INTRODUCING A WIRELESS, PASSIVE AND IMPLANTABLE DEVICE TO MEASURE ECG

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Abstract: A concept aiming at a wireless, passive and implantable device to measure ECG is presented. Modelling as a tool in the designing and results interpretation phase is discussed. Electronics design of the prototype is introduced in more detail and some measurement results concerning the current consumption, operation time and operation distance of the device are presented. The biocompatibility of the device is discussed in general and some possibilities for coating the device are considered. Future considerations concerning the electronics design and miniaturization together with current consumption reduction are discussed in the end.

Introduction

Sensor technology for ambulatory and implantable human psychophysiological applications has been developed to enable measurements of biosignals from inside of the human body. With implantation, one reduces the amount of disturbance the measurement device causes to the actual measurand, the phenomenon to be measured. [1-2] Motion artefacts and powerline interference coupled to the measurement wires can be minimized by implanting and fixing the measurement sensors and using wireless power and data transmission. So far the devices have been often battery run, e.g. [3], which makes the operating time finite, degrades the patient safety and does not enable long term implantation due to need for battery change. The new proposed device is powered by an inductive link which makes it ideal for long term use.

Modelling of physiological systems is combined with the electronics designing and biomaterial techniques to obtain desired result with good accuracy in relatively short time. The physiological signal is modelled with computer software which creates a basis for the estimate of the measured signal. This estimate can be used to guide the design of the device, e.g. in determining the separation of the electrodes and their size.

Combining modelling of physiological systems and measurements with electronics designing and biomaterial techniques enable an effective means of developing implantable physiological applications.

The paper deals first with the modelling aspects and methods where after the electronics of the prototype are discussed in more detail. The electronics section is divided into two parts first of which deals with the reader device and the latter with the implant. Some measurement results are presented in this section. Biocompatibility of the device is discussed shortly by means of the coating and finally, some conclusions and future considerations are presented.

Modelling

Mathematical modelling of physiological systems is used to understand the electrical phenomena of the human body. When designing implants, information regarding the effects of the implantation and the implant itself on the measurement should be available to minimize the *in vitro* and clinical testing.

Modelling offers rather inexpensive and effective means of studying and demonstrating the effects of implantation on the ECG measurement prior to any clinical tests thus providing the designer with valuable information. Modelling can be used e.g. when the effects of ECG electrode implantation on measured signal are studied and compared with surface potential measurements [4].

Use of modelling in designing the implants could reduce the need for expensive testing and iteration rounds in investigating different characteristics of the implant. The effect of dimensions could be tested with models. Thus modelling can be a part of designing and testing prior to any clinical tests but it does not of course eliminate the need for them at later stage.

The lead field and reciprocity approach [5] has been applied with finite difference method (FDM) [6] in the modelling of the implantable bioelectric measurements. With these methods we have studied the effects of implant dimensions and implantation on the measurement sensitivity of the implantable ECG monitor. The effects of all cardiac source locations in the model can be calculated at the same time with the lead field and reciprocity approach. This provides a straightforward approach to calculate and illustrate changes in the properties of the ECG system to detect cardiac sources, i.e. sensitivity distributions. The effects

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of various designs can be tested and reviewed directly with the methods.

Electronics

Power for the device to be implanted will be fed through an inductive coupling between an external coil in the reader device and a coil on the implant. The reader device generates a time varying magnetic field, which induces voltage to the coil in the implant. The power induced has to be high enough to enable measurement of the biosignal in the implant and transmission of the result back to the reader device. See Fig. 1 for schematic of the reader and implant.

Reader device

Purpose of the reader is to transfer power and possibly data to the implant, receive the measurement data and transfer it to the computer. The reader device is designed around read/write –base station by Atmel accompanied with a microcontroller by Microchip. The base station operation frequency is set at 125 kHz. Reader is designed to be used with 9 V batteries which make it portable.

The antenna of the reader device is constructed of a series resonance circuit consisting of a coil, capacitor and resistor. The series resonance circuit is chosen to the reader device because it maximizes the current through the circuit. This is especially advantageous in the power transmitting end of the system. A series resistance is needed to control the bandwidth of the antenna. The bandwidth has to be sufficient for data transmitting purposes. The minimum inductance of the self wound coil is determined by the used serial resistance, band width demands and resonance frequency. In the prototype the inductance was measured to be 511 μH.

The received signal at the antenna is fed into the envelope detector which separates the modulation from the carrier. The envelope detector is connected to the base station circuit which amplifies and treats the signal so that it can be processed in the microcontroller. The microcontroller has the program to interpret data from the implant back to digital form. From the microcontroller, the data is transmitted over RS-232 serial cable to the measurement computer or a blue tooth module made at Tampere University of Technology is used. A real time measurement program made in LabView is used to visualize the results and store the data into file.

Implant

A transponder by Atmel is connected to a parallel resonance circuit consisting of coil and capacitor. The circuit functions as an antenna that receives the magnetic field transmitted by the reader device and by parallel resonance the induced voltage is maximized. A commercial 1.08 mH coil made by Coilcraft is used as the receiver coil. The coil is designed to be used in RFID applications and its frequency behaviour at 125 kHz is therefore very good. Otherwise it is not too good a choice since it is a toroidal coil instead of planar. This limits the orientation of the implant and attenuates the induced voltage. A planar coil of diameter 52.0 mm was also constructed by wounding it on a plastic chassis. This coil was not, however, implemented to the prototype due to its size and unsuitability for implantation. The time variant voltage is rectified and regulated by the internal regulator of the transponder typically to 2.9 V. An external capacitor of sufficient high value is connected to the transponder to secure current supply to the accompanied circuitry during transmission.

The power supply to the implant is single sided and since ECG-signal is, however, a bipolar phenomenon, a reference voltage level is needed between the two extremes of the DC-potentials. The reference voltage is set to half way between the ground of the implant and positive power supply voltage, V_{cc}. Reference voltage is produced from V_{cc} simply by two resistors of equal values and buffering the voltage trough an operational amplifier. The reference voltage is used as virtual ground in the instrumentation amplifier that is used to sense the ECG-signal.

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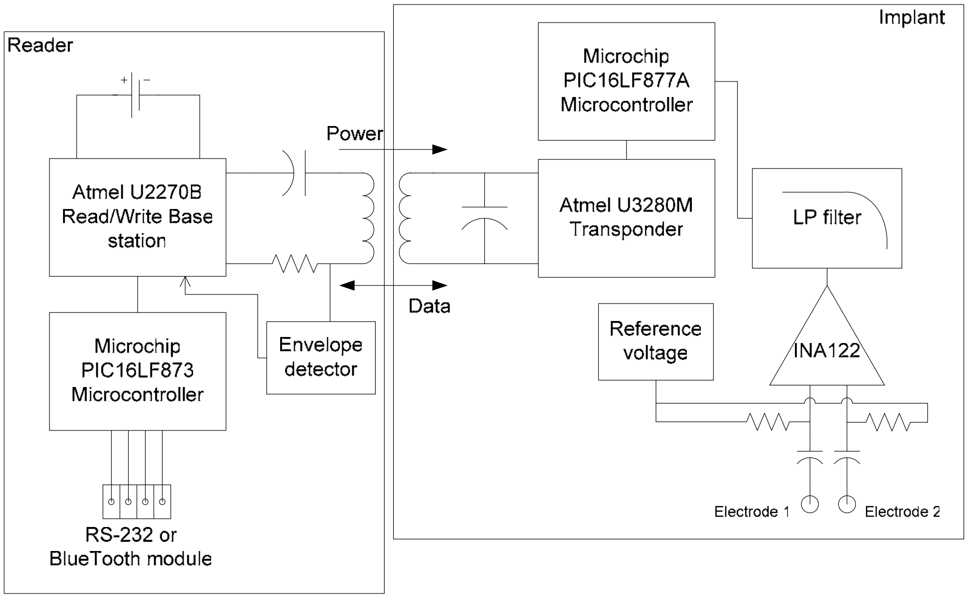

Fig. 1 Schematic figure of the implantable ECG-monitoring device.

The ECG-signal is measured differentially with Au-electrodes that according to [7] show a good biocompatibility and corrosion behaviour in measurement purposes. The electrodes are connected to a simple RC-high pass filter with pole set at 0.52 Hz. The high pass filter is needed to avoid the DC voltage level in the input of the instrumentation amplifier caused by the different half cell potentials of the electrodes. The filtered signal is fed into a microwatt instrumentation amplifier by Burr&Brown, INA122UA, and amplified by approximately 41 dB. The gain defines the interval of the input signal amplitude in *in vitro* tests and is sufficiently high to exceed the noise level of the electronics even with lower signal amplitudes.

According to [4], the implantation of the ECG electrodes 5 mm underneath the skin has an effect of 2 % on the magnitude of the measured ECG signal compared to surface measurements at corresponding locations. In the surface ECG measurements, the average signal amplitude is close to 3.5 mV [8]. Gain of 41 dB will result in signal amplitude of 400 mV at the output. The V_{cc} of the implant being 2.9 V, there is no danger of clipping of the signal but the margin to the maximum possible amplitude is still relatively great. Therefore, some re-design is needed when going from *in vitro* to *in vivo*.

The measured analogue signal is fed to a 10-bit A/D-converter inside the Microchip microcontroller. The sample frequency of the A/D-converter is 360 samples per second which means, according to Nyquist's criteria, that the measured signal must be limited to maximum frequency of 180 Hz. To avoid aliasing in the conversion, a low pass filter is applied before the signal is fed to conversion. The filter is of a Sallen-Key type, second degree active filter, with pole set at 151 Hz to secure the anti-aliasing purpose.

From the microcontroller the digitized signal is transferred to the transponder which transmits the signal to the receiver device. Modulation technique used in the transmission is Differential Bi-Phase (DBP) coding which enables better fault tolerance and possibility to synchronize the data in the receiver end. One sample consists of two bytes, i.e. a sample is 16 bits long. Since the A/D-converter produces a 10-bit result which represents the measurement result, the six first bits of the latter byte are zeros. This is, however, a good thing since these bits can be used i.e. in synchronizing the signal.

Measurement results

Due to unfavourable coil orientation and cross-sectional area, especially in the implant, the operation distance of the implant is as long as planned. According to measurement results reported in details in [9], the operation distance of the implant will be less than 7 mm when the transmitting and receiving coils are placed side by side. The operation distance seems to be 7 mm at maximum irrespective of the coil used in the transmitter end. This is not, however, sufficient for implantation purposes where the depth would be in the range of 5 mm and the tissue will probably cause some attenuation on the signal. The small operation distance of the implant is caused by the small coupling coefficient between the transmitter and receiver coils which leads to low power supply capacity of the inductive link. When the separation between the transmitter and receiver coils is increased, the flux density at the receiver coil decreases which leads to smaller induced voltage. The transponder can only supply voltages over 2.6 V which leads to rapid shut down -mode of the transponder.

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The current consumption of the reader device is dependent on the antenna used. The Coilcraft antenna consumes less current than a self-wound planar antenna with diameter 52.0 mm due to its higher impedance at 125 kHz. Measurement results are shown in Table 1. Due to high current consumption of the reader, the operating time with a standard 1000 mAh 9 V battery remains quite low, under one day in any case. The situation would be better if the biosignal to be measured would not have to be measured constantly, i.e. temperature.

The implant current consumption has been suppressed to minimum by the choosing only very low power components to be used in the device. The greatest contribution to the current consumption of the implant is caused by the microcontroller, approximately 670 µA [9].

Table 1 Measurement results of the reader device and implant. [9]

Property	Value
Current consumption (reader)	
Coilcraft RFID coil	52.5 mA
52.0 mm self-wound coil	70.5 mA
Current consumption (implant)	950 µA
Operation time, reader (1000 mAh)	14 – 19 h
Operation distance	7 mm

Biocompatible coating and sterilization

Demand of implantation makes the biocompatibility of the device a critical parameter. Implantable wireless electrical device will be exposed inside a human body to a highly corrosive and aggressive electrolytic medium in mechanically stressful conditions. The coating of the implant has to be biocompatible in order to prevent undesirable tissue reactions, such as inflammation or even necrosis. The coating should not be penetrated by the particles or molecules of materials and surrounding tissue, which may react chemically resulting in corrosion or toxic products to be released at the tissue interface.

A hermetic sealing of the electronics is the aim of the coating but is difficult to achieve in flexible form. Silicone would be an ideal material to coat the implant thanks to its superior flexibility and biocompatibility. The shortcoming in the use of silicon is its strong tendency to absorb body fluids. Electronics of the implant should be totally protected against body fluids since the fluids are conductive and cause short circuits in the electronics.

Another possibility to coat the implant is with epoxy. It can be also made somewhat flexible if only a thin layer is applied. The problem with epoxy is also the absorption of body fluids and since epoxy will lose its flexibility when applied in thick layers, it may not be a feasible solution.

Alternative possibilities for coating the implant are parylene and titanium oxide (TiO_2). Parylene is shown to be biocompatible by *in vitro* tests in [10]. TiO_2 is proven to be very bio- and blood compatible material [11]. This is due to oxide layer on top of Titanium which also enhances the corrosion resistance of the TiO_2. Oxide has also been shown to inhibit Titanium ion release.

The coated implant has to be sterilized prior to implantation so that it would not carry any bacteria into the body. There are several possible sterilizing methods.

Autoclave sterilization is based on heat and moisture curing of the surface. Typical autoclave procedure is realized at 125 degrees Celsius for 15 minutes under several bars pressure. The problem in this method is the heat tolerance of the electronics and coating together with very rapid water absorption to the coating.

Gamma-ray irradiation is commonly used sterilization method for medical implants. The doses vary but for an implant to be located near heart, the degree of sterilization should be high. Gamma-ray irradiation being very energetic irradiation causes problems to the electronics; latch-up will occur in most semiconductors with small area and narrow gate oxides in CMOS components. This problem was proven in prototype sterilizations.

Ethylene oxide sterilization is the third possibility yet not fully without problems. There is namely a possibility that the procedure will leave toxic residue to the surface of the implant which is not desirable.

Conclusions and future considerations

A prototype of an implantable ECG-monitoring device has been designed and constructed. Modelling of physiological systems and signals has been used to guide the design of the implant. Electronics for the implant has been made with some shortcomings. The operation range of the device is limited to 7 mm which is not sufficient for implantation. With careful antenna design and simulation the operation range can be enhanced. The current consumption in the implant is relatively low, 950 µA, but could be lowered by choosing another microcontroller. With operating voltage of 2.9 V this means a power consumption of 2.8 mW which can be regarded as very low. Electrodes for the prototype were chosen to be of gold but research has been done, [12], and is being done to explore electrode materials with even lower noise and better corrosion resistance.

The reader device is not very portable in the present state since its current consumption will empty 1000 mAh 9-volt battery in at least 19 hours. The current fed into the antenna coil is the dominant part of the current consumption and with better antenna design the coupling coefficient between the reader and implant could be achieved and current consumption decreased.

In the future, electronics inside an implantable device can be miniaturized using 3D packaging technology. When thinned chips and sufficiently thin substrate are used the package thickness can be lowered down to 0,8mm. In order to maximize miniaturization, passive components can be integrated on silicon chips and interconnection of the chips can be done using flip chip technology. With this technology components do not have traditional plastic packages, hence space is saved. Thin and also flexible substrates, e.g. polyimide, could also be used.

A functioning prototype of an ECG-implant is constructed at TUT that works *in vitro* and preliminary measurements are performed with it for the time being. Next stage prototype has also been constructed with one flip chipped component, the transponder in the middle, see Fig. 2.

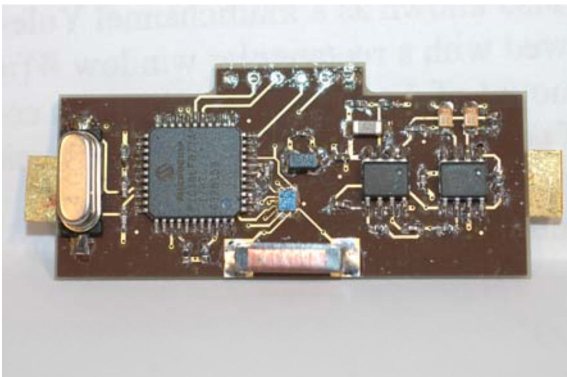

Fig. 2 Photograph of the first implant prototype with transponder flip-chipped.

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