



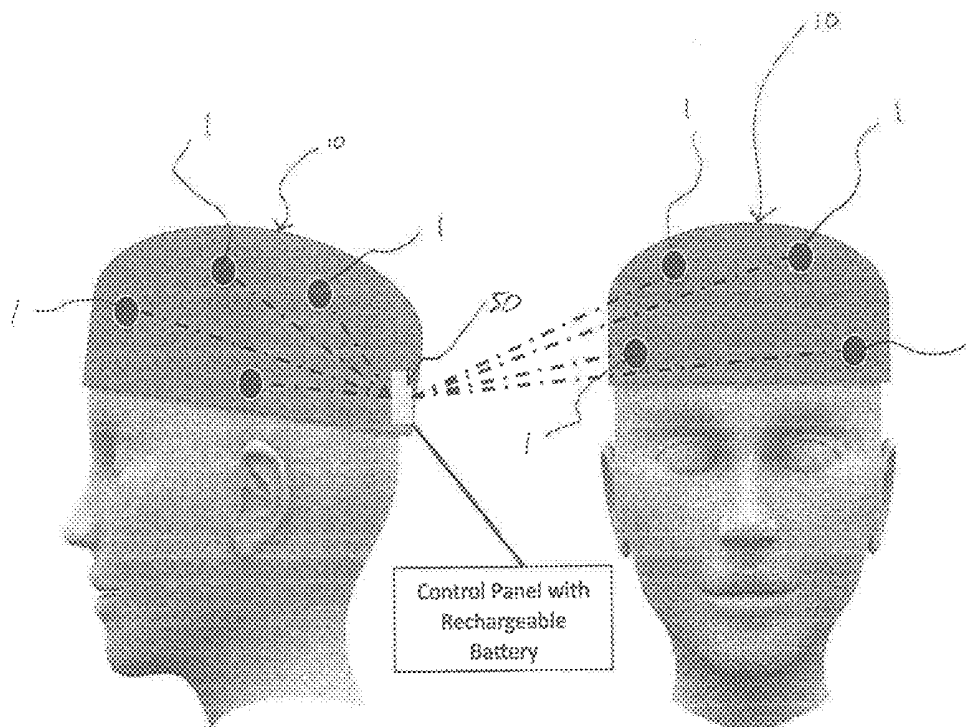
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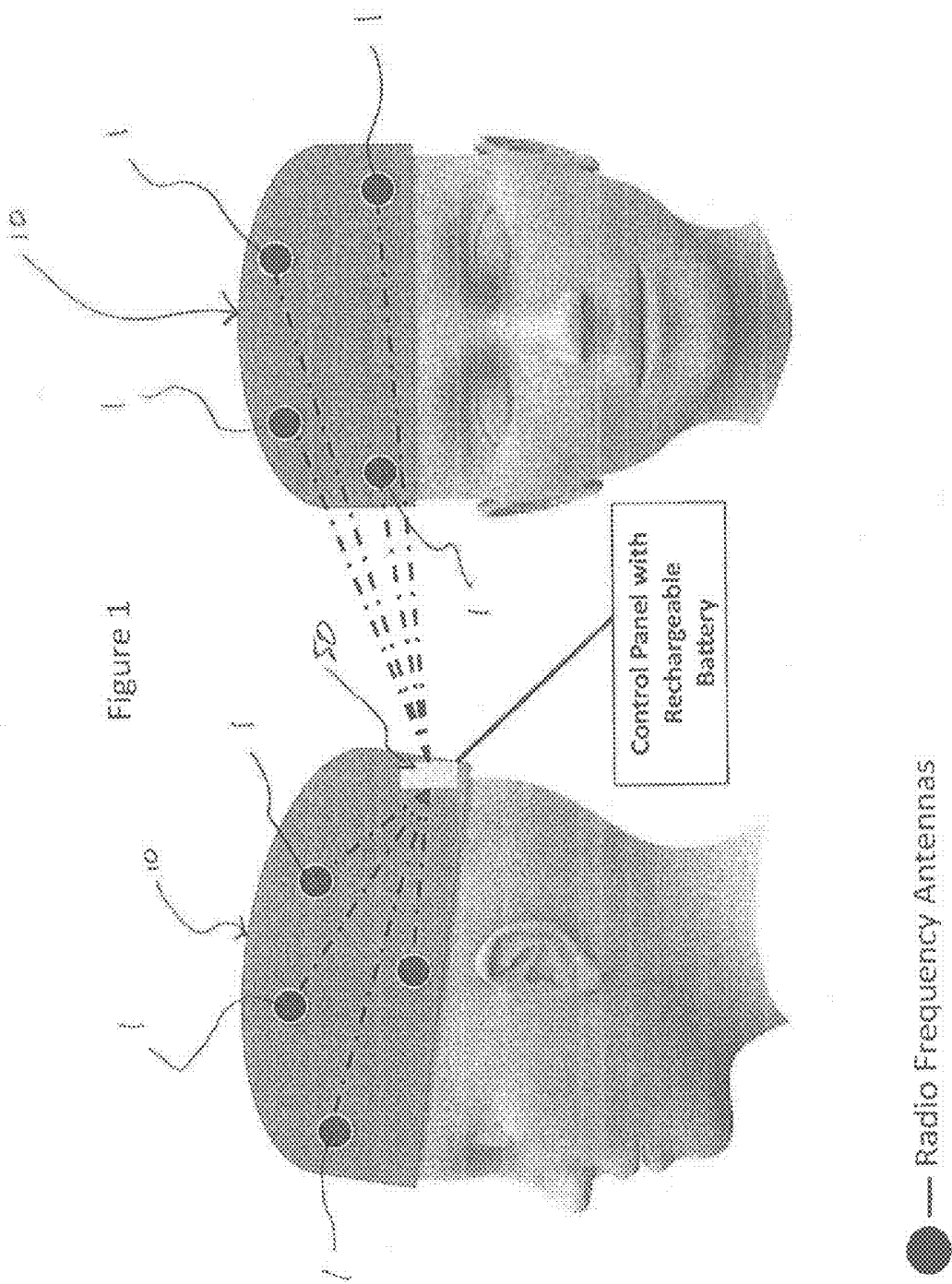
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(43) **Pub. Date: Sep. 11, 2014**(54) **ELECTROMAGNETIC TREATMENT OF
BRAIN AND BODY DISORDERS****Publication Classification**(71) Applicant: **NeuroEM Therapeutics, Inc.,**
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(57)

ABSTRACT

Disclosed are devices, methods, and systems for helping to prevent (or preventing) or treat brain and/or body disorders. Embodiments of the invention have utility for enhancing cognitive function during aging. The invention utilizes electromagnetic stimulation (EMS) that can provide a range of EMS parameters and modalities. The EMS may be utilized in conjunction with physiologic sensors that can provide feedback for possible EMS modifications.

 Radio Frequency Antennas



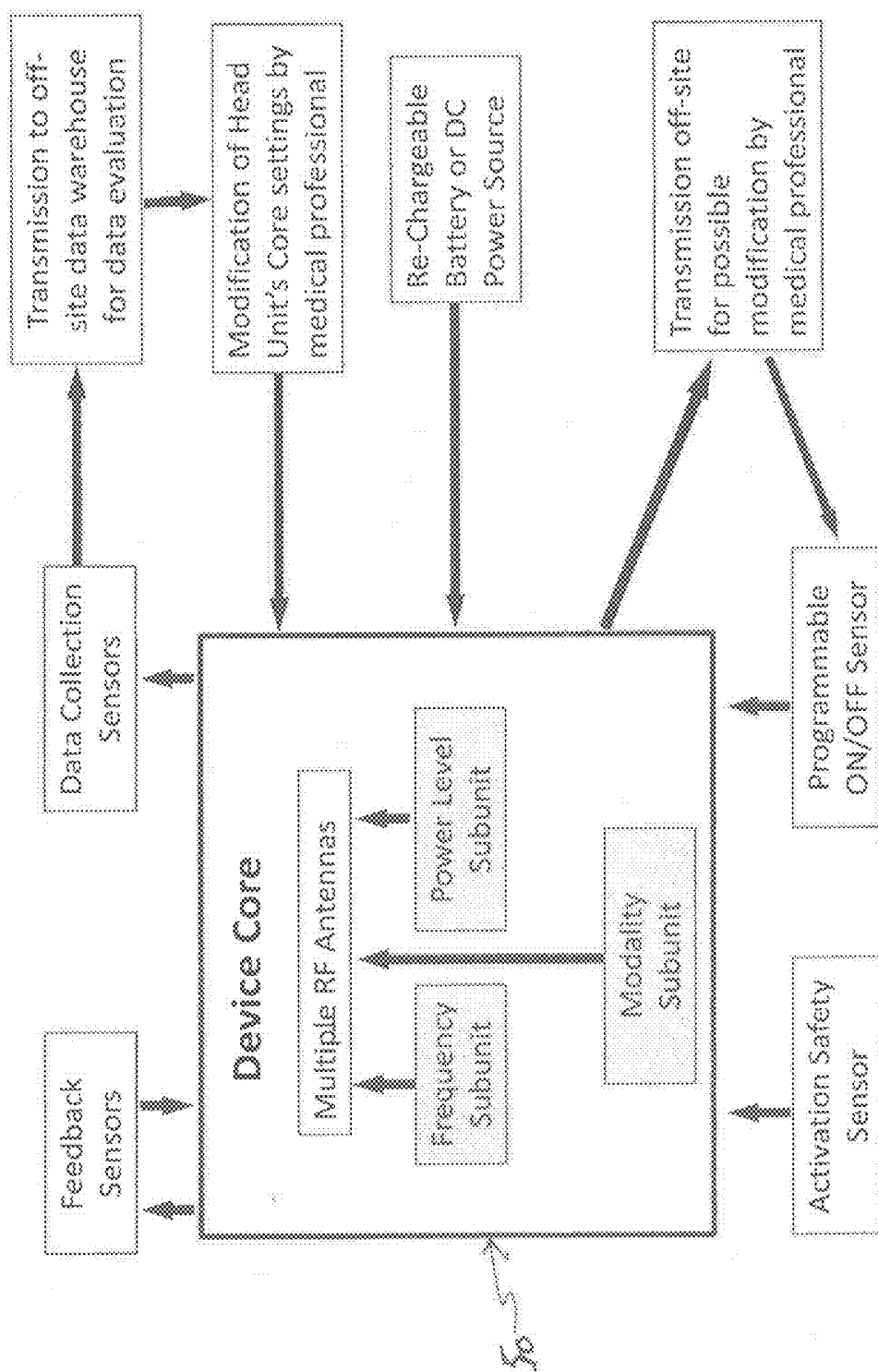
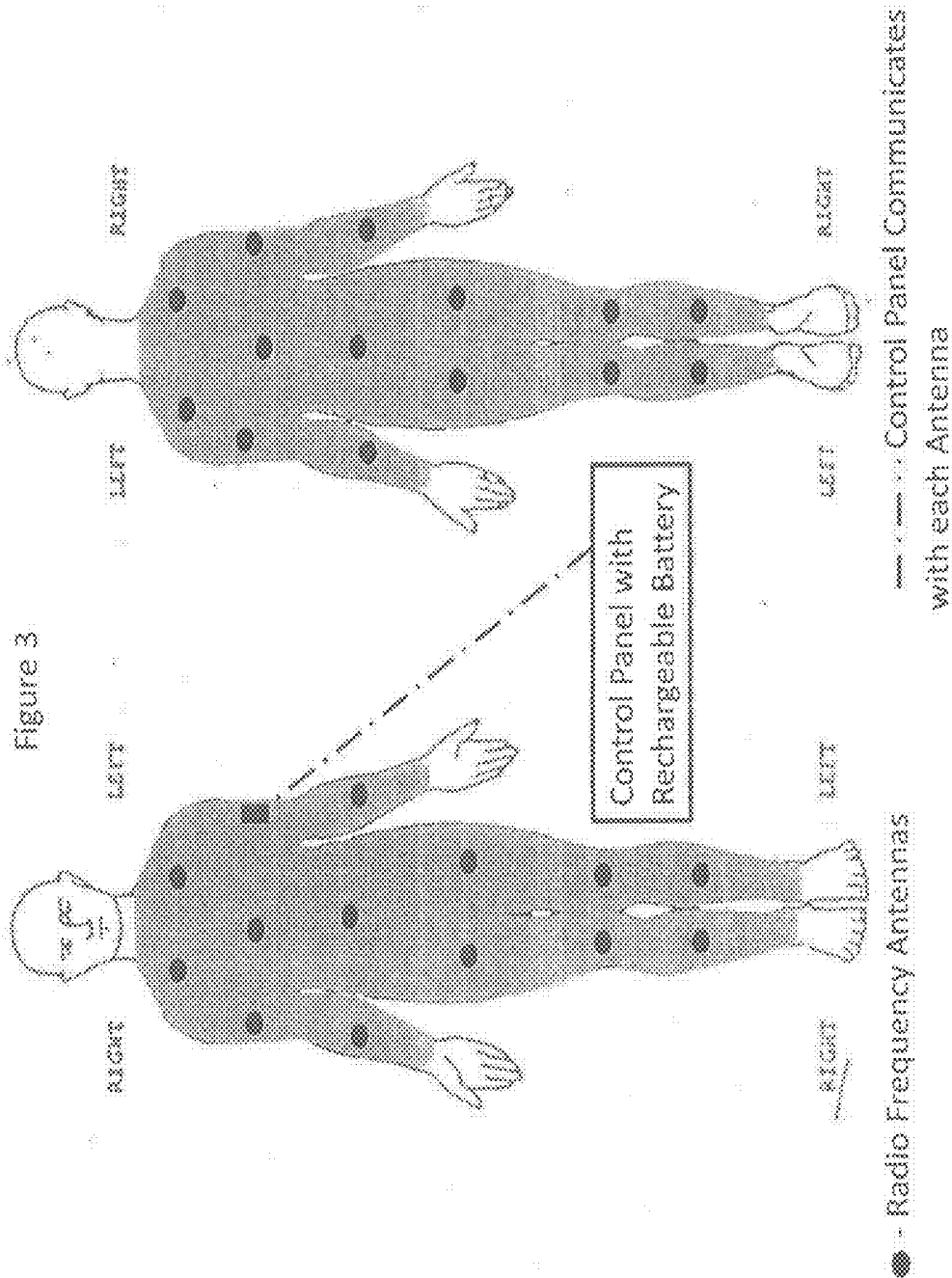


Figure 2



ELECTROMAGNETIC TREATMENT OF BRAIN AND BODY DISORDERS

RELATED APPLICATIONS

[0001] This application claims priority to and incorporates by reference U.S. Provisional Application No. 61/776,097, filed on Mar. 11, 2013.

FIELD OF THE INVENTION

[0002] The invention relates to devices, methods and systems that utilize electromagnetic waves (preferably of ultra-high frequency) and provide therapeutic effects for the brain and/or body and that can help prevent or prevent, ameliorate or eliminate, diseases or disorders, at least some of which are characterized by amyloid protein aggregation, mitochondrial dysfunction, and/or reduced neuronal activity. The invention also relates to devices, methods and systems for providing cognitive benefits to normal individuals, as well as to those with age-associated cognitive impairment or sub-normal cognitive function.

BACKGROUND OF THE INVENTION

[0003] A variety of both neurologic and body disorders involve abnormal amyloid protein aggregation, mitochondrial dysfunction, and/or reduced neuronal activity. Primary among amyloid-aggregating conditions in the brain is Alzheimer's Disease ("AD"), in which the protein β -amyloid ($A\beta$) is abnormally produced by neurons and deposited both within neurons and outside of neurons. The search for a disease-modifying drug to cure, treat or prevent AD has been ongoing, but failed to develop a drug that can prevent and/or treat AD. Other brain disorders, including those characterized by amyloid protein aggregation, for which therapeutics are currently limited or unavailable, include Mixed AD/Vascular Dementia, Cerebral Amyloid Angiopathy, Hemorrhagic Stroke, Multi-Infarct Dementia, Parkinson's Disease, Lewy Body Dementia, Down's Syndrome, Traumatic Brain Injury, Fronto-Temporal Lobe Dementia, Cerebral Traumatic Encephalopathy, Huntington's Disease, and Prion Diseases (Transmissible Spongiform Encephalopathy, Kuru, and Creutzfeldt-Jakob Disease).

[0004] AD and a number of other neurologic conditions are also characterized by mitochondrial dysfunction and/or reduced neuronal activity. Brain mitochondrial dysfunction (low ATP production) occurs in AD, Parkinson's Disease, Huntington's Disease, Amyotrophic Lateral Sclerosis (ALS), mental retardation, stroke, autism, bipolar disorder, schizophrenia, anxiety disorders, mitochondrial encephalomyopathies, epilepsy, migraine headache, and major depression. Reduced neuronal activity is characteristic of AD, stroke and various hyperkinetic disorders such as Huntington's Disease, Dystonia, and Hemiballismus.

[0005] In addition to the aforementioned neurologic conditions characterized by amyloid deposition and/or mitochondrial dysfunction, a number of body disorders also involve one or the other of these two characteristics. Abnormal amyloid deposition/aggregation is present in body disorders such as Type II Diabetes, Cardiac Amyloidosis, Systemic AL Amyloidosis, Atherosclerosis, Rheumatoid Arthritis, Aortic Medial Amyloid, and Familial Amyloid Polyneuropathy. As well, mitochondrial dysfunction is characteristic of body disorders such as Type II Diabetes, Cardiovascular Dis-

ease (including Atherosclerosis), Chronic Fatigue Syndrome, Cardiomyopathy, Coronary Artery Disease, Fibromyalgia, and Hepatitis C.

[0006] Conventional pharmacotherapy has thus far failed to slow or reverse AD adequately, and has minimally-impacted other brain/body conditions characterized by amyloidosis, mitochondrial dysfunction, and/or reduced neuronal activity. There is a need for non-pharmacologic devices, methods, and systems capable of providing effective therapeutic interventions against diseases of the brain and body—all or some having as their common features amyloid deposition, mitochondrial dysfunction, and/or reduced neuronal activity.

[0007] In relation to neurologic conditions, the field of "neuromodulation" involves techniques that can modify brain or peripheral neuronal function at one or several levels. These techniques include the following: Direct Current Stimulation (DCS), Deep Brain Stimulation (DBS), Magnetic Stimulation, and Electromagnetic Stimulation (EMS). With the exception of EMS, these neuromodulatory approaches have drawbacks that hinder their ability to address the afore-mentioned neurologic conditions. These drawbacks include (1) limited brain penetration, (2) only a focal brain area being affected by the treatment, (3) being invasive and expensive, (4) requiring clinical visits, and/or (5) having no demonstrated benefit.

[0008] In contrast to other neuromodulatory approaches against neurologic conditions, studies in AD transgenic mice and normal mice have shown an ability of EMS to prevent or reverse cognitive impairment. Among other things, these studies demonstrate the ability of EMS to: (1) prevent and reverse brain β -amyloid aggregation/deposition in vitro and in vivo, (2) enhance brain mitochondrial function, and (3) increase brain neuronal activity. Such studies are discussed in G. W. Arendash (2012) *Transcranial Electromagnetic Treatment Against Alzheimer's Disease: Why it has the potential to trump Alzheimer's Disease drug development*, Journal of Alzheimer's Disease 32: 243-266 (hereafter, "Arendash 2012"). This article is incorporated herein by reference.

[0009] Since Arendash (2012) shows that EMS enhances cognition in AD mice through anti-aggregation of amyloid proteins, mitochondrial enhancement, and increase neuronal activity, the many neurologic disorders characterized by aggregated amyloid proteins, mitochondrial dysfunction, and/or reduced neuronal activity all can potentially be improved, reversed or prevented by the use of EMS. Moreover, even normal mice respond to EMS with improved cognitive function, enhanced mitochondrial function and increased neuronal activity, indicating the potential for EMS to benefit normal subjects.

[0010] The neuromodulatory approach of EMS has thus far been limited to neurologic disorders. For example, known EMS treatments for AD only teach the use of EMS at a very high frequency and extremely low power (the power is also called the Specific Absorption Rate or "SAR") levels delivered to the ear, and for only a few seconds per session. Prior EMS work involving AD mice has been limited in providing only a specific set of EMS parameters (i.e., 918 MHz, 0.25 W/kg SAR) and a single EMS modality (i.e., GSM, pulsed and modulated), using only a single EMS-emitting antenna, and only full body treatment. For example, such a method is disclosed in U.S. Patent Publication No. 20120065456, the disclosure of which that is not inconsistent with this disclosure is incorporated herein by reference.

[0011] Given the above drawbacks of various neuromodulatory approaches, and the limited nature of the EMS work described above, a need exists for EMS devices, methods, and systems that can provide a range of EMS parameters and modalities for both the body and/or brain. This includes devices, methods, and systems to deliver full body EMS, or restricted EMS to a particular body area (e.g., the heart), and/or restricted to the brain or an area of the brain. For brain conditions/disorders, a need exists for EMS limited to the head via a self-contained device with multiple EMS emitting antennas. Such a need exists not only for such a head-only device against AD, but also against other amyloid-based neurologic conditions, as well as neurologic conditions characterized by mitochondrial dysfunction and/or reduced neuronal activity. In view of the small, but significant, loss of cognitive function/memory during normal aging (commonly called Aged-Associated Memory Impairment, or AAMI), such a head-only method to treat or prevent AAMI would be highly desirable, as would a method that could enhance cognitive function/memory in normal (unimpaired) individuals.

SUMMARY OF THE INVENTION

[0012] Aspects of the present invention include EMS devices, methods and systems for both brain- and/or body-related disorders. The invention has advantages over prior neuromodulatory approaches and known EMS methods, and can address brain and/or body disorders, including those characterized by amyloid protein deposition, mitochondrial dysfunction, and/or reduced neuronal activity.

[0013] In addition to a head-only EMS system, embodiments of the present invention may be or include a whole- or partial-body EMS system that may or may not include the head. A whole-body or partial-body system could be modifiable to provide restricted, focal EMS to a specific body area (such as the heart or knee).

[0014] Novel aspects of embodiments of the invention include: (1) a range of brain and/or body penetration profiles, from wide-spread, deep brain or body penetration to shallow penetration, to penetration of only specific regions of the brain and/or body, (2) a non-invasive device or system, (3) treatment that can be administered at a subject's home, (4) a self-contained system such that long-term daily treatment is possible, and/or (5) treatment that provides disease-modifying mechanisms of neurologic and/or bodily disorders.

[0015] One aspect of the invention that distinguishes over the prior EMS art is that a range of EMS parameters and modalities can be utilized, rather than just a single set of EMS parameters and a single modality. For example, prior EMS work involved a specific frequency of 918 MHz. The present invention covers a range of radio frequencies between 1 MHz and 25 GHz, preferably the ultra-high frequency (UHF) range of 300-3000 MHz, and most preferably within the ISM band of 902-928 MHz.

[0016] Another aspect of embodiments of the invention is that multiple EMS-emitting antennas may be employed via a head-unit device and/or body-unit device that focuses and restricts EMS to either (1) the brain or sub-regions therein, and/or (2) the body or portions thereof. As used herein, the terms "antenna(s)" or "RF antenna(s)" also include non-antenna means of generating electromagnetic waves.

[0017] Another aspect of embodiments of the invention is that the multiple antennas may be activated simultaneously or (more commonly) in sequence. In the latter case, no two antennas are simultaneously transmitting EMS on a given

side of the brain. Antennas may be located at any suitable location, such as on the same side of the head or any suitable areas of the head, different sides of the head, or on one or more areas of the body. Activating antennas in sequence helps provide EMS without exceeding current FDA and FCC limits on SAR levels.

[0018] Another aspect of embodiments of the invention is that it may include a safety sensor that allows only a particular individual, such as the subject, caregiver, or medical care provider to activate it. Another aspect of embodiments of the invention is that it may automatically turn off after a specific period of EMS transmission, thus negating over-exposure of the subject. Further, embodiments of the invention may include physiologic sensors for the purpose of feedback modulation of EMS and the collection of physiologic parameters that could be impacted by EMS. The feedback may be used to modify the EMS therapy either automatically or manually. For example, collected physiologic data could be sent to data storage, and could be retrieved and used by a computer or a medical professional (either on site or at a remote location). The computer or medical professional could then make parameter modifications to a device, system, or method according to the invention, either on site or remotely.

BRIEF DESCRIPTION OF THE DRAWING

[0019] Preferred embodiments and applications of the present invention will be described with reference to the figures below.

[0020] FIG. 1 illustrates a front view of an exemplary device for head-only application of ultra-high frequency EMS in frontal (left) and side views (right).

[0021] FIG. 2 is a schematic diagram of a typical ultra-high frequency EMS system for a head-only, partial-body or whole-body application. The control panel consists of three subunits (frequency, power level, and modality).

[0022] FIG. 3 illustrates both frontal and back views of an exemplary device for whole body (upper) or partial body (chest only) application of ultra-high frequency EMS.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0023] Turning now to the Figures, where the purpose is to describe preferred embodiments of the invention and not to limit same, embodiments of the invention involve devices, methods, and systems for administering radio frequency EMS to either the head alone, to the full body, to the full head and body, or to specific regions of the head and/or body. This use of EMS is believed to provide benefits through at least three mechanisms; namely, prevention/reversal of amyloid aggregation, mitochondrial enhancement, and increased neuronal activity, although the invention is not limited by any theory of operation. Turning now to FIG. 1, neurologic conditions primarily involving the brain can be treated utilizing a head-unit EMS device 10. In this example, four antennas 1 on each side of the head (or eight total) are utilized to provide EMS treatment to the forebrain. A greater or lesser number (one or more) of antennas could be incorporated into a head-unit 10, either around the head and/or over the crown, or at any desired location.

[0024] In the embodiment shown in FIGS. 1 and 2, the EMS-generating device, method and system may be utilized for preventing and treating AD. For this disease, the device

may provide head-only EMS through a control panel **50** (FIG. 2) connected to an array of radio frequency (RF) antennas **1** on each side of the brain (FIG. 1). Each antenna is activated by the control panel **50**, which contains controls for frequency, power level, and modality settings for each antenna **1** (FIGS. 1 and 2). Activation of the one or more antennas **1** by the control panel **50** can occur through wireless or wired connections, with both options being represented in FIG. 2 by broken lines from the control panel to the one or more antennas **1**. The control panel is itself connected to a battery-based or DC-based power source other than a battery, or any other suitable power source. Each or multiple of the one or more antennas could also be connected to one another (not shown). Also within a head unit **10** according to aspects of the invention are preferably physiologic sensors connected to the control panel **50** for data collection and feedback. The head-unit **10** of this particular embodiment employs multiple antennas (one or more located on each side of the brain and/or on the top mid-line region) arrayed to provide EMS to both the cortical and sub-cortical brain areas impacted by AD. A preferred head unit will preferably have 8-16 antennas arranged to generate EMS to the cerebral cortex and sub-cortical brain areas, such as the hippocampus and entorhinal cortex.

[0025] The head unit **10** itself is preferably made of a suitably conforming material (such as cloth, nylon, microfiber, spandex) for antennas **1** to be enclosed therein and positioned in close proximity to the scalp. Alternatively, the head unit may be made to fit more loosely using a rigid helmet material (such as plastic or composite material). In addition, the head unit may contain an RF shielding material (such as a silver mesh, stainless steel mesh, or copper polyester fabric) in order to limit EMF leakage outside of the head region. RF antennas on each side of the head and/or the top mid-line region are preferably programmed to discharge EMS sequentially, such that no two antennas are simultaneously discharging EMS on the same side of the head or on the top mid-line. Alternatively, any two or more antennas **1** within the head-unit **10** may be programmed to discharge simultaneously. The nature of the transmitted EMS may be near-field, far-field, or both.

[0026] Also in this embodiment, the head unit's **10** control panel **50** can be connected to a power supply, such as a battery, located either within the head unit itself or attached to the device (but still on the person) for complete mobility during treatment and comfortable in-home treatment. If the power supply is a battery, it may be rechargeable between treatments, such as with placement of the head unit on or in a recharging device. Alternatively, the power supply can be removed or detached from head unit **10** and charged separately.

[0027] A method according to aspects of the invention comprises applying EMS through the head unit's **10** antennas **1** for therapeutic intervention over a pre-determined period of time. The system administers EMS to the brain, which may be provided in conjunction with one or more of: (1) EMS feedback sensors to modulate treatment efficacy, (2) collection of physiologic data (such as EEG and scalp temperature) from physiologic sensors, and (3) modification of treatment on site or from a remote location, either by a computer or a medical care giver.

[0028] The EMS parameters for embodiments of the invention generally involve a frequency range from 1 MHz to 25 GHz, with a preferred frequency range of 300 to 3,000 MHz, and a most preferred frequency within the ISM band of 902-

928 MHz. Embodiments of the invention also may provide an average specific absorption rate (SAR) ranging from 0.1 to 1.6 W/kg, although higher SAR levels may be used if greater utility is observed using the higher levels. The EMS signal may be continuous or non-continuous (e.g., pulsed or modulated), with the most common modality being GSM-based modulation. Other embodiments involve the EMS signal having UMTS, TETRA, or D-AMPs modulation. For all embodiments, the channel access method (which describes formats in which EMS can be delivered) could instead be TDMA or CDMA (non-pulsed).

[0029] A head-unit and/or full body or partial body device of preferred embodiments of the invention could provide EMS at any desired time intervals, such as once or multiple times daily, every other day, weekly, or any interval. Each session could be of any suitable duration, from a few seconds to a few hours to continuous. A head-unit device is usually located outside of the scalp, but may be located in whole, or part, subcutaneously, beneath the scalp, and may be permanently implanted. Similarly, a partial body device may be subcutaneously implanted in the subject.

[0030] Other aspects of the invention involve the device having a safety sensor unique to an individual, such as an individual's fingerprint, that would allow activation of the device only by the individual, which could be the subject, a caregiver, or other medical professional. Following activation of the device, the device could remain activated for a specific period of time (for example, about one hour), after which it automatically turns off and remains off until reactivated automatically or by a user. Alternatively, it could be manually turned off by the user. The device settings and intervals can be modified by a computer or medical professional, either on site or remotely through electronic transmission.

[0031] Any device, system or method according to the invention may also contain physiologic sensors for the purpose of direct feedback EMS signal modulation and/or the collection of physiologic data (such as EEG and scalp temperature). The collected data could then be saved, such as by being sent electronically to a data warehouse for evaluation by a computer or medical professional, or used for automatic adjustments to the EMS treatment. Appropriate adjustments can be made remotely or on site by a medical professional or a computer.

[0032] Another embodiment of the invention involves the same EMS method and system characteristics as described above. However, this embodiment relates to the prevention and treatment of amyloid-associated neurologic conditions other than AD, including Mixed AD/Vascular Dementia, Cerebral Amyloid Angiopathy, Hemorrhagic Stroke, Multi-Infarct Dementia, Parkinson's Disease, Lewy Body Dementia, Down's Syndrome, Traumatic Brain Injury, Fronto-Temporal Lobe Dementia, Cerebral Traumatic Encephalopathy, Huntington's Disease, and Prion Diseases (Transmissible Spongiform Encephalopathy, Kuru, and Creutzfeldt-Jakob Disease). The EMS parameters and modulation characteristics may be different for these other amyloid-associated neurologic conditions, depending on the brain areas affected. For example, the preferred embodiment of AD treatment involves an EMS profile (i.e., antenna conformation, SAR levels) that provides treatment to the entire forebrain. By contrast, a different EMS profile would be appropriate for Fronto-Temporal Lobe Dementia, wherein EMS treatment would be limited to the fronto-temporal cortex.

[0033] Another embodiment of the invention involves the same EMS device, method and system as described above, but relates to the prevention and treatment of neurologic conditions other than AD that involve mitochondrial dysfunction, including Parkinson's Disease, Huntington's Disease, Amyotrophic Lateral Sclerosis (ALS), mental retardation, stroke, autism, bipolar disorder, Schizophrenia, anxiety disorders, mitochondrial encephalomyopathies, epilepsy, migraine headache, and major depression. The EMS parameters and modulation characteristics (such as wave frequency, power level, treatment time, periodicity, and/or antenna location) may be different for these other neurologic conditions involving mitochondrial dysfunction, depending on the brain areas affected. Another embodiment of this invention involves the same EMS device, method and system as described above, but relates to the prevention and treatment of neurologic conditions other than AD that involve reduced neuronal activity, including stroke, Huntington's Disease, Dystonia, and Hemiballismus. The EMS parameters and modulation characteristics (such as wave frequency, power level, treatment time, periodicity, and/or antenna location) may be different for these other neurologic conditions involving reduced neuronal activity, depending on the brain areas affected.

[0034] Still other embodiments of the EMS device, method and system herein relate to: (1) prevention/treatment of the significant loss of short-term memory during normal aging, referred to as Age-Associated Memory Impairment (AAMI), and (2) enhancement of cognitive function/memory in normal (unimpaired) individuals and those demonstrating sub-normal cognitive function/development (i.e., individuals classified as cognitively unimpaired, but within the lower levels of this classification).

[0035] Another embodiment of the invention relates to use of an EMS device, method and system for whole-body or partial-body treatment for prevention or treatment of various "body diseases", including those characterized by amyloid deposition or mitochondrial dysfunction. A full or partial body device or system would have the same general structure and functionality as described for the head unit **10** except that the shape, number and location of antennas, and functionality would be suited for the area and condition being treated. As shown in FIG. 3, this embodiment provides whole-body or partial-body EMS through a device worn to be in contact with the skin or in close proximity to the area requiring therapy (e.g., the chest for therapy to the heart area). The device would contain one or more RF antennas. The one or more antennas are each activated by a control panel containing wave frequency, power level, and modulation subunits (FIG. 2) and the control panel itself is connected to a power source. This power source is preferably a battery located in the head device or on the subject, a DC source other than a battery, or any suitable power source. Also within the device are preferably physiologic sensors for data collection, transmission, and feedback. The method consists of applying EMS through the device's antenna(s) for therapeutic intervention over a predetermined period of time and given parameter selection (i.e. wave frequency, power level, treatment time, periodicity, and/or antenna location). The system involves administration of EMS to the whole body or to a regional body area, which may be in conjunction with: (1) EMS feedback networks to modulate treatment efficacy, and/or (2) collection of physiologic

data (such as skin temperature) from physiologic sensors to monitor effects of treatment or to modify treatment parameters.

[0036] For whole-body EMS, the device may be independent of the subject, such as a tube device wherein the subject lays supine or a chamber wherein the subject sits comfortably. Alternatively, whole-body EMS could be delivered by means of a body suit made of fabric such as cloth, nylon, microfiber or spandex, wherein antenna(s) would be located for close contact with the body surface. For partial-body EMS, the device may be on the skin surface with the device preferably being as close as possible to the affected body region. A suitable strap or other means of keeping the device in place over the desired body region may be used. It is possible that the device could be worn like a piece of clothing (such as a vest) or as an arm/leg wrap (such as around the knee). In addition, the whole-body or partial-body EMS fabric may contain an RF shielding material (such as a silver mesh, stainless steel mesh, or copper polyester fabric) in order to limit EMF leakage away from the body. If multiple antennas are utilized for either whole-body or partial-body EMS, they will preferably be programmed to discharge EMS sequentially, such that no two antennas are simultaneously discharging EMS into the whole body or into the partial-body region where focal EMS is being administered. Alternatively, any two or more antennas may be programmed to discharge in unison. The nature of EMS may be near-field, far-field, or both. Also in this embodiment, a battery-based power supply may be located either within the device itself or attached to the device (but preferably still on the subject) for ease of mobility during treatment and comfortable in-home treatment. The battery is preferably rechargeable between treatments.

[0037] The EMS parameters for this embodiment generally involve a frequency range from 1 MHz to 25 GHz, with a preferred frequency range of 300 to 3,000 MHz, and a most preferred frequency within the ISM band of 902-928 MHz. This embodiment also involves an average specific absorption rate (SAR) ranging from 0.1 to 1.6 W/kg, although higher SAR levels may be employed if greater utility is observed by the use of higher levels. The EMS signal may be continuous or non-continuous (e.g., pulsed or modulated), with the most common modality being GSM-based modulation. Other embodiments involve the EMS signal having UMTS, TETRA, or D-AMPs modulation. For all embodiments, the channel access method could instead be TDMA or CDMA (non-pulsed).

[0038] The intervals and timing of each EMS treatment could be the same as previously described above with respect to EMS treatment for the head.

[0039] The EMS method and system for whole-body or partial-body treatment of diseases, such as those characterized by amyloid deposition or mitochondrial dysfunction, including Type II Diabetes, Cardiac Amyloidosis, Systemic AL Amyloidosis, Atherosclerosis, Rheumatoid Arthritis, Aortic Medial Amyloid, Familial Amyloid Polyneuropathy, Cardiovascular Disease, Chronic Fatigue Syndrome, Cardiomyopathy, Coronary Artery Disease, Fibromyalgia, and Hepatitis C. The EMS parameters and modulation characteristics (i.e., wave frequency, power level, treatment time, periodicity, and/or antenna location) may differ for these body disorders involving amyloid deposition or mitochondrial dysfunction, depending on the body region(s) affected. For example, it would be anticipated that treatment of cardiac

amyloidosis would involve EMS limited to the cardiac tissue, while treatment of Chronic Fatigue Syndrome (CFS) would involve whole-body EMS. This might require variations in the different parameters (i.e., wave frequency, power level, treatment time, periodicity, and/or antenna location)

[0040] Some specific non-limiting examples of the invention follow:

EXAMPLE 1

[0041] A device to prevent or treat disease with electromagnetic stimulation (EMS), wherein the device comprises one or more antennas, and wherein the antennas are activated by a control panel connected to a power source.

[0042] EXAMPLE 2

[0043] The device of example 1 wherein the disease is Alzheimer's Disease.

EXAMPLE 3

[0044] The device of example 1 wherein the disease is one or more of the group consisting of: Mixed AD/Vascular Dementia, Cerebral Amyloid Angiopathy, Hemorrhagic Stroke, Multi-Infarct Dementia, Parkinson's Disease, Lewy Body Dementia, Down's Syndrome, Traumatic Brain Injury, Fronto-Temporal Lobe Dementia, Cerebral Traumatic Encephalopathy, Huntington's Disease, and Prion Diseases (Transmissible Spongiform Encephalopathy, Kuru, and Creutzfeldt-Jakob Disease).

EXAMPLE 4

[0045] The device of example 1 wherein the disease is one or more of the group consisting of: Parkinson's Disease, Huntington's Disease, Amyotrophic Lateral Sclerosis (ALS), mental retardation, stroke, autism, bipolar disorder, Schizophrenia, anxiety disorders, mitochondrial encephalomyopathies, epilepsy, migraine headache, and major depression.

EXAMPLE 5

[0046] The device of example 1 wherein the disease is one or more of the group consisting of: stroke, Huntington's Disease, Dystonia, and Hemiballismus.

EXAMPLE 6

[0047] The device of either of any of examples 1-5 wherein the EMS is at an ultra-high frequency.

EXAMPLE 7

[0048] The device of any of examples 1-6 wherein the antennas are within the fabric/material comprising a head unit.

EXAMPLE 8

[0049] The device of example 7 wherein there is at least one antenna on the side of the head unit opposite at least one other antenna.

EXAMPLE 9

[0050] The device of example 7 wherein there is at least one antenna on mid-line between the two cerebral hemispheres.

EXAMPLE 10

[0051] The device of any of examples 1-6 or 8-9 wherein the antennas are RF antennas.

EXAMPLE 11

[0052] The device of any of examples 1-6 or 8-10 wherein EMS is delivered without the use of an antenna.

EXAMPLE 12

[0053] The device of any of examples 1-6 or 8-10 wherein the antennas may or may not be connected to one another.

EXAMPLE 13

[0054] The device of any of examples 1-6, 8-10 or 12 wherein there is at least one antenna on each side of the head unit and/or over the crown of the head unit, and the antennas are arrayed bilaterally and/or on mid-line in the head unit.

[0055] EXAMPLE 14

[0056] The device of any of examples 8-13 wherein the head unit is made of a suitable material, (such as cotton, nylon, polyester, spandex, or microfiber), thus allowing both comfort and functionality.

EXAMPLE 15

[0057] The device of any of examples 8-14 wherein the head unit fits immediately next to the skin surface via a conforming fabric (such as those listed in the preceding example) or fits loosely via a rigid helmet (such as plastic or composite material).

EXAMPLE 16

[0058] The device of any of examples 8-10 or 12-15 wherein the head unit contains a radio frequency shield material (such as a silver mesh, stainless steel mesh, or copper polyester fabric) to limit electromagnetic leakage away from the head.

EXAMPLE 17

[0059] The device of any of examples 1-6, 8-10 or 12-16 wherein there is a plurality of antennas, and the antennas are programmed to discharge such that no two antennas are simultaneously discharging on the same side of the head or on mid-line.

EXAMPLE 18

[0060] The device of any of examples 4-7 or 9-19 wherein any two or more antennas are programmed to discharge simultaneously on the same side of the head, or on both sides of the head, or on mid-line.

EXAMPLE 19

[0061] The device of any of examples 1-7 or 9-20 wherein the one or more antennas emit one or more of the group consisting of: near-field or far-field electromagnetic transmission.

EXAMPLE 20

[0062] The device of any of examples 1-18 wherein the power supply is one or more of the group consisting of: a battery or DC power from a source other than a battery.

EXAMPLE 21

[0063] The device of example 20 wherein any battery-based power supply is either within the device or attached to the device.

EXAMPLE 22

[0064] The device of examples 21 wherein any battery-based power supply is re-chargeable.

EXAMPLE 23

[0065] The device of examples 1-22 wherein the EMS has a frequency within a range of 1 MHz to 25 GHz.

EXAMPLE 24

[0066] The device of any of examples 1-23 wherein the EMS has a frequency within a range of 300 MHz and 3,000 MHz.

EXAMPLE 25

[0067] The device of any of examples 1-22 wherein the EMS has a frequency of 902-928 MHz.

EXAMPLE 26

[0068] The device of any of examples 1-25 wherein the range of SAR level is from 0.1 to 1.6 W/kg.

[0069] EXAMPLE 27

[0070] The device of any of examples 1-25 wherein SAR levels are greater than 1.6 W/kg for average power.

[0071] EXAMPLE 28

[0072] The device of any of examples 1-25 wherein the SAR level is greater than 1.6 W/kg.

[0073] EXAMPLE 29

[0074] The device of any of examples 1-28 wherein the EMS signal is non-continuous.

[0075] EXAMPLE 30

[0076] The device of example 29 wherein the EMS signal is pulsed.

[0077] EXAMPLE 31

[0078] The device of example 29 or 30 wherein the EMS signal is modulated.

[0079] EXAMPLE 32

[0080] The device of any of examples 1-28 wherein the EMS signal is continuous.

[0081] EXAMPLE 33

[0082] The device of example 29 wherein the EMS signal is GSM-modulated.

EXAMPLE 34

[0083] The device of any of examples 1-29 wherein the EMS signal is either UMTS-modulated, TETRA-modulated, or D-AMPs-modulated.

EXAMPLE 35

[0084] The device of any of examples 1-34 wherein the EMS signal's channel access method is TDMA or CDMA (non-pulsed).

EXAMPLE 36

[0085] The device of any of examples 1-35 that is located in whole, or in part, subcutaneously on the head.

EXAMPLE 37

[0086] The device of any of examples 1-36 that has a safety sensor unique to an individual that would allow activation of the device only by the individual.

EXAMPLE 38

[0087] The device of example 37 wherein the safety sensor is the individual's fingerprint.

EXAMPLE 39

[0088] The device of any of examples 1-38 that further includes the administration of EMS in conjunction with one or more of the group consisting of: (a) EMS feedback sensors to modulate treatment, (b) sensors to collect and/or transmit physiologic data for monitoring treatment effects and modifying EMS parameters (such as wave frequency, power level, treatment time, periodicity, and/or antenna location).

EXAMPLE 40

[0089] The device of any of examples 1-39 that is a whole-body device or a partial-body device.

EXAMPLE 41

[0090] The device of example 40 wherein the disease being prevented or treated is one or more of the group consisting of: Type II Diabetes, Cardiac Amyloidosis, Systemic AL Amyloidosis, Atherosclerosis, Rheumatoid Arthritis, Aortic Medial Amyloid, Familial Amyloid Polyneuropathy, Cardiovascular Disease, Chronic Fatigue Syndrome, Cardiomyopathy, Coronary Artery Disease, Fibromyalgia, and Hepatitis C.

EXAMPLE 42

[0091] The device of example 40 or 41 wherein the antenna (s) is an RF antenna.

EXAMPLE 43

[0092] The device of example 40 or 41 wherein EMF is delivered without the use of antennas.

EXAMPLE 44

[0093] The device of examples 40-42 that is either independent of the subject or in contact with the body surface via an antenna-containing body fabric.

EXAMPLE 45

[0094] The device of any of examples 40-44 wherein the whole- or partial-body device is made of a suitable material such as cotton, nylon, polyester, spandex, or microfiber.

EXAMPLE 46

[0095] The device of any of examples 40-45 wherein the whole- or partial-body device contains a radio frequency shield material (such as a silver mesh, stainless steel mesh, or copper polyester fabric) to limit electromagnetic leakage away from the body.

EXAMPLE 47

[0096] The device of any of examples 40-46 wherein the EMS generator is on the skin surface, as close to the body region to be affected as possible.

EXAMPLE 48

[0097] The device of any of examples 40-47 that includes a suitable strap or other means of keeping the device in place over the desired body region.

EXAMPLE 49

[0098] The device of any of examples 40-48 that is a vest for cardiac treatment.

EXAMPLE 50

[0099] The device of any of examples 40-48 that is a wrap for arm or leg MS treatment.

EXAMPLE 51

[0100] The device of any of examples 40-50 wherein, if multiple antennas are utilized, they will be programmed to discharge EMS sequentially, such that no two antennas are simultaneously discharging EMS into the whole body or within the body region where focal EMS is being administered.

EXAMPLE 52

[0101] The device of any of examples 40-50 wherein, if multiple antennas are utilized, any two or more antennas will be programmed to discharge EMS simultaneously.

EXAMPLE 53

[0102] The devices of any of examples 40-52 wherein antennas emit either near-field or far-field electromagnetic transmission, or both.

EXAMPLE 54

[0103] The devices of any of examples 40-53 wherein the power supply is a re-chargeable battery or a DC source other than a battery.

EXAMPLE 55

[0104] The device of any of examples 40-54 wherein, for focal EMS of a body region, any battery-based power supply is either within the device or attached to the device, but still on the subject.

EXAMPLE 56

[0105] The device of examples 40-55 wherein the EMS has a frequency of 1 MHz to 25 GHz.

EXAMPLE 57

[0106] The device of any of examples 40-56 wherein the preferred range of EMS frequency is between 300 MHz and 3,000 MHz.

EXAMPLE 58

[0107] The device of any of the examples 40-57 wherein the EMS has a frequency of 902-928 MHz.

EXAMPLE 59

[0108] The device of any of examples 40-58 where the range of SAR levels is from 0.1 to 1.6 W/kg for average power.

EXAMPLE 60

[0109] The device of any of examples 40-58 wherein SAR levels are greater than 1.6 W/kg for average power.

EXAMPLE 61

[0110] The device of any of examples 40-60 wherein the EMS signal is non-continuous (pulsed and modulated).

EXAMPLE 62

[0111] The device of any of examples 40-60 wherein the EMS signal is continuous (continuous wave; CW).

EXAMPLE 63

[0112] The device of any of examples 40-61 wherein the EMS signal is GSM-modulated.

EXAMPLE 64

[0113] The device of any of examples 40-61 wherein the EMS signal is UMTS-modulated, TETRA-modulated, or D-AMPS-modulated.

EXAMPLE 65

[0114] The device of any of examples 40-64 wherein the EMS signal's channel access method is TDMA or CDMA (non-pulsed).

EXAMPLE 66

[0115] The device of any of examples 40-65 that has a safety sensor unique to an individual that would allow activation of the device and system only by the individual.

EXAMPLE 67

[0116] The device of example 66 wherein the safety sensor senses the individual's finger print.

EXAMPLE 68

[0117] The device of any of examples 1-67 wherein the device provides treatment once or multiple times daily, every other day, weekly, or any interval therein for days, weeks, or years.

EXAMPLE 69

[0118] The device of any of examples 1-68 wherein any treatment session is a few seconds to a few hours to continuous.

EXAMPLE 70

[0119] The device of any of examples 1-69 wherein the following activation the device will remain activated for a specific period of time, after which it automatically turns off and remains off for about 8-10 hours.

EXAMPLE 71

[0120] The device of example 70 wherein the device is activated for a few seconds to a few hours to continuous.

EXAMPLE 72

[0121] The device of any of examples 1-71 wherein one or more operating parameters are modified by a medical professional.

EXAMPLE 73

[0122] The device of any of the examples 1-71 wherein one or more operating parameters are modified by a computer.

EXAMPLE 74

[0123] The device of any of examples 72-73 wherein the parameters are modified based upon data received from EMS feedback sensors.

EXAMPLE 75

[0124] The device of any of examples 1-74 that further includes one or more of: (1) EMS feedback sensors to modulate treatment, and (2) sensors to collect and/or transmit physiologic data for monitoring treatment effects and modifying EMS parameters.

EXAMPLE 76

[0125] The device of any of examples 1-39 to prevent or treat Age-Associated Memory Impairment (AAMI).

EXAMPLE 77

[0126] The device of any of examples 1-39 to enhance both normal and sub-normal cognition function/development.

EXAMPLE 78

[0127] The device of any of examples 1-77 wherein EMS is compatible with any concurrent pharmaco-therapeutic being administered for the same neurologic or body condition.

EXAMPLE 79

[0128] The device of any of examples 1-78 wherein different brain and/or body applications will involve different EMS parameters (e.g., wave frequency, power level, treatment time, periodicity, modulation format, antenna location).

[0129] While the foregoing written description of the invention enables one of ordinary skill to make and use what is considered presently to be the best mode thereof, those of ordinary skill will understand and appreciate the existence of variations, combinations, and equivalents of the specific embodiment, method, and examples herein. The invention is therefore not limited by the above described embodiment, method, and examples, but by all embodiments and methods within the scope of the appended claims and legal equivalents thereof.

What is claimed is:

1. A device to treat a subject using electromagnetic stimulation (EMS), wherein the device comprises one or more antennas that discharge electromagnetic waves to create EMS, and wherein the one or more antennas are activated by a control panel connected to a power source.

2. The device of claim 1 wherein the EMS is provided at an ultra-high frequency.

3. The device of claim 1 wherein the one or more antennas are within a material comprising a head unit that fits on the head of the subject being treated.

4. The device of claim 3 wherein there is at least one antenna on a first side of the head unit opposite a second side of the head unit that includes at least one other antenna.

5. The device of claim 1 wherein the one or more antennas are RF antennas.

6. The device of claim 1 that includes a radio frequency shield material to limit electromagnetic leakage away from the device.

7. The device of claim 1 wherein there is a plurality of antennas, and the antennas are programmed to discharge electromagnetic waves such that no two antennas are simultaneously discharging.

8. The device of claim 2 wherein the EMS has a frequency of a range of 1 MHz to 25 GHz.

9. The device of claim 2 wherein the EMS has a frequency within a range within the group consisting of: (a) 300 MHz to 3,000 MHz, and (b) 902-928 MHz.

10. The device of claim 1 that has a range of SAR level from 0.1 to 1.6 W/kg.

11. The device of claim 1 wherein the device has an SAR level greater than 1.6 W/kg.

12. The device of claim 1 wherein the EMS is pulsed.

13. The device of claim 1 that further includes one or more of the group consisting of:

(a) EMS feedback sensors to modulate treatment, (b) sensors to collect and/or transmit physiologic data for monitoring treatment effects and modifying one or more parameters of the EMS.

14. The device of claim 1 that is a whole-body device or a partial-body device.

15. The device of claim 14 wherein the one or more antennas are RF antennas.

16. The device of claim 14 wherein multiple antennas are utilized and are programmed to discharge EMS sequentially, such that no two antennas are simultaneously discharging.

17. The device of claim 14 wherein multiple antennas are utilized and two or more antennas are programmed to discharge EMS simultaneously.

18. The device of claim 1 wherein the power source is a battery that is either within the device or attached to the device.

19. The device of claim 14 wherein the EMS has a frequency of 1 MHz to 25 GHz.

20. The device of claim 14 wherein the EMS has a frequency within a range within the group consisting of: (a) 300 MHz to 3,000 MHz, and (b) 902-928 MHz.

21. The device of claim 14 that has a range of SAR level from 0.1 to 1.6 W/kg.

22. The device of claim 14 wherein the device has an SAR level greater than 1.6 W/kg.

23. The device of claim 14 wherein the EMS is pulsed.

24. The device of claim 14 that further includes one or more of the group consisting of: (a) EMS feedback sensors to modulate treatment, (b) sensors to collect and/or transmit physiologic data for monitoring treatment effects and modifying one or more parameters of the EMS.

25. The device of claim 1 wherein multiple antennas are utilized and two or more antennas are programmed to discharge EMS simultaneously.

26. The device of claim 14 wherein the EMS is provided at an ultra-high frequency.

27. The device of claim 14 that includes a radio frequency shield material to limit electromagnetic leakage away from the device.

28. The device of claim **3** wherein the disease being prevented or treated is one or more of the following: AD, Mixed AD/Vascular Dementia, Cerebral Amyloid Angiopathy, Hemorrhagic Stroke, Multi-Infarct Dementia, Parkinson's Disease, Lewy Body Dementia, Down's Syndrome, Traumatic Brain Injury, Fronto-Temporal Lobe Dementia, Cerebral Traumatic Encephalopathy, Huntington's Disease, and Prion Diseases (Transmissible Spongiform Encephalopathy, Kuru, and Creutzfeldt-Jakob Disease).

29. The device of claim **3** wherein the disease being prevented or treated is one or more of the following: Parkinson's Disease, Huntington's Disease, Amyotrophic Lateral Sclerosis (ALS), mental retardation, stroke, autism, bipolar disorder, schizophrenia, anxiety disorders, mitochondrial encephalomyopathies, epilepsy, migraine headache, and major depression.

30. The device of claim **3** wherein the disease being prevented or treated is one or more of the following: stroke, Huntington's Disease, Dystonia, and Hemiballismus.

31. The device of claim **1** wherein the EMS signal is non-continuous.

32. The device of claim **1** wherein the EMS signal is continuous.

33. The device of claim **14** wherein the disease being prevented or treated is one or more of the following: Type II Diabetes, Cardiac Amyloidosis, Systemic AL Amyloidosis, Atherosclerosis, Rheumatoid Arthritis, Aortic Medial Amyloid, Familial Amyloid Polyneuropathy, Cardiovascular Disease, Chronic Fatigue Syndrome, Cardiomyopathy, Coronary Artery Disease, Fibromyalgia, and Hepatitis C.

34. The device of claim **1** wherein the power supply is a re-chargeable battery or a DC source other than a battery.

35. The device of claim **3** that is used to prevent or treat Age-Associated Memory Impairment (AAMI).

36. The device of claim **1** that enhances both normal and sub-normal cognition function.

37. The device of claim **1** wherein different brain and/or body applications involve different EMS parameters.

38. The device of claim **1** wherein the electromagnetic waves are generated by a source that acts as an antennae.

* * * * *

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摘要(译)

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