**Test Protocol -Backend**

**FDA Unit Test Example**

# Summary

|  |  |
| --- | --- |
| **Identification** | FDA Unit Test Example – Backend |
| **Version** |  |
| **Execution Date** |  |
| **Final Disposition** | ACCEPTED  REJECTED |

# Purpose

This Test Protocol describes the verification protocol for the Backend of the FDA Unit Test Example device. This is a verification procedure that ensures that all device outputs have been properly implemented. When executed and completed, this file serves as a record.

# Background

The Backend is a software item of the FDA Unit Test Example device. It is a smartphone application that is installed onto Apple devices running the iOS operating system.

# Scope

The document applies to the FDA Unit Test Example product.

# Applicable Documents

|  |  |
| --- | --- |
| **Document** | **Description** |
| <doc #> | <doc # for SOP that manages design changes> |

# Responsibility

Engineering is responsible for updating this document

# OTSS Verification

The Off-The-Shelf Software (OTSS) that is contained in the Backend application is located at <otss doc #>. Hazards associated with OTSS items are identified in <hazard analysis doc #>. In the process of its usage, the Backend application executes all functionality of all OTSS that are contained in it. Full execution of this protocol with a final disposition of “ACCEPTED” provides objective evidence that identified OTSS hazards have been addressed, and also validates that the OTSS meets the application’s needs and the intended use of the OTSS. Therefore, full execution of this protocol with an “Accepted” disposition both verifies and validates OTSS contained within the Backend Application.

# Protocol Execution Overview

Fill out the Test Step section making sure to identify the software name and version that is being verified by this protocol. Identify any hardware used during the execution of the protocol. If applicable, additionally fill in the details regarding the operating system version. For full regression testing of a version of the software, all sections of this protocol shall be executed for a given version. However, often it is necessary to test a specific feature or function. In this case, only certain sections will be executed while other sections are skipped. If this is the case, identify the sections that will be executed and a justification as to why only those sections will be executed.

When executing the protocol, follow the directions provided in the “Procedure” column and then observe the results described in the “Expected Result” column. Document the observed results in the “Observed Result” column. If the results observed match the expected, then it is appropriate to identify such by entering “A/E” for “As Expected.” If the observed result is as expected, then mark a “P” in the “Pass/Fail” column. If the observed result is not as expected, then mark an “F” in the “Pass/Fail” column.

If a test fails, document the test number, and describe the result in the “Tester Notes” section of the “Test Report” at the bottom of this protocol. If a test passes, but additional noteworthy results are observed, then also document the test number, and describe the observation and result in the “Tester Notes” section of the “Test Report.” Additional thoughts regarding the test can also be added in the “Tester Comments” section. All documented results will be evaluated by the Reviewer and included in the final disposition of the software.

Test steps with Redlines are documented in the “Tester Notes” section of the “Test Report” and are identified by the test step and the reason for the redline. Redlines to test steps may be needed as long as the requirement is appropriately verified. The following redlines to tests steps are considered appropriate: 1) redlines to the “Procedure” to correct typos, or to allow execution of the protocol, 2) redlines to “Expected Results” to correct typos, or to bring the expected result into conformance with a requirement to ensure that the requirement is verified, 3) other situations which the Reviewer may deem appropriate, but which much be justified as acceptable and as not affecting patient safety. Redlines are not acceptable if they prevent the intended requirement from being adequately verified.

After the Tester completes the Test Plan of the protocol, the Tester will fill out the “Tester Notes” section of the Test Report at the end of this protocol and then submit the filled out protocol to an independent reviewer for Final Disposition

This document can be filled out either electronically or using black/blue ink. When using ink, if an item needs to be corrected, white-out and scribbling out are not permitted -- all corrected items should continue to be readable. Do a single line-out through the written text and then initial and date the line-out.

# Final Disposition

After execution of the Test Plan, the Reviewer shall review the executed protocol to ensure that the Test Plan was appropriately executed. The Reviewer shall evaluate all notes and comments written by the Tester and shall make a disposition as to whether or not the software is ACCEPTED or REJECTED. The following are the appropriate dispositions to be made by the Reviewer for the item under tests

“ACCEPTED, as Is” – all executed test steps pass, requirements have been verified, no comments, and no redlines

“ACCEPTED, with Comments” – test notes and comments have been reviewed and found acceptable, and the software is evaluated to be safe for use

“ACCEPTED, with Redlines” – redlines have been made and are acceptable.

“REJECTED” – requirements were not verified, or the software is not found to be safe or acceptable

If the software is “ACCEPTED, with Comments” or “ACCEPTED, with Redlines”, the reviewer must document their justification and rationale in the disposition evaluation

# Signatures

This document may be signed electronically or using ink. When using ink, sign, and date in the designated locations. When signing using an electronic signature, type your name, and the date of the execution or review, as applicable. The date written in the document is considered the date that the event occurred. The electronic signature on the record is considered an attestation that the contents (including the date written in the document) are true. Due to delays inherent with routing for electronic signatures, it is acceptable for the date of the electronic signature may be different from the date in the record. The date written in the document is considered the date that the event occurred.

# Test Setup

**Software Information**

|  |  |
| --- | --- |
| Software Identification | Backend |
| Software Version |  |
| Operating System Version |  |

**Hardware Information**

|  |  |
| --- | --- |
| Identification |  |
| Make |  |
| Model |  |
| Serial Number |  |

# Test Plan

|  |  |
| --- | --- |
| **Execute the entire protocol?** | YES  NO, document rationale and sections that will be executed: |

# Test Report <to be filled out after completing the verification protocol in the next section>

|  |  |
| --- | --- |
| **Software Identification** | Backend |
| **Software Version** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tester Notes** | | | | |
| **Test Step** | **Observation**  *No observations, table intentionally left blank* | | | **Pass / Fail** |
|  |  | | |  |
|  |  | | |  |
|  |  | | |  |
|  |  | | |  |
| **Tester Comments**  *N/A, Comments intentionally left blank* | | | | |
|  | | | | |
| **Tester Identification** | | | | |
| **Execution Time** |  | | | |
| **Name** |  | **Date:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Final Disposition** | | | |
| ACCEPTED  ACCEPTED, with redlines  ACCEPTED, with comments  REJECTED | | | |
| **Disposition comments**  *N/A, Comments intentionally left blank* | | | |
|  | | | |
| **Reviewer Identification** | | | |
| **Name** |  | **Date:** |  |

# Verification Test Protocol

## <screen>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step** | **Procedure** | **Expected Result** | **Observed Result or**  **“As Expected” (A/E)** | **Pass / Fail** |
|  |  |  |  |  |