Remote Monitoring of Intracranial Pressure

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A wireless, externally powered, implantable device for monitoring of intracranial pressure has been developed at the Brain Instrumentation Laboratory at Brigham Young University. The implantable device is based on low power microprocessor and small dimension pressure transducer conveniently packaged in a biofriendly material. An external interrogator powers and communicates with the subcutaneously implanted device. The developed intracranial pressure monitor system eliminates the need for the battery power supply, and thus avoids the hazards associated with potential leaking of the batteries. Another advantage of the system is its wireless mode of operation compared to wire and bolt based traditional intracranial pressure monitors. Wireless mode of operation does not limit patient mobility, eliminates path for infection, and it is safe for violent patients.By keeping the interrogator in the close proximity of the patient skull, for example in the patient's pillow, the system can be used for continuous monitoring of the intracranial pressure, even while the patient sleeps. A natural extension of the system is to connect the interrogator to a phone line or data network, the ultimate goal being to enable remote monitoring, logging, and analysis of the intracranial pressure.

KEY WORDS: Intracranial Pressure, Subcutaneous Implant, Implantable Pressure Sensors, Remote Monitoring. Wireless Power Transmission

INTRODUCTION

A fundamental requirement in the practice of medicine is having good instrumentation for the measurement of biological functions. In recent years, many new implantable sensors have been developed, capable to collect the data that is directly related to some health matter, [1]. Examples of such devices include pressure, temperature, and flow rate transducers. Subcutaneously implanted electronic circuits present the opportunity to develop new approaches to sensing and monitoring of biological activities where moderate to long-term data collection is important.

In some patients with neurological diseases there is a need for continuous tracking of the intracranial pressure. A traditional approach to measure intracranial pressure is to drill a hole in the patient's skull, insert a pressure sensor, and use wire and bolt attached to the patient's skull to collect the pressure data. Even

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though it offers reliability, easy design, calibration, and use, the transcutaneous wiretap poses safety hazard: it is not portable, limits patient's mobility, offers path for infection, and it is even unsafe for violent patients.

An alternative approach, developed at the Brain Instrumentation Laboratory, Brigham Young University, Provo, Utah, uses wireless communication to externally powered implantable device for monitoring intracranial pressure. The system consists of an implantable biodevice and an external interrogator that provides external power source, [2]. The biodevice and interrogator use wireless communication link to transfer commands and data, [3]. Intracranial pressure monitor system does not limit patient mobility and eliminates the safety hazards due to the wiretaps.

A natural extension of the intracranial pressure monitor is to put the interrogator close to the patient's skull, for example installing the interrogator in the pillow, so that it is in continuous contact with the implanted device. The interrogator is connected to a phone line or data network for remote monitoring, logging, and analysis of the intracranial pressure.

The paper describes a data acquisition system in which an intracranial pressure sensor and its data capture electronics are implanted and the data is externally acquired by means of a wire-

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less interrogator device. The paper gives short descriptions of the biodevice and interrogator, and than explains and extension to provide for remote monitoring of the intracranial pressure.

WIRELESS, EXTERNALLY POWERED INTRACRANIAL PRES-SURE MONITORING SYSTEM

The intracranial pressure monitoring (ICPM) system, Figure 1, consists of an interrogator and subcutaneously implanted biodevice that are connected via wireless electromagnetic link. The interrogator is an external device that provides an external power source, creates a communication link, and controls the biodevice. We use the term "biodevice" to stress that the concept covers general implantable devices that can consist of several sensors and/or actuators. For example, the biodevice can have intracranial pressure as well as a temperature sensor. An example of the actuator would be a tiny valve that can regulate the drain of the intracranial liquid through a pipe down to the throat of the patient.



is related to the physical or chemical processes in the patient's body. The microelectronic implant packages together the coil, modulator/demodulator, power controller, and the microcontroller, see the block diagram in Figure 2. The coil senses the electromagnetic field to inductively receive power and establish data communication to the interrogator. Power controller regulates the induced power and provides the continuous power supply to the microcontroller. Of course, the power link is not without risks, because a high-energy external power source could induce excessive power in the biodevice.



Figure 2. Block diagram of the biodevice

The microcontroller provides all the functionality of the biodevice, including the calibration of the sensors, interpretation of the commands and data from the interrogator, processing the measurements from the sensors, formatting the output data, and error checking and detection. Microcontroller is implemented as a low power microprocessor with limited computational resources.

The data link between the interrogator and biodevice is established in the following way. Interrogator modulates the electromagnetic waves with the outgoing data that are detected by the biodevice demodulator and passed to the microcontroller. The modulator uses the data from the microcontroller to modulate the inductive load that the coil presents to the electromagnetic link. Interrogator senses the change of the inductive load and extracts the data from the biodevice.

Figure 3 shows the block diagram of the interrogator that provides the power, control, and communication link to the biodevice, and performs data logging and processing. The fact that the interrogator is non-implantable part of the ICPM system, relaxes the constraints imposed on its size, power supply, and safety. Consequently, the interrogator is implemented as a stand alone, portable computer, together with the power controller, coil, and modulator/demodulator that are the counterparts of the similar units within the biodevice. In addition, interrogator provides user interface in a form of a simple keyboard and liquid crystal display.

Figure 1. Principal block diagram of the ICPM system

The innovative approach in ICPM system is that the electromagnetic induction is used to both power the biodevice and provide for a communication link. The advantage of the approach is that the biodevice is hermetically sealed before implanting it in a patient, thus making the whole procedure potentially less hazardous to the patient. The elimination of the battery to power the biodevice, avoids the problems related to safety hazards, battery size, power, and duration.

The electromagnetic field created by the interrogator serves as a wireless link for powering and communicating to the biodevice. The communication link is established by an innovative idea based on using the powering electromagnetic waveform for half-duplex communication. Modulation of the electromagnetic waveform in the interrogator and demodulation in the biodevice establish the communication link from the interrogator to the biodevice. Modulation of the inductive load that powers the biodevice is used to create a communication link from the biodevice to the interrogator.

The subcutaneously implanted biodevice consists of two parts: a microelectronic implant and an intracranial sensor probe. The sensor delivers to the microelectronic implant the information that



Figure 2. Block diagram of the interrogator

SYSTEM OPERATION

The two important issues have been addressed during the development of the ICPM system. First, the unreliable electromagnetic link can break the biodevice power supply and the communication at any time. Second, the wireless power and communication links are very noisy and error prone. To compensate for the problems, a special communication protocol has been developed that permanently checks the biodevice operation, and aborts the communication in case of biodevice failure, [2,4].

The communication protocol is based on a dialogue mode of operation, in which the biodevice carries out the interrogator initiated commands. The dialogue mode of operation is selected because it is suitable for the half-duplex and unreliable (due to the unreliable power supply) communication link. Furthermore, the master role in the dialogue is appropriate for the interrogator due to its higher processing power and reliability compared to the interrogator.



Figure 4. Data link layer control protocol state diagram

Figure 4 shows the data link layer control protocol state diagram. Initially, there is no data link between the interrogator and the biodevice. If the interrogator is within the power transmission range, the biodevice is powered, incepts the carrier, and enters verification dialogue. Upon the successful verification, the interrogator and biodevice enter the application state. Typical operations in the application state include transmission of intracranial pressure data from the biodevice to the interrogator and recalibration of the sensor. The application state is followed by the termination state in which the carrier is terminated. If, at any state, the communication fails, the interrogator terminates the carrier.

The highest priority requirements relate to the safety, integrity, and reliability of the ICPM system. The safety requirements are regulated by the FDA and relate to the safe power transmission, packaging of the biodevice, and potential hazards related to the use of the system. Integrity of the ICPM and similar system is addresses in a separate paper.

The ICPM system has to maintain the reliable communication over the noisy and unreliable link, inherent when using the induced power signal to transmit data. As data rate requirements are not critical, the biodevice microcontroller, even with the limited computing power and resources, can implement error detection and correction algorithms. Carefully selected algorithms combined together with the dialogue mode operation improve the reliability of the interrogator-biodevice communication.

REMOTE MONITORING OF INTRACRANIAL PRESSURE

The status of some patients may require continuous monitoring of the intracranial pressure. A natural extension for the ICPM system is to add another communication layer to provide for the remote ICP monitoring. Apparently, remote monitoring enables the patient to stay at home, thus reducing the cost and offering the patient friendly home environment.

The ICPM system uses a simplified, three-layer model of communication shown in Figure 5. Physical layer transmits the bits of data over the wireless communication link by modulating and demodulating the electromagnetic waveform. The data link layer performs the transfer of the blocks of data and error checking and correction. The application layer implements the commandresponse mode of operation and implements the dialogue between the interrogator and biodevice.



Figure 5. Three-layer model of interrogator-biodevice communication

Keeping the interrogator in the close proximity of the patient and establishing a permanent communication link between the inter-

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rogator and a host computer are the essential elements of remote monitoring feature of the ICPM system. For example, a modified interrogator can be embedded into the patient's pillow, so that the ICPM system logs the intracranial pressure data from the biodevice while patient sleeps. The interrogator can be equipped with a large coil for extended range of wireless contact with the biodevice. Interrogator can be connected to the host computer either via phone line, data network, or wireless link. The host computer, located in the medical facility, provides for data storage and analysis, thus enabling the medical personnel to monitor the intracranial pressure of the patient at the remote site.



Figure 6. Adding remote monitoring communication layer

Remote monitoring link is equivalent to adding another layer to the three-layer model of the interrogator-biodevice communication, see Figure 6. The new layer maintains the communication link between the interrogator and the host computer. Of course, the remote monitoring layer is composite and can be further decomposed into the sub layers of its own, but this elaboration is of no interest for the presentation.

CONCLUSION

The paper presents the design of an externally powered, wireless intracranial pressure monitor. The ICPM system consists of an interrogator and subcutaneously implanted biodevice. The electromagnetic inductive link is used to power the biodevice and establish the communication link between the interrogator and the device. The advantages of the ICPM system are twofold: first, it eliminates the safety hazards caused by implanting the battery into the skull, and second, it eliminates the safety hazards related to the wiretaps used in traditional approach.

A natural extension of the ICPM system, by establishing the permanent links between the interrogator and biodevice, and between the interrogator and host computer, supports remote monitoring of intracranial pressure. Medical personnel, with the access to the data logged at the host computer, is able to permanently monitor the intracranial pressure of the patient at the remote site.

Future work and research are directed towards the extension of the system to support the multiple wireless biodevices in both single patient and group of patients.

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