Mechatronic
=medical solutions

Automated testing of embedded systems in medical device development

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Mechatronic AG
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Mechatronic AG

Mechatronic
=medical solutions

- Founded in 1987
- 70 Employees
- Industry: Medical devices
- Business activities:
  - System development
  - Hardware development
  - Software development
  - Production Engineering
  - Manufacturing

Darmstadt
(Head office)

Höhn
(Subsidiary)

Automated testing of embedded systems in medical device development

Agenda

1. Introduction
2. Initial considerations
3. Conception
4. Realization
5. Application example
6. Verification / Validation
7. Summary and perspective

Why use automated testing?

- Generate unambiguous test cases
- Repeat test execution with minimal efforts
- Ensure reproducible test results
- Achieve high test coverage
- Improve efficiency during development (find defects early)
- Implement and use stress testing already during design

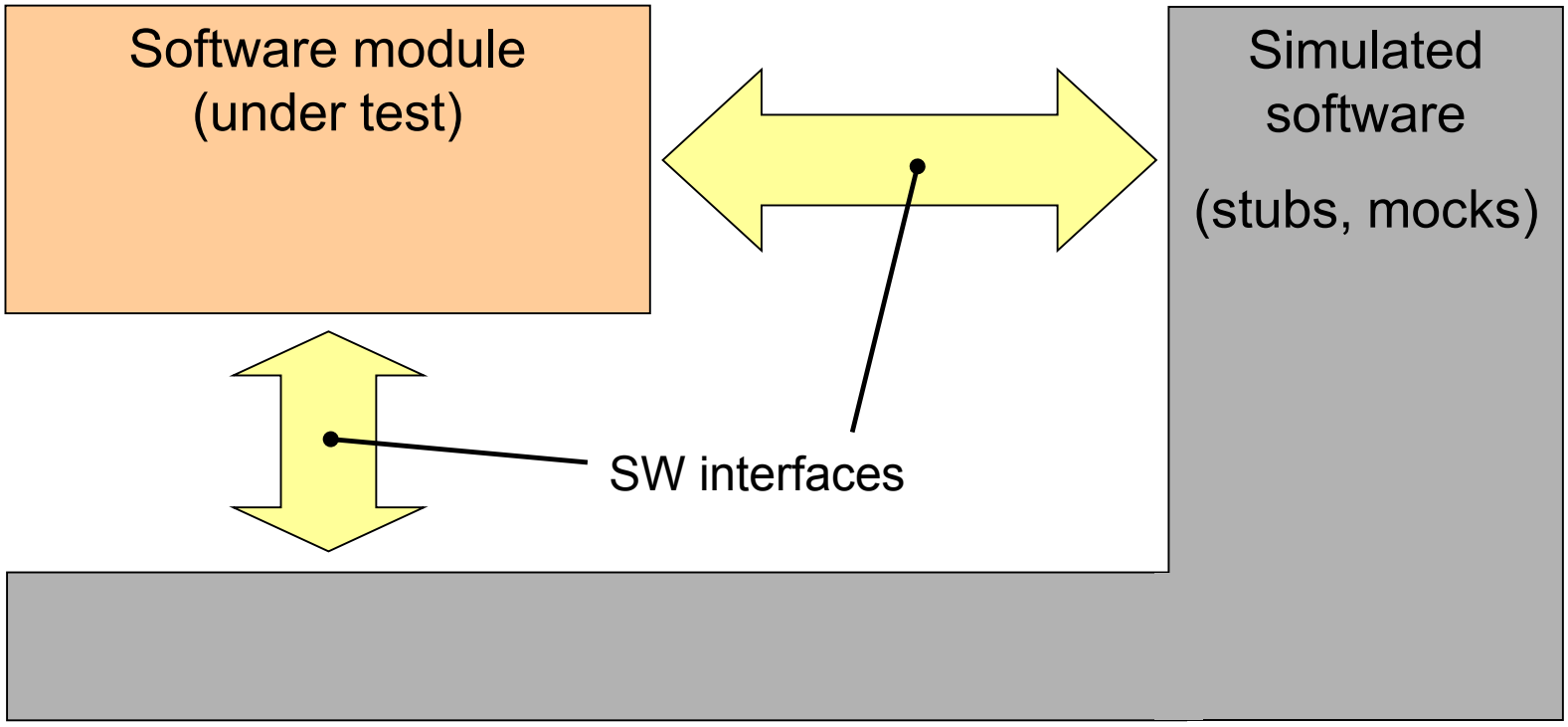
Terms and definitions

Levels of software testing

- **Unit testing**
  Single, isolated software module
- **Integration testing**
  Sub set of integrated software components
- **System testing**
  Fully integrated software system on target platform

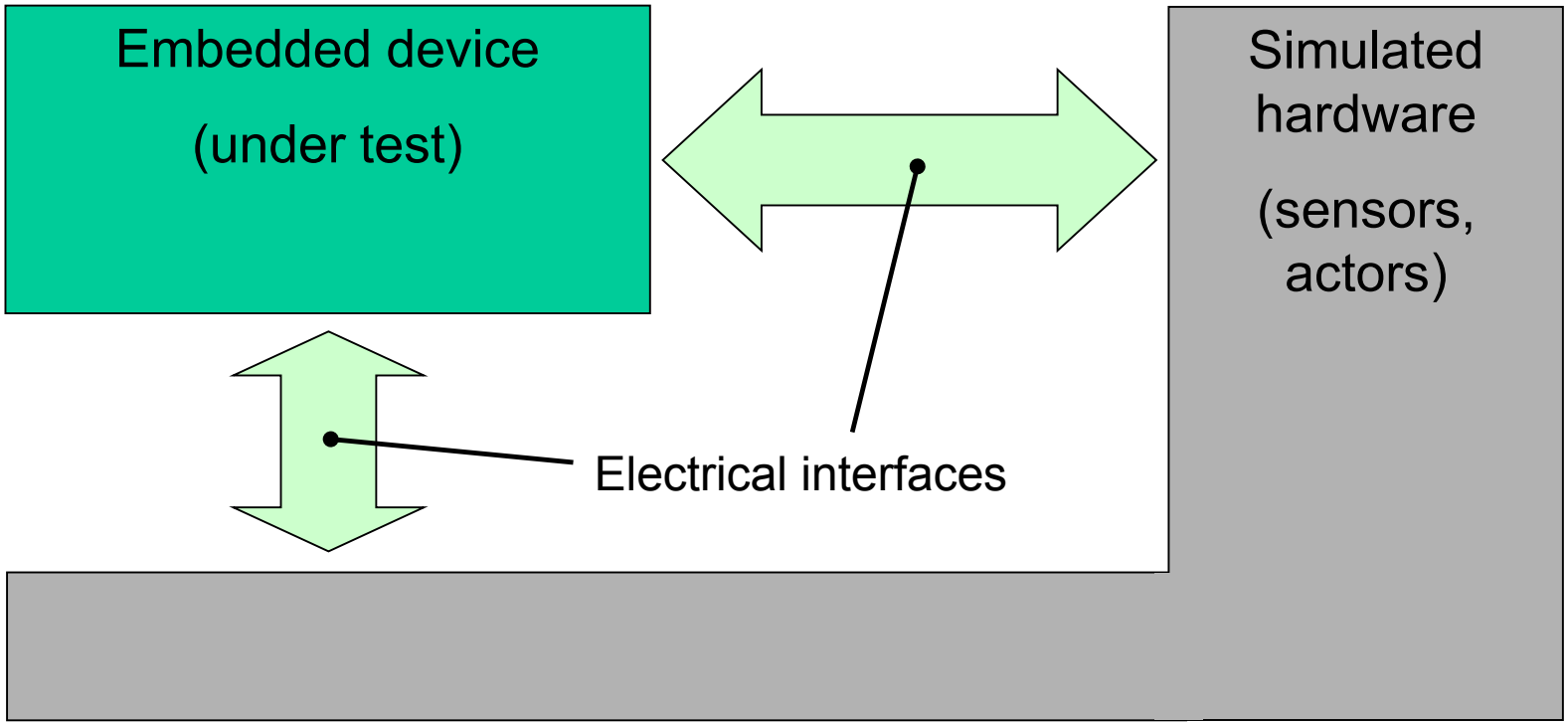
Terms and definitions

SiL (Software in the Loop)



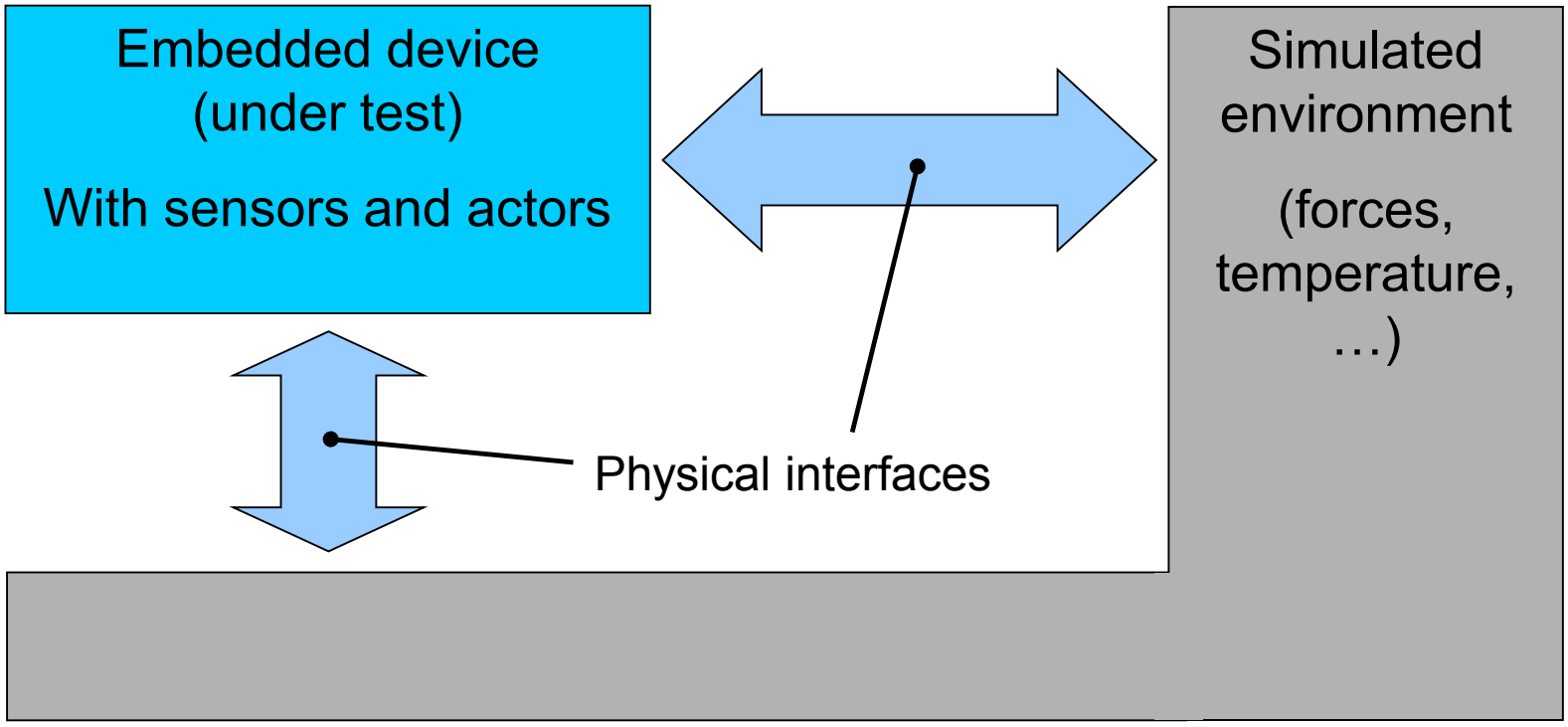
Terms and definitions

HiL (Hardware in the Loop)



Terms and definitions

EiL (Environment in the Loop)



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Core requirements

- System testing on target platform (SiL, HiL, EiL)
- Cross-project automation approach
- Good integration with external hardware
- Simple, comprehensible scripts
- Flexible document generation
- Adaptable to internal processes

Core requirements

Why test on the target?

- Timing critical sequences
- Interrupt-Handling
- Compiler errors
- Memory overflows
- Integration with hardware

Demarcation

- Not for unit level testing
- Not for production testing

Market analysis

- Many tools with SiL approach
  - Relatively simple to implement
  - All-purpose
  - Often strong focus on unit level testing
- HiL/EiL approach under represented
  - Requirements are too diverse
  - External hardware is a must
- **Conclusion: Proprietary development**

Additional challenges with in-house development

- Budgeting (own development project)
- Time lines (delayed availability)
- Sound system concept

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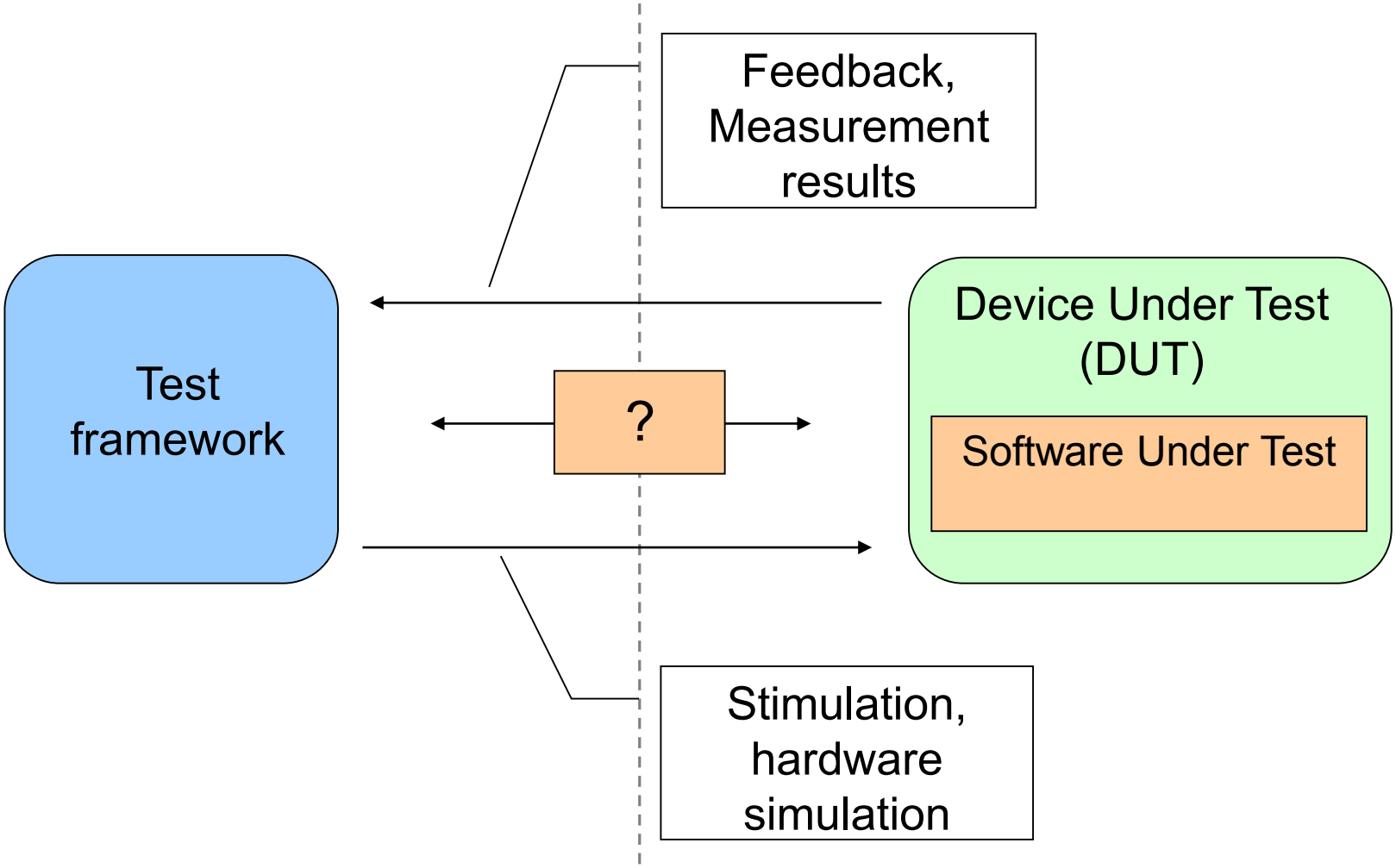
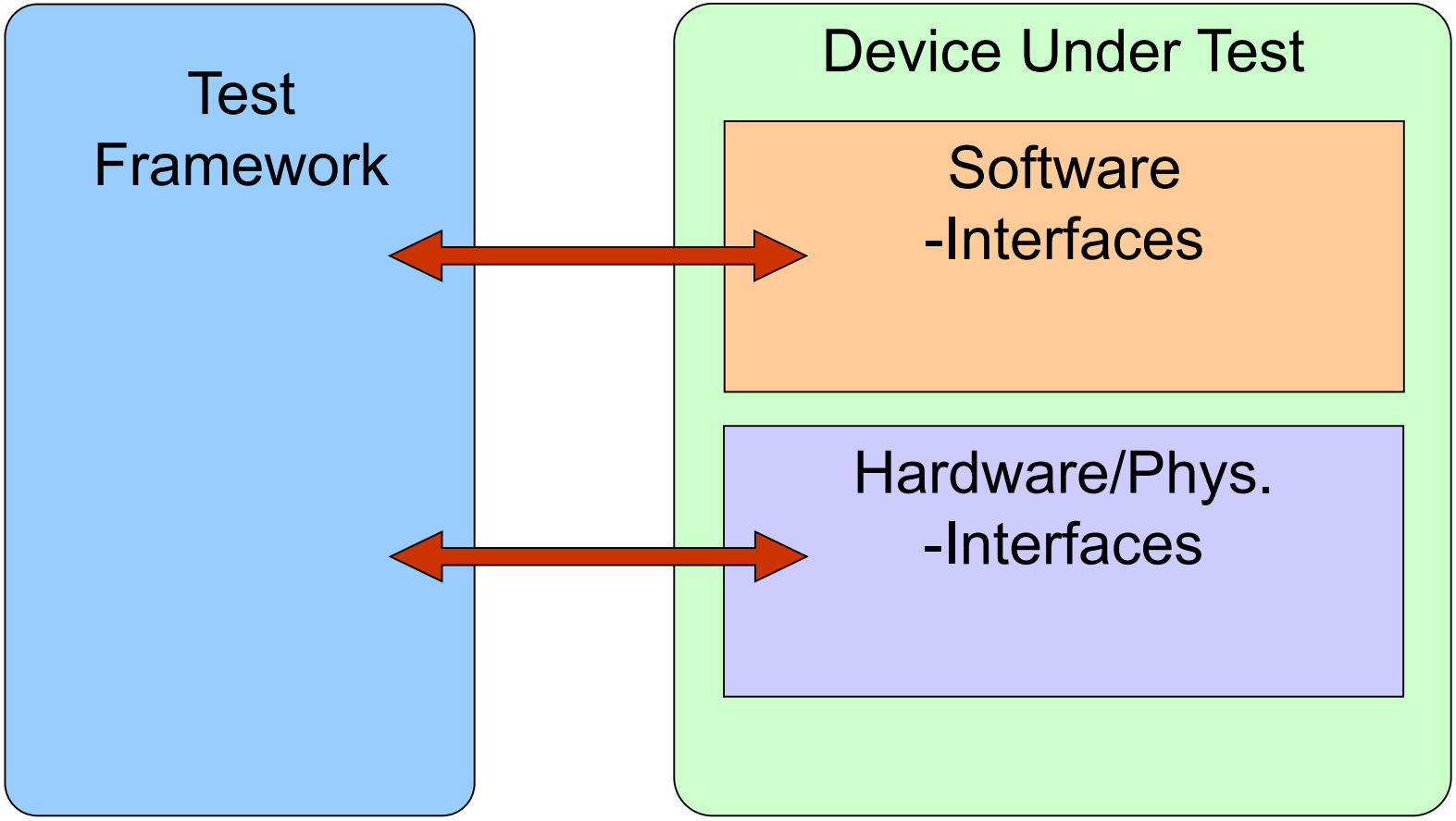
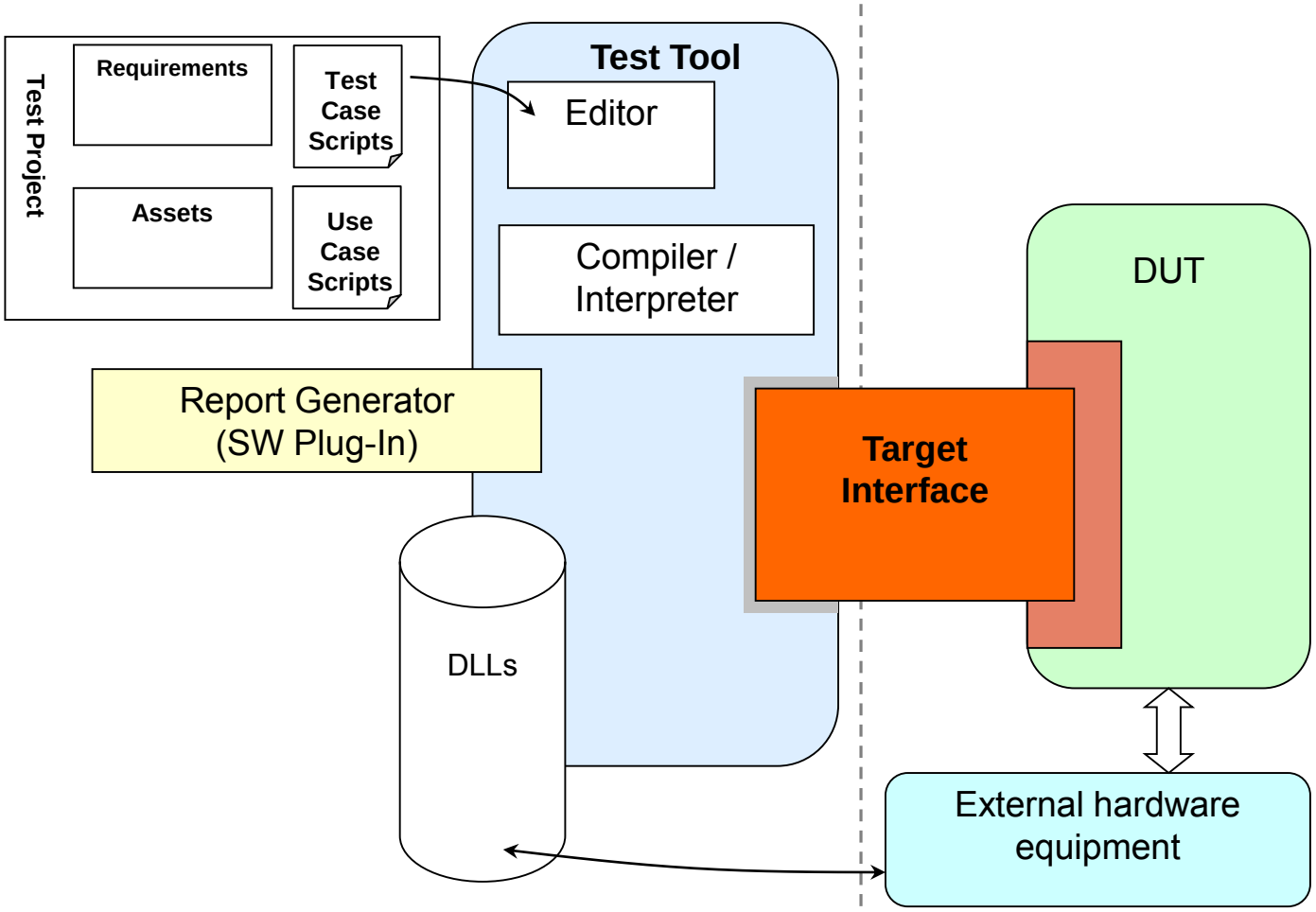
Basic concept



Solution


Test
Framework
Device Under Test
Software
-Interfaces
Hardware/Phys.
-Interfaces

Detailed concept



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Scripts

Requirements for scripts

- Comprehensible and simple to review
- Direct editing in the tool,
  no external editor (usability)
- Access to reference data (assets)
- Adding attachments to report at run time
- Mandatory pass/fail decision
- Textual test description (for protocol and report)

Scripts

Simplification of scripts

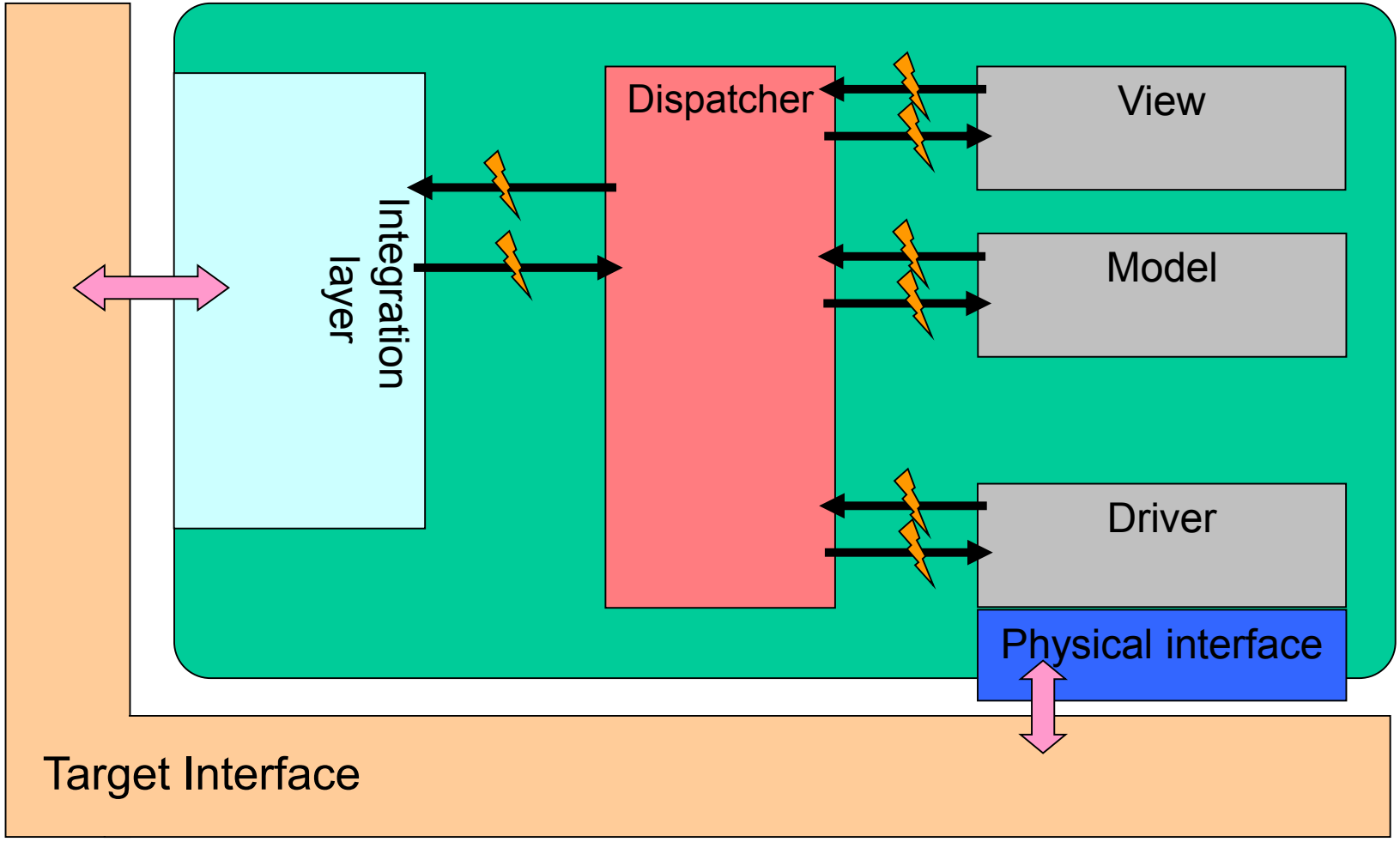
- Outsource complexity as far as possible:
  - Target Interface
  - Libraries
  - Use Case scripts
- Abandonment of language constructs which are difficult to comprehend
  (e.g. lambda expressions, linq, delegates, events)

Scripts

```
bool Run()
{
    var currents_uA = new double[] {12.5, 14.8};

    foreach(var referenceCurrent in currents_uA)
    {
        USECASE.ApplyCurrent(referenceCurrent);

        var measuredCurrent = TARGET.MeasureCurrent();

        ATTACH(referenceCurrent, "ReferenceCurrent [µA]");
        ATTACH(measuredCurrent, "MeasuredCurrent [µA]");

        if (measuredCurrent != referenceCurrent)
        {
            return FAIL;
        }
    }

    return PASS;
}
```

Tolerance limits by operator overloading

Interface DUT ↔ Target Interface



Test execution

- Test execution from within the tool
- Definable set of test cases to be executed
- Storage of results in a file
- Report generation on bases of these data

Requirements for report generator

- Different formats, e.g. WORD and HTML
- Use of templates
- Protocol and report generation for approval
- Trace matrices
- Test summary

Requirements for report generator

- Test case single view
  - Pass/Fail information
  - Textual description
  - Traces to requirements
  - Visualization of attachments

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The product

- Mobile in-vitro diagnostic device
- Part of a device family
- Approx. 1.000 pcs. p.a.
- 32 Bit µC
- New measurement technology

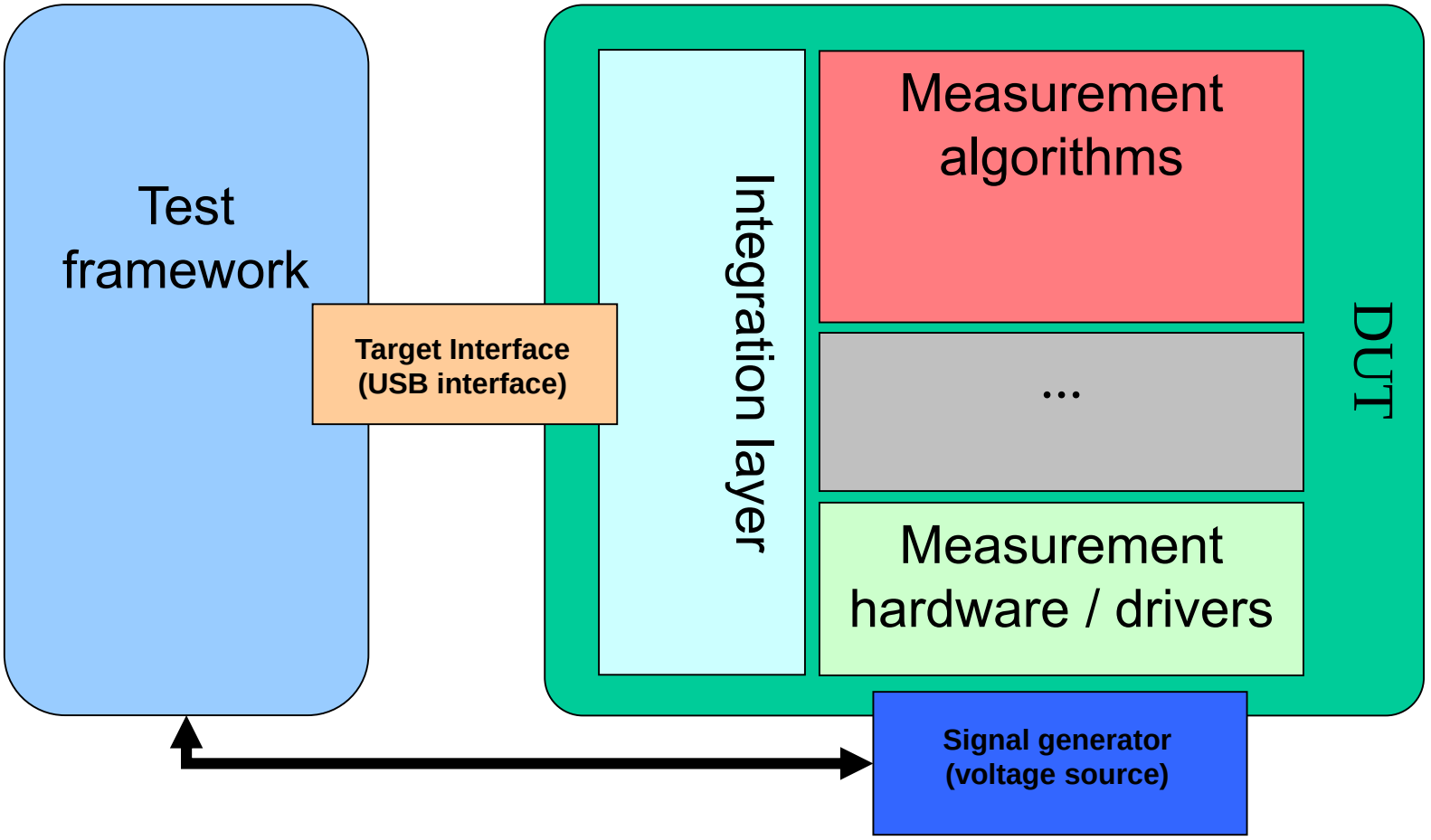
Surrounding conditions

- Communication interface and protocol pre-set by customer (device family)
- Software built on basis of existing code
- Many manual test cases for device family existing and re-usable
- Testing focused on new measurement algorithms
- Implementation of measurement algorithms optimized for automated testing in final system

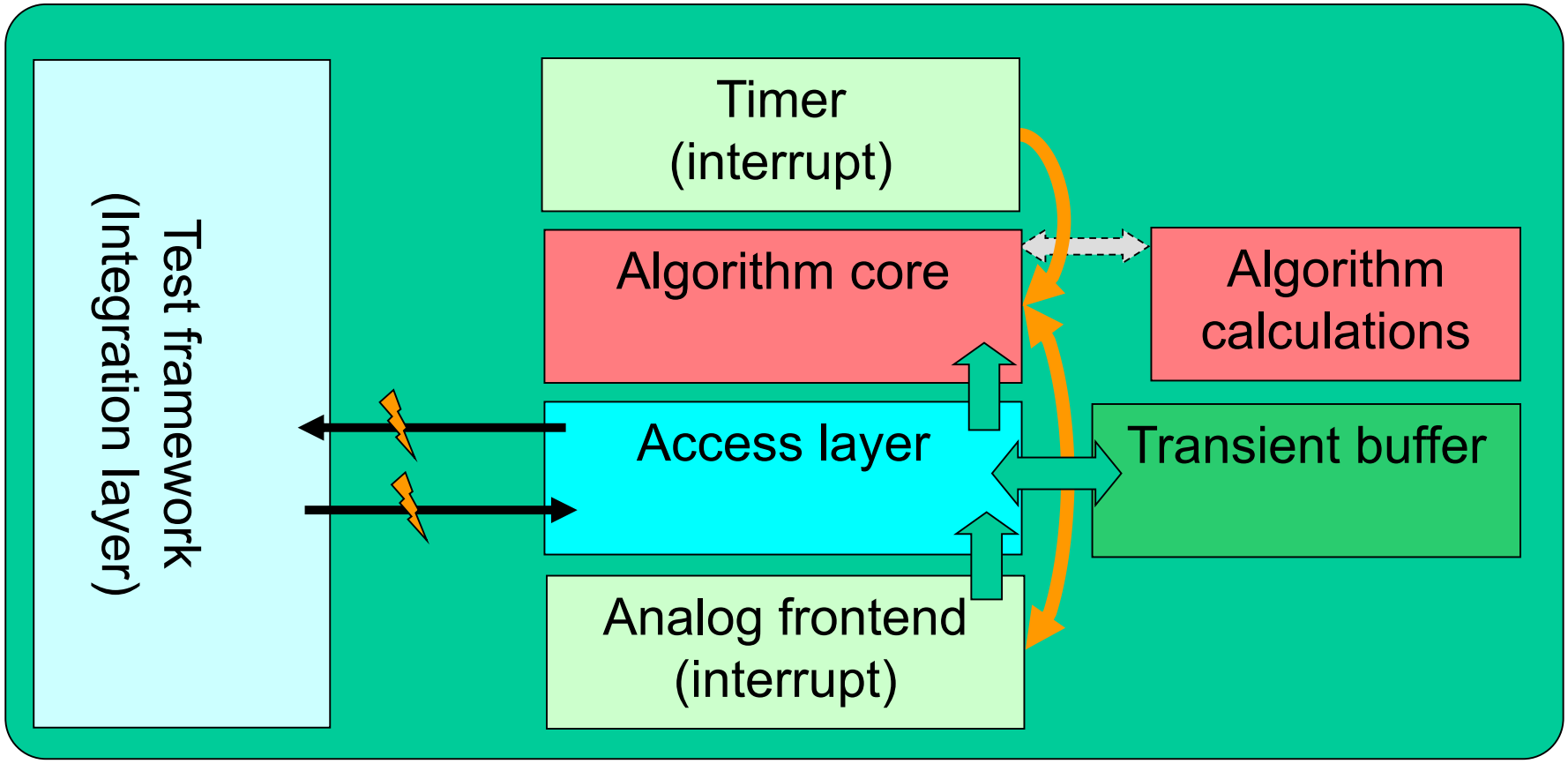
Characteristics of algorithms under test

- Measurement transients consist of several hundred data points
- Complex calculations using floating point math
- Timing critical, interrupt driven
- Extensive error detection mechanisms
- Temperature compensation

Integration into the framework



Software architecture



Core functions of the Target Interface

- Reading and writing of measurement transients
- Injection of simulated temperature values
- Triggering of measurement runs
- Diverse implementation of algorithms in 128 Bit floating point
- Complex comparison operators
- Manipulation of transients

Gained Experience

- Permutations: approx. 7000 in 12 hours
- Proof of stability established early and repetitively
- Script creation < 1 week
- Creation of target interface: approx. 1 month
- Minimal efforts for additional devices of same product family

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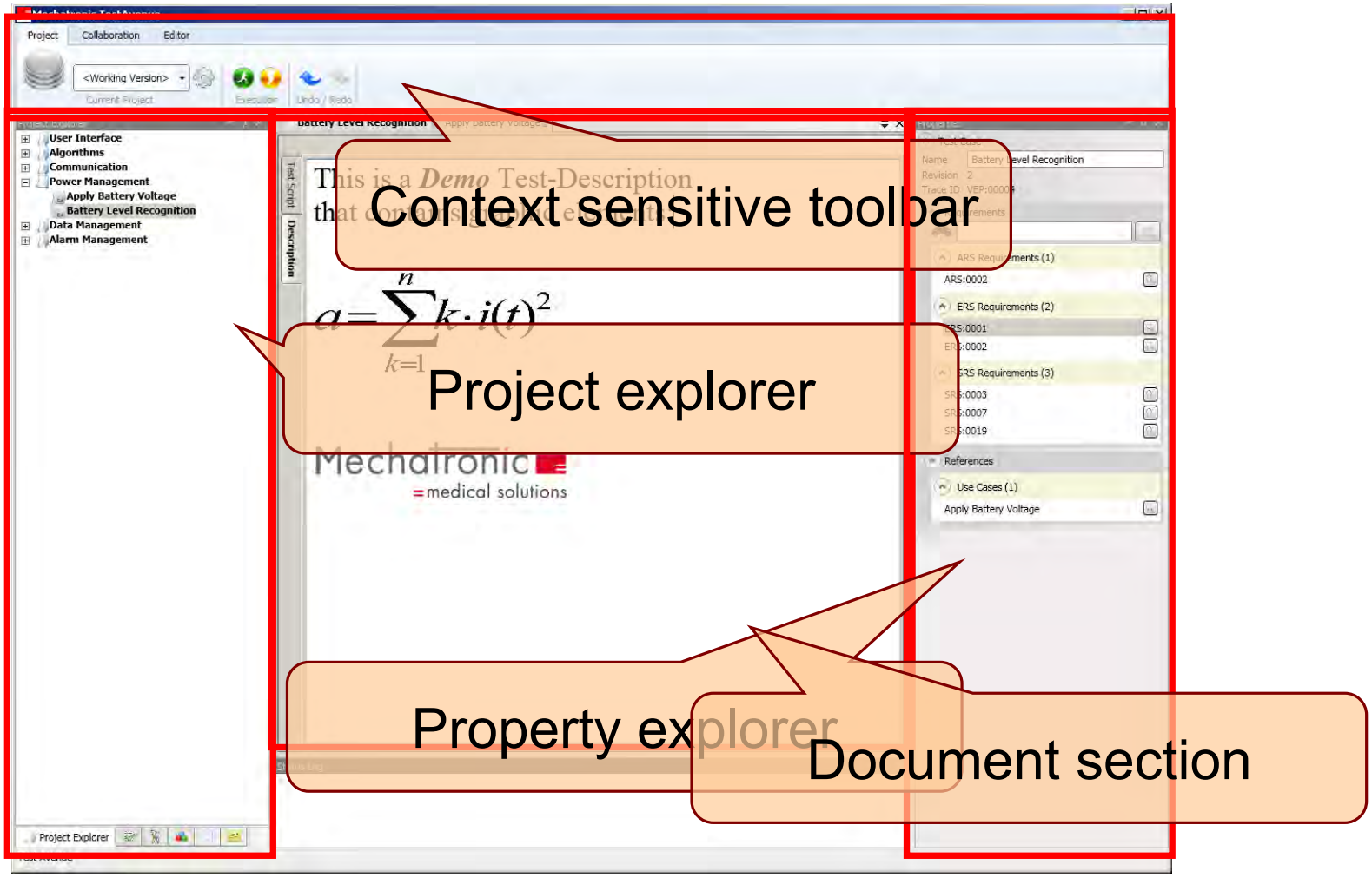
Test tool in general

- Focus on core functionalities
  - Editor
  - Compiler
  - Test Execution
  - Report Provider
  - Tracing

Project context

- Target Interface
  - Test scripts
  - Manual test plan if applicable
  - Review
- Scripts and assets
  - Review
- Libraries
  - Test scripts
  - Unit test and review

Screen shots



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Summary and perspective

- Enhancements test tool:
  - Descriptions as RTF
  - Multi user capabilities
  - Integrated configuration management
  - Expand plug-in approach
  - Improve usability
- Code base (embedded)
  - Generic event interfaces

Conclusion

- Expected advantages confirmed
- Flexible mixing of SiL, HiL and EiL possible
- Testing approach fully scalable
- Tool established cross projects

Good decision!


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