MNT for sensors and medical implant devices
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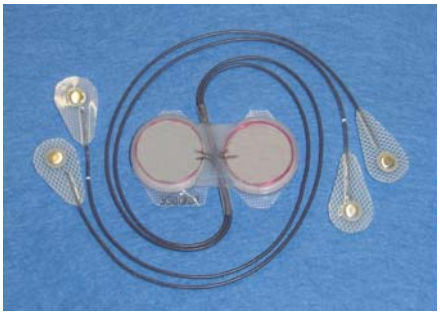
Over the last 4 years ETB has co-ordinated the FP6 project 'Healthy Aims' whose project goals were to develop a range of medical implants and diagnostic tools using micro, nano, bio and wireless technologies [1] [2].

Prototype devices now in, or now ready for clinical trials, successfully demonstrate that these goals have been achieved. Examples of the medical implants now in clinical trials include: retina implant [3]; FES for upper arm movement [4] and bowel control; modiolus electrode for a cochlear implant and an intracranial pressure (ICP) sensor system.

Retina implant

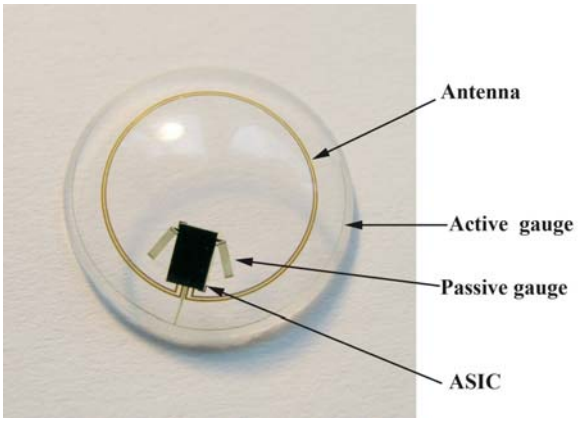


Electrodes for the FES upper limb implant

Modiolus electrode for the cochlear implant

ICP sensor system

Examples of on the body sensor diagnostic equipment in clinical trials include: gait and activity classifier, joint angle monitoring system, glaucoma sensor, plus a catheter sensor system for urodynamics measurement which is in laboratory trials.



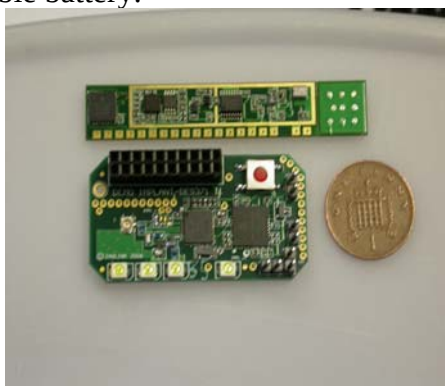
Glaucoma sensor

Catheter for urodynamics measurement

Activity classifier/ gait analyser and joint angle measurement module

In addition to these complete system solutions there are two technologies that have been developed and are now available for integration into new medical implants, not just those developed within Healthy Aims. These comprise a wireless communications system using the Medical Implants Communication Service (MICS) and an implantable rechargeable battery.

Implantable battery

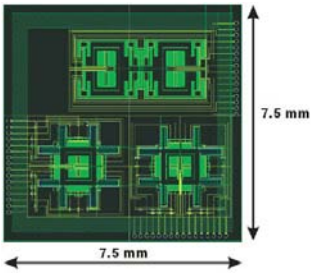


MICS system

Technology developments in biocompatible coatings [5], hermetic enclosures incorporating antennas for wireless communications and electrode and strain gauge technologies on a range of flexible substrates have been developed to a level that can be integrated into other implant devices and a biofuel cell developed to a level which demonstrates its potential for use as power source for low power implants like a pacemaker.

All the diagnostic equipment integrates a MNT sensor; strain, pressure, acceleration or angular rotation. These sensors are either Silicon based or fabricated on flexible substrates such as kapton. Two excellent examples of the sensors developed within the Healthy Aims project are the strain gauge used in the glaucoma sensor and the planar 3-axis gyro for integration into the joint angle system.

The 3-axis gyro is a single Silicon on Insulator (SOI) device with 3 independent resonant structures formed alongside each other. Each of these structures is set into resonance using electrostatic forces and motion in the orthogonal axis is monitored using capacitive techniques.



Layout of the planar 3-axis gyro

Over the 4 years the clinical partners have worked closely with the technology providers, designers and end user manufacturers to ensure that the prototype devices can go into clinical trials. Provided that the trials have been successfully concluded the product will then move into commercial exploitation.

Results so far indicate that the products under development are addressing the forward look of the healthcare sector. The trend is towards intelligent systems which either look after themselves or automatically advise carers/ clinicians or concerned relatives of changes taking place, often referred to as eHealth. Two examples from the project that are in clinical trails and address this specific trend are the FES for upper arm and the gait monitoring system. The FES has successfully been implanted into 3 stroke patients and all of them have seen a marked improvement in their daily activities without any intervention from themselves or their clinical advisor. For example, simple chores like preparing vegetables for dinner, are now possible, with the user being able to grasp and hold objects with the hand that previously was permanently closed. Returning functionality to patients means that they become independent again, improving their quality of life and reducing the burden on the health service. The gait analyser is being used to enhance the diagnosis for cardiac conditions. Current methods rely on the patient fitted with a Holter, which accurately monitors their heart rate, to manually record which type of activity they undertook and when. This manual approach is subjective and often highly inaccurate, for example ‘I walked for about 10 minutes at around 1.30pm’ could have been a slow walk for 2 minutes followed by a brisk walk for 5 minutes at 2pm. If the heartrate increased at 1.30 but reduced at 2pm

then the inaccurate manual record could result in an incorrect diagnosis by the cardiologist. By automatically monitoring the gait profile as well as the heartrate, activity can be accurately correlated to heartrate, with no manual intervention by the patient. Preliminary trials with the gait monitor and Holter by a leading cardiologist are very encouraging and show the way forward in this type of diagnosis.

All systems developed within the Healthy Aims project have intelligence built in, which means that the reliance on the patient providing input is removed. For the diagnostic system data is automatically obtained and provided directly to the clinical expert. With the implants the intelligence is included in the feedback loop with no intervention by the patient.

The Healthy Aims products and underlying technologies are recognised as state-of-the-art at the international level[1] and complements other leading R&D activities in Europe. For example, two major FP6 projects, Neuroprobes and Vector have combined certain research activities on micro-electrode development, joining technologies and clinical trials procedures, resulting in a stronger EU knowledge base in this technology sector and, in the longer term, reducing the time to market for future product development.

In conclusion, the Healthy Aims project has successfully developed a range of intelligent implants which will, in the future, improve the quality of life for patients suffering with conditions that cannot be treated; for example blindness, deafness and loss of limb movement. The diagnostic equipment will improve the accuracy and enable early diagnosis for a variety of medical conditions; for example glaucoma, heart disorders and incontinence. Underlying technologies are also available that can be applied to implants and diagnostic equipment being developed by organisations outside of the Healthy Aims consortium. This work has been enhanced and shared with other EC projects, building upon such initiatives as the EU Micro-nano-bio convergence systems Concertation meetings.

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