# System Requirements

Phoenix

Ambulatory Blood Pressure Monitoring System





# Table of Contents

# Mission, Scope, Stakeholders, Goals

http://www.phoenix.tc-ieee.org/014_Systems_Architecture_and_Engineering/presentations/Scope Vision.ppt

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# Dictionary

- Wearable
  - Suitable for wear or able to be worn on the body
- Activity of daily living (ADL)
  - the things a person normally does in daily living including any daily activity performed for self-care (such as feeding, bathing, dressing, grooming), work, homemaking, and leisure
  - health professionals routinely refer to the ability or inability to perform ADLs as a measurement of the functional status of a person
  - See http://en.wikipedia.org/wiki/Activity_of_daily_living

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## Scenarios, Stories, Use Cases & Exceptions

1. Home-based self care
2. Internet-based individual health surveillance
3. Clinical care
4. Self-care followed by clinical care
5. Public healthcare
6. Research
7. Education
8. Sports training
9. Emergency medical service
10. Combat lifesaving

**See** http://www.phoenix.tc-ieee.org/014_Systems_Architecture_and_Engineering/presentations/Scenarios 2008-05-11.ppt

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## Requirements

1. Value Requirements
2. Functional Requirements
3. Quality Requirements

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# Value Requirements

- Intellectual property essentially free
- Device manufacturable for $10
  - "Less expensive than bushel of yams"
- Computing hardware
  - Readily available
  - Essentially free
- Free software licensing

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# Functional Requirements

- Information model
- Behaviour requirements
- Algorithms

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# Quality Requirements

- Biocompatibility
- Environment requirements
- Human interface look-and-feel
- Operational requirements
- Performance (efficiency) requirements
- Privacy
- Security (integrity)
- Safety requirements
- Required attributes
- Training requirements

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# Quality Attributes

- Functionality
  - Reliability
  - Survivability
  - Usability
  - Interoperability
- Change concerns
  - Maintainability
  - Expandability
    - Adaptability
    - Scalability
  - Flexibility
  - Portability
  - Reusability
- Managerial concerns
  - Designability
  - Verifiability
  - Manageability

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# Quality Requirements

- Expandability
  - Analysis framework must be adaptable to chronobiology scenarios other than blood pressure
- Interoperability
  - A 3rd party must be able to analyze the data received from the device, say for diagnosis


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# Quality Requirements

- Wearability
  - Device is wearable during normal activities of daily living for a continuous period of up to 7 days
    - No rash, no "other" effects
    - Longer periods eventually foreseen but not required
      - The record for a cuff-based device is 20 years, though not continuously
    - Need definitions
      - Wearable
      - Activity of daily living


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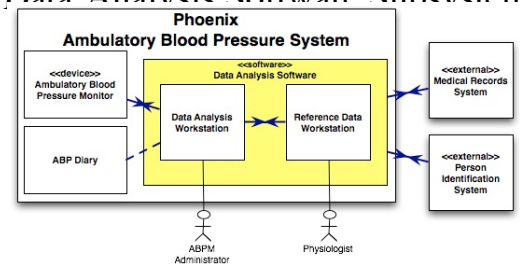
# Component Model

## Data Analysis Software Subsystem




- Analysis Workstation
  - Handles data for a single wearer
- Reference Data Workstation used by Chronobiology Center
  - Handles data for whole populations
- Analysis Workstation relies on model parameters from Reference Data Workstation

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# Sensors

- Phenomenon
  - Blood pressure
  - Heart rate
  - Blood flow
  - Physical activity
- Low cost
- Nonintrusive
- Performance: beat to beat

| | | | | |
|---|---|---|---|---|
| Body | Data Acquisition | Measurement | Data Transport | Time Series |
| Analysis | Tool | Plot / Chart | Reporting | Session |
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# User-Noted Events

- Indicates the time at which something interesting happened
- Provides integration with diary

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# Time

- An issue that covers several layers
- Precision = +- 5 minutes
- Time zones
  - Problem -- how to know time-zone changed
- Measurements of one device must be comparable to measurements of another device
  - Impacts clock sychronization

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# Signal Acquisition

- Digital signal processing (DSP)
  - Collect signal data from sensors
  - Collect user-noted events
- Flexible framework for sensor configuration that varies by
  - Sensor technology
  - Biophysics
  - Target measurements
- Capacity
  - 7 days of data
  - 30 minutes between measurements
- Support variable sampling
  - Over 24 hour period
  - Span always starts at midnight
- Support complex signal-to-measurement conversion
  - One sensor may produce multiple measurements
  - One measurement may require multiple sensors
  - One measurement may require multiple sensor readings
    - e.g., multiple heart beats

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# Data Transport

- Communications with device
- Framework for multiple transports
  - Radio frequency, Bluetooth, serial, USB
- Open protocol
- Integrity assured
- Source authenticated

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# Measurement

## More Digital Signal Processing

- Flexible framework for sensor configuration that varies by
  - Sensor technology
  - Biophysics
  - Target measurements
- Convert signals/events to measurements
  - One sensor may produce multiple measurements
  - One measurement may require multiple sensors
  - One measurement may require multiple sensor readings
    - e.g., multiple heart beats
- Subject to calibration
- Measurement "goodness"
  - Accuracy (calibration)
  - Noise (dispersion)
    - "Was threshold of sensor exceeded?
- Stamp each measurement with:
  - Time
    - Time-zone aware
  - Trustworthiness or "goodness"
    - Extent to which the measure reflects reality
- Analysis Patterns
  - Observations and Measurements (Fowler)

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# *Acquired Data Alarms*

- Framework
  - Assess measurement against some criteria
  - Tag measurement
  - Alert other subsystems
    - To alert user
      ⇒ User-interaction subsystem
  - Alarming deactivatable
    - Example, to avoid audible alarms when collecting data from sleeping wearer
  - Able to incorporate 3rd party alarm subsystem
- Simple alarm subsystem
  - Compare measurement to limit
    - Limit may be user-specific
  - Respond to limit violation
    - Categorize violation
      - Caution
      - Warning
      - Alarm
    - Alert user
      - Beep or vibration

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# Time Series

- Time Series
  - [concept] a sequence of data points
    - measured typically at successive times
    - spaced at (often uniform) time intervals
- Each series encompasses one type of observation
- Acquired Series
  - [concept] Time Series corresponding to data uploaded
    - From a device to an analysis workstation
    - During a single connection session

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# Time Series

- Need
  - Handle sequences of data independently of capacity of data acquisition device
  - Current requirement = 7 days of data
  - Longer cycles are in play
    - E.g., circaseptan cycles in tumor cell growth

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# Time Series

- User can align overlapping series
  - Duplicate data items, uploaded multiple times
- User can link series into super-series
- User can split series into sub-series
- System analyzes any data sequence
  - Series
  - Super-series
  - Sub-series

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# Individual Analysis

- SBP | DBP | HR | Blood flow
  - MESOR
  - Circadian amplitude
  - Circadian acrophase
  - 24-hour cosine curve by least squares (cosinor analysis)
    - Special sampling period requirements
  - Marking of
    - Overswing
      (circadian ampl. > upper limit of 90% of reference set)
    - Underswing
      (circadian ampl. < lower limit of 90% of reference set)
    - Dipping?
- SBP | DBP
  - Hyperbaric index
- Arterial compliance (future?)

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# Population Analysis

- Group sessions into reference sets
- Categorize sessions
  - Age & gender
  - Dynamically determined attributes
- Determine statistical limits of set
  - 10% / 90%

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# Tool

- Framework for integration
- Between analysis worksites/tools

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# Plotting / Charting

## Data Presentation

- Types of plots
  - Scatterplots
  - Bar charts
    - Histograms
  - Line charts
  - Box plots
  - Tables
- Multilayered
  - E.g., best-fit line over scatterplot
- Varying resolution
  - Display types
    - Computer display
    - Paper
  - Peaks / valleys never clipped
    - Not same as clipping when threshold of sensor exceeded
- Annotations
  - Programmatic
    - From analysis algorithms
    - From data acquisition
      - Sensor threshold exceeded
  - Manual
    - From user

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# Reporting

Needs elaboration

- Form-like reports
- Flexible
- Incorporate
  - Charts & graphs
  - Tables
  - Free-form text
- Reports saved and stored

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# Session

- Encapsulates each user experience

Needs elaboration

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# Desktop Integration

- Functions assembled into application
- Graphical user interface
- Printing

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# Person Identity
## Privacy

- Goals
  - Unburden Phoenix of privacy issues
  - Relegate the burden of privacy to caregivers
  - Minimize the constraints posed by Phoenix on a caregiver's process
- Issue
  - "Who has seen my stuff?"

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# Person Identity
## Privacy

- Group data by session
- Identify session by session key
- Primarily identify collected data by session key
- Make the session key available to external systems
- Trace each session to the device employed in the session
- Manage person (patient) identity externally
- Within the system, keep all data anonymous
- Include anonymous fields in reports/displays Anonymous fields are intended for person identity but can be repurposed
- Anonymous fields may be ignored
- Assign labels and values to anonymous fields from an external source

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# Clinical Health Record

- Integration with clinical information systems
  - Clinical Care Support System (CCSS) ⇐ Phoenix
  - Patient Administration Systems (PAS)
  - Electronic Practice Management (EPM) systems
  - Laboratory Information Systems (LIS)
  - Dietary, Pharmacy and Billing systems
  - Electronic Medical Record (EMR) systems
  - Electronic Health Record (EHR) systems
- HL7 — electronic health record interchange standards
- Laboratory test standards
  - Assume chronomedical analysis conducted as laboratory procedure

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# Personal Health Record

- Integration framework
- Future

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# Networking

- Web sites
- Multisite integration
- Community
- Issue
  - Impacts of informed consent
- Cf.
  - Larry Beatty's work
  - Physionet

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# Change Management

- Usage tracking
  - Who used what?

Needs elaboration

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# Justifications

- Chronobiology
- Measuring blood pressure for 7 days
  - Cornélissen G, Delmore P, Halberg F. Why 7-Day Blood Pressure Monitoring? Healthwatch 3, Halberg Chronobiology Center, 2004.
    - http://www.phoenix.tc-ieee.org/0001_Bibliography/HWatch3.pdf; 2.2 MB pdf
- Why target students?

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# PARKING LOT

- Standards concerning interface between body and devices on the body (ref. US Pharmacopeia §9.7)