INTERGATED MICRO-INSTRUMENTATION FOR DYNAMIC MONITORING OF THE GASTRO-INTESTINAL TRACT

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Abstract - ***The introduction of microsystem technology into diagnostic devices is a rapidly growing field where low form-factor can significantly improve device access or patient comfort. In this paper we will present our results on a lab-in-a-pill device that uses laboratory-on-a-chip and system-on-chip technology to deliver analytical data from a range of sensors, and the methodology employed to build the device.***

Keywords - ***micro-instrumentation, sensors, microsystems, system-on-chip***

I. INTRODUCTION

The introduction of microsystem technology into diagnostic devices is a rapidly growing field where low form-factor can significantly improve device access or patient comfort [1]. The devices are also required to have other attributes, such as low cost, robustness, real-time data processing and, if necessary, being disposable after a single usage.

For example, the traditional endoscope with a long (several metres) and thick (at least 8 millimeters in diameter) tube is inconvenient, potentially hazardous and irritable to the patient. These shortcomings might be removed if a suitably functional capsule, or micro instrument, is employed. Such a capsule can be swallowed into the human gastro-intestinal (GI) tract with relative ease, and then be transported from the mouth to the anus, where it is egested normally, by the natural peristaltic motion of the gut. The capsule can be equipped with a large diversity of complex electronics, including sensor interfaces, signal conditioning, a microprocessor core, digital signal processing (DSP), and wireless transmission technology. The micro instrument is required to act as a front-end signal/imaging sensor, submitting the data via wireless transmission to an ambulatory data recorder or networked device worn by the patient. One example of such a device is the camera-in-a-pill device that has recently been given FDA approval [2].

To achieve such a micro instrument, it is desirable to use a design and implementation methodology that lends itself to low cost and can achieve a low form-factor and low-power consumption. Such a methodology is that of system-on-chip (SoC) technology [3], whereby a system containing many intellectual property (IP) blocks can be rapidly designed. In this paper we will present our results on such a lab-in-a-pill device that uses laboratory-on-a-chip and micro electronics technology to deliver analytical data from a range of sensors, and the methodology employed. Since design re-use is an essential component of the SoC methodology, we anticipate that this first implementation will form the basis for development of future micro instruments.

II. SYSTEM SPECIFICATION

In order to achieve a high degree of sophistication e.g. multiple sensors in a single device and multiple devices being used simultaneously by many patients (e.g. in an out-patient clinic), complex electronic and wireless technology are required. In order to facilitate this we have designed an application specific integrated circuit (ASIC) incorporating preamplifiers, signal multiplexors, Analog-Digital-Converter (ADC), Digital-Analog-Converter (DAC) and system controller. The ASIC is used for all the sensor electronics, including data conversion, system scheduling, coding and transmitter control. A finite state machine is used for task scheduling, although in future reconfigurable systems this will be replaced by a small microprocessor. Several de-powering strategies, such as disabling idle function blocks during different task phases have been designed and implemented. The design also employs a simple DSP compression algorithm to achieve low-power serial bit-stream transmission. The algorithm makes decisions on when it is necessary to start the transmitter by comparing the most recent sample with previous samples. The technique is especially effective when the measurement environment is quiescent, a physical condition that occurs in the GI tract.

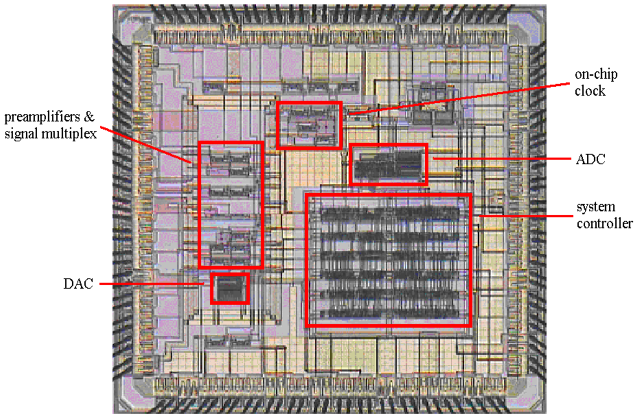


Fig. 1. An optical micrograph of the complete chip.

Other features of the ASIC include an on-chip clock oscillator and serial bit-stream interface to off-chip wireless circuit. The timing precision of the oscillator is very poor due to the fabrication tolerance of on-chip resistors and capacitors, but this is not important for total system specification. The nominal clock frequency of the RC oscillator is 32 kHz. The low clock frequency provides an adequate sample rate whilst keeping dynamic power dissipation to a low level. The ultimate synchronisation/time stamping for the whole micro instrument will be provided by an accurate clock in the ambulatory data recorder. Fig. 1 is the micrograph of the complete ASIC. The ASIC chip, with 16,000 gates, is pad-limited to be 5 mm x 5 mm, since many test pins were incorporated into the design. Future prototypes will contain more functionality on a smaller SoC.

The ASIC is accompanied by two sensor chips, one of which is a modified commercial product and the other of which was made in-house. The sensor chips are comprised of a dissolved oxygen sensor, an ion-selective field effect transistor (ISFET) pH sensor, a PN-junction diode temperature sensor and a dual electrode direct contact conductivity sensor. The complete sensor set is fabricated on two of 5 mm x 5 mm silicon chips (Fig 2).

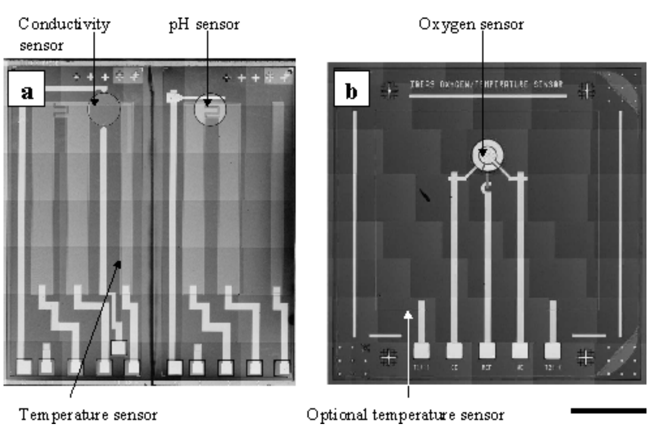


Fig. 2. Two sensor chips

The capsule also contains a simple but small (less than 6 mm on a side) radio transmitter, the transmitter has its own precision oscillator to which the receiver built in ambulatory data recorder is tuned. As a consequence, the transmitter can be turned on at random time intervals and the data still be collected by the ambulatory data recorder. The capsule has a simplex communication link to the data recorder that can handle data from several capsules.

Interconnection between sensor chips and the ASIC, the ASIC and the transmitter is achieved at present by wire bonding to a glass-fibre substrate or by direct connection to adjacent chips. Future implementations will employ more robust packaging technology including flip-chip bonding and flexible polyimide interconnect for the antenna. The power source comprises two standard 24mAh, 1.5V silver oxide button cells. The entire micro instrument, which includes the ASIC, the two sensor chips, the transmitter, the antenna and the power cells, can be easily fitted into a single 40 mm x 15 mm capsule as shown in Fig. 3.

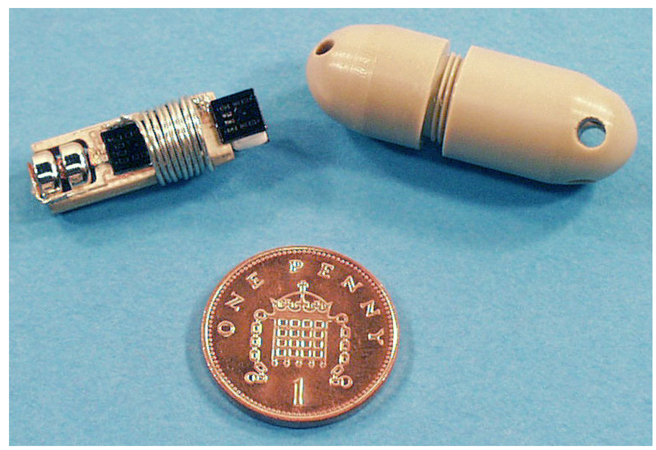


Fig. 3. A micrograph of the entire micro instrument.

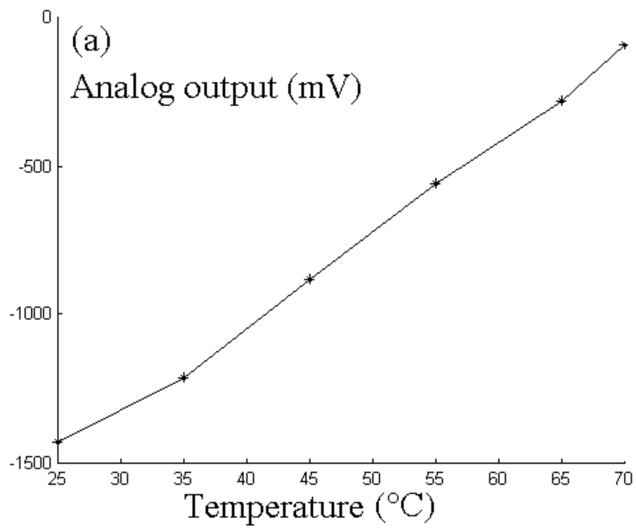
III DESIGN METHODOLOGY

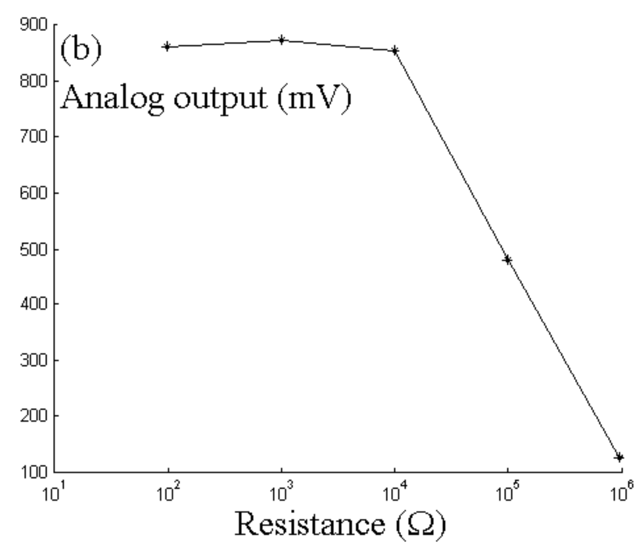
The design methodology we have employed in order to achieve the ASIC uses state-of-the-art EDA solutions that have been selected to provide a relatively straightforward design flow. Cadence® tools are used for analogue simulation, digital simulation and back-end design tasks. Synopsys® tools are used for digital synthesis of VHDL/Verilog behavioural descriptions [4]. Foundry services are provided via Europractice. The foundry service provider is Austria Mikro Systeme (AMS), and the prototype SoC discussed in this paper has been implemented on a 3 V, 2-poly, 3-metal 0.6 micron CMOS process. A key advantage of using the AMS service is the availability of well specified analogue and digital IP blocks, such as ADCs and DACs that have been used to build our design.

IV. RESULTS

The ASIC has been successfully fabricated and tested. The current consumption of the ASIC from a 3 V source is 1.1 mA. In addition, the sensors require an average current of 0.5 mA and the transmitter requires an average current of 1.0 mA when operating at a duty cycle of 15 %. The micro instrument can operate for up to 10 hours under these conditions.

Testing of the ASIC and sensors was carried out on a laboratory testbench. Fig. 4 shows *in vitro* raw analog data from the temperature, conductivity and pH channels that we have so far completed testing.. The voltages are specified from the 0 V connection of a ± 1.5 V power connection (note that this is simply a matter of naming convention). The correct functionality of oxygen sensor channel has also been verified but full testing awaits the completion of the sensor device. The results are summarised in Table 1.





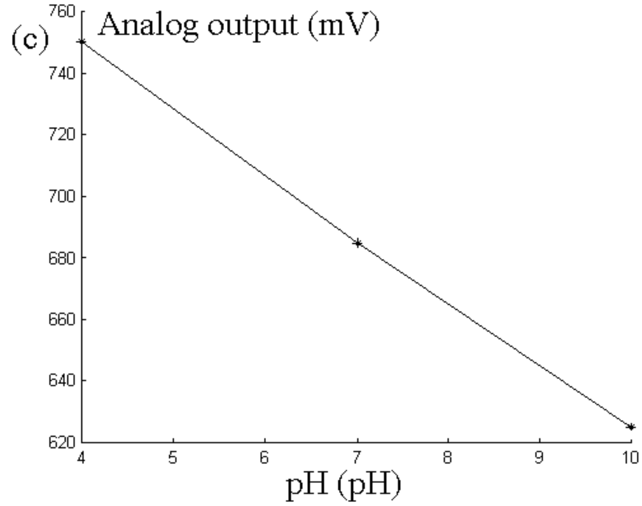


Fig. 4. *in vitro* test results of the temperature (a), the conductivity (b) and the pH (c) channels

Table 1. Summary of the temperature, conductivity and pH channel properties.

Channel	Dynamic range	Linearity (cross-correlation)	Resolution
Temperature	25 °C – 70 °C	0.829	0.4 °C
Conductivity	0.05 mS/cm – 10 mS/cm	0.995	0.02 mS/cm
pH	pH 1 – pH 10	0.993	0.64 pH

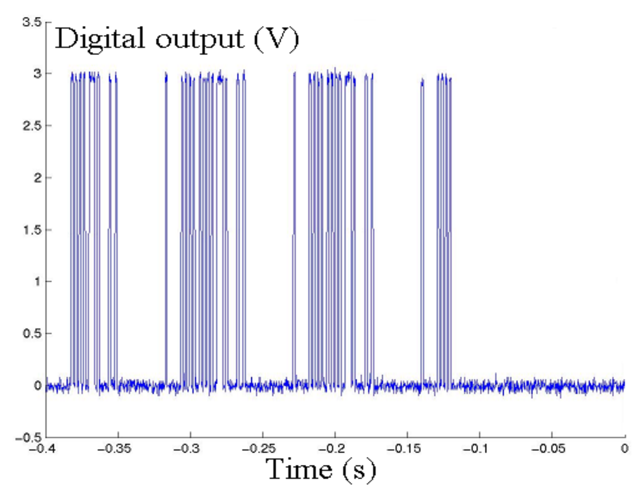


Fig. 5. Output bit stream from the system controller

The digital logic of the ASIC, including the DSP compression algorithm, has also been tested. All data from each channel are sampled with 8-bit resolution and communicated off-chip as a single interleaved data-stream. Fig. 5 shows the output bit stream it generated. The algorithm, implemented as hardware on the chip, has been tested using 67 sets of emulated data from a 24-hour gastric pH measurement from prior art [5]. The raw data has an average kurtosis of 5.3 ± 2.8 and an auto-correlation of 0.99 ± 0.01. The compression ratio, here defined to be the raw data-stream length/compressed data-stream length, is 2.1 ± 0.1 with a distortion degree of 0.8% ± 0.1%. Since the compressor is simple and generates a small system overhead (< 10%), this translates into a power saving of approximately 50% for the off-chip transmitter circuit.

V. Conclusion

We have demonstrated a micro instrument that integrates laboratory-on-a-chip sensor technologies and an ASIC for analysis and diagnosis of GI dysfunction. In the future we will extend the work to use a more advanced SoC methodology to enable the rapid prototyping of a range of micro diagnostic device and implementations that will lead to further miniaturisation and more sophisticated system specification, which include greater sensor diversity, information fusion and dynamic reconfigurability.

VI. Acknowledgments

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