TheraTouch® SW1 Shockwave

SW1000

INSTRUCTION MANUAL

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This manual is valid for the TheraTouch SW1.
This user manual is published by Compass Health Brands Corp.

This manual provided comprehensive information onf the deivce's performance indicators, usage guidelines and maintenance procedures. This is an essential document that should be kept in a convenient place for future reference. Before installing and using this device, the user must read this manual to ensure proper usage, achieve optimal performance and comply with prescribed safety standards.

Compass Health Brands Corp. reserves the right to improve and amend this manual at any time without prior notice. Amendments may be published in new editions of this manual.

SW1000_UM_A_250423

Caution: Federal law restricts this device to sale by or on order of a practitioner licensed by the law of the state in which they practice to order the use of the device.

FCC SUPPLIER'S DECLARATION OF CONFORMITY

Product Name: TheraTouch SW1
Item Number: SW1000
Responsible Party:
Compass Health Brands Corp.
6753 Engle Road,
Middleburg Heights, OH 44130
Phone: 1.888.549.4945

FCC COMPLIANCE STATEMENT

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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SYMBOLS

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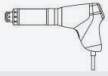
GLOSSARY OF SYMBOLS

	Wired Handpiece
	Stand-by
	Power OFF/ON
	Type BF applied part
	Refer to instruction manual
	Operating instructions
	Keep dry
	Stacking limit by number
	Transportation and storage temperature limitation
	Transportation and storage humidity limitation
	Transportation and storage atmospheric pressure limitation
	Recyclable symbol
	Date of manufacture

GLOSSARY OF SYMBOLS

SN	Serial number
LOT	Batch code
MD	Medical device
UDI	Unique device identifier
	Electrical devices are recyclable material and should not be disposed of with household waste after their useful life. Help us protect the environment and save resources and by taking this device to the appropriate collection point. Please contact the organization which is responsible for waste disposal in your area if you have any questions.
	Caution
	Warning
	Danger
REF	Catalogue number or Reorder number or Part number
	Fragile, handle with care
	This way up
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.
	The device is MR Unsafe.
FC	This device complies with part 15 of the FCC Rules.

SAFETY INFORMATION

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SAFETY AND INDICATIONS

INTENDED USE

The device is intended for relief of minor muscle aches and pains, temporary increase in local blood circulation, and activation of connective tissue.

CONTRAINDICATIONS

The device should not be used:

- When vascular diseases are present in or near the treatment area.
- If local infections are present in the treatment area.
- Around malignant or benign tumors.
- Directly on cartilage surfaces or near the small facet joints of the spinal column.
- Directly over implanted electronic devices such as pacemakers, analgesic pumps, etc.
- In areas, in which mechanical energy in the form of vibrations may lead to tissue damage such as metal implants after a fracture.
- If open wounds are present in or near the treatment area.
- After fractures, torn muscle fibers or muscle tears.
- If blood clotting disorders (including local thrombosis) are present or the patient is receiving treatment that results in a change in the blood clotting behavior. Patients who are concurrently receiving treatment involving a reduction and/or modification of blood clotting or prolongation of the blood clotting time (e.g. with acetylsalicylic acid) should consult their therapist about possibly stopping this treatment as these patients may be more prone to greater hemorrhaging and bruising when radial pressure wave are applied.
- With severe autonomic disorders.
- Treatment of patients treated with cortisone (within the 6-week period following the last local cortisone injection).
- During pregnancy.
- **DO NOT** apply pulses to any regions near large nerves, vessels, the spinal column or head.
- On patients with neurological diseases resulting in impairment of the vasomotor function in the treatment area.
- Radial pressure wave are strongly scattered in air pockets and create reflections that may have negative effects. You **MUST** therefore **NEVER** perform any direct treatments over the lungs (intercostal spaces) or the gastrointestinal area, and also over air-filled cavities such as treatment on the thoracic spine, etc.
- On the pediatric population.
- **NEVER** use this device on patients with impaired sensibility, the unconscious, or anyone who cannot give verbal consent or warnings about pain.

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SAFETY INFORMATION

RISKS AND SIDE EFFECTS

Side effects could occur after a treatment with Radial Pressure Wave therapy. The majority will appear after 1-2 days. **DO NOT** repeat a treatment until the previous side effects have diminished.

Common side effects include:

- Erythema, reddening and discomfort
- Swelling
- Pain
- Hematoma
- Petechiae, red spots
- Irritation

Skin lesions after previous cortisone therapy.

These side effects generally abate after 5 to 10 days.

Residual Risk

The noise levels for the radial pressure wave pulse are within safe levels. However, users and patients may be uncomfortable with the noise after a period of treatment.

INTENDED USER PROFILE

The radial pressure wave device is intended exclusively for use by licensed or qualified medical specialists and is only allowed to be used by qualified and trained medical persons. Operators of the radial pressure wave device must have been adequately trained in using this device safely and efficiently before they operate the device described. An introduction to the principles of operation is provided by Compass Health Brands Corp. with reference to the user manual. The operator **MUST** read this manual before operating the device to understand its use, principle, contraindications and side effects, etc.

INTENDED ENVIRONMENT FOR USE

The device is designed for operation in a clinical setting and can be moved between rooms.

It is **NOT** intended for frequent transport between different facilities and is **NOT** suitable for home use.

SAFETY INFORMATION

PRECAUTIONARY INSTRUCTIONS

In this section, general Precautions and Warnings are listed, that you should be aware of when using the device.

The definition of these symbols including danger, warning, caution and note are as follows:

⚠ DANGER
Refers to a situation of acute danger which, if not avoided, could lead to serious or fatal injury.

⚠ WARNING
Refers to a situation of potential danger which, if not avoided, could lead to serious injury.

⚠ CAUTION
Indicates that incorrect operation could lead to minor injuries.

NOTE
Refers to the additional information concerning specific features or operating instructions.

⚠ WARNINGS

- This device should **ONLY** be used by licensed or qualified medical specialists.
- This device is designed to **ONLY** be used by trained medical professionals who use the medical device in the course of their work and in the framework of a professional healthcare activity, and understand the benefits and limitations of radial pressure wave therapy. For example, physical therapists, occupational therapists, sport medicine therapists, medical doctors and so on.
- This device should **ONLY** be used under the continued supervision of a physician or licensed practitioner.
- Users of this device **MUST** be trained in how to use the system properly and have the appropriate skills.
- Any treatment instructions regarding treatment location, duration and strength require medical knowledge and should **ONLY** be given by authorized doctors, therapists and health paraprofessionals. It is imperative that these instructions are followed.
- Treatment **MUST ALWAYS** be carried out under medical supervision.
- The device is **NOT** designed for persistent use. After a treatment with maximum 6000 shocks, a break of 15 minutes becomes necessary.
- The device is **NOT** designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction of internal components of the system and therefore create a risk of injury to the patient.
- To prevent the risk of electric shock, ensure that the device is electrically grounded by connecting it to a grounded electrical service receptacle in accordance with the applicable national and local electrical codes.
- Operation of this equipment in the vicinity of strong electromagnetic

fields (e.g. tomography, x-ray or diathermy equipment) may interfere with the operation of the device. Please keep a safe distance of several meters (12 feet).
- Modification of this equipment is strictly prohibited. **DO NOT** make any changes to this equipment without authorization from the manufacturer.
- Exercise caution when operating this equipment around other devices. Potential electromagnetic or other interference could occur with this equipment or other devices. Minimize this interference by avoiding the simultaneous use of other equipment.
- The instruments **MUST ONLY** be operated with the mains power cable provided. Protect the mains cable from any mechanical stress.
- This equipment is **NOT** suitable for use in the presence of flammable anesthetics mixed with air, oxygen, or nitrous oxide. There is a risk of an explosion.
- It **MUST NOT** be used in wet areas. If it is used in wet areas, significant damage may occur, and patients and users may be endangered.
- **DO NOT** attempt to service or maintain the device while it is in use.
- Please remove the battery if the device is not likely to be used for some time.

⚠ CAUTION

Please read, understand, and follow the precautionary and operating instructions carefully. Familiarize yourself with the limitations and potential hazards associated with using any radial pressure wave device. Pay attention to the precautionary and operational labels placed on the device.
- Operate this device within the temperature range of 5°C to 30°C (41°F to 86°F) and maintain a Relative Humidity between 20% and 80%.
- Transport and store this device at -10°C to 50°C (14°F to 122°F) and between 10% and 93% Relative Humidity.
- Ambient pressure: 700 hPa to 1060 hPa
- Avoid exposing the device to direct sunlight, heat from radiators, excessive dust, moisture, vibrations, and mechanical shocks.
- If any liquid enters the device, disconnect it from the mains supply immediately and have it checked by authorized service provider.
- Before administering any treatment to a patient, thoroughly understand the operating procedures for each treatment mode, as well as the indications, contraindications, warnings, and precautions. Seek additional information from reliable sources on the application of radial pressure wave therapy.
- If you encounter any issues with this device, such as setup, maintenance, or operation, please contact the manufacturer or dealer for assistance. Additionally, please report any unexpected operation or events to your manufacturer or dealer.
- Treatment with device may occasionally cause irritation, petechiae, bruising, swelling, pain,

SAFETY INFORMATION

⚠ CAUTION (CONT'D)

discomfort and redness on the treatment area.
- Clinicians should assess patients for adverse reactions on the skin where the device has contact, such as redness (erythema), swelling (edema), irritation, sensitization (delayed Type IV hypersensitivity), allergy, immune response, or other reactions.
- You may feel upset by projectile noise after using the applicator for a long time.

NOTE: The SW1000 may **ONLY** be used with the intended components and accessories, i.e. the wired handpiece and battery pack.

PRODUCT DESCRIPTION

INTRODUCTION

The TheraTouch SW1 is a non-invasive, radial pressure shockwave device that uses pressure waves to treat various conditions in the body. Acoustic waves (radial pressure waves) deliver a mechanical force to the body's tissue that carries high energy to painful spots and musculoskeletal tissues.

The device adjusts the intensity and frequency of the pressure pulse output by controlling the coil in the handpiece connected to the main unit and driving the projectile to the applicator. The operator can control the output of the handpiece through the trigger button. The radial pressure wave created by the impact transmits through the skin that is in contact with the applicator.

What Does the Device Do?

The TheraTouch SW1 creates radial pressure waves using an ergonomic handpiece and transmits the radial pressure wave via a special applicator. The device has a maximum penetration depth of about 35mm into the tissue.

THE PRINCIPLE OF THE DEVICE

The TheraTouch SW1 uses the coil in the handpiece to generate a pulsed electromagnetic field. Under the action of the electromagnetic field, the projectile in the coil impacts the applicator in a pulsed impact mode and converts the pulsed sound wave into a radial pressure wave. This action can have positive effects in adjuvant treatment and pain relief for skeletal muscle disease and pain. Medical devices operating on the basis of the above principles are generally referred to as radial shockwave systems in modern medical literature.

Essential Performance

The device has neither life sustaining functions nor diagnostic of life supporting functions.
The following functions are observed:
- No interruption of radial pressure wave output
- No changes of mode
- No changes in set-values

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PACKAGE CONTENTS

THERATOUCH SW1 PACKAGE CONTENTS

Description	SKU#	QTY
TheraTouch SW1	SW1000	1
SW1 Handpiece	SW1000-HP	1
SW1 Handpiece Stand	SW1000-HPS	1
SR 15mm Applicator	SR15-APP	1
CR 15mm Applicator	CR15-APP	1
CR 20mm Applicator	CR20-APP	1
Applicator Removal Tool	SWAPP-RT	1
Shockwave O-Ring, 9.5mm	SWORING95	10
Shockwave O-Ring 15mm	SWORING15	10
Shockwave O-Ring 20mm	SWORING20	10
Shockwave O-Ring 35mm	SWORING35	10
Power Cord	DQ8000X	1
Battery Module	SW1BATT	1
USB User Manual	N/A	1
Optional Accessories		
SR 20mm Applicator	SR20-APP	
SR 35mm Applicator	SR35-APP	
CR 35mm Applicator	CR35-APP	

ABOUT DEVICE

OPERATOR CONTROLS AND ACCESSORIES

OPERATOR INTERFACE

Main Device

No.	Description	No.	Description
1	LCD Touchable Display	7	Handle
2	Screen Power Button	8	Connector for Power Cable
3	Manual Mode Shortcut Button	9	Power Switch
4	Settings Shortcut Button	10	Connector for Wired Handpiece
5	Favorites Shortcut Button	11	Connector For USB
6	Adjustment Knob	12	Battery Pack

Wired Handpiece

No.	Description	No.	Description
1	Applicator	3	Handpiece Plug
2	Trigger Button	4	Wired Handpiece Holder

The handpiece contains the radial pressure wave generator, a fan to dissipate heat and the slot for the different applicator. It is connected to the control main device.

⚠ CAUTION

- When using the handpiece on a patient, it is crucial to securely screw one of the applicators onto the handpiece, ensuring it is tightened as much as possible.
- The cable should **NOT** be stretched beyond its maximum length and **MUST** be protected from any pinching or mechanical damage during usage.
- To prevent the accumulation of heat in the handpiece, it is essential to avoid obstructing the air vents located at the top and base of the handpiece with the hand or any other object. This will allow proper ventilation and maintain optimal performance.

ABOUT DEVICE

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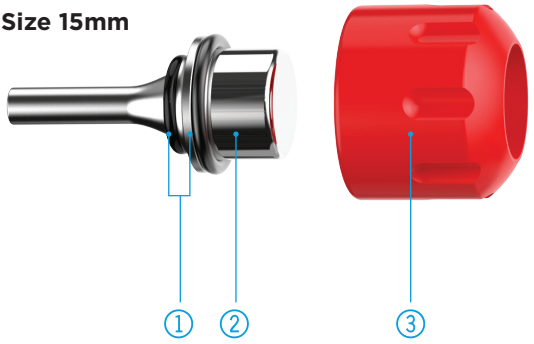
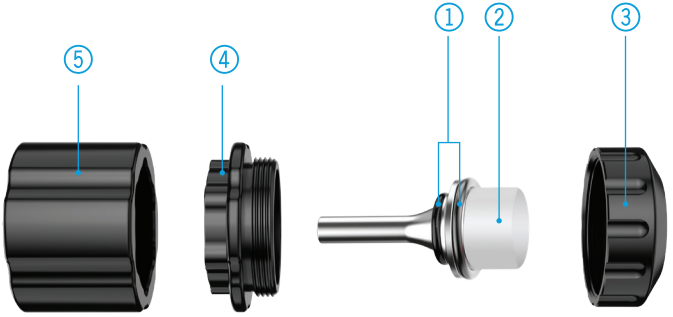
Applicator

Size 15mm



No.	Description
1	O-Ring
2	Applicator Insert
3	Applicator Screw Cap
4	Applicator Inner Screw Cap
5	Applicator Removal Tool

Sizes 20 mm and 35mm



NOTE:
Pictures of wired handpiece and applicator are examples. Individual components may be different from those shown in the illustration. Depending on the therapy to be performed, the handpiece can be equipped with different applicators. Please contact Compass Health Brands Corp. for specific applicator specifications.

The difference between treatment heads is as follows:

- SR Series: Steel Round applicator, the contact part of the applicator is composed of steel and the contact surface is rounded. The SR series is available in 3 sizes (15mm, 20mm and 35mm).
- CR Series: Compound Round applicator, the contact part of the applicator is composed of steel and silica gel composite materials and the contact surface is rounded. The CR series is available in 3 sizes (15mm, 20mm and 35mm).
- The applicator is used to transmit the radial pressure wave.

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ABOUT DEVICE

SR 15

SR 20

SR 35

CR 15

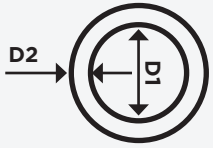
CR 20

CR 35

NOTE:
Each applicator has its corresponding model identification engraved on the impact rod.

O-Ring
The O-ring is used to cushion the applicator while the handpiece is working. Each applicator is equipped with two O-rings, as shown in the diagram below. The O-ring type configured for each applicator is different.

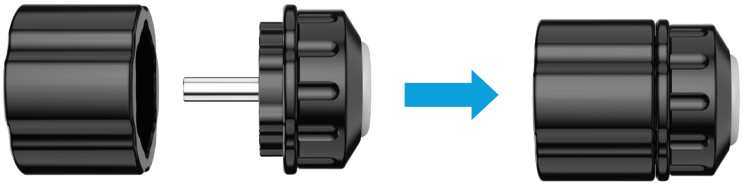
Ref.	Part Number	O-Ring Dimensions	Measurements	Used For
1	SWORING95	D1=9.5mm D2=2.0mm		Applicator SR15/20/35 Applicator CR15/20/35
2	SWORING15	D1=15mm D2=2.0mm		Applicator SR15 Applicator CR15
3	SWORING20	D1=20mm D2=2.0mm		Applicator SR20 Applicator CR20
4	SWORING35	D1=35mm D2=2.0mm		Applicator SR35 Applicator CR35



ABOUT DEVICE

Applicator Removal Tool

The applicator removal tool is used to remove and install the 20/35 mm applicator.



⚠ CAUTION

Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore **NOT** permitted.

DEVICE LIGHT INDICATORS

Control Knob

The control knob will light up when the user can adjust the selected parameters.

INSTALLATION INSTRUCTIONS

TRANSPORT AND STORAGE CONDITIONS

Ambient temperature: -10°C to 50°C (14°F to 122°F)
Relative humidity: 10% to 93%
Ambient pressure: 700 hPa to 1060 hPa

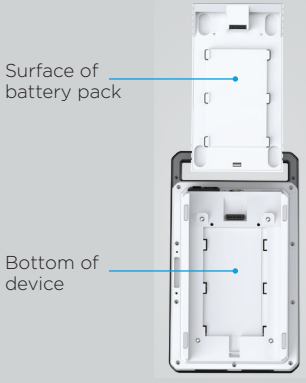
Set-up

NOTE:

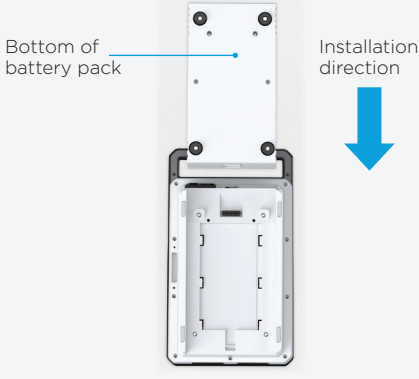
- Please perform the following steps to install the device.
- Before starting up the system, remove the device from its transport case. **DO NOT** operate the device while it is in the packaging.
- Ensure that the device is placed on a stable surface.
- Make sure that the Power Switch on the device is set to 'O'.

Installation of Battery

1. Take out the main device and battery pack from the device carrying case.



2. Insert the surface of battery pack on to the bottom of the device, make sure the bottom of battery is on the outside.



ABOUT DEVICE

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Installation of Battery (cont'd)

3. Push the battery pack into the device until it clicks, locking the battery in place.

Power Up

1. Insert the power cord into the back of the device, and plug it into the power outlet

2. Turn on the device using the power switch located at the back.

Power Off
To completely power off the device, turn off the main device power switch and disconnect the power cable from the socket.

NOTE:
Ensure that the power switch remains accessible at all times, as it can function as an emergency switch.

Functional Check

Perform the following functional checks after the system has been installed:

- Check if there is any damage to the appearance of the main device and handpiece before use.
- Switch on the device.
- Set the energy level to 60mJ and frequency 5 Hz.
- Reset the actual number of shocks on the operating LCD touchable display.
- Press the handpiece trigger button and release shocks in continuous shock mode.
- Check that the triggered shocks are correctly counted on the treatment shock counter.

CONNECTION OF ACCESSORIES

Connecting the Handpiece

- Plug the wired handpiece into the connector on the back of the device.

- Make sure that the red dot on the handpiece plug is aligned with the red dot on the connector of device.

ABOUT DEVICE

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REPLACEMENT OF ACCESSORIES

Replacement of Applicator

To replace the different applicators, please follow these steps:

1. Disconnect the handpiece from the main device, and then hold the handpiece in one hand.
2. With the other hand, unscrew the current applicator from the handpiece in a counterclockwise direction.

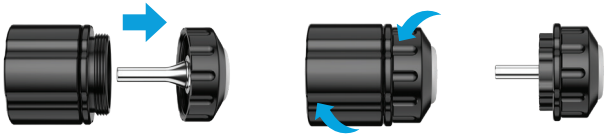
3. Take the desired applicator and securely screw it onto the hand piece in a clockwise direction.

4. Continue tightening until the black outside ring of the applicator rests flush against the handpiece, tighten clockwise until it cannot be tightened anymore. Pay attention **NOT** to use excessive force.
5. Ensure that the applicator is firmly attached to the handpiece to prevent any potential issues during treatment.

NOTE:

There are three different sized applicators. Removing and installing the 15mm applicator is different than removing and installing the 20mm and 35mm applicator.

Before installing the 20mm or 35mm applicator, use the applicator removal tool and screw the applicator inner cap into the applicator head. Rotate the applicator removal tool clockwise to tighten. Remove applicator removal tool once tight.



⚠ **CAUTION**

- Please note that applicators are consumable parts and should be replaced after 1,000,000 shocks to maintain optimal performance.
- Minor or slight deformation or shortening of the rear impact dome will not impact the functionality of the applicator.
- However, if you notice significant deformation or substantial shortening of the rear impact dome, it is essential to replace the applicator promptly to ensure safe and effective treatments.
- If the applicator has worked more than 300,000 times, it is recommended to check at least once a week.

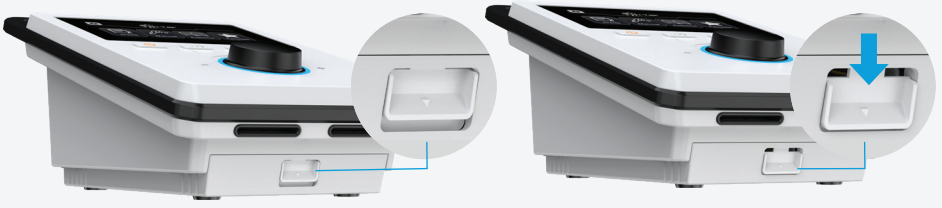
Replacing Battery Pack

The battery pack is powered by a rechargeable battery. To ensure the device always functions optimally, it is necessary to replace the battery when its lifespan ends or when the battery's performance begins to decline. Typically after approximately 200 discharge cycles, the battery's capacity and discharge capabilities start to decrease. In this case, it is recommended to buy a new battery module.

During usage, the battery undergoes charge and discharge cycles. One complete cycle is achieved when the battery accumulates a discharge equal to 100% of its capacity. To prolong the battery lifespan, try to avoid completely depleting or fully changing the battery the battery to 100%. If the device remains unused for an extended period, it is recommended to keep the battery charge level at around 60% and recharge it at least every three months.

Steps for Battery Pack Replacement

1. Ensure the device is turned off.
2. Push the battery lock down and slide the battery out towards the back of the device.



3. Follow the Installation Instructions section to install the new battery pack.

NOTE:

Disposal of the battery pack and its components **MUST** be carried out in accordance with national waste disposal regulations.

OPERATION

OPERATION

USER INTERFACE

No.	Description	No.	Description
1	**LCD Touch Screen Display**	4	**Settings Shortcut Button:** Press to enter settings interface
2	**Screen Power Button:** When the device is working, press this button to stop treatment	5	**Favorites Shortcut Button:** Press to enter favorites interface
3	**Manual Mode Shortcut Button:** Press to enter manual treatment interface	6	**Control Knob**

Power On

Power Outlet: Insert the power cable into the power socket of the device, then connect the other end to the power outlet. Turn on the power switch and the device will power on with the screen lighting up and a startup sound.

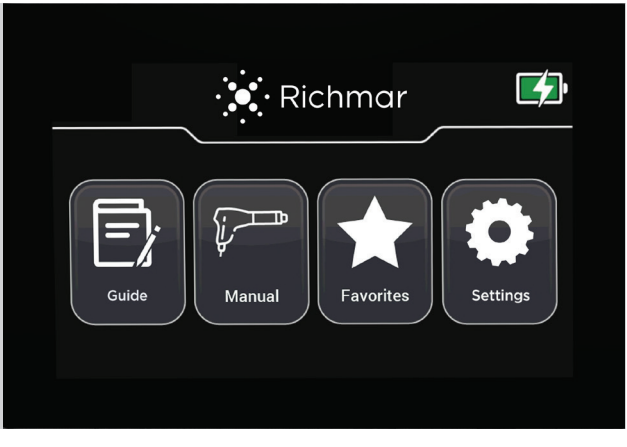
Battery Power Supply: Connect the battery and the device will be in sleep mode. Press the power button to power on the device. If the battery is connected and remains idle and unused it will automatically power off after three minutes.

The Initialization screen below will be shown for a few seconds while the device starts.

Power Off
Power Outlet: Turn off the power switch and the device will power off, then unplug the power cord.

Battery Power Supply: Press the power button to power off the device. If the device remains idle and unused, it will automatically power off after three minutes. If the battery is running low, the device will automatically power off after 30 seconds of inactivity.

Home Screen
Home screen provides access to all of the system modalities and functions. The home screen has the following information.



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Battery Level Icon

When the device detects that battery pack is installed, the battery icon and battery level are displayed in the upper right corner of the screen.

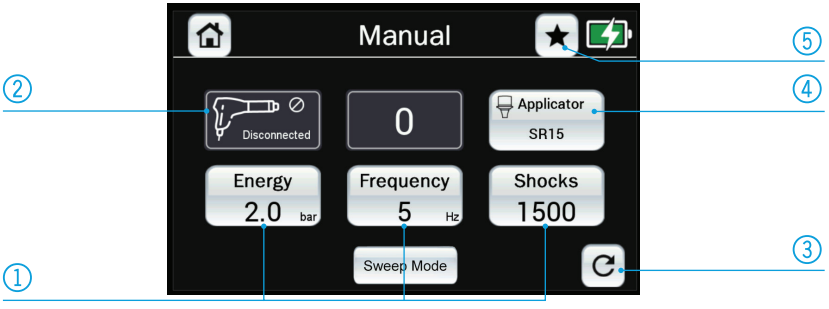
	Indicates that the battery power is full
	Indicates that the battery power is too low
	Indicates that the battery is charging
	Indicates that the battery is fully charged

Treatment Screen
Quick Therapy Guide

By selecting Guide, the screen will change to the pre-programmed protocol therapy treatment screen, including the following information:

1	**Parameters:** Touch to activate each parameter. Once the selected parameter is highlighted, it can be adjusted using the knob.
2	**Pre-programmed Body Part Protocols:** Touch to activate a body part protocol. Once it is highlighted, the program is selected. **Manual Therapy:** Manual therapy can be selected from this screen as well.
3	**Handpiece:** Disconnected: handpiece not connected Ready: handpiece connected Working: handpiece is working
4	**Reset:** Resets the number of shocks to zero.

Manual Therapy Treatment Screen

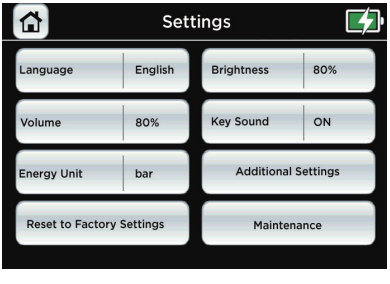


1	**Parameters:** Touch to activate the light gray boxes. Once it is highlighted, it can be adjusted with the knob.
2	**Handpiece:** Disconnected: handpiece not connected Ready: handpiece connected Working: handpiece is working
3	**Reset:** Resets the number of shocks to zero.
4	**Favorites:** Touch to save custom protocol to favorites.
5	**Applicator:** Touch to select the applicator in use.

SYSTEM SETTING

Press  to adjust preferences

Setting Interface



OPERATION

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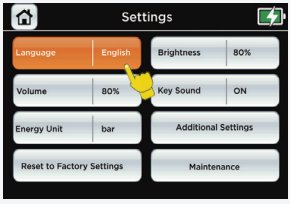
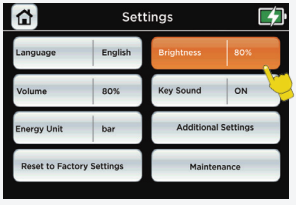
Language

- The device supports multiple languages. Touch the Language Button and then touch to select your chosen language.



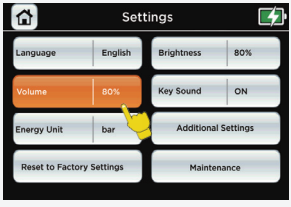
Brightness

- Click the 'Brightness Button' and rotate the knob to adjust the backlight brightness of the main device screen. The range is 20% to 100%, with 10% increments.



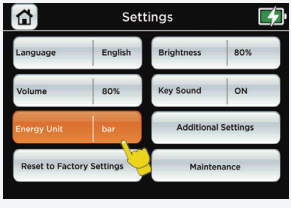
Volume

- Click the 'Volume Button' and rotate the knob to adjust the volume of the main device notification sounds. The range is 0% to 100%, with 10% increments.



Energy Unit

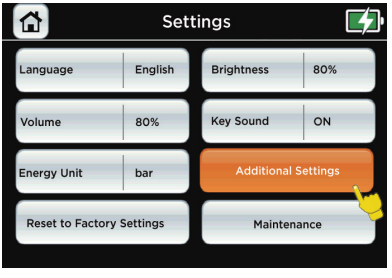
- Touch the Energy unit button to select bar or mJ.

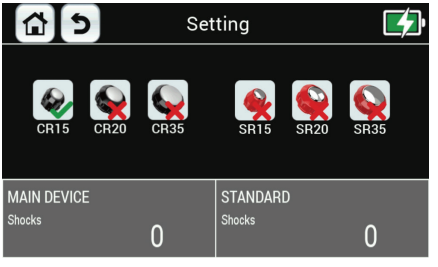


Additional Settings

In this setting, users can select the applicators that are frequently used for treatment. Selecting applicators in settings allows a specific applicator to be chosen during treatment. If no applicators are selected, then the Applicator Button will not be displayed in the treatment interface.

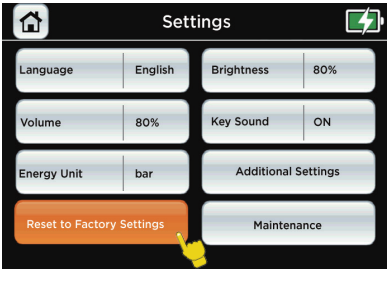
This screen also shows the total number of shocks for the main device and the wired handpiece. The handpiece can be checked and maintained according to the number of shocks.

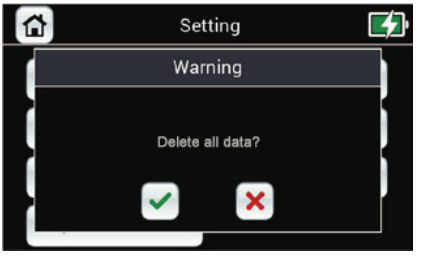




Reset To Factory Settings

This button is used to delete all favorited programs and reset all setting parameters.

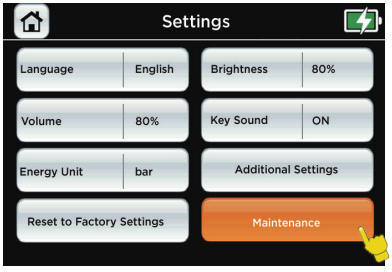




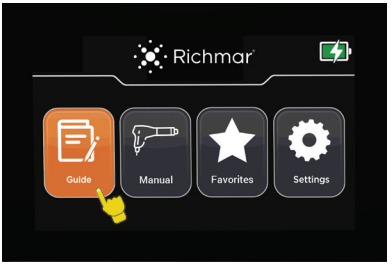
OPERATION

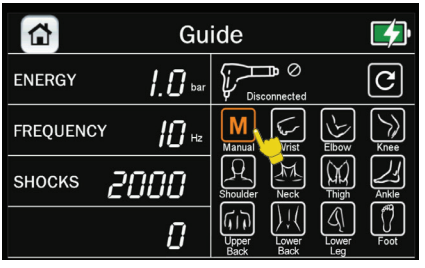
Maintenance

If necessary, the device can be upgraded via USB flash drive. Please contact your dealer or manufacturer for instruction.



QUICK THERAPY GUIDE





Touch the body part box to select your desired program. There are 12 preset programs. The parameters for these programs are as follows:

Programs	Energy (bar)	Frequency (Hz)	Shocks
Manual	1	10	2000
Wrist	1	8	1500
Elbow	1.7	8	2000
Knee	2	10	2000
Shoulder	1.7	10	2000
Neck	1	12	2000
Thigh	2.2	10	2000
Ankle	2	10	2000
Upper Back	1.5	12	2000
Lower Back	2.7	10	2000
Lower Leg	2	10	2000
Foot	2	10	2000

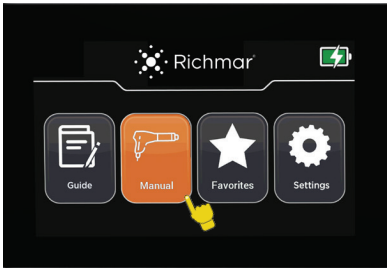
- You can also adjust the preset programs by touching each parameter and using the adjustment knob.
- Once you finished the selection of body part program, you can follow the Application section to start treatment.

⚠ WARNING

The pre-programmed parameter-settings are based on the experiences of medical experts or physiotherapists. They are indicative and can be used as an example, but can also be adjusted to one's own expertise.
Attention: this is at the risk of the operator!

MANUAL THERAPY

Touch the Manual button to enter manual therapy treatment mode.

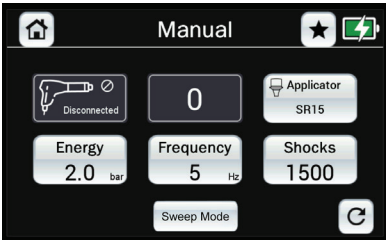


Manual Therapy Treatment Screen
The manual therapy screen displays the handpiece status, number of operations, selected applicator, and energy, frequency and shocks parameters. Manual mode allows the user to set parameters, select a specific applicator and allows users to save custom treatments to favorites.

OPERATION

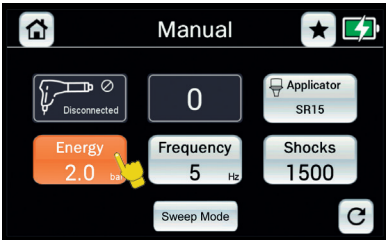
Richmar

Normal Mode



Energy

Touch the Energy button and adjust to desired level with the adjustment knob. The adjustment range is 1-4bar/60-185mJ, in 5mJ increments.



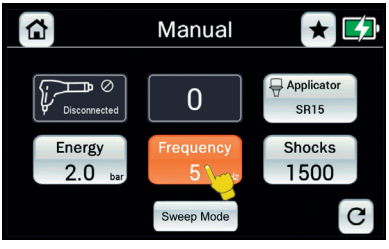
Energy Unit Correspondence:

mJ	60	65	70	75	80	85	90	95	100	105	110	115	120	120
bar	1.0	1.1	1.2	1.4	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4	2.4

mJ	125	130	135	140	145	150	155	160	165	170	175	180	185
bar	2.6	2.7	2.8	2.9	3.0	3.2	3.3	3.4	3.5	3.6	3.8	3.9	4.0

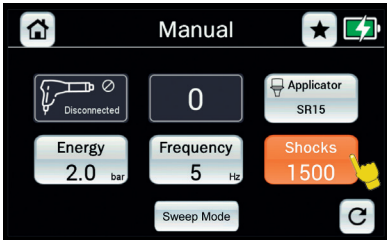
Frequency

Touch the Frequency button and adjust to desired level with the adjustment knob. The adjustment range is 1-22Hz, in 1Hz increments.



Shocks

Touch the Shocks button and adjust to desired level with the adjustment knob. The adjustment range is 100-10,000 shocks, with 100 shock increments.



NOTE:

The adjustment range relationship between frequency and energy is defined here according to the specific device's technical parameters.

Energy Unit Correspondence:

Frequency (Hz)	1	2	3	4	5	6	7	8	9	10	11
Maximum energy (mJ)	185	185	185	185	185	185	185	185	185	185	180

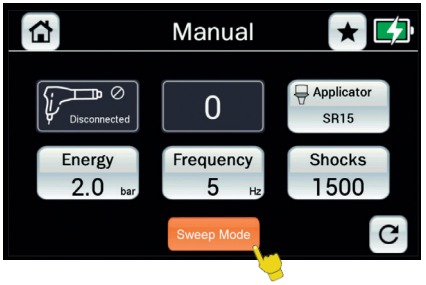
Frequency (Hz)	12	13	14	15	16	17	18	19	20	21	22
Maximum energy (mJ)	170	160	150	140	130	120	110	100	90	90	90

Once you finished the set up of parameters, you can follow the Application section to start treatment.

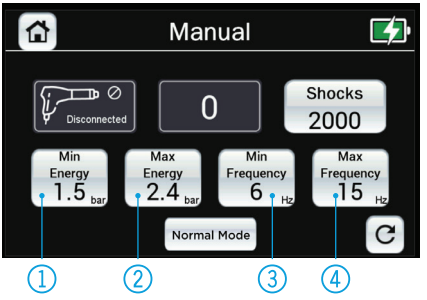
OPERATION

SWEEP MODE

Press sweep mode button to enter the treatment screen of sweep mode.



Sweep Mode Treatment Screen



In this mode, you can set the modulation output for frequency and energy. The output of frequency and energy will conduct from minimum to maximum to minimum as cycles.

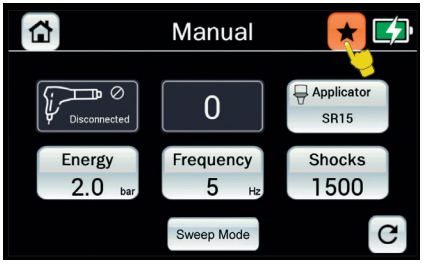
1	**Minimum Energy Output**
2	**Maximum Energy Output**
3	**Minimum Frequency**
4	**Maximum Frequency**

You can touch each icon to adjust your desired levels of shocks, energy, and frequency.

SAVING CUSTOM PROTOCOLS

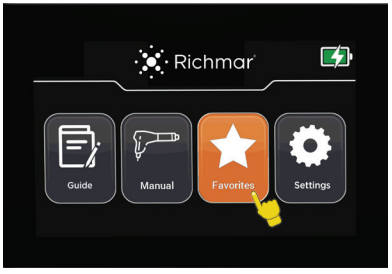
The SW1 allows for up to 30 custom protocols to be saved. After setting your desired parameters, press the Favorites icon in the top right corner of the screen to save your custom protocol.

Name your custom protocol and click save . You can view and manage the custom protocols in Favorites on the home screen.

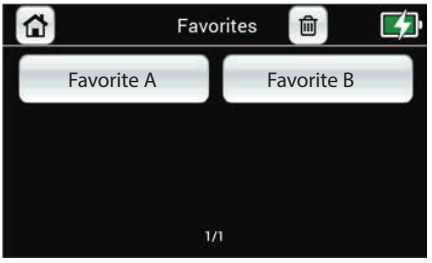


FAVORITES

Press the Favorites button to enter the custom protocol list.

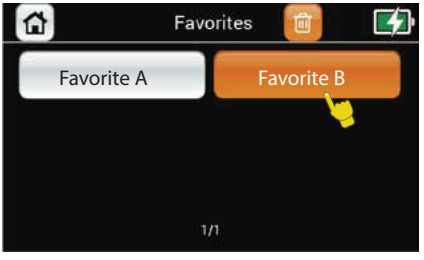


Custom Protocol List

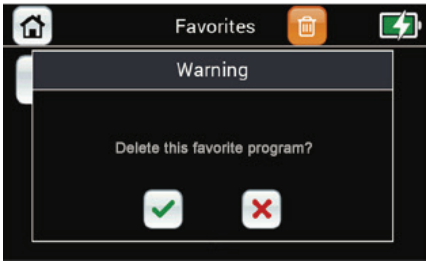


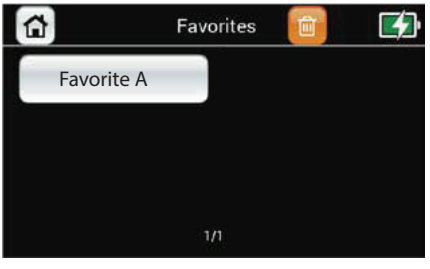
Delete the Favorites Program

Touch the delete button 🗑 and then touch the program you want to delete.



A confirmation pop-up will appear, and upon confirmation, the program will be deleted.





OPERATION

APPLICATION

Patient Preparation

Before applying shockwave therapy to the patient, first prep the patients skin. By properly preparing the patients skin for therapy, it allows more energy to reach the targeted areas and reduces the risk of skin irritation.

To prepare the patients skin for therapy do the following:

1. Thoroughly wash the skin on which the intended treatment is to be administered with mild soap and water or alcohol wipe.
2. Dry the skin thoroughly.
3. Apply the coupling gel generously to the target area on the patient.

- The device operates through mechanical energy transmission, where the patient receives treatment using the handheld applicator. To initiate treatment, the applicator is placed vertically on the target area with the handpiece held firmly in one hand. The radial pressure wave can be activated to work steadily on a single spot or dynamically over a broader area.
- Due to the ergonomic design of the handpiece, applying additional pressure on the treatment area is generally unnecessary. Simply position the handpiece on the target area with a loose grip. However, if needed, gentle pressure may be applied in the direction of the tissue, and the working angle can be adjusted accordingly.
- Let your patient rest in a relaxing position during the treatment session, provide support under their limb for comfort if needed during an elevated treatment.
- Localize the painful points you plan to treat. It might be a good idea to mark up the points with a felt tip pen.
- Talk to your patient and ensure that they understand the following:
  1. Treatment should start at a minimum bar/mJ level.
  2. Bar/mJ level should increase slowly, manually.
  3. Patient is responsible for letting the clinician know at any time if the treatment is becoming painful.
- For optimal performance and patient comfort, it is recommended to use the coupling gel to reduce friction on the skin during treatment.

⚠ CAUTION

- Please note that applicators are consumable parts and should be replaced after 1,000,000 shocks to maintain optimal performance.

- Minor or slight deformation or shortening of the rear impact dome will not impact the functionality of the applicator.
- However, if you notice significant deformation or substantial shortening of the rear impact dome, it is essential to replace the applicator promptly to ensure safe and effective treatments.
- If the applicator has worked more than 300,000 times, it is recommended to check at least once a week.
- This device is **NOT** equipped with coupling gel, please use the coupling gel that is legally marketed in the US under 510(K) procedure. The coupling gel **MUST** be stored, used, and disposed of according to the information supplied by the manufacturer of the product.
- Patients with sensitivity to the coupling gel should use caution when using the device.
- There may be a red and swollen or skin itch if patient is allergic with coupling gel.
- There will be red and swollen on the treatment area after treatment for a short time.
- It is recommended to wear suitable ear protection during treatment to for both user and patient.

NOTE:

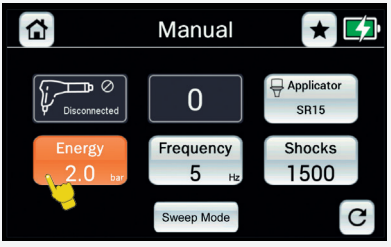
- Although measures have been designed inside the handpiece to eliminate vibration, the inevitable vibration will still cause pressure on the user's hand.
- Recommended protective measure: Limit the duration of exposure.
- The patient should be carefully monitored throughout the treatment.
- If the device malfunctions during normal use, immediately stop treatment and disconnect the power, then consult the instruction manual. If the problem cannot be resolved, please contact Compass Health Brands Corp.

OPERATION

QUICK START TREATMENT GUIDE

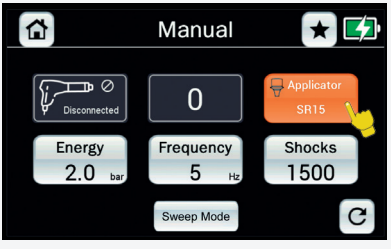
On your chosen treatment screen, you can adjust the parameters to your desired level, by touching a parameter and using the adjustment knob.

1. Select Guide, Manual, Favorites or Settings on the home screen.



2. On your chosen treatment screen, you can adjust the parameters to your desired level, by touching a parameter and using the adjustment knob.

3. Select the proper applicator that will be used during treatment.



4. **Start treatment**
Press the trigger button to start treatment.

5. **Pause treatment**
   Press the trigger button again to pause the treatment.

6. **Stop treatment**
   After pausing treatment through the trigger button on the handpiece, press the screen power button to stop treatment.

7. **End treatment**
   The handpiece will continue working until the actual number of shocks is reaches the preset number of shocks. Treatment then ends. You can restart the treatment by selecting the reset button .

OPERATION

Monitoring the Handpiece Temperature

The generation of mechanical radial pressure wave energy leads to a significant build-up of heat in the handpiece. To ensure the longevity of the handpiece and prevent overheating, we have integrated a temperature switch. This switch acts as an internal safeguard and triggers an automatic switch-off if the temperature becomes too high, requiring the handpiece to cool down.

Once the handpiece reaches the correct operating temperature, the pop-up warning will disappear, indicating that the device is ready for use again. However, in the event of the temperature switch being activated, a message will be displayed on the screen, and the emission of shocks will be temporarily disabled for safety reasons. It is crucial to wait until the handpiece cools down and the warning clears before resuming treatment. This feature is designed to protect the handpiece and ensure optimal performance during each session.

TROUBLESHOOTING

Unplug the power cable from the instrument before you carry out any maintenance work.

ERROR	POSSIBLE CAUSE	CORRECTIVE ACTION
Device does not work	• Power failure. • Defective power cable.	• Check the power supply. • Replace the power cable.
The handpiece is too hot	• Excessive use. • The fan of the handpiece is broken.	• Let the handpiece rest after each use. • Contact authorized service provider.
No radial pressure wave power output	• The handpiece is not connected to the main device. • Blocked or worn projectile. • Device malfunction. • Defective handpiece.	• Check the connector the handpiece. • Clean the guide tube and projectile. • Overhaul the handpiece. • Contact authorized service provider. • Replace the handpiece.
The output energy of the handpiece is irregular or the output energy is significantly smaller	• Wear of applicator heads. Applicator heads are difficult to move due to wear. They are wear parts and should be replaced after a specific number of shocks.	• Removal of parts subject to abrasion. • Remove the applicator heads from the handpiece and clean the rear dome thoroughly. • Then hold the handpiece, without the applicator heads, with the opening downward and, at 2 or 5 Hz frequency, release a few shocks (maximum 10) at the lowest energy level. Then reinsert the handpiece. • If the error still occurs, the handpiece has to be changed.

TROUBLESHOOTING

Richmar

TROUBLESHOOTING (CONT'D)

ERROR	POSSIBLE CAUSE	CORRECTIVE ACTION
The output energy of the handpiece is irregular or the output energy is significantly smaller	• The bullet got caught in the dust.	• Remove the treatment head, bullet and tube to clean the dust.
	• O-ring aging, wear and tear.	• After 1,000,000 shocks O-rings should be replaced. • Replace the new O-ring.
	• Wear of radial pressure wave generator.	• The radial pressure wave generator is an expendable part and should be replaced after 5,000,000 shock. Check the total number of shocks of the device in the configuration menu. • If the total number of 5,000,000 shocks has been reached or exceeded, the tube and projectile should be replaced. • Contact authorized service provider to replace the tube and projectile. • Replace the handpiece.
	• The connection cable of the wired handpiece is damaged.	• Contact authorized service provider to replace the cable. • Replace the wired handpiece.

CLEANING, MAINTENANCE, REPAIR, DISPOSAL

CLEANING

Cleaning the Device and Handpiece

Disinfection between patients is required. With the device disconnected from the power source, clean the device with a clean, lint-free cloth moistened with water and mild soap. **DO NOT** use solvents. If a more thorough cleaning is needed, use a cloth moistened with a mild cleaner.

- Cleaning should be performed daily. **DO NOT** submerse the device in liquids.
- Clean the screen with a clean, dry cloth, the same way as cleaning a computer monitor screen. **DO NOT** use abrasive materials, chemicals, or liquids.
- Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning.
- Disinfect the handpiece with an alcohol-based disinfectant that is suitable for surface cleaning.

⚠ **CAUTION**

- Before starting any maintenance and cleaning measures, the device **MUST ALWAYS** be switched off at the main switch and the power cable unplugged.
- Make sure that during cleaning and disinfection, no liquids penetrate the device. **DO NOT** use sprays.
- If liquid penetrates the device during cleaning or disinfecting, **DO NOT** use the device and contact Compass Health Brands Corp.
- **DO NOT** use cleaning agents that contain strong alkalis, lye, acid, detergents with fluoride or detergents with ammonia.
- Check the power cord and cable of the wired handpiece for damage, such as cracks, splitting or holes. If damage is evident, stop using and contact your local distributor.
- It is recommended to disinfect the unit at least once a week. **ALWAYS** perform cleaning prior to disinfection. Ensure the applicator is cleaned and disinfected prior to treating a patient to maintain optimal performance.

Cleaning the Applicator

Regular cleaning ensures perfect hygiene and operation of the handpiece. The handpiece, in particular the applicator, **MUST** be thoroughly cleaned and disinfected after each therapy session.

CLEANING & MAINTENANCE

Richmar

⚠ WARNING
Disconnect the handpiece from the main device before starting any cleaning or maintenance work.

Component	Procedure	Interval
Handpiece shaft and cushion	Clean and Disinfect	daily or after 20,000 shocks (whichever comes first)
Applicator and O-rings	Clean and Disinfect	after each treatment or contact with a patient

- Before cleaning and disinfection of the applicator, the applicator should be disassembled from the handpiece.
- For the 15mm applicator, the removed applicator screw cap, two O-rings, and the applicator itself should be cleaned. For the 20/35mm applicator, the removed applicator screw cap, applicator inner cap, two O-rings, and the applicator itself should be cleaned. For detailed disassembly procedures, see Installation section.
- When the above parts are cleaned, dry them and install them according to the steps in Installation section.

Cleaning
Tools (Not Included):
- Disposable wipes (cellulose, paper)
- Alcohol-based plastic cleaner (e.g. cleaner for medical devices)

In case of visible contaminations, the housing, the handpiece, the applicator and the applicator removal tool can be cleaned with commercially available alcohol-based cleaners.

Wipe the surface until the contamination is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping wet.

Disinfection
Tools (Not Included):
- Disposable wipes (cellulose, paper)
- Commercially available alcohol-based disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties or wipes. Observe the application instructions of the manufacturer.

The housing, the handpiece, the applicator and the applicator removal tool can be disinfected by wiping. Use a commercially available alcohol-based disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties. Observe the application

instructions of the manufacturer. Wipe all surfaces using a cloth soaked according to the specifications of the manufacturer of the disinfectant.

Then visually observe whether there is dirt on the surface of the device. If there is, wipe the surface several times until the dirt is no longer visible to the naked eye. Finally, dry the device housing, the handpiece, the applicator and the applicator removal tool with a dry soft cloth.

MAINTENANCE

Device Maintenance

The main device is designed for a minimum service life of 5 years of normal usage and proper maintenance. Separate servicing is **NOT** required for this product. Before starting any maintenance or cleaning, the device **MUST ALWAYS** be switched off at the main switch and the plug pulled out. No internal maintenance or routine calibration is required for the device itself.

Battery Pack

The battery pack is powered by a rechargeable battery. To ensure the device always functions optimally, it's necessary to replace the battery when its lifespan ends or when the battery's performance begins to decline. Typically, after approximately 200 discharge cycles, the battery's capacity and discharge capabilities start to decrease. In this case, it is recommended to replace the battery module.

Battery Charge and Discharge Cycles

During usage, the battery undergoes charge and discharge cycles. One complete cycle is achieved when the battery accumulates a discharge equal to 100% of its capacity. To prolong the battery lifespan, try to avoid completely depleting or fully charging the battery to 100%. If the device remains unused for an extended period, it is recommended to keep the battery charge level at around 60% and recharge it at least every three months.

Disposal of Replaced Battery

Follow these environmental guidelines for disposing of the old battery:

- Place the old battery into designated battery recycling bins for proper environmentally-friendly disposal.
- **DO NOT** dispose of the old battery in regular trash bins to avoid environmental pollution.
- If required, you can also return the old battery to designated battery recycling points for proper handling.
- If you have any questions or need further assistance regarding the battery replacement process, please contact Compass Health Brands Corp.

CLEANING & MAINTENANCE

The device contains materials that can be recycled and/or are noxious to the environment.

Specialized companies can dismantle the device and sort out these materials. When you dispose of the device, find out about local regulations concerning waste management.

Software Upgrade
The software can be upgraded via USB flash drive. Before upgrade the software, please contact your dealer or manufacturer.

REPAIR

Repair work on defective device and handpieces **MUST ONLY** be carried out by personnel suitably authorized by manufacturer. **ONLY** original manufacturer parts may be used for this purpose. The suitably authorized personnel can be from manufacturer or be representatives of manufacturer and dealers.

OVERHAUL

Due to friction, the handpiece components will experience continuous mechanical stress, resulting in minor wear over time. The handpiece should be overhauled approximately every 1,000,000 shocks. This overhaul can be performed by the device user using the repair kit (not included), which contains all necessary replacement parts.

SERVICE

Should you have any further questions or require additional information, please feel free to contact your dealer.

DISPOSAL

The device contains materials that can be recycled and/or are noxious to the environment. Specialized companies can dismantle the device and sort out these materials. When you dispose of the device, find out about local regulations concerning waste management.

SPECIFICATIONS

Name	Technical Parameters
Model	SW1000
Power Supply	100-240V~, 50Hz/60Hz, 200VA
Lithium-Ion Battery	DC 22.2V, 2200mAh
Battery Charge Time	≤3h
Operation Times of Fully Charged Battery	Fully charged battery can work for about 20000 shocks when used for 120mJ/10Hz
Conformity	Protection class I/Application class BF
Applied Part	The applicator
Frequency Range	1 Hz–22 Hz
Shock Energy Levels	60–185mJ (at the applicator)
Mode of Operation	Suggested Intermittent use max. 6000 shocks/15mins break
Accuracy	± 20%
Dimension of Handpiece	About 259.2*113.7mm (L*W)
Service Life of Handpiece	5,000,000 shocks (minimum) Applicators exchangeable
Dimension of Applicator	15/ 20/35 mm diameter, ±0.1mm
Weight of Main Unit	About 2.1 kg (with battery module)
Dimension of Main Unit	291mm*170mm*121.5mm (L*W*H), ±2.0mm
Operational Environment	Ambient temperature: 41°F to 86°F (5°C to 30°C) Relative humidity: 20% to 80% Ambient pressure: 700 hPa to 1060 hPa
Storage/Transport	Ambient temperature: 14°F to 122°F (-10°C to 50°C) Relative humidity: 10% to 93% Ambient pressure: 700 hPa to 1060 hPa

SERVICE & LIMITED WARRANTY

SERVICE LIFE OF THE HANDPIECE

The handpiece should be overhauled after around every 1 million shocks. Provided this interval is observed, the average expected service life is approximately:

- 5 million shocks for the handpiece
- 1 million shocks for the applicator

Exceeding the service life can be expected to result in a failure of the device. No warranty claims shall be accepted beyond the information given.

When the device or any accessories require service, contact the selling dealer or Compass Health Brands Corp. Maintenance to this device should only be performed by an authorized service provider.

Expected Life of Device

This device as well as the parts and accessories supplied with it are designed for a minimum service life of 5 years of normal usage and proper maintenance.

Applicator, guiding tube, projectile and o-rings are consumables; they are designed for 1 million shocks expected life.

Repair work on defective device and handpieces **MUST ONLY** be carried out by personnel suitably authorized by manufacturer. Only original manufacturer parts may be used for this purpose. The suitably authorized personnel can be from manufacturer or be representatives of manufacturer and dealers.

NOTE:

- The handpiece of the device has a usage lifespan of 5,000,000 radial pressure waves.
- Under certain conditions, the treatment handpiece may remain effective beyond its specified usage lifespan, depending on performance and frequency.
- Each applicator is designed to deliver a minimum of 1,000,000 radial pressure waves during its usage lifespan.
- Same as the handpiece, the applicator may continue to be effective beyond its specified usage lifespan, depending on performance and frequency.

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SERVICE & LIMITED WARRANTY

LIMITED WARRANTY

Compass Health Brands Corp. warrants that your TheraTouch SW1 is free of defects in material and workmanship. This limited 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, Compass Health Brands will repair or replace the respective product without charge. Compass Health Brands sole obligation in the case of any breach of its limited warranty set forth in the manual shall be, at Compass Health Brands option, to replace the product with a new or factory certified refurbished product, without charge to Compass Health Brands purchaser or to refund the purchase price. It is at the discretion of Compass Health Brands 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 Compass Health Brands. All product repairs **MUST** be performed by Compass Health Brands or an authorized repair facility. Any modifications or repairs performed by unauthorized centers or groups will void this limited warranty.

COMPASS HEALTH BRANDS SHALL RESERVE THE RIGHT TO REQUEST PROOF OF PURCHASE FROM THE END-USER TO VALIDATE THE LIMITED WARRANTY PERIOD.

This limited warranty does **NOT** cover:

1. Replacement parts **NOT** provided by the manufacturer or labor furnished by anyone other than a Compass Health Brands authorized repair facility or technician.
2. Defects or damage caused by labor furnished by someone other than Compass Health Brands 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.

COMPASS HEALTH BRANDS 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.

SERVICE & LIMITED WARRANTY

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*The device limited warranty **ONLY** applies to the device and does **NOT** include any accessories. All accessories have a 12 month limited warranty. Damages to the device or accessories due to non-adherence with the Instruction Manual and its warning and cautions will exclude the limited warranty.

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

1. A claim **MUST** be made within the limited warranty period directly to Compass Health Brands or the company from whom you purchased the device.
2. An RMA number **MUST** be obtained from Compass Health Brands in order to receive replacements parts and/or return defective product under the limited warranty.
3. To contact Compass Health Brands Tech Support Department for troubleshooting and/or replacement request, please call: 888-549-4945, Option 2.

This limited 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.

Information in this document is subject to change without prior notice. The manufacturer of the equipment may have patents, patent applications, trademarks, or copyrights covering material in this document. This document does **NOT** grant license to any of these intellectual property rights. The manufacturer shall **NOT** be liable for any errors and/or omissions for incidental or consequential damages in connection with the performance, or use of this material.

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ELECTROMAGNETIC COMPATIBILITY

ELECTROMAGNETIC COMPATIBILITY (EMC)

- The device is suitable for professional healthcare facility environment.
- **DO NOT** use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Medical electrical devices such as the device are subject to special precautions with regard to electromagnetic compatibility (EMC) and **MUST** be installed and commissioned in accordance with the EMC advice given in the instructions for use and accompanying documents.
- Use of this equipment adjacent to or stacked with other equipment should be avoided as this 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.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The device should only be operated with the original cable specified in the package contents.
- Portable RF communications equipment (including peripherals such as antenna cables, mobile phones and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.
- The presence of applicators near the device could affect its performances. The distances mentioned in the tables prepared by manufacturer could help to prevent any disturbances of the equipment in normal operation.
- The loss or degradation of the following essential performance due to electromagnetic disturbances could result in affecting patient's treatment:
  a) No interruption of radial pressure wave output;
  b) No changes of mode;
  c) No changes in set-values.
- When the operating environment is relatively dry, strong electromagnetic interference usually occurs. At this time, the device may be affected as follows:
  - The device stops output;
  - The device turns off;
  - The device restarts.
- The above phenomenon does **NOT** affect the basic safety and essential performance of the device, and the user can use it according to the instruction. To avoid the above phenomenon, use it according to the environment specified in the manual.

ELECTROMAGNETIC COMPATIBILITY

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- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.
- The maximum length of the power cable for the device is 2.5 m.

DO NOT change the once installed final application due to EM DISTURBANCE. If the environment does **NOT** correspond to the conditions listed by the manufacturer, some actions are required to match those conditions. Please contact the manufacturer.

The climatic environmental conditions could affect the life of critical components of the device.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS	
Emissions Test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY		
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV,±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV,±8 kV, ±15 kV air
Electrical fast transient/ burst IEC 61000-4-4	Power supply lines: ±2 kV 100 kHz repetition frequency	Power supply lines: ±2 kV 100 kHz repetition frequency

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ELECTROMAGNETIC COMPATIBILITY

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY		
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. Line(s)-to-ground(s): ± 0.5 kV, ± 1 kV, ± 2 kV	line(s) to line(s): ±1 kV. Line(s)-to-ground(s): ± 0.5 kV, ± 1 kV, ± 2 kV
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV 100 kHz repetition frequency	Power supply lines: ±2 kV 100 kHz repetition frequency
Surge	line(s) to line(s): ±1 kV.	line(s) to line(s): ±1 kV. Line(s)-to-ground(s): ± 0.5
Conduced RF IEC61000-4-6	3Vrms 0.15 MHz to 80 MHz 6Vrms in ISM bands between 0.15 MHz and 80 MHz	3Vrms 0.15 MHz to 80 MHz 6Vrms in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC61000-4-3	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
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m
NOTE: U_T is the a.c.mains voltage prior to application of the test level.		

ELECTROMAGNETIC COMPATIBILITY

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GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY								
	Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Max Power (W)**	**Distance (m)**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance Level (V/m)**
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9
	5500							
	5785							

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ELECTROMAGNETIC COMPATIBILITY

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY		
Test Frequency	**Modulation**	**IMMUNITY TEST LEVEL (A/m)**
30 kHz	CW	8
134,2 kHz	Pulse modulation [a] 2,1 kHz	65 [b]
13,56 MHz	Pulse modulation [a] 50 kHz	7,5 [b]
a) The carrier shall be modulated using a 50% duty cycle square wave signal. b) r.m.s., before modulation is applied.		

Manufactured for:

Richmar®

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