# ComboCare™

## INSTRUCTION MANUAL

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


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## This manual is valid for the ComboCare™

This user manual is published by Current Solutions™, LLC

Current Solutions™, LLC reserves the right to improve and amend it at any time without prior notice. Amendments may however be published in new editions of this manual.





Declaration of conformity:

Current Solutions™, LLC. declares that the ComboCare™ complies with following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-2-10, ISO 7010
ISO14971, ISO10993-1, ISO10993-5, ISO10993-10

# Contents

# 1. FOREWORD

## 1.1 General information

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.

You can choose between several different amplitude modulation options. The interferential andpremodulated modes offer frequency modulation as well as a staticfrequency 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 ComboCare™ It contains general information on the operation, precautionary practices, and maintenance information. In order to maximize its 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.

# 2. SAFETY INFORMATION

## 2.1 Caution

- Keep yourself informed of the contraindications.
- Read, understand, and practice the warnings, cautions and operating instructions. Know the limitations and hazards associated with using any device. Observe the precautionary and operational decals placed on the unit. Always follow the operating instructions prescribed by your healthcare practitioner
- DO NOT operate this unit in an environment where other devices are being used that intentionally radiates electromagnetic energy in an unshielded manner.
- DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel.
- Inspect Applicator cables and associated connectors before each use.
- This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.
- This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the manual.

- Portable and mobile RF communications equipment can affect this device. Do not use a mobile phone or other device that emit electromagnetic fields, near the unit. This may result in incorrect operation of the device.
- This device has been thoroughly tested and inspected to assure proper performance and operation!

**2.2 Warning:**

- U.S.A. Federal Law restricts these devices to sale by, or on the order of, a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.
- Make certain the unit is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.
- Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
- Before administering any treatment to a patient you should become acquainted with the operating procedures for each mode of treatment available, as well as the indications, contraindications, warnings and precautions. Consult other resources for additional information regarding the application of electrotherapy and Ultrasound.
- To prevent electrical shock, disconnect the unit from the power source before attempting any maintenance procedures.
- The use of accessories, transducers and cables than those specified, with the exception of transducers and cables sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the device.
- This device is not designed to be use in an MRI Environment and should be removed prior to MRI exposure.

**2.3 Contraindications for Therapeutic Ultrasound**

- 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.
- 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.
- Therapeutic ultrasound should not be applied to the eye.
- Applications of therapeutic intensities of ultrasound should be avoided over the heart.
- Neoplastic tissues or space occupying lesions should not be exposed to ultrasound.

- Ultrasound should not be applied to the testes to avoid increases in temperature.
- 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.
- Tissues previously treated by deep x–ray or other radiation should not be exposed to therapeutic ultrasound.
- Ultrasonic treatment over the stellate ganglion, the spinal cord after laminectomy, subcutaneous major nerves and the cranium should be avoided.
- 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.
- Do not apply therapeutic ultrasound over a healing fracture.
- Ultrasound should not be applied over the epiphyseal areas (bone growth centers) of the bones of growing children.

## 2.4 Contraindications for Electrical Stimulation

- 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.
- Do not use this device on patients whose pain syndromes are undiagnosed.

## 2.5 Warnings for Electrical Stimulation

- 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;
- 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;
- 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);
- Do not apply stimulation over, or in proximity to, cancerous lesions;
- 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;
- Do not apply stimulation when the patient is in the bath or shower;
- Do not apply stimulation while the patient is sleeping; and
- 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.

- 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
- Apply stimulation only to normal, intact, clean, healthy skin.
- 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.
- Fresh fractures should not be stimulated in order to avoid unwanted motion.
- Stimulation should not be applied immediately following trauma or to tissues susceptible to hemorrhage.
- Do not apply electrodes directly over the eyes or inside body cavities.
- Do not use electrical stimulation in conjunction with high frequency surgical equipment or microwave or shortwave therapy systems.
- Keep electrodes separated during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.
- 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.

## 2.6 Precautions for Therapeutic Ultrasound

- 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.
- If a patient complains of periosteal pain (deep, achy pain) during ultrasonic treatment, intensity should be reduced to a comfortable level.
- 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 diatheses or bleeding disorders.
- 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.
- Heating of the joint capsule in acute or subacute arthritis should be avoided.
- This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- This device should not be used when cancerous lesions are present in the treatment area.

- 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 diatheses
- 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 actually terminate ultrasonic power output when the timer reaches zero.
- The Ultrasound Applicator with care. Inappropriate handling of use the Ultrasound applicator may adversely affect its characteristics.
- Before each use, inspect the Ultrasound Applicator for cracks, which may allow the ingress of conductive fluid.
- 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 of system and therefore create risk of injury to the patient.

## 2.7 Precautions for Electrical Stimulation

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- The long-term effects of chronic electrical stimulation are unknown.
- Electrical stimulation devices have no curative value.
- Electrical stimulation is not a substitute for pain medications and other pain management therapies
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients;
- The safety of electrical stimulation during pregnancy has not been established;
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians;
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture;
- Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process;
- Use caution if stimulation is applied over the menstruating or pregnant uterus;
- Use caution if stimulation is applied over areas of skin that lack normal sensation.

- Use this device only under the continued supervision of a licensed practitioner.
- Electrical stimulation is ineffective for pain of central origin.
- Use extreme caution when treating desensitized areas or on patients who may not be able to report discomfort or pain
- Patients should not be left unattended during any treatment.
- Keep this device out of the reach of children;

**2.8 Adverse reaction**

- Skin irritation, inflammation, and electrode burns beneath the electrodes are potential adverse reactions.
- Perform the following procedures to avoid the negative effects of ultrasound therapy.
- 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; and
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

**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

## 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 past injuries and scar tissues.
3. Relief of sub-chronic, chronic pain and joint contractures resulting from:
   - Capsular tightness,
   - Capsular scarring

*For TENS, Interferential and premodulated (IFC):*

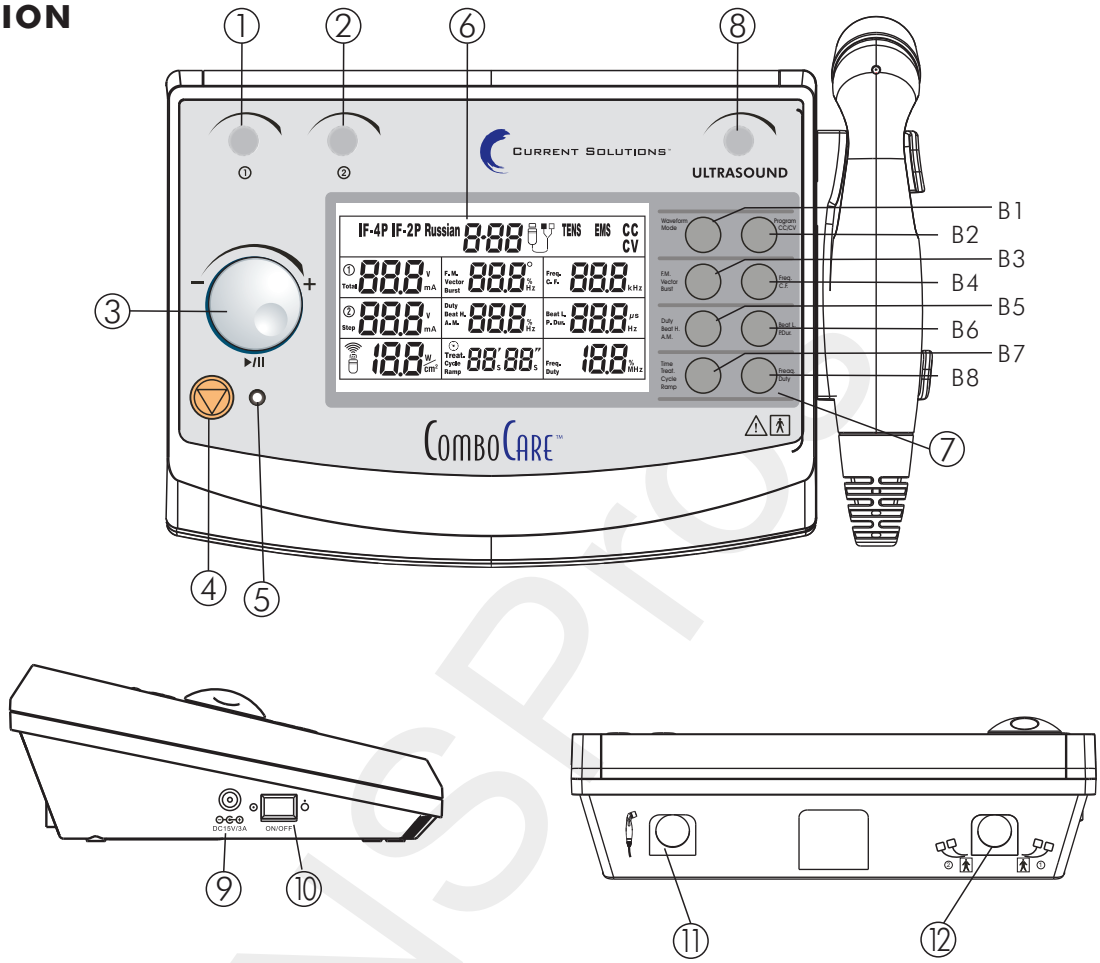
1. Symptomatic relief of chronic intractable pain;
2. Reduction of inflammation;
3. Post-traumatic acute pain and edema;
4. Post-surgical acute pain and edema.

*Additionally 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.

# 4. PRESENTATION

## 4.1 Panel For front view



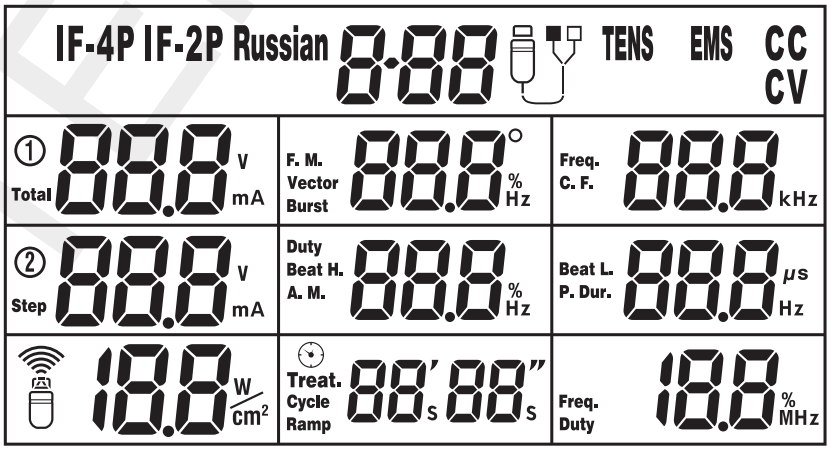

1) Select channel 1 or adjust the output intensity of channel 1.
2) Select channel 2 or adjust the output intensity of channel 2.
3) Parameters control knob and pause button.
4) Stop treatment button.
5) Power indicator.
6) LCD display: Shows the current information of the device.
7) Eight parameters selection buttons, see below for details:
   B1: Toggle the therapeutic mode: Electrical stimulation, Ultrasound therapeutic or Combo therapeutic.
   B2: Toggle the therapeutic program, select the output mode (CC/CV) or switch program types (Common or professional).
   B3: Toggle the parameter F.M./Vector/Burst
   B4: Toggle the parameter Freq./C.F.
   B5: Toggle the parameter Duty/Beat H./A.M.
   B6: Toggle the parameter Beat L./P.Dur.
   B7: Toggle the parameter Treat./Cycle/Ramp
   B8: Toggle the parameter Freaq./Duty for ultrasound

**Symbols:**

- CC — Constant current output mode.
- CV — Constant voltage output mode.
- F.M. — Frequency Modulation
- Burst— Burst Frequency
- Freq. — Frequency
- C.F. — Carrier Frequency
- Duty — Duty Cycle for Russian waveform for B5 button
- Beat H. — Sweep High Beat Frequency
- A.M. — Amplitude Modulation
- Beat L. — Sweep Low Beat Frequency
- P.Dur. — Pulse Duration
- Treat. — Treatment time
- Cycle— Cycle time
- Ramp— Ramp time
- Duty — Duty Cycle for Ultrasound for B8 button
- Freaq. — Frequency for ultrasound

8) Ultrasound output intensity control knob
9) Adapter receptacle
10) ON/OFF switch
11) Output connector: connect with ultrasound applicator
12) Output connector: connect with electrical stimulation cable

## 4.2 User Interface



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

## 5. INSTALLATION

### 5.1 Before Use

Remove the equipment and all accessories from shipping carton and giftbox. 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.

| | Part | Quantity |
|---|---|---|
| 1 | Rubber Electrodes,60x90mm | 2pcs |
| 2 | Rubber Electrodes,70x110mm | 2pcs |
| 3 | Electrode Sponges,70x100mm | 2pcs |
| 4 | Electrode Sponges,80x120mm | 2pcs |
| 5 | Self-adhesive Electrodes,50x50mm | 4pcs |
| 6 | Self-adhesive Electrodes,50x100mm | 4pcs |
| 7 | Elastic Wrap,75x1200mm | 1pc |
| 8 | Elastic Wrap ,75x600mm | 1pc |
| 9 | Electrode wires (black/red) | 2pcs |
| 10 | Adapter 100-240V~47-63Hz | 1pc |
| 11 | Power cord | 1pc |
| 12 | Electrical stimulation cable | 1pc |
| 13 | Electrode wire for ultrasound combination | 1pc |
| 14 | 5cm² AER ultrasound applicator | 1pc |
| 15 | Transmission gel | 1pc |
| 16 | 1cm² ultrasound applicator(Optional) | 1pc |
| 17 | Operating manual | 1pc |

## 5.2 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 stated 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.

## 5.3 Switching on

Switch on the device, using ON/OFF switch (⑩).

## 5.4 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.

# 6. OPERATION

## 6.1 Measures with regard to treatments

### 6.1.1 Electrotherapy Before the 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.

### 6.1.2 Electrode Placement

- Examine the skin for any wounds and clean the skin.
- Apply the electrodes to the treatment area.
- 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 25cm$^2$ 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 stimulators should be used only with the leads and electrodes recommended by the manufacturer.

### 6.1.3 Adhesive electrodes

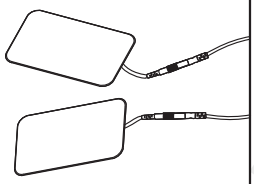
This device is supplied with 4 pieces 50mm×50mm and 4 pieces 50mm×100mm adhesive electrodes. You can select the right adhesive electrodes according to treatment area and output current density.
It is recommended that manufacturer's Electrodes be used whenever possible to ensure the highest level of contact with the treatment area and most uniform delivery of the prescribed electrotherapy treatment. Properly dispose of used Electrodes upon completion of the therapy session.

If you are unsure of your electrode adhesive properties, order new replacement electrodes. Replacement electrodes should be re-ordered through or on the advice of your physician to ensure proper quality. Apply electrodes to the exact site indicated by your physician or therapist, before applying electrodes, be sure the skin surface over which electrodes are placed is thoroughly cleaned and dried. Make sure the electrodes are placed firmly to the skin and make good contact between the skin and the electrodes. Place the electrodes over the skin; attach them properly, firmly, and evenly.

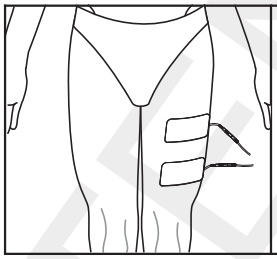
Caution:

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, 50mm x 50mm self-adhering based, square electrodes are used at the treatment area

**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**

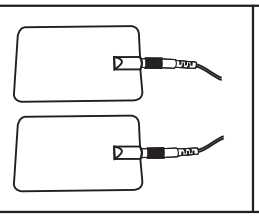
| | |
|---|---|
|  | Remove the adhesive Electrodes from the protective backing and apply to the treatment area as prescribed. Ensure that the entire electrode surface is in contact with patient skin by pressing into place. |

**6.1.4. Rubber electrodes**

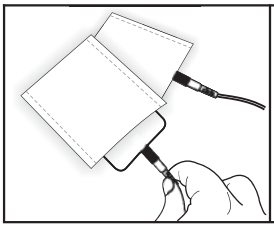
If used for delivery of electrotherapy, there are two conductive mediums for you to select, the first one is use electrode sponges as conductive mediums, another is use other conductive medium such as Transmission Gel.

These Rubber Electrodes should be secured to the treatment area using the Nylon Wraps shipped with the Therapy System.

**Reusable rubber Electrodes Connecting Lead Wires**

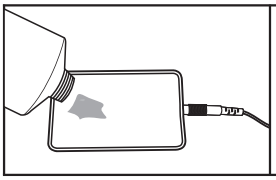
| | |
|---|---|
|  | Insert the lead with the Red (+) electrode connector into one rubber electrode. Insert the lead with the Black (-) electrode connector into the other rubber electrode. Make certain the lead wires are seated completely into the electrodes. |

**Conductive Medium 1**



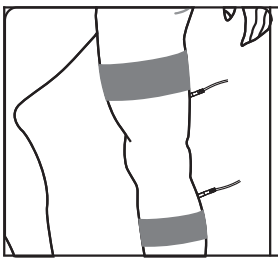
Inserted the Rubber Electrodes into the electrode sponges moistened with distilled water prior to placement on the patient.

**Conductive Medium 2**



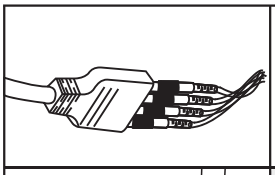
Liberally apply Transmission Gel to electrode prior to placement on patient.
Please note: Please purchase the Transmission gel with CE mark or that is cleared by the FDA.

**Securing Electrodes**

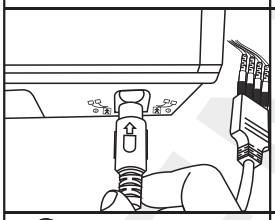


Use Nylon Wrap to secure each rubber electrode in position on the patient.

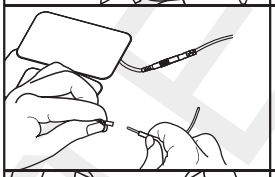
**6.2 Quick Set-up for Electrical Stimulation**



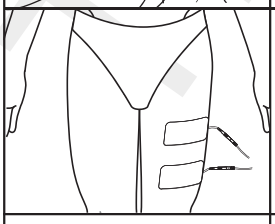
1. Connect the electrode wires to the cable; please note the color of the wires and the color marks on the cable, they should be corresponding.



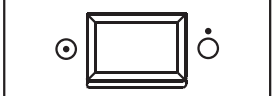
2. ComboCare™ has two connectors, one is electrical stimulation connector, the other is ultrasound connector. In this step, please plug the electrical stimulation cable into electrical stimulation connector (⑫ connectors)



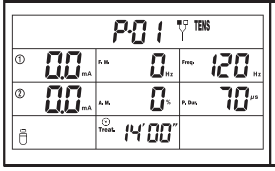
3. Connect the electrodes to electrode wires.



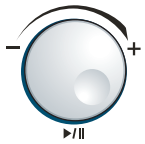
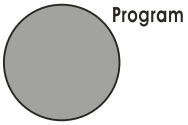
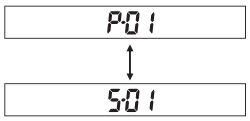
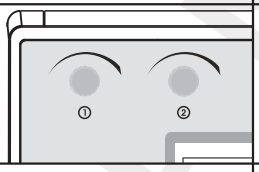
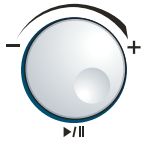
4. Place the electrodes on the patient according to section 6.1.



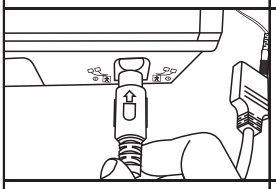
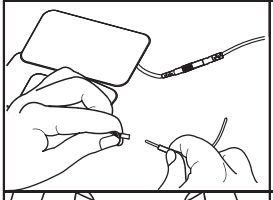
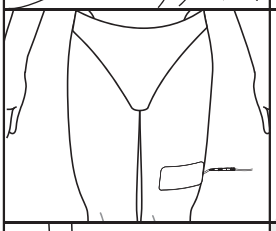
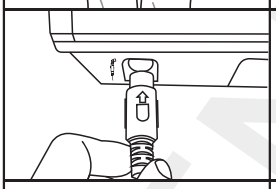
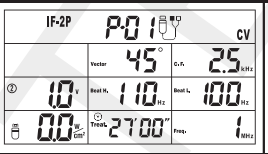
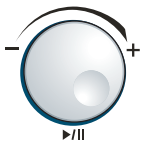
5. In order to turn on the device,please press ON/OFF switch to [⊙] icon which is located on the side of the device

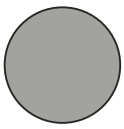
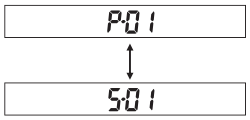
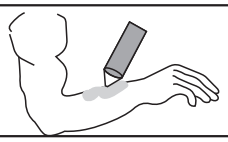
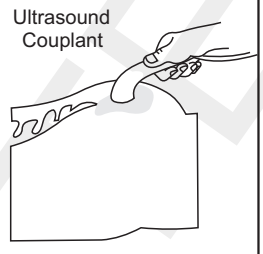


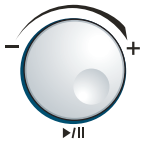

6. When you turn the ComboCare™ on, the device will get down to self- check about 10 seconds, and then the default parameters are displayed the last treatment mode.

| | |
|---|---|
|  | 7.This device has three working mode-electrical stimulation, ultrasound and combo therapeutic you can press "B1" waveform button to select electrical stimulation mode. |
|  | 8. There are 5 therapeutic waveforms for you to select. Rotating the Parameters control knob (③) to select waveform like Interferential, TENS, Russian, and EMS after you selected electrical stimulation therapeutic mode. |
|   | 9. Each therapeutic waveform has 10 programs. The details parameters for each program please refer to section 6.3 in this manual. Press the "B2" program button to toggle the therapeutic program, and then rotating the Parameters control knob to select the therapeutic programs in corresponding waveform. |
|   | 10. There are two types program for you to select --Common program or specialist program. Common program has only one treatment phase and the program displays "P-". In specialist program, there are three treatment phases display and the program displays "S-" like figure. You can press and hold "B2" program button to switch them. |
|   | 11. Press "B2" program button to select "CC" or "CV" control mode. |
|   | 12. Adjust the output intensity and start electrical treatment that you are using by rotating the output intensity adjustable knob on the control panel. |
|   | 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 patient'skin, an alarm buzzer sound will appear and the intensity value flashing. |
|  | 14. Press the "▽" button to stop treatment if any emergency happened.<br>**Caution:**<br>For protecting the device, temperature detection was designed that the device will stop treatment when the feature board temperature over 80℃. The device cannot work again unless the temprature below 60℃. |
|  | 15. Press the "▶/II" button to pause treatment; you can press it again to restart the treatment. |

## 6.3 Quick Set-up for Combo Therapeutic (Ultrasound and Electrical stimulation)

| | |
|---|---|
|  | 1.In Combo therapeutic mode, the Ultrasound probe is the Negative of channel 2, so you should connect the electrode wire (⑬) to positive of channel 2, and channel 1will have no output intensity.<br>**Caution:** please note the color of the wires and the color marks on the cable, they should be corresponding. |
|  | 2.Plug the cable into the corresponding output connector ( ⑫ connector) on ComboCare™ |
|  | 3.Connect the electrodes to electrode wires. |
|  | 4.Place the electrodes on the patient according to section 6.1. |
|  | 5.For ultrasound, plug the ultrasound applicator into the ultrasound connector(⑪connector).<br>**Caution:**Don't plug or pull out the ultrasound applicator when the device turned on. |
|  | 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.When you first turn the ComboCare™ on, the default parameters are displayed the last treatment mode. |
|  | 8.Press "B1" Waveform button until "⌇" indicator display on LCD, means the device enter into Combo therapeutic mode. |
|  | 9.There are 4 therapeutic waveforms can be used for combo therapeutic. Rotating the Parameters control knob (③) to select waveform like Premodulated, TENS, Russian, and EMS. |

| | |
|---|---|
|  | 10.Each therapeutic waveform has 10 programs. The details parameters for each program please refer to section 6.4 in this manual. Press the "B2"Program button to toggle the therapeutic program, and then rotating the Parameters control knob to select the therapeutic programs in corresponding waveform. |
|  | 11. There are two types program for you to select --Common program or specialist program. Common program has only one treatment phase and the program displays "P-". In specialist program, there are three treatment phases display and the program displays "S-" like figure. You can press and hold "B2" program button to switch them. |
|  | 12.Apply a layer of transmission gel to the treatment area. Please note: Please purchase the transmission gel that is cleared by the FDA. |
| ②  | 13.Adjust the output intensity and start electrical treatment that you are using by rotating the output intensity adjustable knob (②) on the control panel. |
|  | 14.Adjust the intensity and start ultrasound treatment that you are using by rotating the ultrasound output intensity adjustable knob(⑧) on the control panel. Press the knob (⑧) to change the ultrasound unit"W" or "W/cm²". |
|  | 15.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. 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. |
|  | 16.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. |

| | |
|---|---|
| | 17. Press the "▽" button to stop treatment if any emergency or error happened.<br>**Caution:**<br>1) For protecting the device, temperature detection was designed that the device will stop electrical stimulation treatment when the feature board temperature over 80℃. The device cannot work again unless the temperature below 60℃.<br>2) For protecting patient, the device will stop ultrasound intensity output and the LED on the applicator will flash if the applicator temperature over 42℃. It will resume again when the temperature below 41℃. |
|  | 18. Press the "▶/II" button to pause treatment; you can press it again to restart the treatment. |

## 6.4 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:

### Interferential Traditional (4 Pole) default parameters:

| Waveform | Program | Phase | CC/CV | Vector (Auto) | Vector (Manual) | C.F. | Beat. H | Beat. L | Ultrasound | Treat. Time |
|---|---|---|---|---|---|---|---|---|---|---|
| Interferential Traditional (4 Pole) **IF-4P** | 1 | 1 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 0min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 0min |
| | 2 | 1 | CC | 0 | 45° | 4.0kHz | 150Hz | 100Hz | 1MHz,50% | 10min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 150Hz | 100Hz | 1MHz,50% | 0min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 150Hz | 100Hz | 1MHz,50% | 0min |
| | 3 | 1 | CC | 0 | 45° | 4.0kHz | 50Hz | 50Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 50Hz | 50Hz | 1MHz,50% | 0min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 50Hz | 50Hz | 1MHz,50% | 10min |
| | 4 | 1 | CC | 0 | 45° | 4.0kHz | 150Hz | 90Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 150Hz | 90Hz | 1MHz,50% | 0min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 150Hz | 90Hz | 1MHz,50% | 0min |
| | 5 | 1 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 0min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 0min |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Interferential Traditional (4 Pole) **IF-4P** | 6 | 1 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | 7 | 1 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | 8 | 1 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | 9 | 1 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | 10 | 1 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 0 | 45° | 4.0kHz | 110Hz | 100Hz | 1MHz,50% | 15min |

**Premodulated Traditional (2 Pole) default parameters:**

| Waveform | Program | Phase | CC/CV | C.F. | Beat. H | Beat. L | Ultrasound | Treat. Time |
|---|---|---|---|---|---|---|---|---|
| Premodulated Traditional (2 Pole) **IF-2P** | 1 | 1 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 0min |
| | 2 | 1 | CC | 2.5kHz | 150Hz | 100Hz | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 150Hz | 100Hz | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 150Hz | 100Hz | 1MHz,50% | 0min |
| | 3 | 1 | CC | 2.5kHz | 50Hz | 50Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 50Hz | 50Hz | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 50Hz | 50Hz | 1MHz,50% | 10min |
| | 4 | 1 | CC | 2.5kHz | 150Hz | 90Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 150Hz | 90Hz | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 150Hz | 90Hz | 1MHz,50% | 0min |
| | 5 | 1 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 0min |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Premodulated Traditional (2 Pole) **IF-2P** | 6 | 1 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | 7 | 1 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | 8 | 1 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | 9 | 1 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | 10 | 1 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 2 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |
| | | 3 | CC | 2.5kHz | 110Hz | 100Hz | 1MHz,50% | 15min |

**TENS default parameters:**

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| TENS | 6 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | 7 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | 8 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | 9 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | 10 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |

**EMS default parameters:**

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| EMS | 6 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | 7 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | 8 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | 9 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | 10 | 1 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 2 | CC | 120Hz | 70μs | 1MHz,50% | 14min |
| | | 3 | CC | 120Hz | 70μs | 1MHz,50% | 14min |

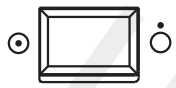
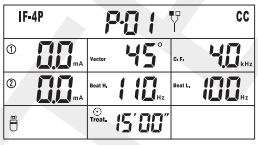
Russian default parameters:

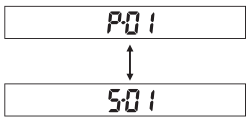
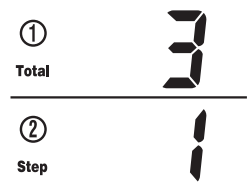
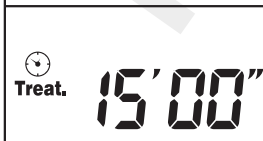
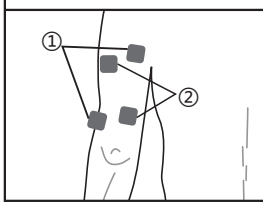
| Waveform | Program | Phase | CC/CV | C. F. | Freq. | Duty | Cycle | Ramp | Ultrasound | Treat. Time |
|---|---|---|---|---|---|---|---|---|---|---|
| Russian | 1 | 1 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 0min |
| | 2 | 1 | CC | 2.5kHz | 50Hz | 50% | 4s/12s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 4s/12s | 1s | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 4s/12s | 1s | 1MHz,50% | 0min |
| | 3 | 1 | CC | 2.5kHz | 50Hz | 50% | 4s/12s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 4s/12s | 1s | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 4s/12s | 1s | 1MHz,50% | 0min |
| | 4 | 1 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 0min |
| | 5 | 1 | CC | 2.5kHz | 50Hz | 50% | 5s/5s | 1s | 1MHz,50% | 20min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 5s/5s | 1s | 1MHz,50% | 0min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 5s/5s | 1s | 1MHz,50% | 0min |

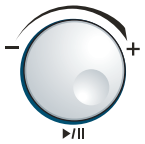
| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Russian | 6 | 1 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | 7 | 1 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | 8 | 1 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | 9 | 1 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | 10 | 1 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 2 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |
| | | 3 | CC | 2.5kHz | 50Hz | 50% | 10s/10s | 1s | 1MHz,50% | 10min |

## 6.5 Stimulation set-up procedure

### 6. 5. 1 Interferential Traditional (4Pole) 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 on the ComboCare™ the device will self- check for 10seconds, and then the default parameters will display the last treatment mode. |
| IF-4P | 3. Press "B1" Waveform button to toggle electrical stimulation mode " ", then rotating the parameters control knob (③) to select waveform, untill "IF-4P" displays on LCD. |
| P01 | 4. Press "B2" Program button to toggle the therapeutic program, and then rotating the parameters control knob (③) to select the therapeutic programs from P01 to P10. You can set and save the parameters, press the stop button(④) to save the parameters. |

| | |
|---|---|
|  | 5. There are two types program for you to select --Common program or specialist program. Common program has only one treatment phase and the program displays "P-". In specialist program, there are three treatment phases display and the program displays "S-". You can press and hold "B2" program button to switch them. |
|  | 6. If you selected specialist program, please press the parameters control knob (③) to select treatment phase from 1 to 3. The parameters of each treatment phase can be set according to following methods. |
|  | 7. Press "B2" Program button to select "CC" or "CV" control mode. |
|  | 8. Press "B3" button to toggle Vector parameter, then rotating the parameters control knob (③) to set the vector (manual) parameter from 0°to 90°,15°/step. |
|  | 9. Press "B3"button again, the vector parameter change to auto mode, the LCD display "0%" like left figure. rotating the parameters control knob (③) to set the vector (auto) parameter from 0 % to 100%, 20%/step. |
|  | 10. Press "B5" button to toggle Beat H. parameter, then rotating the parameters control knob (③) to set the parameter from (Beat. L) Hz to 150Hz, 1Hz/step. |
|  | 11. Press "B6" button to toggle Beat L. parameter, then rotating the adjust parameters contorl knob (③) to set the parameter from 1Hz to (Beat. H)Hz, 1Hz/step. |
|  | 12. Press "B7" button to toggle Treat. time parameter, then rotating the parameters control knob (③) to set the treatment time from 1min to 60min, 1min/step. |
|  | 13. Stick the electrodes on the patient. You will need two electrodes for each channel, four in total. |

| | |
|---|---|
| ① 10.0 mA<br>② 10.0 mA | 14. Adjust the output intensity of channel 1 and channel 2 and start electrical treatment that you are using by rotating the Output intensity adjustable knob (① and ②) on the control panel.<br>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 patient'skin, an alarm buzzer sound will appear and the intensity value flashing. |
|  | 15. Press the "▽" button to stop treatment if any emergency happened.<br>**Caution:**<br>For protecting the device, temperature detection was designed that the device will stop treatment when the feature board temperature over 80℃. The device cannot work again unless the temprature below 60℃. |
|  | 16. Press the " ▶/II " button to pause treatment; you can press it again to restart the treatment. |

## 6.5.2 Interferential Traditional (2 Pole) Set-up Procedure

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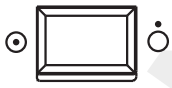
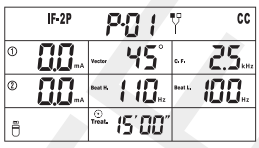
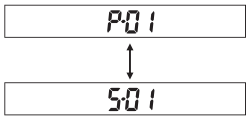
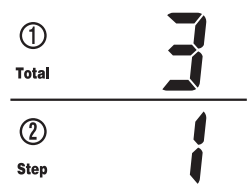
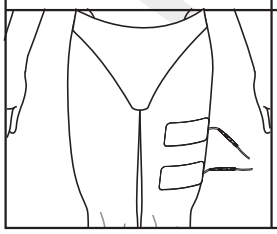
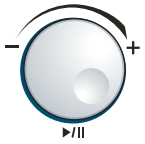
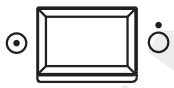
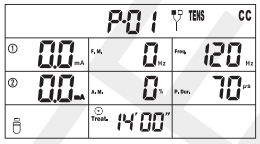
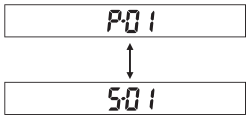
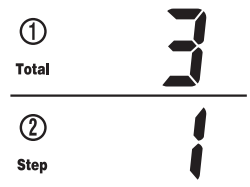
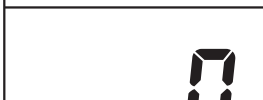
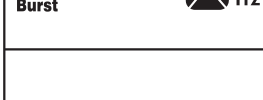
|---|---|
|  | 1. In order to turn on the device, please press ON/OFF switch to[⊙] icon which is located on the side of the device. |
|  | 2. When you turn the ComboCare™ on, the device will self- check for 10 seconds, and then the default parameters are displayed. |
| IF-2P | 3. Press "B1" Waveform button to toggle electrical stimulation mode "Ψ", then rotating the parameters control knob (③) to select waveform, untill "IF-2P" displays on LCD. |
| P-01 Ψ | 4. Press "B2" Program button to toggle the therapeutic program, and then rotating the parameters control knob (③) to select the therapeutic programs , you can set and save the parameters, press stop button (④) to save the parameters. |

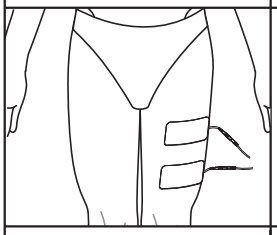
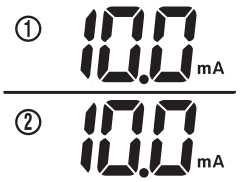
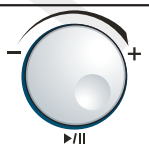
| | |
|---|---|
|  | 5. There are two types program for you to select --Common program or specialist program. Common program has only one treatment phase and the program displays "P-". In specialist program, there are three treatment phases display and the program displays "S-". You can press and hold "B2" program button to switch them. |
|  | 6. If you selected specialist program, please press the parameters control knob (③) to select treatment phase from 1 to 3. The parameters of each treatment phase can be set according to following methods. |
|  | 7. Press "B2" Program button to select "CC" or "CV" control mode. |
|  | 8. Press "B5" button to toggle Beat H. parameter, then rotating the parameters control knob (③) to set the parameter from (Beat. L) Hz to 150Hz, 1Hz/step. |
|  | 9. Press "B6" button to toggle Beat L. parameter, then rotating the parameters control knob (③) to set the parameter from 1Hz to (Beat. H)Hz, 1Hz/step. |
|  | 10. Press "B7" button to toggle Treat. time parameter, then rotating the parameters control knob (③) to set the treatment time from 1min to 60min, 1min/step. |
|  | 11. Press "B7" button again to toggle Cycle time parameter, then rotating the parameters control knob (③) to select the cycle time(work time/rest time) from "-/-(continuous)", "5/5", "4/12", "10/10", "10/20", "10/30" and "10/50". |
|  | 12. Stick the electrodes on the patient. You can use one or two channel as your needs. |

| | |
|---|---|
| ① 10.0 mA<br>② 10.0 mA | 13. Adjust the output intensity of channel 1 and channel 2 and start electrical treatment that you are using by rotating the Output intensity adjustable knob (① and ②) on the control panel.<br>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 patient'skin, an alarm buzzer sound will appear and the intensity value flashing. |
|  | 14. Press the "▽" button to stop treatment if any emergency happened.<br>**Caution:**<br>For protecting the device, temperature detection was designed that the device will stop treatment when the feature board temperature over 80℃. The device cannot work again unless the temprature below 60℃. |
|  | 15. Press the " ▶/II " button to pause treatment; you can press it again to restart the treatment. |

## 6.5.3 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 10 seconds. The default parameters are displayed the last treatment mode. |
| TENS / EMS | 3. Press "B1" Waveform button to toggle electrical stimulation mode " ", then rotating the parameters control knob (③) 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. |
| P01 | 4. Press "B2" Program button to toggle the therapeutic program, and then rotating the parameters control knob (③) to select the therapeutic programs , you can set and save the parameters, press stop button(④) to save the parameters. |

| | |
|---|---|
|  | 5. There are two types program for you to select --Common program or specialist program. Common program has only one treatment phase and the program displays "P-". In specialist program, there are three treatment phases display and the program displays "S-" like figure. You can press and hold "B2" program button to switch them. |
|  | 6. If you selected specialist program, please press the parameters control knob (③) to select treatment phase from 1 to 3. The parameters of each treatment phase can be set according to following methods. |
|  | 7. Press "B2" Program button to select "CC" or "CV" control mode. |
|  | 8. Press "B3" button to toggle F.M. parameter, then rotating the parameters control knob (③) to set the F.M. parameter from 0Hz to 249Hz, 1Hz/step. But F.M.+Freq.≤250Hz. |
|  | 9. Press "B3"button again to toggle Burst rate, then rotating the parameters control knob (③) to set the Burst rate from 0Hz to 10Hz, 1Hz/step. But Burst×8≤Freq. |
|  | 10. Press "B4" button to toggle Freq. parameter, then rotating the parameters control knob (③) to set the frequency from 1Hz to250Hz, 1Hz/step.<br>But Freq. ≥Burst x 8 and Freq.≤ 250-F.M. |
|  | 11. Press "B5" button to toggle A.M. parameter, then rotating the parameters control knob (③) to set the parameter from 0% to100%, 20%/step.(0% means the output intensity always in setting value; 100% means the output intensity changes form 0 to setting value.) |
|  | 12. Press "B6" button to toggle P.Dur. parameter, then rotating the parameters control knob (③) to set the pulse duration from 30μs to 400μs, 5μs/step. |
|  | 13. Press "B7" button to toggle Treat. time parameter, then rotating the parameters control knob (③) to set the treatment time from 1min to 60min, 1min/step. |

| | |
|---|---|
|  | 14. Press "B7" button again to toggle Cycle time parameter, then rotating the parameters control knob (③) to select the cycle time(work time/rest time) from "-/-(continuous)", "4/4", "4/8", "7/7", "5/5", "4/12", "10/10", "10/20", "10/30" and "10/50". |
|  | 15. Stick the electrodes on the patient. You can use one or two channel as your needs. |
|  | 16. Adjust the output intensity of channel 1 and channel 2 and start electrical treatment that you are using by rotating the Output intensity adjustable knob (① and ②) on the control panel.<br>For safety using, load detection was designed in this device after the output intensity surpass 10.0mA/10.0V. (In TENS and EMS mode, load detection is active when the output intensity over 20mA/20V if the pulse width less than 100μs.) If there are no electrodes stuck on patient'skin, an alarm buzzer sound will appear and the intensity value flashing. |
|  | 17. Press the "▽" button to stop treatment if any emergency happened.<br>**Caution:**<br>For protecting the device, temperature detection was designed that the device will stop treatment when the feature board temperature over 80℃. The device cannot work again unless the temprature below 60℃. |
|  | 18. Press the "▶/II" button to pause treatment; you can press it again to restart the treatment. |

### 6.5.4 Russian Stimulation Set-up Procedure

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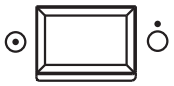
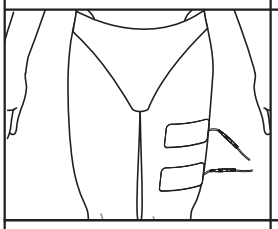
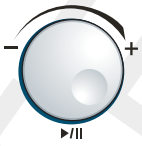
|---|---|
|  | 1. In order to turn on the device, please press ON/OFF switch to [⊙] icon which is located on the side of the device. |
|  | 2. When you turn the ComboCare™ on, the device will self- check for 10 seconds. The default parameters are displayed the last treatment mode. |

| | |
|---|---|
| Russian | 3. Press "B1" Waveform button to toggle electrical stimulation mode "", then rotating the parameters control knob (③) to select waveform, untill "Russian" displays on LCD. |
| P-01 | 4. Press "B2" Program button to toggle the therapeutic program, and then rotating the parameters control knob (③) to select the therapeutic programs , you can set and save the parameters, press stop button(④) to save the parameters. |
| P-01<br>↕<br>S-01 | 5. There are two types program for you to select --Common program or specialist program. Common program has only one treatment phase and the program displays "P-". In specialist program, there are three treatment phases display and the program displays "S-" like figure. You can press and hold "B2" program button to switch them. |
| ① Total 3<br>② Step 1 | 6. If you selected specialist program, please press the parameters control knob (③) to select treatment phase from 1 to 3. The parameters of each treatment phase can be set according to following methods. |
| CC | 7. Press "B2" Program button to select "CC" or "CV" control mode. |
| Freq. 50 Hz | 8. Press "B4" button to toggle Freq. parameter, then rotating the parameters control knob (③) to set the frequency from 20Hz to100Hz,5Hz/step. |
| Duty 50 % | 9. Press "B5" button to toggle Duty parameter, then rotating the parameters control knob (③) to set the parameter from 10% to 50%, 10%/step. |
| Treat. 10'00" | 10. Press "B7" button to toggle Treat. time parameter, then rotating the parameters control knob (③) to set the treatment time from 1min to 60min, 1min/step. |
| Cycle - S - S | 11. Press "B7" button again to toggle Cycle time parameter, then rotating the parameters control knob (③) to select the cycle time(work time/rest time)from "-/-(continuous)", "5/5", "4/12", "10/10", "10/20", "10/30", "10/50". |

| | |
|---|---|
|   | 12. Press "B7" button again to toggle Ramp time parameter, then rotating the parameters control knob (③) to select the ramp time from 1s, 2s and 5s. |
|  | 13. Stick the electrodes on the patient. You can use one or two channel as your needs. |
|   | 14. Adjust the output intensity of channel 1 and channel 2 and start electrical treatment that you are using by rotating the Output intensity adjustable knob (① and ②) on the control panel. 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 patient'skin, an alarm buzzer sound will appear and the intensity value flashing. |
|  | 15. Press the "▽" button to stop treatment if any emergency happened. **Caution:** For protecting the device, temperature detection was designed that the device will stop treatment when the feature board temperature over 80℃. The device cannot work again unless the temprature below 60℃. |
|   | 16. Press the "▶/II" button to pause treatment; you can press it again to restart the treatment. |

## 6.6 Ultrasound Therapeutic Set-up Procedure

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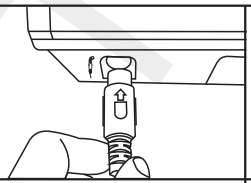
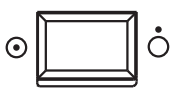
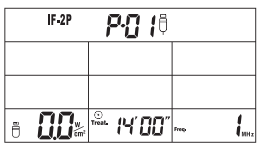
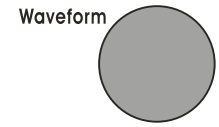
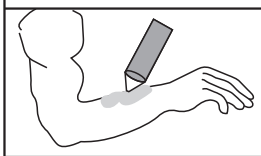
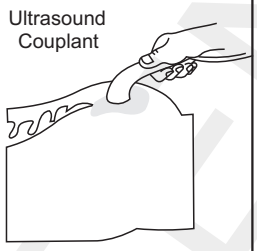
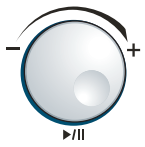
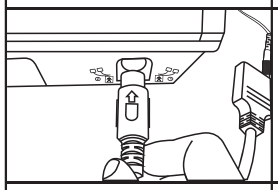
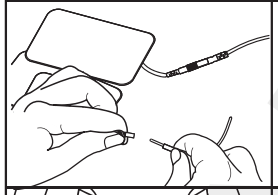
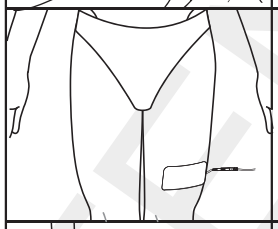
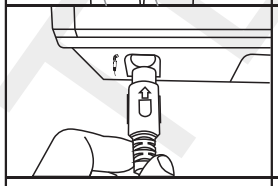
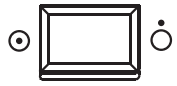
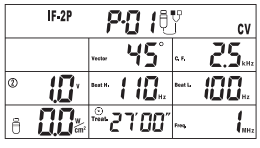
|---|---|
|  | 1.For ultrasound, plug the ultrasound applicator into the ultrasound connector(⑪ connector). **Caution:** Don't plug or pull out the ultrasound applicator when the device turned on. |
|  | 2. In order to turn on the device, please press ON/OFF switch to[⊙] icon which is located on the side of the device. |
|   | 3. When you turn the ComboCare™ on, the device will self- check for 10 seconds. The default parameters are displayed the last treatment mode. |

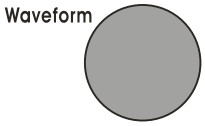
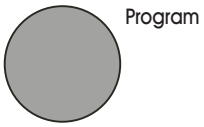
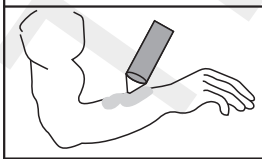
| | |
|---|---|
|   | 4.Press "B1" waveform button until " " indicator display on LCD, means the device enter into ultrasound therapeutic mode. |
|   | 5.Press"B8"button to toggle Ultrasound Frequency, then rotating the parameters control knob (③) to select the frequency 1MHz or 3MHz. |
|   | 6.Press"B8"button again to toggle Ultrasound Duty Factor, then rotating the parameters control knob (③) to set the duty factor from 10% to 100%, 10%/step. |
|   | 7.Press"B7"button to toggle Treat. time parameter, then rotating the parameters control knob (③) to set the treatment time from 1min to 30min, 1min/step. |
|  | 8.Apply a layer of transmission gel to the treatment area. Please note: Please purchase the transmission gel that is cleared by the FDA. |
|   | 9.Adjust the intensity and start ultrasound treatment that you are using by rotating the output intensity adjustable knob(⑧) on the control panel. Press the knob (⑧) to change the ultrasound unit "W" or "W/cm²". |
|   | 10.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. 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. |
|   | 11.For safety using, load detection was designed in this device. If the applicator is inadequate coupling to the patient and the ultrasound output over 0.5W, " "symbol will flash. |
|  | 12. Press the " " button to stop treatment if any emergency happened.<br>**Caution:**<br>For protecting patient, the device will stop ultrasound intensity output and the LED on the applicator will flash if the applicator temperature over 42℃. It will resume again when the temperature below 41℃. |

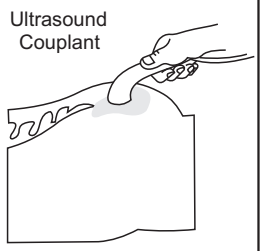
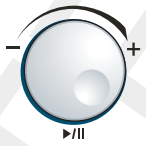
| | |
|---|---|
|  | 13. Press the "▶/II" button to pause treatment; you can press it again to restart the treatment. |

## 6.7 Combination Therapy (Ultrasound and Electrical stimulation) Set-up Procedure

ComboCare™ has both electrical stimulation and ultrasound function. The procedure of Combo therapeutic please refers to below:

| | |
|---|---|
|  | 1.In Combo therapeutic mode, Ultrasound probe as the Negative of channel 2, so you should connect the electrode wire (⑬)Electrode wire for ultrasound combination to positive of channel 2. And channel 1 have no output intensity. **Caution:** please note the color of the wires and the color marks on the cable, they should be corresponding. |
|  | 2.Plug the cable into the corresponding output connector (⑫ connector) on ComboCare™ |
|  | 3. Connect the electrodes to electrode wires. |
|  | 4. Place the electrodes on the patient according to section 6.1. |
|  | 5.For ultrasound, plug the ultrasound applicator into the ultrasound connector(⑪ connector). **Caution:**Don't plug or pull out the ultrasound applicator when the device turned on. |
|  | 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. When you first turn the ComboCare™ on, the default parameters are displayed the last treatment mode. |

| | |
|---|---|
|  | 8. Press "B1" waveform button until "" indicator display on LCD, means the device enter into Combo therapeutic mode. |
|   | 9. There are 4 therapeutic waveforms can be used for combo therapeutic. Rotating the Parameters control knob (③) to select waveform like Premodulated, TENS, EMS and Russian. |
|   | 10.Each therapeutic waveform has 10 programs. The details parameters for each program please refer to section 6.4 in this manual. Press the "B2" program button to toggle the therapeutic program, and then rotating the Parameters control knob to select the therapeutic programs in corresponding waveform. |
|   | 11. Press"B8"button to toggle Ultrasound Frequency, then rotating the parameters control knob (③) to select the frequency 1MHz or 3MHz. |
|   | 12. Press"B8"button again to toggle Ultrasound Duty Factor, then rotating the parameters control knob (③) to set the duty factor from 10% to 100%, 10%/step. |
| Setting electrical stimulation parameters | 13. Setting the electrical stimulation parameters please refer to section 6.5.2～6.5.4 in this manual. |
|   | 14.Press"B7"button to toggle Treat. time parameter, then rotating the parameters control knob (③ to set the treatment time from 1min to 30min, 1min/step. |
|  | 15.Apply a layer of transmission gel to the treatment area. Please note: Please purchase the transmission gel that is cleared by the FDA. |
|   | 16.Adjust the output intensity and start electrical treatment that you are using by rotating the output intensity adjustable knob (②) on the control panel. |
|   | 17.Adjust the intensity and start ultrasound treatment that you are using by rotating the ultrasound output intensity adjustable knob (⑧) on the control panel. Press the knob(⑧) to change the ultrasound unit "W" or "W/cm²". |

| | |
|---|---|
|  | 18. 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. 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. |
|  | 19. 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. |
|  | 20. Press the " " button to stop treatment if any emergency or error happened.<br>**Caution:**<br>1) For protecting the device, temperature detection was designed that the device will stop electrical stimulation treatment when the feature board temperature over 80℃. The device cannot work again unless the temperature below 60℃.<br>2) For protecting patient, the device will stop ultrasound intensity output and the LED on the applicator will flash if the applicator temperature over 42℃. It will resume again when the temperature below 41℃. |
|  | 21. Press the "▶/II" button to pause treatment; you can press it again to restart the treatment. |

**Restore Factory Defaults:**
If you want to restore factory parameter settings, please press and hold "①" and "②" knobs at the same time, and then turn on the device by pressing ON/OFF switch, keep pressing"①" and "②" knobs and the device will keep pealing until all parameters restore factory settings.

## 7. MAINTENANCE

### 7.1 Cleaning of the device

Switch off the device and disconnect it from the power supply. The apparatus 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 apparatus in liquids. Should the unit accidentally become submersed, contact the dealer or Authorized Service center immediately.Do not attempt to use a system that has been wet inside until inspected and tested by a Service Technician Certified by Authorized Service center. Do not allow liquids to enter the ventilation holes.

### 7.2 Cleaning the electrodes

- Apply the protective backing to the tacky side of the electrode. Place the electrode on the side of the protective backing that is labeled with the word on.
- It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turn the surface up to air dry. Over Saturation with water will reduce the adhesive properties.
- Between uses, store the electrodes in the reusable bag in a cool dry place.

**Caution**

- The electrodes are intended for single patient use only.
- If irritation occurs, discontinue use and consult your clinician.
- Always use the electrodes with CE mark, or are legally marketed in the US under 510(K) procedure.

### 7.3 Cleaning the lead wires and cables

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.

### 7.4 Maintenance

- 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 by unauthorized persons.
- Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

## 8. TROUBLESHOOTING

**For optimal use:**

- Replace lead wires annually.
- 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.
- NOTE: If the following measures fail to alleviate the problem, please call the authorized agency or your supplier.

| Problem | Possible Cause | Solution |
|---|---|---|
| Displays fail to light up | Adapter contact failure | Ensure adapter is connect. Check the following contacts:<br>● All contacts are in place.<br>● All contacts are not broken.<br>● Ensure that adapter is connected. |
| Stimulation weak | Electrodes<br>1. Dried out or contaminated<br>2. Placement | 1. Replace.<br>2. Electrodes must be a minimum of 2 inches apart. |
| | Lead wires<br>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 a minimum of 2 inches apart. |
| | 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 25.0cm$^2$. |
| Stimulation is ineffective. | Improper electrode | Reposition electrode |
| | Unknown | Contact clinician. |
| ″E1″ or ″E2″ displays on LCD | Hardware problem | Restart the device, if the problem is still exist, please contact the manufacturer or distributor |

| | | |
|---|---|---|
| "E3" displays on LCD | Temperature sensor failure | The device will stop treatment automatically, please wait several minutes before using again. |
| "E4" displays on LCD | Detected the device over limitative temperature | |
| "E5" displays on LCD | Memorizer failure is detected | Restart the device, if the problem is still exist, please contact the manufacturer or distributor |

## 9. SPECIFICATIONS

### 9.1 General Specifications:

| | |
|---|---|
| Adapter supply voltage: | 100V-240V, 47Hz-63Hz, 1.35A |
| Adapter output: | 15V ⎓ 3A Max. |
| Adapter Dimensions: | 143mm(L)*73mm(W)*40mm(H) |
| Dimensions: | 250mm(L)*185mm(L)*82mm(H) |
| Operating Environmental: | Temperature:10°C(50°F) to 40°C(104°F), Relative humidity: 30%-85% |
| Storage Environmental: | Temperature:-20°C(-4°F) to 55°C(131°F), Relative humidity: 20%-90% |
| 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 |

### 9.2 Ultrasonic Generator Specifications:

| | |
|---|---|
| Frequency (Freq.) | 1MHz ±10%<br>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<br>0.5W-15.0W, when duty factor≤70% for 5cm²<br>0.1W-2.0W, when duty factor≥80% for 1cm²<br>0.1W-3.0W, when duty factor≤70% for 1cm² |
| Effective radiating area($A_{ER}$) | 1. 0cm²(Optional)<br>5. 0cm² |
| Effective intensity(Max) | 3. 0W/cm² |
| Indication accuracy | ± 20% (for any level above 10% of maximum) |

| | |
|---|---|
| $R_{BN}$ (Max) | <8.0 |
| Beam type | Collimated |
| Material of sound head | Aluminium |
| Waterproof Grade | IPX7 Only for Ultrasound applicator |

## 9.3 Waveform Specifications:

### Interferential Traditional (4 Pole)

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

### Interferential Traditional (2 Pole) Mode

| | |
|---|---|
| Waveform Type | Bi-phasic square |
| Mode Selection | CC (Constant Current) or<br>CV (Constant Voltage) |
| Carrier Frequency (C.F.) | 2.5kHz |
| Sweep Low Beat Frequency (Beat H.) | (Beat L.) -150 Hz |
| Sweep High Beat Frequency (Beat L.) | 1-(Beat H.) Hz |
| Output Intensity | 0-100 mA (CC, at 1k ohm load)<br>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 |

**TENS and EMS Mode**

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

**Russian Mode**

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

**Caution:** This device has been thoroughly tested according to tested and inspected to assure proper performance and operation!

## 10 STORAGE

For a prolonged pause in treatment, store the device with the adapter in a dry room and protect it against heat, sunshine and moisture. Store the machine in a cool, well-ventilated place. Never place any heavy objects on the machine.

## 11 DISPOSAL

Please dispose of the device in accordance with the directive 2002/96/EC – WEEE (Waste Electrical and Electronic Equipment). Contact your local distributor for information regarding disposal of the unit and accessories.

## 12 EMC TABLE

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 tested according to tested and inspected to assure proper performance and operation!

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| The ComboCare™ device is intended for use in the electromagnetic environment specified below. The customer or the user of the ComboCare™ should assures that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions CISPR 11 | Group 1 | The ComboCare™ 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 CISPR11 | Class B | The ComboCare™ device is suitable for use in all establishments other than 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 ComboCare™ device is intended for use in the electromagnetic environment specified below. The customer or the user of the ComboCare™ 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 ±8 kV air | ±6 kV contact ±8 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 | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line (s) to line (s) | ±1 kV line (s) to line (s) | Mains power quality should be that of a typical commercial or hospital environment. |
| 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 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds | Mains power quality should be that of a typical commercial 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. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic 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. | | | |

| Guidance and- manufacturer's declaration. Electromagnetic immunity | | | |
|---|---|---|---|
| The ComboCare™ device is intended for use in the electromagnetic environment specified below. The customer or the user of the ComboCare™ should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60501 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the ComboCare™ device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | **Recommended separation distance** |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | $d=1.2\sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | $d=1.2\sqrt{P}$ 80MHz to 800MHz |
| | | | $d=2.3\sqrt{P}$ 80MHz to 2.5MHz |
| | | | 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: |

| | | | |
|---|---|---|---|
| | | | Interference may occur In the vicinity of equipment marked with the following symbol: |
| | | |  |

NOTE I At 80 MHz ends 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 radio 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 ComboCare™ 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 ComboCare™ device.

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

**Recommended distances between portable and mobile RF communications equipment and the ComboCare™ device**

The ComboCare™ device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ComboCare™ device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ComboCare™ 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 transmitterm | | |
|---|---|---|---|
| | 150 kHz to 80 MHZ $d=1.2\sqrt{P}$ | 80 MHz to 800 MHZ $d=1.2\sqrt{P}$ | 800 MHz to 2,5 GHz $d=2.3\sqrt{P}$ |
| 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.<br>NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

## 13. WARRANTY

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

A. The following warranty terms apply:

- The warranty period for ComboCare™ products is 2 years from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
- Defects in material or workmanship will be removed free of change with in the warranty period.
- Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.

B. The following is excluded under the warranty:

- All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
- All damage which is due to repairs or tampering by the customer or unauthorized third parities.
- Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
- Accessories which are subject to normal wear and tear.

- 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.

## 14. SYMBOLS


ON/OFF Switch


Power polarity


Type BF Applied Part


Refer to Instruction Manual


Disposal in accordance with Directive 2002/96/EC


Equipment capable of delivering output values in excess of 10 mA r.m.s. or 10V r.m.s. averaged over any period of 5 s


Stop treatment


Start/Pause the treatment

**IPX7** Protected against the effects of immersion: for the whole ultrasound treatment head


Serial Number

CURRENT SOLUTIONS™

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