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# Introduction

## Document overview

This document is the usability engineering file of XXX system/software.

## 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

Use scenarios listed in this document are constructed according to the following structure:

Scenario Id

Scenario title

Scenario description, steps, alternative steps

Scenario version

Example:

SCN-XXX-000

Title of XXX-000 Scenario

Prerequisite: software is in xxx state, user is willing to do xxx

Step 1: Do This

Step 2: Do that

Step 2bis: Alternatively do that

Version of SCN-XXX-000

# Use Specification

This chapter aims at setting the context use of the medical device (who, what, how, where, when, why), to collect data that will be used to identify hazardous situations in the next chapter.

This chapter should be filled at the beginning of the project, before the specifications phase and before having a mockup or something validated by users.

If you have access to it, you can have a look at AAMI HE75 standard, section 21 on software and 24 on mobile devices, to get food for thought.

## Description, intended use

Functional description of the software, intended use or draft intended use.

## Equipment application specification

### Medical purpose

Description of medical purpose: treatment/diagnosis, diseases

### Patient population

Description of patient population. This is very important when the patient is the user of the software. Give relevant statistical information on the patient population for usability: Eg: Age, patient state (physical/mental disabilities?), level of instruction

### Intended user

Patient is the user/ Patient is not the user.

List the users: patients, medics, paramedics, IT personnel …

There may be more than one type of users with software. E.g.: physicians for use, IT personnel for maintenance.

If the patient is the user, give relevant statistical information on the patient population for usability: E.g.: Age, patient state (physical/mental disabilities?), level of instruction, anything that could impair the use of software.

If the patient is not the user, information on the level of instruction of the personnel may be also relevant for usability specification.

### Application

Everything about the use and its environment, see samples:

Be careful with environment of use of smartphones!

1. Environment: environment of use may be source of human errors, like noisy environment, too dark, telemedicine platform …
   1. General:
      1. Hospital
      2. Home with remote connection
      3. Ambulance
   2. Conditions of visibility:
      1. Ambient luminance 100 – 500 lux
      2. Viewing distance 20 cm to 1 meter
      3. Viewing angle: normal to the scale ± 20°
   3. Physical: physical conditions of temperature, pressure, vibration.
      1. Normal ambient conditions
      2. .
2. Frequency of use:
   1. Once a year
   2. up to 10+ times a day
3. Mobility:
   1. On a standard PC on a desk
   2. Embedded in medical device on a mobile trolley.
   3. On a handheld PC
   4. On a smartphone.

# Risk assessment

## Characteristics related to safety

### Primary operating functions and use scenarios

Do the inventory of most used functions and functions related to safety.

Make use of the convention in section 1.4 to write scenarios.

Use case diagrams may be an adequate presentation.

This inventory shall be done for each type of user

For users without disabilities:

The most used functions are those for which a routine habit or annoyance of user may occur, source of hazardous situations (the user knows “too well” how to use).

The less used functions are those for which the lack of training of user may occur, source of hazardous situation (the user doesn’t know how to use)

### Possible Use errors

List here possible misuse, errors, anything that may go wrong. Source of wrong situation are the user, the patient and their environment.

Note: things can go wrong also during normal use.

Note2: don’t forget maintenance functions

Samples of misuse:

* User mixes-up two buttons and pushes the wrong one.
* User doesn’t interpret the icon of a buttons.
* User performs an incorrect sequence of functions.

And possible causes:

* Control system ambiguous, source of confusion
* Difficult to know the software state
* Ambiguous presentation, information difficult to interpret
* Wrong representation of data
* Wrong correspondence between commands and actions
* Wrong correspondence between displayed data and real state
* Contradictions in displayed data
* Task which requires too much time
* …

## Hazardous phenomena, hazardous situations and hazard-related use scenarios

Hazardous phenomena, hazardous situations and hazard-related use scenarios are described in the risk management file XXX, section XXX

## Critical tasks

FDA specific

Add a table with critical tasks, similar to table 2 found in guidance Content of Human Factors

Information in Medical Device Marketing Submissions of 2022

These tasks shall be evaluated in the summative evaluation

## Hazard-related use scenarios for summative evaluation

You have to define the criteria for selection of scenarios for summative evaluation. For example: criteria based on severity of risk only. Write your own criteria here.

Critical tasks shall be present

You can fill a table with the following columns: hazard related use scenarios, hazardous situation, acceptability of risk and whether they are selected or not. This table gives a summary of the usability engineering before verification.

| **Hazard-related use scenarios ID** | **Hazardous situation** | **Acceptability of risk before mitigation action** | **Summative Evaluation** |
| --- | --- | --- | --- |
| Scenario 1 | User doesn’t see the value | Not acceptable | Yes |
| Scenario 2 – alternative 1 | User can’t grip the handle | Acceptable | No |

## Mitigation actions and the user interface specification

Mitigations actions are documented in the Risk Management File XXX.

User interface specification is documented in XXX.

For software, the user interface specification is documented in the software requirements specifications.

Alternatively, you can document the user interface specification here (not recommended).

# Formative Evaluations

Describe the formative evaluations planned, where, when what and with whom.

Example: two formative evaluations are planned during the project, one before the preliminary design review (PDR) and one before the critical design review (CDR). The formative evaluation before PDR is realized with product managers, with mockups of xxx and evaluates scenarios xx yy zz, the formative evaluation before CDR is realized with product managers, with prototype of xxx and evaluates scenarios not confirmed at PDR.

For agile process, the following can be written:

With the role of end-user proxy for the team, the product owner is responsible for the formative evaluation. He/she does the formative evaluation of the user-stories. He/she may invite another person external to the team (or to the company) to participate to the formative evaluation.

The formative evaluation is done during the demonstration of the software at the end of the sprint. Depending on the results of the formative evaluation, new items related to the user-interface may be added to the backlog and implemented in a further iteration.

Formative evaluations reports are recorded in XXX.

# Summative Evaluations

Describe the summative evaluations planned, where, when what and with whom. Give rationale for the number of users participating to the evaluation, if necessary.

E.g.: one summative evaluation is planned after the verification of the device. Two groups of 5 users, one group for medics and one group for nurses participate to the summative evaluation.

## Summative Evaluation Protocol

Describe the summative evaluations protocols content.

E.g.: the summative evaluation protocol contains the following information:

For each hazard-related scenario, at least a test case shall be established with:

* The hazard-related scenario and alternative evaluated,
* The goal of the evaluation,
* The user-profile participating to the evaluation,
* The environment of evaluation,
* The duration of the evaluation,
* The IFU provided to the user or no IFU,
* The steps of evaluation,
* The expected results
* …

The summative evaluation protocol is recorded in XXX.

## Summative Evaluation Report

Describe the summative evaluations reports content.

E.g.: the summative evaluation report contains the following information:

For each hazard-related scenario, a test record be established with:

* The hazard-related scenario and alternative evaluated,
* The goal of the evaluation,
* The user-profile participating to the evaluation,
* The environment of evaluation,
* The duration of the evaluation,
* The IFU provided to the user or no IFU,
* The results of the evaluation,
* A rationale for setting the result to (i) OK, (ii) not OK, (iii) more information needed, given the goal of the evaluation.

The summative evaluation report ends with a discussion on the overall compliance of the results obtained for all tests. The result of the discussion is one of the three following states:

* Compliant:
  + All tests are OK,
  + All risks related to usability are acceptable,
  + No additional data required,
* Partially compliant:
  + At least one test is not OK,
  + No unacceptable risk is remaining but at least one risk is tolerable,
  + Additional data shall be collected by PMS and/or PMCF,
* Not compliant:
  + At least one test is not OK,
  + At least one unacceptable risk is remaining,
  + Additional studies or design changes are required.

The summative evaluation report is recorded in XXX.