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

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

More and Better HF

Agency Focus/Effort on HF
Frequency of device manufacturers doing HF
Quality of HF Submitted by manufacturers

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

Source: FDA.gov
Contains Nonbinding Recommendations

Applying Human Factors and Usability Engineering to Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016


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

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<td>IEC 60601-1-6:2010</td>
<td><em>Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability</em></td>
<td>Provides a bridge between IEC 60601-1 and ANSI/AAMI/IEC 62366</td>
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<td>IEC 60601-1-8 Edition 2.1 2012-11</td>
<td><em>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</em></td>
<td>Design standard for alarm systems in medical electrical equipment and systems</td>
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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
American Combat Deaths by War

- Northwest Indian War
- Mexican American War
- War of 1812
- War on terror
- American Revolutionary War
- Korean War
- Vietnam
- World War I
- Annual Preventable Medical Error
- American Civil War
- World War II

Total Deaths
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.


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.

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U.S. Department of Health and Human Services
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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
Cost of R&D with and without Human Factors

- Cost with Human Factors
- Cost without Human Factors

Development Phase (Time)

- Early Concept
- Refine User Needs
- 1st Prototype
- Prototype Iterations
- Final Design
- Verification & Validation
- Released Product

R&D Cost
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 tachycardia 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

1. User Research
2. Use FMEA
3. Iterative Prototyping & Usability Testing
4. Usability Validation
5. Human Factors Submission
What is Early Stage Human Factors 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?

- Identify environmental, social, and motivational considerations for the design.
What is Early Stage Human Factors Research?

- Use appropriate sample, representative of ALL user types.


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

User Research

Use FMEA

Iterative Prototyping & Usability Testing

Usability Validation

Human Factors Submission

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

- User Research
- Use FMEA
- Iterative Prototyping & Usability Testing
- Usability Validation
- Human Factors Submission

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

- User Research
- Use FMEA
- Iterative Prototyping & Usability Testing
- Usability Validation
- Human Factors Submission

**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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