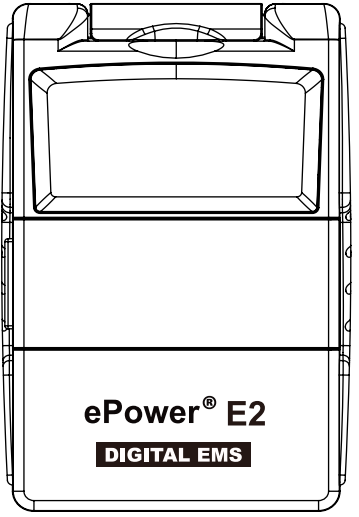
INSTRUCTION MANUAL
FOR
EMS STIMULATOR

ePower® E2



Clinical Health Services, Inc.

This manual is valid for the **ePower® E2** Stimulator

Be sure to read this instruction manual before operation and keep it where safe.

This user manual is published by Clinical Health Services, Inc.

Clinical Health Services, Inc. does not guarantee its contents and reserves the right to improve and amend it at any time without prior notice. However, Amendments will be published in a new edition of this manual.

ePower® E2 Rev. V1.0© 2023, printed on Sep. 16, 2023.

Declaration of conformity:
Clinical Health Services, Inc. declares that the device complies with following normative documents:
IEC60601-1, IEC60601-1-2, IEC60601-1-11, IEC60601-2-10, IEC62304,
ISO10993-5, ISO10993-10, ISO10993-1, ISO14971

TABLE OF CONTENTS

1. FOREWORD

1.1 Introduction

The device is a dual channel output EMS (Electronic Muscle Stimulation) stimulator. Before using, please read all the instructions in this user manual carefully and keep it safe for future use.

1.2 Explanation of 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 frequency and this in conjunction with the square wave pattern allows direct work on muscle groupings. This is being widely used in hospitals and sports clinics for the treatment of muscular injuries and for the re-education of paralyzed muscles, to prevent atrophy in affected muscles and improving muscle tone and blood circulation.

2. SAFETY INFORMATION

2.1 Intended use

The EMS stimulation program stimulates healthy muscles in order to improve and facilitate muscle performance.

The device can be used in the home or hospital, using the object (patient) must be 18 years or older of adults.

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 trans cerebrally (through the head).
5) This device should not be used in

overly enervated areas.

6) 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) If you have had medical or physical treatment for your pain, consult with your physician before use.
2) If your pain is not subdued, which becomes more than mild, or lasts for more than five days, stop using the device and consult with your physician.
3) Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
4) Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.
5) Do not apply stimulation over, or in proximity to, cancerous lesions.
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 when in bath or shower.
8) Do not apply stimulation while sleeping.
9) Do not apply stimulation while driving, operating machinery, or during any activity when electrical stimula-

tion can put you at risk of injury.

10) Apply stimulation only to normal, intact, clean, healthy skin.
11) The long-term effects of electrical stimulation are unknown. Electrical stimulation device cannot replace drugs.
12) Stimulation should not take place while the user is connected to high-frequency surgical equipment, which may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
13) Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
14) Never use it near the cardiac area. 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. There it can increase the risk of ventricular fibrillation and lead to cardiac arrest.

15) Never use it on the eye, head and face area.
16) Never use it near the genitals.
17) Never use it on the areas of the skin which lack normal sensation

18) Keep electrodes separate during treatment. It could result in improper stimulation or skin burns if electrodes are in contact with each other.
19) Keep the stimulator out of reach of children.
20) Consult your doctor if you are in any doubt whatsoever.
21) Discontinue it and do not increase the intensity level if you feel discomfort during use.

2.2.3 ⚠ Precautions

1) Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head.
2) The safety of electrical stimulation during pregnancy has not been established.
3) You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (silica gel).
4) If you have suspected or diagnosed heart disease or epilepsy, you should follow precautions recommended by your physician.
5) Caution if you have a tendency to bleed internally, e.g. following an injury of fracture.
6) Consult with your physician prior to use the device after a recent surgical procedure, because stimulation may disrupt the healing process.
7) Caution if stimulation is intended to be applied over the menstruation or pregnant uterus.
8) For single patient use only.
9) This stimulator should not be used by patients who is non compliant and emotionally disturbed including whom with dementia or low IQ.
10) The instruction of use is listed and should be obeyed; any improper use may be dangerous.
11) Rare cases of skin irritation may occur at the site of the electrode placement following long-term application.
12) Do not use this device in the presence of other equipment which sends electrical pulses to your body.
13) Do not use sharp objects such as a pencil or ballpoint

tip to operate the buttons on the control panel.
14) Check the electrode connections before each use.
15) Electrical stimulator should be used only with the electrodes recommended for use by the manufacturer.

2.2.4 Adverse Reactions

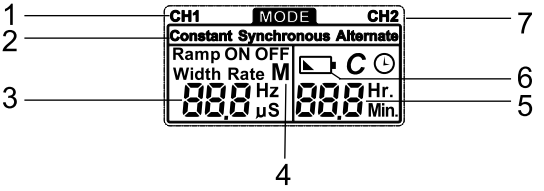
1) Possible skin irritation or electrode burn under the electrodes may occur.
2) If the stimulation makes you uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems continue.

3. GETTING TO KNOW YOUR DEVICE

3.1 Accessories

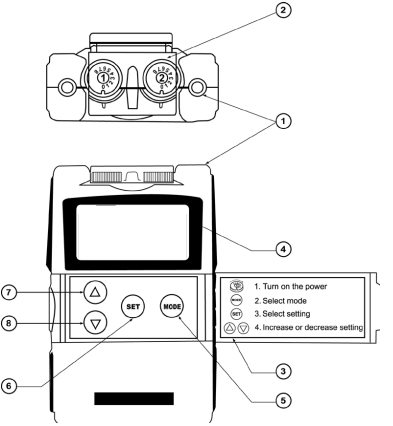
No.	Description	QTY
1	EMS STIMULATOR	1pc
2	Electrode pad （40mm×40mm）	4pcs
3	Electrode wires	2pcs
4	9 Volt Battery	1pc
5	User manual	1pc

3.2 LCD display

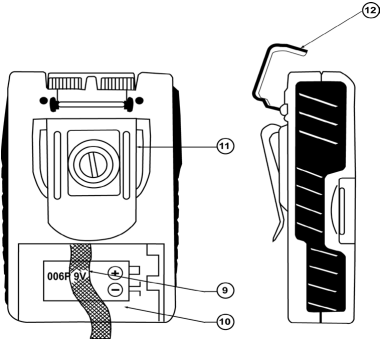


No.	Function description	No.	Function description
1	Icon of Channel 1	5	Treatment time
2	Treatment mode	6	Low battery icon
3	Pulse width or Pulse rate.	7	Icon of Channel 2
4	Memory icon		

3.3 Device illustration



FRONT



BACK SIDE

No.	Description
1	Lead Connector
2	Intensity Control (ON/OFF Switch)
3	Panel Cover
4	Liquid Crystal Display
5	Mode Control
6	Set Control
7	Increment Control
8	Decrement Control
9	Battery Strip
10	Battery Case
11	Belt Clip
12	Protective Cover

4. SPECIFICATION

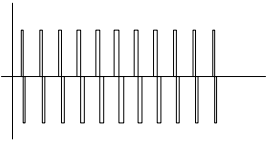
4.1Technical information

Device name	EMS STIMULATOR
Model/type	**ePower® E2**
Power sources	One 9 volt battery
Output channel	Dual channel
Waveform	Bi-phase square-wave pulse
Output current	Adjustable，0-50V
Output intensity	Adjustable,0-100mA at 500 ohm load each channel
Treatment type:	EMS 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	10.1 cm (L) x 6.1 cm (W) x 2.45 cm (H)
Weight	150 grams with battery
Classification	BF type applied part, internal power equipment
Size of electrodes pad	40x40mm, square

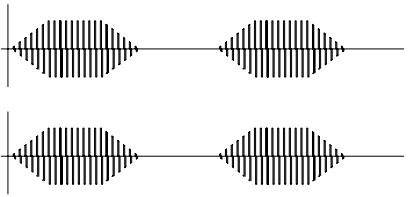
Output precision	±20% error is allowed for all the output parameters
P.W. (Pulse Width)	Adjustable, from 50 to 300 μs, 10 μs/step
P.R. (Pulse Rate)	Adjustable, from 2 to 150 Hz, 1 Hz/step
Time	Adjustable, from 1 to 60 minutes or continuous.
On Time	Adjustable, 2~90 seconds, 1 Sec./step
Off Time	Adjustable, 0~90 seconds, 1 Sec./step
Ramp Time	Adjustable, 1~8 seconds, 1 Sec./step , The "On" time will increase and decrease in the the setting value.
Modes	Constant, Synchronous and Alternate
Constant Mode	Constant stimulation based on setting value. Only pulse width, pulse rate and timer are adjustable in this mode. "Constant" is equal to the "Normal" mode of a TENS unit.
Synchronous mode	Stimulation of both channels occurs synchronously. The “ON” time including Ramp Up” and “Ramp Down” time. Therefore, the setting of ON Time should be no less than two times of the “Ramp” time in this mode. ON TIME ⩾ Ramp up + Ramp down
Alternate Mode	The stimulation of the CH2 will occur after the 1st contraction of CH1 is completed. In this mode, the setting of ON Time should be no less than two times of the “Ramp” time. The OFF Time should be equal or more than the ON Time. ON TIME ⩾ Ramp up + Ramp down OFF TIME ⩾ ON TIME
Patient Compliance Meter	This unit can store 60 sets of operation records. Total recorded time is 999 hours.
Low Battery Indication	A low battery indicator will show up on the LCD when the battery is low.

The waveforms of the 3 stimulation modes are as follows.

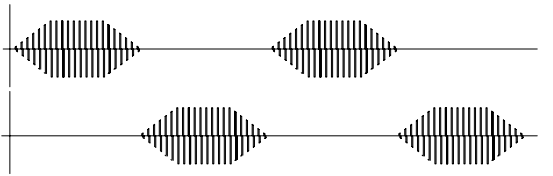
1. Constant



2. Synchronous mode



3. Alternate mode

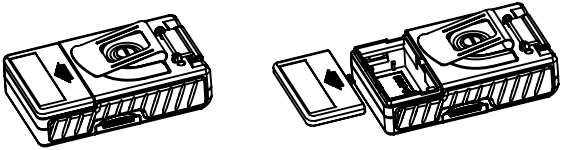


5. OPERATING INSTRUCTION

5.1 Battery

5.1.1 Check/ replace batteries

Open the battery cover, insert one 9 volt battery 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 device.



5.1.2 Disposal of battery

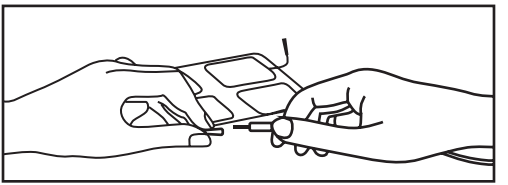
Spent batteries do not belong to the household waste. Dispose of the battery following the current regulations. As a consumer, you have legal obligation to return spent battery to the Recycle Bin.

1. If a battery was swallowed accidentally, please seek medical assistance immediately!
2. In case of battery leakage, please avoid contacting with the battery through skin, eyes and mucus membranes. Once it occurs, please wash the contacted part 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 battery.

5.2 Connect electrode pads to electrode wires

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



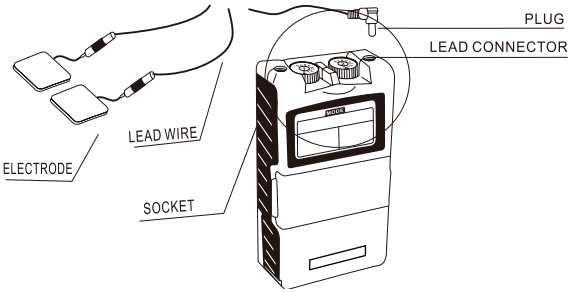
⚠ Caution

Always use the electrode pads which 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 1 and Channel 2 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

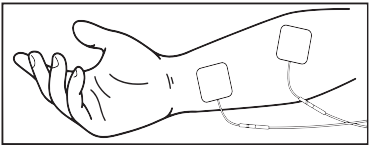
5.4.1 Electrode options

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 re-ordered under the advice of your physician or the device manufacturer to ensure proper quality. Follow application procedures outlined on electrode packing when using the new replacement electrodes to maintain optimal stimulation and to prevent skin irritation.

5.4.2 Place electrodes on skin

Place the electrode 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 electrode connect well.



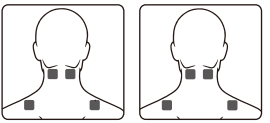
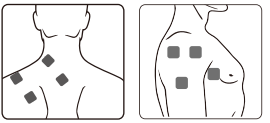
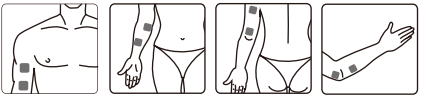
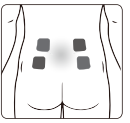
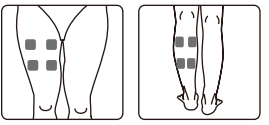
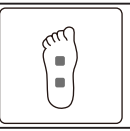
⚠ Caution

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, 1.5"x 1.5" 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 device is an OTC stimulator suitable for home use. Just follow the manual and place the electrode where you need to exercise. Conduct exercise, treatment and adjustment based on your own feeling.

Position of electrode placement under EMS programs

Neck	
Shoulder	
Arm	
Hand	
Back	
Leg	
Foot	

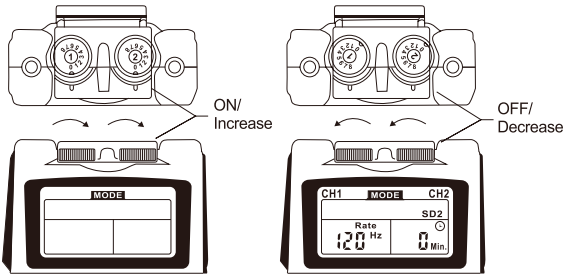
6. INSTRUCTIONS FOR USE

6.1 Power On/Off Switch and Intensity Controls:

If both controls are in the off-position, the device is switched off. By turning the controls clockwise, the appropriate channel is switched on and the indicator of power (CH1 or CH2) will reveal on the LCD. The current strength of the impulses transmitted to the electrodes increases further when the control is turned clockwise.

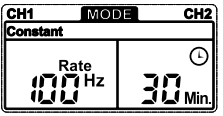
To reduce the amount of current or power off, turn the control counter clockwise to the required setting or off position.

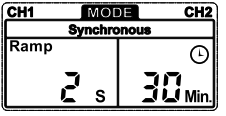
The controls are protected by a cover to prevent inadvertent change of intensity.



6.2 Select treatment mode

Press the [M] button to select which treatment mode (Constant, Synchronous and Alternate) you will use. The LCD displays as follows:





6.3 Configuration Control

By pressing the [SET] button , you can enter the value of configuration to perform. You can begin to set the value by pressing the controls of [△] and [▽] when the value flashes .

6.4 Increment Control △

This button controls the increase of settings . When you press this button, the parameter increase.

6.5 Decrement Control ▽

This button controls the decrease of parameter. When pressing this button, the parameter will decrease.

6.6 Timer

The unit: has a timer of 1- 60 minutes and Continuous. It can be adjusted by pressing the[Set] and [△] or [▽] controls. The treatment time will countdown automatically one minute by one minute. Its output will be shut off when time is up.

6.7 Low Battery Indicator

A low battery indicator will show up on the liquid crystal display when the battery needs to be replaced. The unit may continue to operate for a few more hours depending

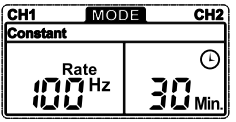
on the settings intensity level.

6.8 To Set Constant parameters

a. Set Pulse Rate

Press [SET] button and the number for “Rate” on the LCD screen will flash. To change the default number, press [△] or [▽] until the desired Pulse Rate number is displayed on the screen.

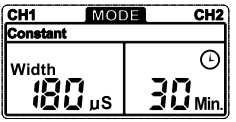
If the default Pulse Rate is the desired number and no change is needed, press[SET] to move on to the next parameter.



b. Set Pulse Width

Press [SET] and the number for “Width” on the LCD screen will flash. To change the default number, press [△] or [▽] until the desired Pulse Width number is displayed on the screen.

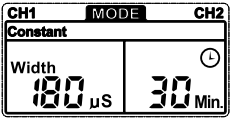
If the default Pulse Width is the desired number and no change is needed, press[SET] to move on to the next parameter.



c. Set Timer

The treatment time is adjustable from 1 to 60 minutes or C

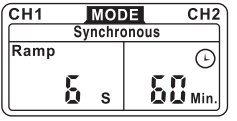
(Continuous).Press [SET] control to enter this menu, then press [△] or [▽] to adjust the setting. Press[△] when the timer shows 60 minutes, it will be switched to continuous stimulation.



6.9 To Set Synchronous and Alternate parameters

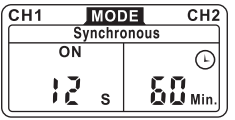
a. Set Ramp Up/Down Time

Press[SET] once and the number for “Ramp” on the LCD Screen will flash.
To change the number, press[△] or [▽] until the desired ramp time isreached.
If the default Ramp time is the desired time and no change is needed, press [SET]to move on to the next parameter.



b. Set Contraction “ON” Time

Press[SET] and the number for “ON” on the LCD Screen will flash. To change the number, press [△] or [▽] until the desired contraction/” ON” time is reached.
Note: The “ON” time must be 2 x times the “Ramp” number or higher. If the default “ON” time is the desired time and no change is needed,press[SET] to move on to the next parameter.

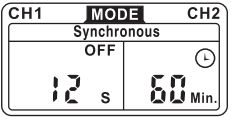


c. Set Relaxation “OFF” Time

Press [SET] button and the number for “OFF” on the LCD Screen will flash. To change the number, press [△] or [▽] until the desired relaxation / “OFF” time is reached.

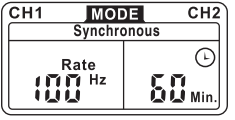
Note 1: For Alternate Mode only, the OFF time must be at least equal to the “ON” time or higher.

If the default “OFF” time is the desired time and no change is needed, press [SET] to move on to the next parameter.



d. Set Pulse Rate

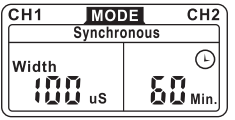
Press [SET] button and the number for “Rate” on the LCD screen will flash. To change the default number, press [△] or [▽] until the desired Pulse Rate number is displayed on the screen.
If the default Pulse Rate is the desired number and no change is needed, press[SET] to move on to the next parameter.



e. Set Pulse Width

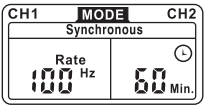
Press [SET] and the number for "Width" on the LCD screen will flash. To change the default number, press [△] or [▽] until the desired Pulse Width number is displayed on the screen.

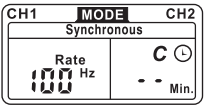
If the default Pulse Width is the desired number and no change is needed, press[SET] to move on to the next parameter.



f. Set Timer

The treatment time is adjustable from 1 to 60 minutes or C (Continuous).Press [SET] control to enter this menu, then press [△] or [▽] to adjust the setting. Press[△] when the timer shows 60 minutes, it will be switched to continuous stimulation.





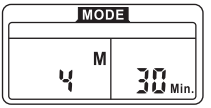
Continuous

6.10 Patient Compliance Meter

This unit can store 60 sets of operation records. Total treatment time up to 999 hours can be stored.

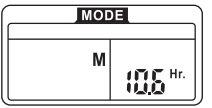
Check and Delete Individual Records

Press [MODE] control and tum on the power simultaneously. The LCD will show the number of records and operation time. Press the [△] and [▽] button to check each record. To delete a record, press [SET] control for 3 seconds.



Check and Delete Accumulative Record

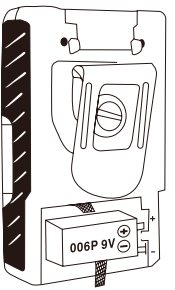
At the individual records menu, press "Mode" control to switch to accumulative record menu. Press the "Set" control first, then press the "Mode" control simultaneously for 3 seconds and all of the records will be deleted followed by a beeper sound.



6.11 Check/Replace the Battery:

Over time, in order to ensure the functional safety of EMS, changing the battery is necessary.

1. Make sure that both intensity controls are switched to off position.
2. Slide the battery compartment cover and open.
3. Remove the battery from the compartment.



4. Insert the battery into the compartment.
Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and press to close.

Notice of batteries:

1. 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.
2. 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.
3. Batteries must not be charged, dismantled, thrown into fire or short-circuited.
4. Protect batteries from excess heat. Take the batteries out of the device if they are spent or in case that you will no longer use the them. This prevents damage caused by leaking batteries.

6.12 Usage of electrode pads

1. The electrode may only be connected with the stimulator. Make sure that the device is turned off when attaching or removing the electrode pads.
2. If you want to reposition the electrode during the application, turn the device off first.
3. The usage of electrode may lead to skin irritations. If you experience such skin irritations, e.g. redness, blistering or itching, discontinue using them. Do not use the stimula-

tor permanently on the same body part, as this may also lead to skin irritations.

4. Electrode pads are private and intended for single person use. Please avoid using them by different persons.
5. The electrode must connect entirely to the skin surface to prevent hot spots, which may lead to skin burns.
6. Do not use the electrode pads for more than approx. 10 times, as connection between the electrodes and the skin deteriorates over time.
7. The adhesive force of the electrodes depends on the skin properties, storage condition, and the number of applications. If your electrode pads no longer fully stick to the skin's surface, replace them with new ones. Stick the electrode pads back onto the protective foil after use and store them in the storage bag to prevent them from drying out. This retains the adhesive force for a longer period.

Caution:

1) Before applying the electrode, it is recommended for users to wash and degrease the skin, and then dry it.
2) Never remove the electrode from the skin while the device is still on.
3) Only use the electrode pads provided by the manufacturer. Usage of other companies' products could result in injuries to the user.

6.13 Where do I attach electrode pads?

1. Each person reacts differently to electric nerve stimulation. Therefore, the placement of the electrodes may

deviate from the standard. If application is not successful, contact your physician to find out which placement techniques are best for you.

2. Do not use any adhesive electrodes with a size smaller than those the original manufacturer attached. Otherwise the current density may be too high and cause injuries.
3. The size of the adhesive pads may not be changed, e.g. by clipping off parts of them.
4. Make sure that the region radiating the pain is enclosed by the electrodes. In case of painful muscle groups, attach the electrodes in such a way that the affected muscles are also enclosed by the electrodes.

Usage advice for EMS:

1. Place the electrodes on the body part you want to treat referring to the picture on Section 5.4.3;
2. 1~2 treatment per day, about one week as a period of treatment;
3. We advise you to use the device for one session per time. If you feel discomfort during treatment, you can either pause the session or decrease the intensity of the output.

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 care 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 EMS stimulator to moisture or dampness. And do not hold the EMS stimulator under running water, nor submerge it in water or other liquids.

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

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

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

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

7.1.7 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 abroad. If your device has any problems, please contact the distributor. 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. Please contact the retailer for repair.

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

Each product in manufacturing 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.

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 foreign body in the battery compartment. 2. The battery has been used up or installed oppositely. 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. If the connection between electrode connects 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 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 into the sealed package.
4. Wrap the lead wires and store into the sealed package.

9.2 Storing the Unit

1. Place the unit, electrodes, lead wires and manual back into the carrying case. Store the box in a cool, dry place, -10°C ~ 55°C ; 10% ~ 95% 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 to the household wastes. Disposal 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 life cycle, 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 manufacture's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user has to assure that 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 IEC61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Not applicable	

Guidance and manufacture's declaration — electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	±8kV direct & indirect contact; ±15kV air discharge	±8kV direct & indirect contact; ±15kV air discharge	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	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 manufacture's 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 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: 
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 1845 1970	1700-1990	GSM1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	Pulse modulation [b] 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217Hz	0.2	0.3	9

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 up link 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 to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if 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 15°. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15°, on either side of the vertical.
LOT	LOT □□□□□□□□ R Year Month Numerical Order R: Product Model
SN	SN □□□□□□□□□□□□ LOT Number Device Serial Number
	Manufacturer information
	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.
   - Damage which have arisen during transport from the manufacturer to the consumer or the service center.
   - Accessories which 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.

Manufactured for:
Clinical Health Services, Inc. Tampa, FL 33684