Data Acquisition Prototype:
Project & System Requirements

Phoenix

Ambulatory Blood Pressure
Monitoring System

3 February 2009

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Agenda

- Purpose and Scope of this Document
- Project Vision
- System Vision & Scope (Business Requirements)
- User Requirements
  - Use Cases
  - Algorithms (Business Rules)
- System Requirements
  - Functional Requirements
  - Major Nonfunctional Requirements
- Requirements Work Outstanding
- Design Direction Details

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Purpose and Scope of this Document

- Specify system requirements for a prototype of a data acquisition device
  - Incorporate system requirements of eventual Phoenix ABPM, but…
  - Do not specify the Phoenix ABPM
  - Supplement Phoenix requirements with prototype-specific requirements
- Incorporate results of sensor prototypes to-date

Project Vision

- Acquire community knowledge about
  - Data acquisition devices
  - Hardware and software co-design
  - Partitioning systems into subsystems
  - Allocating system requirements to subsystems
  - Embedded software architecture options (round robin, round robin w/ interrupts, …, RTOS)
  - Hardware options (gates, clocks, memory, MP, buses, DMA, interrupts, ports, …)
  - Designing low-power devices
  - Acquiring hardware components
  - Testing embedded software
- Document results so they can be reproduced

Project Vision

- Architecture — basic technology
  - Hardware architecture
  - Hardware component selection
  - Embedded software architecture
  - Software language selection
  - Cross-platform development tools
- Prototype
  - Must build a device to evaluate interdependent design options
  - Learning is primary
  - Expect subsequent evolution
  - Willing to abandon device based on lessons learned
- Computing device is primary
  - Sensing is secondary
  - Acquired data may be simulated

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System Vision

- Data acquisition device *(next slides)*
- Embedded analytics *(next slides)*
- Embedded data storage *(next slides)*
- Device allows ambulation during use
  - At least carriable
- Electrically self-contained
  - Does not rely on external power source
- Power-sensitive design
  - Design for either:
    - Low power, or
    - Power measurement

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System Vision

- Data acquisition device
  - Collects continuous analog signals from two sensors
    - At least one is piezoelectric film sensor
      - Measurement Specialties SDT1-028K
  - Collects from piezoelectric film sensor
    - Up to 40 samples per cardiac cycle
    - @ 200 beats per minute (maximum)

    133 samples per second
  - Converts analog signals to digital signals
  - Collects discrete signals from wearer-pressable push-button
    - Button down
    - Button up
  - Turns on and off a human-perceivable device-mounted light

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System Vision

- Embedded analytics
  - Identifies / marks peak of each continuous waveform
    - Voltage
  - Identifies / marks trough of each continuous waveform
    - Voltage
  - Calculates biometrics
    - Heart rate
      - Beats per minute
    - Systolic blood pressure
      - mmHg
    - Diastolic blood pressure
      - mmHg
  - Performs calculations over 5 cardiac cycles every 30 minutes
  - Translates different combinations of button-down and button-up signals into events

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System Vision

- Embedded data storage
  - Timestamps each acquired & calculated value
  - Preserves three days of acquired & calculated data
  - Preserves all acquired values
    - See “Data acquisition device”
  - Preserves all calculated values
    - See “Embedded analytics”

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System Vision

Major Out-of-Scope Capabilities

- Capacity for 7 days of data
- Patient alerts
- Localization outside of U.S.
  - Production
  - Use
- Analog signal processing
  - As alternative to digital signal processing
  - Separate research topic
- HMI beyond simple light bulb
  - Will not display calculated values
  - *Continued exclusion depends on analysis of power management*

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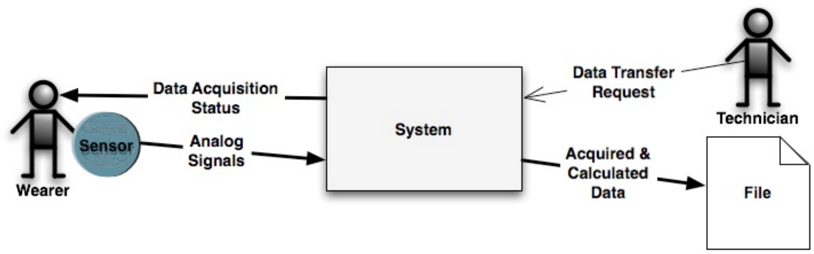
System Context



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Use Cases

- Wearer signals the device to log an event
  - Assures data-acquisition logic despite sensor failure
- Technician or wearer confirms device functions
- Technician connects device to wearer
- System collects data
- Wearer restarts data collection
- Technician off-loads data from device

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Use Cases
Wearer Signals Device to Log Event

1. Wearer pushes button (and holds until step 6)
2. System activates status light
3. System logs button-down
4. Wearer observes status light
5. Wearer may pause
6. Wearer releases button
7. System logs button-up
8. System de-activates status light
9. Wearer observes status light
10. Wearer may pause
11. Wearer repeats sequence according to predefined code

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Use Cases
Technician or Wearer Confirms Device Functions

1. User signals device-start event
2. System runs diagnostics
3. System toggles the status light in a pattern indicating successful start-up
4. Technician observes status light

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Use Cases
Technician Connects Device to Wearer

1. Technician starts device
   - Signals device-start event
   - Use case "Wearer Signals Device to Log Event"
2. Technician confirms device functions
   - Signals run-diagnostics event
   - Use case "Wearer Signals Device to Log Event"
3. Technician places and fastens device on wearer
4. Wearer confirms device is comfortable
5. Technician starts data acquisition
   - Signals acquisition-start event
   - Use case "Wearer Signals Device to Log Event"

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Use Cases
System Collects Data

1. System waits for configured duration
2. System activates status light
3. Systems periodically reads data from each sensor
   - Periodicity configured sensor-by-sensor
4. System timestamps and stores each reading
5. System continues reading data for configured duration
6. System calculates embedded analytics
7. System timestamps and stores each calculated value
8. System deactivates status light
9. Above sequence repeats

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Use Cases
Wearer Confirms Device is Working

1. Wearer signals device-check event
   – Use case “Wearer Signals Device to Log Event”
2. Wearer observes status light to confirm device function

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Use Cases
Wearer Restarts Data Collection

1. Wearer places and fastens device on self
2. Wearer signals acquisition-start event
   – Use case “Wearer Signals Device to Log Event”

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Use Cases
Technician Off-Loads Data from Device

1. Technician connects device to storage system
2. Technician signals download-initiation event
   - Use case “Wearer Signals Device to Log Event”
3. System transforms data into transmission format and transfers transformed data to file, while manipulating status light to signal transfer progressing
4. System signals completion of transfer with status light

Post-condition:

- Off-loaded data is in a state in which it can be used by external systems

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Algorithms

- Calculation of pressure wave
- Waveform peak
- Waveform trough
- Heart rate
- Systolic blood pressure
- Diastolic blood pressure

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Functional Requirements

- Downloaded Data
  - ::=
    - Head
      - Device ID
      - (Absolute base time)
      - Timestamp of download initiation
    - Body
      - { Acquired/calculated Item }*
        - » Sensor ID/Data Source ID
        - » Timestamp of acquisition/calculation
        - » Information type
        - » Value
    - Tail
      - Timestamp of download completion
      - End of data marker
  - If timestamps are relative
    - then download must include absolute base time

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Functional Requirements

- Acquired/calculated information type
  - Acquisition control event
    - Start device
    - Stop device
    - Start acquisition
    - Stop acquisition
    - Run diagnostics
    - Test acquisition
  - Wearer event
  - Acquired continuous value
    - mV
  - Acquired discrete value
    - On/off, down/up, yes/no

- Acquired/calculated information type
  - Calculated values
    - Pulse (heart rate)
      - Units: beats per minute
      - Range: 30–200 bpm
      - Accuracy: ±5%
    - Systolic blood pressure
      - Units: mmHg
      - Range: 60–280 mmHg
      - Accuracy: ±3 mmHg
    - Diastolic blood pressure
      - Units: mmHg
      - Range: 40–160 mmHg
      - Accuracy: ±3 mmHg

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Major Nonfunctional Requirements

- Interfaces
  - Outgoing
    - Downloaded data
      - Free and open format
      - Formal and concise format
      - Human legible
      - Presentable & workable as plain text file (e.g., editable with text editor)
      - Widely used format (e.g., industry standard)
      - *Primary options: XML, HL7*
        - » *However, must understand impact of tagging the data*
  - Physical Connectors
    - Device downloads data via a standard connector
      - *Primary options: Secure Digital, USB*
      - *Excluded option: RS232*
- Physical Constraints
  - Wearer wears or carries device during operation

Major Nonfunctional Requirements

- Legal Requirements
  - Licenses of created works are attributable to the authors
  - Free and open source
    - Rationale — see http://www.phoenix.tc-ieee.org/000_Background/Phoenix_OpenSource.htm
  - Software
    - All software created by the project is free and open
      - As defined by the Open Source Initiative
      - http://www.opensource.org/docs/definition.php (version 1.9, 2006-07-24)
    - All software incorporated from third parties into the product
      - Is free
      - May be freely redistributed
      - May be bundled with free and open source software without impinging on rights of distribution under the open source definition

Major Nonfunctional Requirements

- Legal Requirements
  - Hardware
    - All hardware designs shall be free — Free Hardware Design
      - Design can be freely copied, distributed, modified, and manufactured
      - Does not imply:
        - » that the design cannot also be sold, or
        - » that any hardware implementation of the design will be free of cost
      - Ref: Open Collector
        - » http://www.opencollector.org/Whyfree/definitions.html
    - All hardware designs shall be open — Open Source Hardware
      - The interface to the hardware must be explicitly made public
        - » so the hardware can be used freely
      - The design of the hardware must be made public
        - » so that others can implement it and learn from it
      - The tools used to create the design should be free
        - » so that others can develop and improve the design
      - Ref: Open Collector
        - » http://www.opencollector.org/Whyfree/open_hardware.html

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Major Nonfunctional Requirements

- Safety Requirements
  - Electro-Magnetic Interference
    - Device cannot electrically interfere with other electronic devices
    - Ref: FCC Part 68
    - For prototype, EMI resistance need be sufficient only to assure accurate readings

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Requirements Work Outstanding

- [Bob S] What are the frequency and resolution requirements for:
  - HR?
  - DBP?
  - SBP?
- [Dick S] Background about power management circuits
- [?] Interpretation of FCC Part 68 (EMI)

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Design Direction Details

- Analyze software architecture options
  - Round-robin
  - Round-robin with interrupts
  - Function queue scheduling
  - Real-time operating system
- Analyze algorithms
  - Calculation of pressure wave (e.g., Chen method)
  - Waveform peak
  - Waveform trough
  - Heart rate
  - Systolic blood pressure
  - Diastolic blood pressure

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Design Direction Details

- Analyze software interface standards
  - XML vs HL7 vs other
- Analyze hardware connector standards
  - USB vs Secure Digital
- Define diagnostics
  - Based on design
- Select licenses (may affirm current direction)

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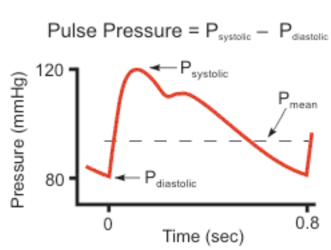
Design Direction Details

Calculation of Pressure Wave

- Chen et. al, US Patent No. 6,599,251
  - Arterial pulse delay proportional to blood pressure
    - $P = a + b \ln(T)$
      - T = Time delay(milliseconds)
      - a,b = constants depending on
        - » nature of the subject
        - » signal detecting device



(Richard E. Klabunde, Ph.D, “Cardiovascular Physiology Concepts”, http://www.cvphysiology.com)

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