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impact neuromod

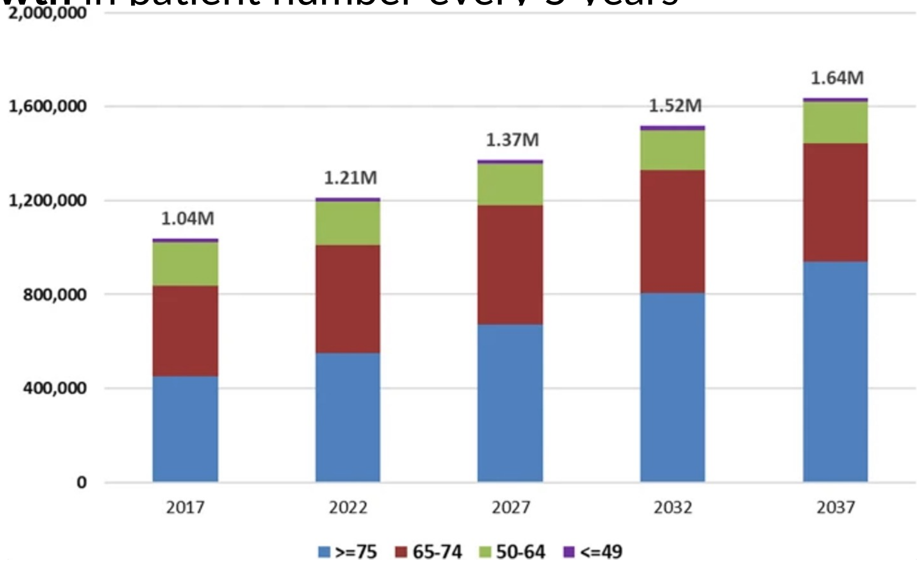
Emily Masterson, TShawn Zhu, Lance Johnson, Aaron Gholston, Adam Vareberg, Lily Xistris, Ido Haber

University of Wisconsin-Madison, Departments of Biomedical Engineering and Mechanical Engineering

3-2-23

Background: Parkinson's Disease

- **Second most** common neurodegenerative disease diagnosed in U.S.
- **More than 250 in 100,000** people age 45+
- **~15% growth** in patient number every 5 years



Projected number of patients by 2037 grouped by age[2]

Onset and progression of Parkinson's Disease

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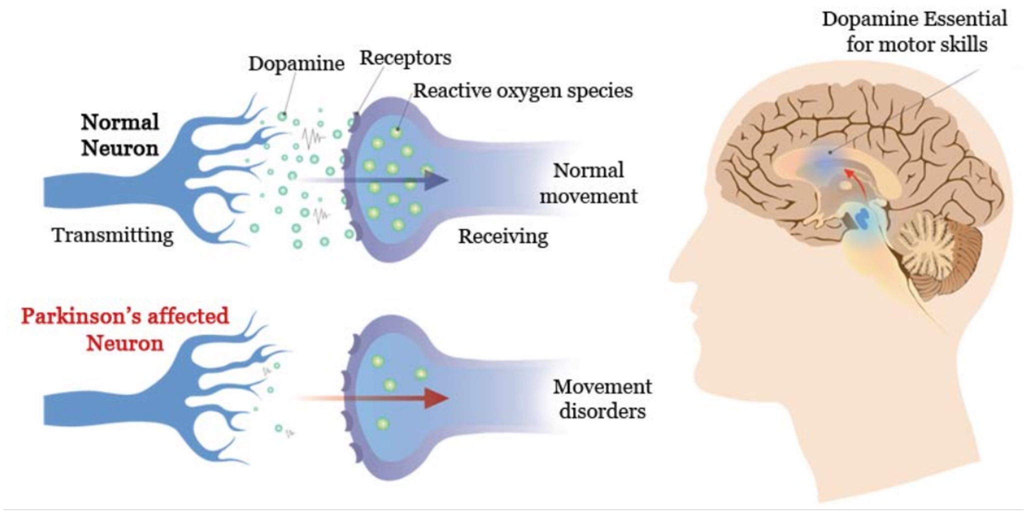
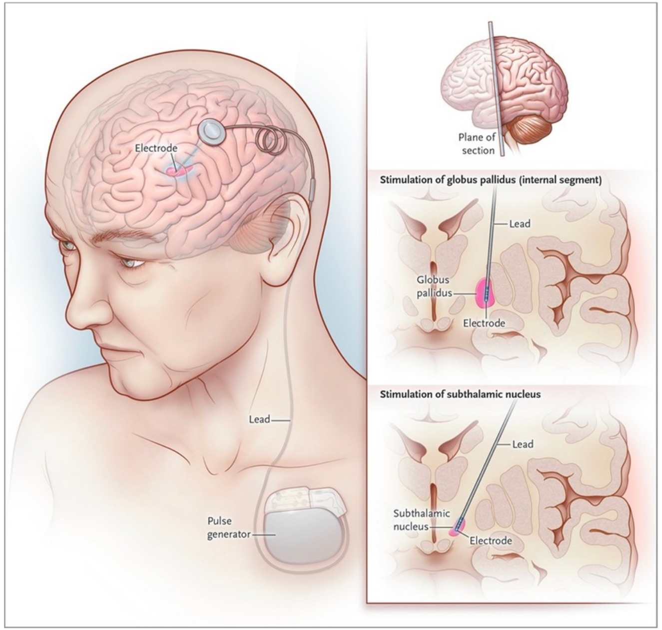
- Loss of nerve cells in the substantia nigra
- Symptoms include:
  - Tremors
  - Slowness of movement
  - Speech impairment
  - Impaired balance and coordination



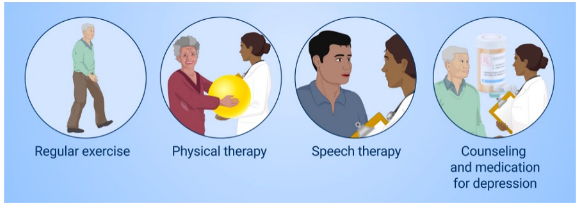
Background: Current treatments

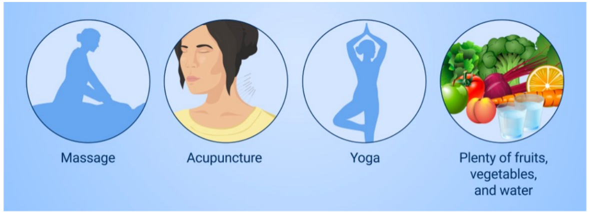
Medications

Surgical Intervention (DBS)



Complementary Therapies





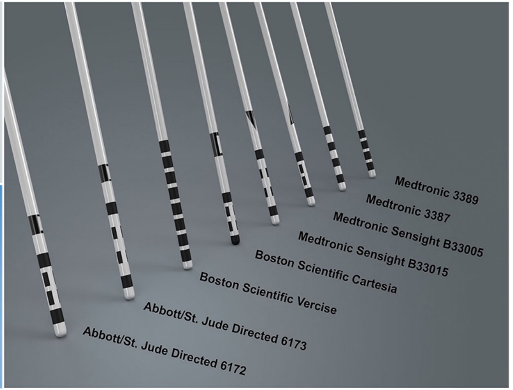
Competition

Wired

- Vercise (Boston Scientific)
- Percept (Medtronic)
- Infinity (Abbott)

Wireless

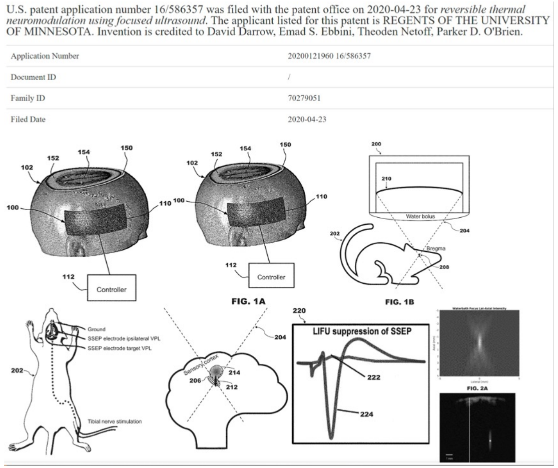
- Neural dust (Iota biosciences)



DBS electrodes(~1.5mm per contact)

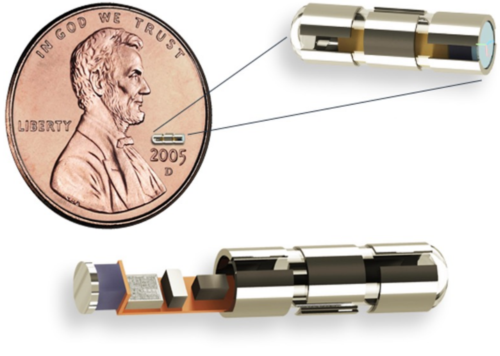
Thermal Stimulation Patent

- Focused ultrasound



U.S. patent application number 16/586357 was filed with the patent office on 2020-04-23 for *reversible thermal neuromodulation using focused ultrasound*. The applicant listed for this patent is REGENTS OF THE UNIVERSITY OF MINNESOTA. Invention is credited to David Darrow, Emad S. Ebbini, Theoden Netoff, Parker D. O'Brien.

Application Number	20200121960 16/586357
Document ID	/
Family ID	70279051
Filed Date	2020-04-23



Neural dust(3 mm length)

Market Limitations: Opportunity for Innovation

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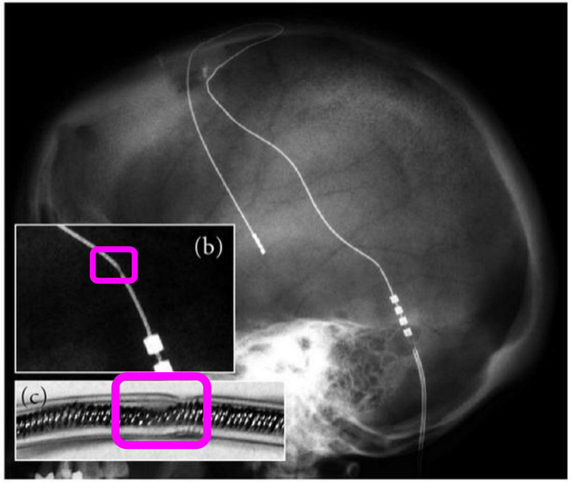
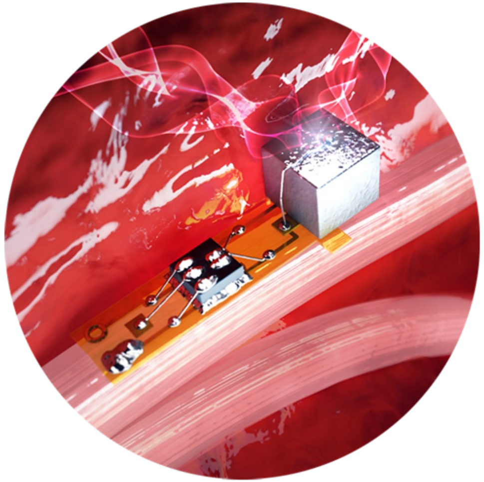


Lead Fracture DBS (Medtronic)

Wired

- Lead misplacement, fracture
- Large footprint, transcranial
- Cost
- More involved surgery

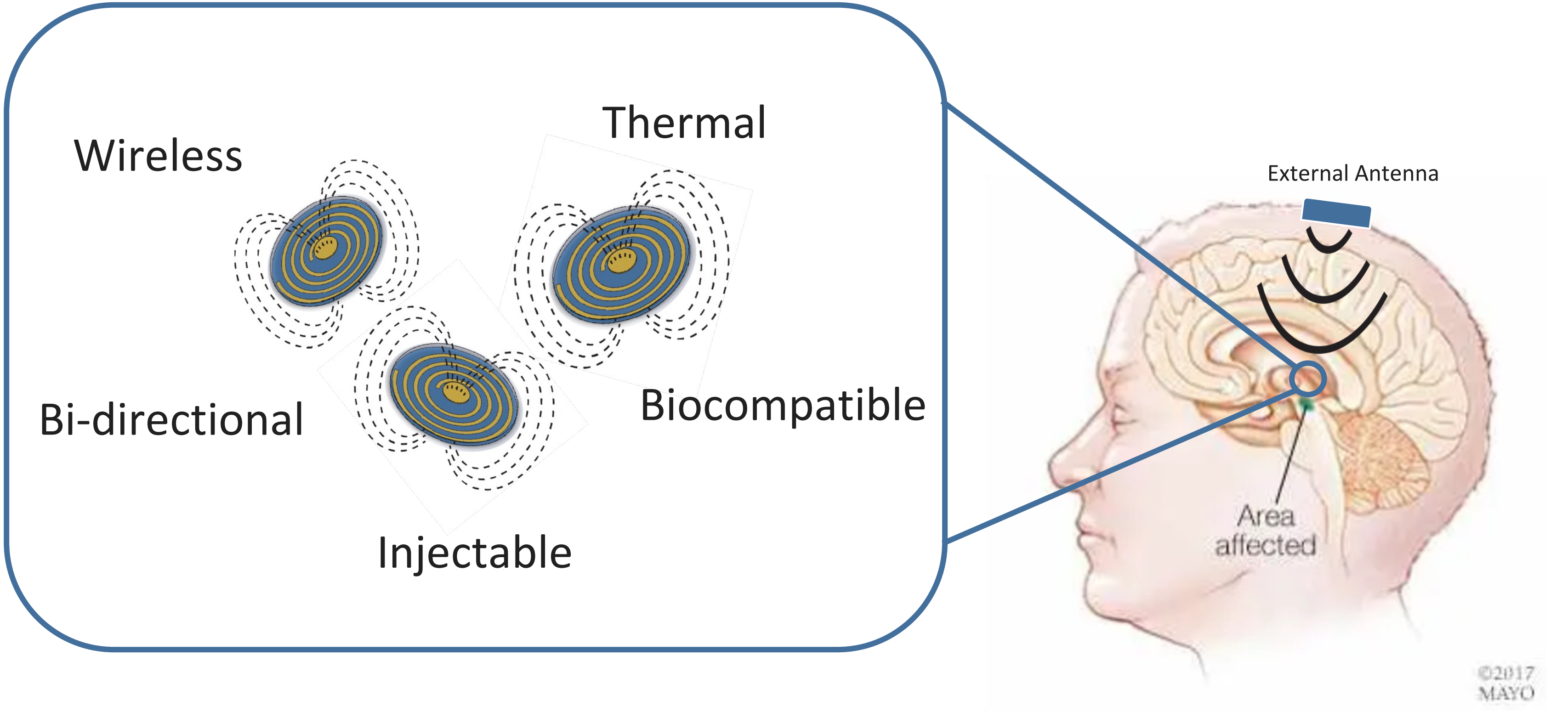


“Neural dust” (Iota Biosciences)

Wireless

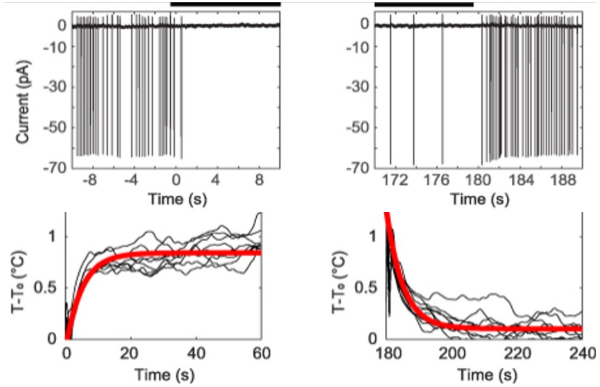
- Ultrasound is highly attenuated by skull
- Primarily spinal cord and peripheral

Where We Fit Into The Landscape

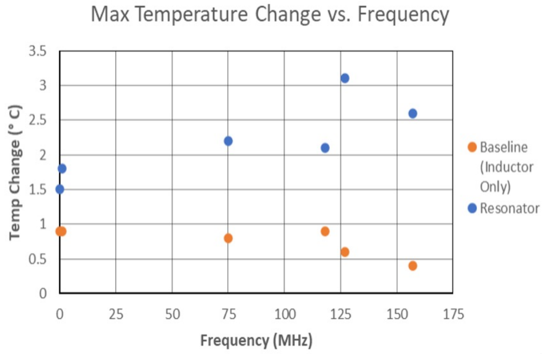


Supporting Data

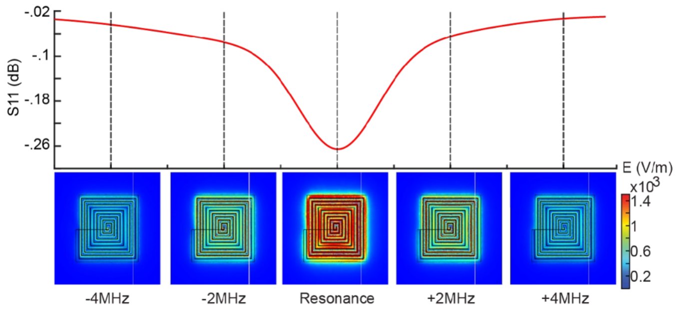
Modulation



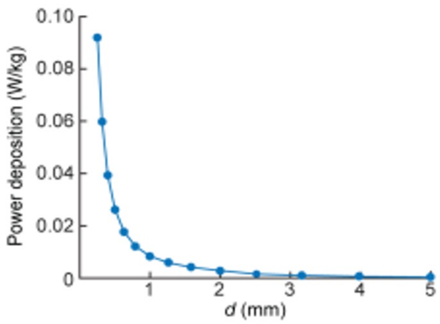
Thermal Dissipation



Wireless Coupling



Safety



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Intellectual Property - Awarded Patent

US20200046224A1
United States

Download PDF Find Prior Art Similar

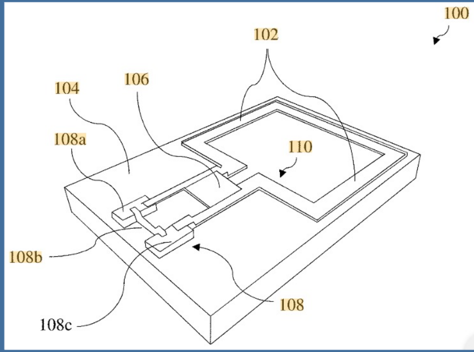
Inventor: Alan Pradip Jasanoff, Virginia Spanoudaki, Aviad Hai

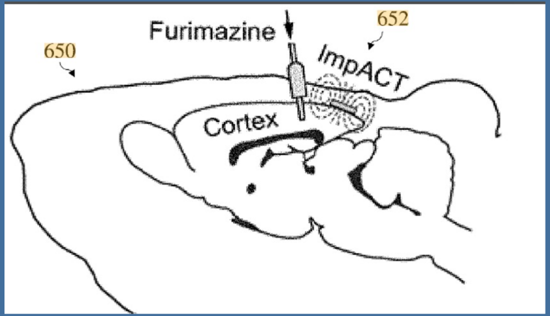
Current Assignee : Massachusetts Institute of Technology

Tunable detectors

Abstract

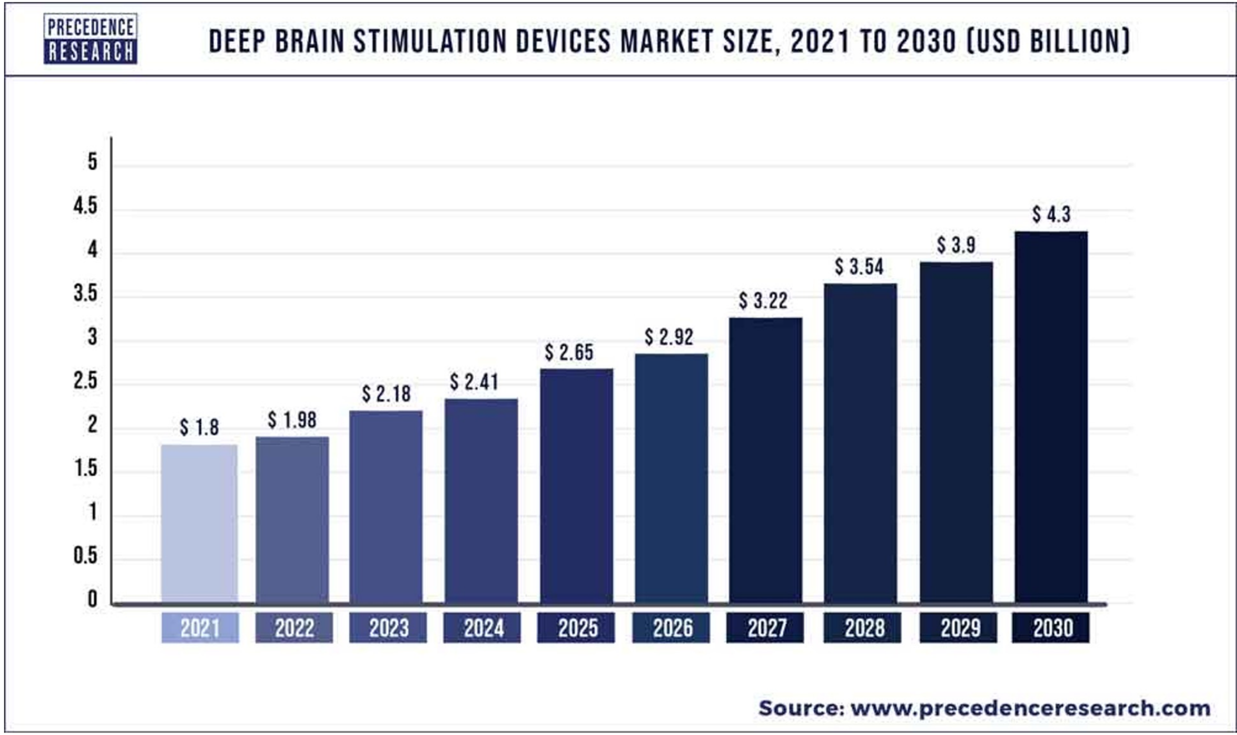
Embodiments described herein relate to detectors and their method of use for sensing electromagnetic fields, electromagnetic signals, biochemical analytes, and/or other conditions in subjects. The device may include an inductively-coupled implantable coil-based transducer that converts electrical, photonic, biochemical signals, and/or other appropriate signals and/or conditions originating in tissues and/or transplanted tissue grafts into changes in a property of the transducer, such as a resonance frequency, that may be detected using an alternating magnetic field that may be provided by a magnetic resonance imaging (MRI) signal and/or other appropriate source. In some embodiments, the detector comprises a FET that changes state upon detection of a subject condition of interest. The change in the FET may change the resonance frequency of an associated LC or RLC circuit. The change in resonance frequency may change the brightness and/or intensity of the detector when detected by an MRI scanner or other appropriate scanner.





Market Opportunities for DBS

- DBS market valued at ~$1.8B in 2021
- Parkinson's disease treatment market $4.55B in 2021 with 11.5% yearly growth



Expected Timeline

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Pre 2023 — Proof of Concept

Government Funds

Prototyping

Bench top testing

IP

Market Analysis

2023 — Functional Validation

In vitro studies

Rodent studies

Development of surgical procedure

Build Core team

Seed 1

2024 — Therapeutic Validation

Early human studies

Clinical & regulatory team

Further IP filing

Partner relationship

Re-design consideration

2025 — Optimization

Double-blind, randomized

Reimbursement finalization

Sales team

2026 — Commercial

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Team - Potential Candidates

CEO

Davilynn Erickson (She/Her) · 3rd
Vice President Finance, CFO Neuromodulation at Medtronic

CMO

Ashwini Sharan · 3rd
CMO Medtronic Neuromodulation Operating Unit

COO

Jeff Erb · 2nd
CEO, Board of Directors, Strategic Advisor

CTO

Rafael Carbunaru · 2nd
Neuromodulation Chief Technology Officer at Boston Scientific Corporation

Scientific Advisory Board:

Dr. Aviad Hai
Inventor

Dr. Aaron Suminski
DBS Surgical Expert

Dr. Kip Ludwig
Neuromodulation Expert

Dr. Justin Williams
Neuromodulation Expert

hai lab
engineering electromagnetic neural interfaces at the nanoscale

WITNe

NIH

DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA

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Funding

Current funding:

NIH ~$2.3M

DoD ~$250K

Biological proof of concept testing

Ask: Seed 1 funding of **$1.5M**

$1M — Hiring leadership team

$100K — IP filing

$400K — Development of hardware and surgical procedure

Thanks for listening
Any Questions?

Emily Masterson, TShawn Zhu, Lance Johnson, Aaron Gholston, Adam Vareberg, Lily Xistris, Ido Haber

University of Wisconsin-Madison, Departments of Biomedical Engineering and Mechanical Engineering

2-28-23

Medtronic Reimbursement

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MS-DRG assignments : Essential tremor, Parkinson's disease, epilepsy, and dystonia (continued)					
Procedure	Scenario	MS-DRG[1]	MS-DRG title[1,2]	Relative weight[1]	Medicare national average[3]
Removal (without replacement)[4]	Whole system (generator [any type] plus leads [one or more])[5]	025	Craniotomy and endovascular intracranial procedures W MCC	4.5405	$31,146
		026	Craniotomy and endovascular intracranial procedures W CC	3.0235	$20,740
		027	Craniotomy and endovascular intracranial procedures WO CC/MCC	2.4954	$17,117
	Generator only (any type)	These codes are not considered "significant procedures" for the purpose of DRG assignment. A non-surgical (ie, medical) DRG is assigned to the stay according to the principal diagnosis.			
	Leads only (one or more)	025	Craniotomy and endovascular intracranial procedures W MCC	4.5405	$31,146
		026	Craniotomy and endovascular intracranial procedures W CC	3.0235	$20,740
		027	Craniotomy and endovascular intracranial procedures WO CC/MCC	2.4954	$17,117
Revision	Leads[6] (one or more)	025	Craniotomy and endovascular intracranial procedures W MCC	4.5405	$31,146
		026	Craniotomy and endovascular intracranial procedures W CC	3.0235	$20,740
		027	Craniotomy and endovascular intracranial procedures WO CC/MCC	2.4954	$17,117
	Generator (any type)	These codes are not considered "significant procedures" for the purpose of DRG assignment. A non-surgical (ie, medical) DRG is assigned to the stay according to the principal diagnosis.			

Physician coding and payment

Effective January 1, 2023 – December 31, 2023

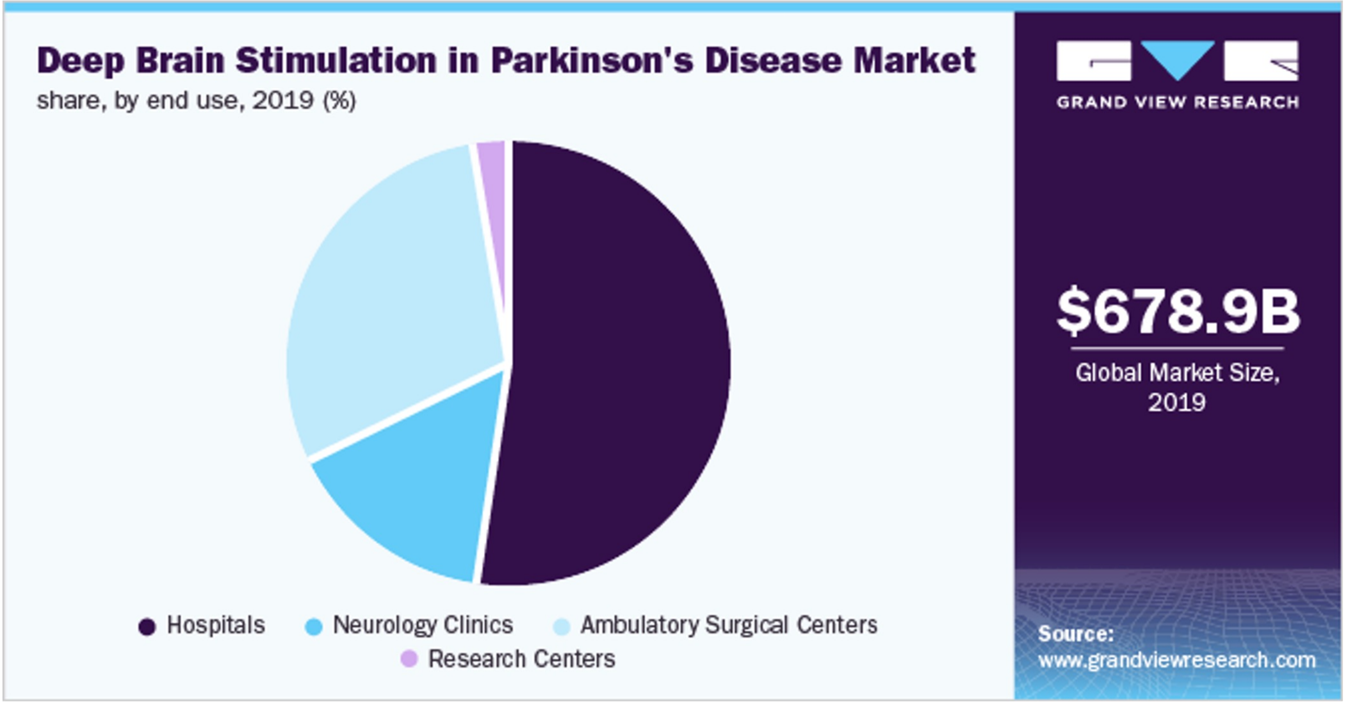
CPT® procedure codes

Physicians use CPT codes for all services. Under Medicare's Resource-Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT code is assigned a point value, known as the relative value unit (RVU), which is then converted to a flat payment amount.

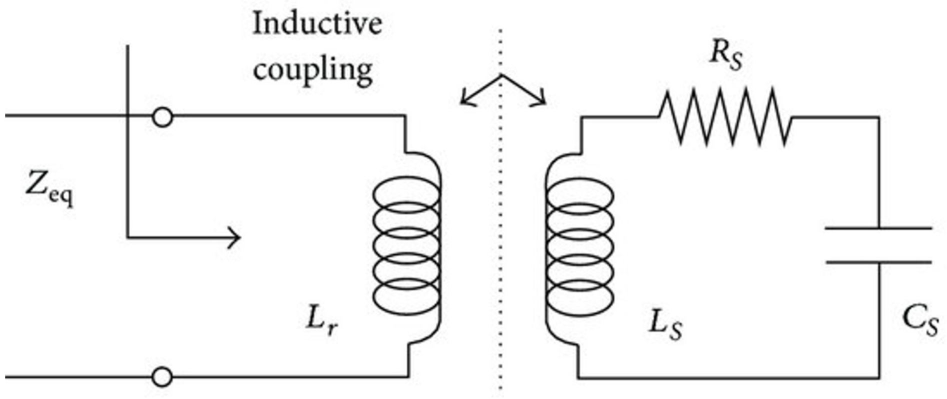
Procedure	CPT code and description[1]	Medicare RVUs[2]		Medicare national average[3]	
		For physician services provided in:[4]			
		Physician office[5]	Facility	Physician office[5]	Facility
Bone marker fiducial placement[6]	–	–	–	–	–
Diagnostic imaging and planning[7,8]	**70450-26** CT, head or brain without contrast material	–	1.20	–	$41
	70551-26 MRI, brain (including brain stem) without contrast material	–	2.10	–	$71
	76376-26 3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality, with image post-processing under concurrent supervision, not requiring image post-processing on an independent workstation[9]	–	1.12	–	$9
	76377-26 3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality, with image post-processing under concurrent supervision, requiring image post-processing on an independent workstation[9]	–	1.12	–	$38
Lead implantation or replacement[10,11]	**61863** Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array	N/A	45.53	N/A	$1,543
	61864 each additional array	N/A	8.45	N/A	$286
	61867 Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array	N/A	68.81	N/A	$2,332
	61868 each additional array	N/A	14.91	N/A	$505

Physician coding and payment - CPT® procedure codes (continued)

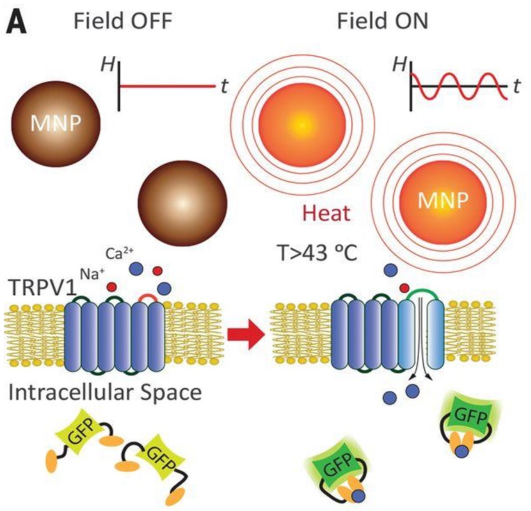
Procedure	CPT code and description[1]	Medicare RVUs[2]		Medicare national average[3]	
		For physician services provided in:[4]			
		Physician office[5]	Facility	Physician office[5]	Facility
Generator implantation or replacement[10,12]	**61885** Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling, with connection to a single electrode array	NA	15.99	N/A	$542
	61886 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling, with connection to 2 or more electrode arrays	NA	26.62	N/A	$902
Intraoperative stimulation with microelectrode recording[8,14]	**95961-26** Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of attendance by physician or other qualified healthcare professional	–	4.70	–	$159
	95962-26 each additional hour of attendance by physician or other qualified healthcare professional	–	5.03	–	$170
Revision or removal of leads or generator[10,11,12]	**61880** Revision or removal of intracranial neurostimulator electrodes	NA	17.83	N/A	$604
	61888 Revision or removal of cranial neurostimulator pulse generator or receiver	NA	12.07	N/A	$409
Analysis and programming	**95970** Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional, with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming[15]	0.56	0.55	$19	$19


Deep Brain Stimulation in Parkinson's Disease Market
share, by end use, 2019 (%)
Hospitals
Neurology Clinics
Ambulatory Surgical Centers
Research Centers
GRAND VIEW RESEARCH
$678.9B
Global Market Size, 2019
Source:
www.grandviewresearch.com

Technical



Inductive coupling
R_S
Z_{eq}
L_r
L_S
C_S



A
Field OFF
Field ON
H
t
MNP
Heat
T>43 °C
Ca2+
Na+
TRPV1
Intracellular Space
GFP

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Unrelated Patent

US20200292646A1
United States

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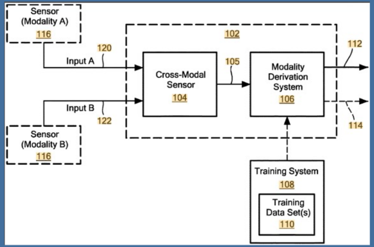
Inventor: Virginia Spanoudaki, Aviad Hai, Alan Pradip Jasanoff, Daniel G. Anderson, Robert S. Langer

Current Assignee : Massachusetts Institute of Technology

Interface responsive to two or more sensor modalities

Abstract

A cross-modal interface includes a multi-modal sensor configured to concurrently receive multiple input signals with each input signal being provided from a different imaging modality and in response thereto providing a single cross-modal output signal to processing circuitry which processes the single cross-modal output signal provided thereto and generates an output comprising information obtained or otherwise derived from each of or a combination of the different imaging modalities.



References

[1] P. Rizek, N. Kumar, and M. S. Jog, “An update on the diagnosis and treatment of Parkinson disease,” *CMAJ Can. Med. Assoc. J.*, vol. 188, no. 16, pp. 1157–1165, Nov. 2016, doi: 10.1503/cmaj.151179.

[2]W. Yang et al., “Current and projected future economic burden of Parkinson’s disease in the U.S.,” npj Parkinsons Dis., vol. 6, no. 1, p. 15, Jul. 2020, doi: 10.1038/s41531-020-0117-1.

[3]D. Seo, J. M. Carmena, J. M. Rabaey, E. Alon, and M. M. Maharbiz, “Neural Dust: An Ultrasonic, Low Power Solution for Chronic Brain-Machine Interfaces.” arXiv, Jul. 08, 2013. Accessed: Mar. 01, 2023. [Online]. Available: http://arxiv.org/abs/1307.2196

[4]J. Frey *et al.*, “Past, Present, and Future of Deep Brain Stimulation: Hardware, Software, Imaging, Physiology and Novel Approaches,” *Front. Neurol.*, vol. 13, p. 825178, Mar. 2022, doi: 10.3389/fneur.2022.825178.