**Usability Evaluation**

**Report**

|  |  |
| --- | --- |
| TITLE: |  |
| AUTHORING GROUP: |  |
| DATE: |  |
| SUPERSEDE PROTOCOL NO.: |  |

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**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 | 4.4 |
| 4.2 | Usability Engineering File | (all) |

1. **Relevant Processes**

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

1. **Related Documents**

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

1. **Summary of Formative Evaluations**
   1. Formative Evaluation 1
2. **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**

| 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

**4.4 Use Errors and Hazards**

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

**5.5 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.

1. **Qualitative Participant Feedback**
2. **Conclusion**