Proposed Senior Design Project: Investigate repackaging COTS BP monitors for continuous wear

Larry Beaty (labeaty@ieee.org)

Twin Cities IEEE Phoenix Project

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Project Description

<u>Introduction:</u> The twin cities IEEE "Phoenix Project" is a small group of engineers volunteering their time to, among other things, design a new kind of ambulatory blood pressure monitor. The purpose of this project is to repackage existing cuff-based blood pressure monitors for the arm and the wrist to be convenient and comfortable to wear, including solving problems such as where to put the battery pack, eliminating moisture collection under the cuff, and increasing device safety.

<u>Background</u>: The Chronobiology Laboratory at the U of MN has known for years that when blood pressure is monitored by an ambulatory (wearable) device every half hour, day and night, for a week, five "Vascular Variability Disorders" can be detected. One of these disorders is a more precise definition of hypertension (high blood pressure) than is currently being used in mainstream healthcare; the others are either unknown or unused in mainstream healthcare. All of the VVDs, however, represent tangible risks of stroke and/or other health concerns. The Phoenix Project goal is the design of a blood pressure monitor that would enable bringing the use of VVD detection into everyday use in mainstream healthcare. This student design project will allow you to be a part of this groundbreaking endeavor.

Current methods for continuously monitoring blood pressure require the use of inflatable cuffs, pumps, and electronics similar to the automatic systems used in clinics and pharmacies. These devices and methods are awkward, intrusive, and not conducive for wearing 24 hours a day for a week. The idea is to design and construct a monitor system that would be comfortable enough to wear for 24 hours a day, and cost effective enough to use at home.

Industrial-grade ambulatory BP monitors currently sell to physicians and hospitals for \$1500 to \$5000. The Phoenix Project would like to convince manufacturers to sell these or similar devices to the general public (a much larger market) for less than \$100, in part by publishing "open source" instructions for building an ambulatory BP monitor using existing home-market monitors and relatively minor modifications. The student project would provide valuable input to this part of the Phoenix Project.

<u>Scope</u>: The project begins with disassembling a COTS non-ambulatory blood pressure monitor, or with building a blood pressure monitor from plans published as "application notes" by a microcontroller manufacturer. Modify the device electronics and programming to take readings on an automated & timed basis, and to increase safety (since the original design was not for a device worn continuously and operating while the wearer is asleep). Then design a new package for the electronics, display, batteries, air pump, and pressure sensor that is attached directly to the arm or wrist, is balanced for comfort, doesn't slide around, and doesn't collect perspiration under the cuff (perspiration leads to rashes and itching when the cuffs are worn continuously for several days).

The student team will choose the starting point (existing off the shelf monitor to disassemble or "kit" to assemble), modify and/or assemble and/or disassemble electronic circuits, add a digital timer and buzzer and additional sensors to the electronics if necessary, package the electronics into one or more (e.g., plastic) enclosures, mount the enclosure(s) to the cuff, and investigate and test alternate materials for absorbing or wicking away moisture. In addition, a hazard analysis similar to one done by a medical device manufacturer is to be performed and reported on.

Project Goals:

- 1) Reverse engineer a COTS BP monitor, or find a suitable "kit", for a monitor that can collect at least 50 readings in memory and offload those readings to a computer.
- 2) Design an automatic time-based triggering mechanism, adjustable to take a reading every 10 min, 15 min, or 30 min.
- 3) Design packaging with everything attached to the arm cuff (no long tubing to a battery pack or pump), or design light, small, balanced packaging for a wrist cuff (try for "as convenient to wear as a wristwatch"). Packaging of existing electronics will probably have to be redesigned to be divided up into 2 or 3 packages to fit comfortably around the arm.
- 4) Attempt to address the problems of sweating and rashes under the cuff when worn continuously.
- 5) Demonstrate success by wearing the monitor for 1 full week and submitting the data for a chronobiological analysis.
- 6) Perform a medical device hazard analysis similar to one the FDA would require for medical device approval. (Some help with this will be provided if necessary.)
- 7) Publish a final report that will be posted on the Phoenix Project website.

Possible stretch goals:

8) Add a Bluetooth or USB interface, eliminate the display and controls from the monitor, and program a cell phone to replace the display and controls.

<u>Known User Specifications</u>: The system should have a path to achieve ease of use, wearability, and low cost (try for less than \$100 CGS – Cost of Goods Sold).

<u>Interdisciplinary Opportunities</u>: For packaging a medical device, including the selection and testing of bio-compatible materials, mechanical engineering and/or biomedical engineering skill might be required. Also, since part of the project would include data acquisition, a computer science / computer programming skill might be needed to design and write programs to interface with the system, program the microprocessor(s), and program the cell phone.

<u>Proprietary Information</u>: The Phoenix Project is completely open source; all information can be freely distributed and discussed. This includes freely discussing the project with prospective employers and inclusion on your résumé.

<u>Available Resources</u>: 1) There are funds available for the materials and supplies needed to build and test the system. 2) There is equipment available in the IEEE student room in Keller Hall (EE/CSci building). 3) The participants of the Phoenix Project will be available for consultation during the project. 4) There are many reference documents that can be made available. 5) There is a list of possible tasks that can be supplied to help get a project plan started.

Examples of blood pressure monitors already determined to likely be suitable for this project:

- Microlife 3AC1-PC arm cuff monitor
- Omron HEM-670IT wrist monitor
- http://focus.ti.com/docs/solution/folders/print/310.html
- http://www.designmsp430.com/Rate.aspx?submission_uuid=9aaf27e5-e7f4-4870-84b3-f64d94300abc
- http://www.designmsp430.com/Rate.aspx?submission_uuid=4d583602-999c-4530-b59c-f2763f57fd2e
- http://www.freescale.com/files/microcontrollers/doc/ref manual/DRM101.pdf
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