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3D-Printing Service Platform for Medical Applications

MASTER'S THESIS

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ABSTRACT

The present work was carried in the context of the "CAMed project (Clinical additive manufacturing for medical applications)". In the future, this research project shall enable the manufacture of patient-specific implants, models and surgical instruments in hospitals. A 3D-printing research center was set up as a part of the CAMed project, in which anatomical models and prototypes of implants and surgical instruments are already being produced. For this production, 3D-printers based on the additive manufacturing process are use. The aim of this work is to improve the ordering process for 3D-printed parts from the 3D-printing research center with the help of a software solution. The current "pen & paper" solution does not cover all used cases and is not embedded in the existing process, which is why a digital solution should improve the process. Above all, the special requirements for the medical application area should be taken into account. Clear and efficient communication and the transmission of both medical and technical requirements to the 3D-printing research center must be guaranteed. Particular attention is paid to the query of technical information, such as the mechanical properties, when ordering. Based on the process of the V-model, all requirements are first recorded, then a structure of the software is sketched and a prototype of the ordering software is created. Finally, to evaluate the software, a usability test was carried out with selected participants. The theoretical part of this thesis deals with the various 3D-printing technologies such as “material extrusion”, “photopolymerization”, “powder bed fusion” or the newly patented “Arburg Freeforming Process”. Furthermore, applications and supporting software products for 3D-printing in the medical field will be presented. An analysis of the mechanical properties of various polymers is given. The procedure of already existing online providers for 3D printing services is checked with regard to the order process and the information collected with it.

Ordering a 3D-printed component digitally has already proven itself in the usability test. It is planned to introduce the software in a timely manner and to continuously develop it further.

KURZFASSUNG

Die vorliegende Arbeit wurde im Rahmen des "CAMed-Projekts (Clinical additive manufacturing for medical applications)" durchgeführt. In Zukunft soll dieses Forschungsprojekt die Herstellung von patientenspezifischen Implantaten, Modellen und chirurgischen Instrumenten im Krankenhaus ermöglichen. Ein 3D-Forschungszentrum wurde im Zuge des CAMed-Projekts eingerichtet, in welchem bereits anatomische Modelle und Prototypen von Implantaten und chirurgischen Instrumenten hergestellt werden. 3D-Drucker, basierend auf dem additiven Herstellungsprozess, werden für die Produktion verwendet. Ziel dieser Arbeit ist die Verbesserung des Bestellvorganges der 3D-Druckteile vom 3D-Druckzentrum mithilfe einer Softwarelösung. Die aktuelle "pen & paper" Lösung deckt nicht alle Anwendungsfälle ab und ist im bestehenden Prozess nicht eingebettet, deshalb soll eine digitale Lösung zur Verbesserung des Prozesses führen. Dabei soll vor allem auf die speziellen Anforderungen hinsichtlich des medizinischen Anwendungsbereichs eingegangen werden. Eine klare und effiziente Kommunikation bzw. die Übermittlung sowohl der medizinischen als auch der technischen Anforderungen an das 3D-Druckzentrum ist zu gewährleisten. Ein spezielles Augenmerk liegt bei der Abfrage von technischen Informationen, wie z.B. den mechanischen Eigenschaften, bei einem Bestellvorgang. Basierend auf dem Prozess des V-Modells werden zuerst alle Anforderungen erfasst, dann ein Aufbau der Software skizziert und ein Prototyp der Bestellsoftware erstellt. Abschließend, zur Evaluierung der Software, wurde ein Usability Test mit ausgewählten Probanden durchgeführt. Der theoretische Teil dieser Arbeit befasst sich mit den verschiedenen 3D-Drucktechnologien wie „Material extrusion", „Photopolymerization", „Powder bed fusion" oder dem neu patentierten Verfahren „Arburg Freeforming Process". Weiters werden Anwendungen und unterstützende Software-Produkte des 3D-Druckens im medizinischen Bereich vorgestellt. Eine Analyse der mechanischen Eigenschaften von verschiedenen Polymeren wird angeführt. Weiters erfolgt eine Untersuchung der Vorgehensweise bereits existierender Onlineanbieter für 3D-Druckdienstleistungen hinsichtlich des Bestellvorganges und der damit erhobenen Informationen.

Ein 3D-gedrucktes Bauteil digital zu bestellen hat sich bereits beim Usability Test bewährt. Es ist geplant, die Software zeitnah eizuführen und ständig weiterzuentwickeln.

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ABREVIATIONS

3D-PRC	3D-Printing Research Center
APF	Arburg Plastic Freeforming
CAD	Computer Aided Design
CAMed	Clinical Additive Manufacturing for Medical Applications
CT	Computer Tomography
DED	Direct Energy Deposition
ERM	Entity–Relationship Model
FDM	Fused Deposition Modeling
IICM	Institute of Interactive Systems and Data Science
MUG	Medical University of Graz
PEEK	Polyetheretherketon
PLA	Polylactide
RE	Requirements Engineering
SLM	Selective Laser Melting
SOP	Standard Operating Procedure

1 Introduction

This thesis was conducted in close cooperation with the Medical University of Graz (MUG). The basic task of this thesis is to provide technical support of a medical project, to create a new digital application for ordering 3D-printed parts from the 3D-printing research center (3D-PRC) and to evaluate specific requirements for the application in a medical environment. The following introduction briefly explains the CAMed project and lists the involved partners. In addition, the motivation for for this work including the problem statement and objectives is shown. The applied method to reach the objectives is briefly introduced.

1.1 CAMed Project

A few years ago, MUG started to investigate the possibilities of producing 3D-printed implants at the point of care with a project called “iPrint”. “iPrint” has already impressed several commissions, which resulted in three awards:

- Science2Business Award der life science Karriere Services (2016)
- Fast Forward Award der Steirischen Wirtschaftsförderung GmbH (2016)
- Science & Business Award des Rudolf Sallinger Fonds (2017)

Following the success of “iPrint”, the CAMed project started in December 2018 with the goal of integrating a 3D-PRC at point of care for the in-house production of cranial implants. (CAMed-Project, 2020)

The vision of the CAMed project is as follows:

„A patient is lying on a surgical bed in a futuristic operating room, having recently been scanned by a cluster of sensors overhead. Across the room, a 3D-printer puts the finishing touches on a custom implant that was designed by the patient's surgeon, who used the scan results to modify a 3D-blueprint downloaded from the internet. When the device is finished printing, the surgeon implants it using surgical instruments 3D-printed for that specific procedure. At the conclusion of the surgery, the doctor discards the used instruments in a special bin for materials to be recycled for future 3D-printing use." (Pomager, 2014)

In the CAMed project, customized implants are jointly developed and manufactured by medical scientists, clinicians, engineers and various industrial partners. Both medical professionals and their patients will benefit from the enormous advantages of clinical

3D-printing in the future. Additive manufacturing in this area of medicine is the main goal of the project. (CAMed-Project 2020)

13 companies and 5 scientific partners form a cooperation network want to optimize 3D-printing in the clinic in order to offer patients the best possible care. Two areas, each with six individual projects, test 3D-printing technologies and materials in different areas of medicine. The structure of the CAMed project is as follows: Two large areas, each with six individual projects (Figure 1), concentrate on different medical areas. In the various areas, 3D printing technologies as well as existing and newly developed materials will be tested. (CAMed project, 2020)

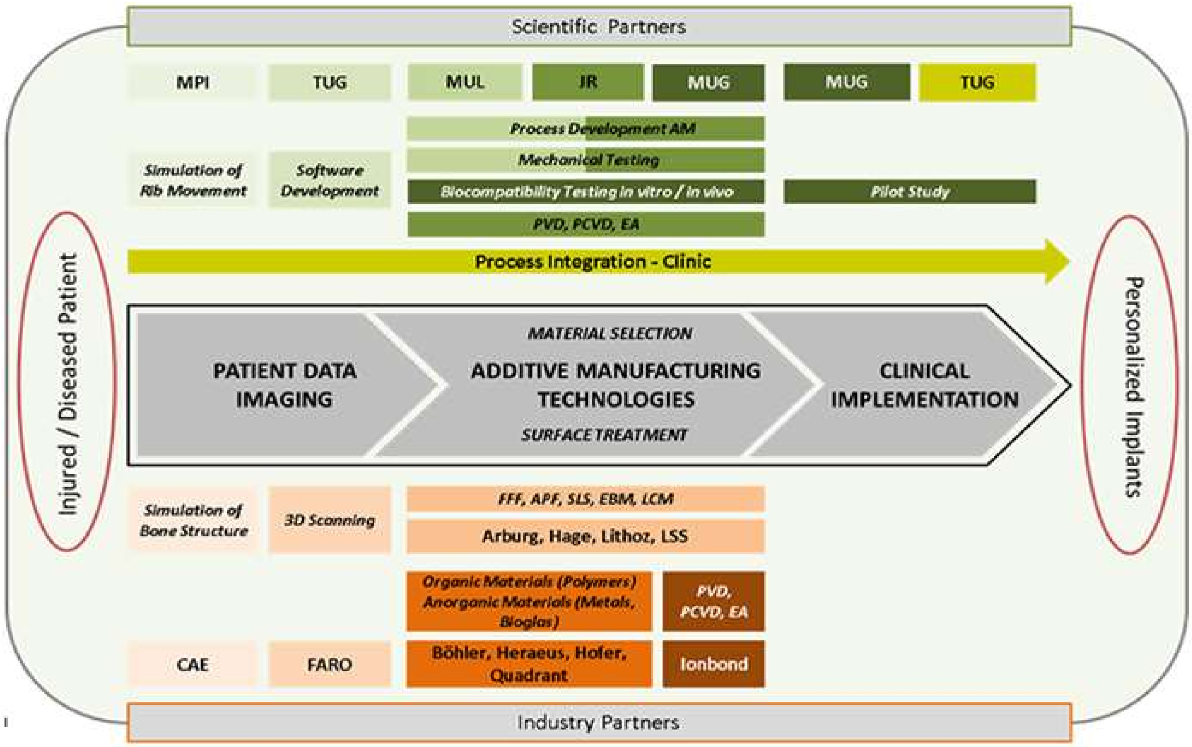


Figure 1: Overview CAMed-Project, Source: CAMed-Project (2020).

CAMed has set itself the goal of setting up a medical 3D PRC directly at the MUG. There, patient-specific implants, prostheses and various tools are to be printed on site. (CAMed-Project, 2020)

CAMed
Clinical additive manufacturing for medical applications

Figure 2: Official project logo "CAMed", Source: CAMed-Project. (2020).

Table 1 describes the key-persons on the project with their respective tasks and departments.

Profession	Role in the Project	Institution/Department
University Professor	Project Manager	Medical University of Graz/ Department of Neurosurgery
Project Assistant and Coordinator	Project Assistant and Coordinator	Medical University of Graz/ Department of Neurosurgery
Doctor of Neurosurgery	Medical Contact Person	University Hospital Graz and Medical University of Graz /Department of Neurosurgery
PhD-Student	Process Development and Supervisor and Advisor of Master Thesis	Graz University of Technology/ Institute of Engineering and Business Informatics
Student of Mechanical Engineering	Introduction of a 3D-Printing Service Platform for Medical Applications	Graz University of Technology/ Institute of Engineering and Business Informatics
Student of Software Engineering and Management	Software Implementation	Graz University of Technology/ Student of Software Engineering and Management
PhD-Student	Material and AM Specialist	CAMed-Project Member/ Department of Neurosurgery
Development Engineer and Additive Manufacturing	CAMed-Project Member	CAMed-Project Member/ Department of Neurosurgery
Software Developer	Design of automatic implant reconstruction software	Graz University of Technology/ Institute of Computer Graphics and Vision
Certificated Health and Hospital Nurse	Clinical Contact Person	University Hospital Graz/ Department of Neurosurgery
Head and Chair of Department	Clinical Contact Person	Medical University of Graz/ Department of Neurosurgery

Table 1: Key project functions of “CAMed”, Source: own illustration based on CAMed-Project (2020).

1.2 Problem and Motivation

One of the first steps in the project was establishing a 3D-PRC in the hospital which made it possible to manufacture printed parts at the clinic for the first time in Graz (MUG). Many surgeons, clinic staff and the customers in the CAMed project were interested in printing tools and special components. The 3D-PRC is a point of contact for a large interest group. The first step of the manufacturing process of a 3D-printed part is to submit an order request. The current order situation for printed parts is not up-to-date and a new software should therefore be developed for this. The structure of this software is difficult to choose because the subject is so extensive. It is difficult to find the right terms to receive the required information from the customer through simple questions. It is also challenging and difficult to get informative details from the customer and at the same time avoiding too many complex questions during the query. The customer should be able to order without additionally contacting the provider, but still be able to reach out and receive support if any problems arise. Another challenge is to meet the high demands of data security, especially if the software should be accessible from anywhere by anyone.
So, if you currently want to order a component from the 3D-PRC, you have to fill out a basic order form (Appendix 1) and place the order at the 3D-PRC in form of a hardcopy. This process is shown in figure 3. This order form was made at the beginning of the project by the project manager in cooperation with the technicians from the 3D-PRC as a first draft (CAMed-Project, 2020).

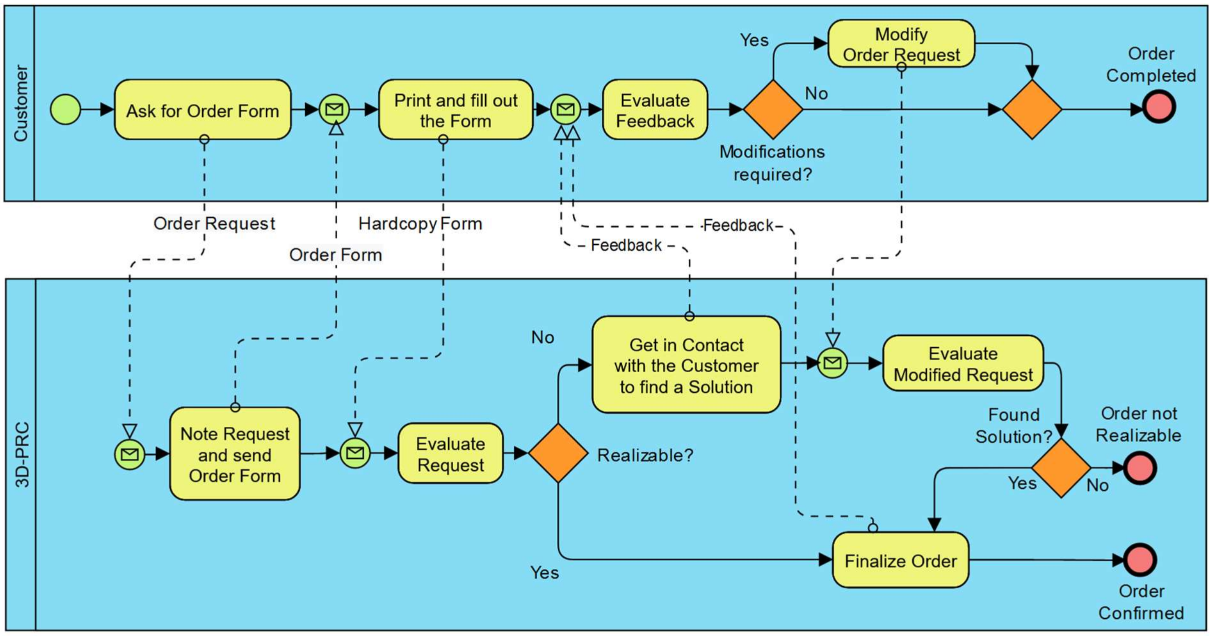


Figure 3: Overview of the current order process, Source: own illustration.

Problems with the current system can arise if the hardware form has to be obtained, filled out and then sent back to the 3D-PRC by the interested party. These problems can lead to various errors such as forms filled out insufficiently or misplaced forms. Furthermore, unreadable handwriting can lead to further problems in the order process. The 3D-PRC does not produce standard products and depending on the application, different aspects are important to note when placing an order.

The following case study should lead to a better understanding of why a question path is of many advantages:

A surgeon wants to order a model of a bone fracture for preoperative preparation. Questions regarding sterilization, mechanical properties or the medical risk class would not be necessary for this application. However, when requesting a cranial implant, this information is absolutely necessary. A static query cannot distinguish the applications and could lead to irrelevant questions which could be misleading.

To improve this situation, an enhanced digital order handling process shall be implemented. This should make it easier to find the form, create better communication between customer and 3D-PRC, offer better quality and the possibility of tracking the order. In addition, every client shall be lead through a question path which results in a customized order form. Using this question path, a distinction can be made between the various applications in order to only ask relevant questions.

1.3 Objectives

In order to simplify the ordering process and minimize errors and problems, a digital order request can be a good solution. A web-based application should be created, where customers only have to answer relevant questions for ordering 3D-printed medical parts. The guidance should be based on the previous selections. Relevant information and terms for medical applications should be shown. A predefined query would be well suited for this. The ordering process should be transparent and traceable. All relevant information should be queried and thereby prevent repeated inquiries and iterations. The query should collect all information that is necessary for the respective application so that the 3D-PRC can work optimally and can manufacture the ordered component in the desired quality. All the data from the orders should be stored in the sense of traceability and thus also enable further statistical evaluations and continuous process improvements. The statistics could range from evaluations of the most frequently used print materials to orders from different departments. The digital solution should improve the overall order handling process. This future order process, which shall be implemented via a digital solution, is shown in Figure 4.

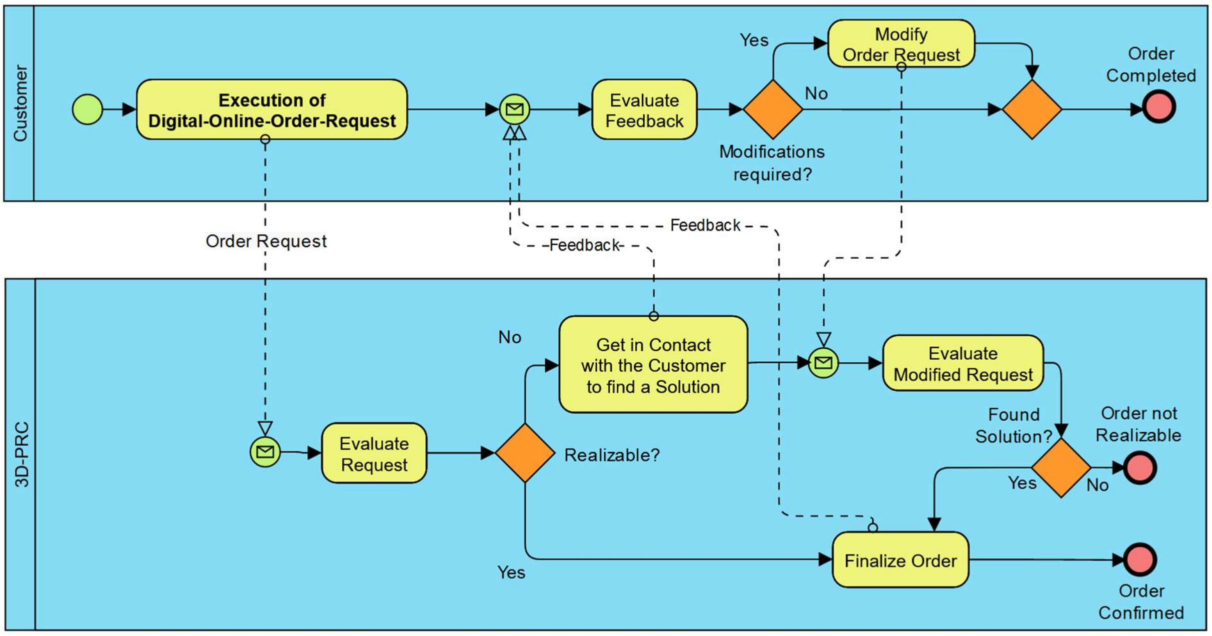


Figure 4: Overview of the planed order process, Source: own illustration.

Table 2 shows a list of advantages to the digital solution.

+	The request form is always available and does not have to be sent, downloaded or printed
+	Better documentability and traceability
+	Easier to expand and create statistics
+	Easier to request even for external parties
+	Less bureaucracy may be time saving
+	Improved guidance, showing only relevant questions depending on previous selections
+	Updates take immediate effect, no risk to use outdated forms

Table 2: Advantages through digitalisation, Source: own illustration.

In addition, digital solutions can also be used as a web application. In contrast to traditional software that is installed on a PC or a local server, web applications have many advantages. They work on any platform and on any device with any browser. In contrast to conventional software, a web application does not require any additional installations on the user's computer, which vastly increases the conformity of web applications and enables a high degree of platform independence. Changes to web applications can be made quickly and only need to be added once on the web server. Of course, all security requirements, such as data security, must be taken into account.

1.4 Structure of the Thesis

For good comprehensibility, this master's thesis is divided into a theoretical and a practical part.

a) Theoretical Part:

At the beginning, 3D-printing in general and 3D-printing technology processes are discussed. The focus lies on Fused Deposition Modeling (FDM). Medical 3D-printing will be the following topic, particularly the production of 3D-printed implants. After that, a short overview of current 3D-printing service providers is given. The end of the theoretical part is about product development, including topics such as “Requirement Engineering” and “Usability Testing”.

b) Practical Part:

After acquiring the theoretical knowledge, the first part of the practical part describes the various steps towards implementing a digital order handling process. A first prototype of the ordering software was made and tested by various potential users.
The second part focuses on simplifying the communication between the customer and the 3D-PRC in an order process.
For example, information about the mechanical properties of a printed part is used. In this way, research results on the mechanical properties of 3D-printed components are presented. The practical part will end with a conclusion that contains the results and the current limitations. Finally, an outlook on how to improve the processes is given.

2 3D-Printing Technologies

This chapter deals with 3D-printing in general. Starting with a short introduction to the history of 3D-printing, followed by various 3D-printing processes and the topic of medical 3D-printing. The mechanical properties of 3D-printed parts and service providers are presented in more detail.

2.1 History of 3D-Printing

The 3D-printing technology was developed for rapid prototyping in the early 1980’s and is based on stereolithography. The objective was to shorten the development time by analysing the product parameters in the product development phase. Today there is a wide variety of materials and 3D-printing technologies that are also used in rapid manufacturing and rapid tooling. The principle of 3D-printing lies in the layered construction of a three-dimensional object by physical or chemical melting or hardening of one or more materials. Based on a digital model, an object is created by building it up layer by layer. In contrast, milling or drilling are subtractive manufacturing processes in which material is removed mechanically using shaping tools. The printing processes differ in many aspects, both in terms of the printing technology and in the selection of the material. (Feldmann et al., 2016)

2.2 3D-Printing Processes

An overview of different 3D-printing processes is given in figure 5. There are seven groups with different manufacturing principles and materials. Each process is described in the following.

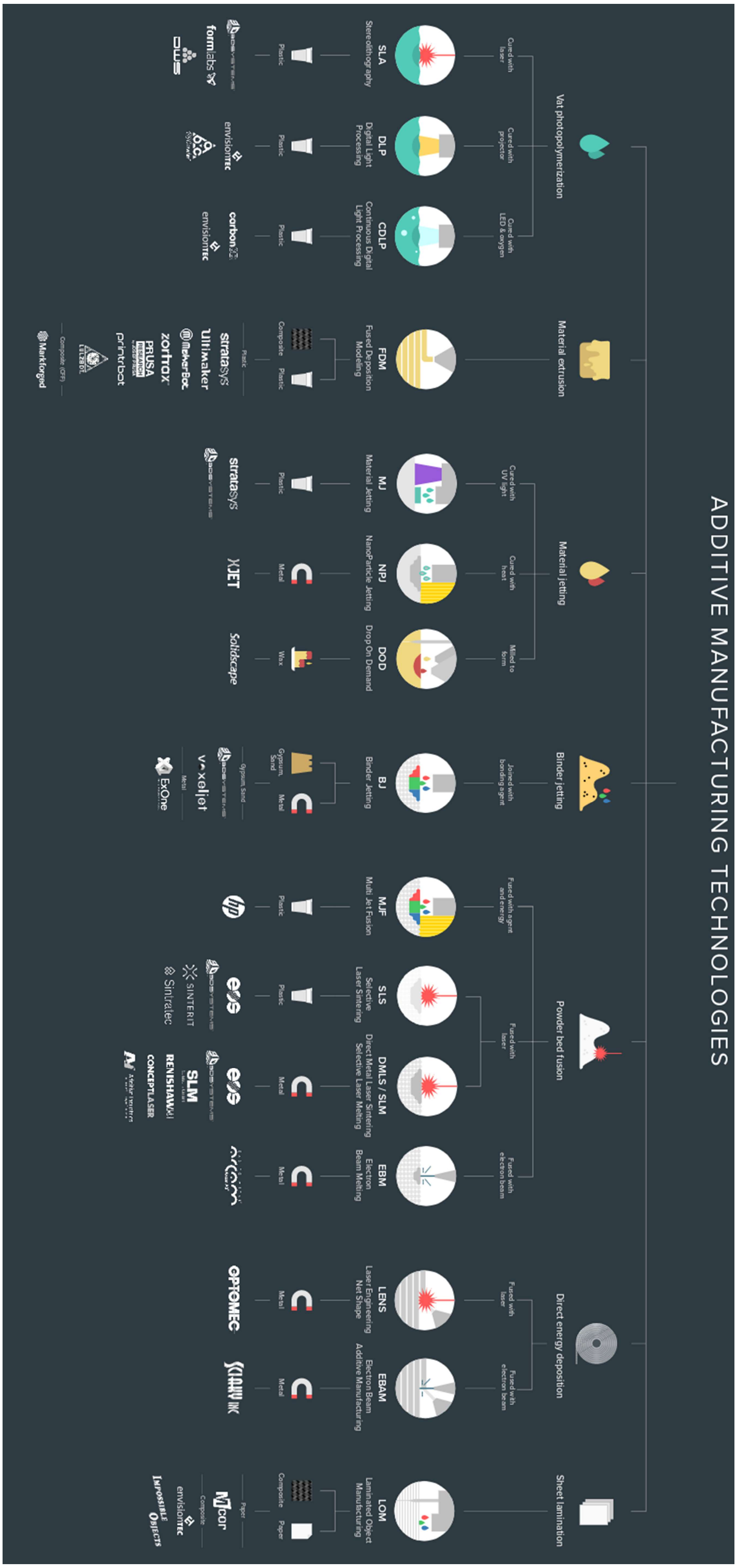


Figure 5: Overview of printing technologies, principles and materials, Source: (XTREMEengineering, 2016).

Photopolymerization:

In the process of photopolymerization, photopolymers, radiation-curable or liquid resins are used as primary materials. Radiation in the ultraviolet (UV) wavelength range causes most photopolymers to react. For this reason, systems are also used that react to visible light. When exposed to radiation, these materials react chemically and become solid. This reaction is known as photopolymerization and is typically complex, involving many chemical participants. (Gibson et al., 2015)

Material Extrusion:

A filament is printed by a heated print head and the thinnest layers of molten plastic are applied to a printing plate.

The part grows after each layer. This principle can be compared to a hot-melt gun. (Feldmann et al., 2016)

Material Jetting:

This process works by grinding up the material into a fine dust, up to the point where it is at a sub-micron level. Contained in a liquid medium, the nanoparticle ink is then applied from the print head to the build plate.

When the ink is deposited, the liquid agent evaporates, leaving behind the deposited metal particles. The separated particles are then melted together with a heating element at a temperature of up to 300°C. Metal parts with a layer thickness of up to 1 micron can be created thanks to the droplet size. (XTREMEengineering, 2016)

Binder Jetting and Powder Bed Fusion:

In this process a vessel is filled with a material like metal powder. There are two possible ways to produce the part. For one, the print head moves over the powder bed, similar to an inkjet printer, and applies liquid binder. The material sticks to the desired position and the part is created layer by layer. An alternative method for building up in layers is the precise electron or laser bombardment of liquid or powder. This is how metals are melted and photosensitive polymers are hardened. (Feldmann et al., 2016)

Direct Energy Deposition (DED):

In the DED process, the starting material is pressed through a nozzle either in the form of a wire or in the form of a metal powder. This material is then melted by an energy source and continuously built up on the platform. Usually, a laser or electron beam is used for this process or an electric arc is generated for this purpose. Either a robotic arm or a gantry system manipulates both the heat source and the nozzle for the material feed. A chamber filled with inert gas, which is hermetically sealed, is used to run the process. With this method, the material properties can be better controlled and the material is protected from oxidation. (Layerbylayer, 2020)

Sheet Lamination

In the manufacture of laminated objects, webs of material are layered on top of one another and bound together with adhesive. Then an outline of the object is cut out in cross section and the excess material is removed. This is done over and over again until the whole object has been built up in layers. Advantages of the objects printed by LOM are accuracy, strength and durability. They can even be drilled or machined after printing. The starting material defines which layer resolution can be achieved. The thickness of the base material is usually between one and a few sheets of copy paper in thickness. (THRE3D, 2020)

There is another process, which is not shown in figure 6. In 2013, the german company Arburg presented their newly patented Arburg Plastic Freeforming (APF) process. (ARBURG, 2020)

Arburg Freeforming Process

Standard granulates that are used in injection molding can also be used for the APF process. This is a key feature of the APF-process. The freeformer system, shown in figure 5, represents a special plasticizing screw in the material preparation unit. After plasticizing, free-form shaping takes place without using a mold. The technology is based on a high-frequency nozzle cap which precisely applies tiny plastic droplets through a movable part-carrier. The layered structure of the three-dimensional plastic parts is even possible for multi-component parts.

The advantages of this process are the production of three-dimensional functional components from tiny plastic drops without a mold, expensive special materials are avoided and standard granulates are used at this point. Another advantage is the processing of several components, e.g., in the flexible hard / soft combination.

APF is used to manufacture products such as implants made from FDA-approved PCU and resorbable materials like polylactide, or components made from two materials with special geometries. (ARBURG, 2020)

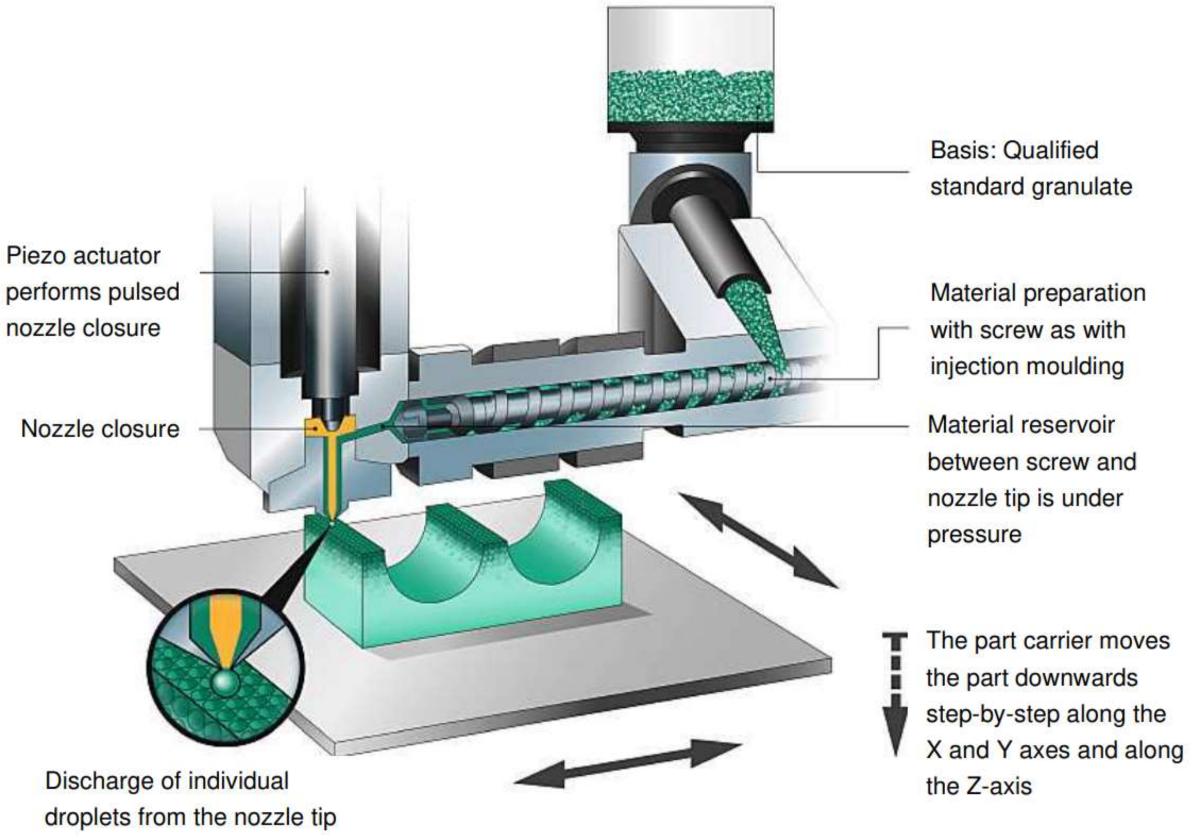


Figure 6: The APF process is based on plastic granules. The material is melted in a plasticizing unit and discharged in the form of drops through a nozzle. Source: own illustration based on ARBURG (2020).

In the CAMed-project (2020) the technology of FDM plays a major role. It is presented in the first diagram as “Material Extrusion” and is discussed further in the next chapter.

2.3 Focus: Fused Deposition Modeling (FDM)

The additive manufacturing process FDM is often used in the production of functional parts and prototypes from common plastics. The starting material is a plastic filament that is heated and pressed through a nozzle tip. A digital model is used to build up the printed part layer by layer on a platform. Figure 7 shows a sketch of a machine. Advantages for consumers, such as industry and science, are that the process is reliable, simple and affordable. Not only did this result in its being widely recognized and used, but also its widespread use in research. Here the process is continuously being improved and new materials are being developed. (Longwei et al., 2016)
FDM is also used in the CAMed project. It is investigated whether this process is suitable for the manufacture of implants. The production of models for pre-surgical planning is already underway.

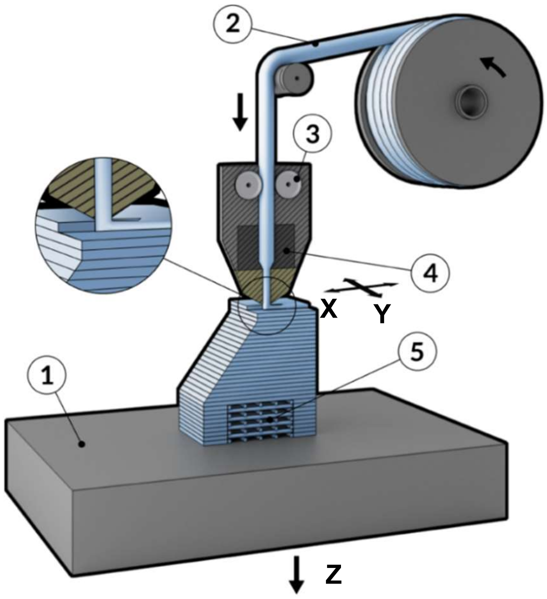


Figure 7: Functional sketch of the FDM procedure, Source: Manufacturing-Guide (2020).

1) Platform
2) Filament
3) Drive mechanism
4) Heater
5) Support

For the medical industry, 3D-printing has several advantages that represent essential improvements. Many geometric shapes can be manufactured and there are only few restrictions in freedom of production; cavities and undercuts are not a problem for this process. It is a cost-effective and rapid technologic solution which can replace a unitary or standardized product. (MissionAdditive, 2021)

2.4 Medical Applications of 3D-Printing

3D-printing has recently been introduced into the medical field, especially in the surgical area as a support for better comprehension of complex anatomy. The quality of diagnosis and preoperative planning are improved and facilitated by patient-specific models. In maxillofacial and craniofacial surgery, this application's benefits have been proven. First studies in neurosurgery, pelvic surgery, spine surgery, visceral surgery and cardiovascular surgery demonstrated a significant improvement in treatment and diagnosis due to better 3D-appreciation of increased accuracy, pathological structure and possibility of pre-planning. By simulating complicated surgical steps in advance, complications that may arise during the operation can become predictable. This not only shortens the operating time, but also saves costs, for example for the use of operating rooms. When planning radiation therapy, rapid prototyping can bring several advantages. In addition, individual radiation protection shields can be produced, for example. (Rengier et al., 2010)
The customers of the 3D-PRC also used the printed parts as models in patient discussions. This helps to show them what happens during an operation. (CAMed-Project, 2020)

To support medical application of 3D-printing, various types of additional software are required. These types of software are described in the next chapter.

2.5 Support Software for Medical 3D-Printing

Depending on the field of application various types of software are required to support the proper production of patient-specific medical products. When creating a patient-specific implant, for example, each step of the production process is supported by a software. First the skull of the patient is scanned in order to design the implant. For this, computer tomography (CT) or an optical laser scanner can be used which also requires a software to run. Another software is used to convert the laser-scanned data into a digital 3D-model. The CT-data must first be segmented and then also converted. Then a CAD-Software (Computer Aided Design) is used to create a 3D-model of the implant. The last step is the digital preparation for the 3D-printing, where all the parameters for the printer are selected. (CAMed-Project, 2020)
Table 3 gives the overview of software systems depending of the activities.

	1st Step	2nd Step	3rd Step	4th Step
Activity	Scan of the Object	Transformation from Scan-Data to Modell	Creation of a Modell	Preparation for Production
Systems/ Software	CT / Optical or Laser Scan System	Segmentation- /Conversion- Tools	Design- Programs	3D-Printing Preparation

Table 3: Overview of Software System at dependent Activities, Source: own illustration based on CAMed-Project (2020).

As an example, the open-source software "MeVisLab"[1] is used to create models for cranial implants. This software has been modified by Egger, et al. (2017). For example, the same skull model must be uploaded twice for this application. The skull models are used to attach markers at the desired positions from which a model is generated. The software has four predefined marker types. At the beginning, marker type 0 is used to trace the outer contour edge of the first skull defect. Marker type 1 is intended to trace the inner contour edge. The second skull model is mirrored over the first model using the transformation matrix. This creates a surface shape in the missing skull area, as shown in figure 8. Marker type 2 is placed on the outer surface of the transformed model in the area of the future implant. If the skull is not symmetrical or if the implant extends beyond the mirror axis, the second model must be brought into the desired position by manual shifting and twisting. Identical to the markers placed on the outer

[1] https://www.mevislab.de/

surface of the future implant, the type 3 marker must be placed on the inner surface. Using all the given points, the software generates the implant automatically. (Egger et al., 2017)

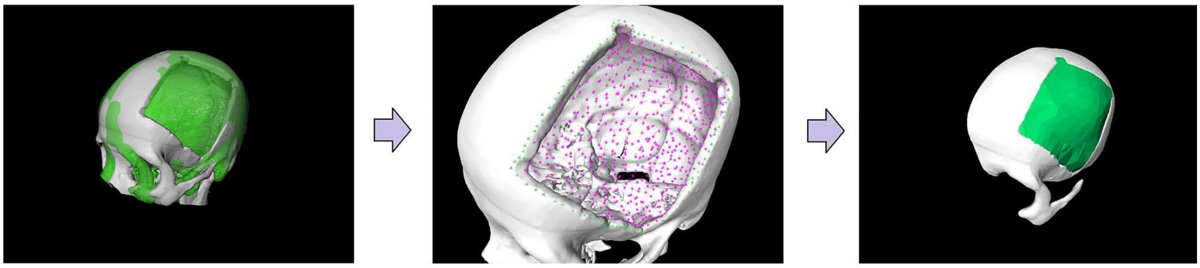


Figure 8: Stepwise workflow during the implant generation process, Source: Egger, et al. (2017).

Egger, et al. (2017) developed a new and automatic software with which the implant for a damaged skull can be created more quickly. They want to use a database of skull scans to automatically reconstruct the broken skull using the software. There are also first prototypes of software products that are accessible online (Cranial Implant Generation, 2020).

With this software, a 3D-model can be created online that corresponds to the geometry of the specific implant. This 3D-model is used for the further production of the component. The 3D-PRC could use it to produce a printed part, however the printed component is not currently allowed to be used as an implant on a patient. It could be helpful in preparing the surgeon and serve as a model. The provision of printed components, such as the 3D-PRC in this case, is offered by companies as a business. This service as a business and the information required for ordering are discussed in the following chapter.

2.6 3D-Printing Service Providers

The provision of 3D-printed parts as a service is already an established business which will be discussed in this chapter. Companies that offer all services, from digital models to the finished object, are defined as 3D-printing service providers. (Rayna et al., 2016; Holzmann et al., 2020)

Since the industry of 3D-printing services has not been around that long, research is correspondingly young (Rogers et al., 2016; Holzmann et al. 2020). According to Rogers et al (2016) there are three different types of services; selective, generative and moderate service. Generative services deal with the generation of printable 3D-models and include, for example, scanning and construction services. Traditional copy shops can be compared with the facilitative services. These focus on producing the 3D printed parts without generating the model itself. The Selective Services aim to generate an enormous database of 3D printable models that customers can choose from. The customer should also have the opportunity to change the model according to his needs. (Rogers et al., 2016; Holzmann et al., 2020)

Holzmann et al. (2020) carried out a scientific study of 3D-printing service providers. The scientific goal is to depict different business models and to compare similarities and differences. From 2014 to the end of 2015, they only collected data from those companies from which they could obtain information on all three business model components. This resulted in a final sample of 141 3D-printing service providers. The data is evaluated using a cluster algorithm (Holzmann et al., 2020). As a result of a cluster analysis, the cases are sorted into homogeneous groups, which are derived from an overall data set into unique and heterogeneous sets of clusters (Ketchen et al., 1996). The cluster algorithm indicates that a five-cluster solution describes the data best; *The digital marketplace model, The single-tech specialist model, The local service center model, The multi-tech champion model* and *the allrounder model* (Holzmann et al., 2020).

The solution offers a remarkable homogeneity of the business model specifications within the clusters and a sufficient differentiation from other clusters. Table 4 represents the five clusters with the various variables used. The numbers 8, 30, 32, 23 and 48 correspond to the number of companies. The table values represent the percentage of accordance between the variable and the companies in the corresponding business model. Values above 0.5 represent more than 50 percent of the companies from this model and are shown in bold. (Holzmann et al., 2020)

	Dimension	Variable	Digital marketplace 8 (5.7%)	Single-tech specialist 30 (21.3%)	Local service center 32 (22.7%)	Multi-tech champion 23 (16.3%)	Allrounder 48 (34%)	Total 141 (100%)
Value proposition	Efficiency	Pre-print service	0.00	**0.60**	0.38	0.04	0.29	0.32
		Convenience	**0.75**	0.30	0.16	0.22	0.31	0.28
		Customer service	0.00	0.10	0.22	**0.61**	0.15	0.22
		Flexibility	0.25	0.17	0.09	0.04	0.33	0.19
		Speed	0.50	0.27	0.13	**0.70**	**0.67**	0.45
		Low cost	0.13	0.30	0.06	0.26	0.38	0.26
	Excellence	Customer innovation and development	0.00	0.03	0.03	0.04	0.19	0.09
		Customer profit	**1.00**	0.10	0.13	0.04	0.08	0.14
		Variety	**0.63**	**0.93**	**0.69**	**0.96**	0.42	0.69
		Confidentiality	0.50	0.07	0.19	0.17	0.46	0.27
		Expertise	0.00	0.13	0.47	**1.00**	**0.60**	0.50
		Quality	0.00	0.30	0.41	**0.78**	**0.65**	0.50
		Reliability	0.00	0.03	0.06	0.00	0.31	0.13
		Software	0.13	0.03	0.03	0.04	0.04	0.04
	Social and environment	Environmental friendliness	0.00	0.03	0.03	0.04	0.00	0.02
		User interaction	**1.00**	0.10	0.16	0.00	0.02	0.12
		Training	0.25	0.50	**0.66**	0.17	0.23	0.38
Value creation	Printing technology	Jetting	0.38	0.17	0.41	**1.00**	0.42	0.45
		Sintering	**0.63**	0.07	0.09	**1.00**	0.46	0.39
		Extrusion	0.50	**1.00**	**0.91**	**1.00**	**0.60**	0.82
		Resin	0.50	0.30	0.16	**0.96**	0.46	0.44
		Powder	0.50	0.13	0.09	0.09	0.27	0.18
	Partner integration	Academic partners	0.13	0.07	0.19	0.00	0.06	0.09
		Professional partners	0.38	**0.87**	**0.75**	**0.74**	**0.58**	0.70
		Customer partners	0.38	0.00	0.06	0.00	0.00	0.04
	Distribution channels	Store	0.00	**0.77**	**1.00**	**0.57**	0.44	0.63
		Web shop	**1.00**	**1.00**	0.09	**0.78**	**0.67**	0.65
	Communication channels	Blog	0.50	0.47	0.34	**0.61**	0.17	0.36
		Online community	0.25	0.03	0.00	0.00	0.08	0.05
		Press releases	0.38	0.03	0.19	0.17	0.10	0.13
		Social media	**1.00**	**0.93**	**0.94**	**0.83**	**0.56**	0.79
Value capture	Revenue sources	Contract work	0.25	0.40	0.47	**0.96**	**0.88**	0.66
		Commission	0.50	0.00	0.00	0.00	0.00	0.03
		Leasing	0.00	0.03	0.13	0.04	0.00	0.04
		Membership	0.13	0.03	0.13	0.00	0.00	0.04
		Premium	0.13	0.00	0.03	0.00	0.00	0.01
		Rental	0.00	0.13	0.34	0.00	0.00	0.11
		Sales	**0.63**	**1.00**	**0.59**	0.30	0.42	0.57

Table 4: The five business models as a solution of the cluster method, Source: (Holzmann et al., 2020).

With the knowledge of possible different business models, it is also examined how ordering a 3D-printed part from existing providers works in order to get a basic understanding of the industry standard. It clarifies what these providers require to create a 3D-printed part, which information is asked first and how the query is structured. Table 5 contains a list of well-known 3D-service providers and after that a brief description of an order request is given.

Name of Provider:	Link to Homepage:
3D Hubs	https://www.3dhubs.com/
Schiner3DRepro	https://www.schiner3drepro.com/
3D Side	https://www.3dside.eu/en/
Oral 3D	https://www.oral3d.eu/en/
Materialise	https://www.materialise.com/de

Table 5: 3D Service Providers. Source: own research.

3D Hubs

To get an instant quote for a printed part from the provider “3D Hubs”, you have to select the technology at the beginning and then upload the file of the part required. The possible technologies are descripted with characteristics as a help to select the best application. The possible processes and the characteristics are shown in figure 9. The upload function accepts many popular file formats, such as STL, STEP, STP or OBJ. After the upload, the price is calculated and the printed part can be ordered immediately. As shown also in figure 9, there is an option to change part specifications like material, layer height, infill, color or even the print orientation. (3D Hubs, 2021)

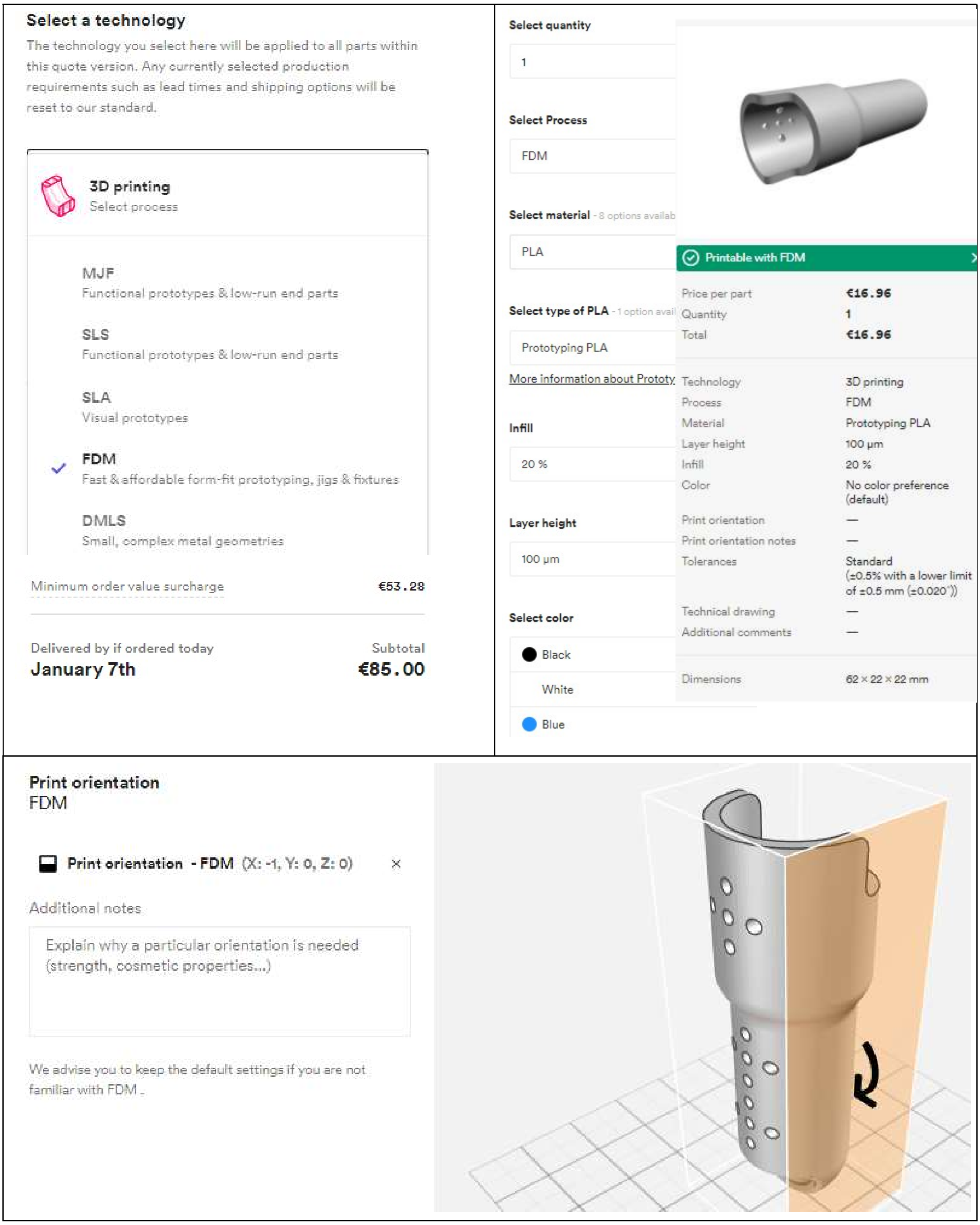


Figure 9: Ordering process from “3D Hubs”, Source: 3D Hubs (2021).

<u>Schiner3DRepro</u>

The provider “Schiner3DReori” does not offer an online order option or upload function. Contact can be made by email or telephone and ready-to-print data has to be sent to an email address.

Schiner3DRepro has a department for medicine called "Digital Anatomic 3D-Printing" and offers services like DICOM file separation, DICOM file 3D-printing service, multi material 3D-printed models and realistic organ models for developing surgeon skills. The workflow from DICOM-TO-PRINT is shown in figure 10. DICOM is the format of the file that is created in a CT. These printed parts only function as a model, not as an implant. (Schiner3DRepro, 2021)

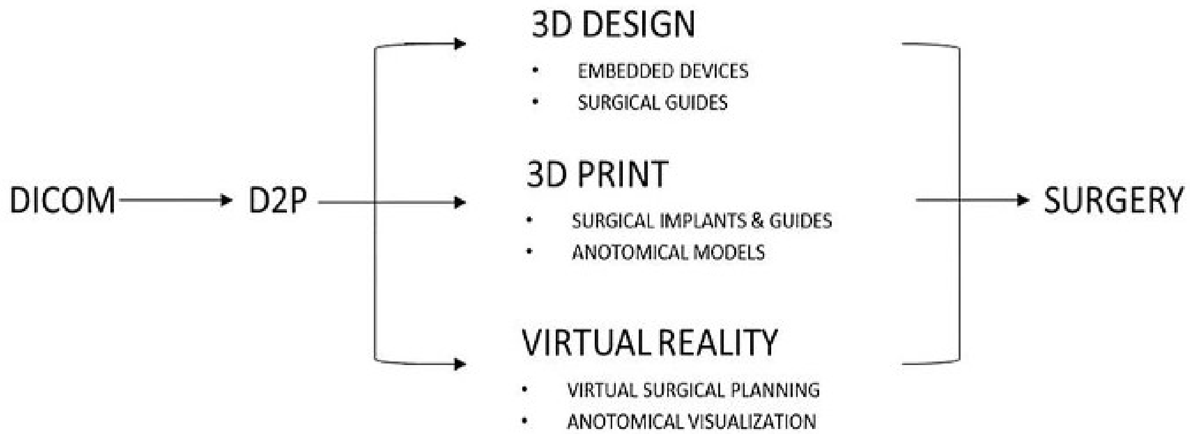


Figure 10: DICOM-TO-PRINT-Workflow from “Schiner3DRepro”, Source: Schiner3DRepro (2021).

3D Side

In addition to 3D-models, “3D Side” also manufactures *“SkullPT”* for the medical sector. On their homepage, "SkullPT" is defined as follows: *“SkullPT is a patient specific mold that can create a patient specific cranial implant from polymethylmethacrylate (PMMA, bone cement) during surgery. Based on the CT-scan of the patient, the mold is manufactured and delivered to the hospital for final sterilization. By setting PMMA in the mold, an implant is created in the operation room. In just a few minutes the implant is ready to be fixated in the patient”* (3D Side, 2021).

To order a SkullPT, “3D Side” needs data as shown in figure 11. There are no more options to determine the properties of the process, this is selected by the provider.

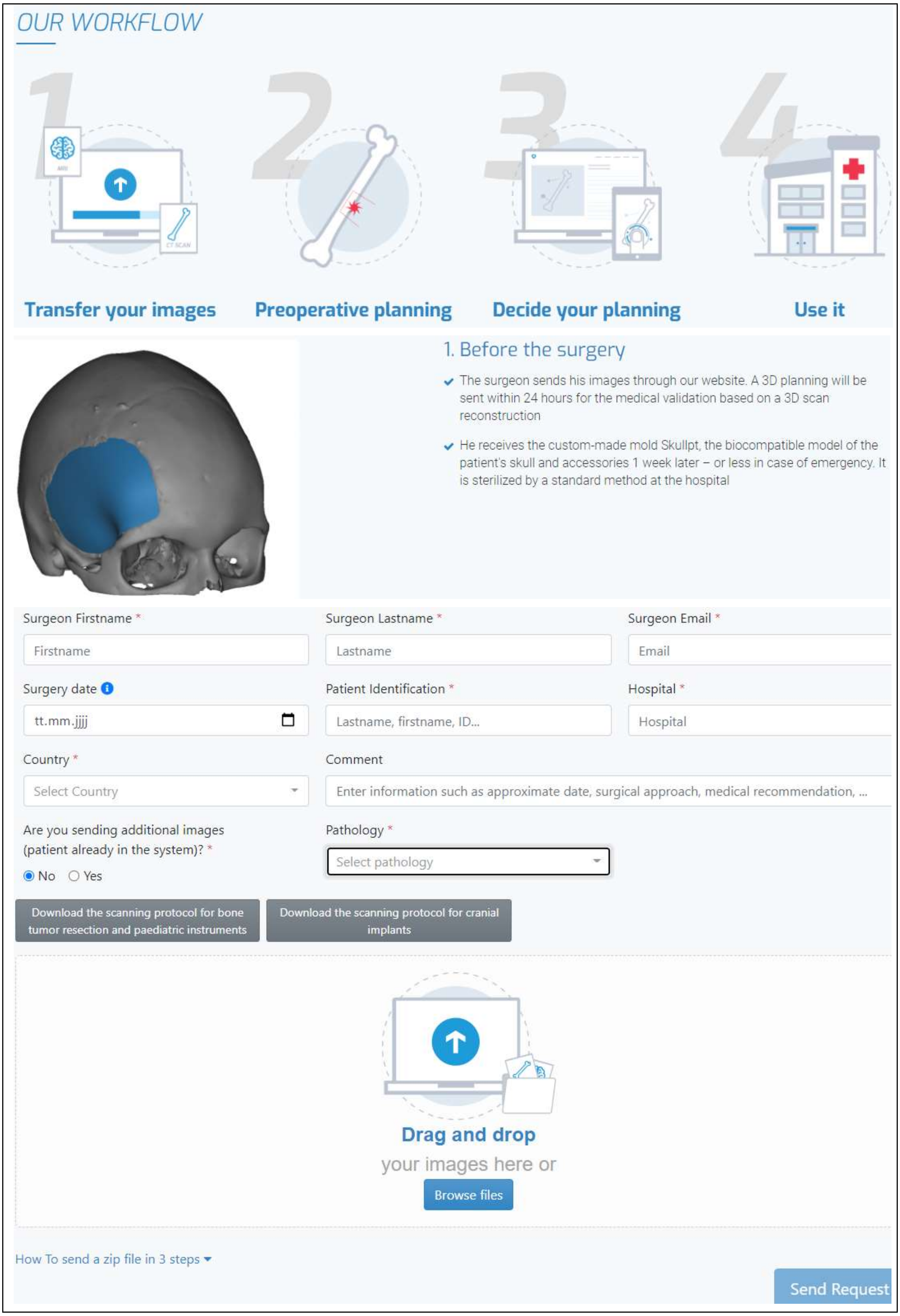


Figure 11: Ordering process of *SkullPT* from “3D Side”, Source: 3D Side (2021).

Oral 3D

Oral 3D offers the option of uploading a file in DCM or STL format. The next step is to select the area of the jaw and then they produce a model. This provider also does not offer any options to select the properties. An overview of the order surface is shown in figure 12. "Oral 3D" specializes in the creation of models of the jawbone. (Oral 3D, 2021)

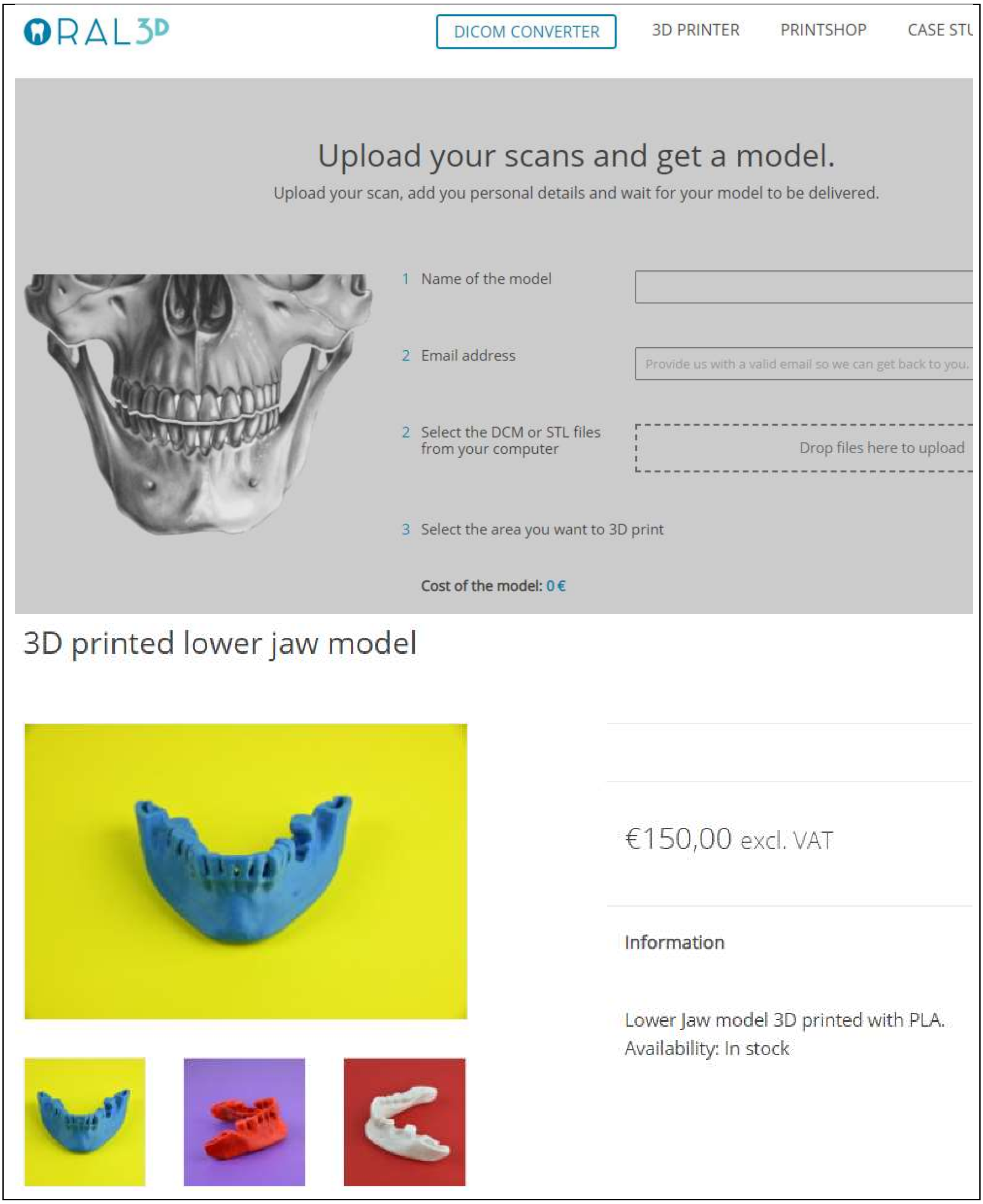


Figure 12: Ordering process from “Oral 3D”, Source: Oral 3D (2021).

Materialise

The service provider “Materialize” is divided into two categories: “Materialise Manufacturing” and “Materialise Medical”.

“Materialise Manufacturing” is similar to “3D Hubs”. A file of the part has to be uploaded and specifications for the process can be selected, shown in figure 13. The price and delivery date are calculated immediately. It is also possible to send individual inquiries. (Materialise, 2021)

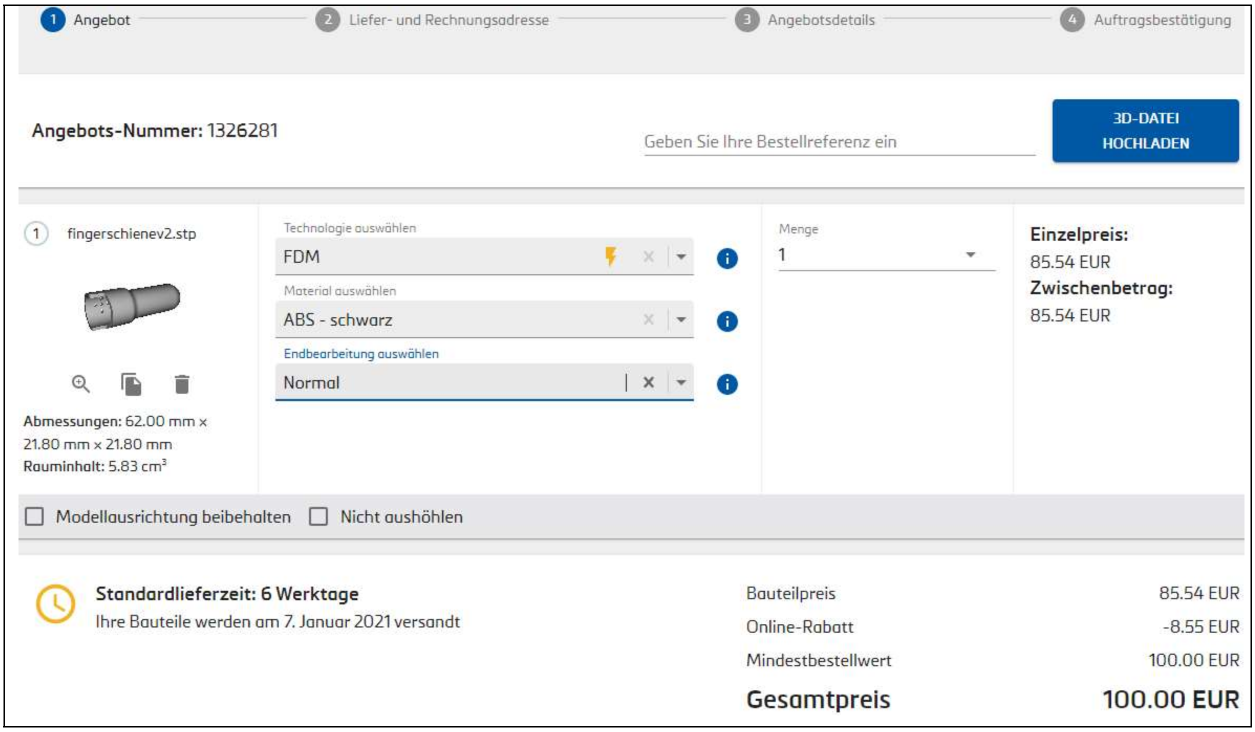


Figure 13: Ordering process from “Materialise Manufacturing”, Source: Materialise (2021).

On the other hand, "Materialise Medical" specializes in the medical field. The request for an anatomical model, a personalized implant or a personalized guide can only be continued after contacting “Materialise Medical”. Once registered, the customers can make use of different services shown in figure 14. (Materialise, 2021)

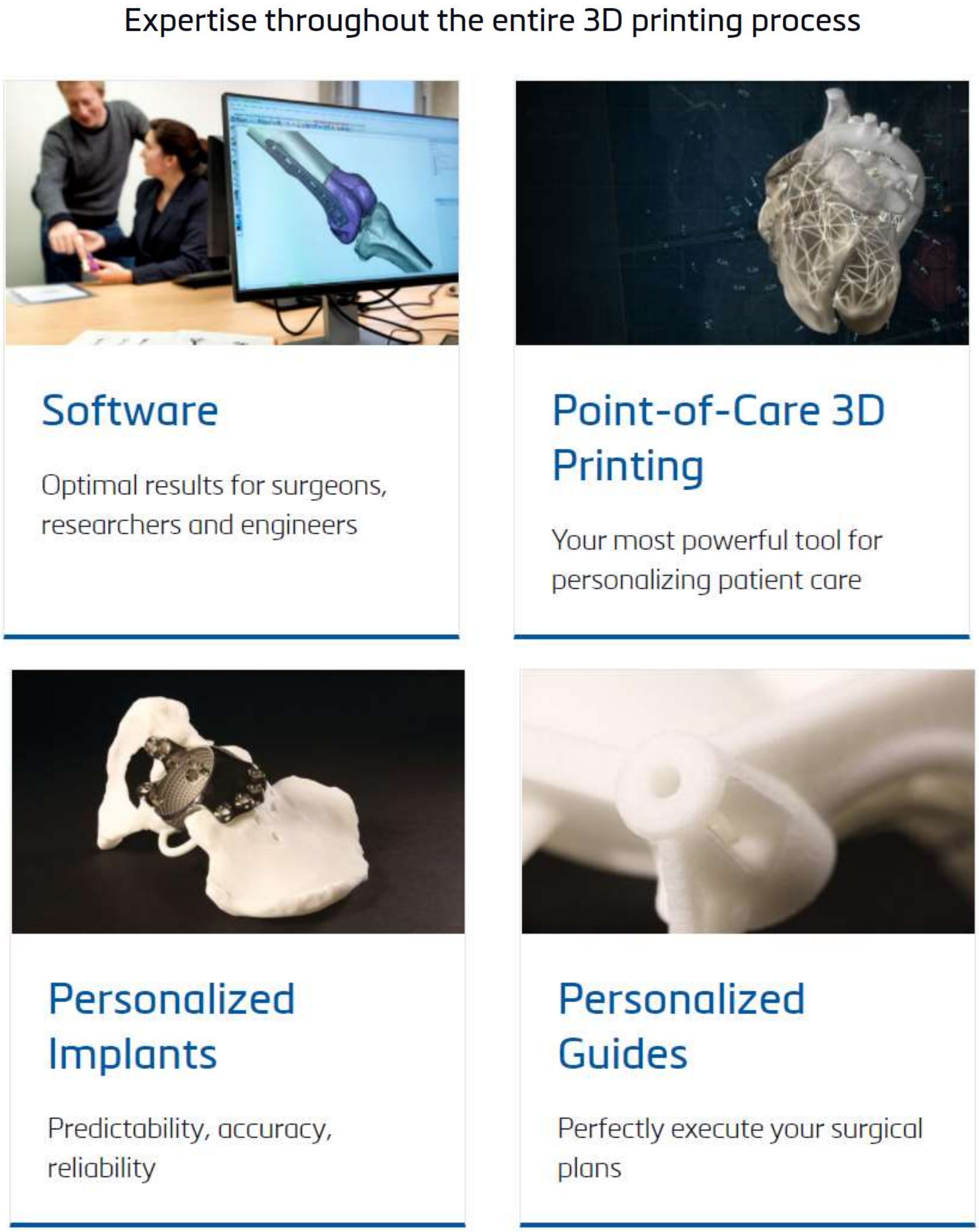


Figure 14: Areas of “Materialise Medical”, Source: Materialise (2021).

In summation, the providers "3D Side", "Oral 3D", “Materialise Medical” and partly "Schiner3DRepro" all specialize in medical products though with limited customer influence. In contrast, providers such as “3D Hubs” or “Materialise Manufacturing” produce 3D-printed parts for everyone and offer more configuration options for the customer. Table 6 shows a comparison of specialization, the business relationship and the ordering process of the providers.

Provider	Specialized in	Business Relation	Ordering Process
3D Hubs	Custom 3D-printing Projects	B2B/B2C	Order Immediately (Data Upload)
Schiner3DRepro	Digital Anatomic 3D-Printing	B2B/B2C	Contact before Ordering (Send eMail)
3D Side	Patient Specific Mold	B2B	Send Request (Data Upload)
Oral 3D	Models of the Jawbone	B2B/B2C	Order Immediately (Data Upload)
Materialise Manufacturing	Custom 3D-printing Projects	B2B/B2C	Order Immediately (Data Upload)
Materialise Medical	Anatomical Model/ Personalized Implant/ Personalized Guide	B2B/B2C	Contact before Ordering (Data Fill-Out)

Table 6: Comparison of Specialization, the Business Relationship and the Ordering Process of the Provider, Source: own illustration.

It turns out that the order depends on the provider and that there is no standardized ordering software. For this reason, an own software, that fulfils the requirements is going to be created.

3 Product Development

Product development includes the totality of activities for solving the technical tasks that lead to a marketable product. Product development begins with the initial idea and extends through to the market launch of the product (the technical solution). The concept of product development was created with the increased use of a systematic and methodical way of working, which significantly supplements the previously prevailing intuitive approach to technical solutions and makes the development of marketable products easier to plan and check. Process models are used in technical projects for product development to minimize errors and achieve better results. The VDI-guidelines define a plan of action and individual methods for designing technical products and are therefore primarily intended for the development of new products. The more recent VDI-guideline 2221 (VDI, 2019) proposes a general procedure for developing and designing technical products, with emphasis on a broad application in mechanical engineering, precision mechanics, software development and the planning of process engineering systems. (Pahl, et al. 2007)

In this thesis the product development is carried out on a prototype of an ordering software. Various suitable process models are listed in this chapter and in particular, the waterfall model and the V-model are presented. This chapter is divided into three sub-chapters. The first subchapter gives an overview of the development of software and its implementation. The main goal, the methods and the problems of requirements engineering (RE) are discussed in a separate sub-chapter. The last sub-chapter deals with usability testing, where the “Thinking Aloud” method is described in more detail.

3.1 System Development Models

Incidents had already led to the realization in the late 1960s that the creation of a software is an extremely complex task that should use disciplined and approached engineering methods. One of the most important findings was that the creation of systems takes place in structured steps. (Partsch, 2009)
The idea of dividing the development and implementation of a system into individual, logically and temporally separable phases represents a principle "from general to detail" and "variant formation". The aim is to divide the development of a solution into manageable sub-steps and this enables a step-by-step process from planning, to decision-making, through to concretization. In system engineering, the course of a project is based on a process model. (Haberfellner, et al. 2019)
There are several different process models. Partsch (2009) writes in his book that each step has a certain development phase that can be divided again. (Partsch, 2009)
There are different models for system development and the most common methods according to Partsch (2009) are:

- Waterfall model
- V-model
- Agile model
- RAD model
- Incremental model
- Prototype model
- Iterative model
- Spiral model

The Waterfall model and the V-model are described in more detail below because they offer a high level of transparency with clearly defined, comprehensible processes. (Partsch, 2009). The V-model was created in 1991 as a process model for the implementation of software and information systems. The predecessor model was the waterfall model from 1956. The models developed for software development are widely used today and are also used for development processes. (Dröschel et al., 1999)

Waterfall Model:

In the Waterfall model, the project activities are divided into linear successive phases. The respective phases depend on the results of the previous ones and correspond to a specialization of the tasks. It tends to be one of the less flexible and iterative approaches because the development progress is in most cases in one direction ("downwards" like a waterfall). (Benington, 1983)
Figure 15 shows the five steps of the waterfall model.

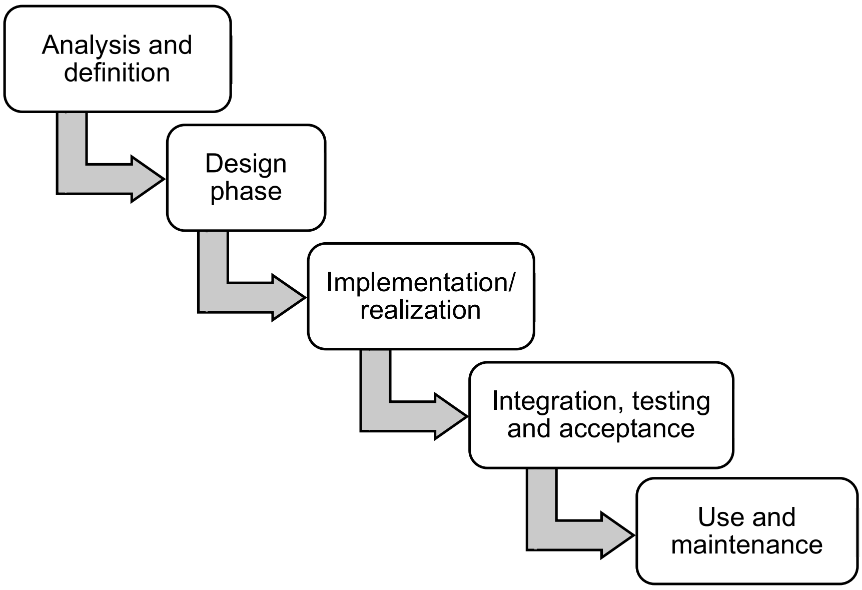


Figure 15: Waterfall Model, Source: own illustration, based on: Partsch, (2009).

According to Partsch (2009), the process steps of the waterfall model are described as follows:

- In the first step of the process, the analysis and definition phase, the task of the system and its functions are carried out. All premises, objectives and expected achievements are set.
- The architecture of the system ("What", "Where" and "How") is defined in the second step in the design phase.
- The implementation of the solution concept by transferring the requirements into an executable program takes place in the implementation phase.
- In the integration, test and acceptance phase, the focus is on checking the function of the system and the usability.
- Use and maintenance include those activities that are carried out on the system after development is complete. This includes error correction as well as perfecting and developing the system further.

This process flow is simplified and in practice, the process steps may also overlap. (Partsch, 2009)

The Waterfall model is an activity-oriented approach in which only one activity is carried out at a time. This is a very simplified ideal that does not correspond to reality. A realistic phase model can be achieved when different aspects of the system are developed in distinct phases. A further development of the Waterfall model, which links development steps with quality assurance measures and project management activities, is the V-model. (Partsch, 2009)

V-model

Figure 16 shows a possible sequence of a V-model.

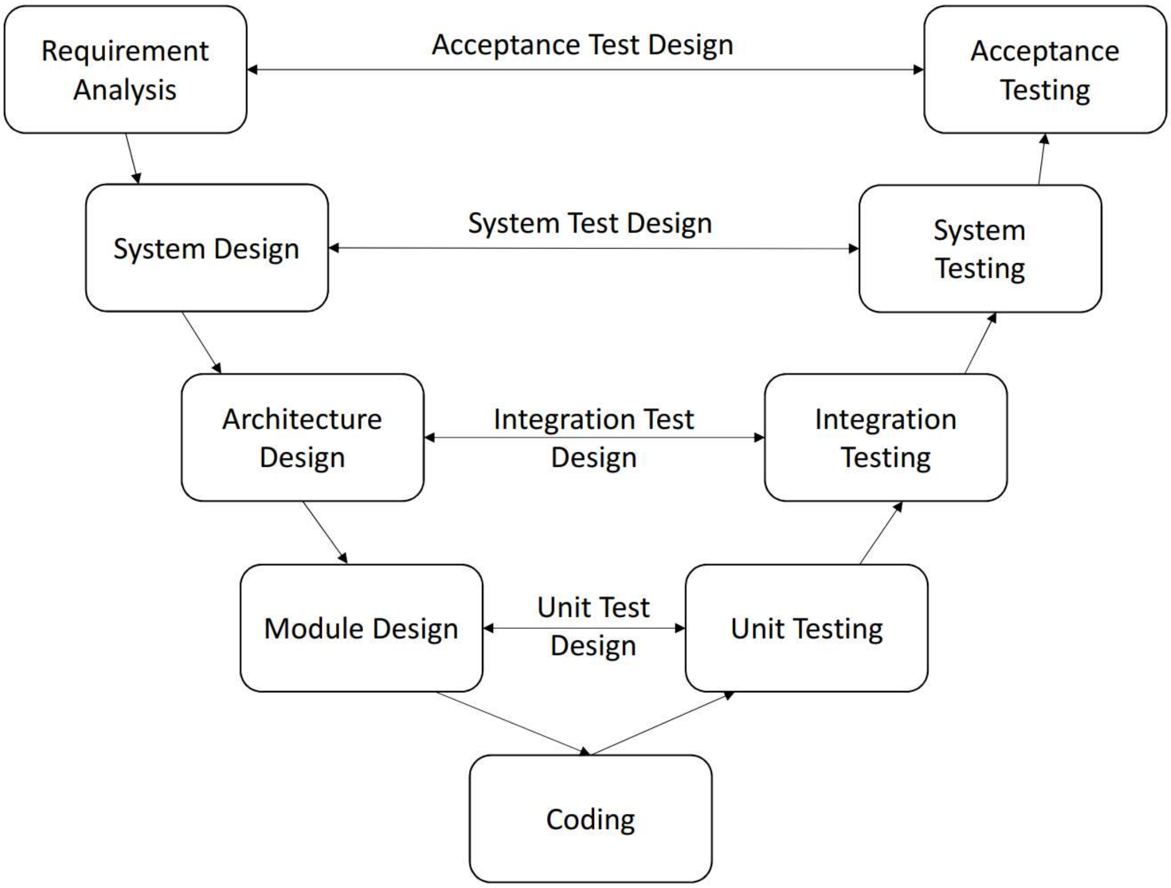


Figure 16: V-model, Source: own illustration, based on Langer (2008).

The development process represented by the V-model can be seen as a further development of the waterfall model. Here, after the coding phase, the process steps are bent upwards, which results in the typical "V-shape". The V-model is often used for the development of technical products, for example in software development. The V-model represents the relationship between each development phase and the associated test phase in the horizontal axis. The development process based on the V-model begins on the upper left side of the V and then runs along the shape. Thus, both the vertical and the horizontal axis represent the project status or the project completeness (from left to right). The V-model can also be seen as a representation of abstraction. From the coarsest abstraction (at the top) to the detailed task (at the bottom). (Forsberg et al, 2015)

According to Müller-Ettrich (1998), the V-model is an internationally recognized development standard for IT systems that defines in a uniform and binding manner what has to be done, how the tasks have to be carried out and what has to be used. According to Müller (1998), in the book entitled *System Development with V-Modell and UML*, the V-model encompasses the following points:

- The Allocation of Methods,
- The Lifecycle Process Model,
- The Functional Tool Requirements;

Langer (2008) describes the following points as the similarities between the V-model and the waterfall model:

- Both models describe the process of product development in steps and both provide for a validation / verification of the individual steps.
- Both models are used for product development and are used in the development of a software.
- Neither the waterfall model nor the V-model are suitable for large and complex projects.

The difference between waterfall model and V-model are shown in table 7:

Waterfall model vs	**V-model**
Relatively linear sequential design approach to develop software projects	Execution of stages in “V” shape
Methodology	
Continuous method	Simultaneous method
Total Defects	
Total errors in the developed application are higher	Total errors in the developed application are lower
Defect Identification	
Errors are identified in the test stage	Errors are identified from the initial phase

Table 7: Waterfall model vs V-model, Source: own illustration, based on Langer (2008).

3.2 Requirements Engineering

"Requirements Engineering is the science and discipline concerned with analysing and documenting requirements" (Thayer et al. 1990).

This definition by Thayer et al. (1990) in their publication of the IEEE computer Society Press Tutorial in 1990 marked an important step in the history of Requirements Engineering (RE). Handling massive, disorganized information is a challenge for the involved persons at the beginning of each project. The first step of the project manager is to organize the information. A critical phase in each project is to pick out the right requirements from the whole information pool in a project. About 70% of projects fail, because many project managers are vastly underestimating the complexity of RE. (Narciso et al., 2009)

Figure 17 shows the costs of fixing an error introduced in the requirements phase; it increases during the project. If the software development process reaches completion, costs to fix errors could rise dramatically. (Boehm, 1981)

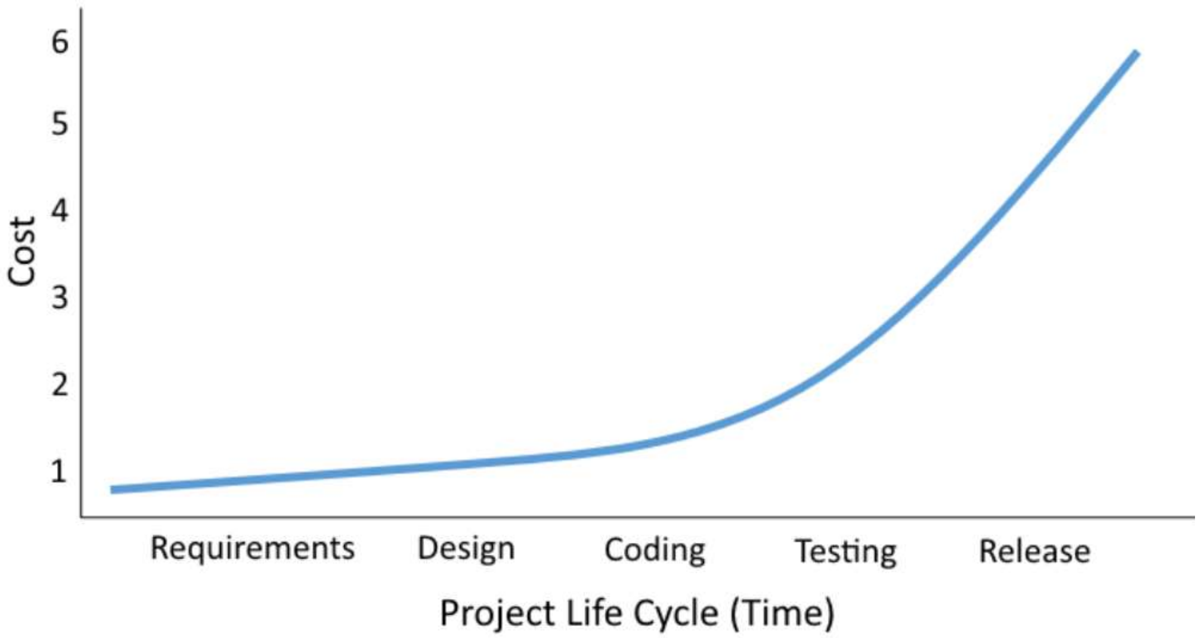


Figure 17: Cost-to-Fix-an-Error Curve (Boehm, 1981)

The goal of RE is to describe what a system should do, not how it should do it. Consequently, before and during system design and development, RE defines all activities that describe the functions the resulting system must have. (Partsch, 2009)

With the deployment of RE, the role of a requirement engineer is defined, as a person or a group focused on documenting, collecting and managing requirements. The main tasks of the requirements engineer include a systematic approach to RE and good communication skills, because they have to mitigate the conflicts and create a set of requirements that all stakeholders need to agree with. (Rupp et al., 2009)

Despite enormous efforts in the area of software engineering, planning and implementation of extensive software systems are still associated with technical and economic risks. Inadequate RE is very often the cause. (Partsch, 2009)
Diagram 18 shows statistics of the success rate of projects between the years 1994 to 2009.

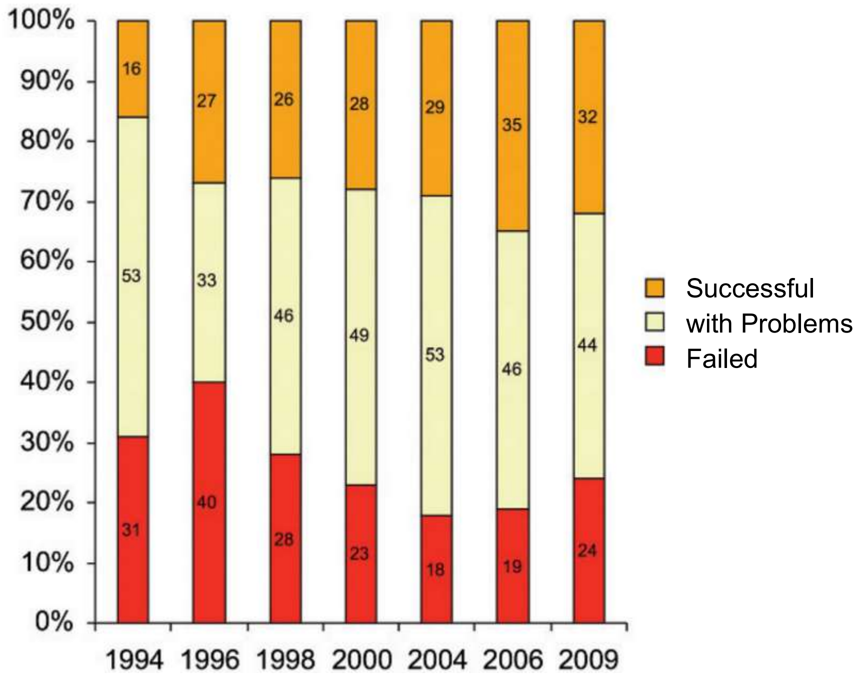


Figure 18: Success rate of projects, Source: (Partsch, 2009)

A trend of improvement can be seen, but there are still projects that fail and the majority of projects have issues. To improve the trend and achieve successful completion of projects, the following four tasks are important, according to Partsch (2009):

- Determination of the requirements
- Documentation of the requirements
- Analysis of the requirement description
- Good communication

The growing importance of RE in the development of technical products, including software and systems development, reflects the growing attention paid to the needs and wishes of stakeholders (Fassin, 2009). As mentioned, all stakeholders need to agree with the requirements. The following chapter discusses stakeholders and their role in the project.

3.2.1 Stakeholder

A person who is indirectly or directly involved in the project is called a stakeholder. Customers, managers, developers or even IT-Support staff are typical examples. (Gessler, 2012)

According to Partsch (2009), a stakeholder is a party that is involved in the development and has to assign requirements for a future system. A stakeholder represents a large number of interest groups. The stakeholder has to represent different perspectives on the project and so to assume several roles. (Partsch, 2009)

"Stakeholder management" proved to be an important and common task in translating business ethics into management strategy and practice. (Fassin, 2009).

Another but similar description of a stakeholder is from Rupp: *"A Group, an organization or a person what have indirectly or directly influence on the requirements is called a stakeholder." (Rupp, et al. 2009, p.36)*

3.2.2 The Main Goal of Requirements Engineering (RE)

According to Partsch (2009), the requirements for the new product must be recorded and described precisely, clearly, consistently and completely. There are different focal points in the objective of RE, which for Partsch (2009) depend on the respective groups:

- Customers and users are concerned with fulfilling their wishes in terms of function and performance.
- Management is interested in quantifying and monitoring the boundary conditions for system creation.
- The system analyst or requirements engineer wants an easily verifiable and changeable document.
- Designers and system developers expect precise specifications for creating the functions with the specified restrictions.
- The system testers expect support to prove that all requirements are met.

<u>Problems of RE:</u>

According to Partsch (2009), the most common problems of RE are the consequences of the problems at project start:

- Unclear goals of what should be achieved.
- Inherent complexity of the task to be solved, which results from the information available and the relationships between the individual components.

- Communication problems, in system manufacturing there are different people with different background knowledge and level of knowledge. The interests of stakeholders often diverge.

Unscheduled changes also create difficulties in the course of the project. In addition, the interaction of various factors can lead to conflicts during the project.

How to resolve conflicts:

Conflicts can arise in different ways. Finding solutions to these problems requires active work in the area of project management, in the technical area and above all in RE. For example, contradicting wishes or needs of different stakeholders or uncoordinated and parallel process steps can cause problems. Resolving a conflict can create a new problem elsewhere as well. However, if a conflict has been identified, its cause should first be analysed. Depending on this, a conflict resolution that is appropriate for the cause should be selected in order to resolve the conflict. The conflict resolution should be documented in consequence. (Partsch, 2009)

According to Partsch (2009), common conflict resolution strategies are:

- Negotiation (exchange of arguments and agreement).
- a creative solution (discarding old points of view, developing a common new solution).
- or a decision (by a higher authority or by vote).

3.2.3 System Modelling for Requirements Engineering

System modelling can support the design and analysis process by introducing formality into the way systems are defined. In system development, images and tables are often used to visualize the development. Much of the systems engineer's creativity and art is expressed in the use of modelling techniques. (Hull et al., 2011)

Some requirements must be met for the successful use of models in RE. It must be clarified in the development process whether the models are explanatory sketches or essential artifacts. Furthermore, the models must be neatly integrated into the development process. Finally, the economic benefits of models and model transformations must be demonstrated. (Partsch, 2009)

Modern software tools could be helpful for better organization and to maintain a better overview. (Hull et al., 2011)

The software tool "objectiFRM"[2], which is also used in CAMed and is currently modern, serves as an example. (CAMed-Project, 2020)

[2] https://www.microtool.de/produkte/objectif-rm/

3.3 Usability Testing

“Would you fly in an airplane that hasn’t been flight tested? Of course not. So you shouldn’t be using software that hasn’t been usability tested.”

[Ben Shneiderman, The Front Desk, BBC Video, 1995]

Usability testing is understood as a process for determining the usability of a product by observing users while they interact with the product (Barnum, 2002). Rubin et al. (2008) shares a similar understanding in their definition. According to them, testing with users is very important to clearly characterize the direction of this methodology:

„[...] a process that employs people as testing participants who are representative of the target audience to evaluate the degree to which a product meets specific usability criteria.“ (Rubin et al., 2008)

Figure 19 is intended to illustrate the development process of a software product in contact with human by using evaluation techniques.

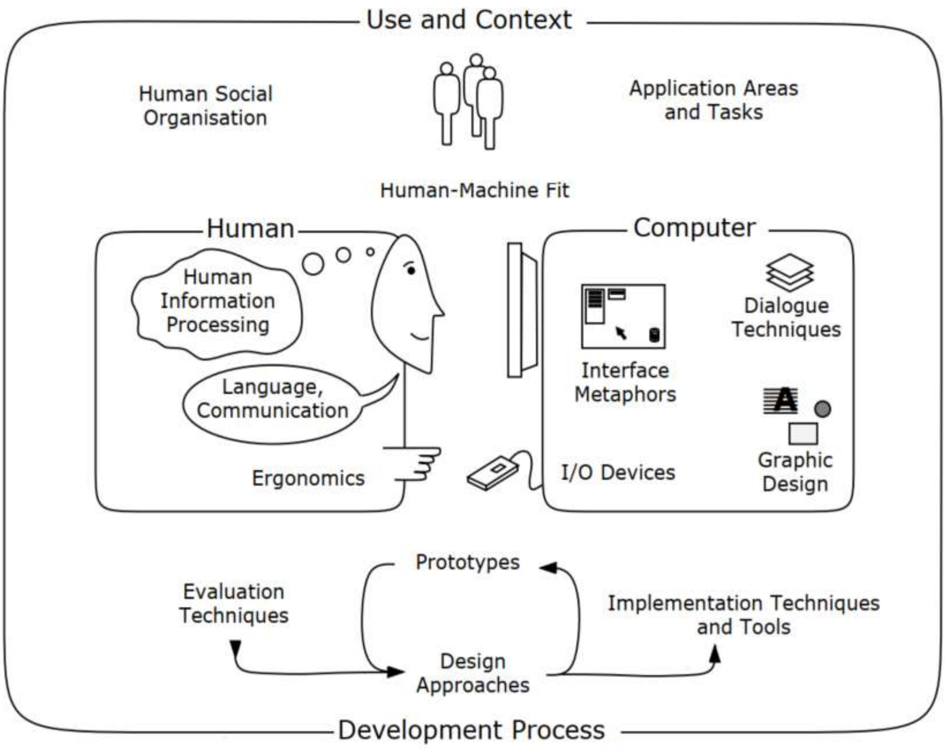


Figure 19: The nature of Human-Computer Interaction, Source: (Rubin et al., 2008).

3.3.1 Usability Testing Methods

Five empirical usability test methods including a description according to Dumas et al. (1999) of the process are listed below:

- *Thinking Aloud:* The test users are encouraged to formulate their thoughts aloud.

- *Co-Discovery:* The participants should consult in pairs. Important insights are gained from this conversation.

- *Formal Experiments: S*tatistical analysis, measurements and controlled experiments.

- *Query Techniques:* Questionnaires and interviews.

- *Usage Studies:* A small number of usage data is collected from users who work on their own tasks over a longer period in their accustomed environment.

3.3.2 Reasons for Usability Testing

Many companies believe that usability tests are an effective way of improving various properties of their products. Customers also benefit from this. For example, product improvements are made using data from representative testers to minimize or eliminate user frustration. The "Handbuch für Usability-Tests" by Rubin et al. (2008) divided the test goals into "Informing Design", "Elimination Design Problems and Frustration" and "Improving Profitability". (Rubin et al., 2008)

Informing Design

The most important goal of usability tests according to Rubin et al. (2008) is to collect dates of problems and malfunctions and to use them to improve the development of the products. According to Rubin et al. (2008), it is intended to guarantee the creation of a product that is:

- Useful to and valued by the target audience.

- Easy to learn.

- Effective and efficient for the user.

- Satisfying to use.

Eliminating Design Problems and Frustration

Ease of use and simplicity is essential for the customer while using the product. According to Rubin et al. (2008), by minimizing the disappointment of using a product for your target group by fixing development bugs before product release, you can also achieve these goals:

- Create a positive relationship between the customer and the company.

- Ensure your items are always of high quality and easy to use.

- It should be clear that the goals and priorities of the customers are very important to the company.

- The article should be efficient, effective and useful for the customer.

Improving Profitability

According to Rubin et al. (2008), the following points are the advantages or goals of testing for a company:

- **Create a historical record of usability benchmarks for future versions** to avoid making the same mistake again.

- **Minimizing the cost of support calls and service.** A more usable product will require minimal support from the company and less service calls.

- **Increasing sales and likelihood of repeat sales.** If an article contributes to the satisfaction of the customers, they advertise it. They talk to other potential users and buyers. In addition, customers who are satisfied with a product are more likely to buy the product's successor.

- **Achieve competitive advantages because usability has become a market separator for products.** Ease of use has become one of the most important methods for customers to separate their own product from a competitor's product. All you have to do is scan the latest advertisements to see products that are described in terms such as "easy" and "simple", among other things. This information is seldom accurate or truthful.

- **Minimizing risk.** All organizations and companies have been conducting usability tests for years. The real name for this type of testing was " testing" and "product release" which involved trying the product in the market. This tactic turns out to be very risky. Conducting usability tests before releasing the product can minimize the significant risk of releasing a product that does not perform well.

Main points why usability test are carried out

According to Lewis et al. (1993), reasons for carrying out a usability test can be the following:

- People believe that they understand other people's behaviour based on their own experiences.

- Experience changes the way we perceive the world.

- It is difficult to put yourself in someone else's shoes and "forget" your own experience.

- For the system developer, the product is usually very simple and understandable.

- For the most part, intuitions are wrong.

3.3.3 Thinking Aloud

As an introduction to the "Thinking-Aloud" method, the abstract from Lewis' (1982) research report is used in which this method is described as follows:

"Thinking-Aloud is a method for studying mental processes in which participants are asked to make spoken comments as they work on a task. The method is appropriate for studying the cognitive problems that people have in learning to use a computer system. This note discusses the strenghs and weaknesses of the method, and gives some suggestions about its use based on laboratory experience at Yorktown."
(Lewis, 1982)

Lewis et al. (1993) has made a very detailed record of the "Thinking Aloud" test method. First of all, the advantages and disadvantages of this method are listed below: (Lewis et al., 1993)

Pros:

++ reveal many usability problems
++ finds the reason why they occur (process data)
+ few test users required (3 to 5)
+ can be used in the early stages of the development process
+ the moderators only have to bring in little specialist knowledge
+ generates various quotations

Cons:

-- thinking aloud makes users work around 17% slower.
- It is a possibility that thinking aloud can change behaviours, such as problem-solving. Some start to think about what to do, rather than just acting.
- performance data cannot be provided (bottom-line data)

<u>Process of a "Thinking Aloud" test</u>

The preparation of the “Thinking Aloud” test is described in the following six points:

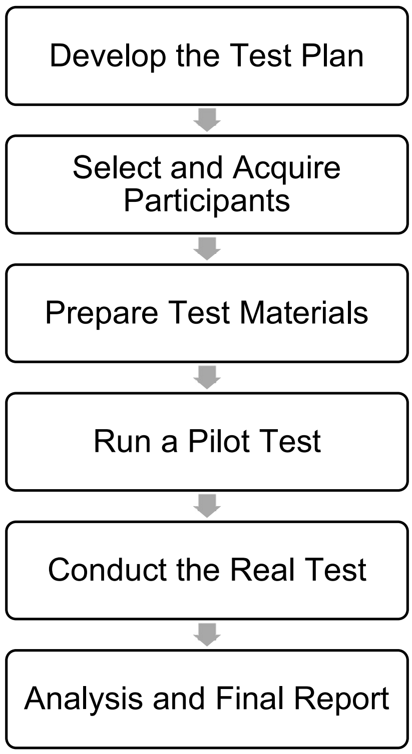


Figure 20: Six Stages of Conducting a Test, Source: own illustration based on Rubin (2008).

In the practical part the individual stages are described in relation to the case study.

3.3.4 Limitations of Testing

It was explained in detail what the goals of the usability test are and what can be achieved with it. Nevertheless, there are limits for each system, as well as for the usability test. The limits of a method must be recognized in order not to go to the extreme. No test can guarantee the success or even the proof that a product can be used. Even the most rigorous formal test cannot guarantee with one hundred percent certainty that a product can be used when it is released. (Rubin et al., 2008)
The following limitations of testing based on Rubin et al. (2008):

- **Performing tests is always an unnatural situation.** Testing in a laboratory, or testing in the field, still depicts the actual usage situation and not the situation itself. Performing a study can already have an impact on the result.

- **Positive test results do not guarantee the functionality of a product.** Even statistically significant test results do not guarantee the smooth functioning of the product, they just indicate that the result was not accidental. This is not a guarantee and depends heavily on the manner in which the test was carried out.

- **The target population can never fully be represented by the participants.** The participants represent their target group only as well as they are able to understand and assess it. Market research is very difficult and the actual consumer is often difficult to describe and identify.

- **Testing doesn't always produce the best results.** There are many ways to evaluate and improve products. In some cases, it is better to seek expert advice, not just to save time and money. This is particularly important at the beginning of the development of a product. There is simply no need to involve many participants in order to reveal the obvious.

4 Practical Part

In the practical part, the knowledge of the theoretical part is applied and implemented in reality. In this chapter the creation and evaluation of a new software is shown. This software is intended to improve the ordering process of a 3D-printed part from a 3D-PRC. The new order process should make ordering easier and faster. The aim is to ask the customer only relevant questions, depending on the application. This should minimize the time required to place an order and reduce the error rate and complexity. As a mechanical engineer, I was responsible for creating and evaluating the new software. It was my job to coordinate and plan the course of this project. Tasks, such

as coding the software, were performed by a software engineering student. A V-model with regard to the course of the project is shown, in which the division of the work steps of the mechanical engineer and the software developer are shown.
In the first chapter (4.1) of the practical part, the process of elicitation the requirements and evaluating the software is described. The second part (chapter 4.2) deals with the communication of specialized information in an order process between the customer and the 3D-PRC. The provision of mechanical properties by medical staff is used as an example. This example is chosen because information on the mechanical properties is very specific, but very important for the 3D-PRC. In general, including in the project, the mechanical properties of polymers are currently being intensively researched. The results of this research, the mechanical properties of polymer implants, are part of the second chapter in the practical part. Subsequently, these research results could serve as an instrument to better convey special information.

4.1 System Development

The method of developing a system, including software, is explained in the theoretical part and is carried out accordingly. Figure 21 shows the V-model as a guide and reminder. The project phases in the blue frame were carried out by myself and the red marked area was implemented with the support of a software developer. This support was an interdisciplinary collaboration between mechanical engineering and software development. The task of the mechanical engineer was to have an overview of the project, to know the information about the required data for the 3D-PRC and to know the requirements of the stakeholders. The software engineer was the specialist in coding the software as effectively as possible.
To repeat, the project phases run from left to right, or from top to bottom and after implementation from bottom to top, according to the course of the V. The methods and tools used for the respective phases, in our case for the development of software, are given in advance as an overview and described in more detail below.

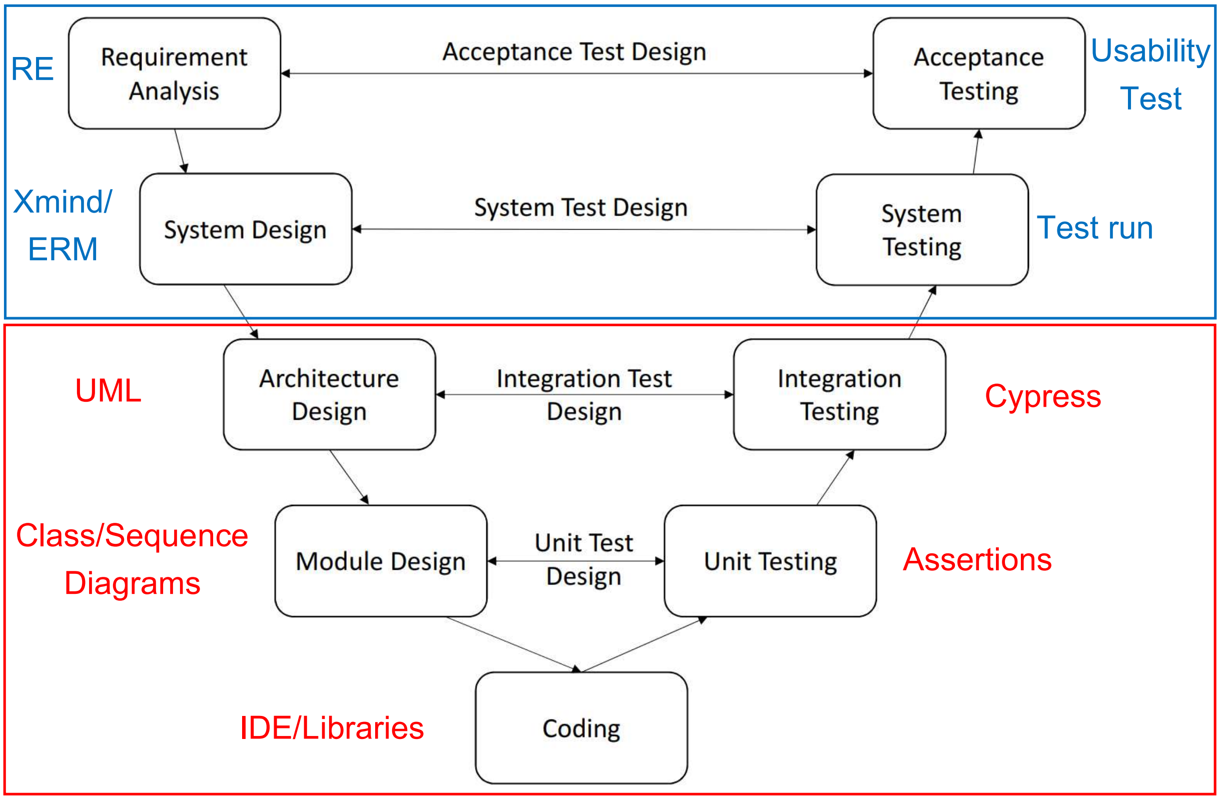


Figure 21: V-model including the Methods and Tools applied, divided into self-developed and outsourced, Source: own illustration, based on Langer (2008)

4.1.1 Requirement Analysis

To gather the requirements, an interview about the current form and printing projects took place at the first meeting with the stakeholders of the 3D-PRC. In this case, the stakeholders are the project manager, the project assistant and coordinator, doctors, technicians from the 3D-PRC and the process manager. During this meeting pros and cons, as well as positive features and negative features of the current process were the content of discussion. Completed orders are talked about and problems are analysed. The process for the future order has been designed. The plan to order digitally and no longer analogous was rated by the stakeholders as an advantage and therefore defined as a functional requirement. The following collection of functional and non-functional requirements is a result of the first meeting. In a further point the stakeholders determine that a demo software should be set up with the support of a software developer. It is then determined that a usability test should be carried out with several participants in order to evaluate the software. The test will be carried out with various types of stakeholders also concerning their personal characteristics: Critic, sceptic, proponent and uninformed people, project members and also employees of different departments and professions. The participants for the test should be selected after consultation with the stakeholders.

The following points (table 8 and 9) are defined as functional requirements. A distinction is made between criteria that must be met and criteria that should be met:

Functional Requirements:

Must-Meet Criteria

FR-MC 001	The necessary information for ordering and producing a 3D-printed part must be requested and collected. This process is explained in more detail in the practical part.
FR-MC 002	When sending an order, a unique order number has to be automatically generated for the protocol and has to be clearly visible on it.
FR-MC 003	This unique order number also has to be meaningful, in terms of date and time of the sent request.
FR-MC 004	Each purchase requisition must be saved permanently. - That traceability can be guaranteed. - That statistics can be created from the stored data. *The following example could be an application for a statistical evaluation: At the moment it is only possible to print polymers in the 3D-PRC. When ordering a component made of ceramic or metal, production must be outsourced. If the statistics show that there is more and more outsourcing going on, it can be used as a decision aid for a new acquisition.* *As an example of traceability:* *If the order form is filled out incorrectly and a product is incorrectly manufactured, traceability can determine the cause of the error.*
FR-MC 005	The software should allow adaptations, extensions and changes. The modification or extension for the modification should be possible without coding.
FR-MC 006	The new order method has to be digital and shall completely replace the current pen and paper solution.

FR-MC 007	The user language has to be German.
FR-MC 008	The use of this software must not lead to data corruption or that patient data enter the network and become public.

Table 8: Functional Requirements, Must-Meet Criteria, Source: own illustration.

Should-Meet Criteria

FR-SC 001	It should be possible to link or implement other software or applications. *An application for payment would be an example for this. Early cost and time estimation would have been considered. The immediate forecast of the delivery date and an estimated value of the price can lead to an early decision support of an order.*
FR-SC 002	The software should be equipped with a decision or recommendation tool. The goal is to propose a system-generated recommendation from the answers given in the selection options below. If not, it should at least be possible to set up or integrate help systems. *For example: Someone orders an implant for the skull. The program immediately makes an ideal suggestion for manufacturing process, material and parameters.*

Table 9: Functional Requirements, Should-Meet Criteria, Source: own illustration.

The following points (table 10) are defined as non-functional requirements:

Non- Functional Requirements:

N-FR 001	The ordering process has to be as simple and self-explanatory as possible. *According to information from project members, hospital employees (especially surgeons) are under great time pressure and do not have much time to try out new software products pointlessly.*

N-FR 002	The current IT security guidelines must be followed because the clinic works with very sensitive patient data.
N-FR 003	Access to the ordering software should be quick and easy for everyone on a computer.
N-FR 004	It should not require a high level of computer expertise to use the ordering software.

Table 10: Non- Functional Requirements, Source: own illustration.

After defining the requirements, the next step in the “V-model” is the phase of system design.

4.1.2 System Design

As described in chapter "1.2 Problem and motivation", the interested parties who want to order a printed 3D-part have to get an order form. The form used in the initial phase of the project is shown in appendix 1.

Filling out a static order form can cause a lot of problems. Once the form is filled out you have to bring back (or scan and mail) the sheet to the 3D-PRC. This process takes a lot of time.

The requirements and information received from the first meeting with the stakeholders are processed with the existing order form. The result should give an overview of the new order process. This overview is made with the software “XMinde”[3], which makes it easier to see and understand the structure and the relationships. The structure of the software is clearly shown in figure 22 and shows the ordering process.
The configuration of the 3D-printed part is a step-by-step query.
For example, the answers to the first question about the department could be:

- Medical University
- External

The following course depends on the answer chosen. The question if you are also a member of the CAMed project is only asked if you have selected “Clinic” as your department.

[3] https://www.xmind.net/de/

The contact details must be filled out by everyone.

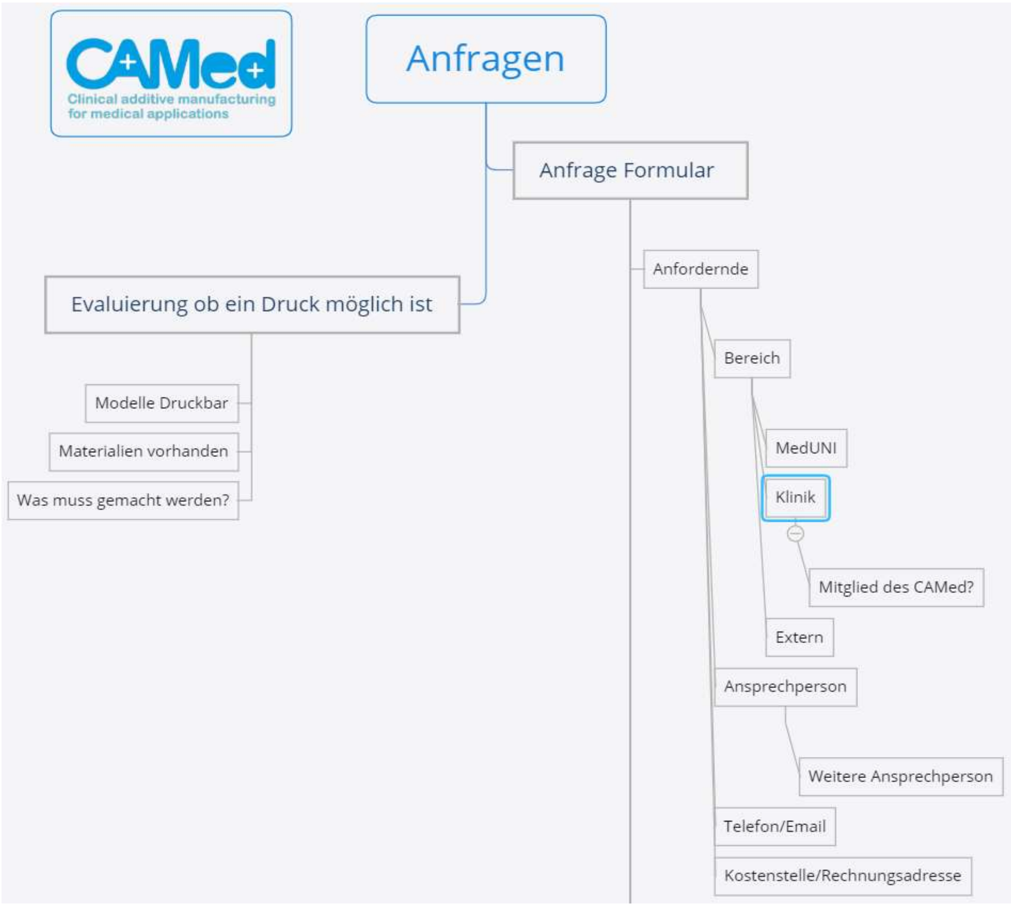


Figure 22: Order Request Structure: Source: own illustration.

Figure 23 is also an overview of the request form and shows that the questions are dependent on the previous answers.

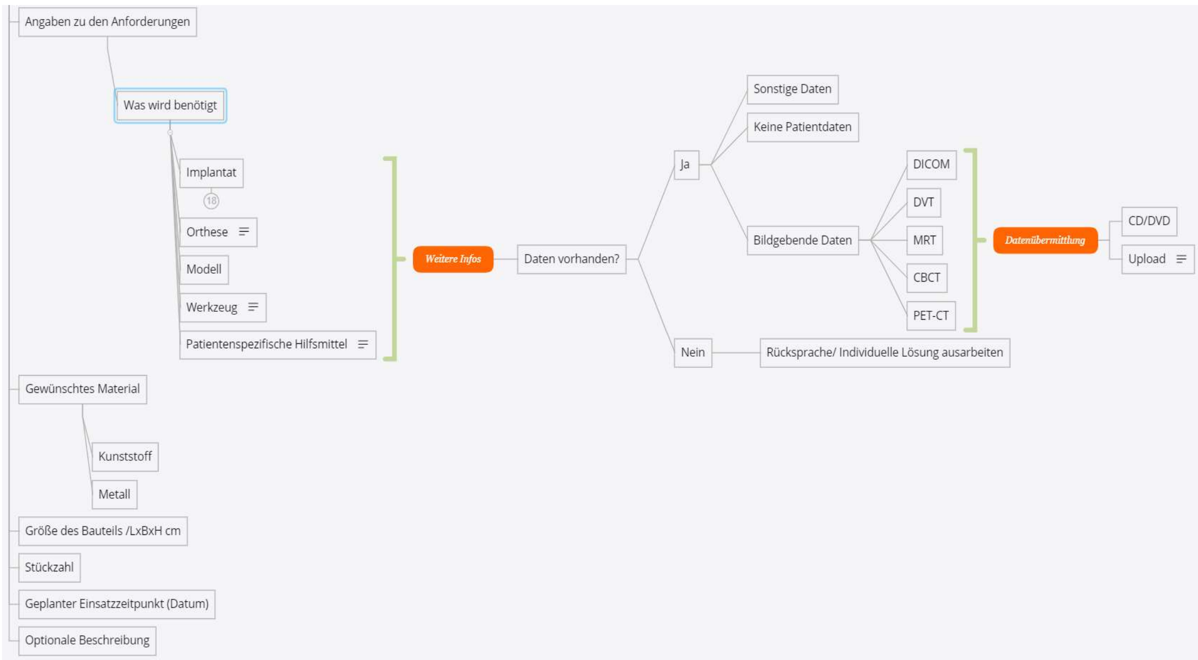


Figure 23: Structure of the Query Path and the Input Options. Source: own illustration.

These structures shown above relate to the ordering software. Another functional requirement is to store the entered data permanently, therefore a database is implemented (FR-MC 004). When developing a database, an Entity-Relationship-Model (ER-model) should first be created. The purpose of an ER-model is to describe the structure of the database and to represent interrelated interesting things in a certain area of knowledge. (Chen, 2002)

Figure 24 shows the ER-model for the database of the ordering software.

The ER-model consists of several entity types and relationships that can exist between the entities. An entity is understood to be an object in the real world that differs from other objects. In software development, the ER-model is typically built to represent things that a company needs to remember in order to execute business processes. The ER-model is a representation of the various information in the data structure that is implemented in the database. (Chen, 2002)

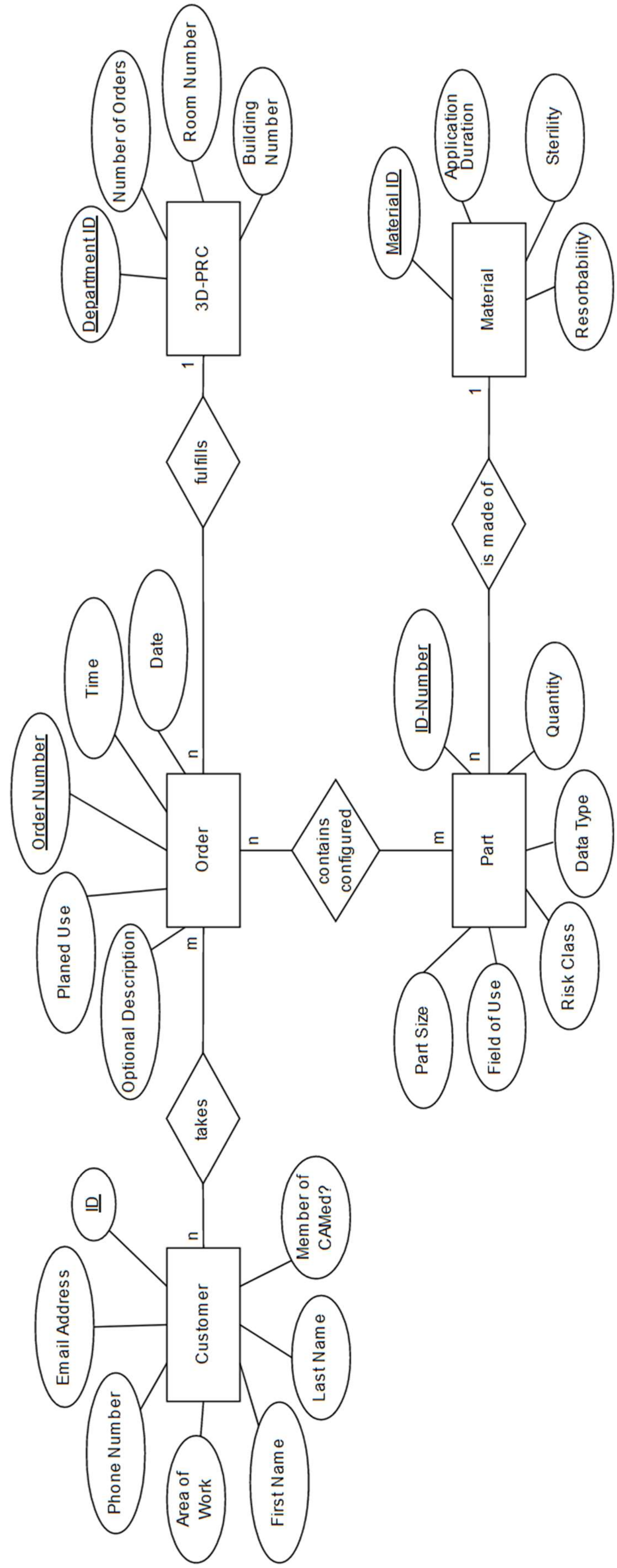


Figure 24: ER-Model, Source: own illustration.

As soon as the system design phase was completed, the cooperation with the software developer started on the basis of the prepared sketches and documents. This is described in the following chapter.

4.1.3 Implementation

In the V-model, the phase "Coding" is at the bottom of the "V". This step includes the first implementations and design steps of the software product. In the V-model, iteration steps and reworking can be assumed. Therefore, the following test points are provided in the V-model to identify errors and correct them in the next steps.
The software was set up by a software engineer student from Graz University of Technology as a master project. In conversations with the software developer, the requirements for creating a first version of the software were discussed. The "Django" framework and the “Python” programming language were used by the software developer to code the software. The new software will be evaluated in a usability test in order to receive initial feedback and suggestions for improvement from customers. This software may only be used for test purposes and not for orders with patient data because the data security is not given yet.
The screenshot (Figure 25) shows the user interface of the software and the comparison of the options available when ordering two different components. If, for example, a tool is required and should be ordered, the following query is different to the order of an implant.
The right image in figure 25 shows that an implant is required, and therefore further detailed questions about the product are asked.
This function was essential for digital ordering (FR-MC 006). With a static form, irrelevant points could lead to confusion or misunderstanding.

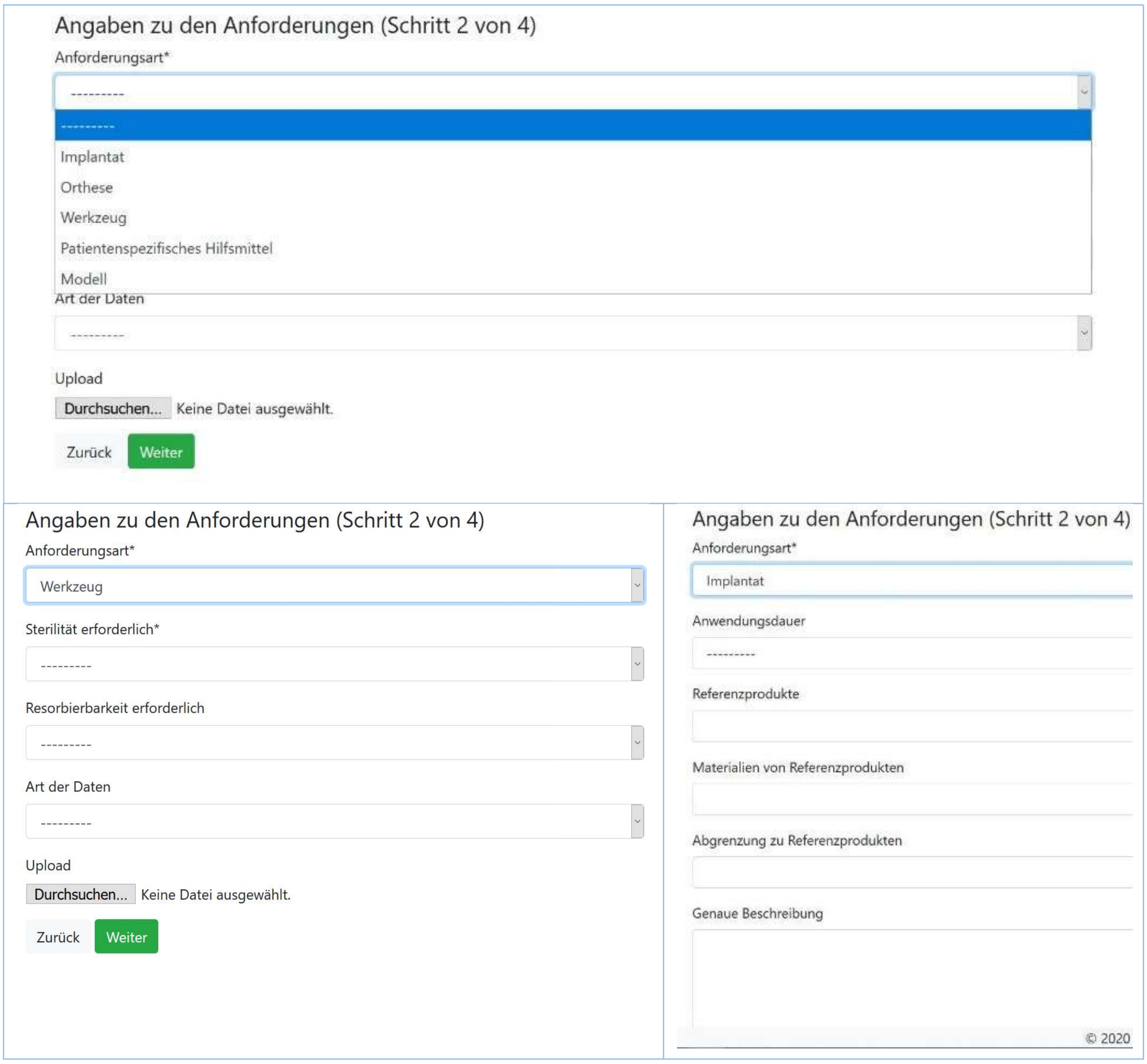


Figure 25: Screenshot of Selection Option in the New Software, Source: own illustration.

Before sending the order, a summary of the entries and the selected items is displayed, as shown in figure 26. It is possible at any time to change the entered data by returning to the corresponding page before sending. After completing the order, the data is saved in a database which can be evaluated if necessary.

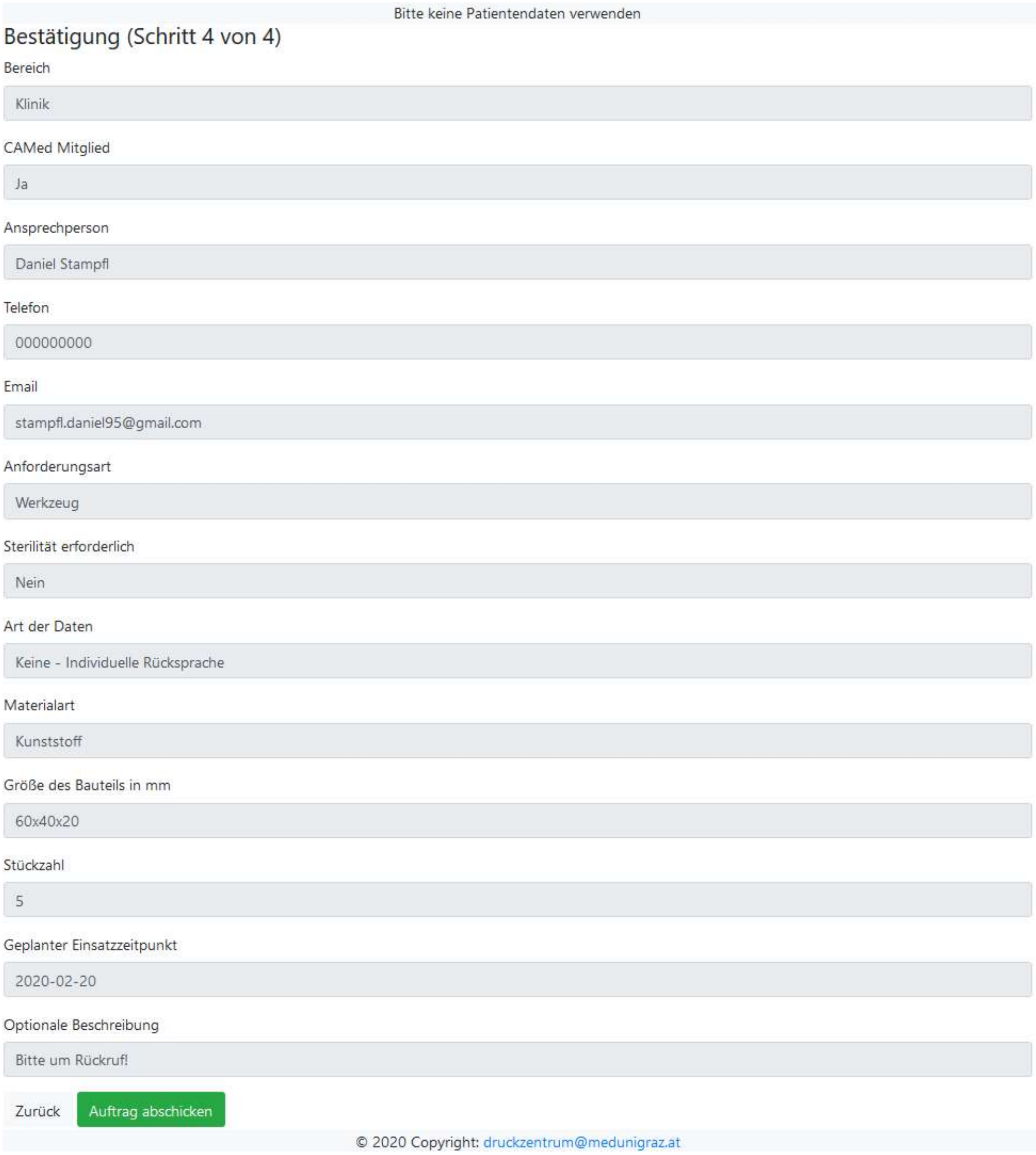


Figure 26: Summary of the Entries and the Selected Items of an Order: Source: own illustration.

The confirmation will be sent to the announced email address. Attached to this mail is a summary ".pdf" file. In addition, a continuous project number is written on this protocol, which was required (FR-MC 002) from the stakeholders. The order number always contains date and time (FR-MC 003). An example of the "pdf summary" is shown in figure 27.

Auftrag Nr.: 2

17.04%.2020 11:28:21

Bereich	Klinik
CAMed_Mitglied	Ja
Ansprechperson	Daniel Stampfl
Telefon	000000000
Email	stampfl.daniel95@gmail.com
Anforderungsart	Werkzeug
Sterilität_erforderlich	Nein
Art_der_Daten	Keine - Individuelle Rücksprache
Materialart	Kunststoff
Größe_des_Bauteils_in_mm	60x40x20
Stückzahl	5
Geplanter_Einsatzzeitpunkt	2020-02-20
Optionale_Beschreibung	Bitte um Rückruf!

Figure 27: Example of Confirmation sent by Email, Source: own illustration.

Another requirement of the stakeholders was the changeability and expandability of the software. Small interventions and changes can be carried out online with administration rights (FR-MC 005). By logging in with administrator rights, you have the option of deleting points or adding new points (Figure 28). For example, a new material could easily be added. On the contrary, if a material is not available, this material could be temporarily removed and then added again. A software developer is not necessary for such small changes. For extensive changes, you should follow the guidelines and edit the software offline (FR-SC 001). Python programming is required for offline changes.

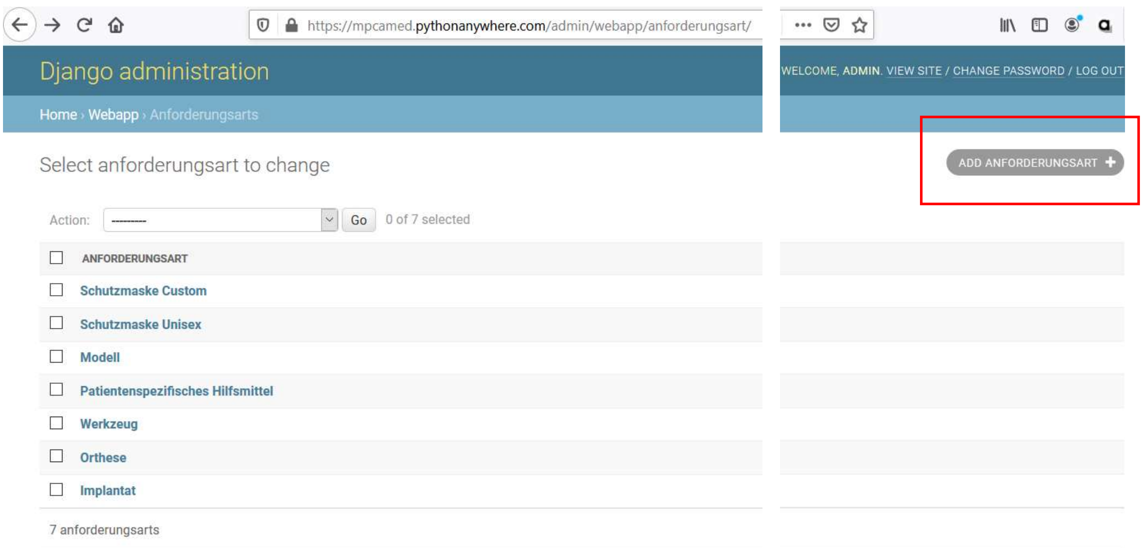


Figure 28: Screenshot of the possibility of minor interventions and changes to the software with the administrator rights online, Source: own illustration.

4.1.4 Integration, Testing and Acceptance

This chapter deals with the evaluation of the software in the practical field, the chosen test method, the evaluation of the questionnaires and the acceptance of the digital solution.

Preparation for the Usability Test

The first step in the integration was the presentation of the first version of the software to the stakeholders involved in a project meeting at the clinic. A “showcase order” was carried out online and presented live on the projector to better convey the intelligibility to those involved. The participants were enthusiastic about the functionality of the software, but there were still open questions and suggestions for changes. For example, the upload-function of patient files was not permitted due to the data guidelines.
The point indicated was revised for the software and an updated version was prepared for the usability test.

Test Plan

To be able to guarantee the structured execution of a test, a test plan must be created. The test plan contains the following points:

- Welcome the participant.
- Short description of the CAMed project and the 3D-PRC.
- Explain the purpose of the test using the orientation script provided.
- Questions about the project and the test should be answered and written down by the facilitator.
- The user has to read and sign the consent form before starting.
- Start recording and perform the test tasks.
- After the test, the participant should fill out a background questionnaire and a feedback form.

The following section describes the criteria according to which the participants were selected for the usability test.

Acquisition of Participants

The criteria for finding the right participants for the usability test were determined during a project meeting. The diversity of experience and knowledge of 3D-printing and the ongoing CAMed project is important (Dumas et al., 1999). The agreed criteria are listed in table 11. After the selection of possible participants, everyone was asked to voluntarily participate in the usability test.

Selected Criteria for Participants in the Usability Test	
- CAMed project member	- No CAMed project member
- Experience with clinic orders	- No experience with clinic orders
- Experience with 3D-print parts	- No experience with 3D-print parts
- Clinical staff (with knowledge about CAMed project)	- Clinical staff (without knowledge about CAMed project)
- Software developer with usability test experience (usability test pilot)	

Table 11: Criteria for the Participants of Usability Test, Source: own illustration based on Outcome of Project Meeting

Test-Setup/ -Equipment

The usability test is carried out with recordings of images and sound. The following materials are used for the implementation:

- **Video Camera**
  Sony HXR-NX30E
- **Microphone**
  Sony ECM-909A
- **Mirror**
- **Computer/Laptop**
  HP ZBook 15u G4

Figure 29 shows a proposed test setup (Rubin 2008). The participant tries to order online and adheres to the test task. The video camera is placed behind the participant, to see the processes on the screen. The mirror shows the participant's facial expressions and gestures, the microphone records what is spoken and what is thought out loud. In this way the test is saved and can be better evaluated, for example by displaying it again.

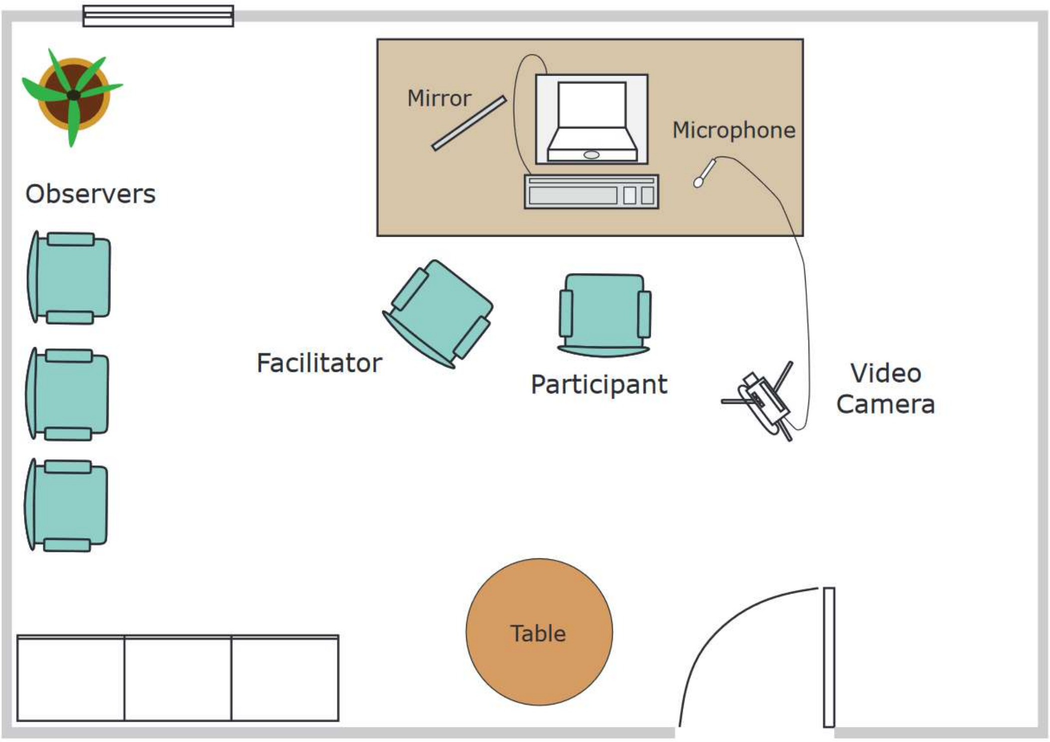


Figure 29: Test Setup, Source: Rubin (2008)

The real test set up is shown in figure 30. The test was carried out in the clinical 3D-PRC. Using the 3D-PRC as a test room has the following advantages:

- The test environment at the clinic is realistic and offers short distances for the participants.
- Participants who have never heard of this project or 3D-PRC before will receive background information and examples of possible use cases.
- Participants who have never heard of the 3D-printing process or have never seen a 3D-printer in progress can take a look inside the machine and see how it works.
- The printed part can be taken into hand and the participant gets a feeling of the haptics.

- If the participant is interested in ordering something and has questions about the printing process or feasibility, the technician and those responsible are present.

- Some prototypes presented in the showroom can lead to inspiration or ideas for the participant.

- After the test, the participant knows where the 3D-PRC is located, should he come into contact with this department again.

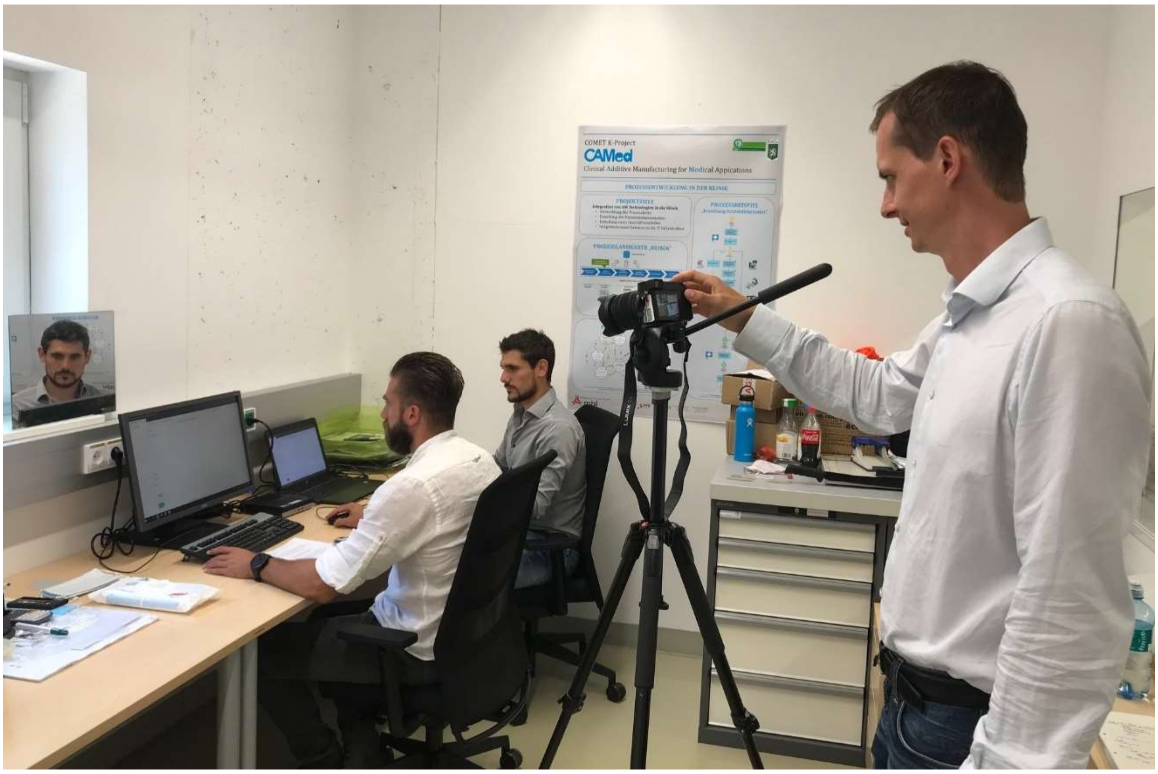


Figure 30: Real Test Setup, Source: own illustration.

Test Tasks

It is evaluated how different participants solve the same tasks. This task only covers one aspect of the ordering process and was therefore chosen as an example. The aim of this test task is to find out whether all stakeholder requirements are met by the software solution. It should help to uncover errors, ambiguities and problems when ordering from the 3D-PRC. The participants should use the ordering software to order an anatomical model for a fictitious patient from the 3D-PRC. Each participant first receives a short introduction to the CAMed project and has to carry out the test task independently after this introduction.
Fictitious files such as CT images and models were made available to the participants in a folder on the desktop in order to make the test situation more realistic. The

following text describes the participant's task, which should be completed during the test.

“You are preparing for an operation on a broken collarbone. In order to better prepare the operation, you want to order a model in the CAMed 3D-PRC.

First step is to open following link: https://mpcamed.pythonanywhere.com/ in the web browser.

The contact details of the questioner are freely selectable. If you enter your contact details, you will receive a confirmation email and an information sheet after submitting the request.

The documents from the "Patient_1" folder on the desktop should help to create an almost real test situation. The documents could be useful and are also fictitious.

Please do not forget to think aloud and say what you see or can’t find.

Thank you very much and enjoy the test.”

Survey

A background questionnaire and a feedback form are the last part of the usability test for the participant. This form has to be filled out and provides an opportunity to write comments. At the beginning are general questions about the participant like educational level, statistics of computer experience or experience with 3D-print parts. This is followed by questions about the comprehensibility of the query, difficulties with using the software and open questions about the ordering process in general. The feedback form is a suitable method to find certain errors and to give the user the opportunity to criticise. The feedback form of the usability test is shown in appendix 2.

With the evaluation of the usability test and their feedback questionnaires, conclusions can be drawn about the communication of correct or incorrect information from the customer to the 3D-PRC. The second part of the practical part deals with the provision of information for the 3D-PRC.

4.2 Provision of Order Information from the Customer to the 3D-PRC

As already announced in the introduction, the second part of the practical part is about the provision of specialized information from the customer for the 3D-PRC.

When ordering a printed component, it is important that the 3D-PRC receives technically correct and usable information from the customer. With digital ordering, only relevant questions have to be asked and errors and ambiguities can be minimized. This concerns for example questions about the mechanical properties of a printed part. Questions about the mechanical properties of a printed part can lead to incorrect answers or confusion for customers. Only a few customers can give the correct answer to difficult questions regarding the stiffness or surface hardness of the component. Such questions are very specific and need to be simplified. If these questions are irrelevant, you can exclude these questions with a digital query.

Example:

When ordering a model, the question about the mechanical properties should not be asked because this model is not exposed to any stresses. In contrast, the mechanical properties are decisive for an implant. For such loads, a suitable material must be used that has been subjected to mechanical testing beforehand. For this reason, it is important to know the mechanical properties of 3D-printed components.

Tests on the mechanical properties have already been carried out in the 3D-PRC and are also part of the CAMed project. This topic is currently the subject of research. Therefore, there are still no clear guidelines that can simply be built into the software. However, a brief overview of current research is given below and how future approaches to material selection could be implemented. Beforehand, an insight into the current research work on the mechanical properties of polymeric implants is given.

4.2.1 Mechanical Properties of Polymeric Implants

Besides the sterilizability and the biocompatibility of various medical materials, the mechanical integrity is substantial. Tensile, compressive, buckling, flexural, shear and torsional loads are acting inside the human body. Muscle forces, for example, lead to tension and thus to undesired stress on the implants. The use of material extrusion (Chapter 2.2) has recently gained importance both in general and in the medical field. This is probably the reason why thermoplastic materials are used. Compared to other material classes, thermoplastics are heavily dependent on the load rate and temperature. The mechanical properties are dependent on these influences, so it is important to characterize these influences. (Petersmann et al., 2020)

Petersmann et al. (2020) carried out several mechanical analyses of 3D-printable polymers, not only to determine the application temperature range, but also to perform tensile tests at various crosshead speeds. Generally, it can be distinguished between acute or repetitive and external or internal loads (Van den Bogert, 1994; Petersmann et al., 2020).

Regarding the human thorax, coughing leads to acute loads and breathing to repetitive ones. Both loads are internal loads. An external load could be like an accidently hitting ones head on a steel body. Acute exposure occurs. In this case, the impact speed and thus the resulting stress value are particularly high. It is not an easy task to carefully consider all of these cases during the implant design process. (Petersmann et al., 2020)

Petersmann et al. (2020) are conducting the tests on six different materials for 3D-printing. The materials are polyetheretherketone (PEEK), polylactide (PLA), poly(methyl methacrylate) (PMMA), glycol-modifed poly(ethylene terephthalate) (PETG), poly (vinylidene fuoride) (PVDF) and polypropylene (PP). They created a printed part for the analysis using different printers and these six materials. The first prints were tested by cutting and grinding cross-sections from untested tensile specimens and analysed using light microscopy to find out the best printing temperature and the best flow factor for the filament. The parameters were set individually for each material so that each cross section had a minimum amount of air gaps with a real filling of 100% being the goal. Table 12 shows the used levels of the printing parameters of all printed specimens. (Petersmann et al., 2020)

Printing parameters	PEEK	PLA	PMMA	PETG	PVDF	PP
Die temperature (in °C)	427	250	250	230	250	230
Build platform material	PEI sheet + PEEK raft	Glass mirror	Glass mirror + Dimafix	Glass mirror + Dimafix	Glass mirror + Dimafix	PP-plate
Build platform temperature (in °C)	160	70	115	100	110	100
Infrared heater temperature (in °C)	380	–	–	–	–	–
Printing speed of the first layer (in mms-1)	30	30	20	20	8	10
Printing speed of the remaining layers (in mms-1)	20	60	20	20	20	20

Table 12: Printing parameters depending on the material, Source: (Petersmann et al., 2020).

The tensile tests were carried out with four different crosshead speeds, namely 10^3, 10^1, 10^{-1} and 10^{-3} mm/s. For each material, the strain at break, the Young's modulus,

the yield strength and the tensile strength are evaluated and compared. “*According to DIN EN ISO 527-1, the Young’s modulus is calculated as the slope of the stress-strain curve in the strain interval between 0.05% and 0.25%, the tensile strength as the global stress maximum and the yield strength as the stress at the yield point. The yield point is characterised by a global stress maximum followed by a stress reduction due to a narrowing of the cross section”* (Petersmann et al., 2020, S.4).
Figure 31 represents stress-strain curves for each material at the highest and the lowest crosshead speed.

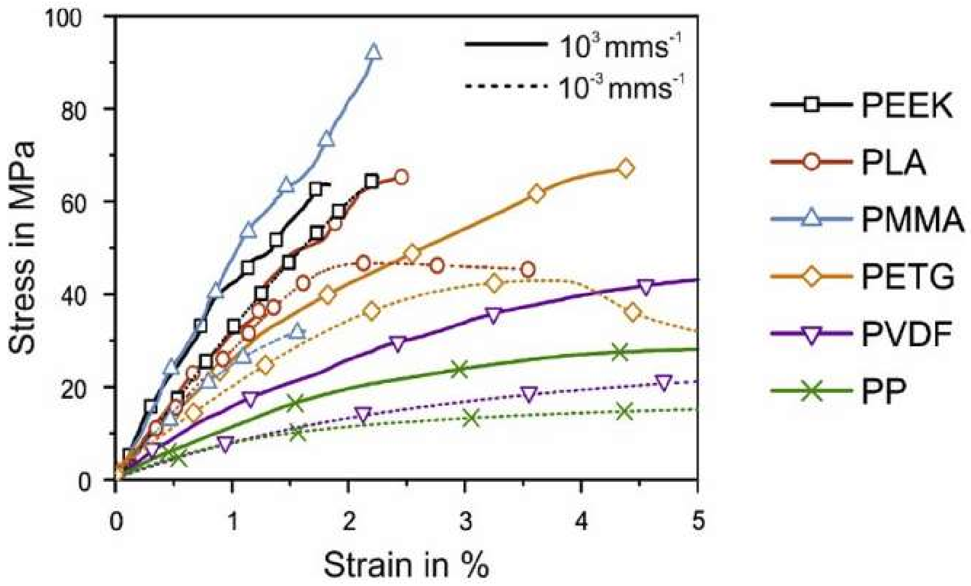


Figure 31: Stress-strain curves, (Petersmann et al., 2020).

The strength of all materials except PEEK is much lower at the lowest test speed (10^{-3} mm/s). The properties of all tested materials are compared, which is of great importance for the implant design. The properties of all tested materials were compared, which is important for the design of the implants. Diagram 32 is intended to be used as an aid in material selection depending on a few but crucial properties of the materials. These polymer materials can be used as materials for 3D-printed implants. (Petersmann et al., 2020)

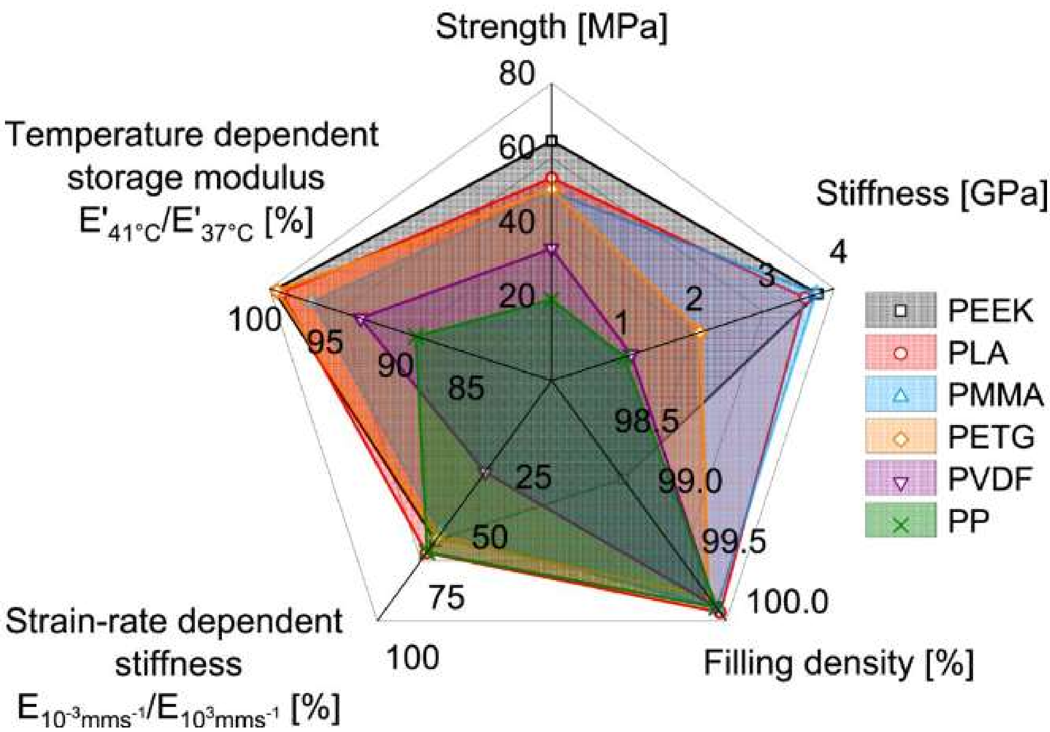
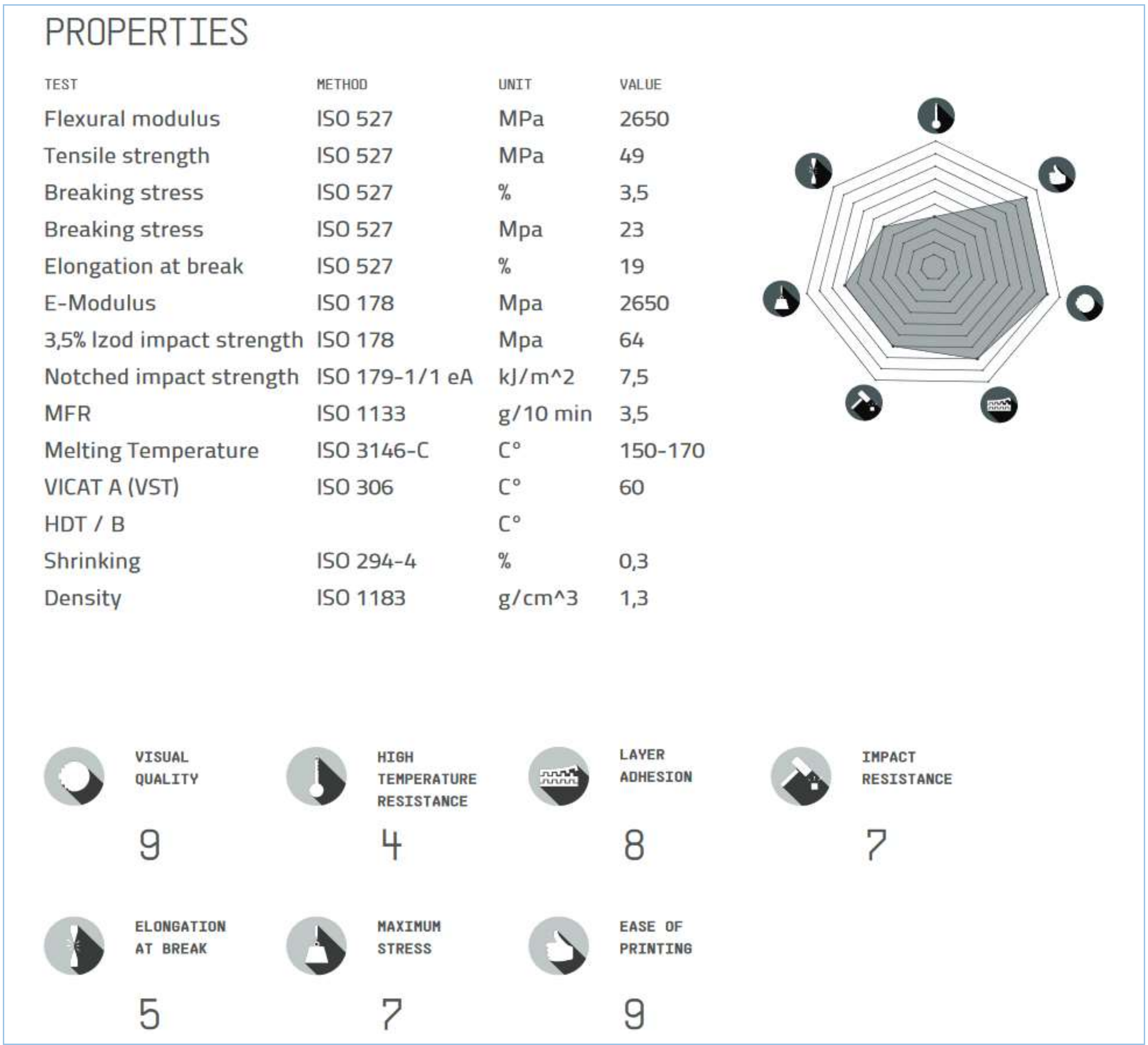


Figure 32: Aid for aterial selection based on Temperature dependent storage modulus, Strength, Stiffness, Strain-rate dependent stiffness and Filling density, Source: (Petersmann et al., 2020).

Research into the mechanical properties of polymers is essential for the project, especially for 3D-PRC, in order to make the right decision about the material. Information on the mechanical properties cannot be expected from a customer when placing an order. For example, information on the strength or stiffness of the components. Such complex questions must be simplified as explained in the following chapter.

4.2.2 Simplifying Specialized Information

For example, a decision- or recommendation-tool could be integrated into the software to simplifying questions (FR-SC 002). It should be a tool where the choice of material is suggested by the software. For this, the customer would only have to evaluate the various criteria with a number between 1 and 10. After completing this task, a graph of the various ratings is made and compared to a graph in the database. The suggestion by the software for a material should be made from a majority of the matches. The following technical sheet 33 could be an example for characteristics and a diagram of the material “PLA”.



PROPERTIES

TEST	METHOD	UNIT	VALUE
Flexural modulus	ISO 527	MPa	2650
Tensile strength	ISO 527	MPa	49
Breaking stress	ISO 527	%	3,5
Breaking stress	ISO 527	Mpa	23
Elongation at break	ISO 527	%	19
E-Modulus	ISO 178	Mpa	2650
3,5% Izod impact strength	ISO 178	Mpa	64
Notched impact strength	ISO 179-1/1 eA	kJ/m^2	7,5
MFR	ISO 1133	g/10 min	3,5
Melting Temperature	ISO 3146-C	C°	150-170
VICAT A (VST)	ISO 306	C°	60
HDT / B		C°	
Shrinking	ISO 294-4	%	0,3
Density	ISO 1183	g/cm^3	1,3

Figure 33: Material Data Sheet PLA NX2, Source: 3DJake (2020).

In this case the various criteria used could be very technical and incomprehensible to non-technicians. The points listed in the first line of table 13 would then have to be adapted and formulated more generally. A possible reformulation is shown in the second line. It is not the same, but it is important to keep it simple and understandable. As a suggestion, the new criteria words could result from experiments and the subsequent evaluation of the questionnaires.

Current Material Properties	VISUAL QUALITY	HIGH TEMPERATURE RESISTANCE	LAYER ADHESION	IMPACT RESISTANCE	ELONGATION AT BREAK	MAXIMUM STRESS	EASE OF PRINTING
Possible Keywords	Visual/Surface Quality	High Temperature Resistance	Colour of Printpart	Stiff or Flexible	Resorbable	Exposed to Stress	Single Use Or Repeated Use

Table 13: Keywords which are asked in an Order and a Decision Tool automatically suggests a Material, Source: own illustration based on 3DJake (2020).

This example of a decision- or recommendation tool is intended to show that this software can still be expanded upon. The adjustments and extensions should be made in close cooperation with the customer.

5 Conclusion

The conclusion includes a summary of the results of the whole project as well as its limitations.

5.1 Results

In the course of this master thesis, a prototype of web application was developed and evaluated for the 3D-PRC. With this software, medical staff, students or external entities can digitally make detailed print requests and send them to the 3D-PRC. The web application guides the user through the individual steps of the ordering process.
The system was set up based on the "V-model". The "V-model" is divided into steps and forms a guideline for developing products. The subtasks of the practical part of this master's thesis correspond to the steps of the "V-model" and are processed accordingly.

Following subtasks were carried out:

- Requirement Analysis
  The requirements for the system were initially defined as part of the RE and discussed with the stakeholders of the project.

- System Design
  The system-structure for the software and its database were defined and created in the design phase.

- Implementation
  The software was programmed in cooperation with a software engineer.

- Testing and Acceptance
  A usability test was carried out with test participants using the prototype of the software. The questionnaire from the usability test provides initial feedback on the software and information on improvements.

The usability test questionnaires have been evaluated and a summary is given:

All participants were familiar with computers and most of them have already used web shops to order something. Everyone was aware of 3D-printing, but not everyone had ordered a 3D-printed part before, and none has ever worked with a 3D-printer themselves. The order was very easy to handle for everyone (N-FR001), and the operation was understandable (N-FR 004). Everyone could order a component and would use the software themselves and recommend it to others because it is very straightforward and does not take up much time. Patient safety was not questioned and no disadvantage for the patients was apparent. Some participants would have liked to have more answers options and the opportunity to provide more information, such as an upload function or being able to determine the arrangement of the part to be produced in the printer (FR-MC 001).
The analysis of the notes, based on the spoken feedback of the participants while they conducted the usability test, revealed further hints for potential improvements of the web application. Some of the statements are very helpful for the evaluation and further development. For example, one participant thought that it was unclear who the contact person was. Furthermore, it was not clear what the reference product was in the order request. One participant noticed that the date of the time of need can be put in the past. He does not consider this to be useful. One participant criticized the layout of the software. It is planned to publish the detailed results of the usability test in a separate article.

Furthermore, the properties of the materials are constantly being researched in order to be able to use them in a more targeted manner. In this way, problems that can arise from wrong selection or incorrect use of a material can be eliminated.
The following chapter summarizes difficulties and challenges that were encountered during the project.

5.2 Challenges

A new project usually presents problems and some risks. There were few problems in this project. Sometimes the problems arise during implementation and require strategies and solutions to solve them. A summary of the problems arising from this project is listed below:

- The first step in system development was to determine the requirements with the CAMed stakeholder. One of these requirements was to automatically generate the delivery date and price for an order request.
  The automatic determination of the price of the printed part would be possible with moderate effort. But the capacity and utilization of the 3D-PRC is not recorded digitally, so it would be very difficult to generate a delivery date. This

requirement was discussed and then removed. The reason for this is that the product range of the 3D-PRC is so broad and the inquiries so individual that a technician for 3D-PRC has to process every order personally until further notice.

- Another point that caused uncertainty in the order request was the upload function. To order a 3D-printed part digitally, there is always a form of data exchange. An upload function has been integrated into the software to solve this problem. If the software can run on an intern (clinical) server, the upload feature would be great and necessary. The upload and storage of patient data via an unknown server is not permitted. If the software is not available online, you have the problem that not every device with internet access can place an order. In addition, the software must be installed on the clinical server by the clinical IT-department. The data upload function therefore had to be completely removed from the software for security reasons. This point was also tedious for the software developer and the software lost significant function. In figure 34 the upload button and also the previously selectable file formats can be seen.

Figure 34: Upload-Function and Selection of Data-Format, Source: own illustration.

The programming code for this upload function was not permanently deleted, it was suggested to be left out in order to facilitate a possible re-commissioning.

In general, arguments against a software solution were raised during the definition of the requirements with the stakeholders and in the course of implementation. The following points were the results of the discussions:

- Computer skills are required to use the order system
- Software has to be created and maintained

- Potential data security issues
- Additional costs could occur

This did not lead to difficulties, but still had to be considered. These arguments were taken into account, which exposed limitations to the software.

5.3 Limitations

Following limitations of the implemented system have to be considered:

- The software created was just a demo software to establish an initial contact with the customers and to carry out a usability test.

- The ordering software is not yet integrated into the IT infrastructure. To use this software, data security must be checked and the rights of the server used must be clarified.

- The usability test was carried out with only six participants.

- The test task of the usability test was fictional and the participants only worked on one scenario.

- The creation of the software did not require any financial means and was set up in the course of a project.

6 Outlook

This work formed the basis for a new ordering system and through the further development of this software current problems are solved and an effective product is offered. Below, a number of current difficulties, suggestions and future ideas will be discussed.

6.1 Current Difficulties

Introducing a new system can often lead to difficulties and complications. The following problems could possibly occur and should be planned in advance:

- The new option to order from 3D-PRC is currently not well known and must be communicated to potential customers.

- If there are few potential new customers, it is difficult to assess whether the further development of the new ordering process is profitable and desirable.
- Errors can occur with the first order from a new customer. This can lead to disinterest in the software.
- There is currently no employee in the project team who has received training in the software and who can use it.
- The must meet criteria of the functional requirements (FR-MC 001) is not fulfilled. Not enough answer options are given.

In summation, the software and the new ordering system were accepted positively in the usability test. Solutions should therefore be found for the problems and the software should be further developed and expanded upon.

6.2 Potential Next Steps

The ordering software is accepted by the customers who have already tried it and therefore the next step should be to further improve the web application based on the gathered feedback from the usability test. For this, the program and all installation instructions are transferred to the 3D-PRC. Another potential next step is to have the stakeholders of the CAMed decide whether the software should be installed on a cloud or on premise. According to the requirements, the challenge here is that the software should be accessible from anywhere and that data security has to be considered. The remaining non-functional requirements should also be implemented. The last of the potential next steps is to increase awareness. As soon as the web application is implemented in the IT infrastructure, customers should be encouraged to use it as the preferred way of ordering a 3D printed part from the 3D-PRC. Receiving more entries will result in a larger database to collect statistics. For each order, a customer feedback concerning the usability of the web application shall be requested to collect further suggestions for continuous improvement of the application,

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Appendix

Med Uni Graz KAGes CAMed Clinical additive manufacturing for medical applications

BESTELLSCHEIN MEDIZINISCHER 3D-DRUCK

Bestellnummer: ____________________ (nicht ausfüllen)

ANFORDERNDE/R:

Klinik: ____

Ansprechperson: ____

Telefon/eMail: ____

weitere Ansprechperson: ____

ANGABEN ZU DEN ANFORDERUNGEN:

Was wird benötigt?

- ☐ Implantat
- ☐ Orthese
- ☐ Modell
- ☐ Werkzeug
- ☐ patientenspezifisches Hilfsmittel

Patientendaten vorhanden?

- ☐ CT-Daten
- ☐ Sonstige Daten: ______________________________
- ☐ keine Patientendaten vorhanden

Ethiknummer (falls vorhanden): ____

Applikation/Bedarfsbeschreibung: ____

____

____

Gewünschtes Material?

- ☐ Kunststoff
- ☐ Metall

Größe des Bauteils? (LxBxH cm) ____

Stückzahl: ____

Geplanter Einsatzzeitpunkt (Datum): ____

Bitte füllen Sie den Bestellschein vollständig aus und schicken Sie ihn an martin.toedtling@medunigraz.at

Medizinische Universität Graz, Auenbruggerplatz 2, 8036 Graz, www.medunigraz.at

Rechtsform: Juristische Person öffentlichen Rechts gem. UG 2002. Information: Mitteilungsblatt der Universität, DVR-Nr. 210 9494.
UID: ATU 575 111 79. Bankverbindung: UniCredit Bank Austria AG IBAN: AT931200050094840004, BIC: BKAUATWW
Raiffeisen Landesbank Steiermark IBAN: AT443800000000049510, BIC: RZSTAT2G

EVALUATION MEDIZINISCHERER 3D-DRUCKBAUTEILE

Auftragsnummer: ________________________________

Frage 1:

Produkt erhalten? ☐ Ja ☐ Nein

Frage 2:

Produkt erhalten im gewünschten Zeitrahmen? ☐ Ja ☐ Nein

Frage 3:

Informationsfluss des Auftragsstatus zufriedenstellend? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Verbesserungsvorschläge: ________________________________

Frage 4:

Produkt nach Ersteinschätzung zufriedenstellend und zur Weiterverwendung entschieden?

☐ Ja ☐ Nein

Verbesserungsvorschläge: ________________________________

Frage 5:

Funktionserwartungen des Produkts wurden erfüllt? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Verbesserungsvorschläge: ________________________________

Frage 6:

Patientenzufriedenheit? (Sofern möglich bzw. Patientenspezifisch verwendet)

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Verbesserungsvorschläge: ________________________________

Skala: 1 = sehr zufrieden; 5 = unzufrieden;

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Appendix 1: First Version of the Hardcopy Order Form, Source: Project.

Fragebogen bezüglich der Bestellsoftware

1. Allgemein:

Was ist Ihr Beruf/Tätigkeit: ____________________________________

2. Verwendung von Computern (z.B. PC, Laptop, Tablet, Smartphone):

a) Wie viele Jahre verwenden Sie bereits einen Computer?

______ *[Jahre]*

b) Wie viel Stunden verwenden Sie ca. einen Computer pro Woche?

Privat	*Für die Arbeit*
____________ *[Stunden]*	____________ *[Stunden]*

3. Erfahrung mit digitalen/online Bestelltools/Webshops (z.B. Amazon, SAP,...) :

a) Wie oft im Monat führen Sie online Bestellungen durch?

Für den privaten Gebrauch	*Für die Arbeit*
o 0	*o 0*
o 1-3	*o 1-3*
o 4-6	*o 4-6*
o >6	*o >6*

4. Erfahrung mit der 3D-Drucktechnologie:

a) Ist Ihnen der Begriff „3D-Druck“ geläufig?

Ja	*Nein*
o	*o*

b) Falls ja, in welchen Bereichen hatten/haben Sie mit 3D-Druck zu tun?

Beruflich? Wenn ja, bitte kurz beschreiben:

____

Privat? Wenn ja, bitte kurz beschreiben:

____

c) Haben Sie schon einmal 3D gedruckte Teile bestellt?

Ja	Nein
o	o

Wenn ja, wie oft?

Täglich	Wöchentlich	Monatlich	Jährlich	Einmalig
o	o	o	o	o

Anmerkungen: ______________________________

c) Arbeiten Sie selbst auch mit einem 3D Drucker?

Ja	Nein
Privat: o Beruflich: o	o

Wenn ja, wie oft?

Täglich	Wöchentlich	Monatlich	Jährlich	Einmalig
o	o	o	o	o

Anmerkungen: ______________________________

5. Erfahrung mit "Usability Tests":

a) Haben Sie bereits an einem Usability-Test teilgenommen?

Ja, als Proband	Ja, für eine eigene Untersuchung	Nein
o	o	o

Feedback bezüglich der Bestellsoftware

1. Anwendung der Applikation:

a)	Benützung der Applikation	Sehr einfach o	Einfach o	Normal o	Kompliziert o	Sehr kompliziert o
b)	Verständlichkeit der Funktion	Selbsterklärend o	Leicht verständlich o	Verständilich o	Schwer verständlich o	Unverständlich o
c)	Verständlichkeit der Auswahlfenster	Selbsterklärend o	Leicht verständlich o	Verständilich o	Schwer verständlich o	Unverständlich o
d)	Erscheinungsbild der Applikation	Sehr übersichtlich o	Übersichtlich o	Neutral o	Unübersichtig o	Sehr unübersichlich o
e)	Zeitaufwand	Sehr niedrig o	Niedrig o	Angemessen o	Hoch o	Sehr hoch o
f)	Verhältnis Nutzen zu Aufwand	Sehr gut o	Gut o	Mäßig o	Nicht gut o	Überhaupt nicht gut o
h)	Wie wahrscheinlich ist es, dass Sie diese Applikation wieder verwenden werden.	Sehr wahrscheinlich o	Wahrscheinlich o	Ungewiss o	Unwahrscheinlich o	Sehr unwahrscheinlich o

2. **Würden Sie sich zutrauen, mit dieser Bestellsoftware etwas zu bestellen?**

Trifft zu	*Trifft eher zu*	*Trifft eher nicht zu*	*Trifft nicht zu*
☐	☐	☐	☐

3. **Bitte bewerten Sie den Einsatz der Applikation in ihrem Anwendungsfall anhand eines Schulnotensystems.**

sehr gut	*gut*	*befriedigend*	*genügend*	*nicht genügend*
☐	☐	☐	☐	☐

4. **Würden sie die Anwendung auch ihn ihrem Arbeitsumfeld verwenden?**

Ja	*Eher ja*	*Eher nein*	*Unsicher*
☐	☐	☐	☐

5. **Haben Sie im Zuge der Verwendung der Applikation Bedenken bezüglich der Wahrung des Datenschutzes?**

Ja	*Nein*
o	*o*

Falls ja, welche:

____

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6. Sehen Sie einen Nachteil für Patienten oder Anwender?

Ja	*Nein*
o	*o*

Falls ja, welche:

____

7. Fanden sie aus ihrer Sicht alle nötigen Angaben für die Bestellung eines 3D Druckteiles zur medizinischen Anwendung vor?

Ja	*Nein*
o	*o*

Wenn nein, welche Angaben haben ihnen gefehlt?

____

8. Weitere Anmerkungen

(Verbesserungsvorschläge, Wünsche, Anregungen, usw.)

Usability-Test der Bestellsoftware Daniel Stampfl

Appendix 2: Background Questionnaire and a Feedback Form, Source: own illustration.

References

3D Hubs. (2021). Website of 3D Hubs. Retrieved from https://www.3dhubs.com/ [Accessed 05.01.2021]

3D Side. (2021). Website of 3D Side. Retrieved from https://www.3dside.eu/en/ [Accessed 05.01.2021]

3DJake. (2020). Website of 3DJake. Retrieved from https://www.3djake.at/ [Accessed 05.12.2020]

ARBURG. (2020). *APF process!* Homepage: Arburg Retrieved from https://www.arburg.com/us/us/products-and-services/additive-manufacturing/apf-process/ [Accessed 05.01.2021]

Barnum, C. M. (2002). *Usability-Testing and Research*, Longman Publishers.

Benington, H. D. (1983). Production of Large Computer Programs. *Annals of the History of Computing, Vol. 5,* (pp. 350–361). https://doi.org/10.1109/MAHC.1983.10102

Boehm, B.W. (1981). *Software Engineering Economics* (1. Edition). Prentice-Hall.

CAMed-Project. (2020). Website of CAMed. Retrieved from https://www.medunigraz.at/camed/ [Accessed 23.11.2020]

Chen, P. (2002). Entity-Relationship Modeling: Historical Events, Future Trends, and Lessons Learned. *Software Pioneers,* (pp. 296–310). https://doi.org/10.1007/978-3-642-59412-0_17

Cranial Implant Generation. (2020). Website of Egger, J. Retrieved from http://studierfenster.tugraz.at/skull_reconstruction/skull_reconstruction.html [Accessed 23.11.2020]

Dröschel, W., Wiemers, M. (1999). *Das V-Modell 97: Der Standard für die Entwicklung von IT-Systemen mit Anleitung für den Praxiseinsatz*. De Gruyter Oldenbourg.

Dumas, J., Redish, J. (1999). *A Practical Guide to Usability Testing* (2. Edition). Intellect.

Egger, J., Gall, M., Tax, A., Ücal, M., Zefferer, U., Li, X., Von Campe, G., Schäfer, U., Schmalstieg, D., Chen, X. (2017). Interactive reconstructions of cranial 3D implants under MeVisLab as an alternative to commercial planning software. *PLoS ONE,* Vol. 12(3), (pp.5-6). https://doi.org/10.1371/journal.pone.0172694

Fassin, Y. (2009). The Stakeholder Model Refined. *Journal of Business Ethics, Vol 84,* (pp. 113–135). https://doi.org/10.1007/s10551-008-9677-4

Feldmann, C., Pumpe, A. (2016). *3D-Druck – Verfahrensauswahl und Wirtschaftlichkeit* (1. Edition). Springer.

Forsberg, K., Mooz, H. (2015). The Relationship of System Engineering to the Project Cycle. *Engineering Management Journal, Vol. 4,* (pp. 36-43). https://doi.org/10.1080/10429247.1992.11414684

Gessler, M. (2012). Kompetenzbasiertes Projektmanagement (PM3). *Handbuch für die Projektarbeit, Qualifizierung und Zertifizierung auf Basis der IPMA Competence Baseline Version 3.0. Band 1. 4. Aufl.,* GPM Deutsche Gesellschaft für Projektmanagement.

Gibson, I., Rosen, D., Stucker, B. (2015). *Additive Manufacturing Technologies* (2. Edition). Springer.

Haberfellner, R.,De Weck, O.,Fricke, E., Vössner, S. (2019). *Systems Engineering* (1. Edition). Birkhäuser.

Holzmann, P., Breitenecker, R., Schwarz, E. J., Gregori, P. (2020). Business model design for novel technologies in nascent industries: An investigation of 3D-printing service providers. *Technological Forecasting & Social Change, Vol 159*, (pp. 1-6). https://doi.org/10.1016/j.techfore.2020.120193

Hull, E., Jackson, K., Dick, J. (2011): *Requirements Engineering* (3. Edition). Springer.

Ketchen J. D., Shook, C. L. (1996). The application of cluster analysis in strategic management research: an analysis and critique. *Strategic Management Journal Vol.*

17, (pp. 441-458). https://doi.org/10.1002/(SICI)1097-0266(199606)17:6<441::AID-SMJ819>3.0.CO;2-G

Langer, A. M. (2008). System Development Life Cycle (SDLC). *Analysis and Design of Information Systems.* Springer. https://doi.org/10.1007/978-1-84628-655-1_2

LayerbyLayer. (2020). *Metall 3D-Druck: Was ist Direct Energy Deposition?* Hompage: LayerbyLayer.
Retrieved from https://www.layerbylayer.de/de/3d-druck-wissen/tutorials/metall-3d-druck-was-ist-direct-energy-deposition.html [Accessed 23.11.2020]

Lewis, C. (1982). *Using the "Thinking-aloud" Method in Cognitive Interface Design.* IBM T.J. Watson Research Center.

Lewis, C., John, R. (1993). *Task-Centered User Interface Design: A Practical Introduction.* Shareware book, University of Colorado, Boulder. http://hcibib.org/tcuid/tcuid.pdf

Longwei, Y., Huichao, S., Xingtian, Q., Wei, Z. (2016). *The Fused Deposition Modeling 3D-Printing. International Conference on Electrical, Mechanical and Industrial Engineering,* (pp. 1-3), ICEMIE 2016. https://doi.org/10.2991/icemie-16.2016.50

Manufacturing-Guide. (2020). Website of Manufacturing-Guide. Retrieved from https://www.manufacturingguide.com/en/fused-deposition-modeling-fdm [Accessed 23.11.2020]

Materialise. (2021). Website of Materialise. Retrieved from https://www.materialise.com/de [Accessed 05.01.2021]

MissionAdditive. (2021). Website of MissionAdditive. Retrieved from https://www.mission-additive.de/vorteile-des-3d-drucks-fuer-die-medizinbranche-a-914948/ [Accessed 03.02.2021]

Müller-Ettrich G. (1998) System Development with V-Model and UML. *Schader M., Korthaus A. The Unified Modeling Language,* (pp. 238-249). https://doi.org/10.1007/978-3-642-48673-9_16

Narciso, C., Verner, J. M. (2009). Why did your project fail? *Communications of the ACM, Vol. (52),* (pp.130-134). https://doi.org/10.1145/1610252.1610286

Oral 3D. (2021). Website of Oral 3D. Retrieved from https://www.oral3d.eu/en/ [Accessed 05.01.2021]

Partsch, H. (2009). *Requirements-Engineering systematisch* (2. Edition). Springer.

Petersmann, S., Spoerk, M., Van De Steene, W., Ücal, M., Wiener, J., Pinter, G., Arbeiter, F. (2020). Mechanical properties of polymeric implant materials produced by extrusion-based additive manufacturing. *Journal of the Mechanical Behavior of Biomedical Materials, Vol 104,* (pp. 2-10). https://doi.org/10.1016/j.jmbbm.2019.103611

Pahl, G., Beitz, W., Feldhusen, J., Grote, K.H. (2006). *Konstruktionslehre. Grundlagen erfolgreicher Produktentwicklung. Methoden und Anwendung, Vol. 5,* (pp. 10). Springer

Pomager, J. (2014). 4 Fragen, die beantwortet werden müssen. *3D-Druck in der Medizin* [Article from 14.04.2014] Retrieved from www.meddeviceonline.com [Accessed 23.11.2020]

Rayna, T., Striukova, L. (2016). From rapid prototyping to home fabrication: how 3D-print is changing business model innovation. *Technological Forecasting & Social Change, Vol. 102,* (pp. 214–224). https://doi.org/10.1016/j.techfore.2015.07.023

Rengier, F., Mehndiratta, A., Von Tengg-Kobligk, H., Zechmann, C. M., Unterhinninghofen, R., Kauczor, H.-U., Giesel, F. L. (2010). 3D-printing based on imaging data: review of medical applications. *International Journal of Computer Assisted Radiology and Surgery, Vol. 5, (pp. 335-341)*. https://doi.org/10.1007/s11548-010-0476-x

Rogers, H., Baricz, N., Pawar, K. S. (2016). 3D-printing services: classification, supply chain implications and research agenda. *International Journal of Physical Distribution & Logistics Management. Vol. 46 No. 10,* (pp. 886–907). https://doi.org/10.1108/IJPDLM-07-2016-0210

Rubin, J., Chisnell, D. (2008). *How to Plan, Design, and Conduct Effective Tests Handbook of Usability-Testing* (2. Edition). Wiley.

Rupp, C., SOPHISTen (2009). *Requirements-Engineering und -Management.* (5. Edition). Carl Hanser Verlag.

Schiner3DRepro. (2021). Website of Schiner3DRepro. Retrieved from https://www.schiner3drepro.com/ [Accessed 05.01.2021]

Thayer, R. H., Dorfman, M. (1990). *Standards, Guidelines, and Examples on System and Software Requirements Engineering* (1. Edition). IEEE Computer Society Press.

THRE3D. (2021). *How laminated object manufacturing (LOM) works!* Homepage: THRE3D Retrieved from https://web.archive.org/web/20140220161700/https://thre3d.com/how-it-works/sheet-lamination/laminated-object-manufacturing-lom [Accessed 05.01.2021]

Van den Bogert, A.J. (1994). Analysis and simulation of mechanical loads on the human musculoskeletal system: a methodological overview. *Exercise Sport Sciences Reviews, Vol 22,* (pp. 23–51).

VDI 2221, (2019). Entwicklung technischer Produkte und Systeme. *Modell der Produktentwicklung*, Blatt 1, VEREIN DEUTSCHER INGENIEURE:

XTREMEengineering. (2016). *3 Additive Manufacturing technologien to watch out for in 2017.* Retrieved from https://medium.com/extreme-engineering/3-additive-manufacturing-technologies-to-watch-out-for-in-2017-7226d310ca56 [Accessed 23.11.2020]