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Ultrasound-Guided Noninvasive Measurement of a Patient's Central Venous Pressure

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***Abstract*— Central Venous Pressure (CVP) is an important physiological parameter, the correct measure of which is a clinically relevant diagnostic tool for heart failure patients. A current challenge for physicians, however, is to obtain a quick and accurate measure of a patient's CVP in a manner that poses minimum discomfort. Current approaches for measuring CVP involve invasive methods such as threading a central venous catheter along a major vein, or tedious physical exams that require physicians to grossly estimate the measurement. Our solution proposes a novel noninvasive method to estimate central venous pressure using ultrasound-guided surface pressure measurement. Specifically, our device works in conjunction with an ultrasound machine and probe that is used to visualize the interior jugular (IJ) vein below the surface of the skin on a patient's neck. Once the interior jugular vein is located, our device detects the pressure on the skin required to collapse the IJ and correlates this value to a central venous pressure reading reported to the operator. This quick and noninvasive measurement is suitable for emergency situations or primary care settings where rapid diagnosis of a patient's CVP is required, and prevents the need for further invasive and costly procedures. The measurement procedure is also simple enough to be performed by operators without extensive medical training.**

I. INTRODUCTION

CENTRAL venous pressure (CVP) is an important physiological parameter, the correct measure of which is a clinically relevant diagnostic tool for heart failure patients. For example, increased venous pressure is indicative of low cardiac output and higher blood volume in the veins. With over 5 million patients [1] in the U.S. presenting with heart failure-like symptoms annually, a current challenge for physicians is to obtain a *quick* and *accurate* measure of a patient's CVP in a manner that poses minimum discomfort.

Current methods of measuring CVP accurately are rather invasive and involve threading a catheter along a major vein until it is within vicinity of the right atrial compartment. Pressure readings are then collected directly from inside the vein. Although this procedure is commonly performed, threading a central line in this fashion carries certain risks. For example, vein cannulation can result in internal bleeding if an artery is accidentally pierced, and a risk of infection is present whenever the skin is punctured. Furthermore, the procedure is also time-consuming and difficult to perform without hospitalization or in primary care settings.

Alternatively, doctors first check the CVP noninvasively by treating the superior vena cava as a manometer to the right atrium. The pressure at the right atrium correlates to the height of the column of blood in the vein, which can be estimated by visually identifying small disturbances in the jugular vein on the surface of the subject's neck [2]. These disturbances are a reflection of atrial pumping and are observed at the top of the column of blood. The actual pressure relative to the heart can be roughly estimated by lifting the subject slowly from a supine position until the fluctuations become visible on the surface of the neck as shown in Fig. 1. The hydrostatic pressure that corresponds to the height difference between the neck and the heart is a measure of CVP [2]. This procedure, however, is prone to error because spotting the exact height where the fluctuations appear is very difficult, especially in patients where layers of fat obscure the jugular vein. The process of physically lifting the patient incrementally is also taxing, time-consuming, and not well-suited for emergency conditions.

Clearly, there is a need for a system that provides an accurate noninvasive measure of a patient's central venous pressure. The proposed device and procedure would allow

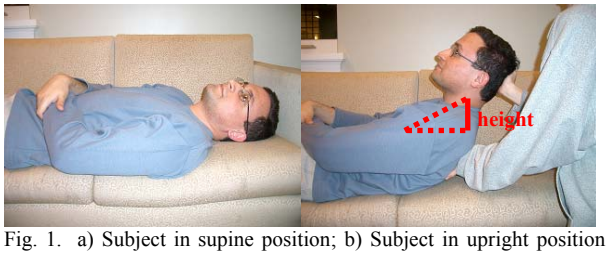

Fig. 1. a) Subject in supine position; b) Subject in upright position corresponding to height at which neck fluctuations are visible.

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physicians to perform a simple and safe check of CVP before deciding whether inserting a catheter is necessary, ultimately reducing the frequency and the need for this invasive procedure. The proposed method would also be cheaper and quicker than existing methods and thus more suitable for rapid diagnosis in emergency situations and primary care environments.

II. Discussion

Our solution proposes a novel noninvasive method to estimate central venous pressure using ultrasound-guided surface pressure measurement. Specifically, our device works in conjunction with an ultrasound machine and probe that is used to visualize the interior jugular (IJ) vein below the surface of the skin on a patient's neck. Once the interior jugular vein is located, our device detects the pressure on the skin required to collapse the IJ and correlates this value to a central venous pressure reading reported to the operator.

This quick and noninvasive measurement is suitable for emergency situations or primary care settings where rapid diagnosis of a patient's CVP is required, and prevents the need for further invasive and costly procedures. The measurement procedure is also simple enough to be performed by operators without extensive medical training.

A. Prototype Design

The prototype device consists of a handheld probe attached to a control unit. The handheld probe is cylindrical in shape, and has a high-precision 5-lb load cell on the tip that detects the applied pressure and transmits this reading to the control unit. The probe also has a button along the longitudinal side of the probe body, which is used to initiate and end the CVP recordings. The control unit consists of an 8-bit microprocessor that analyzes the incoming load cell data, and a digital display that outputs the CVP readings. The probe and control unit are meant to work in conjunction with an ultrasound machine and transducer for visualization of the interior jugular vein. The choice of ultrasound machine is up to the operator since the described device is self-contained and does not require a particular ultrasound machine model. To aid in emergency diagnosis, a portable ultrasound is recommended; to aid in visualization accuracy, a high-frequency linear ultrasound transducer with low penetration depth is recommended. Section IV provides more detailed descriptions and specifications of the prototype device.

The measurement principle assumes that the IJ vein can be modeled as an ideal vessel according to Laplace's Law [3] as described in (1).

$$T = \frac{P \times R}{M} \tag{1}$$

where T is wall tension, P is transmural pressure, R is vessel radius, and M is wall thickness. When transmural pressure (the difference between internal and external pressure) is zero, the tension falls to zero and the vessel collapses.

Fig. 2. a) Operator placement of probe and handheld transducer; b) Visualizing the IJ while collapsing the vein

Therefore, by measuring the external pressure required to collapse a vein, the internal pressure, or CVP, can be inferred. The handheld probe is responsible for this measurement and is used alongside an ultrasound probe capable of visualizing the IJ specifically, which is located underneath the sternocleidomastoid muscle and anteriolateral to the common carotid artery [2]. After locating the vein with the ultrasound transducer, the operator pushes down with the handheld probe on the vein while the control unit display shows the applied pressure in real-time. Operation of the device on a subject is shown in Fig. 2. The operator continues to apply pressure until the IJ vein first begins to collapse (initial pressure), and then pushes the button on the side of the probe to store this value. This step helps factor out the effects of surrounding soft tissue and varying initial skin compliance on the pressure measurement. The user then continues to apply pressure until the IJ is completely collapsed (collapsing pressure), and presses the button again to record this value. Fig. 3 shows ultrasound images of the IJ during each stage of the measurement procedure.

As shown in Fig. 4, the control unit ultimately displays the change in pressure between the initial pressure and the collapsing pressure, which corresponds to the central venous pressure as described in (2).

$$CVP = P_{collape} - P_{initial} \tag{2}$$

The effectiveness of the measurement will depend on factors such as the mechanical characteristics of the patient's

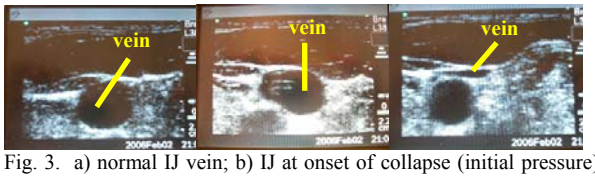

Fig. 3. a) normal IJ vein; b) IJ at onset of collapse (initial pressure); c) collapsed IJ (collapsing pressure)

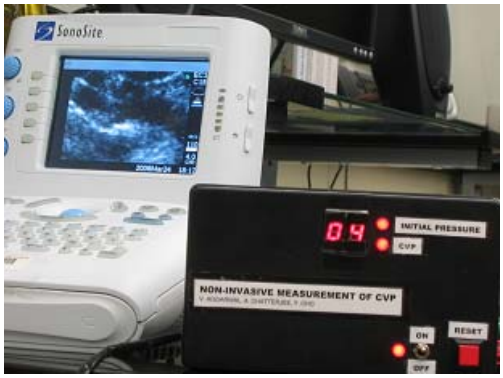

Fig. 4. Final CVP recording after IJ vein is fully collapsed.

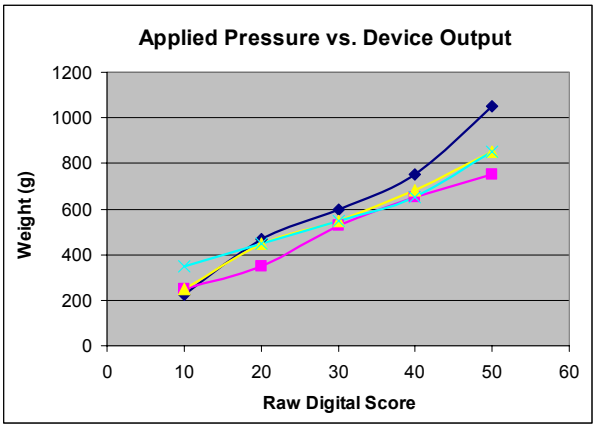

Fig. 5. Device output (raw digital score) as a function of the applied pressure of the handheld probe.

tissue near the IJ, as well as the skill of the operator in probe placement and in pressure application. These effects can be reduced with effective calibration schemes and training.

B. *Functionality Testing*

In order to assess the functionality of our device, we first characterized the pressure-output relationship of the compression load cell. This was accomplished by pressing down on a digital scale for varying weights and recording the raw digital value output from the analog-to-digital converter in our control unit. Since pressure is weight per unit area, and since the applied contact surface of the probe tip on the digital scale was constant, we simply plot weight versus the digital output to reflect the pressure-output trend. As shown in Fig. 5, our experiments find that the digital output of our device is linearly proportional to the applied weight, and thus the applied pressure, within the operating pressure ranges of our application. Confirming this linear behavior is important in developing a mapping function between the raw digital value and the actual central venous pressure of the patient, which will be discussed as part of clinical testing.

Further testing included verifying gross operation of the device on a limited number of subjects. Although difficult to validate the actual CVP reading without proper clinical testing, we did achieve consistent results for repeated trials on the same subject. That is to say we were able to repeatedly observe collapse of the IJ vein in a consistent manner, thus supporting the effectiveness of our noninvasive method of measuring CVP. In addition, the subject was also asked to perform the Valsalva maneuver, which showed a predicted increase in the CVP value for a subject [2,4]. These results are summarized in Table 1.

Table 1. Testing data from Patient 1.

		Normal	Valsalva
Day 1	Trial 1	5	9
	Trial 2	4	10
	Trial 3	4	9
	Average	**4.33**	**9.33**
Day 2	Trial 1	6	11
	Trial 2	6	11
	Trial 3	6	11
	Average	**6**	**11**
Day 3	Trial 1	5	9
	Trial 2	5	10
	Trial 3	4	10
	Average	**4.67**	**9.67**
Day 4	Trial 1	3	9
	Trial 2	3	9
	Trial 3	3	10
	Average	**3**	**9.33**

C. *Clinical Testing*

In order to accurately validate the readings from our device with correct CVP values, access to patients with central venous catheters is required. Therefore, we propose a comprehensive clinical study that samples varying demographics (e.g. age, sex, weight), clinical environments (e.g. Emergency Room, Intensive Care Unit, Cardiac Care Unit), and diagnostic scenarios (e.g. cardiac symptoms, asymptomatic, general check-up). Aside from assessing the efficacy of our device, increased patient testing will also help us develop further ergonomic and feature improvements based on patient and operator feedback.

Our study design proposes testing at least 30 subjects from a broad demographic spectrum. Each subject will have their CVP measured with the device 5 times per session for a total of 5 sessions over a period of one month. This will allow for comparison of the device-measured CVP value with the catheter-measured value over a period of time, as well for assessment of intra-operator measurement variability. To gauge inter-operator variability, a separate set of measurements will be performed on subjects willing to participate in an extra session with multiple operators. Each extra session will consist of 5 measurements per operator for a total of 15 measurements. At time of submission, we are currently in the process of seeking clinical approval from the Johns Hopkins University Institutional Review Board (IRB) and plan to begin a formal clinical study in early summer. The proposed venue for the study is the Johns Hopkins Bayview Medical Center, with clinical and financial support from Dr. David Hellman, Chairman, Department of Medicine, Johns Hopkins Bayview Medical Center and Dr. Roy Ziegelstein, Director, Residency Program in Internal Medicine, Johns Hopkins Bayview Medical Center.

III. SPECIFICATIONS

A. *Prototype Design*

This section describes in detail the design specifications of our prototype device, although many design elements are applicable to the final design as well.

Fig. 6 illustrates the handheld probe, which is cylindrical in shape and 15 cm long. The tip contains a recessed area where a high-precision 5-lb load cell **2** fits in snugly. The top of the load cell is fitted with a cap **1** that allows for a wider and more rounded contact surface for the measurement. The rounded cap surface channels force more effectively from the compliant skin surface to the load cell. Furthermore, since the cap has no direct connection to the probe body, all applied

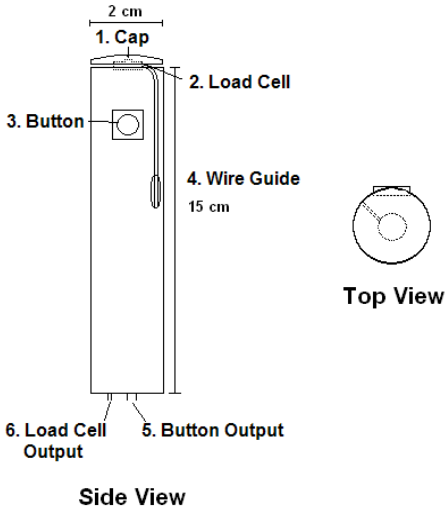

Fig. 6. Side and top view of handheld probe.

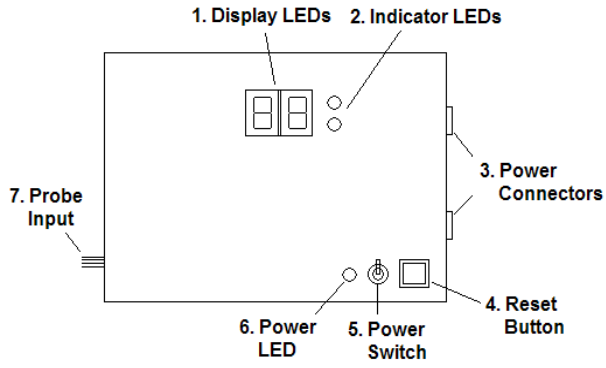

Fig. 7. Top view of control box.

force is funneled through the load cell. The cap remains fixed to the sensor during the measurement via a latex cover that stretches over the probe tip and applies enough tension to keep the cap from falling. This latex cover also serves the dual purpose of providing a sterile surface for measurement that can be replaced between subsequent users, and of insulating the patient from any electrical shock. The power and signal wires from the load cell run down inside the probe through a wire guide **4**. In addition to the load cell, a push button **3** is located on the side of the probe near the tip. This placement is designed to aid the operator in pushing the button without altering position or pressure of the handheld probe, as if it were a pen. The back of the probe contains a connector that transfers power, button output **5**, and load cell output **6** to a cable that runs to the control unit.

Fig. 7 illustrates the control unit of the invention. As shown in the figure, one side of the control unit box contains connections with the handheld probe **7** including power, load cell output, and button output. The output signals are directed to input ports of an 8-bit PIC16F877 microcontroller mounted on an internal circuit board. On the opposite side of the control unit box are three power connectors **3** that supply +5 V, -5 V, and ground to the internal circuit board. The top surface of the box has a toggle switch **5** that ensures power is delivered to the circuitry only when the switch is in the raised "on" position. A power indicator LED **6** next to the switch indicates when the board is powered. On the other side of the switch is a reset button **4** that resets the PIC chip and allows for the start of a new measurement without interrupting the power supply to the board and handheld probe. The output display consists of two seven-segment LEDs **1** that are mounted flush with the box surface. These LEDs are controlled by output registers of the PIC chip and are used to display the central venous pressure values calculated from the load cell input. Next to the display, two indicator LEDs **7** show when the button on the probe has been pushed once (single light) and twice (both lights).

Fig. 8 is a schematic diagram of the internal circuit board, which is primarily used to support the PIC16F877 chip **5**. A differential output signal from the LCKD-5 load cell **1** is passed through an INA128P **3** instrumentation amplifier, which amplifies the analog signal by a gain of 1000. The amplified signal is then passed through an active low-pass filter made with an LM741 operational amplifier **4**. The filter has a cut-off frequency of 0.5 Hz in order to let only DC signals pass. The final amplified and filtered signal is then connected to an A/D converter on the PIC chip for further digital processing and analysis. As previously described, the PIC chip accepts analog input from the load cell and a digital input from the probe button. Output pins are connected to two seven-segment LEDs **6** that display the pressure values, as well as two indicator LEDs that indicate when the button on the handheld probe **2** has been pushed once (single light) and twice (both lights). The PIC chip is accompanied by a crystal oscillator **9** that supplies a 10 MHz clock signal. In addition, a reset button **7** grounds pin 1 of the PIC in order to reset the software and start a new measurement cycle. The overall power supply to the board is routed through a power switch **8**.

The following is a description of the actual output control and measurement calculations performed by software running on the PIC chip. The software works in three stages: 1) initial tension on the load cell due to the latex cover and cap is measured and subtracted out of subsequent measurements so that the readings start at zero; 2) the

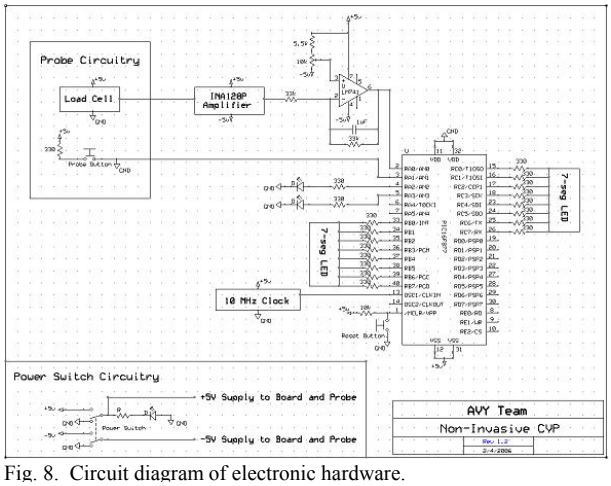

Fig. 8. Circuit diagram of electronic hardware.

program loops continuously and provides real-time measurement and display of pressure readings until the operator presses a button to signal the start of vessel collapse (initial pressure). This action resets the pressure value to zero and subsequent pressure values are measured in reference to this new zero value; 3) a second button push signals the end of the measurement and halts further recording. The display will hold this final central venous pressure measurement until the chip is reset or powered off.

B. Final Design

The final design of our prototype will incorporate several enhancements that would still fall under the original design concept. The possible areas of improvements include: packaging and integration, force measurement, force distribution, software algorithm, visualization mode, data storage, display, and power alternatives.

For starters, the prototype currently consists of a separate probe and control unit connected by a cable. However, as shown in Fig. 9, the electronics of the final design could be miniaturized to the point where the microprocessor and display units are integrated into the probe body itself, forming a single handheld device similar to a digital thermometer. This type of packaging would make the product easier to transport and easier for an operator to use on a patient. The dimensions of the probe could also be altered for better ergonomic design, including grip and comfort for the operator.

For force measurement, the prototype uses a sub-miniature compression load cell with a measurable range from 0–5 lbs. This transducer was chosen for its small size, small force range, and quality of construction; however, the design concept can be carried out by any transducer capable of measuring force accurately at a scale < 5 lbs with a contact area of approximately 2 cm^2. Areas too small would cause the probe to slip past the vein instead of compressing it, whereas areas too large would introduce more unwanted soft tissue effects. Other potential transducers for this application include piezoresistive force sensors and semiconductor pressure sensors.

An important consideration for the prototype was also the distribution of force at the contact point, and whether or not the load cell would detect all of the applied force. Our solution was to construct a rounded cap that would improve contact with the soft skin surface and channel the applied force to the small filament at the tip of the load cell. Although the rounded cap is a key design feature, one consequence of this design was that the cap would not be directly attached to the probe body. With no direct attachment, the cap is prone to falling off when not covered by the latex shield. A better solution would be to directly mount the cap to the force transducer, or attached it to the body via links that would not transmit a compressive force load down the length of the probe body itself. A number of mechanical alternatives could be envisioned, but the goals are still to maintain a rounded surface contact area and to channel all applied force to the transducer.

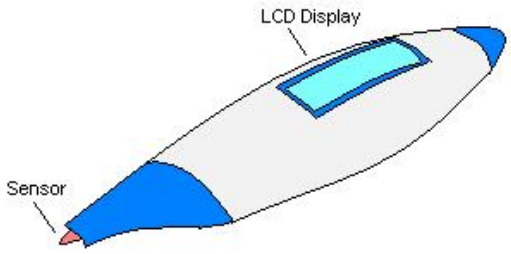

Fig. 9. Conceptual illustration of the final design, with control circuitry integrated into probe body.

The novelty of the pressure measurement algorithm is that it accounts for soft tissue factors by allowing the operator to zero the force measurement when the IJ begins to first collapse. This algorithm could be enhanced with information designed to further correlate the measured pressure with the actual CVP. At the time of writing, the product has not been calibrated to any patient with known CVP values, however scientific studies to elucidate this connection are in the planning stages. The algorithm to convert force readings to CVP values is one aspect of the design concept that will likely be enhanced as more data are collected.

The device works under the principle of Laplace's Law, assuming that vessels with external pressures equal to their internal pressures will collapse. Ultrasound was chosen as the most suitable way for an operator to detect the collapse of the IJ, however, other visualization modes are possible. Doppler imaging of the IJ may also be used to detect the collapse, although the technique is not as user-friendly as ultrasound. Another way is to use acoustic detection of the vein's collapse by listening for characteristic sounds. This method could be less expensive since it does not require the complex processing necessary to reconstruct a 2-D image. The accuracy of any alternative method to detect vein collapse would have to be tested before its compatibility with the design concept could be determined.

The prototype only stores enough information to output one CVP value, after which it must be reset in order to obtain a new reading. The final design would have on-board memory that would allow for storage of multiple CVP values. This would enable the operator to retrieve previously measured CVP values in order to track the trend of CVP measurements of a particular patient.

The prototype display consisted of two seven-segment LED display units that were used to output a two digit value for CVP. This display could be upgraded to an LCD, enabling the product to display numbers with greater accuracy as well as characters in scrolling messages. The utility of this improvement lies in increasing the capability of the display to transmit accurate pressure readings as well as messages pertaining to the status of the device. An LCD with accompanying control inputs would also allow the operator to access previously stored information.

Lastly, the prototype currently runs off an external power supply that supplies +/-5 V and common ground to the circuit board and sensor. Although multiple powering schemes could be envisioned that would be an improvement over the current method, the final design will likely use a battery supply that can be recharged with an AC adapter, enabling the unit to function as a truly portable measurement device. The choice of power source represents mainly a necessary convenience for the function of the product and is not a significant part of the design novelty.

IV. Conclusion

A search for prior art has revealed limited publications in the scientific community, and no patents that describe a measurement technology and procedure at all similar to our submission. Therefore, the area of ultrasound-guided CVP measurement with noninvasive force transduction appears to be fresh intellectual property with no existing patent protection. Further research has led us to conclude that: 1) the patentability of the measurement *procedure* is not very high since some aspects of our procedure have been anticipated by prior publications, and since the patentability of medical procedures in general is rather poor due to their difficulty to enforce; 2) the patentability of the *device* is very good since the lack of commercialization of this technology leaves open avenues for product development accompanied by technology patents. To take advantage of this we have filed a provisional patent through the Johns Hopkins University Technology Transfer Office, and are proceeding towards a non-provisional patent.

Significant regulatory hurdles are not expected since the noninvasive force measurement does not introduce safety concerns if the procedure is performed correctly and appropriately. Furthermore, our device is designed to be used in conjunction with ultrasonic imaging, which has been labeled as a Class II device with performance controls by the FDA. Therefore, our device could follow a standard 510(k) pre-market notification regulatory pathway as opposed to following the more rigorous pre-market approval (PMA) process.

The novelty of the technology may be a deterrent to its adoption by medical practitioners, but clinical studies of the technology and measurement procedure should be pursued to provide hard evidence of its utility. If the data is encouraging, industrial partners would be free to pursue product development and marketing in a wide-open competitive field. Tying the distribution of this product to the ultrasound market is a good idea since the ultrasound market is growing with a compound annual growth rate (CAGR) of 5.9%, expected to reach over $1.89 billion by 2010 with unit sales to top 22,000 [5]. This growth is fueled by the rising demand for ultrasound machines among new end users beyond Radiology and OB/GYN. Our device fits well in this rapidly growing market and allows ultrasound technology to become more useful to a variety of health practitioners ranging from cardiologists and emergency room doctors, to primary care physicians and nurses. This device would most likely make its way to the market as a technology licensed to ultrasound manufacturers that develop the device to enhance the capabilities and the desirability of their product suite. Addition of the device would be a negligible manufacturing cost while providing the seller with a significant competitive advantage over rival manufacturers.

The real impact of this device could be felt in 6,000 ICUs [6] and 35,000 primary care facilities [7] across the country, either as a necessary step in a life-saving procedure or during measurement of key vitals during a standard exam. Critics who consider the price of an ultrasound too high for CVP measurement should also consider the numerous other uses of an ultrasound machine, including guidance in central venous access procedures and visualization of organs such as the heart, liver, and kidneys. Another cost-mitigating factor for the noninvasive approach is the costs and risks associated with central vein cannulation, a procedure that could be performed less often if a cheaper and safer alternative to measure CVP were available. In conclusion, the direct ultrasound-guided noninvasive central venous pressure measurement has the potential to make CVP measurements quicker, easier, and safer. This technology should definitely be evaluated in clinical studies and is a strong candidate for industrial attention and further product development.

V. Illustrations

Additional illustrations include Fig. 10, which shows a working prototype of the proposed device, with both the control box and handheld probe. Fig. 11 provides a closer view of the control box during operation, while Fig. 12

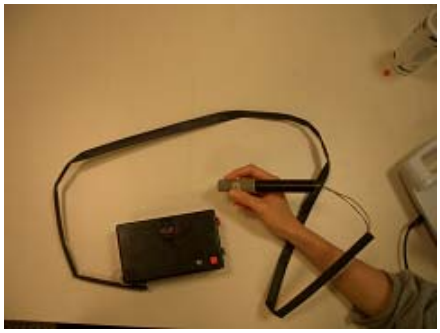

Fig. 10. Control box and handheld probe.

Fig. 11. Close-up view of control box.

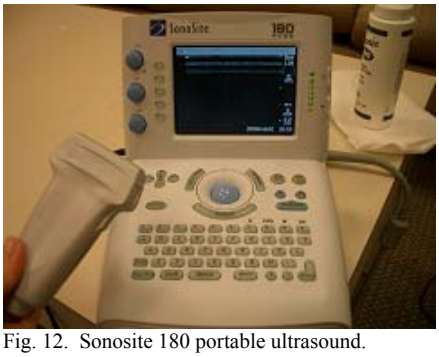

Fig. 12. Sonosite 180 portable ultrasound.

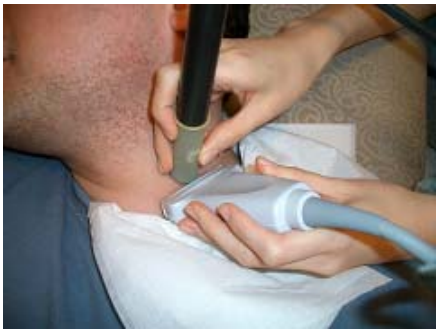

Fig. 13. Probe placement during measurement procedure.

depicts the Sonosite 180 portable ultrasound machine used in conjunction with our device. Fig. 13 demonstrates correct positioning of the ultrasound transducer and handheld probe during patient use.

VI. Verification of Project Success

A full demonstration video of our project is available at www.ece.uwaterloo.ca/~vnaggarw/CVPdemo.wmv.

Acknowledgment

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