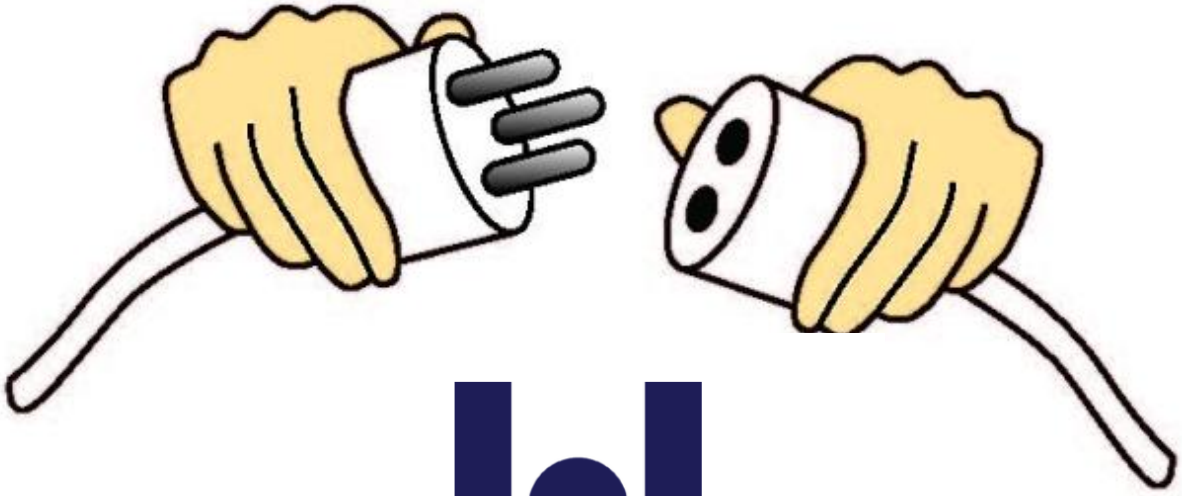
Human Factors:
What Does This Really Mean for Medical Devices



UserWise

Shannon E. Clark

Overview

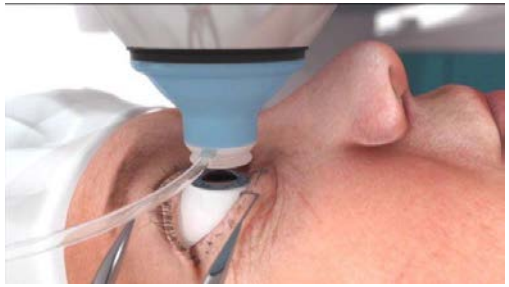
1. What is Human Factors?
2. Why is Human Factors Engineering Important?
3. What is the Human Factors Process for medical device development?

Background: Shannon Clark

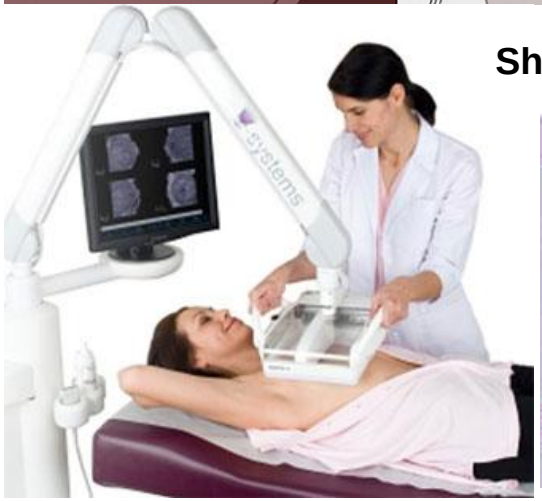
Summary: Over 6 years of experience in medical device development, including human factors engineering, design, usability testing, usability risk analysis, risk management, V&V, CAD modeling, ergonomics, training development, marketing, compliance, auditing quality systems, and supervision

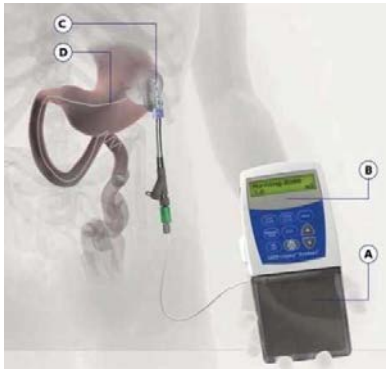
Certifications/Trainings:
•ISO 13485 Lead Auditor (2012)
•AAMI Quality System (2012)
•AAMI Risk Management (2012)
•AAMI Human Factors (2011)
•Certified Professional Industrial Engineer, California (2014)

Articles and Patents
Total Recall: The Consequence of Ignoring Medical Device Usability, UX Magazine, 2012
http://www.usabilityprofessionals.org/uxmagazine/total-recall/
Patent: Method and System for Sizing an Oral Device, U.S. Patent Office #20120037166, February 2012.
Patent: Portable document camera and assembly for enabling same, U.S. Patent Office #20120169888, December 2015



Shannon Clark's Product Development Experience





Abbott

APNICURE

zansors
know yourself
personal health analytics

deton

PRESCIENT SURGICAL™

INTUITIVE SURGICAL®

UserWise Company Information

Location
919 The Alameda, San Jose, CA 95126

Company Mission
Our mission is to inspire usability engineering best practices within medical device companies and to facilitate the development of usable medical devices.

Personnel
- Principal Human Factors Consultant
- Three Human Factors Specialists
- Graphic Designer
- Engineering Intern

What is Human Factors Engineering?

FDA's Definition:

The application of knowledge about human behavior, abilities, limitations…to the design of medical devices including

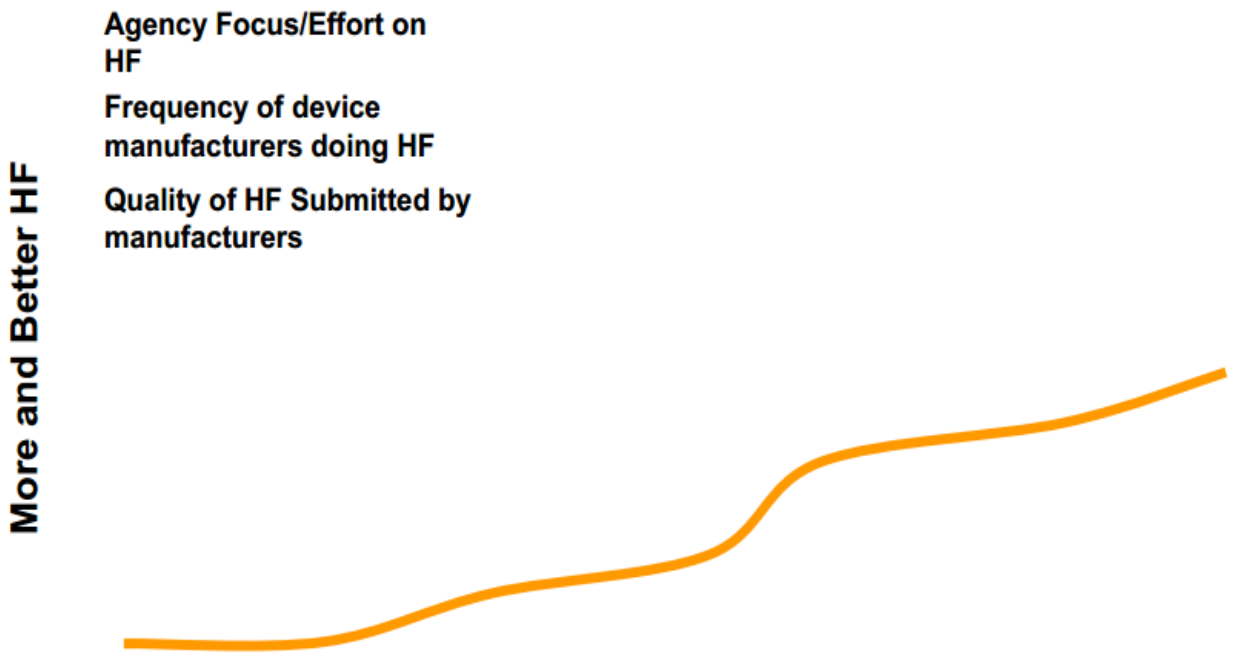
- mechanical and software driven user interfaces…
- user documentation, and
- user training

to enhance and demonstrate safe and effective use.

Synonyms

- human factors engineering
- usability engineering
- user experience design
- user centered design
- cognitive engineering
- human engineering
- ergonomics

Adoption of Human Factors



QSR	2000 Gdnce / HE 74	HF to ODE	HF Staff + / HE75
1996	2000	2006	2009

Source: FDA.gov

Contains Nonbinding Recommendations

Applying Human Factors and Usability Engineering to Medical Devices

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Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016

As of April 3, 2016, this document supersedes "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" issued July 18, 2000.

The draft of this document was issued on June 21, 2011.

For questions regarding this document, contact the Human Factors Premarket Evaluation Team at (301) 796-5580.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

International Human Factors Standards

Standard	Title	Main Purpose
AAMI/ANSI HE75:2009	*Human Factors Engineering – Design of Medical Devices*	Comprehensive reference that includes general principles, management of use error risk, design elements, integrated solutions
ANSI/AAMI/IEC 62366-1:2015	*Medical devices – Part 1: Application of usability engineering to medical devices*	HFE/UE process applied to all applying HF/usability to medical device design, with consideration of risk management
ANSI/AAMI/ISO 14971:2007/(R)2010	*Medical Devices – Application of risk management to medical devices*	Risk management process for medical devices
IEC 60601-1-6:2010	*Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*	Provides a bridge between IEC 60601-1 and ANSI/AAMI/IEC 62366
IEC 60601-1-8 Edition 2.1 2012-11	*Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*	Design standard for alarm systems in medical electrical equipment and systems
IEC 60601-1-11:2010	*Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*	Requirements for medical electrical equipment used in non-clinical environments, including issues involving medical device use by lay users

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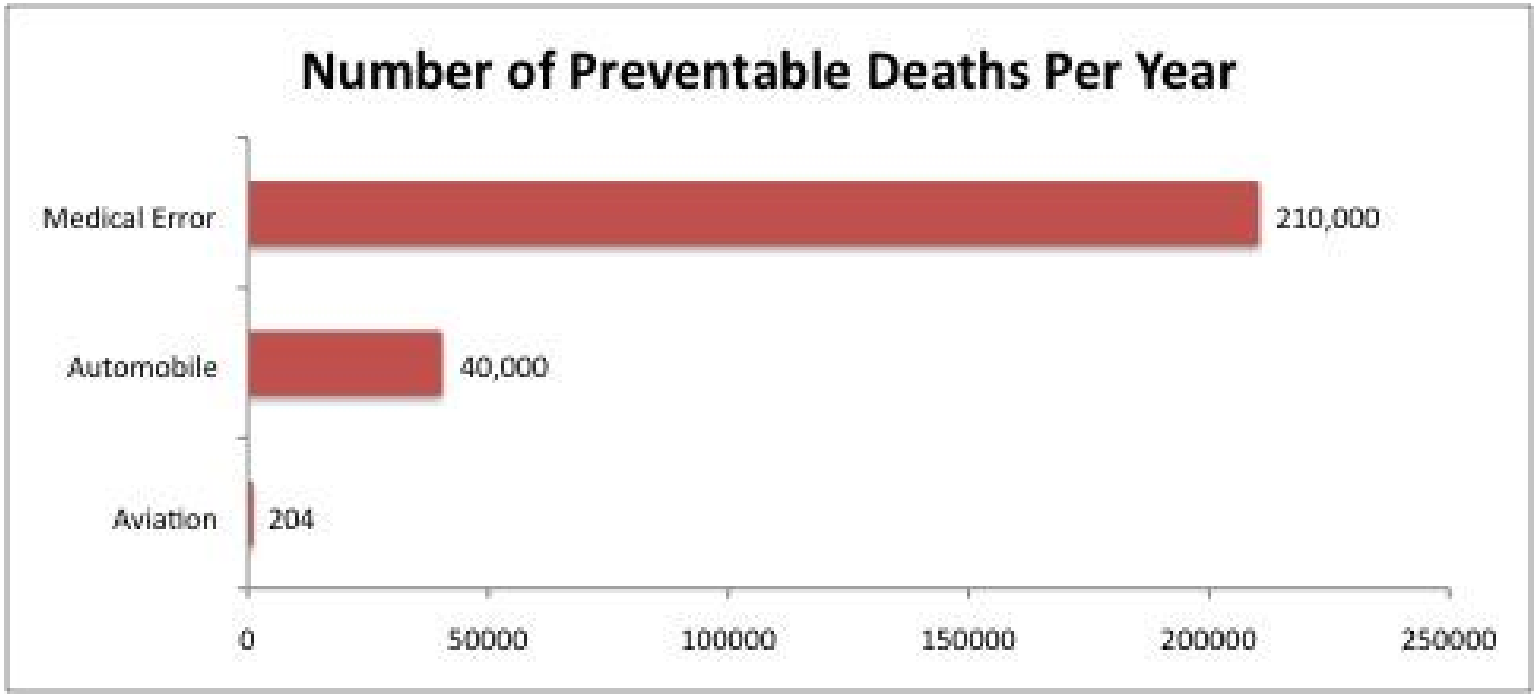
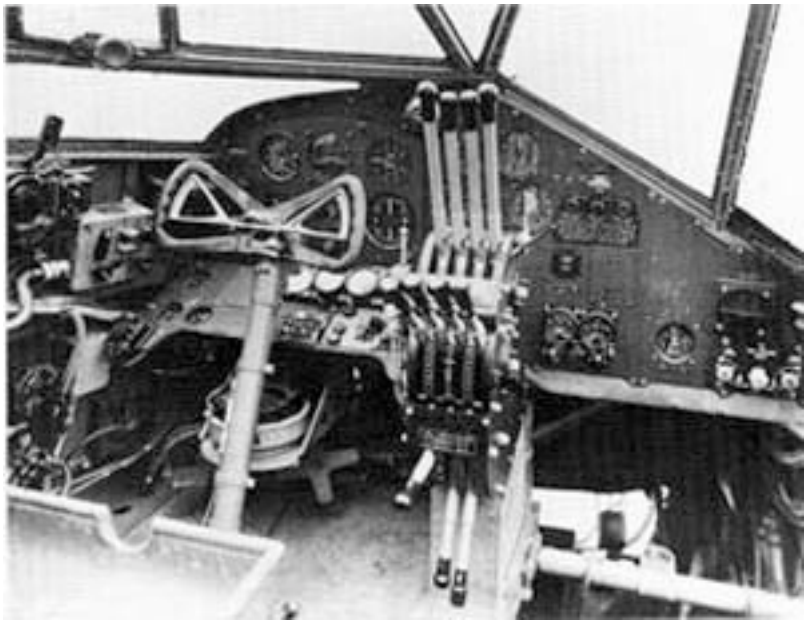


Conservatively estimated, there are 210,000 preventable hospital deaths annually in the United States.

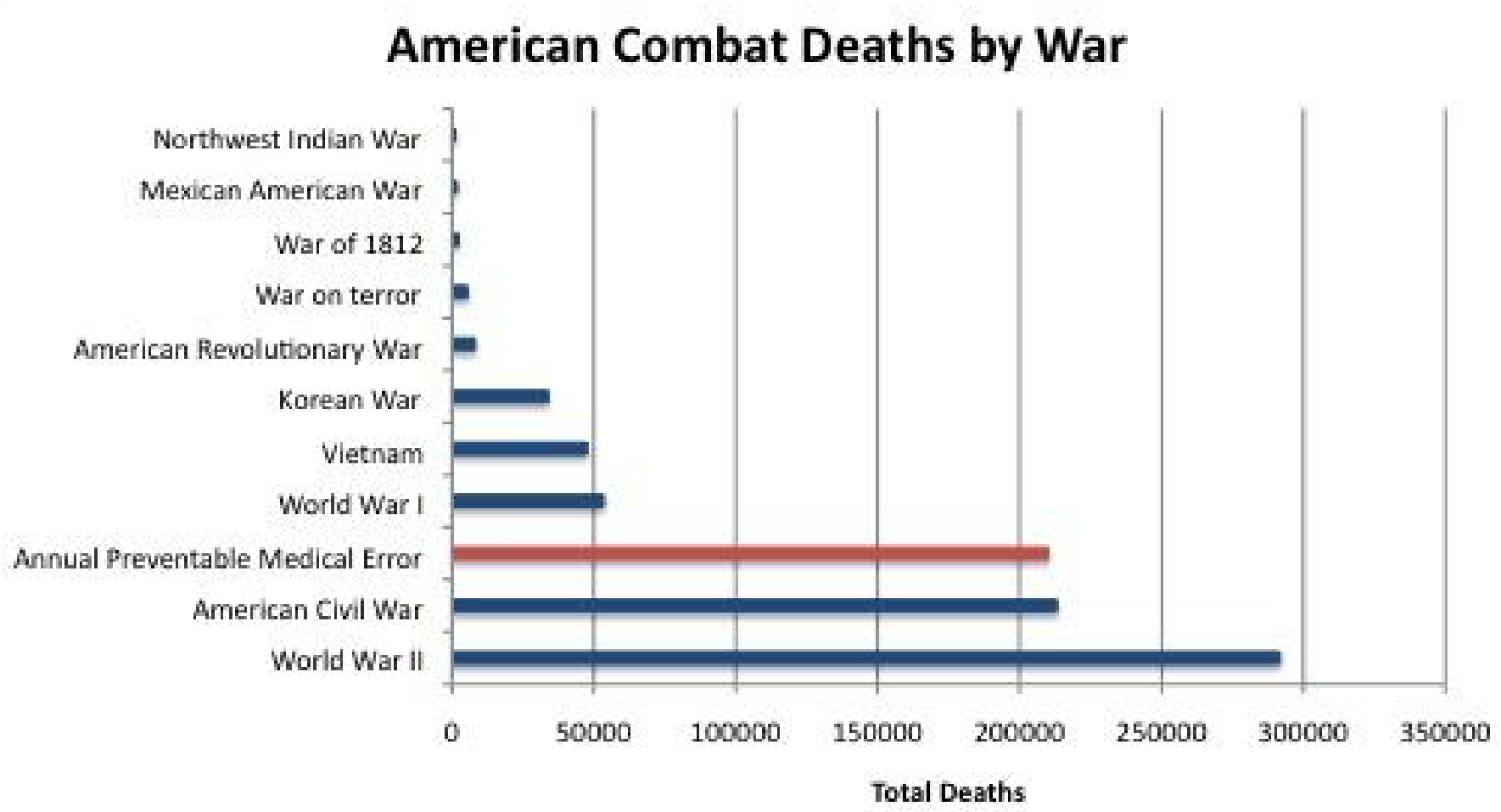
J Patient Saf & Volume 9, Number 3, September 2013

Human Factors in Aviation

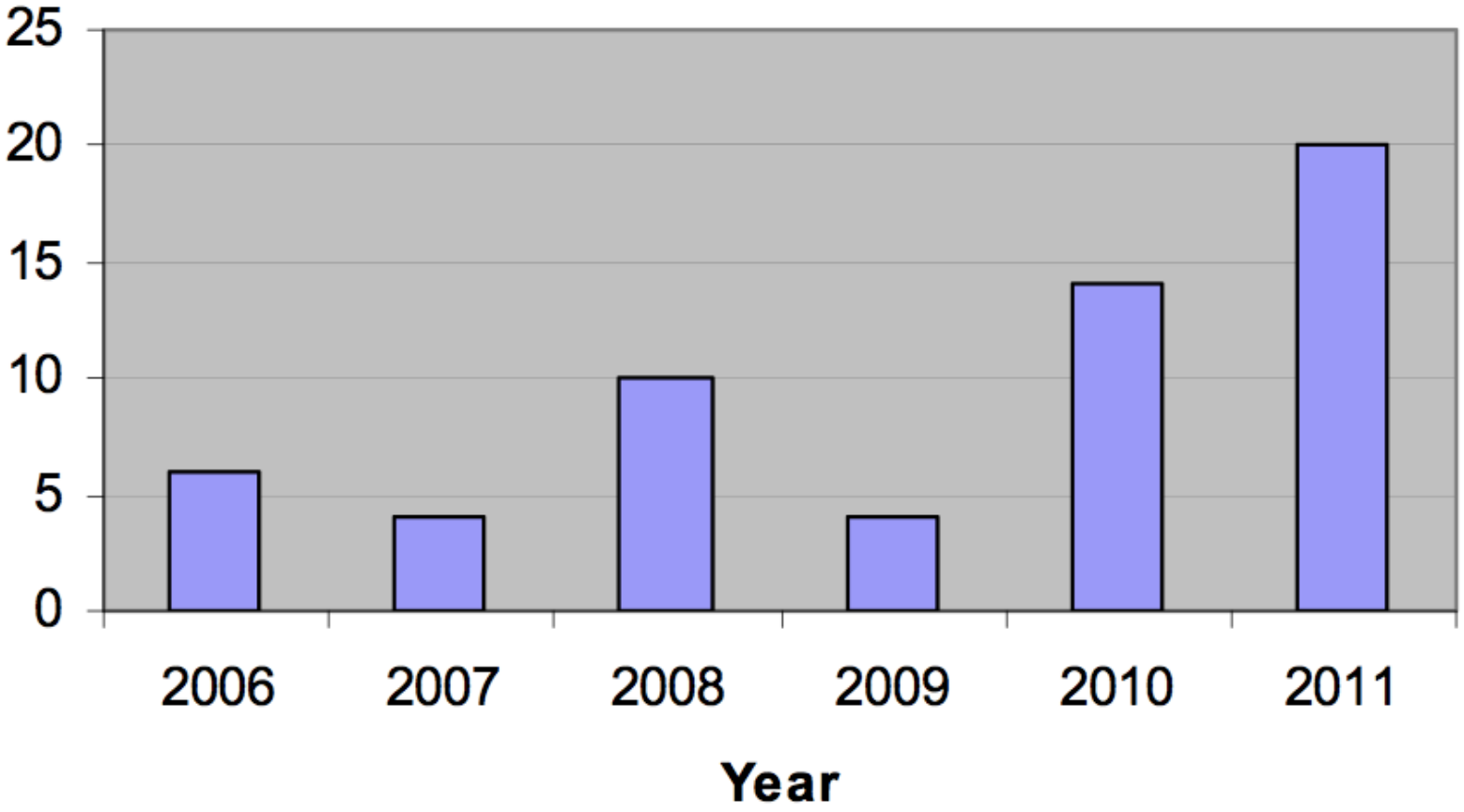


Source: Fitts, P.M., & Jones, R.E. 1947a, Analysis of factors contributing to 460 "pilot error" experiences in operating aircraft controls, Report No. TSEAA-694-12

Image: http://spitfirespares.co.uk/Website%20Products%20284/halifax%20cocpit.jpg



Medical Device Recalls due to Usability Issues



ACUSON Antares Ultrasound system by Siemens

- Ultrasound System was recalled in 2008
- The graphics made users misunderstand the image orientations of the patient's left and right sides. The users made the assumption that the patient's right and left sides were oriented in the same direction as the transducer, but this assumption was incorrect.

Bausch & Lomb MicroFlow 2.2 30 Phaco Needle

- Recalled in 2010
- Users may incorrectly assemble the plastic needle wrench to the phacoemulsification needle resulting in the generation of plastic particulate during cataract surgery.

List of Highest Priority Devices for Human Factors Review

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 February 3, 2016.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

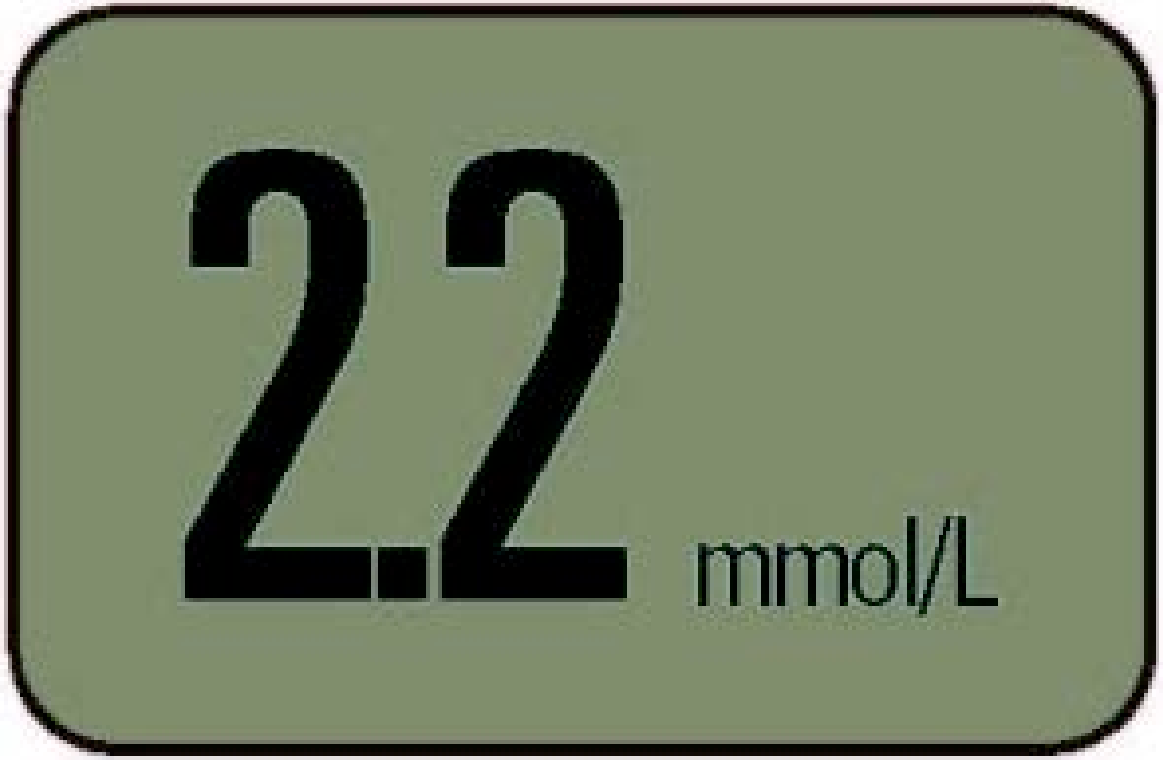
For questions regarding this document, contact the Human Factors Premarket Evaluation Team at (301) 796-5580.

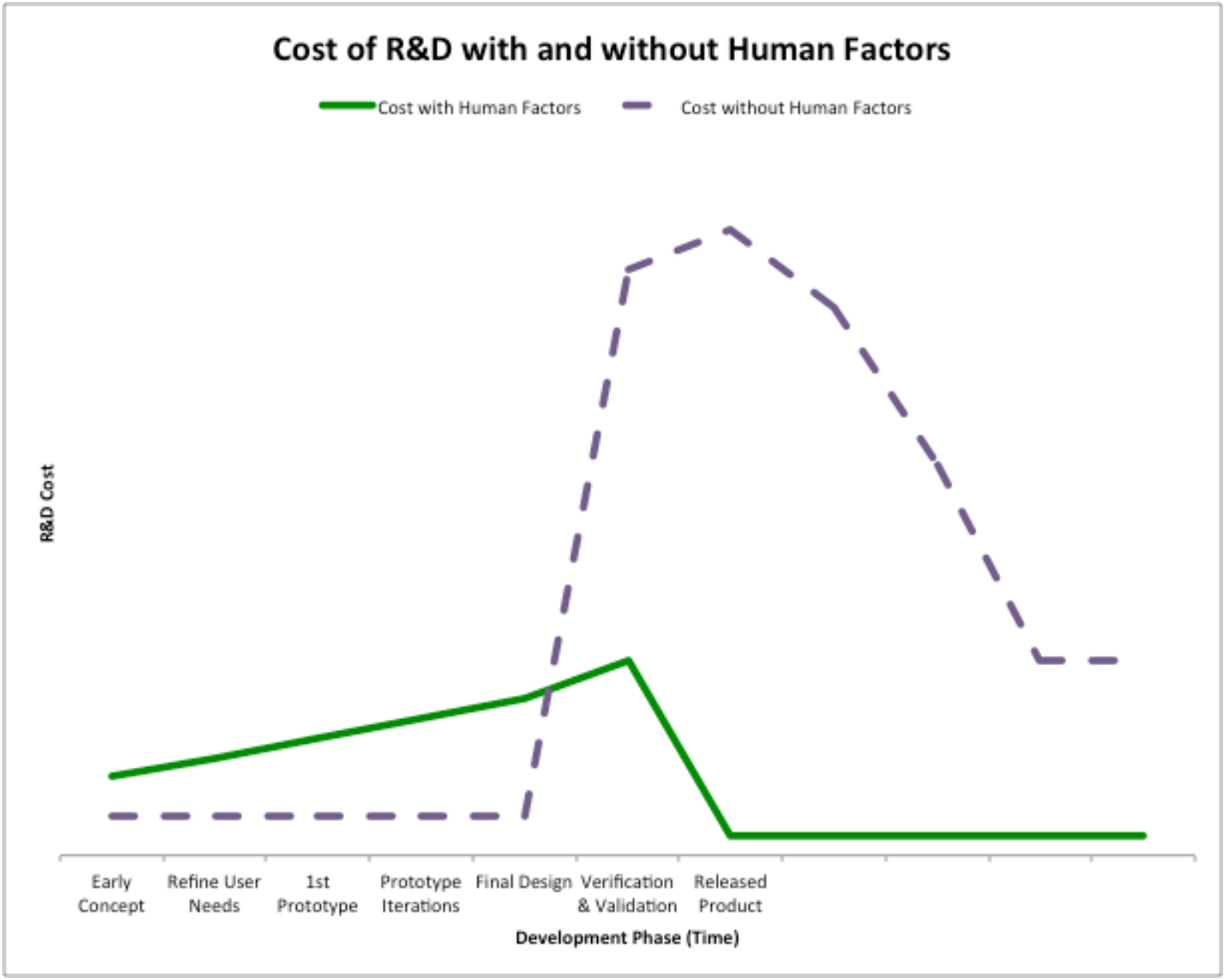
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

AED 10 and MRL Jumpstart Welch Allyn Protocol, Inc

- AED was recalled in 2009
- Possible for users to misunderstand low battery indicator signals and subsequently cease use of the device unnecessarily.

Glucose Meter Recall

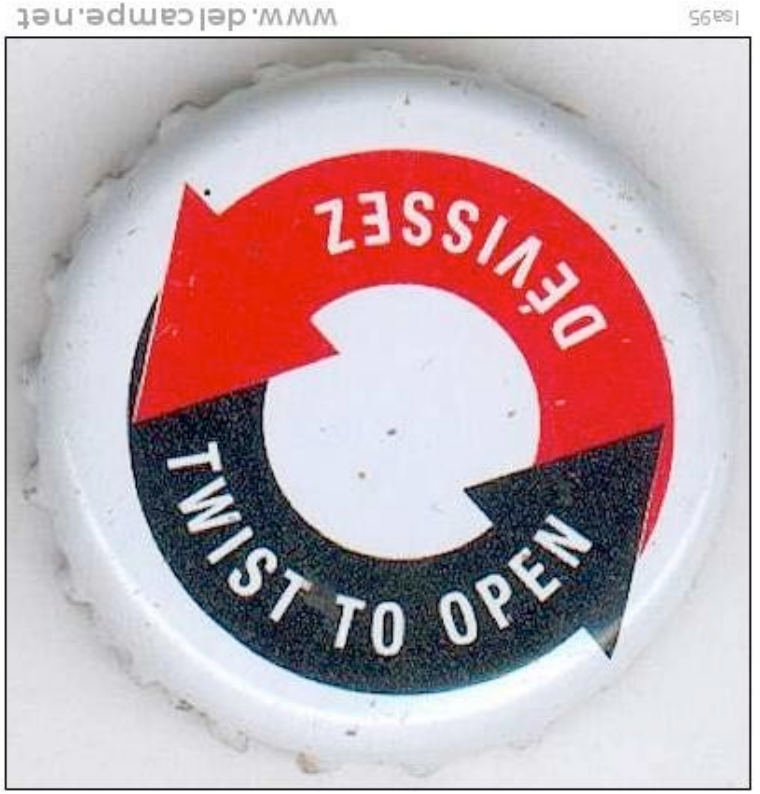




Shannon's Three Mantras

- Give users what they NEED, not necessarily what they say they want.
- Make the user experience "invisible"
- Minimize/Eliminate the need for training, where possible.

Give users what they NEED, not necessarily what they say they want



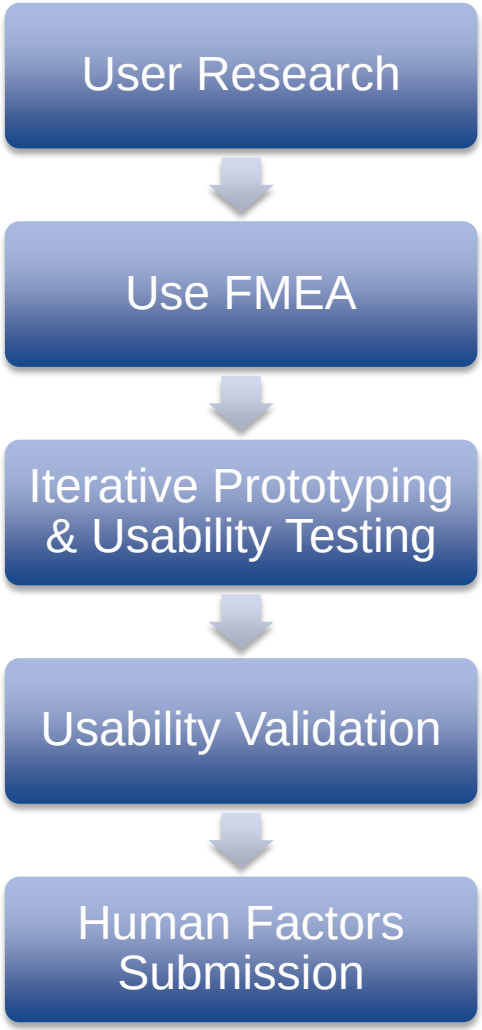
Make the user experience "invisible"

- Sensor that tracks tachychardia in elderly patients
- Upload data to computer?
  - USB cord?
- Does this user interface really need to exist?

Minimize/Eliminate the need for training, where possible

- Hospital Glucose Meter
  - Dose Calculation
  - Patient tracking
  - Cleaning Process

Human Factors Process



What is Early Stage Human Factors Research?

User Research

- Find out what people are really thinking through observation at point of use.
  - Actions speak louder than words.

What is Early Stage Human Factors Research?

User Research

- Identify environmental, social, and motivational considerations for the design.

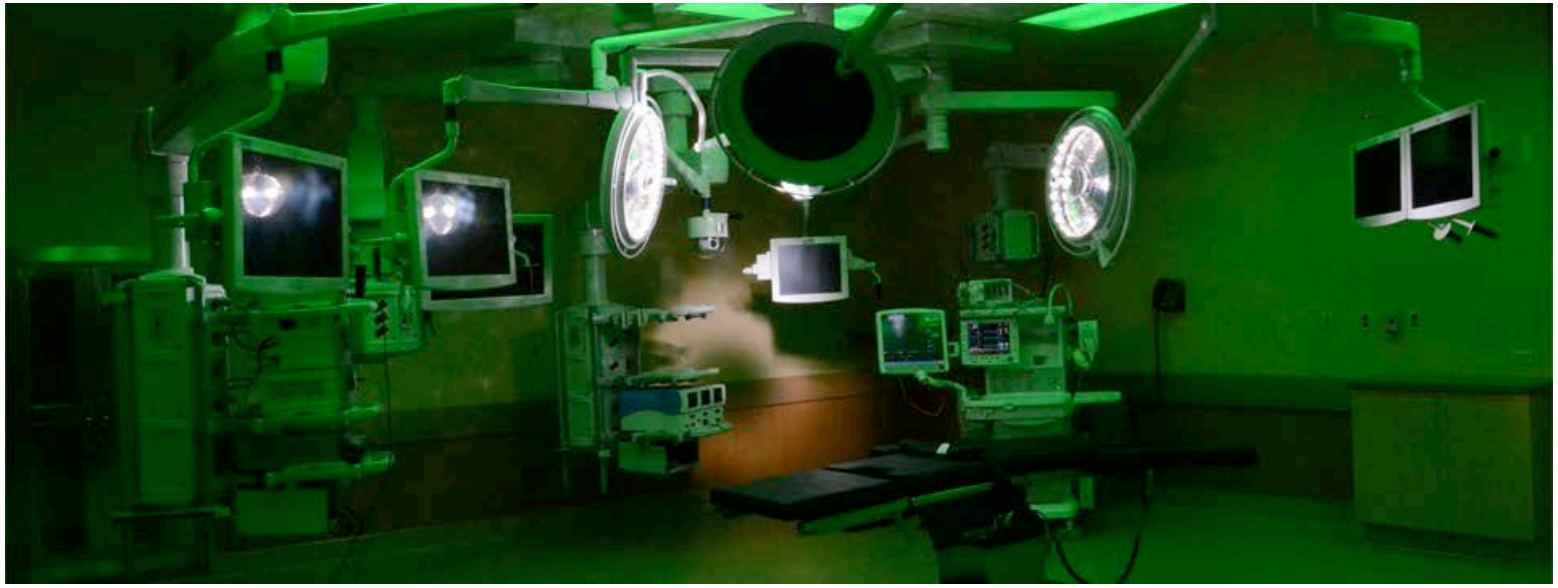


Image: http://www.greenelectric-inc.com/data1/images/operating_room_under_green_light.jpg

What is Early Stage Human Factors Research?

User Research

- Use appropriate sample, representative of ALL user types.

Image: http://www.sumcrenewal.org/wp-content/uploads/NHS.jpg

Image: http://seeclickfix.com/issues/73708-ugly-building

What is Early Stage Human Factors Research?

User Research

- Observation can help you ask better questions

Example 1:

- Do you prefer to use a surgical stapler or suturing for that activity?

  vs.

- What method do you use to achieve a seal?

Example 2:

- What percentage of the time do you clean the injection site, first?

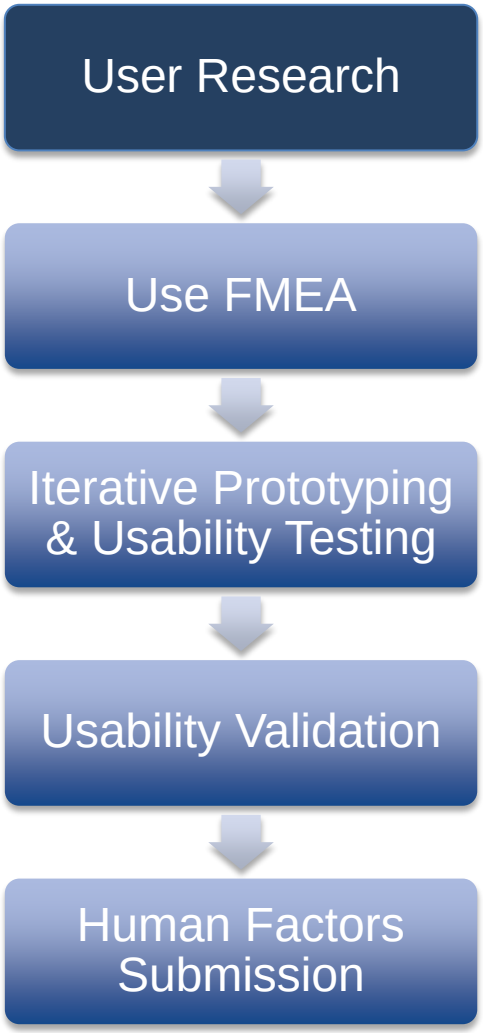
  vs.

- What challenges do you encounter when preparing the site?

Tips for User Research

- Enter with an open mind
- Observe directly
- Don't lead or prompt the user
- Keep neutral body language

Human Factors Process



User Research Outputs:

- User Profile Description
- Use Environment Description
- Training Description
- Known Use Error Summary
- Customer Requirements
- Product Requirements
- Task Analysis

Use FMEA

Task	Hazard	Use Errors	Use Error Probability	Hazard Severity	Risk Level	Method of Control	Effectiveness of Control	Risk Level with Control	Risk Acceptability
1. Open case	Delay in therapy	Difficulty / unable to open case	3	5	15	Use fabric case with hook-and-loop closures	1	15	Acceptable with review
	Broken / torn fingernail	Use fingernail to open latch	1	2	2	No latch	1	2	Acceptable
2. Tear open electrode package	No therapy delivered	Package missing as result of not being replaced from previous use	3	5	15	Design case with slot positions for accessories; missing item obvious; recommend admin procedures using seals	2	30	Acceptable with review
	No therapy delivered	Tear electrode when attempting to open package	3	5	15	Provide "zipper" closure that allows easy opening of sealed package; construct electrode with non-tear backing	1	15	Acceptable with review
	Delay in therapy	Difficult / unable to open package	3	5	15	Provide "zipper" closure that allows easy opening of sealed package	1	15	Acceptable with review
3. Expose upper chest of patient	Non-delivery of shock	Clothing not adequately removed	2	5	10	Provide scissors; provide pictorial and auditory instructions	2	20	Acceptable with review
	Burn caused by metallic object in clothing	Wire in under-garment or metal fastener left in place	2	3	6	Provide pictorial and auditory instructions	3	18	Acceptable with review
4. Peel backing from electrodes	Delay in therapy	Difficulty removing backing	3	5	15	Provide extended tab which allows easy removal of backing	1	15	Acceptable with review
	Non-delivery of shock	Used without moving backing	2	5	10	Detection circuit will alarm because EKG signal will not be detected with insulated electrodes	1	10	Acceptable with review
5. Apply electrodes to chest	Shock not delivered properly	Improper positioning	3	5	15	Provide pictorial and auditory instructions	3	45	Acceptable with review
	Local burn	Electrodes placed too close together	2	3	6	Provide pictorial and auditory instructions	3	18	Acceptable with review

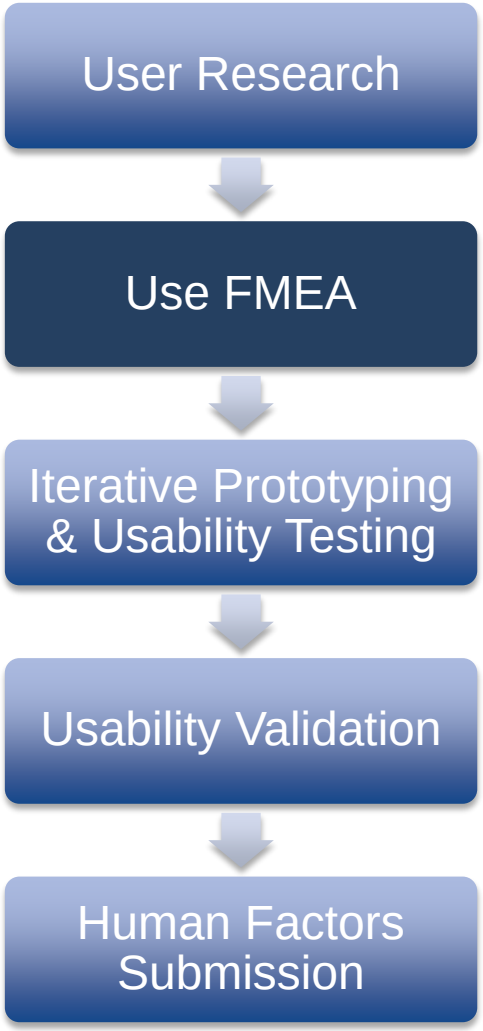
http://uxpamagazine.org/total-recall/

Use FMEA

Use Error Mitigation: Hierarchy of Actions

1. Design out the use error
2. Guard against the use error
3. Warn
4. Information for safety
    a) Labeling
    b) Instructions for Use
    c) Training
5. Remove feature

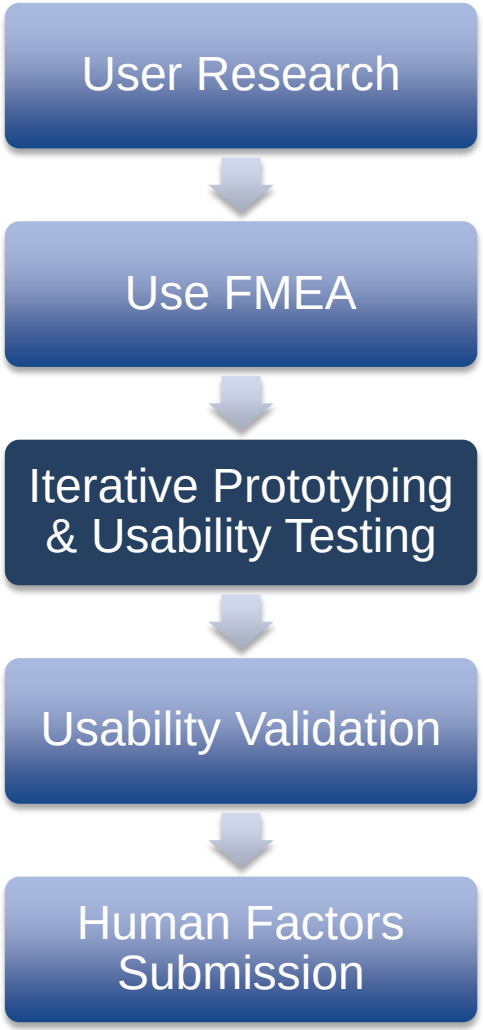
Human Factors Process



Risk Analysis Outputs:

- Use FMEA
- Design Requirements that ensure safe use

Human Factors Process

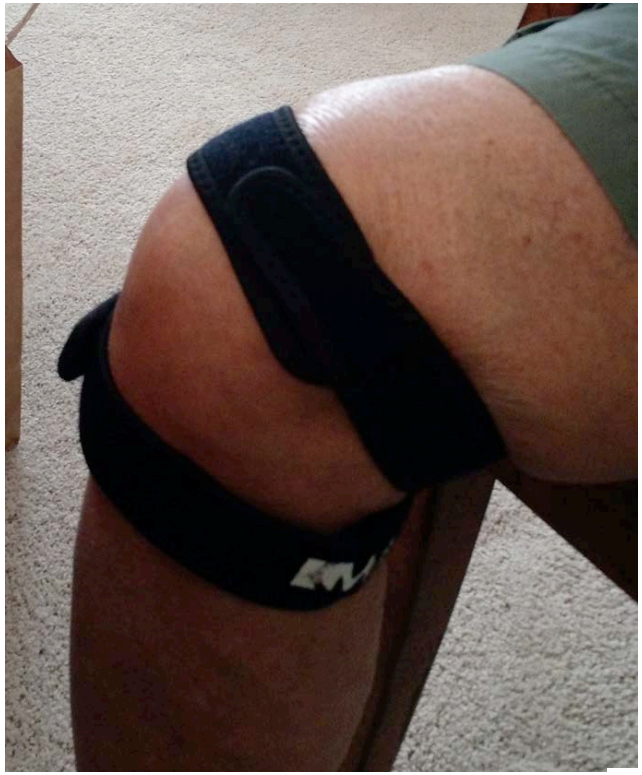


Usability Testing Outputs:

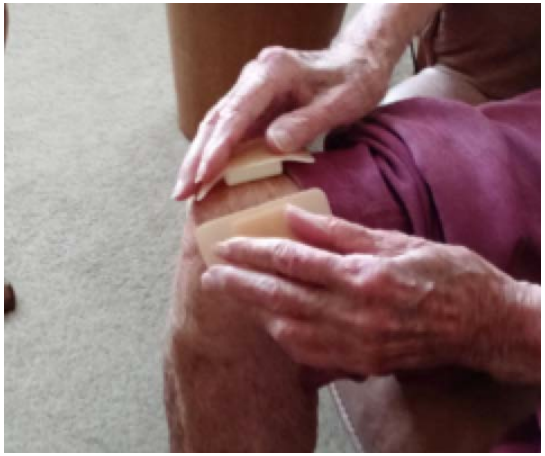
- New Requirements
- Easy-to-use prototype
- Long-term Cost savings
- Usability Test Reports to support robust submission

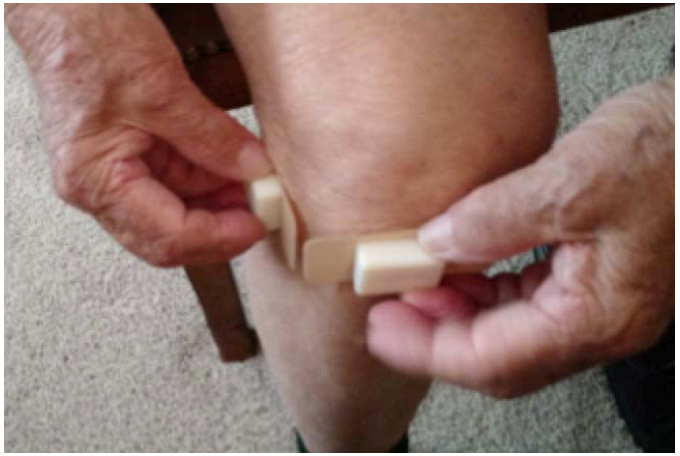
Comparative Usability Study Example

- Where do users naturally place the device?
- Which design is preferred?
- Which design is safest?

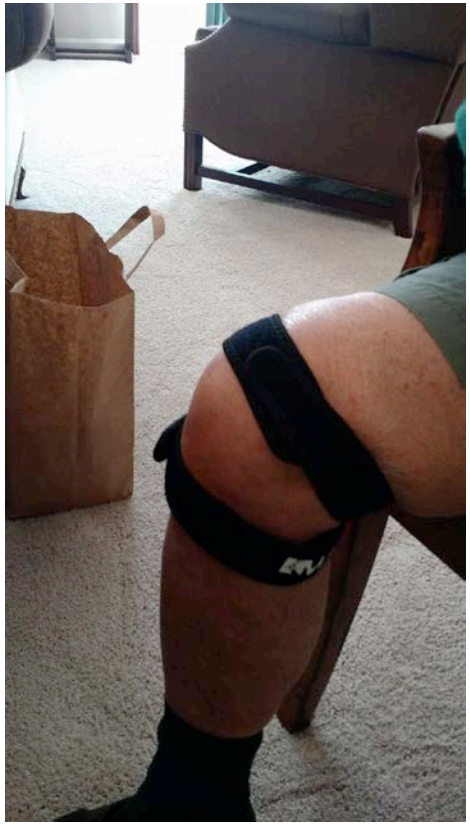


Prototype 1 Placement



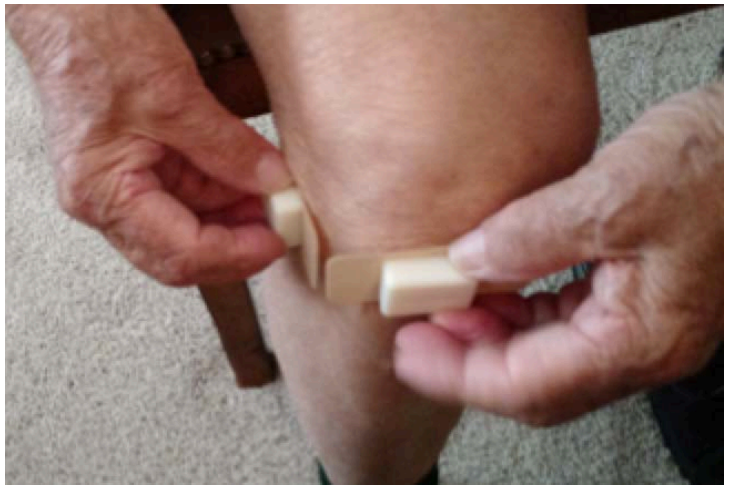


Prototype 2 Placement



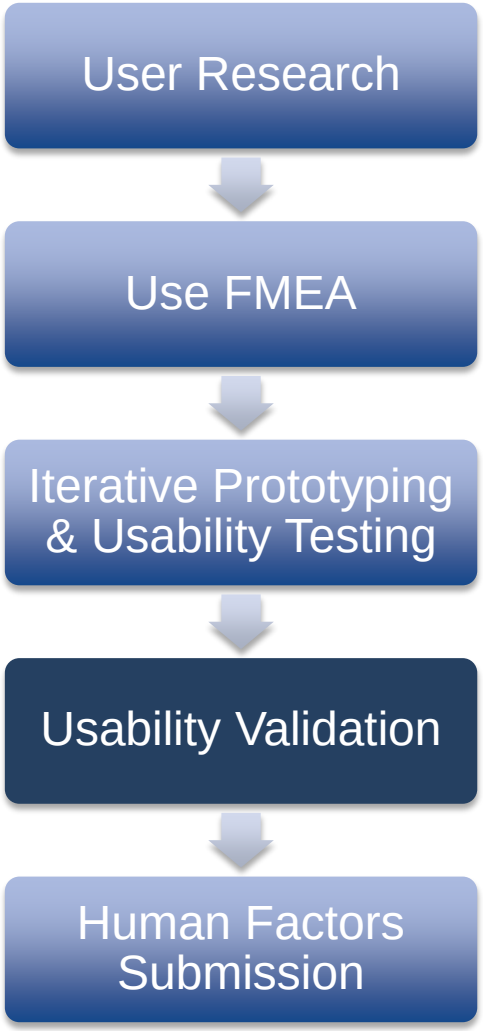
User misinterpreted the purpose of the device

- In one case this led to a user placing the sensors "where the knee hurt"



- Consider making it look different from a Band-Aid

Human Factors Process



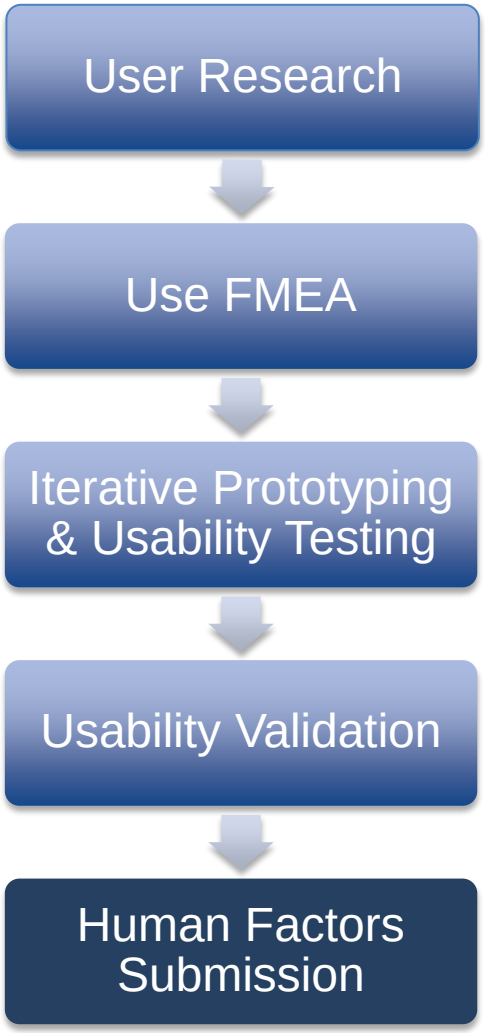
Usability Validation:

- Usability Validation Report for compliance with EU and FDA regulations
- Validated/Confirmed Usability Risk Analysis

Usability Validation Example

- 16 surgeons
- 1-hour sessions
- No training

Human Factors Process



HFE Submission:

- HFE Submission Summary of entire HF process to minimize questions from the FDA
- E.U. requires Usability Engineering File

Summary of UserWise Offerings

User Research

- Literature reviews to investigate known use errors
- Summary of Known Use Errors
- Task Analysis
- Use Scenario Identification
- User Profiles and Personas
- Use Environment Description
- Authoring and Refining User Needs

Risk Analysis

- Use-Related Risk Analysis
- Development of design requirements to ensure safe use

Usability Testing

- Early-Stage Usability Study Protocols and Reports
- Usability Validation Study Protocols and Reports
- Usability Study coordination and execution

HFE Submission Output:

- HFE Submission Report (for 510(k), de Novo, or PMA application)
- Preparation of the Usability Engineering File (oUS)

Conclusion

- The FDA requires adherence to the Human Factors Process
- Follow the process early and often for long-term cost savings
- Make User-Centered Design a priority

Questions?

UserWise

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