Why Securing Medical Devices Leads to Better Care

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TODAY, MEDICAL DEVICE CUSTOMERS DEMAND PROACTIVE SECURITY.

IT USED TO BE ACCEPTABLE FOR MANUFACTURER TO REACT WHEN CYBERSECURITY ISSUES WERE REPORTED.







THREAT LANDSCAPE

Individual Hackers

- Script kiddies
- Fame, curiosity
- Target: computers

Cyber Criminals

- Underground economy
- Stealth, sophistication
- Target: financial gain

Nations & Activists

- Cyber defense & offense
- Espionage, sabotage
- Societies, economies

Hackers for Hire

- Separation of skill and motive
- Organized, skilled

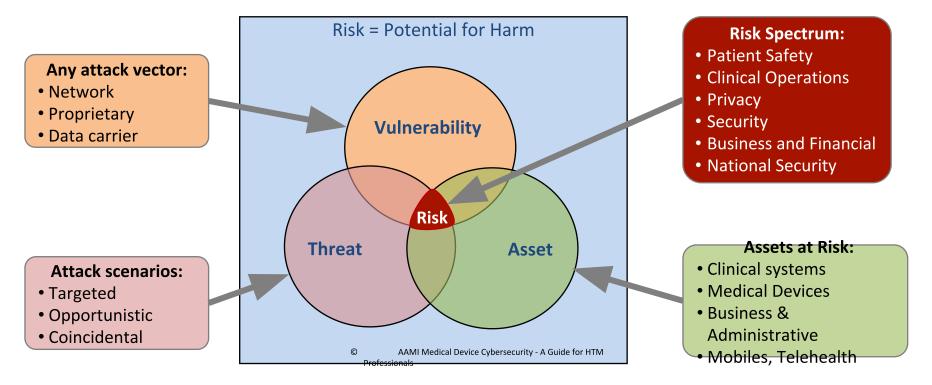
If Cybercrime were a country, it would be the 12th largest economy

YOU HAVE TO ASSUME ANY DEVICE WILL OPERATE IN A HOSTILE ENVIRONMENT

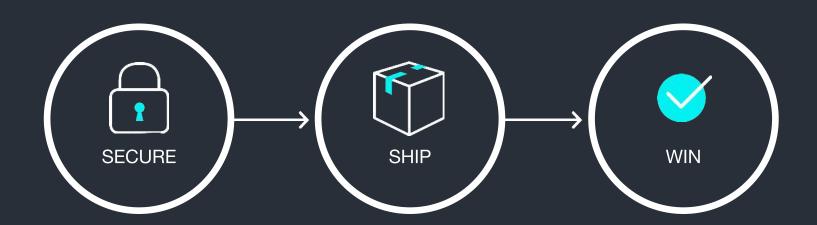


- Use of tools, automation, and services:
 - ~1m malware variants a year (2008) to ~1m a day since 2015
- Our advances and challenges are their opportunity:
 - From IoT, Cryptocurrency, Al/ML, to COVID-19
- Attacks are increasingly sophisticated, well orchestrated, and targeted:
 - Phishing, BEC, IoT DDoS, ransomware, crypto mining, supply chain
- Growing gap between cybersecurity investment and economic losses:
 - Investment: ~\$100b, few % growth. Losses ~\$1t, growing by multiples

PATIENT SAFETY IS AT THE CENTER OF EVERYTHING



NOW, BUYERS REQUIRE SECURITY BE BUILT IN.















HOSPITALS WILL NO LONGER TOLERATE REACTIVE SECURITY.

"Devices that are clinically sufficiently are not immune from needing to meet cybersecurity requirements." -Mayo Clinic

MANUFACTURERS ARE ALL-IN ON DELIVERING PROACTIVE SECURITY.





"At future events – like @Defcon – we encourage manufacturers to increase engagement with the cyber research community through device demos and our #wehearthackers event. This demonstrates a company's commitment to cyber principles: Trustworthiness.

Transparency. Resilience."

 FDA Commissioner, Scott Gottlieb, M.D. (@SGottliebMD) January 29, 2019



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THE FDA EXPECTS PROACTIVE SECURITY

LACK OF SECURITY IS DELAYING MARKET LAUNCH

THE FDA'S MUST-HAVE PRODUCT FEATURES



Cryptography



Behavior Monitoring



Vulnerability Tracking



Contains Nonbonding Recommendations

Draft — Not for Implementation

CONTENT OF PREMARKET SUBMISSIONS FOR MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES

DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF

Draft Guidance

This draft guidance document is being distributed for comment purposes only.

Document issued on October 18, 2018

You should submit comments suggestion regarding this draft document within 150 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.reguilation.gov



What the Pandemic Taught Us

- Crisis requires compromise (what is the higher risk?),
 e.g., HIPAA enforcement discretion
- In an emergency, cybersecurity takes the back seat (WFH, telehealth, remote monitoring, infrastructure surge)
- Telehealth is here to stay: We will be moving more care as well as more critical care out of the hospital

Future

- Cybersecurity is patient safety.
- Proactively securing devices is the only way to get ahead of the security debt
- The economics of security are compelling

Questions?

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