

**HYPER-IMS:****A Fully Implantable Blood Pressure Sensor for Hypertensive Patients**

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**Abstract**

Hypertension and heart failures were and are increasingly two of the main diseases of modern population. As a powerful tool for long-term post surgical evaluation of heart pressure, body temperature and pulse rate, a telemetric controlled sensor-implant without battery is currently developed and evaluated in the course of preclinical in-vivo experiments.

**Introduction**

Over 10 million people suffer from hypertension, solely in Germany. 10% of those are candidates for long-term surveillance. Blood pressure gives us information on the function and health of our heart and cardiovascular system. Knowledge about the intracranial pressures helps us to preclude and treat intracranial anomalies, information of gastrointestinal transient pressure situations helps us to understand postsurgical effects in the gastrointestinal tract to name only few.

Currently available systems are catheters for short-term blood pressure monitoring in hospitals or extracorporeal systems like blood pressure cuffs for individual measurements in home-care and in doctor's practice. While the first are restricted to clinical evaluation in acute situations due to the required permanent access to the body, the latter do not only hinder the patient in daily life, they furthermore do not allow continuous measurements.

The presented system is aimed to overcome these limitations. With up to 30 measurements per second of temperature and pressure, the fully telemetrically controlled implant exemplarily allows precise information on blood pressure, body temperature, transient heart rhythm and possible anomalies like syncopes. Not requiring a battery, the system is predestinated for long-term applications in small body cavities.

**System design**

In order to meet the strong demands on miniaturization, the system is subdivided into three units: a sensor-tip measuring 1.05 mm in diameter and 15 mm in length which is connected by means of a microcable with a transponder unit measuring 17 mm in diameter and 3 mm in height and an extracorporeal, wearable reader unit. While the sensor-tip is located directly in the region of evaluation (e.g. a blood vessel), the transponder unit is fixed extravasal in an easily accessible place beneath the skin. As energy and data are exchanged telemetrically between transponder and reader unit, the implant itself does not require a battery. Figure 1 gives an impression on the main target application: blood pressure monitoring inside the arteria femoralis while wearing the extracorporeal reader unit at a belt [2].

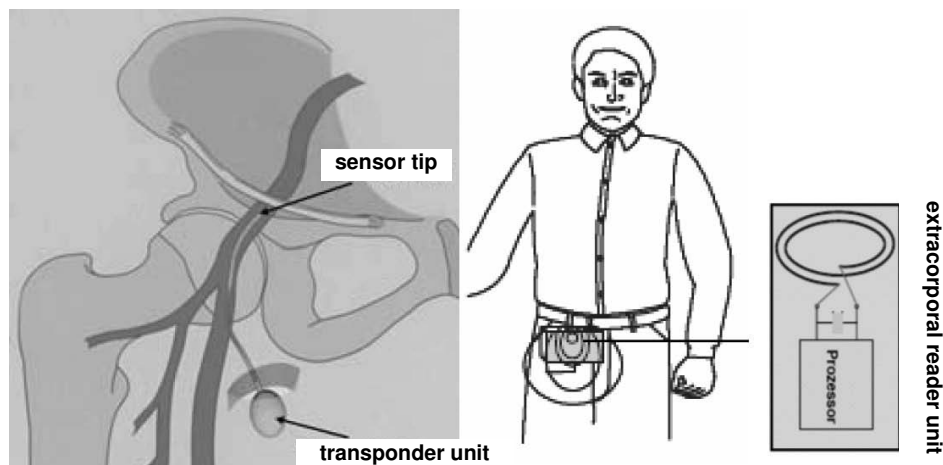


Fig. 1: Illustration of the Hyper-IMS system implanted into the arteria femoralis and the extracorporeal reader unit worn at a belt.

## Sensor specifications

The heart of the HYPER-IMS system is a capacitive CMOS pressure sensor with integrated ASIC circuitry (Fig. 2). An integrated temperature sensor allows to compensate for the influence of changes in temperature on the pressure signal that is measured by means of 48 sensor membranes. The overall dimensions of the sensor-chip are 0.65 mm x 5 mm x 0.4 mm.

The measurement range of the system is 900 mbar (675 mmHg) to 1400 mbar (1050 mmHg) which comprises realistically achievable body pressures. Within a temperature range from 30°C to 45°C, the calibrated accuracy is less than  $\pm 0.66\%$ FSS which corresponds less than  $\pm 3.3$  mbar ( $\pm 2.5$  mmHg). 30 measurement values per second are transported over a distance of up to 80 mm. During its active phase, i.e. when activated by the reader station, the implant consumes not more than 200 to 300  $\mu$ W. A calibration plot of a readily assembled and encapsulated sensor is given in Figure 3.

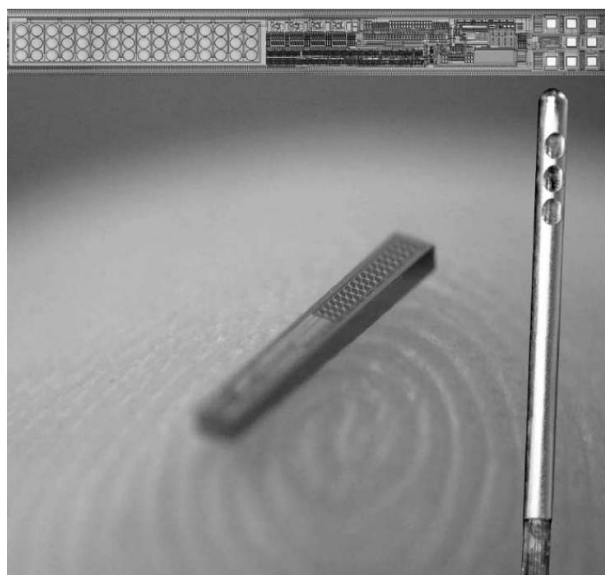


Fig. 2: Sensor-Chip for pressure and temperature with integrated digitizer. Upper section: top view of the Sensor-Chip. Middle section: Sensor-Chip on a finger tip. Right section: Integration of the Sensor-Chip into a tube of stainless steel with diameter of 1.05 mm.

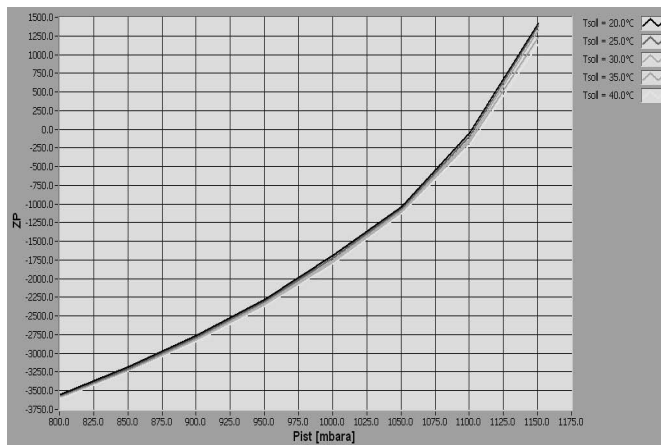


Fig. 3: Calibration of an implant. Absolute pressure plotted against arbitrary output of the sensor.

## System assembly

In order to ease a mechanically robust and thus reliable assembly of the system, the sensor-chip is inserted into a polymer carrier, micro-injection molded with LCP (Liquid Crystalline Polymer). In order to meet the challenging demands on miniaturization, a highly precise geometry without distortion (wall thicknesses of <100  $\mu\text{m}$  over a length of up to 6 mm) is indispensable to allow a reliable assembly (Fig. 4). Sensor and sensor carrier are inserted into a laser-cut tube of stainless steel with an outer diameter of 1.05 mm and 16 mm in length.

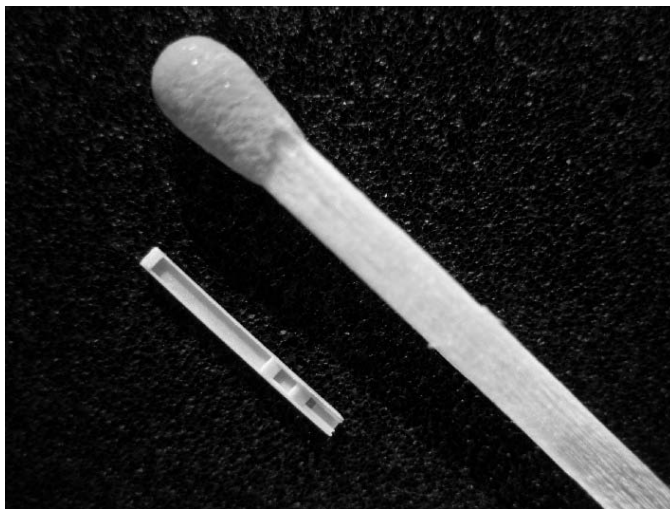


Fig. 4: Micro-injection-molded polymer carrier measuring 9.6 mm in length.

Within the systems housing, the sensor-chip is embedded in Silicone. When applying the sensors in a wet environment, a major problem is drift of the sensor due to water uptake of the polymer. Available systems try to overcome this drawback by an appropriate preconditioning and offset compensation of the sensor. In case of the presented sensor, extensive work and know-how were invested to meet these challenges and to achieve long-term stable sensor signals. Fig. 5 shows a not miniaturized prototype of the extracorporeal reader station (left side) and the readily assembled implant with encapsulated sensor-tip (right side).

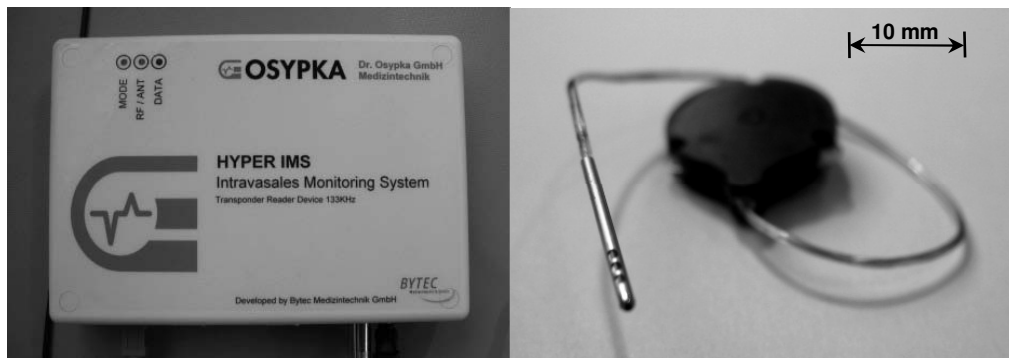


Fig. 5: Telemetry-controlled intravascular monitoring system. Left side: prototype of the extracorporeal reader station. Right side: Sensor implant with sensor tip, microcable and telemetric transponder unit. Lower right side: unpackaged sensorchips.

## In-vivo evaluation

First measurements with the device in a vascular model with pulsating fluid [3] showed promising results (Figure 6).

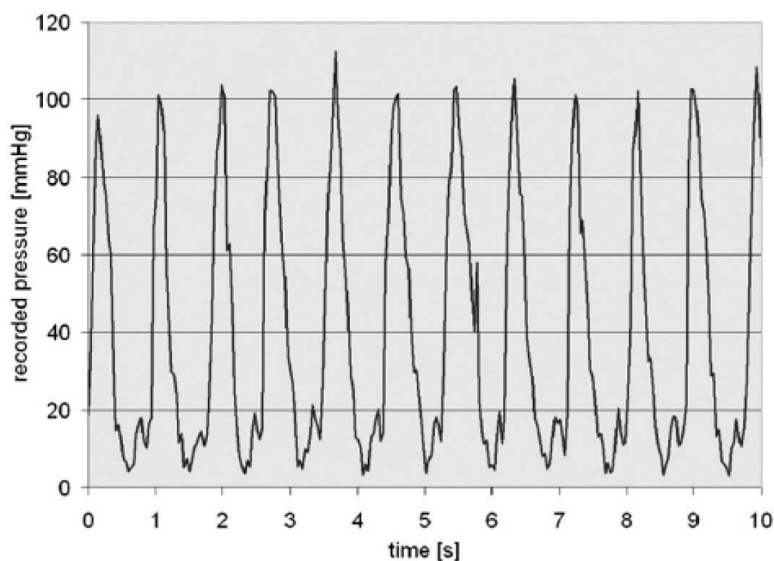


Fig. 6: Measurement of pulsating fluid pressures in vascular model.

For a further evaluation of the system, medical and technical aspects are under examination. From the medical point of view, a safe access of the sensor tip into the femoral artery, the sealing of the vessel and the subcutaneous fixation of the transponder unit have to be considered and evaluated. For this purpose a collagen based insertion instrument has been developed and tested. Currently, first acute and long-term experiments in sheep were performed by accessing the sensor tip into the femoral artery. From the technical point of view, the behaviour of the sensor assembly in the wet and corrosive environment inside the body was matter of intensive testing. Furthermore, a reliable transmission of energy and measurement data through the skin is crucial for a reliable function of the implant. Figure 7 shows the transient blood pressure curve of an anaesthetized sheep, recorded with a distance between the implanted transponder unit and the extracorporeal reader unit of 10 cm. This distance is realistic assuming a subcutaneous placement of the transponder unit and an attachment of the transmission coil of the wearable reader unit to the body of a patient. The transient resolution of the pressure information allows conclusions on the transient blood ejection rate of the heart, which have so far not been attainable with available system for long-term recording of blood pressure.

The rather low levels in blood pressure from 30 mmHg to 80 mmHg are suspected to be matter of the anaesthesia of the sheep.

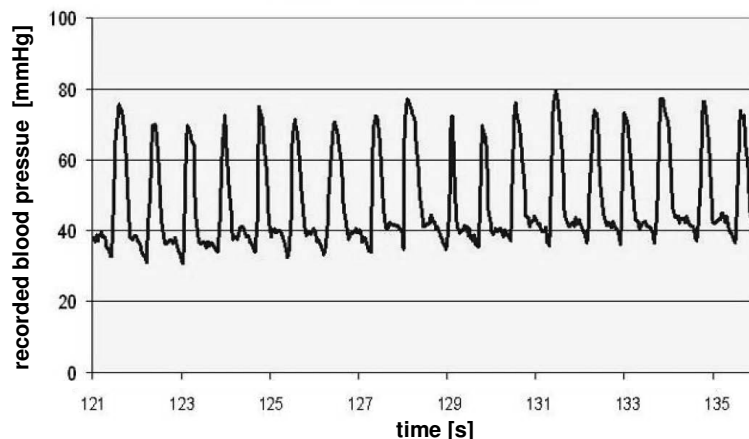


Fig. 7: Transient blood pressure, measured and telemetrically recorded in the femoral artery of an anaesthetized sheep.

## Range of further applications

Blood pressure monitoring is only one of a multitude of possible applications of such an implantable pressure sensor unit. Due to the wireless transmission of energy and thus the ability of the implant to work without battery allows the achieved degree of miniaturization. The digital data transfer allows a wireless transmission and recording of a variety of body pressures without the interferences and noise known from analogue data transmission.

Other realizations with even smaller dimensions of the sensor tip and increased length of the cable are under development to be implanted in deeper and smaller anatomical structures. Due to the galvanic isolation of the sensor from any electrical source, the presented sensor tip represents an interesting alternative even in the field of catheters and endoscopes.

Furthermore, the wireless transmission of transient pressure conditions with a miniaturized system offers new diagnostics and therapies in fields like cranial or gastro-intestinal pressure monitoring etc.

## Conclusions

The successful integration of a capacitive CMOS sensor into a fully implantable device for the 24/7 monitoring of the blood pressure of hypertonic patients was shown. Measurements in a vascular model as well as first in-vivo experiments with sheep showed promising results regarding the transient recording of pressure and temperature data. The data were read out telemetrically over a distance of 80 mm which is a realistic distance when wearing the telemetric reader unit close to the body. Long-term stability of the device in wet and corrosive environments is matter of ongoing evaluation and will be reported in the future.

## Acknowledgements

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