Integration of MNT, biomaterials and wireless comms as an enabler for medical implants and diagnostic equipment

February 2007

Personal health care systems"

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SIXTH FRAMEWORK PROGRAMME

Healthy Aims

Information Society Technologies

Medical implants and diagnostic equipment

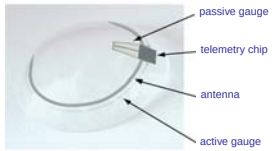
Implanted medical products and diagnostic equipment are in contact with body tissue and need to fit into very small spaces. They also need to communicate information to outside the body. Therefore, medical implants must integrate micro and nano technologies with biocompatible materials and wireless communications.

Healthy Aims is one EU FP6 project with the goal to develop a number of intelligent medical implants and diagnostic systems, integrating a range of underpinning micro- and nano- technologies.

The medical products undergoing patient trials within the Healthy Aims project provide a benchmark of today's state-of-the-art worldwide.

There are six clinical partners in the project, to help develop the system specifications, guide the development work and carry out clinical trials on prototypes.

Products being developed within Healthy Aims



Glaucoma sensor

Intra-cranial pressure sensor

Retina implant

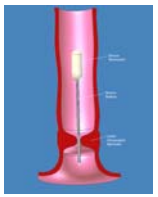
Cochlear implant

Electrical stimulation (FES) for limb motion

Activity monitor

Bladder and bowel electrical stimulators

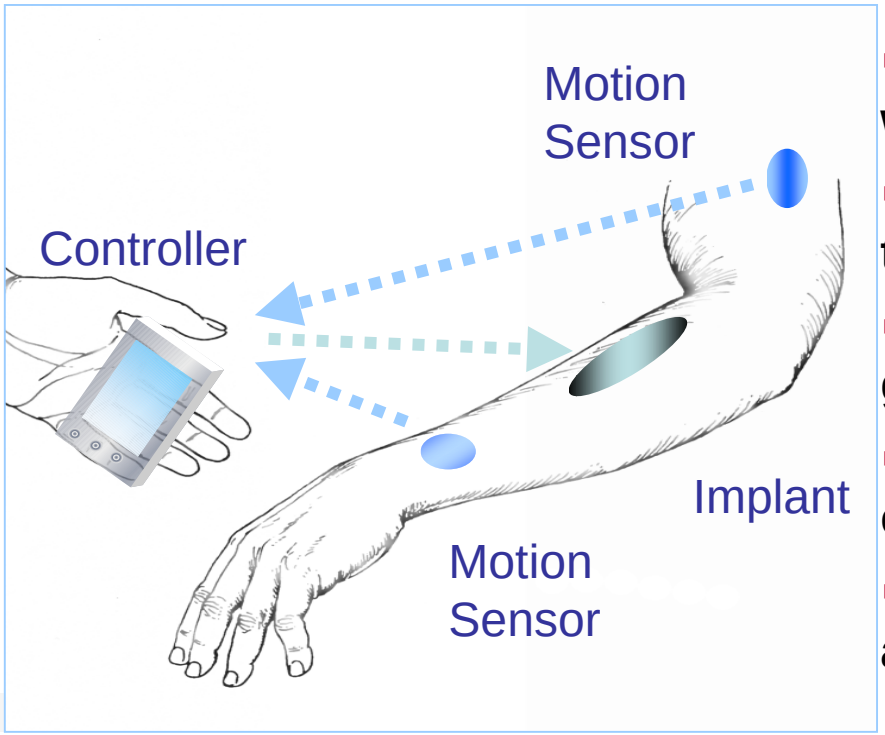
Sphincter sensor



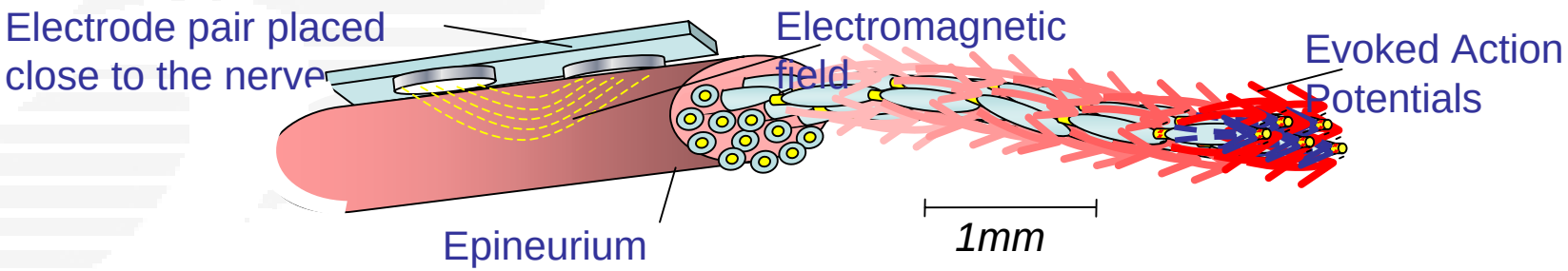
Healthy Aims partners

Functional Electrical Stimulation (FES)

System example



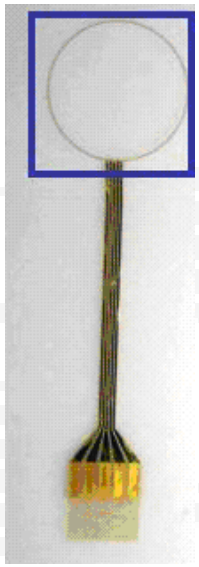
- **Sensor system used to determine when the implant should be triggered**
- **Wireless communication sends signal to trigger the implant**
- **Implanted, encapsulated electronics generate the electric pulse**
- **Electric pulse passed into the electrodes which excites the nerve**
- **Nerve causes muscle movement in the arm**

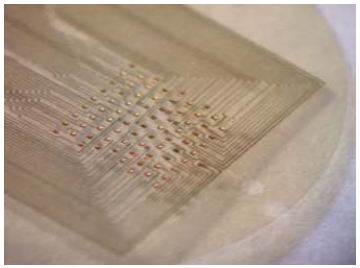


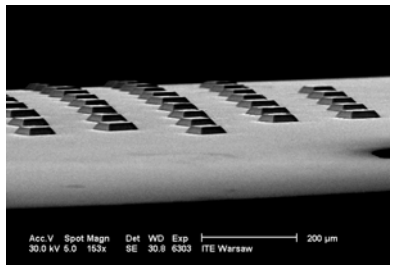
MNT developments within Healthy Aims

- Examples of electrode developments within Healthy Aims that have been applied to the different implants:

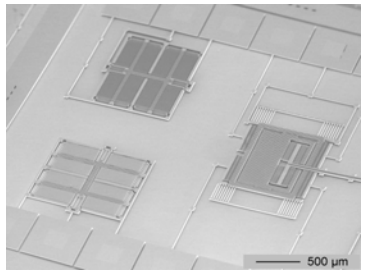
Glaucoma Sensor
Strain gauge







Retina Implant - 3D electrodes



3-axis gyro

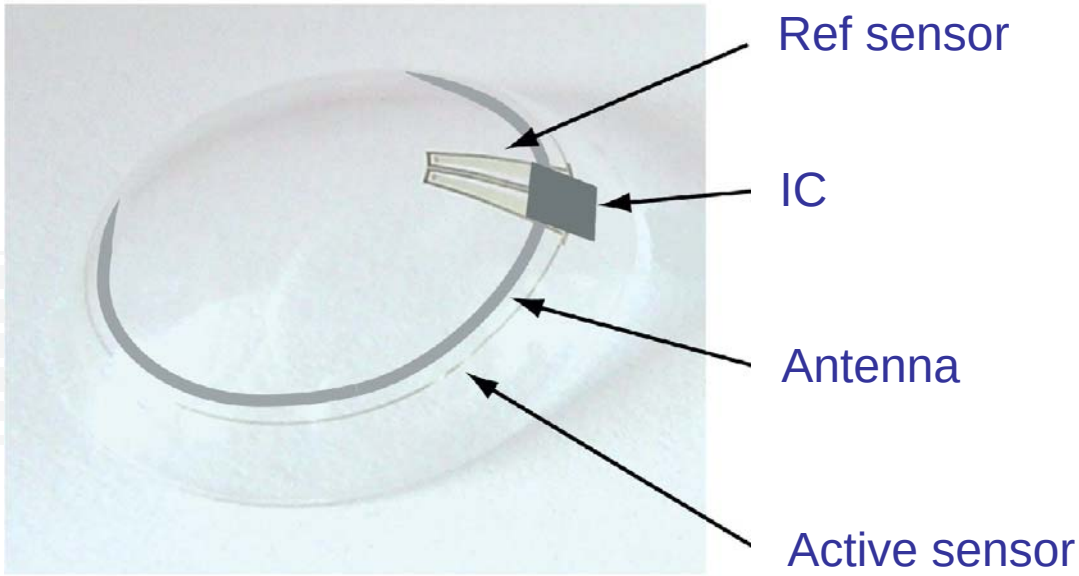
Sphincter Sensor

Cochlear Implant –
Modiolus electrode

Micro-packaging developments

- 3D flexible packaging including ASIC thinning down to 50μm and flip chip bonding is one of the successes from the project so far, which is applicable to a range of products:

- Glaucoma Sensor
- Retina Implant
- Cochlear Implant
- ICP sensor



Glaucoma sensor

Communications from in the body

The implant transmitters must have a wireless method for transmitting data to external receivers.

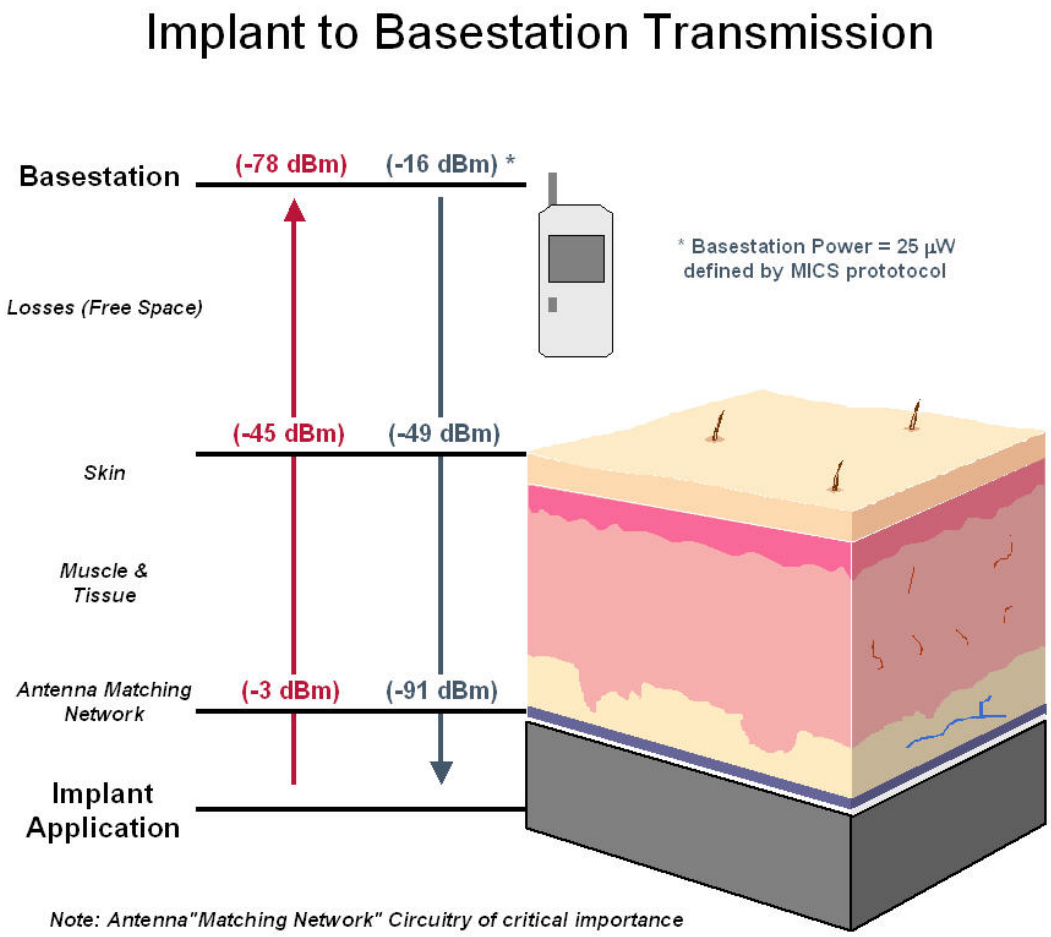
The data transfer method is defined by the specific application and in some applications includes power transmission.

Product	Carrier freq for data
Glaucoma sensor	27.3 MHz
Retina implant	IR
Electrical Stimulation	403 MHz (MICS)
Cochlear implant	5 MHz
ICP sensor	13.56 MHz

On the body communication use Bluetooth or Zigbee

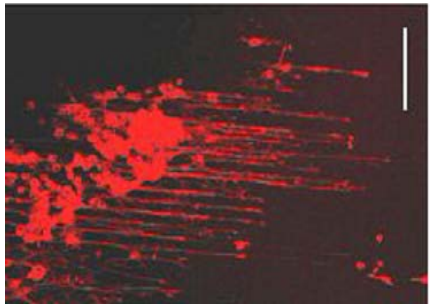
MICS - Communicating data through the body

- **Losses through the body are an important consideration when designing a new system.**
- **The diagram shows the energy loss for the MICS system.**
- **The antenna design is critical to the performance.**

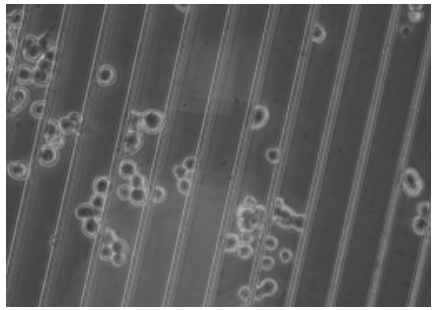


Encapsulating Biomaterials and functional interface between electrodes and nerves in the body

- Means of improving the connection between the electrode and the nerve cells to optimise charge transfer.

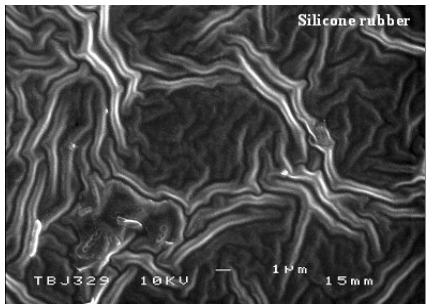


Aligning electrically active neurons to the electrode surface

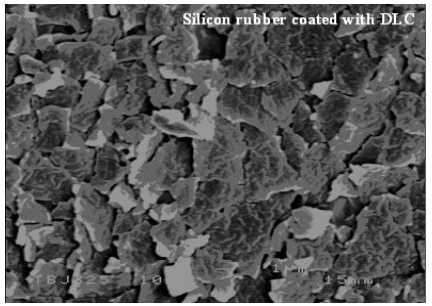


Preventing adhesion of non electrically active cells.

- Biocompatible encapsulating materials to stop water ingress into the implant and prevent leeching of materials from the implant into the body.



Silicone rubber



Silicone rubber coated with diamond-like carbon (DLC)

Implantable Rechargeable Battery

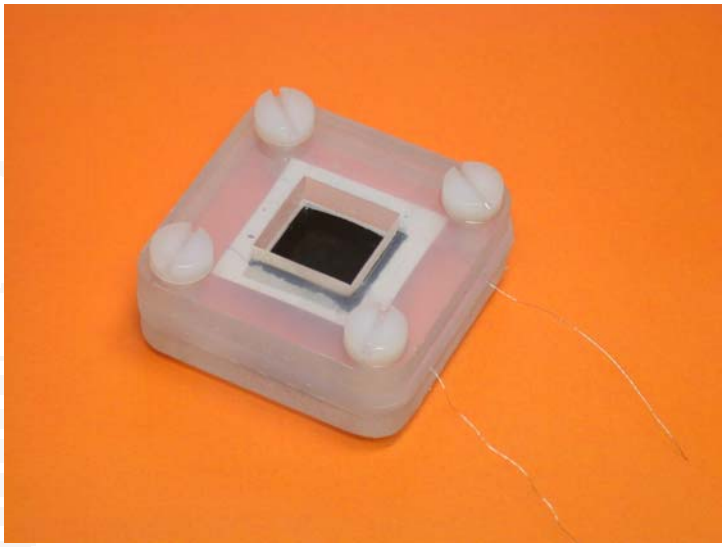
- Implantable power source for the Cochlear & FES systems
- First prototypes available

Parameter	Specification
No. of charges	4000
Life time	10 years
Dimensions	5 x 10 x 22 mm
Minimum voltage	3V
Average current	5mA

Biofuel cell to meet future implant challenges

- A biofuel cell requires no charging - hence ideal for implant applications.

- Suitable for low power implants, like a pacemaker.

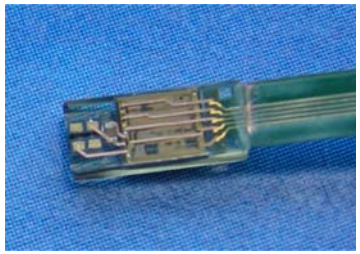


Some Examples of results at end Year 3

Retina implant

Activity monitor

Electrical stimulator for hand and wrist control



ICP Sensor and 3D packaging

Sphincter sensor

Challenges still facing the clinical research community

- The focus of future clinical research activities should aim for:
  - the performance of implantable prostheses to be closer to that of the human,
  - implantable in babies,
  - Lifetime means from 75+ years.

- Medical manufacturers and clinical experts are an essential part of these new development projects to ensure that they meet the clinical need, can be implanted by surgeons and can be manufactured.

Examples of EU citizens we could help

Elderly at risk

Stroke patients

Babies at risk

Healthy athletes

Future R&D for implants

MNT research activities could focus on key areas:

- increase the density of individually addressable electrode arrays.
- provide implantable energy sources that last a lifetime.
- investigate alternative stimulation locations.
- develop alternative methods of providing data communications through the body.
- develop new sensors and embedded software solutions that enable new implants and diagnostic systems to function without any input from the user/ patient.

Summary and acknowledgements

Technologies need to be developed with a clear specification for the end product. Once available they can be integrated into new products and undergo clinical trials. The timeframe for any new products to reach the market can be from 1 to15 years and is dependant upon many parameters including:

the risk,

how much of the device is new,

the experience of the manufacturer regarding clinical approvals.

With the advancement of MNT, wireless communications and biomaterials it is clear that new prostheses could help EU citizens with major disabilities like blindness, deafness and incontinence.

The financial support of the EU FP6 programme is greatly appreciated by the Healthy Aims consortium and has enabled them to develop a range of new medical implants and diagnostic equipment.