INSTRUCTION MANUAL

BioMed® Revived II

BioMedical Life Systems, Inc.
1954 Kellogg Avenue
Carlsbad, CA 92008 (USA)
ww.bmls.com

BioMedical Life Systems, Inc., Carlsbad, California, has manufactured portable electrotherapy devices and accessories for over thirty five years. The result is a comprehensive family of devices and accessories meeting the needs of workers compensation, advanced physical therapy, professional athletics, and individuals worldwide.

BioMed® Revived II Rev. B 2020

Always consult your physician before beginning any therapy program. This general information within this instruction manual is not intended to diagnose any medical condition or to replace your healthcare professional. Please consult with your healthcare professional before using this device.

This manual is valid for the
BioMed® Revived II Stimulator.

Be sure to read this instruction manual before operating and keep it safe where it can be referenced as needed.

TABLE OF CONTENTS

1. INTRODUCTION

ABOUT YOUR DEVICE

The BioMed® Revived II is a dual channel output TENS, EMS, and MASSAGE stimulator. Before using, please read all the instructions in this user manual carefully and keep it safe for future use.

This device belongs to the group of therapeutic practices to aid in a number of therapies. It has three basic modalities – TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscle Stimulation) and MASSAGE.

The device has 22 total programs (9 TENS programs, 8 EMS programs and 5 MASSAGE programs) and applies therapeutic currents in the low-frequency range for therapy. Each program controls the generated electrical impulses, their intensity, frequency, and pulse width.

Based on simulating the body's natural pulses, the mechanism of electrical stimulation equipment is to create electrical impulses that are transmitted to nerves or muscle fibers through the electrode. The intensity of this dual channel equipment can be adjusted independently and applied individually to one body part. This dual channel device can be used with four electrodes, which allows you to stimulate one or more muscle groups simultaneously with a wide selection of standard programs. The electrical pulse is transmitted through the skin; it then transmits stimulation to nerves as well as muscle tissue.

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, nature may have gone too far in its design. Aside from its function in diagnosis, long lasting persistent pain serves no purpose.

Pain does not occur until encoded messages travel to the brain where it is decoded and analyzed. These messages are transmitted to different nerves that travel up the spinal cord to the brain where it is perceived as pain.

WHAT IS TENS?

TENS (Transcutaneous Electrical Nerve Stimulation) is effective in relief of pain. It is used by physical therapists, caregivers, and athletes around the world.

TENS works by stimulating the nerves to block the pain signals traveling to the brain, causing the pain go unperceived. Low frequency TENS currents facilitate the release of our natural morphine derivatives called endorphins which manage pain and is the body's natural painkillers.

Pain can be caused by many different factors. Often pain can affect your mood, social events, and activities with family and friends. Using the BioMed® Revived II can provide relief so you can live and enjoy life pain free.

WHAT IS EMS?

Your muscles work hard. When you exercise, engage in sports, or participate in any sort of strenuous activity, an increased flow of blood is sent to your muscles providing vital nutrients and energy.

Using an EMS device (Electrical Muscle Stimulator) after your activity maintains the high flow of nutrients needed to assist in muscle rejuvenation, reducing lactic acid buildup, and helps to speed recovery.

2. SAFETY INFORMATION

Intended use

TENS mode

TENS is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

EMS mode

EMS is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.

This device can be used at home. Users must be 18 years or older.

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

⚠ 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 never be in the carotid sinus area (anterior neck) or through the head.
5. Do not apply stimulation across the chest, close to the heart. This may cause heart rhythm disturbances, which could be lethal.

6. Do not apply stimulation when in the bath or shower.
7. Do not use with serious arterial circulatory problems in the lower limbs.

⚠ WARNING

1. If you have had medical or physical treatment for your pain, consult with your physician before use.
2. If your pain has not subdued or lasts more than five days, consult with your physician.
3. Do not apply stimulation over your esophagus as it 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 stimulation 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.
12. Electrical stimulation devices cannot replace drugs.
13. 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.
14. Never use it near the cardiac area. Stimulating electrodes should never be placed anywhere in the front of the thorax (marked by ribs and breastbone) and NEVER over 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 separated during treatment.

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

⚠ Precautions

1. TENS is not effective for headaches.
2. TENS is not a substitute for pain medications and other pain management therapies but an alternative.
3. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain.
4. Stimulation should NOT be applied across your head, and electrodes should never be placed on opposite sides of your head.
5. The safety of electrical stimulation during pregnancy has not been established.
6. You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (silica gel).
7. If you have suspected or diagnosed heart disease or epilepsy, you should follow precautions recommended by your physician.
8. If you have a tendency to bleed internally, consult with your physician prior to use the device because stimulation may disrupt the healing process.
9. This stimulator should not be used by patients who are non-compliant and/or emotionally disturbed including those with dementia or low IQ.
10. The instruction of use is listed and should be observed.
11. Any improper use may be dangerous.
12. In cases of skin irritation at the site of the electrode, discontinue use and consult your physician.
13. Do not use this device in the presence of other equipment which sends electrical pulses through your body.

14. Do not use sharp objects such as a pencil or ballpoint pen to operate the buttons on the control panel.
15. Check the electrode connections before each use.
16. Electrical stimulator should be used only with BioMedical
17. Life Systems, BioStim® brand electrodes.

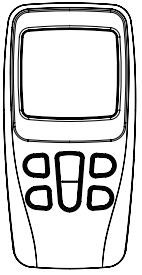
Adverse Reactions

1. Possible skin irritation or an electrode burn under the electrodes may occur.
2. On very rare occasions, first-time user of TENS report feeling light-headed or faint. We recommend that you use the product while seated until you become accustomed to the sensation.
3. 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

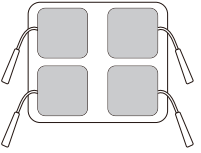
Package Contents

(1) BioMed® Revived II



(2) Lead wires

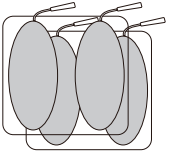
(4) Electrodes



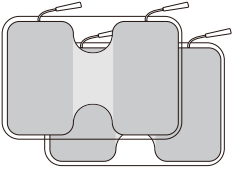
(3) AAA Batteries

Other Available Electrodes

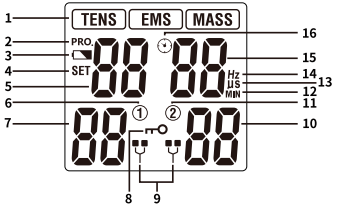
Oval



Butterfly

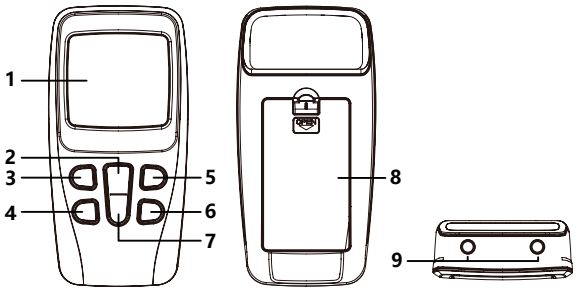


LCD display



No.	Function	No.	Function
1	Treatment mode	9	No Load Indicator (Channel 1 & Channel 2)
2	Symbol of Program	10	Channel 2 Intensity
3	Low battery indicator	11	Channel 2 Symbol
4	Symbol of SET	12	Treatment Time (min)
5	Program number	13	Pulse Width(μS)
6	Channel 1 Symbol	14	Pulse Rate (Hz)
7	Channel 1 Intensity	15	Treatment time
8	Key locking symbol	16	Timer sign

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 CH1 or CH2; At setting mode, press the [+] button to increase 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 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 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 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

Technical information

Device name	Combo Electrotherapy Device
Model/type	BioMed® Revived II
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 relative humidity of 10%-95%, atmospheric pressure from 700 hPa to 1060 hPa

Dimension	109 x 54.5 x 23mm (L x W x T)
Weight	About 70g (without batteries)
Automatic shutoff	1 minute
Classification	BF type applied part, internal power equipment, IP22
Electrodes pad	50x50mm, square
Output precision	±20% error is allowed for all the output parameters

TENS mode

Programs	9
P.W. (Pulse Width)	100-300μs
P.R. (Pulse Rate)	2-120Hz (Hz=vibration per second)
Treatment time	5-90 minutes

EMS mode

Programs	8
P.W. (Pulse Width)	100μs-300μs
P.R. (Pulse Rate)	2-100Hz (Hz=vibration per second)
Treatment time	5-90 minutes

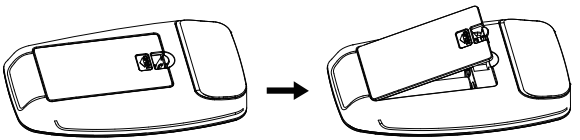
Massage mode

Programs	5
P.W. (Pulse Width)	100μs-250μs
P.R. (Pulse Rate)	8-100Hz (Hz=vibration per second)
Treatment time	30 minutes

5. OPERATING INSTRUCTION

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 device.



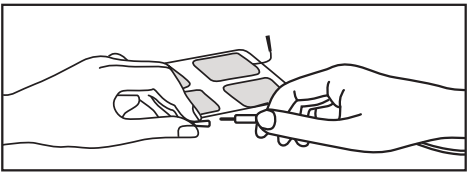
Disposal of battery

Spent batteries do not belong in household waste. Dispose of the batteries following the local regulations. As a consumer, you have a 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 contacting with the battery through skin, eyes and mucus membranes.
3. Once it occurs, please wash the contacted part with plenty of clean water and contact your doctor immediately.
4. Batteries cannot be dismantled, thrown into fire or short circuited.
5. 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.
6. Replace all of the batteries simultaneously!
7. Always replace the device with the same type battery.

Connect electrode wires to device

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



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 1and 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.

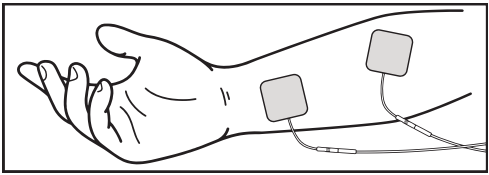
⚠ Caution

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

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 packing when using the new replacement electrodes to

maintain optimal stimulation and to prevent skin irritation.



⚠ Caution

1. Always remove the electrodes from the skin slowly in order to avoid injury.
2. Before applying the self-adhesive electrodes, wash the skin free of dirt and oils, 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 a minimum, 1.97"x 1.97" self-adhesive electrode be used at the treatment area.
6. Never remove the self-adhesive electrodes from the skin while the device is still on.

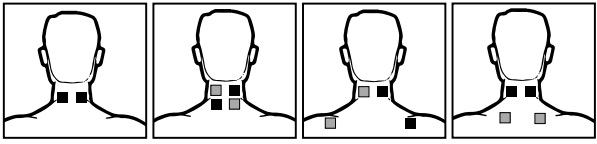
Electrode placement

BioMed® Revived II is an electrical stimulator, suitable for home use and must be use according to the user manual. Surround the pain area so that your pain is in the center of 18 the electrodes. Do not place the electrodes directly on the pain site. For best results, the electrodes should be at least 2 inches apart.

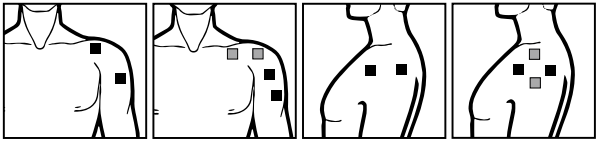
1. Before applying electrodes, wash the area with mild soap and water (do not use alcohol). Rinse and dry thoroughly.
2. Trim excess body hair from the area with scissors (do not shave).
3. It may be helpful to apply skin lotion after using electrodes.

5. ELECTRODE PLACEMENT

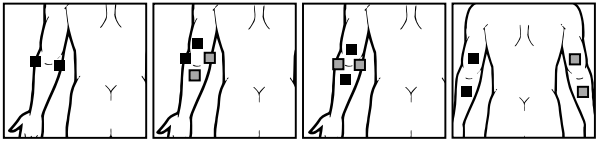
Neck



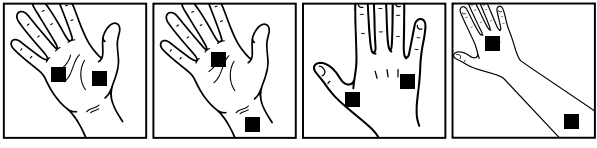
Shoulder



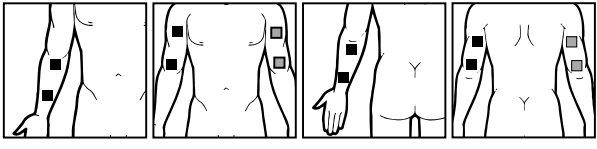
Arm



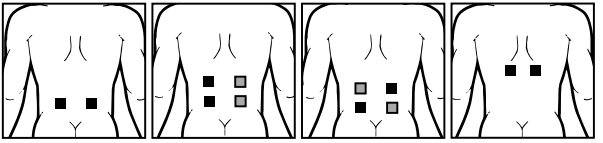
Hand



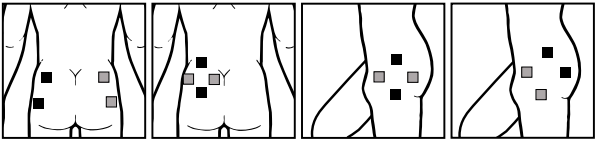
Elbow



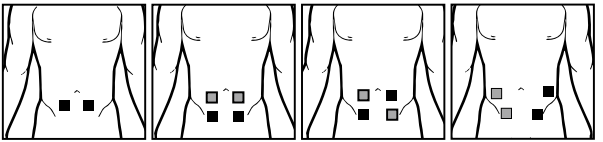
Back



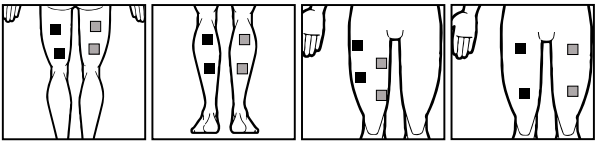
Hip



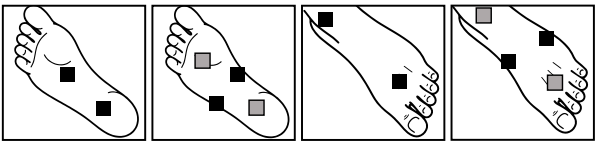
Abdomen



Leg



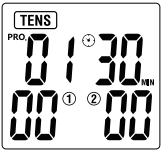
Foot



7. INSTRUCTIONS OF USE

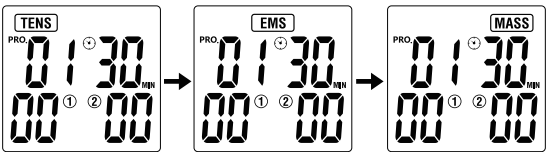
Turn on

When using it for the first time, open the battery cover and insert new batteries (review operating instructions pg.14).
Press the [ON/OFF/M] button to turn the device on, the LCD will be lit and will go into the standby mode as the picture shown below.



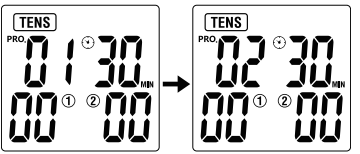
Select treatment mode

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



Select treatment program

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



Choosing pre-programmed treatments

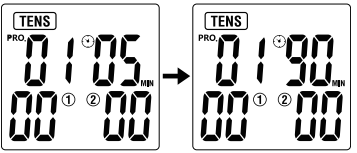
Press the [P] button to select the pre-programmed settings mode for the following:

- TENS programs 01 through 06.
- EMS programs 01 through 05.
- Massage programs 01 through 05.

Mode	Program	Time Adj.	Pulse Rate(Hz)	Pulse Width (μs)	Function
TENS	P01	5-90 min.	100 Hz	150 μs	Modulation
	P02	5-90 min.	60 Hz	200 μs	Continuous
	P03	5-90 min.	15 Hz	260 μs	Continuous
	P04	5-90 min.	2-60 Hz	260-160 μs	Modulation
	P05	5-90 min.	60/50/45/ 10/50/35 Hz	200 μs	Modulation
	P06	5-90 min.	40/6/50 Hz	200 μs	Modulation
EMS	P01	5-90 min.	4 Hz	200 μs	Continuous
	P02	5-90 min.	20 Hz	200 μs	Synchronous
	P03	5-90 min.	50 Hz	200 μs	Synchronous
	P04	5-90 min.	60 Hz	200 μs	Alternate
	P05	5-90 min.	50 Hz	200 μs	Alternate
MASSAGE	P01	30 min.	8 Hz	300 μs	Continuous
	P02	30 min.	100 Hz	300 μs	Continuous
	P03	30 min.	28~45 Hz	120~250 μs	Modulation
	P04	30 min.	25~80 Hz	120~250 μs	Modulation
	P05	30 min.	50~100 Hz	100~240 μs	Modulation

Setting Treatment Time

Once a setting mode has been selected, press and hold the [P] button to adjust the treatment time by pressing [+] button to increase or [-] button to decrease treatment time.



When finished with the treatment time selection, press the [M] button and proceed to “start treatment” on page 24 to begin treatment.

> ⚠ **Caution:** Pre-programmed treatment settings described previously are optimal for most individuals. The following advanced setting procedures should only be used by a physician who is familiar with pulse rate and pulse width settings.

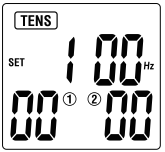
Advanced Program Settings

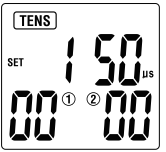
Press the [P] button to select the U setting mode for the follow:

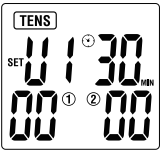
- TENS U programs U1 through U3.
- EMS U programs U1 through U3.

Mode	Program	Time Adj.	Pulse Rate(Hz)	Pulse Width (μs)	Function
TENS	PU1	5-90 min.	2-100 Hz	100-300 μs	Continuous
	PU2	5-90 min.	2-100 Hz	100-300 μs	Modulation
	PU3	5-90 min.	2-100 Hz	100-300 μs	Modulation
EMS	PU1	5-90 min.	2-100 Hz	100-300 μs	Continuous
	PU2	5-90 min.	2-100 Hz	100-300 μs	Synchronous
	PU3	5-90 min.	2-100 Hz	100-300 μs	Alternate

1. After choosing a treatment program, press and hold the
2. [P] button to adjust the pulse rate (Hz) by pressing [+] button to increase or [-] button to decrease. When complete press the [P] button.
3. Press the [P] button to adjust the pulse width (μs) by pressing [+] button to increase or [-] button to decrease.
4. When complete press the [P] button.
5. Press the [P] button to adjust the treatment time by pressing [+] button to increase or [-] button to decrease treatment time. When complete press the [M] button and proceed to “start treatment” on page 24 to begin treatment.

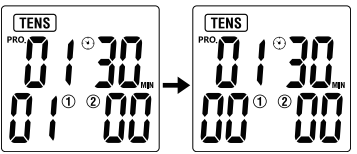






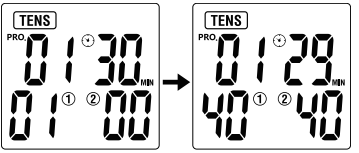
Start treatment

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

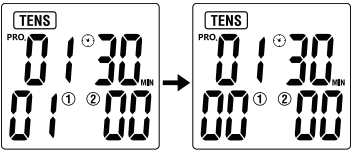


Adjust the output intensity

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 a 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:

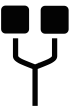


If the sensation feels it too strong, press the [-] button to decrease the intensity to a lower level. The LCD display as follows:



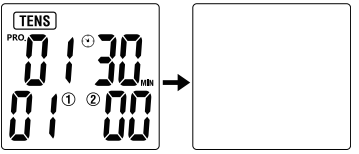
Caution:

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



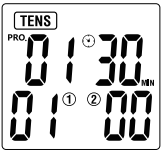
Stop the treatment and turn off the device

Press the [ON/OFF/M] button to stop treatment during the treating mode. Press the [ON/OFF/M] button and hold for 3 seconds to turn off the stimulator, and the LCD will be blank.



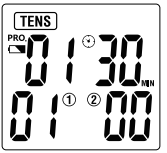
Load detection

This device 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 blinks and the stimulator will return to the standby mode.



Low battery detection

When the battery is low, the  icon will blink. Stop the device and change the battery.



8. CLEANING AND MAINTENANCE

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

BioMed® Revived II

- This device may be wiped clean with a damp clean cloth.
- Do not submerge this device in liquids or expose it to large amounts of water.
- Never use aggressive cleaning products or stiff brushes to clean the device.
- Remove the batteries before cleaning the device.
- Do not use the device unless completely dry and protect it from dirt and moisture.

Electrodes

- Electrodes can become worn or damaged over time or with regular use. To get the maximum benefit from the BioMed® Revived II, it is important that you replace the electrodes at the first sign of wear.
- When the electrodes are not connected to the unit, the electrodes adhesive gel may be cleaned by rubbing with tap water on a finger to remove contaminants and restore adhesion.
- When the electrodes are not in use, always store the electrodes on the plastic sheet they came on and in the plastic bag they came in.

Lead Wires

When disconnected from the unit, the lead wires may be wiped with a damp cloth. If the wires appear brittle, broken or the tingling sensation is turning on and off randomly, (intermittently) or you have been using them for more than six months, it is time to replace the lead wires.

Replacements

You may purchase replacement electrodes and lead wires from the location at which you purchased your BioMed® Revived II. Use only the brand and model number of electrodes and lead wires that came with the BioMed® Revived II. Failure to do so will void the warranty. You may also contact us and we will direct you to the proper source.

BioMedical Life Systems, Inc.
1954 Kellogg Avenue
Carlsbad, CA 92008, USA
PH: (800) 726-8367 (USA)
PH: (760) 579-0801 (INTL)
FX: (760) 929-9953
Email: sales@bmls.com
www.bmls.com

How to Store Your Device

- Store your device at room temperature in a dry place, out of the reach of children.
- If the device will not be used for more than a week, remove the batteries from this device.

9. 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:

Defect	Cause	Remedy
No Power	No batteries or batteries are bad	Replace batteries
No stimulation	Electrodes not connected to skin.	Check connection of electrodes to skin.
	Skin may be too dry.	Wipe skin with damp cloth.
	Lead wires	Check connection of lead wires.
ON and OFF intermittent	Batteries not inserted properly	Insert batteries again or replace batteries
	Battery life span expired	Replace batteries
	The electrode loses connection with the skin.	Check and place the electrode properly on the skin.
Rash or tickle on the skin occurs in the treatment	Treatment time is too long.	Shorten treatment time.
	Electrode does not stick to skin.	Replace electrode with new.
	Electrode is dirty or dry.	Clean or re-wet electrode.
	Skin is sensitive to the electrode.	Hypoallergenic electrodes may be needed vs. standard.

10. STORAGE

Storing the electrode pads and lead wires.

1. Store BioMed® Revived II in a cool dry place.
2. Store the electrodes on the original plastic sheet in the original plastic bag to retain moisture and place bad in a cool dry place.
3. Store lead wires by binding them with the original twist tie.
4. All items including manual should be stored in the original box.

11. DISPOSAL

Spent batteries should never be placed in household waste. Dispose of used batteries 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 in with 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.

12. ELECTROMAGNETIC COMPATIBILITY TABLES

Guidance and manufacture's declaration- electromagnetic emissions		
The device is intended for use in the electromagnetic 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 lEC61000-3-2	Not applicable	
Voltage fluctu-ations/ Flicker emissions lEC61000-3-3	Not applicable	

Guidance and manufacture's declaration- electromagnetic emissions			
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used is such an environment.			
Immunity test	IEC 60601 Test level	Compli-ance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) lEC61000-4-2	±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% UT (>95% dip in UT) for0.5 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 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 UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration- electromagnetic emissions			
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used is such an 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 Blood Pressure Monitor, 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 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 Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the blood pressure monitor.

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)	Max power (W)	Dist. (m)	Immunity Test Level (V/ m)
385	380-390	TETRA 400	Pulse b) modulation 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 b) modulation 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 represent actual modulation. It would be worst case.

13. NORMALIZED SYMBOLS

	Electrical devices are recyclable material and should not be disposed in accordance with national laws after its useful life. Help us protect the environment and save resources. Dispose and recycle properly!
	This symbol means type BF equipment; this device offers protection against electrical shock by standard compliance to leakage currents of electrodes.
	This symbols means “Attention, consult the accompanying documents”
IP22	The first number 2: Protects against solid foreign objects of 12, 5 mm Φ and greater. The second number: Protects against vertically falling water drops when enclosure titled up to 15º. From vertical.
	Manufacture date

14. LIMITED WARRANTY

BioMedical Life Systems, Inc. promises to the original consumer-purchaser to repair or, at the option of BioMedical Life Systems, Inc., to replace any device which malfunctions or proves defective in materials or workmanship under normal use during the warranty period. During this time, BioMedical Life Systems, Inc. will provide all labor and parts necessary to correct such defects or malfunctions free of charge. If the product is no longer available, BioMedical Life Systems, Inc. reserves the right to substitute a comparable product. The consumer-purchaser is responsible for all shipping charges when returning the device to the manufacturer or designated service facility.

Exclusions

This warranty shall not apply to damage resulting from failure to follow these Instructions, accident, abuse, alteration, or disassembly by unauthorized personnel. This warranty does not extend to accessory items such as alkaline batteries, rechargeable batteries, electrodes, and lead wires. These items can be provided by your dealer, but costs for repair or replacement will be the responsibility of the consumer-purchaser. BioMedical Life Systems, Inc. shall not be liable for incidental or consequential damages resulting from the sale or use of the device. In the USA, some states do not allow the exclusion or limitation of incidental or consequential damages, or do not allow limits on how long an implied warranty lasts, so the above limitation may not apply to you.

No Other Warranties

This limited warranty is the only express warranty given by BioMedical Life Systems, Inc. Implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose are limited to the warranty period set forth below. This warranty gives you specific legal rights, and you may also have rights which vary from state to state. If the unit's housing/case is opened or tampered with in any way, all warranty coverage is void.

* In the USA, unless otherwise indicated, the limited Warranty is one year. Outside the USA, please check with your distributor to ascertain the "Limited Warranty Period."

Manufactured For And Distributed By:

Biomedical Life Systems, Inc.
1954 Kellogg Avenue
Carlsbad, CA 92008 (USA)

Ph: (800)726-8367 USA
Ph: (760) 579-0801 Intl
Fx: (760) 929-9953
Web: www.bmls.com
Email: sales@bmls.com