PANTHEON RESEARCH

INNOVATIVE BIOMEDICAL INSTRUMENTS

Pantheon Research Electrostimulator 12c.Pro **Advanced Version** User's Manual

PANTHEON RESEARCH, Inc. · sales@pantheonresearch.com · www.PantheonResearch.com

✉ 8005 Sacramento St, Suite B, Fair Oaks, California, 95628 · ✆ 310.822.4965 or 888-332-3523 ·

PANTHEON RESEARCH

INNOVATIVE BIOMEDICAL INSTRUMENTS

QUICK START #1

How to use **Sweep** frequency Mode

This summary gives rapid set up instructions for the commonly used **Sweep** frequency Mode**.**

1) Turn OFF all blue output knobs.

2) Connect alligator clips to needles.

3) Set **SW TIME/min** knob to .5 min (SWEEP time, low to high).

   Explanation: Frequencies will sweep from low to high,and back high to low in .5 min, or 30 seconds.

4) Choose **CONT FREQ** (LOW START POINT)
   Explanation: This is the low freq start point. If you choose 5 hz, the low freq start point will be 5 hz.

5) and then choose **MIXED FREQ** (HIGH END POINT).
   Explanation: Frequency will sweep up to this high point, then start back down.
   Thus, SWEEP will pulse between the Cont freq and the Mixed freq.

6) Set minute **TIMER** to 40 MIN (or choose the length of treatment).
   Explanation: The duration of the entire treatment is set by the minute Timer.

7) Set **MODE** switch to **SWEEP**. Treatment will START.
   Explanation: This starts the sweep frequency mode.

8) Turn UP blue output knobs to desired setting. (turn clockwise)

Your treatment will now SWEEP between the low and high frequencies. The entire treatment will last for 40 minutes. The time to sweep between low and high frequencies will be .5 minutes (30 sec, up and down in 30 sec).

PANTHEON RESEARCH, Inc. · sales@pantheonresearch.com · www.PantheonResearch.com
✉ 8005 Sacramento St, Suite B, Fair Oaks, California, 95628 · ✆ 310.822.4965 or 888-332-3523 ·

Please note: All settings can be adjusted. You have many choices. Sweep will take place between any two selected frequencies (Cont Freq switch and Mixed Freq). You can also change the Sweep time, how fast it travels between low and high frequencies (SW TIME/MIN) . And, the treatment time is adjusted by the Minute Timer (10 min to 40 min).

Sweep Step

Sweep Step knob will allow the user to choose the amount by which the sweep frequency changes with each iteration. That is, as it progresses between two settings, it will change by the amount indicated in the Sweep Step knob.

Setting 1: the frequencies will step up as follows: 1, 2, 3, etc.
Setting 2: the frequencies will step up as follows: 1, 3, 5, 7, etc.
Setting 3 : " : 1, 4, 7, 11, etc.
Setting 5 : " : 1, 6, 11, 16, etc.
Setting 10: " : 1, 11, 21, 31, etc.

QUICK START #2

How to use the **Pulse Width Sweep** mode (PWS)

1) Set the **PULSE WIDTH** knob to **PWS.**
2) The pulse width will automatically sweep all the pulse width options, including: .02 , .05 , .1, .2, .3, .4, .5 milliseconds.
3) The standard default pulse width time would be .4 milliseconds. Use this time when not using pulse sweep function, unless you choose a different pulse width for your treatment protocol.

What is pulse width? Pulse width is the amount of time, that the individual electrical pulse that goes to the needles, is ON for. That is, each electrical pulse, has a set amount of time, that it is active. Pulse width sweep, chooses each pulse width in sequence, and thus all the pulse width times are used, in a cycle, for the duration of the treatment. All the peripheral nerves in the body are each activated by a select pulse width, so all the pulse widths are sequentially activating each nerve fiber that is sensitive to that pulse width. This allows for a more effective treatment.

Pulse Width sweep, can be used at the same time as Frequency Sweep. Thus, you can benefit from both features to provide the best possible patient treatment.

Please note: some of the pulse width selections will appear stronger to the patient. .5 milliseconds will be felt more strongly than the .02 millisecond pulse width. Thus, adjust the blue output knob, the level knob for the stimulus, such that it is comfortable at the .5 millisecond level to the patient. Do this by turning up the blue knob slowly, such that the entire sweep is cycled through, and it is comfortable on all levels for the patient.

PANTHEON RESEARCH, Inc. · sales@pantheonresearch.com · www.PantheonResearch.com
✉ 8005 Sacramento St, Suite B, Fair Oaks, California, 95628 · ✆ 310.822.4965 or 888-332-3523 ·

Contents

1 READ FIRST!

1.1 Safety

⚠ WARNING!

Read all instructions in the User Manual carefully and completely. Use of Pantheon Research Electrostimulators may result in injury if not used according to the instructions in the User Manual.

1.1.1 Warnings

⚠ WARNING!

1. This device should be used only under the direction and supervision of a physician or licensed medical professional
2. Do not use the equipment anywhere near water or in a humid environment.
3. Do not use the equipment in an environment where explosive or inflammable gases are present.
4. Do not use on patients with artificial heart, lung or other life support devices.

5. Do not use on patients with cardiac pacemakers or other implant medical devices.
6. Do not use on patients who have heart problems.
7. Do not apply needle electro-stimulation to the neck area if there is a chance of inducing laryngospasm.
8. Do not apply needle electro-stimulation across the thorax. Doing so may increases the risk of cardiac defibrillation.
9. Do not apply needle electro-stimulation trans cranially. It may cause effects to brainwaves in sensitive patients.
10. The use of stimulation with excessive current densities may burn the patient at the point of contact with the needles. If the patient experiences skin irritation or if you notice any burning, stop treatment immediately.
11. Do not apply needle electro-stimulation on areas of bleeding.
13. Care should be taken when treating areas of low or impaired sensory response, or patients unable to report discomfort or pain in the injured/treatment area
14. Do not use on pregnant women if there is a possibility of inducing labor.
15. Do not use the equipment in an area susceptible to high magnetic interference. Doing so may produce instability in the waveform output.
16. Do not use the equipment in close proximity to high frequency surgical equipment.
17. Do not use the equipment in close proximity to shortwave or microwave equipment.
18. Do not use the equipment in close proximity to diathermy equipment.
19. Avoid twisting or bending the cord/clips excessively. Doing so may stress the cord to the point where the copper wire within the insulation may disconnect causing intermittent connections. Intermittent connections can cause voltage surges or discomfort.
20. Keep the equipment out of reach of children.

1.1.2 Cautions

CAUTION!

1. Do not pour water onto your machine or immerse it in water to clean it. Doing so will cause permanent damage to your machine.
2. Do not attempt to repair your machine unless we authorize you to do so. Doing so will void the warranty on your machine.

1.2 Indications & Contraindications

1.2.1 Indications

Elecroacupuncture devices are FDA certified for use in acupuncture applications.

1.2.2 Contraindications

This machine is not intended for the following uses:

1. Use on patients with pacemakers (potential cardiac problems)
2. Stimulation across the chest region
3. Stimulation over the neck region particularly the carotid sinuses to prevent laryngospasm
4. Current across the spine, horizontally
5. Use with imbedded neural stimulators
6. Transcranial stimulation (epileptic possibility with 10 – 13 hz)
7. Use on patients with undiagnosed pain syndromes until the etiology is established
8. Stimulation across wound infections.
9. Benign and malignant tumors
10. Stimulation through the eyeball
11. Profound analgesia induced by E-A puts patients at risk of self injury, must be advised or restricted from strenuous physical activity after treatment
12. E-A can over sedate older patients causing risk of falling asleep after treatment. Patient should be driven to and from clinic.
13. Excess E-A can produce tolerance by depleting central serotonin.
14. High frequency or high amplitude application may induce stress, which is contraindicated in cases of hypertension
15. Lower body points during pregnancy, especially during third trimester
16. This list may not be exhaustive, there may be unstated contraindications.

1.3 Nomenclature

 WARNING! This symbol indicates the possibility of injury to the patient.

 CAUTION! This symbol indicates the possibility of damage to the equipment if not used in accordance to the Users Manual.

2 PRODUCT

2.1 Introduction

The Pantheon Research Electro-Stimulator is a carefully engineered electro-acupuncture stimulator, designed specifically for the clinical requirements of the doctor performing percutaneous electrical stimulation with needles. This equipment is the finest available. It is highly reliable in function, very long lasting, effective in treatment, comfortable to the patient, and versatile in performance.

This is the ninth generation design of the Electrostimulator, and the reliability of it is very high. As a result, we offer a one year warranty. If you have any problem with the equipment within two years, we will fix it or provide a replacement.

For over 30 years, the Pantheon Research electrostimulator family of equipment has been used extensively to treat patients for many syndromes including pain, addictions, and it has been used for analgesia during surgery. Dentists have used it widely for dental acupuncture. Veterinarians also are using the equipment for their work with animals. The Pantheon Stimulator is a very popular electro-therapeutic device that was designed to be more effective with its multiple unique features and special waveforms.

The Pro series is more comfortable than other stimulators, due to its specially designed electro-acupuncture electrical waveform. This waveform is very fast, .4 milliseconds, and is charge balanced in the positive and negative components. It does not efficiently stimulate the nerve cells that sense pressure or heat, at .4 milliseconds pulse width time, and thus feels very comfortable, even at high stimulation levels. Patients appreciate this. It is also considered that the bipolar and symmetrical waveform is more physiologically compatible, as the tissues and nerves will be equally polarized and re-polarized with each electrical impulse.

The 12sp. Pro series of Electro-Stimulators has many features that are **distinguishing**. These include:

1. Unprecedented frequency accuracy. Computer chip controlled functions.
2 Special electro-acupuncture waveform for milliampere current stimulation
3. Special electro-acupuncture waveform for microampere current stimulation
4. One year warranty
5. Adjustable and calibrated mixed frequency
6. Adjustable and calibrated continuous frequency.
7. Built in patient cable and clip lead test function

8. Safety output controls : the machine cannot be turned ON if the output switches are not turned OFF
9. Output channel test function to verify the output
10. Manual battery tester
11. Pantheon MicroClips, the smallest clips in the world
12. Frequency Sweep capability. The frequency will sweep, the frequency will change at 3 hz intervals, between two frequencies that are set by the Continuous Freq switch and the Mixed Frequency switch.
13. Sweep time is selectable. The time taken to sweep between two selected frequencies, is selectable using the Sweep Time switch.
14. Pulse Width selection. Pulse width is selectable, in 7 options, by the Pulse Width switch.
15. Timer will select the amount of minutes the device remains ON for treatment.
16. Regulated output power: as the battery is used, the output power is not affected. Out put power will remain constant during any battery status, except low battery status, in which case the device will shut off.
17. Isolated output channels: All output channels can be independently adjusted, without changing or affecting other output channels performance. Turning up, or down, any channel or group of channels, will not cause other output channels to be changed in output power.

2.2 Electrostimulator

2.2.1 Description and functions

See following pages.

PANTHEON RESEARCH, Inc. · sales@pantheonresearch.com · www.PantheonResearch.com
✉ 8005 Sacramento St, Suite B, Fair Oaks, California, 95628 · ✆ 310.822.4965 or 888-332-3523 ·

PANTHEON RESEARCH

INNOVATIVE BIOMEDICAL INSTRUMENTS

PANTHEON RESEARCH

PENS ELECTRO-STIMULATOR 12sp.Pro

Output Testers
Verifies output operation.

Diagnostic Light
Verifies operation of output channels, clip lead and auto or manual battery function.

Sweep
Frequency sweep between 2 sets..... In 3 hz increments

Independently Controlled Channels
Each channel is adjustable without affecting the output of another.

Pulse Width
Select duration of each individual wave form

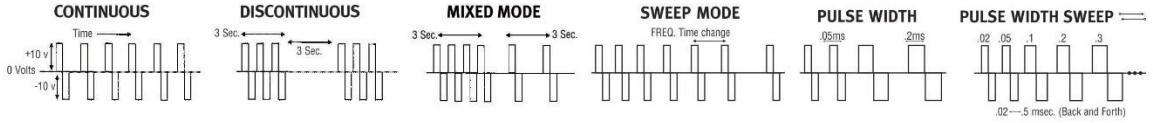
Sweep Time/Min
Duration of sweep

Calibrated Mixed Mode Frequency
Causes stimulator to change frequencies every 3 seconds, between two frequencies. Pantheon PENS are unique in their capability to provide adjustment of both frequencies in mixed (dense-disperse) mode.

Modes of Operation
Microampere waveforms shown.

Timer Machine
Machine stays on for the selected amount of time.

Continuous Frequency
Adjusts from .5 to 200Hz.



OUTPUT PANEL

Milliampere

Microcurrent
[MICROAMPERE]

Built-in Clip Lead Tester
Allows testing of clip lead wires.

*PENS : PERCUTANEOUS ELECTRICAL NERVE STIMULATOR

PANTHEON RESEARCH, Inc. · sales@pantheonresearch.com · www.PantheonResearch.com

✉ 8005 Sacramento St, Suite B, Fair Oaks, California, 95628 · ✆ 310.822.4965 or 888-332-3523 ·

(A) MODE Knob

The Mode knob is located on the left side of the machine face, and is labeled as MODE. The available means of operation or modes are:

1) CONT This is continuous frequency output.

2) DISC This is discontinuous frequency output.

3) MIXED This is mixed frequency output. Also called intermittent or dense/disperse

4) BATTERY TEST: tests battery condition

5) SWEEP Frequency sweeps between two chosen settings, one on the CONT freq knob, and one on the MIXED freq knob .

How to use Sweep Mode

This summary gives rapid set up instructions for the commonly used **Sweep Mode.**

6) Turn OFF all blue output knobs.

7) Connect alligator clips to needles.

8) Set SW TIME/min knob to .5 min (SWEEP time, low to high).

Explanation: Frequencies will sweep from low to high,and back high to low in .5 min, or 30 seconds.

9) Choose CONT FREQ (LOW START POINT)
Explanation: This is the low freq start point. If you choose 5 hz, the low freq start point will be 5 hz.

10) and then choose MIXED FREQ (HIGH END POINT).
Explanation: Frequency will sweep up to this high point, then start back down.
Thus, SWEEP will pulse between the Cont freq and the Mixed freq.

11) Set MINUTE TIMER TO 40 MIN (or choose the length of treatment). Explanation: The duration of the entire treatment is set by the Minute Timer.

12) Set MODE switch to SWEEP. Treatment will START.
Explanation: This starts the sweep frequency mode.

13) Turn UP blue output knobs to desired setting. (turn clockwise)

Your treatment will now SWEEP between the low and high frequencies. The entire treatment will last for 40 minutes. The time to sweep between low and high frequencies will be .5 minutes (30 sec, up and down in 30 sec).

Please note: All settings can be adjusted. You have many choices. Sweep will take place between any two selected frequencies (Cont Freq switch and Mixed Freq). You can also change the Sweep time, how fast it travels between low and high frequencies (SW TIME/MIN) . And, the treatment time is adjusted by the Minute Timer (10 min to 40 min).

CONT: Continuous frequency
This selection setting provides a continuous output of electrical pulses, an unbroken series that continues until the machine is turned off. The basic frequency, or pulse rate, is determined by the Continuous (Cont) position on the Mode switch.

When the CONT. position is selected, the stimulator is turned ON, and the machine is operational. Electrical impulses will be available at the output jacks, , on the top front of the machine, and the treatment can commence if the clips are attached to the patient and plugged into the output jacks. It is important that prior to connecting a patient to a clip lead, that the machine be turned to CONT., and the stimulation Level control knobs be turned all the way to the left, pointing to "O" (you will feel a click at "0")

DISC: Discontinuous frequency.
The output varies between the selected frequency, and no output, and the change occurs every three seconds. This is providing periodic and regular interruptions to the regular stimulation.

MIXED: Mixed Frequency

The electrical impulses will vary intermittently. Each three seconds, the frequency of the pulses will change from the setting indicated on the Continuous knob (C), to the setting indicated on the MIXED knob (D). Thus, the MIXED setting allows two variable frequencies to be provided, both of which are selectable.

SWEEP : Frequency sweep. The frequencies will sweep between two selectable frequencies. The frequency will sweep between the selected **Cont Freq**, and the selected **Mixed** Freq. For instance, if the Cont Freq is set for 2 hz, and the Mixed Freq is set for 100 hz, then the frequencies will move between 2hz and 100 hz in 3 hz steps. It will then move in the opposite direction, from 100 hz back down to 2 hz, in3 hz steps. Any of the frequencies in either switch can be used.

BATT. Test - Manual Battery test
This position will manually test the battery strength. If the battery is good, that is, if it has a voltage above 6 volts, the Batt Test light will light green. If the battery is not good, the Batt Test light (H) will be off. This will be a solid green.

(B) MINUTE TIMER

10, 20, 30, 40 minutes

The machine is turned ON by turning the MODE Knob (A) to either Cont, Disc, Mixed, or Sweep. The timer automatically begins a 10min countdown. At this point you can change the minute timer (B) to 20min, 30min, 40min, or leave it at the default of 10min. The machine will then operate for that time duration, and then shut OFF. When it shuts off, an audible beep sound will be heard. The beeper will shut off when you turn the MODE knob (A) to the OFF position.

SAFETY FEATURE

The safety feature prevents accidental shocking of a patient. It works as follows: If all the level control knobs (E) are not turned to "0", the machine cannot be turned ON.

If any level control knob is above "0" and the machine is turned on by turning the MODE knob (A) to Cont, Disc, Mixed, Batt. Test, you will hear a beeper sound and the diagnostic light (H) will be red. The machine will not function.

EACH level control knob (E) must be turned to "0" (you can feel a click at "0"), then you can change the MODE knob (A) and the machine will operate normally.

(C) Continuous – Frequency HZ

This knob controls the basic frequency or pulse rate of the electrical pulses that are produced by the electro-stimulator. Frequency, or hertz, is the number of times per second that the electrical impulse travels from the machine to the patient.

The electro-stimulator has an extended frequency range. This is click stop selectable to specific therapeutic frequencies including .5, 1, 2, 4, 5, 10, 15, 25, 30, 100, and 200 cycles per second.

These frequencies are produced during the selection of the CONT. position of the MODE knob (A), and during the ON period of the DISC. selection, and during one of the frequency periods of the MIXED (D) selection.

(D) MIXED – Mixed Frequency

This is the same in function to the Continuous (C) frequency knob, but controls the frequencies when the MODE knob (A) is turned to MIXED. These are the adjustable, calibrated mixed frequencies. These frequencies are the same in choice as the Continuous knob (C), but are operating only on the alternate 3 second cycle of the MIXED mode.

(E) LEVEL CONTROL KNOBS

The four knobs on the top of the electro-stimulator machine are the controls for the level of electricity distributed to the patient. This can also be called the "strength", the voltage or amplitude. Simply, as you turn this up more and the patient is connected, he/she feels it more.

These knobs are not connected to each other, and are independent. If you adjust one, you will not cause the others to be effected. This is very important as a feature. They should be turned down, after each treatment, and prior to each treatment. A treatment should never begin without these knobs all being turned all the way to the left, or "0". You can feel a click when you have completely turned the knobs to "0". Then, as the needles are hooked up, the knobs can be slowly turned to the right, or turned up.

A very smooth adjustment is built into the level controls. If you move the knob slowly, the perception of electrical stimulation felt by the patient will very gradually increase. This allows you to carefully adjust the proper amount of power to give each pair of acupuncture points.

Please refer to your clinical application information on how much stimulus is therapeutic. Typically, the level control knobs (E) will be turned up, until the patient reports slight discomfort, and then they will be backed off, or turned down slightly.

The level control knobs control both the milliampere and the microcurrent outputs at the same time.

(F) OUTPUT TESTER - located on the left corner of top panel

You may test the output of any milliampere (L, see pg.6) or microcurrent (M, see pg.6) output. This tells you that there is a stimulus coming out of the machine and that the output jacks are operating. Occasionally, you need to determine if both the clip leads and the outputs are operating. You may suspect the operation of either. With the Clip lead tester (N) and output tester (F), you can check both. This is very useful.

Simply insert the clip assembly plug into any output channel (L) or (M). Turn on the MODE knob (A) to Continuous. Then turn up the level control knob (E) of the corresponding output channel.

Attach the clips of the clip assembly to the Output Test (F) connectors. The red and black lead can go on either connector. If the output is working, that is, if there is an output, then the diagnostic green light (H) will light up with each electrical impulse. Thus, the diagnostic (H) green light will be pulsing at the same time as the PULSE (I) green light.

(G) Sweep Time/Min : This controls the sweet time. The sweep time is the duration required for the entire sweep from low to high, and from high back to low frequency, to occur. The time options are .5 minutes,1 min, 2 min, 3 min, 4 min, and 5 minutes. Thus, the sweep times can be fast, or slow, or intermediate.

(H) Pulse Width: The pulse width is the time in which each individual electrical pulse from the output, into the patient, is ON for. This is the time that the electrical pulse is in the ON state.

The pulse width can be varied starting at :

1) .02 milliseconds
2) .05 milliseconds
3) .1 milliseconds
4) .2 milliseconds
5) .3 milliseconds
6) .4 milliseconds
7) .5 milliseconds

Standard time for pulse width is .4 milliseconds. This is the default pulse width option. If the choice is not known for the desired therapeutic effect, than the option of .4 milliseconds is proper.

(H) DIAGNOSTIC LIGHT FUNCTIONS

The diagnostic light is labeled "DIAG." on the front panel.

The following is a summary of the diagnostic light functions:

Testing Feature	Appearance of Light (H)
1) Safety is ON, and machine will not operate (due to output level controls (E) being above "0")	Solid RED and beep
2) OUTPUT TEST (working)	Blinking GREEN and Pulse light (I) YELLOW
4) Manual Battery Test **(Batt Test Light)**	Solid green if battery good (solid red light if bad)
5) Clip lead tester	Solid green if clip lead is good (no light if bad)

(I) Pulse Light

Light pulses with each electrical impulse sent from the output channels through the wires to the needles.

(J) Continuous Frequency Indicator light

This yellow light will be ON when the position of the continuous freq. knob (C) is determining the output pulse frequency. When the MODE knob (A) is on the "cont." selection position, this light will always be ON. When the MODE knob (A) is on "mixed", this light will be "ON" one half of the time, at three second intervals, and the MIXED (D) frequency indicator light will be on the other half of the time. When the MODE knob (A) is on "disc", this light also is on half of the time, at three second intervals.

(K) Mixed Frequency Indicator light

This yellow light appears ON when the MODE knob (A) is set on "mixed". It will light for half the time while the other half of the time, the Continuous Freq Indicator (J) will be ON, alternating in 3 second intervals.

(L) MILLIAMPERE OUTPUTS (see picture)

The milliampere outputs are located on the top row of the front side panel. They are labeled.

(M) MICROAMPERE OUTPUTS (see picture)

The microampere or microcurrent outputs are located on the bottom row of the front side panel.

The microcurrent outputs operate at the same time with the milliampere outputs. The level control knobs will adjust the microampere and milliampere outputs at the same time.

The current level is adjusted by the level control knobs (E). The level control knobs are labeled 0 through 6. This will correspond with the microcurrent level 0 microamperes to 600 microamperes. Thus, the level control knob set at a level of 3 will yield a microcurrent output level of 300 microamperes.

(N) CLIP LEAD TESTER

You may test the integrity or conductivity of your clip assembly leads with the Clip Lead Tester. This is located on the top side panel (where the outputs are located), bottom row, far right. It is labeled Clip Lead Tester. To use this, insert the plug of the clip asembly to be evaluated, into the Clip Lead Tester port or jack. Then, switch the MODE knob (A) to Cont. , which will turn the machine ON.. With the clip assembly plug inserted into the Clip Lead Tester, the diagnostic light should be OFF. However, just touch the metal clips together, and the green diagnostic light (H) will come ON. This indicates that the clips and clip assembly is good, and conducts electricity.

BATTERY CHANGING

The batteries' compartments are located on the underside of the machine. You have to insert your nail or flat tool and press against the grove to open the small door. There are two 9 volt batteries.

IMPORTANT: These batteries are placed in carefully with the positive terminal and negative terminal in a marked position. Do not violate these markings. Place the batteries in properly.

5) To change the batteries (two 9V), the battery compartment doors are opened and lifted up, exposing the batteries.

6) To open the battery compartment door, insert a small flat screwdriver head, or pen tip, or other small flat object, in the small **slot .**

7) Insert the screw driver head into the slot, and gently push in and then lift up, and the battery compartment door will also lift up.

8) The doors will swing open, exposing the two 9volt batteries.

9) Change the batteries.

10) Replace the battery compartment door by first inserting the top edge of the door, and then pushing down the bottom edge to cause it to snap into place.

Important notes regarding the battery test function:

1) If a blue output adjust knob is turned "ON", or not turned all the way to the left, and clicked "OFF", the manual **Batt Test** function on the MODE switch will cause the diagnostic light to beep and blink, as if there was a low battery. The blue output adjust knobs need to be turned "OFF" when using the **Batt. Test** function.

2.3 Clip Assembly (Applied Part)

Safety Class	 Type BF, not defibrillation proof

Your Pantheon Electrostimulator comes with a set of 12 clip assemblies. In order for your machine to operate correctly and deliver treatment:

1. at least two needles must be inserted in the patient,
2. at least one clip assembly must be plugged into any channel output connector (not the Clip Test connector) on your machine,
3. the clips of the clip assembly must then be clipped onto the needles (one clip is attached to one needle). Both the black and the red clips have to be connected to each inserted needle; otherwise, no current will flow within the patient.

2.4 Using Your Pantheon Research Electrostimulator

- Clean body points with alcohol
- Insert needles and acquire qi or apply TENS pads.
- Adjust electro-stimulator for desired frequency and waveform type:
    - For needle stimulation, set side switch to Acupuncture
- Make sure Mode knob (A) is set to OFF and all four level control knobs (E) are at zero.
- Plug clip into the electro-stimulator
- Attach clips of the clip assembly to the needles for acupuncture .
- Ask patient if everything is still comfortable.

Set the MINUTE TIMER (B) to the desired time limit. If 10 min, just leave as is.

- Turn the MODE knob (A) on the electro-stimulator to the desired mode: Continuous, Discontinuous , Mixed or SWEEP .
- (double-check that the level control knobs (E) are clicked off to zero) At this point the TIMER has begun its countdown.
- Tell patient which pair of points will be stimulated first, what they can expect to feel and what responses they should give. For example, "We'll start with these points …here … and here. I'm going to slowly turn up the intensity, and I want you to tell me when you first start to feel … a light tapping or tickling sensation" (for very slow frequencies) or "a light buzzing or tingling sensation" (for higher frequencies).
- **SLOWLY** turn up intensity with the Level Control knob (E) until the patient feels electrical stimulus.
- If using stronger stimulation, ask the patient to tell you when the stimulus gets strong but still comfortable. It should not be painful. Also remind them to tell you if it gets sharp. **SLOWLY** increase the intensity until the patient tells you it is strong enough for them.
- Repeat the process for each channel used.
- The intensity felt by the patient will generally diminish over time, so, if necessary, **SLOWLY** increase until the patient says it's strong enough again.

When ready to stop treatment:

- When the timer turns off, a beeper will sound off.
- Turn each level control knob (E) channel down **part way**. Then turn each level control knob (E) channel all the way down until it clicks off.
- Turn MODE knob (A) to OFF
- Disconnect clips or lead wires from the needles.
- Remove needles.
- Unplug wires from the electro-stimulator.
- Store or hang all wires straight when not in use. Tightly coiling or wrapping wires around machines will lead to premature breakage and wire failure. Periodically check wires with clip lead tester to ensure their safe use and patient comfort.

3 PRODUCT MAINTENANCE AND TROUBLESHOOTING

3.1 Cleaning, Inspection, and Maintenance

3.1.1 Cleaning

Dirt, oil, grease, rust and all types of gunk can build up on your machine over time. To clean the enclosure of your machine, use a cloth dampened with water or isopropyl alcohol.

CAUTION!

Do not pour water onto your machine or immerse it in water to clean it. Doing so will permanently damage your machine.

3.1.2 Inspection

To improve the lifetime of your machine and clip assemblies, we suggest you do the following inspections:

1. Use a battery tester or voltmeter to measure across the battery terminals. For brand new batteries, this measurement should be greater than or equal to 9 Volts. Refer to the Battery Changing Procedures in the Troubleshooting Section for more suggestions on how to deal with problematic batteries.
2. Inspect the battery snap and its wires to make sure it's not stripped, frayed, or twisted. If you suspect that the battery snap is faulty, call us.
3. Inspect the battery door to make sure it's not cracked. If it is, just call us and we'll send you a new one.
4. Inspect all plastic knob covers to determine if they are cracked or chipped. Also, determine if the set screw located on the side of each plastic knob cover is stripped. If either case is true, simply call us and we'll send you a replacement plastic knob with a set screw.
5. Inspect all of the channel output connectors and the Clip Test connector to verify that they are not cracked. If they are cracked, do not attempt to fix this yourself. Call us to schedule a repair.
6. Go through all of your clip assemblies to see that they are not kinked or twisted. Kinks and twists put stress on your clip assemblies; they will last longer if they are straightened out. If your clip assembly is bad just call us and order a new one.

3.1.3 Maintenance

CAUTION!

Do not attempt to repair your machine unless we authorize you to do so. Doing so will void the warranty on your machine.

To prevent the possibility of shocking your patients, we suggest you do the following maintenance procedures:

1. Go through the Clip Test (see Troubleshooting Procedures) on all of your clip assemblies to determine if any of them are bad. If your clip assembly fails the Clip Test, call us to order a new one.
2. Once you perform the Clip Test, go through the Output Check Test (see Troubleshooting Procedures) to determine if there is output coming out of each connector on your machine. In order to do this test, you must do the Clip Test first because if you use a bad clip assembly to do the Output Check Test, the test will automatically fail. If you find that there is no output coming out of a particular connector, do not attempt to repair this yourself. Call us to schedule a repair.

If you experience degraded performance, go through the Battery Changing Suggestions, Clip Test, and the Output Check Test of the Troubleshooting Procedures to determine whether the problem is due to your machine. If the outcome of the tests determines that the machine is the cause of these problems, call us immediately to schedule a repair.

If you experience unintentional shocking, go through the Clip Test, and the Output Check Test of the Troubleshooting Procedures to determine whether the problem is due to your machine or a bad clip assembly. If the outcome of the tests determines that the machine is the cause of these problems, call us immediately to schedule a repair.

3.2 Troubleshooting

3.2.1 Error Conditions

Use the following table to help you determine what problem(s) you are having with your machine and what tests you should perform.

#	Batt. light	Diag. light	Beeper	Condition
01	No light	No light	Silent	Low battery This occurs when the Mode switch is at Batt. Test position (see Battery Changing Suggestions).
02	No light	Red	Quick beep (≈ 3 times per second)	Blue output knob is on when the Mode switch is turned on. To solve this problem, do the Output Off at Startup Test.
03	Green	No light	Silent	Batteries good This occurs when the Mode switch is at Batt. Test position.
04	No light	Green	Silent	Clips good This occurs when you are performing the Clip Test.
05	No light	Flashing Green	Silent	Output good on the channel you are testing. This occurs when you are performing the Output Check Test.
06	No light	No light	Slow beep (≈ 1 time per second)	Timer expired.

.

3.2.3 Battery Changing Suggestions

1. Don't assume that your batteries are good. If the batteries have been sitting in the drawer in an unopened package for a while, they can actually lose charge over time.
2. Change both batteries not just 1 of the 2 batteries.
3. Buy 4 batteries at a time and swap them in & out. To eliminate the possibility of a bad battery lot, buy 2 batteries at one store and 2 batteries at another store.
4. Don't buy a low quality brand! We use Duracell 9V batteries.
5. Buy a cheap voltmeter or battery tester.

3.2.4 Tests

3.2.4.0 Initial Settings

Before you do any of the following tests, make sure all knobs/switches on your machine are set to the following positions:

1 Mode switch = Off
2 Cont. Freq. = 10
3 Mixed Freq. = 10
4 Minute Timer = Infinity or Off (all the way to the right)
5 CH1 – CH4 blue output knobs = 0 (clicked off al the way to the left)
6 Tens/Acupuncture side switch = Acupuncture

3.2.4.1 Outputs Off at Startup Test

1 Make sure the Mode switch is turned off.
2 Make sure all blue output knobs are switched off.
3 Turn the Mode switch to Cont.
4 Wait 3 seconds. You should see a flashing middle green pulse light.

3.2.4.2 Clip Test

Purpose: to determine whether the cord/clips are good

1. Make sure all of the blue output knobs are turned off.
2. Turn the Mode switch to Cont., Disc., or Mixed mode. (If you get a beeping red Diagnostic light, it means that one of the blue output knobs is on when you turn the machine on. If this is the case, repeat Step 1.After about 3 seconds, you should see the middle green pulse light blinking.
3. Plug a cord into Clip Test connector.
4. Take the black and the red clips of the cord and touch them together. Each time they make contact, a green Diagnostic light should come on.
5. Take the black and the red clips of the cord and clip them together. The green Diagnostic light should turn on.
6. Grab a hold of the wire around the black clip and wiggle it around. Make sure the black and red clips are clipped together as you do so. Verify that the green Diagnostic light remains on and doesn't go off.

7. Grab a hold of the wire around the red clip and wiggle it around. Make sure the black and red clips are clipped together as you do so. Verify that the green Diagnostic light remains on and doesn't go off.
8. Grab a hold of the wire around the jack (the part of the cord that plugs into the Clip Test connector) and wiggle it around. Make sure the black and red clips are clipped together as you do so. Verify that the green Diagnostic light remains on and doesn't go off.
9. If the green Diagnostic light remains on as your perform Steps 4-7, it means that the cord is good. If the green Diagnostic light goes off or never comes on, it means that the cord is bad. Try another cord to see if it passes.
10. The Clip Test can also be performed using facial probes, grounding probes, and even TENS pads.

3.2.4.3 Output Check Test

Purpose: to determine whether you are getting any output on each connector
Note: You must perform the Clip Test before the Output Check Test because the Output Check Test will not pass if you unknowingly use a bad cord/clips to do the test.

1. Make sure all of the blue output knobs are turned off.
2. Turn the Mode switch to Cont., Disc., or Mixed mode. (If you get a beeping red Diagnostic light, it means that one of the blue output knobs is on when you turn the machine on. If this is the case, repeat Step 1. After about 3 seconds, you should see the middle green pulse light blinking.
3. Connect the black clip of the cord which passed the Clip Test to the lower pin where you see "Output Test" on the top panel.
4. Connect the red clip of the same cord to the upper "Output Test" pin. Make sure that neither clips are touching both "Output Test" pins.
5. Plug the cord into CH1 milliampere connector (top row).
6. Turn on the CH1 blue output knob. Turn it up until you see the greenDiagnostic light blink at the same rate as the middle green pulse light. If you see this, then you are getting output on the CH1 milliampere connector. If you don't, then there no output is coming out of this connector
7. Turn off CH1 blue output knob.
8. Unplug from CH1 milliampere connector.
9. Repeat Steps 5-8 for the rest of the connectors both milliampere (top row) and microampere). Make sure that you turn up the blue output knob for the corresponding channel. So, for instance, if your cord is plugged into either the CH4 milliampere or microampere connector, turn up the CH4 blue output knob until you see the green Diagnostic light blink at the same rate as the middle green pulse light.

3.2.5 Contacting Us

Call us before you send your machine in for repair. This way we can troubleshoot over the phone and give you additional information if we tell you to send your machine in. Our phone number is:

(310)822-4965, (888)332-3523 (toll-free)

The best time to call us is between 11 AM – 5 PM Pacific Time when at least two people are available to answer the phones.

3.2.5.1 Before You Call:

1 Go through the Troubleshooting Procudures before you contact us.
2 Have the following close by before you call us:
    1 Your Machine
        Please have your malfunctioning machine close by. If you have access to additional machines, we suggest that you get those as well.
    2 Your Clips
        Please have the clips which you were using at the time the problem occurred close by. If possible, keep track of which clips were plugged into which channels. If you have access to additional clips, we suggest that you get those as well.
    3 Extra Batteries
        If you have a 12sp. Pro and it isn't turning on, we suggest that you get as many batteries as possible. This way you can swap a pair of batteries in and out of the machine in case it turns out that a pair of batteries which you assumed to be good turns out to be bad.

3.2.5.2 When You Call:

1 We are going to ask for the following information:
    1 Your Name
    2 Your Phone #
        We need your phone # in case we get disconnected.
    3 Your Address (NO P.O. BOXES PLEASE!)
        If we tell you to send your machine in, then we will ask you for your address.
    4 Serial # of Your Machine
        This is located on the battery compartment door on the underside of your machine.
    5 Model # of Your Machine

2 Be specific.
    Just telling us that your machine does not work does not help us at all. The goal of the phone call is to isolate the problem to a specific channel, mode, etc. For instance:
    1 If your machine isn't working:
        a Did you see a flashing yellow pulse light?
        b Do you get a beeping red Diagnostic light?
        c Do you see a flashing yellow Battery light?
    2 If you think that you're not getting any output:
        a Which channels were you using?

b Which clips are plugged into those channels?
3 Which mode were you using?
4 What are the frequency dials set to?

3.2.5.3 If We Tell You To Send Your Machine In For Repair:

1 Include a short note with the following information:
  1 Your Contact Information
    Name, Phone #, Address
  2 Problem That You're Experiencing.
    Just write a 1 or 2 sentence description of the problem that you're having with your machine.
2 In addition, we may ask you to include the following in the package:
  1 Batteries that were in the machine at the time the problem occurred
  2 Clips that you were using at the time the problem occurred.

4 PRODUCT SPECIFICATIONS AND OTHER INFORMATION

4.1 Specifications

General		
Class		Internally Powered
Operation		Continuous
Power		
Power Source		18 V (2 9V batteries)
Power Input		0.9W max
Battery Charger		--None
Battery Adapter		None
Applied Part (Cord/Clips)		
Safety Class		 Type BF, not defibrillation proof
Output		
Pulse Amplitude		51.4 Vrms @ no load 5.75 Vrms @ 500Ω
Pulse Current		11.5 mA rms @ 500Ω
Pulse Frequency		(0.5, 1, 2, 4, 5, 10, 25, 30, 100, 200) Hz 12sp; Error ≤ ± 0.5%
Pulse Duration		400 usec normal, 20, 50,100,200,300,400,500 usec optional with switch
DC Component		2.5V max
Load Resistance		> 45KΩ
EMC		
Immunity - Voltage Tolerance		Voltage amplitude during EMC interference ≤ Voltage amplitude without EMC interference + 10%
Components		
Board		
	Manufacturer	4PCB
	Conforms to:	UL #
Wiring		
	Manufacturer	PlasticsOne
	Conforms to:	UL #
Enclosure		
	Manufacturer	OKW
	Model #	
	Material	ABL

	Conforms to:	UL94HB
	Protection Class:	IP41

4.2 Notices

4.2.1 EMC

Operation of this device is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Group 1 Class B device. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not used in accordance with manufacturer's instructions, may cause harmful interference to other devices. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to other devices, radio, or television reception which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between this device and the receiver.
- Relocate both the equipment and the patient to an area that is sheltered from the magnetic interference.
- Consult the manufacturer, dealer, or an experienced radio/TV technician for help.

The result of the RF Tests are displayed in the following 3 tables.

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such environment.		
Emissions test	**Compliance**	**Electromagnetic Environment – guidance**
RF emissions CISPR 11	Group 1 Class B	This 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 CISPR 11	Complies	The device is suitable for use in all establishments, including domestic
Harmonic emissions IEC 61000-3-2	Not applicable	

Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 1: Emissions testing is exempt under FCC Regulations for this prescribed device.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such 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	Floor 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	Not applicable	Not applicable	Battery Operated Equipment
Surge IEC 61000-4-5	Not applicable	Not applicable	Battery Operated Equipment
Voltage dips, short interruptions and voltage variation on power supply IEC 61000-4-11	Not applicable	Not applicable	Battery Operated Equipment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in

			a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated form the equation appropriate to the frequency of the transmitter. Recommended separation distance $D=1.2\sqrt{P}$ 150 kHz – 80 MHz $D=1.2\sqrt{P}$ 80MHz – 800MHz $D=2.3\sqrt{P}$ 800MHz – 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and D is the recommended separations distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey (note A), should be less than the compliance level in each frequency range (note B). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.5 GHz		
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.			
Note A: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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, and electromagnetic site			

survey should be considered. If the measured field strength in the location in which the devices is used exceeds the applicable RF compliance level above, the device should be observed, additional measures may be necessary, such as reorienting or relocating the device.
Note B: Over the frequency range 150 kHz, field strengths should be less than 3 V/m.

4.3 Warranty

Thank you for your purchase. We are here to be of service to you in any way we can. The following outlines our warranty policy. Please call us if you have any questions. We very much look forward to speaking with you.

Full one-year warranty
For one year from the date of purchase, if this Electro-stimulator fails due to a defect in material or workmanship, Pantheon Research will repair it free of charge.

90 Day Warranty on Clip Assemblies, Facial Probes

Return Policy if purchased directly from Pantheon Research Inc.
The electro-stimulator can be returned for up to 30 days from purchase date for a full refund.

Return Policy if purchased from a distributor
The electro-stimulator can be returned to the distributor for a refund according to the policies of the distributor. A refund will be provided by the distributor, according to their terms. Please check with the distributor for information about their refund policy.

What is not covered by this warranty

1. Conditions and damages resulting from any of the following:
    a. Improper maintenance
    b. Any repair, modification, alteration, or adjustment not performed by a Pantheon Research servicer.
    c. Misuse, abuse, or unreasonable use.
    Ex. Any liquids such as oils that have spilt into the machine
2. Warranties are void if the original serial number has been removed, altered, or cannot be readily determined.
3. Battery
4. Shipping cost to send Electro-stimulator to Pantheon Research

To receive Warranty Service <u>please call us first</u>. We often can trouble shoot the problem over the phone. If we are unable to solve the problem over the phone then send your electro-stimulator to:

Pantheon Research
8005 Sacramento St, #B
Fair Oaks, CA 95628

Be sure to include the following information:
Your name, address, telephone number, email address.
A clear description of the problem you are having.

A APPENDIX

A.1 Why Buy Pantheon Research Electrostimulators?

1) Pantheon Research Electro-Acupuncture Stimulators are the only **US made** devices on the market. We are therefore accessible to our clients for technical support service, and high quality is built into the products.

2) Our equipment is sold with a **one year warranty**, which covers parts and labor. Since we are in the U.S., repairs can be made easily and returned promptly to the customer.

3) Pantheon Research can **offer customer service** directly. Customers are welcome to call us with questions about the machines, and we will answer all questions about technical issues. Clinical applications of electro-acupuncture are frequent topics of inquiry, and we make an attempt to assist with these questions. We are not acupuncturists, and make no claims to authority in expertise with clinical applications. We can refer customers to reference materials and provide reference materials to distributors.

4) Our Electro-stimulator line of devices is **extremely reliable**. They are well built, well thought out, engineered to a high standard, and are dependable. They can be expected to have a very long functional life. Consequently, they are an asset to a business that offers electro-acupuncture therapy. They can be relied upon to function after years of use, and to be safe and effective with patients.

5) Pantheon Research Electro-stimulators are built with **advanced features** and unique features unavailable in other machines. It is important that acupuncturists have equipment with the features provided by the Pantheon equipment.

Features *unique* (not available on any other machine) to Pantheon Research Electro-Acupuncture Stimulators

1) **Frequency accuracy of frequencies.**

2) **Safety Mechanism**. All outlets must be turned OFF before the power can be turned ON. This ensures no surprise or pain to your patient should the outlets still be on from a previous treatment.

1) **Self diagnostic features** For the safety of your patients and the effectiveness of your treatments, you can: test the operation of the clips and lead wires; check and validate the functioning of a specific outlet; be alerted when the battery is low and needs replacing

2) **Ergonomic Design** Redesigned for better readability and operational comfort.

3) **Battery Power** Less power is required for E-Stim operation, resulting in longer battery life.

4) **Most effective waveform for treatment**: Our "acupuncture waveform" selectable by switch, is a *symmetrical biphasic* waveform. This is the best waveform to use with needle electro-acupuncture (see appendix notes by Pomeranz). This is the most effective physiologically. It is also the **most comfortable**, and delivers the least pain and discomfort to the patient. To sensitive patients, this waveform is a real advantage in treatment as it is very comfortable.

5) **Microcurrent outputs specifically designed for electro-acupuncture:** Available in models 6c.Pro, 8c.Pro, and 12c.Pro and 12sp., this microcurrent is designed for use with needle stimulation. There are two main types of microcurrent waveform. These are 1) Physiotherapy appropriate microcurrent (applied with large electrodes to the skin surface, either tens pads or Q-tips pads), and 2) Pantheon Research microcurrent, which is designed to be used for needle stimulation (see appendix for technical discussion). We offer the only electro-stimulator that uses electro-acupuncture (or percutaneous needle stimulation) appropriate microcurrent.

6) **Calibrated frequencies:** In all Pantheon models specific therapeutic frequencies are switch selectable and are calibrated to scientific accuracy of over 98%. Frequencies range from .5 Hz to 200 Hz.

7) **Mixed Mode frequency is fully calibrated and adjustable:** The mixed mode, or dense disperse, causes the machine to alternate between frequencies every three seconds, switching back and forth between two separate frequencies. Each of these discrete frequencies is selectable.

8) **Clip Lead tester:** The clip lead tester solves a problem no other machine can; testing the integrity and usefulness of a clip assembly. It will test if a wire and clip assembly is working.

9) **Great features with small size:** The Pantheon Electro-stimulators have the most professionally useful features providing electro-acupuncture therapies to patients yet are small enough to easily fit on a treatment table or to be carried.

10) **MicroClips:** We are the exclusive providers of the Pantheon Research MicroClip. This is the smallest, most reliable electrical clip available on the world market. It is ¼ the weight of a standard alligator clip. It does not use teeth to grip a needle; consequently, it is highly reliable when gripping a needle.

Additional features of the Electro-stimulators

1) **Independently controlled channels: No** output channel will interfere with another when being turned up or down. There is no "cross talk" between channels.

2) **Modes of operation include:** Continuous, mixed, and discontinuous

3) **Battery tester**

4) **Four clips provided with each machine:** Two alligator clips, and two MicroClips

5) **Battery included:** two Duracell batteries for extended battery life

PANTHEON RESEARCH, Inc. · sales@pantheonresearch.com · www.PantheonResearch.com
✉ 8005 Sacramento St, Suite B, Fair Oaks, California, 95628 · ✆ 310.822.4965 or 888-332-3523 ·

A.2 Discussion of Symmetrical Biphasic Waveform

From Basics of Acupuncture; G. Stux & B. Pomeranz; 1998, Springer, pp. 272-273

"Generally the red lead of each pair of wires is positive, and the black is negative. Pulses of electricity are applied to the needles in order to stimulate nerves, with the pulse width being from 0.1 to 1.0 ms in duration (Some stimulators have adjustable pulse width). More expensive, elaborate stimulators use biphasic pulses (negative followed by positive or vice versa) in order to reduce polarization of each needle due to electrolysis. (The negative pulse cleans the electrode of electrolytes deposited by the preceding positive pulse.) **If the pulses are perfectly biphasic, then the net DC current is zero and no polarization occurs.** Polarization is a nuisance as it raises the electrode resistance over time, thus reducing the intensity of stimulation. Also, it can cause the needle to break off in the tissue.

Another advantage of biphasic pulses is that the two needles of each pair receive symmetrical stimuli (one needle being the mirror image of the other). Hence the red lead has a positive pulse followed immediately by a negative pulse, while the black lead has a negative pulse followed by a positive pulse. Since negative pulses cause an action potential on the nerve, it is important that both needles in a pair receive negative pulses, which is only possible in a biphasic stimulator. The intensity of stimulation is under the control of an intensity knob. In less expensive stimulators in which the biphasic pulses are not perfectly matched (the negative wave is not equal to the positive wave); the negative, black lead will give a stronger needle sensation than the positive, red lead. In order to achieve an optimum effect for acupuncture analgesia, the strongest tolerable intensity is required for DeQi (to activate type II and III muscle nerves**). If both leads of a pair deliver symmetrical, biphasic pulses then both needles will be optimally stimulated to give De Qi.** With less expensive devices, however, only one needle of a pair is adequately activated (the needle attached to the black lead)."

A.3 Discussion of Microcurrent Waveform

(not available on the Electrostimulator 4C Pro)

Microcurrent electrotherapeutic devices have been in the market for many years, and they are normally designed to be used with TENS pads, and Q-Tip cotton probes. These electrodes are applied to the external skin, and are physical therapy or physiotherapy applications. When touching acupuncture points, a similar effect to electro-acupuncture occurs.

The classic microcurrent waveform is called a square wave, and it is also denoted by the technical description: 50% duty cycle square wave. This will be explained subsequently. **Microcurrent stimulators that are designed for electrodes that are attached to the skin may not be appropriate or safe for use with electroacupuncture with needles inserted into the body, or percutaneously.**

Pantheon Research electro-stimulators are designed with a microcurrent square wave that is fully safe and effective when used with percutaneous needle stimulation, as used during electro-acupuncture. This waveform is slightly different, and not the same as the 50% duty cycle waveform. The electro-acupuncture compatible waveform has a much faster pulse time than 50% duty cycle, about 5% or less (See Figure 1, pg 14).

Classical microcurrent devices for physical therapy apply the electrical stimulus to large electrodes, either a TENS pad or a Q-Tip cotton probe. The surface area of these electrodes is large, and the electricity is passed through the epidermis. The large surface area of an electrode means that the current density is small. That is, the available electrical current is divided by the surface area of the electrode that touches the skin. In addition, the stratum corneum of the skin has a very high resistance to the passage of electricity. This also reduces the current passing into the body. This is a very safe technique, and very therapeutic for many problems.

However, if this very safe 50% duty cycle square wave is passed into the tip of a needle inserted subcutaneously, different conditions occur. The surface area of a needle tip is very small, and the available electricity is divided by the area of the needle shaft, or possibly the needle tip, under certain conditions. Thus, the current density is large in comparison to a 1 inch square TENS pad. Also, the resistance of the skin is not present.

The problematic condition is most acute when a very slow frequency is being used. Very slow frequencies are most common in electroacupuncture. These are .5 Hz, 1 Hz, and 2 Hz. At 1 Hz, with a 50% duty cycle, the positive pulse will be .5 second in length. At .5 Hz, the positive pulse will be 1 second in length. This begins to appear as DC current, with these slow frequencies, and the problems of electrolysis are possible.

Electrolysis will result in the metal components of the needle being electrically forced into the tissues, and the formation of gas bubbles under the skin and in tissue.

The following quote is taken from the paper by Yoshiaki Omura printed in Acupuncture and ElectroTherapeutics Res. Int. J., Vol. 12, pp. 201-225, 1987, entitled Basic Electrical Parameters for Safe and Effective Electro-therapeutics (Electroacupuncture, TES, TENMS (or TEMS), TENS and Electro-magnetic Field Stimulation with or without Drug Field) for Pain, Neuromuscular Skeletal Problems, and Circulatory Disturbances:

"Undesirable Electrolysis Phenomena Associated with DC Stimulation or Prolonged Application of Electrical Impulses with Excessively Large Pulse Width"

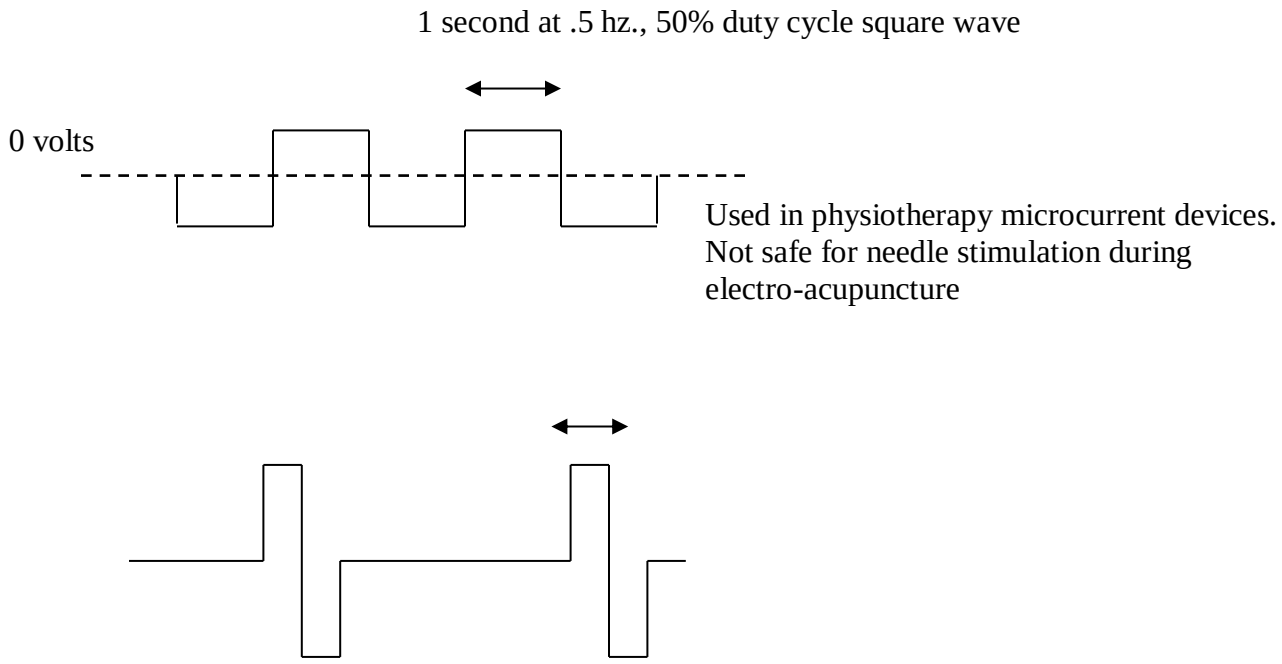
Prolonged electrical pulse stimulation with excessively wide pulse duration or DC electrical stimulation with a significantly large current may result in the following undesirable electrolysis phenomena: 1) strong acid (HCL) formation around the positive electrode and strong alkaline (NaOH) formation around the negative electrode, which may result in necrosis of tissue around the electrodes, 2) hydrogen gas bubbles formation around the negative electrode and oxygen gas bubble formation around the positive electrode as a result of the electrolysis phenomena

of water molecules in the body tissue which reduces the effectiveness of the electrical stimulation by decreasing current, as well as 3) breakage of the positive electrode after prolonged application of large DC currents."

With a very slow frequency, we may have excessively wide pulse duration with significantly large current, especially since the needle tip may be the location of the current movement. The 50% duty cycle microcurrent stimulation has been used now for a few years in electroacupuncture applications, and there have not been widespread reports of electrolysis effects. However, when introducing a new technology into medical practice, a conservative design philosophy is safest and best, until the years pass and all technical issues can be examined. The safety of patients is always the priority.

Whereas theoretically, a potential problem exists with the use of 50% duty cycle current, it has been the practice of Pantheon Research to design a system that is not in question. The microcurrent waveform used has a pulse time of only .4 milliseconds, even at very low frequencies. This corresponds to a duty cycle of 5% or less. This is analogous to standard pulse times on electroacupuncture machines, and is safe. The illustrations below demonstrate the images of the waveforms as seen on an oscilloscope.

Figure 1



Waveform of electroacupuncture microcurrent devices.
400 microsec pulse time. .05% duty cycle.

PANTHEON RESEARCH, Inc. · sales@pantheonresearch.com · www.PantheonResearch.com
✉ 8005 Sacramento St, Suite B, Fair Oaks, California, 95628 · ✆ 310.822.4965 or 888-332-3523 ·