Ref No	Rev No.	Issue Date

Usability Study

1-Introduction

.....

2-Document overview

This document is the usability engineering file of XXX.

3-Abbreviations and Glossary

3.1.Abbreviations

Add here abbreviations

3.2.Glossary

Add here words definitions

4-References:

4.1.Project References

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

4.3.Standard and regulatory References

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

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5-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:

Id:SCN-XXX-000

Title of XXX-000 Scenario

Prerequisite: device is in xxx state, user is willing to do xxx
Step 1:
Step 2:

6-Use Specifications:

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..

7-Description, intended use

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

8-Equipment application specification

……

9-Medical purpose

Description of medical purpose: treatment/diagnosis, diseases

10-Patient population

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

11-Intended user

Patient is the user/ Patient is not the user.

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

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

12-Application

Everything about the use and its environment, see samples:

Be careful with environment of use of device xxxx!

a. Environment: environment of use may be source of human errors, like noisy environment, too dark, telemedicine platform …

a. General:
✓ Hospital
✓ Home with remote connection
✓ Ambulance

b. Conditions of visibility:
✓ Ambient luminance 100 – 500 lux
✓ Viewing distance 20 cm to 1 meter
✓ Viewing angle: normal to the scale ± 20°

c. Physical: physical conditions of temperature, pressure, vibration.
✓ Normal ambient conditions

b. Frequency of use:
✓ Once a year
✓ up to 10+ times a day

c. Mobility:
✓ On a standard PC on a desk
✓ Embedded in medical device on a mobile trolley.
✓ On a handheld PC

13-Risk assessment

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

14-Primary Operating Functions

14.1.Frequently Used Functions:

xxxxxxxxxxxxxxxxxxxx

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

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

16-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.

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

17-Mitigation actions and the user interface specification

Mitigations actions are documented in the Risk Management FileXXX.

User interface specification is documented in XXX.

18-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 yyzz, the formative evaluation before CDR is realized with product managers, with prototype of xxx and evaluates scenarios not confirmed at PDR.

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.

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Formative evaluations reports are recorded in XXX.

19-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.

19.1.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.

19.2.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 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.

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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

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