REBOUND"

THERAPEUTIC WARMING SYSTEM

SHORTWAVE DIATHERMY INSTRUCTIONS FOR USE



Model # RE-100

THE REBOUND SYSTEM SHOULD ONLY BE OPERATED BY TRAINED INDIVIDUALS AND IN ADHERENCE TO THESE INSTRUCTIONS FOR USE. THERE ARE CERTAIN CONTRAINDICATIONS TO THE USE OF THE REBOUND SYSTEM AND SITUATIONS IN WHICH IT MAY BE HAZARDOUS TO USE THE REBOUND SYSTEM. PLEASE STUDY THESE INSTRUCTIONS FOR USE CAREFULLY PRIOR TO OPERATION OF THE REBOUND SYSTEM.

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THERAPEUTIC WARMING SYSTEM

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THE REBOUND ADVANTAGE

THE REBOUND ADVANTAGE

ReGear Life Sciences, Inc. is proud to bring you ReBound[™], a revolutionary deep tissue Therapeutic Warming System which is used to promote pain relief, reduce joint stiffness, and facilitate the body's natural healing process.

Using technology originally developed by the U.S. Navy deep-sea divers and SEAL teams, the ReBound Therapeutic Warming System uses a compact, low-power, radio frequency (RF) ReGenerator, and a family of anatomically designed garments to deliver even and gentle therapeutic warming to injured tissues and facilitate the healing process.

USE STATEMENT

The ReBound System should only be operated by properly trained individuals and in strict adherence to these Instructions for Use. There are certain situations and contraindications to the use of the ReBound System that may result in injury or harm, creation of hazardous situations, or damage to nearby equipment upon failure to adhere to the Instructions for Use. Please familiarize yourself with the safe operation of this device and study these Instructions for Use carefully prior to operation of the ReBound System.

CONTACT US

For any questions, feedback, customer and technical support, or troubleshooting please contact ReBound Customer Support toll-free at 1-888-573-4327, or send an email to support@regearlife.com.

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INDICATIONS FOR USE

The ReBound System is to be used to generate deep heat within body tissues for the treatment of medical conditions such as muscle spasms and joint contractures, as well as for pain relief. The ReBound System is not considered a cure for any of the disease entities discussed; it is, rather, a valuable adjunct that is helpful in management of specific symptoms. Elevation of tissue temperature into the therapeutic range of 100° to 113° F (38° to 45° C) is considered necessary for therapy to be effective.

COMMON COMPLAINTS FOR WHICH HEAT THERAPY IS INDICATED

The ReBound System can be used when heat therapy is indicated for the treatment of a patient's condition. The following is a list of complaints for which heat is commonly recommended.

Muscle spasms, joint contractures, and pain associated with:

- Soft tissue injuries
- Carpal tunnel syndrome
- Non-acute tissue and joint inflammation
 - Tendinitis
 - Tenosynovitis
 - Bursitis
 - Capsulitis
- Osteoarthritis
- Joint rehabilitation
- Extreme muscle fatigue
- Shin splints (periostitis)
- Plantar fasciitis
- Achilles heel injuries
- Fibromyalgia

CONTRAINDICATIONS

The ReBound System is contraindicated for use in patients who have:

- Implanted stimulators such as deep brain stimulators, spinal cord stimulators, and cardiac
 pacemakers. Also, make certain the implanted leads are not still in place after the stimulator has
 been removed as this would represent a serious hazard.
- Impaired blood clotting
- Malignancies
- Acute inflammation
- Impaired sensation
- Impaired cognition
- Acute pelvic inflammatory disease
- Women who are pregnant

The ReBound System is contraindicated in an area over:

- Active inflammation or infection
- Developing fetus
- Developing gonads
- Metal implants

GENERAL WARNINGS AND PRECAUTIONS

CAUTION: Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

- Children under the age of 18 should not use the ReBound System over epiphyseal areas of developing bones because shortwave diathermy may affect bone growth.
- It is not recommended for a patient with poorly vascularized tissue(s) to receive a ReBound treatment.
- Patients with areas of thermal insensitivity should not receive a ReBound treatment over the affected area.
- Patients with acute joint effusion should not receive a ReBound treatment.
- Patients should not receive a ReBound treatment over the ocular and orbital regions (eye area).
- The patient should remove contact lenses if they are receiving a treatment near the eyes such as the shoulders or neck, as the lenses might interfere with evaporative cooling of the cornea.
- Patients with an intrauterine device should not receive a ReBound treatment over this area.
- Patients must remove hearing aid(s) before receiving treatment.

- The patient must remove ALL jewelry, watches or metallic items that are on or near the area to be treated.
- Multiple ReBound Systems should never be used simultaneously to treat areas within 12 inches of each other.
- A patient should receive no more than one therapy session every two hours. Exceeding the recommended time limits can result in tissue becoming overheated and damaged.
- Consistent and vigorous heating can result in edema of the skin, subcutaneous fat, and muscle tissue.
- If the patient notices any adverse effects from using the device, treatments should be discontinued until a physician or qualified individual has been consulted and the patient advised whether to continue treatments. Such adverse effects may include, but are not limited to: pain, edema or swelling of the skin at the site of warming, discoloration of skin, or skin irritation.
- Improper cleaning/disinfecting of the Therapy Garments can result in the spread of bacterial/viral infections, skin irritations and/or a rash for patients.
- Back Therapy Garment should not be used directly against patient's skin.
- The therapy administrator should not be within 10 inches of the treatment area for more than 6 minutes.
- All non-operators should not be within 2-3 feet of the treated area.
- Any persons with a pacemaker should not be within 2-3 feet of the treatment area.
- If therapy recipient feels the heat is too intense, see Page 11 for instructions on how to adjust therapy intensity.
- Do not operate the ReGenerator without a Therapy Garment attached.

GENERAL WARNINGS AND PRECAUTIONS

- Each component of the ReBound System should be inspected prior to use. Do not operate a ReBound System that appears to have damaged power or Therapy Garment cables, an open or cracked ReGenerator or Garment case, missing parts, frayed or damaged Garments, or visible coils or wires.
- To avoid the risk of electrical shock, do not attempt to open the case or disassemble any component of the ReBound System.
- The ReBound system has been designed with electrical safety in mind, consequently, the ReGenerator must be plugged into a grounded outlet.
- The ReBound system is an electrical device and as such should be kept dry and away from any contact with water. The ReGenerator complies with IPX-O water specifications; it is not a waterproof device. Do not apply a direct stream of water onto or submerge the ReGenerator under any circumstances.
- Never deliver a therapy session using a wet or saturated Therapy Garment or Comfort Sleeve, or over wet skin.
- Do not use any electrical adapters or garments other than those provided with the ReBound System. Use of unapproved components, adapters, garments, or accessories may result in electrical shock or equipment failure and will void the product warranty.
- To avoid the risk of electrical shock, always turn off the ReGenerator when not in use.
- Only Garments made by ReGear Life Sciences are warranted and safe to operate with the ReBound System. Aftermarket components may appear compatible with the ReBound System, however, these components CANNOT safely be used with this System.
- The Rebound System has been designed to minimize radiated or conducted high frequency energy, however, in certain circumstances, the device may interfere with or affect other nearby equipment.
- To avoid the risk of trip or fall, route or position all cables and wires out of walkways and areas were foot traffic may occur.
- The ReGenerator should only be operated on a stable surface.
- Keep the device out of the reach of children.
- Carry the ReGenerator using the carrying handle only.
- There are no user serviceable components of the ReBound System. In the event of a suspected failure or malfunction
 of the device or if your ReBound System requires maintenance, please contact ReBound Customer Support at
 1-888-573-4327, or send an email to support@regearlife.com.
- Shortwave diathermy applied to the lower back in women can result in increased menstrual flow during menses.
- Do not leave the ReGenerator in direct sunlight. Exposure to UV light may damage or discolor the ReGenerator.

DESCRIPTION OF DEVICE



ReBound Therapeutic Warming System:

The following items pictured above are needed to begin treatment with the ReBound System:

ReGenerator

- Power Cable
- Instructions for Use
- Therapy Garment(s)



	BUTTONS Page 7
ß	Main Power Toggle Switch: Press the toggle switch on the side of the ReGenerator to the "on" position to power on the ReGenerator (small line indicates the "on" position and circle indicates the "off" position).
9	Power: A single press of this button begins the startup, press again to standby. A power indicator light is located above the Power button. This light will illuminate amber once the main power to the ReGenerator is connected. Once the Power button is pressed, the power indicator light will illuminate green.
A	Volume: Press to cycle through three settings: "High", "Low" and "Mute". All last-used settings are stored in memory provided the main power toggle switch is not turned off or the ReGenerator is unplugged prior to use.
	Continue: This button is used to proceed to tuning after Therapy Garment is attached, to begin therapy after tuning is successful, acknowledge a completed or stopped therapy session, restart therapy after a pause, and acknowledge tuning timeout.
\odot	Therapy Duration: A single press of this button highlights and activates this field allowing the user to adjust therapy duration in one minute increments by turning the knob as shown below. A second press deactivates this field.
	Program: Press this button to cycle through "saved" settings: "1", "2", "3",and "4". The last-used program is the default program for the next use, provided that the main power toggle switch is not turned off or the ReGenerator is unplugged prior to use.
	Pause/Stop: During a therapy session a single press will pause the session and a double-press of the button during therapy ends the therapy session. During tuning, a single press of this button cancels the tuning process and returns the system to the "Ready" state.
	Therapy Intensity: One press of this button highlights and activates the therapy intensity field and permits the user to adjust therapy intensity by turning the knob as shown below. A second press deactivates this field. Total range: 25% - 100% . Adjustability: 5% increments.
	<i>Caution:</i> If during treatment the therapy recipient feels the heat is too intense, the therapy administrator should adjust therapy intensity. To adjust therapy intensity during treatment, see Page 11.
	Adjusting Therapy Duration and Intensity Settings



Knob: This knob is used to adjust therapy duration and intensity settings.



PRIOR TO USE, consult the Contraindications and General Warnings and Precautions sections of this manual to ensure that the therapy is appropriate for each individual.

🔨 Warnings:

- Your ReBound ReGenerator should be plugged into a grounded electrical outlet prior to operation.
- Failure to properly follow the instructions may result in inadequate therapy, harm to the user or damage to the ReGenerator.
- Each component of the ReBound System should be inspected prior to use. Do not operate a ReBound System that appears to
 have damaged power or Therapy Garment cables, an open or cracked ReGenerator or Garment case, missing parts, frayed or
 damaged Garments, or visible coils or wires.

Place the ReGenerator on a stable, non-metal surface in the upright position.

Caution:

The ReGenerator should only be operated in the upright position.

STEP 2:

STEP 1:

/!\

Connect the Power Cable to the ReGenerator and plug the other end into a grounded electrical outlet. The Main Power Toggle Switch, on the side of the ReGenerator, must be in the "on" position. The power indicator light above the "Power" button (located on the front panel of the ReGenerator) will illuminate amber. Once the "Power" button is pressed, the power indicator light will illuminate green, and the front panel display will flash the startup screen and go into "Ready" mode.









attach garment and press 🖒 to begin tuning



Warning:

A patient should receive no more than one therapy session every two hours.



To avoid the risk of trip or fall, route or position all cables and wires out of walkways and areas where foot traffic may occur.



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STEP 3: Connect the Therapy Garment to the ReGenerator by firmly pushing the connector on the Garment Cable into the Garment Cable connector on the ReGenerator and turn clockwise until locked (approximately ¹/₄ turn).



STEP 4: Select the appropriate Therapy Garment. For cylindrical garments, slide the garment onto the patient with the large opening first. Ideally, there should be a spacing of between 1/8 to 1/4 inch (0.3175 to 0.635 centimeters) between the skin and the Therapy Garment for optimum delivery of therapeutic effect.







Marnings:

- Back Therapy Garment should not be used directly against patient's skin.
- The patient must remove ALL jewelry, watches or metallic items that are on or near the area to be treated.
- Patients must remove hearing aid(s) before receiving treatment.
- The patient should remove contact lenses if they are receiving a treatment near the eyes such as the shoulders or neck.
- Patients should not receive a ReBound treatment over the ocular and orbital regions (eye area).

STEP 5: Pre-set therapy programs

The ReGenerator is shipped from the factory with four default, user reprogrammable therapy settings.

- Program 1: 100% intensity and a time of 20 minutes.
- **Program 2:** 75% intensity and a time of 15 minutes.
- Program 3: 50% intensity and a time of 10 minutes.

Program 4: 25% intensity and a time of 5 minutes.



The ReGenerator will default to Program 1 each time the Main Power Toggle Switch is turned off or if the ReGenerator has been unplugged.

To select a different Program, simply press the "Program" button to cycle through the pre-programmed settings. The ReGenerator display will show "1", "2", "3" or "4" and the accompanying values in the top right of the display screen. When the desired program is shown in the upper right hand corner of the display screen, follow the directions below.



Warning: A patient should receive no more than one therapy session every two hours.

To begin treatment

Press the "Continue" button. The Therapy Garment must be "In Tune" to begin Therapy. If the Therapy Garment is not "In Tune" the display will show "Adjust Tuning". To begin tuning, slowly turn the Garment Knob (found on the Therapy Garment) clockwise until it has gone as far as possible then turn in the opposite direction. Continue turning the Garment Knob until the indicator on the tuning bar is as far right as possible and the display screen reads "In Tune", indicating that the Therapy Garment is ready. Once "In Tune" press the "Continue" button to begin therapy. The Auto-Start timer will count down as therapy is administered, and the display will show "Therapy On".

Note: Movement of the appendage during a therapeutic session should be minimized.



STEP 6:

Once the therapy treatment is complete, the front panel display reads "Therapy Done. Press ¹ to acknowledge." After pressing the 6 to acknowledge."

ADDITIONAL **To use customized settings**:

OPTIONS

I o use customized settings:

If you wish to provide therapy using time and/or intensity settings other than the preset programs, it must be adjusted manually. Once you have changed a setting, you may save it by following the instructions below.

To adjust therapy duration:

Press the "Therapy Duration" button to activate the therapy duration field. Turn the knob clockwise to increase therapy duration and counterclockwise to decrease therapy duration by one-minute increments.

To adjust therapy intensity:

Press the "Therapy Intensity" button to activate the therapy intensity field. Turn the knob clockwise to increase therapy intensity and counterclockwise to decrease therapy intensity by 5% increments (25% to 100%). Once the desired duration and intensity is set, refer to Step 5 for step by step instructions to begin the therapy session.

To save a custom program setting:

Press the Program button until the program setting to be modified is in the upper right corner. Set the desired intensity and duration for the new program. Once the settings are correct, press and hold the Program button until the screen flashes, indicating the new program has been saved. Saving a custom program setting will override the factory default setting of the selected program.

Options once treatment is in progress:

To pause therapy once treatment is in progress:

Press the "Pause/Stop" button once. The display will show "Therapy Paused. Press Continue to Restart Therapy". At this time you may adjust therapy duration or therapy intensity. When you wish to continue therapy, press the "Continue" button. If the Therapy Garment has remained in tune, therapy will continue automatically. If the Therapy Garment is not in tune, you will be prompted by the display to "Adjust Tuning". See steps below to readjust tuning.

To stop therapy once treatment is in progress:

Press the "Pause/Stop" button twice. The display will show "Therapy Stopped. Press Continue to Acknowledge". Once the "Continue" button has been pressed, the current therapy session will be cancelled and the ReGenerator will return to the "Ready" state.

To adjust tuning once treatment has begun:

If Therapy Garment goes out of tune while treatment is in progress, the ReGenerator will beep and display "Adjust Tuning" to alert you that your Therapy Garment is out of tune. It is possible that the person receiving therapy simply needs to readjust their body position. If adjusting body position is all that is needed, the display screen will automatically indicate that the Garment is back in tune by beeping and displaying "Therapy On". No further action is required to continue treatment. The treatment timer will continue to count down.

If tuning is not successful by adjusting body position, slowly turn the Garment Knob until the ReGenerator beeps to indicate that the Garment is in tune and the screen displays "Therapy On". No further action is required to continue treatment. The treatment timer will continue to count down.



CLEANING AND DISINFECTING

CLEANING

Therapy Garment:

Therapy Garment(s) should be cleaned between uses and when they become noticeably dirty. To clean, wipe surface with a damp cloth and an anti-microbial mild detergent or antimicrobial wipes. Remove any residue of cleaning solution by a second wiping of the surface with a clean damp cloth. For best results, allow the Therapy Garment to air dry. DO NOT BLEACH, DO NOT APPLY A DIRECT STREAM OF WATER OR SUBMERGE THE THERAPY GARMENTS.

DISINFECTING

To disinfect the Therapy Garment, use a hospital grade disinfectant. Follow directions as indicated. For a detailed list of acceptable disinfectants, refer to the Environmental Protection Agency's website at www.epa.gov.

Warning: Improper cleaning/disinfecting of the Therapy Garment can result in the spread of bacterial/viral infections, skin irritations and/or a rash for patients.

ReGenerator and Therapy Garment Cables:

Clean as needed with soapy water or mild detergent applied by a dampened cloth.

DO <u>NOT</u> USE ANY OF THE FOLLOWING ITEMS TO CLEAN THE REGENERATOR OR THE THERAPY GARMENT CABLE. Doing so will damage the plastics and will void your warranty.

- Phenolic-based disinfectants (such as Amphyl)
- Quaternary Ammonium (such as Virex)
- Bleach solution
- Hydrogen peroxide
- Isopropyl alcohol
- Solvent-based cleaners
- Abrasive materials

Warning: The ReGenerator complies with IPX-O water specifications. It is not a waterproof device and should be kept dry and away from any contact with water. Do not apply a direct stream of water onto or submerge the ReGenerator under any circumstances.

MAINTENANCE

There are no user serviceable components of the ReBound system. In the event of a suspected failure or malfunction of the device, or if your ReBound system requires maintenance, please contact ReBound Customer Support at 1-888-573-4327, or send an email to support@regearlife.com.

STORAGE & OPERATING CONDITIONS

Temperature ranges: Operating: 32° to 122° F (0° to 50° C) Storage: -4° to 140° F (-20° to 60° C) Transportation: -4° to 140° F (-20° to 60° C)

Caution: Do not leave the ReGenerator in direct sunlight. Exposure to UV light may damage or discolor the ReGenerator.

SPECIFICATIONS (ReGenerator)

Size: 8.5" x 9.75" x 5" (215.9 mm x 447.62 mm x 127 mm)

Weight: Approximately 4 lb. (1.8 kg)

ACCESSORIES

The ReBound ReGenerator can be used with any of the following accessories:

- Any ReBound Therapy Garment
- A ReBound Power Cable

Caution: Only Garments made by ReGear Life Sciences are warranted and safe to operate with the

ReBound System. Aftermarket components may appear to be compatible with the ReBound System, however, these components CANNOT safely be used with this System.

TECHNICAL SPECIFICATIONS

	Potential Electric Shock Hazard Present
×	Type B Applied Part
	Caution Warning Consult Instructions for Use
((ı))	Interference may occur in the vicinity of equipment marked with this symbol.

Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

120V AC, 47 – 63 Hz, 1.5 amps

WARRANTY

ReGear Life Sciences Inc. ("ReGear") warrants that the ReBound ReGenerator and Therapy Garments, if properly used, will be free from defects in materials and workmanship for a period of one (1) year after the date the ReBound ReGenerator or applicable Therapy Garment(s) was shipped. If the ReBound ReGenerator or Therapy Garments, which are the subject of this Limited Warranty, fail during the warranty period for reasons covered by this Limited Warranty, ReGear, at its option, will:

- REPAIR the ReBound ReGenerator and/or Therapy Garment, OR
- REPLACE the ReBound ReGenerator and/or Therapy Garment with another ReBound ReGenerator and/or Therapy Garment, OR
- REFUND the original purchase price of the ReBound ReGenerator and/or Therapy Garment.

Extent of Limited Warranty: This limited warranty is subject to compliance with the Instructions for Use and does not apply to defects or damages due to external factors, including, without limitation, accident, usage not in accordance with the Instructions for Use, negligence, neglect, misuse or unreasonable use, modification, tampering, normal wear and tear,

improper or incorrectly performed maintenance, or any other causes not related to defective materials or workmanship. This limited warranty excludes Comfort Sleeves, carry bags, power cables and other consumable items.

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OF SUCH DAMAGES. SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS OR EXCLUSIONS MAY NOT APPLY TO YOU. THIS LIMITED WARRANTY GIVES YOU SPECIFIC RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS THAT VARY FROM JURISDICTION TO JURISDICTION.

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WARRANTY

How to obtain Warranty Service: To obtain warranty service, call toll-free 1-888-573-4327, or email support@regearlife.com. If you qualify for warranty service, you will be issued a Returned Material Authorization (RMA) number. No returns will be accepted without authorization by customer support. If you return the ReBound System, you must assume the risk of damage or loss during shipping. You must use the original packaging or equivalently secure packaging. You may be required to verify in writing that you are the original purchaser of the ReBound ReGenerator or Therapy Garment. ReGear may elect to replace or repair the ReBound ReGenerator or Therapy Garment with either a new or reconditioned product. The returned product shall become the property of ReGear upon receipt. The replacement ReBound ReGenerator or Therapy Garment is warranted under the limited warranty and is subject to the same limitations and exclusions for the remainder of the original warranty period. THIS WARRANTY IS NOT TRANSFERABLE.

ReGear Life Sciences, Inc. www.regearlife.com 1-888-573-4327

ReBound is manufactured for ReGear Life Sciences Inc. by Millennia Technologies, Inc.



THERAPEUTIC WARMING SYSTEM







