Wearables and Remote Patient Monitoring

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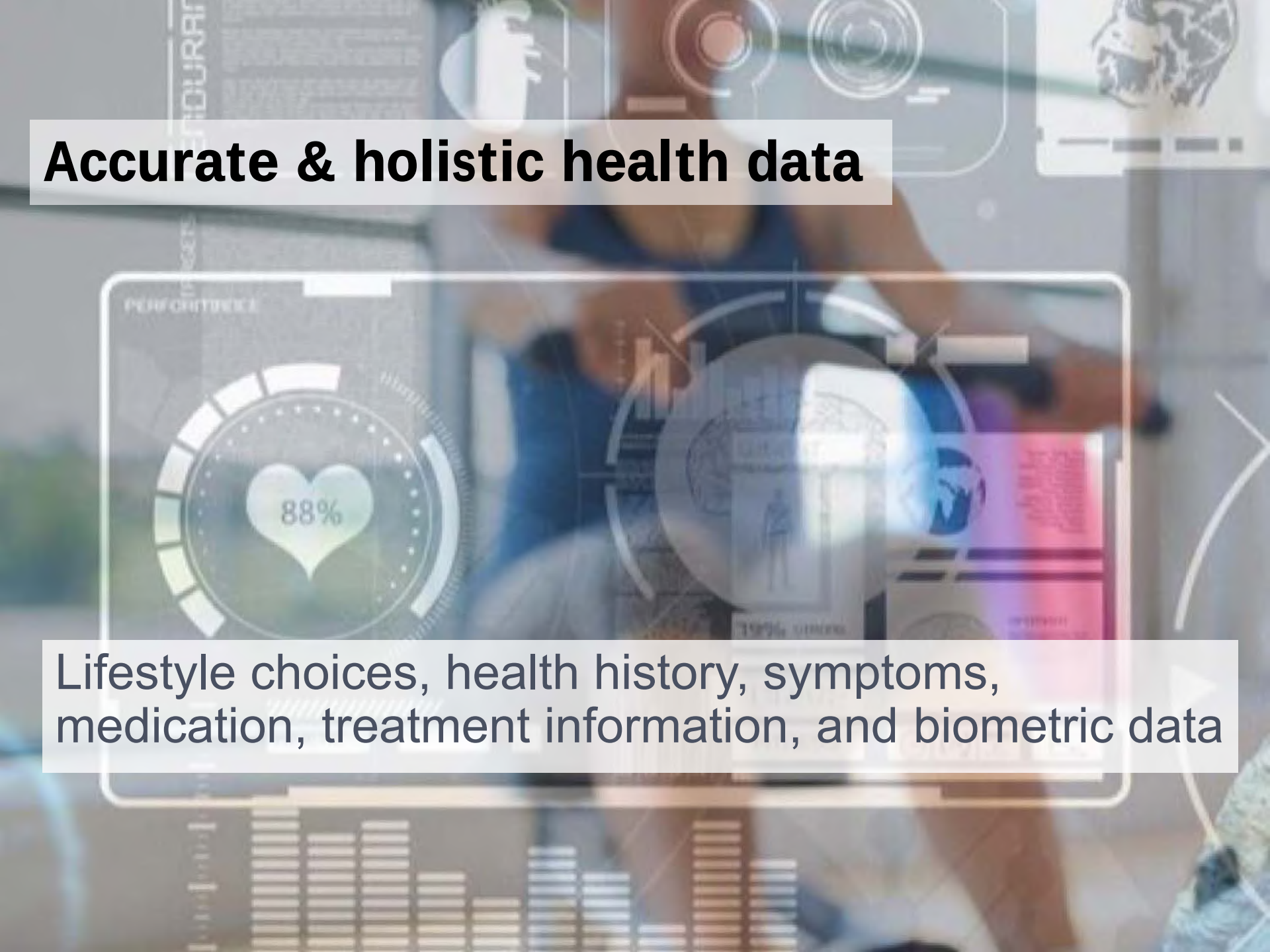
Voler SYSTEMS



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

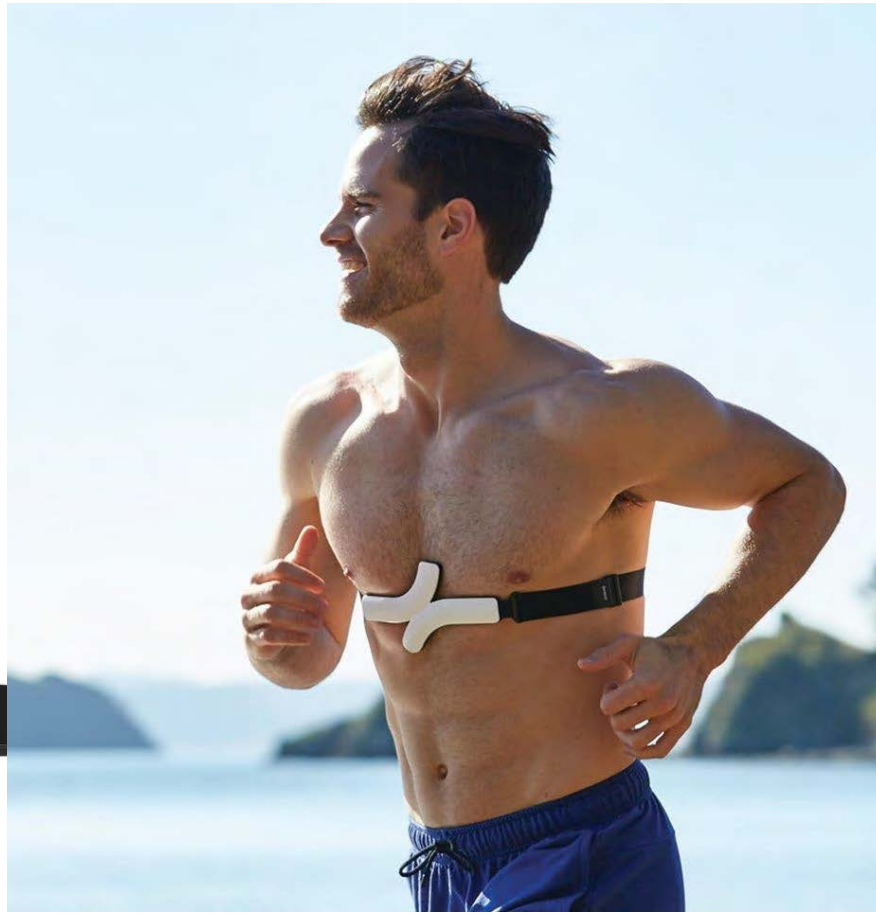


Image source: QardioCore https://store.getqardio.com/products/qardiocoreDec. 2018

Sleep Monitoring

- Blood oxygen
- Body temperature
- Heart rate
- Motion

Diabetes

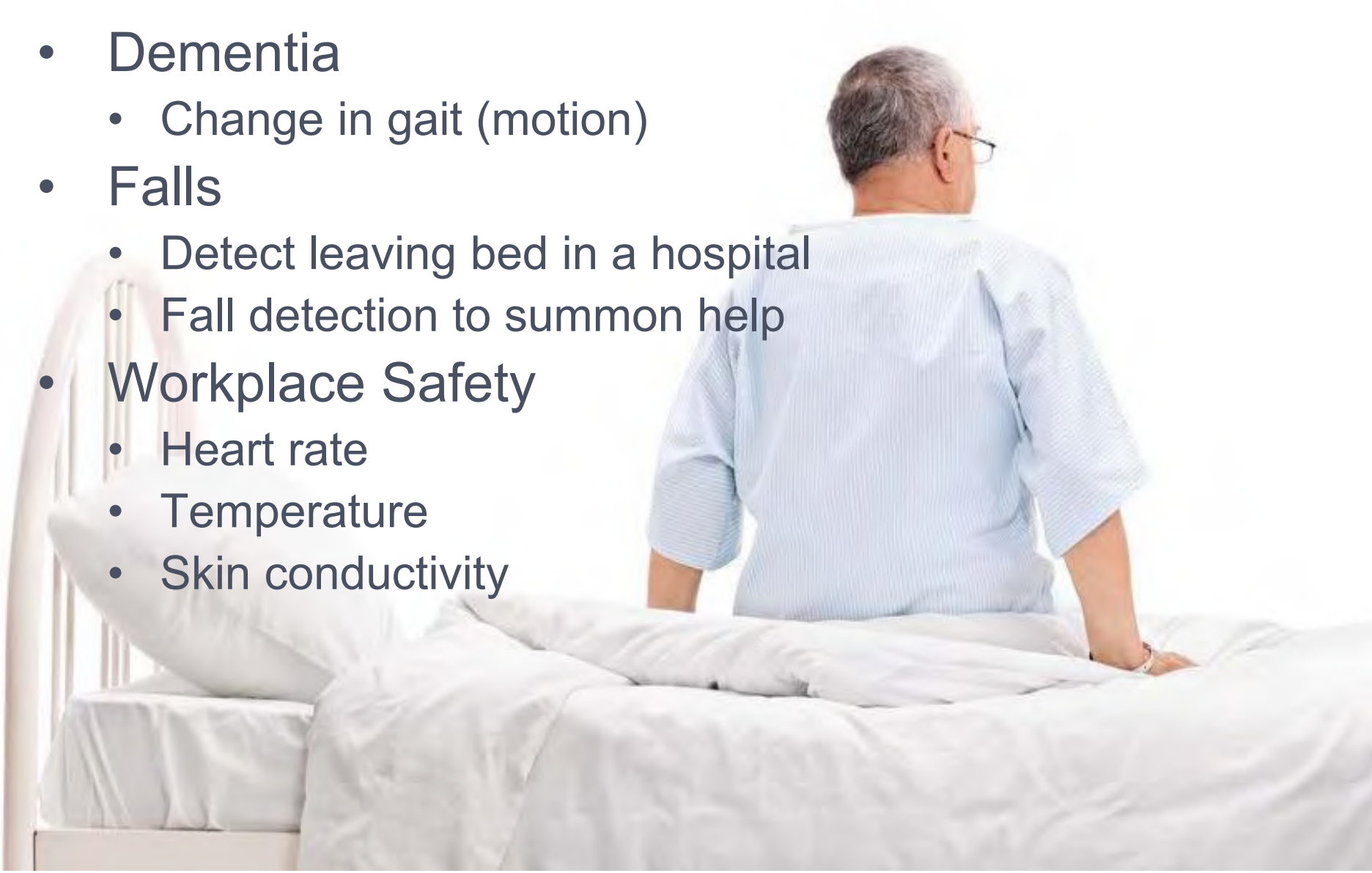
- Glucose
- Operation of insulin pump

Image source: Medtronic

In Hospital Monitoring

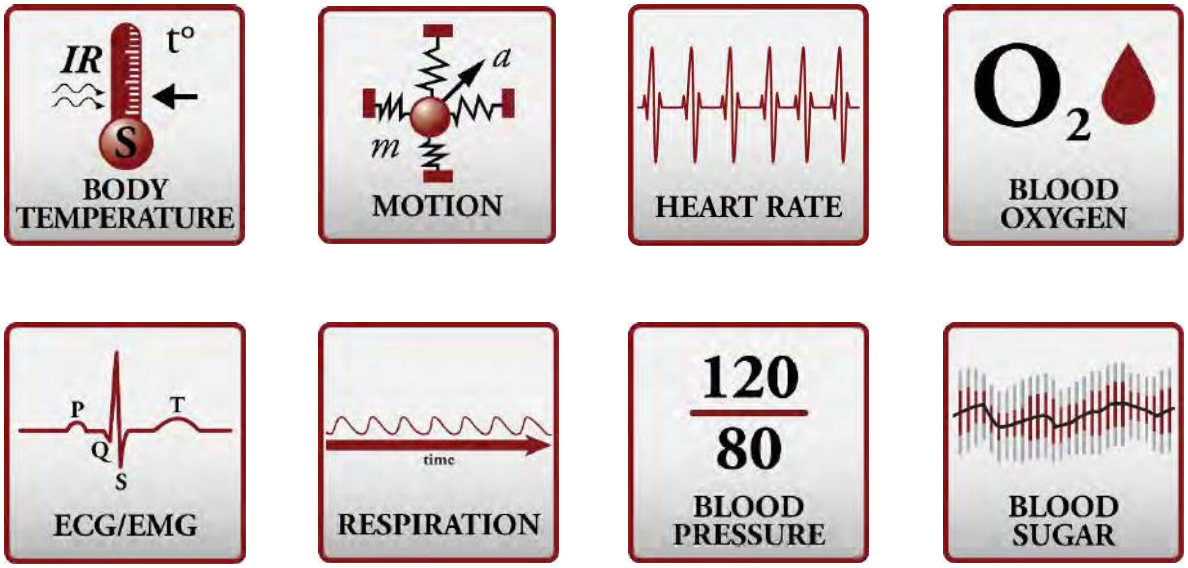
Injury Prevention

- Dementia
  - Change in gait (motion)
- Falls
  - Detect leaving bed in a hospital
  - Fall detection to summon help
- Workplace Safety
  - Heart rate
  - Temperature
  - Skin conductivity

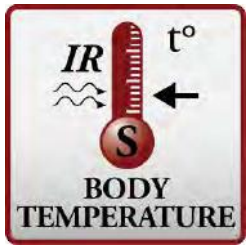


Human body is a complex dynamic system that offers a wealth of data

What kind of data would you like to have?



Body Temperature



- Few good locations to measure core temperature
  - Axilla (under arm) or forehead are best locations
  - Not convenient for a wearable device
- Extremeties (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

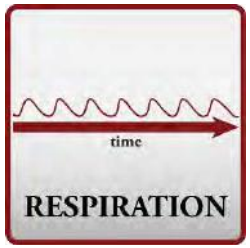
Blood Oxygen

- 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

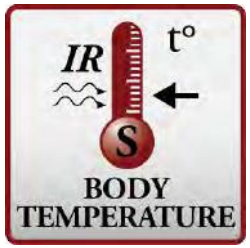


- Number of breaths per minute
  - Few good locations to measure
- Movement of chest
  - Chest strap
  - Not convenient for a wearable device except shirt
- Thoracic Impedance eliminates chest strap
  - Device can be small
  - Difficult on wrist
- EKG signal – filter out heart signal

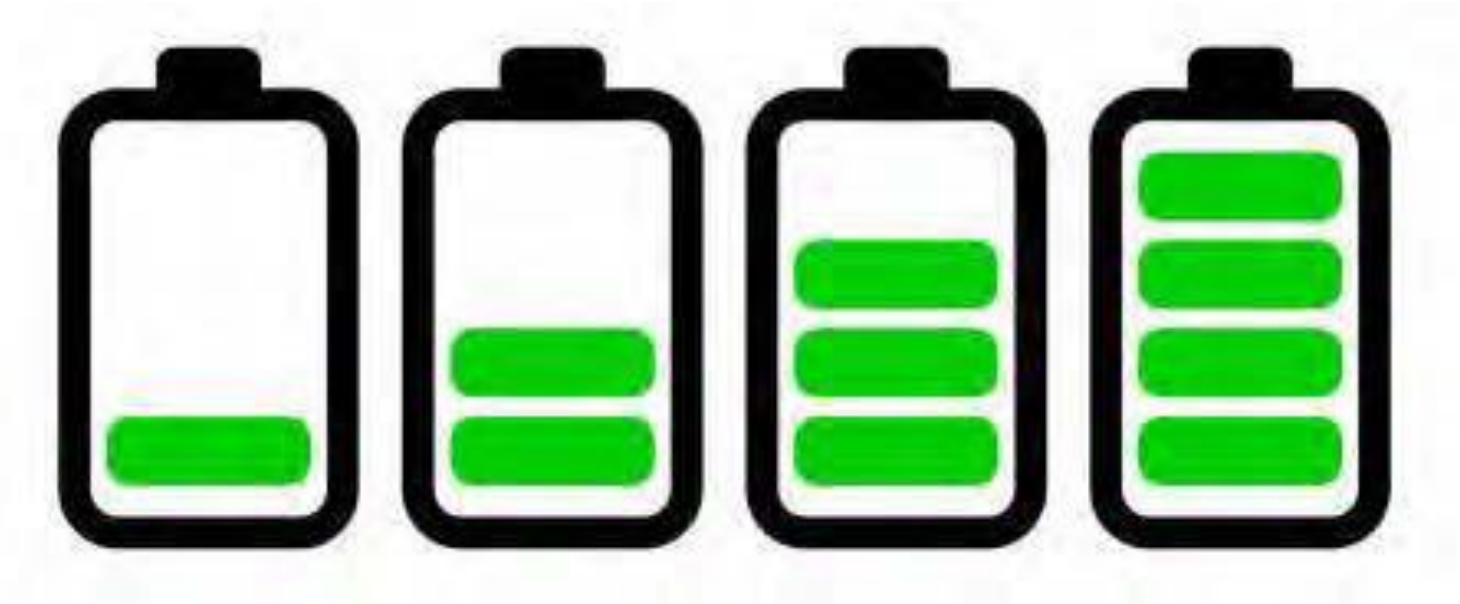
Blood Pressure

- 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

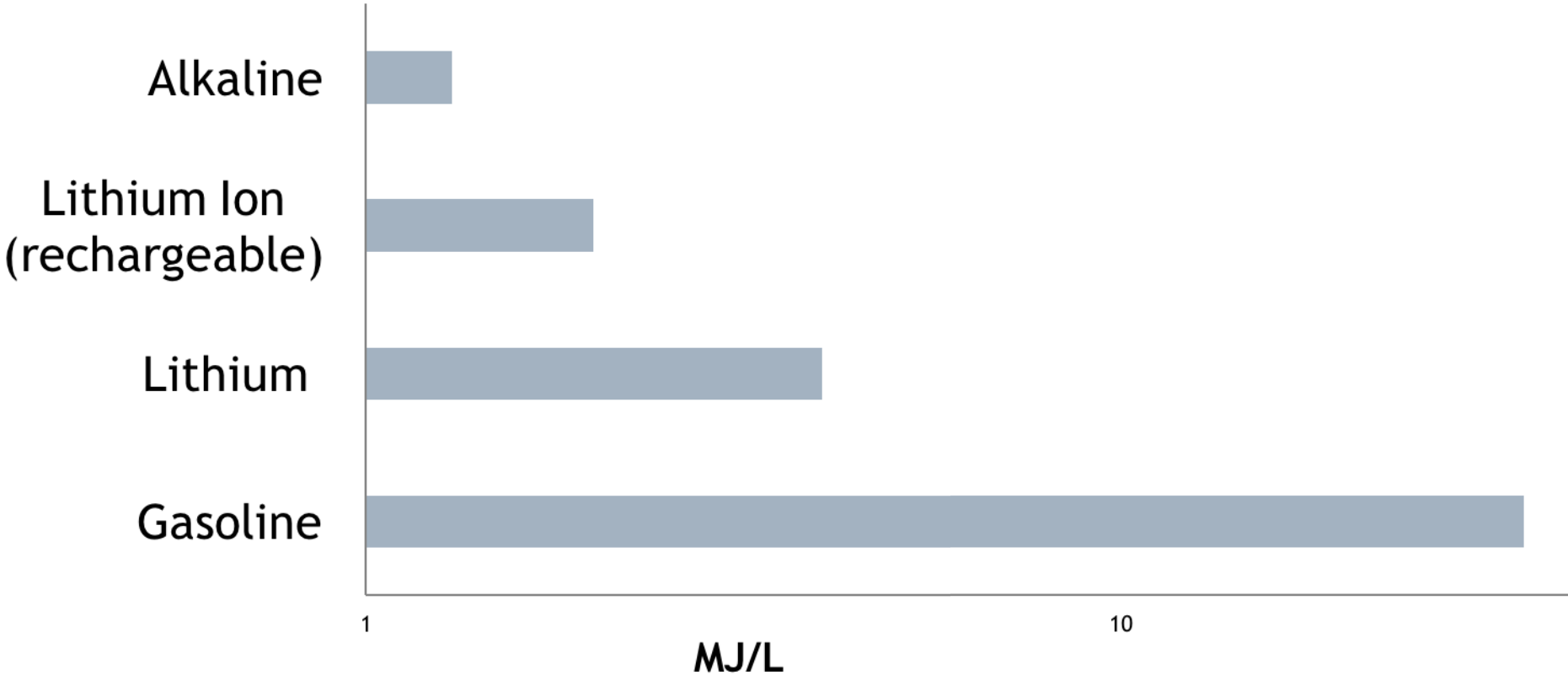
Battery Limitations

- 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



Energy Density and Safety

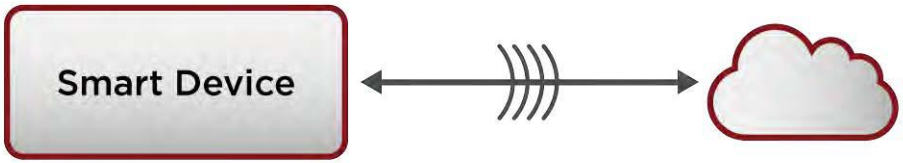
- As energy density has increased, safety has become more of a problem
- Safety circuits are required on Lithium batteries
- Poorly designed batteries can catch fire even with safety circuits
- Shipping of Lithium batteries is restricted and regulated
  - Cells without safety circuit cannot ship by air

5 Areas That Impact Power

- Wireless transmission
- Displays
- Sensors
- Microprocessors
- Software

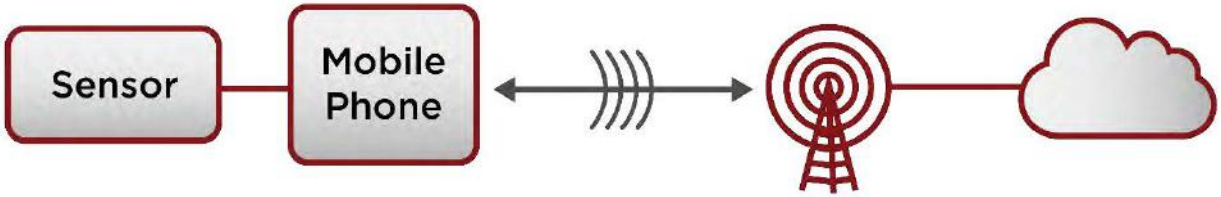
Common Ways to Get Data Into the Cloud

1. Device directly to cloud



2. Sensor to gateway to cloud

3. Sensor to cell phone to cloud



Power- How Much? How Far?

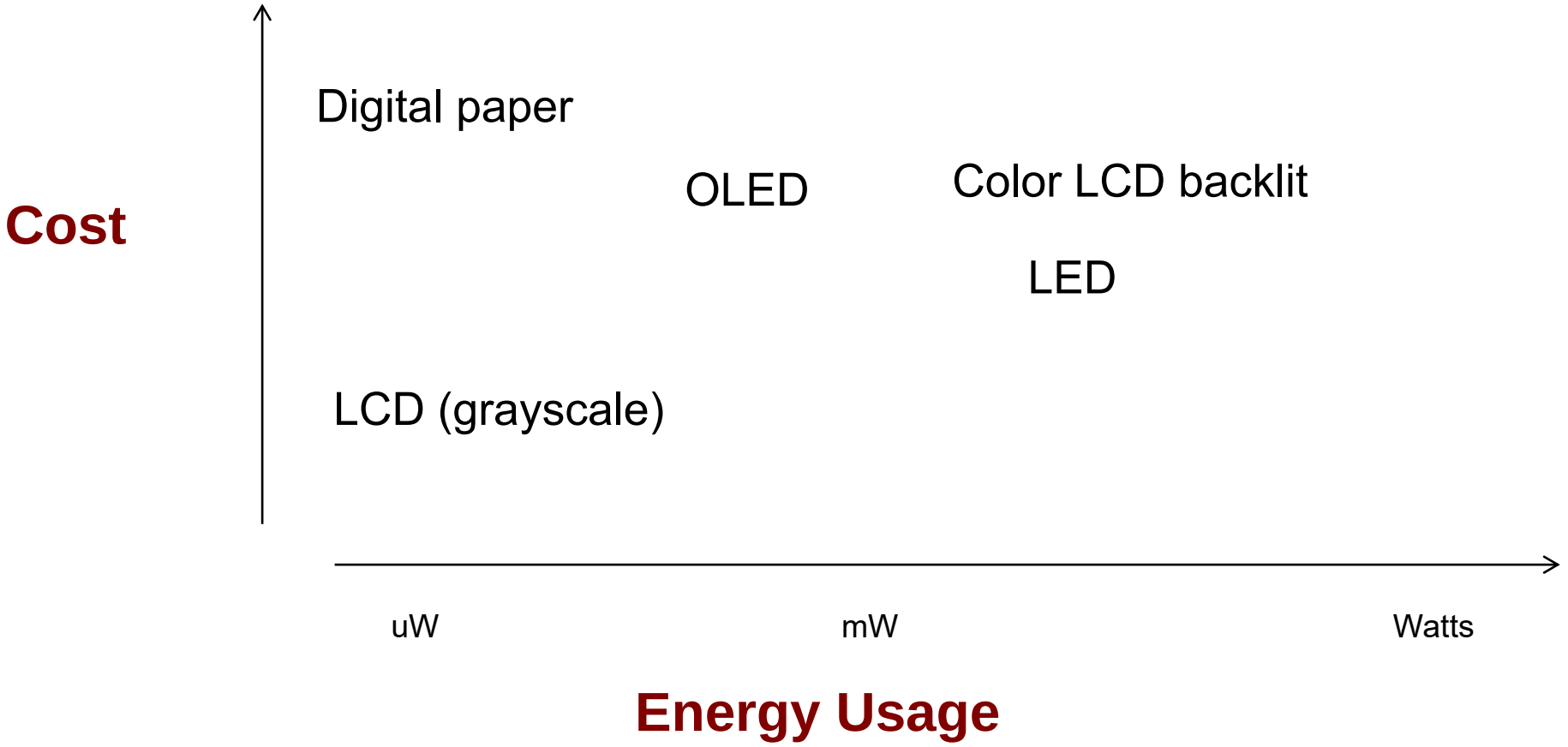
	10 bytes/sec	1 Kbytes/sec	1 Mbytes/sec
1 m	lowest power	data rate	
100 m	distance		
1 km			highest power

Power- How Much? How Far?

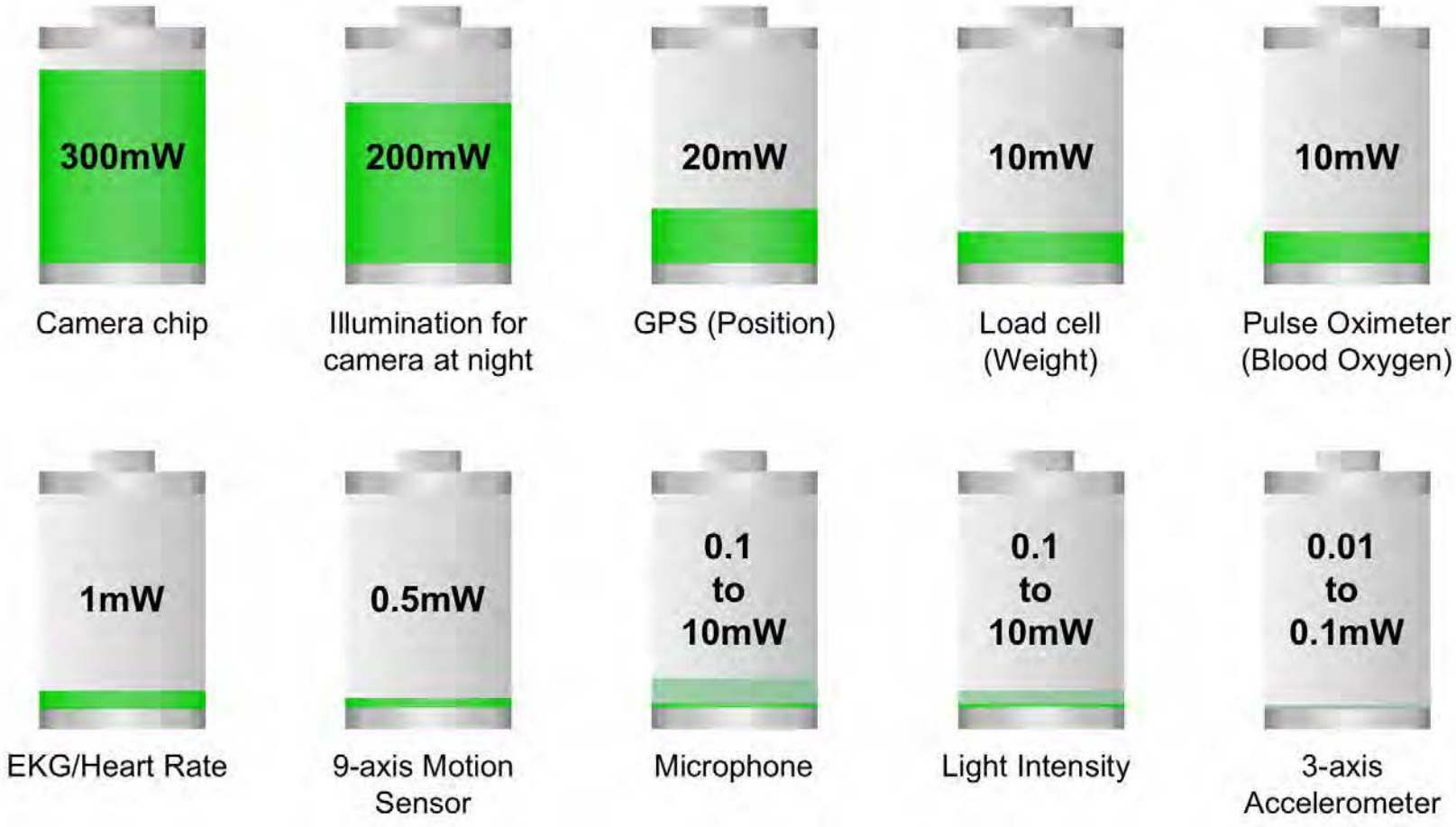
	10 bytes/sec	1 Kbytes/sec	1 Mbytes/sec
1 m	BLE/Zigbee 0.15 LoRa 0.5 Bluetooth 25 WiFi 50	BLE/Zigbee 7.5 LoRa 10 Bluetooth 50 WiFi 75	WiFi 300
100 m	LoRa 0.5 WiFi 100 3G Cellular 100 LTE Cellular 100	LoRa 10 WiFi 100 3G Cellular 120 LTE Cellular 120	WiFi 400 LTE Cellular 500
1 km	LoRa 1 3G Cellular 120 LTE Cellular 120	LoRa 30 3G Cellular 150 LTE Cellular 150	LTE Cellular 700

Power in milliWatts

Display Technologies



How Much Power Do Sensors Use?



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