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Carlo Kriesi

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Thesis for the Degree of
Philosophiae Doctor
Faculty of Engineering
Department of Mechanical and Industrial
Engineering

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Wayfaring in the Biomedical Sector

A Call for Re-Introducing the Toolmaker

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Preface

This thesis has been submitted to the Norwegian University of Science and Technology (NTNU) for the degree of Philosophiae Doctor (PhD). All work has been conducted at the Department of Mechanical and Industrial Engineering (MTP) at NTNU, more specifically within TrollLABS. The research was supported by the Research Council of Norway (RCN) through its user-driven research (BIA) funding scheme, project number 236739/O30.

Trondheim, December 2018

Acknowledgments

I took off from Zurich for what I thought would just be an exchange semester - now, I find myself handing in this thesis, looking back to five amazing years. First and foremost this is due to Prof. Martin Steinert - thank you! Thank you for your trust in me, for exposing me to huge challenges, for giving me freedom to explore, and for coaching me when it was needed. Thank you for building up TrollLABS and accumulating all the great people that make it so special, all the while having the open mind and heart for relaxed summer-fests and great evenings at the good neighbor's place or R1.

Thank you to all of TrollLABS, Heikki, Stephanie, Matilde, Achim, Kristoffer, Andreas, Jørgen, Jørgen, Mat, and Yngve. I learned a ton from all of you on so many different levels and I look forward to building many more prototypes together! You all made me feel like every day at work was a day among friends - which is something that I wish to happen to our second generation of Trolls as well - best of luck on your journeys. Also, this work would have never come to where it is now without the work of all the talented master students that I had the pleasure to work with - thank you all!

I would also like to thank The Interface Group - Virginia, Anastasios, and Claudia - under Prof. Vartan Kurtcuoglu for the great collaboration throughout the development of the Flowchamber and all the great brainstorming and testing sessions. Furthermore, I would like to thank Patrick Sticher from Unitectra for the great help with patenting this invention.

Last but not least I would like to thank my family and friends who visited me far from home and supported me throughout this whole journey. A special thank you goes to Kristin who kept me sane and focused in stressful times and was always there to listen and advice when a project was stuck.

Abstract

This thesis aims to provide an understanding of the *Why?* and *How?* of a modern toolmaker, specifically within the biomedical sector, on a theoretical and practical level and what their role is within a product development process. Over the four years of this PhD work, a total of ten projects were completed by - or with the involvement of - the author. Framed by the grounded theory, these project provide the fundamental data for the conclusions of this thesis. In addition, a total of thirteen scientific contributions were - and will be - published that cover the three cornerstones of the toolmaker: The role of users, the importance of prototyping and how to successfully do it, and how this is used in the biomedical sector.

The structure of this thesis is closely following the three essential stages of product development process as encountered when using the Wayfaring method: *Orienting*, *Probing*, and *Bringing it Home*. In addition to highlighting key-insights from the projects to emphasize the importance of each stage, the thesis is following the development path of the main project, a novel flow-chamber setup for cell research that was developed by the author. This project allows to reflect on a complete product development process from paper prototype to patented beta-version, with a focus on why the toolmaker made all the difference.

The conclusions of this thesis are, given the nature of the scientific method, of qualitative nature and address the initially stated questions of *Why?* the toolmaker had an impact in the projects and *How?* one can implement an according role within a product development team.

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List of Abbreviations

FC	Flow-Chamber
FFE	Fuzzy Front End
FFHTC	Fresh Frozen Human Tissue Cutting
IoT	Internet of Things
IP	Intellectual Property
MVP	Minimum Viable Product
NiCr	Nichrome
PCB	Printed Circuit Board
PD	Product Development
PDP	Product Development Process
TTO	Technology Transfer Office
UU	Unknown Unknown
VT	Vacuum Table
WSS	Wall Shear Stress

Chapter 1

Telescopes and Neurones - The Concept of a Toolmaker

Galileo Galilei (1564 - 1642) is credited with a plethora of inventions, constructions, and findings. Most notably, he built the first high-power (not the *first*) telescope with a magnification of 30x, allowing him to observe the universe at a level of detail previously impossible, describing the surface of the moon, and discovering the *Medicean Stars* (Moons of Jupiter), all famously published in his work *Sidereus Nuncius* (Galilei 1880). He was not the only contemporary curious mind who pointed telescopes at stars, planets, and potential enemy ships, but he had the distinctive skill to ground suitable lenses to achieve such a high level of magnification, so that "one will try in vain to see all the things observed by us in the heavens", as he said, if one did not have access to his telescopes (Biagioli 2000).

At the very core of his discoveries was therefore not only the curiosity of a great mind, but the skill to create a device that allows for new observations. He was, simply put, a highly talented toolmaker, enabling his own science. The role of understanding, developing, and discovering tools for scientific progress is the core topic of this thesis.

1.1 Aim and Scope

The aim of this PhD is to provide an understanding of a modern toolmaker, specifically within the biomedical sector by answering the two questions: *Why?* and *How?* Both questions are answered throughout this thesis on both, a theoretical and practical level. The answer to the latter, arguably more complex question is founded on ten early-stage, prototype-driven product development (PD) projects where a toolmaker was the integral part.

This chapter presents the the thirteen scientific contributions of the author, as well as the ten projects listed in section 1.5. While all projects come from within the biomedical sector and are located in the Fuzzy Front End (FFE) of PD, the scientific contributions focus on specific angles of how PD is understood within this thesis. An according overview along the three core-topics *users*, *prototyping*, and *biomedical sector* is shown in figure 1.1.

All work was exclusively conducted within the research group TrollLABS, more specifically with various degrees of involvement of the author. Furthermore, all of the projects finished with a physical implementation of some sort. Since they further all followed the Wayfaring PD method, and the insights followed the development of the the author's main project, this thesis is structured along the three main stages of this method, namely *Orienting* in chapter 2, *Probing* in chapter 3, and *Bringing it Home* in chapter 4 (Steinert and Leifer 2012). This allows for highlighting the role of the toolmaker throughout each phase of this process, and build the argument on how, and why toolmakers should be re-introduced as a central innovation point, in this thesis specifically in the biomedical sector.

1.1.1 Approach

The levels of coherence throughout all projects allow the author to observe each stage from two different viewpoints: On one hand from the viewpoint of an external observer, highlighting the theoretical importance of the stages, supported by the findings of the listed PD projects. On the other hand from the practical viewpoint of a *toolmaker*, leading through the detailed description of the development of a novel, integrated flow-chamber (FC) setup for observing cells under flow-induced mechanical stress. This project was conducted by the author himself over the course of three years. It underwent all stages of development, from highly exploratory work to patenting and finally handing it out to external users. Consequently, the author impersonates a prototype of a modern toolmaker in the biomedical sector.

1.1.2 Method

This thesis is framed by grounded theory (Strauss and Corbin 1997, Glaser 2017) and are therefore following a non-framed research approach (hence the lack of a clear research question): The projects that provide the fundamental insights and the basis for the conclusions in chapter 5 are not quantifiable, but comparable due to the fact that they all followed the same PD method within the same environment, TrollLABS. The projects are therefore treated as exploratory case studies (Yin 2011; 2013). The argumentation of Eisenhardt (1989) states that repeatably observed phenomena

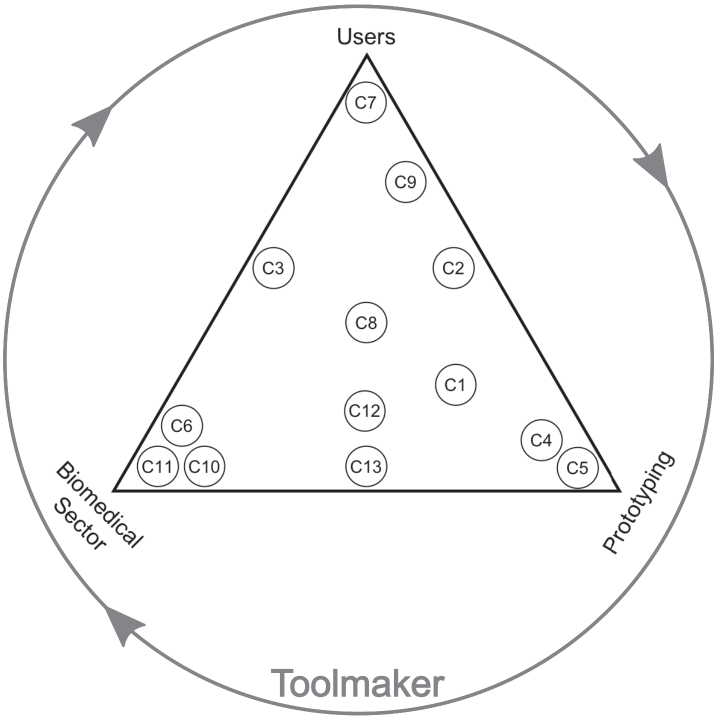

Figure 1.1: The contributions, numbered according to the list in section 1.5, cover the three cornerstones of understanding and working around *users*, *prototyping*, and the *biomedical sector*. The toolmaker, as it is presented in this thesis, ensures an iterative integration of the influences of all of these factors.

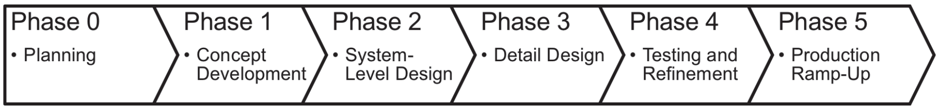

Figure 1.2: The product development process according to Eppinger and Ulrich (2012).

from such cases can be formulated as hypotheses that allow for subsequent controlled testing. In this thesis, the combination of the two viewpoints described above allows us therefore to establish a prototype of *how* and *by whom* future experiments and equipment in the biomedical sector potentially should be developed.

All projects presented within this thesis describe physical prototypes that were designed, built, and tested within TrollLABS. Subsequently, the author applied - and learned - a variety of skills throughout the making of these projects: Classical mechanical design; theoretical calculations and applied simulations in fluid- and thermodynamics; Applied electronics and mechatronics including design and production of printed circuit boards (PCBs); Programming skills for various analyses and implementing an adjustable control system based on the Arduino-platform. The physical implementations of all these skills rely on the author's applied usage of Laser-cutters, 3D printers, CNC mills, lathes, casting techniques, injection molding, and general hand-tool usage.

1.2 The Need for a Toolmaker in the Biomedical Sector

The definition of the biomedical sector used within this thesis is following the very wide definition of Harris et al. (2002): A field that aims at providing medical applications. This means that biomedical engineering is not limited to objects and tools that are in direct contact with patients, but also includes research equipment that are aimed to enable insights that subsequently result in e.g. treatment protocols.

This sector is interesting for PD due to the complexity that arises from combining engineering with living organisms, subsequently reducing the design freedom and the solution space due to e.g. toxicity of some materials or thermal constraints. Without touching the topic of regulations and approval processes, developing experiments or any other device within the biomedical sector is therefore arguably extremely challenging and any errors potentially have far reaching consequences for the users, most notably patients.

It should be noted that the boundary between when something is aimed towards providing a medical application, and when not, is blurry - CERN (Conseil Européen pour la Recherche Nucléaire, Geneva, CH) could be considered the most intricate biomedical project, since medical applications are in the back of their head when colliding particles, and serendipity at CERN just so brought forward positron emission tomography scanners, among other biomedical applications (Heuer 2012).

The motivation to focus on this sector is based on the fact that throughout the roughly four years that TrollLABS has existed, multiple representatives of the biomedical sector sought after help with developing novel products. While this sector is not the only one the laboratory is working together with, the frequency of requests raised the question of where the issue lies within the sector. Throughout multiple interviews with representatives from this sector (see publication in preparation in appendix M), it became obvious that there is a missing link - this sector is lacking a place, skilled personnel, and administrative surroundings where ideas from end-users and researchers can be translated in functional prototypes and subsequent novel research and products. This *link* is what is meant as a toolmaker. It fundamentally differs from the currently governing understanding of a toolmaker, which is along the lines of what dictionaries state: “One (such as a person or company) that makes tools” (Dictionary 2018c). Surely, there are toolmakers that just make tools - but the argumentation of this thesis is precisely that this understanding is fundamentally flawed and attempts to extend this definition to “An entity within physical proximity of a biomedical sector, that iteratively gathers user insights, translates them into prototypes for verifying said insights, and delivers functioning prototypes and according specifications and requirements for future optimization work.”

1.3 The Role of the Toolmaker

The complexity of the biomedical sector and its players, e.g. hospitals or pharmaceutic corporations, makes it safe to say that this sector follows certain managerial structures like any other big corporation. Subsequently, the toolmaker must find its place and value within, adding to the question of *How?* and also *Why?* this should be done.

This thesis shows that the toolmaker fits into the *product champion* model: Schon (1963) defines such champions as internal promoters of an idea that overcome the internal resistance by putting themselves on the line for an idea of doubtful success and subsequently accept potential failure. Quite drastically, Schon (1963) states that “There is nothing incidental or exceptional about this [individuals emerging as product champions] happening. Where radical innovation is concerned, the emergence of a champion is required. Given the underground resistance to change described earlier, the new idea either finds a champion or dies."

The list of different key individuals, among others the product champion was further disseminated and extended by the SAPPHO study (Rothwell et al. 1974), who defined a total of four key individuals and quantified their respective influence on innovation:

- Technical Innovator.
- Business Innovator.
- Product Champion.
- Chief Executive.

Chakrabarti (1974) follows the same fundamental concept and presents an understanding of how innovation works in corporations and quantifies the importance of having a product champion within a managerial structure. By analyzing 45 NASA (National Aeronautics and Space Administration, Washington, D.C., US) projects, he comes to the conclusion that the successful ones (total of 17) had - unlike the non-successful 28 - an internal product champion. Said champion promotes the product to the highest managerial levels, subsequently increasing the foothold and potential success within the company.

He further defines the required skills and competences of a champion:

- Technical competence.
- Knowledge about the company.
- Knowledge of the market.
- Drive and aggressiveness.
- Political astuteness.

Based on the knowledge of these roles, Maidique (1980) started analyzing how the roles change over time due to companies growing and requiring more complex structures (see figure 1.3) - all of them require a technologist who supports the product champion. More studies on the importance of the champion are listed in Howell and Higgins (1990).

In a similar fashion, the *Promotorenmodell* (Folkerts-Mähl 2013) explains that innovation only happens when certain people push for an idea

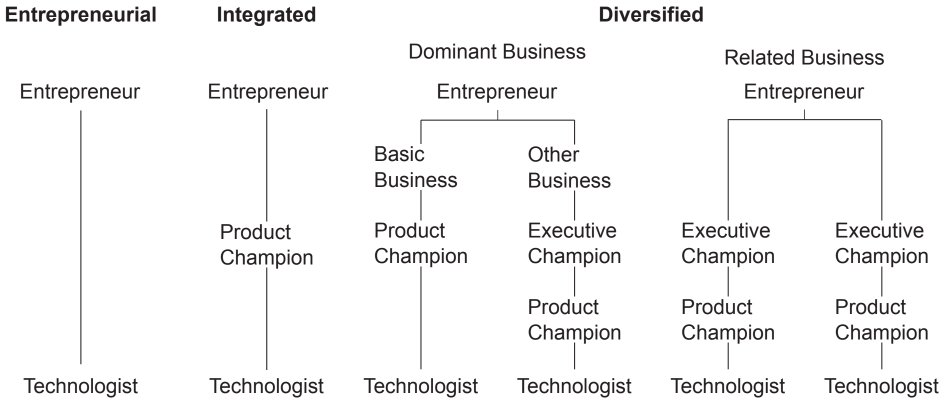

Figure 1.3: The different roles within various company structures: The simplest form of a company is the Entrepreneurial one with one business unit and the entrepreneur is the sole source for technological sponsorship. In slightly more complex company structures (Integrated), the entrepreneur has no longer the chance to follow all technological developments in detail and the technologist needs to rely on a *product-champion* in order to promote ideas. In diversified businesses, the entrepreneur relies on even more layers of roles (Maidique 1980).

on various levels, most importantly the *Fachpromotor* (knowledge promoter) and the *Machtpromotor* (power promoter) who - similar to product champion together with the management - can push innovative ideas together within a company structure.

Van de Ven et al. (1999) further analyses how the different roles should change their frequency of interactions over the development time. For example the critic should challenge novel ideas, but once the development goes towards production, the focus must shift on implementing said production line, and the critic should have little to say.

The special situation of the biomedical sector is as follows: While there is an abundance of various promoters within e.g. a biomedical science laboratory, it is within the wrong context for PD, since e.g. knowledge about cells and which research direction to go forward in is not the same as physically creating new experimental setups. On the other hand, there are plenty of companies that have an abundance of knowledge when it comes to technology, e.g. engineering consulting firms. As will be discussed throughout this thesis and concluded in chapter 5, the role of the toolmaker is to support and translate the needs of the “technologists” in the biomedical sector, which are doctors and researchers.

1.4 Understanding TrollLABS

TrollLABS is a research laboratory located within the Department of Mechanical and Industrial Engineering (MTP) at the Norwegian University of Science and Technology (NTNU) and an essential part of this thesis. The laboratory itself is a room full of equipment and materials where everyone with access is encouraged to build their ideas and prototypes. It is also the environment where the research group meets, where the new master students are following classes, and where all projects of this thesis were conducted. When referring to a "project conducted within TrollLABS", it implies that it:

- Is located within the Fuzzy Front End (FFE) of PD;
- Was mainly built in the laboratory itself;
- Followed the PD-method Wayfaring;
- Used prototypes to learn and as an essential guiding tool.

1.4.1 The Fuzzy Front End

The PD work can be presented as a linear process that goes through certain phases, for example as shown in figure 1.2 after the concept by Eppinger and Ulrich (2012). Herstatt et al. (2006) see the PD process as a similarly segmented, linear construct (see figure 1.4) and define the first two phases - idea generation and concept development - as the FFE of PD.

This thesis follows this definition to a small degree, meaning that one can roughly define PD work in phases that follow each other and that the FFE is seen as the earliest phases in PD where concepts and ideas are still very vague. But: Leaving the *fuzzy* phase of PD implies that the project is *not* fuzzy anymore, therefore implying that everything is *clear*. Referring to figure 1.4, only an idealistic, theoretical PD process can ever define that the "development"-phase is clear. Furthermore, chapter 3 of this thesis shows that defining "prototype development and testing" as non-fuzzy is plain wrong. In addition, this thesis emphasizes the importance of the use of prototyping throughout all stages.

That being said, the FFE of PD[1] is, in the context of this thesis, defined as *every* stage of PD, starting with orienting oneself in the solution space until one has converged to one final working solution. This is due to the pre-requirement, vision-driven setting of all the conducted projects.

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[1] The *FFE of PD* is not to be confused with the *FFE-class*, also mentioned throughout this thesis, a course for master students taught by Prof. Martin Steinert at NTNU. In this class the students are learning the Wayfaring and prototyping skillset through project-based development work within TrollLABS. The course is described in detail in Slåttsveen et al. (2018) in appendix J.

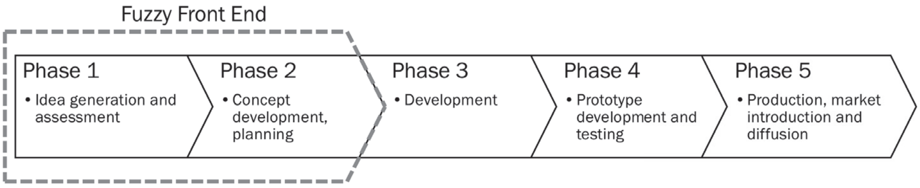

Figure 1.4: The Fuzzy Front End of product development as seen by Herstatt et al. (2006).

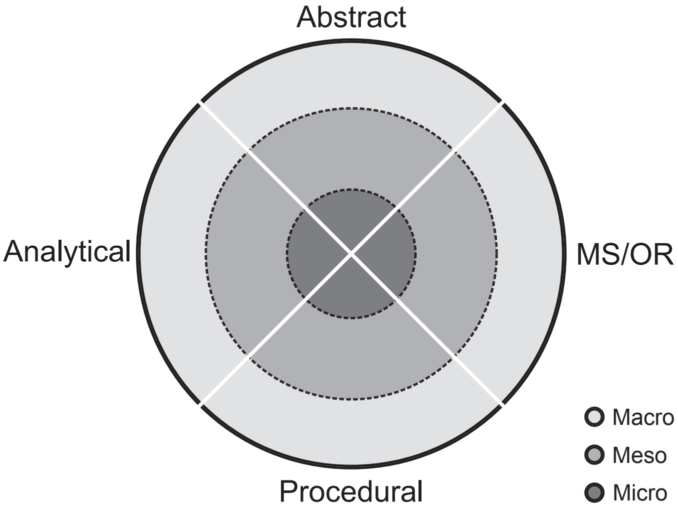

Figure 1.5: Categorizing PD methods along two dimensions and multiple levels of scope, as proposed and shown by Wynn and Clarkson (2017). The focus level is categorized in immediate context (micro), end-to-end flows of tasks (meso), and project structures (macro). Furthermore, they differentiate between procedural vs. abstract, and analytical vs. computational analysis (MS/OR).

1.4.2 Wayfaring

The product development process (PDP) can be described as a linear process consisting of multiple stages and phases, as Eppinger and Ulrich (2012) or Herstatt et al. (2006) describe it (see figure 1.2 and figure 1.4, respectively). How this process, whatever the phases might be, is tackled, is up to the PD method that is applied. The wast, but due to the lack of user-centered methods incomplete compilation and categorization of PD methods by Wynn and Clarkson (2017) (see figure 1.5) shows that there is no lack of such methods, nor a lack of understanding that the PDP is diverse where different methods might help throughout different phases and different levels of focus. If nothing else, it goes to show that there is no key to universal truth when it comes to PD.

With this in mind, it may seem illogical to just follow one method - Wayfaring, as described by Steinert and Leifer (2012) - throughout this thesis. However, the strength of this method is explained by the analogy it is based on: The symbiosis of hunting and gathering. A hunter has the aim of finding food for their village. Just because a herd of deer was spotted at lone location one month ago, it does not mean they are still at the same location, so it is pointless to just run to that spot and use a lot of energy for - most likely - no result. Hunting is therefore a step-wise, explorative task where the next step is aimed according to the latest finding, a trace. These traces can lead the hunter through different environments, e.g. a riverbed or dry lands, meaning that the analysis of the trace requires different skills and potentially locally applied specialized methods. Just finding food, however, is not enough - one has to gather it, and bring it home, a more analytic, straight forward task.

The similarities to the PDP are obvious: PD aims to find the *really big idea* in order to create an advantage and e.g. profit for a company. Simply trying to improve the last product, the known location, most likely does not yield any significant advantages. However, taking small, rapid development-steps in the general direction of the vision allows to adjust the path, which does not follow a straight direction. Each step is called a “probe”, where one concept or critical function is iteratively prototyped, tested, and reflected on. If necessary, this process is done over multiple disciplines in an interlaced knowledge domain in order to make a confident step in the next direction of the development. The final step, the really big idea, is one product that is designed to satisfy the vision set at the beginning. It is not a complete manufacturing plant ready to produce thousands of these products, but that was not the aim. The aim is to provide a functioning prototype that fulfills all the requirements and specifications in order to satisfy the vision. Figure

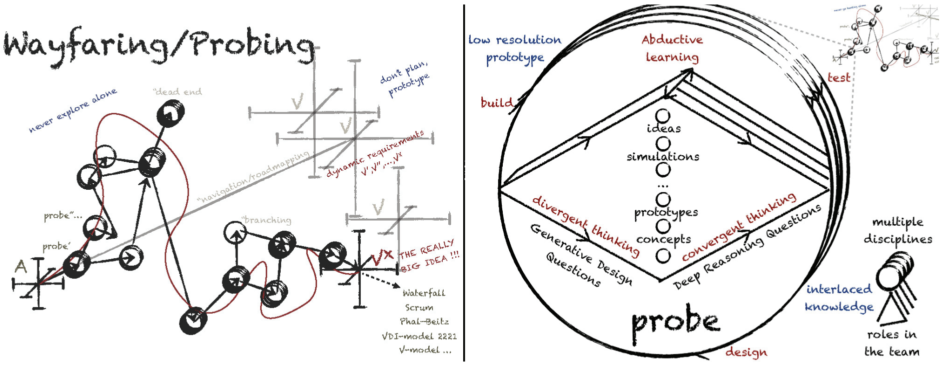

Figure 1.6: Graphical description of the Wayfaring method, where iterative, multidisciplinary probing cirles (right) help guiding the development to the dynamically adjusted goal (left). Both graphics from Gerstenberg et al. (2015).

1.6 graphically depicts the Wayfaring approach and the according probes.

One of the key elements of Wayfaring are therefore the probes itself where the development team has the freedom to use whatever means necessary in order to find the right answer. There are probes where paper prototypes are sufficient, and there are probes where calculations and simulations are in order, or one can seek inspiration from another method. This freedom is the strength since it does not constrain the developers to follow rigid paths, unlike when using rigid processes like e.g. the stage gate model (Cooper 1990), that are not adaptable to dynamically shifting requirements.

One of the essential concepts of TrollLABS and Wayfaring is therefore that PD is not a linear process where one moves in a straight line towards a pre-defined, known target, but rather explores unknown areas within a vast solution space.

1.4.3 Prototype to Learn

The orientation-tool for explorative work within TrollLABS and the Wayfaring model is prototyping, a commonly used approach throughout all fields of engineering. However, neither are all prototyping approaches the same, nor do they all serve the same purpose. According to Eppinger and Ulrich (2012), prototypes are "An approximation of the product along one or more dimensions of interest", and Plattner (2010) defines them as "anything that takes a physical form". Throughout the work presented in this thesis, prototyping has an explorative rather than a proof-of-product role (Ullman 2010) and is used "to learn", as Leifer and Steinert (2011) put it.

The strength of the prototypes is therefore not simply in building them, but in learning from testing specific functions or user interactions and learning about possible implications for further developments. Referring to the hunter-analogy, each prototype is an opportunity to pin-point a track and find the direction for the next step.

Supporting this argumentation within computer science, Taylor and Standish (1982) highlight the underlying problem when developing novel systems: In a perfect world, the requirements are precisely stated and it is known how to implement them. In reality, however, the requirements might be either perfectly stated, but it is unknown how they could be implemented, or vice versa. In both cases, they argue, it is necessary that users are exposed to prototypes of the system so that requirements and possible solutions become aligned and refined to actually solve the problem. The importance of using prototype-test cycles in physical PD is highlighted by the work of Dow et al. (2009) and confirmed by the author (Kriesi et al. 2014), experimentally showing that prototyping increases the quality of the final product, even for experts in the field.

Simply building prototypes is, however, not a guarantee for success. Elverum et al. (2016) states that, in addition to the type of prototype, it is also important to chose the right strategy for prototyping. Jensen et al. (2016a) investigated the effects of material selection, challenge formulation, and a prototyping warm-up session on the outcome of a prototyping challenge. Their results show that all of them have an influence on the prototyping process, highlighting the complexity of this approach. In addition, the resolution of the prototypes can trigger discussions on different levels (Edelman et al. 2009). If done *right*, however, prototypes not only accelerate development, but have the potential to capture and transfer knowledge within corporations (Erichsen et al. 2016). Now what does *right* mean when it comes to prototyping: Combined with Wayfaring, it means that prototypes are built in the fastest way possible, implying the usage of the lowest, while still relevant, possible resolution. They should be built, if applicable, in interlaced knowledge domains, meaning that one iteration can investigate different fields of expertise, e.g. engineering and medicine. And, most importantly, they have to be reflected on so that the learning process is complete and the next step into the solution space can be taken with high confidence.

1.5 Foundation

The foundation for the arguments presented in this PhD work are the ten early stage development projects described below, as well as the thirteen articles. While the projects all are within the biomedical sector, the articles mainly highlight different elements of the Wayfaring principle. All the work

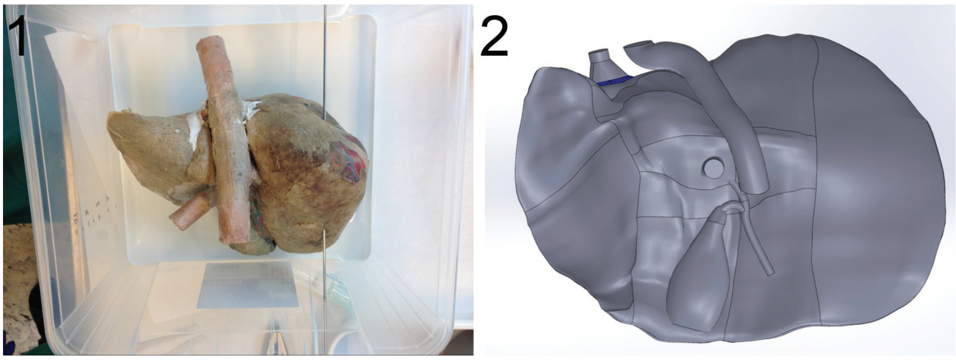

Figure 1.7: The liver phantom was a feasibility study on 3D printed organ models for training laparoscopic surgeries. The old process required two complete human livers for the casting process, one being visible in image (1). Reconstruction from CT-scans, however, allowed for 3D modelling and subsequent 3D-printing of patient specific models (2).

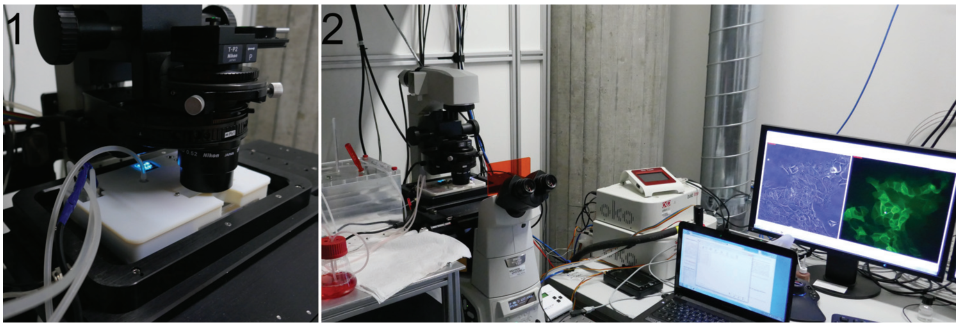

Figure 1.8: The flow-chamber project is motivated by the lack of equipment for investigating cells under physiological levels of mechanical loads. By developing a device that includes all necessary technology and still fits on the microscope (1), one can observe the cells live under mechanical loads (2).

was conducted within TrollLABS throughout the author's PhD work.

1.5.1 Projects: Author was sole or one of the main Contributors

The following projects were either conducted by the author alone, or at least in the leading position, or with him involved in an active coaching role, meaning that he mostly guided the process, but also actively helped with prototyping and technical aspects of the project.

- *Liver Phantom* (2014): This project, with the author as sole contributor, was a feasibility study for the potential of automatically producing liver phantoms for surgeons to practice patient specific laparoscopic surgeries on (see figure 1.7). By combining 3D-prints based on patient-specific CT data and casting techniques, it was shown that it would be possible to create patient specific models that include tumors and main blood vessels in a very short amount of time. A clear improvement from their previous way of manufacturing that required two complete human livers obtained from bodies. A short summary is given in appendix A.

- *The Flow-Chamber* (2015 - ongoing): An previous professor of the author, Prof. Vartan Kurtcuoglu, head of Interface Group at the University of Zurich, pitched the idea of creating a novel system for increasing the throughput of flow-related experiments in the field of biology. Such experiments aim to exhibit a controlled amount of mechanical loads on cells, similar to what they experience in an in-vivo situation. What started off as very explorative work ended in a highly integrated, patent pending system and which is now in the beta-phase, as shown in figure 1.8. The FC was the main project throughout all of the PhD work, with the author being sole contributor on the prototyping side, and will be highlighted within this thesis. The patent itself is attached in appendix B.

- *100x Glass Slide* (2015): Alongside the flow-chamber development, members of the interface group in Zurich raised the wish for a glass slide that can be used within the flow-chamber and allows for 100x magnification. The slides they currently used were only good for magnifications up to 40x due to their thickness, required by the mechanical stiffness for withstanding the internal pressure of the flow-chamber itself. Together with the glass makers at NTNU the author solely developed a glass-slide that is overall stiff enough and has a very thin cut-out section that allows for 100x magnification, therefore widening the use-cases of the FC.

- *Laerdal Eyes* (2016 - 2017): Laerdal Medical (Laerdal Medical, Stavanger, NO), a world leading producer of medical training mannequins challenged TrollLABS to develop a new way of actuating the - up until now - very static eyes of their products. Throughout a pre-master and masters project under the supervision of the author, an interactive solution was developed where an operator sees and controls the eyes at the same time by using a heads-up display and eye-tracking technology, as visible in figure 1.9. The result was demonstrated at the NordiCHI2018 conference in Oslo (see appendix I for the demo paper (Nygaard et al. 2018)).

Figure 1.9: In order to increase the possibilities and levels of interaction with medical training mannequins, TrollLABS developed a set of eyes that is remotely controlled by tracking the eyes of an external observer who has the viewpoint of the mannequin itself.

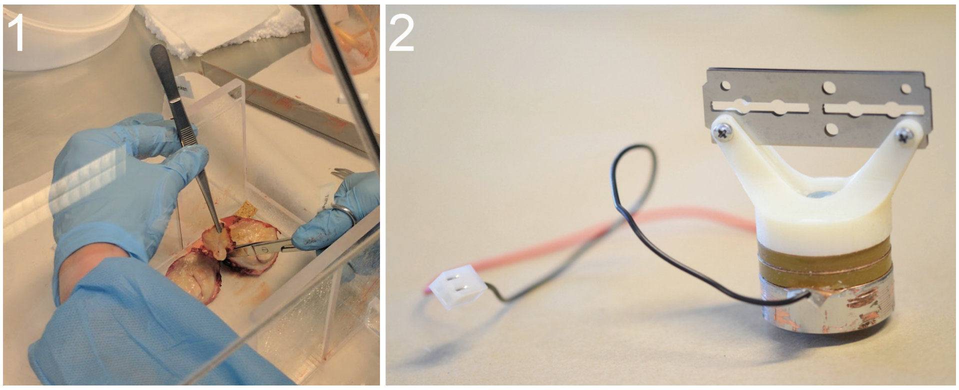

Figure 1.10: Cutting a prostate (1) with the current setup is neither precise, nor convenient for the user. By exploring home-made ultrasonic cutters (2), an automated solution is within grasp.

- *The Pump Project* (2017): From the FC project it became apparent that there is a strong need for highly precise pumps within the biomedical sector since any oscillating / inaccurate flow directly implies inaccurate results. Together with three students from the FFE-class, the author developed a functioning prototype (see figure 1.11) of a pump hat delivers a highly constant flow.

- *Fresh Frozen Human Tissue Cutting* (2017 - ongoing): This project, abbreviated FFHTC, was initiated by Biobank1 (Biobank1 AS, Trondheim, NO) with the aim of improving the process of gathering cancerous tissue samples from surgically removed prostates, as visible in figure 1.10. Within the scope of one pre-master / master cycle under the supervision of the author, TrollLABS is developing a user-friendly and precise way of cutting a thin slice from fresh tissue as well as drilling out a small area of interest from the - later on - frozen slice.

- *REBOA* (2017 - ongoing): Doctors from St. Olav's hospital in Trondheim asked for help to develop a cheap ultra-sound compatible injection system that can be used to train doctors in the usage of so-called REBOA inserts. These "balloons" are used to stop the blood-flow into the lower part of the body by blocking off the according areas of the Aorta. In this project, however, the aim was a different novel context. The invention is currently in the patenting process, and the article about the medical process itself is under review (see appendix L). The development work was performed by one master student under the supervision of the author.

1.5.2 Projects: From within TrollLABS but the Author only had an observing Role

The following projects were conducted within the same manner as the ones mentioned above, but the author was not directly involved but had an external, observing role, allowing him to follow the process nevertheless.

- *Mouse Table* (2016): TrollLABS got approached by the Kavli Institute, a research unit at the St. Olav's hospital and Nobel laureate in medicine 2014, in order to build a new experimental setup. Unlike in their previous experiments, where a mouse is freely running around with a flexible microscope attached to their skull, the planned, new setup required the mouse to stand still. Yet it still had to be able to walk around. This contradiction was solved by a member of

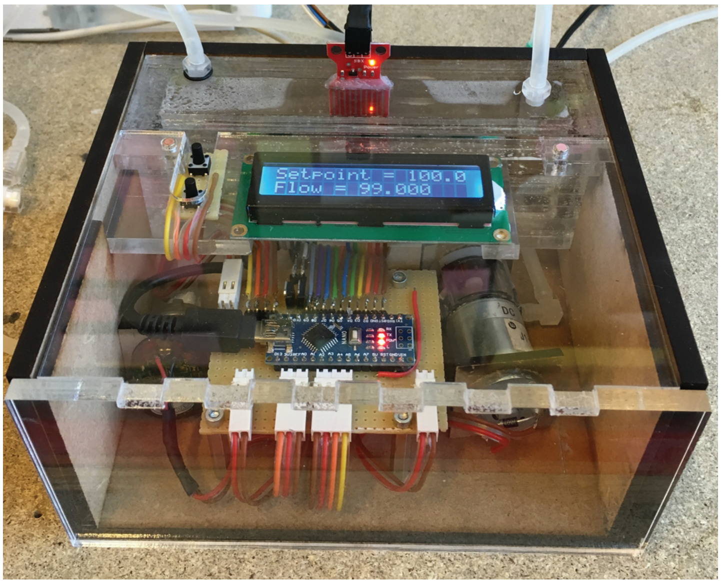

Figure 1.11: The final prototype from the pump project that ran as part of the FFE-class. The pump is able to deliver a highly accurate, stable flow required for experiments that rely on accurate flow-rates.

Figure 1.12: The medical mannequin shown here is prepared for a training session with emergency response personnel and is equipped with an injection port developed in TrollLABS (grey patch, upper right thigh).

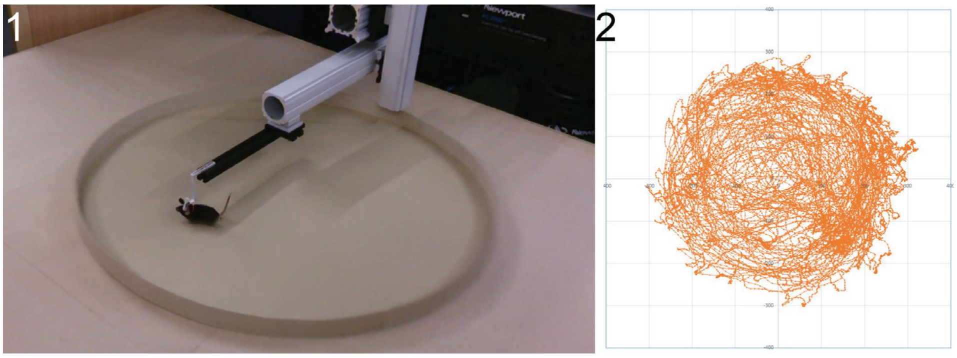

Figure 1.13: In order to explore the possibilities of using a two-photon microscope, members of TrollLABS were challenged with creating a world that revolves around a mouse that stands still. By building an over-sized *air-hockey*-table, the mouse was able to freely run around (1) while their path was tracked in real time (2).

TrollLABS who developed a light, flexible disk that floated on an air-pillow, similar to an air-hockey table. The movement of the floating disk was tracked in real time in order to recreate the path that the mouse took (see figure 1.13).

- *New Rib-cage* (2017 - 2018): On demand of Laerdal Medical a master student of TrollLABS got challenged to develop a new rib-cage construction for CPR training mannequins. While current dolls rely on a simple spring, human rib-cages feel very different when performing CPR on. Not only is the force different than with a spring, but they also tend to break during the treatment. The aim was therefore to develop a training rip-cage that resembles the human rib-cage better and includes a breaking-mechanism.

- *Break a Leg* (2018): Another project that was triggered by the need of Laerdal Medical, but this time with focus on fractures of the lower leg, a common soccer-injury. When such fractures occur, the emergency response doctors need to pull apart the fractured leg and re-align the bones in order to secure blood-flow to the foot before fixating it and transporting the patient to the hospital. This procedure, especially the pulling apart, can currently only be trained on injured people. Three students of the FFE-class developed a solution that emergency doctors were able to test on a real training mannequin, as seen in figure 1.14.

Figure 1.14: Up until now, there was no training equipment on the market that allows for learning the exhausting procedure of re-positioning a fully fractured leg. In this picture, emergency response doctors from St. Olav's hospital in Trondheim are testing the fully functional prototype built by one of TrollLABS' FFE-class teams.

1.5.3 Contributions: Main Author

- *C1*: Carlo Kriesi, Martin Steinert, Mirko Meboldt, and Stephanie Balters. Physiological Data Acquisition for Deeper Insights into Prototyping. In *Proceedings of NordDesign 2014 Conference*:

  As part of the author's master thesis, the prototyping experiment of Dow et al. (2009) was repeated, with the added usage of physiological sensors (ECG and acceleration) in order to track the activity and stress-level of the participants. The conclusion was a confirmation of the results of Dow et al. (2009) and first insights into what seems to be a difference in heart-rate levels between prototyping and non-prototyping participants. The low number of data-points does not allow for any conclusions but the results should be seen as explorative trends. The article can be found in appendix C.

- *C2*: Kriesi, Carlo; Steinert, Martin; Aalto-Setälä, Laura; Anvik, Anders; Balters, Stephanie; Baracchi, Alessia; Bisballe Jensen, Matilde; Bjørkli, Leif Erik; Buzzaccaro, Nicolo; Cortesi, Dario; D'Onghia, Francesco; Dosi, Clio; Franchini, Giulia; Fuchs, Matt; Gerstenberg, Achim; Hansen, Erik; Hiekkanen, Karri Matias; Hyde, David; Ituarte, Iñigo; Kalasniemi, Jani; Kurikka, Joona; Lanza, Irene; Laurila, Anssi; Lee, Tik Ho; Lønvik, Siri; Mansikka-Aho, Anniina; Nordberg, Markus; Oinonen, Päivi; Pedrelli, Luca; Pekuri, Anna; Rane, Enna; Reime, Thov; Repokari, Lauri; Rønningen, Martin; Rowlands, Stephanie; Sjöman, Heikki; Slåttsveen, Kristoffer; Strachan, Andy; Strømstad, Kirsti; Suren, Stian; Tapio, Peter; Utriainen, Tuuli; Vignoli, Matteo; Vijaykumar, Saurabh; Welo, Torgeir; Wulvik, Andreas. Distributed Experiments in Design Sciences - a next Step in Design Observation Studies? In *Proceedings of ICED15*:

  This article presents the experiment of running the prototyping challenge presented in Kriesi et al. (2014) on a global scale, meaning that packages containing all necessary instructions and materials were sent to various universities around the world. The aim was to test whether or not one could establish a global design-studies network where research groups could share and distribute design experiments. If possible, this could lead to better insights into e.g. cultural differences, similar to what is observed in business management (Hofstede 1994). The article, attached in appendix D, is an explorative study and does not present any conclusions regarding the feasibility of such a network.

  Since this first attempt was conducted with researchers and students participating in the CERN-based course Challenge Based Innovation, the author list contains - in true CERN-fashion - everyone who contributed to the experiment.

- *C3*: Kriesi, Carlo; Balters, Stephanie; Steinert, Martin. Experimental Studies in Design Science and Engineering Design Science – A Repository for Experiment Setups. In *Proceedings of NordDesign 2016*:

  This article was triggered by discussions about the robustness of experiments, especially when dealing with human participants. It became apparent to the authors that a lot of studies leave out potentially important details, e.g. at which frame rate a computer interaction is performed. Failure to report such details can lead to non-repeatable experiments, therefore rendering them void. Within this article, EIMR (experimental item-mining repository) was presented, a conceptual repository for storing experimental setups at a very high level of detail. The article can be seen in appendix E.

- *C4*: Kriesi, Carlo; Blindheim, Jørgen; Bjelland, Øystein; Steinert, Martin. *Creating Dynamic Requirements Through Iteratively Prototyping Critical Functionalities. Procedia CIRP*, 2016:

  At the core of this article (see appendix F) is the practical application of the Wayfaring model, specifically when it comes to dynamically adjusting requirements throughout a development process. In this case, the development of a desktop injection molder, as well as the development of the tooling for an ultra-light bike saddle were described.

- *C5*: Kriesi, Carlo; Bjelland, Øystein; Steinert, Martin. Fast and iterative Prototyping for Injection Molding – a case study of Rapidly Prototyping. *Procedia Manufacturing*, 2018:

  Triggered by the need to improve the accuracy of simulations and predictions in order to optimize and reduce material usage in injection molded parts, this article describes a successful case study of direct rapid tooling based on ready available, cheap tooling methods. The article can be found in appendix G.

- *C6*: Kriesi, Carlo; Kurtcuoglu, Vartan; Marmaras, Anastasios; Steinert, Martin. PCT-Patent Application PCT/EP2018/061604 - “Cell Culture Device” - Universität Zürich Prorektorat MNW. *European Patent Office*, 2018):

  The author was main contributor to the patent covering the FC system, see appendix B.

1.5.4 Contributions: Co-Author

- *C7*: Jensen, Matilde; Wulvik, Andreas; Kriesi, Carlo; Boe, Osmund; Anders, Philipp; Jors, Even; Steinert, Martin. Interactions in a World of Intelligent Products - A Case Study of a Smart and Learning Office Chair. In *Proceedings of ICDC 2016*:

  The author supervised one team of the FFE-class that developed a smart chair that was able to automatically detect the seating position of the person sitting on it and subsequently produce a feedback of the usage data for managerial and ergonomical inputs. This article (see appendix H) describes this *CH.AI.R* and analyses the new user-journey from smart products, when comparing to *dumb* ones and concludes on triggering an according discussion for future development work.

- *C8*: Nygaard, Truls; Kriesi, Carlo; Sjöman, Heikki; Steinert, Martin. From the Eyes of the Patient - Real Time Gaze Control of Medical Training Mannequins. In *Proceedings of the 10th Nordic Conference on Human-Computer Interaction*:

  This demo-paper, attached in appendix I for the NordiCHI conference 2018 presents the developments of the *Laerdal Eyes*-project and proposes ways of how this device can be used to train an AI and subsequently to investigate the uncanny valley Ishiguro (2007).

- *C9*: Slåttsveen, Kristoffer; Kriesi, Carlo; Steinert, Martin; Aasland, Knut Einar. Experiences from a Positivistic Way of Teaching in the Fuzzy Front End. In *Proceedings of the 20th International Conference on Engineering and Product Design Education (E&PDE18)*:

  This article (see appendix J) presents TrollLABS' approach to teaching the FFE by describing the FFE-class itself. The focus lies on how the class creates an atmosphere of competition across a diverse set of projects, and without creating any losers or winners.

- *C10*: Danzer, Claudia; Kriesi, Carlo; Meskenaite, Virginia; Steinert, Martin; Kurtcuoglu, Vartan. A Cell Culture System for Experiments under Physiological Flow. In *Personalized Health Technologies and Translational Research Conference 2018*:

  A poster submission (see appendix K) showing preliminary research results from using the FC that was developed throughout this PhD work.

- *C11*: Rødseth Brede, Jostein; Lafrenz, Thomas; Krüger, Andreas J.; Søvik, Edmund; Steffensen, Torjus; Kriesi, Carlo; Steinert, Martin; Klepstad, Pål. Resuscitative Balloon Occlusion of the Aorta (REBOA) in non-traumatic out of hospital cardiac arrest – evaluation of an educational program in *BMC Emergency Medicine*, 2018:

  The first publication, attached in appendix L, coming from the *REBOA* project where the training procedure for emergency response doctors is described and evaluated (Brede et al. 2018).

1.5.5 Contributions: Under Review

- *C12*: Kriesi, Carlo; Sjöman, Heikki; Steinert, Martin. Just do it – Hypotheses on how to accelerate innovation in the biomedical sector. 2018[2]

  This article is based on multiple semi-structured interviews conducted by the author with representatives from the field of biomedical industry, research, and application. The article brings forward the hypothesis that the biomedical sector is in dire need for toolmakers and - if applied correctly - they will push innovation in this sector (Preparing for submission, see appendix M).

- *C13*: Kriesi, Carlo; Steinert, Martin; Kurtcuoglu, Vartan; Marmaras, Anastasios; Danzer, Claudia; Meskenaite, Virginia. Development and Validation of an Integrated, Microscope mountable Flow-Chamber System. 2018[3]:

  This article describes the final prototype of the FC with respect to the original goal of increasing the throughput of flow-related experiments, as well as the results from first controlled experiments with the device (Preparing for Submission, see appendix N).

1.6 List of Grants

The author received three grants totalling just ca. 207'000 USD throughout his work:

- *Travel Grant* (2016): The author received a 15'000 NOK (ca. 1'800 USD) travel grant from the Department of Mechanical and Industrial Engineering at NTNU in context of the patent application where frequent travels to Zurich were necessary.

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[2] Will be submitted by the time of defense.

[3] Will be submitted by the time of defense.

- *NTNU Discovery Main Project* (2017 - 2018): The Author received a grant of 1’000’000 NOK (ca. 118’000 USD) for the development and beta-round of the FC-project over the course of one year from NTNU Discovery. An according press-release can be seen in appendix O.
- *Innovation Scholarship* (2018-2019): The author received a grant of 750’000 NOK (ca. 89’000 USD) for the development of more specialized flow-chamber inserts, specifically for microfluidic inserts, as well as 3D-structures.

1.7 The Main Case: Development of a novel, integrated Flow-Chamber Setup

Throughout this thesis there will be such boxed text-sections that present the specific PDP of the FC setup that was developed throughout the PhD work. The FC-development work is highlighted in such a distinct manner because it started as an explorative prototyping task and evolved into a patent-pending design that is now used in a beta-program with first external users. Furthermore, the author designed, programmed, and built all prototypes completely by himself. An overview over the explored principles, functions, and manufacturing approaches is given in figure 1.15.

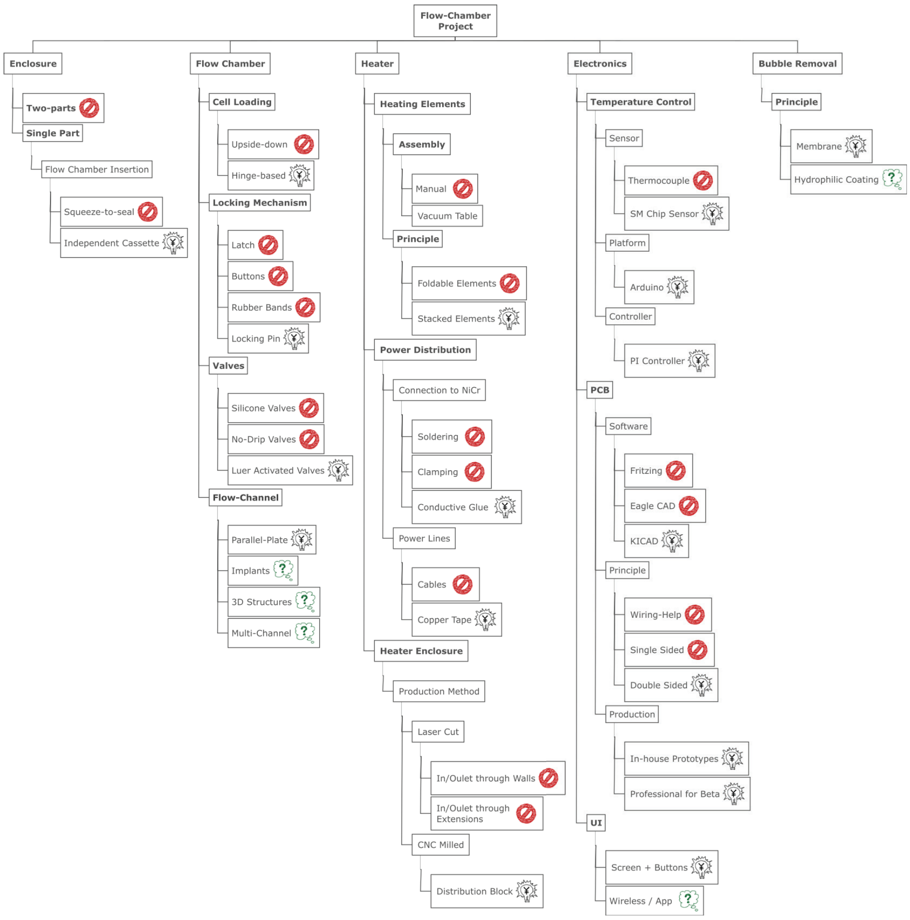

Figure 1.15: This graphic gives a rough overview over the main critical functionalities and the according subfunctions and lists the abandoned (red error sign), successful (black light bulb), and ongoing probes (green question mark). Almost every probe included numerous iterations which are not listed here.

Chapter 2

Orienting - Rapid Prototyping and Learning from the User

This chapter follows up on the hunter-gatherer analogy from section 1.4: The FFE development process starts with what one could describe as leaving the safe village and venture into the wild. Upon departure, the hunter has a bunch of tools and experiences with them. Stepping forward, however, first requires an understanding of the current situation, and where the journey is headed.

The very early PD phase is as fuzzy as it is crucial and the *blank paper* is as much of a space for getting lost in as it is full of opportunities. In the PDP as it is approached within this thesis, understanding the current situation and knowing where to go is deeply interlinked with understanding the need of the prospective users. Throughout this exploratory work, Wayfaring fundamentally differs from random trial and error: While both could make use of rapid prototyping and feedback through testing, the key element of Wayfaring is to reflect on these results and use them as a guideline for the next step.

In addition to the scientific foundation of *why* it is important to understand the user's needs, the highlighted cases in this chapter show *how* the toolmaker accelerated this process in the projects: by closely interacting, testing, and prototyping with the variety of target users, resulting in early understanding of the problem and subsequently a good orientation for the overall direction in the solution space.

2.1 Understanding by Observing

The Wayfaring approach relies on the development team taking reflected steps forward and not just rely on experiences that might be outdated. Especially when starting the development journey, it is important to take the role of the observer.

2.1.1 Needfinding

Needfinding itself can be described as the process of figuring out what the prospective customer actually wants and needs from the product (Leifer and Steinert 2011) and was applied throughout all projects in this thesis. It subsequently leads to stronger products than those who are brought on the market simply because it was technologically feasible (Faste 1987). Patnaik and Becker (1999) present strong arguments and detailed instructions for, and how to deeply embed needfinding in any company structure. Focusing on the reason for why it is so crucial, they state that “looking for needs rather than specific solutions keeps all possible solutions open for consideration and avoids prematurely limiting possibilities”, which is exactly what the PD team should be focusing on when starting the Wayfaring process. Furthermore, they emphasize that “needs last longer than any specific solution” by highlighting the need of storing data on computers. While technology has obviously progressed significantly since that article was published, it still holds true: Punch cards, magnetic tapes, floppy disks have all disappeared from the market, and arguably the same is happening now to hard disk drives due to the rise of flash drives - but the underlying need for storing data has not changed.

The challenge, however, is on how to extract the needs from a certain environment. Eppinger and Ulrich (2012) devote a whole chapter to “identifying customer needs” and recommend to gather insights from one-on-one interviews, by discussing with focus groups, and by observing the product in use. While this sounds straight forward, the question arises of what use interviews are when the user simply does not know what they want or if one is a bad interviewer. Furthermore, extreme environments can make direct observations impossible, although wide-spread photography (Wulvik et al. 2015) and the rising use of action-cameras like GoPro (GoPro, San Mateo, CA, USA) bring forward a steady stream direct views from such environments, allowing for secondary video observations (Blindheim et al. 2016).

2.1.2 Requirements vs. Needs

Within the context of rapid prototyping, user-centered PD, Wayfaring, and therefore this thesis, the terms *requirements* and *needs* are used frequently and should therefore be defined since they are as interlinked as they are different. This discussion is prominent in the field of requriement engineering within Human-Computer Interaction from where the definitions within the context of this thesis will be loosely adopted. Nuseibeh and Easterbrook (2000) states that "the primary measure of success of a software system is the degree to which it meets the purpose for which it was intended. Broadly speaking, software systems requirements engineering is the process of discovering that purpose, by identifying stakeholders and their needs, and documenting these in a form that is amenable to analysis, communication, and subsequent implementation." Although their statement is regarding software, it is just as true for any product - if it fails to meet the purpose, it is not providing a solution. The translational process is not a straight forward task, as Lindgaard et al. (2005) states: "[...] the User-Centred Design practitioner faces the serious problem of documenting and presenting the outcomes of the analysis such that they can easily be translated into user interface design and checked for completeness of the design."

Based on these statements and the description of how users should be understood, the definitions within the context of this thesis are as follows:

- *Needs*: A statement from a target user expressing the desire for a function in the widest sense. These statements are not limited to oral or written expressions but can also be based on observations, an important factor when dealing with users that have no voice, e.g. mice.
- *Requirements*: A specific design constraints for the design of the product, necessarily based on a need in the widest sense.

2.1.3 Users

Like Design thinking (Brown 2009), another powerful prototype-driven PD method (Leifer and Steinert 2011), Wayfaring relies on iterative prototyping to gain insights from the user to reveal their real needs. The users are usually defined as potential customers (Leifer and Steinert 2011, Eppinger and Ulrich 2012) and therefore they are an interesting subject of e.g. interviews. As an example, the author spent many hours with potential end-users in a laboratory in context of the *FFHTC* project. While discussing the current solution, one casually mentions that he does "[...] not like to perform this particular task", an insight that is related to an underlying mood regarding the whole process that would definitely not show up on a list of requirements.

While Patnaik and Becker (1999) state that one has to "define the needer group", their description does in the author's opinion not go far enough. Within this thesis, the *needer* or *user* is an umbrella term for a more general, context dependent point of interaction: Let us assume a research device within a laboratory. A technician is in charge of setting up the experiment. A mouse then interacts with the device in some sort, and it's behavior is tracked by an array of sensors. Each phase (preparation, experiment, and observation) of this example require a different target *user* (human, mouse, and sensor, respectively) where each one imposes different, crucial design constraints that can be contradicting. One can imagine that the technician wishes for a experiment that is very easy and fast to set up, the mouse wants a natural environment where it can roam and behave like mice do, and the sensors require to be as densely packed and as rigid as possible, in order to deliver highly accurate measurements. It goes to show that the PD team has to abstract the term *needer* and chose a context-based user as a decisive stakeholder.

2.2 Understanding by Testing

Patnaik and Becker (1999) warn that observation alone generally does not give clear access to people's reasoning and emotions and propose to make findings "tangible" that should be iterated. This is easier said than done and, as Elverum et al. (2016) states, it requires certain strategies. In order to select a strategy, however, one has to understand the power of prototyping, what it means to "show, don't tell", and how one can build prototypes to learn (Leifer and Steinert 2011).

2.2.1 Choosing Wayfaring

Within this thesis, Wayfaring was the PD method throughout all projects and also to guide the structure of this thesis since it closely follows the development path of the FC project. Wayfaring has strong similarities to other PD methods, e.g. Agile (Smith 2007), and taps into the strength of user-centered design that Design Thinking (Brown 2009) focuses on. However, there are fine but in the author's opinion very important differences to what could be considered the closest relative, Agile: Agile is an umbrella term for certain methods that have their proven strength in software development - SCRUM, Extreme Programming, Lean development, and more fall under this term. A great summary of the key intentions of all the methods is given by Smith (2007) that is presented in table 2.1.

Table 2.1: The table compares certain aspects of Agile (taken from (Smith 2007)) and Wayfaring. As both methods are umbrella terms for a diverse set of practices that can be applied throughout, the table should not be considered complete but rather a list of essential traits.

	Agile	**Wayfaring**
Field of Application:	Mainly software, transitioning to also include hardware.	Hardware focus.
Iteration length:	1-6 Weeks.	As fast as possible.
Iteration goal:	Working software.	Completed probe and subsequent direction for next step.
User Involvement:	Usually at end of iteration.	As often as possible.
Change of Direction:	At end of iteration.	At end of probe.
Team:	Co-located, sometimes multidisciplinary.	Co-located, multidisciplinary.
Application in PDP:	Always	FFE.

Since the two approaches are so similar, it is important to highlight some main differences: Agile comes from a software development side and tries to apply the same rules and approaches to hardware. However, there is the obvious fundamental difference that one can always update software but one can not (easily) update hardware due to daisy chain of production lines behind. This is highlighted in appendix Q where a slightly complex physical prototype already relies on a set of specific tools. In the case of finished products, this is even more extreme, where injection molding dies are almost impossible to update - unlike finished software that can always be changed, even remotely over the internet.

Another important difference is the planning and project ownership and planning throughout a sprint in Agile, something that is not the case in Wayfaring. The point of a probe in Wayfaring is not to deliver a working prototype that can be added to the product, but rather to find the direction for the next step. There, the same procedure is repeated, always with an overarching vision in mind that can be adjusted according to the findings. By planning the next step based on a customer feedback, one risks to avoid dark horse prototypes (see below) that could be a complete game-changer in a PDP.

This is not to say that Agile can not at all or never be applied to hardware development, but it is - as of now, in the author's opinion - not fully compatible with PD and finding requirements within the FFE.

2.2.2 Diverging to Converge

By turning an idea into a prototype and therefore making it tangible, one can make sure that everyone around the table has the same foundation for discussion. They can subsequently be used to stimulate imagination (Hargadon and Sutton 1997) or be used as a source of ideas (Seidel and Fixson 2013). In the context of needfinding, prototypes therefore allow to get direct feedback from a target user on the quality of an idea, or find ways of how to improve it. But orienting in Wayfaring also means that one should do a "360 degree scan of the surrounding space" (Steinert and Leifer 2012). In order to get the best overview, one should therefore bring forward as many ideas as possible and diverge into the solution space. Each design-test-iterate round might bring additional solutions, bringing one even further away from the *one* final solution. This, however, is desired. In fact, Eris (2004) showed that the PDP within a team consists of a constant interplay of generative design questions that diverge the process, followed by deep reasoning questions, as he calls it, that converge the amount of solutions again (Eris 2003).

Further in the context of Wayfaring, each probe is a complete diverge-converge cycle in itself, where one specific aspect of the problem is investigated: The multidisciplinary approach of the probes is ideal for involving the user in divergent phases, where brainstorming around a physical prototype can bring not only user needs, but also future developments that were not originally on the radar. From the authors projects (see section 1.5), this was especially prominent in the *100x glass slide* and the *pump project*. Both were directly motivated through progress on the FC project itself, and the tangible prototypes triggered discussions on how one could extend and improve in various directions.

By converging down to one solution for each *probe* (similarly, section 4.1 is later about converging on a *project*-level), the design team has a list of prototypes at hand that could decide the direction of the next step. The author's experience from the projects is that the initial *360 degree scan* usually results in a lot of crucial insights and learnings about the problem context itself, and is less about actual design probes.

It is normal that each iteration round offers multiple potential next steps, which subsequently requires further prototyping of each idea. Due to this need for a high number of iterations, the resolution of prototypes (Edelman et al. 2009, Jensen et al. 2016a) has to be kept at the minimum required level in order to assess the quality of an idea within a short time frame.

2.2.3 Dark Horse Prototyping

The concept of *dark horse prototyping* is based on the analogy to the world of horse racing, where the horse with the lowest odds of winning also have the highest potential winnings. In the context of a PDP, the *dark horse* is therefore that crazy idea that always comes up but that seems too risky, unrealistic, and too radical to achieve (Carleton and Cockayne 2009). However, if the idea actually worked, it would lead to an amazing product - high risk, high reward.

However, the concept of a dark horse relies on knowing the success rate of the other competitors, otherwise the odds are equal for all of them. If one takes this concept into a more abstract context of the Wayfaring method, one can imagine the early user-insights and first explorative prototypes as areas of light, since the PD team has gained insights and understanding of the situation. Subsequently, there are some obvious next steps, some of which might already have shifted the target slightly. And there are clear areas that lie completely in the dark but which could offer great rewards. Wayfaring encourages the team to explore such areas, since there are only positive outcomes from such a dark horse prototype: Either one finds a great solution, or one knows which solution definitely does not work. The argument that an expert could have predicted a failed outcome has only very limited validity, as will be discussed in section 3.3.

Such dark horse prototypes were used in multiple of the projects, resulting in positive breakthroughs. During the *Laerdal eyes*-project, the possibility of digitally projected eyes was successfully explored, completely changing the constraints of the project; The *Mouse table* developer completely ignored experts' warnings and successfully showed that the requirements were wrong to begin with. One prominent dark-horse prototype of the FC-development will be described in the according section further down.

2.3 Understanding by Dropping and Breaking

So far, only the user-related aspects of orienting and adequate prototyping was touched. There is a second side to prototyping that is just as important: The learning process that prototyping triggers in the PDP.

The “egg-drop challenge” is usually more known as a team-building task, the participants have the challenge to protect a raw egg the best way possible, in order to make it survive a free-fall. Dow et al. (2009) put a scientific twist on that challenge: By clearly defining the build material and the time that a participant has available to come up with a solution, the challenge becomes constrained. Furthermore, the final challenge - dropping the construction from increasing heights - allows to quantify, and subsequently

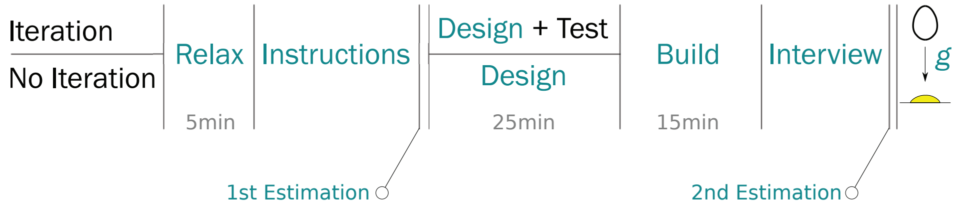

Figure 2.1: The time line of the egg-drop experiment as proposed by Dow et al. (2009) and adapted by Kriesi et al. (2014), as shown here. By controlling all the independent variables of the challenge, one can quantify the effect of prototpying on the quality of a design.

compare the quality of the design. By splitting the (individual) participants into two groups where one is allowed to iterate their design and the other is not, one can therefore observe the influence of one independent variable, namely the ability to prototype, on the quality of the final design. The time line of the experiment is shown in figure 2.1.

The results of Dow et al. (2009) show that, in average, the iterated designs reach a significantly higher maximum drop height than the designs of the non-iteration group (final height of 186 cm vs. 101 cm). Furthermore, the impact of prototyping is even higher for people with previous experience in the egg-drop task, highlighting that expertise is no excuse, but rather motivation for iterative prototyping. In Addition, the participants had to estimate their performance before and after designing their vessel. Again, there is a significant difference between the iteration group and the non-iteration group, where the first shows an increase in their confidence and the latter stays constant. This makes sense since only the iteration group gets a feedback on their design, therefore enabling them to adjust their expectation to reality.

This experiment was repeated by the author and the results were published in Kriesi et al. (2014) (attached in appendix C). The confirmatory nature of this study allowed for exploring additional levels of insights, namely by the means of physiological data acquisition with the aim of observing a difference in the physiological response between the two groups. While there was a notable difference, the small amount of data points does not allow for drawing any final conclusions. It did, however, trigger the development of a global approach to this experiment and subsequent discussions on the accuracy of design science.

2.4 Developing Experiments

Science relies on controlled experimental verification and falsification (Popper 2005) of hypotheses and subsequently requires specifically made experimental setups. These experiments in the broadest sense are implemented by various means based on a fitting research methodology, but first they need to be developed themselves.

The development of a globally distributed egg-drop experiment is described in Kriesi et al. (2015) (attached in appendix D). By shipping out packages that each contained enough material, sensors, and instructions for ten participants, the aim was that locally sourced supervisors can repeat the egg-drop challenge and send back the recorded results. In order to ensure that the packages were, indeed, self explanatory, the setup was iterated multiple times before sending it out. The results from this approach could give insights into local bias and subsequent effects on the effects of prototyping. In addition, it would open the path distribute the load of gathering large amounts of data-points over multiple research units. The results, however, highlighted something much more important: Robustness is underestimated when dealing with human participants and supervisors. While some locations showed the same results as in the original and the first confirmatory studies, other locations showed the opposite, and some showed that the local supervisors of the experiment did not understand any of the instructions whatsoever. These observations triggered a discussion within the group, namely with Dr. Stephanie Balters. At the time, she was herself involved in developing experiments with human participants (the development process followed the Wayfaring method, as presented in Leikanger et al. (2016)). It lead to an article proposing an experimental item-mining repository (EIMR) where experimental setups can be stored in a highly detailed fashion in order to reduce ambiguity throughout interactive experiments involving human participants (Kriesi et al. 2016a) (see appendix E).

The conclusion of this article is that as long as the effect of an independent variable is not fully understood, e.g. the refresh rate of a computer screen on the interactions, the experiment is only repeatable if these variables are described in detail so that an eventual confirmatory study can repeat, and slightly expand the experiment. This insight is also important for the biomedical sector, where living organisms are often at the center, like in the *mouse table* and the FC-projects.

It further goes to show that explorative prototyping should be applied to the development of experiments and “dark horse experiments” should be encouraged throughout.

2.4.1 Users in the Biomedical Sector

As described in section 1 and above, the applied PD method heavily relies on user feedback to gain insights on needs and problems, but also to learn. In the biomedical sector, this task becomes increasingly difficult due to the variety and amount of different, crucial users, as Van der Loos (1995) states with respect to their experience when developing rehabilitation robots. This insight is therefore not novel in the biomedical sector, as the article of Shaw (1985) also shows. Intense collaboration between manufacturers and users has also been proposed for making better solutions in the biomedical sector (Biemans 1991, Lüthje 2003). Furthermore, users in this sector have been shown to be a great source of innovative activities (Hinsch et al. 2014) and Burgar et al. (2000) highlight the helpfulness of user inishgts by stating “by involving patients and clinicians from the beginning of this effort, we have identified and overcome the limitations of our early prototypes.” The importance of addressing the right users is highlighted by Shluzas (2011) who concludes on the following proposition: “Maximizing the ratio of product benefit to physician behavior change increases value to product stakeholders and the likelihood of technology adoption.”

All projects within this thesis are confirming the findings mentioned above, highlighted by two extreme cases. In the case of the *FFHTC* project, all the users are humans, but their roles are highly diverse: The patient has the central interest of getting a diagnosis based on the removed prostate, limiting the potential handling procedures of the tissue. The laboratory technician wants a work flow that fits their skills and interest and does not take too much of their time. In part, this means the device needs to be easy and fast to use, and in part this is related to how easily the system can be cleaned. Understanding how the washing machines work and what they are able to do is therefore part of another user group. With respect to an experiment, the *mouse table* project requires a researcher to set up the experiment and this created some challenges regarding the mobility of the setup. The next crucial user was the mouse itself, who had to be comfortable and behave as natural as possible throughout the experiment. Meanwhile, a sensory system had to track this movement. All three types of users had significant influence on the final design.

2.4.2 Prototyping for living organisms

The most challenging part about the biomedical sector is that by definition a living organism will at some point closely interact with the design, be it an imaging machinery or an implant. Getting a new product on the market often requires extensive licensing and approval from various authorities, pharmaceutical drugs and their development costs being a prime example thereof (DiMasi et al. 2003). Rightfully so, the question arises if low-resolution prototypes are applicable and useful within this field. Investigating the importance of prototyping, the author repeated an experiment from Dow et al. (2009), confirming their results (Kriesi et al. 2014). Furthermore, the group applied rapid prototyping to other engineering areas associated with very high costs, like injection molding. The outcome clearly showed that low-cost, rapid prototyping allows for exploring high-end production tests in a very short amount of time (Kriesi et al. 2016b; 2018). Subsequently, one can say that the justified need for high quality, accuracy and reliability for the licensing process *probably* does not mean that correctly used and applied low-resolution prototypes are not suitable for accelerating the PDP in the biomedical sector, or at least there has not been any evidence against it.

2.5 Understanding the Flow-Chamber Problem

The first interaction with the problem was when the author visited the laboratory of Prof. Vartan Kurtcuoglu of The Interface Group at the University of Zurich. Their vision is to "[...] answer fundamental questions of physiology and address clinical needs through the convergence of engineering, biological and medical research" (The Interface Group 2018). One of their experimental setups hinges on exposing living cell cultures to flow-induced mechanical stress and visually observing their reactions. This research, however, is limited due to a lack of specific equipment. Although the group has their own, home-made FC, it is a tedious task to conduct experiments on it due to the non-user-friendly equipment. Subsequently, the throughput is low and this, in return, hinders in-depth science. Prof. Kurtcuoglu subsequently brought forward the need for a new, integrated FC system that enables efficient, and robust science.

2.5.1 FC: Cells under Stress

The underlying core of the research on the FC lies on the fact that all cells within a living organism are exposed to some mechanical loads. This can be due to breathing, movement, or constant pressure due to gravity. The most prominent example in humans are the hemodynamic forces due to blood flow (Dewey et al. 1981). Over the past almost forty years it has been shown that cells show different behaviour under such mechanical loads than under static conditions (Chakraborty et al. 2016, Franco et al. 2013, Orsenigo et al. 2012, Fan et al. 2016, Illi et al. 2005, Wang et al. 2016, Dewey et al. 1981). Furthermore, the cells do not only react to environmental changes, they also actively interact with with their surroundings. One prominent example is the reserach done by Engler et al. (2006) who were able to show that stem cells develop into different types of cells solely dependent on the mechanical properties of their surroundings. The full implications of such changes in the cell's environment are not yet fully understood yet, partially due to the lack of an efficient research setup. However, one could argue that all research done under static conditions has only limited validity.

The easiest way to exert controlled levels of mechanical loads on cells is by exposing them to a flow-induced rate of wall shear stress (WSS), as expressed by equation 2.1, where τ $[Pa]$ is given in relation to the dynamic viscosity of the medium μ $[Pa \cdot s]$ and the velocity gradient of v $[m/s]$ in the vertical direction z $[m]$ from the ground plane (Dewey et al. 1981). In the special case of laminar flow, as it is present within the FC, the commonly used solution given in 2.2 holds valid where the WSS τ $[Pa]$ is express through the applied the flow-rate Q $[m^3/s]$, the dynamic viscosity μ $[Pa \cdot s]$ of the medium, and the width w and height h $[m]$ of the flow channel (Levitan et al. 2000).

$$\tau = \mu \frac{\partial v}{\partial z} \tag{2.1}$$

$$\tau = \frac{6Q\mu}{wh^2} \tag{2.2}$$

2.5.2 Existing Solutions

The two most commonly used setups to achieve such a flow-induced WSS are so called orbital shakers and parallel-plate FCs. The former operate by swirling liquid on top of cells cultured in cylindrical wells, creating a complex flow- and subsequent WSS-pattern dependent on liquid volume, orbital radius of gyration, and angular speed (Salek et al. 2012). The latter is based on a laminar flow between two plates, creating a highly homogeneous flow- and subsequent WSS-pattern, solely based on on dimensional aspects of the flow-channel, as well as the flow-rate of the cell culture medium (Nauman et al. 1999). Arguably, this means that any research done with orbital shakers is valid for gradients of WSS, but not for evenly distributed, constant levels thereof. Furthermore, the constant motion of the orbital shakers does not allow for constant observation of the cells under a microscope, unlike when using parallel-plate FCs. One advantage of orbital shakers is that they can be used with multiwell plates, allowing for simultaneously gathering a large amount of data-points. Microfluidic devices, which are relatively easy to prototype (Duffy et al. 1998) and the trend for “labs on a chip” push the boundaries of data-points per time. One aim is the personalized treatment of patients, e.g. with the aim of curing cancer and according, complex microfluidic devices are starting to become functional (Eduati et al. 2018). The downside, however, is that microfluidics only allows for small amounts of cells due to size limits, subsequently hindering certain genetic expression analyses. In addition, macro-level research is impossible, for example when observing wound-healing (Liang et al. 2007). Furthermore, the micro-channel arrays - as of yet - do not enable the observation of three dimensional cell cultures where one could observe the transport of a compound through one cell layer into another. Therefore, the simplicity of the parallel-plate FC provides a great starting point for improving cell experiments under physiological conditions.

2.5.3 FC: Status Quo

At the beginning of the project, the group in Zurich was using what could be called a high resolution version of an early-stage parallel-plate FC prototype, as shown in figure 2.2. This FC relied on multiple, external devices that all influence the outcome of the experiment, namely multiple heaters and a pump.

Their protocol for setting up flow-related experiments consisted of the following nine steps, provided by their laboratory technician:

1. Fill the cell culture medium reservoir with 100ml of cell culture medium and warm up to 37 degrees.
2. Pre-warm the flow chamber to 37 degrees.
3. Ensure that the stage-top incubator is equipped with the mounting bracket for the flow chamber.
4. Start the microscope up, including the incubation system and water heater and make sure that the water heater and humidifier are filled with DI water to the recommended height.
5. Assemble and pre-warm the flow circuit.
6. Load the cell slide into the flow chamber and fill flow chamber with cell culture medium.

7. Insert the flow chamber into the flow circuit and remove bubbles.
8. Run flow experiment.
9. Clean up.

2.5.4 Shortcomings

The shortcomings of the device shown in 2.2 are twofold. Firstly, the array of non-standardized equipment, namely heaters, the pump, and the FC make it almost impossible to create a repeatable experimental setup since there is an array of producers that offer similar parts. And even if the same equipment is used: Any variety in tube lengths or room temperature could result in a different temperature the cells are exposed to; The standard pumps, so called peristaltic pumps, work by squeezing the tubing and therefore pushing the liquid further within it. Subsequently any variety in tubing material, diameter and / or pressure onto the tubing results in different flow-rates, resulting in a variation of the WSS as equation 2.2 shows. In reality, researchers work with different heaters, pumps, and FCs, further skewing the comparability. Without questioning their results, Fan et al. (2016) describe their flow-rate as “1 rpm”, not providing any further details of all the influencing factors mentioned above - a prime example of a result that can not be repeated under the same conditions.

Secondly, the user interactions for their current setup is very time consuming, as can be seen by their protocol. This is partially due to the design choices of the FC itself, and partially due to the “bulky pump-flow cell-tubing setups and problems associated with them in terms of manufacturing and sealing”, as Salek et al. (2012) states it. These problems are just as present, though, with orbital shakers, where the whole machinery needs to be placed within an incubator.

The common denominator for both shortcomings is the non-integrated design of the complete setup. A lower amount of required equipment directly results in a reduction in setup time, complexity, “bulkiness”, and therefore in an increase of robustness and comparability of research results.

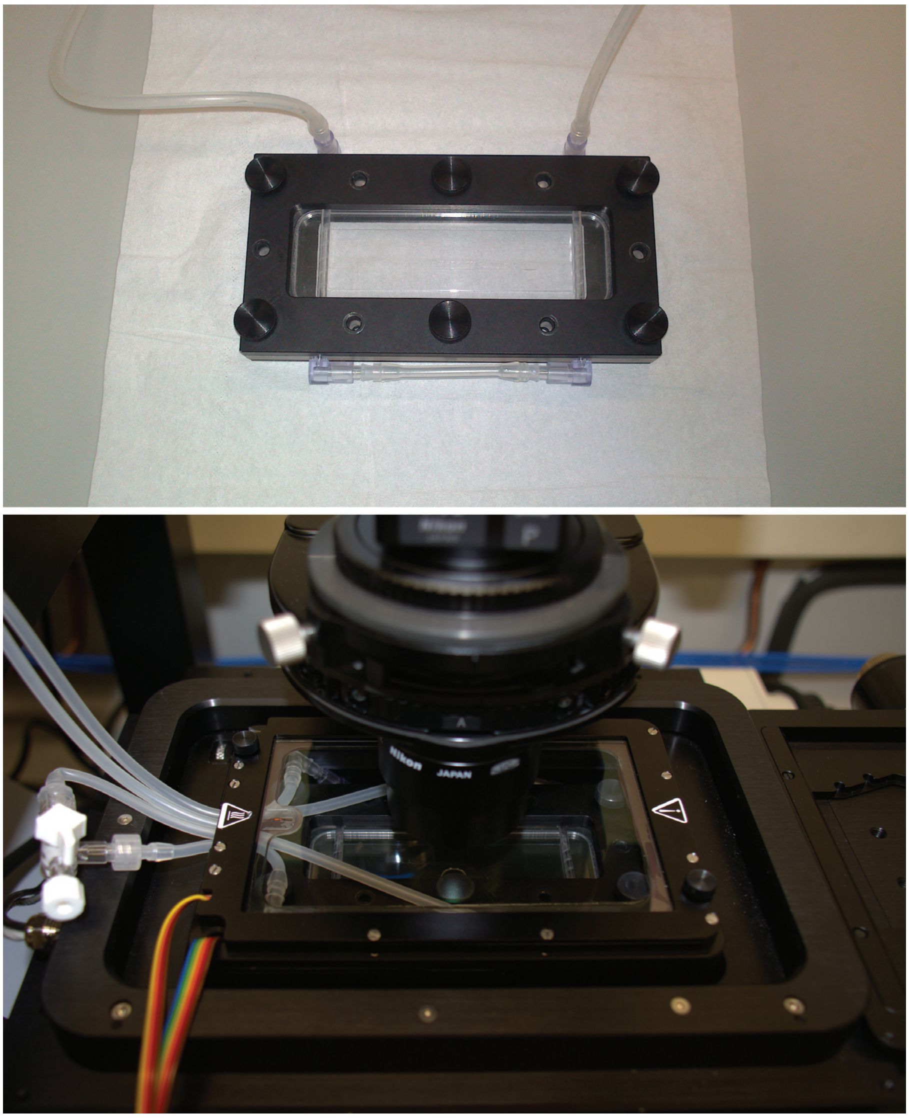

Figure 2.2: The FC setup used by the group in Zurich at the beginning of this project. The FC (top image) required six manually inserted screws (an improvement from previous versions where twelve screws and a tool were required). The chamber was used within a small incubator on the microscope (bottom image). This incubator is designed to keep cell cultures at 37 °C in a closed environment. The flow in/out of the incubator, however, meant that the temperature was always dropping too low for the cell cultures.

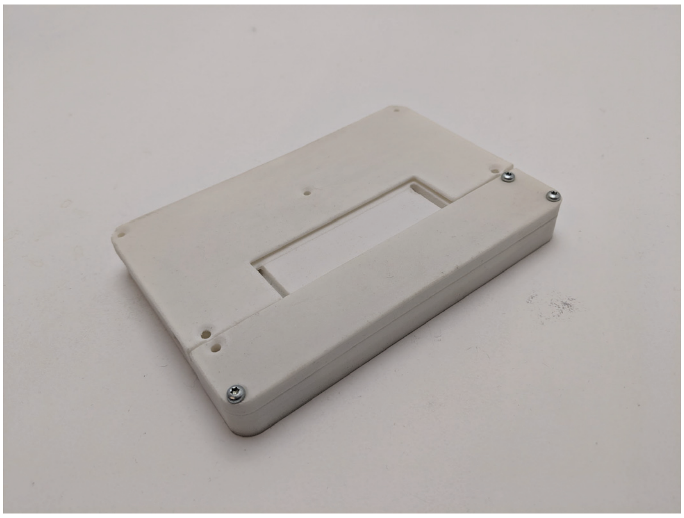

Figure 2.3: The first 3D printed model was non-functional and had no other purpose than making the available building space a tangible discussion platform.

2.5.5 Evident Needs

The stated need of an overall simpler, more efficient FC setup translated into the following, loosely formulated needs:

- *Reduced Bulkiness:* The new device must reduce the amount of required external machinery, most importantly the heating system which needs to be integrated and autonomously react to changes in the environment so that the cell cultures experience a constant thermal environment.

- *Usability:* Tools are not available by default within the research laboratories, they are easily lost, and they imply time consumption. It must therefore be possible to un-/ load cell-cultures without the need of any extra tools.

- *Observability:* The device must be compatible with standard microscope stages and fit in commonly used inverted microscopes in order to enable constant observation of the cell-cultures.

- *Biocompatibility:* For obvious reasons, the device must provide a hospitable environment for the cell cultures. Among other material limitations, no metal is allowed to be in touch with the flowing cell-culture medium.

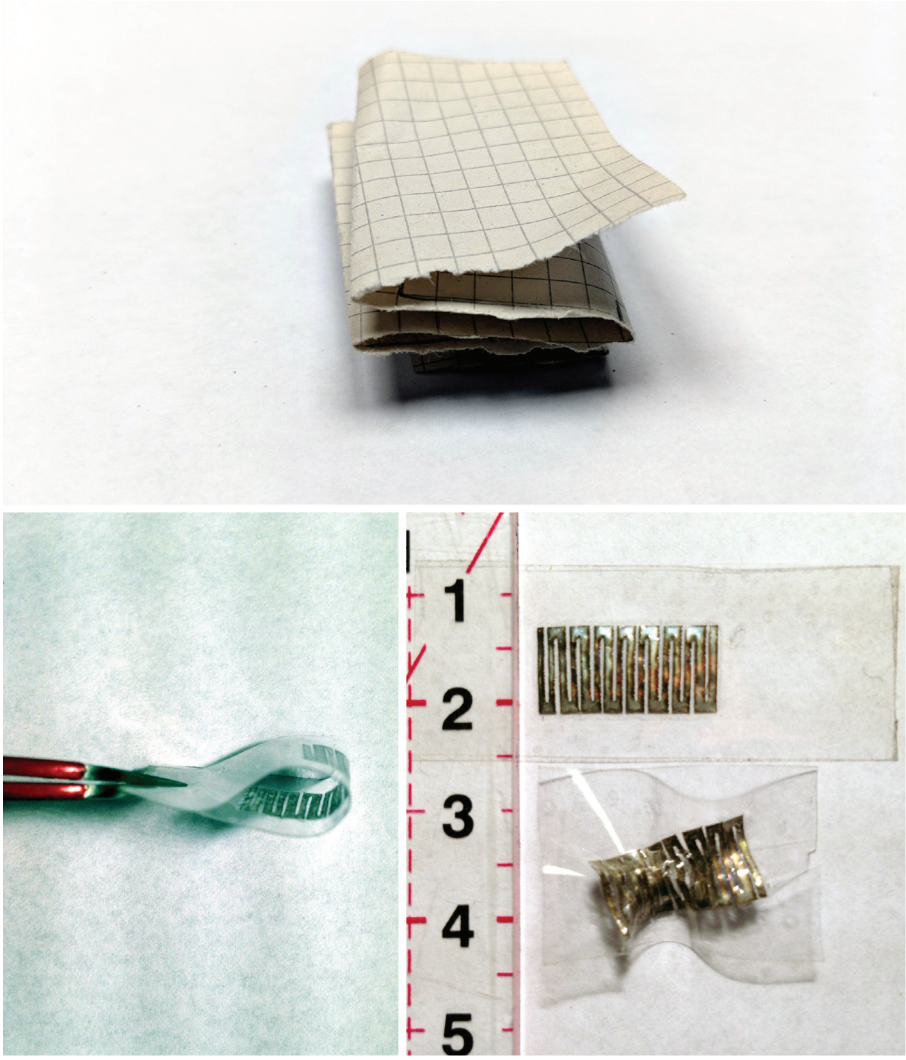

Figure 2.4: The very first heater prototypes made of paper (top) and lasercut 0.01mm NiCr foil wrapped in Scotch tape (bottom). The bottom left image shows the potential flexibility of the heaters. The bottom right image (scale in [cm]) shows both, a new (top) heater and the result from hooking it up to a battery (bottom) to test if it actually works as expected.

2.6 First Heaters

In order to bring the discussion regarding possible solution on a common ground, the author created a rough 3D print of the available building space, as visible in figure 2.3. Especially with respect to one of the key-elements, this prototype helped to brainstorm on potential solutions, most notably the paper prototype of the first heater, as shown in figure 2.4, following the principle of a parallel-plate heat exchanger. While there are large companies on the market that produce very thin heaters, they are not willing to engage in prototype requests or small orders. The conclusion was therefore to find a way to make the heaters in-house. One simple approach is to make an electric heater by using Nichrome (NiCr, a commonly used material for electrical heaters due to its temperature independent electrical resistance) wires or foil. Given the tools at hand within TrollLABS, the laser cutter was an obvious choice for first probes in this direction. However, "expertise" found online clearly stated that the 100 W CO_2 laser at hand is definitely never going to cut metal. In proper dark-horse prototyping mentality, it was attempted nevertheless - and it worked. It brought some challenges regarding manufacturing (see chapter 3), but opened the possibility of building heaters with rapid design changes whenever needed - a factor that rapidly became highly important. The first functional heaters, also visible in figure 2.4, were subsequently made by cutting a pattern into 0.01 mm thin laser-cut NiCr foil, creating a long and thin heating wire. Said foil was then wrapped in Scotch tape, creating a simple first flexible and watertight heater.

With reference to the Wayfaring method, the orienting part led to some conclusions and directions for the next step: Obviously the heater was the wrong size, wrong resistance, not the correct outer material and had no contact ports - but it allowed for successfully testing the principle and proofing that the laser cutter available at TrollLABS is a suitable equipment for making heaters. Especially the latter was surprising, since usually much more powerful lasers are used for cutting metal of any kind. With this in mind the next iteration round was on a theoretical level, determining approximate power requirements for flow rates up to 50 ml/min without overheating the cell-culture medium which denatures at more than 40 ° C. The governing equations are: The fundamental relation between electrical power P $[W]$, the voltage U $[V]$, the current I $[A]$, and the resistance R $[\Omega]$ are described by equation 2.3

and 2.4, respectively; Equation 2.5, describing the necessary power P $[W]$ for heating a liquid with heat capacity c_p $[kJ/kgK]$ by a temperature difference of ΔT $[K]$ while flowing at rate $\dot{m}$ $[kg/s]$; And equation 2.6 for convective heat transfer, where $\dot{Q}$ is the transferred thermal power in $[W]$, A $[m^2]$ is the affected area, α $[W/m^2K]$ is the convective heat transfer coefficient, and ΔT $[K]$ is the temperature difference between the hot and cold element, in this case the heater and the cell-culture medium.

Subsequently, assuming an inlet temperature of 22 °C and a target outlet temperature of 37.5 °C the required power of the heater is roughly 54 W at 50 ml/min flow, using c_p of water at 27 °C (4.179 $kJ/kg \cdot K$) (Moran et al. 2010), which also determines the necessary voltage and current. Following the calculations presented in appendix P, the conclusion was that it is indeed possible to transfer this amount of power into the flow within reasonable building volumes without requiring too complex production methods. That being said, the focus was *not* on optimizing the heater design, but rather a rough estimate of what is needed.

$$P = U \cdot I \tag{2.3}$$

$$U = R \cdot I \tag{2.4}$$

$$P = \dot{m} \cdot c_p \cdot \Delta T \tag{2.5}$$

$$\dot{Q} = A \cdot \alpha \cdot \Delta T \tag{2.6}$$

2.7 Lessons for the Toolmaker

The quote from Salek et al. (2012) about the “bulky setups” is highly telling and arguably reasoning enough on *why* a toolmaker is required: There is a clear need for flow-experiments, not just from The Interface Group, yet the solution is not found in developing fitting equipment, but in resorting to other means that arguably offer worse results, in this case orbital shakers. Situations like this are exactly where the toolmaker needs to come into the picture and understand the research question and user-needs to a degree that allows a holistic problem statement. The FC problem is not about the design of just another FC with less screws, it is about integrating a variety of established equipment in a manner that reduces setup time and increases scientific value. A toolmaker within the biomedical context therefore needs to understand users in a biomedical context, and understand their needs and what their research really is about. They need to deep dive into the problems and understand the overarching vision.

Simultaneously, referring to the *how* a toolmaker should proceed, prototyping first solution approaches in low resolution, like paper-prototypes, allows for a discussion based on tangible references. As highlighted by the examples of the *100x glass slide* and the *pump project*, the *orienting*-phase of Wayfaring is often revealing additional problems, shortcomings, and subsequently potential PDP projects that could lead to successful products. Rapid probes allow for “testing the waters” regarding the complexity of such an emerging, additional promising product without sheering too far off the main task. If the solution is a low-hanging fruit - like it was the case with the glass-slide - there is no reason not to implement it, since it can enable future projects. In this particular case, the same glass-slide will be used in experiments with multiple layers of cells of different types.

Furthermore, as the calculations show, the toolmaker should have a sufficient understanding of the underlying theory in order to assess - based on known requirements - if certain ideas are even remotely possible with a certain technology. This should not be confused with design optimization, since prototyping in the FFE is all about getting far in a short amount of time. Finding an wrongly dimensioned solution is clearly more important than not finding a solution at all.

Chapter 3

Probing - Discovering Unknown Unknowns and Critical Functionalities for Evolving Requirements

The *probing* phase of the Wayfaring PDP is - like the *orienting* phase - an explorative, prototype-driven one. In this phase, however, the aim is no more to get a "360 degree scan" (Steinert and Leifer 2012), but to work towards the vision - the toolmaker leaves the role of understanding the target user, and starts exploring the solution space. In order to understand why this phase of Wayfaring is so crucial, one has to understand the concept of unknown unknowns (UUs), which are explained in-depth in this chapter. Furthermore, research that shows how the probing phase brings forward critical functionalities and according dynamic requirements is highlighted. The implication of this dynamic environment is that the toolmaker must be aware of - and accepting - a constantly shifting target of the development work.

3.1 Shifting Targets due to Unknown Unknowns

Throughout all of the more complex projects in this thesis, the final target was shifted multiple times. While this was partially due to user insights, it was often also due to technological difficulties or surprising outcomes that allow to aim for completely new target altogether.

One example of shifting targets due to new openings from a technological side is the example of the *Laerdal Eyes* project: The original challenge to TrollLABS was to develop a novel way of actuating the eyes of their medical training mannequins. Since the eyes are great indicators of, among others, neural damages, brain injuries, and the mental state of the patient (Wong 2008), the level of realism of a mannequin is strongly influenced by the life-like feel of the interaction with the plastic patient's eyes. At the beginning of the project, the focus was indeed on novel actuation mechanisms, e.g. by the means of magnets. However, a prototyping focus on digital eyes running in parallel in the FFE-class showed that a combination of LCD screens and glass-lenses can display realistic eyes. The original description - developing novel eye actuation - was subsequently rephrased to how an operator could actually interact with the trainees who train on the mannequin. The final prototype was a functioning head-mount display including eye-tracking camera. This allowed the operator to do both, see the view of the mannequin, and at the same time control the movement of the eyes, including blinking.

Compared to the original vision, a better actuation, the digital approach does not only solve the issue of the movement, but enables a whole set of additional levels of realism: Obviously, one can can program different eye-colors or eye-related diseases. But what is even more important is that the operator can act out any diagnosis task, e.g. following a pen, in their perfectly healthy way. With the software layer in-between, however, one can modify the behavior according to e.g. a neural damage that can be diagnosed by the trainee. Furthermore, one can record and subsequently train an AI with natural eye-movements for future fully automated versions of the same mannequin. The prototype was presented in the demo-track of NordiCHI 2018 (see appendix I).

A second example is the case of the *FFHTC* project. The challenge within the context of biobanking consists of two cutting operations: First, a 2 mm thin slice is taken from the center of a freshly removed prostate. While this slice is frozen, the rest of the prostate is fixated and sent to the pathology department for further analysis to determine the type and spread of cancerous tissue. Based on the analysis of the areas adjacent to the now frozen slice, one can determine where in the slice there is cancerous tissue. One can then remove a small (diameter of 2 mm) cylinder probe from said tissue which is further used for various types of analysis.

The target shifted throughout the project when it comes to how one should cut the tissue. While first work treated the cutting instances - slicing and drilling - as two very separate problems, and explorative work was done with respect to blade types and shapes, a low-resolution prototype revealed that ultra-sonic blades are relatively easy to make in-house. Subsequently, the option of making one flexible cutting head for both operations became the new target. In addition, the usage of ultrashort pulse lasers was investigated. While this technology would radically shift the target, the development thereof is not ready within the time line of this project.

Shifting targets are often the consequence of unforeseen events, or realizations of a lack of understanding, knowledge, or technological readiness. The following definition of UUs and how they are different from e.g. known unknowns is given by Sutcliffe and Sawyer (2013), based on the work of Gervasi et al. (2013):

- *Known knowns*: Expressible, articulated, and relevant.
- *Known unknowns*: Not expressible or articulated, but accessible and potentially relevant.
- *Unknown knowns*: Potentially accessible but not articulated.
- *Unknown unknowns*: Not expressible, articulated or accessible but still potentially relevant.

The crucial point to understand is that a UU becomes a known unknown by observation only, without necessarily ever being stated as a UU. Only a reflective process after the discovery defines the now known UU. Taylor and Standish (1982) mentions the discrepancies between stated requirements and actual needs, as well as desired technology vs. available technologies, which arguably are examples of UUs: The users do not know that they do not know an essential need, for example because they adopted a workaround and therefore do not consider it a need anymore.

Figuratively speaking, UUs are like a canyons meandering through the solution space. There are two ways of dealing with them: Either one sets a fixed target with a straight path to it or one slowly inches forward and, if necessary, shifts the target. Developing straight to the target line means that once all the decisions are done and one should implement the working prototype, all the canyons become visible at once and it takes an incredible effort to make it work, if even possible. In a clear opposite approach, the Wayfaring method allows to deal with the canyons whenever they appear. It might appear to take a longer time when not just jumping to a target, but in hindsight it will pay off enormously, especially since in complex developments the envisioned product almost never comes out as planned.

From an engineering standpoint of view, UUs are therefore highly relevant for adapting, shifting, and developing targets and requirements as described in one of the author's articles (Kriesi et al. 2016b). This goes in hand with the findings that requirements which are set too early and too rigid during the PD work can result in overly complicated design specifications (Ward et al. 1995, Kennedy et al. 2014). Especially in complex fields like the biomedical sector with its variety of users that interact with one device, there is a guarantee for encountering UUs throughout the development.

3.2 Critical Functionalities in Interlaced Knowledge Domains

The argument for iteratively probing the path to the shifting target demands a strategy on where to focus next in the development. In Kriesi et al. (2016b) the author and colleagues presented two case studies on the usage of Wayfaring, namely for the development of a desktop injection molder and an ultra-light carbon bike saddle (see appendix F). While the conclusions are also regarding UUs, the core argument is on the strategy of how to find the next design probe when following the Wayfaring principle: Identifying core functionalities of the envisioned product enables to dissect the project into smaller problems and according probes. While this process is conceptually similar to decomposing a problem when using other methods like TRIZ (Altshuller 2002) or any matrix based methods like the design structure system (Steward 1981), it has a fundamental difference: The critical functionalities are discovered from probe to probe and are not subject to any assumptions at the beginning of the project. Subsequently, any final prototype is composed of a set of compatible technical solutions. This approach of Wayfaring critical functionalities sheers off from a point-requirement driven approach and is similar to dynamic functional requirements and evolving set-based requirements (Kennedy et al. 2014, Ward et al. 1995).

The probes throughout the PDP are often required to take place within multiple interlaced knowledge domains, as highlighted in figure 1.6. In the case of the FC, the project involved elements from thermodynamics, fluid dynamics, electronics, mechanics, control systems, and production technology. In the case of e.g. the heater, they all affected each other. A mechanically differently shaped heater element affects the flow, the thermodynamics, and subsequently the control system.

Smart products and applications in the internet of things-concept (IoT) (Jeschke et al. 2017) are highlighting the importance of such multidisciplinary development probes since the development process is becoming ever more complex. In the case of such IoT products, one has to develop not only a user-friendly data gathering unit, but also a data handling side of the product. In order to do this successfully and efficiently, it requires a simultaneous, iterative approach, as described by Sjöman et al. (2018). It is therefore not sufficient anymore to find the critical functionalities only on the digital, or only on the hardware side. Furthermore, the IoT and smart consumer products can do even more things "wrong" when it comes to user interactions. These products are defined by Dawid et al. (2017) as "consumer products that are equipped with intelligence-generating technologies including (i) sensors and/or actuation, either to gather data from the environment or to use the data to change the environment, (ii) computing power for data analysis, and (iii) optional interfaces to exchange information with their environment". Unlike "dumb" products, they therefore have the capability to not only register a user input, but they can also actively give information back to the user. In the case of a pure software product, this can fall in the category of an annoying user interface. However, in the case of e.g. an office chair, these interactions can become much more in-depth: In a work together with Flokk (Flokk AS, Oslo, NO), TrollLABS investigated the world of smart chairs and presented according prototypes not only to the CEO of the company, but also in a research paper the author contributed to (Jensen et al. 2016b). These chairs measured and assessed the seating position of the user by the means of a sensor array in the seating area, enabling not only various types of feedback, e.g. reports, but also the option of actively motivating the user to e.g. change their seating position. These reactive products therefore change the user journey and open up more than ever to the arguably biggest UU: The user themselves. By not only actively, but also passively interacting with a user, the development of an according product becomes even more difficult due to the extra layer of potential pitfalls. Understanding these complex levels of interactions is also relevant for the biomedical sector, e.g. when using video games for rehabilitation purposes: Patients give inputs to a software - in this case a game - and receive a feedback, in this case ideally stimulating the right movements fitting to the rehabilitation process. Finding the right software and the right feedback, however, is a challenge (Lohse et al. 2013), even more so when the software, and potentially the physical interactive parts - e.g. controllers - become smart.

3.3 Expertise and Simulations

An expert, defined as "having, involving, or displaying special skill or knowledge derived from training or experience" (Dictionary 2018b) and simulations, defined as "examination of a problem often not subject to direct experimentation by means of a simulating device" (Dictionary 2018a) have one crucial similarity: They both rely on an exact input, and on an exact understanding of the situation. If either of those is slightly off, the result might not be correct. Given the context of discovering UUs and shifting the target based on the experience from exploring critical functionalities, they are therefore a risky help to use throughout a PDP. The development of the *mouse table* highlights why this is the case: The problem - provide a environment that moves around the mouse - was erroneously thought to be fully understood by the project owner. The requirements were subsequently set without prototyping any solutions and the project owner went off to experts, asking for a stiff, round structure of 1 m diameter that can carry a 30 gr mouse. Since the mouse needs to move this platform, it is not allowed to weigh more than 30 gr and it requires a wall so it cannot walk off the edge. The material experts concluded said that this is impossible to achieve with any known material, which is - given the set requirements - correct. Picking up on the analogy of the canyon-riddled landscape, the project owners had fixed a target and asked an expert to draw a straight line to it, assuming that the landscape is fully understood and flat.

At TrollLABS, the colleague followed a different approach, namely according to the Wayfaring method. First, he went to understand what exactly the experiment is about and how the mice are supposed to behave. Then, he explored various ways of making ultra-light structures and soon had a game-changing realization: The assumption that the platform needs to be stiff enough to *carry* a mouse is completely wrong. Since the mouse is fixed, all that the platform needs to do is to *feel* stiff for them when they walk around on it. Subsequently, a floppy platform that is locally supported to generate the feeling of stiffness is completely sufficient. This insight allowed to redraw the path to the target and the focus was shifted onto the next critical functionality: How can one support something locally, without creating too much friction for the mouse to overcome? After multiple rounds of iteration, the solution was an air-hockey inspired table with a floating platform for the mouse. The solution worked good enough for first, explorative experiments that revealed new insights into how mice orient themselves.

The second topic, simulations, offers similar challenges. Simulations do not need a set of requirements, but rather a list of input variables which they process in a set of equation into a result. The big issue is, however, the equations themselves. By definition, a simulation is only an approximation of what an experiment would reveal, depending on the accuracy of the equations. This was highlighted in the author's work on injection molding (Kriesi et al. 2018) (see appendix G) where the difficulty of simulating complex material behaviors and processes motivated the construction of low-cost molds for rapidly testing injection molded parts.

In the context of development work in the biomedical sector, simulations become even more questionable. While materials can be tested over and over again under varying conditions in order to deduct models, the unbelievable complexity of living organisms and the interplay of chemistry, thermodynamics, fluid dynamics, mechanics, etc. does not allow for the same approach. Most importantly, however, this is due to ethical reasons. This judgment is highlighted by the abysmally unethical work of Pennes (Pennes 1948): Before his work, there was no in-depth understanding of the thermal distribution within a human forearm, most notably due to the lack of understanding of how much energy the tissue itself is releasing. By inserting thermocouples into the forearms of inmates of a psychiatric clinic and observing the temperature development after blocking the blood circulation, he was able to gather data on the thermodynamics within the human body and established the according bioheat transfer equations. These results are still highly relevant today and the according equations are used in modern biomedical developments whenever the thermodynamics of tissue play a crucial role, e.g. in the work of Nightingale et al. (2002), and they allow for simulations, as visible in figure 3.1 (from a programming exercise during the author's bachelors education).

This should definitely not be interpreted as an attempt of justifying the abuse of people or living organisms, but rather the opposite. The biomedical sector must follow the ethical guidelines and rely on observations and ethically correct gathered information.

The key message regarding experts and simulations is that the nature of the UUs makes it impossible to formulate the precise, correct questions beforehand. Both, experts and simulations are, however, extremely powerful tools that can, and should be used but only if the context and the limitations of the results are fully understood.

3.4 Construction Required

In conclusion, the probing phase in engineering the design relies on physical prototyping. Not only due to the reasons mentioned in chapter 2 but due to the inevitable encountering of UUs throughout the development process in complex environments. Overlooking UUs can bring the PDP to a halt or, in the worst case, require a complete re-design at what was supposed to be the end of the project time.

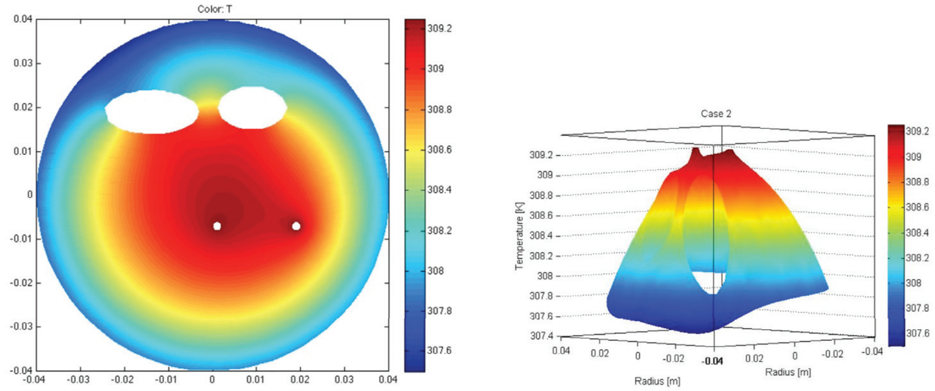

Figure 3.1: This simulation shows the approximate temperature distribution in the human forearm. The two large, white areas represent the bone structures, the two small, white circles are the simplified blood vessels. These simulations, part of an exercise during the author's bachelors education, highlight the difficulty of simulations in the biomedical sector. While they are relatively easy to calculate, obtaining the right set of equations is difficult, if not downright impossible.

3.5 FC: Unknown Unknowns at Every Corner

At almost every probe throughout the development of the FC there were instances of discovering UUs: Air bubbles, handling live cells, creating leak-proof enclosures, and fixing short circuit due to mechanical deformation of solder tracks were unanticipated problems with no immediate solution. While some issues were relatively easy to overcome, others crippled the progress or even exposed dead ends - and some were definitely never identified as UUs.

3.5.1 FC: Dissecting the Problem

The critical functionalities listed below were each probed separately and within the applicable interlaced knowledge domains. In the case of the heater, for example, the development involved the design and production of multiple versions of printed circuit boards and programming an according control system. Although presented as one list, the dissection of the project into the critical functionalities was a dynamic process that required user insights and feedback on low-resolution prototypes. Figure 3.2 shows how early user-interactions were captured and integrated in the design itself.

The following critical functionalities were identified for the complete system:

- *Flow-path*: The flow-path is an integral element and therefore each element needs to be easily dis- / connectable to a pump and reservoir.
- *Embodiment*: The complete system has a very limited building space.
- *Heater*: The heater involves multiple critical functionalities in itself:
  - *Heating*: Obviously, a heater must be able to generate heat.
  - *Power Distribution*: The power must be delivered to the heating elements within the very tight spacial constraints.
  - *Temperature Sensor*: In order to control the temperature, there needs to be a sensor.
  - *Controller*: The sensor information must be translated into a control signal, adjusting the power of the heater.
  - *User Interface*: Due to the different controller requirements at different flow-rates, a user interface is required where one can input target temperature and the flow-rate.
- *Flow-chamber*: The flow-chamber itself where the cells are exposed to the flowing medium has its own subset of critical functionalities:
  - *Tools*: Opening, closing and inserting the FC is not allowed to require any tools.
  - *Loading Cells*: Cells are highly sensitive to being exposed to air since it can result in the cells detaching, or dying due to drying out. Subsequently, the loading process must happen with the cells facing upwards under a layer of liquid.
  - *Exchanging the FC*: It should be possible to exchange the FC within the shortest possible time in order to increase throughout of the experiment itself.
  - *Optics*: The cells must be visible under the microscope. This has certain implications on the dimensions of the embodiment, due to minimum and maximum distances from the lens.

- *Air Bubbles*: Appearing gas bubbles must be removed or at least blocked from flowing across the cells.
- *Cleaning*: The complete system must be cleanable.

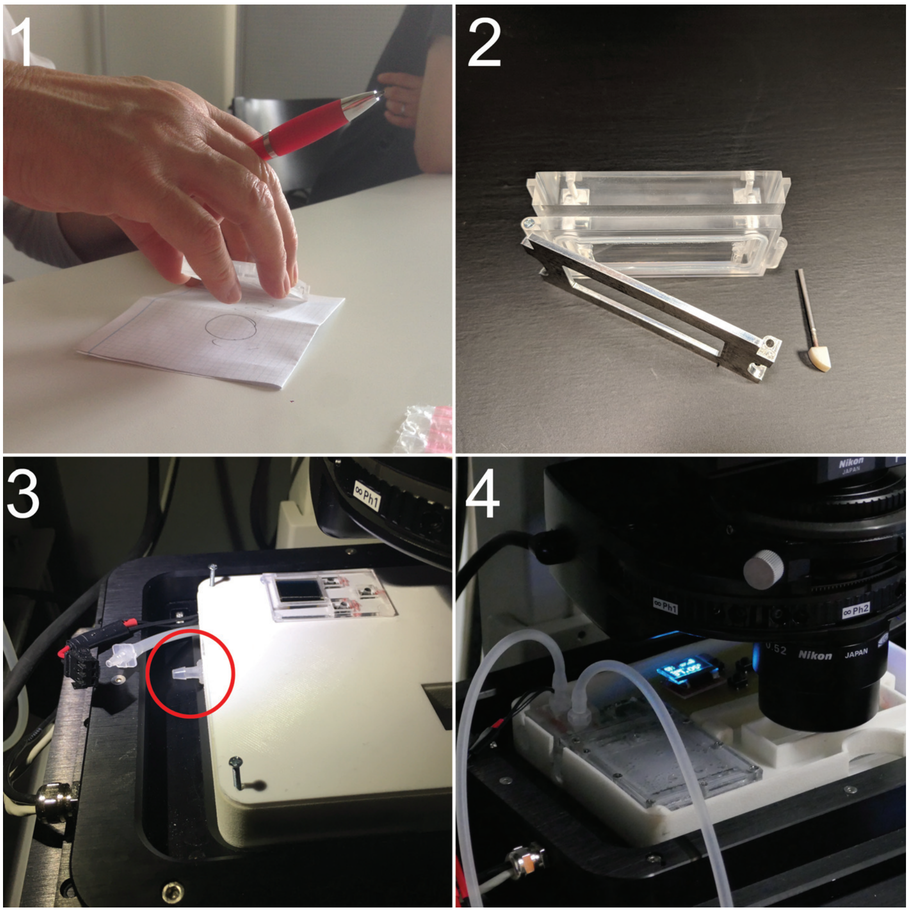

Figure 3.2: An example of how important user-insights are and how they can be captured and integrated in the design: Early prototypes regarding loading glass slides with cells (1) showed a hinge-like movement by the user, which was incorporated and developed to the current state (2). Image 3 shows why early testing is so crucial - the inlet port (red circle) was placed in a inaccessible position, something that would have been expensive to change at the end of the development. This issue was fixed in the following iteration (4).

3.5.2 How to Assemble Heater Elements

The highlighted example is related to the crucial challenge of making a heater that fits within the building volume, as mentioned in chapter 2. It was not only a case of encountering UUs, it is also an example that shows the importance of physically building prototypes.

After figuring out the fundamental principles of producing heaters (see section 2.6), the next step was to make properly sized heating elements, which turned out to be a prime example of a UU: It was not known, that the assembly method of the heating elements was completely unknown.

The total resistance of a NiCr-heater is depending on the cross-section and the length of the wire, as shown in equation 3.1 where R $[\Omega]$ is the electrical resistance, ρ $[\Omega \cdot m]$, l $[m]$ is the length of the wire of cross-section A $[m^2]$. Since the thickness is fixed by the raw material at 0.01 mm and the width reduced to the limit of what can be made on the laser-cutter, the only adjustable variable is the length. At this point no specifications were fixed in any way, therefore the aim was to create an as homogeneous as possible heat distribution within one heater by spreading as much NiCr wire within the area exposed to flowing medium.

$$R = \rho \frac{l}{A} \tag{3.1}$$

Since the NiCr can not be exposed to any liquid due to various reasons, the aim was to sandwich the NiCr itself between two thin (0.2 mm thickness) sheets of silicone foil, provided by Aavid (Aavid, Pleasanton, CA, USA). The main issue with making such heaters, however, became obvious when the first bigger samples were cut: At 0.01 mm thickness, the NiCr foil has neither significant weight nor any mechanical stiffness, making it prone to fold and wrinkle from the slightest airflow, movement, or simply from static charged parts in the immediate vicinity. An assembly method had to be developed in order to handle the fine material and precisely place it. After various tests, the working solution was found by building a vacuum table that fits in the laser-cutter, allowing for holding and releasing thin foils in a controlled manner by the means of an alignment tool. The final, applied production protocol is described in detail in appendix Q.

3.6 Lessons for the Toolmaker

One of the reason why the role of the toolmaker is so crucial in complex development projects is due to the unforeseeable nature of projects, as described in this chapter. What a toolmaker therefore needs to have in their profile is the open mindset and awareness about UUs and how they can interfere with a PDP: They often shift the original target. The author therefore believes that toolmakers need a certain level of stubbornness when it comes to interdisciplinary development teams, highlighting UUs whenever one encounters them is a powerful argument for the seemingly slow approach to developing requirements, when comparing to projects with fixed requirements from the start.

In multiple projects the seemingly slow and prototype driven Wayfaring approach was questioned since one could just ask an expert, or simulate something. Surely, one could run an optimization on the heater power, and the overall surface it requires. One could simulate the flow-profile and the perfect NiCr layout. Yet only physically assembling it reveals the issues related to production that are described above and the necessity of exploring new areas outside of the core problem.

As far as experitise goes, it is not necessarily an essential trait of a toolmaker, but rather a good addition. The results of Dow et al. (2009) make it very clear that experts, while in average better than novices, still showed a significantly better performance when prototyping than their counterparts that solely relied on extensive experience. Therefore, a willingness to engage and explore problems, as well as a certain ability to rapidly build cheap prototypes is required from toolmakers, especially when the solution space resembles a field of expertise. As mentioned above, expertise is only valuable under the right conditions.

In order to avoid getting lost in explorative work throughout the probing phase, first research on the FFE-class shows that it helps to regularly expose your work to a wider audience and see these presentations as a mini-deadline with the chance of showing off progress (see appendix J) (Slåttsveen et al. 2018).

Chapter 4

Bringing it Home - Increasing Robustness to create Minimum Viable Products

This chapter focuses on the last phase the Wayfaring method dictates: A crucial part of a project is not only to prototype and probe solutions, but also to “bring it home” (Steinert and Leifer 2012). This means that the design needs to converge to one solution that is ready to be taken to the market, for example in a closed beta-phase. Fixing the fundamental functionality and the general design does, however, not mean that development work is over - the *gathering*-part of the hunt begins. This chapter shows how the focus can therefore shift towards robustness of the design based on the identified critical functionalities and brings forward an argument on why established production methods can be challenged throughout this process.

4.1 Converging to One

As mentioned before, Eris (2004) showed that the PDP is a continuous process of diverging and converging. However, if one thinks about the hunter-analogy - one sets off to find food for a village, or a really new idea for future business cases - then one, at some point, has to bring something home on a *project*-level. Subsequently, one has to settle for one idea and make the most of it and usually this moment comes when the project time, or funding runs out. This is in accordance with section 2.2 that focused on the divergent-convergent process within one *probe*.

4.1.1 When to head home?

In an ideal scenario, one has infinite time to explore the infinite solution space and find the one, perfect solution. Obviously, that will forever be a utopian concept, leading to the question of what should be considered worth bringing home? What is the *minimum viable product* (MVP), as the modern startup sector would say? Simply put, the lean business (Ries 2011) sector that coined this term has contradicting ideas of what an MVP *is*, too (Lenarduzzi and Taibi 2016). However, the following quote of Moogk (2012) can be applied to describe what an MVP is supposed to *do*, and this concept is the starting point for the definition within this thesis: “The fundamental idea behind the lean startup philosophy is that the real product of an early-stage startup is an experiment, or a slew of experiments, that contribute to reducing the initial extreme uncertainty.” Applying the same argumentation - reducing uncertainty - to the PDP is, obviously, prototyping, and testing. Subsequently, one can define the *extreme* uncertainty in relation to the user-context dependent critical functionalities, into which the project was dissected in the probing phase: The MVP of the Wayfaring PDP is when the critical functionality, or the set of critical functionalities, without which the project would never fly, is solved and the subsequent critical functionalities are known to have a solution, based on additional exploratory prototypes.

The *REBOA*-project is a perfect example of this understanding of the MVP in Wayfaring, within the context of this thesis: The underlying need for the project was to provide a training phantom for intravenous cannulation that allows for a life-like, ultrasound-guided puncture of the femoral artery in order to insert a REBOA balloon. The available time to complete this highly challenging task was very limited since such a phantom was required in order to train emergency response doctors (in this case the helicopter crews), in return leading to data-points on the actual medical research. Subsequently, the question was constantly if the product is ready for the user-driven context, in this case whether or not the training equipment is robust enough so that ten emergency doctors can be trained. What makes the *REBOA*-project such a perfect example is that there was an obvious solution to all the critical functionalities (plastic tube to simulate the Aorta where the balloon is placed, PET bottle as liquid reservoir) - *except* the most important one: The ultrasound compatible injection port that offers a life-like feeling. This one functionality made all the difference between extreme and very little uncertainty, and a “thank you”, and a “Wow!”-project. Again, this perception is only true within the user-specific context: Even though the injection port problem was solved, the solution at hand is definitely not ready for mass-manufacturing or even a beta-round, contexts

Table 4.1: The difference in confidence before and after the design phase of the egg-drop experiments, from Dow et al. (2009).

		Non-Iteration	Difference	**Iteration**
Confidence Level	Before	95 cm	+0 % + 44 %	125 cm
	After	95 cm		180 cm

Table 4.2: The difference in confidence before and after the design phase of the egg-drop experiments, from the confirmatory study of Kriesi et al. (2014).

		Non-Iteration	Difference	**Iteration**
Confidence Level	Before	141 cm	-3 % + 18 %	135 cm
	After	137 cm		160 cm

where the user needs change to robustness and reliability.

4.1.2 Always more than an MVP

In the case of the FFE-class running within TrollLABS, the goal is that each team has to present a working prototyping that solves their challenge, at least in the context of the team's individual understanding thereof (Slåttsveen et al. 2018). The potentially premature end to a project due to deadline does not mean that the problem was a failure overall: The probing process (see chapter 3) - if done right - leaves the PD team with a path of solutions that are inherently compatible and cover the critical functionalities as far as they were discovered throughout the process. In addition, the iterative probing process increases the confidence of the designers, as was shown by Dow et al. (2009) and in the author's work on the egg-drop experiment (Kriesi et al. 2014): By asking the participants at the beginning and at the end of their individual experiment for the height they think they will achieve, one has an indirect proxy for their confidence in their design. While the individuals that were allowed to prototype show an increase in their confidence level, the participants in the control group show little or no change. These results are listed in tables 4.1 (from Dow et al. (2009)) and 4.2 (from Kriesi et al. (2014)), respectively.

Subsequently, it should always be the goal to converge to one solution, even if this means that some promising ideas must be skipped due to the deadline. It is always better to bring home *something* than *nothing* and if one thoroughly follows the Wayfaring principle, chances are very high that one finds a great idea, a *nugget*, that leads to a *wow*-project.

4.2 Increasing Robustness

In software development, the early versions of a new program are tested internally where the feedback cycle is fast and one can constantly debug errors. Once there is a certain level of internal trust in the product, it gets launched to a limited amount of public testers, usually early adopters and expert users. This semi-public launch is the beta phase, which aims to increase the robustness of the software even more by exposing it to less controlled use-cases (Cusumano and Yoffie 1999). In the case of the PDP as presented in this thesis and the Wayfaring method, "bringing it home" allows for a similar gradual opening of the user spectrum: By fixing the solutions to the critical functionalities that were developed in close collaboration with internal users, one can start increasing the robustness of the individual components and how they are interlinked.

4.2.1 Manufacturing

Manufacturability is an essential factor when aiming to push a product to the market and choosing the right production method is not only crucial with respect to production costs, but also with respect to potential robustness of the design. The production method itself influences in return again the design options, since e.g. additive manufacturing offers completely different design freedom than when one only relies on a laser cutter (Leutenecker et al. 2016, Türk et al. 2017). However, increasing the complexity of the manufacturing process also means that new factors need to be taken into consideration, e.g. the orientation of parts when relying on additive manufacturing (Leutenecker-Twelsiek et al. 2016), subsequently driving development time and costs.

The extreme case, mass manufacturing, in general has a very high initial cost for tooling and machinery, therefore only making it a viable option when producing very large quantities. Together with Øystein Bjelland, one of TrollLABS master students, we challenged this perception and explored various aspects of design for mass-manufacturing, namely injection molding. Supported by Flokk, the initial challenge was to create a *cook-book*-style instruction manual for running complex simulations that predict the strength of an injection molded part. The higher the accuracy of the prediction the better the part can be designed for the actual load cases and the more material can be saved. This has both, financial and environmental consequences since around one third of all plastics worldwide are at some point handled with this production method (Rosato and Rosato 2012). It quickly became apparent that the complexity of the desired simulations always requires an in-depth knowledge of the formulas and calculation processed involved, mainly due to the highly complex models required for anisotropic materials like Polypropylene (Fujiyama et al. 1977, Fitchmun and Mencik 1973), rendering the cook-book approach obsolete.

Following the hardware oriented work of TrollLABS, the development then proceeded in the direction of prototyping manufacturing itself, resulting in a desktop injection molder presented in Kriesi et al. (2016b) that allowed for exploring various 3D-printed molds and materials. The exploration were promising enough to run a full-scale injection molding tests with in-house built, inexpensive molds (Kriesi et al. 2018) (see appendix G). While the mold only held up with two injection rounds, the resulting parts are of high-quality. Furthermore, the operator of the machine was convinced that this approach would absolutely work if the injection parameters (pressure, temperature, and injection times) were adjusted correctly. Since the production of the mold was fast and cheap, using multiple attempts to get the settings right would not be an issue. In conclusion, one can say that the high costs of established mass-manufacturing methods can, and should be challenged, implying that one can prototype on a much higher resolution than before.

4.2.2 Intellectual Property

In parallel with the development of the robustness of the prototype itself, one should decide whether whether or not the intellectual property (IP) should be protected. The more functionalities are fixed in a design, the easier it is to file a patent for the overall system or parts of the invention. Since filed patents only allow for limited re-adjustments until being reviewed, it is important that one has tested and gained confidence in the design and the critical functionalities so that the scope of the patent - once it is handed in - does not change on a fundamental level. Within the context of this thesis, one patent for the FC project was developed and filed, and one patent for the findings of the *REBOA*-project is in process.

4.2.3 Challenge the Norm

Especially in the biomedical sector, where one often has to rely on expensive manufacturing processes in order to meet certain standards, one should challenge the norm and - if applicable - explore production methods within short explorative sprints. In the worst case, one knows why a certain manufacturing method is required, and is certain that one has to pay the price. In the best case, one finds a way that opens the path for design changes and small in-house production lines that enable to bring the MVP to a beta-customer segment.

Another example of emerging small-scale manufacturing tools are collaborative robots, such as the Sawyer (Rethink Robotics, Boston, MA, USA). Targeted at novel robot users, their main advantage over conventional robots is the simplicity of the programming interface. Complete structures for fundamental actions, such as pick & place according to patterns, or object recognition, are pre-programmed and can be activated and combined without any programming knowledge. Such a robot was acquired within the scope of the FC project.

4.3 FC: Towards the Beta-program

The aim of the FC project was not only to provide a functioning prototype, but also to bring the product towards the market by giving it out for testing to external researchers. With this vision, the project received the one million NOK in funding from NTNU Discovery (see appendix O). This vision, however, meant that the design had to become more robust and reliable. The example of the flow and power connectors is related to UUs as described in chapter 3, but also shows how changing the complexity of production methods shifts the solution space.

The latest version of the fully functional prototype of the FC is named the “beta-version”, since it is also being promoted and handed out to external researchers. In parallel with the refining developments, a patent covering the complete system was handed in at the European patent office (see appendix B).

Overall, the beta version was fitted with a lot of improvements, with two temperature sensors creating a faster and more robust heater control loop and a completely integrated bubble-trap. Converging to a beta-version also allowed new exploratory work, most prominently in the direction of coatings to help with bubble-issues. The main change, however, is the level of robustness, an essential factor when starting to involve external users.

4.3.1 Robustness

In the FC-project, a variety of production methods come together, namely additive manufacturing, CNC-milling, etching, and laser-cutting. Only when a functionality was deemed robust enough, the production method was - if necessary - taken to a more complex level. Specifically the in- / outlet ports to the heater and the development from crude electronic platforms to industrially produced PCBs are an example of how the complexity of the production method followed the confidence in the design. The development steps of the heater parts are shown in figure 4.1.

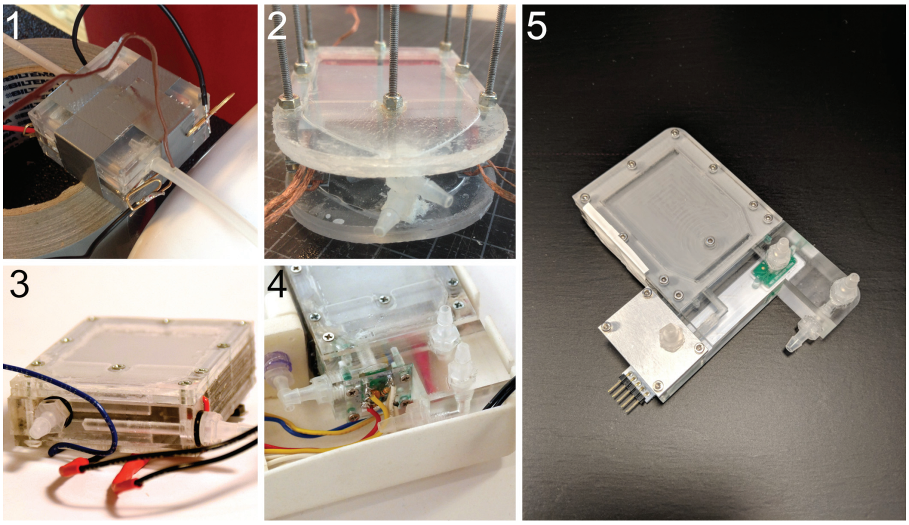

Figure 4.1: The shape and functionality of the in- / outlet ports of the heater was unimportant at the beginning (1), since the focus was on developing the heaters itself. Once these were more under control, the connection points got more attention but it became obvious that the design cannot rely on laser-cut parts alone (2). The first CNC-milled "distribution block" was more time-consuming to change and produce, but offered new, more robust design options (3), and evolved (4) to the point where it was possible to include connectors, bubble trap, and temperature sensors in one piece (5).

Since each major iteration was tested with users, the quality of the use-case increased hand in hand with the robustness. While first tests on the microscope were just to check whether or not the dimensional aspects are correct and one can actually observe the cells, the latest version was running - and exposing cells to flow - for 72 hours, allowing for first controlled experiments, comparing the effects of different coatings on the cell-growth, as visible in figure 4.2.

4.3.2 Patenting Process

It was always clear that the developers of the FC would like to take this project to the market. Subsequently, the patenting process for the FC was initiated in early 2016 together with Unitectra (Unitectra AG, Zürich, CH). Within one year an in-depth patent research was conducted where no competing IP was discovered and the patent draft was developed together with a patent lawyer. The patent was first filed in May 2017 with the option of updating it until May 2018 when it was submitted for review at the European patent office. In November 2018 two claims of the patent application were accepted as both, novel and innovative - the device is therefore no longer patent-pending, but patented. The patent aims to cover the complete system and not just single parts of it and is attached in appendix B.

4.3.3 Beta-Program

With the IP protection in place, the project was - theoretically - ready to be taken to the beta round. Intensive testing revealed certain weak spots in the design, mainly a very fragile heater enclosure. After re-designing the according parts and changing the manufacturing method, the FC beta version is starting to be handed out to various interested, early adopters.

4.3.4 FC: Why just one flow-channel?

Arguably, the beta-program is the MVP of the FC, since it allows for an increased throughput of fundamental flow-related experiments but not much on top of that. However, the flow-channel itself is where the development work can - and is - picked up again and new use-cases require a fresh, explorative round of Wayfaring from that starting point. Among other ideas, the vision is to offer a flow-channel that has separate channels with injection ports for comparative studies, and make it compatible with various 3D structures.

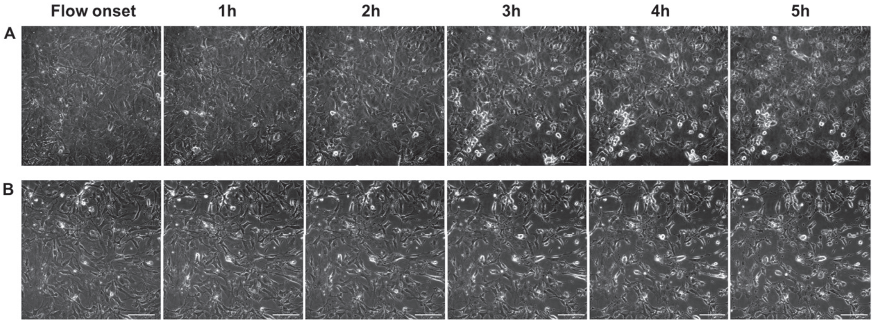

Figure 4.2: Meningothelial cells grown on different coatings. Images are taken over 5 hours at one image per minute. Shown here are t0 at the onset of 6 ml / min flow (3 dyne / cm2 shear stress), and cells after 1h, 2h, 3h, 4h, and 5h of shear exposure. A) Poly-d-lysine coated glass slides and B) fibronectin coated glass slides. Scale bar = 50 µm.

4.4 Lessons for the Toolmaker

As a toolmaker, one has to be closely interacting with the users and therefore one should have a good idea of what the MVP should consist of, and how to identify it. Bringing a project home, however, is as difficult as it is to develop the solutions itself. While the critical functionalities are addressed, the individual implementations might be lacking robustness, requiring extensive re-design around the same fundamental idea. The toolmaker needs to be able to assess when it makes sense to switch production methods in order to reach a required level of reliability and robustness, at the cost of iteration times. Design changes down the line are therefore becoming increasingly expensive, one of the main arguments for low-resolution prototyping to begin with. Nevertheless, as the example of the injection molding shows, one should always challenge the status quo of manufacturing.

Subsequently, the role of the toolmaker is not only to explore, but also to find ways to enable a product on the market by not “going home early” (Steinert and Leifer 2012): Only when a solution is physically implemented and it can be used, the task is done.

Within a research environment, the contradictory nature of publishing research and protecting intellectual property (IP) is making innovation undoubtedly more complex, since publications need to be delayed in order to hand in a patent application. On the other hand, patent applications can be delayed due to the patenting environment at universities, which is arguably more defensive than in the private sector, therefore delaying patent applications in order to maximize confidence in the invention. However, by providing functioning prototypes and results from internal “alpha”-rounds this process can be accelerated, as the experiences from the FC-project show.

Chapter 5

Conclusions

This thesis presented projects and publications that focus around the various stages - namely *Orienting*, *Probing*, and *Bringing it Home* - of the PDP when applying Wayfaring in early stage PD in the biomedical sector. Due to the controlled environment - TrollLABS - where all projects took place, the observed phenomena allow to deduct a prototype of the concept and the role of a toolmaker within the biomedical sector and lead to according conclusions to the two, initially stated questions: *Why* do we need a toolmaker, and *how* is a toolmaker implemented.

5.1 Why - Highlighting the Impact of the Toolmaker

The answer to *why* a toolmaker should be an integral part of a biomedical environment is based on three interlinked arguments:

1. The projects show that a toolmaker accelerates innovation, which helps the biomedical sector overall.
2. The level of complexity in the PDP within the biomedical sector in the pre-requirement phase requires an entity that captures the various user-insights that can then be translated into functioning prototypes and subsequent correct requirements with respect to the discovered UUs.
3. This entity cannot - or only to a limited degree - be represented by a target user of the project. The toolmaker must be an additional, independent element.

The following observations from the *REBOA*-project alone underline and highlight these arguments:

The *REBOA*-project is all about creating an ultrasound-compatible, artificial injection port to an artificial femoral artery so that doctors can train the procedure with a realistic feeling to it. From the kick-off of the project to the first successful training sessions with a total of thirty trainees it took five months. The first applied procedure by emergency response doctors on the field on a real patient happened another six months later, when all the ethical procedures were in place. Simultaneously, the functioning prototypes and the success with the training procedures allowed for a successful grant application over 250k NOK for further developments. Without the effort of TrollLABS and its role as a toolmaker environment, this would not have happened as fast, or not at all.

Highlighting the importance of the user-insights and finding the right requirements is the fact that similar products actually exist on the market, for example the Blue Phantom (CAE, Cote-de-Liesse, CA) training models. However, none of them provides a sufficiently good feeling for conducting the procedure - in addition to high costs. Understanding what a "good feeling" of an injection phantom is necessarily relies on the input from people who actually conducted the procedure hundreds of times. The insufficient level of realism of the models on the market is therefore directly linked to a lack of of user-insights and user-testing throughout the development phase.

Why the toolmaker needs to be an independent unit is highlighted by the simplicity of the actual prototype: Production method and materials are both standard and can easily be sourced. Therefore - theoretically - anyone of the involved doctors could have built it, but they did not. Not because of a lack of talent, intelligence, or technical understanding, but because their interest and subsequently their role in the project is to be the user, not the toolmaker.

The toolmaker needs the independent freedom to operate and a distance from the user to get a complete overview of what is required. This leads to the conclusion on the question of *how* a toolmaker is implemented.

5.2 How - Implementing a Toolmaker Environment

It is crucial to understand that a toolmaker is more than just a person. A toolmaker is a physical space where various people meet, interact, and - most importantly - have the freedom to build, explore, and implement without any administrative hurdles.

As was presented in the context of this thesis, TrollLABS played a significant role throughout all the project. Furthermore, the projects were mostly tackled in teams or at least had a strong exchange with other members of the laboratory due to the physical proximity within the lab. In addition, there was no administrative layer - e.g. funding - between a user-insight and a rapid, low-resolution prototype. Early stage, low-resolution prototypes were simply funded by an overhead of the laboratory itself. After all, paper, tape, and some cardboard are literally freely at hand within a university building.

How to implement a toolmaker is subsequently based on how TrollLABS is set up and therefore requires the following components:

- *Space*: A physical space, ideally in close vicinity to the target users - e.g. within a hospital - where users and the PD team can frequently meet, allowing for fast iterations and forced interactions. Especially in the biomedical sector, users are often limited in their movement due to their job, e.g. a surgeon that is on call. The space must further contain:
  - *Material*: Various materials of different quality that can be used for various resolutions of prototyping.
  - *Machines*: Various machines that allow for a spread of applications and various levels of resolutions.
  - *Tools*: Various hand tools and power tools, adapted to the material and equipment that is at hand.
  - *Mechatronics*: Almost no modern device is purely mechanical, subsequently the space must allow for testing in multiple knowledge domains where mechatronics is the most prominent additional layer.
- *Skills*: People with the capability to understand the user needs and make the ideas tangible in an appropriate resolution. This includes fundamental understandings of relevant engineering and natural science topics.
- *Freedom*: The unpredictable nature of FFE PD does not allow for rigid administrative rules and therefore the toolmaker needs complete freedom to operate within their space. There cannot be an administrative layer and financial questions when starting up a machine, or when cutting a piece of Acrylic. There needs to be an initial overhead covering the fundamental cost. Once prototypes and subsequent MVPs are built, it is easier to apply for grants and additional, project-specific funding.
- *Method*: The FFE is a chaotic place and there must be a method in place on how to approach projects. The Wayfaring method worked

really well throughout all project since it caters the freedom of the toolmaker, while still guiding the work in time towards a fruitful solution.

- *Users*: The toolmaker needs to be an established entity that has access to the users without any administrative hurdles. If one needs one week to organize e.g. a laboratory visit, then the iterative prototyping approach collapses.

5.3 Consequences of a Toolmaker

The consequences of having a toolmaker in place is easier to understand when imagining an extreme situation *without* one, especially in the biomedical research sector: Researchers, doctors, nurses - all would encounter the same situation where equipment is only bought from a selection of vast catalogs from various producers. While the lack of prototypes in use can be understandable in the context of e.g. FDA-approved equipment, for researchers this has the far-reaching consequence that their efforts in pushing for new knowledge are based on known equipment. If everyone buys the same machines and the same equipment from the same catalogs, then everyone ends up doing the same research and encounters the same problems. While this situation might seem far-fetched, it is pretty much the situation that was observed when talking to doctors, researchers, and engineers within the biomedical sector, who are all stuck without an outlet to their ideas (see appendix M).

The consequences of having a toolmaker in place, as shown by the projects in this thesis, are clear: By giving the various parties of the biomedical sector an outlet where their ideas are rapidly implemented, the sector advances at low costs yet high impact. If nothing else, already Galileo Galilei had figured out that having access to novel research equipment automatically means being ahead of everyone else (Biagioli 2000).

Subsequently, the toolmaker addresses an issue in highly complex, but non-technological sectors where there is an abundance of ideas and problems but a lack of technological understanding and manpower to solve them.

5.4 Defining the Role

In addition to the theoretical understanding of the toolmaker, and *How?* and *Why?* they should be integrated, this thesis extends the role of the product champion on a theoretical level (see 1.3). As was demonstrated throughout all the cases in this thesis, the toolmaker is not simply a technology-savvy person that suggests innovation to their superior management, but the toolmaker gathers market insights in the form of needs from product champions of another knowledge domain, translates them into prototypes, and iteratively increases the quality of the product until a beta-version is at hand. Figure 5.1 depicts the role of the toolmaker in the context of a generic, simplified hospital setting. The structure is adopted from Maidique (1980).

Within this definition, the role of the toolmaker stands and falls with the administrative framework of the organization with respect to the PDP: Not understanding the chaotic nature of the FFE leads to desperate attempts to plan and control what cannot be foreseen due to e.g. UUs. Subsequently, pre-planned development paths that are required for e.g. the stage-gate model (Cooper 1990) would break the key benefit of the toolmaker as it is proposed here, since the FFE would be - theoretically - skipped, leading directly to the limited and potentially wrong requirements to external companies.

5.5 Limitations and Future Work

The conclusions presented here are based on the observations from the projects and the experience from the author working as a toolmaker, as well as the research contributions. It is easy to build arguments against the conclusions, since TrollLABS and the individual performances in all the projects are not quantifiable and include a lot of serendipity. There is subsequently no proof that these projects could not have been successful in another environment, or with another PD method. The author's dual role as toolmaker and observer creates the issue of personal bias, arguably skewing the results into a favorable direction. On the other hand, the nature of this thesis is to bring forward the foundation for controlled experiments. Furthermore, the unique constellation of each project - stakeholders, available technology, people in charge of the development - is non-repeatable. Therefore, the observations and conclusions presented in this thesis - albeit coherent - are only true within the context thereof. They do, however, offer a starting point for controlled experiments that can determine the truth, or lack thereof, of the above stated conclusions.

In order to understand the importance of spacial proximity better and in order to create a proper toolmaker environment within a biomedical context, TrollLABS has the unique opportunity to expand by starting up *TrollLABS Medical* - a second prototyping environment, located within the campus of St. Olav hospital in Trondheim.

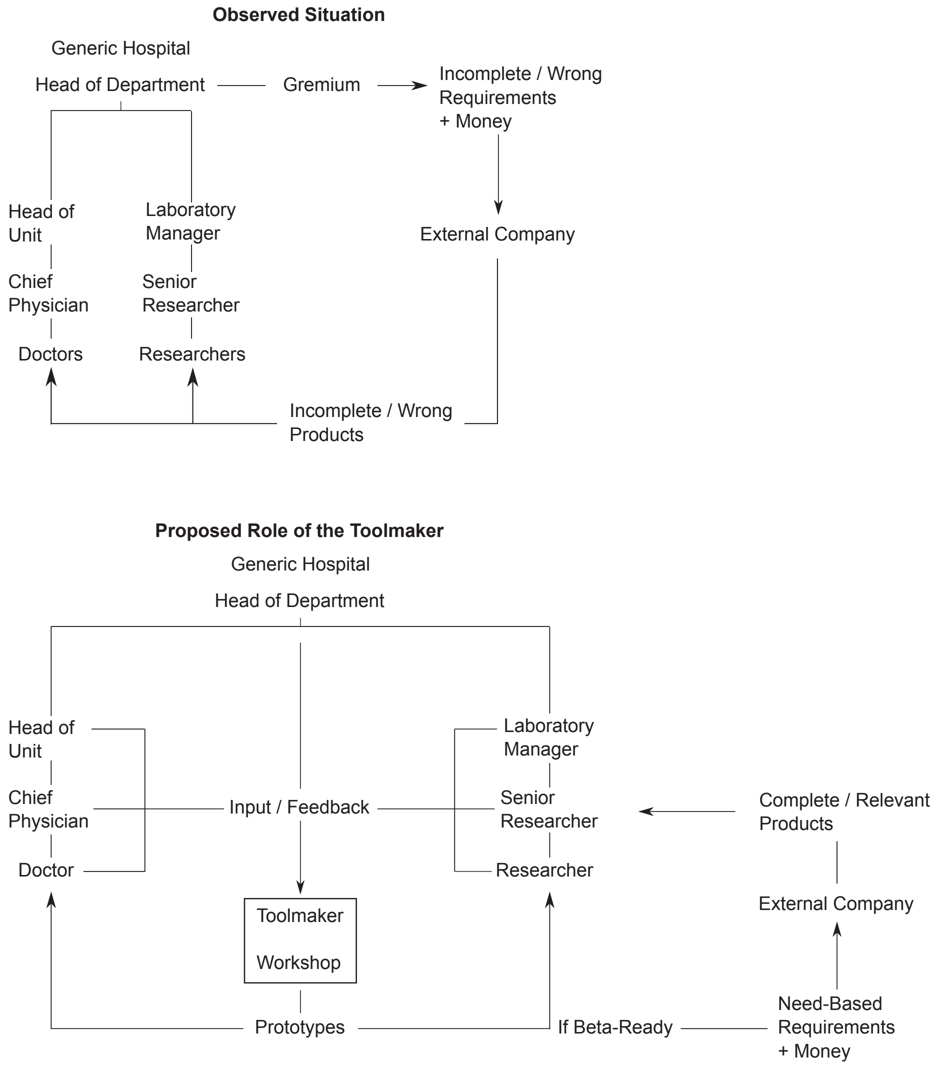

Figure 5.1: The two graphics show how the toolmaker should be intergrated within the biomedical sector, in this case depicted as a generic (and heavily simplified) hospital organisation: In the current situation as observed throughout this thesis, a product idea needs multiple backers, like product champions (see section 1.3). Once the idea has passed all stages, the top management can pull the trigger on an investment, which is based on a set of incomplete requirements / UUs. An external company sells a product based on these specifications. Including a toolmaker in the loop (lower graphic), the requirements are developed in-house based on feedback from all the involved users. Only when the prototypes are accepted as a solution the list of - now complete - requirements goes to an external supplier.

5.6 FC: The Beta Version

The current beta version of the FC is robust enough for external users and the author is developing further solutions for specialized research applications like 3D printed structures, multi-layered cells and testing of implants.

The beta-version of the FC is shown in figure 5.2. It only requires a 20 V power supply to run autonomously and consists of the following key-components:

- *Enclosure*: 3D printed enclosure, fitting into 160 x 110 mm standard K-frame opening.
- *Heater-assembly*: The assembly - together with the distribution block - consists of;
    - Five heating elements.
    - In- and outlet ports.
    - Two temperature sensors incl. according PCB.
    - Bubble trap incl. semi-permeable membrane.
- *Electronics*: The electronics are distributed along the main-PCB containing the controller and power distribution, the Display-PCB including the UI-elements, in addition to the sensor-PCB in the heater assembly.
- *Flow Chamber*: The flow-chamber includes an aluminum lid, inhouse casted silicone O-ring, and fitting glass-slide for the cells.

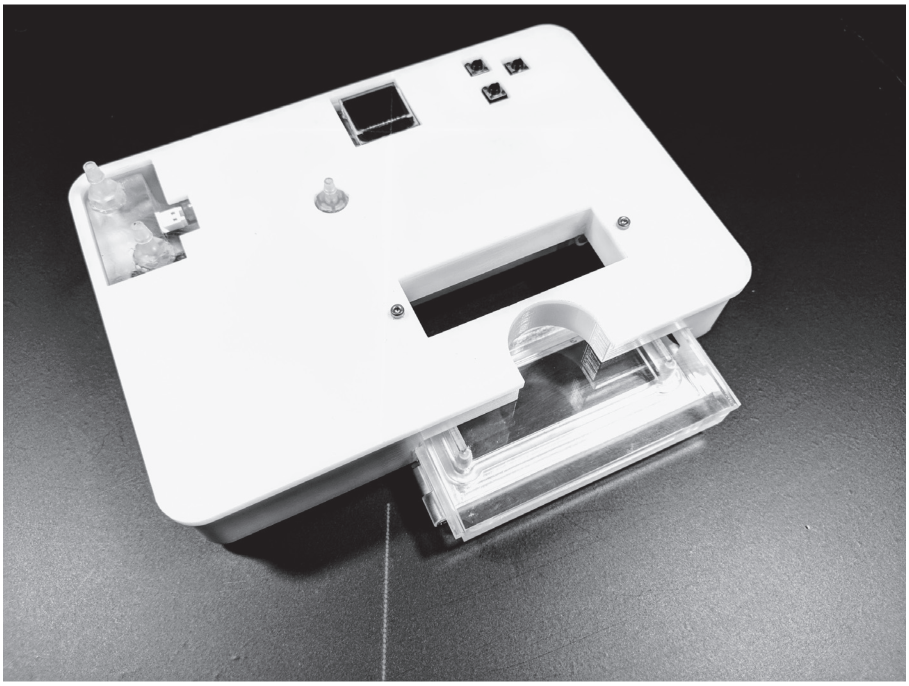

Figure 5.2: The current state of the FC project. The prototpye is fully functional and robust enough for external users. It incorporates a heater including two temperature sensors and an Arduino-based control system and UI, a bubble trap, and the observable flow-channel.

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Appendix A

Liver Phantom

The liver phantom project was started on research that was on-going at St. Olav's hospital at the time. In this project, the doctors used two real, human livers in order to create a live-like, casted model thereof. Clearly, using two human livers to create one replica was not a sustainable adventure. The challenge to TrollLABS was therefore to investigate whether or not this process could potentially be automated and made independent of human organs.

Over the course of three months, the author manually created a 3D body from a point cloud that was exported from CT scans (both visible in figure A.1) and showed that personalized, 3D-printed models can be integrated into a semi-automated production process with the potential of being fully automated. The first step was necessary in order to modify the shape of the liver and the main blood vessels with a standard CAD program. Due to the massive impact and potential of personalized 3D-printed organs, these steps are nowadays automated within one software, provided by e.g. Materialise (Materialise NV, Leuven, BE). The two resulting main 3D models, the outer shape of the liver incl. gall bladder, and main blood vessels within the liver are shown in figure A.2 and figure A.3, respectively. As for production itself, it was shown that 3D prints can be used for various casting procedures, including dissolving the print to enable flow through the artificial blood vessels, therefore enabling not only to create patient specific models, but also without the need of two real livers.

The liver phantom project ran for three months and was concluded in August 2014 with the TTO of NTNU stating that "there is no market" for personalized surgical training and according applications. An according google search today paints a different picture of the market.

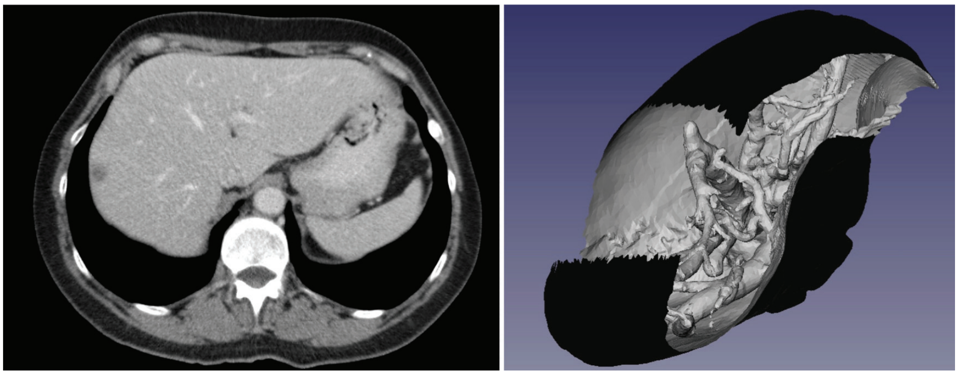

Figure A.1: One slide of the CT scan of a liver (left). The stack of slides was used to extract the point cloud visible on the right, the fundament for reconstructing a 3D-printed replica of the real liver.

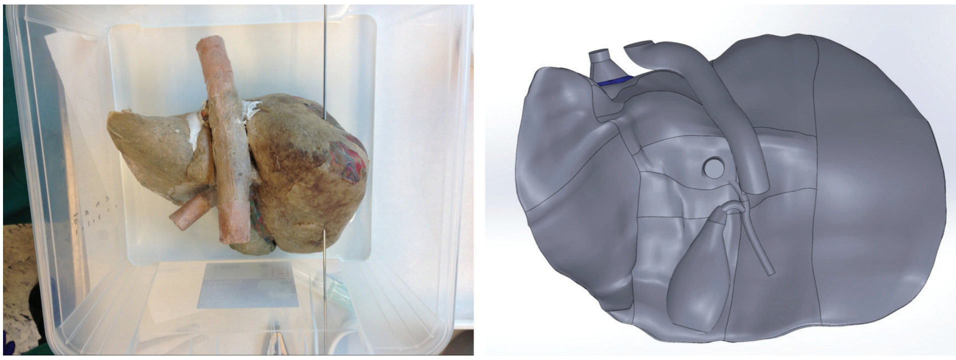

Figure A.2: The original casting process of the liver model included a fixated, human liver (left) that was used as a mold. The 3D model (right) can be 3D printed on demand and replaces the need for the human organ, enabling manufacturing.

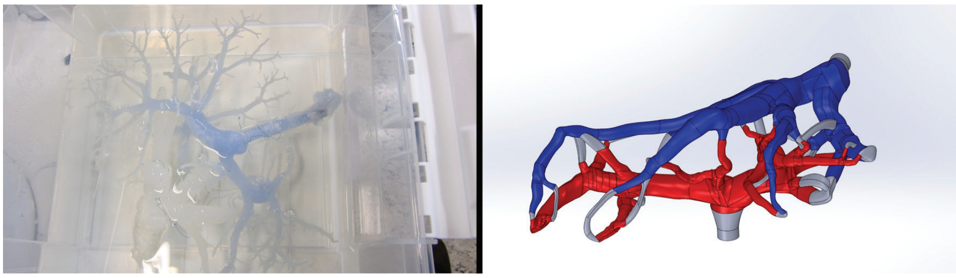

Figure A.3: For the blood vessels, the original process used a wax-cast of a real liver (left) which required dissolving the original organ. The CAD model (right) replaces this process without losing any of the detail.

Appendix B

Flow-Chamber Patent

This appendix contains the following documents from the FC patenting process, as submitted to the European Patent Office:

1. Main patent text and claims.
2. Figures to main patent text.
3. Patent Cooperation Treaty (PCT) request, listing - among other things - the four inventors, including the author.
4. International search report and decision of the European Patent Office stating that claims 2 and 3 are both, novel and innovative, and are therefore fulfilling patent protection.

B.1 The Main Patent Text and according Figures

Cell Culture Device

Specification

The present invention relates to a cell culture device.

Research using living cells in vitro depends on the assumption that experimental conditions resemble those of the in vivo system under examination.

This assumption must, for obvious reasons, hold true for all experimental parameters relevant to the phenomenon under investigation.

For some of these cells, such as endothelial cells, it has been shown that their proper function depends on mechanical stimuli. To study these cells, the in vitro model needs to not only replicate the basic conditions, such as temperature and metabolism, but also replicate mechanical factors in order to produce reliable data. In order to do this, cells are placed in devices termed flow chambers, flow cells, perfusion cells or bioreactors, and exposed to flow generated by a pumping system, typically a peristaltic pump. The level of mechanical stimulus – expressed as shear stress, strain and pressure – is varied by adjusting the flow rate or dimensions of the flow chamber.

However, preparing such cell cultures for observation using an optical microscope often is a cumbersome task especially when one wants to exchange the cell culture with another one and/or needs to transport cell cultures to the microscope for observation.

Based on the above, the problem underlying the present invention is to provide an improved cell culture device that allows to easily and efficiently observe cell cultures of the afore-mentioned kind.

This problem is solved by a cell culture device having the features of claim 1. Preferred embodiments are stated in the sub claims and are described below.

According to claim 1, a cell culture device for use with an optical microscope is disclosed, comprising

- a housing that is particularly configured to be placed onto a stage of an optical microscope below and/or above an objective of the microscope (i.e. in the light path of the microscope), the housing enclosing an internal space of the housing, wherein the housing further comprises a top wall, which top wall comprises a window, and wherein the housing comprises a bottom wall that opposes the top wall,
- a removable flow chamber enclosing an internal space for accommodating a cell culture comprising living biological cells, wherein the flow chamber is configured to be (e.g. manually or automatically) inserted into the internal space of the housing and to be (e.g. manually or automatically) removed from the housing for arranging the cell culture in the flow chamber, wherein the flow chamber is further configured for guiding a flow of a fluid medium (such as e.g. DMEM, RPMI, or artificial CSF) through the internal space of the flow chamber so that the fluid medium can contact and flow along the cell culture, and wherein the flow chamber further comprises a first and a second transparent wall region for observing the cell culture arranged in the internal space of the flow chamber between said transparent wall regions, wherein the transparent wall regions face said window when the flow chamber is inserted into said internal space of said housing,
- a heater arranged in the internal space of the housing for heating said fluid medium to be guided through the flow chamber,
- a first flow path arranged in the internal space of the housing for guiding said fluid medium towards the flow chamber via said heater, and a second flow path arranged in the internal space of the housing for guiding said fluid medium away from the flow chamber,
- a pump for pumping said fluid medium through the first flow path into the internal space of the flow chamber and through the second flow path out of the internal space of the flow chamber when the flow chamber is inserted into the internal space of the housing.

Particularly, the fact that the flow chamber can be (e.g. manually or automatically) inserted or removed from the housing means that installation or removing of the flow chamber can be accomplished without the use of tools and in a non-destructive manner. Thus, the flow chamber can be arranged in the housing and removed from the housing multiple times without significantly affecting the housing.

Thus, advantageously, the present invention provides a flow chamber system that not only provides important functionalities integrated into a single housing but can in particular also be fitted on standard microscope stages, e.g. in an embodiment it can be as small as 110mm x160mm x 25mm, the size of a typical microscope stage, and therefore allows for constant observation of the in vitro experiments, but also allows to easily exchange cell cultures by removing the flow chamber from the housing of the cell culture device, particularly in a tool-free manner (e.g. manually or automatically). For this, the flow chamber may be simply designed to be slid into and out of the housing of the cell culture device (see also below).

The first and the second flow path can comprise conduits, particularly flexible conduits that are arranged in the internal space of the housing. Particularly, the heater forms a section of the first flow path, wherein the heater is configured to heat said fluid medium when it passes said section.

According to an embodiment, the heater comprises a plurality of parallel heating plates. Particularly, each heating plate comprises a conductor. The respective conductor is particularly covered by a cladding of the respective heating plate, which cladding is preferably formed out of a biocompatible material, e.g. silicone. Further, the respective conductor particularly comprises a meandering shape and generates Joule heat when a voltage is applied to opposing ends of the conductor (ohmic heating). Particularly, the respective conductor is formed by a metal foil, particularly a NiCr-foil that may be cut from a blank by means of laser cutting. Particularly, said voltage is applied to the conductors in parallel. The electrical current flowing through the conductors is controlled by a control unit (see also below) which may control a transistor, particularly a MOSFET transistor, via which the electrical current coming from the conductors flows. Particularly, the transistor allows to adjust the amount of electrical current passing the transistor and thus the Joule heat generated by the conductors that heats the heating plates.

Further, particularly, the heating plates are spaced apart from one another so that a gap is provided between each two neighboring heating plates wherein the section of the first flow path that is formed by the heater starts at an inlet of heater for feeding said fluid medium into the heater, extends through the gaps and ends at an outlet of the heater from which the fluid medium is guided towards an inlet of the flow chamber (see also below).

According to an embodiment of the present invention, the cell culture device further comprises a temperature sensor arranged in the internal space of the housing so that the temperature sensor is in thermal contact with the fluid medium guided through the first flow path for measuring the temperature of the fluid medium.

In an embodiment, the cell culture device may also comprise a plurality of temperature sensors that are particularly arranged at different locations along a flow path of the fluid medium. Using several such sensors can make the control unit faster/more robust.

Particularly, the temperature sensor is arranged downstream the heater and upstream the flow chamber along the first flow path.

Further, according to an embodiment of the present invention, the cell culture device further comprises a control unit that is configured to control the heater (e.g. by controlling an electrical current flowing through the heater, e.g. via said transistor described above) such that an actual value of the temperature of the fluid medium measured with the temperature sensor approaches a desired value of the temperature of the fluid medium.

Further, according to an embodiment of the present invention, the cell culture device further comprises a flow sensor for determining a flow rate of the fluid medium. Particularly, the flow sensor can be arranged downstream the flow chamber in the second flow path.

Particularly, the control unit is configured to control said pump such that an actual value of the flow rate of the fluid medium measured with the flow sensor approaches a desired value of the flow rate of the fluid medium.

Further, according to an embodiment of the preset invention, the pump is arranged in the internal space of the housing (e.g. in the first or second flow path). Alternatively, the pump is an external pump being arranged outside said internal space of the housing. Then, particularly, the pump may connect to a conduit via which the fluid medium is guided to an inlet of the cell culture device.

Further, according to an embodiment of the preset invention, the housing comprises a recess for inserting the flow chamber into the internal space of the housing.

Particularly, the housing comprises a lateral wall connecting the top wall to the bottom wall of the housing, wherein said recess is formed into the bottom wall and the lateral wall of the housing.

Further, according to an embodiment of the preset invention, the flow chamber is configured to be slid into the recess for inserting the flow chamber into the internal space of the housing, and configured to be slid out of the recess for removing the flow chamber from the internal space of the housing. Thus, advantageously, the flow chamber can be brought into and out of its operating position by means of simple linear sliding movement.

Further, for facilitating said sliding movement, the flow chamber comprises at least two guide rails according to a further embodiment, which guide rails are each configured to engage with an associated groove formed into the housing, so that the flow chamber can be guided by the guiding rails upon sliding the flow chamber into and out of said recess. Thus, particularly, the guide rails extend longitudinally along the sliding direction.

Further, according to an embodiment of the preset invention, the flow chamber comprises a door being hinged to an (e.g. transparent) body of the flow chamber, particularly to a first lateral side of said body, which body has a recess formed therein on a side facing the (closed) door that forms said internal space of the flow chamber and that can be closed and sealed with said door. Particularly, said door comprises said first transparent wall region, and wherein particularly said body of the flow chamber comprises or forms said second transparent wall region. Further, particularly, the door is flush with the bottom side of the housing when the flow chamber is inserted into the internal space of the housing. Particularly, the bottom side faces away from the objective of the microscope when the cell culture device is arranged with respect to said objective on a stage of the microscope. Due to the arrangement of the window on the top side of the housing and the two transparent wall regions one is able to look through the flow chamber (and the cell culture device’s housing) in order to properly observe the cell culture residing in the flow chamber with said microscope.

Particularly, one of the at least two guide rails protrudes from said first lateral side of said body of the flow chamber, while the other guide rail of said at least two guide rails protrudes from a second lateral side of said body, which second lateral side faces away from the first lateral side.

Furthermore, said door comprises a latch for closing the door according to an embodiment, which latch is particularly configured to engage with a recess formed in the body for closing the door (and particularly also for sealing the internal space of the flow chamber), wherein said recess is formed into said second lateral side of the body.

Further, according to an embodiment of the preset invention, the flow chamber comprises an inlet port for injecting said fluid medium into the flow chamber and an outlet port for discharging said fluid medium out of the flow chamber. Particularly, said inlet port and said outlet port is arranged on a back side of said body of the flow chamber, which back side connects said first lateral side with said second lateral side of the body of the flow chamber.

Further, according to an embodiment of the present invention, the flow chamber further comprises a mechanism for flushing bubbles out of the flow chamber.

In an embodiment, the flow chamber comprises a first one-way valve for filling a fluid medium into the flow chamber and a second one-way valve for flushing a liquid medium as well as bubbles contained therein out of the flow chamber, wherein particularly said one-way valves are also arranged on said back side.

Further, according to an embodiment of the preset invention, the flow chamber is configured to be slid into said recess with the inlet port and the outlet port ahead so that the inlet port engages with a connector of the first flow path and the outlet port engages with a connector the second flow path and a flow connection between the inlet port and the first flow path and between the outlet port and the second flow path is established when the flow chamber is properly inserted/slid into the internal space of the housing.

Furthermore, in an embodiment of the present invention, the first flow path is connected to an inlet arranged on the housing, particularly on the top wall of the housing, while the second flow path is particularly connected to an outlet arranged on the housing, particularly on the top wall of the housing. Further, particularly, the inlet is configured to be connected to a first conduit for guiding said fluid medium into the first flow path via said inlet, while the outlet is particularly configured to be connected to a second conduit for discharging said fluid medium coming from the flow chamber out of the second flow path.

According to an embodiment, the first conduit may connect to a container for storing said fluid medium while the second conduit may connect to a waste bin for discarding the fluid medium. Alternatively, both conduits may connect to said container for recycling the fluid medium, i.e. the fluid medium is pumped into the internal space of the flow chamber via the first flow path and out of the internal space of the flow chamber back into the container via the second flow path. Particularly, the pump can be arranged in the first and or second flow path inside the internal space of the housing, or to the first conduit outside the housing of the cell culture device.

Further, according to yet another embodiment of the preset invention, the height of the housing is smaller than or equal to 25 mm. This allows one to fit the cell culture device onto a stage of a regular optical microscope. Thus, advantageously, the present invention can be used with standard microscopes and does not need dedicated optical instruments for observation of the cell cultures residing in the flow chamber.

Further, in an embodiment the breadth of the housing is smaller than or equal to 160 mm. Further, in an embodiment, the depth of the housing is smaller than or equal to 110 mm.

Furthermore, according to an embodiment of the cell culture device according to the present invention, the cell culture device comprises a bubble trap configured for removing bubbles of a gaseous phase (e.g. air or components thereof) from the fluid medium.

Particularly, according to an embodiment, the bubble trap comprises a first and a second volume, wherein the first and the second volume are separated by a semi-permeable membrane which is impermeable to the fluid medium but permeable for said gaseous phase, so that bubbles of the gaseous phase can rise from the first volume via the membrane into the second volume so as to remove them from the fluid medium. Particularly, the membrane may comprise PTFE.

Furthermore, according to an embodiment, the first volume forms a section of the first flow path, so that the gas bubbles are removed from the fluid medium in the first flow path, i.e. downstream the heater and upstream the flow chamber.

Further, according to an embodiment, the first volume of the bubble trap comprises an inlet connected to an outlet of the heater. Furthermore, according to an embodiment, the first volume comprises an outlet connected to said connector of the first flow path via which connector the flow chamber can be connected to the first flow path. Thus, the fluid medium can be passed from the heater to the first volume of the bubble trap and from the first volume to the flow chamber, wherein, when the fluid medium passes the first volume, bubbles of said gaseous phase can rise from the first volume into the second volume via the membrane so as to remove them from the fluid medium / first flow path.

Furthermore, according to an embodiment, the second volume of the bubble trap is smaller than the first volume.

Further, according to an embodiment the second volume of the bubble trap comprises a smaller pressure than the first volume. Particularly, the second (e.g. smaller) volume is under a vacuum, therefore increasing the amount of gas (e.g. air) that can pass through the semi-permeable membrane.

Further, according to an embodiment, the second volume of the bubble trap comprises an outlet for removing said gaseous phase from the bubble trap. Particularly, according to an embodiment, a pump, particularly a vacuum pump, is connected to said outlet for removing said bubbles via the pump.

Furthermore, according to yet another aspect of the present invention, a method for observing a cell culture using a cell culture device according to the present invention and a microscope is disclosed, wherein a cell culture is arranged in the flow chamber and the flow chamber is inserted into the internal space of the housing of the cell culture device, and wherein the housing of the cell culture device is arranged on a stage of the microscope below and/or in front of an objective of the microscope. Furthermore, particularly, a fluid medium is guided through the flow chamber arranged in the internal space of the housing of the cell culture device, wherein particularly the temperature is adjusted to a desired value and/or the flow rate is adjusted to a desired value.

Further features and embodiments of the present invention are described below with reference to the Figures, wherein

Fig. 1	shows a perspective view of a cell culture device according to the invention comprising an inserted flow chamber, wherein parts of a circumferential lateral wall and a top wall of a housing of the device are omitted to visualize an internal space of the housing of the device;
Fig. 2A-2B	shows illustrations of the housing with mounted components, such as a temperature sensor and a control unit, wherein in Fig. 2A the control unit is not shown so that the connectors for making electrical contact to the control unit can be seen; Fig. 2B shows the housing with inserted control unit; Figs. 2A also indicates flow paths of a fluid medium that is guided through the flow chamber;
Fig. 3	shows a plan view onto a bottom wall of the housing of the cell culture device according to the present invention;

Fig. 4	shows a side view onto a lateral wall of the housing, which lateral wall comprises, together with the bottom wall, a recess for inserting the flow chamber into the internal space of the housing;
Fig. 5	shows a plan view onto the top wall of the housing of the cell culture device according to the invention with the top wall removed in order to show the components arranged inside said internal space such as the heater and the flow chamber;
Fig. 6	shows a perspective view of the flow chamber;
Fig. 7	shows a perspective cross sectional view of the flow chamber;
Fig. 8	shows a side view of the flow chamber (onto a back side of a body of the flow chamber);
Fig. 9	shows a perspective view of a heater of the cell culture device according to the present invention;
Fig. 10	shows a perspective cross sectional view of the heater;
Fig. 11	shows a top view onto the heater, wherein a conductor for ohmic heating of an upper heating plate of the heater is indicated;
Fig. 12	shows a heating plate of the heater shown in Fig. 11;
Fig. 13	shows a lateral view of the housing of the cell culture device arranged on a stage of a microscope;
Fig. 14	shows a front view of the cell culture device and microscope shown in Fig. 13;
Fig. 15	shows the flow chamber being inserted into the housing or removed from the housing of the cell culture device;
Fig. 16	shows an internal pump of the cell culture device;
Fig. 17	shows an embodiment of the cell culture device comprising a bubble trap;
Fig. 18	shows a side view of the bubble trap of Fig. 17;
Fig. 19	shows a perspective view of the bubble trap shown in Figs. 17 and 18; and
Fig. 20	shows primary neurons at 20x magnification, recorded on a cell culture device according to the present invention.

Figure 1 shows in conjunction with Figs. 2A and 2B as well as Figs. 3 to 16 a cell culture device 1 for use with an optical microscope 40. According to Fig. 1 the cell culture device 1 comprises a housing 10 that is configured to be placed onto a stage 43 of an optical microscope 40, so that it is arranged in the light path L of the microscope 40 (i.e. in front of an objective 41 of the microscope 40) as schematically shown in Figs. 13 and 14. The housing 10 may be arranged below the objective 41 of the microscope 40. Alternatively, the objective 41 may also be arranged below the housing 10 as indicated by the dashed line in Fig. 11.

The housing 10 encloses an internal space 11, wherein the housing 10 further comprises a top wall 12 (not shown in Fig. 1) that comprises a window 13 for observing a removable flow chamber, and an opposing bottom wall 14 (cf. Fig. 14). The removable flow chamber 2 (cf. particularly Figs. 6 to 8) encloses an internal space 20 for accommodating a cell culture CC comprising living biological cells (e.g. endothelial cells; epithelial cells; glial cells; neurons; co-cultures, i.e. several cell types cultured at once, e.g. neuronal and glial cells; endothelial cells and fibroblast; etc.) as well as a flow of a fluid medium M (see also above), wherein the flow chamber 2 is configured to be inserted into the internal space 11 of the housing 10 and to be removed from the housing 10 for arranging the cell culture CC to be examined in the flow chamber 2. In order to maintain the cell culture CC in proper conditions, the flow chamber 2 is further configured for guiding said flow of a fluid medium M through the internal space 20 of the flow chamber 2 so that the fluid medium M can contact and flow along the cell culture CC. Particularly, one thereby aims at applying a defined force/stress on the cell culture in order to more accurately replicate in-vivo conditions of the cell culture CC. Further, the flow chamber 2 comprises a first and a second transparent wall region 21, 22 for observing the cell culture CC arranged in the internal space 20 of the flow chamber 2, wherein the transparent wall regions 21, 22 face said window 13 when the flow chamber 2 is inserted into said internal space 11 of said housing 10, so that cell culture CC can be properly observed through the window 13 and the second transparent wall region 22 while proper lighting can e.g. be applied via the first wall region 21 (e.g. Fig. 3) from below. The dimensions H x D x B as shown in Fig. 1 are preferably chosen such that the housing 10 fits onto a stage 43 of a usual microscope 40 (and at the same time below and/or in front of an objective 41 of said microscope 40). Therefore, in an example, said dimensions H x D x B can be smaller or equal to 25 mm x 110 mm x 116 mm.

Further, in order to adjust the temperature of the fluid medium M to a desired value, the device 1 further comprises a heater 3 arranged in said internal space 11 of the housing 10. The heater 3 forms part of a first flow path P1 (cf. Fig. 2A) arranged in the internal space 11 of the housing 10 for guiding said fluid medium M towards the flow chamber 2 (via said heater 3). The device 1 further comprises a second flow path P2 (cf. Fig. 2A) arranged in the internal space 11 of the housing 2 for guiding said fluid medium M away from the flow chamber 2. Said flow paths P1, P2 may comprise conduits, particularly flexible conduits, that are arranged in said internal space 11 of the housing 10 (e.g. along the dashed lines of Fig. 2A or Fig. 16 outside the heater 3 and flow chamber 2).

Further, the device 1 comprises an (internal or external) pump 4 for pumping said fluid medium M through the first flow path P1 into the internal space 20 of the flow chamber 2 and through the second flow path P2 out of the internal space 20 of the flow chamber 2 when the flow chamber 2 is inserted into the internal space 11 of the housing 10. Particularly the fluid medium M can be pumped in a circular flow and is continuously recycled through said heater 3 and flow chamber 2. Particularly, as shown in Fig. 16, the pump 4 can be arranged in the internal space 11 of the housing 10 and may form part of the second flow path P2. Particularly the pump 4 may be arranged downstream the flow chamber 2.

In order to control (e.g. closed-loop) the temperature of the fluid medium M, the cell culture device 1 may further comprise a temperature sensor 5 arranged in the internal space 11 of the housing 10 so that the temperature sensor 5 is in thermal contact with the fluid medium M guided through the first flow path P1 for measuring the temperature of the fluid medium M. Particularly, the temperature sensor 5 is arranged downstream the heater 3 and upstream the flow chamber 2 along the first flow path P1 so that it can measure the actual temperature of the fluid medium M when the latter leaves the heater 3.

This closed-loop control is conducted by a control unit 6 that is configured to control the heater 3 such that an actual value of the temperature of the fluid medium M measured with the temperature sensor 5 approaches a desired value of the temperature of the fluid medium M. The control unit therefore receives the current temperature of the fluid medium M from the temperature sensor 5 (or from several temperature sensors) as an input.

Fig. 2A shows a top view of the cell culture device 1 with a circuit board 6a of the control unit 6 removed from the internal space 11 of the device 1 so that the connectors 60 for the printed circuit board 6a / control unit 6 can be seen. Fig. 2B shows the device 1 with the mounted circuit board 6a and control unit 6 thereon, which circuit board 6a also comprises a display 61 for e.g. displaying a selected desired temperature (or other selected desired quantities such as a desired flow rate of the fluid medium) as well as operating elements (e.g. buttons 62) to manually operate the control unit 6 (e.g. for selecting desired quantities such as a desired temperature or a desired flow rate).

For ohmic heating of the fluid medium M, the heater 3 may comprise a plurality of parallel heating plates 30 as shown in Figs. 9 to 12 that comprise a cladding 31c formed out of an e.g. biocompatible material. A conductor 31 is embedded in said cladding 31c of the respective heating plate 30, wherein the respective conductor 31 particularly comprises a meandering shape as indicated in Figs. 11 and 12 and generates Joule heat when a voltage (e.g. a direct-current voltage, e.g. 19V) is applied to opposing ends or contacts 31a, 31b of the respective conductor 31 (ohmic heating). Particularly, the respective conductor 31 is formed by a metal foil, particularly a NiCr-foil, that may be cut from a blank by means of laser cutting. Particularly, said voltage is applied to the conductors 31 in parallel. The electrical current flowing through the conductors 31 is controlled by the control unit 6 described above which may particularly control a transistor, particularly a MOSFET transistor, via which the electrical current coming from the conductors 31 flows. Particularly, the transistor allows to adjust the amount of electrical current passing the transistor and thus the Joule heat generated by the conductors 31 that heat the heating plates 30. Particularly, Fig. 12 shows one of the heating plates 30 indicating said cladding 31c and the conductor 31 being covered by said cladding 31c, Further, said contacts 31a, 31b protrude out of said cladding 31a so that an electrical current can be applied to the contacts 31a, 31b. As also indicated in Fig. 12, the heating plate 30 comprises a recess which forms part of the first flow path P1 (cf. also Fig 10).

As can be seen in Figs. 9 and 10, the heating plates 30 are spaced apart from one another so that a gap 32 is provided between each two neighboring heating plates 30 wherein the section of the first flow path P1 that is formed by the heater 3 starts at an inlet 33 of heater 3 for feeding said fluid medium M into the heater 3, extends through the stacked gaps 32 along the dashed line in Fig. 10 and ends at an outlet 34 of the heater 3 (cf. e.g. Fig. 9) from which the fluid medium M is guided towards an inlet 200 of the flow chamber 2 which is shown in Figs. 6 and 8 in particular.

Furthermore, the cell culture device 1 further comprises a flow sensor 7 for determining a flow rate of the fluid medium M (cf. Fig. 1). Such a flow sensor 7 can be placed upstream and/or downstream the flow chamber 2, Here, as example, the flow sensor 7 is arranged in the second flow path P2 downstream the flow chamber 2 in the internal space 11 of the housing 10. Determining the flow rate allows one to precisely tune the shear forces acting on the cell culture CC via the flowing medium M. For this, the control unit 6 is configured to control said pump 4 such that an actual value of the flow rate of the fluid medium M measured with the flow sensor 7 approaches a desired value of the flow rate of the fluid medium M.

For sliding the flow chamber into and out of the internal space 11 of the housing 10, which sliding is shown in Fig. 15, the housing 10 particularly comprises a recess 15 that is e.g. formed into a lateral wall 16 of the housing that connects the opposing top and bottom wall 12, 14 of the housing 10 as well as into the bottom wall 14 as indicated e.g. in Figs.4 and 15.

For easy sliding of the flow chamber 2, the latter comprises at least two guide rails 23 as shown e.g. in Fig. 6. The guide rails 23 can be discontinued by other components such as a latch 27 that will be described in more detail below. Each guide rail 23 is configured to engage into a groove 17 formed in the housing 10 (cf. Fig. 4), so that a guided sliding movement is facilitated by the engaging guide rails 23 and grooves 17.

Particularly, according to Fig. 6, the flow chamber may 2 comprise a single guide rail 23 on a first lateral side 26a of a body 26 of the flow chamber 2 as well as two parallel (discontinued) guide rails 23 on a second lateral side 26b of said body 26, which second lateral side 26b faces away from the first lateral side 26a. As shown in Fig. 7, said body 26 comprises a recess 20 forming an internal space 20 of the flow chamber 2 on a side of the body 26 that faces a door 24 that can be hinged (via hinges 25) to said first lateral side 26a of the body 26. The door 24 can be closed (e.g. so as to seal the internal space 20) using said latch 27 which is configured to engage with a recess 28 formed into the second lateral side 26b in order to close the door 24 and seal the internal space 20 of the flow chamber 2.

Particularly, for observing the cell culture CC residing in the internal space 20 of the flow chamber 2, the door 24 comprises said first transparent wall region 21 (e.g. in the form of a window of the door 24), while the opposing body 26 of the flow chamber 2 comprises or forms said second transparent wall region 22. Particularly, the entire body 26 can be transparent.

Further, particularly, when the door 24 is closed and the flow chamber 2 is slid into the recess 15, the door 24 is flush with the bottom side 14 of the housing 10 or slightly recessed with respect to the bottom side 14.

Further, as already stated above, the flow chamber 2 comprises an inlet port 200 for injecting said fluid medium M into the flow chamber 2 and an outlet port 201 for discharging said fluid medium M out of the flow chamber 2, wherein particularly said ports 200, 201 are arranged on a back side 26c of said body 26, which back side 26c connects said first lateral side 26a with said second lateral side 26b of the body 26 of the flow chamber 2 (cf. Figs. 6 and 8).

Further, as indicated in Figs. 6 and 8, the flow chamber 2 comprises on the back side 26c of the body 26 a first one-way valve 202 and a second one-way valve 203 (e.g. for pushing air bubbles out of the flow chamber 2). Particularly, the first valve 202 may serve for filling a fluid medium into the flow chamber 2 and the second valve 203 may serve for flushing a liquid medium out of the flow chamber 2 and subsequently pushing air bubbles out of the flow chamber 2.

In order to establish flow connections between the internal space 20 of the flow chamber 2 and the first and second flow paths P1, P2 inside the internal space 11 of the housing 10 of the cell culture device 1, the flow chamber 2 is further configured to be slid into said recess 15 of the housing 10 with the inlet port 200 and the outlet port 201 ahead so that the inlet port 200 engages with a connector 204 of the first flow path P1 and the outlet port 201 engages with a connector 205 of the second flow path P2 (cf. e.g. Figs. 1 and 6) and a flow connection between the inlet port 200 and the first flow path P1 and between the outlet port 201 and the second flow path P2 is established when the flow chamber 2 is completely slid into the recess 15.

Furthermore, as indicated in Fig. 2A, the first flow path P1 is connected to an inlet 18 arranged on the housing 10, particularly on the top wall 12 of the housing 10, whereas the second flow path P2 is connected to an outlet 19 arranged on the housing 10, particularly on the top wall 12 of the housing 10. Here, the inlet 18 is configured to be connected to a first conduit for guiding said fluid medium M into the first flow path P1, while the outlet 19 is configured to be connected to a second conduit for discharging said fluid medium M coming from the flow chamber 2 out of the second flow path P2.

The first conduit may connect to a container for storing said fluid medium M while the second conduit may connect to a waste bin for discarding the fluid medium.

Alternatively, both conduits may connect to said container for recycling the fluid medium, i.e. the fluid medium M is pumped into the internal space 20 of the flow chamber 2 via the first flow path P1 and out of the internal space 20 of the flow chamber 2 back into the container via the second flow path P2. Particularly, the pump 4 can be arranged in the first and or second flow path P1, P2 inside or outside the internal space 11 of the housing 10.

Furthermore, as shown in Figs. 17 to 19, the cell culture device 1 can comprise a gas bubble trap 50 arranged in the internal space 11 of the housing 10 and configured for removing bubbles of a gaseous phase G from the fluid medium M.

The bubble trap 50 may comprise a separate bubble trap housing that is arranged in said internal space 11 and particularly comprises a first volume 51 and an adjacent second volume 52 on top of the first volume 51, wherein the first and the second volume 51, 52 are separated by a semi-permeable membrane 53 which is impermeable to the fluid medium M but permeable for said gaseous phase G so that bubbles of the gaseous phase G can rise from the first volume 51 via the membrane 53 into the second volume 52 and are thus removed from the fluid medium M.

As can be seen from Fig. 17, the first volume 51 of the bubble trap 50 forms a section of the first flow path P1.

Particularly, the first volume 51 comprises an inlet 51a connected to the outlet 34 of the heater 3 as well as an outlet 51b connected to the connector 204 so that fluid medium M can be passed from the heater 3 to the first volume 51 of the bubble trap 50 and from the first volume 51 to the flow chamber 2, wherein bubbles of said gaseous phase G rise from the first volume 51 into the second volume 52 via the membrane so as to remove them from the first flow path while the liquid phase of the medium M is retained by the membrane 53.

Further, the second volume 52 is particularly smaller than the first volume 51 and particularly comprises a smaller pressure than the first volume 51 during operation of the cell culture device 1. Particularly, the second volume 52 is under a vacuum, therefore increasing the amount of gas (e.g. air) that can pass through the semi-permeable membrane 53. Further, for removing the gaseous phase G from the second volume 52 of the bubble trap 50, the second volume comprises an outlet 52a for removing said gaseous phase G from the bubble trap 50. Particularly, a pump can be connected to said outlet 52a so that the bubbles/gaseous phase G can be removed via the pump.

Finally, as an example, Fig. 20 shows primary Neurons at 20x magnification, recorded using a cell culture device according to the present invention while being exposed to a shear stress of 2.5dyn/cm^2. Shown is the phase contrast image (A), the GFP Signal (B) and the overlay of both (C) after 800s of shear exposure. The dissociated hippocampal neuron culture was obtained from C57B6/JjRj (Janvier Labs, France) mice. Time-mated mice were euthanized at day 16.5 of gestation (E 16.5) and embryos, their brains and then hippocampi were dissected under sterile conditions and digested using Tryple Select reagent (Gibco) 25 min. at 37 C. Obtained hippocampal neurons were plated at density 50,000/cm^2 in Neurobasal medium (Gibco) supplemented with 2% of Gibco B-27 on poly-D-lysine (100 ug/ml; Sigma) coated glass slides.

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Claims

1. A cell culture device (1) for use with an optical microscope, comprising
    - a housing (10) that is configured to be placed onto a stage of an optical microscope in front of an objective of the microscope, the housing enclosing an internal space (11) of the housing (10), wherein the housing (10) further comprises a top wall (12) comprising a window (13) and an opposing bottom wall (14),
    - a removable flow chamber (2) enclosing an internal space (20) for accommodating a cell culture (CC) comprising living biological cells, wherein the flow chamber (2) is configured to be inserted into the internal space (11) of the housing (10) and to be removed from the housing (10) for arranging the cell culture in the flow chamber (2), wherein the flow chamber (2) is further configured for guiding a flow of a fluid medium (M) through the internal space (20) of the flow chamber (2) so that the fluid medium (M) can contact the cell culture (CC) and flow along the cell culture (CC), and wherein the flow chamber (2) further comprises a first and a second transparent wall region (21, 22) for observing the cell culture (CC) arranged in the internal space (20) of the flow chamber (2), wherein the transparent wall regions face (21, 22) said window (13) when the flow chamber (2) is inserted into said internal space (11) of said housing (10),
    - a heater (3) arranged in the internal space (11) of the housing (10) for heating said fluid medium (M) to be guided through the flow chamber (2),
    - a first flow path (P1) arranged in the internal space (11) of the housing (10) for guiding said fluid medium (M) towards the flow chamber (2) via said heater (3), and a second flow path (P2) arranged in the internal space (11) of the housing (2) for guiding said fluid medium (M) away from the flow chamber (2), and
    - a pump (4) for pumping said fluid medium (M) through the first flow path (P1) into the internal space (20) of the flow chamber (2) and through the second flow path (P2) out of the internal space (20) of the flow chamber (2) when the flow chamber (2) is inserted into the internal space (11) of the housing (10).

2. The cell culture device according to claim 1, **characterized in that** the cell culture device (1) further comprises a temperature sensor (5) arranged in the internal space (11) of the housing (10) so that the temperature sensor (5) is in thermal

contact with the fluid medium (M) guided through the first flow path (P1) for measuring the temperature of the fluid medium (M).

3. The cell culture device according to claim 1 or 2, **characterized in that** the cell culture device (1) further comprises a control unit (6) that is configured to control the heater (3) such that an actual value of the temperature of the fluid medium (M) measured with the temperature sensor (5) approaches a desired value of the temperature of the fluid medium (M).

4. The cell culture device according to one of the preceding claims, **characterized in that** the cell culture device (1) further comprises a flow sensor (7) for determining a flow rate of the fluid medium (M).

5. The cell culture device according to claim 3 and 4, **characterized in that** the control unit (6) is configured to control said pump (4) such that an actual value of the flow rate of the fluid medium measured with the flow sensor (7) approaches a desired value of the flow rate of the fluid medium (M).

6. The cell culture device according to one of the preceding claims, **characterized in that** the pump (4) is arranged in the internal space (11) of the housing (10) or that the pump (4) is an external pump being arranged outside said internal space (11) of the housing (10).

7. The cell culture device according to one of the preceding claims, **characterized in that** the housing (10) comprises a recess (15) for inserting the flow chamber (2) into the internal space (11) of the housing (10).

8. The cell culture device according to claim 7, **characterized in that** the housing (10) comprises a lateral wall (16) connecting the top wall (12) to the bottom wall (14) of the housing (10), wherein said recess (15) is formed into the bottom wall (14) and the lateral wall (16) of the housing (10).

9. The cell culture device according to one of the preceding claims, **characterized in that** the flow chamber (2) is configured to be slid into the recess (15) for inserting the flow chamber (2) into the internal space (11) of the housing (10), and

configured to be slid out of the recess (15) for removing the flow chamber (2) from the internal space (11) of the housing (10).

10. The cell culture device according to one of the claims 7 to 9, **characterized in that** the flow chamber (2) comprises at least two guide rails (23) which are each configured to engage with an associated groove (17) formed into the housing (10) for guiding the flow chamber (2) upon sliding the flow chamber (2) into and out of said recess (15).

11. The cell culture device according to one of the preceding claims, **characterized in that** the flow chamber (2) comprises a door (24) being hinged to a body (26) of the flow chamber (2), which body (26) comprises a recess (20) formed therein forming the internal space (20) of the flow chamber (2), wherein particularly said door (24) comprises said first transparent wall region (21), and wherein particularly said body (26) of the flow chamber (2) comprises or forms said second transparent wall region (22), and wherein particularly the door (24) is flush with the bottom side (14) of the housing (10) when the flow chamber (2) is inserted into the internal space (11) of the housing (10).

12. The cell culture device according to one of the preceding claims, **characterized in that** the flow chamber (2) comprises an inlet port (200) for injecting said fluid medium (M) into the flow chamber (2) and an outlet port (201) for discharging said fluid medium (M) out of the flow chamber (2).

13. The cell culture device according to one of the preceding claims, **characterized in that** the flow chamber (2) is configured to be slid into said recess (15) with the inlet port (200) and the outlet port (201) ahead so that the inlet port (200) engages with a connector (204) of the first flow path (P1) and the outlet port (201) engages with a connector (205) of the second flow path (P2) and a flow connection between the inlet port (200) and the first flow path (P1) and between the outlet port (201) and the second flow path (P2) is established when the flow chamber (2) is inserted into the internal space (11) of the housing (10).

14. The cell culture device according to one of the preceding claims, **characterized in that** the height (H) of the housing is smaller than 25 mm or equal to 25 mm,

and/or that the breadth (B) is smaller than 160 mm or equal to 160 mm, and/or that the depth (D) is smaller than 110 mm or equal to 110 mm.

15. The cell culture device according to one of the preceding claims, **characterized in that** the cell culture device (1) comprises a gas bubble trap (50) configured for removing bubbles of a gaseous phase from the fluid medium (M).

16. The cell culture device according to claim 15, **characterized in that** the bubble trap (50) comprises a first and a second volume (51, 52), wherein the first and the second volume (51, 52) are separated by a semi-permeable membrane (53) which is impermeable to the fluid medium (M) but permeable for said gaseous phase.

17. The cell culture device of claim 16, **characterized in that** the first volume (51) forms a section of the first flow path (P1).

18. The cell culture device according to claims 13 and 17, **characterized in that** the first volume (51) comprises an inlet (51a) connected to an outlet (34) of the heater (3), and/or that the first volume (51) comprises an outlet (51b) connected to the connector (204).

19. The cell culture device according to one of the claims 16 to 18, **characterized in that** the second volume (52) is smaller than the first volume (51).

20. The cell culture device according to one of the claims 16 to 19, **characterized in that** the second volume (52) comprises a smaller pressure than the first volume (51).

21. The cell culture device according to one of the claims 16 to 19, **characterized in that** the second volume (52) of the bubble trap (50) comprises an outlet (52a) for removing said gaseous phase from the bubble trap (50).

22. Method for observing a cell culture (CC) using a cell culture device (1) according to one of the preceding claims and a microscope (40), wherein a cell culture (CC) is arranged in the flow chamber (2) and the flow chamber (2) is inserted into the internal space (11) of the housing (10) of the cell culture device (1), and wherein

particularly the housing (10) of the cell culture device (1) is arranged on a stage (43) of the microscope (40) in front of an objective (41) of the microscope (40).

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Abstract

The present invention relates to a cell culture device (1) for use with an optical microscope (40), comprising a housing (10) that is configured to be placed onto a stage of an optical microscope (40) in front of an objective (41) of the microscope (40), the housing (10) enclosing an internal space (11) of the housing (10), wherein the housing (10) further comprises a top wall (12) comprising a window (13) and an opposing bottom wall (14), a removable flow chamber (2) enclosing an internal space (20) for accommodating a cell culture (CC) comprising living biological cells, wherein the flow chamber (2) is configured to be inserted into the internal space (11) of the housing (10) and to be removed from the housing (10) for arranging the cell culture (CC) in the flow chamber (2), wherein the flow chamber (2) is further configured for guiding a flow of a fluid medium (M) through the internal space (20) of the flow chamber (2) so that the fluid medium (M) can contact the cell culture (CC) and flow along the cell culture (CC), and wherein the flow chamber (2) further comprises a first and a second transparent wall region (21, 22) for observing the cell culture (CC) arranged in the internal space (20) of the flow chamber (2), wherein the transparent wall regions face (21, 22) said window (13) when the flow chamber (2) is inserted into said internal space (11) of said housing (10), a heater (3) arranged in the internal space (11) of the housing (10) for heating said fluid medium (M) to be guided through the flow chamber (2), a first flow path (P1) arranged in the internal space (11) of the housing (10) for guiding said fluid medium (M) towards the flow chamber (2) via said heater (3), and a second flow path (P2) arranged in the internal space (11) of the housing (2) for guiding said fluid medium (M) away from the flow chamber (2), and a pump (4) for pumping said fluid medium (M) through the first flow path (P1) into the internal space (20) of the flow chamber (2) and through the second flow path (P2) out of the internal space (20) of the flow chamber (2) when the flow chamber (2) is inserted into the internal space (11) of the housing (10).

Fig. 1

Fig. 1

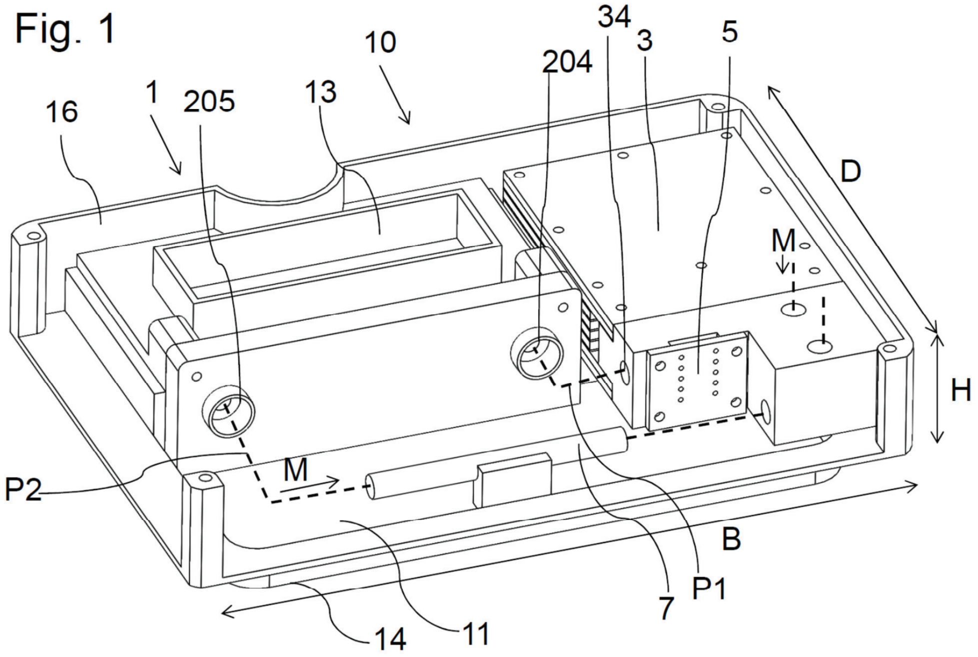
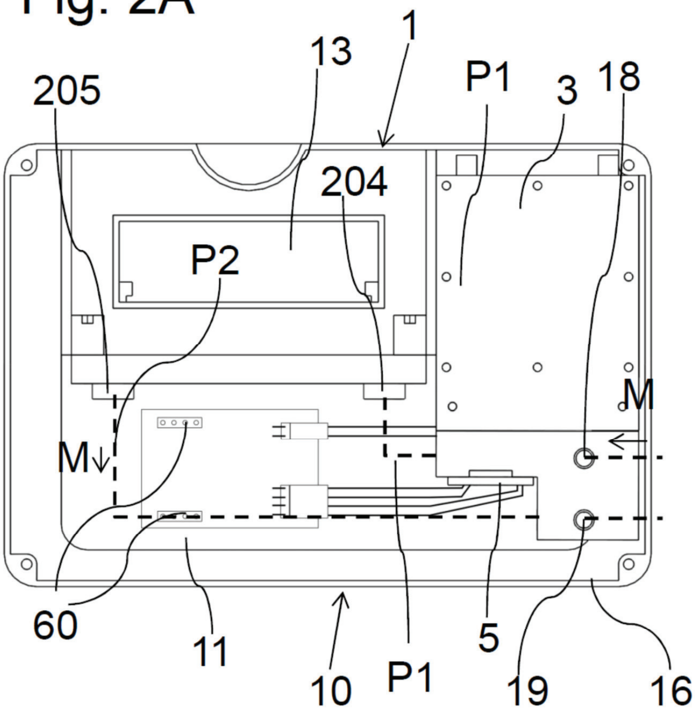


Fig. 2A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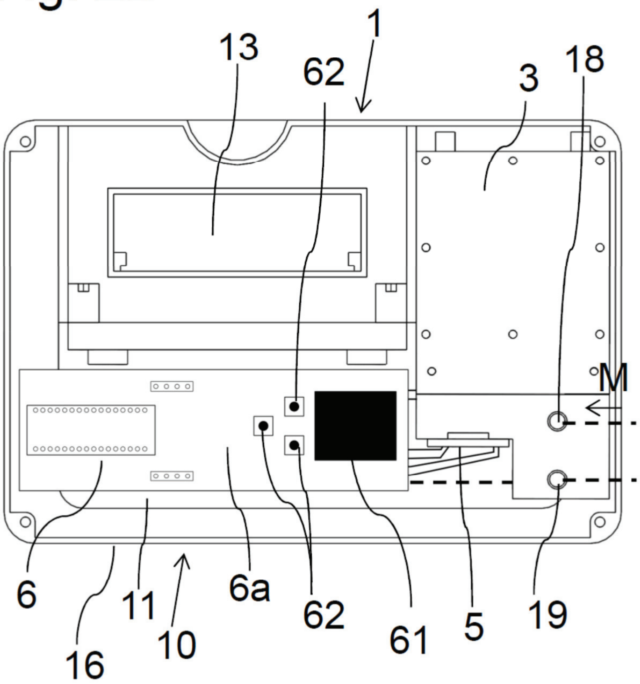
204
P1
3
18
P2
M
M↓
60
11
10
P1
5
19
16

Fig. 2B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18
M
6
11
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10
6a
62
61
5
19

Fig. 3

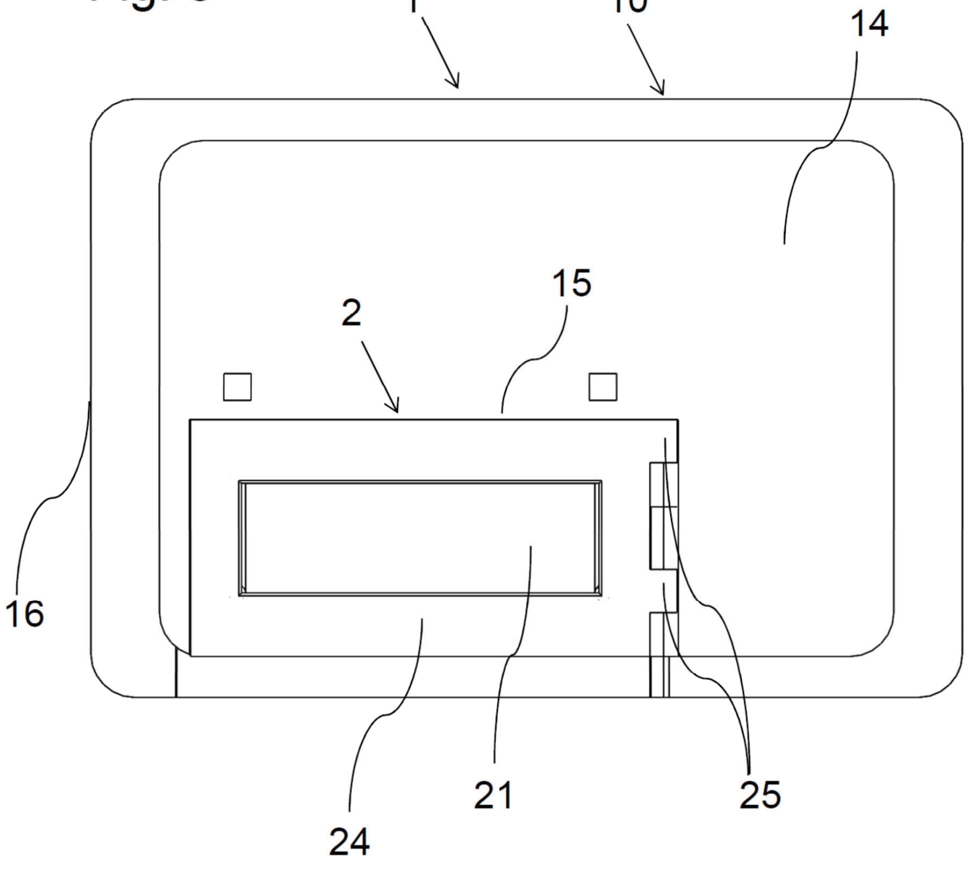
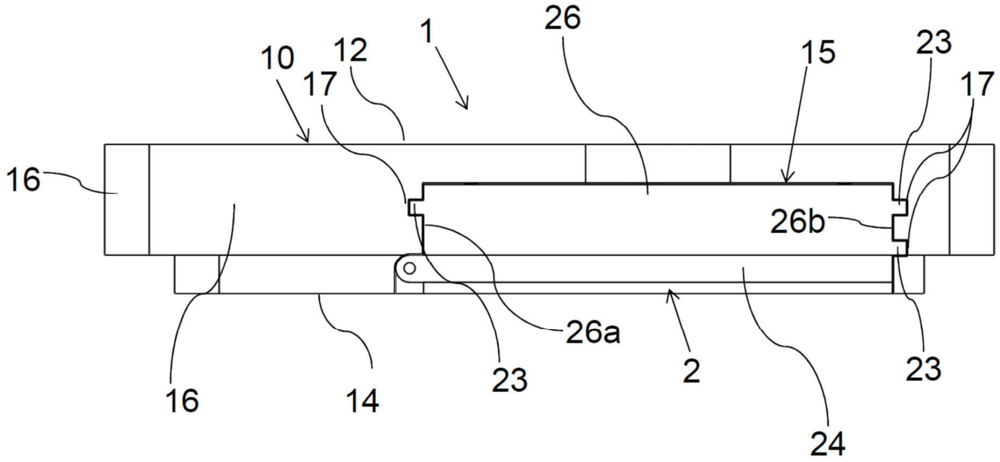


Fig. 4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17
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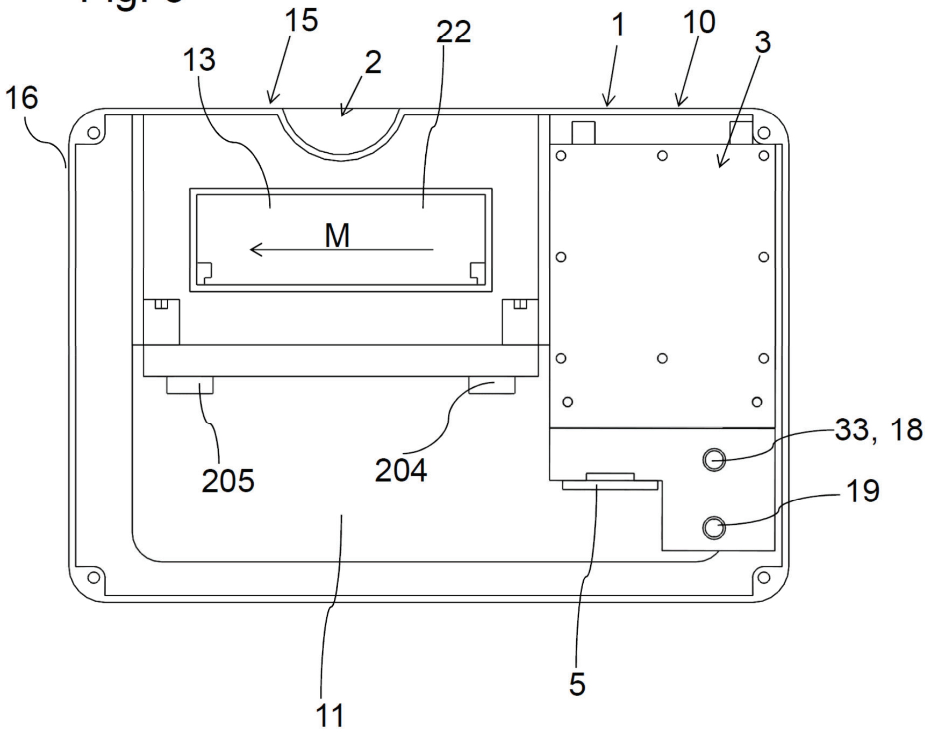
16
14
23
26a
2
23
24

Fig. 5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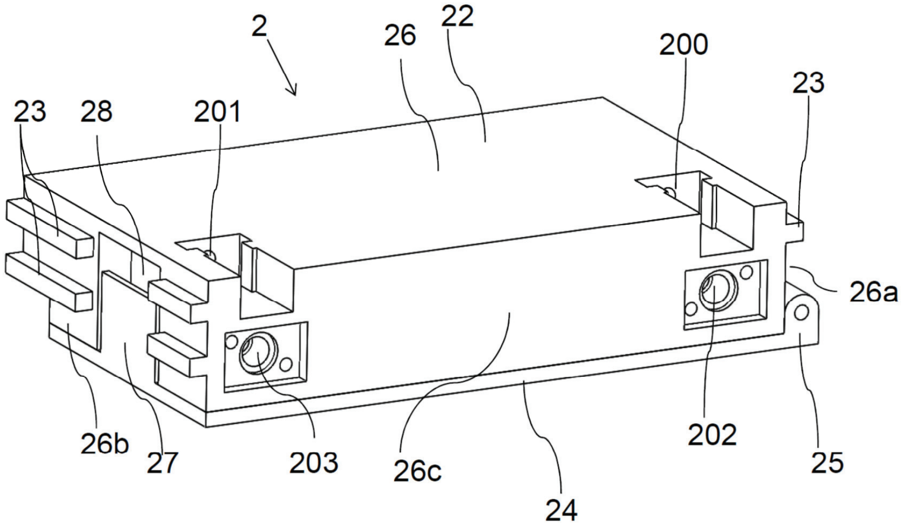
M
33, 18
19
205
204
5
11

Fig. 6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22
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23
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203
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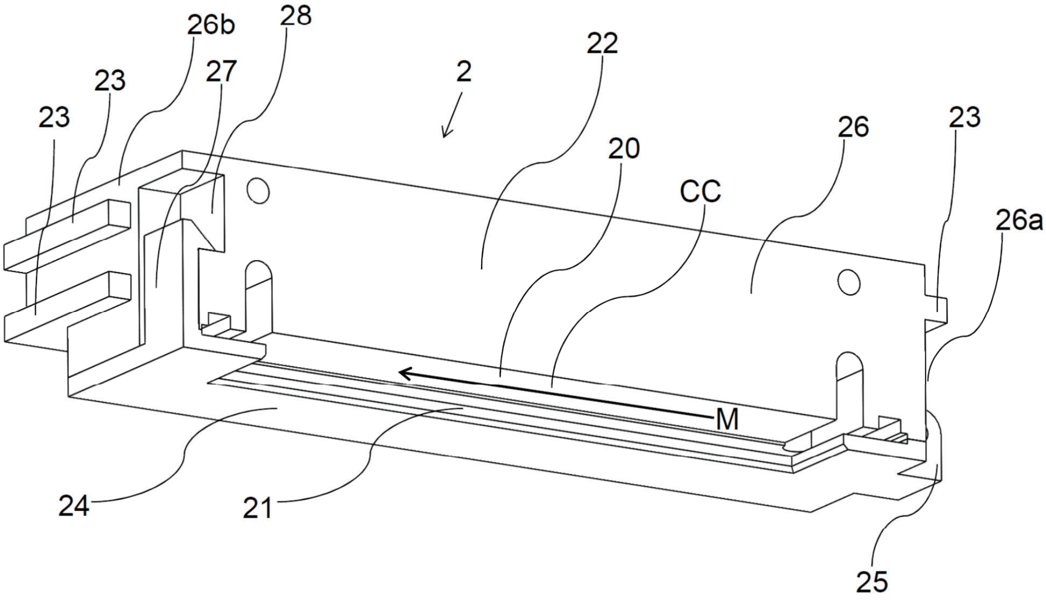
202
25
24

Fig. 7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CC
26a
M
24
21
25

Fig. 8

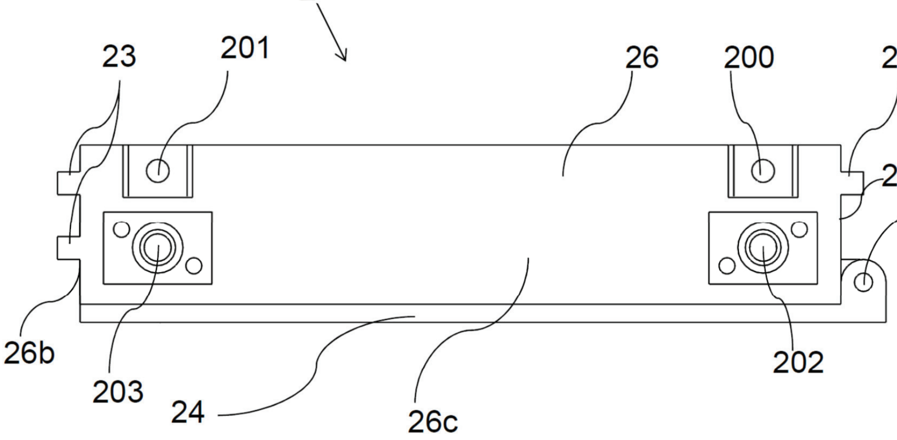


Fig. 9

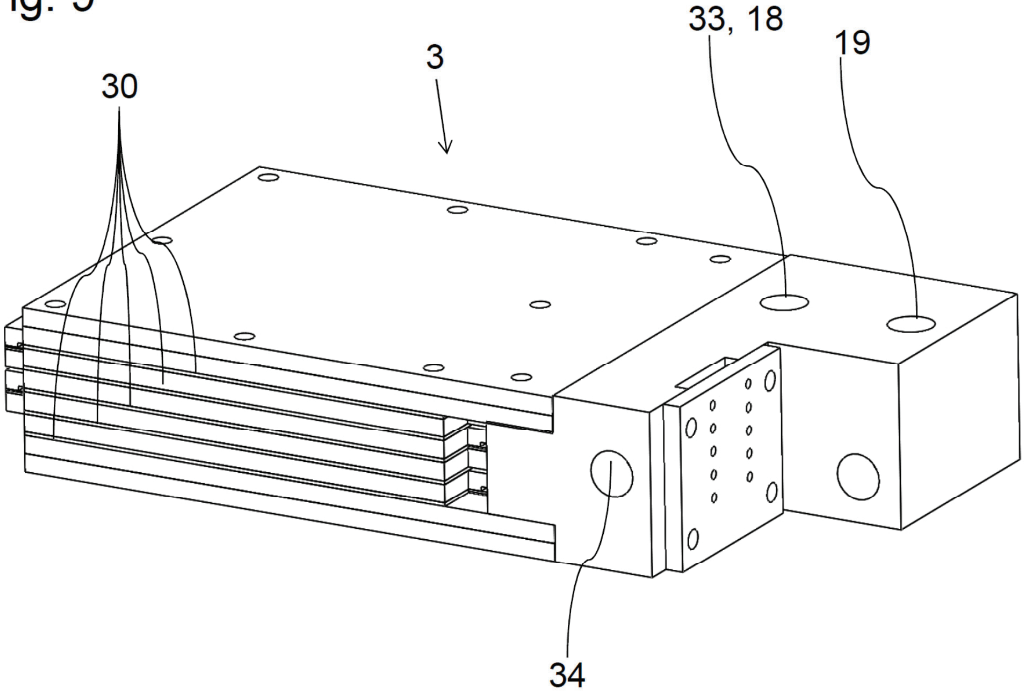


Fig. 10

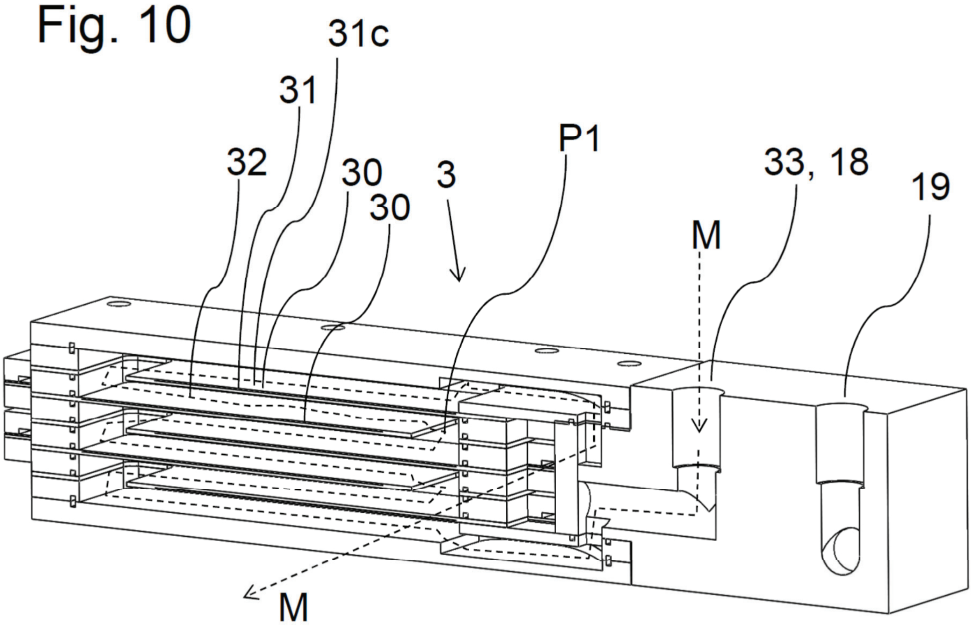


Fig. 11

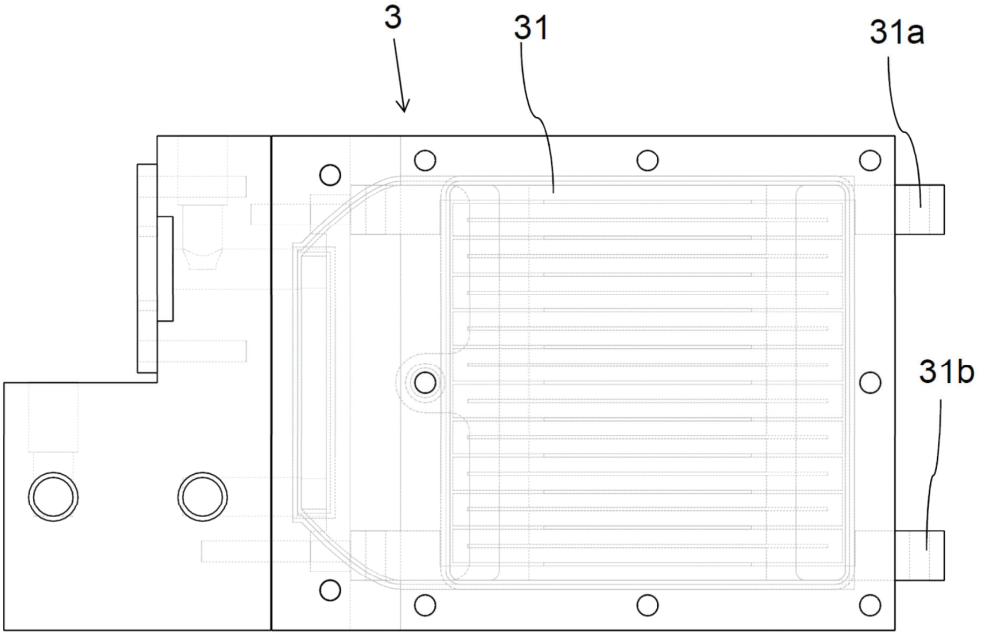


Fig. 12

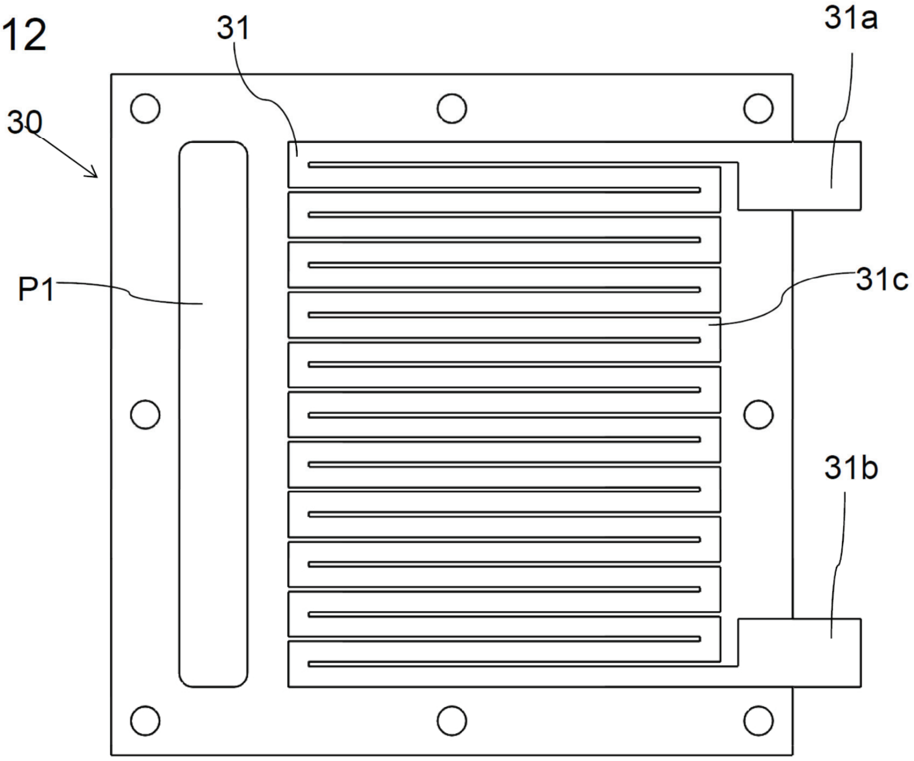


Fig. 13

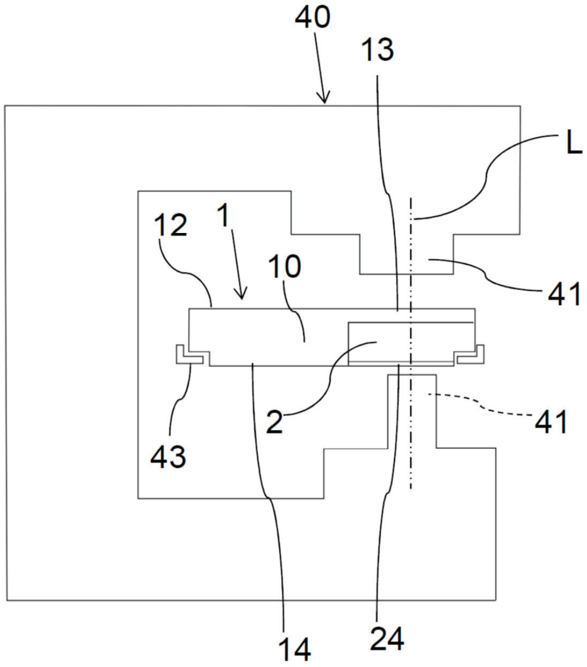


Fig. 14

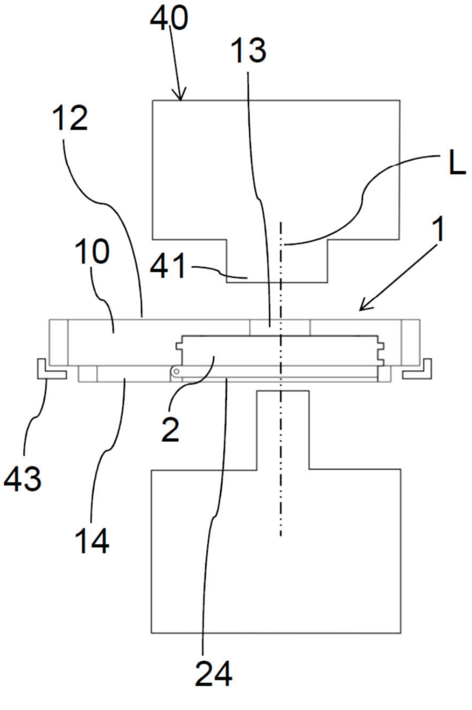


Fig. 15

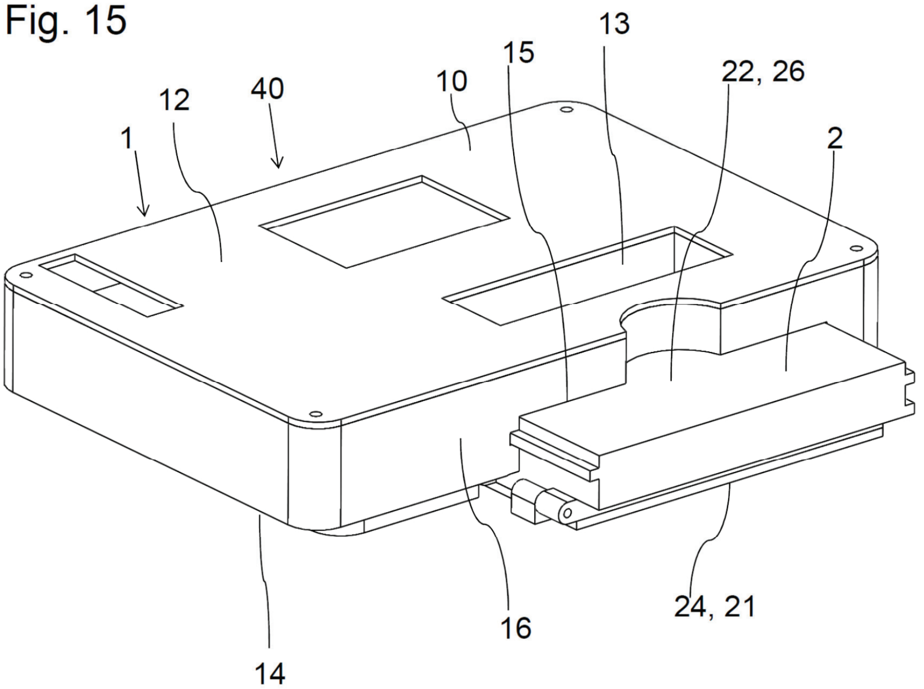


Fig. 16

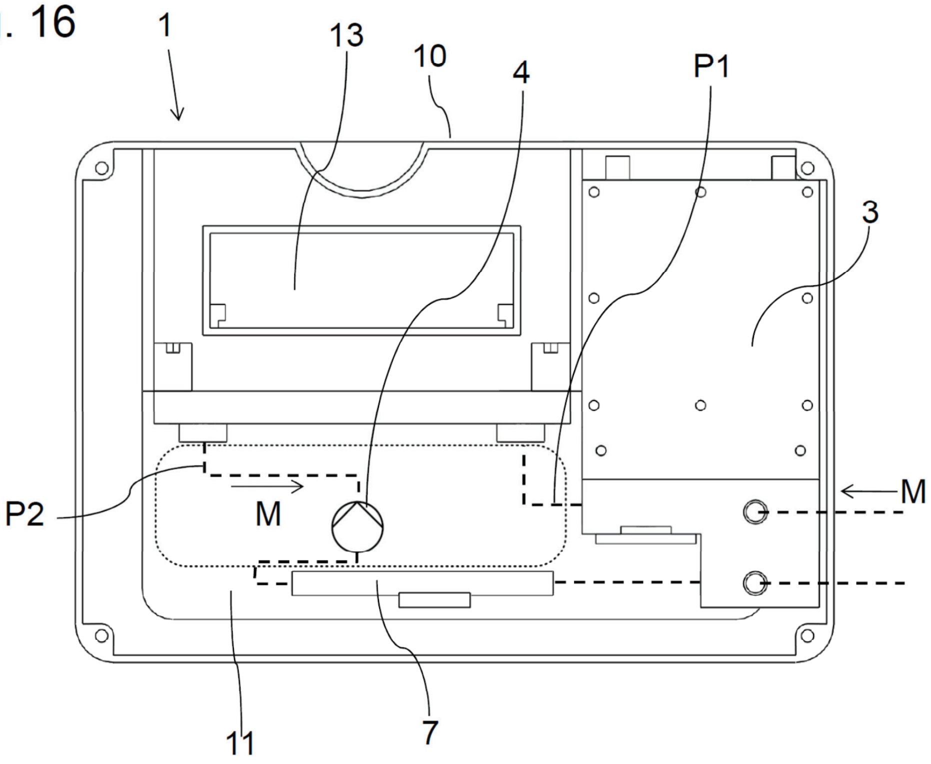


Fig. 17

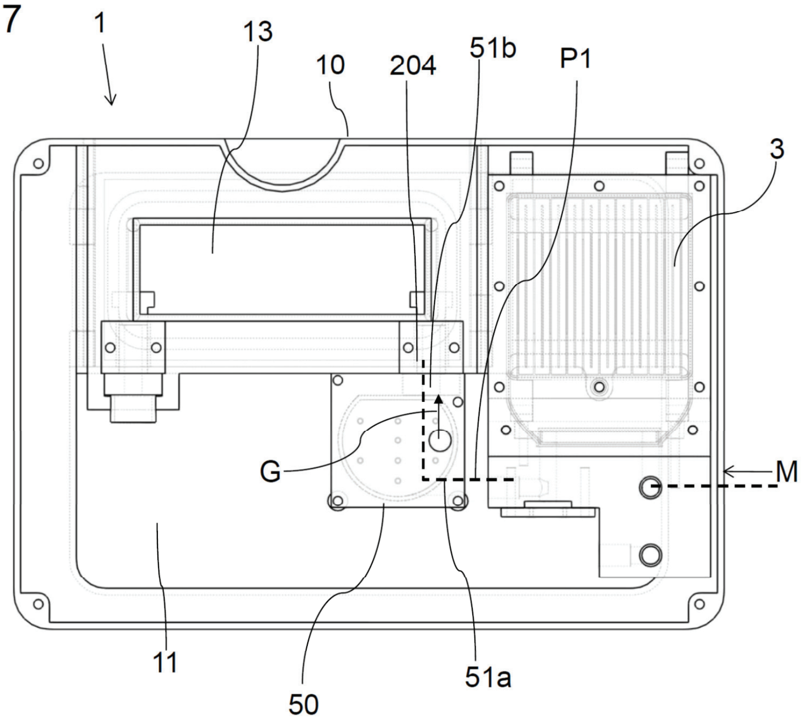


Fig. 18

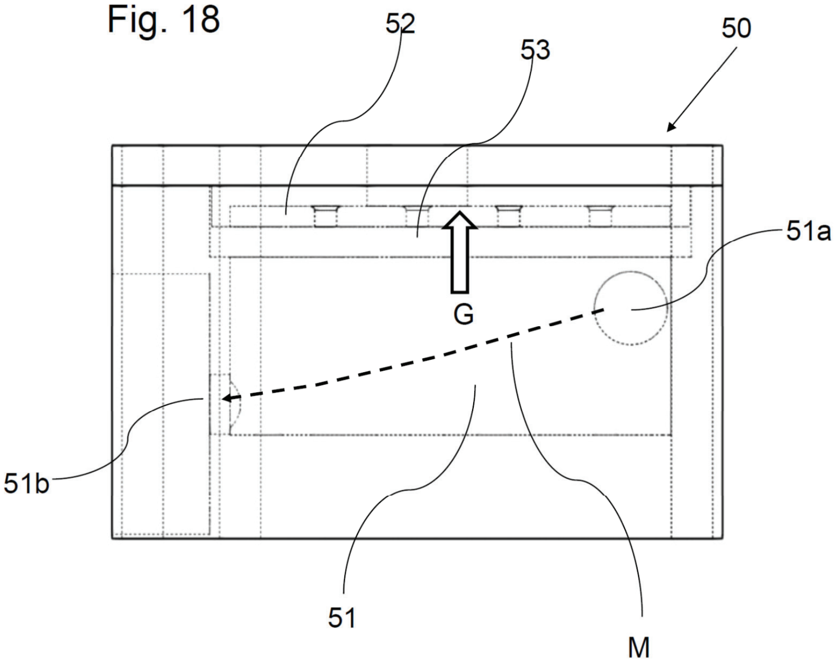


Fig. 19

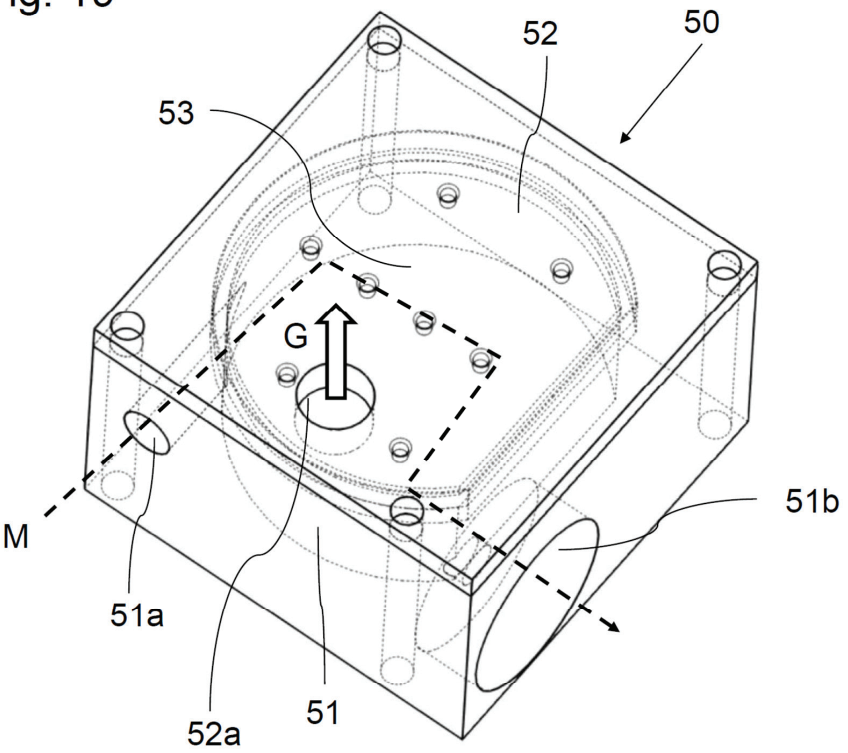
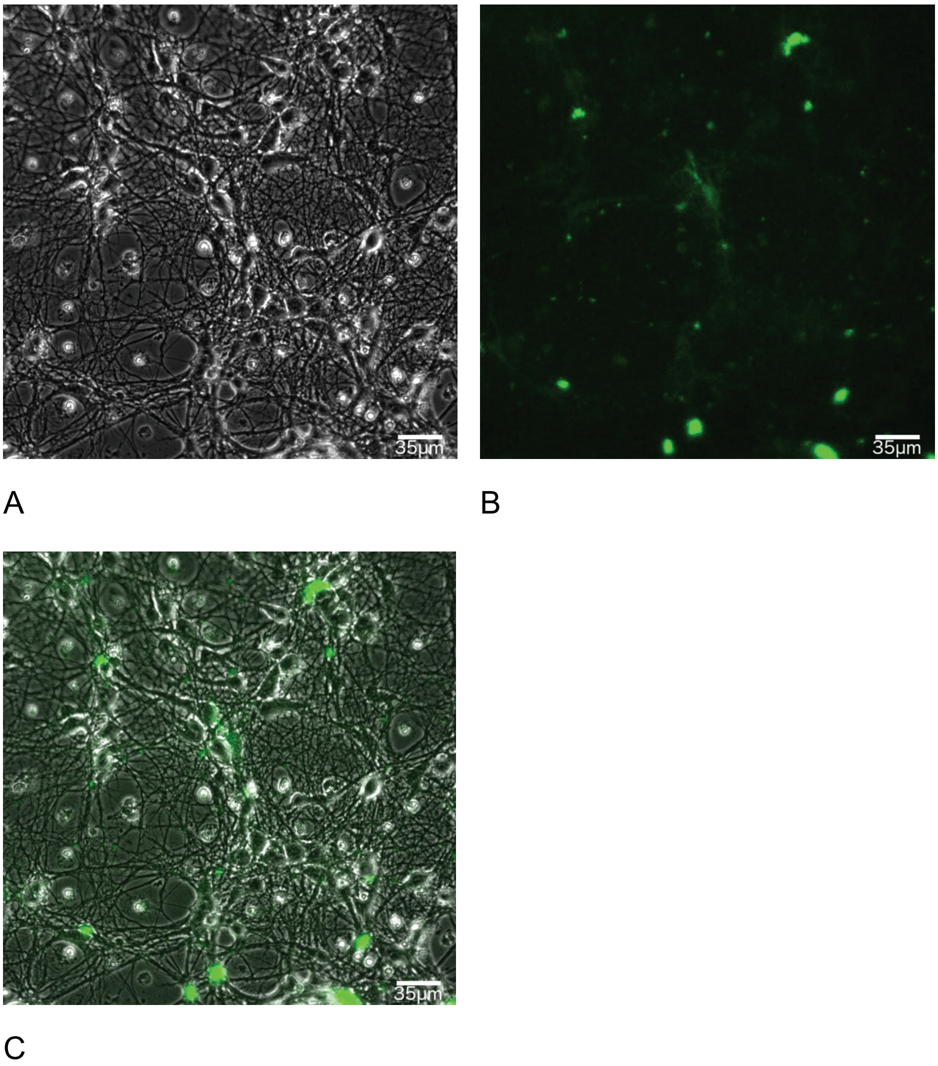


Fig. 20



B.2 PCT Request

PCT REQUEST

Print Out (Original in Electronic Form)

0	**For receiving Office use only**	
0-1	International Application No.	
0-2	International Filing Date	
0-3	Name of receiving Office and "PCT International Application"	

0-4	**Form PCT/RO/101 PCT Request**	
0-4-1	Prepared Using	PCT Online Filing Version 3.5.000.251e MT/FOP 20141031/0.20.5.20
0-5	**Petition** The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	European Patent Office (EPO) (RO/EP)
0-7	**Applicant's or agent's file reference**	uz304wo
I	**Title of Invention**	Cell Culture Device
II	**Applicant**	
II-1	This person is	Applicant only
II-2	Applicant for	All designated States
II-4	Name	Universität Zürich
II-5	Address	Prorektorat VNW Rämistr. 71 8006 Zürich Switzerland
II-6	State of nationality	CH
II-7	State of residence	CH
III-1	**Applicant and/or inventor**	
III-1-1	This person is	Applicant only
III-1-2	Applicant for	All designated States
III-1-4	Name	NTNU - Norges teknisk-naturvitenskapelige universitet
III-1-5	Address	c/o NTNU Technology Transfer AS Sem Sælands vei 14 7491 Trondheim Norway
III-1-6	State of nationality	NO
III-1-7	State of residence	NO

III-2	**Applicant and/or inventor**	
III-2-1	This person is	Inventor only
III-2-3	Inventor for	All designated States
III-2-4	Name (LAST, First)	KRIESI, Carlo
III-2-5	Address	Klostergata 44a 7030 Trondheim Norway
III-3	**Applicant and/or inventor**	
III-3-1	This person is	Inventor only
III-3-3	Inventor for	All designated States
III-3-4	Name (LAST, First)	KURTCUOGLU, Vartan
III-3-5	Address	Institute of Physiology Winterthurerstr. 190, Y23 J 08 8057 Zürich Switzerland
III-4	**Applicant and/or inventor**	
III-4-1	This person is	Inventor only
III-4-3	Inventor for	All designated States
III-4-4	Name (LAST, First)	MARMARAS, Anastasios
III-4-5	Address	Institute of Physiology Winterthurerstr. 190, Y23 J 74 8057 Zürich Switzerland
III-5	**Applicant and/or inventor**	
III-5-1	This person is	Inventor only
III-5-3	Inventor for	All designated States
III-5-4	Name (LAST, First)	STEINERT, Martin
III-5-5	Address	Høgåsen 8 7560 Vikhammer Norway
IV-1	**Agent or common representative; or address for correspondence** The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	Agent
IV-1-1	Name (LAST, First)	SCHULZ, Ben Jesko
IV-1-2	Address	Schulz Junghans Patentanwälte PartGmbB Großbeerenstraße 71 10963 Berlin Germany
IV-1-3	Telephone No.	+49 30/20215420
IV-1-4	Facsimile No.	+49 30/20215422
IV-1-5	e-mail	office@mittepatent.de
IV-1-6	Agent's registration No.	EPO Asso. 392

V	**DESIGNATIONS**	
V-1	**The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.**	
VI-1	**Priority claim of earlier regional application**	
VI-1-1	Filing date	04 May 2017 (04.05.2017)
VI-1-2	Number	17169597.6
VI-1-3	Regional Office	EP
VI-2	**Priority claim of earlier regional application**	
VI-2-1	Filing date	06 November 2017 (06.11.2017)
VI-2-2	Number	17200210.7
VI-2-3	Regional Office	EP
VI-3	**Priority document request** The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1 VI-2
VI-4	**Incorporation by reference :** where an element of the international application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this international application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office, that element or part is, subject to confirmation under Rule 20.6, incorporated by reference in this international application for the purposes of Rule 20.6.	
VII-1	**International Searching Authority Chosen**	European Patent Office (EPO) (ISA/EP)

PCT REQUEST

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VIII	**Declarations**	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	1	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	2	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	

VIII-1-1	**Declaration: Identity of the Inventor** Declaration as to the identity of the inventor (Rules 4.17(i) and 51bis.1(a)(i))	In relation to this international application
	Name (LAST, First) Address	KRIESI, Carlo of Klostergata 44a 7030 Trondheim Norway is the inventor of the subject matter for which protection is sought by way of this international application
	Name (LAST, First) Address	KURTCUOGLU, Vartan of Institute of Physiology Winterthurerstr. 190, Y23 J 08 8057 Zürich Switzerland is the inventor of the subject matter for which protection is sought by way of this international application
	Name (LAST, First) Address	MARMARAS, Anastasios of Institute of Physiology Winterthurerstr. 190, Y23 J 74 8057 Zürich Switzerland is the inventor of the subject matter for which protection is sought by way of this international application
	Name (LAST, First) Address	STEINERT, Martin of Høgåsen 8 7560 Vikhammer Norway is the inventor of the subject matter for which protection is sought by way of this international application

PCT REQUEST

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VIII-2-1	**Declaration: Entitlement to apply for and be granted a patent** Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate: Name (LAST, First)	In relation to this international application NTNU - Norges teknisk-naturvitenskapelige universitet is entitled to apply for and be granted a patent by virtue of the following:
VIII-2-1(ii)		NTNU - Norges teknisk-naturvitenskapelige Universitet is entitled as employer of the inventor, KRIESI, Carlo
VIII-2-1(ii)		NTNU - Norges teknisk-naturvitenskapelige Universitet is entitled as employer of the inventor, STEINERT, Martin

VIII-2-2	**Declaration: Entitlement to apply for and be granted a patent** Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate: Name (LAST, First)	**In relation to this international application** **Universität Zürich is entitled to apply for and be granted a patent by virtue of the following:**
VIII-2-2(ii)		**Universität Zürich is entitled as employer of the inventor, KURTCUOGLU, Vartan**
VIII-2-2(ii)		**Universität Zürich is entitled as employer of the inventor, MARMARAS, Anastasios**

PCT REQUEST

Print Out (Original in Electronic Form)

IX	**Check list**	Number of sheets	Electronic file(s) attached
IX-1	Request (including declaration sheets)	8	✓
IX-2	Description	16	✓
IX-3	Claims	5	✓
IX-4	Abstract	1	✓
IX-5	Drawings	13	✓
IX-7	TOTAL	43	
	Accompanying Items	Paper document(s) attached	Electronic file(s) attached
IX-8	Fee calculation sheet	-	✓
IX-20	**Figure of the drawings which should accompany the abstract**	1	
IX-21	**Language of filing of the international application**	English	
X-1	**Signature of applicant, agent or common representative**	(PKCS7 Digital Signature)	
X-1-1	Name (LAST, First)	SCHULZ, Ben Jesko	
X-1-3	Capacity (if such capacity is not obvious from reading the request)	(Representative)	

FOR RECEIVING OFFICE USE ONLY

10-1	**Date of actual receipt of the purported international application**	
10-2	**Drawings:**	
10-2-1	Received	
10-2-2	Not received	
10-3	**Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application**	
10-4	**Date of timely receipt of the required corrections under PCT Article 11(2)**	
10-5	**International Searching Authority**	ISA/EP
10-6	**Transmittal of search copy delayed until search fee is paid**	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	**Date of receipt of the record copy by the International Bureau**	

B.3 International Search Report

eingegangen am
received on
20. AUG. 2018
Schulz Junghans
Patentanwälte PartGmbB

PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To:
Schulz, Ben Jesko
Schulz Junghans
Patentanwälte PartGmbB
Grossbeerenstraße 71
D-10963 Berlin
ALLEMAGNE

SOP: direkt an Anwalt
Akte: uz304wo
Anwalt: JS
Bearbeiter: Sa
Datum: ROT auf 20.10.18 verl.
Erinnerung: ROT 04.03.19
[illegible]

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

SOP: direkt an Anwalt

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 20 August 2018 (20-08-2018)
Applicant's or agent's file reference uz304wo	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/EP2018/061604 ✓	International filing date *(day/month/year)* 4 May 2018 (04-05-2018) ✓
Applicant UNIVERSITÄT ZÜRICH	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

How? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 - 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	Authorized officer ROTHENBüCHER, Anita Tel: +49 (0)30 25901-706

Form PCT/ISA/220 (July 2017)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference uz304wo	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/EP2018/061604	International filing date *(day/month/year)* 4 May 2018 (04-05-2018)	(Earliest) Priority Date *(day/month/year)* 4 May 2017 (04-05-2017)
Applicant UNIVERSITÄT ZÜRICH		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into ____________, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (see Box No III)
4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract,**
   ☐ the text is approved as submitted by the applicant
   ☒ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority
6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant
      ☐ as selected by this Authority, because the applicant failed to suggest a figure
      ☐ as selected by this Authority, because this figure better characterizes the invention
   b. ☐ none of the figures is to be published with the abstract

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The present invention relates to a cell culture device (1) for use with an optical microscope (40), comprising a housing (10) that is configured to be placed onto a stage of an optical microscope (40) in front of an objective (41) of the microscope (40), the housing (10) enclosing an internal space (11) of the housing (10), a removable flow chamber (2) enclosing an internal space (20) for accommodating a cell culture (CC) comprising living biological cells, a heater (3) arranged in the internal space (11) of the housing (10) for heating said fluid medium (M) to be guided through the flow chamber (2), a first flow path (P1) arranged in the internal space (11) of the housing (10) for guiding said fluid medium (M) towards the flow chamber (2) via said heater (3), and a second flow path (P2) arranged in the internal space (11) of the housing (2) for guiding said fluid medium (M) away from the flow chamber (2), and a pump (4) for pumping said fluid medium (M) through the first flow path (P1) into the internal space (20) of the flow chamber (2) and through the second flow path (P2) out of the internal space (20) of the flow chamber (2) when the flow chamber (2) is inserted into the internal space (11) of the housing (10).

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/061604

A. CLASSIFICATION OF SUBJECT MATTER
INV. C12M1/34 C12M1/00 C12M3/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
C12M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/081664 A1 (FORBES NEIL ST JOHN [US] ET AL) 7 April 2011 (2011-04-07) claims 1-5 -----	1,4-22
A	EP 2 690 167 A1 (TOKAI HIT CO LTD [JP]) 29 January 2014 (2014-01-29) claim 1; figure 1 -----	1-22
A	US 2016/333298 A1 (HUNG PAUL J [US] ET AL) 17 November 2016 (2016-11-17) claim 1; figures 4a-4b ----- -/--	1-22

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 6 August 2018	Date of mailing of the international search report 20/08/2018
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Jones, Laura

2

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE WPI Week 199718 Thomson Scientific, London, GB; AN 1997-196266 XP002783626, & JP H09 51792 A (HIDAN KK) 25 February 1997 (1997-02-25) abstract -----	1-22

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2018/061604

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011081664 A1	07-04-2011	NONE	
EP 2690167 A1	29-01-2014	AU 2011363361 A1	31-01-2013
		CA 2804568 A1	27-09-2012
		CN 103476919 A	25-12-2013
		EP 2690167 A1	29-01-2014
		JP 5709976 B2	30-04-2015
		JP WO2012127523 A1	24-07-2014
		KR 20140008294 A	21-01-2014
		US 2013109081 A1	02-05-2013
		WO 2012127523 A1	27-09-2012
US 2016333298 A1	17-11-2016	US 2012003732 A1	05-01-2012
		US 2016333298 A1	17-11-2016
JP H0951792 A	25-02-1997	NONE	

Information on Search Strategy - Pilot phase (see OJ 2015, A86)

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

PCT/EP2018/061604

TITLE: CELL CULTURE DEVICE

APPLICANT: UNIVERSITÄT ZÜRICH

IPC CLASSIFICATION: C12M1/34, C12M1/00, C12M3/00

EXAMINER: Jones, Laura

CONSULTED DATABASES: EPODOC, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: C12M41/36, C12M29/10, C12M41/12, C12M41/00, C12M23/44, C12M29/20

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
Cell culture device for use with an optical microscope.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)		
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below	
International application No. PCT/EP2018/061604	International filing date *(day/month/year)* 04.05.2018	Priority date *(day/month/year)* 04.05.2017
International Patent Classification (IPC) or both national classification and IPC INV. C12M1/34 C12M1/00 C12M3/00		
Applicant UNIVERSITÄT ZÜRICH		

1. This opinion contains indications relating to the following items:

☒ Box No. I	Basis of the opinion
☐ Box No. II	Priority
☐ Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐ Box No. IV	Lack of unity of invention
☒ Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
☐ Box No. VI	Certain documents cited
☐ Box No. VII	Certain defects in the international application
☐ Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA: European Patent Office Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Jones, Laura Telephone No. +49 30 25901-0

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2018/061604

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2, 3, 8-11, 13-21
	No:	Claims	1, 4-7, 12, 22
Inventive step (IS)	Yes:	Claims	2, 3
	No:	Claims	1, 4-22
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty and inventive step; citations and explanations supporting such statement

Reference is made to the following document:

D1 US 2011/081664 A1 (FORBES NEIL ST JOHN [US] ET AL) 7 April 2011 ✓

Novelty

The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claims 1, 4-7, 12, 22 is not new.

D1 discloses (claims 1-5) a microfluidic device comprising:
a cell culture chamber for culturing a cell aggregate, a flow channel in fluid communication with the cell culture chamber at the proximal end; one or more inlets connected to the flow channel for medium in-flow or cell aggregate packing;
one or more outlets connected to the flow channel for medium out-flow or removal of cell debris; and
a flow system for maintaining medium flow,
wherein the chamber has a filter, and wherein at least a portion of the cell culture chamber is optically accessible through a transparent window.
The device further comprises a temperature-controllable housing for placing the cell culture chamber therein and the cell culture chamber comprises a planar transparent window.

The device has a syringe pump to supply a constant flow of medium (FIG. 2 and [0047]).

D1 anticipates the subject matter of claims 1, 4-7, 12, 22 which cannot be considered novel (Article 33(2) PCT).

Inventive step

The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claims 8-11 and 13-21 does not involve an inventive step.

Dependent claims 2-11 and 13 do not contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step.

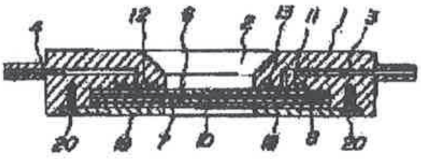
Said claims relate to slight constructional changes in the device of claim 1 which come within the scope of the customary practice followed by persons skilled in the art depending on the circumstances.
Consequently, the subject-matter of claims 8-11 and 13-21 lacks an inventive step (Article 33(3) PCT).

Laura Jones

XP-002783626

AB - Culturing equipment for microbes has 2 glass plates set so that they hold a film spacer. Based on a thickness of the spacer, a space of a flow route can be adjusted. A drain cock is placed in a pipe arrangement which may supply a liquid culturing ground into this invented equipment. Bubbles can be prevented from flowing into the equipment itself.

- USE :
For preventing bubbles from flowing into culturing equipment of microbe.



AN - 1997-196266

AP - JP19950237526 19950811

CPY - HIDA-N

DC - D16
- P81

DW - 199718

ICAI - C12M1/00; C12M1/34; G02B21/34

IN - NARAMOTO S

INW - NARAMOTO S

IW - CULTURE EQUIPMENT MICROBE TWO GLASS PLATE SET HOLD FILM SPACE THICK DETERMINE FLOW RATE

IWW - CULTURE EQUIPMENT MICROBE TWO GLASS PLATE SET HOLD FILM SPACE THICK DETERMINE FLOW RATE

MC - D03-H02 D05-H02

NC - 1

NPN - 1

OPD - 1995-08-11

PA - (HIDA-N) HIDAN KK

PAW - (HIDA-N) HIDAN KK

PD - 1997-02-25

PN - JPH0951792 A 19970225
DW199718

PR - JP19950237526 19950811

TI - Culturing equipment for microbe - has two glass plates set to hold film spacer whose thickness determines flow rate

UPA - 20130325

UPM -

Appendix C

Contribution 1: Physiological Data Acquisition for Deeper Insights into Prototyping

NordDesign 2014
August 27 – 29, 2014
Espoo, Finland / Melbourne, Australia

Physiological Data Acquisition for Deeper Insights into Prototyping

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Abstract

Based on the work of Steven P. Dow & Scott R. Klemmer, "*The efficacy of prototyping under time constraints*", a confirmatory experiment was conducted and two additional questions were investigated in a hypotheses generating, explorative way: How does iterating ideas affect the stress level of the participants while explaining their final design? And; Does the workspace setup influence the activity level of the participant while designing a prototype? The answers were found with the help of physiological data acquisition (electrocardiogram and acceleration). Our results confirm the previously conducted study. The data also suggests that the stress level during the interview is affected: Participants who were able to test their designs show in average a decreasing stress level, compared to participants who were not allowed to test where an increase thereof can be observed. Furthermore, the results show that the workspace setup influences the activity level of the participant.

Keywords: Prototyping, Iteration, Physiological Data, Stress, Bias Towards Action

1 Introduction

Prototyping is at the core of product design and development. To some practitioners and researchers the ability to repeatedly try and obtain feedback through rapid prototyping rounds is essential it seems. The latter has been established, amongst others, by Dow & Klemmer whose work we continue[1] by means of an explorative experiment that operationalizes the effect of an iterative prototyping product development process vs. a planning focused development process by means of a controlled and physiological sensor monitored egg drop task. The study is constructed as confirmatory to [1] and expands the same by also including

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[1] Due to page limitations we kindly ask to consult [1] for a discussion on the the value and manner of executing protoyping as well as its canonical steps: envisioning possibilities, creating a prototype to embody a possibility, getting feedback about the prototype, and reevaluating constraints [2].

stress and workspace as independent variables. The egg drop task challenges individual participants to come up with a design that protects a raw egg from being damaged after a free-fall from increasingly high levels. A predefined set of materials and a limited amount of time are given to fulfill this task. Half of the participants (iteration group) have the possibility to test their prototypes during the design phase, whereas the other half (non-iteration group) only has one egg available and therefore is not allowed to perform any tests. All participants have to estimate their performance before and after the design phase. This individual confidence level, as well as the maximum successful drop height, are recorded.

1.1 Given Results and Confirmatory Study

[1] were able to show that participants in the iteration group reached in average a 85% higher score in the free-fall test than the participants in the non-iteration group (186cm vs. 101cm). Furthermore, the confidence level of the participants who were able to iterate increased in average by 44% (125cm before, 180cm after). Participants in the reference group showed in average a confidence level of 95cm, which stayed constant throughout the test. Table 1 gives an overview of the given results. For our experiments we repeated the egg drop experiment in the same way and were able to confirm the results from the previous study.

Table 1 Given Results: Highest drop height reached and the confidence level before and after designing and building the device. Data from [1].

		Non-Iteration	Difference		**Iteration**
Final Height		101cm	+85%		186cm
Confidence Level	Before	95cm	+0%	+44%	125cm
	After	95cm			180cm

1.2 Stress due to Uncertainty

It has been shown that not only limited amounts of time induce stress on people but also failure in combination with low self-esteem and uncertainty. The latter has been shown in various studies, usually linked to patients and the amount of information they are given during their illness [3-4]. One characteristic of an increased stress level is an increase of the heart rate [5]. To answer the question of how uncertainty during prototyping affects the stress level a sensor recorded the electrocardiogram (ECG) and acceleration values of the participant during the whole experiment. The combination of these two signals can reveal whether or not an increased heart rate is due to physical activity or due to other factors. We analyzed the heart rate of the participants during the interview that takes place before the final drop test. During the interview the participant has to explain the final design and answer several questions regarding various factors that influence the final score, e.g. “How do you think will your design behave during the free-fall? Will it turn upside down?”. Our results show that the participants of the iteration group in average have a decreasing heart rate, unlike the participants of the non-iteration group who show an increasing heart rate.

1.3 Bias Towards Action

In the field of ergonomics, a lot of research is done in order to assess the influence of light, temperature and other external factors on the well-being of an employee [6-7]. Our experiment offered the opportunity to measure the influence of the workspace setup on the activity level of the participant. Half of the iteration group had a setup that supported an upright body position while working, whereas the other half used a setup that strongly suggests working while being seated. The number of iterations each participant went through was recorded. Participants using the standing workspace setup tested more often than the sitting participants.

2 Method

By repeating the experiment of [1] – where the materials list and the procedure is taken from - we first of all wanted to perform a confirmatory study. Furthermore, the experimental setup allowed for testing the following two hypotheses:

- Participants who were allowed to test their designs will show a lower stress level during the interview.
- Participants who are allowed to test their designs and have a workspace setup that supports a bias towards action (standing upright while working) will perform more tests than participants who are sitting comfortably while working.

2.1 Setup

The experiment took place in our ideation space at NTNU Trondheim. The drop-zone for testing was only a few steps away from the workspace itself to enable for quick testing during the design phase. The two different workspace (sitting and standing) setups are described below and shown in Figure 1.

2.1.1 Participant Sitting

Half of the participants of the iteration group had a workspace setup that strongly supported working while being seated. A table (wooden board resting on two sawhorses) with a low height and a matching seating option were used. The chair used is the model *Capisco* from Håg and it is, according to the description, ideal for this purpose: *If you are into innovation, HÅG Capisco is the office chair for you* [8].

2.1.2 Participant Standing

The other half of the participants in the iteration group had the setup that supports standing while working. The table has a comfortable height of roughly 120cm.

Figure 1 Workspace Setups: The two different workspace setups, for standing participants (left) and sitting participants (right).

2.2 Physiological Data Acquisition

To gather information about the heart rate of the participants they were wearing an ECG sensor throughout the experiments. Additionally, an accelerometer measured acceleration data in all three axis directions (X, Y, Z). Both signals (ECG and acceleration) were stored on a microSD card.

2.2.1 Hardware

The five components that were used and their individual functions are:

- Arduino Uno (ARDUINO, Italy): This micro controller is the core component of the whole setup and runs the program that gathers and stores the data from the entire setup.
- CookingHacks eHealth Shield (LIBELIUM COMUNICACIONES DISTRIBUIDAS S.L., Spain): The eHealth shield can be used as a sensor platform for a wide range of vital data sensors. In this case it amplifies the voltage reading (x300) from the electrodes attached to the skin of the participant.
- Sparkfun microSD shield (SPARKFUN ELECTRONICS, CO, USA): This shield enables data storage on a microSD. In this case it was also used as the mounting platform for the accelerometer.
- Sparkfun Triple Axis Accelerometer - MMA8452Q: This sensor measures the acceleration in all three axis directions.
- 9V battery: The battery powers the unit.

The individual components and the complete experiment setup can be seen in Figure 2.

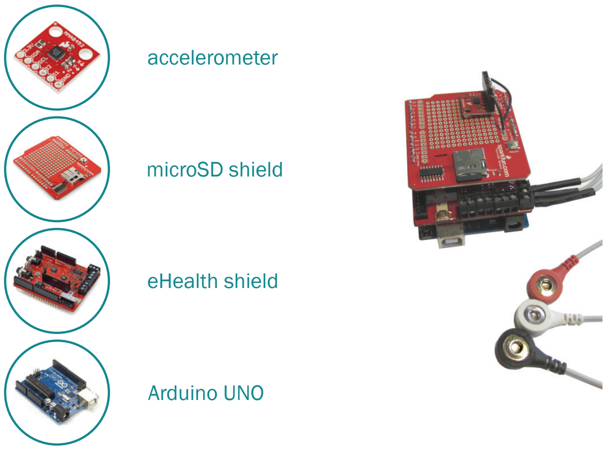

Figure 2 Physiological Data Acquisition: The individual components and the complete sensor package [9-12].

2.2.2 Software

The code running on the Arduino was kept as simple as possible in order to reach a high sampling rate (~50Hz). With every iteration the three acceleration values and the voltage reading from the ECG unit are stored on the microSD card.

2.2.3 Usage

The participant had to attach three electrodes (+, −, and neutral) to his body. During the experiments the sensor package was placed in an antistatic bubble wrap bag and was attached with a quick release strap to the belt loops of the participants. This setup proved not only easy to be used but also exclusively captures the acceleration data of the hip.

2.3 Materials

One set of the following materials was allowed for the final design (see Figure 3):

- 8 pipe cleaners

- 8 rubber bands
- 8 popsicle sticks
- 1 10x20cm poster board
- 1 10x15cm flat foam
- 1 sheet of tissue paper
- 30cm scotch tape

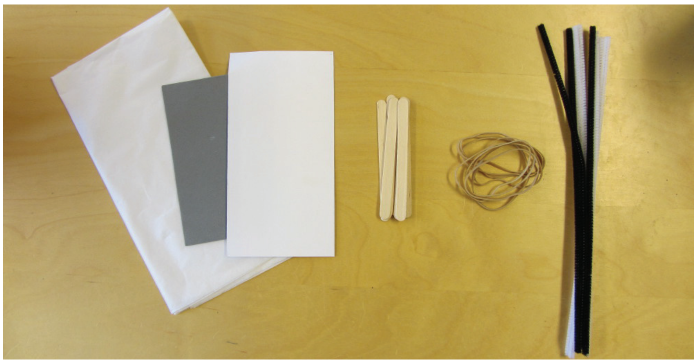

Figure 3 One Set of Materials: (FLTR) Tissue paper, flat foam, poster board, popsicle sticks, rubber bands, pipe cleaners (scotch tape not shown).

2.4 Participants

Our number of participants was N=13 and the average age of the participants was 21.8 years. The iteration group consisted of 6 participants and the non-iteration group of 7 participants. Only 3 participants had previous experience with the egg drop task, none of them with such a limited amount of materials and time though. The participants were uniquely recruited amongst students in their 4th semester of mechanical engineering studies at NTNU as, by passing many exams, they have already shown a high level of motivation for engineering but are not yet focused on only one specific direction thereof.

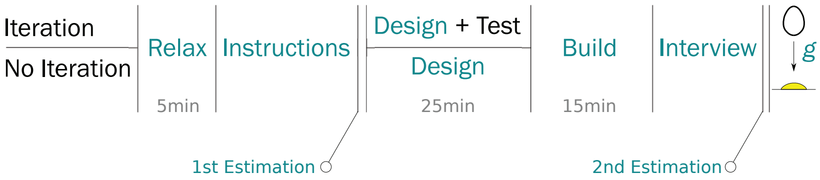

Figure 4 Timeline of the Experiments.

2.5 Procedure

The participant first voluntarily signed a document stating that they allow us to record their data. The participant then attached the three electrodes for the ECG and the now activated sensor package. In order to make the participants feel more at ease and to get their resting heart rate they took a seat and watched a five-minute segment of a relaxing video. After this the participant received the instructions for the task and was shown a complete set of materials. At the drop zone the participant had to give the first estimation of the reachable height (noted as *confidence level before*). The participant then had 25min time to design a device that will protect the egg. Every 5min the participant got informed about the remaining time and was encouraged to test the design (iteration group only). During the design phase the participant had no material restrictions, meaning that the researcher provided more material whenever it was needed. Once the design phase was over the table was cleared from any remaining materials and the participant got a fresh set of materials and 15min time to build the final design. Following the build phase the participant had to explain the final design to the researcher. The interview was completed when the participant was unable to add more information. After estimating the maximum reachable height a second time (noted as *confidence level after*) the device was tested by dropping it from increasingly high levels: Starting at 30cm, the drop height was increased by steps of 30cm until the egg cracked. Figure 4 shows the timeline of the experiments.

2.6 Post Processing

The data gathered by the sensor package consists of a voltage reading in V across the electrodes, three acceleration values in g from the accelerometer, and a timestamp of each iteration. Post processing of the raw data from the sensors was done using a program written in MATLAB (MATHWORKS, MA, USA). The program sums up the absolute values of the three acceleration values, applies various filters to the ECG signal, detects voltage peaks indicating a heart beat and calculates the heart rate based on this information.

3 Results

This section deals with the outcome of our experiments and is segmented into the results of the confirmatory study and the results that answer our hypotheses. Due to the small number of participants we did not perform any significance tests and only claim internal validity for our results.

3.1 Confirmatory Study

With our experiments we were able to confirm both results given by [1]: The participants in the iteration group reached in average a higher final height in the drop test and their confidence level increased. Table 2 summarizes the results.

3.1.1 Results: Maximum Drop Height

Both groups include cases worth highlighting: One participant in the iteration group, who had no previous experience with the task, built such a great device, that it was impossible to break the egg, even when dropping it from the ceiling (510cm). We therefore took this architectonical limitation as the maximum value, even though the real number might be a lot higher. In the non-iteration group three participants broke their one and only egg by testing their design on the worktable. All of them were given a replacement egg for the final drop, even though this is not according to the rules.

Table 2 Confirmatory Study Results: Comparison of the maximum drop height and the confidence level of the two groups. *Three participants in the non-iteration group tested their prototypes on the table during the design phase and subsequently cracked their eggs. Their official result therefore was 0cm. The value in brackets is calculated with the heights they reached with a replacement egg.

		Non-Iteration	Difference		**Iteration**
Final Height*		69cm (103cm)	+154% (+70%)		175cm
Confidence Level	Before	141cm	-3%	+18%	135cm
	After	137cm			160cm

3.1.2 Results: Confidence Level

The participant gave the first estimation (*confidence level before*) after receiving the instructions but before starting the design phase. The estimation *after* was given when the building phase was over. The confidence level of the participants in the iteration group increased by 18%, whereas the confidence level of the participants in the non-iteration group decreased by 3%.

3.2 New Results

The new results contain the answers to the hypotheses stated above. The physiological data recordings proved to be extremely useful and revealed information about the activity level and stress level of the participants. Figure 5 shows the resulting data from one participant (p4) who was part of the iteration group and using the sitting workspace setup. This data set was chosen as an example because p4 was exceptionally motivated and had phases of both, intensive physical activity and high stress levels, both clearly visible in the plots.

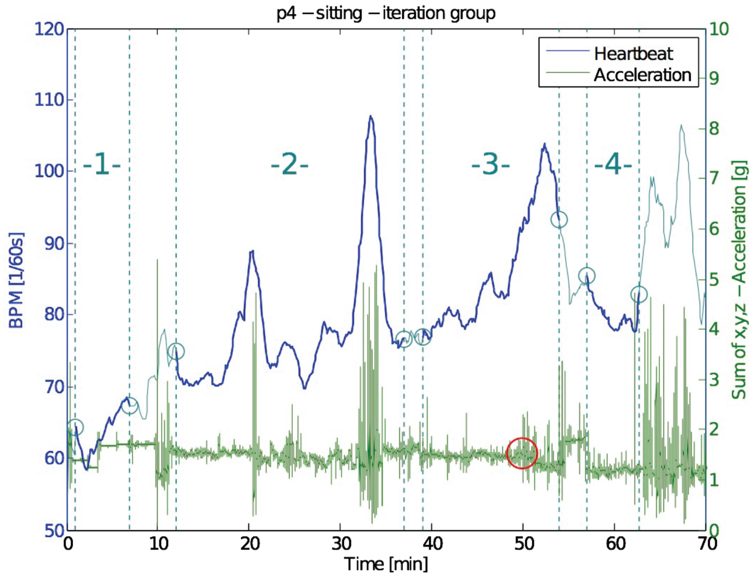

Figure 5 ECG and Acceleration Sample: The blue graph shows the heart rate throughout the experiments and the green graph shows the sum of the absolute values of the acceleration data along the three axis (X, Y, Z). The four phases are: 1 - Relaxing Movie, 2 - Design Phase incl. two test runs, 3 - Build phase with intense stress due to time pressure towards the end, 4 - Interview. The red circle marks the spot where the participant jumped up from his seat and shouted, "I'M SO STRESSED OUT! I'M SHAKING! MY HEART RATE IS THROUGH THE ROOF!".

Table 3 Number of Iterations: Comparison of the number of iterations performed by participants in the iteration group while using different workspace setups.

Standing		**Sitting**	
Participant	*Nr. of Iterations*	*Participant*	*Nr. of Iterations*
p2	5	p4	2
p6	4	p8	4
p10	4	p12	4
Average Standing	**4.33**	*Average Sitting*	**3.33**

3.2.1 Bias Towards Action

As described before, our hypothesis was that the workspace setup has a major influence on the activity level of the participant. We noted the number of prototypes each participant in the iteration group tested during the design phase. The results are listed in Table 3. The participants that were standing during the experiment tested their design in average 30% more often than the sitting participants (4.33 iterations vs. 3.33 iterations).

3.2.2 Stress Level

In order to describe the behavior of the stress level of a participant during the interview the heart rate was averaged over two 15s periods: The first one starts with an offset of 5s after the beginning of the interview, the second one ends 5s before the end of the interview. It has been shown that one characteristic of an increased stress level is an increase of the heart rate [5] and that such short slices of physiological data are sufficient in order to predict or assess the emotional state of a person [13-14]. The interviews lasted in average for 3.9min. The results reveal that only 20% of the participants in the iteration group had an increasing heart rate over the period of the interview, compared to 80% of the participants in the non-iteration group. Also, the heart rate of the participants in the iteration group decreased in average by 2.13%, whereas the heart rate of the participants in the non-iteration group increased in average by 6.82%. Table 4 contains the heart rate values of the individual slices.

Table 4 Stress Level. Comparison of the heart rate at the beginning and at the end of the interview. The heart rate is averaged over two periods of 15s: The first one starts 5s after the start of the interview, the second one ends 5s before the interview is over. p1, p2, and p3 are excluded from the results as their ECG was running on an older, slower code which resulted in insufficiently precise data.

Iteration Group					
Participant	*BPM Interview Start [1/min]*	*BPM Interview End [1/min]*	*BPM Abs. Difference [1/min]*	*Rel. Difference [%]*	*Trend*
p4	84.7	82.2	-2.5	-3.0	-
p6	80.7	78.7	-2.0	-2.5	-
p8	85.0	79.4	-5.6	-6.6	-
p10	77.4	78.8	+1.4	+1.8	+
p12	91.9	91.5	-0.4	-0.4	-
Average			**-1.8**	**-2.1**	**20% +**

Non-Iteration Group					
Participant	*BPM Interview Start [1/min]*	*BPM Interview End [1/min]*	*BPM Abs. Difference [1/min]*	*Rel. Difference [%]*	*Trend*
p5	92.2	93.8	+1.6	+1.7	+
p7	100.7	99.6	-1.1	-1.1	-
p9	76.1	82.1	+6.0	+7.9	+
p11	77.0	88.3	+11.8	+15.3	+
p13	80.1	88.3	+8.2	+10.2	+
Average			**+5.3**	**+6.8**	**80% +**

4 Discussions, Conclusion and Outlook

Even though the number of data points is small, these results reveal interesting starting points for further studies.

4.1 Discussion: Confirmatory Study

Both groups, iteration and non-iteration, reached in average a lower height than the participants in [1]. The relative difference between the two groups, however, is almost twice as big: +152% in our experiments vs. +85% in the given results. The iteration group in our experiments did not show such a strong increase in the confidence level though: +18% in our experiments vs. +44% in the given results. The non-iteration group showed a very similar trend as in the given results: -3% in our experiments vs. 0% in the given results. The differences would most likely become smaller in a study with more participants. Nevertheless, our results show a trend that confirms the outcome of the previous study: Iterating ideas and testing prototypes during the design phase does increase the quality of the final product that is made from the same materials and designed within the same timeframe. An observation worth mentioning are the three participants of the non-iteration group who cracked their egg: They all had clear instructions that they only have one egg and yet they all decided to test their idea on the table during the design phase, rather than finishing a product with an unknown performance. They were all given a fresh egg in order to allow them to finish their design and compete in the final contest - all of them completely changed their designs and reached heights between 60cm and 90cm, which evidently is a lot better than 0cm. This allows us to see how strong the urge to test was amongst the participants and how much information can be gained by just one test run. The outlier in the iteration group clearly is participant p4 who reached 510+cm. This participant is included in the results as he shows that extreme heights are possible with the same set of materials and within the same timeframe that everybody else had available.

4.2 Discussion: Bias Towards Action

We were able to show that participants who are standing while working on their ideas tested 30% more often than sitting participants. One might argue that this outcome is the defined by only two participants, p2 with 5 iterations vs. p4 with 2 iterations. However, experiments that allow a longer time for designing and testing the ideas would most likely result in a bigger difference between the two different workspace setups.

4.3 Discussion: Stress Level

The results show that in average the participants of the iteration group are less stressed while explaining their designs than the participants of the iteration group. One explanation for this is their lower level of uncertainty as they have an idea of what the outcome will look like. It might also be due to the fact that they are convinced of the answers they are giving to questions regarding technical details of their design. The participants of the non-iteration group can only answer based on their general experience and quite often they certainly have not taken some factors into account, e.g. whether or not they expect the prototype to flip over during the free fall.

4.4 Conclusion

The physiological data acquisition proved to be successful and revealed new insights into the stress level of the participant. The results show that, for example, an engineer who is working on a new product will not only deliver a better design if (s)he had the chance to test it, (s)he will also be more confident in his product. These results go together with a decrease of the engineers stress level, which could also be the result of the higher confidence. A lower stress level and gained knowledge from previous tests could offer good conditions to find unusual and creative ideas. One stress factor that will never be eliminated though is time pressure. However, our results suggest that a clever setup of the workspace, creating a bias towards action during the design phase, will increase the number of iterations of ideas. We believe that more iterations once again lead to more knowledge and better results. The quality of the final product therefore is directly affected by the setup of the workspace.

4.5 Outlook

Further studies should be conducted with a larger number of participants. Using a set of different design tasks that consist of a similar procedure and have measurable outputs could also show that the results are independent of the task itself. Also, a more extreme difference between the iteration group and the non-iteration group could provoke even clearer results. For example, the non-iteration group could only be allowed to use pen and paper or a CAD software during the design phase. Regarding the workspace setup, further studies should also reveal the importance of the workspace setup along the timeline of a project: Working while standing supports early stage prototyping – but what should the workspace look like to support the later phases of a project? The goal is to create a workspace that adjusts to the current project phase and supports every step from the first prototype to the product launch.

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Appendix D

Contribution 2: Distributed Experiments in Design Sciences - A next Step in Design Observation Studies?

INTERNATIONAL CONFERENCE ON ENGINEERING DESIGN, ICED15
27-30 JULY 2015, POLITECNICO DI MILANO, ITALY

DISTRIBUTED EXPERIMENTS IN DESIGN SCIENCES, A NEXT STEP IN DESIGN OBSERVATION STUDIES?

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Abstract

This paper describes and proposes a new method for conducting globally distributed design research. Instead of using e.g. a software we tried out a completely analogue approach: Five carefully prepared packages, containing all the necessary materials and instructions for a design challenge, were sent out to supervisors in Norway, Finland, Italy, and Australia. These local supervisors then conducted the egg-drop exercise with students that are part of an international course held at CERN. As the task is conducted according to a previously tested protocol, the results gathered with this new method can then be benchmarked with this available data. This new approach to globally conducted engineering design activities avoids local bias and enables for gathering large amounts of diverse data points. One can also think of a research community where every member can send out one experiment per year and, in return, receives data points from across the world.

Based on the feedback from the supervisors we can say that from an organisational standpoint of view, this method works well. The comparison to the existing data has yet to be done.

Keywords: Research methodologies and methods, Crowdsourcing, Collaborative design, Prototyping, Globally distributed experiment

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1 INTRODUCTION

The paper describes the methodological approach of conducting parallel globally distributed experiments in design science and discusses the advantages and disadvantages of the approach. Besides tactical and analytical advantages, we strongly believe that these instruments may help to better ground the communities research in the science paradigm.

The last two decades saw an emergence of Design Observation Laboratories (Carrizosa et al., 2002; Törlind et al., 2009). The intent has been to conduct engineering design activities and to capture the activities as precisely as possible, mostly trough video and audio capturing. The aim was to identify and explore hypothesis and/or to run controlled and semi controlled experiments on the same (Tang, 1991; Tang and Minneman, 1991). These labs, such as the Design Observatory in Stanford and Luleå or the MEXICO Lab in Grenoble, have been quite successful in generating novel insights – however the setup and running of controlled experiments for example with a 2x2 matrix setup has been less successful. The key problems were:

1. The through piloting of such an experiments takes many rounds and months (space, activities, determination of depended and independent variables, determination of sensors and measurements, analysis preparation),
2. The need to obtain sufficient numbers of subjects that fit the stratified sample (40-80 minimum),
3. The duration of each experimental run (1-3 hours),
4. The potential of specific local biases (we are not sure if experiments conducted at Stanford with Stanford students would stand any closer scrutiny of external validity).

However, the advantages of controlled experiments and especially of confirmatory studies in multiple environments and by various teams are obvious and, at least in the positive sciences, uncontradicted. The current setup with empirical design researchers running complementary but not similar studies, in labs that are varying considerately seems thus not helpful.

In order to mitigate this problem and at the same time generate open access quantitative data sets, we propose a new method for global collaboration in design research that potentially offers an alternative to current approaches and subsequently avoids most challenges and shortcomings of global design studies: distributed experiments that encompass various global and cultural settings. This paper describes this new approach in detail and explains how we intend to benchmark and therefore potentially validate it.

Since this project is run in cooperation with the European Organisation of Nuclear Research (CERN) and the Challenge Based Innovation (CBI) initiates, we are also adopting the comprehensive authorship and open data requirements from CERN. All participants in the experiments are co-author of this paper and all data will be made available publicly. This is an experiment on conducting designs science experiments open and distributed on a global scale.

1.1 Challenges in Global digital Collaboration

With the rising importance of global collaboration, it became of great interest to create software environments that allow for easy communication between globally distributed Research & Development teams. Kolarevic et al. (2000) performed an experiment where students from different cultural and geographical backgrounds had to design a house together by only using a virtual design studio in order to communicate. Their findings suggest that the shared authorship in this kind of projects does not create a problem and that this kind of collaborations can work very well. However, with the introduction of a wide range of collaboration tools, such as digital whiteboards and a wide selection of software, managing global collaboration projects becomes a challenge (Chiu, 2002). Furthermore, a lot of groups propose different approaches to design collaboration research while many of them are focused on the digital component thereof (Cheng, 2003). Kvan (2000) raised the question of what exactly collaborative design is and comes to the conclusion that co-location simulations, such as videoconference systems, do not lead to better work product outcomes. Also, he proposes that people are actually co-operating and compromising rather than collaborating.

Not only the industry, but also researchers engage globally. Within the context of such research collaborations Cummings and Kiesler (2005) state that, on average, multi-university projects were less successful than projects located at only one university. However, a successful prior experience with a collaborator partially reduces the barriers of distance or interdisciplinary hurdles (Cummings and Kiesler, 2008).

1.2 Distributed analogue Approach

Instead of trying to find the perfect software for gathering data from all across the globe, we propose to use a completely analogue and decentralised approach. We prepared a design task (see section 2) in our research hub TrollLABS in Trondheim, Norway and shipped it in 30x35x12cm large boxes to three other universities. The experiments were then ran by colleagues who were informed beforehand about receiving a box and running a design task but were not told what this task will look like. As the same design task has been performed before, we can use the available results as a benchmark.

1.3 Hypothesis

Our hypothesis is that experiments can be conducted without the guidance of the researcher on location while the outcome stays the same and that experimental control assures valid data sets, large enough to run statistics and to identify potential differences based on subjects selection and cultural/educational background.

2 UNDERLYING DESIGN-TASK

In order to be able to benchmark the results from this distributed approach we chose to send out an already existing study that offers both, a detailed description of the procedure and a large set of reference data. Namely, we chose *the egg-drop exercise.* This design task, as introduced by Dow et al. (2011), challenges the participant to protect a raw egg from cracking after a free fall. The highest achieved drop-height of each participant is measured. Furthermore, the participants are separated into two groups: An iteration group that is allowed to test their prototypes and a non-iteration group which does not have the possibility of testing. As both, materials, and time for designing and building are limited, this experiment allows for quantifying the importance of prototyping during a design phase. The egg-drop exercise also requires the participants to estimate the height they will be able to reach before and after designing their vessel. These estimations are an indicator of the individual confidence level.

Additionally, we expanded this experiment by including two hypotheses, which are described in the sections below. A previously conducted proof-of-concept study suggests that these additions have no influence on the original procedure and the outcomes thereof (Kriesi et al., 2014).

We chose to send out the egg-drop exercise for the following reasons:

- It is a design task where the participant does not require any special education beforehand.
- The amount of material that has to be sent out is limited and fits in a 30x35x12cm box (for up to twenty participants).
- The experiment can be supervised without any specific knowledge beforehand.
- The procedure follows a clear structure that allows for sending out a checklist for every participant.
- Our group already has experience with conducting this experiment.
- There are previous data points available that can be used as a benchmark for this approach of globally distributing the experiment.

2.1 Additional Measurements

In a previously conducted proof-of-concept study we expanded the original egg-drop exercise by introducing a variable workspace setup. Furthermore, the participants were wearing an Arduino (ARDUINO, Italy) based sensor package that allows for recording acceleration and heart rate of the participant throughout the experiment.

2.1.1 Activity Level

Earlier studies have shown that stand-up meetings are more time efficient than sit-down meetings while the quality of the outcome is unaffected (Bluedorn et al., 1999). Further exploratory experiments held at NTNU and Stanford show similar results for prototyping and ideation sessions. Grounded on this knowledge we selected two prototyping conditions for the participants of the egg-drop exercise:

Half of the participants conducted the experiment while comfortably sitting in a chair while the other half only had the possibility to work while standing. The aim was to see whether or not this influences the number of tests the participants in the iteration group conduct throughout the design phase.

2.1.2 Physiological Data Acquisition

During the experiment the participants have to state their confidence level twice: Once before designing the vessel and once after having built the final design. The results show that participants of the iteration group experience, in average, an increase in their confidence level, unlike the members of the non-iteration group. Their confidence level stays constant, or in other words, they do not know more about their design than at the beginning. Research has shown that uncertainty can induce stress in humans (Greco and Roger, 2003; Pruessner et al., 1999). One sign of an increase in the stress level is an increase of the heart rate (Appelhans and Luecken, 2006). Based on these facts we decided to record an electrocardiogram (ECG) and the acceleration of the participants throughout the experiment. The ECG can be used to extract the heart rate and in combination with the acceleration values it is possible to distinguish between physical and psychological factors for an increased heart rate. During the interview at the end of the experiment the participant is challenged with questions regarding the design of their vessel. The goal was to see whether or not it is possible to detect a difference in their heart rate at the beginning and at the end of the interview as this can indicate a difference of the stress level (Kriesi et al., 2014).

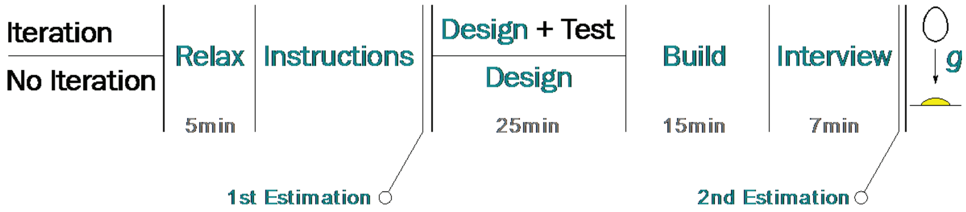

Figure 1. The procedure of the egg-drop exercise.

2.2 Procedure

Expanding the original procedure, a relax phase was introduced at the beginning of the experiment in order to investigate the additional measurement mentioned in section 2.1. Based on the experiences of our previous proof-of-concept study we changed the length of the interview (Kriesi et al., 2014).

After signing a statement regarding the voluntary participation in the experiment, the participant attaches three electrodes to his body and subsequently to the ECG unit of the sensor package. In order to get a reading of the resting heart rate of the participant, they then watch a five-minute video that helps them relax. Only then the participant is confronted with the instructions to the egg-drop exercise, the set of materials that is available for the final design, and the drop zone where the final test is conducted. Figure 1 graphically describes the procedure of the experiment. One complete set of materials consists of the following elements (also depicted in Figure 2):

- 8 pipe cleaners
- 8 rubber bands
- 8 popsicle sticks
- 1 10x20cm poster board
- 1 10x15cm flat foam
- 1 sheet of tissue paper
- 30cm scotch tape

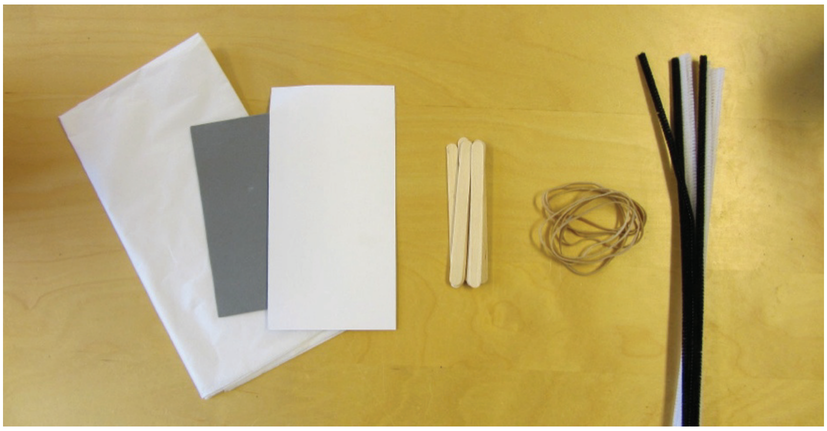

Figure 2. One Set of Materials: (FLTR) Tissue paper, flat foam, poster board, popsicle sticks, rubber bands, pipe cleaners (scotch tape not shown).

Based on this information the participant is then asked to make a first estimation of the final height they can achieve (noted as *confidence level before*). The participant then has 25min to design a vessel that protects the egg. During this phase a member of the iteration group can test as often as they want to. Once the time is over the participant gets one fresh set of materials and 15min time to build the final design. Before performing the final test of the device the participant has to explain their design in an interview with the supervisor and give a second estimation of the final height (noted as *confidence level after*). The questions asked become increasingly specific throughout the interview in order to provoke stress due to uncertainty in the participant. The last part of the experiment is the test where the vessel is dropped from increasingly high levels (increments of 30cm) until the egg cracks. The maximum height the egg survives without taking any damage is the final score.

2.3 Results for Benchmarking

This section presents the results that we will use in order to benchmark the results we are gathering from the globally distributed experiment. The results are from two independent studies: The first one was conducted by Dow et al. (2009) with twenty-eight students. The second one, a proof-of-concept study, was conducted by (Kriesi et al., 2014) with thirteen participants. It followed the same protocol and investigated the additional measurements described in section 2.1.

2.3.1 Drop Height and Confidence Level

The results of from Dow et al. (2009) are listed in Table 1. The key findings are that the iteration group reached in average an 85% higher final drop level than the reference group. Furthermore, the iterating participants showed an increase of 44% in their confidence level, whereas the non-iteration group showed no change thereof.

Table 1. Given results: Highest drop height reached and the confidence level before and after designing and building the device. Data from Dow et al. (2009).

		Non-Iteration	Difference		**Iteration**
Final Height		101cm	+85%		186cm
Confidence Level	Before	95cm	+0%	+44%	125cm
	After	95cm			180cm

The second study conducted by (Kriesi et al., 2014) confirmed these results as shown in Table 2. The additional findings regarding the activity level and the physiological data acquisition as described in section 2.1 were that the standing participants of the iteration group tested 33% more often than the sitting counterparts. Also, the iterating participants showed in average a decreasing heart rate (-2.1%) throughout the interview, whereas the heart rate of the non-iterating participants increased by 6.8%.

These numbers can indicate a decrease and increase, respectively, of the individual stress level. As the number of data points was small, the numbers from the second study should be interpreted as trends.

*Table 2. Given results: Highest drop height reached and the confidence level before and after designing and building the device. *Three participants in the non-iteration group tested their prototypes on the table during the design phase and subsequently cracked their eggs. Their official result therefore was 0cm. The value in brackets is calculated with the heights they reached with a replacement egg. Data from Kriesi et al. (2014).*

		Non-Iteration	Difference		**Iteration**
Final Height*		69cm (103cm)	+154% (+70%)		175cm
Confidence Level	Before	141cm	-3%	+18%	135cm
	After	137cm			160cm

3 GLOBAL IMPLEMENTATION

A local supervisor on location performs the experiment that is described in section 2 with the participants. The focus of the preparation therefore lied on making the content of the packages self-explanatory and the instructions as simple and clear as possible for this local supervisor. Only the following items had to be organised by the supervisors on location:

- Workspace
- Chicken eggs
- Scissors
- Stop watch

3.1 Packages

As described in section 1, our goal was to perform the experiment completely offline. Subsequently, all the materials and instructions had to be enclosed in the boxes. Figure 3 gives an impression of the preparations. The following sections explain the different elements that were shipped.

3.1.1 Materials

To ensure that all participants have the exactly same materials we prepared four complete sets (see Figure 2) per participant on location. Additionally, we prepared a measurement tape for the drop zone so that every test is conducted from the same height levels.

Figure 3. Impressions of the preparation of the packages. All the materials (left) and batteries (right) were shipped in clearly defined amounts.

3.1.2 Sensor Equipment

A sensor unit is necessary for the physiological data acquisition as it is described in section 2.1.2. Our solution is based on the microcontroller Arduino Uno. The voltage reading from the skin is amplified (x300) by a CookingHacks eHealth Shield (LIBELIUM COMUNICACIONES DISTRIBUIDAS S.L., Spain) and results in the ECG data. An accelerometer from Sparkfun (SPARKFUN ELECTRONICS, CO, USA) registers acceleration in all three axis directions. All the data is stored on a microSD card that is accessed by using a Sparkfun microSD shield. Figure 4 depicts the sensor units and the acrylic boxes they were shipped in. A battery powers the sensor unit and one for each participant was shipped in the box. Exchanging the battery was made easy by attaching Velcro tape on both, the battery (see Figure 3 on the right) and the sensor casing. The supervisors were instructed to replace them after every participant in order to ensure that no sensor runs out of power during an experiment. Wearing the sensor unit was made easy by adding an adjustable belt to the casing. Enough electrodes for each participant were shipped as well.

3.1.3 Videos and Data Carrier

In order to get the instructions across in a simple manner we decided to focus on the usage of videos in addition to written documents. A total of seven videos were created, each with a specific topic. An introduction video explains the supervisor the design task itself and one video explains each item that they find in the box. For the participants there is one video that instructs them on how to attach the sensor unit and one for each phase of the experiment: Relaxing phase, design phase (two versions for both, iteration and non-iteration group), and build phase. The videos were delivered on a USB stick that contained a folder for each participant and the supervisor. As there were different versions for the iteration group and non-iteration group this structure ensured that each participant was shown the right video.

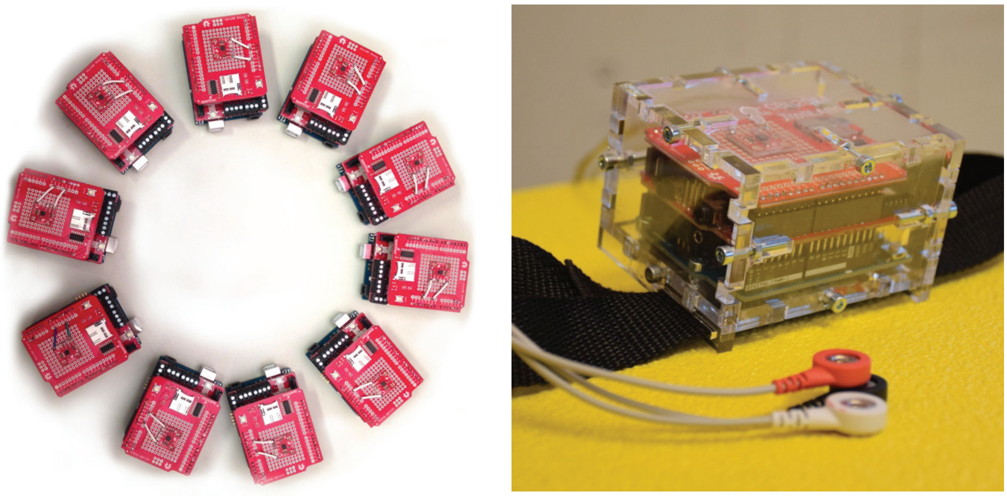

Figure 4. The ten identical sensor units (left) that were shipped in acrylic boxes (right). An adjustable belt allows for easy wearing around the hip.

3.1.4 Checklists and Envelopes

In addition to the videos the supervisor also got an envelope for themselves and one for each participant. For the supervisor this contained a welcome letter and instructions on how to proceed with the USB stick and what they have to prepare. The ones for the participants included the instructions for the experiment and, most importantly, a participant specific checklist. This checklist for the supervisor not only contained the information regarding what setup each participant needed (sitting/ standing, iteration/ non-iteration) it also guided them step by step through the whole experiment. The supervisor had to tick off all the steps, write down important numbers (e.g. drop height) and sign the document at the end. Figure 5 contains an excerpt from a checklist that was sent out.

3.2 Participants and Shipping

For the second time members of CERN organized a class called CBI. The aim of this course is to let the students find a way to bring technology that was developed at CERN into different fields of application than particle physics. Furthermore, the students are forced to collaborate globally as they are located in Melbourne, Australia; Helsinki, Finland; Reggio Emilia, Italy; Barcelona, Spain; Trondheim, Norway. As the students have to present a functioning prototype at the end of the class, the egg-drop exercise is a great tool to show them the importance of iterating ideas. Furthermore, their coaches on location are ideal for supervising the globally distributed experiment. It has to be noted though that none of the supervisors knew beforehand what task they receive in the box. As the student coach in Trondheim was also preparing the experiment, another member of the group, who was not previously involved in the process, conducted the experiments.
All boxes were shipped with a private postal service in order to guarantee fast and save delivery.

14. 3 minutes break ☺ ☐

INTERVIEW (7 minutes):

15. Start interview and follow interview protocol. Feel free to add questions If it is written -this part-, then just ask about any specific part that you see in the participants design: ☐
Write down time shown on stop watch: ______________________
- Questions for minutes 0-2 (general design questions):
  - Please explain me the functional parts of your final design.
  - Explain from inside out (egg to outside) how you built up the design.
  - Is there a thought behind the colour of -this part-?

Figure 5. Excerpt from the checklist that was sent out. It guides the supervisor step by step through one experiment.

4 CONCLUSIONS

From this first iteration of running a globally distributed experiment we can conclude that creating and running the procedure leads to many advantages for the research group. It starts during the preparations of the experiment: The level of detail needed is higher than when running the experiment locally. All instructions have to be on point and easy to understand by any local supervisor that does not know the procedure beforehand. Only by re-enacting the experiment many times and by observing how unprepared members of the group handled the instructions we were able to achieve the desired level of detail. At the same time we gained deeper knowledge about the key factors of the experiment and the setup thereof became more robust. Based on the feedback that we gathered from the coaches who have conducted the experiment, the preparations worked out very well for this first trial. The second major advantage for the research group is the amount and the diversity of potential data sets. This distributed method allows for collecting multiple sets of data points at various locations in parallel. Subsequently, large enough data sets that allow for in depth statistical analyses can be gathered faster. Performing design studies all across the world also means that these data sets have larger validity. The broader set of participants also reduces local bias within the data set and can reveal specific local tendencies at the same time. As Sue (1999) points out, theories and principles may or may not be generally true, however they require evidence and cross-validation to become universally applicable.
We can further conclude that future globally distributed experiments need a very strong focus on the managerial side. Not only did the preparation for shipping become unexpectedly time consuming, also the scheduling of the experiment turned out to lack organisation. It is therefore necessary for further iterations of the distributed approach to stay in very close contact with all prospective collaborators long before the experiment actually begins. Just like with any group of participants one has to anticipate that some collaborators change their minds within the last second.

5 OUTLOOK

In case the results returning from this globally distributed design experiment match the ones from earlier studies (Dow et al., 2009; Kriesi et al., 2014), this method opens up a whole new world of gathering data points in design studies. It would no longer be necessary to either travel to various locations or find one academic or industrial partner that is willing to provide many participants. This can enable smaller research groups with limited financial possibilities to create global research projects as well. As for recruiting participants, similar to sending out questionnaires, many locations could provide a few data points each. Furthermore, one could create a global network where each member has the right to send out one design task per year to all other members. Each location then individually has to conduct the experiment on site and sends back the results. One can also imagine introducing the tradition of confirmatory studies into the field of design research. Experiments that are described in detail can potentially be repeated at large scale without too much effort on location. Additionally, research groups can benefit from iterating pilot studies in a timely manner before running the final experiment with the help of industry partners. Carver et al. (2003) come to the conclusion that such pilot studies are not only beneficial for researchers but can offer great educational potential.

Enabling studies across multiple locations within one industry could further be beneficial for the industries themselves. One can imagine that culturally specific engineering design methods are just as important as culturally specific management skills. The latter have been subject to intensive studies (Hofstede, 1984) and as Hofstede (1994) points out, the structure within multinational companies should ideally follow the culture.

We would like to point out that during the process of writing this paper we already found three universities who are interested in participating in such a research network and who are currently performing a design study that we sent to them.

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Appendix E

Contribution 3: Experimental Studies in Design Science and Engineering Design Science - A Repository for Experiment Setups

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Experimental Studies in Design Science and Engineering Design Science – A Repository for Experiment Setups

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Abstract

This paper answers the design science‘s call for the systematical implementation of research methodology in order to empirically study the principles, practices and procedures of design. As a research methodology, experiments depend on robust study designs that quantify selected dependent variables, independent of time, location, or conducting researcher. However, it has been shown, that experimental science struggles with the repeatability of experiments, as context and participants introduce many unexpected independent and dependent variables to what is otherwise a robust experimental protocol. Crucially, the lack of detailed information in the description of the experimental setup may prevent the fellow researcher to comprehend data outcome along with corresponding cause-effect interpretation and, moreover, may lead to contradicting results when conducting confirmatory studies and/or meta-analyzes.

Grounded in the positive sciences, we strive to minimize this hurdle and present the concept of the *experimental item-mining repository,* targeting to generate a standardized document with detailed information about the experiment. This repository can potentially become mandatory for certain types of journals in the field, so that any published study is properly documented and does not jeopardize the foundations of science. The level of detail required for a successful submission in the repository is very high: from environmental influences, such as noise and temperature, to detailed plans of the rooms, and lists of hardware and software - incl. version number - involved. Along with a call for open source science and the necessity of detailed empirical information, we provide and present the concept of this online repository by providing a design observation example from our own studies. A later version might be incorporated into a new CERN IdeaSquare Journal of Experimental Innovation (CIJ).

Keywords: Design Science Methodology, Open Source Science, Experiment Information, Repository, Repeatability

1 Design Science's Call for Design Methodology and Confirmatory Studies

Design Science (Fuller et al., 1963; Gregory, 1966) and Science of Design (Cross, 2011; Gasparski and Strzalecki, 1990) call for the systematical implementation of research methodology in order to empirically study the principles, practices and procedures of design (Cross, 2011; Bender et al., 2002; Blessing and Chakrabarti, 2009). This 'includes the study of how designers work and think, the establishment of appropriate structures for the design process, the development and application of new design methods, techniques and procedures, and reflection on the nature and extent of design knowledge and its application to design problems' (Cross, 1984). Research methodologies to empirically analyze design activity are proposed to be literature review, observation, interview, case study, participatory design, and experiments, for example (Denzin, 1978; Descomb, 1998; Blender et al., 2002; Blessing Chakrabarti, 2002). With the focus on experiments as empirical method, we aim to generate quantitative (objective) outcome in order to test and derive the impact and effect of the independent variable on the dependent variable. The research question is approached by formulating a hypothesis which is to be falsified (Popper, 2005) in order to generate paradigms (Kuhn, 2012) which eventually form into theories (Lakatos, 1970).

Correspondingly, Lucienne Blessing and colleagues state: 'Unfortunately, many publications do not provide details of their research, such as data collection context and data analysis methods, and validation of the results is rather uncommon" (Blender et al. 2002). Due to this lack of information, fellow researchers are in consequently unable to entirely comprehend and validate the data outcome and proposed interpretation. The basis for empirical scientific discussion is, thus, severely endangered.

In addition to this issue, studies attempting to validate and meta-analyze data, indicate that slight variation in the contextual setting of (1) human-human interaction, (2) machine-machine interaction, (3) human-machine interaction, (4) human-environment, and (5) machine-environment in the experiment, may cause substantial variation in data outcome. Illustrative examples from our field of research of interaction design experiments and affective engineering (Balters and Steinert, 2014, 2015) are among others: simple pictures prime people into voluntarily paying more for their tea (Kahneman, 2011); one vs. two physiological sensors connected to an Arduino microcontroller leading to a difference in sampling rate (Kittilsen et al., 2016) or a different OS does not allow for the same data transfer protocols (Reime et al., 2015); participants performing the same experimental task, yet using different-sized screens (Gilbert et al., 2016); the impact of variation in sunlight onto the data outcome of skin conductance stress measures (Jung et al. 2015); conducting an experiment in the US versus Europe, leading to changes in electromagnetic fields interferences (50 Hz in Europe vs. 60 Hz in the US) (Balters and Steinert, 2015). In order to conduct comparable confirmatory studies and/or meta-analysis, it is, thus, of crucial importance to be, firstly, aware of the existence of cofounding variables and, secondly, to give most detailed information of these human-machine-environment contextual settings, in order to allow the fellow researcher to test the dependent variable(s) under the same experimental conditions.

Addressing the issues of detailed information capturing stated above, this paper proposes the concept of an *experimental item-mining repository (EIMR)*. Final output of this repository is a standardized document including detailed information about an experiment. We propose to submit this standardized EIMR-document *supplementary* to the scientific paper, respectively, to make this document accessible for fellow researchers. This will provide standardized, yet

holistic information data in order to (1) allow the fellow researcher to validate empirical results and to, moreover, (2) enable confirmatory studies and meta-analysis.
The main challenge in generating a standardized EIMR-document is the potential complexity of an experiment itself along with the potential great variation between experiments. We therefore aim for a highly adaptive repository, respectively a subsequently generated standardized document, comprising a very broad coverage while still scanning for, and in detail. Additionally and application-wise, we aim for an intuitive usability when guiding the user through the complex matter. Envisioned is a repository with browser-based interface and complementary app support that guides sequentially along the experimental time line, asking the experimenter to short and precisely characterize the details of and the interactions within the experiment. The semi-active, meaning adaptive, property of the application, aims for use-case-friendly and, thus, time efficient benefits. In addition, the EIMR may serve as a sort of guideline and/or checklist, when setting up experiments.

Along with a call for open source research in engineering and design science in order to enable and promote quantitative-data-based discussion in the community, we will present the concept of the EIMR in this paper. In section 2, we will present the logical structure behind the repository, followed by an illustration of the latter via an exemplary application (section 3). A mock-up of the future graphical interface will be shown in section 4. Conclusively, we will call for more transparent science and propose to support the scientific discussion in design science and engineering design science by means of the *experimental item-mining repository* (section 5).

2 The Building Blocks of an Experiment

A successful repository needs to provide both: Usability - a user-friendly interface and an easily comprehensive structure, and completeness – the possibility to capture all the details necessary. We therefore use our own experimental setups as case studies from which we deduct insights on the meta-level of setting up experiments and highlight essential components thereof, which in return will be the building blocks of EIMR. Before we go through an exemplary use-case scenario of EIMR (see section 3), we introduce the logic behind the repository in this section.

2.1 Component Classes

There are four classes of components that need to be defined in detail:

- Physical Environment: e.g. Building, Rooms, Climate
- Hardware: e.g. Paper, Pens, Sensors, Computers, Screens
- Software: e.g. OS, Programs and their Versions, Resolution Settings
- Individuals: e.g. Participant(s), Supervisor(s), Assistant(s)

2.1.1 Physical Environment

The physical environment is reaching further than just the room we are in. Background noises from cars, construction sites or airplanes need to be described as well. Additionally, all the rooms that are involved have to be characterized in detail. The repository allows for uploading sketches and pictures of the blueprint of a room. Furthermore, details like the height of a room, light sources, direct sunlight, temperature and humidity are asked for. As rooms can be divided for an experiment, one can also define areas of a room, e.g. the material repository, or where the supervisor is located.

2.1.2 Hardware

Any hardware involved in the experiment needs to be described. This can be the writing material that is provided for the participant, or written instructions, but also computers and sensors that are used within the experiment. It is especially important that any electronics are described in detailed since other hardware might measure the same effect, however, with e.g. a different resolution, which subsequently creates different results.

2.1.3 Software

Any electronics device is running on software that defines the behavior thereof. It is therefore of high importance that eventual self made codes or commercially available programs that were used are uploaded or described in detail in the repository.

2.1.4 Individuals

As mentioned in the introduction, individuals are the most crucial element of uncertainty within an experiment. However, one can still try to capture as much as possible, such as their roles within the experiment. Furthermore, especially the recruiting background of the participants is of high interest.

2.2 Interactions

Furthermore, and most importantly, the user can define the distinct interactions that are part of the experimental protocol. One can define at what time the supervisor instructs the participant to engage in a certain action and one can subsequently define with what elements of the setup these interactions takes place.
One can distinguish between three classes of interactions:

- Individual-Individual Interactions: e.g. Receiving instructions orally
- Individual-Object Interactions: e.g. Entering a number in a computer
- Object-Object Interactions: e.g. A sensor sends data to a computer

2.2.1 Individual-Individual

Throughout a design study the participating individual may get information or objects through another individual. However, it is important to distinguish between interactions that are a result – such as interactions between individuals that work as a team – and actions that are an input – such as helping a participant to place a sensor on their body.

2.2.2 Individual-Object

Part of the experimental protocol can be that the participant has to interact on demand with an object, such as a computer or a sheet of paper. It is important to capture the moment of when such an interaction is demanded. The way it is then performed is not part of the controllable experimental setup.

2.2.3 Object-Object

A typical object-object interaction is the connection between a display and a computer. While the software defines the outcome, the physical connection and subsequent display of information can be considered as an interaction. This type of interactions also lets the user define the exact setup, e.g. which display stands on what table but also how a sensor is transferring its data, e.g. Bluetooth or direct cable connection.

2.3 Data Handling

Creating a repeatable and robust experiment does not stop when the protocol is done, as one of the most important parts is still outstanding: Post-processing. By defining the interactions on the timeline as described above, the user also has the chance to define what data streams are measured, stored, and used as results. They can then define the software used for eventual calculations and statistical analyses and subsequently upload relevant code structures.

3 Exemplary Application: *'Mockpit'*-Experiment

In order to highlight the potential complexity of design studies, we present an excerpt from a study that was conducted by our research group. The forth-following details of the experimental setup are taken from Kittilsen et al. 2016. As mentioned above, we used our own experiences as initial steps in order to create the logic behind the repository that is described in section 2.

The general context of the experiment was addressing the interaction design in a ship bridge scenario, with the focus on stress level reduction. As 'stress' is a very vague concept, our group set up an experiment in order to better understand the phenomenon and figure out how stress can be triggered within a controlled environment, and how one can subsequently measure the effects thereof. Throughout the experiment, the participants were hooked up to various physiological data sensors recording, amongst other things, their heart rate, breathing rate, and skin conductivity. They were then asked to solve three different tasks within a mock-up ship bridge (*'Mockpit'*) where they controlled various vessels throughout three situations within a boat-simulator:

- Trial run: The participant is given five minutes to get used to the software mechanics by moving a vessel around an environment provided by the software.
- Cruising task: Similar to the trial run, the participant has no other objective than enjoying a cruise-ride within the simulation for five minutes. The aim of this task is to create a non-stressful environment for the participant.
- Race task: In order to provoke stress in the participant, they are asked to conquer an increasingly difficult racetrack on a vessel that is highly difficult to control. Furthermore, the participant is simultaneously asked to solve calculations shown on a second screen.

Since this experimental setup involved multiple rooms, supervisors, sensors, computers, as well as a complex physical setup itself, we use this example to highlight the level of details of what is normally described in a publication, and the shortcomings thereof. More specifically, the race-task is analyzed on two different levels, in the context of a descriptive text as it can be found in a publication, as well as the EIMR table that aims to comprise all (detailed) experiment information along the logic of the repository.

The aim is not to discredit any published setups or question their validity. The goal is to show that due to limitations, such as maximum page numbers, and the high complexity, one cannot fully capture all interactions and details. Furthermore, this analysis shows that the combination of text, with its sequential structure, and the level of details contained in a table can create a powerful repository that is easy to use.

3.1 Descriptive Text

For the race task the participant, who was wearing earmuffs in order to reduce influences from ambient noise, was seated in the Mockpit, which was set up according to their dominant hand. Centrally in the Mockpit there were two screens, where the smaller one was used to display instructions. Throughout the task, a total of five physiological data sensors recorded

various types of signals. Before and after the race, the participant was asked to fill out an questionnaire. Figure 1. shows the setup for a right-handed participant. The task for the participants was to conquer a premade course within the software called ShipSimulator 2008 by VSTEP (VSTEP, Rotterdam, NL). The course itself took place in the “Atlantic Ocean” environment provided by the software. Various obstacles, such as ships, ramps, and icebergs created a challenging obstacle course. Additionally, the weather conditions became gradually worse whenever the vessel passed checkpoints that were placed in constant, fixed distances within the course. Simultaneously, the participant was instructed on the smaller screen to perform simple calculations and write down the results. These calculation tasks appeared for six seconds and in intervals of 24 seconds. In-between the screen was blank.
In order to further stimulate a competitive mind-set of the participant, the winner was promised a 500NOK gift card for the university cafeteria. Furthermore, the instructions said that the scores would be published on the class homepage, once everybody has participated.

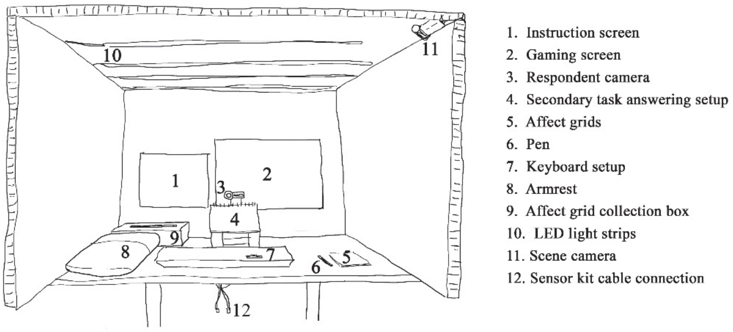


Figure 1. Sketch of the Mockpit setup as it was used in the experiments (setup for right-handed participants). From Kittilsen et al. 2016 (in press)

3.2 Listings

While the descriptive text above gives the reader a good idea about the setup and the types of interactions, many crucial elements can simply not be described in high enough detail. Repeating the experiment along these instruction could potentially result in a very different outcome. Below are two tables, Table 1. and Table 2., that contain a detailed list of the objects according to the classes defined in section 2, as well as a list of interactions. While the descriptions may refer to drawings or code files, this is purely for descriptive purposes within the context of presenting the general idea. Furthermore, the list of interactions is incomplete due to space restrictions.

3.2.1 Objects – Race Task Phase

Table 1. List of objects during the race task according to the four classes of the repository (incomplete)

Physical Environment: Room 2

Area	*3rd floor within university building*
Background Noise	*None in particular*
Climate	*Thermostat controlled 22°C, humidity of 46%*
Floor Plan and Layout	*Room 2 is separated in the experimental ship bridge replica, made of cardboard and a supervisor area that is not visible to the participant.*

	The drawings give a detailed overview, as well as the pictures.

Hardware

Earmuffs	*Industrial grade earmuffs that are used for noise dampening*
Screen 1	*Secondary screen of the Mockpit, 17" LCD monitor, 1280x1024*
Screen 2	*Primary screen of the Mockpit, 24" LCD monitor, 1920x1080*
Pen 1	*Standard BIC roller pen, blue*
PC 1	*2x3.60 GHz CPU 16 GB RAM*
PC 2	*2x3.60 GHz CPU 16 GB RAM*
Keyboard 1	*Logitech Keyboard, only arrow keys visible, rest covered*
Microcontroller 1	*Arduino UNO, ATmega328P chipset, version of 2015*
Ethernet Shield	*Arduino Ethernet Shield R3*
Sensor Shield 1	*Libelium eHealth shield, v2.0*
Sensor 1	*Libelium ECG, version of 2015*
Sensor 2	*Libelium airflow sensor, version of 2015*
Sensor 3	*Libelium temperature sensor, version of 2015*
Sensor 4	*Libelium skin conductivity sensor, version of 2015*
Sensor 5	*Libelium Accelerometer, version of 2015*
WebCam 1	*Creative 73VF068000001, 1080p resolution*
WebCam 2	*Creative 73VF068000001, 1080p resolution*
LED Strips	*IKEA dioder*

Software

Arduino Code	*Arduino Code used, reading sensor inputs.*
ShipSimulator	*ShipSimulator 2008 v. 1.4.2, VSTEP, configuration according to settings file*
iMotions	*iMotions Attention Tool v 5.4*
OS	*Windows 7, SP3*

Individuals

Participant	*Recruited amongst mechanical engineering students (n=34) and employees within engineering department (n=6), 26 male, 14 female, age 23-28*
Experimenter 3	*Third experimenter, male, age 24*

3.2.2 Interactions – Race Task Phase

Table 2. List of interactions identified within the experimental task phase (incomplete). Types of interactions: 'I-I' – Individual-Individual; 'I-O' – Individual-Object; 'O-O' – Object-Object

Type	Location	Objects	Description
I-O	Mockpit	Participant; Earmuffs	*Participant is wearing the earmuffs*
I-O	Mockpit	Participant; Sensors 1-5	*Participant is wearing the sensors 1-5 according to positions shown in drawings*
I-O	Mockpit	Participant; Keyboard	*The participant only has access to the arrow keys and uses them to control the vessel within the program*
I-O	Mockpit	Participant; Screen 2	*Screen 2 displays the ship simulator to the participant*
I-O	Mockpit	Participant; Screen 1	*Screen 1 displays instructions to the*

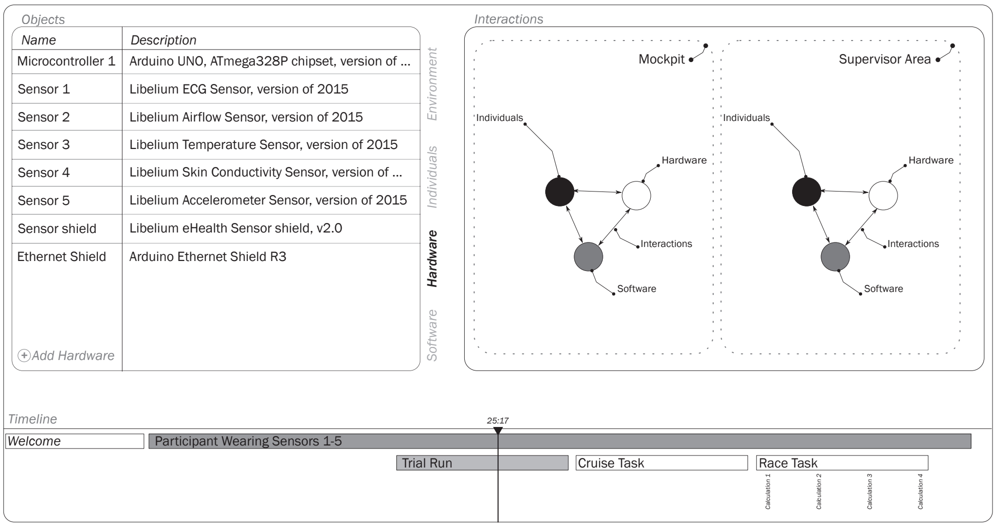
			participant
I-O	Supervisor Zone	Experimenter 3	*The experimenter 3 is responsible for triggering the instructions / slides at the right time*
O-O	Mockpit	Sensors 1-5; Sensor Shield	*The sensors are wired to the sensor shield according to the diagram*
O-O	Mockpit	Sensor Shield; Microcontroller 1	*The sensor shield is attached to the microcontroller*
O-O	Mockpit	PC 1; Microcontroller 1; Ethernet Shield	*The microcontroller is connected to PC 1 via the Ethernet shield and a LAN cable*
O-O	Mockpit	PC 1; Screen 1	*PC 1 is connected to Screen 1, running it at 60Hz, resolution of 1280x1024*
O-O	Mockpit	PC 2; Screen 2	*PC 2 is connected to Screen 2, running it at 60Hz, resolution of 1920x1280*
O-O	Mockpit	PC 2; ShipSimulator	*ShipSimulator is running on PC 2*

3.3 The Temporal Dimension

A static list such as the tables above increases the level of detail when it comes to describing objects and experimental setups. From a usability standpoint of view, however, it is not a suitable solution. The repository needs to follow a timeline that lets the user create two types of interactions along the timeline: On-going interactions, such as the constant wearing of sensors, or the permanent connection between a computer and a screen; And momentary interactions, such as displaying a mathematical problem for six seconds or an input from the experimenter at a specific point in time.

4 GUI/Interaction Design

Based on the conclusions from the case study in section 3, we present a mock-up graphical user interface for EIMR. It is by no means the final design, nor is it a functional software yet.



Name	Description
Microcontroller 1	Arduino UNO, ATmega328P chipset, version of ...
Sensor 1	Libelium ECG Sensor, version of 2015
Sensor 2	Libelium Airflow Sensor, version of 2015
Sensor 3	Libelium Temperature Sensor, version of 2015
Sensor 4	Libelium Skin Conductivity Sensor, version of ...
Sensor 5	Libelium Accelerometer Sensor, version of 2015
Sensor shield	Libelium eHealth Sensor shield, v2.0
Ethernet Shield	Arduino Ethernet Shield R3

Figure 2. Conceptual GUI of the repository.

It is merely to give the reader an idea of the concept. One concept is shown in Figure 2.

4.1 Key elements

The following key-elements create the main user interface of the repository:

- Timeline: Similar to the timelines that are known from e.g. video editing softwares
- Objects: As defined in section 2, the repository defines four classes of objects. One can easily define and add objects to a list and search for pre-defined objects.
- Interactions: By connecting two objects one can create interactions along the timeline, similar to the block diagrams known from e.g. SimuLink (MathWorks, MA, USA)

5 Sharing the experimental item-mining repository with and for the community

With this paper we propose an answer to the design science‘s call for the systematical implementation of research methodology, in order to empirically study the principles, practices and procedures of design. The special focus lied herein on the research method of experiments, which aim to generate quantitative (objective) outcome in order to test and derive the impact and effect of the independent variable onto the dependent variable. Prominent fellows of the community criticize the lack of information given in many publications, “such as data collection context and data analysis methods, and validation of the results is rather uncommon” (Blender et al. 2002). In the field of experimental design and engineering design research, we are additionally facing the risk that context and participants introduce many unexpected independent and dependent variables to what otherwise is a robust experimental protocol. Due to the lack of given information, as well as the lack in detail of given information, fellow researchers are consequently unable to entirely comprehend and validate the data outcome and proposed interpretation. The basis for empirical scientific discussion and the conduction of comparable confirmatory studies and/or meta-analysis in particular, are ergo severely endangered. Given these points, the *experimental item-mining repository* aims to interrogate all crucial information about the experiment. The targeted outcome is a standardized document including *all* information of the conducted experiment. We propose to submit this standardized document supplementary to the scientific paper in order to make information accessible for fellow researchers.

In this paper, we proposed the concept of the *experimental item-mining repository,* initially structured based on the decomposition of an experiment example from our own studies. The next step is to systematically integrate more experimental setups, as well as focusing on external user inputs, and adapting the EIMR structure accordingly. Subsequently, the actual online *experimental item-mining repository* will be constructed, generating the standardized EIMR document. Following the example of IBM, using the method of Creative Commons (https://creativecommons.org/) to crowd-source the adaption and improvement of JAVA scripts yet with super-visionary approval rights, we aim to share the EIMR platform for dynamical improvements in the future with, and for the community. We call for transparent science and aim to support the scientific discussion in design science and engineering design science by means of the *experimental item-mining repository*.

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Appendix F

Contribution 4: Creating Dynamic Requirements through Iteratively Prototyping Critical Functionalities

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Creating Dynamic Requirements Through Iteratively Prototyping Critical Functionalities

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Abstract

This paper introduces the wayfaring model for requirement generation. Rather than pre-fixing requirements, we propose exploring unknown unknowns, and suggest finding and adapting the emerging set-based requirements while exploring. Fundamentally, as primary navigation tool towards final requirements, we propose to find and use critical functionalities iteratively, within interlaced knowledge domains. The model argument is based on two cases: The developments of a conceptual desktop plastic injection molder incl. control system, and the iterative prototyping of molds for a lightweight carbon fiber composite bike saddle. In both projects, the critical functionalities dominate the direction of the next prototype and consequently proven design specifications emerge.

Keywords: Critical Functionality; Prototyping; Case Study; Manufacturing; Abductive Learning; Emerging Requirements

1. Requirement exploration

Prototypes are a powerful tool in product development and can be interpreted in a variety of ways. While some industries might see a prototype as the last few stages before being ready for serial production, we present two case studies where we used *'prototypes to learn'*, as Leifer and Steinert [1] put it. In the early product development phase where the final specifications are not yet known, some 'future' problems are not yet on the radar, and are hence lacking a valid solution ('unknown unknowns') [2]. This pre-lean product development phase is crucial, as later changes to the design and to the requirements will create enormous costs [3]. In this paper we propose a method that helps finding these unknown unknowns when tackling the challenge of developing a completely new product where the problem definition and requirement specifications still contain many degrees of freedom. Once these requirements are established, one can rely on other methods, such as systems engineering and lean, where this proposed method could provide viable requirement inputs, as described in Haskins et al. [4].

1.1. Build to learn

Ulrich and Eppinger [5] give a broad definition of what a prototype is: *'An approximation of the product along one or more dimensions of interest'*. Along the lines of the d.school philosophy we see prototypes as *'anything that takes a physical form'* [6]. Elverum and Welo [7] point out that even for complex physical products where the costs of a prototype are high, it is even more important to understand how to prototype in an efficient manner in order to save money and still have highly valuable learning outcomes. Even quickly built, low-resolution prototypes can give the development team crucial information about potential shortcomings of their design early on in the design process [8,9]. Furthermore, different kinds of prototypes provoke different discussions within design teams [10]. However, they should be *'designed to answer questions'* [11]. We propose to use wayfaring in order to find the right questions and use the answers in the best way possible, namely to iteratively find and further refine requirements for the following development steps.

1.2. Wayfaring and probing a vision

Schrage [11] describes product development cultures in organizations as *'Spec-driven'* and *'Prototype-Driven'*, where in the first case the prototypes are designed according to predefined specifications, and in the latter case the specifications are constant subject to change under the influence of the various learnings from the prototypes. We see the prototype-driven development culture as a crucial element of the wayfaring model [12]. Similar to an explorer in the age of Columbus that sets sail in order to find new lands, a product development team departs to find the really big idea, and follows a vision and some vague and often imprecise or even wrong information (wayfaring). The opposing manufacturing analogy would be today´s cargo ship that create a steady just in time supply route over the oceans by following a pre-defined, optimized route to specific GPS locations (navigation). By prototyping and testing quickly and early on in the journey, the 'explorer' team can learn and consciously reflect on the outcome [13] and, unlike in pure 'trial and error', find new 'tracks' that nudges them in a promising direction towards the vision. Gerstenberg et al. [14] describe the process as follows: The journey consists of many probes, where each '*probe is a circle of designing, building and testing of an idea or prototype'*. In addition, they propose to prototype simultaneously in interlaced knowledge domains, creating multi-level probe-circles where each level represents one discipline involved in the development process. Fig. 1 and Fig. 2 graphically represent this process. Such iterative probing circles also increase the designers' confidence in their solution [8,9].

1.3. Critical functionality and functional requirements

Developing and refining a completely new product is – unlike in incremental product development – a long exploration of unknown unknowns and subsequent specifications. However, how can one find and create these requirements? During the wayfaring journey described above, one will deduct certain critical functionalities from the prototypes that need to be fulfilled in order to arrive at the really big idea. Especially in complex systems, these critical functionalities are often not foreseen since the solution is discovered along the way. By probing solutions for these critical functionalities we discover dynamic functional requirements, or evolving set-based requirements. Studies have emphasized the importance of the latter, as they do not constrain the future development, unlike when working with point-requirements [3,15]. The next prototyping iteration can then build onto the newly discovered functional requirement, until a satisfying solution is found.

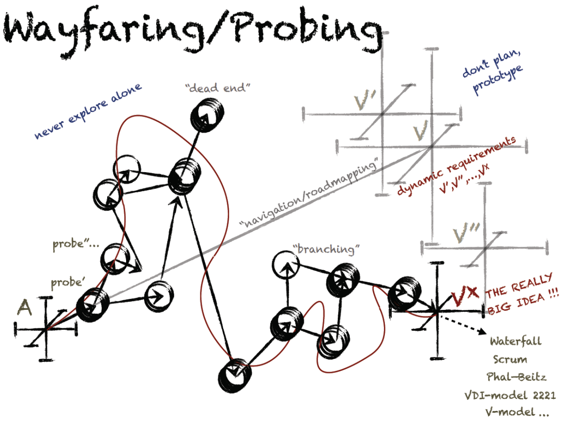

Fig. 1. The Wayfaring Process (From [14]).

Since it is not possible to map out all possible solutions to a complicated problem beforehand, there is no guarantee to arrive at the global optimum. However, through multiple probing cycles one can be confident that one will arrive at the best local optimum within the explored solution-space.

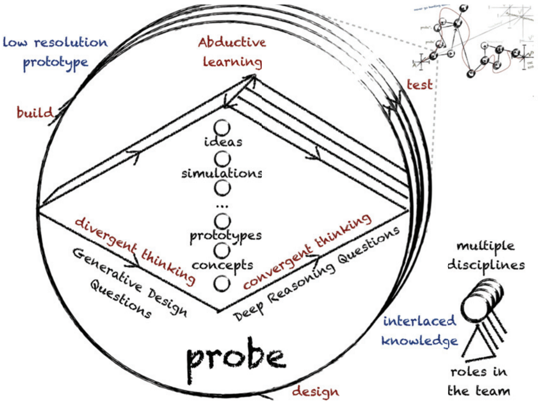

Fig. 2. Multi-Layer Probing Circle (From [14]).

1.4 Case studies

To support our proposition of using the wayfaring as a tool to discover critical functionalities and creating dynamic requirements, which in turn become dominant probing markers and design features, we analyze the following two case studies of development journeys: The development of a desktop injection molder, and the path to the first prototypes for a high-end carbon fiber bike saddle. In both projects, the direction shifted multiple times during the wayfaring process and critical functionalities that emerged along the way became the focus of intensive probing.

2. Case study: desktop plastic injection molder

2.1. Finding a need through wayfaring

Our first example is the development of a desktop sized plastic injection molder. The project started with a vision to improve the handover from CAD-models to injection-molded components in a major Scandinavian company. Because of expensive tooling, the design phase of injection molded plastic parts is critical. Moreover, if a component is designed poorly, and the tooling is manufactured accordingly, significant re-work is required on the tooling. This is both costly and can delay the product launch significantly.

The starting point for the project was initially to do finite element analysis (FEA) of plastic components to obtain knowledge of their structural integrity. However, after doing several rounds of probing, by testing both linear- and nonlinear approaches to FEA, as well as looking into the manufacturing process of injection molding, it became clear that FEA was too time consuming within the boundaries of the project. Therefore, we decided to shift our focus into prototyping.

The idea was now to explore different ways of prototyping injection molded components. We explored several techniques, such as additive manufacturing, indirect- and direct rapid tooling. Several of these techniques seemed very promising. However, a critical obstacle to overcome was to provide realistic mechanical properties in the prototype. From the prototyping techniques listed above, direct rapid tooling was the only technique that would provide these properties. In order to get a first feeling for whether or not we should proceed with this approach, we did a quick round of probing. By making polymer molds using a fused deposition modeling 3D-printer, and using a glue gun to simulate an injection molder. The question was to see if such a simple approach created any useful results.

After seeing that prototyping injection molded components using direct rapid tooling was within reach, we continued pursuing this path. However, a reoccurring problem was that there was no good way to test the various prototyping techniques, as this required full-scale injection molding machinery. Neither the company nor we had direct access to such infrastructure. Thus, we set off to build a simple injection-molding machine that could be used in a near-office situation. The according wayfaring journey is illustrated in Fig. 3.

2.2. Using critical functionality as navigation tools

The basic principles of injection molding are to melt a polymer, and then inject it into a cavity. We therefore continued our wayfaring journey by isolating the *critical functionalities*, namely heat and pressure, and probing them separately.

For pressure, we looked for inspiration in existing solutions, such as hydraulic clamps, full-scale injection molding machinery, and sealant guns. After probing several of these concepts, we learned that a purely mechanical solution would be suitable. The first requirement that emerged was therefore that the injection molder should be hand operated.

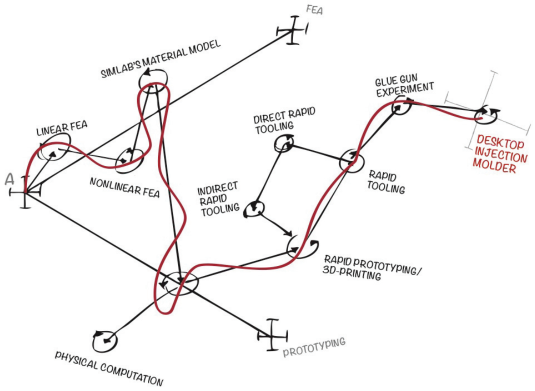

Fig. 3. The wayfaring journey leading up to the injection molder.

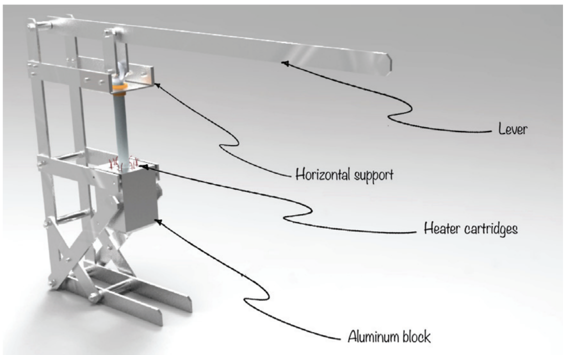

Fig. 4. CAD model of the mechanical structure.

The next round of probing consisted of sketching a cantilever-based design, and building a low-resolution cardboard prototype. Although at this point we only had one requirement, several more would emerge along the way. Because the injection molder had to be able to inject a minimum amount of volume, the height of the injection chamber, and consequently the minimum stroke, emerged. The prototype also showed the need for a horizontal support and a free link connected to the cantilever. Another advantage of the cardboard prototype was that it was easy to move around the pivot points in order to test various cantilever setups. Therefore, a smoothly working mechanism quickly emerged. A rough hand calculation of the theoretical maximum pressure provided by the current design gave a thumbs-up for moving on.

For heat, we considered stovetops, autoclaves and heater cartridges. However, seeing that some additive manufacturing technologies, such as fused deposition modeling, utilize heater cartridges to heat a nozzle, we identified that the same concept could be applied for the injection molder. Essentially, this meant heating a block of metal (in this case aluminum) by the means of heater cartridges. The requirements were therefore that the aluminum block had to fit multiple heater cartridges, serve as a heat medium, an injection chamber, and a nozzle.

2.3. Designing the details

Having found requirements for the critical functionalities, the remaining requirements and subsequent design emerged from what was available in terms of materials in the workshop and as well a few off-the-shelf components.

While physically building the structure, the CAD-model would serve as an interim reference (see Fig. 4). Consequently, if unknown unknowns were discovered while building, and changes had to be made to the design at this point, we would update the CAD-model accordingly.

2.4. Developing the heating system

Critical functionalities were also the main drivers for designing the heating system. This mechatronic system requires prototyping in three interlaced knowledge domains simultaneously, namely the software, electronic, and mechanical domains.

The three different sub-sections of critical functionalities are: Powering the heater cartridges; measuring the temperature; controlling the temperature. All sections were first prototyped independently and then combined with the other sections, in order to form a complete heating system.

For powering the heater cartridges, we used an Arduino Uno microcontroller and a breadboard. This combination allowed for probing several different circuit designs in a short period of time. The idea of our circuit design was to use a low voltage to control a transistor, which in turn controls a higher voltage. It took multiple probing circles of trying various bipolar junction transistors, metal-oxide-semiconductor field effect transistors and solid-state relays (SSR) before experiencing that an SSR was more robust and easier to use.

For measuring and subsequently controlling the temperature in the heater block, we used a k-type thermocouple. The code and circuit for the thermocouple was tested independently, before it was implemented together with the cartridge system. Finally, based on an open source proportional integral differential (PID) algorithm, the different software sections were combined to form a functioning controller.

2.5. Testing

The desktop sized injection molder was finally tested. Although the design had shortcomings, we managed to successfully injection mold simple test geometries. Some of the requirements that emerged along the journey and were tested are:

- The injection molder must be hand operated.
- The lever system must provide enough pressure to inject the polymer melt into the cavity.
- The heater cartridges must heat the aluminum block to at least 200°C.

The developed injection molder is currently being used in a research project investigating how to improve the handover between CAD-models, 3D printed prototypes and injection molded components.

3. Case study: carbon fiber bike saddle

3.1. Introduction

Our second example of employing the wayfaring model is the development of a novel solution for lightweight carbon fiber bicycle saddles. Traditional bike saddles are connected to seat posts in a way that requires a complex design, giving high stress concentration in the connection interfaces. This complex design makes the saddle heavy, and also more prone to failures. The project started with an idea of a new way of joining the saddle to the seat post, to overcome these shortcomings. For patentability reasons, the details of the actual design will not be disclosed here.

The critical obstacle to overcome in this project was to establish a good manufacturing method. Because of the critical functionalities, namely being light and strong, carbon fiber was an obvious material choice for the saddle. However, in order to reduce tooling cost while prototyping, low-resolution manufacturing methods were employed, namely using medium density fiber (MDF) molds for as long as possible. Along the journey, critical functionalities were used as the main navigation tool to allow dynamic functional requirements to emerge.

3.2. Building a proof-of-concept prototype

For obvious reasons, the joint between the saddle and the seat post had to be strong enough to support the weight of a human being. This was our first critical functionality. Before our initial design with respect to this critical functionality, we built a low-resolution prototype out of wood. From this prototype we could decide most requirements for the geometric shape of the joint. However, the prototype provided no information on how the design performed with respect to real life loads. We therefore decided to build a proof-of-concept prototype.

The aim of the next round of probing was to see how the design would perform when made from carbon fiber. We aimed at making the parts in the easiest and cheapest way possible to maintain pace, and have rapid learning cycles. Carbon fiber composite is the preferred material due to the ability to build lightweight structures. The unique thing about carbon fiber is the ability of tuning the material properties by adjusting the fiber orientation within each individual ply. Furthermore, carbon fiber pre-impregnated with epoxy (prepreg) was preferred because it is easier to handle in the manufacturing process when compared to dry fibers. The basic principle of manufacturing laminates is to cut and stack prepreg plies in a mold, and then apply heat and pressure to consolidate the laminate. The molds are usually made from metal, which provides a good surface finish. However, this also makes them expensive. Therefore, we decided to make the molds from a cheaper material.

Using CAD/ tools for modeling the geometry enabled us to CNC-mill the molds from MDF blank. After milling, we sealed the surface of the mold with epoxy, and then sanded it to a smooth finish, as this allowed for easier demolding of the saddle, as well as creating a good surface finish. The finished mold with the prepreg panels was then put in a sealed bag and a vacuum pump was used to pull vacuum, thus compressing the laminate. Finally, an oven was used to add heat during the curing cycle.

The seat post was made using a different approach: We rolled plies of prepreg on a mandrel and firmly wrapped the layup with PET film. When heat was added the film shrank, thus compressing the laminate. The other parts required to assemble the saddle and seat tube were similarly made by compressing prepreg around 3D-printed ABS male molds, which were left within the finished part.

Testing the saddle revealed a lack of strength in the joint, and geometric requirements were further refined and implemented in the CAD model. However, we could clearly see that we were heading in the right direction to realize this product as a lightweight solution.

3.3. Improving the design

For the next iterations of prototyping the focus was to get user feedback on the saddle geometry and joint strength.

To keep the prototyping costs at a low level, we decided to stick to MDF molds. To eliminate the need for sanding thereof we further improved the tooling process by sealing the surface with epoxy before doing the fine milling. This way we could do the rough milling in a soft material, and get a hard surface to do the fine milling afterwards, leaving a high tolerance machined surface with limited need for sanding and polishing. This new approach to making molds successfully enabled for rapid testing of multiple geometries of the saddle in order to increase the rider's comfort.

However, at this point it became apparent that MDF releases fumes at the elevated temperatures during the curing cycle. Unfortunately, these fumes enter the vacuum pump where they condense and gradually damage the pump. Furthermore, heating of the mold is time consuming and inaccurate, as the heat has to be transferred by convection or radiation. Also, the porous nature of MDF, even when coated with epoxy, made it necessary to put the whole mold in a vacuum bag in order to compress it. Another drawback is the exothermal reaction that takes place in laminates due to the low thermal conductivity of MDF.

Despite these disadvantages, using MDF enabled us to test and optimize the saddle design in a cheap and fast way to a point where it satisfied our expectations.

3.4. *Transitioning to aluminum molds and heat control*

The focus for the next iterations was on the critical functionalities of the curing process, namely: Heat, pressure, and debulking of the prepreg. Now that the design of the saddle itself was according to the original vision, it made sense to invest in a high-end mold made of aluminum.

The high conductive heat transfer coefficient of aluminum allows for direct heating of the mold, by the means of heat cartridges, and subsequent precise temperature control. The curing cycle consists of three phases: Ramp up, curing, and ramp down of the temperature, and each phase has to be specifically set according to the prepreg used. An emerging requirement was therefore precise temperature control.

Although there are commercial temperature controllers available, making our own was faster and cheaper. Similar to the heating system for the injection molder described above, we used the Arduino platform to run a PID-controller in combination with an SSR. Adding a touch display allowed for easy tailoring of the curing cycle. Fig. 5 shows the heat controller connected to the aluminum saddle mold.

Also, the upgrade to the aluminum mold enabled us to simplify the vacuum process by using the flange of the molds as sealing points. From struggling with regular vacuum bagging material, we learned that silicone bladders provide a superior solution, since they allow for higher curing temperatures, and are reusable.

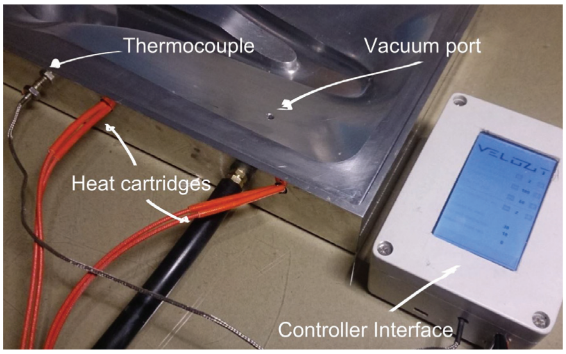

Fig. 5. Detailed view of heating system in the saddle mold.

While the overall quality of the parts increased as expected, it became clear that increased curing pressure was the next critical functionality that needed probing.

3.5. Increasing curing pressure

Prepregs are usually cured at high pressure assisted by an autoclave or by internal bladder inflation in order to reduce voids in the material.

For the first iterations of molding the seat post, we inflated a bicycle tube to achieve the internal pressure required to compress the laminate towards a female mold. From probing different bladder types, the functional requirements thereof emerged. It had to be flexible, and it had to be able to withstand up to 185°C. Silicone is a suitable material for this task. Using additive manufacturing and casting techniques, we were able to make the bladders according to the newly found requirements. Fig. 6 shows an illustration of the design and layup in a seat tube mold.

We realized that the same process can be utilized for the saddles: By clamping a lid on top of the mold, the silicone bladder, originally used to obtain vacuum, is supported by adding external pressure between the lid and the bladder (see Fig. 7).

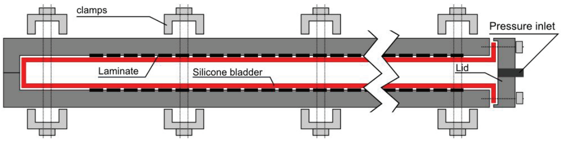

Fig. 6. Design and layup within the seat post mold.

3.6. Summary

This journey of prototyping critical functionalities has taken us from the initial concept idea to arrive at a final product that is adapted to a manufacturing process allowing for low tooling costs and low production costs compared to that of autoclave processed parts. Through iteratively prototyping critical functionalities, ever more specific requirements describing both the product itself and its manufacturing process have been continuously improved. Some of these were:

- The shape of both, the joint and the saddle itself.
- A high-end surface finish.
- Adjustable curing cycles for different prepreg configurations.

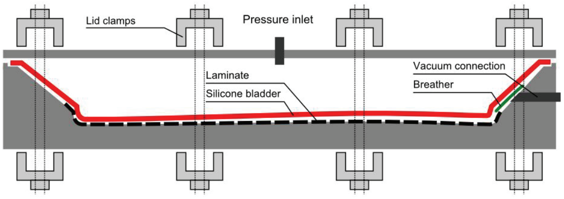

Fig. 7. Design and layup within the seat mold.

4. Closing remarks

We presented and analyzed two case studies of early stage product development processes that used the wayfaring method as a tool to discover critical functionalities and subsequent requirements. This approach helped in two fundamentally different projects: The desktop injection molder, where the external design was driven by the critical functionalities and the fulfillment thereof, and the bike saddle where the critical functionality had to fit in the external design that was predefined by standard dimensions for saddle and seat-post.

A benefit of employing the wayfaring model was the opportunity to discover *unknown unknowns,* for example the damaging nature of MDF molds, and adjust accordingly. This opportunity was primarily enabled by the probing loops of design-build-test. Of course intense simulation and external information gathering may have provided similar insights, but at significant higher costs esp. in terms of time and access/availability of expert information/services.

Furthermore, the iterative, repeating probing cycles allow for the emergence of prototype driven specifications, rather than specification driven prototypes. As pointed out by Schrage [11], are cultures in which prototypes determine specifications, such as in small entrepreneurial companies, more effective when information is scarce, and the outcome ambiguous. E.g. in the case of designing the electrical circuit with transistors instead of relays, testing was absolutely crucial for having a functional circuit. If the circuit had been designed without testing, a major design re-loop would have been inevitable.

Left unaddressed is the viability of this method within an industrial context, as this is part of ongoing research. However, empirical evidence, based on own experiences (e.g. Gerstenberg et al. [14]), and the engineering class ME310 that evolved into a hub for highly visionary industry projects [16], suggest that the iterative prototyping approach have a great potential within projects with high degrees of freedom.

One word of caution: It is unlikely that the wayfaring model as we applied it here provides similarly successful results when it comes to incremental later stage product-development, such as improving a certain product along the same critical functionalities, or when it comes to optimizing e.g. a production process. In these cases there are analysis and improvement tools available, such as lean, which fit a pre-defined solution space significantly better.

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Appendix G

Contribution 5: Fast and Iterative Prototyping for Injection Molding - A Case Study of Rapidly Prototyping

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Fast and iterative prototyping for injection molding – a case study of rapidly prototyping

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Abstract

Injection molding is essential for mass manufacturing plastic parts in all sizes and shapes. However, predicting the quality of a mold is tricky, and while computer simulations are highly advanced, they rely on conservative models, leading to over-dimensioned parts. Furthermore, it becomes practically impossible to prototype a part with the real materials, since a simple mold drives costs and remodeling thereof is time consuming, if not impossible. By building our own desktop sized injection molding machine, we were able to explore the possibilities of prototyping injection molded parts and test a variety of mold materials in order to quantify the outcomes in a three-point bending test. Subsequently, the learnings were applied to a full-scale model, which was tested in an industrial setting. The outcome shows that one can apply rapid prototyping, and subsequent test-build-iteration circles to mass-manufactured parts, allowing for rapidly optimizing material usage, and user interactions.

Peer-review under responsibility of the scientific committee of the 15th Global Conference on Sustainable Manufacturing (GCSM).

Keywords: Prototyping; Wayfaring; Product Design; Additive Manufacturing; Injection Molding;

1. Introduction

In a globalized furniture market, it is important to keep up with current trends in order to stay ahead of competitors. Furthermore, better and cheaper solutions are high in demand, which means that production is either based on cheap manual labor, or fully automated factories. One company that successfully manages to operate out of the high-priced country of Norway is Scandinavian Business Seating (SBS). They manufacture and sell 244’000 chairs worldwide from their production facilities in Røros, Norway. Obviously, such large production numbers require mass-manufacturing methods, such as injection molding. While this is an established means of mass-

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producing plastic parts, consuming about 32wt% of all plastics [1], it also poses several challenges and risks in respect to rapid prototyping and the vision of switching to recycled plastics.

Our work is focused on the fuzzy front end of product development. During this phase, there is a sheer infinite solution space that needs to be explored in order to find the best solution. By iteratively using prototypes to learn [2] and uncover unknown unknowns [3], this process is guided by dynamically emerging requirements. In this article, we argue for rapidly prototyping injection molded plastic components. To support these claims, the test results from a premaster- and subsequent master-project in the prototyping environment TrollLABS are presented: By building a desktop injection molding machine in-house, it was possible to test a large variety of mold materials produced on a variety of 3D printers and a CNC mill. In order to get a comparison to the real part from SBS and simulation results, the most successful attempts were tested in a three-point-bending test. Furthermore, a very complex mold was machined and successfully tested on an industrial injection molding machine.

1.1. Injection molding: Fundamentals

Injection molding works by melting a thermoplastic, and injecting it under high pressure into a cavity where the plastic is left to solidify again. The solid part can then be removed from the mold, while the latter is used over and over again. Designing a good mold is a difficult task, since one has to consider a variety of potential constraints and faults, such as draft angles, warping, and sink marks, to name a few. Machining one steel mold, as they are typically used for injection molding, can easily cost one million Norwegian Crowns (~120’000USD) and in case an error is discovered in the first tests, it has to be shipped back to the manufacturer, which is often in China. Despite all these challenges, injection molding is a fundamental production method for mass-manufactured plastic parts. While one mold is expensive, it can be used tens of thousands of times, subsequently reducing the price per part.

A commonly used plastic for injection molded parts is Polypropylene (PP). While it works great for the manufacturing method itself, it exhibits a problematic range of inconsistencies. It is not homogenous, and the flow during the injection will introduce some anisotropy in the material [4,5]. PP is highlighted since it can be recycled and therefore offers the possibility for a more sustainable product line. It was also the material used for injection molding the small test piece (see section 3).

A common, and great tool for predicting the outcome of an injection molding process is performing a Finite Element Analysis (FEA). The digital model of a part is first split up into volume elements (‘mesh’), and one then applies certain mathematical constraints, describing how they interact with respect to e.g. temperature, or stress. The software then calculates all these interactions based on the applied models and allows the designer to analyze the physical conditions, e.g. stress concentrations within the part under certain load conditions, or the flow of a material during the injection process. Simulating the process of injection molding is feasible and also the industry standard. However, while the models improve their accuracy and subsequent fidelity of an FEA simulation, they still do not *exactly* match the experimental data [6]. With respect to recycled PP, the non-linear behavior of the material makes it extremely complex to fully capture the behavior of a part under loading and unloading conditions [7], and including all of these material properties in a model is highly complex, and induces other challenges, e.g. convergence problems [8]. Simulations with simpler, linear elastic models, do make the problem easier to solve, but do not offer the same resolution as a ‘perfect’ model. Therefore, any design based on simplified models will be over-dimensioned, and subsequently using too much material.

In addition, the more accurate a simulation should be, or the bigger a part, the longer it takes to fully solve the simulation. It is important to point out that a change in the design of a part also requires a highly time consuming recalculation of the previous simulation efforts, thus hindering iterative, physical prototyping.

1.2. Motivation

Given the overview above, this time- and money-consuming approach is not ideal for quick testing of either the mechanical durability of a new part, or the physical feeling thereof. Being able to rapidly prototype an injection molded part therefore helps on multiple levels: Since design-build-test-cycles help to rapidly improve the design during the product development process [9,10], companies should not be waiting for months between two iterations. Furthermore, addressing the different *characteristics* of prototypes, as [11] describes it, means that they have to answer a variety of questions. While including the final materials is not essential at the very beginning of the design phase, it becomes highly important when one wants to test the haptic sensations or ergonomics of e.g. a chair, and how much the backrest should flex, which cannot be replicated by additively manufactured parts. This is not just a mechanical stability issue, but also a user interaction on multiple levels. Quantifying these interactions in detail is still not possible, and subject to research [12,13]. [14] states that *'[...] only pre-production or prototype molding techniques provide true to life information on product performance, moldability, and dimensional tolerances.'* Enabling an iterative test environment with such high-end parts means that the company can rapidly improve their designs based on user experience, in order to not just meet, but exceed their customer's needs.

Another important factor is the ability to dimension a part to the exact needs. For a company that is striving for light and robust designs from recycled PP it becomes crucial to know the exact required dimensions, and not have an over-dimensioned part. This is not only important from a financial standpoint of view, where 1% material savings are directly translated into saving costs, but also from an environmental standpoint of view since being able to exclusively use recycled PP and only the perfect amounts thereof allows for a more sustainable production, and company image.

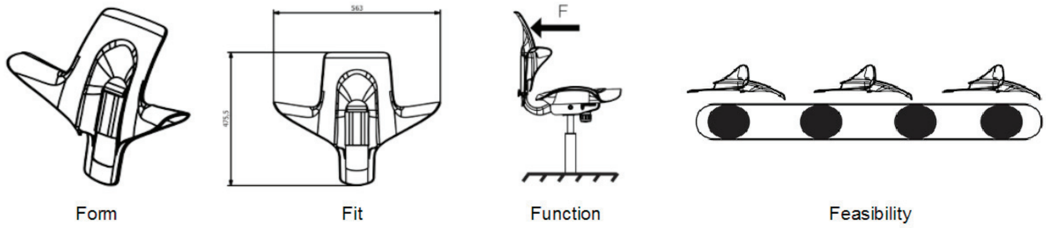
1.3. Method

Following the wayfaring model [15] the project had a focus on prototyping mass manufacturing and iteratively adapting to emerging requirements. A previous publication on this project described the relation between the wayfaring model and this project in detail [16]. We are aware that there is a wealth of ongoing work regarding 3D printing molds, or Direct Rapid Tooling, and some successful attempts have been reported [17,18,19]. However, our contribution is not to claim the best 3D printing or tooling method to produce 1000 parts. The focus lies on the experimental results, and on the low-cost approach that lead to 1-2 very successful prototypes that enable fast (<1 week) iterations regarding design changes. We believe that it is important to raise the awareness of the community that mass manufacturing can be prototyped in a relatively easy and cheap way.

2. Prototyping plastic components

Prototyping plastic components for furniture means prototyping on two levels: On the design side, one has to develop a form and a fit, or in other words a design, with specific dimensions. Prototyping of these two factors can easily be done digitally or analogue, by drawing the parts in a CAD program or simply creating them with soft prototyping materials, e.g. cardboard. More high-end models in the later stage of product development can be done by CNC milling and subsequently checking if the dimensions fit eventual neighboring parts.

On the material side, one has to develop and prototype the function and feasibility: For example, a backrest of a chair is not just a visually important object, the user of the chair is also actively interacting with it. It has to feel comfortable and absorb an eventual fall, which gives certain limitations when it comes to material choices. The feasibility comes from the design constraints given by the production method (see section 1.1), and cost efficiency. Fig. 1. visually describes the 'four Fs'.



Form Fit Function Feasibility

Fig. 1. The 'four Fs' that a plastic prototype should address.

2.1. Desktop injection molding machine

Given the difficulties elaborated above, it was decided to find a solution for the challenges of prototyping plastic components. While there were injection molding machines standing around on campus, administrative obstacles made it impossible to get the easy access required in order to apply an iterative prototyping mind-set. Subsequently, we explored the possibility of building a desktop injection molding machine that yielded in the design that is shown in Fig. 2. The development process is described in [16].

2.2. Prototyping molds

While it is nowhere near the pressure and accuracy levels of an industrial machine, it quickly became obvious that the desktop injection molding machine opens the possibility for investigating how to rapidly prototype injection molded parts. Since the issue for SBS is the time and money used in machining the molds, and the unpredictability of the process, the focus was on exploring cheap and rapidly available manufacturing processes and comparing the quality of the outcome from using these molds on the desktop injection molding machine.

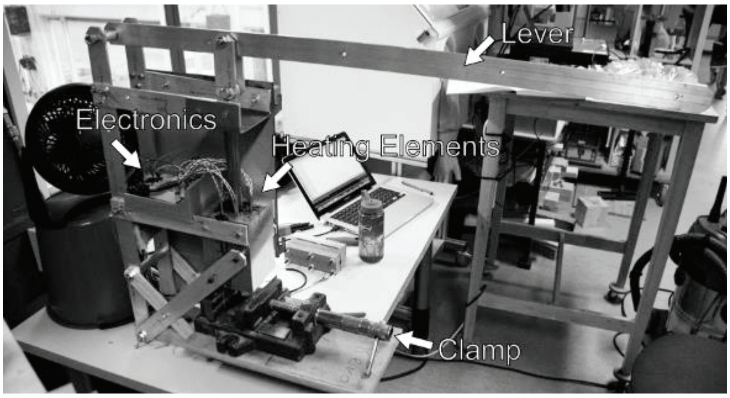


Fig. 2. The desktop injection molding machine in use: Clearly visible are the heating elements and the electronics, as well as the clamp for holding the molds. The long lever is for manually injecting the molten plastics.

3. Small scale test piece

The first test part that was reproduced is a lever from the HÅG Capisco Pulse chair (HÅG, Oslo, Norway), see Fig. 3. The goal was to compare the results from an FEA simulation to those of a three-point bending test, conducted with levers that were made with the desktop injection molding machine. The lever is a good example of both, a functional part, and an interaction point between the user and the chair. With its small size and relatively simple geometry, it offered a great starting point for exploring a variety of mold materials. The mold itself was modelled in Siemens NX9 (Siemens, Berlin, GER). The molds and materials that are highlighted below are the ones that lead to a testable result. The failed attempts and explored dead ends are left out due to limited space.

3.1. Production methods

For producing the molds, all the 3D printers and the benchtop CNC mill available in our research space, TrollLABS, as well as one externally sourced 3D printer were used. The machines as well as the materials that were used are listed in Table 1. The big challenge with cheap materials is that they are often soft, when compared to high quality metals. Since injection molding requires hard and smooth surfaces, the possibilities of coating the molds in order to improve the surface properties in respect to mechanical strength, as well keeping the molten thermoplastic from sticking to the mold, were explored. The successfully applied coatings were the epoxy West Systems 105, as well as the release agent Renlease QV 5110.

Table 1. Overview of the machines and according materials used for making the molds.

Type	Producer and Model	Materials
CNC Mill	Roland MDX-540 (Roland DGA, Irvine, CA, USA)	Wood (Red Oak) High Density Polyurethane (HDPU) Foam Aluminium (AA 6082-T6)
3D Printer (Sintering)	Blueprinter SHS (Blueprinter, Copenhagen, DK – Discontinued)	Nylon powder (Monochrome White)
3D Printer (Polymer Jetting)	Objet Eden 250 (Stratasys, Eden Prairie, MN, USA)	Photosensitive Polymer (VeroBlackPlus)
3D Printer (Fused Deposition Modelling)	Ultimaker 2 (Ultimaker, Geldermalsen, NED)	Polylactic Acid (PLA) Acrylonitrile Butadiene Styrene (ABS) Alloy 910 (Polymer Composite Filament)
3D Printer (Laminated Object)	MCOR Iris (Mcor Technologies, Co. Louth, IRL)	Paper (A4 office paper)
Epoxy	West Systems 105 (Gougeon Brothers, Inc, Bay City, MI, USA)	-
Release Agent	Renlease QV 5110 (Huntsman, The Woodlands, TX, USA)	-

3.2. Procedure

The individual molds were coated with the release agent and in some cases Epoxy. Upon drying, the mold was closed by eight bolts and, by the help of a mechanical clamp, pushed against the extrusion nozzle under the desktop injection molding machine. The PP granulate was heated to 230°C within the injection chamber and manually injected into the mold. The full set up in use can also be seen Fig. 2. Only the aluminum mold required pre-heating due to the very high heat conductivity and subsequent early solidification of the molten plastic. The final production step was to remove the cooled plastic parts from the mold. There was no post-treatment.

3.3. Three-point bending test

A common test to assess the strength of materials is the three-point bending test: A hydraulic press applies force to a part that is supported on two points. The resulting displacement is an indicator for the mechanical strength of the part. The test setup can be seen in Fig. 3. The max. displacement was 30mm at a rate of 3mm/s.

3.3.1. Simulation

In order to compare the test results to a reference value, a nonlinear simulation of the same test in ABAQUS (Dassault Systems, Vélizy-Villacoublay, FR) was conducted. The applied mesh was a tetrahedral mesh for the part, and a hexahedral mesh of size 0.9mm for the pin that was modelled with linear elastic isotropic steel properties (Young’s modulus 210’000MPa, Poisson’s ratio 0.3). The plastic lever was assigned linear elastic and nonlinear plastic isotropic properties, where the material data was based on tensile testing of polypropylene specimens (Young’s modulus 1600MPa, Poisson’s ratio 0.38) [20]. Without going into more detail regarding the simulation, it is important to highlight that the finite element model does not account for failure modes such as fracture, and therefore showed theoretical results throughout the entire enforced displacement.

3.3.2. Results

The plot in Fig. 3. shows the detailed results of the three-point bending test in comparison with the finite element simulation. Details about the mold materials are listed above in Table 1. All samples showed voids in the fracture surface and are made of PP. Due to different materials and a slightly different geometry (not completely filled, unlike the sample specimens), the original lever is not listed in the results.

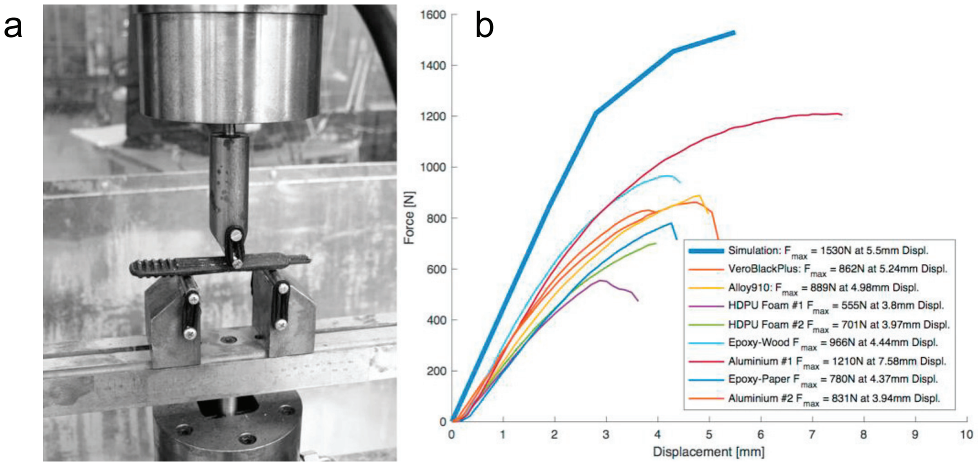


Fig. 3. (a) One of the levers in the three-point bending test setup; (b) Displacement vs. force plot of the three-point bending tests on the levers.

4. Full-scale test piece

While the hand injected parts showed some shortcomings, they were still of surprisingly good quality, given the crude desktop injection molding machine at hand. Based on the findings from the small samples, it was decided to select and test a big, complex part. The aim was to use one of the more successful direct rapid tooling approaches, and try the mold on a full-scale, industrial sized injection molding machine at OM BE Plasts (OM BE Plasts AS, Sellebakk, NO). While Aluminum showed the best test results, the earlier findings also showcased how simply a hard, smooth surface can deliver great results.

4.1. Test piece and test run

The part for the full-scale test was a quite complex and large (327x90x26mm) headrest from the Håg Sofi chair, as it can be seen in Fig. 4. Design features include ribs, bosses, radii, and holes. The large size of the part made it necessary to use the CNC mill and not an additive manufacturing method. The tool insert approach imposed several constraints and more sophisticated features, like holes for the ejector pins. While both, epoxy coated HDPU foam and epoxy coated wood showed good results as mold material, the anisotropy and high sensitivity to moisture of wood gave the upper hand to HDPU foam. Once the two halves of the mold were machined, they were coated with a very low viscosity epoxy, namely Hexion Epikote Resin MGS RIMR135 (Hexion, Columbus, OH, USA), and Hexion Epikote MGS RIMH137 curing agent. The mixing ratio was 100 weight units resin to 30 weight units hardener. The mixed solution was degassed and the coated mold halves were cured in an oven at 60°C for 8 hours. The total production time for the complete mold (excluding CAD modelling) was around three days. The final mold is depicted in Fig. 4. The full-scale trial molding consisted of two injection shots with low viscosity polypropylene of type 401-CB50: cylinder temperature 190°C; injection time 3.55s; post-filling time 5s; cooling time 30s (1st shot) / 120s (2nd shot); clamping force 800kN; injection pressure 100Bar.

4.2. Outcome

In the first attempt, too little resin was injected to completely fill the part. However, except for the very outer ends, all geometry features were well captured. Upon ejection, some of the thicker areas had not yet frozen, and subsequently the geometry of these areas was affected. Otherwise, the general surface finish was excellent when comparing to parts made in a steel mold. The mold was completely intact after the first attempt, and was reusable. For the second attempt, more resin was injected as an attempt to fill the entire part. Unfortunately, the increased volume put too much pressure on the mold, which caused some features to break off. Fig. 4. shows the results from both attempts.

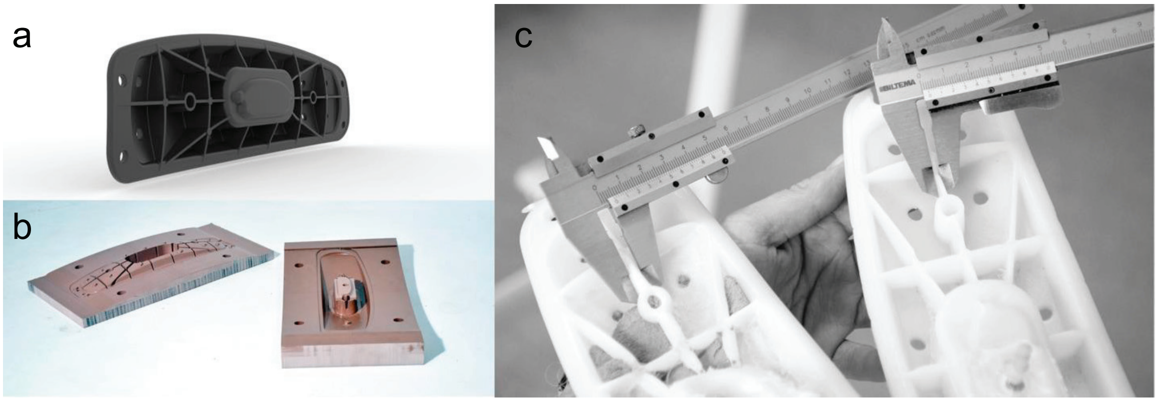


Fig. 4. (a) Rendering of the headrest; (b) the finished molds; (c) the results from the two attempts. The second shot (left) broke the mould due to excess material being injected, the first shot (right) showed very good features.

5. Discussion

The needs that are stated in the introduction are in respect to early stage prototyping and the fuzzy front end product development. While there is still a lot of work to be done in that direction, we contribute a case study that supports prototyping of plastic parts.

The eight small-scale tests are by far not of a statistically relevant sample size, especially since most of them were done in different mold materials. They do, however, give a good first indication of using a desktop injection molding machine. While the machine has some shortcomings with respect to controllability of the injection process per se, it provided sufficient pressure and power for making dozens of small levers (only the most successful attempts were listed in this article).

With respect to the three-point bending test, it was striking that all samples showed cavities of various sizes. This is probably connected to the limited injection pressure of the hand powered device. A more powerful, automatic injection machine would most likely provide much better results. The simulation gives a good indicator for the physical samples, although it did not take fractures into account. One can see that the maximum load of the best sample cracks at 79% of the maximum load in the simulation data (Aluminum #1 at 1210N, vs. 1530N in the simulation). Again, a more consistent and powerful machine could bring the curves even closer together.

While the full-scale part was based on the learnings from the explorative work on the small levers, it provided results of surprising qualities. Despite breaking after two shots, it gave valuable insights into the potential of this approach. Both, us, and the operators of the machine did not anticipate the large differences to a steel mold when it comes to thermodynamic behavior of the mold. Furthermore, the operator did not get enough tries in order to get the right amount of material per shot. Based on the statements of the operator, these shortcomings are possible to overcome if there is the possibility to do more test-runs on this part. Given the production time, it is reasonable to assume a potential of 1-2 full scale tests within one week, for a large, complex part.

5.1. Prototyping – not producing – on a desktop

As stated at the beginning, the aim of this experiment was to find a way to enable rapid, iterative prototyping of injection molded parts – not to find a way of mass producing on a desktop. Although the small levers did not deliver any data for statistical analysis, the full-scale test would not have been possible without the learnings from them. Furthermore, the full-scale test showed that it is possible to prototype injection molding: By making mold(s) from cheap materials, and using them on a regular injection molding machine, one can prototype, and test the plastic parts. Rapid and frequent design changes are no longer equal to high costs, but can be encouraged. This means that future products can not only make use of prototyping as a tool to improve the user experience, and overall outcome. It is also as a mean of exploring the limits of material savings and the implementation of materials that are extremely difficult to predict in simulations, such as recycled PP. If a company with a much broader experience and machine pool follows the same approach, prototyping – not mass production – of injection molding is possible in-house. While it eventually takes an initial investment for the machines, the prospect of 1-2 full scale tests within one week and subsequent material and design optimizations build a strong argument. Furthermore, it greatly reduces the risk of erroneous mold design, and therefore high costs and long production delays. Also, one should explore the possibilities of combining simulations with physical prototypes, as described in [8] in the case of a rotary spring. The work presented here was done by one master student within six months. Further work will hopefully reveal more mold materials and simple injection molding techniques.

Acknowledgments

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Appendix H

Contribution 6: Interaction in a World of Intelligent Products - A Case Study of a Smart and Learning Office Chair

The Fourth International Conference on Design Creativity (4th ICDC)
Atlanta, GA, November 2nd-4th, 2016

INTERACTIONS IN A WORLD OF INTELLIGENT PRODUCTS - A CASE STUDY OF A SMART AND LEARNING OFFICE CHAIR

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Abstract: This paper presents challenges associated with developing Smart, Learning, and Physically Adapting products. Until now, smart products mainly collects user data and digitally adapts user interfaces and information feedback loops from the data-analysis. This paper is focused on the next stage of smart products, where products are additionally physically acting on detected user behaviour. It presents an applied case, where an office chair was equipped with pressure sensors. We demonstrate concrete examples of how users in the future could interact with what we see as a new generation of smart products. Additionally, we bring the theme to a general level by discussing the challenges for designers to consider when designing the next generation of smart products.

Keywords: *smart products, interactions, machine learning*

1. Introduction

This paper presents an applied case of the new interactions in the context of Smart, Learning and Physically Adapting products (SLPA-products). Recent progress in sensor technology and software opens up for new possibilities in smart product behaviour. By showing the case of CH.AI.R - a normal office chair with ten pressure sensors and applied machine learning principles, we provide a concrete example of how users in the future would interact with SLPA-products.

We will use the definition of smart products described by Dawid et al. (2016) which covers; consumer products that are equipped with intelligence-generating technologies including (i) sensors and/or actuation, either to gather data from the environment or to use the data to change the environment, (ii) computing power for data analysis, and (iii) optional interfaces to exchange information with their environment. In the field of Human-Computer-Interaction (HCI) we have seen several examples of software and interfaces adapting to the user (Alonso, Hummels, Keyson, & Hekkert, 2013; Carenini et al., 2014, 2014). However, despite the inclusion of actuation, most research and applications in the field of *physical* smart products are usually limited to products adapting and tracking ambient surroundings rather than actual user behaviour. This is the case of the Nest Thermostate (Hernandez, Arias, Buentello, & Jin, 2014; Yang & Newman, 2013), Service Robots (Cheng et al., 2015), and Smart Fridge (Dawid et al., 2016). Actually, only few examples can be found of products that through smart technologies and machine learning principles actively engage with and physically adapt to the user (Dawid et al., 2016; Stumpf et al., 2009). Vallgarda, Winther, Mørch, & Vizer (2015) is an inspiring example on temporal interfaces that physically changes according to user behaviour. They design several different physical interfaces that changes when a user interact with the object. This research remains on an explorative level and not an applied example of physically adapting products. Hence, the scope of this paper is to provide actual examples of the new possibilities of user interaction with SLPA-products by starting with the case of CH.AI.R.

Dawid et al. (2016) stress the importance of addressing the development of new smart products from a user-centered perspective in order to fully grasp the utility of the smart technology applied. To embrace this suggestion we also investigated the current intended office chair usage by analysing two types of instruction material designed for the chair. We chose the User Journey method in order to illustrate the human-product interaction in this case, as it is well suited to pinpoint distinct moments that are ripe for redesign or improvement (Martin & Hanington, 2012).

We begin this work by highlighting recent examples of SLPA-product strategies and applications. In addition, we describe relevant user interactions deduced from the analysis of two types of instruction material for the office chair. With the insights from recent products and current instruction material, we discuss the difference between the old and new user journeys in the context of CH.AI.R. Finally, we conclude the paper by highlighting the opportunities and challenges designers face when designing future interactions between humans and this next generation of smart products.

2. The Car Telling you: “It’s coffee time” and three Other Recent Examples

In the first part of the analysis we describe four cases, all involving the use of smart sensors and some utilizing machine learning principles.

The goal of the Volkswagen™ Driver Alert System (Driver Alert System, 2016) is to measure and track driving patterns in order to be able to identify abnormal driving patterns indicating user fatigue. The system establishes normal driver behaviour by monitoring the user over a time period of 15 minutes during the beginning of a trip when vehicle speed is above 40 mph. The driver gets an audio-based alarm and a pictogram of a coffee cup on the dashboard that suggest the driver to take a break upon detection of erratic behaviour. This works under the assumption that the user is well rested and alert in the beginning, and fatigue increases over time. In this case the aim of the data monitoring and following feedback is to make users change their behaviour and drive more safely.

Stienstra, Alonso, Wensveen, & Kuenen (2012) describe the case of an affective pen designed to counteract stress related behaviour, such as nervous fidgeting, through changing the physical properties of a pen. The affective pen is able to detect what the authors call rocking and rolling motions, which is used as a proxy for nervous behaviour. One possibility to achieve this is through an inertial measurement unit (IMU) consisting of accelerometers, gyroscopes and potentially magnetometers. Based on the interpreted behaviour from the sensor input, the pen changes physical properties, such as rolling resistance, to speed up or slow down the pen movement speed. This is done without letting the user know about it, and is addressing behaviour on a subconscious level. By combining sensor data from pen movement and changing the physical properties of the pen, the goal of this case was to subconsciously alter user behaviour, reducing stress, through haptic feedback.

Activity monitors such as the Fitbit™ Alta (Fitbit™ Alta, 2016) represent an increasing industry of private consumer wearables. The Fitbit™ tries to counteract user inactivity by sending notifications through vibrations in the wristband as well as visual messages. Inactivity is measured through accelerometer data, and notifications are triggered when acceleration has been below a pre-defined threshold over a certain amount of time. The aim of the feedback is to make users change their behaviour in relation to health issues. In fact one of the main drivers or arguments from companies for buying such devices is the motivational factor. “Motivation is your best accessory” sounds the slogan of the Fitbit™

Alta and this premise is designed in the interaction with the products as well as allowing users to compete with each other in the fitbit community.

Suryadevara, Mukhopadhyay, Wang, & Rayudu (2013) present an indirect multi-input approach for measuring behaviour of elderly people through monitoring use of appliances as a predictor for regular or irregular behaviour. They collect data from appliances in the homes of elderly people and forming a pattern of “normal” activity to be compared with later behaviour patterns in order to detect anomalies. Ampere meters were used to detect the use of electrical appliances, and pressure sensors for non-electrical appliances, such as beds and chairs. In this case the aim of the data utilizations was to be able to make an external intervention to the tracked user by allowing health personal recognizing change of behaviour that could indicate more serious illnesses.

The examples above only in part utilize machine learning principles and physical adaptions. This incompleteness in regards of relevance to the CH.AI.R is due to a lack of relevant examples to be found in literature. This stresses the need for a better understanding of SLPA-product interactions. This knowledge will become even more relevant and saught after as our everyday lives will involve an increased amount of interactions with computers and robots (Kemp, Edsinger, & Torres-Jara, 2007). Even though the aforementioned examples only embody parts of SLPA-product functionalities, they serve as valuable input of strategies to use when designing new interactions between users and SLPA-products.

3. The CH.AI.R Project

In a student project the aim was to explore how one could measure human behaviour in relation to an office chair and which possibilities this information leads to. The chair was rigged with several pressure sensors and included machine learning principles for processing data that allowed the students to train the chair to identify and distinguish between different seating positions, as well as capturing how long a user would sit in different positions (See Figure 1). Eventually it is the ambition to have the chair take action based on user behaviour and physically adapt accordingly. This product idea will for future reference be called CH.AI.R.

In section 3.1. the current user journey of a “normal” chair is described. This is with the aim to identify new possible situations where CH.AI.R could have potential interactions. In section 3.2.-3.5. potentials of applications are explored and described by combining the learnings from the four recent examples and the use cases in the current user journey.

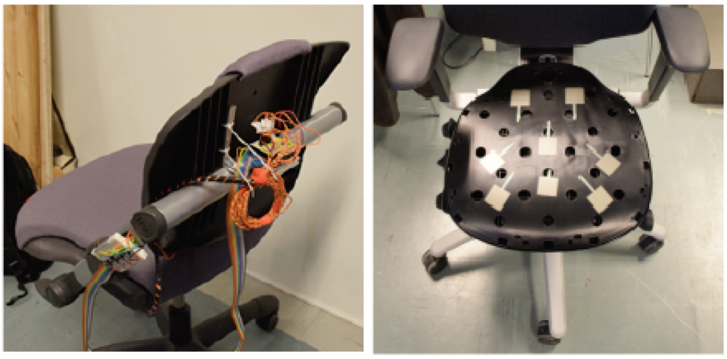


Figure 1 Pictures of CH.AI.R with sensors

3.1. Analysis of current instruction material

This section shows how current instruction manuals present intended user behaviour in the context of office chairs. This analysis is based on five instruction videos (22 min 4 sec) and five written manuals. When investigating the two different types of instruction manuals used in the case, three overall themes were dominant; ergonomics, usability and motivation for correct usage. These three topics will be shortly described in the following section.

Ergonomics This topic covers correct ergonomic sitting positions combined with how the chair supports them. Examples are; correct height of seat, correct support of lower back, correct positioning of neck rest and correct height of arm rests. In addition, external objects, such as the table height, also play a role when adjusting the correct sitting position. The information is communicated through correct angles and distances between user, chair, and table. One of the main ergonomic advices in the teaching material when it comes sitting is the mantra: The next position is the best position captured in the end of each instruction video:

"Sitting still will get you nowhere!"

Usability This topic covers the theme of how to make the chair support correct sitting positions, more specifically where the specific handles are to adjust eg. arm rests and seat in order for the chair to be in the correct position. Moreover, the instruction manuals seek to secure correct future usage by explaining the meaning of pictograms on the different handles.

Motivational Facts Finally, the instruction materials also contain motivational facts that inform the user why the correct sitting positions are important in a work context. On average there are seven pop-up boxes in a 5:30 minute long video. Mainly, there is one tip for each mentioned functionality.

The Current User Journey

By looking through the videos we got an insight in the product designers visions of the intended use of the office chair. These visions made us highlight four use cases from the current user journey: First, the user is being introduced to the chair. Second, the user is using the chair in an non-ideal way. Third, the user changes their sitting position. Fourth and final, the user is dissatisfied with the performance of the chair (See Figure 2).

In two out of four use cases we observed a possible touchpoint and interaction between the user and the chair. Still, this interaction is happening through a third media; the instruction materials. These interactions can in addition be considered as short-term individual interactions. Finally, we believe it is fair to argue that the user will only on rare occations refer to the instruction manuals after the initial setup. In this way the user is very rarely opposed to the hints of correct user behaviour and hence risk to use the chair in a ergonomically wrong way. Indeed, the overall user experience and emotional relation to the chair is at risk.

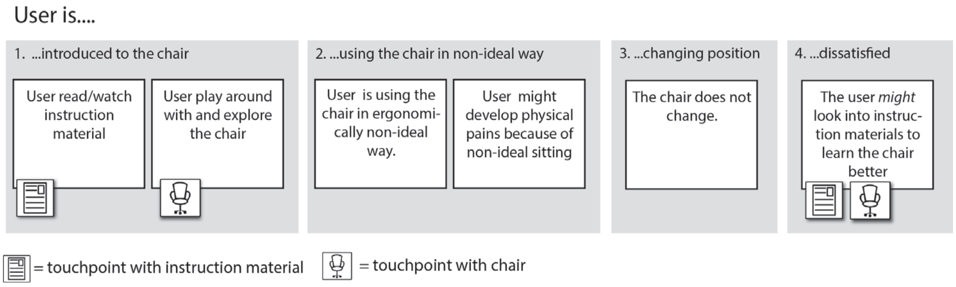
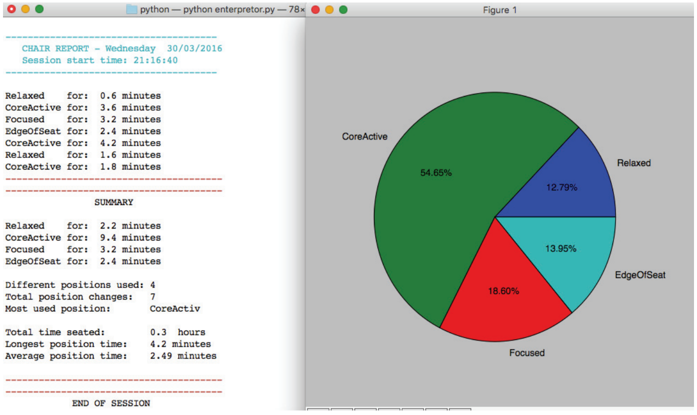


Figure 2 Four use cases from the current user journey

3.2. Possibilities for CH.AI.R and the Topic of Ergonomics - the Perfect Fit

CH.AI.R measures sitting behaviour through pressure distribution and subsequently has the possibility to distinguish between different sitting positions. This creates the obvious possibility of evaluating the users activities according to current ergonomic guidelines. This is similar to the context of the Volkswagen Driver Alert telling you to change your driving behaviour in order to drive more safely. The overall consequence would be less dramatic than a car crash, but rather focuses on the prevention of ailments and pains related to suboptimal sitting positions. In the case of the driver alert, the driving pattern of the user is evaluated through 15 minutes of tracking. Likewise in the case mentioned by Suryadevara et al. (2013), tracking the behaviour of elder people also utilizes time dependent data-tracking to detect irregular behaviour. By applying a similar long-term tracking strategy to CH.AI.R, it is able to map the length of timeperiods of sitting in different positions and suggests changing the sitting positions if a user has remained stationary for too long. Also, CH.AI.R is able to provide the user with a daily CH.AI.R report that summarize the daily usage of CH.AI.R (Figure 3).



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   CHAIR REPORT - Wednesday  30/03/2016
   Session start time: 21:16:40
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Relaxed    for:  0.6 minutes
CoreActive for:  3.6 minutes
Focused    for:  3.2 minutes
EdgeOfSeat for:  2.4 minutes
CoreActive for:  4.2 minutes
Relaxed    for:  1.6 minutes
CoreActive for:  1.8 minutes
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----------------------------------------
                SUMMARY

Relaxed    for:  2.2 minutes
CoreActive for:  9.4 minutes
Focused    for:  3.2 minutes
EdgeOfSeat for:  2.4 minutes

Different positions used: 4
Total position changes:   7
Most used position:       CoreActiv

Total time seated:        0.3  hours
Longest position time:    4.2 minutes
Average position time:    2.49 minutes

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            END OF SESSION
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Figure 3 CH.AI.R report summarizing sitting behavior

The multi-input approach used in the context of elderly could also be utilized with CH.AI.R. Several objects in addition to the chair influence ergonomics, such as work desks. A chair linked to surrounding objects could coordinate adjustments, so that the user does not have to make adjustments individually. In addition, the continuous data-tracking of the user provide a user specific data repostery, which could be utilized in new products with the benefit of already knowing the user.

3.3. Possibilities for CH.AI.R and the topic Usability - a future challenge

In our selected recent examples we only saw brief examples of adaptive behaviour in the case of the affective pen haptically interacting with the user. Due to this lack of examples one needs to ideate on solutions to make sure that CH.AI.R is used correctly. This could either be through communicating proposed changes to the user through ambient or more explicit communication and let the user adjust CH.AI.R, or use actuators to physically nudge the user into certain behaviours, or even make CH.AI.R adapt to the user instead of the other way around. We see the greatest potential in the latter and will deploy AI and machine learning principles to achieve these goals. By doing so, CH.AI.R could take the initiative to inform or adapt to the user based on learned user preferences or predefined suggestions on actions to be made. This would mean a shift of balance when in regard to whom will initiate interaction - the user or CH.AI.R.

3.4. Possibilities for CH.AI.R And The Topic Of Motivational Material - A Subjective Yet Relevant Matter

The motivational aspects of solutions such as the Fitbit^{TM} Alta reveal great opportunities for transforming the motivational material in the instruction material into physical and deliberate interactions with CH.AI.R. Indeed, in the context of CH.AI.R the frequency of such interventions could be considerably higher and the method applied much more intervening than from e.g. a Fitbit. Imagine a chair orally telling you to change position to increase the blood circulation in your legs, or a chair beginning to make an alarm sound when you have been sitting down for too long only stopping if you stand up from the chair for a certain amount of time. Although CH.AI.R would have new possibilities of interacting with the user we acknowledge the challenge of designing a supportive and interacting office chair without making it too intrusive.

3.5. The New User Journey with CH.AI.R

By going through the topics found in the analysis of existing instruction material we will now as a summary describe the use cases from Figure 2 in the context of CH.AI.R:

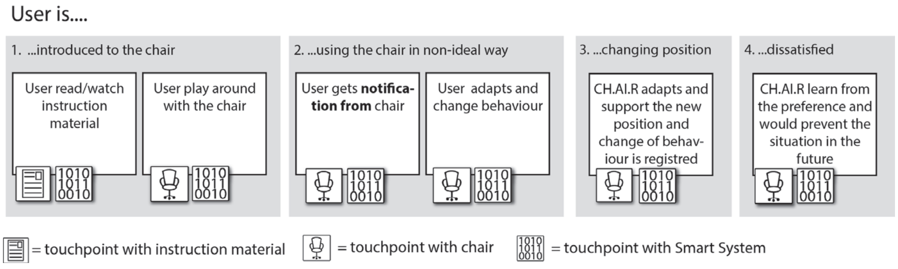

Figure 4 User Journey in the context of CH.AI.R

CH.AI.R transform previous short-term individual product interaction to a long term continuously evolving product-user dialogue. As one can see by comparing Figure 2 & 4 CH.AI.R gives the possibility to interact with the user continously throughout the user journey by increasing the amount of opportunities for interaction between the chair and the user. This is illustrated by the increase of touchpoints between user and CH.AI.R ("Chair" Icon in Figure 2 & 4) as well as Smart System ("Smart System" icon in Figure 4). Most radically, CH.AI.R has the ability to initiate interaction, which is fundamentally different from previous use case (See Use Case 2 in Figure 2 & 4).

4. New Challenges followed by the adoption of SLPA-products

To end this paper we adopt a wider perspective on the context of SLPA-products in general, stressing the challenges and opportunities future designers will face. The following topics will be discussed in this section: Firstly, how to design learning and supportive, yet non-intrusive products. Secondly, considerations on the level of adaptations. Lastly, ethical issues concerning tracking data of human behaviour.

4.1. A Thin Line Between Informing and Intrusive

By intelligently analysing and utilizing the data, SLPA-products can bring customization to a new level and create seamless, tailored experiences. Still, Desmet & Hekkert, (2007) suggest that in order for a user to build up positive emotional relations to a product, there has to be an actual physical interaction or event for the user to actively interpret as either positive or negative. Hence, when it comes to building up a positive emotional relation to SLPA-products, one could argue that a designer should not aim for a perfectly "invisibly" adapting product. This might risk that the user will not be aware of the intelligence of the product, and thus not build any conscious relationship between user and product, potentially not attributing appropriate user value. Another huge challenge is to know whether, and how to address the user on a conscious or subconscious level. Maybe this decision can be left to Artificial Intelligence.

Some research experiments investigate the influence of disturbances from other software platforms eg. email-clients when programmers are working (Addas & Pinsonneault, 2015; Camacho, Hassanein, & Head, 2015; Levy, Rafaeli, & Ariel, 2016). This research focuses mainly on work performance. In the new context of SLPA-products, questions should be directed towards the actual user experience of the product. What defines the fine line between disturbing the user, and providing useful information or adaption?

4.2. Adapting New World

In a world of SLPA-products the designer must decide on which data foundation to base product adaptions. Should adaption be based on short-term interactions with the product, or should adaption be based on historical data containing user behaviour and preferences? Additionally, products could share data among themselves to leverage their individual strengths in a collective optimal way.

Furthermore, the designer needs to have the overall reasoning of product adaption in mind. Are one trying to create an indivudal perfect user-experience or is one trying to make an overall process more efficient? These considerations should be taken into account to design the best possible solution, and naturally leads to the ethical discussion below.

4.3. Ethical Considerations When Tracking Data

An important topic to consider when designing SLPA-products is the ethical treatment of data-collection, transfer, and usage. The question of transparency of data tracking and utilization is already a hot topic in existing academic discussions (Miorandi, Sicari, De Pellegrini, & Chlamtac, 2012; Van Kranenburg & Bassi, 2012; Weber, 2010). It is fair to believe that the world of a private consumer will be involving even more sensors and datatrackers in the years to come which will increase the complexity and lack of clearness of data-collection methods and user privacy. It is a real dilemma since data-collection becomes essential for the user experience, which demand the user to accept the data-tracking to get the intended user-experience. Therefore future designers need to consider carefully how to make users aware and still accept the data tracking, e.g. by having them accept license-agreements for products or for users to accept push-notifications from their office chair.

5. Conclusion

In this work we cover the lack of applied examples of Smart, Learning and physically Adapting products by describing the case of CH.AI.R - an advanced office chair applied with pressure sensors allowing the chair to learn and adapt to the users sitting behaviour. By also analysing the old intended user context through two different types of instruction materials, we map the old and new user journey of the digitalized office chair. The key difference from previous use cases is that CH.AI.R allow continuous long term and customized interactions with the user. Furthermore, CH.AI.R would be able to initiate interactions itself, which is fundamentally different from the current use-case where the user has to start the interaction. This finding is not in particular limited to CH.AI.R, but will be the case of several future SLPA-products. We embrace this disruption of human-product interaction with great expectations and potentials. However, several challenges should be addressed by designers in the future when designing SLPA-products. These concern useful vs. intrusive product initiated interactions; the level of product adaption, and finally ethical consideration on data tracking and sharing from users. The next step in our research is to explore these questions more thorugh by allowing CH.AI.R to make suggestions to the user, or even by CH.AI.R adapting by itself. With this work and experiment we intend to start a discussion regarding the future of human-product interactions in the context of SLPA-products.

Acknowledgment

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Appendix I

Contribution 7: From the Eyes of the Patient - Real Time Gaze Control of Medical Training Mannequins

Appendix J

Contribution 8: Experiences from a Positivistic Way of Teaching in the Fuzzy Front End

INTERNATIONAL CONFERENCE ON ENGINEERING AND PRODUCT DESIGN EDUCATION
6 & 7 SEPTEMBER 2018, DYSON SCHOOL OF DESIGN ENGINEERING, IMPERIAL COLLEGE, LONDON, UNITED KINGDOM

EXPERIENCES FROM A POSITIVISTIC WAY OF TEACHING IN THE FUZZY FRONT END

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ABSTRACT

This paper presents a project based graduate course in early stage product development called Fuzzy Front End. Based on a brief theory-based perspective and data from student interviews as well as stakeholders we provide a discussion ground for the format of the course. The main goal of the course is to educate confident engineers by providing a complete experience of an early stage product development process with all its positive and negative facets. Our findings indicate that the course provides strong motivational factors, as well as a collaborative mind-set amongst the teams that creates a motivational atmosphere for high quality project-outcomes. This insight is the starting point for highlighting shortcomings of a competition-based course format and discussing a potential alternative.

Keywords: Fuzzy Front End, Competition, Project-Based Education, Product Development

1 INTRODUCTION

Competitions and rivalry have throughout the human history driven innovation and pushed boundaries. In a learning context, competitions have become quite common and they create a lot of excitement and enthusiasm among students. In the engineering educational realm, there are many types of competitions present. Some may take place in the classroom or within small local groups, others are international competitions where student teams from different universities compete in various technical disciplines. Competitions as a pedagogical tool can be seen as a positive thing as it motivates effort or trains students for a potentially competitive career. However, it can also be seen as a problematic educational framing, as it dissuades cooperation and creates clear losers. Nevertheless, it would be interesting to reap the benefits from both camps: Present a motivating challenge which encourages extra effort without treading on classmates. Speaking from an educator's standpoint, we would prefer to see our students help, support and learn from each other rather than withhold information, denying access, and lose self-confidence.

This paper presents a graduate course in early stage product development, which is motivated by, among other things, this idea about competing without creating losers. Other aspects of our pedagogical perspectives spring from project-based learning, experiential learning and creative confidence/self-efficacy. The research question for this paper is about understanding if the applied methods, specifically the focus on wayfaring and SCRUM-like reflections, give the intended experiences to the students when they are tackling real stakeholder's challenges. The results provide discussion input for other educators.

The course in question is a one semester product development course where selected students are working on challenges from companies and research groups. Each project is tackled by a group of maximum three students, subsequently limiting the number of participants to ca. 25 students. Section 3 describes the course in more detail.

2 THEORY

There is little doubt in the field of engineering education that practical experience is of high value [1], [2], [3], and that motivation for the students during these often more labour-intensive teaching styles is crucial. One way of achieving this is through competitions, which is a regularly used tool [4], [5]. Common reasons for arranging competitions is that they are motivating and spark interest amongst the participants [4]. There are, however, also researchers that highlight certain negative effects from learning in a competitive setting [6]. Competitions essentially mean that someone wins, and someone loses, success is therefore always experienced at someone else's expense. The winners might experience a boosted self-confidence, while the losers might have theirs reduced, according to Chan and Lam [7].

Bandura's concept of self-efficacy, says that a belief in your own abilities is created from experiencing success and getting positive feedback [8]. Laws has shown the power of self-efficacy in his research of creative self-efficacy, where the performance of R&D scientists was directly connected to their creative self-efficacy [9]. Elms also show that self-esteem is a valuable attribute for an effective engineer to have [10]. Cooperative learning activities are also highlighted as something educators should strive for [11]. In terms of creating motivating learning experiences, there are indications that letting students play with their imagination while encouraging them to build something functional is a great place to start [12].

2.1 Design methodology

Educating design engineers also entails a need to address the choice of methodology. Since all projects in the course are, as we call it, pre-phase 0 projects, when comparing it to the product development phases as described by Ulrich and Eppinger [13], they offer a shear infinite solution space for exploration. The three methodological corner stones that the students follow are as follows:

Firstly, the perspective on early stage development focuses on agile methods, and the authors attempt to make the students work according to the principles for a SCRUM sprint [14], not unlike the work shown by Grimheden [15]. In this course, the implementation of SCRUM is somewhat less rigorous, as some formal steps are left out, such as having a scrum-master. The backlog is kept by the student teams on a project wiki, and weekly scrum sessions are scheduled in the course.

Secondly, the overall approach to the early stage of design is represented in the Wayfaring model [16] [17], where design teams work with short sprints and explore the projects facets in an opportunistic hunter-gatherer style. This should not be confused with a trial and error approach, sine each sprint consists of design probes that answer specific questions about one specific aspect of the project. The subsequent steps are based on these previous experiences. Since each sprint is short (<1 day), and potential time loss is small, the teams can afford to investigate the project with extreme freedom. Figure 1 shows a graphical illustration of the approach. The outcome of this method is a functional prototype that can be used as inputs and requirements for the following phases, e.g. as listed in [13].

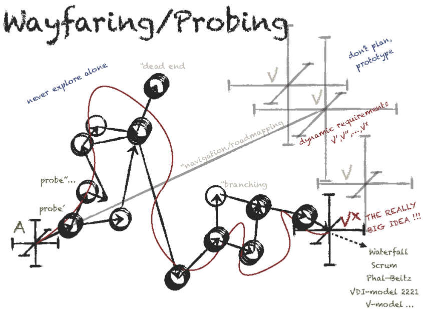

Figure 1. Concept development journey based on the wayfaring model [17]

Lastly, a strong emphasize is placed on bias towards action, and to actively use prototypes throughout the whole process [18]. Prototyping is a helpful method in order to quickly being able to test your ideas and bring the project forward [19], [13], [20], they also help the teams focus their discussion on a common ground.

3 FUZZY FRONT END

The course Fuzzy Front End (FFE) is currently running for the 5th time and is heavily integrated in the physical, and mental context of our product development laboratory TrollLABS at the Norwegian

University of Science and Technology. Below, a short description of the course is given; who is taking part, and what the students are learning and achieving.

3.1 TrollLABS

Inspired from other product development labs like Stanford's d.school, Aalto University's Design Factory, and the Silicon Valley's Maker Movement, our early stage product development lab was founded in 2014. By providing tools, machinery, and materials for creating prototypes of various levels of complexity, the overarching goal is to create an environment for both, project work, and research based on the applied methods and outcomes. The very mobile setup of the machinery, as well as furniture allows for rapid, iterative adjustments of the layout in order to address emerging usage patterns and shortcomings thereof.

3.2 Educational Context

Within the FFE course the focus lies on the project work of the students and that they spend as much time as possible working on them. However, a fundamental understanding of the core ideas of the wayfaring method is necessary. Subsequently, students are preferably selected amongst the graduates of a previous course called Innovation by Design Thinking, which teaches the essential skills needed for applying the wayfaring method: Design Thinking, prototyping, iterating. Further down the road, the most promising students of the FFE course are invited to write their pre-master and master thesis within TrollLABS and related projects. The final subsequent step is to become a PhD student as part of our research group. ***Figure*** 2 displays the hierarchy of the courses mentioned.

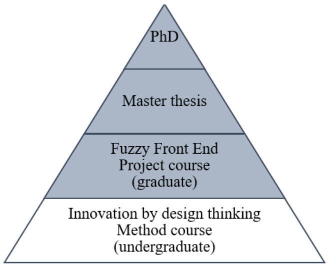

Figure 2. The TrollLABS research group educational path. Grey fields indicate access to the prototyping laboratory

3.3 Fuzzy Front End Course

The FFE course is at graduate level and focuses on project work, where the challenges are proposed by both, industry and research. Both contributors present real problems from their day-to-day activities with a focus on future products. It awards 7.5 ECTS and the official teaching time consists of two afternoon sessions over the week. The challenges provide a clear goal, but no clear path to it. Each project is independent and tackled by teams of three students, which also defines the maximum number of participants (usually 8-9 teams). In addition, each team has a coach (PhDs and Master students) who provides guiding and advice to the team but does not do any actual project work.

Over the first three weeks of the course, initial lectures and project assignment takes place. During these weeks, the course mainly consists of introducing various PD methods that could be of use for the teams. Once the introductions are complete, the teams gradually focus more on their project work. In addition, the teams have to step on a stage every Friday and present their prototypes, progress, problems, and challenges to the whole class. Similar to a SCRUM session, these presentations force the teams to reflect on their current status, where they are heading over the next week, and it gives the opportunity to tap into knowledge of the classmates. Furthermore, it exposes all students to the progress of the other teams. At the end of the semester, all stakeholders are invited to partake in the final presentations of the projects and discuss the results with the students, in some cases this is the first time they see the results in any shape or form.

In accordance with the Wayfaring model, the projects can be roughly divided into three phases: One, the problem space is explored. Two, potential solutions are iterated and tested, subsequently reducing the solution space to the point where one fully functional prototype is built in the last and third phase.

The main deliverable of the course is a functioning prototype that is presented at the final event. Other course deliverables are short weekly quizzes, a short paper, as well as a project report.

Due to space limitations, and the poor justification of project results in pictures, Figure 3 provides a QR code and the embedded link to videos from the project demonstrations of the last two years.

Figure 3. Online link to videos from project presentation.

4 PROBING THE COURSE

While the intentions from an educator's point of view are clear, it is – in accordance with the wayfaring model – essential to probe, and potentially iterate the course setup. With respect to the descriptions of competitions in section 2, the following two questions are the most interesting to evaluate: Do the students experience positive motivation without seeing clear losers throughout the course? And is the course creating useful output for the stakeholders, similar to a competition?

The purely qualitative data is based on feedback from stakeholders, as well as on the inputs from graduates of the course, in the form of three semi-structured interviews.

4.1 Student interviews

All three students that were interviewed are currently working on their master thesis within the research group and they took the FFE course one year ago. All three are male and among the higher achievers from the course. The interviewees were chosen due to availability, they did, however, exhibit quite different personality types. One being a tinkerer and hobbyist character, one a more traditional engineering type comfortable with defined tasks and one more of the artistic type. Two of the students have been following a 5-year integrated master-program with the department and the third one is on a two-year master's program.

The semi-structured interviews were conducted around the following three main topics: 1) How do you think back on the course? What memory stands out? 2) What do you remember about the project process? 3) How do you remember the Friday sessions?

At the end of the interview, the interviewees were also asked if they would recommend the course to someone else.

Our main objective was to investigate the value of these Friday-sessions in light of how they affected the project process and outcome, specifically when comparing to the motivational factor of competitions. Did they help the students identify the value of their ideas, did the presentation of their project initiate or facilitate reflection, or was it a stressful exposure?

4.2 Results

All three interviewees think back on the course as being very work intensive, while also being fun. The high workload is said to be mainly self-induced. The reasons for this internal drive varied: One stated a motivation to do well in the aspects of the course the student experienced as being influential on their grade, and two mentioned an internal motivation for presenting "something cool" every Friday. All students also saw each Friday-session as a deadline, which acted as a driving force for maintaining a high level of effort to produce prototypes and tests. The three interviewees also mentioned a prestige in presenting "something cool" to the other students.

When asked about the project process and the Friday sessions, the interviewees have fewer instant recollections. However, talking about the subject, several interesting aspects emerged: The value of getting feedback from the community; how the community can act as an "immune system" in terms of judging ideas and concepts. One interviewee mentions that he receives comments and feedback on his project more constructively now than before. One interviewee identified a synergy effect from the Friday-sessions, where groups could learn from each other. Since all project-teams were working on different projects, nobody was afraid to share insights and valuable methods with the others. This helped create a community feeling with a helpful and opportunistic atmosphere. The fact that PhD- and master students also take part in the Friday-sessions helped to strengthen this community-feeling.

In fact, one interviewee makes a point of how motivating it is to see the other teams succeed with their project.

An unexpected outcome from the interviews is the value this course has as an introduction to the community of the research group. The authors have been a part of the group from the beginning and have had little experience with how it is to join from the outside. The interviewees all identified themselves as novices in the group during their time in the FFE course. Now that they are working on their master-theses in the same group, they consciously take on the role as tutors for the current FFE class, as they themselves were assisted last year. Helping with introductions to the tools and machinery in our prototyping laboratory, as well as discussing projects and ideas.

Regarding facilitation and motivating mechanisms in the course, one interviewee specifically identifies the professor as an important factor. At least in the beginning of the course, presentations are mainly done addressed to him. However, later in the semester the value of having the community of the class present is identified. Two interviewees highlight the motivational effect of team autonomy regarding decision making. The effects of lectures on the project is said to be small, as it is somewhat disconnected from the day-to-day project effort. However, getting experience with the different methodologies presented there is said to be valuable for later projects, e.g. their master's projects.

When asked if they recommend the course to fellow students, the answers from all interviewees were aligned: "Yes, but you need to be prepared for a large workload and to take responsibility for your own progress." All three see the course as unique, and say it gives experiences not provided in any other course they have attended. Even though the interviewees had taken project-based courses before, this was the first time the project was as disconnected from the academic bubble. One interviewee reported that this was the first time he had started a project in a course without having an idea in the beginning of how the problem might be solved. Another interviewee experienced the setting as being facilitated to experience extreme degrees of freedom in the project. He identified a triangle of *resource access-freedom-task formulation* to be the most influential factors for allowing this project experience.

4.3 Stakeholder feedback

While there were a lot of positive, orally stated feedbacks from high-profile stakeholders, such as CEO's and CTO's, the most solid indicator of meeting or even exceeding the expectations is the fact that most companies and researchers are returning with new and more challenges every year. Furthermore, most stakeholders propose more in-depth master's projects based on the outcome of their FFE challenge.

5 DISCUSSION

The paper has presented a course which focuses on creating a high-energy atmosphere with a pressure of advancing the project, without creating losers. While it is not possible to scientifically quantify and compare the outcomes from different projects and subsequent feedback, the statements from both, participants, and stakeholders, point in a general, positive direction.

The students experience that the course inspires a high self-induced workload and put in a lot of effort because they are driven to present their project progress on a weekly basis, and a failure to do this is not wanted. Any such failure is, however, independent of other teams' success. And seeing others succeed is a motivating factor rather than an explanation for their own failure. This atmosphere also seems to support a collaborative way of working, where students teach each other necessary skills as they are needed and they openly share their ideas, problems and solutions with each other.

Learning the process methodology is expressed as something happening silently in the background as they work on their projects. Confidence in applying methodology is slowly being built up, as they see that the methods actually work. They experience the effects and gain trust in the methods.

The fact that the stakeholders are almost exclusively "returning customers" gives a strong indicator for the high quality of the outcomes and that the projects at least satisfy their expectations.

The amount of data presented is very limited and can therefore not be seen as conclusive proof of whether or not the FFE course succeeds at picking up the best parts of a competition format, while leaving out the negative sides of it. It does, however, indicate that this format provides the experiences we desire to convey, with respect to the theory provided in section 2: It increases the creative confidence level of the students, and creates energetic atmosphere similar to a competition, while emphasizing collaboration, as well as knowledge and skill-sharing.

For future work, we have already started collecting more precise feedback from stakeholders, as well as capturing the team's prototyping progress throughout the course. The aim is to provide a quantitative analysis of performances and outcomes and scientifically solidify the reasoning behind the course format.

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Appendix K

Contribution 9: A Cell Culture System for Experiments under Physiological Flow

A cell culture system for experiments under physiologic flow

Claudia Danzer[1], Carlo Kriesi[2], Virginia Meskenaite[1], Martin Steinert[2], Vartan Kurtcuoglu[1]
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Background

Why study cultured cells under flow conditions?

The translatability of in-vitro findings to in-vivo has been, and still often is a huge challenge in medical research. With the aim of improving this translatability, we developed a next-generation all-in-one system for culturing and live observation of mammalian cells exposed to physiological flow. Here we present our first experiments which show that our device is capable of creating a hospitable environment for various cell types, allowing the constant observation of their reaction to an in-vivo like physiologic environment. In particular, we could show in real-time how meningothelial cells (MEC) adapt differently to physiological shear stress when grown on poly-d-lysine compared to fibronectin, respectively. Soon upon onset of flow, the cells grown on poly-d-lysine start rounding up and loosing attachment. Grown on fibronectin, however, the cells mostly keep their initial morphology, at least up until the first 5 hours of shear exposure. These results enable us to further investigate the barrier function of MEC at the the interface between neuronal tissue and the cerebrospinal fluid (CSF) in the context of different shear loads. In addition to this MEC model, we were able to monitor calcium signaling over a short time frame in primary mouse neurons, establishing an experimental setup which provides us a potential readout to analyze neuronal adaptation to different compounds under physiological flow.

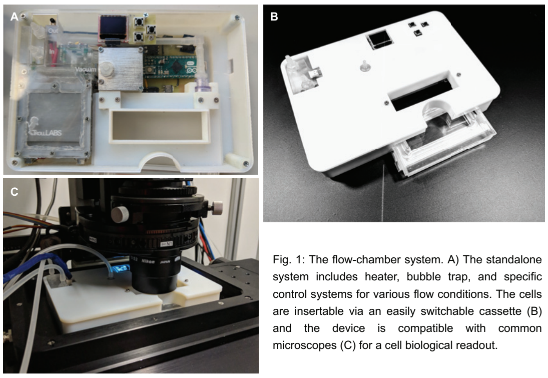

Fig. 1: The flow-chamber system. A) The standalone system includes heater, bubble trap, and specific control systems for various flow conditions. The cells are insertable via an easily switchable cassette (B) and the device is compatible with common microscopes (C) for a cell biological readout.

The flow-chamber system allows for long term observation of cells under shear stress

Meningothelial cells (MECs) form the interface between brain tissue and cerebrospinal fluid (CSF). They are cellular components of the meninges that surround the brain[1]. However, little is known about the influence of pathological conditions on MEC function; e.g., during diseases associated with altered shear rates. Here we show the relevance of the microenvironment on the cellular response to shear stress.

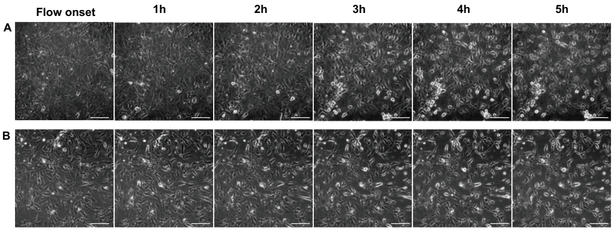

Fig. 2: MEC grown on different coatings. Images are taken over 5 hours at one image per minute. Shown here are t0 at the onset of 6 ml/min flow (3 dyne/cm^2 shear stress), and cells after 1h, 2h, 3h, 4h, and 5h of shear exposure. A) Poly-d-lysine coated glass slides and B) fibronectin coated glass slides. Scale bar = 50 µm.

Disruption of normal CSF circulation is believed to contribute to the development of many diseases, including neurodegenerative conditions such as Alzheimer's disease[2]. Using our device, we successfully established calcium signaling as a readout for neuronal functionality in order to assess the effect of changing shear cues on neurons. This enables us to analyze the effect of shear on neuronal development as well as to investigate new treatments for conditions characterized by impaired homeostasis of cerebral water dynamics.

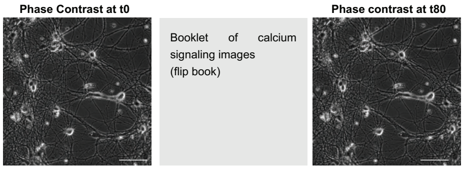

Fig. 3: : Calcium signaling of primary mouse neurons recorded over 80 seconds (one frame per second) under physiological shear stress (6 dyne/cm2). Calcium signaling is shown by a GFP reporter visualized in the booklet between the phase contrast images. Top image at t80, bottom image at t0. Scale bar = 50 µm.

Vision

The power of the flow culture system for translational and personalized medicine

Future applications of our cell culture system can include the perfusion of patient-specific 3D printed multicellular structures, and push forward the translation ability of basic scientific findings towards understanding the physiology of diseases.

The relevance of investigating drug delivery under flow conditions was shown by Han et al. who unveiled that flow stimulates endothelial endocytosis[3]. Also, the development of shear-mediated drug delivery[4] is an area where a standardized cell culture flow chamber system will provide a powerful tool to investigate patient-specific medication strategies.

Finally, our highly controlled perfusion device can enable the investigation of flow-induced, circulating biomarkers for pathologies such as vascular diseases[5], which could allow personalized diagnostics.

Outlook

Design optimization

Advanced testing of this new device with experiments is currently ongoing, and we invite interested research groups to join our test program.

For further information, please contact us via mail at carlo.kriesi@ntnu.no, and visit us at www.trolllabs.no and interfacegroup.ch .

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Appendix L

Contribution 10 (under review): Resuscitative Balloon Occlusion of the Aorta (REBOA) in non-traumatic out of hospital cardiac arrest – evaluation of an educational program

Appendix M

Contribution 11: Just do it – Hypotheses on how to accelerate innovation in the biomedical sector

Is not included due to copyright

Appendix N

Contribution 12: Development and Validation of an Integrated, Microscope mountable Flow-Chamber System

Is not included due to copyright

Appendix O

Press Release regarding NTNU Discovery Grant

Application deadlines:
Research Project: October 24th 2018 kl 10:00 (jury meeting November 6th)
Pilot project: September 4th kl 10:00 - October 24th kl 10:00 - December 4th kl 10:00

Helping researchers secure research results

Medical research requires living cells, and in vivo experiments always yield the best results. This may be about to change. CellFlow mimics the environment of the body and allows for large-scale cell testing.

CellFlow is a tool developed at TrollLABs at NTNU in Trondheim. Researchers know what they want, but until now, there hasn't been a solution. Carlo Kriesi and Martin Steinert at TrollLABS have developed a tool giving researchers the chance to study living cells under stable conditions.

"This is where we started," said Carlo Kriesi, pointing to what looks like a simple, white plastic container. In front of him are five nearly identical devises, but each model is an improvement on the last.

These containers are the stages of "Project CellFlow". The objective was to develop a tool that would enable researchers to carry out experiments on living cells outside the body (*in vitro*), under conditions equivalent to an *in vivo* experiment.

"Why is this important, Carlo?"

"It's important, because research on living cells in test tubes and petri dishes is based on an assumption that these environments are equivalent to the environments found in in vivo experiments, i.e. clinical trials or animal testing. But they're not. In test tubes and petri dishes, the environment is static; the only thing that changes is the chemical environment. In reality, however, all cells in any living organism are constantly subjected to dynamic stress, caused by the organism's heart rate or muscle activity or external stimuli. This is common knowledge—it's just that researchers so far haven't had the tools to do anything about it."

Carlo Kriese and Martin Steinert found a way to mimics the environment of the body that allows for large-scale cell testing.

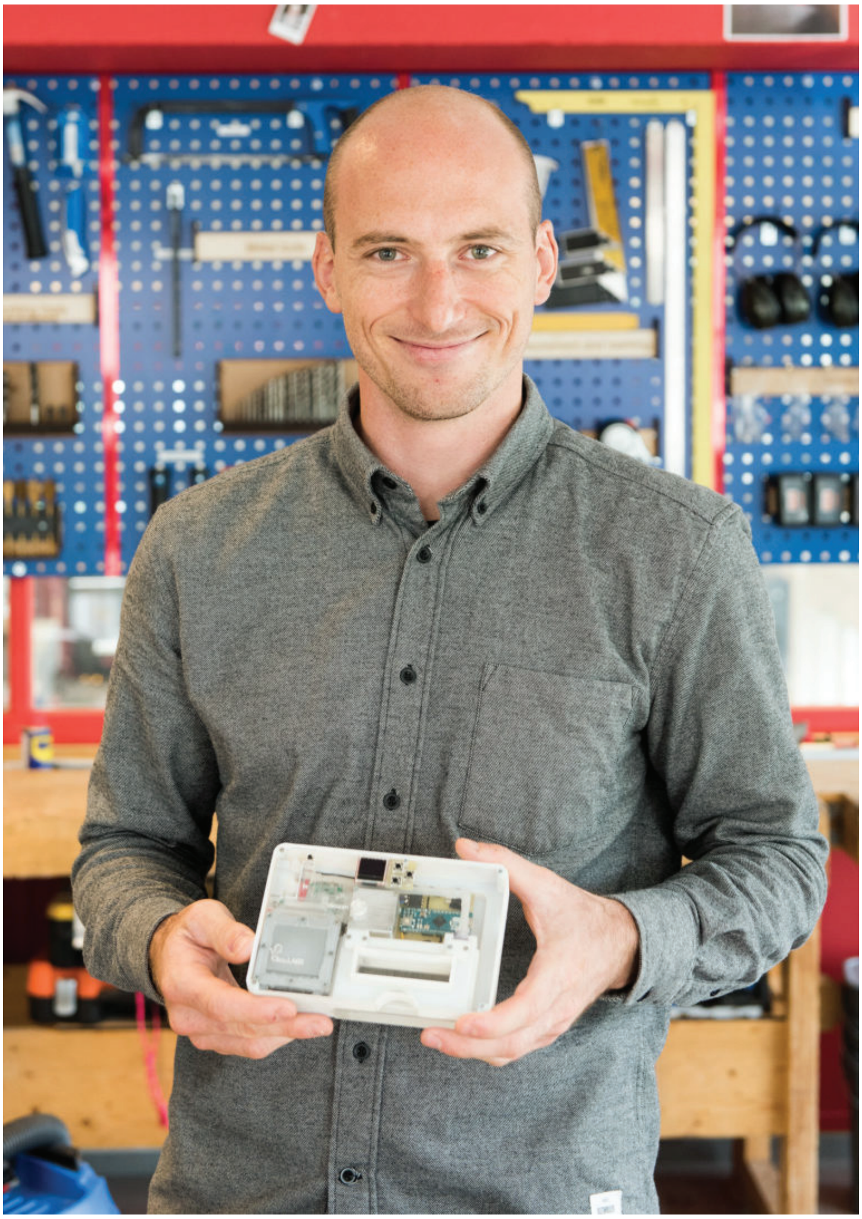
"What we've done is develop a simple, yet robust kit that simulates in vivo conditions. This makes it possible to generate large data sets under identical conditions."

The project won a NOK 1 million grant from NTNU Discovery in the spring of 2017. The grant will, among other things, be used to develop a 10-unit beta solution to be tested by researchers all over the world. “This grant played a key role in making it possible for us to take this project to the next level,” said Kriesi.

Identical conditions for large data sets

Mimicking in vivo conditions for cells outside the body is a tall order. You need a heat source and a pump and some complicated electronics. Carlo Kriesi, Martin Steinert and the rest of the team at TrollLABS found a way to create this in a smart way that also works for large-scale experiments. The Plug and Play unit consists of two parts: a flow chamber, where the cells are placed and kept at the right temperature, and a pump.

The flow chamber was created as part of Carlo Kriesi’s PhD studies in Trondheim, in close collaboration with The Interface Group at the University of Zurich.



“The people at the University of Zurich saw the need to solve this problem, and they simply asked if I wanted to take a crack at it,” Kriesi said. “I had already decided to move to Trondheim, and so I made it a part of my PhD here.”

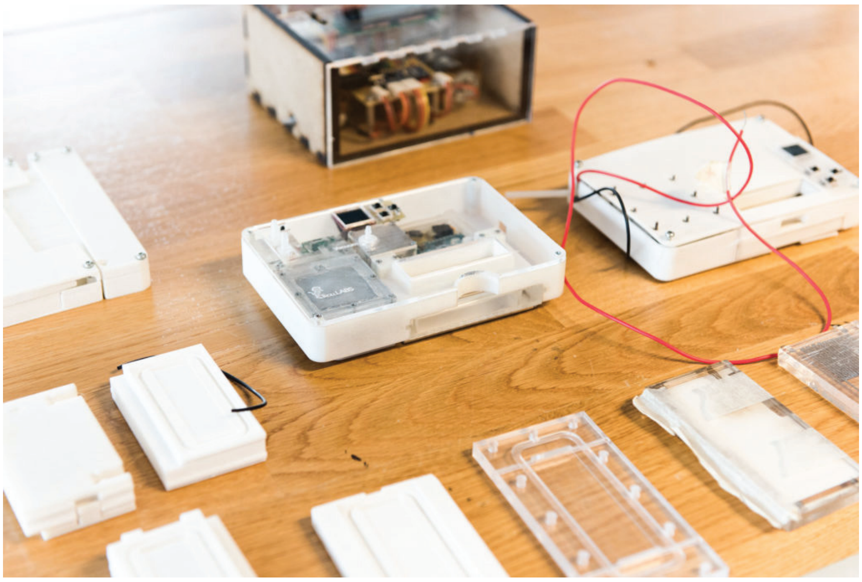
“Martin at TrollLABS gave me the opportunity to build everything from scratch and test it out. It wasn’t easy to figure out how things should look and work. The journey has been interesting and inspiring; we have faced many challenges and have been able to overcome most of them.”

“This is something we’re used to here at TrollLABS,” said Martin. “Many people assume that if you can’t find what you want in the catalogue, it doesn’t exist. But that’s simply not the case. At TrollLABS we have disproved this time and time again. We have a different mindset. Can’t find it? Let’s build it!”

Craftsmanship

Carlo has spent countless hours in the lab, hunched over the laser cutter, cutting tiny little wires from NiChrome foil to use them as heating elements. The idea for the heating element in CellFlow came from a folded-up piece of paper.

CellFlow is a 100-percent proprietary product that makes it easy to load and unload cell cultures, and all of the key components (such as heating, control systems and an observation chamber) are integrated in the design, which fits under a standard microscope.



“Right now, our model can be set up six times faster than the best products of any of our competitors,” Steinert said.

As much as we want to become a manufacturer of this tool, we also want to set up a service, where, for example, major insurance companies can order 1000 data sets of a certain type of cell under pre-defined conditions. This will also be a much faster way to get results.

“There are many pitfalls yet to conquer, even though we have a patent pending. We have great faith in this project,” said Carlo Kriesi.

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Appendix P

Calculations regarding the Heater Design

This chapter covers the calculations done with respect to an initial assessment of whether or not a powerful enough heater finds space within the required dimensional constraints. The main question is whether or not the surface temperature of the heater rises above the critical point of 40 °C where the cell culture medium would denature.

P.1 Model and Assumptions

The underlying model used for the calculations is that of forced convection across a flat plane. Given the design decisions described in chapter 2, one can state certain assumptions in order to simplify the problem:

- The heater can be assumed to be one long plate with liquid flowing across on top.
- The power output per area can be assumed to be constant throughout the whole heater surface.
- Within the overall small temperature range, the temperature difference between heater and liquid can be assumed to be constant. This implies a linear rise of liquid and heater temperature from entrance to exit of the flow channel.
- The system can be assumed to be adiabatic.

P.2 Calculations

Table P.1 shows the underlying constants used throughout the calculations. All material constants are taken from Moran et al. (2010). All

Table P.1: The required dimensional aspects and material properties for assessing the feasibility of the heater.

Environmental Constants			
Channel Height	h	2	mm
Channel Width	w	40	mm
Heater Length	L	400	mm
Heater Area	A	0.016	m^2
Flow Rate	$\dot{V}$	50	ml/min
Temperature Difference	ΔT_{io}	15.5	K
Power	P	54	W
Fluid Properties (H2O at 300 K)			
Density	ρ	997	kg/m^3
Heat Capacity	c_p	4179	J/kg
Conductive Heat Transfer Coefficient	λ	0.613	W/m K
Dynamic Viscosity	μ	$855 \cdot 10^{-6}$	$N \cdot s/m^2$
Kinematic Viscosity	ν	$8.58 \cdot 10^{-7}$	m^2/s
Prandtl Number	Pr	5.83	-

formulas, if not considered common knowledge, are taken from Bergman et al. (2011).

The necessary heating power has been calculated in 2 with equation 2.5. The further required equations are equation P.1 for the local Reynolds number, P.2 for the Nusselt number and therefore calculating the convective heat transfer coefficient α, and P.3 for the convective heat transfer from the heater to the liquid, which needs to be equal to the Ohmic heating power from the heater itself.

$$Re_x = \frac{\rho u_\infty x}{\mu} \tag{P.1}$$

$$\overline{Nu}_x = \frac{\overline{\alpha} x}{\lambda} = 0.664 Re_x^{1/2} Pr^{1/3} \qquad Pr \geq 0.6 \tag{P.2}$$

$$\dot{Q} = \frac{P}{A} = \alpha \cdot \Delta T_\infty \tag{P.3}$$

The bulk flow velocity, $\rho u_\infty x$ is calculated through the volumetric flow rate $\dot{V}$ and the cross section of the flow-path. For calculating Re_x the observed distance across one heater plate is chosen for x. Since the model is based on five heaters that are in contact with the liquid on both sides, the total heater length listed in table P.1 is divided by 10, subsequently 40 mm is used for x.

Table P.2: The numerical results from the calculations presented in this chapter.

Local Reynolds Number	Re_x	242.812	-
Average Nusselt Number	$\overline{Nu_x}$	18.622	-
Convective Heat Transfer Coefficient	α	2996.514	W/m^2 K
Power Flux	$\dot{Q}$	3373.671	W/m^2

The final result of the calculation is that under these conditions the temperature difference between heater wall and liquid, ΔT_∞, is 1.12 K. Given the fact that the regular target outlet temperature of the cell culture medium is 37.5 °C this puts the temperature of the heaters itself at 38.1 °C, leaving a sufficient safety margin to the critical point of 40 °C. The interim numerical results for the calculation are listed in table P.2.

Appendix Q

Heater Production Protocol

This appendix describes the production protocol for all the heaters built throughout this work. While their shape has changed multiple times, the production always followed the same steps with the main tool being a vacuum table (VT). The six main steps of the production are shown in figure Q.1.

1. Install VT in laser cutter and attach vacuum cleaner.
2. Place silicone foil on VT and apply vacuum.
3. Cut silicone foil, turn off vacuum, remove cut parts.
4. Place NiCr foil on VT and apply vacuum.
5. Cut NiCr foil, check that cut is complete.
6. Transfer cut foil on sheet of paper, turn off vacuum.
7. Place alignment tool on VT, place paper with NiCr foil on top of it, apply vacuum.
8. Slowly remove paper and let NiCr foil slide into according grooves.
9. Place silicone foil with sticky side into according grooves on alignment tool.
10. Ensure that silicone foil is sticking thoroughly to NiCr foil, turn off vacuum.
11. Flip the now bond silicone and NiCr foil upside down, apply vacuum.
12. Apply silver paste to contact points and place copper-strips accordingly.
13. Apply silicone around through-holes to ensure perfect sealing.
14. Place second side of the silicone foil on the alignment tool.
15. Turn off vacuum and remove now complete heater.

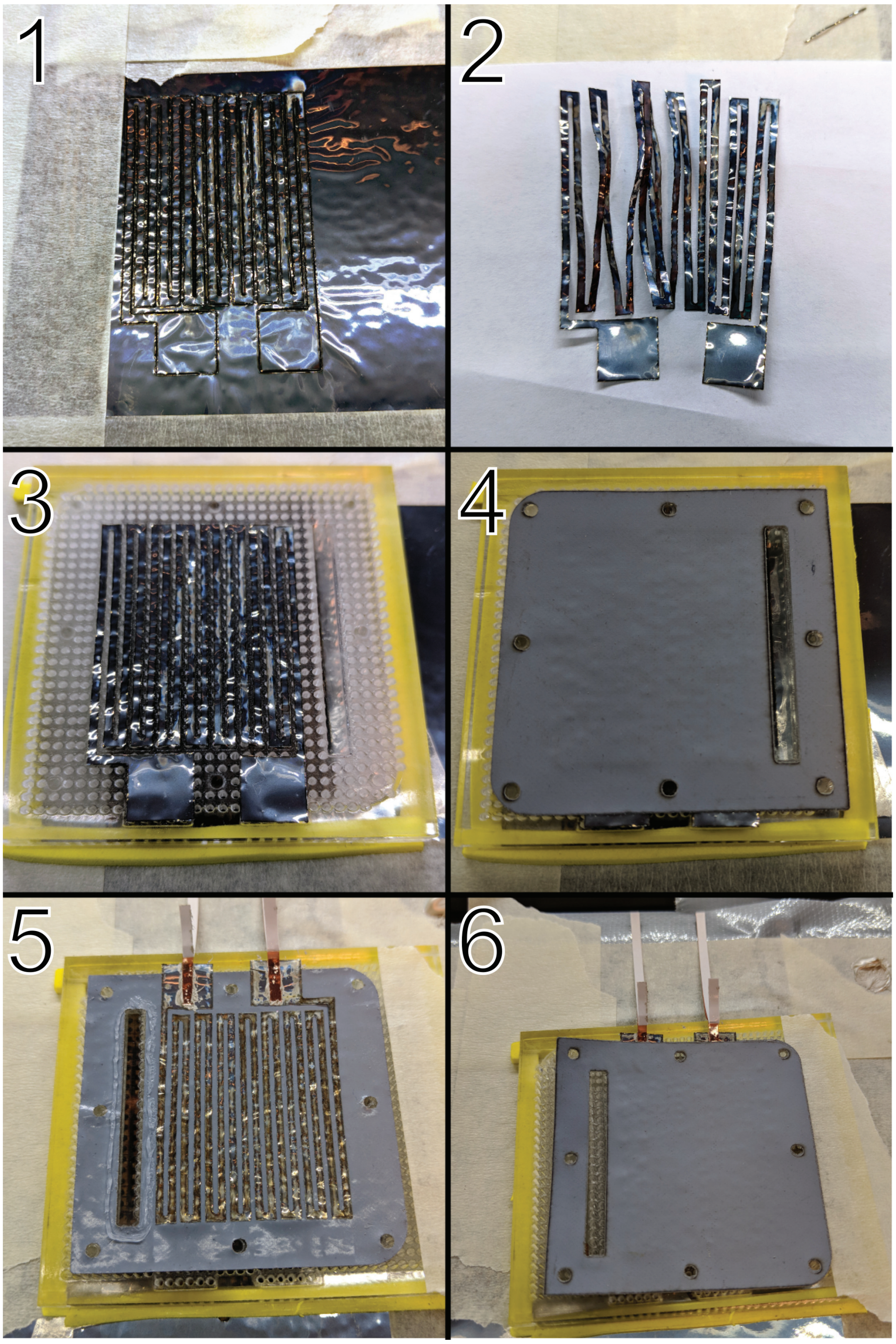

Figure Q.1: The most important steps of the heater production: 1) The laser cut NiCr foil; 2) The cut-out part transferred on a sheet of paper; 3) The cut-out part on the alignment tool; 4) And with the silicone foil in place; 5) The incomplete heater is turned upside down with the power connectors in place; 6) the second silicone foil is glued on, making one heating element complete.