**Software Validation**

**Revision History**

|  |  |  |
| --- | --- | --- |
| **Revision** | **Date** | **Description of changes** |
| 00 | 2018.07.06. | Established the software validation. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Written by** | **Reviewed by** | | **Approved by** |
|  |  |  | Hjpark_signature |
| JungHwan Jang | JaeYoung, Kim | SunYoung, Jeong | Hae-June, Park |
| Manager of  S/W Team, Instrument R&D | Senior Manager of Instrument R&D | RA/MSL | Vise President |

**Table of Contents**

[1. Software Level of Concern 3](#_Toc460336178)

[2. Software Description 4](#_Toc460336179)

[3. Software Hazard Analysis 5](#_Toc460336180)

[4. Software Requirement Specification 11](#_Toc460336181)

[5. Software Design Architecture Specification 14](#_Toc460336182)

[6. Software Design Specification 20](#_Toc460336183)

[7. Traceability Analysis 25](#_Toc460336184)

[8. Software Development Environment 27](#_Toc460336185)

[9. Verification & Validation 29](#_Toc460336186)

[10. Revision Level History 43](#_Toc460336187)

[11. Unresolved Anomalies 43](#_Toc460336188)

1. Software Level of Concern

The level of concern of ELISA Report was determined to be Moderate. The following describes the method used to determine the level of concern and the rationale.

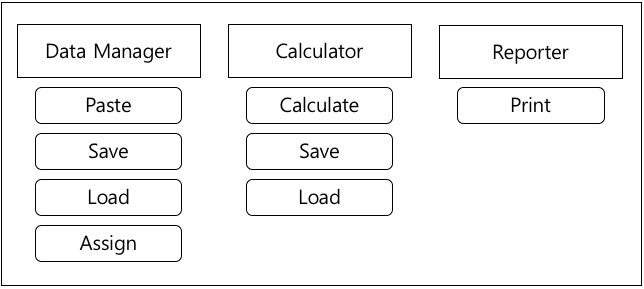
This software of ELISA Report is intended for the professional use for analyze raw data and calculate result. The software performs a quality control assessment of the assay, generates a standard curve, and provides a test result for each subject, as detailed in the Interpretation of Results section.

|  |
| --- |
| * 1. If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major. |
| 1. Does the Software Device qualify as Blood Establishment Computer Software?   No, the Software Device does not qualify as Blood Establishment Computer software. |
| 1. Is the Software Device intended to be used in combination with a drug or biologic?   No, the Software Device is not intended to be used in combination with a drug or biologic. |
| 1. Is the Software Device an accessory to a medical device that has a Major Level of Concern?   No, the Software Device is not an accessory to a medical device, major level of concern. |
| 1. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: |
| 1. Does the Software Device control a life supporting or life sustaining function?   No, the Software Device does not control a life supporting or life sustaining function. |
| 1. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?   No, the Software Device does not control the delivery of potentially harmful energy that could result in death or serious injury. |
| 1. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?   No, the software device does not control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury. |
| 1. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?   No, F200information is not used for diagnosis of diseases or for immediate treatment (such as immediate insulin dosage). It is used only for the initial screening purpose. |
| 1. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?   No, the Software Device does not provide vital signs monitoring and alarms for potentially life threatening situations. |

1. Software Description
2. Software Information
   1. Software Title ELISA Report Software
   2. Version V1.1
   3. Release Date June 20, 2018
   4. Programming Language Object Pascal
   5. Hardware Platform PC
   6. Operating System Windows 8 or Higher
3. Software Overview

The ELISA Report is a PC based application for calculating STANDARD E TB-Feron ELISA test results.

The software consists of 3 principal modules like the followings:



1. Software Hazard Analysis
2. ISO 14971:2007 (EN ISO 14971:2012) Annex C List
3. Hazard Analysis

| Hazard ID | Potential Hazard | Hazardous Situation | Cause | Severity Index | Mitigation | |
| --- | --- | --- | --- | --- | --- | --- |
| H-01 | Calculates error | Standard material OV value does not satisfy the criteria after normalize. | User’s mistake;  *The input raw-data is not satisfy the Criteria.* | 4  (Minor/Remote) | Software Design | The software should display “invalid” label with the Coefficient of Variation and Chart. |
| Label | Invalid |
| H-02 | Calculates error | Use a wrong data | User’s mistake;  *User try to paste contents which format does not text.* | 4  (Minor/Remote) | Software Design | The software should be open the dialog with the message. |
| Message | Invalid format on clipboard. Failed to paste into grid. |
| H-03 | Calculates error | Not enough raw data | User’s mistake;  *User does not ready to enough raw data to using a software* | 4  (Minor/Remote) | Software Design | The software should be open the dialog which message. |
| Message | The clipboard source  does not match the  expected column or row. |
| H-04 | Ignore raw data | Cannot process the jobs at once. | User’s mistake; *expired test device is used.* | 2  (Negligible/Remote) | Software Design | The software should be open the dialog which message. |
| Message | The clipboard source  contains more items than  the column or row. Do  you wish to proceed? |
| H-05 | Calculates error | Polled raw data | User’s mistake;  *The clipboard source modified by a user.* | 4  (Minor/Remote) | Software Design | The software should be open the dialog which message. |
| Message | The clipboard source has different columns count. Failed to paste into grid. |

1. Severity Index Chart

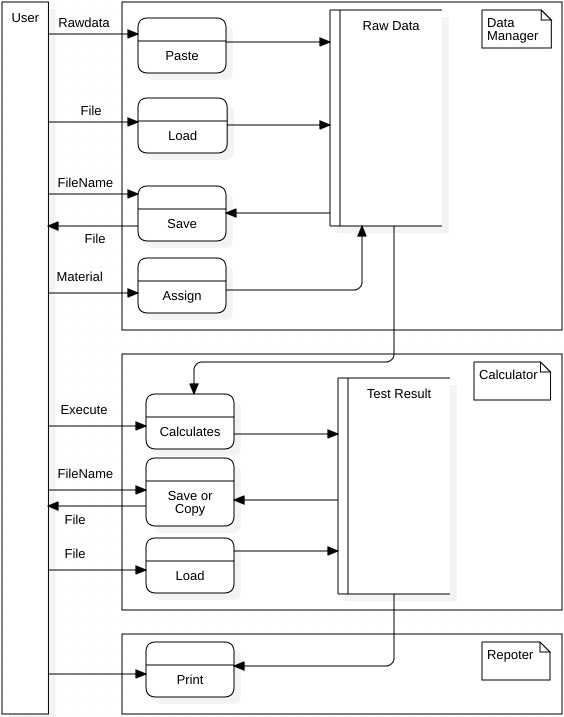
|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Frequent** | 5 | 10 | 15 | 20 | 25 |
| **Probable** | 4 | 8 | 12 | 16 | 20 |
| **Occasional** | 3 | 6 | 9 | 12 | 15 |
| **Remote** | 2 | 4 | 6 | 8 | 10 |
| **Improbable** | 1 | 2 | 3 | 4 | 5 |
| **Total** | **Negligible** | **Minor** | **Serious** | **Critical** | **Catastrophic** |

*Severity index values ≥5 require further mitigation.*

1. Software Requirement Specification

| **SRS ID** | **SRS Name** | | **Requirement** |
| --- | --- | --- | --- |
| **Operation Environment** | | | |
| FSR-A01 | Hardware | Minimum CPU | Intel P4 |
| FSR-A02 | Minimum Memory | 256MB |
| FSR-A03 | Minimum Storage | 20MB |
| FSR-A04 | OS | Windows 8 or higher |
| FSR-B01 | Programming Language | Limited program size | 256MB |
| FSD-C01 | Interface | Display | 1024x768 |
| FSD-C02 | Input Device | Keyboard and Mouse |
| **Operation & Function** | | | |
| FSR-D01 | Data Manager | Paste | Read the raw-data from the clipboard, then display on the grid. |
| FSR-D02 | Edit | When double-clicking the cell, a user can edit it. |
| FSR-D03 | Material Assign | Update the cell’s color and property by the user selected material when clicking the cell.   * Each material represented by the different color with character. |
| FSR-D04 | Standard Material Assign | Update the cell’s color and property by the user selected material when clicking the cell.  Each standard material represented by the different contrast with character. |
| FSR-D05 | Save a test result | If a user wants can save the raw data by a menu. |
| FSR-D06 | Load a test result | The software can load a raw data from a saved file. |
| FSR-E01 | Calculator | Calculates | Calculates using a user input data. |
| FSR-E02 | Display the test results | Display the test result:   * Standard material should show the valid/invalid result with the chart. * The standard material result should show with a chart. * Each material should have the result |
| FSR-E03 | Save a test result | If a user wants Can save the test result by a menu. |
| FSR-E04 | Load a test result | The software can load a test result from a saved file. |
| FSR-F01 | Report | Print | The raw data and a test result can print |
| FSR-F02 | Copy the raw-data as Clipboard | * A user can copy the raw data using a clipboard. * The clipboard contents delimiter should be the tab character. |
| FSR-F03 | Copy the calculate result as Clipboard | * A user can copy the test result using a clipboard. * The clipboard contents delimiter should be the tab character. |
| **Errors and Warning handling** | | | |
| FSR-G01 | Error Message | Invalid | If the standard material values are invalid, should be display with the chart. |
| FSR-G02 | Invalid format on clipboard. Failed to paste into grid. | When a user tries to wrong formatted contents try to paste, should be not assigned and display an error message. |
| FSR-G03 | The clipboard source does not match the expected column or row. | When a user tries to not enough columns or rows to paste, cannot uses that, notify by an error message dialog. |
| FSR-G04 | Warning Message | The clipboard source contains more items than the column or row. Do you wish to proceed? | When a user tries to over the acceptable columns or rows to paste, should notify the contents which over columns or rows of data discarded. |
| FSR-G05 | Error Message | The clipboard source has different columns count. Failed to paste into grid. | When a user tries to paste contents which have a different count of columns or rows, should notify that will be discarded. |

1. Software Design Architecture Specification
2. Data Flow Diagram

****

1. Functional Units

The functional unit consists of 4 modes;

| Mode | Description |
| --- | --- |
| Data Manager | The Data manager consists of four principal methods   * Paste: Acquire raw data from the clipboard. If the raw data is invalid, refuse it and notify error message by dialog. * Load: Load the raw data from the file. * Save: Save the raw data. * Assign: It assign OD values which are standard and material(nil, antigen and mitogen) |
| Calculator | The calculator calculates raw data and display the standard validation result and result of each material by table and chart. It consists of three principal method.   * Calculate: do that calculate material by standard OD values. The standard values do a normalized that used for diagnosis valid or invalid. * Save or Copy: The calculated result can save to file or copy to a clipboard. It can contain raw data and the result. * Load: Load the raw data and the result from the save file. |
| Reporter | The reporter module can be print report or save as pdf file format.  It has one principal method.   * Print: A raw data and the result can print or save as pdf file format. |

1. Software module

| Module | Function |
| --- | --- |
| Data Manager | procedure Paste(const ASrc: TStringList; const AColCount: Integer); |
| procedure AssignDefault(const AMaterial: TCriteriaMaterial); |
| procedure AssignManual(c, r: Integer; const AMaterial: TCriteriaMaterial; const ADir: TMaterialDirection); |
| procedure AssignRandom(const APoint: TMatPoint; const AMaterial: TCriteriaMaterial); |
| procedure RemoveFmt(c, r: Integer); |
| procedure AssignFmtSet(const AValue: TFormatSettings); |
| procedure LoadFromFile(const AFileName: String); |
| procedure SaveToFile(const AFileName: String; const AContainsProperty: Boolean = False); |
| procedure Clear(const AClearWithProp: Boolean = True); |
| procedure ClearStds; |
| procedure ClearSamples; |
| procedure AssignProperties(const AProperty: TGeneralInfo) |
| function MatIDArray: TArray<TMatStrPair>; |
| function IDArray: TArray<String>; |
| function StdArray: TArray<TArray<Double>>; |
| function MtrlArray: TArray<TStringDynArray>; |
| Calculator | procedure Initialize; |
| procedure Clear; |
| procedure ExportToClipboard; |
| procedure ExportToFile(const AFileName: String); |
| function ChartAsBmp(const w, h: Integer): TBitmap; |
| Repoter | procedure Initialize; |
| class procedure Open; |
| procedure frxReportBeforePrint(Sender: TfrxReportComponent); |
| procedure frxReportGetValue(const VarName: string; var Value: Variant); |

1. Traceability Analysis

Software description, requirement, design specification, hazard, verification, validation & testing can be managed through the traceability analysis according the following matrix table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Classification** | **Documentation** | **Identification** | **Remarks** |
| 1 | Software Requirement Specification | To describe what the software is supposed to do. | FSR-A01 |  |
| 2 | Software Design Specification | To describe the implementation of the requirements for the software | FSD-A01 |  |
| 3 | Hazard Analysis | To refer to the Risk Management Report | H-01 |  |
| 4 | Verification, Validation & Testing | Summary list of validation and verification activities and the results of these activities | FSV-A01 |  |
| * A: *performance or function classification code* * *01: the detail feature number for the specific performance or function classification* | | | | |

1. Traceability Matrix

| Hazard ID | Cause | SRS ID | SRS Name | Testing ID | Testing Name | Result |
| --- | --- | --- | --- | --- | --- | --- |
| H-01 | User’s mistake; *Invalid standard material (OD) values assign* | FSR-G01 | Invalid | FSV-G01 | Invalid | *PASS* |
| - | User Instruction Guide Review | *PASS* |
| H-02 | User’s mistake; *Paste invalid formatted raw data.* | FSR-G02 | Invalid format on clipboard. Failed to paste into grid. | FSV-G02 | Invalid format on clipboard. Failed to paste into grid. | *PASS* |
| - | User Instruction Guide Review | *PASS* |
| H-03 | User’s mistake; *Paste the clipboard source which does not match the expected column or row* | FSR-G03 | The clipboard source does not match the expected column or row. | FSV-G03 | The clipboard source does not match the expected column or row. | *PASS* |
| - | User Instruction Guide Review | *PASS* |
| H-04 | User’s mistake; *Paste the raw data which contains more items than the column or row.* | FSR-G04 | The clipboard source contains more items than the column or row. Do you wish to proceed? | FSV-G04 | The clipboard source contains more items than the column or row. Do you wish to proceed? | *PASS* |
| - | User Instruction Guide Review | *PASS* |
| H-05 | User’s mistake; *Paste the raw data which has different columns count.* | FSR-G05 | The clipboard source has different columns count. Failed to paste into grid. | FSV-G05 | The clipboard source has different columns count. Failed to paste into grid. | *PASS* |
| - | User Instruction Guide Review | *PASS* |

# 

1. Verification & Validation
2. Scope & Purpose
3. Scope

ELISA Report

1. Purpose

To verify and validate the software of ELISA Report

1. Normative reference

IEC 62304:2006 Medical device software – Software life-cycle processes

1. Testing Condition

|  |  |
| --- | --- |
| **Testing Date** | 10.July, 2018 |
| **Testing Site** | SD Biosensor, Inc. |
| **Testing Environment** | Windows 10 |
| **Testing Representative** | Mr. JH Jang| Instrument R&D, SD Biosensor, Inc. |
| **Analyzer** | ELISA Report |

1. System and Integration Testing

System and Integration Testing is confirmation that the interactions across software and the system.

| **Testing ID** | **Requirement** | | | **Test Procedure** | **Test P/F Criteria** | | **Result** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | | **Description** | **Expected Screen** | **Description** |
| FSV-D01 |  | Paste | Read the raw-data from the clipboard, then display on the grid. | 1. Copy the raw data from the Excel file. 2. Paste it. |  | All values must be the same. However, for empty cells, it is displayed as N / A. | ■ Pass  □ Non-pass  Note: |
| FSV-D02 | Edit | When double-clicking the cell, a user can edit it. | 1. Double clicking cell excepts value is not N/A. 2. Edit value |  | The left side image describes 0.076 to 0.084 | ■ Pass  □ Non-pass  Note: |
| FSV-D03 | Material Assign | Update the cell’s color and property by the user selected material when clicking the cell. | 1. Default Format -3    1. Clicking In-Tubu(nil, antigen, mitogen) 2. Default format -2    1. Clicking In-Tubu(nil, antigen) 3. Manual format    1. Click Manual button    2. Select Standard sample    3. Click cell    4. Select Subject Samples    5. Click cell which does not selected by standard. |  | Manual format, in a third screen, the N/A cell user cannot assign it. | ■ Pass  □ Non-pass  Note: |
| FSV-D05 | Standard Material Assign | Update the cell’s color and property by the user selected material when clicking the cell.  Each standard material represented by the different contrast with character. | It can only manual format only.   1. Clicking the standard sample’s cell |  | Each standard sample should have a different contrast.  The N/A cell user cannot assign it. | ■ Pass  □ Non-pass  Note: |
| FSV-D06 | Save a test result | If a user wants can save the raw data by a menu. | 1. Clicking a Save button on a format group. 2. Clicking a Load button in a format group. |  | The grid have a same format to FSV-D05 | ■ Pass  □ Non-pass  Note: |
| FSV-E01 | Memory | Calculates | Calculates using a user input data. | 1. Clicking a Calculate button |  | Can execute without any unexpected behavior | ■ Pass  □ Non-pass  Note: |
| FSV-E02 | Display the test results | Display the test result:   * Standard material should show the valid/invalid result with the chart. * The standard material result should show with a chart. * Each material should have the result | 1. Compare each result to the manual calculation. 2. Compare validation result to the manual calculation 3. Compare chart to the manual drawing |  | Left side is validation result, and right side is each subject sample’s result. | ■ Pass  □ Non-pass  Note: |
| FSV-E03 | Save a test result | If a user wants Can save the test result by a menu. | 1. Click File 🡪 Save 2. Typing a file to save. |  | Can execute without any unexpected behavior | ■ Pass  □ Non-pass  Note: |
| FSV-E04 | Load a test result | The software can load a test result from a saved file. | 1. Click [Clear All] 2. Click [File] 🡪 [Load] 3. Select the saved file which is saved by previous test(FSV-E01) |  | * Same grid format to FSV-D006 * Same Result values to FSV-E02 | ■ Pass  □ Non-pass  Note: |
| FSV-F01 | Reporter | Print | The raw data and a test result can print | 1. Click [Print] button 2. Click [Print] button Click [Save as PDF] button |  | * The preview dialog should be popup. * The preview contents should be printed or saved as pdf file. | ■ Pass  □ Non-pass  Note: |
| FSV-F02 | Copy the raw-data as Clipboard | * A user can copy the raw data using a clipboard. * The clipboard contents delimiter should be the tab character. | 1. Click [Result Export]    1. Click [To Clipboard]    2. Click [To CSV File] |  | The export contents which from a clipboard or file should be same the application data. | ■ Pass  □ Non-pass  Note: |
| FSV-F03 | Copy the calculate result as Clipboard | * A user can copy the test result using a clipboard. * The clipboard contents delimiter should be the tab character. | 1. Click Export Data    1. Click [To Clipboard]    2. Click [To Csv File] |  | The export contents which from a clipboard or file should be same the application data. |  |
| FSV-G01 | Error Message | Invalid | If the standard material values are invalid, should be display with the chart. | 1. Build a wrong Standard material OD values with material values by excel. 2. Copy and paste it. 3. Execute calculate. |  | The reason of invalid should be displayed with the chart. |  |
| FSV-G02 | Invalid format on clipboard. Failed to paste into grid. | When a user tries to wrong formatted contents try to paste, should be not assigned and display an error message. | 1. Copy some contents which does not text. e.g., Image, movie and file like that. 2. Execute Paste |  | Can execute without any unexpected behavior after click OK |  |
| FSV-G03 | The clipboard source does not match the expected column or row. | When a user tries to not enough columns or rows to paste, cannot uses that, notify by an error message dialog. | 1. Build a wrong formatted raw data which column or row less than 12x8. 2. Copy and paste it. |  | Can execute without any unexpected behavior after click OK |  |
| FSV-G04 | Warning Message | The clipboard source contains more items than the column or row. Do you wish to proceed? | When a user tries to over the acceptable columns or rows to paste, should notify the contents which over columns or rows of data discarded. | 1. Build a wrong formatted raw data which column or row less than 12x8. 2. Copy and paste it. |  | If click the Yes button, can be continue to the process. |  |
| FSV-G05 | Error Message | The clipboard source has different columns count. Failed to paste into grid. | When a user tries to paste contents which have a different count of columns or rows, should notify that will be discarded. | 1. Copy the normal raw data, paste to notepad. 2. Delete only one cell with tab character for makes a different column count. 3. Execute Paste. |  | Can execute without any unexpected behavior after click OK |  |

1. Software Unit Testing

Unit and Subsystem Verification is confirmation that the Software Unit conforms to the Software Design Specification is the decomposition of the software architecture into the structural components (units) and their interface. These software units are described in Software Architecture.

| Module | Function | Test P/F Criteria | Result | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sample 1 | | | Sample 2 | | | Sample 3 | | |
| **Test 1** | **Test 2** | **Test 3** | **Test 1** | **Test 2** | **Test 3** | **Test 1** | **Test 2** | **Test 3** |
| Data Manager | procedure Paste(const ASrc: TStringList; const AColCount: Integer); | Paste Contents is Same | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure AssignDefault(const AMaterial: TCriteriaMaterial); | Each record equals to AMaterial Parameter | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure AssignManual(c, r: Integer; const AMaterial: TCriteriaMaterial; const ADir: TMaterialDirection); | Each cells are equals to c, r, AMaterial and ADir parameter | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure AssignRandom(const APoint: TMatPoint; const AMaterial: TCriteriaMaterial); | Each points are equals to APoint and AMaterial parameter | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure RemoveFmt(c, r: Integer); | cell that pointed by c and r is set be null value | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure AssignFmtSet(const AValue: TFormatSettings); | The internal format value equalt to AValue parameter | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure LoadFromFile(const AFileName: String); | The internal data are equals to file which name is AFileName | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure SaveToFile(const AFileName: String; const AContainsProperty: Boolean = False); | The file which name is AFilename are equals to internal data | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| Calculator | procedure Clear(const AClearWithProp: Boolean = True); | The all cells set be null value | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure ClearStds; | The all standard cells set be null value | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure ClearSamples; | The all material cells set be null value | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure AssignProperties(const AProperty: TGeneralInfo) | The data manager properties are equals to AProperty. | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| function MatIDArray: TArray<TMatStrPair>; | The return values are equals to data manager’s material ID array. | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| function IDArray: TArray<String>; | The return values are equals to material array ‘s ID values. | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| function StdArray: TArray<TArray<Double>>; | The return values are equals to data manager’s standard array. | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| function MtrlArray: TArray<TStringDynArray>; | The return values are equals to data manager’s material array. | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure Initialize; | The all cells set be null value | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure Clear; | The all cells set be null value except property | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| Repoter | procedure ExportToClipboard; | The clipboard contents are equals to application’s result. | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure ExportToFile(const AFileName: String); | The file contents are equals to application’s result. | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| function ChartAsBmp(const w, h: Integer): TBitmap; | The BMP image are equals to application’s result. | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure Initialize; | Report interanal values are set be null | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| class procedure Open; | Execute without any exception | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure frxReportBeforePrint(Sender: TfrxReportComponent); | Execute without any exception | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |
| procedure frxReportGetValue(const VarName: string; var Value: Variant); | Execute without any exception | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* | *PASS* |

1. Validation

Design validation test is to check for proper operation of the software in its actual use environment, including integration into the final device where appropriate. So, design validation was performed as follows.

|  |  |  |  |
| --- | --- | --- | --- |
| Testing Item | Description | Test P/F Criteria | Result |
| Running on Windows 8 | The software executes on the Windows 8 | All test method should be passed | *PASS* |
| Running on Windows 10 | The software executes on the Windows 10 | All test method should be passed | *PASS* |

1. Revision Level History

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date | Revision | Description | Designer | Coding | Debugging |
| 2018.07.06. | V1.1 | First release | JY Kim | JH Jang | JH Jang |

1. Unresolved Anomalies

None