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Risk-based testing

A must for medical devices

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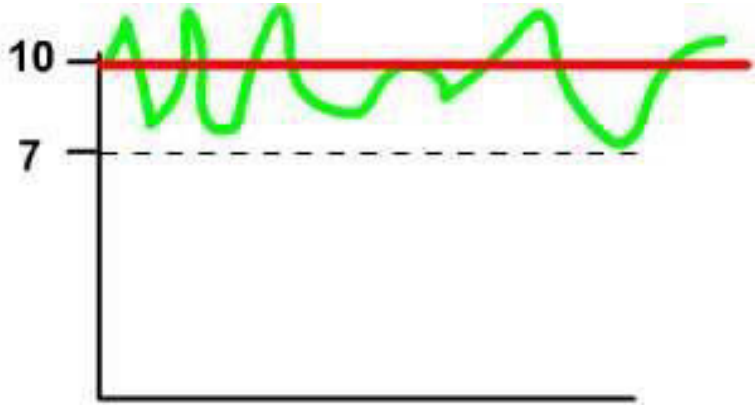
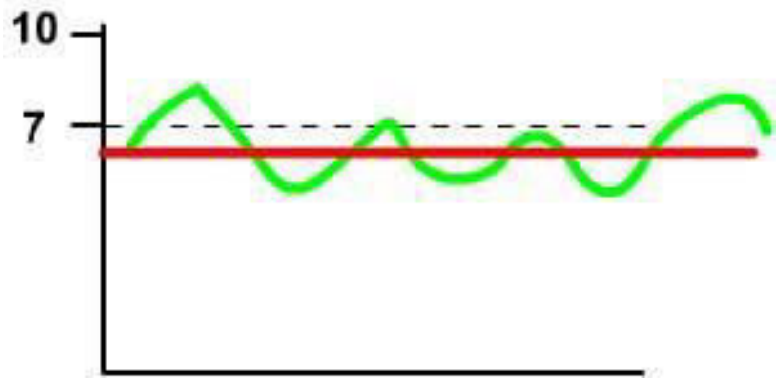
Background: diabetes care

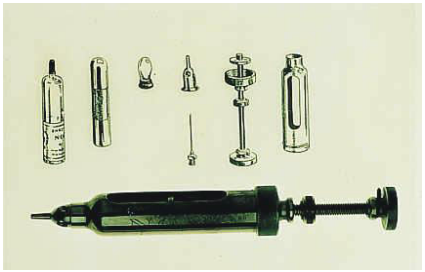
- Diabetes is close to be epidemic
  - at present 220 million people
- Dilemma
  - diabetes can not be cured
- Root cause
  - lack of body blood glucose control
- Blood glucose control
  - insulin injection
  - blood glucose measurement
- Diabetes care
  - providing insulin
  - constantly controlling condition
  - long term control: HbA1c (blood glucose concentration over time)





Devices for diabetes care

- Providing insulin
- Measuring blood glucose



Worst fear in medical device industry

… recalls and market withdrawals …

Example: recall of blood glucose meter

LifeScan, Inc. Announces Worldwide Correction Concerning Certain Blood Glucose Meters

Contact:
LifeScan Customer Services
1-800-515-0915

FOR IMMEDIATE RELEASE -- LifeScan, Inc, a maker of blood glucose testing systems for people
worldwide notification to all users of its OneTouch® Ultra®, InDuo® and OneTouch® FastTake
users to misinterpret their blood glucose results. All three affected meter systems were originall
select one of two units of measure to display their test results. This selection is typically deter
country in which they live. LifeScan, Inc., found that it was possible for consumers, in the cour
time, to accidentally change the unit of measure and thereby misinterpret their blood glucose re

In addition, very rarely, an event such as dropping a meter while in use can cause a brief power
change the unit of measure and/or the code number used to program the meter to match a part

The products are distributed worldwide primarily through retail pharmacy and mail order channels. Shipments of test strips for these systems are not affected.

- Blood glucose meter:
  - Used at least 4 times per day
  - Normal value is 5-6 mmol/l
  - Two units of measurement:
    - mmol/l (EU)
    - mg/dl (US)

This is a result in **mmol/L**. Note the equivalent result in mg/dL on the right.

This is a result in **mg/dL**. There is no decimal point when using the mg/dL equivalent.

Recall: what happened?

- A (EU) user drops the meter on the floor, and the device resets to factory settings **without** notifying the user

  mmol/l -> mg/dl

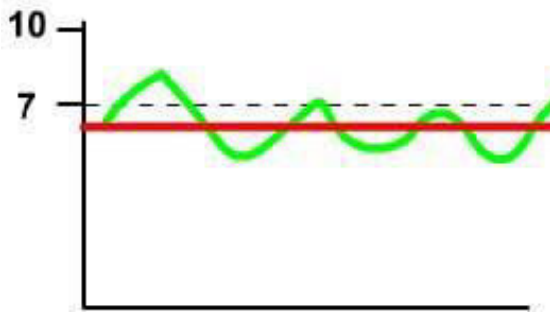
- Then, a measurement with unexpected unit:

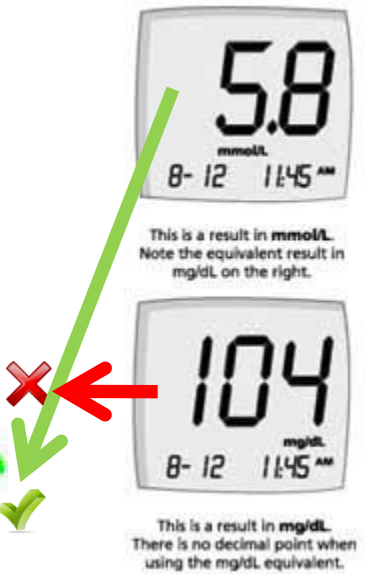
  104 mg/dl (= 5.8 mmol/l)

- Reaction: reading assumed to be

  10.4 mmol/l

- Result: extra insulin intake and **hypoglycaemia**!





How to avoid recalls … first call

- Risk analysis: ”foresee user risks”
  - define user safety
  - conduct user risk analysis
  - include risk mitigations in product requirements

- Process control: ”manage user risks”
  - perform requirement management (tracing)
  - perform configuration control
  - conclude by **risk-based testing**

User safety – design input for your product

- Essential performance
  - delivery of drug within safety accuracy
    - example: insulin overdose max. 2 units
  - measurement of medical value within safety accuracy
    - example: blood glucose measurement within 20%

- Basic safety
  - protection against electric shock
    - example: touch current max. 250 µA
  - enter safe state on single fault
    - example: fatal error disables insulin delivery

Risk analysis

- Stakeholder
  - User only (**not** the FDA)
- User risk
  - "I want to be safe with my medical device"
  - "I want to stabilize my health"
- User risk analysis (severity)
  - S5: "I am in severe danger of dying"
  - S4: "Over time, my health grows worse"
  - S3: "At present, I do not feel comfortable"
- Analysis method:
  - Effect: impact versus likelihood (Risk priority factor)
- Result:
  - S5 and S4 should be as low as reasonably possible

Risk analysis

Likelihood	Risk priority factor RPF				
Frequent 100% (3 times per day)					
Probable 10% (twice per week)					
Occasional 1% (once per month)					
Remote 0.1% (once per year)					
Improbable 0.01% (once per 10 years)					
Incredible 0.001% (once per 100 years)					
	S1	S2	S3	S4	S5
Impact	Negligible functional failure and cosmetic defects	Functional failures without medical significance	Might cause minor deterioration of health	Might cause serious deterioration of health	Might cause death

- Risk priority factor (i.e. effect):
  - **Unacceptable**
  - **ALARP** (as low as reasonably possible)
  - **Acceptable**

Risk analysis

- Risk reduction (mitigation):
  - Risks in the **Unacceptable** area require actions to reduce the risk priority factor at least into the ALARP area.
  - Risks in the **ALARP** area may be followed by actions needed to reduce the RPF.
  - Risks in the **Acceptable** area are put on the observation list (i.e. not forgotten)

Recall example: what to do?

- Possible field risk reduction:
  - No reset to factory settings
  - If not: user confirmation on reset
  - Follow MMI design rules:
    - 5.8 mmol/l -> 5.8 mmol/l
    - 104 mg/dl -> 104 mg/dl
  - Regional software version with only one unit enabled

- Possible early risk reduction (design):
  - Qualified user risk analysis
  - Establish design rules (experience)

This is a result in **mmol/L**. Note the equivalent result in mg/dL on the right.

This is a result in **mg/dL**. There is no decimal point when using the mg/dL equivalent.

Yet another recall – now on process

adversely affect the finished device, as required by 21 CFR 820.100(a) (4). Your firm lacks documentation that verification or validation was performed of the corrective actions taken on the H-TRON [illegible]cts to ensure effectiveness of the changes.

- …
- 3. Failure to perform[illegible]
- [illegible]
- Failure t[illegible] **… procedures to control documents …** omputers or [illegible]CFR 820.70(i).
- …
- [illegible]e that cannot b[illegible]lly verified by subsequent inspection and test.
- …
- 8. Failure to adequately establish and maintain procedures to control documents and document changes to include provisions for change records to record approval date, approval signature and when the change becomes effective, as required by 21 CFR 820.40 and 820.40(b).
- …
- Given the serious nature of these violations of the Act, all products manufactured by Disetronic Medical Systems AG, Burgdorf, Switzerland may be detained without physical examination upon entry into the United States until these

How to avoid recalls – second call

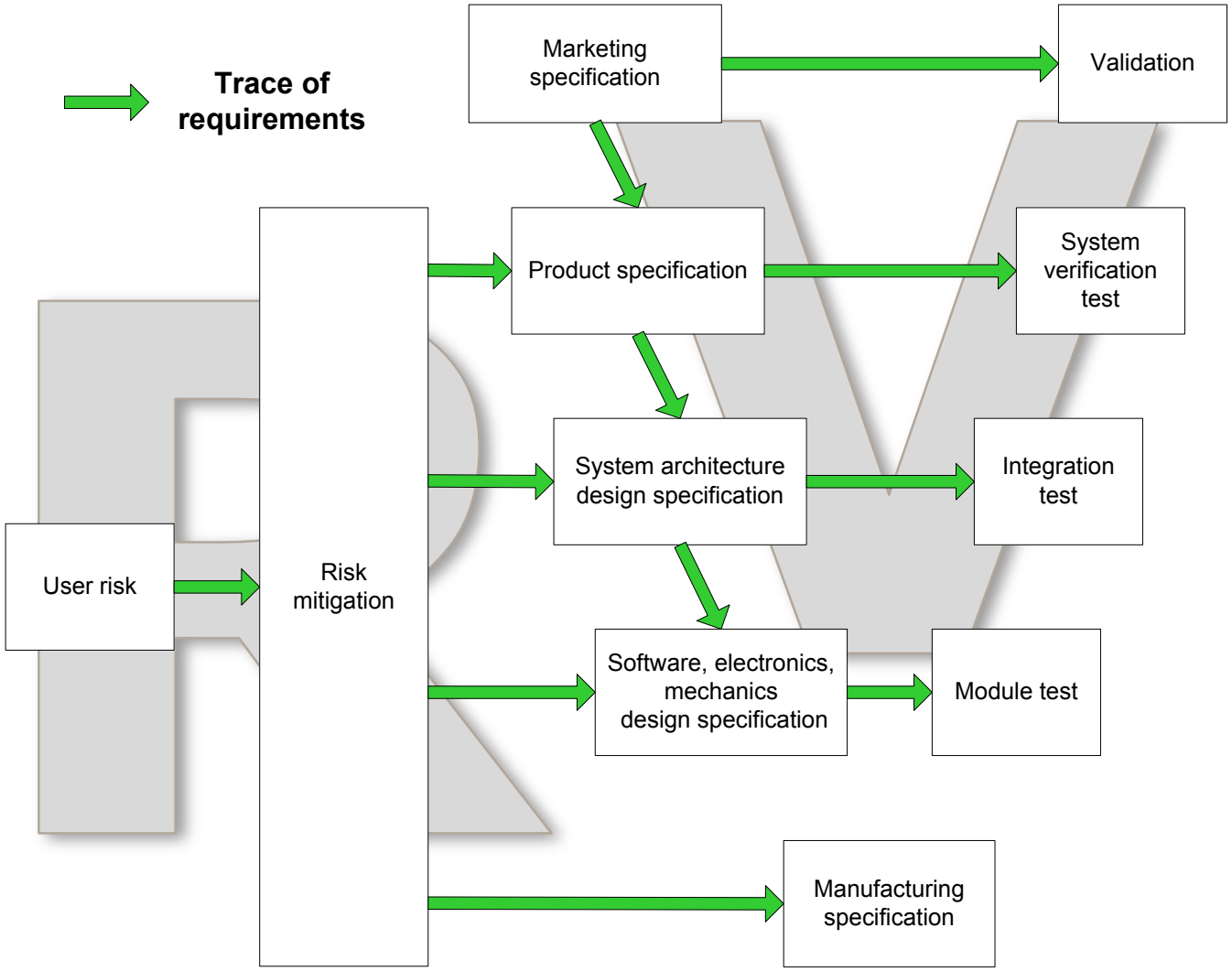
- Risk analysis: ” foresee user risks”
  - define user safety
  - conduct user risk analysis
  - include risk mitigations in product requirements

- Process control: ”manage user risks”
  - perform requirement management (tracing)
  - perform configuration control
  - conclude by **risk-based testing**

Configuration control – what?

- Requirements control
  - Controlling changes in requirements
  - Traceability between requirements
- Document control
  - Version control
    - Successive versions of a document
  - Baseline
    - A configuration of documents at a specific point in time
  - Document control
    - Where are the locally controlled documents?

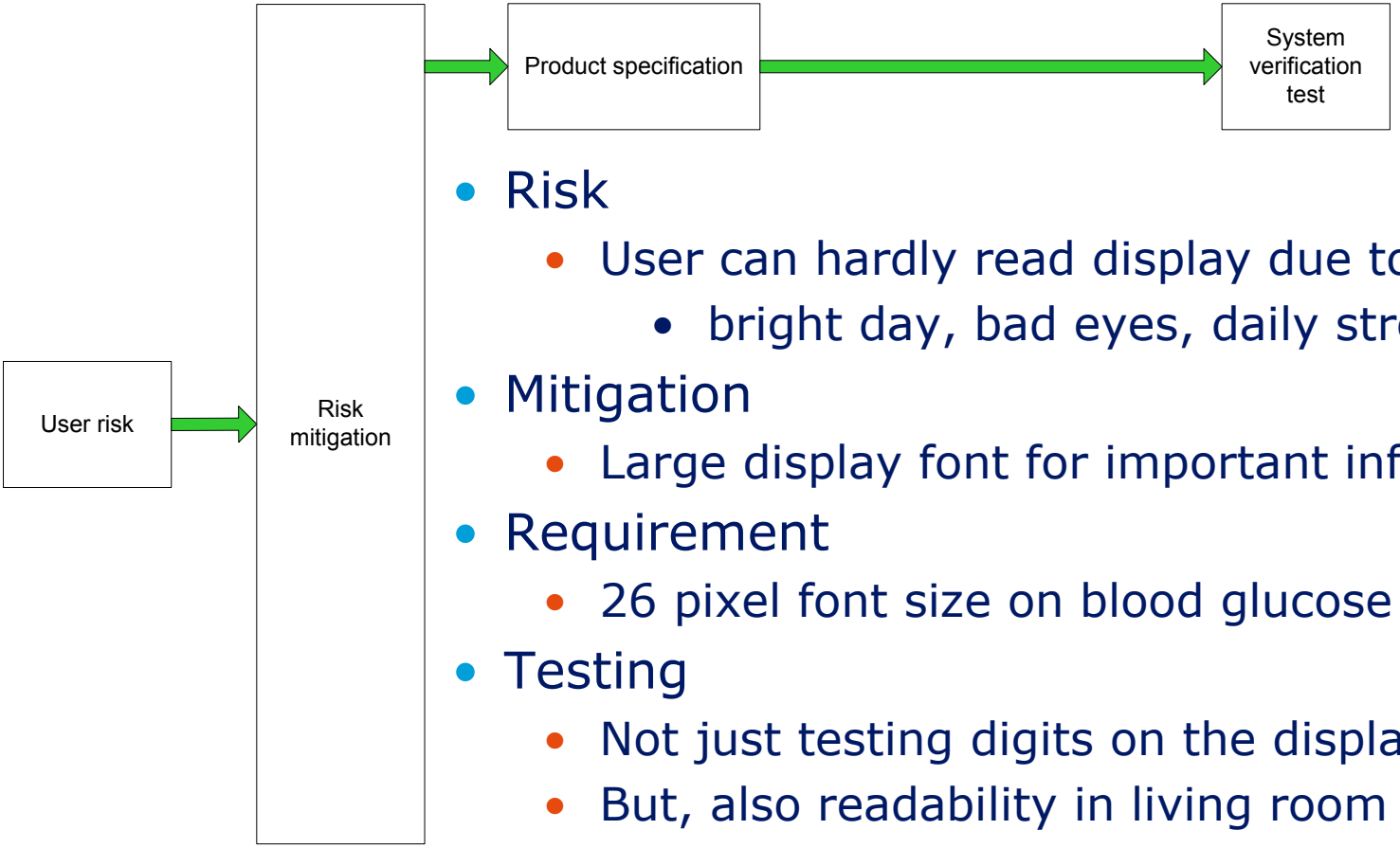
Configuration management (Risk V-model)



Risk-based testing

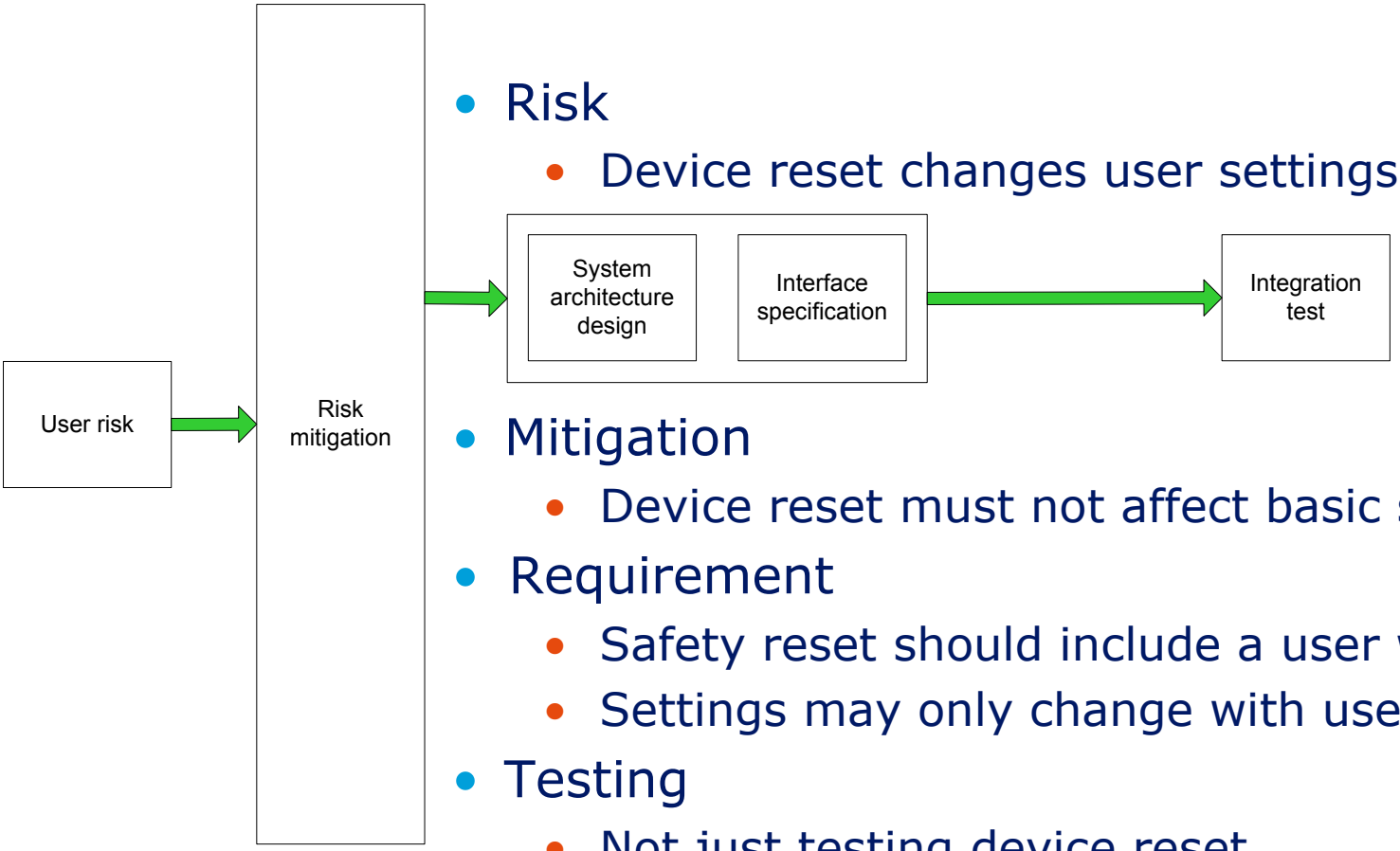
- Did you notice?
  - Until now, no focus on **risk-based testing**
- First, testers have to understand the process
- But then, what to do in **testing**?
- Again, some examples …

Risk-based testing, example



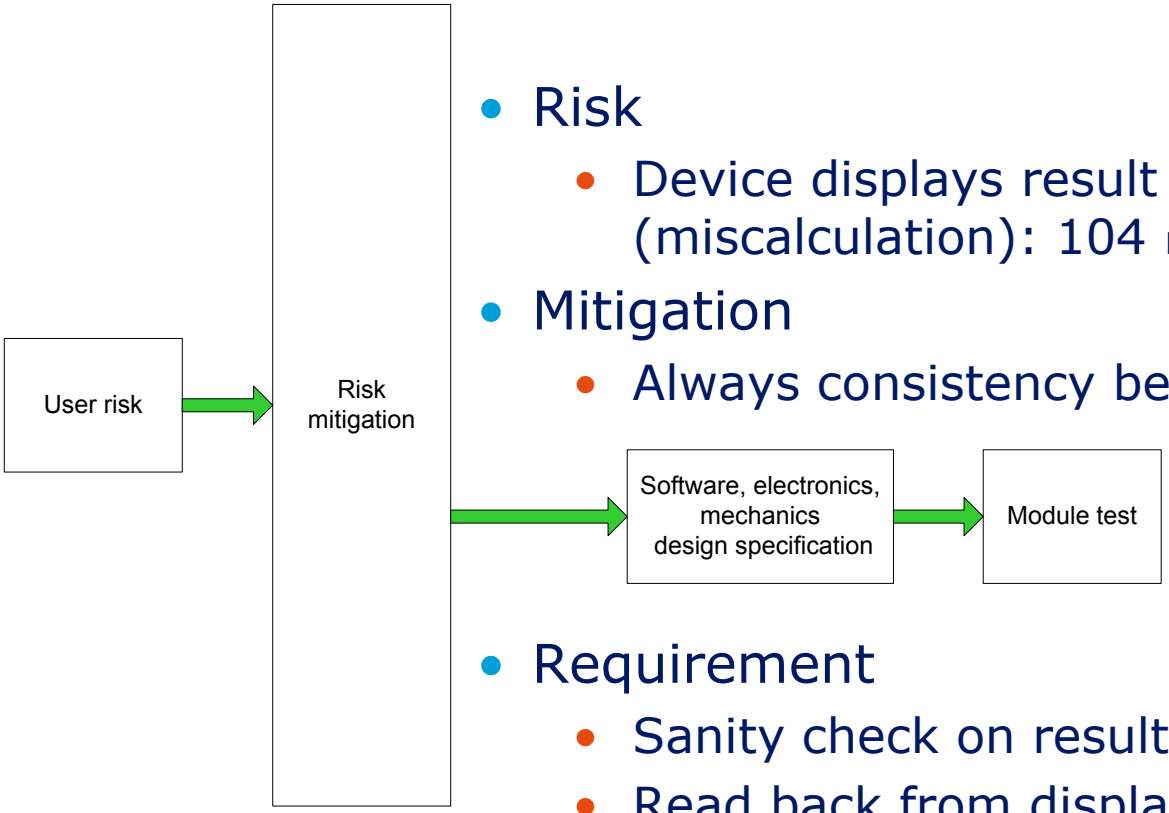
- Risk
  - User can hardly read display due to
    - bright day, bad eyes, daily stress
- Mitigation
  - Large display font for important information
- Requirement
  - 26 pixel font size on blood glucose values
- Testing
  - Not just testing digits on the display
  - But, also readability in living room light
  - **Look through the eyes of the user**

Risk-based testing, example



- Risk
  - Device reset changes user settings
- Mitigation
  - Device reset must not affect basic safety
- Requirement
  - Safety reset should include a user warning
  - Settings may only change with user acceptance
- Testing
  - Not just testing device reset
  - But, also device behaviour after reset
  - **Put yourself in the user's place**

Risk-based testing, example



- Risk
  - Device displays result with wrong unit (miscalculation): 104 **mmol/l**
- Mitigation
  - Always consistency between result and unit
- Requirement
  - Sanity check on result value and regional setting
  - Read back from display
- Testing
  - Not just testing measurement value
  - But, also in combination with changing units
  - **Play around like a user**

Bilateral agreement: User safety and how to avoid recalls

- Risk analysis: ”foresee user risks”
  - define user safety
  - conduct user risk analysis
  - include risk mitigations in product requirements
- Process control: ”manage user risks”
  - perform requirement management (tracing)
  - perform configuration control
  - conclude by **risk-based testing**
- In medical industry: authorities are watching you!
  - recommendation: behave like you were the user yourself

Risk-based testing

- In test design
  - include user risk analysis
  - include risk mitigations
  - do requirements include risk?
- In testing
  - make sure to understand the risks
  - make sure to understand the mitigations
  - open your mind
  - **put yourself in the user's place**
- **And you'll become a profound risk-based tester**

STARtester