

PANTHEON RESEARCH

INNOVATIVE BIOMEDICAL INSTRUMENTS

Pantheon Research Electrostimulator 4cPro, 8cPro User Manual

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INNOVATIVE BIOMEDICAL INSTRUMENTS

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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 serious 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.
8. Do not apply needle electro-stimulation to the thorax. Doing so increases the risk of cardiac defibrillation.
9. Do not apply needle electro-stimulation transcranially.
10. The use of stimulation with excessive current densities may burn the patient at the point of contact with the needles. If the patient

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experiences skin irritation or if you notice any burning, stop treatment immediately.

11. The waveform on our machines is designed such that it delivers a quick pulse of stimulation in the positive direction first then in the negative direction second. After the two pulses, the waveform is neither positive or negative. In other words, the waveform is designed to have a zero DC component unless a positive or negative pulse is being delivered. If there is a DC component in the waveform that is not zero, tissue burning and electrolysis which is the deposition of metal into the tissue may result. If you notice these symptoms, stop treatment immediately and contact us.

12. 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.

15. Do not use the equipment in an area susceptible to magnetic interference. Doing so may produce instability in the waveform output. If you suspect magnetic interference is affecting treatment, stop treatment immediately. You may 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.

16. Do not use the equipment in close proximity to high frequency surgical equipment. Doing so may burn the patients at the points of contact with the needles, and may damage the unit.

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17. Do not use the equipment in close proximity to shortwave or microwave equipment. Doing so may produce instability in the waveform output.
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 often cause patient shock & 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

Microcurrent instruments are FDA approved for marketing as a Class II device in contrast to a Class III device which is experimental. Microamperage is approved under two categories: both as a transcutaneous electrical nerve stimulation device as well as an electronic muscle stimulator.

MICROCURRENT THERAPY HAS BEEN USED TO TREAT THE FOLLOWING:

Chronic and acute pain, swelling, musculoskeletal dysfunctions, soft tissue injuries, synovitis, arthritis, fractures, disc disease, neuropathies, temporalmandibular joint dysfunction, intractable pain syndromes, wound healing and post-operative care.

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

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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

1.3 Nomenclature



This symbol indicates the possibility of

serious injury to the patient.



This symbol indicates the possibility of

damage to the equipment if not used in accordance to the Users Manual.

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

For 20 years, the 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, and for TENS stimulation. Veterinarians also are using the 6c.Pro and 8c.Pro 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 6c.Pro/8c.Pro is more comfortable than other stimulators, due to its specially designed electro-acupuncture electrical waveform. This waveform is very fast, .4 milliseconds, and is equal in the positive and negative components. It does not efficiently stimulate the nerve cells that sense pressure or heat, 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 6c.Pro/8c.Pro Electro-Stimulator has at least ten features that are unique to it alone. These include:

1. Unprecedented frequency accuracy of 99.94%.
2. Special electro-acupuncture waveform for milliamperage current stimulation
3. Special electro-acupuncture waveform for microampere current stimulation
4. Two year warranty
5. Adjustable and calibrated mixed frequency
6. Built in clip assembly tester
7. Safety output controls : the machine cannot be turned ON if the output switches are not turned OFF

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8. Output tester
9. Automatic battery tester
10. Pantheon MicroClips, the smallest clips in the world

2.2 Electrostimulator

2.2.1 Description



(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 CONT, DISC, MIXED. These stand for continuous, discontinuous, mixed (also called intermittent or dense disperse). These will each be explained subsequently.

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 (C) knob.

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 (L) & (M) (see pg. 6), 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 (E) be turned all the way to the left, pointing to "0" (you will feel a click at "0")

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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.

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 diagnostic light (labeled as Diag. (H)) will light green after 4 seconds. If the battery is not good, the diagnostic light (H) will be red. This will be a solid green, or a solid red.

(B) MINUTE TIMER (available on 8c.Pro only)

10, 20, 30, 40 minutes

The machine is turned ON by turning the MODE Knob (A) to either Cont, Disc, Mixed. 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

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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) Acupuncture/TENS Application

Changes from the optimal electro-acupuncture waveform to a TENS compatible waveform. Simply switch to the desired application.

(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)

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- | | |
|---|---|
| 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 |
| 3) Automatic Battery Test | Slow blinking red (need to replace battery) and hear a beep |
| 4) Manual Battery Test | 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 on pg 6)

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

(M) MICROAMPERE OUTPUTS (see picture on pg 6)

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 milliamper outputs. The level control knobs will adjust the microampere and milliamper 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.

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(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 assembly 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.

AUTOMATIC BATTERY TESTER

The diagnostic light (H) will blink red, slowly, when the battery is below 6 volts. This will happen automatically, and will occur when the battery is low, and the MODE knob (A) is on a selected function other than OFF. If the battery is extremely low, below operational level, then the automatic battery tester cannot operate.

BATTERY CHANGING

The batteries' compartment is located on the underside of the machine. You have to insert your nail or flat tool and press against the groove 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.

2.2.2 Battery Changing Instructions

Four pictures illustrate opening the battery compartment, and this is a step by step description of how to open the battery compartment:

- 1) The battery compartment is located on the **underside** of the machine.
- 2) The Pantheon Research label and serial number are attached to **the battery compartment door**, which opens to reveal the batteries (Figure 1).
- 3) The two white arrows point directly to a ¼ inch wide (horizontal width) **slot**

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(Figure 2).

4) This **slot** is located on the lower edge of the battery compartment door (Figure 2).

5) To change the batteries (two 9V), the battery compartment door is 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 (Figure 3 and 4)**.

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 door 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) If the batteries are weak, and go below 5 volts, the DIAG light will shine red and a slow beeping will occur. This will occur automatically, even if the machine is being used. If this occurs, the batteries will require changing.

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FIGURE 1

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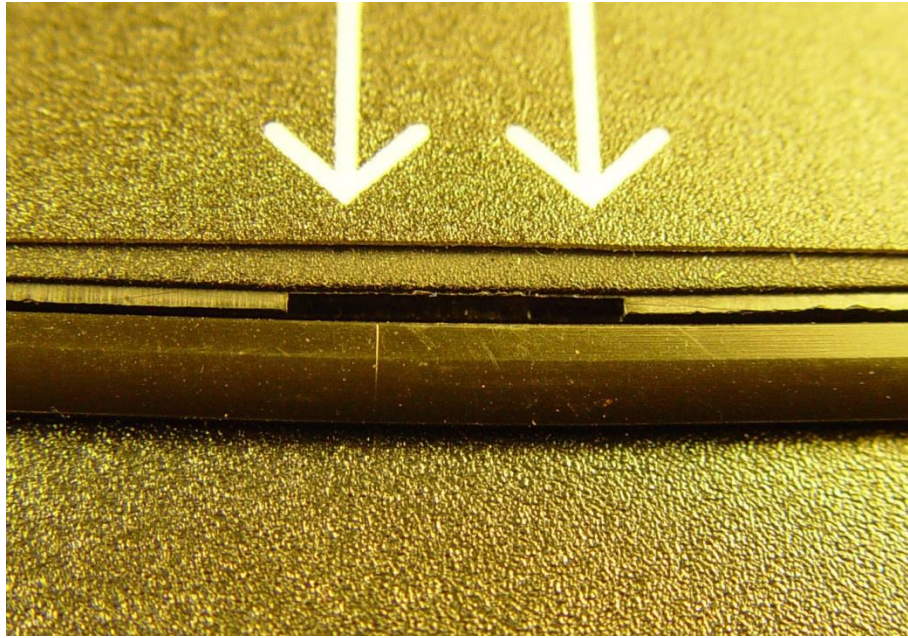


FIGURE 2



FIGURE 3

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FIGURE 4

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2.3 Clip Assembly (Applied Part)

Safety Class



Type BF, not defibrillation proof

Your Pantheon Electrostimulator comes with a set of four 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
 - For TENS stimulation, set side switch to TENS
- Make sure Mode knob (A) is set to OFF and all four level control knobs (E) are at zero.
- Plug clip or TENS leads into the electro-stimulator
- Attach clips of the clip assembly to the needles for acupuncture / lead wires to the TENS pads for TENS application.
- Ask patient if everything is still comfortable.
- **Only 8c.Pro:** 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 or Mixed (double-check that the level control knobs (E) are clicked off to zero) At this point the TIMER (on 8c.Pro only) 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:

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- **Only on 8c.Pro:** 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/TENS pads (You may also remove the needles/TENS pads, then unclip)
- Remove needles/TENS pads if you haven't already
- 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.



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

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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.

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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	Yellow	No light	Silent	Low battery This occurs when the Mode switch is at Batt. Test position (see Battery Changing Suggestions).
02	Flashing Yellow	No light	Silent	Low battery This occurs when the Mode switch is at Cont., Disc., Mixed positions (see Battery Changing Suggestions)
03	No light	Red	Quick beep ($\approx$ 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.
04	Yellow	No light	Slow beep ($\approx$ 1 time per second)	Low battery This occurs when the Mode switch is at Cont., Disc., Mixed positions.
05	Green	No light	Silent	Batteries good This occurs when the Mode switch is at Batt. Test position.
06	No light	Green	Silent	Clips good This occurs when you are performing the Clip Test.
07	No light	Flashing Green	Silent	Output good on the channel you are testing. This occurs when you are performing the Output Check Test.
08	No light	No light	Slow beep ($\approx$ 1 time per second)	Timer expired.

3.2.2 Problems

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3.2.2.1 Problem 1 – Machine Not Turning On

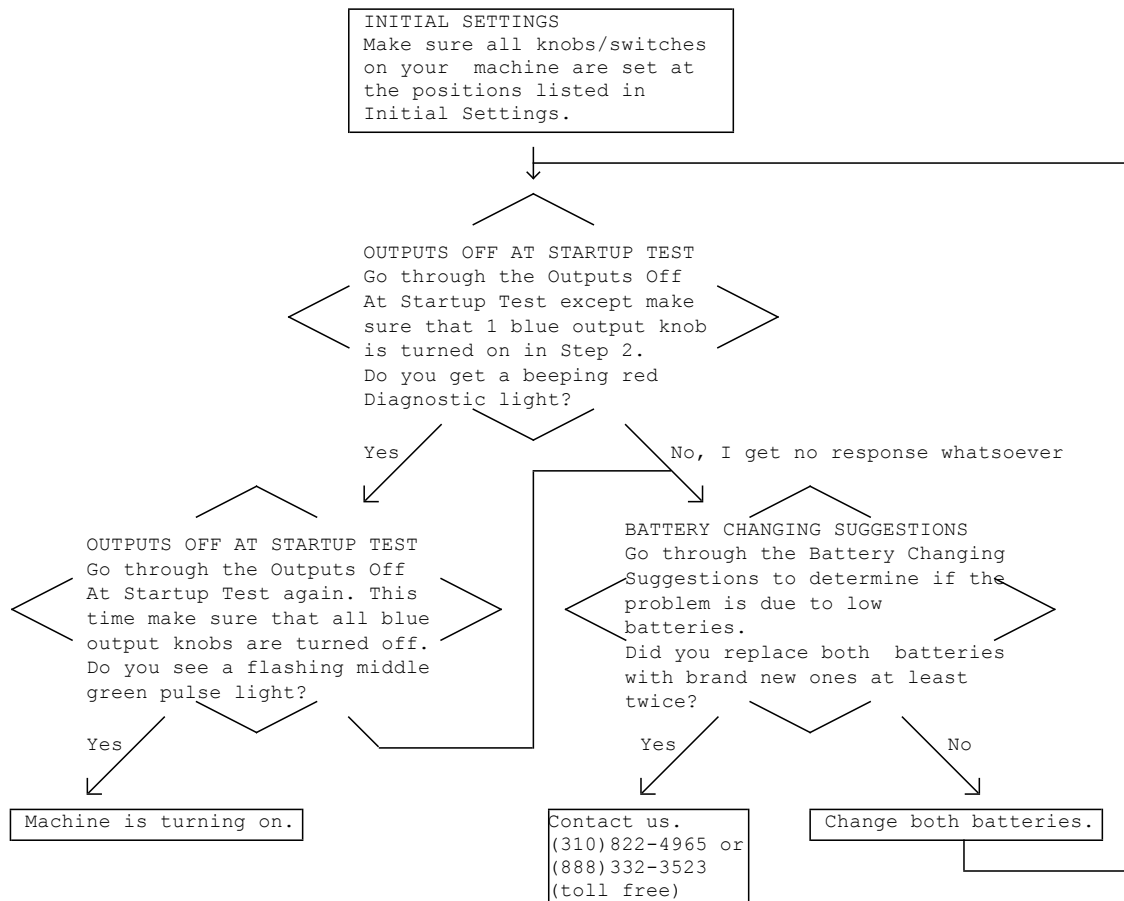
No lights are coming on whatsoever, or

Lights come on, but after a few seconds/minutes, machine shuts off, or

Machine is acting plain weird.

Low battery power causes a wide variety of symptoms, and it makes it difficult to troubleshoot, isolate, and determine the problem. Therefore, we recommend that you buy at least 4 brand new 9V batteries so that you can swap them in and out a pair at a time just to make sure that the problem is not due to low batteries. To eliminate the possibility of a bad battery lot, buy 2 batteries at 1 store and 2 batteries at another store.

PLEASE REFER TO THE TEST SECTION FOR DETAILED STEPS.

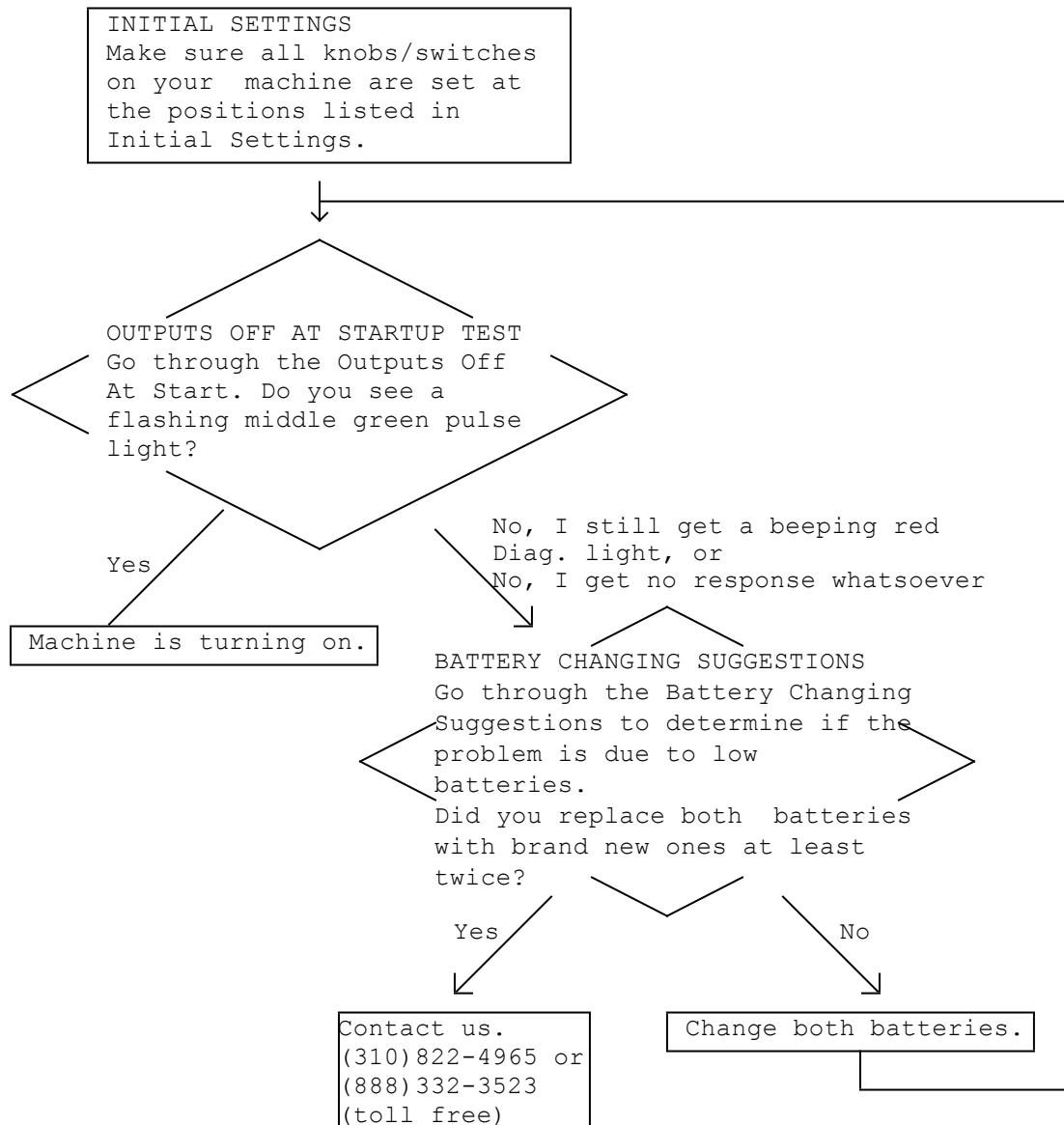


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3.2.2.2 Problem 2 – I Get a Beeping Red Diag. Light

PLEASE REFER TO THE TEST SECTION FOR DETAILED STEPS.



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3.2.2.3 Problem 3 – I Get a Silent Flashing Yellow Batt. Light

I get a silent, flashing yellow Batt. light when the machine is in operation, that is, the Mode switch is at Cont., Disc., or Mixed positions.

PLEASE REFER TO THE TEST SECTION FOR DETAILED STEPS.



Batteries are low on power. Make sure you replace them with at least 2 pairs of brand spanking new batteries. See Battery Changing Suggestions in the Troubleshooting Procedures.

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3.2.2.4 Problem 4 – No Output on 1 or More Channels

My machine is turning on, that is,

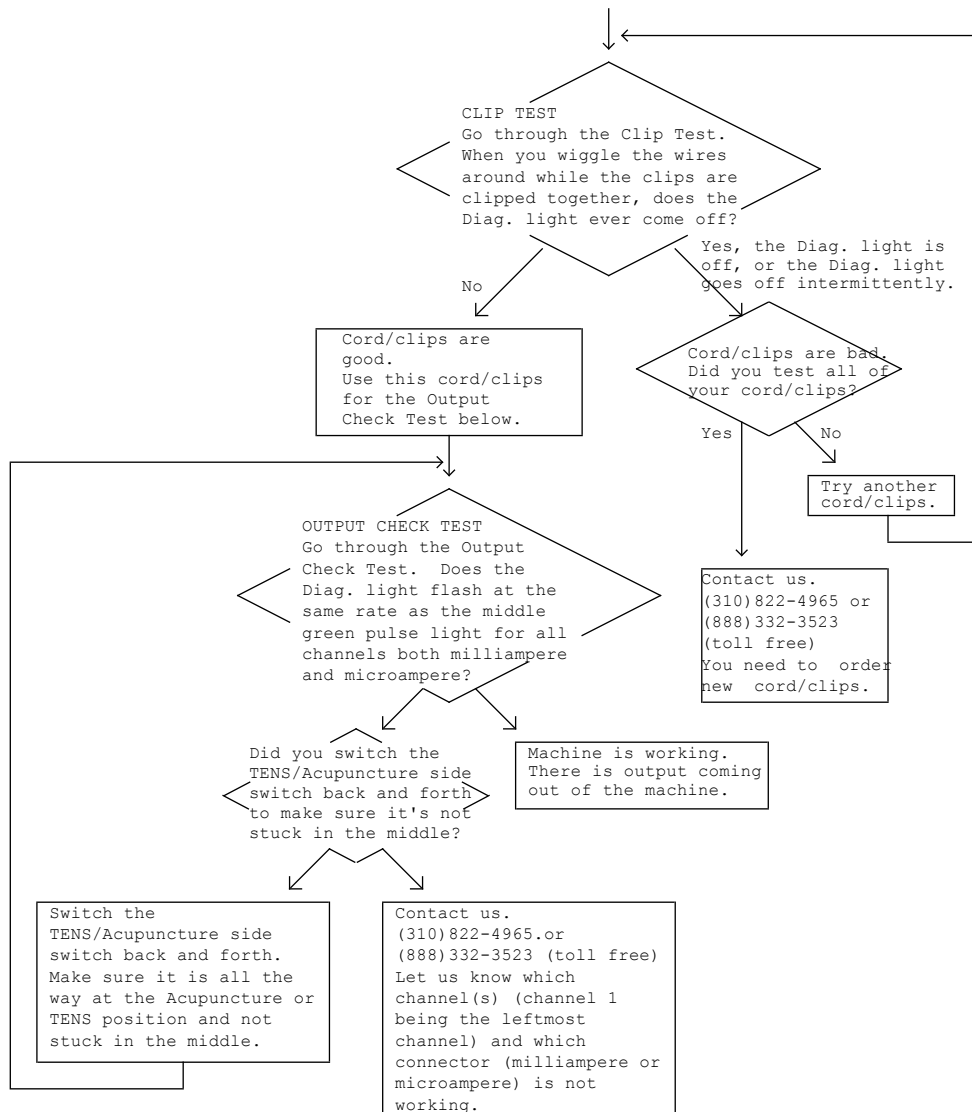
1 I am getting a flashing middle green pulse light, and

2 I am not getting a beeping red Diag light, however

No output is coming out of the machine, or

Patients are not feeling any stimulation whatsoever.

PLEASE REFER TO THE TEST SECTION FOR DETAILED STEPS.



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3.2.2.5 Problem 5 – Machine Is Shocking Patients

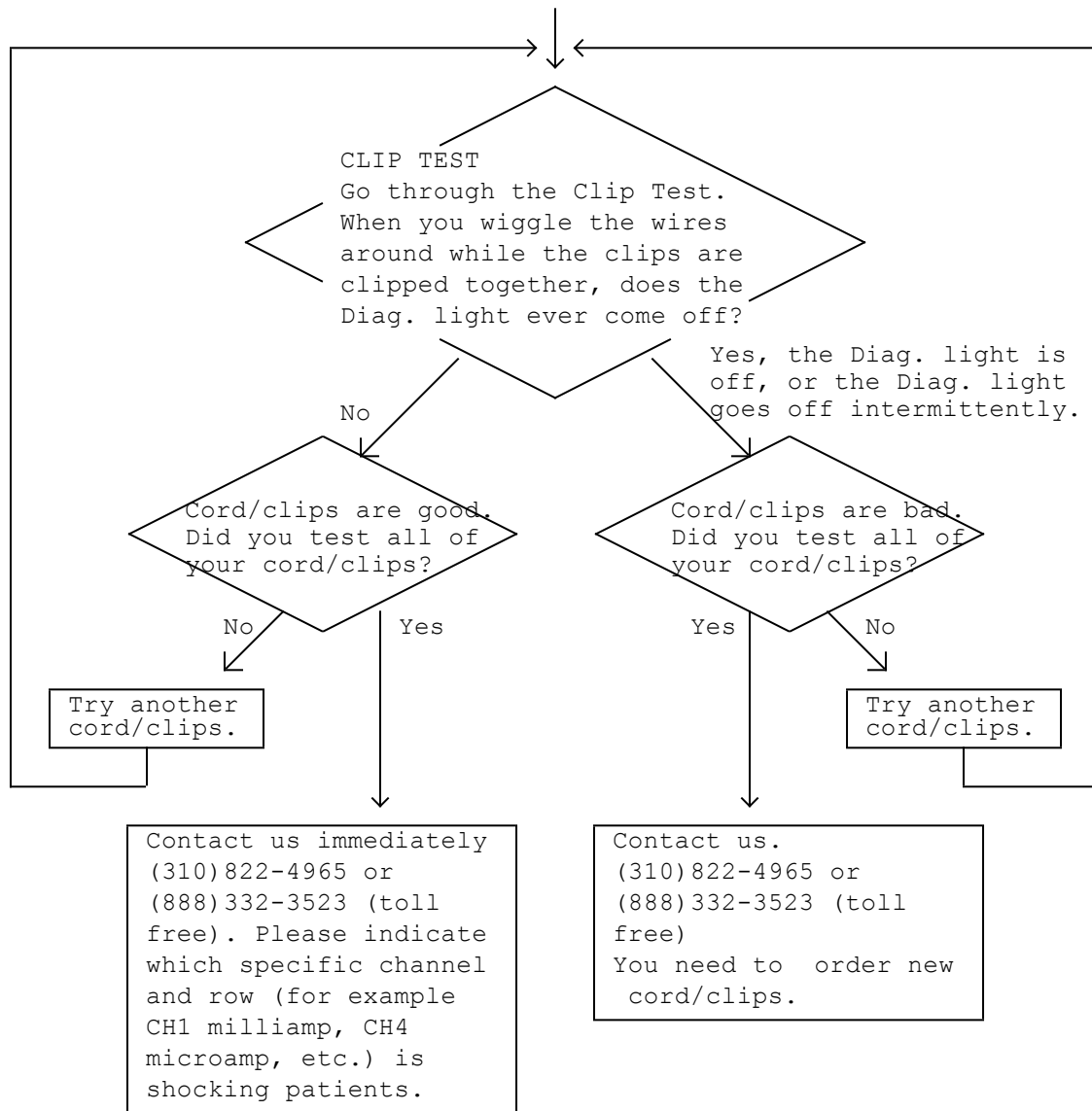
My patients get shocked whether or not I am adjusting the output, or

Machine surges, or

My patients feel a sudden surge whether or not I am adjusting the outputs.

In most cases, sudden shocks or surges are due to bad clips/cord. Therefore, you need to do the Clip Test.

PLEASE REFER TO THE TEST SECTION FOR DETAILED STEPS.



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3.2.2.6 Problem 6 – Machine Is Shocking Patients Even When the Output Knob Is Turned Off

My patients get shocked even when the output knob for the channel that I'm using is turned off.



Contact us immediately
(310) 822-4965 or
(888) 332-3523 (toll
free). Please indicate
which specific channel
and row (for example
CH1 milliamp, CH4
microamp, etc.) is
shocking patients.

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3.2.3 Battery Changing Suggestions

If you notice a silent, flashing yellow Batt. light while the machine is in operation, it means that your batteries are low on power. To confirm this, turn the Mode switch to the Batt. Test position; the yellow Batt. light should come on. Here are some suggestions in regards to changing the batteries.

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 crappy brand! We use Duracell 9V batteries.
5. Buy a cheap voltmeter or battery tester from Radio Shack.

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 all 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.

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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 you 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 milliamper connector (top row).
6. Turn on the CH1 blue output knob. Turn it up until you see the green Diagnostic light blink at the same rate as the middle green pulse light. If you see this, then you are getting output on the CH1 milliamper connector. If you don't, then there no output is coming out of this connector. If this is the case, try moving the TENS/ACUPUNCTURE side switch up and down to make sure it is not stuck in the middle, then repeat this step.
7. Turn off CH1 blue output knob.
8. Unplug from CH1 milliamper connector.
9. Repeat Steps 5-8 for the rest of the connectors both milliamper (top row) and microampere (bottom row 6C Pro, 8C Pro, or 12C Pro models only). 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 milliamper 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

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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 Procedures 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 4C Pro, 6C Pro, 8C Pro, or 12C 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
Is your machine a 4C Pro, 6C Pro, 8C Pro, 12C Pro, 9C3I?
- 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?

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- 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 **DO NOT USE THE POST OFFICE TO SEND REPAIRS TO US. USE UPS OF FED-EX INSTEAD.** The Post Office here in Venice, CA is notorious for losing packages. There will be an expensive fee for retrieving packages from the Post Office if it gets held there.
- 2 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.
- 3 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.

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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	4C Pro, 6C Pro, 8C Pro, 12C Pro, 6C3I--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 on 4C, 6C, 8C, 12C; (0.5, 1, 2, 4, 15, 30, 60, 80, 100, 200, 500, 1000) Hz on 9C3I Error ≤ ± 0.5%
Pulse Duration	450 us max
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 #	

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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,
Harmonic emissions	Not applicable	

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IEC 61000-3-2		including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

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

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			typical location in a typical commercial or hospital environment.
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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 from the equation appropriate to the frequency of the transmitter. Recommended separation distance $D = 1.2\sqrt{P} \quad 150 \text{ kHz} - 80 \text{ MHz}$ $D = 1.2\sqrt{P} \quad 80 \text{ MHz} - 800 \text{ MHz}$ $D = 2.3\sqrt{P} \quad 800 \text{ MHz} - 2.5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and D is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey (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.

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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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed, and 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.

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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 two-year warranty

For two years 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 please call us first. 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
626A Venice Blvd.
Venice, CA 90291**

Be sure to include the following information:

Your name, address, telephone number;

A clear description of the problem you are having.

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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 **two 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 99.94%**. That is a less than .06% error. No other electro-acupuncture equipment manufacturer can make this claim for the entire range of frequencies within a specific device. Scientific research requires the highest standards of accuracy and integrity.
- 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**

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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) **TENS compatibility:** We incorporate a tens capable waveform that is selectable with a switch. This waveform may also be used for electro-acupuncture if either an asymmetrical waveform or more power in stimulus is desired.
- 6) **Microcurrent outputs specifically designed for electro-acupuncture:** Available in models 6c.Pro, 8c.Pro, and 12c.Pro, 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.
- 7) **Calibrated frequencies:** In all Pantheon models specific therapeutic frequencies are switch selectable and are calibrated to scientific accuracy of 99.94%. Frequencies range from .5 Hz to 200 Hz.
- 8) **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.
- 9) **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.
- 10) **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.
- 11) **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

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

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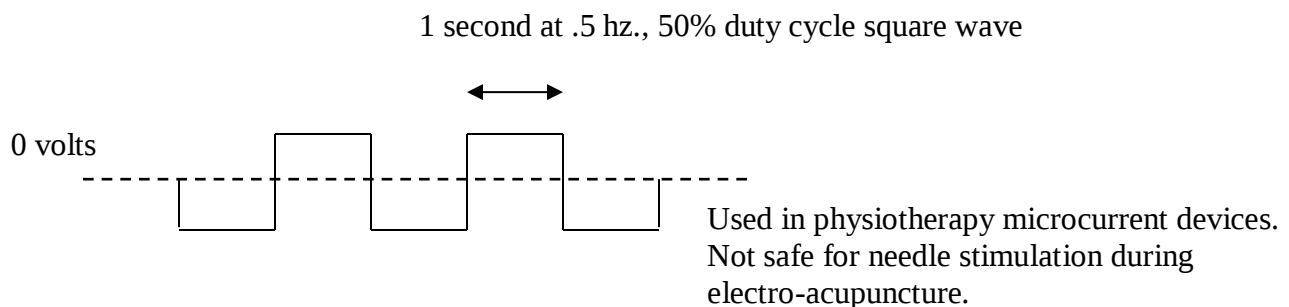
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of water molecules in the body tissue which reduces the effectiveness of the electrical stimulation by decreasing current, as well as 3) breakage of the positive electrode after prolonged application of large DC currents.”

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



.4 milliseconds, 5% duty cycle

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A.4 Microcurrent Therapy—An Overview

Excerpts from the following articles: “*Microcurrent Therapy- What Is It All About?*” published in the Cramer First Aider, Volume 62, Number 1; “*Microcurrent Therapy- Part II*” published in the Cramer First Aider, Volume 62, Number 2; and “*Microcurrent Therapy- Does Polarity Make a Difference?*” published in the Cramer First Aider, Volume 63, Number 3. Authored by Linda Manley Teahen M.Ed., A.T., C., P.T.A.

Electrotherapy has truly become revolutionized in the past fifteen years. Clinicians have begun to change their philosophy from *the more stimulation, the better*, to *lesser is better*, or, *it is more effective to whisper to the cells rather than to shout*, as we have in the past. This new philosophy of electrotherapy, at low-voltage, pulsed microamperage levels, is referred to as **Microcurrent Electrical Neural Stimulation**.

Microcurrent is a subtle but very powerful current. The treatment levels are usually subsensory (below the level of sensation). Researchers believe that the effects expected to occur are at the electrochemical level within the body's tissues; literally at the cellular level. More often than not, the patient will not feel the current to achieve desired results as many patients have been programmed in the past. The “no pain, no gain” theory, is not true for Microcurrent Therapy. At most, the patient may feel a slight tingling or warmth in the treatment area.

Because the current is often not felt during treatment, it is sometimes an obstacle in convincing patients that treatment is actually occurring. Patients must be reassured that even though they may be used to a muscle contraction, that this modality is a different type of current with far different physiological effects.

In comparing Microamperage to Milliamperage, Microamperage is a much smaller current;

1 Microamp (uA) = 1/1000 of a Milliamp (mA)

or

1000 Microamps = 1 Milliamp

Milliamperage current as you know is traditionally used in electrotherapy modalities such as EGS and TENS. Milliamperage can produce a muscle contraction, whereas Microamperage current density cannot excite motor nerves and therefore cannot produce a muscle contraction.

There are several theories and hypothesis as to how Microcurrent works. Researchers in biological electricity and regeneration such as Dr. Robert O. Becker and Dr. Bjorn Nordenstrom, have indicated that Microcurrent may have the ability to stimulate the healing process as well as aid in pain control. Dr. Becker has authored two books, “The Body Electric” and “Cross Currents”. These books discuss electrical currents in the body as well as in the environment and its effect on living tissue in the human body.

One of the most widely used studies on Microcurrent amperage is by Ngok Cheng, MD entitled “The Effects Of Electric Current On ATP Generation, Protein Synthesis and Membrane Transport in Rat Skin.” This study, conducted in Louvain, Belgium produced some very interesting results which appear to be applicable to the Arndt-Schultz Law, the underlying theoretical concept of low-volt pulsed Microamperage Therapy.

Arndt-Schultz Law states: “Weak stimuli increase physiological activity and very strong stimuli inhibit or abolish physiological activity.”

The results of this study showed the following:

“Electrostimulation of the tissue resulted in remarkably increased ATP concentrations. With currents from 50 uA to 1000 uA, the ATP levels were increased threefold to fivefold. With currents from 100 uA to 500 uA the stimulatory

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effects were similar. With currents exceeding 1000 uA, the ATP concentration leveled, and with 5000 uA, they even were reduced slightly as compared with the non-treated controls.

Similar effects were also noted in regard to protein synthesis. At about 500 microamps there is a tremendous enhancement but when you get over 5000 microamps (5 milliamps), the trend reverses into suppression.

This does not mean that other previous forms of electrotherapy are not effective but it does indicate that if we are looking for results beyond those of pain relief, for example, stimulation of the healing process, then perhaps we must look deeper into Microamperage stimulation and its clinical efficacy.

The following is a simplified explanation of the cell physiology of muscle trauma and the potential effects of applying Microcurrent to the area:

When a muscle sustains a trauma, it goes into spasm as a protective response. Muscle spasms decrease the blood supply to the area, which reduces the amount of oxygen and foodstuffs that are able to reach the cells. In addition, metabolic by-products accumulate because muscle spasm results from tonic activity.

Therefore, trauma to a muscle decreases ATP, disrupts the sodium pump, and increases metabolic wastes. All of these events are perceived by an individual as pain. When ATP is replenished in the injured tissues, the membrane active transport is increased, thus allowing the intracellular flow of nutrients and the extracellular flow of waste materials. This process allows the emergence of healthy tissue. ATP also provides the energy source that tissues need to build proteins. MICROCURRENT therefore, initiates the healing process by replenishing ATP, increasing the membrane transport of ions, and facilitating protein synthesis¹

It had been observed by Galvani in 1792 that injured tissues generate electrical currents that differ from those of healthy cells. It is also known now that electricity plays a vital role in cellular function. By altering the internal electrical signals with an external electronic microcurrent, it may be possible to regulate the growth, development, and repair of injured tissues.¹ By adding artificial external microstimulation that is similar to the body's physiologic electrical currents, the body's homeostatic mechanism can be facilitated, thus setting the stage for healing and recovery.²

According to Dr. Robert O. Becker, in a healthy state, the body is normally polarized relatively electropositive along the spinal axis and relatively electronegative distally. This polarity is reversed in hypnosis during anesthesia and following an injury which creates a positive potential at the site of trauma and injury, which reverses the normal polarity in the body. As Dr. Becker speculates, this sets up a current of injury which initiates and signals the beginning of tissue repair and regeneration. Dr. Becker believes that this current of injury is conducted by means of direct current signals conducted throughout the Schwann cell and Glial cell sheath surrounding neurons. He also speculates that so-called acupuncture points may actually be amplifiers along this d.c. system compensating for downstream signal damping as the signal diminishes in strength as it proceeds distally, and thus perhaps the stimulation at these acupuncture points is a means of amplifying these bioelectric signals which can in turn enhance the signaling of tissue repair and regeneration.

There are many books, articles and studies that have become available to clinicians for further explanation of the theories behind the application of Microcurrents. A bibliography can be found at the end of this article to assist you in locating additional Microcurrent studies and abstracts.

A.5 How Microcurrent Stimulation Produces ATP— One Mechanism

By Steven Bailey, DC

ATP (adenosine triphosphate) molecules are the storage and distribution vehicles for energy in the body. The breakdown of ATP into ADP yields energy. It is the cleaving of the phosphate bond that yields the energy. This energy is utilized in almost all energy related cellular reactions. In addition to being integral to the function of virtually every cell in our body, we may also look at ATP function by categories of activity. Such essential functions include: 1) muscle contraction; 2) protein biosynthesis; 3) nerve transmission; and 4) active transport across cell membranes.

In muscle contraction, the process occurs as such: each muscle spindle is composed of muscle fibers. Inside the muscle fibers are many muscle fibrils. These muscle fibrils are suspended in a fluid matrix called sarcoplasm. Suspended in the sarcoplasm are thousands and thousands of mitochondria, which contain large amounts of ATP.

It is ATP that energizes the muscle contraction process by the ATPase activity of the exposed myosin head. When ATP is exposed to the myosin head, it is cleaved and energy is released. It should be noted that along with ATP, magnesium is very necessary in ATP energy releasing reactions. Before ATP can become "active ATP," magnesium must bind between the second and third phosphate. Clinically, magnesium deficiency may be related to such conditions as fibromyalgia and chronic fatigue syndrome.

Synthesis of almost any chemical compound requires energy. That energy is ATP, which is critically important to the biosynthesis of proteins, phospholipids, purines, pyrimidines and hundreds (if not thousands) of other substances. We will take ATP involvement in protein synthesis as a case in point: a single protein may be composed of many thousands of amino acids. It takes the breakdown of four high- energy phosphate bonds to link two amino acids together.

Maximally, two ATP could serve as energy to join two amino acids together, so if our protein is composed of 10,000 amino acids, it may take 20,000 ATP to form just this one protein. It should also be noted that the amino acids themselves utilize ATP indirectly as they are first co-transported into the cells.

ATP is necessary for nerve transmission. Nerve transmission entails the release of nerve transmitter substance from the presynaptic terminal into the synaptic cleft, which simply put is a space between one nerve and another. The nerve transmitter substance spans the cleft and attaches to the receptor of the other cell. The nerve transmitter substance must be constantly formed anew in the presynaptic terminal for future release; the energy for this formation is supplied by ATP. There are many mitochondria in the presynaptic terminal to form and store the ATP for this process. The formation of ATP will be discussed later in relation to the stimulatory effects of microcurrent.

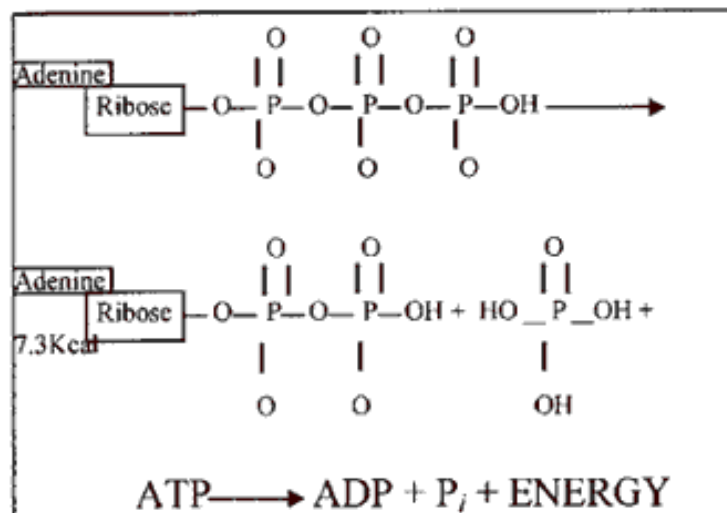
At the post-synaptic terminal, the next nerve cell down the line, it is through active transport of sodium, potassium and calcium that concentration differences across the nerve cell membrane cause nerve firing and propagation of nerve signals to travel to the next presynaptic terminal. These concentration gradients could not be accomplished without ATPase active transport across nerve cell membranes.

Active transport is brought about by the energy release of ATP in the breakdown of its phosphate bonds (see **Figure 1** for ATP chemical structure and energy releasing breakdown).

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FIGURE 1: ATP chemical structure, breakdown, and release of energy.



Active transport is a means of getting molecules across the cell membrane, either into or out of the cell, against a concentration gradient. That concentration gradient may be electrical or a pressure gradient. Sodium, potassium, calcium, glucose, amino acids and many other compounds are transported this way.

To summarize, ATP is the energy currency for our bodies. In reality, virtually every cytological, histological and physiological process is ATP-mediated, which makes ATP clinically important. While our bodies in theory can produce all the ATP we need, the fact is that it doesn't. Microcurrent stimulation between 200-800 microamps is a way of supercharging the tissue with ATP, which will reside there until needed. By this means, much of the research that shows a 200% increase in healing rate can be explained as it applies to hundreds of conditions. In a clinical sense, any healing process takes a great deal of ATP and may be accelerated through a means of increasing ATP in the tissue. Microcurrent stimulation accomplishes this by increasing ATP in the tissue by up to 400%.

Discussion

Microcurrent stimulation to the body causes radically increased production of ATP levels. This allows the body to perform whatever healing process it has undertaken in an accelerated fashion. It may even allow one to get over the proverbial "hump" that was unachievable, due to insufficient ATP concentrations to perform the changes needed.

ATP is the dynamic reservoir of energy in our body. Glucose serves as a more long-term reservoir but in itself does relatively little to fuel the body. Glucose is first converted to ATP. ATP is the storage and distribution vehicle for energy. From the moment an ATP molecule is produced, it is typically consumed within one minute.

The turnover rate for ATP is very high. However, the body does have a vast capacity to store ATP. One can build ATP reserves. This is one reason that, unlike other forms of electric therapy such as interferential, or higher amperage TENS and galvanic, microcurrent stands unique in that it has a cumulative effect, rather than a diminishing effect. Other electric stimulation devices decrease ATP levels.

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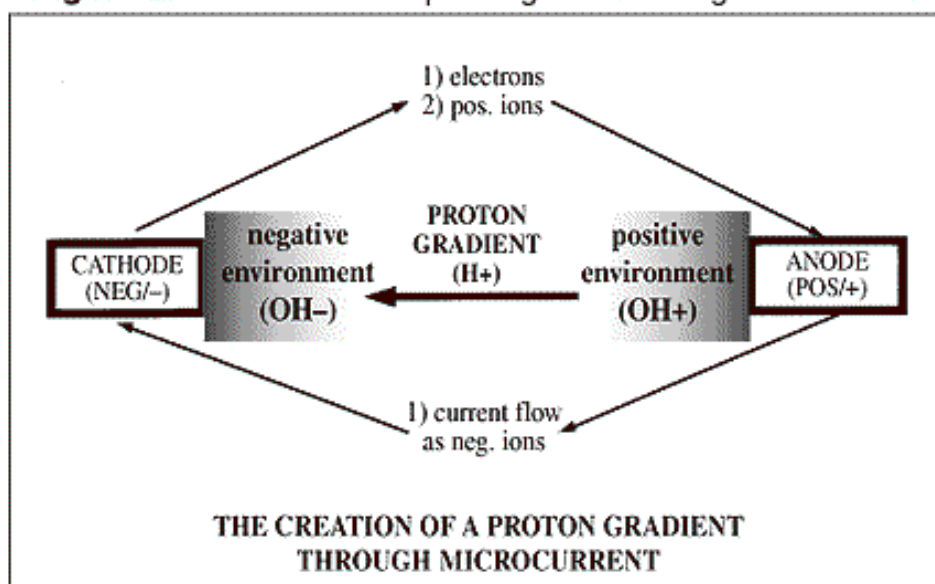
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Moreover, these devices cannot even be thought of in the realms of ATP generation. It has been shown that any stimulation over 1,000 microamps causes plateauing and then reduction in ATP. Microcurrent therapy, which is used from one to usually 600 μ A clinically, is the modality of choice for increased tissue healing. Research and clinical trials have shown that with microcurrent stimulation, there is a 40-50% reduction in healing time of ulcers and sprain/strains; fractures heal faster and stronger; and that even bad scarring (keloid scars) remodel to become a healthier, stronger scar. Other ATP related microcurrent stimulatory effects include decreased inflammation, edema and swelling, and increased physical endurance in sports.

Clinically, microcurrent stimulation is not at all limited to its effects of increased ATP production in its capacity as a treatment modality, but its effects to reduce injury healing time in half are truly dramatic. The mechanism for increased ATP production from microcurrent electric stimulation can be explained. In the following text, its mechanism, from the grosser external application down to the molecular level, is revealed.

A microcurrent instrument delivers a direct current (DC), and so the nature of its electrical flow is the same. **Figure 2** is a representation of a typical circuit in which electrons flow from the cathode to the anode, while current, in the form of negative ions, flows from the anode to the cathode. The negative ions can be thought of as an offset to the electrons which flow the other way. This comprises the circuit.

Figure 2: The creation of a proton gradient through microcurrent.



Of more clinical relevance is what takes place at the anode and the cathode rather than the circuit itself. Around the cathode, which is negative, is an environment of negative hydroxyl ions (OH⁻). This is caused by electron interaction with water molecules at the cathode, hydrolyzing the water molecules into hydrogen and hydroxyl molecules. The same reaction takes place at the anode; however, because the anode is positive in polarity, protons (hydrogen ions) form the environment around the anode.

In the instantaneous moment, both hydrogen and hydroxyl ions are forms around both pad electrodes. However, over time, the ionic environment becomes hydrogen around the anode electrode and hydroxyl around the cathode electrode. Because it is hydrogen that leads to the creation of ATP, it then follows that as a residual effect after the microcurrent stimulator is turned off, ATP production continues at the site.

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Meanwhile, at the negative electrode, ATP production ceases immediately at the turning off of the stimulation because there is no residual hydrogen cloud in the area. Protons (H^+) produce a very powerful effect here. Looking at **Figure 2**, we see that the protons diffuse to an area of less protons, namely from the anode side towards the cathode side. As the protons (H^+) migrate through the tissue, they cause increased formation of ATP.

This ATP formation can be explained through the chemosmotic theory of Mitchell. This theory explains how mitochondria form ATP by familiar processes such as the electron transport chain and Krebs cycle. In Mitchell's theory, we see that ionized hydrogen (protons) trigger the electron transport chain by combining with NADH to form $NADH^+$, as well as FAD to form $FADH_2$ and other mediators. The net effect of each cycle of the electron transport chain is the introduction of six hydrogen ions inbetween the inner and outer mitochondrial membranes.

At this point, hydrogen ATPase is activated by the high intramembrane content of hydrogen and activates ATP production. This is accomplished by the addition of a phosphate group to ADP to form ATP (see **Figure 1**, except note that the process will basically run in reverse to form ATP). This process is known as oxidative phosphorylation. The ATP is at this point transferred out of the mitochondria into the cytoplasm of the cell where it is stored until utilization.

Conclusion and Afterthoughts

ATP can be produced by the body by many means other than those mentioned above. However, it is a very dynamic energy source, and at the site of injury or at a site of overuse and microinjury, ATP supplies can become diminished.

Microcurrent therapy offers a unique and wonderful answer to tissue healing. Clinically, microcurrent therapy is also a therapy of choice for hyperacute injuries in that it produces little if any sensation. It should also be remembered or known that in addition to its uniqueness, microcurrent therapy shares many of the qualities of other electric therapies: namely for application in pain control, muscle relaxation and nerve re-education. It also stands somewhat unique in its ability to increase vascular permeability and in its use as a means of electroacupuncture. MENS microcurrent instruments have the ability to detect the bioelectric state of the human body, and have proven a standard of technical excellence unsurpassed in clinical modality.

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A.6 Electro-Acupuncture Resources

Recommended Internet Websites

- **pubmed.gov**
This is Medline, in easy to use format. Doing a search on **ELECTROACUPUNCTURE** will yield 1163 citations.
- **Medicalacupuncture.org**
Website of the American Academy of Medical Acupuncture. This site has an online journal, and full articles can be accessed directly. It is a very interesting source. Also a full list of journals, organizations, and online resources is present.
- **Acubriefs.com**
A search on **ELECTROACUPUNCTURE** provides 1394 citations. This site accesses many traditional journals of acupuncture, and may be more thorough than Medline.
- **Acuall.org**
Sponsored by the National Acupuncture and Oriental Medicine Alliance.
- **Acupuncture.com**
Summarizes pertinent information from multiple resources.
- **Med.auth.gr/**
Includes web journals, articles, databases, and more.
- **medmatrix.org**
Clinical medical resources, including numerous medical journals.
- **www.nih.gov/pubs/cbm/acupuncture.html**
National Library of Medicine.
Current Bibliographies in Medicine-Acupuncture
- **Pantheonresearch.com**
Includes information on electro-acupuncture products and guidelines