

OPERATOR'S MANUAL



A CAUTION

Federal law restricts these devices 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 devices.

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® 25 Series™ Device, see the "Contraindications, Warnings, and Precautions" in this manual. Read the operating instructions for each modality carefully.

INDICATIONS FOR USE

ELECTROTHERAPY: Electrical muscle stimulation therapy (Russian, Biphasic, High Volt) for:

- 1. relaxation of muscle spasm;
- 2. prevention or retardation of disuse atrophy;
- 3. increasing local blood circulation;
- 4. muscle re-education;
- 5. immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- 6. maintaining or increasing range of motion.

Transcutaneous electrical nerve stimulation and Interferential Current Therapy (Interferential, Premodulated, and High Volt) for: Symptomatic relief of chronic intractable and/or management of post-traumatic or post-surgical pain.

ULTRASOUND THERAPY: 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.

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

08/08/2016- Rev. 0 Inventory 5D00280 All Rights Reserved ISO 13485 NEMKO CERTIFIED DQS CERTIFIED Dynatron® 25 Series™ Operation Manual

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Introduction to the Dynatron[®] 25 Series[™]

The powerful and versitle 25 Series offers 3 and 5 channel devices. All channels allow fully-independent treatment setups offering Interferential, Premodulated, High Volt, Biphasic, Russian, Microcurent, and fixed frequency IFC/Premod. In addition, the 925 and 825 include Dynatronics' Ultrasound Comboplus feature with the power to deliver up to 5 channels of Stim and Ultrasound - all at the same time. All of the Dynatron 25 Series models offer 1, 2, and 3 MHz frequencies for the greatest flexibility in depth of treatment. Choose 1 MHz for deep treatments, 2 MHz for moderate depth, or 3 MHz for superficial depth.

Summary of Features by Device

Feature	925	825	625	525
Electrotherapy				
IFC	Х	Х	Х	X
Premod	Х	Х	Х	X
Biphasic	Х	Х	Х	X
Russian	Х	Х	Х	X
High Volt	Х	Х	Х	X
Combo Electrotherapy/Ultrasound	Х	Х		
Ultrasound	Х	Х		
Available Channels				
Electrotherapy Channels	5	3	5	3

Feature	925	825	625	525
High Volt Channel	1	1	1	1
Ultrasound Channel	1	1		
Combo Channel	1	1		

The 25 Series devices include the standard advantages of Dynatronics engineering, such as customizable treatments, electrode conductance meters, and the popular Target feature. In addition all units offer the option of battery operation, making the devices truly portable. The manufacturer's warranty for these devices is two years (see full warranty details at the back of this manual).

This manual provides operator information and instructions for the four 25 Serises models: the 525, 625, 825, and 925. The section that discusses Ultrasound and Combo treatments applies only to the Dynatron 825 and 925 models. All other sections of this manual apply to all Dynatron 25 Series devices.

Simplified Setup

The design of the 25 Series top panel means treatment setup has never been easier. A few simple key presses are all you need to fully set up a treatment. The User Interface intuitively groups and displays all the options for a modality setup on the large LCD screen to ensure that treatment parameters can easily be selected and adjusted.

Each modality offers default settings which are automatically preset when the modality is selected—saving time in the treatment setup. You can change these defaults to match your own most common treatment setups reducing setup time to a matter of seconds.

WARNING

Power-on the device before attaching electrodes to the patient.

Language Selection

The default language on the 25 Series Family of devices is English; however, both French and Spanish are also available. To change the default language: 1) Begin at the START UP SCREEN. 2) Press the FUNCTION KEY. 3) Use the toggle key under the LANGUAGE WINDOW to select the desired language. 4) Press STOP to return to the START UP 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 attach electrodes, apply ultrasound or light therapy accessories and monitor patient

response to attended or unattended 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 25 Series devices, you should familiarize yourself with all the operating instructions for the modality used, as well as the contraindications, warnings, and precautions for that modality. You should also read the general information about each of the modalities provided in this manual. 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 temperatrue prior to treatment.

Installation and Features

Unpacking

When you receive the unit, immediately unpack it and all accessories and 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

Qty	Part No.	Description: C	ne of the following devices:
1	D925T	Dynatron 925	5-Channel Combination Stim and Ultrasound
1	D825T	Dynatron 825	3-Channel Combination Stim and Ultrasound
1	D625T	Dynatron 625	5-Channel Stim
1	D525T	Dynatron 525	3-Channel Stim

Qty	Part No.	Description: One of the following devices:
1	7B0241	Power Cord (black)
1	5D00280	Operator's Manual
1	7B0268	Protocol Reference Manual for Electrotherapy & Ultrasound (J. Stephen Guffey, P.T., Ed., D.)
1	7B0284	Ultra Polys" self-adhesive electrodes 2" x 4" (5.08cm x 10.16cm) w/ pin connector (pkg. of 4)
1	DW248	2.5" x 48" (6.35cm x 121.92cm) straps (pkg. of 2)
1	7B0191	5" x 8" (12.7cm x 20.32cm) dispersive electrode for High Volt (gray)
1	7B0201	Sponge Fabric for use with 5"x 8" (12.7cm x 20.32cm) dispersive electrodes

Dynatron 825 and 525

1	7B03020	96" (243.84cm) shrouded lead (1 red)
1	7B03030	96" (243.84cm) shrouded lead (1 black)

Dynatron 625 and 925

2	7B03020	96" (243.84cm) shrouded lead (2 red)
2	7B03030	96" (243.84cm) shrouded lead (2 black)

Dynatron 825 and 925 Ultrasound

1	7B0217	DynaGel Ultrasound Gel 100 ml sample
1	7B03040	Combo lead wires

Soundheads

The Dynatron 125 devices may be purchased with one or more applicator soundheads 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:

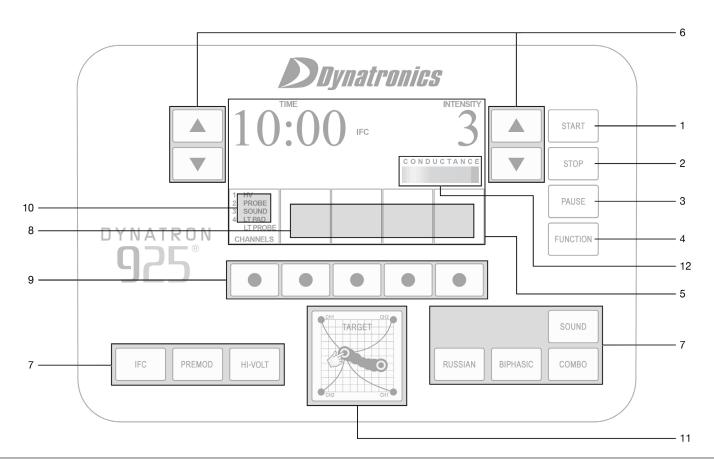
Part No.	Description
D71BAG	Soft Side Carrying Case
D71CART	25 Series Cart
7B0208	2" (5.8cm) diameter carbon electrodes (red)

Part No.	Description
7B0209	2" (5.8cm) diameter carbon electrodes (gray)
7B0063	3" (7.62cm) diameter carbon electrodes (red)
7B0065	3" (7.62cm) diameter carbon electrodes (gray)
7B0059	3" x 5" (7.62cm x 12.7cm) carbon electrodes (red)
7B0061	3" x 5" (7.62cm x 12.7cm) carbon electrodes (gray)
7B0067	1.5" x 2.0" (3.81cm x 5.8cm) carbon electrodes (red)
7B0069	1.5" x 2.0" (3.81cm x 5.8cm) carbon electrodes (gray)
7B0260	2" x 4" (5.8cm x 10.16cm) Ultra Polys adhesive electrodes (w/snap or pin)
7B0261	2" x 2" (5.8cm x 5.8cm) Ultra Polys square adhesive electrodes (w/snap or pin)
7B0077	Bifurcated extension lead wire for High Volt use
7B0082	Pin-to-Banana adapter (black)
7B0079	Banana-to-Pin Adapter (black)
7B0001	Snap adapter
5LTRGEL	Ultrasound Coupling Gel (5 liter container)

Dynatron[®] 25 Series Physical Features

Before operating the Dynatron 25 Series devices, 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, discussions of each modality, definitions of the available options, along with contraindications, warnings, and precautions for all modalities.

Note: The User Interface on the 25 Series devices is engineered with "CapSense Touch Technology" requiring that the user make direct contact with the keys on the faceplate with bare fingers or the use of a glove with a conductive fingertip.



- 1. **START:** Press the green START key on the right side of the Treatment Display Screen to start the treatment timer and treatment proceeds as set up.
 - The START key can also be used to save new treatment DEFAULT settings. After setting up a treatment, press and hold the START key for two seconds. At the end of two seconds, a beep will sound indicating the treatment parameters have been saved. The next time the modality is selected, these parameters will be selected automatically.
- 2. **STOP:** Pressing the red STOP key during a treatment IMMEDIATELY stops the output and sets the treatment time to zero for all modalities. To stop only the focus treatment, reduce the focus treatment's time to zero.
- 3. **PAUSE:** The PAUSE key is designed to pause Ultrasound treatments.
- 4. **FUNCTION:** This key is used to access unique features for High Volt, Ultrasound, Combo treatments and for entering soundhead parameters. The FUNCTION key is also used in conjunction with the STOP key to stop only a treatment in focus. In addition, the FUNCTION KEY provides access to settings for STIM, LANGUAGE, LEAD TESTS AND SYSTEM INFORMATION. Specific instructions for using this key are provided later in the manual as they apply to each function or modality.
- 5. **TREATMENT DISPLAY SCREEN:** Located in the upper center of the USER INTERFACE, the TREATMENT DISPLAY SCREEN allows the clinician to view all of the parameters of the focus treatment such as time, intensity, frequency, duty cycle, contraction rest, ramp time, polarity, or any other setting applicable to a treatment at a glance. In addition, the screen lists all active modalities not in focus along with their active channels and remaining treatment times in small font under the heading RUNNING TREATMENTS. If an error occurs during treatment, an error message will appear on the Treatment Display Screen identifying the treatment modality that triggered the error message.
- 6. **ARROW KEYS:** The UP/DOWN arrow keys are used to increase/decrease the treatment time or other parameters that appear on the TREATMENT DISPLAY SCREEN directly next to the arrow keys being used.
- 7. **MODALITY KEYS:** The 25 Series devices have the following treatment modality options: IFC, Premod, Ultrasound, Combo, Biphasic, Russian, and High Volt. MODALITY KEYS appear at the bottom of the USER INTERFACE. Pressing any of the available MODALITY KEYS will bring the selected modality into focus and the default parameters for that treatment modality will be displayed. Treatment modality parameters may be customized once the treatment is in focus.
- 8. **TREATMENT WINDOWS:** Across the bottom of the TREATMENT DISPLAY SCREEN are five smaller treatment windows providing treatment options and parameters that are unique to each modality. The quick access and visibility of these TREATMENT WINDOWS allow for quick, easy, and accurate setup. On the following pages are illustrations of each modality's TREATMENT WINDOWS and their associated default settings.
 - Note: High Volt, Sound, and Combo treatments all have a secondary set of TREATMENT WINDOWS and treatment options that are accessed when the treatment is in focus and the FUNCTION key is pressed. The arrow between the two boxes indicates the secondary treatment window.

IFC (Interferential)



Premod



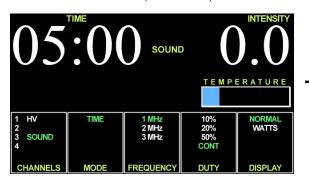
Biphasic



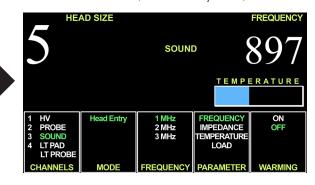
Russian



SOUND (Ultrasound)



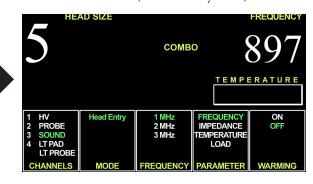
SOUND (Function Key View)

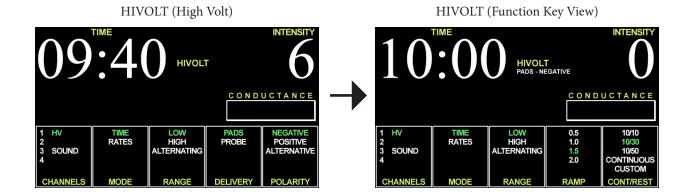


COMBO (Combination)



COMBO (Function Key View)





9. TREATMENT WINDOW TOGGLE KEYS: TOGGLE KEYS are located below the five TREATMENT WINDOWS. Pressing the toggle key directly below a window allows the one to choose an output channel, and select treatment parameters for a treatment in focus. A treatment is in focus when the name of the treatment appears in the center of the TREATMENT DISPLAY SCREEN.

10. CHANNELS WINDOW / CHANGING THE FOCUS TREATMENT

The lights in the CHANNELS window indicate which output channels/jacks are currently in use. The channel(s)/jack illuminated in GREEN indicates the focus treatment and the time, intensity, and other treatment parameters for that active treatment appear on the Treatment Display Screen. A solid YELLOW light indicates a channel/treatment is in use and delivering current, but the intensity, and treatment parameters are not displayed at this time (only one channel's parameters may be displayed at a time). A treatment's parameters may only be modified when the treatment is brought into focus. To bring a treatment into focus, press the CHANNELS TOGGLE key below the CHANNELS window to select a channel to be brought into focus. If a treatment that is active but not the focus treatment times-out, the text in the CHANNELS window will change from YELLOW to WHITE.



11. **TARGET PAD:** There's no easier, more efficient way to focus treatment precisely where it's needed! Simply glide your finger across the TARGET touch pad to move the center of interference to the site of your patient's pain. The patient's input will help direct you. When you lift your finger from the Target pad, the selected point is locked until you change it again.



12. CONDUCTANCE/TEMPERATURE BAR

Conductance.

The 25 Series devices continuously measure conductance during electrical Stim treatments for Interferential, and Premod to ensure that the treatment outcome is optimal and to minimize the possibility of patient discomfort due to poor conductance and/or changes in current density. As conductance is measured, 25 Series displays the results in graph form on the CONDUCTANCE bar located on the right side of the TREATMENT DISPLAY SCREEN. Optimum conductance is displayed as the conductance bar flows RED - YELLOW- GREEN. GREEN indicating the best CONDUCTANCE. If the green bar only partially fills the graph area, the conductance is at a percentage of optimum. Lower INTENSITY may cause the bar to partially fill, but does not mean that the treatment is not effective. Below are some helpful definitions.

Conductance and Worn Electrodes.

Conductance is how readily electrical current is passed from the electrode to the skin surface during a treatment. Conductance affects current density. A worn electrode that does not conduct the current evenly over its entire surface will have "hot spots" where a greater amount of current flows through a smaller area which means the current density is higher at that point than elsewhere on the electrode. "Hot Spots" can lead to patient discomfort. Never risk patient comfort by using worn electrodes or lead wires.

Intensity.

The intensity level is a convenient incremental measurement. However, raising the intensity increases the current delivered to the patient but does not improve conductance.

Current Density.

Current density is the amount of current that passes through a given area of the electrode. Current density varies depending on the size of the electrode, the conductance, and intensity setting; and has an effect on patient comfort. With proper setup and good accessories, current is dispersed evenly over the entire surface of the electrode. The smaller the electrode, the greater the density of the current delivered through the area. To reduce current density and improve patient comfort, use larger electrodes, or lower the intensity setting, or both.

If the number of green displayed segments begin to decrease on the graph during a treatment, it is important to determine the cause of the poor conductance. Remember with poor conductance you may inadvertently increase current density at a small point under the electrode and cause patient discomfort. Following are some considerations to insure proper conductance.

- Check to be sure electrodes are not worn or that self-adhesive electrodes have not lost their adhesiveness. These are the most common causes of poor current delivery. Both self-adhesive and carbon electrodes eventually lose their ability to conduct current effectively. See "Electrotherapy Usage Cautions" in this manual for recommended intensity settings and usage limits.
- Check to ensure the entire surface of the poly adhesive electrode is adhering.
- Self-adhesive electrodes do not require sterilization, however, electrodes should be clean and hydrated (see package instructions or "Self-Adhesive Electrodes" section of this manual).
- Check to be sure the snap adapters haven't fallen off or that the lead wire has not become disconnected from the electrodes or the device.
- Make sure carbon electrodes have a secure connection with the pin ends of the leads. Over time the carbon electrodes may become too loose to use safely and the electrodes must be replaced.

- Check for corrosion on lead ends.
- Make sure carbon electrodes are adequately moistened and free from build-up to allow complete contact across the surface of the electrode.
- Observe the electrode placement. Some areas of the patient's body conduct current better than others. In areas where resistance is high you may be unable to obtain optimum conductivity.
- Check the dryness of the patient's skin. Dry skin does not conduct current well.
- Check to see if the electrodes do not adhere properly when a patient shifts position during a treatment. Worn electrodes could become loose and a significant change in conductance could result.

Temperature.

The 25 Series devices continuously measure temperature during Ultrasound, and Combo Treatment. TEMPERATURE is indicated by the length of the Blue/Green indicator lights on the temperature bar. The longer the length of the colored bar, the higher the temperature. It is not uncommon to have the temperature bar move into the medium length ranges. If the temperature approaches the maximum level of 108° Fahrenheit (42.22° Celsius), the treatment is automatically PAUSED, output power stopped, and treatment time stops counting down. Following a cooling period, the treatment may be continued by pressing START.

Channels and Jacks

13. Front Panel Channels and High Volt Jack

Illustrated below are the dual-channel banana jacks for delivering Interferential, Premodulated, Russian, and Biphasic treatments. These channels are located on the front of the device. As you face the device, channels 1 and 2 are on the left, channels 3 and 4 are on the right with the dedicated High Volt jack for delivering High Volt Pad treatments in the middle. Three channel units (525 and 825) have channels 1, 2, and High Volt only.



14. Left-Side Panel Jacks

SD Card Input. Located on the left-side of the 25 Series devices is the **SD Card Input.** The SD Input provides a way for the 25 Series Devices to receive software updates quickly and easily. Complete instructions for updating the devices using an SD card are found in the "Technical" information section of the manual.



15. Right-Side Panel Jacks

Located on the right-side of the 25 Series are the Ultrasound, Combo Stim Probe Jacks. Non-ultrasound devices (525 and 625) have no input jacks on the right-side panel.



Right-Side Panel Jacks

Input (ElectroStim Combo Jack).

The special combo lead wire for combination treatments is plugged into this jack for a combination treatment setup providing Stim output through the Ultrasound head. The Combination Treatment (Combo) Jack is a simple banana jack connector and requires no special alignment.

Ultrasound Jack.

The Ultrasound Jack is a keyed jack with a "D" shaped configuration. Align the straight bottom of the jack and the round top that matches the configuration found on the Ultrasound cord. Do not force or twist the connector or damage to the pins may occur. When removing the connector, pull the connector's outer sleeve directly away from the chassis. When an Ultrasound probe is connected, the device console will update the probe calibration data. No user inputs will be required to update calibration data.

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.



NOTE: Patient Remote Stop. Adding the Remote Stop requires a custom order. The Patient Remote Stop Jack is located below the Light Probe holder. The remote stop is controlled by the patient during unattended therapy, allowing the patient to stop the treatment at any time. When the button on the remote stop cable is pressed, output for <u>all Stim modalities and pad treatments</u> is stopped. During Combo treatments, both Sound and Stim outputs are stopped.

Current Limit

The Dynatron 25 Series devices continuously measure the actual current output during IFC and Premod treatments and limit the output current to the level set for the device. As the intensity of a treatment is increased the current output is also increased.

When the maximum output current limit is reached, the device will immediately stop increasing the intensity and automatically reduce the intensity a few increments to prevent the possibility of patient discomfort. Simultaneously, the device will beep and one of the following CURRENT LIMIT WARNINGS will appear in the lower right-hand corner of the Treatment Display Screen. Following is a list of CURRENT LIMIT WARNINGS that may occur.

Remember to treat at the patient's comfort level. It is not important to reach a given intensity level. It is only important to set the treatment at a level that is comfortable to the patient. See "Electrotherapy Usage Cautions" in this manual for suggested intensity limits.

CURRENT LIMIT ERROR MESSAGES	CAUSE
"Cannot start treatment with zero intensity"	Intensity not set
Error 101, Error 111, Error 120, Error 130 "Lead error: current too low! Please check or replace your leads and pads!"	Lead issue; electrode issue
Error 100, Error 110, Error 140 "Lead error: High current delivery detected. Adjusting intensity to a safe limit. Please check leads. Space electrodes further apart. Ensure skin is dry between electrodes."	Lead shorted Electrodes touching or too close Hot pack may be too moist

Most warnings will occur during the setup portion of a treatment. It would be rare to encounter a current limit warning during a patient treatment as reaching the current limit would require an intensity setting that is uncomfortable and intolerable to most patients. Below are some possible considerations for exceptions:

- The patient is unable to adequately feel the current and is unable; therefore, to report discomfort at the high intensity level.
- When using four large electrodes for a treatment, current is dispersed over a larger electrode surface area permitting a higher intensity setting without discomfort to the patient.
- For users who need to provide intensity levels above 50mA (not available Japan or Canada), the default may be changed to 100mA: 1) Begin at the START UP SCREEN. 2) Press the FUNCTION KEY. 3) Use the toggle key under the MODE WINDOW to select the 100mA option and confirm your choice when prompted. Press STOP to return to the START UP SCREEN.

As the intensity is increased, ensure that the patient feels the current as expected. If the patient is unable to feel the current, the current could unintentionally be raised to a level much too high and risk causing unnecessary discomfort or possibly burn the patient. Keep the intensity very low if the patient has little or no feeling in the treatment area (see "Contraindications, Warnings, and Precautions" in this manual). If you encounter the Current Limit Warnings, it may indicate that the patient cannot adequately feel the current. Reduce the intensity immediately.

A wide range of factors can cause the patient to lack sufficient feeling in the treatment area, including, but not limited to, pain control drugs, use of ice packs, neurological damage, etc.

Always consider these and other factors when delivering an electrotherapy treatment. Determine intensity settings based upon your medical expertise and judgment.

Error Messages

If an error occurs during any active treatment, whether in or out of focus, the 25 Series will sound a beep. A white box with a red Error message will appear in the Time area of the Treatment Display Screen, if the treatment is in focus. If the treatment error is associated with a treatment that is not in focus, "ERR" will appear next to the active treatment listed on the left-hand side of the screen with other treatments that are currently running but not in focus. Pressing the modality key for the treatment indicated will bring that treatment into focus and details regarding the error will appear on the Treatment Display Screen.

Ultrasound Error Messages

ULTRASOUND ERROR MESSAGES	CAUSE
"No soundhead connected, cannot setup ultrasound/combo treatment."	No soundhead attached
"Soundhead is too hot! Output has been disabled to allow cooling."	Soundhead is too hot
"Caution: soundhead is getting hot!"	Soundhead is getting hot
"Thermistor on soundhead is broken! Please get soundhead replaced."	Thermistor on soundhead is broken

Lead Wires

DID YOU KNOW?

- Lead wires should be replaced at least every six months
- Carbon electrodes should be replaced approximately every six months
- Self-adhesive electrodes should be replaced after no more than 15 uses
- You should never use monitoring electrodes nor ordinary TENS electrodes with this device
- Some brands of electrodes are of very poor quality or are inappropriate for electrotherapy. Your patient may experience discomfort and even skin reaction due to poor distribution of current when using these electrodes
- Failure to replace worn lead wires and carbon electrodes or using cheap, poor quality electrodes are some of the most common causes of patient discomfort.

Even with good care, lead wires will eventually develop breaks (open connections) simply from normal usage, and must be replaced about every six months. Damage can occur due to jerking or pulling on the wires, excessive bending or tight wrapping the wires, or running over the wire with a device cart. When setting up treatments, keep lead wires out of areas where a person could trip on them. When storing, lead wires should be loosely wrapped to prevent any kinking in the lead wire. Never use worn or damaged leads to treat a patient. Using faulty leads may result in injury to a patient.

Test Leads Daily

Lead wires should be tested regularly to ensure they are functioning properly and safely. A simple test performed with the Dynatron 25 Series devices makes daily lead testing convenient. Damaged or worn leads should be discarded and replaced. Instructions for testing are provided below.

Remove Corrosion From Lead Tips

Lead tips will build up corrosion through use. The lead tips must be cleaned and kept free of corrosion in order to function correctly. To remove corrosion from lead tips, use steel wool to gently scrape off the corrosion. Take care not to scratch the metal plating of the tip during cleaning. If the tip's metal surface becomes pitted or uneven, the lead must be replaced.

Testing Leads

To test leads, perform the following steps daily.

- Power on the 25 Series.
- 2. When the device has completed INITIALIZING, press the FUNCTION key located on the right side of the USER INTERFACE to activate the SETTINGS screen.
- 3. Make sure that LEAD TEST is illuminated GREEN in the MODE window.
- 4. Using the LEAD TEST TOGGLE KEY, select ON in the LEAD TEST window. ON will be illuminated GREEN.
- 5. Plug a lead into Channel 1 (no other channel is used for the lead test). Remove snap adapters, if applicable, from the leads.

WARNING

UNDER NO CIRCUMSTANCES SHOULD THE LEADS BE CONNECTED TO A PATIENT DURING THIS TEST!

- Press START.
- 7. Hold the pins securely together, move the leads around, wiggle the cord, especially at the jack end of the cord. The numbers in the CONDUCTANCE window will begin to count up. The quality of the lead is represented on a rolling scale of 0 to 250. The higher the number the better the lead's quality. A count of 200 or more indicates the lead is ready to be used. If the count registers under 100, the leads are probably bad and should be replaced.
- 8. After the test, remove the lead from Channel 1. If other leads need to be tested, plug in the next lead and test in the same way.
- 9. To exit the LEAD TEST function, press the STOP key.

NOTE: The LEAD TEST should be used for testing patient lead wires only. This is not an accurate means of testing carbon electrodes. Contact Dynatronics Customer Service to arrange for free testing of carbon electrodes or for instructions for testing these electrodes.

Carbon Electrodes

This type of electrode lasts a long time and can be used again and again. However, if they are not properly cared for, these electrodes can fail to deliver the desired treatment and can present the possibility for injury to a patient. To ensure greatest safety and effectiveness with your treatments, follow these rules when using carbon electrodes.

1. Carbon electrodes must be well-moistened prior to treatment setup.

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

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

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

2. Carbon electrodes must be free from any build-up.

If electrodes have a build-up from body oils or a moistening agent such as an electrolyte spray, conductivity is greatly impaired. If treatment is allowed to continue, intensity could be inhibited. When using carbon electrodes with any electrotherapy device, you must make sure conductivity is not impaired due to any type of build-up on the electrodes.

3. How to Clean Carbon Electrodes.

Carbon electrodes from Dynatronics may be cleaned using a mild soap and a small brush (such as a nail brush). To sterilize, alcohol may be used. They may also be sterilized in an Autoclave. Daily cleaning is recommended

If seeking a commercial cleanser/disinfectant, it is recommended that a product contain only the following active ingredients to avoid damage to the probe or pads:

OctylDecyl Dimethyl Ammonium Chloride
Dioctyl Dimenthyl Ammonium Chloride
Didecyl Dimenthyl Ammonium Chloride
Alkyl (C14 50%; C12 40%; C16 10
Dimenthyl Benzyl Ammonium Chloride
Other Ingredients not published

4. Carbon electrodes eventually wear out.

Do not assume you can safely use carbon electrodes indefinitely. Over time these electrodes will wear; and when worn, the amount of current delivered through the electrode will decrease and will be inconsistent over the surface of the electrode. As a general rule, carbon electrodes that are used regularly should be replaced at least every six months.

Do not take chances with patient safety! Discard worn carbon electrodes!

If you think that your carbon electrodes are showing wear, you can test them with an ohm meter. Good carbon electrodes should measure resistance between 40 and 200 ohms.

Self-Adhesive Electrodes

Dynatronics' self-adhesive electrodes are intended for multiple but patient specific use due to the danger of cross contamination. Improper use of the electrodes can decrease the life of the electrode and could even result in harm to your patient. The following instructions will help you achieve maximum usage from your electrodes while ensuring patient safety and comfort during treatment.

1. Make sure the electrode is adhering and making contact with the skin across the entire surface of the electrode. Electrodes will lose their adhesive quality when exposed to air, dust, dry skin, etc.

To Retain Adhesiveness:

- Electrodes should be stored in a tightly sealed pouch until used.
- The patient's skin should be thoroughly cleaned and free from oils or flakiness prior to placing the electrodes.

To Restore Adhesiveness:

- Before a Treatment. Before placing the electrode on the patient, moisten the patient's skin with a damp cloth using plain water, then apply the electrode to the skin.
- After a Treatment. Apply one or two drops of water to the adhesive side of the electrode using plain water, rub it lightly with fingertips, reapply the electrode to its plastic backing, and seal it tightly in its storage pouch. Do not use an electrolyte spray to remoisten self-adhesive electrodes as this substance can destroy the adhesive. Self-adhesive electrodes do not require sterilization.
- With this method of re-hydration, after a couple of hours electrodes can regain up to 90 per cent of their original adhesive quality.
- 2. **NEVER** use a self-adhesive electrode for more than 15 treatments (maximum).
- 3. **NEVER** USE STRAPS, WEIGHTS, or other devices to attach self-adhesive electrodes to the skin. If an electrode has lost its adhesive quality, you can use one of the methods given above to re-hydrate the adhesive, or you should

discard the electrode. Using straps and weights with self-adhesive electrodes could have an unpredictable effect on the electrodes and could cause injury.

- 4. **NEVER** use monitoring electrodes such as ECG, or EMG, nor ordinary TENS electrodes.
- 5. If you see the "No Patient Current" screen message, or if you observe poor conductivity indicators, check the electrodes and lead wires for proper connection.

Electrotherapy Information and Usage Cautions

The following general warnings are to be observed during Interferential, Premodulated, Russian, Biphasic, and High Voltage stimulations.

WARNING

- NEVER turn the power ON or OFF while the unit is connected to the patient.
- Always STOP a treatment before removing or attaching electrodes or leads. Leads and electrodes must only be applied to the patient before a treatment is started.
- Never use worn or damaged leads or electrodes as these may result in injury to the patient.
- See the Contraindications, Warnings, and Precautions for Interferential and Premodulated treatments in this manual before administering a treatment.
- Additional warning from the Canadian Health and Welfare Department, Health Protection branch:
 <u>WARNING</u>: Thoracic applications are contraindicated. Cardiac fibrillation may occur if output current is 50mA
 RMS or greater for any output circuit. (For use in Canada and Japan, this device is limited to 50mA output).

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

Current Density

This is the amount of current being delivered to the patient divided by the area through which the current is being delivered (the surface area of the electrodes being used).

Electrode Condition

Worn or dried out electrodes cause the current to concentrate in small areas of the electrode instead being evenly distributed over the entire surface of the electrode. This has the effect of concentrating and increasing the current density into small areas.

Patient Susceptibility

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

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

1. Use only moderate current

It is not always necessary to raise the treatment intensity to just short of the patient's pain threshold to achieve adequate results. Below is a chart comparing the size of the self-adhesive and carbon electrodes with their suggested maximum intensity levels.

NOTE: The intensity settings should be considered maximum and not target intensities. These suggested settings apply to Interferential and Premodulated treatments. For High Voltage pulsed stimulation the intensity is displayed in volts; therefore, these suggested settings do not apply.

For Biphasic or Russian stimulation treatments intended to effect a muscle contraction, it may sometimes be necessary to exceed these recommended limits to achieve the desired results. However, use caution when doing so to ensure that the patient can feel and can comfortably tolerate the electrical current. Also observe all other precautions in this section concerning leads and electrodes to ensure the higher intensity setting is not necessary as a result of defective accessories. In any case, do not exceed patient tolerance in setting the intensity. Consult published medical literature for more information about treatment protocols using each of these electrotherapy modalities.

Use as large an electrode as is practical for the application.

NOTE: The current density in a 1.25" square electrode is over FOUR TIMES the current density in a 1.75" by 3.75" electrode for the same intensity setting. Using larger electrodes allows current to be delivered over a larger area of the body keeping the current density as low as possible and minimizing the possibility for adverse reactions. Below are recommended intensities that correspond to electrode sizes.

Interferential / Premodulated			
	Electrode Size	Maximum Recommended Intensity	
Carbon Electrodes	3" round (7.62cm)	25 - 30	
	3" x 5" (7.62cm x 12.7cm)	30 - 40	
Self-adhesive Electrodes	1.75" square (4.45cm)	10 - 15	
	1.75" x 3.75" (4.45cm x 9.53cm)	25 - 30	
	1.25" round (3.18cm)	10 - 12	
	2" round (5.08cm)	10 - 20	
	3" round (7.62cm)	25 - 30	

When delivering combination Ultrasound and Stim treatments where the Stim current is delivered through the soundhead, the following are the recommended maximum Stim intensities (refers to Premodulated, Biphasic or Russian stimulation only):

Combination Treatment		
Ultrasound Head Size	Maximum Recommended Intensity for Electrotherapy	
2 cm ² Head	2 - 4	
5 cm ² Head	8 - 10	
10 cm ² Head	15 - 20	

2. Ensure that the area on the patient's skin where the electrode is to be placed is clean and free of all foreign matter.

Includes powders, perfumes, as well as body oils, dirt, and grime. Cleaning with an alcohol wipe should be adequate. Allow the alcohol to fully evaporate before applying the electrodes. Iontophoresis occurs with all electrical current therapies and can drive any of the above-surface contaminants below the epidural layer where an allergic reaction may occur.

Any electrode which is suspect should be discarded. It's not worth the price of an electrode to risk harming a patient.

3. Make sure the electrodes being used are in good condition.

The poly adhesive electrodes should have good adhesion over the entire surface area of the electrode. The area where the leads attach to the electrode (either through a lead or a snap) should not be damaged such that the connection to

the foil backing behind the adhesive is broken. Carbon electrodes should be deep black and should be free of cracks in the electrode surface.

4. Some patients tend to be much more sensitive to electrotherapy treatments.

On patients with this tendency, treat with reduced intensity and/or shorter treatment times with possibly more frequent treatments, if required. Most reactions are localized and very short-lived, so limiting the exposure should minimize any potential for adverse reactions.

Interferential / Premodulated Instructions

An Interferential treatment uses two channels and four electrodes (channel pairs 1-2 or 3-4). The device will automatically select the first available channel pair when you select IFC. A Premodulated treatment uses one channel and two electrodes. The device will automatically select the first available channel (1, 2, 3, or 4) when PREMOD is selected. If desired, multiple treatments can be setup using available channels. Note: Channels 3 and 4 are only available on the 925 and 625 devices.

NOTE: Prior to increasing intensity, electrodes must be placed on the patient and the lead(s) attached to the device. **Plug the lead(s) into the channel(s) the device selects for this treatment**. Consult published sources for electrode placements, treatment settings, and treatment times. Make sure electrodes make good contact with the patient's skin over the entire surface area of the electrode. Improper electrode contact may result in patient injury.

Detailed Interferential / Premodulated Setup

1. IFC or PREMOD MODALITY keys

Press the IFC or PREMOD MODALITY keys to choose IFC (Interferential) or PREMOD (Premodulated). When you choose IFC, two channels are automatically selected: 1-2 or 3-4. When choosing PREMOD, the first available single channel is selected. Make sure the patient lead(s) is plugged into the correct jack(s) for the channel(s) selected. The default settings for the modality are automatically selected. If you wish to use the default settings, increase the intensity to the desired level, and press START.

Default Settings

Time:	10 minutes
Frequency Range:	High 80-150 Hz
Target (IFC):	On

If you wish to change or customize the treatment settings, proceed through the following steps:

2. Customize TIME

The default treatment time is displayed at 10:00 min. Use the TIME arrow keys to increase or decrease the treatment time.

3. Customize FREQUENCY (optional)

Default HIGH and LOW Frequency Settings

- HIGH range is 80 to 150 Hz.
- LOW range is 0 to 10 Hz.
- ALTERNATING range alternates every 30 seconds between HIGH and LOW, beginning with LOW.

NOTE: ALTERNATING and HIGH/LOW options may be selected <u>after</u> pressing START. However, Consecutive and Fixed options must be selected <u>before</u> pressing START.

• CONSECUTIVE HIGH/LOW. During the first half of the treatment time the High frequency range is delivered. During the second half of the treatment time the Low frequency range is delivered.

NOTE: Make any desired changes to the treatment time before selecting Consecutive. Treatment time changes made after selecting Consecutive will cause the treatment to revert to an ALTERNATING HIGH/LOW treatment.

• FIXED. A FIXED treatment automatically defaults to a STATIC setting. Press the toggle key under MODE until FREQ is illuminated. A FIXED treatment can be set between 4,000 and 10,000 KHz. Selections progress from 4,000 KHz to 10,000 KHz in 1,000 KHz increments. Once the FIXED rate is set, return to the TIME display by using the MODE toggle key.

NOTE: If INTENSITY has been set during the setup of a FIXED treatment option and a change is made to any other treatment option, INTENSITY will automatically return to "0."

The default High and Low frequency settings may be changed for a single treatment if desired, or new default settings may be saved to apply to all future treatment setups.

- Press the toggle key under the MODE display. Select FREQ (Frequency).
- Press the toggle key under the RANGE display. Select a HIGH or LOW frequency range.
- The HIGH Frequency will appear on the left-hand side of the Treatment Display Screen. The LOW Frequency will appear on the right-hand side of the Treatment Display Screen. Changes to the upper and lower limits are

made using the arrow keys to the side of each displayed setting. If you set both displays to the same value, the treatment will be delivered at that single frequency rather than sweep through a frequency range.

- After pressing START, frequency settings will remain in effect for the duration of the treatment. If you save defaults
 during this treatment, the new frequency settings you have entered become the defaults for this modality. However,
 if you do not save the new settings, the unit will return to the current default settings for the next treatment.
- To SAVE these CUSTOM FREQUENCY settings, hold the START key down until a beep sounds. Once saved, these settings will be used on all IFC or Premod treatments that follow.
- Press the toggle key under the MODE display to return to the TIME display, After 10 seconds with no key presses, the Time display will automatically return.

4. Choose TARGET, SWEEP, or STATIC (for Interferential only)

Using the toggle key located under the TARGET display make your selection from the three available options.

TARGET. Pinpoint the treatment site delivering the full Interferential current where it is needed.

NOTE: The intensity must be set before using the Target Pad so the patient will be able to indicate when the treatment site is found. Also remember, an injured area will often be more sensitive to the current delivered. Therefore, an intensity setting that is comfortable to the patient at first may feel uncomfortable when the treatment site is found using the TARGET PAD. If necessary, reduce the intensity to the patient's comfort level.

SWEEP. The interferential current randomly sweeps the treatment area within the electrodes allowing the general area to be bathed with Interferential current.

STATIC. The interferential current focuses only on the point where the current between electrodes intersects as it follows the path of least resistance.

5. INTENSITY

Press the UP/DOWN arrow keys located next to the INTENSITY display on the right-hand side of the Treatment Screen. When the INTENSITY is increased, current to the patient begins. NOTE: The CONDUCTANCE BAR GRAPH will be operable at this time.

Before selecting the intensity setting for an individual patient, see "Electrotherapy Information and Usage Cautions" in this manual for recommended intensity settings. Also see the section of this manual entitled "Contraindications, Warnings, and Precautions" for specific precautions when treating any conditions contributing to loss of sensation, or any time the patient cannot feel the electrical stimulation.

6. Press START

When you press start, the treatment timer in the TIME display window begins counting down and the treatment proceeds. Remember to set the intensity before pressing START.

7. SAVE DEFAULTS

If the treatment you have just set up is a frequently used, you can save the treatment parameters as new defaults by pressing and holding the START key until a beep sounds indicating the treatment parameters have been saved. The next time you select the modality, these parameters will be selected automatically.

8. MODIFY SETTINGS

Treatment settings can be modified while the treatment is in progress except for a CONSECUTIVE HIGH/LOW treatment. If the TIME setting on a CONSECUTIVE HIGH/LOW treatment is altered, the treatment will be aborted and default to an ALTERNATING HIGH/LOW treatment.

- FREQUENCY RANGE. Use the Range Toggle key to select a different frequency option (High, Low, Alternating High/Low, Consecutive High/Low, or Fixed). Fixed Frequency and Consecutive High/Low cannot be selected after treatment is started.
- TARGET/SWEEP/STATIC. Use the Target Toggle key to select Target, Sweep, or Static (for IFC only).
- TIME. Use the Time Arrow keys to increase or decrease the treatment time.
- **INTENSITY.** Use the Intensity Arrow keys to increase or decrease the intensity.
- **TARGET.** Relocate the treatment site by touching the TARGET PAD at any time during the treatment when TARGET has been selected.

9. **STOP**.

When the treatment time has elapsed, the current to the patient stops and a tone sounds signaling the end of a treatment. Treatments in progress may be stopped at any time using one of the following methods.

Stop One Treatment Only. Press and hold the FUNCTION key and press STOP. This stops only the treatment in focus.

Stop All. Press the STOP key. All treatments at all channels will stop.

Stop Time. Reduce the treatment time using the Time arrow key. The output at the selected channel is stopped, and the device then displays the parameters for the next treatment that remains in progress (if there is an active treatment).

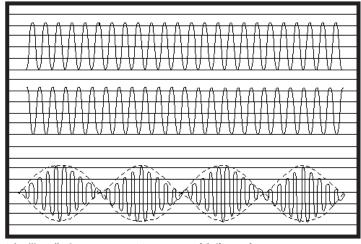
Interferential and Premodulated Modality Information

Interferential (Quadpolar) Therapy

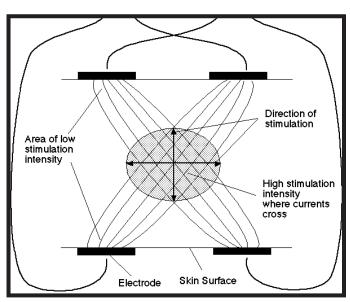
Interferential therapy uses four electrodes to deliver two currents, one current with a constant frequency of 4000 Hz and the other current with a variable frequency of 4000 to 4150 Hz. The paths of these two currents cross resulting in a "beat" that produces the therapeutic frequency at the treatment site.

The resulting frequency is between 1 and 150 Hz. An example of wave forms representing these currents is illustrated here.

In the Interferential mode, two output jacks (Channels 1 and 2, or 3 and 4) are utilized with four electrodes placed in a crisscross fashion, "bracketing" the treatment site. The output from Channel 1 (or Channel 3) is the constant 4000 Hz wave, while the output of Channel 2 (or Channel 4) is the variable 4000 to 4150 sine wave.



The "beat" phenomenon. Two waves of different frequencies over 4000 Hz, combine to produce a beat which is between 1 and 150 Hz.



Stimulation produced by 4 electrodes.

Premodulated (Bipolar) Therapy

Premodulated therapy utilizes one output jack and two electrodes. The current delivered is a composite wave form. In order to produce this composite current, two Frequencies are "mixed" within the device prior to output. One frequency is 4000 Hz while the second frequency covers a range between 4000 to 4150 Hz.

With the Dynatron 25 Series devices, any of the four channels may be used simultaneously to deliver up to four separate, independent Premodulated treatments. A crisscross electrode setup pattern should not be used when setting up multiple Premodulated treatments. Note that a Premodulated treatment usually requires a lower intensity setting than an Interferential treatment since current is dispersed to only two electrodes rather than four (a smaller total coverage area means greater current density at the treatment site).

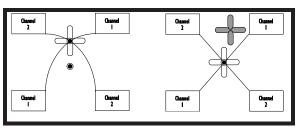
Target

The Dynatronics' TARGET (available for Interferential treatments only) simplifies placing the interferential beat directly on the treatment site. The movement of the finger on the Target paid along with the feedback supplied by the patient allows the user to place the full force of the interferential "beat" directly on the treatment site regardless of conductance variations caused by differences in human tissue (skin, muscle, bone, etc.) that, without Target, make placing the Interferential "beat" a guessing game. Target eliminates the need to move the electrodes to achieve the desired result.

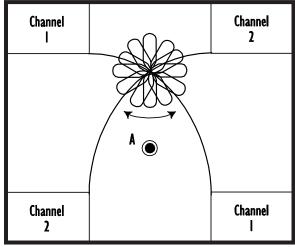
In the diagram the electrodes are placed in a position to treat a point directly in the center of the electrodes. But the center of interference actually occurs at another point. In these illustrations the point of interference is shown in a cloverleaf shape as Interferential treatment affects a cloverleaf-shaped area. Using the Target pad, the point of interference in easily moved to the desired treatment area. Other devices increase current at one channel while decreasing it at the other. This merely rotates the treatment. The center of interference does not move.

Why Is Target Better?

With Target, the voltage output from both channels remains equal at all times; so wherever the treatment is applied, a full, deep Interferential beat occurs. Other devices attempt to achieve this effect by increasing the current from one channel while decreasing the current from the other channel. This method only rotates the cloverleaf-shaped area, but the center of interference does not move. In addition, the depth of the beat is reduced.



Normal Interferential currents cross at a point between electrodes. It is difficult to guess where they will cross as shown in the left diagram. With Target, you move the point of interference without moving electrodes (as shown in the diagram on the right)—just press the touch pad.



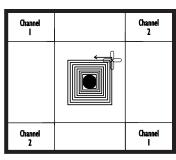
Other devices increase current at one channel while decreasing it at the other. This merely rotates the treatment. The center of interference does not move.

Target Sweep

The Sweep option literally moves the point of interference inward and outward in a somewhat spiral pattern, bathing about 80 percent of the area within the electrodes with the Interferential current. Sweep utilizes the Target feature and moves the point of interference to cover a wider treatment area while still retaining the full Interferential beat. Sweep bathes a larger area with the Interferential current.

Interferential Electrode Placement

When performing Interferential therapy with a two-channel or four-electrode setup, it is important to arrange the electrodes in a crisscross manner so the current from one channel will intersect with the current from the second channel at the point where treatment is to be delivered. Consult published literature for electrode placements for specific sites and conditions.



Interferential Electrode Placement

Interferential / Premodulated Default Settings

The following default settings are set by the manufacturer and are selected when you select IFC or PREMOD. You may change these defaults to your own preferred settings.

Interferential Default Settings

- High 80-150 Hz
- Target
- The first available channel pair (1-2 or 3-4)
- Time: 10 minutes
- Frequency Ranges: High 80-150 Hz; Low 0-10 Hz

Premodulated Default Settings

- High 80-150 Hz
- Target
- The first available channel pair (1 through 4)
- Time: 10 minutes
- Frequency Ranges: High 80-150 Hz; Low 0-10 Hz
- Interferential/Premodulated Therapy: 4000 Hz sine wave frequency modulated by a 4000 to 4150 Hz variable frequency sine wave of equal amplitude

Biphasic / Russian Instructions

In the Russian and Biphasic Stimulation modes the output of the device is a pulsed sinusoidal wave. 25 Series allows the operator to choose a muscle contraction/rest cycle that is most suited for the individual patient and for the desired treatment. Once the cycle is chosen, each muscle-stimulating burst is followed by a rest cycle. See "Russian/Biphasic Parameters" in this manual for further discussion of pulse rate and duration, and illustrations showing the segments of the Russian Stimulation cycle and the Biphasic Stimulation cycle.

25 Series provides four treatment options in Russian and Biphasic Stimulation: Normal, Reciprocal, Co-Contraction, and Custom. After deciding which treatment is to be used, attach the appropriate number of leads required to set up the treatment.

NORMAL: Use one channel with one lead wire (two electrodes). Place the electrodes so as to treat through the muscle. The contraction/rest cycle is selected from an option list of 10/10, 10/30, 10/50, CONT (continuous/no rest cycle), and Custom. Each time period is indicated in seconds. For example, 10/30 indicates 10 seconds of stimulation with 30 seconds of rest. The continuous duty cycle is not recommended for electrical muscle stimulation, but may be used for settings that are intended to effect results other than a muscle contraction.

CO-CONTRACTION: Use two channels and two lead wires (four-electrodes) for this treatment. Each pair of electrodes is placed over a different muscle group. This treatment fires the two muscle groups simultaneously—contraction and rest cycles for both treatment areas occur at the same time. Two channels are required (1-2 or 3-4). Note: 3-4 are available only on the 25 Series 625 and 925.

RECIPROCAL: Use two channels and two lead wires (four electrodes) for this treatment. The reciprocal muscle stimulation fires two muscle groups (such as reciprocal flexors/extensors) one after the other. For example, with a duty cycle of 10/30, the device would deliver stimulation for 10 seconds to the first muscle, followed by 10 seconds of stimulation to the reciprocal muscle. A 30-second rest time follows each stimulation. The timing of the two cycles will overlap (the first muscle group is stimulated after a 30-second rest, even though the second muscle group is 20 seconds into its rest cycle). The Continuous contraction/rest cycle is not available for Reciprocal treatments. Two channels are required (1-2 or 3-4). Note: 3-4 are available only on the 25 Series 625 and 925.

CUSTOM CONTRACTION: The Custom Contraction/Rest cycle feature allows the treatment to be customized by selecting from a Custom Contraction ON time (1 to 60 seconds), and an OFF time (1 to 90 seconds). Treatments can be customized by using the following steps:

- 1. Press the CONT/REST toggle key. Select CUSTOM.
- 2. Press the MODE toggle key. Select CUST C/R (Custom Contraction Rest).
- 3. Press TREATMENT toggle key. Select Normal, Co-Cont, Recip.
- 4. Using the RAMP toggle key, select RAMP time (.05, 1.0, 1.5, 2.0).
- 5. Set CUSTOM CONTRACTION using the arrow keys on the left-side of the Treatment Display Screen (1-60 sec.)
- 6. Set CUSTOM REST using the arrow keys on the right-side of the Treatment Display Screen (1-90 sec.). The REST time cannot be less than the CONTRACTION time.
- 7. Press START.

Biphasic / Russian Quick Setup

- 1. Choose BIPHASIC or RUSSIAN.
- 2. Choose the TREATMENT (Normal, Co-contraction, or Reciprocal using the TREATMENT toggle key). Plug the patient lead(s) into the output jack(s) for the channel(s) selected.
- 3. Choose the CONTRACTION/REST times by pressing the CONTRACTION/REST toggle key.
- 4. Choose the RAMP setting by using the RAMP toggle.
- 5. Change the treatment TIME, by pressing the UP/DOWN TIME ARROW keys, if desired.
- 6. Change the PULSE and DURATION. Using the MODE toggle key select RATE/DUR (rate/duration).
 - Press the PULSE RATE arrow keys to change the PULSE RATE
 - Press the PULSE DURATION arrow keys to change the PULSE DURATION
- 7. Press the MODE toggle key to return to the TIME display window.
- 8. Raise the INTENSITY to the desired level by pressing the INTENSITY ARROW keys on the right-side of the Treatment Screen.
- 9. For co-contraction or reciprocal treatments, set the intensity for the first channel. Press START. The device will automatically select the second channel. Set the intensity for the second channel.
- 10. Press START.
- 11. STOP. Press the FUNCTION and STOP keys simultaneously to stop only the focus treatment appearing in the Treatment Screen. Pressing STOP alone, stops all treatments operating on the device. Using the TIME arrow keys to bring treatment time to zero will also stop a treatment.

Detailed Biphasic / Russian Setup

If you do not understand the terms contraction, rest, ramp time, pulse duration, or pulse rate; consult the diagrams in the section of this manual entitled "Biphasic / Russian Parameters."

Press the BIPHASIC or RUSSIAN

When you select this modality, the default settings are automatically selected. If you wish to use the default settings, you can now increase intensity to the desired level and press START.

Default Setting

Mode	Normal
Cont/Rest Time	10/30
Time	10 minutes
Ramp Time	0.5 sec.

If you wish to change the treatment settings, proceed through the following steps:

2. Choose the TREATMENT.

Use the TREATMENT toggle key to select NORMAL, CO-CONT (Co-contraction), or RECIP (Reciprocal). Connect the patient lead wire(s) to the channel(s) selected.

3. CONTRACTION/REST

Cycle Times Using the CONT/REST toggle key, choose the CONTRACTION/REST cycle times. Available options include 10/10, 10/30, 10/50, Continuous, and Custom. The setting of 10/30, for example, means a 10-second contraction time followed by a 30-second rest time. Note that you may not select Continuous cycle for a Reciprocal treatment. The Continuous duty cycle is not recommended for electrical muscle stimulation, but may be used for settings that are intended to effect results other than a muscle contraction.

4. **Choose the RAMP Setting** (does not affect Continuous treatments).

Press the RAMP TOGGLE key one or more times to select the desired ramp time. Available options include .5, 1.0, 1.5, and 2.0 seconds. The ramp time is applied to both the start and to the end of the contraction time. The ramp time is in addition to the contraction time itself.

5. Change the treatment TIME (optional).

The default time is displayed. Use the TIME arrow keys to increase or decrease the treatment time.

6. Change the PULSE DURATION and/or PULSE RATE (optional)

Press the MODE toggle key to select RATE/DUR (Pulse Duration). The pulse DURATION (width) and RATE may be modified for each channel pair (1-2 and 3-4).

Press the PULSE RATE arrow keys to the left-side of the Treatment Screen to change the PULSE RATE. Press the PULSE DURATION arrow keys to the right-side of the Treatment Screen to change the PULSE DURATION. Press the MODE toggle key and select TIME to return the TIME display. However, if you make no key presses for 10 seconds, the display automatically returns to the TIME display. The ranges and default settings for pulse duration (width) and pulse rate are listed later in this section.

7. Raise the INTENSITY to the desired level.

Set the intensity by pressing the INTENSITY arrow keys located on the right-side of the Treatment Display Screen. Increasing the intensity sends current directly to the patient. Intensity can be decreased by pressing the down arrow key,

Before selecting the intensity setting for an individual patient, see section entitled "Electrotherapy Usage Cautions" for recommended intensity settings. Also see the section of this manual entitled "Contraindications, Warnings, and Precautions" for specific precautions when treating any conditions contributing to loss of sensation, or any time the patient cannot feel the electrical stimulation.

The intensity, pulse rate, and pulse duration must all be considered together when setting up the treatment as all three factors affect patient comfort. It may be necessary to adjust one or more of these parameters somewhat after the initial settings are selected to find the best settings for a given treatment and patient.

8. For co-contraction or reciprocal treatments, select the SECOND CHANNEL and set the INTENSITY.

Intensity is set for each channel separately. For co-contraction or reciprocal treatments, Set the intensity for the first channel. Press START. The device will automatically select the second channel. Set the intensity for the second channel. When setting intensity, only the channel with the solid GREEN light is affected. The first channel will be illuminated in YELLOW.

Press START

When you press START the treatment timer begins counting down. If the intensity is not set before pressing START, the treatment will not begin until the intensity is set. For Reciprocal and Co-contraction treatments, the intensity must be set for each channel separately.

10. SAVE DEFAULTS

If this treatment setup is the most common Biphasic or Russian treatment setup you use, save the treatment parameters as your defaults. After setting up the treatment, press and hold the START key until a tone sounds indicating the treatment parameters have been saved. The next time you select this modality, the saved parameters will be selected automatically.

11. MODIFY Settings

While the treatment is in progress, the treatment settings can be modified. Carefully observe the channel indicator lights when modifying a treatment. When a channel's light is illuminated GREEN, the current treatment parameters for that channel are displayed. Any changes made to the parameters will affect only the channel that is illuminated in GREEN. Use the toggle key to display the parameters of another channel in order to modify parameters.

During a Biphasic or Russian treatment you may make the following modifications:

CONTRACTION/REST cycle.

- RAMP TIME
- TREATMENT TIME
- RATE/DURATION (not available for Reciprocal treatments nor when two "Normal" treatments are running simultaneously on a channel pair—CH 1-2 or 3-4).
- INTENSITY (separately for each channel)

12. **STOP**

When the treatment time has elapsed, the current to the patient stops and a tone sounds signaling the end of a treatment. Treatments in progress may be stopped at any time using one of the following methods.

Stop One Treatment Only. Press and hold the FUNCTION key and press STOP. This stops only the treatment in focus.

Stop All. Press the STOP key. All treatments at all channels will stop.

Stop Time. Reduce the treatment time using the Time arrow key. The output at the selected channel is stopped, and the device then displays the parameters for the next treatment that remains in progress (if there is an active treatment).

Biphasic / Russian Modality Information

Russian Stimulation

With Russian Stimulation mode, the output of the device is a 2500 Hz sinusoidal wave. Russian stimulation currents produce strong muscle contractions.

The Dynatron 25 Series devices allows complete control over all the parameters of the Russian Stimulation treatment. Three treatment modes include Normal for firing one muscle, Reciprocal for firing two different muscles at different times, and Co-contraction for firing two different muscles simultaneously. Choose a muscle contraction/relaxation cycle from options of 10/10 (ten seconds on and ten seconds off), 10/30, 10/50, Continuous, and Custom cycles. The Normal mode requires use of just one output jack (Channel 1, 2, 3, or 4). The Reciprocal and Co-Contraction modes utilize a channel pair (Channels 1-2 or 3-4).

NOTE: The continuous duty cycle is not recommended for electrical muscle stimulation, but may be used for settings that are intended to affect other results than a muscle contraction. Pulse rate, the pulse duration, and the ramp time can all be modified from their default settings.

Biphasic Stimulation

The Biphasic stimulation is similar to Russian stimulation in the parameters that are selected and in the available options. It differs from Russian stimulation in the pulse duration and rate ranges (see parameters below). Additionally, the Biphasic pulse includes just one cycle (one positive phase and one negative phase) per pulse.

Biphasic / Russian Parameters and Defaults

The default settings and the available ranges for Biphasic and Russian are as follows:

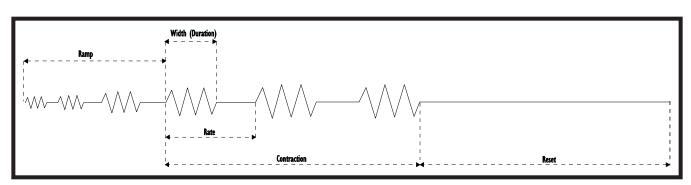
Biphasic / Russian Default Settings		
Mode	Normal	
Contraction / Rest Times	10 / 30	
Treatment Time	10 Minutes	
Ramp Up and Down Time	5 sec.	

Russian Stimulation Contraction Rest Times			
	Default Setting	Valid Range	
Pulse Rate	50 Pulses per sec.	1 - 500	
Pulse Duration	200 μSec	50 to 400 μSec	
50 to 400 μs pulse duration @ 1-200 Hz (50% levels)			
	Default Setting	Valid Range	
Pulse Rate	50 Pulses per sec.	1-500	
Pulse Duration	10 mSec	.04 to 50 mSec	
2500 Hz sine wave amplitude modulated at 50 Hz.			

The pulse rate and duration should not be confused with the contraction/rest times in the treatment as these are different parameters; the pulse occurs only during the contraction time. The diagrams below illustrate the relationship of each of these parameters.

The pulse duration indicates the duration (in milliseconds or microseconds) of the output cycle of the pulse, and the pulse rate is measured in number of pulse occurrences per second. Between pulses, current is at zero.

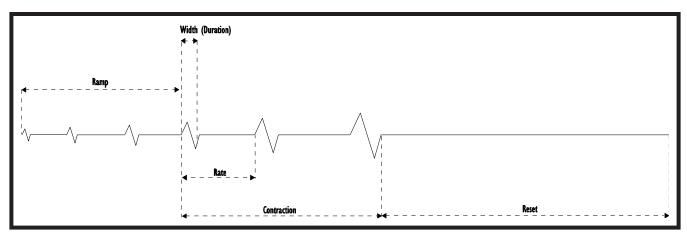
A 50 percent duty cycle or less is the usual duty cycle for Russian stimulation (the duty cycle includes one output cycle period and one zero-current period). A 50 percent duty cycle means that the length of the pulse duration must be equal to or less than the zero-current period. The number of pulses per second affects the allowable range of pulse durations. A greater number of pulses per second means a shorter pulse duration is allowed. The Dynatron 25 Series will not allow you to circumvent this rule.



Russian Stimulation

If a given Russian stimulation treatment has a 50 percent duty cycle, this means the output cycle is continuously repeating for half of the pulse duration (see "Rate" in the diagram above) followed by a zero-current period for the other half of the pulse duration.

Biphasic stimulation differs from Russian stimulation in the pulse duration (width) and rate ranges, as explained above. In addition, the Biphasic pulse includes just ONE output cycle per pulse. **One pulse cycle (including one positive phase and one negative phase) occurs**, followed by a zero-current period.



Biphasic Stimulation

The pulse rate and duration (width) may be modified during setup of a Russian or Biphasic Stimulation treatment or may be modified while a treatment is in progress.

When modifying the pulse rate and duration (width) for a treatment in progress, modify the intensity as well, as all three of these parameters will affect delivered energy and patient comfort.

High Volt Instructions

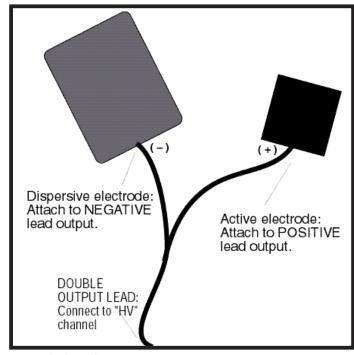
High Volt electrical stimulation is a pulsed DC current with pulse durations in the microsecond range and pulse rates ranging from 1 to 200 Hz, with peak amplitude of up to 500 Volts. The Dynatron 125 devices deliver High Volt utilizing a twin-peak monophasic waveform.

High Volt treatments are delivered using electrodes. The device provides a dedicated channel for High Volt electrodes treatment (HV). During High Volt treatments, the Dynatron 125 device's other output channels (1-2-3-4) remain available for other simultaneously stim treatments.

High Volt Electrode Setup

This treatment setup utilizes a standard lead wire with two electrodes; an active and a dispersive electrode. The size of the dispersive electrode is recommended to be double the area of the active electrode. If desired, the active output of the lead wire may be bifurcated by using an optional bifurcated extension (Part no. 7B0077) to attach additional active electrodes. However, the combined total area of the active electrodes should be no more than half the area of the single dispersive (passive) electrode, as illustrated.

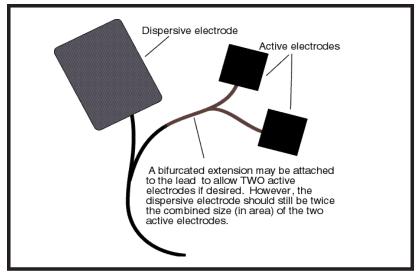
It is best to use a lead that is marked to show polarity. The active electrode is connected to the positive output. The dispersive electrode is connected to the output end that is marked "HV Dispersive" (-). If desired, a bifurcated lead extension may be attached to the positive (HV Active) end of the lead wire, allowing two active electrodes to be used. In this case, be sure the dispersive



High Volt Electrode Setup

electrode is at least twice the size (in area) of the combined sizes of the active electrodes. The bifurcated lead wire extension is an optional accessory available through Dynatronics.

During the treatment current flows in one direction between the active and dispersive electrodes. Changing the polarity in the treatment parameters has the effect of reversing the direction of the current flow between electrodes. It is important to attach the active electrode to the HV Active (+) output of the lead wire to ensure you are delivering the selected polarity. The Lead wires are labeled: HV Active (+), HV Dispersive (-) delivery.



High Volt electrodes with bifurcated active lead.

Detailed High Volt Setup

High Volt Quick Setup

- 1. Press HI VOLT.
 - Plug in lead wire to the HIGH VOLT OUTPUT JACK (HV).
 - Attach electrodes to patient.
- 2. Choose the **POLARITY**. Polarity must be selected before customizing a treatment.
- 3. **TIME**. Select TIME by using the TIME ARROW keys for Electrode Pads treatments only.
- 4. Select (or setup) a **PULSE RATE RANGE** (High/Low) or set a single pulse rate by pressing the MODE toggle key and selecting RATES. Use the arrow keys next to RATE-START and RATE-STOP to set the Pulse Rate Range.
- 5. Set **CONTRACTION/REST** times by pressing the FUNC (Function key). Use the CONT/REST toggle key to make your selection.
- 6. **RAMP TIME.** While in FUNCTION mode use the RAMP TOGGLE key to select RAMP TIME.
- 7. Raise the **INTENSITY** to the desired level.
- 8. Press **START**. Treatment time will begin to count-down for an Electrodes treatment.
- 9. **STOP.** Press and hold the FUNCTION key and press the STOP key to stop only the focus treatment appearing in the Treatment Screen. Pressing STOP alone, stops all treatments operating on the device. Using the TIME arrow keys to bring treatment time to zero will also stop a treatment.

1. Press the **HI VOLT** key.

The High Volt channel and the default settings for High Voltage electrode pulsed stimulation are automatically selected. Using the dedicated High Volt (HV) channel attach leads and place electrodes on the patient now.

Default Setting

TreatmentHigh Volt	Pads Treatment
Duty Cycle	Continuous
Time Electrodes	10 minutes
Polarity	Negative
Pulse Rate	High Range
Range:	High 80-120 Hz

If you wish to use the default settings, increase the intensity to the desired level, and press START. To customize the settings, follow steps 2-8.

ELECTRODE PADS TREATMENTS are timed, and a treatment time in MINUTES is entered at the start of the treatment. The timer counts DOWN for electrode treatments.

2. Choose the **POLARITY**

Press the Polarity toggle key to choose Polarity. Polarity options are Negative, Positive, and Bipolar.

3. Change the treatment **TIME**, if desired.

Use the TIME UP/DOWN ARROW keys to change the TIME for an Electrode treatment. Using the MODE toggle key, be sure TIME is illuminated in the MODE window when entering TIME.

4. PULSE RATE RANGE.

Select a PULSE RATE RANGE (High 80-120 Hz or Low 1-10 Hz) or set a single pulse rate by pressing the MODE toggle key and selecting RATES from 1-120 Hz. Use the arrow keys next to RATE-START and RATE-STOP to set the Pulse Rate Range. These ranges may be changed for a single treatment if desired, or press and hold the START key to set new default settings to be applied to all future treatment setups. The PULSE RATE RANGE must be set before pressing START.

5. CONTRACTION (ON) and REST (OFF) TIMES

FUNCTION KEY: To access CONTRACTION and REST settings, press the FUNCTION key.

Press the CONT/REST toggle key one or more times to select contraction/rest (Duty) cycle times. Available options include 10/10, 10/30, 10/50, CONT (Continuous). and Custom. The setting of 10/30, for example, means a 10-second contraction time followed by a 30-second rest time.

CUSTOM (Duty) CYCLE TIME SELECTIONS

- Press the FUNCTION key located on right-side of the device faceplate.
- Using the CONT/REST toggle key, select CUSTOM in the CONT/REST window.
- Using the MODE toggle key, select CUST CR in the MODE window. Selections will be illuminated GREEN.
- Custom Contraction and Custom Rest cycle times may now be set by using the Up and Down arrow keys located next to Custom Contraction and Custom Rest windows. Available ranges for Contraction (ON) times are 1-120 seconds, for the REST (OFF) times 1 to 300 seconds. Remember, the REST time cannot be less than the Contraction time. Pressing and holding the START key until the beep is heard will save the current Contraction/Rest settings as the default.

6. Choose the **RAMP** setting.

FUNCTION KEY: To access the RAMP settings, press the FUNCTION key.

Press the FUNCTION key on the right side of the face plate. Press the RAMP toggle key to select RAMP time. Selections include: 0.5, 1.0, 1.5, and 2.0. Ramp time is applied to both the start and end of the contraction. Ramp time is in addition to the contraction time itself. A ramp setting is not applied to the Continuous duty cycle except when using a probe. With a probe treatment set to a Continuous duty cycle, a ramp time of 3 seconds is automatically applied.

7. INTENSITY.

Using the Up and Down arrow keys to the right-side of the INTENSITY display, set the Intensity. Remember, when you increase intensity, current to the patient begins. Therefore, START should be pressed immediately after setting the intensity to begin the treatment timer.

NOTE: Never use High Volt to treat any conditions which contribute to loss of sensation, or an area where the patient cannot feel the electrical stimulation.

8. Press START.

Press START. When you press start, the treatment timer begins counting down.

NOTE: SAVING DEFAULTS. If the treatment you have just set up is the most common High Volt setup you use, the treatment parameters can be saved as the defaults for your own device. After setting up the treatment, press and hold the START key for two seconds. At the end of two seconds, a beep will sound indicating the treatment parameters have been saved. The next time this modality is chosen, the parameters will be selected automatically.

9. **MODIFY** Settings

While the High Volt treatment is in progress, TIME, INTENSITY, AND POLARITY can be modified. Carefully observe the channel indicator lights when modifying a treatment. When a channel's light is illuminated GREEN, the current treatment parameters for that channel are displayed. Any changes made to the parameters will affect only the channel that is illuminated in GREEN. Use the Channels Toggle key to display the parameters of another channel in order to modify parameters.

10. **STOP**

When the treatment time has elapsed, the current to the patient stops and a tone sounds signaling the end of a treatment. Treatments in progress may be stopped at any time using one of the following methods.

Stop One Treatment Only. Press and hold the FUNCTION key and press STOP. This stops only the treatment in focus.

Stop All. Press the STOP key. All treatments at all channels will stop.

Stop Time. Reduce the treatment time using the Time arrow key. The output at the selected channel is stopped, and the device then displays the parameters for the next treatment that remains in progress (if there is an active treatment).

High Volt Modality Information

High Voltage pulsed stimulation is a pulsed DC current with pulse durations in the microsecond range and pulse rates ranging from 1 to 200 Hz, with a peak amplitude of up to 1.0 A utilizing a twin-peak monophasic waveform.

The Dynatron 25 Series High Volt treatment setup uses a dedicated channel. Each treatment utilizes the single HV channel with one or more active electrodes and a large dispersive electrode. Electrodes are placed on opposite sides of the affected area so treatment is "through" the affected area.

Limited to less than 500 V, open load At one-half amplitude, pulse width is 25 \(\mu \) so interval spacing

High Volt Waveform for positive polarity

High Volt Waveform

The High Volt waveform is a twin-peak monophasic decaying waveform with either positive or negative polarity.

High Volt Settings

High and Low Sweep Pulse Rate. The user may select High (80-120 Hz) or Low (1-10 Hz) frequency ranges. During a treatment, the device scans through the range of frequencies selected. The settings for these pulse rate frequency ranges may be customized and saved by the user. The available custom range is 1 to 200 Hz.

Continuous Pulse Rate. The pulse rate may be set to a single continuous pulse rate instead of a range. The pulse rate is selected from a range of 1 to 200 Hz.

Selectable Polarity. Positive or Negative monophasic current may be selected. Alternating positive and negative (Bipolar) currents may also be selected. Note: Dual Polarity is not available with a probe treatment.

Custom Contraction/Rest Time Cycles. The Dynatron 25 Series allows for the choice of muscle contraction and relaxation time cycles (Duty Cycles) from options of 10/10 (ten seconds on and ten seconds off), 10/30, 10/50, Continuous or Custom cycles. The Custom time cycle allows for a Contraction (ON) time from 1 to 120 seconds, and a Rest (OFF) time from 1 to 300 seconds. Remember, the Rest time cannot be less than the Contraction time.

Selectable Ramp Speed. You can choose a ramp speed of .5 (1/2) to 2.0 seconds in half-second increments. For patient comfort, the ramp occurs both before and after the "Contraction" segment of the pulse.

Pulse Duration. The pulse duration is fixed at 25 μs (micro-seconds).

Pulse Pair Interval. The interval between the two pulses in the wave form is fixed at 100 μs.

Intensity Display in Volts. Intensity is displayed in volts (peak voltage with no load) with a range of 1 to 500 volts.

High Volt Default Settings

The following default settings are set by the manufacturer and are selected when you choose High Volt. You may change these defaults to your own preferred settings. See "Setting Defaults" in this manual.

- High Volt Pads Treatment
- Continuous Duty Cycle
- Treatment Time Electrodes: 10 minutes
- Polarity: Negative
- Pulse Rate: High Range

Default High Range:	80-120 Hz
Default Low Range:	1-10 H
Available Range:	1-200 Hz

High Volt Waveform Specifications

Waveform:	Twin peak, monophasic
Pulse Duration:	25 μs
Pulse Rate Range:	1 to 200 Hz
Pulse Interval:	100 μs
Maximum Power Output:	Limited to less than 500 V, open load

Ultrasound Instructions

The following Ultrasound Instructions are for 25 Series 825 and 925 USERS ONLY. The Dynatron 25 Series 525 and 625 do not offer the Ultrasound feature.

Ultrasound therapy channels sound waves 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.

If Soundhead Warming is ON and SOUND has been selected but is not the focus treatment, the word SOUND in the CHANNELS window will be illuminated ORANGE.

Although the Soundhead Warming feature defaults to OFF, it can be turned ON at any time. To turn ON the feature, select SOUND, followed by FUNCTION key. Using the WARMING toggle key, select ON.

A CAUTION

- Do not drop the soundhead on the 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 two to four times the size of the soundhead. The full surface of the soundhead should maintain in contact with the patient's skin (except with underwater treatments).

Head Temperature Hot Display

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. The Dynatron 25 Series TEMPERATURE bar reflects the amount of soundhead heating caused by poor coupling to ensure that the patient is receiving the optimal treatment and that the soundhead crystal is protected from overheating.

When the coupling is acceptable, the length of the Blue/Green segment lights on the coupling bar will remain less than half the length of the bar or less. If the soundhead approaches a temperature of 103 degrees Fahrenheit, the TEMPERATURE BAR begins to increase in length and the colored bar moves past the center mark and continues to lengthen.

If the SOUNDHEAD reaches approximately 103 degrees, a caution will appear in the Treatment Display Screen: "CAUTION, SOUNDHEAD IS GETTING HOT." Following the caution, the treatment should be terminated and the soundhead cooled. If the SOUNDHEAD reaches approximately 108 degrees, SOUND will be disabled and the Treatment Display Screen will read: "SOUNDHEAD IS TOO HOT! OUTPUT HAS BEEN DISABLED TO ALLOW COOLING."

NOTE: If the soundhead becomes too hot the SOUNDHEAD HOT warning will appear in the Treatment Screen whether SOUND is the focus treatment or not.

The soundhead must then be cooled down before the treatment can resume. When the soundhead cools sufficiently, press PAUSE or 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/cm²

Power for the Dynatron 25 Series may be displayed as WATTS or W/cm². To choose the desired option, select SOUND, then press the DISPLAY toggle key under the DISPLAY window and select WATTS or W/cm². The default setting for power is W/cm²; however, the display you prefer may be selected at any time before or during a treatment. Power selection may be saved by pressing and holding down the START key until a beep sounds.

Ultrasound Quick Setup

Select SOUND.

- 1. **FREQUENCY.** Using the FREQUENCY toggle key select 1 MHz, 2 MHz, or 3 MHz.
- 2. **DUTY CYCLE.** Using the DUTY toggle key, select 10%, 20%, 50% or CONT (Continuous).
- 3. **TIME.** Change the treatment TIME, if desired using the Up/Down arrow keys.
- 4. **INTENSITY.** Using the Up/Down arrow keys, raise the INTENSITY to desired level.
- 5. Press START.
- 6. **STOP.** Press and hold the FUNCTION and press the STOP key to stop only the focus treatment appearing in the Treatment Display Screen. Pressing STOP alone, stops all treatments operating on the device. Using the TIME arrow keys to bring treatment time to zero will also stop a treatment.

Detailed Ultrasound Setup

1. Press SOUND.

Press SOUND to select an Ultrasound treatment. The Default Parameters automatically appear in the Treatment Display Screen. Following are the Ultrasound Default Parameters:

Frequency1 MHz
DutyContinuous
DisplayW/cm ²
Time5 min.
Press the FUNCTION key to view the following:
ParameterFrequency
Warming OFF

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 toggle key located under the FREQUENCY window to select 1, 2, or 3 MHz. Any one of the three Frequencies may be selected with the 2 cm², 5 cm² or 10 cm² soundhead.

3. Select the **DUTY CYCLE**.

Press the DUTY CYCLE toggle key to select one of the four available options: 10%, 20%, 50%, or Continuous duty cycles.

Press the FUNCTION key located on the console to display additional parameters.

5. **HEAD WARMING.**

Press the **FUNCTION** key to access the Head Warming option. Using the WARMING Toggle key the Head Warming feature may be turned ON or OFF.

6. **TIME.**

The default time is set for a 5 minute treatment. Time can be changed by using the TIME Up/Down arrow keys located to the left of the TIME display.

7. Raise the **INTENSITY**.

Use the INTENSITY Up/Down arrow keys to increase the power to the desired setting. For patient safety and comfort, it is recommended that treatment begins with .1 w/cm², then increase power to the desired level after the treatment begins. Valid ranges are from 0.1 to 2.0 w/cm² (exceptions: valid ranges when using a 10 cm² head at 3 MHz are from 0.1 to 1.0 w/cm²).

8. Press START.

Press START, the treatment timer begins counting down and output is delivered to the soundhead. If you fail to set the Intensity before pressing START, a reminder will appear in the lower-right corner of the Treatment Display Screen: "CANNOT START TREATMENT WITH ZERO INTENSITY."

9. SAVING DEFAULTS. If the treatment you have just set up is the most common Ultrasound setup you use, new defaults may be saved by pressing and holding down the START key for two seconds. At the end of two seconds, a beep will sound indicating the treatment parameters have been saved. The next time SOUND is selected, these parameters will be selected automatically.

10. **MODIFY** a treatment in progress, if desired.

While the treatment is in progress, the following parameters can be modified: FREQUENCY, DUTY CYCLE, TIME, INTENSITY, and DISPLAY of Watts or Wcm².

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

To temporarily PAUSE an Ultrasound treatment, press the PAUSE key. Two quick tones 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 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.

12. **STOP.**

When the treatment time has elapsed, the current to the patient stops and a tone sounds signaling the end of a treatment. Treatments in progress may be stopped at any time using one of the following methods.

Stop One Treatment Only. Press and hold the FUNCTION key and press STOP. This stops only the treatment in focus.

Stop All. Press the STOP key. All treatments at all channels will stop.

Stop Time. Reduce the treatment time using the Time arrow key. The output at the selected channel is stopped, and the device then displays the parameters for the next treatment that remains in progress (if there is an active treatment).

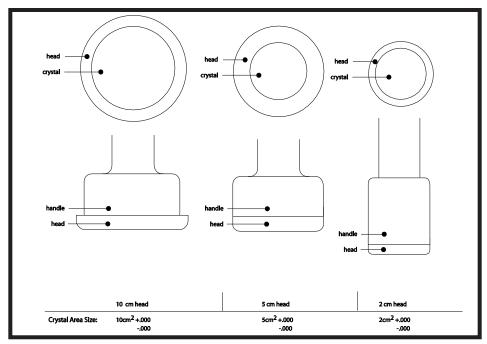
Ultrasound Modality Information

For Dynatron 825, and 925 users only. The Dynatron 525 and 625 do not offer the Ultrasound feature.

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 cm² soundhead can deliver up to 4 Watts and is appropriate for small areas (i.e. hands, fingers, feet).
- A 5 cm² 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 cm² soundhead can deliver up to 20 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 cm² is treated for 5 minutes. Then an area of 200 cm² is treated for 5 minutes. Both receive the same intensity. The 200 cm² 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.

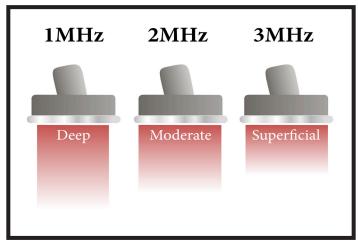
Penetration of Ultrasound Waves

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.

The frequency determines the depth of penetration of the Ultrasonic wave.

- 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 water tight 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

minutes of treatment	_	area to be treated (cm ²)	For Sub-Acute Conditions:
illinutes of treatment	_	1.5 x ERA	
minutes of treatment	=	area to be treated (cm ²)	For Chronic Conditions:
	_	1.0 x ERA	
minutes of treatment	=	area to be treated (cm²)	For Maximal Thermal Effect:
		.8 x ERA	

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.

NOTE: It is very common that intensity is always 1.5 W/cm². 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 25 Series device to output Stim through the soundhead, observe all contraindication, warnings, precautions, and usage cautions provided by the manufacturer for all modalities involved.

Potential 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 off 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 the temperature reaches high enough to read approximately 103°F, causing the overheated soundhead caution to appear in the Treatment Display Screen. This is only a cautionary warning to let you know that the soundhead is 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 you plug it into the console. The keypad may not respond to key presses and you will be unable to use the device 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 delivery of an Ultrasound treatment, the error message "SOUNDHEAD IS NOT CONNECTED, HEAD WARMING WILL BE DISABLED!" will appear in the Treatment Display 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 the Soundhead alert will appear in the Treatment Display 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 then 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.

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 cause 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. Soundheads should still be calibrated on an annual basis.

Ultrasound Specifications

Ultrasound Power output:

2cm² head:	1 MHz, 2 MHz, 3 MHz	0-4 watts; 0-2.0 w/cm ² \pm 10%
5cm² head:	1 MHz, 2 MHz, 3 MHz	0-10 watts; 0-2.0 w/cm ² \pm 10%
10cm² head:	1 MHz, 2 MHz	0-20 watts; 0-2.0 w/cm ² \pm 10%
10cm² head:	3 MHz	0-10 watts; 0-1.0 w/cm ² ± 10%

Ultrasound Regulation and Technical Information

For the Dynatron 825, and 925 Only

The Dynatron 825, and 925 comply 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 25 Series 825 and 925 are accurate to within ±1% of any treatment time.

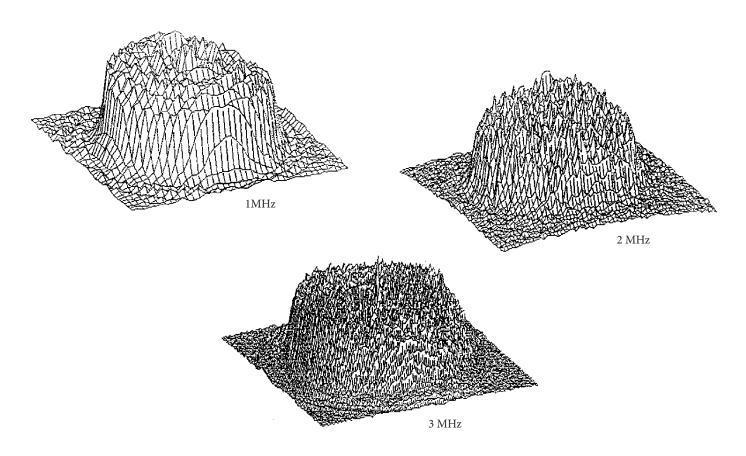
Pursuant to FDA 21CFR 1050.10(f)(1), the uncertainties in magnitude, expressed in percentage error, of the ultrasonic frequency, effective radiating area, and the ratio of the temporal-maximum to temporal-average effective intensity, pulse duration, and pulse repetition rate for the Dynatron 25 Series 825 and 925 are 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%

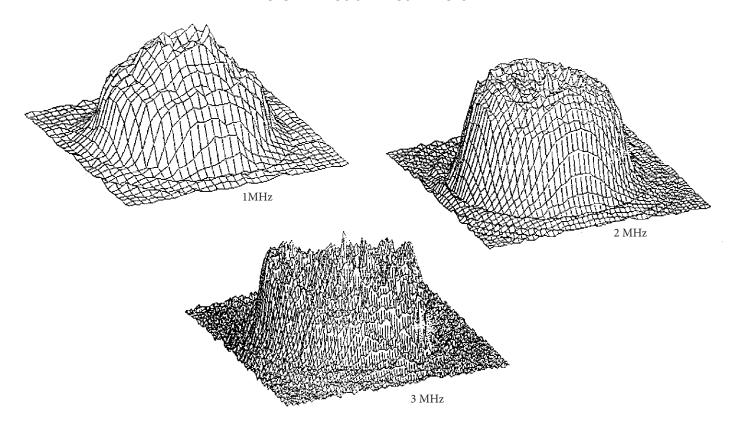
Ultrasound Beam Profiles

(For Dynatron 25 Series 825, and 925 users only. The Dynatron 25 Series 525 and 625 do not offer Ultrasound). The following diagrams show the typical spatial distribution of the radiated field for each size Dynatron 25 Series soundhead. 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.

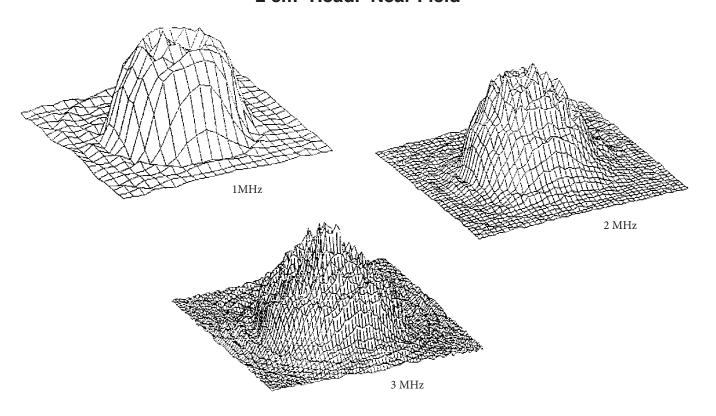
10 cm² Head. Near Field



5 cm² Head. Near Field



2 cm² Head. Near Field



Combination Therapy Instructions

The following combination therapy instructions are for 25 Series 825 and 925 USERS ONLY. The 525 and 625 do not offer the Ultrasound feature.

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.

Comboplus™

Dynatronics' Comboplus feature means you have almost unlimited options in setting up a combination treatment with 25 Series. You can:

• Combine an Ultrasound treatment with the following electrotherapy modalities provided by this device: IFC, Premodulated, Biphasic, Russian, or High Volt.

• Set up a combination treatment by using the ULTRASOUND output jack and the automatically selected default STIM channel.

A special "COMBO" lead wire is provided with the 825 and 925 with the standard accessories for this device to accommodate the ComboPlus feature. This lead wire is plugged into the selected STIM jack; then the banana end of the lead is connected to the COMBO input jack on the right-side of the device, and the pin end of the lead is connected to an electrode to be placed on the patient. It is important to note the channel selected by the device during setup and connect the lead wire to the correct channel before setting intensity for the treatment.

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, you would place one electrode on the patient and use the soundhead as the second electrode site to complete the setup. A patient lead wire designed to accommodate this setup is included in the Dynatron 25 Series standard accessory package for devices with Ultrasound and electrical stimulation capabilities.

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.

When setting up a combination treatment, observe all contraindications, warnings, and precautions for both therapies to be used.

REMEMBER: Use very low Stim intensities for all COMBO treatments!

In order to set up a COMBO treatment, you must be familiar with setup instructions for both the electrotherapy modality to be used and Ultrasound as explained earlier in this manual. Also remember:

- When a modality indicator is highlighted GREEN, the treatment parameters for that output are displayed. Any changes you make to the parameters will affect that channel only.
- When a modality indicator light is highlighted YELLOW, the channel is active, but its parameters are not being
 displayed (in focus) and may not be modified at this time. To bring a treatment's parameters into focus, you must
 first press the CHANNELS toggle key to select the treatment—the modality indicator will then become GREEN and
 modifications are allowed.
- When using the 825 or 925, since Ultrasound and Stim share the TIME and INTENSITY displays during a combination treatment, you will need to carefully observe which modality is in focus when setting up or changing treatment parameters. You may toggle between the Stim and SOUND channel using the CHANNELS toggle key. The treatment timer does not begin until you press START after both modalities have been set up.

Combination Therapy Setup

- 1. **Press the COMBO key** on the 825 and 925. SOUND will be illuminated GREEN in the CHANNELS window and an automatically selected STIM channel will be illuminated in YELLOW. Other available channels not in use will be illuminated in WHITE.
- 2. **Plug the combo lead wire into the active STIM channel jack** of the 825 or 925. The banana connector end plugs into the COMBO input jack on the right-side of the unit. The pin end attaches to the dispersive electrode.
- 3. Apply the dispersive electrode to the patient
- 4. With SOUND illuminated GREEN, **select parameters for the Ultrasound** portion of the COMBO treatment following the instructions found in the manual.
- 5. Press START.

NOTE: Although parameters and settings are selected for ultrasound therapy, no ultrasound power will be delivered until you press START after both the ULTRASOUND and STIM modalities have been set up.

- 6. When using the 825 or 925 **press the single-channel STIM option of your choice.** The selected STIM channel's illumination will change from YELLOW to GREEN and become the focus treatment. NOTE: If selecting a Stim channel, other than the default channel, the illuminated channel will change from WHITE to GREEN. The SOUND channel will now be illuminated YELLOW. Proceed to set up the STIM treatment following the modality instructions found in the manual.
 - Remember, High Volt must use the designated HI-VOLT Channel. The system defaults to a PREMOD treatment selection unless another default therapy has been selected previously.
- 7. **Apply the conductive gel** to the Ultrasound treatment site now. Place the soundhead at the treatment site making good contact with the skin.
- 8. Raise the Stim intensity. KEEP THE STIM INTENSITY LOW! If the soundhead is in proper position and coupling is good, the patient will feel the current. If the patient does not feel the current, check to be sure coupling is good and make sure you have used ample conductive gel.
- 9. **Press START.** Both STIM and ULTRASOUND will be activated.

10. STOP.

When the treatment time has elapsed, the therapy to the patient stops and a tone sounds notifying you of the treatment end. Treatments in progress may be stopped at any time using one of the following methods.

ALL STOP: Press the STOP key to stop all treatments at all channels on the 825 and 925 devices. The output for the channel(s) selected is stopped (both STIM and SOUND channels), and the device then displays the beginning treatment parameters.

STOP ONE TREATMENT ONLY (825 AND 925 Plus): If you have more than one treatment in progress, stop one treatment by either of the following methods. First, press the CHANNELS toggle key to select SOUND or press the active STIM modality key, the channel's light will be illuminated GREEN when selected. Once selected press and hold the FUNCTION key and press the STOP key. Or, REDUCE THE TREATMENT TIME TO ZERO. Press the Time down arrow until the Time display reaches zero. The device beeps when the time reaches zero.

NOTE: Pausing a COMBO Treatment

In COMBO mode, if a treatment is paused by any means (either by pressing the PAUSE key or as a result of a soundhead that has become too hot), the Ultrasound output is stopped and the treatment timer is paused. However, the Stim current continues to be delivered. Therefore, the pause condition should be corrected as quickly as possible and the treatment resumed, or the treatment should be stopped completely by pressing the STOP button.

Modify A Treatment

Modifications to a treatment in progress may be made to both modalities used. See the instructions earlier in this manual for specific modification instructions for each modality.

Combination Default Settings

The factory default for a COMBINATION TREATMENT is an Ultrasound treatment with a Premodulated treatment and the respective default settings for those two modalities.

In COMBO mode you can save new default treatment time and the preferred Stim modality. The Stim settings in a COMBO treatment are determined by the defaults of that modality. Separate Ultrasound default settings may be saved for the COMBO treatment which will not affect Ultrasound-only treatments.

If you save defaults during a COMBO treatment the following settings are saved:

- The Stim modality that is selected for the current COMBO treatment is saved as the default Stim treatment for COMBO.
- Ultrasound parameters for this setup are saved, and become the default Ultrasound settings for combination treatments only (non-combination Ultrasound treatments may have different default settings).
- The treatment time is saved as the default treatment time for combination treatments.

Simultaneous Treatments

The Dynatron 25 Series allows many combinations of simultaneous treatments to be delivered at once using available channels. Simultaneous treatments are not the same as COMBO treatments. A COMBO treatment combines Ultrasound with a Stim therapy into a single treatment. A COMBO treatment is always delivered to one patient. Simultaneous treatments are independent treatments that are set up separately, that have separate treatment timers, and which may be delivered to one or more patients at the same time.

There are very few limitations to the simultaneous treatments that may be set up with the Dynatron 25 Series. You can set up any number of separate treatments as described below with the exceptions noted:

• Channels 1 through 4 may be used for any number of Interferential, Premodulated, Russian, or Biphasic treatments. For treatments using one channel, the device will select the next available channel. For treatments using two channels, the device will select a channel pair (1-2 or 3-4). Note: Channels 3-4 are available on 25 Series 625 and 925 only.

Set Up A Second Treatment

To set up the second (or third) treatment, after you have set up and started the first modality, press the modality key for the second treatment to be set up. The device automatically selects the treatment channel(s) to be used. The GREEN channel light shows you the channel(s) selected for this treatment. Plug the lead or cable into the corresponding output jack(s) before you proceed with setting up the treatment. Select the treatment parameters for the second treatment following the setup instructions for that modality provided in this manual. When parameters have been entered, press START.

Modify Simultaneous Treatments

You may VIEW and MODIFY parameters for the treatment channel(s) that is illuminated GREEN. While two or more treatments may be in progress at once, the TIME / INTENSITY displays can show only the settings for the focus treatment whose operational channels are illuminated GREEN. Other channels in use at that time will be illuminated YELLOW indicating that the channels are active (delivering current) but their parameters are not currently displayed or in focus.

All channels that are currently operational but not in focus, are listed both in the CHANNELS window and in small font on the left-hand side of the Treatment Display Screen under the heading, RUNNING TREATMENTS. Included in the list under RUNNING TREATMENTS, is the active channel(s) illuminated in YELLOW; and the name of the treatment modality with the remaining treatment time, both illuminated in White.

To change the settings for a channel or output that has a YELLOW light, press the CHANNELS toggle key one or more times until the light for the desired channel becomes GREEN. The TIME and INTENSITY displays change to show the parameters currently in effect for that treatment. Once a treatment is in focus, the parameters may be changed.

Contraindications, Warnings, & Precautions

for Interferential, Premodulated, Russian, Biphasic, and High Voltage Pulsed Stimulation.

Contraindications

Thrombosis. It is possible that the current produces chemical changes in the blood leading to alterations in the clotting time. At present there is no specific scientific evidence to support this. Nevertheless, treatment must not be given to any patient who is taking anticoagulants as it may render these ineffective. The effect of the current is on the platelets and would tend to spread any clot with perhaps fatal results in a patient with coronary thrombosis. If a patient has a history of deep vein thrombosis, even many years past, the treatment may increase rather than decrease swelling.

Implanted Electronic Devices. Patients with Implanted Electronic Devices (for example a cardiac pacemaker) should not be subjected to stimulation.

Cardiac Conditions. The electrodes should be placed to avoid the stellate ganglion and the heart itself. If there is a potential for heart problems, the clinician must exercise professional judgment and use adequate precautions. The clinician should not expose the patient to risk if possible heart problems are suspected.

Bacterial Infections. The effect on bacteria is uncertain, and it is advisable that bacterial infections should not be treated.

Malignancy. The use of Interferential, Premodulated, High Volt, Biphasic, or Russian Stim treatment is contraindicated in patients with clinically diagnosed cancer.

WARNING

Thoracic applications are contraindicated: Additional warning from the Canadian Health and Welfare Department, Health Protection Branch. Cardiac fibrillation may occur if output current is 50 mA RMS or greater for any output circuit.

- 1. Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
- 2. Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are positioned over the neck or mouth. The contractions may be strong enough to close the airway or cause difficulty in breathing.
- 3. Caution should be used in the transthoracic application of EMS devices in that the introduction of electrical current into the heart may cause arrhythmia.
- 4. This device should be kept out of the reach of children.
- 5. The Dynatron device should not be used in the following conditions:
 - Pregnancy
 - Acute and sub-acute thrombophlebitis
 - Potentially malignant lesions
 - Implants of any electrical nature
 - Do not use over a carotid sinus
 - Transcerebrally
 - · Disturbances in cardiac rhythm
- 6. The long-term effects of chronic electrical stimulation are unknown.
- 7. This device should not be used to relieve pain syndromes until etiology has been established.
- 8. Current densities for any electrodes exceeding 2 mA r.m.s./cm² may require the special attention of the USER.

Precautions

- 1. Precautions should be observed following recent surgical procedures when muscle contractions may disrupt the healing process.
- 2. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by use of an alternate conductive medium or alternate electrode placement.
- 3. Interferential, Premodulated, Biphasic, Russian, and High Volt therapy must be used cautiously in the presence of any of the following conditions:
 - When there is a tendency to hemorrhage following acute trauma or fracture.
 - Over the menstruating uterus.

4. Use extreme caution when administering a treatment where sensory nerve damage is present or in any\case where there is a loss of normal skin sensation; this includes areas desensitized by medication or ice. When treating an area where there is loss of feeling, there is an increased danger of injuring the patient. Do not treat such areas unless you have sufficient training and experience in applying this therapy for such cases and you are confident you can deliver the treatment safely without injuring the patient.

When treating any conditions contributing to loss of sensation, or any time the patient cannot feel the electrical stimulation, do not exceed an intensity setting of 12-15 when using large electrodes $(3-3/4" \times 1-3/4")$ or an intensity setting of 8-10 when using small electrodes $(1-3/4" \times 1-3/4")$, and select short treatment times (approximately 8 minutes). Be alert for any irregularities in the skin following the treatment.

Never use High Volt therapy to treat an area where there is a loss of normal skin sensation.

- 5. 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.
- 6. 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 or anti-static carpet treatment to remove any static charge from the operator before touching the device.
- 7. To avoid causing possible interference with the operation of the Dynatron device, it should not be connected to anyone who is wearing or holding an RF transmission device (two-way radio, cell phone, beeper, etc.)

Treatment Setup Warnings

- 1. NEVER turn the power on or off while the unit is connected to the patient.
- 2. Always STOP a treatment before removing or attaching electrodes or leads to the patient. Leads and electrodes must only be applied to the patient before a treatment is started.
- 3. Never use worn or damaged leads or electrodes as these may result in injury to the patient. Check leads using the Lead Test function provided by this device.
- 4. Electrodes must be attached and probe placed in contact with the patient's skin (if applicable) prior to starting a treatment.

Adverse Effects

Skin irritation and burns beneath the electrodes have been reported with the use of electrotherapy.

Any electrical stimulation has the potential to burn or irritate a patient's skin. The tendency towards burning is dependent upon several factors; the most important being patient susceptibility and current density. The practitioner has little control over patient susceptibility, other than to observe first time patients carefully. However, current density is totally controllable.

It is important to note that the intensity displayed is not a measurement of the current delivered. For Interferential, Premodulated, Biphasic and Russian Stim, this is a relative reading only. Current delivered at a given intensity setting is dependent upon the current setting, the size and type of electrodes used, and conductance.

Current density is the amount of current delivered, divided by the area through which the current is being delivered. Higher current density increases the tendency to burn or irritate. The current density can be reduced by decreasing the amount of current or increasing the area through which the current is being delivered. The area can be increased by using larger electrodes and/or making sure that the total area of the electrode is actually delivering current. Current density is also reduced when more electrodes are used (four instead of two).

Electrodes which are worn or have lost their adhesiveness, or carbon electrodes which are corroded and are not securely fastened, 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. Also see "Electrotherapy Usage Cautions" in this manual for further discussion regarding safe use of leads and electrodes.

Use Only Dynatronics Accessories

The leads and electrodes provided by Dynatronics have been tested with Dynatronics devices and are appropriate for use with these devices. Dynatronics cannot guarantee the safety or performance of leads and electrodes purchased from other vendors.

Only use electrodes which are designed for use with this device. NEVER use monitoring electrodes such as ECG, EKG, or EMG. NEVER use electrodes specified only for TENS devices as those electrodes may not be adequate for use with the electrotherapies provided by this device.

Contact Dynatronics Customer Service if you have questions about appropriate electrodes for use with this device.

Contraindications, Warnings, & Precautions for Ultrasound Treatment

Contraindications

The Dynatron 25 Series 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 25 Series 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 25 Series 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 25 Series Ultrasound devices must be used cautiously in the presence of any 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



There are no serviceable parts in 25 Series devices.

Setting Defaults

Each of the modalities has default settings that are automatically selected when a modality key is pressed. The default settings feature allows previously used treatment parameters to be set up in just seconds. For guidance in selecting the appropriate settings for each modality, 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. Press the modality key desired (IFC, Premod, Russian, Biphasic, High Volt, Micro, Ultrasound, or Combo).
- 2. Set up a treatment using your preferred settings.
- 3. If this is an actual treatment you may increase the intensity now (intensity is not saved with the default settings). This step is optional.

4. PRESS and HOLD the START key for two full seconds to SAVE the new settings. A beep will sound signaling that the new settings have been saved.

If the intensity was set before you pressed the START key, the treatment will begin upon pressing START. You may proceed with delivering the treatment now, or you may stop the treatment.

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, do the following:

- 1. Turn the machine off and wait five seconds.
- 2. Turn on the machine. Following initialization, DYNATRONICS appears in the Display Screen.
- 3. Press and hold the START key down until three beeps are sounded. The Factory Defaults have now been restored for all modalities. You may now proceed with treatment setup.
- 4. To restore the factory defaults of only one modality, set the defaults to the settings referenced on pages 8, 9, and 10 of this manual. Press and hold the START key until a beep is heard.

Battery Operation

Use ONLY a Dynatronics' Approved Battery

Before purchasing or using an existing battery with a 25 Series device, contact Dynatronics or your Dynatronics Representative to obtain specifications for a battery that may be safely used with a 25 Series device.

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 25 Series devices are manufactured with battery capabilities allowing you to deliver 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 25 Series 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 25 Series console.
- 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.
- 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.

Battery Life

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

- 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 25 Series device.
- 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:



When a battery is employed to operate the 25 Series devices, Ultrasund may deplete the battery rapidly.

- The amperage of the battery pack. Larger amperage will provide longer use.
- The modality used. Light Therapy treatments require more power than Ultrasound or Stim modalities while Ultrasound requires more power than Stim modalities.
- The intensity of the treatments. The higher the intensity, the higher the consumption of power.
- The use of multiple treatments. The more channels used, the more power is consumed.
- 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

Other ranges, accuracy and precision values that are not provided here may be obtained from Dynatronics upon request.

Dynatron 25 Series Specifications

Power Requirements	
Power Consumption	100 Watts
Fuse:	250V, 1.6A slow blow
Dimensions	18.5" W (41.91cm) x 4.0" H (10.2cm) x 12.0" D (30.5cm)
Weight	8.2 pounds (3.7 Kg)

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 $^{+70^{\circ}\text{C}}$
- 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 $+10^{\circ}$ C $+30^{\circ}$ 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 25 Series

- Double redundancy protection on output amplifiers.
- Current sensing. If current reaches the current limit for the device, intensity is automatically reduced.
- 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.

Care and Cleaning Instructions

25 Series Console

- Clean the <u>outer surface of the 25 Series</u> 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 its probes or pads, 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.

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, probe, or the soundheads as severe damage will occur.

Suggested Maintenance Schedule

Service To Be Performed By A Technician:

Every 6 Months

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

Annually

- Annual Ultrasound calibration should be performed by a qualified technician.
- Check the output voltages and currents on all outputs.
- Inspect soundhead connectors on unit and on soundhead.
- Verify DAC calibration and current limits.
- It is recommended that the 25 Series device be sent to the manufacturer for annual calibration.

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:
 - Replace lead wires and carbon electrodes at least every six months.
 - Replace self-adhesive electrodes after not more than 15 uses.
- 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, submersion in water, 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. For older devices contact Dynatronics or your Dynatronics dealer for information and pricing for current upgrades to your device. 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. Immediately report any device malfunction to Dynatronics Customer Service Department (800) 874-6251.

WARNING

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

A 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.

NOTE: 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. See Section below "Returning a Unit for Repair."

Routine Ultrasound Calibration Inspections for 25 Series

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.

Software Updates

When Software updates to the 25 Series devices become available, updates can be made quickly and easily by completing the following steps:

- 1. Turn off the console.
- 2. Insert the SD card supplied by Dynatronics into the SD CARD slot on the left-side of the console (fingers of the SD card facing up, label side down).
- 3. Turn on the console. There will be a 3 to 4 second pause while the card syncs with the 25 Series system software. A RED screen will appear with the following warnings: "DO NOT DISCONNECT POWER," "DO NOT TURN OFF"





25 Series Software Update Screens

4. Press START to begin the download. Follow the instructions on the screen.

NOTE: All custom defaults will remain effective after the new software is downloaded.

A CAUTION

The download process erases the device memory. If the download process is stopped for any reason prior to completion, call Dynatronics for further instructions.

5. Remove the SD card from the SD CARD slot by gently pressing on the card. Turn off the console.

Returning a Unit for Repair

Return Authorization

If it becomes necessary to return a 25 Series unit for repair, contact Dynatronics' Customer Service (800) 874-6251. All returns must have a Service Order Number (SVO). 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.

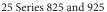
Definition of Symbols and Labeling

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

~	Alternating Current
	Caution
1 ()	On/Off (power: connection to the mains)
*	Type B (patient-applied part)
†	Type BF (patient-applied part)
	Follow Instructions for Use
	Keep Dry
((¿))	Non-ionizing Electromagnetic Radiation
Silt Lake City, Urah	Made in USA
	Temperature
	Humidity
REF	Model Number
SN	Serial Number
	Fuse
C€	European Conformity
	Maintenance
BAT. INPUT + 12V DC	Battery Input
5 5	Secure Digital Card
**	Dynatronics Manufacturer Location
\sim	Manufacturing Date
Nemko US	Safety Certification for Canada and the USA. Certified to IEC60601-1

The following labels appear on the 25 Series consoles, Ultrasound Heads.







25 Series 525 and 625



Manufactures 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. For disposal of accessory batteries, see manufacturer's instructions and follow applicable laws and regulations in your area.

Basic Troubleshooting Techniques

Lead Testing

Leads may easily be tested without any special equipment by using the "Lead Test" function of the 25 Series console. A DMM can also be used to see if the pads and leads are in good working condition. Electricity will always choose the path of least resistance to ground. If it does not have a good path or a complete circuit, it cannot flow and no stimulation will be felt. This is why good leads and pads are so important in the operation of the Dynatron 25 Series electrotherapy device.

- 1. Insert the lead wire that is to be tested into the CH 1 output jack
- 2. Press the "FUNCTION" key on the right side of the User Interface board
- 3. Turn on the LEAD TEST function by toggling the 5th soft key under the right side of the LCD
- 4. Touch the two leads at the end of the cable together
- 5. The conductance bar will increase from left to right indicating the quality of the electrical conductance through the lead wire
- 6. A "good" lead wire will show a green bar greater than 50% of the total conductance bar and a conductance reading of greater than 200
- 7. Prior to touching the two leads together the conductance reading will be "0" and the bar will not display a reading
- 8. A "bad" lead wire will not show conductance or will fluctuate below 200 when the cable is moved around, indicating that the lead has an intermittent open.

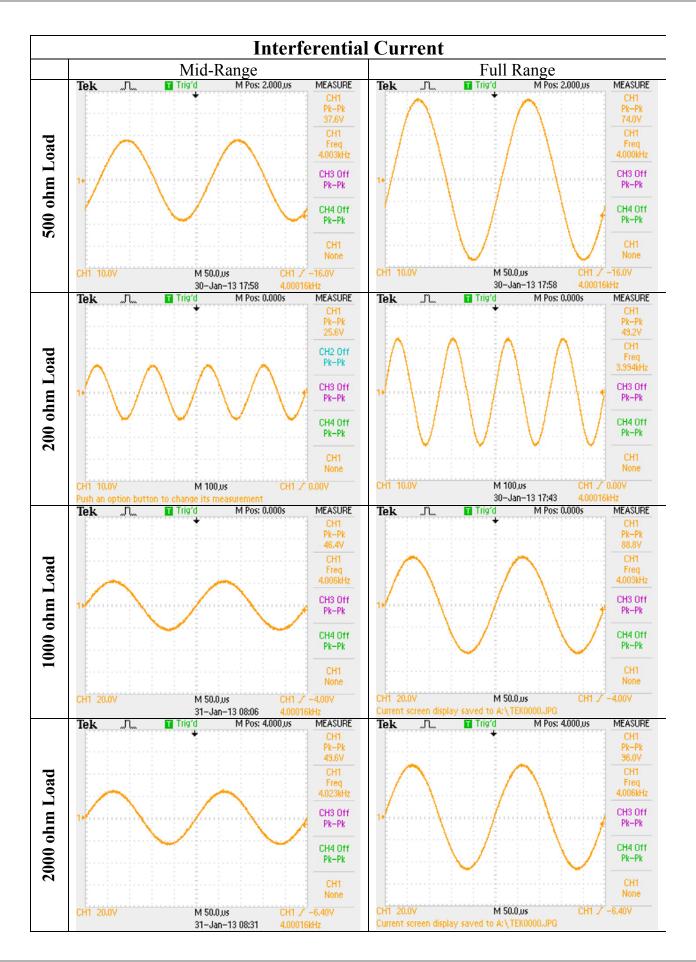
Testing Carbon Pads

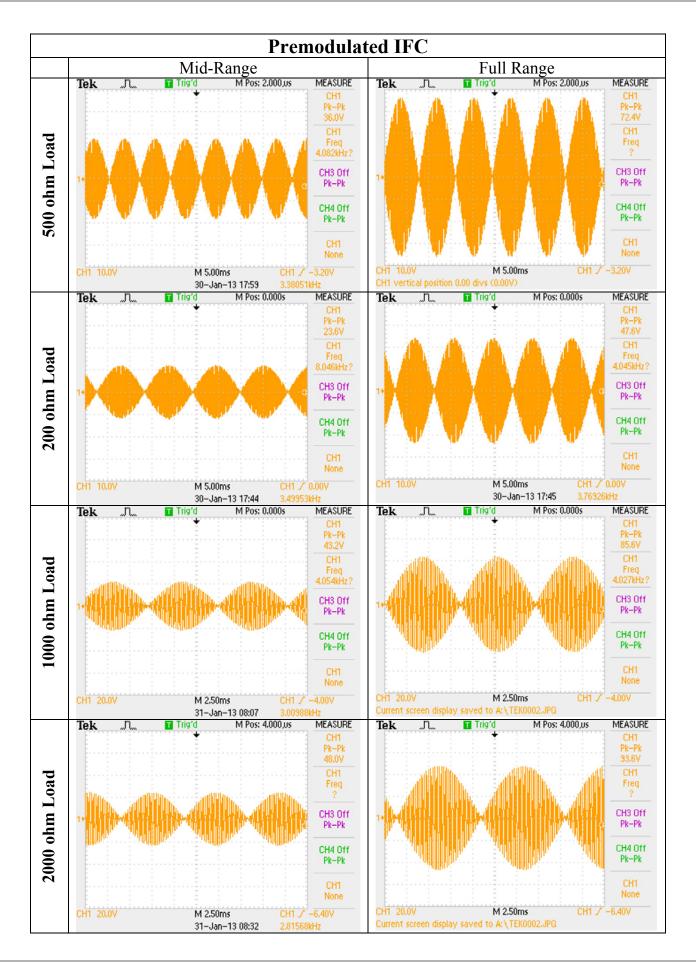
The carbon pads can be checked with the DMM. This is done with the resistance setting of the meter. Set the meter to "Ohms." Plug one of the test leads into the pin receptacle of the pad. Touch the other lead to the black carbon surface of the pad. If a resistance of more than 100 Ohms is seen, the pad is beginning to break down and should be replaced.

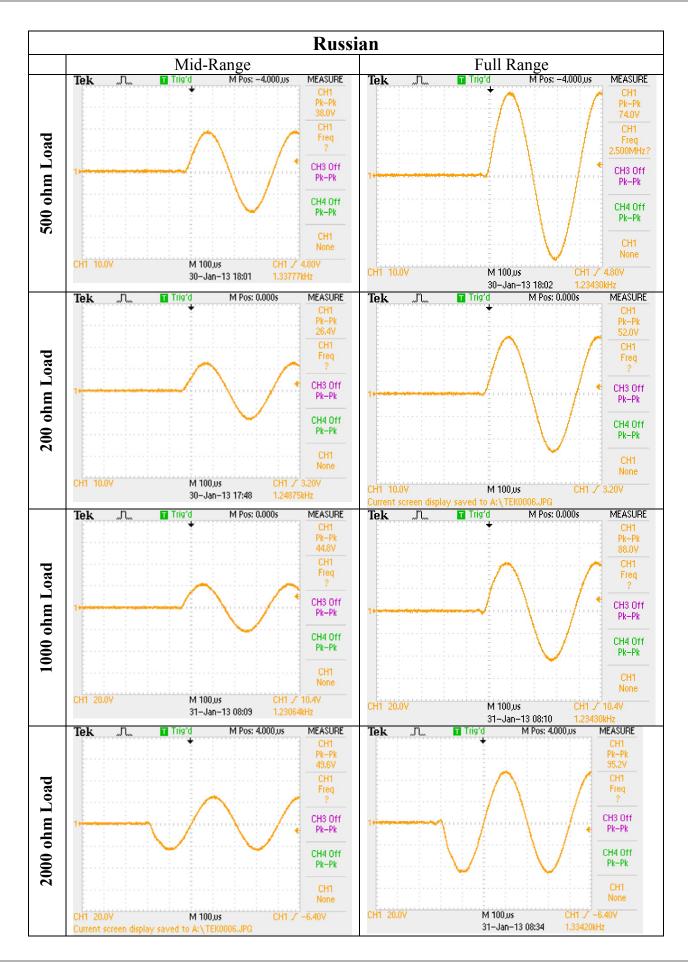
CAN/CSA Waveform Requirements

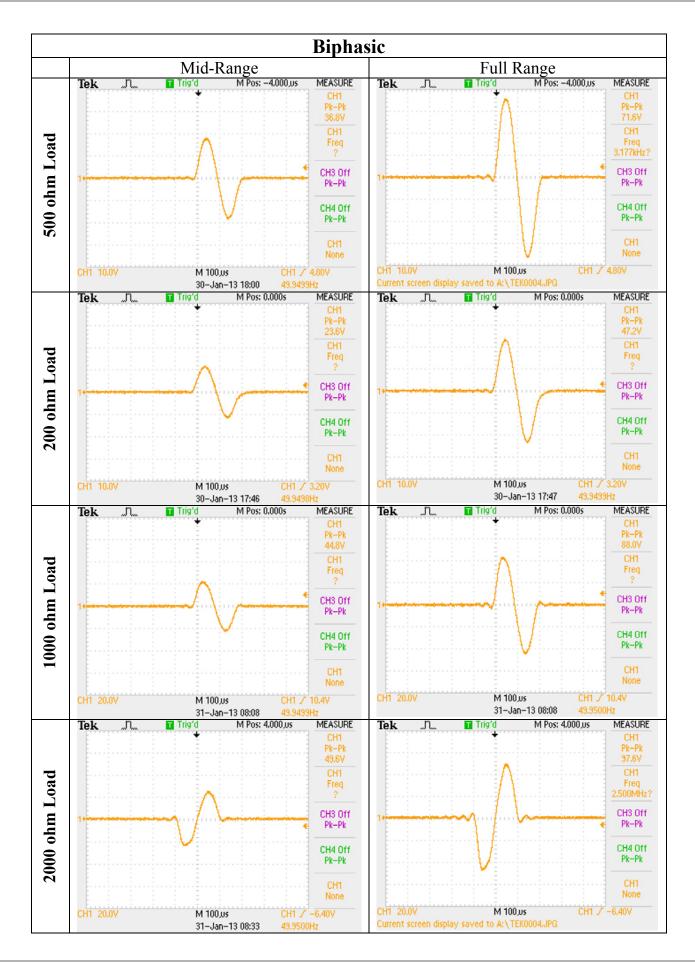
"A graphical representation of typical output signals, showing voltage waveforms at half and full setting of the output control when the EQUIPMENT is connected to resistive loads of 200 ohms, 500 ohms, 1000 ohms and 2000 ohms."

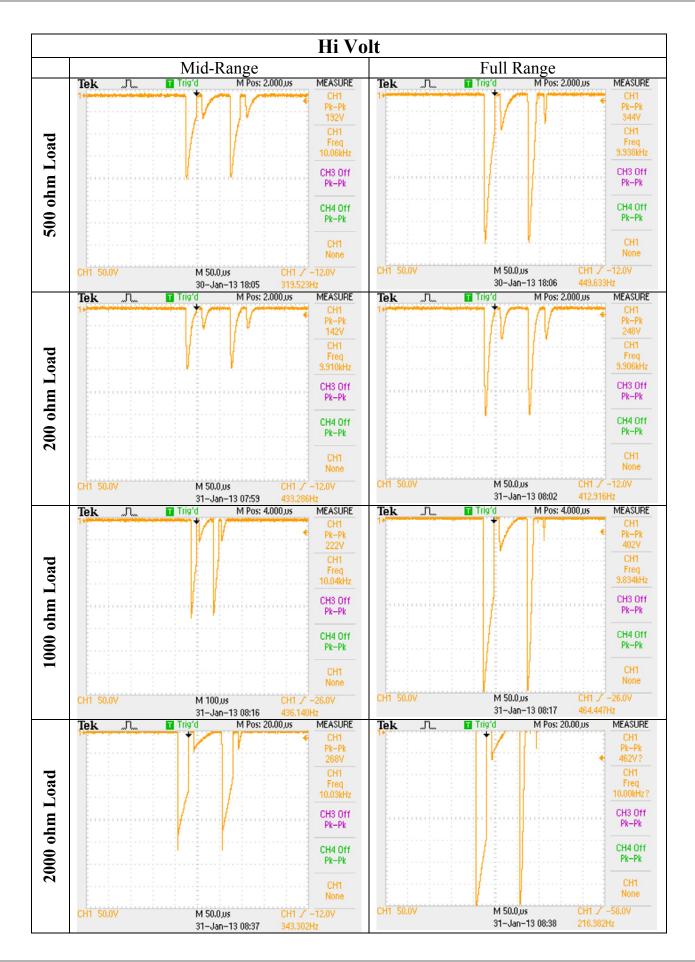
See the following pages for the graphical representations:











Electromagnetic Emissions and Immunity

Tables 1 through 4 below list the Dynatron 25 Series declarations of electromagnetic emissions and immunity, and give user guidance on the Dynatron 25 Series in an electromagnetic environment per IEC 60601-1-2 guidelines.

Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Dynatron 25 Series (and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the Dynatron 25 Series (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 25 Series (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 25 Series (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 25 Series (and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the Dynatron 25 Series (and accessories) should assure that it is used in such an environment.

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic dis- charge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 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 +/- 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 +/- 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 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <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 appli- cable	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 25 Series (and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the Dynatron 25 Series (and accessories) should assure that it is used in such an environment.

Emissions	IEC 60601	Compliance	Electromagnetic Environment Guidance
Test	Test Level	Level	
Conducted RF IEC 61000-4-6 Radiated RF IEC 610000- 4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Dynatron 25 Series (and accessories), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.17 x √P 80 MHz to 800 MHz d = 1.17 x √P 800 MHz to 2.5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range 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 25 Series (and accessories) is used exceeds the applicable RF compliance level above, the Dynatron 25 Series (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 25 Series (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 25 Series (and accessories)

The Dynatron 25 Series (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 25 Series (and accessories) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dynatron 25 Series (and accessories) as recommended below, according to the maximum power of the communications equipment.

	Separation dista	ance (meters) accord	ing to frequency of transmitter
Rated maximum output power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W W	d = 1.17 x√ P	d = 1.17 x√P	d = 2.33 x√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® 25 Series Plus Limited Warranty

DYNATRONICS CORPORATION warrants the Dynatron 25 Series 525, 625, 825, and 925 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 www.dynatron.com • info@dynatron.com

25 Series Warranty Registration

To register the warranty for your Dynatronics unit, complete all information requested, and MAIL, 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 underst	and,
contact your dealer or Dynatronics for instruction. As a trained medical practitioner, you are solely responsible	e 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 numbers your equipment was board on? (Check all that apply)	
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)	
\square Magazines \square Other Practitioners \square Trade Show \square 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 Channe	
□ Portability □ Accessory Package □ Educational Materials □ Company/Dealer St	
□ Price □ User Programmable □ Design □ Other □ Unique Features □ RA □ Number of Modalities	
☐ Safety ☐ Soundhead Frequencies ☐ Quality ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	