# WIRELESS IMPLANTABLE MICRO SENSORS AND SYSTEMS FOR AMBULATORY MONITORING AND CONTROL OF THERAPEUTIC PROCEDURES

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**Abstract – This paper describes the development of implantable telemetric pressure sensor systems under the European project Healthy Aims.**

## INTRODUCTION

Implantable telemetric pressure measurement aims to monitor quality and functionality of therapeutic implants inserted by minimally invasive procedures. In order to reduce the hospital stay of patients to a minimum of days, implantable sensors for therapy control integrated into commercial tele-healthcare applications provide cost-saving alternative monitoring and allow the patient to continue participating in his or her everyday life.

The European project Healthy Aims is funded under the FP6 1st programme (1) and aims to produce next generation intelligent medical implants by developing new enabling technologies and integrating these into exploitable products.

## MARKET BARRIERS

Because of the ageing population in most western countries, health-care systems are undergoing dramatic changes to cope with the rising number of patients. These have led to uncertainty in the reimbursement situation, which is worsened by the fragmented nature of country-specific health-care markets. For example, the redefined diagnosis-related group system being introduced in Germany may block innovations in the short term because of the additional cost of new medical devices, but the potential mid-term cost reductions may accelerate the introduction of new medical products in combination with new health-care service business models.
The perceived relatively low production volumes for some medical applications make the development of medical pressure sensor systems uninteresting to large organisations. The long time to market because of clinical trials, regulatory approval, high development cost and large organisational efforts, make it difficult for small- and medium-sized enterprises to invest in developing the technology.
The well structured partnership in the Healthy Aims project including technology provider, clinicians and medical end user manufacturer can reduce the market risk and promises to accelerate the exploitation of new medical products.

## TECHNICAL CHALLENGE

In a wireless hybrid sensor system approach (Fig 1) as described by T Eggers et al (2), the basic components are

- a long-term stable absolute capacitive pressure sensor,
- an ultra-low power interface circuitry,
- a radio-frequency transponder for bi-directional communication to an outside body area network unit and
- a micro coil for inductive data and energy transmission to the implant.

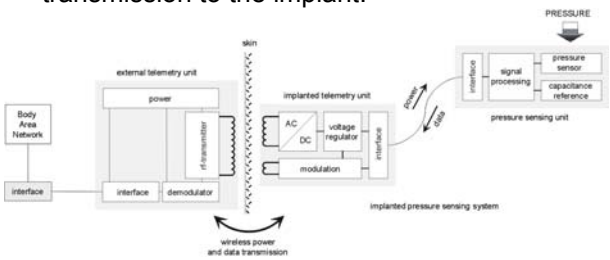


*Fig 1: Block diagram of an implantable telemetric pressure measurement system.*

To avoid the lifetime of the system being limited to the capacity of a battery, contemporary systems use a passive, inductively coupling method to provide the implant with power from outside and, at the same time, to transfer the data over a sufficiently long transmission distance to an external reader unit. Therefore ultra low power consumption on part of the implant is essential.
The encapsulation of the implant has to provide hermetically sealing in order to guarantee a drift-free and highly reliable system over the entire lifetime of the implant. An additional nanotype coating ensures highly biocompatible performance of the implant. The latest three-dimensional micro packaging technologies enable the development of flexible devices like integrated pressure sensor systems that meet the high demands of modern surgical insertion procedures, and can stay stable and reliable inside the human body over a long period of time.
These requirements are considered when developing new technologies under the Healthy Aims project, which then will be integrated into the product development of implantable pressure sensor systems. The involvement of end user manufacturer ensures a development along the needs and requirements of the specific medical market segments.

## APPLICATIONS

Target applications for an implantable telemetric pressure sensor system include the continuous monitoring of intracranial pressure (ICP) or the continuous surveillance of endoluminal stent-grafts (EVAR).
There are several clinical reasons for elevated intracranial pressure. In order to treat hydrocephalus, a shunt valve system is implanted to drain the excessive cerebrospinal fluid and maintain a target pressure level. Despite the enormous development in shunt-therapy of hydrocephalus there are still significant complications associated with the shunt such as over-drainage that often requires a revision of the shunt. Continuous monitoring of intracranial pressure is desired to evaluate the function of the shunt system over time.

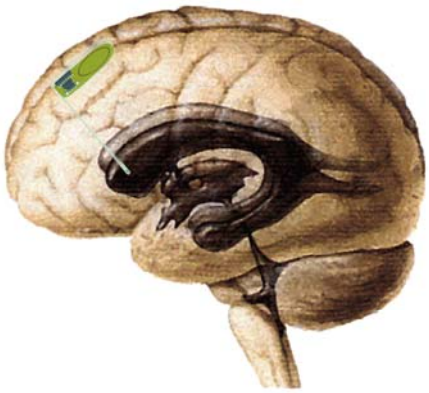

*Fig 2: Telemetric intracranial pressure implant.*

A potentially promising technical solution is to insert a telemetric pressure sensor implant together with the shunt systems provided by different manufacturers to allow pressure monitoring at home, in a similar way to the widely used blood-pressure measurement devices (Figure 2).

A young minimally invasive approach for the repair of aortic aneurysms uses endovascular techniques to place an endoluminal stent-graft inside the aneurysm effectively excluding the enlarged part of the aorta from blood circulation. The ultimate result of a progressing enlargement is rupture of the aneurysm producing life threatening consequences. The therapy is continuously observed via contrast-media-enhanced computed tomography (CT). CT is a very cost-intensive procedure and is associated to x-ray exposure and risks correlating with contrast-media application. There are greatly evidences that the success of therapy depends on the pressure remaining inside the aneurysm. Thus an implantable telemetric pressure sensor connected to an endoluminal stent-graft might be a great alternative to CT scanning.

## SUMMARY

This paper has highlighted the development of a telemetric implantable pressure sensor product inside the European project Healthy Aims (3). The Healthy Aims consortium is able to accelerate the introduction of intelligent medical products by high integration of technical experts, end user manufacturer and clinicians in the development and the production chain.
Implantable telemetric pressure sensors will be of significant value for cost-effective continuous monitoring of therapeutic procedures even under everyday life conditions.

## REFERENCES


1. Sixth framework programme priority 1.1.2 Information Society Technologies
2. Eggers T, Marschner C, Clasbrummel C, Laur R, Binder J, MEMS2000, 2000
3. Healthy Aims Website www.healthyaims.org