System Requirements

Phoenix

Ambulatory Blood Pressure Monitoring System

11 May 2008

1

Table of Contents

I. Mission
II. Scope
III. Stakeholders
IV. Goals & Goal Conflicts
V. Dictionary
VI. Scenarios, Stories, Use Cases & Exceptions
VII. Requirements
VIII. Justifications
IX. Assumptions
X. Agreed Priorities
XI. Acceptance Criteria
XII. Parking Lot

11 May 2008

2

Mission

- Develop an ambulatory blood pressure monitor
  - Inexpensive
  - Unobtrusive
  - Easy to use
  - Collects a week of blood pressure measurements
- Develop a means for chronobiological analysis of the collected blood pressure measurements

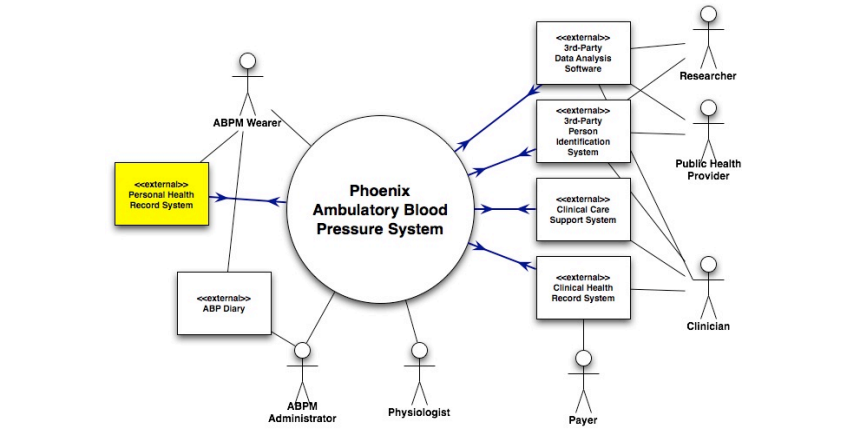
11 May 2008 3

Mission

- Be a learning community
  - IEEE study group
  - Open source
- Deliver the monitor and analytic framework to the Halberg Chronobiology Center
  - For long term use on massive scale to
    - Obtain measures of health
    - Encourage the development of techniques for
      - Diagnosis
      - Prevention
      - Treatment

11 May 2008 4

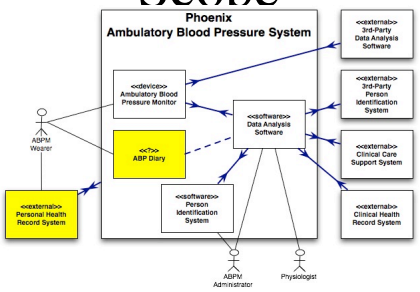
Scope



I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 5

Scope



- Monitor measures the Wearer
- Wearer records observations in the Diary
- Administrator & Physiologist use Data Analysis Software to assess the data collected by the Device
- Diary influences the interpretation of the data
- Wearer optionally tracks results in a Personal Health Record System
- Clinical settings ⇒ data stored in Medical Record System
- Wearer de-identified to assure privacy ⇒ Person Identification System

11 May 2008 6

Stakeholders

http://www.phoenix.tc-ieee.org/014_Systems_Architecture_and_Engineering/all-in-one.html#requirements

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 7

Goals & Goal Conflicts

- Make a monitor that is
  - Inexpensive
  - Unobtrusive
  - Easy to use
  - Collects a week of blood pressure measurements

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 8

Goals & Goal Conflicts

- Inexpensive
  - Price not a barrier to use
  - Less expensive than blood pressure cuff
  - Less expensive than wrist watch
    - < US$50
  - Less expensive than “two bushels of yams”
    - Third-world friendly
    - < US$10

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 9

Goals & Goal Conflicts

- Unobtrusive
  - When wearing monitor, patient can
    - Forget about, be unaware of device
  - No more encumbering than
    - Wrist watch
    - Band-aid™
    - Piece of jewelry
  - Usable wherever the patient is
    - At home
    - At work when allowed
    - Not only at hospital, clinic or doctor's office

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 10

Goals & Goal Conflicts

- Easy to use
  - Easier to use than current:
    - Blood pressure cuffs
    - Home BP monitors
  - Patient can:
    - Ignore device
    - Determine that device is functioning normally
    - Observe a blood pressure and heart rate measurement
  - Device
    - Is automatic
      - measurements taken regardless of patient behavior
    - Allows manually initiated measurements

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

Goals & Goal Conflicts

- Collects a week of blood pressure measurements
  - Must measure
    - Systolic and diastolic blood pressure
    - Heart rate
  - At least as accurate as current:
    - Blood pressure cuffs
    - Home blood pressure monitors
  - Would also like to measure
    - Physical activity
      - To determine if vigorous body movement, such as physical exercise, influenced the blood pressure measurement
    - Blood flow
  - Records measurements
    - at least every half hour
    - for at least 7 days

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

Goals & Goal Conflicts

- The Halberg Chronobiology Center wants the monitor
  - For long term use on massive scale
  - To obtain measures of health
  - To encourage the development of diagnostic, prevention and treatment techniques

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 13

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

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 14

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 Other Deck for Specifics about the Scenarios

11 May 2008 15

Requirements

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

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 16

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

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 17

Functional Requirements

- Information model
- Behaviour requirements
- Algorithms

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 18

Quality Requirements

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

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 19

Quality Attributes

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

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 20

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

11 May 2008 21

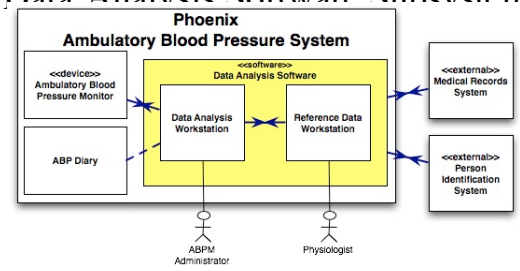
Quality Requirements

- 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

11 May 2008 22

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

11 May 2008 23

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
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 24

User-Noted Events

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

Body	Data Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 25

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 26

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 27

Data Transport

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 28

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)

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 29

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 30

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 31

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 32

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 33

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?)

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 34

Population Analysis

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 35

Tool

- Framework for integration
- Between analysis worksites/tools

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 36

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 37

Reporting

Needs elaboration

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 38

Session

- Encapsulates each user experience

Needs elaboration

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 39

Desktop Integration

- Functions assembled into application
- Graphical user interface
- Printing

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 40

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?"

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 41

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 42

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 43

Personal Health Record

- Integration framework
- Future

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 44

Networking

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

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 45

Change Management

- Usage tracking
  - Who used what?

Needs elaboration

Body	Signal Acquisition	Measurement	Data Transport	Time Series
Analysis	Tool	Plot / Chart	Reporting	Session
Desktop Integration	Person Identity	Health Record	Networking	Change Management

11 May 2008 46

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?

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 47

Assumptions

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 48

Priorities

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 49

Acceptance Criteria

I. Mission	II. Scope	III. Stakeholders	IV. Goals / Conflicts	V. Dictionary
VI. Scenarios	VII. Requirements	VIII. Justifications	IX. Assumptions	X. Priorities
		XI. Acceptance Criteria		

11 May 2008 50

PARKING LOT

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