US 1000 3RD EDITION

INSTRUCTION MANUAL

Richmar®

This manual is valid for the

US 1000 3rd Edition Stimulator

This user manual is published by Compass Health Brands.

United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner

Conformity to safety standards

Compass Health Brands declares that the device complies with following normative documents:
IEC60601-1, IEC60601-1-2, IEC60601-2-5, IEC60601-1-4, ISO10993-5, ISO10993-10, ISO10993-1

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1. GENERAL INFORMATION

1.1 Device Information

The US 1000 3rd Edition generates deep ultrasonic waves within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. Keep out of reach of children.

1.2 Medical Background

EXPLANATION OF ULTRASONIC STIMULATOR EFFECT

The US 1000 is a Therapeutic ultrasound device that generates pulsed high frequency sound waves (1MHz) that are transferred to a specific body are via a sound-headed probe. The Pulsed Sound Waves travel deep into the tissue to generating vasodilation, which helps increase blood flow to the treated area.

Therapeutic Ultrasound is found to help relieve pain and reduce muscle spasms and is the one of the most frequently used therapies by physicians and physical therapists. Most patients will feel nothing at all during treatment, while some patients may feel a very slight warmth.

2. SAFETY INFORMATION

Read instruction manual before operating. Be sure to comply with all "Contraindications", Warnings", "Cautions" and "Adverse reactions" in the manual. Failure to follow instructions may cause harm to user or device.

Safety Symbols Used in this Manual	
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device or other property.

2.1 Contraindications

1. **DO NOT** use over or near bone growth centers until bone growth is complete.
2. **DO NOT** use over a healing fracture.
3. **DO NOT** use over the eyes.
4. **DO NOT** use for patients with implanted neurostimulation systems because tissue damage can occur at the location of the implanted electrodes resulting in severe injury or death. This can also damage the system components.
5. **DO NOT** use to treat malignancies nor in the region with malignant tumors.
6. **DO NOT** use for patients with demand type cardiac pacemakers.
7. **DO NOT** use on someone who is pregnant.
8. **DO NOT** use over ischemic tissues in patients with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.
9. **DO NOT** use over the carotid sinus nerves, arteries, laryngeal or pharyngeal muscles.
10. ⚠ **CAUTION**: Federal law restricts this device to sale by or on the order of a practitioner licensed by the the law of the State in which he/she practices, according to 21 CFR 801.109.

2.2 Warnings, Cautions and Adverse Reactions

⚠ WARNINGS:

1. This device should be used only under the continued supervision of a licensed physician or practitioner.
2. The long-term effects of ultrasound are unknown. Ultrasound devices **DO NOT** have any curative value.
3. **DO NOT** use on patients with hemorrhagic diathesis.
4. Never use on the areas of the skin which lack normal sensation.
5. Keep ultrasound device away from children.
6. **DO NOT** use over an area of the spinal cord following laminectomy, i.e., when major covering tissues have been removed.
7, Avoid bony prominences.
8. When using ultrasound, keep the sound head moving while maintaining contact with skin.
9. If treatment becomes uncomfortable, inform or contact your physician.
10. **DO NOT** immerse the Portable Ultrasound in water or other solvent.
11. **DO NOT** use over metallic implants, especially prostheses with a cement-matrix.
12. **DO NOT** use over anesthetic areas.
13. Consult your doctor if you have any questions or concerns before using this device.
14. A treatment head is a precision instrument. Great care is taken in the development and production in order to obtain the best possible beam characteristics. Rough treatment (jarring, dropping, excessive use in a professional setting, etc.) can adversely affect these characteristics and must be avoided, as it can affect warranty coverage.

⚠ CAUTIONS:

1. Federal law (USA) restricts this device to sale by or on the order of a physician.
2. This device is for single patient use only.
3. Keep yourself informed of the contraindications.
4. This device is not intended for use on an unattended patient who is non-compliant, emotionally disturbed, has dementia, or low IQ.
5. Read, understand, and practice the warnings, cautions and operating instructions. Know the limitations and hazards associated with using this device. Observe the cautionary and operational decals placed on the unit. Always follow the operating instructions prescribed by your healthcare practitioner.
6. The instruction of use was listed; any improper use may be dangerous.
7. **DO NOT** use this device for undiagnosed pain syndromes until consulting a physician.
8. Patients with an implanted electronic device, such as a cardiac pacemaker, implanted defibrillator, or any other metallic or electronic device should not use this device without first consulting a doctor.
9. Patients with the following diseases or symptoms should not use the device
    - Pregnancy or Menses period
    - Acute disease, Heart disease, Tubercle disease, Facial neuralgia, Pernicious tumor, Hemophilia, High fever, abnormal blood pressure patient, or under abnormally health conditions.
    - Patients with sensitive physical conditions such as ringworm, dermatitis, Infectious disease, etc.
    - Person who can't express themselves clearly such as infants, mentally disabled, after drinking alcohol or under extreme fatigue.
    - **DO NOT** apply this product on the following spots"
        - Mucous membranes
        - Neuralgia spots
        - Post surgical area
        - Sun burnt skin
        - Sensitive skin irritated by cosmetic products
        - Areas where metal, plastic or silicone material is present.
    - **DO NOT** use with other electronic equipments such as ECG \ machine, etc., even though this device conforms to the EMC requirements.
10. **DO NOT** use on the thoracic region if you are a pacemaker user.
11. **DO NOT** use on the region with malignant tumors.

12. **DO NOT** use on the region of blood-lacking tissue, because there is not enough blood supplied to meet the metabolic demand, so that the tissues would result in necrosis.
13. For the patient with bleeding physique, **DO NOT** use US 1000.

WARNING

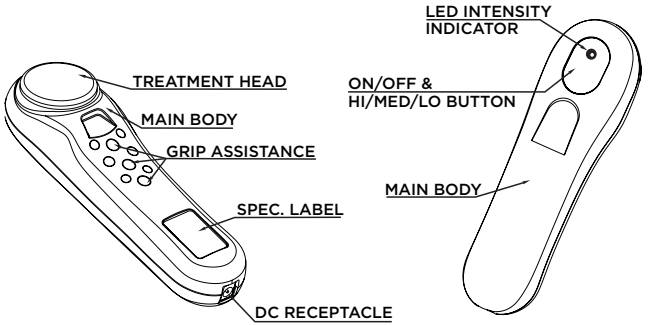
The device complies completely with all parts of 21 CFR 1050. 10 of the performance standard for sonic, infrasonic and ultrasonic radiation-emitting product.

CAUTIONS

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

3. PRESENTATION

3.1 Construction



4. SPECIFICATIONS

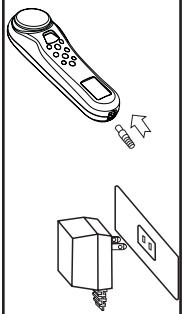
4.1 Accessories

NO	DESCRIPTION	QTY
1	Ultrasound Device (DU1025)	1
2	Wall Adapter (DU1025X)	1
3	Therasonic Ultrasound Gel (LC2828)	1
4	Instruction Manual	1
5	Carrying Case (CC1006)	1

4.2 Technical Information

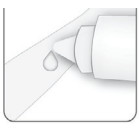
Waveform	Pulsed
Power supply	Switch adapter (Input: AC100-240V, 50/60Hz, Output: DC24V/0.4A)
Operating Conditions	10°C to 40°C, 40% to 90% Relative Humidity
Storage/Transportation Conditions	-10°C to 60°C, 30% to 95% Relative Humidity
Dimensions	6.80 x 2.25 x 1.65 inches (L*W*H)
Weight	4.25 ounces
Frequency	1MHz +/- 10%
Beam Type	Collimated
Pulse Width	8% 0.5ms +/- 10%; 14% 1ms +/- 10%; 29% 2ms +/-10%
Repetition Rate	150 Hz +/- 10%
Temporal Maximum Power	4W +/- 20%
Temporal max. effective intensity	0.65 W/cm² +/- 20%
R_{tpa}	3.45, 7.14, 12.5
ERA (Effective Radiating Area	6.16 square cm +/- 20%
BNR (max)	5.5:1
Auto-time setting	30 minutes +/- 10%
Duty Cycle	(Low) 8%, (Medium) 14%, (High) 29%
Rated Output Power	1.2W

5. INSTRUCTIONS FOR USE



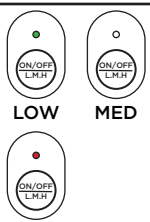
Steps to Connect the Adapter
1. Insert the DC Plug of the adapter into the DC receptacle on the main unit. (as the picture).
2. Please hold the main unit tightly, when inserting the DC plug into the DC. Insert and pull out the DC plug in correct direction.
3. There are many different adapters (specification & shape of the plug) used by different countries.
4. Insert the adapter into the power supply socket. (as the picture) Be sure the power voltage is appropriate. Use only the adapter provided by the manufacturer.

ATTENTION: Please use the original adapter. The user can not re-assemble or change the specification of the adapter. Personal injury or damage to the unit may be caused if you **DO NOT** follow the above instructions and will void warranty.

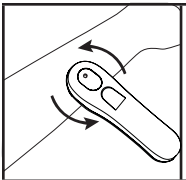


Apply Transmission Gel
Wash the area to be treated so that it is free of oil and dirt. Apply a generous layer of ultrasound transmission gel on the treatment area. The gel acts as a coupling substance and ensures effectiveness. The area treated should be two times the diameter of the sound head.

Turning On the Device
Press On/Off button to turn on the power, the device will beep, and the LED will light up green.



Adjust Output Intensity
To adjust the output intensity, push On/Off button slightly.
• LED: Green, the vibrating is in Low level;
• LED: Orange, the vibrating is in Medium level;
• LED: Red, the vibrating is in High level.
When adjusting the intensity each time, a beep will sound. To return output to low level, press On/Off button again. When the device is working, the device will beep twice every five minutes.

	**Begin Treatment** Use gentle upward or circular motions with the treatment head on treated area. Keep the treatment head gliding over the skin, ⚠ **CAUTION** **DO NOT** stop moving the treatment head as it could cause potential burns or injury.
	**Turning Off the Device** The device will automatically shut down after working 30 minutes with 5 beeps. To turn off power prior to the auto timer shut down, press the On/Off button and hold down for 4 seconds and the device will turn off.

5.1 Function Test of Ultrasonic Action

Place the probe horizontally, then apply several water drops on the surface of the probe. Turn on the device, you can observe the ultrasonic action. The water drops on the probe start to perform one million vibrations per second with slight atomization phenomenon.

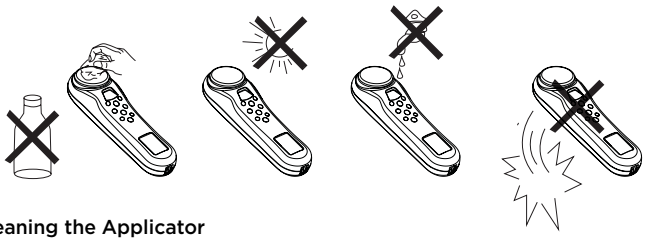
Intensity

LOW: The water drops vibrate slightly.
MED: The water drops vibrate stronger, and with atomization.
HI: The water drops vibrate very strongly, and with atomization.

6. MAINTENANCE AND CLEANING

Switch off the device and disconnect it from the power supply. The device can be cleaned with a damp cloth. Use lukewarm water and a non-abrasive liquid household cleaner (no abrasive, no alcohol content solution). If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

⚠ **CAUTION**: **DO NOT** submerse the device in liquids. Should the unit accidentally become submersed, contact the dealer or Authorized Service center immediately. **DO NOT** attempt to use the device that has been submersed in any liquid substrate until inspected and tested by a Service Technician certified by an Authorized Service Center.



Cleaning the Applicator

The applicator should be regularly inspected for damage, e.g. hairline cracks, which could allow the penetration of liquids. Clean the contact surface immediately after each treatment. Make sure that no ultrasound gel remains on the applicator. We further recommend cleaning the head, cable and adapter daily, using a soft cloth damped with lukewarm water. The applicator can be disinfected using a cloth moistened with an antimicrobial cleaner.

7. STORAGE

1. For prolonged pauses in treatment, store the device in a cool dry room and protect it against heat, sunshine and moisture.
2. Store the device in a cool, well-ventilated place.
3. **NEVER** place any heavy objects on the device.

8. TROUBLESHOOTING

The device is manufactured through complete quality assurance system. If there are any performance problems, please check the chart below for problems you can fix. Performance problems often result from little things that you can find and fix at home without tools. This can save you the cost of a service call.

PROBLEM	CHECK POINTS	POSSIBLE SOLUTION
LED light does not turn on.	1. The plug adapter is not inserted into the socket properly 2. The DC plug of the adapter is not inserted into the DC receptacle on the device correctly. 3. Did not press on the ON/OFF button	1. Insert the plug of the adapter into the socket again. 2. Connect the adapter with the device again correctly. 3. Press the ON/OFF button again
LED is performing normally but no output function occurs	Output intensity button setting is incorrect	Please make sure and set it again.

For technical documentation or support, please contact your local distributor or the manufacturer as shown on the label.

9. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices. In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by Compass Health Brands Corp. conform to this IEC60601-1-2 standard for both immunity and emissions. Refer to EMC table guidance supplied in this manual regarding the EMC environment in which the device should be used.

The device needs to be installed and put into service in accordance with the information provided in the instructions.

Special precautions need to be observed:

1. The use of accessories and cables other than those specified by Compass Health Brands Corp. may result in increased emission or decreased immunity of the device.
2. Care must be taken when operating this device adjacent to or stacked with other equipment. Potential electromagnetic or other interference by not using other equipment in conjunction with it.
3. The performance of the device was determined to be essential performance. This device has been thoroughly tested according to tested and inspected to assure proper performance and operation.

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commerical or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is needed that the device be powered from an uninterruptible power supply.
Surge IEC 61000-4-5	±1 kV for line(s) to line(s) ±2 kV for for line(s) to earth	±1 kV for line(s) to line(s) ±2 kV for for line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	
	40% U_T (60% dip in U_T) for 5 Cycles	40% U_T (60% dip in U_T) for 5 Cycles	
	70% U_T (30% dip in U_T) for 25 Cycles	70% U_T (30% dip in U_T) for 25 Cycles	
	<5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 5 seconds	
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic emissions.

The device is intended for use in the electromagnetic enviroment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = 1.2 √P d = 0.35 √P , 80 MHz to 800 MHZ d = 0.7 √P , 800 MHz to 2.7 GHZ Where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

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

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

[b]Over the frequency range 150 kHz to 80 MHz, field strength should be less than [3,] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device.

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 0.7\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

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

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

10. GLOSSARY OF SYMBOLS

SN	Serial number
	Attention: Read the operating instruction before use! Equipment capable of delivering output values in excess of 10mA r.m.s. or 10V r.m.s. averaged over any period of 5s.
	Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.
	Type BF Applied Part
	Type of protection against electric shock: Class II Equipment
	Refer to instruction manual
IPX7	Only for treatment head: Protected against the effects of temporary immersion water.

11. WARRANTY

Please contact your dealer in case of a claim under the warranty. If you have to send the unit back to your provider, enclose a copy of your receipt and state what the defect is.

The following warranty terms apply:

1. The warranty period for device is six months from date of purchase, including accessories, minus ultrasound gel. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs or replacements under warranty **DO NOT** extend the warranty period either for the device or for the replacement parts.
3. The following is excluded under the warranty:
    a. All damage which has arisen due to improper treatment, e.g. non-observance of the user instruction.
    b. All damage which is due to repairs or tampering by the customer or unauthorized third parties.
    c. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the retailer.
    d. Accessories which are subject to normal wear and tear.
    e. If used in a clinic setting and not for intermittent home use.
    f. If adapter was modified or replaced with adapter not supplied by the manufacturer

Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

1. All products must be returned in original packaging and must contain all components, accessories and user manuals. If any components are missing, you will be responsible for the cost of the replacement component and the 25% restocking fee.
2. All returns must be approved with a Return Authorization Number. Please call our Customer Service Team at (800) 376-7263 to obtain a Return Authorization Number. Provide the following information when calling:
    - Item Number
    - Original Order Number
    - Product Serial Number/Lot Number
    - Reason for Return
3. The Return Authorization Number must be marked clearly on the returned carton and is valid for 10 business days from the date of issue.
4. Returned merchandise must be in the same unit of measure as originally purchased.

5. Return Labels or Call Tags can be issued by our customer service department to return merchandise.
6. Associated fees and return freight charges will apply. All returns of dropshipped items are subject to a restocking fee as well as inbound and outbound freight charges.
7. Returns will not be accepted on items that are:
    - Missing their serial number
    - Special order items
    - Returned more than 30 days after delivery
    - Returned without notification

Manufactured for:

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