INT. J. BIOAUTOMATION, 2023, **27**(4), 181-192 doi: 10.7546/ijba.2023.27.4.000938

# A Physical Framework for Testing and Evaluating of a Mechatronic Shunting System

**Abdelrahman Alkharabsheh[1,*], Lina Momani[2], Yousef Qawaqzeh[3], Amjad Alsakarneh[4]**

[1]*Computer Science Department*
*British Applied College*
*Umm Al Quwain, United Arab Emirates*
*E-mail: abdel.r@acuq.ae*

[2]*Mechanical Engineering Department*
*Higher Colleges of Technology*
*Fujairah, United Arab Emirates*
*E-mail: lmomani@hct.ac.ae*

[3]*Information Technology Department*
*Fujairah University*
*Fujairah, United Arab Emirates*
*E-mail: Yousef.qawqzzeh@uoef.ac.ae*

[4]*Department of Mechanical Engineering*
*Yarmouk University*
*Irbid, Jordan*
*E-mail: Amjad.Alsakarneh@yu.edu.jo*

[*]*Corresponding author*

**Received: June 02, 2023** **Accepted: November 17, 2023**

**Published: December 31, 2023**

***Abstract:*** *Shunt is a flexible tube called a catheter implanted inside the brain where cerebrospinal fluid (CSF) is produced. Existing treatments rely on passive implantable shunts with differential pressure valves. The authors defined, designed, and programmed an intelligent wireless hydrocephalus shunting system. The shunting system was designed, simulated, and tested to carry out many tasks such as regulating the mechatronic valve, collecting Injection Control Pressure (ICP) readings, analyzing these readings, responding to all emergency cases, and diagnosing the whole shunting system. Nowadays, many challenges face clinical trials for new medical devices. Clinical trials are complex and require following several rules and regulations to ensure compliance with different standards. Due to the difficulty of using medical trials, an urgent need for a physical framework for implementing a virtual model of intracranial pressure and cerebrospinal fluid dynamics in hydrocephalus mechatronic shunt testing. Such a physical framework will play a vital role in assessing the functioning of the whole mechatronic shunting system. A framework of a mechatronic shunting system (implanted and external) is illustrated and integrated with embedded management and diagnosis software. Such a framework will help assess, test, and evaluate the main functions of the proposed shunting system.*

***Keywords:*** *Hydrocephalus, Mechatronics Shunt, Simulation, ICP sensor.*

## Introduction

Hydrocephalus is a neurological disorder whereby the cerebrospinal fluid surrounding the brain is improperly drained, causing severe pain and swelling of the head. The current treatment methods are based on passive mechanical shunts with differential pressure valves [4].

An intelligent implantable wireless hydrocephalus shunting system was designed and programmed by the authors [2] to replace the current mechanical shunt.

The proposed mechatronic shunt would provide an inductively powered sensing and transmitting unit which is completely implantable with no wires or tubes penetrating the skin. A bidirectional wireless communication protocol has been designed, programmed, and developed by the authors to wirelessly communicate between implanted and external units [3]. The proposed protocol is mainly used to manage all the proposed shunt functions. The external unit mainly consists of a handheld device interfaced with a microcontroller and transceiver. Such an external unit would receive needed data from the implanted unit. Fig. 1 illustrates the proposed mechatronic shunting system. Such a shunting system mainly consists of two sub-systems: implanted and external sub-systems. The implanted sub-system would mainly consist of an ultra-low-power commercial microcontroller, mechatronic valve, pressure sensor, and low-power transceiver. This implantable shunting system would wirelessly communicate with a handheld smartphone operated by the patient, or on the patient's behalf by a clinician or guardian.

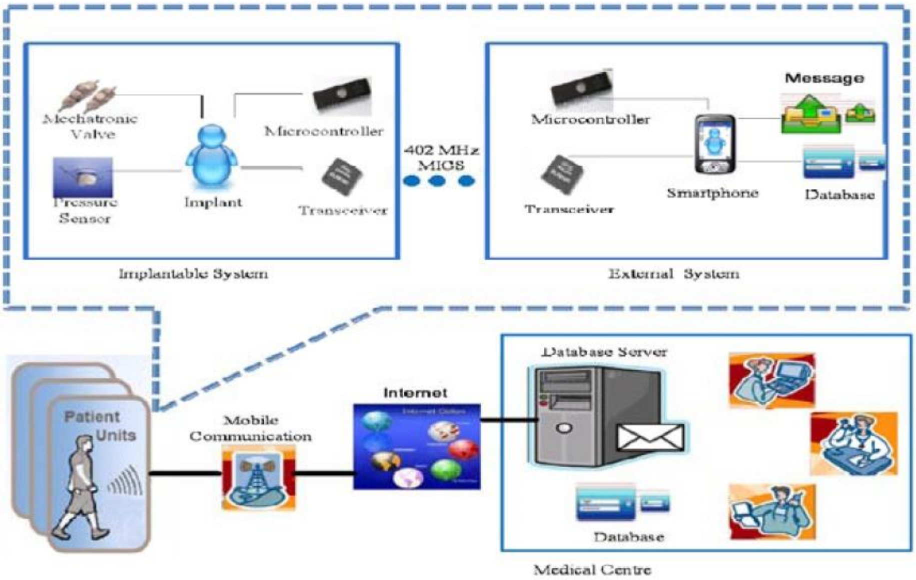

Fig. 1 Proposed mechatronic shunting system [3]

In this research, a prototype of a hydrocephalus shunting system (implanted and external) is illustrated and integrated with embedded management and diagnosis software. Momani et al. [9] have simulated a cerebrospinal fluid (CSF) hydrodynamics model using Simulink for both normal and shunted high-pressure hydrocephalus conditions to study the performance of a mechatronic shunt. Such a system is used to provide an interactive dynamic environment for the proposed prototype. In addition, interfacing between the implantable prototype and intracranial hydrodynamics model is needed to exchange input/output data and control the mechatronic valve and Injection Control Pressure (ICP) sensor. Fig. 2 shows the block diagram of the Momani's model [9].

Furthermore, the two types of existing valves along with the mechatronic valve controlled by different controlling paradigms, namely, scheduled, and closed loop were simulated. In addition, the effect of such systems on intracranial hydrodynamics was investigated using numerical simulations.

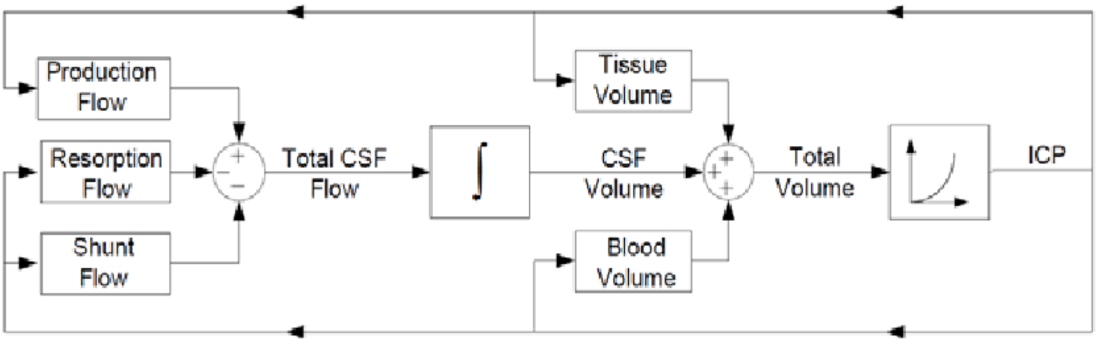

Fig. 2 The block diagram of Momani's model [9]

One of the most difficult challenges of using an implantable microcontroller in medical applications is how to access, modify and replace the implanted program. A bidirectional wireless management protocol for a mechatronic hydrocephalus shunt was designed and developed by the authors [2]. Such an algorithm is used to remotely modify some parameters which are embedded into the microcontroller via RF transceivers. In addition, an intelligent method that would be used to detect any shunt faults or complications without making the patients suffer from frequent hospital visits and shunt revisions was designed and simulated [1].

Shunts are life-saving devices but are notorious for high failure rates and difficulty in diagnosing the failure. Due to the difficulty of assessing or evaluating the performance of integrated mechatronic shunting in medical trials, an essential need for a physical framework to deal with all proposed functions. Such a physical framework would urge the need for a dynamic environment that simulates the intracranial hydrodynamics of hydrocephalus patients and responds to any change in the valve status. The environment can be either a physical (a prototype) or a computer-based (mathematical) model.

## Literature review

Various studies have been done to perform a physical framework for implementing virtual models of intracranial pressure and cerebrospinal fluid dynamics in hydrocephalus shunt testing. Unfortunately, and up to date, there is no study or work has been done that can be used to test and evaluate the mechatronic shunting system. A set of common physiological scenarios was simulated, including oscillations in ICP due to respiratory and cardiac cycles. The authors concluded that the testing of shunts with dynamic ICP and CSF simulations can facilitate the optimization of shunts to be more failure-resistant and better suited to patient physiology. Such a framework is suitable for mechanical shunting systems.

Venkataraman et al. [13] illustrated a physical framework for implementing virtual models of intracranial pressure and cerebrospinal fluid dynamics in hydrocephalus shunt testing.

Lutz et al. [8] illustrated and discuss new and improved ways to treat hydrocephalus: Pursuit of a smart shunt. They present a framework for understanding the challenges and opportunities that will guide the introduction of smart shunts into patient care.

Taylor et al. [12] used a model for the CSF circulation incorporating increased resistance to CSF outflow (24 nimHg/(ml/min)) and decreased hydrodynamic compliance (< 2 ml/mmHg) that are typical conditions in hydrocephalus to test nine of the most used types of hydrocephalus valves. They aimed to document the pressure response to constant rate infusion of a model of CSF circulation with different valves and to define which measures are useful in shunt testing *in vivo*. They concluded that the infusion test can assess shunt function. End-equilibrium pressure recorded during the test has been confirmed to correlate with the shunt's performance. Czosnyka et al. [7] have proposed a new lumped-parameter compartmental model of CSF and blood flow in healthy subjects during the cardiac cycle. The system was divided into five sub-models representing arterial blood, venous blood, ventricular CSF, cranial subarachnoid space, and spinal subarachnoid space. These sub-models are connected by resistance and compliance. The model developed was used to reproduce certain functional characteristics observed in seven healthy volunteers, such as the distribution (amplitude and phase shift) of arterial, venous, and CSF. The results showed a good agreement between measured and simulated intracranial CSF and blood flow.

Work [14] presented a physical intracranial hydrodynamics model that was used for shunt testing. A pump was used as a source of pressure, e.g., constant displacement (syringe and peristaltic) pumps are mostly used in medical laboratories. Coordinating the test sequence and recording data is best done by an automated, preferably computerized, system. Such a system requires a microcontroller to command and receive transducer readings. An accessory (mechanical, electronic, or computer-controlled) device may be added to produce pressure pulses.

There are various clinical techniques to assess shunt functioning in vivo. A laboratory shunt testing methodology (UK Shunt Evaluation Laboratory) has been established by a group of Academic Neurosurgical Unit, Addenbrookes's Hospital, Cambridge, UK to evaluate the result of an infusion test in a physical model of the hydrocephalus. A pump had been used in this model to help represent a CSF under normal conditions. A pulse pressure generator is also used to solve the high sampling rate problem of the ICP signal (100-125Hz) [5]. Another group from the Academic Neurosurgical Unit, Addenbrookes's Hospital, Cambridge, UK had presented another simple physical model of CSF. This model is nearly similar to the previous model. This was used to represent CSF production and circulation. In addition, eleven different hydrocephalus shunts were tested using this model. Most physical properties of CSF were taken into consideration in this study [6]. All previous studies deal with mechanical shunting systems and unfortunately, no one has investigated or given attention to the coming future shunt "mechatronics shunt".

## Proposed physical model

Since the mechatronic valve is under investigation and based on the literature review and the researchers' knowledge, a hydrocephalus physical model that can be used to evaluate the performance of the mechatronic shunting system is not available. This motivates the researchers to study the ability of the proposed physical model. Based on the design of the proposed mechatronic shunting system, the researchers have proposed a physical intracranial hydrodynamic model to assess, test, and evaluate such a shunting system. The proposed system would be suitable for testing and evaluating the functions of the mechatronic shunting system. This model is illustrated in Fig. 3 and it would be mainly composed of the following components: micropump with average flow 0.28-0.33 ml/min; container of special shape to simulate the exponential relation between Transmission Control Protocol (TCP) and total volume of CSF (ICP = AeBV), mechatronic valve (electronic or hydraulic valve) with different resistances, pulse pressure generator that would be used to generate the ICP pulses; needle to mimic the natural drainage of CSF from the brain; ICP transducer to collect the ICP signals; flowmeter to measure the flow change through the valve when it is open, Texas Instruments kit to receive the ICP readings, analyze and make a decision regarding the regulation of the valve; implanted shunt software to regulate the valve and collect ICP readings; stepper motor to control the angle between the CSF tank and the valve to mimic the change in the patient posture, i.e., erect, recumbent at a different angle. Such a proposed model would be a suitable environment to evaluate, test, and validate most of the proposed methods and design of the mechatronic shunting system. Fig. 3 below illustrates a block diagram of the proposed physical framework of the mechatronic shunting system.

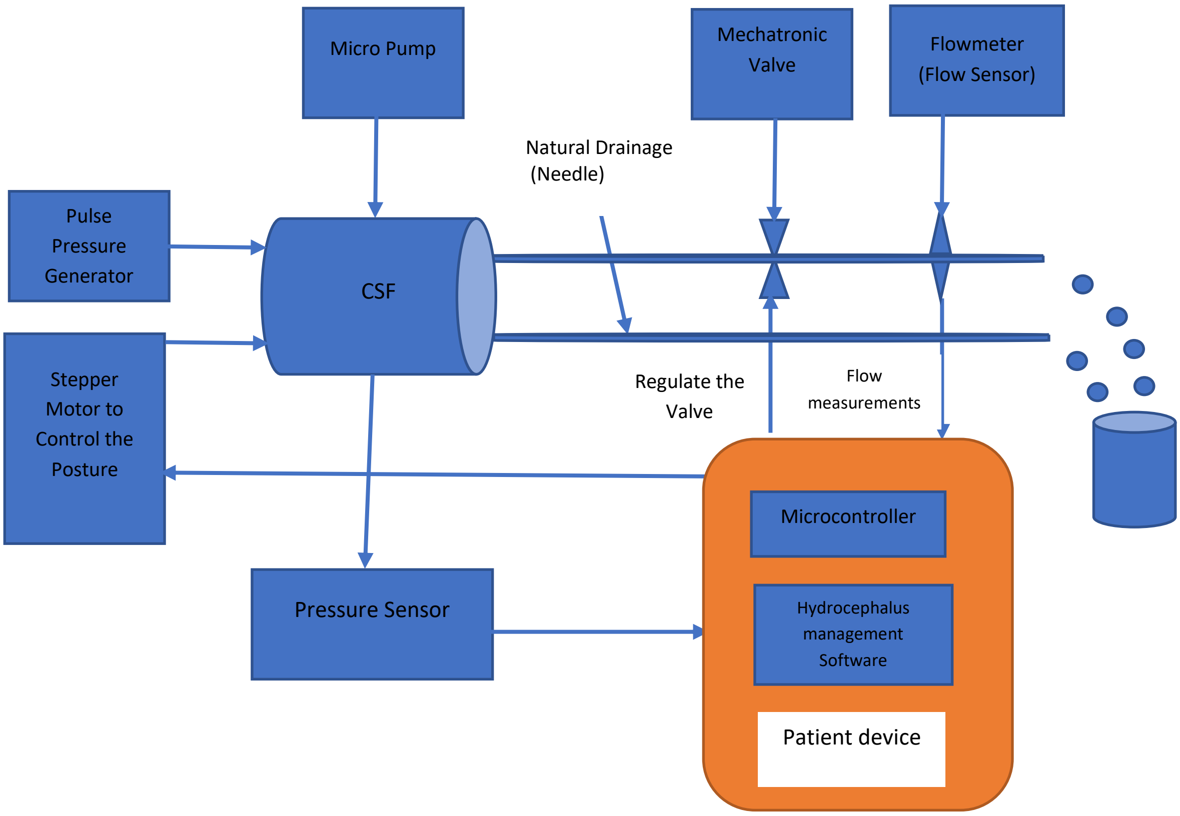

Fig. 3 The proposed physical framework of the mechatronic shunting system

## Methodology and experimental work

This study aims to provide a systematic method to test the performance of the proposed mechatronic shunting system. Therefore, it was decided to follow a prototype-based methodology to support the proposed design methods in hardware and software cases. The experimental work includes five procedures: (1) identify the hardware and software components; (2) interface the implanted shunting prototype with the hydrocephalus patient model; (3) interface the external shunting prototype with management and treatment shunting software; (4) interface between the two shunting prototypes using bidirectional wireless management shunting protocol; and (5) finally, test and evaluate the intelligent shunting system prototype by applying various proposed functions such as shunt diagnosis, valve schedule updating, request a report from implanted part, and activate closed loop option. The proposed physical framework, such operation is divided into five stages as follows.

### *Interactive environment developing*

A comprehensive computer-based model that mimics the behaviour of hydrodynamics in the case of high-pressure hydrocephalus patients (non-shunted and shunted) is an important milestone in understanding hydrocephalus and evaluating current and future treatments. To predict the performance of the proposed shunting system, the model of intracranial hydrodynamics was conceptualized and simulated mathematically and numerically. In this prototype, the Momani's model [9] shown in Fig. 2 is used as a test environment.

Thus, the effect of varying the parameters of the proposed system on the intracranial hydrodynamics can be monitored in real-time.

### *Implanted and external prototypes*

Texas Instruments TRF6901 with MSP430 evaluation kits have been used to prototype the implantable and external shunting systems. The Texas Instruments TRF6901 is a low-cost RF transceiver that is intended for use to establish a frequency-programmable, half-duplex, bidirectional RF link (902 MHz to 928MHz) in the European or North. American industrial, scientific, and medical (ISM) bands. The kit was used in two modes which are standalone mode and system mode. In addition, MSP430FG4618/F2013 experimenter's boards were used in this prototype. The MSP430FG4618/F2013 experimenter's board is a comprehensive development target board that can be used for several applications. The MSP-EXP430FG4618 kit comes with one MSP430FG4618/F2013 experimenter board and two AAA 1.5 V batteries. The MSP430FG4618/F2013 experimenter's board is based on the Texas Instruments ultra-low power MSP430 family of microcontrollers [10, 11]. Wireless communication is possible through the expansion header which is compatible with Chipcon Wireless Evaluation Modules from Texas Instruments. Communication between the two onboard microcontrollers is also possible. In addition, LEDs are also available on this board, and they were used to test and evaluate a valve control schedule. Furthermore, a serial interface also is supported by such a board to give the ability to interface it with any other external device. The implantable shunting software that was designed and developed in [2] was embedded into the microcontroller on one of the boards by using IAR embedded workbench as shown in Fig. 4 below. On the other side, the external shunting software was embedded into the patient device which was replaced by a PC in this work. Fig. 4 shows the prototype of the implanted and external shunting system.

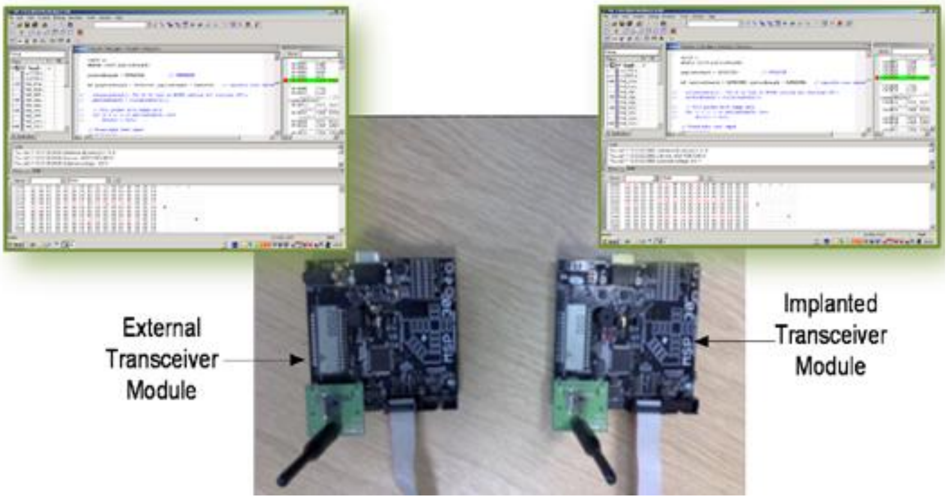

Fig. 4 The prototype of implanted and external shunting system

### *Interfacing of hydrocephalus patient model with implanted prototype*

Due to the complexity of the proposed shunting system, assessment, testing, and evaluation would mainly be based on the Momani's intracranial hydrodynamics (ICH) model [9] as a source of the ICP readings as well as an interactive environment to test, evaluate and validate the valve regulation method. The microcontroller was used to receive the ICP data from the output of the ICH model via the RS232 interface, and then store it in RAM. A specific ICP sensor schedule was used to collect ICP samples. The ICP data were analyzed by the intelligent analyzer sub-routine and the results were passed to the valve management sub-routine. The valve management sub-routine sends the decision, i.e., either open or close the valve, back via

RS232 to the ICH model. The valve in the intracranial hydrodynamics model was regulated based on both the analysis decisions and valve schedule which were stored in RAM. Simultaneously, the ICP level will be affected by the decision and will be sent again to the microcontroller. The RS-232 standard defines the two devices connected with a serial cable as the Data Terminal Equipment (DTE) and Data Circuit-Terminating Equipment (DCE). A block diagram of the proposed implanted prototype is illustrated in Fig. 5.

*Hardware environment*

The hardware environment for this part consists of a microcontroller, PC, and data link between the two. The microcontroller was used to run the embedded implanted shunting software. The PC is used to simulate the patient and to run the Momani's model. The PC also serves as a hydrocephalus patient environment with a mechatronic shunting system. Thus, the microcontroller would collect ICP data through a serial connection from the patient model which is running in real-time on the PC. The requested data is passed into RAM, stored, and analyzed based on the implanted embedded software requirements. A data link is also needed for the microcontroller and PC to communicate. This allows the implanted software to collect ICP data from the Momani's model. In addition, it would regulate the valve and control the pressure sensor that is simulated inside the Momani's Simulink model.

*Software environment*

Serial communication is a low-level protocol used for data communication between two or more devices. As the name implies, serial communication uses a data port to send/receive data in a serial manner, i.e., one bit at a time. Programming two or more devices to communicate serially requires that the devices operate at the same communication rates. In this part, a data communication link was established between the MSP430 board and a PC, where the PC hosts the hydrocephalus patient model, and the microcontroller hosts the implantable shunt software. The selected microcontroller is programmed using a C programming language. MATLAB™ versions 6.1 and higher support serial communication. MATLAB™ also has built-in toolboxes that contain commonly used engineering functions. MATLAB™ code was used in this operation to enable the Momani's model to send /receive data from/ to the microcontroller. A block diagram of the proposed implanted prototype is illustrated in Fig. 5 below.

## *Wireless shunting protocol*

The researchers have proposed a bidirectional wireless management protocol. Such protocol would be able to perform several tasks, including regulating the mechatronic valve based on a dynamically modified time valve schedule and communicating between the two diagnosing sub-systems. As well as remotely reprogramming the implanted shunting system, requesting a daily report from the implantable system and more. The next step is using this communication protocol to communicate between the two prototype parts (i.e. implanted and external). In this section, the implanted derived parameters, ICP data, and other important shunt information were prepared and set into the packet, and then this packet was encrypted and wirelessly sent through RF from the implanted shunt to the external one. On the other side, the packet was received, decrypted, and stored by the external prototype.

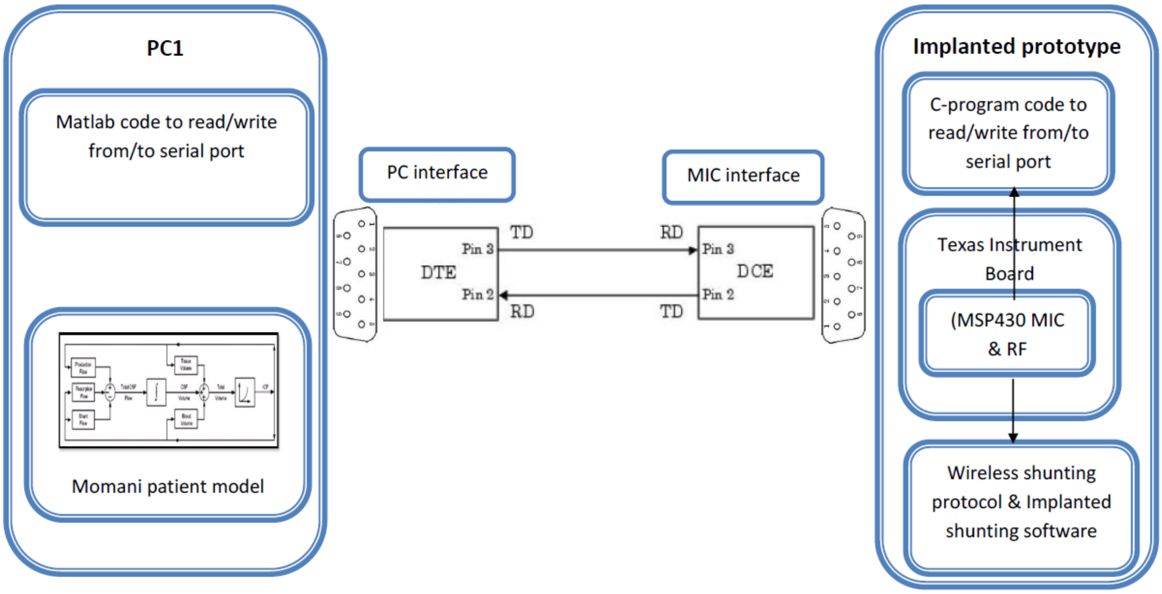

Fig. 5 A block diagram of the proposed implanted prototype

### *Interfacing between shunt management software and external prototype*

The external shunting software is mainly consisting of two parts. The first part is responsible for the management and treatment of hydrocephalus by performing many tasks such as wirelessly auto valve schedule updating, requesting ICP data and parameters, dealing with any emergency case, and activating closed loop mode. The second part is responsible for shunt management and diagnosis. Some of its features are detecting and identifying any implanted shunt fault and dealing with such fault by contacting treatment software as well as the physician or the patient. This software would be embedded into the patient device that is replaced in this work by a PC. To test and evaluate the performance of the shunting system based on the previous functions, an interface is needed between this software located on the PC and the external prototype. The external shunt prototype mainly consists of a PC, microcontroller, and transceiver. The microcontroller and transceiver are integrated into the Texas Instrument Evaluation Board. A data communication link is established between the MSP430 board and a PC, where the PC hosts the external shunting software, and the microcontroller hosts the external part of the wireless shunting protocol. The serial cable, which is used in this prototype, is called the DB-9 serial cable. This serial connection enables data communication between the external software and wireless shunting protocol. Fig. 6 illustrates the block diagram of the proposed external prototype.

## Results and discussion

As a result of this work, a prototype of the shunting system is developed that mainly consists of two Texas evaluation boards, two RF transceivers, two serial cables, batteries, and two PCs. The first step of developing the prototype was testing the interface between the hydrocephalus patient model and the implantable prototype through the serial port. The outcome of the patient model (i.e., ICP data) was sent through the serial port to the microcontroller according to the ICP sensor schedule which is also controlled by the microcontroller through the serial port. Then, the implanted embedded software stores analyze the received data and share the result with other implanted sub-routines.

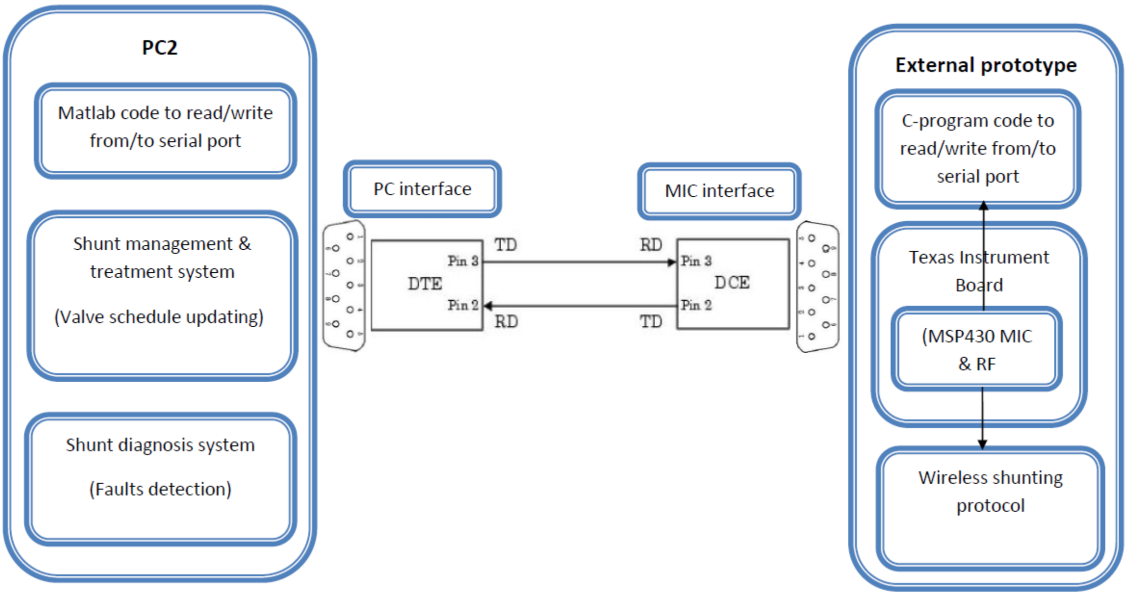

Fig. 6 A block diagram of the proposed external prototype

The second step was testing and evaluating the wireless communication protocol. A packet with ICP readings and derived parameters is prepared and wirelessly sent via RF to the external part. The received packet is then stored in external RAM. The third step was testing the interface between the external prototype and the management and treatment software. The stored data was read from external RAM and sent to the PC through a serial cable. Then, this data was passed to shunt software and used in treatment and diagnosis. On the other hand, the treatment and diagnosis software was used to perform many tasks and then send back various parameters to the implanted shunt software via serial port and through RF transceivers. These parameters were received by the implanted shunt software to update the current values for regulating the valve as well as collecting ICP data tasks. As a result of developing a such prototype, the power consumption algorithm and most system's functions were tested and evaluated i.e., auto valve schedule updating, ICP reading collecting, wireless communication on both sides, and fault detection method. In this work, the Momani's model is used as illustrated above to simulate the hydrocephalus environment (micropump, pulse pressure generator, stepper motor, pressure sensor, and valve).in addition, it is used to generate the ICP data for both normal and shunted high-pressure hydrocephalus conditions to study the performance of a mechatronic shunt. Flow measurement will occur by using a flowmeter and will be performed as future work to test and evaluate the shunt malfunctions. As a result of succeeding the proposed, designing, simulating, and testing the proposed physical framework, the proposed framework will be implanted and tested in the future.

## Conclusion

The outcomes of developing such a prototype are the evaluation of a mechatronic shunting system's overall performance, validation of the proposed methods and system design, testing of different functional aspects under different simulated conditions such as valve blockage, ICP sensor dislocation, valve disconnection, and flowmeter fault. In addition, such evaluation leads to a greater understanding of the behaviour of the system and the critical factors affecting the performance. Furthermore, results regarding the energy, frequency, and other requirements of the system were reached. In addition, the developed prototype was used to prove the proposed method for interference prevention. Many superfluous packets were sent through the system, but they were rejected by the implanted software. To the best of the researcher's knowledge, this work is the first to illustrate, test, and evaluate a prototype of a mechatronic hydrocephalus shunting system.

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**Abdelrahman Alkharabsheh, Ph.D.**
E-mail: abdel.r@acuq.ae

Abdelrahman Alkharabsheh received his B.Sc. Degree in Computer Engineering from Technical College of Mousel-Iraq, M.Sc. Degree in Computer Sciences from Amman Arab University-Jordan, and a Ph.D. Degree in Computer Engineering from the University of Liverpool, UK. His research interests include mechatronic shunting systems, expert systems, fuzzy logic, IoT, multi-agent systems, computer networks, wireless technology, power consumption, and biomedical engineering.

**Assist. Prof. Lina Momani, Ph.D.**
E-mail: lmomani@hct.ac.ae

Lina Momani received her B.S. and M.Sc. Degree in Industrial Engineering from the University of Jordan, and her Ph.D. Degree from the University of Liverpool, UK. Dr. Lina Momani is currently an Assistant Professor at the Higher Colleges of Technology, Faculty of Engineering, United Arab Emirates. Her research interests include hydrocephalus shunting systems, vertical farming, artificial intelligence applications, biomedical engineering, thermal energy storage technology, and gamification in teaching.

**Yousef Qawaqzeh, Ph.D.**
E-mail: Yousef.qawqzzeh@uoef.ac.ae

Yousef Qawaqzeh received his Ph.D. Degree in Computer Engineering. His research interests include artificial intelligence, data sciences, biomedical engineering, and networking.

**Amjad Alsakarneh, Ph.D.**
E-mail: Amjad.Alsakarneh@yu.edu.jo

Amjad Alsakarneh received his B.Sc. Degree in Mechanical Engineering from Jordan University of Science and Technology, M.Sc. Degree in Mechanical Engineering from Jordan University of Science and Technology, and a Ph.D. Degree in Mechanical Engineering from Cork Institute of Technology, Ireland. His research interests include mechatronic systems, neural networks, fuzzy logic, and smart systems.