Portable magnetocardiography device for the diagnosis of functionally relevant coronary artery disease and other CVDs

Tackling the leading cause of death.

QUardiOPM

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Innosuisse – Swiss Innovation Agency

Swiss Heart Foundation
Fighting against Heart Disease and Stroke

Kanton Bern
Canton de Berne

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University of Applied Sciences NW Switzerland (FHNW)
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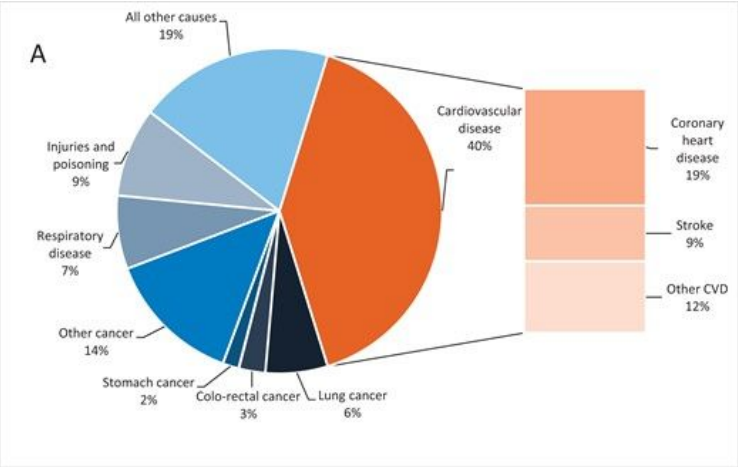
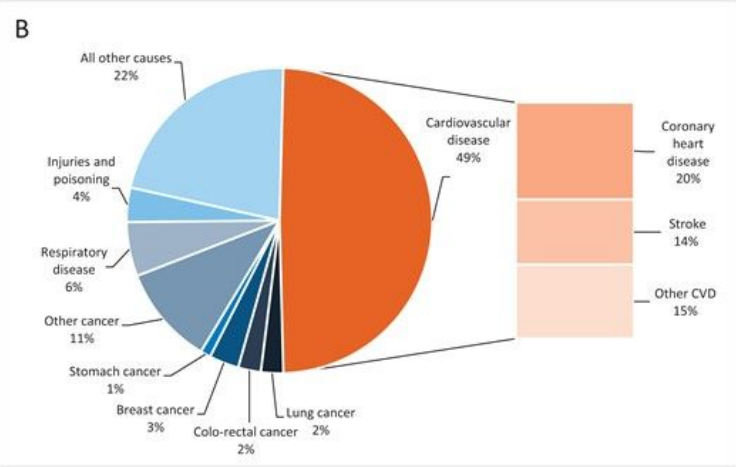
Coronary artery disease (CAD) is the leading cause of death worldwide

Men



Women

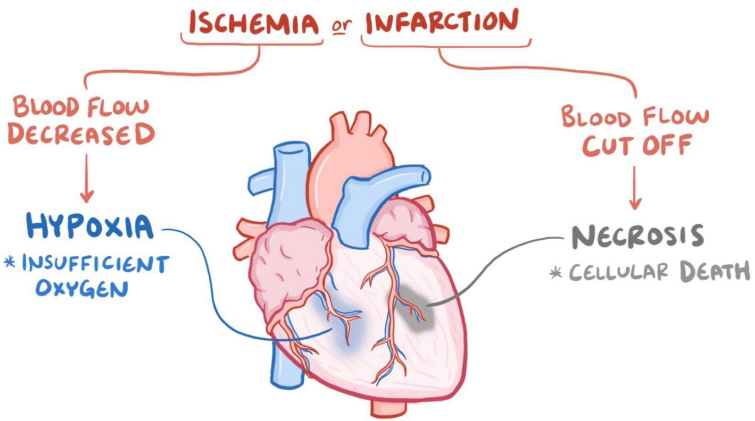


Note: no data available for Andorra.
Source: WHO Mortality Database.

Townsend N. Cardiovascular disease in Europe: epidemiological update 2016. Eur Heart J. 2016;37:3232-3245

Coronary artery disease (CAD) is the leading cause of death worldwide

The manifestation of CAD can remain asymptomatic for long periods or become functionally relevant (fCAD) by causing symptoms of myocardial ischaemia. **Importance of early diagnosis.**



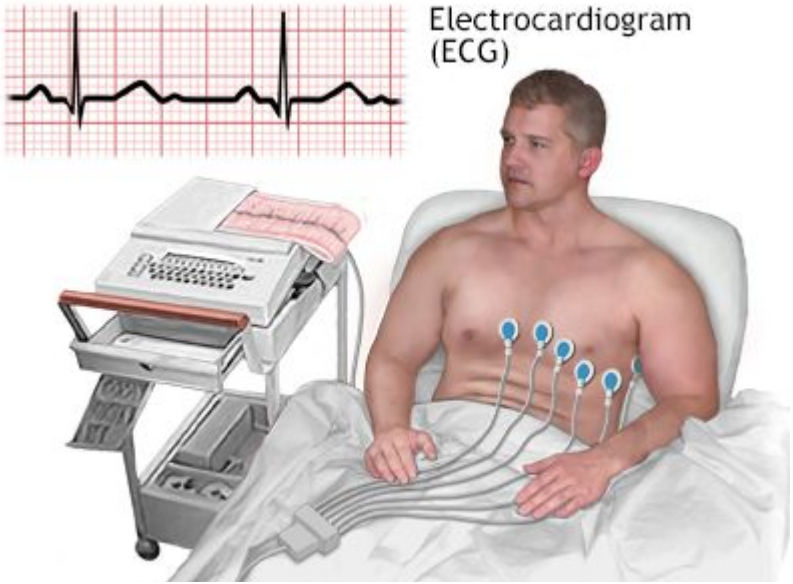
Importance of early diagnosis

At present, diagnosis of fCAD relies primarily on clinical judgment and cardiac stress imaging. While these imaging methods are helpful in the diagnosis of many patients, they are being used unnecessarily in patients with a very low probability of fCAD and expose them to radiation and radiocontrast. **The associated annual cost exceeds $1 billion in the United States alone.**

Beyond CAD prevention, the cost of cardiovascular disease is massive:

- **1.79 Million deaths each year to cardiovascular diseases;**
- **$230 Billion USD annual cost of heart diseases in the U.S. alone;**
- **$3 Billion USD annual cost of evaluating suspected heart attacks.**

Importance of early diagnosis



ECG use is discouraged according to current clinical practice guidelines due to low diagnostic accuracy, as well as unacceptable false negative and positive rates.

Importance of early diagnosis

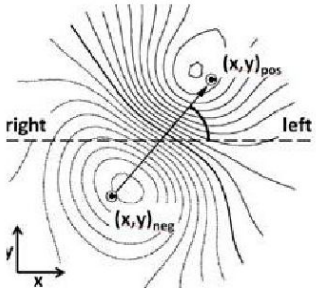
ECG is the predominant tool for cardiac assessment but has limitations in sensitivity and specificity for diagnosing CAD. It limits early detection algorithms to function properly (e.g. BSP Medical).

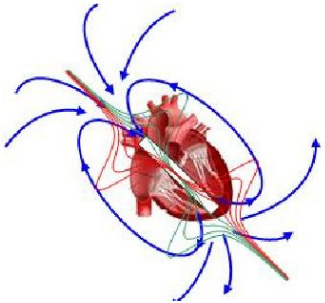
MCG is a non-invasive method that records biomagnetic signals generated by the heart's electrical activity.
Recent research demonstrates MCG's diagnostic capability superior to ECG in detecting myocardial ischemia or CAD.

Importance of early diagnosis

Advancements in sensor technology pave the way for affordable, **compact, and portable MCG devices for unshielded clinical applications**, with potential integration at the IoT edge level with existing state-of-the heart ECG devices, e.g. from market leader Schiller AG.

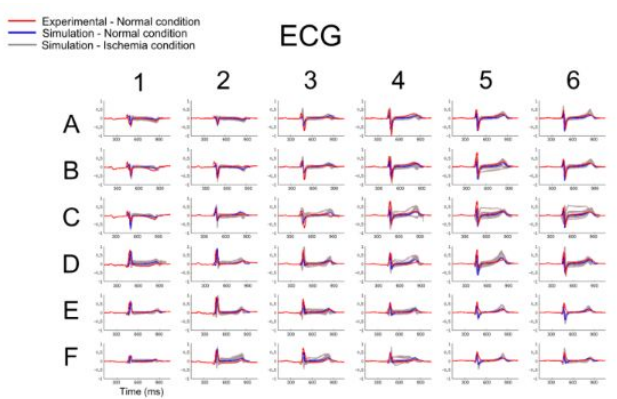
Magnetocardiography (MCG) for fCAD diagnosis





Due to the constant permeability of the human body, **the magnetic fields are hardly influenced**, making the detection of biological phenomena more reliable compared to ECG. In addition, the MCG is **more sensitive to heart surface tangential currents.**

Magnetocardiography (MCG) for fCAD diagnosis



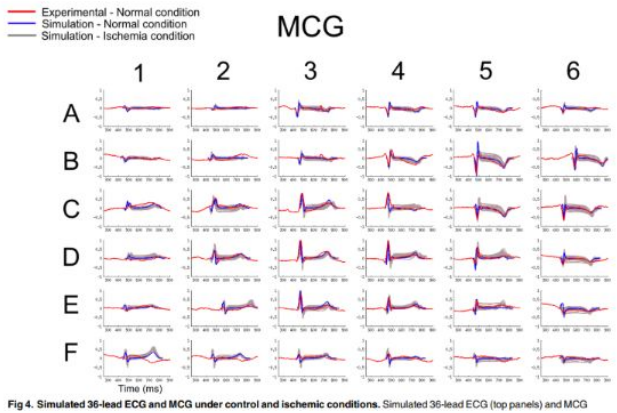
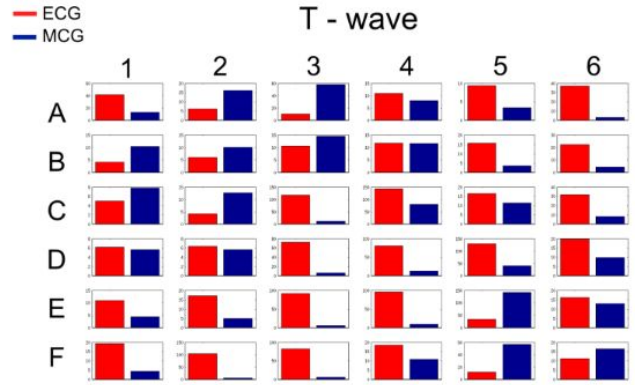


Fig 4. Simulated 36-lead ECG and MCG under control and ischemic conditions. Simulated 36-lead ECG (top panels) and MCG



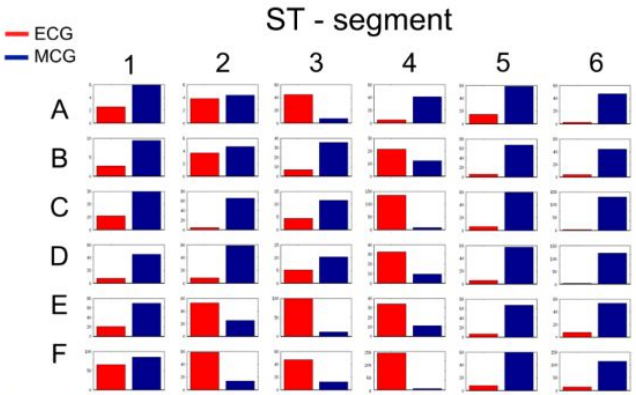


Fig 6. Relative differences of each of the 36-leads ECG and MCG between ischemic and control conditions. Computed relative differences for each

Comparison of Electric- and Magnetic-Cardiograms Produced by Myocardial Ischemia in Models of the Human Ventricle and Torso. PLoS ONE 11(8) (2016)

Magnetocardiography (MCG) for fCAD diagnosis

MCG could reduce hospital patient load and improve CAD prevention on a broad scale.

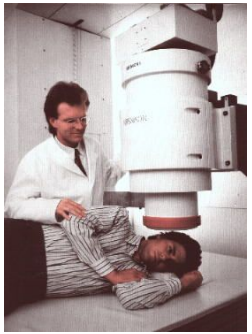
Magnetocardiography (MCG) for fCAD diagnosis

MCG could reduce hospital patient load and improve CAD prevention on a broad scale.

Can we develop a non-invasive MCG sensor integrated into a device and to derive and validate an algorithm to assign patients with suspected exercise-induced myocardial ischemia?

Previously…

a



Not scalable device

b

Cryogenics

c

Bulky magnetic shielding

Extremely weak magnetic field maps (below 100 pT) have to be measured on the patient's body surface…

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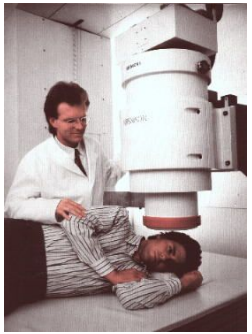
Previously…

a



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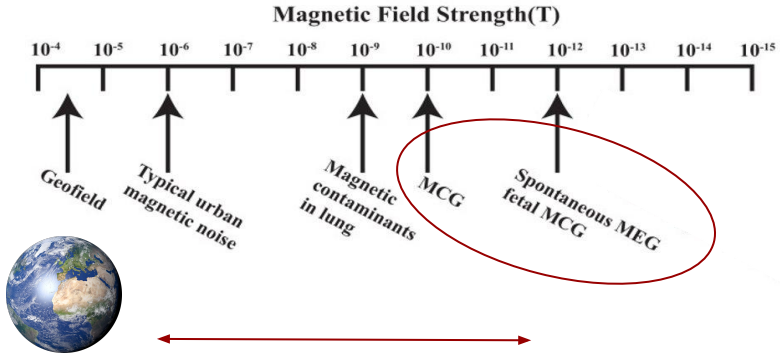

>7 orders of magnitudes

Wakai R.T. The atomic magnetometer: A new era in biomagnetism. AIP Conf. Proc. 2014;1626:46–54. doi: 10.1063/1.4901359.

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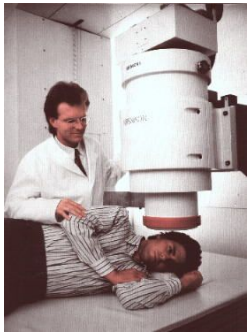
Previously…

a



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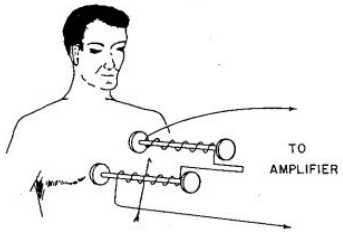
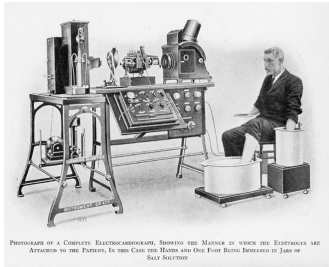


Baule and McFee, 1963…



**First ECG*

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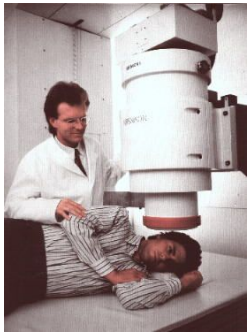
Previously…

a



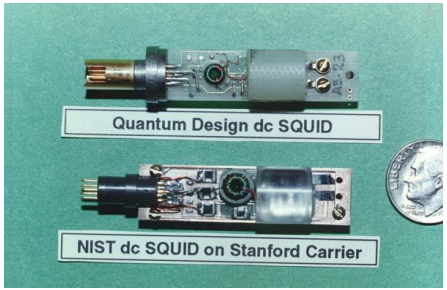
Not scalable device

b

Cryogenics

c

Bulky magnetic shielding



SQUIDs since the 70s

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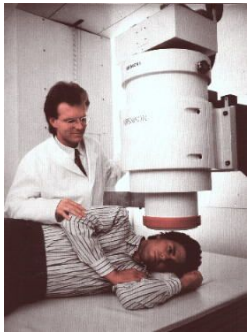
Previously…

a



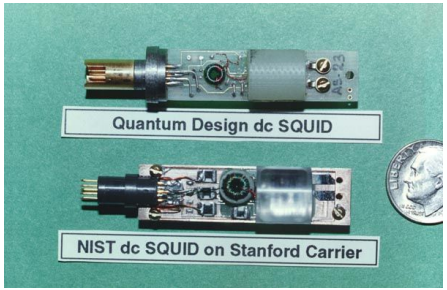
Not scalable device

b

Cryogenics

c

Bulky magnetic shielding



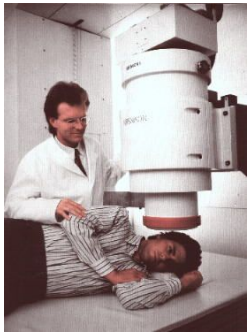
SQUIDs since the 70s

20-30 devices around the globe (US, Germany, Hong Kong, …)
$$$
Success: Fetal MCG

QUardiOPM

Previously…

a



Not scalable device

b

Cryogenics

c

Bulky magnetic shielding

SQUIDs since the 70s

20-30 devices around the globe (US, Germany, Hong Kong, …)
$$$
Success: Fetal MCG

…

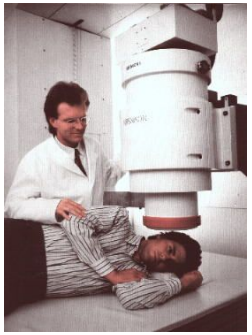
bmp

Genetesis

QUardiOPM

Previously…

a



Not scalable device

b

Cryogenics

c

Bulky magnetic shielding

Commercially available magnetometers range from inexpensive Hall probes to highly sensitive **fluxgate** and **atomic magnetometers** to high-precision **Superconducting Quantum Interference Device (SQUID)** and **Spin Exchange Relaxation Free (SERF) magnetometers**. These devices generally have limited dynamic range: the lower-performing devices operate comfortably in the background ambient field of the Earth, while the highest performing sensors only operate in highly shielded, expensive, special-purpose laboratory facilities.

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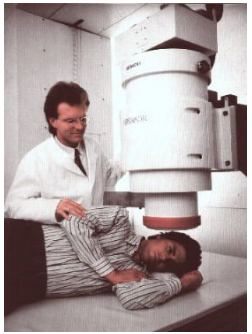
Previously…

a



Not scalable device

b

Cryogenics

c

Bulky magnetic shielding

DARPA

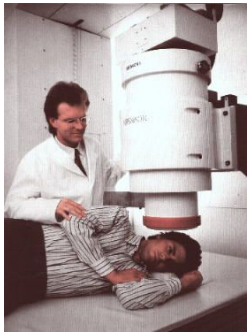
Unshielded since 2020s

…

QUardiOPM

Previously…

a



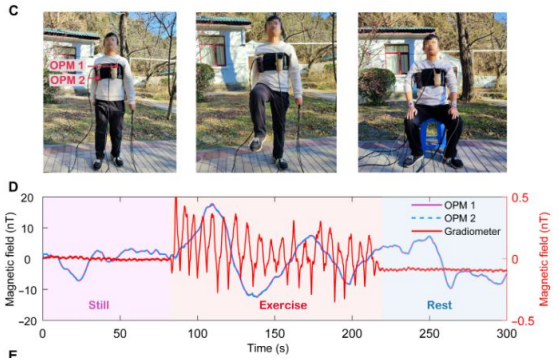
Not scalable device

b

Cryogenics

c

Bulky magnetic shielding



ScienceAdvances

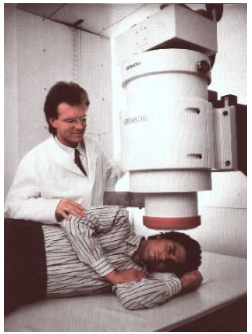
*state of the art (China, 2023): A movable unshielded magnetocardiography system
https://www.science.org/doi/10.1126/sciadv.adg1746

Unshielded since 2020s

QUardiOPM

Previously…

a



Not scalable device

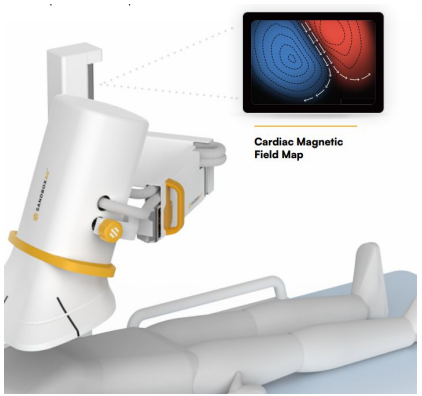
b

Cryogenics

c

Bulky magnetic shielding

SANDBOXAQ

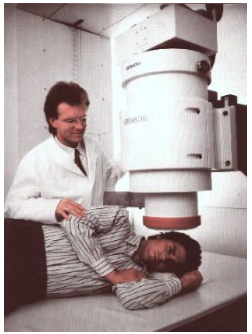


Unshielded since 2020s

QUardiOPM

Previously…

a



Not scalable device

b

Cryogenics

c

Bulky magnetic shielding

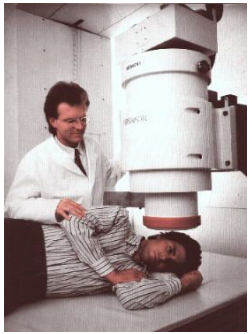
US (from defense) + China
Gap in EU/CH

Unshielded since 2020s

QUardiOPM

Previously…

a



Not scalable device

b

Cryogenics

c

Bulky magnetic shielding

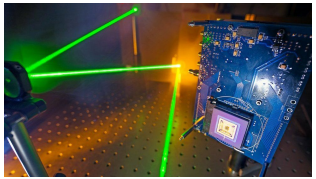
QUardiOPM

d

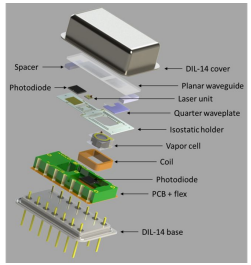
Portable and high-sensitivity for clinical use

*FDA
**mECG

QUardiOPM



Quantum sensing

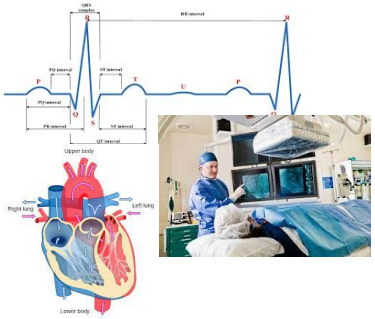


Engineering

csem

This project

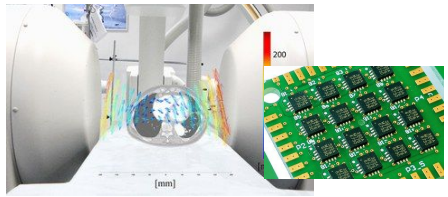
Cardiology
Sig. proc.



Universitätsspital Basel

INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HOPITAL UNIVERSITAIRE DE BERNE
BERN UNIVERSITY HOSPITAL

Magnetic medical sensing



Technology

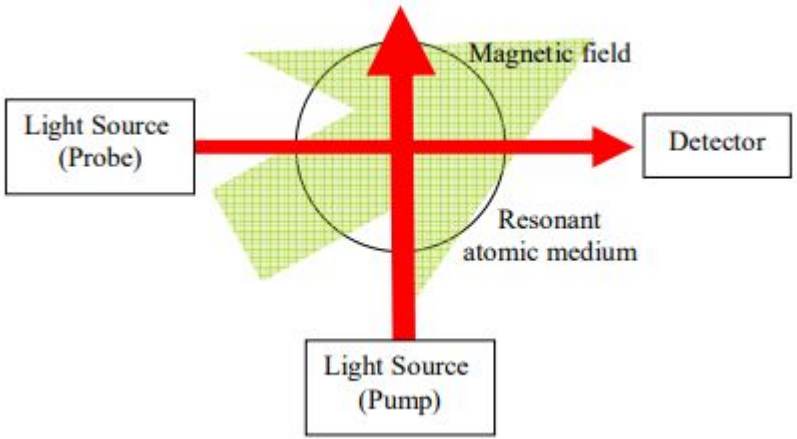
For this project, we leverage proprietary **Swiss technology blocks** mastered by the *research partners,* who also have track record in successful technology transfer to the market:

- quantum sensor development to optimise the technology for compact MCG;
- a unique building block to miniaturise such sensors;
- magnetic sensing expertise for medical devices to go from the lab to patient;
- signal processing for cardiology; data connectivity and compatibility with ECG;
- cardiology expertise to specify and clinically prove the approach.

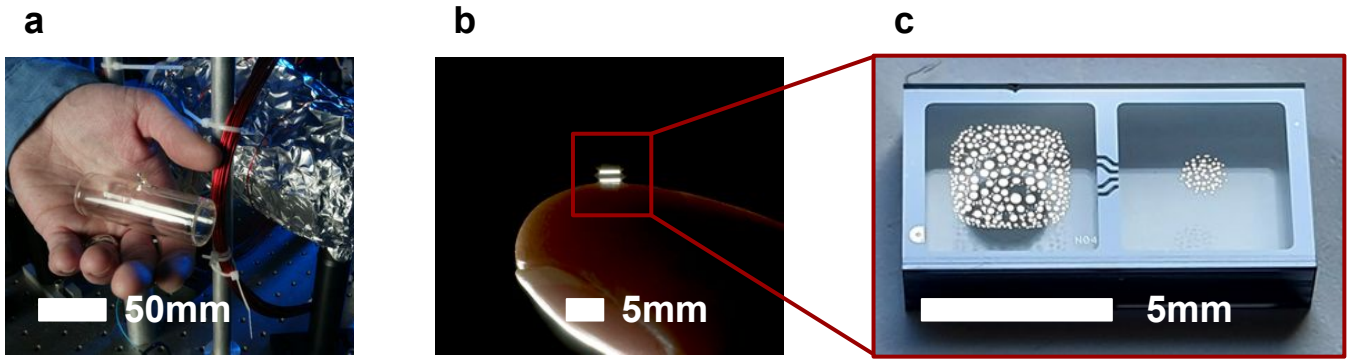
The technology is proven. We have all the blocks in our hands.
-> practical movable multichannel unshielded MCG system that nearly sets no limits to participants and brings another kind of insight into the medical diagnosis of heart disease.

Miniature optically-pumped magnetometers (OPM)

Magnetocardiography using compact **quantum sensors.**



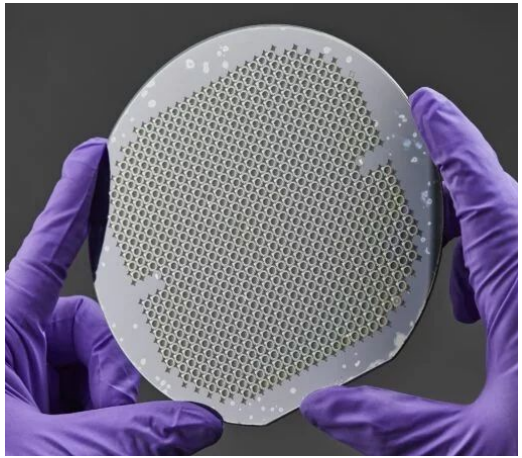
Miniature optically-pumped magnetometers (OPM)

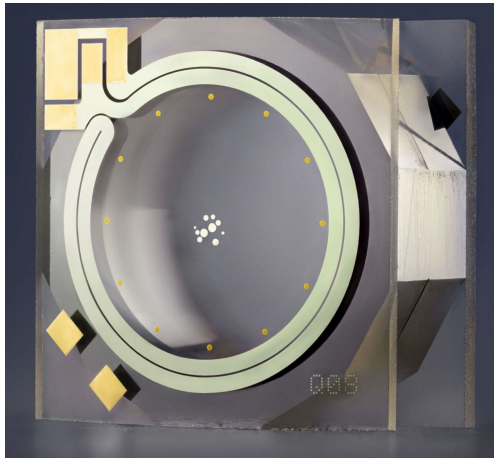


a. *Example of a standard glass blown atomic vapour cell, the length of which is in the 100mm range with a diameter of 25mm.* ***b.*** *Side view of a typical MEMS atomic vapour cell made by anodic bonding of a silicon core with two borosilicate glass windows. The cell thickness is below 2mm.* ***c.*** *Top view of an OPM-specific two-chambers MEMS atomic vapour cell developed in macQsimal. The filling chamber (left) is connected to the measuring chamber (right) by means of 4 microchannels. Droplets of alkali metal are clearly visible in both chambers.*

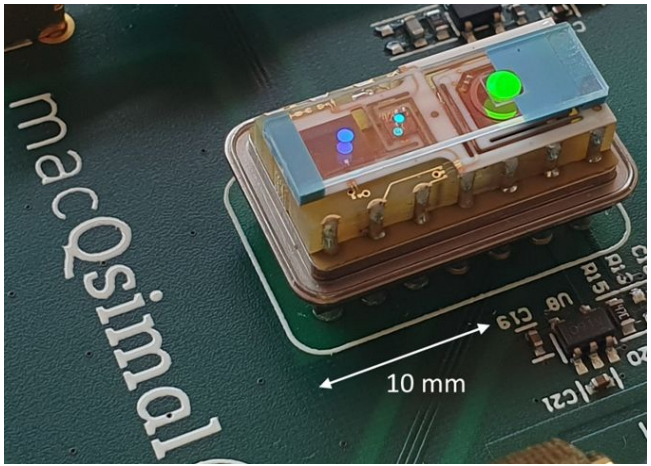
Miniature optically-pumped magnetometers (OPM)

csem





Miniature optically-pumped magnetometers (OPM)



Low-profile miniature atomic clock physics package developed in macQsimal and transferred to the industry.

Jacques Haesler

Sylvain Karlen

Miniature optically-pumped magnetometers (OPM)

= Miniature atomic clocks with precise timing. Example of successful tech transfer with this technology.

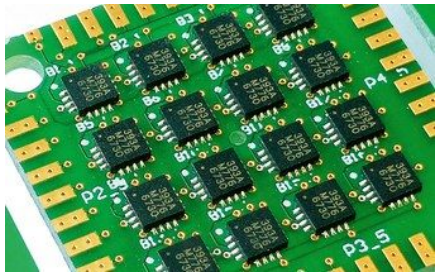
orolia

SAFRAN

Safran acquires Orolia and plans to become the world leader in resilient PNT

JULY 08, 2022 BUSINESS

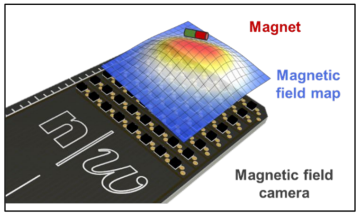
A multimodal sensing approach



Magnetic camera.
+ Accelero + gyro

Description	Isogauss surface 10 G	Bmax at 1 mm from the surface
Apple AirPods Pro case closed	z_{max} = 20 mm	B_{max} = 670 G
Apple iPhone 12 Pro Max	z_{max} = 21 mm	B_{max} = 370 G

In-house magnetic field camera



Which combines application specific OPM with other sensor types (miniaturized fluxgates, accelero + gyro) arranged in a 3D configuration called magnetic camera to allow to compensate for the background magnetic field generated by the environment. Besides, the OPM MCG ***sensors shall be arranged in a pair or triplet (gradiometer configuration) to extract the MCG signal from the background magnetic field.***

A multimodal sensing approach

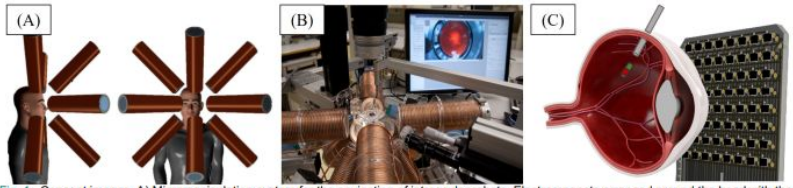


Fig. 1. Concept images. A) Micromanipulation system for the navigation of intraocular robots. Electromagnets arranged around the head with the patient's eyeball at the center. [7] B) OctoMag MMS. The system contains eight 210-mm-long by 62-mm-diameter electromagnets. [21] C) Navigation of the robot to the posterior part of the eye. MFC placed in front of the eyeball to track the robot.

Joris

Pascal

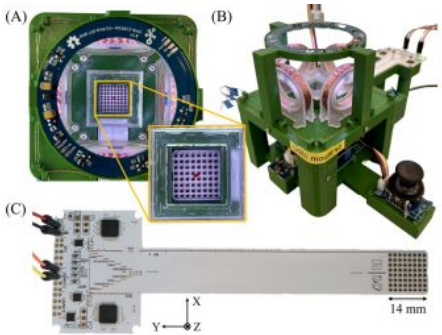


Fig. 3. Experimental setup: (A) Top view of the platform integrating the air-core coils to steer the millirobot (in red), the MFC and the LED lighting. (B) Oblique view of the platform with the joystick controlling the activation of the coils. (C) MFC with a sensing area of 14 mm x 14 mm and a pitch of 2 mm between the sensor chips.

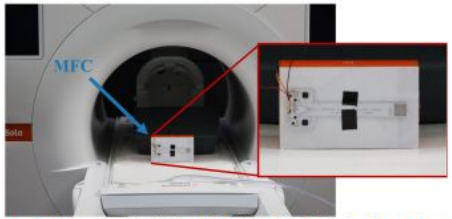
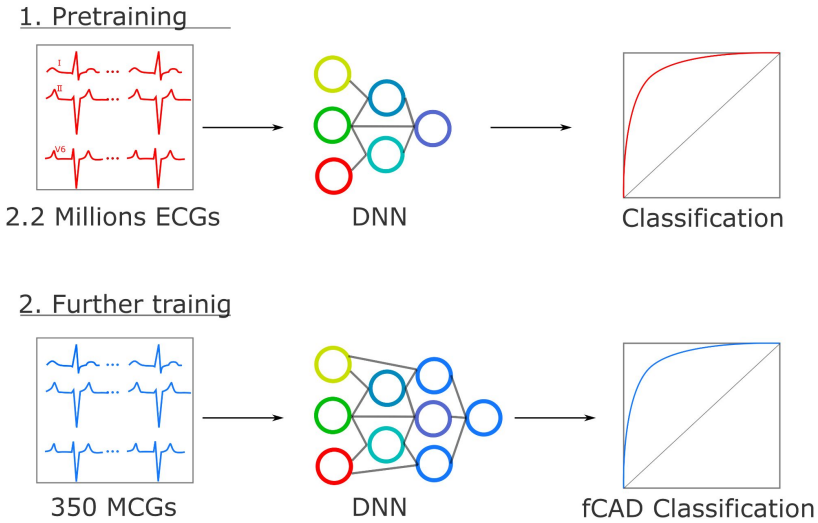


Fig. 7. MFC placed inside the 1.5 T MRI with the Z-axis aligned along the static field

Algorithms and clinical proof for CAD prevention



Pre-trained deep neural network (DNN) will be vertically expanded and further trained on magnetocardiograms (MCGs) to diagnose functionally relevant coronary artery disease (fCAD).

Universitätsspital Basel

Ivo Strebel

Christian Müller

Requirements, applications and clinical proof

\+ partners

QUardiOPM

Development of a novel, portable, and cost-effective MCG system that can be used for clinical applications.

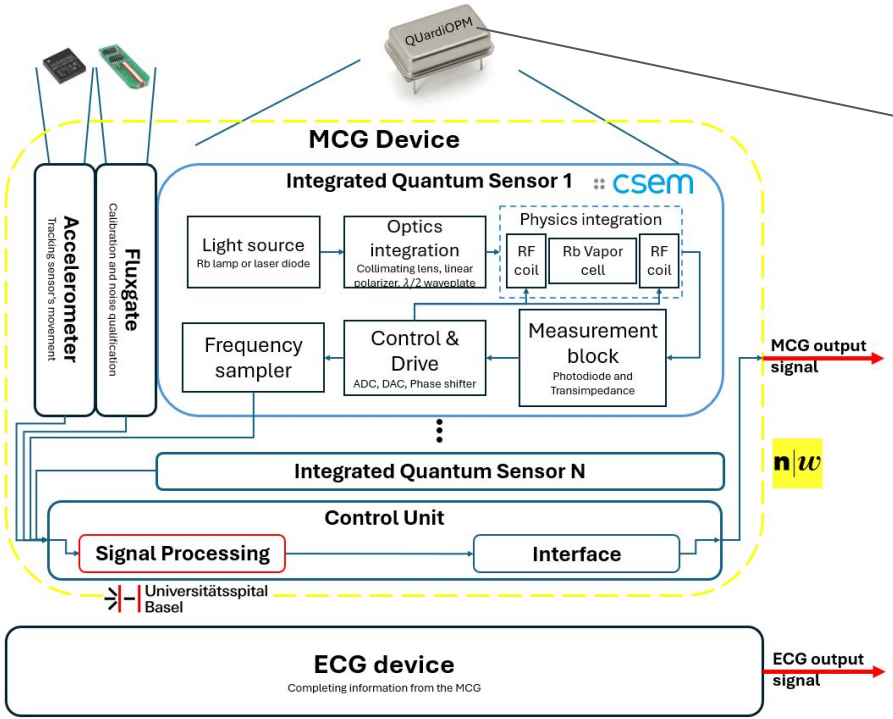
Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

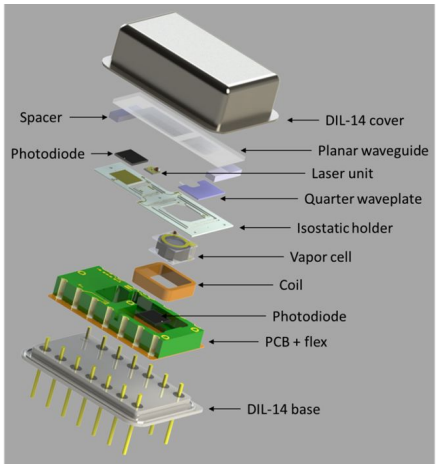
Swiss Confederation

Innosuisse – Swiss Innovation Agency

Portable and high-sensitivity for clinical use

QUardiOPM - system architecture





***Right**: Engineering model exploded-view of the physics package.*

Improved Patient Outcomes

Value creation impact

Our system is designed and built to enable a wide array of applications that have the capability to dramatically improve quality of care and streamline medical processes:

Diagnosing Acute Coronary Syndrome (ACS)
For rapid, accurate emergency room decisions for patient admission or safe discharge.

Detecting Fetal Cardiac Abnormalities
For direct monitoring of fetal cardiac activity during prenatal checkups, allowing early detection and intervention in case of arrhythmias.

Advancing Drug Research
For quantifying the effect of drugs on cardiac diseases accelerating drug development.

Assessing Sudden Cardiac Arrest (SCA) Risks
For early diagnosis of SCA risk among women, young athletes and elite task force members.

Accelerating cardiovascular disease research
For empowering clinical researchers to discover new, highly impactful MCG applications for which no viable alternatives exist today.

Value creation

New medical device tailored for early cardiac disease detection, to enhance ECG toolbox. New opportunities.
Creation of an entity (spin-off) for the commercialization.
Swiss-designed innovative medical technology: EU sovereignty.
Track record in the team.
Strong support.

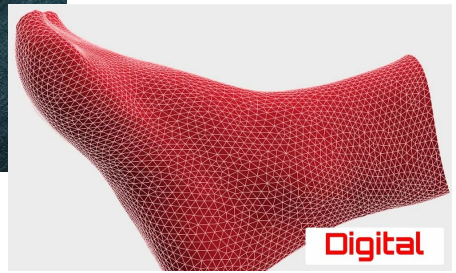
*context image

Value creation - example in the team

Replacing the plaster cast with a 3D scanning-textile and thus closing the gap in digital orthopedics.

Joris

Pascal



New venture with orthopedics

Outro

Let’s develop the next generation of medical quantum sensors for healthcare.

Thank you!