Towards inexpensive home Ambulatory BP Monitors

[Work in Progress]

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Phoenix Project, Twin Cities IEEE

See http://www.phoenix.tc.ieee.org/

then sign up as a volunteer

Phoenix organizations

- The Phoenix *Project* will develop the monitor. It will focus on product development and launch.
- The Phoenix *Measurement Program* will encourage the monitor to be used to obtain measures of normal health. It will focus on public health and policy.
- The Phoenix *Clinical Program* will encourage the use of the monitor in diagnosis, prevention and treatment. It will focus on clinical practice and services.

Phoenix Project goal

To make a blood pressure monitor that is

- inexpensive
- unobtrusive
- easy to use
- collects a week of blood pressure measurements

- A monitor that is worn continuously, automatically taking readings every half hour, useful to chronobiology research and healthcare

Phoenix Project activities

- System architecture
- ABPM technologies
- Design and build ABPM (electronics lab)
- Embedded software
- Data analysis methods, algorithms
- Application software
- Regulatory issues, quality systems

ABPM technologies

- Sensors: Cuffs, Piezoelectrics, Optoelectronics, Microphones (ultrasound), Impedance Plethysmograph
- Algorithms: Oscillometric, Time of Flight (a.k.a. Pulse Transit Time)

- Today's topic: Modifications to commercial off-the-shelf oscillometric BP monitors
  - Can home-quality monitors be useful ABPMs?

A step along the way

- Provide material for a “science project” whereby students make an ABPM and learn about the Sphygmochron™ reports
  - Art, Biology, Electronics, Math, Invention, Writing
  - Use the sphygmochron.org website

- Convince manufacturers of home quality monitors to make useful as ABPMs
  - A&D, OMRON, Microlife, Spacelabs, etc.
  - Make low-cost ABPMs available to general public

The “fanny pack” monitor

The monitor and timer are worn on the waist inside the fanny pack and the cuff is worn on the arm at all times. The unattached USB cable is for uploading the BP data to a personal computer.

Data Analysis

SPHYGMOCHRON-TM Monitoring Profile over Time; Computer Comparison with Peer Group Limits

Blood Pressure (BP) and Related Cardiovascular Summary.

Name:---- Larry Beaty — Patient #: LBea0811
Age: 47 — Sex: M
Monitoring From: 2008-11-16 21:28 — To: 2008-11-24 11:59
Comments: This monitoring session contains data taken with a MicroLife Model BP3AC1-1PC home BP monitor rigged up with a timer to make a rudimentary ABPM. Do not use for healthcare assessment.

CHRONOBIOLOGIC CHARACTERISTICS

	SYSTOLIC BP (mmHg) Patient Value	SYSTOLIC BP (mmHg) Peer Group Reference Limits	DIASTOLIC BP (mmHg) Patient Value	DIASTOLIC BP (mmHg) Peer Group Reference Limits	HEART RATE (bpm) Patient Value	HEART RATE (bpm) Peer Group Reference Limits
ADJUSTED 24-h MEAN (MESOR)	132.9	98.4-135.1 Range	82.5	60.3-87.2 Range	68.1	56.4-81.2 Range
PREDICTABLE CHANGE (DOUBLE AMPLITUDE)	30.01	6.4-39.40 Range	25.24	4.84-29.80 Range	11.91	5.26-36.20 Range
TIMING OF OVERALL HIGH VALUES (ACROPHASE) (hr:min)	16:32	11:48-17:40 Range	15:51	11:08-16:48 Range	18:40	11:44-17:20 Range

	STD (MIN; MAX)*	STD (MIN; MAX)*	STD (MIN; MAX)*
PERCENT TIME OF ELEVATION	14.4%	2.8%	0.0%
TIMING OF EXCESS	20:26 (hr:min)	21:31 (hr:min)	0:00 (hr:min)
EXTENT OF EXCESS DURING 24 HOURS HBI*	9 (mmHg x hour)	1 (mmHg x hour)	0 (mmHg x hour)
10-YEAR CUMULATIVE EXCESS	34 (mmHg x hour)/in 1,000's units	5 (mmHg x hour)/in 1,000's units	0 (mmHg x hour)/in 1,000's units

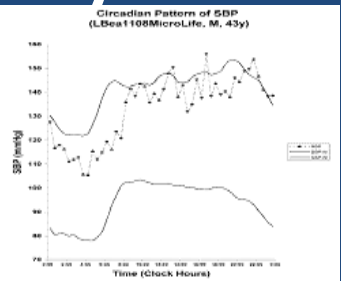
Individualized bounded indices: (STD = Standard) (Min = Minimum) (Max = Maximum) (HBI = Hypertensive Index)

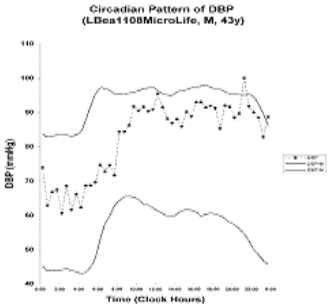
INTERVENTION NEEDED
No
Yes Drug Non-Drug

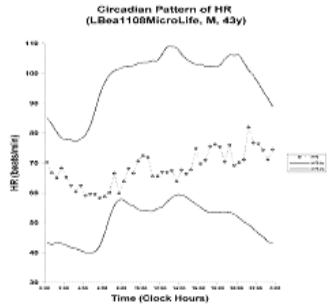
MORE MONITORING NEEDED
Annually
As soon as possible
Other specify_____

Prepared By___Larry Beaty_____Date_11_/_25_/_2008__

1) Unusually long standing or lying down during waking; unusual activity, such as exercise, emotional loads, or schedule changes, e.g. shiftwork; etc.; 2) Salt, calories, kind and amount, other, etc.







Comparison to professional ABPM

	SBP MESOR	SBP Amplitude	SBP Acrophase
Nov 2006 A&D	126	12.4	-257
Nov 2007 A&D	128	12.1	-280
Nov 2008 Microlife	133	15.0	-247
	DBP MESOR	**DBP Amplitude**	**DBP Acrophase**
Nov 2006 A&D	74	12.7	-258
Nov 2007 A&D	80	9.6	-276
Nov 2008 Microlife	82	12.8	-238
	HR MESOR	**HR Amplitude**	**HR Acrophase**
Nov 2006 A&D	64	4.4	-270
Nov 2007 A&D	66	6.2	-290
Nov 2008 Microlife	68	6.0	-281

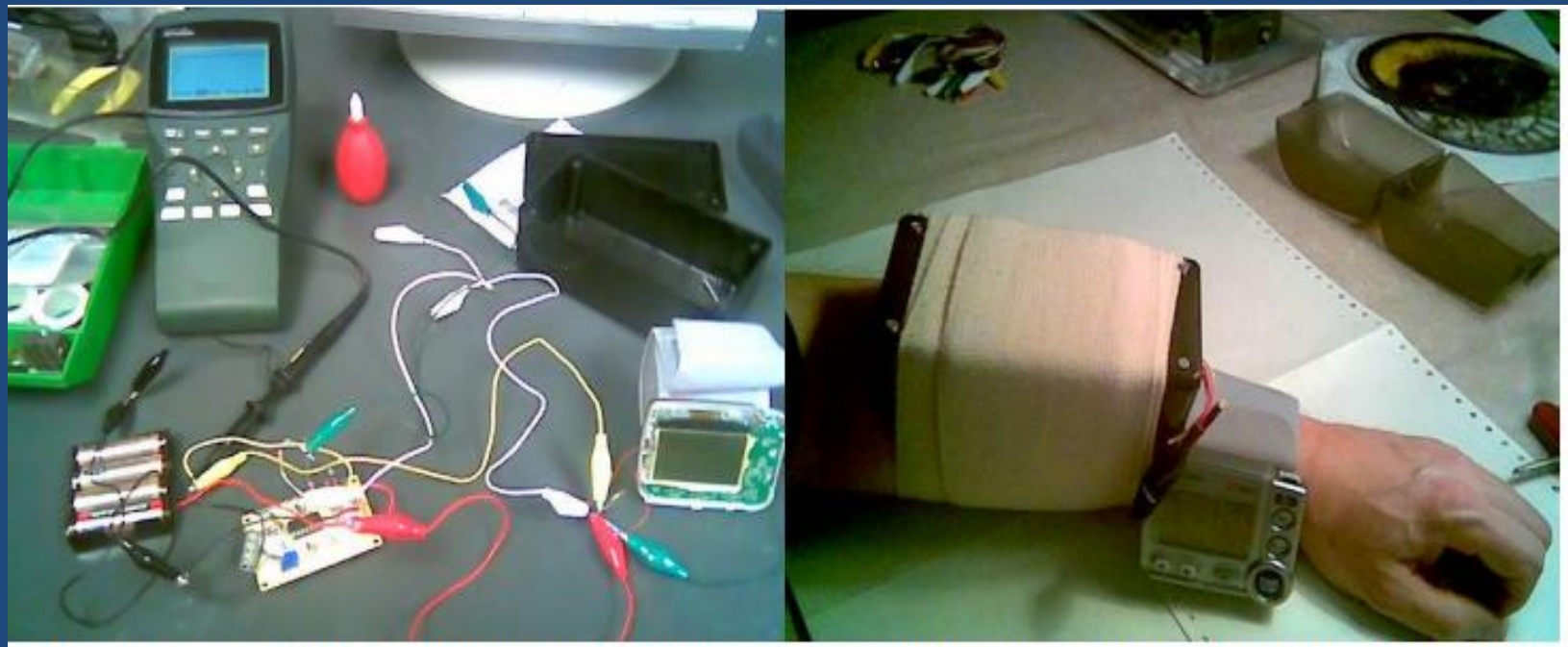
BP MESOR differences are statistically significant (but show a progression, so difference might not be due to the monitor). Overall, monitor appeared to operate adequately.

Advancement: Wrist Monitor

- Wrist monitors “known” to be less accurate, but they are more comfortable to wear. Can the Sphygmochron™ still be useful with these less accurate readings?
  - Surprising to some: Indications are YES

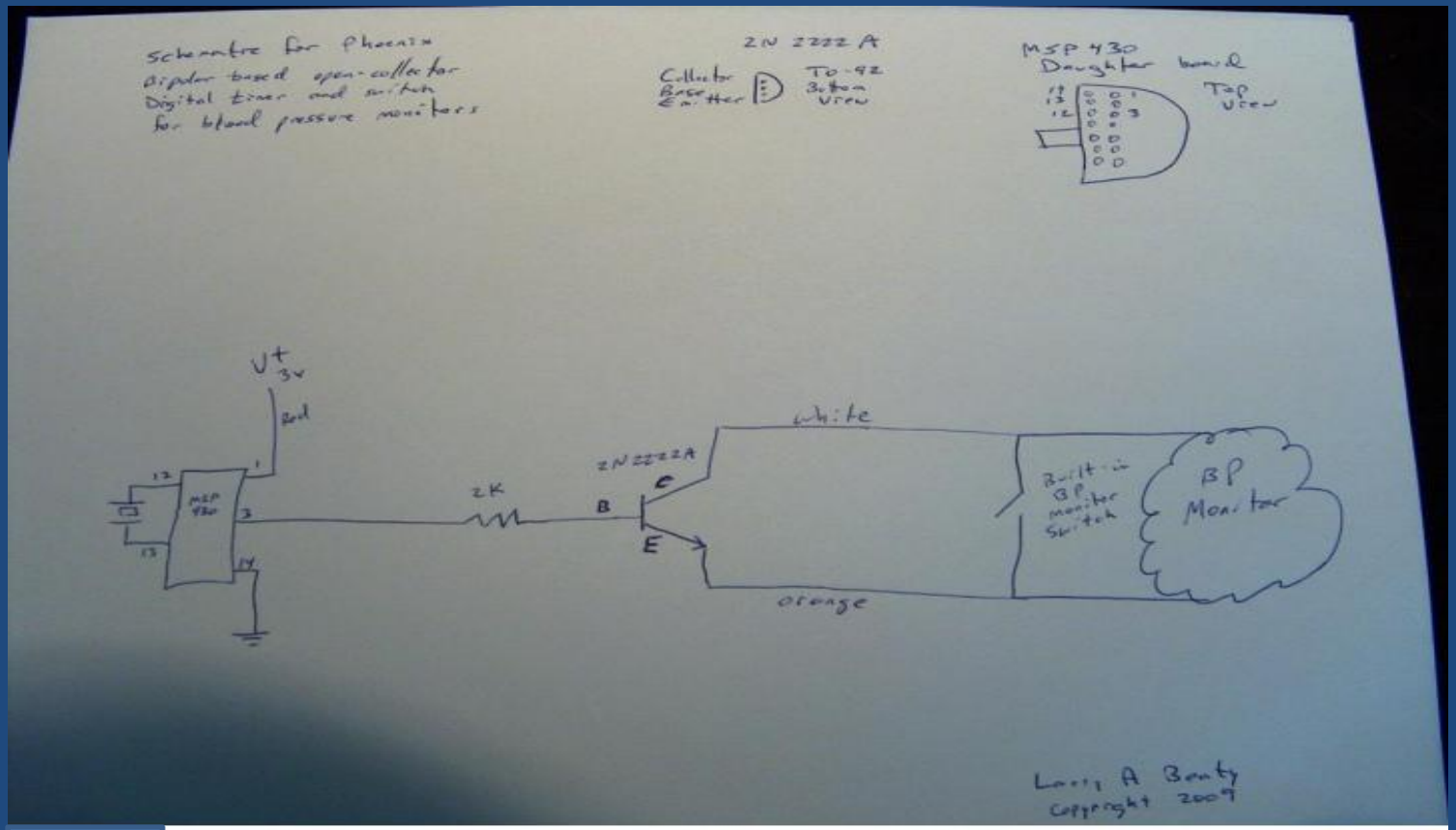
- Digital timer (microcontroller + transistor) added to OMRON and A&D wrist monitors

Analog timer and wrist monitor



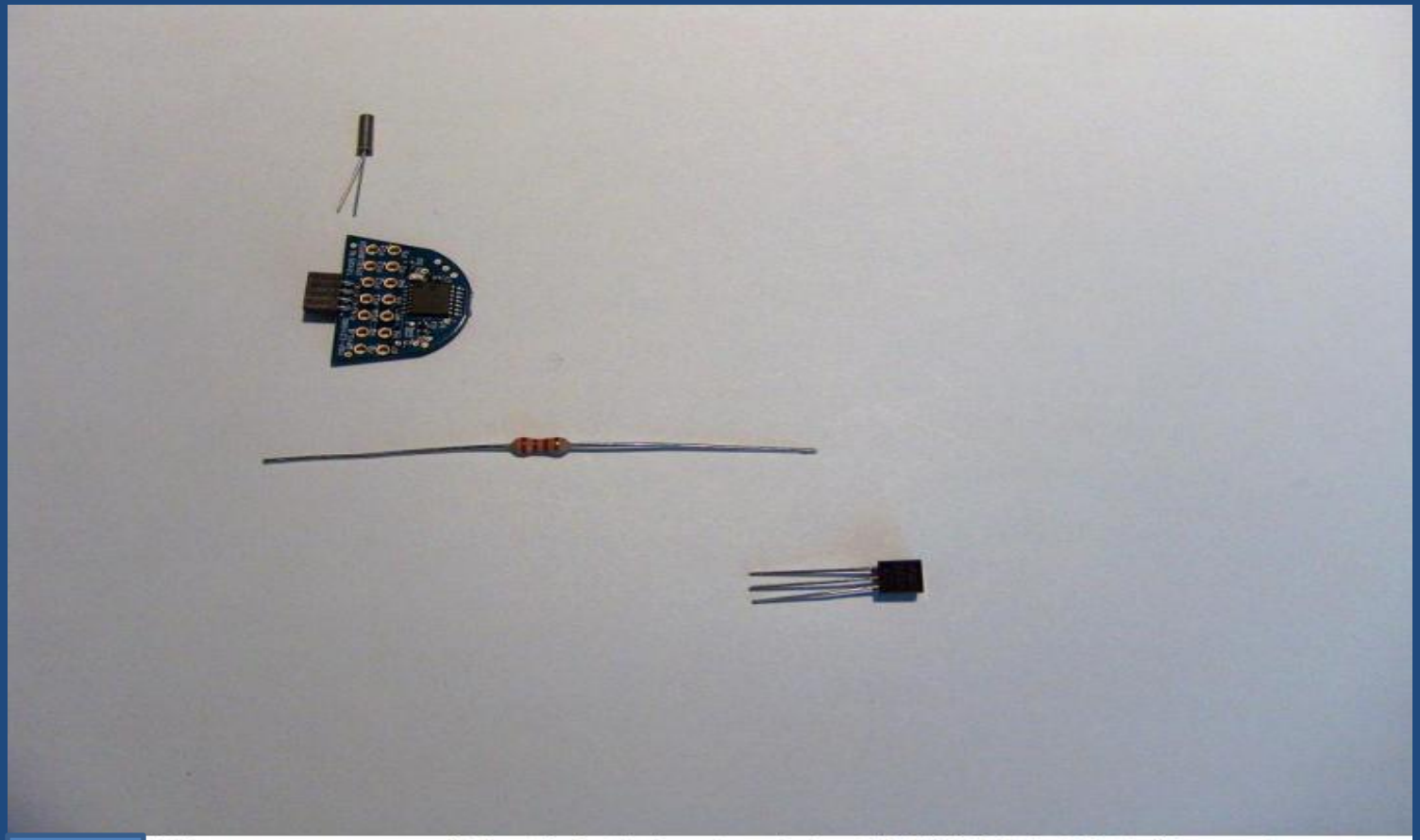
Testing of the analog timer circuit with the wrist-style blood pressure monitor, and a clumsy attempt to protect the battery pack and timer circuit board while wearing the monitor by putting them in a plastic box strapped to the wearer's arm with a cloth bandage.

Digital timer and wrist monitors



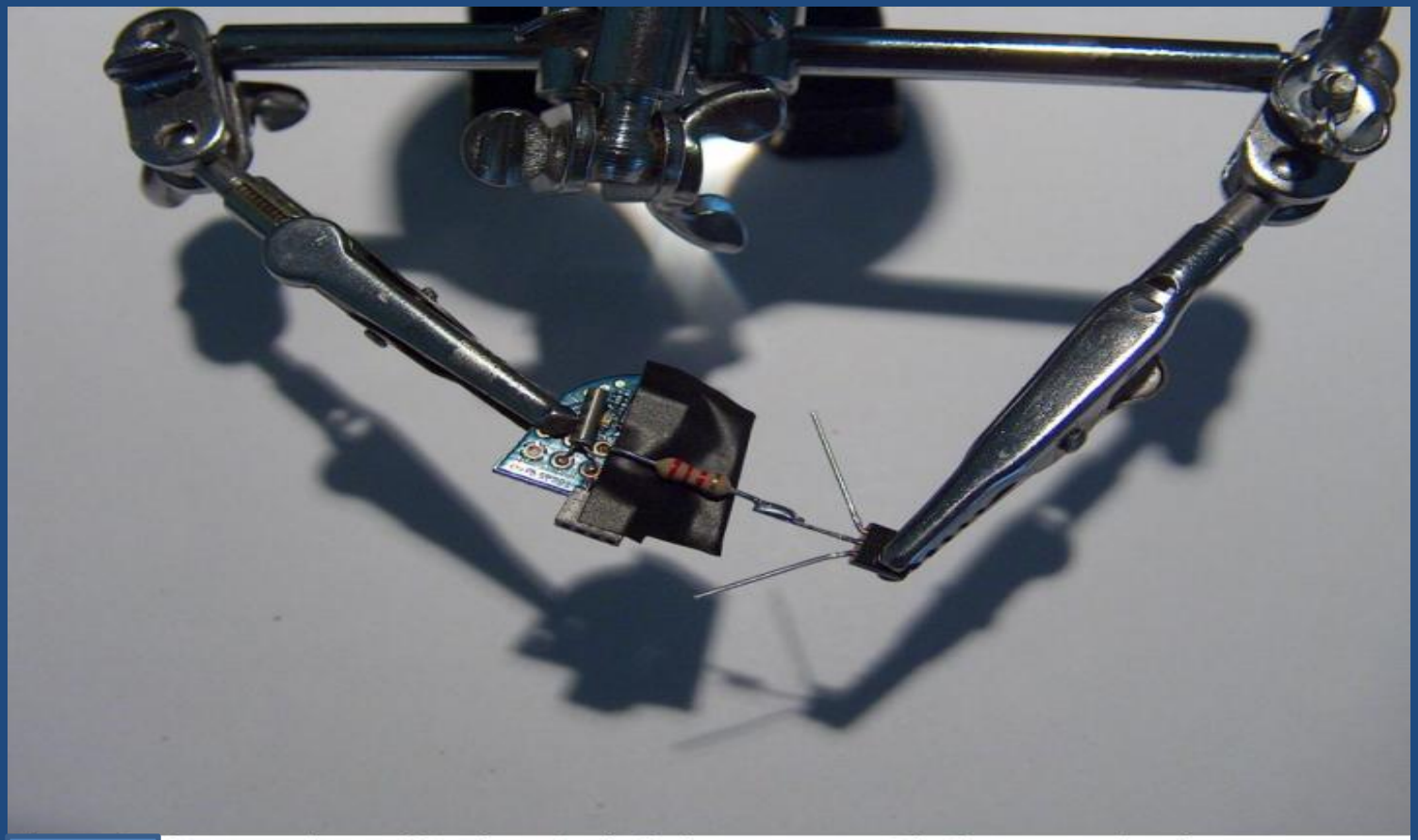
The schematic diagram for the digital timer that I add to blood pressure monitors. From left to right, a crystal is connected to a Texas Instruments MSP430 microcontroller, which is connected to power, ground, and a resistor/transistor combination that acts as a switch. The collector (C) and emitter (E) of the transistor are wired in parallel with the monitor's pushbutton switch, so the monitor can be triggered manually as normal, or by the microcontroller's program.

Digital timer and wrist monitors



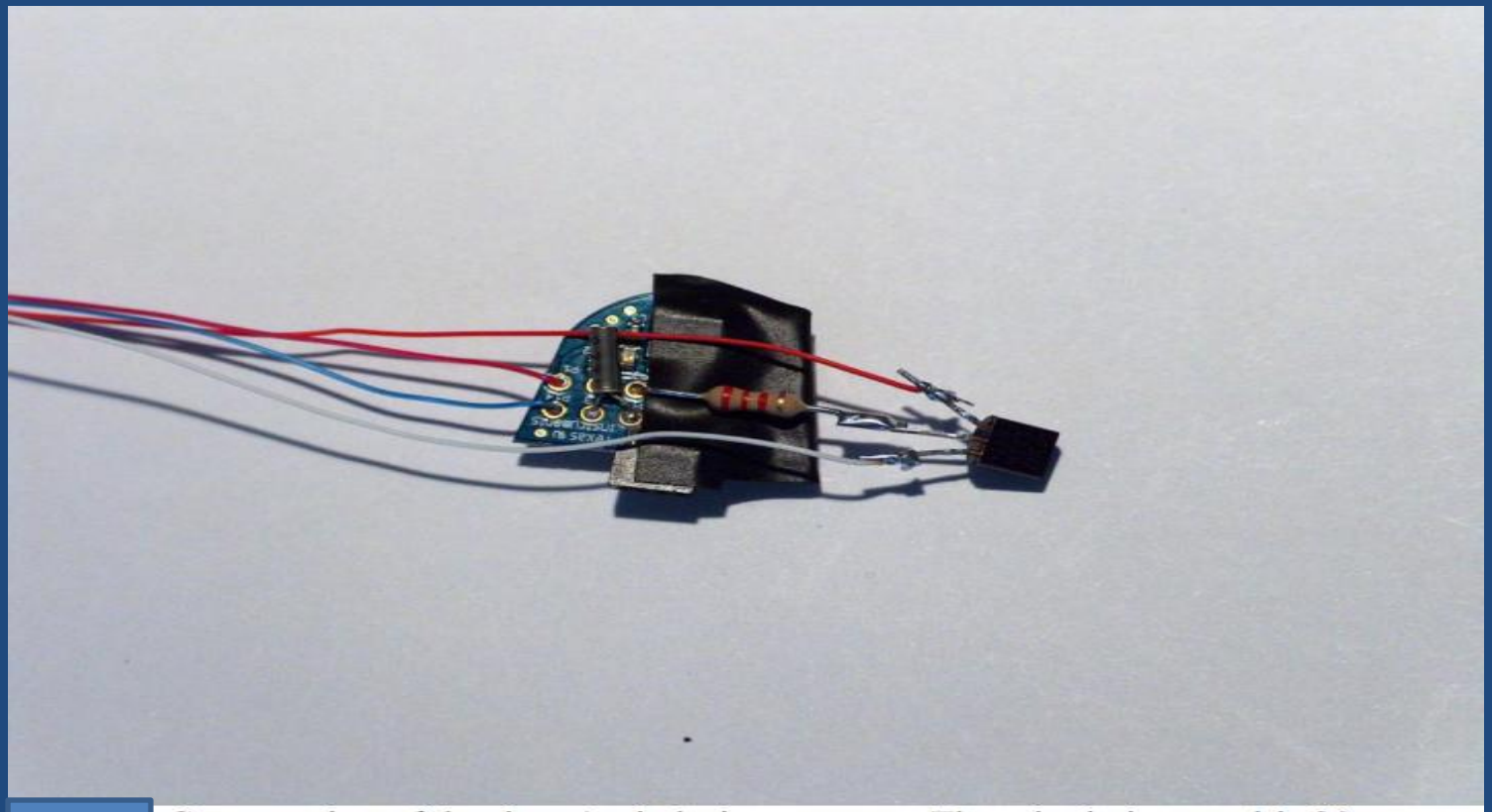
The components of the digital timer/switch. 32.768 KHz 12.5pf crystal, MSP430-2013 microcontroller evaluation board, 2.1K resistor, 2N2222A NPN transistor.

Digital timer and wrist monitors



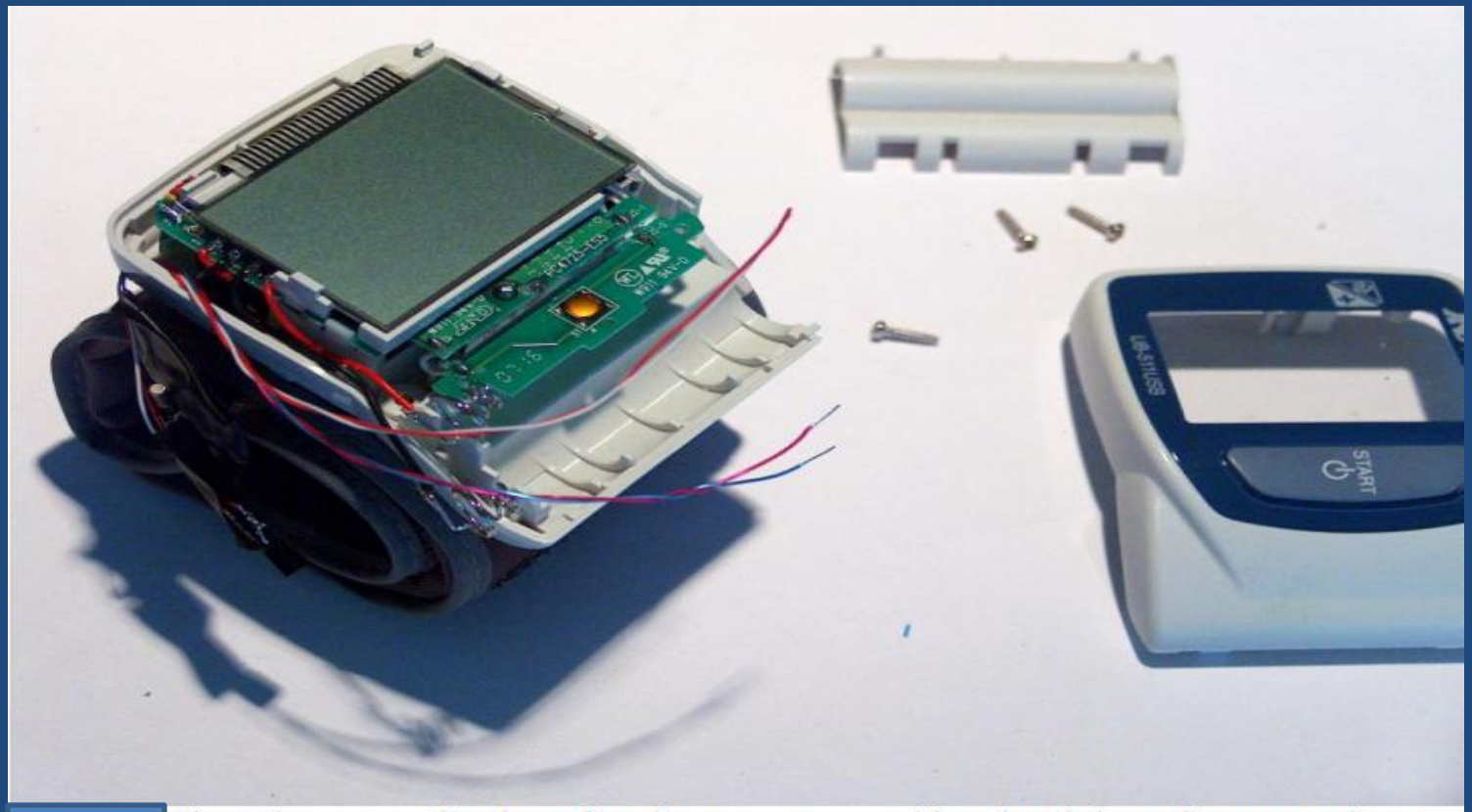
Construction of the timer/switch, in progress. Black non-conductive tape obscures part of the microcontroller board.

Digital timer and wrist monitors



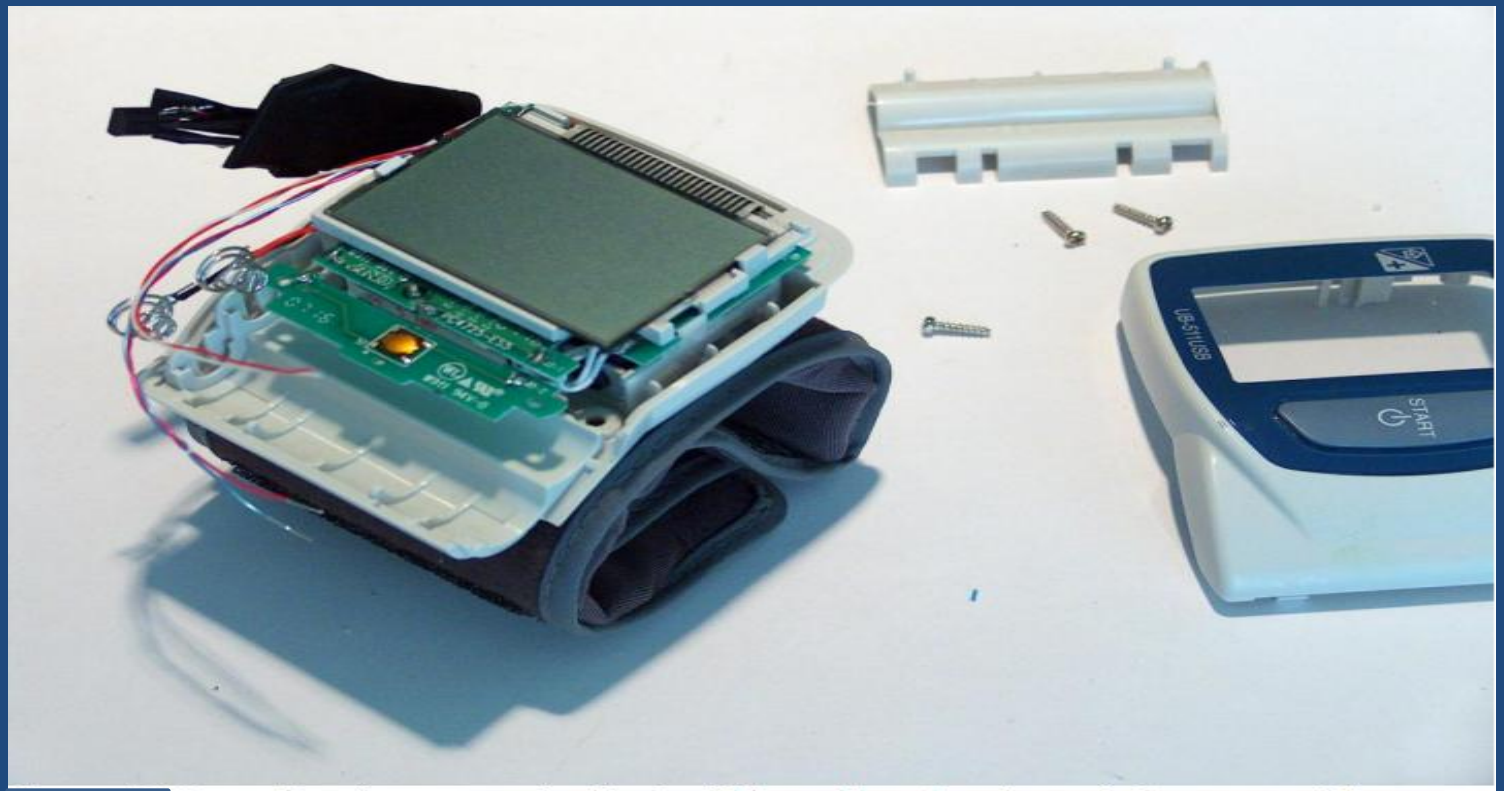
Construction of the timer/switch, in progress. The wire being used is 30-guage steel wire-wrap wire. The red and blue wires provide power to the microcontroller. The orange and white wires connect the monitor's pushbutton switch to the transistor, so the transistor can operate the switch under the control of the microcontroller.

Digital timer and wrist monitors



The microcontroller board and components soldered to it have been taped up with black tape and are hanging on the left side of the monitor (difficult to see because the cuff is nearly the same color). The 4 wires coming from the microcontroller board were threaded through a small hole drilled in the upper left corner of the monitor.

Digital timer and wrist monitors

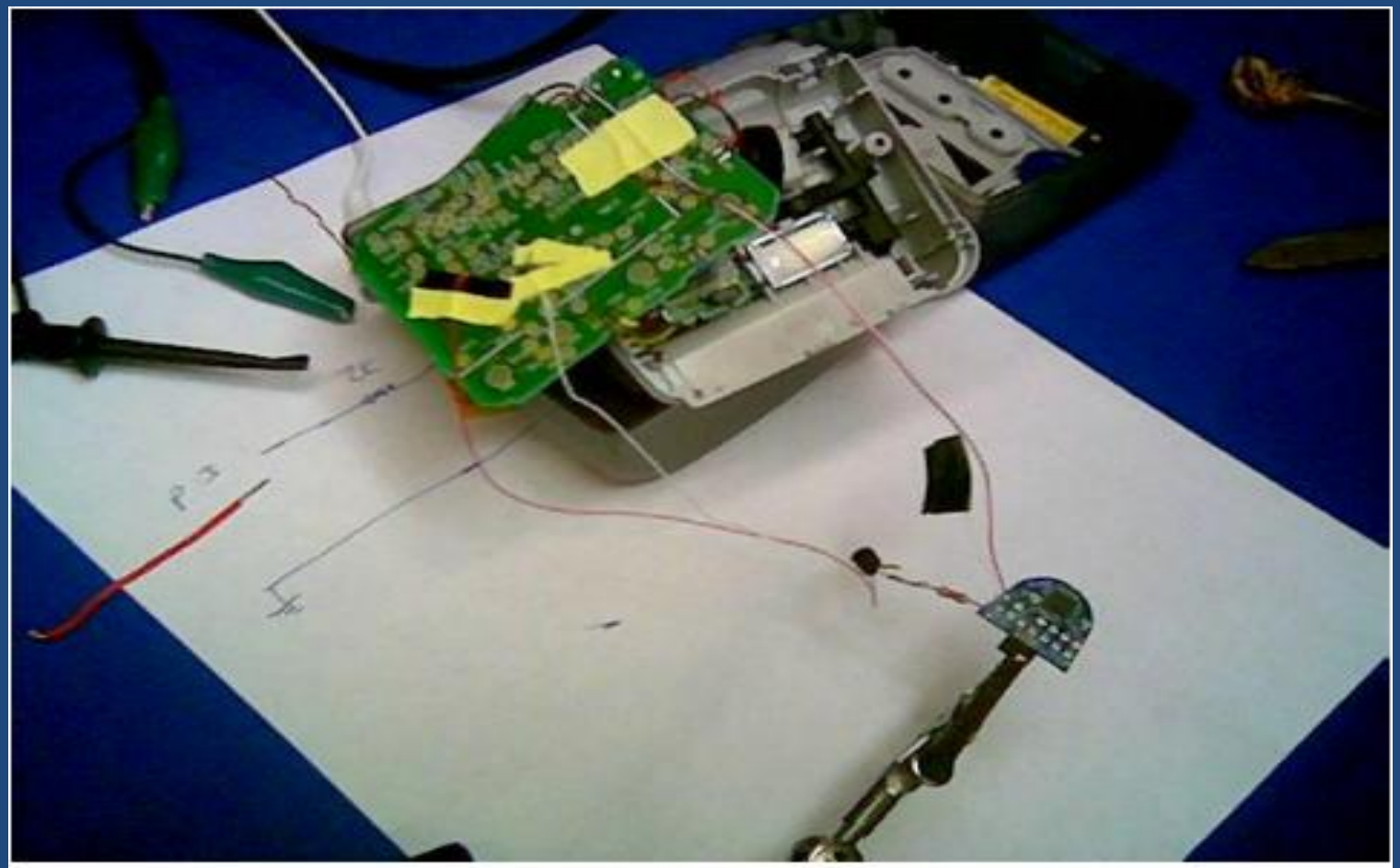


Two wires (orange and white) will be soldered to the switch contacts (the switch is the circular gold component in the center of the visible part of the green circuit board; the switch contacts are at the left and right ends of the circuit board). The other two wires (red and blue) will be soldered to the battery contacts (the coiled springs at the left side of the picture).

Digital timer and wrist monitors

The monitor is closed up and the digital timer/switch is securely taped to the side of the monitor with black non-conductive tape. The wires enter through the drilled hole, which is at the corner of the monitor at the bottom of this picture, under the tape.

Digital timer and wrist monitors



Adding the digital timer to an OMRON HEM-670IT wrist monitor. The wires from the digital timer circuit are soldered to vias on the main circuit board in the wrist monitor.

Digital timer and wrist monitors

[redacted]: The digital timer is taped up and tucked underneath the main circuit board as the wrist monitor is reassembled.

Digital timer and wrist monitors

The only "clue" that the digital timer is in place are the 4 wires running from under the grey display under the circuit board at the lower right.

Comparison to professional ABPM

	SBP MESOR	SBP Amplitude	SBP Acrophase
Nov 2007 A&D	128	12.1	-280
Nov 2008 Microlife	133	15.0	-247
Mar 2009 OMRON	137	15.7	-251
	DBP MESOR	**DBP Amplitude**	**DBP Acrophase**
Nov 2007 A&D	80	9.6	-276
Nov 2008 Microlife	82	12.8	-238
Mar 2009 OMRON	89	15.0	-242
	HR MESOR	**HR Amplitude**	**HR Acrophase**
Nov 2007 A&D	66	6.2	-290
Nov 2008 Microlife	68	6.0	-281
Mar 2009 OMRON	68	7.8	-281

Subject L: BP MESOR differences are statistically significant (but show a progression, so difference might not be due to the monitor).

Comparison to professional ABPM

	SBP MESOR	SBP Amplitude	SBP Acrophase
Apr 2009 A&D	114	13.6	-245
Apr 2009 OMRON	110	12.1	-239

	DBP MESOR	DBP Amplitude	DBP Acrophase
Apr 2009 A&D	68	8.1	-240
Apr 2009 OMRON	71	11.2	-241

	HR MESOR	HR Amplitude	HR Acrophase
Apr 2009 A&D	73	10.8	-245
Apr 2009 OMRON	75	13.6	-240

Subject G: BP MESOR differences are statistically significant, but small.

Comparison to professional ABPM

	SBP MESOR	SBP Amplitude	SBP Acrophase
May 2007 A&D	118	17.9	-248
July 2009 OMRON	111	16.2	-242

	DBP MESOR	DBP Amplitude	DBP Acrophase
May 2007 A&D	72	13.4	-243
July 2009 OMRON	68	13.5	-239

	HR MESOR	HR Amplitude	HR Acrophase
May 2007 A&D	73	9.4	-252
July 2009 OMRON	72	6.6	-250

Subject V: BP MESOR differences are statistically significant, but small.

Comparison to professional ABPM

	SBP MESOR	SBP Amplitude	SBP Acrophase
Nov 2007 A&D	128	12.1	-280
Nov 2008 Microlife	133	15.0	-247
Jul 2009 A&D wrist	146	16.9	-219
	DBP MESOR	**DBP Amplitude**	**DBP Acrophase**
Nov 2007 A&D	80	9.6	-276
Nov 2008 Microlife	82	12.8	-238
Jul 2009 A&D wrist	91	15.0	-217
	HR MESOR	**HR Amplitude**	**HR Acrophase**
Nov 2007 A&D	66	6.2	-290
Nov 2008 Microlife	68	6.0	-281
Jul 2009 A&D wrist	70	7.2	-252

Subject L: BP MESOR differences are statistically significant (but show a progression, so difference might not be due to the monitor).

Comparison to professional ABPM

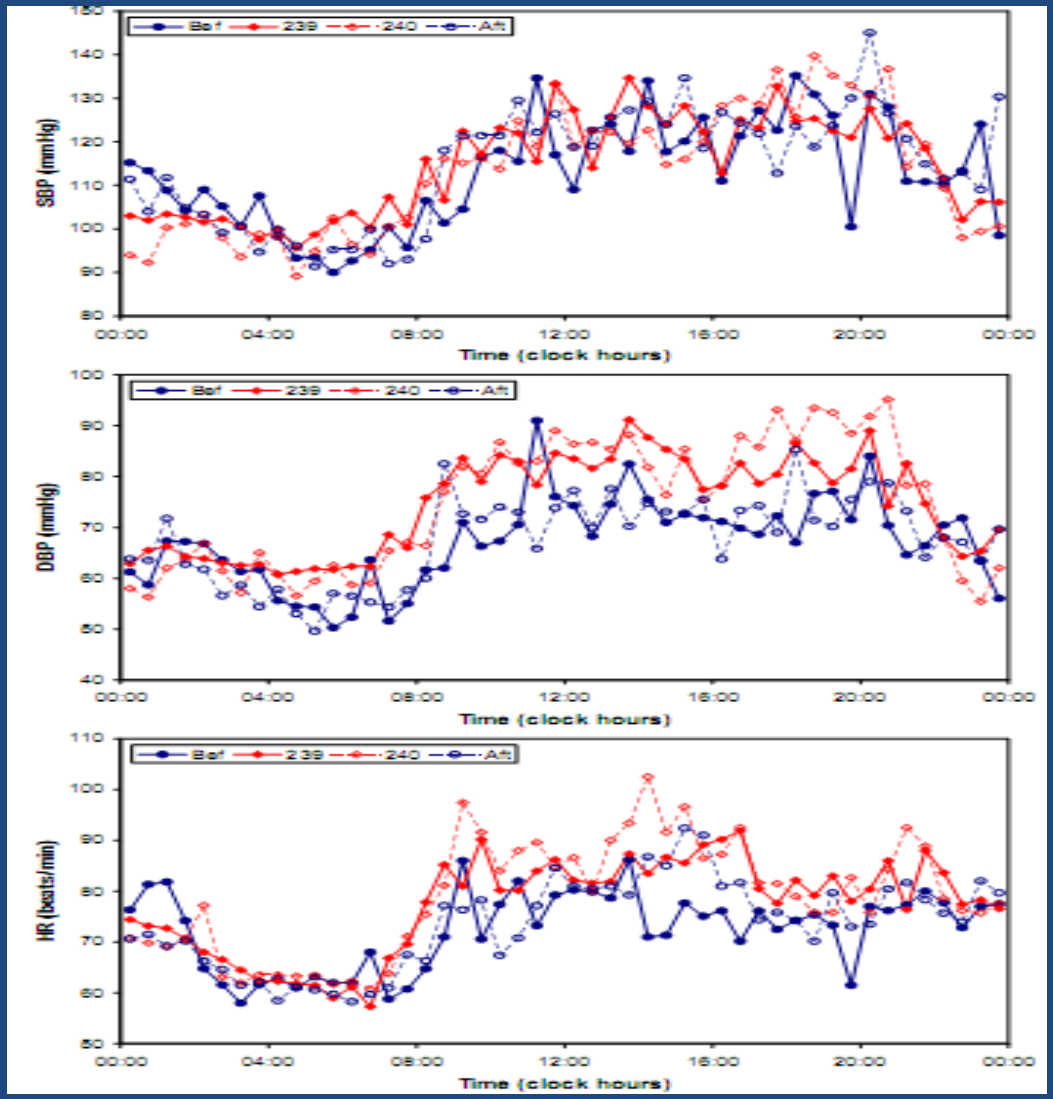
	SBP MESOR	SBP Amplitude	SBP Acrophase
Jul 2009 A&D	113	13.4	-253
Jul 2009 A&D wrist	114	14.3	-233

	DBP MESOR	DBP Amplitude	DBP Acrophase
Jul 2009 A&D	67	8.7	-243
Jul 2009 A&D wrist	74	11.9	-226

	HR MESOR	HR Amplitude	HR Acrophase
Jul 2009 A&D	73	5.7	-252
Jul 2009 A&D wrist	77	10.8	-241

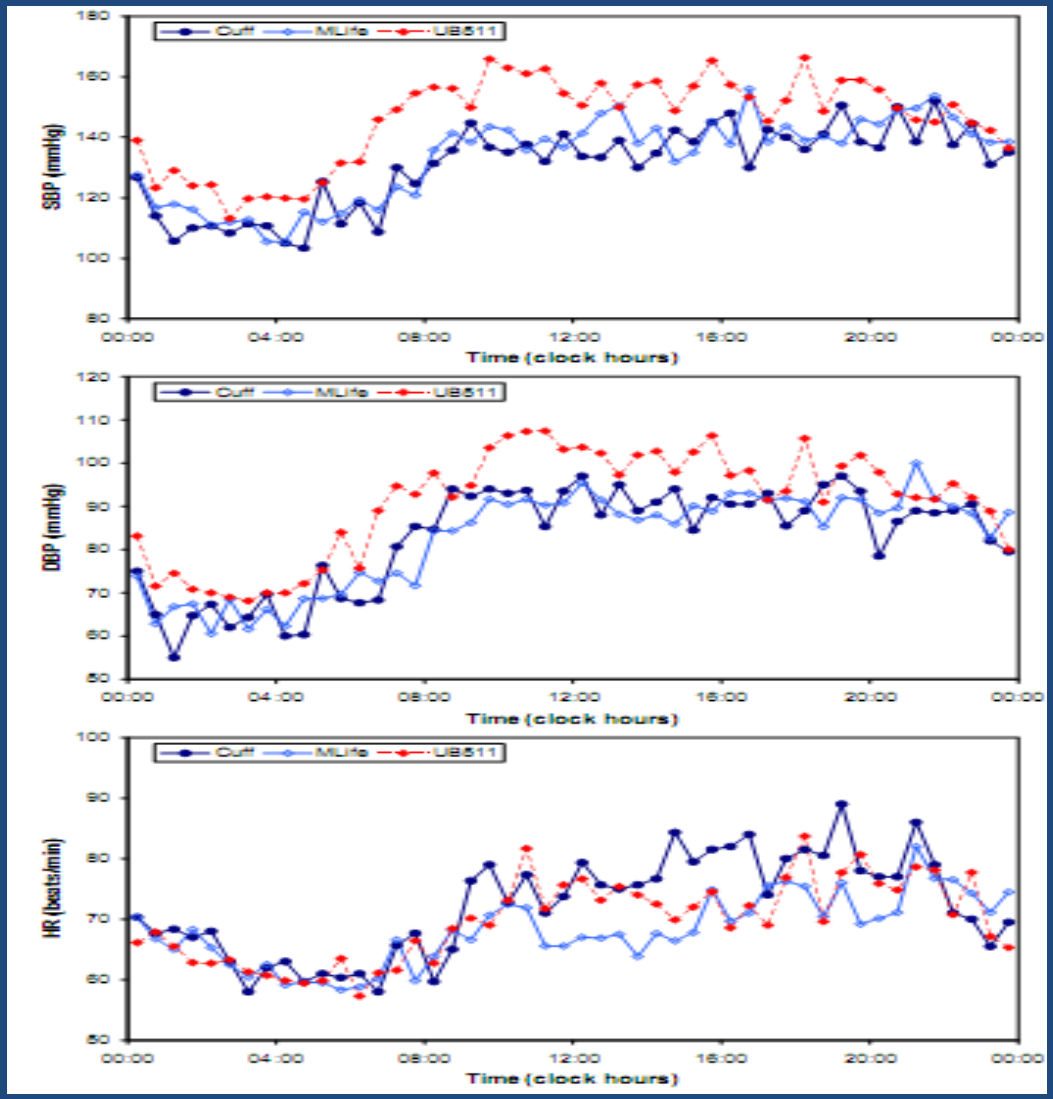
Subject G: BP MESOR differences are statistically significant, but small.

Comparison to professional ABPM



Subject G

Comparison to professional ABPM



Subject L

Wrist monitors: inaccurate readings

- The wrist is lower than the heart during the day
- We look at blood pressure differently, so accuracy of individual readings isn't so important
  - Characteristics of circadian rhythms compared to other rhythms measured the same way – patterns of health or lack of health still emerge
  - Readings from same time of day averaged with each other, so the occasional bad reading is averaged out
  - We can develop correction and cleaning algorithms
    - Irregular Heart Beat detection often indicates bad reading

What is missing from commercial home blood pressure monitors?

- Changes to commercial off-the-shelf wrist monitors that would be “necessary”:
  - Automatic, timed reading capability
  - Audible and Tactile warning
  - Retry failed readings after 1 minute
- Notice that it’s a short list
- It is likely that these features can be implemented using microprocessor capability already in the wrist monitors

What is missing from commercial home blood pressure monitors?

- Changes to commercial off-the-shelf wrist monitors that would be “nice to have”:
  - Programmable time intervals other than 30 minutes
  - More memory – store 350 readings or more (1 week)
  - Motion or position of monitor during readings
  - Audible notifications of low battery
  - Allow use of rechargable batteries
  - Light, small, mount of top of wrist
  - Blank display for privacy
  - Breatheable, washable, replaceable cuffs

What is missing from commercial home blood pressure monitors?

- Changes to commercial off-the-shelf wrist monitors that would be “lower priority”:
  - Reinforced cloth liner
  - Wireless interface to computer or cell phone
  - Usability improvements to the software that is used of offload the data
    - Eliminate the concepts of sessions and needing to erase the data

Costs

ABPMs	Typical Costs
• Professional	• $2000 - $5000
• A&D ABPMs through BIOCOS	• $500
• Home quality monitors	• $50 - $150
• Timer (for science project)	• $30
• Timer (added by manufacturer)	• “Free”

Discussion

- How to take next step in convincing manufacturers to add “ambulatory” capability (wear continuously, automatically trigger readings)?
  - More data from the lab, local people?
  - Develop Statistical corrections to data?
  - Clinical trials?

The Device of the Future

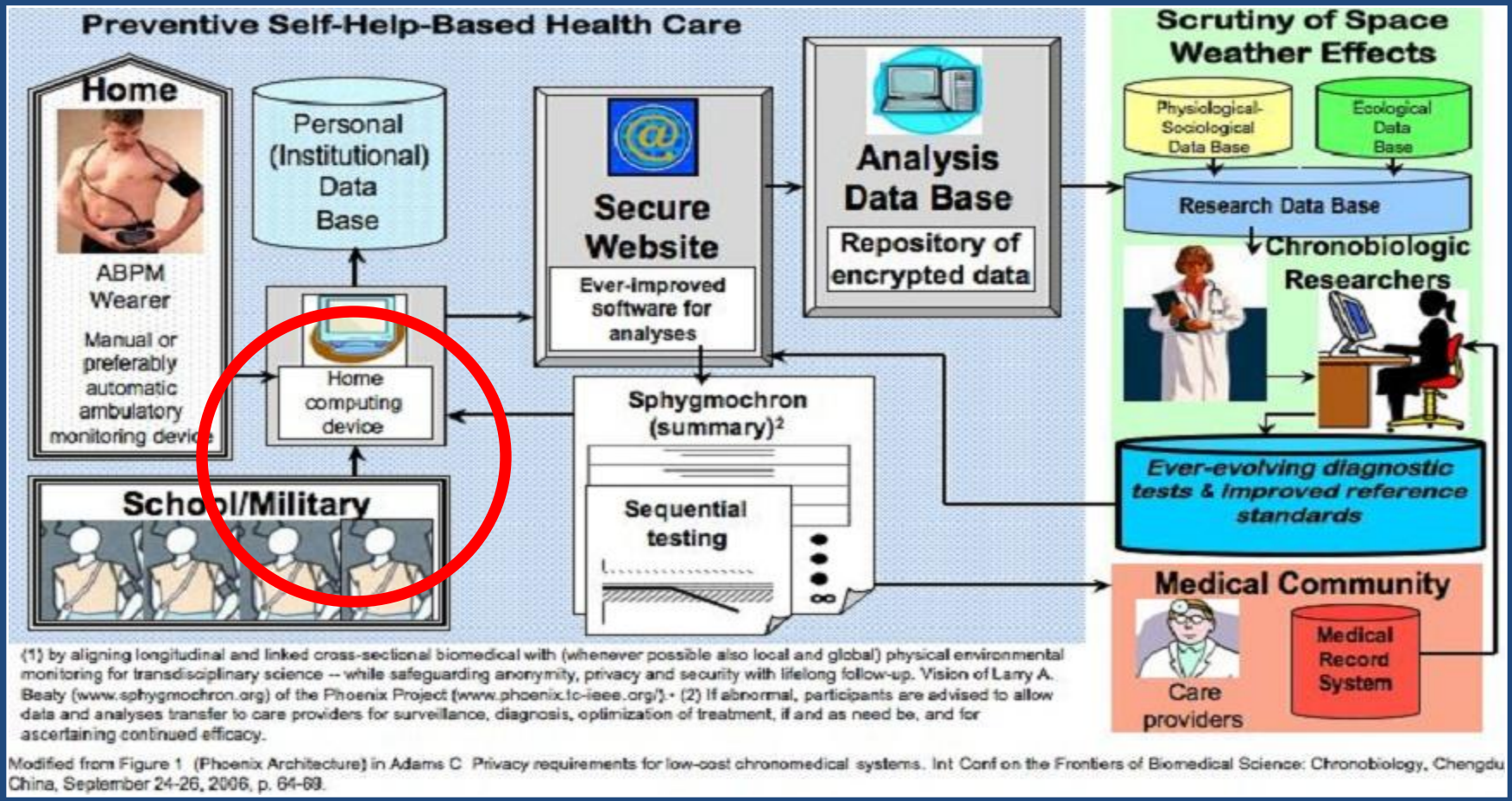
- What would a chronobiological device look like?
- Many people working on concepts
  - Body Area Networks
  - Pervasive computing
  - Wearable devices
- Always monitoring, all-the-time, many characteristics being monitored
- How to predict what will become popular?
  - Ask the kids, they are the future

The Device of the Future

- Twitter web site
- “How do you feel?” updates
- Enjoys large amount of success
- Messaging system, database capability
- Susceptible to being just a fad
  - The device of the future might have to keep up with the fads.

The Device of the Future

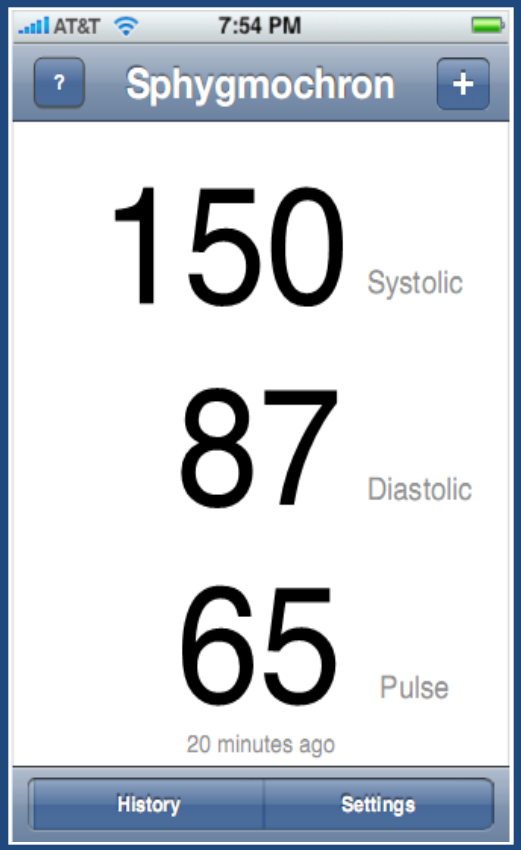
- Cell phones (iPhone, Google smartphone)
- Replace the PC between monitor and web

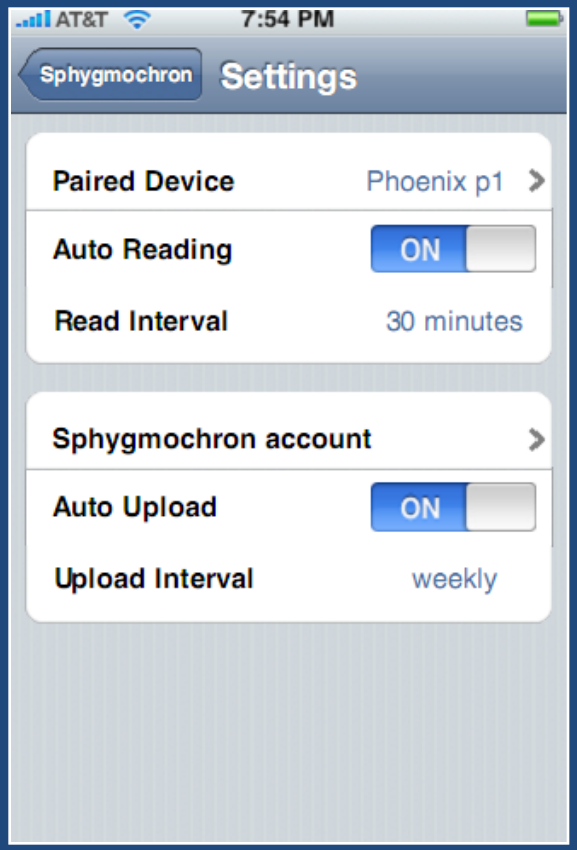


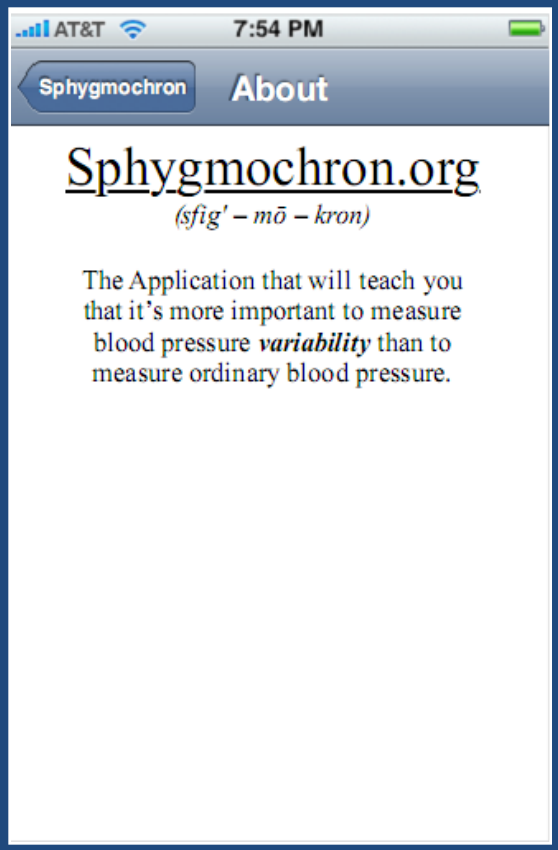
Modified from Figure 1 (Phoenix Architecture) in Adams C Privacy requirements for low-cost chronomedical systems. Int Conf on the Frontiers of Biomedical Science: Chronobiology, Chengdu China, September 24-26, 2006, p. 64-69.

The Device of the Future

- A start on a cell phone user interface







Discussion

- Uploading data from A&D arm cuff to Microsoft Health Vault

- Discussion of how Microsoft Health Vault is useful in research and healthcare contexts?