# 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 | Description | App State / Environment | Instructions | Acceptance Criteria | Observations | Hazards encountered |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |

### 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 |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

### 4.4 Use Errors and Hazards

| Test ID | Description | Use Error | Potential Hazard |
| --- | --- | --- | --- |
|  |  |  |  |

### 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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