

IMPERIAL

MedTechONE Knowledge Base



What steps are involved in the usability engineering process?

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1. The Process Outlined by IEC 62366

The IEC 62366 standard provides a step-by-step framework for integrating usability engineering into medical device design, focusing on user safety by addressing usability-related risks. The process includes:

- **Defining Intended Users and Use Cases:** Identify who will be using the device and in what settings (e.g., hospitals, homes).
- **Identifying Use-Related Hazards:** Determine potential risks or errors that may arise due to poor usability.
- **Mitigating Risks:** Improve the design to reduce these risks (e.g., by making controls intuitive, adding safety features).
- **Formative and Summative Testing:** Conduct usability testing to assess early designs and then validate the final product's usability.
- **Documentation:** Record all findings to meet regulatory requirements.

Example:

- A portable defibrillator for public use must be easy to operate by untrained users in emergencies. The IEC 62366 process would require testing to ensure the device can be used correctly under stressful conditions, with clear instructions, visual aids, and audible prompts

2. How Do You Define User Profiles, Use Environments, and Critical Tasks?

Defining user profiles, use environments, and critical tasks is crucial to ensuring the device's design is appropriate for its intended users and conditions:

- **User Profiles:** These describe the characteristics of the intended users, including their experience level, training, cognitive abilities, and physical capabilities.
 - **Example:** A surgical tool would have surgeons as its primary user group, requiring specific attention to ergonomics and precision.
- **Use Environments:** These refer to the physical settings where the device will be used, such as hospitals, homes, or emergency situations.

- Example: A home-use insulin pump needs to function effectively in varied conditions, like low-light or noisy environments, and with minimal user input.
- Critical Tasks: These are tasks that are essential to the safe and effective use of the device, where user error could lead to serious consequences.
 - Example: The process of setting the correct dosage in a medication infusion pump would be a critical task
- Importance: Accurate definitions help in tailoring usability testing to real-world conditions, ensuring the device functions safely and efficiently for its intended users.

3. Define and Test Critical Tasks & Identify Use-Related Hazards

Defining and Testing Critical Tasks

Critical tasks in the usability engineering process refer to tasks that, if performed incorrectly, could lead to serious adverse events or harm to patients or users. These tasks are integral to ensuring the safe and effective use of medical devices.

Steps Involved in Defining and Testing Critical Tasks:

Step 1: Identify Critical Tasks

- Definition: Critical tasks are tasks that, if not performed correctly, could result in user errors with serious consequences (e.g., harm to patients or incorrect operation of the device).
- IEC 62366 and FDA's Human Factors Guidance mandate the identification of these tasks to ensure safe device operation.
- How to Identify:
 - Start by analyzing the overall use of the device, and break down user interactions into individual tasks.

- Assess each task's potential impact on safety by asking questions such as:
 - Can a mistake in this task lead to patient harm?
 - Is this task performed under stressful or time-sensitive conditions?
 - Is there a risk of critical error if this task is misunderstood?
- Example: For an insulin pump, critical tasks include setting the correct dosage and properly connecting the infusion set, as errors in these areas could lead to dangerous dosing levels.

Step 2: Develop a Task Analysis

- Definition: A task analysis involves breaking down the critical tasks into specific actions that the user must perform. This analysis helps to understand the cognitive and physical demands of each step.
- How to Perform:
 - Break each critical task into smaller steps, such as interpreting displays, entering data, or responding to alarms.
 - Determine which steps are prone to errors, especially in environments where users may be under stress or time pressure.
- Example: A task analysis for a defibrillator would include steps such as recognizing when to use the device, attaching the electrode pads correctly, and following voice or screen prompts.

Step 3: Test Critical Tasks During Formative and Summative Usability Testing

- Formative Testing: Test critical tasks in the early stages of development to gather qualitative data and identify potential user errors. Make improvements based on user feedback.
 - How: Prototype versions of the device are tested by representative users in a controlled environment.
 - Goal: To refine the design and reduce the likelihood of errors during critical tasks before finalizing the device.
- Summative Testing: Final testing with larger groups to validate that the design is safe and effective for performing critical tasks.
 - How: Usability tests should focus on measuring user success rates, error rates, and time taken to perform critical tasks under realistic conditions.

- Goal: To demonstrate that users can complete critical tasks correctly and safely without confusion or error.
- Example: During summative testing for an IV infusion pump, users would be tested on setting up the pump, programming the infusion rate, and responding to alarms under realistic hospital conditions.

Step 4: Document the Results

- Why: Detailed documentation of how critical tasks were identified, analyzed, and tested is essential for regulatory compliance.
- How: Results from formative and summative testing should be compiled in usability reports that meet the requirements of standards such as IEC 62366 and FDA guidance.
 - Include task success rates, user feedback, and any design changes made to address issues during testing.

Identifying Use-Related Hazards

Use-related hazards refer to risks that arise from how users interact with the device, particularly risks stemming from user errors, misuse, or misunderstanding of device functions. Identifying and mitigating these hazards is a core part of usability engineering, aimed at enhancing safety.

Steps Involved in Identifying Use-Related Hazards:

Step 1: Conduct a Use-Error Risk Analysis

- Definition: A use-error risk analysis assesses potential hazards related to how users operate the device. These hazards often arise from poorly designed user interfaces, inadequate feedback, or the device's complexity.
- Key Standard: ISO 14971 (Risk Management for Medical Devices) mandates the identification and assessment of risks, including those related to usability.
- How to Identify Hazards:
 - Analyze every point of user interaction to identify where errors could occur.

- Focus on tasks where cognitive load, decision-making, or physical interaction could cause errors (e.g., complex controls, unclear feedback).
- Look for scenarios where stress, fatigue, or time pressure may increase the likelihood of use errors.
- Example: In a ventilator, hazards could arise if the user interface doesn't clearly differentiate between settings for adult vs. pediatric patients, leading to incorrect ventilation settings.

Step 2: Categorize the Hazards

- Severity and Likelihood: For each identified hazard, assess both the severity of the potential harm and the likelihood of occurrence. This helps prioritize which hazards to address first.
- Key Standard: IEC 62366 emphasizes that hazards with high severity and high likelihood should be mitigated or eliminated through design changes.
- How to Categorize:
 - Assign a risk level (e.g., low, medium, high) based on the potential for harm.
 - Use a Risk Priority Number (RPN) to combine severity and likelihood into a single risk score.
 - For high-risk tasks, create design features that eliminate or reduce the chance of errors.
- Example: A syringe pump might have a high-risk hazard where a user could accidentally program the wrong infusion rate due to ambiguous button labeling.

Step 3: Implement Risk Control Measures

- Purpose: Once use-related hazards are identified, implement risk control measures to minimize or eliminate the risks.
- How:
 - Improve the user interface to make tasks easier to perform correctly (e.g., clearer displays, better feedback mechanisms).
 - Implement error-proofing mechanisms, such as automated checks that prevent users from proceeding with incorrect settings.
 - Ensure that the device provides clear and immediate feedback when a use error occurs, so users can quickly correct mistakes.

- Example: A blood glucose meter might include a step-by-step user guide on the screen and block users from proceeding if they fail to correctly insert the test strip.

Step 4: Verify Risk Mitigation Through Testing

- Purpose: After implementing risk control measures, verify that they are effective through usability testing.
- How: Test scenarios should focus on critical tasks and high-risk use-related hazards to ensure that the risk mitigation measures work as intended.
 - Formative testing helps identify any remaining usability issues, while summative testing validates the final product's safety.
- Example: A dialysis machine could include a locking mechanism that prevents users from changing settings mid-operation, which would be tested during summative usability evaluations to confirm it reduces the risk of use errors.

Step 5: Documentation and Reporting

- Why: Regulatory bodies like the FDA and EU MDR require that manufacturers document how they identified, assessed, and mitigated use-related hazards.
- How:
 - Include risk analysis data, usability testing results, and design changes in the Usability Engineering File.
 - Submit this file as part of the premarket submission (PMA or 510(k) for FDA) or the technical file (for EU MDR).

4. Documentation and Regulatory Submissions

Purpose: Thorough documentation is essential for demonstrating compliance with international usability standards and regulatory requirements.

Key Considerations:

- Create a Usability Engineering File that includes all test plans, risk analyses, formative and summative test results, and any design changes made to address usability issues.

- This file must demonstrate that usability engineering was conducted in line with standards like IEC 62366 and ISO 14971.
- For FDA submissions, provide a Human Factors Validation Report that details how the device's usability was tested and validated to meet safety requirements
- Example: A drug delivery device manufacturer would submit a detailed usability report to the FDA as part of their premarket approval (PMA) submission
- Why: Regulatory bodies like the FDA and EU MDR require detailed documentation showing that usability engineering processes were followed to ensure the device's safety and effectiveness.

5. Post-Market Surveillance and Updates

Purpose: After the device is on the market, it's important to continue monitoring how users interact with it in real-world settings. This helps identify any unforeseen usability issues and address them quickly.

Key Considerations:

- Collect feedback from users on the device's performance in the field, particularly any usability issues that might not have been identified in pre-market testing.
- Monitor user complaints, device recalls, or adverse event reports related to usability.
- Make continuous improvements to the device based on post-market data and, if necessary, update the design or user instructions.
- Example: A home-use dialysis machine might receive feedback from patients that certain interface elements are confusing, prompting the manufacturer to release a software update with a simplified display