Workshop on Brain-Machine Interface – Gardanne, Fr, 19 Feb 2025

Design and clinical validation of WIMAGINE®, an ECoG based wireless Brain Machine Interface

F. SAUTER-STARACE

G. CHARVET

CLINATEC - Edmond J. Safra Biomedical research center located in the technological research center CEA/LETI

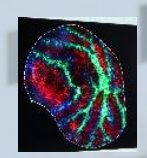
Launched in 2008, under the scientific direction of **Professor Alim-Louis BENABID**

Mission

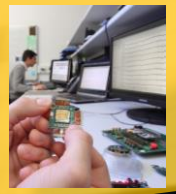
Accelerate the **development and clinical validation** of **innovative medical devices** stemming from **micro-nano technologies** innovations

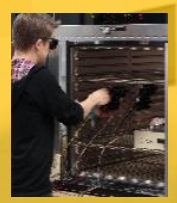
PRECLINICAL facility for early medical device evaluation

Platform for BIOLOGICAL assessment



Platform for TECHNOLOGICAL development





HOSPITAL UNIT for clinical trials

Implantable chronic Brain Machine Interface technology for motor compensation of disabled patients

Decoding of movement intentions from the brain activity

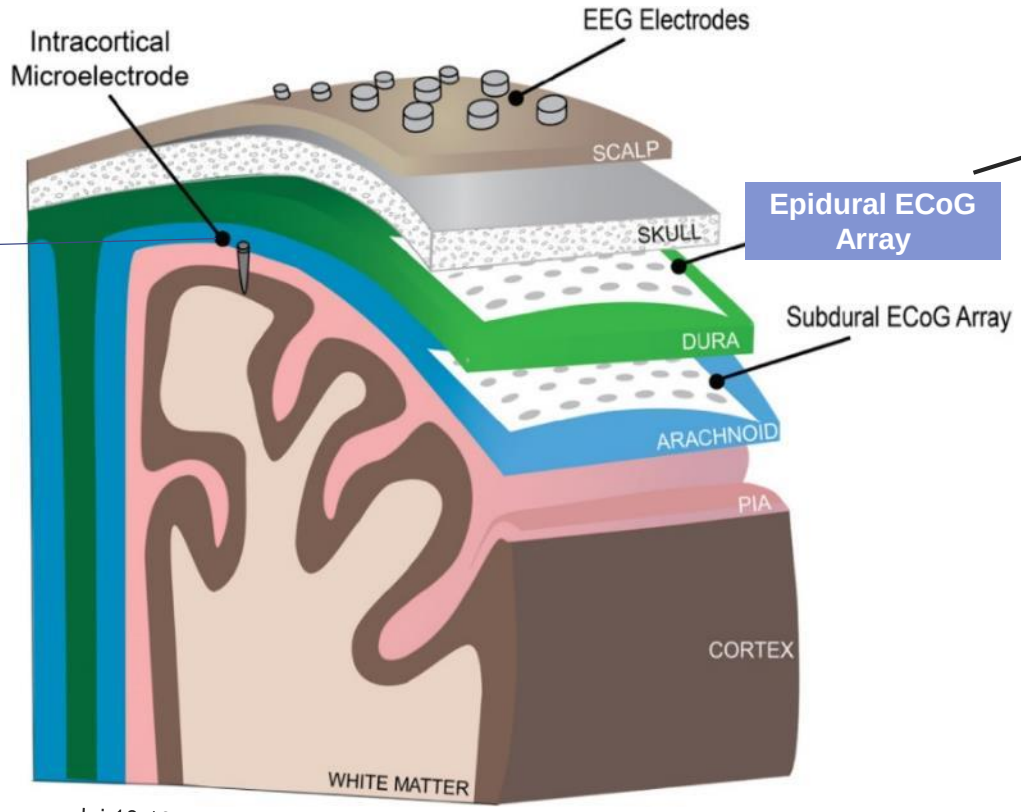
Functional substitution devices

To improve the mobility of patients with motor disabilities

BCI approaches in 2015

Braingate project with UTAH array and associated electronic by Blackrock Neuro

- **Large number of degrees of freedom**
- **Very invasive, stability issues for long-term recordings**



doi:10.1088/1741-2560/12/1/011001

g.tec

- **Non invasive**
- **Few degrees of freedom**
- **Large range of applications**

WIMAGINE® implants

Authorized for Clinical trial

- **Large number degrees of freedom**
- **Semi-Invasive : few risks**
- **Medical Applications**

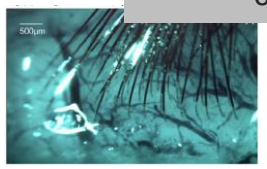
Prototype stage

BCI approaches in 2025

Braingate project with UTAH array and associated electronic by Blackrock Neuro

38 implanted individuals, motor decoding and communication

https://www.nature.com/articles/s44222-024-00239-5



3 implanted individuals cursor control

NEURALINK

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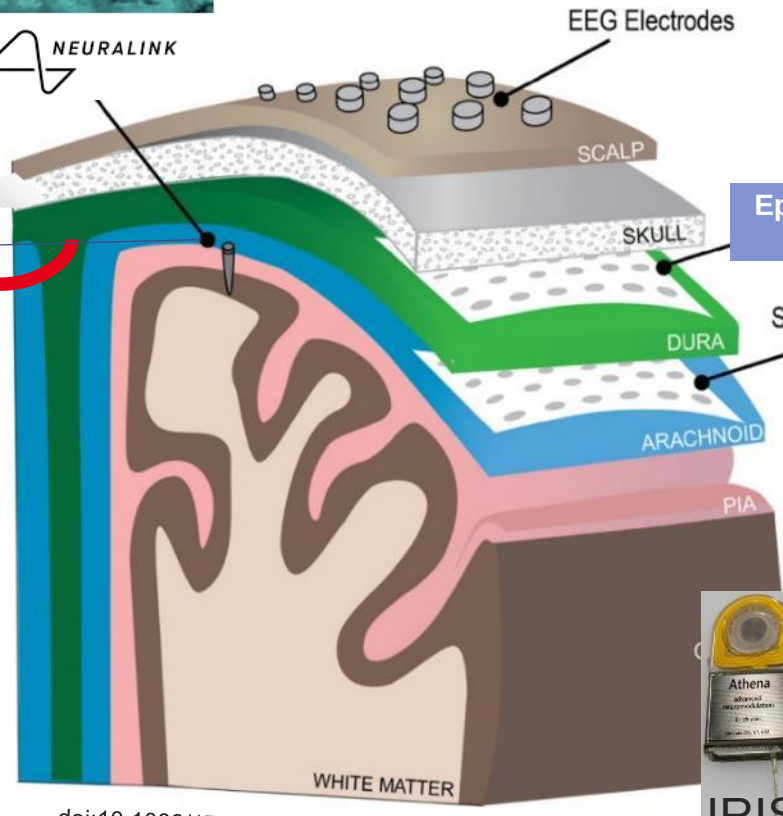
WIMAGINE® implants

7 years of clinical feedback 6 implanted individuals so far

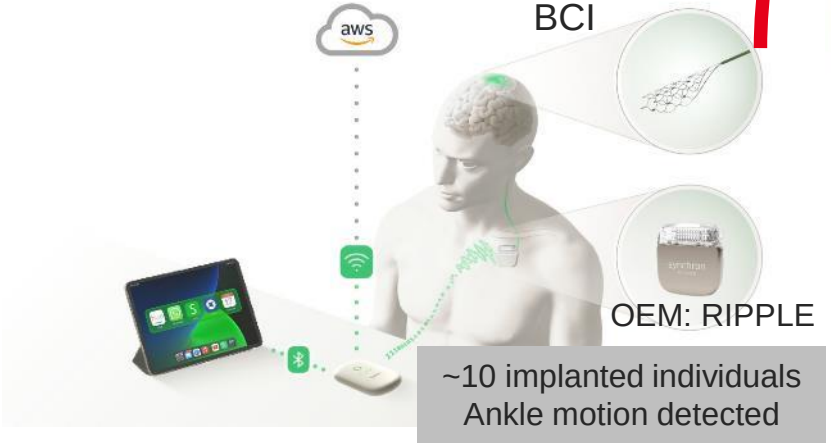


Epidural ECoG Array

Subdural ECoG Array

doi:10.1088/1741-2560/12/1/011001

Synchron's endovascular BCI

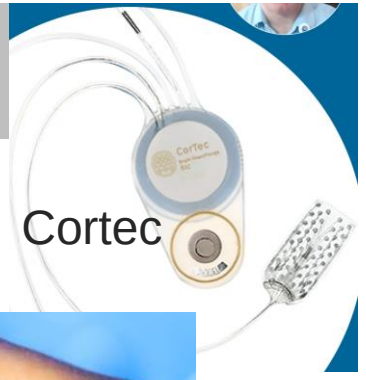


OEM: RIPPLE

~10 implanted individuals Ankle motion detected

https://www.nature.com/articles/s44222-024-00239-5

IDE approval in 2024



Cortec

IRIS/RIPPLE

No clinical trial reported

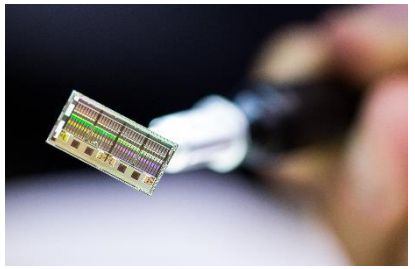
Wyss' Ability

No clinical trial reported

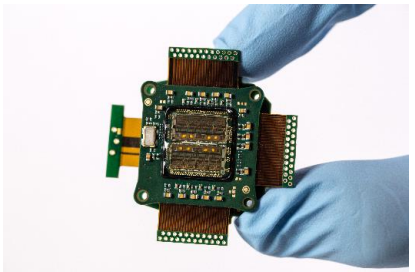
WIMAGINE® Implant development

Integrated circuit for biosignal amplification and digitalization
ASIC CINESIC32

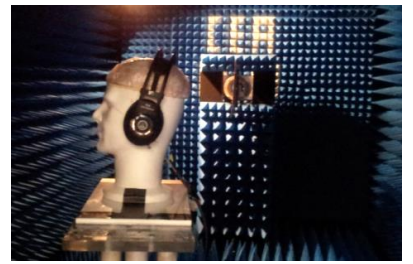
Robinet S. et al. (2011)



Electronic boards with amplification module, wireless communication module and remote power supply module



Antennas for Wireless communication (402-405MHz) and remote power supply (13,56MHz)

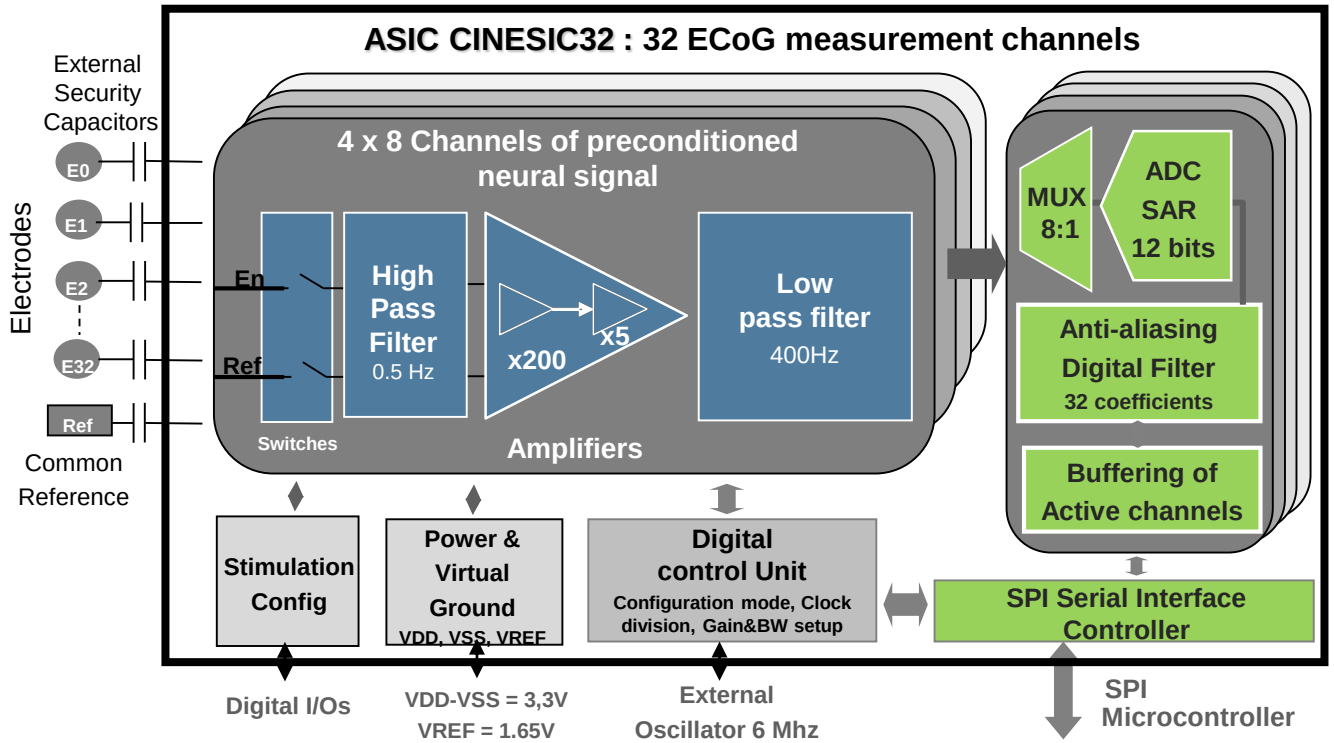


64-Electrodes array
Hermetic and biocompatible packaging

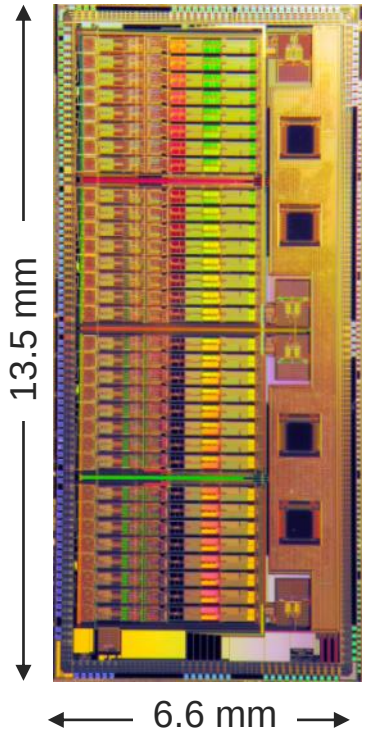
CES INNOVATION AWARDS 2024 HONOREE

Mestais, C. S., Charvet, G., Sauter-Starace, F., Foerster, M., Ratel, D., & Benabid, A. L. (2014). WIMAGINE: wireless 64-channel ECoG recording implant for long term clinical applications. *IEEE transactions on neural systems and rehabilitation engineering*, *23*(1), 10-21.

WIMAGINE® IMPLANT: INTEGRATED CIRCUIT FOR NEURAL SIGNAL RECORDING

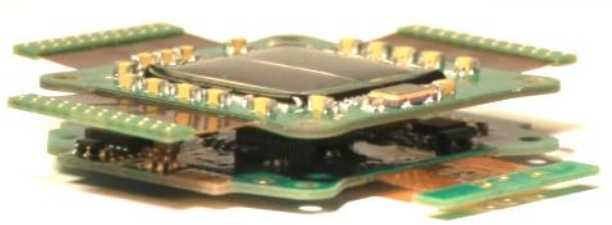


ASIC CINESIC32



General features

- **32 ECoG Channels** measurements
- Very low noise amplifier : **0.7 µVRMS**
- Embedded 12 bits ADC (Analog to digital converter)
- Serial link SPI for communication
- Low power ASIC : 32µA/channel and global consumption ~ **3mA** (in nominal mode: 32 actives channels)

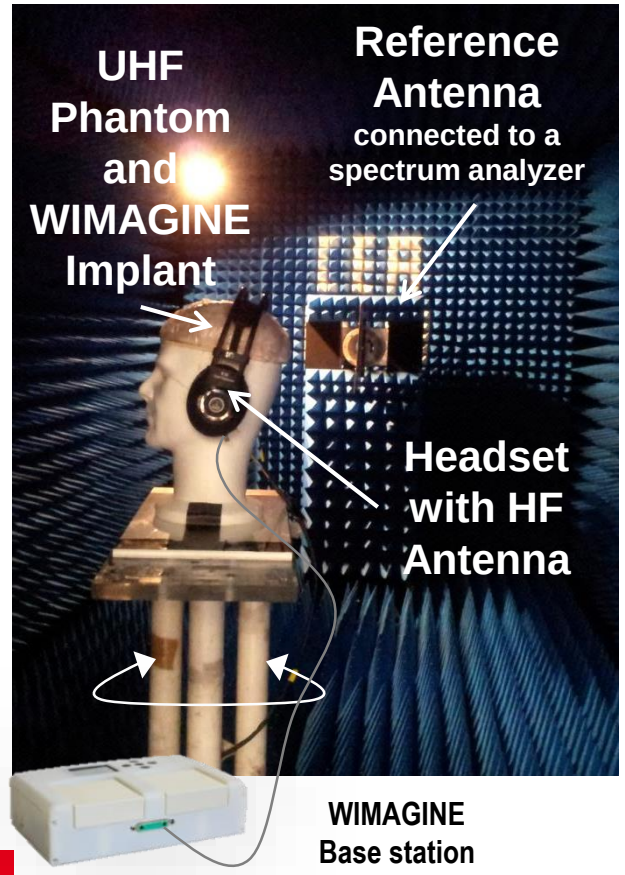


Robinet, S., Audebert, P., Regis, G., Zongo, B., Beche, J. F., Condemine, C., ... & Charvet, G. (2011). A Low-Power 0.7µVRMS 32-Channel Mixed-Signal Circuit for ECoG Recordings. *IEEE Journal on Emerging and Selected Topics in Circuits and Systems*, *1*(4), 451-460.

RF link module : Implant UHF Antenna characterization

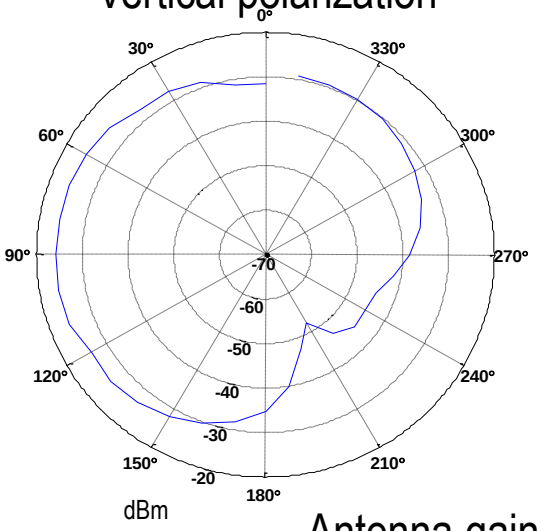
Anechoic Chamber setup

for radiation pattern measurement of Implant's UHF antenna

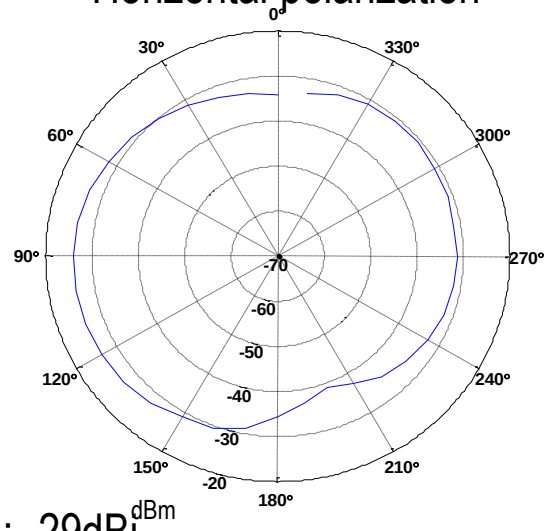


Results: Radiation patterns

Vertical polarization



Horizontal polarization

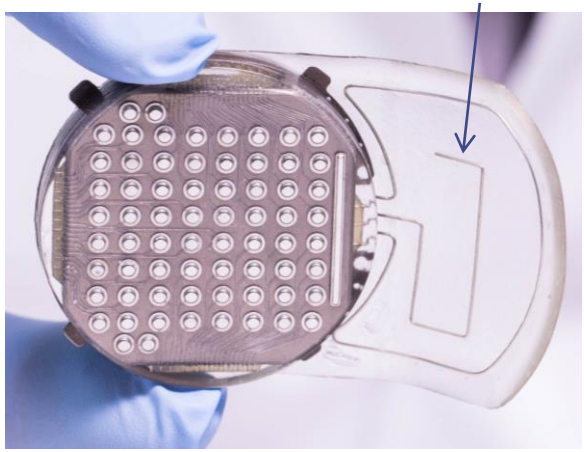


Antenna gain: -29dBi

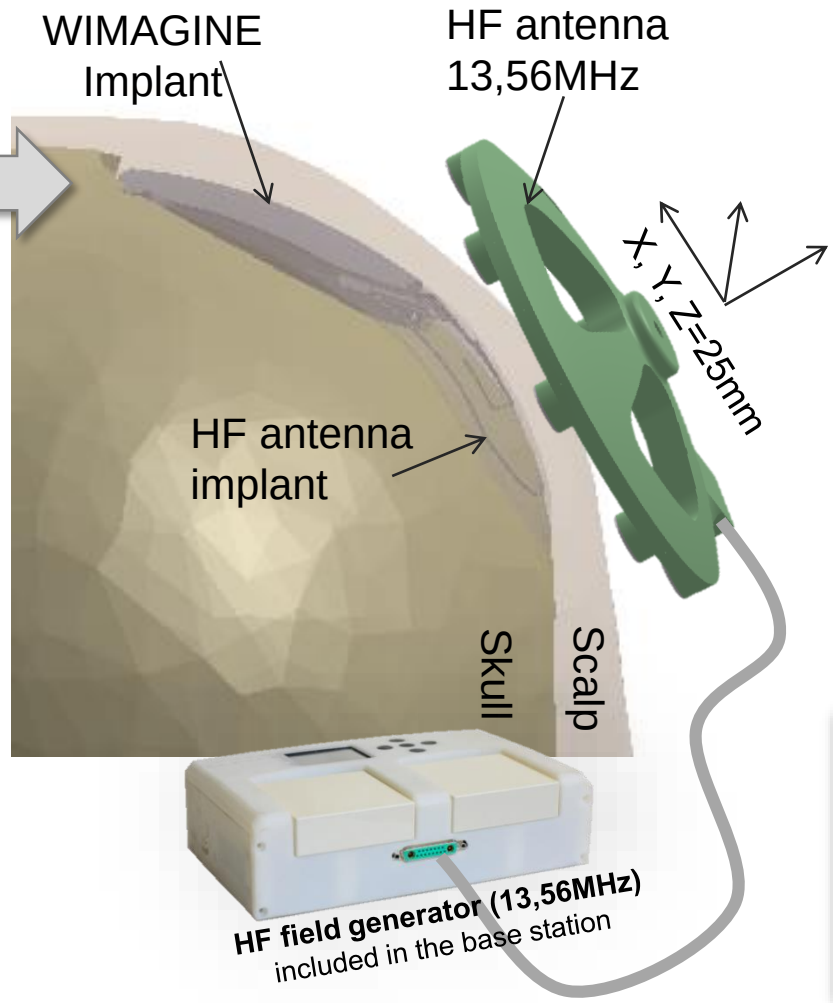
RF link Features

- 402-405 MHz (10 MICS channels)
- RF link based on a Zarlink ZL70102
- Antenna optimized for in-body environment
- Maximum Effective data rate : 450kbps @ 4FSK sensitivity
- Used effective data rate : 250kbps @ 2FSK ➔ 32 channels@12bits- 600Hz/channel ➔ **extended to 64** thanks to digital signal compression in the implant
- Implanted antenna Gain : -29dBi

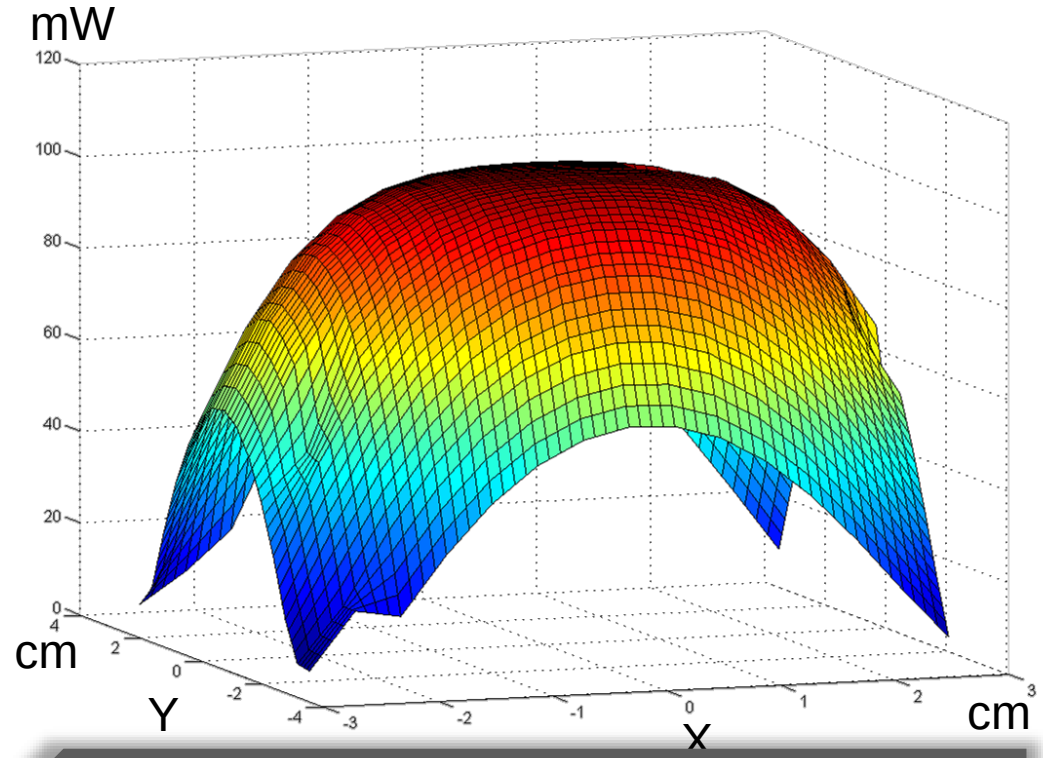
UHF antenna



Inductive power management module



Power received over the inductive link for a distance of 25mm.



Inductive wireless power management module

- Frequency : 13.56MHz
- Wireless power supply: 100mW (30mA @3.3V) at a distance of 2.5 cm
- WIMAGINE power : 21.85mA (for 32-channel @600hz)

WIMAGINE PRECLINICAL ASSESSMENTS

1. Ex-vivo assessment on primate :

Non-human primate chronically implanted with subdural and epidural electrode array with WIMAGINE® in a test-bench

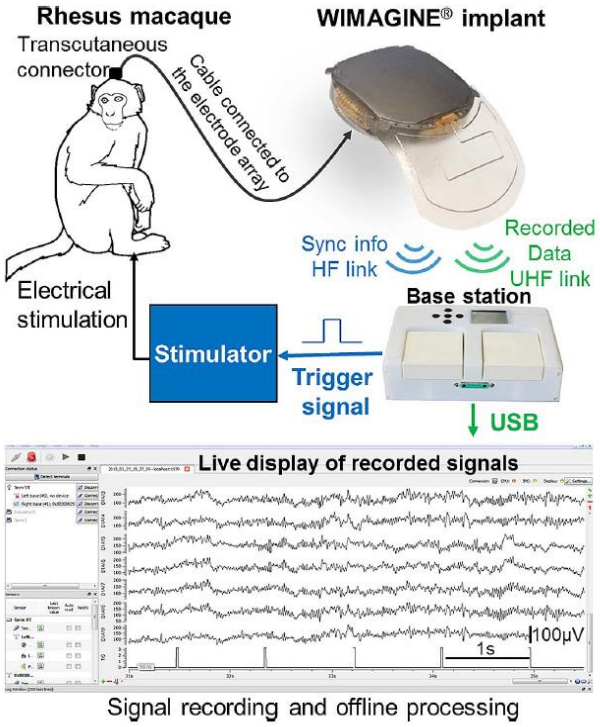
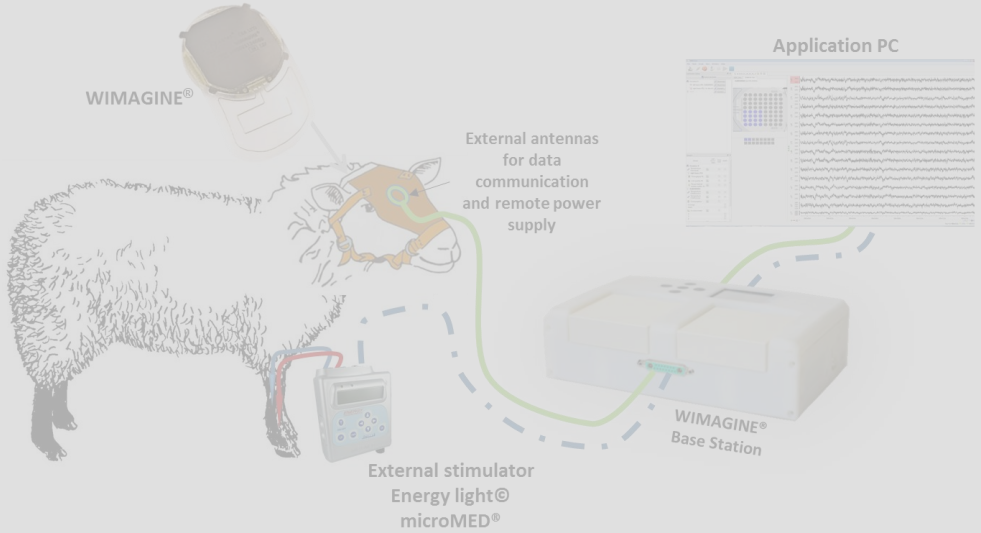


Fig. 13. Experimental setup for SEP acquisition.

Mestais, C. S., Charvet, G., Sauter-Starace, F., Foerster, M., Ratel, D., & Benabid, A. L. (2014). WIMAGINE: wireless 64-channel ECoG recording implant for long term clinical applications. *IEEE transactions on neural systems and rehabilitation engineering*, *23*(1), 10-21.

2. First fully in-vivo' assessment on sheep:

- **Implantation of 1 WIMAGINE in two sheep** for a follow-up period of 10 months
- **Stable power spectra and signal to noise ratios** over time with an effective bandwidth in the range of 230Hz
- **Post-mortem analysis** : no significant inflammation or glial activation in the cortex

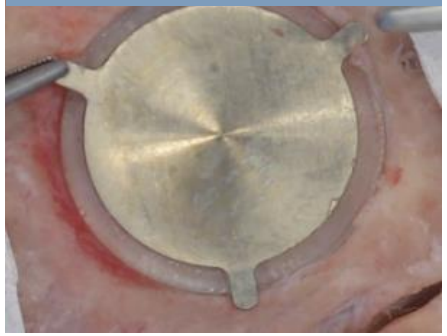


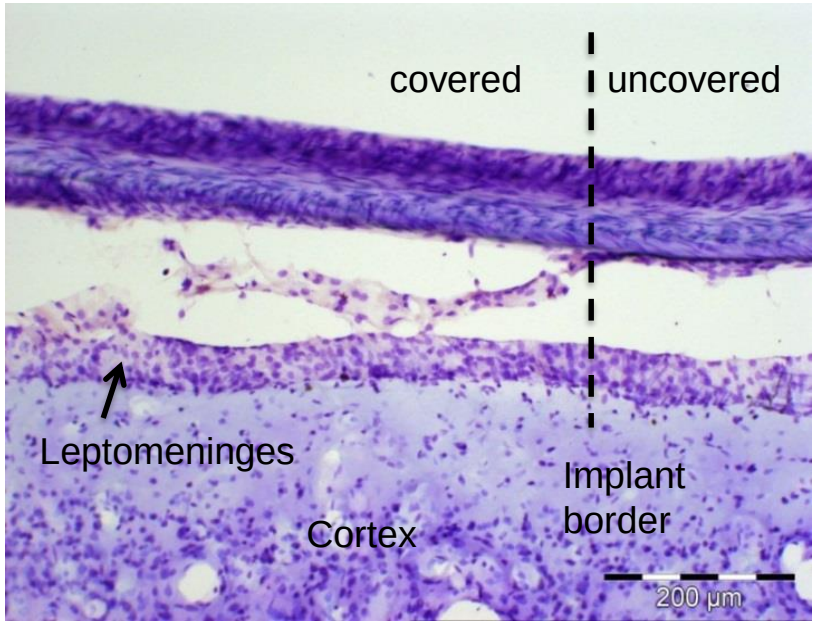
Sauter-Starace, f., Ratel, D., Cretallaz, c., Foerster, m., Lambert, a., gaude, c., ... & Mestais, c. (2019). Long-term sheep implantation of WIMAGINE®, a wireless 64-channels electrocorticogram recorder. Frontiers in neuroscience, 13, 847.

PRECLINICAL ASSESSMENT OF THE DURA-MATER THICKENING, EPIDURAL ECOG

Epidural implantation of a semi-scale device on non human primates

Device before explantation





No tissue reaction after 26 weeks (Nissl staining)

WIMAGINE PRECLINICAL ASSESSMENT

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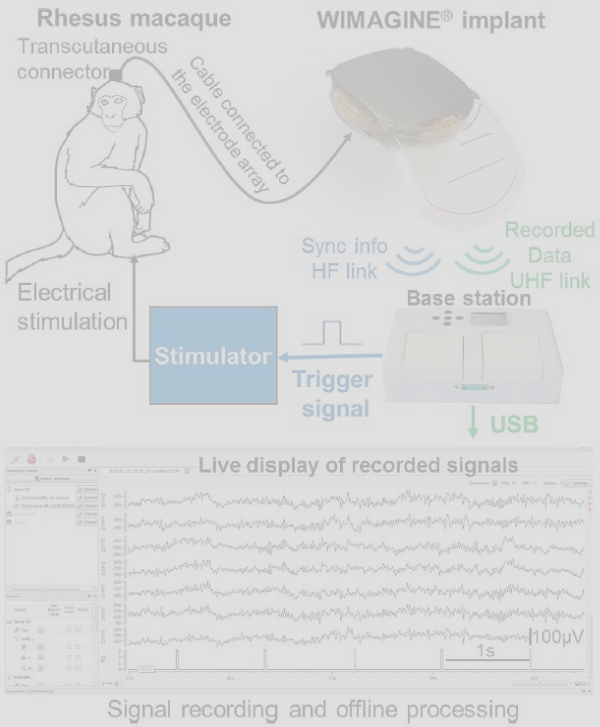

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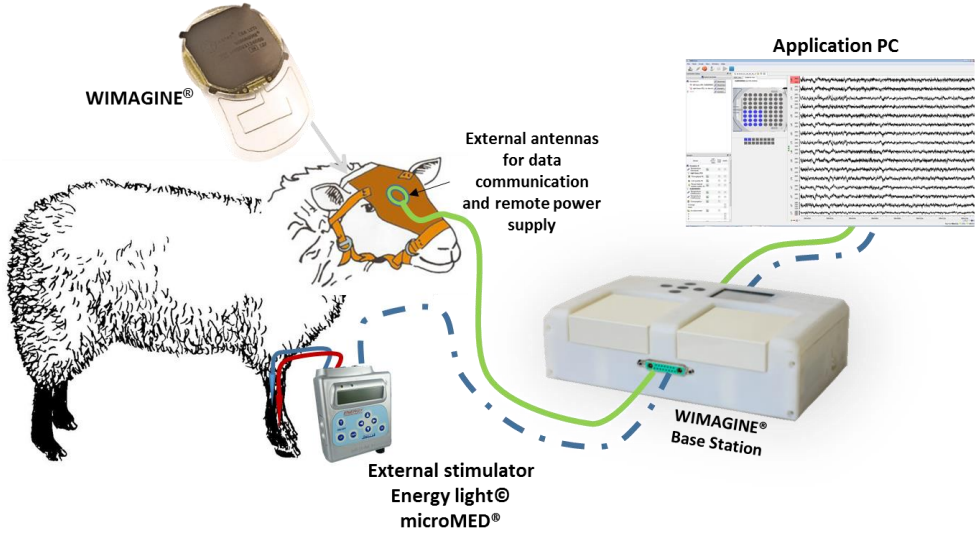

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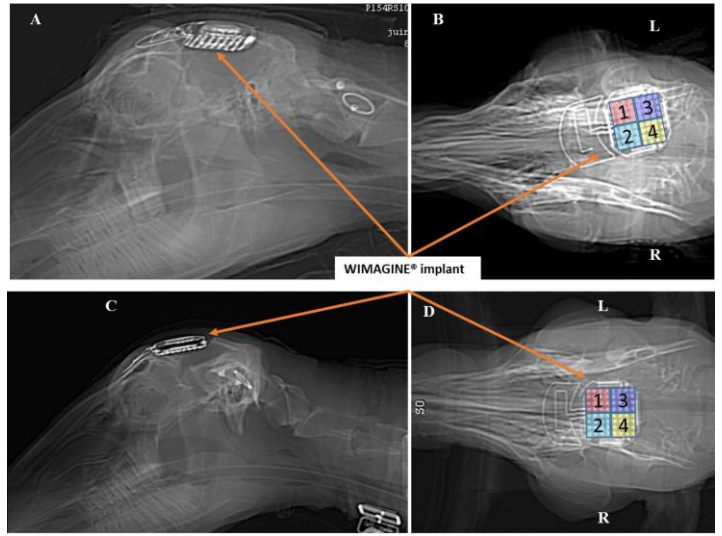
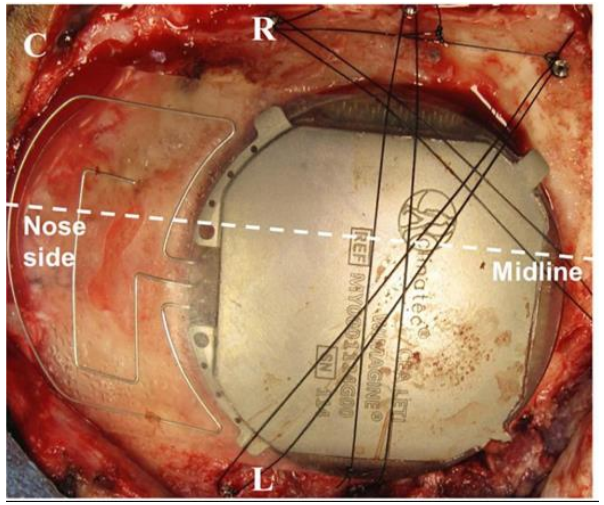
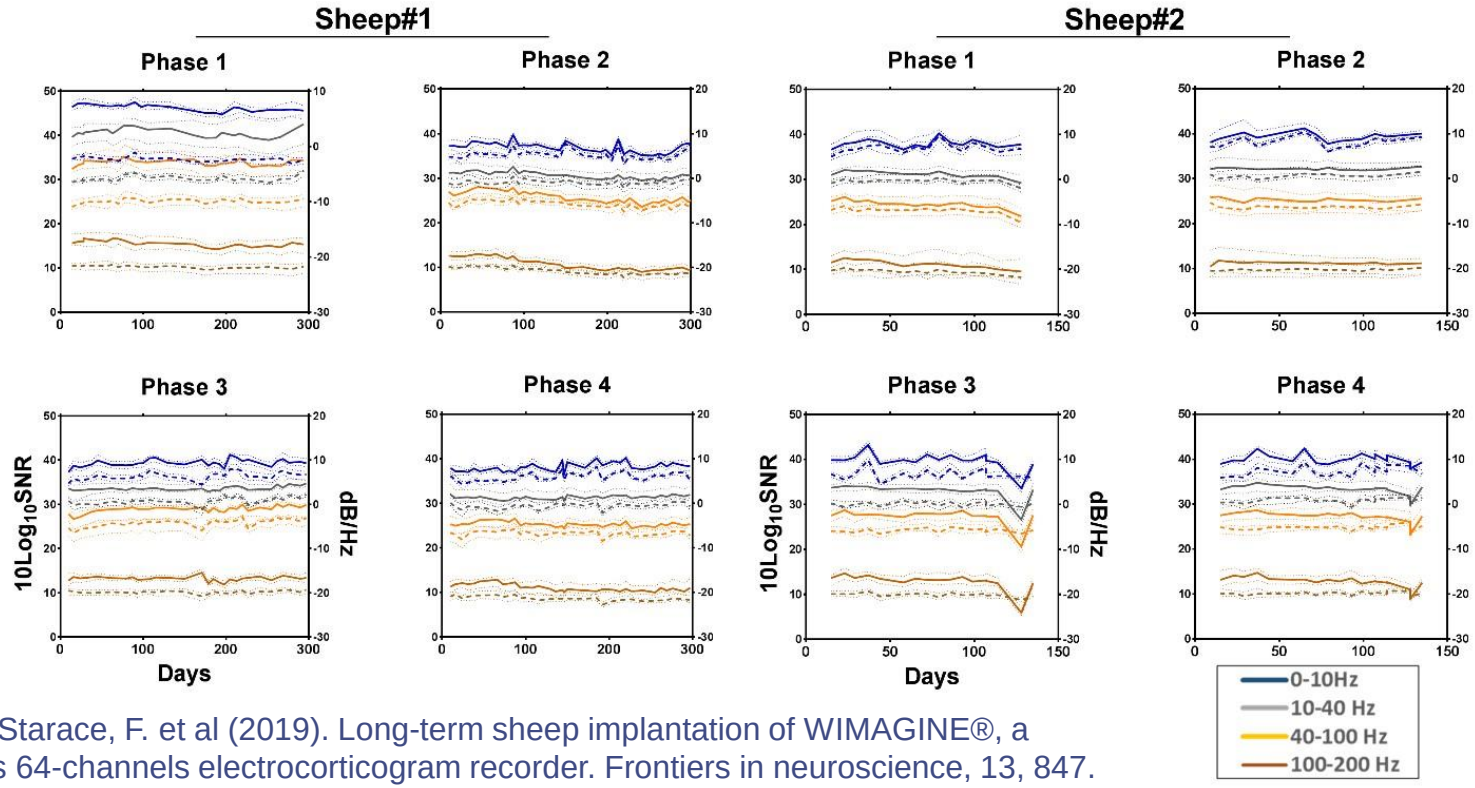
SIGNAL STABILITY ASSESSMENT PRECLINICAL DATA

10 month sheep monitoring described in doi.org/10.3389/fnins.2019.00847

- Signal magnitude (RMS)
- Bandpower on [0-10], [10-40], [40-100], [100-200] Hz
- Signal to noise ratio







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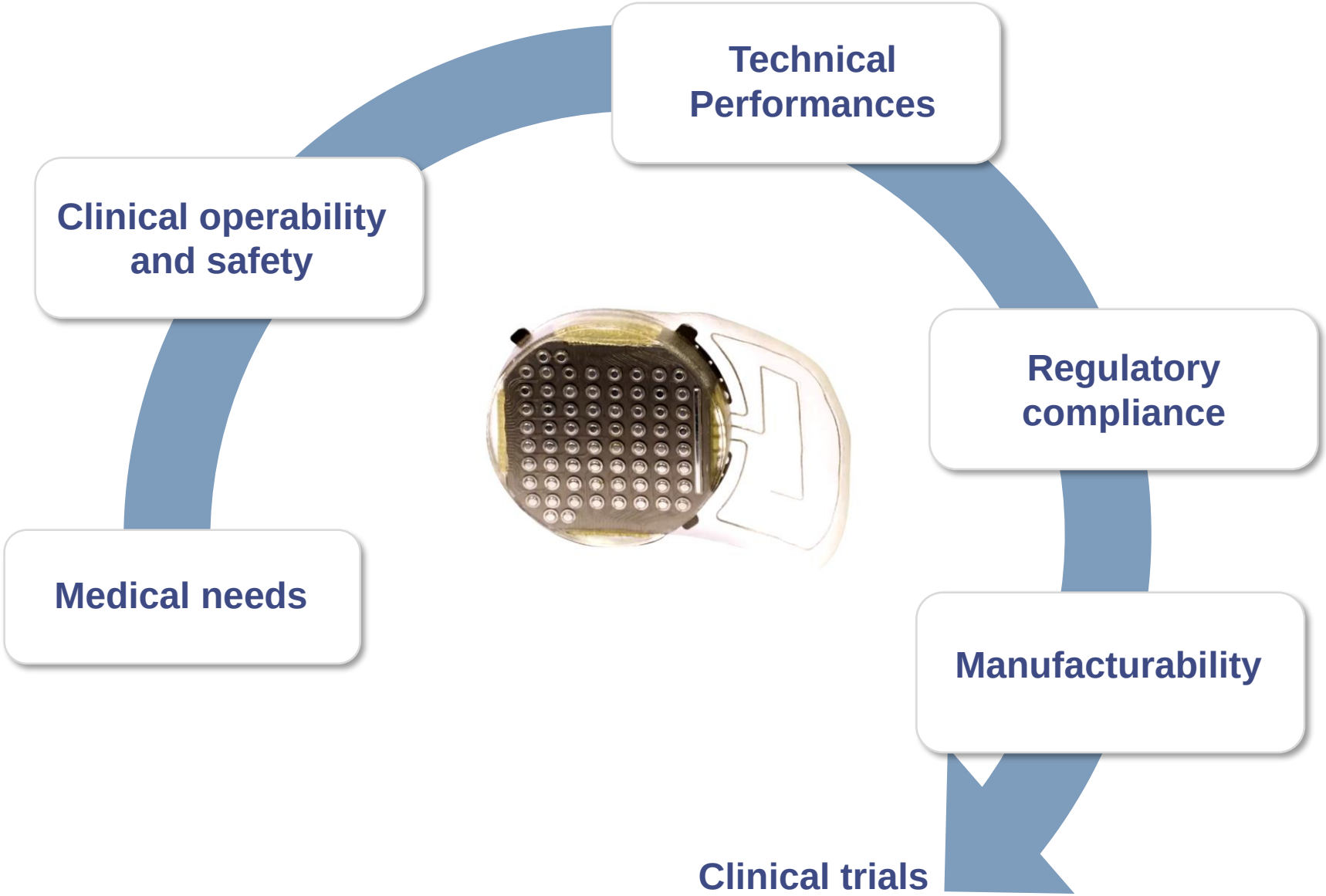
Manufacturing and Normative qualification according to European medical directives

Compliant to Medical Devices Regulation (EU) 2017/745

- **ISO 45502-1 :** Implant mechanical and electrical tests
- **ISO 60601-1 :** electrical security tests for external unit
- **ISO 10993** : long-term biocompatibility evaluation
- **IEC 62304** medical device software life cycle process

ISO 13485 manufacturing process
using a network of subcontractors

Design trade-off of our fully implantable system



Implanted participants with BCI WIMAGINE technology

BCI and tetraplegia
NCT02550522

2 implanted participants
in 2017 and 2019

THE LANCET Neurology

Benabid A. L. et al., 2019

STIMO-BSI & Think2Go
NCT04632290 & NCT06243952

2 implanted participants
in 2021 and 2024

nature

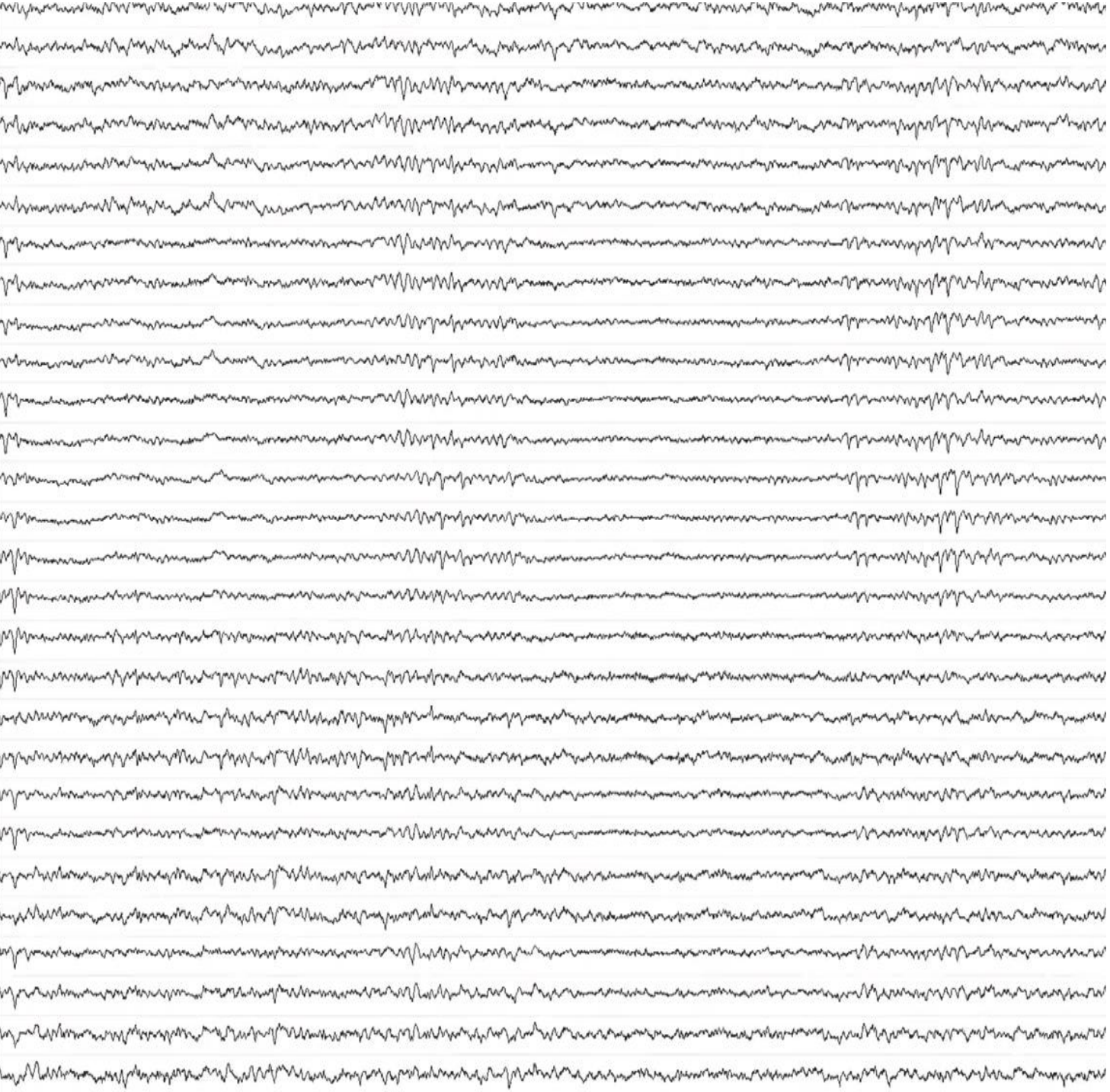
Lorach H. et al., 2023

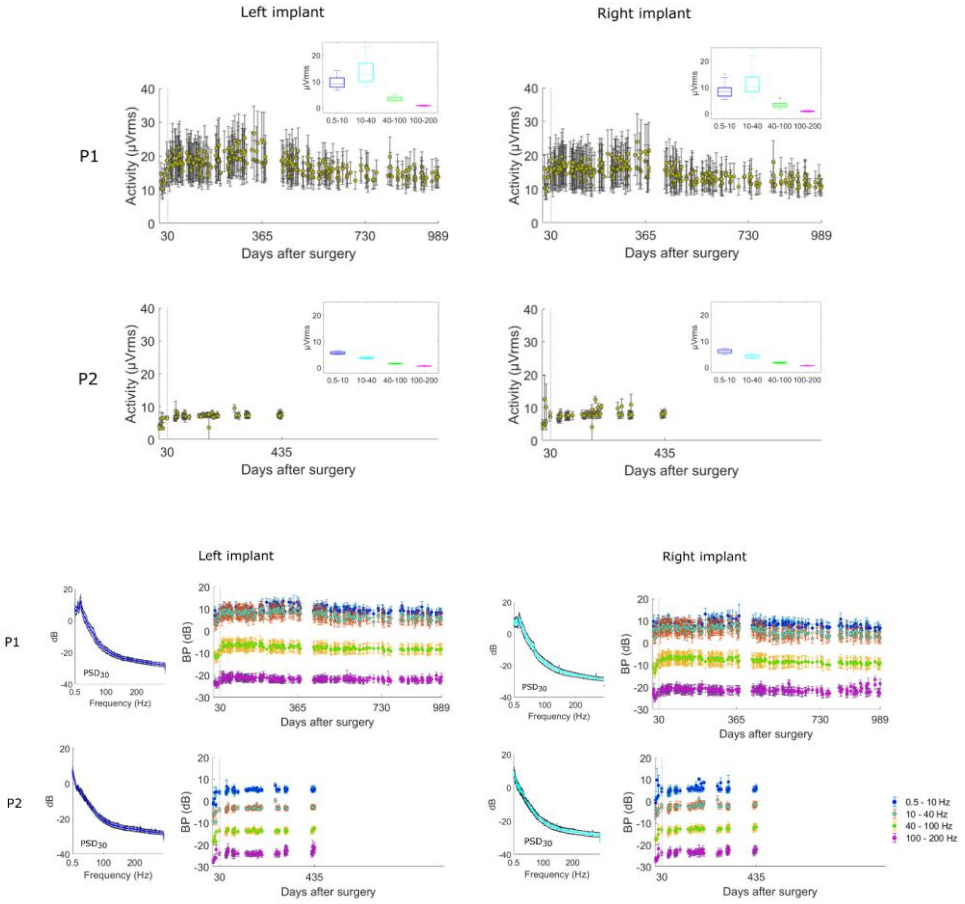
UP2
NCT05665998

2 implanted participants
in 2023 and 2025

Not published yet, in preparation

Stability of the WIMAGINE ECoG signal over 3 years on human





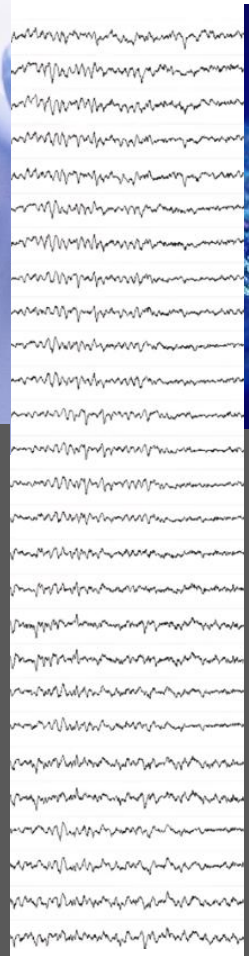
3 years stability published in:
Larzabal C. et al. Journal of Neural Engineering, 2021

WIMAGINE-BCI : current research

WIMAGINE® IMPLANT

- Chronic ECoG recording on 64 channels
- Wireless transmission
- Remote power supply
- AIMD class III regulatory compliance for long-term clinical applications

Mestais et al. 2014 *IEEE transactions on neural systems and rehabilitation engineering.*



BRAIN SIGNAL DECODER

Artificial Intelligence methods

- High dimensional decoding (multi-limb)
- Real time adaptive learning of models
- Stability and Robustness over time

Eliseyev A. et al. PLOS ONE, 2016
Benabid, A. L. et al. The Lancet Neurology 2019
Eliseyev, A., et al. 2017. Scientific reports
Moly, A., et al. 2022 J. Neural Eng.

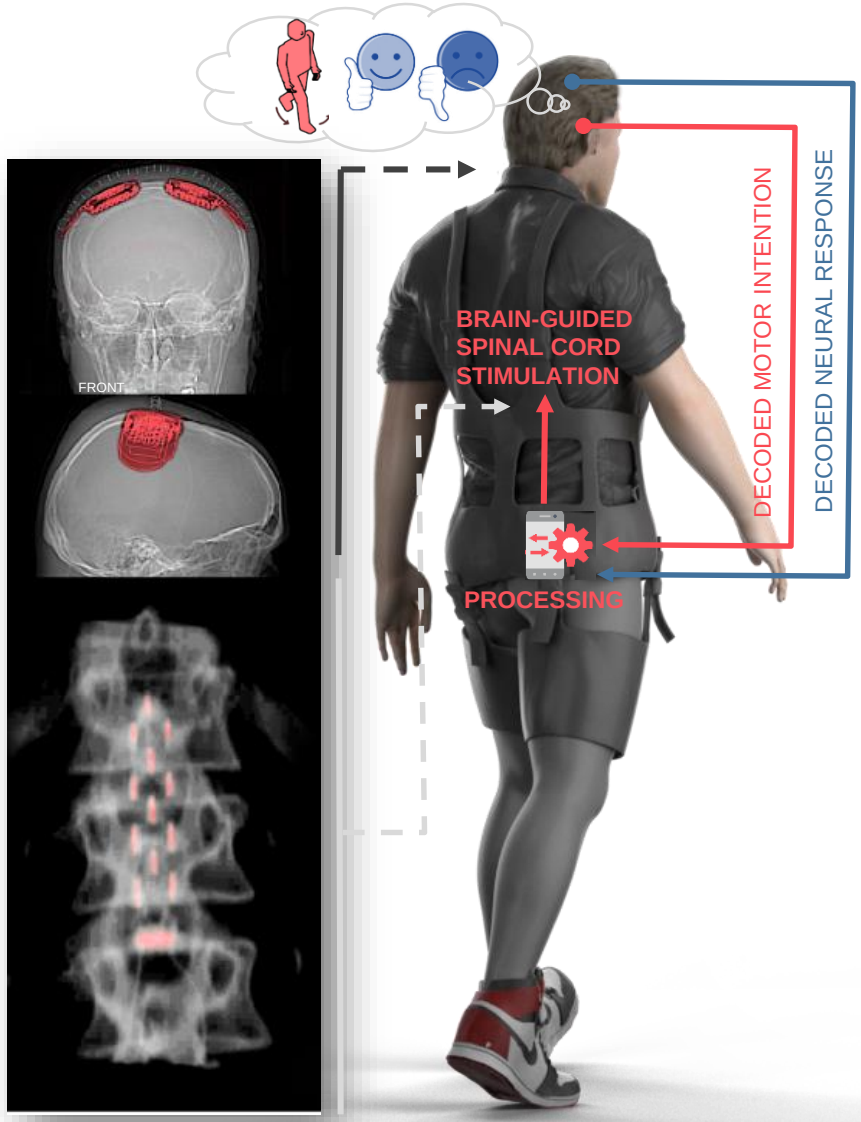
nemo

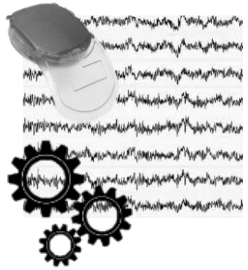
A portfolio of 25 patents on the WIMAGINE-BCI technology

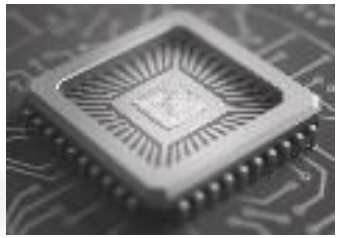
Auto-adaptive NEuroMOrphic Brain-Machine Interface: toward fully-embedded neuroprosthetics from 10/23 to 03/26)

EIC Pathfinder

European Innovation Council







Self-adaptive decoding of motor intentions

Improving BCI algorithms to reduce the need for supervised learning for motor intention decoding model calibration

Brain-guided spinal cord stimulation

Improving the search for the best parameters for electrical stimulation of the spinal cord

Miniaturization of BMI technology

Optimize decoding algorithms to reduce power. Porting to a portable platform & designing an integrated circuit dedicated to decoding

https://nemo-bmi.net/

NEMO-BMI : Frugality, portability of the brain-machine interface system ➔ Algorithm optimization and integrated circuit design

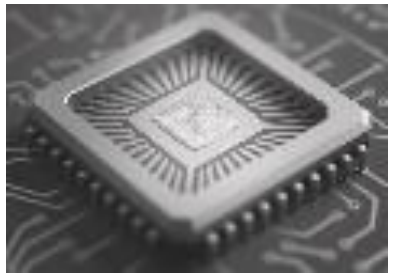
CEA algorithms used in clinical trials on Windows Tablet, powerful surface

Optimizations and port to Raspberry PI board

Integrated circuit for motor decoding

FDSOI technology (GF22FDX)

Windows surface Tablet



CEA granted ONWARD medical with a license on the BCI WIMAGINE technology toward a ARC-BCI therapy (October 2024)

Technology transfer
to industry is essential
to bring
innovations to patients

https://www.onwd.com/brain-computer-interface/

CEA-Leti, Grenoble, France

cea-leti.com

Email: fabien.sauter@cea.fr

T. + 33 (0)4 38 78 06 21

Supported by Defitech Foundation, Rolex Award for Enterprise, International Foundation for Research in Paraplegia, Translational Medical Research Award 2021 from the Leenaards Foundation, Pictet Group Charitable Foundation, ONWARD medical, Medtronic, the Swiss National Science Foundation through the National Centre of Competence in Research in Robotics, Sinergia, the Lead Agency Program with the French National Research Agency, A F Harvey Prize award, Swiss Innovation Agency InnoSuisse, Eurostars, the European Commission, ETH domain PHRT, Fonds de dotation and Institut Carnot Leti.