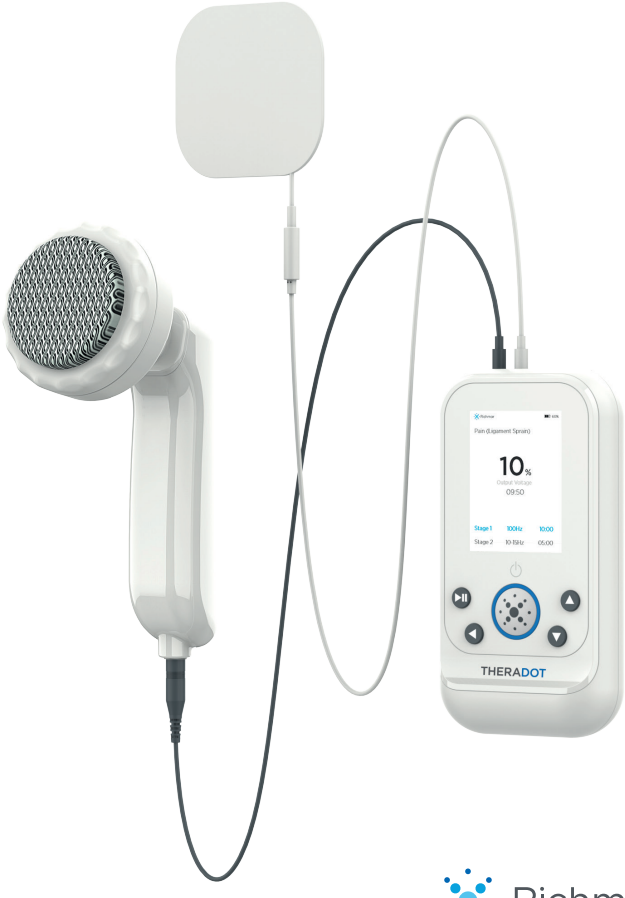
THERADOT™

DEEP OSCILLATION THERAPY DEVICE

INSTRUCTION MANUAL



Richmar®

This manual is valid for the

THERADOT™ Deep Oscillation Therapy Device

This user manual is published by Richmar,
a division of Compass Health Brands.

Conformity to safety standards
Richmar declares that the device complies with following normative documents:
IEC60601-1, IEC60601-1-2, ISO10993-5, ISO10993-10, ISO10993-1

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LEGAL NOTICE

For questions about your THERADOT™ Deep Oscillation Therapy Device:

Richmar, a division of Compass Health Brands
6753 Engle Road
Middleburg Heights, OH 44130
Tech Support: 888-549-4945, Option 2
Email: techcsr@compasshealthbrands.com

LIMITED WARRANTY

Congratulations on your purchase of the Richmar THERADOT™.

Richmar, a division of Compass Health Brands, warrants that your THERADOT™ is free of defects in material and workmanship. This warranty shall remain in effect for three (3) years* from the date of the original end user purchase. If this Product fails to function during the warranty period due to a defect in materials or workmanship, Richmar will repair or replace the respective Product without charge. Richmar's sole obligation in the case of any breach of its warranty set forth in the manual shall be, at Richmar's option, to replace the Product with a new or factory certified refurbished product, without charge to Richmar's purchaser or to refund the purchase price. It is at the discretion of Richmar's purchaser, if they will refund their customer and/or end user. If the Product is requested to be returned and product plus accessories is unopened/unused it can be returned minus a 25% restock fee, to the customer who purchased the Product from Richmar. All product repairs must be performed by Richmar or an authorized repair facility. Any modifications or repairs performed by unauthorized centers or groups will void this warranty.

RICHMAR SHALL RESERVE THE RIGHT TO REQUEST PROOF OF PURCHASE FROM THE END-USER TO VALIDATE THE WARRANTY PERIOD

This warranty does not cover:

1. Replacement parts not provided by the manufacturer or labor furnished by anyone other than a Richmar authorized repair facility or technician.
2. Defects or damage caused by labor furnished by someone other than Richmar or a certified service technician.
3. Any malfunction in the Product caused by product misuse, including, but not limited to, the failure to provide reasonable and required maintenance or any use that is inconsistent with the Product's Manual. RICHMAR SHALL NOT BE LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES. Some locations **DO NOT** allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

*The device warranty only applies to the device and does not include any accessories. All accessories have a 12 month warranty, except the battery, which holds a 6 month warranty. Damages to the device or accessories due to non-adherence with the Instruction Manual and its warning and cautions will exclude the warranty.

To obtain replacement parts, service or a replacement device under this warranty:

1. A claim must be made within the warranty period directly to Richmar or the company from whom you purchased the device.
2. An RMA number must be obtained from Richmar in order to receive replacements parts and/or return defective product under the warranty.
3. To contact Richmar's Tech Support Department for troubleshooting and/or replacement request, please call: 888-549.4549, Option 2.

This warranty gives you specific legal rights and you may also have other rights which vary from location to location. Any representative or agreement not contained in the warranty shall be void.

FOREWORD

This manual has been written for the owners and operators of the THERADOT™. It contains general information on the instructions for safety, intended use, working principle, operation, maintenance, trouble shooting, and warranty. In order to maximize the use, efficiency, and working life of your unit, please read this manual thoroughly and become familiar with the controls, as well as the accessories, before operating the unit.

OPERATOR QUALIFICATIONS

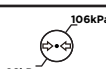
The THERADOT™ is intended for use by medical specialists and is only allowed to be used by an end user if a qualified and instructed medical clinician provides guidance and instructions. Specialists must have the basic physical and cognitive prerequisites such as vision, hearing, and literacy. Also, the basic function of the upper extremities is expected.

SYMBOLS

Symbols on the medical device

	Manufacturer
	Correct Disposal of This Product (Waste Electrical & Electronic Equipment) Statement: Contact the local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories.
	Type BF applied part complying with IEC 60601-1
	This symbol indicates that this device is a Class II equipment according to IEC 60601-1 (when charging)
	Refer to instruction manual/ booklet
	This symbol is the mark that identifies the ON/OFF button.

Symbols on the package

	This side up The transportation package must be vertical and straight up during transportation.
	Fragile, handle with care The product inside the packaging could be easily damaged if dropped or handled without care and attention.
	Keep away from rain The product package should keep out of the rain and not to store it in damp conditions
	Temperature limitation The product package should be stored at a temperature between -4° F and 131°F (-20°C and 55°C).
	Upper limit of humidity The product package should be stored at a humidity less than 93%.
	Atmospheric pressure limitation The product package should be stored at an atmospheric pressure between 86kPa and 106kPa.

PRECAUTIONARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definition of these symbols is as follows:

CAUTION

Text with a **"CAUTION"** indicator will explain possible safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.

WARNING

Text with a **"WARNING"** indicator will explain possible safety infractions that will potentially cause serious injury and equipment damage.

Refer to Instruction Manual/Booklet

NOTE: Throughout this manual, **"NOTE"** may be found. These Notes are helpful information to aid in the particular area or function being described.

Type BF applied part

The treatment head, adhesive electrodes and titanium neutral element are considered as one type BF applied part.

WARNINGS AND CAUTIONS

Please read the user manual entirely before using the THERADOT™ and take care of what follows:

⚠ WARNING

- Read, understand, and practice the precautionary operating instructions. Know the limitations and hazards associated with using the THERADOT™. Observe the precautionary and operational decals placed on the unit.
- Please reference the EMC Guidance at the end of the manual regarding special precautions and electromagnetic environment needed when using the device.
- Improper installation, operation, or maintenance of the THERADOT™ may result in malfunctions of this unit or other devices.
- **DO NOT** use the device in the presence of a flammable anesthetic mixture with air or oxygen, or nitrous oxide.
- In case of device failure or other obvious defects, switch the unit off immediately, and notify a certified service technician.
- **DO NOT** use on persons with implanted demand type cardiac pacemakers or defibrillators.
- **DO NOT** use on persons with severe heart failure or arrhythmia.
- **DO NOT** apply pulsed electrostatic fields over areas in which symptoms of existing thrombosis or thrombophlebitis are present.
- **DO NOT** apply pulsed electrostatic fields over, or in proximity to, cancerous lesions.
- **DO NOT** apply pulsed electrostatic fields over swollen, red, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- **DO NOT** apply pulsed electrostatic fields when the patient is in the bath or shower.

- **DO NOT** apply pulsed electrostatic fields while the patient is driving, operating machinery, or during any activity in which pulsed electrostatic fields can put the patient at risk of injury.

- **DO NOT** use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

- **DO NOT** use this unit for purposes other than treatment indicated in this manual.

- **DO NOT** use the THERADOT™ with high frequency surgical equipment on the patient. It will cause unstable output when the unit is close to the high frequency equipment (in the same room and without shield).

- **DO NOT** use this device simultaneously with other therapeutic device (such as microwave, shortwave), to avoid mis operation. Operation in close proximity (e.g. 3 ft) to a shortwave or microwave therapy device may produce instability in the device output.

- Be sure to use only the specified battery (3.7 V, 2600 mAh, lithium ion battery) provided by the manufacturer. Please contact your distributor to purchase the batteries.

- Please stop using the battery when it appears abnormal, such as bulging, cracked housing, or any shape changes.

- **NEVER** perform unauthorized service work. All service work (except battery replacement) must be performed only by service technicians who have been authorized by the manufacturer.

- Please dispose of the equipment and other accessories according to local regulations. **DO NOT** treat them as household waste. **DO NOT** put the device in fire or water. If the batteries are not properly disposed, it may cause a battery explosion.

- If the unit is not functioning properly or you feel discomfort, immediately stop using the unit. If you feel any discomfort with your body or skin, consult the doctor and follow his/her instructions.

- The adhesive electrodes and membranes are for single patient use only, **DO NOT** use on another patient to prevent infection.

- If the adhesive electrodes loses viscosity, please replace the electrode in order to maintain good electrical connection and to avoid potential injury.

- **DO NOT** secure electrodes with none or little viscosity, using any an other adhesive method such as, tape, bandaid, wraps, etc. Electrodes MUST be replaced if not attached completely to the treatment area, including lifting edges.

- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians before using this device.

- Keep this device out of the reach of children.

- **DO NOT** use this device while sleeping. The main device may malfunction or overheat, or the electrodes may move to an unexpected region or potentially disconnect and cause harm to the patient.

- **DO NOT** use this device if you have the following conditions:

  1. Acute infections;
  2. Acute inflammations with participation of pathogenic agents;
  3. Active tuberculosis;
  4. Acute venous diseases (untreated thromboses);
  5. Untreated malignant processes;
  6. Erysipelas;
  7. Patients and therapists with cardiac pacemakers and other electronic implants;
  8. Untreated heart disorders and diseases, especially cardiac insufficiency, decompensated cardiac edema, and cardiac arrhythmia;
  9. Pregnancy;
  10. Hypersensitivity to electrostatic fields;
  11. Infectious skin diseases;
  12. Vertebrobasilar insufficiency (VBI).

⚠ CAUTION

- **ALWAYS** check the device and the accessories for damage before use.
- Take care not to allow water to enter the device. Liquid penetration could damage the device.
- **DO NOT** use volatile liquids, such as paint thinner or benzene, because they may damage the plastic case.
- Ensure that the connectors are fully dry before connecting to the device.
- Use this device only with the accessories recommended by the manufacturer.
- Handle the device with care. **DO NOT** drop, knock, or shake the device. Rough handling can damage internal circuit boards.
- **DO NOT** press, bend or damage the electric cable.
- **ALWAYS** unplug the power adapter from the device before replacing the battery.
- Please charge the device at least every three months during long-term storage.

PRODUCT DESCRIPTION

The THERADOT™ is a pulsed electric therapeutic electrostatic field which is built up within the applicator and the patient's tissue. Due to the movement of the hand applicator or the therapists' gloved hands, a vibrating or pumping effect with deep impact is induced in the patient's tissue.

INDICATIONS FOR USE

The THERADOT™ is intended for:

1. Muscle relaxation
2. Increase circulation
3. Assists with lymphatic drainage
4. Temporary relief of minor aches and pains
5. Edema reduction
6. Improvement of wound healing

CONTRAINDICATIONS

Patients with the following disease diseases or conditions **MUST NOT** use the THERADOT™:

1. Acute infections;
2. Acute inflammations with participation of pathogenic agents;
3. Active tuberculosis;
4. Acute venous diseases(untreated thromboses);
5. Untreated malignant processes;
6. Erysipelas;
7. Patients and therapists with cardiac pacemakers and other electronic implants;
8. Untreated heart disorders and diseases, especially cardiac insufficiency, decompensated cardiac edema, and cardiac arrhythmia;
9. Pregnancy;
10. Hypersensitivity to electrostatic fields;
11. Infectious skin diseases;
12. Vertebrobasilar insufficiency (VBI).

TECHNICAL SPECIFICATIONS

GENERAL	
Product Name	THERADOT™
Product Model	DO1009
Device Dimensions (W×L×H)	3.01" x 5.65" x 1.4" (76.5 x 143.5 x 35.5mm)
Device Weight	0.5 lbs
Interface	2.8" LCD screen
Software Release Version	A
PERFORMANCE	
Channel:	Two
Output Waveform	Symmetrical biphasic pulse
Output Voltage	Adjustable, 0-900V (p-p), display 0-100%, stepping 10%.
Output Frequency	Adjustable, 5-300 Hz, stepping 1 Hz
Modulation (on/off ratio)	1/4, 1/3, 1/2, 2/3, 3/4, 1/1, 2/1, 3/1, 4/1
Output Impedance	6 MΩ
Timer	Max. 90 mins, divided into up to three stages, each stage is 1-30 mins, default 20 mins, stepping 1 min.
ELECTRICAL	
Power Supply of Adapter	Input AC100-240V, 50/60Hz; output DC 5V, 2A
Battery Specification	3.7V, 2600 mAh, lithium ion battery
Mode of Operation	Continuous
System of Protection	Class II, Type BF Applied Part
Ingress Protection	IPX0
Rated Power	24VA
OPERATION AND STORAGE CONDITION	
Environmental Conditions of Operation::	• Temperature: 41°F to 104°F (5°C to 40°C) • Rel. humidity: ≤80% • Atmosphere Pressure: 86 to 106kPa
Environmental Conditions of Transport and Storage:	• Temperature: -4°F to 131°F (-20°C to 55°C) • Rel. humidity: ≤93% • Atmosphere Pressure: 86 to 106 kPa

DEVICE INSPECTION

Immediately upon unpacking the device, verify that all components are not damaged and all contents are included:

1. Verify the delivery documents to make sure that the delivery is complete.
2. Check the LCD screen when unpacking the product to make sure it is in good condition. Any scratches on the surface after use, will not be covered by the warranty.
3. Check the external components and accessories for possible damage due to transport.
4. Verify that the packaging contains the following:

No.	Description/Item #	QTY	UOM
1	The THERADOT™ device (DO1009)	1	each
2	THERADOT™ stand (DO1009STND)	1	each
3	Wall Adapter & USB Power Cord (DO1009X)	1	each
4	Pin Lead Wires for Electrodes (White) (DO1009PINLW)	2	pack
5	Applicator/Titanium Element Lead Wires (Grey) (DO1009APPLW)	2	pack
6	Applicator Handle (DO1009APP)	1	each
7	Titanium neutral element (DO1009ELEM)	1	each
8	5.5cm Oscillating Head (DO1099APP5)	1	each
9	10cm Oscillating Head (DO1009APP10)	1	each
10	MultiStim Electrodes (400-8772)	4	pack
11	Box of Vinyl Gloves (VGPF3003)	100	box
12	Instruction Manual	1	each
13	Zipper Carrying Case (DO1009BAG)	1	each

THERADOT™ replacement accessories are available for purchase. Please contact your distributor for more details.

OVERVIEW OF DEVICE AND ACCESSORIES

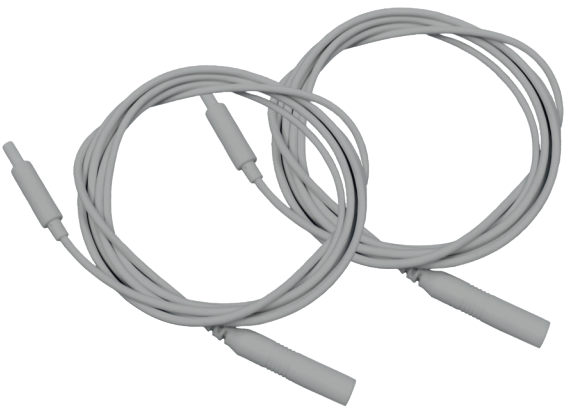
1. Output port 1*
2. Output port 2*
3. Type C power adapter port
4. Display screen
5. Power Button and Select Button
6. UP button
7. DOWN button
8. START/PAUSE/SKIP Phase button
9. Back/STOP button

***NOTE:** Both output ports on the top of the device can accommodate either the white or grey cord, interchangeably.

LEAD WIRES

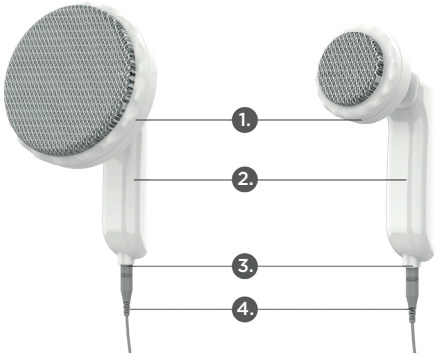
Pin Connection Lead wires for Electrodes (White - 2.0mm plug) - 2/pk
Item #: DO1009PINLW

Applicator/Titanium Element Lead Wire (Grey - 4.0mm plug) - 2/pk
Item #: DO1009APPLW



OSCILLATING HEADS

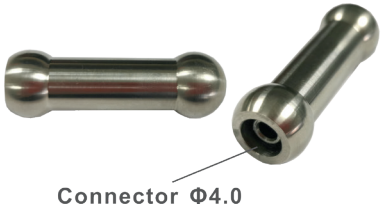
10cm Oscillating Head **5.5cm Oscillating Head**



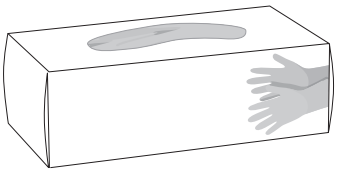
1. Detachable oscillating heads
2. Applicator Handle
3. Applicator Connection
4. Applicator/Titanium Element Lead Wire Connector

ADHESIVE ELECTRODE

TITANIUM NEUTRAL ELEMENT



VINYL GLOVES (100/bx)



THERADOT™ STAND

NOTE: Use replacement parts only supplied by the manufacturer. Contact your local dealer to place an order.

OPERATING INSTRUCTIONS

1. PREPARING BEFORE THERAPY

Charging the Device
The THERADOT™ device will come with a partial charge. In order to complete a treatment, it is recommended to charge the device once it decreases to lower than a 30% charge.

Place the Type C end of the charging cable into the top of the device port by sliding the cover over the two output ports to cover them and expose the charging port.

Place the other end of the charging cable into the ac adapter box and then plug the ac adapter box into the electrical outlet on the wall. The device will show a charging icon on the screen, in the upper right hand corner. **NOTE:** The device cannot be used while charging.

NOTE:

1. If the rechargeable battery of the devices is not fully charged when you start a treatment, the batteries may run out during the treatment. We advise you to **ALWAYS** fully charge the device before you start a treatment. A completely depleted battery should take approximately 2 hours to fully charge.
   ⚠
2 **ALWAYS** disconnect the power adapter from the wall and the device after charging is completed.
3. While the battery is charging, the device does not work.

Treatment Preparation
The THERADOT™ device requires an absolutely dry surface for treatment. Before treatment, prepare the patients skin by making sure there is no moisture in the treatment area. If needed, baby powder can be used in the area to help soak up any moisture.

Treatment Methods

⚠ WARNING

DO NOT turn the device ON until you understand and are familiar with each Treatment Method option indicated below by referencing Correct Cable Connection section in the manual.

There are several ways to apply treatment:
- Clinician Assisted Treatment
- Self (Patient only) Treatment

Clinician Assisted Therapy Options:

Option #A

Clinician Set up: Places one electrode on themselves and applies glove to both hands to administer manual therapy.

AND

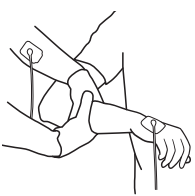
Patient Set up: Place one electrode on the patient OR the patient holds the titanium element in one hand*

*It is recommended for the patient to either place the titanium element between the web of two fingers or hold it with a light grip.

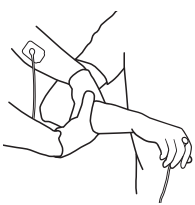
⚠ WARNING

- Use this device only with the accessories recommended by the manufacturer.
- **DO NOT** secure electrodes with none or little viscosity, using any other adhesive method such as, tape, bandaid, wraps, etc.
- Electrodes **MUST** be replaced if not attached completely to the treatment area, including lifting edges.
- The adhesive electrodes and membranes are for single patient use only, **DO NOT** use on another patient to prevent infection.
- If the adhesive electrodes loses viscosity, please replace the electrode in order to maintain good electrical connection and to avoid potential injury.

Option A: Electrode Set Up



Option A: Titanium Element Set Up



Option #B

Clinician Set up: Clinician can choose to use applicator attachment, instead of gloves, for hard to reach or uncomfortable areas.

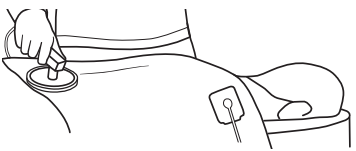
AND

Patient Set up: Holds the titanium element in one hand or has one electrode applied to their body

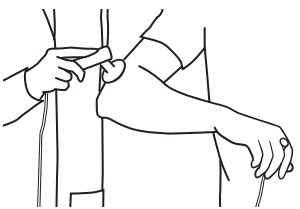
⚠ WARNING

- Use this device only with the accessories recommended by the manufacturer.
- **DO NOT** secure electrodes with none or little viscosity, using any other adhesive method such as, tape, bandaid, wraps, etc.
- Electrodes **MUST** be replaced if not attached completely to the treatment area, including lifting edges.
- The adhesive electrodes and membranes are for single patient use only, **DO NOT** use on another patient to prevent infection.
- If the adhesive electrodes loses viscosity, please replace the electrode in order to maintain good electrical connection and to avoid potential injury.

Option B: Applicator & Electrode Set Up



Option B: Applicator & Titanium Element Set Up



Self (Patient) Treatment Option:

⚠ WARNING

Self Treatment **MUST** only be used after appropriate training by a clinician.

Clinician Set up: No clinician needed.

Patient Set up: Patient uses applicator to apply treatment while either holding the titanium element in the other hand OR placing an electrode on the opposite side of the body being treated.

CORRECT CABLE CONNECTION

Depending on the treatment method chosen on the previous pages (Clinician Assisted Options or Self Treatment Options), the connection of lead wires to the device, and then to the accessories, is important for the device to emit the electrostatic pulses.

IMPORTANT:
If the method chosen requires connection to an oscillating head applicator or the titanium element, it must connect to a GREY lead wire.

If the method chosen requires connection to an electrode, it must connect with a WHITE lead wire.

How to Apply Therapy

The electrostatic pulse occurs between opposing polarities by way of the titanium rod or electrode for the patient and the applicator or gloves for the clinician. Varying movement speeds are used to accomplish different results throughout treatment.

Either the hand applicator or both of the clinicians gloved hands (whichever was the chosen method) should stay in contact with the patient's skin without lifting or stopping using varying pressures with active and passive continuous, repetitive movements.

Movements TOWARD the center of the body should be applied with appropriate and comfortable pressure, while movements AWAY from the center of the body should be applied with light pressure.

Any low frequency treatments (10-40Hz), therapy should be applied especially slow TOWARD the center of the body and quicker AWAY from the center of the body.

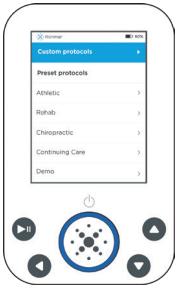
2. START TREATMENT

Power Device On/Off

Press and hold the [⏻] until the LCD screen turns ON the device. Repeat the same to power the device OFF.

NOTE: To preserve the battery life, if the device is not administering treatment or a button hasn't been pressed after 1 minute, the device will automatically power off.

Home Screen



Symbol	Description
START/Pause/ SKIP PHASE button	1. Start or stop treatment. 2. Press and hold to skip to next phase.
Back/STOP Button	1. Press to return to previous screen. 2. Press and hold to Stop Treatment.
ON/OFF and Select Button	1. Press and hold button to turn on or turn off the device 2. Press to select setting
Up Button	1. Press to go up to desired option. 2. Increase adjustable parameters, including intensity.
Down Button	1. Press to go down to desired option. 2. Decrease adjustable parameters, including intensity.
Battery Life	Displays battery life percentage
Custom protocols	Press to input and save a custom protocol for future use.
Preset protocols	The preset protocol options, by discipline, are below this symbol.
Demo	Use this to quickly demonstrate the 3 phase stimulation differences*

*Each phase is only 1 minute (total of 3 mins for complete demo)

3. TREATMENT START UP

There are two options to choose from:

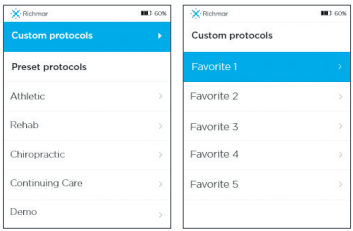
- Custom Protocols
- Preset Protocols

The THERADOT™ allows clinicians to choose and save their own custom parameters to use in the future.

Custom Protocol Setup

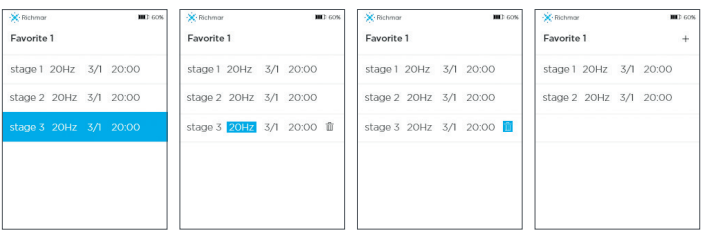
STEP 1: Select a Favorite

1. From the main menu, Custom Protocols should be highlighted blue. Press the [⊗] to advance to the next screen.
2. Select one from Favorites 1-5 by pressing the up [▲] or down [▼] arrow and then press [⊗] to choose the desired Favorite.



Each Favorite has a 3 Stage default. To delete a phase:

1. Press [▼] to highlight the last stage.
2. Press [⊗] and it will highlight the HZ parameter only, in blue.
3. Press the [▲] to highlight the trashcan in blue.
4. Press the [⊗] to confirm deletion of that stage.



*To re-add a stage, that only has 2 stages, simply highlight the parameters and press the [▲] to highlight the + sign in the upper right side of the screen and if you want to change the parameters of the added stage, advance to the Parameter Changes Section of the manual. **NOTE:** The + sign will only be present on the device if there are less than 3 stages.

PARAMETER CHANGES

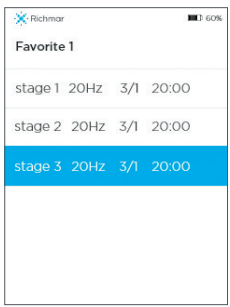
Adjust Output Frequency (Hz)*:

1. Press [⊛] to highlight Hz parameter, blue, instead of blue bar across an entire stage.
2. Press [⊛] again and the blue highlight will start blinking. This indicates it is ready to change the parameter.
3. Press [▲] and [▼] to adjust to the desired Output Frequency (Hz).
4. To accept, press [⊛] again, to highlight solid blue again.

*If you don't want to adjust the Hz, press [▼] to advance and highlight the Modulation (On/off Ratio; 3/1, 1/4, etc.)

Adjust Modulation and Timer:

1. Press [▼] to highlight the parameter blue, you want to adjust.
2. Press [⊛] and blue highlight will blink.
3. Press [▲] and [▼] until the parameter is adjusted to your desired number.
4. Once complete. press [⊛] for a solid blue highlight.
5. Press [⏯] to advance to the Treatment Screen
6. Once in treatment screen press [▲] to increase intensity to the desired percentage. To decrease press [▼].



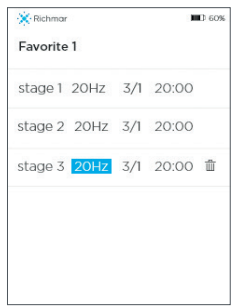


Table: Parameter Settings

Parameters	Range	Step
Output Frequency	3-300 Hz	1 Hz
Modulation (on/off ratio)	1/4, 1/3, 1/2, 2/3, 3/4, 1/1, 2/1, 3/1, 4/1	/
Timer (each stage)	1 - 30 mins	1 min
Output Voltage	0 - 100%	10%

TREATMENT SCREEN INSTRUCTIONS

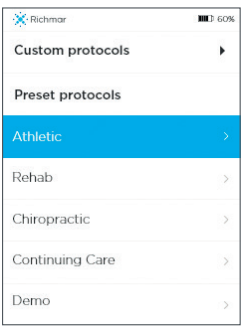
Preset Protocol Setup

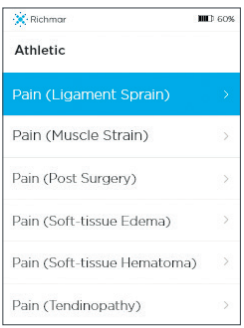
The THERADOT™ has 31 programmed protocols to choose from (not including Demo).

1. From the Home Screen, press [▼] until the desired market is highlighted blue. There are 4 options to choose from:
   - Athletic
   - Rehab
   - Chiropractic
   - Continuing Care
2. Press the [⊛] button to select.

The only paramater that is adjustable in Preset Protocols, is the timer.

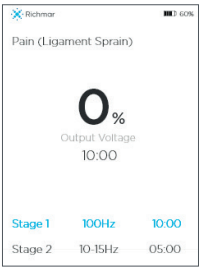
3. To adjust the timer, for any of the 3 stages, press [⊛]. The time will highlight and blink, blue.
4. Press the up [▲] or down [▼] to adjust to the preferable time.
5. Press [⊛] to accept changes.
6. Press [⏯] to advance to the Treatment Screen.

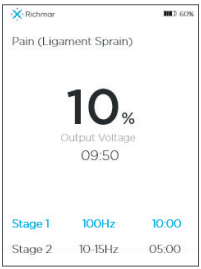




Treatment Screen

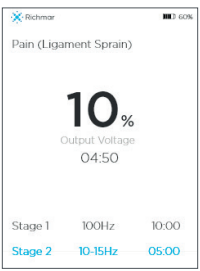
Once in the treatment screen, press the [▲] to increase the intensity (output voltage) desired. Press the [⏯] to start the treatment. Then the timer will start counting down.





After the first stage is complete, the device will emit a beeping sound to let the patient know, it is advancing to the next stage. The device will do this for each stage change.

NOTE: To skip a phase, press and hold the [⏯] to skip the current phase, and move to the next, before the timer is done for that stage.



NOTE: When skipping to the next stage, the output voltage maintains the previous stages value and there is no need to re-adjust.

If it is necessary to change the output voltage during the treatment, please use UP [▲] or Down [▼] button to adjust the value.

Pausing Treatment

Press the [⏯] button and the device will stop the treatment time from counting down so therapy can continue from the time it was paused and not start the total treatment time over. Press the button again to restart treatment when ready.

Stopping Treatment

1. The device will either emit a beeping sound when all three phases are complete and treatment is done.
2. OR you may press and hold the [◀] in the left corner and the device will return to the pre-start stage.

⚠ WARNING

Make sure the device is at either 0% voltage output or device screen is turned completely OFF before removing any accessories or attachments from the patient.

CARE AND MAINTENANCE

Cleaning

Make sure to turn off the device and remove all accessories (including the wall adapter and plug) from the device before cleaning and disinfecting.

Clean the outer surface of the main device (making sure not to get any liquids in any of the attachment openings), the hand applicator, oscillating heads, the wall adapter and connection cables regularly with a clean, soft damp cloth or mild disinfectant wipe with 70% or less medical isopropanol alcohol. Manufacturer suggests using Dismozon plus or similar product.

Oscillating heads will likely need replacement after approximately 25-30 uses or earlier if the oscillating head has excessive oil or debris that will affect the therapeutic connectivity of the device.

⚠ CAUTION

- **DO NOT** use volatile liquids, such as paint thinner or benzene, because they may damage the plastic case.
- Take care not to allow water to enter the device. Liquid penetration could damage the device.
- Ensure that the connectors are fully dry before re-connecting to the device.

ROUTINE MAINTENANCE

Read this maintenance instruction thoroughly before doing any maintenance.

Repairs and calibrations can only be performed by authorized service personnel approved by the manufacturer.

⚠ WARNING

To preserve the product warranty, functionality of device and product safety, it is recommended to only use replacement parts provided by the manufacturer.

The following items should be checked at least monthly to ensure proper operation of this device:

1. Power adapter: Check to make sure the cord is not frayed, kinked, and does not have torn or cut insulation.
2. Connection cables: Check to make sure the cable is flexible, free of kinks, not frayed, and the insulation is intact.

NOTE: If either of the above is observed, immediately discontinue use of the device and obtain manufacturer recommended replacement parts.

⚠ WARNING

NEVER perform unauthorized service work. All service work (except battery replacement) must be performed only by service technicians who have been authorized by the manufacturer.

BATTERY REPLACEMENT

Rechargeable batteries have a limited number of charge cycles and may eventually need to be replaced. Please replace the battery if its power depletes rapidly or needs longer than usual to be recharged.* * A completely depleted battery should take no longer 2-5 hours for a full charge. Be sure to use only the specified battery (3.7 V, 2600 mAh, lithium ion battery) provided by the manufacturer. Please contact your distributor to purchase the batteries.

Replace the battery

Insert a small phillips screw driver to remove the screws from the back of the device and remove the battery cover.

1. Remove the battery from the connector by placing your finger on top of the white connector while taking your other hand and gently pressing your finger on the black and red wires together and pull away from the connector.
2. Connect new battery and wire to the device wire, making sure it is inserted like a puzzle piece, in the right direction. Place the battery back in the compartment so it is flush against the back of the device and the wires are tucked in without damaging them, so you are able to align the battery cover back on the back of the device.*
3. Place the battery cover back on the back of the device and place secure it tightly with the screw.

*If the battery cover doesn't sit flat against the back of the device so you are able to put the screw back in, you will need to adjust the wire or battery until it fits correctly, or the device may not function.

⚠ WARNING

- Please only use the battery supplied by the manufacturer by contacting the dealer who the device was purchased from.
- Stop using the battery immediately when there is there are abnormalities such as bulging, cracking of shell or if the battery shape changes.
- **ALWAYS** unplug the power adapter from the device before replacing the battery.

DISPOSAL

For environmental reasons, **DO NOT** dispose of the device in the household waste at the end of its useful life. Dispose of the device at a suitable local collection or recycling point. Dispose of the device in accordance with local state regulations. If you have any questions, please contact the local authorities responsible for waste disposal.

This symbol indicates that batteries contain substances that may be harmful to human health and the environment. **NEVER** dispose of batteries with normal household waste. Follow the local rules for separate collection of batteries. Correct disposal of batteries helps prevent potentially negative consequences for the environment and human health.

TROUBLESHOOTING

NOTE: If the following measures fail to alleviate the problem, please call Tech Support at 888-549-4945, Option 2

Problem	Possible Cause	Solution
No response after pressing and holding the ON/ OFF button.	The battery is depleted.	Charge the device (see section, "Preparing Before Therapy").
The power turns off while using the device.	The device automatically powers off if a button is not touched or in working mode, for more than 1 minute.	Press and hold the [] button for 2-3s to power on.
	The battery is depleted.	Charge the device (see section, "Preparing Before Therapy").
	The battery is worn out.	Replace with a new battery (see section, "Battery Replacement").
The device cannot be charged.	The adapter is not connected properly.	Check to ensure the adapter is properly connected to the device. Check if the adapter is connected to an electrical outlet.
Device has no output.	Did not press the start button;	Press the start button;
	Did not adjust the output voltage.	Adjust the output voltage.
	The treatment has been paused.	Press the [] button to continue treatment.
	The connection cables are not connected correctly;	Re-connect the connection cables;
	The connection cables have been damaged.	Replace the connection cables..
Treatment is uncomfortable	The output voltage is too high	Decrease the output intensity;

EMC GUIDANCE

The THERADOT™ needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. This device has been thoroughly tested and inspected to assure proper performance and operation.

- **DO NOT** use the THERADOT™ simultaneously with other therapeutic device (such as microwave), to avoid mis-operation.
- **DO NOT** place or use the THERADOT™ nearby radio, television, copy machine and fax machine.
- Keep the THERADOT™ away from active HF surgical equipment and the RF shielded room of a medical device for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of the THERADOT™ adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the THERADOT™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the THERADOT™ could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CABLE INFORMATION:

Item	Cable Length	Cable Shielded
Power cord (adapter)	0.8 m	unshielded
Connection cable	1.6 m	unshielded

Guidance and manufacturer's declaration - electromagnetic emissions		
The THERADOT™ is intended for use in the electromagnetic environment specified below. The customer of the user of the THERADOT™ should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The THERADOT™ use 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	Class A	The THERADOT™ is suitable for use in all establishments, other than those directly connected to public low voltage power supply network purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The THERADOT™ is intended for use in the electromagnetic environment specified below. The customer or the user of THERADOT™ should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
	±2,4,8,15 kV air	±2,4,8,15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Main power quality should be that of a commercial or hospital environment.
	±1 kV for input/ output lines		
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines	± 0.5kV, ± 1 kV line(s) to lines	
	± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle (0°,45°, 90°,135°,180°, 225°,270° and 315°) 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	0% U_T; 0.5 cycle (0°,45°, 90°,135°, 180°,225°, 270° and 315°) 0% U_T; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the THERADOT™ requires continued operation during power mains interruptions, it is recommended that the THERADOT™ be powered from an uninterruptible power supply or a battery.

Guidance and manufacturer's declaration - electromagnetic immunity (cont'd)			
The THERADOT™ is intended for use in the electromagnetic environment specified below. The customer or the user of THERADOT™ should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity (cont'd)			
The THERADOT™ is intended for use in the electromagnetic environment specified below. The customer or the user of THERADOT™ should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Conducted RF	3 Vrms 150 kHz - 80 MHz 6 V rms in ISM bands between 150 kHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 150 kHz - 80 MHz 6 V rms in ISM bands between 150 kHz and 80 MHz 80 % AM at 1 kHz	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	N/A
Proximity fields from RF wireless communica-tions equipment IEC 61000-4-3	See table: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment		N/A

Table: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band (MHz) [a)]**	**Service [a)]**	**Modulation [b)]**	Maximum power (W)	Distance (m)	Immunity TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse Modulation [b)]: 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM [c)] ± 5 Hz deviation 1 kHz sine	2	0.3	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse Modulation [b)]: 217 Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b)]: 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b)]: 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n , RFID 2450, LTE Band 7	Pulse Modulation [b)]: 217 Hz	2	0.3	28

Table: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	**Band (MHz) [a)]**	**Service [a)]**	**Modulation [b)]**	Maximum power (W)	Distance (m)	Immunity TEST LEVEL (V/m)
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation [b)]: 217 Hz	0.2	0.3	9

NOTE:
a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

ASSISTANCE

Any repairs must be performed by the manufacturer or by an authorized repair technician approved by the manufacturer. For assistance on ordering replacement parts or technical support, please contact:

Richmar, a division of Compass Health Brands
Ph: 888-549-4945
6753 Engle Road
Middleburg Heights, OH 44130
www.richmarweb.com

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