ULTRASOUND

# DYNATRON®
# 125

## OPERATOR'S MANUAL

Dynatronics

## ⚠ CAUTION

**Federal law restricts this device for sale by or on the order of a physician, chiropractor, physical therapist, or dentist licensed by the law of the state in which said person practices to use or order the use of the device.**

**Risk of burns and fire: Do not use near conductive materials such as metal bed parts, inner spring mattresses, and the like.**

**DANGER - Explosion Hazard: Do not use in the presence of flammable anesthetics.**

IMPORTANT: Before treating a patient with any Dynatron®125 device, see the "Contraindications, Warnings, and Precautions" in this manual. Read the operating instructions carefully.

**COMPLIANCE:** The contents of this "Instructions For Use" manual are exactly the same in both the printed and electronic forms.

## INDICATIONS FOR USE

**ULTRASOUND:**

Ultrasound therapy is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures; but not for the treatment of malignancies.

Dynatron® 125 Ultrasound Operator's Manual

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# Introduction to the Dynatron® 125™ Ultrasound

The Dynatron 125 Ultrasound device is compact, convenient, and portable. Simple to use and intuitive to operate, the touchscreen control panel allows changes to intensity, frequency, and time while a treatment is in progress, providing maximum treatment flexibility. With the Dynatron 125, there is no longer a need to manually enter soundhead parameters. Soundheads are engineered with SmartHead technology that places calibration parameters directly inside each soundhead.

All of the Dynatronics' devices featuring ultrasound technology, including the 125, are the only devices in the industry offering 1, 2, and 3 MHz frequencies for the greatest range in depth of treatment. Choose 1 MHz for deep treatments, 2 MHz for moderate depth, or 3 MHz for superficial depth. Flexibility doesn't end there, the Dynatron 125 has a Combo Jack for setting up Stim and Ultrasound Combination treatments.

## About Ultrasound

Ultrasound therapy is supported by a wealth of scientific literature. Channeling soundwaves through muscle, nerve, bone, and connective tissue has been documented to aid in reducing pain muscle, spasms, and joint contractures. The "Ultrasound Usage Cautions" in this manual provide some general guidelines for Ultrasound treatments to help ensure you deliver safe and effective treatments to your patients. Further information about Ultrasound may be obtained from published medical literature.

## Simplified Setup

The unique design of the Dynatron 125 display screen means treatment setup has never been easier. A few simple key presses are all you need to set up a treatment. The User Interface intuitively groups and displays all the options on the well lit LCD screen to ensure that treatment parameters can easily be selected and adjusted.

A routine treatment setting can easily be set and saved as the default treatment—saving time in the treatment setup.

## Language Selection

The default language on the Dynatron 125 is English; however, both French and Spanish are also available. To change the default language: 1) Begin at the OPERATIONS SCREEN. 2) Press the SETTINGS key symbol. 3) In the upper right-hand corner, the current language selection will appear. 4) Pressing the LANGUAGE key, toggle to the desired language. 5) Press the symbol in the lower left-hand corner to return to the OPERATIONS SCREEN.

## Operator's Profile

All operators shall be properly trained and certified medical practitioners or those working under the direction of a licensed medical practitioner, capable of reading and comprehending instructions for use as described in this manual. Operators will have reasonable mobility and dexterity to apply ultrasound and monitor patient response to treatments. The operator should be able to hear an audible signal indicating completion of treatments. There should be no other limitations for operating this device.

## Before You Treat a Patient

Before administering a treatment to a patient with the Dynatron 125, familiarize yourself with all the operating instructions for the ultrasound modality, as well as the contraindications, warnings, and precautions. In addition to this information, consult other published sources for additional application and safety instructions regarding use of each type of therapy.

**⚠ CAUTION**

**Device should be at room temperature prior to treatment.**

# Installation and Features

## Unpacking

When you receive the unit, immediately unpack it and all accessories. Check for possible damage, obvious or concealed. In case of damage, immediately notify the freight carrier and take any steps necessary to file a claim for the damage sustained. Do not destroy or discard the shipping carton. The carton should be reused if the device must be shipped for any reason, including calibration. The carton is specially designed to protect the unit from shipping damage. Improper packaging of the unit during transport can result in damage and invalidate the warranty.

Complete the warranty registration form located at the back of this manual and return it to Dynatronics within 30 days of purchase. This is essential to insure you are not billed for services that are covered by the warranty policy. Warranty registration should include serial numbers for both the device and soundheads.

Connect the AC power cord, which is provided as a hospital grade, UL listed plug, to a properly grounded 110/120V 60 Hz AC outlet (the device will automatically switch to 220/240V 50 Hz when connected to a power source with that voltage). The power cord must also be firmly plugged into the device itself. When the cord is properly connected, it cannot be easily pulled out. Do not place the cord or the device in a place where the cord could be tripped over or accidentally pulled out of its socket during a treatment.

Read the operating instructions in this manual before proceeding with a treatment.

## Standard Components

REF The following accessories are included with the Dynatron 125 units:

| Qty | Part No. | Description: One of the following devices plus accessories as listed: |
|---|---|---|
| 1 | D125B | Dynatron 125 Ultrasound |
| 1 | 7B0241 | Power Cord (black) |
| 1 | 5D00270 | Operator's Manual |
| 1 | 7B0217 | DynaGel Ultrasound Gel 100ml Sample |

## Soundheads

Applicator soundheads are available in the following sizes:

| Part No. | Size | Frequencies |
|---|---|---|
| WSH02 | 2 $cm^2$ | Operates at 1, 2, and 3 MHz |
| WSH05 | 5 $cm^2$ | Operates at 1, 2, and 3 MHz |
| WSH10 | 10 $cm^2$ | Operates at 1, 2, and 3 MHz |

## Optional Accessories

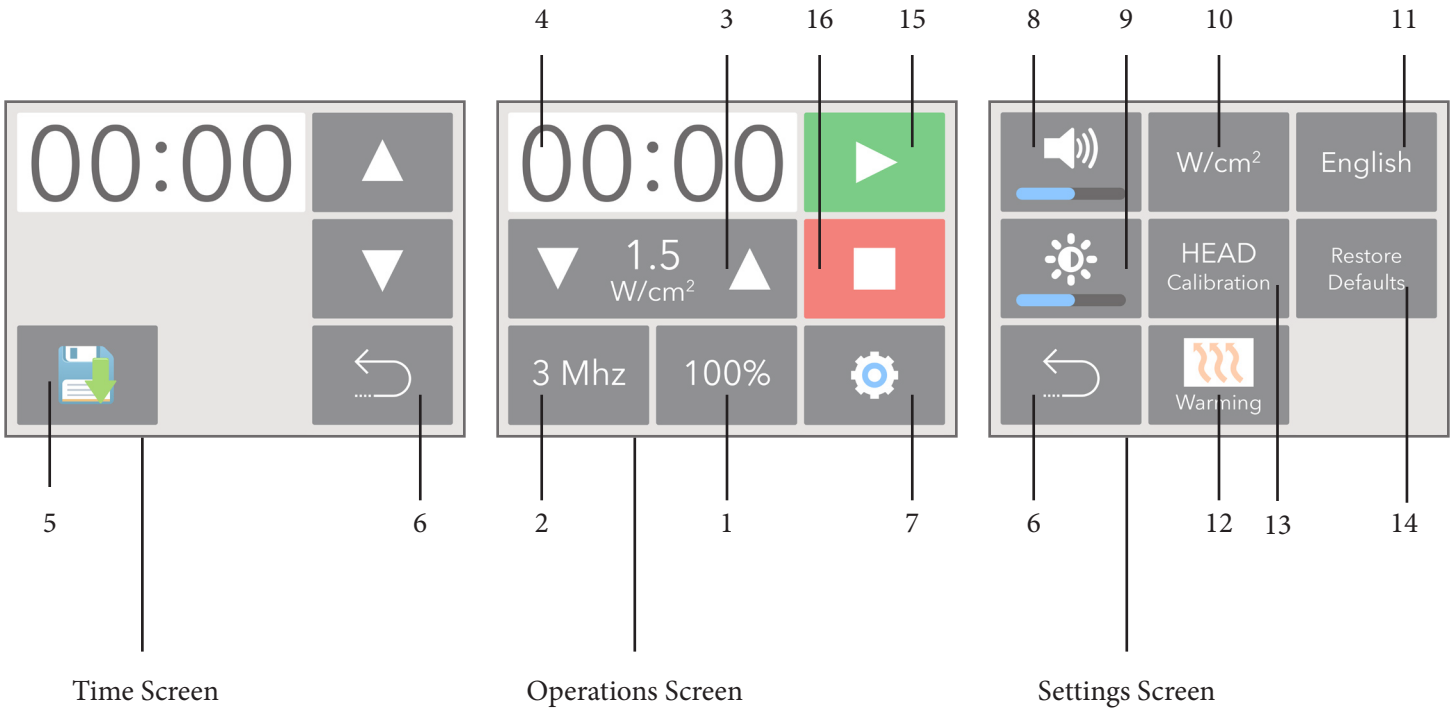
The following optional and replacement accessories may be purchased from Dynatronics or from your Dynatronics' Dealer:

| Part No. | Description |
|---|---|
| 7B0268 | Protocol Reference Manual for Electrotherapy & Ultrasound (J. Stephen Guffey, P.T., Ed., D.) |
| 5LTRGEL | Ultrasound Coupling Gel (5 liter container) |
| 7B0082 | Pin-to-Banana Adapter (black) |

# Dynatron® 125™ Physical Features

Before operating the Dynatron 125 device, acquaint yourself with the control panel by reviewing the illustrations and descriptions on the following pages. The numbered features in the diagrams correspond to the numbered descriptions. Before administering treatment to a patient, read the sections later in this manual that provide specific instructions for performing treatments along with contraindications, warnings, and precautions for all modalities.

Note: The User Interface on Dynatron 125 device is engineered with "CapSense Touch Technology" requiring that the user make direct contact with the keys on the faceplate using dry, bare fingers or a glove with a conductive fingertip.



## Dynatron 125 Physical Features

Before operating the Dynatron 125, acquaint yourself with the control panel by reviewing the illustrations. Each of the features is numbered in the diagram, and a description for each feature follows:

1. **CUSTOMIZABLE DUTY CYCLE**

   The DUTY CYCLE key is a toggle key located at the bottom center of the Operations Screen. Options include 10, 20, 50, and 100% (Continuous) Duty Cycle.

2. **FREQUENCY**

   Located in the lower left-hand corner of the Operations Screen, the FREQUENCY key allows the practitioner to toggle between 1, 2, and 3 MHz frequencies. This value is not saved as a default when changed. The system will default back to 1 MHz when the device is turned off and on again.

3. **INTENSITY**

   INTENSITY is controlled by using the UP and DOWN INTENSITY ARROWS located in the center of the Operations Screen. As the arrows are pressed, modifications are immediately displayed in between the arrows.

4. **TIME / TIME SCREEN**

   When the window is pressed, the TIME SCREEN appears. TIME defaults to 5:00 min. but can be adjusted by using the UP and DOWN ARROW KEYS located on the TIME SCREEN.

5. **SAVING TREATMENT TIME AS A DEFAULT**

   From the TIME screen, pressing the image in the lower left-hand corner after setting the TIME will save the TIME setting as the new default. Once saved, the saved TIME selection becomes the default TIME for all future treatments.

6. **RETURN KEYS**

   Wherever shown, these keys, located on both the TIME screen and the SETTINGS screen, return the display to the Operations Screen.

7. **SETTINGS KEY / SETTINGS SCREEN**

   Pressing the SETTINGS KEY opens the SETTINGS SCREEN. Inside the SETTINGS SCREEN the practitioner can control BRIGHTNESS, VOLUME, LANGUAGE, turn HEAD WARMING ON and OFF, and change the INTENSITY display to either to $W/cm^2$ or WATTS. Once changes are made to Language, Head Warming, or Intensity; these changes become the Default Settings and will remain in place until additional changes are made.

8. **VOLUME**

   The volume of the sound can be changed from low, to medium, to high.

9. **BRIGHTNESS / CONTRAST**

As contrast and clarity of the screen graphics can be affected by the lighting in the area where the Dynatron 125 is used, this key allows for the manual adjustment of the brightness/contrast of the displays.

10. **POWER DISPLAY - W/cm² to WATTS**

This key shows the POWER selected for the current treatment. The Default Power is displayed in WATTS per square centimeter (WATT/cm2). WATT/cm2 is the intensity of the Ultrasound at the head surface; it is the total Watts divided by the effective radiating area of the head. The display may be changed to WATTS, if desired, by pressing the POWER toggle key located on the Settings Screen.

11. **LANGUAGE**

The default language for the Dynatron 125 is English; however, both French and Spanish are also available. To change the language, press the LANGUAGE toggle key until the desired language appears in the display.

12. **HEAD WARMING**

The HEAD WARMING feature defaults to OFF. When HEAD WARMING is ON but idle, the soundhead is warmed automatically. Head warming may be turned OFF or ON by pressing the WARMING key located on the Settings Screen.

13. **HEAD CALIBRATION**

Manually entering parameters for the Dynatron 125 SmartHeads is not necessary. This key provides the capability to enter parameters manually in the event that parameters are lost or the user wishes to enter the parameters manually. This key is also used to access user calibration mode for soundheads.

14. **RESTORE DEFAULTS**

The Dynatron 125 has the following default settings: Soundhead Warming OFF, Time 5:00 min., and Power Display set to Watts/cm². Each of these settings may be changed by the user along with other setting (instructions are provided earlier in this section). If you have changed the settings for this device, but would like to return ALL the default settings to those that were set at the factory, press the RESTORE DEFAULT KEY.

15. **START**

The green key in the upper right corner of the Operations Screen is the START key. Press the START key and the treatment timer will begin to count down. During treatment, this same key will act as the PAUSE key.

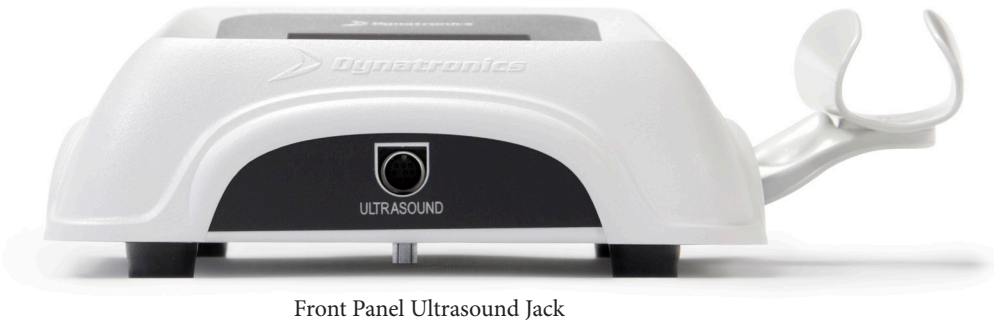
16. **STOP**

Pressing the RED STOP key during a treatment immediately stops the output and sets the treatment intensity to zero.

# Dynatron 125 Console Jacks

**Front Panel - Ultrasound Jack**

Illustrated below is the Ultrasound Input Jack located on the Front Panel of the Dynatron 125.



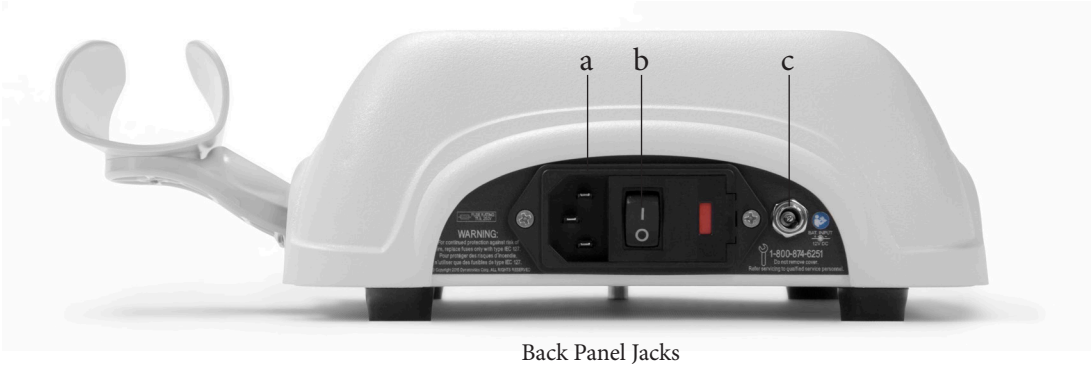

Front Panel Ultrasound Jack

**Left-Side Panel - Combo Jack**

Located on the left-side of the Dynatron 125 is a banana jack designed to accommodate a Combination Lead Wire, connecting the Dynatron 125 to an existing Stim source, making it possible to set up a combination treatment and provide Stim output through the Ultrasound Head.


Left-Side Panel - Combo Jack

**Back Panel Jacks**




Back Panel Jacks

a. **POWER CORD ENTRY MODULE.** This entry module is designed to accommodate a hospital-grade power cord.

b. **Power 1/0 (ON/OFF) Switch**. Located on the back of the unit this switch is labeled "1" and "0." Set the switch to "1" for ON; set the switch to "0" for OFF.

c. **Battery.** This jack may be used to supply power to the device using an optional battery pack. More information about the optional battery operation is provided later in this manual.

## Ultrasound Error Messages

If an error occurs during any active treatment, the Dynatron 125 will sound a tone/beep. An Error Message will appear on the Operations Screen. Below are samples of the error messages that may occur.

| | ULTRASOUND ERROR MESSAGES | CAUSE |
|---|---|---|
| ERR 200 | SOUNDHEAD DISCONNECTED! TREATMENT PAUSED. CORRECT PROBLEM WITH SOUNDHEAD TO RESUME | Soundhead disconnected |
| ERR 201 | THERMISTOR ON SOUNDHEAD IS MALFUNCTIONING! PLEASE REPLACE SOUNDHEAD. | Soundhead has a broken thermistor |
| ERR 202 | SOUNDHEAD CURRENT TOO HIGH! | Soundhead over current |
| ERR 203 | SOUNDHEAD CURRENT TOO LOW! | Soundhead under current |
| ERR 204 | SOUNDHEAD IS TOO HOT! OUTPUT HAS BEEN DISABLED TO ALLOW COOLING. | Soundhead too hot |
| ERR 205 | SOUNDHEAD WAS JUST DISCONNECTED, DISABLING POWER OUTPUT! | Soundhead disconnected during calibration |
| ERR 206 | PATIENT COUPLING. PLEASE REAPPLY SOUNDHEAD TO PATIENT. | Inadequate patient coupling. |
| ERR 207 | SOUNDHEAD CALIBRATION DATA IS CORRUPT. PLEASE RE-INITIALIZE SOUNDHEAD DATA. | US Probe calibration data is corrupted |
| ERR 208 | NO HEAD INTENSITY. TREATMENT WILL NOT START. PLEASE INCREASE INTENSITY. | Intensity not set - or - Head disconnected. Bad soundhead cord. |
| ERR 209 | SOUNDHEAD NOT DETECTED! CORRECT PROBLEM WITH SOUNDHEAD TO RESUME. | Head disconnected. Bad soundhead cord. |
| ERR 210 | ENTERED CALIBRATION DATA RANGE ERROR. CORRECT PROBLEM BY RE-ENTERING DATA. | Soundhead parameters manually entered incorrectly. |

# Ultrasound Instructions

Ultrasound therapy channels soundwaves through muscle, nerve, bone, and connective tissue to aid in reducing pain, muscle spasms, and joint contractures.

The physiological effect of Ultrasound therapy depends upon the frequency of the Ultrasound signal. The lower frequency (1 MHz) penetrates deeper than a higher frequency (such as 2 MHz or 3 MHz), thus the practitioner can decide which frequency to use according to the condition and depth to be treated.

A section in this manual entitled "Ultrasound Usage Cautions" provides some general guidelines for Ultrasound treatment and selection of the appropriate soundhead to help ensure safe and effective treatments are delivered to your patients. Further information about Ultrasound application may be obtained from published medical literature.

**WARNING**

- ALWAYS keep the applicator soundhead in constant motion.
- ALWAYS keep the soundhead properly coupled to the patient's skin or submerged underwater when intensity is turned ON.
- Use ample conductive gel to ensure good coupling throughout the treatment. If needed, apply additional gel during the treatment.
- See the section of this manual entitled "Contraindications, Warnings, and Precautions" for Ultrasound treatments.
- Be alert for any sign of periosteal (bone) pain.
- Be sure to read all instructions for operation before treating a patient.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

Make sure a soundhead is firmly plugged into the device before turning the device ON. When changing to a different size soundhead, turn the machine off first, remove the soundhead, plug in the desired soundhead, then turn the machine on again. **Please acquaint yourself with the following terms and device features prior to delivering an Ultrasound treatment.**

## Soundhead Warming

Soundhead Warming is an optional feature used to maintain a comfortable soundhead temperature for the patient. When Soundhead Warming is ON, the soundhead should remain in its holder as a small amount of Ultrasound output is emitted from the soundhead (0.1 $W/cm^2$). The soundhead warming mode is automatically stopped during a treatment, and resumes automatically as needed after a treatment has ended. Although the Soundhead Warming feature defaults to OFF, it can be turned ON at any time by going to the Setting Screen and pressing the WARMING key.

### ⚠ CAUTION

- Do not drop the soundhead on hard surfaces.
- Do not cool the soundhead with ice water or ice packs.
- Do not allow the soundhead to overheat repeatedly.
- Do not hold the soundhead in the air while a treatment is running.

All of these conditions are likely to damage the soundhead crystal and/or to stress electronic components in the device. Damage caused by these conditions is not covered by warranty.

## Coupling

The term “coupling” refers to the ability to deliver ultrasonic waves from the soundhead to the skin surface with as little impedance or dissipation of power as possible. Coupling (contact between the soundhead and the treatment site) may be provided by a coupling agent such as a gel or lotion. Any material used as a coupling agent must be highly conductive of ultrasonic waves. Air is a very poor conductor of ultrasonic waves. Holding the soundhead in the air while a treatment is running may also damage the soundhead crystal and/or stress electronic components in the device.

If any part of the soundhead is exposed to air during the treatment, coupling is decreased. The air bubbles in a whirlpool, for example, can decrease the effective Ultrasound therapy to the patient. Avoid allowing any air between the soundhead and the treatment area. Water is an excellent conductor of ultrasonic waves; therefore, underwater treatments provide excellent coupling.

During any Ultrasound treatment the soundhead should be moved continuously, covering an area approximately 2-4 times larger than the size of the soundhead. The full surface of the soundhead should maintain contact with the patient’s skin (except with underwater treatments).

## Head Temperature - Over Heating

If coupling (the effective degree to which the Ultrasound energy is delivered from the soundhead to the patient's body) is not adequate during treatment, the temperature of the soundhead rises and the patient does not receive the full intended dosage.

If the SOUNDHEAD reaches approximately 108 degrees, ULTRASOUND will be disabled and the Operations Screen will read: "SOUNDHEAD IS TOO HOT! OUTPUT HAS BEEN DISABLED TO ALLOW COOLING."

The soundhead must be cooled before the treatment can resume. When the soundhead cools sufficiently, press START to resume the treatment. The output power resumes, the display returns to its normal state, and the timer resumes. The soundhead should cool quickly if placed in the soundhead holder or if held exposed to the air. Larger soundheads take longer to cool than smaller heads. If the soundhead is not cooling as quickly as needed to resume the treatment, it can be placed in room temperature water to quicken the cooling process. Sometimes just applying more conductive gel will adequately cool the head.

**NEVER USE ICE OR ICE PACKS TO COOL THE SOUNDHEADS** as this is likely to cause thermal shock to the electronic components of the soundhead and may necessitate a costly repair. Heads damaged by thermal shock are not covered by the warranty.

To prevent overheating of the soundhead, maintain good coupling throughout the treatment by applying ample conductive gel or lotion. Reducing the power when treating an area where it is difficult to obtain good coupling will also keep the soundhead from overheating.

## Display Watts or W/cm$^2$

Power for the Dynatron 125 may be displayed as WATTS or W/cm$^2$. To choose the desired option, select the Settings Key on the Operation's Screen. On the Settings Screen, press the POWER toggle key to select the desired power display. The default setting for power is W/cm$^2$; however, the display you prefer may be selected at any time before or during a treatment.

## Ultrasound Quick Setup

1. Turn ON the main power switch at the back of the unit.
2. FREQUENCY. Using the FREQUENCY toggle key, select 1 MHz, 2 MHz, or 3 MHz.
3. DUTY CYCLE. Using the DUTY toggle key, select 10%, 20%, 50%, or 100% (Continuous).
4. TIME. Change the treatment TIME, if desired, by pressing the time display. Use the up and down arrow keys to select the desired time. Press return after the time has been modified.
5. INTENSITY. Use the Up/Down arrow keys within the INTENSITY button to raise or lower the INTENSITY to the desired level.
6. Press START.
7. **MODIFY** a treatment in progress, if desired. While the treatment is in progress, the following parameters can be modified: FREQUENCY, DUTY CYCLE, TIME, and INTENSITY.
8. **PAUSE**. The PAUSE key may be pressed at any time after a treatment has been started. The output will stop and the timer will PAUSE.
9. **STOP**. Press the STOP key to stop the treatment.

## Detailed Ultrasound Setup

1. Turn the main power switch at the back of the unit to the ON position.

   The following Default Parameters will automatically appear in the Operation's Screen:

   Frequency ..... 1 MHz

   Duty Cycle ..... Continuous

   Display..... $W/cm^2$

   Intensity ..... 0.0 $W/cm^2$

   Time..... 5:00 min.

   Other Default Parameters that are displayed on the Settings Screen:

   Warming ..... OFF

   Language..... English

**If you wish to use the default settings, increase the Intensity to desired treatment level and press START. If you wish to customize settings, follow steps outlined below.**

2. Choose the **FREQUENCY**.

   Press the FREQUENCY display toggle key on the Operations Screen to select 1, 2, or 3 MHz. Any one of the three Frequencies may be used with the 2 $cm^2$, 5 $cm^2$ or 10 $cm^2$ soundheads.

3. Select the **DUTY CYCLE**

   Press the DUTY CYCLE toggle key located on the Operations Screen to select one of the four available options: 10%, 20%, 50%, or 100% (Continuous) duty cycles.

4. **MODIFY TREATMENT PARAMETERS**

   The following parameters can be modified at the time of set-up or while the treatment is in progress. : FREQUENCY, DUTY CYCLE, TIME, INTENSITY, HEAD WARMING, and POWER DISPLAY of WATTS or W/$cm^2$.

   - **HEAD WARMING**
     Access the Settings Screen by pressing the Settings Key in the lower right hand corner of the Operations Screen. On the Settings Screen, press the **WARMING** key to toggle between Head Warming ON and OFF. When the image turns "BLUE," Head Warming is ON. When the display returns to black and white, Head Warming is OFF.
   - **POWER DISPLAY**
     Press the Setting Key on the Operations Screen. From the Settings Screen, select the appropriate toggle key to change the POWER DISPLAY from WATTS to W/$cm^2$.

5. **TIME.**

   Touch the TIME display on the Operations Screen to access the TIME SCREEN. The default time is set for a 5:00 min. treatment. Time can be changed by using the TIME Up/Down arrow keys located to the right of the TIME display. After selecting the treatment time, press the Return Key located in the lower right-hand corner to return to the Operation's Screen.

6. **SAVE SELECTED PARAMETERS AS THE DEFAULT TREATMENT PARAMETERS.**

   To save the treatment TIME that has been selected for a current treatment as the Default TIME, touch the TIME window on the Operations Screen. Press the image in the lower left-hand corner. The selected treatment TIME is now saved as the Default for future treatments. Any changes made to Language, Head Warming, and Intensity Display Units are automatically saved as Defaults.

7. **RAISE THE INTENSITY.**

   On the Operations Screen, use the INTENSITY Up/Down arrow keys located on either side of the Power Display to increase the power to the desired treatment setting. For patient safety and comfort, it is recommended that treatment begins with .1 W/$cm^2$, before increasing power to the desired level after the treatment begins. Valid ranges are from 0.1 to 2.0 W/$cm^2$ (exceptions: valid ranges when using a 10 $cm^2$ head are from 0.1 to 1.0 W/$cm^2$).

8. Press **START**.

   Press the green START key, the treatment timer begins to count down and output is delivered to the soundhead. If Intensity is not set before pressing START, an error message will appear: "NO HEAD INTENSITY. TREATMENT WILL NOT START. PLEASE INCREASE INTENSITY."

9. **PAUSE.** Temporarily PAUSE a treatment, if necessary, while the treatment is in progress.

   To temporarily PAUSE an Ultrasound treatment, press the green START/PAUSE key. A tone will sound indicating that the treatment has been paused. The Ultrasound output from the soundhead stops and the treatment timer is paused without ending the treatment. Press the green START/PAUSE key again to restart the treatment. A tone will sound indicating that the treatment is again in progress. Output resumes and the treatment timer starts from where it was paused.

NOTE: During a COMBO treatment, THE STIM OUTPUT OF THE TREATMENT IS NOT PAUSED when the PAUSE key is pressed, although the Ultrasound output is stopped and the treatment timer is paused.

10. **STOP.**

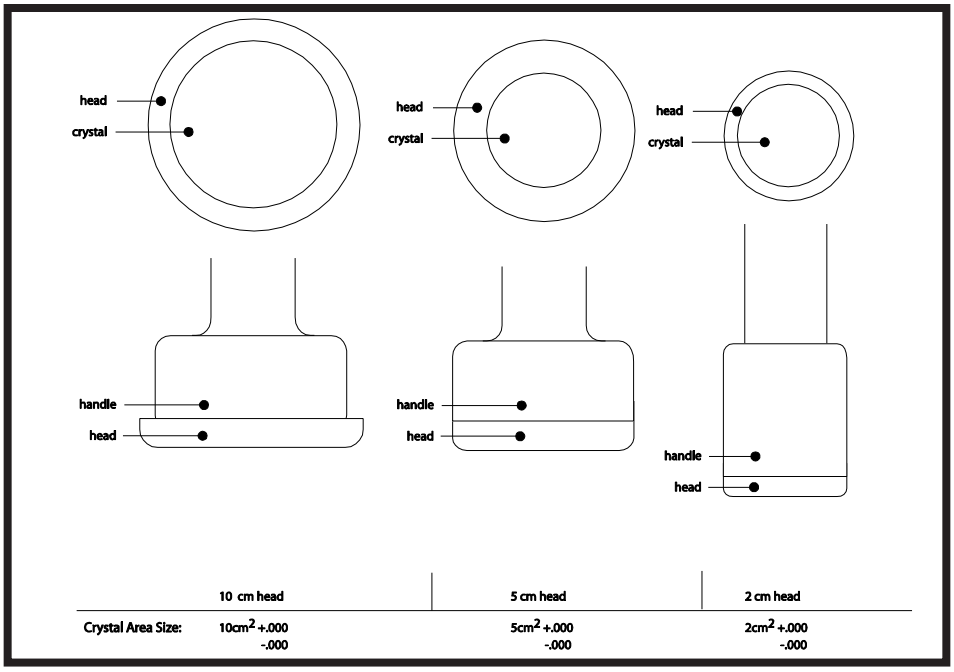
    When the treatment time has elapsed, the ultrasound to the patient stops and a tone sounds signaling the end of a treatment. Treatments in progress may be stopped at any time by pressing the red STOP key.

# Ultrasound Modality Information

Ultrasound, by its very nature, has the ability to irritate the patient's skin. While the benefits of Ultrasound far outweigh any disadvantages, certain precautions should be observed to assure maximum safety and comfort for your patients.

A patient's tendency to have adverse reactions to Ultrasound is dependent upon several factors. Some of these factors are discussed below.

## Selecting the Appropriate Soundhead




Head and Crystal Size Comparison

The selection of the appropriate soundhead is key to the success of the treatment and is based on the size of the area to be treated. Ultrasound treatments should be kept specific to the tissue involved in pathology. A good guideline is 2 to 4 times the size of the soundhead. For example:

- A 2 $cm^2$ soundhead can deliver up to 4 Watts and is appropriate for small areas (i.e. hands, fingers, feet).
- A 5 $cm^2$ soundhead can deliver up to 10 Watts and is appropriate for medium sized areas (i.e. extremities such as arms, legs, and cervical areas).
- A 10 $cm^2$ soundhead can deliver up to 10 Watts and is appropriate for large areas, i.e. torso and back).

Ultrasound is a directed beam of energy. Therefore, not only will the average spatial intensity be a factor in the dosage the patient receives, but the time delivered and area covered will matter as well. For example, an area of 50 $cm^2$ is treated for 5 minutes. Then an area of 200 $cm^2$ is treated for 5 minutes. Both receive the same intensity. The 200 $cm^2$ area however does not receive the same dosage (only ¼ ) because as the soundhead is moved around the area it has to cover represents 4 times as much tissue.

The Soundhead area measurement is the ERA (effective radiating area). Each soundhead has an effective radiating area. It is not necessarily the outside diameter of the soundhead, but the area of the crystal inside, therefore special care should be taken in selecting the correct size soundhead for the area to be treated according to the diameter of the crystal.

NOTE: If a patient experiences pain during a treatment, the size of the soundhead maybe inappropriate for the area being treated, the intensity maybe too high, the treatment time maybe too long, or coupling maybe poor.

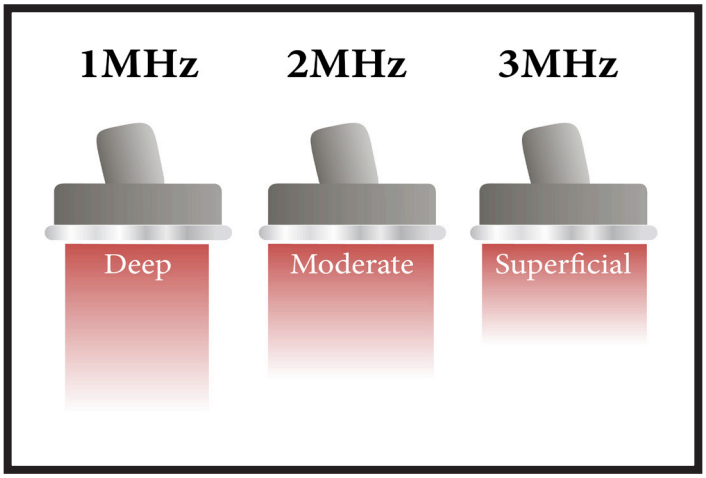
## Penetration of Ultrasound Waves

The correct frequency should be selected for the depth of penetration desired. The amount of penetration needed is determined by the density of tissue and the depth of the site to be treated. Care should be taken to select a penetration level that does not cause periosteal (bone) pain.

<u>The frequency determines the depth of penetration of the Ultrasonic wave.</u>

- Select 1 MHz for deep lesions; provides a Half-Value Distance (HVD) of about 5cm.
- Select 2 MHz for moderate depth lesions; about 2.6cm HVD.
- Select 3 MHz for superficial lesions; about 1.5cm HVD.

HVD is the approximate point at which the Ultrasound energy is reduced to half in the average human tissue.



Multi-Frequency Ultrasound

## Types of Delivery

Ultrasound can be delivered in four different ways. You will likely only see two of the four methods in clinical practice.

1. **Direct Contact Movable.** Here the soundhead is placed in direct contact with the patient. A coupling agent is used between soundhead and the patient's skin. The soundhead is moved slowly, but continuously. This is the method of choice.

   The rate of speed at which the applicator moves across the skin is very important in determining how much Ultrasonic output is delivered. If the rate is too slow, the patient may feel periosteal pain (bone ache/pain). If the rate is too fast, or if the applicator head becomes uncoupled with the skin, the amount of treatment is reduced. Uncoupling can also cause the soundhead to overheat.

2. **Immersion Method.** Here the area to be treated is placed underwater. The soundhead is rated IPX7, so it can be immersed with the area to be treated. The water becomes the coupling agent. The head is always moving around the surface area, but not in contact (1/2 to 1 inch away).

3. **Hydrogel Disk.** For treating crater wounds, cover the wound with a hydrogel disk and apply the soundhead to the disk. This allows direct wound sonation without bringing the soundhead in direct contact with the wound.

4. **Stationary Soundhead.** This method is dangerous. Hot spots can develop. Do not use.

## Treatment Time

$$\text{For Sub-Acute Conditions:} \quad \frac{\text{area to be treated } (cm^2)}{1.5 \times \text{ERA}} = \text{minutes of treatment}$$

$$\text{For Chronic Conditions:} \quad \frac{\text{area to be treated } (cm^2)}{1.0 \times \text{ERA}} = \text{minutes of treatment}$$

$$\text{For Maximal Thermal Effect:} \quad \frac{\text{area to be treated } (cm^2)}{.8 \times \text{ERA}} = \text{minutes of treatment}$$

## Treatment Intensity

Several factors come into play as one decides the level of intensity for the treatment.

1. Superficial lesions require less intensity.

2. Less intensity should be used if bone is superficial to the treatment field.

3. Less intensity should be used when the stage of the injury makes heating questionable.

4. Use a little lower intensity for the first treatment to gauge response.

5. Patient feedback is key. A treatment should feel warm, but the patient should never feel heat, pain, stabbing, pricking or dull ache.

Acute Conditions:..... 0.1 – 0.5 W/cm$^2$ (no appreciable thermal effect).

Sub-Acute Conditions:.....0.5 – 1.0 W/cm$^2$ (Mild to Moderate thermal effect).

Chronic Conditions:.....1.0 – 2.0 W/cm$^2$ (Moderate to Strong thermal effect).

NOTE: It is very common that intensity is always 1.5 W/cm$^2$. This is incorrect in many cases. A more specific intensity should be used based on patient response and stage of injury.

## Frequency of Treatment

Treatment can be given daily. It is not uncommon to give Ultrasound twice daily, but this may be excessive. Some guidelines may be helpful.

1. Daily may be the best maximum frequency.

2. Ultrasound can be effectively given every other day.

3. Ultrasound should give some positive benefits by the 3rd or 4th application. If not, discontinue the treatment and consider other options.

4. A maximum of 12 to 15 Ultrasound treatments should be given. If the result desired has not been reached by this point, Ultrasound may not be the proper choice. EXCEPTION: Some Chronic conditions which cause adhesions.

## Usage Cautions – Combination Treatments

When using a Stim device in conjunction with a Dynatron 125 device to output Stim through the soundhead, observe all contraindication, warnings, precautions, and usage cautions provided by the manufacturer for all modalities involved. Dynatronics' stim devices ae recommended. Any other stim device used must not exceed the voltage levels of a Dynatronics' stim device to ensure safety for the patient.

## Poential for Burns or Periosteal Pain

Some patients' skin is more sensitive to Ultrasound output. This can cause a reaction similar to a heat rash. It is also possible for a patient to suffer a burn from Ultrasound therapy if the therapy is not administered properly. This can occur for the following reasons:

- Intensity (power) too high
- Frequency too low
- Holding the soundhead in one place on the patient's skin
- Moving the soundhead too slowly
- Treating an area where sensory nerve damage is present with a loss of normal skin sensation
- Time (Caution:  Don't treat too long).

Bony prominences are especially susceptible as they reflect sound waves and increase intensity to the periosteum, resulting in a burning sensation. Desensitized areas can be overheated or burned without the patient realizing it, so extreme care must be taken with these patients (e.g. diabetes, neural damage, etc.)

Burns can be avoided as long as the treatment causes no pain, tingling, excess heat, or aching (for patients with normal skin sensation). Use sufficient coupling agent and make sure there are no bubbles in the gel. When treating in water, clear the bubbles off the soundhead and the patient's skin.

An un-calibrated soundhead can also cause tingling, excess heat, aching, or a burning sensation.

Read Ultrasound Contraindication, Warning, & Precaution in this manual for more information.

# Ultrasound Problem Solving

## Whirlpool Treatments

If you are treating in a whirlpool, you may find that the temperature in the whirlpool approaching 103˚F, causing the overheated soundhead caution to appear on the Operations Screen. This is a cautionary warning only to let you know that you are approaching the temperature limit. You may, however, continue with the treatment at this level. If your whirlpool temperature is hot enough to cause the treatment to stop, you will need to adjust the temperature of the whirlpool.

## Soundhead Temperature Too Cold

If the soundhead has been sitting in a very cold room or vehicle, it could be too cold to operate when plugged into the console. The keypad may not respond to key presses and the device will not function until the soundhead is sufficiently warmed. You must raise the temperature of the soundhead to about 60 degrees F in order for the machine to recognize that the soundhead is present and to proceed with setting up a treatment. You can accomplish this with any of the following methods:

1. Press the flat face of the soundhead against the palm of your hand for 30 to 60 seconds to warm it slightly. This usually provides adequate warmth to the crystal to raise the temperature to the minimum acceptable level. Once the crystal reaches this level, you can proceed with treatment.

2. You can also place the soundhead in room temperature water to warm the crystal. However, do not place the soundhead in very hot water when the crystal is this cold as it could damage the crystal.

## No Soundhead

If the device cannot detect a soundhead during setup or during an ultrasound treatment, the error message “SOUNDHEAD DISCONNECTED! CORRECT PROBLEM WITH SOUNDHEAD TO RESUME!” will appear on the Operations Screen.

If this error occurs, check to be sure the soundhead is firmly plugged into its connector. If you are unable to clear the message by reconnecting the soundhead, contact Dynatronics' Customer Service Department at 1-800-874-6251 for assistance.

## Miscellaneous

Certain conditions can cause an error in operation. When this occurs, the machine will not allow a treatment to be set up or delivered and will display an error message. Some errors are easily resolved by the following methods.

- Press STOP to stop the treatment, and turn the machine OFF then ON again. Always wait 5-10 seconds before restarting the device.
- Check to be sure the soundhead has not become disconnected from the machine. The soundhead should be firmly plugged into its port. Only Dynatronics soundheads may be used with this device. If the soundhead has been dropped, it may be damaged. If the device operates normally with one soundhead, but not with another, the problem may be a damaged soundhead and you must contact Dynatronics Customer Service.
- Make sure the soundhead is not too hot. In this case a Soundhead error will appear in the Operations Screen.
- Check to see if conditions may have caused extreme moisture/condensation in the device. This could occur when the machine has become very cold and is brought indoors to a warm, humid environment. Condensation is a not a serious condition. Allow the machine to sit in a dry environment until the condensation dries. The machine will operate normally once the condensation is gone.
- Should the touch screen become unresponsive but the treatment timer continues to count down, you may continue delivering the treatment until it ends. If the touch screen remains unresponsive, cycle the power off/on the device. When the condition persists, contact the Customer Service Department.

If you have tried all of these suggestions, the device may require service by the manufacturer. In this case, make a note of the error message and the sequence of events that caused the error, and contact Dynatronics Customer Service at 1-800-874-6251 for further assistance. Do not send the device to Dynatronics without first contacting the Customer Service Department.

## Replacing the Soundhead

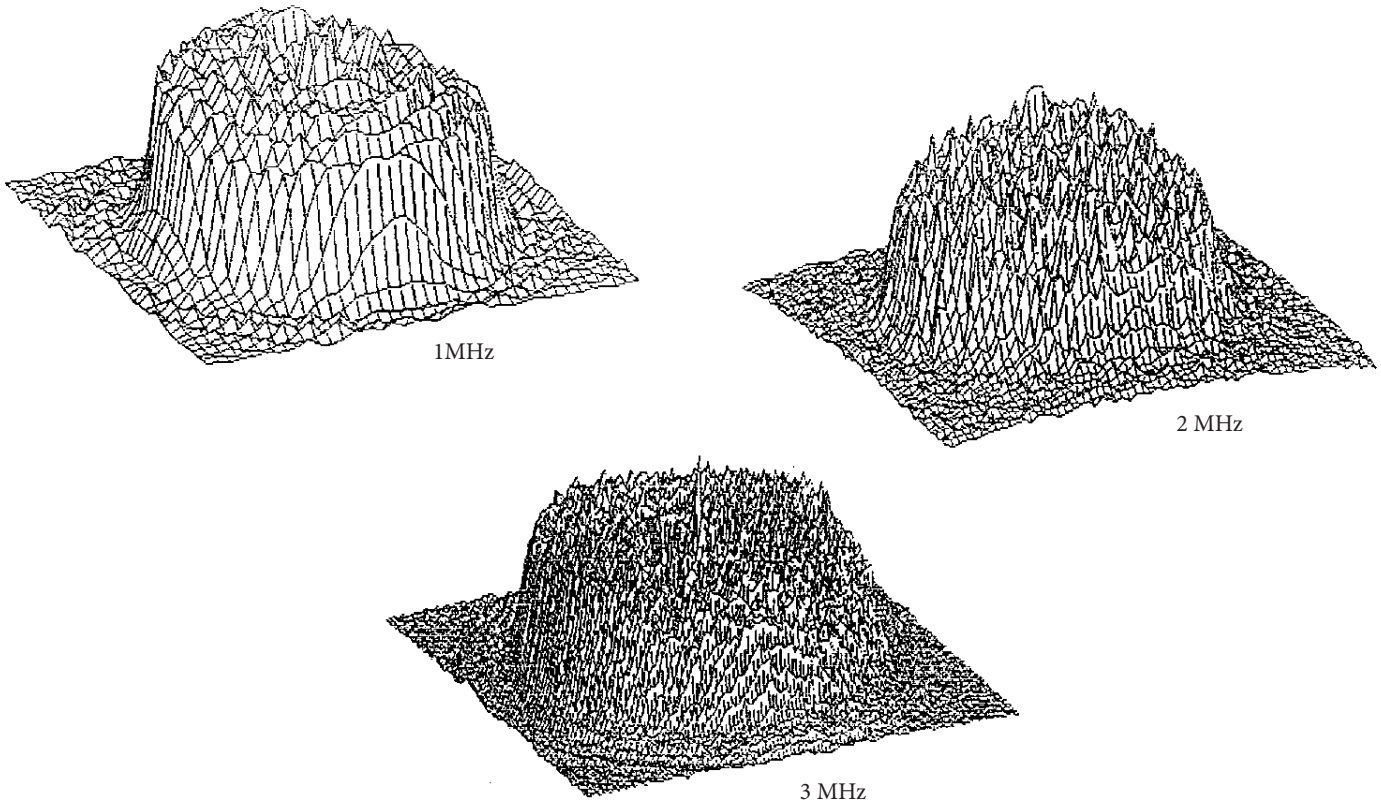
The Ultrasound probe is a "smart" probe. The treatment head contains a microcontroller to store calibration data and communicate that data to the console when the probe is plugged into the device. This feature allows the user to change soundheads on the console without entering the calibration data associated with each soundhead.

In addition, the Dynatron 125 provides a "Head Calibration" key that gives the user the capability to enter parameters manually in the event that parameters are lost or the user wishes to enter the parameters manually. This key, located on the Settings Screen, is also used to access user calibration mode for soundheads. Soundheads should still be calibrated on an annual basis.

# Ultrasound Beam Profiles

The following diagrams show the typical spatial distribution of the radiated field for each size of Dynatron 125 soundheads. This applies to the radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30˚C and with line voltage variations in the range of ±10 percent of the rated value.

## 10 cm² Head. Near Field

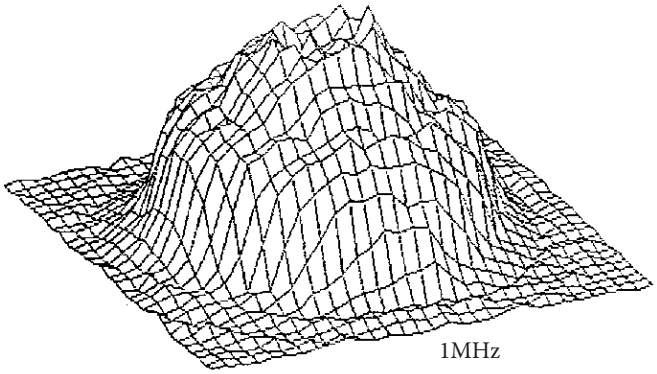


1MHz

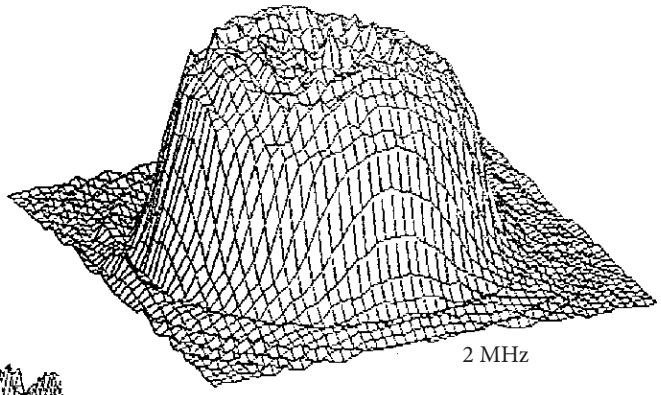
2 MHz

3 MHz

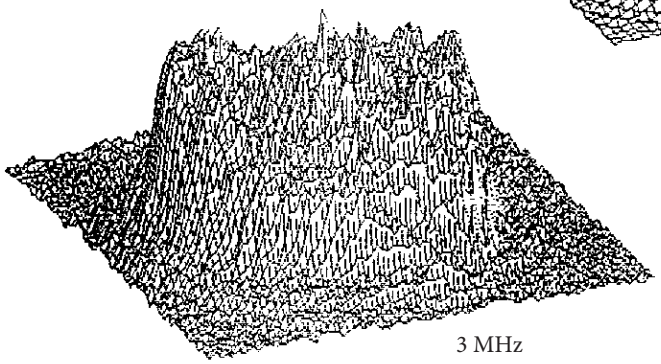
## 5 cm² Head. Near Field



1MHz

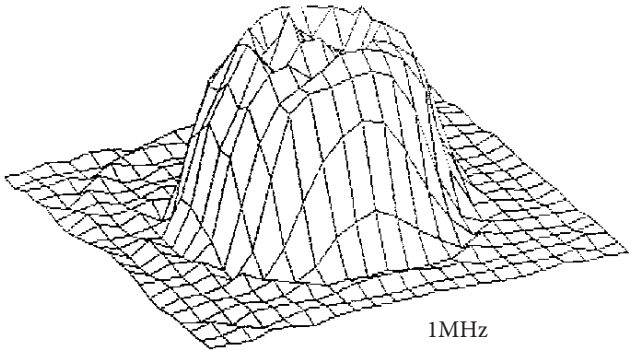


2 MHz

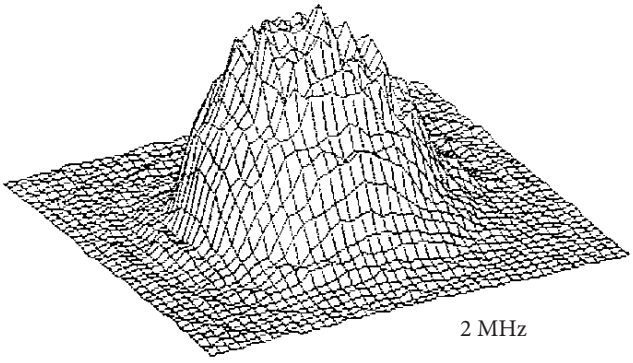


3 MHz

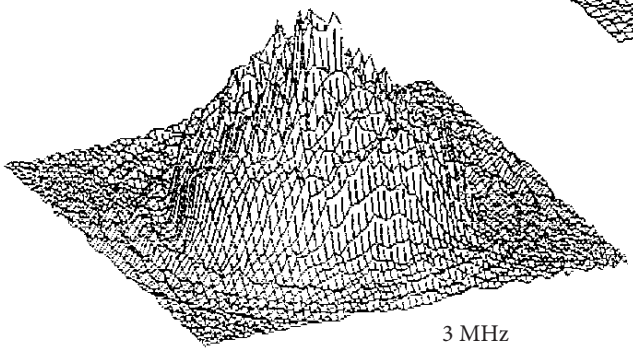
## 2 cm² Head. Near Field



1MHz



2 MHz



3 MHz

# Combination Therapy - Using the Combo Jack

The Combo Jack provides the ability to combine electrical stimulation from an existing electrotherapy device with the Dynatron 125 Ultrasound. The existing stimulator device must comply with **IEC 601-1 and IEC 601-2-10 (general and particular standards) requirements.** The banana jack accommodates a Combination Lead Wire or requires the use of a pin-to-banana adapter in order to provide Stim output through the Ultrasound head. The choice of electrotherapy modalities that can be combined with an Ultrasound treatment depends on the stimulation device being used. Refer to the stimulation device's instruction manual for instructions regarding delivering electrotherapy. Dynatronics' stim devices ae recommended. Any other stim device used must not exceed the voltage levels of a Dynatronics' stim device to ensure safety for the patient.

## WARNING

- DO NOT use combination therapy for underwater treatment. Placing active electrodes underwater poses a serious hazard to the patient!
- Use VERY LOW STIM INTENSITY for COMBO treatments.
- Remember to observe all contraindications, warnings, precautions, and usage cautions for BOTH Ultrasound and Electrical Stimulation therapy when performing combination therapy.
- Since electrical current travels between the electrode and the soundhead during a COMBO treatment, the electrode should be placed in proximity with the treatment area. Do not place the electrode and soundhead in positions that will cause current to pass through contraindicated areas.
- Avoid removing the soundhead from the skin surface during "Stim Through Soundhead" treatments as this may cause a momentary interruption of Stim current which may be uncomfortable to the patient. The soundhead should remain in full contact of the skin until current output is stopped.
- Be alert for any sign of periosteal (bone) pain.

## Stim Through the Soundhead

With combination therapy, the soundhead is used in place of one electrode for a Stim treatment; and electrotherapy current is delivered through the soundhead. This means that for a normal 2-electrode Stim treatment therapy, one electrode would be placed on the patient with the soundhead acting as the second electrode site to complete the setup.

During the treatment, the stim current passes between the soundhead and the other electrode. At the same time ultrasonic waves are introduced into patient tissue through the soundhead. Avoid touching the electrode with the soundhead during the treatment. Keep the soundhead in contact with the patient's skin at all times, and keep the intensity low for the Stim current.

### WARNING

- When setting up a combination treatment, observe all Contraindications, Warnings, and Precautions for both therapies to be used.
- Use VERY LOW STIM INTENSITY for COMBO treatments.
- Carefully comply with all instructions for the use of the existing electrotherapy device when it is used in combination with the Dynatron 125.

# Contraindications, Warnings, & Precautions for Ultrasound Treatment

## Contraindications

The Dynatron 125 Ultrasound should not be applied in the following 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 or other implanted electronic device
- 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.

The Dynatron 125 Ultrasound should not be applied to 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 epiphyseal areas of the bones in growing children
- 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 the new plastics is unknown)
- The Dynatron 125 Ultrasound should not be used over healing fractures.

INTENSITY (POWER) SHOULD BE REDUCED IF PATIENT COMPLAINS OF PERIOSTEAL BONE PAIN (BONE ACHE)

## Precautions

The Dynatron 125 Ultrasound device must be used cautiously in the presence of the following conditions:

- When there is a tendency to hemorrhage following acute trauma or fracture.
- Acute bursitis. Do not use in continuous duty cycle mode.

## Warnings

- Do not use in general area where high-powered, high-frequency transmitting surgical units are being operated. Short wave diathermy should not be turned on or used at the same time as this Dynatron device.
- Do not use the same power outlet or line with a whirlpool and certain traction machines.
- 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. Use a surge suppressor if power problems are encountered.
- Avoid unnecessary exposure to Ultrasound (patient and therapist).

# Technical Information

**⚠ CAUTION**

There are no serviceable parts in the Dynatron 125 devices.

## Setting Defaults

The Dynatron 125 Ultrasound has default settings that are automatically selected when the device is turned on. The default settings feature allows previously used treatment parameters to be set up in just seconds. For guidance in selecting the appropriate treatment settings consult published medical literature.

## Save New Defaults

If your most common treatment settings are different than the ones already set for this device, you can change the defaults to suit your own preferences. Setting new defaults is simple and defaults may be changed again and again whenever needed.

1. Set up a treatment using your preferred settings. Intensity, Frequency, and Duty Cycle cannot be saved as default settings.

2. Touch the TIME window on the Operations Screen. The Time Screen will appear.

3. Press the image in the lower left-hand corner. Treatment Parameters are now saved as the Default Parameters for future treatments.

## Restore Factory Defaults

If you have saved your own defaults, but would like to return **ALL** the default settings to those that were set at the factory, follow the steps below:

4. Touch the SETTINGS icon in the lower right-hand corner of the Operations Screen.

5. Touch "RESTORE FACTORY DEFAULTS." All of the factory defaults are no restored for all future treatments.

## Environmental Conditions

**Transport and Storage**

This equipment, while packed for transport or storage, should not be exposed to environmental conditions outside the following ranges:

a. an ambient temperature range of -40°C  +70°C
b. a relative humidity range of 10% to 100% including condensation
c. an atmospheric pressure range of 500 hPa to 1060 hPa

**Operation**

This equipment is designed to operate in normal use under the following environmental conditions:

a. an ambient temperature range of +10°C  +30°C
b. a relative humidity range of 30% to 75% including condensation
c. an atmospheric pressure range of 700 hPa to 1060 hPa

## Safety Features of the Dynatron 125

- All intensity levels are automatically set to zero at the end of treatment (ensures proper setting of intensity levels for the next patient).
- Internal surge protection protects against line noise, machine switching operation and any other type of interference that could cause patient discomfort.
- The Power Cord is considered the 'disconnect device' when it is necessary to ensure that the device is disconnected from a power source (for service or otherwise). Do not position the device such that it would be difficult to disconnect the power cord from the device.
- Soundhead temperature monitoring prevents the soundhead from becoming too hot, both to protect the soundhead crystal from damage and to ensure patient comfort.

# Battery Operation

### ⚠ Use ONLY a Battery Meeting Specifications

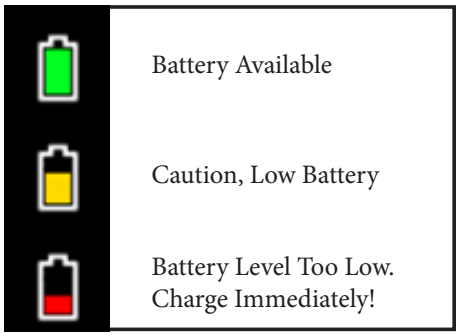
Before purchasing or using an existing battery with the Dynatron 125 device, refer to the section titled "Battery Requirements" in this manual.

**Only use a battery that CANNOT be recharged while it is in use. Disconnect the battery charger from the AC power source before using the battery to supply power to this device.**

All Dynatron 125 devices are manufactured with battery capabilities allowing deliver of treatments wherever power may be unavailable or unreliable. To use the optional battery, do the following:

1. It is recommended that a battery be charged for 24 hours prior to operating the Dynatron 125 device. DISCONNECT the battery charging cable from the battery while it is in use for treatment.

2. Plug the battery adapter into the jack labeled "BAT-INPUT 12V-DC" on the back of the Dynatron 125 console. The green BATTERY ICON will appear in the lower left-hand corner of the Operations Screen.




3. Set up and deliver treatments.

4. When battery power is reduced to approximately 11 volts, a low battery warning will be displayed in the lower right-hand corner of the Treatment Display Screen "CAUTION: BATTERY LEVEL GETTING LOW!" The treatment can continue; however, there will not be enough power to set up and deliver another treatment when the current

treatment has ended. The yellow BATTERY ICON will appear in the lower left-hand corner of the Operations Screen, indicating the battery level.

5. When the available battery power becomes too low to continue operating the device, the following message will appear: "ERROR: BATTERY LEVEL TOO LOW FOR TREATMENT OPERATION. CHARGE IMMEDIATELY!" The treatment intensity will ramp down, any treatments that were running at the time will stop, and the device will shut down. Before battery operation can continue, the battery must be recharged.

Note: If using a smaller gauge wire (20 AWG and up) the BATT LOW error is possible when the battery is not low.

## Battery Requirements

- 12 volt and at least 5 amps hours.
- Battery adaptor cord must match the plug end of the battery pack. The barrel plug end must match the 0.325" barrel jack adaptor plug on the Dynatron 125.
- The cord needs to be a minimum of 18 AWG gauge wire. 14-16 AWG gauge wire will work as well with a 5 amp fast blow fuse.

## Battery Life

The length of time that a unit can be used with a battery pack is dependent on several factors:

- The amperage of the battery pack. Larger amperage will provide longer use.
- The amount of charge remaining on the battery.

As a general rule, the unit may be run continuously for 30 minutes to several hours depending on these factors.

**⚠ CAUTION**

Follow battery manufacturer's instructions for usage and care. When disposing of a used battery, comply with the laws and procedures required in your area.

# General Specifications

## Dynatron 125 Specifications

Power Requirements ..... 100-240 V~, 50/60 Hz

Power Consumption..... 65 Watts

Fuse:.....120V~ - 0.8A; 240 V~-1.6A

Dimensions.....7" W (17.78cm) x 4.0" H (10.16cm) x 9.0" D (22.86cm)

Weight ..... 4.0 pounds (1.81 Kg)

## Ultrasound Specifications / Power Output

$2cm^2$ head:.....1 MHz, 2 MHz, 3 MHz..... 0-4 watts; 0-2.0 $w/cm^2$ ± 10%

$5cm^2$ head:.....1 MHz, 2 MHz, 3 MHz..... 0-10 watts; 0-2.0 $w/cm^2$ ± 10%

$10cm^2$ head: .....1 MHz, 2 MHz..... 0-20 watts; 0-2.0 $w/cm^2$ ± 10%

$10cm^2$ head: .....3 MHz..... 0-10 watts; 0-1.0 $w/cm^2$± 10%

## Ultrasound Regulation and Compliance

The Dynatron 125 complies with the following:

- FDA 21CFR 1050(c)(1)(i). 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 21CFR 1050(c)(1)(ii). The sum of the errors in the indications of temporal-maximum ultrasonic power and the ratio 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 settings greater than 10 minutes.

NOTE: The Dynatron 125 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 ratio of the temporal-maximum to temporal-average effective intensity, pulse duration, and pulse repetition rate for the Dynatron 125 is as follows:

(1) Ultrasonic frequency ..... ±15%
(2) Effective Radiating Area ..... ±20%
(3) Ratio of the temporal-maximum to temporal-average effective intensity ..... ±20%
(4) Pulse duration ..... ±10%
(5) Pulse repetition rate ..... ±10%

## Care and Cleaning Instructions

**Dynatron 125 Console**

- Clean the outer surface of the Dynatron 125 devices with a slightly damp or lightly moistened cloth. Mild household cleaners work well on the frame, but do not use cleaners on the display windows. **Do not spray the solution directly on the unit.** Solvents, caustic solutions and harsh or abrasive cleaners must never be used.
- Do not attempt to sterilize the device or the soundheads using any type of sterilization equipment including autoclaves.
- Avoid stretching cords to full length, bending cords sharply or wrapping cords tightly. Undue stress on cords can damage connections.
- Keep all food and drinks away from the machine and its accessories; spills can cause costly damage to the machine and repairs for this type of damage are not covered by the warranty.
- Do not place hot packs or any items with moisture content on top of the console.

**Ultrasound Head**

- Ultrasound heads should be cleaned with warm water. Always keep the head free from gel buildup. Alcohol may be used to sterilize the soundhead.
- Do not use ice water for cooling soundheads.
- Do not allow soundheads to overheat repeatedly. This could result in thermal shock to the crystal. Damage of this type is not covered by the warranty.
- Do not drop the unit or the soundheads as severe damage will occur.

## Suggested Maintenance Schedule

**Service To Be Performed Annually By A Technician:**

- Annual Ultrasound calibration should be performed by a qualified technician.
- Inspect soundhead connectors on unit and on soundhead.

**Maintenance Performed By User:**

1. 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.

2. Examine Ultrasound heads periodically for cracks which may allow ingress of conductive fluid.

3. If a machine or soundhead is dropped, or if it sustains damage due to lightning, severe power surge, or other incident that could cause damage to electronic components, the device must be examined by a Dynatronics technician before being returned to clinical use.

4. Even if the machine is functioning properly, you can send it to Dynatronics for preventative maintenance service for a nominal charge; call for pricing.

5. Inspect device air vents periodically to ensure air flow is not blocked. An ordinary household vacuum hose may be used to clean dust from air vents externally.

6. There are no serviceable parts in the Dynatron 125. DO NOT attempt to unscrew or tighten the Ultrasound probe heads. Immediately report any device malfunction to Dynatronics Customer Service Department.

**WARNING**

Hazardous electrical output. To reduce the risk of electrical shock, do not remove cover. Refer servicing to qualified service personnel.

**⚠ CAUTION**

For continued protection against risk of fire, replace fuses only with type IEC 60127. For 120/240VAC supply, use 250V, 1.6A slow-blow.

## Routine Ultrasound Inspections for the Dynatron 125

Government agencies regulate the frequency at which Ultrasound units must have their calibration checked. The device must still be examined at the periodic intervals specified by the governing agency for the country in which the device is used. To have the inspection performed by Dynatronics, contact Dynatronics' Customer Service Department. The device will need to be shipped to Dynatronics for the inspection. As an alternative, these periodic checks may be performed in your own locale by an independent contractor, who is expert in checking the calibration of Ultrasound equipment. The calibration procedure MUST be performed by a qualified Ultrasound technician using the proper equipment, and is recommended every 6 to 12 months.

## Returning a Unit for Repair

BEFORE sending a device to Dynatronics for service, you must FIRST obtain a return authorization number. Call Dynatronics' Customer Service Department at (800) 874-6251 and discuss any problems or required service to save time and ensure the machine is returned to you as quickly as possible.

**Autorización de Retorno**

The following information will need to be supplied when calling Dynatronics' Customer Service to obtain a return Service Order Number (SVO):

1. User name and address
2. User phone number
3. Serial number of the unit
4. A description of the problem with the unit

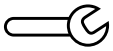
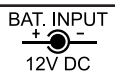
After receiving the Service Order Number (SVO), the number should be clearly written on the outside of the shipping container.

**Packaging and Shipping of Replacement Parts**

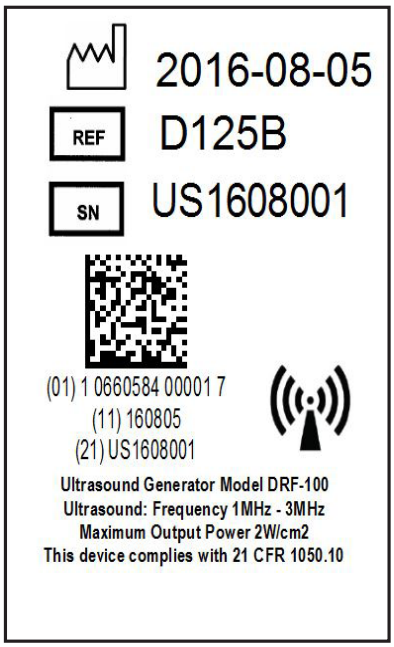
All defective or broken parts should be shipped back to Dynatronics in the original shipping container. These containers are designed to withstand the punishment of shipping. If the original containers are not usable, find containers that are similar in protection so damage in shipping will be prevented. The person or company sending the unit to Dynatronics is responsible for any shipping damage resulting from a poorly packaged part or unit.

## Definition of Symbols and Labeling

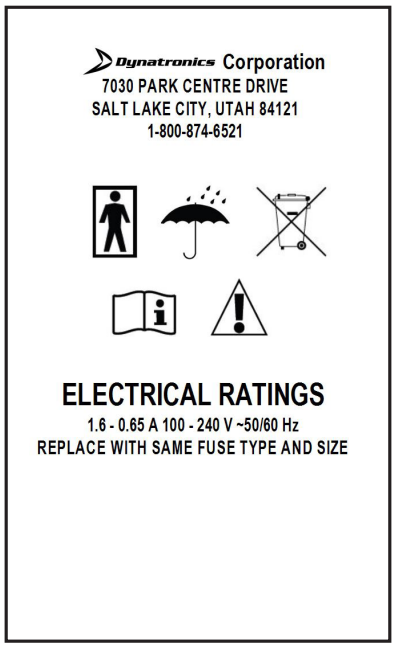
Some or all of the following symbols are included in the labeling for this device. Definitions accompany each symbol.

| | |
|---|---|
|  | Alternating Current |
|  | Caution |
|  | Type BF (patient-applied part) |
|  | Follow Instructions for Use |
|  | Keep Dry |
|  | Non-ionizing Electromagnetic Radiation |
|  | Made in USA |
|  | Temperature |
|  | Humidity |
|  | Model Number |
|  | Serial Number |
|  | Fuse |
|  | European Conformity |
|  | Maintenance |
|   | Battery Input |
|  | Dynatronics Manufacturer Location |
|  | Manufacturing Date |
|   | Safety Certification for Canada and the USA. Certified to IEC6601-1 |
|   | Ingress Protection Rating, protected against the effects of temporary immersion in water |

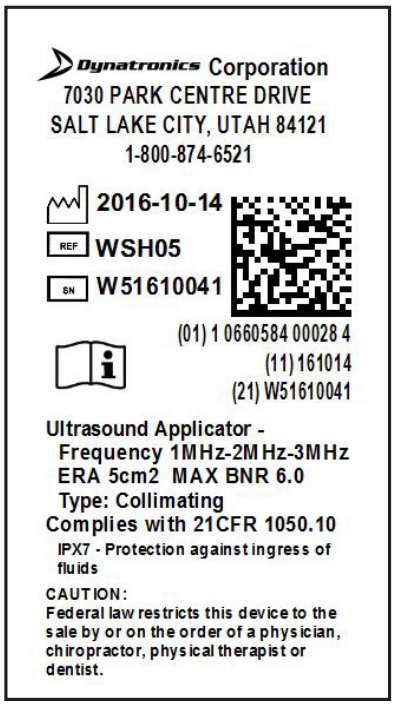
The following labels appear on the Dynatron 125 console, and Ultrasound Heads.




Manufacturer's Label




Electrical Ratings Label




Ultrasound

## Equipment Classification

This device is classified as follows:

- Protection against electric shock: Class I (protectively earthed enclosure)
- Protection against electric shock: Type BF (floating patient-applied part)
- Protection against harmful ingress of water: none
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Mode of operation: Continuous operation

## Disposal of Equipment and Accessories

There is no risk posed in disposal of this equipment or its accessories. These items contain no hazardous materials. Follow the WEEE or the applicable guidelines for your country of residence with respect to the disposal of electrical or electronic equipment. For disposal of accessory batteries, see manufacturer's instructions and follow applicable laws and regulations in your area.

# Electromagnetic Emissions and Immunity

Tables 1 through 4 below list the Dynatron 125 declarations of electromagnetic emissions and immunity, and give user guidance on the Dynatron 125 in an electromagnetic environment per IEC 60601-1-2 guidelines.

**Table 1**

| Guidance and Manufacturer's Declaration - Electromagnetic Emissions | | |
|---|---|---|
| The Dynatron 125 (and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the Dynatron 125 (and accessories) should assure that it is used in such an environment. | | |
| Emissions Test | Compliance | Electromagnetic Environment Guidance |
| RF emissions CISPR 11 EN55011 | Group 1 | The Dynatron 125 (and accessories) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment |
| RF emissions CISPR 11 EN55011 | Class A | The Dynatron 125 (and accessories) is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

## Table 2

| Guidance and Manufacturer's Declaration - Electromagnetic Immunity | | | |
|---|---|---|---|
| The Dynatron 125 (and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the Dynatron 125 (and accessories) should assure that it is used in such an environment. | | | |
| Emissions Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | +/- 8 kV contact<br>+/- 15 kV air | Compliant | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | +/- 2 kV for power supplyline<br>+/- 1 kV input/output lines | Compliant | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | +/- 1 kV differential mode<br>+/- 2 kV common mode | Compliant | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % Ut (>95 % dip in Ut) for 0,5 cycle<br><br>40 % Ut (60 % dip in Ut) for 5 cycles<br><br>70 % Ut (30 % dip in Ut) for 25 cycles<br><br><5 % Ut (>95 % dip in Ut) for 5 seconds | Compliant | Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | Not applicable | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: Ut is the a.c. mains voltage prior to application of the test level. | | | |

## Table 3

### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Dynatron 125 (and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the Dynatron 125 (and accessories) should assure that it is used in such an environment.

| Emissions Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 610000-4-3 | 3 Vrms 150 KHz to 80 MHz<br><br>3 V/m 80 MHz to 2.5 GHz | 3V<br><br>3V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Dynatron 125 (and accessories), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br><br>$d = 1.17 \times \sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = 1.17 \times \sqrt{P}$ 800 MHz to 2.5 GHz<br><br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range<br><br>Interference may occur in the vicinity of equipment marked with the following symbol: |

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Dynatron 125 (and accessories) is used exceeds the applicable RF compliance level above, the Dynatron 125 (and accessories) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dynatron 125 (and accessories).

b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

## Table 4

### Recommended separation distance between portable and mobile RF communications equipment and the Dynatron 125 (and accessories)

The Dynatron 125 (and accessories) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Dynatron 125 (and accessories) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dynatron 125 (and accessories) as recommended below, according to the maximum power of the communications equipment.

| | Separation distance (meters) according to frequency of transmitter | | |
|---|---|---|---|
| Rated maximum output power of transmitter W | 150 kHz to 80 MHz<br>$d = 1.17 \times \sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.17 \times \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.33 \times \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.7 | 3.7 | 7.4 |
| 100 | 12 | 12 | 23 |

For transmitters at a maximum output power listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# Medical Device Reporting Requirements

Under the Safe Medical Devices Act (SMDA), the manufacturer and distributor are required to report specific incidents to the FDA. In the event of any applicable incident, you should report details of the incident to the Dynatronics Customer Service Department at 1-800-874-6251. Reports should be submitted to the manufacturer immediately to allow the manufacturer to report to the FDA within 2 working days based on the following criteria:

- If you receive information that reasonably suggests a probability that a device caused or contributed to a:
    - death
    - serious injury, or
    - serious illness

- If you receive information that reasonably suggests a device malfunction and a recurrence will probably cause:
    - death
    - serious injury, or
    - serious illness

## Definition of serious injury

A "serious injury" is an injury that (1) is life threatening, (2) results in permanent impairment of a body function or permanent damage to body structure, or (3) necessitates medical or surgical intervention by a health care professional to (i) preclude permanent impairment of a body function or permanent damage to body structure or (ii) relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to a body structure.

Reference: Food and Drug Administration, HHS. 21 CFR Ch. 1 (4-1-90 Edition), 803.9 (h).

## Reporting any Incident of Patient Discomfort

Dynatronics recommends that if discomfort of any level is reported by the patient, the treatment be stopped immediately. The device and all accessories in use during that treatment should be isolated and held for inspection. Make a note of treatment parameters that were in use during the treatment including intensity settings. Also note environmental factors that were observed during the treatment (office lights flickering, static electricity discharge, other devices in use on the same power source or in the same room, etc.)

The incident should be reported immediately to Dynatronics Customer Service at 1-800-874-6251. The customer service representative will inform you if it is necessary to send the device and/or accessories to Dynatronics for inspection.

# Dynatron® 125™ Limited Warranty

DYNATRONICS CORPORATION warrants the Dynatron 125 products and the applicator soundheads (excluding other accessories) that are purchased with the unit to be free from factory defects in materials and workmanship under normal use for TWO YEARS from the date of purchase by the original owner. Accessories that accompany this product (which are listed as "accessories" on a list included with each unit) are warranted for 90 DAYS. If this product is defective within the warranty period, DYNATRONICS will, subject to the conditions set forth below:

(1) repair or replace defective parts at no charge within a reasonable period of time with new or remanufactured parts, at DYNATRONICS' option; and

(2) provide labor for the repair or replacement of defective parts under this warranty without charge.

Parts used for replacement under this warranty are warranted for the remainder of the original warranty period. THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS SHALL CONSTITUTE THE SOLE AND EXCLUSIVE REMEDY IN THE EVENT OF A BREACH OF WARRANTY.

REGISTRATION REQUIRED. In order for this warranty to be valid, the warranty registration card (included with the product) must be filled out and returned to DYNATRONICS within 30 days of purchase by the original owner. A copy of an invoice or receipt may be requested to verify purchase date.

REPAIRS. All repairs must be performed by an authorized service facility. Any modifications or repairs by unauthorized parties will void this warranty.

OBTAINING WARRANTY SERVICE. Authorization by DYNATRONICS is required before obtaining service under this warranty. Therefore, before shipping or delivering this product to an authorized service facility for warranty service, call DYNATRONICS and obtain a return authorization number.

PACKAGING AND SHIPPING. Any unit shipped to an authorized service facility for service under this warranty must be in the original shipping carton, freight prepaid, fully insured, and properly packed to prevent damage. DYNATRONICS is not liable for any damage to the unit while in transit. Include a summary of the problem with the product. Write the return authorization number obtained from DYNATRONICS on the shipping label.

SHIPPING COSTS. Within the first 30 days of the warranty period, DYNATRONICS will pay all necessary shipping costs associated with obtaining service under this warranty. After the first 30 days of the warranty period, the owner is responsible for all costs associated with shipping the product to an authorized service facility. DYNATRONICS will pay all costs associated with shipping the product back to the owner after service is completed, and will ship the product using the same carrier or type of carrier and service that was used by the owner for the incoming shipment.

EXCLUSIONS. Any defect, malfunction or failure caused by or resulting from improper installation, service, maintenance or repair, or from abuse, neglect, transportation, accident, act of God, or other cause beyond the control of DYNATRONICS will not be covered by this limited warranty. ANY IMPLIED WARRANTIES COVERING THIS PRODUCT, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO ONE YEAR FROM THE DATE OF PURCHASE BY THE ORIGINAL OWNER. DYNATRONICS SHALL NOT IN ANY CASE BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT, OR OTHER SIMILAR DAMAGES ARISING FROM BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, OR ANY OTHER LEGAL THEORY EVEN IF DYNATRONICS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

For more information concerning repairs, operation, or technical assistance, please contact the DYNATRONICS dealer nearest you, or contact DYNATRONICS directly at: the address below.

**Dynatronics Corporation**

7030 Park Centre Drive • Salt Lake City, Utah 84121 • (801) 568-7000 (800) 874-6251

## Dynatron® 125™ Warranty Registration

To register the warranty for your Dynatronics unit, complete all information requested, and MAI, FAX , or EMAIL to:

Dynatronics, 7030 Park Centre Drive, Salt Lake City, Utah 84121, Fax: 801-568-7711, Email: info@dynatron.com.

| PLEASE TYPE OR PRINT PLAINLY | | | | | |
|---|---|---|---|---|---|
| Purchase Information: | | | | | |
| Purchase Date: | | Model Number: | | Serial Number: | |
| Practitioner / Contact Name: | | | | | |
| Clinic or Institution: | | | | | |
| Address: | | | | | |
| City: | | State: | | Zip: | |
| Dynatronics' Sales Representative: | | | | | |

☐ I have read and understand the information contained in the operator's manual for this device.
☐ I have received in-service training from my dealer and/or Dynatronics for this device.

**IMPORTANT: If there is anything about the operation or use of your Dynatron device that you do not understand, contact your dealer or Dynatronics for instruction. As a trained medical practitioner, you are solely responsible for determining appropriate application of this device for your patients.**

**BEFORE RETURNING A UNIT TO DYNATRONICS FOR SERVICE, YOU MUST OBTAIN A RETURN AUTHORIZATION NUMBER. CALL 1-800-874-6251.**

**Failure to register the warranty may result in a delay in completion of services, and service will be billable.**

**How did you hear about the Dynatronics product you just purchased? (Check all that apply)**

☐ Advertising ☐ Referral ☐ Trade Show ☐ Magazine Article
☐ Mail ☐ Dealer ☐ Catalog ☐ Other_____

**Decision to purchase your equipment was based on? (Check all that apply)**

☐ Advertising ☐ Price ☐ Peer Recommendation ☐ Other (Specify) _____
☐ Product Literature ☐ Features ☐ Dealer _____
☐ Company Reputation ☐ Demo _____

**How do you find information about therapy products you want to purchase? (Check all that apply)**

☐ Magazines ☐ Other Practitioners ☐ Trade Show ☐ Other (Specify) _____
☐ Mail ☐ Dealer ☐ Product Reference _____

**For information about therapy products, what magazines do you read? (Please list all that you read)** _____

_____

**What features are you most interested in when purchasing equipment? (Check all that apply)**

☐ User Friendliness ☐ Warranty ☐ UL Listing ☐ Number of Channels
☐ Portability ☐ Accessory Package ☐ Educational Materials ☐ Company/Dealer Support
☐ Price ☐ User Programmable ☐ Design ☐ Other_____
☐ Unique Features ☐ ERA ☐ Number of Modalities _____
☐ Presets ☐ BNR ☐ User Modifiable _____
☐ Safety ☐ Soundhead Frequencies ☐ Quality _____