

Usability Evaluation Plan

The Usability Evaluation Plan describes the Usability Evaluation activities and their required resources which will be performed for the device.

Mapping of Standard Requirements to Document Sections

IEC 62366-1:2015 Section	Title	Document Section
4.2	Usability Engineering File	(all)
4.3	Tailoring of the Usability Engineering effort	(all)

1. Relevant Processes

Usability Engineering and Evaluation activities are defined in the **SOP Integrated Software Development**.

2. Related Documents

- List of Hazard-Related Use Scenarios
- Usability Evaluation Report

3. Roles

Title	Name(s)
Head of Usability Context / Subject Matter Expert, e.g., physician	

4. Formative Usability Evaluation

4.1 Methods

Formative Usability Evaluation is performed with the following methods:

- **Presentation of mockups or prototypes to subject matter experts:** E.g., by demonstrating the functionality in an in-person or remote screen sharing session.
- **Feedback sessions with UX/UI experts:** Showing concepts, designs, mockups or prototypes to internal or external UX/UI experts with the goal of gathering feedback on potential usability problems and improvements.
- **User Tests:** Letting users of the intended target user group use the device based on a Usability Evaluation protocol, observing them and documenting potential Usability problems. This is essentially the same methods as the

Summative Usability Evaluation, with the only difference being that it's being done on a development (non-final, non-release) version of the device with the goal of gathering knowledge for improving the final device.

4.2 Planning (Overview)

Date	Description
01.01.2021	<i>Formative Evaluation 1</i> (Description of methods incl. environment, participants etc.)

5 Summative Usability Evaluation

5.1 Method

Summative Usability Evaluation is conducted by performing User Tests.

User Tests must comply with the following requirements:

- The user profile is the one specified in the Device Description.
- All Hazard-Related Use Scenarios must be covered by test cases (see IEC 62366, para. 5.7.3 / 5.9).
- Sufficient stakeholder requirements / user needs must be covered by test cases to ensure that the product meets its intended use (see ISO 13485, para. 7.3.7)
- At least five test participants.
- The Usability Test Protocol must be filled out which descriptions of each use scenario and instructions. It is also used to document the observations and discovered hazards.

The following requirements are optional:

- Usability Tests are recorded, e.g., video/audio (either in-person or remotely) and screen recording (of phone / desktop computer)

Results of Summative Usability Evaluation are summarized in the Usability Evaluation Report, most importantly:

- Could all tasks in the Usability Test Protocol be achieved?
 - If not, why?
- Which Use Errors occurred and could they lead to Hazardous Situations?
 - > Risk analysis of use errors

5.2 Planning (Setting)

Participants

Setting

Methods and Analysis

Describe whether it's done in person or remotely and how you will document the results (have a protocol at the minimum), optionally also record the sessions.

Also, describe how you plan to analyse the data.

5.3 Planning (Overview)

Date	Description
02.01.2021	<i>Summative Evaluation 1</i> (Description of methods incl. environment, participants etc.)

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