ZZACOMBO

BodyMed®

TENS/EMS/Massager Combo

Please read this instruction manual prior to operating.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Table of Contents

1. FOREWORD

Introduction

The device ZZACOMBO is a dual channel output TENS, EMS, and MASSAGE stimulator. Before using, please read the instruction manual.

The COMBO stimulator belongs to the group of electrical stimulation systems. It has three basic functions: TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electronic Muscle Stimulation), and MASSAGE.

Function of the COMBO stimulator: The device has 22 programs (9 TENS programs, 8 EMS programs, and 5 MASSAGE programs) and applies electric currents in the low-frequency range for therapy. Each program controls the generated electric impulses, their intensity, frequency, and pulse width.

Based on simulating the body's natural pulses, the mechanism of electrical stimulation equipment is to create electric impulses that are transcutaneously transmitted to nerves or muscle fibers through the electrode.
The intensity of the dual channel can be adjusted independently and applied individually to one body part. This dual channel device can be used with four pieces of electrodes, which allow you to stimulate different muscle group simultaneously with a wide selection of standard programs. The Electrical pulse is first transmitted to the tissue, then it affects the transition of stimulation in nerves as well as muscle tissues in the body parts.

1.2 Medical Background

1.2.1 About Pain

Pain is an important signal in the human body warning system. It reminds us that something is wrong without which abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies. Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. Aside from its function in diagnosis, long-lasting persistent pain is not useful to its original purpose.

Pain does not occur until an encoded message travels to the brain where it is decoded, analyzed, and reacted to from the injured area along the small nerves leading to the spinal cord. There the message is transmitted to different nerves that travel up the spinal cord to the brain. Then the pain message is interpreted, referred to, and pain is felt.

1.2.2 What Is TENS?

TENS (Transcutaneous Electrical Nerve Stimulation) is effective in relief of pain. It is used daily and clinically proven by physiotherapists, caregivers, and top athletes around the world. High-frequency TENS currents activate the pain-inhibiting mechanisms of the nervous system. Electrical impulses from electrodes, placed on the skin over or near the pain area, stimulate the nerves to block the pain signals to the brain, causing the pain go unperceived. Low-frequency TENS currents facilitate the release of endorphins, the body's natural painkillers.

1.2.3 What Is EMS?

Electrical Muscle Stimulation is an internationally accepted and proven way of treating muscular injuries. It works by sending electronic pulses to the muscle needing treatment that causes the muscle to exercise passively. It is a product deriving from the square waveform, originally invented by John Faraday in 1831. Through the square wave pattern, it is able to work directly on muscle motor neurons. The EMS System has low frequencies and this in conjunction with the square wave pattern allows direct work on muscle groupings.

2. SAFETY INFORMATION

2.1 Intended Use

TENS Mode

- Symptomatic relief of chronic intractable pain
- Post traumatic pain
- Post surgical pain

EMS Mode

- Relaxation of muscle spasms
- Prevention of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

2.2 Important Safety Precautions and Warnings

It is important that you read all the warnings and precautions included in this manual because they are intended to keep you safe, prevent risk of injury, and avoid a situation that could result in damage to the device.

SAFETY SYMBOLS USED IN THIS MANUAL

2.2.1 ⚠ Contraindication

1) Do not use this device if you are using a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic devices. Such use could cause electric shock, burns, electrical interference, or death.

2) The device should not be used when cancerous lesions or other lesions are present in the treatment area.

3) Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.).

4) Electrode placements must be avoided in the carotid sinus area (anterior neck) or transcerebrally (through the head).

5) This device should not be used in overly enervated areas.

6) This device should not be used on an inguinal hernia.

7) Do not use on scarred areas following a surgery for at least 10 months after the operation.

8) Do not use with serious arterial circulatory problems in the lower limbs.

2.2.2 ⚠ Warning

1) The long-term effect electrical stimulation is unknown. Electrical stimulation devices do not have any curative value.

2) This device should only be used under the continued supervision of a licensed medical practitioner.

3) Electrical stimulation is not effective for central origin pain such as headache.

4) Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

5) Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

6) Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when electrical stimulation device is in use.

7) 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.

8) 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).

9) Do not apply stimulation while the patient is sleeping.

10) Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

11) Stimulation should not take place while the user is connected to high-frequency surgical equipment, it may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.

12) Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.

13) Never use in environments with high humidity such as in the bathroom or when having a bath or shower.

14) Never use near the heat. Stimulation electrodes should never be placed anywhere on the front of the thorax (marked by ribs and breastbone),but above all not on the two large pectoral muscles. Here it can increase the risk of ventricular fibrillation and lead to cardiac arrest.

15) Never use on the eye area.

16) Never use near the genitals.

17) Apply the electrodes to clean, dry, and unbroken skin only.

18) Keep electrodes separate during treatment, electrodes in contact with other could result in improper stimulation or skin burns.

19) Consult your doctor if you are in any doubt whatsoever.

20) Consult with your doctor before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.

21) Discontinue and do not increase the intensity level if you feel discomfort during use.

22) Secure limbs (e.g. arms, legs) in place during arm and leg stimulation.

23) Avoid standing during leg stimulation to prevent falls.

2.2.3 ⚠ Precautions

1) For single patient use only.

2) Keep yourself informed of the contraindications.

3) This stimulator shall never be used by patients who have noncompliant, emotionally disturbed, dementia, or low IQ.

4) Read, understand, and practice the precautionary and operating according to the instructions. Know the limitations and hazards associated with using any other device. Observe the precautionary and operational decals that placed on the unit.

5) The instruction of use was listed; any improper use may be dangerous.

6) Caution should be used for patients who are suspected or diagnosed with heart problems.

7) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or silicone rubber. If rash develops or pain persists, discontinue use and consult a doctor. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement.

8) Electrode placement and stimulation settings should be based on the guidance of prescribing practitioner.

9) Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain-afflicted patients.

10) Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.

11) The electrodes can only be placed on healthy skin. Avoid skin irritation by ensuring that good contact is achieved between electrodes and skin.

12) If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.

13) 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.

14) Never use the device in rooms where aerosols (sprays) are used or pure oxygen is being administered.

15) Do not use it near any highly-flammable substances, gases, or explosives.

16) Do not use this device at the same time as other equipment, which sends electrical pulses to your body.

17) Do not confuse the electrode cables and contacts with your headphones or other devices, and do not connect the electrodes to other devices.

18) Do not use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.

19) Inspect applicator cables and associated connectors before each use.

20) Electrical stimulators should be used only with the leads and electrodes recommended by the manufacturer.

21) Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

22) TENS is not a substitute for pain medications and other pain management therapies.

23) TENS is a symptomatic treatment and as such suppresses the sensation of pain that would otherwise serve as a protective mechanism.

24) 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.

25) Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture.

26) Safety of powered muscle stimulators for use during pregnancy has not been established.

27) Caution should be used for patients with suspected or diagnosed epilepsy.

28) Caution should be used in the presence of the following:

29) When there is a tendency to hemorrhage following acute trauma or fracture;

30) Following recent surgical procedures when muscle contraction may disrupt the healing process;

31) Over the menstruating or pregnant uterus; and

32) Over areas of the skin that lack normal sensation.

2.2.4 Adverse Reactions

1) Possible skin irritation or electrode burn under the electrodes may occur.

2) Possible allergic skin reaction to tape or gel may occur.

3) If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.

4) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.

5) 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.

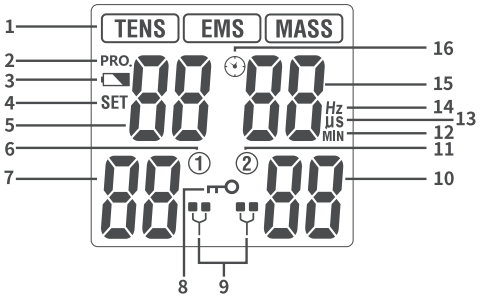
6) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

3. GETTING TO KNOW YOUR DEVICE

3.1 Components Included

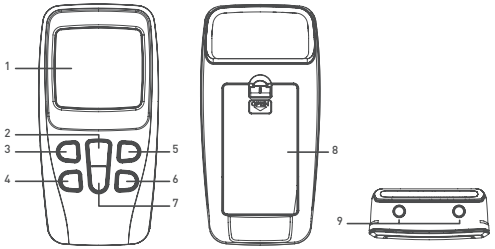
No.	Description	QTY
1	The COMBO Stimulator	1pc
2	Electrode pad (50mm×50mm)	4pcs
3	Electrode wires	2pcs
4	Ordinary batteries (1.5V, AAA)	3pcs
5	Belt clip	1pc
6	User manual	1pc

3.2 LCD Display



No.	Function Description	No.	Function Description
1	Treatment mode	9	Indicator of no load (Channel 1 and Channel 2)
2	Symbol of program	10	Intensity for Channel 2
3	Low battery indicator	11	Symbol of Channel 2
4	Symbol of SET	12	Symbol of treatment time (min)
5	Program number	13	Symbol of pulse width (uS)
6	Symbol of Channel 1	14	Symbol of pulse rate (Hz)
7	Intensity for Channel 1	15	Treatment time
8	Key locking symbol	16	Timer sign

3.3 Device Illustration



No.	Description
1	LCD display
2	[ON/OFF/M] button: At power saving mode, press the [ON/OFF/M] button to turn on the device; At standby mode, press the [ON/OFF/M] button to select treatment mode; At standby mode, press and hold the [ON/OFF/M] button to turn off the device; At treating mode, press the [ON/OFF/M] button to stop the treatment.
3	[+] button: At standby or treating mode, press the [+] button to increase the intensity of CH1; At setting mode, press the [+] button to increase the corresponding data for the pulse rate, pulse width or treatment time.
4	[-] button: At treating mode, press the [-] button to decrease the intensity of the CH1. At the key locking mode, press the [-] button to unlock the keys. At setting mode, press the [-] button to decrease the corresponding data for the pulse rate, pulse width or treatment time.
5	[+] button: At standby or treating mode, press the [+] button to increase the CH1 or CH2; At setting mode, press the [+] button to increase the corresponding data for the pulse rate, pulse width or treatment time.
6	[-] button: At treating mode, press the [-] button to decrease the CH2. At the key locking mode, press the [-] button to unlock the keys. At setting mode, press the [-] button to decrease the corresponding data for the pulse rate, pulse width or treatment time.
7	[P] button: At standby mode, press the [P] button to select the treatment program. At standby mode, press and hold [P] button to enter the setting mode.
8	Battery cover
9	Output socket

4. SPECIFICATION

4.1 Technical Information

Device Name	Combo Electrotherapy Device
Model/type	ZZACOMBO
Power sources	4.5V D.C., 3x AAA batteries
Output channel	Dual channel
Waveform	Bi-phase square-wave pulse
Output current	Max. 120mA (at 500ohm load)
Output intensity	0 to 40 levels, adjustable
Treatment mode:	TENS, EMS, and MASSAGE mode
Operating condition	5° C to 40° C with a relative humidity of 15%–93%, atmospheric pressure from 700 hPa to 1060 hPa
Storage condition	-10° C to 55° C with a relative humidity of 10%–95%, atmospheric pressure from 700 hPa to 1060 hPa
Dimension	109*54.5*23mm (L x W x T)
Weight	About 70g (without batteries)
Automatic shutoff	1 minute
Classification	BF type applied part, internal power equipment, IP22
Size of electrodes pad	50x50mm, square
Output precision	±20% error is allowed for all the output parameters

TENS Mode	
Number of programs	9 programs
P.W. (Pulse Width)	100-300μs
P.R. (Pulse Rate)	2-100Hz (Hz=vibration per second)
Treatment time	5–90 minutes

EMS Mode	
Number of programs	8 programs
P.W. (Pulse Width)	100μs-300μs
P.R. (Pulse Rate)	2-100Hz (Hz=vibration per second)
Treatment time	5–90 minutes

MASSAGE Mode	
Number of programs	5 programs
P.W. (Pulse width)	100-250μs
P.R. (Pulse Rate)	8-100Hz (Hz=vibration per second)
Treatment time	30 minutes

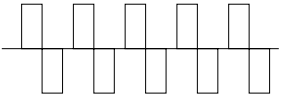
4.2 Treatment Programs

Mode	Pro-gram	Treatment time(min)	Pulse rate(Hz)	Pulse width (us)	Remark
TENS	P1	Default:30 Adj.:(5-90)	100	150	Continuous
	P2	Default:30 Adj.:(5-90)	60	200	Continuous
	P3	Default:30 Adj.:(5-90)	15	260	Continuous
	P4	Default:30 Adj.:(5-90)	2-60	260-160	Pulse Rate and Width Modulation
	P5	Default:30 Adj.:(5-90)	60/50/45/ 10/50/35	200	Pulse Rate Modulation
	P6	Default:30 Adj.:(5-90)	40/6/50	200	Pulse Rate Modulation
	U1	Default:30 Adj.:(5-90)	Default:50 Adj.:(2-100)	Default:180 Adj.:(100-300)	Continuous
	U2	Default:30 Adj.:(5-90)	Default:60 Adj.:(2-100)	Default:160-260 Adj.:(100-300)	Pulse Width Modulation
	U3	Default:30 Adj.:(5-90)	Default:60 Adj.:(2-100)	Default:260 Adj.:(100-300)	Modulation(I.M.)
EMS	P1	Default:30 Adj.:(5-90)	4	200	Continuous
	P2	Default:30 Adj.:(5-90)	20	200	Synchronous
	P3	Default:30 Adj.:(5-90)	50	200	Synchronous
	P4	Default:30 Adj.:(5-90)	60	200	Alternate
	P5	Default:30 Adj.:(5-90)	50	200	Alternate
	U1	Default:30 Adj.:(5-90)	Default:5 Adj.:(2-100)	Default:300 Adj.:(100-300)	Continuous
	U2	Default:30 Adj.:(5-90)	Default:60 Adj.:(20-100)	Default:200 Adj.:(100-300)	Synchronous
	U3	Default:30 Adj.:(5-90)	Default:70 Adj.:(20-100)	Default:200 Adj.:(100-300)	Alternate
MASSAGE	P1	30	8	300	Continuous
	P2	30	100	220	Continuous
	P3	30	28~45	120~250	Pulse Rate and Width Modulation
	P4	30	25~80	120~250	Pulse Rate and Width Modulation
	P5	30	50~100	100~240	Pulse Rate and Width Modulation

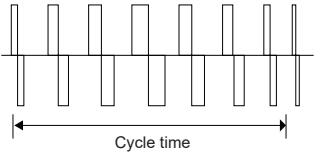
4.3 The waveform of the stimulation program:

TENS

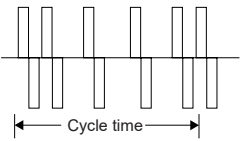
Continuous



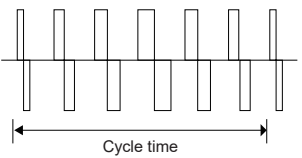
Pulse Width Modulation



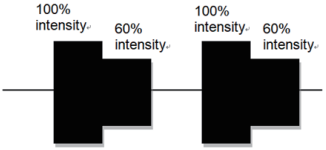
Pulse Rate Modulation



Modulation (Pulse Rate and Width Modulation)

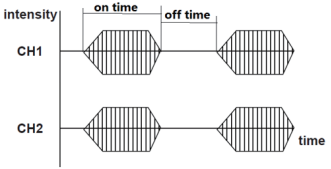


Modulation(I. M)

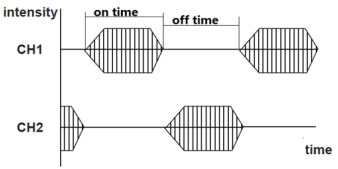


EMS

Synchronous



Alternate

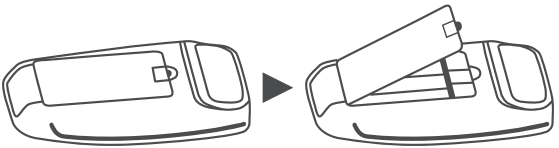


5. OPERATING INSTRUCTION

5.1 Battery

5.1.1 Check/Replace Batteries

Open the battery cover and insert three batteries (type AAA) into the battery compartment. Make sure you are installing the batteries properly. Be sure to place the batteries according to the markings of positive terminal (+) and negative terminal (-) in the battery compartment of the device.



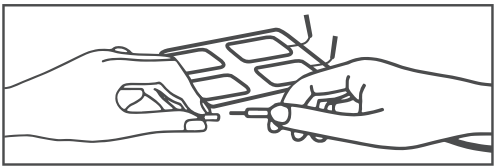
5.1.2 Disposal of Batteries

Spent batteries do not belong in the household waste. Dispose of the batteries following the current regulations. As a consumer, you have legal obligation to return spent batteries to the Recycle Bin.

1. If a battery was swallowed accidentally, please seek medical assistance immediately.
2. In case of battery leakage, please avoid contact with the battery through skin, eyes, and mucus membranes. Once it occurs, please wash the contacted area with plenty of clean water and contact your doctor immediately.
3. Battery cannot be dismantled, thrown into fire or short-circuited.
4. Protect battery from excess heat; take the battery out of the product if they are spent or you don't use it for a long time. This can prevent device from damage due to the battery leakage.
5. Replace all of the batteries simultaneously.
6. Always replace the device with the same type of battery.

5.2 Connect Electrode Pads to Electrode Wires

Insert the electrode wires connector into the electrode connector. Make sure they are properly connected to ensure good performance. Please refer to the picture below.



Caution ⚠

Always use the electrode pads that comply with the requirements of the IEC/EN60601-1, ISO10993-1/-5/-10 and IEC/ EN60601-1-2, as well as CE and FDA 510(K) regulation.

5.3 Connect Electrode Wires to Device

Before proceeding to this step, ensure that the device is completely switched OFF.

Hold the insulated portion of the electrode wire connector and insert the plug into the receptacle on the top of the main device.

Ensure the electrode wires are inserted correctly. The device has two output receptacles controlled by Channel A and Channel B at the top of the unit. You may choose to use one channel with one pair of electrode wires or both channels with two pairs of electrode wires. Using both channels gives the user the advantage of stimulating two different areas at the same time.

Caution ⚠

Do not insert the plug of the electrode wires into any AC power supply socket.

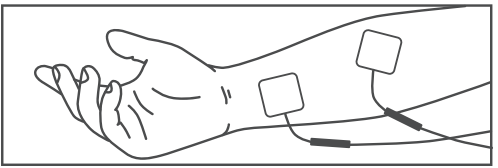
5.4 Electrode

5.4.1 Electrode Options

The electrodes should be routinely replaced when they start to lose their adhesiveness. If you are unsure of your electrode adhesive properties, please order new replacement electrodes. Replacing electrodes should be reordered under the advice of your physician or the device manufacturer to ensure proper quality. Follow application procedures outlined on electrode packaging when using the new replacement electrodes to maintain optimal stimulation and to prevent skin irritation.

5.4.2 Place Electrodes on Skin

Place the electrodes on the body part in need of treatment, according to the instruction of this user manual. Please make the skin clean before use and ensure the skin and electrodes connect well.



Caution ⚠

1. Always remove the electrodes from the skin with a moderate pull in order to avoid injury in the event of highly-sensitive skin.
2. Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
3. Do not turn on the device when the self-adhesive electrodes are not positioned on the body.
4. To remove or move the electrodes, switch off the device or the appropriate channel first in order to avoid unwanted irritation.
5. It is recommended that, at minimum, 1.97"x 1.97" self-adhesive square electrodes are used at the treatment area.
6. Never remove the self-adhesive electrodes from the skin while the device is still on.

5.4.3 Electrode Placement

The placement of electrodes can be one of the most important factors in achieving successful therapy. Please consult a physician to try the various styles of electrode placement to find which method best fits the needs of the individual patient.

Every patient is differing from the responds to electrical stimulation, and their needs may vary from the conventional settings suggested here. If the initial results are not positive, tell your physician to choose alternative stimulation settings and/or electrode placements. Once an acceptable placement has been achieved, mark down the electrodes sites and the settings, so the patient can easily continue treatment at home.

6. INSTRUCTIONS FOR USE

6.1 Turn On

When using it for the first time, open the battery cover and load three new batteries (Please review Section 5.1.1 for the operating steps and schematic diagram).

Press the [ON/OFF/M] button to turn the device on; the LCD will be lit. Then it goes into the standby mode as the picture shown below.

6.2 Select Treatment Mode

Press the [ON/OFF/M] button to select which treatment mode (TENS-EMS-MASS) you will use. The LCD displays as follows:

6.3 Select Treatment Program

Based on your need, press [P] button to select the treatment program. The LCD displays as follows:

6.4 Set Program Parameter

Press and hold [P] button to enter the setting mode.

1) In the program p1 to p6 of the TENS mode and the program p1 to p5 of the EMS mode, press [+]/[-] button to adjust treatment time.

The LCD displays as follows:

2) In the program U1 to U3 of the TENS mode and the program U1 to U3 of the EMS mode, press [P] button to adjust pulse rate -> pulse width -> treatment time by setting the parameter.

3) Press [+]/[-] button to adjust corresponding data.

Treatment Mode	Program NO.	Treatment time (min)	Frequency (Hz)	Pulse width (us)
TENS	U1	Default:30 Adjustable:(5-90)	Default:50 Adjustable:(2-100)	Default:180 Adjustable:(100-300)
	U2	Default:30 Adjustable:(5-90)	Default:60 Adjustable:(2-100)	Default:160-260 Adjustable:(100-300)
	U3	Default:30 Adjustable:(5-90)	Default:60 Adjustable:(2-100)	Default:260 (100-300)
EMS	U1	Default:30 Adjustable:(5-90)	Default:5 (2-100)	Default:300 (100-300)
	U2	Default:30 Adjustable:(5-90)	Default:60 (20-100)	Default:200 (100-300)
	U3	Default:30 Adjustable:(5-90)	Default:70 (20-100)	Default:200 (100-300)

4) Press [ON/OFF/M] button to return to the standby mode.

6.5 Start Treatment

Press the [+] button of CH1 to increase the channel 1 intensity press the [+] button of CH2 to increase the channel 2 intensity. The LCD displays as follows:

6.6 Adjust the Output Intensity

Place the electrodes on the body parts. Press the [+] button to increase output intensity. It will be increased to a higher level after each press. The device has total of 40 levels of output intensity. Please adjust the intensity to the condition that you feel comfortable. The level of output intensity will be shown on the LCD:

If you feel it is too strong, you can press [-] button to decrease the intensity to a lower level each time. When the output intensity of both channels decreases to zero, the stimulator will return to the standby mode. The LCD displays as follows:

Caution ⚠

If you feel or become uncomfortable, reduce the stimulation intensity to a more comfortable level and consult with your medical practitioner if problems persist.

6.7 Stop the Treatment and Turn Off the Device

Press the [ON/OFF/M] button to stop treatment during the treating mode. Press the [ON/OFF/M] button again to turn off the stimulator, and the LCD will be blank.

6.8 Load Detection

It will automatically detect the load if the intensity is above level 4. If it hasn't detected the load or the electrode contacts the skin not well enough, the intensity will automatically return to level 0 and the symbol twinkles. The stimulator returns to the standby mode.

6.9 Low Battery Detection

When the battery is low, the icon will twinkle to indicate. Stop the device and change the battery.

Notice of Batteries:

a. Batteries may be fatal if swallowed. Therefore, keep the batteries and the product out of the reach of children. If a battery is swallowed, go to a hospital immediately.

b.If there's battery leakage, avoid contact with skin, eyes, and mucus membranes. Rinse the affected spots with plenty of clear water immediately and contact a physician right away.

c. Batteries must not be charged, dismantled, thrown into fire, or short-circuited

d.Protect batteries from excess heat. Take the batteries out of the device if they are spent or in case you will no longer use them. This prevents damage caused by leaking batteries.

7. CLEANING AND MAINTENANCE

Fully comply with the following necessary daily maintenance requirements to make sure the device is intact and guarantee its long-term performance and safety.

7.1 Cleaning and Caring for the Device

7.1.1 Pull the electrodes out of the stimulator; clean the device with a soft, slightly damp cloth. In case of heavier dirt build-up, you may also apply a mild detergent.

7.1.2 Do not expose the COMBO stimulator to moisture or dampness. Do not hold the COMBO stimulator under running water, nor submerge it in water or other liquids.

7.1.3 The COMBO stimulator is sensitive to heat and may not be exposed to direct sunlight. Do not place it on hot surfaces.

7.1.4 Clean the surface of the electrode pads carefully with a damp cloth. Make sure the device is turned off.

7.1.5 For reasons of hygiene, each user should use his/her own set of electrodes.

7.1.6 Do not use any chemical cleaners or abrasive agents for cleaning.

7.1.7 Ensure that no water penetrates into the machine. Should this happen, use the device again only when it is completely dry.

7.1.8 Do not clean the device during treatment. Be sure that the device is turned off before cleaning.

7.2 Maintenance

7.2.1 The manufacturer didn't authorize any maintenance agencies. The manufacturer will not be responsible for the results of maintenance or repairs by unauthorized persons.

7.2.2 The user must not attempt any repairs to the device or any of its accessories.

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

Each product has been inspected through the systematic validation. The performance is stable and does not need to undertake calibration and validation. If your product can't reach the expected performance and the basic function has changed in normal use, please contact the retailer.

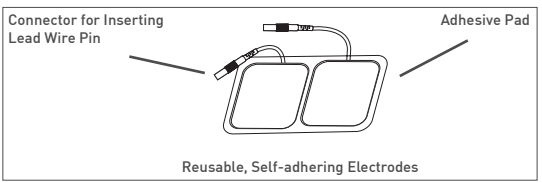
7.3 Electrodes

7.3.1 Use the device only with leads and electrodes provided by the manufacturer. Use only the electrode placements and stimulation settings prescribed by your physician or therapist.

7.3.2 It is recommended to use electrodes measuring 50 x 50mm that are manufactured by BodyMed®.

7.3.3 Inspect your electrodes before every use. Replace electrodes if needed. Reusable electrodes may cause slight skin irritation, lose adhesion, and deliver less stimulation when overusing. Normally, the electrodes can be reused about 20 times.

7.3.4 Please note to check the validity period (1 year) on the electrodes package. Do not use the electrodes if they are beyond their expiry date.



To use these electrodes:

1) Attach the electrode to the lead wire.

2) Remove the protective backing from the electrode surface. Do not throw away the protective backing because it can be reused after the treatment session has been completed.

3) Place the tacky surface to the prescribed skin area by pressing the electrode firmly to the skin.

To remove your electrodes:

1) Lift the corner of the electrode and gently remove it from the skin.

2) 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.

3) 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. Excessive water will reduce the adhesive properties.

4) Between use, put the electrodes in the re-sealable bag and store them in a cool and dry place.

Caution ⚠

1) Do not pull the electrode wire. Doing so may damage the wire and electrode.

2) Do not apply to broken skin.

3) The electrodes should be discarded when they lose adhesiveness.

4) The electrodes are intended for single patient use only.

5) If irritation occurs, discontinue use and consult your physician.

6) Read the instructions for use of self-adhesive electrodes before application.

7.4 Cleaning the Electrodes Cords:

Clean the electrode cords by wiping them with damp cloth. Coating them lightly with talcum powder will reduce tangles and prolong the life.

8. TROUBLESHOOTING

Should any malfunction occur while using the device, check whether the parameters are set appropriately for therapy, and adjust the control correctly. Please see the following table:

Malfunction	Common Reasons	Countermeasure
No display after replacing the battery	1. There's a foreign body in the battery compartment. 2. The battery has been used up or installed incorrectly. 3. There is foreign body in the battery interface. 4. The battery is not the right model or something goes wrong with the battery interface 5. Exception reset.	1. Check and clean the compartment 2. Replace the new battery or install the battery correctly. 3. Check and clean the interface 4. Replace the battery with the right model.
No sensation of stimulation	1. The electrode does not connect well to the skin. 2. The electrode does not connect well to the stimulator. 3. The battery is used up. 4. The skin is too dry.	1. Check and re-paste it on skin. 2. Check the connection. 3. Replace the battery. 4. Wipe the electrode and the skin with a wet cotton cloth.
Automatic halt in the treatment	1. The electrode loses connection with the skin. 2. If the battery is used up.	1. Check and place the electrode properly on the skin. 2. Replace the battery.
Rash or tickle on the skin occurs in the treatment	1.The treatment time lasts too long. 2.The electrode does not stick well to the skin. 3. The interface of the electrodes is dirty or dry. 4. The skin is sensitive to the electrode.	1. Do the treatment once a day and shorten the treatment time. 2. Check and stick the electrode well. 3. Wipe the electrode with a wet cotton cloth before use. 4. Check your allergic history. Please change the sticking place or shorten the treatment time. If your skin is over-sensitive, you should stop the treatment or go to see a doctor.

9. STORAGE

9.1 Storing the Electrode Pads and Lead Wires

1. Turn the device off and remove the lead wires from the unit.
2. Remove the electrodes from your body and disconnect the lead wires from the electrodes.
3. Place the electrodes onto the plastic film and then store in the sealed package.
4. Wrap the lead wires and store in the sealed package.

9.2 Storing the Unit

1. Place the unit, electrodes, lead wires and manual back into the carrying case. Store the case in a cool, dry place, -10C ~ 55C ; 10% ~ 90% relative humidity.
2. Do not keep in places that can be easily reached by children.
3. When not in use for a long period, remove the battery before storage.

10. DISPOSAL

Spent batteries do not belong in the household waste. Dispose of the battery according to the current regulations. As a consumer, you have the obligation to dispose of batteries correctly. Consult your municipal authority or your dealer for information about disposal.

At the end of the product lifecycle, do not throw this product into the normal household garbage, but bring it to a collection point for the recycling of electronic equipment. Obsolete electrical and electronic equipment may have potentially harmful effects on the environment. Incorrect disposal can cause toxins to build up in the air, water, and soil and jeopardize human health.

11. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and Manufactures Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specific below. The customer or the user has to assure it is used in such environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The device is suitable for use in all establishments including those directly connected to the public low-voltage power supply network that supplies to buildings power used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufactures Declaration — Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specific below. The customer or the user has to assure it is used in such environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV direct & indirect contact; ±15kV air discharge	±8kV direct & indirect contact; ±15kV air discharge	Floors should be wood, concrete or 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	Not applicable	Not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	Not applicable	Not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Not applicable (For INTERNALLY POWERED ME EQUIPMENT
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	10V/m	10V/m	Power frequency magnetic fields should be at levels characteristic of a typical location in typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufactures Declaration — Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Radiated RF IEC 61000-4-3	10V/m & table 9	10V/m & table 9	Portable and mobile RF communications equipment should be used not closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (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: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular cordless) telephones and land mobile radios, amateur radio, AM and FM 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment (Table 9)						
Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM c)±5kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	Pulse modulation [b] 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217Hz	0.2	0.3	9
5500						
5785						

NOTE: If it is necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a. For some services, only the uplink frequencies are included.

b. The carrier shall be modulated using a 50 % duty cycle square wave signal.

c. As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because it does not represents actual modulation. It would be worst case.

12. NORMALIZED SYMBOLS

	Electrical devices are recyclable material and should not be disposed of with household waste after use. Help us protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization that is responsible for waste disposal in your area if any questions.
	Applied part of type BF
	Refer to instruction manual
IP22	The first number 2: Protect against solid foreign objects of 12,5 mm Φ and greater. The second number: Protect against vertically falling water drops when enclosure titled up to 15º. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15º, on either side of the vertical.
LOT	LOT ☐☐☐☐☐☐☐☐ R Year Month Numerical Order R: Production Code
	Manufacture date

13. WARRANTY

Please contact your dealer or the device center in case of a claim under the warranty. If you have to return the unit, enclose a copy of your receipt with clear statement of defect description.

The warranty terms are as below:

1. The warranty period for this device is 1 year from the 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.
2. Repairs under warranty should be in the warranty period either for the device or for the replacement parts.
3. The following cases are excluded under the warranty:
   - All damages that arise due to improper operation, e.g. nonobservance of the user instruction.
   - All damages due to repairs or tampering by the customer or unauthorized third parities.
   - Damages that have arisen during transport from the manufacturer to the consumer or the service center.
   - Accessories that are subject to normal wear and tear.
   - Device damages due to privately dissembling devices.
4. 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.

BodyMed®

TENS/EMS/Massager Combo

ZZACOMBO