Human Factors and Usability in Medical Devices: Safety, Regulation, and Practice

Presented by

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Hospitalar
By Informa Markets

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Human Factors Research & Design

Today’s presentation

- Introduction to human factors engineering
- Regulatory HFE expectations
- HFE process overview
- Spotlight on use-related risk analysis (URRA)
- Spotlight on usability testing
- Ultimate objective: evidence of device use-safety

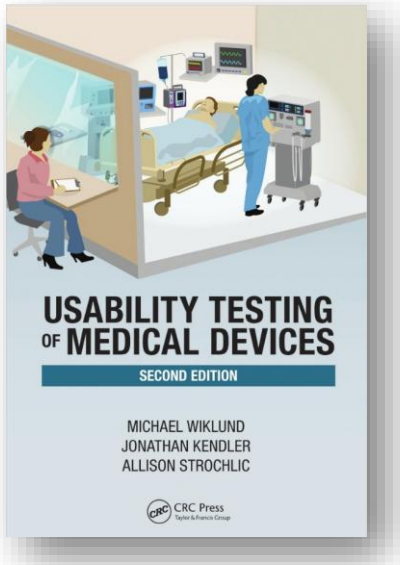
Introduction to human factors engineering

Allison Strochlic MS, CHFP

Senior Research Director – HFR&D, Emergo by UL
Certified Human Factors Professional

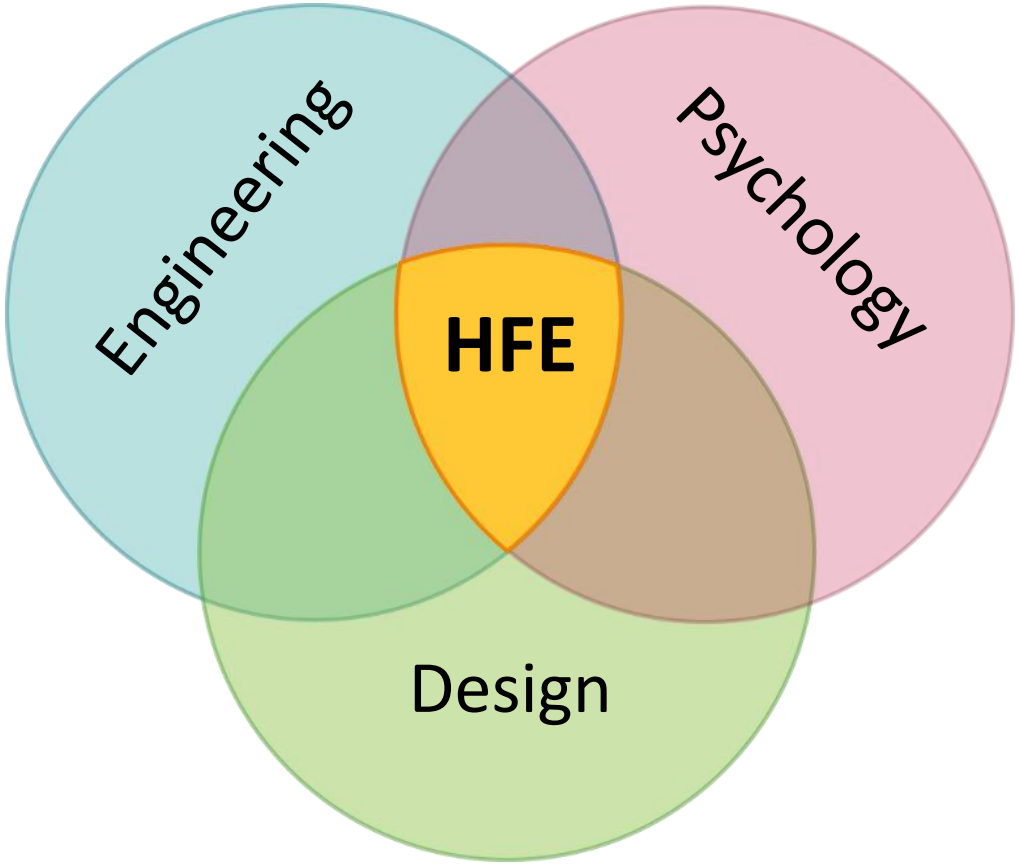
Experience:

- Over 20 years applying HFE to medical product development
- Advising manufacturers on HFE strategy and regulators' expectations
- Overseeing and leading research and analysis activities
- Helping develop and implement HFE plans and fill gaps
- Developing and delivering HFE training
- Developing and implementing HFE QMS procedures and processes



- Senior leader of Emergo by UL's global HFE consulting team
- Co-author of *Usability Testing of Medical Devices book* (1st, 2nd ed)
- Editor for *Human Factors in Healthcare* journal

What is human factors engineering (HFE)?



Key objective

Optimize the quality of interaction between people and products and help make products that are…

Safe

Effective

Satisfying

People-friendly design through science and engineering

Definition from the Human Factors and Ergonomics Society

Human factors engineering (HFE)

Sure, it’s part common sense.

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Human factors engineering (HFE)

Imagine we are designing a teapot

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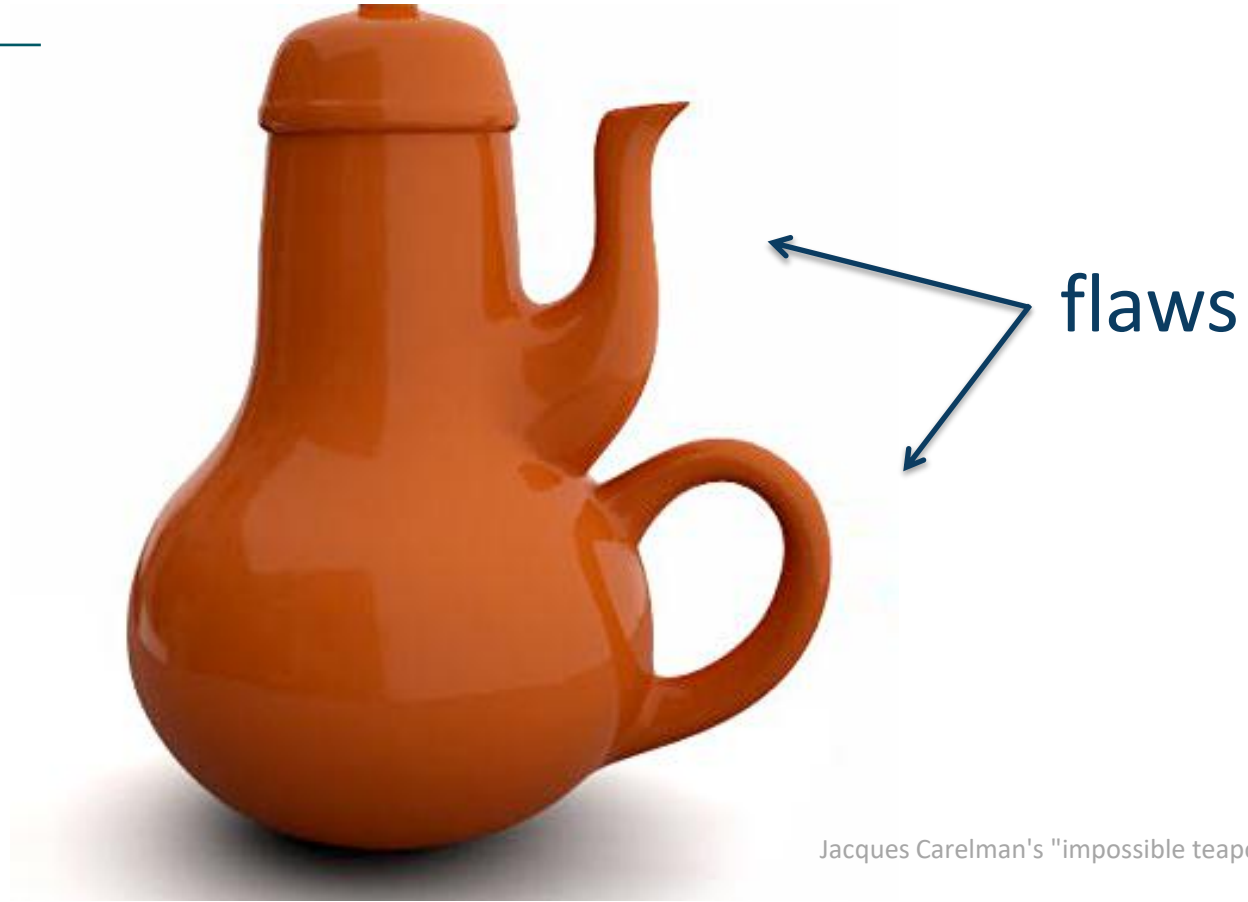
Jacques Carelman's "impossible teapot".

Human factors engineering (HFE)

Sometimes, common sense is not enough.

Detailed specification design inputs

- ☑ Capacity: 1 liter
- ☑ Spout pointing up
- ☑ Large handle
- ☑ Stable base
- ☑ Nonporous
- ☑ Lid



Jacques Carelman's "impossible teapot"

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Which can opener would you rather use?

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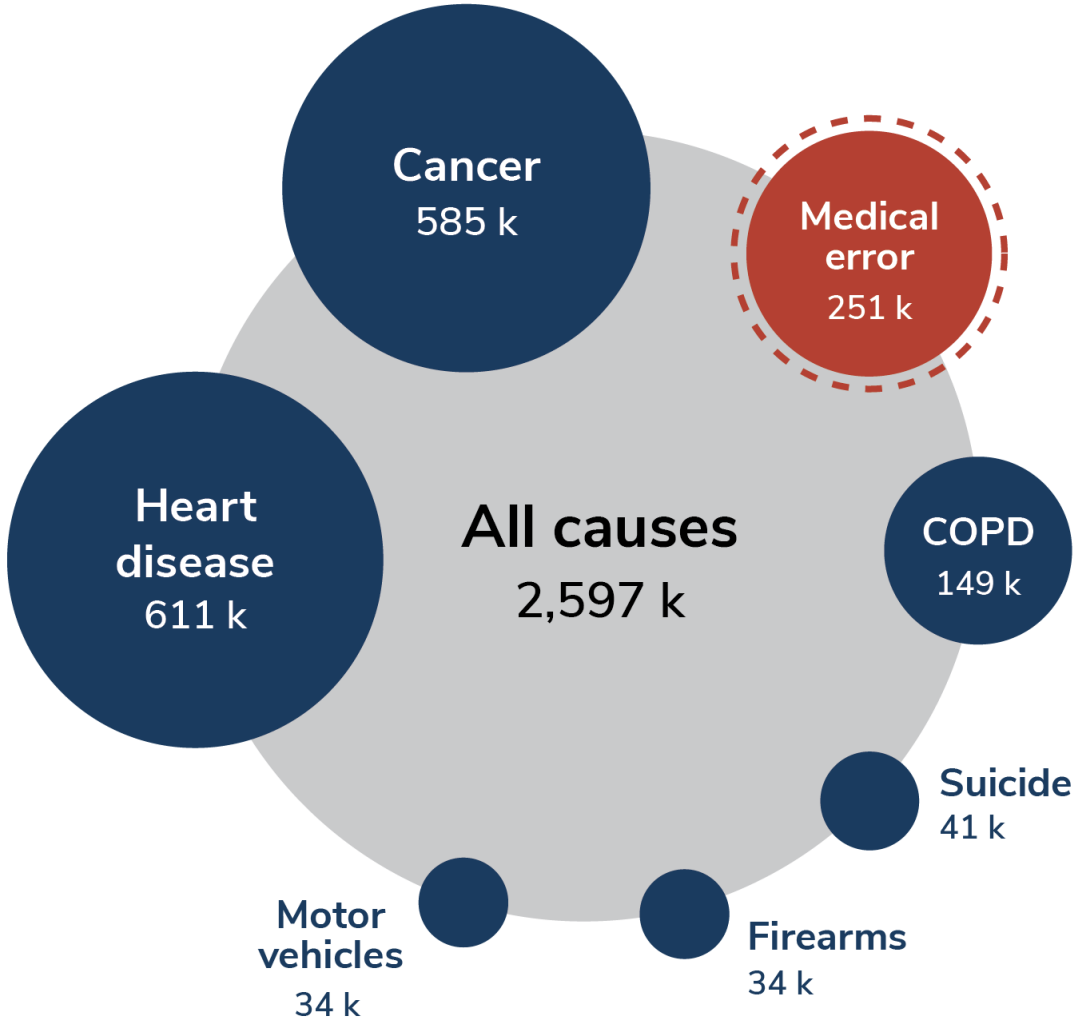
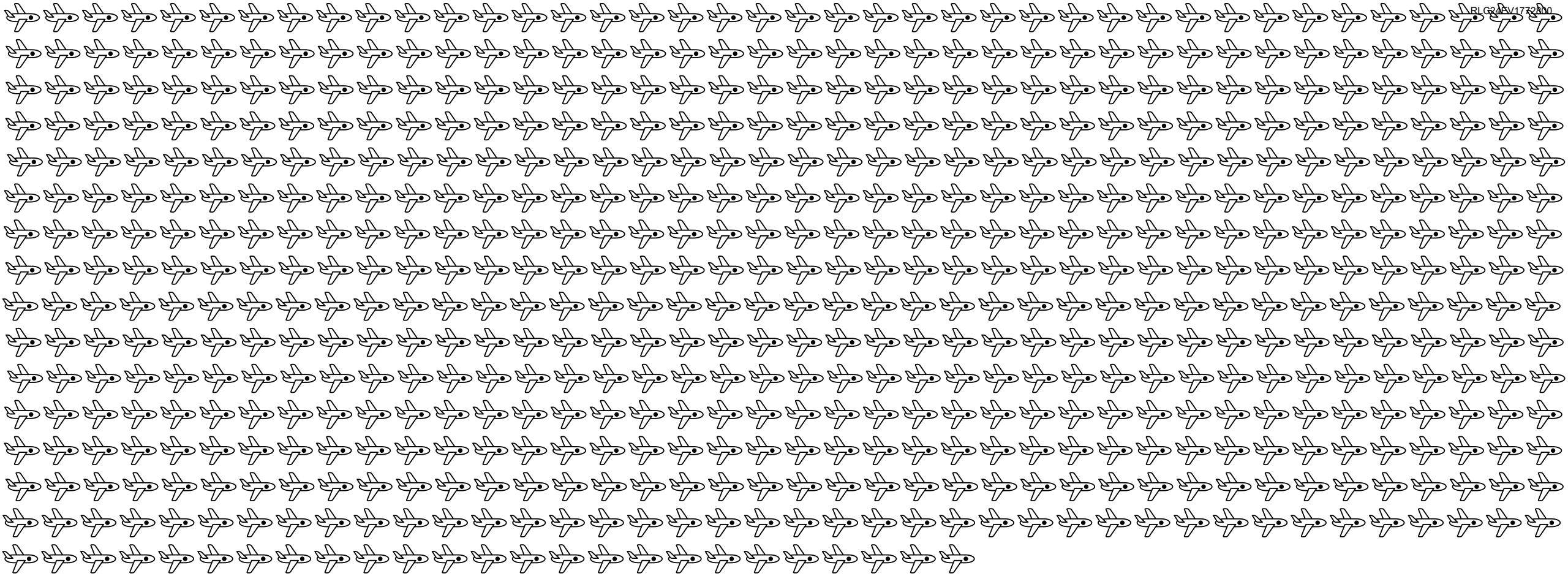
Which blood pressure cuff would you rather use?

Why apply human factors engineering (HFE) to medical devices?

Causes of death in the US, 2013



Data source: http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf



625 airplanes, each loaded with 400 passengers

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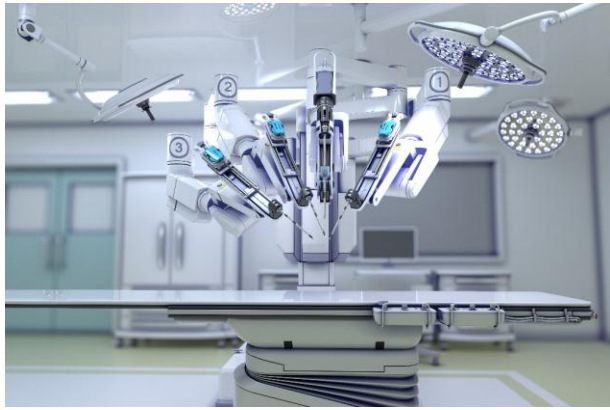
Or, the equivalent of 4 full Maracanã Stadiums

HFE applies to a wide range of medical devices



HFE work should be scaled to reflect product complexity and risk

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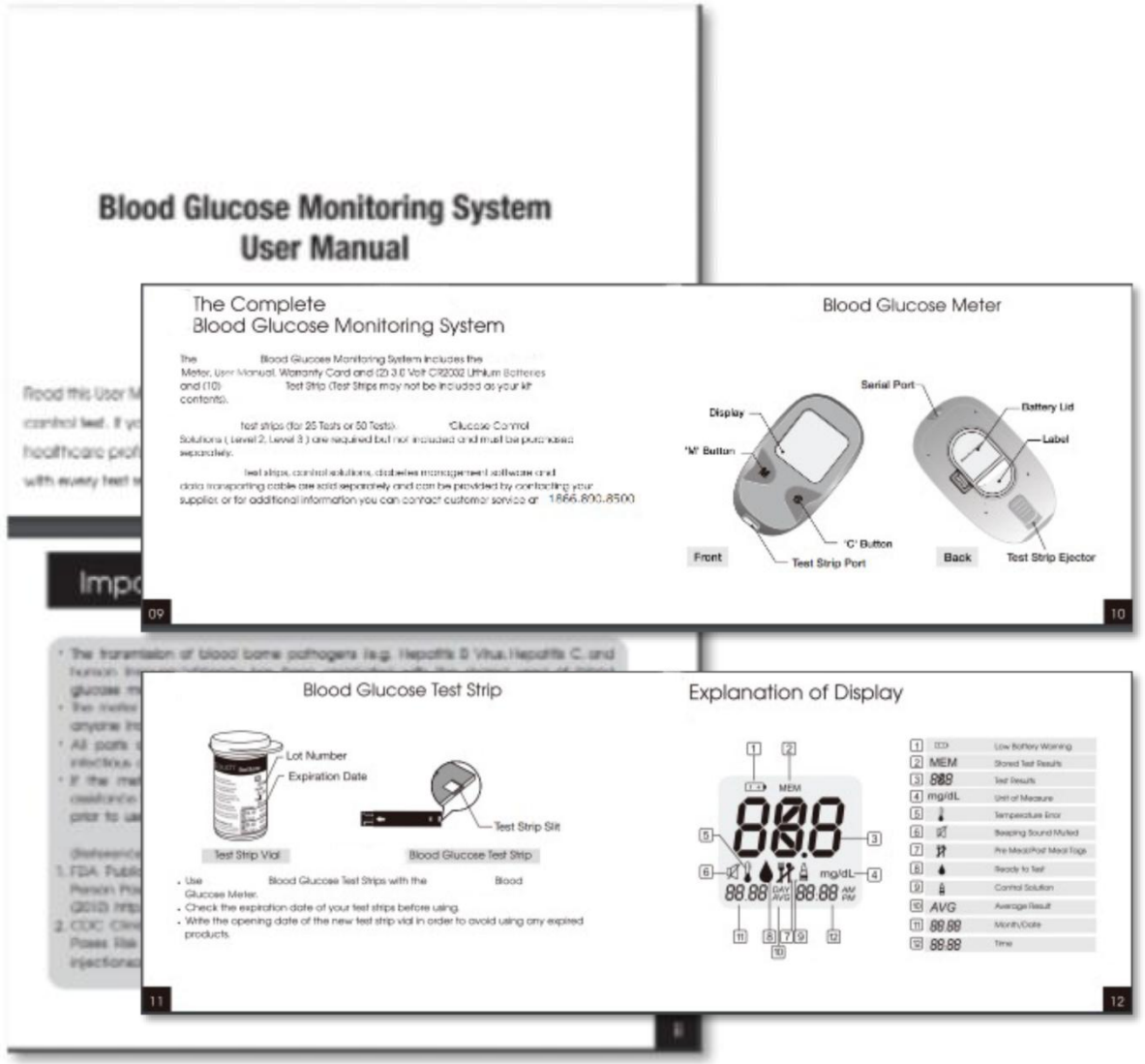
HFE should be applied to all user touchpoints



Regulatory HFE expectations

Key objective

Goal: Optimize the quality of interaction between people and products and help make products that are…

- Safe
- Effective

} Regulatory imperative

- Satisfying
- Efficient

} Commercial imperative

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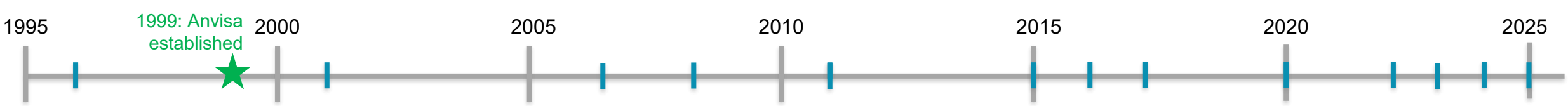

- 1996: US Quality System Regulation (QSR) with indirect HFE requirements
- 2001: ANSI/AAMI HE74 (HFE process standard)
- 2007: ISO/IEC 62366 first version; basis for CE marking as of 2008
- 2009: AAMI HE75 (HFE design standard)
- 2011: US Food and Drug Administrati E guidance
- 2015: IEC 62366-1, expanded and O 14971
- 2016: US FDA final HFE guidance; IE eport
- 2017: EU Medical Device Regulatio E guidance
- 2019: ISO 14971 risk management sta
- 2020: US FDA generic product guidance; Chi NMPA draft guidance; 62366-1:2015+AMD1
- 2021: UK MHRA HFE guidance revised post-Brexit (v2.0)
- 2022: Japanese PMDA J IST IEC 62366-1; US FDA draft submission guidance
- 2023: US FDA combination product HFE guidance

30 years of HFE progress

- 2024: Chinese NMPA final guidance, US FDA draft use-related risk analysis guidance
- 2025: AAMI HE75 updated

Sample of current HFE guidance and standards

FDA IEC AAMI MHRA NMPA CHINA

Global HFE adoption

- Varying levels of regulatory maturity
- Wide range of HFE activities and documentation required for regulatory submissions
- Wide range of review scrutiny and level of feedback provided

USA (FDA)

- High regulatory maturity and enforcement
- Many guidance documents, including for medical devices vs. combination products
- Detailed HFE reviews and feedback
- Trend: high expectations; sponsors must provide HFE data as evidence of use-safety

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Europe (Notified Bodies, European Medicines Agency, Medicines and Healthcare products Regulatory Agency)

- Moderate levels of regulatory maturity and enforcement of HFE standards and best practices
- Generally higher-level (versus detailed) reviews and HFE feedback
- Trend: increased regulatory focus due to elevated requirements

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Asia (Chinese National Medical Products Administration, Japan Pharmaceuticals and Medical Devices Agency)

- Historically, lower level of regulatory maturity and enforcement of HFE
- More recently, Chinese NMPA reviewing HFE documents in detail and providing feedback
- Chinese NMPA trending toward requiring local HFE testing data in submissions

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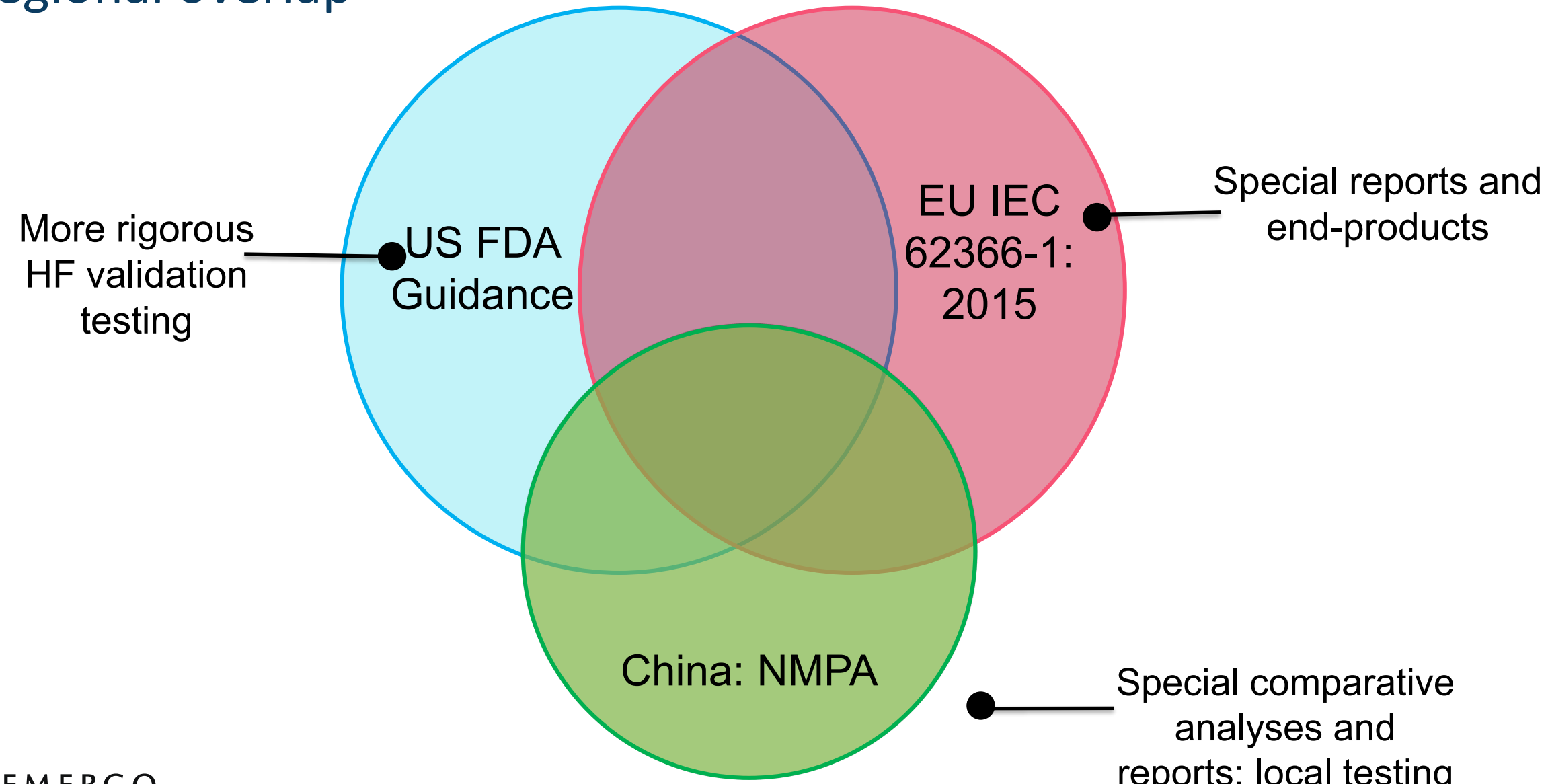
Regional overlap



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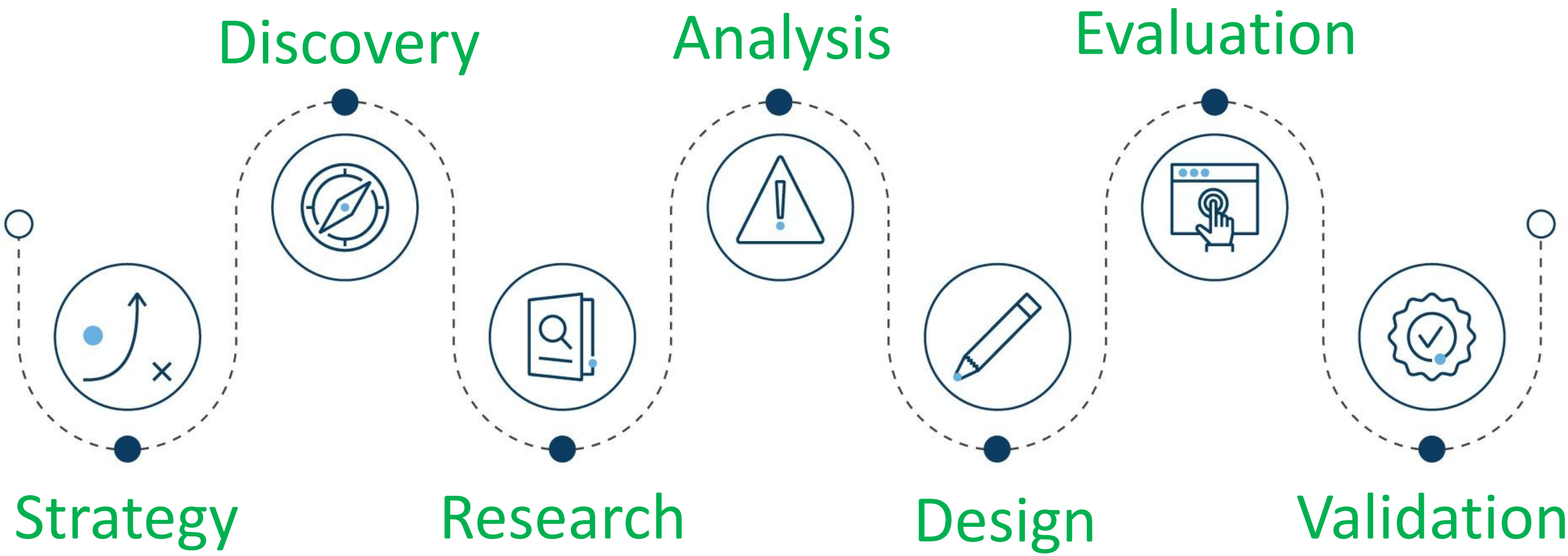
HFE process overview

Human factors process



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Spotlight on use-related risk analysis

Use-related risk analysis (URRA)

Goals:

- Determine possible use errors and harms
- Identify “critical tasks”
- Document risk mitigations, as applicable

Methods:

- Task and hazards analyses
- Known problems analysis (KPA)
- Failure modes and effects analysis

Task #	User Task	Possible use error for this task	Hazardous situation / failure mode that can result	Potential clinical harm to patient / operator	Severity of harm	Critical Task (Y/N)	Risk mitigation(s) (inherent user interface design feature, labels, information for safety, training)	HF Validation method (Simulated use scenario No. / Knowledge Task No. for critical tasks)
Task #1								
Task #2								

Ensure traceability between use-related risks, critical task mitigations, and HF validation methods

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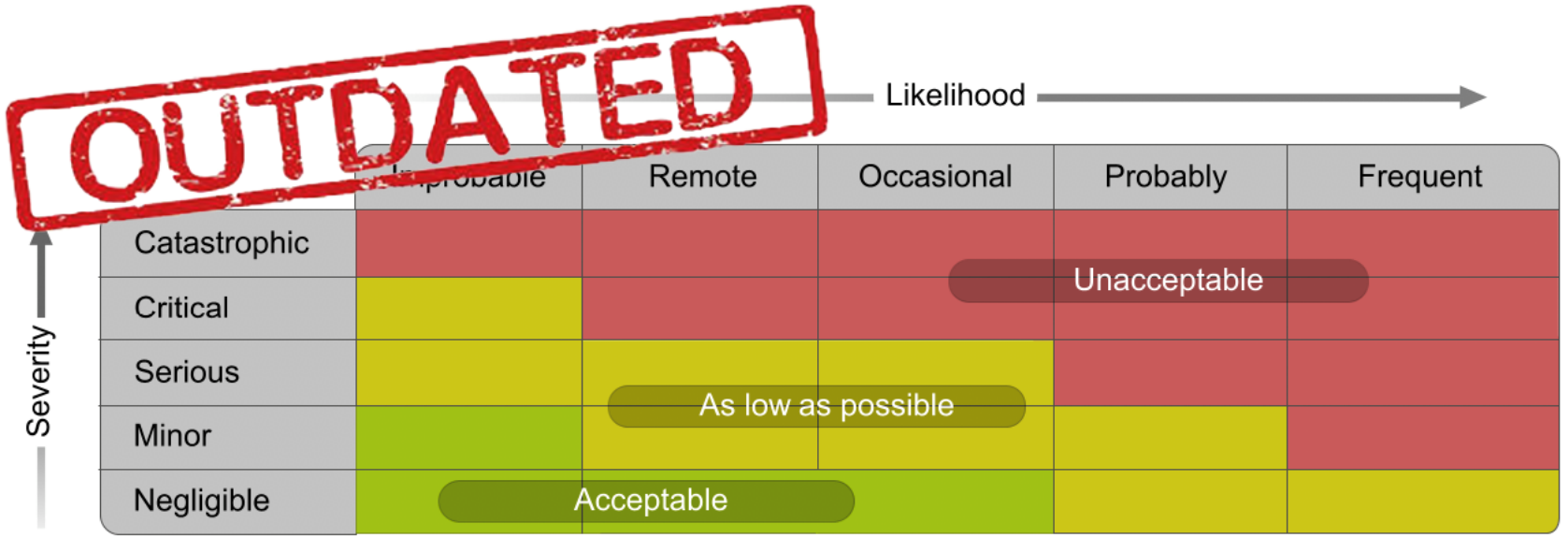
Critical tasks

- For medical devices: “A user task which, if performed incorrectly or not performed at all, **would or could cause serious harm** to the patient or user, where harm is defined to include compromised medical care.” *For combination products, any “harm.”*

- Determined based on **severity of harm only;** critical tasks have higher severity ratings (e.g., ≥ 3 on a 1-5 scale)



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Mitigation hierarchy

1. **Inherent safety by design**
   - Use specific connectors that cannot be connected to the wrong component.

2. **Protective measures** in the medical device itself or in the manufacturing process
   - Incorporate safety mechanisms such as physical safety guards, shielded elements, or software or hardware interlocks.

3. **Information for safety**
   - Provide written information, such as warning or caution statements in the user manual that highlight and clearly discuss the use-related hazard.

Spotlight on usability testing

Usability testing

Goal: Understand representative users' ability to use your product as intended.

Methods:

- Formative evaluations: Conducted iteratively during development to identify design strengths and improvement opportunities.

- HF validation (summative) test: Conducted with the finished product design, focusing on correct use, use-safety, and effectiveness

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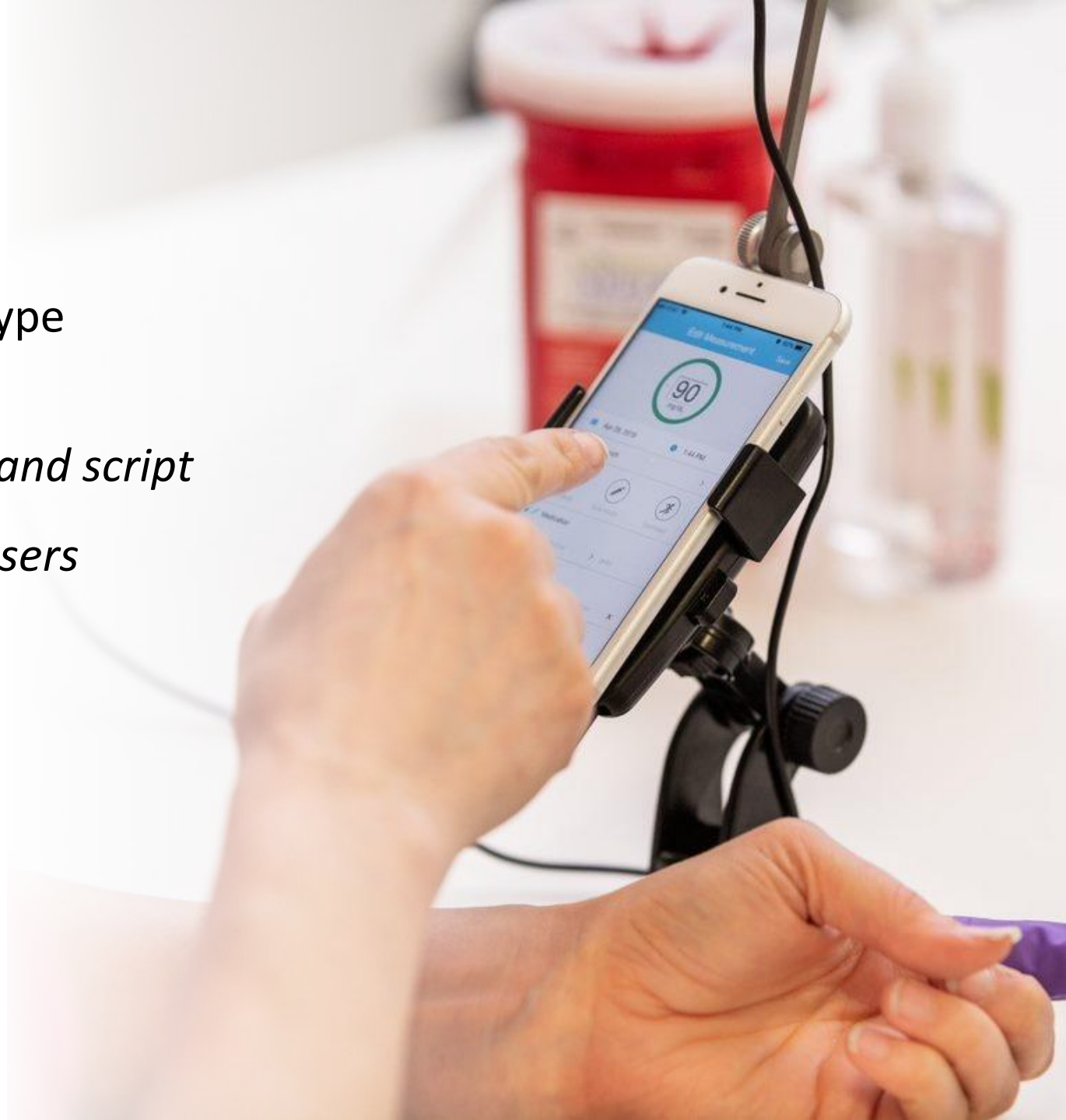
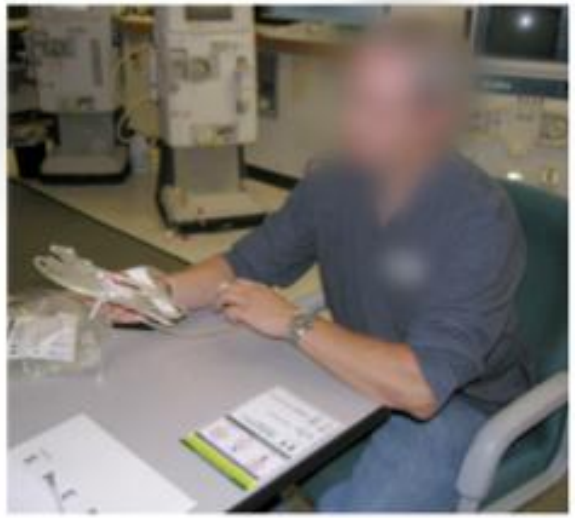
Key steps

- Identify test goals
- Determine necessary device or prototype functionality
- Develop test protocol – with *screener and script*
- Recruit participants – *representative users*
- Conduct test – *realistic scenarios*
- Analyze data – *observations, feedback*
- Write report









Ultimate objective:
Evidence of device use-safety

Summarize all HFE activities

- Prepare summary report, for example:
  - Usability Engineering (UE) file for Europe
  - HFE/UE report for US FDA *(see outline →)*
- Summarize all HFE work completed during product development, including early research, risk analyses, usability testing, etc.
- Include HF validation / summative test data, if needed – and perform residual risk analysis - to demonstrate product use-safety

Table A-1. Outline of HFE/UE Report

Sec.	Contents
1	**Conclusion** The <device> has been found to be safe and effective for the intended users, uses and use environments. • Brief summary of HFE/UE processes and results that support this conclusion • Discussion of residual use-related risk
2	**Descriptions of intended device users, uses, use environments, and training** • Intended user population(s) and meaningful differences in capabilities between multiple user populations that could affect user interactions with the device • Intended use and operational contexts of use • Use environments and conditions that could affect user interactions with the device • Training intended for users
3	**Description of device user interface** • Graphical representation of device and its user interface • Description of device user interface • Device labeling • Overview of operational sequence of device and expected user interactions with user interface
4	**Summary of known use problems** • Known use problems with previous models of the subject device • Known use problems with similar devices, predicate devices or devices with similar user interface elements • Design modifications implemented in response to post-market use error problems
5	**Analysis of hazards and risks associated with use of the device** • Potential use errors • Potential harm and severity of harm that could result from each use error • Risk management measures implemented to eliminate or reduce the risk • Evidence of effectiveness of each risk management measure
6	**Summary of preliminary analyses and evaluations** • Evaluation methods used • Key results and design modifications implemented in response • Key findings that informed the human factors validation test protocol
7	**Description and categorization of critical tasks** • Process used to identify critical tasks • List and descriptions of critical tasks • Categorization of critical tasks by severity of potential harm • Descriptions of use scenarios that include critical tasks
8	**Details of human factors validation testing** • Rationale for test type selected (i.e., simulated use, actual use or clinical study) • Test environment and conditions of use • Number and type of test participants • Training provided to test participants and how it corresponded to real-world training levels • Critical tasks and use scenarios included in testing • Definition of successful performance of each test task • Description of data to be collected and methods for documenting observations and interview responses • Test results: Observations of task performance and occurrences of use errors, close calls, and use problems • Test results: Feedback from interviews with test participants regarding device use, critical tasks, use errors, and problems (as applicable) • Description and analysis of all use errors and difficulties that could cause harm, root causes of the problems, and implications for additional risk elimination or reduction

Claim device use-safety and effectiveness

The [device] has been found to be safe and effective for the intended users, uses and use environments.

Contact information

Emergo by UL HFR&D practice locations

United States (Boston and Chicago) | United Kingdom | The Netherlands | Japan | China

Presenter contact information

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To be added – QR code

Scan to connect on LinkedIn!

For HFE training, tools, and templates, check out our HFE digital platform
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