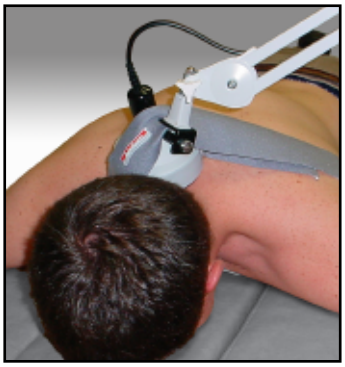
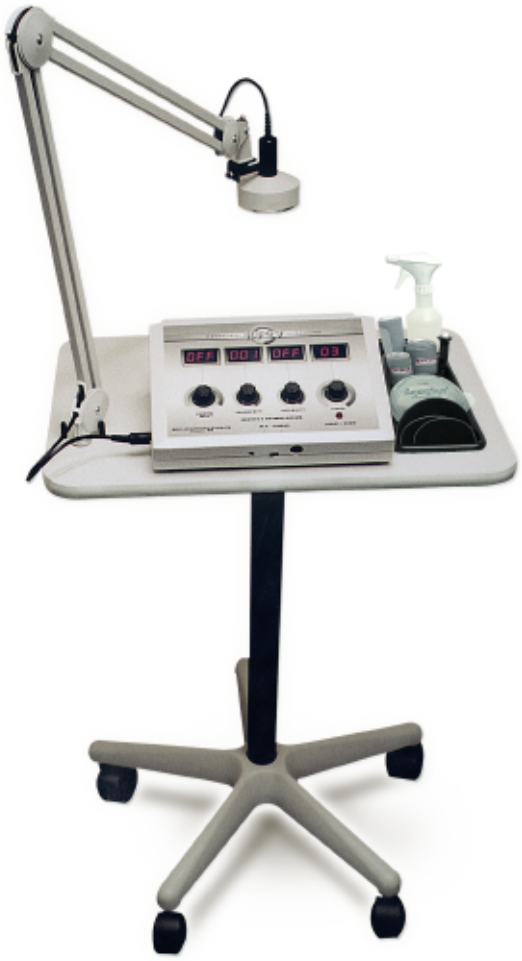
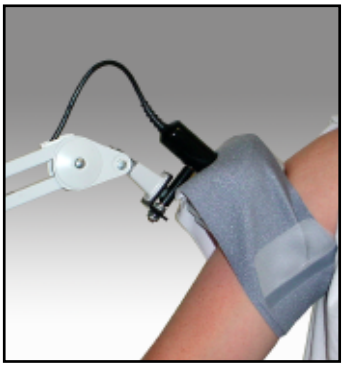
HANDS-FREE HF27 ULTRASOUND

Operator's Manual







Manufactured for

Hill Laboratories COMPANY

Exclusive Distributor

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Table of Contents

Standard Parts List - HF27 Ultrasound Unit

Part	Description	Quantity
1	Table Top-Gray	1
2	Black Stool Post	1
3	Bolts 1/4-20x 3/4Long	4
4	Stool Base (5 Star- Black)	1
5	Stool Base Caster (Gray)	5
6	1/2” SAE Flat Washer	1
7	Swing Arm Assembly with Soundhead	1
8	Utility Tray (Black)	1
9	Muscle Stimulation Wires	1
10	3” Diameter Carbon Flex Electrode	2
11	4” Diameter Carbon Flex Electrode	1
12	Patient Cut-off Switch	1
13	HF27 Ultrasound Card	1
14	12’ Connecting Cord	1
15	Straps	2
16	Retaining Ring	1
17	Gel Pad	1
18	Weight Bag	1
19	DVD	1
20	Spray Bottle	1

HANDS-FREE HF27 ULTRASOUND

Assembly Instructions for the HF-27 Ultrasound Unit

1. Unpack all items being especially careful with the handling of the swing arm assembly (part 07) and the Ultrasound unit (part 13). These items are sophisticated medical equipment and should be handled accordingly.

2. Lay tabletop (part 01) on floor with finished gray side facing down.

3. Place stool post (part 02) in center of table top. Line-up the four holes on the stool post with the four holes on the table top. Place washers on four bolts (part 03) and screw in bolts using a 7/16" wrench.

4. Insert the casters (part 05) into the 5 holes in the stool base arms. This can be accomplished easily by hand. Test stool base to determine if casters are seated properly.

5. Place stool post (part 02) into stool base (part 04).

6. Turn the table right side up and place the black utility tray (part 08) into the precut hole in the table top.

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

8. Place unit on the table top. Make sure the back of the unit is on the same side as the attached cord. Plug in cord.

CAUTION: Spring arm assembly is spring loaded

9. Insert the swing arm post into the steel washer and white plastic shoulder washer. If the unit is facing the assembler, the swing arm should extend out in the opposite direction as pictured below. Plug soundhead cord into unit. The HF27 is now ready to operate.

WARRANTY

From date of sale, the HF27 is sold with a 1-year warranty on the power supply, a 2-year warranty on the soundhead and a 90-day warranty on the accessory parts. The HF27 is warranted to be free from defects in material and workmanship. We agree to repair, at the point of manufacture, without charge, all parts showing such defects, provided the unit is delivered to us, intact for our examination, with all transportation charges prepaid, and provided such examination discloses in our final judgment that the unit is defective.

This warranty does not apply 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 is expressly in lieu of 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 we neither assume for us 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. We make no warranty whatsoever in respect to accessories or parts not supplied by us.

RETURN OF GOODS

To return the unit, you will be issued a return authorization number and an address of where to send the unit for repair. Pack it in the original carton or a heavy carton with bubble wrap or foam padding, insure for full amount and prepay freight. The HF27 must be accompanied with a written summary of the problem, name, address, and phone number. We will repair the unit promptly and return it freight collect.

UNPACKING YOUR HF27

IMPORTANT: When you first remove your ultrasound unit from its shipping box, please check the serialnumber labels on the HF27 Unit and the HF27 Soundhead Arm to be sure that they match. Each unit is calibrated to operate properly only when matched with its appropriate counterpart. If you own more than one HF27 Unit, *Do not use the base unit with a soundhead labelled with a different serial number.* (see pgs. 1 - 2 for Parts List and Assebly Instructions)

INTRODUCTION

The Hands-Free 27 is an updated version of the ultrasound sold for many years by the R. J. Lindquist Company. Although the appearance has changed, the ultrasound retains its proven reliability and function.

The construction of the Hands-Free 27 consists of a 65 cm^2 soundhead with multiple crystals that deliver a large coverage area of ultrasound in a safe and effective manner. The ultrasound frequency is approximately 1Mhz-60 cycles pulsed at 50%. It is mainly designed for the paravertebral and other large body masses such as the legs and buttocks.

ULTRASOUND ENERGY

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 sound in tissue may produce a small amount of heat.

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 HF27 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 applied to the body in therapeutic dosage increases cellular metabolism. The mechanical motion also makes ultrasound effective for decongestion and for breaking up stasis.

Ultrasound can also be used for phonophoresis. Medication applied externally can be driven into the skin and localized areas of soft tissue in small amounts with the application of ultrasound.

It is not only the effect of ultrasonic energy that makes it effective for therapy, but also its ability to be controlled. Ultrasound is propagated through tissue and bone to an appreciable depth. It can also be beamed and directed through tissue to reach almost any selected part in the body with full therapeutic intensity.

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.

Ultrasonic energy in established therapeutic dosage works on the cell body without destructive effects. There is also no build-up of effect over time between treatments. In competent hands and in conservative dosages, ultrasound is a safe therapeutic energy, perhaps one of the safest energies at our command. This has been convincingly established by the vast literature available, the years of experience of clinical investigators, and intense scientific research.

Extensive experimental and clinical investigations have also established the value of ultrasound as an adjunct to physical therapy for the human body. As with other types of physical energy, safe and effective therapeutic results require the therapist supervising the treatment to be thoroughly grounded in the fundamentals of theory and technique.

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 a soundhead, 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. The theory behind the pulsed energy is that the alternating on and off pulses prevent undue heat buildup and permit longer treatments without patient discomfort.

Ultrasound can travel through solids and liquids but cannot penetrate air or a vacuum. When the soundhead is

applied in direct contact with the body, the gel pad, a thin layer of gel, liquid, or emulsion is needed between the body and the soundhead for "coupling". The soundhead must be coupled to the body at all times during treatment because the slightest layer of air will prevent transmission of energy. Water can also be used as a coupling medium by immersing both the part to be treated and the soundhead in water.

PRIOR to USING THE ULTRASOUND

1. Plug the ultrasound into cord attached to the tabletop.

2. The plug coming from the cart outlet should be plugged into a 115V-60HZ grounded wall outlet. (The ultrasound may be ordered to operate at 220V-50/60HZ if needed.)

3. Plug the soundhead cable into the side of the unit.

4. Plug the cut-off switch into the frontal port. When not in use, this switch can be left attached and the button stored in the storage tray.

SOUNDHEAD SETTINGS

The ultrasound calibration readout is based on an effective radiating area (ERA) of 32 cm^2. The soundhead is 65 cm^2 and the ultrasound is experienced throughout the whole surface mass of the soundhead. The following are the settings on the ultrasound:

Total Watts (temporal avg.)	.3	.65	1.25	2.25	4.75	7.0	9.25
Readout Watts per cm^2	.01	.02	.04	.07	.15	.22	.29

Based on ERA

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 (most often in temporal-average) 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" is all that should be experienced by the patient. At some prescribed treatment levels, the patient will have no sensation at all.

ULTRASOUND INDICATIONS

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.

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 be limited as follows: The use of ultrasonic energy in therapy should not be considered as specific treatment for any disease. If applied properly and safely, it may be a useful adjunct in producing relief from such symptoms as pain, soreness, and tenderness associated with:

1. Non-specific types of bursitis, periarthritis, fibrositis, tenosinovitis, myofascitis, and myositis;
2. Rheumatoid arthritis and osteoarthritis; and
3. Non-paralytic forms of neuritis, such as sciatic and brachial neualgia and painful neuromas of the stump after amputation.

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

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

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

ULTRASOUND WARNINGS

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

WARNING
Gel Pad must be used with the HF27 when using the Ultrasound or Combination modes.
Failure to Do so may cause skin irritations or surface burns.

WARNING
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.

WARNING
When the applicator is being used in a hands-on thermal mode, the applicator must be moved in a circular motion around the treatment site.

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 HF27.

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

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

ULTRASOUND USAGE CAUTIONS

CAUTION
To ensure proper coupling, it is recommended that the Gel Pad part number 17 is used with the HF27.

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.

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”.

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

PRECAUTIONS

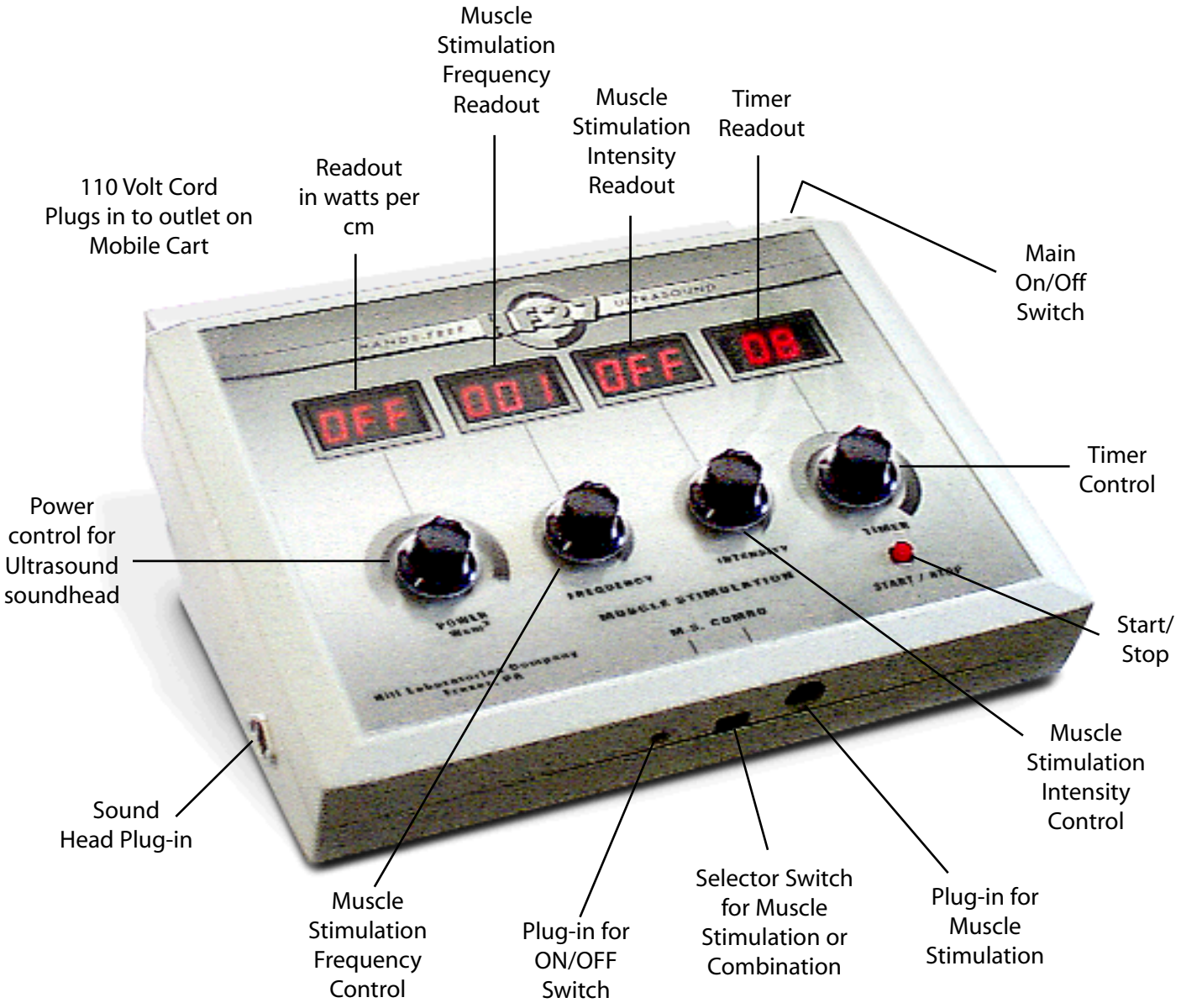
The main precaution to take with ultrasound is to not give too powerful a dosage. Longer treatments at a lower dosage are safe and effective. Never operate the instrument at a level where the patient feels pain, and if you have any doubts about the proper level of dosage, select a lower amount.

Ultrasound Precautions

1 Do not give too powerful a dosage. Longer treatments at a lower dosage are safer and more effective
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/cm2 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

The HF27 Unit

The graphic below identifies the various controls and functions of the HF27 Unit.



Frequency - Frequency is the pulse of muscle stimulation per second. Dial can be set from 1-100.

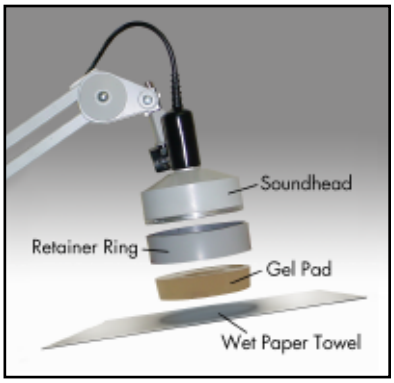
Intensity - Intensity is the amount of electrical muscle stimulation.

Power - Power is Wcm^2 based on 32 ERA (Effective Radiating Area).

Potential for Burns

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.

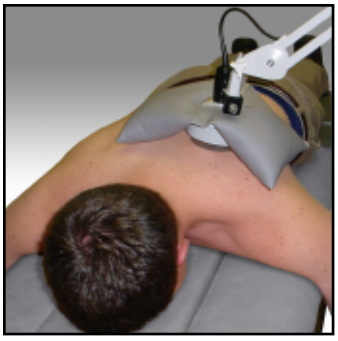


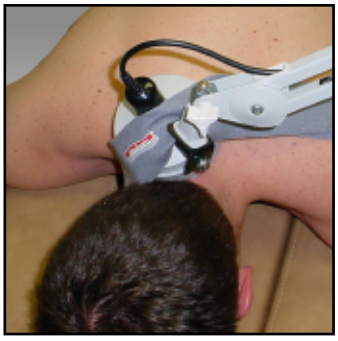
OPERATING THE ULTRASOUND

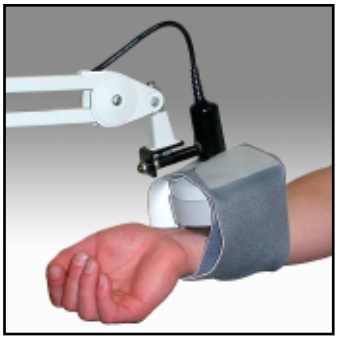
Before you start treating with the Hands-Free 27 Ultrasound, review the "soundhead settings." When treating the back, ultrasound works best with the patient lying down so that the soundhead can make firm contact to the patient. We highly recommend using the Gel Pad. Following the procedures below will make set-up fast and easy.

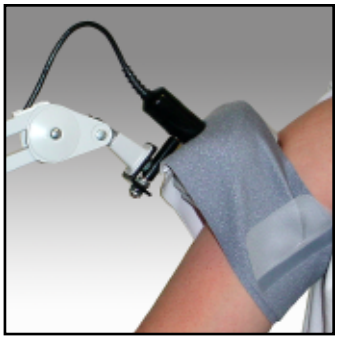
PATIENT SET-UP

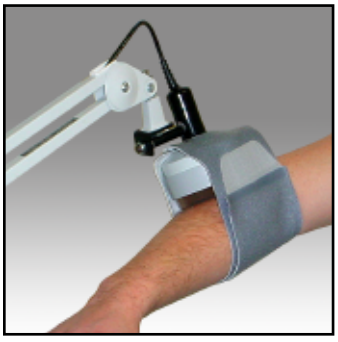
1. Slide the rubber retainer ring halfway on to the soundhead.
   WARNING: If liguid gel is used, make sure to place an ample amount between the soundhead and the patient. Failure to Do so may cause skin irritations during muscle stimulation.
2. The spray bottle can be used to wet a paper towel for use between the gel pad and the patient. If a paper towel is used, make sure it is extremely wet so it conducts the ultrasound waves properly.
3. Place the Gel Pad in the retainer ring then against the paper towel.
4. Place the weight bag or velcro strap, as pictured, to create good contact between the soundhead and the patient.

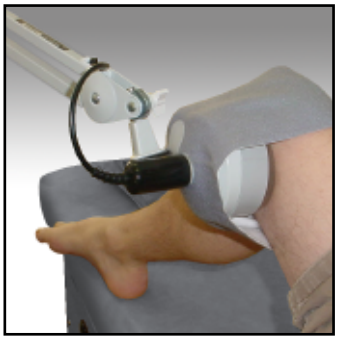

Upper Back

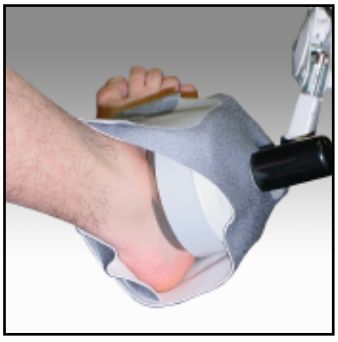

Neck


Wrist

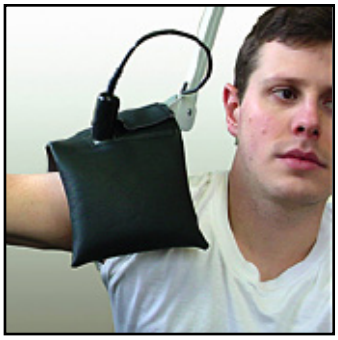

Shoulder


Forearm and Elbow

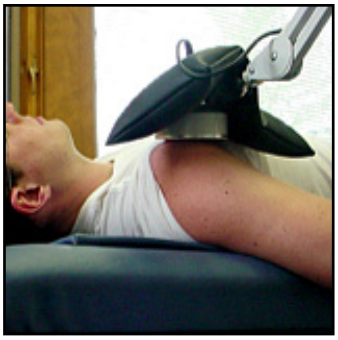

Knee


Side of Foot

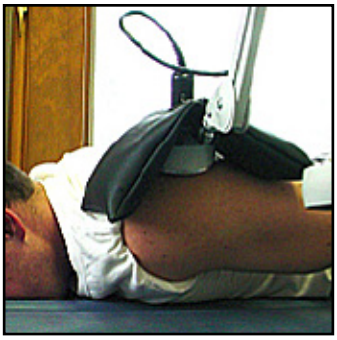

Bottom of Foot



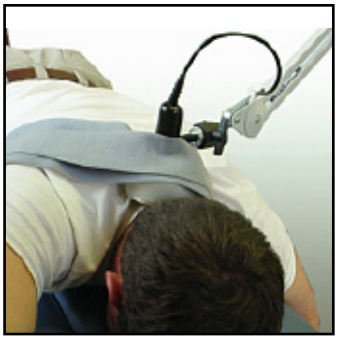
Entire Shoulder



Front Deltoid



Rear Deltoid



Neck

CONTROLS

1. Locate the main power switch on the back of the unit and turn it on. The display will light up left to right, **OFF, 001, 0FF, 00;** if not, turn the knobs completely counter clockwise. **NOTE:** The power switch should be turned off at the end of business hours or when not in use for several hours. The patient should be given the cut-off switch and instructed to turn off the unit and advise the doctor or attendant if he feels any pain or discomfort.

2. To start, turn the timer knob clockwise to desired treatment time and press the Start/Stop Button. The button will blink. (NOTE: If treatment time is not selected, the machine will beep and not start when the start button is pushed.) to change the treatment time, push the Start/Stop Button, set the new time, and restart.
3. Turn the power-control knob to the desired setting. It is extremely important that you Do not exceed over 20% of the power of a conventional moving soundhead. Generally, this will be between .07 to .22w/cm^2. This setting will depend upon the patient, condition, and areas to be treated.

4. The timer will automatically turn the instrument off at the end of treatment time. If necessary, you may also instantly turn the unit off with the "Start/Stop" button. Once the treatment has ended, turn all knobs counter clockwise. For safety reasons, the unit will not turn on again unless the Power Wcm^2 and Intensity knobs for muscle stimulation are set to the **OFF** position.

5. Once the treatment is finished, clean off the soundhead if not using the Gel Pad (with the Gel Pad, a daily cleaning is all that is necessary).

CHECKING POWER OF THE ULTRASOUND

You should periodically check the soundhead to make sure it is functioning properly. It will be easy to determine if the soundhead is working. Turn the unit on and turn the power to .22. Touch the soundhead for a moment with your hand. You should feel a slight vibration. Or, turn the soundhead upside down, spray the sound head with a thin coating of water, turn the machine on, and set the power to .22. You should see movement of the water on the soundhead. If no movement is detected, check the connection of the cable to the side of the unit making certain it is pushed in firmly.

MUSCLE STIMULATION

The muscle stimulation used on the HF27 generates a non-polarized contractual current for stimulation of normally-innervated skeletal muscles. Short-duration phasic pulses of 250 microseconds duration are produced with a repetition frequency (pulses) adjustable from 1 to 100 per second (1to100hz).

Muscle stimulation indications for use

These are the conditions for which Muscle Stimulation can be used.

Muscle stimulation:

- Relaxation of muscle spasms;
- Prevention or retardation of disuse atrophy;
- Increasing local blood circulation;
- Muscle re-education;
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and;
- Maintaining or increasing range of motion.

Note: Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions

Muscle Stimulation Contraindications for Use

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

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.

Muscle Stimulation Warnings

WARNING

The long term effects of chronic electronic stimulation are unknown

WARNING

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

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

WARNING

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

WARNING
Stimulation must not be applied transcerebrally

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

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

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

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

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

WARNING
Electronic stimulation should be kept to below 2 mA/cm2. Burns to tissue may occur quickly if this current density is exceeded.

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

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

WARNING
Never used worn or damaged leads or electrodes

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

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

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

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

Muscle Stimulation Current Cautions and Precautions

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

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

CAUTION
Caution should be used for patients with suspected or diagnosed epilepsy

CAUTION
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

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.

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

CAUTION
Powered muscle stimulators should be kept out of the reach of children

CAUTION
Powered muscle stimulators should be used only with the leads and electrodes recommended for use by Hill Laboratories

CAUTION
Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions

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

Muscle Stimulation 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 HF27 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.

Adverse Effects:

• Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators. This can be caused by excessive current for the size of electrode being used.

Muscle Stimulation Application

Two electrodes are required for muscle stimulation. Place an active electrode in direct contact with the skin over the motor point of the muscle to be stimulated, and an equal, if not larger, indifferent or dispersive electrode on any convenient area of the body. Muscle stimulation produces a low voltage current that causes the muscle to contract.

MUSCLE STIMULATION WARNINGS

- Always give the Cut-Off Switch to the patient prior to treatment.
- Always stop a treatment before removing or attaching electrodes or leads. The leads and electrodes must be applied to the patient before treatment is started.
- Always use a wet paper towel and wrap it around the electrodes.
- Never use worn or damaged leads or electrodes as they may result in injury to the patient.
- Any electrical stimulation has the potential to burn or irritate a patient's skin. The tendency towards burning is dependent on several factors, the most important being patients' susceptibility and current density. The practitioner has little control over patients' susceptibility other than to observe first-time patients carefully. If irritation is present, make a note on the patient's record, turn down the intensity on future visits, and continue to observe the patient's reaction.
- Electrodes which are worn or have lost their adhesive qualities and carbon electrodes which are corroded and are not securely fastened will fail to deliver current evenly as required. These kinds of electrodes may have "hot spots" where higher than normal current density will be delivered. If the patient complains of "pin prick" sensations, the electrode may be delivering current through only a small portion of its area and the electrode should be replaced.
- Only use electrodes that are designed for use with this device.
- ***Never use electrodes on patients that are sitting in whirpools.***

STIMULATION TREATMENT

The stimulation frequency determines the type of muscle contraction produced. Lower frequencies (1 to 5 per second) produce single muscle twitches with nearly complete relaxation of muscles between pulses. Mid-range frequencies (6 to 45 per second) permit vigorous penetrative action with incomplete muscle tetany. Higher frequencies (46 to 100 per second) produce nearly complete muscle tetany.

The INTENSITY dial acts as an on/off switch. Increase the intensity until the desired muscle contraction is obtained. In general, the stronger the muscle contraction, the more beneficial the effect. The higher the frequency, the lower the tolerance level of intensity. To determine the contraction, watch for muscle movement.

Wet the carbon pads and place them over each muscle motor point that is to be treated. The pads must be firmly placed against the patient's skin by using a sandbag and/or straps. Wrapping the wet pads in wet gauze or a wet paper towel before application will keep the pad clean and sanitary and will ensure that they won't dry out during the treatment.

CONTRAINDICATIONS TO STIMULATION

The stimulator is contraindicated for electrically sensitized patients with pacemakers or electrical implants, on infants with developing bones, on the pregnant uterus, and on patients with cardiovascular disease.

It is also contraindicated over anesthetized areas, over malignant tumors, and over acute or severe inflammation.

OPERATING THE MUSCLE STIMULATOR

The muscle stimulation on the HF27 is a high volt muscle stimulator. The frequency of the pulse and the intensity can be varied. Muscle stim can be used by itself or in combination through the soundhead. For using muscle stimulation only, proceed with the following:

1. Turn the main power switch on. It is located in the back of the unit.
2. The Cut-Off Switch should be plugged into the front of the unit and given to the patient. The patient should be instructed to press the button if any discomfort is experienced.
3. Slide the front switch marked "MS-Combo" to the "MS" position. ***Warning: Never move this switch while the patient is being treated.***
4. A wet paper towel should be wrapped around the carbon pads to ensure good contact. Wet the two 3" carbon pads, which are supplied with the unit, and push them onto the red and black dual cable. The other end of the dual cable plugs **firmly** into the front of the machine. Place the pads on the patient in the conventional manner. The pads must be moist to make good contact with the patient at all times. Velcro straps are supplied for securing the pads. A hot pack, or weight bag, could be used to make certain you have good contact. Failure to make good contact will cause

discomfort to the patient. Many doctors and therapists use stick-on electrodes and therefore contact is easily achieved. We highly recommend this method.

5. The frequency knob should be set to the desired pulse rate first and the intensity knob to **off**. With the electrodes securely in place, set the timer to desired treatment time.
6. Press the **start** button. **NOTE:** The unit will not start if the intensity button is not set to **off**. A beeping noise and the display will flash reminding you to turn the knob off. Then press the start button and proceed.
7. Slowly increase the intensity to the desired muscle contraction staying within the patient's comfort level.
8. If you need to change the frequency of the pulses, turn down the intensity before regulating this knob, always noting the patient's comfort.
9. Once the treatment time has elapsed, the unit will signal with several beeps and automatically shut off. The pads can be removed from the patient and stored along with the patient-control switch in the storage tray.

COMBO MODE

Muscle stimulation and ultrasound can be used in combination. Muscle stim is directed through the soundhead in combination with the ultrasound treatment. When using muscle stimulation with ultrasound, keep the stim intensity low.

OPERATING COMBO

1. **Make certain the selector switch is moved to combo.** ***Warning:*** **Never move this switch while the patient is being treated.** Use the dual cable and plug it firmly into the front port of the machine. Wet the 4" carbon pad (we recommend the use of a wet paper towel) and connect it to the **red** cable. The black cable is not used. **(As long as the front panel switch is in combo mode, no electric current will be going to the black cable.)** The 4" pad is the disbursement pad and the patient will feel muscle stimulation through this pad as well as the soundhead. If muscle stim is not desired through the disbursement pad, a larger pad is required (5x7 or 8x10) or a large, wet paper towel. It is extremely important that the disbursement pad is wet. You can wet the carbon pad with water or wrap a wet paper towel around the pad. You must have firm contact against the patient's skin. A sand bag, hot pack or strap is needed to make good contact of the carbon disbursement pad. Make certain the wet paper towel or electrode does not come in contact with the soundhead. Place the disbursement pad on a large muscle group or an adjacent area to the soundhead. If using a self-adhesive pad to the soundhead, make certain it is 3" X 4" or larger.
2. Place the ultrasound head on the desired treatment area. Use the weight bag supplied or velcro strap to insure good contact of the soundhead to the skin. **Failure to have an ample amount of coupling gel and/or good contact of the soundhead and disbursement pad could result in interrupted current causing an unpleasant stinging sensation to the patient. WARNING: Make sure to use the Gel Pad or an ample amount of coupling gel in treatment; failure to do so may cause skin irritations.**
3. The patient should be given the Cut-Off Switch and instructed in its use as previously described in the manual.
4. Turn on the machine and dial the desired dosage of ultrasound. Preset the frequency and slowly dial the intensity, keeping it at a low comfortable level. Just a slight sensation is recommended.
5. When the treatment has ended, clean off the ultrasound head and return it to the warming tray and the cables to the storage tray.

OPERATING MUSCLE STIMULATION IN ONE AREA & ULTRASOUND IN ANOTHER

1. Move the selector switch to MS.
2. The patient should be given the ON/OFF switch and instructed in its use.
3. You can use muscle stimulation in one area while giving ultrasound in another. Follow the previous instructions for setting up the treatment individually for ultrasound and muscle stimulation.

MAINTENANCE AND SERVICE

Suggested Maintenance by a Technician

If the soundhead is dropped, sustains damage due to lightning, severe power surge, or submerged in water past the indicated height described in the manual, it must be examined by the factory or authorized technician.

Every 6 months:

- Test leads and carbon electrodes
- Lead resistance should be less than 10% above mean cable resistance. Greater values indicate strand breakage and leads should be replaced.

Every 12 months:

- Check the calibration
- Inspect soundhead, wire and connector
- Check output voltage and current

If the equipment is out of calibration, the soundhead and power supply should be returned to the factory.

SUGGESTED MAINTENANCE BY THE USER

Keep the unit clean and dry. The soundhead should be wiped clean after every patient. Inspect accessories daily for wear and damage. Examine cables and connectors on the cables for any visible sign of wear or damage. Replace accessories as needed.

- Clean soundhead at least once a day
- Replace lead wires and carbon electrodes at least every six months
- Replace self-adhesive electrodes after not more than 15 uses
- Inspect the air vent in the back of the unit and insure that it is not blocked
- Dust can be removed with a vacuum (unplug first)
- Make sure ON/OFF switch and wires are not damaged. Periodically turn the unit on and press the ON/OFF switch to see if it cuts off the power.

TECHNICAL SPECIFICATIONS

Operating Voltage - - - - - - - - - - 115 volts, 60 cycle A.C. single phase (220 volt 50/60 cycles model also available)
Ultrasonic Frequency - - - - - - - .96 Mhz.
Ultrasonic Pulse Rate - - - - - - - 60 per second
Ultrasound Pulse Duration - - - - 7.6 milliseconds
Ultrasound Wave Form - - - - - - Amplitude modulated, sinesoidal
Peak Pulse Intensity - - - - - - - - 5.4 times average
Stimulation Frequency- - - - - - - 1 to 100 pulses per second
Stimulation Pulse Duration- - - - 250 microseconds
Fuse - - - - - - - - - - - - - - - - - - 3AG, 2 amp.
Generator Size/Weight- - - - - - - 12” wide x 10.5” deep/8.5 lbs.

WARNINGS

Restricted Use

The use of ultrasonic energy in therapy should be limited as follows: The use of ultrasonic energy in therapy should not be considered as specific treatment for any disease. If applied properly and safely, it may be a useful adjunct in producing relief from such symptoms as pain, soreness, and tenderness associated with:

1. Non-specific types of bursitis, periarthritis, fibrositis, tenosinovitis, myofascitis, and myositis;
2. Rheumatoid arthritis and osteoarthritis; and
3. Non-paralytic forms of neuritis, such as sciatic and brachial neualgia and painful neuromas of the stump after amputation. "F.D.A."

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 practices, to use or order the use of this device." . . . F.D.A.

HIGH VOLTAGE

This instrument contains high voltage. Refer service to qualified personnel only.

ULTRASONIC ENERGY

"Caution--Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy." F.D.A.

CALIBRATION/COUPLING

Do not allow the soundhead to operate for an extended time when it is exposed only to air as the soundhead will become hot. Ultrasound is not transmitted through the air and, when exposed only to air, the energy is trapped in the soundhead and converted to heat. This heat can make the soundhead hot and affect the calibration.

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

ULTRASOUND REGULATION

The HF27 complies with the following:

- FDA 21CFR 1050(c)(1)9i). The error in indication of the temporal-average ultrasonic power shall not exceed +20 percent for all emissions greater than 10 percent of the maximum emission.

- FDA 21 CFR 10(c)(1)(ii). The sum of the errors in the indications of temporal-maximum ultrasonic power and the rati• of the temporal-maximum effective intensity to the temporal-average effective intensity shall not exceed +20 percent for all emissions greater than 10 percent of the maximum emission.

- FDA 21CFR 1050.10(c)(2). The treatment timer must be accurate to within 0.5 minute of the preset duration of emission for settings less than 5 minutes, to within 10 percent of the preset duration of emission for settings of from 5 minutes to 10 minutes, and to within 1 minute of the preset duration of emission for setting greater than 10 minutes.

NOTE: The HF27 is accurate to within +1% of any treatment time.

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 rati• of the temporal-maximum to temporal-average effective intensity, pulse duration, and pulse repetition rate for the HF27 are as follows:

F.D.A. REQUIRED INFORMATION

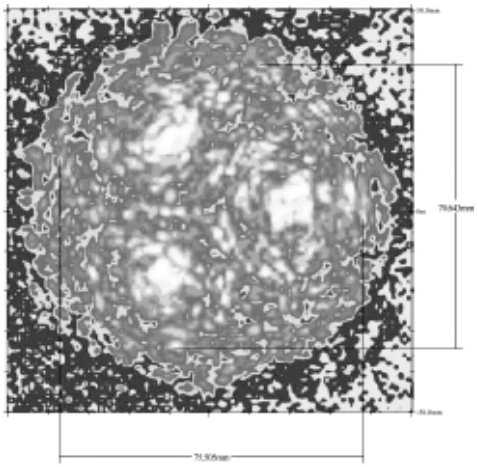
Ultrasonic Frequency ---------- .96 Mhz.
Percent Error of Ultrasonic Frequency ---------- +/- 5%
Percent Error of Effective Radiating Area ---------- +/- 40%
Percent Error of Rati• of Temporal-Maximum to Temporal-Average Effective Intensity ----- +/- 3%
Percent Error of Pulse Duration ---------- +/- 3%
Percent Error in Indication of Radiated Power ---------- +/- 20%

The following abbreviations are used on the soundhead labels:

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

TROUBLESHOOTING

Symptom:	***Check***
Display does not light up when turned on	• Power cord is plugged into outlet • Outlet is providing power • HF27 is plugged into cart outlet • Fuse in back of unit may have blown. Replace with 3ag 2amp.
Unit lights up when power is on but fan does	• Fan needs to be replaced not run
LED display does not light but fan is running	• New display or control board is needed
Start/stop button does not light	• The button might be working but light is not functioning • Check the soundhead with water to see if it is producing any ultrasound. If so, the light/button needs to be replaced.
Button lights but no power is transmitted to ultrasound and/or muscle stimulation	• Make sure ultrasound cable is plugged into the unit and the cable is not worn or cracked
	• Make sure muscle lead wires are not cracked or broken and the "din" plug is firmly connected in the front of the unit
ON/OFF switch does not work	• Replace with one from the factory



HYDROPHONE TEST

The graphic to the left shows the spatial distribution of the radiated field for the HF27.

Direct all inquiries for parts and service to Hill Laboratories Co., P • Box 2028, Frazer, PA 19355, 1-877-445-5020 • (610) 644-2867 FAX 610-647-6297 • hf27@hilllabs.com

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