Journal of
Biomedical Systems & Emerging Technologies

Research Article | Open Access

Programming and Managing Mechatronic Hydrocephalus Shunt: System and Method

Momani L[1]* and Alkharabsheh AR[2]

[1]*Faculty of Engineering Technology and Science, Higher Colleges of Technology, Fujairah, UAE*
[2]*Faculty of Engineering and Computer, Qassim Private Colleges, SA*

Abstract

Parts of a hydrocephalus mechatronic shunting system will be implanted beneath the skin of a patient and frequent physical access to the devices for alteration of the intensity, duration or other characteristics of the therapy is not desirable. From this point, there is an essential need to find out a method to access, update and reprogram the implanted microcontroller wirelessly without a need to physical access to such microcontroller.

In this paper, a system and method has been proposed and developed for wirelessly managing the mechatronic shunting system. This method has three main contributions. First, remotely reprogram the implanted mechatronic shunt by replacing the values of vital implantable parameters such as valve schedules, intracranial pressure threshold values and pressure sensor settings.

Second, the usefulness of this approach was demonstrated using a real time sleeping schedule for the microcontroller to reduce the power needed.

Third, a problem associated with memory size limitations has been addressed by using embedded software to derive the required values and parameters in real time in case there is a need for such parameters without saving these values.

As a result, several wireless data transmission tasks of this method are implemented. The framework of the system is described and the functions of the main system are illustrated. The management shunting method was implemented and tested to demonstrate practicality, reliability and flexibility.

Keywords: Mechatronic hydrocephalus shunt; Wireless data transmission; Hydrocephalus

Introduction

Hydrocephalus is a neurological disorder whereby the cerebro-spinal fluid (CSF) surrounding the brain builds up, causing severe pain and swelling of the head [1]. Mechanical shunts were used for decades to treat hydrocephalus patients, where mechanical valves were the popular type for draining the CSF. Such valve causes many problems such as overdraining and underdraining. These problems may have dramatic effects on the patients such as brain damage.

To address the above problems, an intelligent wireless shunting system was designed [2]. With such shunting system, many problems have been solved such as the hospitalization periods and patient suffering and inconvenience are reduced, the quality of treatment is improved and better understanding of intracranial hydro-dynamics is established thanks to the valuable resource of ICP data collected by an implanted sensor [3].

Mechatronic shunting system

The mechatronic shunting system is an intelligent wireless implantable shunting system for hydrocephalus patients with features that help in reducing or eliminating the problems with current shunts [4]. Such system would provide an inductively powered sensing and transmitting unit which is completely implanted with no wires or tubes penetrating the skin. An external unit outside the body would receive signals from the implanted unit. The received signals may be recorded, displayed or analyzed, or all of these manifestations of the signals may be produced simultaneously.

The mechatronic shunting system shown in (Figure 1) consists of two subsystems; implantable and external subsystems. The implanted subsystem would mainly consist of ultra-low power commercial microcontroller, mechatronic valve, pressure sensor and low power transceiver [2]. This implantable shunting system would wirelessly communicate with a hand-held smartphone operated by the patient, or on the patient's behalf by a clinician or guardian. This device would have a graphical user interface and an RF interface to communicate with the user and the implantable wireless shunt respectively. The main goals of the mechatronic shunting system are to improve the management and treatment of hydrocephalus that should lead to improvements in the quality of life for the hydrocephalus patients.

One of the main functions of the patient device is enabling the patient to control the state of the internal valve, as well as enabling the patient to query the internal pressure transducer and view logs/plots of ICP and valve activity over extended periods. Another function would be all owing a technician to wirelessly reprogram the implantable microcontroller *via* the external patient device and reconfigure the valve schedule, ICP sensor schedule and other important implanted parameters. On the other hand, mobile health technology (M-health) would be used by using remote diagnosis, distance mobile nursing and daily data collection. To deal with the previous functions of mechatronic shunting systems, a method for wirelessly reprogram the implanted microcontroller is proposed in this research

***Corresponding author:** Momani L, Faculty of Engineering Technology and Science, Higher Colleges of Technology, Fujairah, UAE, Tel: +96264790333; E-mail: lmomani@hct.ac.ae

Received October 10, 2017; **Accepted** October 26, 2017; **Published** November 01, 2017

Citation: Momani L, Alkharabsheh AR (2017) Programming and Managing Mechatronic Hydrocephalus Shunt: System and Method. J Biomed Syst Emerg Technol 4: 115.

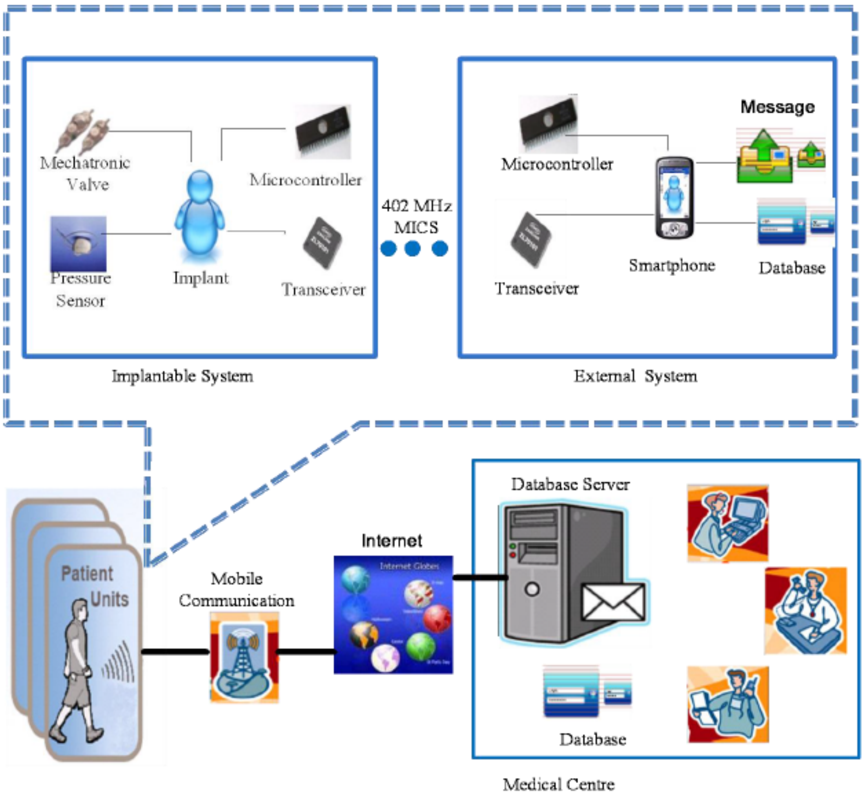

Figure 1: Mechatronic shunting system [2].

Proposed Method

The proposed method will enable physicians monitoring variety of environments for hydrocephalus patients. The researcher investigates a novel communication method which has significant impact on the overall of the mechatronic valves. The wireless monitoring idea is to wirelessly gather ICP readings which are collected from the implanted sensor and environmental data coming from the implanted microcontroller through RF, then Intelligent presentation of patient data for diagnosis. On the other hand, send all implanted system parameters required to make a system work such as update or replace current used valve schedule and more other parameters. Furthermore, it enables the physicians remotely open or closes the valve and stop or start the ICP sensor when it is needed. A management shunting method has been developed to perform these tasks.

In such method, the external device would use the Medical Implant Communications Service (MICS), which operates in 402 to 405 MHz band and allows for much higher bandwidth (250 Kbps) to collect the ICP data from the implanted unit [5]. In later stages, the external device would work on achieving a controlled arrest of the dependence on the shunt. A valve time schedule is needed to control opening or closing the valve. Software inside the implantable system would be used to intelligently generate and derive this valve schedule. A schedule for collecting ICP data (sensor schedule) would also be derived.

Minimizing power consumption is essential for any implantable device. Software based real time clock (RTC), which uses the built-in capabilities of a microcontroller to keep track of time in a "real mode", is used with power consumption algorithm to minimize the power that is consumed by the implantable unit [6]. The microcontroller is set in sleeping mode (that consumes ultra-low power) waiting for a cyclic event from the internal timer or a command from the external system to wake up to be in active mode. During the active mode, the microcontroller checks and performs any tasks required to be executed. After that, the microcontroller returns back to sleeping mode. Such approach allows the microcontroller to be in sleep mode longer and eliminates unnecessary energy that is used in the active mode. As a result, there is a potential power saving. At same time, the implanted software would have the benefit of using the RTC to obtain the current time without requiring any additional hardware. The implanted software would use this clock to make a decision based on fixed time valve and sensor schedule whether is the time to open/close the valve or start collecting ICP readings. Several tasks of this method are discussed and analyzed below in details.

Valve and ICP sensor schedule updating

The mechatronic valve is controlled and regulated by a time based schedule. This schedule shown in Figure 2 equipped for 24 h. For each hour two parameters are identified; open duration (d) and open period (p). The valve should open one or more time per hour on specific times for fixed length. This schedule is stored in the implanted RAM. After each wake up operation, the implanted software reads this schedule, derives the opening and closing times for each hour according to the equations 1-3 and then compares it with a real time clock. Based on this, a control signal is send to open or close the valve.

NPR=60/period (1)

Where NPR is the number of times the valve is opened per hour.

T_o=(i. period) – duration (2)

Where T_o is the time at which the valve is open in minutes and i is counter starts from 1 and end with NPR.

T_c=(i.period) (3)

Where T_c is the time at which the valve is closed in minutes.

The implanted software would also derive the ICP sensor schedule from the valve schedule according to the equations 4-6. Where the sensor schedule identifies the times at which the sensor should collect ICP data. To monitor hydrocephalus and the shunting system and diagnose its faults, the sensor would collect ICP data at the beginning and ending of each open valve duration. In addition, it will collect data at the middle of each closed period to monitor hydrocephalus when valve is closed time.

T_{so}=(i.period)-duration (4)

Where T_{so} is the time at which data is collected at the beginning of each open duration

T_{sc1}=(i.period) (5)

Where T_{sc1} is the time at which data is collected at the ending of each open duration.

T_{sc2}=(i.period)+(period-duration)/2 (6)

Where T_{sc2} is the time at which data is collected at the middle of each closed duration.

One of the novelty aspects of the proposed shunting system is its ability to wirelessly modify or replace an existing implanted valve schedule *via* the external system. A packet as shown in Figure 3 was wirelessly sent to the implanted system with new parameters' values to replace the existing valve schedule. For example, to modify the opening time for specific hour, the packet should include hour index, open period and open duration for that hour. When the packet is received, it will be decoded to find out the requested task and then the current schedule would be modified or replaced by new one. Figure 4 below illustrates this operation.

Valve status is wirelessly controlled

To add more flexibility, this system would enable manual intervention by physician to control and regulate the valve wirelessly. The intervention is wirelessly sent through the external device to the implanted system to open or close the valve for a specific time. The implantable system would receive, encode and analyses this packet. Based on the packet identification, the control signal would be sent to the valve, i.e. if packet identification equals 1 then open the valve, if packet identification equals 2 then close the valve or if packet

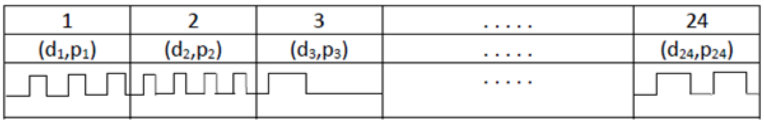

Figure 2: Time based valve schedule.

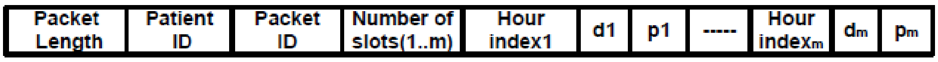

Figure 3: Packet format of valve schedule updating.

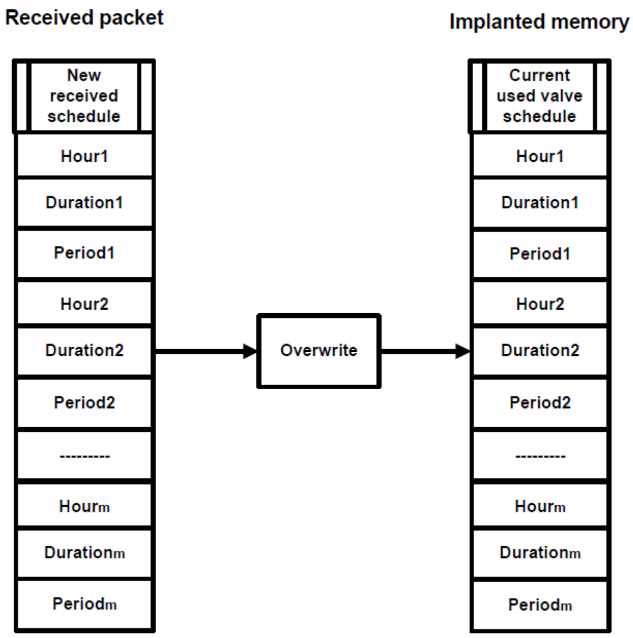

Figure 4: Schedule updating block diagram.

identification equals 3 then follow the routine implanted valve schedule to regulate the valve. At the end of the specified open/closed time the implanted system will switch to the routine schedule. A packet format of this task is shown in Figure 5.

Implanted parameters are wirelessly modified

The modification operation performed by the proposed method does not stand only at modifying the valve schedule but it also extends to modify any other implantable parameters, e.g. ICP thresholds, sensor sampling frequency, that might need to be changed after the shunt being implanted. The need to make the parameters' value dynamic, not fixed, rises due to the dynamic nature of the intracranial hydrodynamics that change with time. For example, in a patient older than 55 the resistance to CSF outflow increases 0.2 mmHg/(ml/min) per year [7]. Such updating will be done by wirelessly sending a packet from external device into implanted microcontroller.

The packet format is shown in Figure 6.

Intracranial pressure monitoring

Measurements of ICP improve the outcome in patients with hydrocephalus [8]. Because ICP measurement is of clinical importance, the proposed shunting system possess a pressure sensor that provide ICP readings noninvasively with no need for hospitalization and not affecting his morbidity thus reducing patients' suffer, improving the quality of treatment and gaining a valuable resource of ICP data for the patient while living his live. The implanted software would determine some important parameters for this ICP data such as mean ICP, valve status when these readings were collected and the time of collecting these readings. The most important challenge in this research is the meaningless of current available ICP data, for example the valve status when this data collected is lack of such parameters in the current available ICP data. It is attempted to solve this problem in this ICP monitoring approach by recording the valve status, the time and mean ICP for each sample. This important clinical data is stored in the implanted memory for 24 h. The external system will automatically backup this data every day. This data is utilised by the external system to manage and treat of hydrocephalus and manage the shunting system itself. An example of this is modifying the implanted valve schedule according to the collected data. Furthermore, it will be helpful in treating other patients, in understanding hydrocephalus and possibly published.

Based on the proposed method, two types of clinical reports would be generated. One of the reports would have ICP readings and valve flow measurements for last collected sample. The external system has ability to request this report or request a sample of ICP readings and flow measurements when they are needed. Such sample would be included in this report and wirelessly send it back to the external system. The other report includes the derived ICP and flow parameters that are calculated for each sample. These samples were collected based on ICP sensor and flow meter schedules which were derived based on valve schedule, i.e. the sensor and flow meter used to collect six seconds window size at very short time before the valve is opening and closing and in the middle of valve closed period. The implantable software derived selected parameters for each sample such as mean ICP, mean absolute deviation, mean valve flow, the valve status when the sample collected and the time of collecting. The derived parameters for 24 h schedule were stored in RAM. The external system automatically requests this daily report or when it is needed. Figure 7 presents the packets format for requesting these two reports.

Closed loop option activating

A closed loop shunt would consist of a mechatronic valve, microcontroller and pressure sensor [4]. In this scenario the valve would be instantaneously managed (opened or closed) according to the measured ICP. Where, the collected ICP would be analyzed by the implanted software (located in the microcontroller) to decide whether it is an appropriate time to open or close the valve. The proposed shunting system is set to work as a closed loop system in cases of emergency to save the patient's life. The external software system or the physician has the ability to wirelessly swap the mode of the implanted system between dynamic shunting and closed loop shunting systems. The implanted shunting system can work as a closed loop system for specific time and then return back to previous mode.

In this research, closed loop option scenario was implemented by sending a packet from external system. Upon receiving this packet, the implanted software decodes and analyses it and set the implanted system to work as a closed loop. As a consequence, the ICP sensor starts collecting data, the software calculates mean ICP and compares it with maximum and minimum ICP threshold values to make a decision whether to open or close the valve. Upon the specified time for closed loop is elapsed, the shunting system returns to work as a dynamic shunting system. The valve status and ICP readings during operating as a closed loop are stored in implanted memory and sent to the external system to be utilised as a resource in understanding patient's case and improve the efficiency of the shunting system. A closed loop scenario is presented in Figure 8.

Emergency cases

One of the benefits of using a mechatronic shunting system is the ability of autonomously monitoring the hydrocephalus patient in real time in any emergency case or system malfunctions. The emergency arises when there is a sudden rise or drift due to different reasons such as shunt malfunctions. The proposed method is designed to deal with such emergency. An emergency request is received from the implanted system or from the physician or patient/in the patient behalf.

Packet Length	Patient ID	Packet ID	Valve status	Duration	Schedule flag

Figure 5: Packet format for wirelessly valve controlling.

Packet Length	Patient ID	Packet ID	Parameter p1	Parameter p2	Parameter p3	--------	Parameter pn

Figure 6: Packet format for implanted parameters modification.

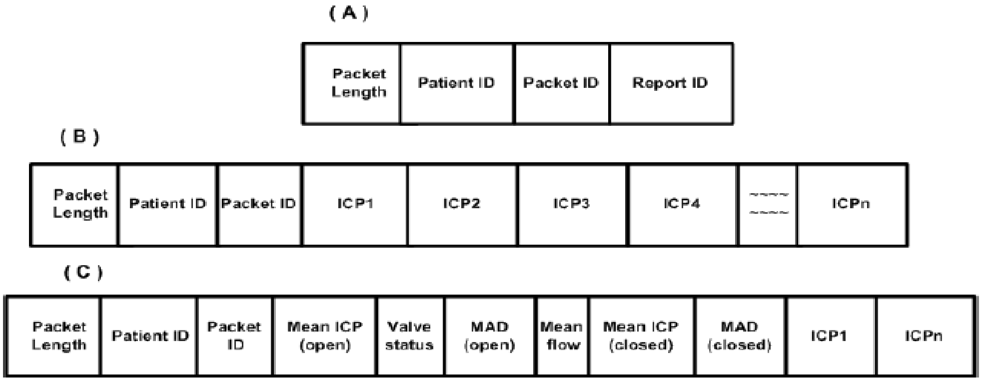

Figure 7: Packet formats for different ICP clinical reports. (A) Request report, (B) ICP data and (C) ICP parameters.

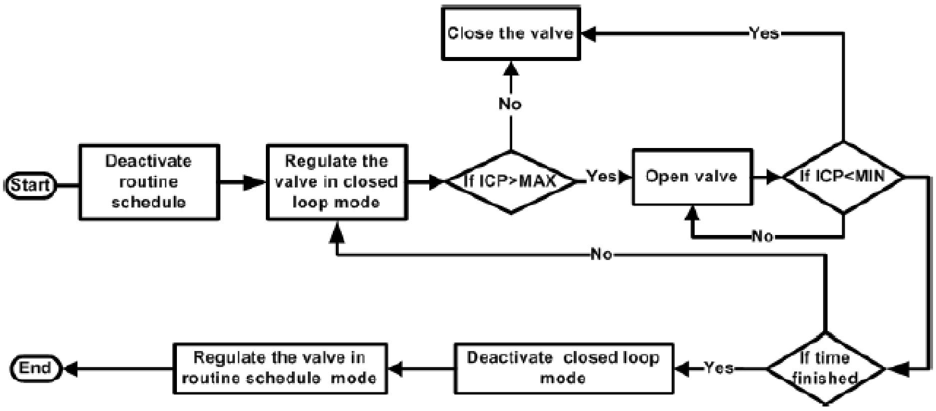

Figure 8: Closed loop scenario.

Three thresholds of mean ICP were selected for emergency case and based on these thresholds; the implanted system would select a risk factor (RF). The risk factor is a number that would be selected by implanted software based on the degree of ICP rise/drift and it will be used externally to decide the degree of emergency request. In this work, the degree of emergency is dividing into three categories: low risk emergency accompanied with RF=1, medium risk emergency accompanied with RF=2 and high risk emergency accompanied with RF=3.

This operation starts calculating the hourly mean ICP for the collected samples and classifying the calculated values based on the stored emergency thresholds. The emergency request would by wirelessly send with risk factor to external system.

Upon receiving the emergency request, the external system would deal with such case as follow, (1) the external module receive the request, analyze it and make a decision based on RF value, (2) the decision will be guided by the following criteria: in case of RF equals 1, shunt will continuous to work as normal but the external will request a sample of ICP readings and flow measurements to be analyzed to check the accuracy of the request. In case of RF equals 2, the external system will directly activate the closed loop option by sending a packet to implanted module as explained in previous section. In case of RF equals 3, would open or close the valve based on case of either rising or drift of ICP, (3) the external system would request ICP emergency report which include ICP readings, flow measurements and valve status after waiting a short time, (4) the external system would analyze the received report and check the status of ICP, (5) and finally the external system would take a suitable final action based on the value of ICP i.e. deactivate closed loop option, open the valve, close the valve, contact the physician or inform patient by a message that the shunt is work normally. The proposed emergency scenario is presented in Figure 9.

Interference prevention

To improve patient safety, the proposed method is designed to prevent any interference problem or communication with an unauthenticated device. The scenario of this task shown in Figure 10 where patient identification number is added as a part of the header of all sending packets. The patient identification is then verified by the receiver to avoid any interference or any unauthorized communication. In case of any mismatch between the stored and received patient id, the communication will be banded and a message will be send informing of occurrence of such problem. On the other hand and if the received packet identifies itself correctly, the communication would start between two shunting subsystems to perform the required task.

Results and Discussion

All management shunting method functions including power consumption are written in C code and compiled by IAR Workbench. MSP430 development kits (each kit includes two microcontrollers and an RF transceiver) shown in Figure 11 are used to test these functions. For all previous tasks, packets are manipulated between these two kits through transceivers. A

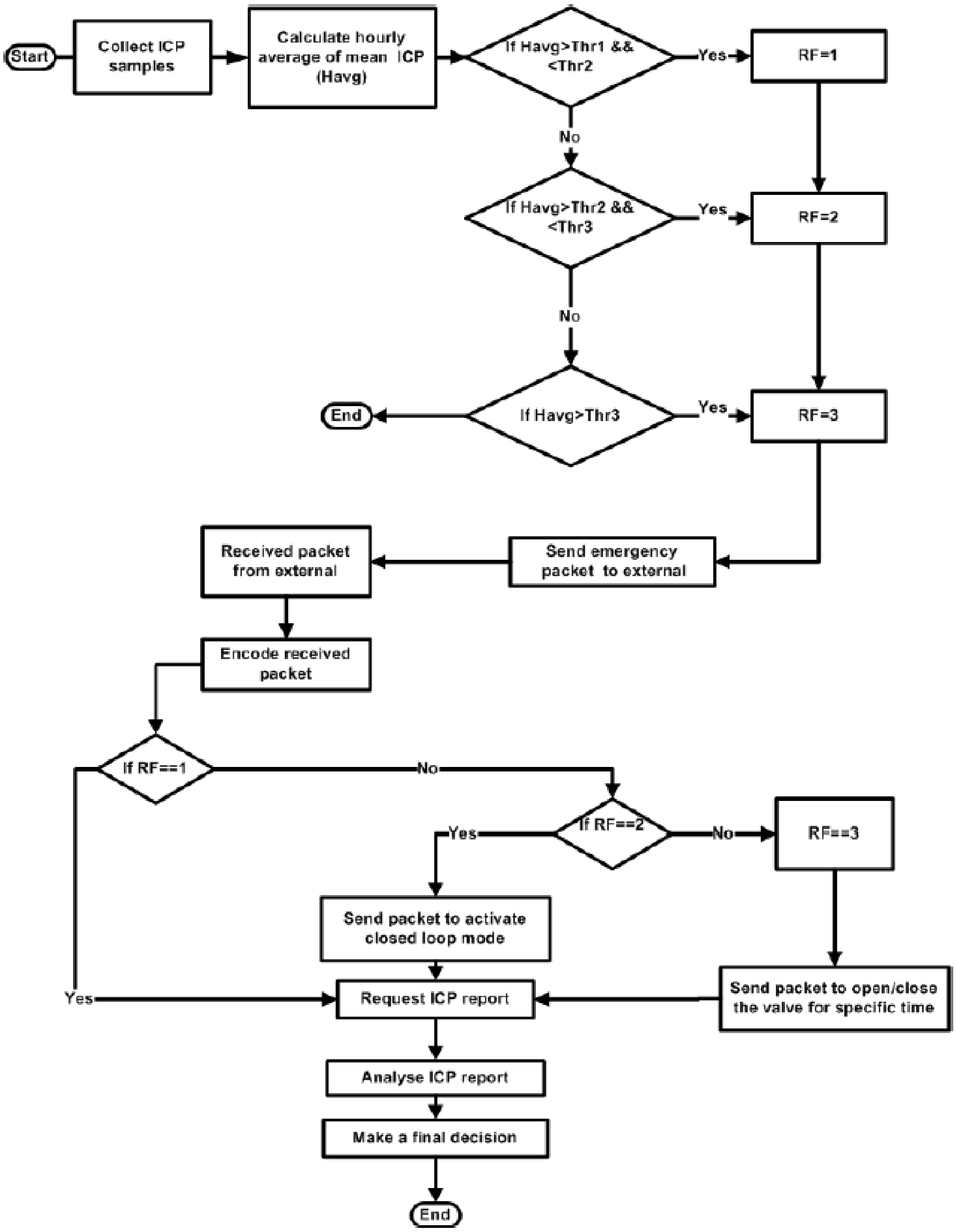

Figure 9: Emergency scenario.

remotely reprogramming of implanted shunting system using management shunting proposed method has been done through RF transceiver. Valve schedule parameters were wirelessly send from external transceiver module then received and stored into implanted transceiver module. The implanted software uses these parameters to replace previous schedule parameters by the calculated one. In addition, the ICP sensor schedule was calculated based on new valve schedule. Both valve and sensor schedule were used to regulate the valve as well as to collect samples of ICP readings without any error. This reprogramming operation has been done without any effect on the system performance. Furthermore, the operation of wirelessly controlling implanted valve was implemented and tested where, LED which is embedded into implanted module, was used to simulate the valve and it is controlled from external by sending a signal to turn on or off this LED. This task was performed as required with high accuracy.

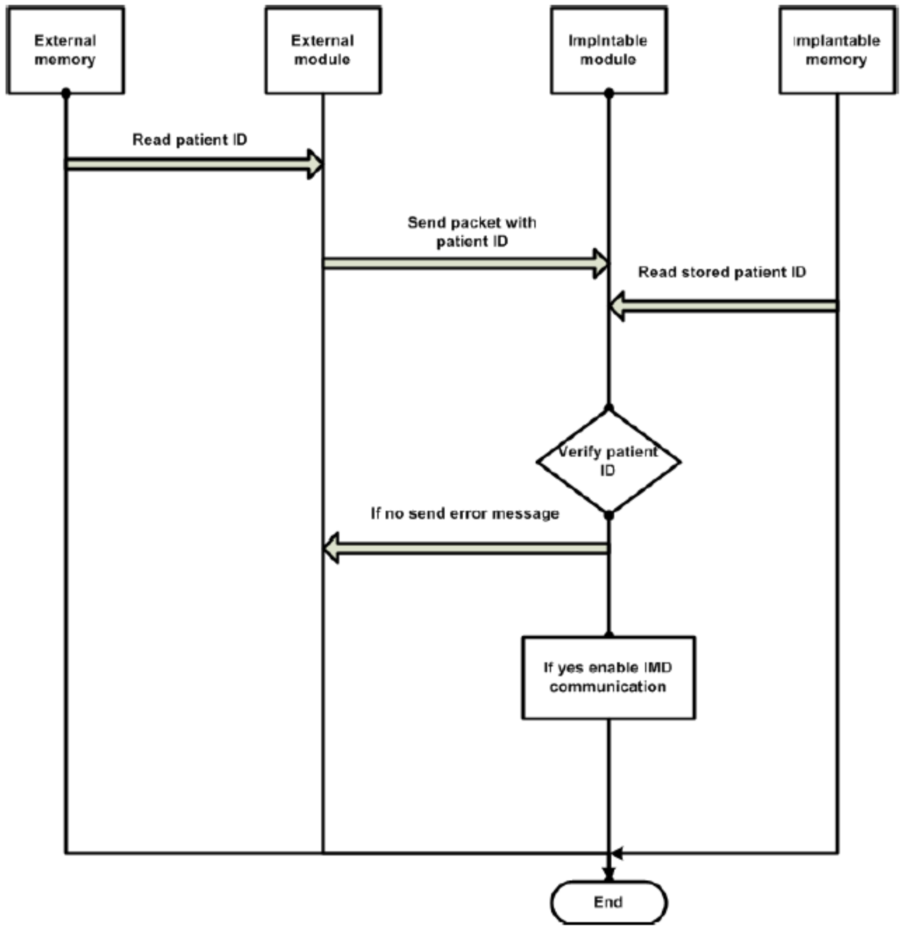

Figure 10: Verification of patient identification.

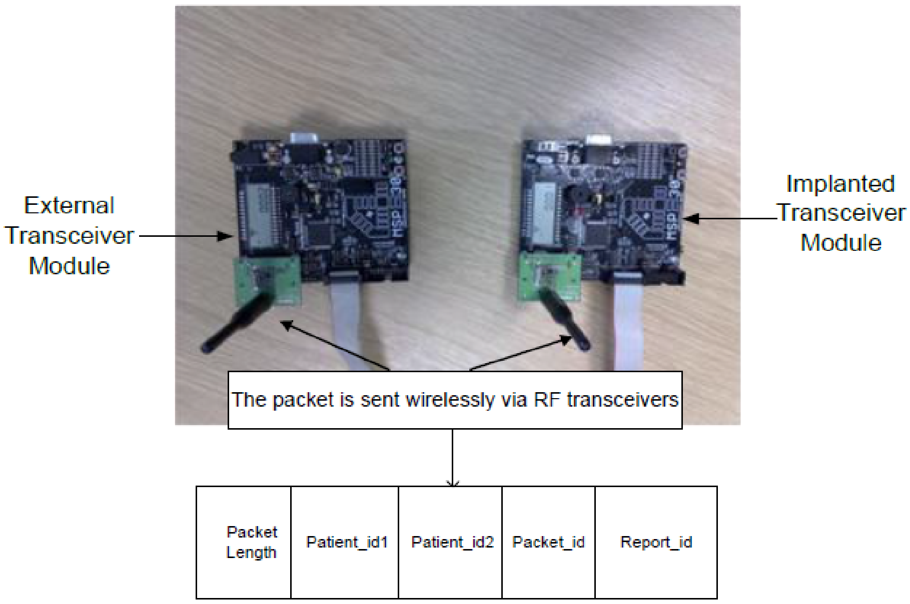

Figure 11: Prototype of microcontroller and wireless units.

The wirelessly non-invasive ICP monitoring operation was implemented and tested through these two modules. A packet was send from external module into implanted one that request samples of ICP readings and the implanted parameters. This packet was encoding by implanted software and then a signal was send to start collecting such samples. A report was prepared and sends back to external module. Such report was stored into external RAM and later was used for analysis. This operation was tested and evaluated and it was repeated daily in regular for seven days. The operation was done with high efficiency as required. A closed loop option was activated wirelessly by sending a packet from external module, where the implanted software encoded the received packet and send a signal to start collect ICP data. The collected data was used to calculate mean ICP and then compared it with the maximum and minimum thresholds values to open or close the valve based on these values. The valve was regulated as a closed loop for specific time which was determined by the external module then it is returned back to follow the routine schedule.

In emergency scenario test, samples of ICP readings which were stored in RAM were used to calculate hourly average of mean ICP (Havg). The Havg was compared with three thresholds values to select the risk factor i.e. if Havg greater than 20 and less than 25, the risk factor is 2. In this case, a packet was send to external with included this factor. This packet was encoded in external module and reverse packet was sending to activate closed loop for five minutes period. Once the time was completed, an auto emergency report was prepared and sends to external system.

An auto bidirectional communication between two transceivers module was tested and evaluated. As a result, this operation was performed as required and the sequence of proposed design worked properly.

Most of the current shunting system problems would be eliminated using such method such as ability of changing the valve schedule after implantation, currant ICP monitoring methods problems, availability of ICP clinical data, implanted memory limitation, ability of opening or closing the valve remotely, ability of activate closed loop option wirelessly and power consumption problems. Implantable intelligent software was used to derive the valve and ICP sensor schedule based on dynamic parameters that would be received from external software. By using such method, all mechatronic shunting system tasks were implemented and tested. As a result, the proposed method functions were evaluated and verified with such method and that increase of the general safety and reliability of the treatment.

Conclusions

One of the most difficult challenges of using an implantable microcontroller in medical applications is how to access, modify and replace the implanted program.

An updating algorithm is used to remotely modify some parameters which are embedded into the microcontroller *via* RF transceivers. An innovative, bidirectional management shunting method was introduced in this paper for reprogramming the implantable mechatronic shunting system that lead to management of hydrocephalus.

The researcher attempted to replace the passive mechanical shunt with a dynamic shunt that would use the management shunting method to maximize the potential quality of life for each patient, reduce hospitalization periods and shunt revisions. Furthermore, a new technique was investigated that would help to circumvent the problem of updating software remotely through RF transceivers.

The proposed shunting system gives hydrocephalus patients the freedom to go anywhere they like while receiving medical services and health care in a timely fashion.

References

1. Association for spina bifida hydrocephalus (2009) Hydrocephalus, available online: http://www.asbah.org/.
2. Alkharabsheh A, Momani L, Al-Zubi N, Al-Nuaimy W (2008) An intelligent implantable wireless shunting system for hydrocephalus patients. In: Proceedings of 13th international conference on biomedical engineering, Suntec, Singapore 210-215.
3. Alkharabsheh A, Momani L, Al-Nuaimy W, Ababneh J, Alwada'n T, et al. (2013) Early fault prediction and detection of hydrocephalus shunting system. IEEE Eng Med Biol 6: 280-290.
4. Momani L, Alkharabsheh A, Al-Nuaimy W (2008) Design of an intelligent and personalised shunting system for hydrocephalus. IEEE Eng Med Biol 779-782.
5. Islama MN, Yuceb MR (2016) Review of medical implant communication system (MICS) band and network. ICT Express 2: 188-194.
6. Real time clock for Texas instrument microcontroller at: www.ti.com.
7. Czosnyka Z, Czosnyka M, Owler B, Momjia S, Kasprowicz M, et al. (2005) Clinical testing of CSF circulation in hydrocephalus. Acta Neurochir 95: 247-251.
8. Czosnyka M, Pickard J D (2004) Monitoring and interpretation of intracranial pressure. J Neurol Neurosurg Psychiatry 75: 813-821.