# Webinar:
# Agile Design Controls Part 3

Paperless V&V to Support Rapid Design Iterations with Medical Devices

April 30, 2019


Arnaud Alberts
Matrix Requirements GmbH

Wolfgang Huber
Matrix Requirements GmbH

Aaron Joseph
Sunstone Pilot, Inc.

# Aaron Joseph
## Principal Consultant – Sunstone Pilot, Inc.

- 20+ years medical device development over a wide range of products:
  - surgical robotics systems, digital x-ray fluoroscopy system, drug inhaler devices, robotic catheter system, x-ray catheter for brachytherapy, laser eye surgery system, heart-lung bypass machine, and multiple wearable/IOT devices
- Assist clients with all aspects of design controls: risk management, requirements management, V&V testing, refining design controls procedures, and training R&D staff
- Avid promoter of lean and agile methods for medical device development
- BSEE - Rice University and  MS Bioengineering - University of Washington
- Based in Silicon Valley

# Arnaud Alberts
## Growth Manager – Matrix Requirements GmbH

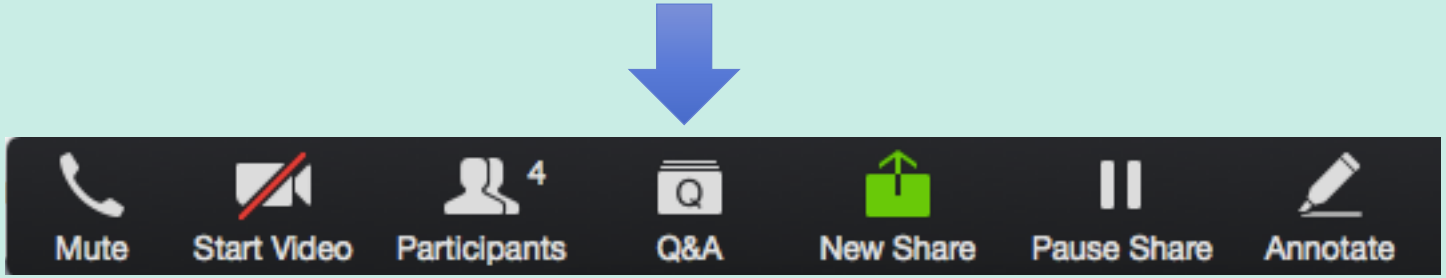
- Helping medical device companies to build their device in an agile way facilitating the management, the documentation and the certification of their product with Matrix Requirements applications.
- QA engineer and Product Management in a Startup Medical Device company
  - Hardware + software class 2 Medical Device
  - Building the QA system for market introduction
  - Validation, Risk assessment and testing
  - Product enhancement, releases, documentation
- M.Sc. Bio-Engineering – ULB Brussels
- Based in Brussels - Belgium

# Wolfgang Huber
## Co-Founder - Matrix Requirements GmbH

- Founder Matrix Requirements
- 15+ years managing medical device development
- 10+ years developing version control and document management systems
- 30 years experience professional software development
- Early adaptor of agile methodologies
- M.Sc. Computer Science – Karlsruhe University
- Based in Munich, Germany || Beziers, France

# Webinar Outline

1. Shortcomings of traditional V&V testing on paper
2. Structuring requirements and testing for V&V
3. Test management with Matrix ALM and Jira
4. Example change scenario and re-testing
5. Computer system validation
6. Q&A

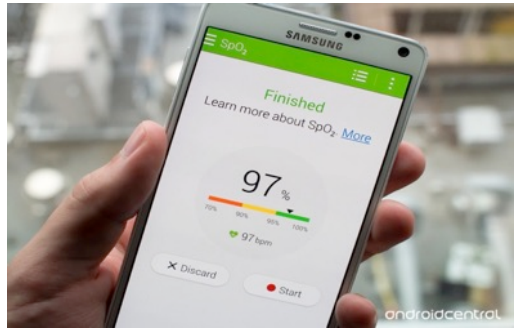


# V&V Testing Challenges

- Highly technical and process intensive (cross-functional synchronization)
- Modern, software-intensive medical devices make V&V even more difficult:
  - Greater complexity
  - More software components
  - More changes late in development and after product launch

Design Verification:
Show that design outputs conform to design inputs
Test against design requirements
*"Did we make the device right?"*

Design Validation:
Show that design meets user needs
Clinical testing or simulated clinical usage
*"Did we make the right device?"*

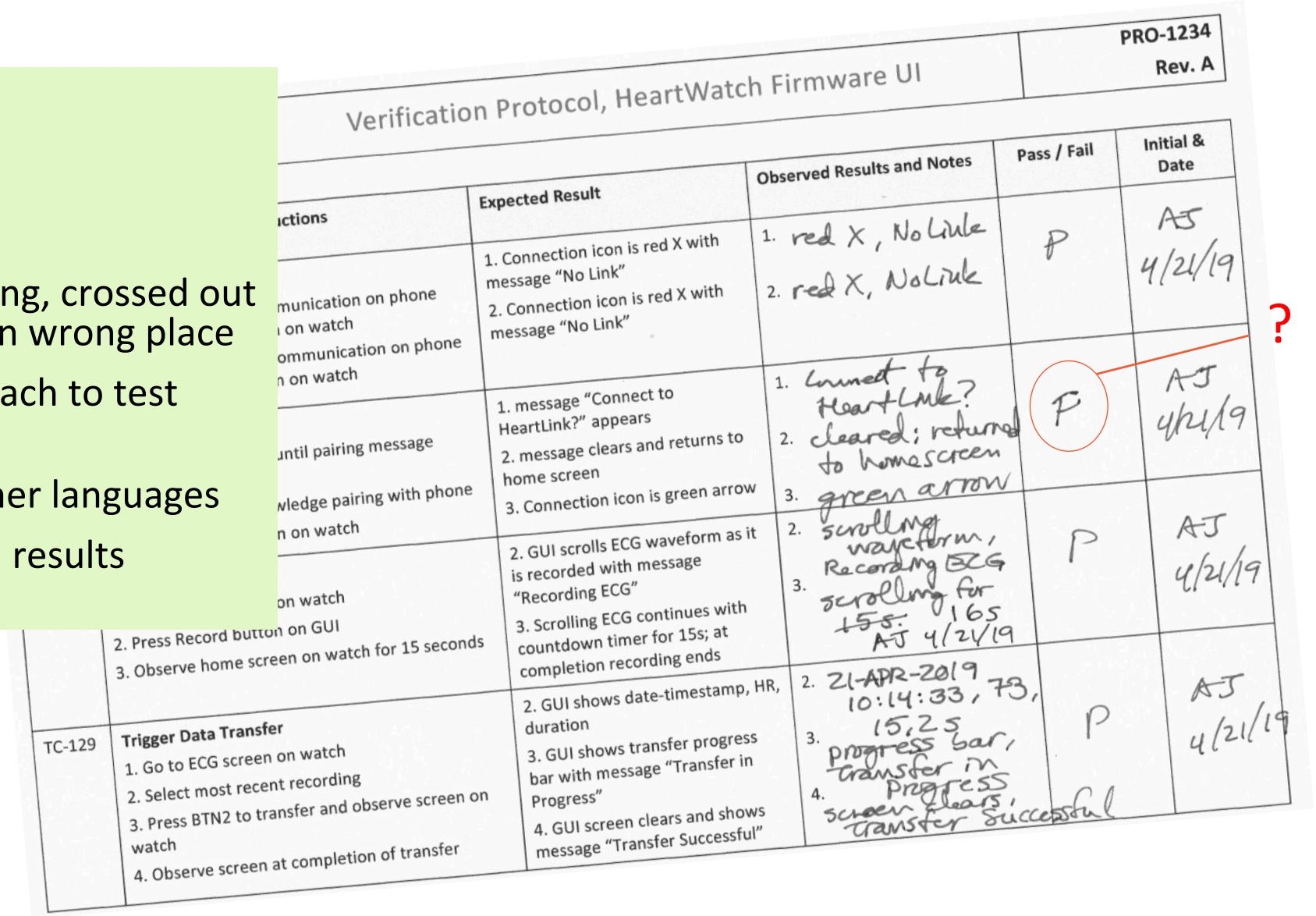



# Traditional V&V Testing on Paper

Paper is difficult!

Shortcomings:

- Error prone--poor handwriting, crossed out test results, results written in wrong place
- Need to scan papers and attach to test reports
- Difficult to translate into other languages
- Cannot electronically search results



Verification Protocol, HeartWatch Firmware UI — PRO-1234 Rev. A

| | | Expected Result | Observed Results and Notes | Pass / Fail | Initial & Date |
|---|---|---|---|---|---|
| | actions | | | | |
| | munication on phone<br>on watch<br>ommunication on phone<br>n on watch | 1. Connection icon is red X with message "No Link"<br>2. Connection icon is red X with message "No Link" | 1. red X, No Link<br>2. red X, No Link | P | AJ 4/21/19 |
| | until pairing message<br>wledge pairing with phone<br>n on watch | 1. message "Connect to HeartLink?" appears<br>2. message clears and returns to home screen<br>3. Connection icon is green arrow | 1. Connect to HeartLink?<br>2. cleared; returned to homescreen<br>3. green arrow | P | AJ 4/21/19 |
| | on watch<br>2. Press Record button on GUI<br>3. Observe home screen on watch for 15 seconds | 2. GUI scrolls ECG waveform as it is recorded with message "Recording ECG"<br>3. Scrolling ECG continues with countdown timer for 15s; at completion recording ends | 2. scrolling waveform, Recording ECG<br>3. scrolling for ~~15s~~ 16s AJ 4/24/19 | P | AJ 4/21/19 |
| TC-129 | **Trigger Data Transfer**<br>1. Go to ECG screen on watch<br>2. Select most recent recording<br>3. Press BTN2 to transfer and observe screen on watch<br>4. Observe screen at completion of transfer | 2. GUI shows date-timestamp, HR, duration<br>3. GUI shows transfer progress bar with message "Transfer in Progress"<br>4. GUI screen clears and shows message "Transfer Successful" | 2. 21-APR-2019 10:14:33, 73, 15,25<br>3. progress bar, transfer in progress<br>4. screen clears, transfer successful | P | AJ 4/21/19 |

# Test Report Generated by a Test Management Tool

**XTC-15** Patient ECG recording (VAL-3)

VERSION

1.2

TESTER

admin

TEST DATE

2019/04/11

TEST RUN RESULT

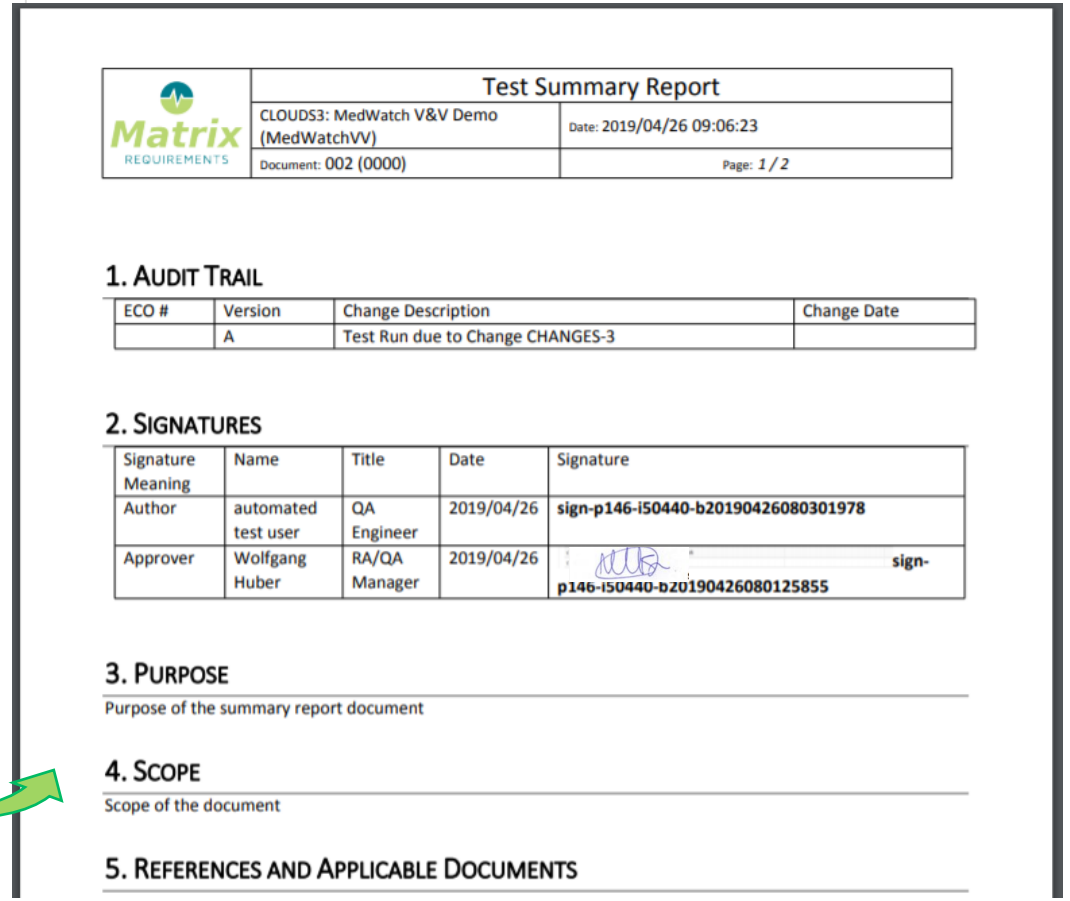
automatic - was 'failed' when last saved

ISSUES FOUND DURING TESTING

PROJX-189 Face Watch ECG Monitoring

TEST CASE STEPS

| | Action Result | Expected Result | Passed/Failed | Comment |
|---|---|---|---|---|
| 1 | Record ECG data | 8 ob 10 Users record data, as described in the manual | failed | PROJX-189 only 7 of 10 users managed to start recording |
| 2 | Find Remote Arrhythmia Data | 8 ob 10 Users find data in app on phone | passed | |
| 3 | Understand Data | 8 ob 10 Users understand data correctly | passed | |



Matrix REQUIREMENTS

Test Summary Report

CLOUDS3: MedWatch V&V Demo (MedWatchVV) | Date: 2019/04/26 09:06:23

Document: 002 (0000) | Page: 1 / 2

## 1. Audit Trail

| ECO # | Version | Change Description | Change Date |
|---|---|---|---|
| | A | Test Run due to Change CHANGES-3 | |

## 2. Signatures

| Signature Meaning | Name | Title | Date | Signature |
|---|---|---|---|---|
| Author | automated test user | QA Engineer | 2019/04/26 | sign-p146-i50440-b20190426080301978 |
| Approver | Wolfgang Huber | RA/QA Manager | 2019/04/26 | sign-p146-i50440-b20190426080125855 |

## 3. Purpose

Purpose of the summary report document

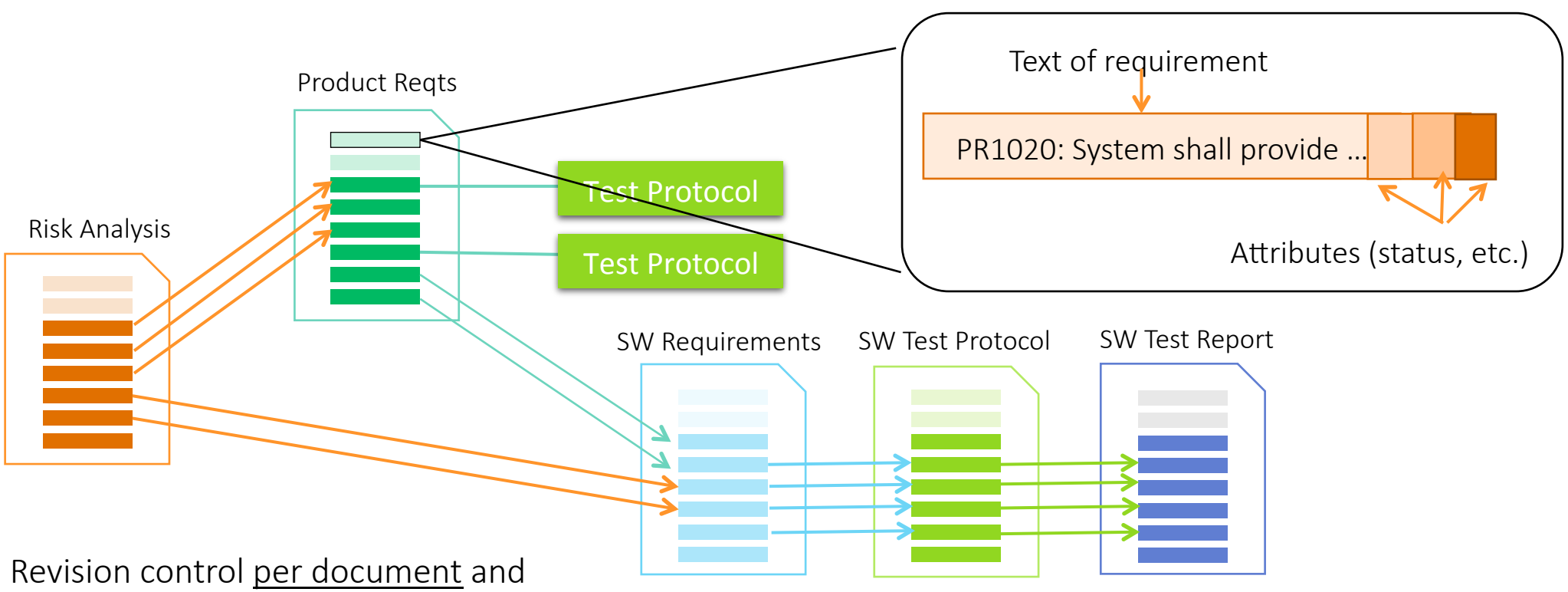
## 4. Scope

Scope of the document

## 5. References and Applicable Documents

# New Way: Product Documentation Stored as Objects

**Documents are groupings of DHF elements**




Revision control per document and per element

Dynamic management of product data

# Example Connected Medical Device

- Wearable device + mobile app + cloud
- Heart monitor (including analysis of other patient data)
- Distributed architecture with multiple software platforms

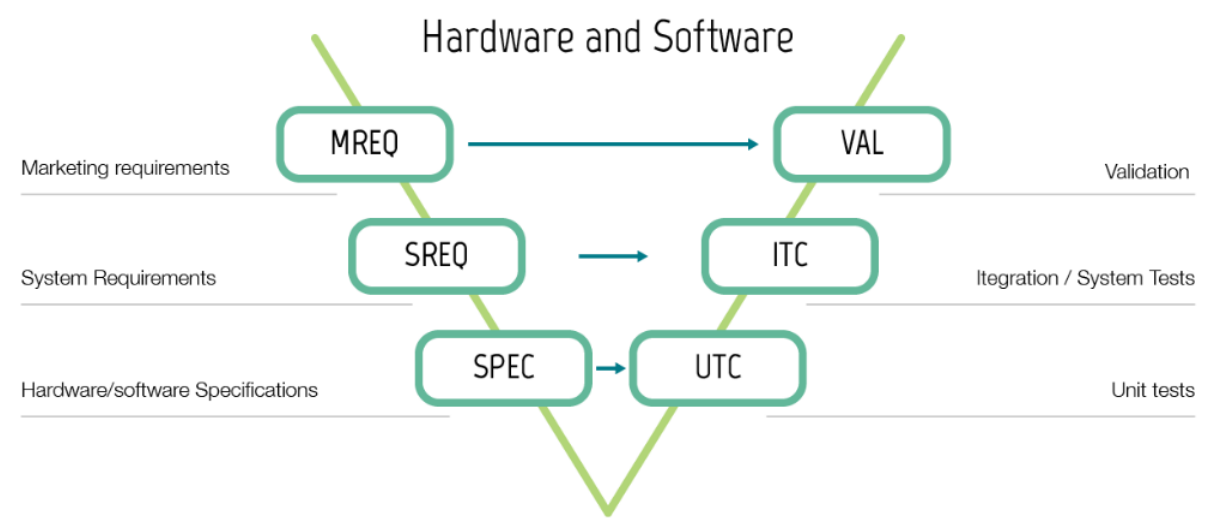

Firmware on watch


Mobile app on smart phone

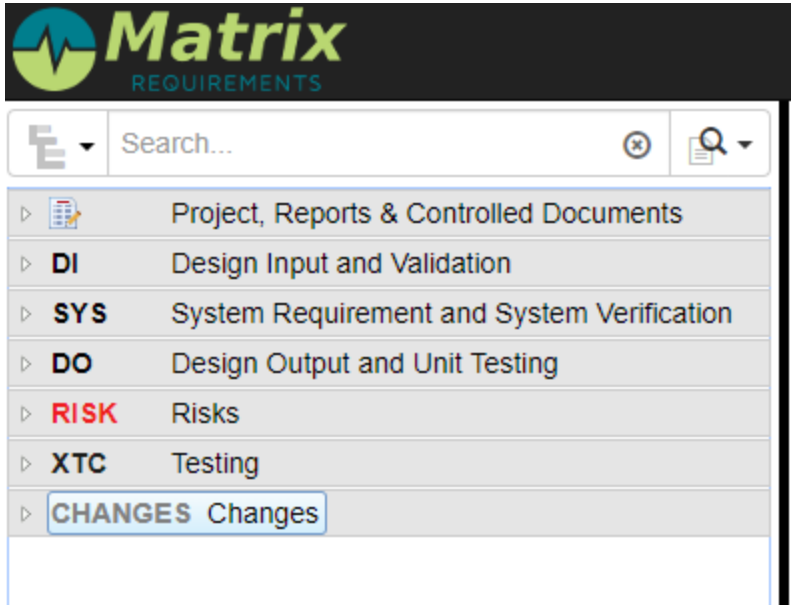
Data analysis and storage on cloud platform

Browser or client app on laptop

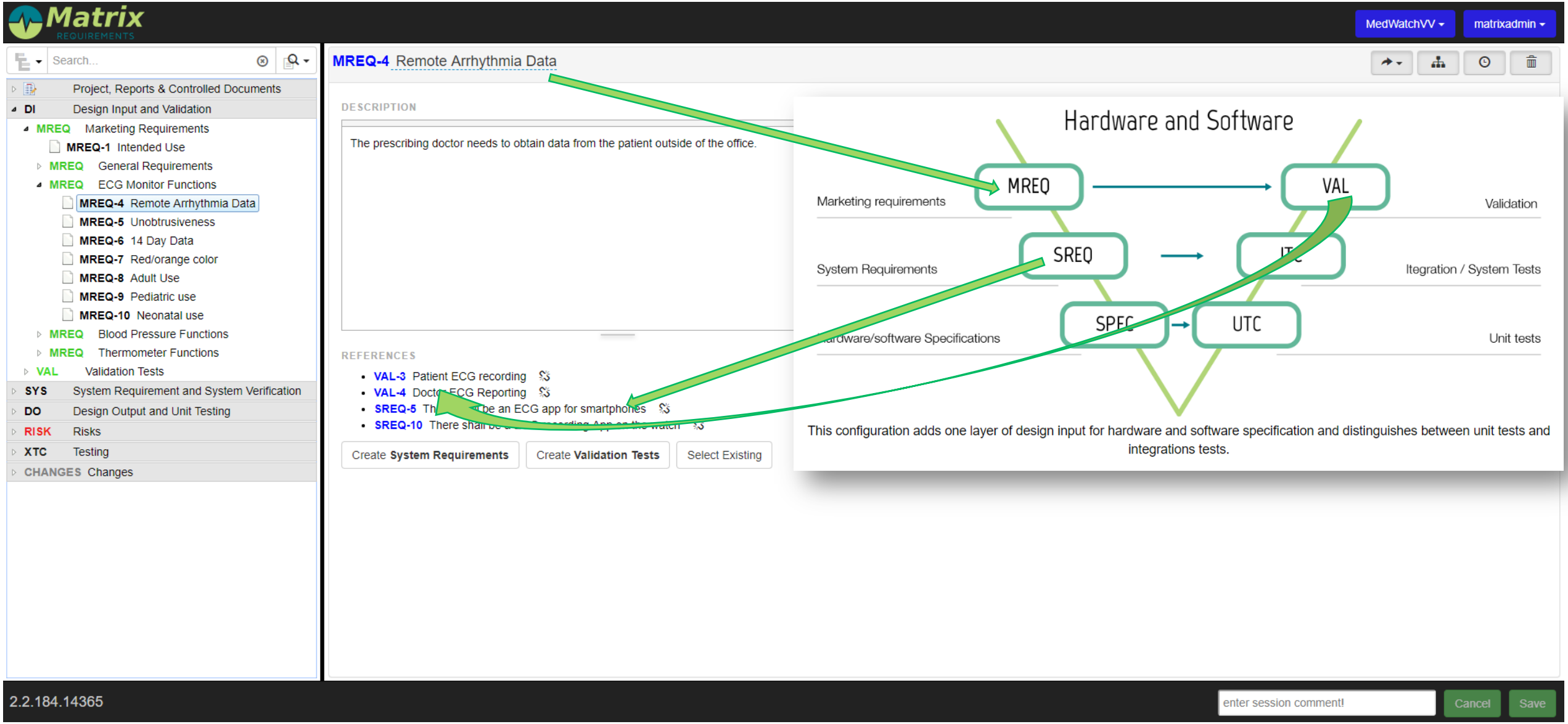
# V-Model integrated in Matrix tree



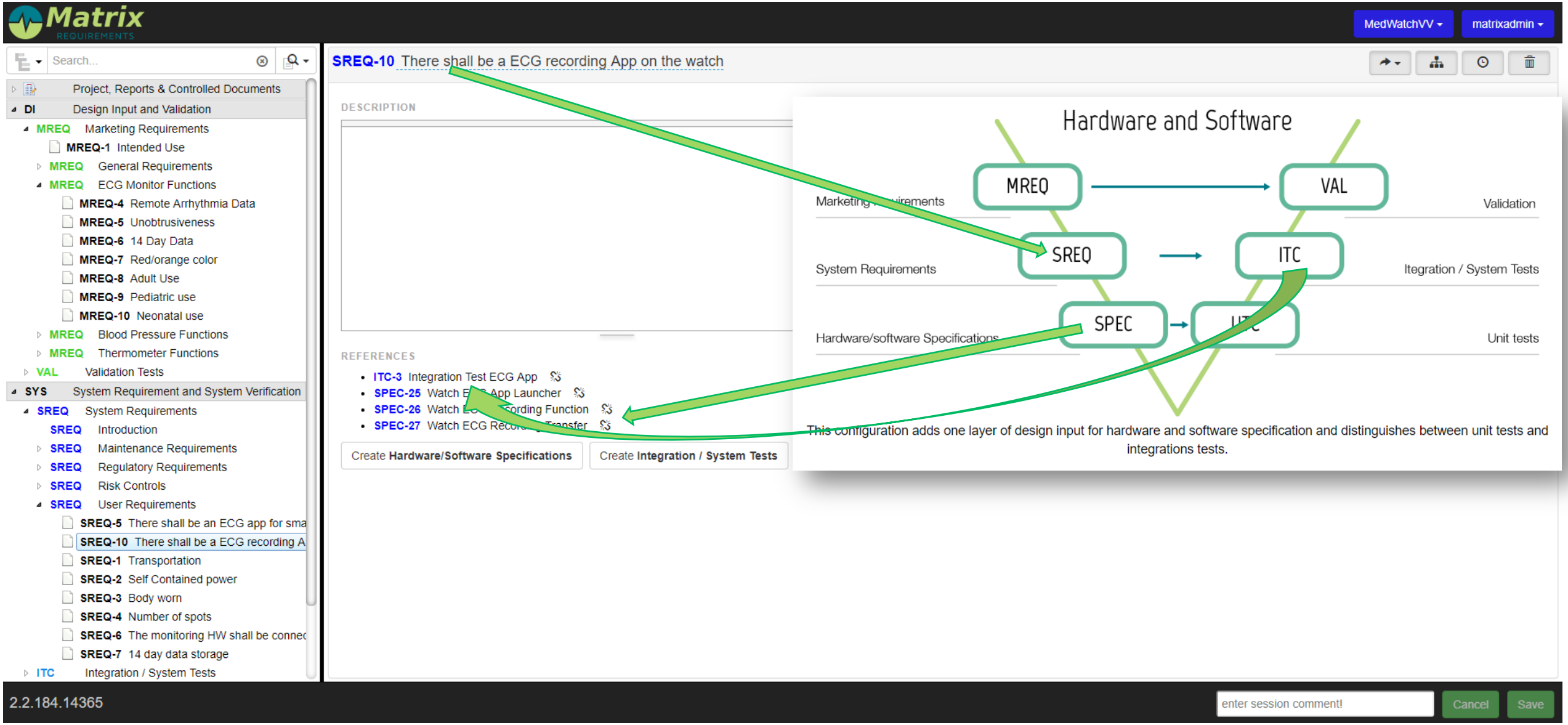

This configuration adds one layer of design input for hardware and software specification and distinguishes between unit tests and integrations tests.



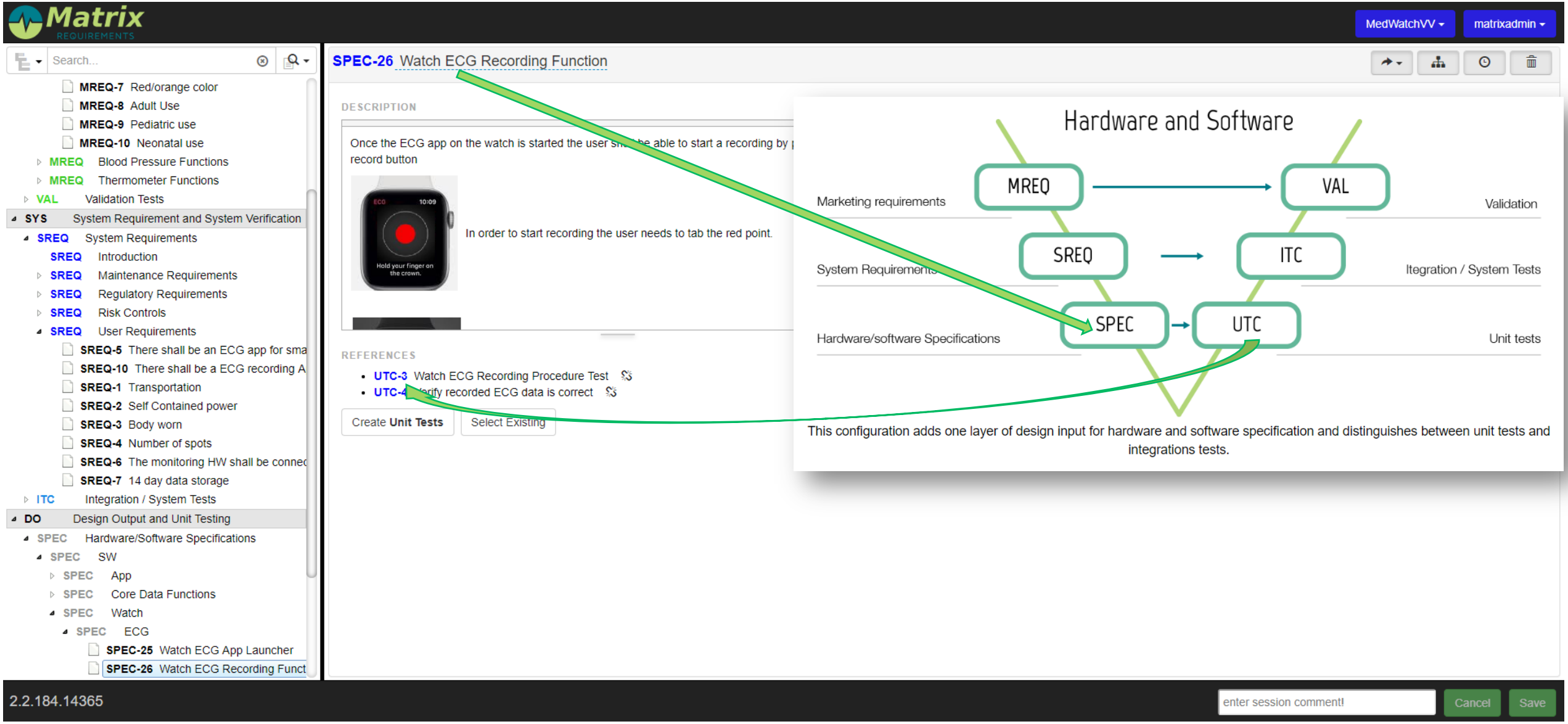
# V-Model integrated in Matrix tree



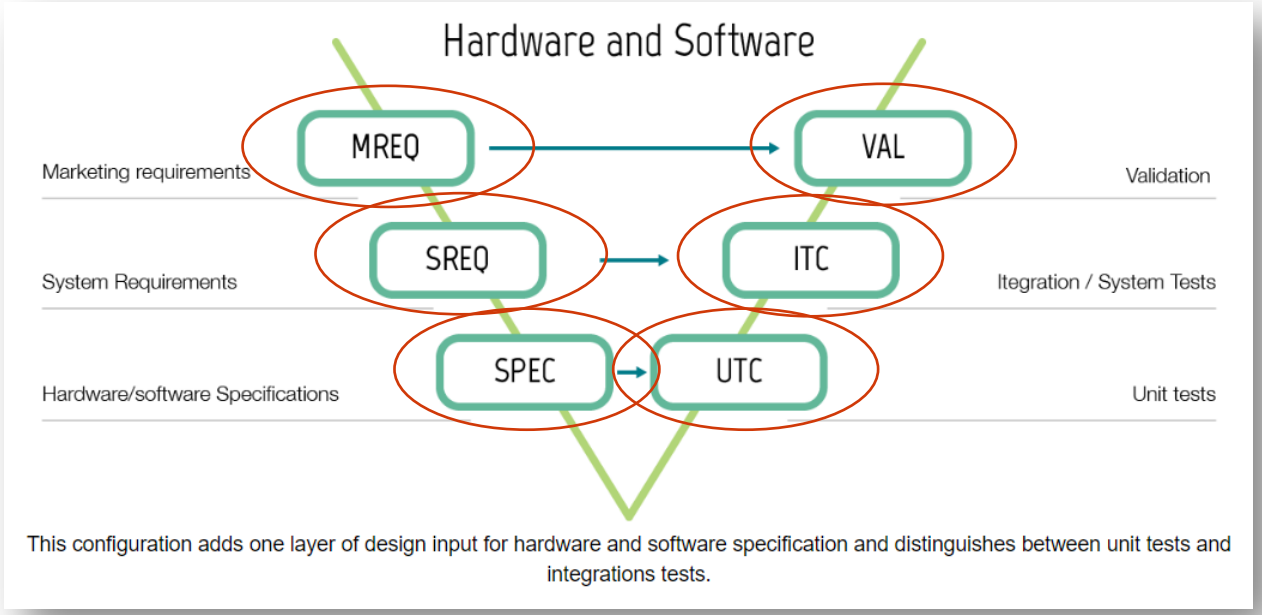
# V-Model integrated in Matrix tree



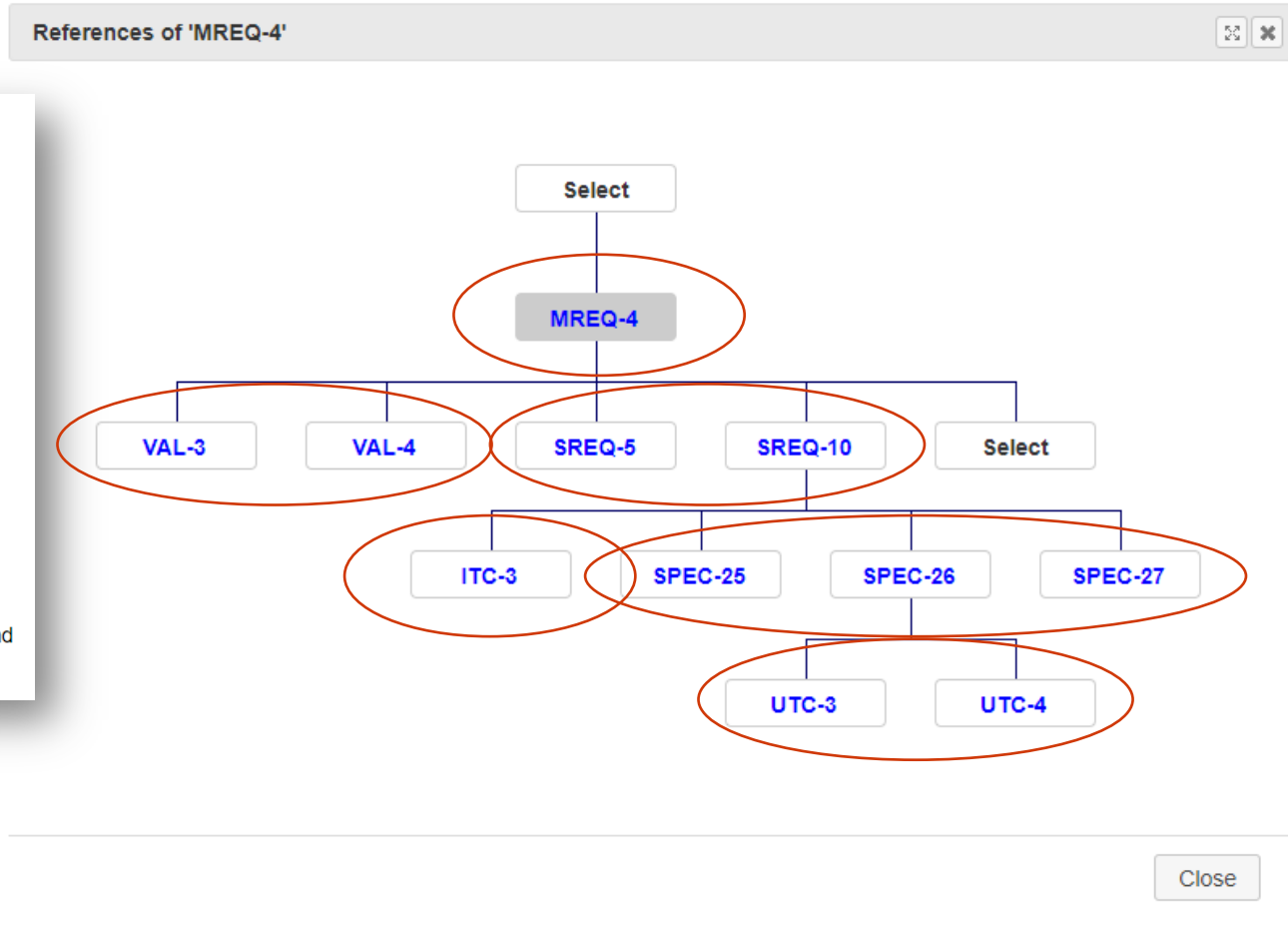
# V-Model integrated in Matrix tree



# V-Model integrated in Matrix tree




This configuration adds one layer of design input for hardware and software specification and distinguishes between unit tests and integrations tests.



# Software Trace Matrix

| Matrix REQUIREMENTS | AUTHOR: | Support Matrix Requirements | PROJECT: | MedWatch V&V Demo |
|---|---|---|---|---|
| | DATE: | 2019/04/26 09:12:31 | REPORT: | Traceability Report |

## Traceability Report

This report takes selected items of the reporting type "Design" and verifies the up and downtraces thereof. It shows all traces for each selected item.

### Traceability tables

Traces and Trace Issues:MREQ

| From | Item | To |
|---|---|---|
| | MREQ-1 Intended Use | there is no system requirement<br>there is no use case |
| | MREQ-2 Device shall be transportable | there is no system requirement<br>there is no use case |
| | MREQ-3 Device shall be operable through app | there is no system requirement<br>there is no use case |
| | MREQ-4 Remote Arrhythmia Data | Rule: must have a system requirement<br>• SREQ-5 There shall be an ECG app for smartphones<br>• SREQ-10 There shall be a ECG recording App on the watch<br>Rule: must have a use case for validation<br>• VAL-3 Patient ECG recording<br>• VAL-4 Doctor ECG Reporting |

### Traceability matrix

| From \ To | RISK | VAL | SREQ | ITC | SPEC | UTC | XTC |
|---|---|---|---|---|---|---|---|
| MREQ-1 Intended Use | | | | | | | |
| MREQ-2 Device shall be transportable | | | | | | | |
| MREQ-3 Device shall be operable through app | | | | | | | |
| MREQ-4 Remote Arrhythmia Data | | • VAL-3 Patient ECG recording<br>• VAL-4 Doctor ECG Reporting | • SREQ-5 There shall be an ECG app for smartphones<br>• SREQ-10 There shall be a ECG recording App on the watch | • ITC-3 Integration Test ECG App | • SPEC-7 Screen ECG Data Transfer<br>• SPEC-8 Screen ECG Recording Overview<br>• SPEC-10 Screen ECG Details<br>• SPEC-9 ECG Configuration Screen<br>• SPEC-25 Watch ECG App Launcher<br>• SPEC-26 Watch ECG Recording Function<br>• SPEC-27 Watch ECG Recording Transfer | • UTC-3 Watch ECG Recording Procedure Test<br>• UTC-4 Verify recorded ECG data is correct | • XTC-7 Integration Test ECG App (ITC-3)<br>• XTC-15 Patient ECG recording (VAL-3)<br>• XTC-22 Watch ECG Recording Procedure Test (UTC-3)<br>• XTC-23 Verify recorded ECG data is correct (UTC-4) |

# Design Changes with Example Medical Device

Firmware on watch

Mobile app on smart phone

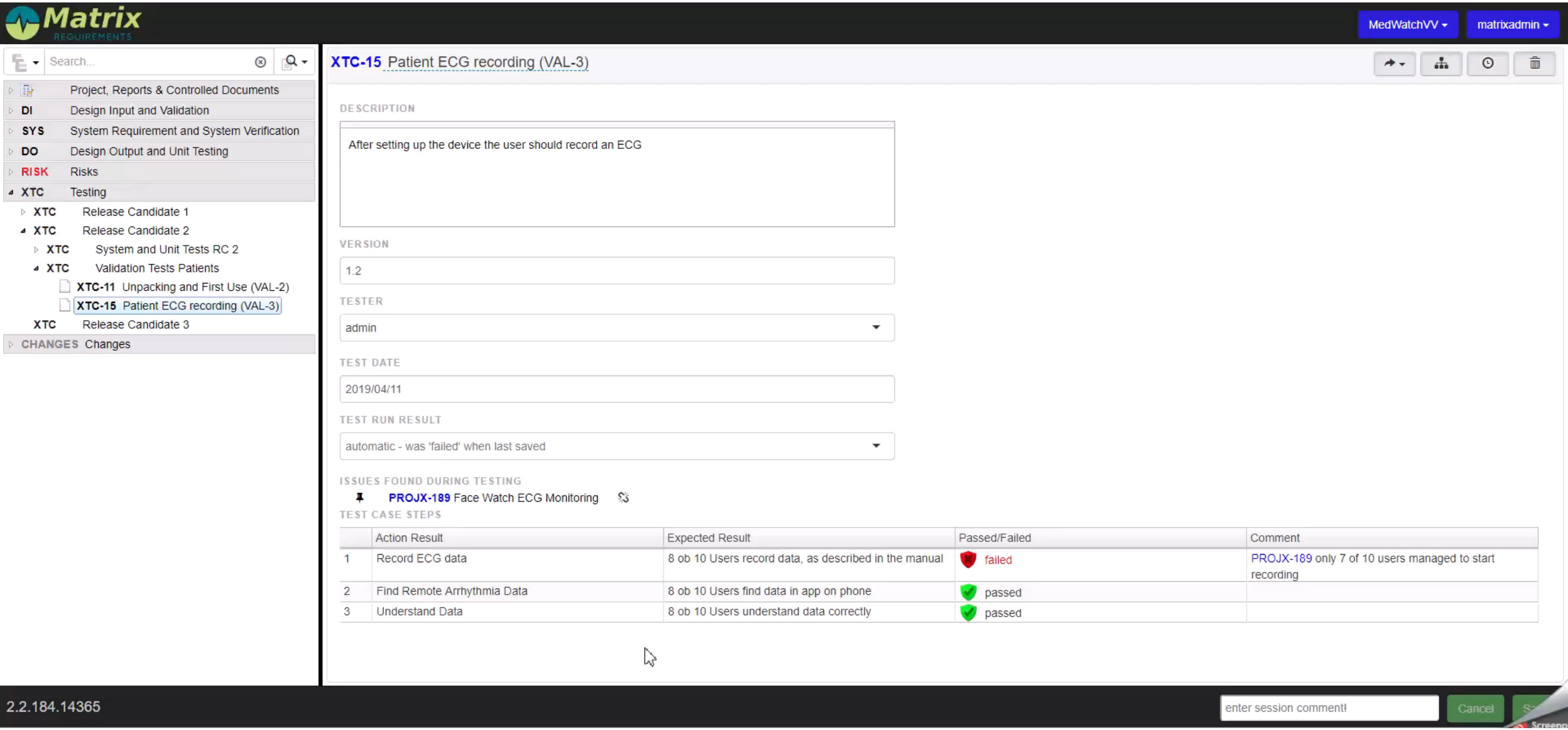
Data analysis and storage on cloud platform

Browser or client app on laptop

Change: late in development, the team discovers a problem during usability testing (FAILURE)
→ necessitates changes to GUI on watch and smart phone and retesting

**DHF documents**

# Validation Test failed



# SPEC updated, TC verification

Matrix REQUIREMENTS

MedWatchVV | matrixadmin

Search...

- Project, Reports & Controlled Documents
- DI Design Input and Validation
- SYS System Requirement and System Verification
- DO Design Output and Unit Testing
- RISK Risks
- XTC Testing
- CHANGES Changes
  - CHANGES Pre-Release
    - CHANGES RC 1
    - CHANGES RC 2
    - CHANGES RC 3
      - **CHANGES-3** Face Watch ECG Monitoring

**CHANGES-3** Face Watch ECG Monitoring

References

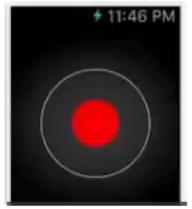
CHANGE DESCRIPTION

**Background:**

- Users tend to leave the finger on the heart instead of tabbing it once.
- This will end the recording immediately before it records enough information.

**Change:**

Instead of the heart a record button shall be used:




DOCUMENTATION

- **SPEC-26** Watch ECG Recording Function

Create **Marketing Requirements** | Create **Validation Tests** | Create **System Requirements** | Create **Hardware/Software Specifications** | Create **Integration / System Tests** | Create **Unit Tests** | Select Existing

IMPLEMENTATION

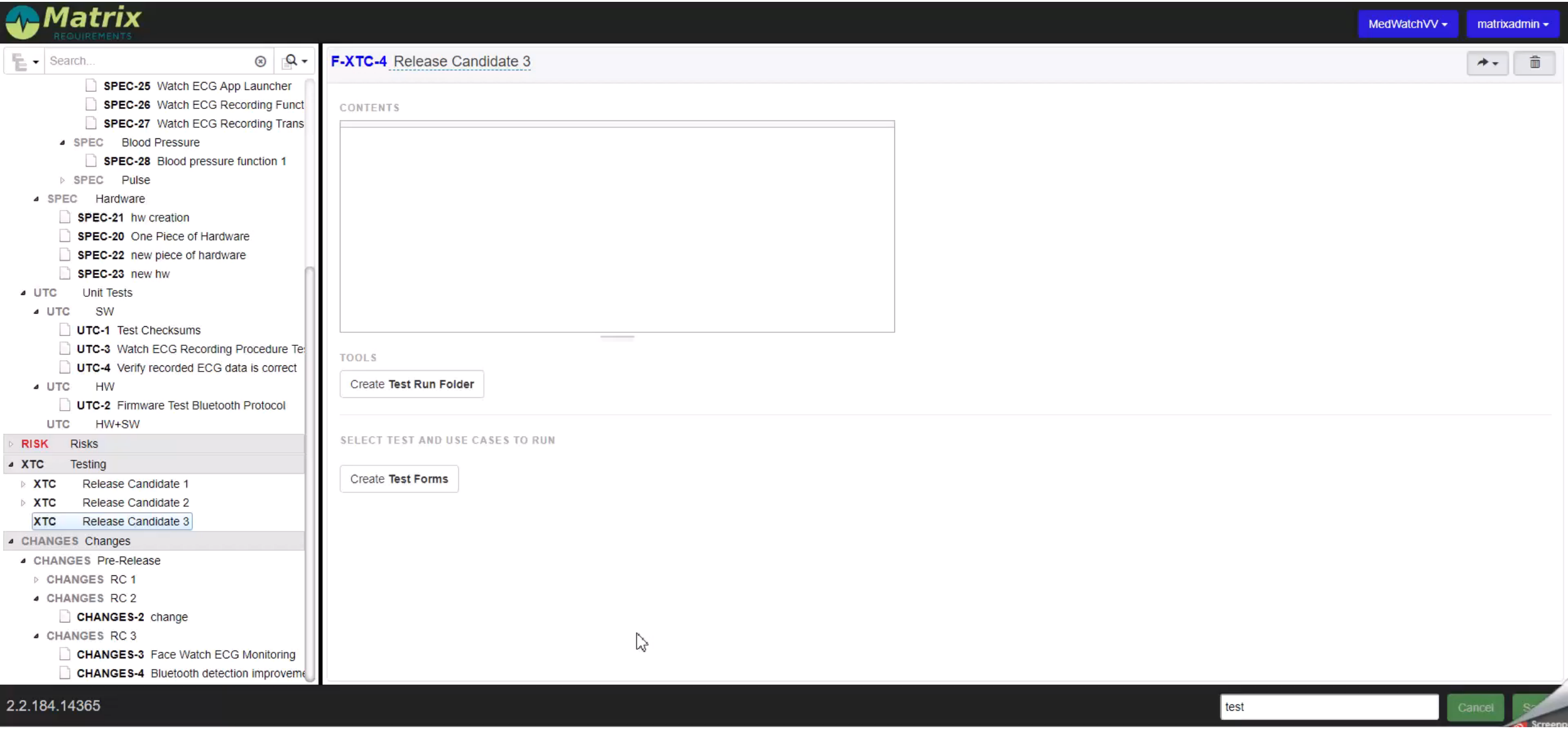
**PROJX-189** Face Watch ECG Monitoring

2.2.184.14365

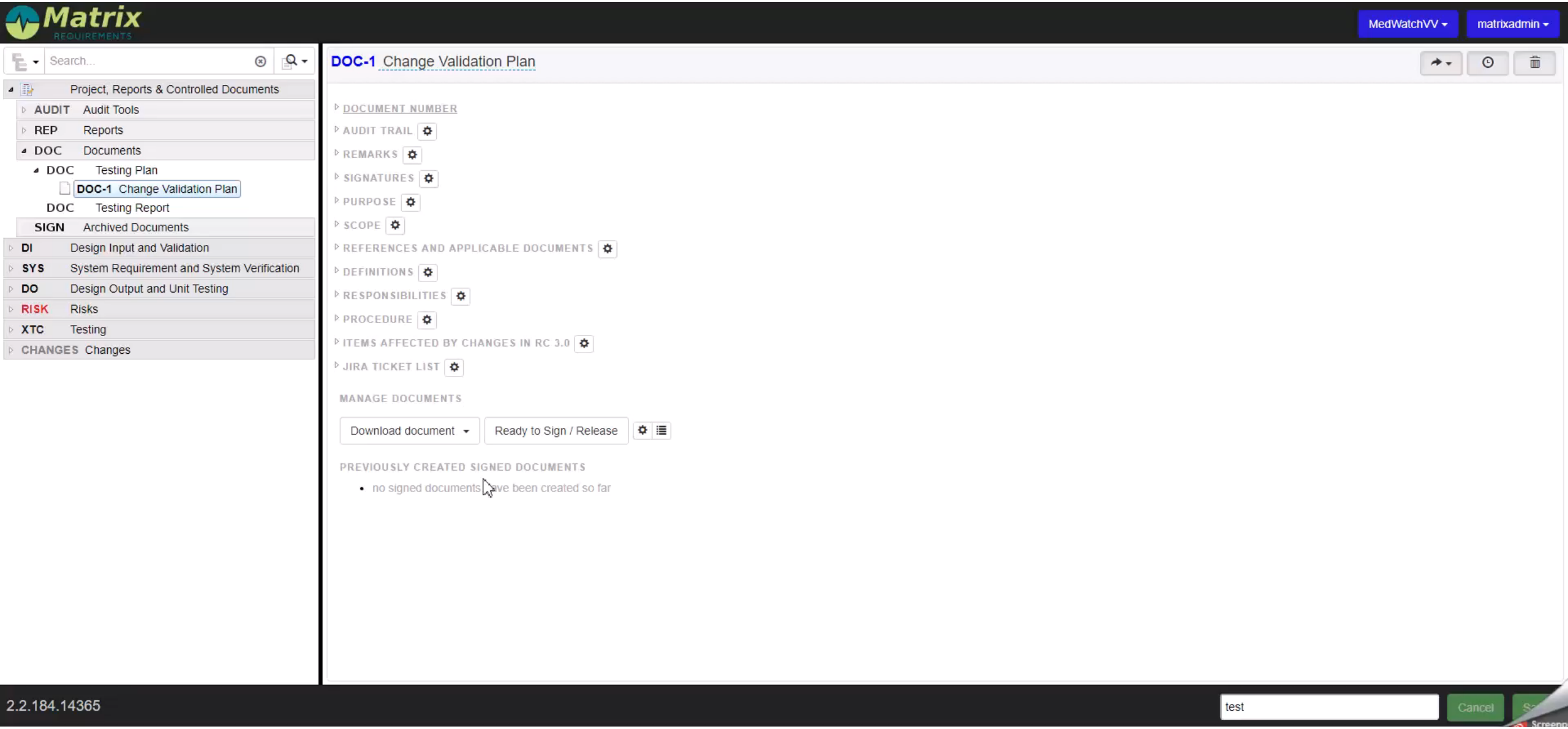
enter session comment!

Cancel

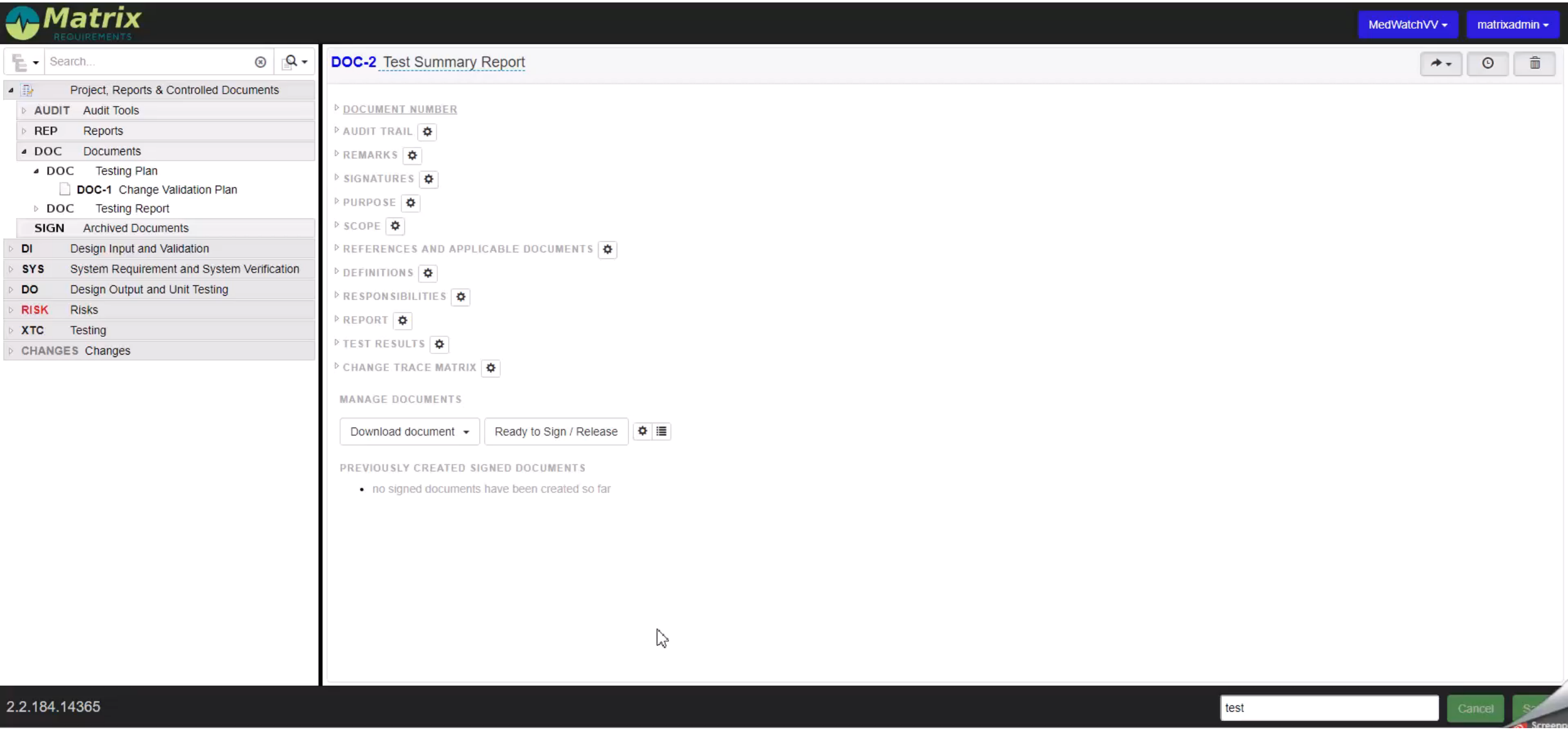
# Prepare for new Test Run



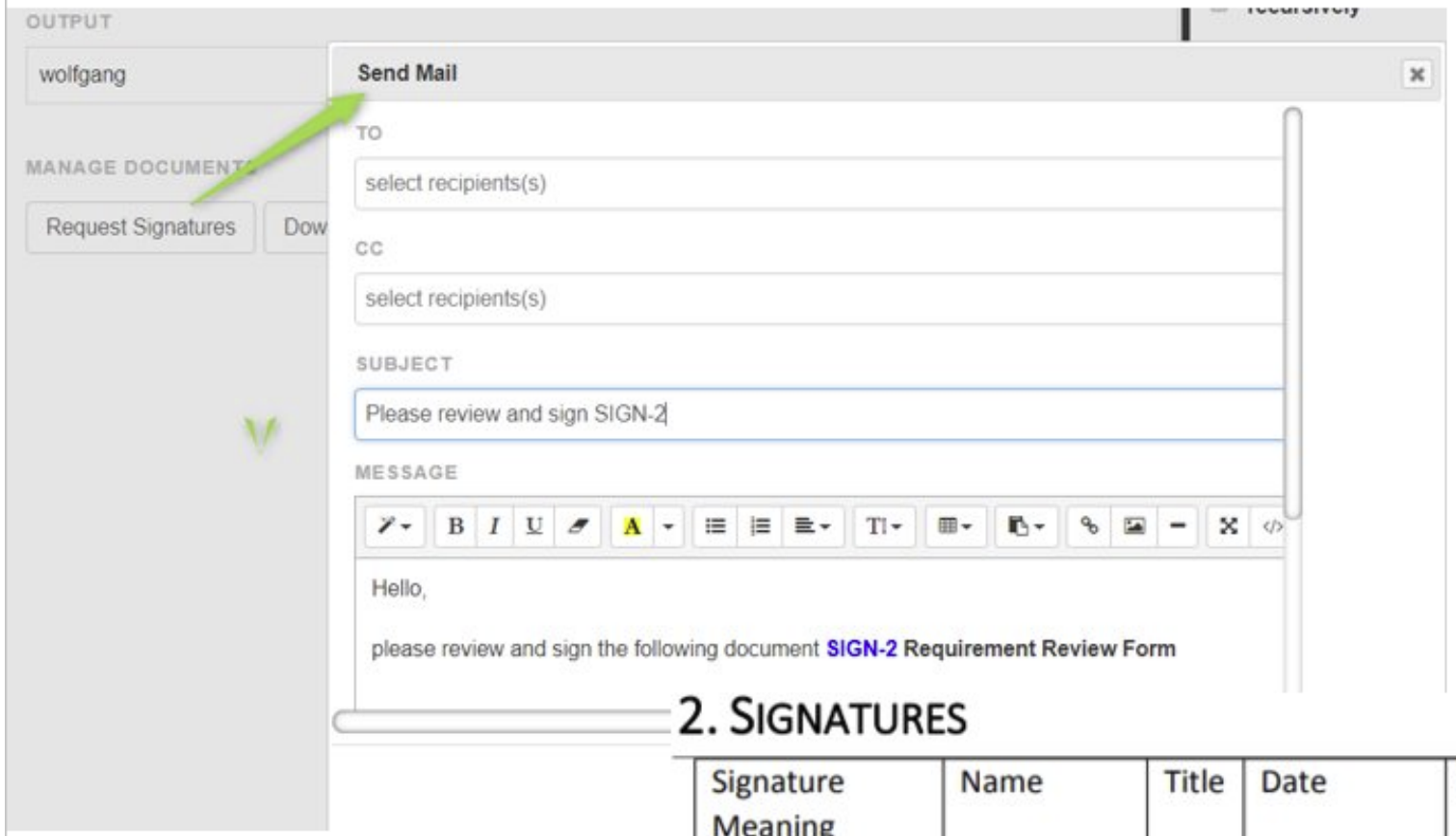
# Documentation: V&V Plan

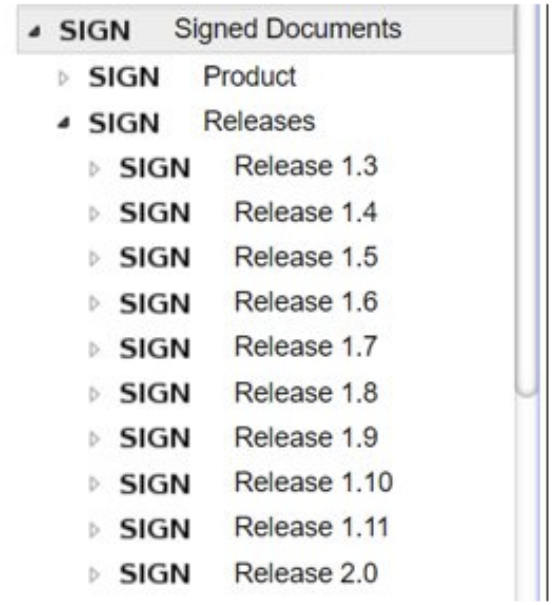


# Documentation: Summary report



# Documentation: E-signature




## 2. SIGNATURES

| Signature Meaning | Name | Title | Date | Signature |
|---|---|---|---|---|
| Reviewer | Arnaud Alberts | gm | 2019/01/04 | sign-p183-i48080-b20190104163812075 |

# Computer System Validation

- Validating SW tools used in generating and approving design controls documentation
- Need to validate system and maintain a validated state
  - Compliance with FDA Part 11 for electronic records & electronic signatures
  - Relying on SW tool to provide “objective evidence” to demonstrate safe and effective medical device
  - Use risk-based approach to plan the validation

**Good guide:  AAMI TIR36:2007 Validation of Software for Regulated Processes**

# Summary

- Paperless V&V:
  - Record test results electronically instead of on paper
  - SW tools: integrated test mgmt with requirements mgmt
  - Highly configurable reporting to generate DHF documents automatically, including trace matrix
  - Electronic signatures and audit trail (FDA Part 11 compliant)
- Integration of testing and defect tracking
- Structured requirements to support rigorous re-testing
- Well-defined procedures for SW configuration and release mgmt

# Q & A


Arnaud Alberts
Wolfgang Huber

Matrix Requirements GmbH - matrixreq.com

Aaron Joseph

Sunstone Pilot, Inc. - sunstonepilot.com