

Usability Evaluation Report

The Usability Evaluation report describes the results of all (formative and summative) Usability Evaluations.

Mapping of Standard Requirements to Document Sections

IEC 62366-1:2015 Section	Title	Document Section
4.1.3	Information for Safety as it relates to Usability	4.5
4.2	Usability Engineering File	(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 Protocol
- Usability Evaluation Plan

3. Summary of Formative Evaluations

3.1 Formative Evaluation 1

4. Summary of Summative Evaluation

4.1 Methods

Copy-paste this section from the Usability Evaluation Plan (5.2 Planning (Setting)).

4.2 Overview over Tests

Copy-paste this table from the Usability Evaluation Protocol.

ID	App State / Description/Environment	Acceptance Instructions/Criteria	Hazards en- countered Observations
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4.3 Pass / Fail Counts of Tests

Count the pass/fail results from the Usability Evaluation Protocol

Test ID	Description	Total Count	Pass Count	Fail Count
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4.4 Use Errors and Hazards

Test ID	Description	Use Error	Potential Hazard
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4.5 Information for Safety

Describe whether information for safety could correctly be perceived and understood by the users and whether it supported the correct use of the medical device.

4.6 Other Findings

5. Qualitative Participant Feedback

6. Conclusion

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