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„Implantable Thermal Flow Sensor for Neurosurgical Applications with Asymmetric Design for High Flow Ranges“

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Implantable Thermal Flow Sensor for Neurosurgical Applications with Asymmetric Design for High Flow Ranges

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INTRODUCTION

Hydrocephalus is an abnormal accumulation of Cerebrospinal Fluid (CSF) inside the brain and can be a severe handicap for children and adults which may end up even with death if not treated correctly. CSF is produced in the ventricles inside the brain, circulates through the ventricular system and is finally absorbed into the bloodstream.

Hydrocephalus occurs when there is an imbalance between the amount of CSF that is produced and the rate at which it is absorbed. The occurrence of hydrocephalus in newborn children is about 1 out of 5'000 – 10'000. Usually, hydrocephalus is treated by a drainage of CSF through a shunt catheter which is inserted in the brain ventricles in a surgery. Per year, more than 100'000 shunt valves are implanted worldwide. However, malfunctioning of the shunt catheter cannot be excluded which might lead to severe complications especially for children [Oikonomou 2001].

In order to allow a better management of hydrocephalus shunted patients, a thermal flow sensor which will be implanted close to the shunt valve has been developed The sensor will allow an improved long-time monitoring of the functioning of the valve as well as a better understanding of the flow of CSF.

MATERIALS AND METHODS

The sensor is based on the principle of thermal flow measurement published by Lammerink et. al. [Lammerink 1993]. The sensors were fabricated in two different processes creating the wafer with sensors and heaters and the wafer carrying the flow channel. After being processed separately, the two wafers were finally bonded anodically.

The Pyrex wafer carrying the sensors was spin coated with MaN 1410 resist, exposed and developed. The sensors were formed by sputtering a 50nm thin Ti layer followed by a 150nm thin film Pt layer. Finally, electrical contacts were formed using 500nm thick gold layers

The flow channel was formed using a Si wafer that was wet etch with BHF in order to remove the native oxide. Then a clean pyrex wafer was anodically bonded to the Si wafer. Then, positive photoresist S1818 was spin coated onto the Si wafer to form a 1 µm thick resist layer. In the next step, the entire plasma etch pattern was exposed, the resist was developed and wet etched with BHF to open the structures. Finally, anisotropic KOH-etching was used to form the flow channels with dimensions *380µm x 3000µm* (height x width). The remaining oxide on the Si wafers was finally removed with BHF.

The leak-tight packaging of sensors, heaters and electronics is achieved by soldering a glass cap onto the Pyrex wafer. This is done by evaporating thin gold films onto the pyrex wafer and the pyrex glass cap and soldering them together. Finally, a pinholefree Parylene coating is applied by a CVD process ensuring biocompatibility and biostability of the joint.

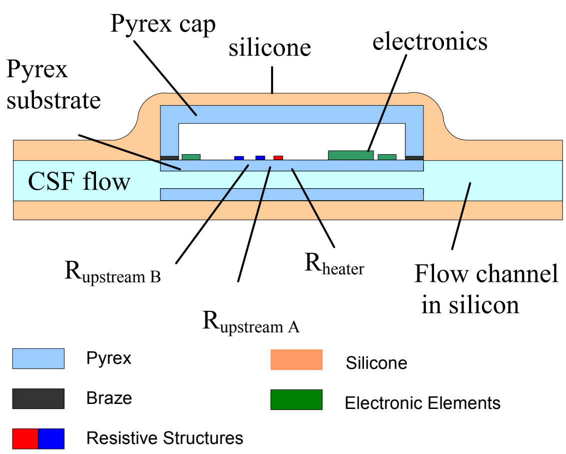

Fig. 1: Packaging design for the thermal flow sensor

Due to the design of the fluid channel, the fluidic inlet and outlet are located at the sides of the sensor thus allowing an easy assembly of the sensor into the silicone tubing of the hydrocephalus shunt valve.

Using a new and unique asymmetric design of the sensor on a 300µm thick Pyrex substrate the flow range could be considerably increased up to 300ml/h compared to a symmetric design, where flow ranges up to 2-3ml/h on Pyrex could be reached.

Compared to a microfabricated capacitive pressure sensor that was developed to be integrated into the CSF valve [Ginggen 2001], an additional energy of about 4mW is needed for heating up the CSF fluid.
The only way to provide the device with sufficient energy for long term application and to read out the measured flow rate is to use passive telemetry [Neukomm 2003]. However, the 13.5MHz electromagnetic radiation having a power of about 500mW used for passive telemetry represents a source of noise for the low-noise electronics. Therefore special care was taken to optimise the shielding of the electronics using an 2.47kHz ac bridge supply with respect to the RF power supply.

RESULTS
The new asymmetric design of the sensor on a 300µm thick Pyrex substrate increased the flow range considerable up to 300ml/h compared to the symmetric design. Using FEM simulations, the design was optimised to have a maximum flow range of 300ml/h with optimised sensitivity at a flow range of 25ml/h, which is assumed to be the normal flow range for CSF. At a flow range of 25ml/h we have a sensitivity of the sensor signal of about 140mV/ml/h. For high flow ranges >270ml/h the sensitivity is still around 5mV/ml/h. As most important result of the optimised sensor ("Packaged sensor" in Fig. 2), the response time of the sensor due to flow changes could be considerably reduced: Compared to the sensor configuration on 500µm Pyrex ("Layout" in Fig 2), we could reduce the response time for a flow step from 0ml/h – 25ml/h by a factor of 4.3 from 9.75s down to 2.25s (Response time: time to reach the +-5% end value). Looking at a flow step from 295 – 0ml/h, a response time of 4s for the optimised and packaged sensor instead of 13.5s for the sensor "Layout" was reached which means a reduction by a factor of 3.4.

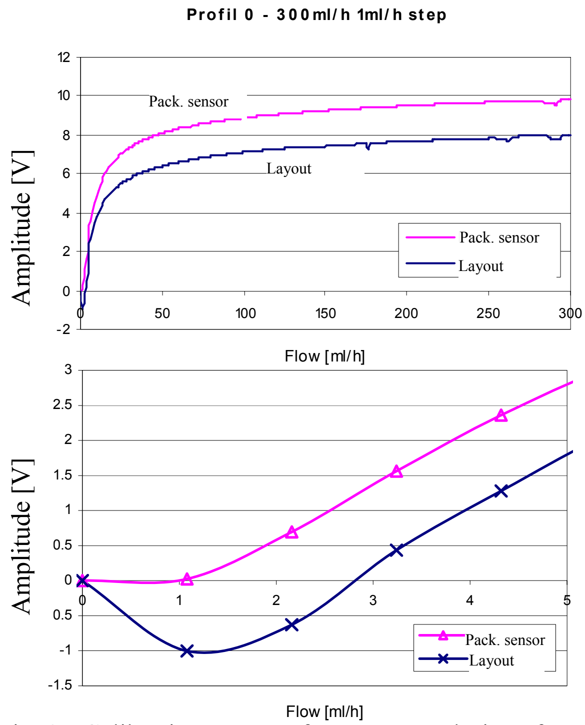

Fig. 2: Calibration curves of two sensor designs from 0ml/h to 300ml/h. A zoomed flow range from 0ml/h to 5ml/h is displayed below to show the reduced "cut-off" flow of the "Packaged sensor". "Packaged sensor" means optimised layout on a 300µm thick Pyrex with integrated flow channel; "Layout" means optimised layout on a 500µm thick Pyrex substrate

DISCUSSION & CONCLUSIONS
The performance of the sensor is very much influenced by the pyrex substrate: Due to the thermal conductivity of Pyrex (k=1.2 W/mK) that is about 2 times higher than that of water (k=0.61W/mK), the sensors sense the temperature change coming partly from the heated substrate due to thermal conduction and CSF where energy transport is caused by conduction and convection. However, Pyrex was chosen as a substrate because of its excellent biocompatibility as it is in contact with CSF.
The sensor design shows a so-called "cut-off"-flow which is a small drawback of the asymmetric sensor design as the sensor signal at the cut-off flow is identical to the signal with no flow (see fig. 2. below). Therefore, the cut-off flow had to be minimized using FEM simulations. However using an additional heater the flow can be detected correctly. For the optimized and packaged sensor on a 300µm thick Pyrex substrate, the cut off flow shows to be around 1.6ml/hr which is sufficiently small.

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