Close Examination of a ZYTO Electrodermal Screening System

by Stephen Barrett, MD

Abstract

Electrodermal screening" ("EDS") devices are claimed to use galvanic skin responses to identify health problems and corrective actions. Thousands are being used to persuade people to buy dietary supplements, diet programs, and other offerings. This study, which involved self-testing with a leading EDS device 43 times in 10 days, found that its assessments and recommendations were preposterous and potentially dangerous. The sale and clinical use of EDS devices should be banned.

Introduction

ZYTO Technologies Inc., of Lindon, Utah, claims that its device systems are useful for determining health problems throughout the body and how to fix them. According to its web site, "Just like a doctor uses a stethoscope to listen to a child's breathing, ZYTO 'listens' to the body's subtle galvanic skin response" and suggests corrective measures.[1]

This use of galvanometric device systems to guide practitioners is commonly referred to as electrodermal screening (EDS). EDS devices are said to detect and respond to skin resistance to the passage of low-level electrical current. At least 40 such devices have been marketed.[2]

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Figure 1
The Zyto hand cradle.
To conduct the test, the device is attached to a computer and ZYTO software is run while the client's palm and fingers rest on six corresponding electrodes.

Early ones displayed skin-resistance measurements as numbers on a gauge or computer screen for the practitioner to relate to the health of the body's organs. Current devices are bundled with software that generates elaborate charts, pictures, and lists of body areas, symptoms, diseases, and corrective measures.

ZYTO Technologies appears to be the leading marketer of EDS systems, with thousands currently in use. EDS users include chiropractors; naturopaths; acupuncturists; massage and colon therapists; "holistic" dentists; veterinarians; physicians who purport to practice "integrative" or "complementary" medicine; and unlicensed "nutritional consultants," "wellness consultants," "health coaches," and distributors for multilevel marketing companies that sell dietary supplements and/or herbs. Many of these providers recommend that testing be done periodically.

ZYTO Systems

ZYTO systems have two components: a hand cradle (See Figure 1) and software that interprets the electronic signals generated by the device.

ZYTO says that its software sends "digital signatures" (unique code numbers) to the body and determines "the body's degree of preference" for measures that will make the body most "biologically coherent."

To run the test, the cradle is connected to a USB port on the practitioner's computer and the patient's hand is placed with the palm and fingers touching the corresponding points on the device. The practitioner then launches the software program and selects the type and scope of test from a sequence of menus that appear on the computer screen. The software then generates numbers and graphics that supposedly indicate (a) whether the function of various organs and body parts are "in range" (favorable) or "out of range" (unfavorable) and (b) which products, procedures, and/or dietary measures show the most "coherent responses" (those that will bring the values "within range"). Changes in skin resistance are said to trigger what gets matched.

To have their products considered during the test process, manufacturers submit them to the company, which creates a "library" of "digital signatures" for each product plus a brief description of what the product can do. ZYTO software also encodes the minimum usage age for the product, the suitability for male or female test subjects, the dosage, yes/no values for the practitioner's favorite product(s), and a few other values that guide the display of the data in the final report. The software is also said to contain "digital signatures" that represent the condition of various organs, teeth, and spinal segments—all of which, the company claims, are connected through "energetic channels" called "acupuncture meridians."[3]

During the scan, ZYTO software takes baseline measurements of the galvanic resistance to low-voltage electricity through the palm and fingers of the test subject and sends product codes to the hand cradle so the body can supposedly respond to product "signatures" as though the test subject had ingested the products. The system re-measures the galvanic resistance of the test subject and then calculates the difference between the "baseline" and second measurements. This process is repeated over and over again through the product line(s) selected by the practitioner. ZYTO states that the system processes over 100 "virtual items" per minute. The apparent goal of the test is to match the supposed characteristics of the patient to the products, services, and/or dietary advice that the practitioner can provide. The length of the test—typically 2 to 20 minutes—depends on how many parameters are chosen. The content of the reports also depends on the parameters selected.

The ZYTO Corporation web site currently offers "libraries" for the products of more than 200 companies. Its lowest-priced system, the ZYTO Compass, sells for $399 plus a $39.95 monthly subscription fee, and includes one library and measurement of 76 "biomarkers." ZYTO's high-end systems, which cost $9,750 or $14,750 plus $50 per month, assess 1,500+ "biomarkers" and provide access to as many libraries as the practitioner wants. Most libraries contain several hundred products. The monthly fee gives access to the password-protected portion of the company's web site, which provides training and marketing materials and enables practitioners to upload their test reports into their individual accounts.

Testing can be done in the presence of the practitioner or done remotely though the internet by hooking a purchased or borrowed hand cradle to the client's computer. The internet-advertised prices of scans run from $10 to $250, but the recommended products often cost hundreds of dollars more. Many practitioners aim to scan everyone who consults them. One provider in Virginia, who has no relevant license but offers remote testing throughout the world, states that he has done more than 20,000 scans.

My personal investigation—the first of its type ever published—examined whether ZYTO testing could produce consistent results, valid diagnostic findings, and rational recommendations.

Study Design

Last year, when presented with an opportunity to operate a ZYTO device with high-end software (Elite 5.0), I ran three series of tests on myself. The first was a basic scan that supposedly evaluated my organs and advised what products would bring them back "in range." The other two were nutritional "biosurveys" to determine what foods I should or should not eat.

The basic scan is said to determine whether "biomarkers" are in or out of range for 20 organs:

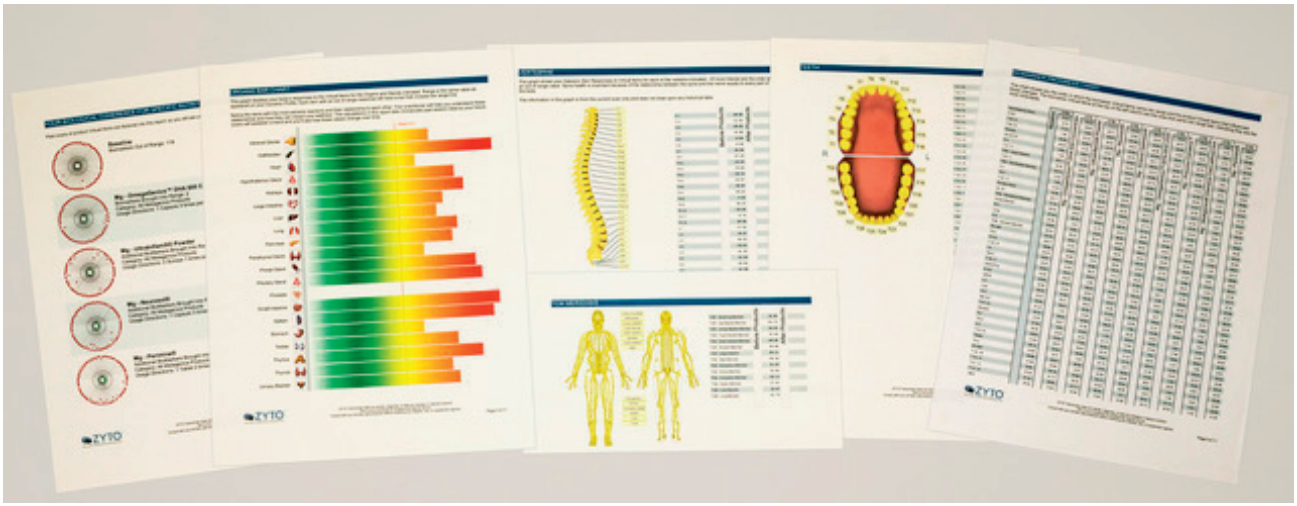

Figure 2
Selected pages from a ZYTO report
The bar graph purports to show whether biomarkers for each of 20 organs are "out of range." The other pages indicate which spinal segments, acupuncture meridians, or teeth have relevant problems and which products can correct the alleged problems. The greater the supposed problem, the longer and redder the bar that crosses the vertical "range line" in the middle of the bar graph. Most scans have a bar for every organ, but this one failed to detect the author's adrenal glands, prostate, and testes.

adrenals, bladder, gallbladder, heart, hypothalamus gland, kidneys, large intestine, liver, lung, pancreas, parathyroid, pineal, pituitary, prostate, small intestine, spleen, stomach, testes, thymus, and thyroid. My basic scans generated reports that were 8–13 pages long. Figure 2 shows portions of six pages from one of my reports. The findings for the organ biomarkers are displayed with a colorful full-page bar graph and as positive or negative numbers elsewhere in the reports.

ZYTO's marketing materials have stated that its nutritional surveys can determine "which foods and supplements are right for you."[4] The reports themselves describe the purpose this way:

> "This Food Biosurvey tests your body's Galvanic Skin Responses to Virtual Items that represents a particular food. Your response to each food Virtual Item is scored with a positive or negative number, and your most extreme responses will be shown on this report. Even though this is NOT a food allergy test, you may wish to avoid the Virtual Items with a negative response, and include in your diet the Virtual Items with a positive response."

The test reports can be configured to assess food categories, "top negative foods," and/or "all positive in-range foods." The food categories are additives, beans/legumes, beverages, dairy/egg, fat/oils, fish/seafood, fruits, grains, meats/poultry, miscellaneous, nuts/seeds, spices/seasonings, sugars/sweeteners, and vegetables. I did one series of tests that assessed the fourteen food categories and two others to assess individual foods. The resultant reports were 2–4 pages long.

My Test Results

Table 1 shows the results of sixteen basic scans, with four done within an hour on each of four consecutive days. These scans found means of 69.2 (SD, 31.9) biomarkers and 11.4 (SD, 5.4) organs that were "out of range," but the organs specified and the supposedly corrective products—a mean of 5.3 (SD, 2.6) per scan—varied considerably from one test to another. The organ with the highest "out-of-range" score, positive or negative, also differed from test to test. Four reports highlighted my adrenal glands, three chose my small intestine, two chose my heart, two chose my thymus, and the other six tests each identified a different, supposedly problematic, organ. Only four of the sixteen scans had any organs "within range."

Even though I have no gallbladder, this organ was reported to be positively "out of range" four times, negatively "out of range" 4 times, and "within range" eight times. I have benign prostatic hypertrophy, but my

Table 1. Summary of basic scan results.

Test Date	July 2, 2016				July 3, 2016				July 4, 2016				July 5, 2016			
"Range" Value	66	37	.01	.01	22	22	22	22	54	54	54	54	55	55	55	55
Adrenals	±47	70	-47	17	-142	±6	34	44	**107**		**107**	**143**	-82	69	**81**	-58
Bladder	±36	-52	64	-28	-168	±18		52		110		57	254			
Gallbladder	±48	-53	-20	**-51**	±0	±17			57	69	-60		164	74		
Heart	±30	±5	**92**	10	51	±18	-31	-34				-92	180	**125**		
Hypothalamus	86	53	-46	30	±6	±10	26	44				80	-120	116		-55
Kidneys	±42	52	-21	-35	-107	**-46**		26		85			139	57		
Large Int.	±48	±6	58	24	257	±18	-36	-58				120		-116	-58	
Liver	±65	**76**	51	20	±13	±6	44	37					-125	94		
Lung	±8	-67		-31	-131	-30		29		96		128	154		-78*	
Pancreas	±49	±9	35	28	113	±21	-37	-60						-108		
Parathyroid	89	60	48	12	79	23	**54**	27	-55		100	96	-115	110		
Pineal	±26	-48	49	39	-144	-35		27		111		129	175		-61	
Pituitary	±40	±6	17	43	177	±16		**-66**		-54		-66		-105		
Prostate	82	51	-51		104	±8	24	29	-63		62	-80	-116	103		
Small Int.	±47	-70	37	**-51**	-151	±17	-36	32		**117**		113	**283**	70		62
Spleen	83	±7	28	48	247		-39	-56		-60				-70	70	
Stomach	114	55	-73	-11	35	±8					58	-110	-100	94		
Testes	±8	-50	76	-28	-119	-27		34		101		121	210			
Thymus	±45	±11	10	41	**275**	±4		-58			-59			-111		**-63**
Thyroid	**135**	70	47	-25	±6	±10	24		-67		67	-99	-96	124	-66	
# of Biomarkers "out of range"	57	74	119	119	101	55	82	94	25	56	36	84	87	82	19	17
# of Organs "out of range"	6	14	19	19	16	5	11	17	6	9	7	14	15	16	6	4
# of Products	6	8	5	4	8	5	8	8	3	2	2	6	8	8	1	2

Table 1
The numbers are said to represent the body's response to code numbers that represent the organs listed in column 1. The software determines a range (baseline) value, compares the response numbers with that value, determines whether "biomarkers" are within that range," and recommends products that supposedly will bring "out of range" biomarkers back "in range." ZYTO reports list the "out-of-range" numbers in a table. The numerical value of the "in range" numbers can be derived by measuring the bars in the bar graph, but their direction is not specified, so they are listed here as "±" numbers. The furthest out-of-range numbers (displayed here in bold-face type) are said to require the most attention. If a table cell is empty, no organ response was reported. All numbers are rounded to the nearest integer.

prostate did not show up in one scan (Figure 2) and was reported to be positively out-of range in 7, negatively out of range in 4, and within range in 4.

To explore how the food biosurveys work, I conducted 12 food-category tests and 15 individual-food assessments. The food-category tests were completed within one hour. As shown in Table 2, the test reports recommended avoiding a mean of 6.4 (SD, 2.4) categories per test, but not necessarily the same ones. Ten of these tests recommended avoiding grains, nine recommended avoiding nuts and seeds, and eight recommended avoiding fruits, and vegetables. Five recommended avoiding all fruits, vegetables, and grains. One recommended only sugars/sweeteners; one recommended only beans/legumes; and one recommended only beverages, fish/seafood, meats/poultry, and spices/seasonings.

The food-category scores disagree so much from test to test that Cohen's kappa is zero (complete randomness). Some numbers in Table 1 are unspecified, but if the "±" numbers are eliminated, its kappa is 0.02, which is nearly random.

The individual-food tests were done in two groups. First there were ten tests that assessed common foods. Two days later, five tests assessed a larger food list. Both groups took less than an hour to complete. As with the basic scans, the individual-food scores were wildly inconsistent, with many foods scoring "positive" (recommended) on one test and "negative" (not recommended) on another administered a few minutes

Table 2. Results from the 12 food-category biosurveys.

Food category	Avoid	1	2	3	4	5	6	7	8	9	10	11	12
Additives	7	-11	-26	-36	-4	-23	19	21	-11	49	39		-18
Beans/Legumes	8	28	-35	-17	-35	-21	-43	28	-32	-33	79	8	-46
Beverages	4	6	38	33	30	28	-13	-71	72	7	-28	-107	
Dairy/Egg	6	-22	1	-20	-9	-14	51	58	-8	41	-36		-11
Fat/Oils	8	32	-30	-7	-33	-23	-44	-2	-26	-36	78	-79	-47
Fish/Seafood	3	9	33	41	43	45	-9	-56	48	5	-26	-118	
Fruits	8	-21	-10	-17	-5	-28	59	66	-31	38	-36		-21
Grains	10	19	-43	-34	-44	-27	-51	-22	-8	-46	78	-41	-60
Meats/Poultry	5	14	43	49	37	34	-11	-19	36	-5	-35	-89	
Meats/Poultry	5	14	43	49	37	34	-11	-19	36	-5	-35	-89	
Misc.	6	-39	-7	-9	3	-16	73	53	-43	61	-57		-8
Nuts/Seeds	9	25	-45	-31	-26	-14	-52	-30	21	-50	84	-41	-57
Spices/Seasonings	5	-6	39	48	37	40	-6	-30	38	7	-22	-95	
Sugars/Sweeteners	3	-26	11	-14	4	-15	65	72	-29	46	-67		11
Vegetables	8	28	-27	-31	-37	-15	-39	-41	21	-57	77		-53

The numbers are said to quantify the body's response to code numbers that represent the listed food categories. The positive numbers are food categories that should be included in your diet. The negative numbers represent the "top negative foods" that should be avoided. The "Avoid" column is the number of times the "top negative" list included the group. All numbers are rounded to the nearest integer.

later. For example, pineapple and red potatoes were listed seven times among the top negative foods and three times among the most positive foods.

Discussion

The claim that ZYTO scanning can provide clinically useful information is preposterous. To demonstrate that a device is capable of measuring something, it is necessary to validate its accuracy and consistency with repeated tests. My basic scan results were so inconsistent that they could not possibly be clinically meaningful.

In addition to being inconsistent, my food-category biosurveys recommended excluding so many foods that the resultant diets could be extremely unhealthful.

To demonstrate that a device can detect organ pathology, it is necessary to do controlled studies of people who have that condition and people who do not. To demonstrate that administering a product or procedure can improve outcome, it is necessary to study whether people who are treated do better than similar people who do not. A Medline search for "ZYTO" in the title yields no relevant publication. Proponent Web sites cite only one small unpublished study that looked for correlations between "organ stress results" reported with a four-minute ZYTO test and organ systems diagnosed as dysfunctional by a medical team.[5] Although the investigators considered the results promising, the data actually show marked discordance.

ZYTO Technologies has not explained how it can construct or validate its organ assessments or product libraries without any underlying clinical studies. Nor is there any logical reason to believe that skin resistance is related to organ health or what people should eat. But even if magical explanations were found, the ZYTO system's moment-to-moment variability would still render its findings useless.

Electrodermal screening tests are also potentially harmful. In addition to money wasted on the test and useless products, the harm can include (a) needless

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worry about nonexistent medical problems suggested by the test reports, (b) the cost of medical care involved in seeking reassurance, (c) failure to seek appropriate medical care for real problems, and (d) the consequences of malnutrition due to excessive dietary restrictions.

Government Regulation

There are two major processes by which medical devices requiring FDA review come to the American market: premarket notification and premarket approval. Premarket notification—described in section 510(k) of Federal Food, Drug, and Cosmetic Act—is commonly referred to as the "510(k) process." A successful 510(k) submission results in clearance to market the new device. Clearance merely requires that the new device be "substantially equivalent" to a device that was previously cleared or approved. It is not the same thing as approval, which requires that clinical trials demonstrate safety and efficacy for its intended purpose. Some device manufacturers skirt the law by obtaining 510(k) clearance for one purpose when the device is actually used for another.

In 2011, the FDA cleared the ZYTO hand cradle for sale as a galvanic skin response measurement device (product code GZO).[6] Because moistness of the skin affects the ability of the skin to conduct an electrical current, a few devices in category GZO have legitimate medical use in the management of sweat-gland disorders. Aside from this, however, galvanic skin resistance has no proven or logical relationship to the diagnosis or management of any medical problem. ZYTO's software is separately registered as a medical device data system (product code OUG) that stores, controls, and/or transfers medical device data. Devices in this category are not legally authorized for patient monitoring.[7]

ZYTO devices are not FDA-approved. They were cleared because their 510(k) application and software registration did not indicate how practitioners would use them.

ZYTO's marketing materials state that its devices are "not intended to be used in the diagnosis, cure, treatment, mitigation, or prevention of any disease or medical condition." However, "intended use" is based on the context in which a device is used and is not necessarily changed by the use of disclaimers or contrived terminology.

In 2015, the FDA[8] warned ZYTO Technologies Inc. that, "The promotion of the ZYTO Hand Cradle for use in diagnosing a disease or condition, predicting biological responses to a wide range of virtual stimuli including drugs and nutritional supplements . . . fall outside of the device's cleared intended use to measure galvanic skin response and constitutes a major change or modification to the device's intended use." The marketing language to which the FDA objected included these claims:

- Clinical studies have compared ZYTO scan reports with results produced by generally accepted diagnostic methods.
- The hand cradle measures your body's galvanic skin response. ZYTO's various software offerings take this input and interpret it in terms of what we call your biological preference.
- Biological preference simply means those stimuli your body responds most favorably to. Using this information, you and your healthcare provider can decide on a clinical strategy developed specifically for you, based on your body's responses.
- ZYTO's technology measures your body's responses to a specific library of nutritional products, asking your body which it prefers.
- When your scan is complete, a report is generated that provides you and your healthcare provider with helpful information that was obtained. This report may provide insights that will prompt a closer look at specific organs and body systems, and explore your biological preference for medicine,

nutritional supplements, and treatments you could benefit from.

- General nutritional assistance biosurveys will help to identify your patient's biological preference for the products you sell. Other biosurveys may provide you with information specific to disease, toxins or organs and body functions.

In 2016, presumably as a result of FDA pressure, ZYTO Technologies announced a voluntary recall of 1,252 ZYTO Select and Elite software programs due to "claims exceeding the 510(k) clearance."[9] ZYTO has modified some of its marketing language, but there is no reason to believe this will influence how its EDS devices are used.

In 2017, the Federal Trade Commission obtained a consent agreement with the marketers of the NutriMost Ultimate Fat Loss System, which was developed by a chiropractor and franchised to other chiropractors.[10] The 40-day program, which included a very-low-calorie diet (only 600 to 800 calories per day) and supplement products, typically cost from $1,995 to $2,300, depending on the payment plan chosen. Advertisements claimed that the ZYTO scan would be used to create a "personalized and customized plan that will address your body's top organ stressors as well as finding the best products to balance those stressors." The supplement products were claimed to have been imprinted with "energetic resonant frequencies" that provide "information to your body's cells about how to more effectively detoxify."[11] In 2017, NutriMost redesigned its approach along more standard lines, abandoned use of the ZYTO device, and promised the FTC that any future weight loss and health claims would be supported with competent and reliable scientific evidence.

The use of EDS devices by practitioners is subject to regulation by the states. In 2015, the Arizona State Board of Chiropractic Examiners ordered three chiropractors to stop using ZYTO bioscan technology, and the Texas Medical Board reprimanded a physician for making improper advertising claims that included some about the ZYTO. I am not aware of any other ZYTO-related disciplinary actions.[12]

Conclusion

There is no scientific evidence or logical reason to believe that galvanic skin response testing can determine a person's health status or strategies for health improvement. All such devices and associated software that are used for these purposes should have their FDA 510(k) clearance revoked and be removed from the marketplace.

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