DESIGNING AN ASIC CHIP TO CONTROL AN IMPLANTABLE GLUCOSE MEASUREMENT DEVICE

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Diabetes is a widespread metabolic disorder, and having it puts people at increased risk for heart disease and stroke. There are two types of diabetes patients: type 1 patients for whom the pancreas is not producing any insulin, and type 2 patients for whom the body cells have a resistance against insulin. Patients with type 1 need continuous monitoring of their glucose value and an insulin pump that injects insulin into the body via a catheter in the blood stream. The usual procedure is that the patient measures his or her glucose value using a drop of blood, a test strip, and a monitor. Then, the patient adjusts the insulin pump, according to the value. There are several approved continuous glucose measurement (subcutaneous measurement) devices available, but they usually are used for only a few days time.

Developing the Microchip Technology

Senseonics, Inc., Germantown, MD, developed a sensor based on fluorescent technology to be used in an implantable continuous glucose measurement device. Zentrum Mikroelektronik Dresden AG (ZMDI), Dresden, Germany, partnered with Senseonics and developed a new microchip for use in that device. ZMDI's design specifications for this application-specific integrated circuit (ASIC), which is implemented as a system- on-a-chip (SoC) for control and analysis had to meet the following main requirements: LED driver, measurement and analysis of reflected light, data pre-processing, memory, wireless interface for data transfer, no battery due to extremely low power and low voltage requirements, medical certification, and special form factor.

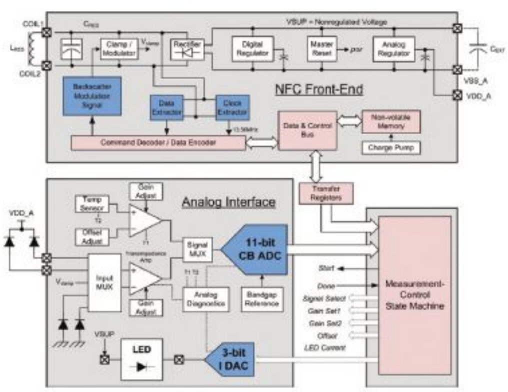

Fig. 1 – Block diagram of the SoC ASIC for continuous glucose measurements.

The ZMDI engineers selected a semiconductor technology that is usually used for hearing aids. This technology can use an operation voltage as low as 0.85V and has very low leakage currents. Two additional important criteria were the integration of electrically erasable programmable read-only memory (EEPROM), which is used to store small amounts of data that must be saved when power is removed, and on-chip photodiodes using this technology. (See Figure 1) Based on the selected technology, the following architecture has been defined:

ISO15693 (RFID) Front-End: For energy harvesting and for communication to an external reader, a wireless radio-frequency identification (RFID) interface based on the ISO15963 standard was implemented. During the development of the circuit, extreme care was taken to ensure that changes in the power supply did not cause unwanted backscatter feedback in the wireless communication. The wireless interface protocol between the chip and the reader was implemented via a “hard-wired” logic designed with a focus on minimum power consumption.

Measurement-Control State Machine: The ASIC's measurement- control block controls the analog interface unit. It also provides communication between the analog front-end and the ISO controller. The unit was designed with hard-wired logic in order to reach an optimum size vs. performance.

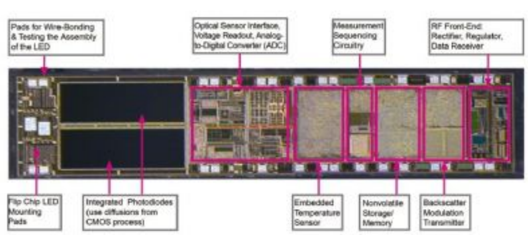

Fig. 2 – ASIC developed by ZMDI.

Analog Interface: The ASIC's analog interface block contains the LED driver, which is controlled by a 3-bit digital-to-analog converter (DAC). The DAC allows switching on the LED smoothly so that it does not cause abrupt voltage drops. The sensor signals from the integrated temperature sensor, the integrated photodiode, the optional external photodiodes, and the actual field strength of the supplying magnetic field are measured via the input multiplexer, transimpedance amplifier, and 11-bit analog-to-digital converter (ADC). The resulting data is transferred by the measurement-control state machine to the RFID interface and transmitted to an external reader.

A primary focus of the ASIC development has been power management for the chip. Because the design of the complete system is very size-limited and the receiver antenna in the implant is very small, the efficiency of the energy transfer from the reader to the device is very low, which causes only a limited amount of energy to be available for the device. Therefore, extreme care was taken to reduce power consumption in the chip as much as possible. It is also very important not to disturb the wireless communication due to abrupt voltage drops when the analog interface and, especially, the LED driver turn on. The system is designed so that blocks are only powered up if their functionality is needed.

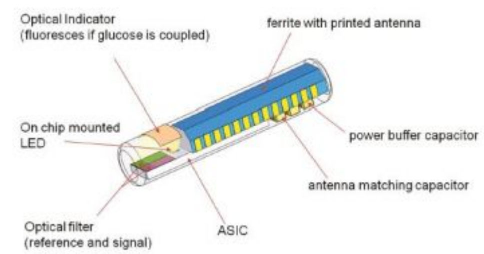

Fig. 3 – System-level design for the body of the sensor.

The chip has the following main energy states:

• Power consumption for data transfer between the reader and sensor (e.g., RF status, field strength, data transfer): 1.1 mW
• Power consumption for complete measurement cycle including driving the LED: 10mW
• Power consumption for programming the on-chip nonvolatile memory: 14mW

Since ZMDI already had extensive prior experience in the field of low-power/low-voltage design, the first version of the ASIC was fully functional and could be used for the clinical studies. Figure 2 shows the chip and identifies its respective functional blocks. The ASIC is the central unit of the implantable continuous glucose monitor. The composition of this lab-in-the-package is shown in Figure 3.

Implantation of the Sensor

The sensor's size is only 15mm x 3mm, and it can be implanted either at the wrist or at the upper arm. (See Figure 4) A special watch was developed at Senseonics for the wrist application. In this case, the watch is placed above the sensor and powers the sensor approximately every three minutes. The sensor starts the measurement procedure and sends the data back to the watch, which displays the glucose value. For use on the upper arm, a special bandage was developed that contains the reader and Bluetooth® interface. For this application, the data is sent via Bluetooth to a smartphone, which displays the glucose value and makes a statistical evaluation. The data can then be sent from the smartphone via GSM directly to the patient's physician for review. Figure 5 shows the complete system as it is currently under evaluation.

Fig. 4 – Sensor.

The sensor remains in the body for approximately six months, and then it must be replaced because the biochemical fluorescent sensor material will be bleached out. The system is currently in clinical trials in the US, Canada, Germany, and India. CE certification is expected in the first quarter of 2014. After certification, the system will be available in the European market.

This development based on the ZMDI ASIC is a first step in the direction of an artificial pancreas. The sensor measures the glucose value continuously and sends it to an external communication unit, such as a smartphone. The external unit itself can then control an insulin pump according to the data received and the complete system acts as a closed loop, which replaces the functionality of the pancreas.

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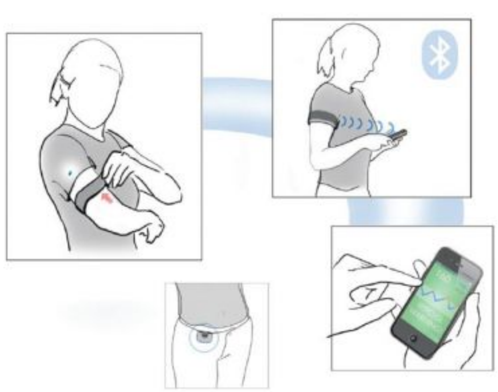

Fig. 5 – The complete system.

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