



ARE FREQUENCY OUTPUTS OF COMMERCIAL ELECTROACUPUNCTURE STIMULATORS ACCURATE? (PILOT PROJECT)

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ABSTRACT

We investigated six commercial electroacupuncture stimulators for frequency accuracy and waveform characteristics, and found that these devices did not completely comply with the manufacturer's stated specifications. Frequency errors ranged from 0.10% to over 50.1%. Better-designed circuits and quality components may ameliorate this deficiency. We recommend that all electroacupuncture stimulators meet the precision and calibration requirements of the National Institute of Standards and Technology (NIST).

key words

PENS, Stimulators, Frequency, Precision, Electroacu-puncture, Waveforms

INTRODUCTION

Electroacupuncture (or, PENS [percutaneous electrical nerve stimulation]) is frequently employed as a therapeutic modality in the acupuncture clinic, and it has been part of Traditional Chinese Medicine since the early 1800s. Even though electroacupuncture seems to be quite modern, it has the longest history of any electrical therapy. Renewed interest in acupuncture in France during the 1800s coincided with the period of research and exploration of electrical phenomena. Sarliniere le Chevalier (1825) of France and da Camino (1834, 1837) of Italy were the first to apply percutaneous electrical nerve stimulation. By 1900, electrotherapy fell into disuse, but was revived in the 1970s when it was discovered that electroacupuncture (PENS) was being used in lieu of anesthesia for surgery in China.¹

There are many different models of electronic stimulators available to the clinician. These stimulators are capable of producing various frequencies, waveforms, current and voltage outputs for therapeutic benefit. While one may assume that the manufacturer's specifications are accurate and reliable, this premise may not be correct.

Procuring an electroacupuncture stimulator should be based on the intentions of its clinical usage: output specifications. Careful consideration to manufacturer reliability and safety should be paramount.² The accuracy and stability of these parameters is influenced by circuit design, electronic component tolerances, power source, ergonomic design, and operator error. All equipment procured from the manufacturer should be within its stated specifications. A prescribed frequency of 5 Hz should output at 5 Hz, and not 2 or 10 Hz. This deviation becomes more critical at higher frequencies where safety becomes an issue. The frequency range of the stimulator should progress smoothly and accurately if an analog dial is employed. The waveform should be electronically free from distortion. If the device produces a biphasic (negative and positive) wave, it should be balanced with a net direct current (DC) of zero to avoid burning of the skin, electroplating of the metal needle into the tissues, and electrolysis of water producing hydrogen and oxygen bubbles into the

interstitial spaces where the stimulation is occurring. A low-voltage battery indicator or warning system should be employed to prevent further degradation of the electronic circuit and signal output so that the operator can replace the battery in a timely fashion.

The purpose of this article was to survey 6 popular electronic stimulators that are most likely used by the clinician, and compare the actual frequency and waveform characteristics to the manufacturer's specifications. We do not believe at this time that it would be appropriate to identify the manufacturer or model of the stimulators tested because the specimen-to-specimen variation was not determined, as only 1 specimen of each type was investigated.

Omura states that there are approximately 10 basic electrical parameters that can be measured from acupuncture stimulators (Table1).³

Frequency is one of the primary variable output parameters that is commonly utilized by the clinician. Thus, it is important and fundamental that we look at this output, i.e., accuracy, fluctuation, and its associated waveform.

MATERIALS AND METHODS

Pulse frequency and waveform were measured using 2 test instruments. These were the Fluke 123S (Fluke Corp, Everett, WA [www.fluke.com]), and the Newport P6000A digital frequency meter (Newport Electronics Inc, Santa Ana, CA [www.newport.co.uk/]).

The waveform and frequencies above 5 Hz were measured using the Fluke 123 Industrial

Table 1. Stimulator Parameters
These parameters vary considerably from model to model because a paucity of clinical research has not determined optimum values.
1) Pulse width
2) Rise time
3) Fall time
4) Polarity
5) Pulse distortion
6) Pulse amplitude
7) Pulse offset voltage
8) Pulse repetition rate
9) Output impedances for both positive and negative polarity
10) Each component of pulse wave complex recorded on oscilloscopic photography

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Table 2. RESULTS:STIMULATOR 1

Frequency	5 Hz	10 Hz	25 Hz	100 Hz	200 Hz	500 Hz
Trial 1	4.974	9.983	24.88	100.7	200.2	506.8
Trial 2	4.970	9.966	24.88	100.7	200.1	507.1
Trial 3	4.961	9.966	24.88	100.6	200.1	506.8
Trial 4	4.961	9.966	24.88	100.6	200.0	506.8
Trial 5	4.987	10.000	24.98	101.0	200.8	507.5
Average Freq.	4.971	9.976	24.90	100.7	200.2	507.0
% error	0.60	0.20	0.40	0.70	0.10	1.40

Table 3. RESULTS:STIMULATOR 2

Frequency	5 Hz	10 Hz	30 Hz	100 Hz	300 Hz
Trial 1	3.870	7.920	14.97	63.82	151.1
Trial 2	3.950	7.900	14.98	72.65	151.1
Trial 3	3.730	6.320	14.97	77.24	151.1
Trial 4	3.960	6.320	14.97	75.27	151.1
Trial 5	4.110	6.320	14.98	75.59	151.1
Average Freq.	3.924	6.956	14.97	72.91	151.1
% of error	21.00	30.50	50.10	27.00	49.60

Table 4. RESULTS: STIMULATOR 3

Frequency	5.5 Hz	20 Hz	20 Hz	30 Hz	150 Hz	150 Hz	210 Hz	500 Hz
Trial 1	3.560	17.04	17.54	23.79	138.9	133.5	176.1	463.4
Trial 2	3.490	17.04	17.16	23.79	138.9	133.5	176.1	463.4
Trial 3	3.650	17.04	17.16	23.56	138.9	133.5	173.0	463.1
Trial 4	3.550	17.04	17.18	23.50	138.9	133.5	174.6	463.0
Trial 5	3.520	17.04	17.21	23.57	138.9	133.5	174.9	463.1
Average Freq.	3.560	17.04	17.25	23.64	138.9	133.5	174.9	463.1
% of error	35.20	14.80	13.70	21.20	7.40	11.00	16.70	7.40

Table 5. RESULTS: STIMULATOR 4

Frequency	1 Hz	2.5 Hz	5 Hz	10 Hz	20 Hz	40 Hz	80 Hz	160 Hz
Trial 1	1.310	3.314	6.678	13.47	27.03	54.33	108.8	218.9
Trial 2	1.425	3.552	7.083	14.11	28.08	55.86	110.9	221.3
Trial 3	1.429	3.580	7.186	14.43	28.94	58.04	116.4	234.5
Trial 4	1.471	3.692	7.402	14.84	29.74	59.71	119.7	239.8
Trial 5	1.504	3.776	7.571	15.19	30.45	60.17	123.1	244.5
Average Freq.	1.428	3.583	7.184	14.41	28.85	57.62	115.8	231.8
% of error	42.80	43.30	43.70	44.00	44.20	44.00	44.60	44.90

Table 6. RESULTS:STIMULATOR 5

Frequency	5 Hz	10 Hz	80 Hz	160 Hz
Trial 1	6.703	14.08	118.5	206.0
Trial 2	6.682	14.05	119.2	206.6
Trial 3	6.614	13.92	118.1	203.5
Trial 4	6.656	13.92	118.1	203.5
Trial 5	6.340	13.88	117.8	203.6
Average Freq.	6.599	13.97	118.4	204.7
% of error	32.00	39.70	48.00	27.90

Table 7. RESULTS:STIMULATOR 6

Frequency	2 Hz	5 Hz	10 Hz	20 Hz	50 Hz	100 Hz
Trial 1	2.050	5.050	10.18	19.47	50.20	99.80
Trial 2	2.226	4.920	10.15	20.47	50.03	99.75
Trial 3	2.030	5.010	10.18	20.17	50.16	100.3
Trial 4	2.131	5.270	10.09	19.95	50.27	100.0
Trial 5	2.524	4.500	9.73	20.20	50.07	99.87
Average Freq.	2.192	4.950	10.07	20.05	50.15	99.87
% of error	9.60	1.00	0.65	0.25	0.30	0.23

ScopeMeter test tool. This is a portable, hand-held digital oscilloscope which incorporates many capabilities for research testing, including recording functions for full hard copy archival capability.

Frequencies at 5 Hz and below were measured, but the waveforms were not recorded, using the Newport P6000A digital frequency meter. This is a microprocessor based, 6-digit frequency meter that allows high accuracy/low-frequency measurements from .000001 Hz to 7 MHz.

Measurements taken with the Fluke 123S meter were recorded by linking to a personal computer (PC). The ScopeMeter was connected to the PC via optically isolated RS-232 interface. Measurements were recorded on PC and stored on CD disc using FlukeView ScopeMeter software for Windows (SW90W). Thus, all measurements of frequency above 5 Hz were recorded on computer with hardcopy archiving for data storage and analysis.

Multiple readings were taken to ensure accuracy of recording, and to confirm redundancy and consistency of measurement and output of stimulator frequencies.

The 2 test instruments were calibrated for accuracy prior to this study. (The calibration was carried out by ANMAR Metrology, Inc, San Diego, CA [www.anmar.com]). This calibration is traceable to the National Institute of Standards and Technology (NIST) specifications⁵ or other nationally recognized measurement systems, or have been devised from accepted values of natural physical constants or ratio type of self-calibration techniques. Calibrations were performed in accordance with ISO 9002, ISO 1012-1, ANSI/NC SL Z540-1, and other national systems guidelines and meet a minimum of a 4:1 accuracy ratio unless noted. All equipment receiving this certification is considered within specifications of accuracy and standardization for a period of 1 year. Testing

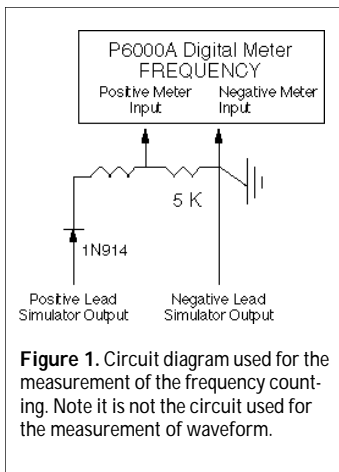


Figure 1. Circuit diagram used for the measurement of the frequency counting. Note it is not the circuit used for the measurement of waveform.

WAVEFORMS

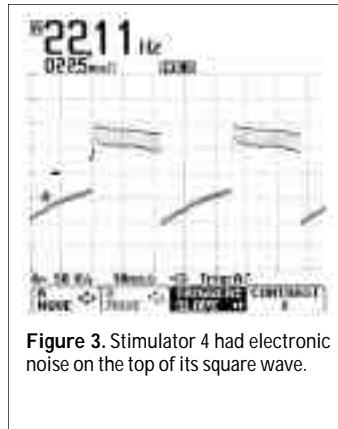


Figure 3. Stimulator 4 had electronic noise on the top of its square wave.

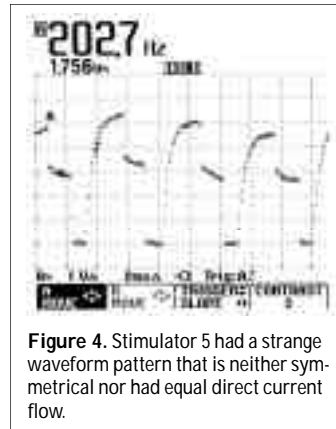


Figure 4. Stimulator 5 had a strange waveform pattern that is neither symmetrical nor had equal direct current flow.

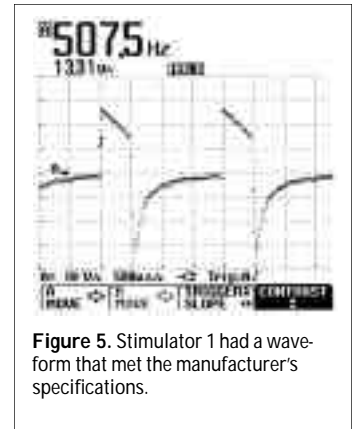


Figure 5. Stimulator 1 had a waveform that met the manufacturer's specifications.

and measurements in this report were completed within 1 week after our test instruments received a certificate of calibration.

The testing environment for both instruments was at normal room temperature, normal atmospheric pressure of sea level, normal humidity, with no known exceptional electromagnetic interference levels. The power supply for the equipment was commercial 110 V, 60-cycle alternating current (AC), in order to rule out battery fluctuation variables.

All electroacupuncture stimulators tested were brand new or recently reconditioned from the factory. All received new, fresh batteries prior to testing. Warm-up periods were not controlled closely. Devices were turned on and tested for approximately 30 minutes. This closely parallels the normal clinical usage. Five measurements of each device were completed to determine frequency and waveform aberrations.

Signal inputs to the Fluke 123S from electroacupuncture units being tested were routed through commercially supplied electroacupuncture alligator clips, directly into the 1:1 test probe of the meter. Each electro-stimulator was tested at normal operating voltage levels, i.e., the amplitude of the output signal was one-half the full dial capability (stimulators were turned up half-way). The red positive lead of the alligator clip assembly was connected to the positive input of the Fluke test probe. The black, negative lead was connected to the short, common ground connector of the test probe. All readings were taken using the "A" channel.

Signal inputs, to the Newport P6000A meter, were routed through the same type of alligator clip assemblies. The signals were conditioned with a simple diode and resistor divider providing less than 10 V of positive DC pulse to the meter, as required by the specifications of this meter (Figure 1).

Stimulators tested were first turned to their lowest frequency settings. As all electroacupuncture stimulator models do not share the same frequency outputs, the lowest frequency on each stimulator was the starting point. Measurements were taken and recorded either manually (P6000A) or via computer (Fluke 123S above 5 Hz). After each reading, the next higher frequency was selected and recorded. After the highest frequency was selected and recorded, the process of selection and recording was repeated, beginning with the original low frequency. The entire process was repeated 5 times for each stimulator being tested.

Stimulators that had pre-set, click-stop dials for frequency knobs enabled us to test each device at the exact settings.

The following procedure was used with stimulators that had continuously turning, analog dials with approximate labeling: the dials were turned to the closest approximation of the indicated dial setting that was possible with a careful and deliberate attempt to be exact. The dials were viewed from directly above to eliminate, as much as possible, any visual error or parallax, and the dials were turned to the most

exact position using visual acuity that represented the respective labeled frequency. (This is a more exacting process than is typically used in clinical practice, but was necessary for these measurements.)

Error Percentage

Error percentage was calculated by taking the average of the 5 trial measurements for each frequency and subtracting from it from the stated frequency given by the manufacturer. That result was then divided by the manufacturer's stated frequency and multiplied by 100. For example, Stimulator 1 had an average frequency of 4.971 Hz. The manufacturer stated that the frequency should be 5.0 Hz. Therefore, $5.000\text{Hz} - 4.971 = 0.029$ $(0.029/5.00) \times 100 = 0.58\%$ error or rounding off to 0.60%.

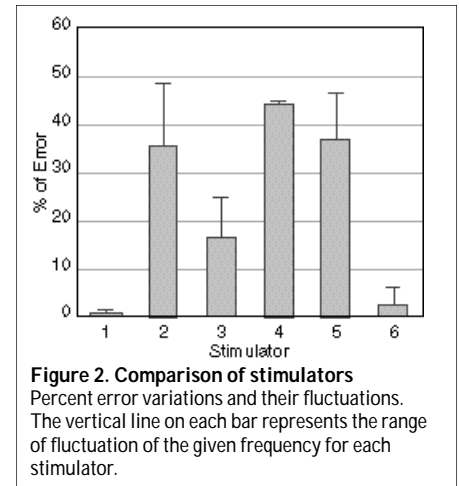


Figure 2. Comparison of stimulators
Percent error variations and their fluctuations. The vertical line on each bar represents the range of fluctuation of the given frequency for each stimulator.

RESULTS

Tables 2-7 depict results from the stimulator testing.

DISCUSSION

Frequency errors for all of the stimulators are summarized in Figure 2. Stimulators 1, 4, and 5 had click-stop dials. Stimulators 2 and 3 had analog dials, and stimulator 6 had an analog dial and a digital meter to read the frequency output. Stimulators 1 and 6 most likely had a higher quality circuit design. Stimulators 4 and 5, despite their click-stop dials, suffered from frequency inaccuracies.

Frequency variation from click-stop dials appeared the most accurate and easy to use. Accuracy from outputs that had either a marked scale or number, and requiring the operator to "line-up," were problematic. Frequency error ranged from 0.1% to over 50.1%. Comparing all 6 stimulators' frequencies (Figure 2), the vertical line on the top of each bar graph represents the deviation or how the data is scattered from its average value. In Figure 2, we delineate that stimulator 2 has a wide range of frequency deviation. However, the frequency errors for stimulator 4 did not change markedly, even though it has the highest error among the stimulators and thus, its deviation is small.

Certainly, we reached error thresholds that are not acceptable for

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either clinical or research utilization. Besides frequency, waveform influences the safety and efficacy of clinical outcomes. Waveforms that are distorted with noise or display bizarre stimulation patterns impact on the quality and safety of electroacupuncture stimulation, and are not acceptable in clinical or research practice (e.g., see Figures 3–5).

CONCLUSION

Further clinical research is needed to recommend optimal electrical stimulation parameters to produce desired therapeutic electroacupuncture effects. However, this research revealed that electroacupuncture stimulators in current use may be fraught with poor frequency and waveform outputs that do not represent the manufacturer's specifications.

Our recommendation is that an annual review of stimulator quality be sponsored, published, and thus made available to practitioners. We recommend that all electroacupuncture stimulators meet the precision and calibration requirements of the National Institute of Standards

and Technology. Further discussion should be undertaken to standardize frequency reporting parameters and to agree on optimal calibration specifications.

The acupuncture profession must demand that the manufacturing of electro-stimulators meet specified outputs and safety configurations.

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