Practical Considerations for Developing Software in Connected Health Solutions and the Assessment of Sustainability in Respiratory Devices

IPAC-RS Webinar

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What we'll cover:

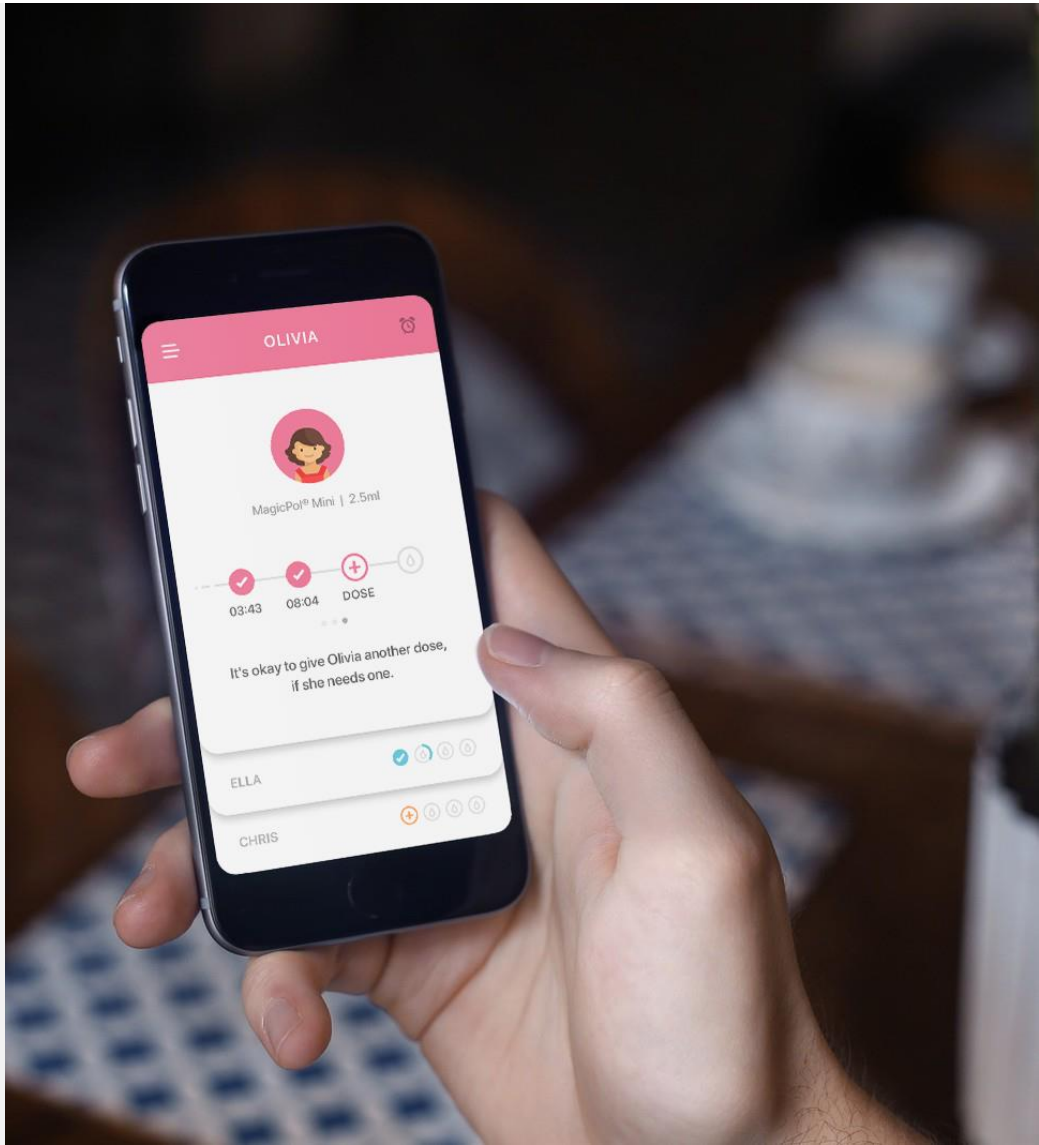
1. Considerations on going digital & hot topics
2. Assessment of sustainability
3. The environmental trade-off of adding connectivity
4. Medical software considerations and connectivity technologies
5. Cybersecurity concerns and regulations
6. Medical software & maintenance

Going digital/connected

Connected products
- Increased usages in both clinical trial and real-use settings
- Gathering better quality use data
- Pressure for improvements in device adherence and competence

Increasing use of data analytics:
- Driving innovation
- Understand patient trends & behaviour
- Improve safety and risk management (e.g. PMS)

Supporting users:
- On-boarding (i.e. first time use)
- Track symptoms and dose history
- Support to manage conditions at home
- Monitoring of environment:
    - i.e. Air pollution or for critical for temperature / time sensitive formulations



Hot Topics

Poor adherence is a major clinical and environmental concern

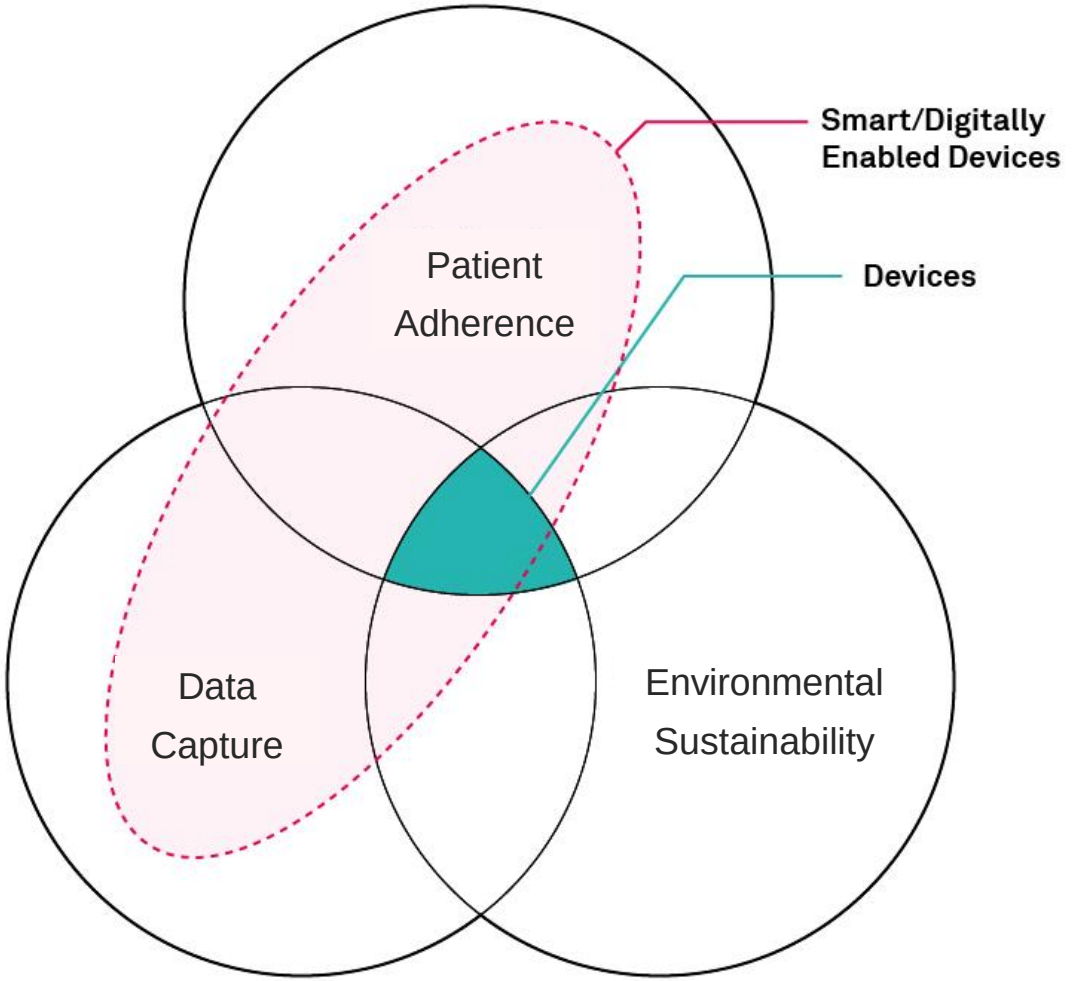
Associated with inadequate disease control, increased hospital admissions and higher mortality rates

Smart or connected devices can help to address this…

…but more device complexity equals more carbon output

Complex issue of **balancing patients needs and health against the health of the planet**

How do we control and monitor this?



Assessment of Sustainability

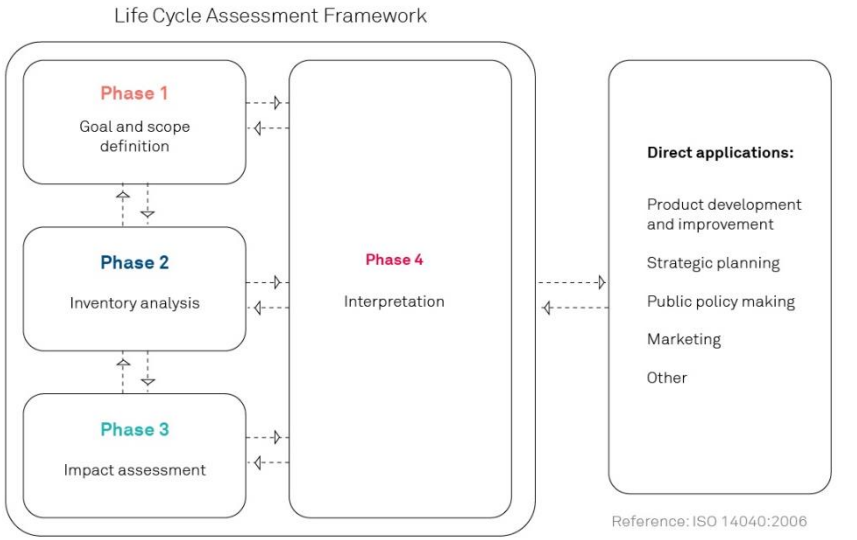
Life cycle Analysis:

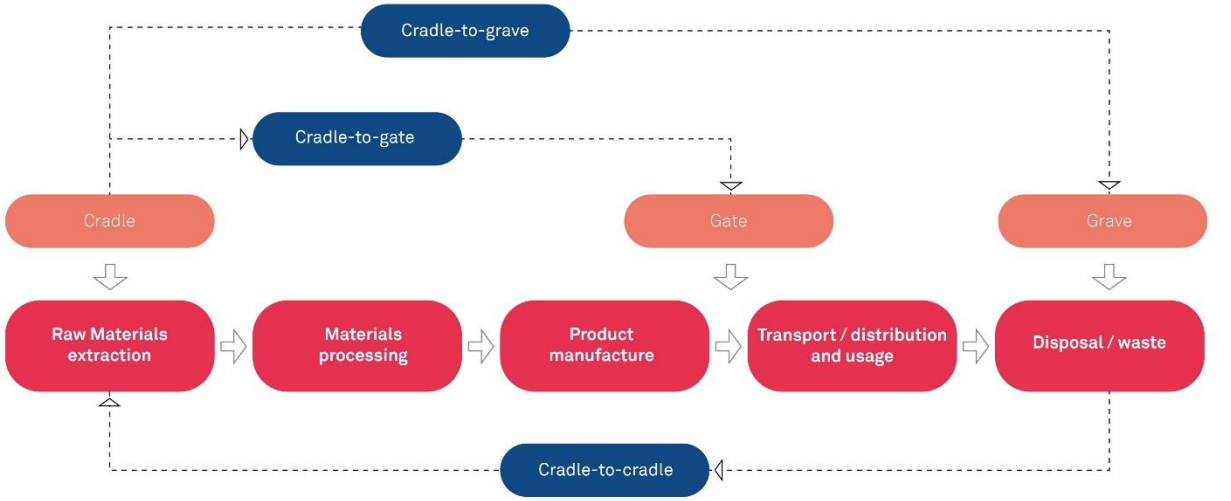
Methodology for the assessment of the environmental impact of a product or a process over its lifetime

Enable insight-driven improvements of environmental performance

ISO 14040:2006

1. Goal and scope definition
2. Inventory analysis
3. Impact assessment
4. Interpretation phase





Comparing carbon footprint of non-connected & connected devices

1. Non-connected

- A pressurised metered dose inhaler (pMDI) device with an integrated breath actuation mechanism (BAM) and dose counter

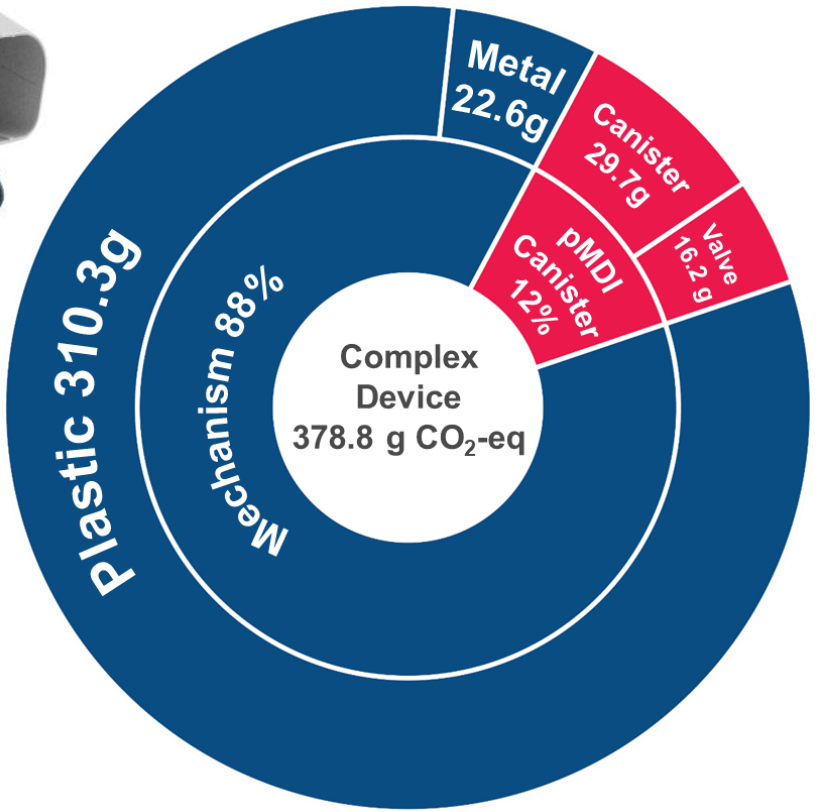
2. Connected

- pMDI device with an integrated breath actuation mechanism (BAM) and dose counter **+** added digital connectivity and sensing capabilities

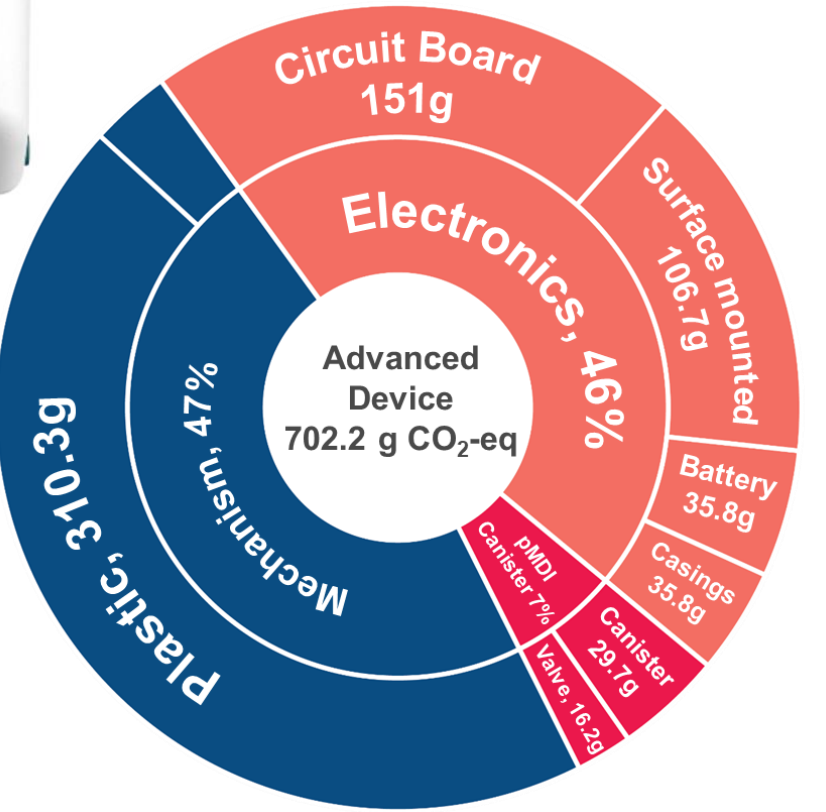
1.

2.

Excluding formulation carbon footprint



pMDI & BAM – Non connected



pMDI & BAM - Connected Device

Considerations for going connected

When electronics are introduced into drug delivery devices they are a significant contributor to carbon footprint

By using good DfM principals with Design for Sustainability we can minimise the environmental burden over the entire lifecycle

But… carbon footprint of the device is only one of several factors to consider

- Improved usability and adherence will also directly contribute to overall sustainability

Medical software considerations

Adding connectivity to an inhaler will require consideration of additional areas which you might not need to do when designing a traditional inhaler.

Connectivity technologies

Many connectivity technologies exist but which one is appropriate?

Medical software regulations

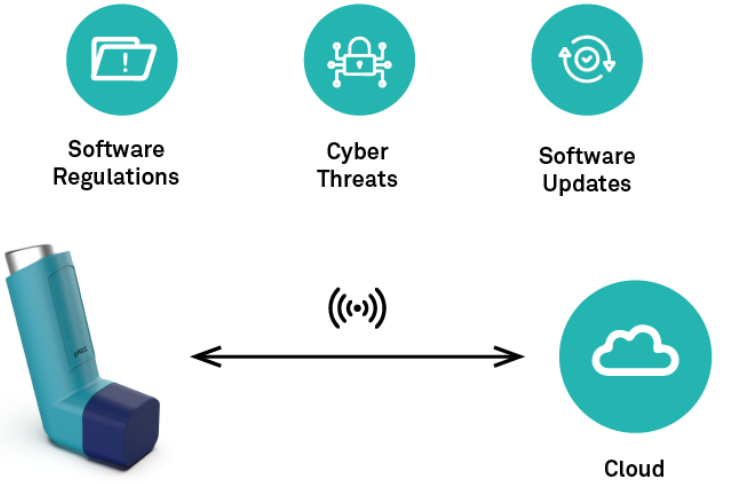
Medical software is heavily regulated. What does this entail?

Cybersecurity concerns

Connectivity brings a lot of benefits and potential convenience when using a device, however it is opens the door to cyberthreats. What should we be aware of?

Software maintenance

Software developed and shipped with the device. What happens if a defect is found in the software, how can we update the software?



Connectivity technologies

BLE, Wi-Fi, NFC

Typical technologies considered when adding connectivity to inhalers

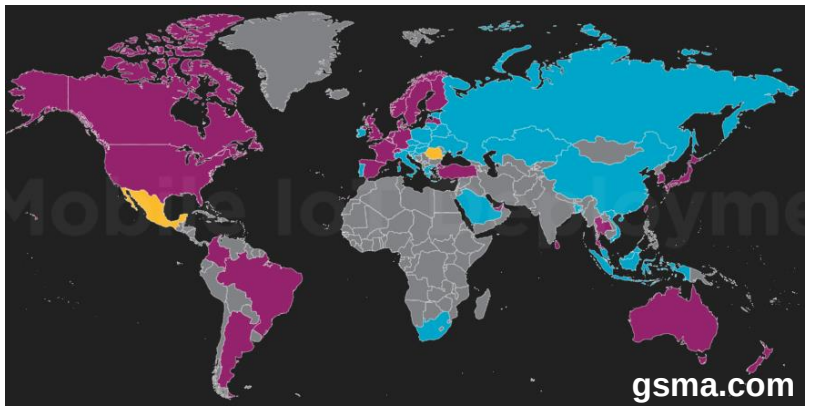
Technology	Advantages	Disadvantages
Bluetooth Low Energy (BLE)	Low Power Lower Cost than Wi-Fi	Requires User Intervention (BLE pairing)
Wi-Fi	Doesn't require a mobile phone for pushing data to the cloud	High Power Requires a mobile phone to setup Wi-Fi credentials the first time
Near Field Communication (NFC) Active, Passive	Low Power Does not require user setup, just tap on phone to device Security, authentication is simpler	Requires a mobile phone in close proximity for data exchange

Connectivity technologies

LoRa, Sigfox, NB-IoT

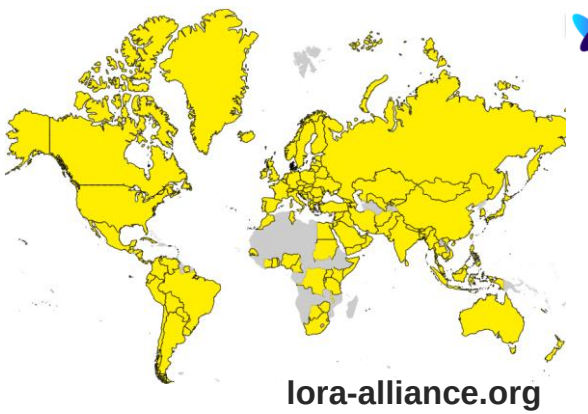
Interested in monitoring device and drug as soon as it leaves the factory
i.e. Drug/Device temperature, humidity, exposure to light

Long Range Technologies such as **LoRa, Sigfox, NB-IoT**



Advantages

- Low Power
- Long Range
- Do not require user setup



Disadvantages

- Relatively new technologies
- Higher cost
- Coverage can be patchy
- Best only for sending data from the device not receiving

Cybersecurity concerns

Cybersecurity regulations

Cybersecurity risk assessment process

- TIR 57 Principles for medical device security – Risk management

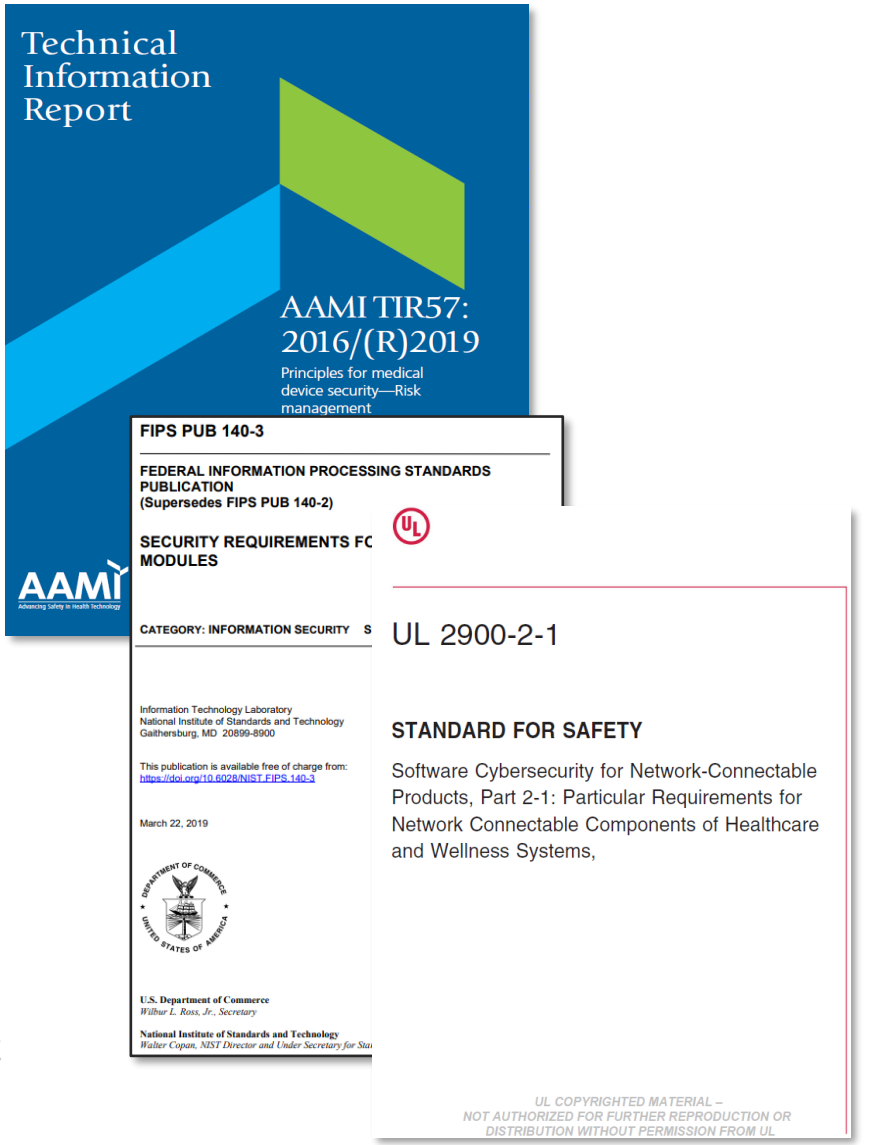
Process document on cybersecurity risk assessment and how cybersecurity risk assessment relates to safety risk assessment.

Software requirements related to cybersecurity

- FDA, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Draft 2018), (Final 2014),
- UL 2900-2-1 Software Cybersecurity for Network-Connectable Products: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems.

Relevant to cryptographic modules, libraries

- FIPS 140-3 Security requirements for cryptographic modules
- NIST SP 800-140C Approved security functions
- NIST SP 800-140D Approved sensitive security parameter establishment method



Medical software regulations

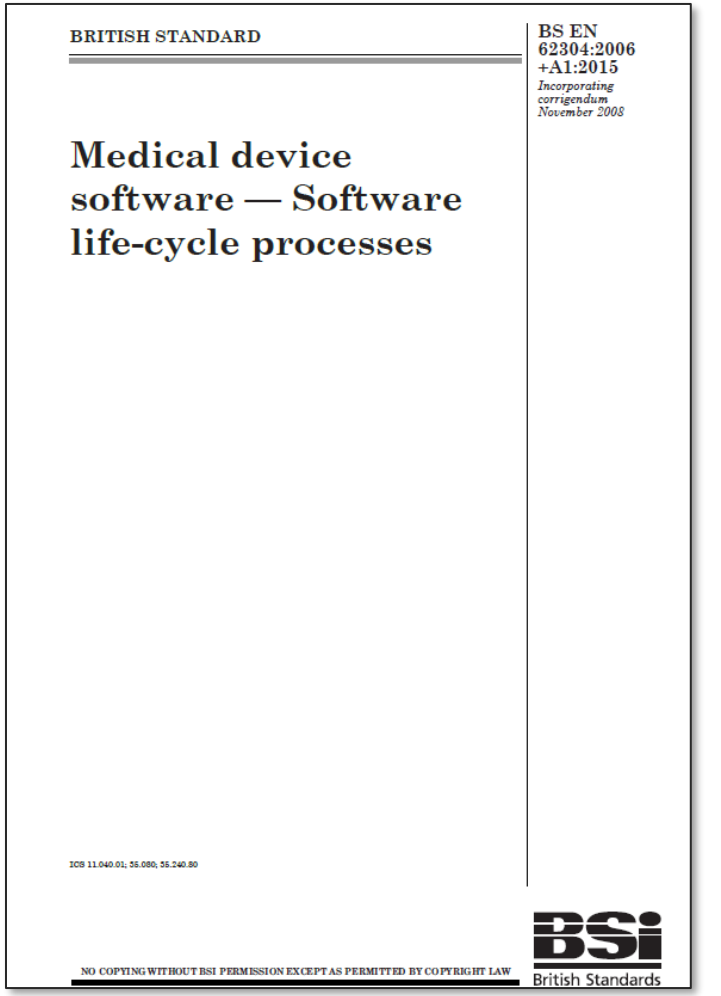
Key software regulations

Key Software standards to be aware of:

International
- IEC 62304 “Medical device software – Software life-cycle process”

FDA
- “General Principles of Software Validation”
- “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”
- The IEC 62304 is an FDA recognised standard

Key points
- Software standards have to be applied early on in the process
- These standards are **not** to be applied after development is completed and are **not** just paperwork to be completed during verification


BRITISH STANDARD

BS EN 62304:2006 +A1:2015
Incorporating corrigendum November 2008

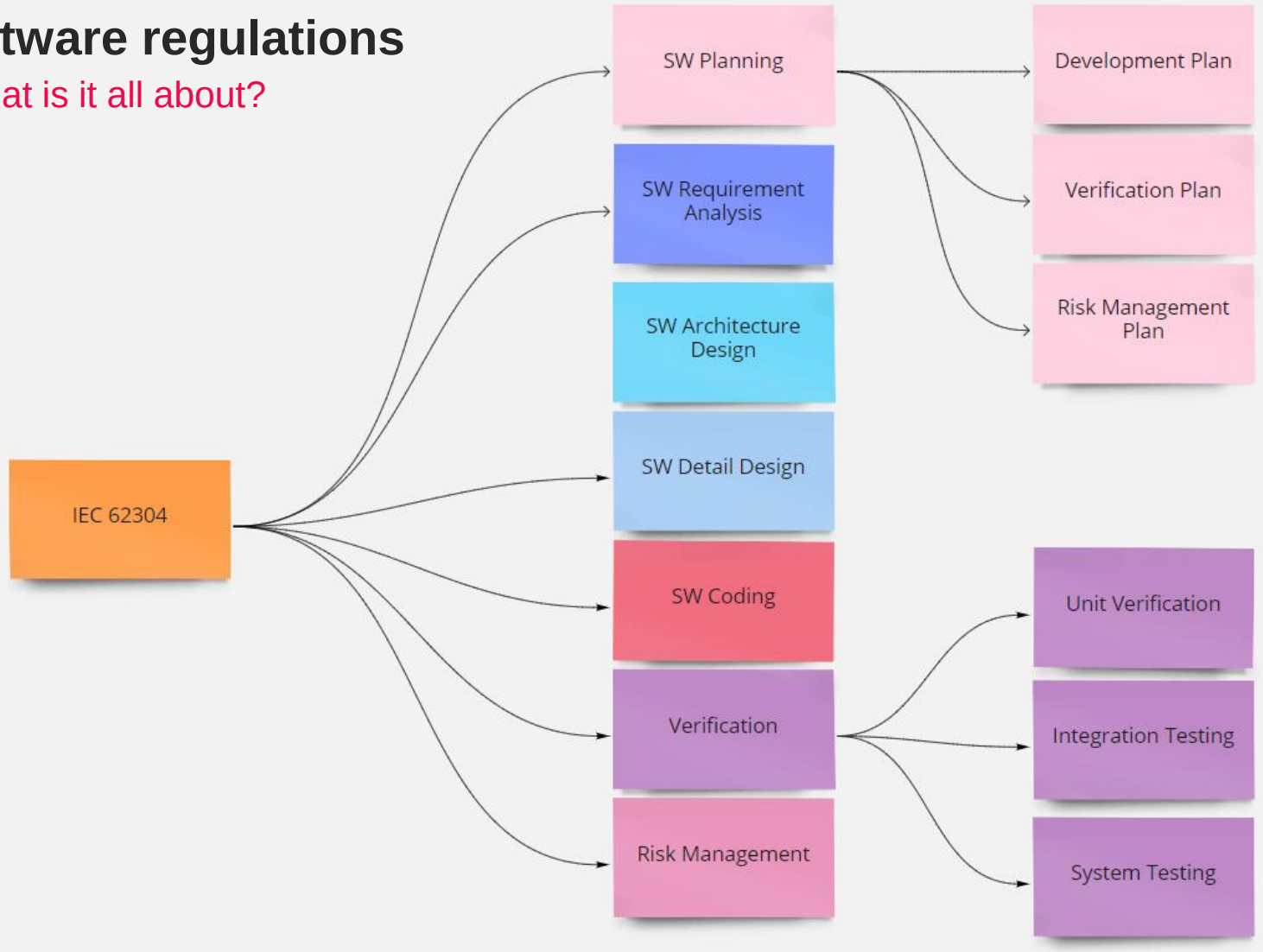
Medical device software — Software life-cycle processes

ICS 11.040.01; 35.080; 35.240.80

BSI British Standards

Medical software regulations

IEC 62304 – What is it all about?



Medical software regulations

Medical Software Classification

Software safety risk Classification between EU and the FDA is similar

Failure of Software	IEC 62304	FDA
Will result in no injury to patient or operator	Class A	Minor Level of Concern
Could directly or indirectly result in minor injury to patient or operator	Class B	Moderate Level of Concern
Could directly or indirectly result in death or major injury to patient or operator	Class C	Major Level of Concern

Key points

- Unlike IEC 62304, for the FDA risk controls can not be used as a mitigation to reduce the severity of the software
- FDA, Software **likely** to be major level of concern if the Software Device intended to be used in combination with a drug or biologic?

Software maintenance

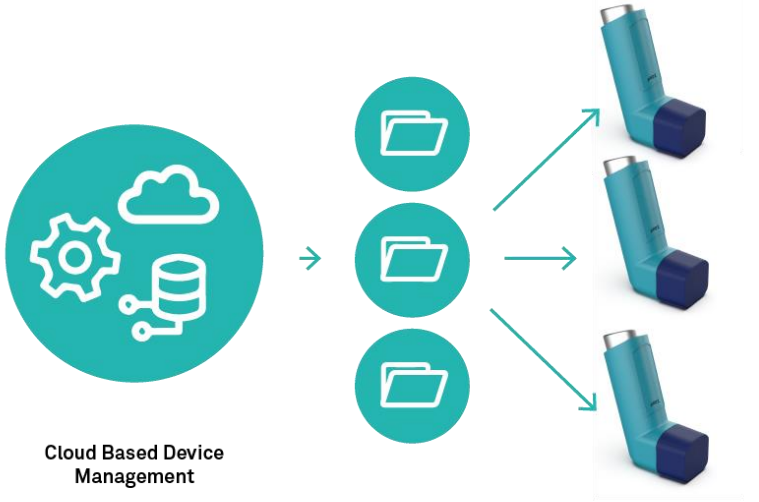
How to update software

Although software does not wear out, you might need to update it:

- Required performance updates
- Phone updates or new features you might need to support
- Security updates to fix cybersecurity flaws
- Software bug fixes (or device issues)

Software maintenance (Software maintenance is covered by IEC 62304)

- Setup a software maintenance plan from early on
- Plan how to manage software updates, return to base or over the air (OTA) updates
- For the OTA consider using cloud IoT frameworks to manage software updates. Could simplify the security of software updates



Summary

- Device developers need to carefully weigh up the benefits of added connectivity with environmental costs
- Select appropriate connectivity technology for the use case
- Address cybersecurity risks early on as it can effect design and manufacturing
- Plan how the software can be updated after the product has been released

Thank you!

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