**Software Test Description & Report**

**(STD/STR)**

for the

*[Software/ Product name]*

| **Signature** | **Date** | **Name** | **Position** |
| --- | --- | --- | --- |
| - | - | - | SW Engineer/ Manager |
| - | - | - | System Development Manager |
| - | - | - | SW QA Engineer/ Manager |
| - | - | - | QA Engineer/ QE Manager |

**Change history:**

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| **Changed By** | **Change Description** | **Date** | **Revision** |
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*<General instructions and examples for document’s filling are written in blue.  
 These instructions should be deleted or replaced by applicable information>*

## **STsections**

**[1.](#_Toc138112401)****[Introduction](#_Toc138112401)**

**[1.2.](#_Toc138112402)****[Scope](#_Toc138112402)**

**[1.3.](#_Toc138112403)****[Acronyms and Abbreviations](#_Toc138112403)**

**[1.4.](#_Toc138112404)****[Referenced Documents](#_Toc138112404)**

**[2.](#_Toc138112405)****[Test Plan](#_Toc138112405)**

**[2.1.](#_Toc138112406)****[Method](#_Toc138112406)**

**[2.2.](#_Toc138112407)****[Sequence](#_Toc138112407)**

**[3.](#_Toc138112408)****[Overview of Test Results](#_Toc138112408)**

**[4.](#_Toc138112409)****[Test preparations](#_Toc138112409)**

**[5.](#_Toc138112410)****[Detailed Tests Descriptions & Results](#_Toc138112410)**

**[6. Validation &Verification Results Summary](#_Toc138112411)**

**[6.1.](#_Toc138112412)****[Defects](#_Toc138112412)**

**[6.2.](#_Toc138112413)****[Changes from Plan](#_Toc138112413)**

**[7.](#_Toc138112414)****[Conclusions](#_Toc138112414)**

# **Introduction**

This document is called the "Software Test Description & Report (STD/STR) for the *[Software/ Product name]*", and is identified as *[Document ID]*

## **Purpose**

The purpose of this document is to define and describe in first phase the software test plans, preparations, test cases, and test procedures for the *[Software/ Product name]*.

This document forms the baseline for the formal qualification testing of the software in this system. During test execution, the document will be used to record the test run and will become a Software Test Report.

First version of this document will include Test Descriptions (STD phase) and next version will include the test results (STR phase).

The purpose of the STR form of the document is to certify that all planned tests in the STD have been sufficiently completed to state that the system is ready for production.

This document will be written and run by the software testers, and approved by SW QA manager

# **Scope**

This document is the Software Test Description (STD) for *[Software/ Product name]*. It defines the software tests for each requirement on the system level.

## 

**Test Case** - A set of test steps that verify a set of requirements. A test case includes objectives, a list of requirements, expected results, verification method and any other information necessary to execute the test case.

**Test Procedure** - a test procedure is a collection of test cases and information necessary to execute them. After a manual test run, a test procedure becomes a record of the test run and is considered a test report

**Test Run** - A single execution of the STD/STR on a single configuration.

**Test Step** - A test case consists of one or more test steps. A test step has the following components: Step Number, Action, Expected Results, an area to enter Results/Comments, an area to enter a defect ID for non-passing results.

# **Acronyms and Abbreviations**

A list of terms, acronyms and abbreviations used, with their associated meanings are shown below.

STD - Software Test Description

STR - Software Test Report

SRS - Software Requirement Specification

*[Add any other acronyms or abbreviations]*

# **Referenced Documents**

The references and standards listed here should be considered when applying this guide. Referenced documents will be binding only if referred to by this document, and then, only to the extent to which they are referred to. Unless stated otherwise, the latest revision is applied.

In the event of conflict between the documents referenced herein and the contents of this specification, the contents of this specification shall be considered a superseding requirement.

|  |  |  |  |
| --- | --- | --- | --- |
| Ref # | Document Name | Rev # | Doc ID |
| [A1] | Std 016/IEEE Std 1498, Software Development and Documentation |  |  |
| [A2] | IEEE Std 829-1998, IEEE Standard for Software Test Documentation |  |  |
| [A3] | IEEE Std 610.12-1990, IEEE Standard Glossary of Software Engineering Terminology |  |  |
| [A4] | IEC 62304 – 2006 Amend. 2015, Medical device software, Software life-cycle processes |  |  |
| [A5] | ISO14971:2012, Medical devices — application of risk management to medical devices |  |  |
| [A6] | FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices |  |  |
| [A7] | *List proper name and reference for Risk Analysis* |  |  |
| [A8] | *List proper name and reference for Software Test Plan* |  |  |
| [A9] | *List here any additional references* |  |  |

# **Test Plan**

# **Method**

* *To test the [Software/ Product name], the following method, based upon with appropriate tailoring, is applied:*
* *Cover all software requirements listed in the SRS-s by test cases.*
* *Cover the software related Safety Risks listed in the Risk Management procedure by test cases.*
* *Each software or safety requirement is covered at least by one test case, and if necessary, by several test cases.*
* *The coverage of the software requirements and of the risks is reported in the traceability table in Traceability section.*
* *Some requirements are covered by unit tests and some by system tests. The reference to relevant tests reports will be attached in the STR file*
* *The test cases include detailed descriptions of the test, expected results, and pass/fail criteria for each step.*

# **Sequence**

The tests are built in the following sequence:

* *Tests preparation: preparation of all related hardware devices and relevant software applications (if needed).*
* *Standard application flow by testing general system features.*
* *Additional*

# **Overview of Test Results**

*<This paragraph is Not Applicable on the STD phase of this document>*

This section contains the overview of the validation test results performed on the software.

## **Overall Assessment of the Software Tested**

## *< Include a statement summarizing the results of all the verification activities, such as >*

The overall assessment of the validation tests performed on the software version listed is that the software is ready for production.

*< Describe additional activities that may be required as a result of the execution of the tests. For instance, if the product is conditionally ready for production, then identify the pre-conditions that must be met before/during/etc. >*

## **Configuration Of the Software Tested**

The system validated contains the following software items:

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Name** | **Version** | **Comment** |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

The tests were performed on [Day/Month/Year]

## **Impact of Test Environment**

## There was no impact of the test environment on the testing.

## **Summary of Execution**

*<Summarize the failures found and comment them.*

*List the tests not tested and provide the reason. Ex: missing or inadequate hardware.*

*List the requirements that are not met as results of failures or missing tests*

*Evaluate improvement of test definition>*

## **Recommended Improvements**

Software improvements to be implemented in the following versions of the program include:

*<Add any recommendation or write No recommended improvements are noted.>*

# **Test preparations**

This section describes the test preparations for the various tests to be performed.

*[Specify general preparations that need to be done in order to perform the tests. e.g., calibration of the device, accessories needed, software readiness, defects resolving, STD approved, etc.]*

## **Hardware Preparation**

*[Specify Hardware needed and preparations that need to be done in order to perform the tests]*

## **Software Preparation**

*[Specify Software preparations that need to be done in order to perform the tests.]*

# **Detailed Tests Descriptions & Results**

Here will be a description of all tests needed to be performed on the software version. The tests will be divided to several categories according to their functionality.

*<The test definition contains the documentation needed to run the test:*

*State how to run the test. The test cases should have a format that is appropriate to the particular test. The test procedure consists on succession of test with numbered steps, actions, expected results for each action, how to collect the data from the test run, and space to record results, initial the results and room to record a defect number if a failure is found in supporting code or hardware.>*

## [Test Category Name]

*<Give a name to the category in the title. Ex: System tests, Interface tests, etc. Give a short description of the test category>*

This section describes all tests to be done under this category.

| **Test ID** | **Req. #** | **Test Name** | **Test Steps** | **Expected Results** | ***To be filled in the STR stage*** | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Pass/Fail** | **Failure Description** | **Bug #** |
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## [Test Category Name]

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| **Test ID** | **Req. #** | **Test Name** | **Test Steps** | **Expected Results** | ***To be filled in the STR stage*** | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Pass/Fail** | **Failure Description** | **Bug #** |
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# **Validation &Verification Results Summary**

*<This paragraph is Not Applicable on the STD phase of this document>*

## *<This section should contain the list of reports with their final results, on which version each test was performed and justification for it; Fields should contain: Part number, Description, Result, Deviations, Version Run, Comments>*

# **Defects**

*<The table with list of defects that remained open on current version, for future projects and updates, this may be separated to new defects found in this project and a separate part for known defects from previous versions, it is vital to separate defects from issues/anomalies, defects must be added here, while anomalies and issues can either be listed below, or a reference to another controlled external document which documents them>*

## **Open Bugs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Bug # | Title | Detailed Description | Severity | Rationale |
|  |  |  |  |  |
|  |  |  |  |  |
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# **Changes from Plan**

*<List any changes from the V&V Plan, consider, sample size, execution of protocols, use of non-production equivalent units etc.>*

No Changes for the Design Verification and Validation plan have been made during testing.

# **Conclusions**

# *<This paragraph is Not Applicable on the STD phase of this document>*

*<This section should conclude all software V&V test results. For example:*

1. Software Verification and Validation was executed according to the Design Verification and Validation plan. All tests were performed trained V&V personnel. All tests were performed in full and passed according to each tests specific acceptance criteria, and the overall software verification and validation process passed according to the overall acceptance criteria.
2. Defects found during the V&V cycles, were all reviewed, classified and approved. Defect classification board approved the system for release with ## open anomalies / issues (see paragraph 6). None of the open issues are related to safety or efficacy.
3. All tests were completed successfully. The system functions as required and is safe for use.

Regarding the scope tested during the Design V&V activities, it is concluded that *[Software/ Product name]* meets all requirements and specifications.

-End of Document -