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December 09, 2019

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APPLICATION NUMBER: *62/772,284*
FILING DATE: *November 28, 2018*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US62/772,284*

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PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2018ID112818
	Application Number	
Title of Invention	ISOLATED NEUROSTIMULATOR CIRCUIT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
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☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	IGOR		IZYUMIN	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	PLEASANTON	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	2748 KERR STREET		
Address 2			
City	CASTRO VALLEY	State/Province	CA
Postal Code	94546	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	24737		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	ISOLATED NEUROSTIMULATOR CIRCUIT		
Attorney Docket Number	2018ID112818	Small Entity Status Claimed	☐
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	4	Suggested Figure for Publication (if any)	

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2018ID112818
	Application Number	
Title of Invention	ISOLATED NEUROSTIMULATOR CIRCUIT	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
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This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)

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Approved for use through 11/30/2020. OMB 0651-0032
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2018ID112818
	Application Number	
Title of Invention	ISOLATED NEUROSTIMULATOR CIRCUIT	

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2018ID112818
	Application Number	
Title of Invention	ISOLATED NEUROSTIMULATOR CIRCUIT	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

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☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2018ID112818
	Application Number	
Title of Invention	ISOLATED NEUROSTIMULATOR CIRCUIT	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	KONINKLIJKE PHILIPS N.V.		
Mailing Address Information For Applicant:			
Address 1	HIGH TECH CAMPUS 5		
Address 2			
City	EINDHOVEN	**State/Province**	
Country	NL	Postal Code	5656 AE
Phone Number		Fax Number	
Email Address			

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Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2018ID112818
	Application Number	
Title of Invention	ISOLATED NEUROSTIMULATOR CIRCUIT	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

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Address 2			
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Country i		Postal Code	
Phone Number		Fax Number	
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Signature:

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This Application Data Sheet must be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Sherry Austin/			Date (YYYY-MM-DD)	2018-11-28
First Name	Sherry	Last Name	Womack Austin	Registration Number	62,356

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2018ID112818
	Application Number	
Title of Invention	ISOLATED NEUROSTIMULATOR CIRCUIT	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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ISOLATED NEUROSTIMULATOR CIRCUIT

The present invention comprises an isolated, multi-channel stimulator circuit with a high voltage compliance range and improved performance. A cascode architecture reduces the operating voltage of the current source device and permits direct connection to the channel controller, thus allowing individual channels to be galvanically isolated from each other, improving safety and performance while minimizing component count.

Background

Electrical neurostimulators are widely used in a variety of clinical and research contexts. These devices are commonly used for cortical stimulation in conjunction with an electroencephalography (EEG) system for functional mapping.

Problems or disadvantages overcome by the invention

Existing approaches to electrical stimulation have several limitations addressed by this invention. It is desirable for a stimulator to have a high compliance voltage to allow the use of high-impedance electrodes. In some cases, voltages up to 250V may be necessary. However, circuit architectures typically used for neurostimulators typically expose the main current source transistor to the full compliance voltage. Since the current source is controlled by low-voltage digital and mixed-signal circuits, this approach necessitates the use of costly and esoteric analog isolation circuitry, such as photo-MOS transistors and optical isolators. In addition to cost, analog optical isolation limits achievable stimulation bandwidth and decreases linearity and accuracy. In the present invention, high-voltage cascode transistors are used to reduce the voltage seen by the main current source transistor, permitting direct connection between the high-voltage current source and the low-voltage channel controller.

Additional complexity arises when multiple stimulation channels are used. Existing approaches typically place all of the stimulator channels in one isolation domain, which results in poorly-controlled current paths, reducing stimulation effectiveness and increasing risk to the patient. Mitigating these added risks requires significant circuit complexity and increases cost, size, and power consumption. The present invention places each stimulation channel into a dedicated isolation domain, and places the channel controller on the isolated side to eliminate the need to send analog signals across the galvanic isolation barrier. Risk to the patient is minimized, because current flow between channel circuits is not possible.

The main element(s) of the invention

The present invention comprises an isolated, multi-channel stimulator circuit. Each stimulator channel is a galvanically isolated unit comprising an isolated power source, isolated digital data link, a step-up DC/DC converter, an H-bridge current source, control circuits, and safety circuits. The H-bridge uses high-voltage switch transistors configured as cascode source followers to reduce the maximum voltage seen by the main current source to logic levels. This permits all control and supervision functions to be performed by a standard, low-cost microcontroller or FPGA with a minimum of additional interface or isolation circuitry.

Detailed description of how to build and use the invention

The stimulator system comprises a system controller and one or more mutually galvanically isolated stimulation channels. The system controller generates the appropriate stimulation parameters, communicates them to channel controllers, and monitors system operation and safety (for example, by monitoring current consumed by each stimulation channel and periodically polling the status of each channel controller).

A block diagram of the isolated stimulator channel circuit is shown in the preceding figure. The channel receives galvanically isolated low-voltage power and digital data and optionally timing signals thorough the block labelled "isolation". A DC/DC step-up converter converts the low voltage power to the appropriate voltage for stimulation (typically in the range of 20..250V). This DC/DC converter may employ a variable conversion ratio to allow operation with different electrode impedances and stimulation current ranges. Optionally, the ratio can be adjusted dynamically to maintain current source compliance by measuring the voltage at the drain of M5 during stimulation and adjusting the conversion ratio to maintain a sufficient compliance margin.

The current source unit comprises the switch FETs (M1, M2), cascode FETs (M3, M4), a current source FET (M5), a sense resistor (R1), and an error amplifier (A2). To generate both positive and negative currents, the switches and cascode FETs are configured as an H-bridge. For example, to produce a current from the + electrode to the – electrode, SW_HP and SW_LN are driven high, while SW_LP and SW_HN are driven low; this turns on M2 and M3 and turns off M1 and M4. ISET is driven with a voltage proportional to the desired current; the error amplifier adjusts the current through M5 so that it is equal to V(ISET)/R(R1). The cascode devices M3/M4 limit the voltage on the drain of M5 to below V(+5Vi), allowing high-speed, low-voltage devices to be used for M5 and A2, thus improving bandwidth.

Other features of this configuration include the ability to short the electrodes to either the +HV or the ISOGND rails. It is important to maintain charge balance during stimulation to prevent polarization and unwanted chemical reactions at the skin-electrode interface. Since it is not possible to guarantee perfect matching between the total charge of the positive and negative halves of the stimulation waveform, a small amount of imbalance charge will build up on the electrode capacitance after every stimulation pulse train. Shorting the electrodes between stimulation pulses is a simple and effective way of removing this charge. Shorting the electrodes to the +HV rail is also an effective way of precharging the parasitic capacitance between the isolated channel and the patient, thus avoiding artifacts and excessive current flow at the beginning of the stimulation pulse, or when switching polarity.

A channel controller block (comprising at least one processing element, such as an FPGA or MCU, and associated interface circuits) controls the operation of the stimulator channel. The primary function of the controller block is to generate a voltage proportional to the programmed current on the ISET output and to control the operation of the SW_xx switches to generate the appropriate waveform on the patient electrodes. The main system processor communicates with the channel controller via a galvanically isolated digital interface (such as an asynchronous serial port).

The channel controller is also responsible for monitoring system status to ensure patient safety. The measured parameters may include compliance voltage (drain of M5), return current sense voltage V(ISENSE1), and the supply current sense voltage V(ISENSE2). Faults in the current source circuit will result in a mismatch between the supply and return currents and/or a mismatch between the programmed and sensed currents. Upon detection of a fault, the controller can put the circuit in a failsafe state by disabling the DC/DC converter and turning off all switches. Optionally, the system controller may shut down the isolated power supply to the faulty channel and/or disconnect the patient electrodes from the current source outputs.

To ensure safety against single faults, the controller may incorporate auxiliary safety monitoring circuits, such as watchdog timers and auxiliary processing elements. For example, the main processing unit may be an FPGA, and an auxiliary supervisor MCU may provide parallel supervision. If either processing unit detects a fault or is unable to communicate with the other unit, it may generate a fault signal and the channel put in a failsafe state.

The primary application of this invention is in the neurology field. It has direct applicability to the GTEN project in the Philips Neuro business unit, and significant applicability in a variety of new products currently being conceptualized and/or developed by Philips Neuro. The primary

application field is clinical intraoperative monitoring, functional mapping, and neurology research.

ISOLATED NEUROSTIMULATOR CIRCUIT

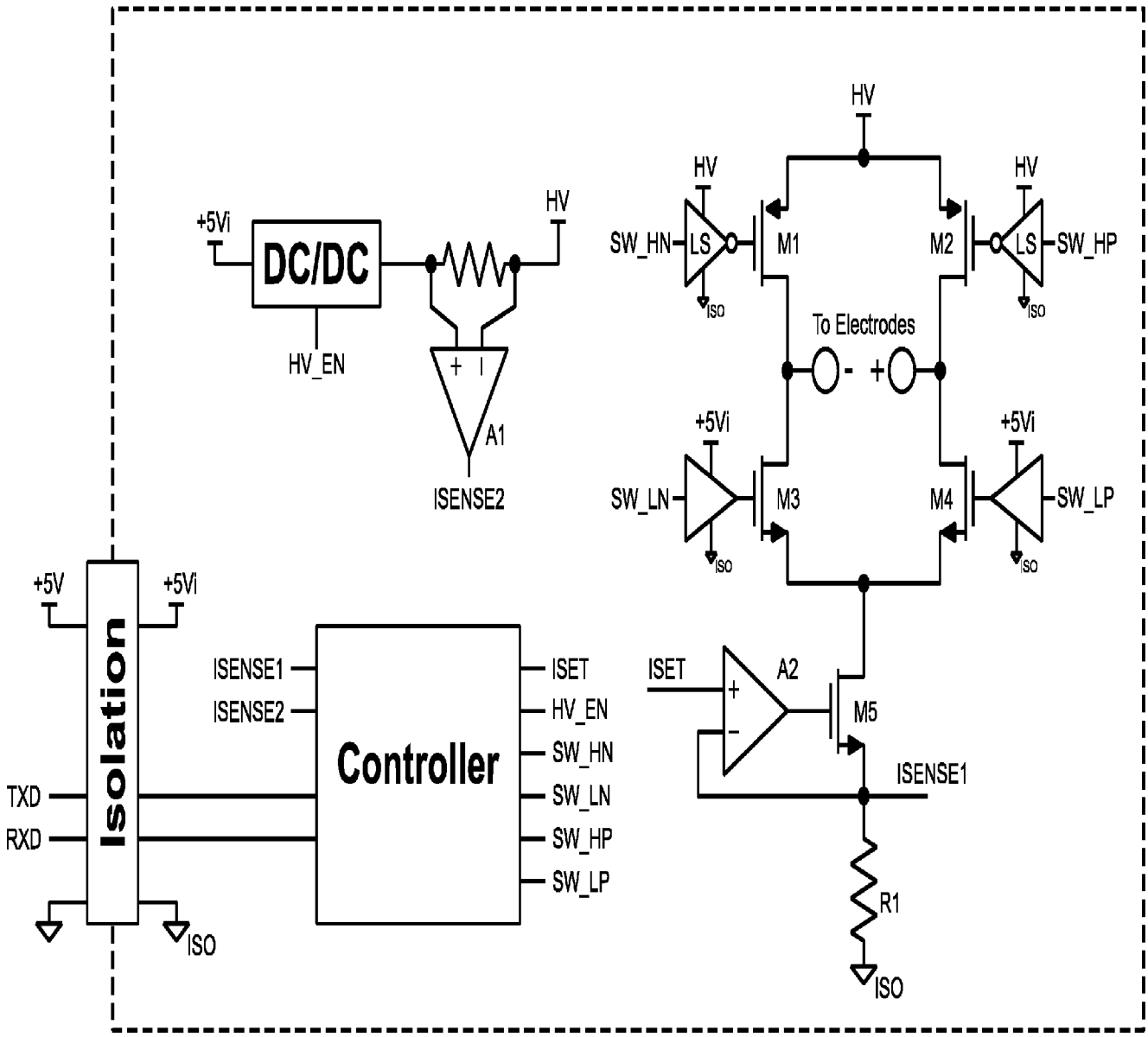

FIG. 1

Electronic Acknowledgement Receipt

EFS ID:	34422035
Application Number:	62772284
International Application Number:	
Confirmation Number:	7555
Title of Invention:	ISOLATED NEUROSTIMULATOR CIRCUIT
First Named Inventor/Applicant Name:	IGOR IZYUMIN
Customer Number:	24737
Filer:	Sherry Ann Womack/Noemi Chapa
Filer Authorized By:	Sherry Ann Womack
Attorney Docket Number:	2018ID112818
Receipt Date:	28-NOV-2018
Filing Date:	
Time Stamp:	14:47:57
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$280
RAM confirmation Number	112918INTEFSW00013598141270
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	2018ID112818_ADS_SIGNED.pdf	1255852 31343aa06f6d67afb3e354b305c65dab044bb151	no	8
Warnings:					
Information:					
2	Specification	2018ID112818_Specification.pdf	44325 7409b23ecad2c280f311e875db2a97f5a1d16fb3	no	4
Warnings:					
Information:					
3	Drawings-only black and white line drawings	2018ID112818_Drawings.pdf	46590 dff2cfb7e663cc85d16589db3cd0e50b75a9e5d8	no	1
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	29791 12633ce5e0098adc727e5f44ba95934701ac3233	no	2
Warnings:					
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.