

DESCRIPTION

TITLE

**SEQUENTIALLY PROGRAMMED MAGNETIC FIELD THERAPEUTIC
SYSTEM (SPMF)**

FIELD OF THE INVENTION

The invention relates to systems for generating and inducing sequentially programmed magnetic fields (SPMFs) in biological tissue(s) and methods for inducing cellular regeneration and / or degeneration processes and methods of treatment based on such processes using such a system. More particularly, it relates to an apparatus or system for generating and applying SPMFs to biological tissue(s) which resonates therein.

BACKGROUND OF THE INVENTION

It is known that electromagnetic fields of certain frequency ranges and intensities are indigenous to living tissues and it has been found that inciting the inherent resonance by exogenous treatment using electromagnetic fields [EMF], electric fields, and magnetic fields can induce cellular regeneration and degeneration processes. EMF in a range from 0.1-150Hz have been reported to stimulate bone cells. It has also been reported that bone resorption that normally parallels disuse can be prevented or even reversed by the exogenous induction of electric fields. Electromagnetic fields

below 10 microV/cm, when induced at frequencies between 50 and 150 Hz for 1 h/day, are sufficient to maintain bone mass even in the absence of function. Reducing the frequency to 15 Hz makes the field extremely osteogenic. This frequency-specific sinusoidal field initiated more new bone formation than a more complex pulsed electromagnetic field (PEMF), though inducing only 0.1% of the electrical energy of the PEMF.

A range of PEMF machines have been introduced in the market. PEMF therapy has been reported to decrease pain, improve sleep, enhance circulation, regenerate nerves, help in healing of wounds, enhance immunity and improve bone density.

An area of immense interest has been the use of magnetic stimulation in rehabilitating injured or paralyzed muscle groups. Magnetic stimulation of the heart has been considered to be superior to CPR or electrical stimulation, because both of those methods apply gross stimulation to the entire heart all at once. A magnetic stimulator can be used as an external pacer to stimulate each chamber of the heart separately in the proper sequence. Another area in which magnetic stimulation is proving effective is treatment of the spine. The spinal cord is difficult to access directly because vertebrae surround it. Magnetic stimulation may be used to block the transmission of pain via nerves in the back, e.g., those responsible for lower back pain. Magnetic stimulation also has proven effective in stimulating regions of the brain thereby providing a number of treatment options including several classes of anti-depressant medications (Sari's, MAI's and tricyclics), lithium, and electroconvulsive therapy (ECT). Recently, repetitive transcranial magnetic stimulation (rTMS) has also been shown to have significant anti-depressant effects for patients that do not respond to the traditional methods. The membranes are depolarized by the induction of small electric fields in excess of 1 V/cm that are the result of a rapidly changing magnetic field applied non-invasively.

The use of electromagnetic fields (EMFs) for healing has been known from time immemorial. Even many centuries back, simple magnets were used for regenerative purposes. It is only in the last 50 years that specific use of electromagnetic fields has been clearly defined to aid in or facilitate biological tissue regeneration or

degeneration. Much research has gone into this use of electromagnetic fields. In the last 50 years research has established a scientific basis for use of electromagnetic devices in the treatment of illness, although many applications have yet to be specific enough to achieve the desired changes.

When high frequency fields are applied with external signal generators such as micro current devices, magnetic pulses or the plasma tubes or Rife devices, electrical charging of the cell membrane occurs causing an increase in cell membrane capacitance and increased conduction of current through the cell membrane. This is distinctly described by Haliwanger also in 2003. This means that the devices that generate low frequency current will have different biological effects and the device that generates high frequency can have different biological effect. In summary, increase in cell membrane capacitances would change cell membrane permeability and could cause significant changes in cell behavior.

Scientific research has proven that cells are electromagnetic in nature and they generate their own electromagnetic fields and are also capable of harnessing external electromagnetic energy in the right wave length and strength to communicate control and drive metabolic functions as described by Adey in 1988 and 1993 as also by Becker in 1990. The application of a varying magnetic flux to the area of the body will induce an electric field along the perimeters of the area. When varying magnetic fields are applied to human tissues that contain free or charged carriers these charge carriers are accelerated by the electric field thereby generating eddy currents. The induced electric field or the generated current depends on the rate of change of the magnetic field. Time varying magnetic fields that induce cell growth acceleration, enzyme activation and changes in membrane in metabolism have been described earlier by Enforte in 1990.

It is known that when weight is put on the knees, the cartilage gets compressed and this itself is the stimulus for the regeneration to start and there is forced efflux of protons causing changes in the cell membrane potential. This capacity is lost in a osteoarthritic patient. However, by selectively altering this cell membrane potential

by use of time varying electromagnetic fields which are tuned to this specific resonating frequency one can re-induce this change into the cell at rest.

The use of electromagnetic fields in cancer therapy has been fairly summarized by Marc Neveu in his article on Explore Volume 12 Nov 4, 2003. Cancer is the end result of a series of genetic alterations that modify the control of promoting (oncogenes) or inhibit (suppressor gene) cell proliferation. Conventionally chemotherapy and radiation employ nonspecific toxic effects to inhibit the proliferation of both normal and tumour cells they are aimed at cells which are proliferating very rapidly and they have very significant side effects. The co-ordination between cell membrane potential and cancer cell proliferation has been known for decades, one of the pioneers of this is Clarence Cone who in 1970 authored a classic paper. Direct measurements have shown that there are 6-7 times higher conductance in tumours compared to normal tissue. The electrical changes occur because of rapid proliferating and transformed cells have lower membrane potential when compared to normal cells. The cancer cells have transmembrane potential which is about 20-30 mv which is much reduced as compared to normal cells which is about -70 to -90 mv. These magnetic fields can modulate the activity of sodium potassium pump that is responsible for setting transmembrane potential. Recent studies in Columbia University have mapped the original frequency to control the activity of numerous enzymes including the sodium potassium pump which is described in the Journal of Biochemistry 53171-4 /2001. The specific cellular machinery that turns the knob on and off in response to the electromagnetic frequency has been recently identified as has been described in the Journal of Cell Biochemistry GS Cell Biochem 81143-8 2001. Recent studies have demonstrated that specific frequencies can inhibit cancer by blocking the tumour blood supply as has been described by Anti Cancer Research 21388791 2001.

US Patent PublicationNo. 2007/0208249 discloses an apparatus for the application of what is claimed to be a rotational focused quantum magnetic resonance on any part of human body. The apparatus consist of a plurality of guns for the delivery of the quantum magnetic resonance , a travelling platform for carrying the person under

treatment, an electronic switching system for controlling the guns, said electronic switching system being controlled by a main computer through an on board microprocessor and means for cooling and dispersing the heat generated during the operation. Further in this system the 96 guns are used at an angle of 11.25°.

The following aspects of the US Patent Publication No. 2007/0208249 are noted:

- The construction of the guns as described in the patent specification is constructed of special cores of high permeability material that is precisely coiled with pure copper. It is apparent that such a construction is not the desired method capable of producing a focused magnetic field;
- The placement of the guns at 11.25° cause interference due to the magnetic field generated by the two adjacent guns thereby causing magnetic field inhomogeneity;
- The system as disclosed cannot produce a “magnetic resonance” as there is only a magnetic field and no associated radio frequencies to produce the magnetic resonance and therefore the concept of “for the delivery of the quantum magnetic resonance”, as stated in the patent specification is misleading and consequently cannot be the basis for any treatment; the specification is devoid of any constructional details; the specification does not disclose any method of treatment; the specification also states that the magnetic field is rotating which means that the field remains on all the time and the switching system rotates the magnetic field a specific rate details of which are not disclosed in patent specification; the above patent application neither teaches the construction of the apparatus nor does it describe any method of treatment.

The conventional systems described above lack homogeneity of magnetic fields which is an essential condition for effectiveness of treatments, and also flexibility of options in terms of field directions, orientations, etc. Further, most literature in this field lack the desired details of the apparatus and / or the methods of treatment

making it practically impossible for a person trained in the art to either reproduce the reported effects and / or build the scantily described apparatus.

There is a long felt need to provide a comprehensive system for inducing cellular regeneration and/or degeneration processes and methods of treatment based on such processes that can be easily be applied to diverse states of tissue abnormalities or dysfunctions.

SUMMARY OF THE INVENTION:

The main object of the invention is to provide a system for generating and inducing sequentially programmed magnetic fields (SPMFs) in biological tissue(s) and methods for inducing cellular regeneration and / or degeneration processes and methods of treatment based on such processes using such a system.

Yet another object of the invention is to provide a system for generating and applying SPMFs to biological tissue(s) which resonates therein.

Yet another object of the invention is to provide a Sequentially Programmed Magnetic Field (SPMF) therapeutic system to produce sequentially programmed pulsed magnetic fields at a focal region, the pulsing being controlled by a switching system operably linked to a computer that generates the operating protocol based on an embedded logic that is dependent on the biological condition of the tissue to achieve the pre-determined desired effects on of the said biological tissues.

Yet another object of the invention is to provide SPMF Therapeutic System to induce cellular regeneration and / or the degeneration processes and methods of treatment based on such processes.

Yet another object of the invention is to provide SPMF Therapeutic System in which electromagnetic fields of certain frequency ranges and intensities produced to incite the inherent resonance that are indigenous to living tissues to induce cellular regeneration and / or degeneration processes.

Yet another object of the invention is to provide SPMF Therapeutic System in which the apparatus is so constructed to enable the placement of the biological tissues including a patient in the system so as to subject the tissues and / or the patient to the sequentially programmed pulsed magnetic fields at a focal region.

Yet another object of the invention is to provide SPMF Therapeutic System in which the apparatus has multiple magnetic field generators so designed as to produce substantially homogeneous magnetic field as a focal region

It is yet another object of the invention to provide methods for inducing cellular regeneration and/or degeneration and for methods of treating certain diseases, disorders, or conditions using a pulsed magnetic field to a desired tissue in a sequential substantially rotary pattern

The features and advantages of the invention will be made apparent from the following detailed description of illustrative embodiments that proceeds with reference to the accompanying drawings.

DESCRIPTION OF THE DRAWINGS:

The foregoing and other aspects of the present invention are best understood from the following detailed description when read in conjunction with the accompanying drawings For the purpose of illustrating the invention, there is shown in the drawings embodiments that are presently preferred, it being understood, however, that the invention is not limited to the specific instrumentalities disclosed. Included in the drawings are the following figures:

FIGS. 1A and 1B are schematics of the section of magnetic field generating device;

FIG. 2 is a schematic of the ferrite rod;

FIG. 3 shows a block diagram of the embedded system;

FIG. 4 is a schematic of system configuration;

FIG. 5 shows an exemplary wound magnetic field generating device;

FIG. 6 shows an exemplary wound magnetic field generating device;

FIG. 7 shows a layout of exemplary MFG devices;

FIG. 8 shows a layout of exemplary MFG devices;

FIG. 9A-9E diagnostic images of a 30 year old female - Synovial Sarcoma with Mets in right lung and Mediastinal Lymph Nodes; (9A diagnostic CT Scan, 9B pretreatment CT Scan, 9C Mid-treatment CT scan, 9D immediately post-treatment scan, 9E – post treatment scan);

FIG. 10A-10I are diagnostic images of a 55 year old male - Left Posterior Frontal - GBM (WHO Grade- IV); (10A, B, C pretreatment scans, 10D, E, F immediately post-treatment scans, 10G, H, I 4 months post treatment, 10J, K, L, 9 months post treatment);

FIGS. 11A-11D is an exemplary case summary for Osteo Arthritis;

FIG. 12 and 12A is a flowchart illustrating exemplary logic for a sequentially programmed magnetic field (SPMF) therapeutic system.

DETAILED DESCRIPTION OF THE INVENTION:

The Sequentially Programmed Magnetic Field (SPMF) therapeutic system is a computer controlled device which generates sequential pulsed magnetic fields, by employing a plurality of Magnetic Field Generators (MFGs). The magnetic field can be precisely controlled and applied onto the cells and/or tissues that require to be treated. The MFGs are fired in a programmed sequence to facilitate the focusing of the magnetic field and is believed to result in better patient outcomes.

Inciting the inherent resonance by exogenous treatment using SPMFs can induce cellular regeneration and / or degeneration processes. In the case of regeneration and

degeneration of cells, the pulsing frequencies are in the range of about 0.1 Hz to about 2000 Hz based on the indication of the disease type which is determined by the patient's MRI, CT, Ultrasound or other diagnostic information.

As such, the apparatus's method of operation may be used in certain conditions where cellular regeneration and/or degeneration is advantageous. In some embodiments, the apparatus may be used in: (i) a method of operation for regeneration of cartilage with the help of the aforesaid apparatus; (ii) a method for degeneration of cancerous tissues by subjecting them to magnetic field generated and applied by the aforesaid apparatus, (iii) a method for regenerating the islet cells by the use of the aforesaid apparatus; (iv) a method of operation for degeneration and/or multiple sclerosis by the use of the aforesaid apparatus; (v) a method to operation for degenerative disorders. (vi) a method of operation for various other conditions that could benefit from regeneration or degeneration of tissues.

An apparatus for inducing a SPMF in biological tissue(s) comprises means for generating and applying magnetic fields to the biological tissue(s) from one or more pairs of oppositely placed means for generating and applying magnetic fields. The magnetic field is generated simultaneously by mated opposed pairs of MFGs. In some embodiments, the magnetic field is applied in a sequential programmed manner by different mated opposed pairs. In some embodiments, a magnetic field of the same strength is generated and applied to the said tissue(s) from each oppositely placed MFG in each pair. The sequential application may be conducted in mated opposed pairs or in selected groups of mated opposed pairs of MFGs. The sequential program, in some embodiments, is generally rotary in nature, wherein the firing sequence of the MFGs generally flows circumferentially from one adjacent MFG to the next. In the case of the system having multiple rows of MFGs, in some embodiments, the firing sequence continues to the next adjacent row for sequential circumferential firing of the MFGs, and so on until the desired program is completed.

Referring to Figs. 1A and 1B, each MFG comprises a hollow cylindrical base body ending in a funnel, made of material capable of magnetic conduction. The body houses a rod-like structure having good magnetic conductivity. An electrical coil is wound around the hollow base body and its funnel end and connected to an electrical supply to generate magnetic field. An external cover may be optionally provided to minimize or prevent leakage of magnetic field. The one or more pairs of MFGs are housed in a tubular gantry, preferably in transverse rows of more than one and circumferentially at an angle of about 15 to about 90 degrees with respect to one another based on the focal point located on a transverse axis of the tubular gantry, where the biological tissue to be treated is placed.

The methods proposed by this invention for regeneration or degeneration of tissues involves planning the exposure of the tissues to a SPMF generated by the apparatus and thereby to induce a pulsed magnetic field. The extent of the exposure to such pulsed magnetic field would depend upon the amount of progression of the condition, for example the amount of degeneration that is already set in and other factors depending on the condition to be treated. The plan results in a determination of one or more of the following, frequency to be used, field width, field intensity, duration of each pulse, pattern of the sequential program, duration of individual treatments, number of treatments required, etc.

The area to be treated is made to locate at the focal point. A sensitizing treatment phase may be used depending upon the treatment plan and the condition to be treated. Then, a stimulating treatment phase wherein the magnetic field is generated and applied according to the plan. The magnetic field is generated and applied in a sequential pattern. After the desired number of treatments, the patient can be reevaluated and the plan adjusted and/or reassessed if necessary.

In the case of regeneration and degeneration of cells, the pulsing frequencies are in the range of about 0.1 Hz to about 2000 Hz based on the indication of the disease type which may be determined, for example, by either the patient's MRI, CT, Ultrasound or other technique. In some embodiments, the pulsing frequencies are in the range of about 120 Hz to about 2000 Hz. In some embodiments, the pulsing frequencies are about 5 Hz to about 120 Hz. In some embodiments, the pulsing frequencies are in the range of about 1 Hz to about 600 Hz. In some embodiments, the pulsing frequencies are about 8 Hz to about 50 Hz. In some embodiments, the pulsing frequencies are about 30 Hz to about 120 Hz.

THE APPARATUS

In accordance with embodiments of the invention a Sequentially Programmed Magnetic Field (SPMF) therapeutic system and method comprise a plurality of arrays of MFGs to produce sequentially programmed pulsed magnetic fields at a focal region, the pulsing being controlled by a switching system operably linked to a computer that generates the operating protocol based on an embedded logic that is dependent on the disease type and the treatment to be administered.

Generally, the apparatus comprises a plurality of MFGs 100 to generate and apply magnetic field. The MFGs 100 are fixed circumferentially on a tubular gantry 101 in regular intervals of about 15 to about 90 degrees with respect to adjacent MFGs 100 with reference to the focal axis 500.

Each MFG 100 consists of a hollow cylindrical base body 2 extending into a funnel 4. It is made of material capable of magnetic conduction; a rod like structure (FIG. 2, 30) having good magnetic conductivity fixed within the cylindrical base body 2 extending into the funnel 4; an electrical coil 95 wound around the hollow cylindrical base body 2 and the funnel 4.

The electrical coil 95 is connected to an electrical supply. The electrical coil 95, on passing of electric current generates magnetic field. The funnel end 4 of each MFG 100 faces inside the tubular gantry 101 toward the focal axis 500.

The rod like structure in the MFG increases the strength and uniformity of the magnetic field thereby increasing the efficacy of the apparatus. The MFGs are located at such an angle θ and at such a distance D from each other so as to reduce or eliminate interference between the magnetic field generated by the given means and the residual magnetic field of the adjoining means. FIG. 3 shows a block diagram of the embedded system, Fig. 3a shows the angle between adjacent MFGs. The distance between circumferentially adjacent MFGs is shown as D, and depends on the size of the machine, the number of MFGs, and the angle θ between them. In one exemplary arrangement with 24 circumferential MFGs, θ is 15 degrees and the distance D between adjacent circumferential MFGs is 129.25mm.

In some embodiments, the invention provides an apparatus, further comprising a tubular gantry, defining from about 1 to about 12 transverse planes with respect to the central axis of said gantry along which the plurality of MFGs are located. In some embodiments, the gantry defines from about 1 to about 9 transverse planes. In some embodiments, the gantry defines about 1 to about 5 transverse planes. On each transverse plane, about 2 to about 24 MFGs are disposed radially over the circumference of the gantry. Diametrically opposite MFGs are operatively coupled to form about 1 to about 12 pairs wherein each of the pairs can be excited to generate a magnetic field.

In some embodiments, circumferentially adjacent MFGs are displaced from each other by regular intervals of about 15 to about 180 degrees. As will be appreciated, the number of MFGs and the angle are directly related to one another. A pair of MFGs will be about 180 degrees from each other. In an apparatus employing 24 circumferential MFGs each MFG will be about 15 degrees from the next adjacent MFG. For example, when the MFGs are placed at regular intervals the following table sets forth the number of pairs, the number of MFGs in each transverse plane, and the approximate angle between adjacent MFGs.

Pairs	1	2	3	4	5	6	7	8	9	10	11	12
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MFGs	2	4	6	8	10	12	14	16	18	20	22	24
Angle θ	180	90	60	45	36	30	25.71	22.50	20	18	16.4	15

Shielding of housing of the MFGs and/or the system by an external cover may be employed to limit or prevent leakage of the magnetic field thereby increasing the efficacy of the apparatus and making it safe to operate.

The apparatus may contain additional components that make the apparatus more useable or user friendly or enhance performance. For example: a fan can be employed to circulate air around the tubular gantry 101 to prevent collection of dust and static charge which potentially interferes with the magnetic field. An external cover may be provided to shield the tubular gantry 101 against leakage of magnetic field. A bed on a supporting stand having cushion may be used, sliding a patient lying thereon into the tubular gantry 101 with the help of supporting motor (not shown), gear railings, bearings and supporting railings. As such tissues of the patient which are to be treated can be positioned at the focal point where the magnetic field generated from the MFGs 100 is focused.

In most other treatment devices with energizing coils, the coils are unidirectional. In this method, the coils are bidirectional because the coils which are approximately 180 degrees opposite to each other in the tubular gantry 101 are energized at the same time and out of phase so that the net magnetic flux passes through the core of the tissue or the centre of the region of interest i.e. the mated opposed pairs of MFGs fire simultaneously from opposite directions. The constant switching or the energizing of coils in a rotary pattern causes the focusing to occur in a relatively small area which is the tissue to be treated. The net magnetic flux can be directed at the center of the region of interest (i.e. focal point) with very little emission required from each of the MFGs.

Data is fed into a computer coupled to and controlling the apparatus. Based on the disease type, the duration, and nature of the disease etc., the computer software

calculates the duration of the exposure, the pulse frequency, the frequency of the firing and the amount of SPMF depending on the patient and the disease.

The following embodiments describe how the entire system functions as a comprehensive apparatus to produce the SPMF specifically for a particular disease type. The embedded system comprises a computer, high speed processing controller, power supplies, MFGs, a cylindrical gantry that, in some embodiments, includes a total of 216 MFG's that produce the sensitizing and stimulating frequency's required to treat specific disease types. More or fewer MFG's could be employed depending upon the application, size and arrangement of the apparatus. Particularly, it should be noted that full body apparatus are contemplated as shown in the drawings, but smaller models suitable for treatment of, e.g. the elbow or knee are also contemplated.

In accordance with one embodiment of this invention, the sequential programmed magnetic field generation system may include:

- an embedded system comprising a high speed processing microcontroller configured with a power drive module that comprises a digital to analog converter for set voltage reference of regulated field strength, pulse width modulation circuit, optional current sensing circuit configured with operational amplifier, digital to analog converters, PWM supported ASICS & MOSFETs, optical isolations to ensure complete isolation between processor system and analog system;

- a pulse drive module comprising power MOSFETs in "H" bridge formation with heat sinks, gate drive systems through optically isolated drive modules and a set of transistors, optical isolation system for isolating main processor module with power MOSFETs system, a set of LED's for physical verification of proper excitation of magnetic coils, power rectifier's fuses and surge protection system;

- a step down transformer configured with main AC power supply; personal computer; set of fault monitoring LEDs;

- wherein the embedded system is provided with interrupt provision that enables serial communication, timers for controlling the sequential operation of

exciting the coils of the core, power monitoring facility wherein if voltage drops below designed value, the critical parameters are saved in the flash memory of central processing unit;

wherein the embedded system is configured with a plurality of MFGs;

wherein plurality of such MFGs are circumferentially disposed on the internal diameter of a cylindrical structure such that the devices are disposed diametrically opposite to each other in each cross section of the cylinder;

wherein the surface of the cylindrical structure is mounted with such MFGs in longitudinal direction;

wherein the magnetic field generating device is controlled by the embedded system to generate tailored pulsed magnetic fields directed to a region of interest or focal point;

an initialization module wherein peripherals and sub systems are configured wherein baud rate for serial transfer of data between PC and processor, timer periodicity and wait time for packet transfer set / initialized;

a serial – data receiving module to receive the data and command from the personal computer and validate the packets received , accept/reject packets and send acknowledgment;

a packet evaluation module to evaluate the packet for correct node address, CRC check and ensure commands and data are within the acceptable limits;

an acknowledgement module to transmit any and requested data packets to the personal computer;

an executive command module to initiate process in respect of treatment sequence, stop on set time expiry, pause or stop command issued by system operator from the personal computer;

wherein the diametrically disposed coils of the paired MFGs are connected in series and subjected at a time to a rectangular pulse operating out of phase with respect to each other to produce an effective magnetic field at the region of interest; wherein

the pulse characteristics are selected from frequency of about 0.1Hz to about 2KHz, pulse count of about 2 to about 50, current of about 0.1 to about 5 amps, voltage from about 20 to about 65 V, producing effective magnetic field of about 0.01 to about 5 mT, wherein the time duration between the switching off and the switching on of the adjacent pair diametrically disposed MFGs is about 1 msec to about 5 msec.

These features of the processes have been illustrated in FIG. 12 - system flowchart.

FIG. 1A and FIG. 1B describe one embodiment of a magnetic field generating device (MFG) 100 employed in the magnetic field generating system. As shown, the magnetic field generating device 100 may comprise a disc shaped base mounting member 1 wherein cylindrical base body 2 is disposed substantially perpendicular to the first surface 6 of the disc shaped mounting member 1 and stands upwards from the first surface of the disc shaped mounting member. A mounting provision 90 as indicated in FIG. 6 (as seen in the bottom view of the mounting member 1) in the form of a preferably threaded hole is provided in the center of the cylindrical base body 2 wherein the opening of the hole is on the second surface 9 of the disc shaped mounting member 1. The other end portion 3 of the cylindrical base body 2 develops up in to a conical structure or funnel 4 as seen in FIG. 1A with outwardly diverging slant lateral surface (of generation) that forms the surface of the cone wherein the cross section of the apex portion which is the apical portion of the funnel 4 is equal to the diameter of the cylindrical base body 2. A base portion is provided with a rim like substantially flat portion 10.

A concentric cavity 11 is provided inside the cylindrical base body 2 wherein the cavity opens in the inner portion 15 of the conical member 4 at the opening 7 that elevates inside the conical portion wherein the opening 7 forms apical portion of a second conical frustum 20 comprising lateral surface of generation 8 extending downwards towards the cylindrical base body 2 wherein the lateral surface 8 intersects the inside lateral surface of the conical member 4 to form annular space 16 as shown in FIG. 1B which is the top view of the FIG. 1A. The cavity 11 is adapted

to receive a ferrite rod 30 (FIG. 2) wherein one of the end portions 31 is in the form of a truncated conical geometry.

The outer surface 21 of the cylindrical base body 2 is provided with one or plurality of axial slots 25 wherein portion of the slot extends in the lateral surface of generation of the conical member 4. The mounting member 1 is provided with one or plurality of holes 26 as illustrated in FIG. 5 and FIG. 6 for insertion of wire / conductor terminals 91 and 92.

The outer surface of the conical member 4 and the cylindrical base body 2 may be wrapped with a magnetically permeable paper (e.g., elephant paper). An electrical coil 95 is wound over the entire outer surface to form the magnetic field generating device which is illustrated in FIG. 5. The electrical coil 95 may be a copper conductor. It can be seen that the electrical coil 95 is wound from the mounting member 1 up to the rim like portion 10. The conductor terminals 91 and 92 are inserted from the holes 26 provided in the base 1 as shown in the FIG. 5 and FIG. 6 (bottom view).

In some embodiments, the cylindrical base body 2 is made from EN1A leaded steel, the ferrite rod is about 35 mm in length, about 8 mm in diameter and about 25 degree slope, and the diameter of the exemplary 29G copper wire winding is about 46 mm and the length of about 60 mm. The number of turns is about 4200. This arrangement results in an impedance of between about 80 and about 90 ohms. FIG. 3 and FIG. 7 depict circumferential disposition of the plurality of MFGs 100 on a cylindrical structure 101 subtending at an angle of about 15 degrees to about 90 degrees to each other based on the application and end use. The MFGs 100 are arranged in pairs disposed diametrically opposite to each other about focal axis 500. FIG. 4 depicts front and side views of the structure wherein the surface of the cylindrical structure 101 includes multiple MFG pairs mounted in rows wherein each of the rows comprises a plurality of the MFGs as shown in the front view.

In some embodiments, the MFGs are arranged in a clustered configuration on the tubular gantry 101 as depicted in FIG. 7. In some embodiments, the gantry 101 may be divided into a plurality of segments. For example, it may be divided into three

segments A, B and C as indicated in the FIG. 7. It may be noted that the segments in the FIG. 7 are indicated separately for better elaboration and appreciation of the aspect of clustered configuration only, it should not be construed that the three segments of the cylindrical structure are physically separated. Each of the segments is provided with rows arranged in the longitudinal direction along the focal axis 500 disposed over the circumference of the segment wherein each of the segment rows 200 include three MFGs 100a, 100b and 100c. The devices in other rows are indicated with dashed lines in the FIG. 7. In the embodiment depicted in FIG. 7, there are total 9 MFGs in one longitudinal row across the gantry clustered into a set of three devices on each of the segments A, B and C.

In the illustrated embodiment, there are 24 MFGs disposed radially over the circumference of the gantry 101 in each transverse plane to the axis 500. The diametrically opposite devices are paired to form twelve such pairs wherein each of the pairs is excited to generate a magnetic field. Assuming three such transverse planes in each segment corresponding to each of the MFGs (such as 100a, 100b and 100c), there are 24 devices in each transverse plane and three such planes totaling 72 MFGs in each segment. In another embodiment, the number of such devices in each row and transverse plane may vary depending on end application.

The MFGs of each of the segments are configured or operatively coupled to a control means. In some embodiments, there are three such control means corresponding to the three segments. The control means is configured with the embedded system for controlling magnetic field strength, sequence and frequency of field excitation in a tailored manner according to the treatment protocol.

The MFGs 100 of the system are configured with the embedded system 50 that is represented in the form of a block diagram in FIG. 3. The embedded system 50 comprises a high speed processor 51 wherein in one embodiment the processor is an analog device 32 bit ARM based processor working at about 40MHz frequency microcontroller comprising peripherals such as serial communication interface, circuit for set voltage controller reference system and Logic IC'S for coordinated

operation for power MOSFETs at digital TTL level that is configured with, for example:

a power drive module comprising digital to analog converter for set voltage reference of regulated field strength, pulse width modulation circuit, optional current sensing circuit configured with operational amplifier, digital to analog converters, PWM supported ASICs & MOSFETs. Further, the module has optical isolations 54 to ensure complete isolation between processor system and analog system;

pulse drive module comprising power MOSFETs in “H” bridge formation with heat sinks, gate drive systems through optically isolated drive modules & set of transistors, optical isolation system for isolating main processor module with power MOSFETs system, set of LED’s for physical verification of proper excitation of magnetic coils, power rectifier’s fuses & surge protection system;

step down transformer 59 configured with main AC power supply 60;

personal computer 58;

set of fault monitoring LEDs;

wherein the embedded system is provided with interrupt provision that enables serial communication, timers for controlling the sequential operation of exciting the magnetic coils of the core, power monitoring facility wherein if voltage drops below about 3.3 volts, the critical parameters are saved in the flash memory of central processing unit;

wherein the main AC power supply of about 230V, about 50 Hz is stepped down to the desired voltage level using the step down transformer 59. Further the stepped down voltage is rectified, filtered and regulated in the power supply circuitry 61 that comprises first circuitry for DC Voltages of about +15V and about -15V that is necessary for operational amplifier, second circuitry for DC Voltage of about 5V that is necessary for logical circuitry, third circuitry for DC Voltage of about 5V and power on indicator circuitry that uses LED as visual indicator. The high speed processor 51, optical isolation circuitry 54 comprising LED and phototransistor integrated together wherein the circuitry 54 provides isolation

between analog and digital circuit. The voltage signal from 54 is fed to the field control bridge circuitry 52 along with the signal from the processor 51 that transmits signal based on pulse strength, pulse frequency, pulse Sequence & pulse counts based on the object to be treated. The signals from 54 and 52 are fed to the bridge circuitry 52 that comprises power MOSFETs. The pulse duration, pulse frequency and sequence is controlled using input from the processor.

As shown in FIG. 12, the embedded system operation module may comprise:

initialization module wherein peripherals and sub systems are configured wherein baud rate for serial transfer of data between PC and processor, timer periodicity and wait time for packet transfer is set / initialized;

serial – data receiving module to receive the data & command from the personal computer and validate the packets received , accept/reject packets and send acknowledgment;

packet evaluation module to evaluate the packet for correct node address, CRC check and ensure commands and data are within the acceptable limits;

acknowledgement module to transmit any and requested data packets to the personal computer;

executive command module to initiate process in respect of treatment sequence, stop on set time expiry, pause or stop command issued by system operator from the personal computer;

In one embodiment, the embedded system software may be structured to:

Call sub-routines to perform the specific tasks;

System Initiation which starts the peripheral and sub systems as derived by the software;

Validate all data that is being transmitted or received;

Start, executive, command and monitor specific protocol sequences;

Initiate the start sequence, the stop sequence, the frequency and power required for the specific protocol;

Set the pulse strength, pulse frequency, pulse count and pulse counts;

Save all critical parameters in the flash memory of the processor in the event of a power failure.

SPMF method of operation is used to regenerate and/or degenerate the cells for the following disease types; cancer, arthritis, neuro degenerative diseases.

Process for arriving at the MFG operating conditions to regenerate and/or degenerate the cells using SPMF

In the case of regeneration and degeneration of cells, the pulsing frequencies are in the range of about 0.1 to about 2000Hz based on the indication of the disease type which was determined, for example, by either the patient's MRI, CT Ultrasound, or other diagnostic information.

In one of the embodiments, the SPMF method of operation is used by causing degeneration of tumor cells wherein the pulsing frequencies are in the range of about 120 to about 2000Hz.

In one of the embodiments, the SPMF is used in the treatment of the degeneration of the cartilage cells by causing regeneration of cartilage wherein the pulsing frequencies are in the range of about 8 to about 50Hz.

Protocols for degeneration of cancer cells

Exposure of cells to SPMF therapy normalizes the cell membrane potential, thereby halting the process of cell proliferation, followed by programmed cell death (Apoptosis). A cascade of effects follows normalization of cell membrane potential, i.e. increased influx of Calcium, Potassium ions and Oxygen and efflux of Na and H₂O out of cells, and reduction in intracellular acidity.

The normal cells are substantially unaffected by the SPMF. Furthermore, the signals are modulated depending on the proton density of the tumor tissue and impedance of

normal cells mitochondrial sensors. The energy delivered during the therapy is well within the safety norms prescribed by the International Commission for Non-Ionizing Radiation Protection (ICNIRP).

The method of operation starts with first localizing the tumor which would be the region of interest (ROI) using the ideal form of imaging i.e. MRI, CT or ultrasound. For example, head and neck tumors are best seen on MRI and lung tumors are best seen on CT scan and thyroid tumors are best viewed on an ultrasound. Once the tumor is localized a specific proton density image (short TE and a long TR) is done through the center of the lesion. Using this proton density image, specific algorithms are obtained based on signal intensities between the skin and the tumor which are different with different tissues and it would cause differential impedance of the SPMF. For the proton density image, the ROI that would be a tumor is marked and uploaded on to a software by which these densities are converted to pixel intensities from the skin to the center of the tumor. The intensities are calculated along lines drawn at about 15 degrees from the center of the tumor which would denote the placement of each MFG. The parameters of the signal strength would be different based on how much penetration and frequency is required from the MFG coil based on the intensities of tissue that are between the skin and tumor. The method of operation protocol lasts for a period divided into 2 or more phases of predetermined duration where in the first duration the frequencies applied are the frequencies which essentially sensitize the cell membrane and are followed by subsequent duration(s) of stimulating frequency which finally causes change in cell membrane potential. In one embodiment, the treatment protocol lasts for approximately 1 hour and is divided into 2 phases where the first 30 minutes (approximately), the frequencies applied are the frequencies which essentially sensitizes cell membrane and is followed by 30 minutes (approximately) of stimulating frequency which finally causes change in cell membrane potential. Different protocols are set based on proton densities of the tumor. Tumors having high proton density are treated with a high ratio and sensitizing and stimulating that could go to the range of around 0.1 Hz to 2000 Hz. Tumors with low density are

treated with lower sensitizing and stimulating frequencies ratio and these frequencies range to about 120 Hz.

The process of operating the apparatus for the method of operation for the purpose of degeneration of cancer cells tissues the operating conditions for the MFGs are arrived at correcting for the differential attenuation of the SPMF at the desired region to be subjected to SPMF. First the region of interest and the center of the tumor are marked and the pixel intensities are calculated along the skin to the center of the tumor about every 15 degrees (or other increment) which corresponds to the placement of each MFG. This information is input into the computer so that the energizing of each MFG can be different based on the field required for a particular MFG. Signal strength is derived from the MRI, CT Ultrasound image or other diagnostic information. Once this is calculated, the dose information is input into the computer. In some embodiments, the protocol first sensitizes the cellular structure and then stimulates the cell to start the regeneration process and initiate the degeneration process. In some embodiments, the treatment protocol first sensitizes the cellular structure at a frequency range of about 1 Hz to about 600 HZ and then stimulates the cellular structure at a frequency range of approximately 600 Hz to about 2000 Hz to start the regeneration process and initiate the degeneration process. In some embodiments, the treatment would be for a duration of about 1 hour per day for about 28 days.

The treatment protocol lasts for a period divided into 2 or more phases of predetermined duration where in the first duration the frequencies applied are the frequencies which essentially sensitize the cell membrane and are followed by subsequent duration(s) of stimulating frequency which finally causes change in cell membrane potential. In one embodiment, the treatment protocol lasts for approximately 1 hour and is divided into 2 phases where the first 30 minutes (approximately), the frequencies applied are the frequencies which essentially sensitizes cell membrane and is followed by 30 minutes (approximately) of stimulating frequency which finally causes change in cell membrane potential.

Different protocols are set based on proton densities of the tumor. Tumors having high proton density are treated with a high ratio and sensitizing and stimulating that could go to the range of around 2000 Hz. Tumors with low density are treated with lower sensitizing and stimulating frequencies ratio and these frequencies range to about 120 Hz.

The process of arriving at the operating conditions of the MFGs for tumours having High Proton Density is as follows:

The minimum density is derived by discarding the 2 lowest recorded proton density pixel values (formula and the program will register the 3rd lowest value as the “minimum density”. Minimum Density = 3rd minimum of Pixel Value

$$S = PD \exp(-TE/T2) (1 - \exp(-TR/T1)) (n)$$

wherein, S is the brightness (signal) measured at some particular point in the image--at some particular "pixel"; PD is "Proton Density", the number of hydrogen atoms in the region corresponding to that pixel; and T1 and T2 are the corresponding time constants for that pixel.

The maximum density is derived by discarding the 2 highest recorded proton density pixel values (formula and the program will register the 3rd highest value as the “maximum density”. This methodology is being used because the density value of bone is very high and would distort the calculation. Maximum Density = 3rd Maximum of Pixel Value

$S = PD \exp(-TE/T2) (1 - \exp(-TR/T1)) (n)$ wherein, S is the brightness (signal) measured at some particular point in the image--at some particular "pixel"; PD is "Proton Density", the number of hydrogen atoms in the region corresponding to that pixel; and T1 and T2 are the corresponding time constants for that pixel.

$$\text{Average Density} = (\text{Sum of Pixel Values} / \text{No. Of Pixel Values})$$

The average density is derived by dividing the sum of the all the Pixel Values in the region of interest divided by the total number of pixels in the region of interest

$$\text{Skin To Target} = \text{Root}((x_e - x_s)^2 + (y_e - y_s)^2)$$

The Skin to Target value is derived by the root value of x_e (x axis target) - x_s (x axis Skin) squared plus y_e (y axis target) - y_s (y axis skin) squared

$$\text{Sensitizing Frequency} = \text{Min density} * 6.28$$

The minimum density as described in (1a) is multiplied by 6.28 which is 2π

$$\text{Download Sensitizing Frequency} = \text{HEX}(65536 - (500000 / \text{SeF}))$$

This equation is the hexadecimal input for the Sensitizing Frequency

$$\text{Stimulating Freq} = \text{Max density} * 1.57$$

The maximum density as described in (2a) is multiplied by 1.57 which is $\pi/2$

$$\text{Download Stimulating Frequency} = \text{HEX}(65536 - (500000 / \text{StF}))$$

This equation is the hexadecimal input for the Stimulating Frequency $k = (\text{Maximum Density} * \text{Minimum Density}) / (\text{AvgDensity})$

k is used to calculate the pulse count and is derived from multiplying the maximum density by the minimum density and divided by the average density

$$\text{Pulse Count Sensitizing} = \text{Sensitizing freq} / k$$

The pulse count for sensitizing is derived by dividing the sensitizing freq by k

$$\text{Pulse Count Stimulating} = \text{Stimulating freq} / k$$

The pulse count for stimulating is derived by dividing the stimulating freq by k

The process of arriving at the operating conditions of the MFGs for tumours having Low Proton Density

$$\text{Minimum Density} = 3^{\text{rd}} \text{ minimum of Pixel Value}$$

$$S = PD \exp(-TE/T2) (1 - \exp(-TR/T1)) (n$$

$$\text{Maximum Density} = 3^{\text{rd}} \text{ Maximum of Pixel Value}$$

$$S = PD \exp(-TE/T2) (1 - \exp(-TR/T1)) (n)$$

$$\text{Average Density} = (\text{Sum of Pixel Values} / \text{No. Of Pixel Values})$$

$$\text{Skin To Target} = \text{Root}((x_e - x_s)^2 + (y_e - y_s)^2)$$

$$\text{Sensitizing Freq} = \text{Average density} * 3.14$$

$$\text{Download Sensitizing Frequency} = (65536 - (500000 / \text{SeF}))$$

$$\text{Stimulating Freq} = \text{Max density} * 3.14$$

$$\text{Download Stimulating Frequency} = \text{HEX}(65536 - (500000 / \text{StF}))$$

$$k = (\text{Maximum Density} * \text{Minimum Density}) / (\text{AvgDensity} * 3.14 * 3.14)$$

k is used to calculate the pulse count

$$\text{Pulse Count Stimulating} = \text{Stimulating freq} / k$$

If PCSt >= 50; Then PCSt = 50;

If PCSt <= 10; Then PCSt = 10

$$\text{Pulse Count Sensitizing} = (\text{sensitizing freq} / \text{stimulating/freq}) * \text{Pulse Count Stimulating}$$

Effect of SPMF in Cellular degeneration processes:

Cancerous tissues are morphologically and functionally more primitive than their tissue of origin, have uncontrolled growth, have capacity to invade surrounding tissue, metastasize at different sites and derive its energy by glycolysis and the cells have low membrane potential (e.g., -15mV to -30mV).

Cone (Oncology 24: 438-470 (1970) postulated a functional relationship between transmembrane potential (TMP) and mitotic activity in general, including both normal, proliferative activity (eg, growth, healing wounds) and malignancy. Specifically he proposed that cells with normal TMP demonstrated virtual absence of mitotic activity while cells with low TMP showed greatly increased proliferation. He demonstrated that electrical trans-membrane potential is correlated to degree of mitotic activity similar structural alteration could occur in the mitochondrial membrane affecting oxidative phosphorylation.

Exposure of cells where the cell membrane is below normal conditions SPMF normalizes the potential, thereby arresting the process of cell proliferation. A cascade of effects follows normalization of cell membrane potential, i.e. increased influx of Calcium, Potassium ions and Oxygen and efflux of Na and H₂O out of cells, and reduction in intracellular acidity. SPMF also increases the impedance of mitochondrial membrane potential and restores energy production.

SPMF effects the regulation of cell membrane potential and gap junction inter-cellular communication aberrations thereby impacting carcinogenesis and neutralizing these effects.

SPMF targets the basic cellular abnormalities and normalizes cellular functions by restoring transmembrane potential, thereby normalizing the disrupted or aberrant intracellular and intercellular connection, preventing electron efflux which is responsible for absolute decrease in TMP, restoring gap junction inter cellular communication with surrounding normal cells by regulating the passage of Ca⁺ ions and cAMP.

SPMF further restores the p53 function as cell mitosis is arrested by the change in orientation of centrioles during cell division which prevents Cyclin E-dependent reduplication of both centrioles and centrosomes in a single cell division cycle thereby irreversibly marking the cell for apoptosis. The SPMF also reduces blood volume density in tumor thus decreasing chances of distant metastasis.

Protocols for regeneration of cells

The methods of using SPMF for regeneration involves planning of the exposure which is based on the amount of degeneration that is already set in and other factors relevant to the particular condition to be treated. Once the dose planning is done, the patient is marked using ultrasound or other techniques. At the same time, the joint is evaluated for any effusion and marking is done at one or two points where SPMF needs to be administered. Once the patient is marked, the patient is taken into the

SPMF system, for example on a sliding platform, and the magnetic field is focused on to the region of interest, for example with the help of the laser guide, and the treatment runs for the period of time that is designated based on the factors mentioned above.

A predetermined dose profile is formed based on the grade, severity and the permittivity index. Patients who have early stage degeneration of the cartilage cells receive a low sensitizing frequency in the range of about 8 Hz to about 20 Hz, a stimulating frequency in the range of about 12 Hz to about 40 Hz. Patients who have severe degeneration of the cartilage cells and a high permittivity index receive a sensitizing frequency of about 10 Hz, and a stimulating frequency up to about 40 Hz. In some embodiments, the treatment is for a duration of about 45 min to about 1 hour per day for about 21 days.

The results confirm significant regeneration of cartilage, increase in the strength and stability of, e.g., the knee joint and improvement in quality of life, as measured with a MRI system and internationally accepted American Knee Society rating system.

The operating conditions of the apparatus for treatment of regeneration of cells is based on a predetermined dose profile dependent on the grade and severity of the degeneration of the cartilage cells and the permittivity index. Patients who have early stage degeneration of the cartilage cells will receive a low sensitizing frequency in the range of 8 Hz to 20 Hz, a stimulating frequency in the range of 12 Hz to 40 Hz. Patients who have severe degeneration of the cartilage cells and a high permittivity index will receive a sensitizing frequency of 10 Hz, and a stimulating frequency up to 40 Hz. as per the table.

Table

Class	Sensitizing Frequency	Stimulating Frequency
High Permittivity Grade – I	8	9
High Permittivity Grade – II	8	10

High Permittivity Grade – III & above	8	11
Low Permittivity Grade – I	8	10
Low Permittivity Grade – II	8	12
Low Permittivity Grade – III & above	8	14

SPMF IN REGENERATION OF CELLS:

SPMF causes the regeneration of cartilage and pain relief in patients that have degeneration of the cartilage cells; In degenerated cartilage, there is loss of collagen and proteoglycans preventing generation of piezoelectric stimulus or failure of this stimulus to stimulate the chondrocytes. Exposure of cartilage cells to SPMF re-creates the physiological piezoelectric stimulus. Exposure of cartilage cells in patients to specific regulated SPMF therapy fields leads to denovo-synthesis of centrioles from the microtubules and the protein surrounding them, leading to regeneration of cartilage cells.

Relief of pain after few SPMF exposure is brought about by reduction in synovial inflammation that is due to reduction in gap junction mediated secretion of pro-inflammatory cytokines. SPMF lowers the threshold of nociceptive afferents innervating the joint capsule.

Neuro Degeneration

Protocols for regeneration of cells in Neurodegenerative & Neural Disorders

Neuro degeneration, the progressive loss of nerve cells, occurs in aging and in neurodegenerative disorders, such as Alzheimer's, Parkinson's, ALS, and Huntington's disease, in retinal degeneration, and other damage to sensory systems (e.g., visual, auditory, somatosensory), in stroke, head and spinal trauma, epilepsy,

in drug and alcohol abuse, in infectious diseases, in exposure to industrial and environmental toxicants, and, perhaps, in mental disorders and chronic pain. Primarily, these diseases are characterized by chronic and progressive loss of neurons in discrete areas of the brain, causing debilitating symptoms such as dementia, loss of memory, loss of sensory or motor capability, decreased overall quality of life and well-being, disability, and eventually, premature death.

Neurodegenerative indications are broadly divided into two groups according to phenotypic effects, although these are not mutually exclusive: Conditions causing problems with movements, such as ataxia, and conditions affecting memory and related to dementia.

Some specific neurodegenerative indications and disorders include but are not limited to Adrenoleukodystrophy (ALD), Alcoholism, Alexander's disease, Alpert's disease, Alzheimer's disease, Amyotrophic lateral sclerosis (Lou Gehrig's Disease), Ataxia telangiectasia, Batten disease (also known as Spielmeyer-Vogt-Sjögren-Batten disease), Bovine spongiform encephalopathy (BSE), Canavan disease, Cockayne syndrome, Corticobasal degeneration, Creutzfeldt-Jakob disease, Familial fatal insomnia, Frontotemporal lobar degeneration, Huntington's disease, HIV-associated dementia, Kennedy's disease, Krabbe's disease, Lewy body dementia, Neuroborreliosis, Machado-Joseph disease (Spinocerebellar ataxia type 3), Macular Degeneration, Multiple System Atrophy, Multiple sclerosis, Narcolepsy, Niemann Pick disease, Parkinson's disease, Pelizaeus-Merzbacher Disease, Pick's disease, Primary lateral sclerosis, Prion diseases, Progressive Supranuclear Palsy, Refsum's disease, Sandhoff disease, Schilder's disease, Subacute combined degeneration of spinal cord secondary to Pernicious Anaemia, Spielmeyer-Vogt-Sjogren-Batten disease (also known as Batten disease), Spinocerebellar ataxia (multiple types with varying characteristics), Spinal muscular atrophy, Steele-Richardson-Olszewski disease, Tabes dorsalis, Toxic encephalopathy, Path physiology and others.

The treatment pulsing frequencies for the neuro protocols are in the range of about 30 Hz to about 120 Hz. The treatment protocol first sensitizes the cellular structure at a frequency range of about 30 Hz to 60 HZ and then stimulates the cellular

structure at a frequency range of about 90 Hz to about 120 Hz to start the regeneration process. The treatment time is approximately 1 hour a day for 21 days.

In some embodiments, the SPMF is used for a variety of degenerative or regenerative applications where specific parameters can be determined through similar techniques as used and described above.

The use of electromagnetic fields in neural regeneration has been tried earlier with little success. However the SPMF method and the protocols enhance the efficacy of treatment, as the SPMF can be targeted on specific areas (region of interest) based on tissue type.

The process of arriving at the operating conditions of the MFGs for regeneration of cells in Neuro Degenerative & Neural Disorders are as follows:

First, proton density, MRI of the brain is performed, then the area mapping is carried out based on the algorithm described below, and then the dose pattern is mapped out for the patient.

NEURO DEGENERATIVE CONDITIONS

MinimumDensity = 3rd minimum of PixelValue

MaximumDensity = 3rd Maximum of PixelValue

AverageDensity = (Sum of Pixel Values \ No. Of Pixel Values)

SkinToTarget = Root((xe-xs)² +(ye-ys)²)

Sensitizing frequency= (X) = Min density*2 Π

Constant_Sensitizing_Frequency= (X) / ($\Pi^2 * \ell$) $\ell \approx 2.718$ (Euler's constant)

If Sensitizing Frequency >= 60 Then

Sensitizing Frequency = 60

Else If Sensitizing Frequency <= 30 Then

Sensitizing Frequency = 30

DownloadPulse Sensitizing =HEX(65536-(500000 / Sensitizing Frequency))

$$\text{Stimulating Frequency} = Y = \text{Max density} * (\Pi/2)$$

$$\text{Constant_sti_Frequency} = (Y) / (\Pi^2)$$

If Stimulating Frequency ≥ 120 Then

$$\text{Stimulating Frequency} = 120$$

ELSE If Stimulating Frequency ≤ 80 Then

$$\text{Stimulating Frequency} = 80$$

$$\text{DownloadPul Stimulating} = \text{HEX}(65536 - (500000 / \text{Stimulating Frequency}))$$

$$k = \Pi * \ell \quad (\ell \approx 2.718 \text{ (Euler's constant)})$$

$$\text{Pulse Count Sensitizing} = \text{Sensitizing Frequency} / k$$

$$\text{Pulse Count Stimulating} = \text{Stimulating Frequency} / k$$

For hair cell degeneration in the inner ear the pulsing frequencies are in the range of about 8 to about 30Hz.

Hair cell degeneration in the inner ear is an abnormality of the inner ear causing a host of symptoms, including vertigo or severe dizziness, tinnitus or a roaring sound in the ears, fluctuating hearing loss, and the sensation of pressure or pain in the affected ear. The disorder usually affects only one ear and is a common cause of hearing loss.

The process of arriving at the operating conditions of the MFGs for hair cell degeneration in the inner ear.

$$\text{MinimumDensity} = 3^{\text{rd}} \text{ minimum of PixelValue}$$

$$\text{MaximumDensity} = 3^{\text{rd}} \text{ Maximum of PixelValue}$$

$$\text{AverageDensity} = (\text{Sum of PixelValues} \setminus \text{No. Of PixelValues})$$

$$\text{SkinToTarget} = \text{Root}((x_e - x_s)^2 + (y_e - y_s)^2)$$

$$\text{Sensitizing Frequency} = (X) = \text{Min density} * 2 \Pi$$

$$\text{Constant_Sensitizing_Frequency} = (x) / (4 * \Pi)$$

```

If Sensitizing Frequency >= 10 Then
    Sensitizing Frequency = 10
Else If Sensitizing Frequency <= 8 Then
    Sensitizing Frequency = 8
    Download Pulse Sensitizing =HEX (65536-(500000 / Sensitizing
    Frequency))
    Stimulating Frequency = (y) = Max density * (Π/2)
    Constant_Stimulating_Frequency=(y) / (4 * Π)
    If Stimulating Frequency >= 30 Then
        Stimulating Frequency = 30
        DownloadPul Stimulating =HEX(65536-(500000 / Stimulating
        Frequency))
        k = (maxd * mind) / ("AvgDensity")
        PulseCount Sensitizing = Sensitizing Frequency / k
        pulseCount Sensitizing =4 /* Constant Value */
        PulseCount Stimulating = Stimulating Frequency / k
        If plusecount Stimulating <= 4 Then
            plusecount Stimulating = 4
        Else If plusecount Stimulating >= 14 Then
            plusecount Stimulating = 14

```

Macular Degeneration (Degeneration of tissue) (medical condition usually of older adults that results in a loss of vision in the center of the visual field (the macula) because of damage to the retina). SPMF when applied to such indications have several advantages in terms of it being a non-invasive procedure, decreasing the pain significantly without exhibiting side effects, and at the same time providing long lasting cure, enabling natural cell growth,

EXAMPLES OF BENEFICIAL EFFECTS OF SPMF:-

The follow sections describe the methods of treatments including non limiting examples to illustrate the utility of the SPMF system.

Clinical examples:

Since 2009, 31 patients have been treated in a clinical trial. Some of the benefits of SPMF treatment include The improvement in the quality of life, halting the progression of the disease, significantly decreasing pain, effective alternative to radiation therapy, long term cure benefits. patient convenience as It is an outpatient treatment.

Example 1: Case Study for degeneration of cells

Case Summary: 30 year old female Diagnosed with Synovial Sarcoma with Mets in Right lung and Mediastinal Lymph Nodes

Since July 2007 the patient had progressively increasing swelling in the lower Post Chest wall; The CT Scan is given in FIG. 9A. The FNAC- 24th Aug 2007 was inconclusive; Excision of soft tissue mass on 7th Sept 2007, at Sydney, Australia; Post Op Biopsy- Synovial Sarcoma; Post op Radiotherapy- 25#, 10/10/07 to 4/12/2007; Chemotherapy- Ifosphamide and doxorubicin- 2#, from 1/01/08 onwards, stopped because of side effects; 25/12/08- PET CT well defined nodule in the apical segment of lower lobe of right lung, S/O metastases; 16/01/09-Surgery-Rt. Lower Lobectomy done; Post op Biopsy- Rt. Lower lung Nodule- conclusive of metastatic Synovial Sarcoma; July 2009- CT Chest + abdomen- Multiple lobulated Pleural masses and a mass in Rt. Perihilar region, the surgical Clips in the Left Lumbar region and Lower lobe Bronchus in situ; 23/3/09-CT chest/abdomen- No evidence of Metastasis; 22/7/09-Biopsy of Lung Mass- recurrence of Monoplastic Synovial

Sarcoma; spindle shaped cells focally +ve for EMA; Severe pain in the Rt. lower chest (patient on Fentanyl patch, 50mg +NSAIDS); rapid loss in weight of 4 Kgs in 2 months;

The Pre-treatment CT of 19/09/2009 is given in FIG. 9B;

Was subjected to SPMF Therapy from 20/09/09 to 17/10/09;

The Mid-treatment CT of 07/10/2009 is given in FIG. 9C, the Post-treatment PET/CT of 29/10/2009 is given in FIG. 9D and the Post-treatment CT of 05/11/2009 is given in FIG. 9E; Palliative RT for SVC syndrome, 12 Gy/3# - 19/10/09, 21/10/09 and 22/10/09; 10 days after SPMF therapy, she was off the pain killer; Breathlessness reduced (Climbed 2 flights of stairs without breathlessness) Wt. stabilized.

Example 2 : Case Study for degeneration of cells

Case Summary; 55 Male Diagnosis- Left Posterior Frontal- GBM (WHO Grade- IV) Diagnosis- Left Posterior Frontal- GBM (WHO Grade- IV) Onset: 26th March 2007; Presenting symptoms-seizure; MRI Brain dated 21/05/07, films only; Small dense nodular enhancing lesion in left frontal lobe (6 x 5 x 6 cms); Multiple small chronic lacunar infarcts B/L centrum semiovale, parietal lobe & periventricular region; Given ATT and antiepileptic drugs for 06 months. Recurrence of symptoms; MRI Brain dated 27/12/07: Well defined nodular enhancing region in Right frontal convexity 6 x 4 cms with perilesional edema and adjoining Meningial enhancement; Surgery Left posterior frontal craniotomy with excision of tumor on 10/01/2008; HPR : Diffuse infiltrating astrocytoma Gr-II. Improved symptomatically; Post-op RT- 54 Gy/30# dated 10/03/08 to 25/04/08; Recurrence of symptoms- Generalized Seizure and Right Hemipareses in Nov / Dec 2008; Second Surgery- Left posterior frontal craniotomy with excision of tumor on 01/01/2009. HPR: GBM Grade IV dated 14/01/2009. (Reported at National Institute of Mental health and

neurosciences, Bangalore, India.) Symptomatic improvement with residual right Hemipareses; Complaints of Right Hemipareses, pain in both legs and headache;

SPMF Therapy was done from 04/04/09 to 01/05/09 (28 days); Post SPMF there was no headache and leg pain and the muscle power improved in Right upper and lower limbs;

Pre SPMF MRI : lesion size 2.2 x 3.8 Cms. FIG. 10A, B, C; Immediate Post SPMF : Lesion size 2.0 x 3.5 Cms. FIG. 10D, E, F and Post SPMF 04 months: lesion size 1.4 x 1.5 Cms. FIG. 10G, H, I;

The significant improvements are clearly seen in the figures which are self explanatory.

Example 3. Case Study for regeneration of cells

Since 2009, treated over 150 patients were treated in a commercialized model. The Range of Motion (ROM) increased progressively with improvement in Total Functional Scores (TFS) and Total Knee Score (TKS) in all patients and they were able to walk comfortably for considerable distances at the end of the treatment. There was a significant increase in the cartilage thickness after SPMF therapy leading to improved stability and power of the knee joint. The Cure has been long lasting and progress of the disease halted with significant decrease in pain. Further the treatment enables natural growth of cartilage and increases its thickness as against placement of foreign substance and provides an effective alternative to knee replacement. Further both knees can be treated simultaneously and can be conducted as an outpatient treatment without any disruption of the normal activity during the course of the treatment.

Patient case history;

FIGS. 11A, B, C, D, present the case of SPMF Treatment was performed for 21 days on a patient with Osteo Arthritis. After 90 days of treatment the total knee score (TKS) increased from 55 to 80 illustrated in FIG. 11a, and the cartilage thickness increased from .05mm to .06mm illustrated in Fig11b,c,d; Progress Report for

SPMF Therapy, FIG. 11a; MRI Image of the left knee Pre SPMF Therapy FIG. 11b; MRI Image of right knee Pre SPMF Therapy FIG. 11c; MRI Images of both knees Post SPMF Therapy MRI Images FIG. 11d;

Clinical Outcomes treatments using SPMF for Neuro disorders

Clinical Data examined – Patient Dr. C aged 60 years patient of Spinocerebellar Ataxia 1 came with significant speech defects ataxia and hence has difficulty in walking since 2 years was unable to walk on a smooth surface without support and had episodes of frequent fall and she was unable to go to her clinic and continue her clinical practice. She was treated with SPMF therapy for 4 weeks after which she started showing improvement gradually and the next 3 months, her speech and gait improved to an extent that she could walk independently and she could go back to seeing patients in her clinic and in 6 months, she had almost reached normalcy.

CONCLUSIONS :-

In accordance with embodiments of the invention a Sequentially Programmed Magnetic Field (SPMF) therapeutic system and method comprise a plurality of arrays of magnetic field generators (MFGs) to produce sequentially programmed pulsed magnetic fields at a focal region, the pulsing being controlled by a switching system operably linked to a computer that generates the operating protocol based on an embedded logic that is dependent on the disease type and the treatment to be administered.

The invention SPMF Therapeutic System is a system that induces cellular regeneration and / or the degeneration processes and methods of treatment based on such processes. Electromagnetic fields of certain frequency ranges and intensities are indigenous to living tissues and it has been found that inciting the inherent resonance by exogenous treatment using an SPMF can induce cellular regeneration and / or degeneration processes.

Some embodiments of the invention provide an apparatus for generating and applying a magnetic field to a desired tissue comprising: a plurality MFGs to produce sequentially programmed pulsed magnetic fields at a focal region; and a switching system to control the pulsing dependent on the disease type and the treatment to be administered.

Some embodiments of the invention further provide a tubular gantry for housing the MFGs; wherein the MFGs are fixed circumferentially on the tubular gantry in regular intervals of about 15 to about 180 degrees with respect to an adjacent MFGs with reference to the central axis of said tubular gantry, which is the focal axis. In some embodiments, the plurality of MFGs are operatively coupled in mated, opposed pairs, such that pairs of MFGs which are about 180 degrees opposite to each other in the tubular gantry are energized at the same time and out of phase so that the net magnetic flux passes through the core of the tissue or the centre of the region of interest.

In some embodiments, the invention provides an apparatus, further comprising a tubular gantry, defining from about 1 to about 12 transverse planes with respect to the central axis of said gantry along which the plurality of MFGs are located. In some embodiments, the gantry defines from about 1 to about 9 transverse planes. In some embodiments, the gantry defines about 1 to about 5 transverse planes. On each transverse plane, about 2 to about 24 MFGs are disposed radially over the circumference of the gantry. Diametrically opposite MFGs are operatively coupled to form about 1 to about 12 pairs wherein each of the pairs can be excited to generate a magnetic field.

In some embodiments, circumferentially adjacent MFGs are displaced from each other by regular intervals of about 15 to about 180 degrees. As will be appreciated, the number of MFGs and the angle are directly related to one another. A pair of MFGs will be about 180 degrees from each other. In an apparatus employing 24 circumferential MFGs each MFG will be about 15 degrees from the next adjacent MFG. For example, when the MFGs are placed at regular intervals the following

table sets forth the number of pairs, the number of MFGs in each transverse plane, and the approximate angle between adjacent MFGs.

Pairs	1	2	3	4	5	6	7	8	9	10	11	12
MFGs	2	4	6	8	10	12	14	16	18	20	22	24
Angle θ	180	90	60	45	36	30	25.71	22.50	20	18	16.4	15

In some embodiments of the invention, each MFG comprises a magnetically conductive hollow cylindrical base body extending at one end into a funnel; a magnetically conductive rod-like structure extending through said hollow cylindrical base into said funnel; and an electrical coil wound around the hollow cylindrical base body and the funnel.

In some embodiments the rod-like structure defines a frusto-conical end which extends into said funnel.

In some embodiments, an external magnetic shield is provided to the MFG for limiting leakage of magnetism except through the funnel end.

In some embodiments, the cylindrical base body and funnel are made from leaded steel, such as, but not limited to EN1A. In some embodiments, the rod-like structure is a ferrite rod. The ferrite rod is about 35mm long, and about 8 mm in diameter. In some embodiments, the electrical coil is a copper wire. In some embodiments, the copper wire is 29G copper wire winding of about 46mm and length of about 60 mm, and the number of turns is about 4200. In some embodiments, the magnetic field generating device has an impedance of from about 80 and about 90 ohms.

Some embodiments of the invention provide methods for inducing cellular regeneration and/or degeneration and for methods of treating certain diseases, disorders, or conditions.

Some embodiments provide a method for inducing cellular regeneration and / or degeneration in a patient in need thereof comprising: applying a pulsed magnetic field to a desired tissue in a sequential pattern. In some embodiments, the sequential pattern is substantially rotary.

In some embodiments, the pulsed magnetic field is generated by a plurality of mated and opposed pairs of MFGs, wherein mated and opposed pair fire simultaneously and out of phase, and each pair is fired in a sequential, substantially rotary pattern.

Some embodiments provide a method of operation for the degeneration of cells for patients in need thereof, comprising applying a pulsed magnetic field to a desired tissue in a sequential pattern, wherein the pulsing frequencies are in the range of about 120 to about 2000Hz. In some embodiments of the method of operation for degeneration of cells when applying the pulsed magnetic field further comprises: applying a sensitizing treatment phase at a frequency range of about 0.1 Hz to about 600 HZ; and then applying a stimulating treatment phase a frequency range of approximately 600 Hz to about 2000 Hz.

In some embodiments, the treatment may be administered for about 1 hour per day for about 28 days.

Some embodiments provide a method for regeneration of cells in a patient in need thereof, comprising applying a pulsed magnetic field to a desired tissue in a sequential pattern, wherein the pulsing frequencies are in the range of about 8 to about 50Hz.

In some embodiments of the method of regeneration of the cartilage cells, the step of applying the pulsed magnetic field further comprises: applying a sensitizing treatment phase at a frequency range of about 8 Hz to about 20 HZ; and then applying a stimulating treatment phase a frequency range of approximately 12 Hz to

about 40 Hz. The treatment is administered for about 45 minutes to 1 hour per day for about 28 days.

In some embodiments, the invention provides a method for treating neurodegenerative disorders in a patient in need thereof, comprising applying a pulsed magnetic field to a desired tissue in a sequential pattern, wherein the pulsing frequencies are in the range of 30 Hz to about 120 Hz. In some embodiments, the step of applying the pulsed magnetic field further comprises: applying a sensitizing treatment phase at a frequency range of about 30 Hz to about 60 HZ; and then applying a stimulating treatment phase a frequency range of approximately 90 Hz to about 120 Hz. The treatment may be administered for about 1 hour per day for about 21 days. In some embodiments, the neurodegenerative disorder to be treated is selected from Alzheimer's, Parkinson's, ALS, and Huntington's disease, in retinal degeneration, and other damage to sensory systems associated with stroke, head and spinal trauma, epilepsy, drug and alcohol abuse, infectious diseases, mental disorders, or from exposure to industrial and environmental toxicants, and chronic pain.

WE CLAIM:

1. A sequentially programmed magnetic field therapeutic (SPMF) system for generating and applying a magnetic field to a desired tissue comprising:
 - a plurality of magnetic field generators to produce sequentially programmed pulsed magnetic fields at a focal region, and
 - a switching system to control the pulsing dependent on the disease type and the treatment to be administered,
 - wherein the magnetic field generators are fixed circumferentially in regular intervals of about 15 to about 180 degrees with respect to an adjacent magnetic field generator with reference to a central axis in the focal region; and
 - wherein the plurality of magnetic field generators are operatively coupled in mated, opposed pairs, such that pairs of magnetic field generators which are 180 degrees opposite to each other in said tubular gantry are energized at the same time and out of phase so that the net magnetic flux passes through the focal axis.
2. The SPMF system as claimed in claim 1 wherein the magnetic field generators are housed in a tubular gantry;
 - wherein the magnetic field generators (MFGs) are fixed circumferentially on the tubular gantry in regular intervals of about 15 to about 90 degrees with respect to an adjacent magnetic field generators with reference to the central axis of said tubular gantry, which is the focal axis.
3. The SPMF system as claimed in claims 1-2 wherein

from 1 to 12 transverse planes are defined on the tubular gantry with respect to the central axis of said gantry along which said plurality of magnetic field generators are located;

in each transverse plane, 2-24 magnetic field generators are disposed radially over the circumference of the gantry; and

diametrically opposite magnetic field generators are operatively coupled to form 1 to 12 such pairs wherein each of the pairs can be excited to generate a magnetic field.

4. The SPMF system as claimed in claims 1-3 wherein circumferentially adjacent magnetic field generators are energized in a substantially rotary manner to produce sequentially programmed pulsed magnetic fields at the focal region.
5. The SPMF system of claim 1, wherein each magnetic field generator comprises:
 - a magnetically conductive hollow cylindrical base body extending at one end into a funnel;
 - a magnetically conductive rod-like structure extending through said hollow cylindrical base into said funnel; and
 - an electrical coil wound around the hollow cylindrical base body and the funnel.
6. The SPMF system of claim 5, wherein said rod-like structure defines a frusto-conical end which extends into said funnel.
7. The SPMF system of claim 5, further comprising an external magnetic shield limiting leakage of magnetism except through said funnel.

8. The SPMF system of claim 5, wherein said cylindrical base body and funnel are made from leaded steel.
9. The SPMF system of claim 5, wherein said rod-like structure is a ferrite rod.
10. The SPMF system of claim 9, wherein said ferrite rod is about 35mm long, and about 8 mm in diameter.
11. The SPMF system of claim 5, wherein said electrical coil is a copper wire.
12. The SPMF system of claim 11, wherein said copper wire is 29G copper wire winding of 46mm and length of about 60 mm, and the number of turns is about 4200.
13. The SPMF system of claim 5 wherein each magnetic field generator has an impedance of from about 80 and about 90 ohms.
14. A method for inducing cellular degeneration comprising:
 - applying a pulsed magnetic field to a desired tissue in a sequential, substantially rotary pattern;
 - wherein said pulsed magnetic field is generated by a plurality of mated and opposed pairs of magnetic field generators, wherein each magnetic field generator in a mated and opposed pair fires simultaneously and out of phase, and each pair is fired in a sequential, substantially rotary pattern.
15. The method of claim 14, wherein the cellular degeneration is induced in a cancer cell.

16. A method for inducing degeneration of a tumor comprising:
- applying a pulsed magnetic field to a desired tissue in a sequential, substantially rotary pattern, wherein the pulsing frequencies are in the range of about 120 to about 2000Hz;
 - wherein the step of applying the pulsed magnetic field further comprises:
 - applying a sensitizing phase at a frequency range of about 0.1 Hz to 600 HZ;
 - and then applying a stimulating phase a frequency range of approximately 600 Hz to 2000 Hz;
 - wherein the process is administered for a predetermined duration and interval.
17. The method of claim 16, wherein the tumor is a high proton density tumor and wherein:
- a Sensitizing Frequency of the sensitizing phase = a minimum density*6.28;
 - a Stimulating Frequency of the stimulating phase = a maximum density*1.57;
 - a Pulse Count of the Sensitizing phase = a Sensitizing Frequency/ k; and
 - a Pulse Count of the Stimulating phase = a Stimulating Frequency/ k
- where $k = (\text{Maximum Density} * \text{Minimum Density}) / (\text{"Average Density"})$.
18. The method of claim 17, wherein the tumor is a low proton density tumor and wherein:
- a Sensitizing Frequency of the sensitizing phase = Average density* 3.14
 - a Stimulating Frequency of the stimulating phase = Maximum density * 3.14

a Pulse Count of the Stimulating phase (PCSt) = a Stimulating Frequency/k,
wherein if PCSt ≥ 50 , PCSt = 50; and wherein if PCSt ≤ 10 , PCSt = 10; and

a Pulse Count of the Sensitizing phase = (the sensitizing Frequency/ the
stimulating Frequency) * PCSt;

where $k = (\text{Maximum Density} * \text{Minimum Density}) / (\text{Average Density} * 3.14 * 3.14)$.