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Assessing the Technology and Market Readiness Level of a Software System - An Analysis Based on AMPEL

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List of Abbreviations

AMPEL	Analyse- und Meldesystem zur Verbesserung der Patientensicherheit durch Echtzeitintegration von Laborbefunden
B2B	Business-to-Business
CDSS	Clinical Decision Support System
CIS	Clinical Information System
COM-RL	Competitive Supply Readiness Level

CUS-RL	Customer Readiness Level
DEM-RL	Demand Readiness Level
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level 7
INT-RL	Integration Readiness Level
IPR	Intellectual Property Rights
IPR-RL	Intellectual Property Rights Readiness Level
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers Names and Codes
M-RL	Market Readiness Level
MAN-RL	Manufacturing Readiness Level
PCI	Problem-Centered Interview
PRO-RL	Product Readiness Level
POC	Proof of Concept
POCT	Point-of-Care Testing
T-RL	Technology Readiness Level
ULMC	University Leipzig Medical Centre
USP	Unique Selling Proposition

1 Abstract

With the growing number of patients with more than one disease and a work intensification in hospitals, including hundreds of biomarkers, the work of clinicians is getting more complex. Clinical decision support systems (CDSS) can help to keep the overview and to make better decisions based on data. One of these systems is AMPEL, developed at the University Medical Center Leipzig. In order to support the development and the launch of an innovative software system, the Technology Readiness Level and Market Readiness Level framework (T-RL/M-RL framework) can be used. However, as this framework has only been used for physical products, this thesis modifies them so that they are applicable for software products as well. The research showed that especially for research projects like AMPEL, the T-RL is high, but the M-RL needs more focus. Moreover, the thesis also looked at ethical criteria, since this aspect is getting more important for software development. Additionally, expert interviews revealed factors concerning the ease-of-use and usefulness of CDSSs. These factors are directly related to the technology acceptance. Specifically, if a CDSS offers the ability to highlight unexpected results and motivates the clinician for additional thinking, the system not only reaches a higher user acceptance but is also from great importance for the patient safety and treatment quality. The thesis also provides insights into the decision criteria of the buying process of software systems in hospitals. The total number of 28 different criteria in seven categories shows the complexity of purchasing processes in hospitals and help suppliers develop their software according to these.

2 Introduction

Today, laboratory medicine is able to deliver numerous information with great importance for diagnostic and therapy decisions. Depending on the certain disease, 60 to 70 percent of all therapy decisions are fully or partially based on laboratory results (Regan & Forsman, 2006). Laboratory diagnostics are crucial for several processes in a hospital such as diagnosis, start of therapy and control of patients. Laboratory results, which have not been recognized or interpreted the right way, lead to dangerous situations for patients. Clinical decision support systems (CDSSs) can help clinicians in interpretating results and giving the right medical response at the right time (Eckelt et al., 2020).

2.1 Problem Statement

In order to lift the potential of laboratory analysis it is crucial that the treating clinician considers (a) all provided results and (b) receives them promptly. These two factors are important and hard to achieve, because the work of clinicians is getting more complex. The number of elderly patients increases and so does the number of patients with more than one disease (BMBF, 2014). Moreover, the work intensification in the health sector and growing numbers of biomarkers in the diagnostics propose additional challenges (BIOPRO, 2011). As an example: The Institute for Laboratory Medicine at the University of Leipzig Medical Center provides around 10,000 laboratory findings and more than 1,500 test results for patients every day (Kaiser, 2020).

It is critical to keep an overview and make the right decision at the right time. Studies show that medical errors are one of the most common causes of death and a bigger proportion of them are diagnostical mistakes (Makary & Daniel, 2016; Panesar et al., 2016). Additionally, a great amount of important laboratory findings is either late or not at all taken into consideration (Kilpatrick & Holding, 2001; Poon et al., 2004). That is why, a CDSS is inevitable and can save lives.

A consortium, including the Institute of Laboratory Medicine of the Leipzig University, Muldental Clinics Inc. (non-profit) and XANTAS AG, is currently developing such a CDSS with a project called AMPEL. The acronym stands for ‘Analyse- und Meldesystem zur Verbesserung der Patientensicherheit durch Echtzeitintegration von Laborbefunden’, which can be translated to English as ‘Analysis and Reporting System for the Improvement of Patient Safety through Real-Time Integration of Laboratory

Findings'. After finishing the project, XANTAS wants to sell the system as a commercial product. Therefore, it is important to know if the technology and the market are ready for such a software. This thesis tries to find a solution for this issue.

2.2 Aim of Thesis

The aim of this thesis is to analyse the market and technology readiness level of a CDSS called AMPEL. This framework has been used for several evaluations of innovative products before. However, as these products have always been physical products, there is no case study for a software solution. Consequently, this research will not only assess the technology-market-fit of AMPEL, but it will also show the use of the technology readiness level and market readiness level framework (T-RL/M-RL framework) for a software solution.

In the end, four research questions should be answered:

1) How is the alignment between T-RL and M-RL at the AMPEL system?
2) How does AMPEL reflect ethical criteria?
3) Is the technology going to be accepted?
4) Which criteria are of high importance during the purchase process of AMPEL?

The above stated research questions show that the research will also deal with the ethical situation of the software as this topic is getting more important, especially through smarter computer algorithms and complex statistical models. Additionally, this thesis also reflects on the technology acceptance of a software solution and the decision criteria in the buying centre. Both will help to better understand users as well as stakeholders of the system and to receive insights about their needs.

In the end, the thesis will offer a coherent analysis of a software solution using the T-RL/M-RL framework and additional aspects such as ethical criteria, technology acceptance and the buying centre.

2.3 Structure of the thesis

In order to answer all research questions and provide a deep insight into the topic, this thesis includes a theoretical background, a methodological description as well as a presentation and discussion of the research results.

Chapter two consists of theoretical information. It starts with an explanation of the CDSS and highlights the relevance of it. This is followed by a description of AMPEL, which provides further information about the functionality and the usage of the system. Furthermore, the chapter includes a detailed definition and explanation of the T-RL/M-RL framework including all sub-dimensions.

Chapter three illustrates the methodology. This includes the study design, the study setting and study material. Here, the research questions and hypotheses are presented and explained. Additionally, the complete research process is described in detail.

Chapter four summarizes all results and presents them in a coherent way. In order to make the reading of the thesis easier to follow the results are presented in different theme blocks according to the interview guideline.

Chapter five discusses the previously presented results. Here, all research questions will be answered, and any specialties highlighted.

The last chapter includes practical implications, limitations and a research outlook.

3 Clinical Decision Support Systems

The work of physicians is getting more complex. The number of elderly patients increases and so does the number of patients with more than one disease (BMBF, 2014). Moreover, the work intensification in the health sector and growing numbers of biomarkers in the diagnostics propose additional challenges (BIOPRO, 2011).

It is critical to keep an overview and to make the right decision at the right time. There are different reasons for the development of a clinical decision support system (CDSS). Information systems in hospitals are filled with important and valuable data. CDSSs can use this data to increase patient safety and tackle upcoming challenges like a higher workload in less time. Moreover, there is an increasing pressure to use digital medical records meaningfully. Additionally, there is always the desire to improve services and make processes more effective and efficient (Musen et al., 2014).

Studies show that medical errors are one of the most common causes of death and a bigger proportion of them are diagnostical mistakes (Makary & Daniel, 2016; Panesar et al., 2016). Additionally, a great amount of important laboratory findings is taken late or not at all into consideration (Kilpatrick & Holding, 2001; Poon et al., 2004). That is why, CDSSs are inevitable and can save lives.

3.1 Definition and Functionalities of a CDSS

As described in the introduction to this chapter, CDSS are crucial for clinics as the work and requirements are getting more complex. Berner and La Lande (2007) define CDSSs as "computer systems designed to impact clinician decision making about individual patients at the point in time that these decisions are made". Another definition is made by Osheroff et al. (2007), who state that it "provides clinicians, staff, patients, or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care".

There are already many CDSSs on the market and experts think that they have the potential to make changes in the way medicine is practiced. Especially the publication of "To Err Is Human: Building a Safer Health System" (Kohn et al., 2000) brought a greater attention towards support systems in hospitals. The book shows that medical

errors are the third most common causes of death. Intelligent computer systems could help minimize these errors and increase patient safety.

Recently, suppliers of CDSSs incorporate these systems in computer-based patient records or hospital information systems. Nevertheless, there are many differences between different CDSSs. According to Metzger and MacDonald (2002) a CDSS differs in four dimensions: (1) timing in the decision-making process, (2) active or passive support, (3) customization and (4) ease of access. The first dimension focuses on the time at which the system provides support: this might be before, during or after the decision-making process. The second dimension defines whether the support is active or passive. Active support appears automatically whereas passive support requires an action by the user to receive the desired information. The third dimension focuses on the customization and modification to individual clinical situations. Systems are more useful if they can easily adapt to different situations at different hospitals. The fourth dimension describes the differentiation in the ease of access: the usefulness increases when the accessibility is better (Metzger & MacDonald, 2002).

Apart from that, CDSSs can be differentiated in another way. It is possible to categorize them either as *knowledge-based system* or as *non-knowledge-based* one. The former describes a system, which provides information based on an underlying knowledge base. It consists of three parts: a knowledge base, a reasoning engine and a mechanism for communication with users. The ladder might be in the form of a user interface, but it also includes connections to other clinical systems. The knowledge base includes compiled information mostly as 'if-then-rules'. The reasoning engine consists of formulas to combine rules or associations within the knowledge base with patient data. The communication mechanism defines how the patient data gets into the system and how the output gets to the user. Mostly, the input is being entered by hospital employees and the output is in form of alerts or recommendations (Berner & La Lande, 2007). These kinds of systems can be regarded as expert systems, which are defined as softwares emulating human behavior in a narrow, defined area of knowledge (Liebowitz, 1995).

In contrast to that, non-knowledge-based systems are based on machine learning algorithms or other pattern recognition approaches. Thus, they are capable of learning from previous experiences and see patterns in clinical data. Generally, there are two types of these systems: a) artificial neural networks and b) genetic algorithms. The former describes a system consisting of neurodes and connections transmitting signals between them. This simulates the human thinking, and the underlying statistical

models are able to learn from examples and past decisions. Hence, there is no direct input from experts necessary, the system works even with incomplete data and does not need a large data base. However, the training process is rather time-consuming, and the resulting formulas are difficult to interpret, which may cause concerns regarding the accountability and reliability of the system (Berner & La Lande, 2007).

Genetic algorithms, in contrast to artificial neural networks, are less common in healthcare. They evaluate different components of sets of solutions to a certain issue and keep the best sets. In a next step they recombine these sets and mutate them to form a new set, which can solve the issue. Here, patient data delivers the required knowledge (Berner & La Lande, 2007).

3.2 Effectiveness and Relevance of a CDSS

Searching for CDSSs, one can find many different studies and reviews of successfully implemented systems (search link: https://scholar.google.com/scholar?hl=de&as_sdt=0%2C5&q=cdss&btnG=). These systems support the decision-making process of clinicians and aim on a greater efficiency of processes in the hospital. Consequently, they can improve the quality of treatment and reduce cost of care (Berner & La Lande, 2007). Additionally, CDSSs minimize errors occurring during the work in hospitals. Alerting systems, for instance, can prevent dangerous drug situations or complications (Berner & La Lande, 2007).

Nevertheless, there are also indicators that CDSSs sometimes fail to deliver the desired outcome. Teich et al. (2000) claim that alerting or reminder systems might work, but as soon as a system questions the judgement of clinicians or intervene with their care plans, the acceptance suffers. A case study by Galanter et al. (2002) supports this assertion showing that clinicians repeatedly ignored the advice of a system despite several warnings of a dangerous drug level. These findings show that there might be significant resistance towards a CDSS. Chapter 1.3 presents several aspects, which should be taken under consideration for a successful implementation of a CDSS.

In total, it is quite difficult to make a general statement about the effectiveness of CDSSs. Bryan & Austin Boren (2008) reviewed several studies about these systems and came to the conclusion that a major challenge for the assessment is the interpretation and variation in the implementation of CDSSs. There are many differences in the interaction with hospital employees and system requirements. Thus,

most studies can only evaluate the effectiveness of a certain CDSS in a particular environment rather than a general setting (Bryan & Austin Boren, 2008).

Nonetheless, CDSSs have the potential to have a significant impact on improving the quality of healthcare. The commercialization of these systems is likely to increase in the next years. Moreover, a stronger focus on patient safety will support various initiatives leading to a better incorporation of CDSSs (Berner &L La Lande, 2007). All in all, indicators signal a continued progress in development of CDSSs in the future, which will lead to a higher effectiveness and acceptance of these systems.

3.3 Implementation of a CDSS

Implementing new software systems is mostly difficult because one has to respect and consider many different aspects, among others usability, acceptance, integrability. Moreover, absorptive capacity plays an important role, which is defined as "a firm's ability to recognize the value of new information, assimilate it, and apply it to commercial ends" (Cohen & Levinthal, 1990). When it comes to CDSS the situation becomes even more complex as these systems influence the patient safety, for instance, and patient data requires a strong cyber security.

One main implementation challenge is the data entry or, in other words, how the data is getting into the system. Providers of CDSSs should avoid a second entry of the same data. If the CDSS is not connected to the main hospital information system and employees need to enter patient data manually to the system, it will lower the acceptance, increase the likelihood of mistakes and take longer. Another challenge is to figure out who enters the data: normally, clinicians make the decisions but they mostly do not interact with these systems because of time constraints. Furthermore, it must be secured that the language of the system equals the language of the users. CDSSs might use short terms or a different vocabulary for certain situations, which makes it hard to understand for users (Berner & La Lande, 2007). Especially this last aspect decreases the understandability, which in turn reduces the willingness to use and increases the resistance of the willingness to pay for the product (Köberl, 2020).

Another study points out two important aspects: firstly, CDSSs should be easy to use since the level of computer skills is not too high among clinicians, and secondly, these systems interfere with the work of clinicians. They might perceive them as a loss of autonomy, which is a threat for a successful implementation (Khalifa, 2014).

Khalifa (2014) used a Delphi technique at the King Faisal Specialist Hospital and Research Center, in Jeddah, Saudi Arabia, to collect information from experts and professionals. The author then described ten major topics, which should be taken into consideration for a successful design and implementation of a CDSS:

1. Having suitable content and data
2. High validity and reliability of provided information
3. Delivered messages that are simple and easy to understand
4. Scientific references underlining the output
5. Time-saving for user
6. Integration into clinical workflow and systems
7. Fast system with low response time
8. Optimization of the system into passive or active alert mechanisms
9. Incorporating CDSSs into the hospital information system
10. Ongoing maintenance

In addition to that, Kawamoto et al. (2005) analyzed success factors for CDSS across several studies. They found that four factors have great importance overall:

1. Automatic alerts
2. Recommendations at the decision point
3. Actionable recommendations
4. Digital process

It is obvious that many different aspects must be considered in order to implement a CDSS in the desired way. The system must fit into the culture and organization as well as into the process of care. Furthermore, it is important to communicate the limitations of a CDSS so users know what they can expect from the system and what proved limitations there are. In addition to that, the used knowledge and models must be coming from reputable and reliable sources. In order to assure a great acceptance and quality of the system, users must receive proper and persistent training (Berner & La Lande, 2007).

If suppliers of CDSSs take all the factors stated above into consideration, the success rate will increase. Nevertheless, every CDSS is unique and has different requirements and objectives. Hence, a stronger focus on individual technology and market aspects is necessary, which is going to be provided by the use of the T-RL/M-RL framework.

4 AMPEL – A Clinical Decision Support System

Today, laboratory medicine is able to deliver numerous information with great importance for diagnostic and therapy decisions. Depending on a certain disease, 60 to 70 percent of all therapy decisions are fully or partially based on laboratory results (Regan & Forsman, 2006). However, in order to lift the potential of laboratory analysis it is crucial that the treating clinician considers (a) all provided results and (b) receives these promptly. These two factors are important and hard to achieve, because the work of clinicians is getting more complex. The number of elderly patients increases and so does the number of patients with more than one disease (BMBF, 2014). Moreover, the work intensification in the health sector and growing numbers of biomarkers in the diagnostics propose additional challenges (BIOPRO, 2011). As an example: the Institute for Laboratory Medicine at the University of Leipzig Medical Center provides around 10,000 laboratory findings and more than 1,500 test results for patients every day (Kaiser, 2020).

A consortium, including the Institute of Laboratory Medicine of the Leipzig University, Muldental Clinics Inc. (non-profit) and XANTAS AG, is currently developing a CDSS called AMPEL. The acronym stands for 'Analyse- und Meldesystem zur Verbesserung der Patientensicherheit durch Echtzeitintegration von Laborbefunden', which can be translated to English as 'Analysis and Reporting System for the Improvement of Patient Safety through Real-Time Integration of Laboratory Findings'. The following sub-chapters will provide an overview of the functionalities of AMPEL, the operation area, target group and the relevance of the project.

4.1 Origin and Relevance of AMPEL

The results of laboratory diagnostics are crucial for diagnoses, therapy decisions and therapy success. The importance is steadily increasing: as stated above, 60 to 70 percent of all therapy decisions are fully or partially based on laboratory results (Regan & Forsman, 2006). Additionally, the demographical change, multimorbidity as well as a growing number of biomarkers make the work in hospitals more complex (Kaiser et al., 2020). Studies show that:

- medical errors are one of the most common causes of death (Makary & Daniel, 2016)
- diagnostical errors are a greater part of medical errors (Panesar et al., 2016)

- many laboratory diagnostics are getting noticed late or not at all (Kilpatrick & Holding, 2001; Poon et al., 2004)

Thus, improving the processes of diagnostics and therapy decisions can increase patient safety and treatment measures. All processes of the laboratory diagnostics are divided into three parts: pre-analytics, analytics and post-analytics (Lundberg, 1990). Figure 1 provides a visual representation of the processes including all necessary tasks.

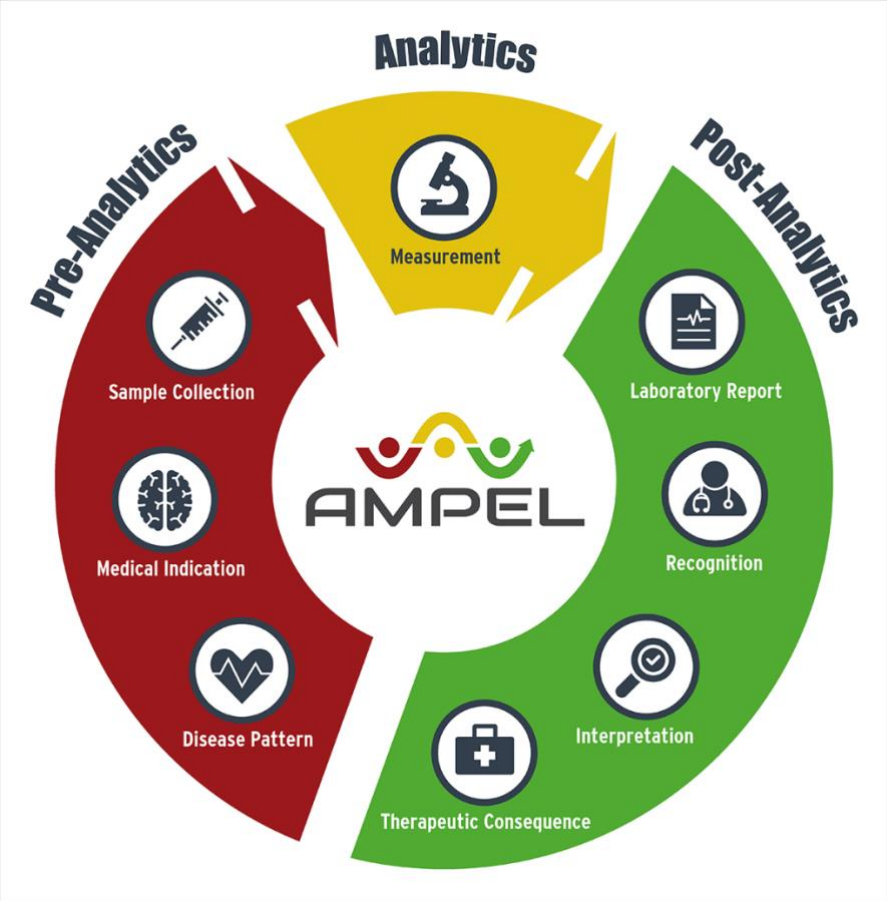

Figure 1: Phases of Laboratory Diagnostics (Eckelt et al., 2020)

In total, the quality of laboratory diagnostics is highly assured. Specifically, the phase of analytics is under control by different quality measures. However, the post analytics process has not been part of any specific laboratory quality measures yet (Eckelt et al., 2020). Research showed that this process includes the most mistakes -19 to 47 percent of all laboratory errors. The reasons for this are delayed or non-reported results, wrong validation or transcription errors (Plebani, 2006).

In order to reduce these errors, a CDSS is a helpful option. The laboratory medicine is a particularly good basis for a CDSS, because it already provides many quality-proven medical pictures in a structured form. Nevertheless, a literature research from 2019

showed that only a few CDSS with connection to the laboratory medicine have been developed (Eckelt et al., 2020). The leader of the project named several reasons for that during a conductedinterview. According to him, people in the medical sector are generally rather sceptical about these systems and clinicians accept new systems only after successful, data-based studies. This is a long way many companies do want to go. In addition to that, the other member of the AMPEL team stated that developing a CDSS is time-consuming as well as expensive, which is another barrier.

These findings show the relevance of a CDSS for the laboratory medicine – specifically the post analytics processes. Such a system could decrease medical errors and hence increase patient safety and treatment quality. The AMPEL system aims to provide this missing quality assurance.

4.2 Objectives and Functionalities of AMPEL

The goal of AMPEL is to give clinicians the right information at the right time in the right form. Therefore, the data of the laboratory diagnostics are analyzed in real-time to inform the clinicians in time for any critical constellations. All in all, the AMPEL system focuses on eight objectives (AMPEL, 2021):

- Improvement of clinical care
- Alert in case of inadequate or delayed therapeutic action
- Patient safety enhancement
- Interpretation aids for specific constellations of findings
- Development of regulatory frameworks
- Transferability of the results
- Documentation of diagnoses and findings
- Medical coding of diagnoses and findings

The stated objectives also give a first glance on what the system should be able to do. The main element of AMPEL is the reporting system, which triggers alarms for clinicians if it indicates acute clinical patterns or delays in diagnosis and treatment (AMPEL, 2021). Clinicians receive the information as an alarm through the laboratory information system, the hospital information system, via mail or phone. In addition to the alarm, the user receives further information about the patient and the disease, which helps to interpret the laboratory results (Eckelt et al., 2020).

In order to maximize the acceptance of the system, the development team aims to minimize false alarms and achieve high specificity (Kaiser et al., 2020). Asked about false alarms, the team leader clarified in the interview that both, false positives as well as false negatives are tried to be minimized. However, the team focuses more on false positives, because

> "a great number of false positives leads to an alarm fatigue and alarms with a high importance might be not getting noticed. And too many alarms distract clinicians, which are already exposed to many different amenities and even more amenities would support the risk of medical errors" (Interview 8, 03.06.2021).

Therefore, the system is being developed in close collaboration with clinical experts and evaluation through cooperating clinics (Eckelt et al., 2020). This assures a development with respect of practical issues and customer needs.

The system is based on different set of rules for various biomarkers. These are not only responsible for triggering the alarms, but also for supporting the documentation of diagnoses and the medical controlling. The set of rules is based on decision trees with respect to recent findings in the literature and retrospective analyses of laboratory diagnostics. Additionally, methods of machine learning will be included to further improve the set of rules and increase the specificity and sensitivity of the system (Eckelt et al., 2020).

The AMPEL system already proved its feasibility through a proof-of-concept (POC) and is already in full use at the University Leipzig Medical Center and the Muldental Clinics (Walter Costa et al., 2021). For the POC, the system has been used to support patients with hypokalaemia, a disease that requires fast treatment and control through laboratory medicine. The test showed that additional alerts lead to a faster treatment for patients with a severe hypokalaemia. The results were significant and the group supported by the AMPEL system received treatment 11 hours earlier (Kaiser et al., 2020).

At the moment, five set of rules are in use at two clinics: hypercalcemia, hyperlactatemia, hyponatremia, hypokalemia and acute kidney injury (Walter Costa et al., 2021). Furthermore, two other algorithms are in the pre-release phase, because they are more complex and require machine learning methods. The team is also developing 23 more algorithms to further increase the content of the system.

4.3 Implementation

Having a CDSS as a product, it is very important to implement the system into the established clinical system architecture correctly and with a high compatibility. Figure 2 shows the integration of a laboratory CDSS - like AMPEL - into a clinical software infrastructure.

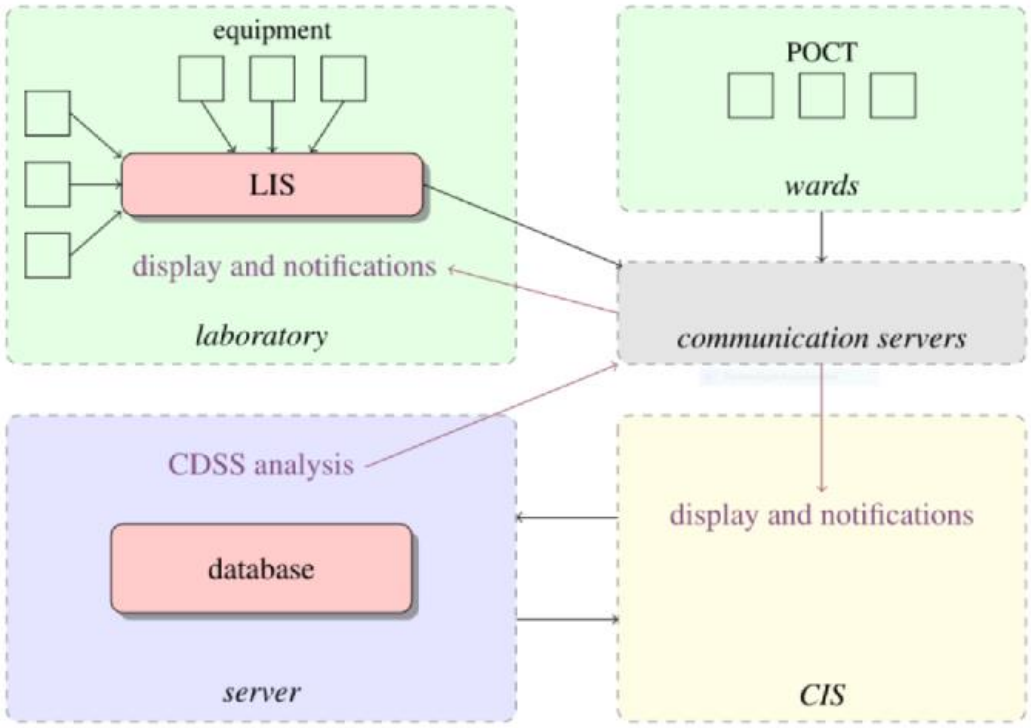

Figure 2: Clinical Software Infrastructure with CDSS (Walter Costa et al., 2021)

The green boxes are the input components. AMPEL can receive information from the laboratory information system (LIS) or data from measurements at the Point-of-Care-Testing (POCT) in the different wards. Here, it is necessary to use standard data formats of eHealth, like HL7 or ASTM (Walter Costa et al., 2021).

In a next step, the information is sent to a communication server, which transfers it right to the clinical information system (CIS) and further to the server. This is the box colored in purple, which is the key component of the CDSS. Here, the data is stored in a data warehouse, which makes it possible to perform the CDSS analysis (Walter Costa et al., 2021). In a last step, the output component, which is the clinical information system (CIS) colored in yellow, receives the final data of the CDSS. The results are showed in the overview of the CIS and notifications are sent out to the clinicians (Walter Costa et al., 2021).

At the ULMC, AMPEL receives information from SAP R/3, the CIS. AMPEL itself is implemented in SAP BW, which is the data warehouse of the hospital. In SAP BW, all information is being processed and analysed. The system then generates notifications in form of items at the phone list of the laboratory. Consequently, the laboratory team calls the clinician to inform about a critical situation of a patient (Walter Costa et al., 2021).

Additionally, an AMPEL column is assigned to the CIS and shows either a green, yellow or red light for a patient (see Figure 3). With a click on this traffic lights symbol, the clinician jumps to the AMPEL report, which presents all notifications of a patient and interpretational support (see Figure 4). If a clinician checked all yellow and red parameters of a patient and attend to her or him, a checkmark is displayed. This informs colleagues that the respective patient already received treatment (Walter Costa et al., 2021).

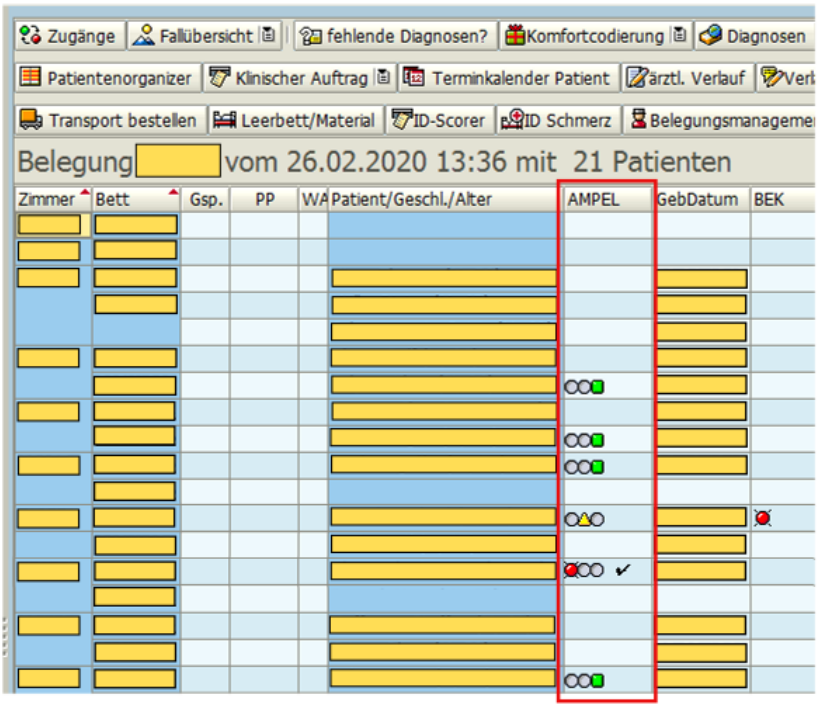

Figure 3: Screenshot of AMPEL-column in SAP R/3 (Walter Costa et al., 2021)

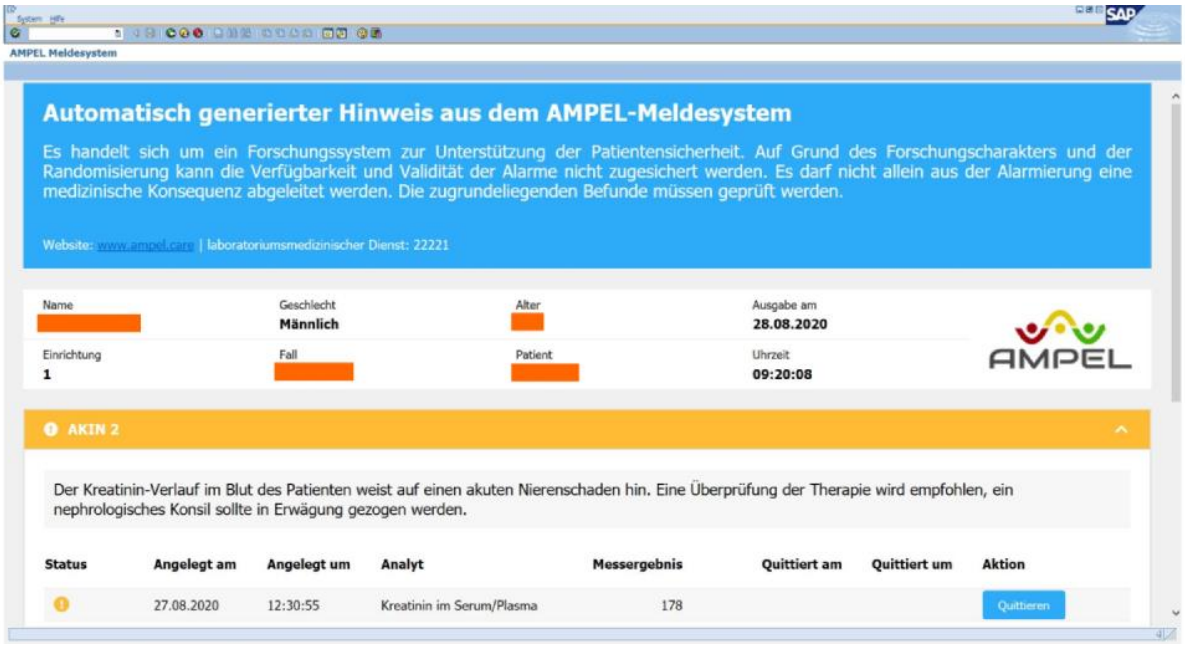

Figure 4: Screenshot of AMPEL-Dashboard (Walter Costa et al., 2021)

5 The T-RL/M-RL Framework

Innovations try to solve problems, serve special needs, increase productivity or maximize the output. In the past, the focus has been set on the technology only to assess the readiness of a product. However, recent research added the market and customers as an additional factor. Hence, the innovation process also includes a market orientation providing a new perspective and trying to reduce risks of failing with the final product (Dent und Pettit, 2011). Consequently, in order to make innovative products valuable and successful, two factors are important: the market readiness level (M-RL) and the technology readiness level (T-RL). The former shows if there is a market for the product and potential customers accepting and willing to buy it and pay for it. In this thesis, 'market' is defined according to the definition by Robinson (n.d.), which states that a market is "a means by which the exchange of goods and services takes place as a result of buyers and sellers being in contact with one another, either directly or through mediating agents or institutions." The latter, whereas investigates the product development and the progress of this process (Eljasik-Swoboda et al., 2021).

The combination of M-RL and T-RL is quite new. Originally, T-RL has been invented and defined by NASA in 1989 (Sadin et al., 1989). Years later, in 2011, Dent und Pettit (2011) added the M-RL to also include the market potential as this is a risk for the

product launch in later stages. Hasenauer et al. (2015) then defined further sub-dimensions for M-RL and T-RL to better explain the given levels.

Using both, M-RL and T-RL, together gives the advantages of having a two-dimensional approach. Consequently, additional informational value will be provided because the relationship between M-RL and T-RL is directly visible, and risks can be identified earlier and easier. Figure 1 shows a visualization of the T-RL/M-RL framework.

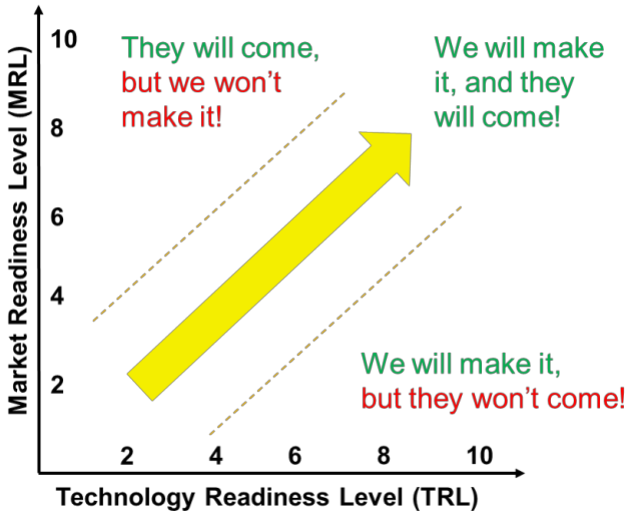

Figure 5: Visualization of the T-RL/M-RL framework (Hasenauer et al., 2015)

The visualization shows the problems of having a high T-RL but low M-RL or vice versa. It might be that the product itself is state-of-the-art and easy to produce but there are no customers to buy it. However, it might be also the case that the market would accept the product and actually buy it, but the technology development is not far enough to serve all needs. Therefore, every company should strive to reach level ten at the M-RL and T-RL so they can sell a state-of-the-art product that attracts the attention and serves the needs of the customers - which means the market entry of the product.

As mentioned before, M-RL and T-RL are further divided into sub-dimensions. There are three dimensions expressing the T-RL: integration readiness, intellectual property right readiness and manufacturing readiness. Moreover, there are four dimensions expressing the M-RL: demand readiness, competitive supply readiness, product readiness and customer readiness (Hasenauer et al., 2015).

The following chapters will give information about the M-RL, T-RL and their associated sub-dimensions. It has to be mentioned that most of the readiness levels were

designed to evaluate physical products. Software solutions, on the other hand, have different requirements and aspects that have to be looked at, for example a different interpretation of the supply chain or different ways of using the product.

That is why it is necessary to make adjustments to some readiness levels, so it is possible to analyse a software solution with the T-RL/M-RL framework in a proper way. Nevertheless, recent literature only provides modifications for software products for some of the readiness levels. Hence, some adjustments have been performed for the purpose of this paper which serve as a potential analysis method for future software evaluations.

5.1 Technology Readiness Level

The technology readiness level was originally developed by NASA in the 1980's to support the decision-making regarding the development of new technologies. It is a strong tool to assess the technology development and common for innovative products. The model consists of a scale of ten levels, which has been adapted and adjusted over time (Dent/Pettit, 2011). Table 1 gives an overview of all technology readiness levels including a description for software solutions. It shows that basic research on the feasibility of the project and basic product development only qualifies for a medium high T-RL.

Level	Stage	Software Solution Description
1	Fundamental research	Scientific knowledge supports planned software solution
2	Applied research	Practical applications for desired software solution
3	Research to prove feasibility	Limited functionality verifies crucial properties and predictions
4	Laboratory demonstration	Main software components integrated and validated; testing environment defined and performance in it predicted

5	Technology development	Development of end-to-end software system meeting desired performance; successful test in testing environment; forecast for performance in operational environment
6	Whole system field demonstration	Software test in operational environment
7	Industrial prototype	Prototype can be used for full-scale practical problems; software system partially integrated
8	Product Industrialization	Software system fully integrated and debugged; successful deployment in operational environment
9	Market/Sales certification	Software system meets all required norms
10	Business model defined coherently	Commercialization of software system through coherent business model

Table 1: Technology Readiness Level Overview (Hasenauer et al., 2016; NASA, n.d.)

The first level marks the start of the technology development process including a translation of fundamental research into applied research. For software solutions it is especially important that the planned solution can be based on scientific knowledge. At the next level, practical applications of the research in the first level are identified and formulated. In case of a software solution, this includes the coding of basic principles and experiments with synthetic data (NASA, n.d.). In a next step, laboratory-based studies as well as analytical studies are performed to give a proof-of-concept and show whether the predictions are useful. Therefore, the software solution must have limited functionality.

In order to reach level four, basic technology parts need to be implemented to form a first prototype, which are able to perform a laboratory test. Even though the system might be in the early stages, itshould meet the most important requirements of the final product (Mankins, 2004). Software solutions should have main software components integrated and validated at this stage, as well as a testing environment should be defined and the performance in it predicted (NASA, n.d.). At level five it is

necessary to have a first user experience in a wider technology infrastructure including user testing and validation. For this, prototypes with medium fidelity are being tested in the lead markets. In case of a software solution, the project team developed an end-to-end software system and tested it successfully in the testing environment. These results help to make a forecast for the performance in an operational environment (NASA, n.d.).

In order to fulfil level six, the product is demonstrated in an operational environment. Moreover, a pilot line is producing a small number of sample products. Level seven includes the finalization of industrial prototypes, which launch at early adopter markets (EARTO, 2014). This means, in terms of software solutions, that the prototype can be used for full-scale practical problems, however, the software system is only partially integrated at this point (NASA, n.d.).

Level eight demands an almost finalized manufacturing process; here, the product is in the last phase of its development (EARTO, 2014). The software system is fully integrated and debugged. Furthermore, the deployment in the operational environment was successful (NASA, n.d.). To complete level nine, it is necessary to have a final product that only requires smaller adjustments over time. Additionally, a successful launch and expansion also demands certifications required for the target markets (being in compliance with legal and industrial standards). The last level is reached, if the team also finalized its business model with a clear focus on the goals and a plan on how to reach them (Hasenauer et al., 2015).

Nevertheless, the previously mentioned ‘original’ ten technology readiness levels might not represent every important aspect. That is why Hasenauer et al. (2015) defined three additional dimensions concerning the technology readiness, which help to assess the T-RL more precisely and accurately. These additional dimensions are each divided into nine or ten levels. The intellectual property right readiness shows the degree of legal protection of the innovation against imitation and breaching intellectual property rights, the manufacturing readiness gives an insight into the production of the product and into the integration readiness examines whether the product can be used and implemented properly in the envisaged target functional environment (Dent & Pettit, 2011).

The following chapters will present each dimension and provide further information on them.

5.1.1 Intellectual Property Right Readiness Level

Innovative technologies might give a company a competitive advantage and a product ahead of the competition. This technology, however, must be protected in order to avoid any forms of copying. Therefore, the intellectual property right readiness level tries to measure protection and includes problems like research or collaboration agreements as well as patenting (KTH, 2012, as cited in Hasenauer et al., 2016). Table 2 gives an overview of all nine levels. As this readiness level can be used for all kinds of products equally, no modification regarding software solutions is necessary.

Level	Stage
1	Hypothesizing on possible IPR (patentable inventions)
2	Identified specific patentable inventions or other IPR
3	Detailed description of possible patentable inventions. Initial search of the technical field and prior art.
4	Confirmed novelty and patentability; decided on alternative IP protection if not patenting
5	First complete patent application filed, Draft of IPR strategy done
6	Positive response on patent application; initial assessment of freedom to operate, patent strategy supporting business
7	Patent entry into national phase; other formal IPR registered
8	First patent granted, IPR strategy fully implemented, more complete assessment of freedom to operate
9	Patent granted in relevant countries, strong IPR support for business

Table 2: Intellectual Property Readiness Level Overview (KTH Royal Institute of Technology, 2012)

The first level only includes brainstorming about a possible patenting process. It gets clearer with level two, where patentable inventions are being identified. At the next level, the process is going more into detail with a full description of patentable inventions. This includes research about similar technology and prior art.

If the technology is confirmed as being novel and patentable, level four is reached. at the same time, it must be decided which alternative protection might be possible if patenting is not successful. Level five includes a complete application form for the patenting process as well as a concept for the intellectual property right strategy. The next level is reached if the patenting office approved it. Moreover, it must be clear how the patent strategy supports the business, and the team should assess whether the product might infringe other patents.

At level seven, it is necessary to reach out to the national patent office to apply for a national patent next to which other possible forms of intellectual property right (IPR) should be in process. Level eight is reached if the first patent is granted and the IPR strategy is finalized. In addition, the limits of the patent and its relation to other patents regarding limitations or overlaps are being explored. The highest level includes patents in all target markets and countries as well as a valuable support of the business through the IPR.

5.1.2 Manufacturing Readiness Level

The main function of the manufacturing readiness level is to show the maturity of manufacturing capabilities and whether they are managed effectively and efficiently. The connection to the technology readiness level is, in addition, quite clear: manufacturing processes will not reach high levels until the product development is almost finished and stable (DoD, 2018). All in all, the ten levels represent the manufacturing readiness presented in Table 3.

Level	Stage	Software Solution Description
1	Basic manufacturing implications identified	Identification of most important software components
2	Manufacturing concepts identified	Identification of necessary software elements and development processes through applied research

3	Manufacturing proof of concept developed	Validation of development concept through experiments in testing environment; limited functionality tested in experiment; processes for scalability identified
4	Capability to produce the technology in a laboratory environment	Supporting software systems & components identified; scalability risks identified; concept for scalability finished
5	Capability to produce prototype components in a production relevant environment	Scalability concept refined; critical interfaces and software components identified; cost model constructed
6	Capability to produce a prototype system or subsystem in a production relevant environment	Scalability processes defined, but still ongoing software changes; software prototype tested in different operational environments to assess scalability
7	Capability to produce systems, subsystems, or components in a production representative environment	Scalability approved; risks identified and actively managed; ongoing process development
8	Pilot line capability demonstrated; ready to begin low-rate initial production	Beta version for first clients; risks under control
9	Low-rate production demonstrated; Capability in place to begin full rate production	Software and processes improved according to beta test
10	Full-rate production demonstrated and lean production practices in place	Full scalability possible

Table 3: Manufacturing Readiness Level Overview (DoD, 2018)

The first level includes basic research about the manufacturing process and a focus on opportunities to fulfil the objectives (DoD, 2018). In case of software solutions, it is necessary to identify the most important software components, which are crucial to develop the system. These are specifically interfaces to other software, the user interface and the data basis. At the second level a first manufacturing concept is being identified through the help of applied research. This might be reached through studies, further analysis and approaches of different processes (DoD, 2018). Moreover, all needed software elements and development processes are being identified through applied research.

The next level consists of experiments, which validate the manufacturing concepts and through which it will be made clear which processes are possible and feasible (DoD, 2018). If the project aims to develop a software solution this stage includes the validation of the development concept through experiments in a testing environment. The project team also testes the software with limited functionality in an experiment and identifies processes to scale the solution.

To reach level four in manufacturing readiness, the product should already reach the same level at the technology readiness scale, because then it is possible to start the risk reduction phase, specifically scalability risks when it comes to software solutions (DoD, 2018). It includes the identification of required investments, possible manufacturing risks and cost drivers. Furthermore, systems and components, which may support the desired software solution are being identified and a concept describing and defining the scalability is being finished. The next level consists of the identification of possible manufacturing sources and the team's analysis of critical components, technologies and interfaces (DoD, 2018). The concept to scale the software solution is being refined and the project team is constructing a cost model.

At level six, the development of the manufacturing process is even further, the assessment of critical components or technologies as well as the producibility is completed and the team identified crucial supply chain elements (DoD, 2018). If the project is about a software solution, then the scalability process is being finished and defined, but ongoing software changes are respected. Moreover, a software prototype is being tested in different operational environments to assess scalability. The next level includes the performance of manufacturing processes in a production-like environment and the start of campaigns to reduce unit costs. The development of a production plan and quality objectives is being completed (DoD, 2018). In case of a

software solution, the scalability is approved at this level and possible risks are identified as well as actively managed while the development process is still going on.

Level eight marks the start of an initial low-rate production. At this stage, producibility risks do not have significant influence on the production anymore and the cost model is being updated with the results from the prototype production (DoD, 2018). Here, selected clients are able to use a beta version of the software to identify bugs and errors; meanwhile, all risks are under control and will not significantly change the outcome. Level nine demands an almost stable production system with only smaller improvements; tools, materials as well as manpower meet the necessary production schedule. The management of risks and possible issues is being monitored (DoD, 2018). The software solution and development processes are being improved according to the results of the previous beta test.

The last and highest level is matched if there is a full-rate production. Here, every part of the manufacturing process meets the necessary requirements and all processes are being reviewed for ongoing, smaller improvements (DoD, 2018). Regarding software solution, full scalability is possible at this point.

5.1.3 Integration Readiness Level

An innovative product or technology is only successful and useful if all components work together and it matches the environment. Integration is not only a process of combining all components but also creating a working system in the relevant environment. It begins with implementation and is completed with a validated and verified system. The assessment of the integration readiness is needed because the technology readiness level does not properly represent the risk of implementing a new product into an existing, mostly complex, system (Sauser et al., 2008). According to Sauser et al. (2008), the integration readiness level "is a systematic measurement of the interfacing of compatible interactions for various technologies and the consistent comparison of the maturity between integration points".

In order to capture the progress and assess the integration readiness a scale of nine levels shows the current status of a technology. Those levels are presented in Table 4. As this readiness level can be used for all kinds of products equally, no modification regarding software solutions is necessary.

Level	Stage
1	An interface between technologies has been identified with sufficient detail to allow characterization of the relationship
2	There is some level of specificity to characterize the interaction (i.e., ability to influence) between technologies through their interface
3	There is compatibility (i.e., common language) between technologies to orderly and efficiently integrate and interact
4	There is sufficient detail in the quality and assurance of the integration between technologies
5	There is sufficient control between technologies necessary to establish, manage, and terminate the integration
6	The integrating technologies can accept, translate, and structure information for its intended application
7	The integration of technologies has been verified and validated with sufficient detail to be actionable
8	Actual integration completed and mission qualified through test and demonstration, in the system environment
9	Integration is mission proven through successful mission operations

Table 4: Integration Readiness Level Overview (Sauser et al., 2008)

The first level of the integration readiness is reached, when a medium for integration has been identified, which allows further work on the technologies. Level two is completed if a certain approach leads to an interaction between the technologies; this stands for the integration proof-of-concept. As the integration process matures and moves on, technologies are even able to communicate in the same language with each other. Consequently, that marks the completion of level three (Sauser et al., 2008).

Level four requires a quality management checking whether the data sent equals the received data. In a next step, the development of the technologies move on to a point,

where it can control and maintain itself. One level further, the technology has the ability to specify exchanged information, label them and translate data structures from other systems to the own system (Sauser et al., 2008).

At level seven the integration process meets all requirements and is also verified. The next step includes an actual demonstration as a system in the specified environment. This last test shows any errors or bugs that might need corrections. At the highest level the final product has been integrated in the desired system and it is working successfully (Sauser et al., 2008). It is important that system-specific challenges like real-time issues, strict safety requirements or cyber protection standards are being overcome at this point.

5.2 Market Readiness Level

Having a great product does not necessarily mean it will be successful at the market. If the technology is state-of-the-art but the market is not, it is going to result in failure. It is necessary to transfer the value of the technology to the customer. Possible reasons for this value transfer may be lower costs, a higher performance or lower use of resources. However, one of the main difficulties is switching from the phase of 'early adopters' to the phase of 'market penetration' (Kobos et al., 2014).

In order to make the market readiness of an innovative technology measurable, a scale of ten levels is needed to make the degree of maturity visible. Table 5 provides a good overview on this topic. As this readiness level can be used for all kinds of products equally, no modification regarding software solutions is necessary.

Level	Stage
1	Unsatisfied needs have been identified
2	Identification of the potential business opportunities
3	System analysis and general environmental analyzed
4	Market Research
5	Target defined

6	Industry analysis
7	Competitors analysis and positioning
8	Value proposition defined
9	Product/service defined
10	Business model defined coherently

Table 5: Market Readiness Level Overview (Hasenauer et al., 2016)

At the beginning, market research must be conducted to identify potential market needs as well as a first product concept must be demonstrated to get a first glance of the final product (Muradovich, 2017). For the second level it is necessary to analyze the potential market even closer and define the requirements. It is crucial to speak to potential customers at this point to involve them early in the product development phase and match their needs (Muradovich, 2017). At the end of level two, potential business opportunities must be identified. The third level consists of a complete analysis of the system and the general environment. At level four, a coherent market research must be conducted. This helps finding any competitors, provides numbers about the market size and underlines special customer needs.

Level five is reached when the final targets of the project have been finalized. It is not only important to define the objectives of the product development, but also the goals for the time after the launch. At level seven, all main competitors are being analyzed and the team defines a strategy to successfully position the future product in the market. The next step includes a value proposition, which should match with the customer needs. At this level it is important to close the gap between the proposed or desired unique selling proposition (USP) of the project team and the expected USP of the customer. Additionally, it is necessary to focus on the absorption capacity at this point, as this might decelerate the market entry. The absorption capacity is defined as "the ability of a firm to recognize the value of new, external information, assimilate it, and apply it to commercial ends" (Cohen & Levinthal, 1990).

Level nine consists of a final product and service definition, which respects all market and customer information. The highest level has been reached if the business model has been finalizedHowever, in order to specify the market readiness even further and receive greater insight, the following four dimensions will be of support: competitive

supply readiness, demand readiness, customer readiness and product readiness. The following chapters provide greater insight into all of them.

5.2.1 Competitive Supply Readiness Level

Competition is always important but especially for innovative products it is necessary to keep the competition as far away as possible in order to keep the advantage. Usually, it is difficult to receive information about the progress of competitive solutions. Mostly it is only possible to receive insights through information trading. Von Hippel (1987) defines this as "the extensive exchange of proprietary know-how by informal networks of process engineers in rival (and non-rival) firms".

The competitive supply readiness level uses this informal information trading as well as free accessible facts and figures of the market to identify the advantage of an innovation over a competitive solution. It is divided into nine levels, which are presented in Table 6. As this readiness level can be used for all kinds of products equally, no modification regarding software solutions is necessary.

Level	Stage
1	Information sources for target market research identified
2	Sources for competitor observation identified
3	First ranking of important direct competitors done
4	IPR comparison ranking
5	Technological functional comparison ranking
6	Competitive target product physically evaluated
7	Competitive product-market fit evaluated
8	Innovation half-life evaluated
9	Plan for proactive countermeasures elaborated

Table 6: Overview Competitive Supply Readiness Level (ONTEC, 2021)

The first level starts with the identification of sources for research in the target market; these might be scientific papers, official statistics, interviews or articles. In a next step, trustworthy sources for the observation and analysis of competitors are being identified, whereas at level three, a ranking of the most important direct competitors based on the previous research is completed.

At level four, a ranking of IPR of the different solutions is being completed in order to compare protection of the own product with competitive products. Moreover, the team knows to what extent competitive products are patented or protected. In the next step, the technological functions of all known solutions have been ranked and are ready to be compared. If the project team is able to have a look at the competitive target product and evaluate it, level six is reached.

Based on the information of this evaluation a product-market fit of the competitive product can be performed, which marks level seven. In a next step, the project team computes the innovation half-life. The innovation half-life period describes the time span after which half of the competitive and innovative technology advantage over the closest direct competitor is gone (Hasenauer & Störi, 2007). At the highest level, a plan is available, that describes measures to defend the own position against the competition.

5.2.2 Demand Readiness Level

Having an innovative product is not a guarantee for a successful product. In fact, if no customers need the product it will fail. Hence, there must be a demand for a new, innovative product, otherwise it will be withdrawn from the market rather quickly.

In order to measure the need for a new product, Paun (2011) introduced the 'demand readiness level' measuring the maturity of the demand of an innovation in the target market. The scale includes nine levels, which are presented in Table 7. As this readiness level can be used for all kinds of products equally, no modification regarding software solutions is necessary.

Level	Stage
1	Occurrence of the feeling "something is missing"

2	Identification of a specific need
3	Identification of the expected functionalities for the new product/service
4	Quantification of the expected functionalities
5	Identification of the systemic capabilities (including the project leadership)
6	Translation of the expected functionalities into needed capabilities to build the response
7	Definition of the necessary and sufficient competencies and resources
8	Identification of the experts possessing the competencies
9	Building the adapted answer to the expressed need on the market

Table 7: Demand Readiness Level Overview (Paun, 2011)

At the beginning, the market recognizes that a certain technology is not available. The demand reaches level two, if a specific need has been identified and defined. One step further, at level three, more specifications of the technology are identified, which include the expected functionalities. If those functionalities are also quantified and hence, clearly explained and described, level four is reached.

In order to reach level five, the systematic capabilities need to be identified showing what might be possible for the technology. In a next step, the expected functionalities from market must be translated into the capabilities of the technology. This is already a big step towards the final product. At level seven, all necessary competencies and resources for the finalization of the product must be defined.

If the team identified the experts, which can execute the concept and have the required competencies, level eight is completed. One step further, at the highest level, the team is able to develop the desired technology serving the needs of the market.

5.2.3 Customer Readiness Level

Especially in B2B markets, customers and users are often not identical. Whereas users might see the need for a specific product, the customer in form of an organization or company is not ready to buy it yet, since the product might be too expensive or does not fit in the internal environment. This differentiates the customer readiness level from the previously described demand readiness level.

All in all, the customer readiness level consists of nine stages. They are presented in Table 8. As this readiness level can be used for all kinds of products equally, no modification regarding software solutions is necessary.

Level	Stage
1	Hypothesizing on possible needs in market
2	Identified specific needs in market
3	First market feedback established
4	Confirmed needs from several customers and/or users
5	Established relations with target customers and/or users
6	Benefits of the product confirmed through partnerships and/or first customer testing
7	Customers in extended product testing and/or first test sales
8	First products sold
9	Widespread product sales

Table 8: Overview Customer Readiness Level (ONTEC, 2021)

The first level is reached when the project team states hypotheses about the needs in the desired market. If they have been identified and specified these needs, level two is reached. In the next step, it is necessary to gather feedback from the potential customers about the product. This might in the form of interviews or surveys.

If the project team is able to confirm their claimed needs based on the feedback, level four is reached. During the product development phase, the relationship with target

customers must be strengthened and established. This provides ongoing feedback and possible first sales after finishing the product. In order to reach level six, it must be ensured that the benefits of the solution are confirmed through partnerships or a first testing at customers.

If it is possible to have first sales or the testing of the product with chosen customers is getting further, level seven is reached. One step further, at level eight, the sales are being increased and a smaller number of products are being sold. At the highest level, sales jump and the product finds many customers on the market.

5.2.4 Product Readiness Level

The product readiness level shows the marketability of a product and whether it can be launched at the market in compliance with the established norms and standards. The higher the level the easier it is to not only launch the software but also to establish it at the market with the goal of becoming the leader. All in all, there are nine product readiness levels, which are presented in Table 9. As this readiness level can be used for all kinds of products equally, no modification regarding software solutions is necessary.

Level	Stage
1	Target market identified
2	Markets segments defined; Lead users' needs defined; Competing products analysed
3	Plan for product options & extended product family formulated
4	Marketing plan developed
5	Promotion and launch materials developed
6	Field testing facilitated
7	Regulatory approval / certification obtained

8	Early production ramp-up products placed with preferred customers; Active Service & Support secured
9	Product promotion and market entry

Table 9: Product Readiness Level Overview (Hasenauer, 2017)

The first level starts with an identified target market, a mission statement and clear business goals for the project. At the second level the desired market segments are being identified, competing products are being investigated and lead users are being spotted. Moreover, the concept development is being started including the estimation of production costs, investigation of production or scaling feasibility and the selection of only one concept for the development. For the next level it is necessary to have a plan for possible product options. Furthermore, it is the phase of system-level design, which includes a make-or-buy analysis and the identification of key suppliers (Hicks et al., 2009).

In order to reach level four, a marketing plan is necessary and the product development should reach the detail design phase. Part of this is a control documentation, quality assurance processes and the definition of production or scaling processes. Level five starts the phase of testing and refinement, which will continue until level seven. It is obligatory to develop launch and advertisement material as well as pursue field-testing. At this level, the production or scaling and quality assurance processes are being modified and improved. Additionally, the sales plan is being completed and crucial certifications are being obtained (Hicks et al., 2009).

Level eight marks the production or scaling ramp-up and includes the launch of the product for preferred customers. Moreover, the work force is fully trained for all tasks and the manufacturing processes have already started. With the official product launch – the highest level – starts the product promotion, the full production or scaling as well as service and support (Hicks et al., 2009).

6 Methodology

This chapter provides a detailed overview of the selected study design, the study setting and study material. In order to acquire all necessary information to answer the research questions, a qualitative research approach has been used. Several

participants were part of problem-centred expert interviews, which were analysed through a content analysis.

6.1 Study Design

This thesis aims to use the T-RL/M-RL framework to evaluate the readiness of a software solution called AMPEL. Therefore, the needs of potential users has been looked at: the current project status has been analyzed and the willingness to use has been examined.

In the end, two main goals should be reached: a) having a clear view on the status of the project and where it needs additional development work as well as b) present a general guide for evaluating software solutions with the T-RL/M-RL framework. The second goal is especially important, as up to this point almost every application of the framework was connected to a physical product. However, as software solutions have a different development process and different requirements, the frameworks need some adjustments. These are presented in chapter four.

In order to reach the proposed goals, it is necessary to answer all research questions, which are presented in Table 10. Each research question further consists of various hypotheses. The information gathered during the interview process leads to accepting or rejecting the hypotheses, which in turn provide support to answer the research questions.

RQ1	How is the alignment between T-RL and M-RL at the AMPEL system?
H1	Technology and market readiness level have the same level.
H2	Technology and market readiness level are both at 10.
RQ2	How does AMPEL reflect ethical criteria?
H1	The product follows the rules concerning data protection.
H2	The algorithms and rules of the software are based on scientific research.

RQ3	Is the technology going to be accepted?
H1	The perceived usefulness will positively affect continuance intention to use of AMPEL.
H2	The perceived ease-of-use will positively affect continuance intention to use of AMPEL.
RQ4	Which criteria are of high importance during the purchase process of AMPEL?
H1	IT employees focus on integration, compatibility and support services from the supplier.
H2	Laboratory physicians and clinicians focus on usability, visualization and functional range.

Table 10: Overview of research questions and hypotheses

As shown in the table above, there are four main research questions, each of them with 2-3 hypotheses respectively. The first research question aims directly at the T-RL/M-RL framework and how the AMPEL system is positioned in it. The second research question is important for software solutions since ethical criteria play an increasing role in the development of them. Especially the topics data protection and science-based contents are crucial in this context as the AMPEL system works with patients' data and influences the patients' well-being. These two aspects are in line with the ACM Code of Ethics and Professional Conduct, which proposes the right of privacy and a high quality for processes and products (ACM, 2018). The third research question is connected to the technology acceptance model. This model states that the acceptance of software solutions is strongly influenced by the perceived usefulness and the perceived ease-of-use. If both are high, it is much likely that users accept the new technology (Davis et al., 1989). The fourth research question refers to the buying process of software solutions in hospitals. If the supplier knows the most important criteria of each stakeholder during the buying process, the selling process is likely to be more successful. Moreover, users will be more satisfied with the final solution as the producing company focuses on the respective key characteristics of the solution.

In order to gain enough information to answer all research questions, problem-centred expert interviews have been conducted. A problem-centered interview as such is

described as a dialogue, which focuses on the individual perspective, makes the gathered information comparable and can be used to build inductive or deductive theories (Döringer, 2020). Weitzel and Reiter (2012) define it "as a qualitative, discursive-dialogic method of reconstructing knowledge about relevant problems." The great advantage of problem-centred interviews are open questions, which allows the interviewer to receive wider view on the specific topic and interviewees can express their thoughts and expressions better than with given answer options.

As problem-centred interviews (PCI) are very flexible and can be used for a variety of situations, it is beneficial to conduct expert interviews using this approach. According to Weitzel and Reiter (2012) expert interviews "correspond[s] perfectly" with PCIs. According to Meuser und Nagel, experts are people who have "privileged access to information about [a] group of people or decision processes".

The analysis of the interviews is in form of a content analysis. As the first step, the answers of each interview group (clinicians, laboratory medicine, IT) have been summarized for each question of the interview guideline. In the following step, these summarized results have been used to define the T-RL and M-RL as well as to accept or reject the stated hypotheses and answer the research questions.

Finally, in order to aggregate the different levels of the sub-dimensions to one technology and one market readiness level in coherent way, the *infimum rule* have been used. Here, the pair of lowest levels of the sub-dimensions (T-RL / M-RL) have been used to define the overall technology or market readiness level (Rudin, 1976). For example, if the sub-dimension *Manufacturing Readiness Level* is at level three but the other sub-dimensions of the T-RL are at level nine, the overall T-RL will still be level three. This method is used, because it is not possible to neglect any sub-dimension, otherwise a market entry will not be successful. Exceptions of the *infimum rule* can be made, but they require an explanation.

6.2 Study Setting

The study has been conducted with several participants from five hospitals in Austria and Germany. As the study is completely anonymized it is not possible to provide the names of the hospitals. However, table 11 shows the size of them indicating that larger as well as smaller clinics have been part of the study. This provides greater insights,

since larger hospitals often have a larger IT infrastructure and different requirements compared to smaller hospitals.

Hospital	Houses	Employees	Beds
Hospital 1	1	➢ 250	➢ 150
Hospital 2	1	➢ 1.000	➢ 400
Hospital 3	2	➢ 800	➢ 300
Hospital 4	2	➢ 3.000	➢ 1.000
Hospital 5	1	➢ 7.000	➢ 1.800

Table 11: Overview of participating hospitals

The study included 12 expert interviews with participants from the hospitals presented above. As the AMPEL system influences clinicians, laboratory medicine and the IT, interview partners have been selected accordingly. As every participant has been in the respective field for several years, all of them can be seen as an expert according to the definition presented in chapter 5.1.

In total, every hospital provided three interview partners each: one expert from the clinical sector, one expert from the laboratory medicine and one expert from the IT. XANTAS AG, a member of the AMPEL consortium, helped in finding suitable interview partners. The entire interview process, however, was independent and not influenced by or in any way connected to the company. Additionally, members of the project team for the AMPEL system also have been interviewed. These interviews provided insights into the current project work and upcoming tasks. This is especially helpful to define the T-RL and M-RL.

In order to give a brief overview of all interviews, Table 12 presents the most important information. It is not possible to present any names as the responses are anonymous.

Interview	Organization	Place & Duration	Description of Interviewees
Interview 1	AMPEL	Phone call, 30min	Medical employee, defining and establishing rulebooks, clinical consulting

Interview 2	Hospital 1	Phone call, 30min	Assistant clinician
Interview 3	Hospital 2	Phone call, 30min	Head of IT
Interview 4	Hospital 2	Video call, 45min	Head of Gynaecology Department
Interview 5	Hospital 2	Phone call, 30min	Head of Laboratory Medicine
Interview 6	Hospital 3	Phone call, 30min	Head of Information and Communication Technology
Interview 7	Hospital 4	Video call, 20min	Head of Applications
Interview 8	AMPEL	Video call, 45min	Leader of the project
Interview 9	Hospital 4	Questions answered in writing	Laboratory Physician
Interview 10	Hospital 3	Video call, 30min	Head of Internal Medical Department & Head of Laboratory (one person)
Interview 11	Hospital 5	Phone call, 30min	Head of IT
Interview 12	Hospital 5	Phone call, 20min	Head of Laboratory
Interview 13	AMPEL	Phone call, 20min	IT employee, developing the system technically

Table 12: Overview of participants

The interview process also included three test interviews for each of the three categories: clinicians, laboratory medicine and IT. Therefore, three experts closely related to the AMPEL project have been selected and a simulated interview has been conducted. This helped to practice the interviews and improved details on the interview guidelines.

6.3 Study Session Setting and Material

Due to the restrictions of the corona pandemic, it was not possible to opt for focus groups or interviews in a face-to-face setting. Thus, all expert interviews have been conducted online via video call. To better focus on the respective interview, all of them were recorded and analysed afterwards.

All participants received the interview guidelines and information about the AMPEL system beforehand. The latter included a reference to the AMPEL website, a link to a short video explaining AMPEL and a sample of screenshots. Hence, all participants had a first glance at the interview topic and the AMPEL system. Additionally, before questions about the AMPEL system had been asked during the interview, all participants received a short explanation of the system including screenshots and the mentioned video. They could also ask questions beforehand to make sure they have a good understanding of the software.

For creating the interview guideline, the SPIN approach has been used. The SPIN approach stands for 'situation, problem, implication and need'. Developed by Neill Rackham in 1988, the SPIN selling methodology is aimed to help anticipation and navigation through tough selling situations (Rackham, 1988). However, this approach is also very useful to structure an interview guideline as it starts with rather general questions and gets closer to the actual topic question by question.

Within the situation phase, the researcher aims to collect facts and background data about the customer's existing situation. Within the problem section, the researcher must address questions which lead to the implied needs of the interviewee: problems, difficulties and/or dissatisfactions (Rackham, 1988). For the implication phase, the researcher has to address questions about the effects, consequences or implications of the customer's problems. In the last phase – the need –, the researcher has to focus on the value or usefulness of solving a problem. Therefore, the interviewee attention should be shifted towards the potential solution - and not the problem - in order to create a positive problem-solving atmosphere (Rackham, 1988).

The described setting and material lead to an optimized interview process, which results in high quality information for the research.

7 Results

The following sub-chapters present the results of the primary research, which has been described in the previous chapter. The results are based on a content analysis and structured by research questions. In order to make the results comprehensible, all findings are based on quotes from the interviews or content of published papers by the AMPEL project team.

7.1 RQ1: How is the alignment between T-RL and M-RL at the AMPEL system?

The main research question of this thesis gives an insight into the technological development of the software as well as showing the marketability of it. The results show the current level of the T-RL and M-RL for AMPEL. The first sub-chapter presents the results of the T-RL as well as the corresponding sub-dimensions, followed by a sub-chapter about the M-RL and the sub-dimensions belonging to it. The third sub-chapter discusses the hypotheses and answers the research question.

Technology Readiness Level

The technology readiness level shows the development status of a product. The higher the level the more sophisticated a product is technology-wise and the closer it is to being considered state-of-the-art. This phase is reached with level ten at the T-RL scale.

The analysis of AMPEL, which has been based on interviews and published papers, resulted in a T-RL of eight. The following table provides an overview and shows why the product reaches a high level but could not be at the maximum.

Level	Description	Proof of (not) reaching level
1	Scientific knowledge supports planned software solution	Analysis of data for severe potassium deficiency to check if alarming system is useful

2	Practical applications for desired software solution	Design of research/development concept for public funding
3	Limited functionality verifies crucial properties and predictions	Proof of concept through analysis of data for severe potassium deficiency
4	Main software components integrated and validated; testing environment defined and performance in it predicted	Regular software testing through simulation with clinical partners
5	Development of end-to-end software system meeting desired performance; successful test in testing environment; forecast for performance in operational environment	Regular software testing through simulation with clinical partners
6	Software test in operational environment	System in full use at University of Leipzig Medical Centre and Muldental Clinics
7	Prototype can be used for full-scale practical problems; software system partially integrated	System in full use at University of Leipzig Medical Centre and Muldental Clinics
8	Software system fully integrated and debugged; successful deployment in operational environment	System in full use but still not all tests are finished and more feedback required
9	Software system meets all required norms	No certification as medical device
10	Commercialization of software system through coherent business model	No business model

Table 13: Overview of T-RL-Analysis for AMPEL

The first level demands scientific knowledge that supports the planned software solution. This is reached, because the project team did an analysis with a set of data for severe potassium deficiency to check whether an alarming system would have a positive impact. The project leader said that they have "processed data for a severe potassium deficiency to see if an alarming system would increase the patient safety and it was like that" (Interview 8, 03.06.2021). These findings have been published in a research paper showing that the time until a potassium check has been reduced from 32.9h to 4.9h with the help of AMPEL (Eckelt et al., 2020).

The second level includes practical applications for the desired software solution. The project leader said during the interview that "the practical application has been discussed with our technical partner XANTAS. We came to the conclusion that an alarming system is feasible as long as we receive public funding. We received this funding from the Saxon State Ministry of Social Affairs" (Interview 8, 03.06.2021). The third level, which requires the verification of limited functionality, has also been reached in the early stages of the project. As described above, the project team proved the usefulness of AMPEL with an analysis of data for severe potassium deficiency. Eckelt et al. (2020) calls this the "proof of concept", which verifies the general properties and predictions of the system.

Level four requires the integration and validation of main software components. AMPEL reached this level due to regular software testing through simulation with clinical partners. The leader of the project told that they have "clinical partners always on board. We have them in discussion rounds, we ask them, we show them our retrospective analyses and simulations of our system to show them how it works. We discuss it with them and receive feedback about their requirements" (Interview 8, 03.06.2021). As this information also implicates successful tests in a testing environment and performance checks, level five is also completed.

The next level demands a test in an operational environment and level seven goes even further with a prototype to solve problems and a partial integration. Both levels are completed, because AMPEL is already in full use at the University Leipzig Medical Center (ULMC) and at the Muldental Clinics, as stated by the project leader, "the system is already fully used at the ULMC. Our clinical colleagues are very satisfied with the system" (Interview 8, 03.06.2021).

However, level eight has not been reached for now. This level requires a fully integrated and debugged system, which AMPEL has not completely reach yet. The

leader of the project told that they "are waiting for the results of the feedback forms now" (Interview 8, 03.06.2021). Additionally, another project member said that "at the moment every alarm gets checked whether it was correct. This extra check will be abrogated step-by-step" (Interview 13, 08.06.2021) This suggests that the system might still have some errors and bugs, which does not allow a T-RL eight.

In order to reach level nine - norms and certifications - the system needs the certification as a medical device. "Here, we are not very far. We have planned the next steps but cannot present a timetable yet", said the leader of the project (Interview 8, 03.06.2021). The results for the highest level - having a business model - are very similar. According to the project leader, there were first discussions about a future business model, but this topic still needs to be more thought-over and needs more discussions.

Intellectual Property Right Readiness Level

The intellectual property rights readiness level shows the patenting status of a product. The higher the level the more protection through patents and similar agreements has the product. The following table provides an overview of the analysis and shows the current level for intellectual property rights.

Level	Description	Proof of (not) reaching level
1	Hypothesizing on possible IPR (patentable inventions)	Project team knows about patentable aspects/components of the product
2	Identified specific patentable inventions or other IPR	Project team knows about patentable aspects/components of the product
3	Detailed description of possible patentable inventions. Initial search of the technical field and prior art.	No further analysis/action on patenting, because project team focuses on technology development and status as public research project limits patenting options

4	Confirmed novelty and patentability; decided on alternative IP protection if not patenting	See level 3
5	First complete patent application filed, Draft of IPR strategy done	See level 3
6	Positive response on patent application; initial assessment of freedom to operate, patent strategy supporting business	See level 3
7	Patent entry into national phase; other formal IPR registered	See level 3
8	First patent granted, IPR strategy fully implemented, more complete assessment of freedom to operate	See level 3
9	Patent granted in relevant countries, strong IPR support for business	See level 3

Table 14: Overview of IPR-RL-Analysis for AMPEL

The first level requires thinking and hypothesizing on possible patentable inventions. The AMPEL team did this as the project leader said "the public funding means that we are obligated to make our research and development accessible for others. However, we can use patenting for new rules or algorithms we develop after the research project has ended" (Interview 8, 03.06.2021). This shows that the team knows about the patenting options and rules and hence identified specific patentable inventions. This means level two is also reached.

Nevertheless, the public funding of the project limits the possibilities of patenting, as the project leader even said they "do not have any chance to protect the system" (Interview 8, 03.06.2021). Hence, the project team focuses on development and no further level on the Intellectual Property Rights scale can be fulfilled. Despite that, the leader of the project is optimistic and said that they "have a deep insight into the system and an advantage of a couple of years, even though the algorithms are being published" (Interview 8, 03.06.2021).

This situation also shows the limits of the Intellectual Property Rights Readiness Level, as it is not feasible for public projects. The legal limitations on patenting making this sub-dimension difficult to use. That is why it will not be considered to determine the overall T-RL.

Manufacturing Readiness Level

The manufacturing readiness level shows the production or, in case of software, the scalability status of a product. The higher the level the more advanced is the production or scalability process of a product. The following table provides an overview of the analysis and shows the current level for the manufacturing readiness.

Level	Description	Proof of (not) reaching level
1	Identification of most important software components	Team knows the important interfaces and technologies
2	Identification of necessary software elements and development processes through applied research	Design of research/development concept for public funding; proof of concept successful
3	Validation of development concept through experiments in testing environment; limited functionality tested in experiment; processes for scalability identified	Regular software testing through simulation with clinical partners
4	Supporting software systems & components identified; scalability risks identified; concept for scalability finished	Team works on scalability of software and knows requirements
5	Scalability concept refined; critical interfaces and software components identified; cost model constructed	Team works on scalability of software and knows requirements; risks/difficulties known

6	Scalability processes defined, but still ongoing software changes; software prototype tested in different operational environments to assess scalability	System in full use at ULMC and Muldental Clinics
7	Scalability approved; risks identified and actively managed; ongoing process development	If technical requirements are met software is scalable and useable in other hospitals
8	Beta version for first clients; risks under control	No first clients possible, because status as research projects does not allow it
9	Software and processes improved according to beta test	See level 8
10	Full scalability possible	See level 8

Table 15: Overview of MAN-RL-Analysis for AMPEL

The first level requires an identification of the most important software components. This is completed, because the project team knows about all necessary interfaces, technologies and the software content. "The system must have different interface formats, such as HL7 or FHIR. In general, it needs an extreme high connectivity", said the leader of the project (Interview 8, 03.06.2021). The project team also published a paper, which includes all necessary software components and how they interact with each other (Walter Costa et al., 2021).

The second level includes the identification of all necessary software elements as all as a development process through applied research. This is also completed by AMPEL as the team designed a research and development concept for the public funding and already finished the proof of concept successfully. The third level consists of validation of the development concept and the identification of processes for scalability. This level is reached as the project team tests the software with clinical partners regularly through software tests. According to the project leader, scalability is also part of the development. "In the end, the system must be transferable to other hospitals. Here, we also have to consider the infrastructure. I imagine AMPEL integrated into a patient information system or even better as a stand-alone solution" (Interview 8,

03.06.2021). This also suggests a concept for scalability and the necessary components and technologies. Hence, the fourth level is, too, completed.

The fifth level demands a refinement of the scalability concept as well as an identification of the critical interfaces and software components. This level is also completed, and the project team gives more insight into the necessary components in a recently published paper. Here, all "technical requirements and functional components" are described (Walter Costa et al., 2021). Level six includes a software test in different operational environments to evaluate scalability. AMPEL reached this level by having the software implemented at two clinics, which are participating in the research project: the University Leipzig Medical Center and the Muldental Clinics (Walter Costa et al., 2021).

The seventh level consists of an approved scalability and continuous product development. The leader of the project told that they "cannot implement the system in other hospitals, because it does not have the status of a medical device yet. If we implement it in another hospital, then only if it is part of our research project" (Interview 8, 03.06.2021). This suggests that it is possible to scale it while the product development is still ongoing. The statement also implies that the eighth level cannot be fulfilled yet, because first clients are missing as a result of the absent classification as medical device.

Integration Readiness Level

The integration readiness level shows the progress on integrability and compatibility of a product. The higher the level the better is the integration and compatibility with other technologies and systems. The following table provides an overview of the analysis and shows the current level for the integration readiness.

Level	Description	Proof of (not) reaching level
1	An interface between technologies has been identified with sufficient detail to allow characterization of the relationship	Team knows the important interfaces and technologies

2	There is some level of specificity to characterize the interaction (i.e., ability to influence) between technologies through their interface	Team knows the important interfaces and technologies
3	There is compatibility (i.e., common language) between technologies to orderly and efficiently integrate and interact	System in full use at two clinics and compatible with the technologies/systems there
4	There is sufficient detail in the quality and assurance of the integration between technologies	Colleagues checking alarms manually at the moment but full automation step-by-step
5	There is sufficient control between technologies necessary to establish, manage, and terminate the integration	AMPEL sends error messages and checks if everything is working by itself
6	The integrating technologies can accept, translate, and structure information for its intended application	AMPEL proofs data itself and structures it afterwards
7	The integration of technologies has been verified and validated with sufficient detail to be actionable	Extensive validation of the system was successful
8	Actual integration completed and mission qualified through test and demonstration, in the system environment	System in full use at ULMC and Muldental Clinics
9	Integration is mission proven through successful mission operations	System needs some more development work and feedback

Table 16: Overview of INT-RL-Analysis for AMPEL

The first level consists of an identified interface between the different technologies. This level is approved, because, as mentioned previously, the team already knows the important interfaces and technologies. This also fulfils the requirement of level two, which is more precise characterization of the important interfaces.

Level three demands compatibility between the different technologies for a good integration interaction. The system also matches this criterion because it is already in use at two hospitals and the use has been successful so far. This implies a good compatibility with the given systems in the respective hospitals. Level four demands sufficient detail in the quality and assurance of the integration between technologies. This is also fulfilled, as a team member said "right now every alarm is getting checked by colleagues, if it was necessary. But we cancel these extra assessments step-by-step" (Interview 13, 08.06.2021).

The fifth level includes a control between the used technologies. AMPEL also fulfils this level, because it was told during the interviews that the system sends error messages automatically and it checks itself whether everything is working correctly (Interview 13, 08.06.2021). The next level requires that the system can accept, translate and structure information by itself. This level is approved, since a team member said that "the system proofs the input data independently and structures it afterwards" (Interview 13, 08.06.2021).

Level seven includes a detailed validation of the integrated technologies. This level is also fulfilled, because AMPEL passed the performance checks. "The error messages are very low and were stable during the last year. All errors came from other systems and AMPEL just announced them. There were no errors because of system algorithms so far" (Interview 13, 08.06.2021). At the moment, the system updates itself every hour, but it could run even faster with updates every 15 minutes, however, the SAP system at the ULMC does not allow faster cycles. "This is not an issue, because for the current algorithms and set of rules faster cycles are not necessary", said a team member (Interview 13, 08.06.2021).

The eighth level consists of a complete integration through demonstration and test. This is completed, because AMPEL is already in full use at the ULMC and at the Muldental Clinics. The highest level, however, is not reached yet. It requires a proven integration through a successful mission operation. The project team is still waiting for the results of the feedback forms for the current live version of the system.

Market Readiness Level

The market readiness level shows the marketability of a product. The higher the level the better prepared is a product to get launched at the market and the stronger is the need for it. This phase is reached with level ten at the T-RL scale.

The analysis of AMPEL, which has been based of interviews and published papers, resulted in a M-RL of three. The following table provides an overview and shows why the product reaches only a lower level.

Level	Description	Proof of (not) reaching level
1	Unsatisfied needs have been identified	Project leader worked in both positions, clinician and laboratory physician, and thus their needs
2	Identification of the potential business opportunities	Experience of team leader; successful proof of concept; discussions with clinical partners
3	System analysis and general environmental analyzed	Discussions with clinical partners
4	Market Research	Discussions with clinical partners, but no further market research
5	Target defined	Target group is defined generally, target group analysis missing
6	Industry analysis	Market entry barriers known, no coherent industry analysis
7	Competition analysis and positioning	General knowledge about competition, no structured analysis
8	Value proposition defined	Value proposition defined but not tested with potential customers
9	Product/service defined	No final product definition

10	Business model defined coherently	No business model

Table 17: Overview of M-RL-Analysis for AMPEL

Level one includes the identification of unsatisfied needs. This is fulfilled, because the project leader has experiences as a clinician and as a laboratory physician and thus knows their needs.

> "Started working in the internal medicine but switched to the laboratory medicine. I had the fear that laboratory results are not reaching the clinicians in time. So, we have examined this with retrospective data for a potassium deficiency. It turned out that indeed there were cases, where patients did receive treatment too late, despite their critical situation. Based these findings we started the project and received public funding" (Interview 8, 03.06.2021).

This statement also proves an identification of a business opportunity. Hence, level two is also reached.

The third level consists of an analysis of the system and the general environment. This level is reached, because the team regularly discusses the development of AMPEL with their clinical partners and shows them simulations of the current system. This implies that the team has sufficient knowledge about it. The fourth level demands an extensive market research. This level is not reached yet, because the mentioned discussions with clinicians suggest that the team has some knowledge of the market. However, the project leader admitted that they did not do a systematic market research so far.

Level five requires a detailed target definition. The team knows about possible target customers, but they did not do a deep target analysis yet. Asked about possible target customers, the project leader said that the following:

> "[T]arget clinicians in hospitals in general. Also, outpatient clinics might be possible, but we probably have to modify our set of rules and algorithms. The size of the hospitals does not matter, even smaller clinics can benefit from the system, for example through the provided interpretations. We can also modify the system to regional or national guidelines, so an internationalization is also possible" (Interview 8, 03.06.2021).

Level six includes an industry analysis. The team already identified some market barriers but did not perform a systematic analysis so far. According to the project leader "SAP is an obstacle, because with a given SAP system it will be difficult to use AMPEL. Also, the diagnostical industry already has contracts with hospitals, which give them a strong argument. And we have to make sure, users accept our system" (Interview 8, 03.06.2021). Similar findings are for level seven, which requires a competition analysis. The project leader said that "no systematic competition analysis

has been performed yet. But we know where the other competitors are. We think that this is the right moment for such a system, with lots of interest but few competitors" (Interview 8, 03.06.2021).

The eighth level demands a defined value proposition, which has also been tested on customers. The team already has an idea about the unique characteristics of AMPEL but they did not test it so far. According to the project leader, the medical competence of the team and a high acceptance of the system are the most important advantages (Interview 8, 03.06.2021). Another team member added that the design as an open system, where users can modify and develop a lot on their own, is an additional crucial feature (Interview 1, 06.04.2021). Level nine and ten are also not fulfilled yet. Neither is the product in a final version, nor has the team a business model designed.

Customer Readiness Level

The customer readiness level shows acceptance to use and adopt a product. The higher the level the more likely it is that users and stakeholders will use the product in the desired way. The following table provides an overview of the analysis and shows the current level for the customer readiness.

Level	Description	Proof of (not) reaching level
1	Hypothesizing on possible needs in market	Experience of team leader; proof of concept
2	Identified specific needs in market	Experience of team leader; proof of concept
3	First market feedback established	Discussions with clinical partners
4	Confirmed needs from several customers and/or users	Discussions with clinical partners
5	Established relations with target customers and/or users	Discussions with clinical partners

6	Benefits of the product confirmed through partnerships and/or first customer testing	System in full use at ULMC and Muldental Clinics
7	Customers in extended product testing and/or first test sales	No first clients possible, because status as research projects does not allow it
8	First products sold	See level 7
9	Widespread product sales	See level 7

Table 18: Overview of CUS-RL-Analysis for AMPEL

The first level includes making hypotheses on needs in the market. This is fulfilled, because the team confirmed the concerns of delayed treatment for patients through a proof of concept and is in touch with the clinical partners through discussion rounds. This is also prove for completing the second level, which demands the identification of a specific need in the market.

The third level consists of an established marked feedback, which the team receives through their discussions with their clinical partners. This circumstance is also approval for level five and six, which are about confirming the proposed needs from customers or users as well as establish relations with them.

Level six includes confirmed product benefits through partnerships or testing with customers. AMPEL reaches this level, because the system is already in use at two clinics. The seventh level, however, cannot be fulfilled by the product yet. It demands extended testing with customer or first test sales. This is not possible at the moment, because AMPEL is still classified as a research project, which limits the number of users to the partners of this project. Hence, the other two levels, including product sales, cannot be completed.

Demand Readiness Level

The demand readiness level shows the actual need of a product. The higher the level the stronger is the need of the market and hence the more likely is a purchase of the

product. The following table provides an overview of the analysis and shows the current level for the demand readiness.

Level	Description	Proof of (not) reaching level
1	Occurrence of the feeling "something is missing"	Experience of team leader
2	Identification of a specific need	Successful proof of concept; discussions with clinical partners
3	Identification of the expected functionalities for the new product/service	Discussions with clinical partners
4	Quantification of the expected functionalities	Paper about AMPEL includes functionalities
5	Identification of the systemic capabilities (including the project leadership)	Paper about AMPEL includes systematic capabilities
6	Translation of the expected functionalities into needed capabilities to build the response	Paper about AMPEL includes needed capabilities, discussions with clinical partners
7	Definition of the necessary and sufficient competencies and resources	Paper about AMPEL gives insights
8	Identification of the experts possessing the competencies	Research consortium includes experts for medical content and technical requirements
9	Building the adapted answer to the expressed need on the market	Discussions with clinical partners and system in use at ULMC and Muldental Clinics

Table 19: Overview of DEM-RL-Analysis for AMPEL

The first level includes the feeling that there might be a need in the market. This is level is fulfilled, because it was mentioned previously that the project leader had the feeling for such a need due to his job experience. The second level, the identification of specific needs, is also completed by the AMPEL team. The successful proof of concept ahead of the project start and the ongoing discussions with clinical partners show the need. The ladder is also proof for level three, because it helps to identify the desired functionalities of the system.

The fourth level demands a quantification of the expected functionalities. The project team has published them in a paper recently. Here, they describe that the most important functionality is to send alarms if specific biomarkers are in a critical area or the treatment is not on time. The performance of the system will then be measured "as the time a notification takes to be delivered" (Walter Costa et al., 2021). The mentioned paper also delivers information to approve level five, the identification of system capabilities. It is described which input and output components are necessary, what information about the inference as well as which knowledge representation are given and which local computational infrastructure is covered (Walter Costa et al., 2021).

This content also proofs level six of the demand readiness level, because it gives an insight into the needed capabilities. Additionally, the discussion rounds with clinical personnel will also provide answers about the capabilities of the system. The seventh level consists of a definition of the needed competencies and resources. The team described these aspects in an earlier paper in which it is mentioned that the team needs the public funding to have a financial basis for the project and that the co-operations with the clinical partners support the development of the medical content but presents also information about the needed IT infrastructure (Eckelt et al., 2020).

Level eight - the identification of experts for the project - is also completed. Besides the mentioned clinical partners the consortium also includes the software company XANTAS AG, which is specialized in the development of clinical software. Moreover, the project team can be seen as interdisciplinary with computer scientists, clinicians and data analysts (Kaiser et al., 2020). The highest level, consisting of building a solution for the expressed market needs, is also fulfilled. AMPEL is already in full use at two clinics and the team receives feedback during the discussion rounds with the clinical partners.

Product Readiness Level

The product readiness level shows the marketability of a product and whether it can be launched at the market in compliance with the established norms and standards. The higher the level the easier it is to not only launch the software but also to establish it at the market with the goal of becoming a leader. The following table provides an overview of the analysis and shows the current level for the product readiness.

Level	Description	Proof of (not) reaching level
1	Target market identified	Target group roughly defined
2	Markets segments defined; Lead users' needs defined; Competing products analysed	Market segments roughly defined, lead user needs through use at ULMC and Muldental Clinics, competition known
3	Plan for product options & extended product family formulated	Product modifications and extensions/possibilities known
4	Marketing plan developed	No marketing plan
5	Promotion and launch materials developed	See level 4
6	Field testing facilitated	Test runs and full use at ULMC and Muldental Clinics; no level approval because previous level not reached yet
7	Regulatory approval / certification obtained	No certifications
8	Early production ramp-up products placed with preferred customers; Active Service & Support secured	See level 4
9	Product promotion and market entry	See level 4

Table 20: Overview of PRO-RL-Analysis for AMPEL

The first level includes an identification of the target market. As described previously, the project team already knows their target group and defined it roughly, a detailed target analysis, however, is not done yet. The second level consists of defined market segments, a lead user definition and an analysis of competing products. This level is fulfilled, as the project team provided information for all three aspects. According to the project leader, the market segments are smaller and larger hospitals in Germany, but an internationalization is possible (Interview 8, 03.06.2021). The users of the system at the two clinics, where the system is already rolled out, can be seen as lead users, because they receive all updates immediately and give valuable feedback. The competition is also known. The project leader said that "there are other similar systems, but they are at the very beginning. For example, there is a system without content. But a system without content is not ideal, because then you have to develop the rules on your own. This is not easy with limited resources" (Interview 8, 03.06.2021).

The third level, plans for product options and extensions, is also already completed. Walter Costa et al. (2021) describe that "the system is constantly being evaluated and extended and has the capacity for many more algorithms." Additionally, the team wants to include machine learning algorithms to alarm for complex diseases, like sepsis. The project leader said during the interview that they "are at the beginning with machine learning. We have an area under the curve of 0.9. A biomarker is not capable of this precision. This is a good starting position, but it would still mean that we have to send out 10 false alarms to detect one real one. This would harm the acceptance and lead to alarm fatigue" (Interview 8, 03.06.2021).

The fourth level - developing a marketing plan - is not completed by the team yet. As it is still an official research project, they focus more on development work. Therefore, level five, having promotion and launch materials, cannot be fulfilled either. The sixth level includes field testing, which can be seen as fulfilled, because the system is in use at two hospitals. However, the level cannot be checked due to the missing of previous levels.

Another missing part is the lack of necessary certifications, like the status as medical device. Therefore, level seven is not completed either. "We have planned the next steps in this case but do not have a concrete timetable", said the leader of the project (Interview 8, 03.06.2021). Level eight and nine are also still open, because product placements and promotions are not possible with an unfinished system.

Competitive Supply Readiness Level

The competitive supply readiness level provides insights on the competition for the product. The higher the level the better can the product team respond to any competitive actions and retain their market position. The following table provides an overview of the analysis and shows the current level for the competitive supply readiness.

Level	Description	Proof of (not) reaching level
1	Information sources for target market research identified	Rough knowledge about market and competition
2	Sources for competitor observation identified	Rough knowledge about market and competition
3	First ranking of important direct competitors done	Literature analysis about other CDSS
4	IPR comparison ranking	See level 3
5	Technological functional comparison ranking	See level 3
6	Competitive target product physically evaluated	See level 3
7	Competitive product-market fit evaluated	See level 3
8	Innovation half-life evaluated	See level 3
9	Plan for proactive countermeasures elaborated	See level 3

Table 21: Overview of COM-RL-Analysis for AMPEL

The first level consists of the identification of sources for a market research. The team has already a rough knowledge about the market and performed a literature research about clinical decision support systems, which is proof for a competition of this level (Eckelt et al., 2020). The second level includes finding sources to observe competitors.

This level can be seen as fulfilled, because the project leader mentioned information about the competition several times during the interview. He spoke about a system, which is similar but lacks content and he also mentioned the diagnostical industry as a possible threat.

Level three can also be seen as completed. It demands a ranking of direct competitors. As mentioned above, the performed two literature analyses about other CDSSs: one for CDSSs in 2019 and another for CDSSs in connection to laboratory medicine (Eckelt et al., 2020). Despite the fact that they did not rank them, it gives them a very good insight into the market and knowledge about direct competitors. However, all the other levels cannot be fulfilled, because the team lacks an extensive competition and a market analysis.

Answer for RQ1

The first research question asks for the alignment between the T-RL and the M-RL at the AMPEL system. The goal is to see the progress of the system regarding the technological development on the one side and the marketability on the other. Consequently, it is possible to see, where the team has to put more focus on before launching the product.

In order to support the answers to the first research question, two hypotheses have been proposed:

H1: The technology and market readiness level have the same level.

H2: The technology and market readiness level are both at level ten.

The analysis will show whether the proposed hypotheses can be accepted or rejected. As described in the chapter Methodology, the infimum rule will be used to calculate the overall T-RL and M-RL based on the respective sub-dimensions. The following table gives an overview of all readiness levels.

T-RL	IPR-RL	INT-RL	MAN-RL	M-RL	CUS-RL	DEM-RL	COM-RL	PRO-RL
7	2	7	8	3	6	9	3	3

Table 22: Overview of all Readiness Levels for AMPEL

In the end, AMPEL reaches a quite high technology readiness level (7), whereas the market readiness level is only at three. This leads to a rejection of both hypotheses. Neither are T-RL and M-RL at the same level, nor does AMPEL reach level ten at any of them.

Reasons for the relatively high T-RL are the strong focus on the development work by the team because they have still the status of an official research project. This, in turn, leads to open tasks for the market side. The team did not perform an extensive market and competition analysis yet, still misses a marketing plan and needs to do more work on positioning.

What needs to mentioned is the exception of the infimum rule at the technology readiness level for the intellectual property rights readiness level. AMPEL is only at level two, which would also decrease the overall T-RL to this level. However, this is not reasonable and would undermine the advanced development of the system. The IPR-RL was taken out of the calculation, because the received public funding and status as research project limits the opportunities for patenting of the AMPEL team. "The public funding means for us that we responsibility to make our results accessible for the public, so they can use and benefit from them", said the project leader (Interview 8, 03.06.2021). This also shows the limitation of the IPR-RL, as it is not feasible for public funded projects or any other projects with restrictions on patenting.

7.2 RQ2: How does AMPEL reflect ethical criteria?

The second research question looks at ethical criteria and whether they play a role in the development of AMPEL. Especially when working with data, and in the case of AMPEL with patient data, it is important to act responsibly. A study conducted in the United Kingdom found that over 60% of the adult population is not comfortable with using personal data to improve healthcare (Fenech et al., 2018). Hence, ethics and fairness are crucial for software development, especially in the health sector.

In order to support answering the research question, two hypotheses have been proposed:

H1: The product follows the rules concerning data protection.

H2: The algorithms and rules of the software are based on scientific research.

Both hypotheses were created with the help of the *ACM Code of Ethics and Professional Conduct* from the Association of Computing Machinery (ACM, 2018). The first hypothesis refers to principle 1.6, which states that computing professionals always have to respect privacy. The second hypothesis refers to principle 1.2, which is about avoiding harm. Here, the code says that "computing professionals should follow generally accepted best practices" (ACM, 2018).

Asked about the ethics, the project leader revealed some interesting information, and it became clear that AMPEL is developed in compliance with ethical guidelines. Before the project officially started, the team needed an approval of an ethical commission. The project leader told that "a project start was only possible with an ethics committee vote. We had to present our plans to an ethics commission and they made a risk-benefit-analysis. AMPEL is based on patient data and patients need to know what happens with their data. So, we follow the rules of the ethics commission, and we will also do that after finishing the research project" (Interview 8, 03.06.2021). Additionally, he explained that with the rules of medical devices other ethical guidelines are coming, which need to be respected. And finally, since the majority of the colleagues are clinicians, they have to follow the medical-ethical guidelines. This information is proof for hypothesis one, which is accepted.

AMPEL along with its underlying algorithms and rules is also developed according to scientific research. The team needs a lot of time to use the system for more diseases, because it evaluates the rules and algorithms carefully. The project leader said that they "evaluate very long before a set of rules is going live. For example, we want to include malnutrition, which is very complex and needs some time to be developed" (Interview 8, 03.06.2021). Walter Costa et al. (2021) additionally mentions that "each algorithm is carefully developed by a team of physicians, scientists and IT personnel (computer scientists, computer engineers, and bioinformaticians) under close consideration of literature as well as extensive practical experience." This information is proof for hypothesis two and therefore, accepted.

Consequently, both hypotheses are proved and accepted. It is obvious that the project reflects and respects all necessary ethical criteria.

7.3 RQ3: Is the technology going to be accepted?

The third research question focuses on the acceptance of the system. This is a rather complex topic, which is why the technology acceptance model is used to answer the question. This model states that the acceptance of software solutions is strongly influenced by the perceived usefulness and the perceived ease-of-use. If both are high, it is much likely that users accept the new technology (Davis et al., 1989).

In order to support answering the research question, two hypotheses have been proposed:

H1: The perceived usefulness will be high for AMPEL.

H2: The perceived ease-of-use will be high for AMPEL.

The conducted interviews with clinicians, laboratory physicians and computer scientists delivered information to accept or reject proposed hypotheses and consequently answer the research question, therefore, there was a focus on statements regarding the usefulness and ease-of-use of CDSSs during the interviews. Then, it has been compared with AMPEL to check whether the desired characteristics are already included or not.

At first, the results for the perceived usefulness of systems like AMPEL have been analyzed. The following table gives an overview of the different aspects stated by the interviewees and whether AMPEL offers them.

Aspects supporting usefulness of the system	AMPEL
Real-time communication	System able to update every 15min, but currently running on 1h-updates-cycles
LOINC codes	LOINC (Logical Observation Identifiers Names and Codes) codes are supported
Informational overview	Column with traffic light symbols and additional information about critical parameters provide informational overview

Unexpected results	AMPEL sends immediate alarm if critical situations are detected
Motivation for thinking	Interpretational support and triggered alarms support thinking process
Interpretational support	AMPEL offers interpretational support
Minimizing false alarms	Team focuses on minimizing them, especially false positives
Transparency	Team works on making algorithms clear to users and let understand them
Automated processes	Alarms are sent automatically through system

Table 23: Overview of perceived usefulness

The first aspect is **real-time communication**. Some interviewees told that this is an advantage, if the system offers a real-time communication. Other interviewees only said, the communication should be with the lowest time delay possible. This suggests that in this case a soft real-time is sufficient, which requires an answer of the system in a given time period and it is acceptable as long the response is in the tolerated time area (Wörn & Brinkschulte, 2005). AMPEL is able to perform like this, because, as one project member told "the system updates itself every hour, but it could run even faster with updates every 15 minutes. However, the SAP system at the ULMC does not allow faster cycles. However, this is not an issue, because for the current algorithms and set of rules faster cycles are not necessary" (Interview 13, 08.06.2021).

Another aspect is the ability of the system to **communicate via LOINC codes**. "The system should support LOINC codes, because this ensures a vast analysis", said a computer scientist (Interview 3, 04.05.2021). LOINC is short for Logical Observation Identifiers Names and Codes and is a universal code for medical terminology. It helps exchange data between systems and is used by several standards in the health care sector (LOINC, 2021). AMPEL supports this standard according to their website (XANTAS, 2021).

Having an **informational overview** is the next aspect for usefulness. It has been described that clinicians often need to look at different systems to find all necessary parameter and values for one patient. "Without an overview of all relevant information

clinicians must look at laboratory results, having critical values in mind and put this information into another system. Thus, errors can happen" (Interview 4, 04.05.2021). AMPEL offers such an informational overview through the additional column with traffic lights symbols (red, yellow, green). Additionally, the system also provides more information about the critical parameters with one click in the system.

The next aspect is **being informed about unexpected results**. This might be the most important criterion for the usefulness of systems like AMPEL. Especially in situations where patients do not show any symptoms of a certain disease clinicians might overlook critical parameter caused by an informational overload through the laboratory results. A laboratory physician said "I can imagine that a system like AMPEL might be very helpful when it comes to unexpected results. Results, which clinicians did not think of and might be overlooked" (Interview 5, 07.05.2021). AMPEL is designed for these situations, because it immediately informs clinicians via alarm when critical parameters are detected. However, unexpected results might also lead to confusion, especially when clinicians focus more on the possibility of a finding than on plausibility, which is connected to the theory of potential surprise (Derbyshire, 2017). It depends on the absorptive capacity of clinicians, because the higher that is the greater is the ability to understand the value of an information and use it for better outcomes (Cohen & Levinthal, 1990).

A similar aspect is the **motivation for thinking**. Clinicians are getting pro-actively informed about a critical situation and receive additional information from the system. Thus, they think more about the patient and the situation, which avoids fast, error-prone decision-making. One interview partner told that "clinicians must not follow the system, but they have a motivation to overthink their decision, which makes the process safer" (Interview 5, 07.05.2021). AMPEL support this aspect with the triggered alarms and the **interpretational support**. The ladder is, moreover, the next mentioned criterion by the interview partners. It has been said that "clinicians need to have all critical values in mind, hence support for the interpretation of biomarkers is necessary" (Interview 4, 04.05.2021). AMPEL offers exactly this functionality.

Minimizing false alarms is also an important factor for the perceived usefulness. Too many of them harm the acceptance and lead to an alarm fatigue. Several interview partners stated that false alarms would negatively influence the trust in the system. The team knows about this risk and works extensively on minimize them, especially the false positive rate. False positive alarms are generated, when the system sends an alarm, which, in fact, has not been an alarm. The other type of false alarms are false

negatives. In this case, the system does not generate an alarm, but it should have done so. The leader of the project said "it depends on the disease, whether we focus on minimizing the false positives or false negatives. However, in case of doubt it is best to concentrate on the false positives. Having a high rate of them would lead to alarm fatigue and people would be too much distracted from work" (Interview 8, 03.06.2021).

Another important factor is **transparency**. Users of the system want to know, how an alarm is triggered and how the algorithms and set of rules work. A clinician explained that "it must be transparent and comprehensible, how results and interpretations have been generated" (Interview 4, 04.05.2021). The project team knows about this issue and wants to be as transparent as possible. The project leader said "it is important to inform users about the background of the respective algorithms. Trainings and workshops are a crucial element in this case" (Interview 8, 03.06.2021).

The last aspect for the perceived usefulness is having an automated process. The system should work automatically, which means it should trigger and send alarms by itself without interference of another person. One interview partner explained "calling clinicians via phone if there is a critical value is a manual process, which is error-prone" (Interview 6, 25.05.2021). AMPEL sends all alarms automatically. As mentioned previously, all alarms are getting checked by the team at the moment, but this is just a check if the systems work correctly and these extra checks will be cancelled step-by-step. During this learning phase, the developers also have to consider how cumulative errors will affect the outcome. CUSUM procedures with V masks or parabolic masks might intelligently help to stabilize a potential loss of trust into the system (SAS Institute, 2021).

Next, the perceived ease-of-use will be analysed. The following table gives an overview of the different aspects stated by the interviewees and if AMPEL offers them.

Aspects supporting ease-of-use of the system	AMPEL
Highlighting important results	Column with traffic light symbols and alarms highlight results
Integration into clinical system	Integration proved through use at two clinics

Uniformity	Project team targets uniformity
Customization	Customization is only planned to a very limited degree
No additional effort	Users do not have to change their processes or systems, just have an alarm in case of an emergency
Easy to use	System only requires a few clicks to work
Pro-active communication	New AMPEL-column in system always available and AMPEL alarms the user actively

Table 24: Overview of perceived ease-of-use

The first aspect is the **highlighting of important results**. A clinician told that "users often face a lot of information and many of them are not necessary. Therefore, it might be helpful to highlight the important results" (Interview 4, 04.05.2021). Another interviewee added, "critical values should be highlighted to make it easier for clinicians" (Interview 5, 07.05.2021). This function is included in AMPEL through an extra column in the patient information system showing traffic light symbols: green, yellow and red. This provides an easy overview of any critical parameter. Additionally, the alarm is another factor to inform about the results.

The next aspect is the **integration into the clinical system**. This point has been mentioned by computer scientists as well as clinicians. One clinician told that "AMPEL is only useful if I do not have to click through many sub-layers. It makes sense, if I have my overview of the hospital ward and an extra button there to see the critical parameters" (Interview 4, 04.05.2021). This represents the aspect from a user's view, which computer scientists also care about but with the focus on the work of new integrations. "It is always the topic that you rather want to renew existing systems instead of using a completely new one. You might have fewer functionalities, but it is simpler" (Interview 6, 25.05.2021). AMPEL covers this requirement as it can be integrated in the patient information system and proved this by being in full use in two clinics at the moment.

The next two aspects are a bit contradictory. On the one side, users want to have **room for customization** in order to change the system according to their needs and behaviour. On the other side, they also want the **system to be uniform** and have the

same look on every device and at every time. One interview partner mentioned both aspects at once, when he said "it would be helpful, if I could change the frontend by my own. So, that I can make the system suitable for me and it would not be me who has to be suitable for the system. […] The system must be in the same look and structure everywhere I use it" (Interview 4, 04.05.2021). This suggests that a compromise might be necessary. AMPEL focuses more on uniformity and less on customization, because there is the fear of the development team that too many customizing options could harm the output of the system. The project leader explained "the acceptance could suffer from too much customizing. There might be some options for the visualization but only a few. Customization is always a bit problematic, when users turn off important settings or change the system in a way that is not working in the desired way anymore" (Interview 8, 03.06.2021). Another important factor in this context is the context-dependent memory, which is stating that people use memory target to recall specific information (Gruneberg & Morris, 1994). In this case, it would mean that users reach a better understanding of the system, when the frontend is looking the same on every device and in every situation, because then it is easier for users to work with it.

Another factor regarding the ease-of-use is the effort to use the system. The software should **not require introducing new time-consuming processes**. One interviewee told "clinicians mostly have their own, well-rehearsed processes. It must be implemented in a way that it demands very little extra effort to use it" (Interview 5, 07.05.2021). The system should be integrated in the existing processes, so users do not lose any time working with it. AMPEL respects that, because it is very easy to use and to be integrated into existing processes as well as clinical systems. According to the project leader, "the use for clinicians is very simple. They see the alarm and have more information with only one click. Then there is one more 'quit button' and with that they already use the system entirely" (Interview 8, 03.06.2021).

Next, users also want a system that is **easy to handle and to understand**. One clinician said that "input and processes must be designed easy to get the necessary information very fast" (Interview 4, 04.05.2021). A laboratory physician added, "the system must be easy to use and should not require a lot of time" (Interview 5, 07.05.2021). As stated above, AMPEL only requires a few clicks to work making the use very simple.

The last aspect is **pro-active communication**. Users want that the system informs them automatically, so they do not need the extra step of checking the system by

themselves very often. AMPEL offers this functionality by updating itself every hour and alarming the users immediately if a critical situation has been detected.

After analysing the different aspects for the perceived usefulness and perceived ease-of-use, it is possible to accept or reject the proposed hypotheses. The first hypothesis stated that the perceived usefulness for AMPEL is high. The findings show that AMPEL respects all stated aspects, therefore, hypothesis one is accepted. The second hypothesis stated that the perceived ease-of-use for AMPEL is high. The results show that AMPEL again respects all mentioned aspects, except customization. However, as this is only one out of seven factors, the hypothesis will be accepted. In the end, AMPEL has a high perceived usefulness as well as a high perceived ease-of-use. This will positively affect the technology acceptance.

7.4 RQ4: Which criteria are of high importance during the purchase process of AMPEL?

The fourth research question looks at the decision criteria for the purchase of systems like AMPEL. There is not much research about this topic so far, which makes it very interesting for all companies developing and selling software systems, especially CDSSs, to hospitals. The interviews with clinicians, laboratory physicians and computer scientists provided very good insights into the most important criteria for purchase decisions.

In order to support answering the research question, two hypotheses have been proposed:

H1: Computer scientists focus on integration, compatibility and support services from the supplier.

H2: Laboratory physicians and clinicians focus on usefulness, visualization and functional range.

These hypotheses help structuring the decision criteria. The following table shows the stated criteria for purchases structured by the categories of the hypotheses. Additionally, it is checked, which interview group named the respective decision criteria.

Category	Decision criteria	Computer scientists	Clinicians	Laboratory physicians
Integration	Integration into existing systems	x	x	
	Based on standards & latest technologies	x		
	Connectivity	x	x	
Compatibility	Working interfaces	x	x	
	No system changes necessary to work with AMPEL	x		x
	Requirements on data warehouse, user administration, etc.	x		
	Compatibility with operating system	x		
	Option for cloud	x		
Support services	Test phase		x	
	Support at implementation phase and afterwards		x	
Usefulness	Minimizing false alarms			x
	No additional effort to work with system			x
	Easy to use			x
	Real-time communication	x	x	

Functional range	LOINC codes	x		
	Documentation		x	x
	Interpretational support			x
	Literature references for interpretations		x	
	Customization		x	
	Uniformity		x	
Visualization	Important results highlighted		x	x
	Chronological sequences		x	
Others	References			x
	Size of supplier		X	
	GDPR conformity	x		
	Medical device regulation			x
	Key user	x		
	Costs for licenses	x		

Table 25: Overview of decision criteria

The table looks a bit overwhelming at first but going through the several categories one-by-one will help understand it and gives more insights into the purchasing process of hospitals. The first category is about integration, which in this context means bringing together the different sub-systems to have one aggregated system (Gilkey, 1960).

One important criterion in this category is the **easy integration into the existing systems**. This point as been mentioned by computer scientists as well as clinicians and has been described in the previous chapter. Users and stakeholders of the system

demand an easy integration, because it makes the use less complex, less time-consuming and cheaper.

Another aspect are **common standards and state-of-the-art technology**, which the system should be based on. A computer scientist said that "in general, it is about standards and interoperability when introducing new software. It is important that they support new technologies, for example FHIR. The systems should be state-of-the-art" (Interview 3, 04.05.2021). FHIR stands for Fast Healthcare Interoperability Resources and "is a standard for exchanging healthcare information electronically" (Health Level Seven International, 2021). The degree of integrability might also vary depending on the type and variety of data structures as well as the type of software configuration and programming language. Additionally, high modularity and easy coupling of modules increases contextual ease of use, which is also important in the application context of AMPEL.

Connectivity is an additional criterion, which also has been mentioned by computer scientists and clinicians as well. The ladder said that "the connection between systems is sometimes not given. Then I have to search for information in different systems, which is very circuitous" (Interview 4, 04.05.2021). One computer scientist said something similar, when he explained they "want to avoid that clinicians and other employees have to switch between systems to get all necessary information" (Interview 6, 25.05.2021).

The next category is compatibility. This is closely related to integration and defined as the ability of at least two system or software components to perform as wished while sharing the same environment together (Testing Standards Working Party, 2021). A very important criterion at this topic is **working interfaces**. One clinician said that it is important to know whether the interfaces are uni- or bidirectional. The former describes an informational exchange in only one direction, whereas the latter offers an exchange of data or information in both directions (IBM, 2020). A computer scientist added that "without working interfaces the usage is limited and it is getting more expensive" (Interview 7, 02.06.2021).

Another aspect of good compatibility is the situation that **users do not have to change systems to work with** AMPEL. This was mentioned by several interviewees. One interviewee said, as stated previously, that system changes tried to be avoided, because it would mean additional effort, which do not help in the complex and stressful clinical work. This leads to the next criterion, **requirements on data warehouse,**

user administration and more. The interviewees did not go more into detail, but it is obvious that new systems need interfaces and a toleration for common file formats in order to get used and being compatible with the given data warehouse or the user administration. Moreover, in one interview it became clear that a **compatibility with the operating system** is required, which was Windows in that case. "The system must be running on a Windows-server with an anti-virus-software. Furthermore, it must be possible to perform Windows-Updates" (Interview 6, 25.05.2021).

Lastly, the possibility of **running the system in the cloud** is not yet crucial but it might be a knockout criterion in the future. This is why, suppliers should consider an option for the cloud. One computer scientist said that in their hospital everything is still running on-premises. "Everything what can be run in-house should stay in-house" (Interview 6, 25.05.2021). Another computer scientist, however, had a different view on this topic. "I always try to think through the option of a cloud first. But still many cloud-projects do not start, because there are issues with data protection" (Interview 3, 04.05.2021). This is definitely an aspect, which needs to be closely watched in the future and where suppliers might gain a competitive advantage.

The next category is support services. This focuses on any additional support by the supplier during the implementation phase and afterwards. One important aspect is the possibility of **having a test phase**, which was mentioned by a clinician, too. "It is important to test the system in a smaller group first before it is getting enrolled in the clinic" (Interview 4, 04.05.2021). A laboratory physician added that "a new system needs to get tested first in order to validate it before it is getting used at the entire clinic" (Interview 5, 07.05.2021). These official tests are unavoidable for AMPEL as it is a hospital application and thus belongs to safety critical systems, which have to fulfil special legal requirements according to the medical device regulation (European Commission, 2021).

The other aspect is connected to this as users want **support during the implementation phase and even afterwards**. It has been expressed that "suppliers must provide help and an introduction to the system during the implementation phase. And there is also the question, if the supplier provides ongoing support during the use" (Interview 4, 04.05.2021). It has not been further explained, how exactly this support should look like, but it would be quite helpful in general to have a contact person in the beginning helping with upcoming errors and explaining the new system step-by-step.

The next category is usefulness. Here, the easiness of the handling of the system and the expected advantages play a role. One aspect is **minimizing false alarms**, which has been stated by a laboratory physician, who explained that "the only reason not to use AMPEL would be, in my opinion, too many false alarms, so that you cannot trust the system" (Interview 5, 07.05.2021). Additionally, the interviewees also told that the system should **not demand any additional effort to use it**. Especially for a CDSS, users expect to do not have any additional effort to work with the system. It should be integrated in their existing processes, so they do not lose any time using it.

Next, it is also important that the system is **easy to handle and to understand**. As mentioned in the previous chapter, users demand simple processes, which require only little extra time. Another aspect is real-time communication. As mentioned previously, some interviewees told that it is a benefit, if the system offers **real-time communication**. Other interviewees only said that the communication should be with the lowest time delay possible. As the project team also mentioned that a hard real-time is not necessary for all of their implemented algorithms, a soft real-time might be enough. It is not possible to state an exact time delay, which is acceptable for a soft time solution. However, one project member said that they have a delay of up to four hours currently due to the characteristics of the underlying SAP system, which is appropriate for the used algorithms (Interview 13, 08.06.2021).

The next category is functional range. Here, the focus is on the different features and functionalities a system offers. One important aspect is that the system must **use or tolerate LOINC codes**, in order to keep a standard and to be compatible with other systems. More information about this aspect has already been presented in the previous chapter. The next aspect is **documentation**. There are different explanations on this term to make it clear. One clinician said "it should be visible, who has looked at the information or alarm in the system. If only a younger, unexperienced clinician looked at it, it might need another look by an experienced colleague" (Interview 4, 04.05.2021). However, another interview partner mentioned in the context of documentation that "it would be good if the system would show the drug history of the patient" (Interview 10, 24.06.2021).

Next comes the **interpretational support** through the system. One interview partner said "clinicians need to have all critical values in mind. Therefore, support for the interpretation of biomarkers is necessary" (Interview 4, 04.05.2021). Several other interviewees also mentioned this aspect. Connected to this is the wish for **literature references for interpretations**. "If systems provide interpretation, it must have a

literature reference with a link to it, so I can check it and read more about it" (Interview 4, 04.05.2021).

The next two aspects are contradictory to some extent. It has been mentioned during the interviews that **customization as well as uniformity** are wished for. As described previously, these two factors are kind of going into different directions. The former asks for a system, where a lot of changes and modifications can be done by the users individually, whereas the ladder describes a solution being the same in every situation. This shows that there might not be one perfect solution for these criteria and users as well as suppliers have to make a trade-off at some point.

The next category is visualization, focuses and the actual look of the system as well as the design. Interestingly, only two criteria have been mentioned in this context. First, the **highlighting of important results**, so users can find them easier. It has been mentioned previously that users would like to have a support finding or indicating any important laboratory findings. Second, users would like to see the values of different parameters in a **chronological sequence**. It has been said that "it is helpful to have graphs showing the biomarker in a chronological sequence. In the given moment, I have to keep the different values in mind" (Interview 4, 04.05.2021).

The last category is called others, because these criteria did not fit to any other category, but they are still important during the decision process. One criterion mentioned is **having references**. One interview partner explained, "references are important, because you can talk to users about the system and you can have a first glance at it" (Interview 5, 07.05.2021). Another criterion directly **related to the company is the size of it**. Here, the number of employees is important in order to ensure that the supplier can handle the project and does not go out of business. One interview partner said, "if a supplier is too small, only one to three employees, it might be that the company does not exist for long, which is a risk for the software solution" (Interview 4, 04.05.2021).

Next comes the **GDPR conformity**. GDPR is short for General Data Protection Regulation and a European law on data protection and data privacy. This law is very strict and companies need to follow their guidelines closely in order to not get fined (GDPR, 2021). Another important aspect mentioned by the interviewees is the **medical device regulation**. This is an EU regulation aiming to ensure the health of patients and users through the use of any medical devices. The classification as a

medical device for many products in the healthcare sector is a requirement to be sold (European Commission, 2021).

Supporting or having **key users** is also a criterion for some hospitals. These are users, who are working the most with the system and have already a vast knowledge of it. They can function as intermediary receiving information from the supplier and share it with their colleagues afterwards. One computer scientist explained "it is best to have key users that are getting informed about all updates in workshops" (Interview 6, 25.05.2021).

The last criterion in this category is the **cost for licenses**. Pricing is always a factor and especially smaller hospitals do not always have the great investment possibilities like clinics of a bigger size. One interview mentioned "costs for licenses always play a role, especially for SAP" (Interview 6, 25.05.2021). It became clear during the interviews that SAP systems are more costly than other systems, which might decrease the willingness to pay and willingness to use.

After analysing the different decision criteria, it is possible to accept or reject the proposed hypotheses. The first hypothesis stated that the stakeholders - in this case computer scientists - who do not actively use the system, will focus more on criteria for a smooth integration, high compatibility and extensive support services. The table shows that, indeed, computer scientists mostly mentioned criteria from the named categories. They also named some other aspects, but the focus lies on the categories stated in the hypothesis. Therefore, hypothesis one is accepted.

The second hypothesis stated that the users - in this case clinicians and laboratory physicians - will focus more on criteria for usefulness, a good visualization and a wide functional range. The results show that many of the mentioned criteria belong to these three categories, but they also named a lot of other criteria for the rest of the categories. Therefore, the hypothesis is rejected.

Generally, it is interesting to see that users, too, see the importance of a good integration and support services. This might be the case, because both improves the performance of a system and leads to better user experience. The presented results give a good overview of the important decision criteria during the buying process of software systems in hospitals and gives an extensive answer to the research question. Unfortunately, the research was not deep enough to present a ranking of the decision criteria, in order to see the weighted importance of each aspect.

7.5 Results Discussion

In the end, the AMPEL system reaches a T-RL of seven and a M-RL of three. It became clear that the software is already far more developed technology-wise, but still needs more analyses and knowledge about the marketability. The reason for this might be that it is still a research project. Hence, the team sets the full focus on the target of this project, which is the development of a state-of-the-art CDSS with a lot of content. In order to reach the highest level at the technology readiness, the team needs to finish their tests at the two clinics completely and successfully. Moreover, the AMPEL system must meet all requirements for the necessary norms and certificates, especially the medical device regulation. Finally, the team needs to develop a business plan.

There is more work to do concerning the market readiness, which is currently at level three. The reasons for this are the relatively poor product and competitive supply readiness level. The team needs more research and analysis on the competition. Furthermore, they need to work on the marketability of the product, including marketing plans and promotion material. The knowledge about customers is already good, but more information and feedback from them regarding the final product is needed. In contrast to that, the demand readiness level is at the maximum, which shows that there is a need at the market. Consequently, the team needs to intensify the work on bringing the product to the market and learn more about the market and the competitors.

Apart from that, it became obvious that AMPEL reflects all necessary ethical criteria. In times where users are getting more concerned about intelligent software solutions it is an important factor to increase acceptance. Furthermore, it helps to protect the product from more strict future laws, which otherwise might harm the development or distribution.

AMPEL also shows a high perceived usefulness and perceived ease-of-use, which increases the possibility of technology acceptance. Especially the aspects of getting noticed about unexpected results and receiving a motivation for additional thinking are strong characteristics of the system. The only aspect, where the team might keep an eye on during the development phase, is customization. As described, there will be a compromise needed between customization and uniformity, in order to let users individualize the system without turning off any crucial functionalities.

In the end, the research also gives an overview of important decision criteria for the purchase of a software system for hospitals. These criteria should be considered by any company, that wants to sell software products to clinics. The wide range of factors also shows that buying processes are complex and many different aspects play a role for choosing a new system.

8 Conclusion

After presenting all results of the study it is important to provide some information about the managerial implications of the thesis and its limitations. Moreover, the research outlook includes ideas for further studies.

8.1 Managerial Implications

This work gives a lot of insight and information for companies working on software systems for hospitals, but also for any other company developing and distributing software solutions. The modified T-RL/M-RL framework can be used by any company to evaluate a new software solution. This framework is not limited to the healthcare sector and can be used for any software system. In connection with ethical criteria, it is a powerful model to prepare the market entry.

Moreover, the thesis showed that there is a clear need at the market for a CDSS. Almost all interview partners said that they would support a purchase of the AMPEL system. Additionally, the findings also show that users would most likely accept the AMPEL system. The information about the perceived usefulness and perceived ease-of-use also can be used to assess the acceptance of other software systems for hospitals.

Finally, the thesis gives a valuable overview of decision criteria during the purchase of new software solutions for hospitals. These are important information for any company operating in this market. The findings can be used to improve the own solution according to the criteria, which will also help users and stakeholders of the system buying better solutions matching their needs.

8.2 Limitations

This thesis aimed on assessing the technology and market readiness level for software solutions with an analysis based on AMPEL. Both, the analysis of software systems and their use in hospitals is rather complex. That is why this study has some limitations.

Regarding the interviews, there were only interview partners from Austria and Germany. Hence, the findings might differ in other countries, especially in countries, where the degree of digitization is very different. Moreover, a qualitative research method has been used, which is always subjective to some extent. The used content analysis aimed on reducing the subjectivity to the minimum but there will always be a bit left of it.

Another limitation is the focus on the AMPEL system. In order to set a focus, only one software system has been analyzed. The findings might differ when using another CDSS. Additionally, as AMPEL is currently still in development, there might be changes in the different readiness levels in the near future.

There is also some limitation to the analysis of the decision criteria. The findings only show a selection of various aspects, but do not give insights on the importance. So, it is not possible to say which criteria are most important and thus should get attention.

8.3 Research Outlook

The T-RL/M-RL framework is a quite new model and research about CDSSs or software systems in hospitals in general is not as advanced as in other sectors. That is why, this thesis could not cover all aspects and leaves a lot of room for future research. First, it would be important to see, how the presented T-RL/M-RL framework for software systems works with other software solutions, especially with products from other sectors. Second, it would be useful to perform an analysis on AMPEL again, once the system is distributed to the market in order to see if the results of this study supported a potential success of the product.

Another aspect is the purchasing process of software systems in hospitals. The thesis only presented a selection of decision criteria but did not show the importance of them and also did not give insight into the exact processes during a purchase at hospitals. Here, a detailed buying centre analysis would reveal more insight.

Furthermore, some information has been presented about the absorptive capacity and the assimilation gap in this thesis. However, it has not been very detailed, which leaves room for more research on this topic. It is very interesting to find out, if a big assimilation gap exists for clinical systems and which actions can be taken in order to tackle this issue.

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10 Appendix

A. Interview Guideline for Clinicians and Laboratory Physicians

1. Was ist Ihr Beruf und welche Tätigkeiten üben Sie dabei aus?
2. Wie läuft normalerweise die Kommunikation zwischen Labormediziner und Kliniker ab?
3. Wo sehen Sie Probleme bei der Kommunikation zwischen Klinikern und der Labormedizin?
4. Können Sie sich an eine Situation erinnern, bei welcher Informationen von der Labormedizin übersehen wurden? Wie kam es dazu?
5. Wie wird derzeit sichergestellt, dass es zu keinen Informationsverlusten zwischen Labormedizin und Kliniker kommt?
6. Erhalten Sie Unterstützung bei der Interpretation der Laborergebnisse?
    a. Falls Ja: Wie sieht diese Unterstützung aus? Wie zufrieden sind Sie mit der Unterstützung? Fehlt Ihnen etwas?
    b. Falls Nein: Wünschen Sie sich Unterstützung? In welcher Form?
7. Wie schwer ist es den Überblick über alle Patienten inkl. kritischer Laborwerte zu behalten?
8. Wie gut können Sie sich derzeit aus dem klinischen Informationssystem einen Überblick über ihre Patienten verschaffen? Was fehlt Ihnen hier am meisten?
9. Was würde Sie davon abhalten AMPEL zu nutzen? Warum?
10. Wo sehen Sie Schwierigkeiten beim Einsatz eines Systems wie AMPEL?
11. Können Sie sich an Situationen erinnern, in denen ein solches System geholfen hätte? (Beispiele geben lassen)
12. Kennen Sie bereits ähnliche Systeme?
13. Worauf legen Sie bei einem solchen System besonderen Wert?
14. Wie sieht ein Beschaffungsprozess für unterstützende Softwarelösungen / Module aus? Was sind die Entscheidungskriterien?
15. Sind Sie der Meinung, dass man sich auf ein solches System bei der Entscheidungsunterstützung verlassen kann? (z.B. Alarme falsch gesetzt (insb. false negative))
16. Sehen Sie Bedarf für ein System wie AMPEL? (Ja/Nein mit Begründung)

B. Interview Guideline for Computer Scientists

1. Was ist Ihr Beruf und welche Tätigkeiten üben Sie dabei aus?
2. Für welche Systeme sind Sie verantwortlich?
3. Wie läuft der Prozess in der Kommunikation zwischen Labormedizinern und Klinikern ab und welche Systeme sind dabei im Einsatz?
4. Wo sehen Sie Probleme bei der Kommunikation zwischen Klinikern und der Labormedizin, besonders hinsichtlich der verwendeten Systeme/Kanäle?
5. Wie wird derzeit sichergestellt, dass es zu keinen Informationsverlusten zwischen Labormedizin und Kliniker kommt?
6. Glauben Sie, dass die Labormediziner und Kliniker von einer Entscheidungsunterstützung bei der Interpretation der Laborergebnisse profitieren können? (Wenn ja, warum?)
7. Welche Schwierigkeiten treten bei der Integration unterstützender Systeme (Softwarelösungen / Module) in der Regel auf?
8. Wie lässt sich die Integration von unterstützenden Systemen vereinfachen/verbessern?
9. Welche Probleme treten oftmals mit den jeweiligen Herstellern der unterstützenden Systeme auf?
10. Welche Anforderungen muss ein System erfüllen, um bei Ihnen eingesetzt zu werden? (Kompatibilität, Wartung, Updates, etc.)
11. Was würde Sie davon abhalten ein System wie AMPEL in ihre bestehende Systemlandschaft zu integrieren?
12. Wo sehen Sie Schwierigkeiten beim Einsatz eines Systems wie AMPEL?
13. Kennen Sie bereits ähnliche Systeme?
14. Worauf legen Sie bei einem solchen System besonderen Wert?
15. Wie sieht ein Beschaffungsprozess für unterstützende Softwarelösungen / Module aus? Was sind die Entscheidungskriterien?
16. Würden Sie eine Beschaffung von AMPEL unterstützen? (Ja/Nein mit Begründung)

C. Interview Guideline for AMPEL Employees

1. Was ist Ihre genaue Aufgabe beim Projekt AMPEL?
2. Wie lauten Ihre Projektziele?

3. Können Sie bitte das Projekt AMPEL kurz erklären? Knowledge-based oder non-knowledge-based → Gibt es nur Regelwerke oder werden auch Ansätze von AI/ML hinzugefügt?
4. Weshalb wurde das Projekt AMPEL initiiert?
5. Wer ist die Zielgruppe von AMPEL? (Berufsgruppe, Land)
6. Was ist die USP von AMPEL? Was ist der einzigartige Wettbewerbsvorteil von AMPEL?
7. Wie ist der aktuelle Entwicklungsstand von AMPEL?
    a. Gibt es bereits ein MVP?
    b. Ist MVP bereits für die Krankheit „Kaliummangel" / „akutes Nierenversagen" einsetzbar?
    c. Wo gibt es derzeit noch Mängel? Und welcher Art sind die Mängel? (gesetzliche Anforderungen, technische Mängel, inhaltliche Mängel)
    d. Welchen Erfüllungsgrad hat MVP hinsichtlich der Zertifizierung als Medizinprodukt?
    e. Was muss noch entwickelt werden, bevor es von der Zertifizierungsstelle freigeben wird für den Verkauf an Kunden?
    f. Wann sollen potentielle Kunden das Produkt kaufen können?
8. Gibt es bereits ähnliche Systeme?
    a. Falls Ja: Welche Unterschiede gibt es zu AMPEL?
    b. Falls Nein: Woran ist eine Entwicklung bisher gescheitert?
9. Was sind die Ergebnisse der bisherigen Markt- und Wettbewerbsanalyse?
10. Inwiefern wurde das System bereits unter realen Situationen eingesetzt? Wie erfolgreich war dieser Einsatz?
11. Worauf muss geachtet werden, wenn man das System bei Kunden implementiert? (Wie kann man einem möglichen Assimilation Gap entgegenwirken?)
12. Wie einfach lässt sich AMPEL in bestehende Systeme integrieren und welche Anforderungen müssen die bestehenden Systeme erfüllen?
13. Wie wird die Qualität bei der Integration mit anderen Technologien sichergestellt.
14. Wie wird kontrolliert, dass die Integration immer problemlos laufen?
15. Kann das System eigenständig Informationen akzeptieren, übersetzen und strukturieren?
16. Inwiefern wurde die Integration zu anderen Technologien bereits validiert?

17. Wurde das Thema intrinsic safety (Eigensicherheit) mit ins Projekt eingebracht?
18. Wo sehen Sie Schwierigkeiten beim Einsatz des Systems? Welche Art von Schwierigkeiten? (Bedienung, legale Aspekte, Wartung, Nutzbarkeit, Implementierung in bestehende Systeme, Kompatibilität, Umfang)
19. Muss das Produkt spezielle Zertifikate oder Normen vorweisen bzw. einhalten?
20. Welche gesetzlichen Anforderungen muss das Produkt erfüllen?
21. Wie kann sichergestellt werden, dass die Kunden das System auch im vollen Funktionsumfang anwenden können?
22. Wie ist der aktuelle Patentstatus?
23. Was sind aus Ihrer Sicht Markteintrittsbarrieren?
24. Wie sieht das zukünftige Business Model aus?
25. Inwiefern berücksichtigt AMPEL ethische Standards und Richtlinien der Softwareentwicklung?