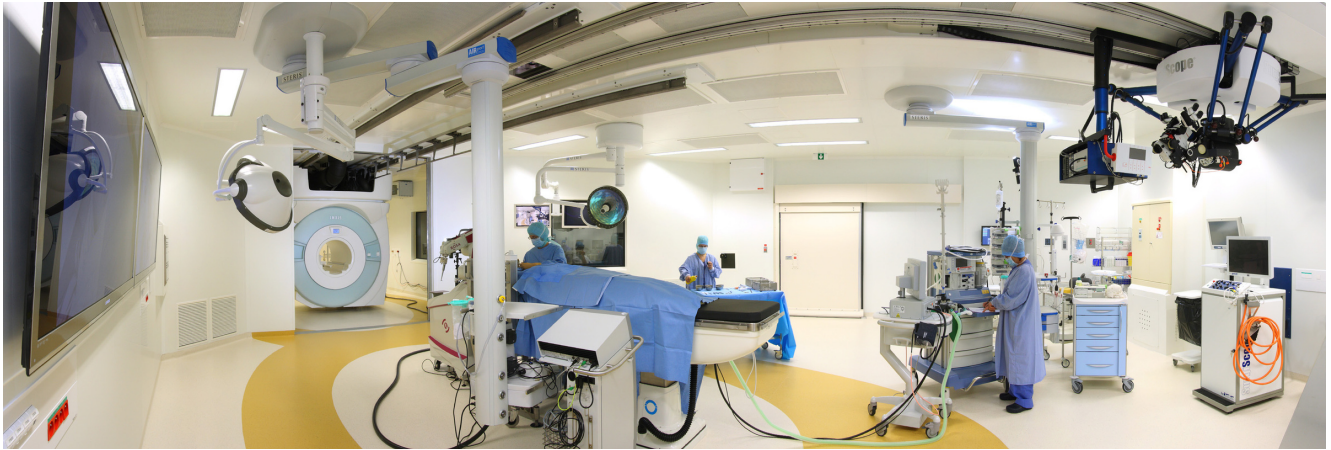


TESTING OF INNOVATIVE MEDICAL DEVICES

Operating room and its equipment



Testing of innovative medical devices dedicated to the operating room in real or realistic environment and/or evaluation of their MRI compatibility

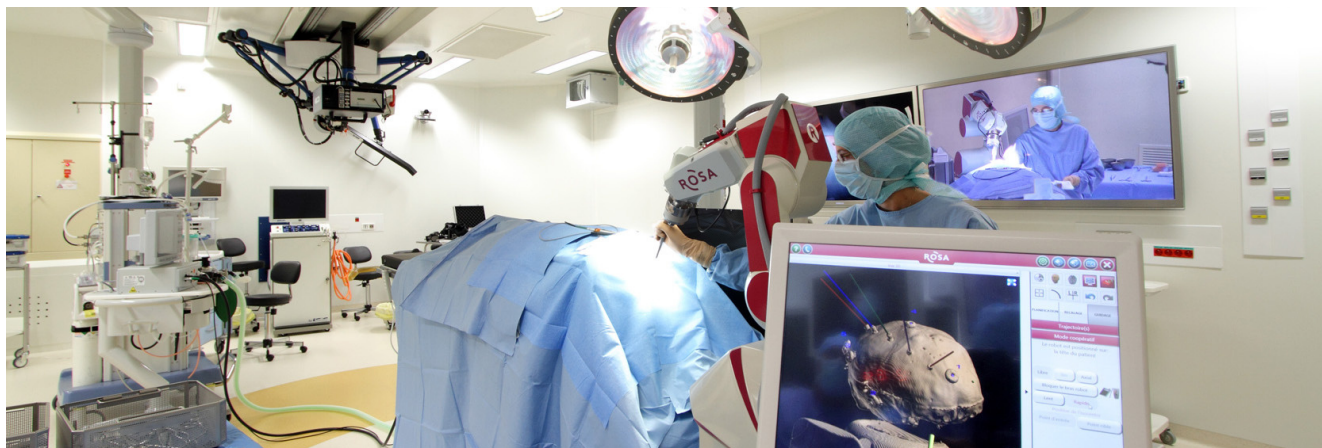
Acquisition & Technical features

- Operating room (surgical and anesthetic equipment MRI-compatible)
- Equipped with:
 - Neuro navigation robotic system ROSA
 - Intraoperative 1,5T MRI (Espree, Siemens): positioned on a rail to go into the operating room during surgery
 - Mobile X-ray unit (General Electric)
 - Stereotaxis interventional radiography chain (Apelem)
 - Robot for microscope-assisted neurosurgery
- 6 hospitalisation rooms
- MRI acquisitions: anatomy or fMRI with audio, visual and sensitive stimulation equipment

A modular service offering

- Provision of infrastructure "on a rental basis":
 - For usability/technical testing and evaluation of medical devices without patients
 - For MRI compatibility evaluation of medical devices
 - Access to dedicated workstation
- Be a clinical study site in the case of a multicenter clinical study
- Conduct a full interventional clinical study
 - See below: clinical and regulatory support
 - Access to Grenoble Hospital's network of clinicians
 - Ethical and societal reflection at the service of patients

Operating room and its equipment



Clinical and regulatory support

Complementary & Optional services

- Assistance with the design of regulatory files and clinical study projects:
 - Assistance with medical writing: Creation and provision of essential study-specific documents
 - Assistance in completing study documents
- Assistance with regulatory submissions in compliance with applicable laws and requirements
- Patients enrolment
- Clinical study follow-up and monitoring
- Support for scientific dissemination/publication

Studies in progress or completed

- **Deep Brain Stimulation-related studies:**
 - **Obsessive Compulsive Disorders:**
 - Study EQOLOC : NCT02844049
 - Study LFP-DBS: NCT03874611
 - **Tinnitus:**
 - Study TINNOP3 : NCT04296097
 - **Parkinson disease:**
 - Study SIV-2 : NCT02402569
- **Photobiomodulation – Parkinson disease:**
 - Study Ev-NIRT: NCT04261569
- **Brain Computer Interface – neuroprosthetic control of a motorized exoskeleton**
 - BCI : NCT02550522 ; Benabid et al



TO DEVELOP YOUR PROJECT

Madjid HIHI
Abdelmadjid.HIHI@cea.fr
04 38 78 96 58

Léa GUERBER
lea.guerber@cea.fr
04 38 78 17 11



MEG

Magnetoencephalography



Functional neuroimaging technique for mapping brain activity in real-time by recording magnetic fields induced by brain's electrical activity

Acquisition & Technical features

- 204 gradiometers, 102 magnetometers & 128 EEG channels
- Audio, visual and sensitive stimulation equipment
- Equipment for recording subjects' responses
- Dedicated HPC workstation for real-time signal processing
- Combined MRI acquisitions (anatomy/fMRI)
- Coming soon: Optically pumped magnetometers (OPM)

A modular service offering

- Provision of equipment and infrastructure "on a rental basis":
 - With dedicated workstation and data-storage for daily-use analysis
- Complete or collaborative data acquisition with our MEG experts
- Complete or collaborative analysis of acquired data:
 - Elekta-embedded software for pre-process and quality control
 - MatLab/Brainstorm, Field Trip, MNE available
 - Access to a 1000+ processors cluster for heavy calculations
- Complete clinical evaluation of the medical device

MEG

Magnetoencephalography



Clinical and regulatory support

Complementary & Optional services

- Assistance with research of funding
- Assistance with the design of regulatory files and clinical study projects:
 - Assistance with medical writing: Creation and provision of essential study-specific documents
 - Assistance in completing study documents
- Assistance with regulatory submissions in compliance with applicable laws and requirements
- Communication and interaction with the sponsor
- Patients enrolment
- Clinical study follow-up including vigilance and monitoring
- Support for scientific dissemination/publication

Studies in progress or completed

- **Development of the clinical research protocols**
 - Prelude: NCT05698810
- **Hypnotic trance:** cerebral signal study
 - HYPNOTE study : NCT04020731
- **Deep Brain Stimulation-related studies:** MEG/LFP simultaneous recordings using DBS electrodes ; MEG measurements during active DBS and concurrent LFP/MEG calculation
 - **Obsessive Compulsive Disorders:**
 - EQOLOC : NCT02844049
 - LFP-DBS: NCT03874611
 - **Tinnitus:**
 - TINNOP3 : NCT04296097
- **Pain management:** exploratory study in collaboration with industrial partner – localisation/study of specific brain areas:
 - RESOM : NCT04801550
- **Motor cortex area mapping and real-time avatar control** – for medical device optimal positioning and development/validation of BCI algorithms:
 - TAPFINGER : NCT02574026
 - BCI : NCT02550522 ; Benabid et al
 - BSI : NCT04632290 ; Lorach et al



TO DEVELOP YOUR PROJECT

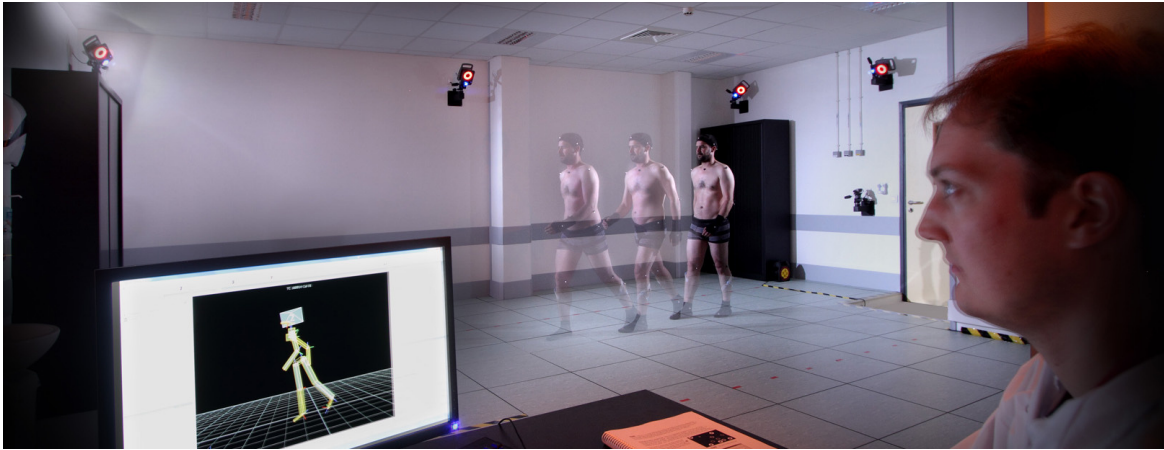
Madjid HIHI
Abdelmadjid.HIHI@cea.fr
04 38 78 96 58

Léa GUERBER
lea.guerber@cea.fr
04 38 78 17 11



A ROOM DEDICATED TO THE PRECISE ANALYSIS OF PATIENTS

Motion Analysis Laboratory



A room dedicated to the precise analysis of patients' or robots' movements in space, for the purposes of technological development or clinical trials (e.g. GAIT studies for Parkinson's patients)

Acquisition & Technical features

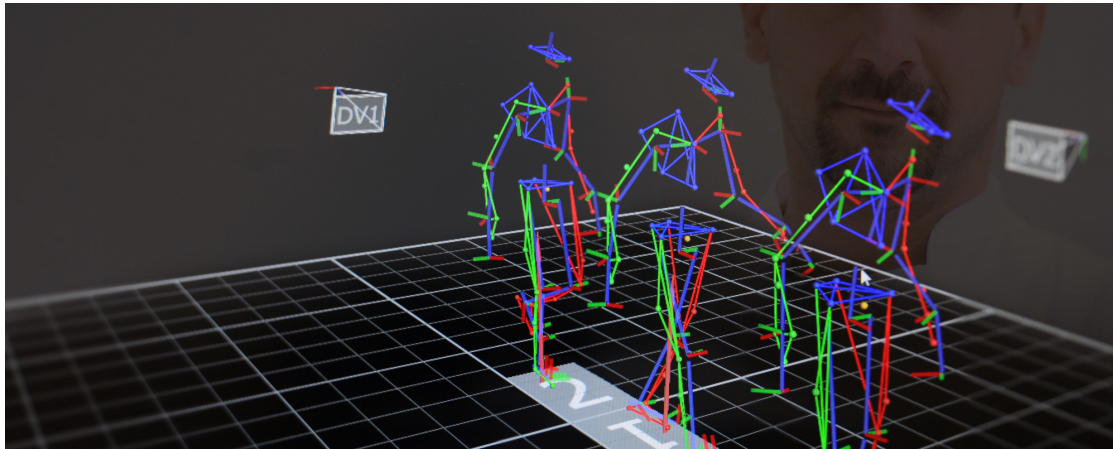
- 8 infrared cameras, 2 high-resolution cameras, 2 plantar pressure sensors
- Wireless pressure sensors and non-invasive electromyographic sensors (system Cometa)
- 3D movement analysis system: full body motion analysis, definition of an anatomical model, motion sequence with an exoskeleton, movement tracking of robotics
- Coming soon: GAITrite system (walk analysis)

A modular service offering

- Provision of equipment and infrastructure "on a rental basis"
 - With dedicated workstation and data-storage for daily-use analysis
- Complete or collaborative data acquisition with our experts
- Complete or collaborative analysis of acquired data:
 - Vicon Motion-embedded software for pre-process and quality control
 - Polygon software for specified motion analysis

A ROOM DEDICATED TO THE PRECISE ANALYSIS OF PATIENTS

Motion Analysis Laboratory



Clinical and regulatory support

Complementary & Optional services

- Assistance with research of funding
- Assistance with the design of regulatory files and clinical study projects:
 - Assistance with medical writing: Creation and provision of essential study-specific documents
 - Assistance in completing study documents
- Assistance with regulatory submissions in compliance with applicable laws and requirements
- Communication and interaction with the sponsor
- Patients enrolment
- Clinical study follow-up including vigilance and monitoring
- Support for scientific dissemination/publication

Studies in progress or completed

- **Development of the clinical research protocols**
- Study Prelude: NCT05698810
- **GAIT analysis**
 - Parkinson disease:
 - study Ev-NIRT: NCT04261569
 - SIV-2 : NCT02402569
- **Motion sequence evaluation with an exoskeleton:**
 - Tetraplegic patients with BCI : NCT02550522 ; Benabid et al



TO DEVELOP YOUR PROJECT

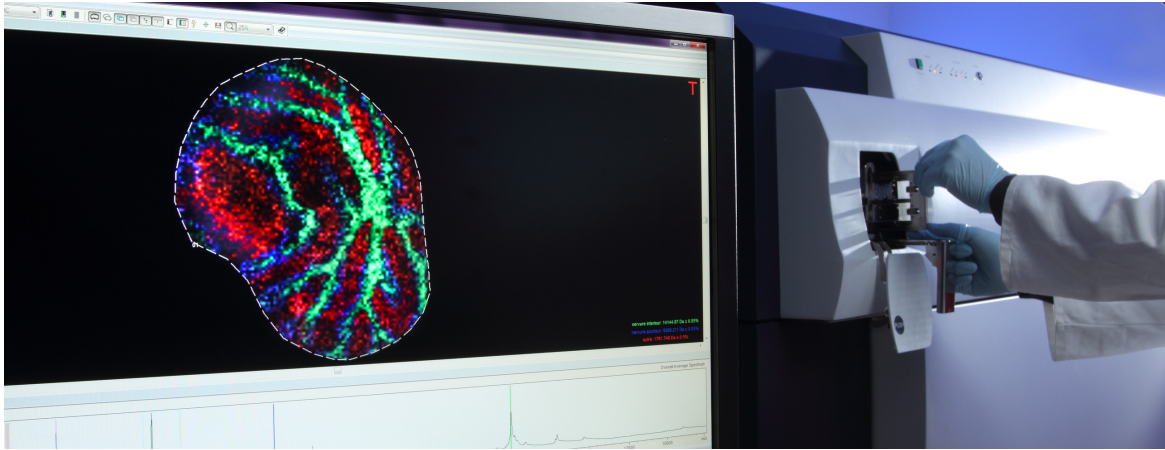
Madjid HIHI
Abdelmadjid.HIHI@cea.fr
04 38 78 96 58

Léa GUERBER
lea.guerber@cea.fr
04 38 78 17 11



MALDI : MATRIX ASSISTED LASER DESORPTION IONISATION

Mass spectrometry platform



Analytical technique by ionisation to detect multiplex spatial distribution of molecular species in biological tissue or in complex biological samples

Description

- Rapid and sensitive biotyping of tissues and cells
- Molecular anatomopathology for diagnostic and prognostic
- Wide range of molecules/particles detectable

Platform & Technical features

- Bruker MALDI Ultraflextreme III
- HTX imagingsprayer
- Leica CM3050 S Cryostat2
- Analysis options: Ex vivo Imaging or Profiling
- Analysis time frame: low spectrum density (1 hour) vs. high spectrum density (15hours)

Mass spectrometry platform



A modular service offering

- 1st feasibility study to set up & to optimise the research protocol
- Sample conservation (-20°C / -80°C) and storage
- Full sample preparation with our experts:
 - Cryostat cutting of unfixed, fresh-frozen tissue
 - Matrix deposition with HTX and drying
 - Staining of sections and acquisition of visible microscopy images
- Full sample analysis using Fleximaging & Flexcontrol
- Full or collaborative data analysis with provision of a final report

Studies in progress or completed

- Ex vivo imaging studies:
 - Multiplex detection of neurotransmitters in mouse brain sections
 - Biomarker discovery, tissue-typing and tumor heterogeneity analysis
 - Quantification of bioactive compounds and nanoparticles in skin biopsies
 - European project REFINE: Biodistribution of biomarkers in the kidney or liver
- Profiling studies
- Types of tissue studied: brain, skin, liver, kidney, pituitary adenomas, etc.
- Elements detected with MALDI: small proteins and peptides, lipids, nanoparticles.



TO DEVELOP YOUR PROJECT

Madjid HIHI
Abdelmadjid.HIHI@cea.fr
04 38 78 96 58

Léa GUERBER
lea.guerber@cea.fr
04 38 78 17 11

