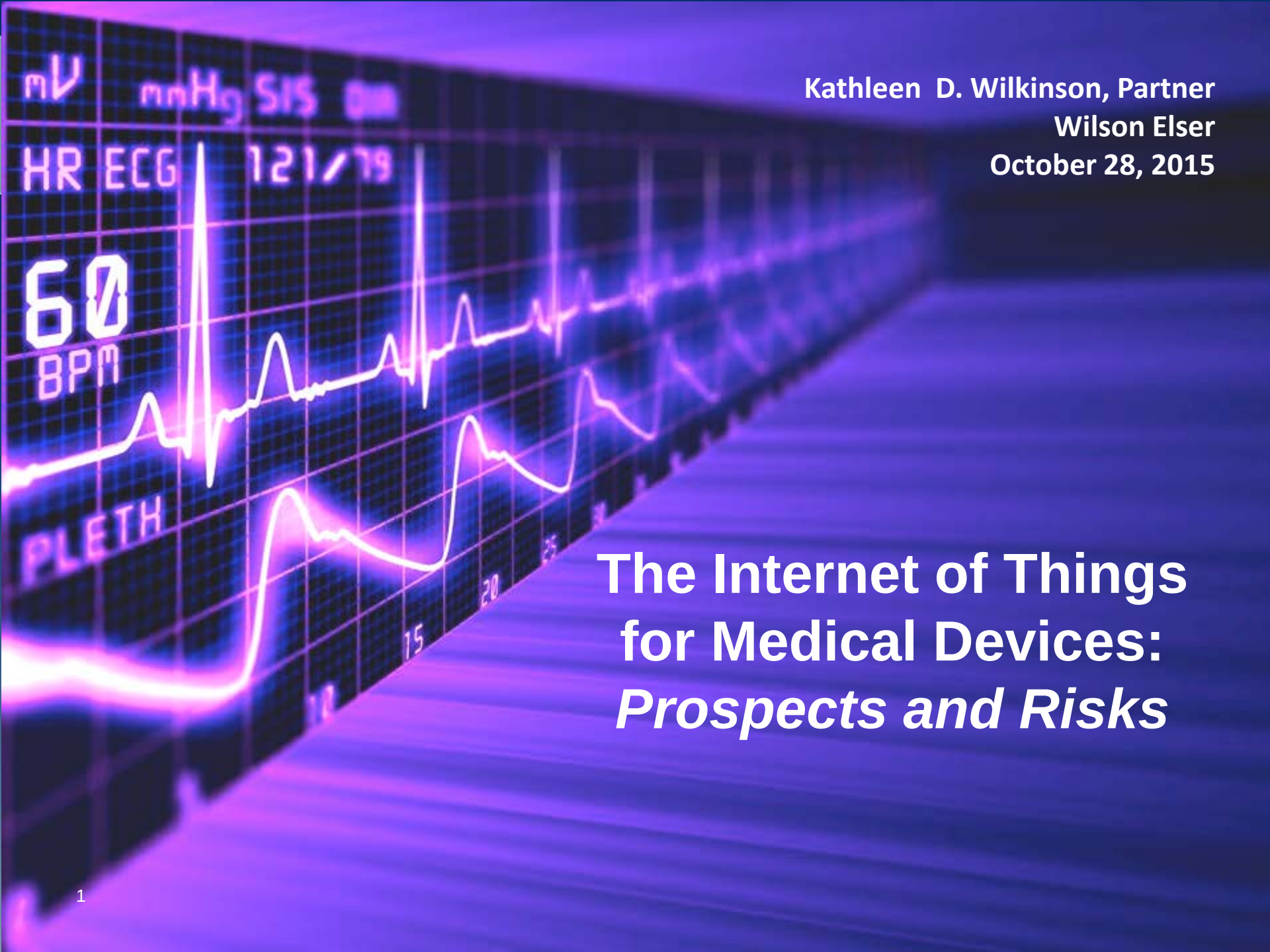
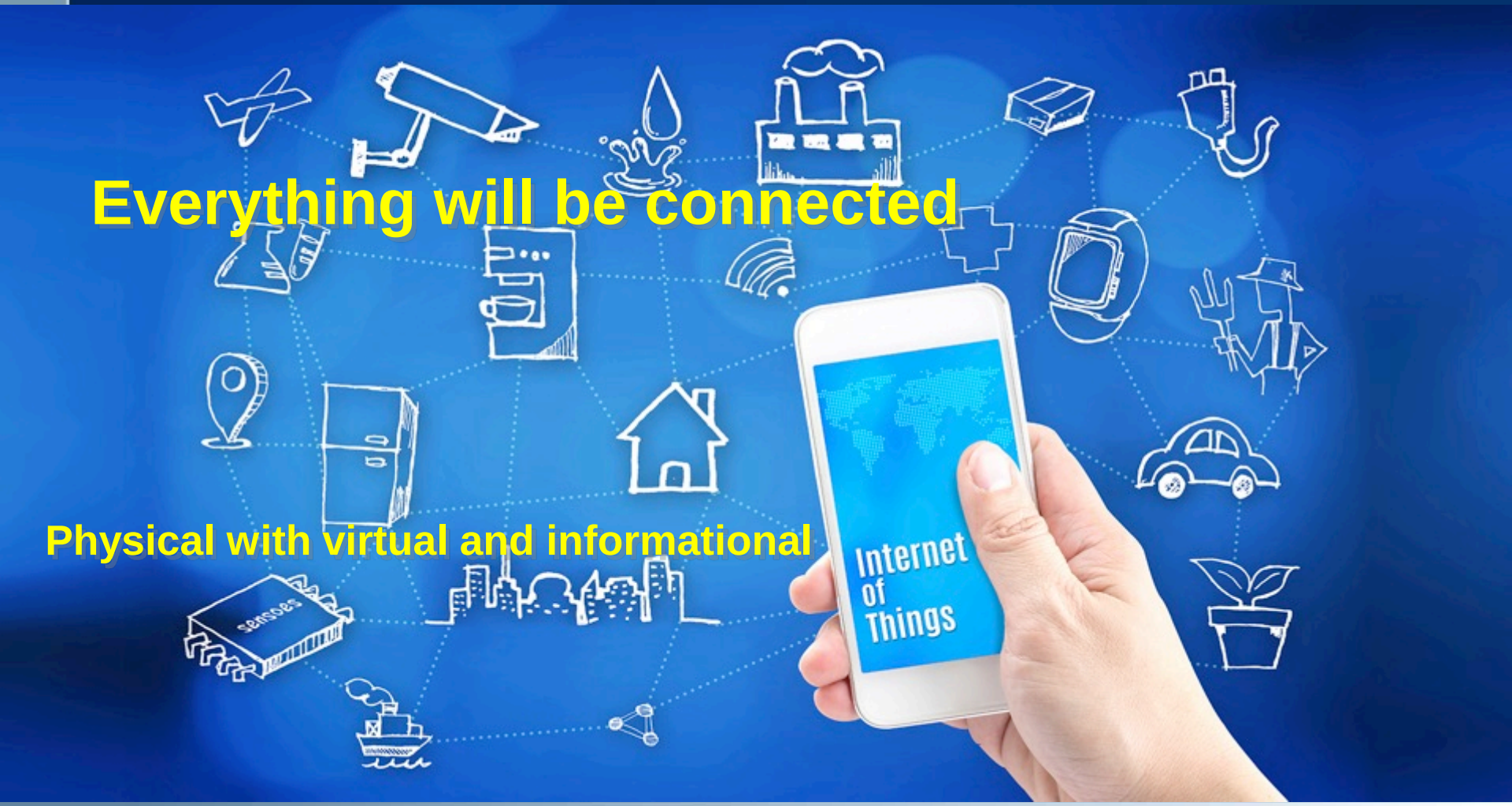


Kathleen D. Wilkinson, Partner
Wilson Elser
October 28, 2015

The Internet of Things for Medical Devices: *Prospects and Risks*

What is the Internet of Things?

25 billion connected devices by 2020



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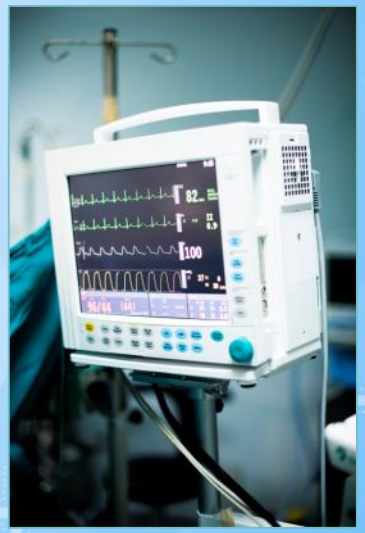
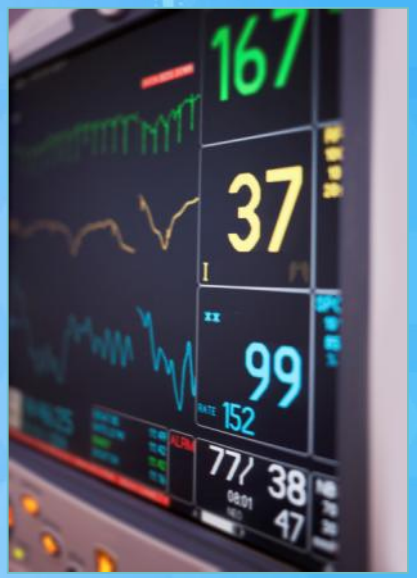
IoT and the Medical Device Arena

Problems Interfacing/ Interference With Other Devices

Things-related services

Heterogeneous devices





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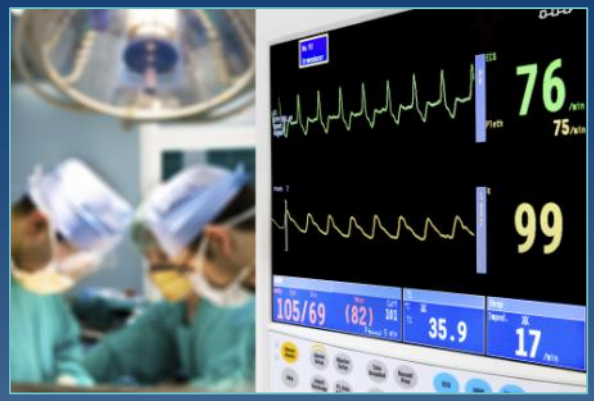
How Does FDA Classify Medical Devices?

- Class I – devices deemed low risk; low level of regulatory control
- Class II – higher risk than Class I; requires greater regulatory control
- Class III – highest risk devices; typically approved by FDA



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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Medical Device Regulation and Guidance

- FDA issued guidance for medical devices which involved medical technology

- http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf

Medical Device Regulation and Guidance

- In 2014, the FDA issued recommendations to manufacturers for managing cybersecurity risks to better protect patient health and information

- https://www.federalregister.gov/articles/2014/10/02/2014-23457/content-of-premarket-submissions-for-management-of-cybersecurity-in-medical-devices-guidance-for

IoT: Good for Patients, but Potentially Risky

Privacy

HIPAA

Security

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HIPAA

- HIPAA protects privacy of individually identifiable health information
- HIPAA Security Rule governs security of such information
- Patient Safety Rule protects such information used to analyze patient safety events and improve patient safety
- http://www.hhs.gov/ocr/privacy/

Patient Information

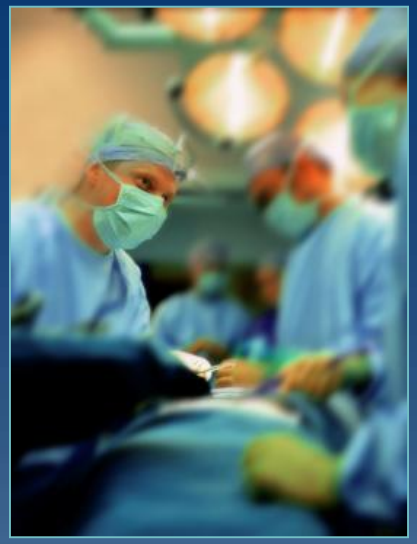
DOB: xx/xx/78

SSN: xxx-xx-1234

IoT Risks: What You Need to Know

WARNING

Negligence



MISREPRESENTATION

Strict Product Liability

Breach of Warranty

Examples of Possible IoT Problems

Litigation Risks

Joint and Several Liability

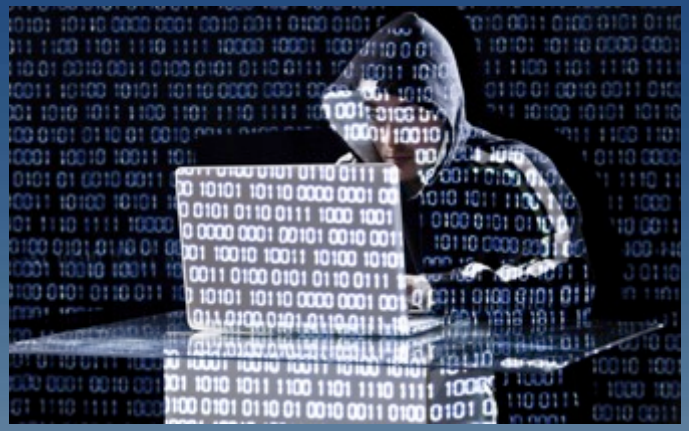
Learned Intermediaries

Other Medical Device Considerations

- Medical device issues
- Medical device recalls
- Environment where device is located and cybersecurity

Medical Devices, Healthcare and Problems

- Hackers have breached hospital networks
- Medical devices could be programmed improperly or altered to perform tasks not intended to be performed by medical professionals
- Some of the medical devices hackers can access include implantable heart devices, infusion pumps and medical imaging equipment



Possible Medical Device IoT Scenarios - I

IoT Devices Used at Hospitals

- What happens if the IoT device manufacturer's protocols do not align with the hospital's protocol perfectly?
- How to anticipate quick turnaround time needed for IoT equipment?
- Is hospital delegating work to third parties?
- Is system secure, meet HIPAA and FDA requirements?
- Can you differentiate IoT devices so user does not mix up incompatible devices?

Possible Medical Device IoT Scenarios - II

IoT Devices Used At Home

- When does glucose monitoring for diabetes at home through remote devices become risky for patients?
- How to secure monitoring of patient care remote IoT devices from interconnectivity/cyber issues?
- What are the possible real time issues?

Possible Medical Device IoT Scenarios - III

IoT Devices Used at Doctor’ s Office

- How can patient be protected?
- How can device be compatible with other systems used?
- What issues or policies of doctor’s office could interfere with device use?

Internet of Things and Lawsuits

- While patients benefit from the prospects of the IoT, care must be exercised to prevent injuries from use of medical devices
- In addition, hacking, malware, cyber attacks, identity theft, need to be prevented with cyber security of the medical devices in the IoT
- As the number of medical products that are part of the IoT grows, it is important to anticipate all potential risks in order to avoid mass torts claims and litigation

Questions

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