Application of MBSE to a start-up in the medical device domain:

the added value!
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- Post-Master degree in **Systems Engineering**

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1. Introduction
1. Introduction

7 mio stroke patients in need of arm therapy (worldwide p.a.)

Problem • Arm therapy is often forgotten during daily routine • Arm rehabilitation often takes years of training • Lacking motivation for arm training outside the therapy setting

Patients need a tool that … • Reminds them to train their arm in everyday life • Documents arm training in everyday life

Therapists need a tool that … • Monitors patients rehabilitation efforts and progress continuously • Objectively documents all activities in the clinic and at home
1. Introduction

**A therapy bracelet** to monitor and motivate arm rehabilitation in everyday life

**Early prototype developed** • Patients were exited about prototype • Therapist are convinced of usefulness for therapy

**Feasibility proven** • Activity counts for arm activity have been developed and are working • The feasibility of the implementation was confirmed

**Timeline**

- 2011
  - Idea
  - ZHdK BA thesis
- 2015
  - Feasibility study
  - Incorporation of company
  - Start product development
- 2016
  - Prototypes
  - Testing
- 2017
  - Clinical study
  - Commercialization
1. Introduction
1. Introduction

For patients:
Tracker and Smartphone app

For Rehabilitation Clinics:
Set of trackers and evaluation SW

Medical devices! Regulations apply
2. Early system definition
### 2. Early system definition

<table>
<thead>
<tr>
<th>Phase</th>
<th>Duration</th>
<th>Institution</th>
<th>Key Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Hyper-) Acute</td>
<td>0 – 24 h</td>
<td>Stroke unit</td>
<td>Neurologist Nurse</td>
</tr>
<tr>
<td>Early rehabilitation</td>
<td>Up to 3 months</td>
<td>Inpatient rehab center</td>
<td>Neurologist Physical Therapist</td>
</tr>
<tr>
<td>Late rehabilitation</td>
<td>Up to 6 months</td>
<td>Outpatient rehab center</td>
<td>Neurologist Physical Therapist Caregiver</td>
</tr>
<tr>
<td>Chronic</td>
<td>years</td>
<td>Outpatient or physical therapist</td>
<td>Physical Therapist Caregiver</td>
</tr>
</tbody>
</table>

- Generic description of processes
- No links between processes and systems functionalities
2. Early system definition

Description
The wearable shows the status towards reaching the daily target. The daily target is automatically calculated and the difficulty slightly rises over time. The daily target shows the patient how much training needs to be done per day.

Pre-condition
- Wearable is running
- Results from previous days (Daily targets reached, might be 0)

Basic Flow
- At 24:00 the tracker automatically stores the daily target reached
- Thereafter the tracker automatically calculates the daily target for the next day using the following formula: \((\text{Average of the daily targets over 30 days}) \times (\text{Daily Target Scaling Factor})\)
- Tracker stores new daily target as daily target
- Thereafter the wearable adds each arm activity to the daily target actual
- Result is stored in “daily target actual” after every Arm Activity Interval.
- The tracker signals to the user when 25% are reached by vibration and visually.
- The tracker signals to the user when 50% are reached by vibration and visually.
- The tracker signals to the user when 75% are reached by vibration and visually.
- The tracker signals to the user when 100% are reached by vibration and visually.

Post-condition
- Status is determined and stored in “daily target actual”.

- List of use cases
- Textual descriptions
- No derivation of lower level functionalities
- Missing a systematic approach
2. Early system definition

- Missing a functional architecture
- Generic description of a physical architecture
3. Methodology applied
3. Methodology applied

Business Processes (or rather Stakeholder Requirements) analysis leads the development of a new System, Service or System of Systems (SoS).
3. Methodology applied

System of Systems

Business Processes
SoS Functional Analysis
SoS Requirements
SoS Architecture

Top-Down approach

Stakeholders Requirements 1
System 1 Functional Analysis
System 1 Requirements
System 1 Architecture

Stakeholders Requirements 2
System 2 Functional Analysis
System 2 Requirements
System 2 Architecture

Stakeholders Requirements 3
System 3 Functional Analysis
System 3 Requirements
System 3 Architecture
3. Methodology applied

System of Systems

System 1

System 2

System 3

Recursion

Top-Down approach

Iteration
4. Case study: MBSE applied to a medical device start-up
4. Case study

The use of a shared model provides an added value:

- Enhanced definition of business processes and stakeholders
- Better traceability between systems requirements and architectures and business requirements
- Enhanced gathering and sharing of information

To date, concerning the case study:
4. Case study

Business Process examples:
- Sales
- Delivery
- Maintenance
- Setup
- Operational
  - Rehab inpatient
  - Rehab outpatient

Main scope:
To define activities that will be carried out with the system.
4. Case study

Direct definition of use cases from process activities:

- **Existing use cases** have been traced towards **business activities**
- **New activities** have led to **new use cases**

Complete traceability between business process and use cases (and system functionalities).
4. Case study

Model-based description of use cases simplifies the allocation process of system functionalities.

- **Sequence diagrams** for dynamic modeling (messages between objects).
- **Activity diagrams** for functional modeling (messages between activities).

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4. Case study

Allocation of functionalities to systems

Functional architecture
4. Case study

Physical architecture:
• Definition of systems and interfaces
• Definition of a SoS configuration
4. Case study

Interface requirements:

- BLE protocol
- Definition of shared messages
- Description of messages directly in the model
- Allocation of messages to systems
4. Case study

<table>
<thead>
<tr>
<th>Use Cases towards Business Activities</th>
<th>BLE protocol allocation</th>
<th>Functions towards Systems</th>
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5. Conclusion
5. Conclusion

From the analysis of Business Processes -> New use cases have been derived
Lower level functionalities have been defined
5. Conclusion

Traceability on multiple levels

Collection of information in one model
Creation of documents is simplified
Enhanced change management
5. Conclusion

«At yband therapy AG we are convinced that a systematic approach to define a system is tremendously helpful in the medical device business. It forces the team to analyze a system in detail. We uncovered numerous gaps that we systematically closed. Communication with external partners proved to be easy as we had systematic documentation. This documentation is also a sound basis for regulatory clearance and future change management.

System engineering is the perfect methodology for the development of medical devices. I wouldn’t develop a product without using it.”

Christoph Rickert, CEO
yband therapy AG
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