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(54) Title: CONTROLLER AND FLEXIBLE COILS FOR ADMINISTERING THERAPY, SUCH AS FOR CANCER THERAPY

(57) Abstract: Disclosed herein are systems and methods for providing a portable magnetic field therapy system for treatment of diseases and adverse health conditions, such as cancer.

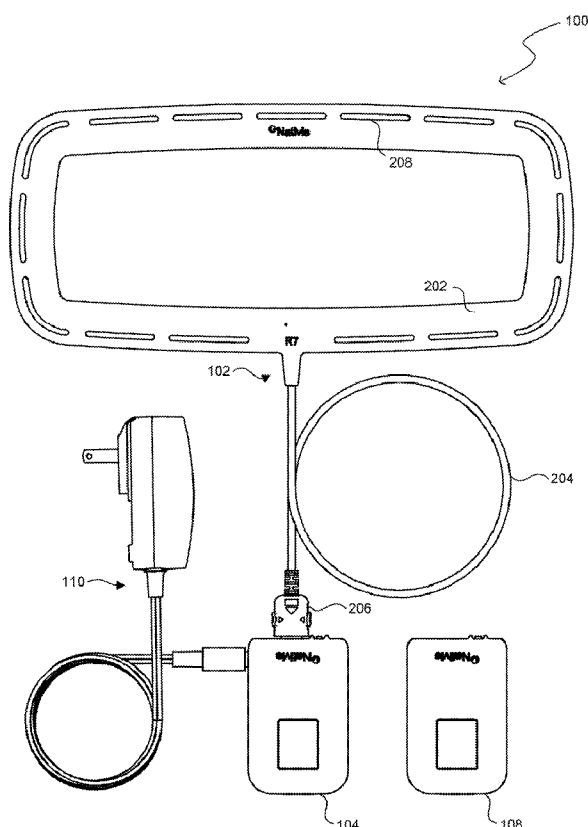


FIG. 2



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CONTROLLER AND FLEXIBLE COILS FOR ADMINISTERING THERAPY, SUCH AS
FOR CANCER THERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to the assignee's U.S. Provisional Application No. 61/792,547, filed March 15, 2013, incorporated herein by reference.

BACKGROUND

[0002] Various diseases and adverse health conditions affect people and animals. An example of a disease that affects people and animals is cancer, otherwise known medically as a malignant neoplasm. Cancer includes a broad group of various diseases that involve unregulated cell growth. In 2007, cancer attributed to approximately 13% of all human deaths worldwide, approximately 7.9 million people. Because of its effect on worldwide populations, new treatments for cancer are continually sought and researched.

[0003] Traditional treatments for cancer, such as chemotherapy, radiation therapy, and surgery, can be intrusive, can be life altering, and can leave the patient unable to perform routine day-to-day functions. Alternative treatments are desirable.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] Figure 1 is a diagram of a therapy system in use on a canine patient;

[0005] Figure 2 is another diagram of the therapy system of Figure 1;

[0006] Figure 3 is a diagram of variations of coils used for providing electromagnetic or magnetic field therapy;

[0007] Figure 4 is a diagram of variations of shapes and sizes of coils used for providing electromagnetic or magnetic field therapy;

[0008] Figures 5A-5B are views of the manufacture of a cable for the therapy system;

[0009] Figure 6 is a view of a connector for the cable;

- [0010] Figure 7 is a schematic view of the connector for the cable;
- [0011] Figure 8 is a flow diagram of a method of manufacturing a coil for the therapy system;
- [0012] Figure 9 is an exploded view of a housing of a controller for the therapy system;
- [0013] Figure 10 is an electrical schematic of microprocessor circuitry for the controller;
- [0014] Figure 11 is an electrical schematic of memory for the controller;
- [0015] Figure 12 is an electrical schematic of various components for the controller;
- [0016] Figure 13 is an electrical schematic of an LCD interface for the controller;
- [0017] Figure 14 is an electrical schematic of signal generator circuitry for the controller;
- [0018] Figure 15 is an electrical schematic of power regulation circuitry for the controller;
- [0019] Figure 16 is flow diagram of a method of operating the therapy system;
- [0020] Figures 17A-17B show diagrams of an example apparatus for securing the therapy system to the cranium of a human patient; and
- [0021] Figure 18 is a chart comparing U87 glioblastoma multiforme human cell line solid tumor volume of control mouse subjects to treated mouse subjects in a mouse study model.

DETAILED DESCRIPTION

[0022] The systems and methods described herein provide example embodiments of a non-intrusive delivery mechanism for treating diseases such as cancer and other adverse health conditions. As discussed above, traditional therapies associated with cancer treatment can leave undesirable side-effects. The Applicant has disclosed, in

related patents and patent applications noted herein, systems and methods for detecting and recording molecular signals from chemical, biochemical, or biological molecules or from chemical, biochemical, or biological agents. In some implementations, the recordings represent molecular signals of the chemical, biochemical, or biological molecules or agents used to provide therapy for cancer, ailments or other adverse health conditions. The systems and methods disclosed herein may be configured to deliver the effect of chemical, biochemical, or biologic therapy to a patient without the use of drugs, by generating electromagnetic or magnetic fields that simulate or mimic molecular signals of particular chemicals, biochemical, or biologics. Thus, the systems and methods allow a patient to receive an electronic "prescription" or dosage of electromagnetic or radio frequency energy with, for example, the click of a button. The embodiments of the systems and methods describe a therapy system that is non-invasive, non-thermal, and mobile.

[0023] Note, as used herein, the term "drug" is used broadly to define any chemical, biochemical or biologic molecules including proteins, RNA and DNA sequences, etc. As used herein, and described in more detail below, the terms "magnetic field," "electromagnetic field" and similar terms are used interchangeably to represent the presentation of energy to a selected region to address adverse health effects, where the presented energy has a characteristic reflecting that of a specific drug.

[0024] Figure 1 illustrates an embodiment of a therapy system 100 for applying magnetic signals to a patient, such as a canine, to provide therapeutic treatment, such as to selectively reduce or inhibit growth of particular types of cells. In some implementations, the therapy system 100 may be used to treat cancer cells by applying electromagnetic or magnetic fields to affected areas. These fields are induced or generated to expose an affected area with signals that mimic signals produced by chemotherapy drugs. Of course, while a canine is shown, and cancer treatment is discussed in general herein, the present system may be used with other patients such as humans, and with many other forms of treating disease or other ailments. The

acquisition of the signals produced by chemotherapy drugs is discussed in great detail in patent applications and patents that are co-owned by the assignee of the instant application. These patents and applications include US Patents Nos. 6,724,188; 6,995,558; 6,952,652; 7,081,747; 7,412,340; and 7,575,934; and PCT Application No. PCT/US2009/002184, each of which is hereby incorporated by reference in their entirety.

[0025] The therapy system 100 may provide various advantages over traditional cancer treatments. For example, the therapy system 100 may be portable and worn or carried by a patient to allow the patient to receive therapy while at home, at work, at school, and during recreation. Furthermore, the therapy system 100 may enable a patient to receive treatments without visiting a health care facility, without incurring extensive recovery time, and possibly without experiencing other traditional side-effects such as: nausea, fatigue, loss of appetite, and the development of infections. The therapy system 100 includes a coil and cable assembly 102 coupled to a controller 104. In accordance with various implementations, the therapy system 100 may be secured to the patient using fasteners 106 (inclusive of 106a, 106b, and 106c), such as tape, elastic bandages, gauze, or the like.

[0026] Figure 2 illustrates the therapy system 100 as it may be provided to a physician or patient. In addition to the coil and cable assembly 102 and the controller 104, when delivered to a customer, the therapy system 100 may also include an additional controller 108 and a battery charging device 110. For various security reasons which are discussed below, each controller may be manufactured so that a housing for the controller cannot be opened easily. The tamper-resistant housing may therefore make it difficult to interchange one battery for another. Therefore, to allow a patient to continuously receive therapy with the therapy system 100, one or more additional controllers 108 may be provided to allow the patient to receive therapy while the controller 104 is charging with the charging device 100. The coil, cable and connector assembly 102 may be disposable, or the system as a whole together with the one or more controllers 104, 108. Thus the coil and cable assembly 102 and/or

controller 104, 108 are preferably provided for a single therapeutic session and for one prescription, so that the controller and coil assembly are not to be reused, thereby preventing cross contamination, etc.

Therapy System Coil and Cable Assembly

[0027] In Figure 2, the coil and cable assembly 102 includes an encapsulated coil 202, a cable 204, and a connector 206. The coil 202 includes one or more conductors configured to generate a magnetic or electromagnetic field to mimic drug-simulating signals. As used herein, a drug-simulating signal includes a signal that approximately reproduces magnetic fields that emanate from one or more predetermined chemical, biochemical, and/or biological molecules or agents. The coil 202 may be configured to have various electrical characteristics. Additionally, the coil 202 may be enclosed in a plastic or other composite material to both protect the windings of the coil and to provide a comfortable interface for the wearer. The coils can be flexible and malleable, can have a variety of shapes, can have different sizes or types, and can also include rigid coils. Advantageously, these coils can be externally secured to a patient to provide treatment, as opposed to subcutaneous insertion of the coil into a patient.

[0028] Figure 3 illustrates diagrams of variations to the shape of the encapsulated coil 202. As illustrated, the coils used by the therapy system 100 may include a small circular encapsulated coil 302, a large circular encapsulated coil 304, a rectangular encapsulated coil 306, and/or a substantially square encapsulated coil 308. Each shape may provide advantages for treating particular parts of the body of the patient.

[0029] Figure 4 illustrates examples of coils having various shapes and various dimensions. A variety of dimensions for the coils may be manufactured to more effectively apply therapy to areas to be treated that vary in size. Each of the coils 402a, 402b, 402c, 402d, 402d, 402f can have inner and/or outer diameters or lengths, ranging from just a few centimeters to several feet, according to various implementations.

[0030] Figures 5A and 5B illustrate before and after diagrams of the cable 204 during manufacture. The cable 204 connects a coil, e.g., coil 202, and to the connector

206 to enable the controller 104 to transmit various signals to the coil. The cable 204 may include two or more conductors 502a, 502b, a shield 502c, and a strength-providing member 502d (collectively conductors 502). Each of the four conductors and members may be configured to perform a particular function. For example, conductors 502a and 502b may be electrically coupled to either end of the coil 504 to enable current to flow to and from the coil 504 to activate, stimulate, induce, or otherwise excite the coil 504. Shield conductor 502c may be coupled to ground and be configured to provide electromagnetic shielding for the conductors 502a and 502b. Strength member 502d may be anchored to the coil 504 and to the connector 206 to provide strain relief to the conductors 502a-502c. In some implementations, the strength member 502d is manufactured with a shorter length than the other conductors so that the strength member 502d receives a majority of any strain applied between the coil 504 and the connector 206.

[0031] As illustrated in Figure 5B, the connector 206 may include three parts, a connector core 506, and connector housings 508a and 508b. The connector housings 508a and 508b may encapsulate the connector core 506 to protect the traces and electronic devices carried by the connector core 506. Figure 6 illustrates an implementation of the connector core 506. The connector core 506 has a controller end 602 and a cable end 604. The controller end 602 is configured to mateably couple to the controller 104, and the cable end 604 is configured to provide an interface for the conductors 502. In some implementations, the strength member 502d may be anchored to one or more holes 606 to provide strain relief. The conductor core 506 may also carry a plurality of traces 608 to which the conductors 502a-c may be electrically coupled to facilitate communication the controller 104.

[0032] As a security feature of the coil and cable assembly 102, the connector core 506 may also carry an integrated circuit 610. The integrated circuit 610 may be a microprocessor or may be a stand-alone memory device. The integrated circuit 610 may be configured to communicate with the controller 104 through the controller end 602 using communication protocols such as I2C, 1-Wire, and the like. The integrated

circuit 610 may include a digital identification of the coil with which the connector core 506 is associated. The digital identification stored on the integrated circuit 610 may identify electrical characteristics of the coil, such as impedance, inductance, capacitance, and the like. The integrated circuit 610 may also be configured to store and provide additional information such as the length of the conductor of the coil, physical dimensions of the coil, and number of turns of the coil. In some implementations, the integrated circuit 610 includes information to prevent theft or reuse in a knock-off system, such as a unique identifier, cryptographic data, encrypted information, etc. For example, the information on the integrated circuit 610 may include a cryptographic identifier that represents measureable characteristics of the coil and/or the identification of the integrated circuit. If the cryptographic identifier is merely copied and saved onto another integrated circuit, for example, by an unauthorized manufacturer of the coil and cable assembly, the controller 104 may recognize that the cryptographic identifier is illegitimate and may inhibit signal transmissions. In some implementations, the integrated circuit stores one or more encryption keys, digital signatures, stenographic data or other information to enable communications and/or security features associated with public key infrastructure, digital copy protection schemes, etc.

[0033] Figure 7 illustrates a schematic diagram of the connector core 506. As shown, according to some implementations, the integrated circuit 610 may be configured to communicate with the controller 104 over a single wire, e.g., from input-output-pin 702.

[0034] Figure 8 illustrates a method 800 of manufacturing a coil and cable assembly, e.g., the coil and cable assembly 102, for use in providing a therapy system that is non-invasive, non-thermal, and mobile.

[0035] At block 802, an electrical coil is encapsulated in a flexible composite. The flexible composite allows the electrical coil to be comfortably secured to the body of the patient to provide magnetic field therapy.

[0036] At block 804, the electric coil is coupled to a connector through a cable to facilitate secure transfer between the connector and the electrical coil. The cable may include multiple conductors that deliver signals between the connector and the electrical coil while providing mechanical strain relief to the signal carrying conductors.

[0037] At block 806, an integrated circuit is coupled to the connector, the cable, or the electrical coil. The integrated circuit may be coupled, for example, to the connector via one or more electrical conductors that may or may not also be coupled to the electrical coil.

[0038] At block 808, information is stored to the integrated circuit that identifies or uniquely identifies the individual or combined electrical characteristics of the integrated circuit, the connector, the cable, and/or the electrical coil. The information may be a hash or other cryptographically unique identifier that is based on information that can be unique to the integrated circuit and/or the remainder of the coil and cable assembly. This security feature can be used to prevent or deter unauthorized remanufacture of coil and cable assemblies that are compatible with the controller for the therapy system. Additional security features are described herein, e.g., in connection with the operation of the controller for the therapy system.

Therapy System Controller

[0039] Referring briefly back to Figure 2, the therapy system 100 includes a controller 104 to provide an interface to the patient, to distribute and regulate drug-simulating signals to the coil 202, and to prevent unauthorized copying and/or distribution of the drug-simulating signals. According to various implementations, the controller 104 can include various features such as a housing, a processor, memory, visual and audio interfaces, in addition to other features which are described hereafter in Figures 9-15.

[0040] Figure 9 illustrates a housing 900 for the controller 104. The housing 900 may include three parts, a housing front 902 (inclusive of 902a, 902b), a housing back 904 (inclusive of 904a, 904b), and a clip 906. The housing front 902 may have a

window 908 through which a visual interface may be viewed or manipulated. Although not shown, the housing front 902 may include various apertures through which buttons, dials, switches, light emitting indicators, and/or a speaker may pass or be disposed. The housing front 902 includes a cut-away or port 910 for coupling the controller 104 to the coil and cable assembly 102. The housing back 904 may include a number of pegs 912 for mateably attaching/securing the housing back 904 to the housing front 902. While coupled together, the housing front 902 and the housing back 904 may form a seal along the edge 914, preventing water, moisture, dust, or other environmental elements from entering the housing 900. In some implementations, an adhesive or solvent is used to permanently bond the housing front 902 to the housing back 904 to deter or prevent unauthorized tampering with or viewing of the internal electronics, though in other implementations the front and back may be formed to permanently snap-fit together. As shown, the housing back 904 may include a cutout, aperture, or port 916 to allow connection to a recharging device or communication information to/from the controller 104. The clip 906 may be securely fastened or detachably coupled to slot 918 of the housing back 904 to secure the controller 104 to the wearer.

[0041] Figures 10-15 illustrate schematics of electronics that the controller 104 may include to perform the various functions described above. The various electronics may be integrated into one or more programmable controllers or may include discrete electronic components electrically and communicatively coupled to each other.

[0042] Figure 10 illustrates microcontroller circuitry 1000 for operating the controller 104. The circuitry 1000 includes a microprocessor 1002, a reset circuit 1004, and a volatile memory 1006. The microcontroller may be a standard microprocessor, microcontroller or other similar processor, or alternatively be a tamper-resistant processor to improve security. The microprocessor 1002 may include a number of analog and/or digital communication pins to support communications with electronics that are both external and internal to the housing 900. The microprocessor 1002 may include USB pins 1008 to support communication via the USB protocol, display pins

1010 to communicate with a visual interface, audio pins 1012 to provide an audio interface, in addition to other data communication pins.

[0043] Microcontroller 1002 can be configured to use the USB pins 1008 to securely receive prescription files from one or more external devices. Encryption of the prescription file may increase security of the contents of prescription file. Encryption systems regularly suffer from what is known as the key-distribution-problem. The standard assumption in the cryptographic community is that an attacker will know (or can readily discover) the algorithm for encryption and decryption. The key is all that is needed to decrypt the encrypted file and expose its intellectual property. The legitimate user of the information must have the key. Distribution of the key in a secure way attenuates the key-distribution-problem.

[0044] In some embodiments, the microcontroller 1002 is configured to use the Advanced Encryption Standard (AES). AES is a specification for the encryption of electronic data established by the U.S. National Institute of Standards and Technology (NIST) and is used for inter-institutional financial transactions. It is a symmetrical encryption standard (the same key is used for encryption and decryption) and can be secure while the key distribution security is maintained. In some implementations, the microcontroller 1002 uses a 128 bit AES key that is unique to each controller and is stored in non-volatile memory 1100 (illustrated in Figure 11). The encryption key can be random to reduce the likelihood of forgery, hacking, or reverse engineering. The encryption key can be loaded into non-volatile memory 1100 during the manufacturing process or before the controller is delivered to customers (physicians or patients). Using AES encryption, the prescription file can be encrypted and uploaded to one or more servers to facilitate selective delivery to various controllers 104. For example, a physician or other medical professional may obtain authorization to download prescription files to controllers for his/her patients. When the physician contacts and logs in to a server to obtain a prescription file, the physician may first need to provide certain information, e.g., may need to identify the target device (the controller), for the server (e.g., by a globally unique ID (GUID) stored in the controller) so that the server

can look up the target device in a database and provide a prescription file that is encrypted with a key that is compatible with the controller. The encrypted prescription file can then be loaded into the non-volatile memory 1100 via the microcontroller 1002, using USB or another communications protocol. Alternatively or additionally, the encrypted prescription file may be stored directly to the non-volatile memory 1100 during the manufacturing process to reduce the likelihood of interception of the prescription file, and before the front and back portions of the housing are sealed together.

[0045] The microcontroller 1002 can also be configured to log use of the therapy system 100 by a patient. The log can be stored in a non-volatile memory 1100 and downloaded by a medical professional when a patient delivers a controller 104 back to the prescribing medical professional, e.g., after the prescribed time allotment for the controller 104 has depleted. The log can be stored in a variety of data formats or files, such as, separated values, as a text file, or as a spreadsheet to enable a medical professional to display activity reports for the controller 104. In some implementations, the microcontroller 1002 is configured to log information related to errors associated with coil connections, electrical characteristics of the coil over time, dates and times of use of the therapy system, battery charge durations and discharge traditions, and inductance measurements or other indications of a coil being placed in contact with a patient's body. The microcontroller 1002 can provide log data or the log file to a medical professional using a USB port or other mode of communication to allow the medical professional to evaluate the quality and/or function of the therapy system and the quantity and/or use of the therapy system by the patient. Notably, the microcontroller 1002 can be configured to log any disruptions in signal delivery and can log any errors, status messages, or other information provided to the user through user interface of the controller 104 (e.g., using the LCD screen).

[0046] The microcontroller 1002 can be configured to use the volatile memory 1006 to protect the content of the prescription file. In some implementations, the prescription file is encrypted when the microcontroller 1002 transfers the prescription

file from an external source into non-volatile memory 1100. The microcontroller 1002 can then be configured to only store decrypted versions of the content of the prescription file in volatile memory 1006. By limiting the storage of decrypted content to volatile memory 1006, the microcontroller 1002 and thus the controller 104 can ensure that decrypted content is lost when power is removed from the microcontroller circuitry 1000.

[0047] The microcontroller 1002 can be configured to execute additional security measures to reduce the likelihood that an unauthorized user will obtain the contents of the prescription file. For example, the microcontroller 1002 can be configured to only decrypt the prescription file after verifying that an authorized or legitimate coil and cable assembly 102 has been connected to the controller 104. As described above, the coil and cable assembly 102 may include an integrated circuit that may store one or more encrypted or not encrypted identifiers for the coil and cable assembly 102. In some implementations, the microcontroller 1002 is configured to verify that an authorized or prescribed coil and cable assembly 102 is connected to the controller 104. The microcontroller 1002 may verify the authenticity of a coil and cable assembly 102 by comparing the identifier from the integrated circuit of the coil and cable assembly 102 with one or more entries stored in a lookup table in either volatile memory 1006 or non-volatile memory 1100. In other implementations, the microcontroller 1002 may be configured to acquire a serial number of the integrated circuit and measure electrical characteristics of the coil and cable assembly 102 and perform a cryptographic function, such as a hash function, on a combination of the serial number and the electrical characteristics. Doing so may deter or prevent an unauthorized user from copying the contents of the integrated circuit of the coil and cable assembly 102 into a duplicate integrated circuit associated with an unauthorized copy of a coil and cable assembly.

[0048] The microcontroller 1002 can be configured to delete the prescription file from volatile memory 1006 and from non-volatile memory 1100 in response to fulfillment of one or more predetermined conditions. For example, the microcontroller

1002 can be configured to delete the prescription file from memory after the controller has delivered the prescribed drug-simulating signals for a specific period of time, e.g., 14 days. In other embodiments, the microcontroller 1002 can be configured to delete the prescription file from memory after the controller detects a coupling of the controller 104 with an unauthorized coil and cable assembly. The microcontroller 1002 can be configured to delete the prescriptive file after only one coupling with an unauthorized coil and cable assembly, or can be configured to delete the prescription file after a predetermined number of couplings with an unauthorized coil and cable assembly. In some implementations, the microcontroller can be configured to monitor an internal timer and delete the prescription file, for example, one month, two months, or longer after the prescription file has been installed on the controller 104.

[0049] The microcontroller 1002 can be configured to delete the prescription file from volatile memory 1006 and from non-volatile memory 1100 in response to input from one or more sensors. Figure 12 illustrates a sensor 1202 that may provide a signal to the microcontroller 1002 in response to a physical disruption of the housing 900 of the controller 104. For example, the sensor 1202 can be a light sensor that detects visible and non-visible wavelengths within the electromagnetic spectrum. For example, the sensor 1202 can be configured to detect infrared, visible light, and/or ultraviolet light. Because the detection of light within the housing 900 can be an indication of intrusion into the housing 900, the microcontroller 1002 can be configured to delete and/or corrupt the prescription file upon receipt of a signal from the sensor 1202. In some implementations, the sensor 1202 is a light sensor. In other implementations, the sensor 1202 can be a pressure sensor, a capacitive sensor, a moisture sensor, a temperature sensor, or the like.

[0050] In response to detection of unauthorized use of the controller 104, or to increase the user-friendliness of the therapy system 100, the microcontroller 1002 can use various indicators or interfaces to provide information to a user. As examples, Figure 12 illustrates an LED 1204 and an audible buzzer 1206. The microcontroller 1002 can illuminate the LED 1204 and/or actuate the audible buzzer 1206 in response

to user error, unauthorized tampering, or to provide friendly reminders of deviation from scheduled use of the therapy system 100. Although one LED is illustrated in the LED 1204, multiple LEDs having various colors can also be used. Additionally, although the audible buzzer 1206 is described as a buzzer, in other implementations, the audible buzzer 1206 can be a vibrating motor, or a speaker that delivers audible commands to facilitate use of the therapy system 100 by sight impaired professionals and/or patients.

[0051] Figure 13 illustrates an LCD interface 1300 that the microcontroller 1002 can manipulate to interact with a user. The LCD interface 1300 can receive various commands from the microcontroller 1002 at input pins 1302. In response to inputs received from the microcontroller 1002, an LCD screen 1304 can be configured to display various messages to a user. In some implementations, the LCD screen 1304 displays messages regarding battery status, duration of prescription use, information regarding the type of prescription being administered, error messages, identification of the coil and cable assembly 102, or the like. For example, the LCD screen 1304 can provide a percentage or a time duration of remaining battery power. The LCD screen 1304 can also provide a text-based message that notifies the user that the battery charge is low or that the battery is nearly discharged. The LCD screen 1304 can also be reconfigured to provide a name of a prescription (e.g., corresponding name of the physical drug) and/or a body part for which the prescription is to be used. The LCD screen 1304 can also provide notification of elapsed-time or remaining-time for administration of a prescription. If no additional prescription time is authorized, the LCD screen 1304 can notify the user to contact the user's medical professional.

[0052] The LCD screen 1304 can be configured to continuously or periodically provide indications regarding the status of the connection between a coil and the controller. In some implementations, the LCD screen 1304 can be configured to display statuses or instructions such as, "coil connected", "coil not connected", "coil identified", "unrecognized coil", "reconnect coil", or the like. In some implementations, the LCD screen 1304 can provide a graphical representation of a coil and flash the coil when the coil is connected properly or improperly. Alternatively or additionally, the controller can

monitor an impedance from the coil to detect a change, a possible removal, or loss of the coil from the area to be treated, and provide a corresponding error message. The LCD interface 1300, in other implementations, can be a touch screen that delivers information to the user in addition to receiving instructions or commands from the user. In some implementations, the microcontroller 1002 can be configured to receive input from hardware buttons and switches to, for example, power on or power off the controller 104. The switch on the device permits an on-off nature of therapy so that patients may selectively switch on and off their therapy if needed.

[0053] Figure 14 illustrates signal generation circuitry 1400 that may be used to drive the coil and cable assembly 102 with the drug-simulating signals. The circuitry 1400 may include an audio coder-decoder 1402, and output amplifier 1404, and a current monitor 1406. The audio coder-decoder 1402 may be used to convert digital inputs received from volatile memory 1006, non-volatile memory 1100, or from microcontroller 1002 into analog output signals useful for driving the coil and cable assembly 102. The audio coder-decoder 1402 may be configured to output the analog output signals to the output amplifier 1404. In some implementations, the output amplifier 1404 is programmable so that the intensity or amplitude of the signals transmitted to the coil may be varied according to the treatment prescribed for the patient.

[0054] Because the controller 104 can be connected with coils having different sizes, shapes, and numbers of windings, the output amplifier 1404 can be configured to adjust an intensity level of signals delivered to the coil so that each coil delivers a drug-simulating signal that is uniform between different coils, for a particular prescription. The coil dimensions and electrical characteristics can determine the depth and breadth of concentration of the magnetic field, so programmatically adjusting the output intensity of the output amplifier 1404 to deliver uniform drug-simulating signals can advantageously enable a medical professional to select a coil that is appropriate for a particular patient's body or treatment area, without concern for inadvertently altering the prescription. As described above, the controller 104 can determine the dimensions and

electrical characteristics of a coil by reading such information from the integrated circuit 610 (shown in Figures 6 and 7). The signal generation circuitry 1400 can be configured to use the dimensional and electrical characteristic information acquired from the coil to programmatically adjust the level of intensity of signals output by the output amplifier 1404.

[0055] The output amplifier 1404 may include a low pass filter that significantly reduces or eliminates output signals having a frequency higher than, for example, 50 kHz. In other implementations, the low pass filter can be configured to significantly reduce or eliminate output signals having a frequency higher than 25 kHz. The signal generation circuitry 1400 may use the current monitor 1406 to determine electrical characteristics of the coil and cable assembly 102 and/or to verify that output signal levels remain within specified thresholds. The signal generation circuitry 1400 may also include a connector 1408 that mates with the connector 206 of the coil and cable assembly 102. The connector 1408 can provide the electrical interface between the microcontroller 1002 and the coil and cable assembly 102.

[0056] In other implementations and as noted above, the signal generation circuitry 1400 can also include inductance detection circuitry. The inductance detection circuitry can be configured to detect changes in the coil inductance. The coil inductance changes when the coil is brought into proximity of a patient's body. By monitoring coil inductance, the signal generation circuitry 1400 and the controller 104 can track and record, i.e., log, a patient's use of the therapy system 100. For example, if a medical professional prescribes 10 hours of use of the therapy system 100, but the controller 104 only logs three hours of use of the therapy system 100, the medical professional may be in a better position to evaluate a patient's improving, non-improving or deteriorating condition. In some implementations, the inductance detection circuitry is implemented as a source follower circuit.

[0057] Figure 15 illustrates power control circuitry 1500 for receiving and regulating power to the controller 104. The power control circuitry 1500 includes power input circuitry 1502 and power regulation circuitry 1504. The power input circuitry 1502

can include a connector 1506, e.g., a micro-USB connector, to receive power from an external source for recharging a battery 1510. The power input circuitry 1502 can also include a charging circuit 1508 that monitors a voltage level of the battery 1510 and electrically decouples the battery from the connector 1506 when the battery 1510 is sufficiently charged. The power regulation circuitry 1504 can be used to convert a voltage level of the battery 1510 to a lower voltage for use by the various circuits of the controller 102. For example, when fully charged, the battery 1510 may have a voltage of about 4.2 to 5 volts, whereas the microcontroller may have an upper voltage threshold of 3.5 volts. The power regulation circuitry 1504 can be configured to convert the higher voltage of the battery, e.g., 4.2 volts, to a lower voltage, e.g., 3.3 volts, that is usable by the electronic devices of the controller 102.

[0058] Figure 16 illustrates a method 1600 of operating a portable therapy system that may be used to provide magnetic field therapy that is non-invasive, non-thermal, and mobile.

[0059] At block 1602 an electromagnetic transducer is coupled to a signal generator. The electromagnetic transducer can be a coil having various shapes and sizes according to the size or condition of an ailment to be treated.

[0060] At block 1604 the electromagnetic transducer is secured to an area of the patient to be treated. The transducer may be secured using elastic bandages, gauze, tape, or the like.

[0061] At block 1606, the signal generator checks for an appropriate connection to the electromagnetic transducer. The signal generator can be configured to verify an identification or electrical characteristics of the electromagnetic transducer, such as a resistance or impedance of the transducer to ensure that an appropriate transducer is coupled to the generator. In some implementations, the signal generator can be configured to periodically monitor the electrical characteristics of the electromagnetic transducer to ensure that an appropriate connection is maintained. For example, if the signal generator detects an increase in resistance or decrease in inductance, the signal generator may be configured to cease delivery of signals to the electromagnetic

transducer. The signal generator may cease delivery of signals when unexpected electrical characteristics are detected to protect the health and safety of the patient and to prevent unauthorized attempts to acquire generated signals. As discussed above, the signal generator may be configured to log the periodic checks of the electrical characteristics of the electromagnetic transducer and can provide the log data to a medical professional for review. Other security checks may be performed as described herein.

[0062] At block 1608 the signal generator decrypts a therapeutic signal stored by the signal generator in response to verification that an appropriate connection between the electromagnetic transducer and the signal generator exists.

[0063] At block 1610 the electromagnetic transducer generates a magnetic signal directed to an area of the patient to be treated. The magnetic signal is representative of the therapeutic signal stored at the signal generator. According to various implementations, the magnetic signal has a frequency in the range of 1 Hz to 22 kHz.

[0064] In some implementations, a signal from a sample of a drug, biologic, or molecule (chemical, biochemical, biological), may be acquired by placing a sample in an electromagnetic shielding structure and by placing the sample proximate to at least one superconducting quantum interference device (SQUID) or magnetometer. The drug sample is placed in a container having both magnetic and electromagnetic shielding, where the drug sample acts as a signal source for molecular signals. Noise is injected into the drug sample in the absence of another signal from another signal source at a noise amplitude sufficient to generate stochastic resonance, where the noise has a substantially uniform amplitude over multiple frequencies. Using the superconducting quantum interference device (SQUID) or the magnetometer, output radiation from the drug sample is detected and recorded as an electromagnetic time-domain signal composed of drug sample-source radiation superimposed on the injected noise in the absence of the another generated signal. The injecting of noise and detecting of the radiation may be repeated at each of multiple noise levels within a

selected noise-level range until the drug sample source radiation is distinguishable over the injected noise.

[0065] Figures 17A and 17B illustrate example embodiments of headgear 1700 (inclusive of 1700a and 1700b) that may be used to position or secure a coil 1702 around the cranium of a human patient. The headgear can include a breathable mesh 1704, elastic straps 1706, and a band 1708. The breathable mesh 1704, elastic straps 1706, and the band 1708 can provide a comfortable apparatus for carrying, securing, or otherwise positioning the coil 1702 around the cranium of a patient. The headgear 1700 may also include fasteners 1710 (inclusive of 1710a, 1710b, 1710c) for securing the band 1708 over the coil 1702. The fasteners 1710 may be influenced with Velcro, snaps, or other types of securing devices. In Figure 17A, the headgear 1700a illustrates the coil 1702 in an exposed or unsecured position. In Figure 17B, the headgear 1700b illustrates the coil 1702 in a secured position.

[0066] Figure 18 is a chart 1800 comparing tumor volume of control mouse subjects to treated mouse subjects in a mouse study model. In the study, 10 tumors, U87 glioblastoma multiforme human cell line solid tumors in mice, were monitored in each of the control group and the treated group. As part of the study, no treatment was administered to the control group, and a system similar to the therapy system 100 delivered drug-simulating signals or radio frequency energy signals to the treatment group. The chart 1800 includes a y-axis 1802 that displays tumor volume in cubic millimeters. The chart 1800 also includes an x-axis 1804 that displays elapsed time on a scale of days. As shown in the mouse study, a possibility exists that administration of particular drug-simulating signals may maintain or reduce a volume of malignant growths or tumors over an extended period of time.

Definitions

[0067] The terms below generally have the following definitions unless indicated otherwise. Such definitions, although brief, will help those skilled in the relevant art to more fully appreciate aspects of the invention based on the detailed description provided herein. Other definitions are provided above. Such definitions are further

defined by the description of the invention as a whole (including the claims) and not simply by such definitions.

[0068] "Radio frequency energy" refers to magnetic fields having frequencies in the range of approximately 1 Hz to 22 kHz.

[0069] "Magnetic shielding" refers to shielding that decreases, inhibits or prevents passage of magnetic flux as a result of the magnetic permeability of the shielding material.

[0070] "Electromagnetic shielding" refers to, e.g., standard Faraday electromagnetic shielding, or other methods to reduce passage of electromagnetic radiation.

[0071] "Faraday cage" refers to an electromagnetic shielding configuration that provides an electrical path to ground for unwanted electromagnetic radiation, thereby quieting an electromagnetic environment.

[0072] "Time-domain signal" or "time-series signal" refers to a signal with transient signal properties that change over time.

[0073] "Sample-source radiation" refers to magnetic flux or electromagnetic flux emissions resulting from molecular motion of a sample, such as the rotation of a molecular dipole in a magnetic field. Because sample source radiation may be produced in the presence of an injected magnetic-field stimulus, it may also be referred to as "sample source radiation superimposed on injected magnetic field stimulus."

[0074] "Stimulus magnetic field" or "magnetic-field stimulus" refers to a magnetic field produced by injecting (applying) to magnetic coils surrounding a sample, one of a number of electromagnetic signals that may include (i) white noise, injected at voltage level calculated to produce a selected magnetic field at the sample of between 0 and 1 G (Gauss), (ii) a DC offset, injected at voltage level calculated to produce a selected magnetic field at the sample of between 0 and 1 G, and/or (iii) sweeps over a low-frequency range, injected successively over a sweep range between at least about 0-1 kHz, and at an injected voltage calculated to produce a selected magnetic field at the

sample of between 0 and 1 G. The magnetic field produced at the sample may be readily calculated using known electromagnetic relationships, knowing a shape and number of windings in an injection coil, a voltage applied to coils, and a distance between the injection coils and the sample.

[0075] A "selected stimulus magnetic-field condition" refers to a selected voltage applied to a white noise or DC offset signal, or a selected sweep range, sweep frequency and voltage of an applied sweep stimulus magnetic field.

[0076] "White noise" refers to random noise or a signal having simultaneous multiple frequencies, e.g., white random noise or deterministic noise. Several variations of white noise and other noise may be utilized. For example, "Gaussian white noise" is white noise having a Gaussian power distribution. "Stationary Gaussian white noise" is random Gaussian white noise that has no predictable future components. "Structured noise" is white noise that may contain a logarithmic characteristic which shifts energy from one region of the spectrum to another, or it may be designed to provide a random time element while the amplitude remains constant. These two represent pink and uniform noise, as compared to truly random noise which has no predictable future component. "Uniform noise" means white noise having a rectangular distribution rather than a Gaussian distribution.

[0077] "Frequency-domain spectrum" refers to a Fourier frequency plot of a time-domain signal.

[0078] "Spectral components" refers to singular or repeating qualities within a time-domain signal that can be measured in the frequency, amplitude, and/or phase domains. Spectral components will typically refer to signals present in the frequency domain.

CONCLUSION

[0079] The system described herein transduces a specific molecule signal to effect a specific charge pathway and may be configured to deliver the effect of chemical, biochemical or biologic therapy to a patient and treat an adverse health condition,

without the use of drugs, alternative therapies, etc. For example, the system can transduce RNA sequence signals to regulate metabolic pathways and protein production, both up regulation and down regulation.

[0080] The system provides numerous other benefits. The system is scalable to provide treatment to a variety of patient regions. The coil, cable and connector are disposable, or the device as a whole with the controller, are preferably provided for a single therapeutic session and for one prescription, so that the device and coil are not to be reused, thereby preventing cross contamination, etc. The switch on the device permits an on-off nature of therapy so that patients may selectively switch on and off their therapy if needed.

[0081] Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise," "comprising," and the like are to be construed in an inclusive sense, as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to." The word "coupled", as generally used herein, refers to two or more elements that may be either directly connected, or connected by way of one or more intermediate elements. Additionally, the words "herein," "above," "below," and words of similar import, when used in this application, shall refer to this application as a whole and not to any particular portions of this application. Where the context permits, words in the above Detailed Description using the singular or plural number may also include the plural or singular number respectively. The word "or" in reference to a list of two or more items, that word covers all of the following interpretations of the word: any of the items in the list, all of the items in the list, and any combination of the items in the list.

[0082] The above detailed description of embodiments of the invention is not intended to be exhaustive or to limit the invention to the precise form disclosed above. While specific embodiments of, and examples for, the invention are described above for illustrative purposes, various equivalent modifications are possible within the scope of the invention, as those skilled in the relevant art will recognize. For example, while processes or blocks are presented in a given order, alternative embodiments may

perform routines having steps, or employ systems having blocks, in a different order, and some processes or blocks may be deleted, moved, added, subdivided, combined, and/or modified. Each of these processes or blocks may be implemented in a variety of different ways. Also, while processes or blocks are at times shown as being performed in series, these processes or blocks may instead be performed in parallel, or may be performed at different times.

[0083] The teachings of the invention provided herein can be applied to other systems, not necessarily the system described above. The elements and acts of the various embodiments described above can be combined to provide further embodiments.

[0084] All of the above patents and applications and other references, including any that may be listed in accompanying filing papers, are incorporated herein by reference. Aspects of the invention can be modified, if necessary, to employ the systems, functions, and concepts of the various references described above to provide yet further embodiments of the invention.

[0085] These and other changes can be made to the invention in light of the above Detailed Description. While the above description details certain embodiments of the invention and describes the best mode contemplated, no matter how detailed the above appears in text, the invention can be practiced in many ways. Details of the signal processing system may vary considerably in its implementation details, while still being encompassed by the invention disclosed herein. As noted above, particular terminology used when describing certain features or aspects of the invention should not be taken to imply that the terminology is being redefined herein to be restricted to any specific characteristics, features, or aspects of the invention with which that terminology is associated. In general, the terms used in the following claims should not be construed to limit the invention to the specific embodiments disclosed in the specification, unless the above Detailed Description section explicitly defines such terms. Accordingly, the actual scope of the invention encompasses not only the disclosed embodiments, but also all equivalent ways of practicing or implementing the invention under the claims.

CLAIMS

WE/I CLAIM:

1. A portable apparatus for generating electromagnetic signals to provide treatment for mammalian ailments, the apparatus comprising:
 - an electromagnetic transducer portion having a connector, a signal output portion, and a lead coupling the connector with the signal output portion,
 - wherein the connector includes identification circuitry, and
 - wherein the signal output portion includes a wire coil having multiple windings; and
 - a signal generator comprising –
 - a port configured to receive the connector of the electromagnetic transducer;
 - an amplifier coupled to the port;
 - first memory for storing a low-frequency, time-domain therapeutic signal,
 - wherein the stored therapeutic signal is obtained from a drug sample, and
 - wherein the stored therapeutic signal has a frequency range between 1 Hz to 22 kHz;
 - at least one processor communicatively coupled among the amplifier and first memory;
 - a battery coupled among the amplifier, the first memory and the processor, and
 - a housing for carrying the amplifier, the first memory, the processor and the battery,

wherein the processor is programmed to provide the stored therapeutic signal for amplification by the amplifier and delivery to the electromagnetic transducer when –
the connector is received within the port, and
the processor receives information obtained from the identification circuitry; and
wherein the electromagnetic transducer produces a magnetic field signal in response to the stored therapeutic signal to provide treatment to a mammalian patient at a location proximate to the signal output portion.

2. The apparatus of claim 1 wherein the stored therapeutic signal is generated by:

providing the drug sample within an electromagnetic shielding structure and proximate to at least one superconducting quantum interference device (SQUID) or magnetometer;

placing the drug sample in a container having both magnetic and electromagnetic shielding, wherein the drug sample acts as a signal source for molecular signals;

injecting noise into the drug sample in the absence of another signal from another signal source at a noise amplitude sufficient to generate stochastic resonance,

wherein the noise has a substantially uniform amplitude over multiple frequencies;

detecting, via the superconducting quantum interference device (SQUID) or magnetometer, output radiation from the drug sample and recording an electromagnetic time-domain signal composed of drug sample source radiation superimposed on the injected noise in the absence of the another generated signal; and,

repeating the injecting and detecting at each of multiple noise levels within a selected noise-level range until the drug sample source radiation is distinguishable over the injected noise.

3. The apparatus of claim 1, further comprising a visual display device coupled to the processor, and wherein the processor is configured to provide signals to the display device for providing at least two of: a status of a countdown timer, a status of the battery, a status of the electromagnetic transducer portion, and an identification of the stored therapeutic signal.

4. The apparatus of claim 1, wherein the first memory is nonvolatile memory, wherein the apparatus includes a second memory coupled to the processor, wherein the second memory is volatile memory, wherein the stored therapeutic signal is stored in an encrypted format within the first memory, and wherein the processor is further programmed to:

- perform a security check;
- when the security check succeeds, decrypting the stored therapeutic signal;
- storing the decrypted therapeutic signal in the second memory;
- initiating a timer; and,
- when the timer expires or reaches a threshold, erasing at least the decrypted therapeutic signal stored in the second memory.

5. The apparatus of claim 1, wherein the electromagnetic transducer portion is one of several different electromagnetic transducer portions each having different sized signal output portions to be used for providing magnetic field signals to different sized areas, respectively,

- wherein the identification circuitry provides information related to a size of the signal output portion, and

wherein the processor provides an amplitude adjustment signal to the amplifier based on the information obtained from the identification circuitry.

6. The apparatus of claim 1, wherein the identification circuitry and the processor communicate via a 1-wire protocol, and wherein the processor provides an amplitude adjustment signal to the amplifier based on the information obtained from the identification circuitry.

7. The apparatus of claim 1, wherein the processor performs an electromagnetic transducer impedance or resistance check before providing the stored therapeutic signal to the amplifier.

8. The apparatus of claim 1, wherein the identification circuitry stores a unique identifier or security key, and the processor performs a security check based on the unique identifier or security key before providing the stored therapeutic signal to the amplifier.

9. The apparatus of claim 1, further comprising a sensor coupled to the processor, wherein the sensor is configured to provide a signal to the processor indicating a tampering with the housing or the signal generator, and in response thereto, the processor erases the stored therapeutic signal.

10. A method for providing a signal to induce an effect of a chemical or biochemical agent to a mammalian patient, wherein the mammalian patient is capable of being responsive to the agent, the method comprising:

providing a portable system having an electromagnetic transducer portion connected to a signal generator portion,

wherein the signal generator portion includes a stored therapeutic signal obtained from a sample of the chemical or biochemical agent,
wherein the stored therapeutic signal is within a frequency range of about 1 Hz and 22 kHz, and
wherein the stored therapeutic signal is secured within the signal generator portion;
securing the signal generator to the patient and the electromagnetic transducer portion to an area of the patient to be treated;
checking for an appropriate connection between the electromagnetic transducer portion and the signal generator portion;
unsecuring the stored therapeutic signal;
initiating a timer;
generating a magnetic signal directed to the area of the patient to be treated, wherein the magnetic signal is based on the stored therapeutic signal; and
when the timer reaches a predetermined value, disabling the signal generator portion to prohibit reuse of the stored therapeutic signal.

11. The method of claim 10 wherein the stored therapeutic signal is encrypted within the signal generator portion, and wherein unsecuring the stored therapeutic signal includes decrypting the stored therapeutic signal.

12. The method of claim 10 wherein disabling the signal generator portion includes erasing the stored electromagnetic signal.

13. The method of claim 10 wherein checking for an appropriate connection includes determining a type of the electromagnetic transducer portion, and wherein the method includes adjusting an amplification of the magnetic signal based on the determined type.

14. The method of claim 10 wherein checking for an appropriate connection includes reading identification information from the electromagnetic transducer portion.

15. The method of claim 10 wherein checking for an appropriate connection includes periodically confirming that the electromagnetic transducer portion continues to maintain a physical resistance value within tolerance.

16. The method of claim 10 wherein the stored therapeutic signal is obtained from the sample of the chemical or biochemical agent by:

providing the sample of the chemical or biochemical agent within an electromagnetic shielding structure and proximate to at least one superconducting quantum interference device (SQUID) or magnetometer;

placing the sample in a container having both magnetic and electromagnetic shielding, wherein the sample acts as a signal source for molecular signals;

injecting noise into the sample in the absence of another signal from another signal source at a noise amplitude sufficient to generate stochastic resonance,

wherein the noise has a substantially uniform amplitude over multiple frequencies;

detecting, via the superconducting quantum interference device (SQUID) or magnetometer, output radiation from the sample and recording an electromagnetic time-domain signal composed of sample source radiation superimposed on the injected noise in the absence of the another generated signal; and

repeating the injecting and detecting at each of multiple noise levels within a selected noise-level range until the drug sample source radiation is distinguishable over the injected noise.

17. The method of claim 10 wherein checking for an appropriate connection includes providing a user-perceivable alarm when the connection between the electromagnetic transducer portion and the signal generator portion is not detected or is detected outside of a prescribed tolerance.

18. The method of claim 10, further comprising periodically checking, directly or indirectly, whether an inductance of the electromagnetic transducer portion is within a prescribed tolerance.

19. The method of claim 10, further comprising periodically checking, directly or indirectly, whether an inductance of the electromagnetic transducer portion is within a prescribed tolerance so as to check proximity of the electromagnetic transducer portion to the patient.

20. The method of claim 10, further comprising recording a data log capable of being displayed to a user, wherein the data log includes data representing: a status of the timer, any interruptions of the timer, status of the connection between the electromagnetic transducer portion and the signal generator portion, and any error codes.

21. An apparatus for generating signals to provide treatment for ailments, the apparatus comprising:

an electromagnetic transducer portion having a terminal and a signal output portion coupled to the connector; and,

a signal generator comprising –

a switch;

a memory for storing a therapeutic signal,

wherein the stored therapeutic signal is obtained from a sample of a chemical or biologic molecule including proteins, RNA and DNA sequences, and

wherein the stored therapeutic signal has a frequency range between 1 Hz to 22 kHz;
at least one processor coupled to the memory, the switch and the terminal;
a battery coupled at least to the processor, and
a housing for carrying the memory, processor and battery,
wherein the processor is programmed to provide the stored therapeutic signal for delivery to the electromagnetic transducer when the switch is in an on position, and
wherein the electromagnetic transducer produces an electromagnetic field signal in response to the stored therapeutic signal to provide treatment for ailments at a location proximate to the signal output portion.

22. The apparatus of claim 21 wherein a user may actuate the switch, and wherein the processor is configured to provide the stored therapeutic signal for delivery to the electromagnetic transducer when the switch is in the on position and discontinue providing the stored therapeutic signal for delivery to the electromagnetic transducer when the switch is in an off position.

23. The apparatus of claim 21 wherein a size of the signal output portion of the electromagnetic transducer portion has a selected internal area to define a breadth and depth of a treatment area for the electromagnetic field signal.

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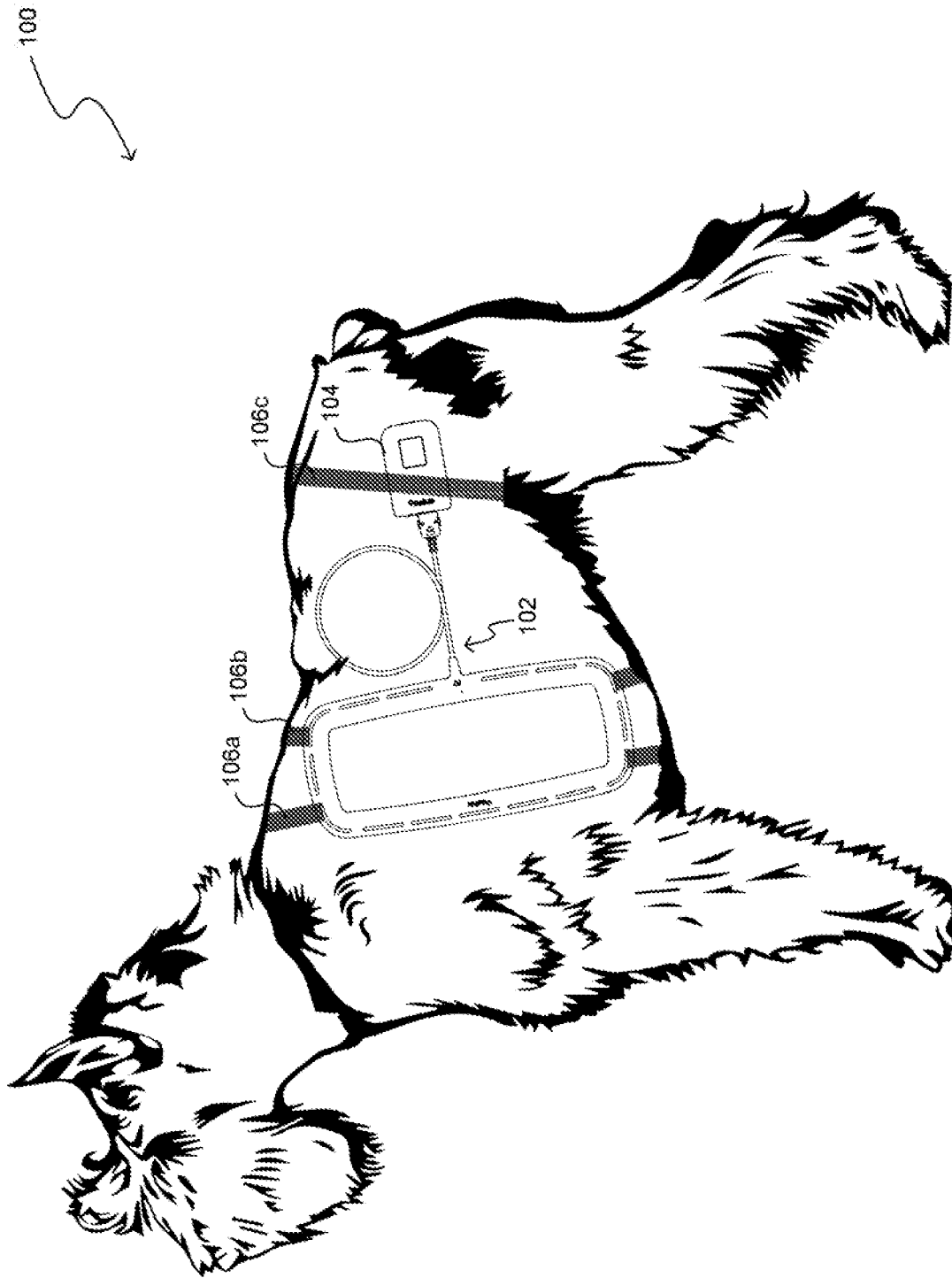


FIG. 1

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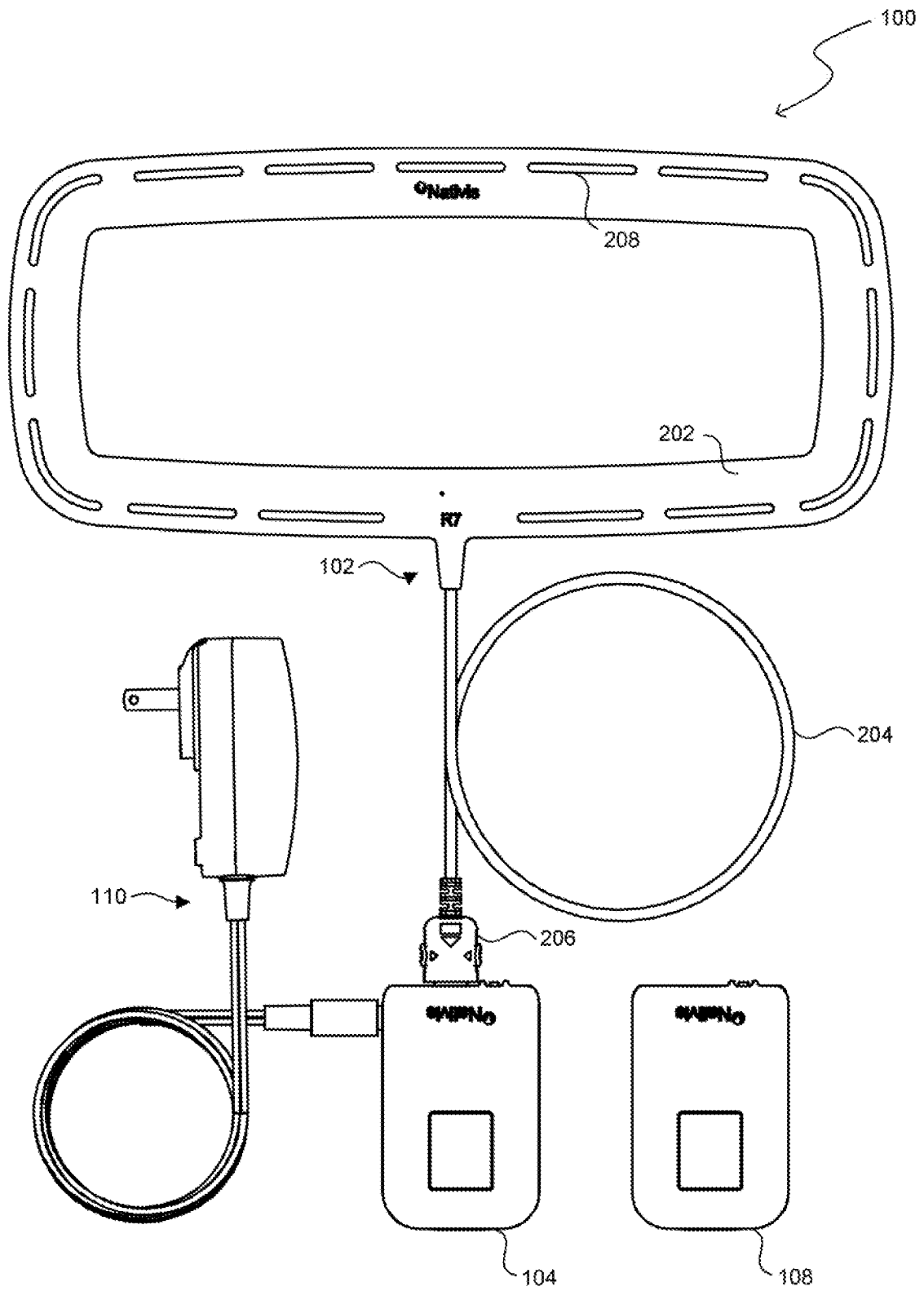


FIG. 2

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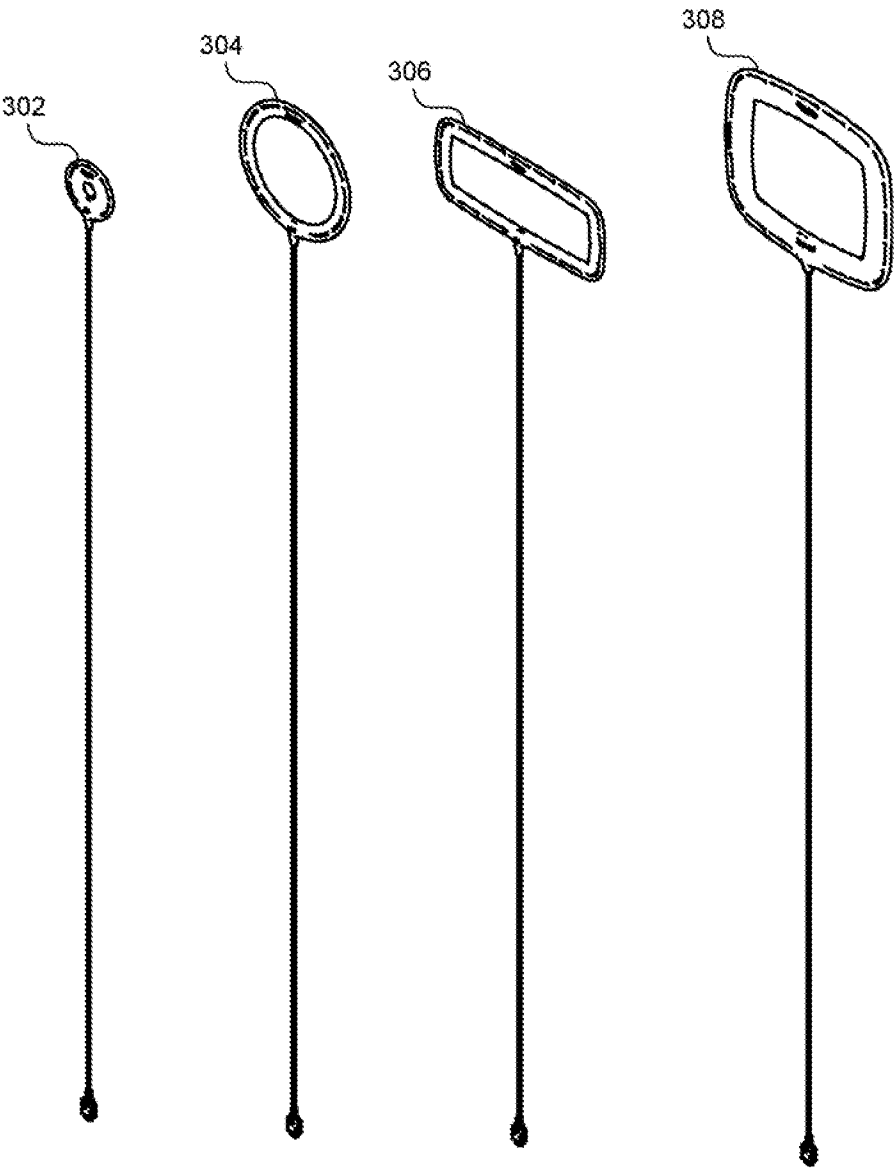


FIG. 3

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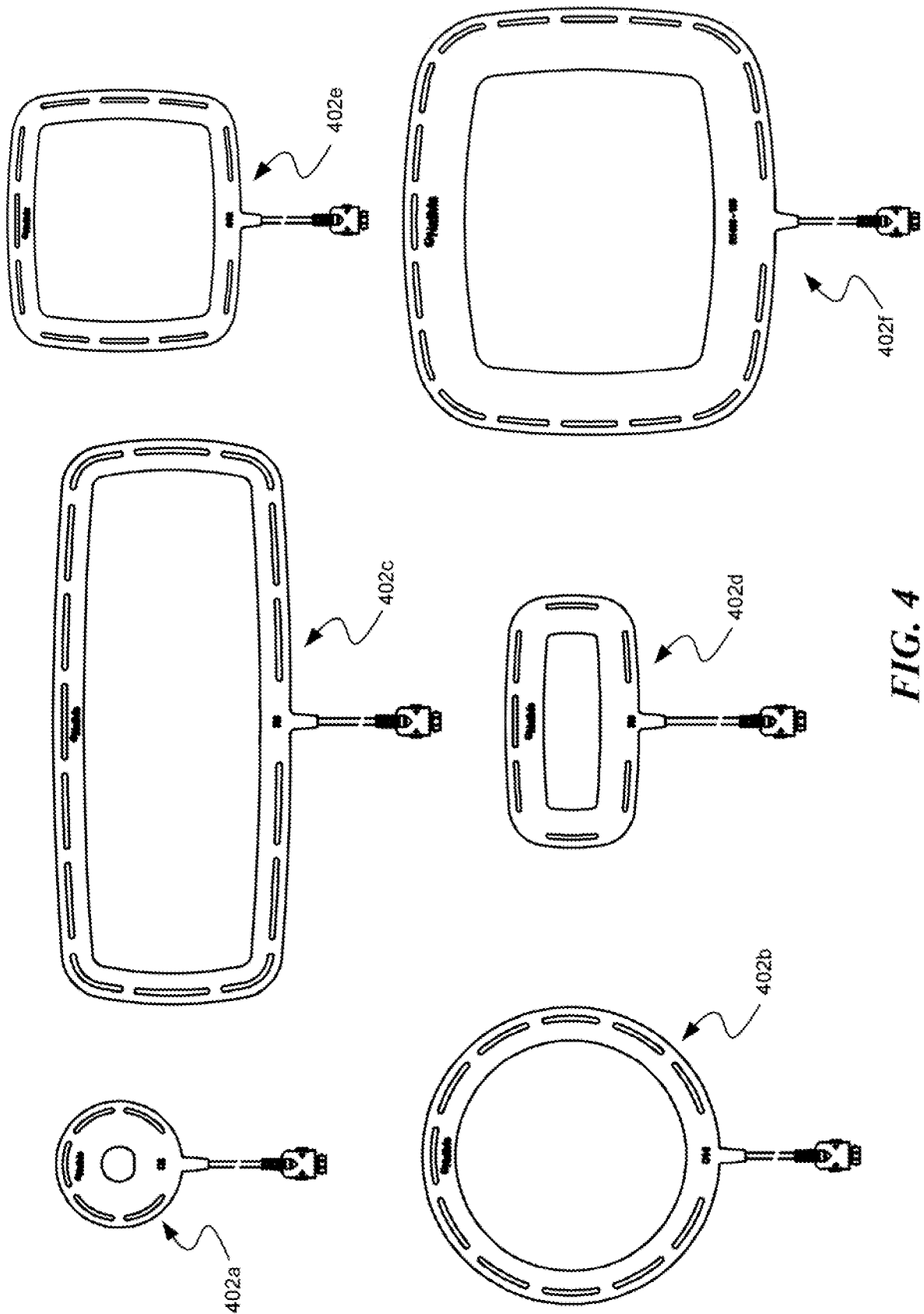


FIG. 4

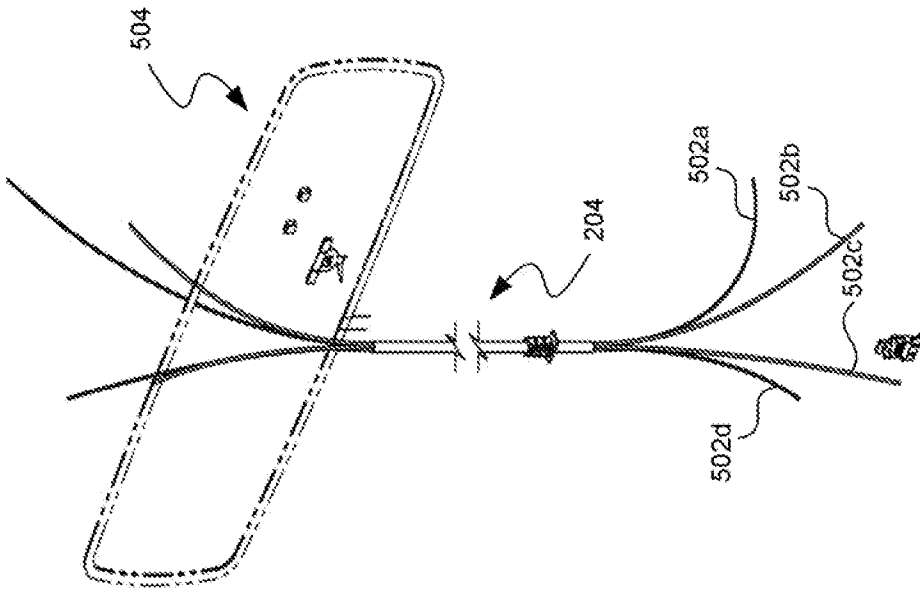


FIG. 5A

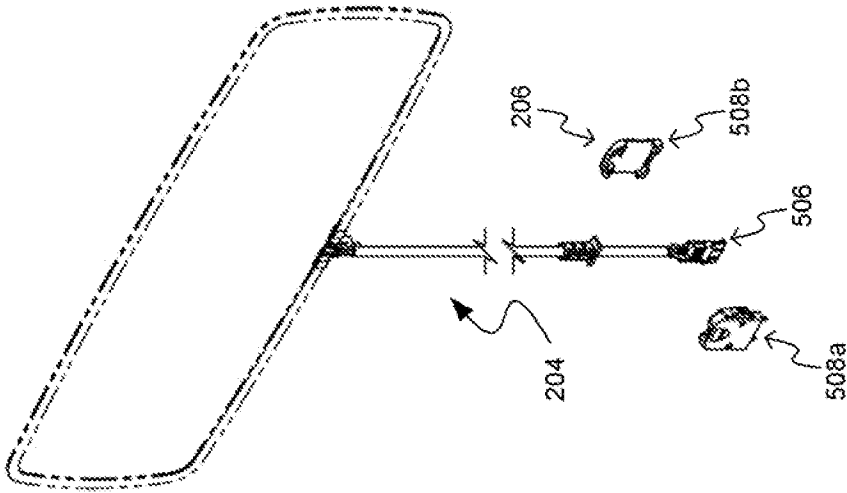


FIG. 5B

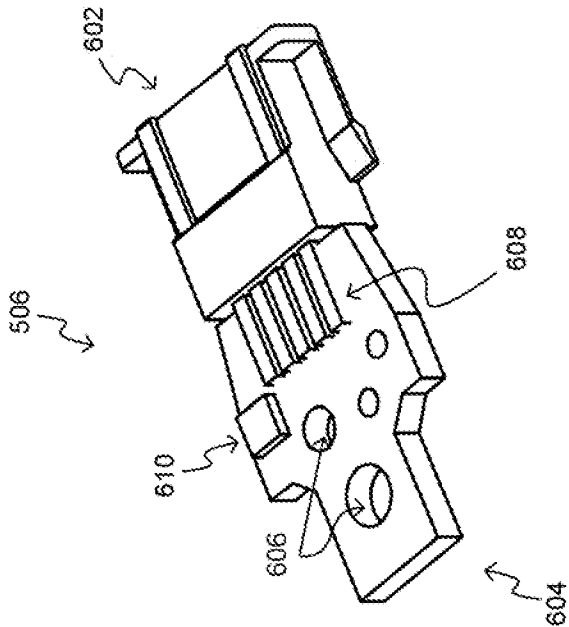


FIG. 6

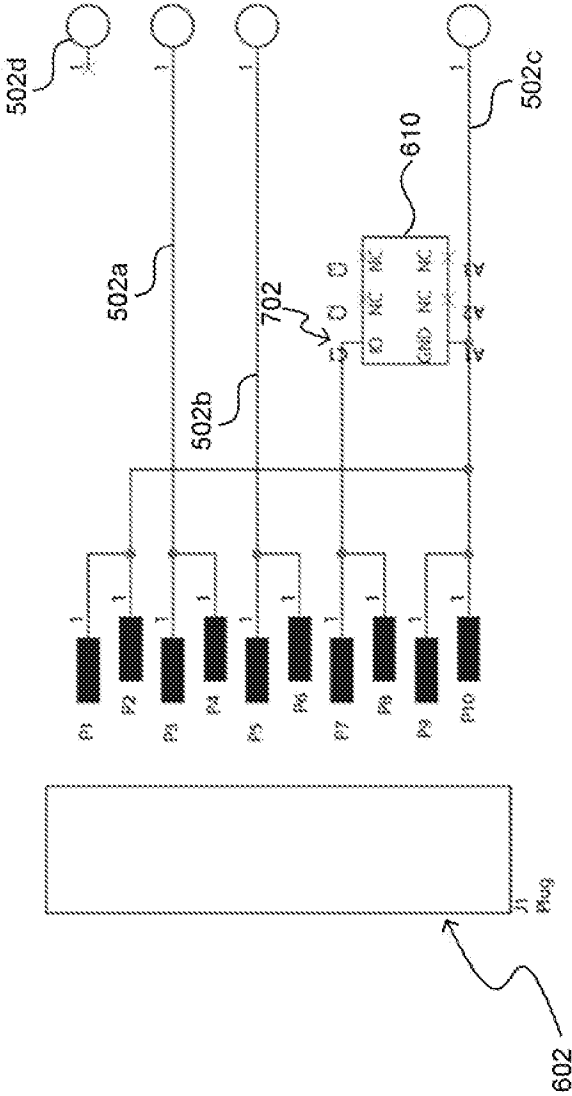
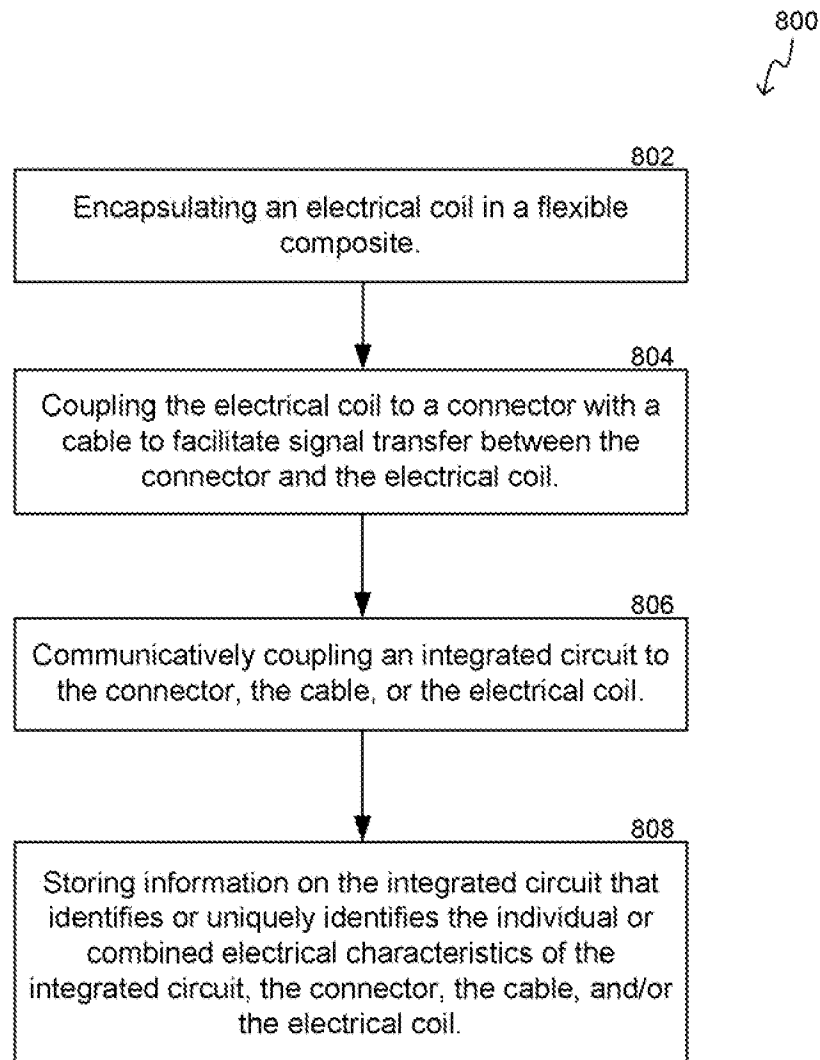


FIG. 7

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**FIG. 8**

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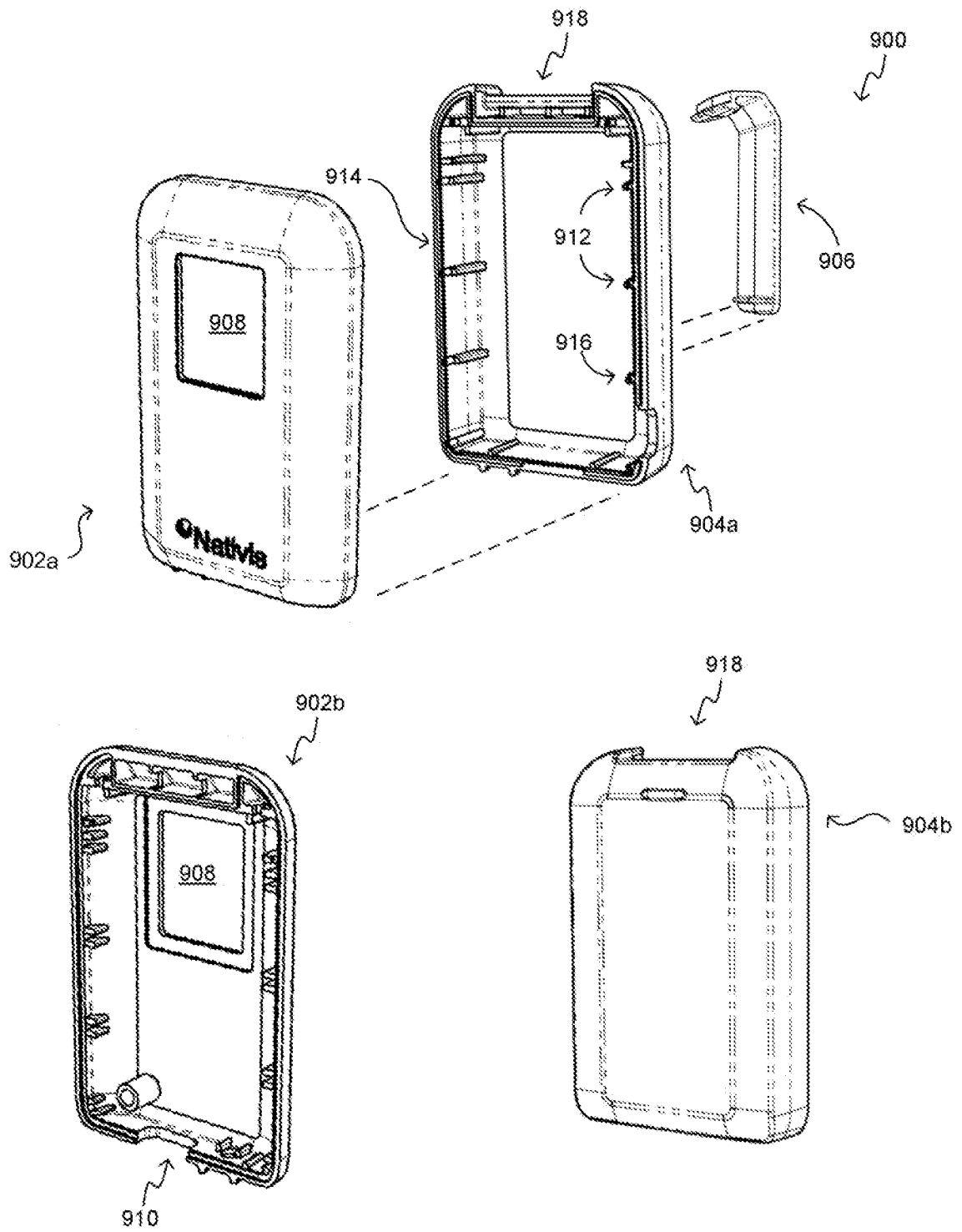


FIG. 9

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1000

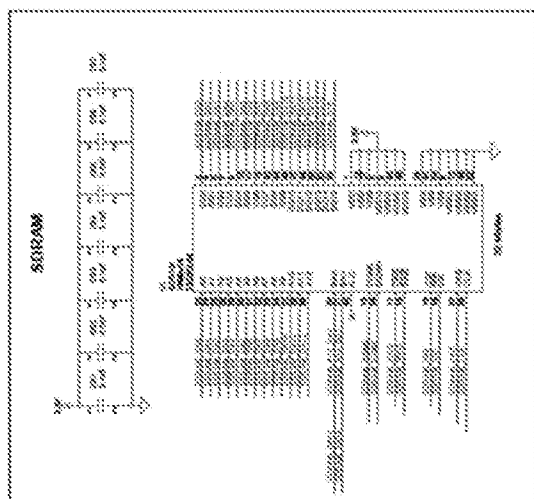
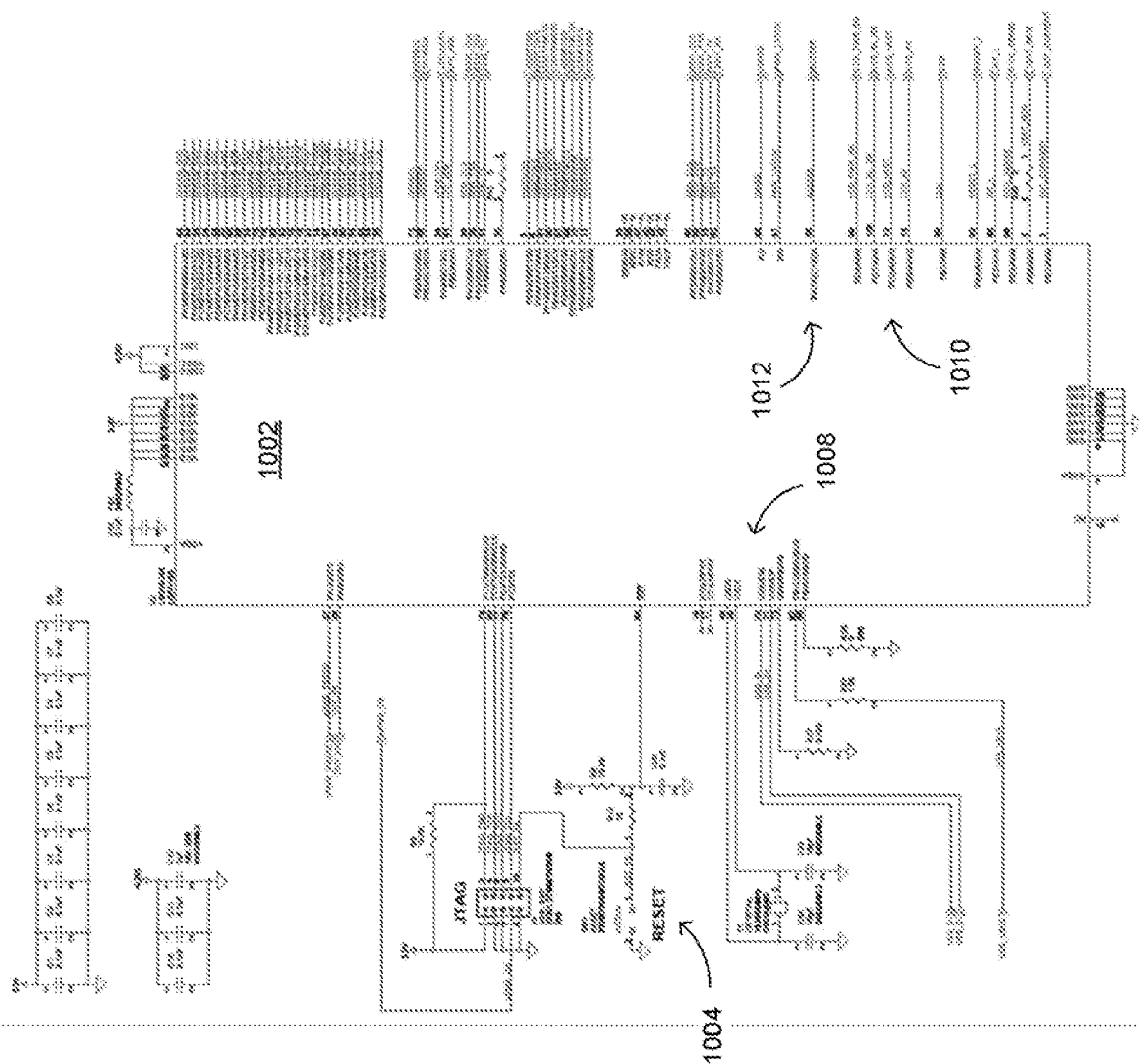


FIG. 10



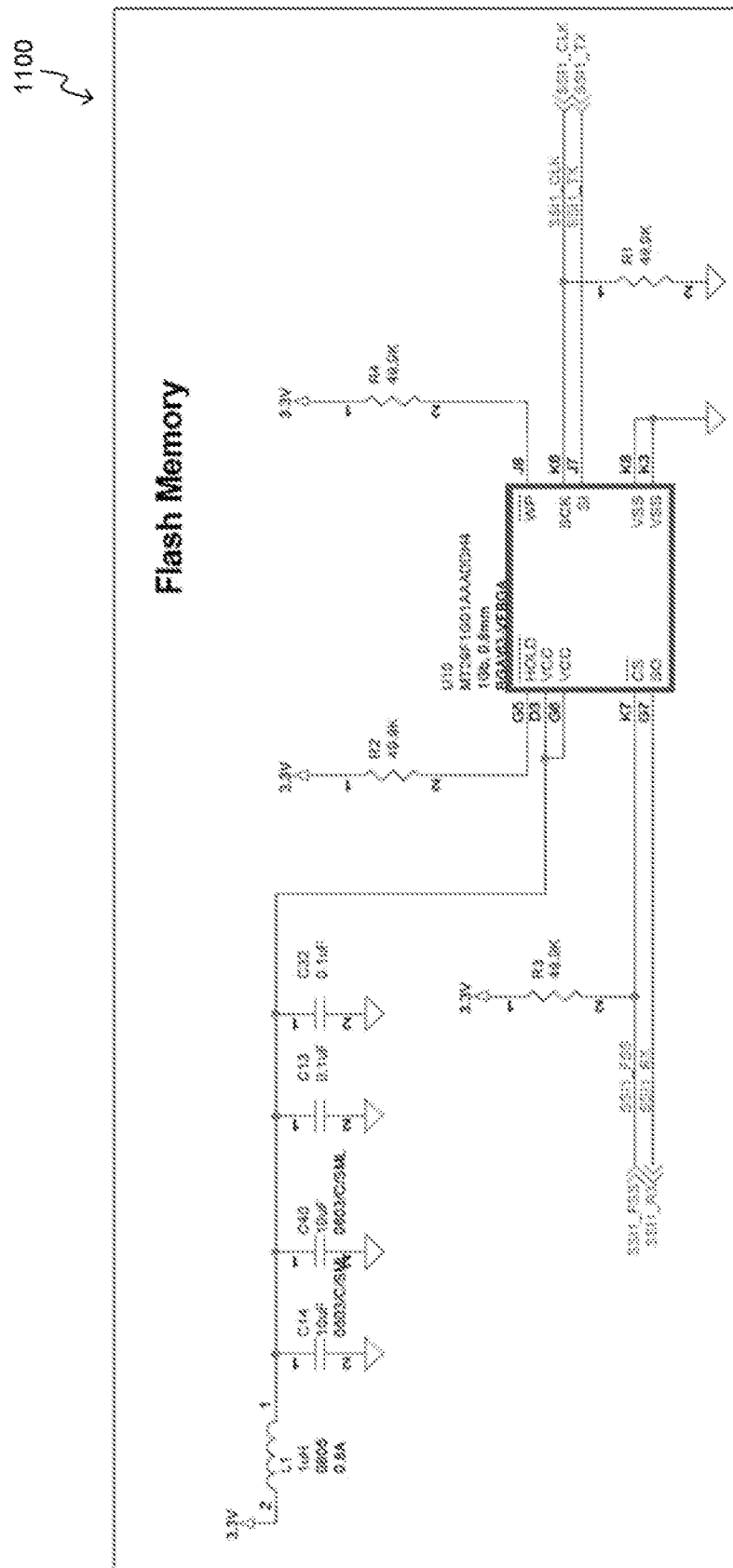


FIG. 11

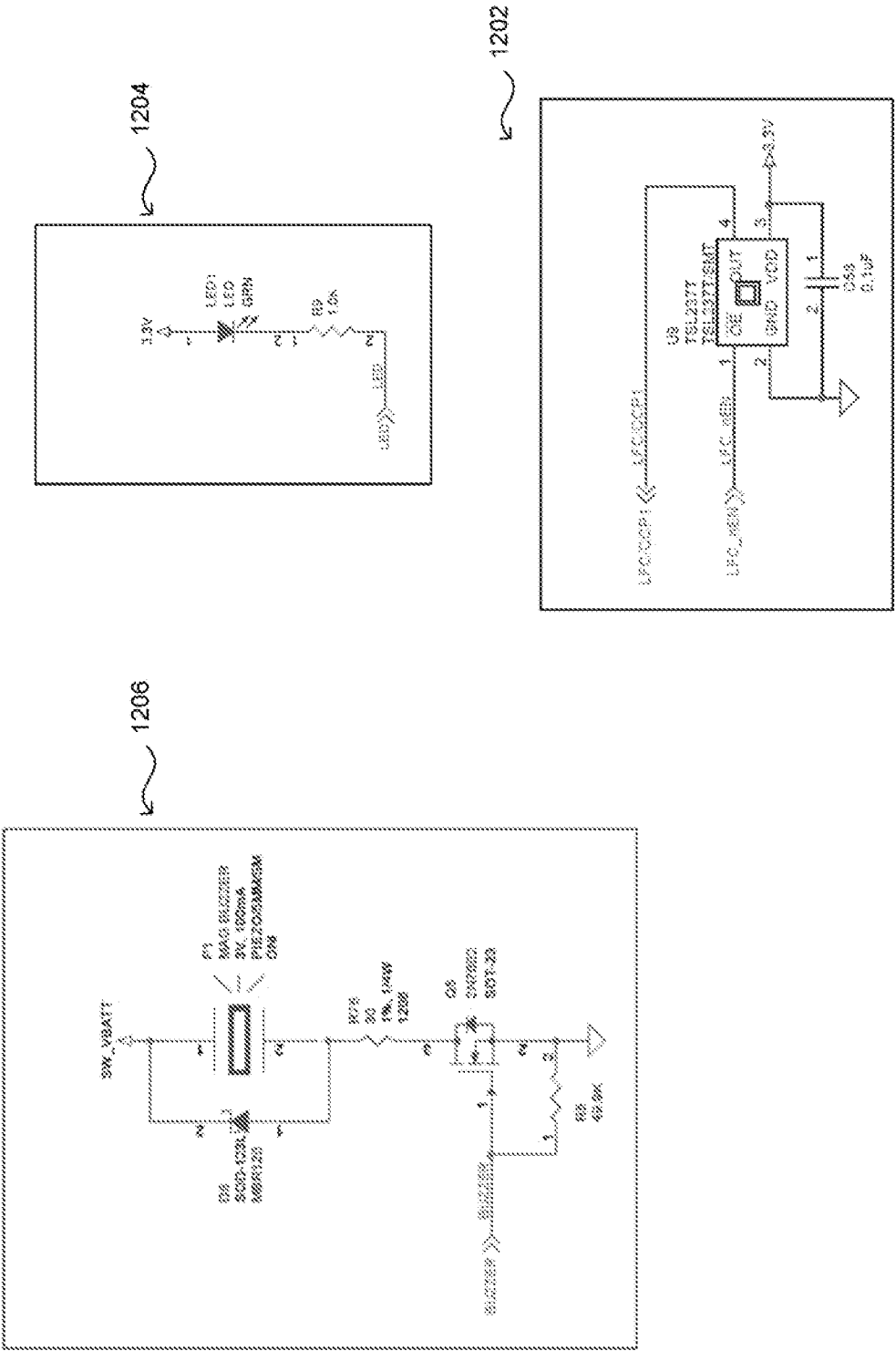


FIG. 12

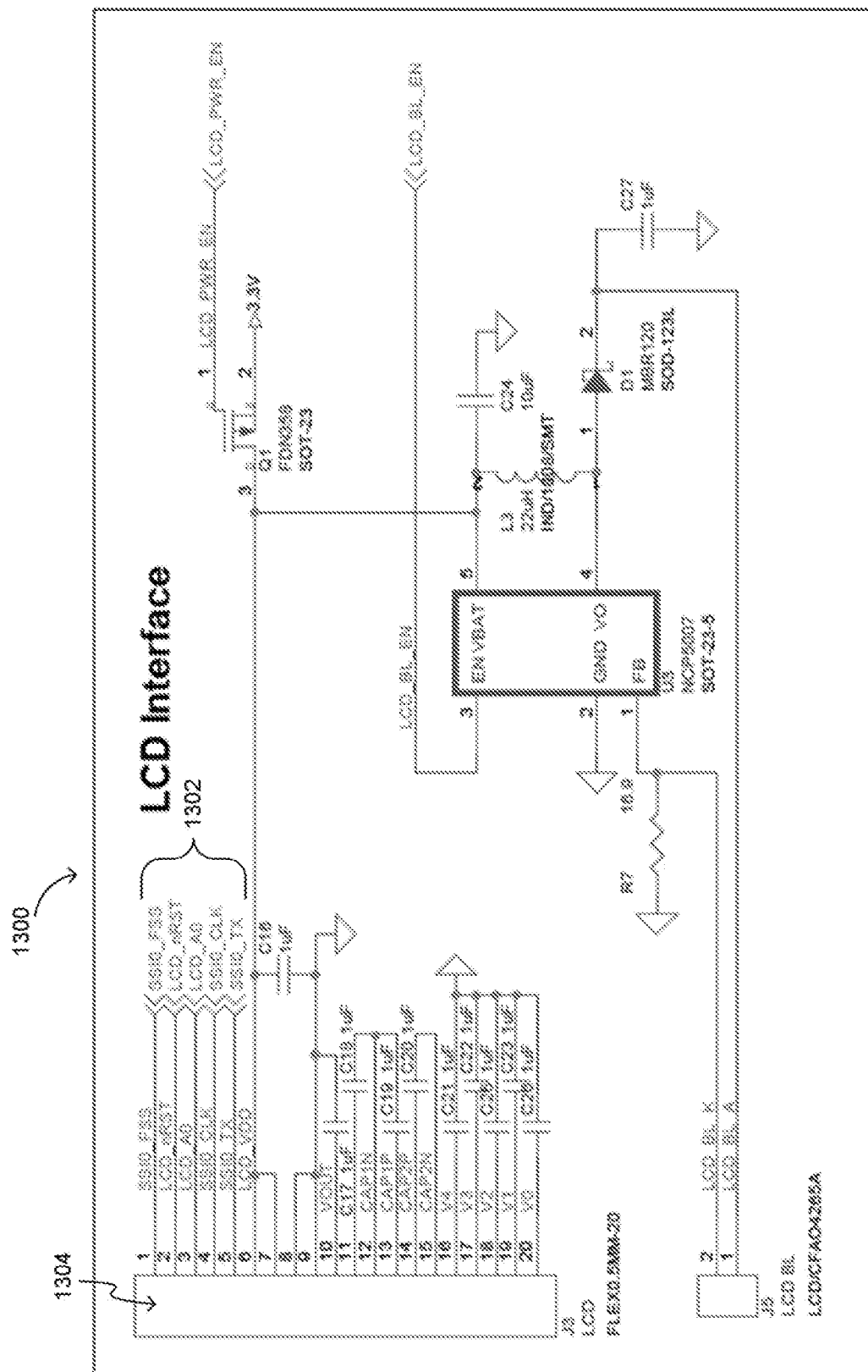


FIG. 13

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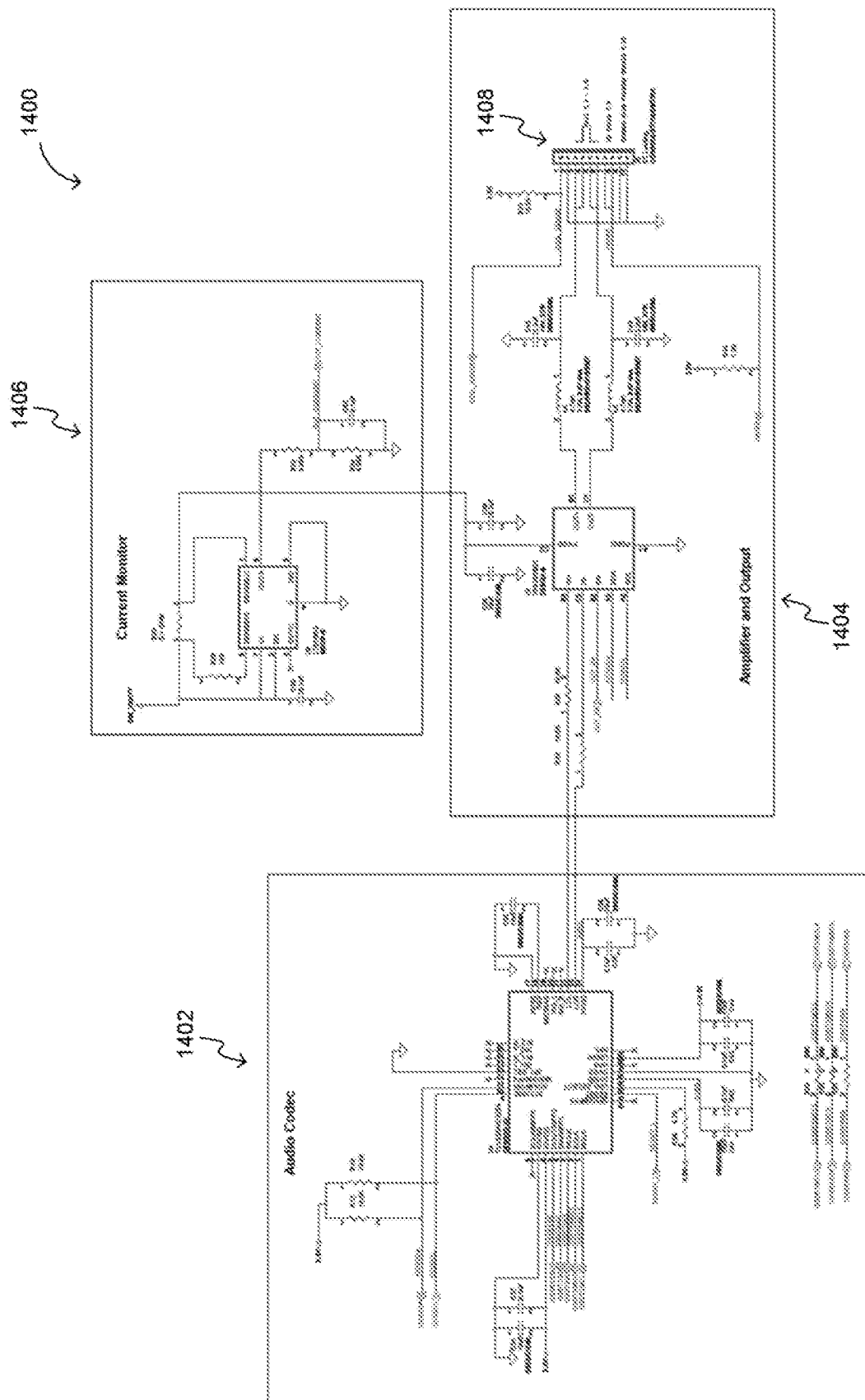


FIG. 14

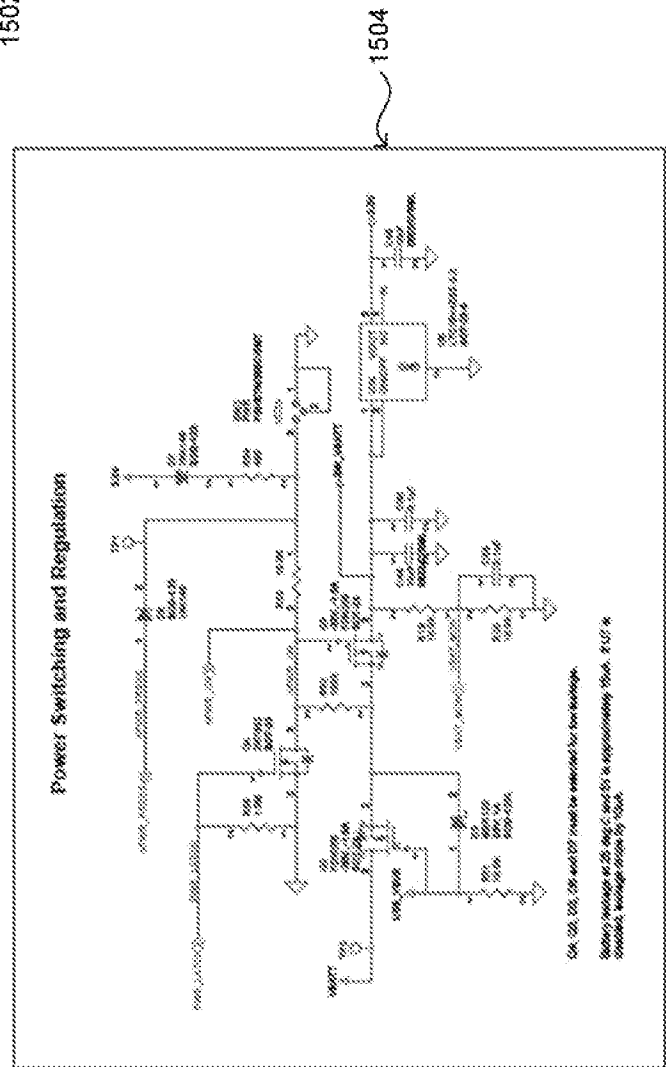
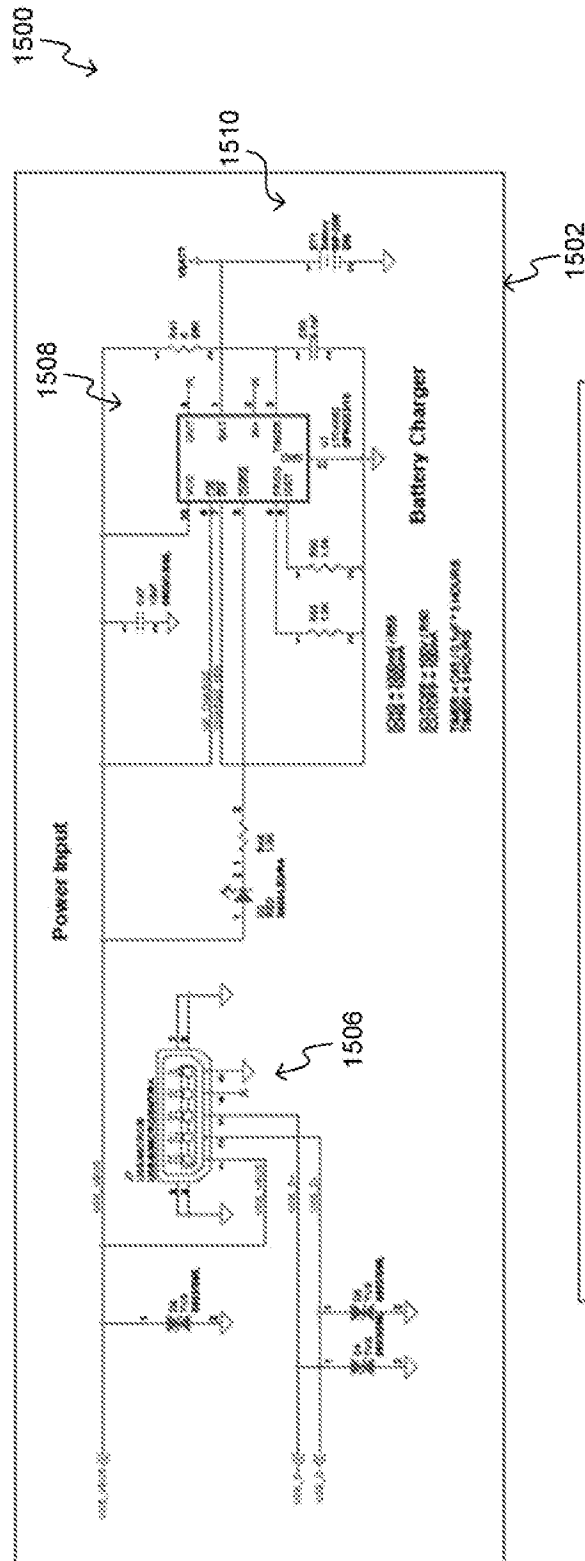
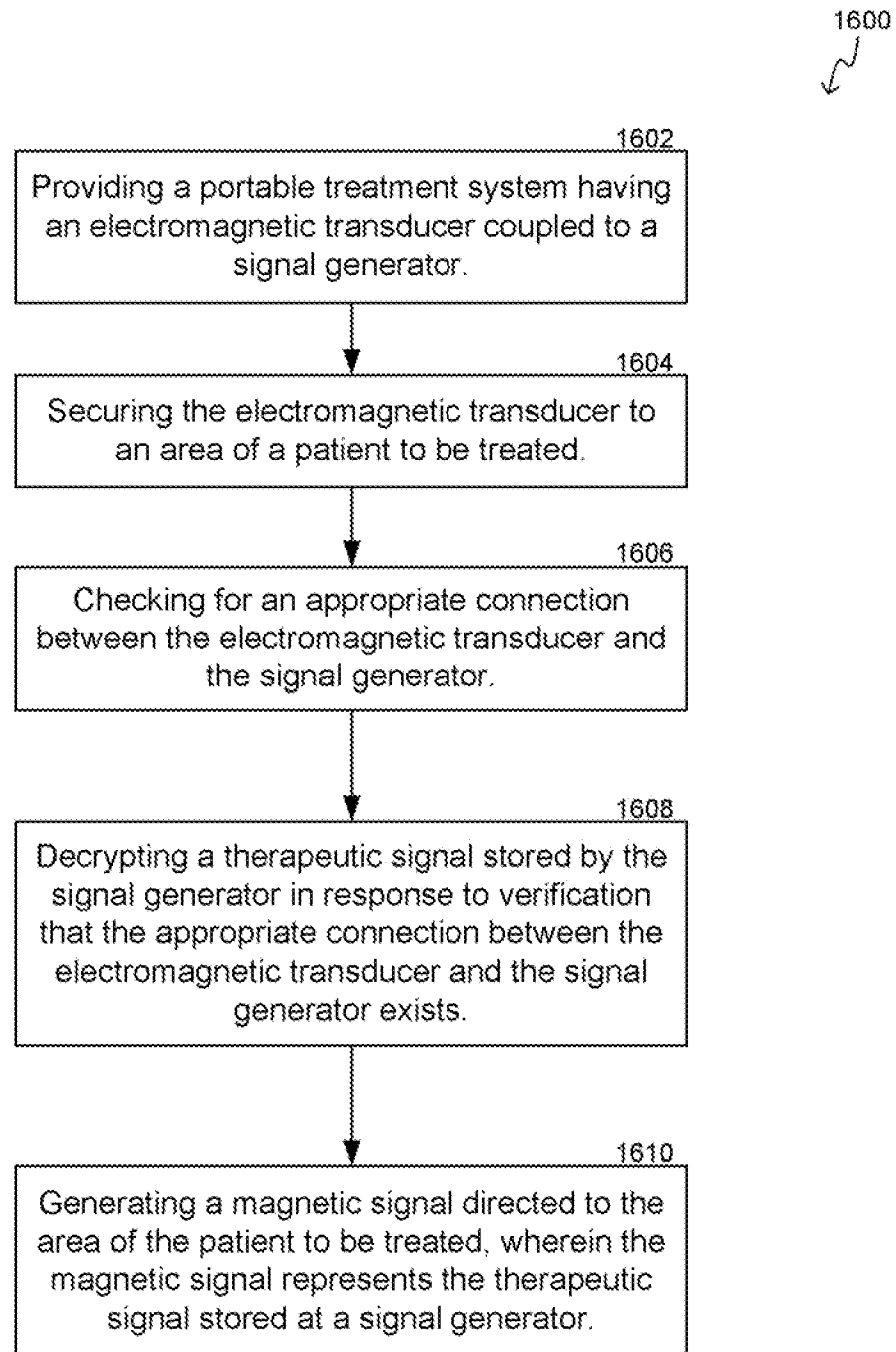


FIG. 15

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**FIG. 16**

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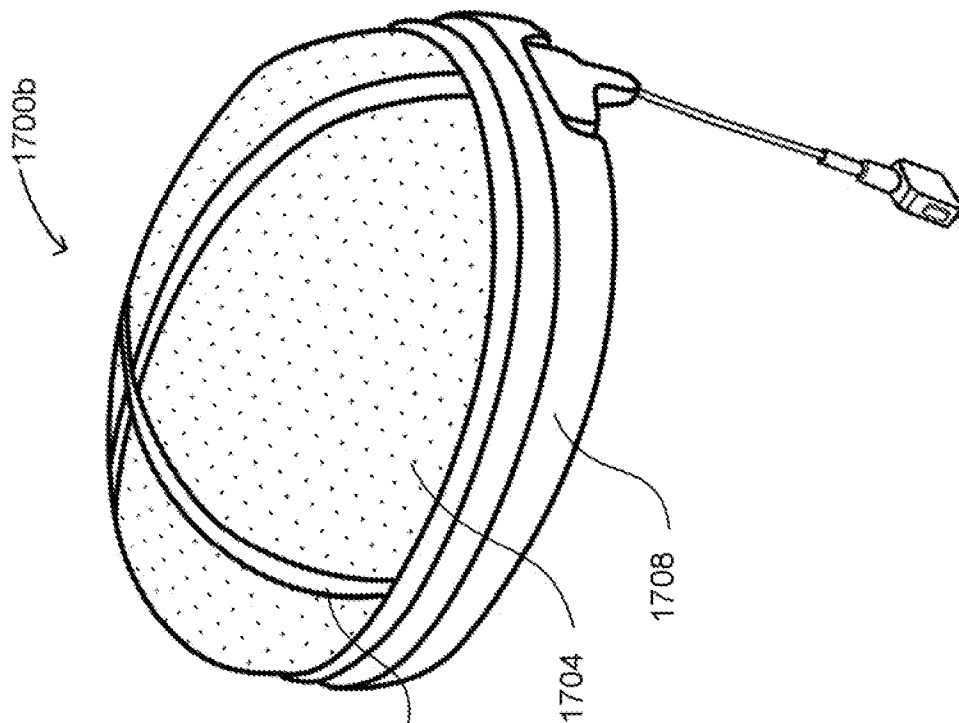


FIG. 17B

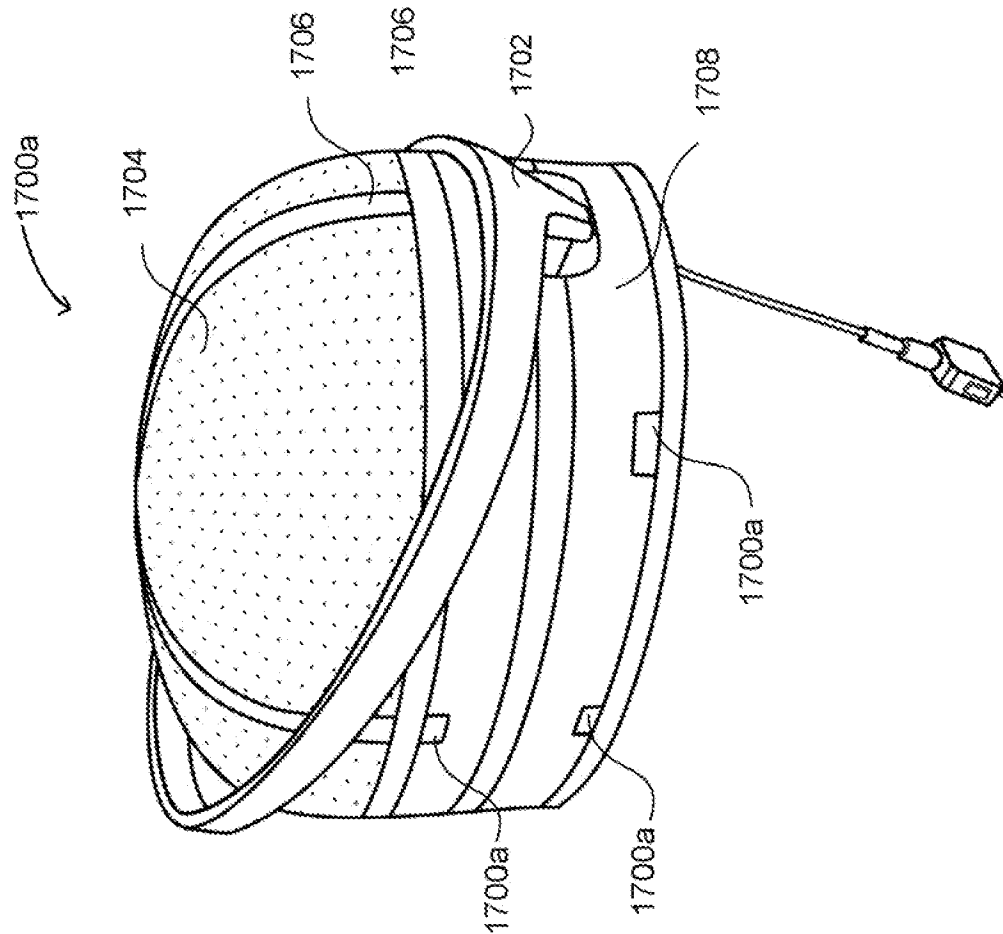


FIG. 17A

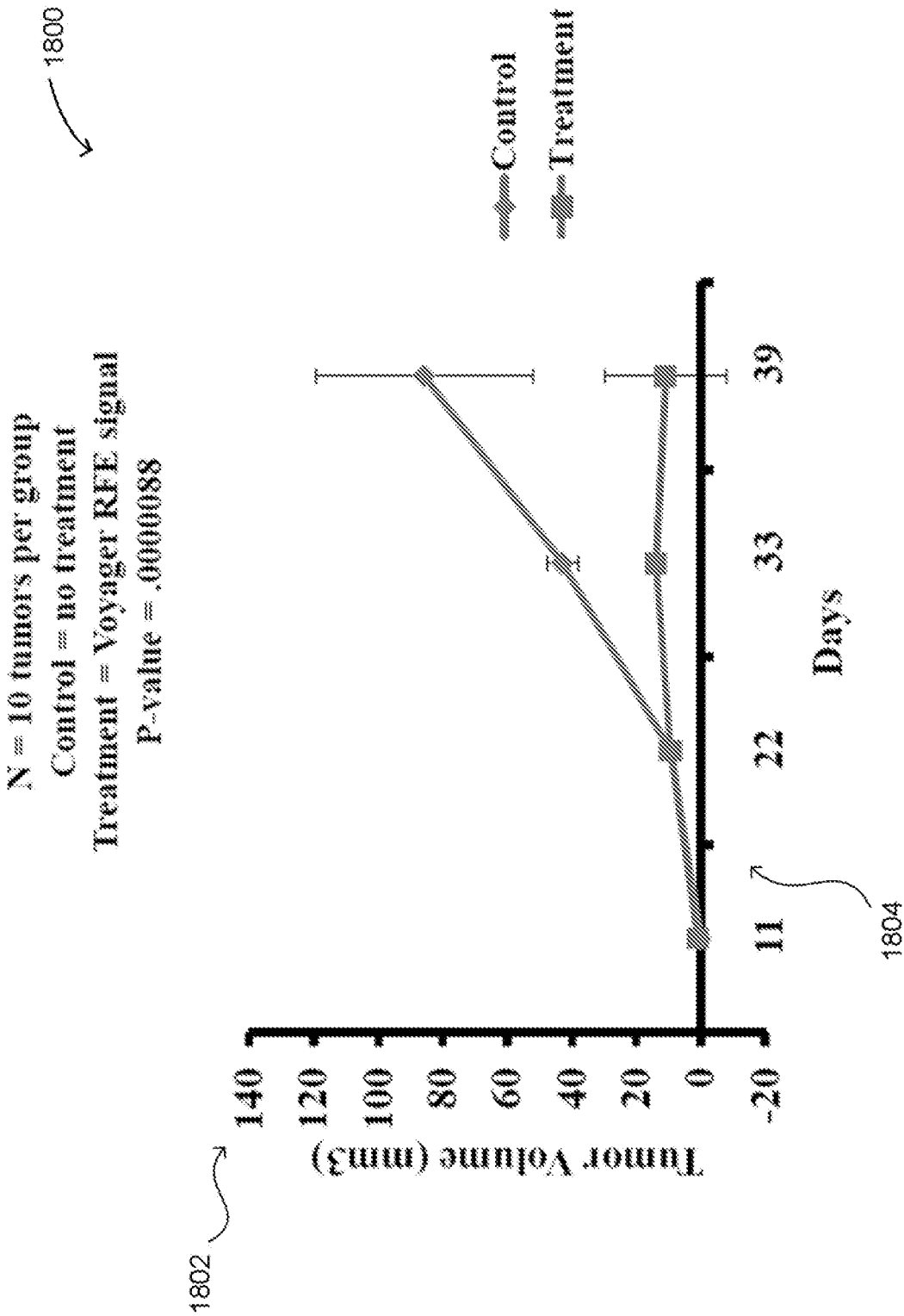


FIG. 18