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# Introduction

## Document overview

This document is the usability summative evaluation protocol and report of XXX system/software.

You may split this document in two: the summative evaluation protocol, and the summative evaluation report.

## Abbreviations and Glossary

### Abbreviations

Add here abbreviations

### Glossary

Add here words definitions

## References

### Project References

| # | Document Identifier | Document Title |
| --- | --- | --- |
| [R1] | ID | Add your documents references.One line per document |
|  | XXX | Risk Management File |
|  | XXX | User Interface Specification |
|  | XXX | Software Requirement Specification |

### Standard and regulatory References

|  |  |  |
| --- | --- | --- |
| # | Document Identifier | Document Title |
| [STD1] | IEC 62366-1:2015 | Medical devices – Part 1: Application of usability engineering to medical devices |
|  |  | Add your documents references.One line per document |

## Conventions

Add here conventions, if any

# Introduction

Objective of the document blah blah

Example: The Summative Evaluation Plan and Report aims to validate that the users defined in the Use Specification (see doc xxx) can use the device easily and safely. The scope of the summative evaluation is the software device xxx in version xxx.

# Summative Evaluation Plan

## Conditions of Tests

Define the tests conditions, example:

5 users with medical degree and 5 users with a paramedical degree perform free tests in the following conditions:

* They haven’t been trained to the use of the device,
* The IFU is not available.

## Tests scenarios

Define the tests scenarios, use sub-sections if you have many scenarios. The scenarios shall be the ones selected in the usability engineering file.

Example:

The tested scenarios are:

1. Performing a query on the PACS,
2. Loading a patient study

## Evaluation form

The evaluation form to be filled by each user participating to the test.

See Annex A.

## Evaluation criteria

The minimal success rates expected for the evaluation are listed below:

List the criteria, you can use a table like below

|  |  |  |
| --- | --- | --- |
| # | Scenario | #of successful user / total users |
| 1 | Performing a query on the PACS | 10 / 10 |
| 2 | Loading a patient study. | 10 / 10 |
| 3 | Drawing a ROI | 10 / 10 |
| 4 | Saving a key image | 10 / 10 |

# Summative Evaluation Report

This part is filled only when the summative evaluation is completed.

It may be recorded in a separate document

## Overview of summative evaluation

Give a few information about the evaluation.

The XXX software (version x.y.z) was tested on the xxx test platform located in xxx, from the yyyy/mm/dd to the yyyy/mm/dd.

The users who performed the tests are:

* beep-beep,
* coyote
* daffy duck
* …

Describe the impact of test environment, if any.

Mainly, difference between evaluation conditions and real conditions, like ambient conditions, software test tools, a simulator or hardware…

Example: The users who performed the tests had to stop the free tests, due to a temporary network connection failure. This event had no impact on the test results: only delays to load PACS images.

Give a qualitative overall assessment of tests.

Example:

* All scenarios where run by the users
* 2 users also perform additional free tests on xxx
* …

## Tests results

The success rates are given below:

Copy the table of 2.3, with the results

Give a summary of the results:

Examples with success or failures

No score below the minimal success rates defined in section 2.3

Or

Two scores were below the minimal success rates defined in section 2.3

## Conclusion

Give a conclusion of the summative evaluation

If all criteria are passed and no new user error was detected during the evaluation, then the summative evaluation is successful and the usability of the user interface is validated.

If one criterion didn’t pass or new user errors not present in the usability engineering file were detected then the summative evaluation is

* either unsuccessful: a new round of design is required (too bad!);
* successful but with reservations. The user interface is validated and the reservations can be monitored in post-market surveillance.

# Annex A : Evaluation Form

|  |  |  |
| --- | --- | --- |
| User:  |  | Adress, e-mail, phone: |
| Contact:  |  |
| Device: xxx |  |
| Version:  |  |

Copy the content of the table in section 2.3

Have you been able to:

|  |  |  |
| --- | --- | --- |
| 1 | Perform a query on the PACS? | No □ Yes □ |
| 2 | Load a patient study | No □ Yes □ |
| 3 | Draw a ROI | No □ Yes □ |
| 4 | Save a key image | No □ Yes □ |

In a scale between 0 (impossible to use) to 10 (very easy to use), how would you rate this device?

|  |
| --- |
| User:Date:Signature: |