INSTRUCTION MANUAL

FOR THE

Premier Stim Plus

DIGITAL TENS/EMS

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V1.1

EVERYWAY

Read Before Use CE 2460

Model No.: EM-6000

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Chapter 1: GENERAL DESCRIPTION

The Premier Stim Plus TENS/EMS is a fully digital battery operated pulse generator that sends electrical impulses to the nerves and underlying muscle groups. This unit is a combination stimulator of TENS and EMS which can be used for pain relief and muscle stimulation. The device is provided with two controllable output channels, each independent of the other. A pair of electrodes can be connected to each output channel. The intensity level and settings are controlled by press buttons.

Chapter 2 : INTRODUCTION

EXPLANATION OF PAIN

Pain is a warning system and the body's method of telling us that something is wrong. Pain is important; without it 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 value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until coded messages travel to the brain where they are decoded, analyzed, and reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is interpreted and pain is perceived.

EXPLANATION OF TENS

Transcutaneous Electrical Nerve Stimulation is a non-invasive, drug-free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

HOW TENS WORKS

There is nothing "magic" about Transcutaneous Electrical Nerve Stimulation (TENS). TENS is intended to be used to relieve pain. The TENS unit sends comfortable impulses through the skin that stimulate the nerve (or nerves) in the treatment area. In many cases, this stimulation will greatly reduce or eliminate the pain sensation the patient feels. Pain relief varies by individual patient, mode selected for therapy, and the type of pain. In many patients, the reduction or elimination of pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, pain is only modified while stimulation actually occurs. You may discuss this with your physician or therapist.

EXPLANATION OF EMS

Electrical Muscle Stimulation is an accepted and proven way of treating muscular injuries. It works by sending electronic pulses to the muscle needing treatment; this causes the muscle to contract.

It is derived from the square waveform, originally invented by John Faraday in 1831. It works by directly stimulating motor neurons which causes muscle contraction. It is 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 improve muscle tone and blood circulation.

HOW EMS WORKS

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

The EMS units send comfortable impulses through the skin that stimulate the nerves in the treatment area. When the muscle receives this signal it contracts. As the signal strength increases, the muscle contracts as in physical exercise. Then when the pulse ceases, the muscle relaxes and the cycle starts over again, (Stimulation, Contraction and Relaxation.) Powered muscle

stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

IMPORTANT SAFETY INFORMATION

Read instruction manual before operation. Be sure to comply with all “CAUTIONS” and “WARNINGS” in the manual. Failure to follow instructions can cause harm to user or device.

Chapter 3 : CAUTIONS

TENS

1. Federal law (USA) restricts this device to sale by or on the order of a physician.
2. Do not use this device for undiagnosed pain syndromes until consulting a physician.
3. Patients with an implanted electronic device, such as a cardiac pacemaker, implanted defibrillator, or any other metallic or electronic device should not undergo TENS treatment without first consulting a doctor.
4. Patients with heart disease, epilepsy, cancer or any other health condition should not undergo TENS treatment without first consulting a physician.
5. Stimulation delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax or across the chest because it may cause a cardiac arrhythmia.
6. Do not place electrodes on the front of the throat as spasm of the Laryngeal and Pharyngeal muscle may occur. Stimulation over the carotid sinus (neck region) may close the airways, make breathing difficult, and may have adverse effects on the heart rhythm or blood pressure.
7. Do not place electrodes on your head or at any sites that may cause the electrical current to flow transcerebrally (through the head).
8. This device should not be used while driving, operating machinery, close to water, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

9. Turn the TENS off before applying or removing electrodes.
10. Isolated cases of skin irritation may occur at the site of electrode placement following long term application. If this occurs, discontinue use and consult your physician.
11. If TENS therapy becomes ineffective or unpleasant, stimulation should be discontinued until its use is re-evaluated by a physician
12. Keep this device out of the reach of children.
13. The device has no AP/APG protection.
    Do not use it in the presence of explosive atmosphere and flammable mixture.

EMS

1. Federal law (USA) restricts this device to sale by or on the order of a physician
2. Safety of powered muscle stimulators for use during pregnancy has not been established.
3. Caution should be used for patients with suspected or diagnosed heart problems.
4. Caution should be used for patients with suspected or diagnosed epilepsy.
5. Caution should be used in the presence of the following:
   a. When there is a tendency to hemorrhage following acute trauma or fracture;
   b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   c. Over the menstruating or pregnant uterus; and
   d. Over areas of the skin which lack normal sensation.
6. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
7. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
8. Powered muscle stimulators should be kept out of the reach of children.
9. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
10. Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Chapter 4 : WARNINGS

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. 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.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

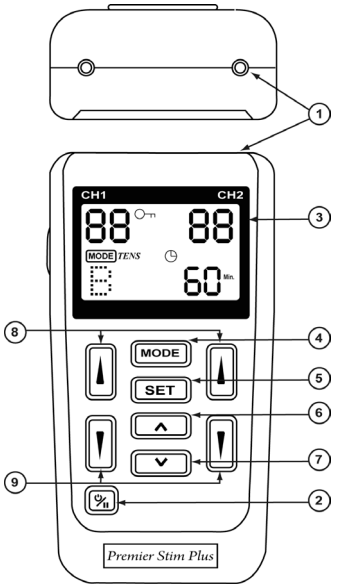
Chapter 5: CONTRAINDICATION

Electrical stimulators should not be used on patients with cardiac demand pacemakers.

Chapter 6: ADVERSE REACTIONS

On rare occasions skin irritation and burns beneath the electrodes have been reported with the use of electrical stimulators. If irritation occurs, discontinue use and consult your physician.

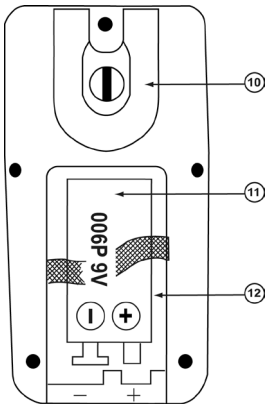
Chapter 7 : CONSTRUCTION



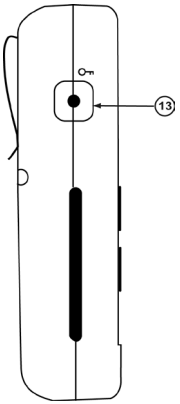
FRONT

(1) LEAD CONNECTOR
(2) ON/OFF/PAUSE CONTROL
(3) LIQUID CRYSTAL DISPLAY
(4) MODE CONTROL
(5) SET CONTROL
(6) SETTING INCREMENT CONTROL
(7) SETTING DECREMENT CONTROL
(8) INTENSITY INCREMENT CONTROL
(9) INTENSITY DECREMENT CONTROL

BACK



SIDE



BACK

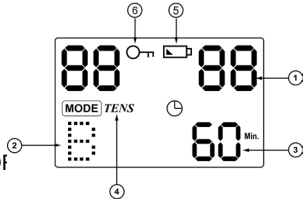
(10) BELT CLIP
(11) BATTERY STRIP
(12) BATTERY CASE

SIDE

(13) KEY LOCK FACILITY

Liquid Crystal Display

1. INTENSITY LEVEL
2. MODE
3. SETTINGS
4. STIMULATION TYPE
5. LOW BATTERY INDICATOR
6. LOCK



Chapter 8 : TECHNICAL SPECIFICATIONS

The technical specification details of Premier Stim Plus Digital TENS/EMS are as follows:

	MECHANISM	TECHNICAL DESCRIPTION
01	Channel	Dual, isolated between channels
02	Pulse Amplitude	Adjustable, 0-100 mA peak into 500 ohm load each channel.
03	Wave Form	Asymmetrical Bi-Phasic Square Pulse
04	Voltage	0 to 50V (Load: 500 ohm)
05	Power source	One 9 Volt Battery.
06	Size	11.8cm(L) x 6 cm(W) x 3.1cm(H)
07	Weight	157 grams with battery.
08	Pulse Rate	Adjustable, from 2 to 150 Hz, 1 Hz/step
09	Pulse Width	Adjustable, from 50 to 300 microseconds, 10 µs/step
10	On Time	Adjustable, 2~90 seconds , 1 Sec./ step
11	Off Time	Adjustable, 2~90 seconds , 1 Sec./ step
12	Ramp Time	Adjustable, 1~8 seconds, 1 Sec./ step, The “On” time will increase and decrease in the setting value.
13	Mode	Six TENS Modes: B(Burst), N(Normal),M (Modulation Rate & Width),S1(Modulation Width), S2 (Modulation Width) and P Three EMS Modes:C(Constant), S (Synchronous), A(Alternate)
14	Burst Mode	Burst rate: Adjustable, 0.5 – 5Hz Pulse width adjustable, 50~300µs Frequency fixed = 100 Hz
15	Normal Mode	The pulse rate and pulse width are adjustable. It generates continuous stimulation based on the setting value.
16	Modulation Mode	Modulation mode is a combination of pulse rate and pulse width modulation. The pulse rate and width are automatically varied in a cycle pattern. The pulse width is decreased by 50% from its original setting

		in 0.5 second, then the pulse rate is decreased by 50% from its original setting in 0.5 second. Total cycle time is 1 second. In this mode, pulse rate(2-150Hz) and pulse width(50-300μs) are fully adjustable.
17	S1 Mode	Pulse width is automatically varied in a cyclic pattern over a nominal 10 second period. Pulse width decreases over a period of 4 seconds from the initial setting to a value 40% less. The narrower pulse width continues for 1 second. It then increases over a period of 4 seconds to its initial setting. The cycle is then repeated. Pulse rate and pulse width are fully adjustable.
18	S2 Mode	Pulse width is automatically varied in a cyclic pattern over a nominal 10 second period. Pulse width decreases over a period of 4 seconds from the initial setting to a value 70% less. The narrower pulse width continues for 1 second. It then increases over a period of 4 seconds to its initial setting. The cycle is then repeated. Pulse rate and pulse width are fully adjustable.
19	Constant Mode(C)	The pulse rate and pulse width are adjustable. It generates continuous stimulation is delivered .
20	Synchronous Mode(S)	Output from both channels occurs synchronously. The "ON" time includes "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.
21	Alternate Mode(A)	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"

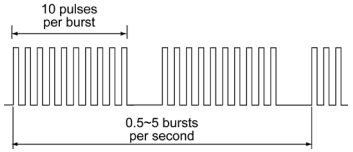
		time. The OFF Time should be equal to or greater than the ON Time. ON TIME ≥Ramp up + Ramp down OFF TIME ≥ON TIME
22	Mode P	**The pre-set parameters of the 9 programs are as given below:**

Program	Mode	Pulse Rate	Pulse Width	Timer
P1	Constant	80Hz	180μs	Continue
P2	Burst	100Hz (Burst Rate:2Hz)	180μs	Continue
P3	P.W. Modulation	80Hz	70μs -180μs	Continue
P4	Mixed Frequency	15Hz in 3 Sec / 2Hz in 3 Sec	180μs	Continue
P5	Mixed Frequency	80Hz in 3 Sec / 2Hz in 3 Sec	180μs	Continue
P6	Constant	10Hz	180μs	Continue
P7	Constant	80Hz	60μs	Continue
P8	Constant	80 Hz	180μs	30 Minutes
P9	Burst	100Hz (Burst Rate:2Hz)	180μs	30 Minutes

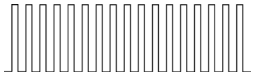
23	Timer	Adjustable, from 5 to 60 minutes minutes and continue(C), 5 minutes each step
24	Patient Compliance Meter	This unit can store 60 sets of operation records. Total recorded time is 999 hours.
25	Low Battery Indicator	A low battery indicator will show up when the battery is low.
26	Operating Condition	Temperature:0°~40°C Relative Humidity: 30%~75% Atmosphere Pressure : 700Hpa~1060Hpa
27	Remark	There may be up to a +/-10% tolerance of all parameters and +/-20% tolerance of output amplitude & voltage.

The waveforms of the TENS modes are as follows.

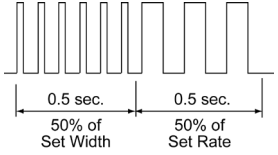
1. Burst



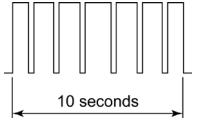
2. Normal



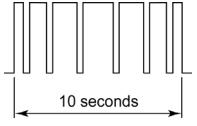
3. Modulation



4. S1 (Strength-Duration)



5. S2 (Strength-Duration)



Chapter 9 : REPLACEABLE PARTS

The replaceable parts and accessories of Premier Stim Plus DIGITAL TENS/EMS devices are as given below -
Except leads, electrodes, battery and battery case cover, please do not try to replace the other parts of a device.

	PARTS
1.	Lead Wires
2.	Electrodes
3.	Belt Clip
4.	Lead Connector
5.	Main PCB
6.	Press Buttons
7.	LCD Cover
8.	9V Battery
9.	Device Case

Chapter 10 : ACCESSORIES

Each Premier Stim Plus Digital TENS/EMS comes complete with standard accessories and the standard labels as given below:

I. Accessories

REF. NO.	DESCRIPTION	Q'TY
1. KF4040	40 X 40 mm Adhesive Electrodes	4 pieces
2. KB-24	Electrodes Leads	2 pieces
3. GC-01	9 V Battery, type 6F22	1 piece
4.	Instruction Manual	1 piece
5.	Carrying Case	1 piece

II.LABEL

The label attached to the back of device contains important information about this device- model, supply voltage, CE number and caution. Please do not remove.

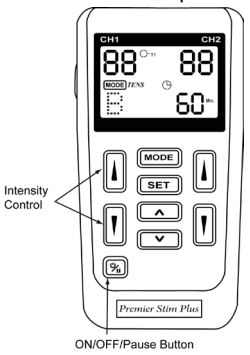
Chapter 11 : GRAPHIC SYMBOLS

1. Degree of Electrical Protection BF
2. Do not insert the plug into AC power supply socket.
3. Timer
4. Increment
5. Decrement
6. Consult Instructions for use
7. Manufacturer
8. SN Serial Number
9. Lock
10. Low Battery
11. Pause
12. DC Current(DC Power source)
13. Power

Chapter 12: OPERATING INSTRUCTIONS

1) Insert the 9V battery into the device's battery compartment. Make sure that the plastic seal on the 9V battery is removed. Line up the positive and negative terminals on the battery with their corresponding terminals in the device. Make sure that the unit is turned off.
2) Insert the lead wires into the lead wire sockets on top of the device.

3) Open the electrode package. Then insert each lead wire pin into the pig tail of the electrodes
4) Place the electrode on your body as directed by your physician.
5) Turn on the power by pressing the power On/Off/Pause button.
6) Select the mode and settings as directed by your physician.
7) Slowly increase or decrease the intensity by pressing the intensity control buttons.
8) You may press the On/Off/Pause button if you want to stop treatment for a while.
9) After treatment, turn the device off by pressing the On/Off/Pause button.



Chapter 13 : PARAMETER CONTROLS

PULSE DURATION

Wider pulse duration settings will deliver stronger stimulation for any given intensity setting. As mentioned in the Controls section, by using a combination of intensity and pulse duration different nerve fibres are stimulated.

The wider pulse duration is needed to recruit motor fibres, whereas the narrow pulse duration is used on the more sensory fibres. The choice of which pulse duration to use is partially dependent upon the Treatment Mode and Protocol selected.

PULSE RATE

The Pulse Rate (hertz or pulses per second) chosen depends greatly upon the type of electrode placement given to the patient.

When using contiguous and dermatome electrode placements (i.e. stimulating directly through the area of pain or localized innnervation), a higher pulse rate (setting greater than 80Hz on the Pulse Rate Control) is required. The patient should not perceive individual pulses but rather have the sensation of steady continuous stimulation.

When using point treatments, it has been suggested that lower pulse rates be utilized (less than 10Hz). With this setting the patient should be able to perceive individual pulses.

When using multiple electrode placement strategies, such as combinations of point and contiguous electrode placements, the higher pulse rates are suggested.

Despite the above recommendations, individual patients may require slight variations of the above settings, according to the nature of their condition.

TREATMENT MODE

Normal or Conventional TENS offers the practitioners complete control over all the various treatment parameters of the instrument.

Burst Mode is analogous to the Low Rate TENS technique except the low frequency individual pulses are replaced by individual "bursts" of 7-10 individual pulses. It is thus a combination of Conventional TENS and Low Rate TENS. In Burst Mode, the treatment frequency is adjustable at the range between 0.5Hz ~ 5Hz.

Modulated Mode attempts to minimise nerve accommodation by continuously cycling the treatment intensity. Advise the patient to increase the intensity very slowly when using modulation mode.

INTENSITY

Each patient responds differently to different levels of intensity, due to varying degrees of tissue resistance, enervation, skin thickness, etc. Intensity instructions are therefore limited to the following settings:

Perception – The intensity is increased so that the patient can feel the stimulation, but there is not any muscular contraction.

Slight Contraction – Intensity is increased to a barely visible muscular contraction that is not strong enough to move a joint. When using low pulse rate settings, this will show as individual twitches. At higher pulse rates there will simply be increased muscle tension.

Strong muscular contraction is typically not used in TENS therapy. However, muscular contraction may be useful if the pain involves

a cramped or spastic muscle. The TENS can be used as a traditional muscle stimulator in the circumstances to quickly break the spasm. Use a higher pulse rate, wide pulse duration and set the intensity to visible contraction (still within patient tolerance). Twenty or thirty minutes of such a tetanized muscular contraction will generally break the spasm. In all cases, if the patient complains that the stimulation is uncomfortable, reduce intensity and/or cease stimulation.

TIME DURATION

The onset of pain relief should occur shortly after the intensity setting has been determined. However, in some cases, pain relief may take as long as 30 minutes to achieve, especially when using point electrode placements and slow pulse rates.

TENS units are typically operated for long periods of time, with a minimum of 20 ~ 30 minutes and in some post-operation protocols, as long as 36 hours.

In general, pain relief will diminish within 30 minutes of the cessation of stimulation. Pain relief obtained through point electrode placements may last longer (perhaps because of the presence of endorphins).

CONTRACTION / RELAXATION

The contraction time and relaxation time of EMS is adjustable. Stimulation will commence at the contraction setting time and cease at the relaxation setting time. Then the cycle starts over again - Stimulation, Contraction and Relaxation.

RAMP

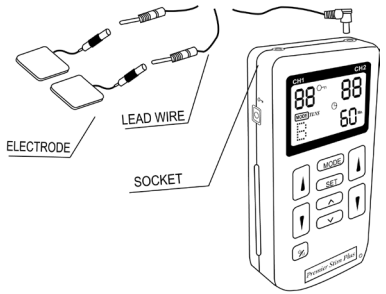
In order to achieve a comfortable exercise and avoid discomfort because of immediate current onset, each contraction may be ramped so that the signal comes on gradually and smoothly. The intensity of electrical current will reach the set level within the Ramp time. It will NOT reach the desired level if the ramp time is greater than the total contraction time.

OUTPUT MODE

The output of both channels are adjustable. Stimulation can be synchronous or alternate. Stimulation of both channels will occur at the same time when synchronus pattern is selected. In alternating mode, the stimulation from CH2 will occur after contraction of Ch1 is finished.

Chapter 14 : ATTACHMENT OF ELECTRODE LEAD WIRES

The wires provided with the system insert into the jack sockets located on top of the device. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.



After connecting the wires to the stimulator, attach each wire to an electrode. Use care when you plug and unplug the wires. Jerking the wire instead of holding the insulated connector body may cause wire breakage.

CAUTION

Do not insert the plug of the patient lead wire into any AC power supply socket.

Chapter 15: LEAD WIRE MAINTENANCE

Clean the wires by wiping with a damp cloth. Coating them lightly with talcum powder will reduce tangling and prolong life.

Chapter 16 : ELECTRODE OPTIONS

The electrodes are disposable and should be routinely replaced when they start to lose their adhesive nature. If you are unsure of your electrode adhesive properties, order replacement electrodes. Replacement electrodes should be re-ordered through or on the advice of your physician to ensure proper quality. Follow application procedures outlined in electrode packing, to maintain optimal stimulation and to prevent skin irritation.

Chapter 17: ELECTRODE PLACEMENT

The placement of electrodes can be one of the most important parameters in achieving success with TENS or EMS therapy. It is important that the physician experiments to determine optimum electrode placement.

Every patient responds to electrical stimulation differently and their needs may vary from the conventional settings suggested here. If the initial results are not positive, speak to your physician about alternative stimulation settings and/or electrode placements. Once an acceptable placement has been achieved, mark the electrode sites and the settings, so that effective treatment may effectively continue at home.

Chapter 18: TIPS FOR SKIN CARE

To avoid skin irritation, especially if you have sensitive skin, follow these suggestions:

1. Wash the area of skin where you will be placing the electrodes, using mild soap and water before applying electrodes, and after taking them off. Be sure to rinse soap off thoroughly and dry skin well.
2. Excess hair may be clipped with scissors; do not shave stimulation area.
3. Wipe the area with the skin preparation your physician has recommended. Let this dry. Apply electrodes as directed.
4. Many skin problems arise from the "pulling stress" from adhesive patches that are excessively stretched across the skin during application. To prevent this, apply electrodes from center outward; avoid stretching over the skin.
5. To minimize "pulling stress", tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.
6. When removing electrodes, always remove by pulling in the direction of hair growth.
7. It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
8. Never apply electrodes over irritated or broken skin.

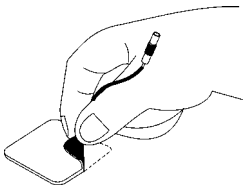
Chapter 19: APPLICATION OF RE-USABLE SELF ADHESIVE ELECTRODES

Application

1. Clean and dry the skin at the prescribed area thoroughly with soap and water prior to application of electrodes.
2. Insert the lead wire into the pin connector on the pre-wired electrodes.
3. Remove the electrodes from the protective liner and apply the electrodes firmly to the treatment site. Make sure that the unit is turned off prior to applying the electrodes.

Removal

1. Turn off the unit prior to removing the electrodes.
2. Lift at the edge of electrodes and peel; do not pull on the lead wires because it may damage the electrodes.
3. Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.



Care and Storage

1. Between uses, store the electrodes in the resealable bag in a cool dry place.
2 . It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turn the surface up to air dry. Over Saturation with water will reduce the adhesive properties.

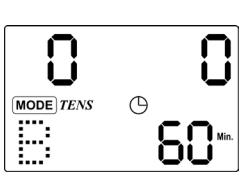
Important

1. Do not apply to broken skin.
2. The electrodes should be discarded and re-ordered from your physician when they are no longer adhering.
3. The electrodes are intended for single patient use only.
4. If irritation occurs, discontinue use and consult your physician.
5. Read the instructions for use of self-adhesive electrodes before application.

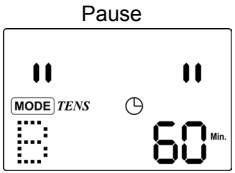
Chapter 20 : ADJUSTING THE CONTROLS

1. Power On/Off/Pause Button

   The power of unit can be turned on by pressing the On/Off/ Pause button. You may start to adjust the settings when the liquid crystal is light up. Press and hold for 2 seconds to switch off. To pause stimulation press the button once. To resume stimulation press the button again and stimulation will be restored in 2 seconds.
   If the unit is not used (buttons not pressed or output level at 0) for 5 minutes, the power will be shut off automatically.

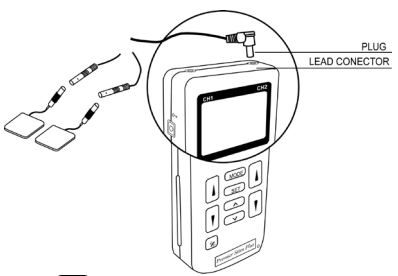


Pause



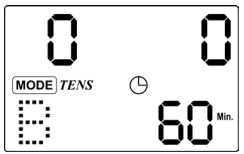
If the unit is not used(buttons not pressed or output level at 0) for 5 minutes, the power will be shut off automatically

2. Lead Connector
   Connection of the electrodes is made with the two-lead connector (lead wires) on the top of unit. The device must be turned off before connecting the cables.
   Electrodes must be in firm contact with the skin.



3 Mode Control MODE

There are 5 TENS modes(B, N, M, S1, S2) and 3 EMS modes (C, S, A) available. The mode is selected by pressing the “Mode” control. When a TENS mode is selected, the LCD shows "TENS". When EMS mode is selected, the LCD shows "EMS"



4. Set Control SET

   By pressing the "Set" control you select the setting you intend to adjust. The value is set by pressing the "Increment" or "Decrement" controls when the "Set" value is flashing.

5. Increment Control ∧

   This button controls the increase of settings.

6. Decrement Control ∨

   This button controls the decrease of settings.

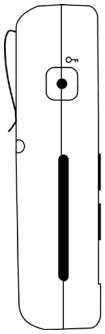
7. Intensity Increase Control

   The intensity level can be increased by pressing this button. There are 99 steps of intensity adjustment control. Press the button until the desired intensity level is reached.

8. Intensity Decrease Control

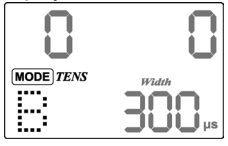
   The intensity level can be decreased by pressing this button. There are 99 steps of intensity adjustment control. Press the button until the desired intensity level is reached.

9. Key Lock Facility
Pressing the "Lock" buttons prevents the settings being changed but the output may be stopped by pressing the "On/Off/Pause".



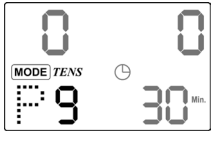
10. Steps to Set a TENS Program
The settings can be adjusted as follows
a. Turn on the Power
After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, turn the unit on by pressing the On/Off/Pause button. The settings will be displayed on the LCD screen.

b. Select a Mode
Select a mode by pressing the "Mode" control. The mode you selected will show up on the top of liquid crystal display. There are 5 modes of your option including - B(Burst), M(Normal), M(Modulation), S1, S2 and P. When a TENS mode is selected, it shows "TENS" on the liquid crystal display.



After a mode is selected, always press "Set" to enter next setting, and press " ^ " or " v " to adjust its value.
The settings will be stored immediately after selected.

There are 9 preset programs of your option on P mode. Press " ^ " or " v " to select a program desired after P mode is selected. These programs are not adjustable.

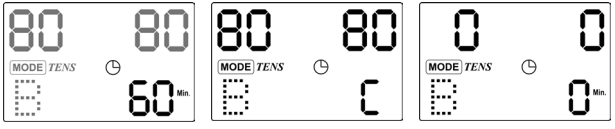


c. Set Pulse Width
Pulse Width is adjustable from 50 µs to 300 µs. Press "SET" control to enter this menu, then press " ^ " or " v " to adjust the setting. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 µs setting.

d. Set Pulse Rate
Pulse rate is adjustable from 2Hz to 150 Hz . Press "SET" control to enter this menu, then press " ^ " or " v " to adjust the setting. Unless otherwise instructed, set the pulse rate l to the 70-120 Hz range.

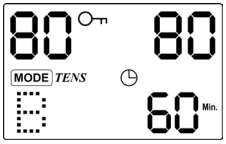
e. Set Timer
The treatment time is adjustable between 5 - 60 minutes and Continue(C). Press "SET" control to enter this menu, then press " ^ " or " v " to adjust the setting. The liquid crystal will show the balance treatment time after the stimulation is started. Output will be terminated when time is up. Turn off the unit when the output is off.

Continuous End of Treatment



f. Adjust Intensity

There are 99 steps within the intensity range. Set the desired level by pressing the " ▲ " or " ▼ " controls. Press the "Lock" button to prevent accidental changes.



11. Steps to Set a EMS Program

The settings can be adjusted according to the following steps.

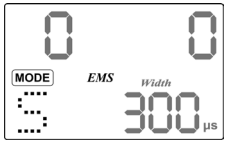
a. Turn on the Power

After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, turn the unit on by pressing the On/Off/Pause button. The settings will show up on LCD for your further adjustment.

b. Select a Mode

Select a mode by pressing the "Mode" control. The mode you selected will show up on the top of liquid crystal display. There are 3modes of your option including - C(Constant), S(Synchronous), A(Alternate). When an EMS mode is selected, it shows "EMS" on the liquid crystal display. After a mode is selected, always press "Set" to enter next setting, and press " ∧ " or " ∨ " to adjust its value.

The settings will be stored immediately after selected.



c. Set Ramp Time

The ramp time controls the time taken to reach maximum and

the time taken to fall to zero I order to make the contraction more comfortable. The ramp time is adjustable between 1 - 8 seconds..

d. Set On Time

The On Time controls the length of stimulation. By pressing the "Set" control, the contraction time can be adjusted. Both channels' stimulation is cycled on and off by the contraction and relaxation settings. The range is adjustable from 2 seconds to 90 seconds.

The total "ON" time must be at least twice the "Ramp" time

e. Set Off Time

The Off Time controls the length of relaxation. By pressing the "SET" control, the relaxation time can be adjusted. Both channels' stimulation is cycled on and off by the contraction and relaxation settings. The range is adjustable from 2 seconds to 90 seconds.

In Alternate mode, the OFF Time should be equal or more than the ON Time. (OFF TIME ≥ ON TIME)

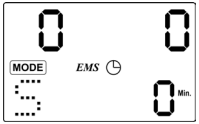
f. Set Pulse Width
Pulse Width is adjustable from 50 μs to 300 μs. Press "SET" control to enter this menu, then press " ^ " or " v " to adjust the setting. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 μs setting

g. Set Pulse Rate
Pulse rate is adjustable from 2Hz to 150 Hz . Press "SET" control to enter this menu, then press " ^ "or " v " to adjust the setting.
Unless otherwise instructed, set the pulse rate to the 70-120 Hz range.

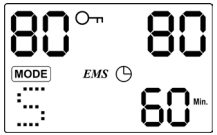
h. Set Timer
The treatment time is adjustable between 5 - 60 minutes and Continue(C). Press "SET" control to enter this menu, then press "Increment" or "Decrement" to adjust the setting. The liquid crystal will show the balance treatment time after the stimulation is started. Output will be terminated when time is up. Turn off the unit when the output is off.

Continuous

End of Treatment

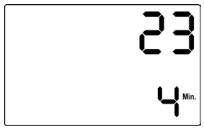


i. Adjust Intensity
There are 99 steps within the intensity range. Set the desired level by pressing the " | " or " ! " controls. Press the "Lock" button to prevent accidental changes.

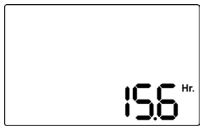


12. Compliance Meter
The individual treatment time and total treatment time can be checked and deleted by the following steps. Sixty sets of treatment records can be stored. Total recorded time is 999 hours.

Check & Delete Treatment Record
Press "Mode" control and turn on the power simultaneously. The LCD will show the individual operation time. Press "Mode" control to check the accumulated treatment time. The record can be deleted by pressing the "SET" button for two seconds.

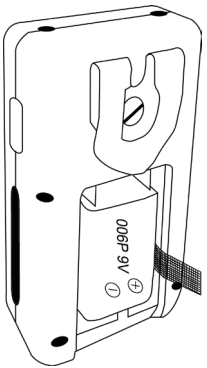


Individnal Record



Accumulated

13. Check/Replace the Battery:
    Over time, in order to ensure the functional safety of TENS/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.



Chapter 21: BATTERY INFORMATION

PRECAUTIONS

1. Remove battery if equipment is not likely to be used for some time.
2. Please recycle the used battery in accordance with domestic regulation.
3. Do not throw the used battery into fire.
   If you use rechargeable batteries, please follow the instructions.

RECHARGEABLE BATTERIES(NOT INCLUDED)

Prior to the use of a new unit, the rechargeable battery should be charged according to the battery manufacturer's instructions. Before using the battery charger, read all instructions and cautionary markings on the battery and in this instruction manual.

After being stored for 60 days or more, the batteries may lose their charge. After long periods of storage, batteries should be charged prior to use.

BATTERY CHARGING

(1) Plug the charger into any working 110 or 220/240v mains electrical outlet. The use of any attachment not supplied with the charger may result in the risk of fire, electric shock, or injury to persons.
(2) Follow the battery manufacturer's instructions for charging time.
(3) After the battery manufacturer's recommended charging time has been completed, unplug the charger and remove the battery.
(4) Batteries should always be stored in a fully charged state.
    To ensure optimum battery performance, follow these guidelines:
    (a) Although overcharging the batteries for up to 24 hours will not damage them, repeated overcharging may decrease useful battery life.
    (b) Always store batteries in their charged condition. After a battery has been discharged, recharge it as soon as possible. If the battery is stored more than 60 days, it may need to be recharged.
    (c) Do not short the terminals of the battery. This will cause the battery to get hot and can cause permanent damage. Avoid storing the batteries in your pocket or purse where the terminals may accidentally come into contact with coins, keys or any metal objects.
    (d) WARNINGS:
        1. Do not attempt to charge any other types of batteries in your charger, other than rechargeable batteries made for your charger. Other types of batteries may leak or burst.
        2. Do not incinerate the rechargeable battery as it may explode!

Chapter 22 : MAINTENANCE, TRANSPORTATION AND STORAGE

1. Non-flammable cleaning solution is suitable for cleaning the device.
   Note: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.
5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment (acid may leak from used batteries and damage the device). Put the device and accessories in carrying box and keep it in cool dry place.
6. The packed TENS device should be stored and transported under the temperature range of -20°C ~ + 60°C, relative humidity 20% ~95%, atmosphere pressure 500 hPa ~ 1060 hPa.

Chapter 23: SAFETY-TECHNICAL CONTROLS

For safety reasons, review the following checklist before using your Premier Stim Plus DIGITAL TENS/EMS.

1. Check the device for external damage.
- deformation of the housing.
- damaged or defective output sockets.
2. Check the device for defective operating elements.
- legibility of inscriptions and labels.
- make sure the inscriptions and labels are not distorted.
3. Check the usability of accessories.
- patient cable undamaged.
- electrodes undamaged.
- Battery is not corroded

Please consult your distributor if there are any problems with device and accessories.

Chapter 24 : MALFUNCTIONS

Should any malfunctions occur while using the Premier Stim Plus Digital TENS/EMS, check

- whether the parameters are set to the appropriate form of therapy. Adjust the control correctly.
- whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets.
- whether the LCD reveals the menu. If necessary, insert a new battery.
- for possible damage to the cable. Change the cable if any damage is detected.

* If there is any other problem, please return the device to your distributor. Do not try to repair a defective device.

Chapter 25: CONFORMITY TO SAFETY STANDARDS

The Premier Stim Plus DIGITAL TENS/EMS devices are in compliance with
the following standards:
EN 60601-1-2: 2014 Medical electrical equipment -
Part 1-2: General requirements for basic safety and essential performance
-Collateral standard: Electromagnetic compatibility -
Requirements and tests
EN 60601-1:2006 Medical electrical equipment -
Part 1: General requirements for basic safety and essential performance

Chapter 26 : WARRANTY

All Premier Stim Plus Digital TENS/EMS models carry a warranty of one year from the date of delivery. The warranty applies to the stimulator only and covers both parts and labour relating thereto.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alteration or disassembly by unauthorized personnel.

Manufacturer:
Everyway Medical Instruments Co., Ltd.
3F., No.5, Ln. 155, Sec. 3, Beishen Rd.,
Shenkeng Dist., New Taipei City 22203,
Taiwan (R.O.C.)

Representative in the EU:
REHAB EUROPA SL
SANT GERVASI DE CASSOLES, 96 3º 4ª
08022 BARCELONA , SPAIN.

Edition : V1.1
Printed in June, 2017

Chapter 27: ELECTROMAGNETIC COMPATIBILITY INFORMATION

The device complies with current specifications with regard to electromagnetic compatibility and is suitable for use in all premises, including those designated for private residential purposes. The radio frequency emissions of the device are extremely low and in all probability do not cause any interference with other devices in the proximity.It is recommended that you do not place the device on top of or close to other electronic devices. Should you notice any interference with other electrical devices, move the device or connect it to a different socket. Radio equipment may affect the operation of this device.

Guidance and manufacturer's declaration - electromagnetic emissions		
The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The unit must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The unit is suitable for use in all establishments other than domestic those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class C	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity

The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 % .
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) and neutral	± 1 kV line(s) to line(s) and neutral	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % 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 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the unit requires continued operation during power mains interruptions, it is recommended that the unit be powered from an uninterruptible power supply or a battery. Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment . guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$ 80 MHz bis 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz bis 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	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. 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 unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the unit.

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

Recommended separation distances between portable and mobile RF communications equipment and the unit

The unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the unit as recommended below, according to the maximum output power of the communications equipment.

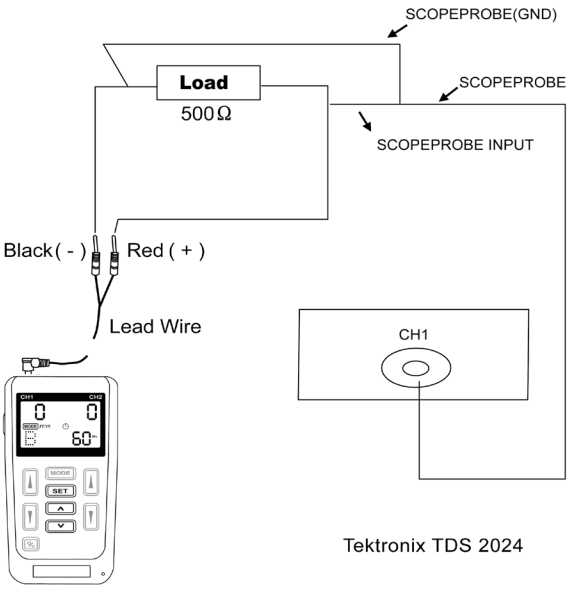
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150KHz bis 800MHz $d = 1,2\sqrt{P}$	80MHz bis 800MHz $d = 1,2\sqrt{P}$	80MHz bis 2.5GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2.3
10	3,8	3.8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

(Appendix I) Test Environment

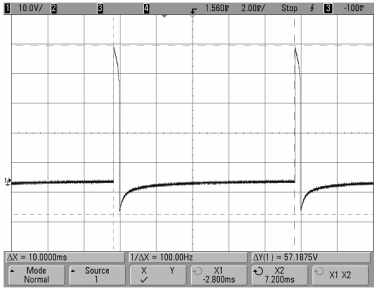


(Appendix II) Waveform of EM-6300 Digital TENS/EMS

TENS

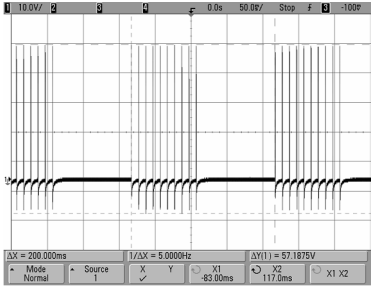
1. B Mode(Burst)

   Load: 500 ohm
   Pulse Rate: 150Hz
   Pulse Width: 300μs



Scope A :

VERT:10.0V/DIV
HORIZ:2mS
OUTPUT:57.1875Vpk-pk
Pulse Rate:100Hz

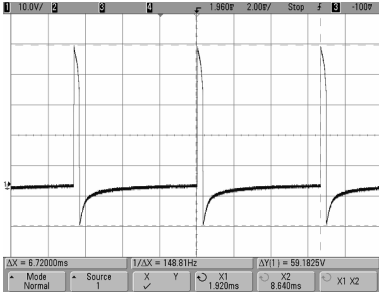


Scope B:

VERT:10.0V/DIV
HORIZ:50mS
Pulse Rate:5.000Hz

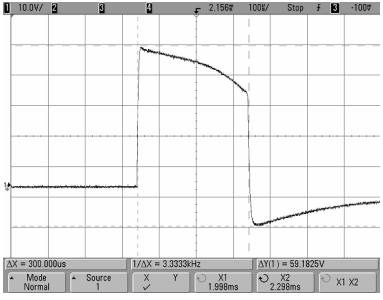
2. N MODE(Normal):

   Load: 500 ohm
   Pulse Rate: 150Hz
   Pulse Width: 300μs



Scope A :

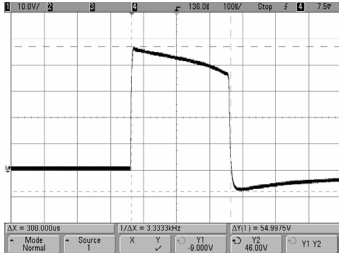
VERT:10.0V/DIV
HORIZ:2mS
OUTPUT:59.1825V pk-pk
Pulse Rate:148.8Hz



Scope B :

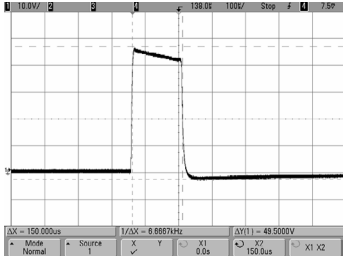
VERT:10.0V/DIV
HORIZ:100μs
OUTPUT:59.1825V pk-pk
Pulse Width:300μs

3. M MODE(-50% Pulse Width & Rate Modulation):
   Load:500 ohm
   Pulse Rate:150Hz
   Pulse Width:300μs



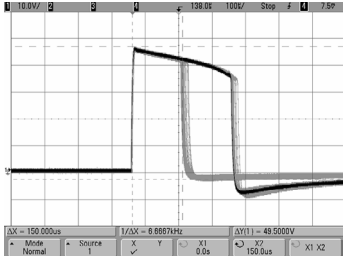
Scope A:

VERT:10.0V/DIV
HORIZ:100μs
OUTPUT:54.9975Vpk-pk
Pulse width:300μs



Scope B:

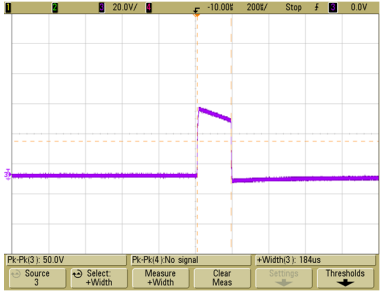
VERT:10.0V/DIV
HORIZ:100μs
OUTPUT:49.5000V pk-pk
Pulse width:150μs



Scope C:

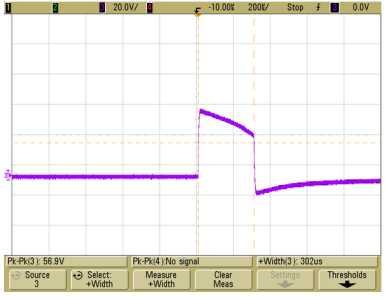
Modulation: -50%

4. S1 MODE(-40% Pulse Width Modulation):
   Load: 500 ohm
   Pulse Rate: 150Hz
   Pulse Width: 300 μs



Scope A:

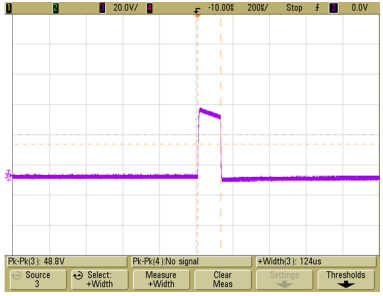
VERT: 20.0V/DIV
HORIZ: 200 μs
OUTPUT: 50.0V pk-pk
Pulse width: 184 μs



Scope B:

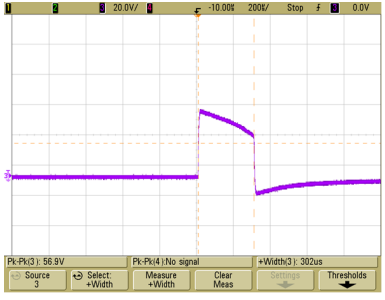
VERT: 20.0V/DIV
HORIZ: 200 μs
OUTPUT: 56.9V pk-pk
Pulse width: 302 μs

5. S2 MODE(-70% Pulse Width Modulation):
   Load: 500 ohm
   Pulse Rate : 150Hz
   Pulse Width: 300μs



Scope A:

VERT: 20.0V/DIV
HORIZ: 200μs
OUTPUT: 48.8Vpk-pk
Pulse width: 124μs

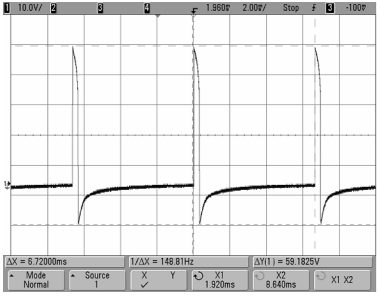


Scope B:

VERT: 20.0V/DIV
HORIZ: 200μs
OUTPUT: 56.9Vpk-pk
Pulse width: 302 μs

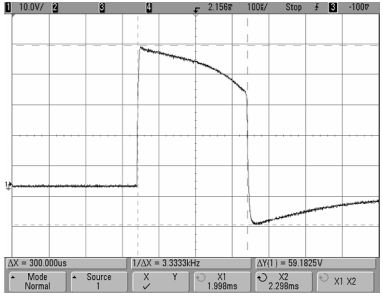
EMS

1. C MODE :
   Load: 500 ohm
   Pulse Rate : 150Hz
   Pulse Width: 300 μs



Scope A:

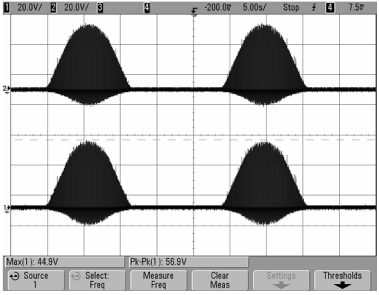
VERT:10.0V/DIV
HORIZ: 2mS
OUTPUT:59.1825V pk-pk
Pulse Rate:148.8Hz



Scope B:

VERT:10.0V/DIV
HORIZ:100μs
OUTPUT:59.1825V pk-pk
PulseWidth:300μs

2. S MODE(Synchronous):
   Load:500 ohm
   Pulse Rate:150Hz
   Pulse Width:300μs
   Contratction Time:12 Sec
   Relation Time:12 Sec
   Ramp Time:6 Sec



3. A MODE(Alternate):
   Load: 500 ohm
   Pulse Rate :150Hz
   Pulse Width:300μs
   Contratction Time :12 Sec
   Relation Time:12 Sec
   Ramp Time: 6 Sec