# IMPERIAL

# MedTechONE
# Knowledge Base

# What are the main methods used for usability testing?

1  Formative Testing

2  Summative Testing

3  Heuristic evaluations

4  Cognitive walkthroughs

5  Further testing types

# 1. Formative Testing

Purpose: Formative usability testing is conducted early in the design and development process to identify and resolve usability problems before the final design is completed. It focuses on improving the design through iterative feedback.

- **Process:**
    - Users interact with early prototypes or mockups of the device, while researchers observe and gather data on how they perform tasks.
    - Formative testing typically involves small groups of users who provide qualitative feedback, helping to identify areas where users struggle, make errors, or get confused.
    - Based on feedback, the design is revised and improved in an iterative cycle.

- Example: A medical device company might conduct formative testing on a prototype of an insulin pump, asking users to complete tasks like setting dosage or inserting the infusion set. User feedback would help refine the interface before it goes into final production

# 2. Summative Testing

Purpose: Summative usability testing is conducted after the design is finalized to validate that the device meets usability and regulatory standards. It is more formal and structured than formative testing and is typically required for regulatory submissions.

- **Process:**
    - Larger groups of users perform tasks under realistic conditions to demonstrate that the device can be used safely and effectively.
    - Quantitative data, such as task completion rates, error rates, and time on task, are gathered and analyzed to ensure that usability goals are met.
- The test results are then documented and used to support regulatory approval (e.g., FDA, EU MDR).

- Example: A manufacturer of a home-use blood glucose monitor would conduct summative testing by having a diverse group of users perform all the steps needed to measure their glucose levels and record data on their accuracy, errors, and ease of use

# 3. Heuristic evaluations

Purpose: Heuristic evaluation is a review-based method where usability experts assess the design against established usability principles or heuristics (e.g., Nielsen's 10 Usability Heuristics). The focus is on identifying usability issues based on expert judgment rather than user testing.

- **Process:**
  - A team of experts reviews the device's user interface to ensure it adheres to usability principles such as consistency, feedback, error prevention, and user control.
  - Experts highlight design flaws that could cause user confusion or lead to errors, providing recommendations for improvement.

- Example: Experts might perform a heuristic evaluation of a ventilator's control panel, ensuring that important settings like ventilation modes are easy to locate and adjust without ambiguity

# 4. Cognitive walkthroughs

Purpose: A cognitive walkthrough is a task-based method where evaluators simulate a user's thought process step-by-step to identify potential usability issues, particularly those related to how users learn and understand the system for the first time.

- Process:
  - Evaluators "walk through" the critical tasks that users need to perform, asking questions at each step, such as: "Will the user know what to do next?" or "Will they be able to interpret the feedback correctly?"
  - The goal is to evaluate the design from the perspective of a novice user, identifying areas where the user might become confused or make errors.

- Example: A cognitive walkthrough might be used for an automated external defibrillator (AED), evaluating whether a first-time user, such as a bystander in an emergency, can follow the device's instructions and use it correctly.

# 5. Further testing types

### Think-Aloud Protocol
- Purpose: The think-aloud protocol is used to gain insights into the user's cognitive processes by having participants verbalize their thoughts while interacting with the device. This method reveals how users approach tasks, what confuses them, and where they encounter problems.
- Process:
  - Users are asked to speak out loud as they complete tasks, describing what they are thinking, why they are making certain decisions, and what they find confusing or intuitive.
  - Researchers capture the verbal feedback, which provides a deeper understanding of the user's thought process and any misunderstandings that occur during the interaction.

- Example: For a portable oxygen concentrator, users might be asked to verbalize their steps when setting the flow rate or connecting the device, allowing researchers to identify unclear instructions or confusing design elements

### Remote Usability Testing
- Purpose: Remote usability testing allows users to test the device in their natural environment, such as their home or workplace, rather than in a controlled lab. This method is particularly useful for devices designed for home use or when in-person testing isn't feasible.
- Process:
  - Users perform tasks with the device while being observed remotely via video conferencing or specialized software. Researchers can observe in real-time or review recordings later.
  - This method provides insights into how the device performs in everyday settings, capturing real-world usability issues that might not be evident in a lab environment.

- Example: A company developing a telemedicine platform might use remote usability testing to observe how patients navigate the interface for virtual consultations, ensuring it works well in a variety of home settings

## A/B Testing

- Purpose: A/B testing is used to compare two versions of a device or interface to determine which one performs better in terms of usability. This method is useful for testing design alternatives or incremental changes.
- Process:
  - Two versions of the device or interface (Version A and Version B) are tested by different groups of users.
  - The results from each group are compared to determine which version leads to fewer errors, faster task completion, or higher user satisfaction.

- Example: A medical device company might use A/B testing to evaluate two different user interfaces for an electronic medical record system to determine which layout allows doctors to input patient data more efficiently

## Concluding Remarks:

Each of these usability testing methods offers a different approach to evaluating how users interact with medical devices. By applying a combination of formative and summative testing, heuristic evaluations, cognitive walkthroughs, think-aloud protocols, and remote usability testing, manufacturers can ensure that their devices are safe, effective, and user-friendly. These methods also help identify potential issues early in the design process, ensuring compliance with regulatory requirements such as IEC 62366.