

# Webinar: Agile Design Controls Part 1

How to Support Rapid Design Iterations for Software-Intensive Medical Devices

February 13, 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

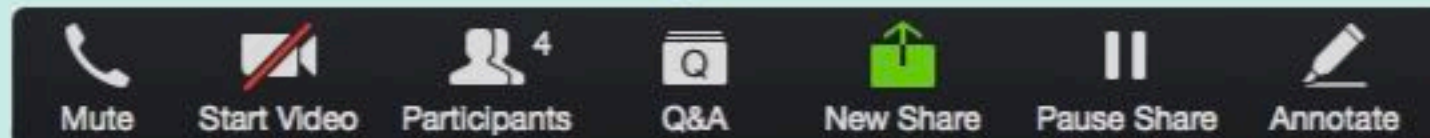


- Founder Matrix Requirements
- 15+ years managing medical device development
- 10+ years developing version control and document management systems
- 30 years experience professional software development
- Early adaptor of agile methodologies
- M.Sc. Computer Science – Karlsruhe University
- Based in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



# Webinar Outline

1. Challenges of software and connected devices
2. Managing design changes and documentation
3. Example change scenario
4. Implementing changes with JIRA and Matrix
5. Processes and tools to support rapid design iterations
6. Q&A



# New Capabilities → New Challenges

- **More features** → greater complexity, more software components, more 3<sup>rd</sup> party software
- **Connected** → cybersecurity risks, privacy risks, interoperability challenges

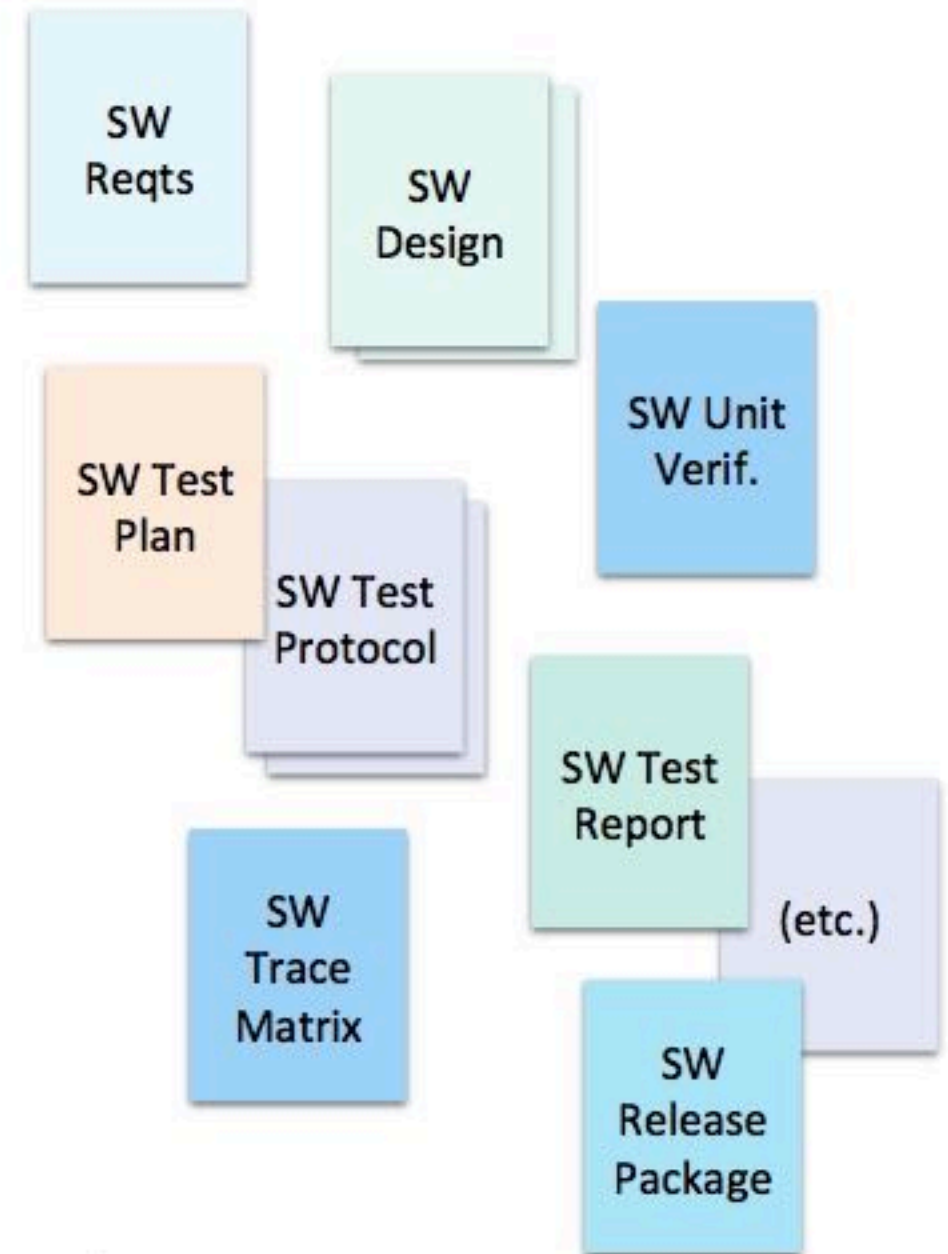
+ Greater regulatory scrutiny!



# Documentation Burden

- Many DHF documents for SW Release
- Each document reviewed and approved (days? weeks?)
- Information is interconnected and interdependent
- ~~CONCLUSION: only release the software once!~~

**No! Refine your processes and tools to be able to manage SW releases rapidly (days not weeks)**

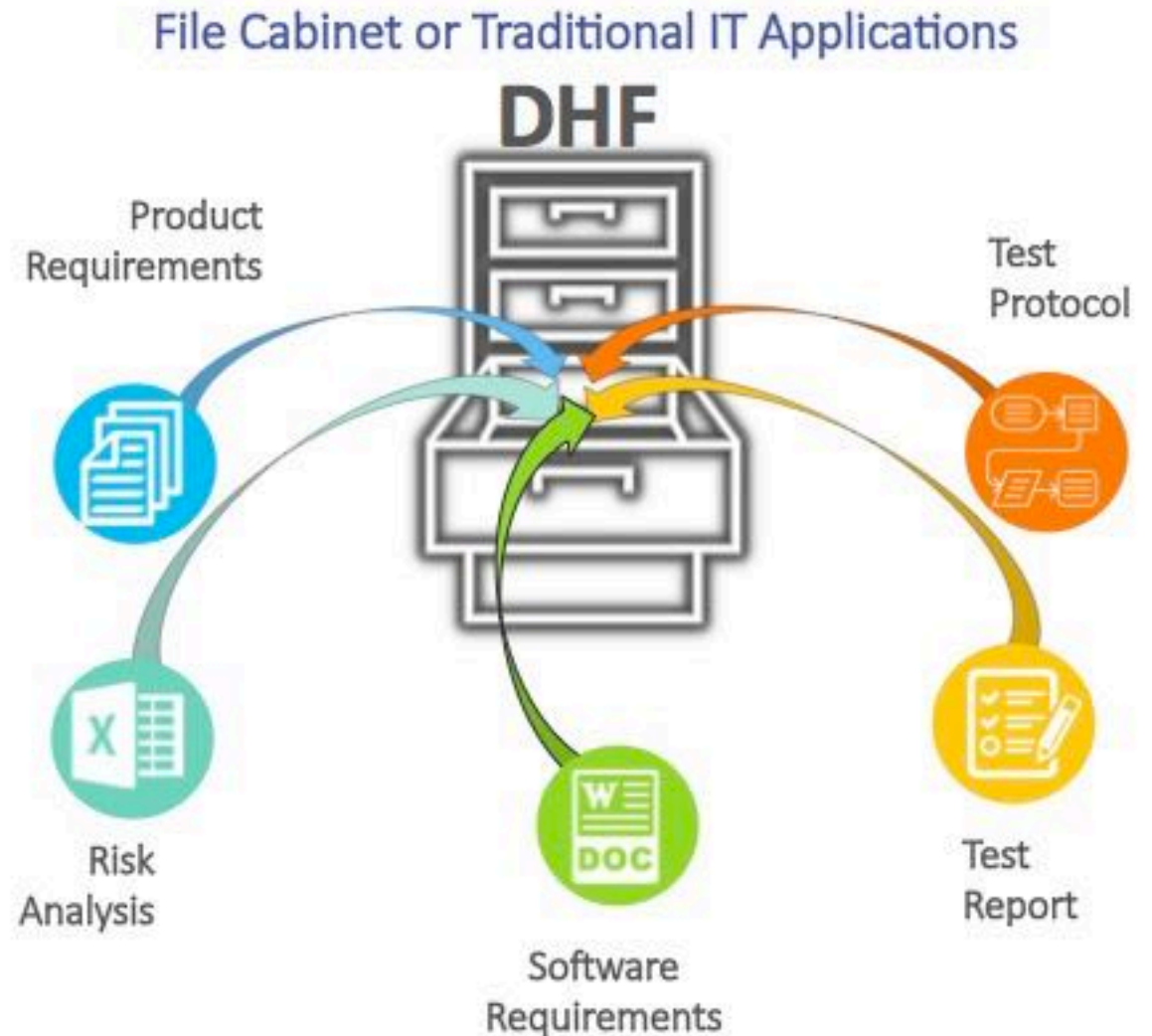




# Challenges of Traditional Document Centric Approach

- Traceability is static
- No defined workflow
- Difficult to manage changes

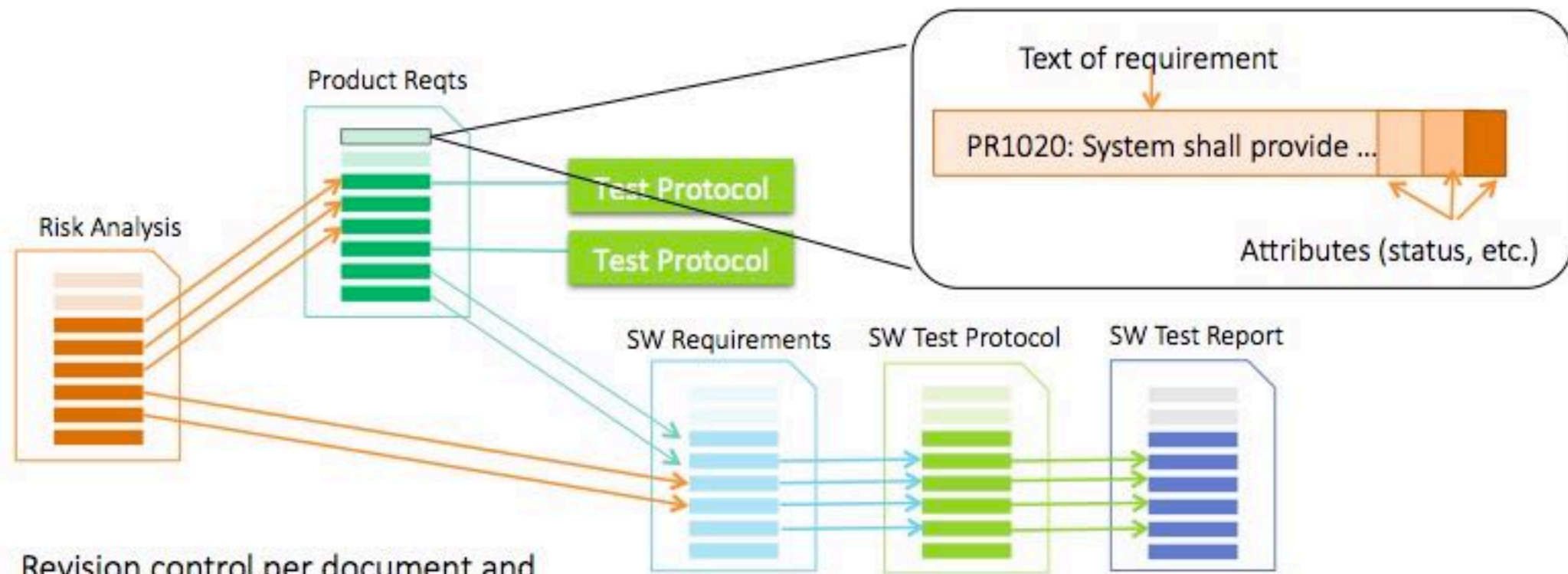
Good for archiving but not fast moving product development





# New Way: Product Documentation Stored as Objects

Documents are groupings of DHF elements



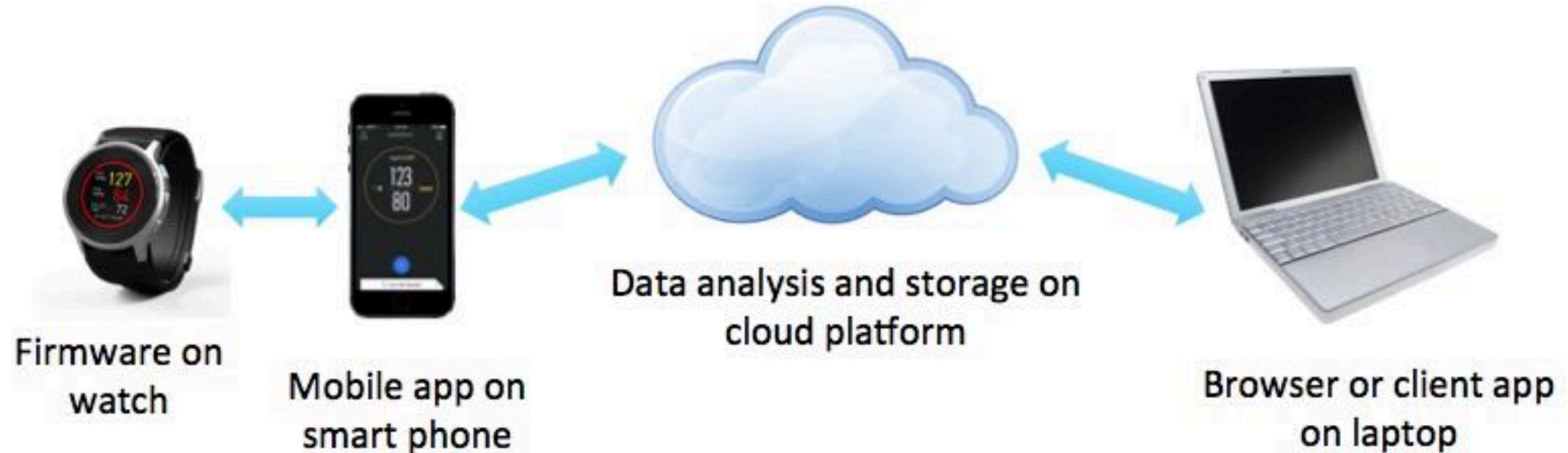
Revision control per document and per element

Export a set of documents from the database  
for submissions

Dynamic management of product data

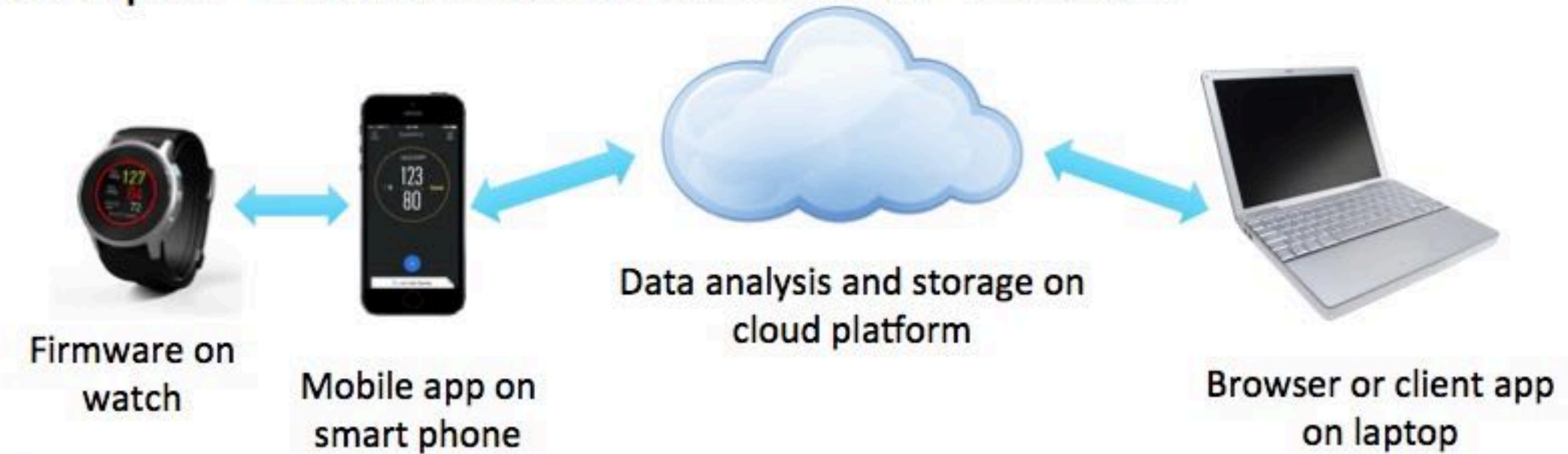
# Example Connected Medical Device

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





# Example Connected Medical Device



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

**DHF documents**



# Change Scenario (before product release)

- **PROBLEM:** usability testing late in development showed that in 25% of cases the user pressed the wrong button on the watch
- **SOLUTION:**
  - Change GUI functions on watch and on mobile app
  - Update user manual
  - Re-test the software
  - Re-run the usability testing
- **CHALLENGE:** don't miss any details while making rapid changes!

**Planned**

**Tracked**

**Synchronized**

**Completed**



# Plan the change in Jira

The screenshot displays the Jira ProX interface for 'ProX Sprint 1'. The left sidebar contains navigation options: PROJECTX Software project, ProX Board, Backlog, Active sprints, Reports, Releases, Issues and filters, Pages, Components, Add item, and Project settings. The main board is divided into three columns: TO DO, IN PROGRESS, and DONE. The 'TO DO' column contains 'Login Workflow Improvements' (PROJ-163) and 'Database Failures' (PROJ-168). The 'IN PROGRESS' column contains 'Monitoring Delay Blood Pressure' (PROJ-176) and 'Face Watch ECG Monitoring' (PROJ-189). The 'DONE' column contains 'ECG Monitoring Failure' (PROJ-172). A green arrow points to the 'Face Watch ECG Monitoring' issue. At the top right, there is a timer showing '9 days remaining' and a 'Complete sprint' button.

TO DO	IN PROGRESS	DONE
Login Workflow Improvements PROJ-163	Monitoring Delay Blood Pressure PROJ-176	ECG Monitoring Failure PROJ-172
Database Failures PROJ-168	Face Watch ECG Monitoring PROJ-189	

# Link the ticket with a change object in Matrix

The screenshot displays the Matrix Requirements tool interface, divided into two main panels. The left panel shows a ticket titled "Face Watch ECG Monitoring" (PROJX-189) with a status of "IN PROGRESS". The ticket details include Type: Improvement, Priority: Major, Labels: None, Sprint: ProX Sprint 1, and Importance: 50. The description states: "User validation showed that 20% of users do not intuitively understand how to start a recording session." The "Issue links" section is highlighted with a green box and contains a link to "MedWatch/CHANGES-3 Face Watch ECG Monitoring". A large green arrow points from this link to the right panel. The right panel shows the "CHANGES-3 Face Watch ECG Monitoring" change object. The "CHANGE DESCRIPTION" section includes a "Background" section with two bullet points: "Users tend to leave the finger on the heart instead of tapping it once" and "This will end the recording immediately before it records enough information". The "Change" section states: "Instead of the heart a record button shall be used." Below this is a diagram of a heart with a red dot in the center. The "DOCUMENTATION" section lists "REQ-15 Recording ECG" with a link to "PROJX-189 Face Watch ECG Monitoring". The "IMPLEMENTATION" section lists "PROJX-189 Face Watch ECG Monitoring" with a link to "PROJX-189 Face Watch ECG Monitoring".

PROJX-189

## Face Watch ECG Monitoring

Edit Comment Assign Stop Progress Resolve Issue Close Issue Admin

Type: Improvement Status: IN PROGRESS

Priority: Major Resolution: Unresolved

Labels: None

Sprint: ProX Sprint 1

Importance: 50

### Description

User validation showed that 20% of users do not intuitively understand how to start a recording session.

### Attachments

Drop files to attach, or browse.

### Issue links

relates to

MedWatch/CHANGES-3 Face Watch ECG Monitoring

### Activity

All Comments Work log History Activity Svn Gateway

There are no comments yet on this issue.

Comment

## CHANGES-3 Face Watch ECG Monitoring


### CHANGE DESCRIPTION

Background:

- Users tend to leave the finger on the heart instead of tapping 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

- REQ-15 Recording ECG

Create Marketing Requirements Create System Requirements Create Software Requirements

Create Specification Create Hardware Create Test Cases Create Integration Tests

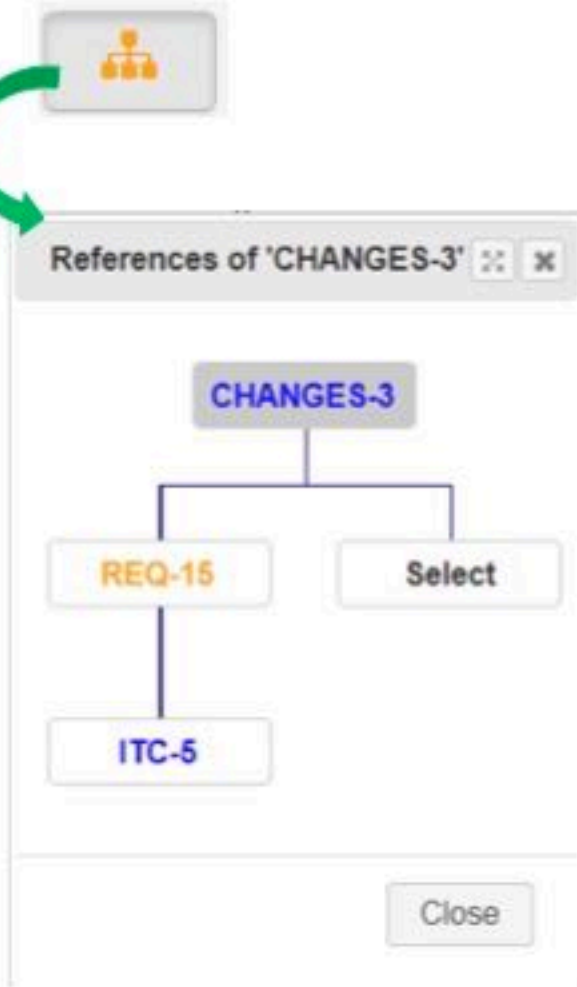
Select Existing

### IMPLEMENTATION

- PROJX-189 Face Watch ECG Monitoring



# Traceability



Filter LOCK Alpha Beta Sample In Work Ready for Review Reviewed MedWatch matrxadmin

### CHANGES-3 Face Watch ECG Monitoring

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

- REQ-15 Recording ECG

IMPLEMENTATION

- PROJX-189 Face Watch ECG Monitoring

References of 'CHANGES-3'

```
graph TD; CHANGES-3 --> REQ-15; CHANGES-3 --> Select; REQ-15 --> ITC-5
```

Close

Downlinks Smart Links

☒ recursively ☒ REQ ☒ ITC

REQ-15 Recording ECG

DESCRIPTION

 In order to start recording the user needs to tab the heart.

 Once tabbed the recording will start

REFERENCES

- ITC-5 ECG Recording Test

LABELS

[Clear Req](#) [Clear ITC](#)

ITC-5 ECG Recording Test

DESCRIPTION

Requires, watch worn normally

enter session comment! Cancel Save

# Filter to see the corresponding tests only

The screenshot displays the Matrix Requirements software interface. On the left, a navigation tree shows a hierarchy of test categories: HW (Hardware), SOUP (Software Requirements), ITC (Integration Tests), and RUN (Testing). Under ITC, there are sub-categories like Watch Tests and ECG. The 'ITC-5 ECG Recording Test' is selected. A green arrow points from the 'Filter' button in the top toolbar to the 'Create Test Forms' dialog box on the right. The dialog box shows a search filter: 'mrql:category=ITC and uplinkm=F-CHANGES-5'. Below the search bar, it indicates '1 matching items found' and lists 'ITC-5 ECG Recording Test'. A dropdown menu is open, showing options like 'outdated links', 'last week', 'failed tests', and 'Integration Tests RC 1', 'Integration Tests RC 2', 'Integration Tests RC 3', and 'Miracle Help'. The main window displays the details for the 'ITC-5 ECG Recording Test', including a description, a table of test steps, and a table of expected outcomes.

**Matrix Requirements**

and uplinkm=F-CHANGES-5

1 matching items found

☐ Un/Select all

nothing selected

☒ ITC-5 ECG Recording Test

outdated links  
last week  
failed tests  
Integration Tests RC 1  
Integration Tests RC 2  
Integration Tests RC 3  
Miracle Help

Next Cancel

**ITC-5 ECG Recording Test**

DESCRIPTION

Requires, watch worn normally.

DATA

no items found

TEST STEPS

Action	Expected Outcome
1. Select ECG Face Watch	Face watch shown
2. Press button to record	Progress bar is shown, ECG curve is shown
3. Do some physical activity	Verify ECG changes and stays visible in watch
4. Wait for end	Verify that recording was done in less than 10 seconds

2.2.57.14177

enter session comment

Cancel Save



# DHF update

**DOC-17** Software Requirements

DOCUMENT NUMBER

▲ ADDITIONAL

Version	Change Description	Change Date
RC 0	First Release Candidate For Smoke Test	Jan. 08h 2019
RC 1	Added Changes for RC-1	Feb. 10 2019

REMARKS

SIGNATURES

PURPOSE

SCOPE

REFERENCE AND APPLICABLE DOCUMENTS

DEFINITIONS

APPENDIX: SOFTWARE REQUIREMENTS

Include the following items: **F-REQ-1** Software Requirements

TRACE MATRIX SW TO INTEGRATION TESTS

Traces from: **F-REQ-1** Software Requirements

Traces to: **F-TC-1** Integration Tests

DOCUMENT FILTER

REVIEW

MANAGE DOCUMENTS

Download document

PREVIOUSLY CREATED / USED DOCUMENTS

- SIGN-4** Software Requirements RC 0 - Smoke Test

added

unchanged

**Matrix** **Software Requirements**

CLOUDS Medical Watch (MedWatch) Rev: 2019/02/05 15:10:40  
Document: NO ID (0000) Page: 1 / 10

**SOFTWARE REQUIREMENTS**

**ADDIT**

Version	Change Description	Change Date
RC 0	First Release Candidate For Smoke Test	Jan. 08h 2019
RC 1	Added Changes for RC-1	Feb. 10 2019

**SIGNATURES**

Signature Meaning	Name	Title	Date	Signature
Author	Wolfgang Huber	SW Engineer		
Approver	pm	CEO		

Purpose

Scope

Requirements

Definitions

Appendix

Trace Matrix

Filter

Review

Manage Documents

Previously Created / Used Documents

**Matrix** **Software Requirements**

CLOUDS Medical Watch (MedWatch) Rev: 2019/02/05 15:10:40  
Document: NO ID (0000) Page: 4 / 10

**RC0-11 SW**

Author	Date	Revision
Wolfgang Huber	2019/02/05 08:36:23	1

Software Requirements / WATCH Firmware / Software driven alarms, warning and operator messages / SW

Updates:

Downloads:

**RC0-11 Recording ECG**

Author	Date	Revision
Wolfgang Huber	2019/02/05 15:07:34	1

Software Requirements / Watch Firmware / User Interface Requirements / Watch Faces Recording / Recording ECG

Updates:

- CHANGES - 1 Face Watch ECG Monitoring**

Downloads:

- ECG-1 ECG Recording Test**

Description

 In order to start recording the user needs to tap the red point.

 Once tapped the recording will start.

**RC0-11 Recording Temperature**

Author	Date	Revision
Wolfgang Huber	2019/02/05 09:58:12	1

All dates and times are in the project's default time zone and formatting.

# Archiving docs with electronic signature

OUTPUT  
wolfgang

MANAGE DOCUMENTS  
Request Signatures

**Send Mail**

TO  
select recipients(s)

CC  
select recipients(s)

SUBJECT  
Please review and sign SIGN-2

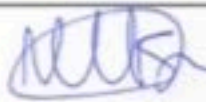
MESSAGE

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	 <b>sign-p183-i48080-b20190104163812075</b>

# Document version history

The screenshot displays the Matrix Requirements software interface, specifically the 'History of 'REQ-15'' window. The interface is divided into several sections:

- Left Sidebar:** Contains navigation links for 'Project, Reports & Controlled Documents', 'AUDIT Audit Tools', 'REP Reports', 'DOC Documents', and 'SIGN Archived Documents'. Under 'SIGN', there are links for 'SIGN-1 About this project', 'SIGN-2 Requirement Review Form', 'SIGN-3 Requirement Review Form', 'SIGN-5 System Requirements', and 'SIGN-7 Software Requirements'.
- Top Section:** Displays 'SIGN-8 Software Requirements, RC 1' with a table showing signatures. The table has columns for 'wofgang' (signed at 2019/02/05) and 'ann' (not yet signed).
- Redline Section:** A pop-up window titled 'Redline' showing differences between 'SIGN-7 Software Requirements (2019/02/05 15:15:32)' and 'SIGN-8 Software Requirements, RC 1 (2019/02/05 15:17:06)'. It lists 'REQ-15 Recording ECG' with versions v7 and v8, and a 'compare versions' link.
- History of 'REQ-15' Section:** A detailed view of the document's history. It includes a calendar for February 2019, a table of versions (rev 1 to rev 8), and a 'VERSION INFO' section. The 'VERSION INFO' section shows that version 7 was deleted and version 8 was restored. The 'DESCRIPTION' section shows a sequence of images illustrating the steps to start recording an ECG: 'In order to start recording the user needs to', 'tab the heart', 'start', 'Once tabbed the recording will', and 'start'.

Green arrows highlight the 'compare versions' link in the Redline section and the 'VERSION INFO' section in the History of 'REQ-15' window.



# Processes Prepared for Change

- Agile methods for product development
  - Design iterations are expected during development (and after product launch)
  - Design controls are not forced to be sequential (don't create a "waterfall" framework)
  - Multiple iterations of risk management, design inputs, design outputs, V&V testing
- Streamlined compliance
  - Minimize delays in review, approval, and release
  - Eliminate redundant records
- Centralized issue tracking (not compartmentalized)
- Test automation
- Documentation automation
- Product testing vs. confirmational (formal) testing



# Key Characteristics for SW Tools

- Configurable defect tracking and task management (day-to-day changes)
- Integrated test management (to enable "paperless V&V")
- Support for risk management (risk assessment and traceability of risk controls)
- Highly configurable reporting to generate DHF documents automatically
- Electronic signatures and audit trail (FDA Part 11 compliance)
- Straightforward to validate (and tool will not be automatically updated outside of your control)
- Efficiently support multiple versions of products (keep track of v1.0 while also managing v1.1 and v2.0)

# Q & A

Arnaud Alberts  
Wolfgang Huber

Matrix Requirements GmbH - [matrixreq.com](https://matrixreq.com)

Aaron Joseph

Sunstone Pilot, Inc. - [sunstonepilot.com](https://sunstonepilot.com)