

# Implantable Telemetric Pressure Measurement

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Highly miniaturised implantable pressure sensors can be used for wireless monitoring of different therapeutic procedures. This article presents an outlook on the market potential of these systems.

## Market drivers

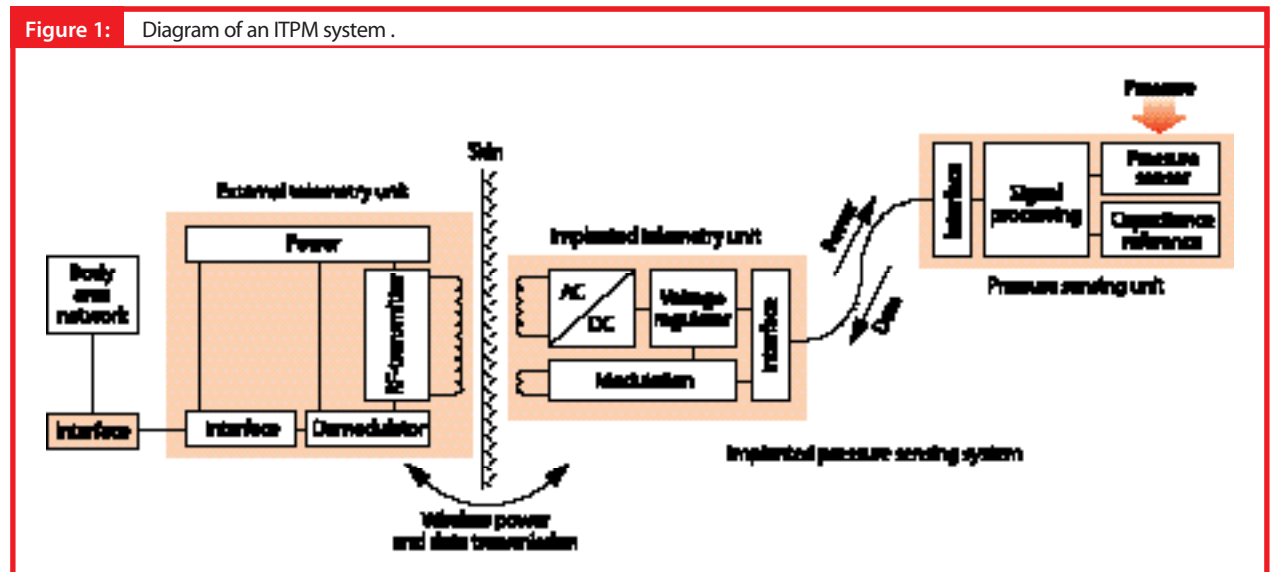
Implantable telemetric pressure measurement (ITPM) aims to monitor quality and functionality of therapeutic implants inserted by minimally invasive procedures. A large number of implantable biotelemetric systems for measuring physiological pressure inside the human body have been developed since the 1970s, but few have been successfully commercialised. Most of those systems have been developed for clinical research and do not offer the

reliability required for successful medical device approval. Moreover, the production technology that has existed has not allowed manufacturing of highly miniaturised and long-term stable sensors.

In recent years, health-care systems have changed rapidly in most western countries to reduce exploding costs and increase the quality of medical treatment. To reduce the hospital stay of patients to a minimum of days, commercial telehealth-care applications provide cost-saving alternative

monitoring and allow the patient to continue participating in his or her everyday life. In addition, new, enabling microelectromechanical systems and nanotechnologies are evolving that show promising results for solving the technical challenges of ITPM. A feature of this area of development is the high degree of specialisation in single technologies, which requires the involvement of different specialised partners in the production chain to enable the introduction of new and reliable products.

Figure 1: Diagram of an ITPM system .



### Technical challenges

In a hybrid-system approach, that is, a system comprising more than one chip, the basic components are

- a long-term stable absolute pressure sensor, preferably based on capacitive measurement
- an ultralow power interface circuit
- a radio-frequency transponder for bidirectional communication to an outside body area network unit
- a microcoil for inductive coupling of data and energy to the implant.

Figure 1 shows a 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. Mounting, assembly and packaging have to ensure a hermetically sealed implant by providing a diffusion barrier to guarantee a drift-free and highly reliable system over the lifetime of the implant. An additional nanotype coating must ensure biocompatible performance of the implant. The latest three-dimensional micropackaging technologies such as MicroFlex Interconnection Technology (Fraunhofer Institute of Biomedical Engineering, [www.ibmt.fhg.de](http://www.ibmt.fhg.de)) or 3D-Chip-Size-Packaging (microTEC, [www.microtec-d.de](http://www.microtec-d.de)) enable the development of flexible devices such as integrated pressure sensor systems or intelligent electrode systems that meet the high demands of modern surgical insertion procedures.

Some of the medical applications of hybrid ITPM systems are described below.

### Intracranial pressure monitoring

There are several clinical reasons for elevated intracranial pressure (ICP). To treat hydrocephalus, a shunt valve system is implanted to drain the excessive cerebrospinal fluid and maintain a target pressure level. More than 25 000 of these surgical procedures are performed in the United

States (US) each year ([www.hydrocephalus.org](http://www.hydrocephalus.org)). Despite the enormous development in shunt-therapy of hydrocephalus, there are still significant complications associated with the shunt such as over-drainage that often require a revision of the shunt. Continuous monitoring of intracranial pressure is desired to evaluate the function of the shunt system over time. A potentially promising technical solution is to insert an ITPM system 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).

### Intraocular pressure monitoring

Untreated glaucoma leads to damage of the optical nerve and is one of the most common causes of blindness worldwide. Most cases of glaucoma correlate with increased pressure within the eye. This disease can be continuously monitored by an ITPM integrated into an artificial lens that conventionally replaces the natural ocular lens in cataract surgery (Figure 3). There are approximately 2.5 million cataract procedures worldwide each year. The results of a United Kingdom national data collection have shown that 11% of cataract patients have a coexistence of glaucoma disease.<sup>1</sup> That value is representative of Western Europe and the US and presents the potential for an ITPM integrated into an intraocular lens.

### Abdominal aortic aneurysm

A minimally invasive approach for the repair of aortic aneurysms uses endovascular techniques to place an endoluminal stent-graft inside the aneurysm that effectively excludes the enlarged part of the aorta from blood circulation. The ultimate result of progressing enlargement is rupture of the aneurysm, which leads to life-threatening consequences. The therapy is continuously observed via contrast-media-enhanced computed tomography (CT). CT is a cost-intensive procedure and is associated with X-ray exposure and risks corre-

lating with contrast-media application. There is strong evidence that the success of therapy depends on the pressure remaining inside the aneurysm. Thus, an ITPM connected to an endoluminal stent-graft may be an alternative to CT scanning. In the US, approximately 205 000 new patients are diagnosed each year with the most common abdominal form of aortic aneurysms.<sup>2</sup> The incidence continuously grows as a result of the ageing US population. Endovascular stent-grafts are applicable for use in 30–40% of cases.

### 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

Figure 2: ITPM system implanted into the brain.

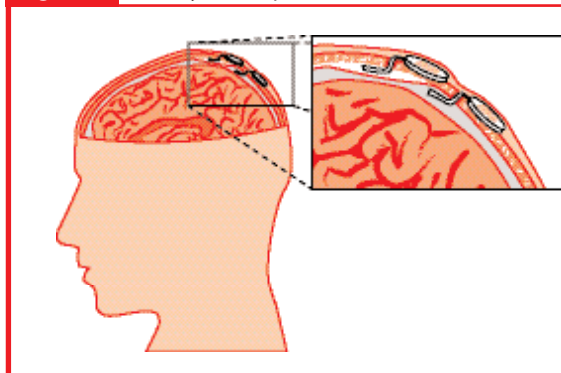
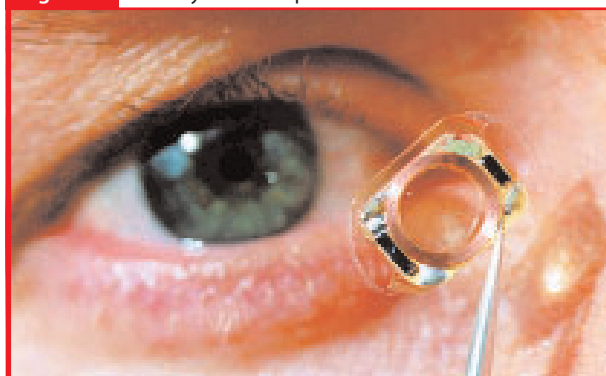


Figure 3: ITPM system incorporated into an intraocular lens.



new medical devices, but the potential mid-term cost reductions may accelerate the introduction of ITPM in combination with new health-care service business models.

The perceived relatively low production volumes for some medical applications make the development of ITPM systems uninteresting to large organisations. The long time to market because of clinical trials and regulatory approval, and high development costs and large organisational efforts, make it difficult for small- and medium-sized enterprises to invest in developing the technology.

A big concern is product liability issues in the case of an ITPM failure: showing incorrect pressure values may lead to late or incorrect treatment and possible harm to the patient. Product liability issues become even more important when introducing close-loop systems such as self-regulating active shunt valves for the treatment of hydrocephalus, which are technically feasible today. The functioning of the therapeutical device then would be controlled by an integrated pressure sensor.

Recently, a large European Commission funded project called "Healthy Aims" started work on unsolved problems in existing and upcoming products to accelerate their introduction into future health-care markets ([www.healthyaims.org](http://www.healthyaims.org)).

## References

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