Applying Human Factors to Medical Device Design

Standards and Guidelines

MEDEC 2016

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About Tim Reeves

- Founder and Managing Director of Human Factors MD Inc.
- Ten-person human factors consultancy working exclusively with medical device and pharmaceutical clients since 2001
- Member of Association for the Advancement of Medical Instrumentation’s (AAMI) Teaching Faculty and Human Factors Committee
- 20+ years experience as human factors professional with medical devices including drug delivery devices
- Certified Human Factors Professional
- PhD in Cognitive Psychology from University of Toronto
What is Human Factors?

Methods

- Task Analysis
- Contextual Inquiry
- FTA
- Cognitive Walkthrough
- Use FMEA
- Heuristic Review
- Function Analysis
- Simulated-Use Testing

Knowledge


Applying Human Factors to Medical Device Design

ISO/IEC 63266: 1 2015
ISO/IEC TR 62366-2 2016
AAMI HE 75 2009

Methods
Knowledge
• Manufacturers shall establish, document and maintain a **Usability Engineering Process**...the process shall address user interactions with the medical device.

• If the Usability Engineering process...met acceptance criteria documented in the Usability Validation Plan...**residual risks** associated with usability shall be...**acceptable** in accordance with ISO 14971

• Usability Engineering Process may be **scaled**...based on the nature of device...extent of modifications...determined by risk analysis.

• Includes provisions for User Interfaces of Unknown Provenance.
62366-1 Medical devices - Part 1:
Application of usability engineering to medical devices

- Prepare a Use Specification
- Identify user interface characteristics related to safety and potential use errors
- Identify known or foreseeable hazards and hazardous situations
- Identify and describe hazard-related use scenarios
- Select hazard-related use scenarios for summative testing
- Establish user interface specification that includes risks mitigations
- Establish a user interface evaluation plan
- Perform UI design, implementation, and formative evaluations
- Perform summative evaluations
62366-2 Medical devices - Part 2: Guidance on the application of usability engineering to medical devices

How to...

- Contextual inquiry
- Focus groups, interviews & survey techniques
- Expert reviews
- Task Analysis
- Function Analysis
- Use FMEA and Fault Tree Analysis
- Heuristic Reviews
- Cognitive Walkthroughs
- Simulated-Use Testing
HE75 Contents

General Considerations
- General Principles
- Managing Risk of Use Error
- Basic Skills and Abilities
- Anthropometry & Biomechanics
- Environmental Consideration
- Usability Testing
- Accessibility Considerations

Design Elements
- Signs, Symbols, Markings
- User Documentation
- Packaging Design
- Cross-Cultural/Cross-National Design
- Design for Post-Market
- Alarm Design
- Use of Automation
- Displays
- Controls Design
- Connectors/Connections
- Software User Interfaces
- Design of Hand Tools

Integrated Solutions
- Mobile Devices
- Home Health Care Considerations
- Workstation Design
19.3.5.2 - Luminance contrast: Luminance contrast is one of the most important factors in display legibility. It is defined as the difference in luminance between the foreground and background of displayed elements.

19.4.1.2 – Optimal character height: The minimum character height should be 16 minutes of visual angle (ANSI/HFES 100). The preferred height of characters should be 20 to 22 minutes of visual angle when displayed characters are viewed frequently or rapid comprehension is essential (ISO 9241-3).

19.4.2 – Font style: Displays should be designed to avoid misinterpretation when a seven-segment display is inverted. Seven segment displays (typically light-emitting diodes [LEDs] or LCDs) are commonly used to display numeric information (and some alphabetic characters) in medical devices.
HE75 Example: Hand-held pulse oximeter redesigned display
11.2.3.5 Facilitate translating the instruction into action: Users should not be required to interpret or translate instructions into actions by having to recall experiences from their past or employ guesswork about what the instruction means. Therefore, simple stimulus–response approaches to writing instructions are preferred: When you see/hear/feel X [stimuli], do Y [action].

11.2.3.8 - Simplify language for ease of understanding:
Write in short, declarative, active voice sentences and avoid providing background information...Use precise terms. Instructions are intended to guide user behavior. Direct, behavioral descriptors are more effective in guiding user performance.

11.2.3.11 - Use visuals and graphics to facilitate performance: Visual illustrations and graphics should never be used instead of text. The text should be fully understandable before visual illustrations and graphics are even considered. Visuals should be simple line drawings.
**HE75 Example: Preparation of a suspension**

### Preparation Instructions

1. **Materials needed but not supplied:**
   - Two 1 mL syringes
   - Two 18-20G needles
   - Two blunt, flexible administration needles
   - Alcohol pads
   - Optional: ice pack and sterile gauze to keep BRAND NAME vial cold

2. **Hold the BRAND NAME vial by the aluminum seal at the crown to prevent gelation.** Shake the vial vigorously from side to side for a minimum of X seconds to ensure a homogenous suspension. (or mix well until a visibly homogenous suspension is obtained). Do not hold vial by the glass as it will cause BRAND NAME to gel.

3. **Using a sterile 18-20G needle, withdraw 0.3 mL of the suspension into the syringe.**

4. **Replace the needle with the blunt, flexible needle to be used for injection and prime the syringe to an injection volume of 0.1 mL (0.1 cc).**

5. **Repeat Steps 3 and 4 to prepare a second syringe for the other ear and dispose of the vial.**

### Storage and Handling

- **Store at refrigeration (2-8°C) and protect from light.**
- **BRAND NAME must be kept cold during preparation:** BRAND NAME vial can be placed on an ice pack covered with sterile gauze to keep cold or placed back in the refrigerator if BRAND NAME gels during preparation.
- **Hold vial by the crown and not the glass to prevent gelation.**
- **Keep prepared syringes at room temperature in the horizontal position until time of administration. BRAND NAME should be administered within X hours to prevent settling in the syringe.**

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**BRAND NAME PREPARATION INSTRUCTIONS**

**Step 1: Preparation**
- **Materials needed:**
  - 1 vial of BRAND NAME (enough for 2 doses)
  - Two 1 mL luer lock syringes
  - Two 18-21G needles
  - Two 20-24G, 2-3 inch blunt, flexible administration needles
  - Alcohol pads
  - Optional: ice pack and tape to keep BRAND NAME vial cold
- Keep product cold during preparation.

**Step 2: BRAND NAME Mixing**
- Hold the BRAND NAME vial by the aluminum seal to prevent gelation. Shake the vial for 5 to 8 seconds to mix well until a visibly homogenous suspension is obtained.
- Always hold the vial by the aluminum seal to prevent gelation.

**Step 3: BRAND NAME Removal**
- Using an 18-21G needle, withdraw 0.3 mL of the suspension into the 1 mL syringe.

**Step 4: Syringe Preparation**
- Replace the needle with a 20-24G, 2-3 inch blunt, flexible needle to be used for administration.
- Prime the needle leaving a dose of 0.1 mL (0.1 cc).
- Use a different syringe for each ear.

**Step 5: Second Syringe Preparation**
- Repeat Steps 3 and 4 to prepare a second syringe for the other ear and dispose of the vial.

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**Important Storage and Handling Information**
- **Store BRAND NAME in a refrigerator (2-8°C): 38-68°F and protect from light.**
- **BRAND NAME is easier to prepare cold. Prior to preparation, vials can be placed on an ice pack covered with sterile gauze to keep cold.**
- **During preparation, always hold the vial by the aluminum seal. If BRAND NAME breaks during preparation, place the vial back in the refrigerator.**
- **After preparation, syringes can be kept at room temperature prior to administration.**
- **Keep syringes on their side. Discard if not administered in 4 hours.**
## Other Human Factors Standards

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
<th>Main Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC TR 60878:2003</td>
<td>Graphical symbols for electrical equipment in medical practice.</td>
<td>Collects existing symbols applicable to medical devices and presents them in 15 medical device categories.</td>
</tr>
<tr>
<td>ISO 15223-1:2007</td>
<td>Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied.</td>
<td>Part 1 – Lists MDD + IVD Symbols Part 2 – Symbol development, selection and validation</td>
</tr>
<tr>
<td>ISO 15223-2:2010</td>
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<tr>
<td>IEC 60601-1-8:2006</td>
<td>Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.</td>
<td>Recommends visual and auditory alarm design parameters, e.g., color, frequency and cadence.</td>
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<td>ISO 14971:2007</td>
<td>Medical devices – Application of risk management to medical devices.</td>
<td>The definitive standard on principles of risk management, e.g., FTA, FMEA to medical devices.</td>
</tr>
<tr>
<td>IEC 60601-1-11:2011</td>
<td>Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.</td>
<td>Describes particular requirements for home healthcare medical devices.</td>
</tr>
<tr>
<td>AAMI TIR50: 2014</td>
<td>Post-market surveillance of use error management.</td>
<td>Outlines methodology for how best to collect, assess, and leverage post-market use error data to mitigate product risk and improvement patient safety and usability.</td>
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<td>Guidance, 2016</td>
<td>Applying Human Factors and Usability Engineering to Medical Devices</td>
<td>Outlines the FDA's approach to the application of human factors for the management of use-related hazards.</td>
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<tr>
<td>Draft Guidance, 2016</td>
<td>List of Highest Priority Devices for Human Factors Review</td>
<td>List of devices for which human factors testing is definitely required.</td>
</tr>
<tr>
<td>Draft Guidance, 2016</td>
<td>Human Factors Studies and Related Clinical Study Considerations in Combination Product Design</td>
<td>DMEPA guidance on conducting human factors studies.</td>
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<tr>
<td>Guidance, 2016</td>
<td>Design Considerations for Devices Intended for Home Use</td>
<td>Includes human factors considerations in the design of products intended for non-clinical environments, including home use.</td>
</tr>
<tr>
<td>Guidance 2016</td>
<td>Safety Considerations for Product Design to Minimize Medication Errors</td>
<td>Includes human factors considerations in the design of drug products user interfaces including labels, packaging and container/closure systems.</td>
</tr>
</tbody>
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The End

Thank you!