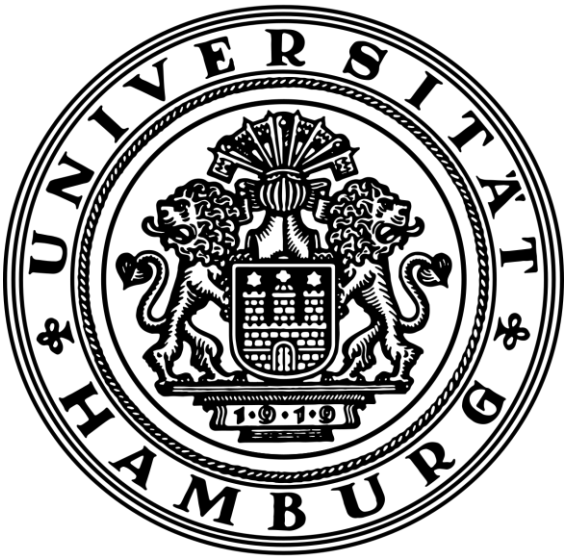
Requirements Analysis Document



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1. Introduction

1.1 Purpose of the system

The system implemented is going to serve as a basis for a mobile tables application which combines the human computer interfaces of the different medical devices used by emergency doctors (namely the ECG-monitor, defibrillator and ventilation devices). In line with the combination of the devices the system will also serve as a manager for the different alarms, visual and auditory. The system will also display the input of aforementioned devices and the alarms.

1.2 Scope of the system

The backend interface of the system will be based on the output of the following four devices whose output is already overlapping:

- Corpuls monitoring and defibrillation device
- Meduvent ventilation device
- Oxylog 3000 plus ventilation device
- Physio-Control Lifepak 15 monitoring and defibrillation device.

It will also incorporate information from UKE patient stories and thus will be an interface which could be adapted to the 3-in-1-device currently in development by the UKE

1.3 Objectives and success criteria of the project

The goal is to display the main parameters and visualize them in the required graphic fashion. In addition to those parameters different alarms will provide auditory and visual feedback. Concurrent and successive alarms of different priorities will be handled by the system in a non-disruptive and supportive manner. The app will be usable with touch functions especially to adjust parameters and their limits.

1.4 Definitions, acronyms, and abbreviations

ECG	electrocardiogram
etCO2	end-tidal CO2: the partial pressure or maximal concentration of carbon dioxide (CO2) at the end of an exhaled breath
Flow	describes the flow of air in and out of a patients' lungs, inspiration are counted as positive values, expiration as negatives
IBP	invasive blood pressure
NIBP	non-invasive blood pressure
respiratory rate	breathing frequency
SpO2	oxygen saturation of the blood

1.5 References

To get an overview of the functions, alarm systems and the values displayed by the existing devices this document refers to the provided manuals of the Corpuls C3 v2.3, the Weinmann Medumat Standard2 v4.15 and the Weinmann Meduvent Standard v2.1. In addition to that, the patient stories provided by the UKE are used to understand the real processes, situations and conditions under which the devices are used.

2. Current system

In a situation stressful and/or critical for the patient alarms often are mixed up which can result in a sensory overload for the user. The usage of a mute button, for either single alarms or in general, are the rule. Especially the general mute for two minutes can lead to critical situations due to the missing alarms about drastically changing values while the user is busy or unable to pay attention to the monitoring devices and ventilator.
The to be designed tablet app combines the interfaces of the known devices in one while managing the alarms in an auditory and visual way.

3. Proposed system

3.1 Overview

The app is going to be the combined user interface of the monitor respectively defibrillator and the ventilator and therefore centralize the users interactions. Furthermore the alarms coming from one united device are going to be managed depending on their priorities. The interface will likely differ from known systems but still be oriented on those designs.

3.2 Functional requirements

1. When the patient is connected to the devices and no conflicting conditions are in place the system shall be able to display the following values with additional curve display:
    - Heart frequence/ECG
    - SpO2
    - etCO2
    - Flow
    - Airway pressure
    - Blood pressure
    - Pulse frequency
    - IBP

2. When the patient is connected to the devices and no conflicting conditions are in place the system shall be able to display the following values (with additional information required displayed in parentheses):
    - NIBP (Number plus Trend)
    - Patient temperature
    - O2 Mode
    - Respiratory frequency

3. When the patient is connected to the devices and no conflicting conditions are in place, the system shall have the ECG, SpO2 and CO2 curves and values in the primary display.

4. The system shall provide the user with the ability to set all parameter limits of the underlying devices in one menu.

5. The system should provide the user with the ability to set parameter limits by directly interacting with the parameter.

6. The system should provide the user with the ability to mute all active alarms, displaying new alarms.

7. The system should provide the user with the ability to mute a single active alarm.

8. The system shall display alarms visually, prioritizing the most relevant ones.

9. The system should display alarms underlined with an audio component, prioritizing the most relevant ones.

10. The system shall provide the user with the ability to switch in a defibrillation mode.

11. The system shall provide the user with the ability to set defibrillation shock settings.

12. The system shall provide the user with the ability to set ventilation settings.

13. The system shall provide the user with the ability to enter patient values (e.g. age, weight).

14. The system shall differentiate between different alarm sources (e.g. monitoring, ventilation and the device itself) and play distinguishable alarms.

3.3 Nonfunctional requirements

3.3.1 Usability

The system needs to offer an easy and fast option for the user to switch into the defibrillation mode. In addition to that, new selected parameters and curves need to be displayed without delay. Furthermore the settings for alarm limits shall be reachable during usage.

3.3.2 Reliability

The system shall not fail during usage. The visualized parameters and their curves should match the values.

3.3.3 Performance

The user adjusts parameters and its limits, so a real-time-interaction needs to be guaranteed. Furthermore the visualization of changes and graphic presentation, for example curves, need to be displayed without delay.

3.3.4 Supportability

The system should offer the ability to add new alarms (and values) to the current version of the app’s backend as well as to the display options since the first version will probably not cover each possible alarm.

3.3.5 Implementation Requirements

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3.3.6 Interface Requirements

The position of parameters and their curves should be fixed and not changed. The size is not affected by that requirement.

3.3.7 Packaging Requirements

The system should be designed for a tablet with a resolution of 1920x1200 pixels in a 16:10 format with a 10 Inch display.

3.3.8 Legal Requirements

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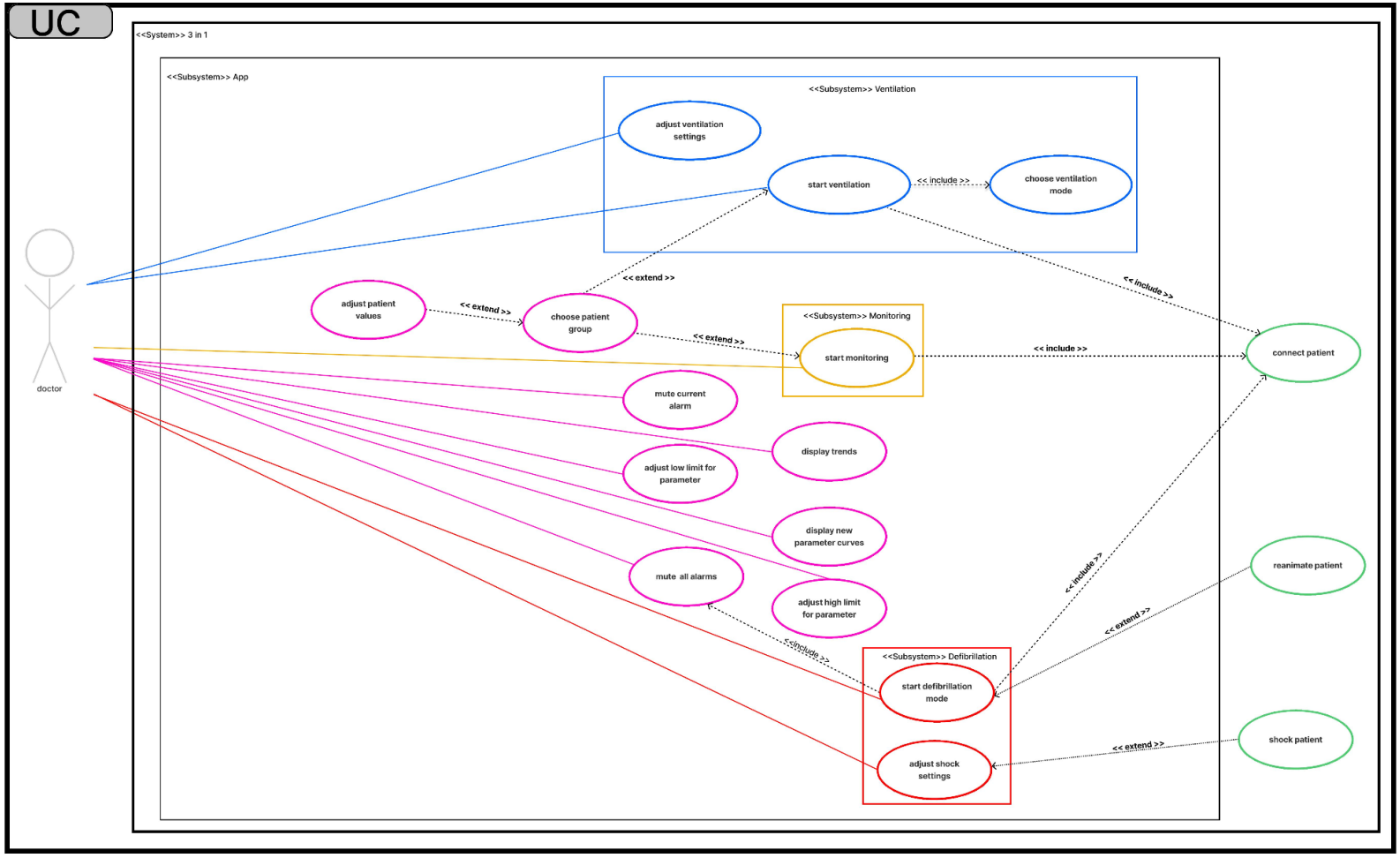
3.4 System models

3.4.1 Scenarios

To get to know how users interact with the current system and to understand the situations the given “patient-stories” describe up to 6 different real life scenarios. Those provided a base for the first customer meetings and to derive main use cases.
The purpose of the stories is to retrace a doctor's interactions while monitoring, ventilating or defibrillating a patient under real circumstances. For the UKE the main focus is put on the Corpuls C3 as well as the Weinmann Meduvent Standard2 v4.1 and Weinmann Meduvent Standard v2.1. The stories build up from an arriving scenario only using monitoring to a more critical situation needing a ventilator. The last steps of the scenarios describe the serious case of reanimating a patient.

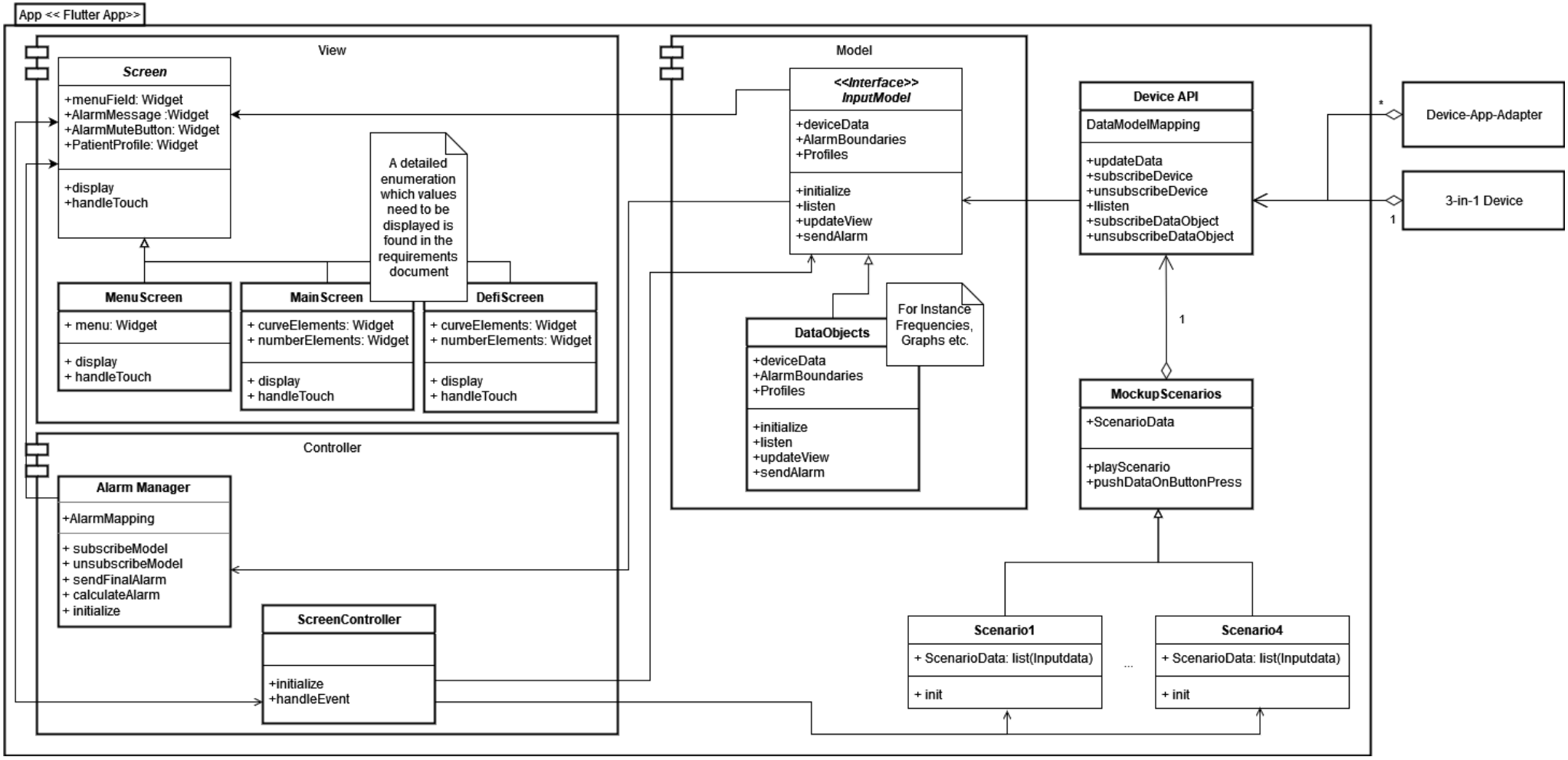
3.4.2 Use case model

For the use case model 3 main use cases were detected: Monitoring, ventilation, defibrillation. To organize the users' interaction with a 3-in-1 device the detailed use cases are organized in subsystems.



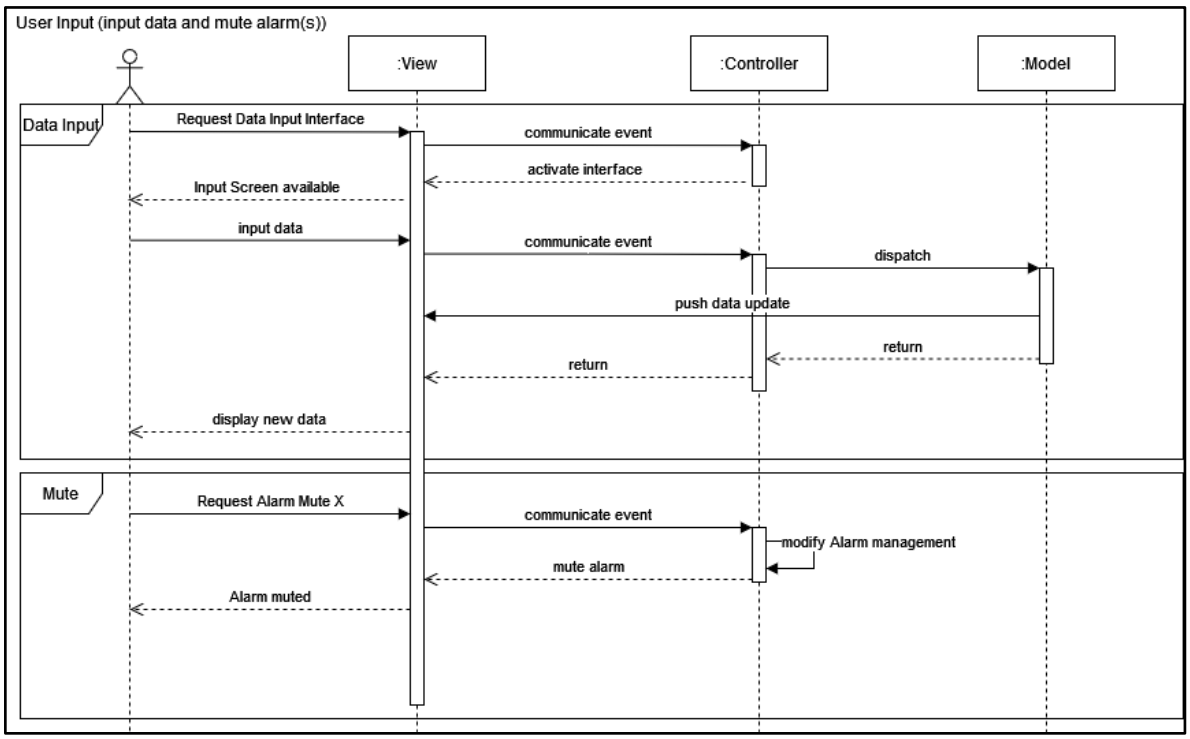
3.4.3 Object model

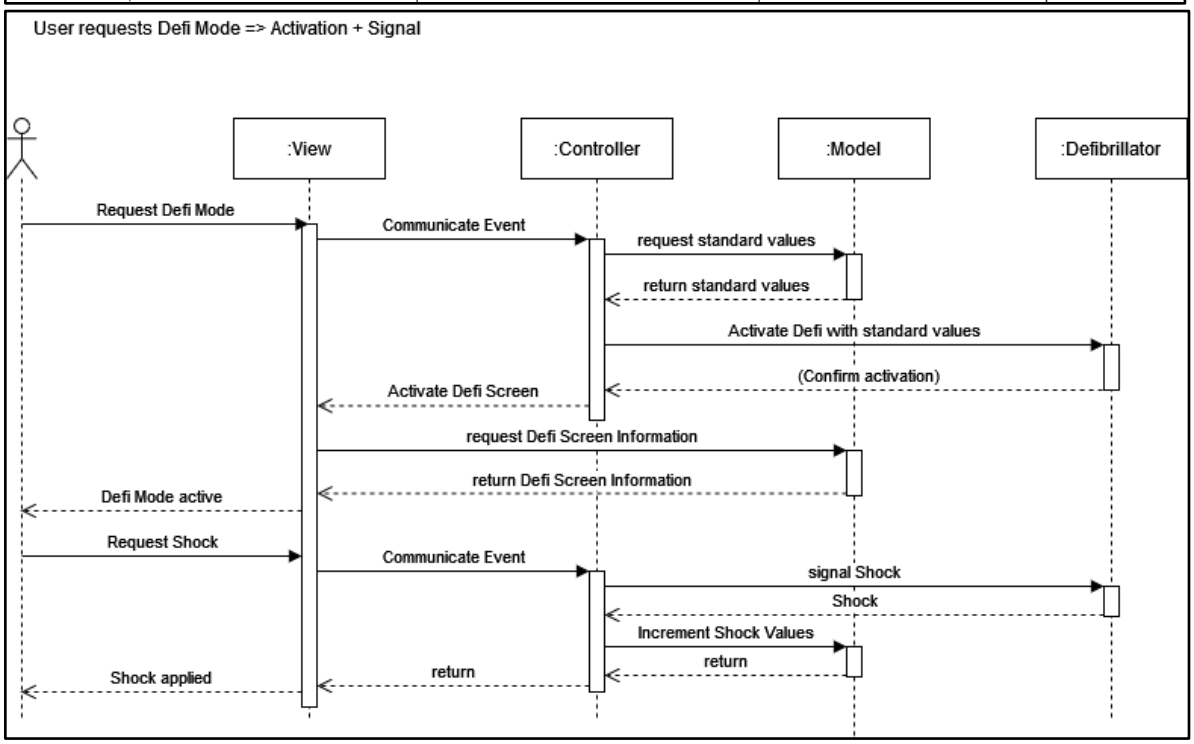
Based on the mentioned use cases and the requirements to change limits and screens, the object model follows the model-view-controller pattern.

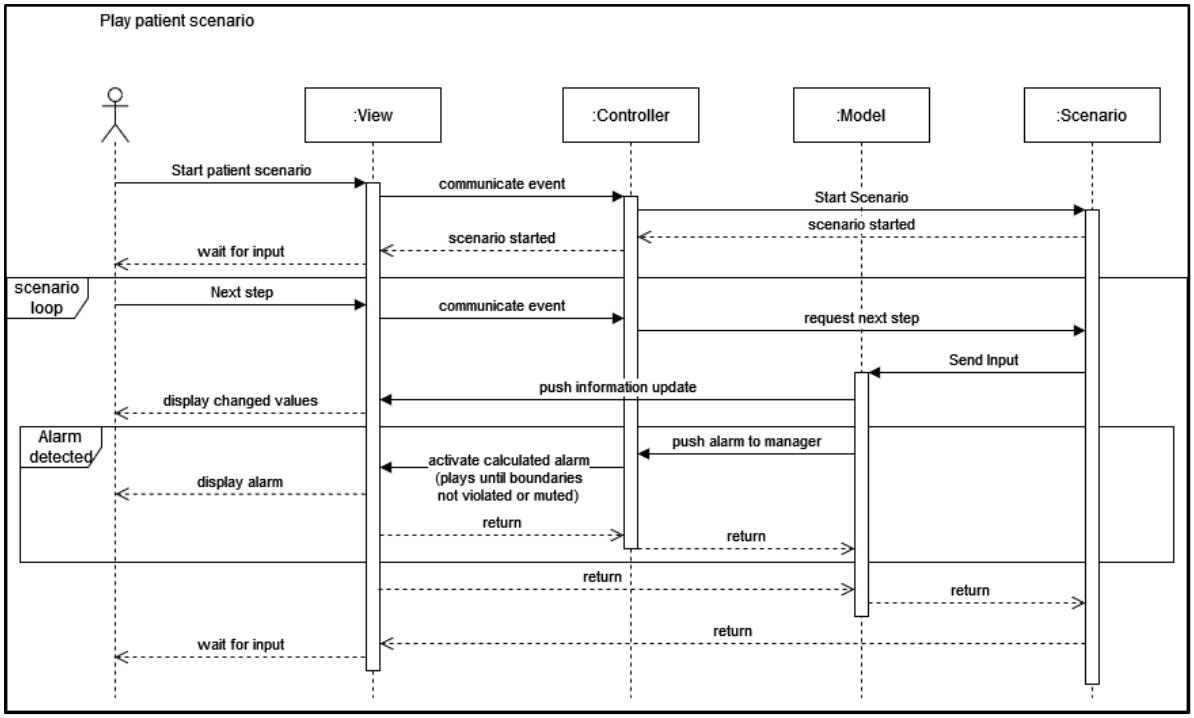


3.4.4 Dynamic model

The following sequence-diagram describes a users' request to input new data into the system with the option to mute alarms. Other program scenarios are the need to activate the defibrillation mode or to demonstrate patient stories.

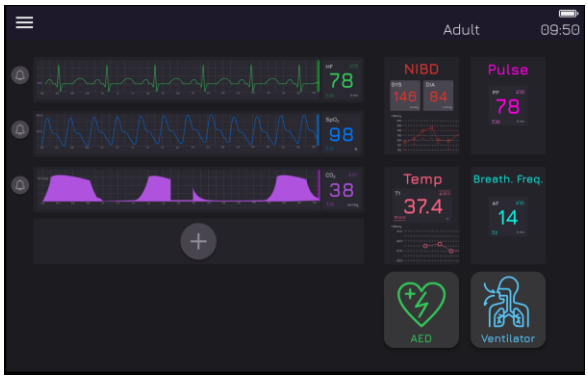


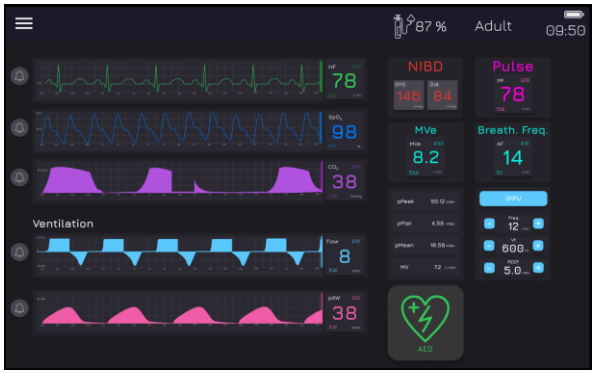




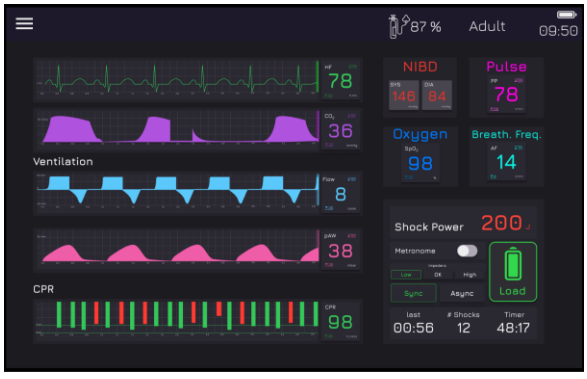
3.4.5 User interface

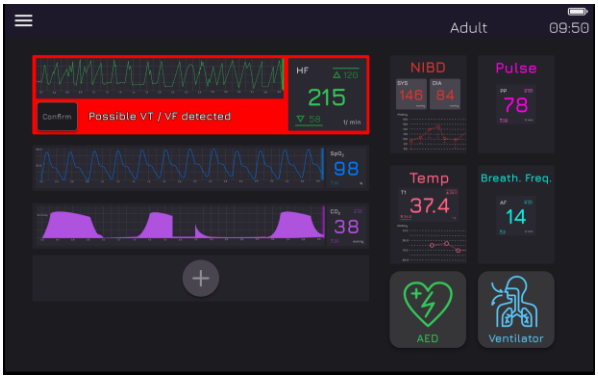
Main screen and main screen without and with ventilation:





Defibrillation mode and high priority alarm:





4. Glossary