Wearables and Remote Patient Monitoring

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Accurate & holistic health data

Lifestyle choices, health history, symptoms, medication, treatment information, and biometric data
Increased use of data is driving enormous transformations in health care

• Empowered patients who are taking increasing ownership of their health far beyond the walls of their doctor’s office

• Healthcare providers are improving care and being alerted early to health problems

• Information is becoming easier to collect, analyze and understand
Uses of Wearable Devices

• Lifestyle choices
  • Individuals tracking their diseases
  • Individuals tracking exercise and weight loss
  • General health monitoring by individuals

• Health history
  • In hospital
  • At home

• Medication
  • Monitoring effects of drugs – by doctors or drug companies

• Preventing hospital readmissions
  • Monitoring at home
Data is permeating every component of the health care ecosystem:

- Medical research
- Daily life
- Patient experience
- Ongoing care
- Prediction and prevention
Remote patient monitoring is developing into a new standard of care.

Wearable gadgets make monitoring patients more effective.
Benefits of Patient Monitoring

- Convenience
- Timeliness - reported continuously
- Accuracy
- Safety and security
- Mobility – continuous monitoring
Key Applications of Wearable Devices
Cardiovascular

- Heart rate and ECG
- Breathing rate
- Blood oxygen
- Motion

Image source: QardioCore https://store.getqardio.com/products/qardiocoreDec. 2018
Sleep Monitoring

- Blood oxygen
- Body temperature
- Heart rate
- Motion
Diabetes

- Glucose
- Operation of insulin pump
In Hospital Monitoring
Injury Prevention

- Dementia
  - Change in gait (motion)
- Falls
  - Detect leaving bed in a hospital
  - Fall detection to summon help
- Workplace Safety
  - Heart rate
  - Temperature
  - Skin conductivity
Human body is a complex dynamic system that offers a wealth of data.
What kind of data would you like to have?

- **Body Temperature**
- **MOTION**
- **Heart Rate**
- **Blood Oxygen**
- **ECG/EMG**
- **Respiration**
- **Blood Pressure**
- **Blood Sugar**
Body Temperature

- Few good locations to measure core temperature
  - Axilla (under arm) or forehead are best locations
  - Not convenient for a wearable device
- Extremities (eg wrist) have variable temperature
- Algorithms can partially adjust over time
- Good contact is important – heat flow causes errors
Motion

- The most studied and used parameter
- Step counts
- Gait analysis (illness)
- Types of motion (walking, standing, sitting)
- Dead reckoning (9-axis motion)
- Works on wrist, ankle, torso, etc.
  - Different algorithms at different locations
- Motion sensor manufacturers provide advanced software algorithms
Heart Rate

- Measured by
  - ECG electrodes – two are sufficient
  - Pulse oximeter sensing – transmissive
    - Transmitted works on finger and ear
  - Pulse oximeter – reflected
    - Works more places on body
  - Pressure sensing of the pulse in the wrist
- Wrist measurement works well for Heart Rate, but not for ECG
Blood Oxygen

- Oxygen saturation in blood
- Measured by pulse oximeter (infra-red) technology
  - Measure loss through body of 2 IR wavelengths
  - Separates changes in blood from other changes
  - Measure pulse at the same time
- Transmissive or reflective measurement
  - Reflective for more places on body
  - Transmissive for better accuracy
  - Transmissive – on finger or ear only
ECG / EMG / EEG

- Measure of electrical and muscle activity
- ECG measurement points have to be rather far apart
  - At least one and a half inches – larger devices needed
  - More leads is better (up to 12 for standard ECG)
- EMG requires accurate placement (millimeters)
  - Measure the wrong muscle
- EEG must use electrodes on the head
Respiration Rate

- Number of breaths per minute
  - Few good locations to measure
- Movement of chest
  - Chest strap
  - Not convenient for a wearable device except shirt
- Thoracic Impedance eliminates chest strap
  - Device can be small
  - Difficult on wrist
- EKG signal – filter out heart signal
Blood Pressure

• Measure of systolic and diastolic pressure
• Accurate measurement requires pressure cuff that is compressed and released
  • Does not work as well on wrist
• Pulse Transit Time – measure at wrist or elsewhere
  • Currently not accurate enough for medical diagnosis
  • Currently not medically accurate
• EKG – using neural network
  • It is not medically accurate
Blood Sugar (Glucose)

- Measure of glucose level in blood sample
- Widely used
- Becoming a wearable
  - with microneedles or implanted
- Frequent calibration required
- Attempts to not use finger tip – less accurate
- Not accurate on wrist
- Closed loop system replaces the pancreas
  - Measure and control glucose with a pump
Battery lifetime is a big challenge in wearable devices
Battery Limitations

- Slow pace of improvement
  If improved like semiconductors:
  Size of a pin head, could power your car, cost 1 cent
- Must always work around limitations
- Long time between charging vs small size
When Will Battery Technology Improve?

- Chemical energy storage is approaching the limit of its efficiency
- Nuclear energy is out of the question
- A lot of research being done on higher density and better safety
  - Perhaps 2 times higher density in a few years
  - Will safety suffer?
Energy Density

- Alkaline
- Lithium Ion (rechargeable)
- Lithium
- Gasoline
Energy Density and Safety

• As energy density has increased, safety has become more of a problem
• Safety circuits are required on Lithium batteries
• Poorly designed batteries can catch fire even with safety circuits
• Shipping of Lithium batteries is restricted and regulated
  • Cells without safety circuit cannot ship by air
5 Areas That Impact Power

- Wireless transmission
- Displays
- Sensors
- Microprocessors
- Software
Common Ways to Get Data Into the Cloud

1. Device directly to cloud
   - Smart Device → Cloud

2. Sensor to gateway to cloud
   - Smart Device → Gateway → Cloud

3. Sensor to cell phone to cloud
   - Sensor → Mobile Phone → Cloud
# Power - How Much? How Far?

<table>
<thead>
<tr>
<th></th>
<th>10 bytes/sec</th>
<th>1 Kbytes/sec</th>
<th>1 Mbytes/sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 m</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>100 m</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>1 km</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

- **Distance**: The distance is highlighted for each data rate.
- **Lowest Power**: The lowest power consumption is shown at 1 m for 10 bytes/sec.
- **Data Rate**: The data rate increases as the distance increases from 1 m to 1 km.
### Power - How Much? How Far?

<table>
<thead>
<tr>
<th>Distance</th>
<th>10 bytes/sec</th>
<th>1 Kbytes/sec</th>
<th>1 Mbytes/sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 m</td>
<td>BLE/Zigbee 0.15</td>
<td>BLE/Zigbee 7.5</td>
<td>WiFi 300</td>
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<tr>
<td></td>
<td>LoRa 0.5</td>
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<td></td>
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<tr>
<td></td>
<td>WiFi 100</td>
<td>WiFi 100</td>
<td>LTE Cellular 500</td>
</tr>
<tr>
<td></td>
<td>3G Cellular 100</td>
<td>3G Cellular 120</td>
<td></td>
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<tr>
<td></td>
<td>LTE Cellular 100</td>
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<tr>
<td>1 km</td>
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<td>LoRa 30</td>
<td>LTE Cellular 700</td>
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<tr>
<td></td>
<td>3G Cellular 120</td>
<td>3G Cellular 150</td>
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</tr>
<tr>
<td></td>
<td>LTE Cellular 120</td>
<td>LTE Cellular 150</td>
<td></td>
</tr>
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</table>
Display Technologies

Cost

Energy Usage

Digital paper

OLED

Color LCD backlit

LED

LCD (grayscale)

uW

mW

Watts

uW

mW

Watts
How Much Power Do Sensors Use?

- Camera chip: 300mW
- Illumination for camera at night: 200mW
- GPS (Position): 20mW
- Load cell (Weight): 10mW
- Pulse Oximeter (Blood Oxygen): 10mW
- EKG/Heart Rate: 1mW
- 9-axis Motion Sensor: 0.5mW
- Microphone: 0.1 to 10mW
- Light Intensity: 0.1 to 10mW
- 3-axis Accelerometer: 0.01 to 0.1mW
Wireless Charging

• No cable to plug in
• No connector
• Convenient and reliable – no cable
• Easier to seal the enclosure
  • Good for sterilized devices
• Great for implanted devices
Wireless Charging Limitations

- Must design so device is properly place on charger
- Device must be very close to charger
  - Work on long distance charging, but not available for real products
- Slower charging (typically)
- More expensive than wired chargers
Wireless Charging Standards

- Qi – up to 4 cm distance, 5 Watts (higher available), well adopted
- AirPower – by Apple, based on Qi
- Older standards merged to form AirFuel Alliance
  - Rezence, WiPower, PMA
  - Multiple standards
  - Not compatible with Qi
  - Less well adopted
- Proprietary
  - Some devices don’t need to use a standard, ie medical devices
Data Security

• The FDA issued a guidance document at the end of 2016 regarding end-to-end security for medical devices.

• End-to-end security requires:
  • Detect a device that is not authorized
  • Ensure the data is valid when received in the cloud
    • From a known device
    • The right data – right time, right user, etc
    • Accurate
  • Store data in the cloud securely
  • Ensure software updates come from right source
Data Security Solutions from Third Parties

- SecureRF Corporation has an encryption algorithm that runs on processors as small as 8 bits.
  - Most algorithms too slow, need powerful processors
- Intrinsic ID Corporation generates secret key from random SRAM power-up state
  - Provides authentication device to cloud
- SecurePush Corporation provides end-to-end solution with
  - System on a chip
  - Mobile app
  - Cloud service
Getting FDA Clearance

• Follow design controls
  • Clear and carefully written requirements
• Risk analysis
• Careful verification and validation testing
• Verification and validation testing
  • Simple or none for class I
  • Rigorous for class II
  • Leave no stone unturned for class III
• Work with the FDA
  • Discuss issues openly
  • Be prepared when you talk with the FDA
Clearing Wearable Devices

- FDA requires no premarket submission for smartphone apps that
  - Help people self-manage their disease or condition without providing specific treatment suggestions
  - Help patients document, show or communicate potential medical conditions to health care providers
  - Enable patients or providers to interact with Electronic Health Records.
  - Automate simple tasks for health care providers
- Sensing and transmitting devices are subject to the same rules as other medical devices
We are Experts at Devices That Collect Data

- Sensors
- Wireless communication
- Wearables – batteries a major limitation
- Wireless charging
- Security
Universal-Sensor Health Platform
Pre-engineered platform

• Ready to accept nearly any sensor
  • Data accuracy
  • Power management
  • Wireless data transmission

• Quickly get accurate data
  • Into the cloud
  • To a smart phone
  • On a USB
  • To a laptop
Innovate Quickly

- Find out quickly if a sensor works or where to locate it
- Cost savings
- Fast development
- Compact size – for use on humans as a prototype
- Voler’s experience selecting sensors and incorporating them into a device
What Success Can Look Like

- In 6 months built 500,000 units
- 500 that didn’t work (0.1% failure rate)
- Careful design and transfer to manufacturing
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Quality Electronic Design & Software
Wearable Devices and IoT
Sensor Interfaces
Wireless
Motion Control
Medical Devices