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Human Factors at FDA's Center for Devices and Radiological Health (CDRH)

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FDA /CDRH / ODE

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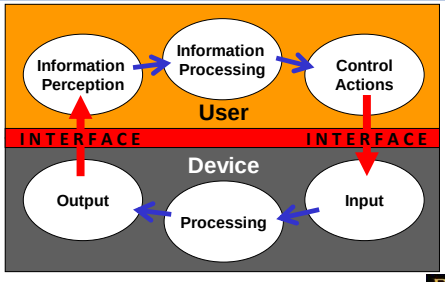
Device-User Interactions



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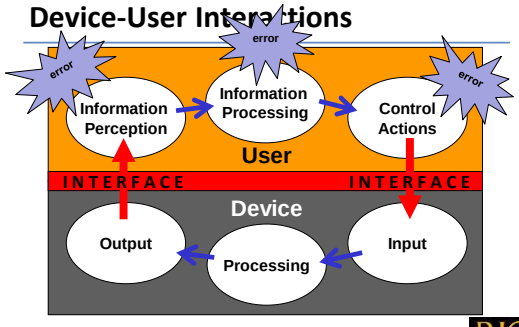
Device-User Interactions



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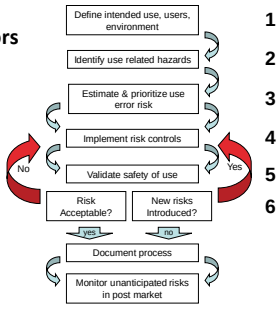
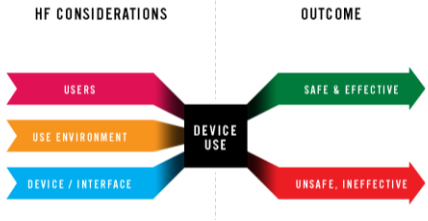
Human factors engineering process for medical devices



Source: ANSI/AAMI HE75:2009

Human Factors of Device Use

Define intended use, users, environment 1



Preliminary Analyses

Identify use related hazards 2
Estimate & prioritize use error risk 3

Two ways to discover use-related hazards:

1. **Apply analytical techniques**
   - Apply variety of techniques to identify use-related hazards and risks
     - *Can be difficult to anticipate all hazards*
2. **Conduct user-based evaluations**
   - Conduct hands-on testing to identify unanticipated hazards
     - *Sometimes called "Usability Testing" or "Use Testing" or "User Testing" or "Formative" Evaluations*

Risk Control

Implement risk controls 4

- **Develop risk mitigation strategies as needed:**
  - Modify the interface design, user instructions, and/or training to address the problems found
- **Re-test to assess whether mitigation strategies:**
  - Effectively reduced the known risks and
  - Did not introduce any new risks
- **Residual risk can be acceptable if it is:**
  - Reasonably limited, difficult to eliminate or further reduce, and outweighed by the device's benefits

Human Factors Validation

Validate safety of use 5

- **Demonstrates and provides evidence that a medical device, as designed, can be used safely and effectively:**
  - By people who are representative of the intended users
  - Under expected use conditions
  - For core tasks and safety-critical tasks

Human Factors Validation Testing

- **Test populations**
  - Represent all major intended user groups
    - Healthcare professionals, pharmacists, patients, etc.
    - Pediatric & geriatric populations need careful consideration
- **Device testing conditions**
  - Use finalized design of device, packaging, and labeling
  - Provide realistic training
  - Present device within the typical context of use
    - Incorporate expected use conditions that might affect user interactions with the device
  - Allow realistic device-user interactions

Human Factors Validation Data

- **Objective (performance) data:**
  - Facilitator observes and notes all use errors, failures and difficulties, including details about performance, e.g.:
    - Task success or failure, use error, close call, reference to instructions for use, need for assistance, evidence of difficulty or confusion, unsolicited comments
- **Subjective (narrative comment) data:**
  - Discuss user performance after use, particularly regarding reasons for any core task and critical task errors, failures and difficulties
  - Solicit participant feedback on design of device, packaging, labeling and training

Validation Data Analysis

Risk Acceptable? | New risks Introduced? 6

- **Analyze all use errors and failures**
  - Determine root cause and potential clinical consequences
  - Determine need to modify device, labeling, or training
  - Identify true residual risks
- **Use errors/failures are not of equal importance**
  - Some errors might be frequent but inconsequential
  - Some errors might be rare but reveal a hazardous design deficiency that was not previously recognized

FDA Expectations for HF Data

- **Conduct a comprehensive hazard/risk assessment, including all use-related hazards/risks**
- **Identify and mitigate serious hazards/risks**
  - Identify use-related hazards/risks that could result in serious harm to the user or patient
- **Conduct human factors/usability validation testing**
  - Particularly on any strategies implemented to mitigate serious use-related hazards/risks
- **Compare device's residual risks to its benefits**

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Key Standards & FDA Guidance Docs

- **ANSI/AAMI/ISO 14971: 2007,** *Medical devices – Application of risk management to medical devices*
- **IEC 62366: 2007,** *Medical devices – Application of usability engineering to medical devices*
- **FDA (2000):** *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*
- **FDA (2010, draft):** *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*

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www/fda.gov/humanfactors

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