem is happening frequently, call for assistance;
E136, E137	**Extra low or extra high temperature of ESTIM Channel #2 amplifier section**	• Device detected extra low (E136) or extra high (E137) temperature of ESTIM Channel #2 amplifier section; • Switch off the device and take the rest of ~30min in order to device will be adjusted on ambient temperature. • If the problem is not solved or if it is happening frequently, call for assistance;
E406, E412	**Problem with HF Ultrasound Applicator on Channel #1 (A)**	• Device detected some problem with HF Ultrasound Applicator installed on Channel #1 (A); • Double check the connection of HF Ultrasound Applicator on Channel #1 (A); • If the problem is not solved, take the rest of ~30min in order to cooling down the Applicator; • Restart the treatment; • If the problem is not solved or if it is happening frequently, change the HF Ultrasound Applicator installed on Channel #1 (A) with fresh one; • If the problem is not solved, call for assistance;
E407, E413	**Problem with HF Ultrasound Applicator on Channel #2 (B)**	• Device detected some problem with HF Ultrasound Applicator installed on Channel #2 (B); • Double check the connection of HF Ultrasound Applicator on Channel #2 (B); • If the problem is not solved, take the rest of ~30min in order to cooling down the Applicator; • Restart the treatment; • If the problem is not solved or if it is happening frequently, change the HF Ultrasound Applicator installed on Channel #2 (B) with fresh one; • If the problem is not solved, call for assistance;
E409	**Over-temperature condition of amplifier section in HF Ultrasound Generator**	• Device detected that the HF Ultrasound Generator has the over-temperature condition; • Stop the treatment on HF Ultrasound channel and take the rest of ~30min in order to cooling down the generator section; • Restart the treatment; • If the problem is not solved or if it is happening frequently, call for assistance;
E408, E410, E411, E420, E421, E422, E423, E424	**Problem with HF Ultrasound Generator**	• Device detected some problem with HF Ultrasound Generator. • Restart the device in order to the device will try to automatically recover the full functionality of this part of system; • If the problem is not solved or if it is happening frequently, call for assistance;
E441	**HF Ultrasound is not ready**	• Device detected this problem when the user started the treatment on HF Ultrasound channel and when the HF Ultrasound is not ready or if the applicator is not plugged. This indication covers the problem on both HF Ultrasound channels. • Double check that the HF Ultrasound Applicator is properly connected with device; • If the problem is not solved or if it is happening frequently, change the HF Ultrasound Applicator with fresh one; • If the problem is not solved after the applicator is changed, call for assistance;

E500, E501, E502	**Not proper conditions for COMBO mode**	• System detected that the user is forcing to start COMBO mode when there are no proper conditions for COMBO mode. • Please, follow the instructions for select and start the COMBO mode.
E200, E218, E219, E220, E221, E222, E223, E224, E230, E241	**Problem with Standard Ultrasound Generator**	• Device detected some problem with Standard Ultrasound Generator. • Restart the device in order to the device will try to automatically recover the full functionality of system; • If the problem is not solved or if it is happening frequently, call for assistance;
E201	**Standard Ultrasound Applicator is not installed or Applicator is unplugged during the treatment**	• Device detected that the Standard Ultrasound Applicator is unplugged; • Stop the treatment and provide the proper connection of Standard Ultrasound Applicator and device; • Restart the treatment; • If the problem is not solved or if it is happening frequently, call for assistance;
E204	**Over-temperature condition for Standard Ultrasound Applicator Piezo (transducer)**	• Device detected that the Standard Ultrasound Applicator has the over-temperature condition of piezo / transducer section; • Stop the treatment on Standard Ultrasound channel and take the rest of ~10min in order to cooling down the piezo / transducer; • Restart the treatment; • If the problem is not solved or if it is happening frequently, change the Standard Ultrasound Applicator with fresh one; • If the problem is not solved with fresh applicator, call for assistance;
E203, E205, E206, E207, E212, E213, E214, E216,	**Problem with Standard Ultrasound Applicator**	• Device detected some problem with Standard Ultrasound Applicator which can be critical for regular using of applicator; • Change the Standard Ultrasound Applicator with fresh one; • If the problem is not solved, call for assistance;
E215	**Over-temperature condition of amplifier section in Standard Ultrasound Generator**	• Device detected that the Standard Ultrasound Generator has the over-temperature condition; • Stop the treatment on Standard Ultrasound channel and take the rest of ~30min in order to cooling down the generator section; • Restart the treatment; • If the problem is not solved or if it is happening frequently, call for assistance;
LED assigned to Standard Ultrasound is blinking (this is E240 but there is no error code indication on display)	**Standard Ultrasound is not ready**	• This state indicates that the Standard is not ready to start the treatment due to many reasons (applicator is not plugged, some recovery state, cooling down of device …). This state is indicated through The LED assigned to Standard Ultrasound which will blinking when the Standard Ultrasound is selected as the USG output. • Double check the connection of Standard Ultrasound Applicator with device; • If the problem is not solved, take the rest of ~30min in order to cooling down the generator section; • Restart the treatment; • If the problem is not solved or if it is happening frequently, call for assistance;

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