Bilag 1

Contents

Projektphases

Phase 1- Domain Analysis

Milestones

- **Clinical Problem**
- **Physiological Mechanisms**
- **Motivation for physiological modelling**
- **SOTA**
- **Problem Statement**

Phase Description

In the domain analysis phase, the problem will be analyzed based on its relevant aspects.

The clinical aspect investigates how the instance of the healthcare sector is affected by the issue - how does it affect the clinician's workflow, what is the effect on variables of interest in patient outcome and other significant factors.

The physiology will be described at a level of detail which encapsulates the effect on the patient's physiological systems in a clear and concise manner, without introducing unnecessary complexity with insignificant influence on outcome.

The motivation section investigates the necessity for creating physiological models in the context of researching clinical phenomena.

The state of the art (SOTA) section will investigate the performance and architecture of current non-invasive physiological models used for researching the clinical problem. The SOTA section will have high influence on the requirements for the final system, as it bridges the gap between the previously described theory, and current scientific/clinical application of the theory.

Methods applied for reaching milestones

Method	**Description**	**Associated Milestone**
Unstructured Literature Search	Conducted based on initial curiosity, without formal research questions, search process and literature review process.	*All*
Structured Literature Search	Formally investigates a set of research questions, conducted through a well defined search process in peer	*All*

	reviewed databases. Found literature is filtered based on inclusion/exclusion criteria, and reviewed based on standardized review schemes.	
Interview	A semi-structured interview, wherein a clinician or similar expert in the field shares their expert knowledge on the problem in a formal setting, documented for future usage.	*Clinical Aspect SOTA*

Phase 2- Requirement Engineering

Milestones

- **Requirement Elicitation**
- **Requirement Analysis**
- **Requirement Specification**

Phase Description

The requirement engineering phase defines a set of constraints to which the system must adhere.

Elicitation defines the needs of the clinician/researchers which the system will support, based on the research conducted in the domain analysis phase

System requirements constrain the system on a technical- and user experience level, without necessarily impacting the core support provided for the clinician/researchers.

Requirements analysis filters the identified requirements, based on available resources. Resources can include manpower, allocated project time and economical aspects, among others.

Methods applied for reaching milestones

Method	**Description**	**Associated Milestone**
Structured literature search	See Domain Analysis phase	*Requirement Elicitation*
Interview	See Domain Analysis phase	*Requirement Elicitation*

MoSCOW	MoSCOW is an acronym for must-, should-, could- and would- have. Requirements are given a priority level based on their relevance for the project. The priority level is used as a threshold when subsequently filtering requirements.	*Requirements Analysis Requirements Specification*

Phase 3- Solution Analysis

Milestones

- **Data Source**
- **System Description**
- **Physiological Modelling**
- **System Architecture**
- **Implementation Methods**

Phase Description

The Solution Analysis phase aims to identify a suitable solution to the problem statement, in accordance with constraints posed by the system- and user- requirements.

The data source section describes the clinical trials from which the trials originate. Furthermore, the data relevant to the problem solution is described in detail.

The system description bridges the gap between domain analysis, requirement engineering and clinical implementation, by providing the context for the clinicians' usage of the system in their workflow.

Physiological modelling provides the architecture of the systems data processing engine at a unit- and module level.

The system architecture encapsulates the full system at relevant levels of detail. This includes database connectivity, user interfaces, interactions between modules and other relevant factors.

The implementation method section contains a description of the tools applied in building and testing the system.

Methods applied for reaching milestones

Method	**Description**	**Associated Milestone**
Bioelectrical modelling	Bioelectrical modelling (BE) identifies the circuit diagram analogues of the relevant physiological mechanisms. BE provides a high level architecture of the physiological models, assisting as a useful tool for stakeholder communication and guiding implementation.	*Physiological Modelling* *System Architecture*
Compartment modelling	Compartment modelling structures the physiological mechanisms into encapsulated	*Physiological Modelling* *System Architecture*

	compartments. They contain more detail than BE, describing state variables as well as independent variables and interactions between these. This provides a level of the architecture which is closer to the physiology than BE, allowing for the same communicative and implementational benefits as BE, but from a different perspective.	

Phase 4- Solution Implementation and testing

Milestones

- **Individual Compartment Implementation**
  - **Individual Compartment Testing**
- **Module Implementation**
  - **Module Testing**
- **System Implementation**
  - **System Requirement Testing**
  - **User Requirement Testing**

Phase Description

This phase is a distillation of the work performed in the previous phases.
First, the individual compartments will be implemented and tested according to the tests designed in the test plans.
The same process will be conducted at the module level of the architecture. In this case, modules are defined as a coherent collection of compartments, influencing a common module state variable. E.g. the heart consists of six compartments, with the modules state variable being pulse pressure.
Finally, the individual modules will be assembled into the full system, which is then tested on the system- and user- requirements.

Methods applied for reaching milestones

Method	**Description**	**Associated Milestone**
Mathematical Toolbox	Depending on the available data, different methods can be applied for computing the	*Individual Compartment Implementation* *Module Implementation*

	systems state variables. Thus, ODE Solvers, optimization algorithms, integration and differentiation etc. can be applied, depending on the context.	*System Implementation*
Test Design	Depending on the requirements and physiological constraints of the system, tests will be designed to test its capabilities of handling different usability scenarios.	*Individual Compartment Testing Module Testing System- and user-requirement testing*

Phase 5- Report Writing

Milestones

- **Problem Analysis**
- **Problem Statement**
- **Solution Analysis**
- **Methods**
- **Results**
- **Discussion**
- **Conclusion**

Phase Description

The report writing phase consists of disseminating the research conducted in the previous phases.

The report is structured into different sections, which aid in disseminating the results of the work in a structured and scientific manner.