

Webinar: Agile Design Controls Part 3

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

April 30, 2019

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Matrix Requirements GmbH

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- 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

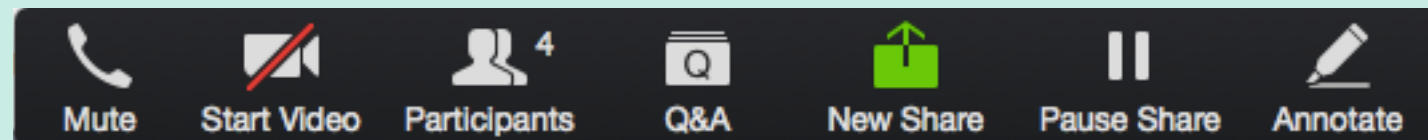
Co-Founder - Matrix Requirements GmbH



- 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

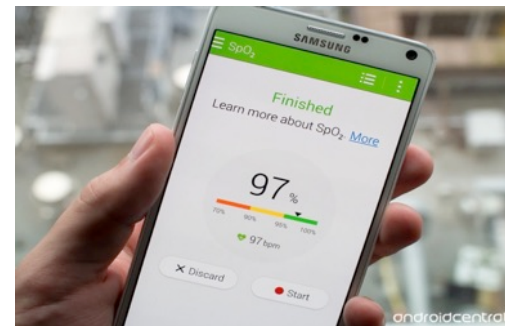
“Did we make the device right?”

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	
Actions	Expected Result	Observed Results and Notes	Pass / Fail	Initial & Date
1. Communication on phone 2. Communication on watch 3. Communication on phone 4. Communication on watch	1. Connection icon is red X with message "No Link" 2. Connection icon is red X with message "No Link"	1. red X, No Link 2. red X, No Link	P	AJ 4/21/19
1. Wait until pairing message 2. Acknowledge pairing with phone 3. Acknowledge pairing on watch	1. message "Connect to HeartLink?" appears 2. message clears and returns to home screen 3. Connection icon is green arrow	1. Connected to HeartLink? 2. cleared; returned to homescreen 3. green arrow	F	AJ 4/21/19
1. Press Record button on GUI 2. Press Record button on GUI 3. Observe home screen on watch for 15 seconds	1. GUI scrolls ECG waveform as it is recorded with message "Recording ECG" 2. GUI scrolls ECG waveform as it is recorded with message "Recording ECG" 3. Scrolling ECG continues with countdown timer for 15s; at completion recording ends	1. scrolling waveform, Recording ECG 2. scrolling for 15s. 3. 16s AJ 4/21/19	P	AJ 4/21/19
TC-129 Trigger Data Transfer 1. Go to ECG screen on watch 2. Select most recent recording 3. Press BTN2 to transfer and observe screen on watch 4. Observe screen at completion of transfer	1. GUI shows date-timestamp, HR, duration 2. GUI shows transfer progress bar with message "Transfer in Progress" 3. GUI screen clears and shows message "Transfer Successful"	1. 21-APR-2019 10:14:33, 73, 2. 15.25 3. progress bar, transfer in progress 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


	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	

	Test Summary Report	
	CLOUDS3: MedWatch V&V Demo (MedWatchVV) Document: 002 (0000)	Date: 2019/04/26 09:06:23 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

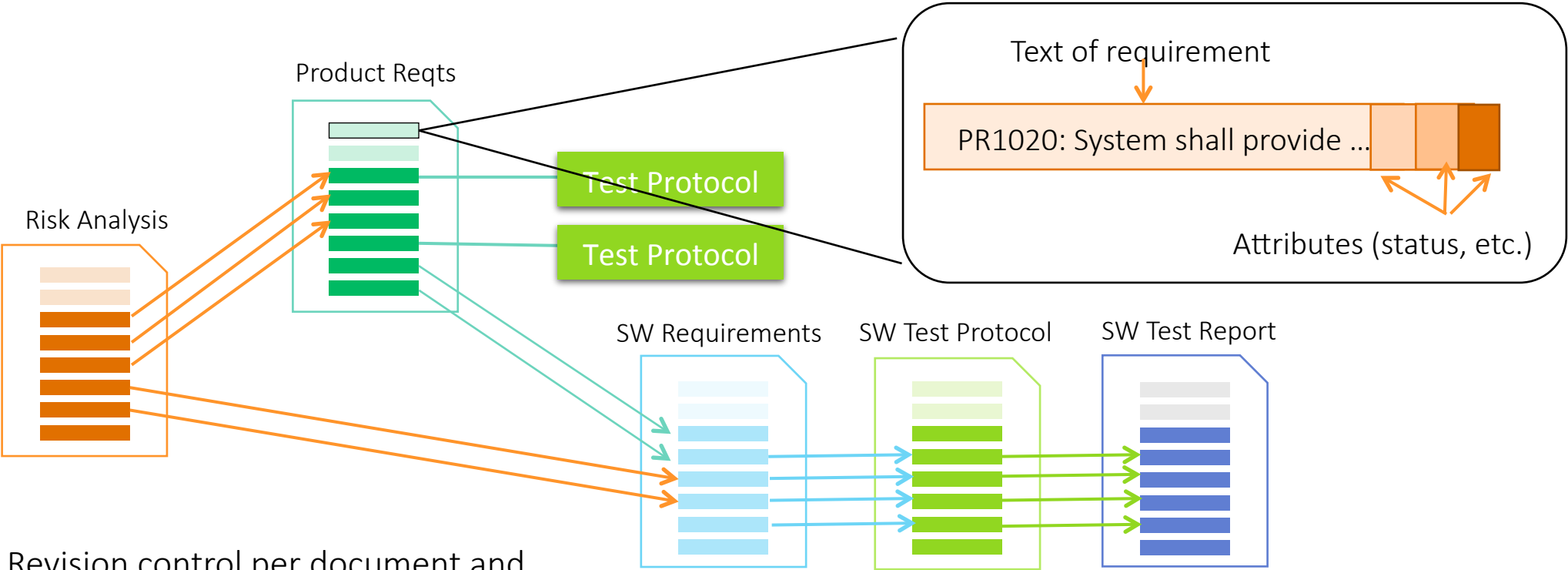
3. PURPOSE
Purpose of the summary report document

4. SCOPE
Scope of the document

5. REFERENCES AND APPLICABLE DOCUMENTS

New Way: Product Documentation Stored as Objects

Documents are groupings of DHF elements



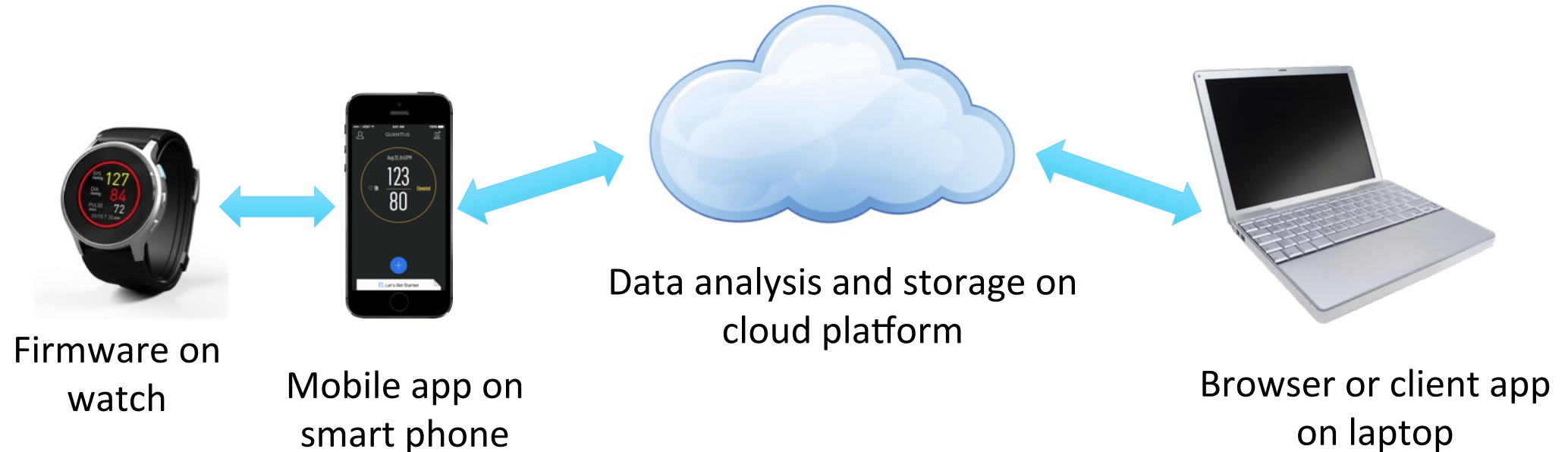
Export a set of documents from the database for submissions

Revision control per document and per element

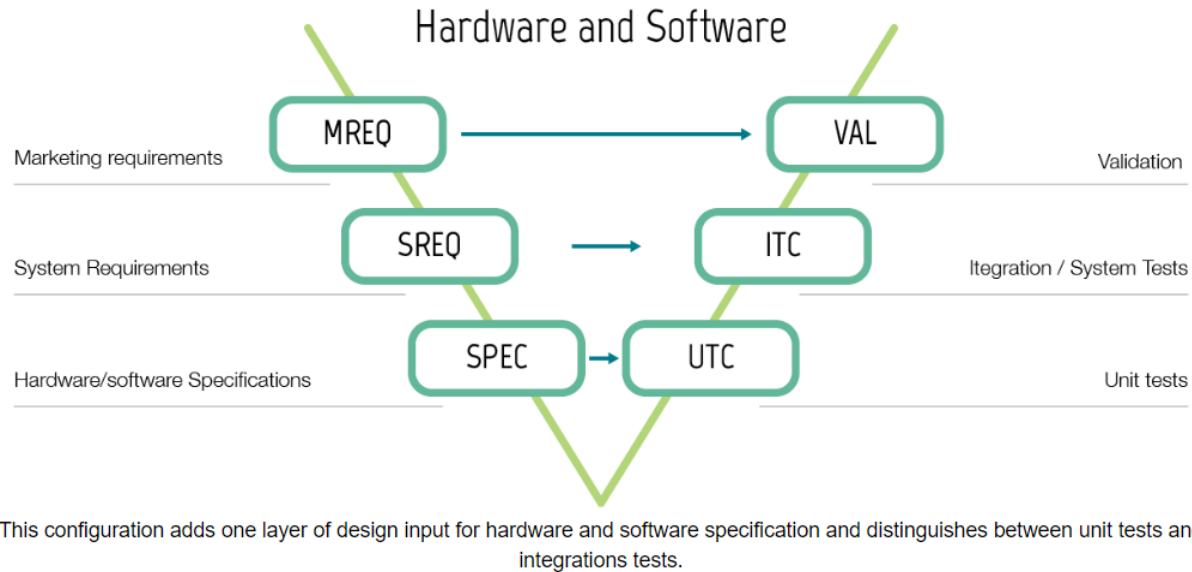
Dynamic management of product data

Example Connected Medical Device

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



V-Model integrated in Matrix tree



Matrix
REQUIREMENTS

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

V-Model integrated in Matrix tree

The screenshot displays the Matrix Requirements software interface. On the left is a navigation tree with categories like 'Marketing Requirements', 'General Requirements', 'ECG Monitor Functions', and 'Validation Tests'. The main area shows the details for requirement 'MREQ-4 Remote Arrhythmia Data', including a description and a list of references. A V-model diagram is overlaid on the right side of the interface, with green arrows connecting it to the software elements. The diagram is titled 'Hardware and Software' and shows a V-shape with nodes: MREQ (Marketing requirements) at the top left, VAL (Validation) at the top right, SREQ (System Requirements) in the middle left, ITC (Integration / System Tests) in the middle right, and SPEC (Hardware/software Specifications) at the bottom left, with UTC (Unit tests) at the bottom right. Arrows indicate the flow from requirements down to specifications and from specifications up to tests. A text box at the bottom of the diagram states: 'This configuration adds one layer of design input for hardware and software specification and distinguishes between unit tests and integrations tests.'

2.2.184.14365

enter session comment!

V-Model integrated in Matrix tree

Matrix REQUIREMENTS MedWatchVV matrixadmin

Search...

Project, Reports & Controlled Documents

DI Design Input and Validation

- MREQ Marketing Requirements
 - MREQ-1 Intended Use
 - MREQ General Requirements
 - MREQ ECG Monitor Functions
 - MREQ-4 Remote Arrhythmia Data
 - MREQ-5 Unobtrusiveness
 - MREQ-6 14 Day Data
 - MREQ-7 Red/orange color
 - MREQ-8 Adult Use
 - MREQ-9 Pediatric use
 - MREQ-10 Neonatal use
 - MREQ Blood Pressure Functions
 - MREQ Thermometer Functions
- VAL Validation Tests
- SYS System Requirement and System Verification
 - SREQ System Requirements
 - SREQ Introduction
 - SREQ Maintenance Requirements
 - SREQ Regulatory Requirements
 - SREQ Risk Controls
 - SREQ User Requirements
 - SREQ-5 There shall be an ECG app for sma
 - SREQ-10 There shall be a ECG recording A
 - SREQ-1 Transportation
 - SREQ-2 Self Contained power
 - SREQ-3 Body worn
 - SREQ-4 Number of spots
 - SREQ-6 The monitoring HW shall be connec
 - SREQ-7 14 day data storage
 - ITC Integration / System Tests

SREQ-10 There shall be a ECG recording App on the watch

DESCRIPTION

REFERENCES

- ITC-3 Integration Test ECG App
- SPEC-25 Watch ECG App Launcher
- SPEC-26 Watch ECG Recording Function
- SPEC-27 Watch ECG Recording Transfer

Create Hardware/Software Specifications Create Integration / System Tests

Hardware and Software

MREQ → VAL

SREQ → ITC

SPEC → ITC

Marketing Requirements → Validation

System Requirements → Integration / System Tests

Hardware/software Specifications → Unit tests

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

2.2.184.14365 enter session comment! Cancel Save

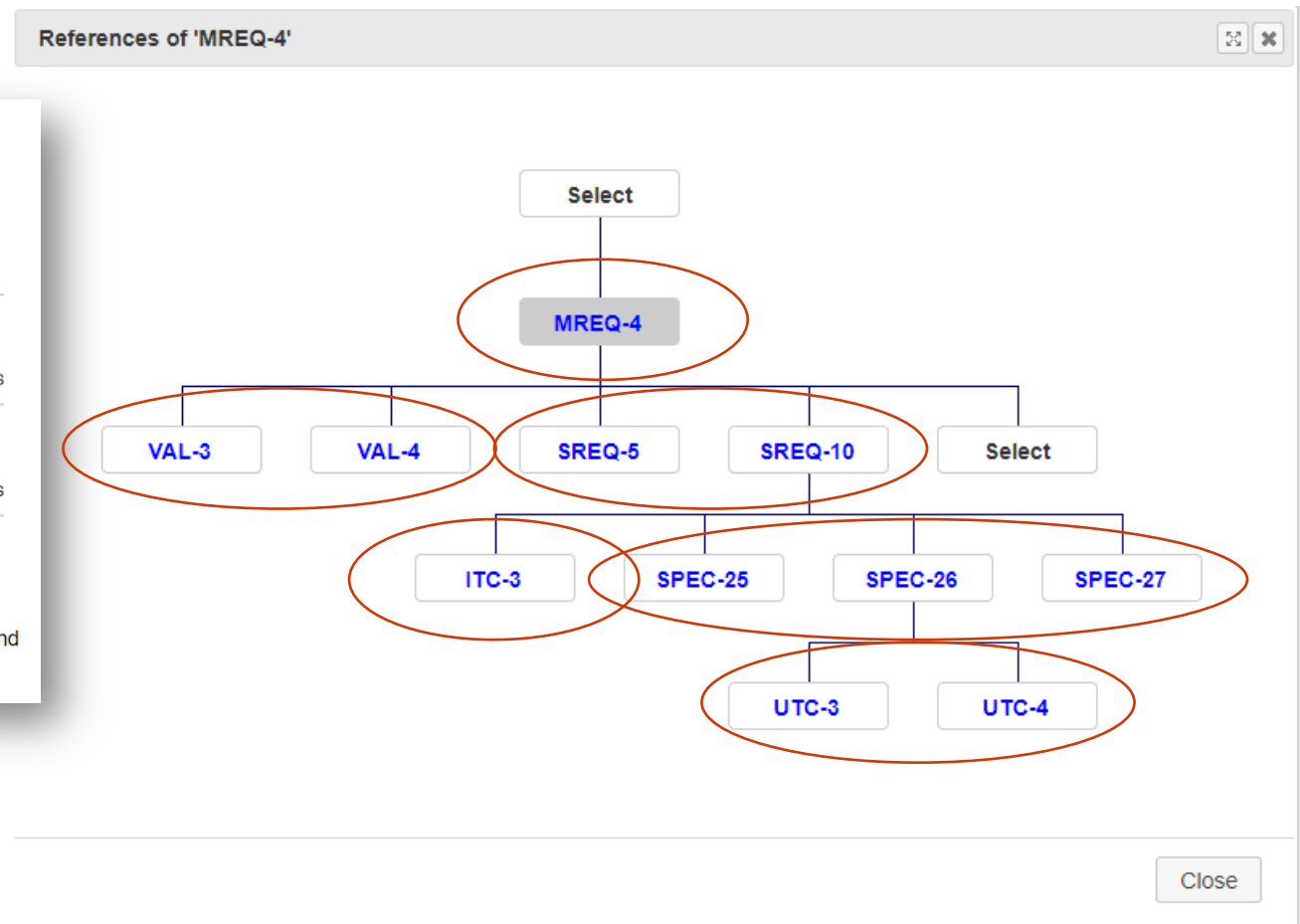
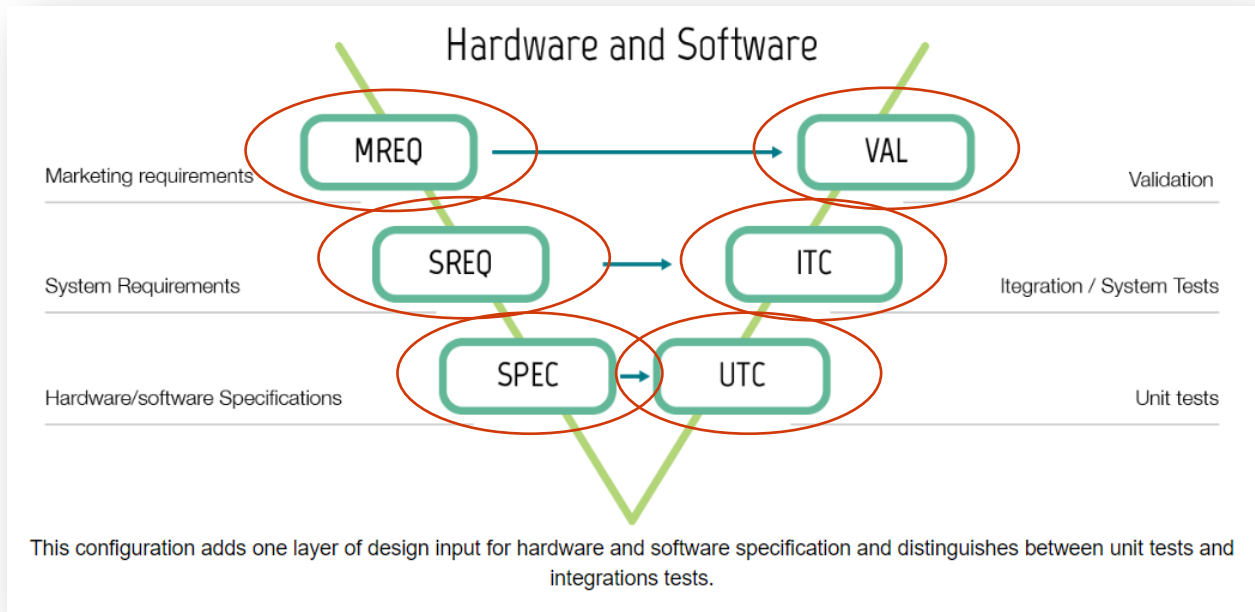
V-Model integrated in Matrix tree

The screenshot displays the Matrix Requirements application interface. On the left is a tree view of requirements, with 'SPEC-26 Watch ECG Recording Function' selected. The main area shows the details for this requirement, including a description, a reference to a user requirement (SREQ-4), and a reference to a unit test (UTC-4). A V-model diagram is overlaid on the right side of the screen, illustrating the relationship between requirements and tests. The diagram is structured as follows:


- Marketing requirements:** MREQ (Marketing Requirements) leads to VAL (Validation).
- System Requirements:** SREQ (System Requirements) leads to ITC (Integration / System Tests).
- Hardware/software Specifications:** SPEC (Hardware/Software Specifications) leads to UTC (Unit tests).

Horizontal arrows indicate the flow from MREQ to VAL, SREQ to ITC, and SPEC to UTC. Vertical lines connect MREQ to SREQ, SREQ to SPEC, and VAL to ITC. A diagonal line connects ITC to UTC. A green arrow points from the 'SPEC-26' requirement in the tree to the 'SPEC' box in the V-model. Another green arrow points from the 'UTC-4' reference in the requirement details to the 'UTC' box in the V-model. A text box at the bottom of the V-model diagram states: "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



Software Trace Matrix

	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

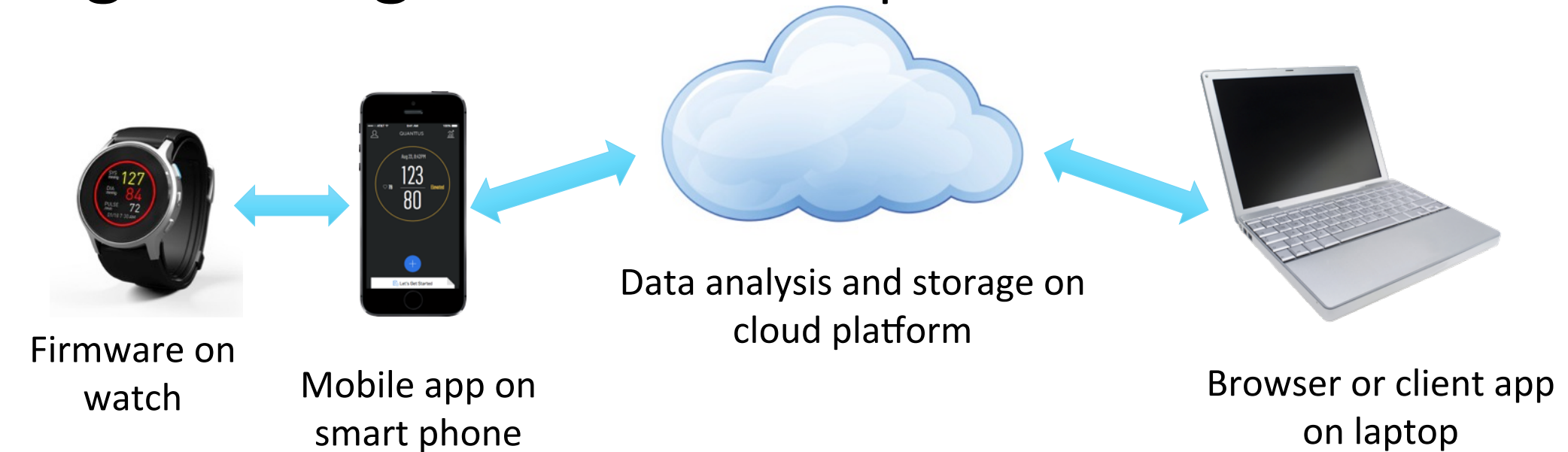
Traces and Trace Issues:MREQ

From	Item	To
	MREQ-1 Intended Use	<p>there is no system requirement</p> <p>there is no use case</p>
	MREQ-2 Device shall be transportable	<p>there is no system requirement</p> <p>there is no use case</p>
	MREQ-3 Device shall be operable through app	<p>there is no system requirement</p> <p>there is no use case</p>
	MREQ-4 Remote Arrhythmia Data	<p>Rule: must have a system requirement</p> <ul style="list-style-type: none"> SREQ-5 There shall be an ECG app for smartphones SREQ-10 There shall be a ECG recording App on the watch <p>Rule: must have a use case for validation</p> <ul style="list-style-type: none"> VAL-3 Patient ECG recording 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		<ul style="list-style-type: none"> VAL-3 Patient ECG recording VAL-4 Doctor ECG Reporting 	<ul style="list-style-type: none"> SREQ-5 There shall be an ECG app for smartphones SREQ-10 There shall be a ECG recording App on the watch 	<ul style="list-style-type: none"> ITC-3 Integration Test ECG App 	<ul style="list-style-type: none"> SPEC-7 Screen ECG Data Transfer SPEC-8 Screen ECG Recording Overview SPEC-10 Screen ECG Details SPEC-9 ECG Configuration Screen SPEC-25 Watch ECG App Launcher SPEC-26 Watch ECG Recording Function SPEC-27 Watch ECG Recording Transfer 	<ul style="list-style-type: none"> UTC-3 Watch ECG Recording Procedure Test UTC-4 Verify recorded ECG data is correct 	<ul style="list-style-type: none"> XTC-7 Integration Test ECG App (ITC-3) XTC-15 Patient ECG recording (VAL-3) XTC-22 Watch ECG Recording Procedure Test (UTC-3) XTC-23 Verify recorded ECG data is correct (UTC-4)

Design Changes with Example Medical Device



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

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
 - XTC Release Candidate 1
 - XTC Release Candidate 2
 - XTC System and Unit Tests RC 2
 - XTC Validation Tests Patients
 - XTC-11 Unpacking and First Use (VAL-2)
 - XTC-15 Patient ECG recording (VAL-3)
 - XTC Release Candidate 3
- CHANGES Changes

XTC-15 Patient ECG recording (VAL-3)

DESCRIPTION

After setting up the device the user should record an ECG

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	

enter session comment! | Cancel

SPEC updated, TC verification

The screenshot displays the Matrix Requirements software interface. The top left corner features the Matrix Requirements logo. The top right corner shows the user 'MedWatchVV' and 'matrixadmin'. A search bar is located below the logo. The left sidebar contains a navigation tree with categories: 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); and CHANGES (Changes). Under CHANGES, there are sub-categories: Pre-Release, RC 1, RC 2, and RC 3. The selected item is 'CHANGES-3 Face Watch ECG Monitoring'.

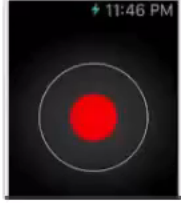
The main content area is titled 'CHANGES-3 Face Watch ECG Monitoring'. It includes a 'CHANGE DESCRIPTION' section with the following text:

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:



The image shows a red heart icon on a black background, with a timestamp '11:46 PM' at the top. The heart is surrounded by a white circle, and there is a small green plus sign above the timestamp.

Below the description is the 'DOCUMENTATION' section, which includes a link to 'SPEC-26 Watch ECG Recording Function'. There are several buttons for creating documentation: 'Create Marketing Requirements', 'Create Validation Tests', 'Create System Requirements', 'Create Hardware/Software Specifications', 'Create Integration / System Tests', and 'Create Unit Tests'. A 'Select Existing' button is also present.

The 'IMPLEMENTATION' section shows a link to 'PROJX-189 Face Watch ECG Monitoring'.

Prepare for new Test Run

The screenshot displays the Matrix Requirements software interface. The top left corner features the Matrix logo and the text "Matrix REQUIREMENTS". The top right corner shows the user name "MedWatchVV" and "matrixadmin". The main interface is divided into a left sidebar and a main content area.

Left Sidebar: A search bar is at the top. Below it is a tree view of requirements categories:

- SPEC-25 Watch ECG App Launcher
- SPEC-26 Watch ECG Recording Funct
- SPEC-27 Watch ECG Recording Trans
- ▲ SPEC Blood Pressure
 - SPEC-28 Blood pressure function 1
- SPEC Pulse
- ▲ SPEC Hardware
 - SPEC-21 hw creation
 - SPEC-20 One Piece of Hardware
 - SPEC-22 new piece of hardware
 - SPEC-23 new hw
- ▲ UTC Unit Tests
 - ▲ UTC SW
 - UTC-1 Test Checksums
 - UTC-3 Watch ECG Recording Procedure Te
 - UTC-4 Verify recorded ECG data is correct
 - ▲ UTC HW
 - UTC-2 Firmware Test Bluetooth Protocol
 - UTC HW+SW
- RISK Risks
- ▲ XTC Testing
 - XTC Release Candidate 1
 - XTC Release Candidate 2
 - XTC Release Candidate 3**
- ▲ CHANGES Changes
 - ▲ CHANGES Pre-Release
 - CHANGES RC 1
 - ▲ CHANGES RC 2
 - CHANGES-2 change
 - ▲ CHANGES RC 3
 - CHANGES-3 Face Watch ECG Monitoring
 - CHANGES-4 Bluetooth detection improvem

Main Content Area: The title bar reads "F-XTC-4 Release Candidate 3". Below the title bar is a "CONTENTS" section with a large empty rectangular box. Underneath is a "TOOLS" section with a button labeled "Create Test Run Folder". Below that is a "SELECT TEST AND USE CASES TO RUN" section with a button labeled "Create Test Forms".

At the bottom of the interface, there is a search bar containing the text "test", a "Cancel" button, and a partially visible "Screen" button.

Documentation: V&V Plan

The screenshot displays the Matrix Requirements software interface. The top left corner features the Matrix Requirements logo. The top right corner shows the user 'MedWatchVV' and 'matrixadmin'. The left sidebar contains a navigation tree with categories: Project, Reports & Controlled Documents; AUDIT (Audit Tools); REP (Reports); DOC (Documents), which is expanded to show 'DOC - Testing Plan' (containing 'DOC-1 Change Validation Plan' and 'DOC - Testing Report') and 'SIGN (Archived Documents)'; DI (Design Input and Validation); SYS (System Requirement and System Verification); DO (Design Output and Unit Testing); RISK (Risks); XTC (Testing); and CHANGES (Changes). The main content area is titled 'DOC-1 Change Validation Plan' and includes several expandable sections, each with a gear icon for settings: DOCUMENT NUMBER, AUDIT TRAIL, REMARKS, SIGNATURES, PURPOSE, SCOPE, REFERENCES AND APPLICABLE DOCUMENTS, DEFINITIONS, RESPONSIBILITIES, PROCEDURE, ITEMS AFFECTED BY CHANGES IN RC 3.0, and JIRA TICKET LIST. Below these sections is a 'MANAGE DOCUMENTS' section with a 'Download document' dropdown, a 'Ready to Sign / Release' button, and a gear icon. The 'PREVIOUSLY CREATED SIGNED DOCUMENTS' section shows a message: 'no signed documents have been created so far'. At the bottom right, there is a search bar with the text 'test' and a 'Cancel' button.

Documentation: Summary report

Matrix
REQUIREMENTS

MedWatchVV | matrixadmin

Search...

Project, Reports & Controlled Documents

- AUDIT Audit Tools
- REP Reports
- DOC Documents
 - DOC Testing Plan
 - DOC-1 Change Validation Plan
 - DOC Testing Report
- SIGN Archived Documents
- DI Design Input and Validation
- SYS System Requirement and System Verification
- DO Design Output and Unit Testing
- RISK Risks
- XTC Testing
- CHANGES Changes

DOC-2 Test Summary Report

- DOCUMENT NUMBER
- AUDIT TRAIL ⚙
- REMARKS ⚙
- SIGNATURES ⚙
- PURPOSE ⚙
- SCOPE ⚙
- REFERENCES AND APPLICABLE DOCUMENTS ⚙
- DEFINITIONS ⚙
- RESPONSIBILITIES ⚙
- REPORT ⚙
- TEST RESULTS ⚙
- CHANGE TRACE MATRIX ⚙

MANAGE DOCUMENTS

Download document ▾ Ready to Sign / Release ⚙ ☰

PREVIOUSLY CREATED SIGNED DOCUMENTS

- no signed documents have been created so far

Documentation: E-signature

OUTPUT

wolfgang

MANAGE DOCUMENTS

Request Signatures Down

Send Mail [X]

TO
select recipients(s)

CC
select recipients(s)

SUBJECT
Please review and sign SIGN-2

MESSAGE

Hello,

please review and sign the following document [SIGN-2 Requirement Review Form](#)

- ▾ **SIGN** Signed Documents
 - **SIGN** Product
 - ▾ **SIGN** Releases
 - **SIGN** Release 1.3
 - **SIGN** Release 1.4
 - **SIGN** Release 1.5
 - **SIGN** Release 1.6
 - **SIGN** Release 1.7
 - **SIGN** Release 1.8
 - **SIGN** Release 1.9
 - **SIGN** Release 1.10
 - **SIGN** Release 1.11
 - **SIGN** Release 2.0

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