Trends in Medical Devices and Sensors

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Agenda

• Trends
• Examples of Sensors and Applications
• Sensor Innovation
• Current Challenges
Future Medical Device Markets

1. Wearable Devices
2. Home Health - Devices for the Aging
3. Digital Health – Big Data
   • This Talk: My Perspectives from What People are Designing and Investing In
   • Many Devices Not Medical (FDA Regulated)
   • Low Investment in Medical Devices for Healthcare Providers
Huge Market Potential

- Market for Wearable Devices = 300 million People over 5 Years Old in U.S.
- Market for Home Health = 115 million Households in U.S.
- Market for the Aging = 40 million Over 65 in U.S.
Future of Wearable Devices

• It’s Just a Fad
  - No One in Kansas will Ever use this Stuff

• Explosive Growth is Almost Here
  - A Killer App will make Wearables Mainstream

• Evolutionary Change
  - Wearables are Well Adopted
    - Jewelry, Watches, Eyeglasses, Hearing Aides, Smart Phones
  - Changes Will Make Them Better
  - Interconnected Data Will Make Them Smarter
Home Health and Wearable Device Innovation

Watch
- Pebble Smart Watch

Eyeglasses
- Google Smart Glasses

Hearing Aid
- Sonitus in the Mouth Hearing Aid

Activity Tracker
- Fit Bit Activity Monitor

Detection
- Scanadu Tricorder
Evolutionary Change in Wearable Devices

• Successful Wearable Devices Now
  ♦ Jewelry
  ♦ Wrist Watches – 1 Billion Sold Each Year Worldwide
  ♦ Eyeglasses
  ♦ Hearing Aides
  ♦ Smart Phones (Wearable?)

• What Makes These Successful?
  ♦ Beautiful
  ♦ Functional
  ♦ Inobtrusive
Future Wearable Devices

- Will There be a New Class of Device?
- Will Google Glass Succeed?
Future Of Home Health

- Device For The Aging
  - Aging Population
  - Desire to Age In Place
  - Baby Boomers Familiar with Electronics

- Lower Cost Distribution - Hearing Aids in Walmart

- Better Ways Of Doing Things - Tricorder

- Many Devices Will Not Be Medical Devices

- Remote Monitoring To Healthcare Provider
  - Proven To Lower Cost and Improve Outcomes By Veterans Administration
Home Health Monitoring

- Huge Potential Benefit
- Worldwide in 2025*
- $15 Trillion cost of treating chronic disease
  - 10% to 20% cost reduction in 2025 through remote health monitoring
- 50 million nurses for inpatient monitoring
  - ½ to 1 hour per day saved for each nurse through remote health monitoring

*McKinsey Global Institute analysis, May 2013
Existing Home Health

Lively – elder monitor
Future Home Health

• Better Function
  ◦ Smart Fall Monitors for Elderly
  ◦ Better Passive Activity Tracking – Is Mom OK?
    ▪ Alzheimer’s Tracking
  ◦ Better Medication Adherence Monitoring

• Medical Sensors in Smart Phones Will Lead to:
  ◦ More Medical Apps

• Remote Health Monitoring – Growing

• Implanted Sensors – for Hearing, Now Available
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Sensor and Device Examples

- **Fit Bit**
  Activity Monitor

- **Scanadu**
  Tricorder

- **PuraCath**
  Catheter Sterilizer

- **Active Mind**
  Golf Game Tracker
Example: Activity Monitor

- Sensor: Accelerometer
- Senses Each Step
- App Converts Steps into Calories Burned
- Tracks Quality of Sleep

Fit Bit
Example: “Tricoder”

- Temperature Sensing
- Heart Rate Sensing
- ECG
  - Heart Rate Variability
  - Pulse Wave Transit Time (Blood Pressure)
- Oximetry (Blood Oxygen Level)
- Urine Analysis
- Stress
Example: Home Dialysis

- Ultraviolet Light Sterilization of Connections
- Connects Implanted Peritoneal Dialysis Tube to Dialysate Bag and Drain Bag
- Sensors
  - UV Light
  - Enclosure Open
Example: Golf Game Tracking

• Sensors
  - GPS
  - Accelerometer
  - NFC

• Records Swings
• Records Travel of Ball
• Complete Record of Game on Map of Golf Course
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Sensors Critical To Advances

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www.SensorsCon.org
March 6 2014
Santa Clara, CA
Rapid Innovation In Sensors

• Growth Of Sensors And Electronics
  ◦ Miniaturization
  ◦ Lower Cost
  ◦ Smarter Systems

• Advances Create New Markets Which Drives More Sensor Innovation
Common Sensors Now

- Temperature
- Pressure
- Vibration / Acceleration
- Gyroscope
- Magnetometer
- Flow
- Vision, Microphones, Photodetectors
- Combination: Accelerometer, Gyroscope, and Magnetometer On A Chip
Future Of Sensors

• Chemical Sensors
  • Gene Detection Chips – Getting Better
  • Lab on a Chip – for Fluids
  • Paper Based - Disposable
• Fibier Optic Sensors
  • Pressure, Temperature, Strain, Force, Displacement
• Non-contact Glucose Sensor?
• Big Data to Analyze Sensor Data
  • Make Sensors Smarter with Software
Fiber Optic Sensors

• Advantages
   Safe – No Wires to Sensor
   Small – 0.25 mm Diameter
   Operate in Harsh Environments, No EMI
   Multiplex Sensors on One Fiber

• Disadvantages
   Support Electronics still Expensive
   Electronics Can Get Cheap in Volume

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Current Challenges

• Wearables – Batteries a Major Limitation
• Limitations in Sensors
• Complex Needs of the Elderly
• Adoption by Healthcare Providers
• Islands of Data**
• Are You Making a Medical Device??
• Regulations Don’t Keep Up with Technology**

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Battery Limitations in Wearables

• 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
  ♦ Short Time Between Charging vs Small Size
  ♦ Limited Wireless Transmission Range
    ▪ ie Bluetooth instead of WiFi or Cellular
  ♦ Wireless Transmission in Short Bursts
    ▪ Devices Slow When Listening for Transmission
  ♦ Use of Accelerometers Instead of GPS
Limitations In Sensors

- Low Cost Devices are Not as Accurate
  - Non-linearity and Offset Errors
  - Calibration or Auto-calibration
- Challenging to Get Good Data
  - Need Well Designed Data Acquisition Electronics
  - Software Can Make Data Better
- Cameras – Lighting Often a Problem

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Complex Needs of the Elderly

- Who Will pay? - Often the Children
- Stigma - I’m Not Sick –Make It Pretty or Cool
- Must Be Incredibly Easy to Use
  - Decline in Ability of Users
- Many Products Don’t Solve a Problem
  - No Medication Adherence Device Works for Everyone.
- Biggest Issues Of The Elderly Not Addressed
  - Isolation, Loneliness, No Sense Of Purpose
Adoption by Healthcare Providers

- What is the Standard of Care?
- How Do We Change It?
- How to Avoid Adoption of Technology That Costs More and Is Not Efficacious?
Adoption by Doctors

• Must Improve Outcomes and/or Make Doctors’ Lives Easier
• Consider Two Medical Innovations of 1846
  ♦ Anesthesia
  ♦ Hand Washing
• Why Was Anesthesia Adopted Within Months?
• Hand Washing Still Not Fully Adopted
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Market Drivers for Sensors

- **Automobiles**
  - Since 1980s
  - Cars Are Now Full of Sensors

- **Smart Phones**
  - Last Few Years
  - Smart Phones Make Sensors Wearable

- **Future Market Driver For Sensors**
  - Home Health
  - Wearable Devices
  - Internet of Things
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Quality Electronic Design & Software 

Sensor Interfaces  
Wireless  
Motion Control  
Medical Devices
Islands of Data

- Devices Collect Isolated Data
- How to get it to the Doctor?
- How to Collect from Many Devices?
- Will The Solution Create Electronic Health Records (EHR)?
  - Highly Regulated
- HIPAA is a Problem - Patient Confidentiality
  - Severe Penalties for Violations
Islands of Data Partial Solutions

EmPowerYu

Qualcomm Life

Infometers

IoTango
Are You Making a Medical Device?

• Cell Phone App Can Be A Medical Device
  - FDA Issued Guidelines for Mobile Apps in October 2013.
  - FDA Can Force A Company Out of Business for Violating Regulations

• Changing the “Instructions For Use” May Make It Not a Medical Device
  - Pulse Oximeter Example
Are These Medical Devices?

- **Nike Fuelband**: NO
- **Thermometer**: YES
- **Scanadu**: YES
- **Lively – elder monitor**: NO
- **Zosano**: YES
- **Azumio**: ?
Regulations are Out of Date

- HIPAA
  - Is There a Legal Way to Solve Islands of Data?
- What Is a Medical Device?
  - Does the Definition Need to Change?
- Example: Tricorder was Science Fiction
  - Technology Has Advanced Since Regulations Were Written
  - Regulations Need to Catch Up
Example: Patch to Detect if Pill is Taken

- Patch Worn on Abdomen
- IC Chip on Each Pill
- Chip is Activated by Stomach Acid
- Chip Sends Signal to Patch Over Proprietary Low Frequency Link
- Patch Relays Signal to Local Device
Example: Wearable Artificial Pancreas

• Separate Modules
  ◦ Glucose Sensor
  ◦ Insulin Pump – Lowers Blood Glucose
  ◦ Glucagon Pump – Raises Blood Glucose
  ◦ Control Module

• Claims to be Artificial Pancreas
Cameras: Recent Advances

- Small
- Low Cost
- High Resolution
- Integrated Optics