Architectural Overview & Requirements Brainstorm

Phoenix Ambulatory Blood Pressure Monitor

Table of Contents

- 5 minutes of requirements (skip)

- 30 seconds of constraints (skip)

- Major subsystem interfaces

- Diary subsystem (skip)

- Analysis software subsystem (skip)

- Device subsystem (requirements only — skip architecture)

Requirements

- Collects a week of blood pressure measurements
- Inexpensive
- Unobtrusive
- Easy to use

Requirement
Week of Measurements

- Records measurements at least every half hour for at least 7 days
- Measures systolic and diastolic blood pressure
- Measures heart rate
- Measures physical activity
- Measures blood flow

Requirement
Inexpensive

- Price is not a barrier to using the monitor
- Less expensive than:
  - Blood pressure cuff
  - Wrist watch (<$50)
  - "Two bushels of yams" (<$10)
    - 3rd-world friendly

Requirement
Unobtrusive

- ## When in place
  - Patient can forget about it — not be aware of it
  - No more encumbering than
    - wrist watch
    - band-aid
    - piece of jewelry

- ## Usable wherever the patient is, such as at home or at work when allowed
  - Not just for hospital, clinic or doctor's office

Requirement
Easy to Use

- Better than devices with blood pressure cuffs:
  - Easier to use
  - Equally accurate

- Patient:
  - Should be able to ignore it, but
  - Can determine whether functioning normally
  - Can observe a blood pressure and heart rate measurement

- Automatic — measurements taken regardless of patient behavior

- Allows manually initiated measurements

Constraints

- ## Open-source
  - ### Major impact on design
    - Must be buildable by fluid, virtual organization
    - Developers have major say in content
   - 3rd-party components must pass licensing constraints

Recap

- 5 minutes of requirements
- 30 seconds of constraints
- Major subsystem interfaces ⟸
- Diary subsystem
- Analysis software subsystem
- Device subsystem

Major Subsystems & Interfaces
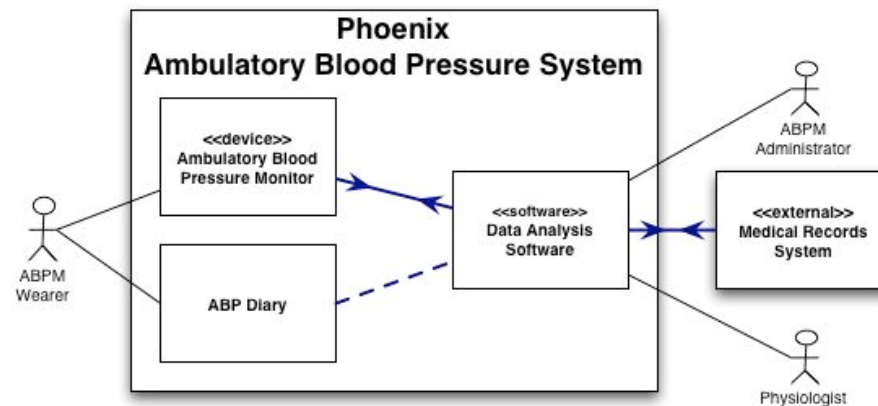
- Monitor measures the Wearer
- Wearer records observations in the Diary
- Administrator & Physiologist use Data Analysis Software to assess the data collected by the Device
- Diary influences the interpretation of the data
- Clinical settings: data stored in Medical Record Systems
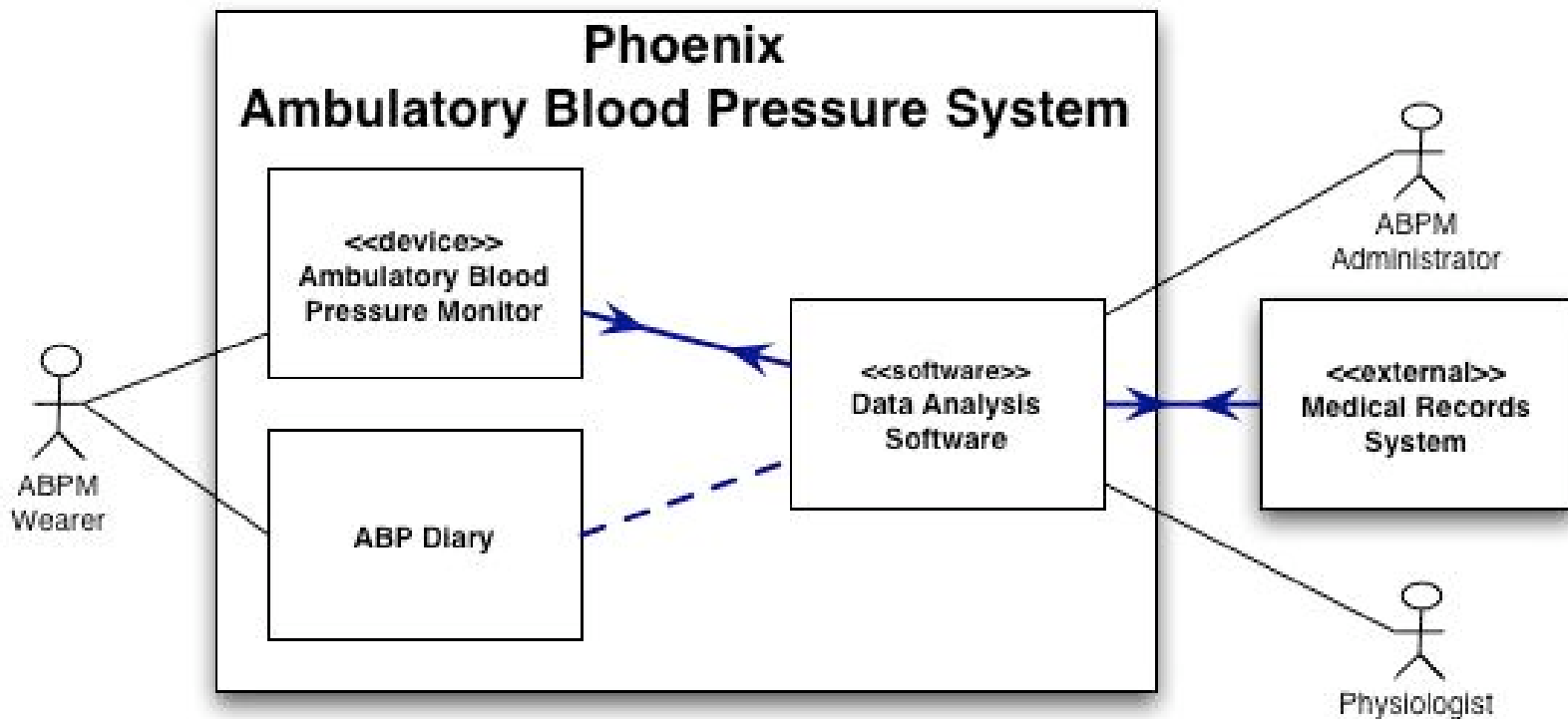
Diary Subsystem
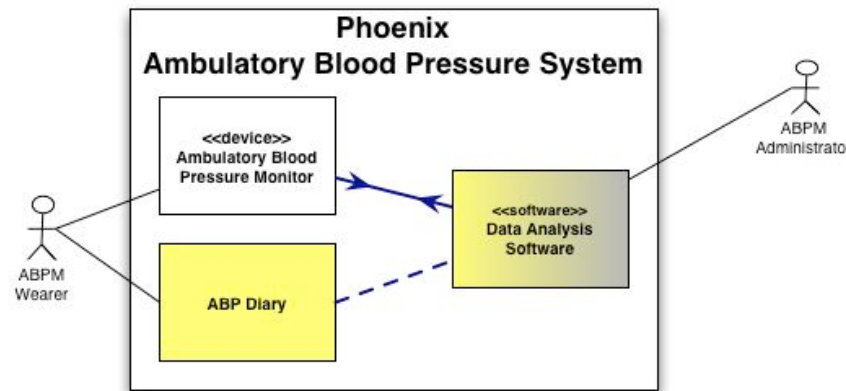
- Observations influencing diagnosis
- Defined content
  - Patient identity *(new subsystem?)*
  - Background, demographics
  - Daily entries
    - Exceptions to background

- Multiple formats
  - Paper   PDA
  - …
- Integrated device feature
- Could be an electronic device
  ➔ Phoenix ≈ 2+ devices

Analysis Software Subsystem
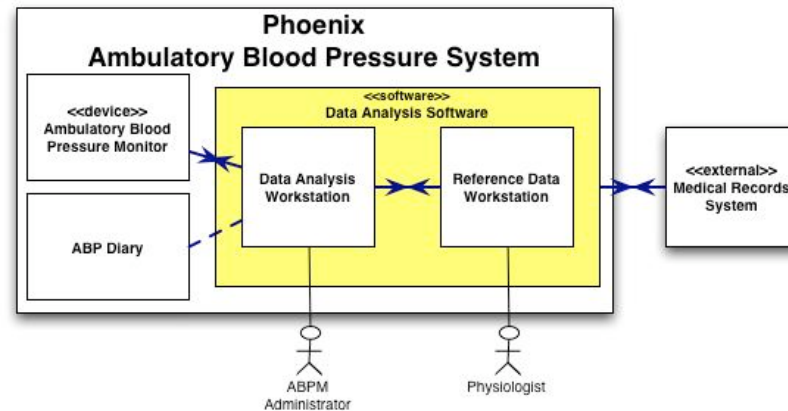

- Analysis Workstation
  - Handles data for a single wearer
  - Nominally a desktop application
  - Multiple implementations ⇐
    - Clinical Care Support System
    - Personal care support tool
- Reference Data Workstation used by Chronobiology Center
  - Handles data for whole populations
  - Could be a distributed or internet application
- Analysis Workstation relies on model parameters from Reference Data Workstation
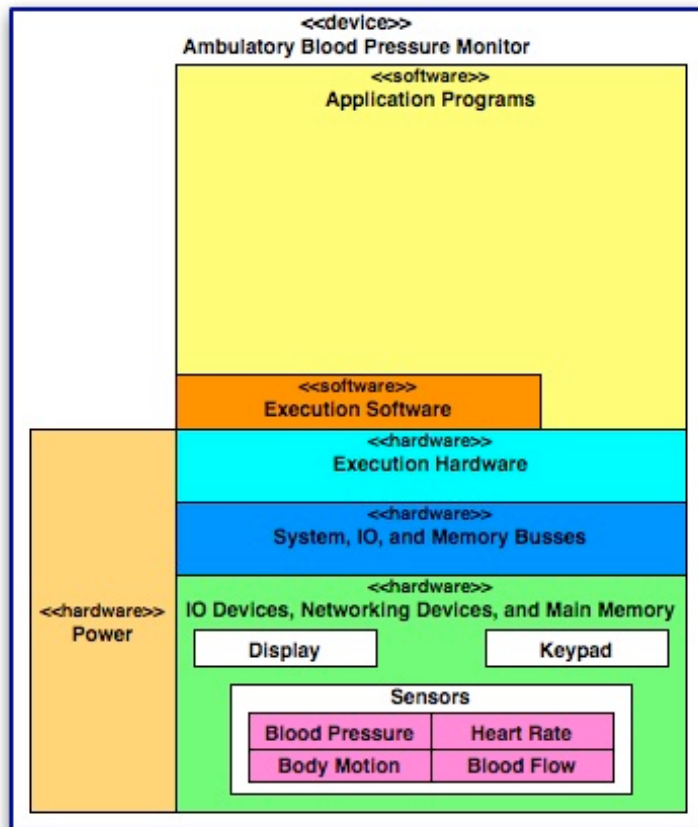
Recap

Device Subsystem

- Small, wearable computer
- Related subprojects:
  - Low Power Microprocessor
  - Power
    - Subsystem must be modular for easy substitution
    - thin-film battery would be cool
- Real-time embedded software ⇐
- Execution software =?
  - RTOS? OS? No OS?
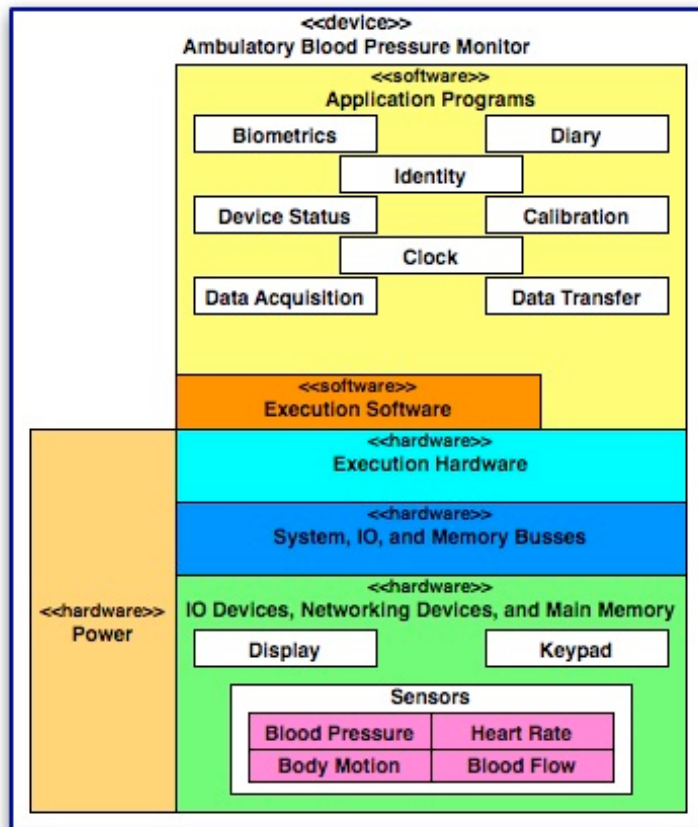- Functionality may be allocated to multiple, linked devices
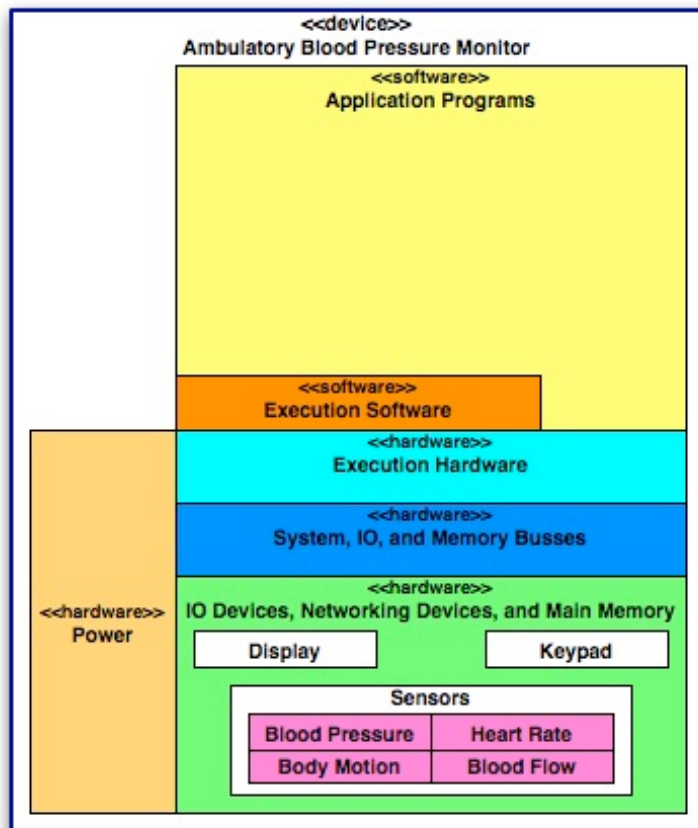
Device Subsystem

- Display
- Keypad
- Sensors
  - Blood pressure
  - Heart rate
  - Body motion
  - Blood flow
- Issues
  - Sensor proximity & bundling
  - Number of devices

Device Subsystem

1. Clock
2. Identity
3. Diary
4. Calibration
5. Device status
6. Biometrics
7. Data transfer
8. Data acquisition

Requirements
Clock

- Timestamp every sample
  - Include date
  - Record in UCT
- Display time-of-day for diary recording
  - Display precision = 1 minute
  - Do not display date
  - Display in local time ➔ need timezone
- Precision
  - Current devices require about 1 minute to take a single measurement
  - Sampling Beat-to-beat ➔ 300 beats per min x 25 samples per cycle = 125 samples per sec = 8 msec per sample ➔ precision = 1 msec
- Set time, date, and timezone at "initialization"

Requirements
Identity (Onboard/Offboard)

- Unique device id
  - Serial number of instrument

- Unique patient id
  - Issues:
    - HIPAA constraints (Health Insurance Portability & Accountability Act of 1996)
      - Individually Identifiable Health Information (IIHI)
      - Protected Health Information (PHI)
    - Do not yet know if patient ID is needed onboard
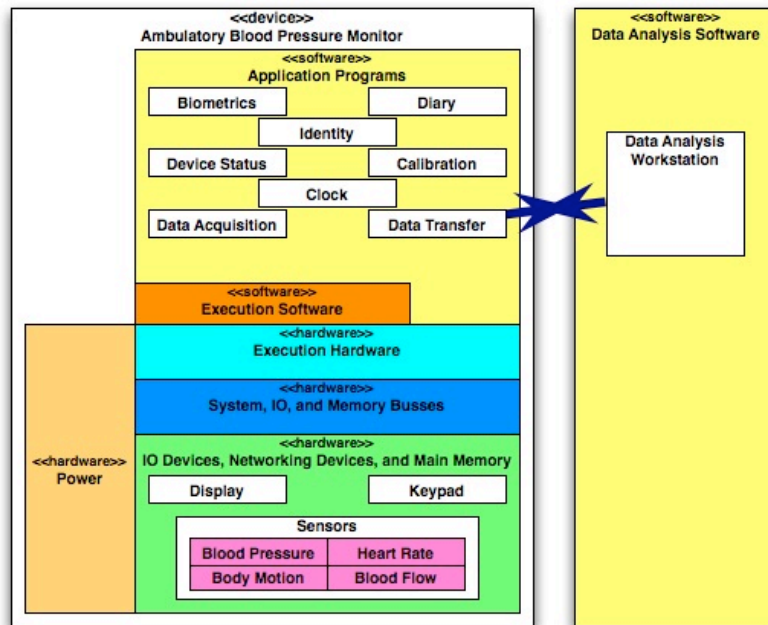
Requirements
Diary (Onboard)

Requirements
Device Status

<u>Requirements</u>
Calibration

Requirements
Biometrics (Onboard)

Requirements
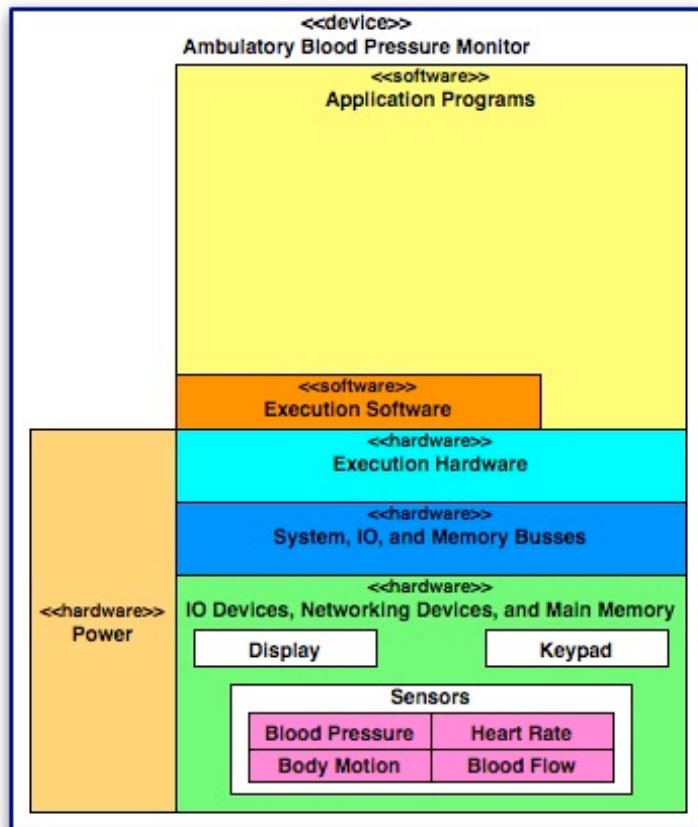## Data Transfer — Standards

- HL7

- IEEE 1073, "Standard for Medical Device Communications"

  – Defines "Medical Information Bus"

  – May be superceded

- ISO/IEEE 11073, "Standards for Point-of-Care Medical Device Communication"

Requirements
Data Transfer—Content

Requirements
Data Acquisition

UI Requirements

- Display
- Keypad