Data Acquisition Prototype:
Project & System Requirements

Phoenix

Ambulatory Blood Pressure
Monitoring System

24 August 2008

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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

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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

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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

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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 up to x (40?) samples per second from piezoelectric film sensor
  - 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
- Device calibration
- 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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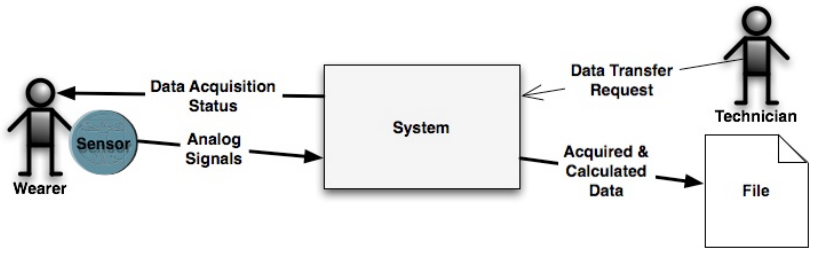
System Context



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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 or wearer confirms data acquisition
- Technician connects device to wearer
- System collects data
- Wearer restarts data collection
- Technician downloads data to a file

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Use Cases
Wearer Signals Device to Log Event

1. Wearer pushes button
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 or Wearer Confirms Data Acquisition

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 confirms data acquisition
   - Signals device-start event
   - Use case “Wearer Signals Device to Log Event”
6. Technician starts data acquisition
   - Signals acquisition-start event
   - Use case “Wearer Signals Device to Log Event”

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 confirms data acquisition
   - Use case "Technician Confirms Data Acquisition"
3. Wearer signals acquisition-start event
   - Use case "Wearer Signals Device to Log Event"

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Use Cases
Technician Downloads Data to File

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 downloads transformed data to file, while manipulating status light to signal download progressing
4. System signals completion of download with status light

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Algorithms

- 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
    - Heart rate
      - Beats per minute
    - Systolic blood pressure
      - mmHg
    - Diastolic blood pressure
      - mmHg

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Major Nonfunctional Requirements

- Interfaces
  - Outgoing
    - Downloaded data is well-formed XML
      - *Want to understand impact of tagging the data*
  - Physical Connectors
    - Device downloads data via a USB device
- Physical Constraints
  - Wearer wears or carries device during operation
- Legal Requirements
  - *All software to be publicly licensed*
- Safety Requirements
  - *Electro-Magnetic Interference*
    - *Device cannot electrically interfere with other electronic devices*
    - *Ref: FCC Part 68*

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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
- Analysis of algorithms

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