

(12) **United States Patent**
Mazanec et al.

(10) **Patent No.:** **US 12,390,634 B2**
(45) **Date of Patent:** **Aug. 19, 2025**

(54) **FULLY IMPLANTABLE MODULAR
COCHLEAR IMPLANT SYSTEM**

(71) Applicant: **Envoy Medical Corporation**, White
Bear Lake, MN (US)

(72) Inventors: **Paul R. Mazanec**, Ham Lake, MN
(US); **Joshua J. Wibben**, New
Brighton, MN (US); **Timothy J.
Earnest**, Vadnais Heights, MN (US);
Benjamin R. Whittington, Maplewood,
MN (US)

(73) Assignee: **Envoy Medical Corporation**, White
Bear Lake, MN (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 1221 days.

(21) Appl. No.: **16/840,968**

(22) Filed: **Apr. 6, 2020**

(65) **Prior Publication Data**

US 2020/0238075 A1 Jul. 30, 2020

Related U.S. Application Data

(63) Continuation of application No. 15/679,755, filed on
Aug. 17, 2017, now Pat. No. 10,646,709.
(Continued)

(51) **Int. Cl.**
A61N 1/02 (2006.01)
A61N 1/05 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61N 1/025** (2013.01); **A61N 1/0541**
(2013.01); **A61N 1/36017** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC .. A61N 1/025; A61N 1/36038; A61N 1/0541;
A61N 1/36017; A61N 1/36125;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,827,041 A 3/1958 Pierson
4,400,590 A 8/1983 Michelson
(Continued)

FOREIGN PATENT DOCUMENTS

CN 104394930 A 3/2015
CN 110086237 A 8/2019
(Continued)

OTHER PUBLICATIONS

European Patent Application No. 17842124.4 European Search
Report dated Apr. 1, 2020, 7 pgs.

(Continued)

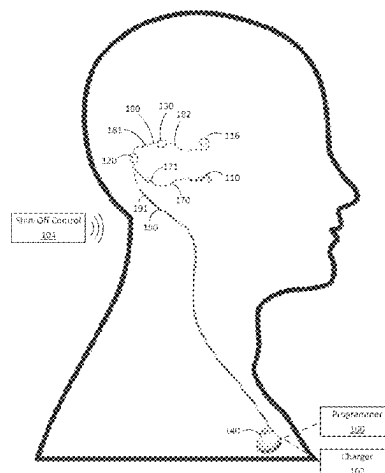
Primary Examiner — Lindsey G Wehrheim

(74) *Attorney, Agent, or Firm* — Fredrikson & Byron,
P.A.

(57) **ABSTRACT**

Cochlear implant systems can include a cochlear electrode,
a stimulator in electrical communication with the cochlear
electrode, a signal processor in communication with the
stimulator, and an implantable battery and/or communica-
tion module. The signal processor can receive an input
signal from an input source and output a stimulation signal
to the stimulator based on the received input signal and a
transfer function of the signal processor. The implantable
battery and/or communication module may be configured to
provide electrical power to the signal processor. The signal
processor may include circuitry and a can surrounding and
housing the circuitry as well as a first impedance between
the circuitry and the can to reduce unintended electrical
communication. The implantable battery and/or communi-
cation module may include circuitry and a can surrounding
and housing the circuitry as well as a second impedance
between the circuitry and the can to reduce unintended
electrical communication.

21 Claims, 19 Drawing Sheets



Related U.S. Application Data			
(60)	Provisional application No. 62/376,195, filed on Aug. 17, 2016, provisional application No. 62/376,198, filed on Aug. 17, 2016.	2002/0039425 A1	4/2002 Burnett et al.
		2002/0099421 A1	7/2002 Goldsmith et al.
		2004/0230254 A1	11/2004 Harrison et al.
		2005/0033384 A1	2/2005 Sacha
		2005/0197677 A1	9/2005 Stevenson
		2006/0122664 A1	6/2006 Sacha et al.
		2006/0183965 A1	8/2006 Kasic, II et al.
(51)	Int. Cl.	2008/0195179 A1	8/2008 Quick
	<i>A61N 1/36</i> (2006.01)	2008/0300658 A1	12/2008 Meskens
	<i>A61N 1/372</i> (2006.01)	2009/0018616 A1	1/2009 Quick et al.
	<i>A61N 1/378</i> (2006.01)	2009/0082831 A1	3/2009 Paul et al.
	<i>H04R 25/00</i> (2006.01)	2009/0171421 A1*	7/2009 Atalar A61N 1/06
	<i>A61N 1/08</i> (2006.01)		607/63
(52)	U.S. Cl.	2009/0187233 A1	7/2009 Stracener
	CPC <i>A61N 1/36038</i> (2017.08); <i>A61N 1/36125</i>	2009/0192565 A1	7/2009 Lee et al.
	(2013.01); <i>A61N 1/36128</i> (2013.01); <i>A61N</i>	2010/0010582 A1	1/2010 Carbanaru et al.
	<i>1/36146</i> (2013.01); <i>A61N 1/36192</i> (2013.01);	2010/0030012 A1	2/2010 Meskens
	<i>A61N 1/372</i> (2013.01); <i>A61N 1/37223</i>	2010/0042183 A1	2/2010 Beck
	(2013.01); <i>A61N 1/3787</i> (2013.01); <i>H04R</i>	2010/0179615 A1	7/2010 Zhang et al.
	<i>25/554</i> (2013.01); <i>A61N 2001/083</i> (2013.01);	2010/0317913 A1	12/2010 Conn et al.
	<i>A61N 1/36039</i> (2017.08); <i>H04R 2225/55</i>	2011/0082521 A1	4/2011 Botros et al.
	(2013.01); <i>H04R 2225/61</i> (2013.01); <i>H04R</i>	2011/0098785 A1	4/2011 Mishra
	<i>2225/67</i> (2013.01); <i>H04R 2430/01</i> (2013.01)	2011/0116669 A1	5/2011 Karunasiri
(58)	Field of Classification Search	2011/0137180 A1	6/2011 Johnson et al.
	CPC A61N 1/36128; A61N 1/36146; A61N	2011/0144719 A1	6/2011 Perkins et al.
	1/36192; A61N 1/372; A61N 1/37223;	2011/0160808 A1	6/2011 Lyden et al.
	A61N 1/3787; A61N 1/36039; A61N	2011/0280426 A1	11/2011 Bachler
	2001/083; H04R 25/554; H04R 2225/55;	2011/0295331 A1	12/2011 Wells et al.
	H04R 2225/61; H04R 2225/67; H04R	2012/0063610 A1	3/2012 Kaulberg et al.
	2430/01	2012/0215285 A1	8/2012 Tahmasian et al.
	See application file for complete search history.	2012/0277835 A1	11/2012 Della Santina et al.
		2013/0018216 A1	1/2013 Beckerle et al.
		2013/0023953 A1	1/2013 van den Honert
		2013/0193914 A1	8/2013 Gaddam et al.
		2013/0197613 A1	8/2013 Kelly et al.
		2013/0223664 A1	8/2013 Meskens et al.
		2013/0238055 A1	9/2013 Marnfeldt et al.
(56)	References Cited	2013/0268025 A1	10/2013 Ranu
	U.S. PATENT DOCUMENTS	2013/0278226 A1	10/2013 Cong et al.
	4,495,384 A 1/1985 Scott et al.	2013/0317584 A1	11/2013 Stevenson et al.
	4,729,366 A 3/1988 Schaefer	2014/0058482 A1	2/2014 Gupta et al.
	4,850,962 A 7/1989 Schaefer	2014/0070761 A1	3/2014 Labbe et al.
	4,918,745 A 4/1990 Hutchison	2014/0155947 A1	6/2014 Kroll et al.
	5,540,095 A 7/1996 Sherman et al.	2014/0247954 A1	9/2014 Hall et al.
	5,755,742 A 5/1998 Schuelke et al.	2014/0270211 A1	9/2014 Solum et al.
	5,762,583 A 6/1998 Adams et al.	2014/0275730 A1	9/2014 Lievens et al.
	6,195,585 B1 2/2001 Karunasiri et al.	2014/0309712 A1	10/2014 Masaki et al.
	6,212,431 B1 4/2001 Hahn et al.	2014/0350652 A1	11/2014 Suwito
	6,259,951 B1* 7/2001 Kuzma A61N 1/0541	2015/0125012 A1	5/2015 Sabin
	607/57	2015/0174416 A1	6/2015 Angara et al.
	6,272,382 B1* 8/2001 Faltys A61N 1/375	2015/0224312 A1	8/2015 Platz et al.
	607/57	2015/0374988 A1	12/2015 Laudanski
	6,308,101 B1 10/2001 Faltys et al.	2015/0375003 A1	12/2015 Meskens
	6,358,281 B1 3/2002 Berrang et al.	2016/0050500 A1	2/2016 Liao et al.
	6,391,024 B1 5/2002 Sun et al.	2016/0227333 A1	8/2016 Babico
	7,225,028 B2 5/2007 Della Santina et al.	2017/0043162 A1	2/2017 Lopez-Poveda
	7,319,906 B2 1/2008 Kuzma et al.	2017/0077938 A1	3/2017 Heubi
	7,376,563 B2 5/2008 Leysieffer et al.	2017/0094396 A1	3/2017 Chandramohan et al.
	7,524,278 B2 4/2009 Madsen et al.	2017/0161449 A1	6/2017 Meskens
	7,729,775 B1* 6/2010 Saoji H04R 25/70	2017/0259072 A1	9/2017 Newham et al.
	607/57	2017/0360364 A1	12/2017 Heasman et al.
	8,554,329 B1 10/2013 Mann et al.	2018/0028811 A1	2/2018 Van Gerwen et al.
	8,626,308 B2 1/2014 Meskens	2018/0028827 A1	2/2018 Schilling et al.
	8,655,449 B2 2/2014 Haller et al.	2018/0041848 A1	2/2018 Nielsen et al.
	8,954,158 B2 2/2015 Smith	2018/0050197 A1	2/2018 Mazanec et al.
	9,061,140 B2 6/2015 Shi et al.	2018/0050198 A1	2/2018 Mazanec et al.
	9,205,272 B2 12/2015 Suaning et al.	2018/0050203 A1	2/2018 Mazanec et al.
	9,504,076 B2 11/2016 El-Hoiydi et al.	2018/0059870 A1	3/2018 Krah
	9,539,430 B2 1/2017 Mishra et al.	2018/0264269 A1	9/2018 Meadows
	9,693,155 B2 6/2017 Meister et al.	2018/0317027 A1	11/2018 Bolner et al.
	9,716,952 B2 7/2017 Mauger	2018/0333577 A1	11/2018 Nygard et al.
	9,999,770 B2 6/2018 Walraevens et al.	2018/0361151 A1	12/2018 Ridler et al.
	10,201,704 B2 2/2019 Meskens	2019/0045308 A1	2/2019 Chen et al.
	11,324,958 B2 5/2022 Anderson et al.	2019/0046116 A1	2/2019 Shah et al.
	11,330,378 B1 5/2022 Jelcicova et al.	2019/0190296 A1	6/2019 Paralikar et al.
	2002/0015506 A1 2/2002 Aceti et al.	2019/0217101 A1	7/2019 Shi et al.
	2002/0035309 A1 3/2002 Leysieffer	2019/0231203 A1	8/2019 Harczos
		2019/0344073 A1	11/2019 Baker et al.
		2019/0358450 A1	11/2019 Lo et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2020/0054877	A1	2/2020	Calixto et al.
2021/0084417	A1	3/2021	Bagazov et al.
2021/0121707	A1	4/2021	Fried et al.
2021/0135704	A1	5/2021	El-Hoiydi et al.
2021/0187293	A1	6/2021	Friedling
2021/0361194	A1	11/2021	Arab et al.
2022/0203104	A1	6/2022	Hernandez et al.
2022/0339445	A1	10/2022	Litvak et al.

FOREIGN PATENT DOCUMENTS

DE	4419070	A1	12/1994
DE	60107062	T2	11/2005
DE	102013214049	B4	3/2015
EP	1043914	A2	10/2000
EP	1683544	B1	11/2010
EP	2884766	B1	2/2018
EP	3120579	B1	2/2020
JP	2016024111	A	2/2016
TW	201142830	A	12/2011
WO	2007137032	A2	11/2007
WO	2010056768	A1	5/2010
WO	2012012159	A1	1/2012

WO	2014037888	A1	3/2014
WO	2014054215	A1	4/2014
WO	2015077773	A1	5/2015
WO	2016122606	A1	8/2016
WO	2017100866	A1	6/2017
WO	2018035329	A1	2/2018
WO	2018144732	A1	8/2018

OTHER PUBLICATIONS

International Patent Application No. PCT/US2017/047354, International Search Report and Written Opinion mailed Dec. 22, 2017, 25 pages.

Yip et al. "A Fully-Implantable Cochlear Implant SoC With Piezo-electric Middle-Ear Sensor and Arbitrary Waveform Neural Stimulation" IEEE J Solid-State Circuits, Author Manuscript; Available in PMC Jan. 1, 2016, p. 36.

Envoy Medical Corporation, Internal Document Regarding Aspects of Esteem Implant Sensor with Explanatory Cover Sheet, aspects of the sensor were in public use at least earlier than Aug. 17, 2015, 8 pages.

European Patent Application No. 21163363.1 European Search Report dated May 11, 2021, 10 pages.

* cited by examiner

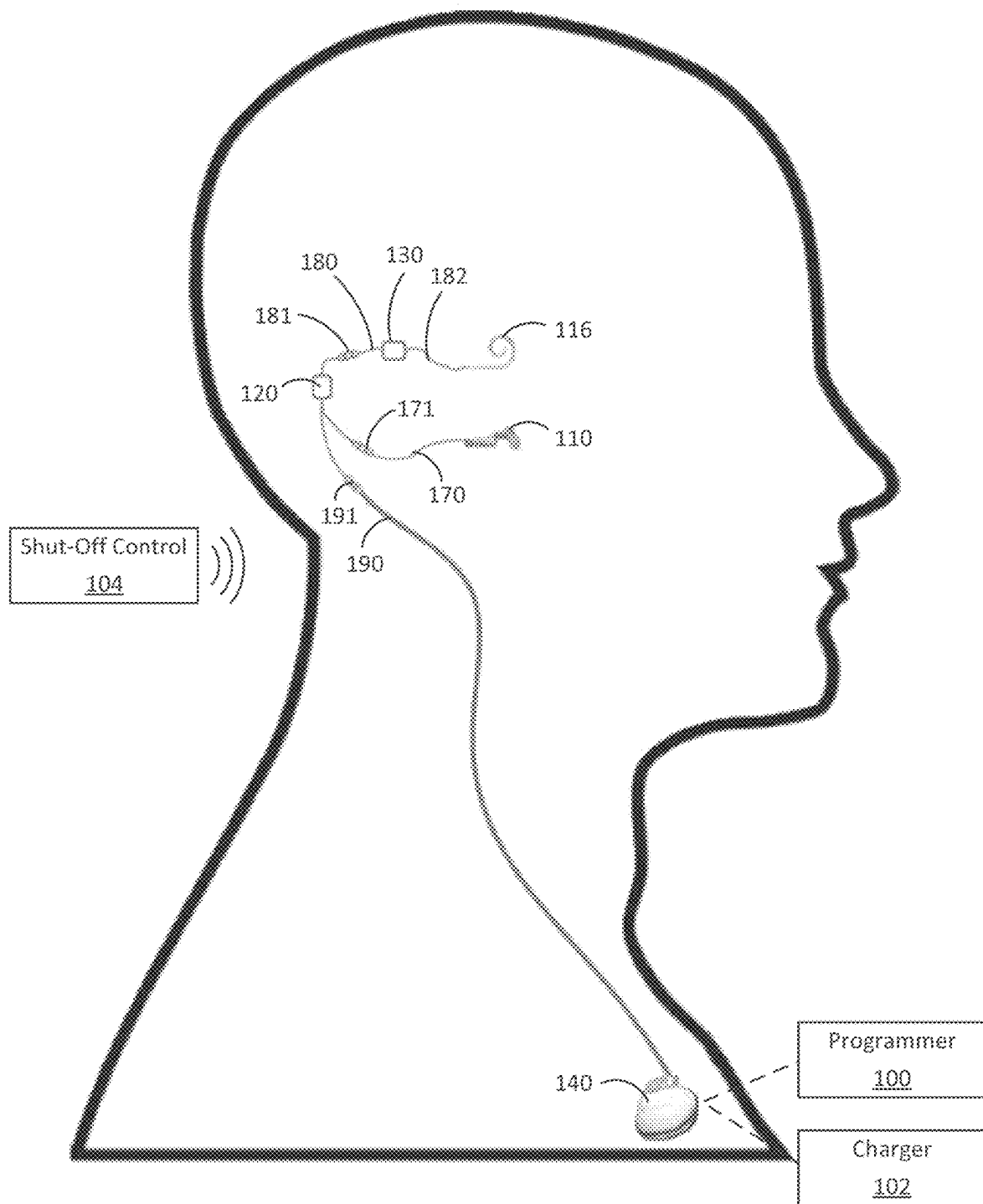


FIG. 1

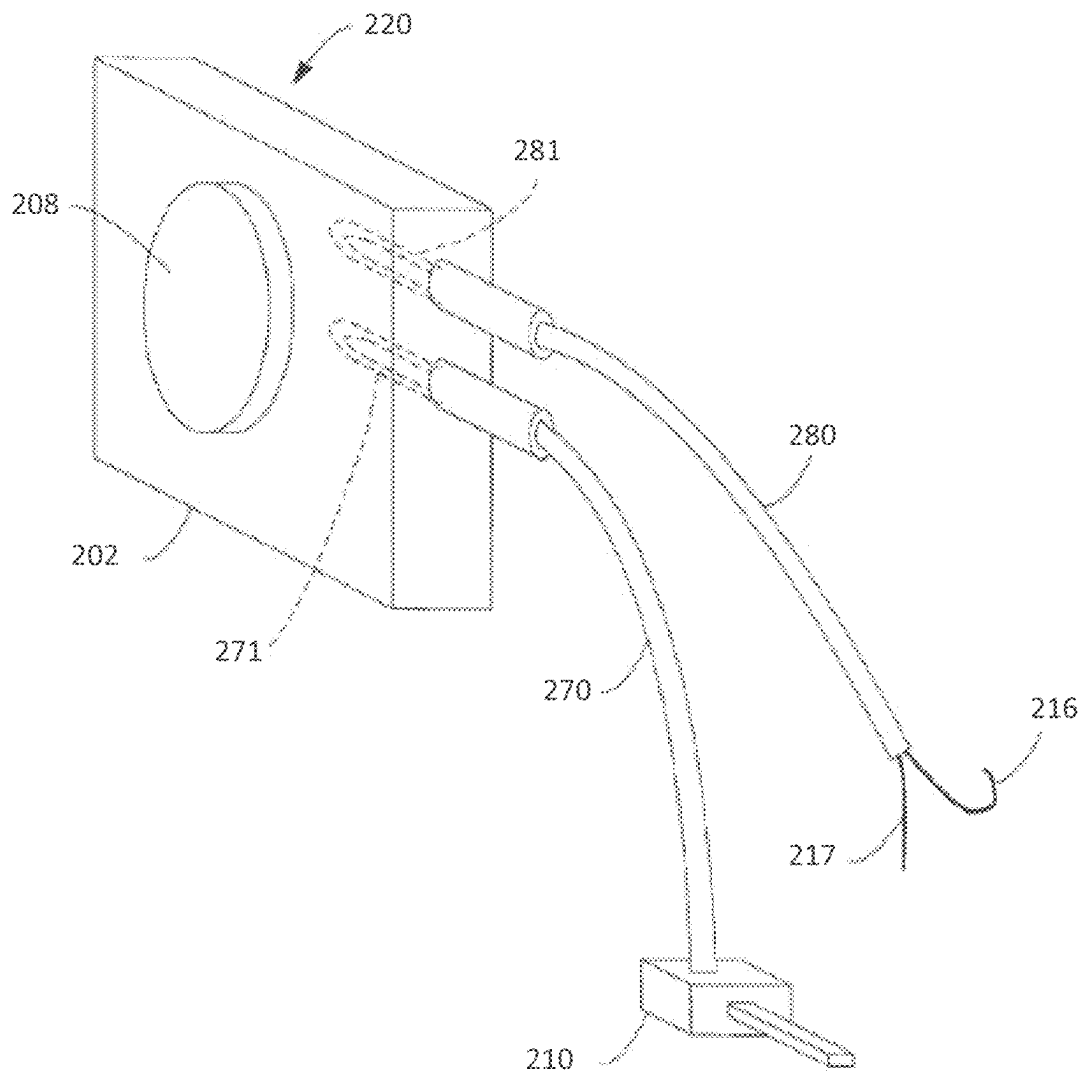


FIG. 2

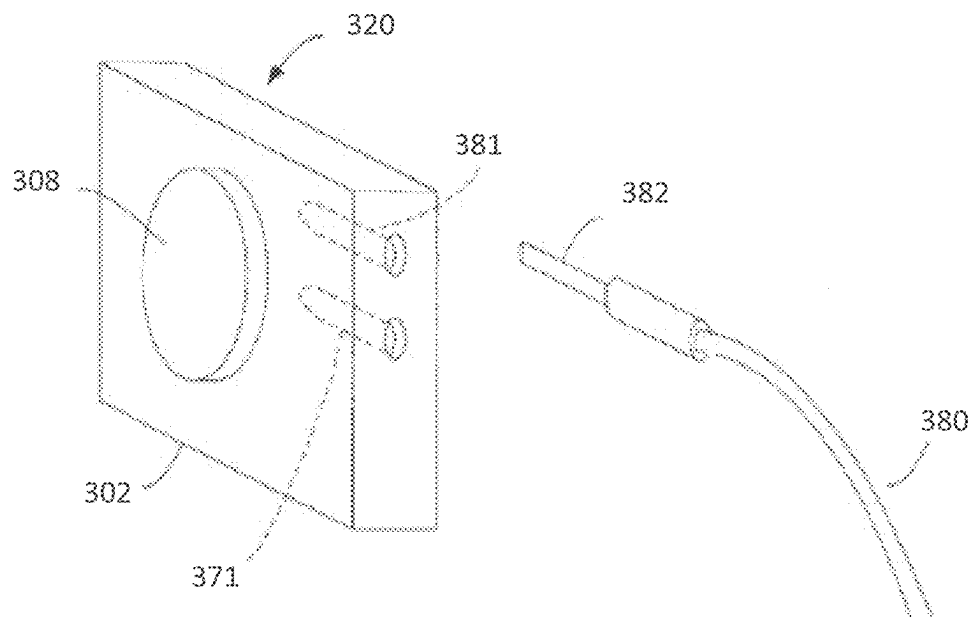


FIG. 3A

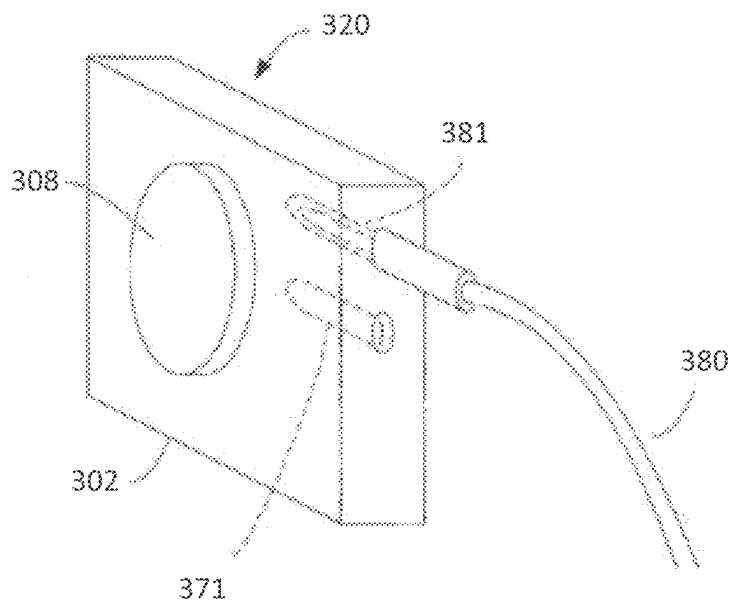


FIG. 3B

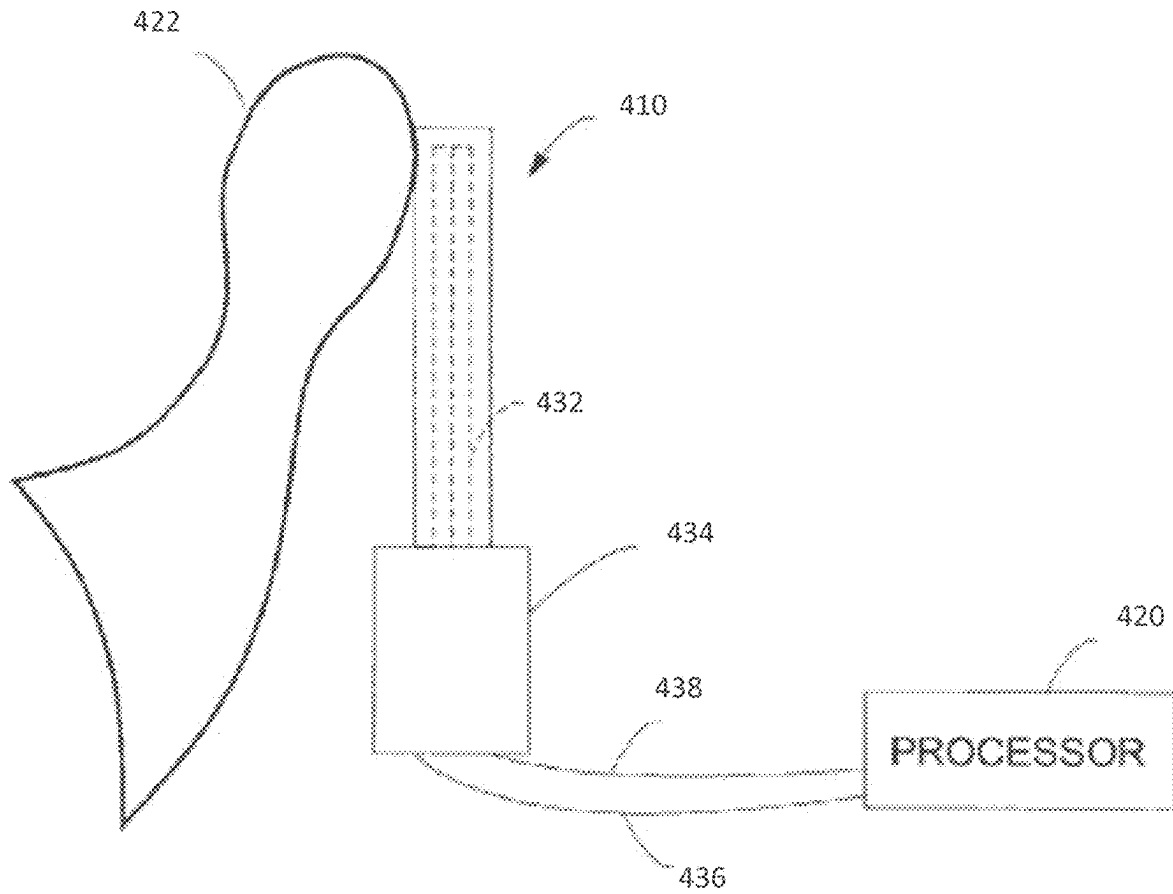


FIG. 4

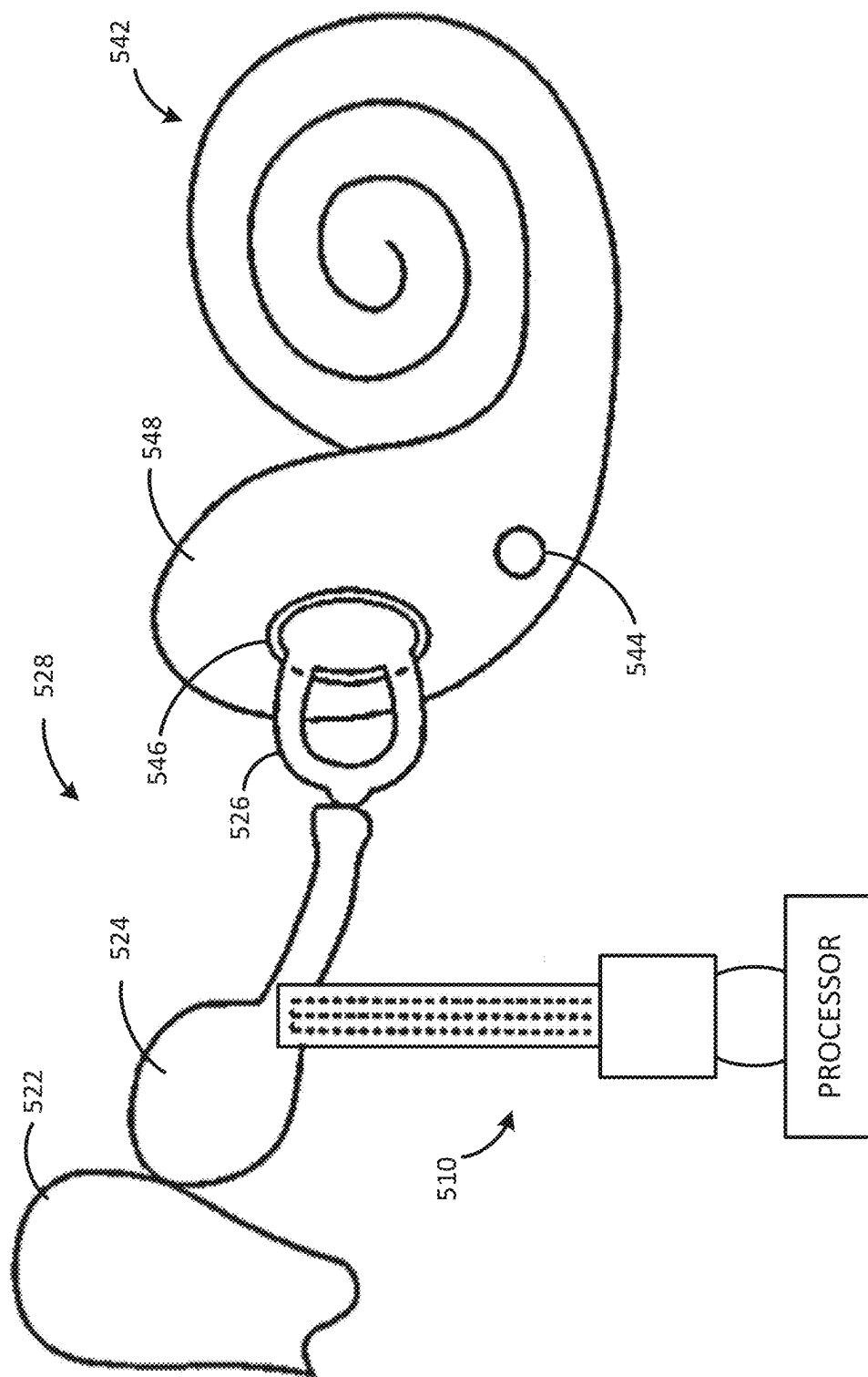


FIG. 5

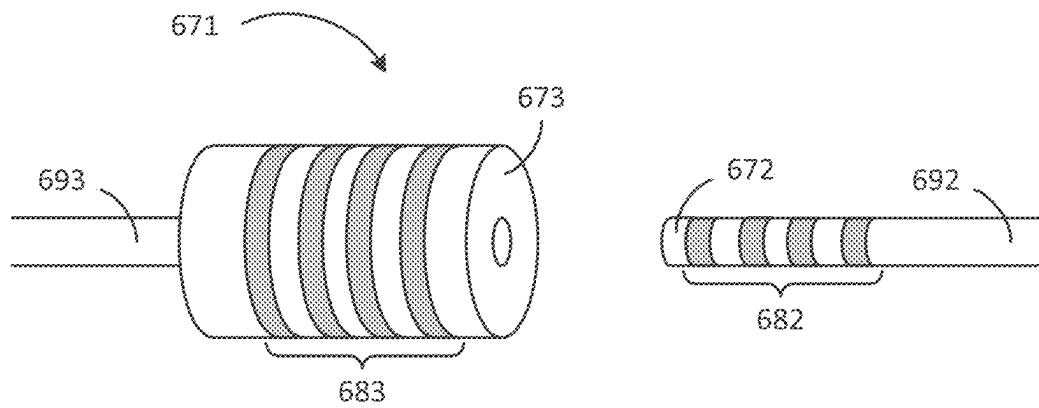


FIG. 6

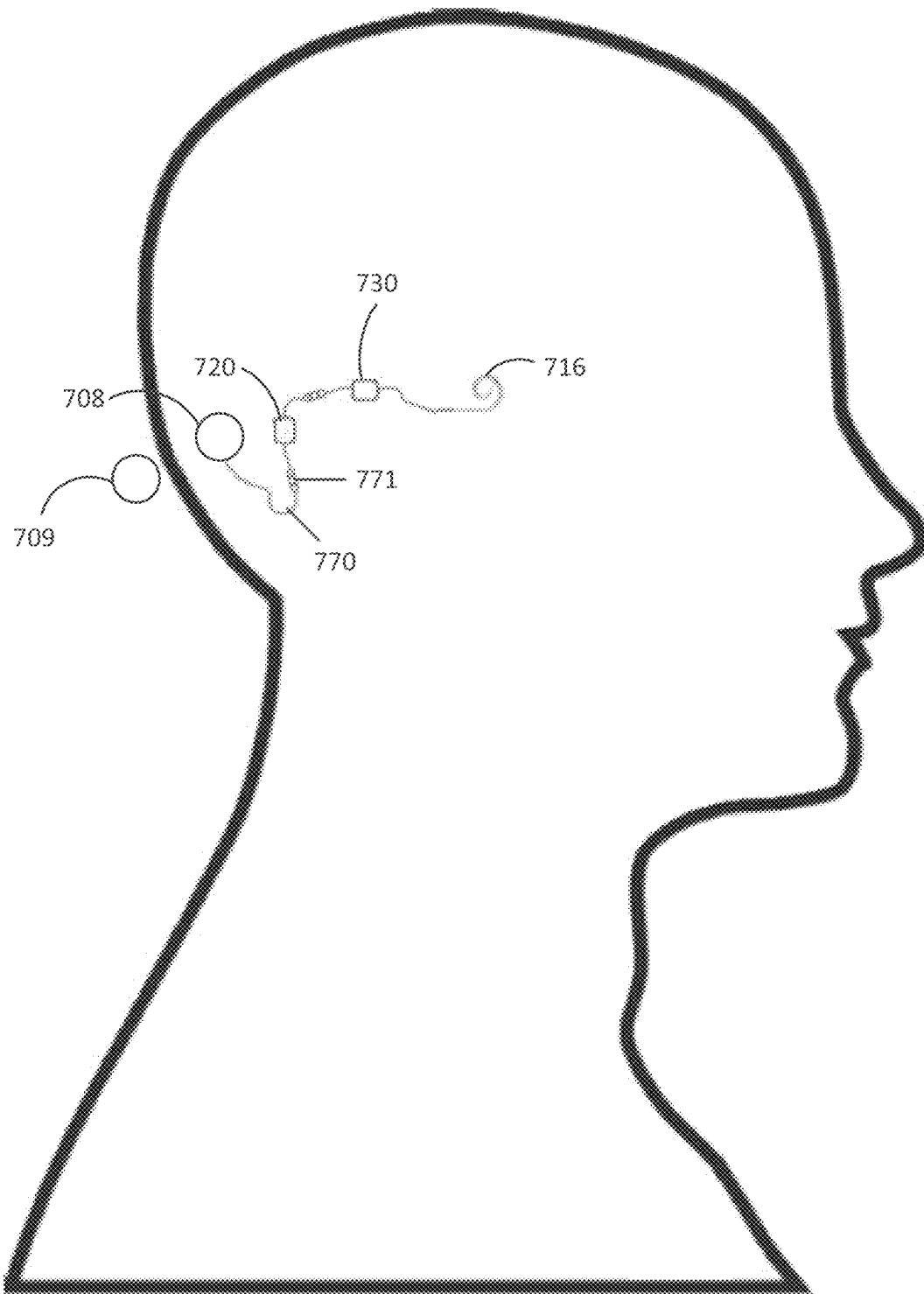


FIG. 7

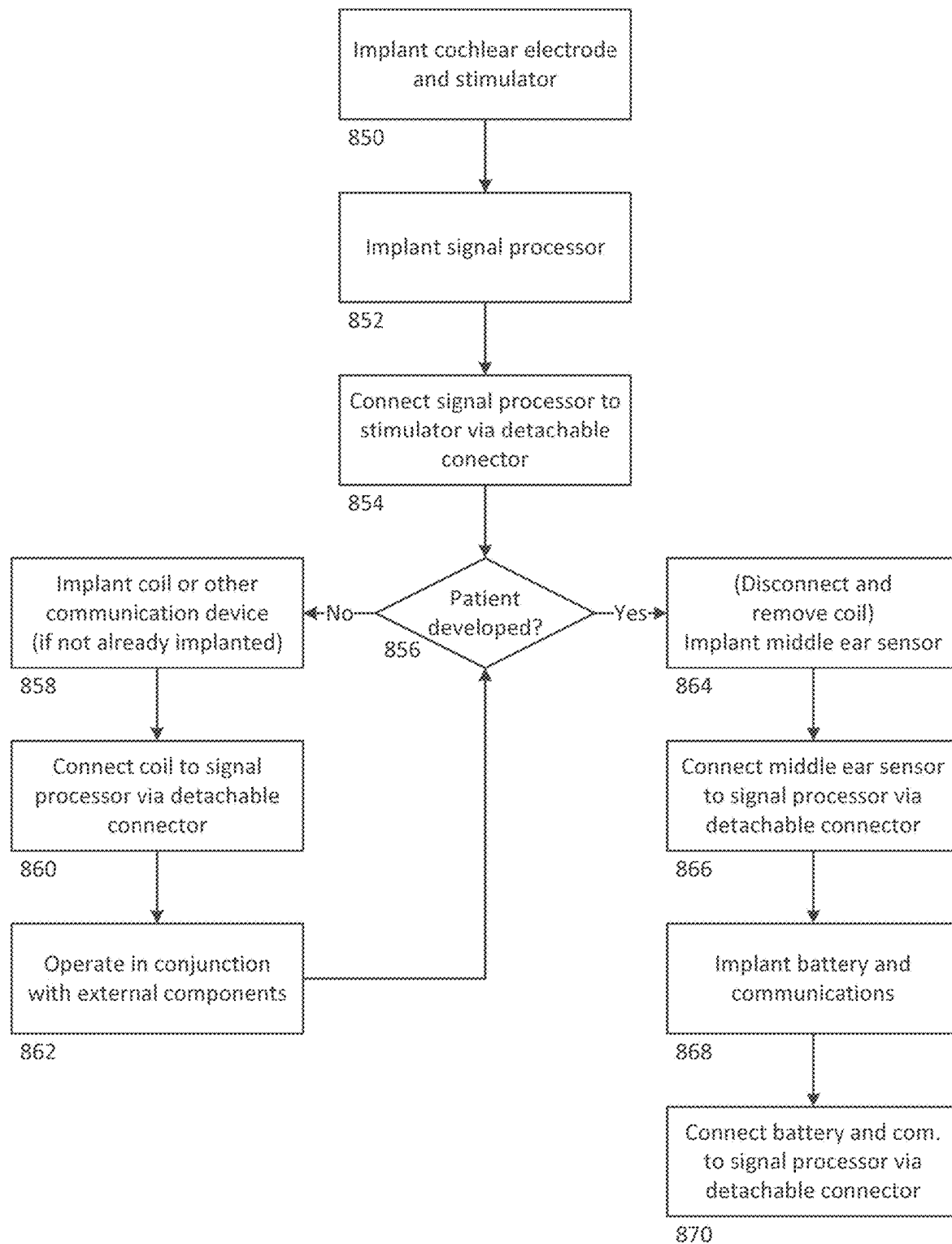


FIG. 8

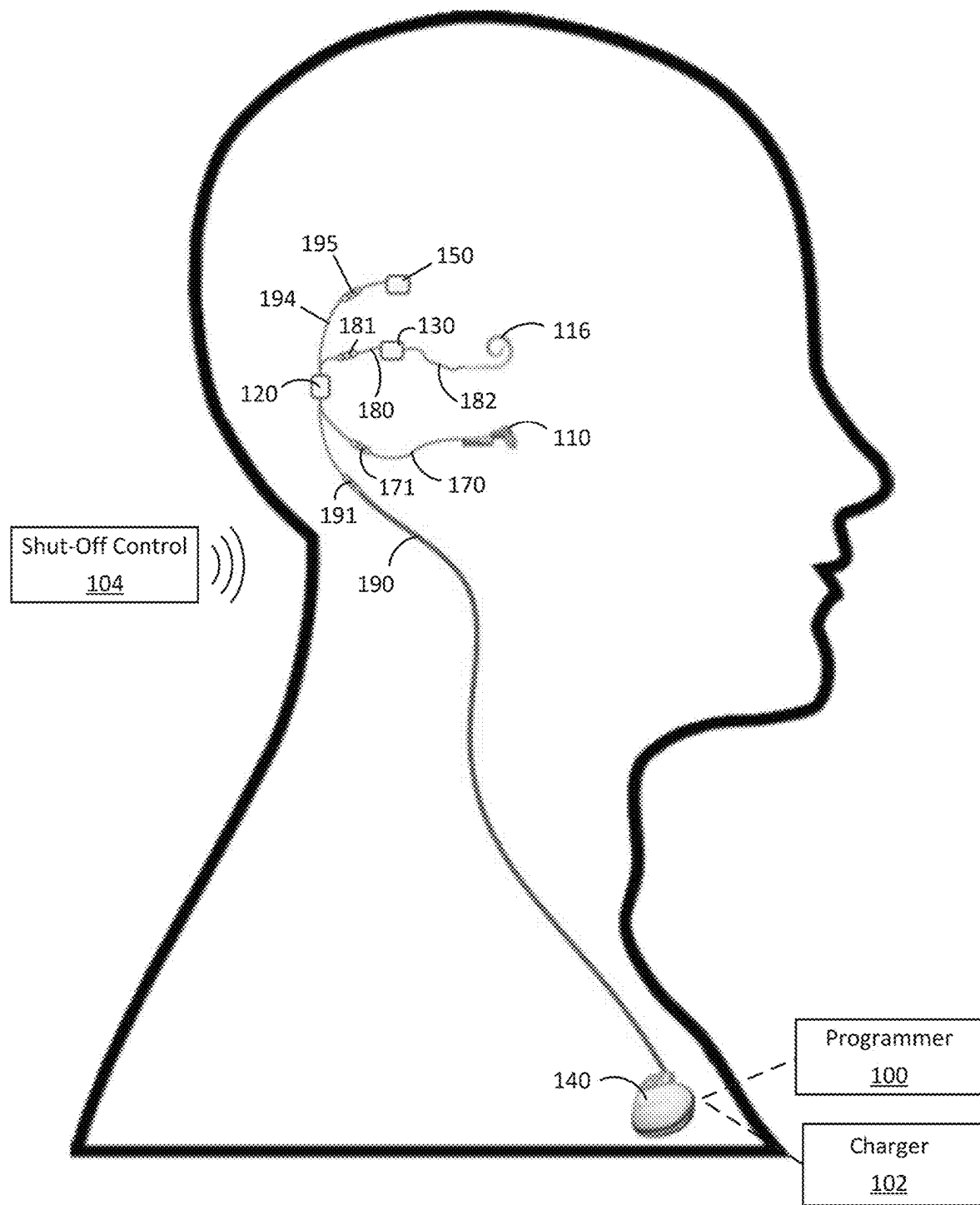


FIG. 9

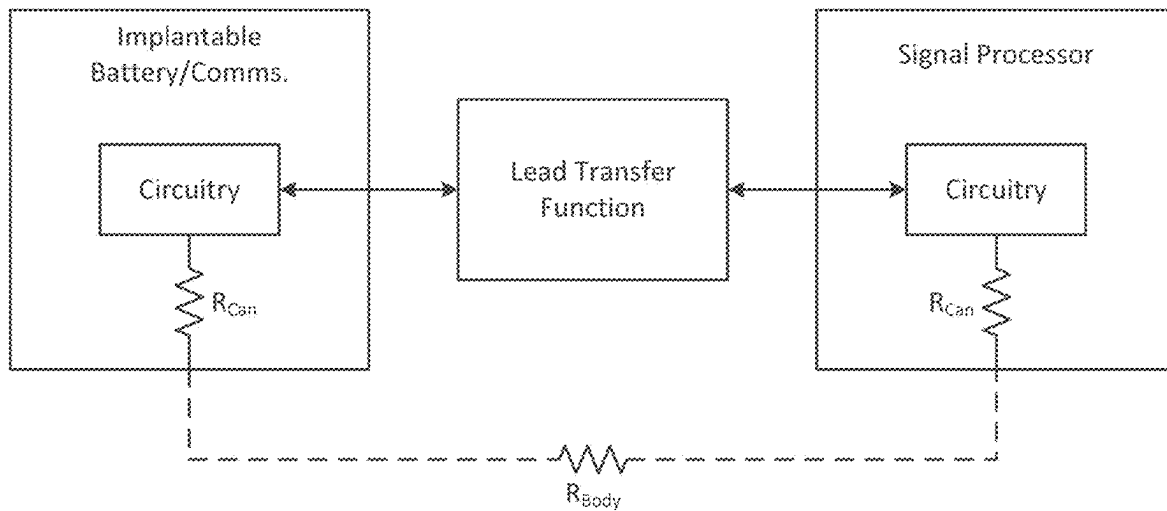


FIG. 10A

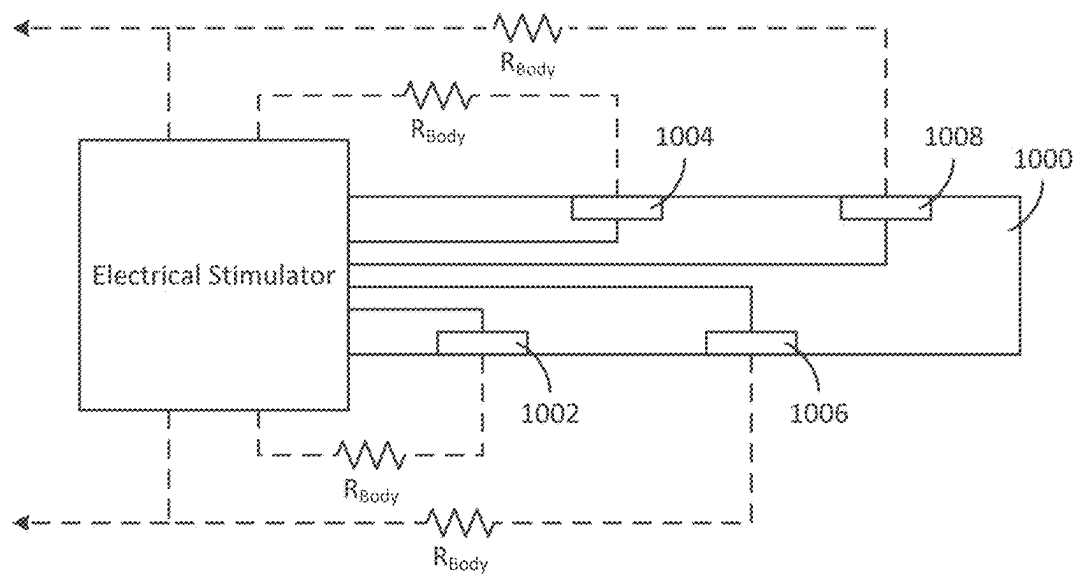


FIG. 10B

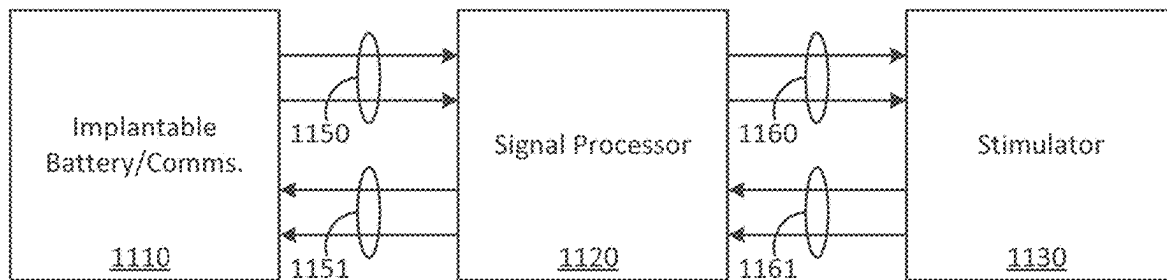


FIG. 11A

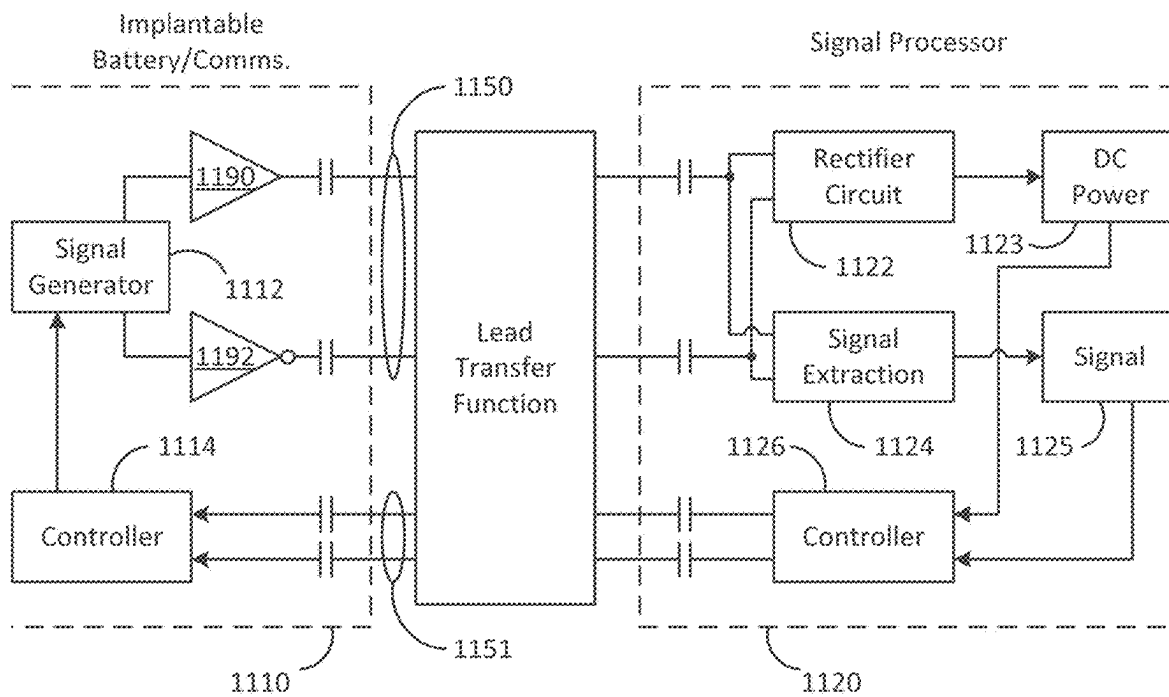


FIG. 11B

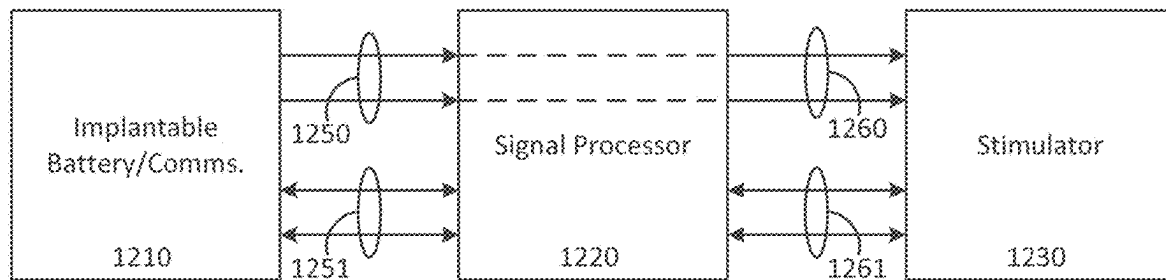


FIG. 12A

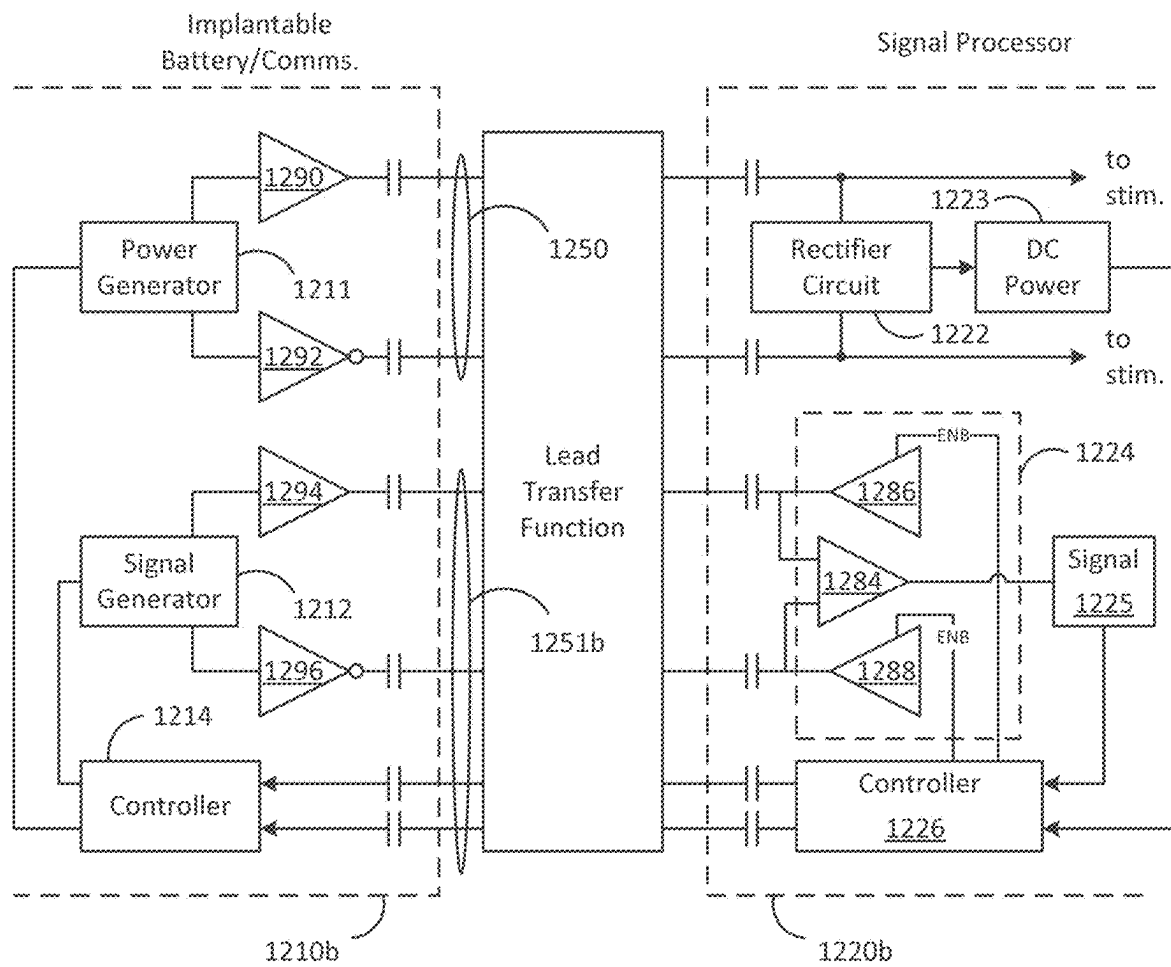


FIG. 12B

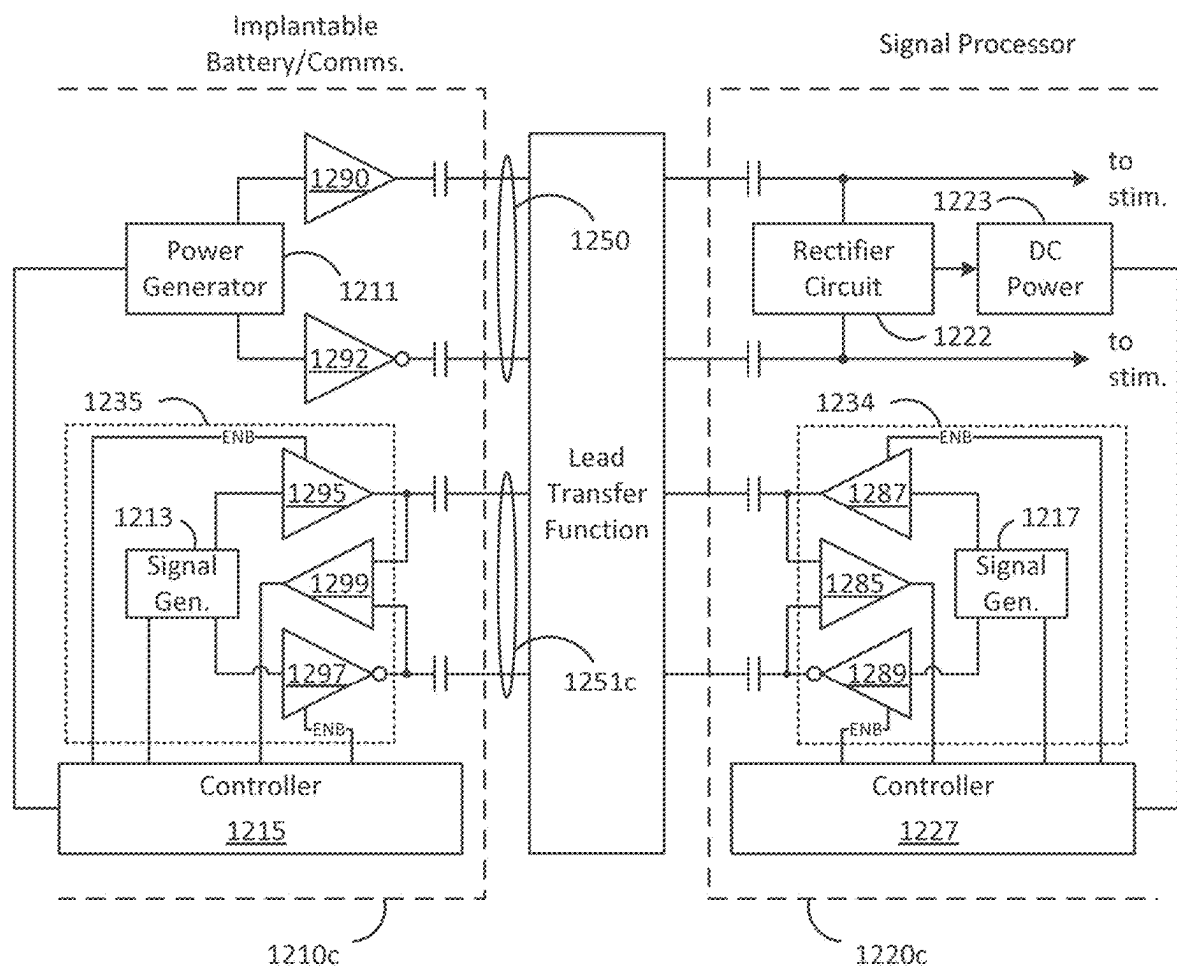


FIG. 12C

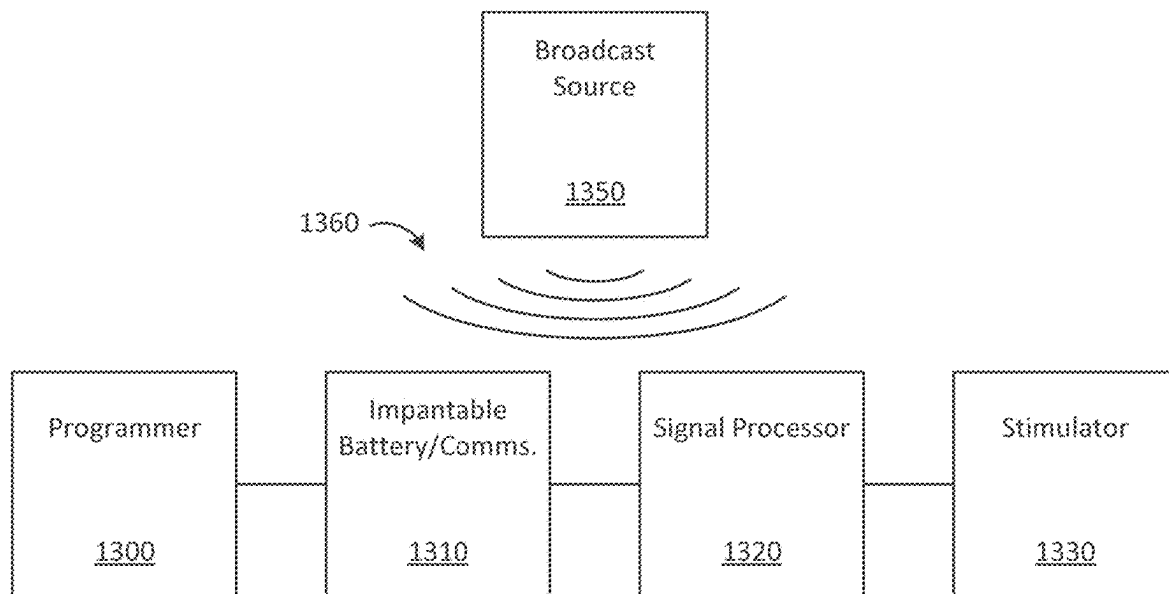


FIG. 13

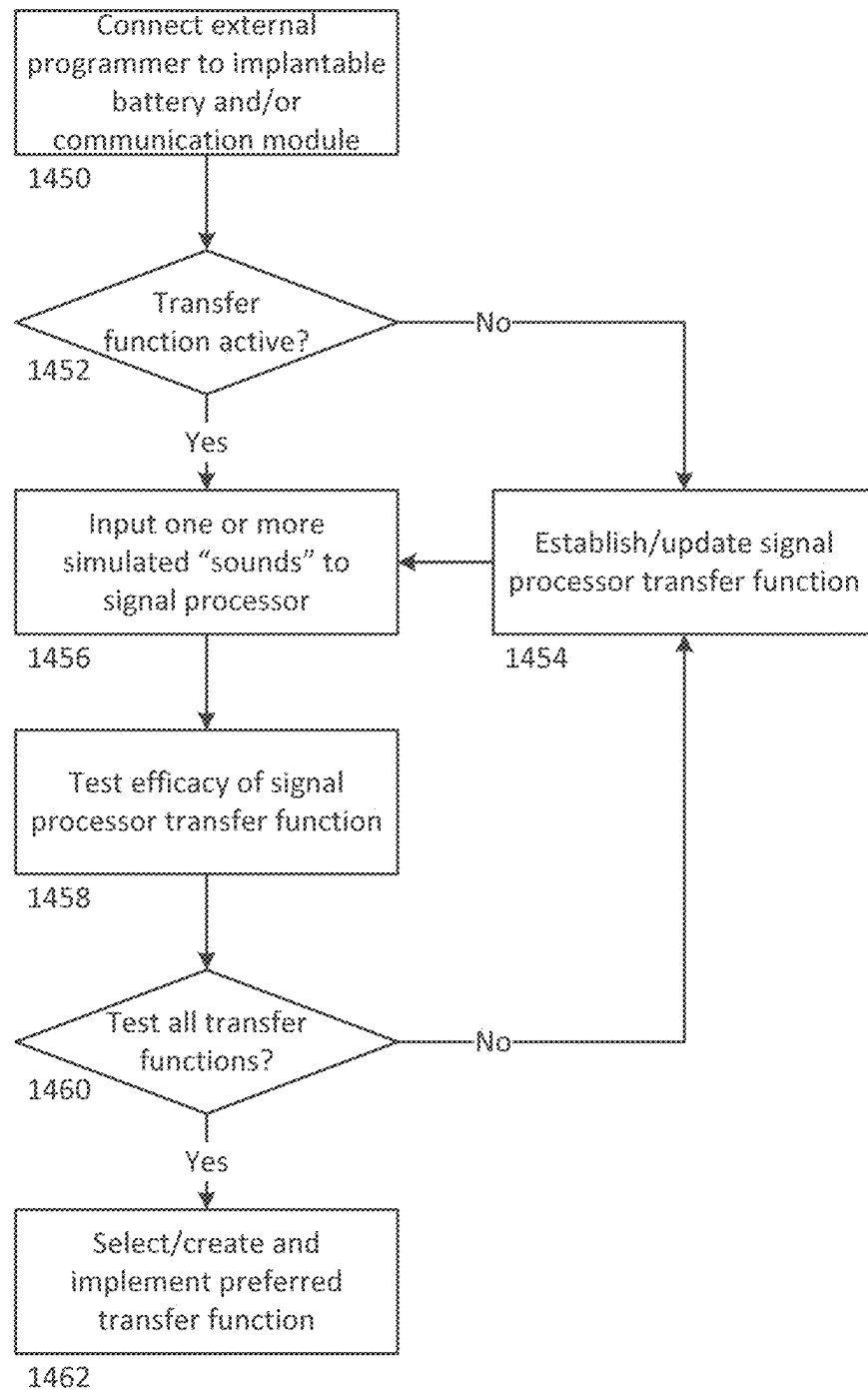


FIG. 14

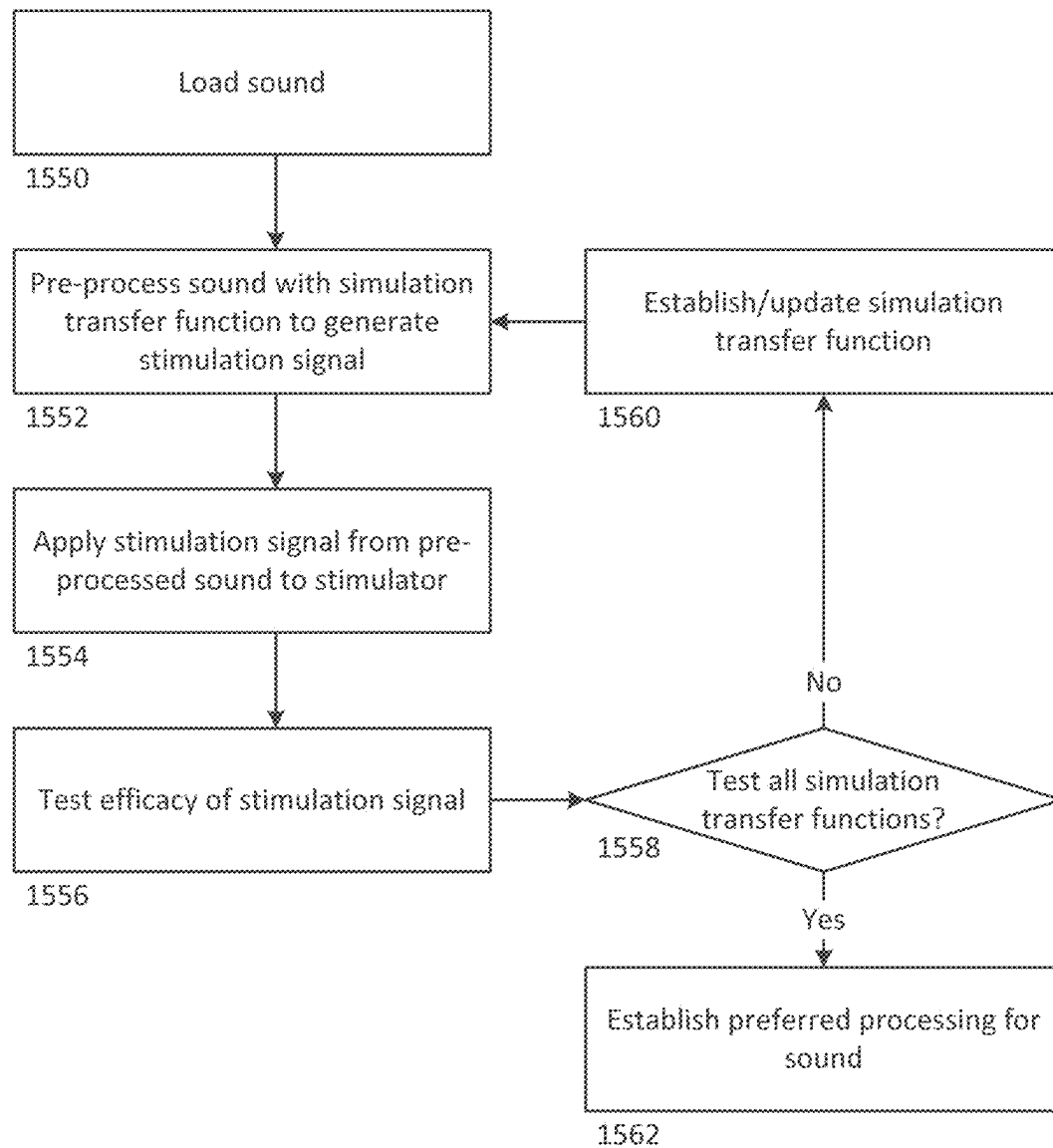


FIG. 15

	Simulated Transfer Function 1	Simulated Transfer Function 2	Simulated Transfer Function 3	...	Simulated Transfer Function m
Sound 1	Stimulation Signal (1,1)	Stimulation Signal (1,2)	Stimulation Signal (1,3)	...	Stimulation Signal (1,m)
Sound 2	Stimulation Signal (2,1)	Stimulation Signal (2,2)	Stimulation Signal (2,3)	...	Stimulation Signal (2,m)
Sound 3	Stimulation Signal (3,1)	Stimulation Signal (3,2)	Stimulation Signal (3,3)	...	Stimulation Signal (3,m)
⋮	⋮	⋮	⋮	⋮	⋮
Sound n	Stimulation Signal (n,1)	Stimulation Signal (n,2)	Stimulation Signal (n,3)	...	Stimulation Signal (n,m)

FIG. 16

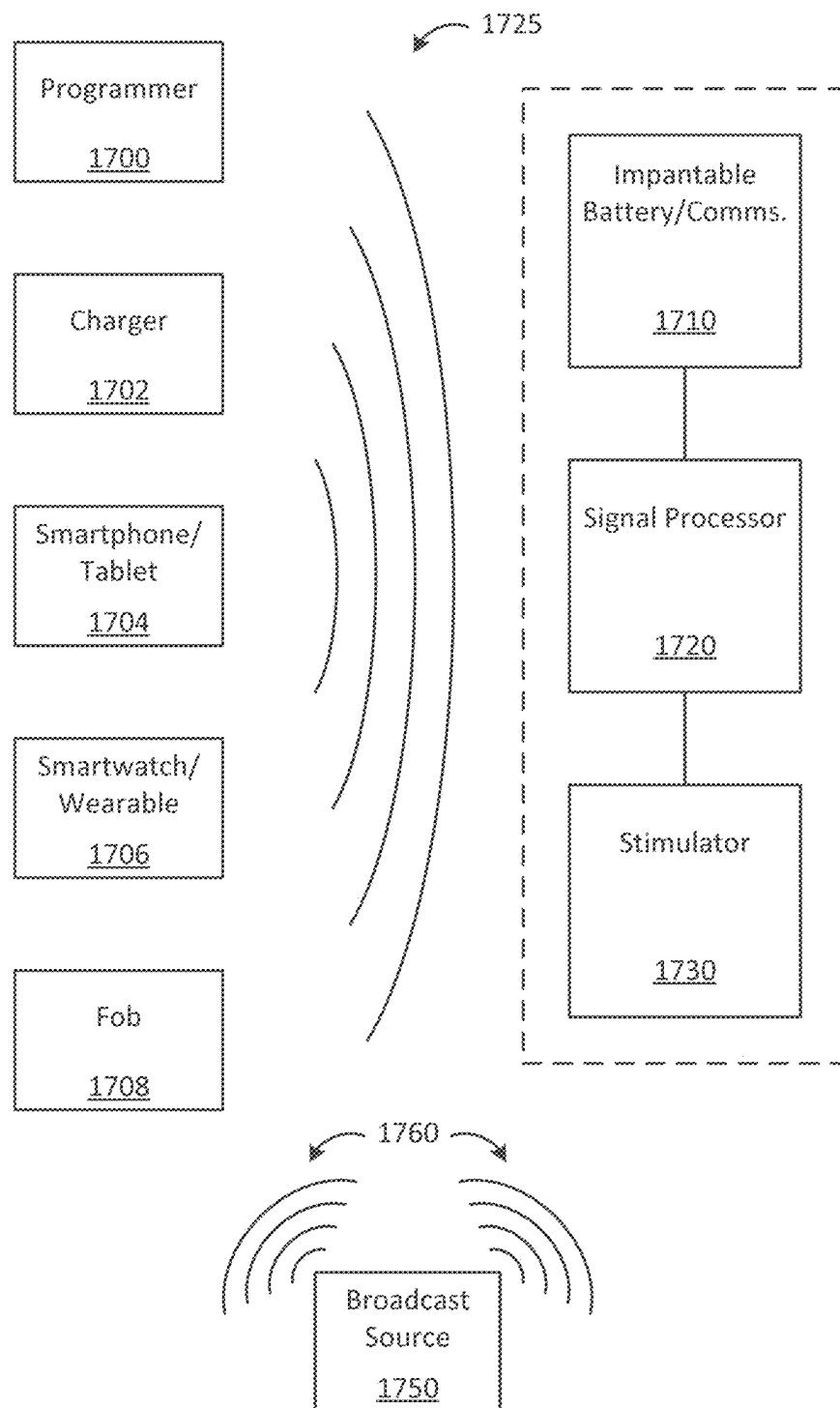


FIG. 17

	Programmer	Charger	Smartphone/Tablet	Smartwatch/Wearable	Fob
On/Off	X	X	X	X	X
Switch Profile/ Transfer Function	X	X	X	X	X
Adjust Volume	X	X	X	X	X
Adjust Mix	X	X	X	X	
Receive Audio Stream	X		X	X	
Broadcast Audio Stream	X		X	X	
Emergency Shut-off	X	X	X	X	X

FIG. 18

FULLY IMPLANTABLE MODULAR COCHLEAR IMPLANT SYSTEM

CROSS-REFERENCES AND PRIORITY CLAIM

This application is a continuation of U.S. patent application Ser. No. 15/679,755, filed on Aug. 17, 2017, which claims priority to U.S. Provisional Patent Application No. 62/376,195 and U.S. Provisional Patent Application No. 62/376,198, each of which was filed Aug. 17, 2016. All of these applications are incorporated herein by reference in their entirety.

BACKGROUND

A cochlear implant is an electronic device that may be at least partially implanted surgically into the cochlea, the hearing organ of the inner ear, to provide improved hearing to a patient. Cochlear implants may include components that are worn externally by the patient and components that are implanted internally in the patient.

External components may include a microphone, a processor, and a transmitter. Cochlear implants may detect sounds via an ear level microphone that conveys these sounds to a wearable processor. Some processors may be worn behind the patient's ear. An electronic signal from the processor may be sent to a transmission coil worn externally behind the ear over the implant. The transmission coil may send a signal to the implant receiver, located under the patient's scalp.

Internal components may include a receiver and one or more electrodes. Some cochlear implants may include additional processing circuitry among the internal components. The receiver may direct signals to one or more electrodes that have been implanted within the cochlea. The responses to these signals may then be conveyed along the auditory nerve to the cortex of the brain where they are interpreted as sound.

Some cochlear implants may be fully implanted and include a mechanism for measuring sound similar to a microphone, signal processing electronics, and means for directing signals to one or more electrodes implanted within the cochlea. Fully implanted cochlear implants typically do not include a transmission coil or a receiver coil.

Internal components of such cochlear implant systems typically require electrical power to operate. Thus, a power supply is typically included along with the other internal components. However, performance of such power supplies often degrades over time, and the power supply may require replacement. Additionally, processing circuitry technology continues to advance quickly. Improvements to processing technology over time may render the processing technology in the implanted processing circuitry outdated. Thus, there may be times when it is advantageous to replace/upgrade the processing circuitry.

However, such replacement procedures can be difficult. The location of the implanted internal components is not the most amenable to surgical procedures, and tends not to fully heal after many incisions. Additionally, replacement of some components, such as a signal processor, can require removing and reintroducing components such as electrical leads into the patient's cochlear tissue, which can be damaging to the tissue and negatively impact the efficacy of cochlear stimulation.

Additionally, different challenges exist for communicating electrical signals through a patient's body. For example, safety standards can limit the amount of current that can

safely flow through a patient's body (particularly DC current). Additionally, the patient's body can act as an undesired signal path between different components within the body (e.g., via contact with the housing or "can" of each component). This can lead to reduced signal strength and/or undesired communication or interference between components. In some cases, electrical signals may even stimulate undesired regions of the patient's cochlear tissue, interfering with the efficacy of the cochlear implant.

SUMMARY

Some aspects of the disclosure are generally directed toward module cochlear implant systems. Such systems can include a cochlear electrode, a stimulator in electrical communication with the cochlear electrode, an input source, a signal processor, and an implantable battery and/or communication module. The signal processor can be configured to receive an input signal from the input source and output a stimulation signal to the stimulator based on the received input signal and a transfer function of the signal processor. The implantable battery and/or communication module may be configured to provide electrical power to the signal processor.

In some embodiments, the signal processor may include circuitry and a can surrounding and housing the circuitry. Furthermore, the signal processor may include a first impedance between the circuitry and the can to reduce unintended electrical communication between the cochlear electrode and the circuitry of the signal processor. The implantable battery and/or communication module may include circuitry and a can surrounding and housing the circuitry. Furthermore, the implantable battery and/or communication module may include a second impedance between the circuitry and the can to reduce unintended electrical communication between the cochlear electrode and the circuitry of the implantable battery and/or communication module. The first impedance and the second impedance may be the same or different.

Additionally or alternatively, the signal processor may include a first set of circuitry and a first housing surrounding the first set of the circuitry. The implantable battery and/or communication module may include a second set of circuitry and a second housing surrounding the second set of circuitry. In some embodiments, the first housing may comprise insulating circuitry between a patient and the first set of circuitry and/or the second housing may comprise insulating circuitry between the patient and the second set of circuitry. The insulating circuitry may comprise resistances, capacitances, and/or an open circuit.

Some additional aspects of the disclosure are generally directed toward a cochlear implant system to be implanted into a patient. Such systems can include a stimulator, a signal processor in communication with the stimulator, an input source in communication with the signal processor, and an implantable battery and/or communication module being configured to provide electrical power to the signal processor. In some embodiments, the stimulator may comprise an acoustic stimulator configured to provide mechanical stimulation to a portion of the patient's ear structure. Additionally or alternatively, the stimulator may comprise an electric stimulator in electrical communication with a cochlear electrode.

In some embodiments, the signal processor may include circuitry and a can surrounding and housing the circuitry. Furthermore, the signal processor may include a first impedance between the circuitry and the can to reduce unintended

3

electrical communication between the cochlear electrode and the circuitry of the signal processor. The implantable battery and/or communication module may include circuitry and a can surrounding and housing the circuitry. Furthermore, the implantable battery and/or communication module may include a second impedance between the circuitry and the can to reduce unintended electrical communication between the cochlear electrode and the circuitry of the implantable battery and/or communication module.

This disclosure incorporates by reference in their entirety both of the following patent applications that are owned by the owner of this disclosure: U.S. patent application Ser. No. 15/679,740, titled "COMMUNICATION SYSTEM AND METHODS FOR FULLY IMPLANTABLE MODULAR COCHLEAR IMPLANT SYSTEM," (now U.S. Pat. No. 10,549,090) and U.S. patent application Ser. No. 15/679,768, titled "WIRELESS INTERFACE SYSTEMS AND METHODS FOR FULLY IMPLANTABLE COCHLEAR IMPLANT SYSTEM," (now U.S. Pat. No. 10,569,079).

The details of one or more examples are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a schematic illustration of a fully implantable cochlear implant system.

FIG. 2 shows an embodiment of a fully-implantable cochlear implant.

FIGS. 3A and 3B are exemplary illustrations showing communication with the signal processor.

FIGS. 4 and 5 illustrate embodiments of an exemplary middle ear sensor for use in conjunction with anatomical features of a patient.

FIG. 6 shows an illustration of an exemplary detachable connector.

FIG. 7 shows an exemplary cochlear implant system in a patient that is not fully physically developed, such as a child.

FIG. 8 is a process-flow diagram illustrating an exemplary process for installing and/or updating an implantable cochlear implant system into a patient.

FIG. 9 is a schematic diagram illustrating an exemplary implantable system including an acoustic stimulator.

FIG. 10A is a high level electrical schematic showing communication between the implantable battery and/or communication module and the signal processor.

FIG. 10B illustrates an exemplary schematic diagram illustrating a cochlear electrode having a plurality of contact electrodes and fixedly or detachably connected to an electrical stimulator.

FIG. 11A shows a high level schematic diagram illustrating an exemplary communication configuration between an implantable battery and/or communication module, a signal processor, and a stimulator in an exemplary cochlear implant system.

FIG. 11B is a schematic diagram illustrating exemplary electrical communication between an implantable battery and/or communication module and a signal processor in a cochlear implant system according to some embodiments.

FIG. 12A is an alternative high-level schematic diagram illustrating an exemplary communication configuration between an implantable battery and/or communication module, a signal processor, and a stimulator.

FIG. 12B is an alternative schematic diagram illustrating exemplary electrical communication between an implant-

4

able battery and/or communication module and a signal processor in a cochlear implant system similar to that shown in FIG. 12A.

FIG. 12C is another alternative schematic diagram illustrating exemplary electrical communication between an implantable battery and/or communication module and a signal processor in a cochlear implant system similar to that shown in FIG. 12A.

FIG. 13 is a process flow diagram illustrating an exemplary process for establishing a preferred transfer function for a patient.

FIG. 14 is a process flow diagram illustrating an exemplary process for establishing a preferred transfer function for a patient.

FIG. 15 is a process flow diagram showing an exemplary method of testing the efficacy of one or more sounds using one or more transfer functions via pre-processed signals.

FIG. 16 is a schematic representation of an exemplary database of pre-processed sound signals.

FIG. 17 is a schematic diagram illustrating possible communication between a variety of system components according to some embodiments of a fully-implantable system.

FIG. 18 is a chart showing the various parameters that are adjustable by each of a variety of external devices.

DETAILED DESCRIPTION

FIG. 1 shows a schematic illustration of a fully implantable cochlear implant system. The system of FIG. 1 includes a middle ear sensor 110 in communication with a signal processor 120. The middle ear sensor 110 can be configured to detect incoming sound waves, for example, using the ear structure of a patient. The signal processor 120 can be configured to receive a signal from the middle ear sensor 110 and produce an output signal based thereon. For example, the signal processor 120 can be programmed with instructions to output a certain signal based on a received signal. In some embodiments, the output of the signal processor 120 can be calculated using an equation based on received input signals. Alternatively, in some embodiments, the output of the signal processor 120 can be based on a lookup table or other programmed (e.g., in memory) correspondence between the input signal from the middle ear sensor 110 and the output signal. While not necessarily based explicitly on a function, the relationship between the input to the signal processor 120 (e.g., from the middle ear sensor 110) and the output of the signal processor 120 is referred to as the transfer function of the signal processor 120.

The system of FIG. 1 further includes a cochlear electrode 116 implanted into the cochlear tissues of a patient. The cochlear electrode 116 is in electrical communication with an electrical stimulator 130, which can be configured to provide electrical signals to the cochlear electrode 116 in response to input signals received by the electrical stimulator 130. In some examples, the cochlear electrode 116 is fixedly attached to the electrical stimulator 130. In other examples, the cochlear electrode 116 is removably attached to the electrical stimulator 130. As shown, the electrical stimulator 130 is in communication with the signal processor 120. In some embodiments, the electrical stimulator 130 provides electrical signals to the cochlear electrode 116 based on output signals from the signal processor 120.

In various embodiments, the cochlear electrode 116 can include any number of contact electrodes in electrical contact with different parts of the cochlear tissue. In such embodiments, the electrical stimulator 130 can be config-

ured to provide electrical signals to any number of such contact electrodes to stimulate the cochlear tissue. For example, in some embodiments, the electrical stimulator **130** is configured to activate different contact electrodes or combinations of contact electrodes of the cochlear electrode **116** in response to different input signals received from the signal processor **120**. This can help the patient differentiate between different input signals.

During exemplary operation, the middle ear sensor **110** detects audio signals, for example, using features of the patient's ear anatomy as described elsewhere herein and in U.S. Patent Publication No. 2013/0018216, which is hereby incorporated by reference in its entirety. The signal processor **120** can receive such signals from the middle ear sensor **110** and produce an output to the electrical stimulator **130** based on the transfer function of the signal processor **120**. The electrical stimulator **130** can then stimulate one or more contact electrodes of the cochlear electrode **116** based on the received signals from the signal processor **120**.

Referring to FIG. 2, an embodiment of a fully-implantable cochlear implant is shown. The device in this embodiment includes a processor **220** (e.g., signal processor), a sensor **210**, a first lead **270** connecting the sensor **210** to the processor **220**, and a combination lead **280** attached to the processor **220**, wherein combination lead **280** contains both a ground electrode **217** and a cochlear electrode **216**. The illustrated processor **220** includes a housing **202**, a coil **208**, first female receptacle **271** and second female receptacle **281** for insertion of the leads **270** and **280**, respectively.

In some embodiments, coil **208** can receive power and/or data from an external device, for instance, including a transmission coil (not shown). Some such examples are described in U.S. Patent Publication No. 2013/0018216, which is incorporated by reference. In other examples, processor **220** is configured to receive power and/or data from other sources, such as an implantable battery and/or communication module as shown in FIG. 1. Such battery and/or communication module can be implanted, for example, into the pectoral region of the patient in order to provide adequate room for larger equipment (e.g., a relatively large battery) for prolonged operation (e.g., longer battery life). Additionally, in the event a battery needs eventual replacement, a replacement procedure in the patient's pectoral region can be performed several times without certain vascularization issues that can arise near the location of the cochlear implant. For example, in some cases, repeated procedures (e.g., battery replacement) near the cochlear implant can result in a decreased ability for the skin in the region to heal after a procedure. Placing a replaceable component such as a battery in the pectoral region can facilitate replacement procedures with reduced risk for such issues.

FIGS. 3A and 3B are exemplary illustrations showing communication with a signal processor. For example, referring to FIGS. 3A and 3B, the processor **320**, includes a housing **302**, a coil **308**, and a generic lead **380** are shown. The lead **380** is removable and can be attached to the processor **320** by insertion of a male connector **382** of the generic lead **380** into any available female receptacle, shown here as **371** or **381**. FIG. 3A shows the processor **320** with the generic lead **380** removed. FIG. 3B shows the processor **320** with the generic lead **380** attached. The male connector **382** is exchangeable, and acts as a seal to prevent or minimize fluid transfer into the processor **320**.

FIGS. 4 and 5 illustrate embodiments of an exemplary middle ear sensor for use in conjunction with anatomical features of a patient. Referring to FIG. 4, an embodiment of

the sensor **410** of a fully-implantable cochlear implant is shown. Here, the sensor **410** is touching the malleus **422**. The sensor may include a cantilever **432** within a sensor housing **434**. The sensor **410** may be in communication with the processor **420** by at least two wires **436** and **438**, which may form a first lead (e.g., **270**). Both wires can be made of biocompatible materials, but need not necessarily be the same biocompatible material. Examples of such biocompatible materials can include tungsten, platinum, palladium, and the like. In various embodiments, one, both, or neither of wires **436** and **438** are coated with a coating and/or disposed inside a casing, such as described in U.S. Patent Publication No. 2013/0018216, which is incorporated by reference.

The illustrated cantilever **432** includes at least two ends, where at least one end is in operative contact with the tympanic membrane or one or more bones of the ossicular chain. The cantilever **432** may be a laminate of at least two layers of material. The material used may be piezoelectric. One example of such a cantilever **432** is a piezoelectric bimorph, which is well-known in the art (see for example, U.S. Pat. No. 5,762,583). In one embodiment, the cantilever is made of two layers of piezoelectric material. In another embodiment, the cantilever is made of more than two layers of piezoelectric material. In yet another embodiment, the cantilever is made of more than two layers of piezoelectric material and non-piezoelectric material.

The sensor housing **434** of the sensor **410** may be made of a biocompatible material. In one embodiment, the biocompatible material may be titanium or gold. In another embodiment, the sensor **410** may be similar to the sensor described in U.S. Pat. No. 7,524,278 to Madsen et al., or available sensors, such as that used in the ESTEEM™ implant (Envoy Medical, Corp., St. Paul, Minn.), for example. In alternative embodiments, the sensor **410** may be an electromagnetic sensor, an optical sensor, or an accelerometer. Accelerometers are known in the art, for example, as described in U.S. Pat. No. 5,540,095.

Referring to FIG. 5, an embodiment of the sensor **510** of a fully-implantable cochlear implant is shown. Also shown are portions of the subject's anatomy, which includes, if the subject is anatomically normal, at least the malleus **522**, incus **524**, and stapes **526** of the middle ear **528**, and the cochlea **548**, oval window **546**, and round window **544** of the inner ear **542**. Here, the sensor **510** is touching the incus **524**. The sensor **510** in this embodiment can be as described for the embodiment of sensor **410** shown in FIG. 4. Further, although not shown in a drawing, the sensor **510** may be in operative contact with the tympanic membrane or the stapes, or any combination of the tympanic membrane, malleus **522**, incus **524**, or stapes **526**.

FIGS. 4 and 5 illustrate an exemplary middle ear sensor for use with systems described herein. However, other middle ear sensors can be used, such as sensors using microphones or other sensors capable of receiving an input corresponding to detected sound and outputting a corresponding signal to the signal processor. Additionally or alternatively, systems can include other sensors configured to output a signal representative of sound received at or near a user's ear, such as a microphone or other acoustic pickup located in the user's outer ear or implanted under the user's skin. Such devices may function as an input source, for example, to the signal processor such that the signal processor receives an input signal from the input source and generates and output one or more stimulation signals according to the received input signal and the signal processor transfer function.

Referring back to FIG. 1, the signal processor 120 is shown as being in communication with the middle ear sensor 110, the electrical stimulator 130, and the implantable battery and/or communication module 140. As described elsewhere herein, the signal processor 120 can receive input signals from the middle ear sensor 110 and/or other input source(s) and output signals to the electrical stimulator 130 for stimulating the cochlear electrode 116. The signal processor 120 can receive data (e.g., processing data establishing or updating the transfer function of the signal processor 120) and/or power from the implantable battery and/or communication module 140. In some embodiments, the signal processor 120 can communicate with such components via inputs such as those shown in FIG. 3.

In some embodiments, the implantable battery and/or communication module 140 can communicate with external components, such as a programmer 100 and/or a battery charger 102. The battery charger 102 can wirelessly charge the battery in the implantable battery and/or communication module 140 when brought into proximity with the implantable battery and/or communication module 140 in the pectoral region of the patient. Such charging can be accomplished, for example, using inductive charging. The programmer 100 can be configured to wirelessly communicate with the implantable battery and/or communication module 140 via any appropriate wireless communication technology, such as Bluetooth, Wi-Fi, and the like. In some examples, the programmer 100 can be used to update the system firmware and/or software. In an exemplary operation, the programmer 100 can be used to communicate an updated signal processor 120 transfer function to the implantable battery and/or communication module 140. In various embodiments, the programmer 100 and charger 102 can be separate devices or can be integrated into a single device.

In the illustrated example of FIG. 1, the signal processor 120 is connected to the middle ear sensor 110 via lead 170. In some embodiments, lead 170 can provide communication between the signal processor 120 and the middle ear sensor 110. In some embodiments, lead 170 can include a plurality of isolated conductors providing a plurality of communication channels between the middle ear sensor 110 and the signal processor 120. The lead 170 can include a coating such as an electrically insulating sheath to minimize any conduction of electrical signals to the body of the patient.

In various embodiments, one or more communication leads can be detachable such that communication between two components can be disconnected in order to electrically and/or mechanically separate such components. For instance, in some embodiments, lead 170 includes a detachable connector 171. Detachable connector 171 can facilitate decoupling of the signal processor 120 and middle ear sensor 110. FIG. 6 shows an illustration of an exemplary detachable connector. In the illustrated example, the detachable connector 671 includes a male connector 672 and a female connector 673. In the illustrated example, the male connector 672 includes a plurality of isolated electrical contacts 682 and female connector 673 includes a corresponding plurality of electrical contacts 683. When the male connector 672 is inserted into the female connector 673, contacts 682 make electrical contact with contacts 683. Each corresponding pair of contacts 682, 683 can provide a separate channel of communication between components connected via the detachable connector 671. In the illustrated example, four channels of communication are possible, but it will be appreciated that any number of commu-

nication channels are possible. Additionally, while shown as individual circumferentially extending contacts 683, other configurations are possible.

In some embodiments, male 672 and female 673 connectors are attached at the end of leads 692, 693, respectively. Such leads can extend from components of the implantable cochlear system. For example, with reference to FIG. 1, in some embodiments, lead 170 can include a first lead extending from the middle ear sensor 110 having one of a male (e.g., 672) or a female (e.g., 673) connector and a second lead extending from the signal processor 120 having the other of the male or female connector. The first and second leads can be connected at detachable connector 171 in order to facilitate communication between the middle ear sensor 110 and the signal processor 120.

In other examples, a part of the detachable connector 171 can be integrated into one of the middle ear sensor 110 and the signal processor 120 (e.g., as shown in FIG. 3). For example, in an exemplary embodiment, the signal processor 120 can include a female connector (e.g., 673) integrated into a housing of the signal processor 120. Lead 170 can extend fully from the middle ear sensor 110 and terminate at a corresponding male connector (e.g., 672) for inserting into the female connector of the signal processor 120. In still further embodiments, a lead (e.g., 170) can include connectors on each end configured to detachably connect with connectors integrated into each of the components in communication. For example, lead 170 can include two male connectors, two female connectors, or one male and one female connector for detachably connecting with corresponding connectors integral to the middle ear sensor 110 and the signal processor 120. Thus, lead 170 may include two or more detachable connectors.

Similar communication configurations can be established for detachable connector 181 of lead 180 facilitating communication between the signal processor 120 and the stimulator 130 and for detachable connector 191 of lead 190 facilitating communication between the signal processor 120 and the implantable battery and/or communication module 140. Leads (170, 180, 190) can include pairs of leads having corresponding connectors extending from each piece of communicating equipment, or connectors can be built in to any one or more communicating components.

In such configurations, each of the electrical stimulator 130, signal processor 120, middle ear sensor 110, and battery and/or communication module can each be enclosed in a housing, such as a hermetically sealed housing comprising biocompatible materials. Such components can include feedthroughs providing communication to internal components enclosed in the housing. Feedthroughs can provide electrical communication to the component via leads extending from the housing and/or connectors integrated into the components.

In a module configuration such as that shown in FIG. 1, various components can be accessed (e.g., for upgrades, repair, replacement, etc.) individually from other components. For example, as signal processor 120 technology improves (e.g., improvements in size, processing speed, power consumption, etc.), the signal processor 120 implanted as part of the system can be removed and replaced independently of other components. In an exemplary procedure, an implanted signal processor 120 can be disconnected from the electrical stimulator 130 by disconnecting detachable connector 181, from the middle ear sensor 110 by disconnecting detachable connector 171, and from the implantable battery and/or communication module 140 by disconnecting detachable connector 191. Thus, the signal

processor 120 can be removed from the patient while other components such as the electrical stimulator 130, cochlear electrode 116, middle ear sensor 110, and battery and/or communication module can remain in place in the patient.

After the old signal processor is removed, a new signal processor can be connected to the electrical stimulator 130, middle ear sensor 110, and implantable battery and/or communication module 140 via detachable connectors 181, 171, and 191, respectively. Thus, the signal processor (e.g., 120) can be replaced, repaired, upgraded, or any combination thereof, without affecting the other system components. This can reduce, among other things, the risk, complexity, duration, and recovery time of such a procedure. In particular, the cochlear electrode 116 can be left in place in the patient's cochlea while other system components can be adjusted, reducing trauma to the patient's cochlear tissue.

Such modularity of system components can be particularly advantageous when replacing a signal processor 120, such as described above. Processor technology continues to improve, and will likely continue to markedly improve in the future, making the signal processor 120 a likely candidate for significant upgrades and/or replacement during the patient's lifetime. Additionally, in embodiments such as the embodiment shown in FIG. 1, the signal processor 120 communicates with many system components. For example, as shown, the signal processor 120 is in communication with each of the electrical stimulator 130, the middle ear sensor 110, and the implantable battery and/or communication module 140. Detachably connecting such components with the signal processor 120 (e.g., via detachable connectors 181, 171, and 191) enables replacement of the signal processor 120 without disturbing any other components. Thus, in the event of an available signal processor 120 upgrade and/or a failure of the signal processor 120, the signal processor 120 can be disconnected from other system components and removed.

While many advantages exist for a replaceable signal processor 120, the modularity of other system components can be similarly advantageous, for example, for upgrading any system component. Similarly, if a system component (e.g., the middle ear sensor 110) should fail, the component can be disconnected from the rest of the system (e.g., via detachable connector 171) and replaced without disturbing the remaining system components. In another example, even a rechargeable battery included in the implantable battery and/or communication module 140 may eventually wear out and need replacement. The implantable battery and/or communication module 140 can be replaced or accessed (e.g., for replacing the battery) without disturbing other system components. Further, as discussed elsewhere herein, when the implantable battery and/or communication module 140 is implanted in the pectoral region of the patient, such as in the illustrated example, such a procedure can leave the patient's head untouched, eliminating unnecessarily frequent access beneath the skin.

While various components are described herein as being detachable, in various embodiments, one or more components configured to communicate with one another can be integrated into a single housing. For example, in some embodiments, signal processor 120 can be integrally formed with the stimulator 130 and cochlear electrode 116. For example, in an exemplary embodiment, processing and stimulation circuitry of a signal processor 120 and stimulator 130 can be integrally formed as a single unit in a housing coupled to a cochlear electrode. Cochlear electrode and the signal processor/stimulator can be implanted during an initial procedure and operate as a single unit.

In some embodiments, while the integral signal processor/stimulator/cochlear electrode component does not get removed from a patient due to potential damage to the cochlear tissue into which the cochlear electrode is implanted, system upgrades are still possible. For example, in some embodiments, a module signal processor may be implanted alongside the integral signal processor/stimulator component and communicate therewith. In some such examples, the integral signal processor may include a built-in bypass to allow a later-implanted signal processor to interface directly with the stimulator. Additionally or alternatively, the modular signal processor can communicate with the integral signal processor, which may be programmed with a unity transfer function. Thus, in some such embodiments, signals from the modular signal processor may be essentially passed through the integral signal processor unchanged so that the modular signal processor effectively controls action of the integral stimulator. Thus, in various embodiments, hardware and/or software solutions exist for upgrading an integrally attached signal processor that may be difficult or dangerous to remove.

Another advantage to a modular cochlear implant system such as shown in FIG. 1 is the ability to implant different system components into a patient at different times. For example, infants and children are typically not suited for a fully implantable system such as shown in FIG. 1. Instead, such patients typically are candidates to wear a traditional cochlear implant system. For example, FIG. 7 shows an exemplary cochlear implant system in a patient that is not fully physically developed, such as a child. The system includes a cochlear electrode 716 implanted into the cochlear tissue of the patient. The cochlear electrode 716 of FIG. 7 can include many of the properties of the cochlear electrodes described herein. The cochlear electrode 716 can be in electrical communication with an electrical stimulator 730, which can be configured to stimulate portions of the cochlear electrode 716 in response to an input signal, such as described elsewhere herein. The electrical stimulator 730 can receive input signals from a signal processor 720.

In some cases, components such as a middle ear sensor are incompatible with a patient who is not fully physically developed. For example, various dimensions within a growing patient's anatomy, such as spacing between anatomical structures or between locations on anatomical structures (e.g., equipment attachment points) may change as the patient grows, thereby potentially rendering a middle ear sensor that is extremely sensitive to motion ineffective. Similarly, the undeveloped patient may not be able to support the implantable battery and/or communication module. Thus, the signal processor 720 can be in communication with a communication device for communicating with components external to the patient. Such communication components can include, for example, a coil 708, shown as being connected to the signal processor 720 via lead 770. The coil 708 can be used to receive data and/or power from devices external to the user. For example, microphone or other audio sensing device (not shown) can be in communication with an external coil 709 configured to transmit data to the coil 708 implanted in the patient. Similarly, a power source (e.g., a battery) can be coupled to an external coil 709 and configured to provide power to the implanted components via the implanted coil 708. Additionally, processing data (e.g., updates to the signal processor 720 transfer function) can also be communicated to the implanted coil 708 from an external coil 709. While generally discussed using coil 708, it will be appreciated that communication between external and implanted components (e.g., the signal processor 720)

11

can be performed using other communication technology, such as various forms of wireless communication. As shown, in the embodiment of FIG. 7, the signal processor 720 is coupled to the coil 708 via lead 770 and detachable connector 771. Accordingly, the coil 708 can be detached from the signal processor 720 and removed without disrupting the signal processor 720.

When a patient has become fully developed, for example, to the point that the patient can safely accommodate a middle ear sensor and an implantable battery and/or communication module, the coil 708 can be removed and remaining components of the fully implantable system can be implanted. That is, once a patient is developed, the cochlear implant system (e.g., of FIG. 7) can be updated to a fully implantable cochlear implant system (e.g., of FIG. 1). In some examples, the patient is considered sufficiently developed once the patient reaches age 18 or another predetermined age. Additional or alternative criteria may be used, such as when various anatomical sizes or determined developmental states are achieved.

FIG. 8 is a process-flow diagram illustrating an exemplary process for installing and/or updating an implantable cochlear implant system into a patient. A cochlear electrode can be implanted in communication with the patient's cochlear tissue and an electrical stimulator can be implanted in communication with the cochlear electrode (850). A signal processor can be implanted into the patient (852). As described elsewhere herein, the signal processor can be connected to the electrical stimulator via a detachable connector (854). In examples in which the signal processor is integrally formed with one or more components, such as the stimulator and cochlear electrode, steps 850, 852, and 854 can be combined into a single step comprising implanting the cochlear electrode, stimulator, and signal processor component.

If, at the time of implementing the process of FIG. 8, it can be determined if the patient is considered sufficiently developed (856). If not, a coil (or other communication device) such as described with respect to FIG. 7 can be implanted (858). The coil can be connected to the signal processor via the detachable connector (860), and the cochlear implant can operate in conjunction with external components (862), such as microphones and external power supplies and coils.

However, if a patient is, or has become, sufficiently developed (856), additional components can be implanted into the patient. For example, the method can include implanting a middle ear sensor (864) and connecting the middle ear sensor to the signal processor via a detachable connector (866). Additionally, the method can include implanting a battery and/or communication module (868) and connecting the battery and/or communication module to the signal processor via a detachable connector (870). If the patient had become sufficiently developed after having worn a partially external device such as that described with respect to FIG. 7 and steps 858-862, the method can include removing various components that had been previously implanted. For example, a coil, such as implanted in step 858, can be disconnected and removed during the procedure of implanting the middle ear sensor (864).

The process of FIG. 8 can be embodied in a method of fitting a patient with an implantable hearing system. Such a method can include implanting a first system (e.g., the system of FIG. 7) into a patient at a first age. This can include, for example, performing steps 850-862 in FIG. 8. The method can further include, when the patient reaches a second age, the second age being greater than the first,

12

removing some components of the first system (e.g., a coil) and implanting the not-yet implanted components of second system (e.g., the system of FIG. 1), for example, via steps 864-870 of FIG. 8.

Transitioning from the system of FIG. 7 to the system of FIG. 1, for example, via the process of FIG. 8, can have several advantages. From a patient preference standpoint, some patients may prefer a system that is totally implanted and requires no wearable external components. Additionally, an implanted battery and/or communication module in communication with the signal processor via lead 190 (and detachable connector 191) can much more efficiently relay power and/or data to the signal processor when compared to an external device such as a coil.

Such modular systems provide distinct advantages over previous implantable or partially implantable cochlear implant systems. Generally, previous systems include several components included into a single housing implanted into the patient. For example, functionality of a signal processor, electrical stimulator, and sensor can be enclosed in a single, complex component. If any such aspects of the component fail, which becomes more likely as the complexity increases, the entire module must be replaced. By contrast, in a modular system, such as shown in FIG. 1, individual components can be replaced while leaving others in place. Additionally, such systems including, for example, coil-to-coil power and/or data communication through the patient's skin also generally communicate less efficiently than an internal connection such as via the lead 190. Modular systems such as shown in FIGS. 1 and 7 also allow for a smooth transition from a partially implantable system for a patient who is not yet fully developed and a fully implantable system once the patient has become fully developed.

While often described herein as using an electrical stimulator to stimulate the patient's cochlear tissue via a cochlear electrode, in some examples, the system can additionally or alternatively include an acoustic stimulator. An acoustic stimulator can include, for example, a transducer (e.g., a piezoelectric transducer) configured to provide mechanical stimulation to the patient's ear structure. In an exemplary embodiment, the acoustic stimulator can be configured to stimulate one or more portions of the patient's ossicular chain via amplified vibrations. Acoustic stimulators can include any appropriate acoustic stimulators, such as those found in the ESTEEM™ implant (Envoy Medical Corp., St. Paul, Minn.) or as described in U.S. Pat. Nos. 4,729,366, 4,850,962, and 7,524,278, and U.S. Patent Publication No. 20100042183, each of which is incorporated herein by reference in its entirety.

FIG. 9 is a schematic diagram illustrating an exemplary implantable system including an acoustic stimulator. The acoustic stimulator can be implanted proximate the patient's ossicular chain and can be in communication with a signal processor via lead 194 and detachable connector 195. The signal processor can behave as described elsewhere herein, and can be configured to cause acoustic stimulation of the ossicular chain via the acoustic stimulator in response to input signals from the middle ear sensor according to a transfer function of the signal processor.

The acoustic stimulator of FIG. 9 can be used similarly to the electrical stimulator as described elsewhere herein. For instance, an acoustic stimulator can be mechanically coupled to a patient's ossicular chain upon implanting the system, and coupled to the signal processor via lead 194 and detachable connector 195. Similarly to systems described elsewhere herein with respect to the electrical stimulator, if

the signal processor requires replacement or repair, the signal processor can be disconnected from the acoustic stimulator (via detachable connector 195) so that the signal processor can be removed without disturbing the acoustic stimulator.

In general, systems incorporating an acoustic sensor such as shown in FIG. 9 can operate in the same way as systems described elsewhere herein employing an electrical stimulator and cochlear electrode only substituting electrical stimulation for acoustic stimulation. The same modularity benefits, including system maintenance and upgrades as well as the ability to convert to a fully implantable system when a patient becomes sufficiently developed, can be similarly realized using acoustic stimulation systems. For example, the process illustrated in FIG. 8 can be performed in an acoustic stimulation system simply by substituting the electrical stimulator and cochlear electrode for an acoustic stimulator.

Some systems can include a hybrid system comprising both an electrical stimulator and an acoustic stimulator in communication with the signal processor. In some such examples, the signal processor can be configured to stimulate electrically and/or acoustically according to the transfer function of the signal processor. In some examples, the type of stimulation used can depend on the input signal received by the signal processor. For instance, in an exemplary embodiment, the frequency content of the input signal to the signal processor can dictate the type of stimulation. In some cases, frequencies below a threshold frequency could be represented using one of electrical and acoustic stimulation while frequencies above the threshold frequency could be represented using the other of electrical and acoustic stimulation. Such a threshold frequency could be adjustable based on the hearing profile of the patient. Using a limited range of frequencies can reduce the number of frequency domains, and thus the number of contact electrodes, on the cochlear electrode. In other examples, rather than a single threshold frequency defining which frequencies are stimulated electrically and acoustically, various frequencies can be stimulated both electrically and acoustically. In some such examples, the relative amount of electrical and acoustic stimulation can be frequency-dependent. As described elsewhere herein, the signal processor transfer function can be updated to meet the needs of the patient, including the electrical and acoustic stimulation profiles.

With further reference to FIGS. 1 and 9, in some examples, a system can include a shut-off controller 104, which can be configured to wirelessly stop an electrical stimulator 130 from stimulating the patient's cochlear tissue and/or an acoustic stimulator 150 from stimulating the patient's ossicular chain. For example, if the system is malfunctioning or an uncomfortably loud input sound causes an undesirable level of stimulation, the user may use the shut-off controller 104 to cease stimulation from the stimulator 130. The shut-off controller 104 can be embodied in a variety of ways. For example, in some embodiments, the shut-off controller 104 can be integrated into other external components, such as the programmer 100. In some such examples, the programmer 100 includes a user interface by which a user can select an emergency shut-off feature to cease stimulation. Additionally or alternatively, the shut-off controller 104 can be embodied as a separate component. This can be useful in situations in which the patient may not have immediate access to the programmer 100. For example, the shut-off controller 104 can be implemented as a wearable component that the patient can wear at all or most times, such as a ring, bracelet, necklace, or the like.

The shut-off controller 104 can communicate with the system in order to stop stimulation in a variety of ways. In some examples, the shut-off controller 104 comprises a magnet that is detectable by a sensor (e.g., a Hall-Effect sensor) implanted in the patient, such as in the processor and/or the implantable battery and/or communication module 140. In some such embodiments, when the magnet is brought sufficiently close to the sensor, the system can stop stimulation of the cochlear tissue or ossicular chain.

After the shut-off controller 104 is used to disable stimulation, stimulation can be re-enabled in one or more of a variety of ways. For example, in some embodiments, stimulation is re-enabled after a predetermined amount of time after it had been disabled. In other examples, the shut-off controller 104 can be used to re-enable stimulation. In some such examples, the patient brings the shut-off controller 104 within a first distance of a sensor (e.g., a magnetic sensor) to disable stimulation, and then removes the shut-off controller 104 within a second distance of the sensor, stimulation can be re-enabled. In various embodiments, the first distance can be less than the second distance, equal to the second distance, or greater than the second distance. In still further embodiments, another device such as a separate turn-on controller (not shown) or the programmer 100 can be used to re-enable stimulation. Any combination of such re-enabling of stimulation can be used, such as alternatively using either the programmer 100 or the shut-off controller 104 to enable stimulation or combining a minimum "off" time before any other methods can be used to re-enable stimulation.

In some embodiments, rather than entirely disable stimulation, other actions can be taken, such as reducing the magnitude of stimulation. For example, in some embodiments, the shut-off sensor can be used to reduce the signal output by a predetermined amount (e.g., absolute amount, percentage, etc.). In other examples, the shut-off sensor can affect the transfer function of the signal processor to reduce the magnitude of stimulation in a customized way, such as according to frequency or other parameter of an input signal (e.g., from the middle ear sensor).

With reference back to FIG. 1, as described elsewhere herein, the implantable battery and/or communication module can be used to provide power and/or data (e.g., processing instructions) to other system components via lead 190. Different challenges exist for communicating electrical signals through a patient's body. For example, safety standards can limit the amount of current that can safely flow through a patient's body (particularly DC current). Additionally, the patient's body can act as an undesired signal path from component to component (e.g., via contact with the housing or "can" of each component). Various systems and methods can be employed to improve the communication ability between system components.

FIG. 10A is a high level electrical schematic showing communication between the implantable battery and/or communication module and the signal processor. In the illustrated embodiment, the implantable battery and/or communication module includes circuitry in communication with circuitry in the signal processor. Communication between the circuitry in the implantable battery and/or communication module and the signal processor can be facilitated by a lead (190), represented by the lead transfer function. The lead transfer function can include, for example, parasitic resistances and capacitances between the leads connecting the implantable battery and/or communication module and the signal processor and the patient's

15

body and/or between two or more conductors that make up the lead (e.g., **191**). Signals communicated from the circuitry of the implantable battery and/or communication module to the circuitry in the signal processor can include electrical power provided to operate and/or stimulate system components (e.g., the middle ear sensor, signal processor, electrical and/or acoustic stimulator, and/or cochlear electrode) and/or data (e.g., processing data regarding the transfer function of the signal processor).

As discussed elsewhere herein, the body of the patient provides an electrical path between system components, such as the “can” of the implantable battery and/or communication module and the “can” of the signal processor. This path is represented in FIG. **10A** by the flow path through R_{Body} . Thus, the patient’s body can provide undesirable signal paths which can negatively impact communication between components. To address this, in some embodiments, operating circuitry in each component can be substantially isolated from the component “can” and thus the patient’s body. For example, as shown, resistance R_{Can} is positioned between the circuitry and the “can” of both the implantable battery and/or communication module and the signal processor.

While being shown as R_{Can} in each of the implantable battery and/or communication module and the signal processor, it will be appreciated that the actual value of the resistance between the circuitry and respective “can” of different elements is not necessarily equal. Additionally, R_{Can} need not include purely a resistance, but can include other components, such as one or more capacitors, inductors, and the like. That is, R_{Can} can represent an insulating circuit including any variety of components that act to increase the impedance between circuitry within a component and the “can” of the component. Thus, R_{Can} can represent an impedance between the operating circuitry of a component and the respective “can” and the patient’s tissue. Isolating the circuitry from the “can” and the patient’s body acts to similarly isolate the circuitry from the “can” of other components, allowing each component to operate with reference to a substantially isolated component ground. This can eliminate undesired communication and interference between system components and/or between system components and the patient’s body.

For example, as described elsewhere herein, in some examples, an electrical stimulator can provide an electrical stimulus to one or more contact electrodes on a cochlear electrode implanted in a patient’s cochlear tissue. FIG. **10B** illustrates an exemplary schematic diagram illustrating a cochlear electrode having a plurality of contact electrodes and fixedly or detachably connected to an electrical stimulator. As shown, the cochlear electrode **1000** has four contact electrodes **1002**, **1004**, **1006**, and **1008**, though it will be appreciated that any number of contact electrodes is possible. As described elsewhere herein, the electrical stimulator can provide electrical signals to one or more such contact electrodes in response to an output from the signal processor according to the transfer function thereof and a received input signal.

Because each contact electrode **1002-1008** is in contact with the patient’s cochlear tissue, each is separated from the “can” of the electrical stimulator (as well as the “cans” of other system components) via the impedance of the patient’s tissue, shown as R_{Body} . Thus, if the circuitry within various system components did not have sufficiently high impedance (e.g., R_{Can}) to the component “can”, electrical signals may stimulate undesired regions of the patient’s cochlear tissue. For instance, stimulation intended for a particular contact

16

electrode (e.g., **1002**) may lead to undesired stimulation of other contact electrodes (e.g., **1004**, **1006**, **1008**), reducing the overall efficacy of the system. Minimizing the conductive paths between system components (e.g., to the contact electrodes of a cochlear electrode) due to the patient’s body, such as by incorporating impedances between component circuitry and the corresponding “can” via R_{Can} , can therefore improve the ability to apply an electrical stimulus to only a desired portion of the patient’s body.

It will be appreciated that the term R_{Body} is used herein to generally represent the resistance and/or impedance of the patient’s tissue between various components, and does not refer to a specific value. Moreover, each depiction of R_{Body} in the figures does not necessarily represent the same value of resistance and/or impedance as the others.

FIG. **11A** shows a high level schematic diagram illustrating an exemplary communication configuration between an implantable battery and/or communication module, a signal processor, and a stimulator. In the example of FIG. **11A**, the implantable battery and/or communication module **1110** is in two-way communication with the signal processor **1120**. For instance, the implantable battery and/or communication module **1110** can communicate power and/or data signals **1150** to the signal processor **1120**. In some examples, the power and data signals **1150** can be included in a single signal generated in the implantable battery and/or communication module **1110** and transmitted to the signal processor **1120**. Such signals can include, for example, a digital signal transmitted with a particular clock rate, which in some embodiments, can be adjustable, for example, via the implantable battery and/or communication module **1110**.

In some embodiments, the signal processor **1120** can communicate information to the implantable battery and/or communication module **1110** (e.g., via signals **1151**), for example, feedback information and/or requests for more power, etc. The implantable battery and/or communication module **1110** can, in response, adjust its output to the signal processor **1120** (e.g., an amplitude, duty cycle, clock rate, etc.) in order to accommodate for the received feedback (e.g., to provide more power, etc.). Thus, in some such examples, the implantable battery and/or communication module **1110** can communicate power and data (e.g., via **1150**) to the signal processor **1120**, and the signal processor **1120** can communicate various data back to the implantable battery and/or communication module **1110** (e.g., via **1151**).

In some embodiments, similar communication can be implemented between the signal processor **1120** and the stimulator **1130**, wherein the signal processor **1120** provides power and data to the stimulator **1130** (e.g., via **1160**) and receives data in return from the stimulator **1130** (e.g., via **1161**). For example, the signal processor **1120** can be configured to output signals (e.g., power and/or data) to the stimulator **1130** (e.g., based on received inputs from a middle ear sensor or other device) via a similar communication protocol as implemented between the implantable battery and/or communication module **1110** and the signal processor **1120**. Similarly, in some embodiments, the stimulator can be configured to provide feedback signals to the signal processor, for example, representative of an executed stimulation process. Additionally or alternatively, the stimulator may provide diagnostic information, such as electrode impedance and neural response telemetry or other biomarker signals.

FIG. **11B** is a schematic diagram illustrating exemplary electrical communication between an implantable battery and/or communication module and a signal processor in a cochlear implant system according to some embodiments. In

the illustrated embodiment, the implantable battery and/or communication module 1110 includes a signal generator 1112 configured to output a signal through a lead (e.g., 190) to the signal processor 1120. As described with respect to FIG. 11A, in some examples, the signal generator 1112 is configured to generate both data and power signals (e.g., 1150) for communication to the signal processor 1120. In some embodiments, the signal generator 1112 generates a digital signal for communication to the signal processor 1120. The digital signal from the signal generator 1112 can be communicated to the signal processor 1120 at a particular clock rate. In some examples, the signals are generated at approximately 30 kHz. In various examples, data and power frequencies can range from approximately 100 Hz to approximately 10 MHz, and in some examples, may be adjustable, for example, by a user.

In the illustrated embodiment, the implantable battery and/or communication module 1110 includes a controller in communication with the signal generator 1112. In some examples, the controller is capable of adjusting communication parameters such as the clock rate of the signal generator 1112. In an exemplary embodiment, the controller and/or the signal generator 1112 can communicate with, for example, a patient's external programmer (e.g., as shown in FIG. 1). The controller and/or signal generator 1112 can be configured to communicate data to the signal processor 1120 (e.g., via 1151), such as updated firmware, signal processor 1120 transfer functions, or the like.

As shown, the signal generator 1112 outputs the generated signal to an amplifier 1190 and an inverting amplifier 1192. In some examples, both amplifiers are unity gain amplifiers. In some examples comprising digital signals, the inverting amplifier 1192 can comprise a digital NOT gate. The output from the amplifier 1190 and the inverting amplifier 1192 are generally opposite one another and are directed to the signal processor 1120. In some embodiments, the opposite nature of the signals output to the signal processor 1120 from amplifiers 1190 and 1192 results in a charge-neutral communication between the implantable battery and/or communication module 1110 and the signal processor 1120, such that no net charge flows through the wearer.

In the illustrated example of FIG. 11B, the receiving circuitry in the signal processor 1120 comprises a rectifier circuit 1122 that receives signals (e.g., 1150) from the amplifier 1190 and the inverting amplifier 1192. Since the output of one of the amplifiers 1190 and 1192 will be high, the rectifier circuit 1122 can be configured to receive the opposite signals from the amplifiers 1190 and 1192 and generate therefrom a substantially DC power output 1123. In various embodiments, the DC power 1123 can be used to power a variety of components, such as the signal processor 1120 itself, the middle ear sensor, the electrical and/or acoustic stimulator, or the like. The rectifier circuit 1122 can include any known appropriate circuitry components for rectifying one or more input signals, such as a diode rectification circuit or a transistor circuit, for example.

As described elsewhere herein, the implantable battery and/or communication module 1110 can communicate data to the signal processor 1120. In some embodiments, the controller and/or the signal generator 1112 is configured to encode the data for transmission via the output amplifiers 1190 and 1192. The signal processor 1120 can include a signal extraction module 1124 configured to extract the data signal 1125 from the signal(s) (e.g., 1150) communicated to the signal processor 1120 to produce a signal for use by the signal processor 1120. In some examples, the signal extraction module 1124 is capable of decoding the signal that was

encoded by the implantable battery and/or communication module 1110. Additionally or alternatively, the signal extraction module 1124 can extract a signal 1125 resulting from the lead transfer function. In various examples, the extracted signal 1125 can include, for example, an updated transfer function for the signal processor 1120, a desired stimulation command, or other signals that affect operation of the signal processor 1120.

In the illustrated example, the signal processor 1120 includes a controller 1126 that is capable of monitoring the DC power 1123 and the signal 1125 received from the implantable battery and/or communication module 1110. The controller 1126 can be configured to analyze the received DC power 1123 and the signal 1125 and determine whether or not the power and/or signal is sufficient. For example, the controller 1126 may determine that the signal processor 1120 is receiving insufficient DC power for stimulating a cochlear electrode according to the signal processor 1120 transfer function, or that data from the implantable battery and/or communication module 1110 is not communicated at a desired rate. Thus, in some examples, the controller 1126 of the signal processor 1120 can communicate with the controller 1114 of the implantable battery and/or communication module 1110 and provide feedback regarding the received communication. Based on the received feedback from the controller 1126 of the signal processor 1120, the controller 1114 of the implantable battery and/or communication module 1110 can adjust various properties of the signal output by the implantable battery and/or communication module 1110. For example, the controller of the implantable battery and/or communication module 1110 can adjust the clock rate of the communication from the signal generator 1112 to the signal processor 1120.

In some systems, the transmission efficiency between the implantable battery and/or communication module 1110 and the signal processor 1120 is dependent on the clock rate of transmission. Accordingly, in some examples, the implantable battery and/or communication module 1110 begins by transmitting at an optimized clock rate until a change in clock rate is requested via the signal processor 1120, for example, to enhance data transmission (e.g., rate, resolution, etc.). In other instances, if more power is required (e.g., the controller of the signal processor 1120 determines the DC power is insufficient), the clock rate can be adjusted to improve transmission efficiency, and thus the magnitude of the signal received at the signal processor 1120. It will be appreciated that in addition or alternatively to adjusting a clock rate, adjusting an amount of power transmitted to the signal processor 1120 can include adjusting the magnitude of the signal output from the signal generator 1112. In some embodiments, for example, with respect to FIGS. 11A-B, power and data can be communicated, for example, from implantable battery and/or communication module 1110 to the signal processor 1120 at a rate of approximately 30 kHz, and can be adjusted from there as necessary and/or as requested, for example, by the signal processor 1120.

FIG. 12A is an alternative high-level schematic diagram illustrating an exemplary communication configuration between an implantable battery and/or communication module, a signal processor, and a stimulator. In the example of FIG. 12A, the implantable battery and/or communication module 1210 provides signals to the signal processor 1220 via communication link 1250, and is further in two-way communication with the signal processor 1220 via communication link 1251. In the example of FIG. 12A, the implantable battery and/or communication module 1210 can provide power signals to the signal processor 1220 via

communication link **1250** and otherwise be in two-way data communication with the signal processor **1220** via communication link **1251**. In some such examples, the power and data signals can each include digital signals. However, in some embodiments, the power and data signals are transmitted at different clock rates. In some examples, the clock rate of the data signals is at least one order of magnitude greater than the clock rate of the power signals. For example, in an exemplary embodiment, the power signal is communicated at a clock rate of approximately 30 kHz, while the data communication occurs at a clock rate of approximately 1 MHz. Similarly to the embodiment described in FIG. 11A, in some examples, the clock rate can be adjustable, for example, via the implantable battery and/or communication module **1210**.

As described with respect to FIG. 11A, in some embodiments, the signal processor **1220** can communicate information to the implantable battery and/or communication module **1210**, for example, feedback information and/or requests for more power, etc. (e.g., via two-way communication **1251**). The implantable battery and/or communication module **1210** can, in response, adjust the power and/or data output to the signal processor **1220** (e.g., an amplitude, duty cycle, clock rate, etc.) in order to accommodate for the received feedback (e.g., to provide more power, etc.).

In some embodiments, similar communication can be implemented between the signal processor **1220** and the stimulator **1230**, wherein the signal processor **1220** provides power and data to the stimulator **1230** and receives data in return from the stimulator **1230**. For example, the signal processor **1220** can be configured to output signals power signals (e.g., via **1260**) and data signals (e.g., via **1261**) to the stimulator **1230** (e.g., based on received inputs from a middle ear sensor or other device). Such communication can be implemented via a similar communication protocol as implemented between the implantable battery and/or communication module **1210** and the signal processor **1220**. In some examples, the power signals provided to the stimulator **1230** (e.g., via **1260**) are the same signals received by the signal processor **1220** from the implantable battery and/or communication module **1210** (e.g., via **1250**). Additionally, in some embodiments, the stimulator **1230** can be configured to provide feedback signals to the signal processor **1220** (e.g., via **1261**), for example, representative of an executed stimulation process.

FIG. 12B is an alternative schematic diagram illustrating exemplary electrical communication between an implantable battery and/or communication module **1210b** and a signal processor **1220b** in a cochlear implant system similar to that shown in FIG. 12A. In the illustrated embodiment of FIG. 12B, the implantable battery and/or communication module **1210b** includes a power signal generator **1211** and a separate signal generator **1212**. The power signal generator **1211** and signal generator **1212** are each configured to output a signal through a lead (e.g., **190**) to the signal processor **1220b**. In some embodiments, the power signal generator **1211** and the signal generator **1212** each generates digital signal for communication to the signal processor **1220b**. In some such embodiments, the digital signal (e.g., **1250**) from the power signal generator **1211** can be communicated to the signal processor **1220b** at a power clock rate, while the digital signal (e.g., **1251b**) from the signal generator **1212** can be communicated to the signal processor **1220b** at a data clock rate that is different from the power clock rate. For instance, in some configurations, power and data can be communicated most effectively and/or efficiently at different clock rates. In an exemplary embodiment, the

power clock rate is approximately 30 kHz while the data clock rate is approximately 1 MHz. Utilizing different and separately communicated power and data signals having different clock rates can increase the transfer efficiency of power and/or data from the implantable battery and/or communication module **1210b** to the signal processor **1220b**.

In the illustrated embodiment, the implantable battery and/or communication module **1210b** includes a controller **1214** in communication with the power signal generator **1211** and the signal generator **1212**. In some examples, the controller **1214** is capable of adjusting communication parameters such as the clock rate or content of the signal generator **1212** and/or the power signal generator **1211**. In an exemplary embodiment, the controller **1214** and/or the signal generator **1212** or power signal generator **1211** can communicate with, for example, a patient's external programmer (e.g., as shown in FIG. 1). The controller **1214** and/or signal generator **1212** can be configured to communicate data to the signal processor **1220b**, such as updated firmware, signal processor **1220b** transfer functions, or the like. Additionally or alternatively, the controller **1214** can be configured to transmit signals such as audio or other signals streamed or otherwise received from one or more external devices as described elsewhere herein.

As shown, and similar to the example shown in FIG. 11B, the power signal generator **1211** outputs the generated signal to an amplifier **1290** and an inverting amplifier **1292**. In some examples, both amplifiers are unity gain amplifiers. In some examples comprising digital signals, the inverting amplifier **1292** can comprise a digital NOT gate. The output from the amplifier **1290** and the inverting amplifier **1292** are generally opposite one another and are directed to the signal processor **1220b**. In the illustrated example, the receiving circuitry in the signal processor **1220b** comprises a rectifier circuit **1222** that receives signals from the amplifier **1290** and the inverting amplifier **1292**. Since the output of one of the amplifiers **1290** and **1292** will be high, the rectifier circuit **1222** can be configured to receive the opposite signals from the amplifiers **1290** and **1292** and generate therefrom a substantially DC power output **1223**.

In various embodiments, the DC power **1223** can be used to power a variety of components, such as the signal processor **1220b** itself, the middle ear sensor, the electrical and/or acoustic stimulator **1230**, or the like. The rectifier circuit **1222** can include any known appropriate circuitry components for rectifying one or more input signals, such as a diode rectification circuit or a transistor circuit, for example. In some embodiments, signals from the power signal generator **1211** are generated at a clock rate that is optimal for transmitting power through the lead (e.g., approximately 30 kHz). In the illustrated example of FIG. 12B, the rectifier circuit **1222** can be arranged in parallel with power lines that are configured to communicate power signals to other components within the system, such as the stimulator **1230**, for example. For instance, in some embodiments, the same power signal (e.g., **1250**) generated from the power signal generator **1211** and output via amplifiers **1290** and **1292** can be similarly applied to the stimulator **1230**. In some such examples, the stimulator **1230** includes a rectifier circuit **1222** similar to the signal processor **1220b** for extracting DC power from the power signal and the inverted power signal provided by amplifiers **1290** and **1292**, respectively. In alternative embodiments, the signal processor **1220b** can similarly provide signals from a separate power signal generator **1211** to provide power signals (e.g., at approximately 30 kHz) to the stimulator **1230**.

21

similar to how power is provided from the implantable battery and/or communication module **1210b** to the signal processor **1220b** in FIG. **12B**.

In the example of FIG. **12B**, the signal generator **1212** outputs a data signal (e.g., **1251b**) to an amplifier **1294** and an inverting amplifier **1296**. In some examples, both amplifiers are unity gain amplifiers. In some examples comprising digital signals, the inverting amplifier **1296** can comprise a digital NOT gate. The output from the amplifier **1294** and the inverting amplifier **1296** are generally opposite one another and are directed to the signal processor **1220b**.

As described elsewhere herein, in some embodiments, the controller **1214** and/or the signal generator **1212** is configured to encode data for transmission via the output amplifiers **1294** and **1296**. The signal processor **1220b** can include a signal extraction module **1224** configured to extract the data from the signal(s) **1225** communicated to the signal processor **1220b** to produce a signal **1225** for use by the signal processor **1220b**. In some examples, the signal extraction module **1224** is capable of decoding the signal that was encoded by the implantable battery and/or communication module **1210b**. Additionally or alternatively, the signal extraction module **1224** can extract a resulting signal **1225** resulting from the lead transfer function. In various examples, the extracted signal can include, for example, an updated transfer function for the signal processor **1220b**, a desired stimulation command, or other signals that affect operation of the signal processor **1220b**.

In the example of FIG. **12B**, the signal extraction module **1224** includes a pair of tri-state buffers **1286** and **1288** in communication with signals output from the signal generator **1212**. The tri-state buffers **1286** and **1288** are shown as having “enable” (ENB) signals provided by controller **1226** in order to control operation of the tri-state buffers **1286** and **1288** for extracting the signal from the signal generator **1212**. Signals from the signal generator **1212** and buffered by tri-state buffers **1286** and **1288** are received by amplifier **1284**, which can be configured to produce a signal **1225** representative of the signal generated by the signal generator **1212**.

In some examples, communication of signals generated at the signal generator **1212** can be communicated to the signal processor **1220b** at a clock rate that is different from the clock rate of the signals generated by the power signal generator **1211**. For instance, in some embodiments, power signals from the power signal generator **1211** are transmitted at approximately 30 kHz, which can be an efficient frequency for transmitting power. However, in some examples, the signals from the signal generator **1212** are transmitted at a higher frequency than the signal from the power signal generator **1211**, for example, at approximately 1 MHz. Such high frequency data transmission can be useful for faster data transfer than would be available at lower frequencies (e.g., the frequencies for transmitting the signal from the power signal generator **1211**). Thus, in some embodiments, power and data can be communicated from the implantable battery and/or communication module **1210b** to the signal processor **1220b** via different communication channels at different frequencies.

Similar to the embodiment shown in FIG. **11B**, in the illustrated example of FIG. **12B**, the signal processor **1220b** includes a controller **1226** that is in communication with the implantable battery and/or communication module **1210b**. In some such embodiments, the controller **1226** in the signal processor **1220b** is capable of monitoring the DC power **1223** and/or the signal **1225** received from the implantable battery and/or communication module **1210b**. The controller

22

1126 can be configured to analyze the received DC power **1223** and the signal **1225** and determine whether or not the power and/or signal is sufficient. For example, the controller **1226** may determine that the signal processor **1220b** is receiving insufficient DC power for stimulating a cochlear electrode according to the signal processor **1220b** transfer function, or that data from the implantable battery and/or communication module **1210b** is not communicated at a desired rate. Thus, in some examples, the controller **1226** of the signal processor **1220b** can communicate with the controller **1214** of the implantable battery and/or communication module **1210b** and provide feedback regarding the received communication. Based on the received feedback from the controller **1226** of the signal processor **1220b**, the controller **1214** of the implantable battery and/or communication module **1210b** can adjust various properties of the signals output by the power signal generator **1211** and/or the signal generator **1212**.

In the illustrated example of FIG. **12B**, bidirectional communication **1251b** between the implantable battery and/or communication module **1210b** and signal processor **1220b** comprises signals from the amplifiers **1294** and **1296** in one direction, and communication from controller **1226** to controller **1214** in the other direction. It will be appreciated that a variety of communication protocols and techniques can be used in establishing bidirectional communication **1251b** between the implantable battery and/or communication module **1210b** and signal processor **1220b**.

For example, in some embodiments, the implantable battery and/or communication module **1210b** need not include amplifiers **1294** and **1296**, and instead transmits a signal and not its inverse to the signal processor **1220b**. In other examples, the signal processor includes amplifiers similar to **1294** and **1296**, and outputs a signal and its inverse back to the implantable battery and/or communication module **1210b**. Additionally or alternatively, in some embodiments, the signal generator **1212** can be integral with the controller **1214** and/or the signal extraction module **1224** can be integral with controller **1226**, wherein controllers **1214** and **1226** can be in bidirectional communication via signal generator **1212** and/or the signal extraction module **1224**. In general, the implantable battery and/or communication module **1210b** and the signal processor **1220b** can be in bidirectional communication for communicating data signals separate from the power signals provided by power signal generator **1211**.

As described, separate communication channels for power (e.g., **1250**) and data (e.g., **1251b**) can be used for providing both power and data from the implantable battery and/or communication module **1210b** and the signal processor **1220b**. This can allow for separate data and power clocking rates in order to improve the power transmission efficiency as well as the data transmission efficiency and/or rate. Moreover, in some examples, if the bidirectional communication (e.g., **1251b**) between the implantable battery and/or communication module **1210b** and the signal processor **1220b** fails (e.g., due to component failure, connection failure, etc.), data for communication from the implantable battery and/or communication module **1210b** can be encoded in the power signals from the power signal generator **1211** and transmitted to the signal processor **1220b** via **1250**. Thus, similar to the embodiment described with respect to FIG. **11B**, both power and data can be transmitted via the same signal.

In some examples, the signal extraction module **1224** can be configured to receive data received from the power signal generator **1211**, for example, via an actuatable switch that

can be actuated upon detected failure of communication **1251b**. In other examples, the signal extraction module **1224** and/or the controller **1226** can generally monitor data from the power signal generator **1211** and identify when signals received from the power signal generator **1211** include data signals encoded into the received power signal in order to determine when to consider the power signals to include data.

Accordingly, in some embodiments, the configuration of FIG. **12B** can be implemented to establish efficient, bidirectional communication between the implantable battery and/or communication module **1210b** and the signal processor **1220b**. Failure in bidirectional communication **1251b** can be identified manually and/or automatically. Upon detection of failure in the bidirectional communication **1251b**, the controller **1214** can encode data into the power signal output from the power signal generator **1211**, and power and data can be combined into a single signal such as described with respect to FIG. **11B**.

FIG. **12C** is another alternative schematic diagram illustrating exemplary electrical communication between an implantable battery and/or communication module **1210c** and a signal processor **1220c** in a cochlear implant system similar to that shown in FIG. **12A**. Similar to the embodiment of FIG. **12B**, in the illustrated embodiment of FIG. **12C**, the implantable battery and/or communication module **1210c** includes a power signal generator **1211** configured to output a signal through a lead (e.g., **190**) to the signal processor **1220c**. In some embodiments, the power signal generator **1211** generates a digital signal (e.g., **1250**) for communication to the signal processor **1220c**, for example, at a power clock rate. The power signal generator **1211** and corresponding amplifiers **1290**, **1292**, as well as rectifier circuit **1222**, can operate similar to described with respect to FIG. **12B** in order to extract DC power **1223** and, in some examples, output power signals to further system components, such as stimulator **1230**.

In the illustrated embodiment, the implantable battery and/or communication module **1210c** includes a signal generator **1213**, which can be capable of providing data signals to the signal processor. In some embodiments, the signal generator **1213** generates a digital signal for communication to the signal processor **1220c**. In some such embodiments, the digital signal (e.g., **1251c**) from the signal generator **1213** can be communicated to the signal processor **1220b** at a data clock rate that is different from the power clock rate. For instance, as described elsewhere herein, in some configurations, power and data can be communicated most effectively and/or efficiently at different clock rates. In an exemplary embodiment, the power clock rate is approximately 30 kHz while the data clock rate is approximately 1 MHz. Utilizing different and separately communicated power and data signals having different clock rates can increase the transfer efficiency of power and/or data from the implantable battery and/or communication module **1210c** to the signal processor **1220c**.

The embodiment of FIG. **12C** includes a controller **1215** in communication with the power signal generator **1211** and the signal generator **1213**. In some examples, the controller **1215** is capable of adjusting communication parameters such as the clock rate or content of the signal generator **1213** and/or the power signal generator **1211**. In an exemplary embodiment, the controller **1215** and/or the signal generator **1213** or power signal generator **1211** can communicate with, for example, a patient's external programmer (e.g., as shown in FIG. **1**). The controller **1215** and/or signal generator **1213** can be configured to communicate data to the signal pro-

cessor **1220c**, such as updated firmware, signal processor **1220c** transfer functions, or the like.

Similar to the example in FIG. **12B**, in the example of FIG. **12C**, the signal generator **1213** outputs a data signal (e.g., **1251**) to an amplifier **1295** and an inverting amplifier **1297**. In some examples, both amplifiers are unity gain amplifiers. In some examples comprising digital signals, the inverting amplifier **1297** can comprise a digital NOT gate. The output from the amplifier **1295** and the inverting amplifier **1297** are generally opposite one another and are directed to the signal processor **1220c**.

As described elsewhere herein, in some embodiments, the controller **1215** and/or the signal generator **1213** is configured to encode data for transmission via the output amplifiers **1295** and **1297**. The signal processor **1220c** can include a signal extraction module **1234** configured to extract the data from the signal(s) communicated to the signal processor **1220c** to produce a signal for use by the signal processor **1220c**. In some examples, the signal extraction module **1234** is capable of decoding the signal that was encoded by the implantable battery and/or communication module **1210c**. Additionally or alternatively, the signal extraction module **1234** can extract a signal resulting from the lead transfer function. In various examples, the extracted signal can include, for example, an updated transfer function for the signal processor **1220c**, a desired stimulation command, or other signals that affect operation of the signal processor **1220c**.

In the example of FIG. **12C**, similar to signal extraction module **1224** in FIG. **12B**, the signal extraction module **1234** includes a pair of tri-state buffers **1287** and **1289** in communication with signals output from the signal generator **1213**. The tri-state buffers **1287** and **1289** are shown as having "enable" (ENB) signals provided by controller **1227** in order to control operation of the tri-state buffers **1287** and **1289** for extracting the signal from the signal generator **1213**. Signals from the signal generator **1213** and buffered by tri-state buffers **1287** and **1289** are received by amplifier **1285**, which can be configured to produce a signal representative of the signal generated by the signal generator **1213**.

As described elsewhere herein, in some examples, communication of signals generated at the signal generator **1213** can be communicated to the signal processor **1220c** at a clock rate that is different from the clock rate of the signals generated by the power signal generator **1211**. For instance, in some embodiments, power signals from the power signal generator **1211** are transmitted at approximately 30 kHz, which can be an efficient frequency for transmitting power. However, in some examples, the signals from the signal generator **1213** are transmitted at a higher frequency than the signal from the power signal generator **1211**, for example, at approximately 1 MHz. Such high frequency data transmission can be useful for faster data transfer than would be available at lower frequencies (e.g., the frequencies for transmitting the signal from the power signal generator **1211**). Thus, in some embodiments, power and data can be communicated from the implantable battery and/or communication module **1210c** to the signal processor **1220c** via different communication channels at different frequencies.

In the illustrated example of FIG. **12C**, the signal processor **1220c** includes a signal generator **1217** and controller **1227** that is in communication with the signal generator **1217**. Similar to the operation of signal generator **1213** and amplifiers **1295** and **1299**, the signal generator can be configured to produce output signals to amplifiers **1287** and

1289, which can be configured to output signals to the implantable battery and/or communication module 1210c.

In some embodiments, the controller 1227 in the signal processor 1220c is capable of monitoring the DC power 1223 and/or the signal received from the implantable battery and/or communication module 1210c. The controller 1226 can be configured to analyze the received DC power 1223 and the signal and determine whether or not the power and/or signal is sufficient. For example, the controller 1227 may determine that the signal processor 1220c is receiving insufficient DC power for stimulating a cochlear electrode according to the signal processor 1220c transfer function, or that data from the implantable battery and/or communication module 1210c is not communicated at a desired rate. Thus, in some examples, the controller 1227 of the signal processor 1220c cause the signal generator 1217 to generate communication signals to send to implantable battery and/or communication module 1210c. Such signals can be used to provide feedback regarding signals received by the signal processor 1220c, such as the DC power 1223.

In the example of FIG. 12C, amplifiers 1295 and 1297 are shown as including tri-state amplifiers (e.g., tri-state buffers) controllable by the controller 1227. Similar to the configuration in the signal processor 1220c, the implantable battery and/or communication module 1210c includes a signal extraction module 1235 configured to extract data from the signal(s) communicated to the implantable battery and/or communication module 1210c from signal generator 1217 of the signal processor 1220c. The signal extraction module 1235 includes tri-state amplifiers 1295 and 1297 in communication with signals output from the signal generator 1217. Signals from the signal generator 1217 and received at tri-state buffers 1295 and 1297 are received by amplifier 1299, which can be configured to produce a signal representative of the signal generated by the signal generator 1217 to controller 1215 of the implantable battery and/or communication module 1210. Thus, in some embodiments, the controller 1227 of the signal processor 1220c is configured to communicate data back to the implantable battery and/or communication module 1210a via amplifiers 1287 and 1289.

As described with respect to other embodiments, based on the received feedback from the controller 1227 of the signal processor 1220c, the controller 1215 of the implantable battery and/or communication module 1210c can adjust various properties of the signals output by the power signal generator 1211 and/or the signal generator 1213.

Thus, in the illustrated example of FIG. 12C, bidirectional communication 1251 between the implantable battery and/or communication module 1210c and signal processor 1220c includes communication between different signal extraction modules 1235 and 1234. As shown, both the implantable battery and/or communication module 1210c and the signal processor 1220c include a controller (1215, 1227) that communicates with a signal generator (1213, 1217) for producing output signals. The signal generator (1213, 1217) outputs signals via tri-state amplifiers, including one inverting amplifier (1297, 1289) for communication across bidirectional communication 1251c for receipt by the other signal extraction module (1234, 1235).

Thus, in some embodiments, bidirectional communication 1251c between the implantable battery and/or communication module 1210c and the signal processor 1220c can be enabled by each of the implantable battery and/or communication module and the signal processor receiving and transmitting data via approximately the same communication structure as the other. In some such examples, the

implantable battery and/or communication module 1210c and the signal processor 1220c include data extraction modules 1235 and 1234, respectively, configured both to output signals from a signal generator (e.g., via 1213 or 1217) and receive and extract signals (e.g., via 1299 and 1285).

In the example of FIG. 12C, of tri-state amplifiers 1295 and 1297 that selectively (e.g., via “enable” control from controller 1215) output the signal from signal generator 1213, amplifier 1297 is shown as an inverting amplifier. Similarly, of tri-state amplifiers 1287 and 1289 that selectively (e.g., via “enable” control from controller 1227) output the signal from signal generator 1217, amplifier 1289 is shown as an inverting amplifier. As described elsewhere herein, communicating a signal and its inverse (e.g., via 1295 and 1297) allows communication with no net charge flow between the implantable battery and/or communication module 1210c and the signal processor 1220c. Thus, bidirectional communication between the implantable battery and/or communication module 1210c and the signal processor 1220c can be performed without a net charge flow between the components.

As described elsewhere herein, power from power generator 1211 and data from signal generator 1213 (and/or signal generator 1217) can be communicated at different clocking rates to optimize power and data transfer. In some examples, if data communication (e.g., via bidirectional communication 1251c) fails, the controller 1215 can be configured to control power generator 1211 to provide both power and data signals via amplifiers 1290 and 1292, for example, as described with respect to FIG. 11B.

Accordingly, in some embodiments, the configuration of FIG. 12C can be implemented to establish efficient, bidirectional communication between the implantable battery and/or communication module 1210 and the signal processor 1220. Failure in bidirectional communication 1251 can be identified manually and/or automatically. Upon detection of failure in the bidirectional communication 1251, the controller 1215 can encode data into the power signal output from the power signal generator 1211, and power and data can be combined into a single signal such as described with respect to FIG. 11B.

As discussed elsewhere herein, different safety standards can exist regarding electrical communication within the patient's body. For example, safety standards can limit the amount of current that can safely flow through a patient's body (particularly DC current). As shown in FIGS. 11B, 12B, and 12C, each of the illustrated communication paths between the implantable battery and/or communication module and the signal processor are coupled to output capacitors. The capacitors positioned at the inputs and outputs of the implantable battery and/or communication module and the signal processor can substantially block DC current from flowing therebetween while permitting communication of AC signals.

As described elsewhere herein, in some embodiments, the data communicated between the implantable battery and/or communication module and the signal processor (e.g., from the signal generator) is encoded. In some such examples, the encoding can be performed according to a particular data encoding method, such as an 8b/10b encoding scheme, to achieve DC balance in the communicated signal. For example, in some embodiments, data is encoded such that the numbers of high and low bits communicated between components at each clock signal meet certain criteria to prevent a charge of a single polarity from building up on any of the capacitors. Such encoding can minimize the total

charge that flows between the implantable battery and/or communication module and the signal processor during communication.

While described and illustrated as representing communication between the implantable battery and/or communication module and the signal processor, it will be appreciated that communication configurations such as shown in FIGS. 10, 11A, 11B, 12A, 12B, and 12C can be implemented between any pair of devices generally in communication with one another. For example, isolating circuitry (e.g., R_{Can}) can be included in any of the system components (e.g., middle ear sensor, acoustic stimulator, electrical stimulator, etc.) to effectively isolate the ground signals from each component from its respective can. Similarly, the exemplary capacitive AC coupling with DC blocking capacitors and DC balancing encoding as described elsewhere herein can be incorporated as the communication interface between any two communicating components.

As described, data can be communicated from the implantable battery and/or communication module to the signal processor for a variety of reasons. In some examples, data is that communicated to the implantable battery and/or communication module from an external component, such as a programmer as shown in FIG. 1. In an exemplary process, a programmer, such as a clinician's computer, can be used to communicate with a patient's fully implanted system via a communication configuration such as shown in FIG. 11B, 12B, or 12C. For example, a programmer can communicate wirelessly (e.g., via Bluetooth or other appropriate communication technique) with the patient's implantable battery and/or communication module. Signals from the programmer can be sent from the implantable battery and/or communication module to the signal processor via the communication configurations of FIG. 11B, 12B, or 12C.

During such processes, a clinician can communicate with the signal processor, and, in some cases, with other components via the signal processor. For example, the clinician can cause the signal processor to actuate an electrical and/or an acoustic stimulator in various ways, such as using various electrical stimulation parameters, combinations of active contact electrodes, various acoustic stimulation parameters, and various combinations thereof. Varying the stimulation parameters in real time can allow the clinician and patient to determine effectiveness of different stimulation techniques for the individual patient. Similarly, the clinician can communicate with the signal processor to update transfer function. For example, the clinician can repeatedly update the transfer function signal processor while testing the efficacy of each one on the individual patient. In some examples, combinations of stimulation parameters and signal processor transfer functions can be tested for customized system behavior for the individual patient.

Additional Input Signals/Sources

As described elsewhere herein, while many examples show a middle ear sensor being in communication with an implanted signal processor, in various embodiments, one or more additional or alternative input sources can be included. For instance, in some embodiments, a microphone can be implanted under a user's skin and can be placed in communication with the signal processor (e.g., via a detachable connector such as 171). The signal processor can receive input signals from the implanted microphone and provide signals to the stimulator based on the received input signal and the signal processor transfer function.

Additionally or alternatively, one or more system components can be configured to receive broadcast signals for converting into stimulation signals. FIG. 13 is a schematic

system diagram showing an implantable system configured to receive broadcast signals from a broadcast device. As shown in the example of FIG. 13, a broadcast source 1350 broadcasts a signal via communication link 1360. The communication link 1360 can include communication via a variety of communication protocols, such as Wi-Fi, Bluetooth, or other known data transmission protocols. Broadcast source 1350 can include any of a variety of components, such as a media source (e.g., television, radio, etc.), communication device (e.g., telephone, smartphone, etc.), a telecoil or other broadcast system (e.g., at a live performance), or any other source of audio signals that can be transmitted to an implanted system or to an external component of an implanted system (e.g., a system programmer, etc.).

An implantable system including a programmer 1300, an implantable battery and/or communication module 1310, a signal processor 1320, and a stimulator 1330 can generally receive the data from the broadcast source 1350 via communication link 1360. In various embodiments, any number of components in the implantable system can include a receiving device, such as a telecoil, configured to receive broadcast signals for eventual conversion into stimulation signals.

For instance, in some embodiments, programmer 1300 can include a telecoil relay configured to receive broadcast telecoil signals from a broadcast source 1350. The programmer can be configured to subsequently communicate a signal representative of the received broadcast signal to the implantable battery and/or communication module 1310 and/or the signal processor 1320, e.g., via a Bluetooth communication. If the communication is received from the programmer 1300 via the implantable battery and/or communication module 1310, the implantable battery and/or communication module 1310 can communicate the signal to the signal processor, for example, as described in any of FIG. 11A, 11B, 12A, or 12C.

In some such embodiments, the signal processor 1320 can be configured to receive such signals from the implantable battery and/or communication module 1310 and output stimulation signals to the stimulator 1330 based on the received signals and the signal processor transfer function. In other examples, the signal processor 1320 can include a telecoil relay or other device capable of receiving broadcast signals from the broadcast source 1350. In some such embodiments, the signal processor 1320 processes the received signals according to the signal processor transfer function and outputs stimulation signals to the stimulator 1330.

In some embodiments, the signal processor 1320 can be in communication with a plurality of input sources, such as, for example, a combination of an implanted microphone, a middle ear sensor, and a broadcast source 1350 (e.g., via the implantable battery and/or communication module 1310). In some such examples, the signal processor can be programmed with a plurality of transfer functions, each according to respective input sources. In such embodiments, the signal processor can identify which one or more input sources are providing input signals and process each such input signal according to the transfer function associated with its corresponding input source.

In some examples, a signal processor 1320 receiving a plurality of input signals from a corresponding plurality of input sources effectively combines the signals when producing a stimulation signal to the stimulator 1330. That is, in some embodiments, input sources are combined to form the stimulation signal from the signal processor 1320. In some

such examples, a user may be able to mix the various received input signals in any way desired. For example, a user may choose to blend a variety of different input streams, such as an input from a middle ear sensor or other implanted device, a signal received from an external device (e.g., a telecoil relay, a Bluetooth connection such as to a smartphone, etc.), and the like. In an exemplary configuration, a user may elect to equally blend two input sources such that the stimulation signal is based 50% on a first input source and 50% on a second input source.

Additionally or alternatively, a user may elect to effectively “mute” one or more input sources so that the signal processor 1320 outputs stimulations signals based on input signals received from unmuted sources. Similarly, a user may be able to select a single source from which to process received input signals. For example, in some embodiments, a user may select to have signals received from broadcast source 1350 processed and converted into stimulation signals while having signals received from, for example, a middle ear sensor, disregarded.

In some examples, direct communication with the signal processor can be used to test the efficacy of a given signal processor transfer function and associated stimulation (e.g., acoustic or electrical) parameters. For example, the programmer can be used to disable input signals from a middle ear sensor or other input source and provide a customized signal to the signal processor to simulate a signal from the input source. The signal processor processes the received signal according to its transfer function, and actuates the electrical stimulator and/or the acoustic stimulator accordingly. The processor can be used to test a variety of customized “sounds” to determine the efficacy of the signal processor transfer function for the given patient for each “sound.”

FIG. 14 is a process flow diagram illustrating an exemplary process for establishing a preferred transfer function for a patient. The method can include connecting an external programmer to the implantable battery and/or communication module (1450). Connecting can include, for example, establishing a wireless connection (e.g., Bluetooth communication) between an external programmer and the implantable battery and/or communication module. The external programmer can include any variety of components capable of providing programming instructions to the implantable battery and/or communication module, such as a computer, smartphone, tablet, or the like.

Once communication is established, if there is no signal processor transfer function active (1452), a signal processor transfer function can be established (1454). If a transfer function is already active, or after one has been established (1454), the programmer can be used to input one or more simulated “sounds” to the signal processor. Such “sounds” can be received and treated by the signal processor as if they were received from an input source such as a middle ear sensor. The “sounds” can be, for example, computer-generated signals designed to simulate various input signals, such as a range of frequencies, phonetic sounds, or other distinguishable sound characteristics.

The process can further include testing the efficacy of the signal processor transfer function (1458). This can include, for example, determining how well the patient responds to each sound provided a given signal processor transfer function. In some examples, this can include rating the transfer function under test for each of the “sounds” and determining an aggregate score for the transfer function based on the score(s) associated with the one or more “sounds.”

After testing the efficacy of the signal processor transfer function, if not all desired transfer functions have been tested (1460), the signal transfer function can be updated (1454). The one or more simulated “sounds” can be input to the signal processor (1456) and processed according to the updated transfer function, and the efficacy of the updated transfer function can be tested (1458). Once all desired transfer functions have been tested (1460), a signal processor transfer function for the user can be created or selected and implemented for the patient (1462). In some examples, a best transfer function of the tested transfer functions is selected based on a user preference, a highest score, or other metric. In other examples, composite results from the tested transfer functions can be combined to create a customized transfer function for the patient.

In other examples, rather than continually updating the signal processor transfer function, simulated “sounds” can be pre-processed outside of the signal processor, for example, on site with a clinician or audiologist. For instance, in an exemplary process, one or more simulated sounds can be pre-processed using processing software to establish simulated stimulation signals that would result from a particular input signal being processed via a particular transfer function. In some examples, such signals can be transferred to, for example, the signal processor for directly applying stimulation signals to the wearer.

Communication to the stimulator can be performed, for example, directly from various system components, such as a programmer. In other examples, such communication can be performed via the implantable battery and/or communication module and signal processor. For instance, in an exemplary embodiment, pre-processed signals can be communicated to the implantable battery and/or communication module via a wireless (e.g., Bluetooth) communication. The implantable battery and/or communication module can communicate the pre-processed signals to the signal processor, which can be configured with a unity transfer function. Thus, the signal processor merely passes the pre-processed signals on to the stimulator for performing stimulation.

FIG. 15 is a process flow diagram showing an exemplary method of testing the efficacy of one or more sounds using one or more transfer functions via pre-processed signals. In the method of FIG. 15, a sound can be loaded (1550), for example, into an application or processing software capable of processing the received sound. In some examples, the sound can be a simulated sound, such as a computer-generated signal representing a desired sound. In other examples, the sound can include a recording of an actual sound, such as a person’s voice or other stimulus. The loaded sound can be pre-processed according to a transfer function to generate a stimulation signal (1552). The pre-processing can be performed, for example, on a stand-alone work station, a system programmer, or the like.

The method of FIG. 15 further comprises the step of applying the stimulation signal from the pre-processed sound to the stimulator of the implanted system (1554). As described elsewhere herein, such communication of the stimulation signal to the stimulator can be performed in a variety of ways, such as directly to the stimulator (e.g., from an external workstation, the user’s programmer, etc.) or through the signal processor.

Upon applying the stimulation signal (1554), the method can further include the step of testing the efficacy of the stimulation signal (1556). This can include, for example, testing a user’s comprehension of the initial sound from the received stimulation signal, receiving a rating score from the user, or any other appropriate way of testing the efficacy of

the stimulation signal. Since the stimulation signal applied in step 1554 is based on the sound and the transfer function used for pre-processing, testing the efficacy of the stimulation signal is similar to testing the efficacy of the transfer function for the given sound.

After testing the efficacy of the stimulation signal, it can be determined whether all simulation transfer functions have been tested for the given sound (1558). If not, the method can include the step of establishing or updating a simulated transfer function (1560), and repeating the steps of pre-processing the sound to establish a stimulation signal (1552), applying the stimulation signal (1554), and testing the efficacy of the stimulation signal (1556) all according to the updated transfer function. Thus, a given sound can be processed according to a plurality of transfer functions, and a plurality of corresponding stimulation signals can be tested with respect to a given user.

In some examples, the process of FIG. 15 can be performed in real time. For instance, in some embodiments, a device in communication with the stimulator in an implanted system (e.g., directly via wireless communication with the stimulator or indirectly via signal processor) can cycle through various simulated transfer functions while pre-processing sound signals prior to communicating them to the user's system. In some such examples, after establishing a preferred processing technique (e.g., simulated transfer function) for a given sound (e.g., in step 1562), the user's signal processor transfer function can be updated to reflect the preferred transfer function for the given sound.

Additionally or alternatively, the process of FIG. 15 can be repeated for a plurality of different sounds. In some embodiments, a plurality of sounds can be pre-processed according to a plurality of different simulated transfer functions, and the resulting generated stimulation signals can be stored in a database. A testing device, such as a workstation, programmer, etc., can be used to carry out the method of FIG. 15 while using the database of stimulations signals to test the efficacy of various transfer functions with respect to various sounds for a user.

In some examples, such a database can be used to fit a user with a particular implant system. For example, stimulation signals generated by pre-processing a plurality of sounds can be communicated to the implanted stimulator of a user having an implanted stimulator and cochlear electrode in order to test the efficacy of the transfer function simulated in the pre-processing. In various examples, a plurality generated stimulation signals associated with a given sound can be applied to the stimulator until a preferred simulated transfer function is established. In other examples, generated stimulation signals representative of a plurality of sounds can be established for each of a plurality of transfer functions, such that each transfer function can be tested on a user for a plurality of sounds prior to testing another transfer function.

FIG. 16 is a schematic representation of an exemplary database of pre-processed sound signals. As shown, the database is represented as a table having n rows corresponding to different sounds (sound 1, sound 2, . . . , sound n) and m columns corresponding to different simulated transfer functions (simulated transfer function 1, simulated transfer function 2, . . . , simulated transfer function m). As shown, at the intersection of each row (i) and each column (j), pre-processing a sound i with a simulated transfer function j results in stimulation signal (i,j). In some embodiments, a table such of stimulation signals generated from pre-pro-

cessed sounds such as shown in FIG. 16 can be stored in a database of pre-processed sound signals for device fitting for a user.

As described elsewhere herein, in various fitting processes, a sound may be selected from database (e.g., sound 1), and a plurality of different stimulation signals (e.g., stimulation signal (1,1), stimulation signal (1,2), . . . , stimulation signal (1, m)) can be communicated to an implanted stimulator. Such stimulation signals generally correspond to the result of the sound (e.g., sound 1) being pre-processed according to various simulated transfer functions (1- m). As described with respect to FIG. 15, a preferred stimulation signal (and thus, a preferred corresponding simulated transfer function) can be established for the given sound (e.g., sound 1). A similar process can be repeated for each sound in the database. In various examples, one or more signal processor transfer functions can be communicated to the signal processor based on the determined preferred simulated transfer function(s). For instance, in some example, the simulated transfer function that was preferred among the most sounds may be implemented as the signal processor transfer function. In other embodiments, the signal processor include a plurality of transfer functions, and can apply different transfer functions to different detected sounds depending on the preferred transfer function for each sound.

In other exemplary fitting processes, a plurality of stimulation signals (e.g., stimulation signal (1,1), stimulation signal (2,1), . . . , stimulation signal (n ,1)) corresponding to a single simulated transfer function (e.g., simulated transfer function 1) can be applied to a stimulator. Such stimulation signals correspond to a plurality of sounds that are pre-processed according to the single simulated transfer function. This can be used to test the efficacy of the selected transfer function. The process can be repeated for a plurality of simulated transfer functions (e.g., 2- m) in order to determine a best transfer function across a variety of sounds (e.g., sounds 1- n).

In general, a database of stimulation signals generated by pre-processing sound signals via various transfer functions such as shown in FIG. 16 can be useful for expediting the testing of such transfer functions for a particular user. Pre-processing such sounds allows for the processing to be done, for example, in a lab or on a workstation prior to any fitting process, and allows for efficient application of stimulation signals corresponding to different transfer functions to a user's stimulator without requiring updates of the signal processor. Additionally, such pre-processing can allow for more advanced or computationally demanding processing techniques to be tested for efficacy even if such processing techniques may not yet be effectively implemented by an implanted signal processor (e.g., due to various hardware limitations). Testing the efficacy of such processing techniques can motivate evolution of processing methodologies and hardware capability, for example, in an effort to employ more complex processing techniques in the future.

Various features and functions of implantable systems have been described herein. As described, in various embodiments, system operation(s) can be adjusted based on communication with the implanted system from components located outside of the body while the system remains implanted. In some embodiments, the system may include any number of external components capable of interfacing with the system in a variety of ways.

FIG. 17 is a schematic diagram illustrating possible communication between a variety of system components according to some embodiments of a fully-implantable

system. In the illustrated embodiment, implanted components (outlined in broken line) of a system include an implantable battery and/or communication module **1710**, a signal processor **1720**, and a stimulator **1730**. Such implanted components can operate according to various examples as described herein in order to effectively stimulate a user (e.g., via electrical and/or acoustic stimulation) in response to received input signals.

The schematic illustration of FIG. **17** includes a plurality of external devices capable of wirelessly interfacing with one or more of the implanted components, for example, via communication link **1725**. Such devices can include a programmer **1700**, a charger **1702**, a smartphone/tablet **1704**, a smartwatch or other wearable technology **1706**, and a fob **1708**. In some examples, such components can communicate with one or more implantable components via one or more communication protocols via wireless communication link **1725**, such as Bluetooth, Zigbee, or other appropriate protocols. In various embodiments, different external devices are capable of performing one or more functions associated with system operation. In some such embodiments, each external device is capable of performing the same functions as the others. In other examples, some external devices are capable of performing more functions than others.

For example, a programmer **1700** can be capable of interfacing wirelessly with one or more implantable components in order to control a variety of operating parameters of the implanted system. For example, in some embodiments, programmer **1700** can be configured to adjust a signal processor transfer function or select an operating profile (e.g., associated with a particular signal processor transfer function according to a particular user, environment, etc.). In some examples, the programmer **1700** can be used to establish user profiles, such as preferred signal processor transfer functions, as described elsewhere herein. The programmer **1700** can additionally or alternatively be used to turn the system on or off, adjust the volume of the system, receive and stream input data to the system (e.g., the implantable battery and/or communication module **1710**). In some embodiments, the programmer **1700** includes a display for displaying various information to the user. For example, the display can be used to indicate a mode of operation (e.g., a loaded user profile), a remaining power level, or the like. In some such embodiments, the display can function as a user interface by which a user can adjust one or more parameters, such as volume, profile, input source, input mix, and the like.

In some embodiments, a charger **1702** can be used to charge one or more internal batteries or other power supplies within the system, such as in the implantable battery and/or communication module **1710**. In some examples, the charger **1702** can include the same functionality as the programmer **1700**, including, for instance, a display and/or user interface. In some such embodiments, the programmer **1700** and the charger **1702** can be integrated into a single device.

In some embodiments, various external devices such as a smartphone or tablet **1704** can include an application ("app") that can be used to interface with the implanted system. For example, in some embodiments, a user may communicate (e.g., via link **1725**) with the system via the smartphone or tablet **1704** in order to adjust certain operating factors of the system using a predefined app to provide an interface (e.g., a visual interface via a display integrated into the external device). The app can assist the user in adjusting various parameters, such as volume, operating profile, on/off, or the like. In some examples, the smart-

phone/tablet **1704** can be used to stream input signals to the implanted system, such as media or communication playing on the smartphone/tablet **1704**.

In some systems, a smartwatch or other wearable technology **1706** can interact with the system in a similar way as the smartphone/tablet **1704**. For example, the smartwatch or other wearable technology **1706** can include an app similar to that operable on the smartphone/tablet to control operation of various aspects of the implanted system, such as volume control, on/off control, etc.

In some embodiments, the fob **1708** can be used to perform basic function with respect to the implanted system. For instance, in some embodiments, a fob **1708** can be used to load/implement a particular operating profile associated with the fob **1708**. Additionally or alternatively, the fob **1708** can function similar to the shut-off control **104** of FIG. **1**, and can be used to quickly disable and/or mute the system. As described elsewhere herein, in some examples, the same device used to disable and/or mute the system (e.g., fob **1708**) can be used to enable and/or unmute the system.

The schematic diagram of FIG. **17** further includes a broadcast source **1750** configured to broadcast signals **1760** that are receivable via one or more external devices and/or one or more implanted system components. Similar to the broadcast source **1350** in FIG. **13**, broadcast source **1750** can be configured to emit signals that can be turned into stimulation signals for application by stimulator **1730**. Broadcast signals **1760** can include, for example, telecoil signals, Bluetooth signals, or the like. In various embodiments, one or more external devices, such as a programmer **1700**, charger **1702**, smartphone/tablet **1704**, smartwatch/wearable device **1706**, and/or fob **1708** can include a component (e.g., a telecoil relay) capable of receiving broadcast signal **1760**. The external device(s) can be further configured to communicate a signal to one or more implanted components representative of the received broadcast signal **1760** for applying stimulation to the patient based on the broadcast signal **1760**.

Additionally or alternatively, in some embodiments, one or more implanted system components, such as an implantable battery and/or communication module **1710**, a signal processor **1720**, and/or a stimulator **1730** can be configured to receive broadcast signals **1750**. Such component(s) can be used to generate stimulation signals for applying to a user via stimulator **1730** according to the received broadcast signals **1750**.

As described, in various embodiments, different external devices can interface with implanted components to adjust operation of the system in various ways. In some embodiments, not all components are capable of performing the same functions as other components. FIG. **18** is a chart showing the various parameters that are adjustable by each of a variety of external devices according to some exemplary systems. In the example of FIG. **18**, entries in the chart including an 'X' represent a component configured to perform a corresponding function. Other examples are possible in which different components include different functionality than is represented by the example of FIG. **18**.

Generally, the modularity of such systems allows system modifications, such as repairing, replacing, upgrading, etc., of system components and/or transitioning from a partially- to fully-implantable system, to be performed with minimal disturbance of implanted system components. For example, an implanted cochlear electrode and electrical stimulator and/or acoustic stimulator can remain in place while other system components are implanted and/or replaced, reducing the risk of additional procedures damaging the patient's

35

cochlear tissue. Additionally, the communication techniques as described herein can be used to help customize and/or optimize a signal processor transfer function for a particular patient, as well as enable the system to meet safety standards, provide adequate power and data transfer rates between system components, and operate at a high efficiency. It will be appreciated that, while generally described herein with respect to implantable hearing systems, communication techniques described can be used in a variety of other implantable systems, such as various neuromodulation devices/systems, including, for example, pain management, spinal cord stimulation, brain stimulation (e.g., deep brain stimulation), and the like.

Various non-limiting embodiments have been described. These and others are within the scope of the following claims.

The invention claimed is:

1. A cochlear implant system comprising:
 - a cochlear electrode;
 - a stimulator in electrical communication with the cochlear electrode;
 - a signal processor in communication with the stimulator, the signal processor including first circuitry, a first can surrounding and housing the first circuitry, and a first impedance between the first circuitry and the first can to reduce unintended electrical communication between the cochlear electrode and the first circuitry of the signal processor;
 - an input source in communication with the signal processor; and
 - an implantable battery and/or communication module, the implantable battery and/or communication module being configured to provide electrical power to the signal processor and including a signal generator configured to generate digital signals for communicating to the signal processor, second circuitry, a second can surrounding and housing the second circuitry, and a second impedance between the second circuitry and the second can to reduce unintended electrical communication between the cochlear electrode and the second circuitry of the implantable battery and/or communication module; wherein
 - the signal processor is in communication with the implantable battery and/or communication module via a first lead.
2. The cochlear implant system of claim 1, wherein the signal processor is coupled to the first lead via a first capacitive coupling, and the implantable battery and/or communication module is coupled to the first lead via a second capacitive coupling.
3. The cochlear implant system of claim 1, wherein the implantable battery and/or communication module includes:
 - a non-inverting amplifier having an input coupled to the signal generator; and
 - an inverting amplifier having an input coupled to the signal generator; and wherein
 - the signal generator provides an output signal to both the non-inverting amplifier and the inverting amplifier; such that
 - the output signal and the inverted output signal are both transmitted to the signal processor via the first lead.
4. The cochlear implant system of claim 3, wherein the signal processor comprises a rectifier circuit configured to receive the output signal and the inverted output signal from the implantable battery and/or communication module and generate a substantially DC output signal based on the received output signal and inverted output signal.

36

5. The cochlear implant system of claim 4, wherein the signal processor comprises a signal extraction module configured to receive the output signal and the inverted output signal from the implantable battery and/or communication module and to output a signal representative of the output signal generated by the signal generator.

6. The cochlear implant system of claim 5, wherein the signal processor further comprises a controller in communication with the first lead, the controller being configured to analyze the substantially DC output signal generated by the rectifier circuit, and, in the event that the substantially DC output signal is insufficient, communicate with the implantable battery and/or communication module via the first lead to increase the electrical power provided to the signal processor from the implantable battery and/or communication module.

7. The cochlear implant system of claim 1, wherein the signal processor is programmed with a signal processor transfer function such that the signal processor receives an input signal from the input source and outputs a stimulation signal to the stimulator based on the received input signal and the signal processor transfer function; and the signal generator is configured to generate an output signal configured to update the signal processor transfer function.

8. The cochlear implant system of claim 7, further comprising an external programmer in wireless communication with the implantable battery and/or communication module, the external programmer not being implanted into the patient and being configured to adjust operation of the signal processor via communication with the implantable battery and/or communication module.

9. The cochlear implant system of claim 8, wherein the external programmer is configured to:

- disable input signals from the input source to the signal processor; and
- provide one or more custom input signals to the signal processor; such that
 - the signal processor processes the one or more custom input signals according to a signal processor transfer function; and
 - outputs a stimulation signal to the stimulator based on the received custom input signals.

10. The cochlear implant system of claim 9, wherein the external programmer is further configured to, for a plurality of signal processor transfer functions, change the signal processor transfer function and provide the one or more custom input signals to the signal processor to test the efficacy of the plurality of signal processor transfer functions.

11. The cochlear implant system of claim 1, further comprising a charger configured to wirelessly charge the implantable battery and/or communication module.

12. The cochlear implant system of claim 1, further comprising a shut-off control configured to wirelessly disable operation of the stimulator.

13. The cochlear implant system of claim 1, wherein the first impedance comprises an open circuit and/or the second impedance comprises an open circuit.

14. A cochlear implant system to be implanted into a patient, the cochlear implant system comprising:

- a cochlear electrode;
- a stimulator in electrical communication with the cochlear electrode;

37

a signal processor in communication with the stimulator, the signal processor including a first set of circuitry and a first housing surrounding the first set of circuitry; an input source in communication with the signal processor; and

an implantable battery and/or communication module, the implantable battery and/or communication module being configured to provide electrical power to the signal processor and including a signal generator configured to generate digital signals for communicating to the signal processor, a second set of circuitry, and a second housing surrounding the second set of circuitry; wherein

the signal processor is in communication with the implantable battery and/or communication module via a first lead;

the first housing comprising insulating circuitry between the patient and the first set of circuitry; and

the second housing comprising insulating circuitry between the patient and the second set of circuitry.

15. The cochlear implant system of claim 14, wherein the stimulator comprises a third set of circuitry and a third housing surrounding the third set of circuitry; wherein the third housing comprises insulating circuitry between the patient and the third set of circuitry.

16. The cochlear implant system of claim 14, wherein: the insulating circuitry of the first housing comprises a first impedance to reduce unintended electrical communication between the first set of circuitry and objects outside the first housing; and

the insulating circuitry of the second housing comprises a second impedance to reduce unintended electrical communication between the second set of circuitry and objects outside the second housing.

17. The cochlear implant system of claim 16, wherein the first housing comprises a first can and the second housing comprises a second can.

18. A cochlear implant system to be implanted into a patient, the cochlear implant system comprising:

a stimulator configured to stimulate to a portion of the patient's ear;

a signal processor in communication with the stimulator, the signal processor including first circuitry, a first can surrounding and housing the first circuitry, and a first impedance between the first circuitry and the first can

38

to reduce unintended electrical communication between elements external to the first can and the first circuitry of the signal processor;

an input source in communication with the signal processor; and

an implantable battery and/or communication module, the implantable battery and/or communication module being configured to provide electrical power to the signal processor and including a signal generator configured to generate digital signals for communicating to the signal processor via a lead, second circuitry, a second can surrounding and housing the second circuitry, and a second impedance between the second circuitry and the second can to reduce unintended electrical communication between elements external to the second can and the second circuitry of the implantable battery and/or communication module; wherein

the signal processor is further configured with a transfer function such that the signal processor receives an input signal from the input source and outputs a stimulation signal to the stimulator based on the received input signal and the transfer function.

19. The cochlear implant system of claim 18, wherein the stimulator comprises an acoustic stimulator configured to provide mechanical stimulation to a portion of the patient's ear structure.

20. The cochlear implant system of claim 18, further comprising a cochlear electrode; and wherein the stimulator comprises an electric stimulator in electrical communication with the cochlear electrode and the signal processor.

21. The cochlear implant system of claim 18, wherein the stimulator comprises an electric stimulator and an acoustic stimulator; and the cochlear implant system further comprises:

a cochlear electrode;

the electric stimulator in electrical communication with the cochlear electrode and the signal processor;

the acoustic stimulator configured to provide mechanical stimulation to a portion of the patient's ear structure; and

the signal processor outputs a stimulation signal to at least one of the acoustic stimulator and the electric stimulator based on the received input signal and the transfer function.

* * * * *