

# Top Five Medical IoT Trends for Product Designers – Specialist Panel



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# Panel Introduction



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# Talking Points

Top Five Medical IoT Trends for Product Designers – Specialist Panel

- 1 Device Characteristics
- 2 Security
- 3 Regulations
- 4 Smart Hospitals
- 5 Artificial Intelligence (AI)

# Device Characteristics: Size, Accuracy, Connectivity



## MINIATURIZATION

- Greater comfort for patients
- Less invasive techniques
- Ease of use resulting in faster recovery
- Overall cost reduction



## ACCURATE MEASUREMENT

- Accuracy of measurement defined by the FDA
- Accuracy requirements include all error sources
- Analog requirements call for precision vs. speed



## CONNECTIVITY

- Reporting of the dosage delivery
- Raising alarms to avoid wrong usage
- Big data management
- Sharing of information

# Security in Medical IoT

## SECURITY RISKS INCREASING



### Breaches in Medical

- HIPAA reported ([January 2023](#)) over 30 million people in the USA were affected by data breaches in 2022
- The average cost of a data breach is at an all-time high of \$10.1 million in 2023
- A combination of simultaneous IT and OT attacks is becoming typical
- Cybercriminals are becoming professionals offering Ransomware-as-a-Service
- Examples of medical field attacks are numerous
- Legislation and regulations are on the rise
- Standards IEEE 2621 & IEC62304 for risk management

## IOT SECURITY REQUIREMENTS



### Emerging Local Pivot Attacks

Portable Medical devices are attacked for ransom, destroy the brand and compromise end-user data privacy



### Governmental Legislation

Legislations like the California Consumer Privacy Act (§ SB-327) requires 'reasonable security features' for all connected devices

### Attack Vectors

#### Insert malicious code to make the device execute the wrong SW

- Software authentication is critical; this is also true for the phone app.
- Over-the-air offers a way to repair, but is also a potential attack vector

#### Use open ports to trigger false hardware behavior

- The debug port can access the entire device and needs to be protected
- Keeping the possibility to perform field failure analysis is very important

#### Join the network using cloned ICs or boards

- Identification of the ICs should happen before network commissioning
- Old devices should be de-commissioned to avoid cloning/re-use

#### Steal encryption keys using DPA attacks

- Encryption keys can be vulnerable if not generated the proper way
- DPA attacks can be performed easily using ChipWhisperer

# Regulation in Medical IoT

*“Cybersecurity in Medical Devices will require SDLC”*

March 30, 2023 - US Food and Drug (FDA)

## Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act

### Guidance for Industry and Food and Drug Administration Staff

Document issued on March 30, 2023.



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

#### II. Policy

Effective March 29, 2023, the FD&C Act is amended to include section 524B “Ensuring Cybersecurity of Devices.” Among section 524B’s cybersecurity provisions are:

(a) IN GENERAL.—A person who submits an application or submission under section 510(k), 513, 515(c), 515(f), or 520(m) for a device that meets the definition of a cyber device under this section shall include such information as [FDA] may require to ensure that such cyber device meets the cybersecurity requirements under subsection (b).

(b) The sponsor of an application or submission described in subsection (a) shall-

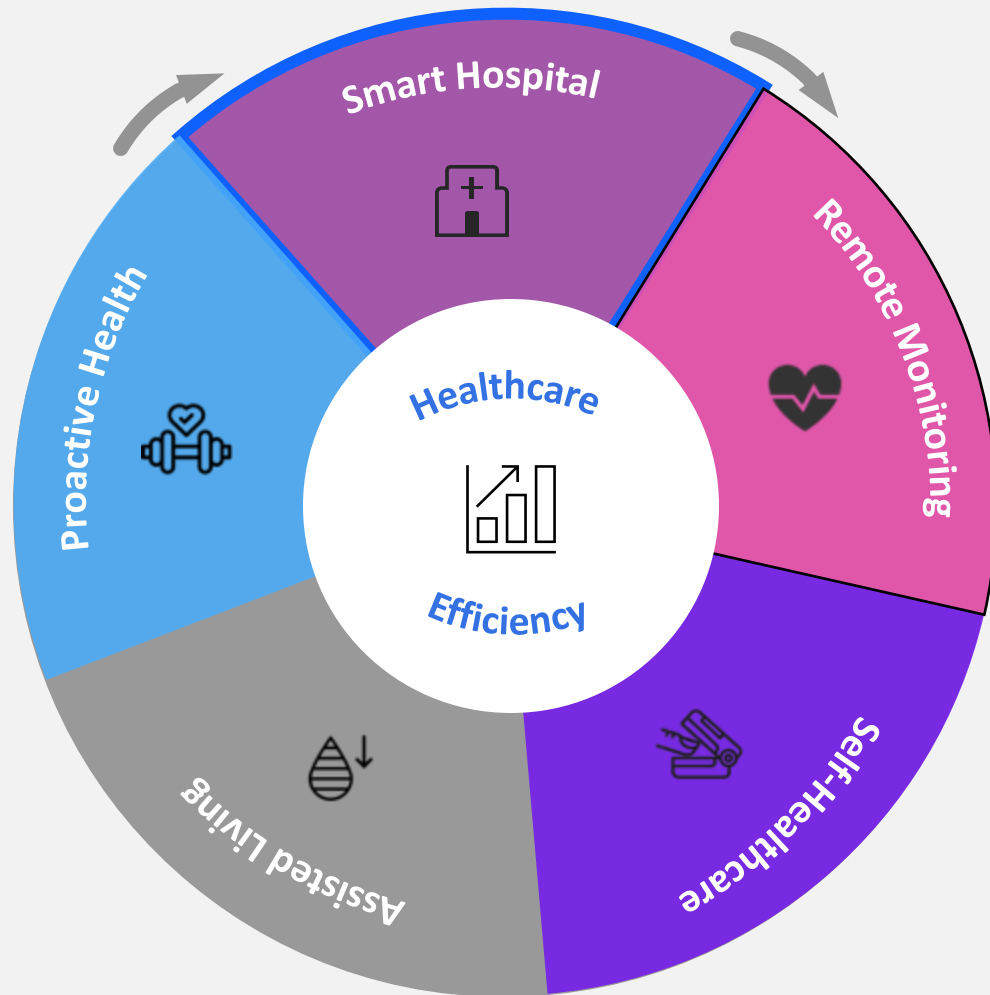
**(1) submit to the Secretary a plan to monitor, identify, and address, as appropriate, in a reasonable time, postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures;**

**(2) design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecurity,** and make available postmarket updates and patches to the device and related systems to address—

**(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and**

**(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks;**

# Smart Hospital



## Patient Journey

- In/out of smart hospital
- Inside smart hospital

## Smart Hospital Benefits

- Hospital efficiency
- Safety
- Patient experience
- Process streamlining
- Cost savings

## Applications

- Continuous Positive Airway Pressure (CPAP)
- Real-time asset tracking
- Patient tracking
- Staff workflow
- Instrument monitoring and management

## Challenges

- Multiprotocol wireless: Wi-Fi, Bluetooth
- Security
- Integration to hospital backend



# Growing AI/ML Application Space in Smart Health and Wearables



## LIFE QUALITY

- Eating and drinking behavior
- Stress detection
- Sleep quality detection
- Snore detection
- Smart Toothbrush – IMU patterns to check quality of wash



## HEALTH

- Preventive illness detection
- Non-invasive health measurements - Track biometric signals, predict or identify health disruptions. e.g. Glucose metering
- Post-procedure recovery monitoring
- Pharma trial monitoring
- Elder Care
- Fall and accident detection
- ECG/PPG



## HUMAN TASKS

- Human-machine interface
- Voice commands
- Natural language processing
- Acoustic event detection
- Improve process based on recorded IMU on movements



## PERFORMANCE

- Identify various types of deviations from normal signal variation
- Human activity classification
- Performance metrics
- Predicting heat exhaustion
- Sport equipment



EXECUTIVE TEAM

# Meet the IPS Team

## Industry Experts Driving Innovation



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# Intelligent Product Solutions: Your Partner in End-to-End Product Development



**Intelligent Product Solutions (IPS)** is a team of diverse designers, engineers, and scientists who are passionate about innovation and problem-solving. We specialize in every stage of product development, **from research and discovery to manufacturing readiness**. Our expertise includes systems architecture, industrial and UI/UX design, mechanical engineering, software development, electrical engineering, embedded systems, and design for manufacturing. IPS serves various industries such as **Medtech, Wearables, Industrial, IoT, Commercial, Equipment, Defense, Aerospace, Smart Vending, Opto-mechatronics, and Consumer Products**. Through collaborative work across our teams, we efficiently bring our clients' visions to life, **reducing development risks** and creating innovative solutions that provide significant value to our clients.

## Key Services

- Hardware Design
- Firmware Development
- RTOS
- Gateways
- Software Development
- Cybersecurity
- Network Stack Development
- IOS, Android Native App Development
- Web Front End Development
- Backend Development
- Cloud Services
- UX and UI Design
- Industrial Design
- RF Certification (FCC, ETSI, etc)
- RF Design
- Testing Service

### Supported Product Categories

- Low power system design
- Embedded system design
- IoT devices
- Bluetooth Low Energy
- Wi-Fi
- Z-Wave

### Supported Solutions

- **Medical Devices\*\***
- Industrial & Commercial
- Industrial IoT | Condition Monitoring Predictive Analytics
- Industrial Asset Tracking
- Predictive Maintenance
- Metering

### IPS Contact Information

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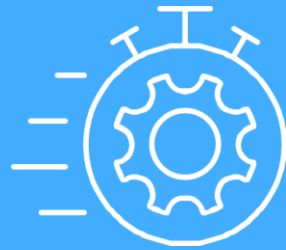
CAPABILITIES

## Delivering Expertise Across Disciplines



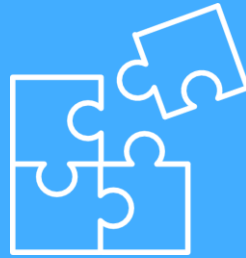
### Subject Matter Expertise

IPS brings deep knowledge in a broad range of industries.



### Quick Turn Prototyping

Rapid development cycles ensure fast time-to-market.



### Turnkey Solutions

Full project lifecycle management



### Custom & Off-the-Shelf

Flexibility to deliver tailored or existing solutions.

*IPS ensures high-quality outcomes with minimal lift required from our clients.*





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Thank You