ComboCare™

INSTRUCTION MANUAL

Richmar®

This manual is valid for the

ComboCare™

This user manual is published by Richmar.

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

Conformity to safety standards
Richmar declares that the device complies with following normative documents:
IEC60601-1, IEC60601-1-2, IEC60601-2- 10, IEC60601-1-4, ISO10993-5, ISO10993-10, ISO10993-1
Complies with MDD 93/42/EEC and Amended by directive 2007/47/EC requirements

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1. GENERAL INFORMATION

1.1 General Description

Thank you for purchasing the ComboCare™. The microprocessor controlled ComboCare™ provides interferential (4-pole), premodulated (2-pole interferential), medium frequency (Russian), EMS and TENS waveforms and Ultrasound.

You can choose between several different amplitude modulation options. The interferential and premodulated modes offer frequency modulation as well as a static frequency option.

The ComboCare™ can provide electrical stimulation, ultrasound therapy or combination therapy.

1.2 Introduction to This Manual

This manual has been written for the users of the ComboCare™. It contains general information on the operation, precautionary practices, and maintenance information. In order to maximize use, efficiency, and the life of the system, please read this manual thoroughly and become familiar with the controls, as well as the accessories before operating the system.

1.3 Indications For Use

Therapeutic Ultrasound

Application of therapeutic deep heat for the treatment of selection sub-chronic and chronic medical conditions such as:

1. Pain relief, muscle spasms and joint contractures.
2. Relief of pain, muscle spasms and joint contractures that may be associated with
   - Adhesive capsulitis
   - Bursitis with slight calcification
   - Myositis
   - Soft tissue injuries
   - Shortened tendons due to pas injuries and scar tissues
3. Relief of sub-chronic, chronic pain and joint contractures resulting from Capsular tightness or Capsular scarring.

For TENS, Interferential and premodulated (IFC)

1. Symptomatic relief of chronic intractable pain
2. Reduction of inflammation
3. Post-traumatic acute pain and edema
4. Post-surgical acute pain and edema

For EMS and Russian:

1. Relaxation of Muscle spasms and edema reduction
2. Prevention of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Maintaining or increasing range of motion
6. Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

2. IMPORTANT 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.

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

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

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

Danger: Text with a "DANGER" indicator will explain possible safety infractions that are imminently hazardous situations that would result in death or serious injury.

2.1 Warnings, Cautions and Adverse Reactions

⚠ WARNINGS:

1. **DO NOT** apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
2. **DO NOT** apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal;
3. **DO NOT** apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e . g., phlebitis, thrombophlebitis, varicose veins);
4. **DO NOT** apply stimulation over, or in proximity to, cancerous lesions;

5. **DO NOT** apply stimulation in the presence of electronic monitoring equipment (e. g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
6. **DO NOT** apply stimulation when the patient is in the bath or shower;
7. **DO NOT** apply stimulation while the patient is sleeping; and
8. **DO NOT** apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.
9. Consult with the patient's physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals; and
10. Apply stimulation only to normal, intact, clean, healthy skin.
11. This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed. Patients with arterial or venous thrombosis or thrombophlebitis are at risk of developing embolisms when electrical stimulation is applied over or adjacent to the vessels containing the thrombus. If a patient has a history of deep vein thrombosis, even many years past, the affected area should not be stimulated .
12. Fresh fractures should not be stimulated in order to avoid unwanted motion.
13. Stimulation should not be applied immediately following trauma or to tissues susceptible to hemorrhage.
14. **DO NOT** apply electrodes directly over the eyes or inside body cavities .
15. **DO NOT** use electrical stimulation in conjunction with high frequency surgical equipment or microwave or shortwave therapy systems.
16. Keep electrodes separated during treatment. Electrodes in contact with each other could result in improper stimulation or skin burn s .
17. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.

Contraindications

1. Therapeutic ultrasound should not be applied over the pregnant or potentially pregnant uterus. Therefore, therapeutic ultrasound should not be applied over the uterus unless specific assurance can be attained from the patient that she is not pregnant.
2. Patients who have cardiac pacemakers should be protected from direct ultrasound exposure over the thorax to protect the lead wires and pacer from such exposure.
3. Therapeutic ultrasound should not be applied to the eye.
4. Applications of therapeutic intensities of ultrasound should be avoided over the heart.
5. Neoplastic tissues or space occupying lesions should not be exposed to ultrasound.
6. Ultrasound should not be applied to the testes to avoid increases in temperature.
7. Areas of thrombophlebitis should not be treated with therapeutic ultrasound due to the increased possibility of clotting or dislodging a thrombus. Conditions where this might occur are deep vein thrombosis, emboli and severe atherosclerosis.
8. Tissues previously treated by deep x-ray or other radiation should not be exposed to therapeutic ultrasound.
9. Ultrasonic treatment over the stellate ganglion, the spinal cord after laminectomy, subcutaneous major nerves and the cranium should be avoided.
10. **DO NOT** treat ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.
11. **DO NOT** apply therapeutic ultrasound over a healing fracture.
12. Ultrasound should not be applied over the epiphyseal areas (bone growth centers) of the bones of growing children.
13. **DO NOT** use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
14. **DO NOT** use this device on patients whose pain syndromes are undiagnosed.

⚠ CAUTIONS:

For Therapeutic Ultrasound

1 Ultrasound should not be applied in areas of reduced sensation or circulation. Patients having reduced sensation will not be able to notify the practitioner of discomfort if ultrasound intensities are too high. Patients with compromised circulation may have an excessive heat buildup in the treatment area.
2. If a patient complains of periosteal pain (deep, achy pain) during ultrasonic treatment, intensity should be reduced to a comfortable level.
3. Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care, therefore, should be used in treating patients with therapeutic ultrasound who have hemorrhagic diathesis or bleeding disorders.
4. Moving technique of the applicator should be used when applying therapeutic ultrasound at intensities greater than 0.5 W/ cm 2 to assure even exposure of tissues to ultrasound.
5. Heating of the joint capsule in a cute or subacute arthritis should be avoided.
6. This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
7 This device should not be used when cancerous lesions are present in the treatment area.
8. Additional precautions should be used when ultrasound is used on patients with the following conditions:

- Over an area of the spinal cord following:
- Laminectomy, i.e., when major covering tissues have been removed
- Over anesthetic areas
- On patients with hemorrhagic diathesis

9. Ultrasound should be routinely checked before each use to determine that all controls function normally, especially that the intensity control does properly adjust the intensity of the ultrasonic power output in stable manner. Also, determine that the treatment time control does terminate ultrasonic power output when the timer reaches zero.
10. The Ultrasound Applicator with care. Inappropriate handling of the Ultrasound applicator may adversely affect its characteristics.

11. Before each use, inspect the Ultrasound Applicator for cracks, which may allow the ingress of conductive fluid.
12. The ultrasound therapy controls unit is not designed to prevent the ingress of water or liquids. Ingress of water of liquids could cause malfunction of internal components or system and therefore create risk of injury to the patient.

For Electrical Stimulation

1. Federal law (USA) restricts this device to sale by or on the order of a physician.
2. The long-term effects of chronic electrical stimulation are unknown.
3. Electrical stimulation devices have no curative value.
4. Electrical stimulation is not a substitute for pain medications and other pain management therapies
5. Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients;
6. The safety of electrical stimulation during pregnancy has not been established;
7. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium(gel);
8. Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians;
9. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
10. Use caution when the patient tends to bleed internally, such as following an injury or fracture;
11. Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process;
12. Use caution if stimulation is applied over the menstruating or pregnant uterus;
13. Use caution if stimulation is applied over areas of skin that lack normal sensation.
14. Use this device only under the continued supervision of a licensed practitioner.
15. Electrical stimulation is ineffective for pain of central origin.
16. Use extreme caution when treating desensitized areas or on patients who may not be able to report discomfort or pain
17. Patients should not be left unattended during any treatment.
18. Keep this device out of the reach of children;

ADVERSE REACTIONS:

1. Skin irritation, inflammation, and electrode burns beneath the electrodes are potential adverse reactions.
2 Patients may experience headache and other painful sensations during, or following the application of, electrical stimulation near the eyes and to the head and face.
3 The clinician should stop using this device and should consult with the patient's attending physician should the patient experience any adverse reactions from treatment used with this device.

Note: Always use devices that are legally marketed and sold in the United States under 510K guidelines.

4. If the stimulation levels are uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if any problems persist.

Applicator Movement

If movement of the applicator is too slow, the patient may feel periosteal pain characterized by a deep ache or pain. If motion is too fast, or if the applicator does not maintain good contact with the skin, the therapeutic effect of the sound waves will be reduced and the applicator may overheat.

Patient Susceptibility

Some patients are more sensitive to ultrasound output and may experience a reaction similar to a heat rash. Be sure to inspect the treatment area during and following treatment, and discontinue if an adverse reaction does occur.

Coupling

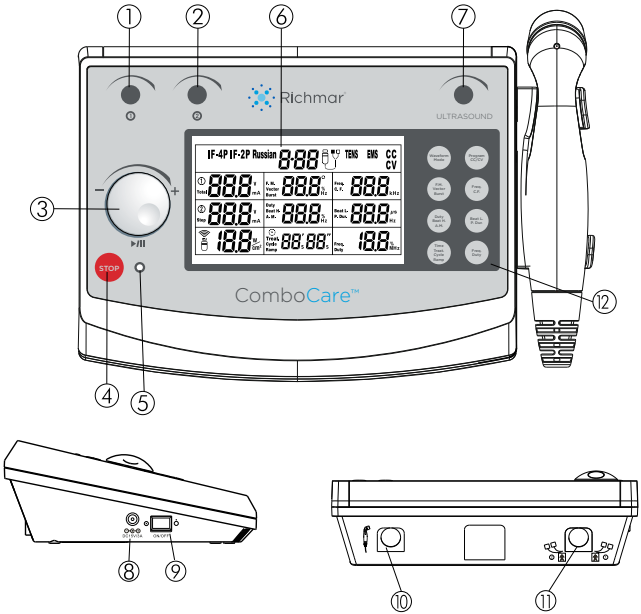
Coupling is described as contact between the applicator and the treatment site and may be accomplished through the use of a coupling agent, such as gel, lotion. Anything used as a coupling agent must be highly conductive. Air is a very poor conductor of ultrasonic waves.

⚠ WARNING

1. The device complies completely with all parts of 21 CFR 1050. 10 of the performance standard for sonic, infrasonic and ultrasonic radiation-emitting product.
2. 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

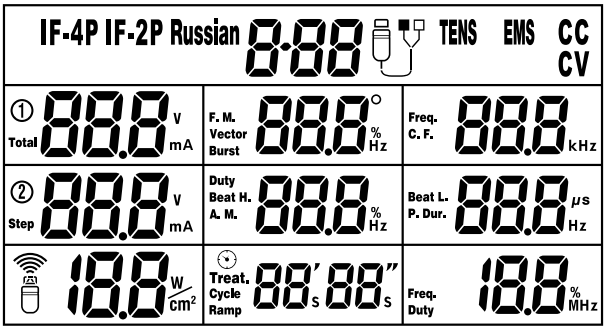
3.1 Panel for Front View



1. Select Channel 1 or adjust the output intensity of channel 1.
2. Select Channel 2 or adjust the output intensity of channel 2.
3. Central Controller Dial and Pause button.
4. Stop treatment button.
5. Power indicator.
6. LCD display: Shows the current information of the device.
7. Ultrasound output intensity control knob
8. Adapter receptacle
9. ON / OFF switch
10. Output connector: connect with ultrasound applicator
11. Output connector: connect with electrical stimulation cable
12. Eight parameters selection buttons, see next page for details:

Button	Remark	
	Waveform Mode	Choose between therapeutic modes: Electrical stimulation, Ultrasound therapeutic or Combo therapeutic
	Program CC—Constant Current output mode CV—Constant voltage output mode	Choose the therapeutic program, select the [CC/CV] or switch program types (Common or professional)
	F.M.—Frequency Modulation Vector Burst—Burst Frequency	Choose the parameter F.M/Vector/Burst
	Freq.—Frequency C.F.—Carrier Frequency	Press to adjust Freq. and Carrier Freq.
	Duty—Duty Cycle for Russian Waveform Beat H. Sweep High Beat Frequency A.M.—Amplitude Modulation	Press to adjust Duty/Beat H./A.M.
	Beat L.—Sweep Low Beat Frequency P. Dur—Pulse Duration	Press to adjust Beat L./P. Dur
	Time Treat.—Treatment Time Cycle—Cycle time Ramp—Ramp Time	Press to adjust Treat./Cycle/Ramp
	Freq.—Frequency for Ultrasound Duty—Duty Cycle for Ultrasound	Choose the parameter Freq./Duty for ultrasound

3.2 User Interface



Symbol Definitions			
IF-4P	IFC-Interferential (Traditional 4 Pole)		Ultrasound output indicator
IF-2P	IFC-Interferential (Traditional 2 Pole)	CC	Constant current control
① ②	Electrical output channel indicator	88.8	Parameter
	Electrical Stimulation/ Ultrasound therapeutic/ Combination therapy		Time indicator
8:88	Therapeutic program	CV	Constant Voltage control

4. Installation

Remove the equipment and all accessories from shipping carton and gift-box. Visually check if there is any damage or missing parts or accessories. If yes, please report to local dealer or retailer where you purchase this unit. Your ComboCare™ equipment contains the following accessories.

No.	Part #	Part	Quantity
1	ER2535B2	Rubber electrodes 2.5"x3.5"	2
2	ER2743B2	Rubber electrodes 2.75"x4.3"	2
3	ES2740Y2	Electrode Sponges 2.75"x4"	2
4	ES3047Y2	Electrode Sponges 3.0"x4.75"	2
5	E1P2020WC2	Self-adhesive Electrodes 2"x2"	4
6	E1P2035WC2	Self-adhesive Electrodes 2"x3.5"	4
7	EW2023BW2	Elastic Wrap 3"x23.5"	1
8	EW3047BW2	Elastic Wrap 3"x47"	1
9	WQ6005PLUG	Electrode wires (black/red)	2
10	DQ2001MGC	Adapter 100-240V~47-63Hz	1
11		Power Cord	1
12	DQ8432CPLUG	Electrical Stimulation Cable	1
13	WW1001PLUG	Electrode Wire for Ultrasound Combination	1
14	DQ9275W5	5cm² Aer ultrasound applicator	1
15	LC5288	Transmission gel	1
16	DQ9275W1	1cm² ultrasound applicator (optional)	1
17		Operating manual	1

4.1 Connection of the Power Adapter

- Connect the power cord to the power adapter
- Connect the power adapter to the device connector
- Connect the power adapter to a wall socket

⚠ CAUTION:

- Prior to connecting this apparatus to the power supply, check that the voltage and frequency states on the rating label match with the available power supply.
- The power adapter is a part of the supply circuit on which the device's safety partly depends. The approvals for ComboCare™ are only valid if used in combination with this type of adapter.

4.2 Switching On

Switch on the device, using ON/OFF switch **[⊙]**

4.3 Switching Off and Disconnect Power Adapter

- Switch off the device by switching the ON/OFF switch from **[⊙]** to **[⏻]** position.
- Pull out the power adapter from the wall socket.
- Pull out the power adapter from device.

5. OPERATION

5.1 Check Before Treatment

- Ensure there are no contraindications to treatment.
- Inspect the treatment area skin seriously for any abrasions, inflammation, surface veins etc.
- Clean the skin of the treatment area with soap or alcohol (70%).
- If the skin is hairy, shaving can get optimal treatment.
- Test the heat sensibility of the treatment area.

5.1.1 Electrode Placement

- Examine the skin for any wound and clean the skin.
- Apply the electrodes to the treatment area or around the treatment area. At least 2" but no more than 6" apart, per channel
- Ensure that the electrodes are applied securely to the skin.
- Ensure good contact between each electrode and the skin.
- Check the electrode contact regularly during the treatment.
- Examine the skin again after the treatment.
- Choose electrodes that fit the anatomy.
- Follow electrode manufacturer;s instructions.
- To avoid skin irritation due to high current density, **DO NOT** use electrodes smaller in surface area than 25cm² self-adhesive electrode.

⚠ CAUTION:

- Keep electrodes separated during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.
- Output current density is related to electrode size. Improper application may result in patient injury. If any question arises as to the proper electrode size, consult a licensed practitioner prior to therapy session.
- Powered muscle stimulator should be used only with the leads and electrodes recommended by the manufacturer.

5.1.2 Adhesive Electrodes

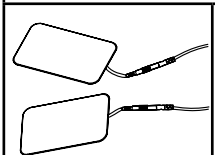
This device is supplied with 4 pieces 2"x2" and 4 pieces 2"x3.5" adhesive electrodes. You can select the right adhesive electrodes according to treatment area and output current density. It is recommended that manufacturer's electrodes be used whenever possible to ensure the highest level of contact with the treatment area and most uniform delivery of the prescribed electro-therapy treatment. Properly dispose of used Electrodes upon completion of the therapy session.

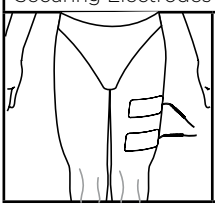
After the electrodes no longer stick to the treatment site completely, dispose of electrodes and start with new electrodes. Replacement electrodes should be re-ordered through or on the advice of your physician to ensure proper quality.

⚠ CAUTION:

1. Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
2. **DO NOT** turn on the device when the electrodes are not positioned on the body.
3. **NEVER** remove the self-adhesive electrodes from the skin while the device is still turns on.
4. It is recommended that, at minimum, 2"x2" self-adhering based, square electrodes are used at the treatment area.

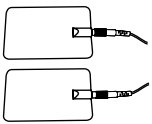
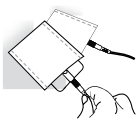
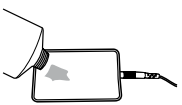
5.1.3 Electrode Instructions

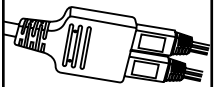
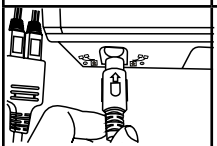
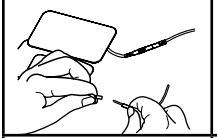
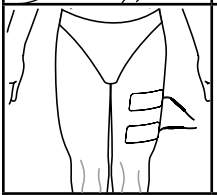
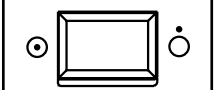
Connecting Lead Wires	
	Insert the lead with the Red (+) electrode connector into one adhesive Electrode. Insert the lead with the Black (-) electrode connector into the other electrode. Make certain the lead wires are seated completely into the electrodes, there are no bare metal of the pins exposed.

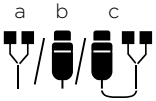
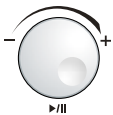
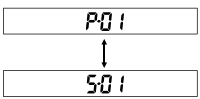
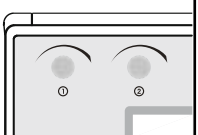
Securing Electrodes	
	Remove the adhesive Electrodes from the protective backing and apply to the treatment area as prescribed. Ensure that the entire electrode surface is in contact with patient skin by pressing into place.

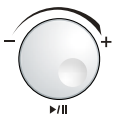
5.1.4 Rubber Electrodes

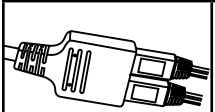
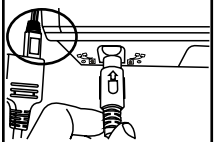
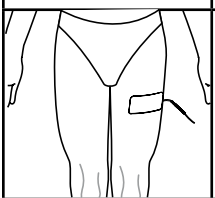
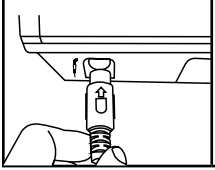
If used for delivery of electro-therapy, there are two conductive mediums for you to select, the first one is use electrode sponges as conductive mediums, another is use other conductive medium such as Transmission Gel. If using sponges, make sure the sponges are damp before putting electrodes into the sponges. These rubber Electrodes should be secured to the treatment area using the Nylon Wraps shipped with the Therapy System.

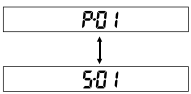
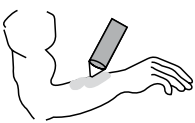
Rubber Electrodes - Connecting Lead Wires 	Insert the lead with the red (+) electrode connector into one adhesive electrode. Insert the lead with the black (-) electrode connector into the other electrode. Make certain the lead wires are seated completely into the electrodes, and there are no bare metal parts of the pins exposed.
Conductive Medium 1 	Insert the rubber electrodes into the electrode sponges that have been moistened with distilled water.
Conductive Medium 2 	Liberally apply transmission gel to electrode prior to placement on the patient. Please note: purchase the transmission gel with CE mark or that has been cleared by the FDA.
Elastic Straps to secure rubber electrodes in place 	Use Nylon Wrap to secure each rubber electrode into position on the patient.

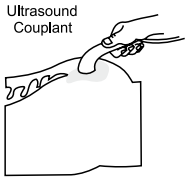
5.2 Quick Set-up for Electrical Stimulation	
	1. When you turn the ComboCare™ on, the device will get down to self-check about 10 seconds, and then the default parameters displayed are the last treatment mode. ⚠ **DO NOT** turn device on with patient attached to the device as it could shock the patient during device self-check. Connect patient AFTER device has been turned on.
	2. Connect the electrode wires to the cable; please note the color of the wires and the color marks on the cable, they should be corresponding.
	3. ComboCare™ has two connectors, one is electrical stimulation connector, the other is ultrasound connector. In this step, please plug the electrical stimulation cable into electrical stimulation connector.
	4. Connect the electrodes to electrode wires.
	5. Place the electrodes on the patient. You will need to use at least one channel, with two electrodes. You can also use two channels with four electrodes as shown in the figure to the left. Place electrodes at least 2” but no more than 6” apart, per channel.
	6. In order to turn on the device, please press ON/OFF switch to **[⊙]** icon which is located on the side of the device.

	7. This device has three working modes: a. Electrical Stimulation Only b. Ultrasound Only c. Combination Stim & Ultrasound Press **[Waveform/Mode]** button to select electrical stimulation mode.
	8. There are 5 therapeutic waveforms for you to select. Rotate the Central controller dial to select waveform like Interferential, TENS, Russian, and EMS after you selected electrical stimulation therapeutic mode.
	9. Each therapeutic waveform has 10 programs. Press the **[Program/CC/CV]** button to choose between P1-P10 by rotating the central controller dial until the desired program is displayed on the screen.
	10. There are two programs on this device: • Common program • Specialty program. Common program has only one treatment phase and the program displays “P-”. In specialty program, there are three treatment phases display and the program displays “S-” like figure. You can press and hold **[Program/CC/CV]** button to switch them.
	11. Press the **[Program/CC/CV]** button to choose CC for constant current.
	12. To adjust the output intensity, press the corresponding channel being used for treatment and rotate the knob clockwise until a strong but comfortable stimulation is felt. The “STIM” symbol indicates when the device is giving the patient an active stimulation. When “STIM” is not present on the screen, **DO NOT** increase intensity anymore until it is displayed again, to avoid any sudden spikes.

① 10.0 mA ② 10.0 mA	13. For safety using, load detection was designed in this device after the output intensity surpass 10.0mA/10.0V. If there are no electrodes stuck on patients' skin, an alarm buzzer sound will appear and the intensity value will flash .
	14. Press the **[STOP]** button to stop treatment of the current channel(s). If you want to stop the other channel(s) treatment, press corresponding channel button first, and then press the **[STOP]** button. ⚠ **CAUTION**: This will only stop the selected flashing channels, not both channels.
	15. To pause a channel, press the corresponding channel knob on the top of the device and then press the central controller dial to pause that channel. Each channel must be paused individually.

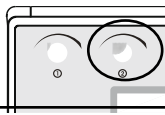
5.3 Quick Set-up for Combo Therapeutic (Ultrasound and Electrical Stimulation)	
	1. In Combo therapeutic mode, the Ultrasound probe is the Negative of channel 2. To create a combination US/EStim connection, connect the combination lead wire (1 lead) to the positive side of channel 2. Channel 1 will have no output.
	2. Plug the cable into the corresponding output connector on ComboCare™. Connect the electrode to the Channel 2 connector on the back of the device. Channel 1 will remain open. 3. Connect combination lead wire (red) to the grey connector. Channel 1 should remain open (as shown circled, to the left).
	4. Connect one electrode to the combination lead wire (red) and place near (above or below) area being treated with combination therapy. **Note:** Make sure electrode is far enough away from treatment site so it does not come in contact with ultrasound gel during treatment.
	5. For ultrasound, plug the ultrasound applicator into the ultrasound connector. ⚠ **CAUTION:** Don't plug or pull out the ultrasound applicator when the device turned on.

	6. Press **[Waveform/Mode]** button until [🕯] indicator display on LCD.
	7. There are 4 therapeutic waveforms that can be used for combo therapeutic. Rotate the Central controller dial to select waveform like Premodulated, TENS, Russian, and EMS.
	8. Each waveform has 10 programs. Press the **[Program/CC/CV]** button to choose between P1-P10 by rotating the central controller dial until the desired program is displayed on the screen.
	9. There are two programs on this device: • Common program • Specialty program Common program has only one treatment phase and the program displays “P-”. In the specialty program, there are three treatment phases display and the program displays “S-” like the figure. You can press and hold **[Program/CC/CV]** button to switch them.
	10. Apply a layer of transmission gel to the treatment area. Please note: Please purchase the transmission gel that is cleared by the FDA.



11. Couple the applicator to the treatment area by keeping the entire surface of the applicator in contact with the gel that has been applied to the patient. Move applicator in a slow but continuous circular motion. This will ensure an efficient delivery of therapeutic ultrasound to the patient. Green LED on either side of the applicator will light when coupling is achieved.

12. Adjust the intensity and start ultrasound treatment that you are using by rotating the ultrasound output intensity adjustable knob on the control panel. Press the knob to change the ultrasound unit “W” or “W / cm²”.



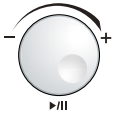
13. Adjust the output intensity of the CH2 to start electrical treatment that you are using by rotating the output intensity adjustable knob on the control panel to the patient’s comfort level.

14. For safety using, load detection was designed in this device after the stimulation output intensity surpass 10.0V or the ultrasound intensity over 0.5W. If there are no electrodes stuck on patient’ skin or the applicator is inadequate coupling to the patient, an alarm buzzer sound will appear, the stimulation intensity value and [] symbol will flash.

15. Press the **[STOP]** button to stop treatment if any emergency or error occurs.

⚠ **CAUTION:**

1. For device protection, a temperature detection feature was designed to stop electrical stim when temps reach over 160°F. The device will not work again unless the temperature reaches 140°F.
2. To protect the patient, the device will stop ultrasound intensity output and the LED on the applicator will flash if the applicator temperature over 107°F. It will resume again when the temperature below 105°F.

	16. To Pause treatment, first press CH2 knob and then press the central controller dial to pause the treatment.

5.4 The Default Parameters

Each therapeutic waveform has 10 programs, you can set and save the parameters of all programs, the details about default parameters please refer to below:

Waveform	Pro-gram	Phase	CC/ CV	Vector (auto)	Vector (manual) (°)	C.F. (kHz)	Beat H. (Hz)	Beat L. (Hz)	Ultra-sound (MHz, 50%)	Treat. Time (min)
Interferential Traditional (4 pole)	1	1	CC	0	45	4.0	110	100	1	15
		2	CC	0	45	4.0	110	100	1	0
		3	CC	0	45	4.0	110	100	1	0
	2	1	CC	0	45	4.0	150	100	1	10
		2	CC	0	45	4.0	150	100	1	0
		3	CC	0	45	4.0	150	100	1	0

Waveform	Pro-gram	Phase	CC/ CV	Vector (auto)	Vector (manual) (°)	C.F. (kHz)	Beat H. (Hz)	Beat L. (Hz)	Ultra-sound (MHz, 50%)	Treat. Time (min)
Interferential Traditional (4 pole)	3	1	CC	0	45	4.0	50	50	1	15
		2	CC	0	45	4.0	50	50	1	0
		3	CC	0	45	4.0	50	50	1	10
	4	1	CC	0	45	4.0	150	90	1	15
		2	CC	0	45	4.0	150	90	1	0
		3	CC	0	45	4.0	150	90	1	0
	5	1	CC	0	45	4.0	110	100	1	15
		2	CC	0	45	4.0	110	100	1	0
		3	CC	0	45	4.0	110	100	1	0
	6	1	CC	0	45	4.0	110	100	1	15
		2	CC	0	45	4.0	110	100	1	15
		3	CC	0	45	4.0	110	100	1	15
	7	1	CC	0	45	4.0	110	100	1	15
		2	CC	0	45	4.0	110	100	1	15
		3	CC	0	45	4.0	110	100	1	15
	8	1	CC	0	45	4.0	110	100	1	15
		2	CC	0	45	4.0	110	100	1	15
		3	CC	0	45	4.0	110	100	1	15
	9	1	CC	0	45	4.0	110	100	1	15
		2	CC	0	45	4.0	110	100	1	15
		3	CC	0	45	4.0	110	100	1	15
	10	1	CC	0	45	4.0	110	100	1	15
		2	CC	0	45	4.0	110	100	1	15
		3	CC	0	45	4.0	110	100	1	15

Waveform	Pro-gram	Phase	CC/ CV	C.F. (kHz)	Beat H. (Hz)	Beat L. (Hz)	Ultrasound (MHz, 50%)	Treat. Time (min)
Premodulated Traditional (2 Pole)	1	1	CC	2.5	110	100	1	15
		2	CC	2.5	110	100	1	0
		3	CC	2.5	110	100	1	0
	2	1	CC	2.5	150	100	1	10
		2	CC	2.5	150	100	1	0
		3	CC	2.5	150	100	1	0
	3	1	CC	2.5	50	50	1	15
		2	CC	2.5	50	50	1	0
		3	CC	2.5	50	50	1	10
	4	1	CC	2.5	150	90	1	15
		2	CC	2.5	150	90	1	0
		3	CC	2.5	150	90	1	0
	5	1	CC	2.5	110	100	1	15
		2	CC	2.5	110	100	1	0
		3	CC	2.5	110	100	1	0
	6	1	CC	2.5	110	100	1	15
		2	CC	2.5	110	100	1	15
		3	CC	2.5	110	100	1	15
	7	1	CC	2.5	110	100	1	15
		2	CC	2.5	110	100	1	15
		3	CC	2.5	110	100	1	15
	8	1	CC	2.5	110	100	1	15
		2	CC	2.5	110	100	1	15
		3	CC	2.5	110	100	1	15
	9	1	CC	2.5	110	100	1	15
		2	CC	2.5	110	100	1	15
		3	CC	2.5	110	100	1	15
	10	1	CC	2.5	110	100	1	15
		2	CC	2.5	110	100	1	15
		3	CC	2.5	110	100	1	15

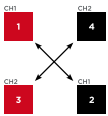
Waveform	Program	Phase	CC/CV	Freq. (Hz)	P. Dur. (μs)	Ultrasound (MHz, 50%)	Treat. Time (min)
TENS	1	1	CC	120	70	1	14
		2	CC	120	70	1	0
		3	CC	120	70	1	0
	2	1	CC	200	60	1	20
		2	CC	200	60	1	0
		3	CC	200	60	1	0
	3	1	CC	10	180	1	20
		2	CC	10	180	1	0
		3	CC	10	180	1	10
	4	1	CC	80	100	1	30
		2	CC	80	100	1	0
		3	CC	80	100	1	0
	5	1	CC	180	30	1	16
		2	CC	180	30	1	0
		3	CC	180	30	1	0
	6	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14
	7	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14
	8	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14
	9	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14
	10	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14

Waveform	Program	Phase	CC/CV	Freq. (Hz)	P. Dur. (μs)	Ultrasound (MHz, 50%)	Treat. Time (min)
EMS	1	1	CC	120	70	1	14
		2	CC	120	70	1	0
		3	CC	120	70	1	0
	2	1	CC	200	60	1	20
		2	CC	200	60	1	0
		3	CC	200	60	1	0
	3	1	CC	10	180	1	20
		2	CC	10	180	1	0
		3	CC	10	180	1	10
	4	1	CC	80	100	1	30
		2	CC	80	100	1	0
		3	CC	80	100	1	0
	5	1	CC	180	30	1	16
		2	CC	180	30	1	0
		3	CC	180	30	1	0
	6	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14
	7	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14
	8	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14
	9	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14
	10	1	CC	120	70	1	14
		2	CC	120	70	1	14
		3	CC	120	70	1	14

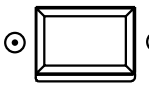
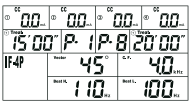
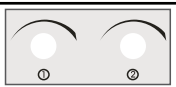
Wave-form	Pro-gram	Phase	CC/ CV	C.F. (kHz)	Freq. (Hz)	Duty (%)	Cycle (s/s)	Ramp (s)	Ultrasound (MHz, 50%)	Treat. Time (min)
Russian	1	1	CC	2.5	50	50	10/10	1	1	10
		2	CC	2.5	50	50	10/10	1	1	0
		3	CC	2.5	50	50	10/10	1	1	0
	2	1	CC	2.5	50	50	4/12	1	1	10
		2	CC	2.5	50	50	4/12	1	1	0
		3	CC	2.5	50	50	4/12	1	1	0
	3	1	CC	2.5	50	50	4/12	1	1	10
		2	CC	2.5	50	50	4/12	1	1	0
		3	CC	2.5	50	50	4/12	1	1	0
	4	1	CC	2.5	50	50	10/10	1	1	10
		2	CC	2.5	50	50	10/10	1	1	0
		3	CC	2.5	50	50	10/10	1	1	0
	5	1	CC	2.5	50	50	5/5	1	1	20
		2	CC	2.5	50	50	5/5	1	1	0
		3	CC	2.5	50	50	5/5	1	1	0
	6	1	CC	2.5	50	50	10/10	1	1	10
		2	CC	2.5	50	50	10/10	1	1	10
		3	CC	2.5	50	50	10/10	1	1	10
	7	1	CC	2.5	50	50	10/10	1	1	10
		2	CC	2.5	50	50	10/10	1	1	10
		3	CC	2.5	50	50	10/10	1	1	10
	8	1	CC	2.5	50	50	10/10	1	1	10
		2	CC	2.5	50	50	10/10	1	1	10
		3	CC	2.5	50	50	10/10	1	1	10
	9	1	CC	2.5	50	50	10/10	1	1	10
		2	CC	2.5	50	50	10/10	1	1	10
		3	CC	2.5	50	50	10/10	1	1	10
	10	1	CC	2.5	50	50	10/10	1	1	10
		2	CC	2.5	50	50	10/10	1	1	10
		3	CC	2.5	50	50	10/10	1	1	10

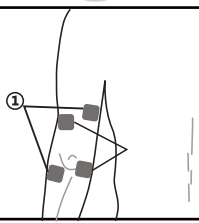
5.5 Each Stimulation Set-Up Procedure

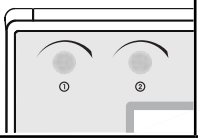
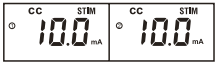
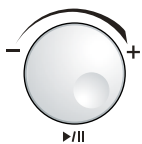
WARNING: When using IF-4P, you must use 2 channels (4 electrodes) and criss cross the channels as shown in the picture to the right. If using IF-2P, only use one channel (two electrodes).



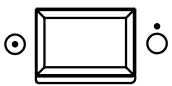
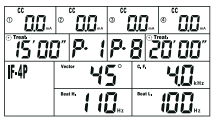
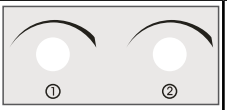
5.5.1 4-Pole Interferential Stimulation Set-up Procedure

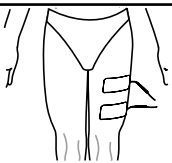
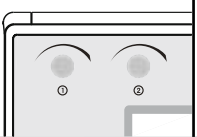
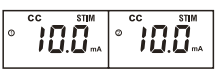
	1. In order to turn on the device, press ON/ OFF switch to [⊙] icon which is located on the side of the device
	2. When you turn the ComboCare™ on, the device will perform a self-check for about 6-8 seconds, and then the default parameters will display the last treatment mode.
	3. Press channel 1 or 2 button to enter channel 1 and channel 2 parameter setting mode.
	4. Press the **[Waveform]** button to choose the therapeutic waveform, and then rotate the central controller dial ( ) to select "**IF-4P**" waveform.
	5. Press the **[Program/Save]** button to choose between P1 – P10. Then rotate the central controller dial ( ) to until the desired program number is displayed.
 	6. There are two modes in the device: Normal/Default Mode Professional Mode To switch from Normal to Professional, press and hold the **[Step]** button until you hear a "beep". The program will change from P1 to S1 for professional mode. In Professional Mode, each program has 2 treatment steps. Press the **[Step]** button again and the display will show like the figure to the left. The parameters of each step can be set according to the following methods.

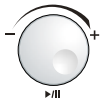
CC	7. Press the **[Waveform]** button to choose CC for constant current.
Vector F.M. Burst Vector 0 %	8. Press the **[Vector]** button, once to choose a manual vector degree. Press the **[Vector]** button a second time to choose the auto vector percentage (%) setting. Then rotate the Central controller knob ( ) to adjust to the desired setting.
Beat H. A.M. Duty	9. Press the **[Beat H.]** button, and then rotate the central controller dial ( ) to set the parameter from (Beat. L) Hz to 150Hz, 1Hz/step.
Beat L. P. Dur. Freq.	10. Press the **[Beat L.]** button, and then rotate the central controller dial ( ) to set the parameter from 1Hz to(Beat. H)Hz, 1Hz/step. (**Note**: Beat L. parameter will not exceed Beat H. setting.
Time Cycle Ramp	11. Press the **[Time]** button, and then rotate the central controller dial ( ) to set the treatment time from 1min to 60min, 1min/step.
Program Save	12. Press and hold the **[Save]** button until you hear a “beep” sound if you want to save all settings. **Note**: The settings will not be saved if you have not followed the steps above.
	13. Place the electrodes on the patient. You will need to use at least one channel, with two electrodes. You can also use two channels with four electrodes as shown in the figure to the left. Place electrodes at least 2” but no more than 6” apart, per channel.

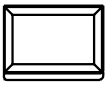
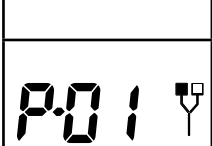
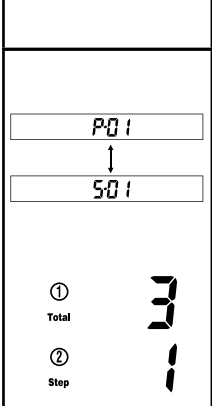
	14. To adjust the output intensity, press the corresponding channel being used for treatment and rotate the knob clockwise until a strong but comfortable stimulation is felt. The “STIM” symbol indicates when the device is giving the patient an active stimulation. When “STIM” is not present on the screen, **DO NOT** increase intensity anymore until it is displayed again, to avoid any sudden spikes.
	15. For safety purposes, the load detection function was designed so when the output intensity surpasses 10.0mA/10.0V, and there are no electrodes placed on the patient’s skin or the device has not been connected to electrodes, an alarm buzzer will sound and the intensity value will flash and reset to zero.
	16. To pause a channel, press the corresponding channel knob on the top of the device and then press the central controller dial to pause that channel. Each channel must be paused individually.
	17. Press the **[STOP]** button to stop treatment of the current channel(s). If you want to stop the other channel(s) treatment, press corresponding channel button first, and then press the **[STOP]** button. ⚠ **CAUTION**: This will only stop the selected flashing channels, not both channels.

5.5.2 IF 2-P Interferential Stimulation Set Up Procedure

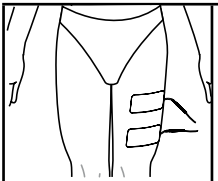
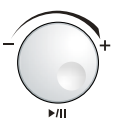
	1. To turn on the device, press the ON/OFF switch to [⊙] icon which is located on the side of the device.
	2. When you turn the ComboCare™ on, the device will perform a self-check for about 6-8 seconds, and then the default parameters will display the last treatment mode.
	3. Press channel 1 or 2 knob to enter channel 1 and channel 2 parameter setting mode.
	4. Press the **[Waveform]** button to choose the therapeutic waveform. Then rotate the central controller dial (⚙) to select "**IF-2P**" waveform.
	5. Press the **[Program/Save]** button to choose between P1-P10. Then rotate the central controller dial (⚙) until the desired program number is displayed.
 	6. There are two modes in the device: Normal/Default Mode Professional Mode To switch from Normal to Professional, press and hold the **[Step]** button until you hear a "Beep". The program will change from P1 to S1 for professional mode. In Professional Mode, each program has 2 treatment steps. Press the **[Step]** button again and the display will show like the figure to the left. The parameters of each step can be set according to the following methods.

CC	7. Press the **[Waveform]** button to choose CC for Constant Current
Beat H. A.M. Duty	8. Press the **[Beat H.]** button, and then rotate the central controller dial ( ) to set the parameter from (Beat. L) Hz to150Hz, 1Hz/step.
Beat L. P. Dur. Freq.	9. Press the **[Beat L.]** button, and then rotate the central controller dial ( ) to set the parameter from 1Hz to (Beat. H) Hz, 1Hz/step. (**Note**: Beat L parameter will not exceed Beat H. setting)
Time Cycle Ramp	10. Press the **[Time]** button, and then rotate the central controller dial ( ) to set the treatment time from 1min to 60min, 1min/step.
Program Save	11. Press and hold the **[Save]** button until you hear a "beep" sound if you want to save all settings. **Note**: The settings will not be saved if you have not followed the steps above.
	12. Place the electrodes on the patient. You will need to use at least one channel, with two electrodes. You can also use two channels with four electrodes as shown in the figure to the left. Place electrodes at least 2" but no more than 6" apart, per channel.
	13. Adjust the output intensity and start treatment by rotating the output intensity adjustment knobs on the control panel. (0.5mA/step or 0.5V/step.) The "STIM" symbol in the LCD indicates there is intensity output. Some waveforms have a pause in the middle of treatment and then it will start up again. **DO NOT** increase intensity if "STIM" is not blinking at the top.
	14. For safety purposes, the load detection function was designed so when the output intensity surpasses 10.0mA/10.0V, and there are no electrodes placed on the patient's skin or the device has not been connected to electrodes, an alarm buzzer will sound and the intensity value will flash and reset to zero.

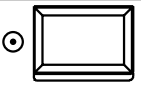
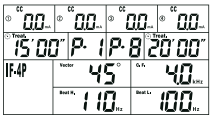
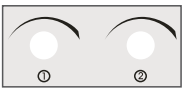
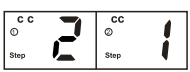
	15. To pause a channel, press the corresponding channel knob on the top of the device and then press the central controller dial to pause that channel. Each channel must be paused individually.
	16. Press the **[STOP]** button to stop treatment of the current channel(s). If you want to stop the other channel(s) treatment, press corresponding channel button first, and then press the **[STOP]** button. ⚠ **CAUTION**: This will only stop the selected flashing channels, not both channels.

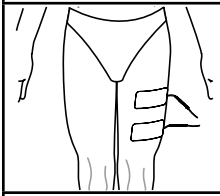
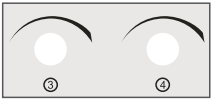
5.5.3 TENS and EMS Stimulation Set-up Procedure	
	1. In order to turn on the device, please press ON/OFF switch to [⊙] icon which is located on the side of the device.
	2. When you turn the ComboCare™ on, the device will self-check for about 10 seconds, and then the default parameters will display the last treatment mode.
	3. Press **[Waveform/Mode]** button to choose electrical stimulation mode [ ], then rotate the Central controller dial to select TENS or EMS mode. In TENS mode, the symbol “TENS” will display on LCD; in EMS mode, the symbol “EMS” will display on LCD.
	4. Each waveform has 10 programs. Press the **[Program/CC/CV”]** button to choose between P1-P10 by rotating the central controller dial until the desired program is displayed on the screen.
	5. There are two programs on this device: • Common program • Specialty program. Common program has only one treatment phase and the program displays “P-”. In specialty program, there are three treatment phases display and the program displays “S-” like figure. You can press and hold **[Program/CC/CV]** button to switch them. If you selected specialty program, please press the Central controller dial to select treatment phase from 1 to 3. The parameters of each treatment phase can be set according to following methods.
	6. Press the **[Program/CC/CV]** button to choose CC for constant current.

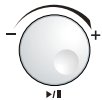
F. M. 0 Hz	7. Press **[F.M./Vector/Burst]** button and then rotate the central controller dial ( ) **Note**: to set the F.M. PLUS Freq. (next setting) must be ≤ 250Hz.
Burst 0 Hz	8. Press **[F.M./Vector/Burst]** button and then rotate the Central controller dial to set the Burst rate from 0Hz to 10Hz, 1Hz/step. But Burst x 8 <Freq.
Freq. 120 Hz	9. Press **[Freq./C.F.]** button and then rotate the central controller dial ( ) **Note**: to set Freq. correctly, note that Freq. (next setting) must be .≤ 250 MINUS F.M. Setting.
A. M. 0 %	10. Press **[Duty/Beat H./A.M.]** button then rotate the central controller dial ( ) to set the parameter from 0% to 100% "A.M." means amplitude modulation, the setting value indicates percentage of modulation, e.g.: "0%" means no modulation, the intensity is outputting at the setting value continuously. "100%" means the output intensity is modulated between 0 and the setting value.
P. Dur. 70 µs	11. Press **[Beat L./P.Dur.]** button and then rotate the central controller dial ( ) to set the pulse duration from 30µs to 400µs,5µs/step.
Treat. 14'00"	12. Press **[Time Treat./Cycle/Ramp]** button to and then rotate the central controller dial ( ) to set the treatment time from 1min to 60min, 1min/step.
Cycle - S - S	13. Press **[Time Treat./Cycle/Ramp]** button again to choose Cycle time, and then rotate the central controller dial ( ) to select the cycle time from "-/-(continuous)", "4/4", "4/8", "7/7", "5/5", "4/12", "10/10", "10/20", "10/30" and "10/50".

	14. Place the electrodes on or around the treatment area. You can choose to use one channel or two channels but must have at least two electrodes placed on the patient as shown in the figure to the left. Electrodes should be at least 2” but no more than 6” apart, per channel..
① 10.0 mA ② 10.0 mA	15. For safety purposes, the load detection function was designed so when the output intensity surpasses 10.0mA/10.0V, and there are no electrodes placed on the patient’s skin or the device has not been connected to electrodes, an alarm buzzer will sound and the intensity value will flash and reset to zero. Note: If the pulse duration is less than 80μs, the load detection function will activate when output intensity surpasses or equal 40.0mA/40.0V.
STOP	16. Press the **[STOP]** button to stop treatment if any emergency or error happened. ⚠ **CAUTION:** 1. For device protection, a temperature detection feature was designed to stop electrical stim when temps reach over 160°F. The device will not work again unless the temperature reaches 140°F. 2. To protect the patient, the device will stop ultrasound intensity output and the LED on the applicator will flash if the applicator temperature over 107°F. It will resume again when the temperature below 105°F.
	17. Press the Central controller dial to pause a channel, press the corresponding channel knob on the top of the device and then press the central controller dial to pause that channel. Each channel must be paused individually.

5.5.4 Russian S/A Stimulation Set-up Procedure

	1. To turn on the device, press the ON/OFF switch to [⊙] icon which is located on the side of the device.
	2. When you turn the ComboCare™ on, the device will perform a self-check for about 6-8 seconds, and then the default parameters will display the last treatment mode.
	3. Press channel button to enter channel 1 and channel 2 parameter setting mode.
	4. Press the **[Waveform]** button to choose the therapeutic waveform. Then rotate the central controller dial ( ) to select "**Russian S**" or "**Russian A**" waveform.
	5. Press the **[Program/Save]** button to choose between P1-P10. Then rotate the central controller dial until the desired program number is displayed.
 	6. There are two modes in the device: Normal/Default Mode and Professional Mode To switch from Normal to Professional, press and hold the **[Step]** button until you hear a "Beep". The program will change from P1 to S1 for professional mode. In Professional Mode, each program has 2 treatment steps. Press the **[Step]** button again and the display will show like the figure to the left. The parameters of each step can be set according to the following methods.
	7. Press the **[Waveform]** button to choose CC for constant current.
	8. Press the **[Duty]** button, and then rotate the central controller dial ( ) to set the parameter from 10% to 50%, 10%/step.

Beat L. P. Dur. Freq.	9. Press the **[Freq.]** button and then rotate the central controller dial ( ) to set the frequency from 20Hz to100Hz, 5Hz/step.
Time Cycle Ramp	10. Press the **[Time]** button, and then rotate the central controller dial ( ) to set the treatment time from 1min to 60min, 1min/step.
Cycle S S	11. Press the **[Time]** button again to choose Cycle time, and then rotate the central controller dial ( ) to select the cycle time (contr/ relax) from "-/-(continuous)", "5/5", "4/12", "10/10", "10/20", "10/30" and "10/50".
Ramp S	12. Press the **[Time]** button again to choose Ramp time, and then rotate the central controller dial ( ) to select the ramp time from 1s, 2s and 5s.
Program Save	13. Press and hold the **[Save]** button until you hear a "beep" sound if you want to save all settings. **Note**: The settings will not be saved if you have not followed the step above.
	14. Place the electrodes on the patient. You will need to use at least one channel, with two electrodes. You can also use two channels with four electrodes as shown int he figure to the left. Place electrodes at least 2" but no more than 6" apart, per channel.
	15. Adjust the output intensity and start treatment by rotating the output intensity adjustable knobs on the control panel. (0.5mA/step or 0.5V/step). The "STIM" symbol in the LCD indicates there is intensity output. Some waveforms have a pause in the middle of treatment and then it will start up again. **DO NOT** increase intensity if "STIM" is not blinking at the top.

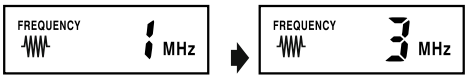
	16. For safety purposes, the load detection function was designed so when the output intensity surpasses10.0mA/10.0V, and there are no electrodes placed on the patient's skin or the device has not been connected to electrodes, an alarm buzzer will sound and the intensity value will flash and reset to zero.
	17. To pause a channel, press the corresponding channel knob on the top of the device and then press the central controller dial to pause that channel. Each channel must be paused individually.
	18. Press the **[STOP]** button to stop treatment of the current channel(s). If you want to stop the other channel(s) treatment, press corresponding channel button first, and then press the **[STOP]** button. ⚠ **CAUTION**: This will only stop the selected flashing channels, not both channels.

Remark:

1. There is a "beeping" sound which will appear for approximately 20 seconds to alert the user after the treatment has finished. Press any button to cancel the "beeping" sound.
2. If you want to restore factory parameter settings, turn the device off then press and hold knobs (1) and (2) at the same time, and then turn on the device by pressing the ON/OFF switch, keep pressing the (1) and (2) knobs and the device will continuously beep until all parameters are restored to the factory setting.

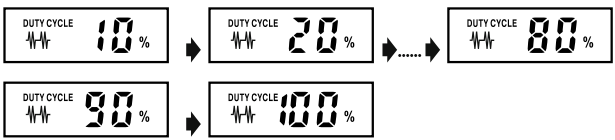
5.5.5 Ultrasound Set-Up Procedure

Select the Ultrasound Frequency: 1MHz or 3MHz
Freq Up/Down Selection: Press ▲▼ button next to FREQUENCY to choose the desired frequency for treatment.

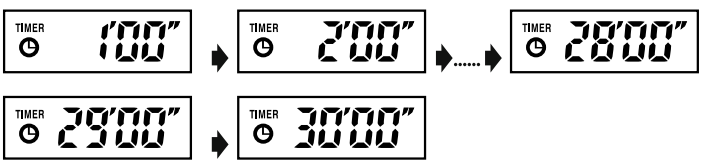


⚠ **CAUTION**:
When only one sound head is connected, the device will automatically detect which one is connect and the sound head that is not plugged in will show as not selectable on the treatment screen.

Select Duty Cycle
Duty Cycle Selection: Press ▼ or ▲ button next to DUTY CYCLE to increase or decrease the duty cycle for desired treatment. 100% duty cycle is continuous. 99% or less is pulsed.



Select Treatment Time
Treatment Time Selection: Press ▼ or ▲ button next to TIME to decrease or increase treatment time for desired treatment time.



5.5.5.1 Start Treatment

Place a generous amount of ultrasound gel on the treatment area. Place the ultrasound head on treatment area and move in slow circular motions while rotating the central controller dial to clockwise to slowly increase the intensity to a comfortable level to the patient.

5.5.5.2 Ultrasound Intensity

The ultrasound intensity is adjusted with intensity control knob. The ultrasound intensity can only be adjusted during treatment. The 2 ultrasound intensity can be displayed in W or W/cm . (Press the buttons 2 [1], [2], [3], [4],[8] can change the displayed W or W/cm^2)

5.5.5.3 Check Patient Before Treatment

- Put the patient in a comfortable position. The area to be treated should be properly supported and exposed and perfectly relaxed
- Ensure there are no contraindications to treatment.
- Inspect the skin treatment area for any abrasions, inflammation, surface veins etc.
- Clean the skin treatment area with soap or alcohol (70%).
- Shaving or clipping excessive hair on the skin treatment area can provide optimal treatment.
- Test the heat sensitivity of the treatment area.

5.5.5.4 During the Treatment

- The sound head must be moved in slow circular motions, constantly during treatment.
- Ask the patient regularly about his/her experiences. If necessary, the treatment can be adjusted. By using the central controller dial, the output can be reduced or increased to a comfortable level
- In case of indications of poor transmission of ultrasound energy, it is advised to add the contact-gel or reposition the ultrasound-head.
- If the LED light blinks green or is not producing output, reposition the sound head and continue to move in a slow circular motion and/or more ultrasound gel may be needed.

- If the LED light is solid green, there is good contact and the ultrasonic energy is being emitted.
- If the treatment is paused or the sound head is not connected properly, there will be no green LED light on the top of the sound head.

⚠ CAUTION:

The movement performed with the sound head should be applied with regular movement, not too slow to avoid inducing heat, nor too fast to prevent a bad contact which would reduce the effectiveness of the treatment.

⚠ WARNING:

If replacing the sound head is necessary, the device must be switch off before disconnecting and replacing the sound head.

5.5.5.5 After the Treatment

- Clean the treatment area well before treatment as well as the treatment head by using a towel or a tissue.
- The treatment head should be cleaned with a 70% alcohol solution.
- Check if there are any signs of improvement (e.g. pain, circulation and mobility).
- When entering the next treatment session, the patient is instructed to report any possible reaction.

5.5.5.6 Pause or Stop Treatment

Press the central controller dial to pause the treatment. Press the dial again to continue the treatment.

Emergency stop

Press STOP to stop treatment immediately.

The Treatment head

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 or dropping) can adversely affect these characteristics, and must therefore be avoided

The Contact Medium

In order to ensure efficient transfer of energy, a contact medium is required between the sound head and the body. Air causes virtually total reflection of the ultrasound energy. The best medium for the transfer of ultrasound energy is ultrasound/conductive gel.

- Liberally apply ultrasound/conductive gel to the treatment area on the patient.
- Move the treatment head during therapy session in a circular motion. The area treated should be two times the diameter of the treatment head.z
- If the body surface is very irregular, making it difficult to obtain good contact between the treatment head and the body, or if direct contact must be avoided (e.g. due to pain), the affected area may be treated under water (subaqual method). The water should be degassed (by previous boiling) in order to prevent air bubbles arising on the treatment head and body.
- Sound head should not be submerged in water further than the aluminum portion of the sound head. If submerged further, the sound head is not sealed past this point and will damage the sound head and render it defective for use. DO NOT let liquid enter into unsealed areas of the sound head.

⚠ CAUTION:

NEVER apply the gel to the treatment head. The treatment head will register this as contact and may emit ultrasound energy, which could damage the treatment head. Always use gel with the requirements for medical use, such as with CE mark, or are legally marketed in the US.

Disconnecting from the Wall Socket Power Supply

Switch the button on the side of the device to the OFF position first. There should not be anything displayed on the LCD screen to indicate it was turned off. Disconnect the adapter from the wall socket.

6. CLEANING AND CARE

6.1 Tips for Skin Care

Follow these suggestions to avoid skin irritation, especially if you have sensitive skin:

1. Clean the treatment area with mild soap and water. Rinse thoroughly and dry area completely before placing electrodes on or around the treatment area.
2. Excess hair may be clipped with scissors; **DO NOT** shave stimulation area.

6.2 Cleaning the Device

1. Unplug the device before you clean the device.
2. Clean the device after use with a soft, slightly moistened cloth. For hard to clean situations, you can also moisten the cloth with mild soapy water.
3. **DO NOT** use any chemical cleaners or abrasive agents for cleaning.

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

6.3 Cleaning the Electrodes

1. Apply the protective backing to the tacky side of the electrode before storing.
2. It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive on the electrode and turn the surface up to air dry. Over-saturation of the electrode with water will reduce the adhesive properties. This can only be done once, then electrodes need to be replaced. If any electrodes are not sticking completely to the skin (no edges lifting) replace with new electrodes, to avoid possible injury.
3. The rubber electrodes should be cleaned with lukewarm water. To disinfect the electrodes or to remove stubborn stains of dirt, use a 70% alcohol solution. The alcohol solution may discolor the electrode; however, this does not affect the operation of the electrodes.

4. Ensure electrode is completely dry before using the treatment. Check with patient to ensure the patient is not allergic to any cleaning solution used to clean the rubber electrodes, prior to administering treatment.
5. The sponge pads should be washed in warm water, using a household cleaner. After washing, they must be rinsed with clear water, thoroughly drained and then dried. Damaged sponge pads should be replaced.
6. Between uses, store the electrodes in the reusable bag and in a cool dry place.

⚠ **CAUTION**:

1. The self-adhesive electrodes are intended for single patient use only.
2. If the electrodes **DO NOT** adhere completely to the patient's skin, it may cause a slight shock.
3. If irritation occurs, discontinue use and consult your clinician.
4. Always use the electrodes with CE mark, or are legally marketed in the United States under an approved 510(K) procedure

6.4 Cleaning the Lead Wires and Cables

1. Periodically wipe the lead wires clean with a cloth dampened in a mild soap solution, and then gently wipe them dry. Use of rubbing alcohol on the lead wires will damage the insulation and dramatically shorten their life. It is the manufacturer's recommendation to replace lead wires every six months

6.5 Maintenance

1. Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs completed by any unauthorized person(s).
2. Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

7. TROUBLESHOOTING

For optimal use:

1. Please follow the directions on the electrode packaging for the care of electrodes. The life of the electrodes varies, depending on skin conditions, skin preparation, storage and climate. Replace electrodes that no longer stick.
2. **NOTE**: If the following measures fail to alleviate the problem, please call your dealer.

Problem	Possible Cause	Solution
Displays fail to light up	Adapter contact failure.	Ensure adapter is connected. Check the following contacts: • All contacts are in place. • All contacts are not broken. • Ensure that adapter is connected.
Stimulation is weak	Electrodes 1. Dried out or contaminated 2. Placement	1. Replace. 2. Electrodes must be at least 2" and no more than 6" apart, per channel..
	Lead wires old/worn/ damaged.	Replace
Stimulation stops	Poor electrode contact.	Reapply electrodes, secure firmly.
	Damaged or worn electrodes or lead wires.	Replace.
Stimulation is uncomfortable	Intensity is too high.	Decrease intensity.
	Electrodes are too close together.	Reposition the electrodes.
		Electrodes must be at least 2" and no more than 6" apart, per channel..
	Damaged or worn electrodes or lead wires.	Replace.
	Electrode active area size is too small.	Replace electrodes with ones that have an active area no less than 25.0cm².
Stimulation is ineffective	Improper electrode.	Reposition electrode.
	Unknown.	Contact clinician.

“E1” or “E2” displays on LCD	Hardware problem.	Restart the device.
“E3” displays on LCD	Detected the device is over temperature limit.	The device will stop treatment automatically, please wait several minutes before using again.
“E4” displays on LCD	Detected the working current is over the limit.	
“E5” displays on LCD	Memorizer failure is detected.	Restart the device, if the problem still exists, please contact the manufacturer or distributor.

Remark: If there is a failure, a beeping sound will appear until the failure has been corrected or eliminated, or until the button on the panel has been pressed.

8. SPECIFICATIONS

8.1 General Specifications:

Adapter supply voltage	100V-240V, 47Hz-63Hz, 1.35A
Adapter output	15V ⎓ 3A Max.
Adapter Dimensions	3.5" (L) x 2.0" (W) x 1.15" (H)
Dimensions	9.8" (L) x 7.3" (W) x 3.25" (H)
Operating Environmental	Temperature: 50°F (10°C) to 104°F (40°C), Relative humidity: 30%-85%
Storage Environmental	Temperature: -4°F (-20°C) to 131°F (55°C), Relative humidity: 30%-85%
Maximum Treatment Time	60 minutes—electrical stimulation
Timer Accuracy	±3%
Classification of protection against electric shock	Class I medical equipment
Classification of applied part	Type BF

8.2 Ultrasonic Generator Specifications:

Frequency (Freq.)	1MHz±10% 3MHz±10%
Duty Factor (Duty)	10%-100%, Stepping 10%
Pulse Repetition Rate	100Hz
Treatment time	Max. 30 minutes
Output power	0.5W-10.0W, when duty factor>80% for 5cm² 0.5W-15.0W, when duty factor<70% for 5cm² 0.1W-2.0W, when duty factor>80% for 1cm² 0.1W-3.0W, when duty factor<70% for 1cm²
Effective radiating area (AER)	1. 0cm² (Optional) 5. 0cm²
Effective intensity (Max)	3. 0W/cm²
Indication accuracy	±20% (for any level above 10% of maximum)
RBN (Max)	<8.0
Beam type	Collimated
Material of Sound Head	Aluminum
Waterproof Grade	IPX7 Only for Ultrasound applicator

8.3 Waveform Specifications:

8.3.1 Interferential Traditional (4 Pole)

Waveform Type	Bi-phasic square
Mode Selection	CC (Constant Current) or CV (Constant Voltage)
Vector	Auto: 0%-100% Manual: 0°-90°
Carrier Frequency (C.F.)	4.0kHz
Sweep High Beat Frequency (Beat H.)	(Beat L.) - 150 Hz
Sweep Low Beat Frequency (Beat L.)	1-(Beat H.) Hz
Output Intensity	0-100mA(CC, at 1k ohm lead) 0-100 V (CV, at 1k ohm load)
Treatment time	1-60 minutes

8.3.2 Interferential Traditional (2 Pole)

Waveform Type	Bi-phasic square
Mode Selection	CC (Constant Current) or CV (Constant Voltage)
Carrier Frequency (C.F.)	2.5kHz
Sweep High Beat Frequency (Beat H.)	(Beat L.) - 150 Hz
Sweep Low Beat Frequency (Beat L.)	1-(Beat H.) Hz
Output Intensity	0-100mA (CC, at 1k ohm lead) 0-100 V (CV, at 1k ohm load)
Treatment time	1-60 minutes
Cycle time (cycle)	Continuous, 5/5, 4/12, 10/10, 10/20, 10/30, 10/50
Ramp time (Ramp)	2 seconds

8.3.3 TENS and EMS Mode

Waveform Type	Mono- or Bi-phasic square
Mode Selection	CC (Constant Current) or CV (Constant Voltage)
Frequency	1-250 Hz
Frequency Modulation (F.M.)	0-249Hz
Burst rate (Burst)	0-10Hz (7 pulse)
Phase duration (P. Dur.)	30-400 μs
Amplitude Modulation (A.M.)	0%-100%
Output Intensity	0-100mA (CC, at 1k ohm lead) 0-100 V (CV, at 1k ohm load)
Treatment time	1-60 minutes
Cycle time (cycle)	Continuous, 4/4, 4/8, 7/7, 5/5, 4/12, 10/10, 10/20, 10/30, 10/50
Ramp time (Ramp)	1 second

8.3.4 Russian Mode

Waveform Type	Bi-phasic square
Mode Selection	CC (Constant Current) or CV (Constant Voltage)
Carrier Frequency (C.F.)	2.5kHz
Burst Frequency (Freq.)	20-100Hz
Output Intensity	0-100mA (CC, at 1k ohm lead) 0-100 V (CV, at 1k ohm load)
Duty Cycle	10%, 20%, 30%, 40%, and 50%
Treatment time	1-60 minutes
Cycle time (cycle)	Continuous, 5/5, 4/12, 10/10, 10/20, 10/30, 10/50
Ramp time (Ramp)	1s, 2s, and 5s

⚠ **CAUTION:** This device has been thoroughly tested and inspected to assure proper performance and operation.

9. STORAGE

1. For prolonged pauses in treatment, store the device with the adapter 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.

10. DISPOSAL

Please dispose of the device in accordance with the directive 2002/96/EC WEEE(Waste Electrical and Electronic Equipment). Please dispose of the device in accordance with the laws in your area.

11. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

1. The device needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information supplied in this manual.
2. Care must be taken when operating this device adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this 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 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 assures 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	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply	±2 kV for power supply	Main power quality should be that of a commercial or hospital environment.
	±1 kV for input/ output lines	±1 kV for input/ output lines	
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	
	±2 kV common mode	±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle	<5% UT (>95% dip in UT) for 0.5 cycle	
	40% UT (60% dip in UT) for 5 Cycles	40% UT (60% dip in UT) for 5 Cycles	
	70% UT (30% dip in UT) for 25 Cycles	70% UT (30% dip in UT) for 25 Cycles	
	<5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 5 sec	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60501 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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 $d=[\frac{3.5}{V1}]\sqrt{P}$ $d=[\frac{3.5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E1}]\sqrt{P}$ 800 MHz to 2.5 MHz 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.
Radiated RF IEC 61000-4-3	3 V/m80 MHz to 2.5 GHz	3 V/m	

NOTE I. 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 propagation is affected by absorption and reflection from structures, objects and people.

1. 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.
2. Over the frequency range 150 kHz to 80 MHz, field strength should be less than (Vi) W/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) as recommended below, according to the maximum output power of the communications equipment

Rate maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	800 MHz to 2,5 GHz $d=[\frac{3.5}{V1}]\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

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.

12. 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.
	The name and address of the manufacturer
LOT	Batch Code
CE 0197	Complies with the European Medical Device directive (93/42/EEC) and amended by directive 2007/47/EC requirements. Notified body TÜV Rheinland (CE0197)
CB	The electrical safety meet the CB system requirements
	Indoor use only
	Risk of electric shock
c UL us E230351	Complies with the safety requirements of Canada and U.S. The certification body is UL, the certificate number is E230351

13. WARRANTY

Please contact your dealer or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

1. Richmar's sole obligation in the case of any breach of its warranties set forth in the manual shall be, at Richmar's option, to replace the Product with a new or factory certified refurbished product without charge to the purchaser or to refund the purchase price of the Product. If the product is unopened/unused it can be returned minus a 25% restock fee. The warranty period for the ComboCare® device is two years from date of purchase and does not include accessories.
2. For defective products, please contact your distributor or Richmar directly at 800-376-7263 to speak with Tech Support. If product cannot be remedied over the phone, a prepaid shipping label will be sent to you with the authorized RMA number (if product is within warranty). Any product sent back without an authorized RMA number will be returned to the sender. Richmar will not be responsible for damage due to improper packaging or shipment. If Richmar determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Richmar will replace the product with a new or factory certified refurbished product at Richmar's expense or refund the purchase price to the original purchaser for the price of the defective product (minus shipping costs). If Richmar determines in its sole reasonable discretion that the Product does not contain defective workmanship, materials, or it is observed that product has been mishandled, abused or device has been opened, Richmar will inform the Purchaser and return the product, freight billed to the purchaser.
3. Repairs or replacement under warranty DO NOT extend the warranty period either for the device or for the replacement parts. Replacement lead wire, applicators and power cords have a one year warranty from date of original device purchase.

4. The following is excluded under the warranty:
   a. All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
   b. Any device that has been opened or has a damaged warranty seal, automatically voids the warranty and no refund or warranty replacement will be provided.
   c. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
   d. Accessories which are subject to normal wear and tear.
5. 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.
6. Serial number is a sequential and unique identification number that represents date of manufacture.

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