

# 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
----	--	-------------------------------------	--

### 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

---

Template Copyright openregulatory.com. See template license.

Please don't remove this notice even if you've modified contents of this template.