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Medical Device Connectivity: HIPAA, FDA and IP Considerations

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About BakerHostetler

- About 950 attorneys in 14 domestic offices
- About 150 IP attorneys
  - More than 100 registered patent attorneys and agents
    - Including many former examiners, SPEs, and an APJ
  - Majority of about 4,000 applications filed per year for domestic clients
- More than 75 partners in our Life Sciences and FDA groups
  - Multiple attorneys who have worked at or contracted with FDA
- Represent a broad range of companies and institutions, including pharmaceutical, medical device, pharmacy, pharmacy distribution, biologic, cosmetic, nutritional supplements and more.

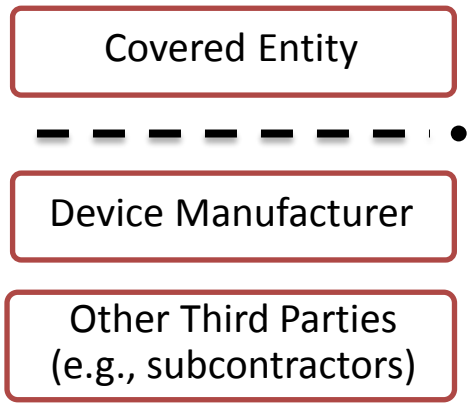
Topics

- HIPAA Compliance
- FDA Cybersecurity
  - Premarket
  - Post market
- Software for Wireless Control & Reception
  - Mobile Applications
  - Stand Alone Software as a Medical Device (SaMD)
- Patent Claiming Strategy + Copyright
- Benchmarking

HIPAA for Connective Medical Devices

HIPAA - Overview

- Who Should be in Compliance?
  - Does the device transmit Protected Health Information?
    - Individually identifiable
    - Consists of data regarding individual's health
  - Is entity subject to compliance with HIPAA?
    - Covered entities – health plans, health care clearinghouses, health care providers
    - Business associates – third party that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity



HIPAA – Business Associates

- Evaluation is very fact dependent
- Business associate activities and services include:
  - data analysis, processing or administration;
  - utilization review;
  - data aggregation
- Typical cases include:
  - When medical device generates protected health information and medical device company transmits PHI to covered entity
  - When a covered entity shares PHI with the medical device company

HIPAA – Compliance Requirements

- Covered entity and business associate required to execute a business associate contract
  - Describe the permitted and required uses of PHI by the business associate;
  - Provide that the business associate will not use or disclose the PHI other than as permitted or required by the contract; and
  - Require the business associate to use appropriate safeguards to prevent a use or disclosure of the PHI
- Key issues:
  - Privacy
  - Security (also ties in FDA)

General Considerations - Security

HIPAA and FDA regulated

- Connected medical devices incorporate software that is vulnerable to threats
- When medical device vulnerabilities are not addressed, this can serve as access points for entry into healthcare networks
  - Data confidentiality
  - Data integrity
  - Data availability
- Shared responsibility between healthcare facilities and providers and medical device manufacturers

HIPAA – Privacy Rule

- Basic framework – entities cannot disclose PHI except:
  - As permitted by Privacy Rule
  - When authorized by a patient in writing
- Permitted uses and disclosures include:
  - Treatment, payment, health care operations
  - Research
  - Limited data set

HIPAA – Security Rule

- Basic framework – entities must:
  - Ensure confidentiality, integrity, and availability of PHI;
  - Identify and protect against reasonably anticipated threats to the security or integrity of the PHI;
  - Protect against reasonably anticipated, impermissible uses or disclosures; and
  - Ensure compliance by workforce
- Rule does not dictate specific measures, but recommends entities to:
  - Perform risk analysis
  - Implement security measures that reduce risk
    - Administrative (security management process, personnel)
    - Physical (facility access and control, workstation security)
    - Technical (access control, audit controls, integrity controls)

FDA Guidance for Connective Medical Devices

FDA – Cybersecurity Guidelines

- Guidance provided in:
  - Premarket Submissions for Management of Cybersecurity (finalized 6/14/2013)
  - Postmarket Management of Cybersecurity (finalized 12/28/2016)
- General considerations:

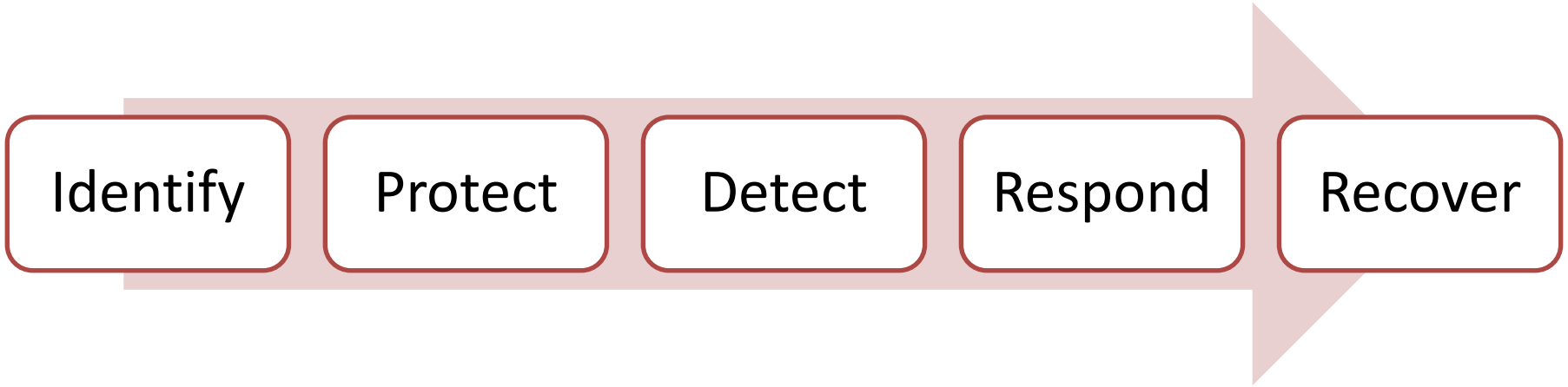
  Expands upon HIPAA considerations
  - Device manufacturers should incorporate specific controls into design of products
  - Device manufacturers should consider risk to patients as well as environment in which device is used

Recommendations for Premarket Submission

- Description of device
- Risk-based approach for verification and validation
- Test data summaries
- Labeling related to wireless medical devices

FDA – Premarket Management

- Core functions:



FDA – Premarket Management

- Identify and protect
  - Limit access to trusted users
  - Employ technical and physical access controls
- Detect, respond, and recover
  - Implement features that allow for security compromises to be detected, recognized, logged, timed, and acted upon
  - Provide information on appropriate actions to take once device has been compromised
  - Implement device features that protect critical functionality
  - Provide methods for retention and recovery of device

FDA – Premarket Management

- Cybersecurity documentation
  - Hazard or risk analysis:
    - Provide information on risks that were considered
    - Provide justification for controls used to address risks
  - Traceability matrix that links cybersecurity controls to the cybersecurity risks that were considered
  - Summary documentation on:
    - Plan for providing validated software updates and patches as needed throughout the lifecycle of the medical device
    - Controls that are in place to assure that the medical device software will maintain its integrity
  - Device instructions for use and product specifications related to cybersecurity controls

Selection and Performance of Wireless Technology

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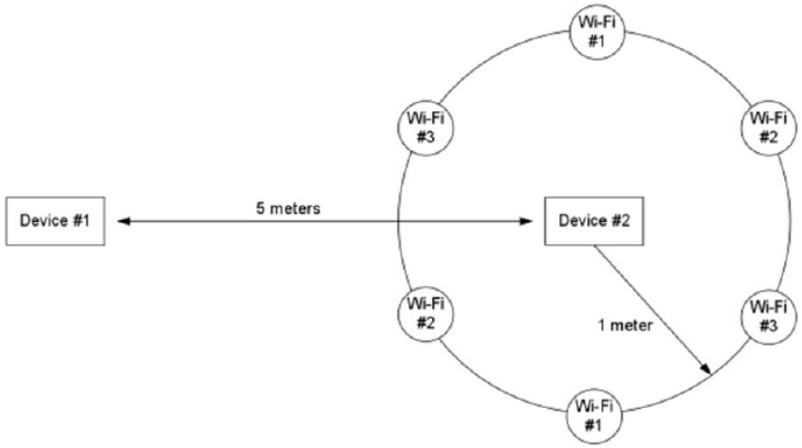
1) Quality of Service - Integrity of data transmitted wirelessly
2) Wireless Coexistence
   - Operating on unlicensed bandwidth?
   - Licensed bandwidth - Incumbent users of selected and adjacent bands
3) Electromagnetic compatibility - tissue propagation and absorption rate
4) Security
5) Maintenance

Wireless Quality of Service

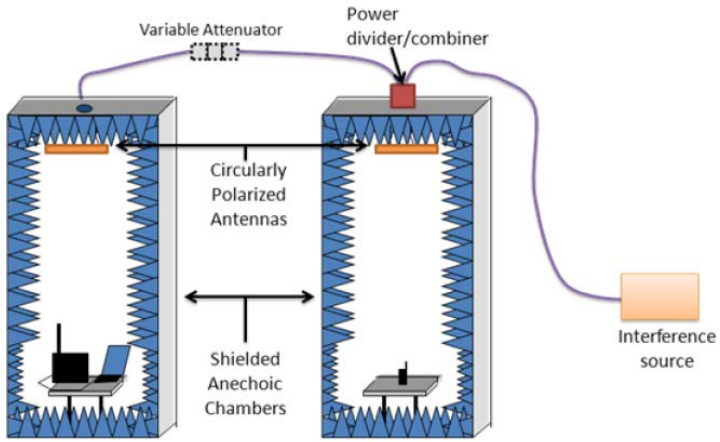
- Necessary level of service and performance needed for wireless functions of the medical device (e.g., latency and throughput, corruption control and prevention, signal to noise ratio)
- Potential Risks:
  - Connections lost without warning
  - Failure to establish connections
  - Degradation of service
- Justification of acceptable risk or demonstration of risk mitigation
  - Study fail modes
  - Regularly update patches
  - Ensure patient education

Wireless Coexistence Testing

- Appropriate testing required to demonstrate appropriate risk mitigation



Environmental Testing
Unlicensed Spectrum



Controlled Testing
Licensed Spectrum

[“An FDA Perspective on Medical Device EMC and Wireless”]

Electromagnetic Compatibility (EMC) of Wireless Technology

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1. Considerations for interference to/from other equipment (e.g., overlapping frequency bands)
2. Risk analysis of potential interference (EMI) from environmental sources
   - Most EMI reports occur in defibulators (ICDs), pacemakers, neurostimulators, and infusion pumps
   - Case studies show probable EMI from common devices, such as electric razors and metal detectors
3. Biocompatibility - Comply with IEC 60601 (e.g., radiation, leak current, protective grounding, etc.)

Security of Wireless Signal and Data

- Access Control - Protection against unauthorized wireless access to device control
  - Prevent automatic detection of other devices (e.g., discovery mode of Bluetooth)
- Encryption - Software protection of wireless data transmission against unauthorized access
  - Latest wireless encryption encouraged – examples provided in October 2, 2014 guidelines

Labeling

- Specification (standard) and performance (e.g., power, range, bandwidth…) of wireless data transmission
- Information on limitations (e.g., max power or proximity to other in-band devices)
- Recommended security and encryption measures
- Information on issues that might arise and what to do
- Information on international limitations
- Appropriate FCC labeling

Common Bandwidths

- **Inductive Implants** (e.g., control or monitor cardio activity): Bands below 200 kHz at distances less than one foot
- **Medical Device Radiocommunication Service (formerly "MICS")**: Licensed bandwidth of 401-406MHz at distances up to about 10 feet.
- **Wi-Fi, Bluetooth and Zigbee**: Unlicensed bandwidth commonly used with cell phones, handheld devices and personal computers, operate in 902-928, 2400-2483.5 and 5725-5850 MHz bands at distances up to a few hundred feet.
- **Ultra-Wideband**: New uses of unlicensed ultra-wideband technologies are starting to emerge for medical telemetry and imaging applications.
- **Medical Micropower Networks**: New licensed spectrum to accommodate operation of implanted microstimulator devices in the 413-457MHz band at distances up to a few feet.
- **Medical Body Area Networks**: Licensed spectrum to allow a wireless personal area network ("PAN") of multiple body sensors to monitor or control patient functions. Operate in the 2360-2400 MHz band at distances up to a few feet.

FDA – Postmarket Management

- Implement cybersecurity risk management programs:
  - Identify hazards associated with the cybersecurity of a medical device
  - Estimating and evaluating the associated risks
  - Threat modeling to define how to maintain safety and essential performance of device
  - Controlling the associated risks
  - Monitoring the effectiveness of the controls
- Programs should focus on assessing <u>risk of patient harm</u> by assessing:
  - Exploitability of cybersecurity vulnerability
  - Severity of patient harm if exploited

FDA – Postmarket Management

FDA – Postmarket Management

- Controlled vs. uncontrolled risk
  - Controlled (acceptable) risk:
    - Implement routine updates and patches, device enhancements, etc. in timely fashion
    - Premarket review for software change is not typically required
  - Uncontrolled (unacceptable) risk:
    - Implement risk remediation measures as quickly as possible
    - Provide information on controls and residual risks to customers
    - Report vulnerability to FDA under Part 806 except when:
      - No adverse events
      - Remediate within timeline (60 days)
      - Active participant in an Information Sharing and Analysis Organization

Maintenance for Manufacturer

- Continue to manage risks associated with wireless technology
  - Implement routine updates and patches, maintain up-to-date encryption protocols
- Mandatory Reporting
  - Death
  - Serious Injury
  - Malfunctions that caused or could have caused death or serious injury
- Must investigate known failures

FDA Guidance and Legislation on Software for Medical Devices

Legislative Exclusions of Software (21st Century Cures Act)

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- Streamlines FDA procedures to prioritize Breakthrough Devices
- Reduces or eliminates review of medical devices deemed to be low risk
- Requires the FDA to finalize guidance on software by November 7, 2017
- Removes five categories of software from FDA review with some categories capable of being brought back under FDA review

Software Excluded from FDA Review

- Category A: Software for administrative support of healthcare facilities
  - e.g., processing and maintaining financial records, claims and billing information, appointment schedules
- Category B: "Healthy lifestyle" software that provides no diagnostic, prevention or treatment function
- Category C: Electronic patients records, but not interpret or analyze patient records
- Category D: Software for transferring, storing, converting formats, or displaying test data lab tests or med device data, but not interpret or analyze patient records
- Category E: Clinical Decision Support Software (CDSS)
  - Software that provides recommendations based on medical information (e.g., peer-review)
  - Must enable independent review of the basis of the recommendations
  - Category E does not include medical imaging or *in vitro* testing

Recapture of FDA Jurisdiction by Congress

- FDA may bring Categories C, D, and E back under regulation with a showing of:
  - Likelihood and severity of patient harm
  - Extent to which software is intended to support clinical judgement
  - Reasonable opportunity for a health care professional to review the basis of the information
  - Intended user and use environment
- Requires Notice and Comment Rule Making

Mobile Applications (Apps) – 2015 Guidance

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- Is the software a medical device under FDA regulations?
- FDA defines 3 broad categories that are regulated:
  - App controls a medical device – FDA considers it an accessory.
    - Example: Software that controls an insulin pump.
  - App that transforms the mobile device into a regulated device. May include attachment for standard mobile device. App may be labeled for medical specific uses.
    - Example: App that allows for control of attached transducer that converts a smartphone into a glucose meter.
  - App that performs patient-specific analysis and provides patient-specific diagnosis or treatment recommendations
    - Example: App that calculates dosage or creates a dosage plan for radiation therapy.
    - Potential overlap with Category E of the Cures Act

Stand Alone Software as a Medical Device (SaMD) – 2016 Guidance

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- SaMD = software used for one or more medical purposes without being part of a hardware medical device
- Medical device not necessary to achieve function (peripheral)
- Examples of SaMD
  - Software that allows commercially available devices to view and process images for diagnostic purposes
  - Treatment planning software that supplies information used in a linear accelerometer
- SaMD does not include:
  - Software that drives or controls a medical device
  - Embedded software - Firmware
  - Non-medical software that just encrypts data (medical records)
  - Enables clinical communication and workflow such as patient registration, scheduling visits, voice calls, and video calling

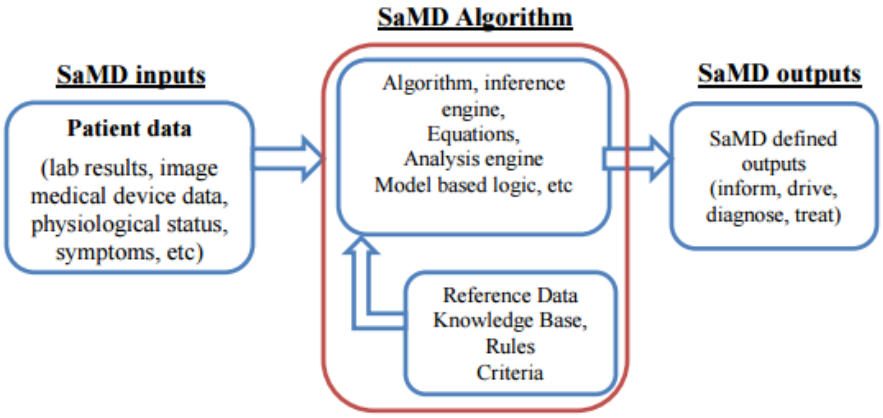

Figure 2: High Level SaMD Components

SaMD Categories

- SaMD grouped by four categories (I-IV) and three types (i-iii):
  - Category breakdown - Significance of the information provided by the SaMD
    - Inform clinical management
    - Drive clinical management
    - Treat or diagnose
  - Type breakdown - State of the healthcare situation or condition
    - Non-serious
    - Serious
    - Critical
  - Treat or diagnose for Critical type is fourth category

Clinical Evidence and Expectations of SaMD

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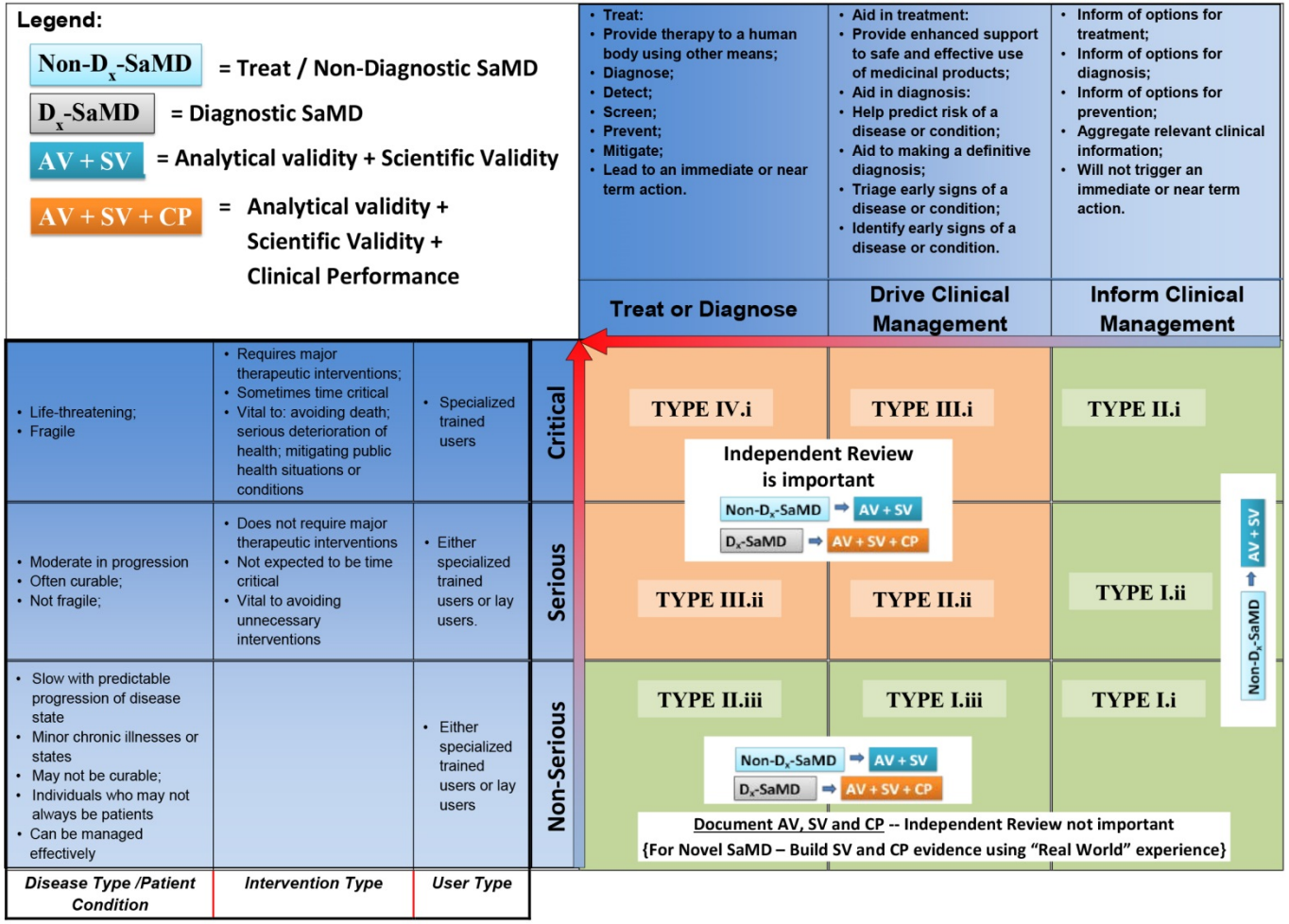

Figure 8 – Summary of Clinical Evidence and Expectations by SaMD Category

Patent Claim Strategy and Benchmarking

Strategies for Claim Drafting

- Focus claims on a single actor
  - Devices are connected - ecosystem is inherently a multi-actor
  - Ensures coverage for your system
  - Higher likelihood of infringement by direct competitors
- What can be protected?
  - Hardware
    - Combination of device/system-on-chip
      - Currently common with implantable devices
    - Position on device, in-vitro protection, material, etc.
  - Software
    - Processing and data collected by:
      - Device
      - Gateway (bedside receiver, router, mobile phone, etc.)
      - Server (hospital, manufacturer, or other covered entity)
  - Data structures
  - Graphical User Interface (GUI)
  - Trade secret for software details

Claiming Software

- Communication protocol (process) between actors
- Software for data collection
- Software for data analytics
  - Account for and analyze bad or unreliable data
  - Determine and transmit insight from data
    - Data visualization to deliver insight from data for hospitals and similarly situated patients
- Utility patent for GUI
  - Federal Circuit recently found claims to a GUI to be eligible. *See Trading Technologies International, Inc. v. CQG, Inc.* (2017).

Overcoming Alice

- Alice not as rigorously applied in the medical device art units as the business method art units
  - Understanding that there is some specialty hardware (device) associated with the process
  - The concept of connected medical devices and big data processing is **inherently new**
    - Not an old "fundamental concept"
- Recommend including details of the device collecting the data, the type of data collected, the algorithms used to process the data
- Explain changes that may result from processing – e.g., activating an alarm, cause update of firmware, change sensitivity or modality, etc.
- Discuss **practical benefits provided by the** invention

International Filing

- Device claims and method of manufacturing claims (more rare) patent eligible worldwide
- Methods of surgery and medical treatment methods
  - Patentable in the United States and Australia
  - Not in Europe, Japan, South Korea, or Canada
  - Sometimes can covert to “use” claims without mentioning human body
    - Manipulate device in novel way

Design Patent for GUIs

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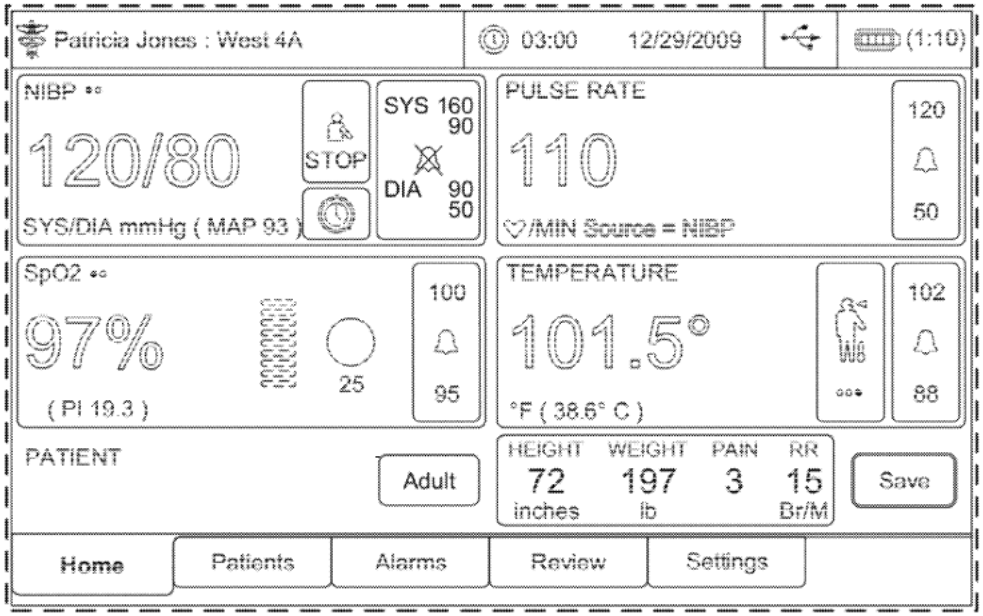
- Cover static structure of a GUI
  - Does not include the dynamic data (dashed out)
  - Bedside monitor
  - App for monitoring



Design Patent for GUIs

- Cover dynamic functionality by showing GUI over time or in response to user input
- Example: Apple's Slide to Unlock (D675,639)

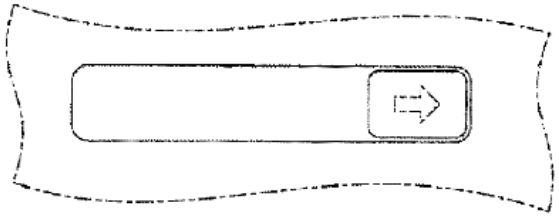


FIG. 4

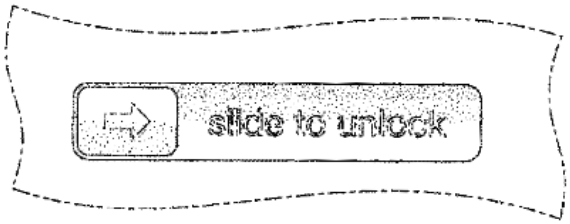


FIG. 5

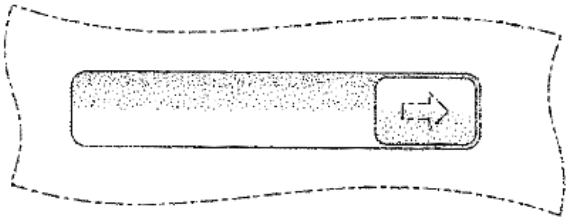


FIG. 6

Protecting Patient Monitoring

- Multi-tiered approach
  - Process for data collection
  - Process for data processing
    - Data validation/correction
    - Data visualization
    - Alert/alarm processing
  - GUI
    - Utility
    - Design
  - Process for patient input

Protectable Features of Databases

- Databases generally have copyright protection in the US
  - Per the Compendium sec. 1002.6—"[A] database generally consists of two fundamental elements:
    - (i) a data set or multiple data sets, and
    - (ii) an information retrieval program or system that serves as the sole entry point into the underlying data, information, or files.
  - Typically, the party that created the information retrieval program or system is not the same party that created the copyrightable content contained within the database.
  - An application to register a database typically covers the selection, coordination and/or arrangement of data, information or files, but does not cover the data, information or files unless they are specifically claimed in the application.

Increased Filings

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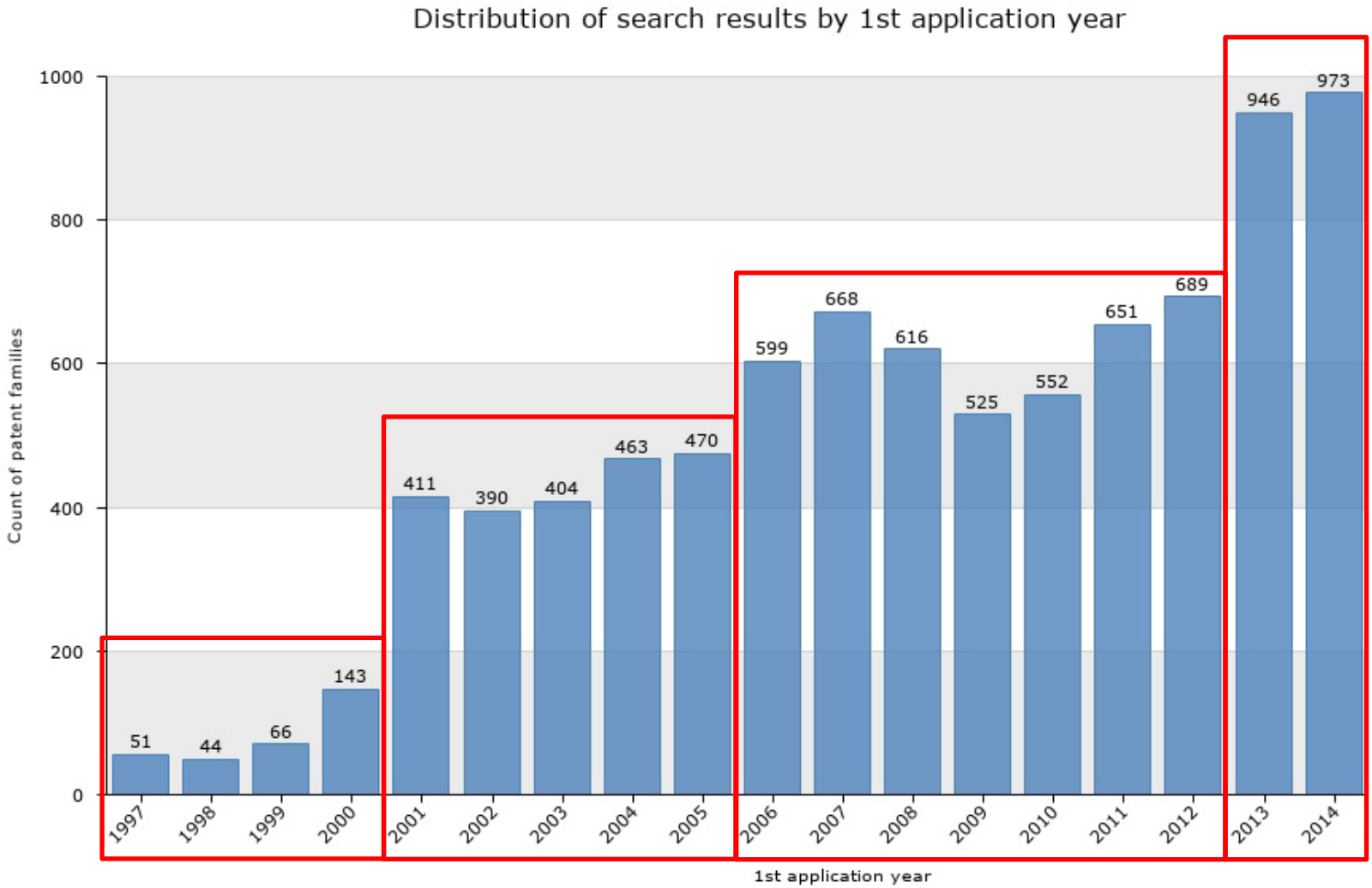

Where being filed?

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