Continuous Urine Output Monitoring System

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Executive Summary

In neonatal care units there is a need for a noninvasive, safe, and simple way to accurately measure and monitor a patient’s urine output. On a standard bedside monitor there are only four patient outputs being monitored including heartbeat, respiration, blood pressure, and oxygen saturation level. Without being able to monitor the urine output of a patient it is difficult to diagnose and treat hydration problems the patient may be having.

The current technology used today in neonatal intensive care units is to weigh new and soiled diapers. This current process is not only a health risk for health care providers, but it also is inaccurate given that urine and fecal matter can’t be weighed separately. Catheters may also be used and can accurately measure and monitor the urine output of a patient, but catheters can cause infections and are uncomfortable.

A sensor will be designed in order to monitor patients’ urine output in the neonatal intensive care unit. The sensor will be attached to the lower abdomen and will use ultrasound technology to constantly measure the size of the patients’ bladder. There will be a single output on the bedside monitor that will allow health care providers to easily monitor and treat the patients’ hydration problems.
1.0 Introduction

1.1 Background

Dr. Leonard Eisenfeld in conjunction with the Neonatal Care Unit at The Connecticut Children’s hospital, request assistance in the development of device that will monitor the urinary output of infants. This monitor will work for the staff of both doctors and nurses caring for the infant, to maintain a watchful eye on hydration issues that might be causing internal problems for the patient. Currently in order to determine how much a baby voids hourly, a highly labor intensive process of weighing the diapers occurs. Prior to the baby wearing the diaper, it is weighed, and then once the baby voids the diaper is weighed again and the starting weight is subtracted from the final weight to get an idea of how much urine the baby outputted. The problem with this procedure is its immense spectrum of inaccuracy, where the presence of stool along with a void will create and unsure guess at how much is stool and how much is urine, affecting the way in which the caretakers can use the gathered information to assist the patient. Another way in which urine output is measured is the insertion of catheters. Catheters are inserted into the urethra and carry out the urine to a concealed bag which allows for decently accurate measurement of a void. However, the insertion of this device is considerably less difficult in female patients then male, and in either case both run the risk of infection and trauma to the urinary tract as it remains a foreign object that is not necessarily readily accepted by the human body. The need for an easier more efficient and safer way to measure urine is extremely prevalent in the current health care industry.
1.2 Purpose of the Project

The theoretical device would be comprised of a sensor used to pick up on vital signs and bodily functions using a sensor to ultimately determine the size and volume of an infant patient’s bladder. The device would be placed on the patient’s lower abdomen, so as to remain in the diaper area and contain a sensor with signal reception and filtration in order to accurately display a wireless analysis. Ultimately the finished design will possess the power to use the received signal and send this signal to a monitoring system, where caretakers can look at the information and analyze the data in a way that will allow them to best care for the patient. The display system will also be attached to an alarm system which will allow for an alert of any problems or changes in the infants ability to void. The alarm is essential as the infants urine output is directly related to the amount of nourishment the baby may or may not need, as with infants, especially neonatal patients, feeding is extremely hard and often the caretakers require more information to decide how much food the patient requires. The urine output also directly relates back to internal, or septic, shock, as well as circulation and diffusion of oxygen in the blood of the patient.

1.3 Previous Work Done By Others

Currently there is no medical device that accurately works in determining and analyzing the urine output of infants. The addition of this medical device will provide infant caretakers with a great piece of mind, no longer requiring the labor intensive process of weighing the diapers, and allowing for the immediate knowledge of the baby’s hydration through the use of the display and alarm system. The end goal is to develop a sensor device that will be attached to the infant’s lower abdomen that provides signal reception, filtration, display, and analysis. This device will promote an
easier, safer, and more accurate monitoring procedure that will better assess the patient’s immediate well-being, especially as it relates to their hydration.

1.3.1. Products

There are monitoring systems on the market which have been used to monitor critical fluid output, while also monitoring core temperature and relaying the data to a display system. Currently The BARD® CRITICORE® Monitoring System is used in ERs and ORs for full sized patients, to enhance patient care and keep track of the daily physiological processes that are critical in the full analysis of a patient. There have been many other attempts to produce an electronic device that can be used to monitor the urinary output of an infant. However, many have run into the same type of problem of not being able to correctly identify the type of sensory device that is best suited in conveying the overall nature of the patient’s health according to their urinary output.

1.3.2. Patents

The BARD® CRITICORE® Monitoring System is a patented product with the overall product description of consisting of a fluid output and core temperature monitoring system. The overall system uses a disposable collection system, which prevents disease transmission from person to person. The system is able to measure the fluid output electronically by using ultrasound technology, which is the overall goal of the current project. The patent number is P1 3336 and it was issued on June 1, 1997 and underwent extensive amounts of testing.
2.0 Project Description

2.1 Objective

Using ultrasound technology, such as 3D ultrasound machines, a sensor will be designed to measure the size of a patients’ bladder. The device will be safely secured to the lower abdomen of the patient using a nonirritant gel to ensure the sensor remains in the proper location. The sensor will continuously measure the size of the bladder. The information gathered from the sensor will be run through computer software in order to calculate the urine output level of the patient. The software will output a single value that will be displayed on the bedside monitor for health care providers to easily read and understand.

The device will be a small enough unit that it will fit on premature as well as full term neonatal intensive care patients. The sensor will also be placed in a secure and safe case or protective plastic in order to prevent patients from coming in contact with exposed wires from the sensor.

The software will be user friendly in order to prevent health care providers from having to get trained to use the program. LabView will most likely be used as software to convert readings from the ultrasound into a single value for the bedside monitor. The software will save data for 24 hours and allow the health care providers to permanently save any portion of the monitor readings to the patients’ file as well. The health care providers will also be able to set in alarm values that will cause an alarm to go off if the urine output level outside of the set parameters. This will help health care providers provide the correct amount of nourishment and fluids to a patient. Eventually the sensor will become wireless in order to remove unneeded wires from the patients’ bodies.
2.2. Methods/Materials

The casing of the continuous urine output monitoring system will be a strong high-impact resistant polymer (probably HDPE, but the exact plastic has not been decided). The reason for this is if any person drops the device limited damage will occur to the device. Also, plastic has been shown to be the best material for human interaction by the FDA, USDA and NSF. Plastic can be easily manufactured to be soft and without hard edges, thus injury to the infant will be very limited. Plastic does not cause skin irritation, which would be a significant factor since electronic devices become hot during operations. The infant will not feel uncomfortable and device will be more effective. Despite these advantages, electromagnetic radiation is a major concern not addressed. This is because, while the inner microprocessor will be working, friction will cause heat to be produced, thus warming the device and also emitting significant electromagnetic radiation. In order to counter this Soft&Safe Sheilding™ fabric will be placed on the bottom of the device in order to protect against electromagnetic radiation. This device is made of 70% Bamboo and 30% Silver, giving it unique antibacterial and anti-odor characteristics. The inside of the device will contain a microprocessor or other type of integrated circuit made of silica or some blend of metalloids.

The device will be specially designed to fit the lower abdomen region of the infants. Moreover, it will be circular in shape and will strap around the infant in the diaper region (see Fig 1):
Fig 1: “Assembly” of the device monitoring urine output

**Electrical**

The device must communicate wirelessly with the monitor in the hospital so all the healthcare staff can easily view it. Instead of having the device constrained by a wire, Bluetooth technology will be used to communicate the data to the monitor. As stated before, some type of microprocessor will be required in order to work the device.

**Software/Programming**

The objective is not to invent a new device, but rather to develop novel monitoring techniques. Thus, the team’s real job is connecting existing technology efficiently to convey the data required. Initially it was thought to develop a system to measure the volume of the bladder. However, this system is clearly deficient, as different infants will have different bladder sizes. Also, during the bladder voiding cycle, the bladder itself always contracts and relaxes, changing the shape of the bladder every voidance. According to programming, 3-D ultrasound is very complex and few other people have expertise in the area, making this option less valuable.
The given algorithm/plan for the monitoring system is still in its early stages. The team must still meet with Ledyitee Wheagar and Dr. Philip Smith (both recommended by the client) in order to gain better understanding of the technologies already trying to solve this issue. Also, other meetings must take place with ultrasound specialists at UConn in order to better understand how this technology works (the plan set forth will heavily depend on ultrasound).

Primarily, a brief introduction to what ultrasound actually is and how it is useful for the problem in question. Ultrasound is high-frequency sound pulses that are pulsated through the body via probe. The sound hit various boundary tissues and reverts back, whilst other waves reach other boundary points and revert back. These reflected waves are picked up by the probe and given to a computer device that calculates the distance between the probe and tissue and thus creates a 2-D image.

The plan is to use an ultrasound probe and somehow program it so that it can display numerical data wirelessly onto the monitor (see Fig 2).
The ultrasound process will be similar to one that is used by urologists to diagnose urinary retention and observe residual volume. In essence, residual volume will indicate actually how much the infant has voided, if there are any retention problems and how much the child is voiding normally. The continuous data will be fed to LabView (preferred over Matlab) that will consistently store this data point and send it via Bluetooth to the monitor to display. It is still to be decided if a graph or numerical data will be displayed. Most medical data is displayed as both numerical and graphical (i.e. ECG, EKG etc.).

A possible program might include the “Read from Measurement File” element from the LabView controls palette being connected to a while loop and finally a display. The “Read from Measurement File” has a close correlation to the desired command for the LabView program in this case. That is, read the data and store it for further processing. The ultrasound data would have to be saved onto a file on a computer, then inputted into LabView and finally sent via wireless to the monitor. Again, the exact configurations for the design are not yet known (some of the information may be incorrect; the team needs to meet with many advisors who were unavailable before this proposal was due). Maybe the Labview program can itself project the digital information on the monitor, or there may have to be another monitor just displaying the data.
3.0 Budget

Currently the budget for two projects remains 1000 US Dollars, and the following table breaks down the materials required to complete the Urine Output Monitor portion of our project.

<table>
<thead>
<tr>
<th>Components</th>
<th>Pricing in USD</th>
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<tr>
<td>HDPE (2 Natural Sheets of 0.125&quot;x24&quot;x96&quot;)</td>
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</tr>
<tr>
<td>Soft&amp; Safe Shielding Fabric (4 linear feet)</td>
<td>$100</td>
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<td>Matlab</td>
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<td><strong>Total:</strong></td>
<td><strong>$310</strong></td>
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4.0 Conclusion

A senior design project will be created for Dr. Leonard Eisenfeld and the Neonatal Care Unit at the Connecticut Children’s Hospital. The project will be designing and building urine output continuous monitoring system for NICU patients. The device will be used to monitor the output of urine for a patient to ensure they are receiving the proper amount of nutrition and fluids. The sensor will be placed on the lower abdomen of the patient and send a single output to the bedside monitor. Ultrasound technology will be used for the sensor and LabView will be used as software to convert data collected from the sensor to a single value to be displayed. The ultrasound will measure the size of the patients’ bladder and calculate urine output level based on changes in bladder size. The sensor will be small enough and have an adjustable waistband in order to accommodate both premature and full term NICU patients. Creation of the urine output continuous monitoring system will allow medical providers to easily monitor and respond to hydration issues for NICU patients.