The Politics of Computerized Electrodermal Screening

by James Hoyt Clark

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New inventions and societal progress require pioneers. The information in this article comes from my twenty years of experience as a pivotal pioneer in the field of Computerized Electrodermal Screening (CEDS). CEDS is an unparalleled health-optimizing device available to health practitioners in any health discipline. In essence, CEDS appraises health imbalances from every imaginable angle enabling *every* health discipline to become empowered as never before.

This article defines CEDS, gives you a brief history of the development of this remarkable device, covers the "blizzardous" process of governmental regulation in regard to CEDS development and deployment, and concludes with a vision quest success story, thereby illuminating CEDS' destiny, both today and tomorrow.

Defining CEDS

The human body is a complex organism made of chemicals that are controlled and organized by energy. Thus, both physics and chemistry are required to help physicians measure health. Chemicals give structure and provide function to the human body. The interrelationship of electrons within the body governs all chemical behavior. Freed electrons traveling together are pure electricity. By measuring, recording and comparing this energetic interaction along each meridian, CEDS gives an unprecedented view into the molecular structure and function of every organ, tissue and cell of the body in any state of health. By definition, CEDS is a true physiological "quantum" analyzer!

CEDS: A Powerful Device

Meridians are energy pathways that embroider the body. The Chinese began mapping meridians approximately 5,000 years ago. In 1992, Jean-Claude Darras, Pierre de Vernejoul and Pierre Albarede mapped the Urinary Bladder and Gallbladder meridians using a radioactive tracer. The tracer, technetium-99m, was injected at a point on the meridian. The migration of the tracer was monitored by a scintillation camera with computer imaging. The researchers found that the tracer accurately depicted the classical Chinese meridians (Darras et al., 1992).

Studies of acupuncture points show constant dynamic changes at their skin surface points (Dumitrescu, 1971). Toxins, diet, exercise and emotions affect the amount of electron activity within the body, just as they change the anatomy and physiology of the organs, tissues and cells. This flow of electrons is perfectly reflected within corresponding meridians, and inescapably alters the resistance at each acupuncture point. These changes can be measured, graphed and compared by CEDS.

In essence, the body's electron activity can become imbalanced in response to spicy food, running a race, bacteria, or other lifestyle influences. In a healthy person, when the process completes, the electron activity normalizes. However, in an unhealthy person, the process cannot re-achieve normalacy, so the body's electron activity succumbs to the rules of Selye's General Adaptation Syndrome.

A CEDS unit measures the behavior of the electrons within the human body in ohms using an ohmmeter circuit and a stimulus. An operator uses a test plate or the signal generator to apply a stimulus to acupuncture points on the hands or feet. By contacting points with probes from the ohmmeter, the operator is able to measure the resistance values of each point. The resistance measurements show a pattern that can be interpreted as an energy balance or imbalance. In this case, balance means the "normal" flow of electrons through the body as evidenced by a well established standard resistance value. An imbalance is reflected by a higher or lower resistance measurement to standard.

An operator uses the CEDS device to store, retrieve, graph, compare, and print the resistance values. CEDS rapidly provides and organizes a *large* amount of data. Each meridian measurement generates four data readings: the rate of rise (RISE), the maximum (MAX), the rate of fall (FAL) and the minimum (MIN). So, 40 meridian readings times the four data values generates 160 values for each patient. By using Multiple Variant Analysis (MVA), one latest version of CEDS – BioLINKS – provides an unsurpassed biopsy of the whole human body, pinpointing "HOT" points requiring remeasurement to detail the prime causes of the point's imbalance. In essence, BioLINKS' highest purpose is to expose the true and ultimate causes of an energy imbalance, plus the stimuli required to causally re-balance the entire patient.

Balancing the Patient for Good Health

A diagnosis is a label wherein a health practitioner describes a failure in the structure or function of a patient. Most medical tests produce a number that labels a patient as normal or abnormal. Often, the label can be important for the doctor to learn about a chemical imbalance. Sometimes, the diagnosis can help the doctor know what to do and other times, the diagnosis is hollow and amounts to nothing more than symptoms fitting a label.

Conventional medicine prefers reductionism to define health, i.e., the management of numbers derived from an "experientialess" Cartesian methodology. Those numbers reflect a three-dimensional position in a range of values and include cholesterol levels, pulse, temperature, blood chemistry, weight, vision and hearing, and usually not "energy" that governs all of the above. We now know that energy is quantum in nature, involving much more than three dimensions. To conventional medicine, abnormal means some specific numerical data value that is the "effect" that falls outside of an accepted range, rather than the actual "cause" of the abnormality. For example, a person's cholesterol value should be in an accepted range. Hence, it is difficult to imagine "effects" truly defining the true reality of health and disease.

BioLINKS produces many data values, oftentimes including the "causal" energy values underlying the total structural, functional and psychological well being of the patient. This is more akin to the definition established by the World Health Organization that, "Health is a state of complete physical, psychic and social well-being, and not merely the absence of diseases and infirmities."

CEDS is not a diagnostic device, it is a screening procedure for changes in resistance. A CEDS unit provides a true causal snapshot of someone's health at any moment in time. It gives

you an instantaneous multi-vector viewport into the most core events of an organ, tissue, or even cell. For example, the resistance value for the Large Intestine meridian can be too high or too low and precisely "linked" by BioLINKS to eating spicy food or to a most rare and bizarre toxin. Thus, the values determined by BioLINKS do not define a disease. BioLINKS simply reveals and links the core event energy patterns (causes) associated with effects labeled as "diseases," all accurately catalogued for easy reference and comparison in my proprietary database library. In essence, CEDS does not make a conclusion; it displays and patterns the data. A trained health practitioner must then interpret the results. By coupling the CEDS results with diagnostic tests typical to any practitioner's discipline, the outcome is causal empowerment to that specialist's ability to arrive at the best diagnosis possible.

The History of CEDS

Ironically, due to its relative technological youth, CEDS is unknown to most of the world. CEDS practitioners are pioneers making the best use of the oldest and youngest concepts in medicine, chemistry, physics and electronics.

The development of CEDS began with the discoveries by Yoshio Nakatani in Japan (Nakatani, 1956) and J.E.H. Niboyet (Niboyet, 1958), Bratu (Bratu, 1960), Brunet (Brunet, 1959, 1960), Voll (Voll, 1975) and Wing (Wing, 1977) in Europe. They discovered that acupuncture points were characterized by a lower resistance than the surrounding skin.

In the 1950's and 1960's, Yoshio Nakatani and Reinhold Voll developed two distinct Electro-Dermal Scanning (EDS) techniques. Nakatani developed Ryodoraku, which measures points on the wrists and ankles. Reinhold Voll developed Electroacupuncture According to Voll (EAV) which measures points all over the body. The term now commonly used in publications is EDS to avoid confusion with standard electroacupuncture techniques. H.W. Schimmel developed another EDS procedure called Vegatest which measures only one to three points on the hands. Vegatest uses products called filters to determine body-wide imbalances.

Voll originally used an external stimulus by applying an electrical signal to the acupuncture point which changed the imbalance as measured through an ohmmeter. Later, Voll introduced a product to change the resistance, a process called medicine testing. A product was placed on the test plate that was connected in the ground (earth) side of the hand electrode held by the patient. The product could be homeopathic, herbal, chemical, or any other exogenous stimulus.

In 1981, with training as a bioengineer and exercise physiologist, I was the first to computerize the ohmmeter reading and the medicine testing. My first CEDS production device was called the Accupath 1000.

Governments' Views

Most of the world's regulatory agencies classify CEDS as a safe and effective acupuncture device because it is non-invasive. Amazingly, although not a food or a drug, in the United States, CEDS is regulated by the Food and Drug Administration (FDA). This happened in May of 1976 when the United States Congress authorized the FDA to regulate medical devices.

The FDA is quite influential in the world; therefore, my company considers it prudent to present the FDA's position on CEDS. The FDA considers CEDS an investigational device, despite claims to the contrary. Manufacturers and operators of investigational devices are not allowed to make claims or to engage in commercial marketing. The CEDS manufacturer must "place" the device with operators that make no claims and who, with training, want to participate in exciting yet formal research. Operators and practitioners must inform all patients that the device is considered investigational. To obtain FDA clearance, manufacturers send research conducted through reputable third parties (i.e., a university) demonstrating the safety and efficacy of a device. Unfortunately, the FDA does not have a policy for allowing manufacturers to demonstrate new devices to them directly.

If the device is similar to devices manufactured before May 1976, the device can be "grandfathered" in. That is, if the device was sold in the United States prior to 1976 with a similar use and function, the FDA can clear the manufacturer to sell the device.

Research must be conducted on each device manufactured after May of 1976. However, each manufacturer must provide original research. Research on a similar device from another manufacturer cannot be used. Before beginning the research, the manufacturer must establish an Institutional Review Board (IRB). The IRB is asked to reject or approve research proposals and to decide if the device should be classified as significant risk (SR) or nonsignificant risk (NSR). If the device is considered to be SR, then the FDA must remain part and parcel to the ongoing research; if the device is considered to be NSR, the FDA does not have to be told about the research until it is submitted to the FDA.

After the data is collected and analyzed, the research can be submitted to the FDA for a pre-market approval (PMA). Within 45 days, the FDA decides if the research is statistically sound and has a scientific basis. Note that the FDA does not reject the research. They determine if the research fits their official policy. If the FDA decides the research is not statistically

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Table 1. FDA Clearance Classifications for Medical Devices

Classification	Definition	Example
Class 1	Devices have a use, but no function.	Thermometer
Class 2	Devices have a use and a function.	Electrocardiograph Biofeedback
Class 3	Devices have a use and a function, and are used for patient life support and surgery	Electrocardiograph used in an intensive care unit. **Any experimental device.**

sound or has no scientific basis, they ask for further information; if the FDA decides it is sound, they send the study to a peer review board where people in the academic community review the research. The FDA can still decide to clear or not clear the device regardless of whether the peer review board accepts or rejects the research.

When clearances are granted, each device is given one of three classifications. Table 1 shows the classifications.

STAR TECH HEALTH has letters from IRBs and from the FDA stating that our device is a nonsignificant risk device (NSR). It is non-invasive, low energy and used by an operator. BioLINKS requires electrical power isolation for the patient and the operator whether the computer is plugged in or is running on batteries. The BioLINKS *hardware* is called the Digital Conductance Meter (DCM) – serving as a computer card installed in a computer, or as a portable unit that communicates through a fiber optic cable or transmitted signal – the DCM Portable. Based on the paperwork submitted, the DCM is considered safe and effective for relaxation training as a Class II biofeedback device. From start to finish, the clearance took three years and nine months.

So what is the position of the FDA when CEDS hardware is *combined* with CEDS software? It is new technology clear and simple. Biofeedback is defined as a process measuring and reporting back immediate information about physiological systems of a patient being monitored so he or she can *consciously* learn to influence that system. CEDS accomplishes this, but it also utilizes its extensive database libraries to influence (i.e., balance) that system. *It does **not** typically involve conscious exercises by the patient to influence their system.* Therefore, after submitting a PMA for four years for CEDS, the FDA determined that the technology is new, it is a nonsignificant risk (NSR), and *by their ruling* it is considered acupuncture, *not biofeedback*. Therefore, any use of CEDS as a billable biofeedback service may presently be considered fraud!

Now CEDS *is* related to acupuncture, but it is not acupuncture. They both share the concept of a system of meridians, but acupuncture is an invasive treatment, while CEDS is a non-invasive screening. Nevertheless, since CEDS measurements are taken at acupuncture points, the FDA labels CEDS as acupuncture. In response to petitions submitted by the acupuncture community, the FDA has reclassified acupuncture needles for general use from Class III, a category in which clinical studies are required to establish safety and effectiveness, to Class II, a category which involves less stringent controls by FDA but requires good manufacturing and proper labeling. This process took the better part of twenty years and there is no telling how long it might take CEDS to achieve Class II status.

Remember, the FDA does not accept, approve, or register a device, but clears it for marketing and sales. After clearing a device the FDA issues a K number. To state in any advertising or promotional literature that "the FDA has approved" a device or given the clearance number is considered misbranding and is grounds for terminating the clearance to market a device. Manufacturers of CEDS devices have an obligation to the health of everyone. To be respected by physicians, their patients and those that make and shape the rules, CEDS manufacturers must tread lightly and respect the rules reflective of the FDA's position on CEDS.

The Success of CEDS' Vision Quest

Stunning articles appearing in the peer-reviewed literature about CEDS continue to break all the molds in securing the true well-being of a patient. CEDS has been shown astoundingly efficacious in identifying and modulating:

- Sensitivities (Tsuei 1984, Krop 1985, Brostoff 1987, Fox 1987, Ali 1989, Hejjaoui 1990, Remington 1990, Boczko 1993),
- AIDS (Brewitt 1996), Diabetes (Tsuei 1989)
- Teeth problems (Voll 1978, Madill 1980)
- Degeneration (Lam 1983, Sullivan 1985, Goldberg 1997)
- Hypoglycemia (Madill 1980)
- Peripheral nerve injuries (Richter 1943) and many other health imbalances (Podshibiaky 1955, Voll 1976-7, Becker 1976, Remington 1990, Royal 1991, Siegel 1994, Tsuei 1996).

Many books (Voll 1976-7, Werner 1979, Kenyon 1983) painstakingly discuss the CEDS screening of the lymph, lung, large intestine, nerves, circulation, allergy, organ, endocrine, heart, small intestine, pancreas, spleen, liver, joints, stomach, fibroid tissue, skin, fat tissue, gallbladder, kidneys and urinary bladder. CEDS also holds enormous value for veterinary sciences (Dodd 1984, Limehouse 1994).

Since I developed CEDS, operators around the world have introduced many exciting and beneficial protocols based on the ohmmeter and my database libraries. Case studies and research now abound that CEDS has consistently and miraculously helped health practitioners solve the most perplexing and complicated disease presentations. CEDS is truly a lifesaving tool (Voll 1980, Remington 1990, Royal 1995, West 1995, Tsuei 1996). The focus now needs to move toward greater societal and governmental acceptance of CEDS.

The Future of CEDS

Irrespective of the education and experience of all the different health practitioners, governments and licensing boards still tell them how to practice. In some countries, they often severely limit the practitioner's choices. It takes five to 50 years before new research, techniques or devices become part of the mainstream.

The picture is improving. Practitioners of different fields are working together in interdisciplinary clinics. Doctors are now seeking unprecedented training and acquiring combinations of degrees in the alternative arena. In my opinion, there can be no finer or greater alternative medical education than that provided by CEDS training and credentialization, because of its overall empowerment, as well as its ease of implementation. For an extensive list of CEDS peer-reviewed literature and for more information on how to become totally empowered with CEDS technology, I invite you to call 801-229-1114 or Toll Free 888-229-1114 anytime during normal business hours.

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