A true story from a developer's perspective

When: When to test

What: What to test

Why: Why to test

Morandi Bridge
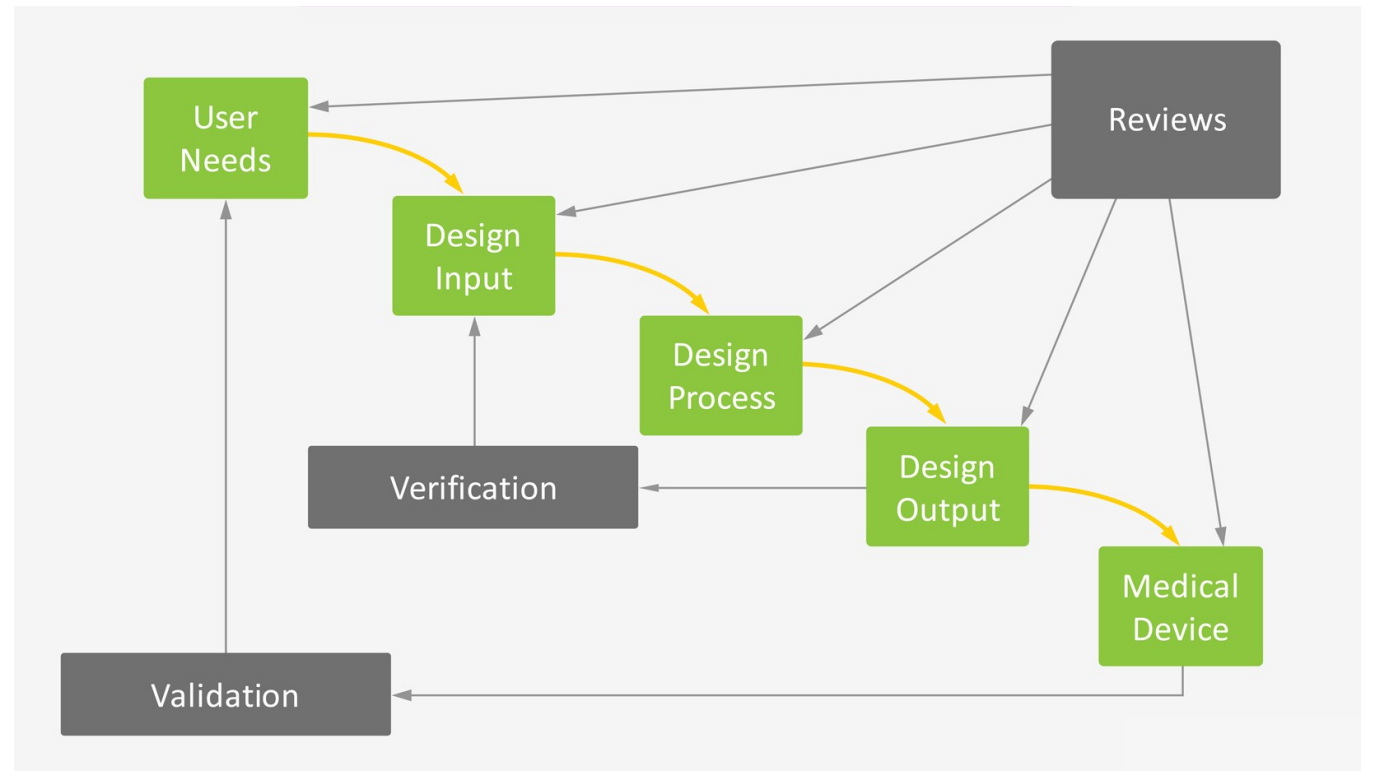
Lacation: Genoa

Hight: 45m

Age   51

Test: whitewashed

Why testing

- ISO 13485
  Quality Management System

  - Requires a verification and validation plan
  - Applies to devices, processes and tools

Why testing

- ISO 14971
  Risk Management

  - It is all about tracing risks and verifying the risk mitigation
  - Applies to devices, processes and business

Pain

Intended Use

Clinical Study

Proof

Usability

Requirements

Mitigation

Post Market Study
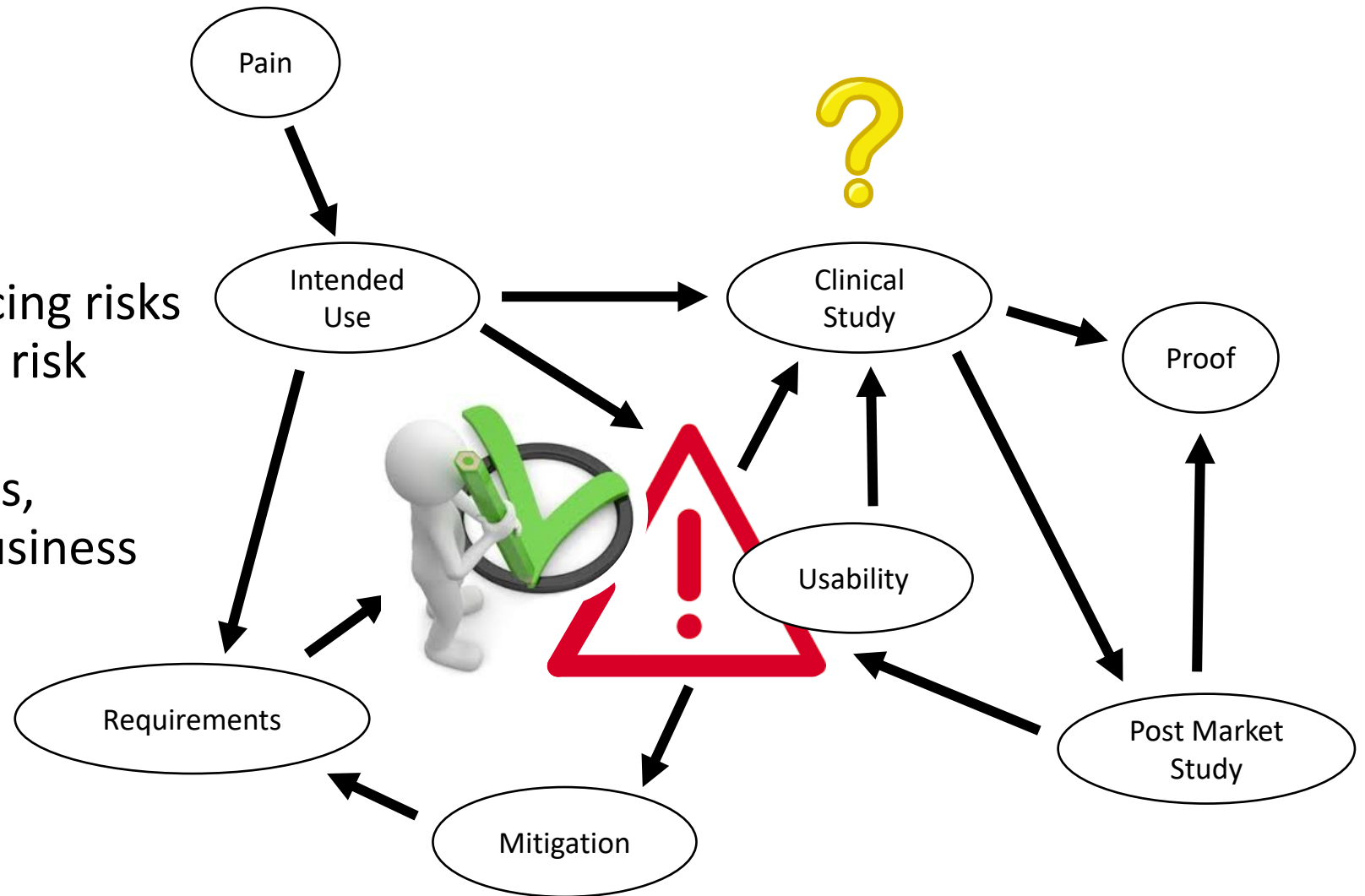
Why testing

- **Medical Standards:**
  - 60601-1
    - Drop / Impact test
    - Electrical isolation test
  - 60601-1-2
    - EMV & ESD test
    - Essential performance !
  - 62304
    - Software / Firmware / SOUP
    - Risk based testing strategies
      - Code review
        - No 'default' case
        - Extensive use of logs
  - 62366
    - Primary operational functions
    - Both verification / validation

Simplified V-model

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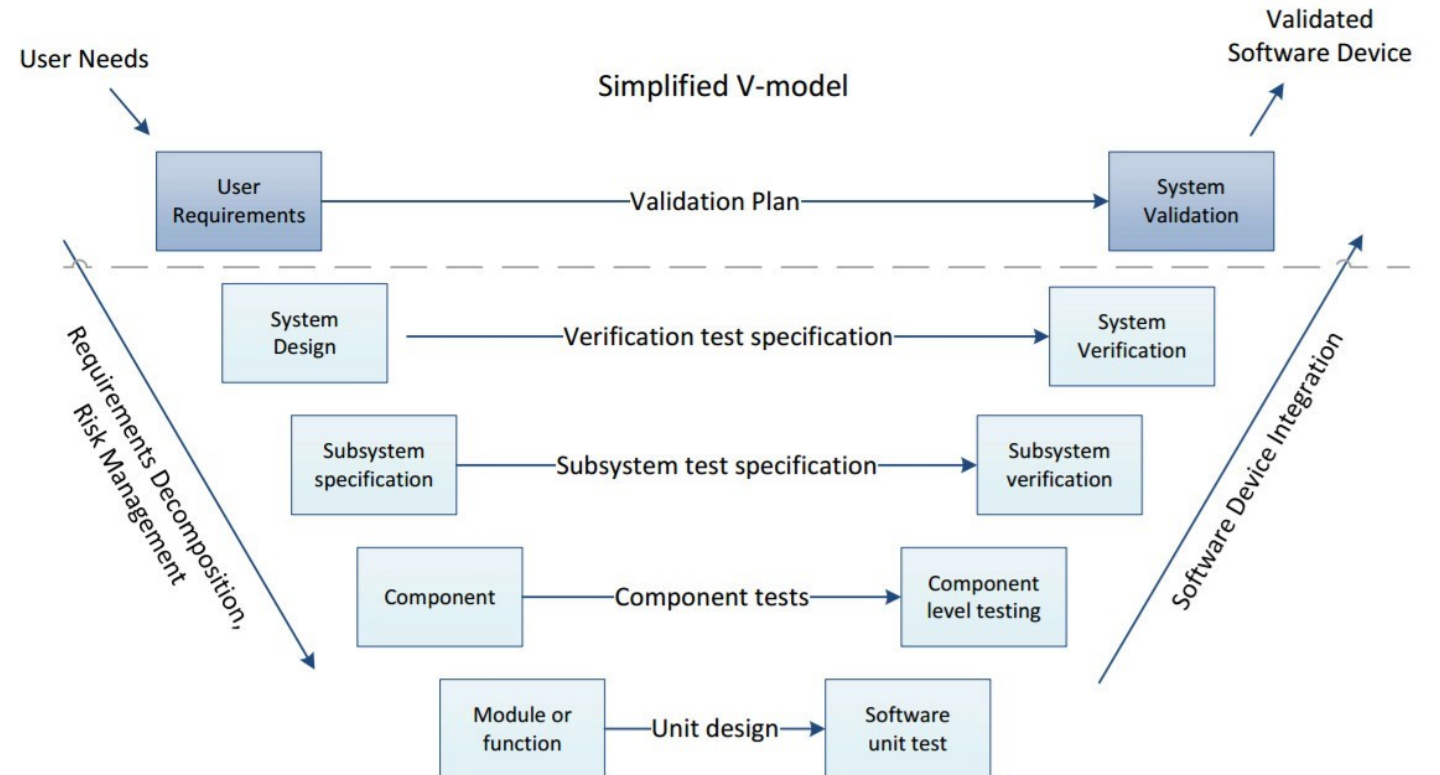
The essential questions to ask

- For whom are we testing
  - For the Notified Body

- When do we start testing
  - Once we have a design freeze

- What are we testing
  - The requirements

- How are we documenting
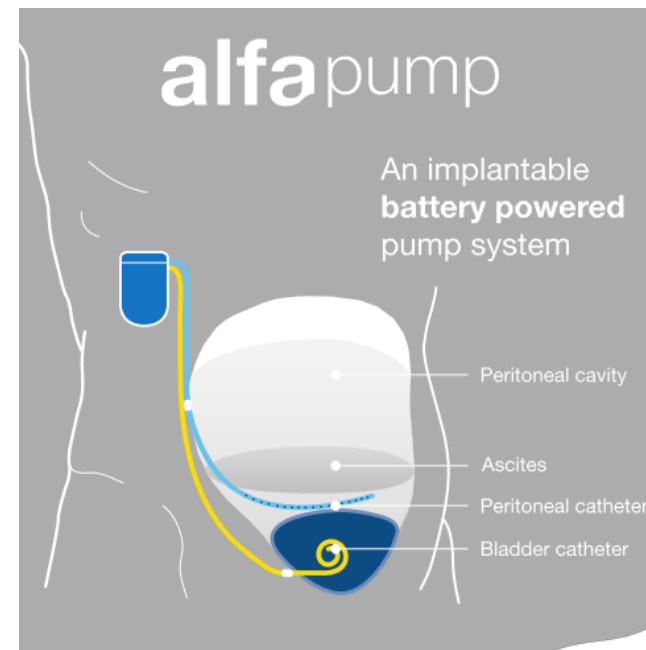 - Test Spec, Test Plan, Test Report

The essential questions to ask

- For whom are we testing
  - For us and for the patient

- When do we start testing
  - It is the first and last activity

- What are we testing
  - How to break the device

- How are we documenting
  - As much as needed, but always
  - Goal, Steps, (expected) results
 - *Not documented = not done*

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The essential questions to ask

- For whom are we testing
  - For us and for the patient

- Sequana Medical AG
  - Pump for Ascites

alfapump

An implantable **battery powered** pump system

- Peritoneal cavity
- Ascites
- Peritoneal catheter
- Bladder catheter

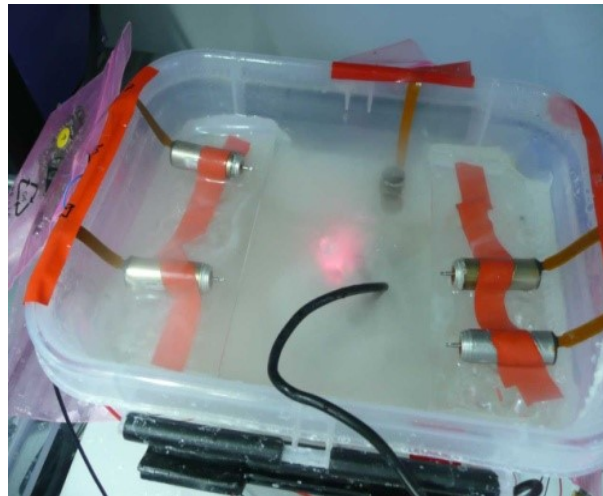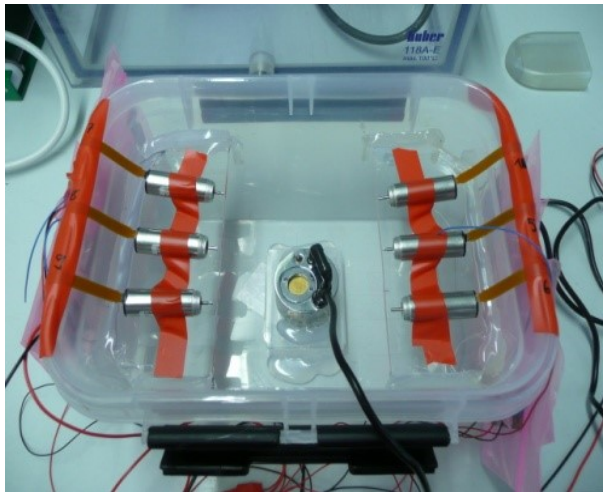*thomas.degen@hslu.ch*

The essential questions to ask

- For whom are we testing
  - For us and for the patient

- Test
  - Catheters
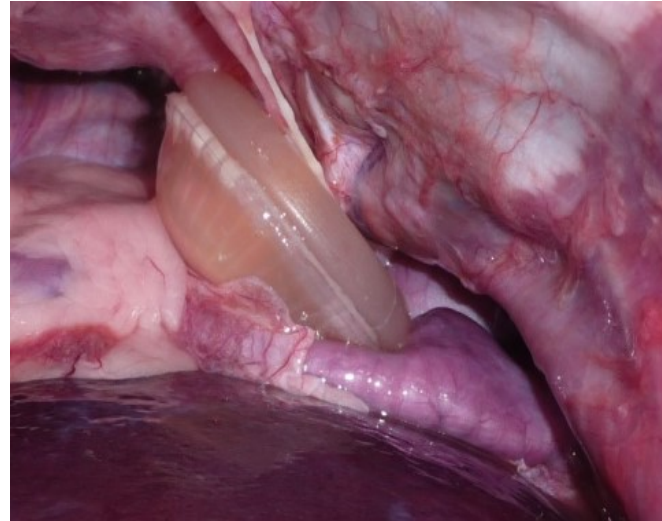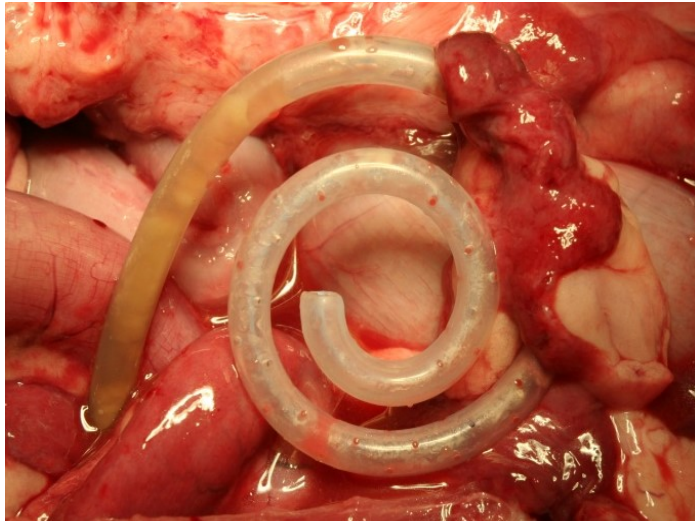
Animal Model led to 6 Months survival time – human model 11 days

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The essential questions to ask

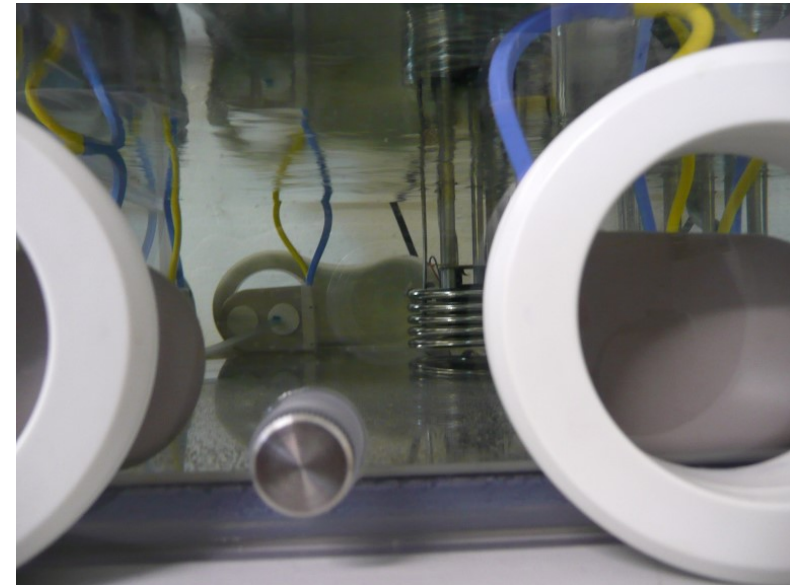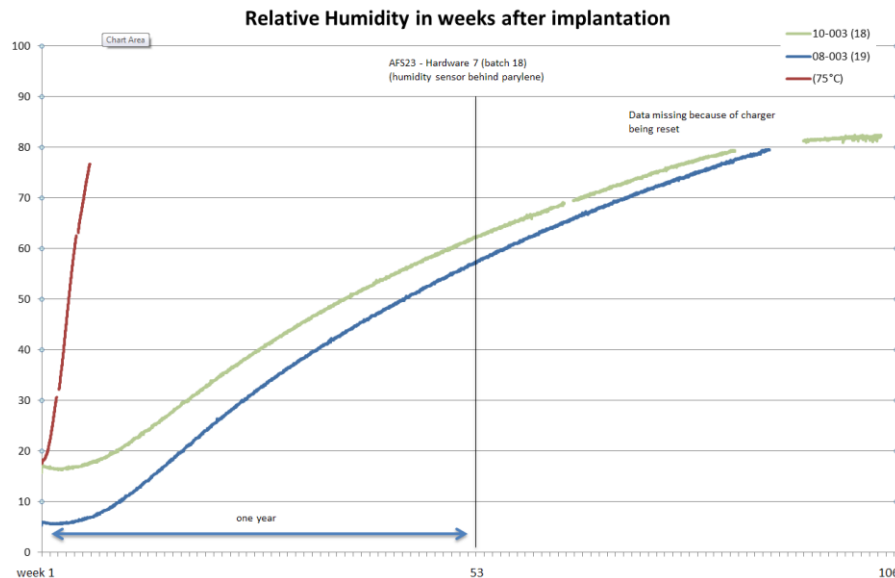- For whom are we testing
  - For us and for the patient

- Test
  - Motors

Original Motors survived 100 cycles autoclaving – but 5 min. in saltwater

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The essential questions to ask

- **For whom are we testing**
  - For us and for the patient

- **Test**
  - Lifetime

Accelerated aging with a factor of 12 – corrected later to a factor of 8

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The essential questions to ask

- For whom are we testing
  - For us and for the patient

- Takeaways
  - Test are essential for the development. They confirm simulations (or not) but also tests are only part of the truth

Do plan for a test to fail

The essential questions to ask

- For whom are we testing
  - For us and for the patient

- **When do we start testing**
  - It is the first and last activity

- Biovotion AG
  - Vital Sign Monitor

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The essential questions to ask

- **When do we start testing**
  - It is the first and last activity
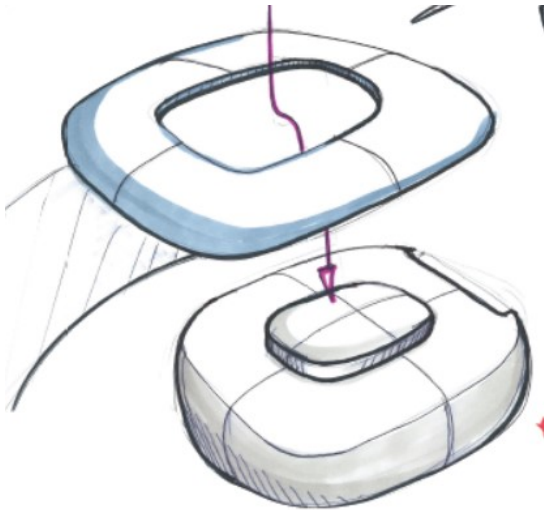
- **Test**
  - Usability

From drawings to crude models to rapid prototyping – from 12 to 1

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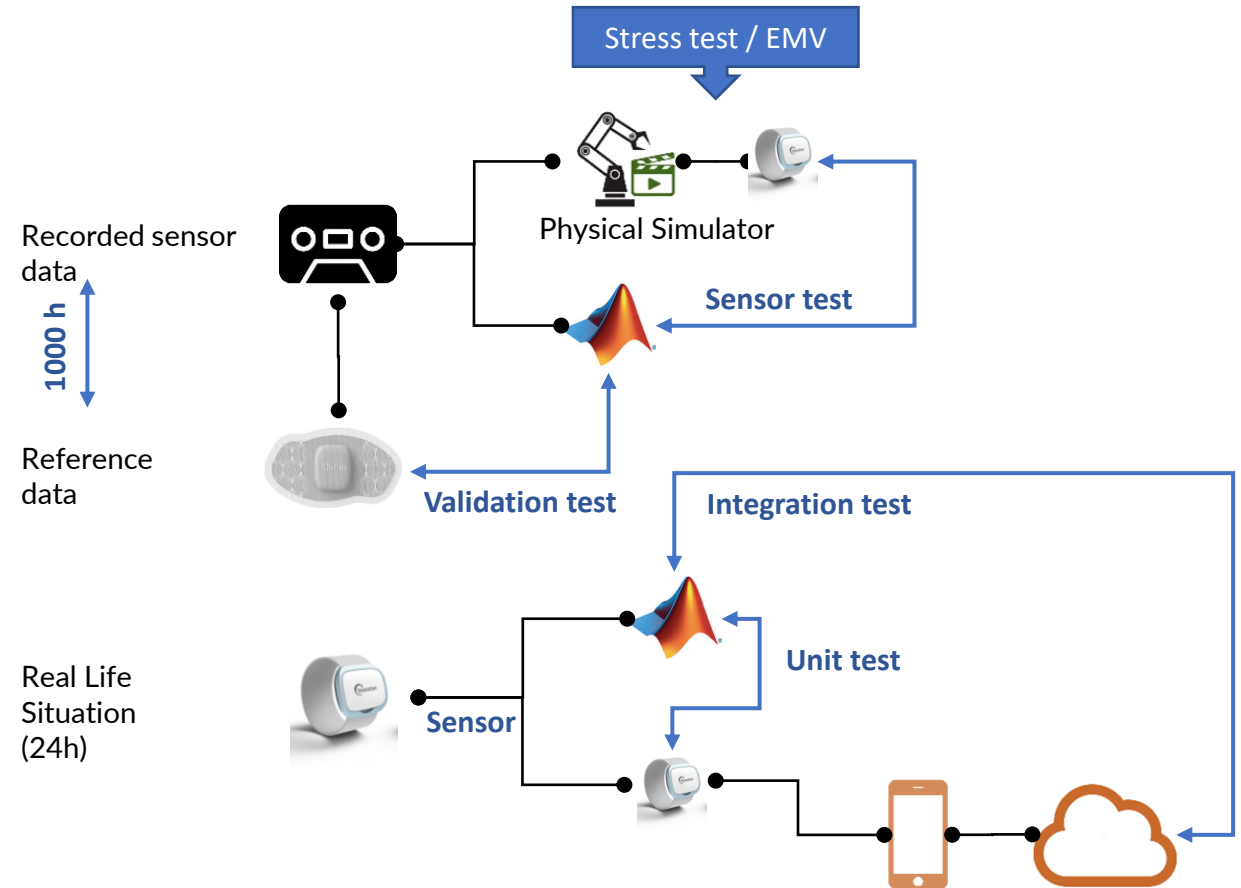# The essential questions to ask

- **When do we start testing**
  - It is the first and last activity

- **Test**
  - Usability

From good to better – the device serves the user – not the opposite

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The essential questions to ask

- ## When do we start testing
  - ### It is the first and last activity

Stress test / EMV

Physical Simulator

Recorded sensor data

1000 h

Reference data

Sensor test

Validation test

Integration test

Real Life Situation (24h)

Sensor

Unit test

A new Firmware is based on 1000h of data, 16h of Testrun and 24h Life

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The essential questions to ask

- When do we start testing
  - It is the first and last activity

- Takeaways
  - Your first task is to test your idea, then your concept, then the most important components, then your prototype and then, perhaps, your device

Tests start the development

The essential questions to ask

- For whom are we testing
  - For us and for the patient
- When do we start testing
  - It is the first and last activity
- **What are we testing**
  - How to break the device

- **Sequana Medical AG**
  - Pump for Ascites
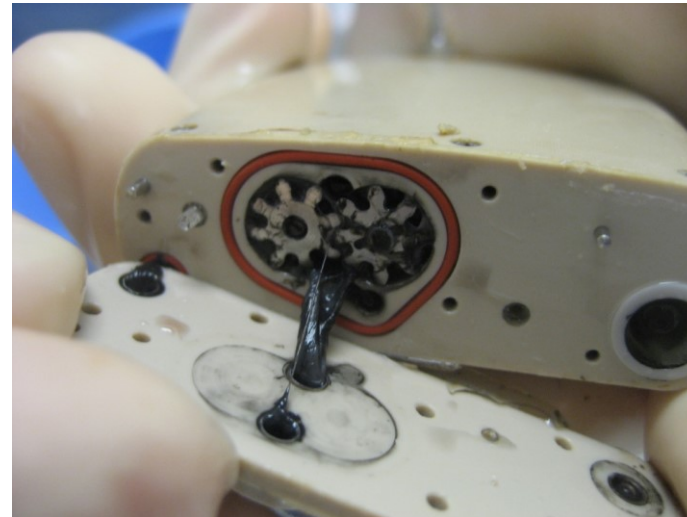
The new unblocking algorithm used 50% less power – when tested right

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The essential questions to ask

- What are we testing
  - How to break the device

- Takeaways
  - A test is not finished when it passed, but when there was no way for the test to fail

Only good tests do fail

The essential questions to ask

- For whom are we testing
  - For us and for the patient
- When do we start testing
  - It is the first and last activity
- What are we testing
  - How to break the device
- How are we documenting
  - As much as needed, but always
  - Goal, Steps, (expected) results
  - *Not documented = not done*

- Sequana Medical AG
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alfapump
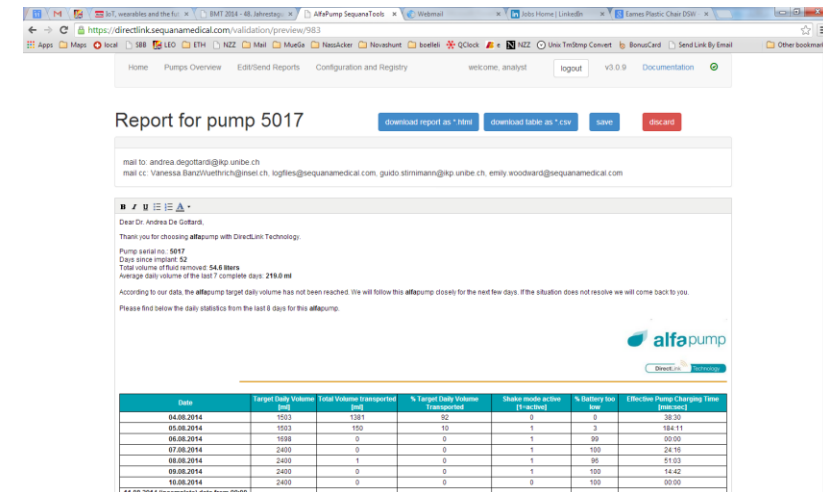
Smart Charger

Programming

Remote Data Monitoring

The essential questions to ask

- How are we documenting
  - As much as needed, but always
  - Goal, Steps, (expected) results
  - *Not documented = not done*

- Test
  - Data integrity

IF FW=2.58 THEN MULTIPLY VOLUME BY 1.5

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The essential questions to ask

- How are we documenting
    - As much as needed, but always
    - Goal, Steps, (expected) results
    - *Not documented = not done*

- It was a Bugfix
    - There was no plan to fix the bug
    - There was no four-eyes principle
    - There was no code-review
    - There was no impact analysis
    - There was no regression test

> A bugfix requires a new test

The NB requested data worth six months of work prior to release

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The essential questions to ask

- How are we documenting
  - As much as needed, but always
  - Goal, Steps, (expected) results
  - *Not documented = not done*

- Takeaways
  - Documentation of failed tests is as important as documentation of passed tests

first document then fix

Personal Credos

- Don't ask yourself when to start testing (you're already too late then)
  - Ask what to test now
  - Don't wait for a design freeze
  - Test components first RISK based
- Document every little test in the Lab book and start with what result you expect
  - Don't forget to document failed tests
- Don't start before you know what you expect but don't stop when it happens
  - Find the limit when the system brakes
- Start with writing the unit test when coding a new function

- Celebrate the one who found the error don't blame anybody
  - Never have him fix the error though (he will never find another error)
- It is 50% of your documentation, it should be at least 50% of your time
  - If you plan with fixed timelines you plan the outcome of the tests
- Tests before Spec
  - We do need tests to verify the specifications, we write specifications to know what to test
  - If you cannot test it, don't build it !

Quality of tests equal quality of product

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Value Testing – Make it an event not a burden

20 Everions climb the Kilimanjaro

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Thank you for your attention

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