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Wyss Center for Bio and Neuroengineering

New horizons in neural recording systems

The Wyss Center for Bio and Neuroengineering is an independent, non-profit research and development center based in Geneva, Switzerland. The Wyss Center team, together with academic and clinical collaborators, and a network of industrial technology partners, is pushing the boundaries of implantable neuro-devices to improve quality of life and provide independence for people with paralysis.

The clinical need for neurotechnology

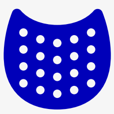
Losing the ability to communicate or move your body while still being conscious is a reality for some people living with motor neuron disorders, spinal cord injury, head trauma or stroke across the world. While many retain some muscle control, others gradually or suddenly progress to a locked-in state in which they are completely paralyzed and for which there are currently no assistive devices that can help them move, communicate or bring them independence. The situation is extremely challenging for patients, families, and their caregivers.

Fortunately, even in severe paralysis, large parts of the brain may still be functional. This is an opportunity for researchers and clinicians. Technologies measuring blood flow, magnetic fields or electrical impulses are evolving and are capable of monitoring brain activity in ever greater detail resulting in considerable potential for this data to be used to restore lost functions.

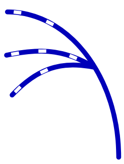
More specifically, in the area of electrophysiology, a better understanding of the electrical patterns of neural activity has allowed researchers to use neural recording systems, also known as a brain-computer interfaces (BCIs), to diagnose neurological disorders, assist in rehabilitation and, in some cases, enable users to communicate.

These systems measure electrical signals generated by neurons using a variety of electrodes.

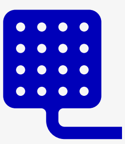
Measuring the electrical activity of the brain



Electroencephalography (EEG) is used to record signals from the scalp usually with a cap or net. The need to reapply gel or liquid to the head to ensure good electrode contact limits the long-term usability of EEG and the fact that the electrodes are outside the skull and scalp reduces the quality of the signal. EEG signals are nonspecific, which means that processes involving only small brain regions, for example the fine motor control for handwriting, are difficult or impossible to decode.

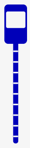


A new modality, subscalp EEG, records electrophysiological data from beneath the scalp. Minimally invasive electrodes are surgically implanted beneath the scalp. The approach enables the electrodes to record over very long periods of time without the need to wear a cap or reapply gel. For more on subscalp recording see the Wyss Center's Epios system.



Electrocorticography (ECoG) uses grids of flat electrodes implanted beneath the skull to record signals directly from the cortical surface. Placement directly on or beneath the dura - the brain's protective membrane - gives a higher resolution image of brain activity as each electrode measures activity only from nearby neurons. It becomes possible to detect the difference between opening and closing a hand and even movement of individual fingers.

Intracortical recordings use electrodes surgically implanted beneath the skull that penetrate the surface of the cortex. They include microelectrode arrays (MEAs) in which a grid of fine needles records the activity of individual neurons. At this resolution, it becomes possible to decode hand and finger position with high accuracy. A drawback of this technology is that relatively small areas of the brain can be observed at a time.



Stereo encephalography – or stereo-EEG – uses electrodes that penetrate deep into the brain. They target very precise locations and are often used to identify where epileptic seizures start.

The primary advantage of implantable electrodes over scalp EEG is the quality of the neural signals measured. Implantable electrodes are better shielded from environmental noise and, the closer the electrodes are to the neurons, the easier it is to pick up the small voltages they generate over the background noise.

Of the implantable technologies, ECoG electrodes have the advantage of being able to record from a large area of brain. They cannot, however, record action potentials - the electrical activity of individual neurons -. Instead, ECoG picks up the synchronous neural activity of many neurons working together as a network. Researchers are now exploring how to use this network activity to decode attempted speech [1] or movements in real time. In one clinical study, devices with only a few ECoG channels enabled locked-in patients to communicate [2]. Patients learned to modulate the neural activity measured by the electrodes to control a speller program, with the high reliability level required for independent home use.

To capture the brain signals involved in playing the piano for example, the recording electrodes must pick up action potentials from individual neurons in the motor cortex, located close to the surface of the brain. These signals, which can be as short as one millisecond, are recorded with intracortical MEAs that record large amounts of high frequency neural information in a short period of time. The limitation though, is that they record from only a small area of the brain.

Over the last decade, signals from MEAs have already been used to demonstrate potential applications for brain-machine interfaces. Paralyzed people moved computer cursors [3] and robotic arms [4,5], with brain-controlled muscle stimulation they could move limbs and fingers to grasp objects and play Guitar Hero [6-8], and they could write at almost normal speed just imagining handwriting [9]. Even completely locked-in people, who cannot communicate with conventional assistive technology - for example, eye trackers - may benefit from this kind of BCI. In a clinical case-study, Wyss Center scientists worked with a person who has amyotrophic lateral sclerosis (ALS) – a progressive neurodegenerative disease in which people lose the ability to move and talk. He was able to communicate by modulating his neural activity to produce yes/no responses which he used to select letters and spell sentences [10].

These efforts show the potential of the technology to restore lost function. However, those studies that recorded a large volume of high frequency signals, all relied on data transfer via a wired connection through the skull and scalp to an external computer.

The need for breakthrough neural implants

Despite the advances, current technologies are largely limited by the physical connection - wires - between the electrodes and the computer. A percutaneous connection through the scalp presents an infection risk and, as the patient must remain tethered to an external recording system when the system is in use, it limits usability outside a clinical environment.

Wireless implantable neural recording systems would offer reduced infection risk as the device is fully implanted beneath the scalp. They would also allow users increased independence and greatly simplify handling for caregivers.

There is however currently no system designed to meet the needs of severely paralyzed people in daily life.

While the benefits are clear, long-term fully implantable neural implants face engineering challenges:

- The delicate internal electronics must be protected from the warm, wet and salty environment of the human body.
- Biocompatible materials must be carefully selected to keep the body's immune response at a minimum.
- Raw neural signals recorded from many electrodes require exceptionally high data transfer rates.
- Real-time wireless communication between an implant and wearable device requires careful assessment of energy dissipation and thermal properties to ensure temperature stability.
- Powering a wireless implantable device requires a specialized power transfer system.
- The electronic design must accommodate many miniaturized components in a tight space.
- Accommodation of different electrode technologies requires a versatile implant.

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Pushing the boundaries of implantable neuro-devices

The Wyss Center team has employed a series of novel approaches to overcome these engineering challenges.

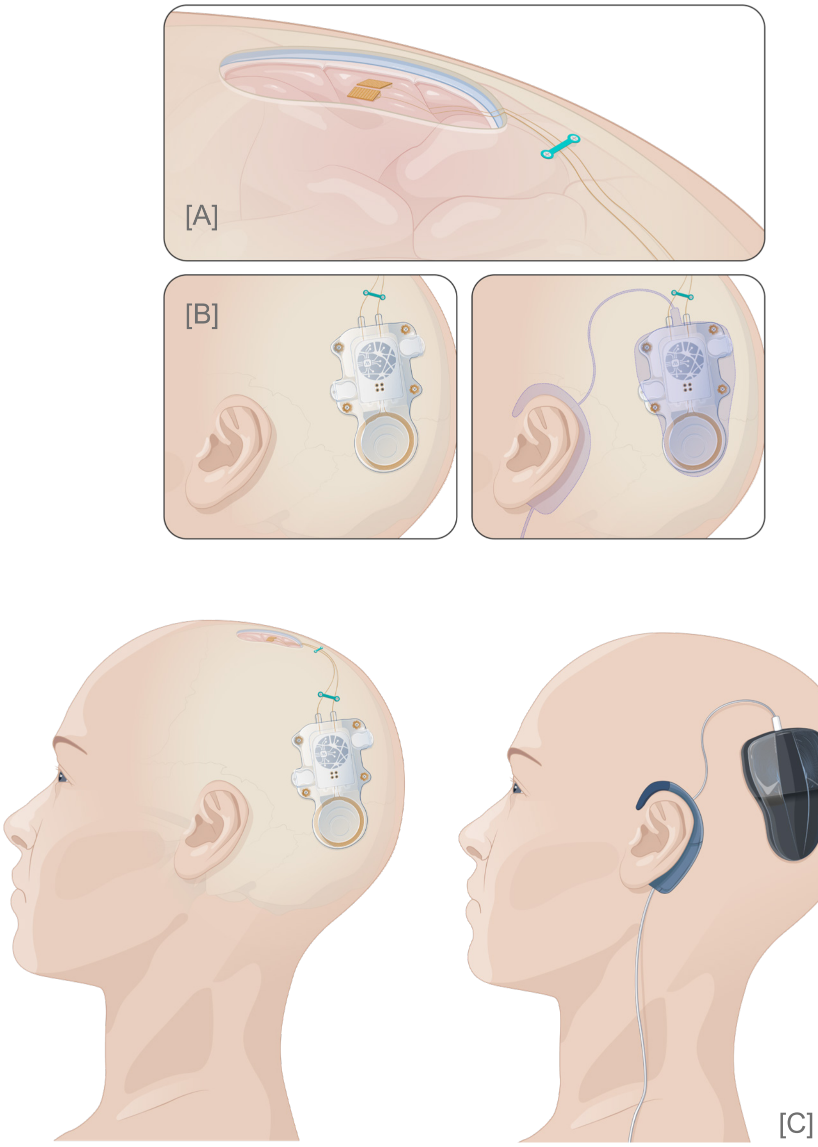
ABILITY is a fully implantable neural recording system designed to amplify and wirelessly transmit high channel count, high frequency neural data from the brain to a computer. Compatible with both MEA and ECoG technology, and designed for 24/7 home use, it represents a versatile and user-friendly system.

ABILITY: Active Brain Implant Live Information Transfer sYstem. ABILITY is designed for long-term implantation to enable applications such as restoration of communication and movement for people with severe paralysis.

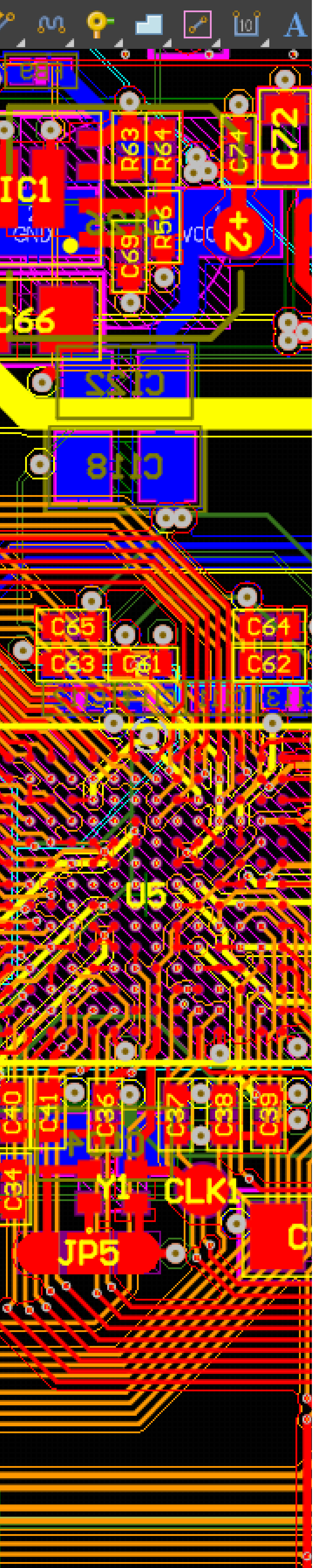
The system integrates multiple unique features. The biocompatible active implant is encapsulated in a protective housing and continuously records up to 128 channels of high-resolution neural signals. Hermetic feedthroughs allow microwires from the electrodes to enter and connect to the implant, while keeping moisture away from the internal electronics.

An innovative real-time optical data transfer link securely transmits broadband neural data at 50 Mbits/s from the implant to the external wearable device.

Powered by induction, the system does not require implanted batteries or percutaneous connectors.



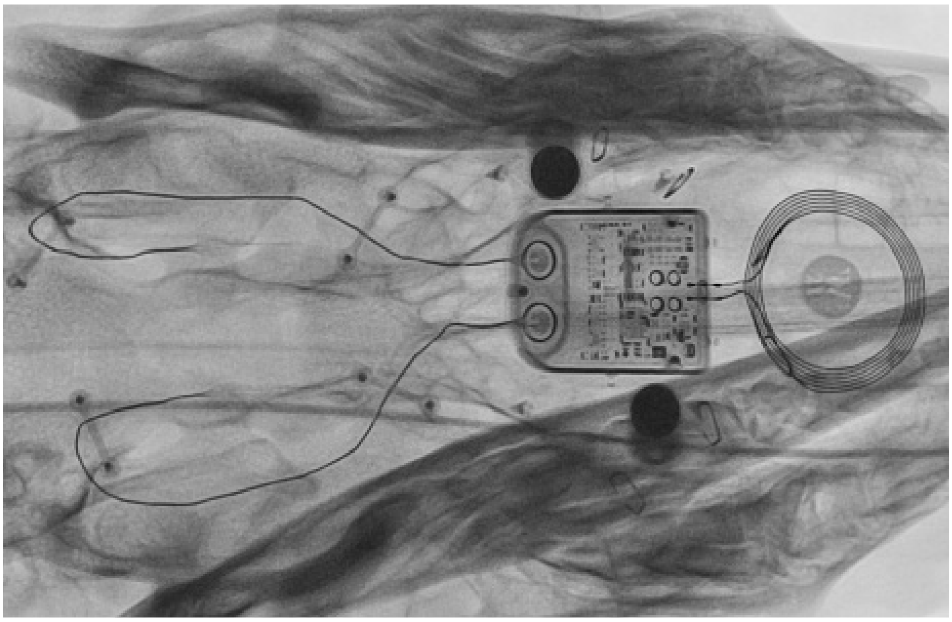
Surgically implanted electrodes (A), connected to the implant (B), detect high frequency brain signals. The implant wirelessly transmits neural data to the wearable (C) in real-time via an innovative optical data transfer link. The wearable non-implantable components comprise a head piece magnetically aligned directly over the implant and an earpiece. These wirelessly power the implant through the skin via induction. The wearable sends the neural data to an external processing unit via a wired connection. Here, ABILITY is seen connected to two microelectrode arrays - other electrode technologies may also be connected.



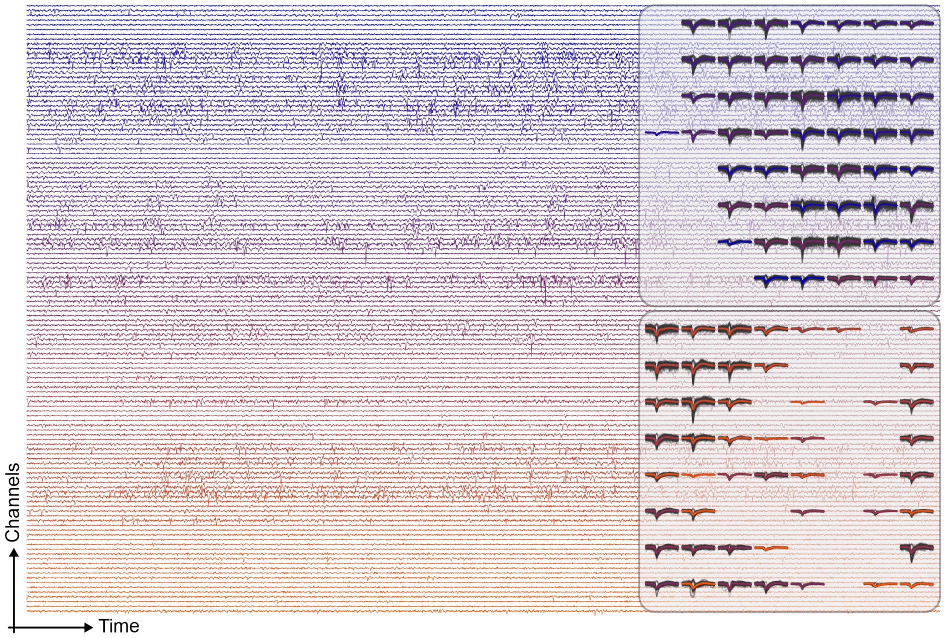
ABILITY's external electronic brain. The printed circuit board layout of the USB adapter in the ABILITY wearable. The central square - U5 - is the system coordinator. It is a field programable gate array (FPGA) that reads neural data recorded from implanted electrodes, manages the system's power and communicates with the implant and the wearable components.

First preclinical proof-of-concept

A crucial step towards development of a fully implantable device is to show that it is safe and functional. In a first preclinical proof-of-concept trial of the ABILITY system in sheep, high bandwidth neural data was received in real time over a period of months with the device functioning safely. Further extensive studies will be performed to demonstrate that ABILITY meets the very strict regulatory requirements for human use before commencing the planned clinical trials in people.



X-ray view of the ABILITY device implanted on the animal's forehead.



Example of neural data filtered in the spike band, recorded from 128 channels simultaneously over 250 ms. The inserts show locations of channels with action potentials from individual neurons (spikes) on maps of the two electrode arrays. Each spike waveform represents the position of a microelectrode in the array. Not all 128 microelectrode channels show spiking activity in this graphic.

First clinical application

Human clinical trial for restoration of communication

Building on the Wyss Center's previous clinical case-study demonstrating BCI communication with a wired connection in a locked-in patient, and the ongoing pre-clinical trials of ABILITY, a new clinical trial is being prepared that will use the wireless ABILITY system in people locked-in as a result of amyotrophic lateral sclerosis (ALS) or brainstem stroke.

The EU and Swiss-funded research consortium is led by the UMC Utrecht Brain Center in collaboration with Graz University of Technology. Customized ECoG grids, developed by partner CorTec GmbH, a medical device company, will connect to ABILITY. This first clinical application of the ABILITY system will validate its use in the home environment and explore new algorithms for brain to speech decoding.

The team will initially develop algorithms to allow participants to control a computer with their brain as if they were using a mouse and keyboard. In a next step, novel AI algorithms will decode imagined or attempted speech in real-time, to enable patients to communicate directly with family and caregivers. Device control algorithms will be designed to meet the patients' individual needs and capabilities. Together, these features aim to significantly improve quality of life, provide independence, and enable effective and efficient healthcare.

The unprecedented wealth of brain data collected during the clinical study will improve speech translation algorithms, as well as the functionality and use of the device. The data will be openly shared and will contribute to advancing scientific knowledge of human brain function and therapeutic opportunities of BCI.

Finally, and importantly, the clinical study will assess the users' needs and the acceptance of implantable BCIs by patients, caregivers, and health care professionals.

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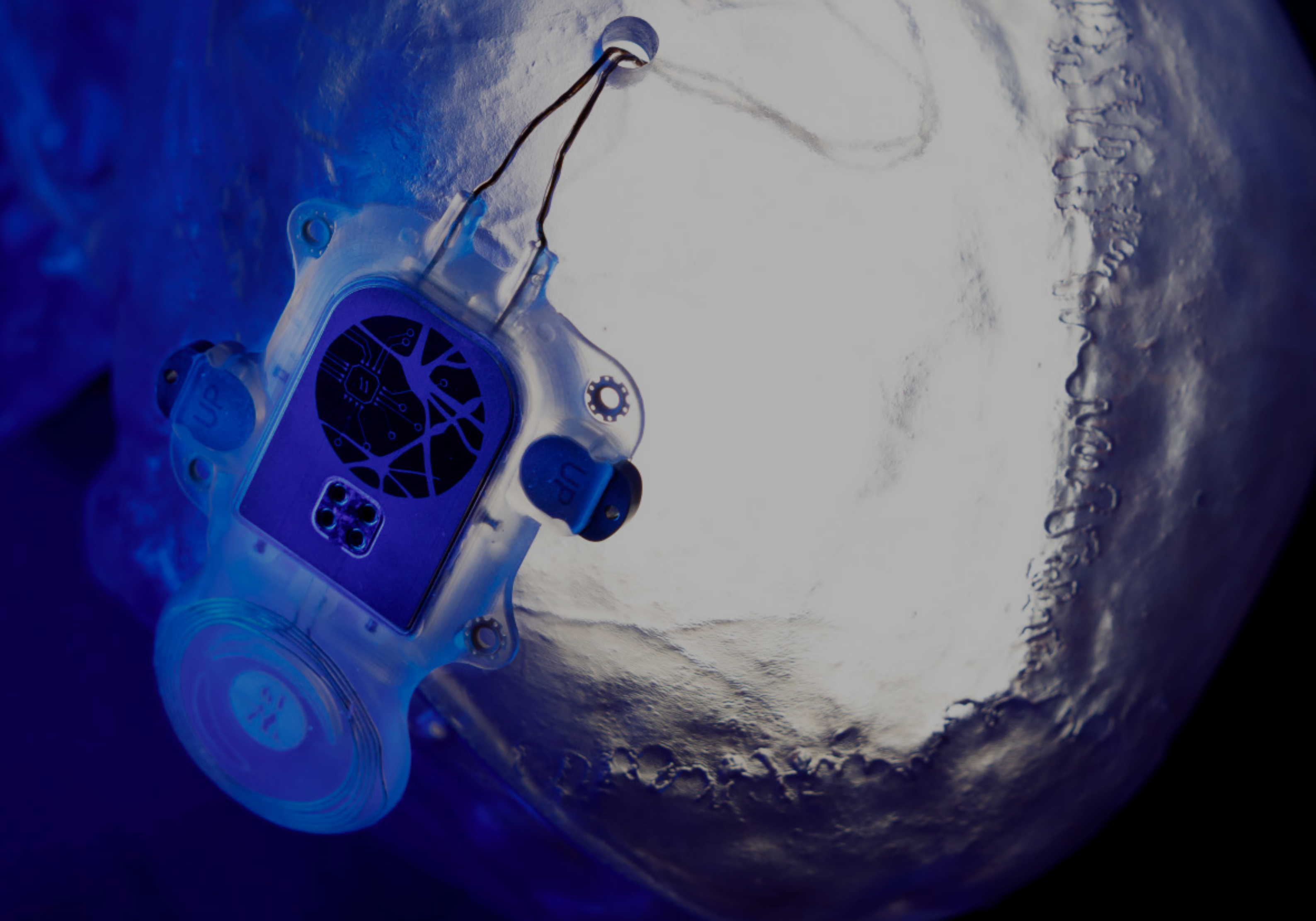
AI algorithms will decode high resolution neural data collected with the brain surface lining ECoG electrode grids to translate brain signals to computer speech in real-time.



The Wyss Center welcomes the opportunity to connect with groups around the world to address the challenges associated with realtime brain signal recording and decoding to help people with impaired movement and communication.

Connect with us

Get in touch about partnership or collaboration opportunities.

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For more information, please visit our website

www.wysscenter.ch

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