Semg, Myovision, Insight, Subluxation Station

Ventura Rating

Static SEMG: Is This Smoking Gun Shooting Magic Bullets or Blanks?
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This paper will prove to be unpopular with many in the profession because of the high profile nature of the companies, their generosity to the colleges, and the number of doctors that have bought into the technology.
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Why did I write this paper? My entire adult life I have fought against false and misleading advertising claims. This is simply the latest product on which I've rendered an opinion. ?xml:namespace>

Is sEMG a valid technology? Absolutely! Does it have a prominent place in a chiropractor's office? That's the question I hope to answer. ?xml:namespace>

My Take on Static sEMG ?xml:namespace>

This paper is broken down into two sections. ?xml:namespace>

1. Are the claims made by some manufacturers supported by the FDA? ?xml:namespace>

2. Does the technology actually support the claim of subluxation detection? ?xml:namespace>

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Section One: **Are the claims made by some manufacturers supported by the FDA regulations? ?xml:namespace>**

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Some sEMG companies would have you believe that there is a direct connection between static scan results and the presence or improvement of a Chiropractic Subluxation (CS). Do the facts support this, or is it wishful thinking on the part of the companies in order to create a market for the technology? ?xml:namespace>

One company names their unit a "Subluxation Station" and their website calls the unit a "Subluxation Analysis System", implying that their unit can detect Chiropractic Subluxations, "with Certainty". Are they legally allowed to do that? ?xml:namespace>

Another company wants you to believe that a static sEMG scan provides the same objective evidence of a Chiropractic Subluxation, as a plaque pill can provide evidence of dangerous plaque build-up on the teeth. Can it? ?xml:namespace>

For the past year I have been absorbing as much information about the technology as I could find, and following the marketing strategies of the two biggest companies. You may be surprised, or upset my conclusions. I invite

you to do your own research. ?xml:namespace>

FDA Regulates Medical Devices ?xml:namespace>

Let’s start at the beginning. The United States Food and Drug Administration is the governing authority for all medical devices marketed in the United States. They are charged with assuring the public that a device is "safe and effective”. The FDA does not actually test devices or drugs, but through various committees, the marketing applications for devices are reviewed. If after review of the application’s technical specifications the device is found to be "substantially equivalent” to devices already approved for marketing, the FDA will allow the interstate sale of the device. ?xml:namespace>

Also included in the FDA’s review of the device submission is the labeling intended for the device. To some, it is the labeling of the device that garners the closest FDA review. Labeling includes instruction manuals, ad copy, website text and spoken words used to describe the device. It’s the labeling of the device that gets most companies into trouble. For example, you can market a TENS machine for certain types of pain control. You cannot claim it will grow hair. If you make the hair growth claim, you have misbranded and adulterated the device. ?xml:namespace>

If you make claims for a device outside the narrow labeling approvals of the FDA, you must prove those claims. The proof can come in the form of clinical trials, or in the collection of investigational data. But you cannot market the device until the FDA reviews the additional information and accepts your claim. Most likely a new classification will be assigned to your device. ?xml:namespace>

A company that misbrands a device can be subject to FDA penalties that may include fines and device seizures. ?xml:namespace>

In reality, a company can seek approval for a substantially equivalent device, but then market the device for completely unapproved uses, knowing that an

understaffed FDA will not target them unless serious complaints of safety are made. ?xml:namespace>

So lets look at the classification and labeling requirements for sEMG devices. ?xml:namespace>

The FDA lists the sEMG devices I looked at as therapeutic biofeedback devices, under section 882.5050. The following is taken directly from FDA regulations. ?xml:namespace>

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN

SERVICES--(Continued)

PART 882--NEUROLOGICAL DEVICES--Table of Contents

Subpart F--Neurological Therapeutic Devices

Sec. 882.5050 Biofeedback device.

(a) Identification. A biofeedback device is an instrument that

provides a visual or auditory signal corresponding to the status of o

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or more of a patient’s physiological parameters (e.g., brain alpha wa
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activity, muscle activity, skin temperature, etc.) so that the patien
t

can control voluntarily these physiological parameters.

(b) Classification. Class II (special controls). The device is

exempt from the premarket notification procedures in subpart E of par
t

807 of this chapter when it is a prescription battery powered device

that is indicated for relaxation training and muscle reeducation and

prescription use, subject to Sec. 882.9. ?xml:namespace>

[44 FR 51730-51778, Sept. 4, 1979, as amended at 63 FR 59229, Nov. 3,

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1998]
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So, according to FDA definitions, the purpose of a sEMG device is to provide continuous feedback to the patient of skin temperature and/or muscle activity so the patient, through biofeedback techniques, such as relaxation training and muscle reeducation, can control these physiological responses.
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To my knowledge, the bridge between what is allowed and what is being claimed has not been established to the satisfaction of the FDA. Don't tell me that the FDA is part of the Medical/Drug companies conspiracy. They only want simple proof that the claims of a device can be substantiated.
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So, it would seem to me that claims like the following ?xml:namespace>

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Product Literature
      ?xml:namespace>e fastest, most versatile subluxation analysis s
ystem in the world."      ?xml:namespace>
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Website #1 ?xml:namespace>

" Computerized Spinal Examination, specifically Surface Electromyography (SEMG) is used to evaluate the relative levels of electrical activity associated with Vertebral Subluxations."

Website #2 ?xml:namespace>

The SEMG shows the muscular component of the Vertebral Subluxations. ?xml:namespace>

Go well beyond the approved uses of the device and represent unapproved use. ?xml:namespace>

Again, it would be like calling my TENS device a "Hair Regeneration System". I'm taking an approved device and promoting it for an unapproved use. If I claim using my TENS device will grow hair, I've got to prove it. If through clinical trials it turns out to be true, then the FDA will allow me to make those additional claims. ?xml:namespace>

So, does calling a sEMG biofeedback unit a "subluxation analysis system" misbrand the device? Is the buyer mislead as to what the device is legally allowed to do? ?xml:namespace>

Part Two: **Does the technology actually support the claim of subluxation detection? ?xml:namespace>**

There are several reasons why sEMG is not reliable as a chiropractic subluxation analysis tool. Why it cannot be used "With Certainty." ?xml:namespace>

<u>Reason #1 No Reproducibility Studies.</u> ?xml:namespace>

No study has even been published that shows a static sEMG scan can be reproduced over an extended period of time. For example, comparing the scan results obtained on Monday to scans obtained on Wednesday and Friday. Why is this important? Before you can determine that a change has been made by treatment, you must first determine that a consistent pattern exists. ?xml:namespace>

You cannot perform a single exam and glean any important information. Only after you compare it over time can you determine that a pattern exists. ?xml:namespace>

<u>Incredibly, no company has performed this most basic of tests. Why?</u> ?xml:namespace>

Most likely, because a person's sEMG pattern is in a constant state of flux. ?xml:namespace>

Remember from part one; sEMG devices are listed as biofeedback units to be used by the patient to help control their physiological responses. ?xml:namespace>

So, the patient, independent of a chiropractic subluxation, can create an abnormal sEMG reading. How? More on that later. ?xml:namespace>

Other reasons for inconsistent pattern readings over time include . . . ?xml:namespace>

1. You cannot place electrodes with enough accuracy to get repeatable resting values. ?xml:namespace>

2. Not only does the sEMG vary from location to location over the belly of a muscle, but the skin impedance also varies from moment to moment. ?xml:namespace>

<u>Many Things Can Cause an Abnormal sEMG Scan</u> ?xml:namespace>

Here is a short list from Jeffrey Cram, PhD, quite possibly the leading authority on sEMG. ?xml:namespace>

1. **Psychophysiological, Stress Related Hyperactivity ?xml:namespace>**

sEMG activity at rest or during movement is elevated either due to general maladaptive coping to stressful situations or a conditioned emotional response to a traumatic event (Post Traumatic Stress Syndrome). ?xml:namespace>

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2. Simple Postural Dysfunction ?xml:namespace>

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Aberrant motor activity is shown to be a direct function of posture. ?xml:namespace>

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3. Weakness and Deconditioning ?xml:namespace>

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This may be due to immobilization after injury or surgery, or as the cumulative effect of poor motor habits and decreased activity. ?xml:namespace>

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4. Acute Reflexive Spasm and Inhibition ?xml:namespace>

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Spasm is defined as an involuntary hypertonicity induced by the spinal reflex system . Spasm is commonly triggered by noxious mechanical or chemical stimulation of the pain receptors within the muscle or the associated joint. ?xml:namespace>

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5. **Learned Guarding or Bracing ?xml:namespace>**

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This pattern of neuromuscular activity differs from the reflex spasm model, in that the pattern of muscle activity is "learned" or operantly conditioned rather than being strictly mandated by a reflex. The heightened muscle activity usually occurs upon movement or postural loading and is done in an attempt to avoid pain and the "possibility" of further injury. ?xml:namespace>

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6. **Learned Inhibition and Weakness ?xml:namespace>**

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This syndrome is similar to the protective guarding and bracing model presented above. It differs in that it focuses on the "inhibition" side of the perspective.

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7. **Direct Compensation For Joint Hypermobility or Hypomobility ?xml:namespace>**

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In this syndrome, the neuromuscular system compensates by attempting to stabilize lax joint structures, by affecting movement against joint stiffness, or by subserving linked compensatory movements over kinetic chains. ?xml:namespace>

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8. **Chronic Faulty Motor Programs ?xml:namespace>**

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An amalgamation and perpetuation of all of the above syndromes. Here, we assume that the central nervous system learns to cope with pain, muscle weakness, joint instabilities, trigger points, myofascial extensibility issues, etc. ?xml:namespace>

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Add to the above, the chiropractic subluxation, and the operator only has a one in nine chance of being right. A little more than 11% chance that the readings on the sEMG machine are the result of a chiropractic subluxation. If even that high, since some authorities think there are even more conditions that can contribute to abnormal readings. ?xml:namespace>

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So, the next time you are using sEMG at a spinal screening and you are thinking about using the results to explain a clear indication of the presence of a chiropractic subluxation, think again. Unless, of course, you have already performed the multi-point differential diagnosis to eliminate the above as possibilities. ?xml:namespace>

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Hardly the "Certainty" the clinician is looking for. ?xml:namespace>

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Next let's look at what the sEMG readings are supposed to be showing. ?xml:namespace>

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Two of the manufacturers claim that their sEMG device is measuring the effects of muscle guarding at the location of a subluxation and that the device is recording the protective mechanism of the subluxation. ?xml:namespace>

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A point commonly left out is that the protective action occurs deep in the body at a level unlikely to be picked up by the sEMG device. Too much noise from the muscles above. ?xml:namespace>

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Here is a direct quote from Dr. Cram. "Personally, all this talk about using sEMG to isolate segmental patterns of activation is poppy cock. The best resolution that I believe is anatomically possible to identify with sEMG is 4 segments." ?xml:namespace>

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So, if the results from static sEMG can be caused from a wide range of conditions, and you can't use it to accurately identify a level of involvement, exactly what good is this technology in identifying the presence of a chiropractic subluxation? ?xml:namespace>

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This is why I call static sEMG a "So what" technology. The results should have no impact on the diagnosis or treatment in the office of the average doctor of chiropractic. ?xml:namespace>

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Show me that a change in EMG measures is related to some factor of patient wellness or functional improvement. ?xml:namespace>

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In conclusion ?xml:namespace>

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Here, in my opinion, are the major problems associated with using a sEMG device for static scans in an attempt to use the results to verify the presence or absence of a chiropractic subluxation. ?xml:namespace>

1. **The FDA guidelines, under which these devices are strictly regulated, don't allow for claims as a "subluxation analysis system". No company has provided the FDA with the materials necessary to prove the claims that the systems can detect and identify muscle guarding that is the result of a CS. Remember; these are biofeedback devices to be used by patients to control their own physiological responses. ?xml:namespace>**

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So, in my opinion, these companies are operating outside the FDA regulations when such claims are made. ?xml:namespace>

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2. **NO studies to show that a consistent baseline reading can be obtained over a time greater than a day. How can you possibly use a sEMG reading to show improvement if it hasn't been shown that doing nothing causes the first reading to remain unchanged over time? This incredible oversight virtually invalidates research papers that purport to show changes from one visit to the next. ?xml:namespace>**

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3. **Many, many conditions, not the least of which is the patient's emotional state, can create abnormal readings. So many things can affect the reading, that unless a through differential diagnosis is made, the results are useless to the average doctor of chiropractic. ?xml:namespace>**

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The question to ask when investing in new technology should always be "Will this device improve the quality of care for my patients." ?xml:namespace>

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I think all of us want to find the CS "smoking gun". SEMG isn't it. It takes years of training and use to be able to glean significant information. It is not suited for the average office. ?xml:namespace>

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The information contained in this letter is easily found from public sources such as fda.gov and semg.org. I invite you to do your own

research before attacking the content of this letter. ?xml:namespace>

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Sincerely, ?xml:namespace>

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Joseph Ventura, D.C. ?xml:namespace>

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