

[54] **METHOD AND APPARATUS FOR MONITORING AND COUNTERACTING EXCESS BRAIN ELECTRICAL ENERGY TO PREVENT EPILEPTIC SEIZURES AND THE LIKE**
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[58] **Field of Search**..... 128/2.1 R, 2.1 B, 2.1 P, 128/2.1 Z, 2.06 D, 419 R, 419 S, 422, 1 C, 410

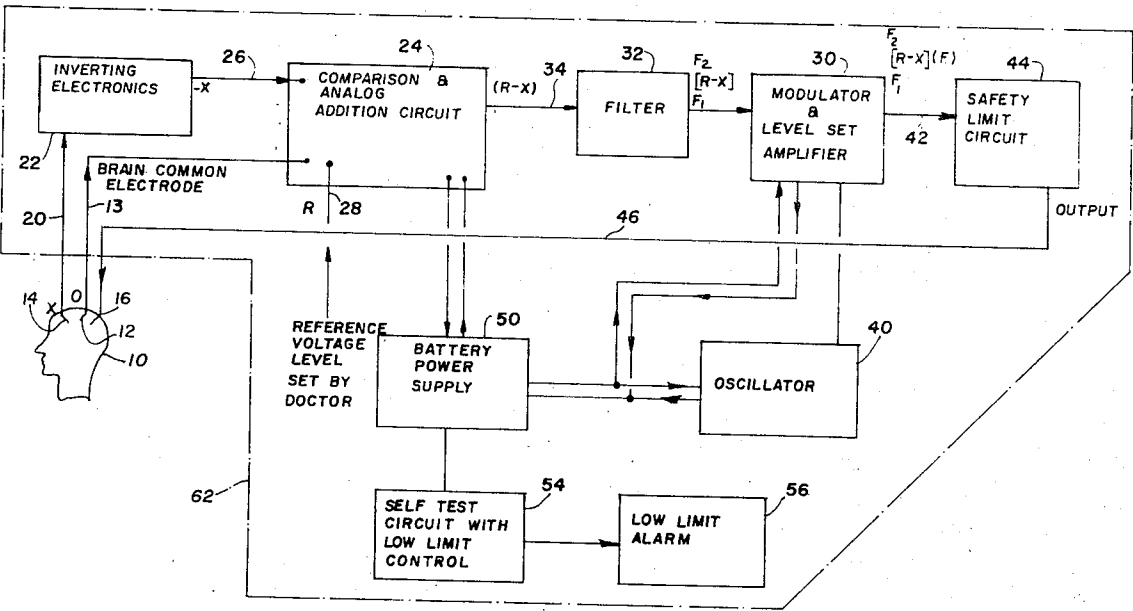
[56] **References Cited**
UNITED STATES PATENTS
3,032,029 5/1962 Cunningham..... 128/2.1 R
3,495,596 2/1970 Conduct..... 128/1 C
3,510,765 5/1970 Baessler..... 128/2.06 A
3,513,834 5/1970 Suzuki et al..... 128/2.1 B
3,587,563 6/1971 Ragsdale..... 128/2.06 A
3,699,970 10/1972 Brindey et al..... 128/419 R

OTHER PUBLICATIONS
John Osmundson, "Matador with Radio Stops Wired Bull" New York Times Newspaper, pg. 1 & 20, 5-17-65.

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[57] **ABSTRACT**
This invention pertains to a biomedical detecting and control apparatus wherein electrical signals in the brain of mammals are continuously monitored by electrodes implanted in certain critical places in the brain wherein excess electrical energy is manifest during epileptic seizure conditions as well as during psychic storms of some types of mental illness. Such signals are processed via electrical systems of various circuits for inversion, comparison, vector analog addition, filtering, modulation, level set, safety level limits and self test to provide a controlled signal output which automatically reduces or eliminates the excess electrical energy at the point of detection. The points of detection and control may be, but do not have to be, the same spots on the brain. The probes may be near the surface of the brain or deep set in the brain depending upon the area affected. In addition to the method, there is described an electronic device which is contemplated to be housed in a small housing outside the body of the mammal and connected through wire conductors connected to the electrodes at the point of detection and at the other end of the conductors to outlet connectors in the housing providing the point of control.

10 Claims, 3 Drawing Figures



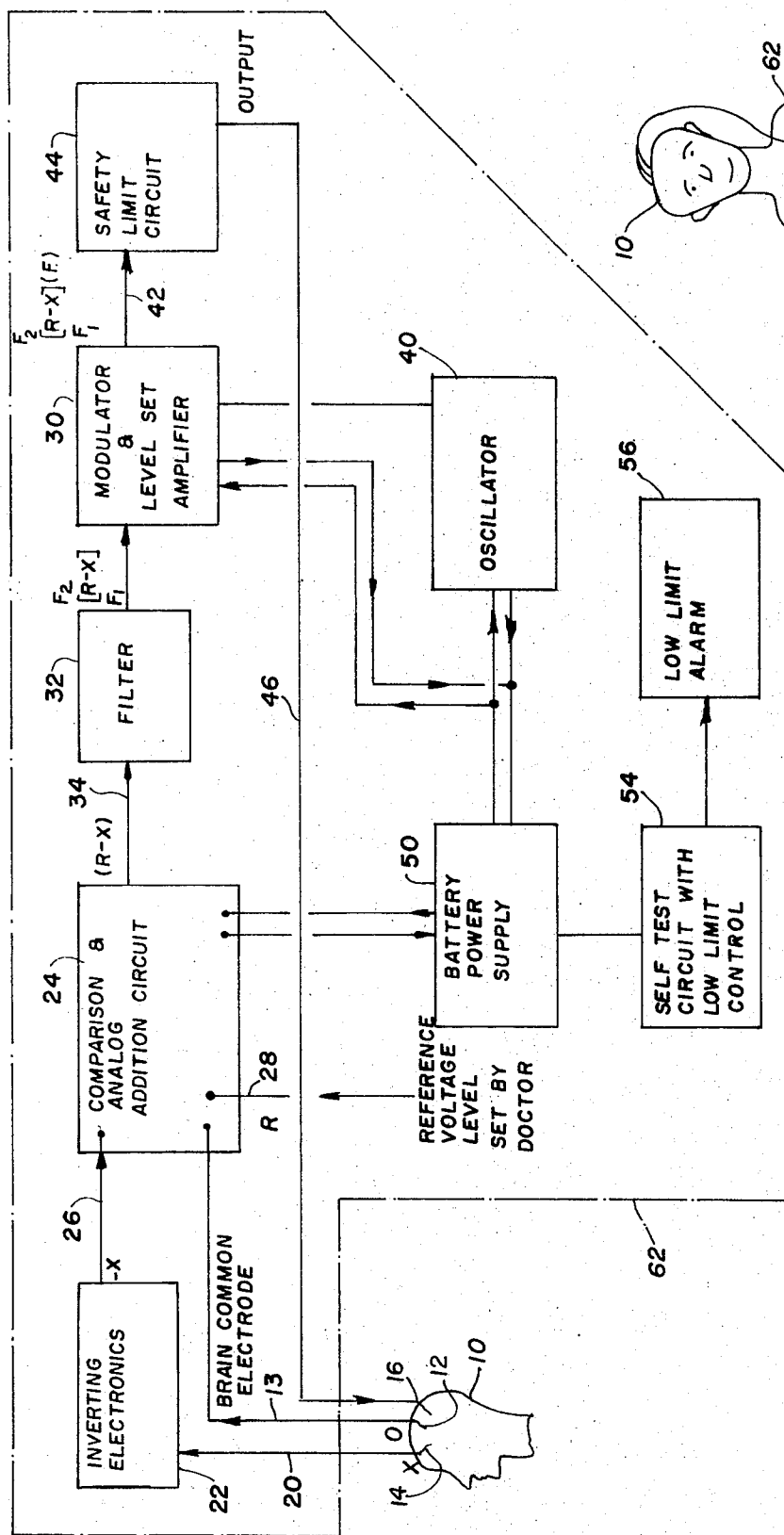


FIG. 1

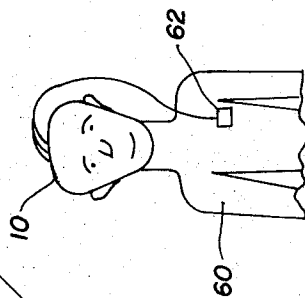


FIG. 3

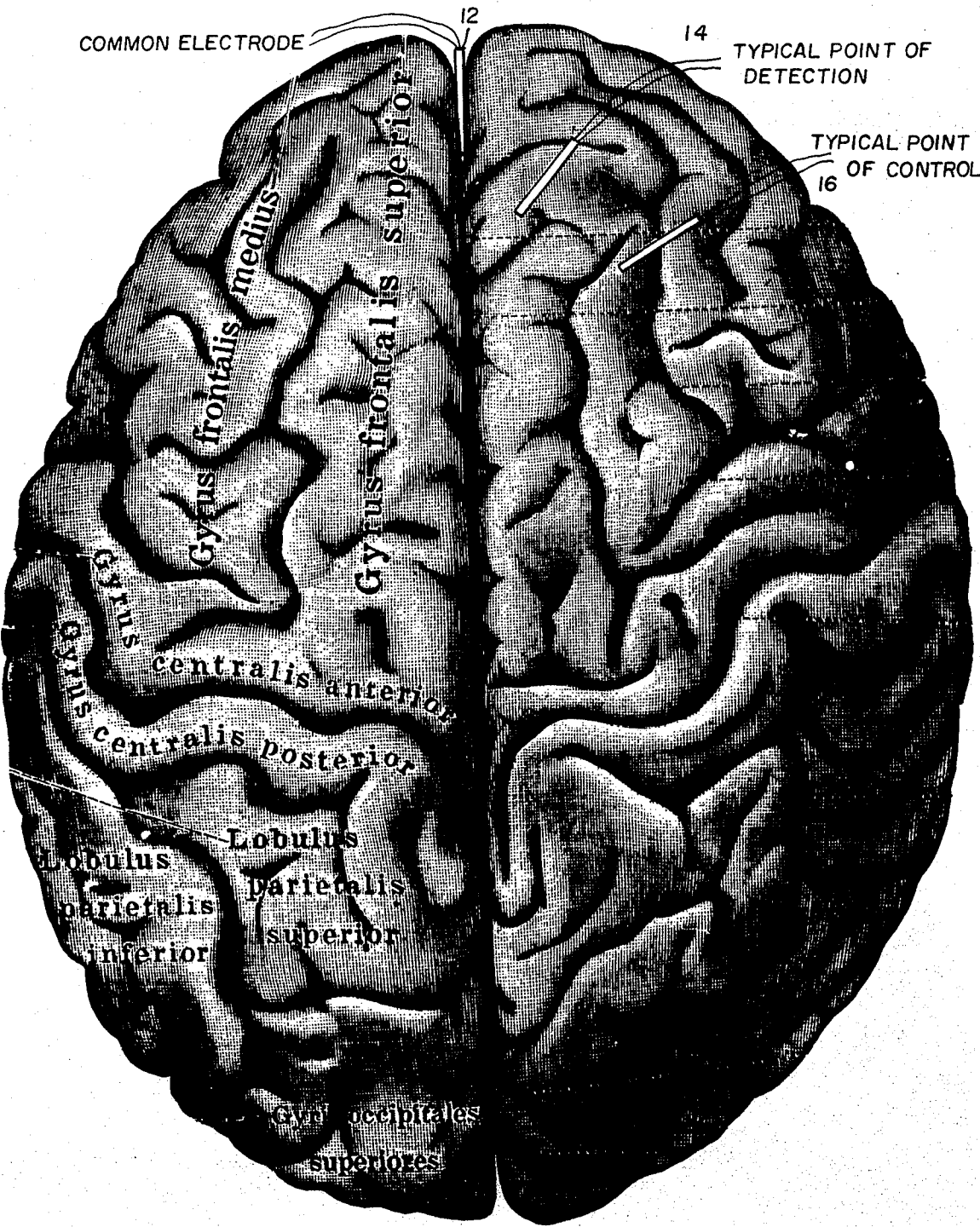


FIG.2

METHOD AND APPARATUS FOR MONITORING AND COUNTERACTING EXCESS BRAIN ELECTRICAL ENERGY TO PREVENT EPILEPTIC SEIZURES AND THE LIKE

BACKGROUND OF THE INVENTION

1. Field of the Invention

With reference to the classification of art as established in the U.S. Patent Office the present invention pertains to art found in the Class entitled, "Surgery" (Class 128) and the subclass of "pulsating and alternating electric circuits" (subclass 421).

2. Description of the Prior Art

Many patents are directed toward analysis of and conditions causing mental illness. These studies of mammal brains and the resulting behaviors have confirmed that electrical impulses within the brain cause predicted results in parts of the body associated with specific areas of the brain. Among these patents are U.S. Pat. No. 3,495,596 to CONDUCT as issued on Feb. 17, 1970; U.S. Pat. No. 2,368,207 to EATON as issued on Jan. 30, 1945 and U.S. Pat. No. 2,473,378 to LIBERSON as issued on June 14, 1949.

As a result of these studies of mammals, including humans, it has been found that there are certain types of epilepsy and psychic diseases (mental illness) wherein an aura condition exists prior to the happening of an epileptic or psychic storm. During that period of time it has been found that the level of electrical activity rises by a magnitude of 5 to 10 times the normal 10 millivolt level typically found in the average human brain. The frequency of the brain signals change from 5 to 8 herz down to one-half to one herz. During this storm period in particular areas of the brain, the pattern of electrical activity or irregularity can spread to other various spots and areas of the brain much in the way worn electrical insulation may give way to excess electrical potential causing an electrical discharge either locally or in large areas depending on the specific characteristics of insulation and voltage application. Just as electrical systems of extreme precision are protected and controlled by regulators, filters, fuses, etc. so also is it a purpose of this device to counteract automatically any excess electrical energy in the brain at the spots being monitored and detected.

Cases have been reported wherein olfactory senses have been utilized to overcome the aura effect and by this means prevent the consequential seizure. This has produced a belief that, at least in some cases, the electrical energy in the brain indicated by such reaction can be duplicated under controlled conditions and can be used to control a brain center other than at the place at which the excessive aberrant energy is resent. Hence, the method and present. of this invention contemplates conditions where implanted electrodes for detection and control may be placed in selected parts of the brain not directly involved with the excessive pattern.

Temporal lobe epilepsy is a typical disease where it is believed to be necessary to provide deep implanted electrodes; first of all to detect the electrical presence of the aberrant energy and second of all to counteract locally this excessive aberrant energy. The method and apparatus of this invention is intended to provide the detection means and the electrical signals necessary to counteract and restrain these excesses.

SUMMARY OF THE INVENTION

This invention may be summarized at least in part with reference to its objects. It is an object of this invention to provide both the method and the means of monitoring the brain of a mammal by means of permanently inserted electrodes in selected critical areas of the brain. By connecting these electrodes to a monitoring device, safety limits for brain signal outputs can be evaluated and upon indications of excess outputs counteracting signals can be fed to the brain to prevent aberrant activity as produced in certain mental illness conditions and epilepsy seizures.

In addition to the above summary the following disclosure is detailed to insure adequacy and aid in understanding of the invention. This disclosure, however, is not intended to prejudice that purpose of a patent which is to cover each new inventive concept therein no matter how it may later be disguised by variations in form or additions of further improvements. For this reason there has been chosen a specific circuit diagram showing a means of employing the signals within a brain of a mammal and by monitoring and counteracting excessive energy showing a preferred means for preventing these excesses. This specific embodiment has been chosen for the purposes of illustration and description as shown in the accompanying drawings wherein:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 represents a block diagram showing the principal operation of the apparatus;

FIG. 2 represents a pictorial representation of a human brain and the typical implanting of three electrodes for control of epileptic seizure conditions, and

FIG. 3 represents a diagram showing the attachment of and the support of the apparatus to and by a human.

In the following description and in the claims various details will be identified by specific names for convenience, these names, however, are intended to be generic in their application. Corresponding reference characters refer to like members throughout the three figures of the drawings.

The drawings accompanying, and forming part of, this specification disclose certain details for the purpose of explanation of the broader aspects of the invention, but it should be understood that details may be modified without departure from the concept of the invention and that the invention may be incorporated in other structural forms than shown.

PRINCIPLE OF OPERATION AS SEEN IN THE ASSOCIATED BLOCK DIAGRAM

In the skull or head 10 of the mammal a common electrode 12 is placed into the frontal bone or other zero level activity point from which to detect levels of normal and abnormal electrical energy created in the brain. This electrode is connected by a conductor 13 to an electronic circuit.

The second detecting electrode 14 is placed into one of the critical brain areas such as the epileptogenic lesion portions of the skull 10, while a third electrode 16 is placed into a control point of the brain. This may be in the same area as the detecting electrode or a different area of the brain.

Signals from electrode 14 are fed through a conductor 20 to an inverting electronic device 22 which changes the electrical phase of the detected signal in preparation for use by a comparison circuit 24. The signal from the inverter 22 is fed to the comparison circuit through a conductor 26.

A reference voltage level R, which typically may be about 10 millivolts in the case of a human, is set by the doctor in charge who has determined by appropriate tests the level of voltage in the brain beyond which the patient to which the device is affixed needs a counter-motive force brought to action to quell the ensuing anticipated storm. This reference voltage after the level has been established is set and then is fed to the comparison circuit 24 through a conductor 28.

The comparison and analog addition circuit 24 will perform a vector addition so that the resultant R-X should be a quantity negative in phase to that of the original detected value X from electrode 14. The resultant is such that $X+(R-X)$ equals the value R, the normal set level. However, it may be found that the point of control as compared to the point of detection may be scale factors apart. When this occurs a level set amplifier 30 provides compensation for such a condition.

Between the output from comparison circuit 24 which is fed to amplifier 30 is a filter 32 which receives the output (R-X) from circuit 24 as fed through conductor 34. This filter 32 is used to prevent the electronics of the brain analysis from interfering with other electrical functions such as heart beat and respiration. An oscillator 40 is adapted to generate a high frequency signal which signal is used as a carrier for the feedback information being communicated to the brain point of control.

Since the synaptic chains (in the brain) have the manifestation of semiconductors in that they act as diode detectors as in a radio circuit the information provided to the synaptic circuits is oriented in such a manner that the normal operation of the nervous system will now detect the control data at minimum energy level to accomplish the needed reduction of the brain energy at the localized areas and provide an elimination of the excess electrical energy in the brain.

Signals from the modulator 30 are sent through conductor 42 to a safety limit circuit 44 which provides standby passive and active networks which act as a limiting fuse to insure and prevent any excessive energy from the said electrical apparatus to be fed to the brain to cause or affect the brain or other nervous system. Signals from the circuit 44 to electrode 16 is carried by conductor 46. A battery power supply 50 energizes the circuit and because of the serious nature of this control device and what a deficiency in energization would cause preferably includes a self test circuit with a low limit control 54 and an alarm 56 for extra protection.

Referring next to FIG. 3, there is depicted the normal arrangement and mounting of the apparatus on the patient. The electrodes 12, 14 and 16 are implanted in the brain in the skull 10 of the patient 60 to be treated and controlled. Conductors 13, 20 and 46 carry the signals and controlling voltage to the electronic circuits carried in a small case 62. The components carried by the case are enclosed in phantom outline in FIG. 1. Except for the battery power which is contemplated to be a small battery, the circuits providing the inverter 22, the

comparison and analog addition 24, filter 32, modulator 30, safety circuit 44, oscillator 40 and self test circuit 54 are all contemplated to be solid state miniaturized as much as possible. The reference voltage set is usually an adjustable resistor located within the case and set by key means to prevent an accidental change. It is contemplated that the case 62 when used externally is less than the size of a package of cigarettes. With integrated circuitry the case 62 may be made even smaller for implanting under the skin of the patient 60.

USE AND OPERATION

Automatic feedback control is the essence of this invention in that this control receives signals indicating aberrant energy from the brain, analyses it electronically as necessary and with a proper safety and power supply means then feeds electric energy back into the brain in opposition to the original aberrant level so that the net resultant voltage, current and/or electrical field in localized areas on the brain is maintained at no level greater than that experienced during normal behavior. The electronic feedback device of this invention is applied not only to those types of epilepsy where aura is electrically seen prior to an actual seizure (typified by some types of Grand Mal and Temporal Lobe Epilepsy) but also is applied to some types of mental illness where psychic storms occur providing electrical activity in the brain similar to that of epilepsy but having as its manifestations psychic storms instead of physiological seizures.

The means of detecting and controlling the voltage level of the brain is through the use of implanted electrodes 12, 14 and 16. The reason for employing implanted electrodes as compared to surface electrodes is to provide the exact point of application in the brain where either the point of detection or the point of control can be found without having the electrical path through the skull either deteriorate the signal in terms of the detection signal due to the impedance of the fluids, tissue, skull bone and other media between such point of detection and an external point. Similarly, a control signal for feedback data, if applied externally, would require a larger electrical signal to produce a comparable control. Typical electrical voltages represented in medical research studies reveal that when monitored internally a normal brain pattern signal can reach 10 millivolts while the same signal monitored outside the skull produces a level of approximately 10 microvolts.

The aura condition of an epileptic seizure can in fact increase the electrical activity a factor of 10 times to a level 100 millivolts (when monitored internally). Hence, for a corrective signal to be applied in opposition to such an aberrant level, a minus 90 millivolts level would be internally applied whereas approximately minus 90 volts would be externally applied; a quantity which could be dangerous. Therefore, in the present invention internal electrodes are to be used so that the voltage control will be at low levels which is safe.

The concept of automatic feedback has been used in the field of servo technology for many years. The uniqueness of the present invention is the application of automatic feedback theory and devices wherein the electrical energy of a mammal such as a human is considered part of a servo loop in the automatic feedback.

The normalizing of this current flow provides a resultant improvement in the mammal's performance where without such feedback control afflictions such as epilepsy and mental illness prevent the normal behavior of that particular mammal and the resulting deterioration caused by the affliction.

The employment of this system requires implanted electrodes, transdermal wires and external electronics. It is noted that just as history with heart pacemakers has shown that totally implanted devices can be made practical, so also is it anticipated that this device with sufficient experience and history will be implanted with the application of electronic miniaturization. The miniature electronic detection and control device of this invention will be capable of being totally implanted thus eliminating transdermal wire with the inherent possibility of damage and failure of the system.

In use, detected signal from electrode 14 is carried by conductor 20 to an inverting circuit 22 where the signal is reversed in polarity (minus the reference voltage level) in order to be added to the aberrant brain electrical level during the epileptic or psychic storms. This causes the brain voltage to be reduced to that of the reference level. This action is similar to that of adding several voltages together in an analog computer at a "summing junction" where the resultant electrical levels are the algebraic sum of all voltages added at that point. This, of course, takes into consideration the sign or phase of the voltages being added.

The "common" or "ground" electrode 12 is used as a reference point against which the electrical levels at the point of detection, the point of control and all other computing reference and safety electrical levels is judged and conditioned.

The inverted signal $-X$ from circuit 22 is carried by conductor 26 to the comparison and analog addition circuit 24. Also to electronic circuit 24 is fed signal R which is carried by conductor 28 and is the reference voltage level set by the doctor. Another signal is the brain signal from the "common" electrode 12 which is fed to this comparison circuit. Direct current power to operate the electronic circuitry is derived from the power supply 50 which has its own related safety and self-test circuitry 54 which when used as a permanently installed unit includes a low limit alarm 56 which indicates when a malfunction or voltage loss occurs.

The comparison and analog addition circuitry 24 receives the inverted signal $-X$ from conductor 26 and combines this algebraically with signal R carried by conductor 28 so that the electrical quantity $R-X$ is produced as a raw signal yet to be conditioned for use as the ultimate feedback signal. This raw signal is fed by conductor 34 to the filter 32 which removes all frequency components which could effect vital functions such as respiration and heart action. The frequency band usable for these functions is approximately 5 to 40 herz. The signal entering the modulation and level set amplifier 30 is the electrical quantity $R-X$ limited within the frequencies of F to $F2$ (approximately 5 to 10 herz).

The oscillator 40 and modulator level set amplifier 30 are both operated from the same battery power supply 50, noted above.

The oscillator generates a high frequency carrier signal wherein there is created a selected frequency having a range from 40,000 herz to 1 million herz. The need to use a high frequency carrier is so as to utilize

the lowest voltage possible in the carrier electrical signals and also to utilize the inherent electrical phenomenon manifest in the synapsis of the brain. Since the electrical nerve pathways in the body are really composed of synapsis which react to provide electrical energy transfer similar to the semiconductor devices called diodes the operator of the device is able to forecast the utilization of these synaptic pathways as diode detectors. This means that the diode characteristic which is used in radio circuits to separate the audio information from the high frequency carrier signal is like the present circuit of this invention where it is planned to use the conditioned feedback signal to detect and provide for brain control utilizing the brain synapsis. The brain synapsis is employed to demodulate the correct data from the high frequency carrier which by itself is not seen by the rest of the body. The level set amplifier 30 is set by the doctor so that the particular mammal being treated has the determined electrical levels set to compensate for the particular levels required to stabilize the brain activity of that mammal. If the control signal is fed back into the same area from which the electrode received signals are set, the voltage is likely to be at unity value with respect to the originating signal. However, when it is necessary to apply the control signal at a point of control which is different from the point of detection by the electrodes it will be required to use a ratio scale to increase or decrease the control signal experimentally to determine that signal level necessary at the point of control which is required to quell or stabilize the detected aberrant energy in the brain.

The modulator 30 receives the high frequency signal generated by the oscillator 40 and impinges on the signal the envelope of frequencies entering the modulator and level set amplifier 30. These frequencies include the electrical signal quantity $R-X$ filtered from $F1$ to $F2$ by filter 32 which modulates in amplitude the high frequency signal. The resulting conditioned electrical signal is sent by conductor 42 to the safety limit circuit 44.

This safety limit circuit 44 provides additional electrical safeguards to prevent either momentary or long term pulses or continuous electrical signals from developing to a level which will be injurious to the mammal involved. As the time constant of energy of the physiological mammal is in terms of milliseconds and the electrical condition and functioning of the control circuit is in terms of microseconds, the electronic circuit acts at a rate which is responsive and available to assist the physiological needs of the mammal.

Self-test circuit 54 is designed to assure the mammal, when human, to which this device is connected that the electronic circuit is in an operative condition ready for activation without any jeopardy of the operation arising from low battery voltage.

It is anticipated, as above noted, that the initial electronics and power source (battery and control safety circuits) will occupy a volume less than a pack of standard cigarettes and be externally carried on the user. With the use of micro electronics it is further anticipated that this size can ultimately be further reduced and the electronics and power source be mounted beneath the skin surface of the user in the form of a small wafer.

Terms such as "left," "right," "up," "down," "bottom," "top," "front," "back," "in," "out" and the like

are applicable to the embodiment shown and described in conjunction with the drawings. These terms are merely for the purpose of description and do not necessarily apply to the position in which the apparatus for monitoring and counteracting excess brain energy may be constructed or used.

While this particular embodiment of the apparatus and method of use has been shown and described it is to be understood the invention is not limited thereto since modifications may be made within the scope of the accompanying claims and protection is sought to the broadest extent the prior art allows.

What is claimed is:

1. Apparatus for monitoring, analyzing and when required counteracting excess brain electrical energy of a patient to prevent epileptic seizures and the like, said apparatus including: (a) three electrodes adapted to be implanted in the brain being monitored, each electrode connected through conductors to a constantly energized and connected electronic circuit, said electrodes including a first implantable electrode adapted to be placed in a zero activity point of the brain, the electrical output from this first electrode detecting the levels of normal and abnormal electrical energy and feeding this output as a signal to the electronics circuit portion of the apparatus, a second implantable electrode adapted to be placed in a typical point of detection area of the brain, the output from this electrode sent as a signal from this area to the electronic circuit, and a third implantable electrode adapted to be placed in a typical point of control of the same brain, this electrode receiving counter motive forces from the electronic circuit when said circuit so determines; (b) an electronic means and an amplifier means in said electronic circuit, said electronic means receiving the output of the implantable second electrode and inverting this output after which the resulting electrical signal is fed to said amplifier means of the electronic circuit, said amplifier means providing a comparison and addition means to incoming signals; (c) a conductor connected to the first electrode, said conductor being connected to said amplifier means and carrying the electrical energy level of the zero activity portion of the brain to the amplifier which analyzes and compares this energy level in relation to previously established normal; (d) means for sending a reference voltage to the amplifier comparison and addition circuit, this reference voltage established and set by the operator in accordance to previously determined electrical thresholds of the brain of the patient in which the electrodes are to be implanted, this reference voltage being compared by and in said amplifier circuit and where necessary a vector addition is made by this amplifier circuit to add voltage to the inverted received voltage; (e) a circuit means in the electronic circuit for receiving and monitoring the signal from the comparison and addition circuit means and when this signal exceeds a set level amplifies this signal a determined amount; (f) a circuit means providing both passive and active electronic network means for receiving the monitored and amplified signal indicative of excess energy outputs from the second electrode and within predetermined maximum limits provides a counter motive force which is sent through a conductor to the third electrode which force quells this storm in the brain, and (g) a power means connected to the electrical circuit to supply a constantly "on" power

necessary to energize the electrical circuit to normal operating levels.

2. Apparatus for monitoring and counteracting excess brain electrical energy as in claim 1 in which the power means is a battery whose energy level is monitored by a self test circuit means and there is additionally circuit means connected to said power means providing a limit control and an alarm which is actuated when the voltage drops below that set by the limit control.

3. Apparatus for monitoring and counteracting excess brain electrical energy as in claim 2 in which there is provided an oscillator which generates a high frequency signal connected to the circuit means for receiving and monitoring the signal from the comparison and addition circuit, this high frequency signal being used as a carrier for a feedback signal when such a signal is sent to the third electrode.

4. Apparatus for monitoring and counteracting excess brain electrical energy as in claim 3 in which the electronic circuit includes a filter connected between said comparison and analog addition means and said circuit means for receiving and monitoring the signal from the comparison and analog addition means which receives the signal output from electronic circuit means providing the comparison and analog addition function and filters the electronic flow to prevent this flow from interfering with other electrical brain functions such as heart beat and respiration, said filtered signal being conducted and fed to the circuit means for receiving and monitoring the signal from the comparison and addition circuit means.

5. Apparatus for monitoring and counteracting excess brain electrical energy as in claim 4 in which the electrodes are adapted to be permanently implanted and the electronics and battery therefore are encased so as to provide a small size unit which may be easily carried on and by the body of the one being monitored.

6. A method for monitoring and counteracting excess brain electrical energy to prevent epileptic seizures which includes the steps of: (a) implanting three electrodes in the brain of the mammal being monitored, the first electrode being placed in a zero activity point of the brain and from this electrode feeding its electrical output to a constantly energized and connected electronic circuit, the second electrode being placed in a typical point of detection area of the brain and a third electrode being placed in a typical point of control of the same brain; (b) connecting the electronic circuit to the second electrode by a conductor and inverting electronically the output of the brain from this second electrode and feeding the resulting inverted signal to an electronic means in said circuit to provide a comparison and addition means to incoming signals; (c) connecting a conductor to the first electrode which carries the electrical energy level of the zero activity in the brain, this electrical energy being fed to the comparison circuit for analysis of the energy in relation to a normal energy level; (d) setting by the one in charge of the apparatus a reference voltage control level, this reference voltage being fed to the electronic means providing the comparison, said means performing vector addition when necessary; (e) feeding the output signal current of the addition means to a level set amplifier portion of the electronic circuit, which, when necessary, amplifies this current signal; (f) sending the signal

from the level set amplifier to a safety limit circuit portion of the electronic circuit, this portion providing passive and active electronic networks which receive this signal and in the cases of excessive energy outputs from the second electrode and the comparison circuit feeds a countermotive force to the third electrode to quell an anticipated storm in the brain, and (g) providing a power means which enables the electronic circuit portion of the apparatus to be constantly energized.

7. The method for monitoring and counteracting excess brain electrical energy as in claim 6 in which the step of providing the power means is a battery whose energy level is monitored by a self-test circuit having a low voltage limit control and an alarm.

8. The method for monitoring and counteracting excess brain electrical energy as in claim 7 which includes the further step of connecting an oscillator which generates a high frequency signal so as to feed said oscillating signal to the level set amplifier portion of the electronic circuit with this high frequency signal providing

a carrier for the feedback signal to the third electrode.

9. The method for monitoring and counteracting excess brain electrical energy as in claim 8 which includes the step of providing a filter which receives the signal output from the electronic means providing the comparison and analog addition and filters the electronic current therefrom to prevent this current signal from interfering with other electrical brain functions such as the heart beat and respiration and feeding said filtered signal to the level set amplifier portion of the electronic circuit.

10. The method for monitoring and counteracting excess brain electrical energy as in claim 9 which includes permanently implanting the electrodes and further includes encasing the electronics and battery to provide a small unit which may be easily carried on the body of the one monitored.

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