MEDICAL DEVICE EVALUATION REPORT

September 26, 1989

Device: BIOPATH SYSTEM Diagnostic Device
Primary Source
Odem, Utah

Type of Evaluation: Advertisement, Device Labeling, Hardware/Software Efficacy

Evaluation by: Mark R. Emmerson, Biomedical Engineer
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This evaluation has been performed on a sampled device first made available to me on August 1, 1989, by MARTHA VILLEGAS, Investigator with the Food and Drug Branch, Sacramento District Office. On August 23, 1989, STEVEN KENDALL, Compliance Officer with the U.S. Food and Drug Administration (FDA), San Francisco District Office, provided me with a copy of the "BIOPATH SYSTEM MANUAL, Version 1.03". Advertisement materials were also given to me for evaluation during this period.

The device consists of the following components:

Headstart PS/2 type computer with internal hard disk
Sumsung Vendrex VGA graphics monitor
Keyboard
Printer
Internal interface board
Electrode probe and ground
Metal plate
BIOPATH software
Footswitch
Various cables

Advertisements

The advertisement materials provided me consist of a FAX copy dated 7/25/89 from the FDA entitled "The Biopath System, Computer Assisted Systemic Evaluation" under THE BIOPATH SYSTEM, INC. author logo with stated business location of Box 210, Cameron Park, CA 95682 (Attachment A). Telephone numbers are (800) 323-5788, (800) 942-8742 (Calif), and (916) 677-7930 (FAX).

The advertisement states, "This computerized prediagnostic evaluation system is actually a sophisticated combination of electronic biofeedback technology and computer information for testing reactions to foods, chemicals and medications... Because the procedure only requires the measurement of changes in skin resistance at topical meridians it is non-invasive... Before the patient is aware of a pathological process and long before most clinical data can be obtained, Biopath technology can come forth with accurate results... Because electronic biofeedback is based on elementary scientific facts, all measurements of human ills can be repeatedly demonstrated and documented... The Biopath System is more than just a means of monitoring physiological states. It is used to accurately select nontoxic formulations that possess a long history of alleviating specified conditions... The Biopath quickly determines where the patient may have an imbalance in his body and then accurately determines the appropriate homeopathic remedy to restore proper balance." Additionally, the advertisement states that a diploma is issued to Licensed Health Professionals upon successful completion of a twenty (20) hour Biopath System indoctrination and training program.

The second piece of advertising material is a "Dear Doctor" letter and accompanying order form for homeopathic drug remedies (Attachment B). The letter refers to a Homeopathic Research Institute located at 3294 Royal Oaks Drive, Suite 203, Cameron Park, CA 95682. The letter focuses upon the use of the BIOPATH SYSTEM in the practice of the Chiropractic. The order form lists homeopathic drug preparations (remedies) which may be ordered presumably based upon the indication of diseases or conditions diagnosed by the BIOPATH device.

Based upon statements in the advertising materials supplied to me, I conclude the following about the BIOPATH device:

1. The device is a noninvasive diagnostic device intended for the diagnosis of diseases by licensed health care professionals.

2. The device is promoted in the advertising material as being safe and effective for the purpose of diagnosing diseases and conditions.

3. The device is a prescription device as identified in the California Health and Safety Code (HSC), Section 26660, because of the toxicity or other potentiality for harmful effect of some types of homeopathic drug remedies which may be indicated by the device.

Because the composition of the device is not generally recognized by experts as having been adequately shown to be safe and effective for the intended use as indicated in the advertisement materials, I conclude that the device is a "new device" as defined is HSC, Section 26020. This device would be a "significant risk device" as defined in Title 22, Code of Federal Regulations (CFR), Part 812.5(m)(3) if the device is used for diagnosis without benefit of confirmation by another, medically established diagnostic product or procedure.

A recent conversation on September 14, 1989 with VIVIAN DAVIS, Executive Director with the Board of Chiropractic Examiners, indicates that the treatment of diseases such as cancer, heart disorders, venereal diseases, renal diseases, and a variety of other diseases falls outside the scope of chiropractic practice.

Device Labeling

In review of the BIOPATH SYSTEM MANUAL (Attachment C), I found no warning statement for prescription devices as required by HSC, Section 26664. Likewise as the device is concluded to be a "new device" and therefore subject to CFR, Part 812 et seq., I found no warning statement such as "Caution -- Investigational Device, limited by Federal law to investigational use" as required. These two required statements were also not evident on the label of the device.

The manual provides the basis of the theory of operation and operating procedures indicating that the device is intended for use as described in the Advertising section of this evaluation. The basic theory of operation stated is a point measurement, or group of point measurements, of skin resistance. The points are identified acupuncture points corresponding to the function of various body organs. "Abnormal" reading(s) indicate acute or chronic body disfunction or disease which can be "balanced" or treated with a corresponding indicated homeopathic drug remedy(ies). The use of the term "biofeedback" used in the manual and in the advertising material relates to the alleged ability of the device to obtain other point measurements after the patient has come into contact with a "balancing" homeopathic drug remedy prescribed to treat the disease or condition first indicated by the device.

Hardware Evaluation

The device is a personal computer made unique as a diagnostic device by virtue of its custom interface board, footswitch, metal plate, electrodes, and software.

The function of this board appears to be that of supplying a constant current source for the determination of body point resistance as a function of varying voltage between the probe and ground electrodes. This resistance signal is converted from analog to digital form and then used by the BIOPATH software.

The approximate 10" by 6" by 0.5" aluminum metal plate is placed in series with an electrode. There are a number of holes drilled to one-half depth on one side of the plate apparently to hold some other component. Its purpose is unclear; however, there is an indication in the BIOPATH SYSTEM MANUAL that an indicated homeopathic drug remedy or "item" can be placed to "effect" the client. The plate may be a repository for such items. The footswitch is used within the BIOPATH program to change the diagnostic area under

measurement, a function which can be performed also with the cursor arrows of the keyboard.

The hardware used for this measurement process cannot be considered as new technology. Similar methodologies are employed for a variety of medical devices including: impedance cardiographs, galvanic skin response (GSR) measurement devices, breathing rate measuring devices, and any similar device which measures biological resistivity and a function of varying measured biological voltage. The use of the metal plate, however, cannot be recognized as performing any useful function.

Software Evaluation

The BIOPATH software is accessed using a standard DOS operating system. The programs on this device reside in a BIOPATH subdirectory from the Root directory. Initiation of the BIOPATH is accomplished by starting the program: AA.EXE. Various files are evident in the subdirectory such as:

AA.EXE	executable BIOPATH program in machine code.
LISTTUT	an ASCII listing called "The Inventory" describing a Vision System 4000.
*.DAT	various ASCII files referencing indexes, eg: ARBIG.DAT - Area list BIG.DAT - Items list POINT.DAT - Code and list of acupuncture testing points. HOLD.DAT - Temporary items hold list.
HELPS.HLP	an ASCII help file to aid operation.
NOTE.PAD	an ASCII code referencing a patient.
*.PCX	various picture graphics files.

BIOPATH has three primary modules which are: Tutorials, Functions, and Tests. The Tutorial module consists of basic information on the theory and standard nomenclature of the point measuring technique complete with some instruction on point measuring locations located on the hand and foot. The Functions module provides basic information of the hardware parameters of the computer and is not incidental to the operation of BIOPATH device other than to specify some operational parameters.

The Test module consists of a client database entry screen, an "Areas" list, and an "Items" list. The "Areas" list consists of 16 general categories of homeopathic drug remedies and diseases such as: Environmental Pollutants, Pesticides, Radiation, Allergy Food List, and Arnica. Inclusive in the "Items" list are what appears to be a number of diagnostic results and homeopathic drug remidies, including, in part, cancer diseases, microbial diseases, and renal diseases, as part of the ARNICA category. The ARNICA list is included as Attachment D.

From the BIOPATH SYSTEM MANUAL, I am able to discern one method of device operation:

1. Obtain "base" point resistivity readings on acupuncture points corresponding to diseases or conditions under evaluation.

2. Use the "scan" feature to determine which "Area" is indicated, eg: Arnica, Environmental Pollutants, and Pesticides, by obtaining a "post" point resistivity reading. Based upon the "balancing" of this "post" reading, the appropriate "Area" is selected by the BIOPATH device.

3. After an "Area" is indicated, use the "scan" feature to determine which "Item" is indicated.

Using this procedure but simulating the point resistivity values using a known resistance, I was able to operate the BIOPATH device in an attempt to discover if the device did indeed purport to diagnose diseases or conditions, or prescribe treatments in the form of homeopathic drug remedies. Based upon my responses to the BIOPATH device to whether or not a resistivity reading was "balanced", the device selected certain "Items" such as lymphogranulomatose and chondrosarcomium, both which are human cancerous diseases. Lymphogranulomatosis is an infectious granuloma of the lymphatic system also known as Hodgkin's disease, and chondrosarcoma is a malignant tumor derived from cartilage cells or their precursors.

There is indication that the device-selected "Item" can "balance" the disease or condition by "effecting" the patient with the corresponding homeopathic drug remedy. In using a static resistance of 100 Komhs (nominal skin resistance value) in parallel with a 0.1 uF capacitor which creates an "abnormal" resistivity reading, I observed no change in either the "base" or "post" measurements for an indicated item. It is therefore unclear if the BIOPATH software is able to artificially "balance" the disease or condition by virtue of its intrinsic programming and thereby provide indication that the corresponding homeopathic drug remedy would function similarly. The BIOPATH device purports to have the capability of specifying the dosage of the homeopathic drug remedy which would provide the correct "balancing" or treatment for a patient. I was unable to duplicate this function in my investigation.

Based upon my initial investigation using the above described procedures in operation of the BIOPATH device, it was unclear to me whether the device purports to diagnose diseases or conditions, or to prescribe treatments for diseases or conditions. However based upon my contact with TRYSHA TROTTI, Food and Drug Investigator who has a working knowledge of the device, I believe the device purports to diagnose diseases or conditions while at the same time purports to prescribe what homeopathic drug remedy(ies), including dosage, is indicated for the diagnosed disease(s).

Discussion and Conclusions

Measurement of body point resistivity, the basis for the operation of the BIOPATH device, is highly dependant upon a number of factors including:

STANFORD, CALIFORNIA 94305-2205

DEPARTMENT OF MATERIALS SCIENCE AND ENGINEERING

January 24, 1990

Mr. Floyd E. Weston, President
The Biopath System, Inc.
3294 Royal Drive, Suite 203
Cameron Park, CA 95682

Dear Floyd:

I have read the report "Medical Device Evaluation" of September 26, 1989, by Mr. Mark R. Emmerson, and would like to direct a couple of comments to the technical competence of his measurement tests.

First, he tries to simulate the electrical characteristics of the skin with a resistor and a capacitor. This is not satisfactory, as careful studies show that the electrical equivalent circuit of the skin has both a high frequency (short-time constant) circuit in series with a low frequency (long-time constant) circuit and each of these consists of a parallel capacitor, resistor and diffusional admittance (time-varying impedance). This leads to a time-varying current with both a rising and a falling portion that form the basis of quantitative measurement by the device. His simple test circuit could not possibly mimic the essential behavior of the Biopath device.

Second, his connection between an inadequate electrical measurement and a software homeopathic remedy representative, designed to perturb the electrical characteristics of a living system, has no relevance since he has an inappropriate input.

Much more could be said but this should be sufficient to show that Mr. Emmerson did not do his homework correctly and performed a totally inadequate test of the device.

Sincerely yours,

Bill

William A. Tiller
Professor

WAT/mp
Encl.