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# Purpose

This document lists traces from requirements to verification test protocols.

# Scope

The attachment to this document [REF-03] gives per row the traceability between the requirement tag, the test result, and the test record(s) and if applicable a justification and/ or remarks.

# Terminology & Abbreviations

This table contains the definitions and abbreviations used in this template and in the attachment [REF-03]

| **Terminology & Abbreviations** | **Description/Definition** |
| --- | --- |
| DICOM | Digital Imaging and Communications in Medicine |
| DIN | Deutsches Institut für Normung (German Institute for Standardization) |
| IEC | International Electrotechnical Commission |
| IHE | Integrating the Healthcare Enterprise |
| SRS | System Requirements Specification |
| dRMM | detailed Risk Management Matrix |
| tag | Unique identifiable item |
| TE TM | Test Environment Traceability Matrix |
| TRF | Test Report Form |
| TTM | Test Traceability Matrix |
| UID | User Interaction Design |
| WEEE | Waste Electrical and Electric Equipment directive |

# Requirements Traces

## 4.1 SRS Requirements to Requirements

This traceability document will not provide traceability from SRS requirements [REF-02] to other system related requirements.

| **Requirements SRS** | | **Requirements** | |
| --- | --- | --- | --- |
| Doc. Ref. | ID | Doc. Ref. | ID |
| - | - | - | - |

## 4.2 SRS Requirements to Test Protocols

The traceability from SRS requirements [REF-02] to Test Protocols is documented in the attachment [REF-3]. Following evidence is provided:

* New and regression evidence.  
  The SRS tags that need to be covered are defined in the Product Verification Plan [REF-01].
* Re-used test evidence.  
  Test evidence is "re-used" when the SRS tag and its implementation is not impacted by any product change implemented in Azurion R3.0 and therefor did not require any new test.

# References

Below find the list of references used in both this document and its attachment [REF-03]:

| **Reference Number** | **Document Title** | **Document ID** |
| --- | --- | --- |
| [REF-01] | Product Verification Plan Azurion R3.0 | DHF354356 Rev G |
| [REF-02] | SRS Azurion R3.0 | DHF334523 Rev F |
| [REF-03] | TestTraceabilityMatrix SRS Azurion R3.0 – Attachment: TestTraceabilityMatrix SRS Azurion R3.0.xlsx | DHF346502 Rev D |
| [REF-04] | TE TM Azurion R3.0 | DHF375003 Rev E |
| [REF-05] | TTM UID Azurion R3.0 | DHF354251 Rev D |
| [REF-06] | TTM dRMM Azurion R3.0 | Rev F |
| [REF-07] | DICOM Conformance Statement Azurion R3.0 | D000720013 Rev B |
| [REF-08] | IHE Statement Azurion R3.0 | D000720014 Rev A |
| [REF-09] | Product recycling passport Azurion R3.0 | D001235868 Rev B |
| [REF-10] | Test report- Modulys 200kva iec/40kva ul, | DHF354069 Rev 00 |
| [REF-11] | Verification Report Certeray | GTC-DAT-0210-18 (OVR EVR) |
| [REF-12] | DIN-1A Raumklasse-1A report Rembrandt | DHF333110 Rev A |
| [REF-13] | TRF IEC 60601-1 Azurion R3.0 | D001331205 Rev B |
| [REF-14] | Product security vulnerability scan report | D001283021 Rev A |
| [REF-15] | System Certification Azurion R3.0 | AE 08714891 |

# Legend of column headers

The table below contains the legend of the column headers used in the TAB “TTM(Automated)-0”.

See [REF-03].

|  |  |  |
| --- | --- | --- |
| Requirement Tag | | Define the tag name of the SRS requirement as retrieved from the System Requirements Specification document ("References" sheet). |
| Change | | Use the information from the test plan to indicate that the change to the requirement is a:   * “Major” indicating Major change compared to the predecessor * “Minor” indicating Minor change compared to the predecessor * “-“ indicating No change compared to the predecessor |
| Requirement Doc ID | | Define the document ID / reference ("References" sheet) of the System or Software Requirements Specification containing the related Requirement Tag. |
| Requirement Covered By Test | Text | Define the Test Protocol Name as specified in the test protocol document (i.e. TC\_xx and/or name). |
| Last Result | Intermediate State: Blocked: During execution of a test a blocking issue is encountered (i.e. availability of the test environment), which is blocking the execution.   * “No Run”: Test protocol is not executed yet   End State at authorization of this document:   * “Failed”: A nonconformity is observed during the execution of the test protocol and a Development Problem is submitted. * “N/A”: No execution of Test Protocol is required, thus no result. * “Passed”: Test protocol is executed successfully, meaning SRS requirement is covered. |
| Remarks | In case the test result is Passed based on re-used test evidence write down "Re-use", see impact analysis in the applicable test plan. In all other cases use '-' or additional remarks. |
| Justification | Define the justification when the result has not the result Passed.  When result “Passed” or “No Run” fill in '-'.  When the result is “Re-used” fill in “-“; SRS tags and the related implementation that have not changed the current test evidence is Re-used, no additional tests are required. |
| Test Document ID Test Protocol Collection | Doc ID | Direct reference to the Document Identification of the Test Protocol and Test Record with Revision ID. |
| Document Short Title | Document Short Title of the Test Protocol and Test Record. |

# 

# Document Revision History

| **Revision** | **Release Date** | **Author** | **Description of changes** | **CR / Reason** |
| --- | --- | --- | --- | --- |
| 00 | 2019 May 06 | A.J. van den Berg | Initial version | - |
| A | 2022 Dec 09 | Philip Brouwers | Change: Converted to latest template.  Change: SRS tags were incomplete have been added.  Change: Added generated TTM from Windchill RV&S | - |
| B | 2023 Mar 13 | Ariane Mulder | Version for end of SVER:   * Regenerated TTM from Windchill RV&S to include test results. * Open issue regarding missing bump and vibration tests for Larc3 reported in rev A of this document is solved, evidence is added to TC\_SRS.Allura.Phys.MechanicalEnvironmentalConditions. | - |
| C | 2023 Sep 12 | Wilbert Mos | Updated references to latest released revisions.  Resolved Open Issue:  Added evidence for  SRS.Allura.SLS.structural-integrity  SRS.Allura.Phys.ClimaticEnvironmentalConditions  SRS.Allura.Phys.ElectromagneticCompatibility(EMC)  SRS.Allura.Phys.Noise  SRS.Allura.Phys.Cleanability  SRS.Allura.SLS.patient-contamin-airborne  SRS.Allura.SLS.electr-shock-prev-staff-patient  SRS.Allura.SLS.safe-surfaces  SRS.Allura.SLS.acoustic-noise  SRS.Allura.SLS.thermal-safety  SRS.Allura.SLS.ECO.ProductLabeling | - |
| D | 2023 Sep 29 | Wilbert Mos | SRS.Allura.SLS.ListOfApplicableStandards:add reference to AE 08714891 for System Certification Azurion R3.0 evidence. | - |

# Open Issues

None.