TU Clausthal

STPA in the Product Line Development of Medical Cyberphysical Systems

Michaela Huhn

Joint work with Sara Bessling

Clausthal University of Technology, Department of Informatics

Introduction

- Michaela Huhn
  - PhD in Computer Science: Formal design methods and verification
  - Areas of interest
    - Formal verification, also light-weight
    - Model-based design methods
    - Software-intensive embedded systems
    - Model quality
    - Model-based safety analysis
    - Assessment of software safety
    - Software Certification

Motivation

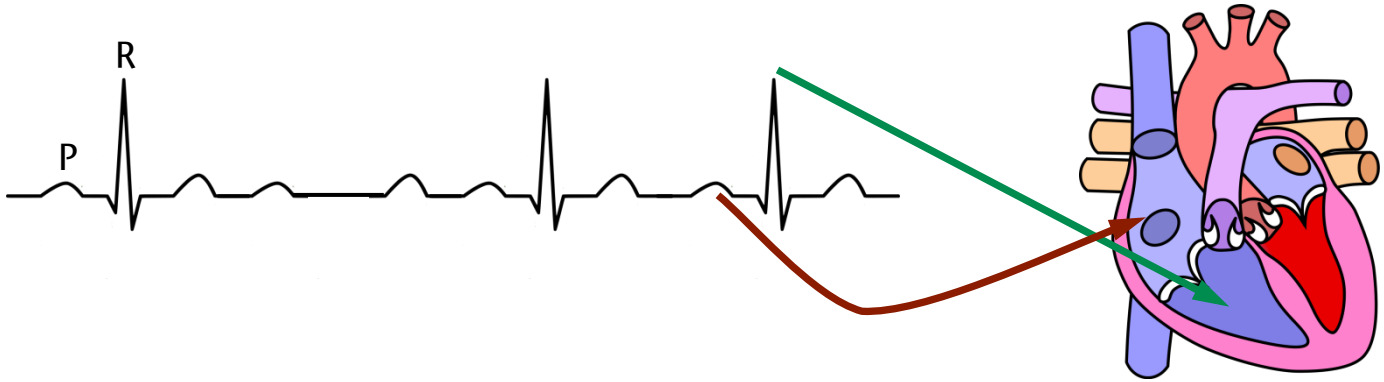
- Medical devices: software-controlled and dependable
- Patient or disease-specific needs → Many variants

- Feature-oriented product line development promises a productivity gain in software development
- Observation: Safety requirements often refer to the specific features of a medical product variant.

- Research question:
  - How to integrate advanced safety analysis and formal verification in product line development?

Case study details from the Pacemaker Grand Verification Challenge:
- Based on a pacemaker specification by Boston Scientific

Case Study: Cardiac Pacemaker Product Line



- A pacemaker senses the natural pulses in the atrium and/or the ventricle and - under specified conditions - it generates an artificial pace.

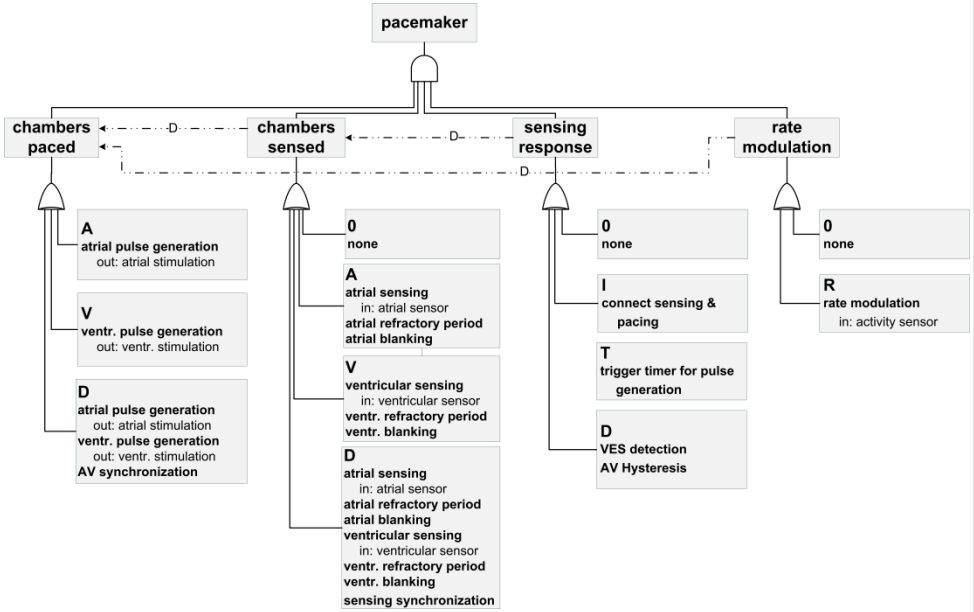
- The NASPE/BPEG Code characterizes the pacemaker variants:
  - 1st letter: Chamber(s) paced: A(trium), V(entricle), D(ual)
  - 2nd letter: Chamber(s) sensed: 0 (none), A(trium), V(entricle), D(ual)
  - 3rd letter: Response mode: 0 (none), I(nhibited), T(riggered), D(ual)
  - 4th and 5th letter: Additional features: e.g. R(ate Modulation)
- E.g. DDD or VVI

Feature-Oriented Product Line Development

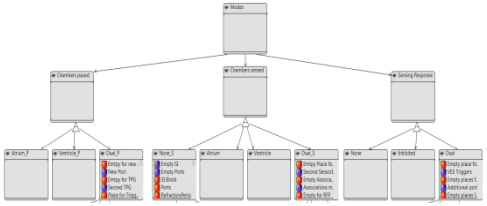
- Key paradigm: modeling of variability, i.e. „commonalities and differences in terms of requirements, architecture, components, and test artifacts.“

- Variability is represented by features, i.e.
  - a hierarchical decomposition of functionality
  - Operators:
    - AND
    - OR, group cardinalities, XOR, Optional
    - Attributes
    - Constraints

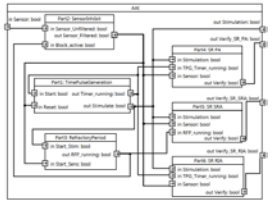
- A product is specified by selecting its features



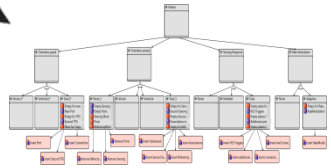
Feature-Oriented Product Line Development



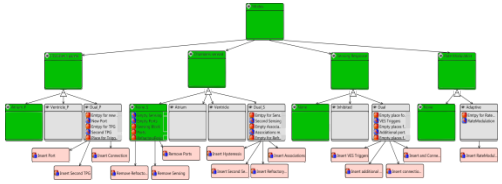
feature model at requirements level



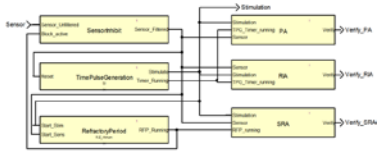
base model: here SCADE System



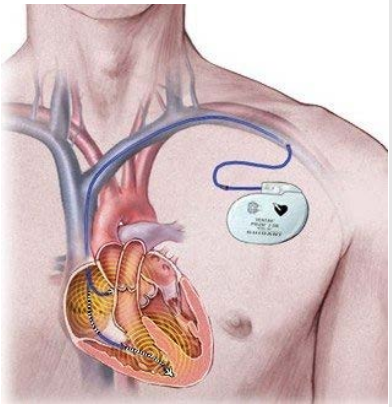
variability model at design time: described with CVL or VIATRA



resolution model: generated using CVL or VIATRA



generation of DSL model: here SCADE



STPA Step 1: System-level Hazards and Safety Constraints

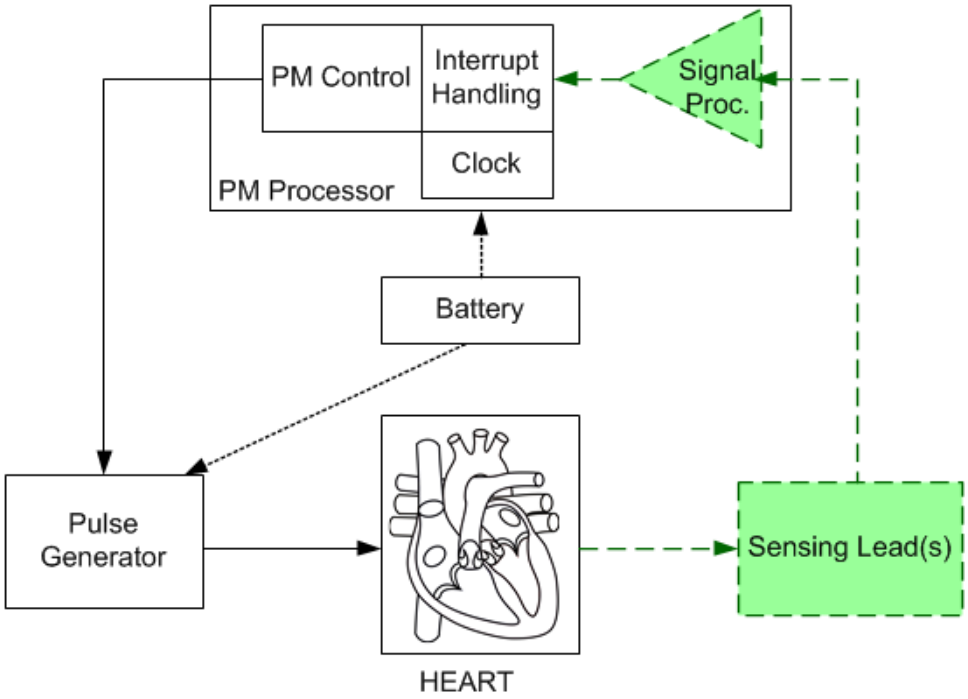
Hazards

- H1: Bradycardia: missing stimulation (transient or permanent)
- H2: Cardiac arrhythmia: stimulation in a vulnerable phase or over-stimulation
- H3: Cicatrization of cardiac tissue: conduction failure
- H4: Shortening of battery life time: High energy consumption
- H5: Pacemaker mediated tachycardia (PMT): unwanted interference heart ↔ pacemaker

Safety Constraints

- S1: In case the natural pace is missing, an artificial pace is generated (each BI), lower rate limit
- S2: Refractory and blanking periods: ARP, VRP, PVARP, PAVB, AB,VB, PVAB, upper rate limit
- S3: Artificial paces only when the natural pace is missing, AV Hysteresis
- S4: ECU sleep modi (design constraint)
- S5: Upper rate limit, Anti-PMT-heuristics

Basic Control Structure



- Control structure, hazards and safety constraints are product-specific:
  - 0-2 sensing leads
  - Simplified S1 and not S3 for non-sensing variants, less timing constraints in S2 for single chamber variants, H5 only for Dxx variants

STPA Step 2: Potential for Inadequate Control

- Step 2.1: Feature-wise analysis
- Step 2.2: Product-wise analysis (feature interaction)
- Example
  - A00, V00:
    - Single chamber pacing in a patient-specific rate, no sensing

Control Action	Not Providing Causes Hazard	Providing Causes Hazard	Wrong Timing /Order Hazard	Stopped Too Soon /Applied Too Long
Pace	No pace within BI	*Normal behavior*	Pace within refractory period BI inappriopriate	Generated pulse applied too long /too short
No pace	Pacing with low battery	--	--	--

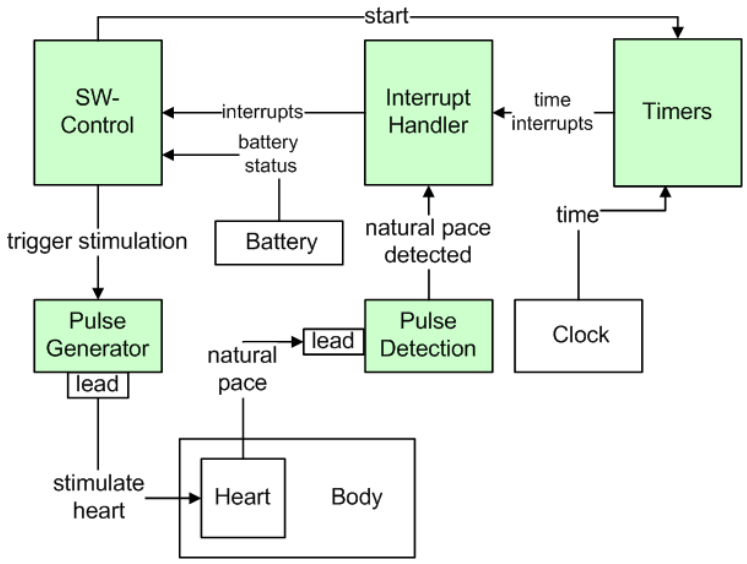
STPA Step 2: Potential for Inadequate Control

- Step 2.1: Feature-wise analysis
  - e.g inappropriate refractory period (timing)
- Step 2.2: Product-wise analysis (feature interaction)
  - E.g. inappropriate AVI hysteresis (timing)
- DDD:
  - Dual chamber pacing, dual sensing, patient-specific rates & intervals

Control Action	Not Providing Causes Hazard	Providing Causes Hazard	Wrong Timing /Order Hazard	Stopped Too Soon /Applied Too Long
Pace	Neither a natural nor artificial atr./ ventr. pace within BI	Pace generated in the presence of natural pace	Pace within refractory periods Inappropriate timing	Generated pulse applied too long /too short
No pace	Natural and artificial pace Pacing with low battery	Neither a natural nor artificial atr./ ventr. pace within BI	Inappropriate timing	--

STPA Step 3.1: Causal Scenarios for Unsafe Actions

- Part 1: Logical architecture



Pacemaker variants: VVI, AAI

3.1.1: Feature-wise analysis

- May a feature-specific design component cause an unsafe control action?

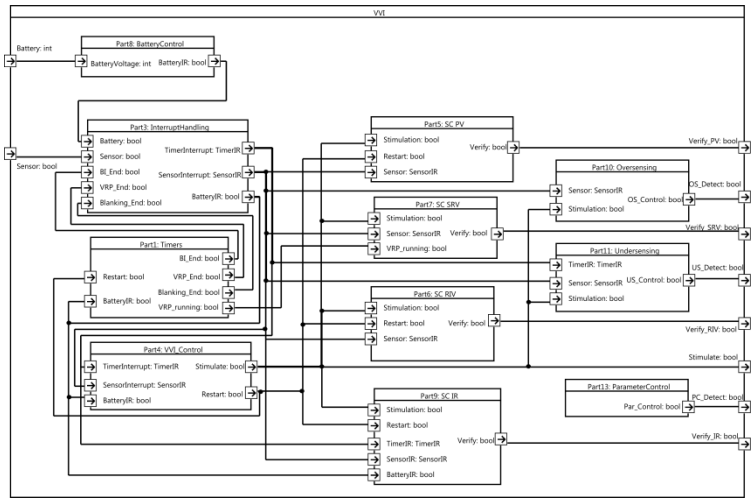
3.1.2: Product-wise analysis (feature interaction)

- May a control action be missing because a feature is missing or suppressed by another one dominating the control loop?
- Does the timing or the resource allocation depend on the feature selection?
- Are control actions doubled/ suppressed because different features address the same safety constraint?
- Do parameters of a control action depend on an added/missing feature?

Analysis of positive and negative (logical) feature interactions

STPA Step 3.2: Causal Scenarios for Unsafe Actions

- Part 2: Technical architecture
  Pacemaker: VVI, AAI



VVI architecture: SW control + HAL with faults + safety constraints (observers) (SCADE System Designer view)

Analysis of

- Deployment
- Faults and their consequences
- Interference of physical action principles

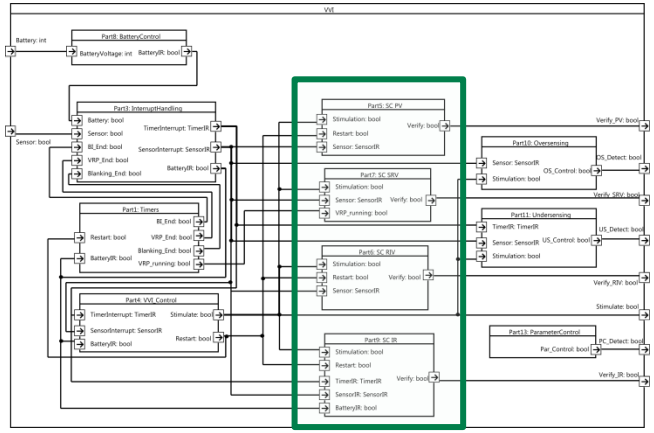
3.2.1: Feature-wise analysis

- Fault models for feature-specific hardware, fault injection.

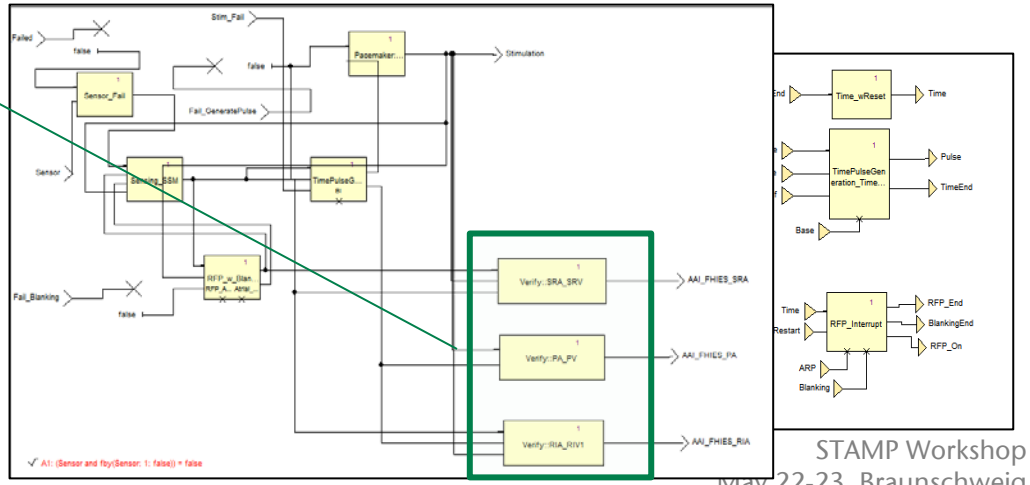
3.2.2: Product-wise analysis (feature interaction)

- Does the timing / ressource allocation rely on the deployment of feature-specific design components?
- Does a control action rely on a (physical) action principle that interferes with the action principles of another feature (even in non-safety-related control)
  - E.g. activity sensor for rate modulation may measure the respiratory rate, atrial rate, QT or AV interval, or pressure,...
- Fault propagation
- Common cause analysis

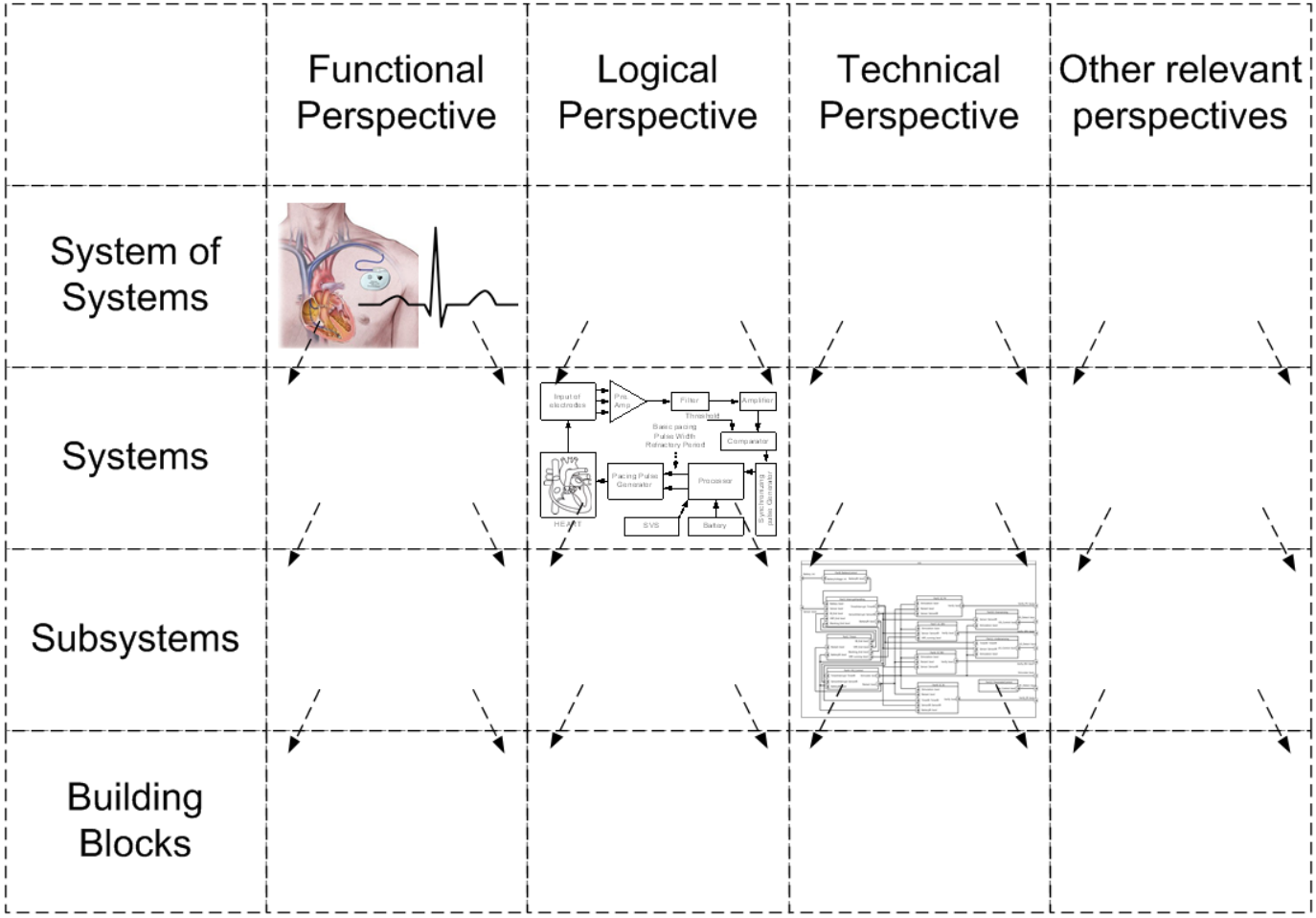
Next Design Step: Feature Selection and Product Generation



Observer nodes specifying safety constraints enable formal verification using Design Verifier



Safety Analysis: Layers considered so far



Functional Correctness - SCADE Verification Results

	PA	PV	PSyn	SRA	SRV	R0A	R0V	RIA	RIV	RSynIV	RVES	RM
A00	✓	-	-	-	-	✓	-	-	-	-	-	-
V00	-	✓	-	-	-	-	✓	-	-	-	-	-
D00	✓	✓	✓	-	-	✓	✓	-	-	-	-	-
AAI	✓	-	-	✓!	-	-	-	✓	-	-	-	-
VVI	-	✓	-	-	✓!	-	-	-	✓	-	-	-
DDD	✓	✓	✓	✓*	✓*	-	-	✓*	✓*	✓*	✓	-
DDDR	✓	✓	✓	✓*	✓*	-	-	✓*	✓*	✓*	✓	✓

✓ proven within seconds
* only proven with time constants divided by 10 due to complexity problems
! Needs more than an hour
- property doesn't apply

Observations

- The feature-oriented design with automated product resolution
  - enforced a uniform handling of development artifacts and a uniform interaction architecture
  - many safety constraints could be assigned to single features
    - resulting safety constraints tend to be more fine-grained
  - increased reuse
  - more efficient verification
- STPA allows for a more systematic investigation of the potentially hazardous behavior and derivation of safety constraints
  - Feature-wise analysis has to be complemented with explicit product-wise analysis (feature interaction): (only a few savings)
  - Investigating the technical architecture level really adds issues
- SCADE allows for automated code generation and formal verification.
  - But: slight modifications (design or safety constraint) might induce significant differences in verification times → Further experiments and classification needed

Conclusion

- STPA applied on a product line of software-controlled medical devices
  - Features considered as first class architectural concept
  - Systematic investigation of hazardous behavior by feature- and product-wise STPA ensures that feature interaction is analyzed explicitly
    - the technical architecture view
      - (extending pure software safety considerations)

- Next steps are
  - to complete and extend the case study
    - mode switches, anti-PMT algorithms, ...
  - to complete formal verification (in the presence of faults)
  - to validate the findings in another case study (infusion pump)
  - comparison to other safety analysis approaches, e.g. wrt. coverage of derived safety constraints

Thank you for your attention!