Requirements Analysis Document

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1 Introduction

1.1 Purpose of the System

The purpose of the system is to support the user, mainly doctors and paramedics who are working with the current medical devices for monitoring, ventilation, and defibrillation, on an almost daily basis. The project was initiated by the University Medical Center Hamburg Eppendorf in cooperation with the University of Hamburg. Combining those mentioned devices into a 3-in-1 device will result in reduced weight for the user to carry. For the M-Lab project, the group will design a new interface and develop an alarm management system with new visual and auditory behaviour. The provided patient scenarios will be used to demonstrate the application.
The application and result of the M-Lab project will be used by the doctors of the UKE and project partners for evaluating and making propositions for the future device. The university will be grading the results.

1.2 Scope of the System

The scope of the system is defined by a new, modern design and a combination of interfaces for monitoring, ventilation, and defibrillation. In the final version of the project, the different interfaces of the devices' functionalities will all be accessible via one screen. Furthermore, it is part of the project to develop a new alarm management system that handles the united alarm behaviour in a different way to support the user. A special focus is placed on a smart boundary adjustment behavi. New approaches and aspects for the UX Design and the alarm management system with special regard to Software Engineering are encouraged. The project will be implemented for a tablet app for Android and iOS devices. Interfaces to real external sensors that would transmit real-time data are not planned to be implemented. Furthermore, exact representations of complex ventilation modes are not fully represented for the showcase. Patient scenarios serve as the basis for demonstration and will contain certain data and alarm sets. The setting options will refer to the medical and general use aspects and will not focus on accessibility.

1.3 Objectives and Success Criteria of the Project

The goal is to display the main parameters and visualise them in the required graphic fashion. In addition to those parameter values, different alarms will provide auditory and visual feedback. The system will handle concurrent and successive alarms of different priorities in a non-disruptive and supportive manner. During the usage, it should be possible to adjust parameter limits and switch into the defibrillation mode as fast as possible.

To demonstrate the alarms and visualisation of parameters, the application will offer the ability to play provided patient scenarios. The app will be usable with touch functions.
Further goals and requirements are described in detail in section 3. Proposed System.

1.4 Definitions, Acronyms and Abbreviations

Corpuls	manufacturer of the current device for monitoring and defibrillation
CO2	the concentration of carbon dioxide (CO2) during exhalation
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 is counted as positive values, expiration as negatives
Monitor	a medical device to conduct the patient monitoring
Monitoring	refers to the observation of a patient with ECG graph, heart frequency, pulse etc.
NIBP/ IBP	non-invasive blood pressure
parameter	general term for the displayed values with associated graph and sensor names, e.g. heart frequency, NIBP, SpO2, Flow etc.
respiratory rate	breathing frequency
SpO2	oxygen saturation of the blood
UHH	University of Hamburg
UKE	University Medical Center Hamburg-Eppendorf
Weinmann	manufacturer for the current device for ventilation and future 3-in-1 device

1.5 References

To get an overview of the functionalities, e.g. alarm system and 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 and an overview of alarms referring to the scenarios are used to understand the real processes, situations, and conditions under which the devices are used. For the app development, the project group will use the (open source) framework Flutter and will work

with packages, libraries and documentation provided by Flutter. For the visualisation of the patient graphs, e.g. heart frequency, Syncfusion is utilised.

2 Current System

The current system consists of up to three devices: one device each for monitoring, ventilation, and defibrillation. It is possible to combine the devices for monitoring and defibrillation into one, as shown with the Corpuls. The mentioned devices are used by people with a medical background, mainly doctors or paramedics, during an ambulance mission, in hospitals or operating rooms.
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 is common for either single alarms or in general. Especially the general mute which persists for two minutes can lead to critical situations in case the user is unable to pay attention to the monitor while new alarms occur, which is an unwanted behaviour since it hinders the user instead of supporting them. The different functions being separated into three devices has a side effect that functions are distributed redundantly to the devices, which leads to multiple alarms from different devices for the same issue. Furthermore, the adjustment for alarm limits takes up to 20 steps, which is very time-consuming.

3 Proposed System

3.1 Overview

The app is going to be the combined user interface of the monitor, defibrillator and ventilator and centralizes the user's 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 will still be based on those designs. In addition to that, the app is going to offer the ability to play known patient scenarios to demonstrate the system with realistic simulation data.

3.2 Functional Requirements

1. After starting the application, the user should be able to choose a preset for adults, children, or infants from a start screen. This option should be skippable if the monitoring has to be started directly.
2. After having chosen a preset, the user should be able to enter patient data for weight and height, so certain settings, for example the power needed for defibrillation, can be calculated.
3. With activated monitoring and ventilation, the system should display the following parameters:
    - Heart frequency/ECG (absolute value + curve)
    - CO2 (absolute value + curve)
    - SpO2 (absolute value + curve)

- etCO2 (absolute value + curve)
- Flow (absolute value + curve)
- Airway pressure (absolute value + curve)
- NIBP (absolute value + history of last measurements)
- Pulse frequency (absolute value)
- Respiratory frequency

4. The user should be able to add certain parameter curves, for example, the NIBP history or an derivation of the ECG.
5. The user should be able to set all parameter limits of the underlying devices in one menu.
6. The user should be able to set one parameter limit by directly interacting with the parameter.
7. The user should be able to mute all active alarms, displaying new alarms.
8. The user should all be able to mute a single active alarm.
9. The system should emit alarms visually, prioritizing the most relevant ones.
10. The system should emit alarms underlined with an audio component, prioritizing the most relevant ones.
11. The user should be able to switch in a defibrillation mode.
12. The user should be able to set defibrillation shock settings.
13. The user should be able to set ventilation settings.

3.3 Nonfunctional Requirements

3.3.1 Usability, Consistency & Familiarity

The system needs to offer an easy and fast option for the user to switch into the defibrillation mode with a maximum of 2 steps offering a “Defibrillator” or “AED” button. In addition to that, customizing the screen for individual preferences, for example adding a NIBP history graph/curve or a derived ECG curve, should be offered directly at the parameter or via an add-button. Furthermore, the settings for alarm limits should be reachable with a maximum of 3 steps for a single parameter, but also for all parameters. Moreover, the system should differentiate between alarm sources (e.g., monitoring or ventilation) and play distinguishable alarms.

The layout for the parameters’ value boxes should be standardised to increase accessibility, with set positions in each value box for the alarm boundaries and the unit. The absolute values should be headlined to improve the ease of learning since the application is aimed not only at doctors but also at emergency paramedics. The colours should be based on known schemes, like having the heart frequency displayed in green and the NIBP in red.

3.3.2 Reliability

The system should not fail during usage. During interactions with the tablet app, the app should not freeze or stutter due to performance issues. The visualised parameters and their curves should match the displayed values. Reliability does not refer to external connections like medical sensors.

3.3.3 Performance

The user is going to adjust parameters and their limits, so a real-time interaction needs to be guaranteed. Furthermore, the visualisation of changes and graphic presentation, for example, curves and new alarm limits, needs to be displayed without delay. Graphs should be visualised in a fluid and continuous manner, displaying new values on each update.

3.3.4 Supportability

The system should offer the ability to add new values and corresponding alarms to the current version of the app since the M-Lab prototype does not have to cover each possible alarm. Furthermore, a new style theme for light mode or a colour blindness mode should be added with no problems.

3.3.5 Implementation Requirements

There are no implementation requirements or restrictions for this project. The app will be programmed in Flutter, following the suggestion of the M-Lab supervisor team.

3.3.6 Interface, Efficiency & Flexibility Requirements

The position of parameters and their curves should be fixed and not changed. The size of the graphs is not affected by this, as long as they are not stretched or compressed in such a way that an interpretation of the values would change fundamentally. The user should reach certain settings, such as adjusting a single parameter limit, with a maximum of 3 steps. The goal is to reduce the number of steps for adjusting settings in general to a maximum of 5.

The system should be designed for a tablet with a resolution of 1920x1200 pixels in a 16:10 format with a 10 Inch display. Limited by the hardware selection with mentioned specifications, the interface will be designed responsively to changing display sizes from 9 to 13 Inches.

3.3.7 Packaging Requirements

The finished project will be handed over as a functioning Flutter project for iOS and Android devices with documentation including a style guide and approaches for the alarm management.

3.3.8 Legal Requirements

While the current system needs to document the doctor's actions for the health insurance and the ECG during the emergency service, the tablet app does not have to fulfil these requirements or further known legal requirements.

3.4 System Models

3.4.1 Scenarios

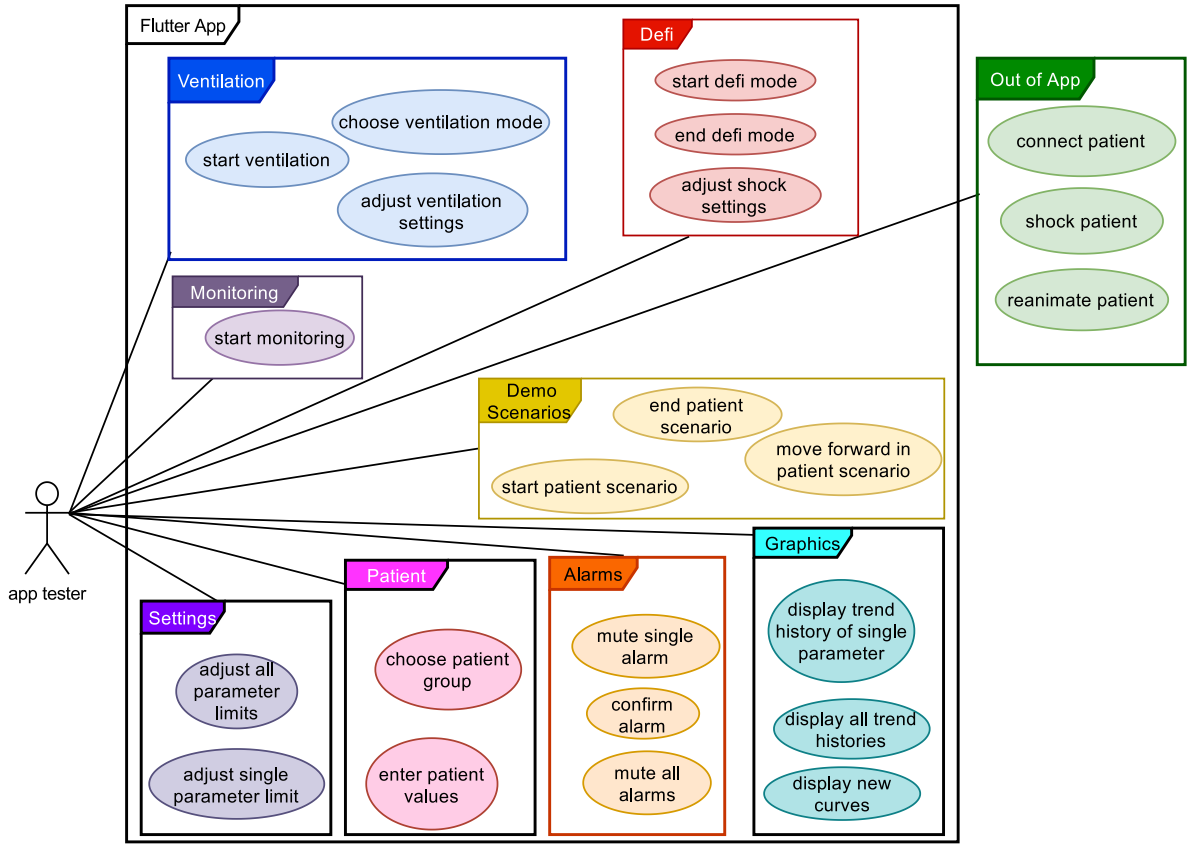
To get to know how the user interacts with the current system and to understand the situations, the given "patient stories" describe 6 different real-life scenarios. They provided a base for the first customer meetings and to derive main use cases.

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 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 arrival scenario, using only monitoring, to a more critical situation requiring a ventilator. The last steps of the scenarios describe the serious case of reanimating a patient. For the application, the parameter values and settings that are adjusted by the doctors or paramedics during the scenarios are going to be the basis for the demonstration to trigger different alarms. The scenarios cover different alarm sets and handle all priorities (notification, yellow alarm, red alarm). Furthermore, concurrent alarms that would occur on the single devices are also part of the scenarios and can be integrated into the alarm management, which should handle those.

3.4.2 Use Case Model

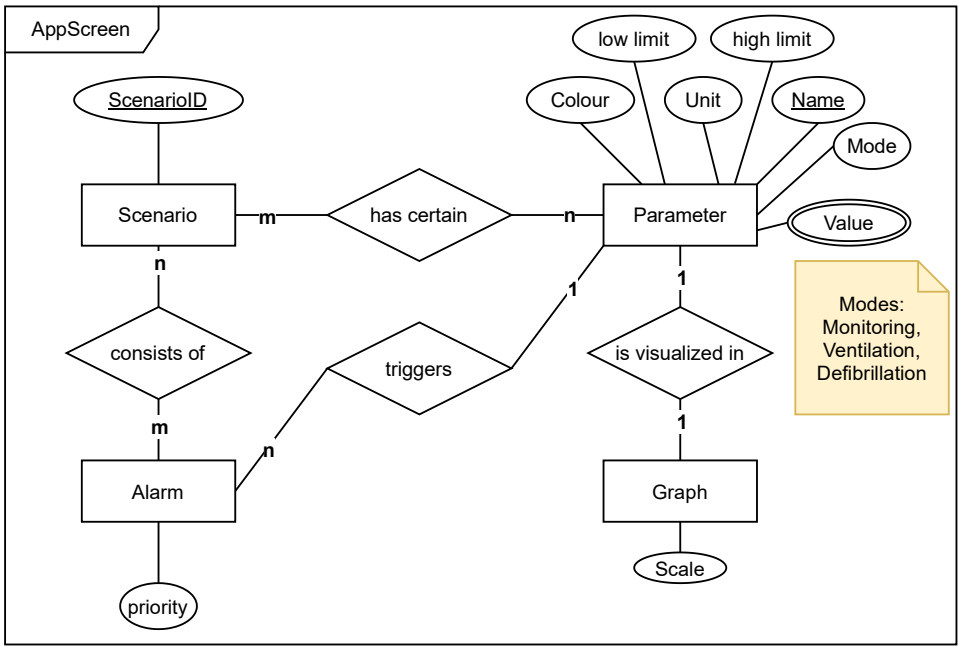
During the requirement elicitation, three main use case groups were detected: *Monitoring*, *ventilation*, and *defibrillation*. To get a better overview of the affiliation, related activities are grouped in subsystems. This applies especially to activities that belong to more than one of the three main use cases, e.g., *adjusting a single parameter limit*. Furthermore, there are also more general use cases, for example *muting an alarm*, which is gathered in the alarm subsystem. In addition to the general use of an interface for the future 3-in-1 device, the app needs to offer the ability to start the known *demo scenarios*. There are also some "*out of app*" activities that are not relevant to the project.

The app will be tested by people with a medical background, meaning doctors of the UKE, paramedics or stakeholders of the research project as well as supervisors from the university, responsible for the M-Lab project.



3.4.3 Object Model

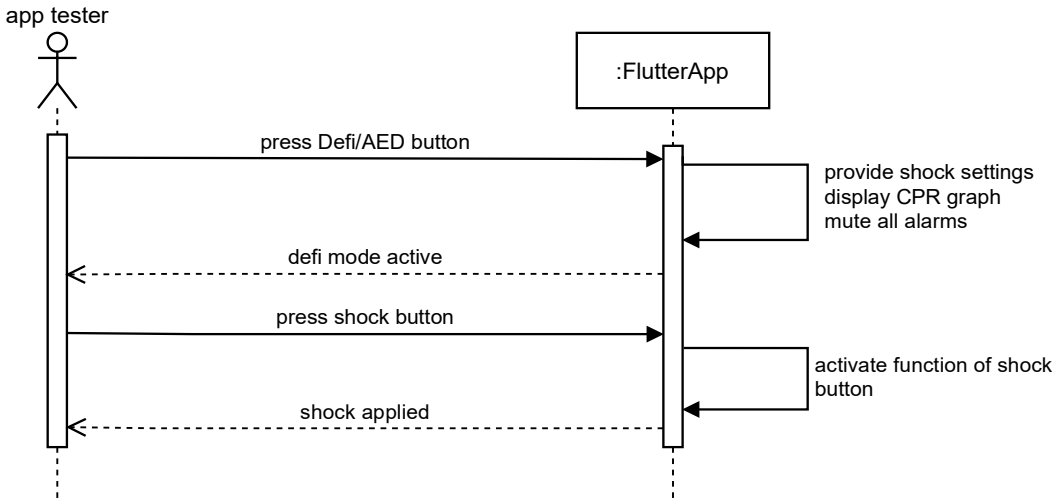
The application is going to display *parameters* with their *values* and their *graphs* if required. The *app tester* (doctors/ paramedics) wants to interact with parameters directly to adjust settings like the *alarm limit*. Certain parameters belong to the different modes: for example, the heart frequency belongs to *monitoring* and the respiratory rate to *ventilation*. Each *Scenario* has a unique number, and has certain parameters and alarms.



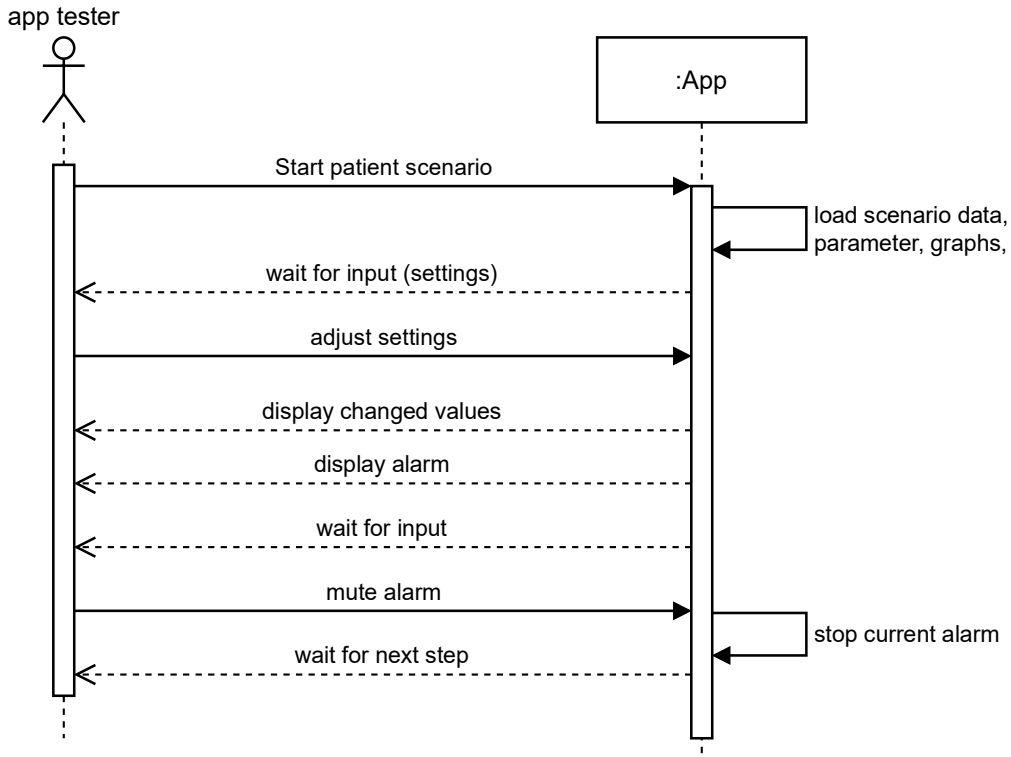
3.4.4 Dynamic Model

The app tester is going to interact with the Flutter App via buttons. Those can be defined explicitly, for example a button to start the defibrillation mode, or can be hidden when the app tester interacts with the parameter directly. In the following sequence diagrams, the Flutter App reacts to the user inputs and returns the requested data or starts the requested actions, for example switching into defibrillation mode. To retain overview, the diagrams focus on the user-app interactions and do not detail the internal processes of the app.

1. Switching into defibrillation mode via "Defi-Button":



2. Start a patient scenario and set some settings (e.g., ventilation settings):



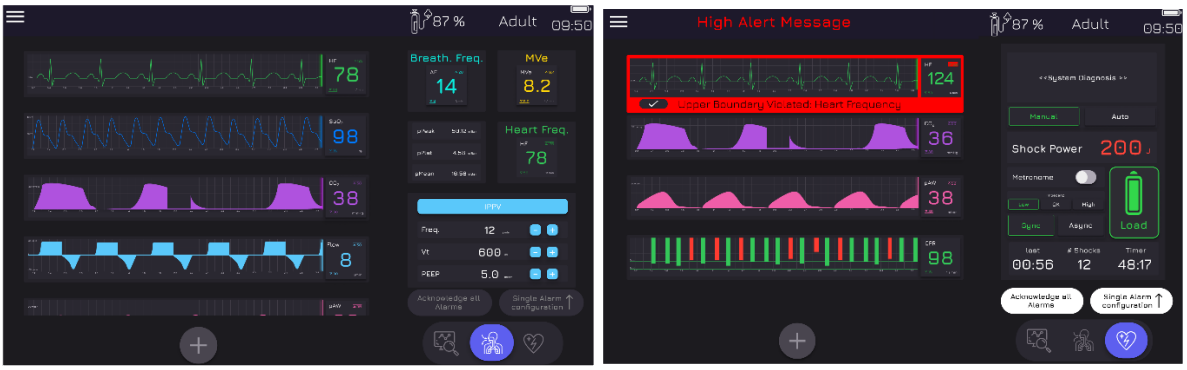
3.4.5 User Interface

The design will update the current system's display in a modern style and with contrasting colours. The light mode can be enabled as a feature that can be added in the future. The accessibility for people who are affected by colour blindness will be neglected in the scope of the M-Lab project. Because of the restricted display size, not all parameters and settings will be displayed at the same time. Changes can be made with dynamic interface actions such as tapping on toggle-buttons on the right side.

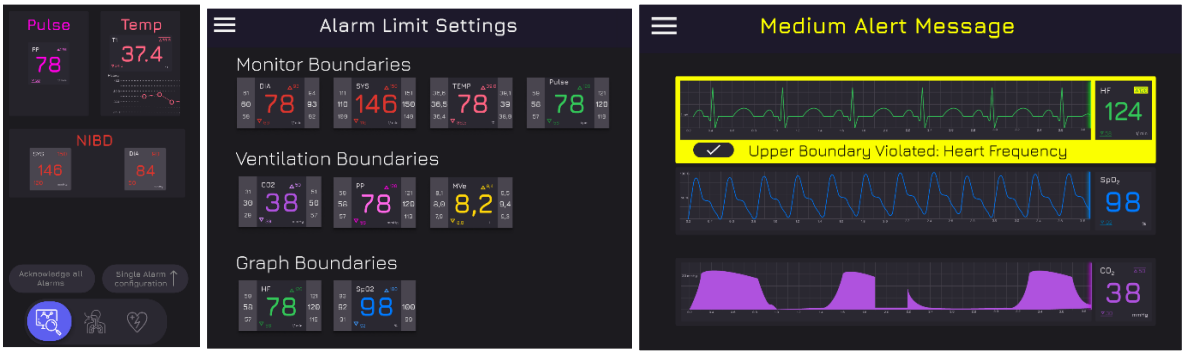
3.4.6 Figma Style-Protoype

For a complete style-overview, please refer to the Figma-Protoype.

Monitoring with ventilation and defibrillation mode with high alert:



Navigating carousel, overview all alarm limits and possible middle alarm:



Start screen and add-graph interface, NIBP history graph:

Set single parameter limit: