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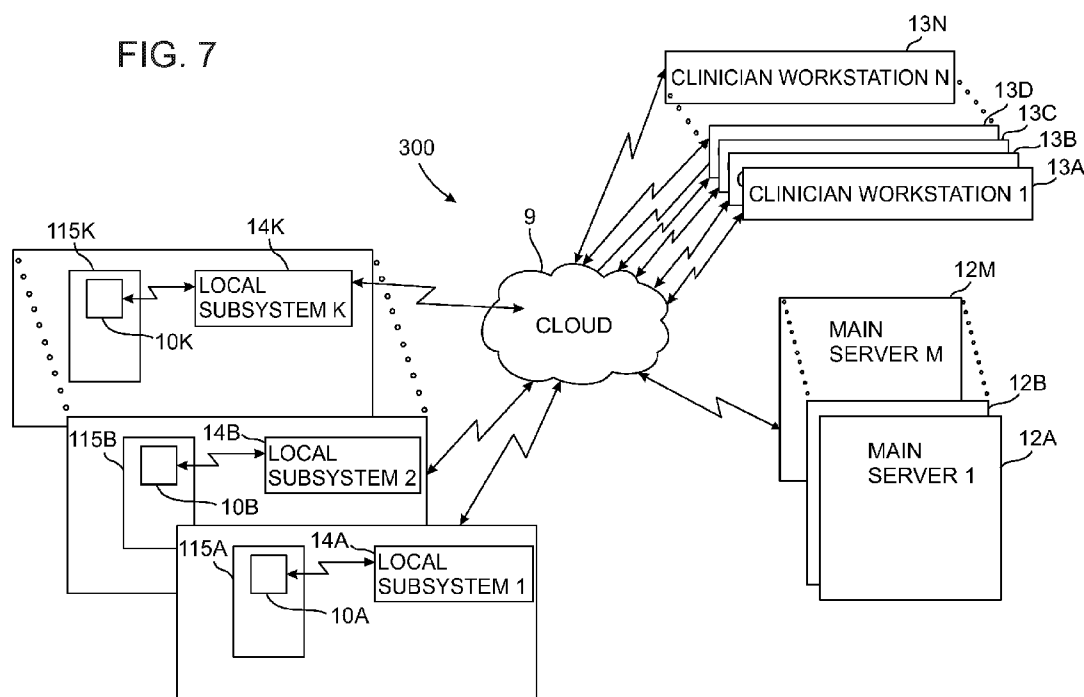
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FIG. 7



(57) Abstract: A system including an implant for delivering therapy to a patient, an energizing pod for wirelessly energizing the implant, a local subsystem including one or more mobile or wearable communication/processing devices capable of wirelessly controlling the operation of the implant and of communicating with a clinician workstation to receive a digital prescription data file (DPF) including therapy parameters from the clinician workstation. The local subsystem is configured to receive patient input selecting values of one or more patient modifiable therapy parameters, to generate an implant control data file (ICF) including the values of the patient modifiable therapy parameters and to wirelessly transmit the ICF file to the implant via the energizing pod for controlling the operation of the implant.

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THERAPEUTIC SYSTEMS WITH DIGITAL PRESCRIPTION, ENERGIZING PODS FOR SUCH SYSTEMS AND METHODS OF USE THEREOF

RELATED APPLICATIONS

5 This application claims the benefit of priority of U.S. Provisional Patent Application No. 63/617,097 filed 3 January 2024, the contents of which are incorporated herein by reference in their entirety.

FIELD AND BACKGROUND OF THE INVENTION

10 The present invention, in some embodiments thereof, relates to the field of devices and systems for delivering a therapeutic treatment (electrical, or other therapy type) to a patient using one or more implants, and more particularly to such systems including a local subsystem capable of receiving and storing a digital data file for controlling therapy and for allowing the patient to set the values of one or more therapy parameters.

15 Brain recording and/or stimulating methods may also be used for modulating the brain physiology to enhance cognitive function in healthy individuals or to improve cognitive function in some patients having neuropsychiatric diseases affecting cognitive performance such as, inter alia, depression, ADHD, OCD, various eating disorders, epilepsy and many other psychiatric, neurodegenerative, neurological and neuropsychiatric disorders. Cortical sensing and stimulation
20 may also be used to treat a wide array of motor disabilities.

 Implants, systems and methods for sensing electrical brain activity and for delivering therapeutic electrical signals to the brain are disclosed, inter alia, in published international applications WO/2019/130248, WO/2019/244099, WO/2020/161555 and WO/2021/144730, incorporated herein by reference in their entirety.

25 Implantable devices with active electronics require a power source to operate, often implemented as a battery, large capacitor, or super-capacitor. Many implantable devices have an internal primary-cell battery to power active electronics that must be replaced after extended use depletes the battery's stored energy. Replacing an implant's battery requires a surgical procedure in which the component that houses the battery is disconnected, removed, and replaced with a new
30 component that has a fully charged battery. This is repeated as often as the battery is depleted through use, resulting in additional costs related to the procedure and replacement parts and additional surgical risk to the patient.

 To overcome these limitations, some implantable devices have an internal re-chargeable battery. Re-chargeable batteries have lower energy storage capacity than primary batteries and

must be re-charged on a regular basis, sometimes daily. In both cases, the size of the battery often dominates the overall size of the implant. By removing the internal battery, the overall size of the implant can be drastically reduced. Without an internal battery, power for the implantable device must be derived from an external source when in use.

5 Power can be delivered wirelessly from an external system to the implant using a number of energy transfer methods including, but not limited to, inductive coupling, resonant inductive coupling, microwave coupling, optical coupling, ultrasonic coupling, and hybrid methods that combine multiple coupling methods. Each of these methods has varying performance characteristics, including energy transfer efficiency, tissue penetration depth, focality, and overall
10 system size, weight, and power. For example, ultrasonic coupling can achieve deep and focused energy transfer, but requires large and complex external systems that consume a lot of power. Alternatively, resonant inductive coupling can involve relatively less complex, smaller, and lower power external systems, but energy transfer into tissue is relatively shallow and less focused. During wireless power transfer to an implant, the external energizing component of the system
15 needs to be aligned over the implant for optimal performance. This can be achieved by manually holding the charger over the implant, by magnetic coupling (like cochlear implants), or by integrating power transfer coils into clothing, like a vest, that maintains the proper alignment. The external energizing component of the system must also be powered. If the external energizing component is powered by a power source such as, for example, a battery or other energy storage
20 unit, the power source must be periodically re-charged or replaced. The alignment of the external energizing component over the implant and the re-charging of the external energizing component both require actions by a user. The required burden and cost of performing these actions need to be minimized in order to achieve maximum usability, especially when the system is to be used on-the-go.

25 A wireless data link is required to re-program an implantable device and to receive important data from the implantable device. The configuration of the implantable device may be wirelessly re-programmed to switch between different system states (such as, for example, stimulation or sensing) or to configure specific channels (for example by connecting/disconnecting individual channels and/or by changing reference electrodes and/or ground electrodes). Stimulation
30 parameters may also be wirelessly re-programmed to titrate therapies or to adapt to long-term changes in physiology. Many implantable systems include both a patient programmer and a clinician programmer, each having varying levels of permissions for changing parameters. Patient programmers typically have a restricted range or subset of parameters that can be updated compared to clinician programmers. Therefore, re-programming the device may require a trained

professional with a clinician programmer to determine whether a change needs to be made (for example, by conducting a clinical evaluation), determine what new parameters or configuration is best, and then update the implantable device using an external programmer. These steps are typically performed during clinical visits to ensure proper changes are implemented safely.

5 However, additional clinical visits result in additional patient burden and cost. The need to develop multiple external systems (for example, one system for patients and one system for clinicians) makes the systems more complex and costly. These programmers are typically bulky and sometimes attached to wands or pads for re-charging the device. It is additionally burdensome to patients to have to purchase, carry, and re-place these external devices in order to use their
10 implanted system.

Implantable devices with sensing capabilities may wirelessly stream data or provide periodic status updates to an external device for monitoring or analysis. Wireless data links are increasingly important for closed-loop systems that trigger or adjust stimulation based upon data sensed by the implanted device or other connected devices. In some cases, data transmitted out from an
15 implantable device may be processed or stored on a local computational system (for example, a smartphone, a programmer, or a computer) or may be transmitted over a network link for processing or storage (for example, in cloud resources). Processing and storing data on external systems can be advantageous due to relaxed constraints on system size, weight, and power compared to implanted systems. In addition, external systems are easier and less costly to update
20 and replace.

Wireless data transfer can be achieved via a number of different energy transfer techniques, including, but not limited to, inductive coupling, resonant inductive coupling, microwave coupling, optical coupling, ultrasonic coupling, and hybrid methods that combine multiple coupling methods. Use of industry standard wireless transfer protocols (such as, for example,
25 Bluetooth, Bluetooth Low Energy) has the advantage of more easily integrating with other wireless devices, but may be less efficient than custom wireless data solutions. Custom protocols can achieve higher performance due to optimization for specific use cases but may require encapsulation or re-formatting of data to integrate with other wireless devices. In some cases, wireless power and wireless data may be combined for maximizing overall system efficiency. For
30 example, wireless power may be modulated to encode data. Similarly, the implantable device may modulate its coupling to the external device such that data is encoded in reflected energy that can be measured by the external device.

Security of wireless data links is essential for safe performance. Security may be implemented as encryption to protect data, authentication to protect access, and user-defined permissions to

ensure safe use across multiple users (such as, for example, patients, clinicians, emergency care providers). Security is also challenging for integrating the implantable system with networked devices, including use of hand-held computing devices (such as, for example, smart phones) and cloud services. Security is also an important factor for patient's comfort and trust in the use of an implantable device, especially when the device is continuously functioning within their body. In some applications, including neuropsychiatric disorders, there may be a heightened sensitivity to security and trust, which emphasizes the need for system designs that bolster security and provide assurance to the user that they are always in control of the device and its operation within their body.

Personalization, ease of use, and feedback are also important factors for achieving optimal functionality of an implantable system. Variations in individuals' physiology, presentation of symptoms, disease state, and daily life may significantly impact the efficacy of the system and may even affect patient compliance in proper use of the system. To date, most implantable devices have very limited capabilities in personalizing and adapting therapies. Most implantable devices also lack sufficient feedback to patients and clinicians to effectively adapt diagnoses and therapies at all, let alone at relevant time scales. Feedback to patients is valuable to adjust and reinforce behavior that may impact the efficacy of the implantable device. For example, current implantable devices lack sufficient integration with daily-life devices (such as, for example, smartphones) and activities to effectively predict, remind, and reinforce when the system should be used and when it should not be used. Increased integration with social platforms is also lacking, which could have the benefit of reinforcing usage through community support and on-demand access to support from peers or clinical resources. Seamless integration with devices and media platforms that are commonly used on a daily basis provides an opportunity to enhance data that can be used to personalize system functionality, adapt behavior through community support and provide effective feedback to users. The need for this integration is further underscored for non-medical, or augmentative, use of implantable systems, where users may benefit from integration with their smart phone, smart watch, computer, augmented reality goggles, or other systems that are commonly used in their daily lives.

The challenges with wireless power, wireless data, replenishing power, security, integration with readily available networked devices, personalization and feedback, and burdensome in-person clinical visits negatively affect the efficacy and usability of implantable systems. Increased user burden and cost result in overall reduced use, which, for medical implantable devices, impacts the user's health and well-being.

Published International Patent Application WO/2012/077088 discloses an implantable system and method including an implantable component having a rechargeable implantable power supply that is trans-cutaneously re-charged by an external charger. In addition, an auxiliary charger is described, that re-charges and communicates with the external charger. The system does not enable
5 bi-directional wireless data communication. The recharging protocol remains limited, wherein the docking station is not the preferred medium, and there is no electrical communication with external computing devices.

U.S. Pat No. 7,212,133 to Goetz, et al. discloses a method and apparatus for communicating via telemetry with an implanted medical device. The method and apparatus include a physician
10 programmer that when launched, configures a data layer of the telemetry module to enable communication of the implanted device. However, the three-layer protocol stack of Goetz et al. supports only a limited signal reception spectrum and is not patient friendly. Moreover, the system described by Goetz et al. necessitates external intervention to recharge a rechargeable power source in the implanted medical device.

U.S. Pat. No. 6,308,101 to Faltys et al. discloses a fully implantable cochlear implant system and method including an implantable cochlear stimulator unit permanently connected to a primary coil through which magnetic or inductive coupling may occur with a similar coil located externally during recharging, programming, or externally-controlled modes of operation. The system size and its “wired system” embodiment constitute a fundamental limitation, via the integrated speech
15 processor (ISP) unit, the two joint, detachable multi-conductor cables and supplemental microphone.

Published International Application WO/2012/154247 Discloses a bridge device that communicates between a consumer electronics device, such as a smart telephone, and an implantable medical device. The bridge contains a first transceiver that operates according to a
25 communication protocol operating in the consumer electronics device and a second transceiver that operates according to a communication technique operating in the implantable medical device. A software application is installed on the consumer electronics device, which provides a user interface for controlling and reading the implantable medical device. The software application is downloadable using standard cellular means. The bridge is preferably small, and easily and
30 discreetly carried by the implantable medical device patient. The bridge is preferably also simple to operate and may have only a simple user interface, or no user interface at all. The overall system’s modus operandi is fundamentally limited by the requirement to control the implantable medical device by means of a consumer electronics device-based User I/O.

There is, therefore, a need for a system that effectively addresses the challenges with power and data, that is easy to use, portable, secure, and compatible with common peripheral and computational systems that users carry on a daily basis.

There is also a need for a system that allows the patient to have control over some of the therapy parameters while enabling the clinician to determine the degree of patient control over such parameters to increase patient confidence and compliance in a safe and convenient way.

There is also a need for patients to have ready access to social and clinical support wherever they go, and a need for clinicians to have ready access to patient data (derived from physiological signals and ecological data from user devices and platforms) for monitoring the patient's health and behavior, monitoring patient's compliance and determining necessary therapy updates without the burden and cost of multiple in-person clinical visits.

SUMMARY OF THE INVENTION

There is therefore provided, in accordance with some embodiments, an energizing pod for wirelessly energizing an implant implanted in a patient. The implant is configured for delivering electrical therapy sessions to the brain of the patient. The energizing pod includes a housing, an attachment mechanism for positioning the energizing pod on the skin of the patient and for aligning the energizing pod over the implant's induction coil, a power transmitting module disposed within the housing and configured for wirelessly energizing the implant, one or more transceivers disposed within the housing and configured for wirelessly communicating with the implant and with an external communication device having data processing capability. The energizing pod includes a processor/controller disposed within the housing and operatively connected to the power transmitting module and to the transceiver module. The processor/controller is configured for controlling the operation of the power transmitting module, controlling the receiving and transmitting operation of the one or more transceivers. The processor/controller is configured for controlling the operation of the implant by processing an implant control data file (ICF) and/or a digital prescription data file (DPF) received from the external communication device. The DPF received from the external communication device includes at least a first set of DPF data representing clinician preselected therapy parameter values that cannot be modified by the patient and a second set of DPF data representing ranges of one or more patient modifiable therapy parameters. The external communication device is programmed to allow the patient to determine values of the one or more patient modifiable therapy parameters to be used in an electrical therapy session and to transmit to the energizing pod the ICF. The ICF includes at least a first set of ICF data representing the clinician preselected therapy parameter values and a second set of ICF data

representing one or more therapy parameter values determined by the patient using the external communication device. The energizing pod also includes a memory disposed within the housing and operatively coupled to the processor/controller unit and a power source disposed within the housing and electrically connected to the processor/controller, the power transmitting module and the one or more transceivers to provide power thereto.

In accordance with some embodiments of the energizing pod, the ICF also includes data selected from an ICF version number, a unique therapy session identifier, data representing a copy of the DPF data, a Hash or CRC for checking data integrity, and any combinations thereof.

In accordance with some embodiments of the energizing pod, the therapy parameters are selected from the number of sensing and/or stimulating channels of the implant to be used, the configuration of sensing and/or stimulating electrodes in a channel, the number of sensing and/or stimulating electrodes in a channel, voltage pulse width, voltage pulse amplitude, inter-pulse time interval, voltage pulse shape, voltage pulse polarity, number of pulses in a pulse train, frequency of pulses in a pulse train, pulse train duration, number of pulse bursts in a pulse burst train, number of pulse burst trains in a therapy session, inter-burst time interval, number of pulses in a pulse burst, frequency of pulses in a pulse burst, timing of each pulse in a pulse burst, duration of a pulse burst, burst train duration, time interval between consecutive pulse trains, the total number of pulses in a therapy session, and any non-redundant combinations thereof.

In accordance with some embodiments of the energizing pod, the implant includes one or more stimulating electrodes and the electrical therapy sessions delivered to the patient comprises electrical signals delivered to the brain of the patient.

In accordance with some embodiments of the energizing pod, the attachment mechanism is selected from a magnet attached to or included within the housing, a headband attached to the housing, a flexible strip of material attached to the housing, a cap attached to the housing and wearable on the head of the patient, a spectacle or spectacle-like framework wearable on the patient's head, optical glasses, sunglasses and an xR headset (such as, for example, a virtual reality headset, an augmented reality headset, or a mixed reality headset).

In accordance with some embodiments of the energizing pod, the DPF also includes data selected from, data representing a DPF version number, data representing a unique DPF identifier, data representing approved energizing pod(s) unique identifier(s), data representing approved implant(s) unique identifier(s), data representing DPF creation time and date, data representing DPF expiration time and date, data representing a total permissible number of therapy sessions allowed within a DPF validity time period, data representing a minimum and/or a maximum and/or

recommended time allowable between therapy sessions, a digital signature, a CRC, and any combinations thereof.

5 In accordance with some embodiments of the energizing pod, the external communication device is selected from, a smartphone, a laptop, a tablet, a phablet, a smartwatch and any combination thereof.

In accordance with some embodiments of the energizing pod, the DPF is received by the external communication device over the internet.

10 In accordance with some embodiments of the energizing pod, the external communication device is a smartphone, wherein the DPF is received by the smartphone over the internet, and wherein the selecting of values of the patient modifiable parameters is performed by the patient using a parameter setting screen displayed on a display of the smartphone and the parameter values selected by the patient are communicated by the smartphone in the ICF to a transceiver of the one or more transceivers of the energizing pod.

15 In accordance with some embodiments of the energizing pod, the energizing pod includes a user interface and the external communication device transmits the DPF to the energizing pod for storage in the memory of the energizing pod.

In accordance with some embodiments of the energizing pod, the selecting of the values of the patient modifiable therapy parameters by the patient is performed using the user interface of the energizing pod and the DPF stored in the memory of the energizing pod.

20 In accordance with some embodiments of the energizing pod, the user interface includes components selected from one or more mechanical buttons, one or more capacitive buttons, one or more microphones, one or more light sources, one or more speakers (or buzzers), one or more displays, one or more touch sensitive displays one or more inertial measuring units (IMU), one or more cameras, one or more photosensors and any combinations thereof.

25 In accordance with some embodiments of the energizing pod, the energizing pod includes a user interface, the ICF also includes at least the first set of DPF data and the second set of DPF data and the ICF is transmitted by the external communication device to the energizing pod for storage in the memory of the energizing pod.

30 In accordance with some embodiments of the energizing pod, the selecting of the values of the patient modifiable parameters by the patient is performed using the user interface of the energizing pod, the first set of DPF data and the second set of DPF data.

In accordance with some embodiments of the energizing pod, the energizing pod includes a user interface and the ICF also includes the entire data contents of the DPF.

In accordance with some embodiments of the energizing pod, the selecting of the values of the patient modifiable parameters by the patient is performed using the user interface of the energizing pod and the ICF.

5 The energizing pod according to claim 1, wherein the power source is selected from a rechargeable power source and a non-rechargeable power source.

10 In accordance with some embodiments of the energizing pod, the power source is a rechargeable power source and the charging of the power source is performed using a method selected from wired charging using charging contacts included in the energizing pod, wireless charging using a charging induction coil included in the energizing pod, and a combination of wired and wireless charging using charging contacts included in the energizing pod and a charging induction coil included in the energizing pod. The charging of the energizing pod may be either wired or wireless.

15 In accordance with some embodiments of the energizing pod, the one or more transceivers include a first transceiver for wirelessly transmitting data to the external communication device and for receiving data and control signals from the external communication device and a second transceiver for transmitting data and/or control signals to the implant and for receiving data from the implant.

In accordance with some embodiments of the energizing pod, the second transceiver is also configured for transmitting power to a power harvesting module included in the implant.

20 In accordance with some embodiments of the energizing pod, the energizing pod is programmed to receive from the implant, after each therapy session, data including one or more of, a therapy log data and data representing electrical signals recorded from the brain of the patient by one or more sensing electrodes included in the implant.

25 In accordance with some embodiments of the energizing pod, the first set of DPF data also includes data representing values of sensing parameters and the sensing parameters are selected from number of sensing electrodes to be used for sensing, configuration of sensing electrodes to be used for sensing, duration of a sensing time period(s) to be used, time of initiation of sensing period(s) with respect to timing of stimulation periods, time to start sensing, sampling frequency of sensing, sensing filter configuration, and any combinations thereof.

30 In accordance with some embodiments of the energizing pod, the energizing pod is programmed to enter a locked state in which a therapy session cannot be initiated if the voltage level of the power source is lower than a voltage threshold value or if the time interval T_s that

passed since the last date and time synchronization of an internal clock of the energizing pod was performed is greater than a preset value **X**.

5 In accordance with some embodiments of the energizing pod, the energizing pod is programmed to enable a therapy session to be delivered to the patient only by an implant that is pre-registered with the energizing pod.

In accordance with some embodiments of the energizing pod, each of the therapy parameter ranges of the first set of DPF data and the second set of DPF data includes a minimum parameter value, a maximum parameter value and a default parameter value.

10 In accordance with some embodiments of the energizing pod, for one or more parameters in the first set of DPF data, the minimum parameter value, and the maximum parameter value are equal to the default parameter value.

In accordance with some embodiments of the energizing pod, for each parameter in the second set of DPF data the minimum parameter value and the maximum parameter value are different than the default parameter value.

15 In accordance with some embodiments of the energizing pod, the energizing pod and the external communication device are programmed to simultaneously store a plurality of different DPFs.

20 In accordance with some embodiments of the energizing pod, the external communication device and the energizing pod are programmed to enable the patient to select a specific DPF from the plurality of DPFs for use in delivering a therapy session.

In accordance with some embodiments of the energizing pod, the second set of DPF data includes data representing a bundled parameter including two or more single stimulation parameters and the selection by the patient of a value for a bundled parameter results in setting of parameter values for the two or more single stimulation parameters in the ICF.

25 In accordance with some embodiments of the energizing pod, the DPF also includes data representing instructions to offer the patient supplemental therapy session(s) different than the electrical therapy sessions, before, during or after an electrical therapy session.

30 In accordance with some embodiments of the energizing pod, the supplemental therapy sessions are selected from playing a game using the external communication device, listening to music using the external communication device, delivering therapeutic visual stimulation using the external communication device, delivering therapeutic audio stimulation using the external communication device, prompting a sleep session, providing dietary instructions, prompting physical exercise, and any combinations thereof.

In accordance with some embodiments of the energizing pod, the site of implantation of the implant and the electrical therapy sessions are adapted to treat a disorder selected from depression, major depression, drug resistant depression, ADHD, ADD, anxiety disorder, OCD, schizophrenia, bipolar disorder, an eating disorder, obesity, bulimia, anorexia, and PTSD.

5 In accordance with some embodiments of the energizing pod, the first set of data also includes for each clinician preselected therapy parameter a minimum parameter value and a maximum parameter value.

There is also provided a method of communication of data between the energizing pod, the external communication device and the implant. The method includes the steps of: receiving by
10 the external communication device over the internet the DPF, allowing the patient to set stimulation parameter values for the second set of DPF data, generating the ICF from the stimulation parameter values set by the patient and from the clinician preselected values of therapy parameters included in the first set of DPF data, and transmitting the ICF from the external communication device to the energizing pod for storage and/or for transmission to the implant.

15 In accordance with some embodiments of the method, the step of generating comprises including some or all of the data of the DPF in the ICF.

In accordance with some embodiments of the method, the method also includes the step of transmitting a command to the energizing pod to wirelessly transmit the ICF from the energizing pod to the implant.

20 There is also provided a computing device implemented method for controlling the delivery of electrical therapy to the brain of a patient by an implant implanted in the patient. The method includes the steps of: receiving over the internet and processing a digital prescription data file (DPF) remotely generated by a clinician. The DPF includes at least a first set of DPF data representing clinician preselected therapy parameter values that cannot be modified by the patient
25 and a second set of DPF data representing value ranges of one or more patient modifiable therapy parameters. The method also includes the steps of providing output to the patient enabling the patient to select a value for each of the one or more patient modifiable therapy parameters, receiving from the patient input representing selected values for each of the one or more patient modifiable therapy parameters, generating an implant control file (ICF) including at least the
30 clinician preselected therapy parameter values and the values selected by the patient for the one or more patient modifiable therapy parameters, and transmitting the ICF to an energizing pod configured for energizing the implant and for transmitting the ICF to the implant for controlling the operation of the implant.

In accordance with some embodiments of computing device implemented method, the steps of providing output and the second step of receiving are performed by a user interface included in the computing device.

5 In accordance with some embodiments of computing device implemented method, the user interface is selected from a visual user interface, an audio user interface, a tactile interface, and any combination thereof.

10 In accordance with some embodiments of computing device implemented method, the user interface is selected from a touch sensitive input device, a microphone, a speaker, a physical keyboard, a virtual keyboard displayed on a touch sensitive display, one or more light sources, a camera, a photosensor and any combination thereof.

15 In accordance with some embodiments of computing device implemented method, the DPF also includes data selected from data representing a DPF version number, data representing a unique DPF identifier, data representing approved energizing pod(s) unique identifier(s), data representing approved implant(s) unique identifier(s), data representing DPF creation time and date, data representing DPF expiration time and date, data representing a total permissible number of therapy sessions allowed within a DPF validity time period, data representing a minimum and/or a maximum and/or recommended time allowable between therapy sessions, a digital signature, CRC and any combinations thereof.

20 In accordance with some embodiments of computing device implemented method, the ICF also includes data selected from an ICF version number, a unique therapy session identifier, data representing a copy of the DPF data, a Hash or CRC for checking data integrity, and any combinations thereof.

25 In accordance with some embodiments of computing device implemented method, each parameter of the second set of DPF data includes a minimum parameter value, a maximum parameter value and a default parameter value, and the second step of receiving includes the step of using the default parameter value as the value of the patient modifiable therapy parameter of the ICF if the patient does not provide input representing the parameter value within a preset time interval starting from presenting a parameter value selection screen.

30 In accordance with some embodiments of computing device implemented method, the computing device is selected from a smartphone, a laptop, a tablet, a phablet, and a smartwatch.

In accordance with some embodiments of computing device implemented method, the method also includes the steps of automatically acquiring collected data representing objectively quantified parameters of use of the computing device by the patient.

In accordance with some embodiments of computing device implemented method, the method also includes the step of wirelessly sending the collected data to another computer over the internet.

In accordance with some embodiments of computing device implemented method, the computing device is also a communication device and the collected data representing objectively quantified parameters of use of communication device by the patient includes data selected from one or more of, data representing use of one or more software applications of the portable communication device by the patient, data representing a number and/or frequency of calls made by the patient using the portable communication device, data representing a number or frequency of SMS text messages sent by the patient using the portable communication device, data representing the duration of phone calls made by the patient using the portable communication device, data representing the total number of times the screen of the portable communication device is turned on per day, data representing the total amount of patient's screen time per day, data representing acceleration of the portable communication device, data representing the frequency of use and/or the total time of use of one or more software applications installed on the portable communication device, data representing the frequency of use and/or the total time of use of the one or more software applications categorized by application category, data representing the number of photos taken by the patient per day using the portable communication device, patient's call log data, patient's social network data, and any combinations thereof. Data representing the portable device configuration such as screen brightness, audio settings, power saving settings (how long until the device goes to power saving mode), device working mode (for example: focus, do not disturb, sleep, etc.).

There is also provided in accordance with some embodiments a data processing device including means for carrying out the steps of the computing device implemented method.

There is also provided a program for a data processing device, the program includes instructions which, when the program is executed by the data processing device, cause the data processing device to carry out the steps of the of the computing device implemented method.

There is also provided a computer readable medium including instructions which, when executed by a computer, cause the computer to carry out the steps of the computing device implemented method.

There is also provided, a communication device usable by a patient, the patient has an implant configured for delivering electrical therapy sessions to a brain of the patient. The communication device includes a processor/controller, a memory operatively coupled to the processor/controller, a user interface operatively connected to the processor/controller for

providing output to the patient and for receiving input from the patient, and a power source for energizing the processor/controller, the memory and the user interface. The communication device is programmed by a software application stored in the memory for performing the following steps:

receiving over the internet and processing a digital prescription data file (DPF) remotely generated by a clinician, the DPF comprises at least a first set of DPF data representing clinician preselected therapy parameter values that cannot be modified by the patient and a second set of DPF data representing value ranges of one or more patient modifiable therapy parameters, providing output to the patient enabling the patient to select a value for each of the one or more patient modifiable therapy parameters, receiving from the patient input representing selected values for each of the one or more patient modifiable therapy parameters, generating an implant control file (ICF) including at least the clinician preselected therapy parameter values and the values selected by the patient for the one or more patient modifiable therapy parameters, storing the ICF in the memory, and transmitting the ICF to an energizing pod configured for energizing the implant and for transmitting the ICF to the implant for controlling the operation of the implant.

In accordance with some embodiments of the communication device, the user interface is selected from, a touch sensitive input device, a microphone, a speaker (or as buzzer), a physical keyboard, a virtual keyboard displayed on a touch sensitive display, one or more light sources, a camera and any combination thereof.

In accordance with some embodiments of the communication device, the DPF also includes data selected from, data representing a DPF version number, data representing a unique DPF identifier, data representing approved energizing pod(s) unique identifier(s), data representing approved implant(s) unique identifier(s), data representing DPF creation time and date, data representing DPF expiration time and date, data representing a total permissible number of therapy sessions allowed within a DPF validity time period, data representing a minimum and/or a maximum and/or a recommended time allowable between therapy sessions, a digital signature, CRC and any combinations thereof.

In accordance with some embodiments of the communication device, the ICF also includes data selected from, an ICF version number, a unique therapy session identifier, data representing a copy of the DPF data, a Hash or CRC for checking data integrity, and any combinations thereof.

In accordance with some embodiments of the communication device, each parameter of the second set of DPF data includes a minimum parameter value, a maximum parameter value and a default parameter value, and the second step of receiving includes the step of using the default parameter value as the value of the patient modifiable therapy parameter of the ICF if the patient

does not provide input representing the parameter value within a preset time interval starting from presenting a parameter value selection screen.

In accordance with some embodiments of the communication device, it is programmed to automatically acquire collected data representing objectively quantified parameters of use of the communication device by the patient and to wirelessly send the collected data to a computer over the internet and/or for storage in the cloud.

5 In accordance with some embodiments of the communication device, the communication device is programmed to receive from the energizing pod, after a therapy session, data including one or more of, a therapy log data and data representing electrical signals recorded from the brain of the patient by one or more sensing electrodes included in the implant.

In accordance with some embodiments of the communication device, the first set of DPF data also includes data representing values of sensing parameters.

10 In accordance with some embodiments of the communication device, the sensing parameters are selected from, the number of sensing electrodes to be used for sensing, the configuration of sensing electrodes to be used for sensing, the duration of a sensing time period(s) to be used, the time of initiation of sensing period(s) with respect to timing of stimulation periods and any combinations thereof.

In accordance with some embodiments of the communication device, the collected data representing objectively quantified parameters of use of the communication device by the patient, comprises data selected from one or more of, data representing use of one or more software applications of the portable communication device by the patient, data representing a number and/or frequency of calls made by the patient using the portable communication device, data representing a number or frequency of SMS text messages sent by the patient using the portable communication device, data representing the duration of phone calls made by the patient using the portable communication device, data representing the total number of times the screen of the portable communication device is turned on per day, data representing the total amount of patient's screen time per day, data representing acceleration of the portable communication device, data representing the frequency of use and/or the total time of use of one or more software applications installed on the portable communication device, data representing the frequency of use and/or the total time of use of the one or more software applications categorized by application category, data representing the number of photos taken by the patient per day using the portable communication device, patient's call log data, patient's social network data, and any combinations thereof. Data representing the portable device configuration such as screen brightness, audio settings, power

saving settings (how long until the device goes to power saving mode), device working mode (for example: focus, do not disturb, sleep, etc.).

In accordance with some embodiments of the communication device, the communication device is selected from, a smartphone, a laptop, a tablet, a phablet, and a smartwatch.

There is also provided a system for controlling the delivery of electrical therapy sessions to the brain of a patient. The system includes:

5 an implant implantable in the head of the patient, the implant includes at least one processor/controller, a memory operatively connected to the processor/controller, a plurality of electrical signal generators operatively connected to the processor/controller and two or more stimulating electrodes electrically connected to the electrical signal generators, the implant is configured for delivering electrical therapeutic signals to the brain of the patient, and

10 a local subsystem including at least a first portable communication device having processing power and at least one energizing pod for wirelessly energizing the implant and for wirelessly communicating with the implant. The at least first device is programmed for:

wirelessly communicating with the energizing pod, and is programmed for receiving over the internet and storing a digital prescription data file (DPF) remotely generated by a clinician, the
15 DPF includes at least a first set of DPF data representing one or more values of therapy parameters set by the clinician and at least a second set of DPF data representing a range of values and a default value for each therapy parameter of the patient modifiable therapy parameters,

presenting to the patient on the first communication device the second set of DPF data to allow the patient to select a single value from each range of patient modifiable parameter values,

20 receiving from the patient a third set of DPF data representing a patient selected parameter value for each one of the patient modifiable therapy parameter values,

generating an implant control data file (ICF) comprising at least the first set of DPF data and the third set of data; and

25 Wirelessly transmitting the ICF to the at least one energizing pod for wirelessly transmitting the ICF to the implant for controlling the operation of the implant.

In accordance with some embodiments of the system, the at least first portable communication device is selected from, one or more smartphones, one or more laptops, one or more tablets, one or more phablets, one or more smart watches, and any combinations thereof.

30 In accordance with some embodiments of the system, the first set of DPF data also includes data representing DPF expiration time and date.

In accordance with some embodiments of the system, the first set of DPF data also includes one or more data selected from, data representing a DPF version number, data representing a

unique DPF identifier, data representing approved energizing pod(s) unique identifier(s), data representing approved implant(s) unique identifier(s), data representing DPF creation time and date, data representing DPF expiration time and date, data representing a total permissible number of therapy sessions allowed within a DPF validity time period, data representing a minimum and/or
5 a maximum and/or a recommended time allowable between therapy sessions, a digital signature, CRC and any combinations thereof.

In accordance with some embodiments of the system, the therapy parameters are selected from: the number of stimulating channels of the implant to be used, the configuration of stimulating electrodes in each channel, the number of stimulating electrodes in each channel, the
10 voltage pulse width, the voltage pulse amplitude, an inter-pulse time interval, the voltage pulse shape, the voltage pulse polarity, the number of pulses in a pulse train, the frequency of pulses in a pulse train, the pulse train duration, the number of pulse bursts in a pulse burst train, the number of pulse burst trains in a therapy session, the inter-burst time interval, the number of pulses in a pulse burst, the frequency of pulses in a pulse burst, the timing of each pulse in a pulse burst, the
15 duration of a pulse burst, the burst train duration, the time interval between consecutive pulse trains, the total number of pulses in a therapy session, and any non-redundant combinations thereof.

In accordance with some embodiments of the system, the implant also includes one or more sensing electrodes operatively connected to one or more amplifiers for recording electrical signals
20 from the brain of the patient.

In accordance with some embodiments of the system, the therapy parameters are selected from, the number of sensing and/or stimulating channels of the implant to be used, the configuration of sensing and/or stimulating electrodes in a channel, the number of sensing and/or stimulating electrodes in a channel, the voltage pulse width, the voltage pulse amplitude, the inter-
25 pulse time interval, the voltage pulse shape, the voltage pulse polarity, the number of pulses in a pulse train, the frequency of pulses in a pulse train, the pulse train duration, the number of pulse bursts in a pulse burst train, the number of pulse burst trains in a therapy session, the inter-burst time interval, the number of pulses in a pulse burst, the frequency of pulses in a pulse burst, the timing of each pulse in a pulse burst, the duration of a pulse burst, the burst train duration, the time
30 interval between consecutive pulse trains, the total number of pulses in a therapy session, and any non-redundant combinations thereof.

In accordance with some embodiments of the system, the energizing pod and the at least one communication device are programmed to simultaneously store a plurality of different DPFs.

In accordance with some embodiments of the system, the ICF also includes data selected from, an ICF version number, a unique therapy session identifier, data representing a copy of the DPF data, a Hash or CRC data for checking data integrity, and any combinations thereof.

5 In accordance with some embodiments of the system, the energizing pod is programmed to enable a therapy session to be delivered to the patient only by an implant that is pre-registered with the energizing pod.

In accordance with some embodiments of the system, the energizing pod and the portable communication device are programmed to simultaneously store a plurality of different DPFs.

10 In accordance with some embodiments of the system, the external communication device and the energizing pod are programmed to enable the patient to select a specific DPF from the plurality of DPFs for use in delivering a therapy session.

In accordance with some embodiments of the system, the second set of DPF data includes data representing a bundled parameter including two or more single stimulation parameters, and the selection by the patient of a value for a bundled parameter results in setting of the parameter
15 values for the two or more single stimulation parameters in the ICF.

In accordance with some embodiments of the system, the DPF also includes data representing instructions to deliver to the patient supplemental therapy sessions different than the electrical therapy sessions, before, during or after an electrical therapy session.

20 In accordance with some embodiments of the system, the supplemental therapy sessions are selected from, playing a game using the portable communication device, listening to music using the portable communication device, delivering therapeutic visual stimulation using the portable communication device, delivering therapeutic audio stimulation using the portable communication device, prompting a sleep session, providing dietary instructions, prompting physical exercise and any combinations thereof.

In accordance with some embodiments of the system, the at least first communication device is also programmed for automatically acquiring collected data representing objectively quantified parameters of use of the at least first communication device by the patient.

In accordance with some embodiments of the system, the collected data representing objectively quantified parameters of use of the at least first portable communication device by the patient, comprises data selected from one or more of, data representing use of one or more software applications of the portable communication device by the patient, data representing a number and/or frequency of calls made by the patient using the portable communication device, data representing a number or frequency of SMS text messages sent by the patient using the portable communication device, data representing the duration of phone calls made by the patient using the

portable communication device, data representing the total number of times the screen of the portable communication device is turned on per day, data representing the total amount of patient's screen time per day, data representing acceleration of the portable communication device, data representing the frequency of use and/or the total time of use of one or more software applications installed on the portable communication device, data representing the frequency of use and/or the total time of use of the one or more software applications categorized by application category, data representing the number of photos taken by the patient per day using the portable communication device, patient's call log data, patient's social network data, and any combinations thereof. Data representing the portable device configuration such as screen brightness, audio settings, power saving settings (how long until the device goes to power saving mode), device working mode (for example: focus, do not disturb, sleep, etc.).

Finally, in accordance with some embodiments of the system, the site of implantation of the implant and the electrical therapy sessions are adapted to treat a disorder selected from depression, major depression, drug resistant depression, ADHD, ADD, anxiety disorder, OCD, schizophrenia, bipolar disorder, an eating disorder, obesity, bulimia, anorexia and PTSD.

5

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings, in which like components are designated by like reference numerals. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

FIG. 1 is a schematic block diagram, illustrating the components of a system including an implant for delivering therapeutic treatment to a patient, in accordance with an embodiment of therapeutic systems of the present application;

FIG. 2 is a schematic diagram illustrating a specific implementation of a therapeutic system including an implant for delivering electrical therapeutic signals to the brain of the patient, in accordance with an embodiment of the systems of the present application;

FIG. 3 is a schematic block diagram illustrating the components of an exemplary embodiment of an implant, usable in the systems of the present application;

FIG. 4 is a schematic block diagram illustrating the components of an exemplary embodiment of an interactive wireless energizing pod useable in the systems of the present application; and

FIGs. 5 and 6 are schematic cross-sectional views illustrating two different possible
5 implantation methods of the implants of the present application;

FIG. 7 is a schematic block diagram, illustrating the components of a system for delivering therapeutic treatment to multiple patients supervised by multiple clinicians, in accordance with an embodiment of therapeutic systems of the present application;

FIG. 8 is a schematic isometric view of a magnetic wireless energizing pod, in accordance
10 with an embodiment of the wireless energizing pods of the present application;

FIG. 9 is a schematic cross-sectional view of the energizing pod of FIG. 9, taken along the lines IX-IX;

FIG. 10 is an isometric view illustrating in more detail the energizing pod charger of FIG. 2;

FIGs. 11A-11B are schematic flow diagrams illustrating the steps of a method for
15 generating a digital prescription file on a clinician workstation, in accordance with an embodiment of the methods of the present application;

FIG. 12 is a schematic flow diagram illustrating the steps of an exemplary method for performing a secure login by a main server of the systems of the present application;

FIG. 13 is a schematic flow diagram illustrating a method for downloading a digital
20 prescription data file (DPF) from the main server(s) to an application operating on a device included in the local subsystem of the present application;

FIGs. 14A-14B are schematic flow diagrams illustrating the steps of an exemplary method for cleaning up DPFs by the main server(s), in accordance with an embodiment of the methods of
25 the present application;

FIG. 15 is a schematic flow diagram illustrating a method for time synchronization between the main server and an energizing pod, in accordance with an embodiment of the methods of the present application;

FIG. 16 is a schematic flow diagram illustrating the steps of a method for creating a new
30 DPF by the main server(s), in accordance with an embodiment of the methods of the present application;

FIG. 17 is a schematic flow diagram illustrating the steps of a method for performing a secure login by a patient application operating on one or more of the devices included in the local subsystems of the present application;

FIG. 18 is a schematic flow diagram illustrating a method for connecting and data exchange between a patient application operating on one or more of the devices included in the local subsystems and a pod, in accordance with an embodiment of the patient application of the present application;

5 FIG. 19 is a schematic flow diagram illustrating a method for downloading a new DPF from the main server(s), by a user application installed on one or more devices of the local subsystem, in accordance with an embodiment of the methods of the present application;

10 FIG. 20 is a schematic flow diagram illustrating a method for periodically cleaning up DPFs by a patient application, in accordance with an embodiment of the methods of the present application;

FIG. 21 is a schematic flow diagram illustrating a method (software subroutine) for using a patient application to enable the patient to set or modify the value of one or more patient modifiable therapy parameters included in a DPF, in accordance with an embodiment of the methods of the present application;

15 FIGs. 22A-22B are schematic flow diagrams illustrating a method (software subroutine) for using a patient application to enable the patient to set or modify the value of one or more patient modifiable therapy parameters including single modifiable parameters and/or multiple bundled parameters included in a DPF, in accordance with an embodiment of the methods of the present application;

20 FIGs. 23A-23B are schematic flow diagrams illustrating the steps of an exemplary method (subroutine) included in the patient application and usable for initiating a therapy session, in accordance with an embodiment of the methods of the present application;

FIG. 24 is a schematic flow diagram illustrating the steps of a method (subroutine) for updating therapy files (DPF) on energizing pod(s) by a patient application, in accordance with the methods of the present application;

25 FIG. 25 is a schematic flow diagram illustrating the steps of a program operating on an energizing pod for checking if a time synchronization action is needed, in accordance with an embodiment of the methods of the present application;

FIG. 26 is a schematic flow diagram illustrating the steps of an exemplary method or subroutine usable for connecting an energizing pod to a patient application operating on a communication device included in the local subsystem of FIGS. 1, 2 and 7, and for exchanging data with such a device;

FIG. 27 is a schematic flow diagram illustrating the steps of an exemplary embodiment method or subroutine operable on an energizing pod of the present application and usable for

initiating a therapy session by communicating with an implant and with a patient application installed on a device included in the local subsystem of FIGS. 1-2;

FIG. 28 is a schematic flow diagram illustrating the steps of an exemplary implementation of a method or subroutine operating on an energizing pod for directly initiating a therapy session by using a user interface of the energizing pod, in accordance with an embodiment of the methods of the present application;

FIG. 29 is a schematic flow diagram illustrating the steps of a method or subroutine operable on an implant of the present application and usable in initiating a therapy session; and

FIGs. 30A-30B are a schematic flow diagrams illustrating the steps of a method or subroutine using a trainable artificial intelligence (AI) algorithm to automatically generate a DPF for a patient, in accordance with the methods of the present application;

FIG. 31 is a part cross-sectional diagram illustrating another possible implantation method of the implants usable in the systems of the present application; and

FIG. 32 is a schematic flow diagram illustrating the steps of operation of a software application operable on a portable communication device included in the systems of FIGS. 1-2 and 7 for acquiring collected data representing objectively quantified parameters of use of the portable communication device.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

Abbreviations:

The following abbreviations are used throughout the specification and the claims of the present application:

Abbreviation	Means
DPF	Digital prescription data file
ICF	Implant control data file
LED	Light emitting diode
CRC	Cyclic redundancy check
CSF	Cerebrospinal fluid
IMU	Inertial measurement unit
HRV	Heart Rate Variability
PCB	Printed circuit board
USB	Universal serial bus
EMA	Ecological momentary mood assessment

Abbreviation	Means
AI	Artificial intelligence
ADHD	Attention deficit hyperactivity disorder
PTSD	Post-traumatic stress disorder
OCD	Obsessive-compulsive disorder
ADD	Attention deficit disorder
I/O	Input/Output
CRC	cyclic redundancy check
xR headset	Virtual reality/augmented reality/mixed reality headset
VoIP	Voice over Internet protocol
WiFi	Wireless Fidelity
VoWiFi	Voice over WiFi
SIM	Subscriber identity module
e-SIM	Electronic SIM

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will be the accepted definition. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

Implementation of the method and/or system of embodiments of the invention can involve performing or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware or by a combination thereof using an operating system.

For example, hardware for performing selected tasks according to embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing

instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disc and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the examples. The invention is capable of other embodiments or of being practiced or carried out in various ways. It is expected that during the life of a patent maturing from this application many relevant types of smart personal devices will be developed and the scope of the terms "smartphone" "smartwatch", "communication device" and "computational and communication device" is intended to include all such new mobile personal assisting, computational and communication devices and technologies *a priori*. As used herein the term "about" refers to $\pm 10\%$. The word "exemplary" is used herein to mean "serving as an example, instance or illustration." Any embodiment described as "exemplary" is not necessarily to be construed as preferred or advantageous over other embodiments and/or to exclude the incorporation of features from other embodiments.

The word "optionally" is used herein to mean "is provided in some embodiments and not provided in other embodiments." Any particular embodiment of the invention may include a plurality of "optional" features unless such features conflict.

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean "including but not limited to".

The term "consisting of" means "including and limited to".

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

When the term "patient" is used in the specification and in the claims of the present application in relation to an action performed by the patient during use of a software or program or subroutine, it may be construed as "either the patient or a user". Such a user may be, for example, a medical technician or clinician operating the energizing pod and/or the external communication device for any purpose.

The term "clinician" is used herein to mean any person authorized to medically treat and/or supervise a patient, such as, for example, a physician or a psychiatrist.

The term “local subsystem” is used herein to mean one or more mobile and/or portable and/or hand held and/or wearable devices that may be located in the vicinity of a patient having a medical implant. The one or more devices have computational processing power and communication capabilities, wherein at least one of the one or more devices is programmed to bidirectionally interact with the patient to provide information and instructions to the patient and to receive from the patient input that may be used to control at least some parameters of a therapeutic patient’s treatment performed by the implant.

As used herein, the singular form “a”, “an” and “the” include plural references unless the context clearly dictates otherwise. For example, the term “a compound” or “at least one compound” may include a plurality of compounds, including mixtures thereof.

Throughout this application and claims, the term “plurality” means “two or more”.

Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases “ranging/ranges between” a first indicate number and a second indicate number and “ranging/ranges from” a first indicate number “to” a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals there between.

The systems described hereinafter may include multiple devices that are commonly connected to external computational devices (such as, for example, a smartphone) which could include smartwatches, wearable sensors, and earphones. This networking allows flexibility in connecting to networks of devices that are used in daily life and offers advantages over state of the art in integrating multi-modal data to improve diagnostic and predictive accuracy, providing feedback to patients and clinicians in a readily accessible manner and on-the-go, and also in leveraging inherent connectivity, security, and flow of information between devices and users.

Reference is now made to FIGS. 1 and 2. FIG. 1 is a schematic block diagram, illustrating the components of a system including an implant for delivering therapeutic treatment to a patient,

in accordance with an embodiment of therapeutic systems of the present application. FIG. 2 is a schematic diagram illustrating a specific implementation of a therapeutic system, including an implant for delivering electrical therapeutic signals to the brain of the patient, in accordance with an embodiment of the systems of the present application.

5 The System 100 includes an implant 10 implantable in a patient 115. The implant 10 is designed to deliver therapeutic treatment to the patient 115. The system 100 may also include a local subsystem 14 in communication with the cloud 9 over the internet. The system 100 may also include a clinician workstation 13 that may be connected to the cloud 9 over the internet in a wireless or wired communication method. The system may also include a main server 12 that may
10 be connected to the cloud 9 over the internet in a wireless or wired communication method.

 The clinician workstation 13 may be any type of a computing device connectable to the internet, such as for example, a desktop computer, a laptop computer, a server, a tablet, a phablet, a smartphone, or any other type of computing device having wired and/or wireless communication capabilities.

15 The main server 12 may be any type of a computing device connectable to the internet, such as for example, a server, a desktop computer, a workstation or any other type of computing device having wired and/or wireless communication capabilities and capable of communicating over the internet. The main server 12 may be situated at the headquarters of a company providing clinicians with clinical services or may be situated in a server farm anywhere and operated by such a
20 company. The main server 12 may perform various identification, authentication, validation and clinical service functions. The main server 12 may be used for storing and maintaining a master database for recording various clinician and patient data, patient treatment history, and other types of data.

 It is noted that in systems in which all the computations are locally performed by system
25 components (such as, for example, the implant 10, the pod 19, the smartphone 11 and the personal laptop 15 or by any selected combination thereof), there may still be a need for the main server 12 and/or the clinician workstation 13. For example, the main server 12 and/or the clinician workstation 13 may wirelessly receive (over the internet) relevant data from the system 100 or 200 for storing in a database including the long-term history of the operation of the system 100 or 200
30 for each individual patient. Such a database may record, inter alia, data representing the stimulation parameters used in each stimulation session on the patient 115, data representing the 2D location in the Cartesian coordinate system (x,y) of the computed centroid of the biomarker(s) peak intensity, the computed size and/or shape of the biomarker(s) intensity map computed using the linear Gaussian approximation method (disclosed in detail in published international application

WO/2021/144730, EMA data or any other patient-related data obtained before the stimulation session, the HRV data obtained prior to a stimulation session, and any other clinically relevant data helpful to the psychiatrist or physician or caretaker monitoring the treatment of the patient 115.

5 This data stored in the historical database may enable the clinician (or caretaker) to follow up and supervise the effects of the therapeutic treatment of the patient 115 in order to assess therapeutic efficacy of the treatment over time. The clinician workstation 13 may also be used for presenting the data in graphical for use by the caretaker. Additionally, the clinician workstation 13 may be used by the clinician or psychiatrist to remotely and wirelessly reprogram and change
10 any selected parameters of the stimulation regime deliverable in stimulation sessions, to change or modify the efficacy of treatment, based on the historical database data, or, during an initial stimulation fine-tuning time period that may enable the determining of individually tailored stimulation paradigms to each individual patient. For example, the clinician or caretaker may change any of the stimulation session parameters such as, for example, the anodic pulse amplitude,
15 the cathodic pulse amplitude, the anodic pulse duration, the cathodic pulse duration, the inter-pulse interval within a pulse train, the frequency of pulses within a pulse train, the number of pulses in a pulse train, the frequency of trains (the intervals between trains), and the number of pulse trains delivered within a stimulation session.

Such individually tailored stimulation session parameters may be stored in the database and
20 may be communicated, wirelessly and uploaded to the energizing pod 19 or the smartphone 11 or the personal laptop 15 for wirelessly uploading to the implant 10 directly or through the pod 19.

The implant 10 may be any type of implant capable of delivering therapeutic treatment to the patient, including, for example, electrical signal therapy to the brain or to any part of the peripheral and/or central nervous system, drug delivery therapy and any combinations thereof. The
25 implant 10 may also perform sensing of electrical signals or of any other bio-signals or other patient related signals (such as, for example, heart rate, blood pressure, rate and frequency of patient's movements, or any other suitable patient related signal) from the patient, in order to monitor the patient's condition as well as to assess the efficacy of therapy.

The local subsystem 14 may include one or more mobile and/or portable and/or wearable
30 devices (not shown in detail in FIG. 1, for the sake of clarity of illustration). However, FIG. 2 below illustrates a specific description of such a local subsystem. Such devices may be carried by the patient 115 or may be worn by the patient 115 and/or may be carried by the patient 115 or at least may be locally available to be accessed the patient at least part of the patient's time. The local subsystem 14 may include one or more smartphones, one or more phablets with wireless

communication capabilities one or more wirelessly energizing pods (as described in detail hereinafter with respect to FIGS. 2 and 4), a portable laptop, a notepad, one or more pod charging stations (such as the energizing pod charger 17 of FIG. 2), one or more smartwatch(s) such as the smartwatch 117 of FIG. 2). Generally, the local subsystem 14 may include any type of a portable device(s) having wireless communication capabilities, processing capabilities and a bidirectional user interface for providing information to the patient 115 and for receiving input from the patient 115.

Turning to FIG. 2, the system 200 may include the implant 10 (of FIG. 1) implanted in the calvarial bone of the head 3 of a patient 115 suffering from a mood disorder (such as, for example, depression). However, the implant (or devices) of system 200 may also be any of implants disclosed in the present application or disclosed in International published applications WO/2019/130248, WO/2020/161555 and WO/2021/144730.

The system 200 may also include a detachably attachable wirelessly energizing pod 19 for wirelessly providing electrical energy to the implant 10. In some embodiments, the pod 19 may also be configured to bi-directionally wirelessly communicate with the implanted device 10 and may relay data, status signals and commands signals from and to the implant 10 and/or to one or more of the other components included in the system 200. The system 200 may also include a smartphone 11, a wearable smart watch 117, a personal laptop 11, a main server 12 and a clinician workstation 13.

The system 200 may also include an energizing pod charger 17 that may be used for charging a power source (not shown in FIG. 2 for the sake of clarity of illustration, but described in detail with respect to FIG. 5 hereinafter) included in the pod 19. The system 200 may (optionally) include one or more additional pods 29 which may be used instead of the pod 19 if it is not charged or if it malfunctions.

In some embodiments, re-charging of the pods 19, 29 and 39 may be implemented by electrical contact between electrically conductive pins (or pads) on the energizing pod with corresponding electrically conductive pins (or electrically conducting pads) on the pod charger 17 (as disclosed in detail in FIGS 8-10 hereinafter). In some embodiments, re-charging is implemented by establishing a wireless power link between the energizing pod and the pod charger, such that the energizing pod receives energy wirelessly transmitted from the pod charger when docked to it (in such an embodiment there are no electrically conductive pins/pads in the energizing pod or in the pod charger, as the power is wirelessly transmitted). The implementation of such wireless charging of an energizing pod may be similar to wireless charging commercially used in high end smartphones.

In some embodiments the energizing pod may also exchange data with the pod charger through electrical contact between the electrically conductive pins (or pads) on the energizing pod and the conductive pins (or pads) on the energizing pod charger when the pod(s) are docked in the pod charger.

5 In some embodiments the energizing pod may be directly connected to the pod charger by a suitable cable assembly (not shown) such that power and data are exchanged through the cable assembly. In such embodiments when the patient 115 uses the energizing pod to deliver therapy, the energizing pod is tethered (connected) to the pod charger during the therapy session. Such an embodiment is referred to as a “tethered pod” embodiment. In such tethered pod embodiments
10 that include the cable assembly, the energizing pod’s re-charge circuitry and energy storage unit are not necessary (and are not included in the energizing pod) and the energizing pod’s wireless power transmitter/data transceiver module 22 may be directly powered through the cable assembly.

In some embodiments, the energizing pod (such as, for example, the energizing pod 39 of
15 FIG. 8) may be directly attached to a handheld computing/communication device (such as, for example, the smart phone 11) by a suitable charging/data cable (not shown) that may be connected to the port 68 of the energizing pod 39 and that mates to a port on the handheld computing device (such as, for example, a USB port or a lightning port or a thunderbolt port), enabling power for recharging the energizing pod 39 to be drawn directly from power pins on the port and data to be
20 exchanged across data pins of the port on the port on the hand held computing/communication. In some embodiments, the pod charger may include docking members to detachably connect the pod charger to a handheld computing device. In some embodiments, docking the pod charger 17 with a handheld computing device may include electrically connecting the pod charger 17 to a port on the handheld computing device (such as, for example, the smart phone 11 or the laptop 15) via a
25 mating connector (not shown) to facilitate direct power transfer and data exchange.

The energizing pods 19, 29 and 39 provide a distinct advantage over state-of-the-art energizing solutions by supplying power to the implantable device in manner that preserves the patient’s confidence that they are always in control of the implantable system. This is particularly important for systems including implantable devices used in neuropsychiatric applications, which
30 are notably more personal to patients than other types of applications (such as, for example a cardiovascular disease) due to their inherent link to one’s perception of self. At any time, the patient may remove the energizing pod from his/her head and have confidence that the implantable device (the implant) is not functioning against their will.

In some embodiments, the pod charger 17 may be detachably attached to the smartphone 11, or to the laptop 15 or to any other notebook or phablet or tablet computer included in the local subsystem 14, such that the two devices act as a single monolithic device. This connection may be implemented by mechanical attaching members or magnets, or Velcro®, or by any other suitable other attachment means suitable to interlock the two devices together. In some embodiments, the mechanical and electrical connection between the pod charger and the computational device (such as the smartphone 11, the laptop 15, or a tablet or notebook or phablet included in the local subsystem 14) may be integrated together. The connection between the pod charger and the computational device may be disposed at the bottom, top, side, front, or back of the computational device. Mechanically connecting the two devices together provides the advantage of only needing to carry a single “monolithic” device, rather than multiple separate devices, which improves usability, especially on-the-go.

The smartphone 11 may be any type of suitable smartphone and may have an application installed therein operating thereon for obtaining ecological momentary mood assessment (EMA) data of the patient 115 and/or collected data representing objectively quantified parameters of use of the smartphone 11 by the patient 115 and for wirelessly communicating the EMA data and/or the collected data to one or more of the pod 19, the personal laptop 15, the main server 12 or the remote clinician workstation 13, or to any selected combination thereof, depending on the particular configuration and combination of the components included in different embodiments of the system 200. The smartphone 11 may also be used to enable the system 200 to bi-directionally communicate with the patient 115. For example, the system 200 may notify the patient 115 by displaying on the smartphone 11 that it is the prescribed stimulation time and that the patient 115 should attach the pod 19 (or the pod 29, if necessary) to the scalp region above the implant 10. Such notification may be performed by any suitable means, such as, for example by using either a telephone call, or a voice message or a text message or a suitable audio signal (such as, for example, a beep, or a musical tune, a predetermined ringtone or any other suitable auditory and/or visual signals or combinations thereof).

It is noted that the software application operating on the smartphone 11 (or on the laptop 15 or on any other tablet, phablet or notebook included in the local subsystem 14) may, in some embodiments, include functions for controlling, configuring, initiating, monitoring, and stopping sensing sessions (such as, for example, the sensing of cortical electrical signals sensed by the sensing electrodes 25A-25-D of the implant 28). These functions may include visualization of sensed data in either raw or processed form. For example, neural data may be displayed to the patient 115 on the display of the smartphone 11 during a sensing/recording session (either with or

without therapeutic stimulation) so that the patient 115 may know that the implant is functioning properly.

In some embodiments, the sensed data may be processed and displayed in a graph or through any other abstract visual form. In some embodiments the sensed data may be combined, processed, and displayed in combination with other data. Such other data may optionally include, inter alia, the time of the day, sleep data, heart rate data, work meetings, and any other type of useful data. In some embodiments of the application, a timer may be displayed on the screen of the smartphone 11 that represents how much time has expired or remains till the end of the sensing session and/or to the stimulation therapy session. The timer may be displayed as any combination of alphanumeric text, graph, or other image.

In some embodiments, the patient application may issue notifications to the patient 115 that an updated digital prescription is available. Such notifications may be delivered by any desired combination of text, icon, or graph. In some embodiments, a notification may include an auditory signal or a vibration.

In some embodiments, the application may include security measures, including authentication via a user name and password and/or fingerprint and/or facial recognition and/or retinal pattern, or any other acceptable means of authentication. For example, once a notification of a new digital prescription is received, the application may authenticate the user prior to securely downloading the new digital prescription. Similarly, authentication may be used during pairing of devices or in transferring the digital prescription to the energizing pod, as is disclosed in detail in FIGS. 11A-11B, 12-28 and 29 hereinafter.

In some embodiments, the patient application may include functions for controlling, configuring, initiating, monitoring, and stopping stimulation therapy sessions. Such functions may include visualization of stimulation or graphical displays that are synchronized to stimulation. For example, during a stimulation therapy session, the patient application may present to the patient 115 (on the display of the smartphone 11 or of the laptop 15 or a tablet, phablet or notebook substituting the laptop 15) calming visualizations, sounds, music, or guided meditations. In some embodiments, visualizations, sounds, music, and/or guided meditations may be customized for the specific patient. In some embodiments, the visualizations, sounds, music, and/or guided meditations may be synchronized with the sensing and stimulation therapy. Synchronization of the visualizations, sounds, music, and/or guided meditations with the delivered therapeutic electrical stimuli is expected to have an amplified effect by entraining stimulation to natural rhythms of the brain.

In addition, audiovisual stimuli may be presented to the user in the form of a computer game (on the display of the smartphone 11 or of the laptop 15 or a tablet, phablet or notebook substituting the laptop 15)) and/or in the form of a task-based assessment. Such a presentation may have the advantages of assessing physiological responses to the stimuli that may be indicative of the patient's disorder, reinforcing modulation of physiology that augments or amplifies the therapeutic effect, and of achieving more holistic therapeutic effects via multi-modal stimulation. For example, modulation of neural activity may be visualized by the movement of a cursor that the patient tries to control to acquire or track various targets. This type of neural training has the advantage of modifying neural rhythms involved in neuropsychiatric diseases and disorders. In some embodiments, the application may synchronize audiovisual displays, sensing, or stimulation activity between the implant 10 or 28 and other peripheral devices, including, but not limited to, earphones (not shown), the smart watch 117, body sensors (not shown), and/or augmented reality glasses (not shown).

In some embodiments, a timer may be displayed to the patient 115 by the patient application that represents how much time has expired or remains for a stimulation session. The timer may be displayed as any combination of alphanumeric text, graph, or image. In some embodiments, the user may have control over a subset or all therapy parameters, including stimulation amplitudes, pulse widths, frequencies, burst frequencies, pulses in a train, trains in a session, number of sessions a day, etc. In some embodiments, the DPF may restrict various stimulation parameters based upon authentication of who the user is. For example, using the same application, a clinician may be able to access all stimulation parameters, whereas, a patient may only be able to access a restricted subset of patient modifiable parameters or range of parameters for a therapy. Therapy parameters may be accessed by any combination of graphical interfaces, including text fields, sliders, drop-down menus, or other suitable input tools.

In some embodiments, the patient application may include a graphical display that represents temporal changes in their disorder or disease. In some embodiments, this graphical display may represent numerous statistics, including mean, variance, skewness, kurtosis, trends, history, and predictions of patient state. For example, for depression, the graphical display may represent mood, whereas for cognitive applications, the graph may represent attention level or working memory performance. In some embodiments, the graph may be adjusted and viewed on multiple interactive time scales to highlight short-term and long-term changes, which may be further highlighted using data filtering and smoothing on multiple time scales. In some embodiments, the graphs may be displayed along with goals that have been set by the patient 115 or by the clinician.

In some embodiments, the patient application includes alarms to notify the user of important time-sensitive information, including, but not limited to, device status, when a therapy should be initiated, when a clinical appointment is scheduled, and when a digital prescription is expired or renewed. In some embodiments, alarms are automatically generated by the application, though they may also be set directly by the user.

In some embodiments, the patient application may include functions implemented as subscription services. The subscription services may include, but are not limited to, clinician monitoring, suicide monitoring, automatic digital prescriptions, journaling, integration with the user's calendar, integration with the user's social media accounts and/or social support groups, and/or clinical support groups, telemedicine services, games, and/or a meditation program. Add-on services like the above disclosed subscriptions may provide patients with a more customized experience that may improve long-term use. Additionally, a subscription service platform may improve scalability, expansion of services, and access to the latest third-party applications and features that may improve user experience, diagnoses, therapies, therapy conformance, and predictive measures.

In some embodiments, algorithms related to these activities may be performed on the computational device, (such as, an example, algorithms generating reminders/alarms for starting a stimulation session), and/or performed by a remote cloud computing resource (such as, for example, the main server(s) 12, and/or a commercial cloud server providing computer game and/or music subscription services). In some embodiments, the patient 115 or other qualified supporting users (such as, for example, clinicians) may be automatically notified of predicted issues that may include non-compliance, worsening symptoms, and suicidality. For example, if the device is being used to treat depression, and if the patient is determined to be at high risk for suicide, a warning may be automatically generated and sent to a clinical support team.

The (optional) smartwatch 117 may be any type of smartwatch that has the capability to sense and record one or more physiological parameter of the patient 115, when the patient 115 wears the smartwatch 117. For example, the smartwatch 117 may be able to record the heart rate (HR) of the patient 115 or other physiological parameters of the patient 115 that may be indicative of or may be correlated to the mood of the patient 115. The smartwatch 117 may wirelessly communicate with the smartphone 11 that may receive the heart rate data from the smartwatch 117. The smartphone 11 may have a suitable application installed therein that may use the HR data to compute the heart rate variability (HRV) of the patient 115. The HRV parameter is known to be correlated with the severity of depressed mood of depressive patients. The data representing the physiological parameter(s) measured by the smartwatch 117 and sent to the smartphone 11,

may be communicated wirelessly to the clinician workstation 13 and/or to the main server 12 for storage and processing to determine the state of the patient 115, for monitoring and/or for informing the clinician of the efficacy of the treatment.

For example, a review article by Andrea Sgoifo, Luca Carnevali, Maria de los Angeles Pico Alfonso, and Mario Amore, entitled "Autonomic dysfunction and heart rate variability in depression" published in *Stroke* (2015, Vol 18(3): pp 343-352) describes a correlation between HRV and the mood of depressive patients. Another review paper by Paniccia et al. entitled "Clinical and non-clinical depression and anxiety in young people: A scoping review on heart rate variability", published in *Autonomic Neuroscience: Basic and Clinical* (2017, Vol 208: pp. 1-14) concluded that "Changes in HRV were found across the spectrum of clinical and non-clinical populations of young people with depression or anxiety."

It is noted that methods for collecting EMA data are not the subject matter of the present application, are known in the art and are therefore not described in detail herein. Briefly, EMA data may be collected using the smartphone 11 of the system 200 as described in detail in international published application WO/2019/244099 and the references cited therein which are incorporated herein by reference in their entirety for all purposes.

Methods, programs and devices for collecting depressive state correlated EMA data are disclosed in detail in the following references:

- 1) Published international application WO /2019/244099.
- 2) Robert LiKamWa, Yunxin Liu, Nicholas D. Lane and Lin Zhong entitled "MoodScope: Building a Mood Sensor from Smartphone Usage Patterns", published in MobiSys'13, June 25–28, 2013, Taipei, Taiwan.

Automatic and voluntary EMA assessment methods

To collect self-monitored mood data (the target of the prediction task), the systems disclosed herein may use eMate, an EMA mobile phone application developed at the Vrije Universiteit Amsterdam. This application prompts participants to rate their mood on their smartphone at five set time points per day (i.e., approximately at 09:00, 12:00, 15:00, 18:00, and 21:00). As shown in the article by Robert LiKamWa et al (2013), mood may be assessed through the circumplex model of affect described in an article by James A. Russel entitled "A Circumplex Model of Affect" published in the *Journal of Personality and Social Psychology*, Vol. 39, No. 6 pp 1161-1178 (1980). which conceptualizes mood as a two-dimensional construct comprising different levels of valence (positive/negative affect) and arousal. Levels on both dimensions may be tapped on a 5-

point scale scored from -2 to 2 (low to high). Because recent studies suggest that single-item mood measures can provide predictive information on the development of depressive symptoms (for details see Gerard D. van Rijsbergen et al 2012 article in the reference list hereinafter), one may also add a one-dimensional mood question, which asked participants to rate their current mood on a 10-point scale, with 1 as the negative and 10 as the positive pole.

Automatic Unobtrusive Ecological Momentary Assessment of Mood Predictors

For automatically performed unobtrusive mood assessment, the systems/methods of the present application may use **iYouVU**, a faceless mobile phone application based on the Funf open-sensing-framework (Aharony, N., Gardner, A., Sumter, C., & Pentland, A. (2011). Funf: Open sensing framework.), and prior research into communication habits based on mobile phone data collected without the user's full awareness. This application runs in the background, unnoticeable to the user, to automatically collect designated sensor data and application logs. The application logs call events (i.e., time/date of the call, duration, and contact of both incoming and outgoing calls), short message service (SMS) text message events (i.e., time/date and contact), screen on/off events (i.e., time/date), application use (i.e., what applications were launched, when, and for how long), and mobile phone camera use (i.e., the time/date a picture was taken). All collected sensitive personal data, such as contact details (names, phone numbers), may be anonymized during data collection by the application through the built-in cryptographic hash functions of the Funf framework. At set intervals during each day, and only when participants' mobile phones are connected to Wi-Fi, the app sends collected data over the Internet to a remote central data server, in chunks of approximately five to ten megabytes (MB) per data file. Additional data may also include global positioning system (GPS) location data and accelerometer data.

In accordance with some embodiment of the systems, the data collected by the smartphone 11 may be sent over WiFi to the internet (or by using cellular network data transmission protocols) to a remote central data server for cloud processing and/or data logging. Data resulting from such remote processing and logging may be accessed by the smartphone 11 or by the laptop 15 (or by any other communication device included in the local subsystem 14) and may be used for computing values such as a mood index **MX**, and/or a modulation index **MI**, or other values required for the operation of the methods disclosed in published international application WO /2019/244099. Alternatively, the processing and/or computations may be offloaded to the cloud remote server that may communicate any computed values (such as, for example **MX** and/or **MI** disclosed in detail hereinafter) over the internet (using WiFi or cellular data transmission protocols, or any other suitable communication protocols) to the smartphone 11 and/or to the laptop 15 for

use and/or for telemetrically sending such values to the implant (such as, for example, the implant 10 of FIGS. 1-2, the implants 10A-10K of FIG.7, the implant 28 of FIG. 3, the implant 52 of FIG. 5, the implant 62 of FIG. 6 and the implant 72 of FIG. 31.

Data Preprocessing and Feature Engineering

5 As disclosed in detail in the article by Joost Asselbergs et al (2016) cited in the reference list hereinbelow, raw EMA and unobtrusive EMA data may be preprocessed into a data file that summarized each day of each participant in a row of 53 variables.

Prediction Targets: Ecological Momentary Assessment Mood

10 As in the LiKamWa et al. study, EMA data (i.e., both the one-dimensional mood measure and the two measures of the circumplex model, valence and arousal) are aggregated to daily averages as targets for the mood prediction algorithms. Daily averages are standardized within each participant (i.e., using means and standard deviations calculated for each participant separately).

Mood Prediction Feature Set

15 Raw unobtrusive EMA data are aggregated into daily summaries and from these daily summaries the feature set may be derived as disclosed in detail in Table 1 of the Asselbergs et al. article cited in the reference list hereinafter.

For phone calls and SMS text messages, the number of interactions participants had with their five most frequent contacts are counted. Following LiKamWa et al., a histogram of this interaction frequency over a 3-day history window may be created and the normalized frequency count may
20 be used as samples in the feature table. Similarly, a normalized 3-day histogram of call durations with the top five contacts may be created. Most participants interact only incidentally with persons outside their top five through calls or SMS text messages. Altogether, raw call/SMS text message data are summarized into three predictive features (top five call frequency and duration and top five contact SMS text message frequency), comprising 15 variables.

25 Raw screen on/off events of the communication device (such as, for example the smartphone 11, the laptop 15, the smartphone 117, a tablet or a phablet) are transformed into two features: (1) the total number of times the screen is turned on per day and (2) the total amount of screen time per day (calculated as the differences between the times of the screen on/off events). Both features are transformed to standard normal variables within each participant.

30 Accelerometer data represents the acceleration of the smartphone 11 on the x, y, and z planes. Acceleration is sampled for 5 seconds each minute (at sample frequencies estimated to vary from

20-200 Hz, as determined by the hardware and software characteristics of participants' mobile phones). Raw data are summarized (on the phone through Funf's Activity Probe) into a high activity variable by calculating the percentage of time at which the summed variance of the device's acceleration (on the x, y, z planes) was above a set "high activity" threshold (i.e., in which the summed variance exceeded 10 m/s²). These percentages are aggregated to the day level to provide an approximate measure of daily activity.

As daily measures of mobile phone application use, two 3-day normalized histograms for the daily frequency and duration of the five most frequently used mobile phone apps are created. In addition, normalized histograms of frequency and duration of the use of application categories are created. In accordance with the LiKamWa et al. study, applications such as either built-in, communication, entertainment, finance, games, office, social, travel, utilities, other, or unknown (11 categories altogether) are categorized. Categories of logged applications are determined through a scripted query of the Google Play Store. Applications that are unknown to the Google Play Store were manually categorized on the basis of an Internet search. In sum, the final dataset consists of four features based on application usage logs: top five applications frequency, top five applications duration, application category frequency (11 categories), and application category duration (11 categories). These features result in 32 variables (5+5+11+11).

Mobile Phone camera logs are used to determine the number of photos taken per day. Next, this number of photos taken per day data is transformed to the 0-1 scale for each participant separately by dividing all values by the maximum number of photos taken.

Finally, similarly to LiKamWa et al, the predictive feature set with a simple representation of mood history, by adding lag 1 and lag 2 transformations of each mood variable (standardized within each participant), is extended.

In total, a 53-dimensional variable set is derived from thirteen distinctive predictive features. Because regression models are sensitive to large differences in the scales of independent variables, the scales of the variables are transformed to the standard normal distribution (i.e., 99.7% of values ranging between -3 and 3). Interrelated variables (e.g., top 5 call and top 5 application use) are normalized to the 0-1 range, following the methods of LiKamWa et al.

It is noted that the external communication device may also be implemented as a smartwatch. For example, if the smartwatch 117 includes a SIM or an eSIM and is capable of making telephone calls by itself, the application for automatically acquiring EMA data and/or collected data representing objectively quantified data of parameters of use of the communication device by the patient may be installed in the smartwatch 117 and may operate thereon to automatically collect such data in the background. In such an embodiment, the smartwatch 117 may also be used to

collect additional sensor's data using any sensors included in the smartwatch 117 as described in detail hereinabove or hereinafter.

As therapeutic brain stimulation is delivered, the results of this stimulation may also be periodically interrogated with ecological momentary mood assessments (EMA) or with automatically acquired collected data representing objectively quantified parameters of use of the communication device (such as, for example, the smartphone 11, the laptop 15, the smartwatch 117, or any other communication device included in the local subsystem 14 such as a tablet, a phablet,) to determine the impact of the stimulation on the reported mood and the resultant patient physiology. Based on mood, reporting and physiologic parameters, the stimulation parameters may also evolve and change. This could include changes in amplitude of stimulation, stimulating pulse width, and pulse frequency. The end result is a dynamic recording and stimulating system that continually self-assesses performance based on the patient's reporting. This will enable biomarkers to not only be patient specific, but also to adjust over time should the patient's baseline physiology be non-stationary or should their fundamental brain states and physiologies change over time.

In some embodiments of the systems of present application, a communication device is included in the local subsystem 14. The communication device may be, for example the smartphone 11, the smartwatch 117, the personal laptop 15, a tablet (not shown), a phablet (not shown) or any other portable communication device having computational and communication capabilities). The communication device may have an application software program or subroutine installed thereon and operation in the background for automatically acquiring collected data representing objectively quantified parameters of use of the communication device by the patient.

Reference is now briefly made to FIG. 32 which is a schematic flow diagram illustrating the steps of operation of a software application operable on a portable communication device included in the systems of FIGS. 1-2 and 7 for acquiring collected data representing objectively quantified parameters of use of the portable communication device.

In an exemplary embodiment, the software application may be operated in the background to acquire collected data representing objectively quantified parameters of use of the communication device by the patient (step 530). The collected data may be acquired for a preset time period that may be determined by the clinician. For example, in some embodiments the time period may be twenty-four hours. However, the time period of collecting the data may be any suitable time period, such as, for example, twelve hours, or six hours or any other desired time period, depending, inter alia, on the specific individual patient typical behavior during the day and

night hours, the clinicians' decision based on historical data indicating the most active time periods of use of the communication device during the day, and other considerations.

In some embodiments, the collected data representing objectively quantified parameters of use of the communication device by the patient, may include data selected from one or more of, data representing use of one or more software applications of the portable communication device by the patient, data representing a number and/or frequency of calls made by the patient using the portable communication device, data representing a number or frequency of SMS text messages sent by the patient using the portable communication device, data representing the duration of phone calls made by the patient using the portable communication device, data representing the total number of times the screen of the portable communication device is turned on per day, data representing the total amount of patient's screen time per day, data representing acceleration of the portable communication device, data representing the frequency of use and/or the total time of use of one or more software applications installed on the portable communication device, data representing the frequency of use and/or the total time of use of the one or more software applications categorized by application category, data representing the number of photos taken by the patient per day using the portable communication device, patient's call log data, patient's social network data, and any combinations thereof. Data representing the portable device configuration such as screen brightness, audio settings, power saving settings (how long until the device goes to power saving mode), device working mode (for example: focus, do not disturb, sleep, etc.).

In some embodiments, the data collected by the communication device may also include in addition to the objectively quantified parameters of use of the communication device by the patient, other types of data such as, for example, subjective data of mood self-assessment acquired by requesting the patient to subjectively assess his or her mood (the assessment may be performed using any of the methods described in detail in Published international application WO /2019/244099 and in LiKamWa et al.)

The program may periodically check if the preset data collection time period has passed (step 532). If the data collection period has not passed, the program continues to acquire the collected data by returning control to step 530. If the data collection time period has passed, the program stores the collected data (either in the memory of the communication device or in the cloud) and may send the collected data to other devices of the system (step 534), and transfers control to step 530 to acquire collected data for the next data collection time period.

It is noted that in some embodiments, after the collected data is stored in step 532, the data may either be immediately sent to the other devices of the system (such as, for example, the Clinician's workstation 12 and/or the main server(s) 13), provided that communication with the

other devices may be established by the communication device (in such embodiments, the communication device actively pushes the collected data to the other devices). In some embodiments the stored collected data may be sent or communicated to the other devices at preset time or times within the day (for example, any stored collected data may be communicated to the clinician's workstation 12 and the main server(s) 13 at 12 PM each day or at any other desired time or times every day).

In embodiments in which the collected data is stored in the cloud, the clinician's workstation 12 and/or the main server(s) 13 may actively and periodically download the collected data from the cloud independent from the activity of the communication device. In such embodiments the clinician's workstation 12 and/or the main server(s) 13 may be programmed to periodically check if a new batch of collected data is available on the cloud and to download the new batch of collected data from the cloud if it is available.

It is noted that the communication device may be the smartphone 11, the smartwatch 117, the laptop 15, a tablet, a phablet or any other portable communication device known in the art that has communication capabilities and the capability of executing software programs and/or software applications installed therein.

In some embodiments of the system 200 that include the smartwatch 117 capable of recording the heart rate of the patient 115, the HRV parameter may be used by the system 200 to control the stimulation of the cortical tissues by the implanted implant 10.

In some embodiments of the system 200, the smartwatch 117 may be capable of computing the HRV from the HR measurements and to wirelessly communicate the HRV data to one or more of the pod 19, the smartphone 11, the personal laptop 15, the main server 12 and the clinician workstation 13. The HRV data may then also be used to control the stimulation of the cortex by the stimulating electrodes of the implant 10 as disclosed in detail in the methods disclosed in detail in published international application WO/2019/244099.

It is noted that not all the components illustrated in FIG. 2 need to be included in the system 200. For example, the personal laptop 15 is optional and is not an obligatory component of the system 200, because some or all of the computations of the system may be performed by either the smartphone 11, the main server 12 (using cloud processing), or by the clinician workstation 13 or by both the main server 12 and the clinician workstation 13. As the smartphone 11 may also be needed for communicating messages and/or notifications from the system 200 to the patient 115, in embodiments in which EMA data acquisition and/or the acquisition of collected data representing objectively quantified parameters of use of the smartphone 11 (or of any other communication device as disclosed hereinabove) by the patient are not needed or not used, it is

possible to replace the smartphone 11 by any other suitable device that has wireless communicating capabilities, such as, for example a pager or any other suitable hand held or wearable computational/communication device known in the art (not shown in FIG. 2). Such communication devices may communicate with the patient 115 using beeps or any other auditory and/or visual signals or audio/visual signal combination.

The main server 12 of the system 200 may wirelessly receive data, from the implant 10 (for example, over the internet using Wi-Fi and/or any desired internet communication protocols such as, for example, TCP/IP or any other wireless communication means and protocols) and may process the received data. The data received from the implant 10 may be wirelessly relayed from the implant 10 to the pod 19 and from the pod 19 to the smartphone 11 or (optionally) to the personal laptop 15 and may be communicated over the internet to the main server(s) 12 and/or to the clinician workstation 13.

The smartwatch 117 is also an optional component and may not be included in some embodiments of the system 200 that do not make use of HRV data to control the cortical stimulation.

In some embodiments of the system 200, the pod 19 may have integrated Wi-Fi or Bluetooth communication circuitry (not shown in FIG. 2) and may directly wirelessly relay data from the implant 10 to the smartphone 11 or over the internet (World Wide Web) to the main server(s) 12 and/or to the clinician workstation 13 (depending on the configuration of the system 200).

In operation of the system 200, a clinician (not shown in Fig. 2) may use the clinician workstation 13 to prepare a digital prescription data file (DPF). The DPF is a digital data file that is created by the clinician workstation 13 or by the main server(s) 12, as will be disclosed in detail hereinafter (with reference to TABLE 1). The DPF includes a plurality of data fields. Some of the data fields represent values of the parameters of a patient therapeutic session that are preset by the clinician. These data fields include a single parameter value set by the clinician. Some other data fields, include data that defines a range of values for each patient modifiable parameter. The data fields of each patient modifiable parameters include a minimum parameter value, a maximum parameter value and a default parameter value.

The therapy parameters that may be specified by the DPF may include but are not limited to: the stimulation/sensing channels enabled (in some embodiments, each channel may corresponds to one electrode in some other embodiments a different number and configurations of sensing and stimulating electrodes per channel may be used), the number and/or configuration of the stimulating electrodes, voltage pulse width, voltage pulse amplitude, inter-pulse time interval, the voltage pulse shape, the voltage pulse polarity, number of pulses in a pulse train, the number of

bursts of pulses in a pulse-burst train, parameters of trains of bursts (such trains of bursts may include multiple bursts of pulses and the relevant parameters may include the number of bursts in a train, the inter-burst time interval and the number and/or the frequency of the pulses in a pulse burst and the burst train duration, the number of pulse burst trains in a therapy session, the timing of each pulse in a pulse burst, duration of a pulse burst, the time interval between consecutive pulse trains, the total number of pulses in a therapy session, the therapy session duration, and any non-redundant combination of the above parameters.

The DPF may also include additional data fields, such as, for example, a version number field identifying the DPF version number, a unique prescription identifier field for identifying the specific DPF, an approved pod unique ID list field for identification of all the pods (such as, for example, the pods 19 and 29 associated with the patient 115 of FIG. 2), an approved implant ID field that includes a list of unique implant IDs of all the implants implanted in the patient 115, a creation date field including the time and date of creation of the DPF on the clinician workstation 13 or on the main server(s) 12, an activation date field including the time and date at which the DPF becomes active, an expiration date field including the date and time at which the DPF become invalid and cannot be used by the local subsystem 14, a number of total allowable therapeutic sessions field including a number representing the total number of therapeutic sessions allowed within the DPF validity time period (the time period between the DPF activation date and the DPF expiration date), a minimum time between sessions field including a number representing the minimum time (in minutes or seconds or any other suitable time units) that has to pass from the end of a therapeutic session in order to allow the initiation of another therapeutic session, and a digital signature field that is generated from a private key provided by the main server(s) 12. Both the public and private keys are generated by the main server(s) 12. The private key is kept securely by the server, the public key is available for anyone to review. The public and private keys are used to authenticate the server so the patient (through the patient application) can be sure that he is communicating with the legitimate server(s) 12 and not with an attacker.

TABLE 1 below is an example of a typical DPF and the data fields included therein, in accordance with an exemplary embodiment of the DPF files useable in the systems of the present application.

TABLE 1

Description	Data format	Exemplary Data size	Comment	Data Source
DPF Version Number	Number	4 Bytes		Main Server(s) 12
Unique Prescription Identifier	Alpha-numeric sequence	64 Bytes		Main Server(s) 12
Approved Pod unique IDs	List	32 x number of devices + 1 Bytes	1 byte is a counter for the number of devices	Main Server(s) 12
Approved Implant device unique IDs	List	32 x number of devices + 1 Bytes	1 byte is counter for number of devices	Main Server(s) 12
Creation date	Date/time	Date/time	DPF creation time/date	Main Server(s) 12
Activation date	Date/time	Date/time	Time/date DPF becomes active	Clinician (using clinician workstation 13)
Expiration date	Date/time	Date/time	Time/date when DPF is no longer valid (*May be a negative number)	Clinician (using clinician workstation 13)
Permissible Number of total therapeutic sessions	Integer	4 Bytes	The total number of therapeutic sessions allowed within the DPF validity time period	Clinician (using clinician workstation 13)
Minimum time between sessions (Minutes or Hours)	Integer	4 Bytes		Clinician (using clinician workstation 13)

N*3 Therapeutic stimulation parameters	N*3 Numerical values	4*N*3 Bytes	Parameter Minimum value, parameter default value, and parameter Maximum value, * (N is a positive integer)	Clinician (using clinician workstation 13)
Digital Signature	Signature	512 Bytes	Generated from Company private key	Main Server(s) 12

• NOTE: In TABLE 1, for some stimulation parameters the order of minimum, default and maximum parameter value may be reversed when displayed on the smartphone or other device, indicating that minimum parameter value results in higher stimulation efficacy and a maximum parameter value results in lower stimulation efficacy.

It is noted that the values specified in the “Data Format” and “data size” columns of **TABLE 1** above are exemplary values only and may be different than the values indicated if necessary.

The DPF may be sent to one or more devices of the local subsystem 14, such as, for example the smartphone 11, or the laptop 15 from which the DPF may be communicated (wirelessly or in a wired manner) to the pod 19 or to the pod 29. The smartphone 11 or the laptop 15 may interact with the patient 115 by prompting the patient 115 to select values for all the user modifiable therapy parameters.

In an exemplary embodiment, this parameter value selection process may be performed by presenting a suitable graphic user interface (GUI) to the patient 115 that sequentially presents to the patient 115 for each patient modifiable parameter a “slider” on a scale linearly (or non-linearly) representing the range of parameter values beginning in the minimum parameter value and ending in the maximum parameter value. The patient 115 may select a value by moving the graphic slider on the display and touching a “set value” button displayed near the slider scale. If for any reason the patient 115 fails to select a parameter value the application uses a default value included in the DPF as the selected parameter value (for example, see steps 314-316 of FIG. 21 hereinafter).

In some embodiments, the DPF may include limitations on any combination of the following: the day and time that a therapeutic session can be initiated, the number of times a therapeutic session can be initiated before the prescription expires, the length of time that a DPF remains valid, the therapeutic stimulation parameters that the patient can adjust (referred to as "patient modifiable parameters" hereinafter), the range of stimulation parameter values within which the patient may adjust, the electrode configuration for sensing, the length of time for sensing, the parameters for

triggering stimulation responsive to sensed data. Sensed data may include biological or non-biological signals recorded by the implant, signals recorded by another implant, data from an external device (such as, for example, a heart rate monitor, a smartwatch or a smartphone), or any combination thereof. In some embodiments, the DPF may be derived solely from patient-specific data or patient population data, or any combination of the two.

In some embodiments, the DPF is periodically updated based upon any combination of biological or non-biological data collected by the system, including population data from other patients. In some embodiments, the DPF is generated by an automated algorithm (see, for example, the method illustrated in FIGS. 30A-30B), and/or by an analysis by a trained expert. In some embodiments, a notification of an updated digital prescription is provided to the patient via a patient application on a handheld computing device (such as, for example, the smart phone 11 the laptop 15 or any tablet, phablet or notebook substituting the laptop 15) or any another computational/communication device included in the local subsystem 14. In some embodiments, a notification of the current digital prescription status (such as, for example, an expiration date, the number of therapies remaining) may be provided to the patient by the patient application.

After the patient value selection process is completed, the smartphone 11 (or the laptop 15) uses the patient selected values (or the default parameter values) and some of the data included in the DPF to create and store an implant control data file (ICF). The ICF is a digital file that includes a plurality of data fields usable for controlling the operation of the implant 10 during a therapeutic session.

The ICF is a digital data file generated by a software application installed and operating on the smartphone 11 or on the laptop 15 or on the smartwatch 117 or on any other device included in the local subsystem 14 (such as, for example, a tablet, a phablet, a notebook or any other suitable device that is portable or wearable by the patient and that has computational and communication capabilities and a user interface that allows communication with the patient and that is capable of receiving input from the patient).

The ICF may be downloaded to the memory 6 of the energizing pod 19 (or to the memory of the energizing pod 29) and may be wirelessly transmitted to the implant 10 (or to the implant 28). The ICF may include all the data/information necessary for enabling the implant (10 or 29) to deliver a therapy session to the patient 115, as disclosed in detail hereinafter.

TABLE 2 below is an example of a typical ICF and the data fields included therein, in accordance with an exemplary embodiment of an ICF useable in the systems of the present application.

TABLE 2

Description	Data format	Data size	Comment
ICF Version Number	Number	4 Bytes	
Unique Therapy Identifier	Number	4 Bytes	
Digital Prescription File	Data structure (as in TABLE 1)	variable	
P Therapeutic parameter values selected by patient *	Numerical values (Integer or real)	Variable	** See note below TABLE 2
Hash or CRC	[Tal – CRC as defined in standards]		For checking Data integrity

* Or default parameter values if patient has not selected values.

** Possible parameters are listed in the detailed list of parameters disclosed hereinabove.

In tables 1 and 2 above, the version number is necessary because as the system is developed and refined, there may be changes implemented in the structure, order and contents of the data fields in the DPF and ICF. Therefore, the version number of the DPF and ICF files may be used by the patient application to recognize and properly read the data fields of the file. The use of the version numbers in the DPF and ICF allows adding and/or removing data fields, as the system is developed. In operation, if the patient application identifies that the file version is not supported by the patient application, it will prompt the user that there is a versioning problem and that he/she needs to download the latest patient application version (from the main server(s) 12). The unique therapy identifier is an integer number that uniquely identifies the therapy session to be delivered. The digital prescription file (DPF) is a data structure (including multiple data fields) that includes all the data of the DPF as described in TABLE 1 above. The ICF also includes **P** numerical values of therapeutic parameters selected by the patient 115. **P** could be any integer number of parameters that may be modified by the patient 115 as is determined by the clinician when the DPF is generated on the clinician workstation 13.

The ICF may also include a hash or CRC for data integrity checking as is known in the art.

TABLE 3 below represents an exemplary embodiment of a “therapy log” that may be logged by the implant 10 or 28. The therapy log may be saved at the end of a therapy session (For example, steps 470 and 472 of FIG. 28 hereinbelow describe such logging).

TABLE 3

Description	Data format	Data size	Comment
Version Number Of Therapy Log	Number	4 Bytes	
Unique Therapy session Identifier	Number	4 Bytes	
Digital Prescription ID	Alpha-numeric	64 Bytes	
Date/time of applied therapy	Date/time	8 Bytes (using Unix time stamp, i.e. seconds since 1970-01-01 00:00:00 UTC))	Data size depends on format
Therapy completion and/or duration of therapy	Number	4 Bytes (representing seconds)	Provides information if therapy session was completed and if interrupted what was the duration of therapy delivered to patient
ID of connected Pod	Unique ID using 32 hex digits	16 Bytes	
Hash or CRC	CRC as defined in standards	4 Bytes	For checking data integrity

Reference is now made to FIG. 3 which is a schematic block diagram illustrating the components of an exemplary prior art implant, usable in the systems of the present application. It is noted that the structure and operation of the exemplary implant 28 of FIG. 3 are not the subject matter of the present application and are disclosed in detail in published international application WO/2021/144730. However, some details are briefly described herein, for providing a better understanding of the operation of the systems of the present application. Briefly, the implant 28 may deliver electrical therapy signals to the cortex 50 of the patient 115. The implant 28 is capable of sensing cortical activity related electrical signals for assessing and monitoring the state of the patient 115 and is also capable of delivering therapeutic electrical signals to the cortex 50 of the patient 115. The implant 28 may include at least one processor/controller(s) 140, a power harvesting module 145, a first electrode selecting module 120, a signal conditioning module 122, a digitizing/ multiplexing module 139, a multichannel voltage pulse generator module 170 and a second electrode selecting module 124.

The power harvesting module 145 may include an inductance coil 55 for receiving electromagnetic energy transmitted from an external energizing coil (not shown) that may be included in an external energizing device (such as for example, the energizing pods 19 and 29 of FIG. 2). It is noted that the construction and operation of such external energizing coils is well known in the art, is not the subject matter of the present application and is therefore not described in detail herein. For example, US patent No. 6,246,911 to Seligman discloses the construction and use of inductance coils for energizing cochlear implants.

In some embodiments of the implant 10 and 28, there may not be an internal energy storage device, such that the implant is directly powered by the energizing pod. In some other embodiments, the implant 10 or 28 may include a small energy storage device suitable for temporarily maintaining power during brief periods where the wireless power transfer from the energizing pod is lost. (The energy storage device is not shown in FIG. 3 for the sake of clarity of illustration). Such an energy storage device may be, for example, a rechargeable battery, a capacitor or multiple capacitors, a supercapacitor or multiple supercapacitors. In some other embodiments, the implant may include a larger energy storage device (not shown) that may support primary use of the implant's functions but is periodically re-charged. Such energy storage devices include batteries, capacitors, and supercapacitors.

The sensing/recording electrodes 25A, 25B, 25C and 25D and the reference electrode 30E of the implant 28 may be electrically and switchably connectable to the first electrode selecting module 120 of the implant 28. The first electrode selecting module 120 may be implemented as a solid-state multi-channel switching device. The first switching module 122 is suitably coupled to the signal conditioning module 122. The first switching module 120 is suitably connected to the processor/controller (s) 140 that controls the switching operation of the first switching module 122 which may controllably connect or disconnect any selected electrodes from the signal conditioning module 122. The signal conditioning module 122 may include electronic circuitry suitable for performing various signal conditioning types on the electrical cortical signals fed from the sensing/recording electrodes 25A, 25B, 25C and 25D. The signal conditioning operations may include signal filtering, frequency band limiting, low pass filtering, or any other type of desired signal conditioning operations. The conditioned signals may be then fed into suitable channel amplifiers 80 for amplifying the conditioned signals performing differential recording against the reference signal fed from the reference electrode 30E. The conditioned amplified signals output from the amplifiers 80 may be (optionally) digitized by the (optional) digitizing/multiplexing module 139 to form digitized signals. The digitizing/multiplexing module 139 may be suitably coupled to the processor/controller(s) 140 for controlling the digitizing and/or multiplexing

operations thereof. The digitized signals may be further filtered, averaged, decimated to a lower sampling rate, and/or compressed to reduce data throughput. The digitized signals may be fed into the telemetry module 138 for wirelessly transmitting to an external receiver (or transceiver) outside the body of the patient. In some exemplary embodiments, the external receiver or transceiver may be the wireless power transmitter/data transceiver module 22 or the transceiver 20 or the transceiver 18 of the energizing pod 19 (of FIG. 4 below). The digitized signals transmitted from the implant 28 may be further processed and/or stored by the energizing pod 19 (or pod 29). Alternatively, in some embodiments, the conditioned/amplified analog signals output from the amplifiers 80 are not digitized and are fed to the Telemetry module 138 to be transmitted to the external receiver or transceiver (not shown).

The processor/controller(s) 140 may be operatively connected to the telemetry module 138 for controlling the operation thereof. The processor/controller(s) 240 may include integral memory unit(s) 142 or may additionally or alternatively be connected to one or more suitable data storage device (not shown). In some embodiments of the implant 28, in which the processor/controller(s) has sufficient processing power, the digitized recorded signals may be sent directly to the processor/controller(s) 140 for further processing to detect cortical activity indicative of the need for cortical stimulation or cortical inhibition or stimulation of some cortical regions and inhibition of other cortical regions. For example, such data processing methods and algorithms are disclosed in detail in published international application WO 2018/109715 and may be implemented herein for data analysis and processing by suitable programming of the processor/controller(s) 140.

Alternatively, in some embodiments in which the processor/controller(s) 140 does not possess sufficient processing power, the digitized signals or the analog signals are telemetrically transmitted to an external receiver (or transceiver) and are communicated (preferably wirelessly) to one or more processors disposed outside the body of the patient or person (such as, for example, directly to the pod 19 or the pod 29) and from the pod 19 to the smartphone 11, or the laptop 15, or to any other hand held or wearable or mobile computational/communicating device which may have sufficient processing power to perform the required signal analysis and data processing. Such more powerful processing devices may detect that the cortex requires stimulation/inhibition and may wirelessly transmit control signals to the telemetry module 138. Such control signals may be communicated to the processor/controller(s) 140 and may result in the processor/controller(s) 140 initiating cortical target stimulation and/or inhibition, as is disclosed in detail hereinafter.

A multi-channel voltage (or current) pulse generator module 170 of the implant 28 is suitably connected to the processor/controller(s) 140 for controlling the operation thereof. The

multi-channel voltage (or current) pulse generator module 170 may include individually and selectively operable controllable variable voltage (or current) pulse generators 90 that are operatively connected to a second electrode selecting module 124. Each of the stimulating electrodes 30A, 30B, 30C and 30D is switchably electrically connectable to one of the four voltage (or current) pulse generators 90. It is noted that the number of four pulse generators is not obligatory and may depend, inter alia, on the number of the stimulating electrodes included in the implant.

An auxiliary electrode 30F and any other auxiliary electrodes included in the device may be electrically connected to the multi-channel voltage (or current) pulse generator module 170. The auxiliary electrode 30F may be held at a voltage of zero volts (0V) and may be operating as a current sink or a current source or a current sink/source, depending on the polarity of the voltage applied to each of the stimulating electrodes 30A, 30B, 30C and 30D. It is noted that the voltage (or current) pulses generated by each one of the four voltage pulse generators 90 may be positive voltage (or current) pulses (referenced to the voltage of the auxiliary electrode 30F), or negative voltage (or current) pulses (referenced to the voltage of the auxiliary electrode 30F) and the pulse voltage (or current) may be controllably held at any (positive or negative or zero) voltage level within a given voltage range (for example, +10V to -10V).

For example, if the auxiliary electrode 30F is grounded at 0V (zero volts), a square voltage pulse of +5V may be applied to the stimulating electrode 30A, while a square voltage pulse of +2.5V may be applied to the stimulating electrode 30B, a square voltage pulse of -2.5V may be applied to the stimulating electrode 30B and a voltage of 0V may be applied to the stimulating electrode 30D. In another example, if the auxiliary electrode 30F is grounded at 0V (zero volts), a square voltage pulse of -5V may be applied to the stimulating electrode 30A, while a square voltage pulse of +8V may be applied to the stimulating electrode 30B, a square voltage pulse of +4.5V may be applied to the stimulating electrode 30B and a square voltage pulse of -4.5V may be applied to the stimulating electrode 30D.

It is noted that, typically, in order to prevent excess charge in the tissue and to ensure patient safety a negative pulse may be added after a positive pulse, the positive pulse (and vice versa for negative pulses), such that the duration of the positive pulse multiplied by the positive voltage amplitude equals the duration of the negative pulse multiplied by the negative voltage amplitude. For example, a stimulating square pulse of one second duration and +2V amplitude may be followed with a negative pulse having an amplitude of -2V and a pulse duration of one second or negative square pulse having an amplitude of -1V and a pulse duration of two seconds or a negative square pulse having an amplitude of -0.5V and a pulse duration of 4 seconds, such that

the amount of charge in a positive pulse may be balanced by the amount of charge in as negative pulse and vice versa.

The voltage differences between the auxiliary electrode 30F and each stimulating electrode (that has a voltage that is different than the voltage value applied to the auxiliary electrode 30F) may cause a current to flow between each selected pair of electrodes provided that there is a non-zero voltage difference between the two electrodes of the pair. Such currents will flow between electrodes and penetrate the brain tissues underlying the implant 28.

In principle, any combination of voltage (or current) pulses with various different polarities and various different amplitudes may be applied to the stimulating electrodes 30A, 30B, 30C and 30D. Each different applied voltage combinations may result in a current flow having a specific three-dimensional (3D) shape and current density map. By changing the selected combination of electrodes used for cortical stimulation/inhibition and/or the specific voltages applied thereto, it is also possible to perform current steering to modify the cortical regions that are being stimulated and/or inhibited as disclosed in detail in published international application WO/2021/144730.

It is noted that while the multi-channel voltage pulse generator module 170 may be used to deliver voltage pulses to the stimulating electrodes 30A-30D, in some embodiments of the implant 28, the multi-channel voltage pulse generator module 170 may be replaced by a multi-channel voltage pulse generator (not shown in FIG. 3). Such an embodiment having a multi-channel voltage pulse generator may actually operate more satisfactorily in situations where the stimulating electrode impedance may change over time after implantation of the implant 28 due to changes in electrode surface properties and also due to changes in the impedance of the tissues underlying the stimulating electrodes. The use of constant current pulses by such a multi-channel voltage pulse generator may therefore be more effective, in long term implantation, for achieving long term stability of the desired current density distribution in the tissues underlying the stimulating electrodes 30A, 30B, 30C and 30D.

The stimulating electrodes 30A-30D may be grouped into channels, where a channel may include one or more electrodes, and all permutations and combinations of the stimulating electrodes 30A, 30B, 30C and 30D may be possible. For example, a stimulating channel may include one stimulating electrode or two stimulating electrodes or three stimulating electrodes or four stimulating electrodes. More than one stimulating channel may be used in a therapy session. For example, a first stimulation channel may include the single electrode 30A while a second stimulation channel may include the two stimulation electrodes 30C and 30B (in this non-limiting example the electrode 30B may not be used for stimulation).

In another example two stimulation channels may be used each including two stimulating electrodes (such as, for example, electrodes 30A and 30B are included in a first stimulation channel and electrodes 30C and 30D are included in a second stimulation channel).

It is noted that because the stimulating electrodes 30A-30D may be arranged in different positions on the surface of the implant, different combinations of stimulating electrodes in a channel may result in different current density distributions, depending inter alia, on the arrangement or configuration of the electrodes on the surface of the implant.

For example, if the stimulating electrodes 30A, 30B, 30C and 30D are arranged on the implant as illustrated in FIGS. 4-5 of international publication No. WO 2021/144730, a stimulation channel including the two electrodes 30B and 30C may produce a different current density distribution in the underlying brain tissue than a stimulation channel including the two stimulating electrodes 30A and 30C.

It is further noted that as an implant may have a different number (smaller or larger) of stimulating electrodes than the four stimulating electrodes 30A-30D, the number of possible stimulating electrodes in a stimulating channel may vary accordingly.

Moreover, different numbers and combinations of stimulation channels may be used for stimulating depending, inter alia, on the total number of stimulating electrodes available in the implant and the total number of separate current or voltage pulse generators available in the implant.

Furthermore, the configuration of the stimulating electrodes in a stimulating channel and the exact voltage amplitude pulse shape, pulse polarity applied to each stimulating electrode within each of the stimulation channel may be used for current steering for more precise stimulation of a desired cortical stimulation target, as disclosed in detail in international publication No. WO 2021/144730.

In a similar manner, a sensing channel may include any desired combination or configuration of the sensing electrodes 25A-25D as described above for the stimulating channel(s). If the embodiment of the implant includes more than four sensing electrodes, a sensing channel may include any combination and/or configuration of the sensing electrodes available in the implant.

It is noted that while the stimulation waveforms described herein refer to pulsatile shapes, non-pulsatile therapeutic electrical signal shapes may be used to activate or inhibit neural activity. For example, sinusoids, exponentials, and gaussian wavelets could be assembled to create electrical signal patterns that provide advantages in activating or inhibiting specific cell types,

minimizing power consumption, and minimizing undesirable current distributions on the electrode surface that may lead to electrode degradation.

The implant 28 may include a magnet 5 that may be used for magnetically attaching and/or aligning a wireless energizing pod (such as, for example the energizing pod 19 or 29, or 39 (of FIG. 2 hereinabove, and FIG. 8 hereinafter, respectively)).

In some embodiments of the implants of the present application, the bi-directional data link between the implant and the energizing pod is asymmetric, providing higher data rates in one direction of communication than the other direction. For example, streaming neural signals out of the implant will often require a higher data rate than periodically transferring stimulation parameters to the implant. In other embodiments, the bi-directional link is symmetric, providing equal data rates in both directions of communication. For example, a Bluetooth radio may be used to establish a symmetric bi-directional link between the implant and the energizing pod. In some embodiments the transfer of data is implemented through any combination of inductive, resonant inductive, radio-frequency, volume conductive, optical, or ultrasonic couplings between the implant and external pod. In some embodiments the wireless power and wireless data links are combined such that a modulated signal transmitted from the energizing pod also powers the implanted device. In some embodiments, data is transmitted from the implant to the energizing pod via backscatter modulation, which reduces power consumed within the implant.

Reference is now made to FIG. 4 which is a schematic block diagram illustrating the components of an exemplary embodiment of an interactive wireless energizing pod useable in the systems of the present application. The wireless energizing Pod 19 may include a processor/controller 8, and a memory unit 6 suitably coupled to the processor/controller 8 or integrated within the processor/controller 8. The energizing Pod 19 may also include a wireless power transmitter/data transceiver module 22, a user interface 32, a permanent magnet 24 (optional), a transceiver 20, a transceiver 18 (optional) and a power source 4. The power source 4 may be any suitable type of electrical power source, such as any known type of rechargeable battery (such as, for example, a lithium-ion rechargeable battery a lithium polymer rechargeable battery), a super-capacitor, or any other type of suitable rechargeable electrical power source.

In some embodiments, the optional transceiver 18 may be or may include a power receiver configured to wirelessly receive power from the pod charger 17, for charging the power source 4, such as, for example, by using an inductance coil (not shown for the sake of clarity of illustration) wirelessly couplable to a corresponding inductance coil (not shown in detail) disposed within the pod charger 17. In some embodiments the transceiver 18 is not included in the energizing pod and the power source 4 may be charged by suitable electrical contacts (such as, for example the two

electrically conducting contacts 37A and 37B of the energizing pod 39 of FIG. 9 hereinafter that are configured to be in electrical contact with the two spring-loaded pins 58A and 58B of FIG. 10 hereinafter.

5 The (optional) permanent magnet 24 may be any type of permanent magnet (such as, for example, a neodymium-Iron–boron based permanent magnet), but other permanent magnet types may also be used. The permanent magnet 24 may be attached to or enclosed within the energizing pod 19 or 29 and may be used to enable the attachment (and possibly the alignment) of the pod 19 to the scalp of the patient 115 using the magnetic attracting force of another permanent magnet (not shown) disposed within or on the implant 10 (the use of such magnets is disclosed in detail in
10 published international patent applications WO/2019/130248, WO/2019/244099, WO/2020/161555 and WO/2021/144730). The use of magnetic attraction to hold the energizing pod is not the subject of the present application and is therefore not disclosed in detail hereinafter.

Moreover, the use of such permanent magnets is not obligatory and other methods for attaching the pod 19 to the scalp region overlying the implant 10 may be used such as, for example
15 a headband, or a strap (not shown) to attach the energizing pod 19 to the scalp, a wearable hat or head cover (not shown) to which the energizing pod 19 may be detachably attached, or any other type of suitable attaching method.

The power source 4 is suitably controllably couplable to the wireless power transmitter/data transceiver module 22 for providing power thereto. The providing of power to
20 the wireless power/transmitter/data transceiver module 22 may be controlled by a suitable solid state switching device 26. The solid-state switching device 26 may be connected between the power source 4 and the wireless power transmitter/data transceiver module 22 and may be electrically connected to the processor/controller 8 for providing control signals from the processor/controller 8 to the solid-state switching device 26.

25 The power source 4 may be suitably electrically connected to the processor/controller 8, the transceiver 18, the transceiver 20, the memory 6, and the user interface 32 for providing electrical power thereto. However, the connections of the power source 4 to the above components are not shown in FIG. 4 for the sake of clarity of illustration.

The wireless power transmitter/data transceiver module 22 includes an inductance coil 23
30 that may be operated for transmitting power to the induction coil 55 of the implant 10 or of the power harvesting module 145 of the implant 28.

The transceiver 20 may be used for bidirectional communication with the smartphone 11. If the smartphone 11 is used for receiving input from patient 115 regarding the selected values of the user modifiable therapy parameters, the smartphone 11 may wirelessly transmit the ICF to the

pod 19 (or 29) using the transceiver 20. The transmitting may be performed using any transmission protocol such as, for example, Bluetooth, Wi-Fi, a cellular packet protocol or any other suitable transmission protocol. The ICF may then be stored in the memory 6 by the processor/controller 8 for later transmission to the implant 10 (or the implant 28).

5 After the DPF has been transmitted from the smartphone 11 to the pod 19 (and/or to the pod 29), the DPF may be stored in the memory 6 of the pod 19 (and/or the pod 29) for at least the duration of DPF validity. This may ensure that the pods 19 and 29 may be usable in receiving input from the patient 115 and generating an ICF independently from the smartphone 11. For example, in some cases, when the patient 115 does not have access to the smartphone 11 (such as
10 for example low or no battery power in the smartphone 11, or when the patient 115 forgot to bring or even lost the smartphone 11), the patient may still use the pod 19 (or the pod 29) for directly inputting the values of the patient modifiable therapy parameters into the pod 19. The input from the patient 115 may be fed to the pod 19 through the user interface 32.

The user interface 32 may include button(s) 34 that may be pressed or touched by the
15 patient 115, the user interface 32 may also include one or more light source(s) 36 which may be used to provide various visual signals serving as cues to the patient 115. Typically (but not obligatorily) the light source(s) 36 may be implemented as one or more light emitting diodes (LED). However other types of light sources may be used, such as, for example, electroluminescent light sources, or any other type of light sources having a low operating voltage
20 and a low current consumption.

In an example, in an embodiment in which there is a single button in the pod 19, in order to select a value for a therapy parameter (such as, for example, the stimulating pulse amplitude), the patient 115 may press the button (not shown) for a long press (four seconds or more) to start a parameter value input session which may result in one of the light source(s) 36 to exhibit a blinking
25 orange light to indicate the starting of the input session, the patient 115 may then press the button three short presses to input an stimulus amplitude level of three out of five selectable amplitude values (or the patient 115 may use five short button presses to input the maximum allowable stimulus amplitude, etc.). After selection of a level the patient 115 may press the button for a long press again to input the selected value, this may result in a green LED light of the Light source(s)
30 36 blinking three times to indicate that the input has been received. Through such (exemplary) use of the button(s) 34 and light source(s) 36, the patient 115 may be able to enter (input) his parameter value selections of one or more patient modifiable parameter values into the pod 19. The button (or buttons) 34 may also be used for activating the pod 19 for starting a therapeutic session. For example, the pod 19 may be activated by the patient 115 by pressing the button 34

with three consecutive long presses which may cause a red LED of the Light source(s) 36 to blink intermittently indicating that the patient 115 needs to put the pod 19 on the location of the head 3 above the implant 10 (or the implant 28) to start a therapeutic session.

It is noted that while using the button(s) 34 and light source(s) 36 is a simple and convenient way to operate the pods 19 and 28 of the present application, this is not obligatory and other ways of pod operation may be used alternatively and/or additionally. The user interface 32 may include an (optional) speaker (or buzzer) 38, an (optional) microphone 40, an (optional) inertial measurement unit (IMU) 42 and an (optional) display screen 44.

The user interface 32 and/or the implant 10 may also include an optional vibrator (not shown in FIG. 4). Feedback to the patient 115 may also be provided by the speaker 38 or the vibrator (if a vibrator is included in the user interface 32) of the energizing pod 19. Vibrations emitted from such a vibrator (or by the speaker 38) may be heard or felt by the user because such vibrations or sounds may be transferred to the patient's inner ear by sound/vibration bone conduction. In many applications, discreet use of the system will be important to the patient, which will make feedback via a speaker undesirable. Therefore, in some embodiments, discreet auditory signals may be provided to the user via bone conduction, where small vibrations emitted by a vibrator included in the implant 10 or in the energizing pod(s) 19, 29 and 39 are conducted via the calvarial bone to the user's ear. This type of feedback is preferred for discreet use and is well-suited for implants that are embedded in or near bone.

In some embodiments, the user interface 32 may (optionally) include a camera 33. The camera 33 may be used (in combination with a suitable software operating on the processor/controller 8) for gesture recognition, facial expression recognition and pupillometry tracking. The camera 33 may also be useful for obtaining luminometry data. Such luminometry data (representing the ambient light intensity) combined with data representing the time (in hours) may be useful for determining whether the patient is staying outside and exposed to the sun or staying indoors. In some embodiment the user interface 32 may include a photosensor (not shown) instead of the camera 33, for obtaining the luminosity data. Optionally, the user interface 32 may also include a touch sensitive display (not shown in FIG. 4 for the sake of clarity of illustration).

In some embodiments, the pod 19 may enable the patient 115 to use the display 44 to present text or graphic symbols to convey messages to the patient 115 and to interact with the patient 115 and to receive input from the patient 115. In some embodiments, the display may be used to present messages and/or instructions to the patient 115 while the patient input is received by pressing the button(s) 34 as disclosed in detail hereinabove. In some embodiments, the display

screen may be a touch screen that may be used to present messages and/or instructions to the patient 115 as well as to receive input from the patient through the same touch screen.

In some embodiments, the speaker 38 and the microphone 40 may be used for interacting with the patient 115 by providing audible messages and instruction to the patient 115. In some other embodiments, the microphone 40 may be used to receive input from the patient 115 by recording verbal commands and data spoken by the patient 115. For example, the speaker 38 may emit voice requests asking the patient to verbally say a value selected from one to five as the value of the stimulating voltage pulse. The patient 115 may then say a word, such as, for example, “four” which may be picked up by the microphone 40. A speech recognition software program operating on the processor controller 8 may then analyze the sound and store the value “4” as the chosen value of the parameter “stimulating pulse amplitude” in the DPF stored in the pod 19.

It is noted that embodiments of the pod 19 including the microphone 40 and the speaker 38 may have suitable software for generating sound operating on the processor/controller 8 for performing sound generation to operate the speaker 38. Such embodiments may also include sound generating circuitry (not shown in FIG. 4 for the sake of clarity of illustration) and may include suitable software for human speech recognition operating on the processor/controller 8 for analyzing voice input picked up by the microphone 40. However, as the operation of such software may require higher processing power than that available to the processor/controller 8, in some embodiments, the sounds recorded by the microphone 40 may be wirelessly transmitted (after digitizing, or in analog form) to the smartphone 11 or to the laptop 15 or to any other device included in the local subsystem 14 that has adequate processing power to perform the speech analysis. In such embodiments, the speech analysis software may be operating on a processor of the smartphone 11 or the laptop 15 or any other device included in the local subsystem 14 instead of operating on the processor/controller 8 of the pod 19. Furthermore, the device performing the speech analysis may also send some data over the internet for performing the speech analysis using cloud processing. In such embodiments, the decoded speech content may be transmitted wirelessly back to the pod 19 and used by the pod 19 to update the DPF and/or to be used as command signals for operating the pod 19. For example, the analyzed words “start therapy” may be used to send to the pod 19 a signal causing the pod 19 to initiate a therapy session.

In some embodiments, the microphone 40 and the processor 8, may also be used for voice analysis, which may be used to assess the patient’s state. The patient’s state may be useful as part of a broader class of ecological data used for decoding the patient’s state. For example, changes in the patient’s voice may be used to predict stress or mood for neuropsychiatric applications. Additionally, or alternatively, the patient’s state related data as detected by such voice analysis

may be also transmitted (with an appropriate measurement time data) wirelessly or in a wired manner to the smartphone 11 and may be included in the EMA data and/or the collected data representing objectively quantified parameters of use of the smartphone 11 by the patient for patient mood assessment (the use of such EMA data and objectively quantified parameters of use of the smartphone 11 (or other communication device) for mood assessment is disclosed in more detail in Published international application WO/2019/244099).

In some embodiments, the (optional) IMU 42 may be used to sense the acceleration of the pod 19 in order to detect when the patient 115 taps the pod 19. The IMU 42 that may include any combination of an accelerometer, a gyroscope, and a magnetometer capable of sensing/detecting acceleration. Such taps may be used by the patient 115 for interacting with the pod 19 as well as for providing input from the patient 115 to the pod 19. For example, if the speaker 38 is used to deliver an audio request asking the patient 115 to “select a value of one to five for pulse amplitude by tapping”, the patient 115 may respond by tapping three short taps on the pod 19. The taps may be sensed by the IMU 42 and the signals from the IMU 42 are sent to the processor/controller 8 for processing. The processor controller analyzes the sensed signals and determines the number of taps (for example by detecting the number of voltage threshold crossings in the IMU signals, as is known in the art), the processor/controller 8 may then save the value “3” in the appropriate field in the DPF representing the value of the stimulating pulse amplitude.

It is noted that the embodiments of the pod 19 (and/or the pod 28) disclosed hereinabove and their methods for interacting with the patient 115 are not limited to the examples disclosed hereinabove. Any of the methods (and the corresponding components of the user interface 32) usable for interacting with the patient 115 may be used by the pod 19 including any non-mutually exclusive combinations thereof. For example, the messages and/or prompts to the patient 115 may be sent as audible human speech by the speaker 38 while the input from the patient 115 may be collected by pressing on one or more of the button(s) 34. In another embodiment, the messages and prompts to the patient 115 may be exhibited on the display 44, while the input from the patient 115 may be collected by detecting tapping of the patient 115 using the IMU 42. In another embodiment, the display 44 may be a touch-sensitive display, the messages and prompts to the patient 115 may be exhibited on the touch sensitive display 44, while the input from the patient 115 may be collected by detecting the patient 115 touching the touch-sensitive display 44. Any other combinations of such methods of patient interaction may be used, in the energizing pods of the present application.

Furthermore, in accordance with some embodiments of the pod 19, there may be some redundancy in the components of the user interface 32 used for delivery of messages/prompts to

the patient 115 and/or for receiving input from the patient 115. For example, in an embodiment, both the speaker 38 and the display 44 may be used for delivering messages/prompts to the patient 115 by using audible sound messages and/or prompts and also exhibiting the same messages and/or prompts on the display 44. In such an embodiment, the receiving of the input from the patient 115 may be done by either using the speaker 38 to receive audible verbal responses from the patient 115 or by using taps by the patient 116, or by using pressing of one or more of the button(s) 34, as disclosed in detail hereinabove.

This input/output method redundancy may have the advantage that each individual patient may use the input method preferred by him/her or more convenient for him/her. Another advantage is the increase resilience of the pod 19 to a malfunction of one or more of the components of the user interface 32. For example, if the microphone 40 malfunctions, the patient 115 may still use the taps method and/or the button pressing method to provide input to the pod 19. Similarly, if the speaker 38 malfunctions, the patient 115 may still receive messages and/or prompts by looking at the display 44. Another advantage of this redundancy is that a patient having a disability may still be able to use the pod 19. For example, a blind patient may be able to receive messages and/or prompts from the speaker 38 and to enter input using the microphone 40 and speech recognition. Similarly, a deaf patient may be able to receive messages and/or prompts by using the display 44 and/or the Light source(s) 36 and to enter input through the taps and/or button pressing methods. A mute patient may receive messages and/or prompts by using the display 44 and/or the Light source(s) 36 and may enter input to the pod 19 by using the taps and/or button pressing methods.

It is noted that the implants of the present applications are not limited to the implants 10 and 28 disclosed hereinabove. Rather any of the implant types disclosed in published international applications WO/2019/130248, WO/2019/244099, WO/2020/161555 and WO/2021/144730, may be used in the systems of the present application.

In some embodiments of the energizing pod, the wireless link to other devices included in the local subsystem 14 (such as, for example, to the smartphone 11 or to the laptop 15), may be implemented with the same data transceiver used to establish a wireless link to the implantable device. This implementation has the advantage of only requiring a single telemetry unit, which reduces system complexity, size, power, and wireless interference between multiple radios. For example, a single Bluetooth radio in the energizing pod may be used to connect to both the implantable device and a smart phone. In some embodiments, the wireless link to other devices included in the local subsystem 14 may be implemented with one or more different data transceivers than the data transceiver(s) that communicates with the implantable device. For

example, a Bluetooth radio may be used to connect the energizing pod 19 to the implant 10 and a WIFI radio may be used to connect the energizing pod 19 to devices such as the smartphone 11 or the laptop 15.

In some embodiments the wireless link to any combination of devices included in the local subsystem 14 may be implemented with a single transceiver such that data is exchanged in a time-division multiplexed protocol. In other embodiments the wireless link to any combination of devices included in the local subsystem 14 may be implemented with a combination of multiple transceivers such that data is exchanged between multiple devices in parallel. For example, a Zigbee radio may communicate between the energizing pod 19 and other energizing pods while at the same time a Wi-Fi radio may communicate between the energizing pod and a cloud computing service (or with the main server(s) 12 and the clinician workstation 13). This implementation has the advantages of optimally sizing data rates (and resulting power consumption) to the specific type of communication needed between different classes of devices and also allowing communication between all devices to proceed simultaneously and without interruption.

According to some embodiments, the memory units 142 and the processor/controller 140 are capable of performing “smart caching” of data during streaming. For example, if the data connection to the energizing pod is temporarily lost, the implant 10 or 28 may temporarily store data in the memory unit(s) 142 until the wireless link is re-established. This has the advantage of not losing data even during temporary loss of data links. In some embodiments, smart caching may also be implemented in the energizing pods, in the pod charger 17, in the smartphone 11, in the laptop 15 or in any other computational/data streaming device included in the local subsystem 14.

Reference is now made to FIGS. 5-6 which are schematic cross-sectional views illustrating two possible different implantation methods of the implants of the present application.

The implants of the present application (such as, for example, the implant 10 or the implant 28) may be implanted in the calvarial bone 44 of the skull of the patient 115. Two of the main methods of implantation of the implant are shown in FIGS. 5-6.

Turning to FIG. 5, the implant 52 may be implanted within a recess 31 made in the calvarial bone 44. The recess 31 may penetrate the outer table (not shown for the sake of clarity of illustration) and the cancellous bone layer (not shown for the sake of clarity of illustration) of the calvarial bone 44 and may or may not partially penetrate the inner table (not shown for the sake of clarity of illustration) of the calvarial bone 44. Thus, the recess 31 does not fully breach the calvarial bone 44. The bottom side 52A of the implant 52 is in the vicinity of the bottom side 31A of the recess 31 such that at least some part of the calvarial bone 44 intervenes between the bottom

side 52A and the surface 50A of the cortex 50. The dura 46 and a layer of the cerebrospinal fluid (CSF) 48 also intervene between the bottom side 52A of the implant 52 and the surface 50A of the cortex 50. The implant 52 may be firmly attached to the calvarial bone 44 by two bone screws 54 and 56, as is illustrated in FIG. 5. The implantation method illustrated in FIG. 5 has the advantage of reducing the probability of injury and/or infection of the cortex 50.

Turning to FIG. 6, the implant 62 may be implanted within a hole 61 passing through the calvarial bone 44. The hole 61 penetrates the outer table, the cancellous bone layer and the inner table of the calvarial bone 44. Thus, the hole 61 fully breaches the calvarial bone 44. The bottom side 62A of the implant 62 may be in contact with the dura 46 and may be closer to the surface 50A than the bottom side 52A of the implant 52 (assuming that the thicknesses of the calvarial bone 44, the dura 46 and the layer of CSF 48 are identical in FIGS. 5 and 6). This implantation method may increase the signal to noise ratio (S/N) of the cortical signals recorded by the recording electrodes (such as, for example, the electrodes 25A-25D of FIG. 3) and may also reduce the amount of current that needs to be applied by the stimulating electrodes (such as, for example, the electrodes 30A-30D of FIG. 3) in order to cross the excitation threshold of at least some cortical neurons underlying the stimulating electrodes 30A-30D. It is noted that, typically, the recording electrodes 25A-25D and the stimulating electrodes 30A-30D may be disposed on the bottom surface 52A of the implant 52 and on the bottom surface 62A of the implant 62. The implant 62 may be firmly attached to the calvarial bone 44 by two bone screws 54 and 56, as is illustrated in FIG. 6.

It is noted that the details of the above implantation methods are disclosed in more detail, for several different embodiments of intra-calvarial implants, in published international applications WO/2019/130248, WO/2019/244099, WO/2020/161555 and WO/2021/144730.

It is also noted that, while the methods of implantation illustrated in FIGS. 5-6 above are quite efficient, they are not obligatory and other implantation methods may also be used. For example, the implant may be implanted by making an incision in the scalp of the patient and inserting the implant between the scalp and the outer surface of the calvarial bone, and closing the incision. Such an implantation method may have the advantage of greater simplicity and reduced invasiveness as it does not involve any bone drilling or removing a portion of the calvarial bone. However, it should be born in mind that the use of such a subcutaneous implantation method may necessitate the use of higher voltages applied to the stimulating electrodes of the implant in order to pass sufficient current densities to stimulate the underlying brain tissue because of the greater thickness of intervening bone between the stimulating electrodes and the cortical target region.

Reference is now briefly made to FIG. 31 which is a part cross-sectional diagram illustrating another possible implantation method of the implants usable in the systems of the present application. The Implant 72 may include an implant housing 73 having two attachment flanges 73A and 73B. The attachment flange 73A has a through hole 73C formed therein and the attachment flange 73B has a through hole 73D formed therein. Bone screws 54 and 56 may be used to firmly attach the implant 72 to the calvarial bone 44. The implant 72 may also include an electronics module 76, an induction coil 74 a permanent magnet 75 and stimulating electrodes 77A and 77B. It is noted that only two stimulating electrodes 77A and 77B may be seen in the cross-sectional view of Fig. 31. However, the implant 72 may include any suitable number of stimulating electrodes.

The electronics module 76 may include the power harvesting module 145, the telemetry module 138, the processor/controller 140, the memory unit(s) 142, the digitizing/multiplexing module 139, the multi-channer voltage pulse generating module 170 and any other of the components shown in detail in FIG. 3. It is noted that no details of such components are shown in detail in FIG. 31 for the sake of clarity of illustration.

The stimulating electrodes 77A and 77B may be used for delivering electrical signals to the cortex 50 underlying the calvarial bone 44 within electrical therapy sessions as disclosed hereinabove. The stimulating electrodes 77A and 77B may be electrically connected to the electronics module 76 by electrically conducting wires 78 and 79, respectively, to deliver electrical signals from a suitable signal generator (not shown in detail in FIG. 31) included in the electronics module 76 (However, see FIG. 3). Furthermore, the implant 72 may also (optionally) include sensing electrodes (not seen in the cross-sectional view of FIG. 31) for sensing electrical signals generated within the regions of the cortex 50 underlying the implant 72.

The implant 72 may be implanted between the outer surface 44A of the calvarial bone 44 and the scalp 53 of the patient as illustrated in FIG. 31. After implantation, the energizing pod 39 may be placed on the scalp 53 of the patient. A detailed explanation of the components and operation of the energizing pod 39 are provided hereinabove with respect to FIGS 8-9.

The magnet 4 of the energizing pod 39 is attracted by the magnet 75 of the implant 72 firmly attaching the energizing pod 39 to the scalp 53 region above the implant 72. This attachment also ensures proper alignment of the inductance coil 23 with respect to the inductance coil 74 of the implant 72 allowing proper wireless coupling and efficient electrical power harvesting by the power harvesting module 145 that may be electrically coupled to the inductance coil 74 of the implant 72.

Reference is now made to FIG. 7, which is a schematic block diagram, illustrating the components of a system for delivering therapeutic treatment to multiple patients supervised by multiple clinicians, in accordance with an embodiment of therapeutic systems of the present application.

The system 300 may include **M** main servers 12A-12M and **N** clinician workstations 13A-13N that are in wireless or wired bidirectional communication with the cloud 9 over the world wide web. The system 300 may also include **K** local subsystems 14A-14K that may be bidirectionally in wired or wireless communication with the cloud 9 over the world wide web. Each one of the local subsystems 14A-14K may be in the vicinity of a single patient of a plurality of patients 115A-115K, respectively. Each one of the multiple local subsystems 14A-14K may be in wireless communication with a corresponding implant of the **K** implants 10A-10K implanted in the patients 115A-115K, respectively. For example, the local subsystem 14A is in communication with the implant 10A that is implanted in the calvarial bone of the patient 115A, the local subsystem 14B is in communication with the implant 10B that is implanted in the calvarial bone of the patient 115B, and so forth. The main servers 12A-12M may be located in a server farm or in the headquarters of the company that provides the implants 10A-10K and various services and/or software³ to subscribing clinicians having clinician workstations.

N, **M** and **K** may be any positive integer numbers. Typically (but not obligatorily), $K > N$ and $N > M$. Each subsystem of the local subsystems 14A-14K, may be operated to deliver therapeutic sessions to the patients 115A-115K, respectively, as disclosed hereinabove with respect to FIG. 1. Each clinician workstation of the clinician workstations 13A-13N, may be operated by a different clinician, as disclosed with respect to FIG. 1 above. It is noted that in some embodiments of the system 300, the main servers 12A-12M may be implemented as a single main server 12 (as illustrated in FIG. 1). However, multiple main servers 12A-12M may be required in systems that have a large number of clinician workstations 13A-13N. Each of the clinician workstations 13A-13N may be used by a clinician to generate multiple DPFs for multiple patients and to monitor the treatment of these multiple patients. The DPFs generated for a specific patient may be used by any of the components of the patient's local subsystem 14. If the local subsystem 14 of a patient includes multiple energizing pods (such as, for example, the pods 19 and 29 of the local subsystem 14 of FIG. 2), a DPF generated by the clinician workstation 13 may be used by any of the energizing pods included in the local subsystem 14 of that patient and registered with the patient, as is disclosed hereinafter.

Furthermore, if the patient 115 has more than one smartphone, the DPF may be used by any of the smartphones included in the local subsystem 14 of the patient 115. Similarly, if the patient has several laptops or several tablets or several phablets or several notebooks, or any combinations of such devices that are included in the local subsystem 14 of the patient 115, the DPF may be used by any of the devices included in the local subsystem 14.

Reference is now made to FIGS. 8-9. FIG. 8 is a schematic isometric view of a magnetic wireless energizing pod, in accordance with an embodiment of the wireless energizing pods of the present application. FIG. 9 is a schematic cross-sectional view of the energizing pod of FIG. 9, taken along the lines IX-IX.

The energizing pod 39 may include a housing 26. According to some embodiments, the housing 26 is made from an electrically insulating and biocompatible material, such as, for example an injection-molded plastic. In some embodiments (not shown), in order to optimally fit to a curved surface of the body (such as, for example, the head 3 of the patient 115), the housing 26 may be curved, concave, or flexible. Typically, the energizing pod has a low profile such that it is not easily seen on the surface of the body. The pod 17 may also include a speaker 38 facing suitable holes 43 perforating the housing 26. The holes 43 allow sound emitted from the speaker 38 to be heard outside the pod 17. The pod 17 may also include a multi-function button 67 for user inputs (such as, for example, turning the device on or off, and for activating light sources 65 and 66 that are included in the energizing pod 17 and may function as charge level indicators. The light sources 65 and 66 may be implemented as linear LED arrays each including several LEDs.

The energizing pod 39 may include the power source 4 (of FIG. 4) for providing electrical power the energizing pod 39. The power source 4 may be implemented as a rechargeable battery, a primary battery a capacitor, a super capacitor, or other suitable energy storage device. Typically, in some embodiments, the power source 4 is a re-chargeable power source, in such an embodiment, the energizing pod 17 may include two electrically conducting contacts 37A and 37B electrically connected to the power source 4 for recharging the internal power source 4. However, if the power source 4 is a primary electrochemical cell or battery, the power source 4 may be removed from the energizing pod 17 and replaced.

The energizing pod 39 may include the power transmitting inductance coil 23 (of FIG. 4) that may be used to implement an inductive power link. The nominal diameter for the inductance coil 23 coil may be about two-three centimeters, which is sufficient to transmit power to an implant with a receiving inductance coil 55 (of FIGS. 3 and 4) having a diameter of approximately one and a half to two centimeters, through approximately 1-2 cm of tissue. The specific diameters, number of turns, and electrical properties of the inductance coils 23 and 55 may vary according to

the specific application and may be tuned for optimal power transfer efficiency. In some embodiments, a ferrite element (not shown) may be included within the implant or the wireless energizing pod to achieve optimal power transfer by shaping the magnetic field. The wireless energizing pod 39 may include a magnet 41 for magnetically coupling the wireless energizing pod 39 to the magnet 5 disposed in the implant 28 or to a magnet (not shown) disposed within the implant 10 (of FIG. 1). The magnet 5 may be similar in structure and magnetic properties to the magnet 24 (of FIG. 4)

Typically, the magnet 41 is located closest to the surface that makes contact with the scalp of the patient 115 to achieve a maximum force of attraction to the implant 10 or 28. In some embodiments, the ferrite element (not shown) and the magnets 5, 24 and 41 may be detachable and/or removable from the implant 10 or 28 and/or from the pods 19, 29 and 39), which may improve functional magnetic resonance imaging (fMRI) that can be blurred by ferrous and /or magnetic materials. In some embodiments, a re-chargeable energy storage unit may be directly recharged via electrical contact pins or pads that are exposed through the surface of the energizing pod enclosure. These pins, for example, may form an electrical connection with re-charge circuits and re-charge pins (as may be seen in FIGS. 8-10) in the energizing pod charger when docked. The wireless energizing pod 17 of Figure 9 may include a printed circuit board (PCB) 21. The PCB 21 may include one or more of the processor/controllers 8, the memory 6, the transceiver 20, the optional transceiver 18, the wireless power transmitter/data transceiver module 22 and one or more of the components of the user interface 32 disclosed hereinabove and illustrated in FIG. 4. For example, the IMU 42, the speaker 38 and a multifunction button 34 may be seen in the cross-sectional view of FIG. 9 as attached to the PCB 21.

The speaker 38 may also be used as a vibrator or may be substituted by an electromechanical vibrator (not shown). Such a vibrator (if used) may be used to provide tactile/vibrational signals that may be sensed by the patient 115 and provide information to the patient 115. For example, in some embodiment such a vibrator may provide a short duration vibratory signal to notify the patient 115 of the beginning and end of the therapeutic session. Such vibratory signals may be conducted by the skull bone of the patient 115 and may be sensed by the inner ear.

The user interface 32 that is integrated into the energizing pods 19 and 39 may enable the patient 115 to use the energizing pod without any other external components (such as the smartphone 11 or the laptop 15), so that the user may initiate therapies, monitor progress, receive notifications or alarms, turn the energizing pod on/off, pause or stop therapies, and adjust therapy settings as is disclosed in detail in the flowchart of FIG. 27 hereinafter. When the smartphone 11

is available to the patient 115, these functions may be implemented, for example, via the smartphone's touchscreen, buttons, display, or speaker. Without the smartphone 11, for example, the user may turn on the energizing pod by pressing the multi-function button 34. The Button(s) 34 may be implemented using capacitive sensors (not shown) and/or as mechanical or electromechanical buttons.

Different inputs may be achieved by varying the duration, pressure, or number of touches to the button(s) 34. In some embodiments, the energizing pods 19 and 39 may include an optical sensor (not shown), or a camera (not shown), to collect patient input through gestures, facial expressions, or environmental information. Feedback to the patient 115 may be implemented via the light sources 35 or 36 that may light up to indicate, for example, system status, battery power, or confirmation of user input. Feedback signals may also be implemented in some embodiments, by using the speaker 38 or a vibrator (not shown) to emit sounds or vibrations, respectively, that can be heard or felt by the patient 115. In some applications, discreet use of the system may be important to the patient 115, which will make feedback via the speaker 38 undesirable. Therefore, in some embodiments, discreet auditory/vibratory signals may be provided to the patient 115 via bone conduction, where small vibrations in the implant 10 are conducted via the surrounding bone to the inner ear of the patient 115. This type of feedback is preferred for discreet use and is well suited for implants that are embedded in or near a bone of the patient 115.

In some embodiments of the energizing pods, the pod 39 may include a charging port 68, that may be implemented as a USB port (such as, for example, a USB A port, a USB B port, A USB C port and the like). The charging port 68 may be useful for charging the energizing pods of the present application without using the pod charger 17, if necessary, as disclosed in detail hereinafter. In some embodiments, the charging port 68 may also be used to transfer data from the energizing pods 19 and 39 to the smartphone 11 or the laptop 15 or to any other component included in the local subsystem 14, as is disclosed in detail hereinafter.

Figure 10 is an isometric view illustrating in more detail the energizing pod charger 17 of FIG. 2. The Pod charger 17 may be any suitable charger that may charge one or more energizing pods (such as, for example the pod 19 and the pod 29 of FIG. 2). The pod charger 17 may include a housing 26 made from any suitable, preferably non-electrically conducting, material such as, for example, engineering plastic. A power source (not shown in FIG. 10) is disposed within the housing 68. The power source may be any electrical power source, such as, for example, a rechargeable electrochemical cell, or a capacitor, or a super-capacitor. Typically, the charger power source is a rechargeable lithium-ion rechargeable battery or lithium polymer rechargeable battery. The energizing pod charger 17 may include a charging port 58, that may be used for

electrically connecting the pod charger 17 to a DC power supply (not shown). In some embodiments, the charging port 58 may be implemented as a USB port and the DC power supply may be a standard five-volt (5 V) power supply.

The pod energizing charger 17 may include two docking mechanisms 63 and 64 implemented as two cylindrical recesses. The docking mechanism 63 may have two spring-loaded pins 58A and 58B that match the charging contacts 37A and 37B of the energizing pod 39 (of FIG. 8). The docking mechanism 64 may have two spring-loaded pins 58C and 58D that match the charging contacts 37A and 37B of the energizing pod 39. When the energizing pod 39 is placed in the docking mechanism 63, the spring-loaded pins 58A and 58B make contact with the contact pads 37A and 37B and recharging of the power source 4 of the energizing pod 39 by the power source included in the pod charger 17.

The pod charger 17 may include a multifunction button 67, and two charging indicator light sources 65 and 66. The charging indicator lights 65 and 66 may be implemented as linear LED arrays, as is known in the art. The pod charger 17 may include a lid 57 that may cover the two docking mechanisms 63 and 64. The pod charger 17 may include standard charging regulating circuitry (not shown) disposed within the housing 68 and electrically connected between the recharging port 58 and the power source (not shown) of the pod charger 17, as is known in the art.

The pod charger 17 may also include a speaker or buzzer (not shown in the isometric view of FIG. 10) disposed opposite speaker holes 59 passing through the housing 68. The speaker may be used to provide auditory user feedback. In an example, when an energizing pod is placed in one of the docking mechanisms 63 or 64, and the multifunction button 67 is pressed with a long (greater than 3 seconds) press, the speaker may beep once indicating proper placement and the beginning of recharging of the pod(s). During the charging of the pod(s), when the multifunction button 67 is pressed with two short presses (shorter than one second and separated by an interval having a duration of two seconds or shorter), the speaker (not shown) of the pod charger 17 may beep twice and the indicator light source(s) 65 or 66 or both 65 and 66 may indicated the charge in the pod(s) by lighting a number of LEDs proportional to the percent of the total full charge of the power source 4 of the pod(s).

It is noted that the construction and operation of the pod charge 17 is not the subject matter of the present application and is therefore not described in detail hereinafter. The construction and operation of such chargers is known in the art of chargers for wireless earphones.

In some embodiments of the pod charger 17, the charging of the energizing pods may be performed wirelessly, by induction coils (not shown) disposed within the housing 68 underneath the docking mechanisms 63 and 64. In such embodiments, the spring-loaded pins 37A –37D

become redundant and are not included in the pod charger 17. In some embodiments, the charging port 58 may include any combination of power and data connections for bidirectional data transmission between the pod(s) and the pod charger 17. According to some embodiments, the energizing pod charger 17 may include a lid 40 that closes over and retains the energizing pods within the energizing pod charger.

It is noted, that the energizing pod charger 17 is not the only possibility for charging the energizing pods of the present application. In some embodiments, the energizing pod may be electrically connected to an external computational device (such as, for example, the smart phone 11 or the laptop 15) and may draw power directly from the external computational device. In some embodiments, the pod charger 17 may include a connector port 58 suitable for recharging the energizing pod charger's internal energy storage unit. This connector port 58 may be implemented as a USB connector that is readily connected to a wide variety of computational devices, including wall-mounted power sources. In some embodiments the connector port 58 may include any combination of power and data connections.

Reference is now made to FIGS. 11A-11B, which are schematic flow diagrams illustrating the steps of a method for generating a digital prescription file on a clinician workstation, in accordance with an embodiment of the methods of the present application.

The method may be implemented as a software program or application operating on the clinician workstation 13 of FIGS. 1-2 and on the clinician workstations 13A-13N of FIG. 7.

The program may start by presenting a login screen on the display 7 of the clinician workstation 13 (step 82). After the clinician enters his credentials, the program reads the user credentials (step 84). The program then checks the user credentials (step 86). If the read credentials do not match those of a trusted user, such as, for example matched by a two-factor authentication, the program transfers control to step 82 to present the login screen again. If the read credentials match those of a trusted user, the clinician workstation 13 establishes a connection with the main server(s) 12 (over the internet) and receives from the main server(s) 12 server updates (step 88). Such server updates of step 88 may include, inter alia, information about patients that received stimulation, analysis of data of patients and patient text messages. The program may then present the most recently received updated list of patients on the display 7 (step 91). The list could be based on a list of patients that have an update notification.

Typically, each clinician has a list of patients he supports. The list is stored on the main servers(s)12. When connecting to the main server(s) 12, the clinician gets an update from the main server(s) 12 regarding each one of his patients (for example, did patient(s) use the device, were there any issues or events during the therapy delivery, etc.). These updates are stored on the main

server(s) 12 and are received from the patient's smartphone 11 or pod 19 or 21 each time these devices are used to stimulate, sense data, login to the system and other patient- related events.

The clinician may then choose which patient profile to present on the display 7 or may choose to create a new patient profile (step 92). The program may then check if there is a recommended DPF update for the selected patient received from the main server 12 (step 94). If there is a recommended therapy update, the program presents a screen (on the display 17) with the recommended therapy parameter values and/or parameter constraints (step 96). If there is a recommended therapy update received from the main server 12, the program presents on the display 17 a selection screen with the recommended parameter values and/or parameter constraints (step 96).

If there is no recommended update for the selected patient, the program presents on the display 17 a selection screen with the latest used therapy parameters and/or parameter constraints (step 98). If the patient is a new patient that has never received a therapy, the clinician may elect to use a standard preset list of parameter values and/or parameter constraints or alternatively may choose to manually enter the values of each therapy parameters and/or parameter constraints. The program may receive the entered clinician's updates to the therapy (step 102). It is noted that in step 102, the clinician may elect to enter no updates and to accept and enter the recommended therapy parameter values and/or constraints as received from the main server 12 without any changes.

The program may store the new therapy parameter values and constraints (step 104) and submit new data for the new DPF to the main server 12 for a conformance and safety check (step 106). The program may then check if the new DPF has been verified by the main server to conform with approved parameter ranges and/or constraints (step 108). If the new DPF has not been verified (approved) by the main server 12 to conform with approved parameter ranges and/or constraints, the program presents on the display 17 an error indication screen indicating the non-conforming and/or unsafe parameter values and/or parameter constraints (step 110) and transfers control to step 102 to enable the clinician to enter new parameter values or parameter value constraints.

If the new DPF has been verified (approved) by the main server 12 to conform with approved parameter ranges and/or constraints, the program presents a confirmation screen on the display 17, stores the approved DPF for transmission to the local subsystem 14 over the internet (step 112) and ends.

It is noted that while the method of operation of the software program disclosed in FIGS. 11A-11B has the advantage of giving the clinician the option to get personally acquainted with and selectively change any therapy parameter values and/or parameter value constraints in the

beginning stages of the patient's therapy, this may not always be necessary. For example, in accordance with some embodiments of the methods of the present application, the above disclosed steps of the software program (possibly with the omission of the presentation in some or all of the steps 84-112 including displaying the various screens on the screen 17 for the clinician), could be replaced by a suitably trained artificial intelligence (AI) program to automatically generate new DPFs without a clinician interaction or involvement.

Reference is now made to FIG. 12 which is a schematic flow diagram illustrating the steps of an exemplary method for performing a secure login by a main server of the systems of the present application.

When a user of the clinician workstation 13 wishes to start a session with the server(s) 12 in order to get updates or study a patient's therapy history or to prepare a new DPF or perform any other interaction with the main server(s) 12, the user (such as a certified clinician) sends a secure login request to the main server(s).

The main server(s) 12 receives the secure login request from the clinician's workstation 13 (step 202). For example, the secure login request could include a username and password, or google login credentials or any other suitable login request. The main server(s) 12 checks whether the user's credentials are valid (step 204). If the user's credentials are not valid, the main server(s) refuses connection, logs the failed login event (step 206) and ends the login session.

Alternatively, some embodiments (not shown in FIG. 12) may send a notification to the clinician's workstation 13 that the login failed and allows the user to repeat entering the user's credentials a fixed number of times (for example, three more times) after which if all logins failed the session is terminated after logging of the failed login attempts by the main server(s) 12.

If the user credentials are valid, the main server(s) 12 sets up a secure connection (step 208). The secure connection may be any type of suitable secure connection, such as, for example using the secure socket layers (SSL) protocol. Other suitable protocols may also be used such as, for example, TLS, DTLS, HTTPS, POP3 and IMAP. The main server(s) 12 checks the user's notification log and replies with the relevant notifications (step 210) and ends.

Reference is now made to FIG. 13 which is a schematic flow diagram illustrating a method for downloading a DPF from the main server(s) to an application operating on a device included in the local subsystem of the present application. The main server(s) 12 receives a secure request on an established secure link, to download a DPF (step 214). The main server(s) 12 checks whether the patient 115 is allowed to download an updated DPF. The main server(s) 12 receives the DPF (with a specific ID) for a specific patient from the clinician workstation 13. When the patient tries to download a DPF from the main server(s) 12, the main server(s) 12 receives (in step

212) the patient ID to make sure he/she is attempting to download the correct DPF. If the patient 115 is not allowed to download the DPF, the main server(s) 12 refuses the download request and logs the event (step 216). If the patient is allowed to download the DPF, the main server(s) 12 securely replies to the download request by uploading the updated DPF to the device that requested the downloading of the DPF (step 218). The main server(s) 12 then logs the download event (step 220) and ends the procedure. The device requesting the download of the DPF may be any of the devices included in the local subsystem 14, such as, for example, the smartphone 11, the laptop 15 (or a tablet or phablet used by the patient 115), the smartwatch 117 (assuming the smartwatch 117 includes a suitable application operating thereon and is able to communicate with the energizing pod 19 and/or 29) and, in some embodiments, the energizing pod 19 or 29.

Reference is now made to FIGS. 14A-14B which are schematic flow diagrams illustrating the steps of an exemplary method for cleaning up DPFs by the main server(s) 12, in accordance with an embodiment of the methods of the present application.

As each patient may have multiple prescriptions issued by the clinician and stored in the patient's database on the main server(s) 12, there is a need to periodically perform a cleanup program for all patients' data stored in the main server(s) 12 to keep the database updated. The main server(s) 12 may initiate the digital prescription file cleanup program at a preprogrammed time. For example, in the exemplary method illustrated in FIGS. 14A-14B, the program may be initiated once a day at time 00:00 (step 222). It is noted that the time of initiating the cleanup program may vary. For example, the prescription cleanup program may be initiated every two days (forty-eight hours) at time 00:00, or at any other desirable time interval and may start at any desired hour. This program is necessary because each patient may have several DPFs stored on the main server(s) 12 because the clinician may frequently change or modify the DPF of any patient supervised by the clinician.

When the program is operated, the main server(s) 12 fetches the first patient data that is present in the patient database of the main server(s) 12 (step 223). The program then checks whether a DPF is available for the patient (step 224). If no new DPF is available for the selected patient (for example, when a DPF has not yet been provided by the clinician for the patient), the program checks if the specific patient is the last patient in the patient database (step 225). If the patient is not the last patient, the program fetches the record of the next patient in the database (step 231) and transfers control to step 224. If the patient is the last patient, the program terminates.

In step 224 if a DPF is available in the patient's data, the program fetches the DPF data (step 226). The program checks if the number in the expiration date field in the DPF is a negative number (step 227). If the number in the expiration date field in the DPF is a negative number, this

indicates that the DPF should not be deleted by the DPF cleanup program and control is transferred to step 224.

It is noted that step 227 is useful in cases in which the clinician does not want a particular DPF to ever be deleted by the cleanup procedure. This may be achieved, for example, by entering a negative number in the “expiration date” data field of **TABLE 1**. For example, if the “expiration date” field is an X digit integer of the format “**HHmmDDMMYYYY**” where **HH** is a two digit integer representing the hour, **mm** is a two digit integer representing minutes, **DD** is a two digit integer representing the day of the month, **MM** is a two digit integer representing the month and **YYYY** is a four digit integer representing the year, and the clinician wants to specify that a certain DPF should not be deleted by the DPF cleanup program the clinician may enter - **HHmmDDMMYYYY** (which is a negative integer number, as indicated by the minus sign preceding the number) in the expiration date field of **TABLE 1**. In such an embodiment, any program or subroutine that needs to use the expiration date of the DPF may be modified to use the absolute value of the number in this field (**| -HHmmDDMMYYYY |**) before performing any calculation on the value in this field.

If the number in the expiration date field in the DPF is not a negative number, the program checks if the current time and date exceeds the value in the “expiration date” field of the DPF (step 228). If the current time and date exceeds the value in the “expiration date” field of the DPF the program main server 12 deletes the DPF from the database (step 229) and transfers control to step 224.

If the current time and date does not exceed the value in the “expiration date” field of the DPF the program checks whether the patient has requested to download a new DPF (step 230). In step 230, if the patient has requested to download a new PDF, the program transfers control to step 224. If in step 230, the patient has not requested to download a new DPF, the program checks whether a threshold amount of time has passed from the time the clinician uploaded the DPF to the main server(s) 13 to current time without the patient requesting to download a new DPF (step 234). The threshold amount of time may be preset by the clinician on the main server(s) 12. For example, the threshold amount of time may be set to seven days or fourteen days or 30 days or any other suitable time period or any other time amount (or time period). If the threshold amount of time (as measured from the time the clinician uploaded the DPF to the main server(s) 13 to the current time) has not been exceeded, the program transfers control to step 224. If the threshold amount of time measured from the time the DPF was uploaded to the main server(s) 13 to the current time has been exceeded, the program adds a notification to a clinician’s notification log

that the patient did not download a new DPF within the threshold amount of time (step 234) and transfers control to step 224.

The clinician notification log may be accessed by the clinician using the clinician's workstation 13. For example, when the clinician initiates a new session of working on the clinician's workstation 13, all the new notifications for all the patients treated by the specific clinician may be actively pushed by the main server(s) 12 to the clinician's workstation 13 and may be automatically displayed to the clinician. In this way the clinician is kept updated of the status of patient's DPF request for all his patients. These notifications may be useful for monitoring patient's conformance to scheduled treatments. The program (or subroutine) illustrated in FIGS. 14A-14B enables the main server(s) 12 database to be periodically up to date regarding the DPF records for all patients.

Reference is now made to FIG. 15 which is a schematic flow diagram illustrating a method for time synchronization between the main server and an energizing pod, in accordance with an embodiment of the methods of the present application. The energizing pods of the present application (such as, for example, the pods 19, 29 and 39) need to keep track of time as they may need to record the time of performing therapy sessions and/or may need to record or log the timing of other events occurring during the operation of the energizing pods. While the processor/controller 8 of the energizing pod 19 may include timing electrical circuitry (not shown in FIG. 4) that may internally and autonomously keep time, there may arise a problem of the accuracy of time keeping by such internal time keeping circuitry due to several factors such as, for example, environmental temperature changes, and the limited accuracy of the clock circuits causing a drift in clock time over long time period. Additionally, if a pod is left uncharged for an extended period of time, the clock circuit time may be seriously off once the pod is recharged. In order to solve such problems, the pod internal clock circuitry needs to be periodically synchronized with time keeping circuits of the main server(s) 12.

In such a time synchronizing method (or program/subroutine), the main server(s) 12 may receive a request for a secure/authenticated connection from an energizing pod (such as, for example, the pod 19, or 29 or 39) over a secure patient application link (step 236). The secure patient application (operative on the processor/controller 8 of energizing pod) link may be implemented using SSL protocols or any other suitable secure/encrypted protocol. The main server(s) 12 checks whether the pod's credentials are valid and are registered to the patient (step 238). If the pod's credentials are not valid and/or are not registered to the patient, the program refuses connection, logs an event on the main server(s) 12 (step 240) and terminates. If the pod's credentials are valid and are registered to the patient, the program sets up a secure link with the

energizing pod (step 242), securely replies to the request from the energizing by providing the pod with the current date/time of the main server(s) 12 (step 244), logs the time synchronizing event (step 246) and terminates.

It is noted that the requesting of a time synchronization by an energizing pod may be automatically initiated at fixed or present time interval. For example, the energizing pod's software program may initiate such a request every three days or every seven days or every any other suitable time period based on the internal timing circuitry of the energizing pod. Additionally, if an energizing pod has not been recharged for an extended time period due to patient negligence, or a malfunction of the pod charger 17, or any other reason, and the pod lost the ability to keep time, once the energizing pod is recharged and the pod's software program is turned on, the pod's software program initiates a request for date/time. Additionally, the pod's software program may be programmed to issue a date/time synchronization request each time the pod is placed on the patient's scalp in preparation for a therapeutic session.

It is noted that the duration of the time interval separating such automatically initiated pod date/time synchronization requests may depend, inter alia, on the accuracy of the internal clock circuitry of the pod and on the desired accuracy of time recording for event logging by the main server(s) 12.

Reference is now made to FIG. 16 which is a schematic flow diagram illustrating the steps of a method for creating a new DPF by the main server(s), in accordance with an embodiment of the methods of the present application. The main server(s) 12 receives from a trusted clinician workstation 13 over a secured link a new DPF for a registered patient (step 248). The main server checks whether the DPF is in conformance and safe (step 250). The check of step 250 is based on a comparison of the relevant therapy parameters (and/or the specified parameter value ranges of the patient modifiable parameters) with preset safe values and ranges that are stored in the memory of the main server(s) 12. If the DPF is not in conformance and safe, the program notifies the clinician of the non-conformance or safety issue, recommends (if possible) corrective action to the clinician (step 252) and transfers control to step 248. It is noted that in some embodiments, the recommendation for corrective action may be implemented as flagging or indicating the non-conforming or unsafe parameter value (s) entered into the DPF by the clinician and prompting the clinician to enter a new parameter value(s) or parameter value ranges that conform with the main server(s) allowed values and value ranges and is safe.

If the DPF is in conformance and safe the program creates a DPF using an encryption key, stores the encrypted DPF and transmits a notification to the clinician's workstation that a new DPF

is available (step) 254). The program then adds a notification to the patient's notification log that a new DPF is available (step 256) and terminates.

It is noted that in some embodiments, the corrective action may be more sophisticated. For example, the main server(s) 12 may have an AI program or application operative thereon that may use historical, patient specific DPF data together with corresponding ecological momentary mood assessment (EMA) data and/or the collected data representing objectively quantified parameters of use of the communication device by the patient recorded for the same patient to automatically generate a set of therapy parameter values for a DPF. Such an embodiment is illustrated and disclosed in detail in FIGS. 30A-30B hereinafter.

Reference is now made to FIG. 17 which is a schematic flow diagram illustrating the steps of a method for performing a secure login by a patient application operating on one or more of the devices included in the local subsystems of the present application.

The method may be a subroutine or subprogram of a patient application operating on one or more devices included in the local subsystems 14 (of FIGS 1-2), and 14A-14K (of FIG. 7). For example, the method may be operating on the smartphone 11, and/or on the energizing pods 19, 29 and 39, and/or on the laptop 15 (or a tablet computer, or notebook or phablet used instead of the laptop 15), and/or on the smartwatch 117. The subroutine may be part of a patient application used by the patient 115 to control at least some of the parameters of the therapy and to initiate therapy sessions. In an embodiment in which the patient application is installed on the smartphone 11 or on the laptop 15 (or on a tablet or phablet or notebook substituting the laptop 15 as disclosed hereinabove), the smartphone 11 or the other devices on which the patient application is installed may be also used for obtaining ecological momentary mood assessment (EMA) data indicative of (or correlated with) the mood of the patient's 115 and/or the collected data representing objectively quantified parameters of use of the smartphone 11 by the patient 115 and for wirelessly communicating with the main server(s) 12. The main server(s) 12 may store and process the EMA data and/or the collected data representing objectively quantified parameters of use of the smartphone 11 by the patient 115. The main server(s) 12 may also record and process electrical signals sensed by the sensing/recording electrodes 25A-25D of the implant 28 (of FIG. 3) and wirelessly communicated by the energizing pods 19, 29 and 39 to the main server(s) 12. The main server(s) 12 may use results of the stored results to obtain data indicative of the patient mood and may possibly use the indicative data and the processed EMA data (and/or the collected data representing objectively quantified parameters of use of the smartphone 11 by the patient 115) to compute a value of a mood index (MI) based on the EMA data with or without data obtained from the recorded cortical electrical signals as disclosed in detail in published international application

WO /2019/244099. Such mood index values may be useful for monitoring the efficacy of the therapeutic sessions delivered to the patient 115 by the implant 10 or 28. Besides assisting the clinician in charge of monitoring the patient 115 in assessing the effect of changing therapeutic parameters on the patient's mood, such mood index values may also be used by a suitable AI software (possibly operating on the main server(s) 12) to optimize therapy parameters and even to automatically generate DPFs for use in therapy, as is disclosed in detail and illustrated in FIGS. 30A-30B, hereinafter.

The secure login subroutine of FIG. 17 starts by presenting a login screen on a device such as, for example, the smartphone 11, or the laptop 15 or in some embodiments the smartwatch 117 (step 258). After the patient 115 finishes entering his or her credentials, the subroutine reads the user credentials (step 260). The subroutine then checks whether the read credentials (a two-factor authentication may be used, such as, for example a user name and/or a password) match those of a trusted user (step 262). If the credentials read do not match those of a trusted user, the subroutine may return control to Step 258 to present a login screen again (possibly with an indication to the patient that the credentials do not match or that there is an error in the user's name or in the password). If the credentials read match those of a trusted user, the subroutine establishes a secure link with the main server(s) 12 (step 264). The subroutine may then send updates to the main server(s) 12 (step 266). The updates may include the date/time of the last activation of the implant (for sensing and/or stimulation), patient requests (for example, a patient may request a DPF that prescribes a more intense stimulation, or a longer session time, and/or additional updates, such as, for example, text message from the user, information about the device activation times, sense data, failure logs (i.e. the user tried to activate and failed for some reason), locked states (i.e. the device is locked for some reason). The subroutine receives updates and/or patient notifications (from the patient notifications log of the main server(s) 13, presents the updates and/or notifications to the patient (step 268) and terminates.

Reference is now made to FIG. 18 which is a schematic flow diagram illustrating a method for connecting and data exchange between a patient application operating on one or more of the devices included in the local subsystem 14 and a pod, in accordance with an embodiment of the patient application of the present application. The method may be implemented as a subroutine or subprogram of a patient application operating on one or more devices included in the local subsystems 14 (of FIGS 1-2), and 14A-14K (of FIG. 7). For example, the method may be operating on the smartphone 11, and/or on the laptop 15 (or a tablet computer, or notebook or phablet used instead of the laptop 15), and/or on the smartwatch 117.

In an exemplary embodiment the patient application may be operating on the smartphone 11. The subroutine starts by performing a secure login (step 270), a login screen may be presented on the smartphone display as disclosed in detail hereinabove. After successfully completing the login, the patient may be presented by an option menu and may choose to request a connection to an energizing pod. The subroutine detects a user request to connect to a pod (step 272). The subroutine may then search for available and approved energizing pods (step 274) and presents to the patient a screen with a list of available approved energizing pods (step 276). The patient may select a desired available pod from the list. The subroutine reads the pod selected by the patient (step 278). The subroutine may then connect to the selected energizing pod over a secured link (step 280). The subroutine queries the energizing pod for updates and/or notifications (step 282), and presents the notification on a screen (if there is a notification) (step 284). The subroutine then checks whether the connected pod is in a locked state (step 286). If the connected pod is not in a locked state, the subroutine terminates. If the connected pod is in a locked state the subroutine checks whether an internet connection is available on the smartphone 11 (step 288). If an internet connection is not available to the smartphone 11, the subroutine notifies the patient that the pod is locked and prompts the patient to establish an internet connection (for example, by activating a Wi-Fi connection) (step 290). After an (optional) time delay, the subroutine transfers control to step 288. If an internet connection is available, the subroutine enables a secure connection between the pod and the main server(s) 12 which unlocks the pod (step 292), the subroutine then transfers control to step 286.

Details of how the pod may be locked and unlocked are disclosed with respect to FIGS. 24 and 25, respectively, hereinafter.

It is noted that while in the exemplary subroutine (of FIG. 18), the patient application is installed and operates on the smartphone 11, in other embodiments, the patient application may be installed on the laptop 15 or on a tablet, phablet or notebook substituting the laptop 15.

Reference is now made to FIG. 19 which is a schematic flow diagram illustrating a method for downloading a new DPF from the main server(s) 12, by a user application installed on one or more devices of the local subsystem, in accordance with an embodiment of the methods of the present application. While in the exemplary embodiment disclosed in FIG. 19, the patient application is installed on the smartphone 11. It is noted that while in the exemplary subroutine (of FIG. 18), the patient application is installed and operates on the smartphone 11, in other embodiments, the patient application may be installed on the laptop 15 or on a tablet, phablet or notebook substituting the laptop 15.

The subroutine starts by performing a secure login procedure (step 294) in which a login screen is presented on the screen of the smartphone 11, and the patient 115 may enter his credentials into the appropriate places in the login screen (for example, a user name and a password) (step 294). After the patient is securely logged in, the subroutine may present on the display of the smartphone 11 an operation selection screen to the patient. The subroutine detects if the user selected the operation of downloading a new DPF (step 295) and requests a download of a new DPF from the main server(s) 12 over a secure link (step 296). The subroutine receives and stores a new PDF on the smartphone 11 (step 297), stores the new DPF in the memory of the smartphone 11 (step 298), and terminates.

Reference is now made to FIG. 20 which is a schematic flow diagram illustrating a method for periodically cleaning up DPFs by a patient application, in accordance with an embodiment of the methods of the present application.

It is noted that while in the exemplary subroutine of FIG. 20, the patient application is installed and operates on the smartphone 11, in other embodiments, the patient application may be installed on the laptop 15 or on a tablet, phablet or notebook substituting the laptop 15.

The DPF cleanup procedure may be necessary because there may be multiple DPFs loaded on the smartphone 11 (or on any other of the devices indicated above on which the patient application may be installed and operating). The program (or subroutine) of FIG. 20 iterates through all such DPFs. If there is a memory shortage, the procedure may delete expired DPFs as described in detail hereinafter. It is noted that since modern smartphones may have quite a large memory capacity, the deletion of old expired DPF may not be necessary ever. However, the procedure is used to avoid memory shortage problems in cases such as the patient downloading large amounts of data (such as, for example games or video content) to the memory of the smartphone 11 or to any other device on which the patient application is operating. Additionally, if the device being used by the patient 115 to modify the patient modifiable stimulation parameters is a device having a limited memory capacity (such as, for example, the energizing pod 19 or 29 or the smartwatch 117) there may be a need to conserve memory space by using the DPF cleaning subroutine.

The patient application may initiate the DPF cleanup procedure at a preprogramed time. For example, in the exemplary method illustrated in FIG. 20, the procedure may be initiated once a day at time 00:00 (step 302). It is noted that the time of initiating the cleanup procedure may vary. For example, the DPF cleanup procedure may be initiated every two days (forty- eight hours) at time 03:00, or at any other desirable time interval.

After the cleanup subroutine is initiated in step 302, the smartphone 11 checks whether there is a memory shortage (step 303). If there is no memory shortage, the subroutine terminates (without deleting any of the DPFs stored in the memory of the smartphone 11). If there is a memory shortage, the subroutine checks whether one or more DPFs are stored in the memory of the smartphone 11 (step 304). If there are no DPFs stored in the memory of the smartphone 11, the program terminates. If there are one or more DPFs stored in the memory of the smartphone 11, the subroutine fetches the first DPF data from memory (step 305). The subroutine then checks if the current date/time exceeds the DPF's expiration date/time (step 306).

If the current date/time exceeds the DPF's expiration date/time, the subroutine deletes the DPF (step 307) and transfers control to step 308. If the current date/time does not exceed the DPF's expiration date/time, the subroutine transfers control to step 308.

In step 308, the system checks if the current DPF is the last DPF stored in the memory of the smartphone 11. If the current DPF is the last DPF stored in the memory of the smartphone 11, the subroutine terminates. If the current DPF is not the last DPF stored in the memory of the smartphone 11, the subroutine fetches the next DPF data (step 309) and transfers control to step 306.

Reference is now made to FIG. 21 which is a schematic flow diagram illustrating a method (software subroutine) for using the patient application to enable the patient to set or modify the value of one or more patient modifiable therapy parameters included in a DPF, in accordance with an embodiment of the methods of the present application.

It is noted that while in the exemplary subroutine (of FIG. 21) the patient application is installed and operates on the smartphone 11, in other embodiments, the patient application may be installed on the laptop 15 or on a tablet, phablet or notebook substituting the laptop 15. Additionally, a version of such a patient application may also be loaded and operated on the energizing pods of the present application to enable the patient to activate a therapy session and modify the patient modifiable therapy parameters in the absence of the smartphone 11 (or of the laptop 15 or the tablet, notebook or phablet of the local subsystem 14).

The subroutine starts by performing a patient login on the smartphone 11 (or on the pod 19 or 29, if the smartphone 11 is not available), as is disclosed hereinabove (step 310). The subroutine presents an operation selection screen to the patient 115. If the user (such as, for example, the patient 115) requested a screen for modifying the values of patient modifiable therapy parameters (by inputting a suitable selection from a menu screen), the subroutine detects the user input (step 312) and presents a parameter modifying screen to the patient 115 (step 313). It is noted that, if the patient 115 is using the energizing pod 19 instead of the smartphone 11 to initiate

and control therapy, the patient application of the energizing pod 19 or 29 may use (in steps 310, 313, 316, 320, below) any of the components of the user interface 32 to provide the user with interactive input/output means such as the display 44 (that may, optionally, be a touch-sensitive display, the light source(s) 36, the buttons 34 and/or the microphone 40 and the speaker 38).

5 The subroutine checks whether the patient has entered parameter values (using the parameter modifying screen presented in step 313) within a preset time period (step 314). If the patient 115 has not entered parameter values within the preset time period, the subroutine uses the default parameter values of the DPF (step 315) and transfers control to step 322. If the patient 115 has entered parameter values within the preset time period, the subroutine reads the entered
10 parameters (step 316). The subroutine checks whether the entered parameter values are within the valid value ranges (step 318). If the entered parameter values are not within the valid value ranges, the subroutine notifies the patient that the entered parameter(s) values are invalid and provides an explanation why the parameter(s) values are invalid (step 320), and returns control to step 314. If
15 all the patient entered parameter values are within the valid ranges, the subroutine generates an implant control data file (ICF) based on the parameter values entered by the patient 115 and the clinician set parameter values provided in the DPF (step 322), stores the ICF on the smartphone 11 (step 324) and terminates. It is noted that if the patient application is being operated on the energizing pod 19 or 29 in the absence of the smartphone 11, step 324 should read “store ICF on
20 pod”. It is noted that the subroutine repeats all the steps included within the dashed line 311 until all the patient modifiable parameters have been assigned values by the patient 115 or are assigned default values if the patient 115 has not selected parameter values.

It is noted that the while the parameter modifying screen (of step 313 of FIG. 21) may allow patient control over single stimulation parameters (as described in detail hereinabove and illustrated in FIG. 21), this is not obligatory. In some embodiments of the patient application, the
25 subroutine may bundle multiple parameters into a single displayable parameter. For example, the frequency, amplitude, and duration parameters in the DPF may be bundled and displayed as a single parameter represented as a parameter named “stimulation level” (or any other desired name) that may be displayed as a bundled parameter on the parameter modifying screen of the smartphone 11 (or on any other device being used to enable the patient 115 to modify stimulation
30 parameters).

Using the presented parameter modifying screen, the patient 115 may enter the desired values for one or more patient modifiable therapy parameters. For example, the smartphone 11 may display the selection options as “HIGH”, “MEDIUM” and “LOW”, allowing the patient 115 to choose between these options using selection buttons, in which case the application will

calculate the ICF parameter value using the minimum, default and maximum values for that parameter from the DPF. If the application bundled several parameters into a single displayed parameter, the patient selection may apply to all parameters included in the parameter bundle. For example, if the patient selected “LOW” for a displayed parameter bundle called “Pulse” which is a bundle of pulse frequency, pulse amplitude, and pulse duration, the application operating on the smartphone 11 may modify all three parameters setting the pulse frequency, the pulse amplitude and the pulse duration to the minimum values of the DPF.

In some embodiments, there may be bundling of any combination of single parameters in accordance with the experimental results in each individual patient. In some embodiments, there may be a need to bundle several unrelated single stimulation parameters. For example, a parameter bundle may include the stimulating pulse duration, the stimulating pulse amplitude and the number of pulses in a pulse train. In another example, the parameter bundle may include the stimulating pulse amplitude and the inter pulse interval. Thus, a bundled parameter may include any desired combination of single stimulation parameters. Such bundling decisions may be performed by the clinician (or by a suitably trained AI program) after implantation of the implant in each individual patient based on testing (during a testing time period) the effects of varying each stimulation parameter alone and/or in selected parameter combinations. Such parameter bundling may be based on the experimental data obtained in each individual patient during such testing time period to determine which stimulation parameters may be bundled to result in a more effective stimulation.

Reference is now made to FIGS. 22A-22B which are schematic flow diagrams illustrating a method (software subroutine) for using a patient application to enable the patient to set or modify the value of one or more patient modifiable therapy parameters including single modifiable parameters and/or multiple bundled parameters included in a DPF, in accordance with an embodiment of the methods of the present application;

The subroutine starts by the patient performing a secure login procedure (step 600). The subroutine presents an operation selection screen to the patient 115. If the patient 115 inputted a selection of modifying values of patient modifiable therapy parameters, the subroutine detects the selection (step 602) and presents a parameter modifying screen to the patient 115 (step 604). It is noted that, if the patient 115 is using the energizing pod 19 instead of the smartphone 11 to initiate and control therapy, the patient application of the energizing pod 19 or 29 may use (in steps 600, 602, 604 and 620) any of the components of the user interface 32 to provide the user with interactive input/output means such as the display 44, the light source(s) 36, the buttons 34 and/or the microphone 40 and the speaker 38).

The subroutine checks whether the patient has entered parameter values (using the parameter modifying screen presented in step 604) within a preset time period (step 606). The preset time period may be any desired time period suitable for deciding whether the patient complied by timely entering a parameter value. For example, the preset time period may vary
5 between 10-60 seconds but other time values outside the above indicated range may also be used, depending, inter alia, on the patient's condition, severity of patient's depressive symptoms, patient's age, experimentally determined patient's average response time, type and dose of any medication prescribed to the patient and other considerations.

If the patient 115 has not entered parameter values within the preset time period, the
10 subroutine uses the default parameter values of the DPF (step 608) and transfers control to step 622. If the patient 115 has entered parameter values within the preset time period, the subroutine reads the entered parameter value (step 610). The subroutine then checks whether the parameter for which the patient 115 entered a value is a bundled parameter (step 612). In some embodiments, the checking may be performed by accessing a suitable lookup table (LUT) stored on the
15 smartphone 11 (or any other device used for modifying the stimulation parameters (such as, for example the energizing pods 19 or 29, or the smartwatch 117). In other embodiments, the subroutine is programmed to determine whether the parameter is a bundled parameter or not by tracking the presentation order of the patient modifiable parameters.

For example, the subroutine may be programmed to display three (or any other desired
20 number) user modifiable stimulation parameters in a fixed order, and to increase a counter by one each time a patient modifiable stimulation parameter is displayed to the patient (this is not explicitly shown in FIGS. 22A-22B, for the sake of clarity of illustration and because other different software implementations may be used). In a non-limiting example, the subroutine may be programmed to treat a counter reading of "1" as a single (non-bundled) parameter, a counter
25 reading of "2" as a bundled stimulation parameter, and a counter reading of "3" as a single (non-bundled) parameter. It is noted that the above indicated example is not obligatory and that any other desired combination of single stimulation parameters and bundled stimulation parameters may be used, depending, inter alia, on the experimentally determined stimulation efficacy of various single stimulation parameters and bundled stimulation parameters during the above-
30 escribed testing time period.

In some embodiments, the DPF (generated by the clinician) may include data that indicates whether a stimulation parameter is a bundled parameter. For example, the parameter data field may include a flag that may identify the parameter as belonging to a group of suitably flagged parameters a bundled parameter.

If the parameter is a bundled parameter, the subroutine selects the value for each stimulation parameter included in the bundled parameter based on the patient's 115 (or other user's) input (step 614). For example, if "Pulse" is a bundled stimulation parameter including the three parameters of pulse frequency, pulse amplitude, and pulse duration and the patient 115 (or
5 another user, such as the clinician or a technician) selected the value "LOW" (out of three possible selections of "LOW", "MEDIUM" and "HIGH") for the bundled "Pulse" parameter, the subroutine selects the minimum parameter value from the DPF for each of the parameters pulse frequency, pulse amplitude, and pulse duration.

If the parameter is not a bundled parameter, the subroutine selects the value for the
10 stimulation parameter based on the patient's 115 (or other user's) input (step 616). For example, if the parameter is the number of pulses in a pulse train, and the patient selected "HIGH" for the parameter, the subroutine selects the maximum value of the pulse number in a pulse train specified by the DPF.

The subroutine then checks if the parameter(s) value(s) are within the valid value ranges
15 (step 618). If the entered parameter values are not within the valid value ranges, the subroutine notifies the patient that the entered parameter(s) values are invalid, provides an explanation why the parameter(s) values are invalid (step 620) and returns control to step 604. If all the patient entered parameter values are within the valid ranges, the subroutine generates an implant control data file (ICF) based on the parameter values entered by the patient 115 and the clinician set
20 parameter values provided in the DPF (step 622), stores the ICF on the smartphone 11 (step 624) and terminates. It is noted that if the patient application is being operated on the energizing pod 19 or 29 in the absence of the smartphone 11, step 624 should read "store ICF on pod". Similarly, if the patient application is operated on any other device included in the local subsystem 14 the ICF will be stored on the respective device being used (such as, for example, the laptop 15, the
25 smartwatch 117, a tablet (not shown), a phablet (not shown) or any other device included in the local subsystem 14.

It is noted that the subroutine repeats all the steps included within the dashed line 603, until all the patient modifiable parameters have been assigned values by the patient 115 or are assigned default values if the patient 115 has not selected parameter values.

It will be appreciated that for some stimulation parameters, there may not be a monotonous
30 relationship between the parameter value and the efficacy of the stimulation. For example, while increasing the stimulating pulse width may initially increase the efficacy of stimulation, increasing the pulse width beyond a certain value may not result in a further increase the stimulation efficacy and may actually reduce the stimulating efficacy. Similarly, the stimulation efficacy may not

necessarily be a linear function of the stimulating pulse frequency beyond a certain limited range of frequencies. Therefore, there may be cases in which a “HIGH” selection of a specific single stimulation parameter by the patient 115 may actually correspond with a lower numerical value of the parameter while a “LOW” selection of the parameter may correspond with a higher numerical value of the same stimulation parameter.

Such non-monotonous and/or nonlinear behavior may preferably be investigated during the test time period for each individual patient. After experimentally determining the relationship between a stimulation parameter value and the resulting stimulation efficacy, it may be possible to address such behavior by either limiting the valid range for a specific stimulation parameter to a range within which the dependence of stimulation efficacy on the parameter value behaves monotonously (or in certain cases linearly or close to linearly, if possible). It may also be possible to use a “reversed” value range in which the minimum numerical value stored in the parameter value field results in a higher stimulation efficacy and the maximum numerical value stored in the parameter value field results in a lower stimulation efficacy. In such a case when the patient 115 is presented with a parameter value selection screen for such a parameter, the selection by the patient 115 of a “HIGH” value will result in a selection of the minimum parameter value for storing in the ICF and a selection of a “LOW” value by the patient 115 will result in a selection of maximum value for storing in the ICF.

In a similar manner, for bundled parameters, it may be possible that the selection of “LOW” by the patient 115 may result in assignment of a maximum parameter value for some of the parameters included in the parameter bundle and the assignment of the minimum values for other parameters included in the parameter bundle. Any such combinations may be possible depending, inter alia, on the empirically determined behavior of the stimulation parameters determined in the testing time period for each individual patient. Moreover, in different individual patients, some parameters may behave differently in different patients.

Reference is now made to FIGS. 23A-23B which are schematic flow diagrams illustrating the steps of an exemplary method (and subroutine) included in the patient application and usable for initiating a therapy session, in accordance with an embodiment of the methods of the present application.

It is noted that while in the exemplary subroutines (of FIG. 21 and 22A-22B) the patient application (including the subroutine) is installed and operates on the smartphone 11, in other embodiments, the patient application may be installed on the laptop 15 or on a tablet, phablet or notebook, substituting the laptop 15 or on the smartwatch 117.

The subroutine starts by connecting to an energizing pod (such as, for example, the pods 19 or 29 or 39). In some embodiments, the patient may need to perform a login procedure prior to performing the subroutine (for example, if the patient application needs to be activated or opened on the smartphone 11). Such a login procedure (not shown in FIGS. 23A-23B) may be performed as disclosed in detail in steps 258-264 of FIG. 17. After a successful patient login, the subroutine connects the smartphone 11 to the energizing pod (such as, for example, the pods 19 or 29 or 39) over a secure link (step 326). It is noted that the pod to which the smartphone 11 is connected in step 326 may be a pod that was selected by the method disclosed hereinabove and illustrated in FIG. 18 for selecting a pod to establish a connection with. For example, in some embodiments step 326 may include performing steps 270-292 of the method of FIG. 18 and then transferring control to step 328 of FIGS. 23A-23B.

Once the smartphone 11 is connected to an energizing pod, step 328 of the subroutine may present to the patient a screen with selectable actions and the patient 115 may select the action of initiating a therapy session. The subroutine detects that the patient's input requested starting a therapy session (step 328). The subroutine checks whether the energizing pod connected to the smartphone is communicatively connected to a registered implant such as, for example, the implant 10 or 28 (step 330). If the energizing pod is not connected to a registered implant, the subroutine prompts the patient to place the energizing pod on the patient's head 3 over the implant (step 331) and returns control to step 330. If the energizing pod is connected to a registered implant the subroutine may present to the patient a screen showing the approved (valid) DPFs available for use (step 332).

After the patient 115 has selected a desired DPF (for example, by touching an appropriate selection button displayed on the therapy selection screen displayed on the smartphone 11) the subroutine detects the patient's input indicating the desired DPF (step 333) and transfers control to step 334. It is noted that if only one type of DPF is currently available, steps 332 and 334 may be skipped by the subroutine. The subroutine may then check if the patient wishes to set the patient modifiable parameters (step 334). This check may be performed, for example, by presenting on the display of the smartphone 11 a dialog box with the appropriate choice options (such as, for example, a "yes" and "no" virtual buttons). If the patient does select the option of setting the patient modifiable parameters, the subroutine performs a parameter setting subroutine, generates an ICF and downloads the ICF to the energizing pod (step 335) and transfers control to step 341. The parameter setting subroutine may be performed, for example, by steps 313, 314, 315, 316, 318 and 320 illustrated in FIG. 21.

If the patient does not wish to set the values of the patient modifiable parameters, the subroutine checks whether there is more than one valid ICF stored in the memory of the energizing pod (step 336). If there is more than one valid ICF stored in the memory of the energizing pod, the subroutine presents to the patient a list of all valid ICFs available for use on the energizing pod (step 337), detects a patients input selecting a desired ICF (step 339) and transfers control to step 341.

If there is not more than one valid ICF stored in the memory of the energizing pod, the subroutine checks if there is a valid ICF loaded on the memory of the energizing pod (step 338). If there is no valid ICF loaded in the memory of the energizing pod, the subroutine uploads a valid ICF to the memory of the energizing pod (step 340) and transfers control to step 341. If there is a valid ICF loaded in the memory of the energizing pod, the subroutine transfers control to step 341.

In step 341, the subroutine sends to the energizing pod a command to initiate a therapy session and collect data and transfers control to step 342.

The data collected by the energizing pod after receiving the command to initiate a therapy session and collect data in step 341 may include, *inter alia*, data representing neurophysiological cortical electrical signals sensed by the sensing electrodes 25A-25D of the implant 28, the date and time of the therapy session, the therapy log (received from the implant at the end of the therapy session), and therapy type, and may (optionally) include other data such as, for example, the patient's body temperature data, accelerometer data indicative of whether the patient is moving or lying down and luminosity data indicative of whether the patient is outside. In some embodiments, such luminosity data may be obtained by the imaging sensor of the camera 33 of the energizing pod. In some embodiments that do not include the optional camera 33, the energizing pod may include an (optional) photosensor (not shown in FIG. 4) that may provide luminosity data.

In step 342, the subroutine collects the above indicated data from the energizing pod and logs the data in a patient log file (stored on the memory of the smartphone 11, and if the main server(s) 12 is online and connected to the smartphone 11, the subroutine updates the main server(s) 12 by uploading the patient log file to the main server(s) 12 and terminates. It is noted that if the main server(s) 12 is not online, the updating of the main server(s) 12 may be performed at a later time. For example, in step 266 of Fig. 17 hereinabove.

It is also noted that in some embodiments the collection of data by the smartphone 11 from the energizing pod may be performed after the therapy session ends. In some embodiments, the energizing pod may wirelessly collect some types of data from the implant "on the fly" during the therapy session. Such an embodiment may be advantageous in cases in which the amount of

memory in the implant is too limited and is insufficient for storing the entire amount of cortical signal data sensed by the implant during the entire therapy session. In such an embodiment, the implant may wirelessly transmit sensed signal data to the energizing pod during the therapy session in order to periodically clear the memory of the implant for storing additional sensed signal data.

- 5 In such an embodiment, the memory capacity of the energizing pod may be significantly larger than the memory capacity of the implant as it is practically easier to have larger capacity memory in the energizing pod due of the significantly larger size.

Reference is now made to FIG. 24 which is a schematic flow diagram illustrating the steps of a method (subroutine) for updating digital prescription files (DPFs) on energizing pod(s) by a patient application, in accordance with the methods of the present application. It is noted that while in the exemplary subroutine (of FIG. 24) the patient application (including the subroutine) is installed and operates on the smartphone 11, in other embodiments, the patient application may be installed on the laptop 15 or on a tablet, phablet or notebook substituting the laptop 15.

The method (or subroutine) starts by connecting to one or more pods over a secure link (Step 346). The subroutine may present the patient 115 with a selection screen for selecting several actions and the patient 115 may select to update DPF. The subroutine detects the patient's input (step 348) and queries the connected pod(s) for any preloaded DPFs (step 350). The subroutine checks whether any preloaded DPFs are expired (step 352). If there are preloaded PDFs that are expired, the subroutine sends the pod(s) a command to delete any old expired DPF and log the event (step 354) and transfers control to step 356. If no preloaded PDFs are expired, the subroutine detects patient's selection for a valid therapy file to be downloaded to pod(s) (step 356).

The subroutine checks whether the pod(s) contain an old DPF referencing the same digital prescription as the new DPF (step 358).

If the pod(s) contain an old DPF having the same the same ID as the new DPF, the subroutine sends a command to the relevant pod(s) to delete the old DPF, logs the event (step 360) and transfers control to step 362. If the pod(s) do not contain an old DPF referencing the same digital prescription as the new DPF, the subroutine transfers aa new DPF to the relevant pod(s) (step 362) and terminates.

It is noted that the subroutine of FIG. 24 is directed to an embodiment where the ICFs downloaded to the energizing pod also include the entire data content of the DPF (for example, as disclosed in TABLE 2 hereinabove). Accordingly, the use of the term "DPFs" in FIG. 24 means "the DPFs included in the ICFs" and the term "DPF" means "the DPF stored in the ICF".

However, in some embodiments, the data of the DPF is not included in the ICF. In such embodiments the subroutine of FIG. 24 is still valid by replacing the term "DPF" by the term

“ICF” in steps 348, 354, 356, 358, 360 and 362, and by replacing the term “DPFs” by the term “ICFs” in steps 350 and 352.

It is generally noted that in some embodiments, the smartphone 11 (or any one of the devices included in the local subsystem 14 of FIG. 1) may store more than one DPF at the same time. For example, the smartphone 11 may store simultaneously one or more DPFs for use in an anti-depression therapy session and one or more DPFs for use in a session for enhancing cognitive performance of the same patient using the same implant.

In some embodiments, the energizing pod may store more than one ICF at the same time. For example, the energizing pod may store simultaneously one or more ICFs for use in an anti-depression therapy session and one or more ICFs for use in a session for enhancing cognitive performance of the same patient using the same implant. In another example, the energizing pod may include one ICF for low efficacy therapy and another ICF for high efficacy therapy.

In some embodiments of the system the patient may have more than one implant (for example, a first implant implanted in a first position of the skull of the patient for treating depression and a second implant implanted in a second different position on the skull of the same patient for treating another type of disorder (for example, anxiety disorder, ADHD, PTSD, an eating disorder (such as, for example, obesity, bulimia, anorexia), Schizophrenia, OCD, or any other type of disorder). In some embodiments, the patient may also have an implant that may be used for cognitive enhancement and another implant for treating a neurological or neuropsychiatric disorder. In such embodiments, the smartphone 11 (or any one of the devices included in the local subsystem 14 of FIG. 1) may store more than one DPF at the same time.

For example, the smartphone 11 may store in its’ memory a DPF for treating depression using the first implant and a DPF for treating Anxiety using the second implant. In such embodiments a DPF may also include an additional data field (not included in TABLE 1 above) that specifies a compatible implant ID. Some of the subroutines disclosed hereinabove may have to be modified by adding steps that instruct the energizing pod once it is placed on the skull above an implant and after establishing a wireless connection to the implant to compare the implant ID with the contents of the data field in the DPF that specifies the compatible implant. If the implant ID matches with the contents of the compatible implant data field, the subroutine proceeds to perform all the remaining steps. If the implant ID does not match the contents of the compatible implant data field, the subroutine may notify the patient that the DPF does not match the implant and may either prompt the user to remove the energizing pod and replace it on another implant or simply terminate. In either case, the subroutine may (optionally) log the failed pod placement

attempt in a patient log file of the energizing pod which may be transmitted to the smartphone 11 to update the patient log file on the smartphone 11.

If there is only one implant implanted in the patient, the above indicated steps are not necessary.

Reference is now made to FIG. 25 which is a schematic flow diagram illustrating the steps of a program operating on an energizing pod for checking if a time synchronization action is needed, in accordance with an embodiment of the methods of the present application. The subroutine starts by checking whether the power source voltage in the power source 4 of the pod 19 (of FIG. 4) is lower than a preset voltage threshold value (step 364). If the voltage in the power source 4 is smaller than a preset threshold value, which means that the charge level in the power source is too low to properly operate the pod 19, the subroutine notifies the patient to charge pod (step 363), puts the pod in a locked state (step 369) and terminates.

If the voltage level of the power source 4 is greater or equal to the threshold voltage value, the subroutine checks whether a preset time interval **X** (as measured by the internal clock circuitry of the pod 19) has passed since the last time a date/time synchronization was performed (step 365). If the preset time interval has not passed, the subroutine waits for a time period **T** (step 367) and transfers control to step 364. If the preset time interval **X** has passed since the last time a date /time synchronization was performed, the subroutine puts the pod in a locked state (step 366) and transfers control to step 367.

The locked state of a pod (such as, for example, the pod 19 or 29 or 39) does not allow the delivery of a therapy session by the locked pod until a time synchronization is performed by the pod with the current time on the main server(s) 12. For example, steps 286-292 of the subroutine illustrated in FIG. 18 and disclosed in detail hereinabove, disclose such checking of the locked/unlocked state of a pod and performing a time synchronization with the server(s) 12 if the pod is in a locked state. Thus, as long as there is sufficient charge in the power source of the pod (for example, in the power source 4 of the pod 19), the subroutine will keep periodically (every time period **T**) checking the power source voltage (in step 364) and checking whether the preset time interval **X** has passed (in step 365). If the pod losses power and the voltage of the power source of the pod drops below the voltage threshold value, the pod will be put in a locked state and the subroutine is terminated until the pod is recharged.

It is noted that the time interval **X** and the time period **T** may be different time periods. For example, in some embodiments **T** may be preset to five minutes and **X** may be preset to two weeks. However, other values of the time interval **X** and the time period **T** may be used, depending, inter alia, on the pod's current consumption in the resting state (when the pod is not being charged and

is not being used for energizing an implant), the accuracy of the pod's internal clock circuitry, and other considerations.

Reference is now made to FIG. 26 which is a schematic flow diagram illustrating the steps of an exemplary method or subroutine usable for connecting an energizing pod to a patient application operating on a communication device included in the local subsystem of FIGS 1, 2 and 7, and for exchanging data with such a device. It is noted that while in the exemplary subroutine (of FIG. 26) the patient application (including the subroutine) is installed and operates on the smartphone 11, in other embodiments, the patient application may be installed on the laptop 15 or on a tablet, phablet or notebook substituting the laptop 15.

The subroutine may operate on the energizing pods of FIGS. 2, 4, 8 and 9. The subroutine starts by checking if the patient application operating on the smartphone 11 is connected to the energizing pod over a wireless secure connection (step 368). If the patient application is connected to the energizing pod, the subroutine transfers control to step 380. If the patient application is not connected to the energizing pod, the subroutine advertises a wireless connection (step 372), waits for a connection request from the patient application of the smartphone 11 (step 374), establishes a secure link with the patient application (step 376) and uploads data to the smartphone's log (step 378).

The data uploaded by the subroutine in step 378 may be data about therapy session(s) that were initiated directly by the patient 115 (without using the patient's application of the smartphone 11) in cases in which the smartphone 11 was not available. In such cases, the initiation of therapy session(s) may be performed by using the user interface 32 of the energizing pod 19 of FIG. 4 as disclosed in detail hereinabove with respect to Fig. 4. When such a therapy session is directly initiated using the user interface 32 of the energizing pod 19, the relevant therapy session data is stored on the memory 6 of the pod 19 (because the smartphone 11 is not available). Such stored session data is uploaded to the smartphone 11 and stored in the patient application's log on the smartphone 11 in step 378.

After the uploading of the session's data, the subroutine checks whether the pod is in a locked state (step 380). If the pod is not in a locked state, the subroutine terminates. If the pod is in a locked state, the subroutine notifies the application (operating on the smartphone 11) that the pod is in a locked state (step 382), requests a secure connection to the main server(s) 12 via the patient application (step 384), requests a date/time synchronization from the main server(s) 12 and starts a reply timer running while waiting for the main server(s) reply with date/time data (step 386). The subroutine then waits for a reply from the main server(s) 12 (step 388). The subroutine checks whether the reply signature is valid and the reply timer time is below a preset threshold

value (step 390). If the reply signature is not valid or the reply timer time is not below a preset threshold value, or both the reply signature is not valid and the reply timer time is not below a preset threshold value, the subroutine transfers control to step 386. If the reply signature is valid and the reply timer time is below a preset threshold value, the subroutine synchronizes the internal
5 pod clock circuitry with the main server(s) 12 date/time (step 392), unlocks the pod from its locked state and notifies the patient application of the pods unlocking (step 394) and terminates.

Reference is now made to FIG. 27 which is a schematic flow diagram illustrating the steps of an exemplary embodiment of a method or subroutine operable on an energizing pod of the present application and usable for initiating a therapy session by communicating with an implant
10 and with a patient application installed on a device included in the local subsystem 14 of FIGS. 1-2. The subroutine maybe installed on an energizing pod such as, for example, the energizing pods 19, 29 and 39 of the present application. It is noted that while in the exemplary subroutine (of FIG. 27) the patient application is installed and operates on the smartphone 11, in other embodiments, the patient application may be installed on the laptop 15 or on a tablet, phablet or
15 notebook substituting the laptop 15.

When the patient 115 wishes to start a therapy session, the patient 115 may place an energizing pod (such as, for example the pod 19 or 29 or 39) on his or her scalp above the position of the implant 10 (see FIG. 2). The patient may then initiate a therapy session by using the patient application installed on the smartphone 11

The subroutine starts by waiting for the patient application operating on the smartphone 11
20 to connect (step 396). Once the smartphone 11 is connected to the energizing pod through the patient application, the subroutine of the energizing pod receives from the patient application a command to wirelessly connect to the implant 10 (step 402). The subroutine checks whether the pod is sufficiently charged such that it has a charge level sufficient to complete a therapy session
25 (step 403). If the pod does not have a charge level sufficient to complete a therapy session, the pod notifies the patient to charge the pod (step 405) and terminates. The value of such a sufficient charge level for completing a therapy session may be set as a charge level that is sufficient to energize the implant for a "worst case scenario" therapy session which is the therapy session requiring the highest energy expenditure that is possible to deliver using the implant to which a
30 preset safety margin is added (such as, for example, an additional 20% of the charge requirement required for completing the most energy consuming type of therapy session) to account for the relevant communication processes necessary before, during and after the therapy session.

If the pod has a charge level sufficient to complete a therapeutic session, the pod initiates wireless power transmission to the implant 10 (step 404) and connects to an implant available in

proximity of the energizing pod (step 406). The subroutine checks whether the implant is registered with the energizing pod (step 408). If the implant is not registered with the energizing pod, the subroutine notifies the patient application and searches for a different implant (step 410)

It is noted that steps 408 and 410 are useful in preventing a pod from communicating with an implant that is not registered with the pod. For example, a case where the patient has two or more implants implanted in the patient's skull. For example, if the therapy the patient needs is for treating major depression, the patient may have two implants implanted in different locations in her/his skull, a first implant may be implanted in a position suitable to electrically stimulate the left dorsolateral prefrontal cortex (DLPFC) and a second implant may be implanted in the same skull in a position suitable to electrically stimulate the right DLPFC. In such an example, two pods may be needed to energize and communicate with the two implants. Since the stimulation regime to be delivered to the each one of the two pods may be different and may require a different DPF, it may be possible that a first implant may be registered with a first pod and a second implant may be registered with a second pod. Therefore, if the patient places the second pod over the first implant, in step 408 the subroutine will detect that the first implant is not registered with the second pod, may notify the patient 115 (in step 410) and may also prompt the patient 115 to use the (second) pod to search for a registered implant by repositioning the second pod near or above the second implant and transferring control to step 406 for communicating with the second implant.

In another exemplary situation, the patient may be in an environment having multiple different patients having implants. For example, two or more patients may cohabit in the same home, such as a husband and wife each having an implant. In this example, the husband may pick up a pod belonging to his wife and vice versa. If this happens, steps 408 and 410 will detect that the husband's implant is not registered with the mistakenly used wife's pod and notify the husband to pick up and use the correct pod, and vice versa.

Another possible environment where a patient's implant is not registered with a pod that the patient is trying to use is a clinic or hospital environment that may have several patients with their pods being present in the same room for testing or routine checkup.

If the implant is registered with the energizing pod, the subroutine notifies the patient application (of the smartphone 11) that the implant is connected (step 412), requests and downloads the therapy log stored on the implant (step 414), replies to a request from the patient application by sending data to the patient application indicative of the available DPF that is loaded in the energizing pod (step 416) and waits for a "start Therapy" command from the patient application or for a new DPF if a new DPF is sent from the patient application (step 418).

The subroutine checks whether the therapy requested by the patient application is within the constraints of the existing or new DPF based on the current date/time and the therapy log (step 422). The therapy log is saved on the implant in step 472 (of FIG. 29 below). The pod retrieves the therapy log from the implant in step 442 (of FIG. 28 below). This therapy log contains the needed information for the check performed in step 422. For example, if the patient has two pods and the DPF prescribes only one therapy per day. The same DPF may be uploaded to both pods of the patient. The patient may use the first pod to start a therapy session. The implant stores the session information in the log (including the time and date of the therapy session and possibly other information). After the patient initiates a therapy session using the first pod, this therapy session is logged and saved in the implant. If the patient tries to use the second pod to start another therapy session within the same day, the second pod will download the therapy log from the implant, detect that a therapy session has already been initiated within the same day and refuse to initiate the second session.

If the requested therapy is not within the constraints of the DPF, the subroutine notifies the patient application that therapy is not allowed, logs the event (step 424) and terminates. If the requested therapy is within the constraints of the DPF, the subroutine sends the therapy parameters (as an ICF) to the implant and initiates a therapy session (step 426). After the therapy session is completed, the subroutine requests an updated therapy log from the implant (step 428), wirelessly transmits the data of the therapy log to the patient application of the smartphone 11 (or another device being used) and terminates.

The data transmitted from the energizing pod to the patient app in step 430 may be transmitted to the main server(s) 12 as disclosed in detail and illustrated in FIG. 17 (see, for example, step 266 of FIG. 17).

Reference is now made to FIG. 28 which is a schematic flow diagram illustrating the steps of an exemplary implementation of a method or subroutine operating on an energizing pod for directly initiating a therapy session by using a user interface of the energizing pod, in accordance with an embodiment of the methods of the present application.

The subroutine of FIG. 28 is installed and operative on an energizing pod (such as, for example the energizing pod 19, or 19 or 39). The subroutine is usable for directly initiating a therapy session, without using the patient application installed on the smartphone 11 or on the laptop 15 or on any portable computing and communication device such as a notebook, a phablet, a tablet computer that may substitute the laptop 15.

The subroutine starts by detecting a patient command to connect to an implant (step 432). For example, the command may be entered by the patient 115 by using any part of the user

interface 32 of the pod 19 as disclosed in detail hereinabove with respect to FIG. 4. After the command to connect is detected, the subroutine checks whether the pod is sufficiently charged such that it has a charge level sufficient to complete a therapy session (step 433). If the pod does not have a charge level sufficient to complete a therapy session, the pod notifies the patient to charge the pod (step 435) and terminates. The value of such a sufficient charge level for completing a therapy session may be set as a charge level that is sufficient to energize the implant for a "worst case scenario" therapy session which is the therapy session requiring the highest energy expenditure that is possible to deliver using the implant to which a preset safety margin is added (such as, for example, an additional 20% of the charge requirement required for completing the most energy consuming type of therapy session) to account for the relevant communication processes necessary before, during and after the therapy session.

If the pod has a charge level sufficient to complete a therapeutic session, the subroutine initiates wireless power transmission (step 434) and connects to an available implant in proximity of the energizing pod (step 436). The subroutine checks if the implant is registered with the pod (step 438). If the implant is not registered with the pod, the subroutine notifies user via the user interface 32, searches for another implant until it finds another implant (step 440) and transfers control to step 438. If the energizing pod cannot find and connect to an implant, the subroutine on the energizing pod may remain in a search mode until it runs out of power.

Alternatively, in some embodiments, if the energizing pod repeats steps 438 and 440 and does not find an implant registered with the pod, after a preset time period of searching for implants (two minutes, for example), the pod will stop searching, and go to a low power (sleep) mode.

It is noted that the notification of the patient in step 440 may be performed by any of the output capable components of the user interface 32 of the pod 19. For example, such a notification should be a long beep generated by the speaker 38 or a red LED of the light source(s) turning on, or by an audio message generated by the speaker 38 (such as, for example, a voice message saying "Pod not registered"), or a text displayed on the display 44, reading "Pod not registered", or any combination of the above-described outputs.

If the implant is registered with the pod, the subroutine requests and downloads the therapy log from the implant (step 442), waits to receive a therapy "start" command entered by the patient using any of the input options available in the components of the user interface 32 (such as, for example, pressing one of the buttons 34), and (after such a start command is received) loads the latest DPF from the pod's memory 6 (Step 444). The subroutine checks whether the requested therapy is allowed within the constraints of the DPF based on the date/time and the therapy log of the energizing pod (step 446). If the requested therapy is not allowed within the constraints of the

DPF, the subroutine notifies the patient 115 that the therapy is not allowed, logs the event in the pod's log (step 448) and terminates. The notification to the patient 115 may be performed using any output means of any of the components included in the user interface 32, as disclosed in detail hereinabove. For example, the notification may be delivered by simultaneously blinking a red and an orange LED of the light sources(s) 36, or by using the speaker 38 to generate a voice message "Therapy is not allowed", or by displaying a message "therapy is not allowed" on the display 44, or by using any combination of such outputs.

If the requested therapy is allowed within the constraints of the DPF, the subroutine sends the ICF to the implant and initiates therapy (step 450). After the therapy session is completed, the subroutine requests the updated therapy log from the implant (step 452). The subroutine stores the updated implant's therapy log in the pod's memory 6 (step 454) and terminates.

The data of the stored implant's therapy log may be later transmitted to the patient application when the patient 115 has regained access to the smartphone 11 (or to the laptop 15 or to the notebook, phablet, or tablet which substitute for the laptop 15), and may then be communicated to the main server (s) 12, as disclosed in detail hereinabove for the subroutines of the patient application (operating on the smartphone 11 or laptop 15) and the subroutines operating on the main server(s) 12, respectively.

Reference is now made to FIG. 29 which is a schematic flow diagram illustrating the steps of a method or subroutine operable on an implant of the present application and usable in initiating a therapy session.

The subroutine starts by "waking up" when wireless power is received from an energizing pod (such as, for example one of the pods 19, 29 and 39) and advertises wireless data connection to the energizing pod supplying the power (step 456). The subroutine checks whether the pod is a trusted pod (step 458). For example, a trusted pod is a pod whose ID and/or other credentials are stored in a trusted pod list stored in the memory unit(s) 142 of the implant 28. Such a trusted pod list may be implemented as a look up table (LUT). If the pod is not a trusted pod, the subroutine refuses the connection, logs the event in an implant's event log (step 460) and terminates. If the pod is a trusted pod, the subroutine receives from the pod a request for the implant's therapy log and transmits the current implant's therapy log from the memory unit(s) 142 to the pod (step 462), receives an implant control file (ICF) from the pod (step 464), receives a "start therapy" command and a date/time from the pod (step 466), and checks whether the therapy parameters of the received ICF are within safety limits.

If the parameters of the ICF are not within safety limits, the subroutine notifies the energizing pod that the parameters are invalid and logs an event in the implants event log (step

469) and terminates. If the parameters of the ICF are within safety limits, the subroutine logs the initiation of a therapy session and saves the unique therapy ID and the date/time in the implants memory unit(s) 142 (step 470). After the subroutine completes the therapy session, the subroutine logs the completion of the therapy session (step 472) and terminates.

5 After a therapy session is completed, the memory 6 of the energizing pod 19 may store a log of the therapy, including any data that may have been collected by the implant 10 or by the energizing pod 19. In the absence of a data connection (link) to the smartphone 11 or the laptop 15 (or any hand-held device included in the local subsystem 14) or to a cloud resource, the energizing pod 19 may store the data until such data may be downloaded to a suitable external
10 device, such as, for example the smartphone 11, a tablet, the laptop 15 or a custom designed device (not shown). The data stored in the energizing pod 19 may include, but is not limited to, bio-signals sensed/recorded by the implant 10 (such as, for example, electrical cortical signals), data related to the status of the implant 10, therapy parameters data, the number of therapy sessions delivered to the patient 115, date and time of the therapy session, and data from the IMU 42.

15 Reference is now made to FIGS. 30A-30B which are schematic flow diagrams illustrating the steps of a method or subroutine using a trainable artificial intelligence (AI) algorithm to automatically generate a DPF for a patient, in accordance with the methods of the present application.

In some embodiments, the subroutine may be installed and operative on the main server(s)
20 12. The subroutine may start by checking whether a new DPF is due (step 502). For example, the subroutine may check if a new DPF is due by checking if the validity date/time for the latest DPF for the patient has expired. If a new DPF is not due yet, the subroutine terminates. If a new DPF is due, the subroutine checks whether the accumulated DPF number exceeds the usability threshold (step 504). The usability threshold's value may be a preset (positive) integer number that is the
25 number of previously tested DPFs that were therapeutically applies to the patient. Since for most AI algorithms a minimal set of acquired data is needed to train the AI algorithm, if the number of tested data is below the usability threshold, it may not be sufficient to generate a recommended DPF. Thus, if the accumulated number of DPFs therapeutically applied to the patient does not exceed the value of the preset usability threshold, the subroutine transfers control to step 518.

30 If the accumulated number of DPFs therapeutically applied to the patient exceeds the value of the preset usability threshold, the subroutine fetches the cumulative historical DPF data and the corresponding respective collected data representing objectively quantified parameters of use of the communication device by the patient and/or other types of EMA data collected before, during and after the delivery of the therapy sessions and/or the electrical signal data sensed and recorded

by the implant during the therapy sessions using the respective DPF parameters recorded for the patient (step 506), processes the fetched data to train the AI and to generate a recommended DPF based on the training (step 508), sends the recommended DPF to the clinicians workstation 13 over a secured link for approval (step 510), receives the clinician's response from the clinician's workstation 12 over the secured link (step 512) and checks whether the clinician approved the DPF recommended by the AI algorithm (step 514).

If the clinician did not approve the recommended DPF, the subroutine sends over a secure link to the clinician's workstation 13 a request for a manually generated DPF (step 518), receives a manually generated DPF from the clinician's workstation 13 over the secure link (step 520) and checks whether the received manually generated DPF is in conformance and safe (step 522). If the received manually generated DPF is not in conformance and safe, the subroutine notifies the clinician of the non-conformance or safety issue and, if possible, recommends a corrective action (step 524) and transfers control to step 520. If the received manually generated DPF is in conformance and safe, the subroutine creates a DPF using an encryption key, stores the DPF and transmits a notification to the clinician workstation that a new encrypted DPF is available (step 526), adds a notification to the patient notification log that a new DPF is available (step 528) and terminates. In step 514, if the clinician approved the AI recommended DPF, the subroutine transfers control to step 526.

In some embodiments, the energizing pod memory 6 may store modelled data (for example, implemented as a look up table) that is used to adjust stimulation settings in response to sensed data. For example, a look up table may be used to select an optimal set of stimulation parameters to more effectively focus stimulation based upon the calculated location and shape of a target region of tissue. The target may be calculated by the energizing pod's processor/controller 8 using any combination of data sensed by the implant 10, or sensed by multiple implants, or provided by an external device.

In some embodiments, IMU 42 of the energizing pod 19, may collect data related to head orientation and movements of the patient 115 during therapeutic sessions. This information may be used for determining the state of the patient 115 during a therapy session. The information about the state of the patient 115 may be used modify the stimulation parameters. For example, when laying down, the brain 2 of the patient 115 may shift or move relative to the implant 10 that is embedded in the skull, requiring an adjustment of stimulation parameters to focus the therapy on a precise cortical target.

In some embodiments of the systems of the present application, the energizing pod(s), implant(s), the smartphone 11, the laptop 15 or any other devices included in the local subsystem

14 and other external devices to which the energizing pods 19, 29 and 39 may connect (such as, for example, the main server(s) 12 and the clinician's workstation 13) may store secure pairing information, encryption keys, and authentication information that are used to connect to the patient's specific implant and other specific external devices securely and uniquely. This implementation has the advantage of ensuring that the energizing pods from one patient's system cannot be used with another patient's system (which could result in misuse of the system, potential harm to the user, and a compromising of private data). In some embodiments of the systems, data that is wirelessly transferred through the networked system is encrypted and data stored on individual devices is encrypted. In some embodiments, unique pairing of the networked devices occurs through a user interface on the patient's hand-held computing device. For example, modern smartphones include a wide variety of integrated biometric sensors, cameras, and other security tools (such as, for example, passwords, and multi-factor authentication) that can be leveraged to establish secure and trusted connections between networked devices.

In some embodiments, the security tools that are integrated into a handheld computational device (such as, for example, the smartphone 11, the laptop 15 etc.) are used to authenticate the user or patient and confirm the initiation of activities performed by the energizing pod and connected devices. For example, prior to initiating a therapy, a password, finger print, or facial recognition check may be performed on the patient's smart phone 11 to ensure the patient's identity and allowable permissions. In some embodiments, the security tools that are integrated into a computational device may be used to determine allowable permissions for different patients, where permissions may vary between patients. For example, a clinician using the clinician's workstation 13 may have broader permissions to change stimulation parameters and device configuration than a patient. A clinician may also have permissions to limit functions or parameters that the patient can access and change. In some embodiments, security, authentication, and permissions may be modified remotely. For example, a system reset may be initiated remotely (for example, by the main server(s) 12).

It is noted that the systems disclosed in the present application have the telemetry and computational capabilities for receiving, transmitting, processing and integrating signals having multiple different modalities, such as, for example, neuronal electrical signals (such as, for example, the cortical electrical signals sensed by the implants 10 or 28), physiological signals (such as heart rate signals sensed by the smartwatch 117), patient auditory signals sensed by the microphone 40, and movement signals sensed by the IMU 42), and patient's behavior related data (such as, for example EMA data sensed and processed by the smartphone 11), and/or collected

data representing objectively quantified parameters of use of a communication device (such as, for example, the smartphone 11) by the patient.

It is noted that while EMA data may include the collected data representing objectively quantified parameters of use of a communication device (for example, the smartphone 11) it may also include, in some embodiments, data representing self-assessment of mood by the patient based on periodic assessment of the patient's mood. For example, the communication device may be programmed to periodically present to the patient a mood self-assessment screen requesting the patient to grade his or her mood on a scale of 1-5 where a grade of 1 represents the worse mood and a grade of 5 represents the best mood of the patient.

In contrast, the collected data of step 530 of FIG. 32 includes only objectively quantified parameters of use of the communication device by the patient and does not include any subjective patient's mood self-assessment data. This may have several advantages. One advantage of such objectively quantified data is that it may be a more reliable way to determine the patient's mood because it is not based on and does not include the subjective assessment of mood by the patient which may be less reliable. Another advantage is that the acquisition of such objectively quantified data may be performed less obtrusively because it is performed automatically in the background without necessitating the periodical disturbing of the patient and the more obtrusive requesting of the patient to provide a mood self-assessment that may be inconvenient to the patient by disrupting or disturbing the patient's daily routine. Another advantage is that since the collected data is acquired automatically, it does not depend on the patient's compliance (such as, for example the patient's compliance with responding to mood self-assessment requests. Such compliance may by itself depend on the severity of the depressed mood of the patient. As the degree of patient compliance may vary and fluctuate making the subjective self-assessment of mood less reliable, the use of such automatically acquired collected data representing objectively quantified parameters of use of the communication device by the patient is advantageous as it does not depend on patient's compliance.

As opposed to the systems disclosed in GOETZ et al., the systems disclosed in the present application are patient-centric, where the patient 115 has autonomous control over the recharging of the system components of the local subsystem 14.

The systems and methods disclosed in the present application solve the limitations of the systems disclosed in WO/2012/154247 by providing the patient 115 with the possibility to control the therapy and interact with the energizing pod bi-directionally, without any other external interface components.

The flexibility of the systems and methods disclosed in the present application enables therapies to be updated remotely with low cost and low burden.

Furthermore, the systems and methods disclosed herein advantageously enable patients to have some control over therapy parameters and timing (within safe and approved limits), and protects from unsafe use or overuse of the system.

Furthermore, in some embodiments, the implants of the present application may include any combination of stimulation and sensing units. For example, stimulation units may include any combination of electrical, magnetic, ultrasonic, micro-fluidic drug, or mechanical stimulation used for therapeutic or augmentative applications. Sensing units may include any combination of electrical, magnetic, ultrasonic, micro-fluidic, electro-chemical or mechanical sensing used for therapeutic or augmentative applications. In some embodiments, the implants may have only stimulation.

In some embodiments, stimulation may be triggered by data sensed by the implant and may involve processing of sensed data with algorithms implemented on the processor/controller and the memory unit(s) to enable closed loop applications.

While the exemplary implants of the present application include a power receiving unit that couples to a power transmitting unit within the energizing pod, such that it receives power from the energizing pod, in some embodiments, the transfer of power is implemented through any combination of inductive, resonant inductive, radiofrequency, volume conductive, optical, or ultrasonic couplings between the implant and energizing pod.

It is noted that while in the examples of the implants disclosed hereinabove there is no internal energy storage device and the implant is directly powered by the energizing pod, this is not obligatory. In some embodiments, the implant (such as, for example, the implants 10 and 28) may include a small energy storage device suitable for temporarily maintaining power during brief periods where the wireless power transfer from the energizing pod is lost. For example, such an energy storage device may be a supercapacitor or any other suitable capacitor.

In some embodiments, the implant may include an energy storage device having a high volumetric energy density that may support primary use of the implants functions and may be periodically re-charged. Such energy storage devices (not shown in detail in FIGS 1 and 4, for the sake of clarity of illustration), may include high energy density rechargeable batteries, high energy density capacitors, and high energy density super capacitors that may provide enough power for performing at least one therapy session before requiring recharging. In such embodiments, the internal high energy density storage device(s) may be recharged between therapy sessions by placing the energizing pod (such as, for example the energizing pods 19, 29 and 39) on the scalp

of the patient 115 as disclosed in detail hereinabove and initiating a charging session. For example, such a charging session may be initiated by using the user interface 32 of the energizing pod to provide a charging command input. In some non-limiting examples, the charging command may be performed by pressing and holding pressed the multifunction button 34 of the energizing pod 39 for 20 seconds and then placing the energizing pod 39 on the scalp over the implant. In another example, the charging command may be performed by a voice command input using the microphone 40 and voice recognition software operating on the processor/controller 8 of the energizing pod 19. In such an embodiment, after the charging session the energizing pod may be removed from the scalp of the patient after the initiation of the therapy session, since the energy storage device of the implant may have sufficient charge to perform an entire therapy session without requiring power from the energizing pod. Such embodiments of the implant may advantageously allow the patient to undergo a therapy session without having to have the energizing pod attached to the scalp (for example, while taking a shower, meeting with friends or any other activity in which the placing of the pod on the scalp may not be possible or may be embarrassing or inconvenient to the patient).

Furthermore, the systems disclosed herein have additional modularity and flexibility by allowing the patient 115 to temporarily conduct therapeutic sessions even in the absence of certain components of the local subsystem 14 at least for a certain period of time. For example, the patient 115 may start a therapy session by using either the smartphone 11, or the laptop 15, or by using only the energizing pod(s) 19, 29 and 39 (in the absence of the smartphone 11 or the laptop 15).

It will be appreciated that while the systems and devices disclosed in the present application make use of an implant (such as, for example, the implants 10 and 28) that are implanted in the skull of the patient 115 and deliver therapy by delivering therapeutic electrical signals to the cortex 50 of the patient 115 for treating depression, this is by no means intended to limit the scope of the systems and methods disclosed herein. Rather, the systems and methods of the present application may be adapted for treatment of many other neurological or neuropsychiatric disorders such as, for example, any type of depressive disorder, bipolar disorder, obesity, obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD), attention deficit hyperactivity disorder (ADHD), ADD, schizophrenia, an eating disorder (such as, for example, obesity, bulimia, anorexia) and epilepsy by suitably changing the site of implantation of the implants 10 or 28 to deliver therapeutic signals to various different cortical regions, depending on the particular disorder being treated.

It is noted that in some embodiments of the system, methods programs, external communication device(s) and energizing pods disclosed hereinabove, in addition to delivering

electrical signal therapy sessions to the patient, the systems and methods may also be able to provide to the patient supplemental therapy sessions, such as, for example, playing a game using the portable communication device, listening to music using the portable communication device, delivering therapeutic visual stimulation using the portable communication device, delivering therapeutic audio stimulation using the portable communication device, prompting a sleep session, providing dietary instructions, prompting physical exercise and any combinations thereof. Such supplemental therapy sessions may be provided at any time before, during or after the electrical therapy sessions described above.

For example, after an electrical therapy session, the smartphone 11 may prompt the patient to take a nap. In another example, before or after an electrical therapy session, the smartphone 11 may present to the patient a prompt screen offering listening to music using earphones connected to the smartphone 11. In another example, during the delivery of an electrical stimulation session, the smartphone 11 may offer to the patient to watch visual or audio-visual stimuli presented on the display of the smartphone 11 and/or the speaker of the smartphone 11 or earphones connected to the smartphone 11. In another example, prior to or after an electrical stimulation session, the smartphone 11 may present a message to the patient to perform a brief physical exercise (such as, for example, performing pushups and/or other gymnastic exercises, or practicing Tai Chi). In another example, before or after an electrical therapy session, the smartphone 11 may provide the patient with instruction to avoid consuming certain foods or beverages or may recommend eating certain foods or beverages (for example avoiding alcoholic drinks).

It is noted that in some embodiments, such supplemental therapy sessions may be triggered by the delivery of an electrical therapy session or by the patient's request to deliver an electrical therapy session.

In some embodiments, such supplemental therapies may be prescribed to the patient 115 by the clinician in a manner which does not depend on the delivery of an electrical therapy sessions. For example, the DPF may include (optional) data fields specifying some parameters of such supplemental therapy sessions. Such parameters may include, the timing of delivery of a supplemental therapy session and the duration of a supplemental therapy session. In an example, The DPF may include data specifying that an audiovisual or audio supplemental therapy with a duration of 10 minutes should be delivered (or offered) to the patient twice daily at 10:00 and 19:00, irrespective of any electrical therapy delivered to the patient during the day or the absence of such electrical therapy on that day.

When a supplemental therapy is delivered to a patient before during or after an electrical therapy session it may advantageously have a synergistic effect increasing the overall therapeutic

efficacy as compared to only delivering an electrical therapy session without a supplemental therapy session.

It is also noted that while the implants 10 and 28 are implanted in the skull of the patient 115, this is not obligatory for practicing the invention and that the systems disclosed herein may include implantable device(s) located elsewhere within the body, such as, for example, a drug pump implanted in the patient's body, an implant for stimulating or inhibiting a nerve (such as, for example, the vagus nerve or a cranial nerve) or any other suitable implant.

Moreover, as security and privacy of the DPF and data transfer between the various components of the systems of the present application is warranted for safe and secure use, in some embodiments, the secure transfer of the DPF and/or other data may include, but is not limited to, any combination of encrypted links, authentication methods (including multi-factor authentication), secure sockets, digital certificates, and block-chain technologies. Encryption may include asymmetric or symmetric implementations, though symmetric implementations (like AES) are viewed as advantageous due to its more flexible implementation across the multiple devices described herein. Multi-factor authentication may include, but is not limited to, a user password, thumb print, iris scan, retinal scan, facial recognition, and voice recognition. Multi-factor authentication has become well-established in devices like smartphones and may be implemented in any of the devices and systems of the present application. Block-chain methods are well-suited for managing and securing the digital prescription data files of the present application, and may have greater security compared to traditional client-server networks, and can be readily implemented via cloud services.

It is noted that with respect to the communication device or devices of the systems disclosed herein and the EMA data and/or the collected data representing objectively quantified parameters of use of such devices by the patient, when using the term "call" or "calls" made by the patient, such calls are not limited to telephone calls made by the patient using a mobile phone or a smartphone or a cellular telephone or a tablet having a cellular SIM or supporting e-SIM technology (Virtual SIM) installed therein which use cellular communication protocols. Rather, the term "call" or "calls" is used in the present application in a broader sense and means any type of call performed on any device using any type of communication protocol. For example, a call may be performed by using VoIP (voice over internet protocol) or VoWiFi (voice over WiFi protocol) from a smartphone or a mobile phone or a tablet or a phablet or a laptop which has a suitable software application installed therein and that has access to the internet using cellular data protocols and/or WiFi protocols. Examples of such software applications may include "WhatsApp", "Skype", "ICQ", "Messenger", or any other application that enables performing

voice calls over the Internet. Thus, the terms “call” and “calls” refer to voice call(s) performed using any type of telephony or communication methods.

It is the intent of the applicant(s) that all publications, patents and patent applications referred to in this specification are to be incorporated in their entirety by reference into the specification, as if each individual publication, patent or patent application was specifically and individually noted when referenced that it is to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting. In addition, any priority document(s) of this application is/are hereby incorporated herein by reference in its/their entirety.

WHAT IS CLAIMED IS:

1. An energizing pod for wirelessly energizing an implant implanted in a patient, the implant is configured for delivering electrical therapy sessions to a brain of the patient, the energizing pod comprising:

a housing;

an attachment mechanism for positioning the energizing pod on the skin of the patient and for aligning the energizing pod over the implant;

a power transmitting module disposed within the housing and configured for wirelessly energizing the implant;

one or more transceivers disposed within the housing and configured for wirelessly communicating with the implant and with an external communication device having data processing capability;

a processor/controller disposed within the housing and operatively connected to the power transmitting module and the transceiver module, the processor/controller is configured for controlling the operation of the power transmitting module, controlling the receiving and transmitting operation of the one or more transceivers, the processor/controller is configured for controlling the operation of the implant by processing an implant control data file (ICF) and/or a digital prescription data file (DPF) received from the external communication device, wherein the DPF received from the external communication device comprises at least a first set of DPF data representing clinician preselected therapy parameter values that cannot be modified by the patient and a second set of DPF data representing ranges of one or more patient modifiable therapy parameters, wherein the external communication device is programmed to allow the patient to determine values of the one or more patient modifiable therapy parameters to be used in an electrical therapy session and to transmit to the energizing pod the ICF including at least a first set of ICF data representing the clinician preselected therapy parameter values and a second set of ICF data representing one or more therapy parameter values determined by the patient using the external communication device;

a memory disposed within the housing and operatively coupled to the processor/controller unit; and

a power source disposed within the housing and electrically connected to the processor/controller, the power transmitting module and the one or more transceivers to provide power thereto.

2. The energizing pod according to claim 1, wherein the ICF also includes data selected from, an ICF version number, a unique therapy session identifier, data representing a copy of the DPF data, a Hash or CRC for checking data integrity, and any combinations thereof.

3. The energizing pod according to any one of claims 1-2, wherein the therapy parameters are selected from, number of sensing and/or stimulating channels of the implant to be used, configuration of sensing and/or stimulating electrodes in a channel, number of sensing and/or stimulating electrodes in a channel, voltage pulse width, voltage pulse amplitude, inter-pulse time interval, voltage pulse shape, voltage pulse polarity, number of pulses in a pulse train, frequency of pulses in a pulse train, pulse train duration, number of pulse bursts in a pulse burst train, number of pulse burst trains in a therapy session, inter-burst time interval, number of pulses in a pulse burst, frequency of pulses in a pulse burst, timing of each pulse in a pulse burst, duration of a pulse burst, burst train duration, time interval between consecutive pulse trains, the total number of pulses in a therapy session, and any non-redundant combinations thereof.

4. The energizing pod according to any one of claims 1-3, wherein the implant includes one or more stimulating electrodes and the electrical therapy sessions delivered to the patient comprises electrical signals delivered to the brain of the patient.

5. The energizing pod according to any one of claims 1-4, wherein the attachment mechanism is selected from, a magnet attached to or included within the housing, a headband attached to the housing, a flexible strip of material attached to the housing, a cap attached to the housing and wearable on the head of the patient, a spectacle or spectacle-like framework wearable on the patient's head, optical glasses, sunglasses and an xR device.

6. The energizing pod according to any one of claims 1-3, wherein the DPF also includes data selected from, data representing a DPF version number, data representing a unique DPF identifier, data representing approved energizing pod(s) unique identifier(s), data representing approved implant(s) unique identifier(s), data representing DPF creation time and date, data representing DPF expiration time and date, data representing a total permissible number of therapy sessions allowed within a DPF validity time period, data representing a minimum and/or a maximum and/or recommended time allowable between therapy sessions, a digital signature, a CRC, and any combinations thereof.

7. The energizing pod according to any one of claims 1-3 and 6, wherein the external communication device is selected from, a smartphone, a laptop, a tablet, a phablet, a smartwatch and any combination thereof.

8. The energizing pod according to any one of claims 1-3 and 6-7, wherein the DPF is received by the external communication device over the internet.

9. The energizing pod according any one of claims 7-8, wherein the external communication device is a smartphone, wherein the DPF is received by the smartphone over the internet, and wherein the selecting of values of the patient modifiable parameters is performed by the patient using a parameter setting screen displayed on a display of the smartphone and the parameter values selected by the patient are communicated by the smartphone in the ICF to a transceiver of the one or more transceivers of the energizing pod.

10. The energizing pod according any one of the preceding claims, wherein the energizing pod includes a user interface and wherein the external communication device transmits the DPF to the energizing pod for storage in the memory of the energizing pod.

11. The energizing pod according to claim 10, wherein the selecting of the values of the patient modifiable therapy parameters by the patient is performed using the user interface of the energizing pod and the DPF stored in the memory of the energizing pod.

12. The energizing pod according to any one of claims 10-11, wherein the user interface comprises interface components selected from, one or more mechanical buttons, one or more capacitive buttons, one or more microphones, one or more light sources, one or more speakers, one or more displays, one or more inertial measuring units (IMU), one or more cameras, one or more photosensors and any combinations thereof.

13. The energizing pod according to any one of claims 1-3 and 6-9, wherein the energizing pod includes a user interface, wherein the ICF also includes at least the first set of DPF data and the second set of DPF data and wherein the ICF is transmitted by the external communication device to the energizing pod for storage in the memory of the energizing pod.

14. The energizing pod according to any one of claims 10-13, wherein the selecting of the values of the patient modifiable parameters by the patient is performed using the user interface of the energizing pod, the first set of DPF data and the second set of DPF data.

15. The energizing pod according to claim 10, wherein the user interface comprises interface components selected from, one or more mechanical buttons, one or more capacitive buttons, one or more microphones, one or more touch sensitive input devices, one or more light sources, one or more speakers, one or more displays, one or more inertial measuring units (IMU), one or more cameras, one or more photosensors and any combinations thereof.

16. The energizing pod according to claim 1, wherein the energizing pod includes a user interface and the ICF also includes the entire data contents of the DPF.

17. The energizing pod according to claim 16, wherein the selecting of the values of the patient modifiable parameters by the patient is performed using the user interface of the energizing pod and the ICF.

18. The energizing pod according to any one of claims 16-17, wherein the user interface comprises interface components selected from, one or more mechanical buttons, one or more capacitive buttons, one or more microphones, one or more touch sensitive input devices, one or more light sources, one or more speakers, one or more displays, one or more inertial measuring units (IMU), one or more cameras, one or more photosensors and any combinations thereof.

19. The energizing pod according to any one of the preceding claims, wherein the power source is selected from a rechargeable power source and a non-rechargeable power source.

20. The energizing pod according to claim 1, wherein the power source is a rechargeable power source and wherein charging of the power source is performed using a method selected from,

wired charging using charging contacts included in the energizing pod,

wireless charging using a charging induction coil included in the energizing pod, and

a combination of wired and wireless charging using charging contacts included in the energizing pod and a charging induction coil included in the energizing pod, wherein the charging of the energizing pod may be either wired or wireless.

21. The energizing pod according to claim 1, wherein the one or more transceivers include a first transceiver for wirelessly transmitting data to the external communication device and for receiving data and control signals from the external communication device and a second

transceiver for transmitting data and/or control signals to the implant and for receiving data from the implant.

22. The energizing pod according to claim 21, wherein the second transceiver is also configured for transmitting power to a power harvesting module included in the implant.

23. The energizing pod according to any one of the preceding claims, wherein the energizing pod is programmed to receive from the implant, after each therapy session, data including one or more of, a therapy log data and data representing electrical signals recorded from the brain of the patient by one or more sensing electrodes included in the implant.

24. The energizing pod according to claim 23, wherein the first set of DPF data also includes data representing values of sensing parameters and wherein the sensing parameters are selected from, number of sensing electrodes to be used for sensing, configuration of sensing electrodes to be used for sensing, duration of a sensing time period(s) to be used, time of initiation of sensing period(s) with respect to timing of stimulation periods, time to start sensing, sampling frequency of sensing, sensing filter configuration, and any combinations thereof.

25. The energizing pod according to any one of the preceding claims, wherein the energizing pod is programmed to enter a locked state in which a therapy session cannot be initiated if the voltage level of the power source is lower than a voltage threshold value or if the time interval T_s that passed since the last date and time synchronization of an internal clock of the energizing pod was performed is greater than a preset value X.

26. The energizing pod according to any one of the preceding claims, wherein the energizing pod is programmed to enable a therapy session to be delivered to the patient only by an implant that is pre-registered with the energizing pod.

27. The energizing pod according to any one of the preceding claims, wherein each of the therapy parameter ranges of the first set of DPF data and the second set of DPF data includes a minimum parameter value, a maximum parameter value and a default parameter value.

28. The energizing pod according to claim 27, wherein for one or more parameters in the first set of DPF data the minimum parameter value, and the maximum parameter value are equal to the default parameter value.

29. The energizing pod according to claim 28, wherein for each parameter in the second set of DPF data the minimum parameter value and the maximum parameter value are different than the default parameter value.

30. The energizing pod according to any one of the preceding claims, wherein the energizing pod and the external communication device are programmed to simultaneously store a plurality of different DPFs.

31. The energizing pod according to claim 30, wherein the external communication device and the energizing pod are programmed to enable the patient to select a specific DPF from the plurality of DPFs for use in delivering a therapy session.

32. The energizing pod according to any one of the preceding claims, wherein the second set of DPF data includes data representing a bundled parameter comprising two or more single stimulation parameters, wherein the selection by the patient of a value for a bundled parameter results in setting of parameter values for the two or more single stimulation parameters in the ICF.

33. The energizing pod according to any one of the preceding claims, wherein the DPF also includes data representing instructions to offer the patient supplemental therapy sessions different than the electrical therapy sessions, before, during or after an electrical therapy session.

34. The energizing pod according to claim 33, wherein the supplemental therapy sessions are selected from, playing a game using the external communication device, listening to music using the external communication device, delivering therapeutic visual stimulation using the external communication device, delivering therapeutic audio stimulation using the external communication device, prompting a sleep session, providing dietary instructions, prompting physical exercise and any combinations thereof.

35. The energizing pod according to any one of the preceding claims, wherein the site of implantation of the implant and the electrical therapy sessions are adapted to treat a disorder selected from depression, major depression, drug resistant depression, ADHD, ADD, anxiety

disorder, OCD, schizophrenia, bipolar disorder, an eating disorder, obesity, bulimia, anorexia, and PTSD.

36. The energizing pod according to any one of the preceding claims, wherein the first set of DPF data also includes for each clinician preselected therapy parameter a minimum parameter value and a maximum parameter value.

37. A method of communication of data between the energizing pod of claim 1, the external communication device of claim 1 and the implant of claim 1, the method comprising the steps of:

receiving by the external communication device over the internet the DPF of claim 1;

allowing the patient of claim 1 to set stimulation parameter values for the second set of DPF data;

generating the implant control data file (ICF) of claim 1 from the stimulation parameter values set by the patient and from the clinician preselected values of therapy parameters included in the first set of DPF data; and

transmitting the ICF from the external communication device to the energizing pod for storage and/or for transmission to the implant.

38. The method according to claim 37, wherein the step of generating comprises including some or all of the data of the DPF in the ICF.

39. The method according to any one of claims 37-38, wherein the method also includes the step of transmitting a command to the energizing pod to wirelessly transmit the ICF from the energizing pod to the implant.

40. A computing device implemented method for controlling the delivery of electrical therapy to the brain of a patient by an implant implanted in the patient, the method comprising the steps of,

receiving over the internet and processing a digital prescription data file (DPF) remotely generated by a clinician, the DPF comprises at least a first set of DPF data representing clinician preselected therapy parameter values that cannot be modified by the patient and a second set of DPF data representing value ranges of one or more patient modifiable therapy parameters;

providing output to the patient enabling the patient to select a value for each of the one or more patient modifiable therapy parameters;

receiving from the patient input representing selected values for each of the one or more patient modifiable therapy parameters;

generating an implant control file (ICF) including at least the clinician preselected therapy parameter values and the values selected by the patient for the one or more patient modifiable therapy parameters; and

transmitting the ICF to an energizing pod configured for energizing the implant and for transmitting the ICF to the implant for controlling the operation of the implant.

41. The method according to claim 40, wherein the step of providing output and the second step of receiving are performed by a user interface included in the computing device.

42. The method according to claim 41, wherein the user interface is selected from a visual user interface, an audio user interface, a tactile user interface, and any combination thereof.

43. The method according to any one of claims 41-42, wherein the user interface is selected from, a touch sensitive input device, a microphone, a speaker, a physical keyboard, a virtual keyboard displayed on a touch sensitive display, one or more light sources, a camera, a photosensor and any combination thereof.

44. The method according to any one of claims 40-43, wherein the DPF also includes data selected from, data representing a DPF version number, data representing a unique DPF identifier, data representing approved energizing pod(s) unique identifier(s), data representing approved implant(s) unique identifier(s), data representing DPF creation time and date, data representing DPF expiration time and date, data representing a total permissible number of therapy sessions allowed within a DPF validity time period, data representing a minimum and/or a maximum and/or recommended time allowable between therapy sessions, a digital signature, a hash or CRC data and any combinations thereof.

45. The method according to any one of claims 40-44, wherein the ICF also includes data selected from, an ICF version number, a unique therapy session identifier, data representing a copy of the DPF data, a Hash or CRC data for checking data integrity, and any combinations thereof.

46. The method according to any one of claims 40-45, wherein each parameter of the second set of DPF data includes a minimum parameter value, a maximum parameter value and a default parameter value, and wherein the second step of receiving includes the step of using the default parameter value as the value of the patient modifiable therapy parameter of the ICF if the patient does not provide input representing the parameter value within a preset time interval starting from presenting a parameter value selection screen.

47. The method according to any one of claims 40-46, wherein the computing device is selected from, a smartphone, a laptop, a tablet, a phablet, and a smartwatch.

48. The method according to any one of claims 40-47, wherein the method also includes the steps of automatically acquiring collected data representing objectively quantified parameters of use of the computing device by the patient.

49. The method according to claim 48, wherein the method also includes the step of wirelessly sending the collected data to another computer over the internet.

50. A data processing device comprising means for carrying out the method of any one of claims 40-49.

51. A program for a data processing device, the program comprising instructions which, when the program is executed by the data processing device, cause the data processing device to carry out the method of any one of claims 40-49.

52. A computer readable medium comprising instructions which, when executed by a computer, cause the computer to carry out the method of any one of claims 40-49.

53. A communication device usable by a patient, the patient has an implant configured for delivering electrical therapy sessions to a brain of the patient, the communication device comprising:

a processor/controller;

a memory operatively coupled to the processor/controller;

a user interface operatively connected to the processor/controller for providing output to the patient and for receiving input from the patient; and

a power source for energizing the processor/controller, the memory and the user interface, wherein the communication device is programmed by a software application stored in the memory for,

receiving over the internet and processing a digital prescription data file (DPF) remotely generated by a clinician, the DPF comprises at least a first set of DPF data representing clinician preselected therapy parameter values that cannot be modified by the patient and a second set of DPF data representing value ranges of one or more patient modifiable therapy parameters,

providing output to the patient enabling the patient to select a value for each of the one or more patient modifiable therapy parameters,

receiving from the patient input representing selected values for each of the one or more patient modifiable therapy parameters,

generating an implant control file (ICF) including at least the clinician preselected therapy parameter values and the values selected by the patient for the one or more patient modifiable therapy parameters,

storing the ICF in the memory, and

transmitting the ICF to an energizing pod configured for energizing the implant and for transmitting the ICF to the implant for controlling the operation of the implant.

54. The communication device according to claim 53, wherein the user interface is selected from, a touch sensitive display, a microphone, a touch sensitive input device, a speaker, a physical keyboard, a virtual keyboard displayed on a touch sensitive display, one or more light sources, a camera and any combination thereof.

55. The communication device according to any one of claims 53-54, wherein the DPF also includes data selected from, data representing a DPF version number, data representing a unique DPF identifier, data representing approved energizing pod(s) unique identifier(s), data representing approved implant(s) unique identifier(s), data representing DPF creation time and date, data representing DPF expiration time and date, data representing a total permissible number of therapy sessions allowed within a DPF validity time period, data representing a minimum and/or a maximum and/or a recommended time allowable between therapy sessions, a digital signature, CRC and any combinations thereof.

56. The communication device according to any one of claims 53-55, wherein the ICF also includes data selected from, an ICF version number, a unique therapy session identifier, data representing a copy of the DPF data, a Hash or CRC for checking data integrity, and any combinations thereof.

57. The communication device according to any one of claims 53-56, wherein each parameter of the second set of DPF data includes a minimum parameter value, a maximum parameter value and a default parameter value, and wherein the second step of receiving includes the step of using the default parameter value as the value of the patient modifiable therapy parameter of the ICF if the patient does not provide input representing the parameter value within a preset time interval starting from presenting a parameter value selection screen.

58. The communication device according to any one of claims 53-57, wherein the communication device is programmed to automatically acquire collected data representing objectively quantified parameters of use of the communication device by the patient and to wirelessly send the collected data to a computer or server over the internet.

59. The communication device according to any one of claims 53-58, wherein the communication device is programmed to receive from the energizing pod, after a therapy session, data including one or more of, a therapy log data and data representing electrical signals recorded from the brain of the patient by one or more sensing electrodes included in the implant.

60. The communication device according to any one of claims 53-59, wherein the first set of DPF data also includes data representing values of sensing parameters.

61. The communication device according to claim 60, wherein the sensing parameters are selected from, a number of sensing electrodes to be used for sensing, a configuration of sensing electrodes to be used for sensing, a duration of a sensing time period(s) to be used, a time of initiation of sensing period(s) with respect to timing of stimulation periods, and any combinations thereof.

62. The communication device according to any one of claims 53-61, wherein the communication device is selected from, a smartphone, a laptop, a tablet, a phablet, and a smartwatch.

63. A system for controlling the delivery of electrical therapy sessions to the brain of a patient, the system comprising,

an implant implantable in the head of the patient, the implant includes at least one processor/controller, a memory operatively connected to the processor/controller, a plurality of electrical signal generators operatively connected to the processor/controller and two or more stimulating electrodes electrically connected to the electrical signal generators, the implant is configured for delivering electrical therapeutic signals to the brain of the patient; and

a local subsystem including at least a first portable communication device having processing power and at least one energizing pod for wirelessly energizing the implant and for wirelessly communicating with the implant, the at least first communication device is programmed for wirelessly communicating with the energizing pod, and is programmed for,

receiving over the internet and storing a digital prescription data file (DPF) remotely generated by a clinician, the DPF includes at least a first set of DPF data representing one or more values of therapy parameters set by the clinician and at least a second set of DPF data representing a range of values and a default value for each therapy parameter of the patient modifiable therapy parameters,

presenting to the patient on the first communication device the second set of DPF data to allow the patient to select a single value from each range of patient modifiable parameter values,

receiving from the patient a third set of DPF data representing a patient selected parameter value for each one of the patient modifiable therapy parameter values,

generating an implant control data file (ICF) comprising at least the first set of DPF data and the third set of data; and

Wirelessly transmitting the ICF to the at least one energizing pod for wirelessly transmitting the ICF to the implant for controlling the operation of the implant.

64. The system according to claim 63, wherein the at least first portable communication device is selected from, one or more smartphones, one or more laptops, one or more tablets, one or more phablets, one or more smart watches, and any combinations thereof.

65. The system according to any one of claims 63-64, wherein the first set of DPF data also includes data representing DPF expiration time and date.

66. The system according to any one of claims 63-65, wherein the first set of DPF data also includes one or more data selected from, data representing a DPF version number, data representing a unique DPF identifier, data representing approved energizing pod(s) unique identifier(s), data representing approved implant(s) unique identifier(s), data representing DPF creation time and date, data representing DPF expiration time and date, data representing a total permissible number of therapy sessions allowed within a DPF validity time period, data representing a minimum and/or a maximum and/or a recommended time allowable between therapy sessions, a digital signature, CRC data and any combinations thereof.

67. The system according to any one of claims 63-66, wherein the therapy parameters are selected from, a number of stimulating channels of the implant to be used, a configuration of stimulating electrodes in each channel, a number of stimulating electrodes in each channel, a voltage pulse width, a voltage pulse amplitude, an inter-pulse time interval, a voltage pulse shape, a voltage pulse polarity, a number of pulses in a pulse train, a frequency of pulses in a pulse train, a pulse train duration, a number of pulse bursts in a pulse burst train, a number of pulse burst trains in a therapy session, an inter-burst time interval, a number of pulses in a pulse burst, a frequency of pulses in a pulse burst, a timing of each pulse in a pulse burst, a duration of a pulse burst, a burst train duration, a time interval between consecutive pulse trains, a total number of pulses in a therapy session, and any non-redundant combinations thereof.

68. The system according to any one of claims 63-67, wherein the implant also includes one or more sensing electrodes operatively connected to one or more amplifiers for recording electrical signals from the brain of the patient.

69. The system according to any one of claims 63-68, wherein the therapy parameters are selected from, a number of sensing and/or stimulating channels of the implant to be used, a configuration of sensing and/or stimulating electrodes in a channel, a number of sensing and/or stimulating electrodes in a channel, a voltage pulse width, a voltage pulse amplitude, an inter-pulse time interval, a voltage pulse shape, a voltage pulse polarity, a number of pulses in a pulse train, a frequency of pulses in a pulse train, a pulse train duration, a number of pulse bursts in a pulse burst train, a number of pulse burst trains in a therapy session, an inter-burst time interval, a number of pulses in a pulse burst, a frequency of pulses in a pulse burst, a timing of each pulse in a pulse burst, a duration of a pulse burst, a burst train duration, a time interval between consecutive

pulse trains, a total number of pulses in a therapy session, and any non-redundant combinations thereof.

70. The system according to any one of claims 63-69, wherein the energizing pod and the at least one communication device are programmed to simultaneously store a plurality of different DPFs.

71. The system according to any one of claims 63-70, wherein the ICF also includes data selected from, an ICF version number, a unique therapy session identifier, data representing a copy of the DPF data, a Hash or CRC for checking data integrity, and any combinations thereof.

72. The system according to any one of claims 63-71, wherein the energizing pod is programmed to enable a therapy session to be delivered to the patient only by an implant that is pre-registered with the energizing pod.

73. The system according to any one of claims 63-72, wherein the energizing pod and the portable communication device are programmed to simultaneously store a plurality of different DPFs.

74. The system according to claim 73, wherein the external communication device and the energizing pod are programmed to enable the patient to select a specific DPF from the plurality of DPFs for use in delivering a therapy session.

75. The system according to any one of claims 63-74, wherein the second set of DPF data includes data representing a bundled parameter comprising two or more single stimulation parameters, wherein the selection by the patient of a value for a bundled parameter results in setting of parameter values for the two or more single stimulation parameters in the ICF.

76. The system according to any one of claims 63-75, wherein the DPF also includes data representing instructions to deliver to the patient supplemental therapy sessions different than the electrical therapy sessions, before, during or after an electrical therapy session.

77. The system according to claim 76, wherein the supplemental therapy sessions are selected from, playing a game using the portable communication device, listening to music using

the portable communication device, delivering therapeutic visual stimulation using the portable communication device, delivering therapeutic audio stimulation using the portable communication device, prompting a sleep session, providing dietary instructions, prompting physical exercise, and any combinations thereof.

78. The system according to any one of claims 63-77, wherein the site of implantation of the implant and the electrical therapy sessions are adapted to treat a disorder selected from depression, major depression, drug resistant depression, ADHD, ADD, anxiety disorder, OCD, schizophrenia, bipolar disorder, an eating disorder, obesity, bulimia, anorexia and PTSD.

79. The computing device implemented method according to claim 48, wherein the computing device is also a communication device and wherein the collected data representing objectively quantified parameters of use of communication device by the patient comprises data selected from one or more of, data representing use of one or more software applications of the portable communication device by the patient, data representing a number and/or frequency of calls made by the patient using the portable communication device, data representing a number or frequency of SMS text messages sent by the patient using the portable communication device, data representing the duration of phone calls made by the patient using the portable communication device, data representing the total number of times the screen of the portable communication device is turned on per day, data representing the total amount of patient's screen time per day, data representing acceleration of the portable communication device, data representing the frequency of use and/or the total time of use of one or more software applications installed on the portable communication device, data representing the frequency of use and/or the total time of use of the one or more software applications categorized by application category, data representing the number of photos taken by the patient per day using the portable communication device, patient's call log data, patient's social network data, and any combinations thereof.

80. The communication device according to claim 58, wherein the collected data representing objectively quantified parameters of use of the communication device by the patient, comprises data selected from one or more of, data representing use of one or more software applications of the portable communication device by the patient, data representing a number and/or frequency of calls made by the patient using the portable communication device, data representing a number or frequency of SMS text messages sent by the patient using the portable communication device, data representing the duration of phone calls made by the patient using the portable communication device, data representing the total number of times the screen of the portable communication device is turned on per day, data representing the total amount of patient's

screen time per day, data representing acceleration of the portable communication device, data representing the frequency of use and/or the total time of use of one or more software applications installed on the portable communication device, data representing the frequency of use and/or the total time of use of the one or more software applications categorized by application category, data representing the number of photos taken by the patient per day using the portable communication device, patient's call log data, patient's social network data, and any combinations thereof.

81. The system according to any one of claims 63-78, wherein the at least first communication device is also programmed for automatically acquiring collected data representing objectively quantified parameters of use of the at least first communication device by the patient.

82. The system according to claim 81, wherein the collected data representing objectively quantified parameters of use of the at least first portable communication device by the patient, comprises data selected from one or more of, data representing use of one or more software applications of the portable communication device by the patient, data representing a number and/or frequency of calls made by the patient using the portable communication device, data representing a number or frequency of SMS text messages sent by the patient using the portable communication device, data representing the duration of phone calls made by the patient using the portable communication device, data representing the total number of times the screen of the portable communication device is turned on per day, data representing the total amount of patient's screen time per day, data representing acceleration of the portable communication device, data representing the frequency of use and/or the total time of use of one or more software applications installed on the portable communication device, data representing the frequency of use and/or the total time of use of the one or more software applications categorized by application category, data representing the number of photos taken by the patient per day using the portable communication device, patient's call log data, patient's social network data, and any combinations thereof.

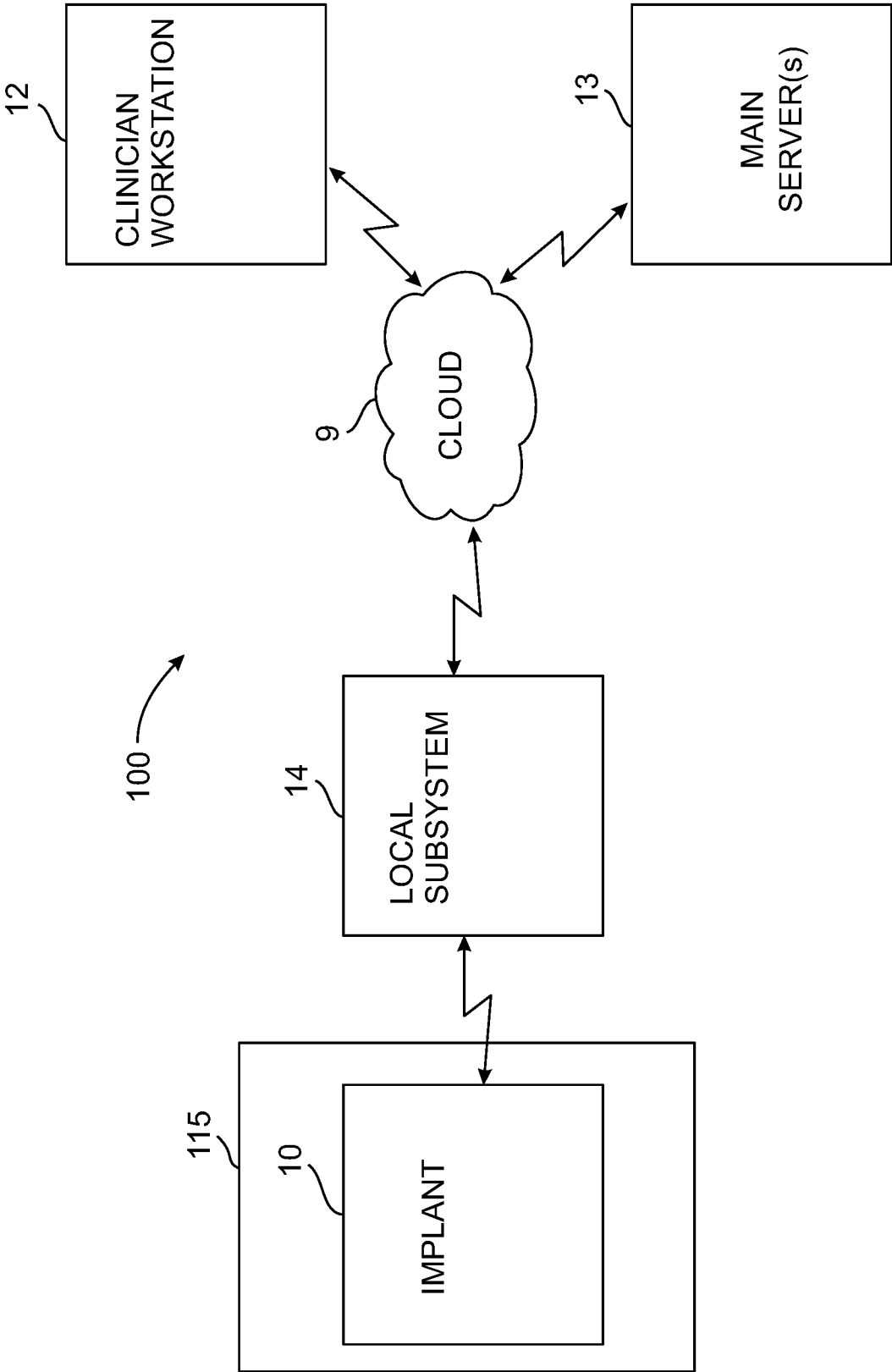


FIG. 1

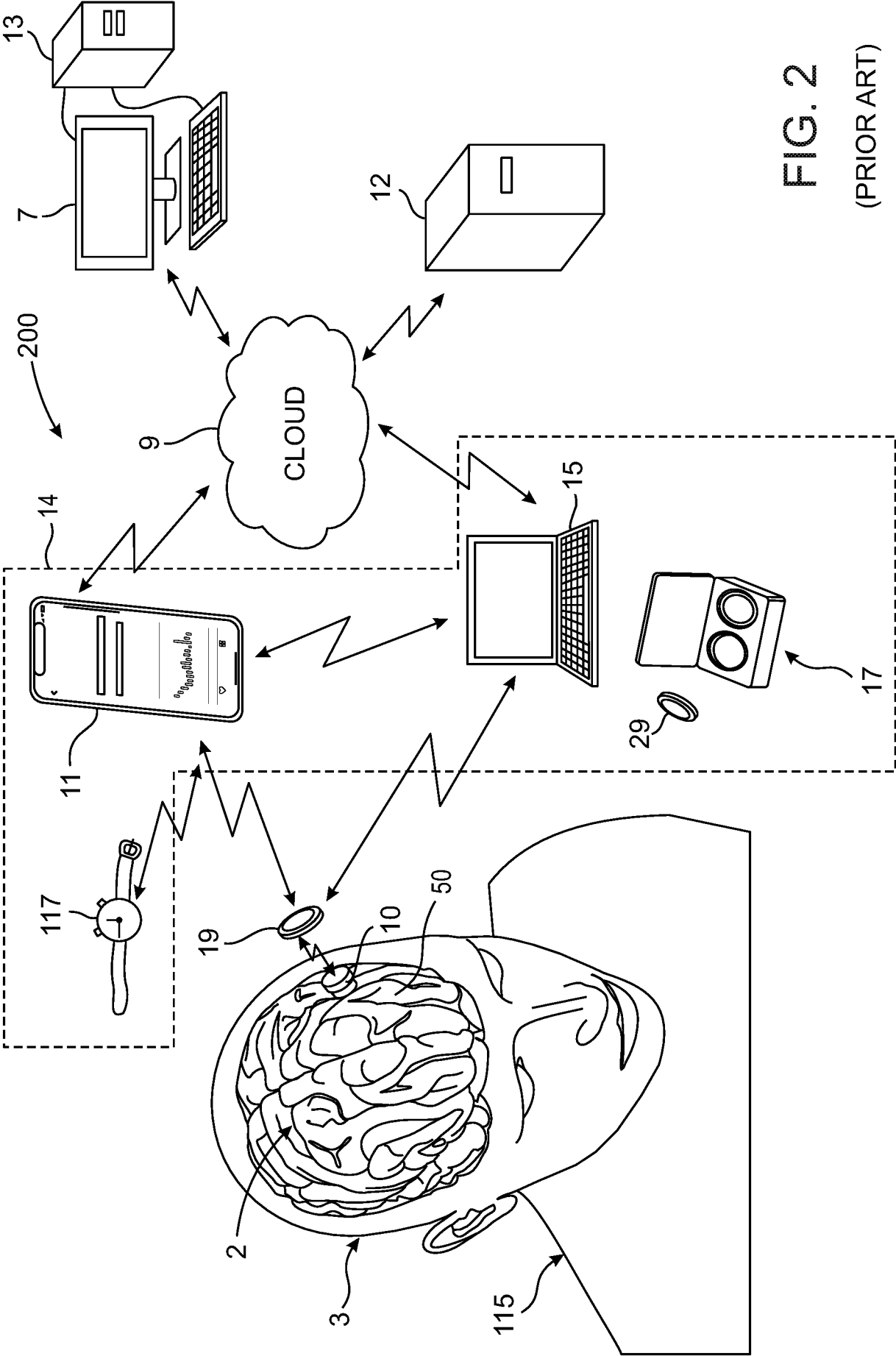
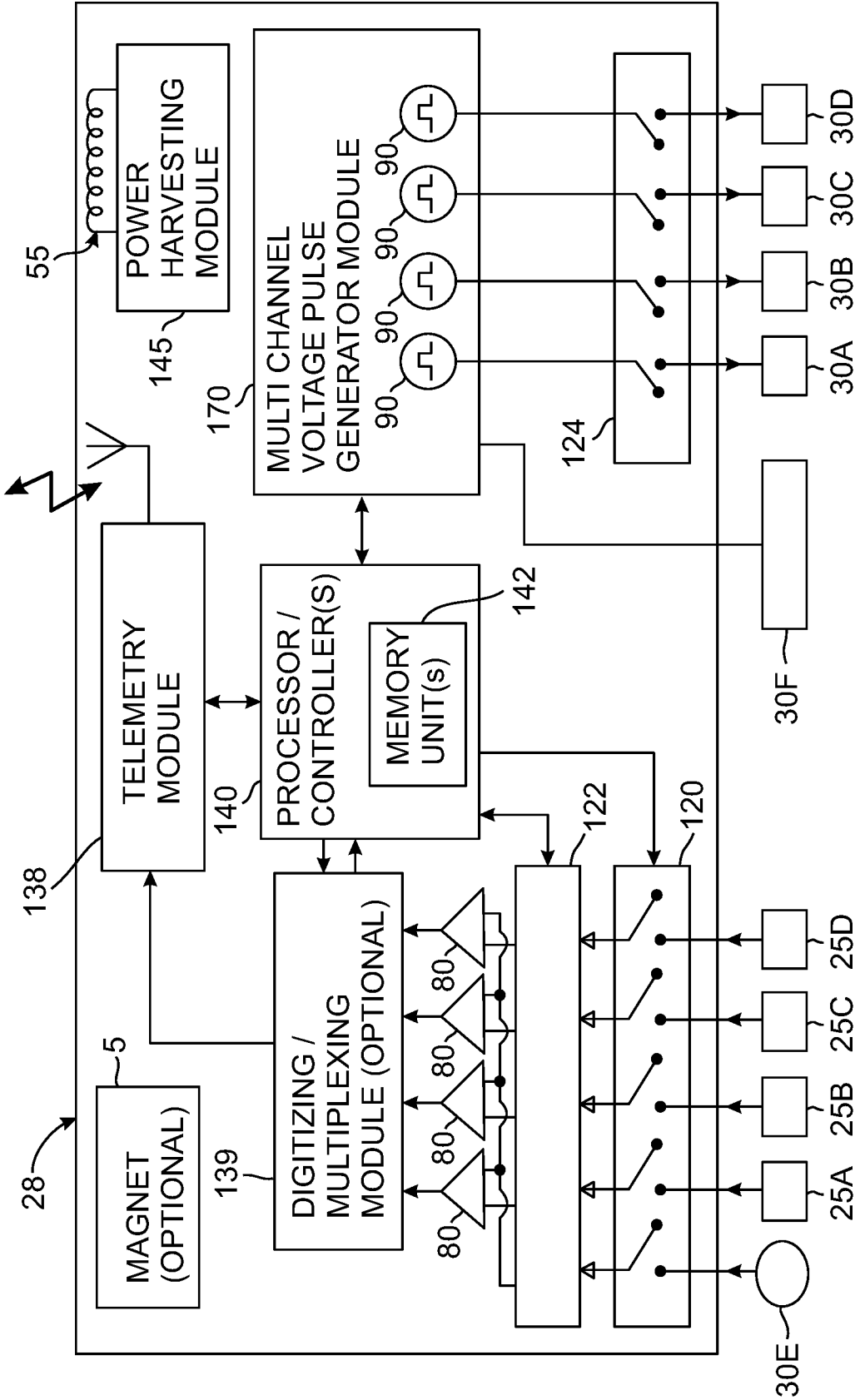


FIG. 2
(PRIOR ART)

FIG. 3
(PRIOR ART)



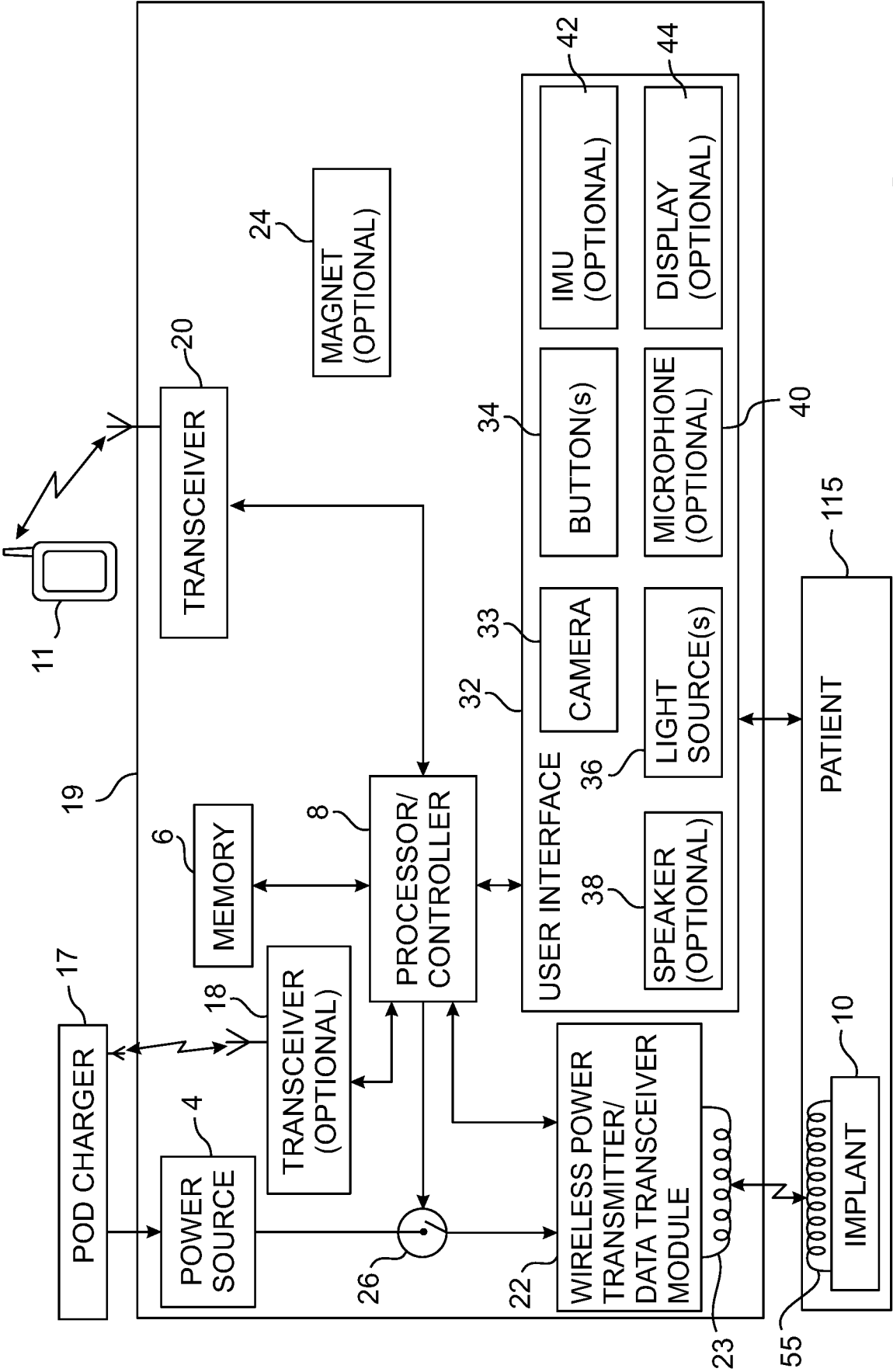


FIG. 4

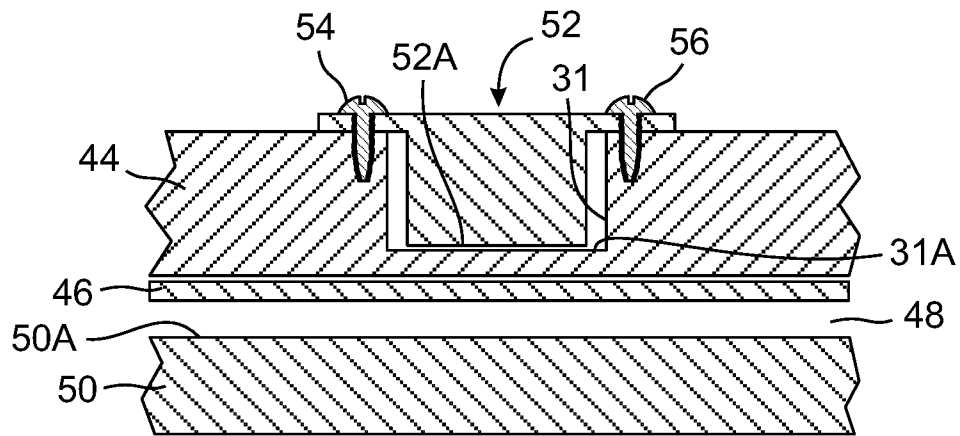


FIG. 5

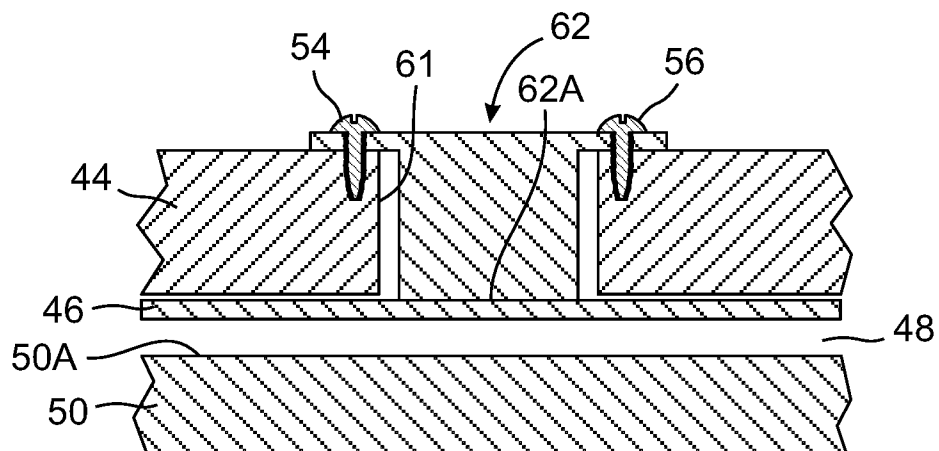


FIG. 6

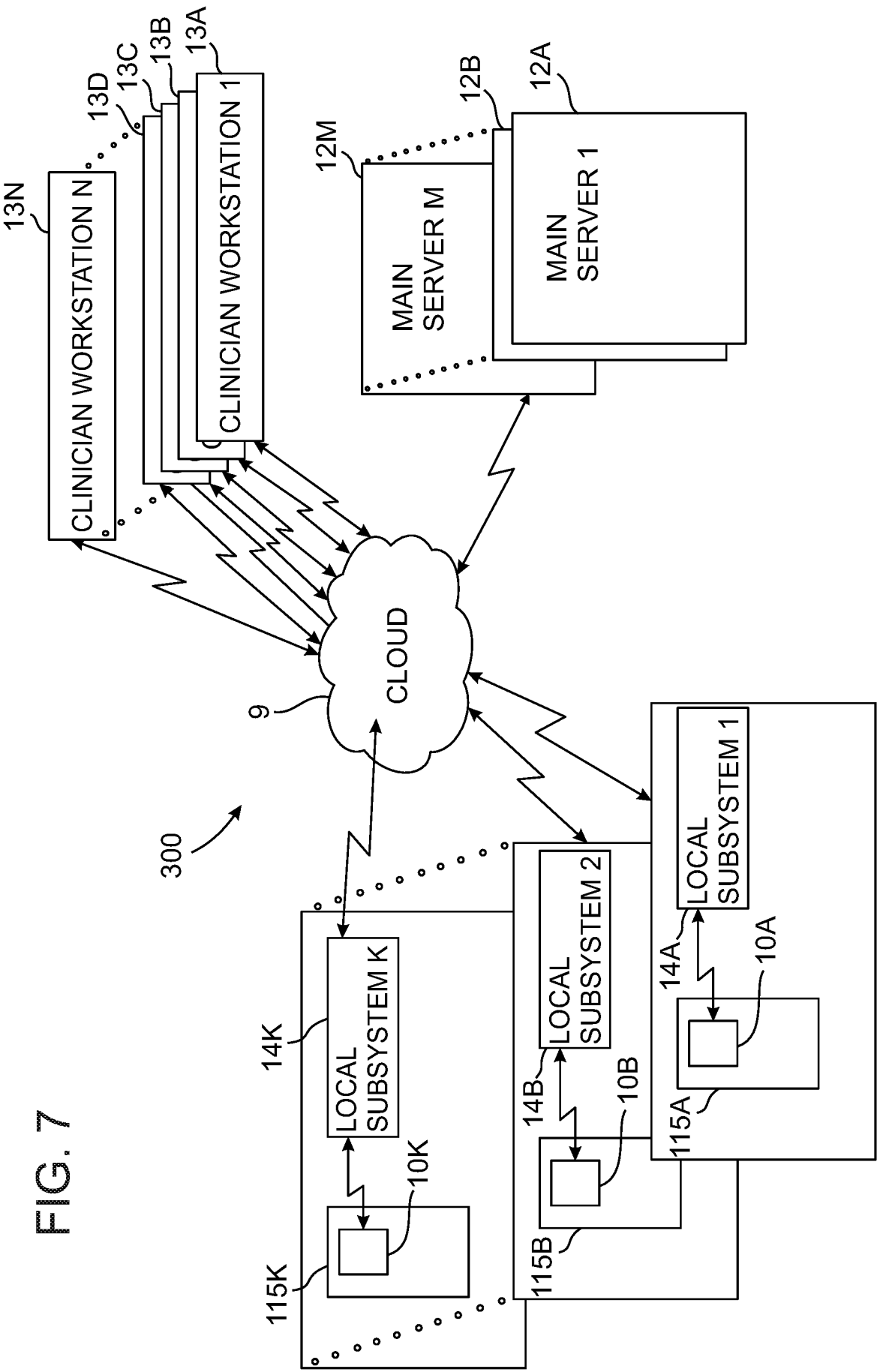


FIG. 7

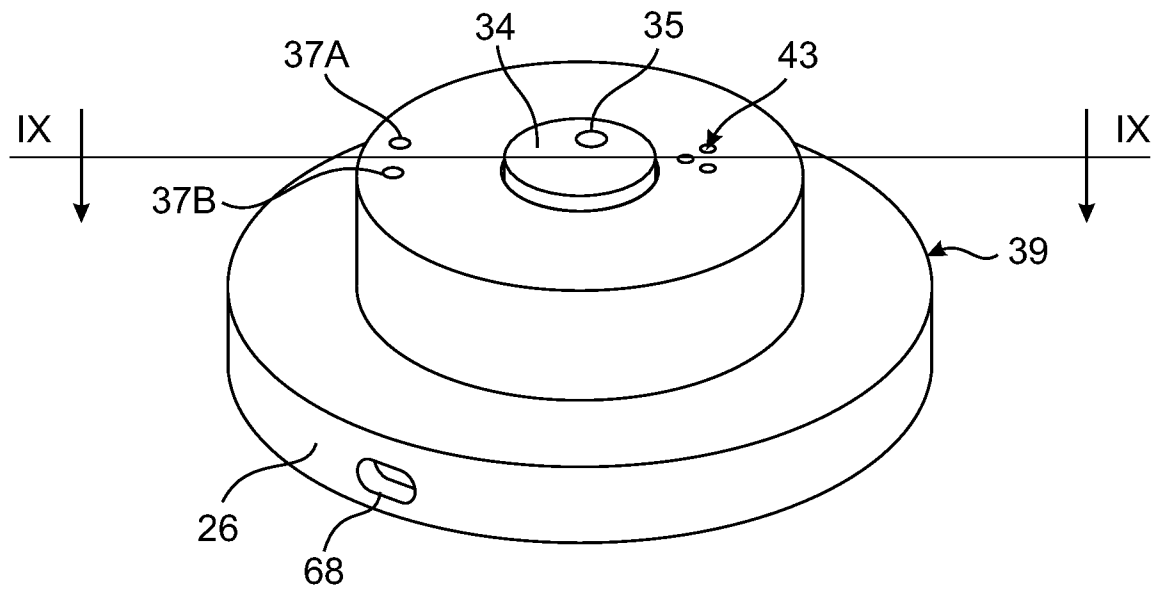


FIG. 8

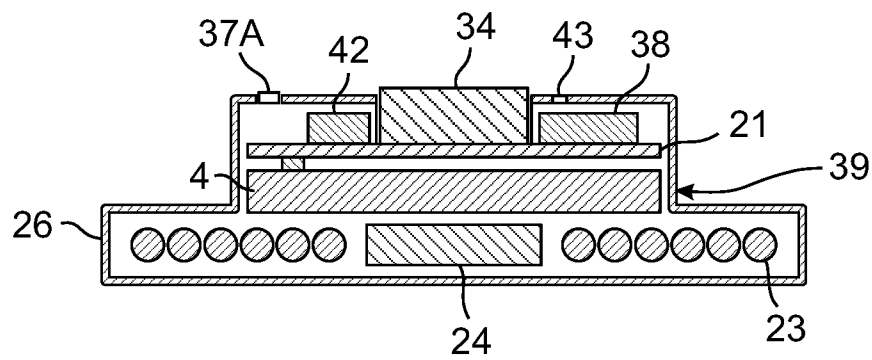


FIG. 9

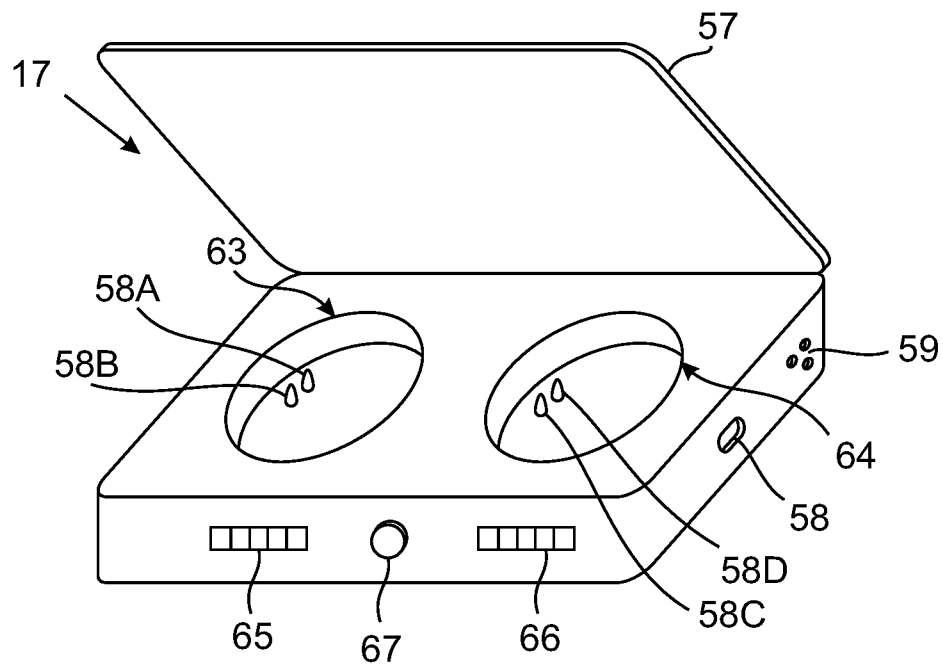


FIG. 10

FIG. 11A

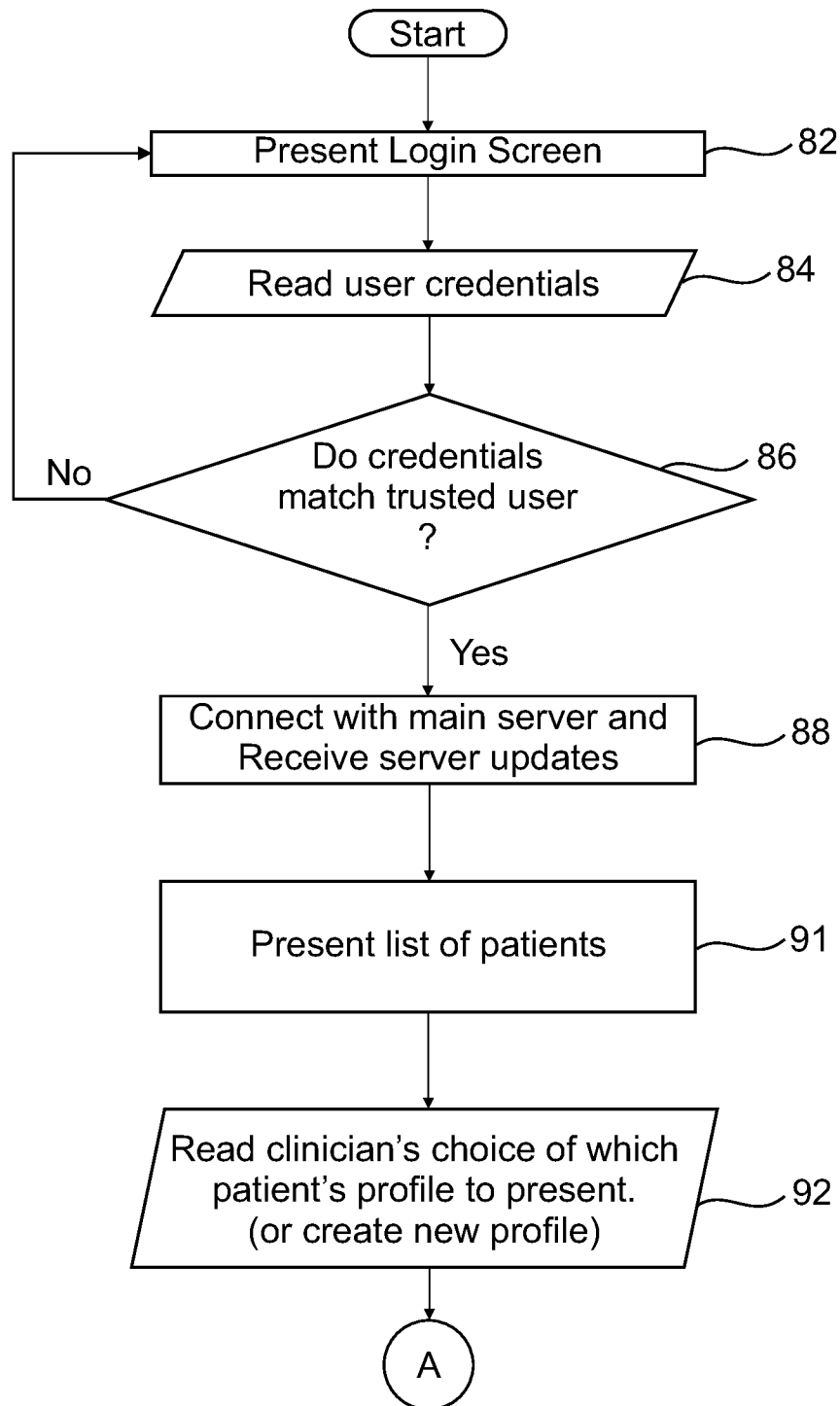


FIG. 11B

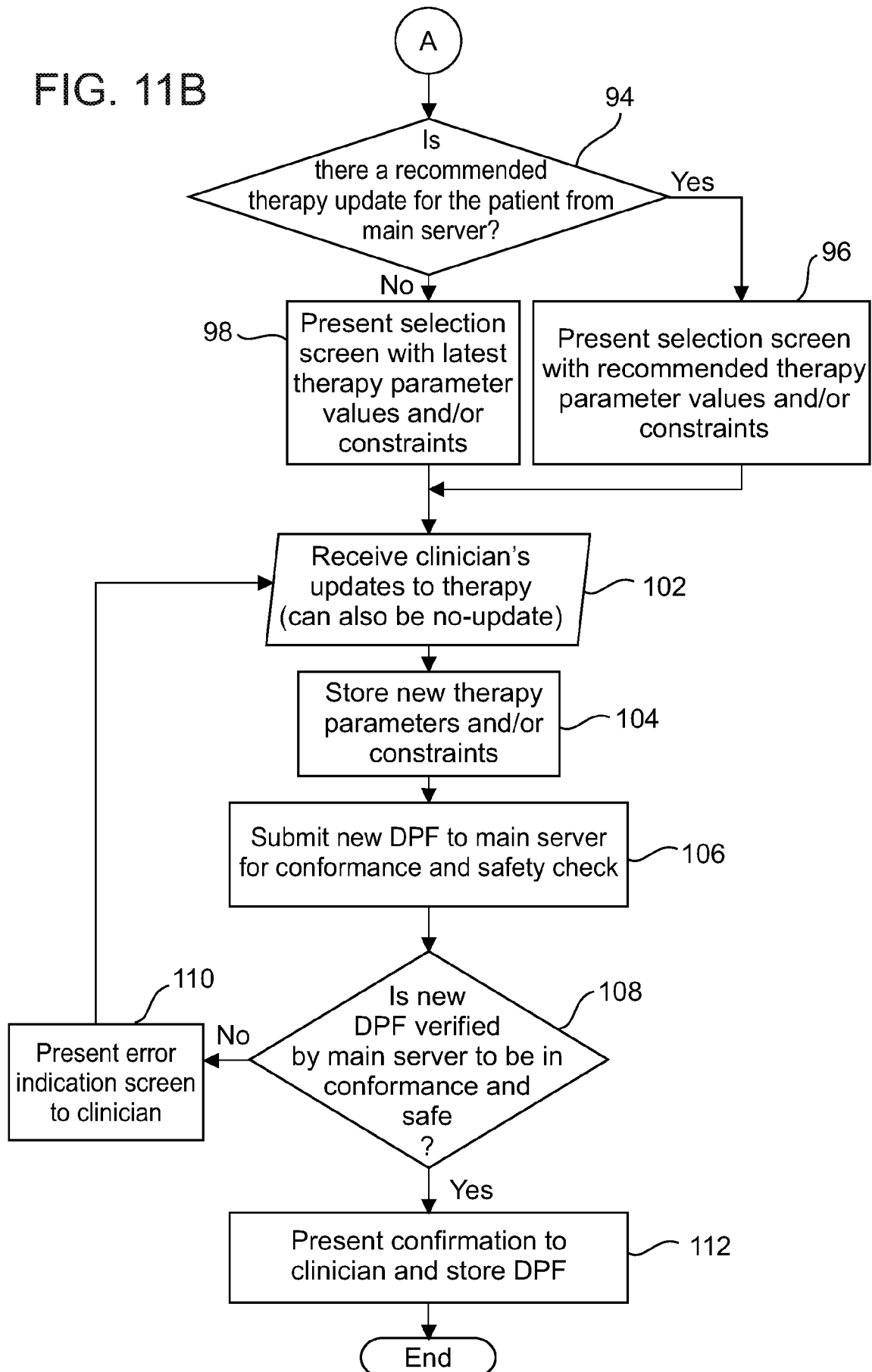


FIG. 12

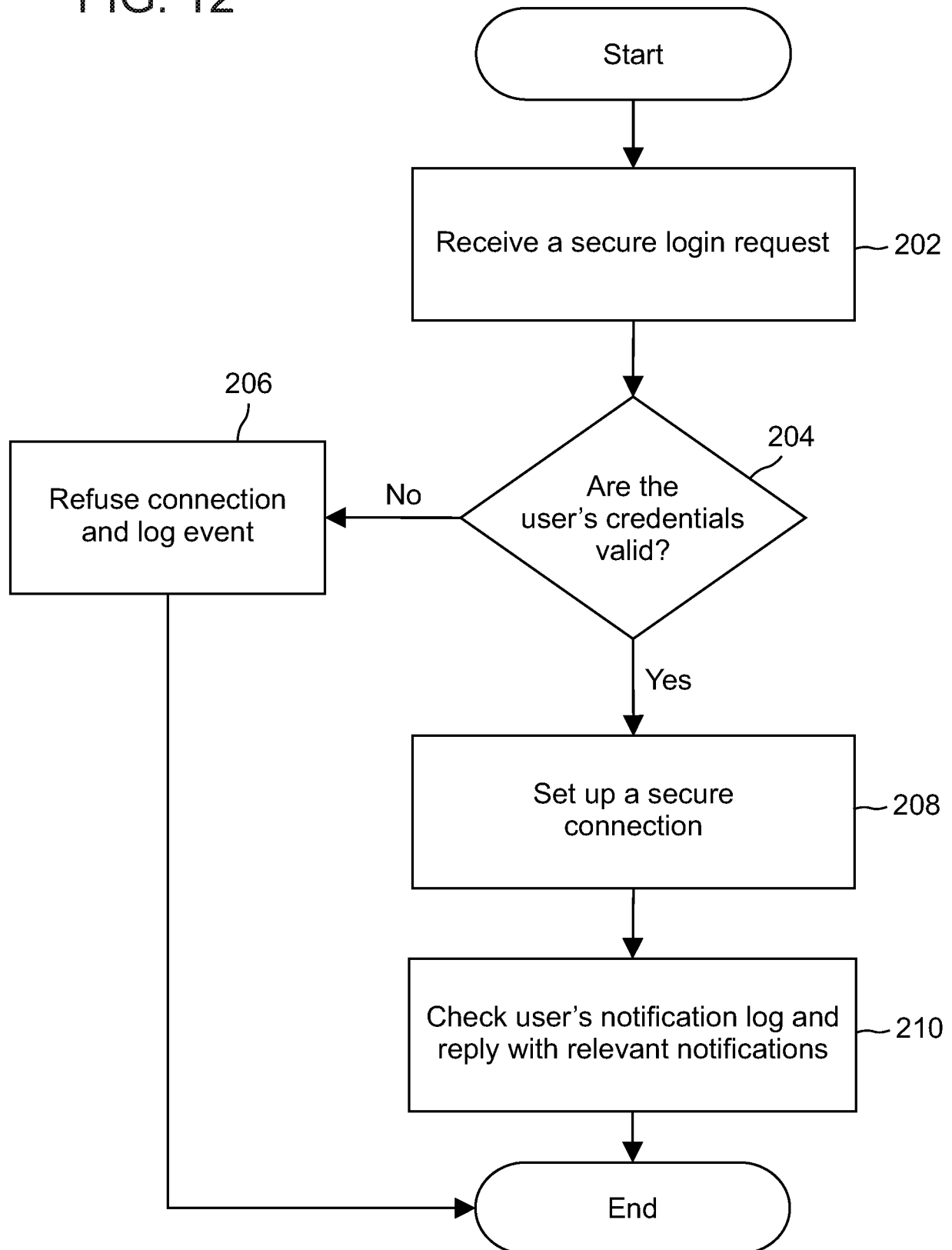


FIG. 13

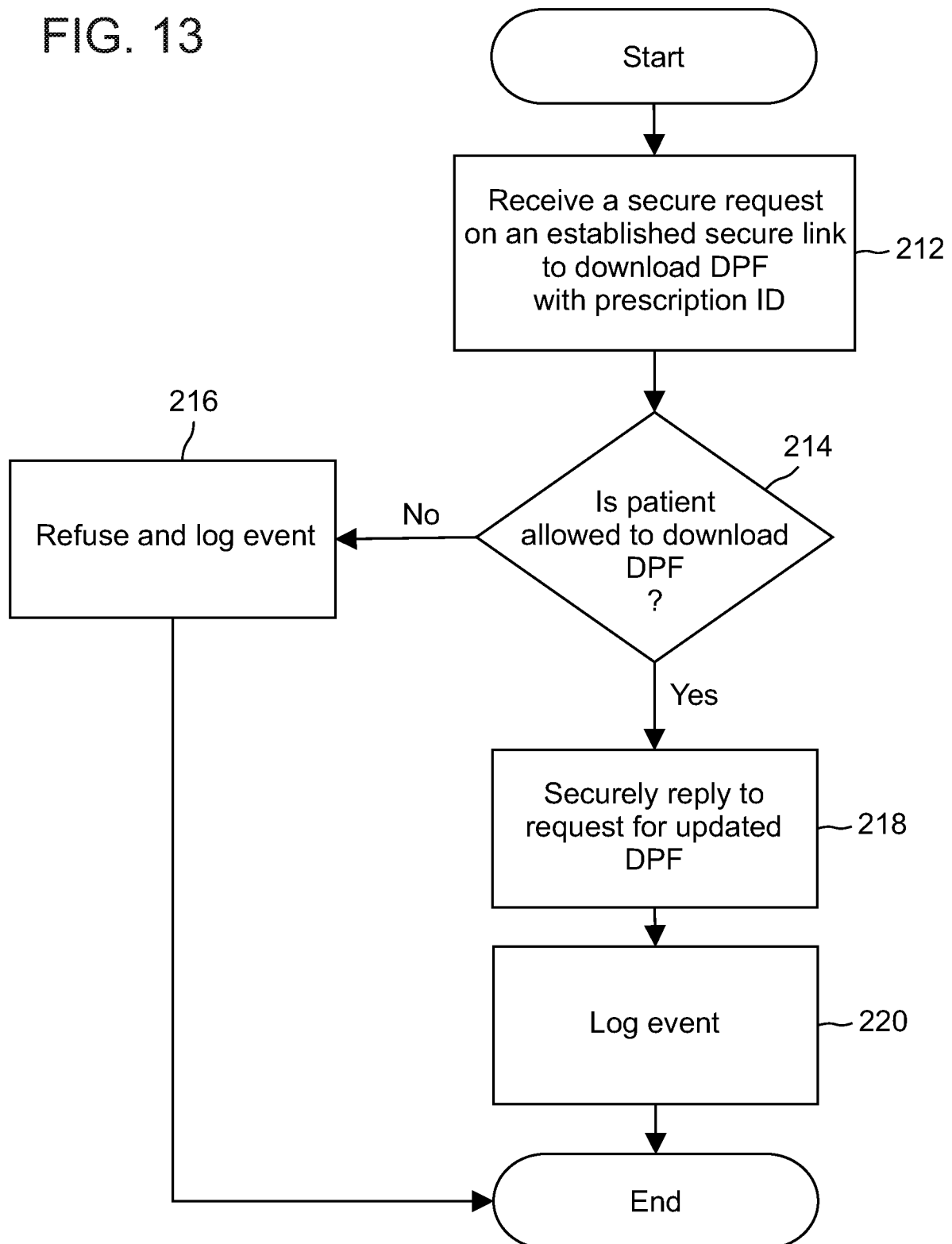


FIG. 14A

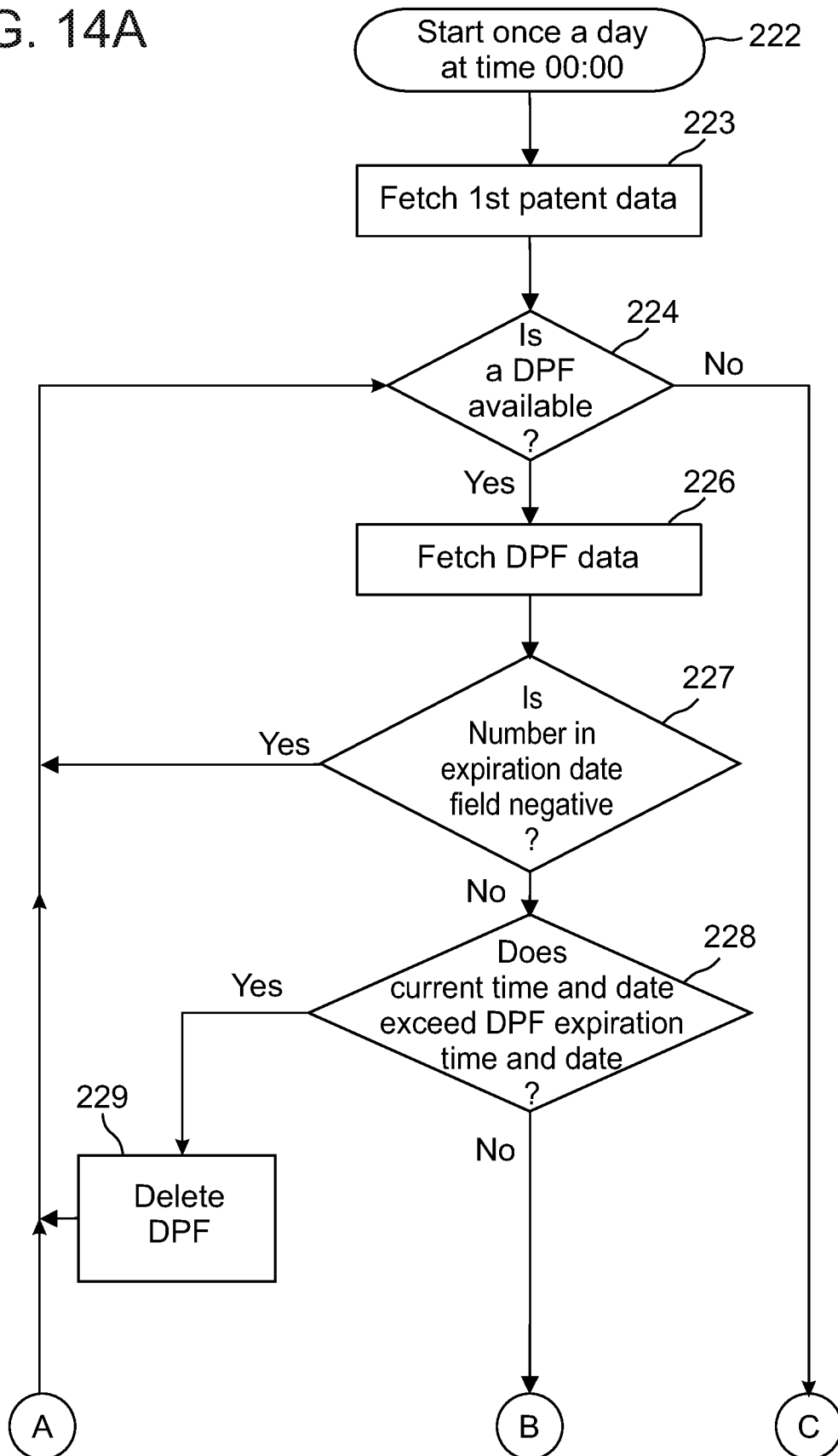


FIG. 14B

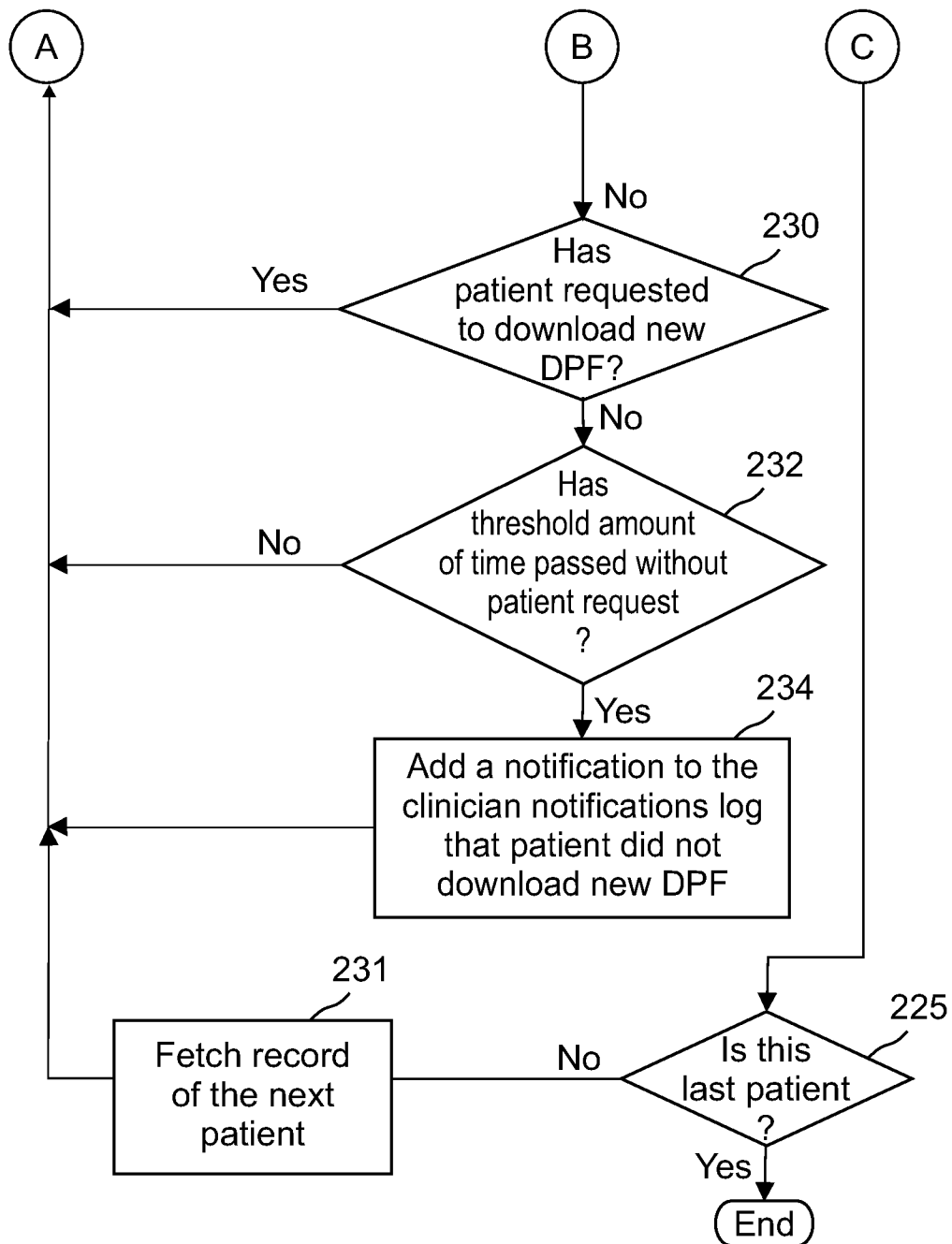


FIG. 15

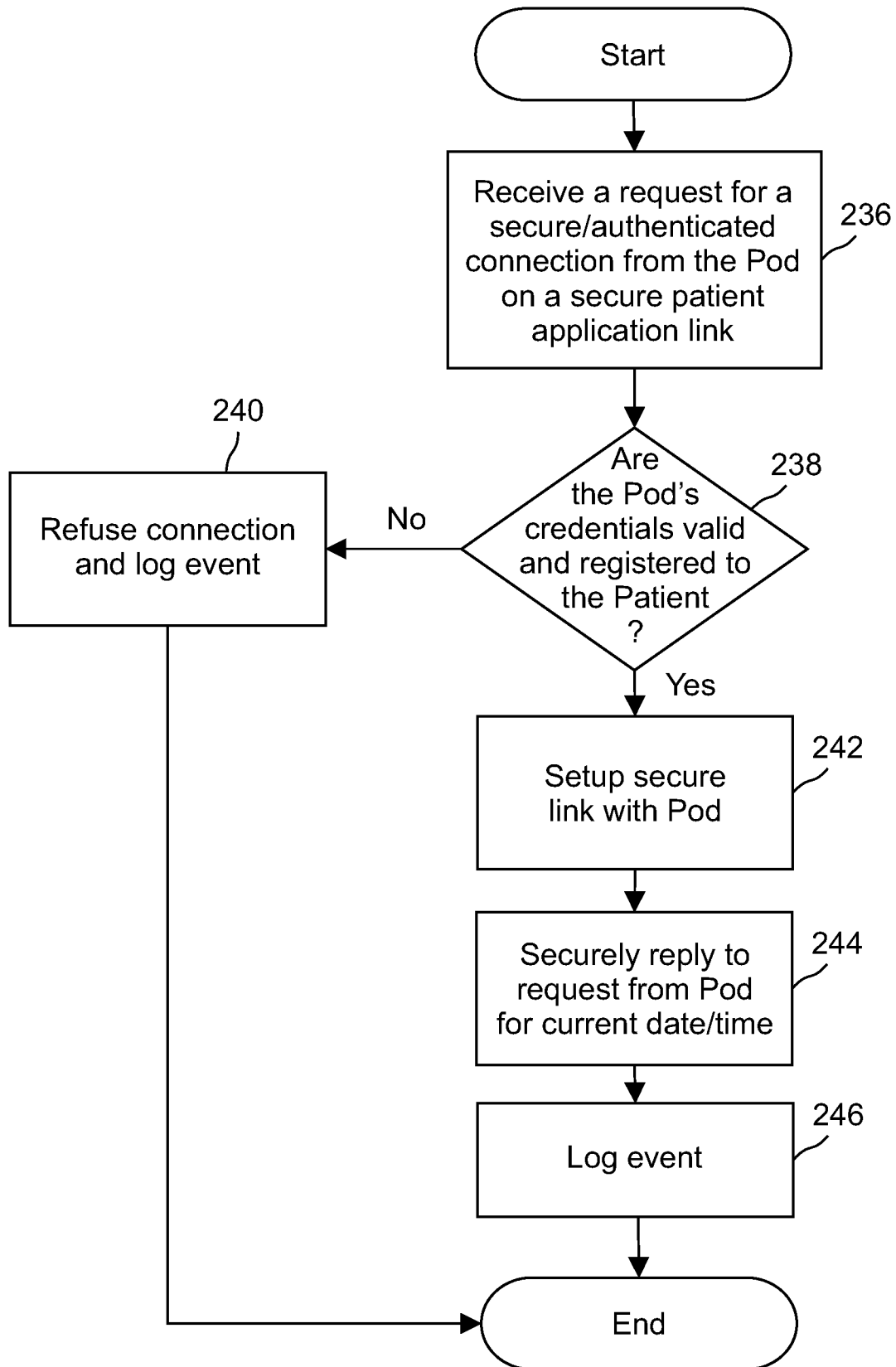


FIG. 16

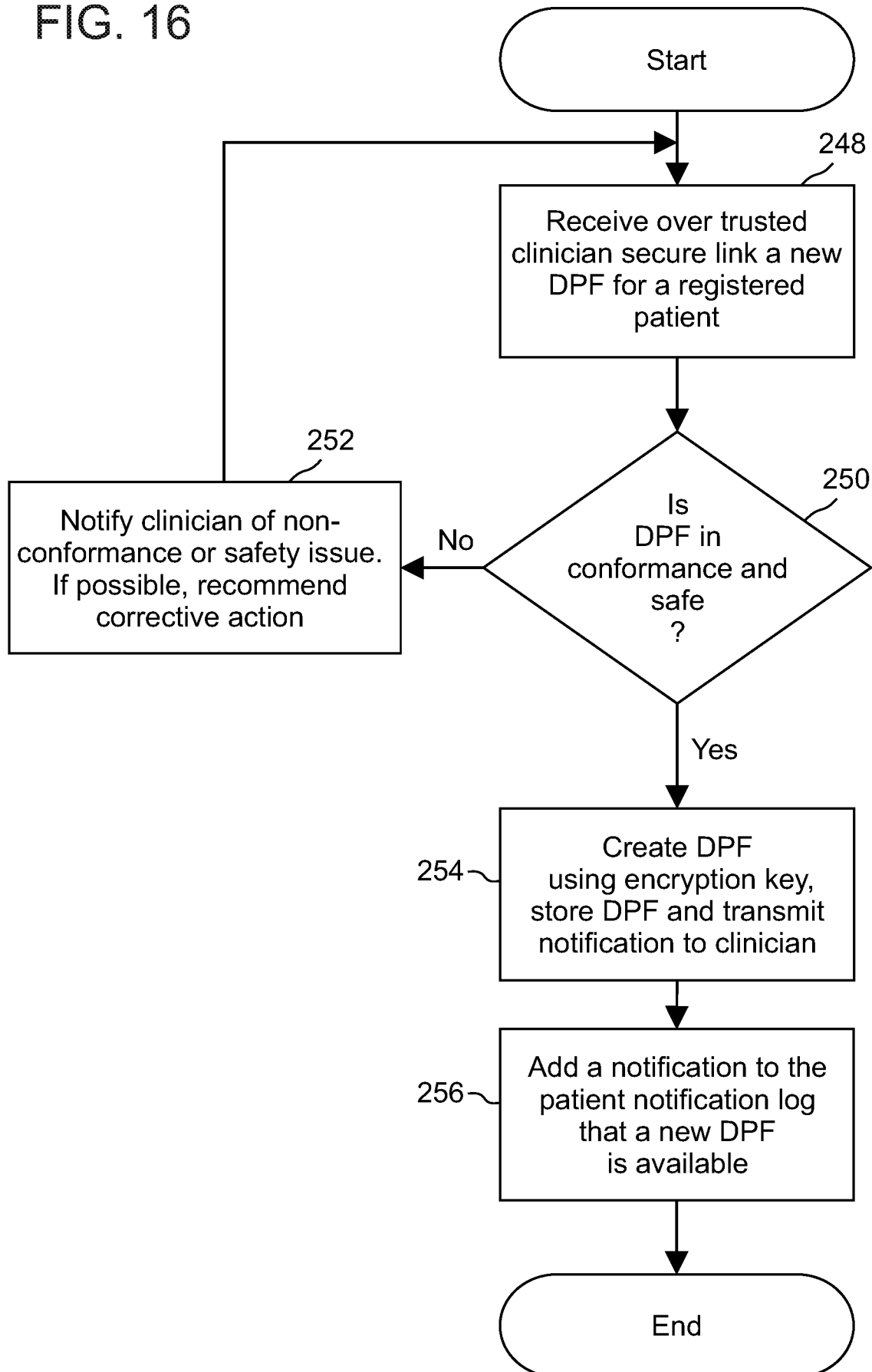


FIG. 17

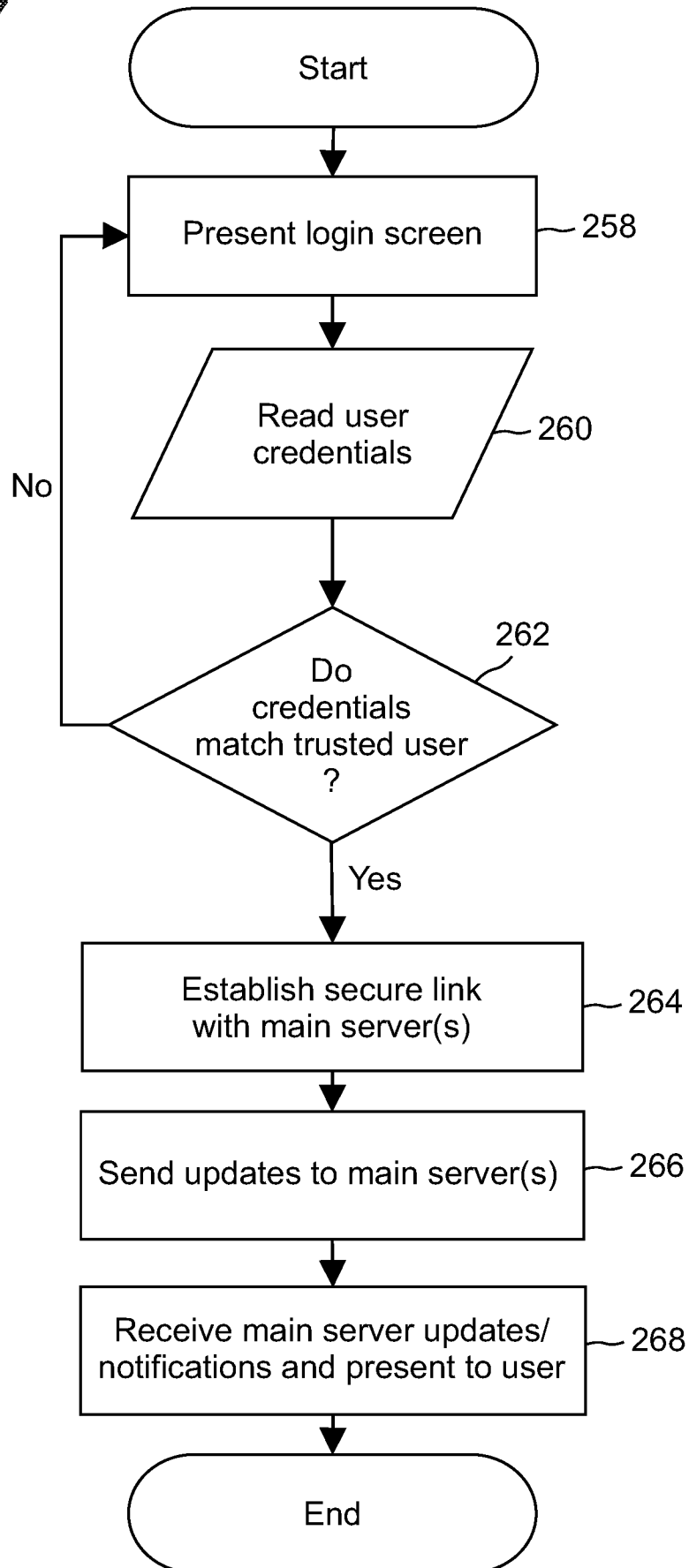


FIG. 18

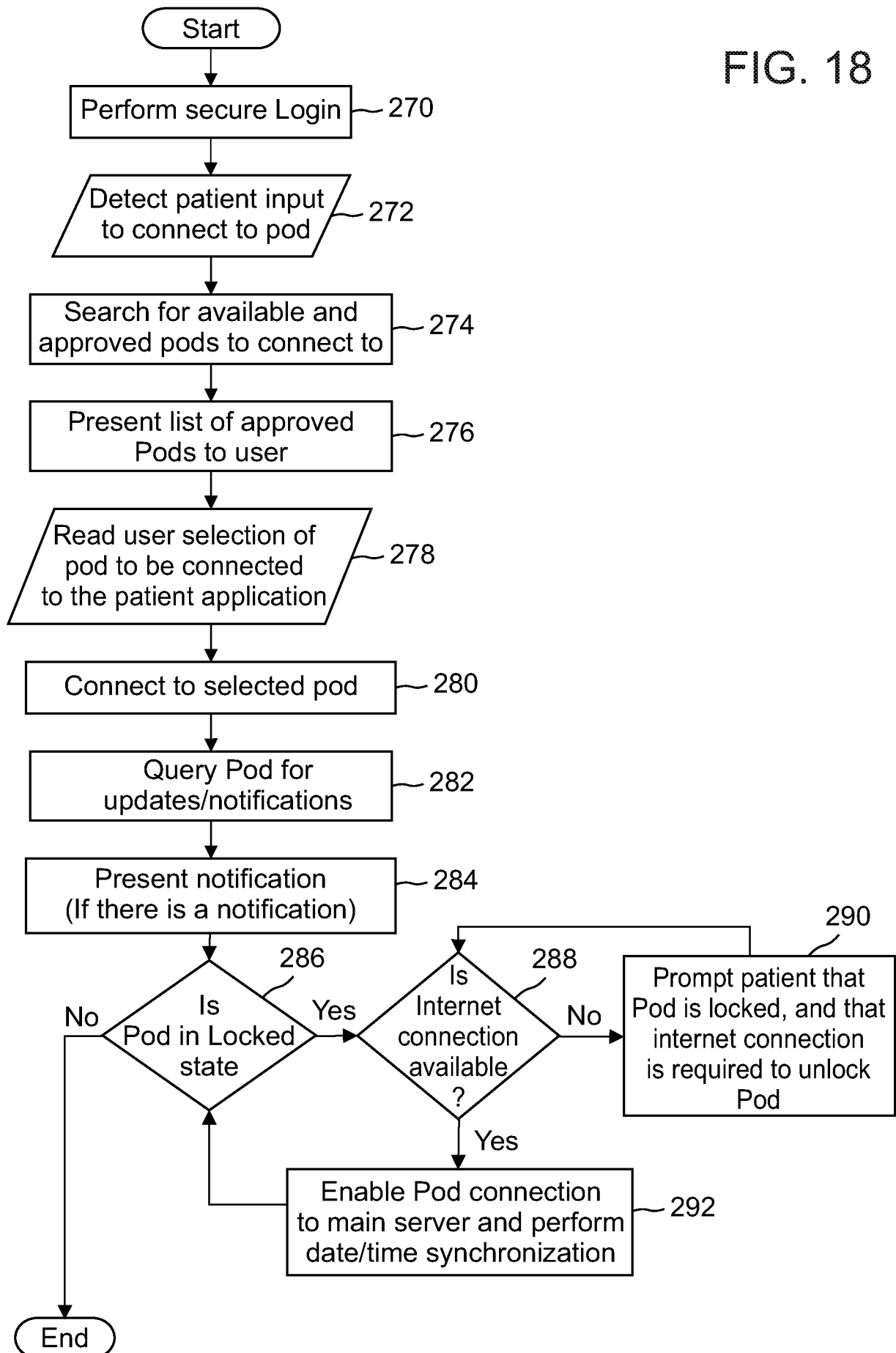


FIG. 19

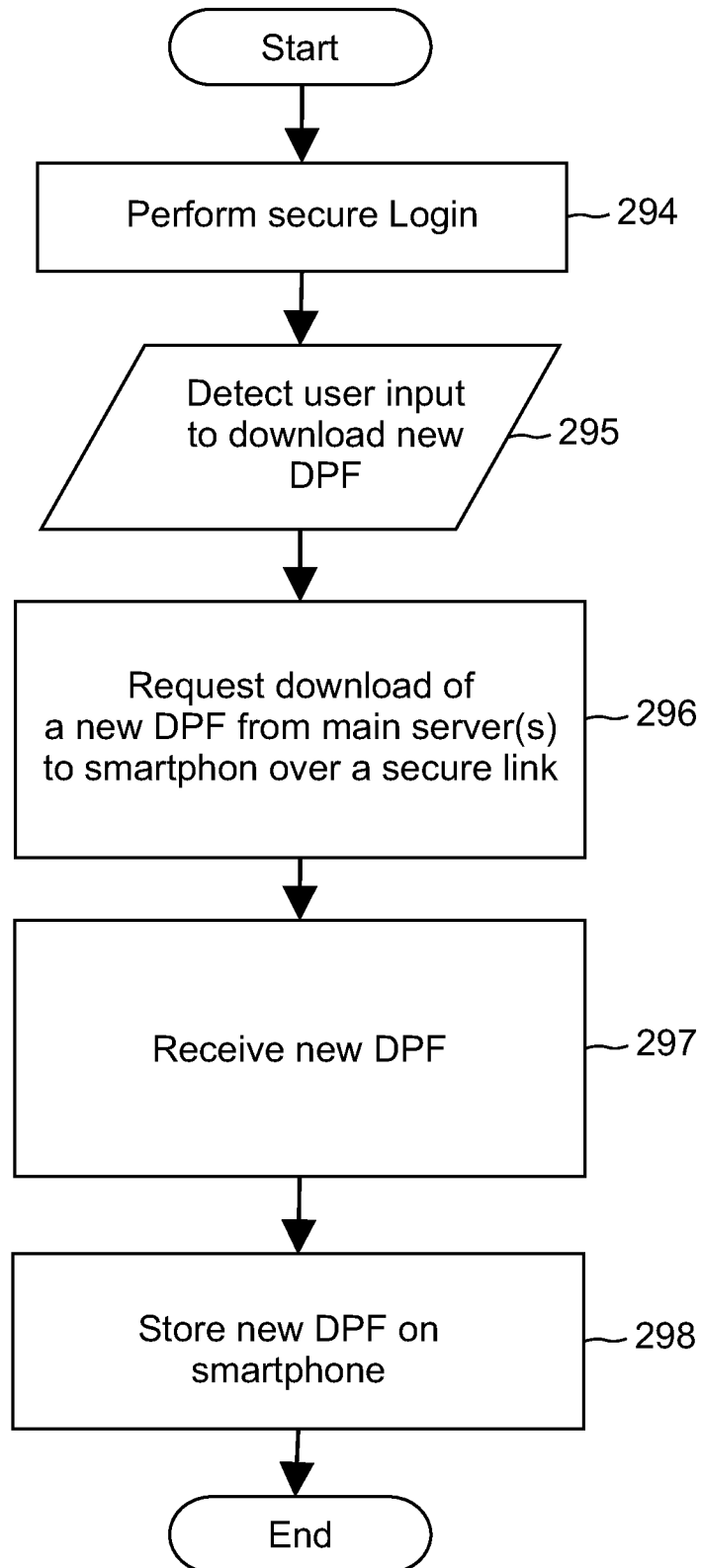


FIG. 20

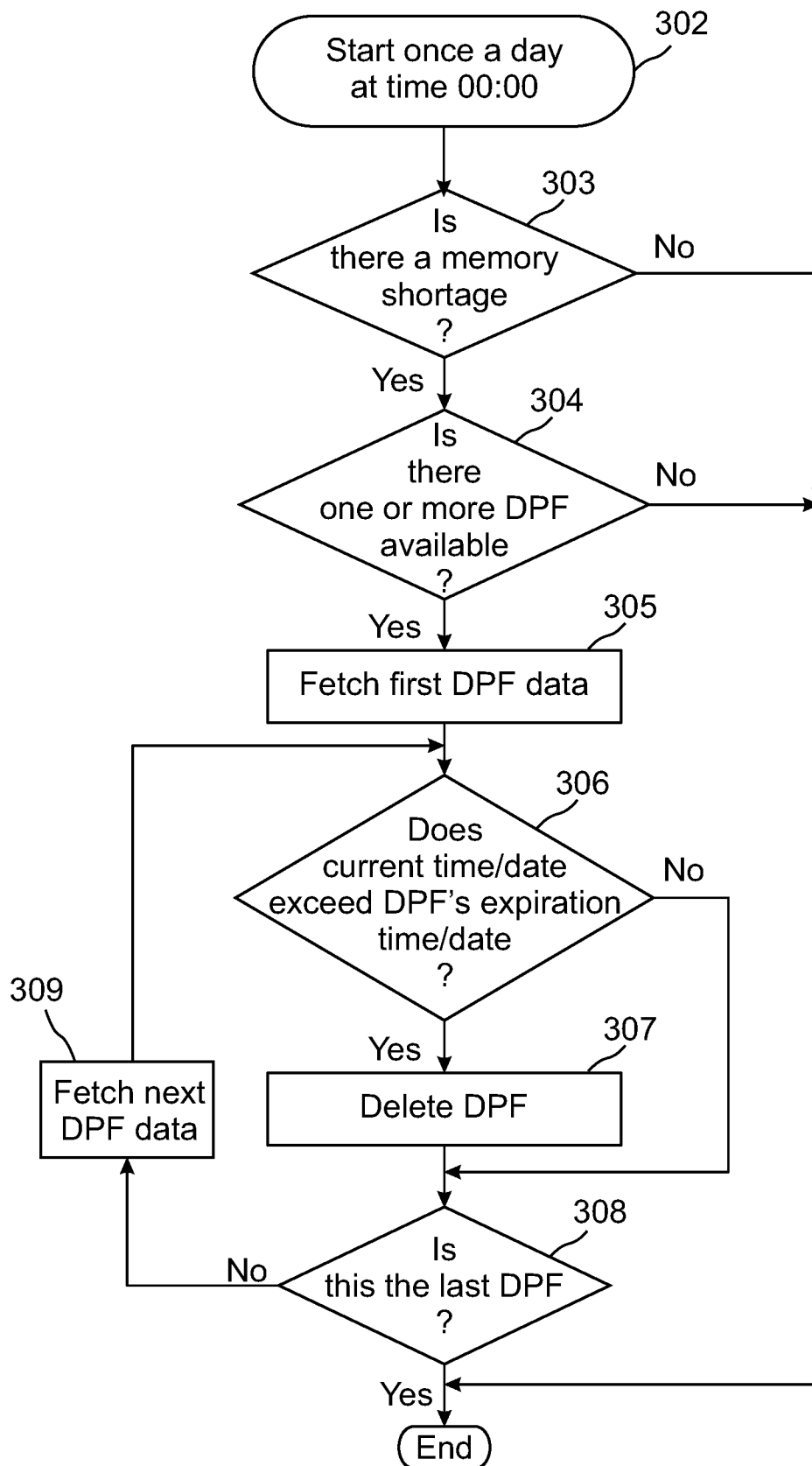


FIG. 21

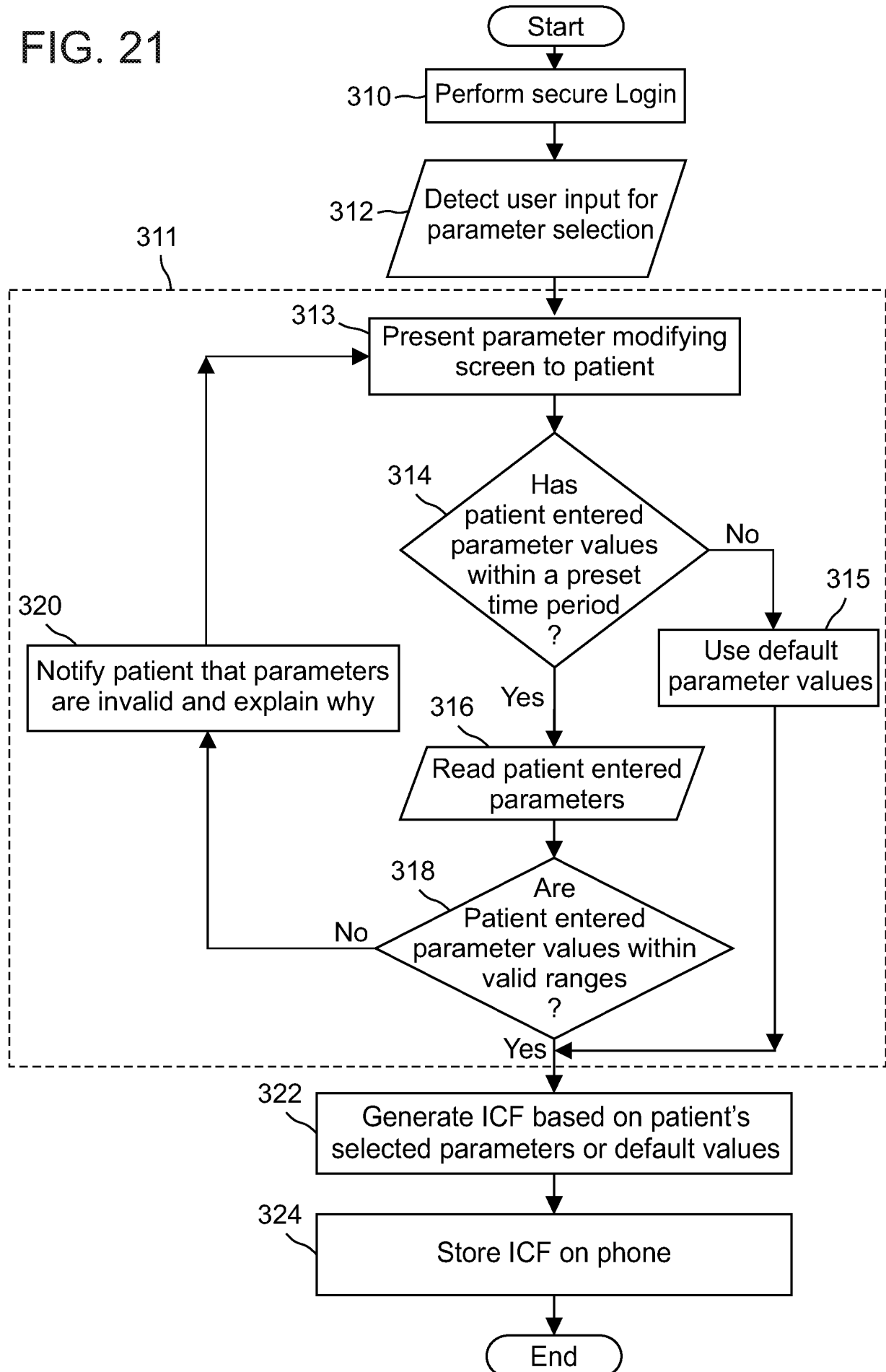


FIG. 22A

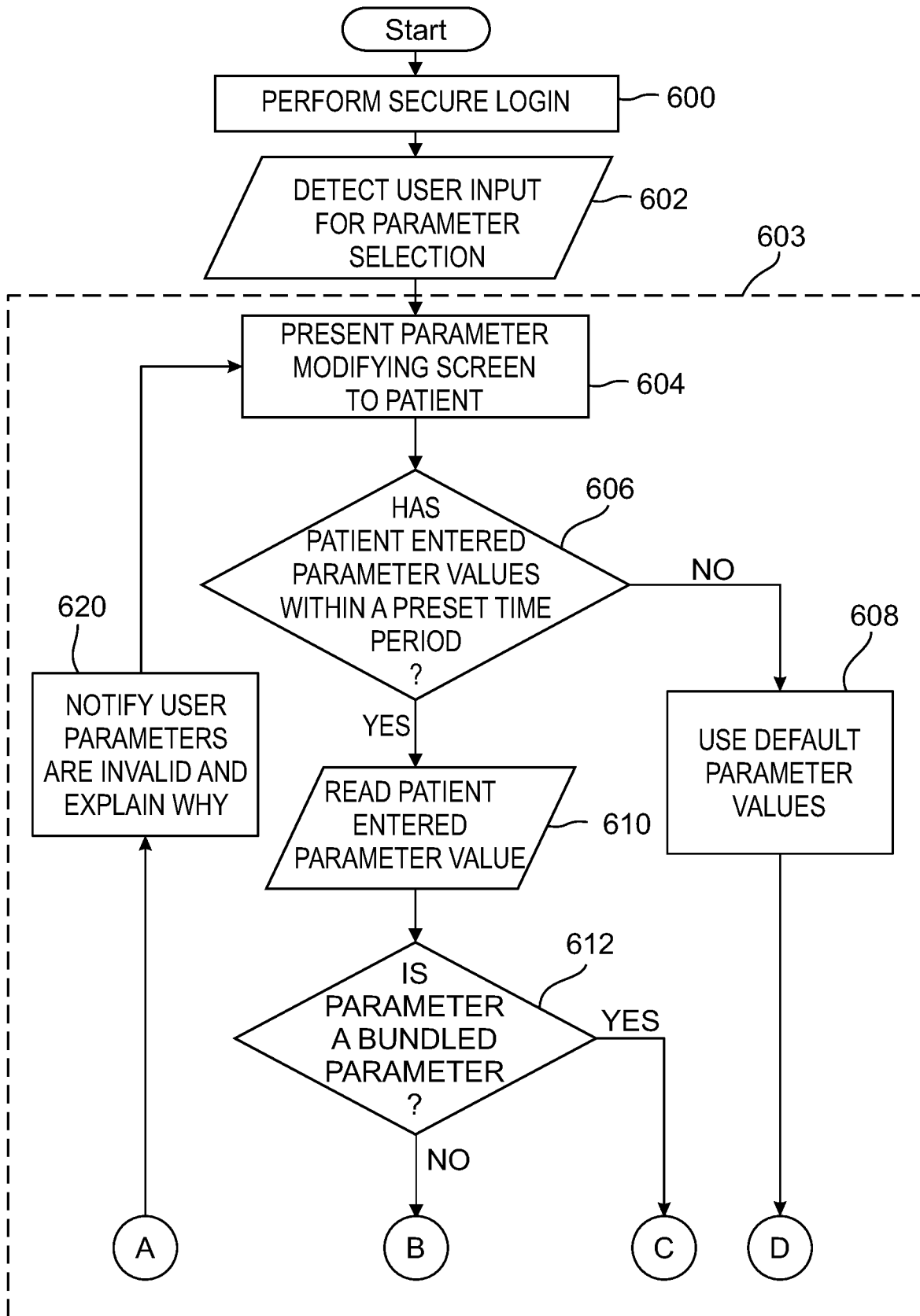


FIG. 22B

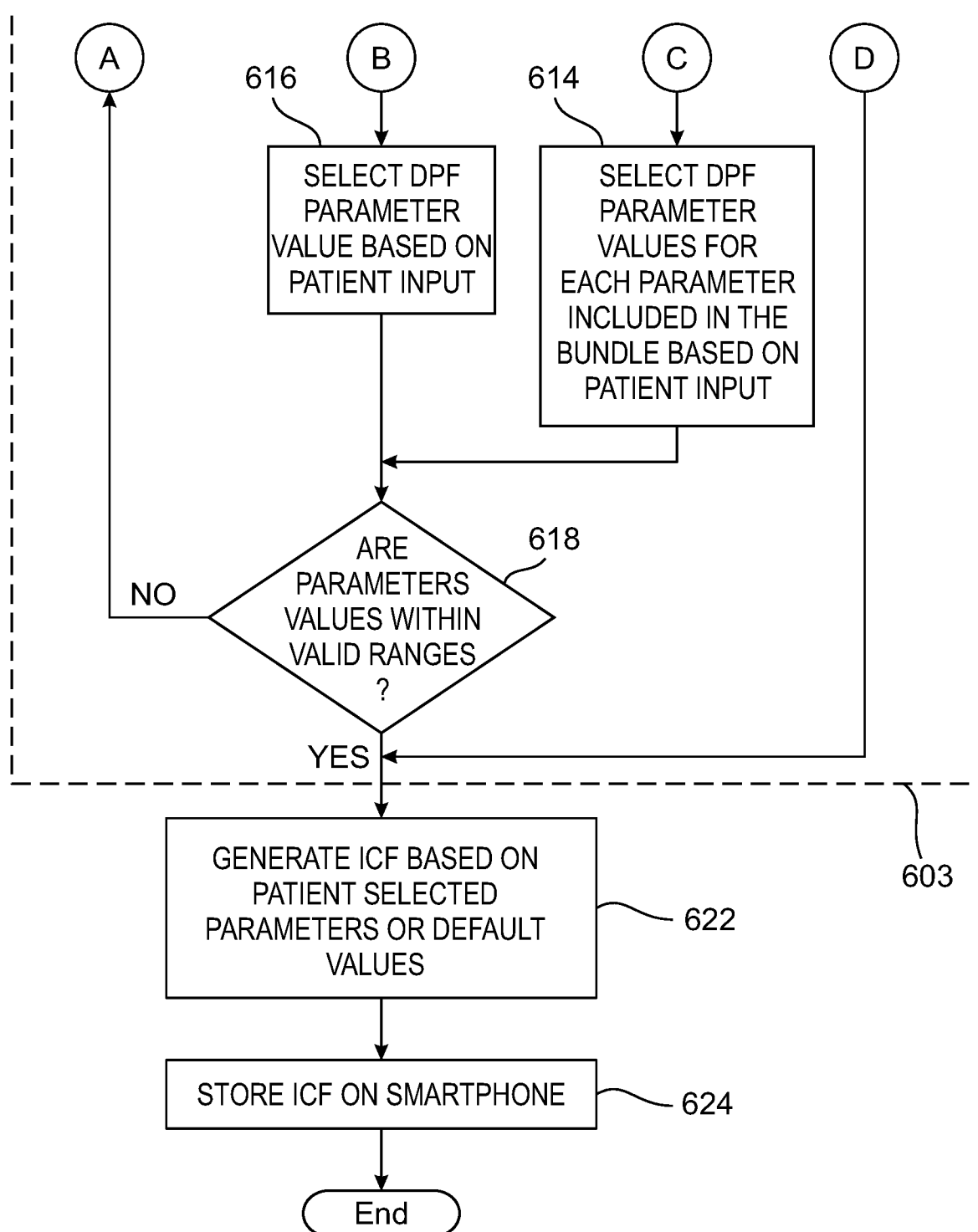
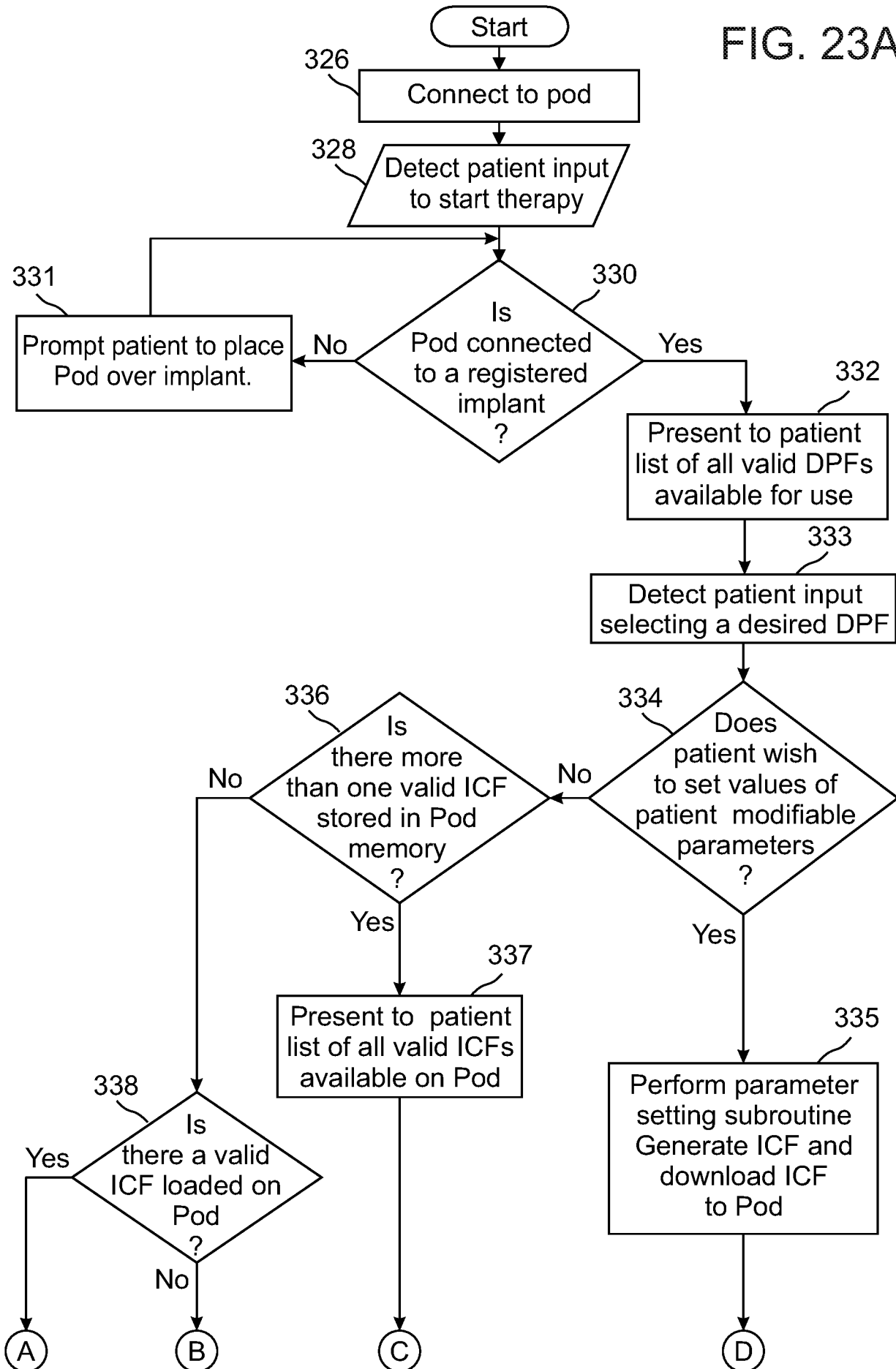


FIG. 23A



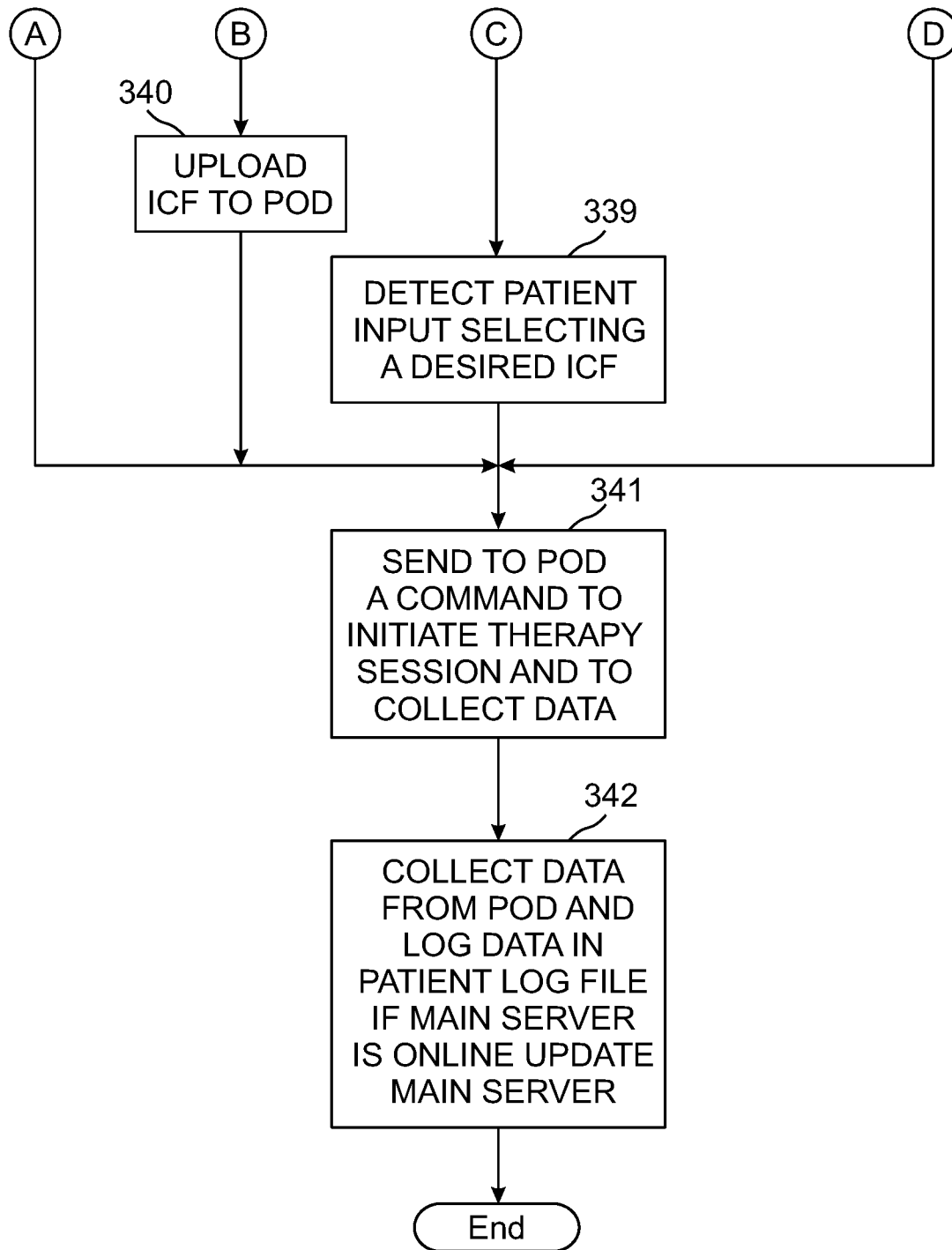


FIG. 23B

FIG. 24

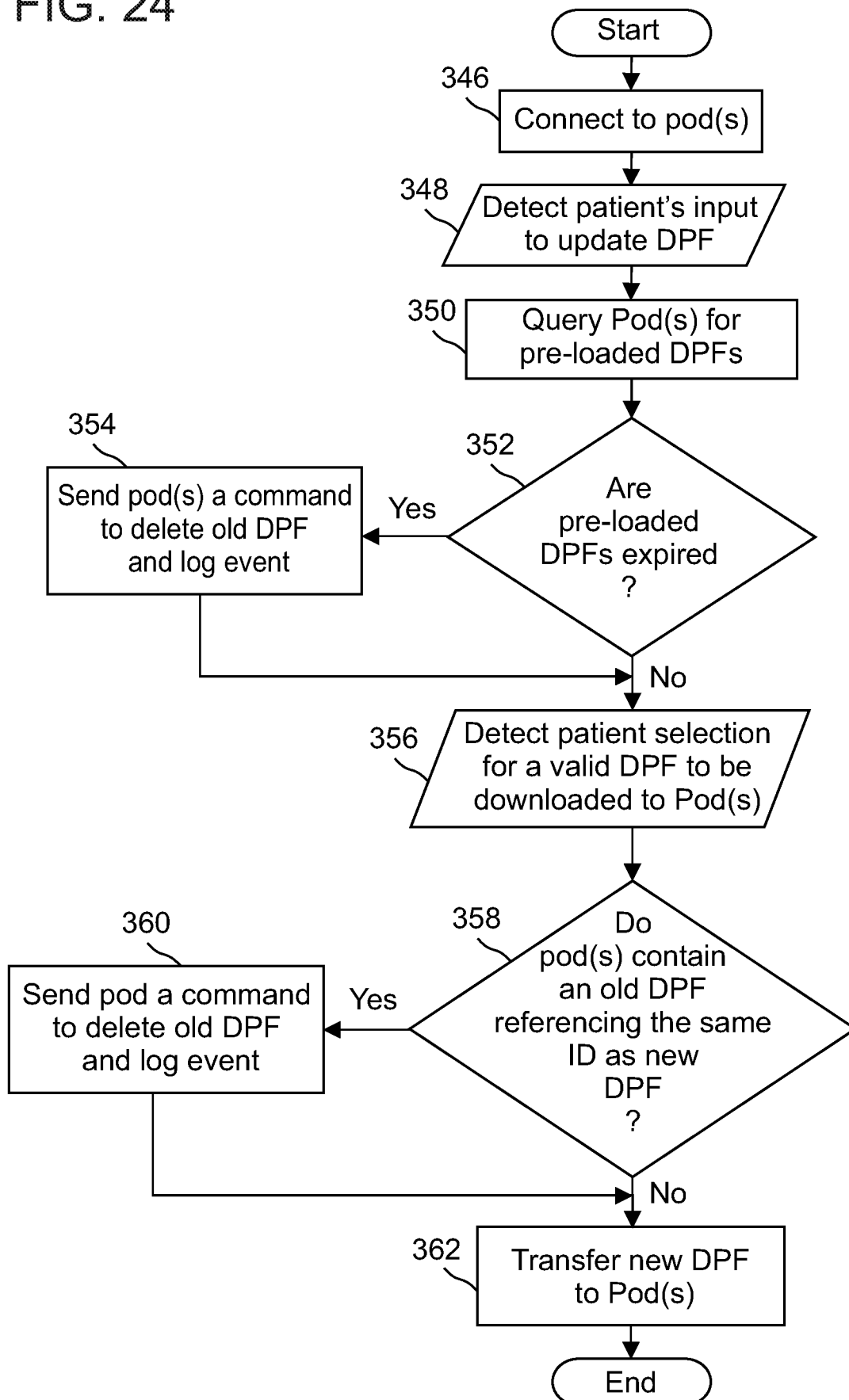


FIG. 25

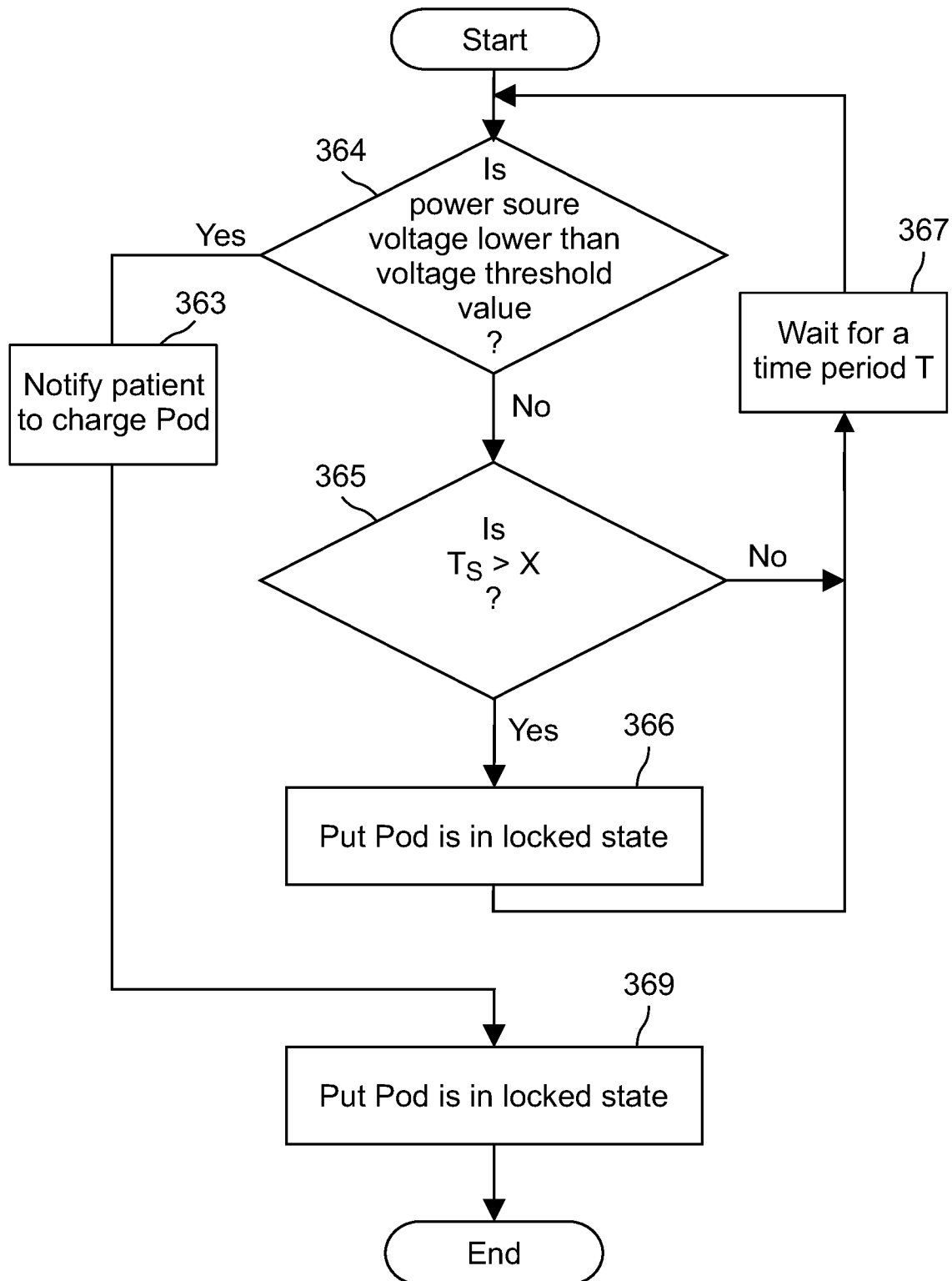


FIG. 26

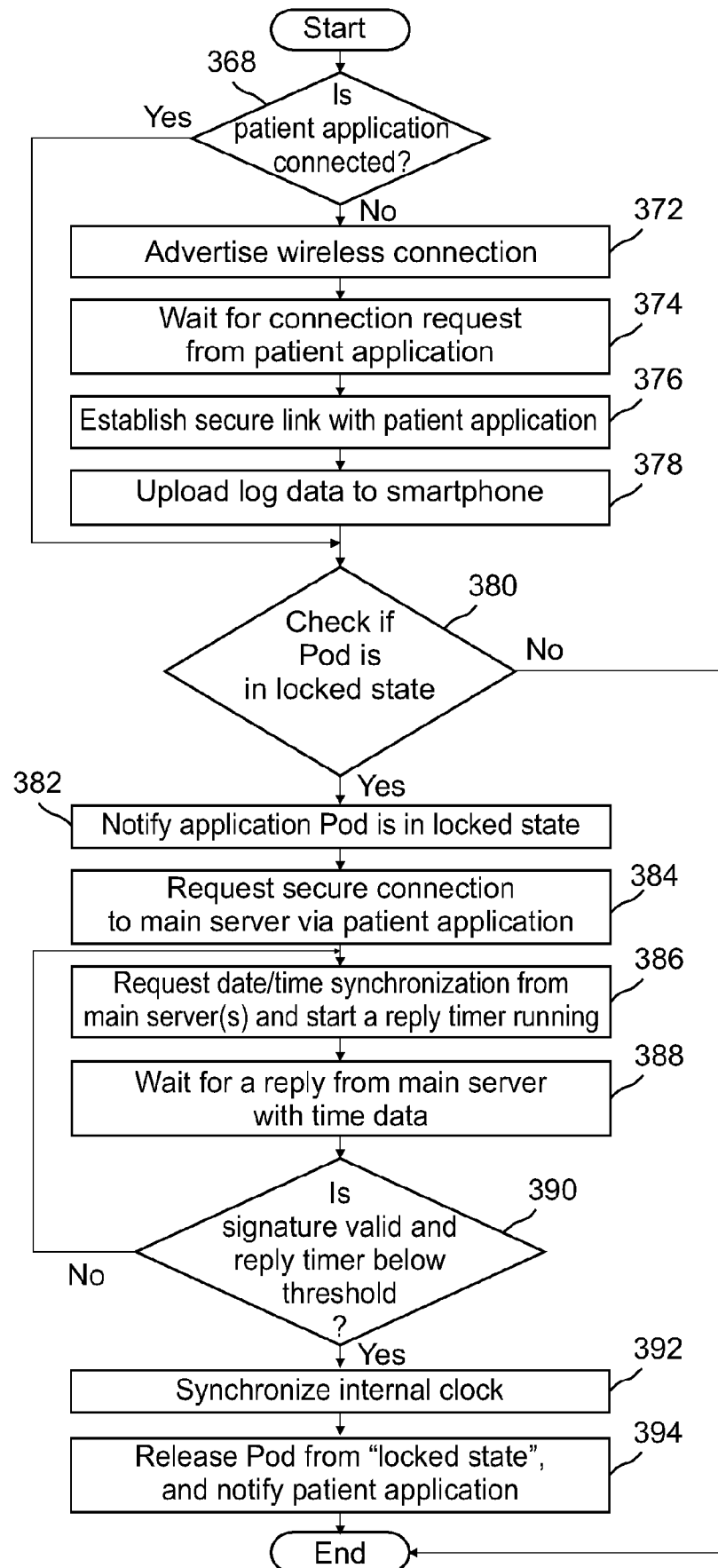


FIG. 27

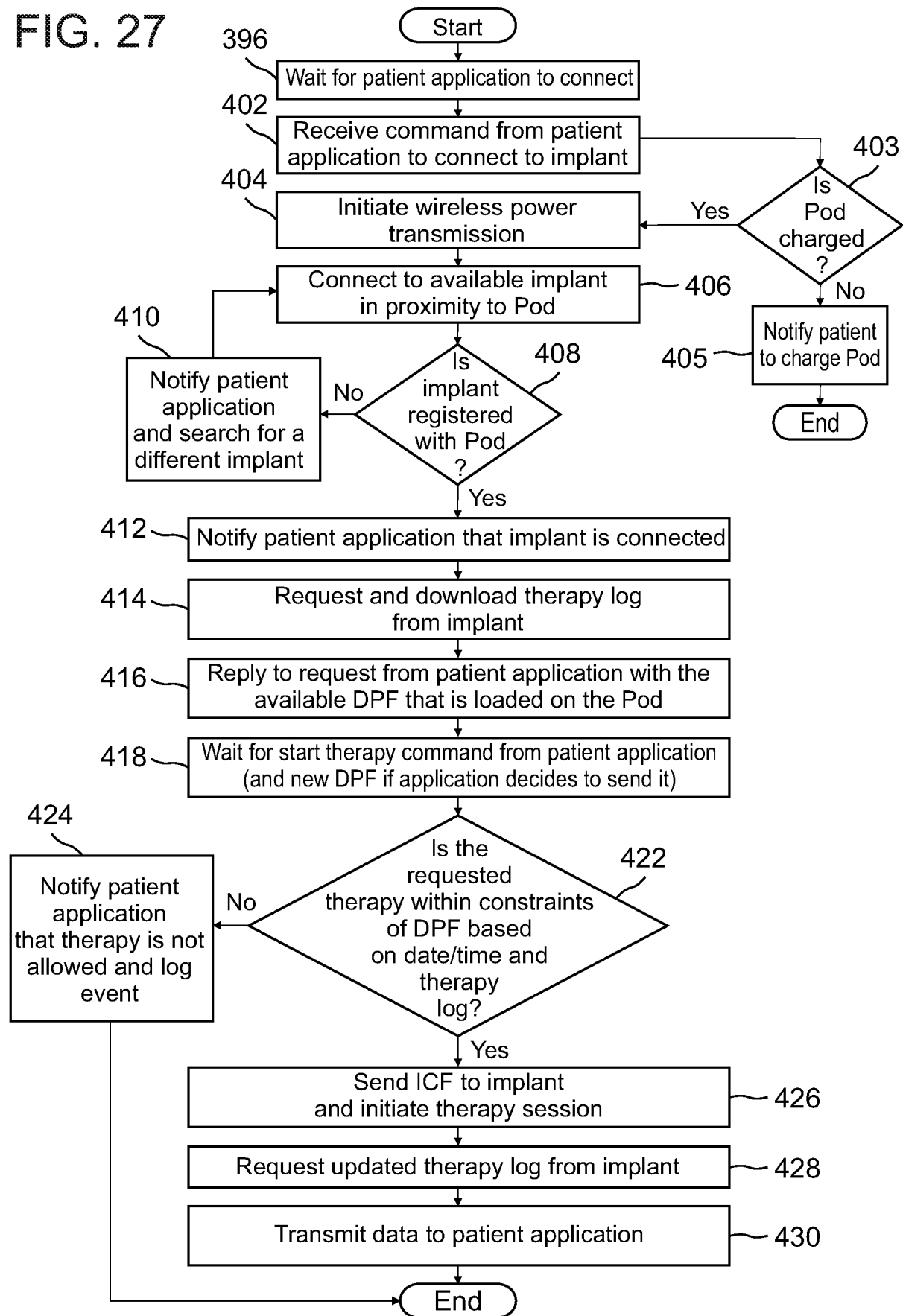


FIG. 28

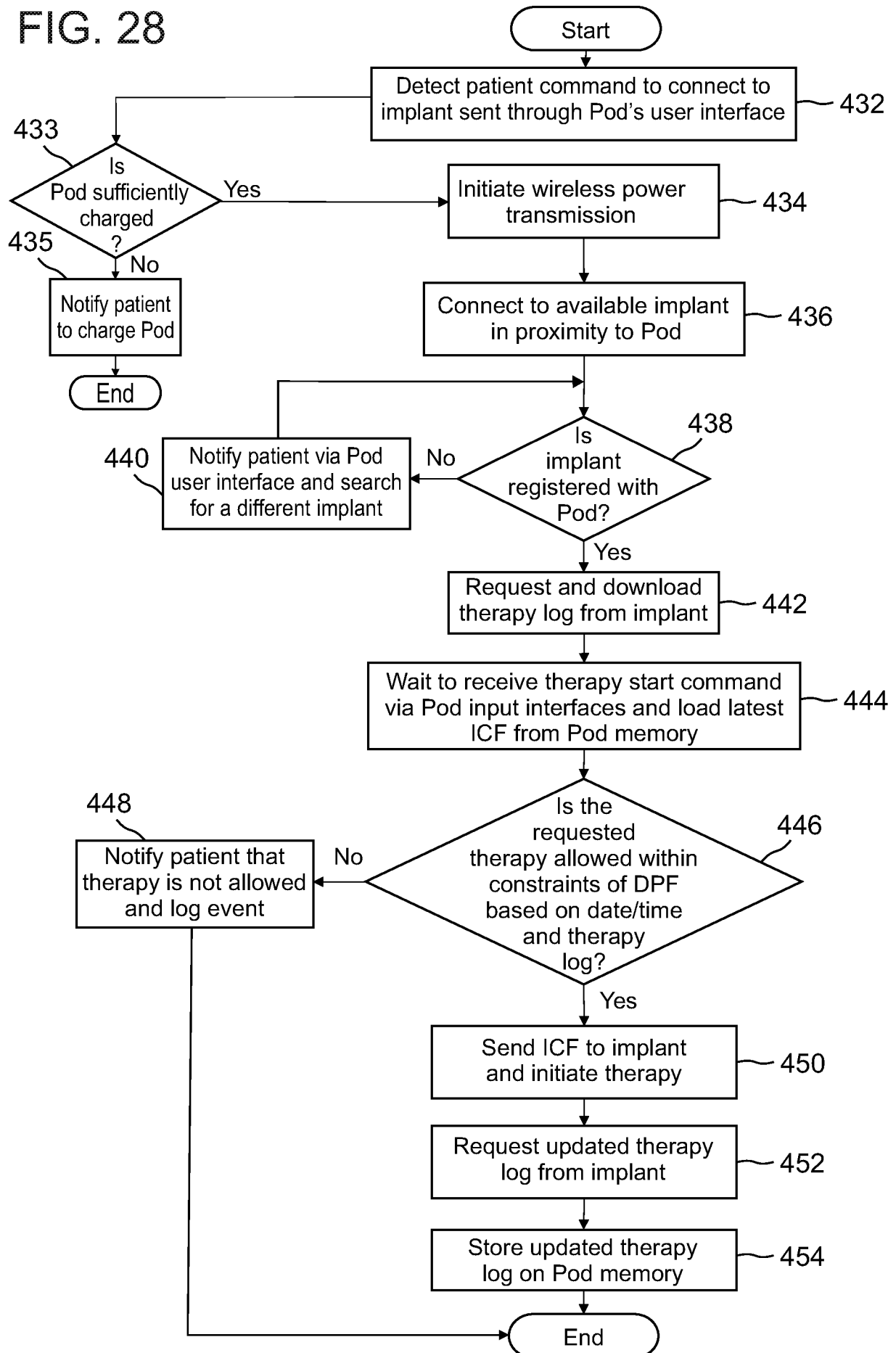


FIG. 29

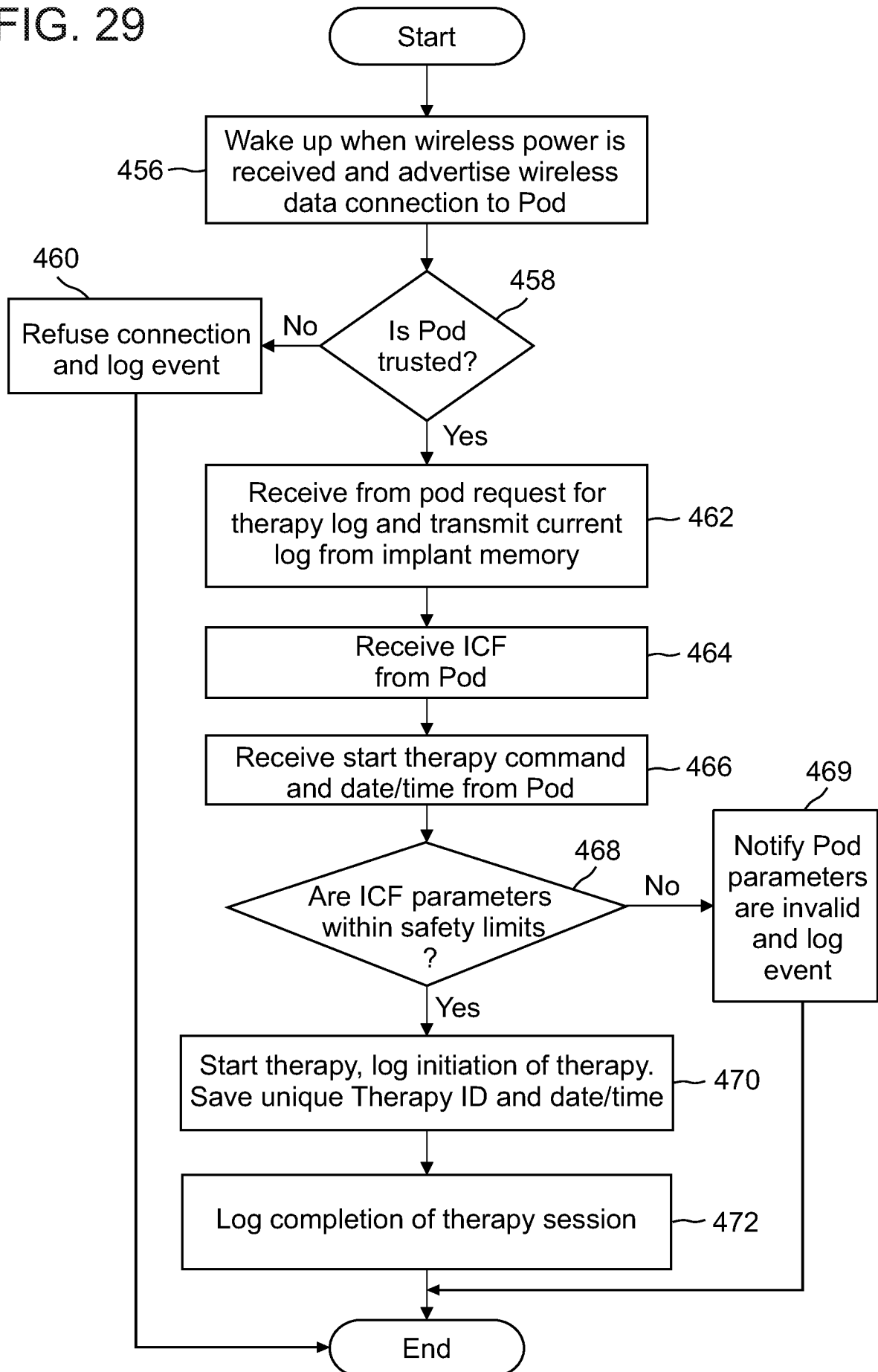


FIG. 30A

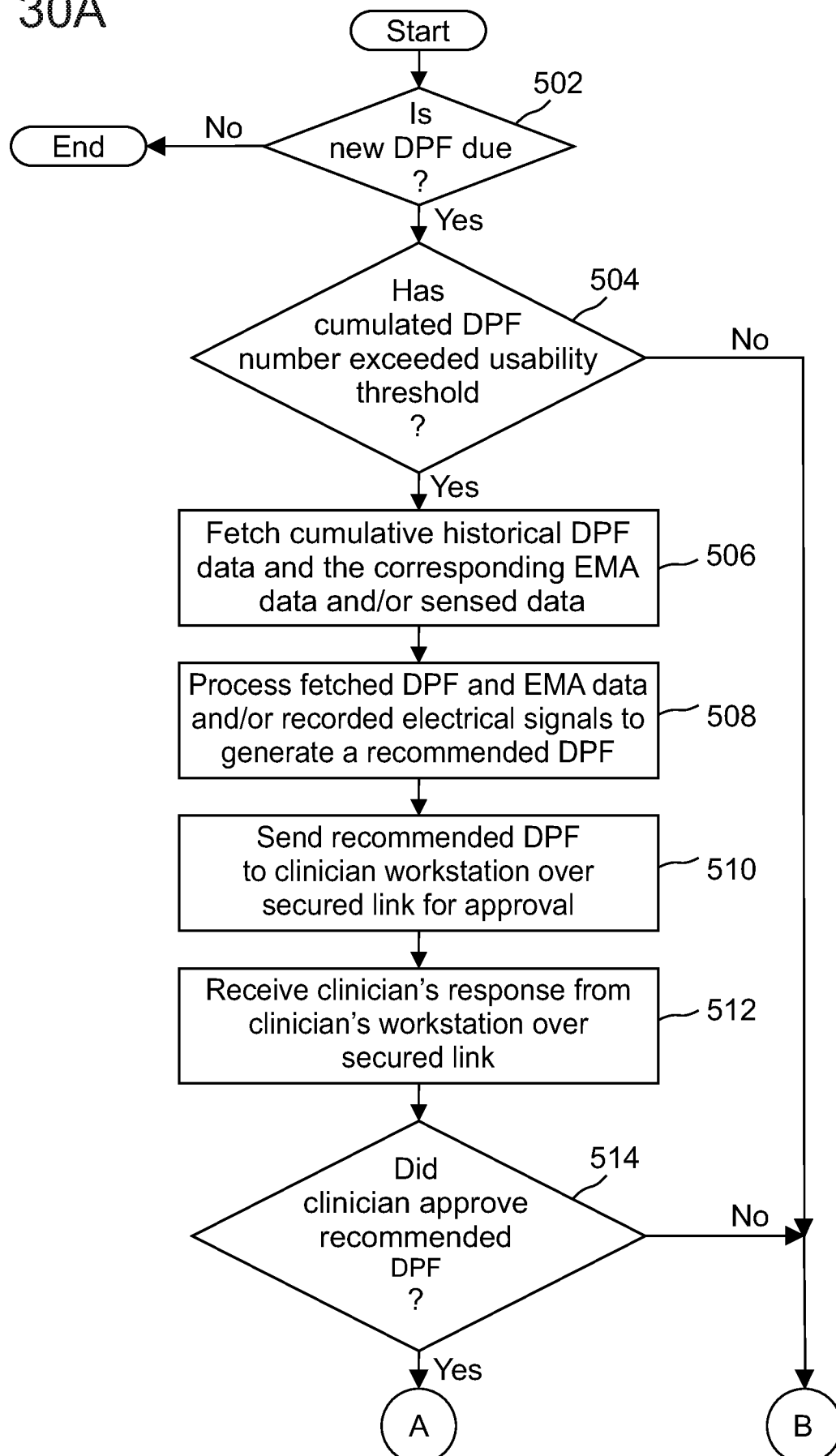
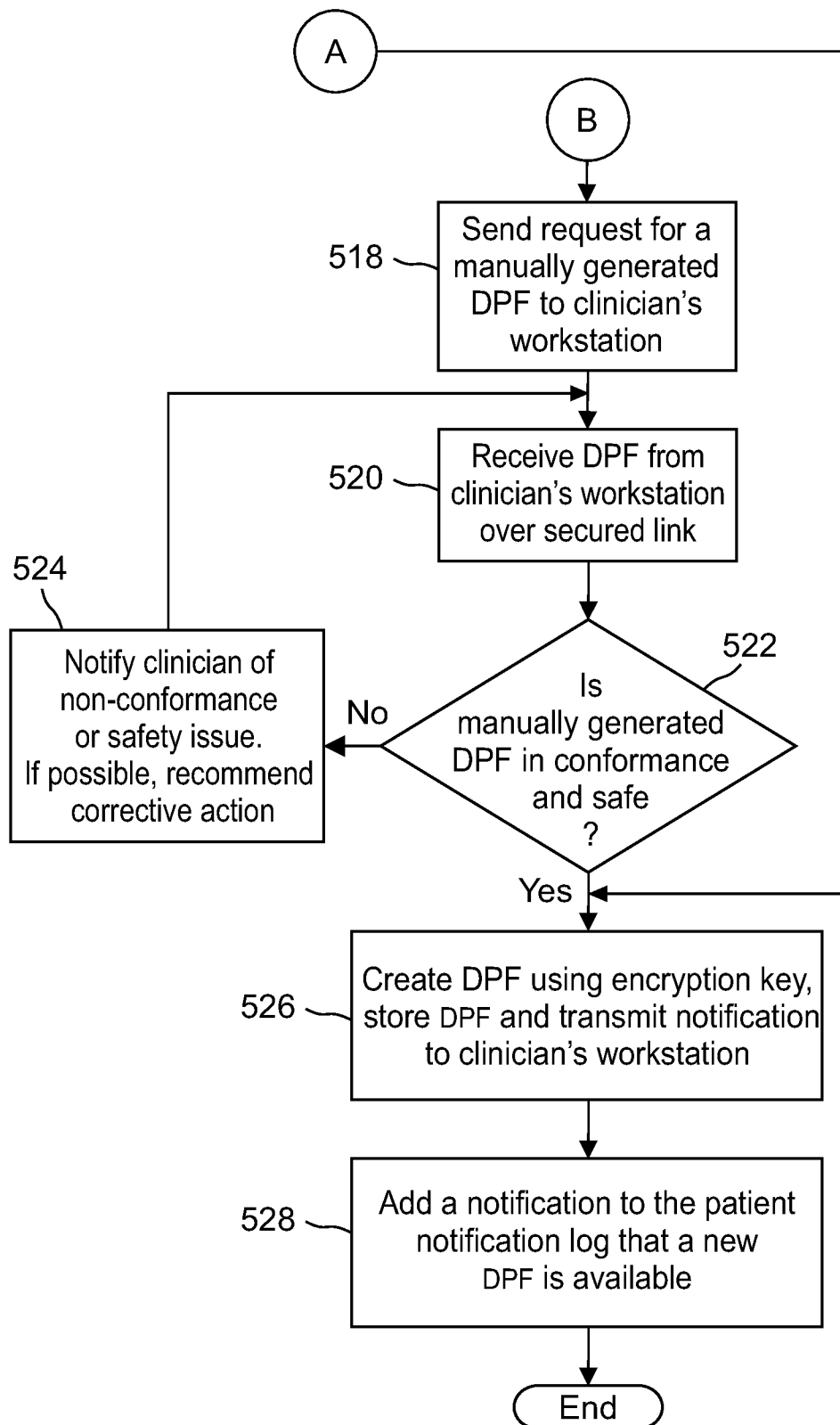


FIG. 30B



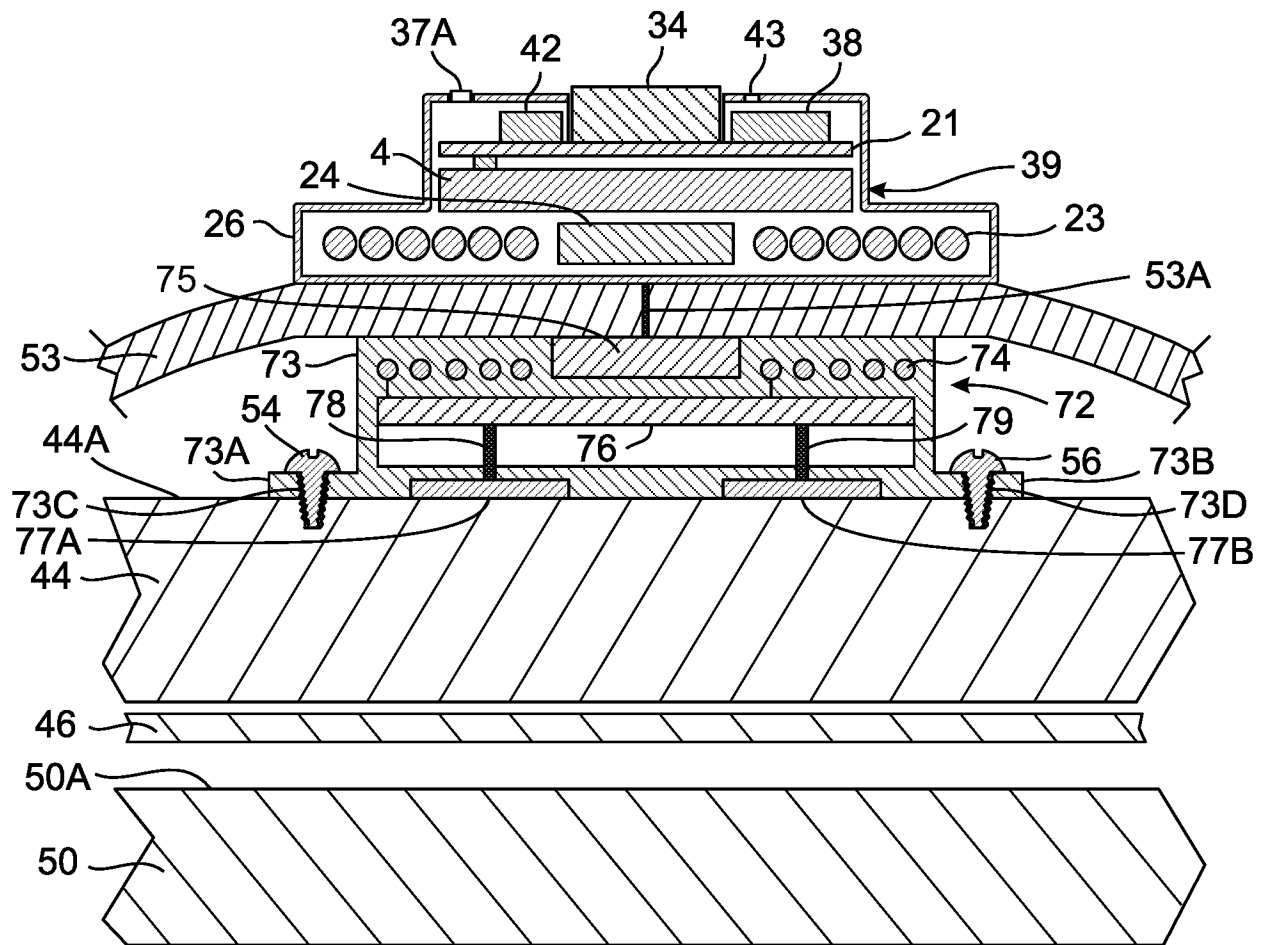


FIG. 31

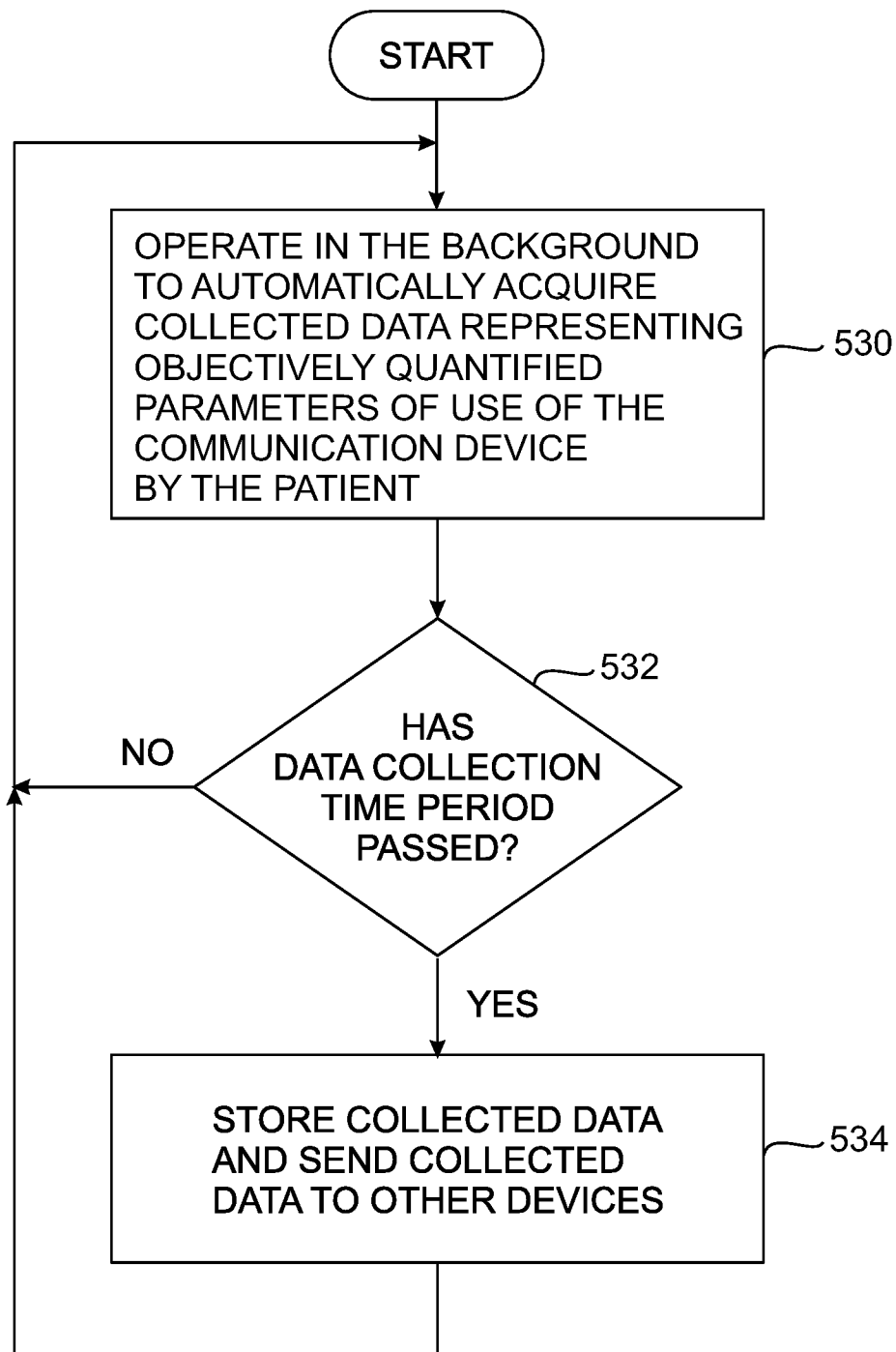


FIG. 32

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2024/062882

A. CLASSIFICATION OF SUBJECT MATTER		
INV.	G16H20/40	G16H40/63
	A61N1/372	A61B5/00
	A61N1/05	
ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
G16H A61B A61N		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2021/144730 A1 (INNER COSMOS INC [US]) 22 July 2021 (2021-07-22) the whole document -----	1 - 82
☐ Further documents are listed in the continuation of Box C.		
☒ See patent family annex.		
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"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	
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"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search	Date of mailing of the international search report	
19 February 2025	06/03/2025	
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Gardiner, Alexander	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2024/062882

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2021144730 A1	22-07-2021	US 2023075205 A1	09-03-2023
		WO 2021144730 A1	22-07-2021
