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Glucose Monitoring System Based on Osmotic Pressure Measurements

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Abstract: This paper presents the design and development of a prototype sensor unit for implementation in a long-term glucose monitoring system suitable for estimating glucose levels in people suffering from diabetes mellitus. The system utilizes osmotic pressure as the sensing mechanism and consists of a sensor prototype that is integrated together with a pre-amplifier and data acquisition unit for both data recording and processing. The sensor prototype is based on an embedded silicon absolute pressure transducer and a semipermeable nanoporous membrane that is enclosed in the sensor housing. The glucose monitoring system facilitates the integration of a low power microcontroller that is combined with a wireless inductive powered communication link. Experimental verification have proven that the system is capable of tracking osmotic pressure changes using albumin as a model compound, and thereby show a proof of concept for novel long term tracking of blood glucose from remote sensor nodes. *Copyright © 2011 IFSA.*

Keywords: Glucose sensor, Continuous, Semipermeable membrane, Osmosis, Osmotic pressure.

1. Introduction

Diabetes mellitus is a metabolic disorder which entails a reduced or absent blood glucose control in the body by means of insulin dependence (Type 1) or insulin intolerance (Type 2) [1].

In order to prevent severe long term complications affecting body tissues and organs caused by diabetes, the patients need to follow a tight metabolic control of the disease [2], in which the blood glucose value is tracked throughout the day. This is currently achieved by using traditional blood glucose meters based on the enzyme sensor technology developed by Leyland C. Clark [3] in 1962. This method requires manual sampling of blood by puncturing the finger and placing a drop of blood on a disposable sensor strip of the measuring device several times a day. The procedure is quite painful and the accuracy of the measurements relies on the number of samples performed.

This procedure can be troublesome especially for the young and elderly suffering from diabetes which requires additional medical assistance at home during day time as well as during sleep (Ambient Assisted Living) [4-6]. It is clearly a need to develop a glucose monitoring system that both can provide glucose levels data continuously and to reduce the number of measurements required to keep the blood glucose under control [7-11].

Osmotic detection of glucose represents a novel sensing technology that aims to conduct practically pain free measurements for the patient. The power conservative nature of the sensor as well as the adaptability to miniaturization by microfabrication will make the monitoring system small enough to permit subcutaneous implantation under the skin by injection alone. Thus there will be no requirement for surgery [12].

The main reason to believe that minimally glucose measuring systems are one of the most accurate and promising alternatives to the traditional measuring method [3] relates with the fact that the sensors are located inside the human body (in vivo), performing measurements at the location of the parameter [13].

Additional advantages are the use of chemically inert materials (biocompatible) that increases the operational lifetimes of the implant [12, 14], as well as the sensing technology being inherent simple and thereby extremely power conservative [14]. Besides these characteristics, the sensor does not consume any reagents nor generate any toxic product that could disturb the accuracy of the preformed glucose measurements [14].

This paper presents a prototype glucose monitoring system based on an osmotic pressure sensor, which aims to estimate blood glucose levels by detecting the concentration changes of glucose in the interstitial fluid of human tissue. This pilot study describes the implementation of an osmotic glucose sensor with an amplifier unit and a microcontroller operated by wireless communication.

The osmotic pressure response of the sensor was first simulated according to in vivo conditions of the human body (continuously cycling glucose concentrations at body temperature) over a period of time.

Albumin was used as a model compound for the experimental assay that was tested out in subsequent trails.

2. Materials

The block diagram depicted in Fig. 1 illustrates the operation of measurements carried out by the proposed glucose monitoring system.

The pressure transducer detects the osmotic pressure induced from the interstitial fluid by glucose concentration changes. After the resulting signal is amplified by an instrumentation amplifier, the microcontroller will evaluate and process the received signal by means of a 10 bit ADC (*Analog-to-Digital Converter*). The processed signal will be then transmitted by RF (radiofrequency) to a

receiving unit (reader), which will display the received signal and send sound alarms if the glucose levels are not within normal limits (hypoglycemic and hyperglycemic events). The use of inductive coupling would provide means of a power supply to the transponder, and thus avoiding the requirement of batteries.

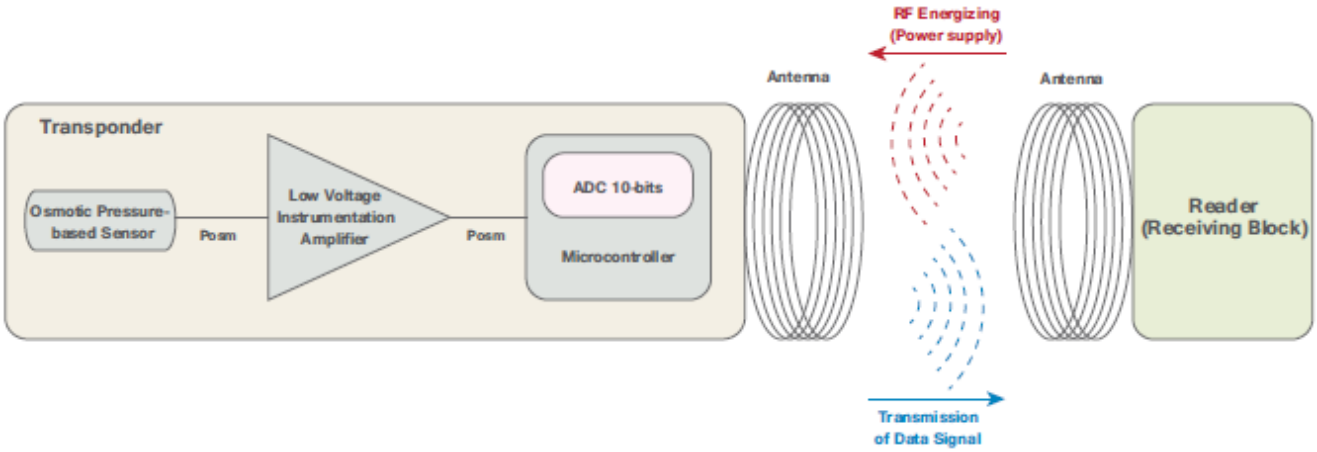

Fig. 1. Block Diagram of the proposed glucose monitoring system.

2.1. Sensor Prototype

In the presence of low glucose concentration in the interstitial fluid, the water molecules diffuse down the concentration gradient (from the high solute concentration medium to the low solute concentration medium) through a nanoporous (semipermeable) membrane that separate a reference solution kept within the osmotic chamber of the sensor from the external environment. As a result of the attempt to stop this osmosis phenomenon and to achieve concentration equilibrium, the osmotic pressure in the reference chamber increases. In contrast, an increase in glucose concentration in the interstitial fluid will implicate the passage of water from the reference chamber of the sensor back to the interstitial fluid through the semipermeable membrane, triggering a decrease in the osmotic pressure.

Therefore, osmotic pressure is a result from the diffusion of water down its own concentration gradient through a semipermeable membrane [15] separating two mediums of different solute concentration:

$$\Pi = i \sum c_i \times R \times T \tag{1}$$

The osmotic pressure Π (bar) is expressed as the molar concentration of dissolved components (solute in solution), c_i (M or mol·L^{-1}), adjusted for the Van´t Hoff correction factor (number of species of the ionized solute), i, the universal ideal gas constant, R (8.316 J·K^{-1}·M^{-1}), and absolute temperature in Kelvin, T (K) [14].

The osmotic sensor prototype (Fig. 2) was supplied from Vestfold University College (HVE), Norway. The sensor was constructed from 316L stainless steel and used to explore the sensor and membrane characteristics in a reference system. The 16 mm diameter prototype incorporates in its base (A) an embedded 2x2 mm^2 large silicon MEMS absolute pressure transducer with a dynamic range of 15 psi (1.03 bar) (*SW415 PRT, SensorNor, Norway*). Due to the use of an absolute pressure sensor, another pressure transducer with identical operational characteristics needed to be used as reference sensor to sense the atmospheric pressure and to compensate its variations [12].

The pressure transducers where attached to a silicon carrier with epoxy (*Araldite 2020, Vantigo, Switzerland*), connected by wire bonding and insulated by Epotek H70 E-2 (*Epoxy Technology Inc., USA*), prior to soldering leads to the silicon carrier [12].

As illustrated in Fig. 2, a 9×1.5 mm O-ring (*Kalrez, Dupont, USA*) separates the base (A) from the front plate (B) in which a 12 mm diameter reverse osmosis (RO) nanoporous polyamide membrane with a molecular-weight-cut-off (MWCO) of 0 Dalton (Da) was incorporated. A 0.3 mm stainless steel laser machined support plate (C) was used for stabilization of the nanoporous (semipermeable) membrane [12].

The assembly of the sensor prototype was completed by attaching the front plate (B) to its base (A) by means of eight 1.0 mm screws. This constitution permits the formation of a shallow 0.5 mm high reference chamber between the base, semipermeable membrane and the now compressed O-ring. Prior to attaching the front plate to the base, this reference chamber was filled with a reference solution of constant osmotic strength, in which the osmotic pressure will be generated through interactions between this reference solution and the solute concentration outside the sensor [12].

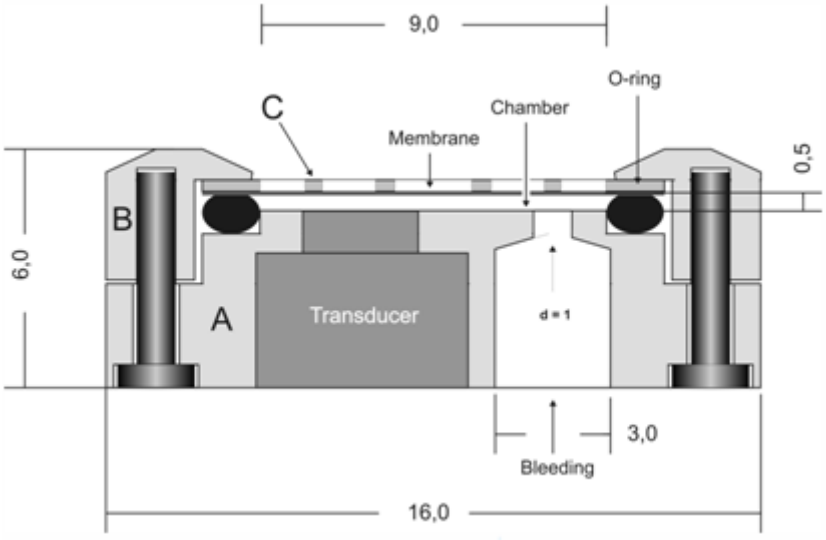

Fig. 2. Cross sectional view of the osmotic pressure sensor. The assembly of the sensor prototype was made such that the pressure transducer is opposing the semipermeable membrane, forming a reference chamber in between. All units in mm.

2.2. Low-Voltage Instrumentation Amplifier

The instrumentation amplifier that will be implemented in our glucose monitoring system is illustrated in Fig. 3. This amplifier unit consists of a buffer amplifier (Op Amp 1 and Op Amp 2) and a basic differential amplifier (Op Amp 3).

For the implementation of these amplifier units, low-voltage operational amplifiers (OPAMP) will be used (Fig. 4.). This type of OPAMP is ideal for the implementation of a low power consumption glucose monitoring system. Thus, the inductive coupling used for the RF data transmission could also serve as the form of power supply of the implantable glucose monitor. It is also relevant to refer to the need of using a low power consumption microcontroller.

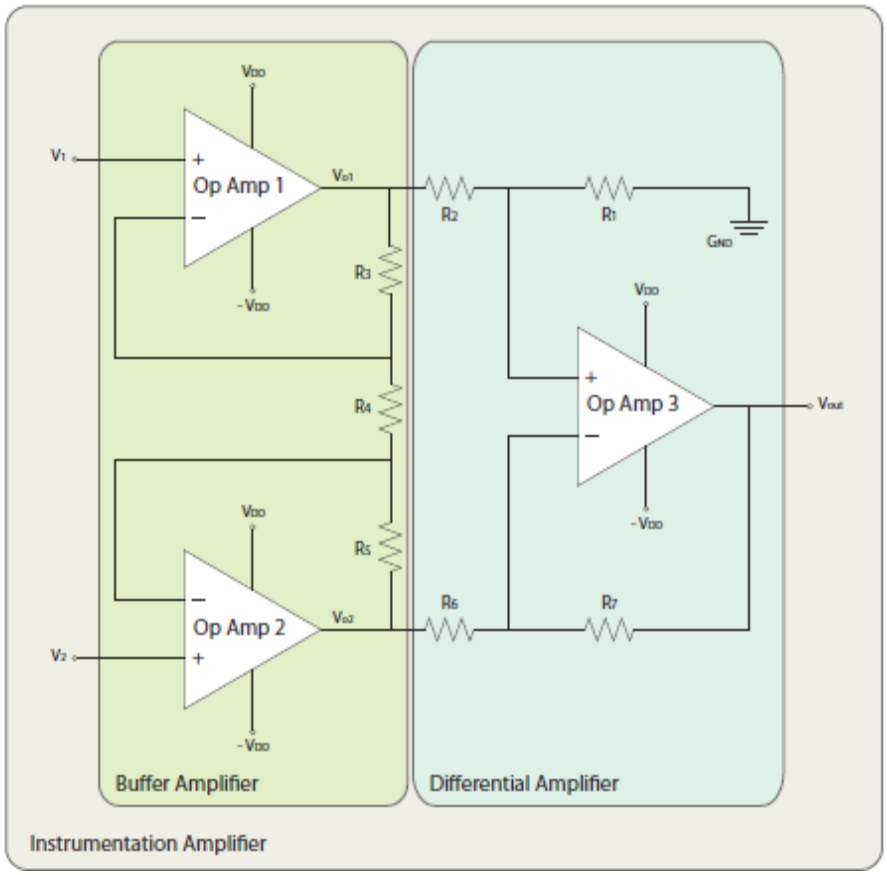

Fig. 3. Conventional Architecture of the three op-amps based Instrumentation Amplifier [16].

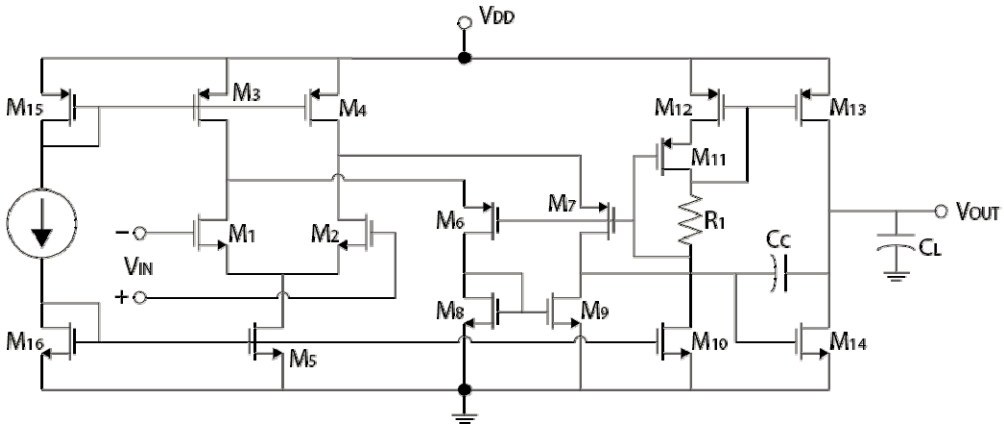

Fig. 4. Example of a low-voltage, two-stage operational amplifier (OPAMP) [17].

3. Methods

3.1. Pre-Amplifier Unit and Data Acquisition Circuit

In order to be able to test the glucose monitoring system we make use of macro devices that incorporates two amplifiers, a microcontroller, an osmotic sensor and a reference transducer. Thus, the developed pre-amplifier and data acquisition unit is illustrated in Fig. 5.

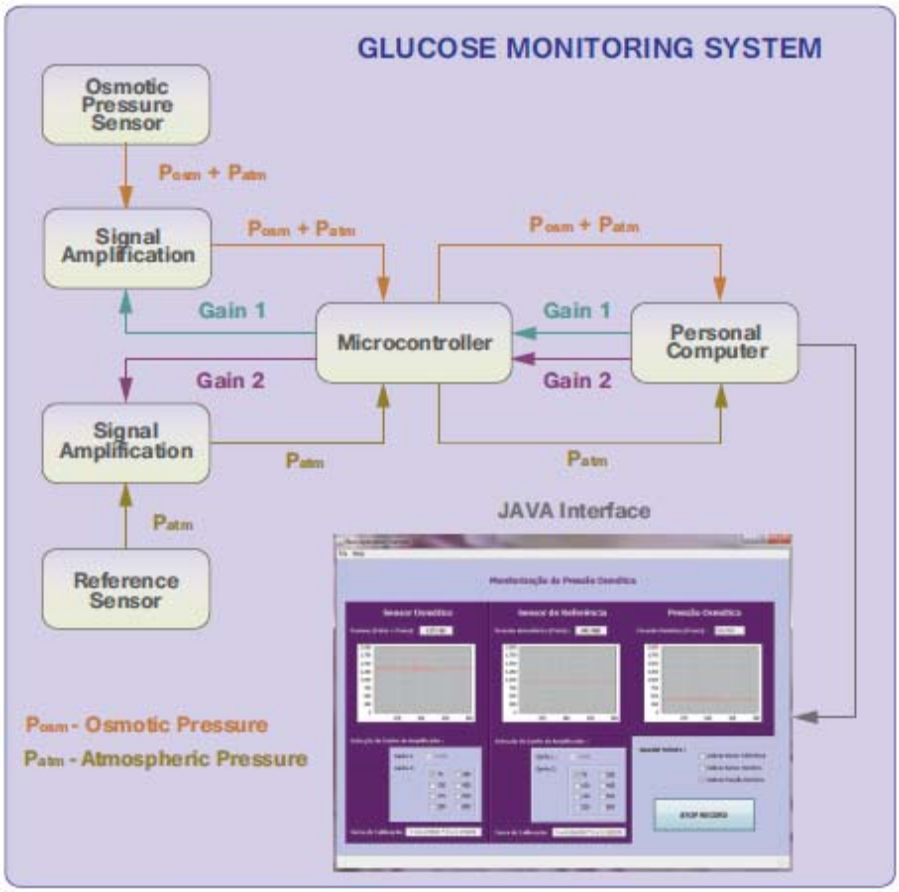

Fig. 5. Block Diagram of the developed pre-amplifier and data acquisition unit.

Both pressure transducer (osmotic pressure sensor and reference sensor) are connected to pre-amplifier units with programmable gain (*AD8556 - Digitally Programmable Sensor Signal Amplifier with EMI Filters*) that allow its amplification in such a way that the signal dropouts and noise are reduced, avoiding significant detrimental effects in both stability and resolution of the system.

Prior to the input in the microcontroller (*PIC18F2610*) where signal data processing is performed, the output signals from these amplifier units are filtered by means of 1st order passive low-pass filters with cutoff frequency of 500 kHz.

The used microcontroller incorporates a 10-bit analog-to-digital converter module (ADC), offering both a higher resolution and a serial port communication (RS-232) of the resulting sensor data to a personal computer with a JAVA interface.

As explain previously in this paper, the osmotic pressure transducer is absolute and for that reason it detects both osmotic pressure as well as atmospheric pressure. Thus, the reference transducer of the system is only used to cancel atmospheric pressure variations.

The developed JAVA interface captures both resulting processed sensor signals and the osmotic pressure is a result of the difference between these two sensor signals, which is displayed as well as the two original sensor signals.

The same Java interface allows the user to define and change the gain values of each of the amplifier units, which can be programmed for a range from 70 to 800 V/V.

3.2. Experimental Assays

In order to complete the experimental assays in means of testing our glucose monitoring system, both pressure transducers (osmotic pressure sensor and reference sensor) need to be previously calibrated.

The calibration process of the osmotic sensor was based on exposing the pressure transducer to predefined amounts of pneumatic pressures. This was achieved by removing the transducer from the sensor housing and connecting both the pressure transducer and its reference inside a pressure chamber, which was connected to a pneumatic pressure generator. Thus, by means of this pneumatic pressure generator a specific pressure will be induced to the pressure transducer. By varying the pressure in the chamber in intervals of 100 mbar, from 0 to 1 bar, the corresponding voltage response from the sensor connected to its amplifier unit was recorded. With the collected data a calibration curve can be elaborated in means of estimating a relation between a pressure and a voltage value. These calibration assays were repeated tree times and the average data were estimated in order to obtain accurate calibration data.

After the calibration process was completed the pressure transducers were removed and disconnected from the pressure chamber. The reference transducer was integrated on the pre-amplifier and data acquisition circuit board in order to measure the atmospheric pressure. The osmotic pressure transducer was re-placed inside the base of the sensor housing and insulated by means of translucent silicone.

The experimental assays were performed using albumin (*albumin from bovine serum, EC No. 232-9362, M_W = 67 kDa, Fluka, USA*) in concentrations of 0, 0.5 and 1 mM in order to simulate low, medium and high solute concentration, respectively. To accomplish the study of pressure variation according to solute concentration change, both the laser machined support plate (1) and semipermeable membrane (2) were integrated into the front plate of the osmotic pressure sensor (Fig. 6.).

As illustrated in Fig. 6, this set of constituents along with the O-ring (3) were placed inside a plastic stopper and filled with an osmotically active reference solution (1 mM albumin dissolved in distilled water) with a syringe, prior to sensor housing assembly (4, 5). After the closing the sensor housing, the sensor was immersed in each of the test solutions of 1, 0.5 and 0 mM concentration during 12, 8 and 8 hours, respectively.

The osmotic pressure changes were generated in the internal reference chamber of the sensor by means of the interactions through the semipermeable membrane between the reference solution and the externally placed test solutions. Thus each of the three test solutions used in the experiments would reflect different osmotic pressure levels. The resulting osmotic pressure responses were recorded during the entire measurement process and repeated three times to obtain accurate average data. The experimental assays were performed in room temperature (≈ 20 ºC).

4. Results and Discussion

4.1. Calibration of the Pressure Transducers

The average calibration curve obtained from the 3 calibration tests performed on the osmotic pressure transducer connected to its amplifier unit is illustrated in Fig. 7 and translates the linear equation:

$$y = m\,x + b = 0.270531\,x + 0.170036, \quad (2)$$

where the variable y represents the induced pneumatic pressure (bar), the variable x represents the obtained voltage value for that applied pressure (V), the constant m expresses the gradient of the line and adopts the value of 0.270531, and the constant term b determines the *y*-intercept and defines that the line crosses the *y*-axis at the value of 0.170036.

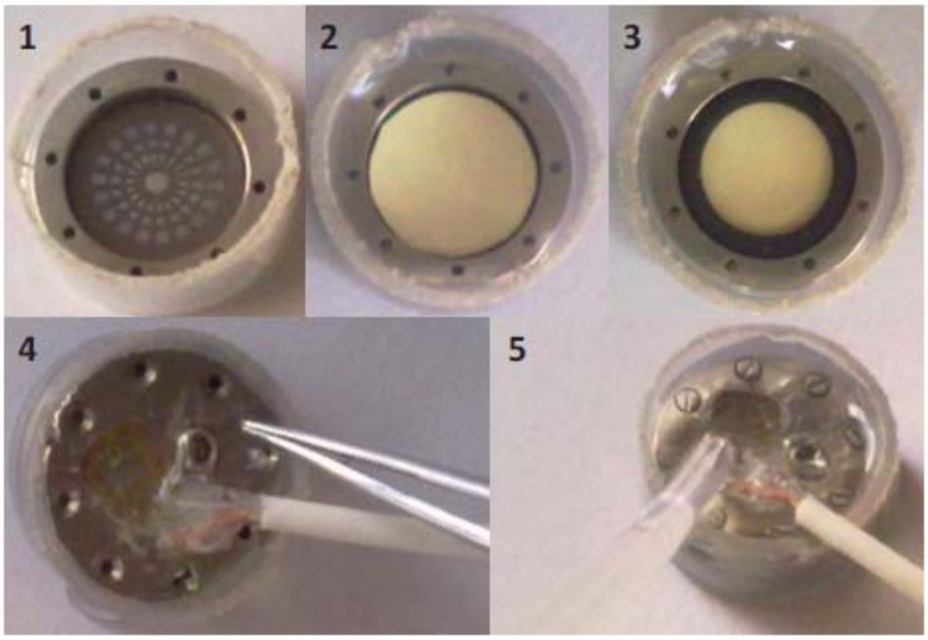

Fig. 6. Sensor assembly steps for the experimental assays. (1) Placement of the front plate along with the laser machined support plate inside a plastic stopper; (2) Placement of the semipermeable membrane of 0 Da molecular weight-cut-off and filling of the plastic stopper with 1mM albumin reference solution; (3) Placement of the O-ring; (4) Placement of the metallic housing base; (5) Closure of the osmotic sensor prototype and last filling with reference solution.

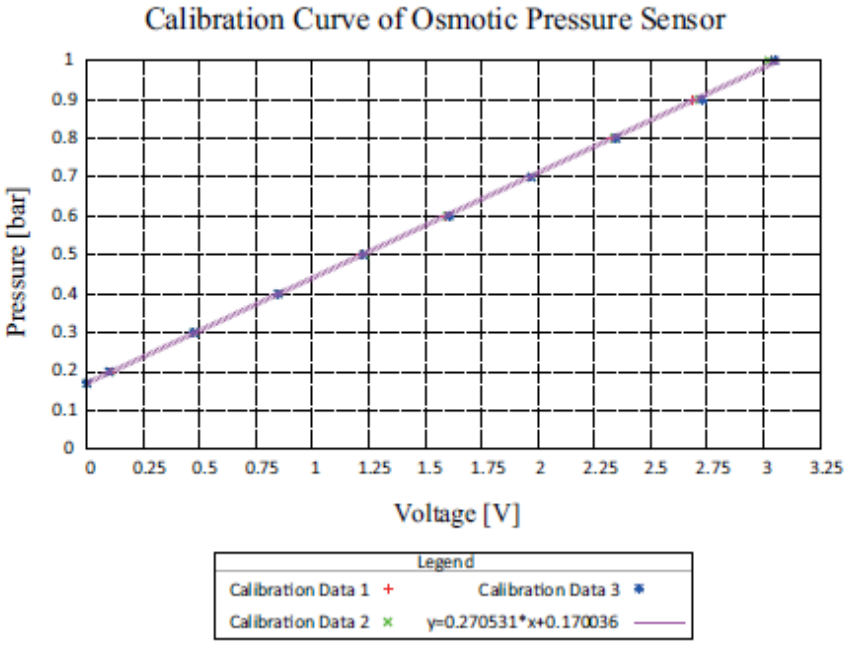

Fig. 7. Calibration curve of the osmotic pressure transducer combined with its amplifier unit.

The average calibration curve obtained from the 3 calibration tests performed on the reference pressure transducer connected to its amplifier unit, is presented in Fig. 8 and which is translated according the linear equation:

$$y = m\,x + b = 0.264434\,x + 0.165239, \tag{3}$$

where the variable y represents the induced pneumatic pressure (bar), the variable x represents the obtained voltage value for that applied pressure (V), the constant m expresses the gradient of the line and adopts value of 0.264434, and the constant term b determines the *y*-intercept and defines that the line crosses the *y*-axis at the value of 0.165239.

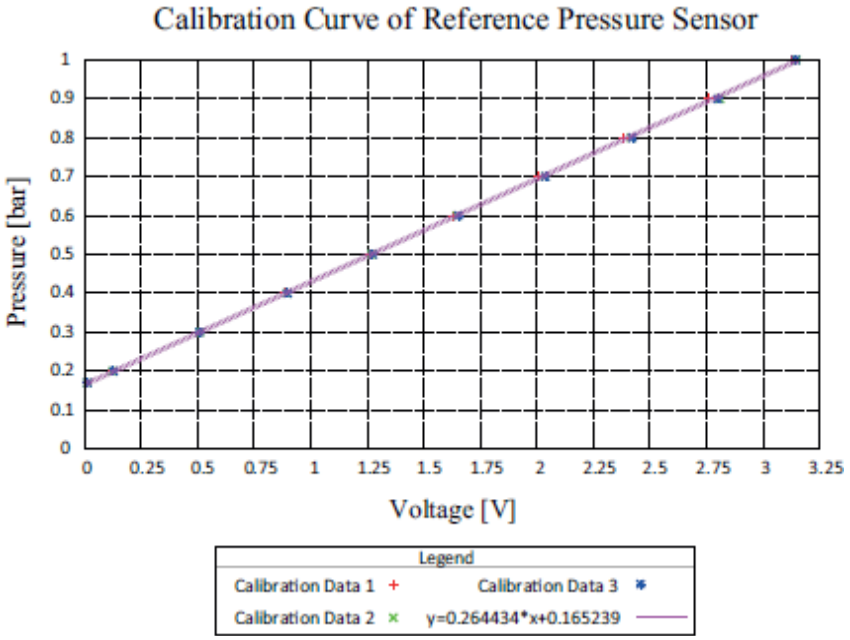

Fig. 8. Calibration curve of the reference pressure transducer combined with its amplifier unit.

4.2. Osmotic Pressure Measurements

The obtained behavior of the developed monitoring system to the performed experiments is illustrated in Fig. 9. From the analysis of this behavior, we can conclude that the system showed a positive response to the different albumin concentrations in means of osmotic pressure variations.

Regarding Fig. 9, points referenced with "1" describe the relationship between the 1 mM albumin concentration and the measured osmotic pressure. The osmotic pressure variations resulting from the 0.5 mM albumin concentration are referenced in points "2", while points referenced with "3" show the relationship between the 0 mM albumin concentration and the respective osmotic pressure variation. In the first case ("1"), the osmotic pressure demonstrated an accentuated initial decrease of 8833 seconds (≈ 2.5 hours) before its stabilization. The second ("2") and third ("3") case behaved similarly with the exception that the corresponding osmotic pressure changes demonstrated a positive commutation before they achieve a stable value, with corresponding response times of 14543 seconds (≈ 4 hours) and 6777 seconds (≈ 2 hours). These response times consists in the time necessary to replace the previous solution, still present in the semipermeable membrane, with the new solute concentration.

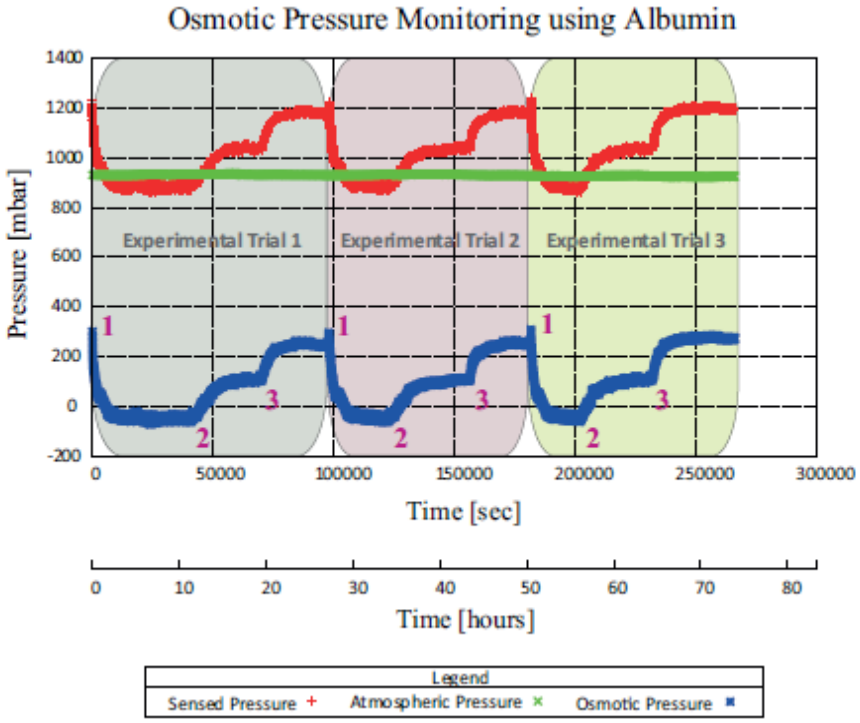

Fig. 9. Osmotic pressure changes during the three experimental trials performed to albumin solutions with external concentration of 1 ("1"), 0.5 ("2") and 0 mM ("3").

An osmotic pressure of -44.7736 mbar, 103.6019 mbar and 255.6319 mbar was recorded from an external albumin concentration of 1, 0.5 and 0 mM (Table 1), which equals a transmembrane concentration gradient of 0, 0.5 and 1.0 mM respectively. These data are higher than the theoretical prediction from dilute solutions following Eq. (1), and can be explained by interactions between the albumin particles that become predominant at higher concentrations of the protein. However, this phenomenon needs to be subject to further investigations.

Table 1. Osmotic Pressure using albumin solutions.

Albumin Concentration [mM]	Osmotic Pressure [mbar]					
	Mean	Median	Standard deviation	Maximum value	Minimum Value	Range (ΔP)
0	255.6319	256.8567	7.1083	271.4113	231.7537	39.6577
0.5	103.6019	103.5957	7.2163	123.3993	83.8215	39.5778
1	-44.7736	-44.5553	7.4219	-22.1864	-67.8752	45.6888

The aim of the performed experiments consists in the demonstration that the developed system can distinguish different solute concentration by reading different osmotic pressure values.

Further analysis demonstrates that the nature between osmotic pressure and particle concentration suggests a linear relationship (Fig. 10). Possible errors could be due drift in the osmotic pressure transducer induced by the silicon carrier of the pressure transducer flexing in response to osmotic pressure changes. Other perturbing factors could be water absorption, which leads the used adhesive components to swell, different temperatures in the external solutions that were used or the growth of bacteria in the albumin solution inside the reference chamber that releases proteolytic enzymes that breaks down albumin into smaller fragments.

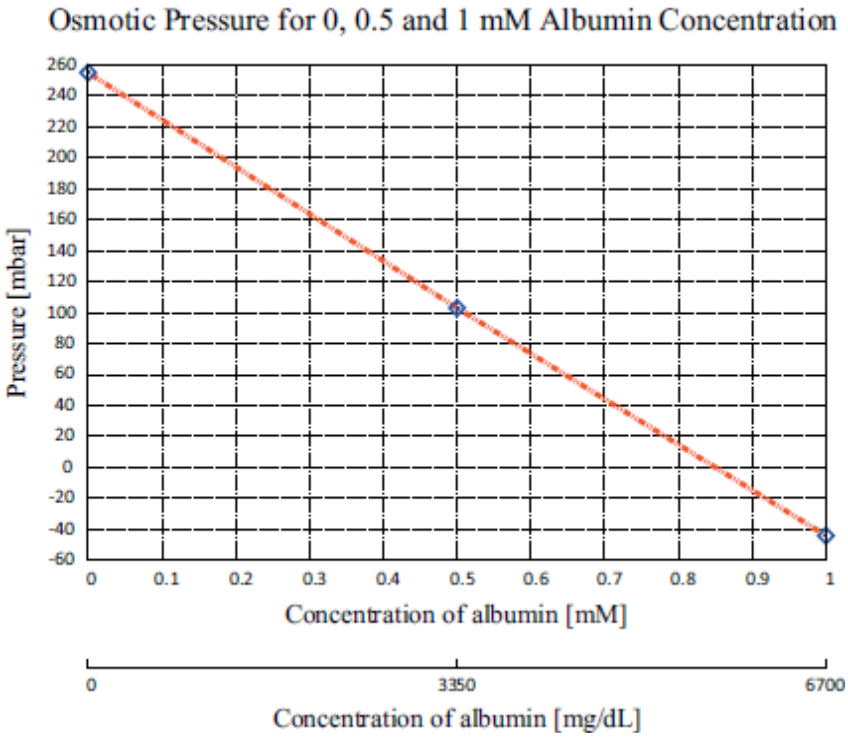

Fig. 10. Osmotic pressure changes [mbar] recorded from a concentration gradient of 0, 0.5 and 1 mM albumin.

5. Conclusions and Future Work

The results obtain by this investigation demonstrate the feasibility and capability of the developed system in detecting solute particle variations with the aid of osmotic pressure. The silicon pressure transducers and ASIC (*Application-Specific Integrated Circuit*) have been characterized and implemented in a macroprototype for verification prior to integration into a microfabricated package.

In order to complete a glucose monitoring system based on osmotic pressure measurements, a microcontroller unit with 10 bits ADC (*Analog-to-digital converter*) will be integrated into the system. RF transmission will be investigated to permit wireless data communication between the implantable device and an external reader. This external reader will be mounted as a wristwatch and receive the measurement data for processing and presentation to the patient. In case of abnormal glucose levels, the reader would sound an alarm to remind the patient of potentially hypoglycemic or hyperglycemic events in time to take measures against it. Long term implantation in subcutaneous tissues will be permitted through the integration of an inductive power supply coupled to the reader.

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Sensors & Transducers Journal

Guide for Contributors

Aims and Scope

Sensors & Transducers Journal (ISSN 1726-5479) provides an advanced forum for the science and technology of physical, chemical sensors and biosensors. It publishes state-of-the-art reviews, regular research and application specific papers, short notes, letters to Editor and sensors related books reviews as well as academic, practical and commercial information of interest to its readership. Because of it is a peer reviewed international journal, papers rapidly published in *Sensors & Transducers Journal* will receive a very high publicity. The journal is published monthly as twelve issues per year by International Frequency Sensor Association (IFSA). In additional, some special sponsored and conference issues published annually. *Sensors & Transducers Journal* is indexed and abstracted very quickly by Chemical Abstracts, IndexCopernicus Journals Master List, Open J-Gate, Google Scholar, etc. Since 2011 the journal is covered and indexed (including a Scopus, Embase, Engineering Village and Reaxys) in Elsevier products.

Topics Covered

Contributions are invited on all aspects of research, development and application of the science and technology of sensors, transducers and sensor instrumentations. Topics include, but are not restricted to:

- Physical, chemical and biosensors;
- Digital, frequency, period, duty-cycle, time interval, PWM, pulse number output sensors and transducers;
- Theory, principles, effects, design, standardization and modeling;
- Smart sensors and systems;
- Sensor instrumentation;
- Virtual instruments;
- Sensors interfaces, buses and networks;
- Signal processing;
- Frequency (period, duty-cycle)-to-digital converters, ADC;
- Technologies and materials;
- Nanosensors;
- Microsystems;
- Applications.

Submission of papers

Articles should be written in English. Authors are invited to submit by e-mail editor@sensorsportal.com 8-14 pages article (including abstract, illustrations (color or grayscale), photos and references) in both: MS Word (doc) and Acrobat (pdf) formats. Detailed preparation instructions, paper example and template of manuscript are available from the journal's webpage: http://www.sensorsportal.com/HTML/DIGEST/Submition.htm Authors must follow the instructions strictly when submitting their manuscripts.

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