Integrated Digital Manometer

for

Lumbar Puncture

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1. Problem Description

Lumbar puncture, sometimes called a spinal tap, is a meticulous procedure used to collect cerebrospinal fluid (CSF) for diagnostic purposes and therapeutic treatments. Diagnostic indications include infectious diseases, inflammatory processes, cancer, and metabolic disorders [1].

Surprisingly, the procedure for lumbar puncture and measurement of CSF has not changed in over 20 years. A long needle inserted through the back pierces the subarachnoid space below the cauda equina, allowing CSF to flow. A pressure reading is taken using a u-tube manometer that connects to the needle. CSF fills the graduated tube slowly, and once stabilized a manual reading is taken of the fluid level. The procedure is painful and complications arise from this delicate procedure, particularly in young and obese patients.

The u-tube manometer is too cumbersome a tool for this sensitive procedure. The doctor must steady the tube until CSF equalizes with atmospheric pressure before taking a pressure reading, extending the procedure and increasing the artificial flow of CSF [2].

2. Project Objective Statement

Our design is a replacement for the u-tube manometer used in conventional spinal tap procedures. Our compact microelectronic device is as accurate, disposable, and easy to use as the u-tube manometer. The invention is easy to hold in one hand, fast, and minimizes the flow of CSF from the patient.

To show that this idea is technically feasible, we built and tested a prototype device that demonstrates how hydrostatic pressures can be digitally measured through a needle.

3. Documentation of the Final Design

The lumbar puncture digital manometer is a hub that attaches to the conventional cannula used in spinal taps [Appendix 2: Final Design]. The manometer replaces the traditional u-tube manometer that is connected to the needle after its insertion.

The hub includes a pressure transducer, microcontroller with integrated analog to digital converter (ADC), compact battery, numerical display and buttons compactly encased in plastic. The device is enabled by pulling a slip of paper separating the battery connection during shipping and storage. The device automatically powers on, checks the transducer for malfunctions, and auto-calibrates. The device then displays measurements taken in one second intervals. The user can press the 'hold' button to freeze a measurement of interest or press a reset button to reinitialize the device.

The device will be sold as part of lumbar puncture package in a similar fashion to existing kits. These convenient kits provide all the tools necessary for lumbar puncture in a sterilized and fully disposable bundle. The lumbar puncture digital manometer is designed to be a disposable component of this kit.

Some of the risks associated with lumbar puncture include post–spinal tap headache nerve root trauma, CNS infection or cranial, cervical and lumbar subdural hematoma [3]. The risks associated with CSF pressure measure will not change with the implementation of the lumbar puncture digital manometer. All of the parts contacting the body are the same as those currently in use. Our device does not contact bodily fluid beyond the hub body. By minimizing the volume of CSF used to measure the pressure, this device may make lumbar puncture a safer technique.

4. Prototype

The prototype of our device can be described in four parts: the cannula and hub, pressure transducer, electronics, and power supply [Appendix 3: Prototype Photograph; Appendix 4: Prototype Schematic]. The prototype software is also outlined in this chapter.

The first section consists of the cannula and hub, and is the only section of the four in contact with the patient and the CSF. For our team's safety, the prototype employs a relatively short cannula, as the conventional needles used in lumbar puncture are quite long. The hub is fashioned from a syringe. Capillary tubing exits the side of the syringe, and transmits the sample pressure to the pressure transducer.

Freescale Semiconductors provided our team with samples of their MPXV4006G analog pressure transducers [4]. The transducer output is wired to the microcontroller.

The prototype uses an Olimex AVR-MT-128 development board centered around an Atmega128 microcontroller, an 8-bit RISC clocked at 16MHz [5]. This IC has an integrated 10-bit, 32 kHz ADC [6], which receives output from the pressure transducer.

The development board also includes a 5 V power regulator, an alphanumerical LCD display, a small speaker, an LED and some push-buttons. The prototype system is powered using a 9 V battery and starts automatically when power is supplied.

Software was written in C++ using the freely available WinAVR compiler. On power-up, a welcome message is briefly displayed before the device auto-zeroes and checks for hardware malfunctions. Next the user is instructed to press the button to measure the CSF pressure. The pressure is displayed on the LCD in cmH_2O. Multiple measurements can be taken be repeatedly pressing the button.

5. Proof that the Design is Functional and will Solve the Problem

The accuracy of the prototype was experimentally tested. A nitrogen gas tank, Cole-Parmer pressure controller, PTFE tubing of several different inner diameters and air-tight interconnects from Upchurch Scientific were used to supply various measured pressures to the pressure transducer. The digital conversion result from the ADC was compared against simultaneous measurements of the same pressure supply recorded using an industrial precision digital manometer made by Fisher Scientific.

High pressure gas flows from the nitrogen tank into the pressure regulator, which releases a lower gas pressure. This flows through the tubing and splits into two equal branches. These branches from the junction bring pressure to the industrial manometer (the control) and to our prototype. There is a static pressure in the system.

The supply pressure was varied across a range of fourteen pressures (10.3 to 30.3 cmH_2O). It was not possible to generate lower pressures using available equipment. To overcome this limitation, a zero-pressure measurement was recorded.

Our device was calibrated by applying comparing pressure values from the industrial manometer to the digital values presented by the microcontroller of our prototype.

The output of the prototype showed strong correlation ($r=0.99995$) to the measurements taken using the digital manometer [Appendix 5: Data Analysis]. We also found that the sensitivity and DC offset were the same as prescribed by the transducer manufacturer [4].

Using the linear correlation the transduction equation was entered into software, enabling output in cm H_2O. Direct comparison to the industrial manometer showed accuracy to within 0.1 cm H_2O.

6. Patentability

There are no existing patents or patent applications that directly address the problem of efficiently measuring pressure during lumbar puncture. Among the current patents related to CSF pressure monitoring devices for lumbar puncture are a spinal puncture fluid collection apparatus for CSF sampling [7]. There are some devices used for monitoring pressure such as an intraocular lens pressure monitoring device [8], and an implantable device for in-vivo intracranial and cerebrospinal fluid pressure monitoring [9]. There also exists a non-invasive method of measuring CSF pressure [10] [Appendix 6: Abstracts of related patents].

The main objective of our device is to obtain cerebrospinal fluid (CSF) pressure quickly and accurately. The existing kit for lumbar puncture uses a u-tube manometer for measuring CSF pressure. This instrument is bulky, cumbersome and time consuming resulting in a painful procedure for the patient. In comparison, our product offers various advantages over the existing instrument such as convenience to patient and physician, less cumbersome, quicker, economical, compact and accurate. In our device, the CSF pressure measured by the pressure transducer is an analog signal which is fed to an analog to digital converter. The digital output is sent to a microprocessor which displays the final output on a LCD screen on the device. The spinal tap procedure for collecting the CSF remains similar to the existing procedure. But the innovative idea is that the pressure is measured by a pressure transducer and displayed on an LCD screen instead of a u-tube manometer thus making the process faster and easier for both patient and physician. Thus considering all the advantages and originality of the idea, this device meets all the criteria for patentability laid down by the U.S. Patent and Trademark Office.

7. Anticipated Regulatory Pathway

The digital lumbar puncture device can be approved for commercial distribution in the United States using the Food and Drug Administration (FDA) 510(k) premarket notification form [11]. The premarket notification form petitions the FDA to determine the invention is substantially equivalent to equipment currently approved for use in the market. The 510(k) will allow us to bypass extensive and costly pre-market approval (PMA).

Before a 510(k) can be submitted, it must be demonstrated that the digital lumbar puncture manometer is substantially equivalent to a preexisting medical device. The digital manometer fits into this category because the needle, stylus, and cannula will be identical in shape, size and material to conventional lumbar puncture kits. The novel parts of our invention do not impair the conventional lumbar puncture procedure.

8. Estimated Manufacturing Costs

The following describes an estimation of costs for the electronic and medical components, as well as the cost of assembly and marketing of the lumbar puncture kit. The estimated total unit cost for mass production is about $30. Prices were estimated from quotes from various manufacturers, including Bectin Dikinson and Fisher Scientific and estimations from other sources. The value of the prototype device is estimated to be over $100, assuming the components are purchased individually instead of in bulk. Cost of assembly and marketing for a single prototype is assumed to be negligible. Thanks to the generosity of campus and corporate donors we only spent $85 constructing our prototype [Appendix 7: Estimated Manufacturing Costs].

9. Market Analysis and Sales Strategy

The product will undergo careful scrutiny of neurologists who have been using the conventional u-tube manometer for several years, and will be welcomed for its fast operation and ease of use.

One of the major problems associated with the lumbar puncture procedure is pseudo-pseudotumor cerebri (incorrect measurement of opening pressure) [12]. About 400,000 lumbar punctures are performed every year in the United States [13]. The device will be packaged in a lumbar puncture kit that includes all the materials necessary to perform the procedure. Transitioning to this device does not require significant modification to the lumbar puncture procedure, and sales are estimated to pick up within the first year of its inception. Due to the low-impact transition the device is estimated to become an integral part of the lumbar puncture toolkit within the five years of its inception, selling a million units annually worldwide.

The profit margin will be considerable due to the convenience offered by the device, the estimated selling price is about $150.

The device can be distributed either by direct distribution or by third party distribution. Direct distribution offers more control over sales and pricing, using a third party with a proven track record would be profitable as they would have strong contacts within the medical community [14].

Planning of a reimbursement strategy is required which states that the use of the device will be covered by insurance companies. The effective positioning of a product within the insurance community is crucial to securing coverage, receiving the proper reimbursement and ultimately, achieving success for the product [15].

10. Executive Summary

I. Problem

Lumbar puncture, sometimes called a spinal tap, is a meticulous procedure used to collect cerebrospinal fluid (CSF) for diagnostic purposes and therapeutic treatments. The procedure is risky and is particularly difficult to perform in obese and young patients.

Lumbar puncture frequently includes measurement of the CSF pressure. The existing kit for lumbar punctures includes a u-tube manometer used to measure CSF pressure. Reading the tiny measurement lines marked on the side of the glass while steadying the 40 cm long tube is a challenge. This instrument is bulky, cumbersome, time consuming and drains unnecessary CSF volume, resulting in a painful procedure for the patient. An advanced device is needed which is more convenient for both patient and physician.

II. Solution

Our solution is a compact microelectronic pressure measurement system contained in a handheld casing easily operated in one hand. Our invention utilizes a pressure transducer to convert pressure variations to changes in a voltage signal. These voltages are digitized and analyzed using a microcontroller, which displays the final pressure on a numerical display. The innovative idea is that the pressure is measured by a pressure transducer and displayed on an LCD screen making the process faster and easier for both patient and physician. Our device is as accurate and as disposable as the u-tube manometer. The device is easier to hold in the hand, faster, and minimizes the flow of CSF from the patient.

III. Competition

There are no competitors offering such a product. Related devices have been used to measure other biometric pressures, including blood pressure and intraocular pressure, noninvasive pressure measurement and implantable monitoring systems.

IV. Differentiation

Our product offers vast advantages over the existing instrumentation such as convenience to patient and physician, faster procedures, accuracy, ease of use, and safety. The total cost of the product will be low compared to the total cost of a conventional lumbar puncture kit, and it will add substantial value to the package.

V. Technical Feasibility

We have built a prototype that shows CSF pressure can be measured by a pressure transducer fed through an analog to digital converter. The digital output is sent to a microcontroller which displays the final output on a LCD screen on the device. The spinal tap procedure for collecting the CSF remains similar to the existing procedure.

VI. Regulatory and Reimbursement

The 510(k) will allow us to bypass extensive and costly pre-market approval (PMA). The digital manometer fits into this category because the needle, stylus, and cannula will be identical in shape, size and material to conventional lumbar puncture kits. The novel parts of our invention do not impair the conventional lumbar puncture procedure.

VII. Sales and Marketing

The product will be welcomed by neurologists for its fast operation and ease of use. Transitioning to this device does not require significant modification to the lumbar puncture procedure, and strong sales are expected within five years of inception.

Appendix 1: References

[1] Ellenby M.S., Tegtmeyer K., Lai S., et al. Videos in clinical medicine: Lumbar Puncture. N Engl J Med 2006;355:e12. Retrieved 24 Jan 2007 from www.nejm.org

[2] Renato Gonik, M.D. Pediatric Neurologist at Shands Hospital, Universi ty of Florida. January 23, 2007.

[3] Sucholeiki, R. Lumbar Puncture (CSF Examination). WebMD. Retrieved 24 Feb 2007 from www.emedicine.com/neuro/topic557.htm

[4] Freescale Semiconductor, Inc.: MPXV4006G Datasheet. Retrieved 22 Feb 2007 from www.freescale.com/files/sensors/doc/data_sheet/MPXV4006G.pdf

[5] Olimex Ltd.: AVR-MT-128 Schematic. Retrieved 13 Feb 2007 from www.olimex.com/ dev/avr-mt128.html

[6] Atmel Corp.: ATmega128(L) Datasheet. Revision O, October 2006. Retrieved 13 Feb 2007 from www.atmel.com/dyn/products/product_card.asp?part_id=2018

[7] Strittmatter WJ, inventor; Duke University, assignee; Spinal puncture fluid collection apparatus. US Patent 5396899. March 14, 1995.

[8] Frenkel REP, inventor; Frenkel REP, assignee; Intraocular lens pressure monitoring device. US Patent 5005577. Apr 9, 1991.

[9] Ericson MN, McKnight TE, Smith SF, Hylton JO, inventors; UT-Battelle, LLC, assignee; Implantable device for in-vivo intracranial and cerebrospinal fluid pressure monitoring. US Patent 6533733. Mar 18, 2003.

[10] Borchert MS, Lambert JL, inventors; California Institute of Technology, assignee; Non-invasive method of measuring cerebral spinal fluid pressure. US Patent 6129682. Oct 10, 2000.

[11] U.S. Food and Drug Administration. Center for Devices and Radiological Health: Device Advice. Available at: http:www.fda.gov/cdrg/devadvice/314.html. Accessed March 9, 2007.

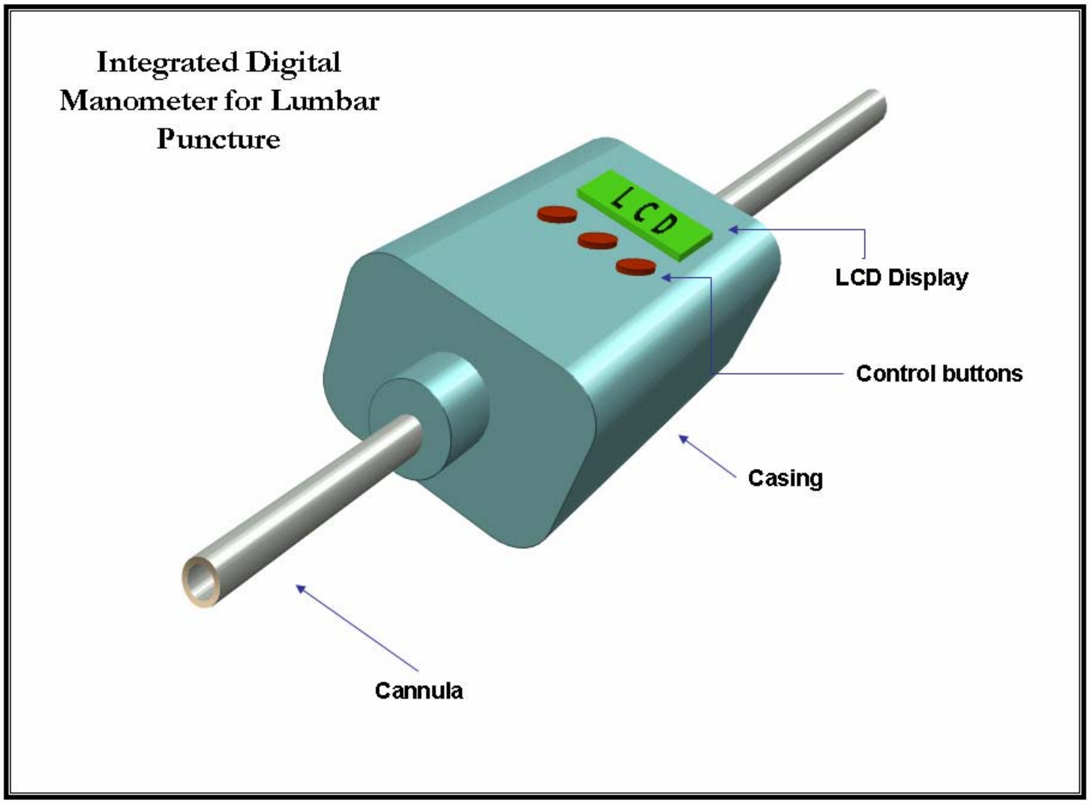
[12] Evans RW. Complications of Lumbar Puncture and their Prevention with Atraumatic Lumbar Puncture Needles. Retrieved 27 Mar 2007 from www.medscape.com/ viewarticle/420288

[13] Acad Emerg Med 2006 Jul;13(7):767-73.

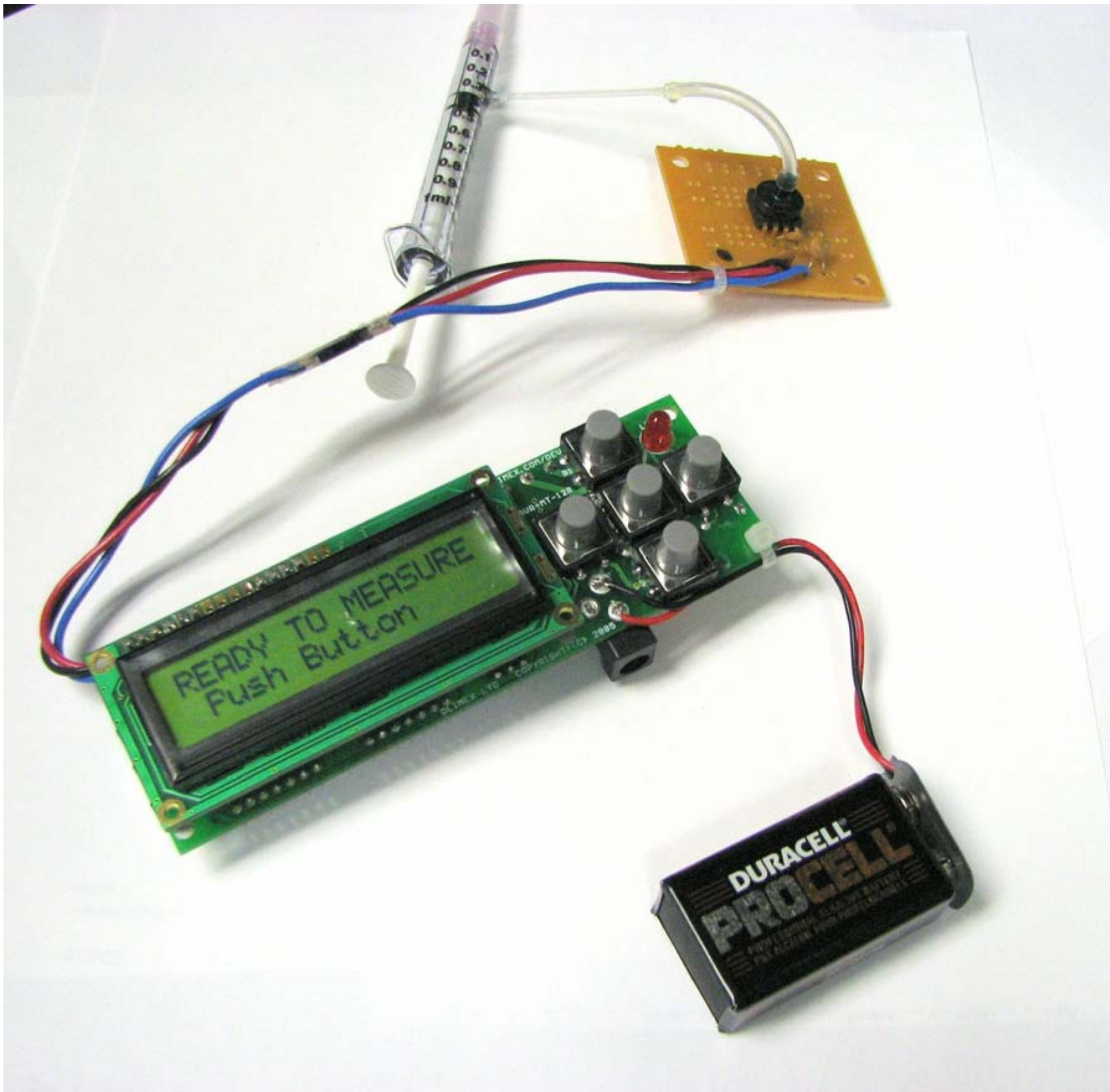
[14] Parker L. Medical device link. Medical Device Distribution in an International Market. Retrieved 27 Mar 2007 from www.devicelink.com/mddi/archive/ 97/01/020.html

[15] Aequitas. Reimbursement Strategy. Available at www.aequitas.us/services/ reimbursement.html Accessed Mar 27, 2007.

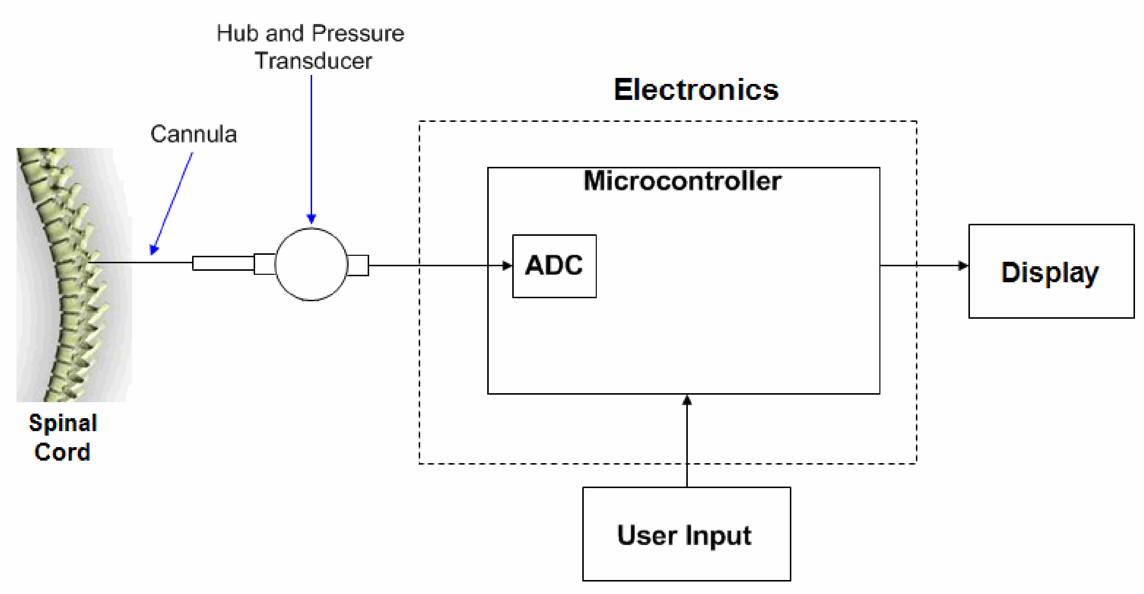
Appendix 2: Final Design



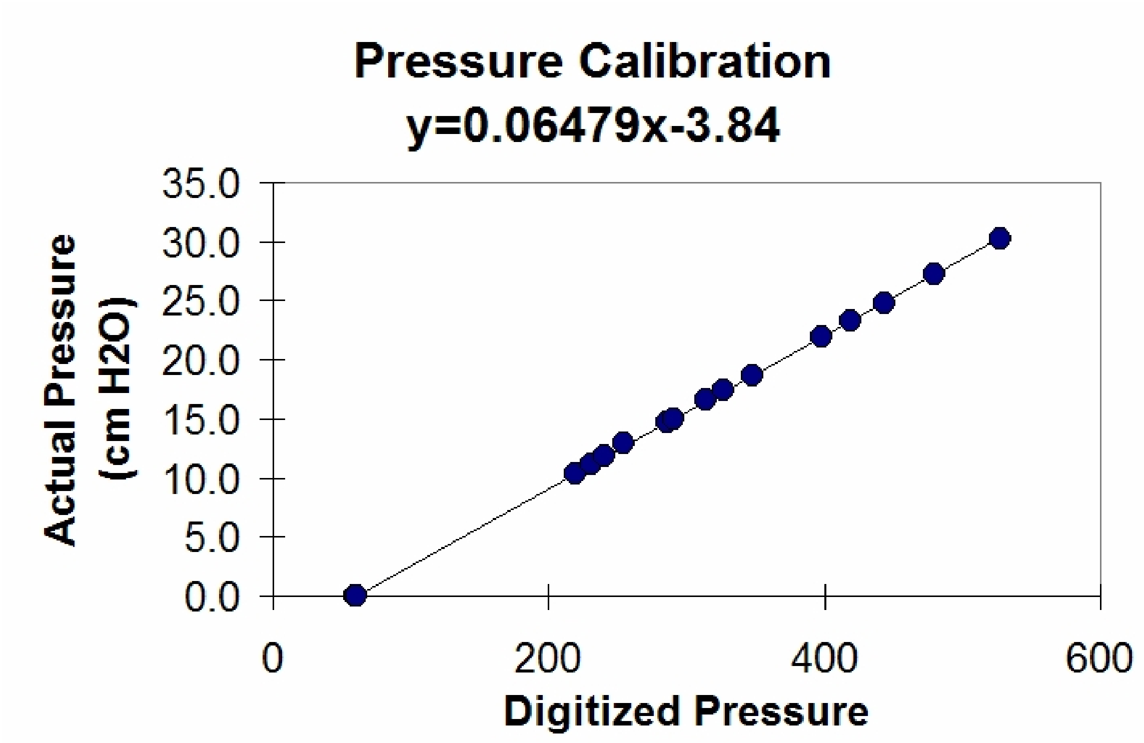
Appendix 3: Prototype Photograph



Appendix 4: Prototype Schematic



Appendix 5: Prototype Data Analysis



Appendix 6: Abstracts of related patents

[7] Strittmatter WJ, inventor; Duke University, assignee; Spinal puncture fluid collection apparatus. US Patent 5396899. March 14, 1995.

An apparatus used for performing a lumbar puncture to obtain a sample of cerebrospinal fluid. The spinal puncture apparatus is designed to interface with a sample container. A sample container apparatus is also disclosed, as is a kit for use in performing spinal puncture on a subject to obtain a sample of cerebrospinal fluid.

[8] Frenkel REP, inventor; Frenkel REP, assignee; Intraocular lens pressure monitoring device. US Patent 5005577. Apr 9, 1991.

The apparatus monitors intraocular pressure using an implantable intraocular lens which includes an affixed sensor apparatus for detecting the intraocular pressure.

[9] Ericson MN, McKnight TE, Smith SF, Hylton JO, inventors; UT-Battelle, LLC, assignee; Implantable device for in-vivo intracranial and cerebrospinal fluid pressure monitoring. US Patent 6533733. Mar 18, 2003.

This is a completely implantable intracranial pressure monitor, which couples to fluid shunting systems and other internal monitoring probes.

[10] Borchert MS, Lambert JL, inventors; California Institute of Technology, assignee; Non-invasive method of measuring cerebral spinal fluid pressure. US Patent 6129682. Oct 10, 2000.

Intracranial pressure is calculated non-invasively from eye measurements such as the intraocular pressure and a parameter of the optic nerve.

Appendix 7: Estimated Manufacturing Costs

COST ANALYSIS			
	UNIT COSTS		
	Est. Volume	**Est. Prototype**	**Actual**
ELECTRONICS			
Pressure Transducer	$ 8.00	$ 30.00	$ -
I/O (LCD, Buttons…)	$ 2.00	$ 40.00	$ -
Microcontroller	$ 1.50	$ 15.00	$ 85.00
Passive Components	$ 1.00	$ 5.00	$ -
Other Parts	$ 1.00	$ 5.00	$ -
Passive Components	$ 0.75	$ 2.50	$ -
Power Supply	$ 0.25	$ 5.00	$ -
SUB-TOTAL	$ 14.50	$ 102.50	$ 85.00
MEDICAL			
Hub / Syring	$ 1.00	$ 1.15	$ -
Cannula	$ 1.00	$ 1.30	$ -
Adhesive	$ 0.10	$ 5.00	$ -
Misc. Tubing	$ 0.10	$ 0.50	$ -
SUB-TOTAL	$ 2.20	$ 7.95	$ -
MANUFACTURING			
Unit PCB Assembly	$ 5.00	$ -	$ -
Labor	$ 0.60	$ -	$ -
Packaging	$ 1.00	$ -	$ -
Sterilization	$ 1.00	$ -	$ -
SUB-TOTAL	$ 7.60	$ -	$ -
MARKETABILITY			
Advertising	$ 5.00	$ -	$ -
Misc Costs	$ 2.00		
SUB-TOTAL	$ 7.00	$ -	$ -
TOTAL UNIT COST:	**$ 31.30**	**$ 110.45**	**$ 85.00**