Applying Human Factors and Usability Engineering to Medical Devices

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I am a Human Factors Engineer in the Medical Device Industry.

I conduct Usability Engineering for the design and development of technology for robotic-assisted surgery.

Human Factors Engineering in Medical Device

Medical Devices require FDA approval before they can be released on the market.

In order to obtain FDA approval, the device must be proven to be ***Safe*** and ***Effective***.

Safe and ***Effective*** use is proven through a thorough Usability Analysis.

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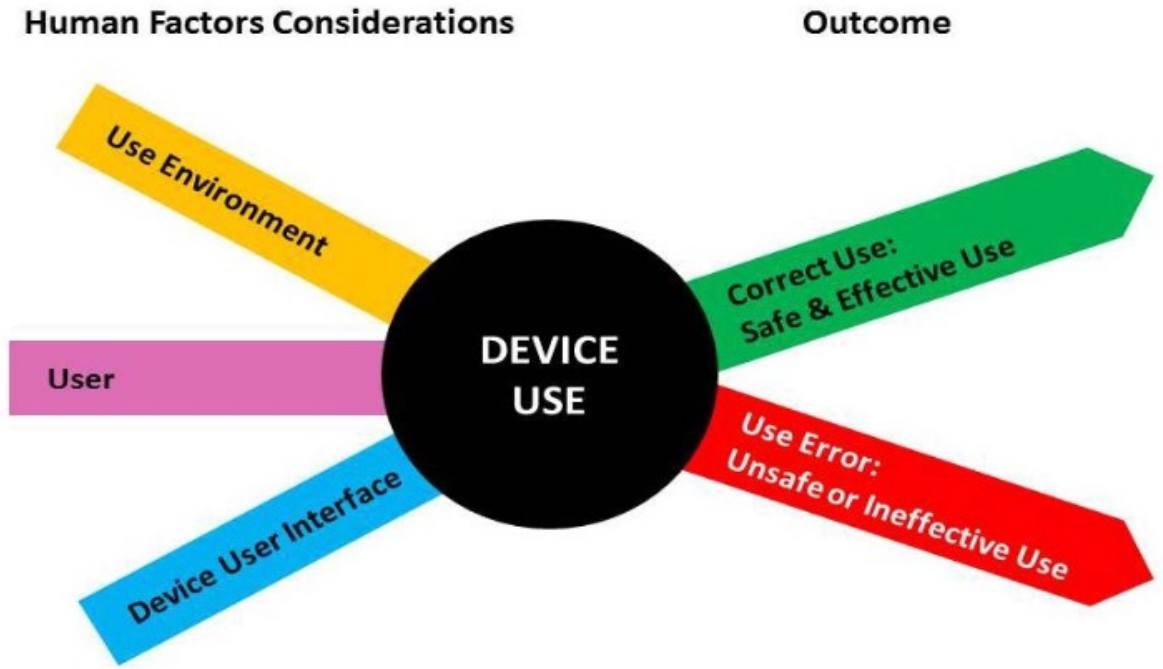


HFE/UE as a Risk Mitigation

Human Factors Engineering/ Usability Engineering is used to mitigate design-related problems that contribute to unsafe use.

Use-related hazards are related to one or more of the following situations:

- Device use requires physical, perceptual, or cognitive abilities that exceed the abilities of the user.
- Device use is inconsistent with the user's expectations or intuition about device operation.
- The use environment affects operation of the device, and this effect is not recognized or understood by the user.
- The particular use environment impairs the user's physical, perceptual, or cognitive capabilities when using the device.
- Devices are used in ways that the manufacturer could have anticipated but did not consider.
- Devices are used in ways that were anticipated but inappropriate (e.g., inappropriate user habits) and for which risk elimination or reduction could have been applied but was not.

Steps to HFE/UE Analysis

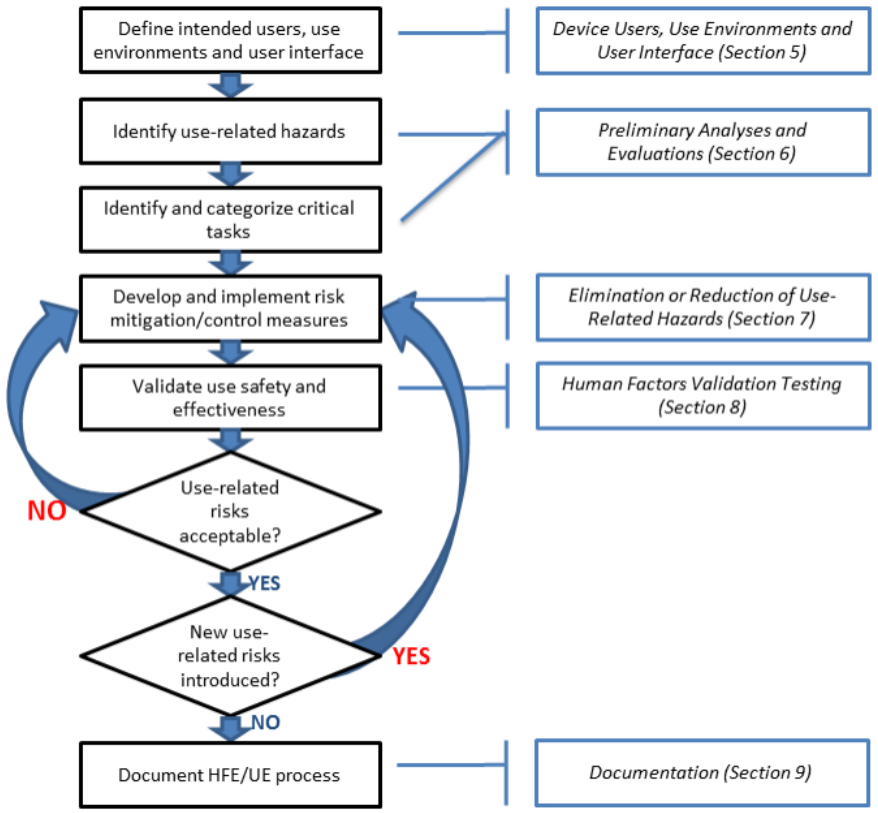
HFE/UE considerations and approaches should be incorporated into device design, development, and risk management processes.

3 steps are essential for performing a successful HFE/UE analysis:

1. Identify anticipated use-related hazards and initially unanticipated use-related hazards (derived through preliminary analyses and evaluations) and determine how hazardous use situations occur.

2. Develop and apply measures to eliminate or reduce use-related hazards that could result in harm to the patient or the user.

3. Demonstrate whether the final device user interface design supports safe and effective use by conducting human factors validation testing.



Device Users, Use Environments and User Interface

Create Use Specification

INTENDED USE → The indication for use of the device, the goal of the device's use, and the functions it enables.

INTENDED USERS → **Demographics:** average age, height, nationality, languages used, foreseeable impairments (prevalence of low-vision, color blindness, etc.)

Experience: analyzing expert users (we look at low, medium and high levels of experience).

INTENDED USE ENVIRONMENTS → Lighting, layout, line of sight considerations, etc.

DEVICE USER INTERFACE → All equipment involved; everything that might be interacted with.

Preliminary Analyses and Evaluations

Create Task Analysis

ACTIVITY

General function or Goal.

TASK

- **Ancillary:** necessary, but low-risk tasks
- **Critical:** essential tasks with moderate risk
- **Safety:** high-risk task

SUB-TASK

- **Perception:** what user is perceiving
- **Cognition:** what user has to cognitively process
- **Action:** what user physically does

USE ERROR

Potential failure mode of sub-task.

ACTIVITY	TASK	TYPE OF TASK	SUB-TASK	PCA TYPE	PCA DESCRIPTION	USE ERROR
System Setup	Start System	A	Turn Power On	P	Sees the power button.	Does not see the power button.
System Setup	Start System	A	Turn Power On	C	Understands that power button will turn on system.	Does not understand that power button will turn on system.
System Setup	Start System	A	Turn Power On	A	Presses the power button.	Fails to press the power button.

Preliminary Analyses and Evaluations

Create uFMEA (User Failure Modes and Effects Analysis)

TASK ANALYSIS

Derived from **Use Error** of **Action Sub-Task**

CAUSE OF USE ERROR

Potential causes of the use error that are **device related**

USE ERROR RANKING

- **Impact Rating:** 1-5
- **Detectability Rating**: 1-3
- **Use Error Ranking:** derived from Impact and Detectability ratings to rank failure modes as Low, Medium, or High

COMPENSATING PROVISIONS AGAINST USE ERROR

Derived from system design requirements that should address each cause of use error.

EFFECT OF COMPENSATING PROVISIONS

Safety related failure modes, and **Medium/ High risk** use errors *have* to be evaluated in Usability Evaluations and designed out before Summative.

ACTIVITY	TASK	USE ERROR	CAUSES OF USE ERROR	IMPACT RATING	DETECTABILITY RATING	USE ERROR RANKING	CP'S	EFFECT OF CP'S
System Setup	Start System	User fails to press the power button.	1. The button is located in a place that is difficult to access. 2. The design of the button does not indicate it's function.	2	1	LOW	1. By design, the button is located on the face of the device. 2. By design, the button is green and labeled 'ON'.	1, 2. Proven effective in Formative Evaluation.

Preliminary Analyses and Evaluations

Design and Execute Formative Evaluations

Executed early and iteratively throughout design process.

DESIGN FEATURE LAB	PROOF OF CONCEPT LAB	TRAINING LAB
Evaluate user's initial perceptions of first prototype and gather feedback, recommendations, and needs.	Evaluate usability issues with a more finalized design.	Evaluate if the developed training content/ strategy is efficient for use of the design.

STRATEGIES:

- Simulated Use Testing with Expert Users + Simulated Environment
- Usability Performance Metrics
- Cognitive Walkthroughs / Think Aloud Protocol
- User VOC (Voice of Customer) / User Experience

Elimination or Reduction of Use-Related Hazards

Remove Design-Related Hazards with Human Factors Recommendations

Analyze lab data, draw conclusions, determine HF solutions, and debrief with design teams and other stakeholders.

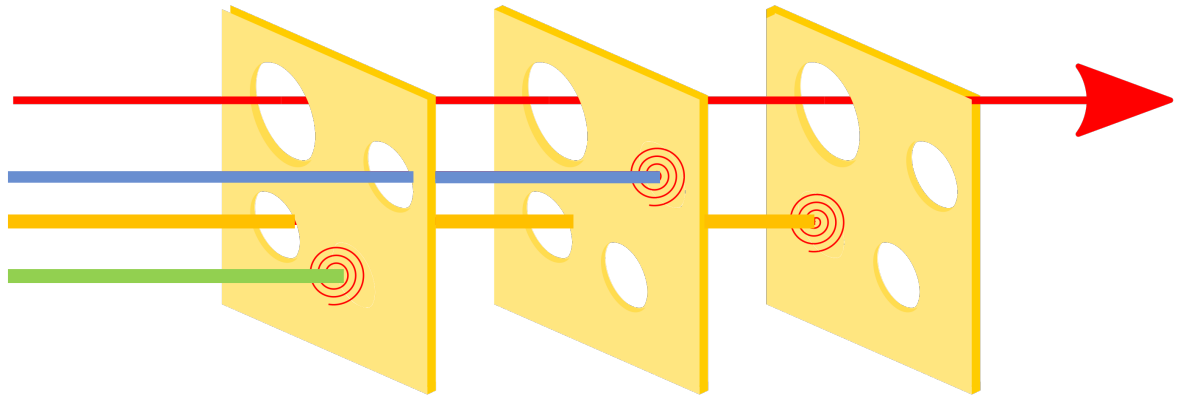
Not everything can be designed out.

There is a lot that goes into it:

- It's not feasible or reasonable to develop.
- Changes are not consistent with similar technology on the market.
- It's not reasonable within a certain timeline.
- Design Engineers ✨ *Simply Disagree* ✨

Swiss Cheese Model

1. **Inherent safety by design**
2. **Protective measures in design:** warnings, alerts, safeguards
3. **Information:** user guides and training



Human Factors Validation Testing

Design and Execute Summative Evaluation

To prove SAFE and EFFECTIVE use:

Evaluate final design, final training/ certification content, and application user guides.

Evaluate and prove that all safety related failure modes in uFMEA are designed out or mitigated with training/ warnings/ user guides.

Evaluate expert users (FDA requires minimum of 15 per user group) in all indicated tasks in simulated use environment.

Everything *has to* pass, or residual risk *has to* be documented and justified.

Prepare 510k premarket submission for FDA approval!