Wearable Wireless Pulse Oximetry for Physiological Monitoring

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Masimo Ex. 1050
IPR Petition - USP D947,842

Presentation Outline

- Motivation
- Goal
- Background
- Development of a Wearable Pulse Oximeter
- Measurement Validations
- Future Development

Motivation

Telemedicine using wearable sensors can provide useful information for emergency first responders and facilitate life saving rescues of:

- *Soldiers*
- *Firefighters*
- *Mountain climbers*

- **Operating in harsh and hazardous environments**
- **Operating over large geographical terrains**

Motivation

- Data derived from sensors can provide input information in models developed to assess and predict the health status of wounded soldiers.
- The reliability of the wearable sensors used and the data extracted is essential for the successful implementation of these predictive models.

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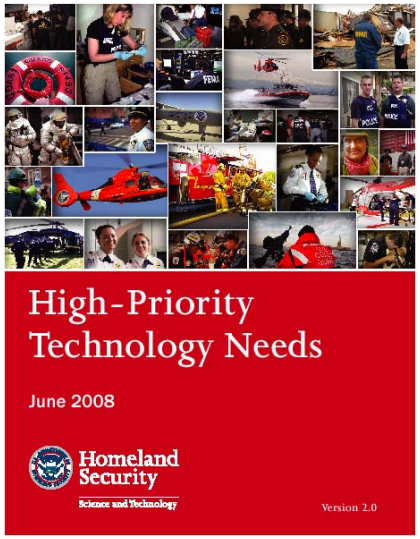
Motivation



Representative Technology Needs for Improved Incident Management:

Personnel monitoring (*physiological monitoring of firefighters*) capability — In particular, integrated body-worn sensor suite to provide real-time health analysis and issue alarms to both wearer and command staff.

DHS Leads: Federal Emergency Management Agency and Office of Emergency Communications

Motivation

- Firefighters experience tremendous CV demands with high-levels of short-term strenuous physical workloads and overexertion.
- Increased HR and core body temperature leads to increased physiological stress.
- Risks related to exhaustion, overheating and inhalation of combustion products can lead to work injuries and fatalities.

What are the Needs

Physiological Monitoring

?

Wearable

Our Goal

Development of a Robust Wearable Pulse Oximeter for Field Applications

Background

Pulse oximeters are commonly employed in nearly all hospital areas where patients are at an increased risk of developing hypoxemia

- **OR (Anesthesia)**
- **ER**
- **ICU**
- **Ambulances**

⋮

Background

- Appeared in the early 1980's.
- Gained overnight popularity.
- By 1987, the standard of care for the administration of a general anesthetic in the USA included pulse oximetry.
- Transformed monitoring hypoxemia from a crude and imprecise visual color assessment into a reliable, quick, noninvasive and objective measurement.
- Now a mature technology in hospitals.

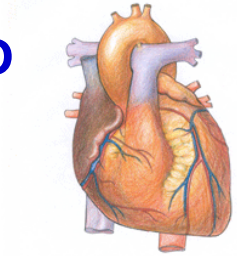
Background

- Life depends on uninterrupted O_2 supply.
- Different organs and tissues can survive lack of O_2 for different lengths of time: The brain is the most rapidly and irrevocably damaged organ.

- Because the brain regulates breathing and circulation, supplying O_2 to the whole body, deprivation of O_2 supply to the brain can be fatal.
- Mild cases of hypoxia can cause poor judgment and uncoordinated movement. Severe cases death is inevitable.
- After ~5 min, cutting off blood supply to the brain causes cells to die.
- Timing is everything!

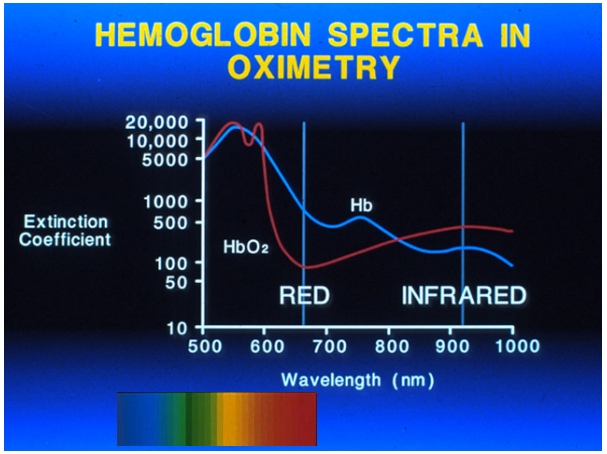
Background

PULSE OXIMETERS RELY ON SPECTROPHOTOMETRIC PRINCIPLES TO DERIVE SpO_2 AND HR FROM A PULSATING VASCULAR TISSUE BED

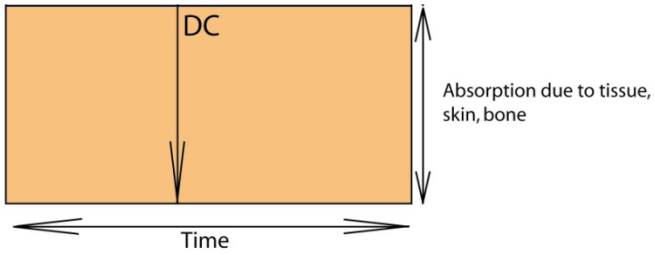


Blood depleted of O_2 appears purple

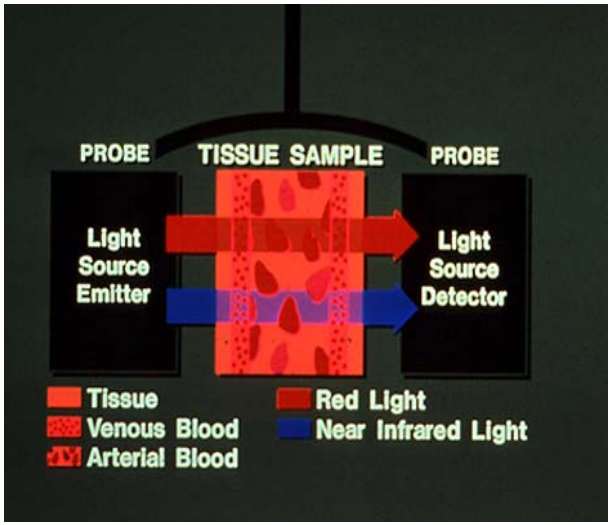
Blood rich in O_2 appears bright red

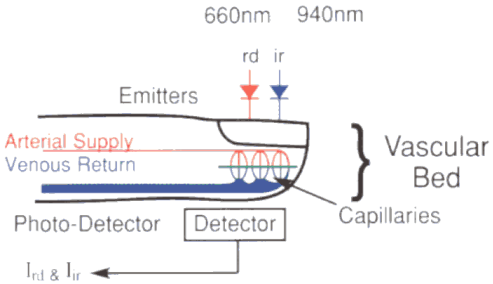


Background

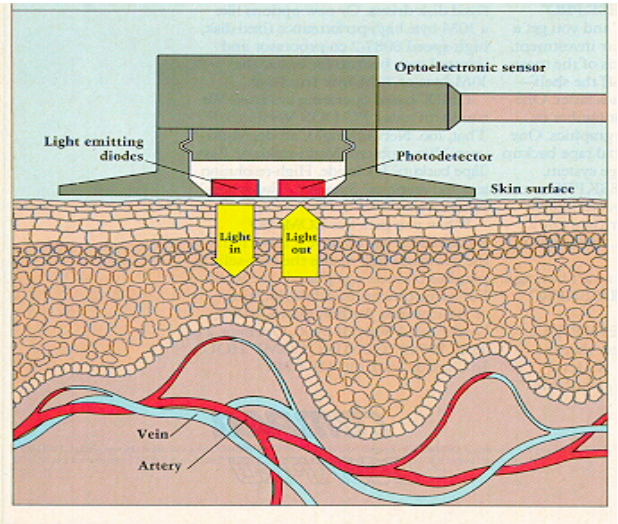


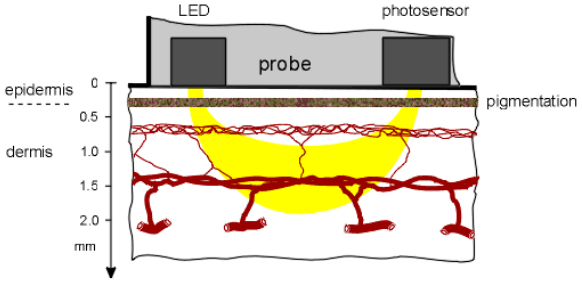
Transmittance Mode





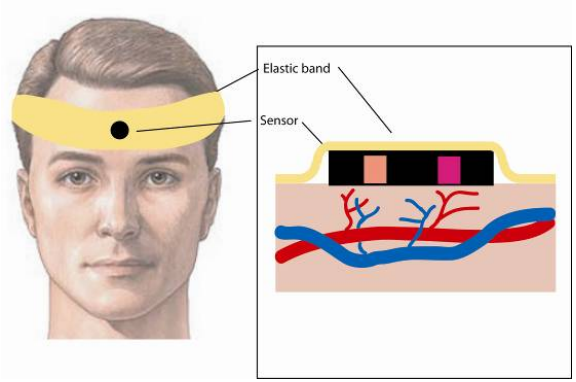
Reflectance Mode



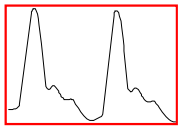


Advantage of Reflectance Mode

Why the Forehead ?



- **Does not impede hand movements.**
- **Easy sensor attachment.**
- **More motion tolerant location (skull provides mechanical support).**
- **Provides strong and clean PPG signals.**

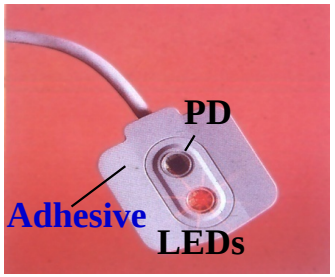


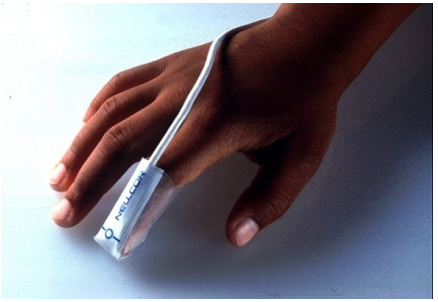
COTS Pulse Oximeters

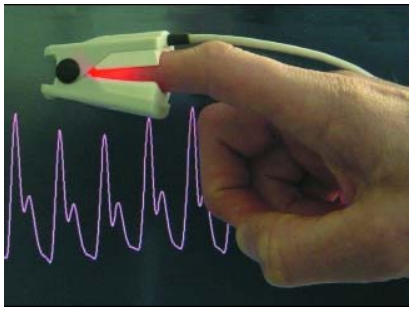
Designed for Clinical Settings

(Patient movement relatively constrained)

Commercial Sensors

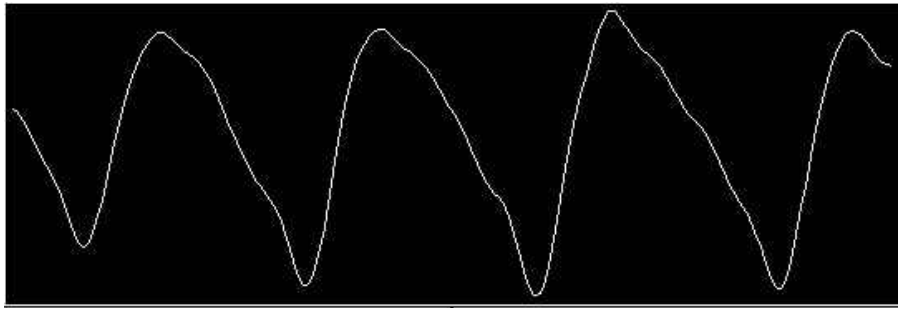




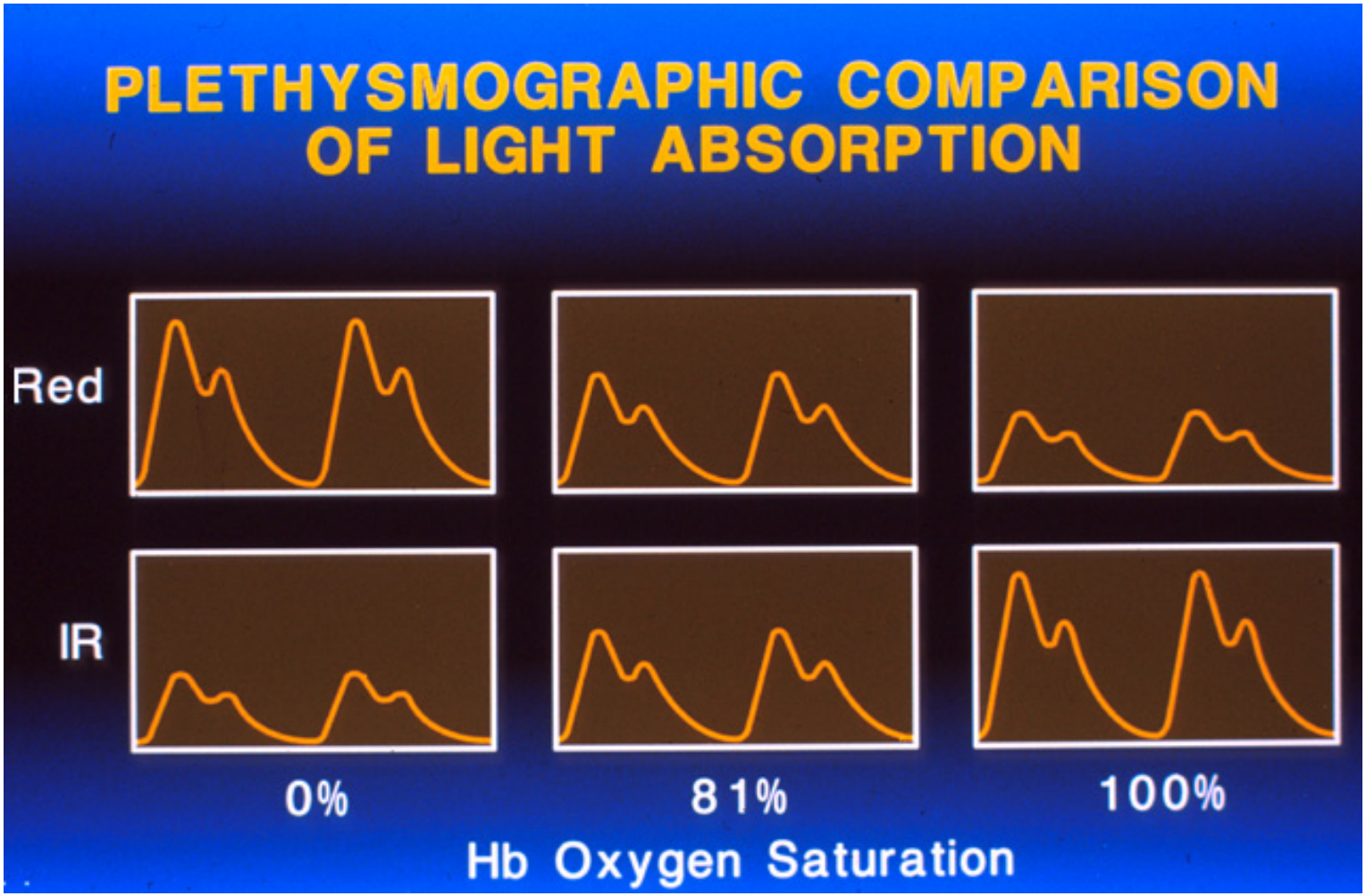


Principle

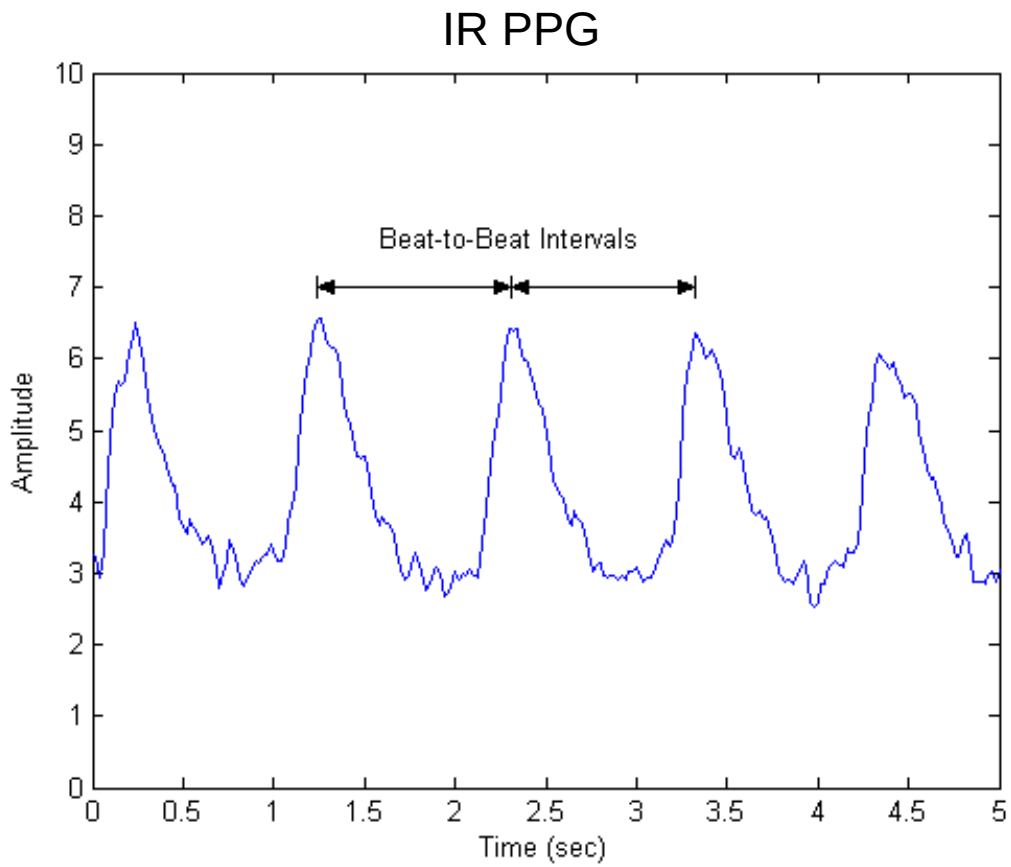
- Several prominent features can be extracted from the Photoplethysmogram (PPG).
- Monitoring multiple variables using a single sensor has distinct advantages.



Principle (SpO_2)

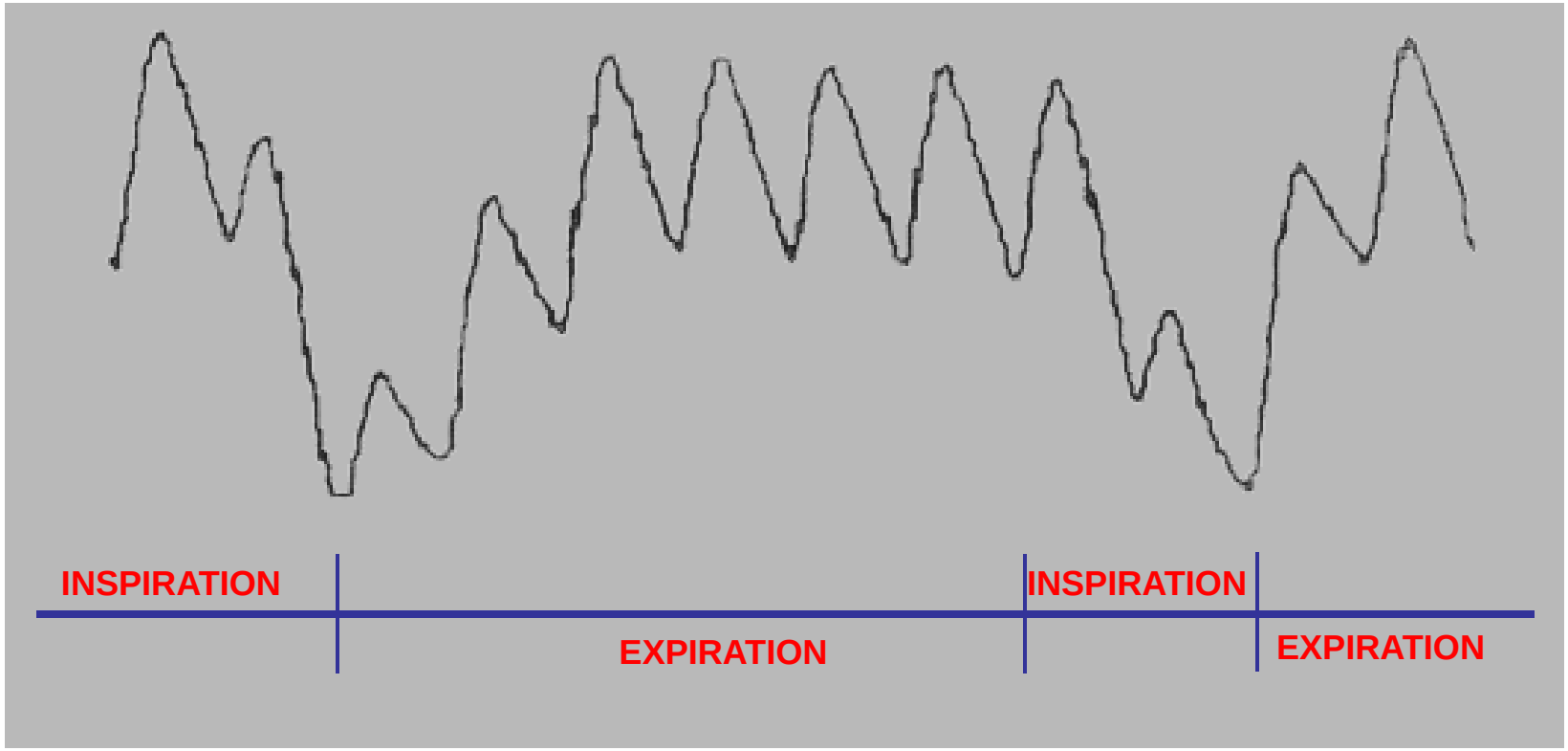


Principle (HR)



Principle (RR)

IR PPG



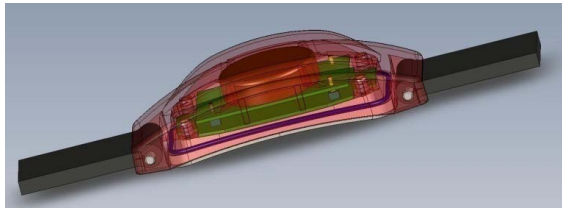
Use of Commercial Pulse Oximeters as a Wearable Device in the Field is Challenging

- Must operate reliably under adverse environmental conditions.
- Can not limit normal activities.

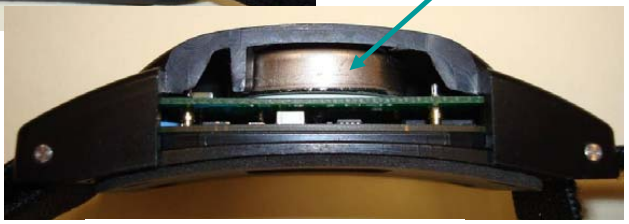
Design Criteria

- Multiple physiological variables
- Low power consumption
- Cost effective
- Small size
- Light weight
- Easy sensor attachment
- Transparent to user (“wear-and-forget”)
- Adequate computation power
- Wireless communication
- Improved immunity to motion artifacts

Wearable Pulse Oximeter

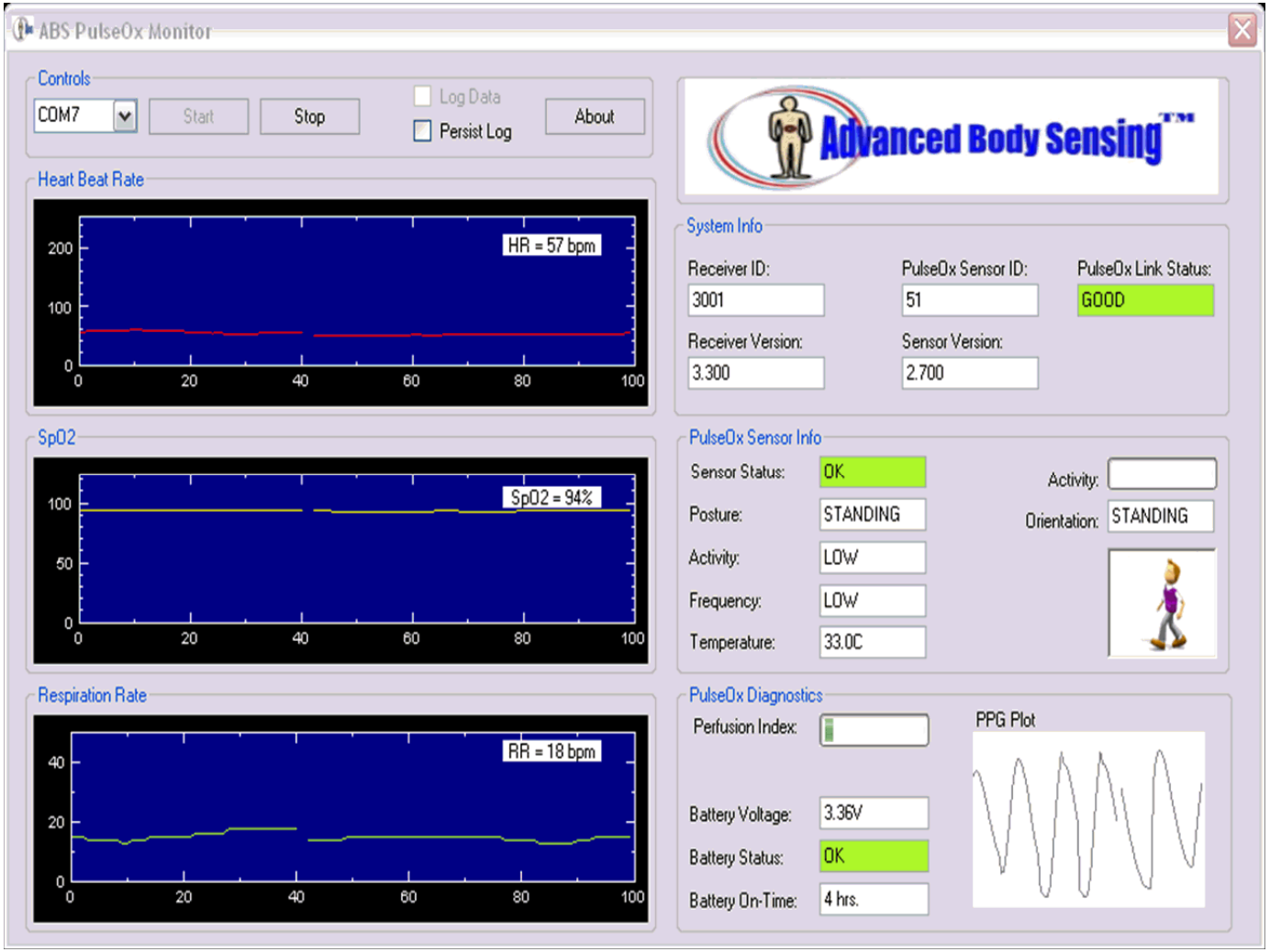


Battery Module

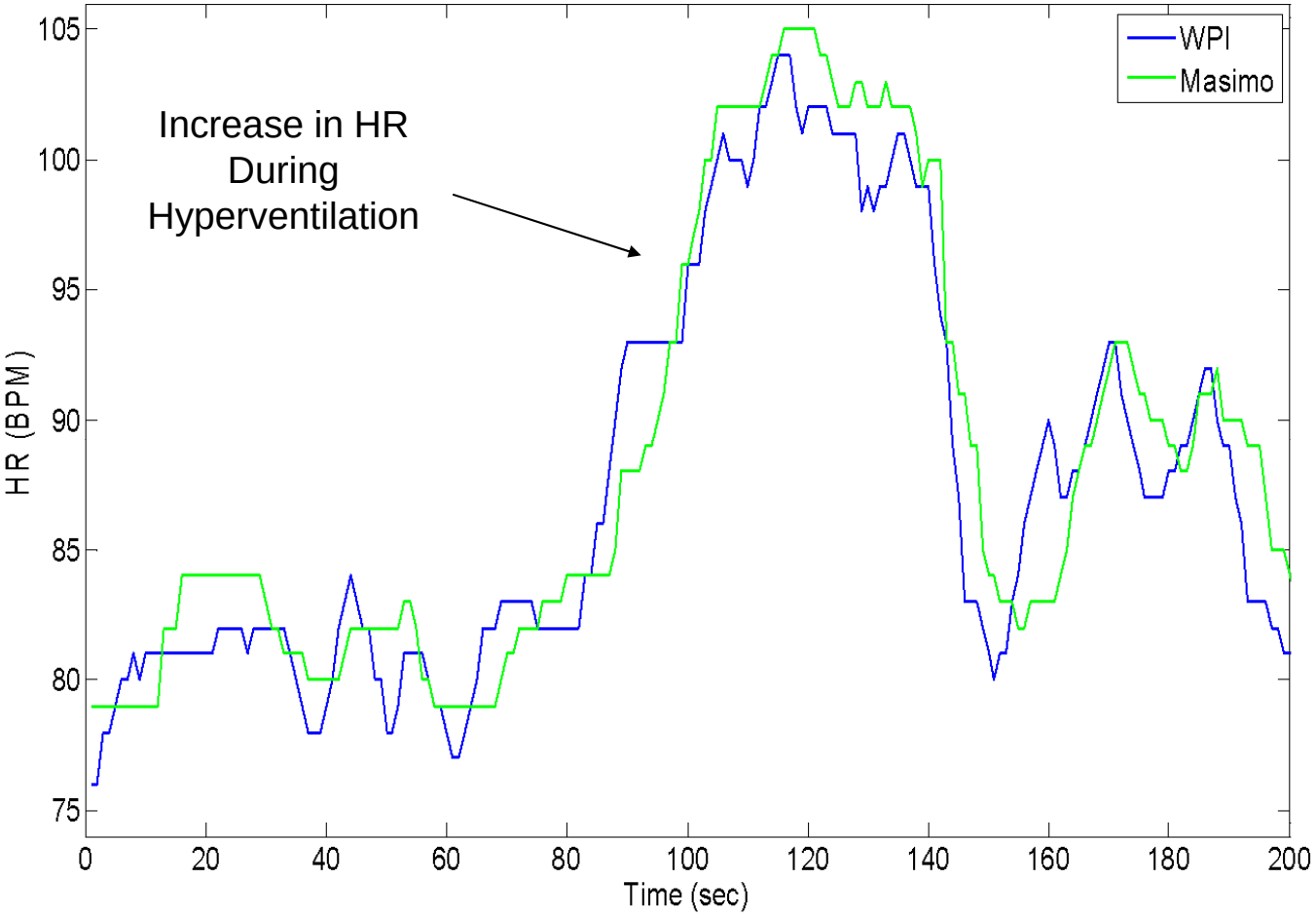


USB-Based Receiver

User Interface



Measurement Validation (rest)



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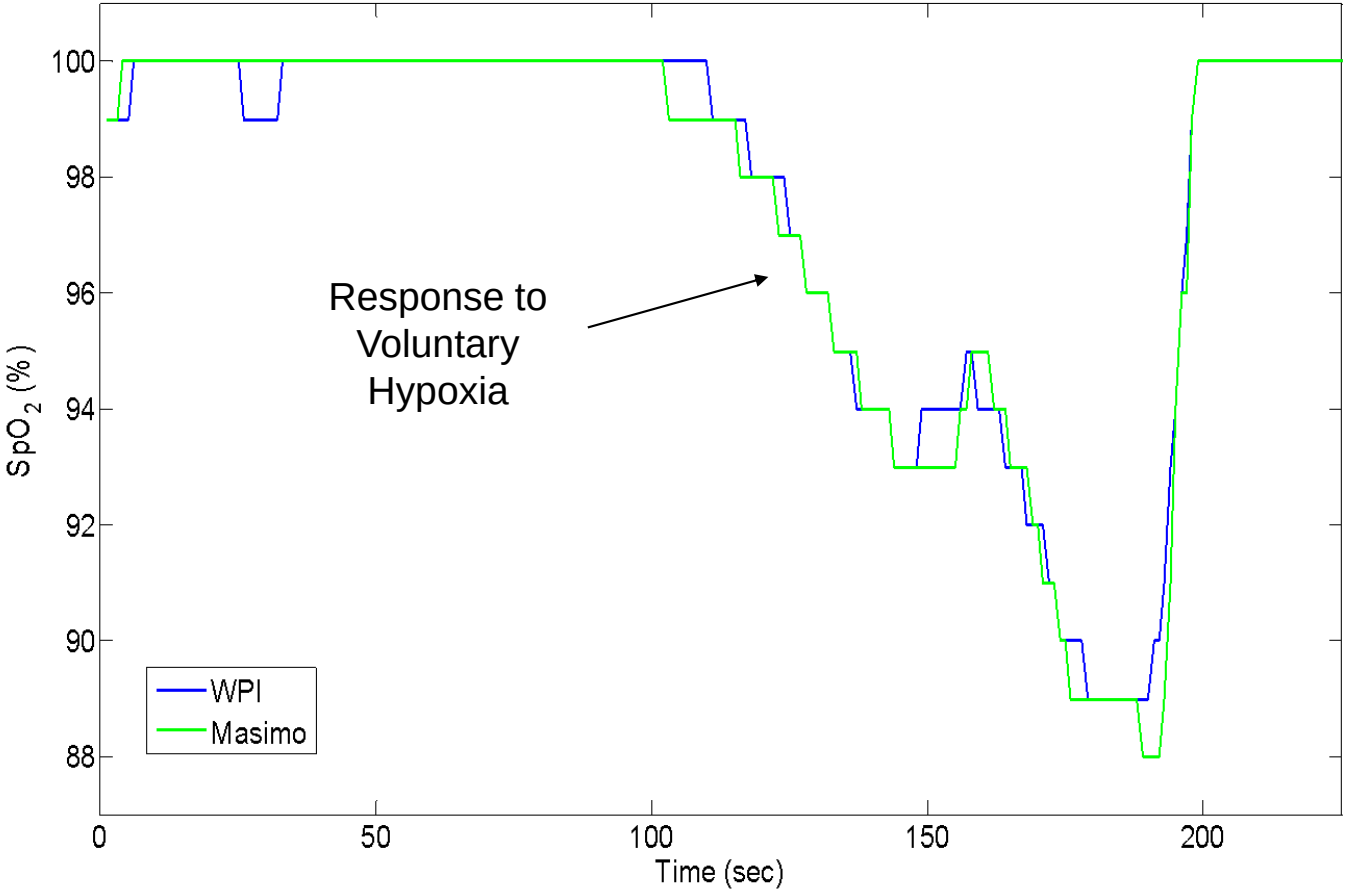

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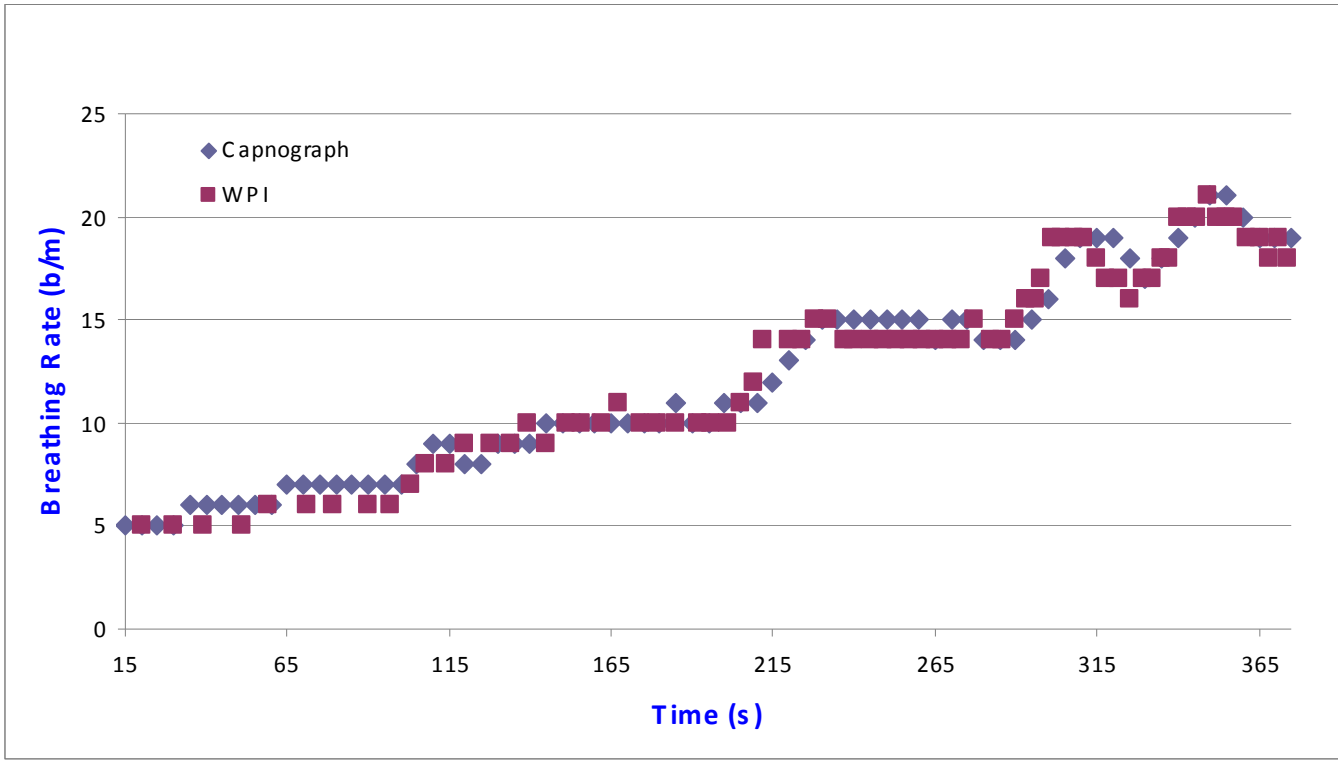
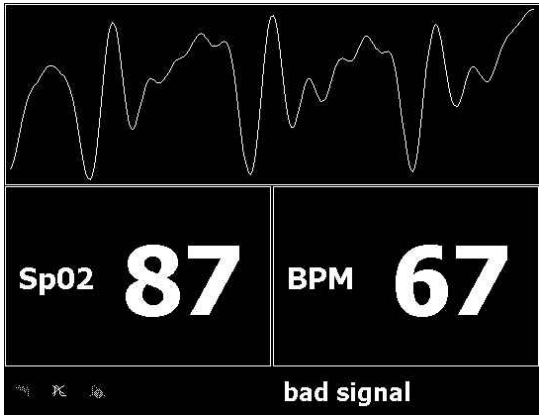
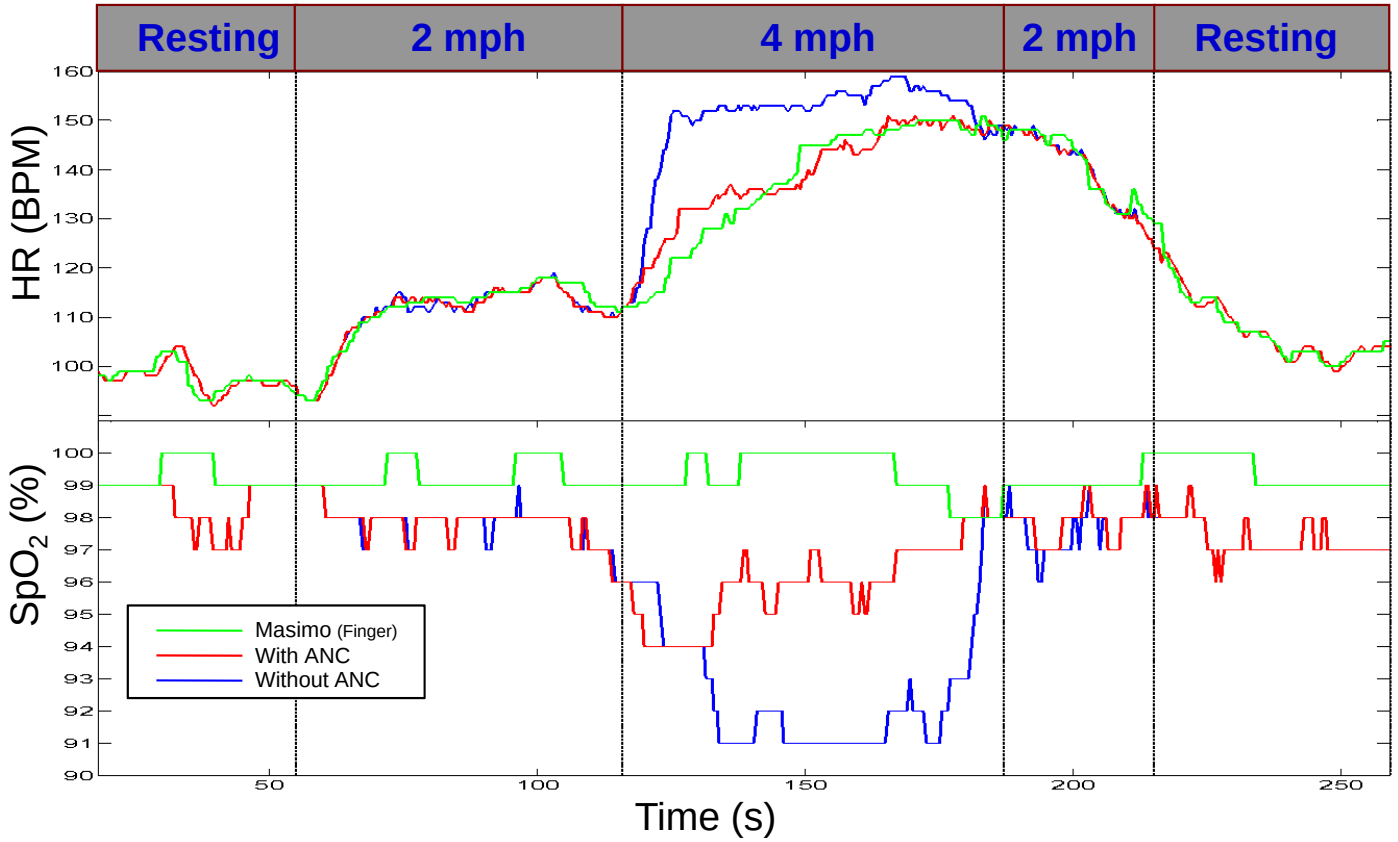


Limitations of Pulse Oximetry

- Highly reliable when used on motionless subjects.
- Motion artifacts can obscure the true PPG signal with noise, leading to inaccurate readings, false alarms, dropouts, and missed true alarms.



Adaptive Noise Cancellation in Pulse Oximetry



Future Developments

- Firefighters can experience inhalation of CO (e.g. malfunctioning furnaces) and Cyanide (e.g. burning plastic products).
- Acute CO and HCN poisoning renders the blood unable to carry sufficient amount of O_2.
- Symptoms of acute exposure include general weakness, headache, confusion, anxiety, nausea and vomiting.
- If exposure is severe, unconsciousness and death.

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Future Developments

- Traditional testing of HbCO and MetHb involves blood sampling and waiting for lab results.
- Conventional pulse oximeters use only <u>two</u> wavelengths of light.
  - They cannot distinguish between HbO_2, HbCO and MetHb.
  - Provide false readings when CO and MetHb levels are elevated.

- Multi-wavelengths to measure SpO_2, HR, HbCO and MetHb, simultaneously.

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ACKNOWLEDGEMENTS

Development Supported by:

- WPI/BEI
- USAMRMC/TATRC
- Advanced Body Sensing
- PSI/*QinetiQ*

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Thank You!

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