A Co-Design Tool for Medical Product Development

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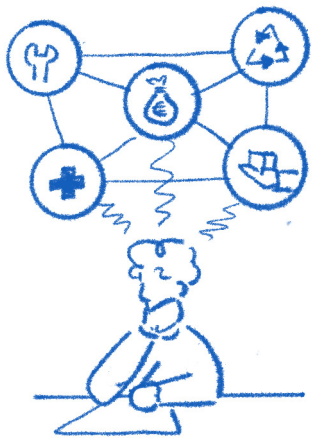


Preface

In the context of medical innovation, the quest to develop valuable products and services that fulfill the needs of its users while also answering to regulations, safety, and environmental impact, and more, remains a great challenge. Fruitful collaboration with stakeholders is crucial to find important design inputs that must be acquired to set a basis for a successful product. This graduation project aims to find a new approach to collaborative design in health care innovation. The upcoming chapters describe a journey of exploration, ideation, conceptualization, and validation of a co-design tool specifically developed for the complex nature of medical device development.

Table of Contents

01

Introduction

Summary

The client of this graduation project, Dune Innovation, aims to facilitate and execute a structured design process for medical device development. This is a complex task most notably during the early ‘discover’ phase, or fuzzy front end. In medical device development, the first stages of the design process are crucial in ensuring the adoption chances of a new product. During the discover phase, the focus is to gather design inputs or requirements to reduce the uncertainty and risk in future project development. By logic, Dune Innovation does not have sufficient knowledge on all design criteria to solve these uncertainties. Therefore, the company seeks interaction with stakeholders to find unknown design inputs that can help to make progress. To do so, the intention is to organize meetings or interviews with these stakeholders. Unfortunately, this is no easy task. Stakeholders in the medical field often are short on time and don’t prioritize collaboration with Dune Innovation. Even if they manage to make time, standard interview methods are suboptimal for creativity and exploration. This struggle leads to ongoing uncertainties and longer lead times in projects.

This thesis project delivers a new approach to interview settings during the discover phase of medical device development for Dune Innovation. This is achieved by developing a tool which embraces co-design strategies during stakeholder interview settings. By providing transparency on the clients’ design process towards the interviewee, the desired effect is to increase engagement, improve the quality of discussion and outputs. The goal of the session is to generate new design inputs together with the interviewee that are relevant for the projects design process. The concept of the co-design tool is based on these issues and aims to enable a structured co-design session between a facilitator and a stakeholder in a physical interview setting. The tool offers a functionality that should help in reaching a shared understanding between both parties, as a foundation for the following co-design sessions. The tool should engage participants to actively contribute their expertise, insights, and ideas during a 90-minute interview session, with the goal to generate new inputs for the project. The printable design of the tool encourages the use of pens and post-it’s to spark design thinking and creativity.

Validation rounds showed a great potential of the tool. All participants shared their enthusiasm after concluding a session. It showed that during use of the tool participants were engaged for the entire length of the session. Both the facilitators and interviewees had enjoyable experiences. The validation rounds proved that shared understanding could be reached within 15 minutes. Validation also showed that the tool encourages sketching, writing, and unexpected discussion, which led to new design inputs for the client. Although more testing Is necessary, the concept shows great value for future implementation.

02

Background

2.1 Complexity in Healthcare

Before diving into this project, it is important to understand healthcare organizations and what it means to design for this context. For starters, health care organizations can be seen as complex systems (Institute of Medicine 2001; Plsek and Greenhalgh 2001; Sweeney and Griffiths 2002). They explain that "a complex adaptive system consists of individual agents with the ability to act in ways that are not completely predictable." These agents' actions are interconnected, meaning that one agent's actions can affect the context for other agents. This means that a designed products or services may be experienced differently depending on the user. As a result, the design of a medical product for complex systems is a delicate task where needs form multiple actors must be collected and integrated.

In order to comprehend the approach to design in this complex systems, different types of problems are identified by Glouberman and Zimmerman (2002). In their paper they make a distinction between simple, complicated, and complex problem solving (figure 01). They provide three examples to illustrate the difference:

• "Baking a cake can be seen as a simple problem. Simple problems are well-suited for a systematic approach, such as following a recipe. The process and outcomes can be applied in a broad sense, and while having culinary skills is advantageous, it is not a prerequisite for achieving success.

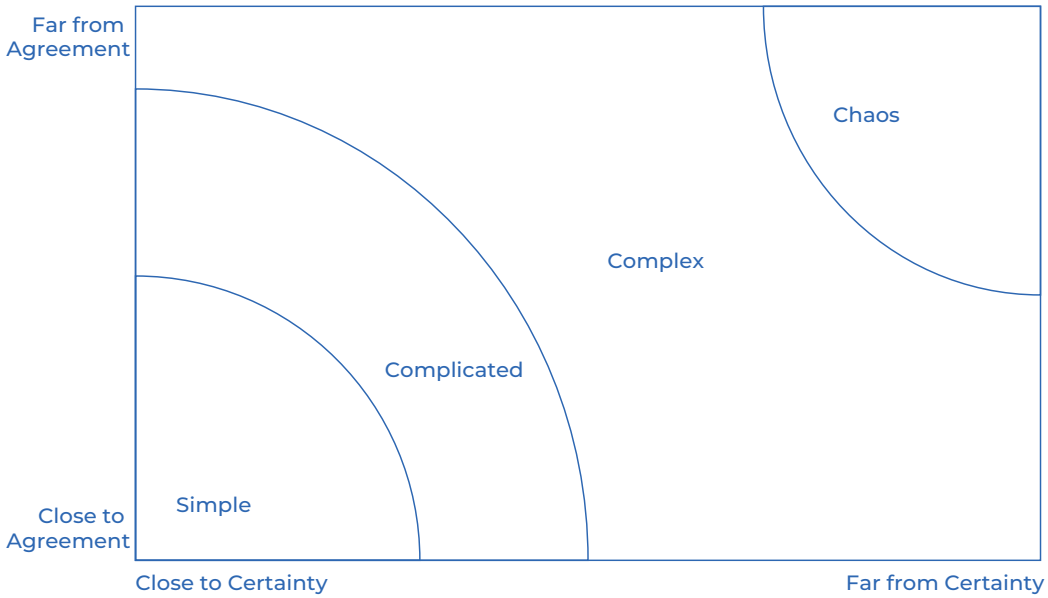


Figure 01 | Simple, complicated and complex problems

• Sending a rocket to the moon serves as an illustration of a complicated problem. complicated problems are best tackled using existing formulas and expertise. The overall challenge can be systematically divided into various components (booster rocket, cabin environment, navigational equipment, etc.) and assigned to teams of experts who employ proven methodologies in their respective fields. Rockets share similarities, which means that succeeding with one rocket provides reasonable assurance of success with future rockets. In the event of unexpected occurrences, one can analyze and learn from them, integrate improvements into the system, and thereby increase the likelihood of future success.

• In contrast to simple and complicated matters, raising a child exemplifies a complex problem. Achieving success in raising one child does not guarantee success in raising another. Previous experience, along with guidance from experts, can serve

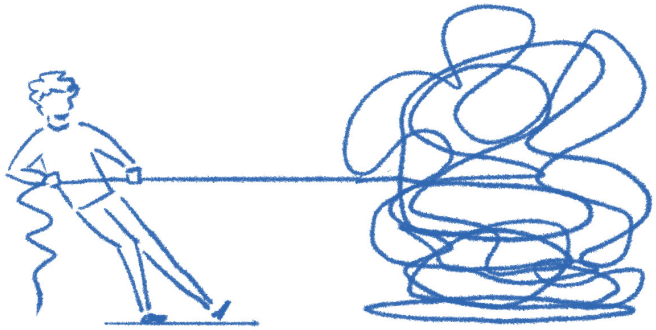


Figure 02

as a starting point. However, simply applying the same formula that worked before may not lead to success and may even result in failure due to the second child feeling resentful about being treated in a similar manner."

Many organizations tend to tackle problems with complicated problem solving, even when the problem is complex. This happens in healthcare on a large scale. Plsek et al. (2003) argue that despite the complex nature of healthcare organizations, novel medical technology is still "routinely implemented" within the system. In other words, taking the simple or at most, complicated problem-solving approach. This leads to great uncertainties when it comes to the adoption of the product or service. The innovation either is adopted or fails.

These findings suggest that innovation for healthcare organizations require a complex problem-solving approach. A difficult task that facilitated by Dune Innovation, the client of this graduation project. Before more is explained about Dune Innovation and their mission, the process of medical device development will be briefly explained in the next paragraph.

2.2 Medical Device Development

Medical device development is a process where science, engineering and healthcare come together. At its core, the aim is to create innovative solutions that improve the overall quality of our healthcare. To do so, developing a medical device not only requires scientific knowledge, but a complete understanding of the demands of different medical disciplines. This delicate process often involves balancing multiple design criteria like user functionality, usability, safety, regulatory compliance and more. For instance, parties that develop medical devices or drugs must adhere to a wide set of regulations. An example is ISO13485, which "specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements" (iso.org, 2023). This standard makes it mandatory for a company in medical devices to be able to provide transparency during the design process.

One of the tools provided by the ISO standard are the design controls (FDA), figure 03. The design controls are a crucial guide in ensuring the safety, effectiveness, and quality of medical devices. These controls are a set of regulations and guidelines that guide the development and manufacturing processes of medical

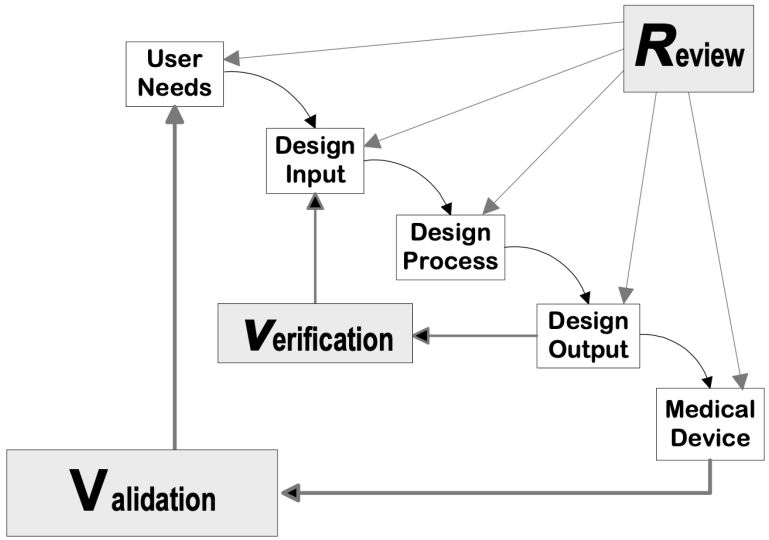


Figure 03 | FDA design controls (FDA, 2023)

devices. By implementing design controls, the FDA aims to minimize risks associated with device failures, design flaws, and inadequate performance. They require manufacturers to follow a systematic approach to design, including documentation, risk management, validation, and testing. Design controls help to identify and mitigate potential safety hazards, conducting testing, and ensuring that devices meet the intended purpose and user needs. By enforcing these controls, the FDA promotes the development of reliable, safe, and innovative medical devices, ultimately safeguarding public health and enhancing patient care (Ross, 2021).

The design controls, while essential for ensuring safety and quality in medical device development, have limitations when it comes to complex and creative problem solving. Design controls follow a linear procedure, focusing on well-defined requirements, specifications, and engineering solutions. However, complex problem-solving requires flexibility, adaptability, and iterative approaches to navigate design directions and discover innovative solutions. During the early phase of product design, the strict adherence to design controls may limit creativity and experimentation, and the exploration of alternative ideas. Managing creativity within the boundaries of standardized regulations is a demanding task carried out by Dune Innovation, the client of this graduation project.

2.3 Dune Innovation

Dune Innovation is a medical design agency that creates medical innovations. Their aim is to increase the number of successful innovations and shorten their time to market. During the process, Dune Innovation recognizes the importance of complex problem solving in the field of medical device development. By including experts with different backgrounds in the core team, Dune Innovation has the ability to facilitate a process that tackles the challenges from multiple angles. In their approach, the multidisciplinary team at Dune Innovation takes charge of project management, ensuring the discovery, development, and delivery of a product that effectively addresses the needs and interests of users and other relevant stakeholders (figure 04). During early stages, Dune Innovation strives to engage and collaborate with stakeholders, with the goal to gain knowledge to reduce uncertainties the design process. Reaching out to external stakeholders is often required to find new inputs. Therefore, Dune Innovation aims for a more efficient and effective process in collaborative problem solving with other parties (Dune Innovatio, 2023).

Project Management

For internal and external communication purposes, Dune Innovation manages project

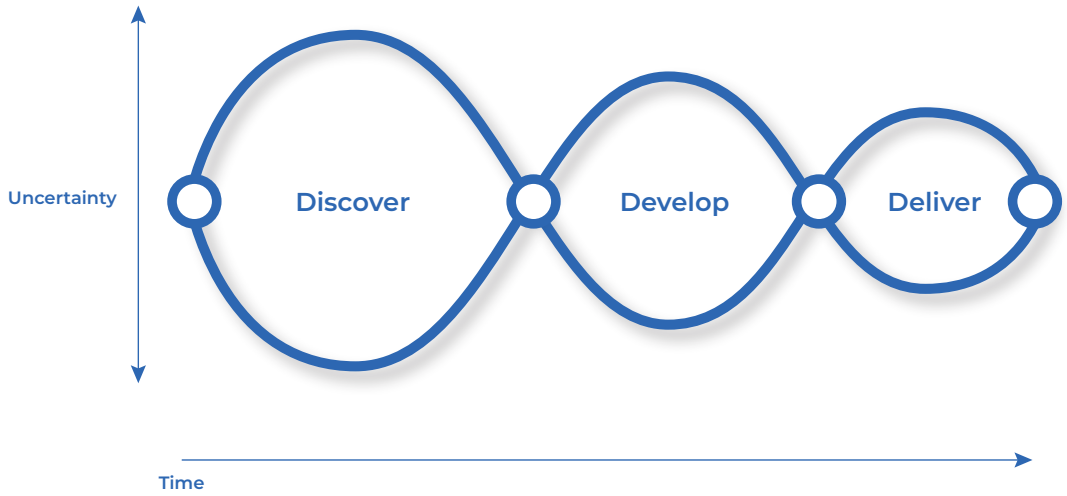


Figure 04 | Project management by Dune Innovation (Dune Innovation, 2023)

following a standardized design process. This process is based on the Double Diamond method, licensed by the Design Council (2005). The original method consists of four phases in sequence, while diverging and converging two times. The phases are discover, define, develop and deliver. Based on experiences in medical device development, Willem Mees van der Bijl has altered this sequence to three phases of divergence and convergence better fitting with the FDA design controls: discover, develop and deliver. Each phase also includes a 'define' phase. The three phases are briefly described:

- **The discover phase** 'helps to understand, rather than simply assume, what the problem is' according to the Design Council (2005). 'It involves speaking to and spending time with people who are affected by these issues.'
- **The develop phase** aims to find different answers to a clearly defined problem, resulting from the discover phase. For Dune Innovation, this means developing a device according to a final set of design inputs or requirements, collected during the discover phase. The aim is to eliminate as much uncertainties as possible to ensure the 'right' solution is developed. During the development phase, great expenses are made. Therefore, finding the right design inputs is crucial before commencing development.
- **The deliver phase** involves testing out the solution and implementation on a small

scale. If necessary, adjustments can be made to the design of the product with the goal to eventually deliver a product that successfully adapts.

The Importance of the Discover Phase

For Dune Innovation, the discover phase holds immense significance in medical device development. This critical phase serves as the gateway to successful product development, ensuring that the company is taking on the right path and designing the right solutions. Herstatt & Verworn (2004) also argue that "within innovation processes, the early phases (the fuzzy front end, figure 05) have the highest impact on the whole process and the result, since it will influence the design and total costs of the innovation extremely."

Dune Innovation recognizes that investing time and effort upfront in exploring and defining the problem space is essential for mitigating risks, minimizing costly iterations, and ultimately delivering innovative and impactful medical devices. During this phase, the company conducts extensive research, engages with stakeholders, and gathers valuable insights to gain a deep understanding of user needs, market dynamics, and technological possibilities. This exploration enables Dune Innovation to identify unknown needs, reduce risk, and seize opportunities for disruption and innovation within the project domain. By investing time in the discover phase, the company can lay a strong foundation for the following stages of development, and delivery.

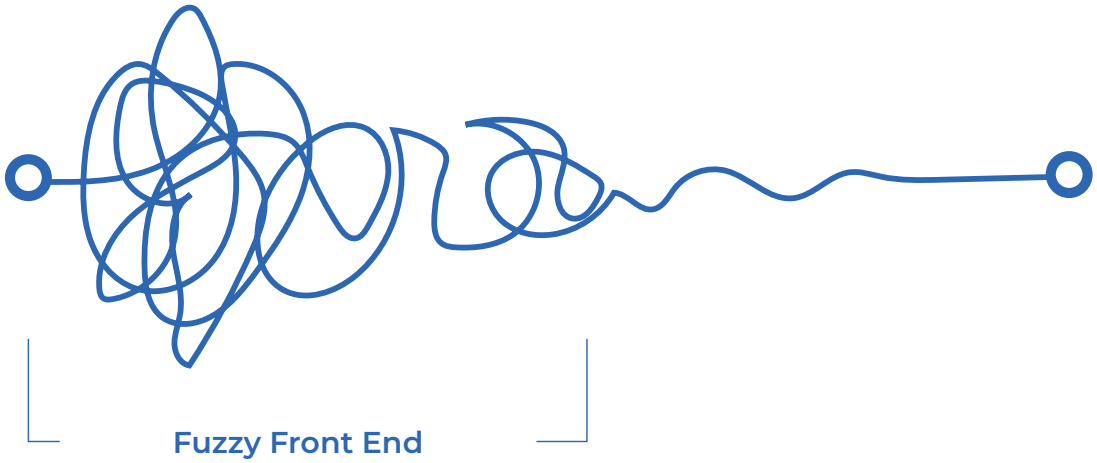


Figure 06 | Visualization of the fuzzy front end (Sanders, Stappers, 2008)

The significance of the discover phase resonates with the focus of this thesis project. The proposed development of a co-design tool for the discover phase aligns perfectly with the objectives of Dune Innovation and the broader context of medical device development. By establishing an structured and efficient approach to the fuzzy front end, this thesis project aims to contribute to the company's goal of designing the right solutions and minimizing risk and time to market. By providing a structured tool to explore user needs and concepts by engaging stakeholders, this thesis project strives to empower Dune Innovation and similar organizations to navigate the discover phase with clarity, confidence, and a greater chance of success.

03

Problem Definition

3.1 Challenges during the Discover Phase

Earlier, Dune Innovation's approach towards medical product development was explained in detail. Although the importance of the discover phase is recognized by the company, the strategy during this period is still far from optimized. Because of the aim to reduce uncertainties early in the design process, the company is dependent on input from external stakeholders, as explained in the previous chapter. To uncover new inputs, the company must reach out to these stakeholders with the goal to facilitate interviews or meetings. Experiences and observations at Dune Innovation have provided insights on the difficulties in organizing these contact moments with external stakeholders. There are multiple reasons for this.

For starters, the physical distance between Dune Innovation and its relevant stakeholders forms an obstacle in making contact. This is an issue that often count for many stakeholders. Distances between stakeholders like manufacturers, users, investors and notified bodies can be great. Manufacturing companies for instance, are often located outside the EU due to low labor costs. Organizing physical meetings, costs time and effort and therefore online meetings or calls are often preferred. Online meeting environments have become more common since the pandemic while providing benefits such as sharing digital documents and organizing group sessions. However, according to Karl et al., (2021), videoconferencing leads to users feeling physically and mentally exhausted, which is highly undesirable when trying to have in-depth, collaborative meetings on medical products. Especially during the fuzzy front end of a design process, real life meetings are preferred over online environments. Located in the Erasmus Medical Center, Dune Innovation has made a strategic choice to position itself amidst the center of the action and partly solve this issue. The hospital environment provides possibilities to reach out to medical staff, patients, procurement, and research facilities that are needed to tackle the complexity of medical product innovation. In some cases, this lowers the barrier for stakeholders to be involved in the design process. Nonetheless, a strategic location is no guarantee for fruitful stakeholder collaboration.

Additionally, differences in priorities are an aspect that further complicates the process. Stakeholders that hold valuable knowledge and that can provide important design inputs are often occupied due to busy schedules, specifically medical staff. Similarly, other stakeholders such as notified bodies or manufacturers have responsibilities towards other client and therefore prioritize their planning. Unless they are closely involved, it's frustrating task to bring these stakeholders to the proverbial drawing table. In some cases, weeks or months are lost in the process of reaching the right stakeholders. This results in persisting uncertainty in the design process and increasing lead times.

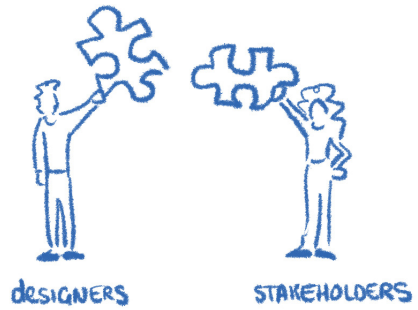


Figure 07

Lastly, many stakeholders in the medical field have demanding time schedules and responsibilities. Due to their limited availability, dedicating time to collaborate with designers and engineers is a great commitment. It is therefore often unlikely for them to cooperate during these early phases of the design process. This makes it complicated to retrieve the needed design inputs in time from the company's perspective.

Even when Dune Innovation succeeds in organizing a meeting with a stakeholder, it's no guarantee for valuable outcomes. The background of the stakeholder and the means of communication have a great impact on the quality of the discussion and its outcomes. According to Kleinsmann en Valkenburg (2008), in design processes, communication with stakeholders from other disciplines is 'difficult and delicate.' They illustrate this with an example of an electrical engineer and an ergonomist both working on a handheld device. The essence is that based on a user need, the ergonomist has a maximum size requirement for the circuit board. However, from the engineer's perspective, that is not feasible. The electrical engineer and the ergonomist both try to explain themselves using their own tools, but they fail to brainstorm together in a productive way to solve the problem (Kleinsmann & Valkenburg, 2008). It shows that both persons can provide good arguments but still fail to reach shared understanding. Reason for this is that they have 'different representations of the design' and 'other responsibilities' to adhere to. To add to this, they also state that profession related jargon further complicates reaching a shared understanding. This is also suggested by Drahota et al. (2016), who state that collaboration in research is challenging due to the lack of standardized terminology and conceptual definitions. In practice, stakeholders often communicate orally or with textual documents. These ways of interaction are susceptible to jargon

Figure 08 | Miscommunication caused by jargon

and might lead to miscommunication, again failing to reach shared understanding.

To conclude, the effects of these issues combined can lead to extended lead times and increased expenses while Dune Innovation retains uncertainty and risk in the design process. Building upon these uncertainties may impact the overall quality and adoption chances of the final product. The need for a standard approach that includes stakeholder collaboration during the discovery phase becomes evident. Addressing this challenge includes designing a strategic solution that engages stakeholders, facilitates a collaborative environmenta and is optimized to accommodate the constraint of the medical field.

3.2 Project Aim

The aim of this graduation project is to find an answer to the problem definition. It involves the exploration and design a solution that aids Dune Innovation in delivering successful innovation and shortening lead times. The hypothesis is that this effect is reached by increasing engagement with stakeholders and improving the quality of outputs. The solution should be applicable during the discovery phase of their design process to help identify promising design directions and reduce overall risk. The project aim from this perspective is formulated as follows:

'Design of a co-design tool that increases engagement and improves quality of discussions and outputs of stakeholder meetings during the discovery phase.'

Why: The aim is formulated to address the challenge presented in the problem definition. Reducing risk and shortening lead times should eventually lead to the acceleration of the innovation process at Dune Innovation. This is important to solidify a strategic position in the market of medical device development.

How: Reasons described above are expected to be related to stakeholder collaboration. A solution will be designed that closes the gap between Dune Innovation and external stakeholders, enabling more effective collaboration. By designing a structured

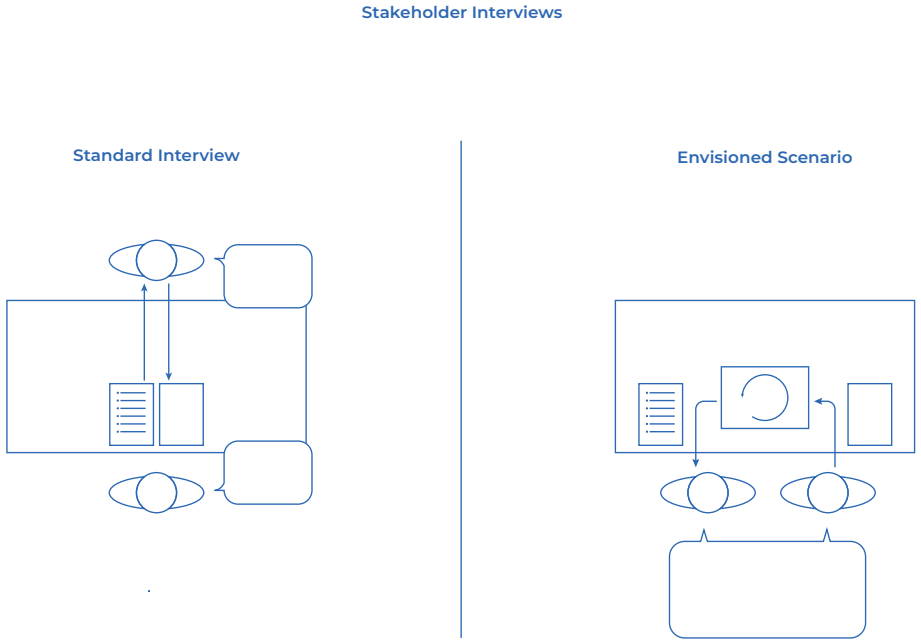


Figure 09 | standard and envisioned scenario

'Design of a co-design tool that increases engagement and improves quality of discussions and outputs of stakeholder meetings during the discovery phase.'

solution, engagement, and quality of discussion and output should improve.

What: The desired outcome of this project is the creation of a co-design tool that aligns with the defined aim. This tool will empower Dune Innovation to optimize stakeholder contact moments during the discovery phase. It will provide a structured framework for stakeholder meetings, streamlining the process of gathering insights, brainstorming, and refining design outputs. The co-design tool will serve as an innovative solution that offers an alternative to standard interview techniques.

For this graduation project, the client has provided the opportunity to validate the concept in a real-life casus. It offers a valuable possibility to design and test the tool by implementing it in real interview scenarios. In consequence, this graduation report also covers parts of the design process for 'Spatium Medical' (figure 09). This is a device for laparoscopy surgery that is being developed by Dune Innovation. From this project's perspective the aim is as follows:

'Design of an optimal patient kit for Spatium Medical to reduce the burden of insufflation on patients while minimizing environmental impact.'

The tool should help Dune Innovation

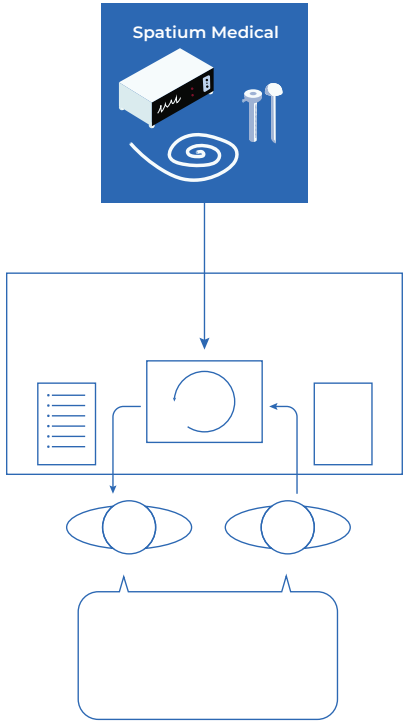


Figure 10 | Test casus set-up

in uncovering needs and requirements specifically to quantize and mitigate environmental impact in the design process of the patient kit. For the sake of keeping this report comprehensible, the project on Spatium Medical will be explained in more detail during the validation chapter of this report.

3.3 Project Scope

The project scope for this graduation project includes a selection of tasks that delve into the complexities of healthcare innovation and the development of medical products within the context of Dune Innovation. Some of those tasks include complex systems, healthcare innovation, co-design methodologies, visual communication, and the realm of laparoscopic surgery. Through the exploration phase, I'll be engaging with a diverse group of stakeholders, ranging from users and engineers to designers, procurement experts, and sustainability specialists to define solution spaces.

The project will cover a series of phases, namely contextual research, exploration, ideation, conceptualization, validation, and the formulation of recommendations to improve the final concept. However, it's important to note that certain areas are not within the purview of this project. This includes regulatory and safety considerations, financial aspects, clinical trials, as well as the intricacies of delivery and implementation strategies. Thorough adaptation, digital optimization or conducting large-scale validation efforts will not be part of this project. By focusing on these specific areas and steering clear of unrelated tangents, the aim is to provide insights that can effectively support Dune Innovation's journey in innovating medical products.

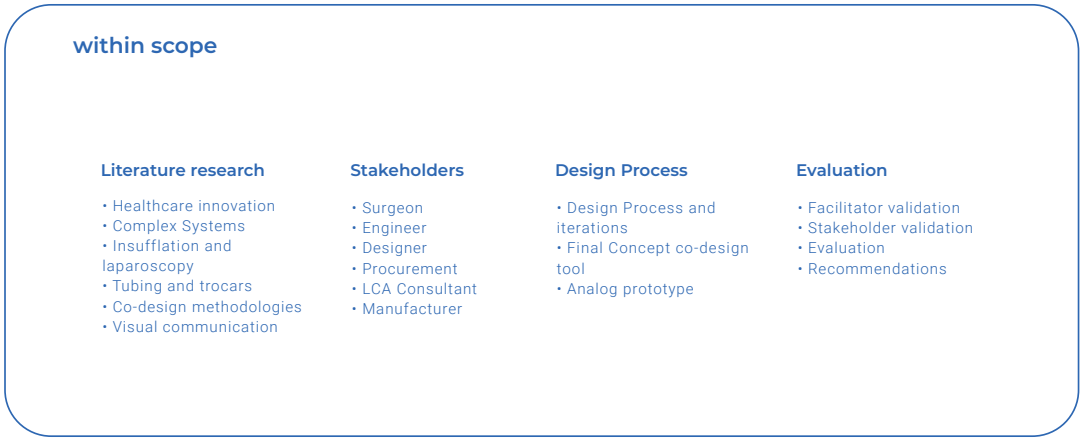


Figure 11 | Project scope

In Scope:

• Conduct literature research on complex systems, healthcare innovation, co-design, visual communication, and laparoscopic surgery.
• Engage with stakeholders, including users, engineers, designers, procurement specialists, and sustainability experts.
• Explore, ideate, conceptualize, validate, and recommend a solution.
• Produce output for Spatium Medical by implementing the tool.

Outside of Scope:

• Address regulatory, safety, clinical, and funding considerations.
• Focus on delivery and implementation strategies.
• Optimize digitalization aspects on a large scale.

Graduation Goals

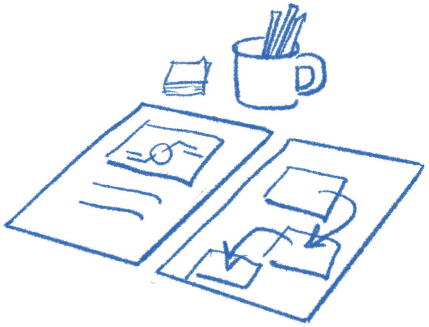


Figure 12

Analog Tool Prototype

The first deliverable is an analog prototype of the co-design tool, which serves as a tangible representation of concept. This prototype will be used for further testing and validation in real interview sessions. It should enable stakeholders to engage in the co-design process and provides a physical platform for collaboration and ideation.

Figure 13

Concept Validation

The second deliverable is a validation of the co-design tool. The actual preparation and use of the tool during interview sessions must prove if the design confirms the hypothesis. Testing criteria towards functionality and usability will be most important during this process.

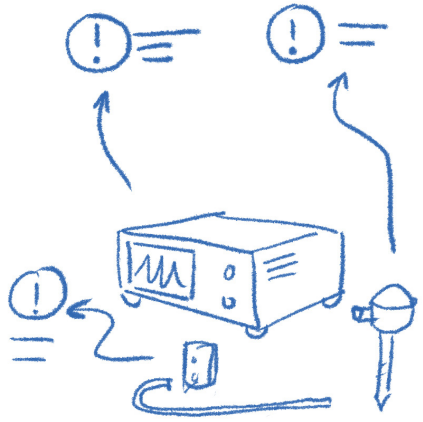


Figure 14

Tool Ouptut

The validation of the tool should show its ability or inability to generate outputs for the test casus Spatium Medical. The client expects new requirements that must be uncovered during these validation sessions. The findings for Spatium Medical will be presented to the client as a part of this graduation project.

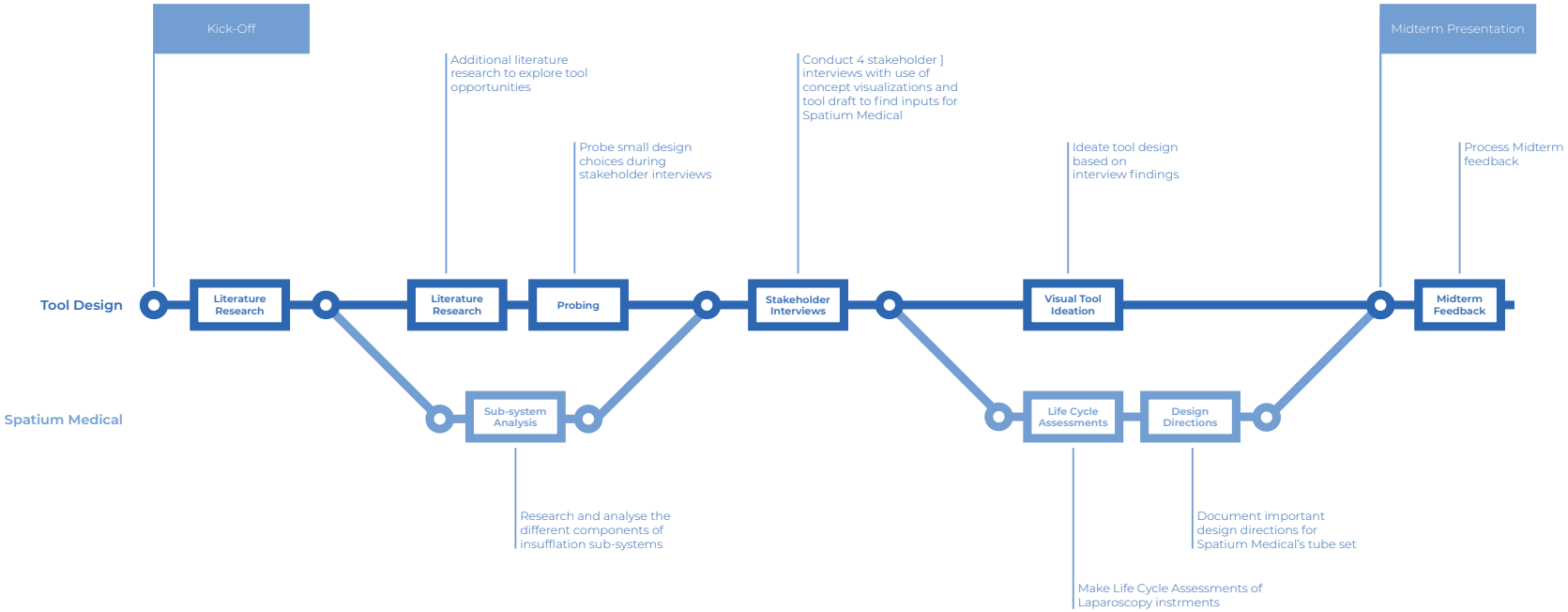


Figure 15 | Graduation planning

Project Planning

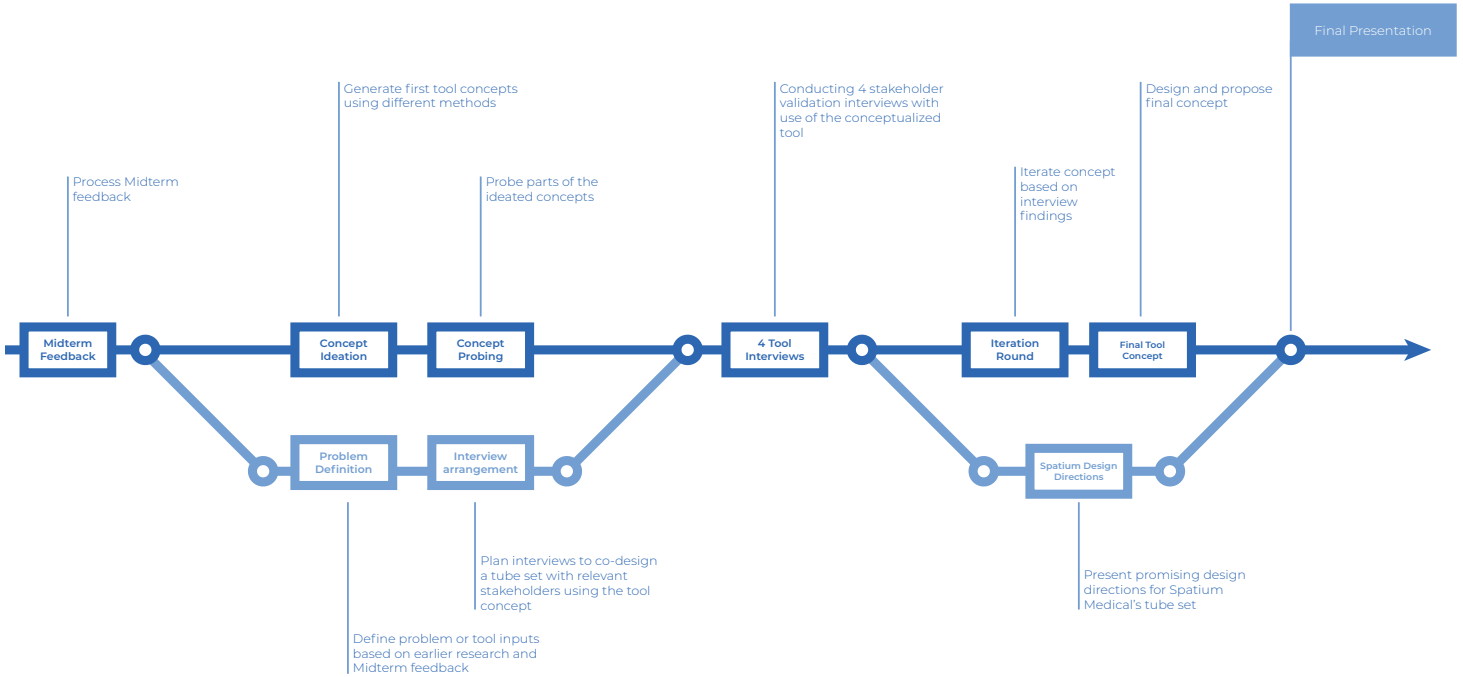
The planning of this graduation project is structured into two distinct phases, each with its own set of goals and activities, all of which should lead to the development of an effective co-design tool.

Phase 1 Contextual Understanding:

• Initiated with relevant literature research and field observations.
• Engaging stakeholders through insightful interviews to get essential insights.
• Derive a precise problem definition, laying the foundation for identifying needs and requirements.
• Conduct a thorough analysis of the Spatium Medical case, delving into its nuances.
• Perform life cycle assessments of various components within the Spatium Medical patient kit.
• Leveraging the knowledge and identified needs for exploration and ideation of the co-design tool.
• Present mid-term findings to validate progress and align with project objectives.

Phase 2 Tool Design and Validation:

• Carefully process and incorporate received feedback to refine the design process.
• Conceptualization of the co-design tool, integrating needs and insights.
• Thoroughly probing the generated concepts, getting an idea of their viability and alignment with project aims.
• Organizing the arrangement of validation sessions, an important step toward verifying the tool's effectiveness.



• Execution of validation sessions within the context of Spatium Medical, capturing invaluable feedback and outputs.
• Concluding the project by evaluating gathered data, extracting insights, and formulating recommendations.
• Presenting the finalized co-design tool, supported by compelling evidence of its utility and value.

Spanning a period of 6 to 9 months, this project diligently navigated through these phases to ultimately craft a tool that addresses the complexities of medical innovation by fostering collaborative design and informed decision-making.

04

Design Process

4.1 Approach

Similarly, to medical device development, the tool's design process can be considered as complex problem solving, as the outcome is not defined beforehand. Designing for complex problem solving has no standardized approach (Glouberman and Zimmerman, 2002). Therefore, probing is used as a strategy to implement and verify small pieces of possible design outputs. By doing so, one can iteratively make small adjustments throughout the design process. The core approach of the design process is based on User-Centred Design; 'a design approach that focuses on the user perspective to create valuable and usable products, interfaces, services, or systems. (Delft Design Guide, 2020). In other words, this approach prioritizes the usability aspect in the design process. This is crucial when designing a tool. If the design is not usable, the tool would be worthless. Moreover, this approach "is relevant in any domain where there is a gap between designer and user". As a graduation student from outside the organization of the client, the aim should be to learn from active involvement of future users, to be able to design a tool that fits the user's needs. The User-Centered Design approach consists of five steps that are iteratively pursued in this graduation project:

• Front-end user research: get to know the user group, their needs, capabilities, and context of use
• Define: Set goals, requirements, and limitations. Describe user group and context of use
• Create: Synthesize a solution that incorporates knowledge from users and capture a new desired state.
• Prototype: Create simulations that allow participants to experience the future design
• Evaluate use: assess the use and user experience of the design through user involvement and/or representation.

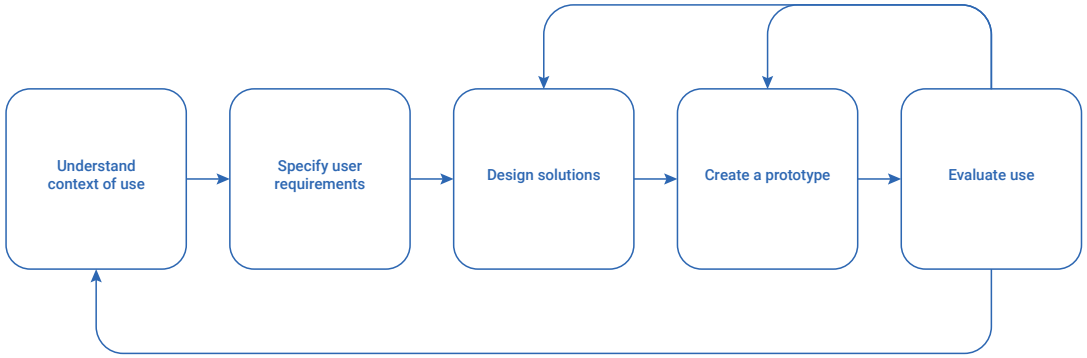


Figure 16 | Steps in user-centered design (Delft Design Guide, 2020)

Methods

Throughout the project, qualitative research is used to gain insights and experiences on the project management of Dune Innovation. Observations, interviews, and literature research helped to translate the macro project aim to a more tangible assignment by finding useful design inputs.
In the upcoming chapter, we dive into the requirements for the multi-stakeholder visual communication tool. These requirements have been derived from the findings obtained through the qualitative research and probing conducted as part of the user-centered design approach. Through observations, interviews, and thorough literature research, understanding on users, theirs needs and context regarding Dune Innovation have been gathered. These findings have played a crucial role in shaping the requirements, as they provide a deep understanding of the challenges, needs, and expectations of the stakeholders involved. This 'define' step of user-centered design translates these insights into concrete requirements that will serve as the foundation for the subsequent ideation phase. By aligning the tool's design with these defined requirements, we aim to create a solution that is primary usable and answers the project aim.

4.2 Co-Design

The challenges in healthcare are too complex to be tackled with one discipline. Proper collaboration among stakeholders is of great importance to ensure that solutions provide a valuable answer to the user's needs. Co-design is an approach that could provide a solution to the issues presented in the problem definition by actively involving stakeholders in the design process. Co-design is described as "an act of creating with stakeholders specifically within the design development process to ensure the results meet their needs and are usable" (Stratos Innovation Group, 2020). It is explained in more detail in research by Kleinsmann (2006): "Co-design is the process in which actors from different disciplines share their knowledge about both the design process and the design content. They do that in order to create shared understanding on both aspects, to be able to integrate and explore their knowledge and to achieve the larger common objective: the new product to be designed." This approach could clearly be of value within the complex nature of medical device development. However, co-design is an umbrella term, and it is carried out in many forms. Therefore, it is important to understand what aspects contribute to successful co-design, before conceptualizing a co-design-based tool. According to Kleinsmann en Valkenburg (2008), 'knowledge creation and integration are the goal of the co-design process. If actors are not able to create and integrate knowledge, they will not be able to design

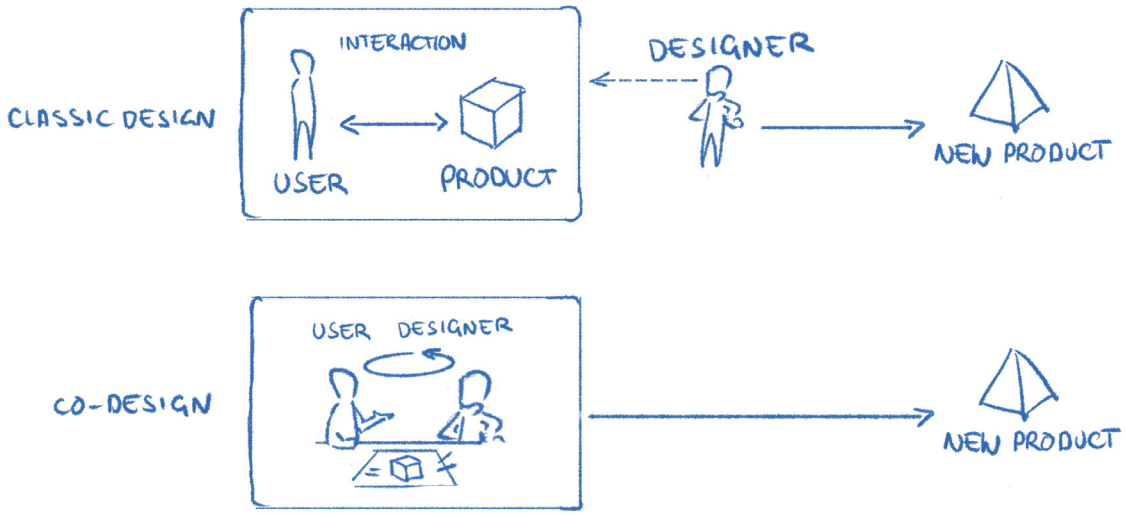


Figure 17 | Classic design and co-design | Based on: Sanders, E., & Stappers, P. J. (2008). Co-creation and the new landscapes of design. CoDesign, 4(1), 5–18. https://doi.org/10.1080/15710880701875068

a new product.' In other words, successful co-design processes rely on clear communication and knowledge exchange. This is referred to as creating 'shared understanding' in research.

Shared Understanding

Shared understanding means that stakeholder's knowledge is aligned in three ways: by agreeing on the goal of the project, by agreeing on the best strategy towards success and by agreeing on the stakeholder's roles and responsibilities during this process (Parker, 2023). Currently, it is debatable how often shared understanding is established when Dune Innovation meets with external, or even internal parties. In many cases, communication happens through text or speech. Both are susceptible to jargon and might lead to miscommunication, failing to reach shared understanding and making successful co-design unlikely. These findings will serve as an important foundation for the design of the tool.

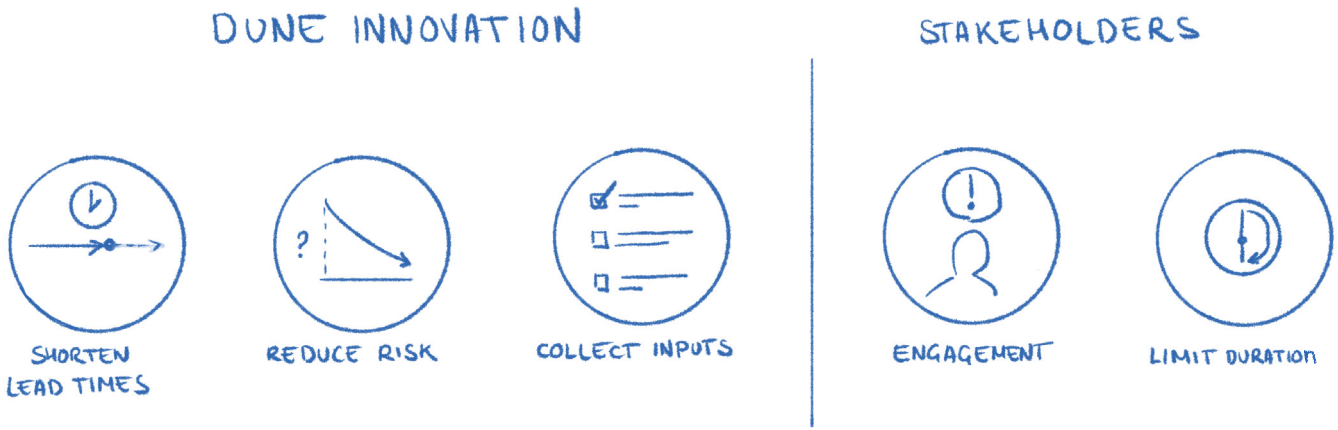


Figure 18 | Overview of user needs from Dune Innovation and its stakeholders respectively

4.3 User Needs

The user needs driving the requirements for the co-design tool are twofold, both Dune Innovation's needs and those of the stakeholders involved in medical device development. From Dune Innovation's perspective, the tool should optimize the constrained time available for stakeholder interviews by ensuring efficient sessions within a limited timeframe. It should facilitate shared understanding between facilitators and interviewees, allowing for structured discussions that generate valuable inputs for iterative co-design. Flexibility is essential, enabling the tool to adapt to various participants, projects, and settings. The tool should encourage creativity through visual cues and empty spaces, promoting easy sketching and brainstorming without usability constraints. A printable and modular design is preferred for practicality and future adaptability within different project scenarios.

Stakeholder needs center around the desire for engagement, improved discussion quality, and enhanced outputs. Interviewees benefit from a tool that accommodates their time limitations while taking part in a more open and productive conversation. In this process, it is valuable to be able to react to other stakeholders involved in the process. They gain from easy communication, to make the subject discussable despite its complex nature. Lastly, it is desirable to offer a more enjoyable and collaborative experience compared to traditional methods to give stakeholders a sense of ownership.

These user needs collectively shape the requirements for the co-design tool, steering the design process towards creating an effective, adaptable, and user-centered solution.

4.4 Requirements

1. Session Management and Duration

• The session must be ended within a maximum of 90 minutes.
• The topic of the session must be effectively explained within 15 minutes.

2. Editability, Accessibility, and Compatibility

• The tool should be editable for both the facilitator and interviewee during meeting.
• The tool should be editable digitally for the facilitator.
• Realize integration with Dune Innovation's traceability system and trace matrix.
• Compatibility with existing project management tools or platforms.
• Design printable tool that allows for non-digital use.

3. Flexibility and Adaptability

• The tool must be fit for different interview settings and locations.
• It should enable stakeholders to react to earlier session inputs, outputs, and validations.
• The tool should be designed in a modular way for future reuse and expansion.

4. Functionality and Features

• Possibility to formulate 'needs'.
• Possibility to formulate 'requirements'.
• Possibility to mention source of inputs.
• Possibility to include concept visuals.
• Possibility to show status of inputs/ concepts.
• Ability to formulate session questions.
• Functionalities to transcribe the discussion.
• Ability to trace comments added by the facilitator and/or interviewee.
• Sufficient space to allow for creative freedom.
• Drawing and sketching options to encourage visual communication.

5. Usability

• Provide manual for effective use by different facilitators and interviewees.
• Implement user-friendly interface and intuitive use-cues.
• Sufficient guidelines to explain the session's goal and process during session.
• Include visual cues to enhance readability.

6. Collaboration and Communication

• Enable real-time collaboration with facilitator and interviewee
• Facilitate simultaneous input, discussion, and feedback exchange.
• Option to refer to other stakeholders to create discussion.

7. Security

• Implement NDA to protect sensitive information.
• Adhere to privacy regulations.

8. Scalability

• Ensure the tool can handle project growth, multiple users, and increasing complexity.
• Ensure session inputs are collected in a structured procedure.

4.5 Ideation

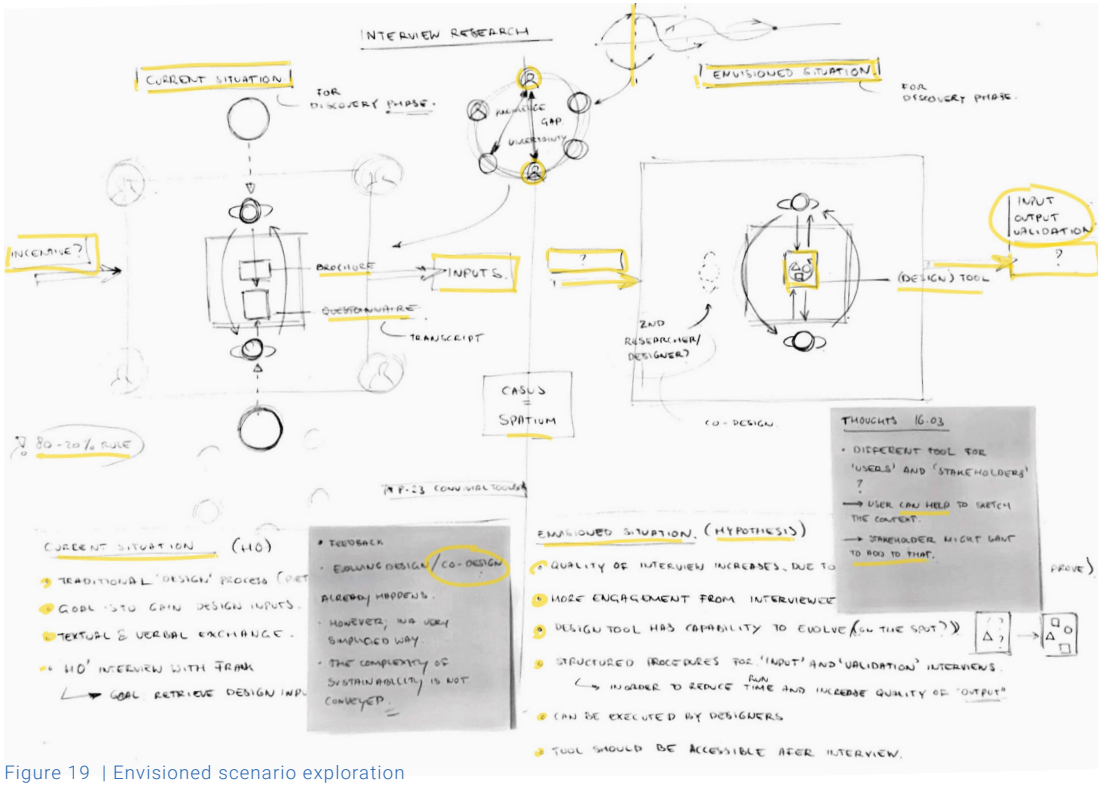


Figure 19 | Envisioned scenario exploration

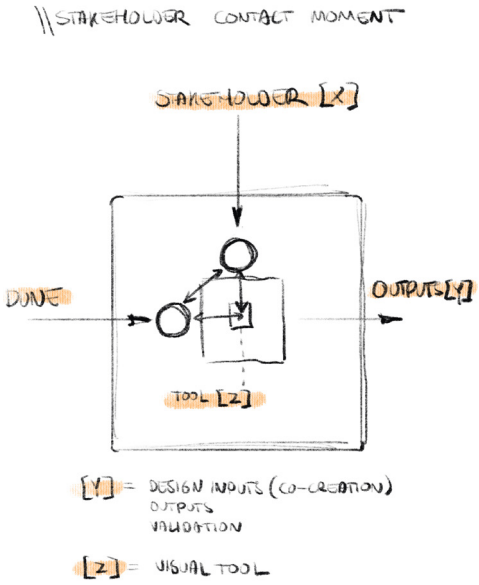


Figure 20 | Interview session with tool

Early Ideation

The ideation has been an ongoing process since the start of this graduation project. The project was initiated with the belief that visual communication can play a signification role in medical innovation, supported by research by Star and Griesmer(1989), who found that "visualization in design engineering has the capacity to be flexible and can be 'read' different by groups particular to their needs." The first ideas were sketched based on these findings and observations at the Dune Innovation office. The existing interview protocol was designed in a way to mostly foster design inputs during interviews with stakeholders. It made use of a classic interview approach where a list of questions would be presented and answered by an interviewee. The first ideation explored the idea of using these sessions to host a more dynamic interview, making use of 'a resource'. This could be a visual or empty sheets, as long as it invited the interviewee to actively take part in a discussion. This idea also proposed different outcomes of the interview. Instead of only producing either design inputs, design outputs or validation, this session could produce all three aspects at once (figure 18, 19).

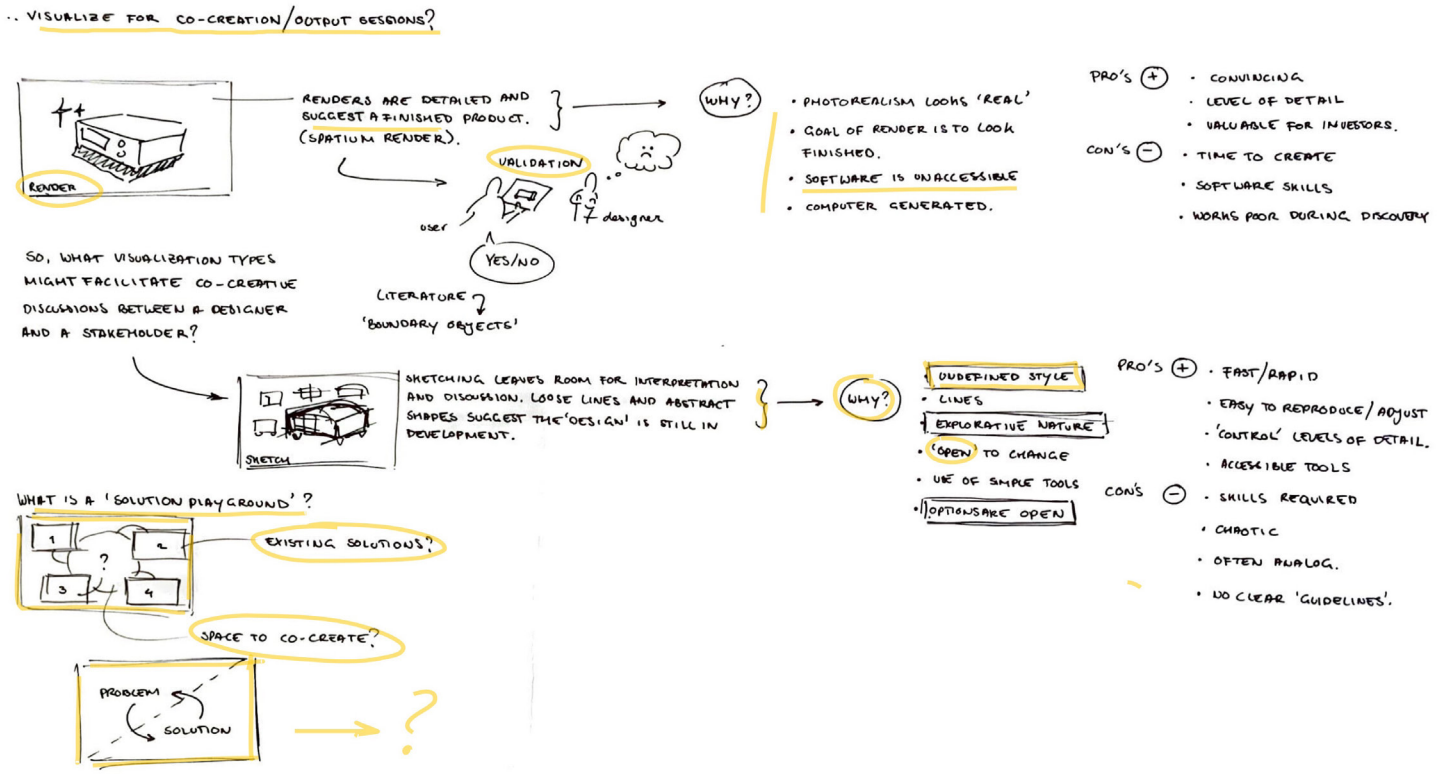


Figure 21 | Visualization as communication method

Sketching or Rendering?

The next step highlighted exploration of different means to use visualization techniques for the purpose of improving discussion quality and engagement. Something noteworthy was that one specific render of the envisioned insufflator was reappearing in numerous documents. This party confirmed the statement that visuals can provide aid in cross discipline collaboration. The visualization techniques of sketching and rendering were compared to find how they provoke different reactions and discussions. An important insight is that renders require specific skills and a significant amount of time to produce. This is undesirable in the discover phase. Designers and co-designers must be able to share ideas with a high pace. It also became apparent that the tool must provide 'space' to draw or make comments for it to enable co-designing activities.

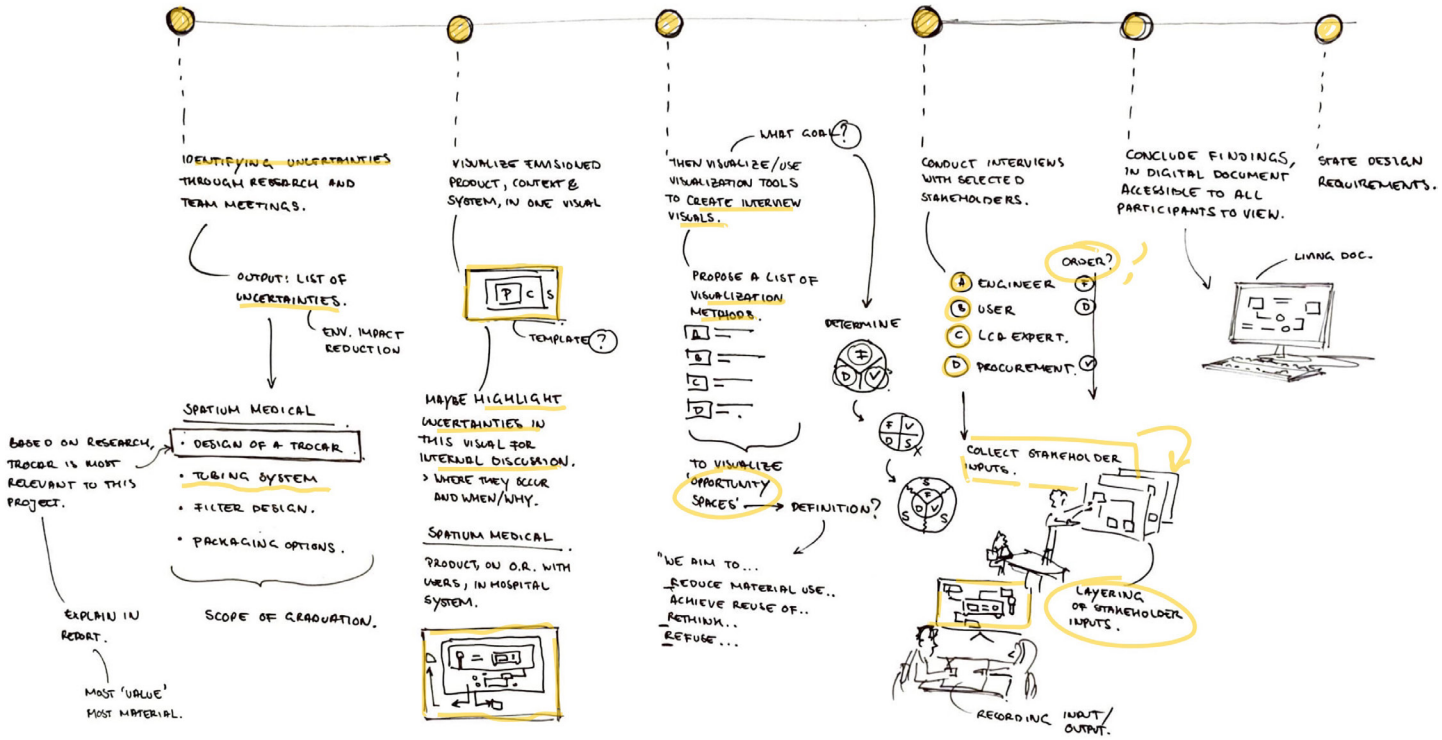


Figure 22 | Scenario exploration

Scenario Exploration

Figure 21 shows a scenario approach with the goal to find design inputs for the tool. This exploration shifted the focus from product to scenario and desired effects. A timeline with a starting and ending point sketches different steps and interactions that the tool should provoke during use. It is a first attempt to envision a standardized approach with defined steps. This ideation suggests templates to visualize product, context, and the system it operates in. Step 3 introduces the term 'opportunity spaces' which implies a certain moment in the sessions where the facilitator and interviewee are invited to collaborate on ideas without predetermining a design direction. Step 4 presents the idea of information layering: a functionality that enables the facilitator to organize information generated during the sessions. This layering of information makes it possible to visualize the different inputs, outputs and validations of project stakeholders.

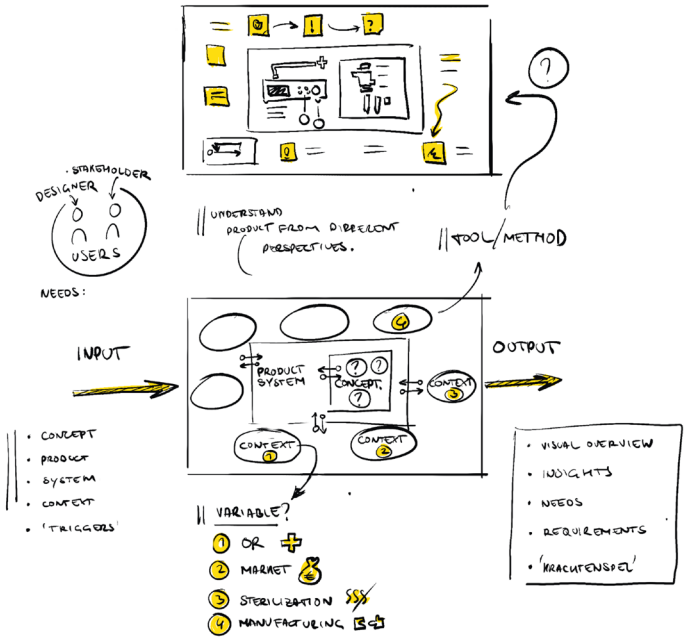


Figure 23 | Tool perspectives

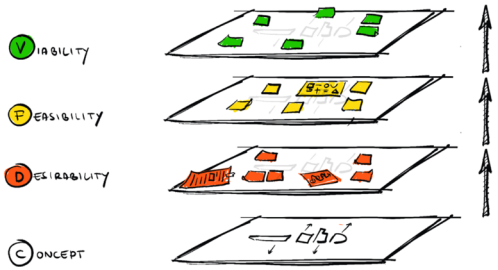


Figure 24 | Information layering in tool

Perspectives

Analyzing and conducting interviews on Dune Innovation's case Spatium Medical (explained in chapter 6), helped to understand the complex nature of medical product development. Talking to different stakeholders showed that there are several different perspectives towards to project, which can also be interpreted as 'layers (figure 22, 23). It seems that in many cases, stakeholders are representing their own interests. The first interview was conducted with Frank Sterke, a biomedical engineer at Spatium Medical. The most important take-away was that engineers will mainly want to conversate about functionality and the feasibility of the project. Their priority is to meet technical requirements of the product to deliver a feasible concept. An interview with John Vlot, a pediatric surgeon, provided a different perspective to the project. As was experienced during the interview, an end user is more likely to talk about his or her user experience with related products. Nevertheless, usability is crucial to the adoption chances of the product and have a significant effect on the desirability of the project. Lastly, Maarten Timmermans was interviewed who was a former procurement employee at the Erasmus Medical Center. This interview proved that product don't succeed when there is no market strategy. Unit prices, as well as patient kit prices and selling strategies are important to the viability aspect of a product. In conclusion, feasibility, desirability, and viability form the basis for a successful product. These criteria are equally relevant during the design phase, and it is therefore important that users of the tool get insight into these different perspectives. During this part of ideation, different ways to visualize these 'layers' were explored.

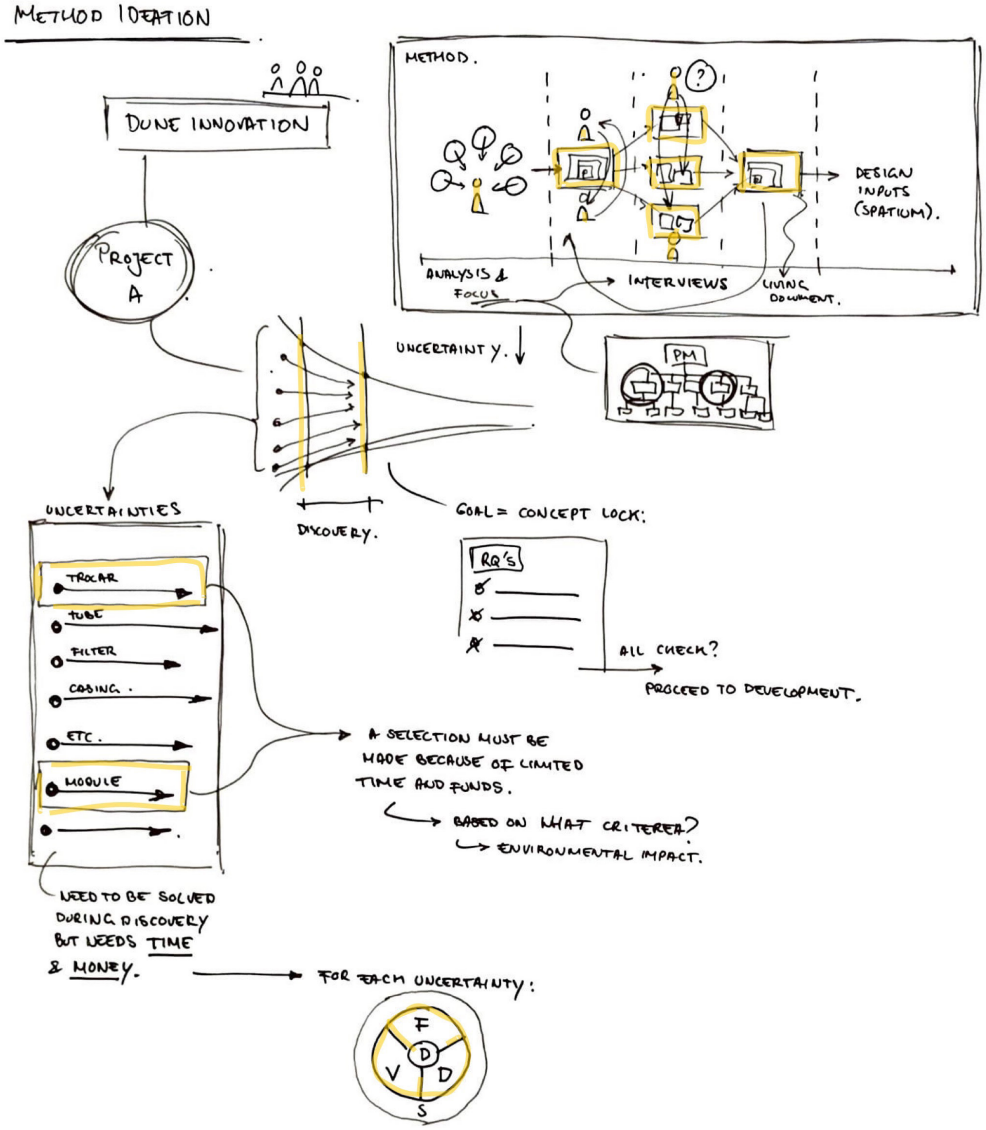


Figure 25 | Tool ideation

Tool Inputs and Outcomes

Free ideation was a valuable way of finding creative design directions without the constraints of the real-life scenario. However, at this point it became necessary to envision the concept within the scope of Dune Innovation. Framing the concept in a concrete scenario aided in understanding the goals that the tool should achieve. As stated in the project aim and requirements, the tool should enable shared understanding and co-design with the goal to minimize uncertainty in choosing design directions. This means that for each session, there must be a defined input and output. In order to make the interview topic tangible, it was found that the inputs of the session should be specific uncertainties regarding the Spatium Medical. For instance, 'which trocars work best with the insufflator?' or 'how to optimize a tube set while mitigating environmental impact?'. Since not all uncertainties can be resolved, Dune Innovation must choose specific uncertainties with the highest amount of risk. The goal is that the co-design sessions resolve these predefined uncertainties in order to make it possible for Dune Innovation to take well informed design decisions.

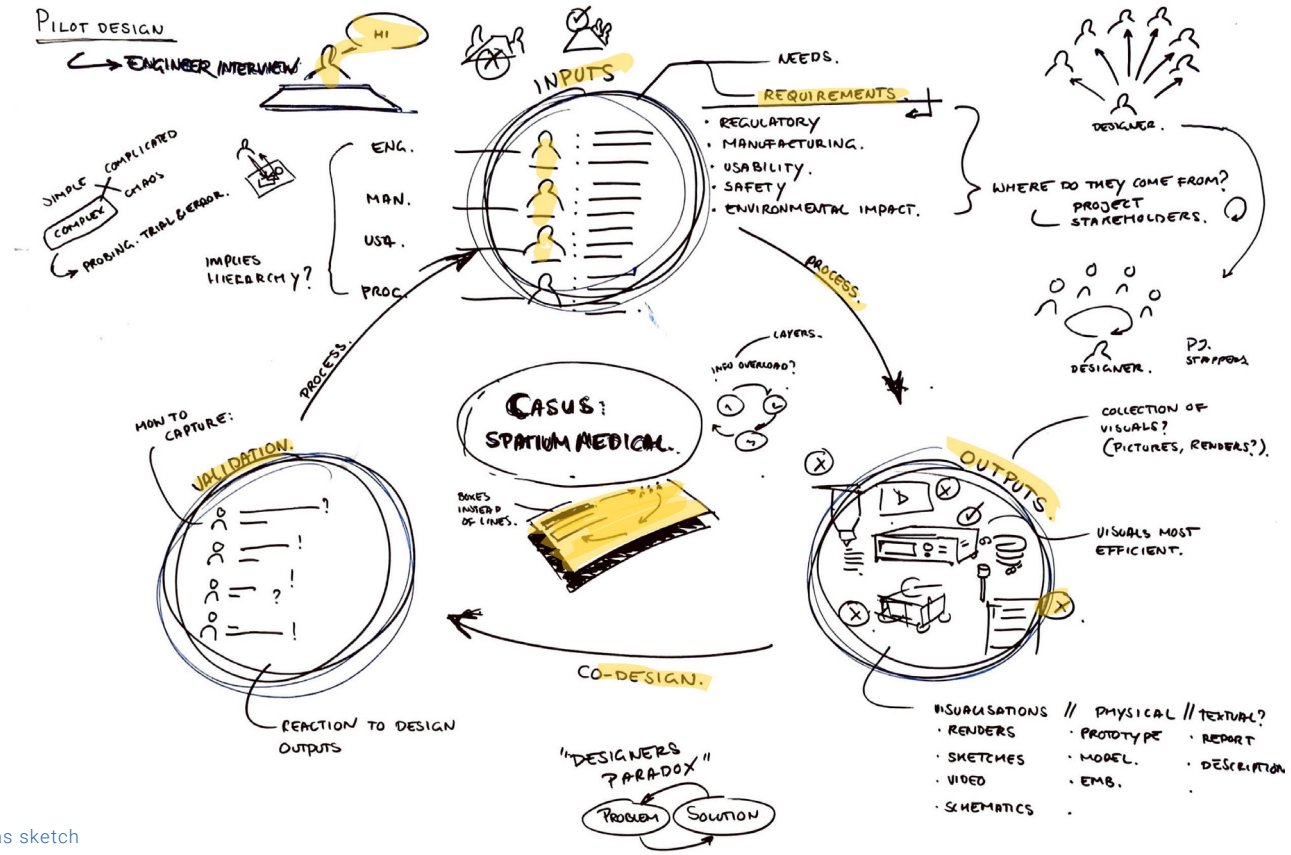


Figure 26 | First canvas sketch

First Canvas Ideation

Figure 25 shows a first sketch that represents the idea for a co-design canvas. Based on earlier findings, it supports the sessions by visualizing the complete design process. The foundation is based on the design controls format regulated by the FDA (FDA, 2022). The idea suggests three distinct spaces. The first one is intended to discuss user needs and requirements, also referred to as 'design inputs'. Interviewees should be able to share their interests and needs while also having the opportunity to react to other stakeholders. The inputs should be documented in a way that it remains clear which stakeholder represent which design inputs. The same idea is applicable for the next steps, outputs and validation. Participants should get the chance to co-create together with the designer. The output space must provide freedom for sketching and writing. Lastly, the validation section is a reserved space where participants can react to generated outputs. By formulating their reactions in a clear fashion, it might lead to the documentation of new, unforeseen design inputs.

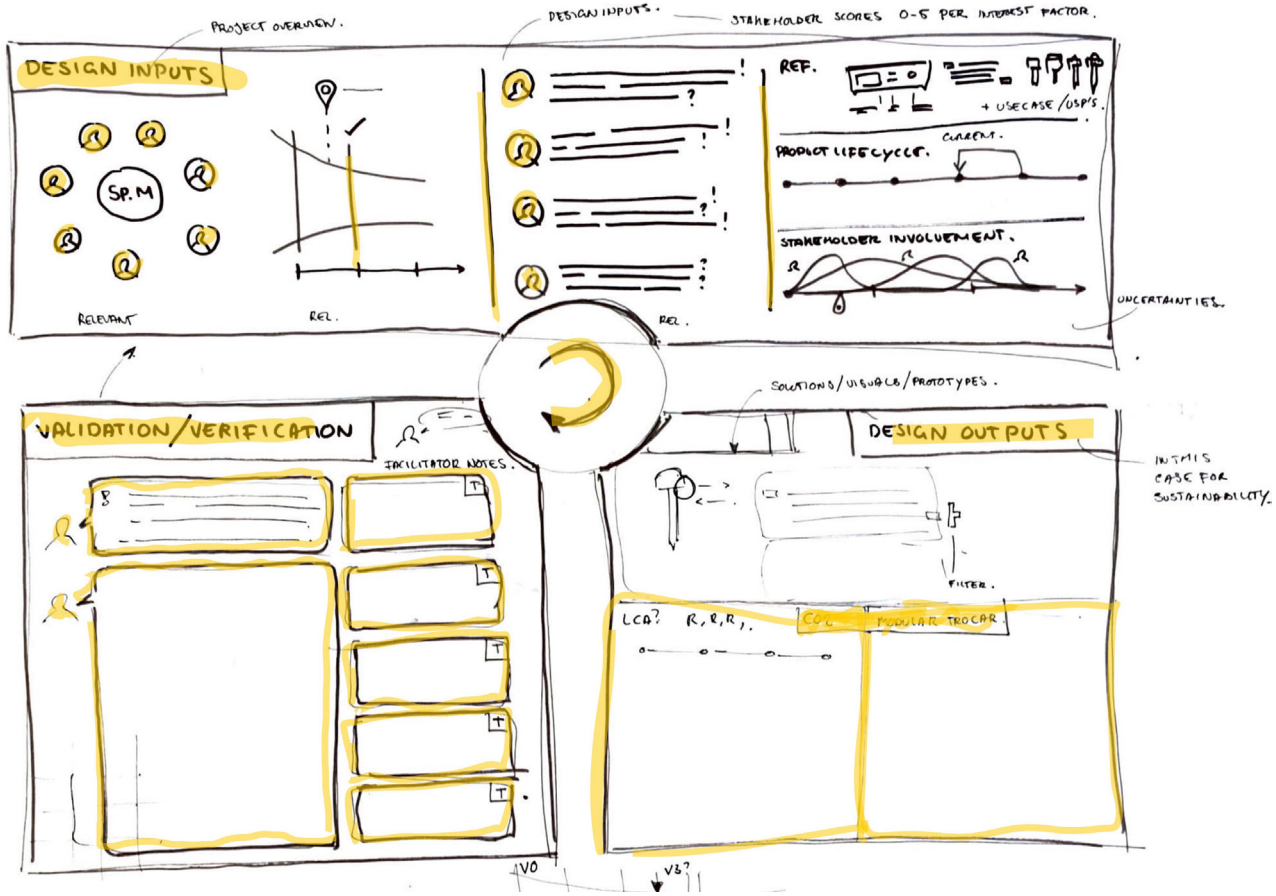


Figure 27 | Co-design canvas ideation

Second Canvas Ideation

The second canvas iteration is a more elaborated representation of a co-design template. This visualization highlights the three defined 'design steps' with a designated 'space' for co-design activities. It is also a first attempt to give substance to the specific steps during the co-design session. The 'design inputs' section contains relevant project information that should help the participant to understand the goal of the project and interview. Examples are a project timeline, involved stakeholders, a product system visual and stakeholder involvement. The middle section is intended to document inputs. The 'design outputs' sections are divided in three parts all representing a 'solution space'. There is room for ideation and discussion. Lastly, the validation tab presents a chat-like interface which should enable the participants to structurally document reactions based on the design outputs.

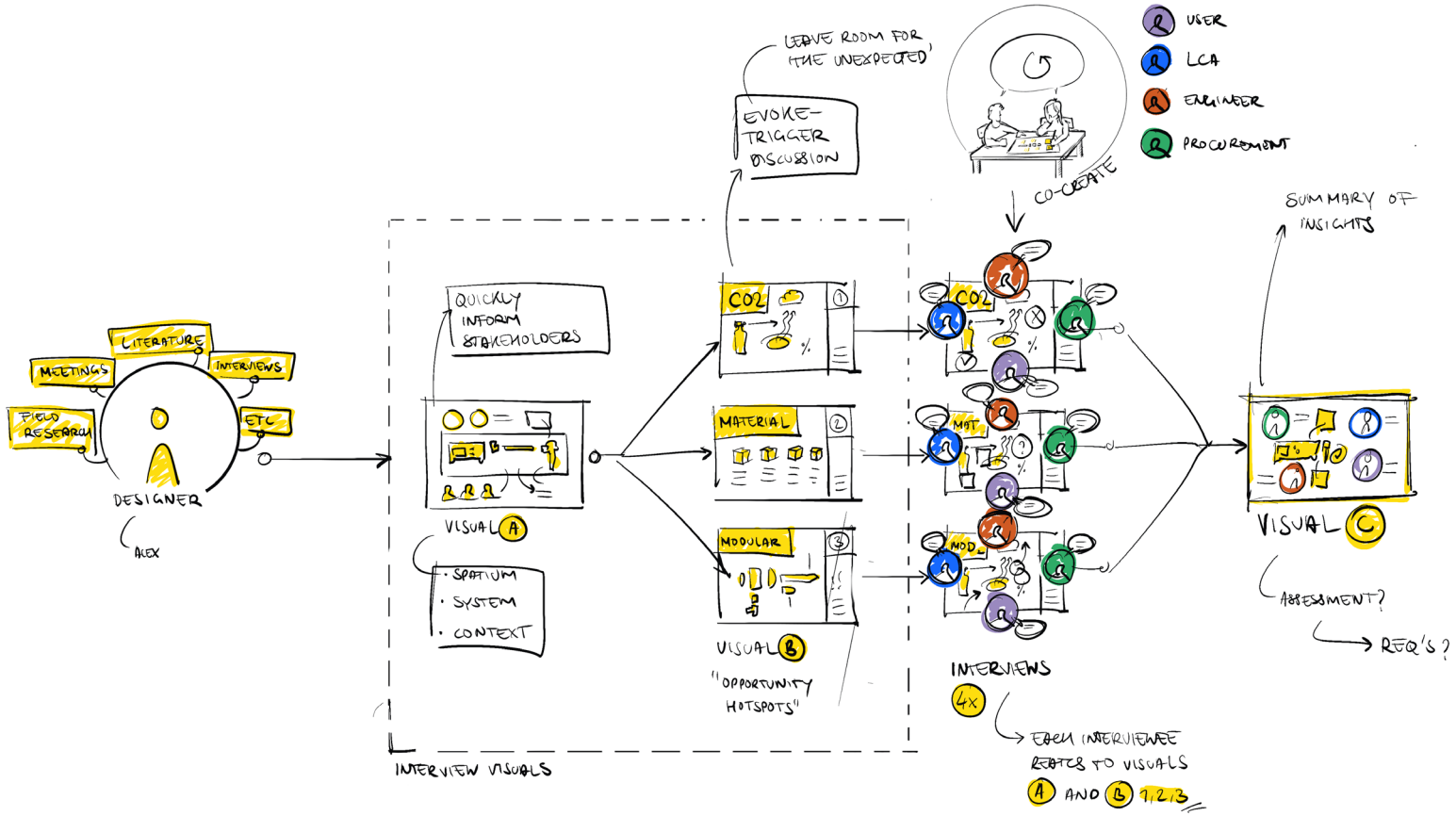


Figure 28 | Procedure flow ideation

Procedure Ideation

This procedure visual explores an early form of a user scenario. This scenario begins with a future session facilitator that first takes the necessary time to get familiar with the complexity of the project. This facilitator then defines which stakeholders would be valuable to get in touch with. The exploration sketch suggest that the tool could have the ability to diverge into different 'layers' or subproblems related to the project. This idea is proposed to be able to collect more specific input on certain components or criteria of the project at hand. This generated input would later be converged back into one part of the tool. This summarizing part of the tool would show input or reactions from different stakeholders, that could be used in successive sessions to initiate discussions.

First Digital Ideation

During multiple rounds of ideation, significant insights were obtained to further develop the design. For the next iteration rounds, Illustrator software was used to try a digital approach in designing the tool. Some relevant insights that were integrated in this digitalization step included layering of criteria, inputs from multiple stakeholders, dedicated space for co-design and a structured procedure. One of the challenges was to find a way to offer freedom of creativity while also providing guidelines in the process. A solution for this challenge to make use of a 0.5 mm grid background for the canvas (figure 28). This grid makes it possible to use modular 'digital post-its' while retaining an organized document that had clear user guidelines. Similar to the previous ideation sketches, this canvas represents the iterative design process, based on the FDA design controls. New additions are categorized interest, highlighted with icons. Furthermore, icons are added to the comments to communicate which interest category they are dedicated to. Next to that, the design input section now also includes a chat-interface. Inputs from different stakeholders are documented in chat box post-it's and documented with a name, date, and traceability-code. These design decisions are based on the need to facilitate a 'dialogue between stakeholders', without having them present at the same time. The design output- and validation space also include the digital post-its to provide a designated space for idea generation. One of the new issues encountered was a lack of overall space. This concept was printed on A3 papers to experience the canvas in an interview setting. It quickly became apparent that the digital post-it's don't provide enough freedom for creativity. A next iteration should integrate more empty spaces while also explaining more about the interview session.

Grid Design

The grid design offers a great functionality. In illustrator the grid enables 'snapping'. This means when a new shape is made, the outlines automatically snap on the grid. This aids in adding structure to the documents and might help the designer to quickly design or adjust the session canvas.

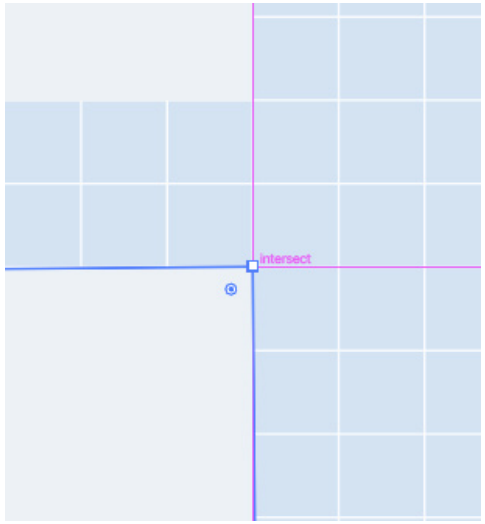


Figure 29 | Grid design in illustrator

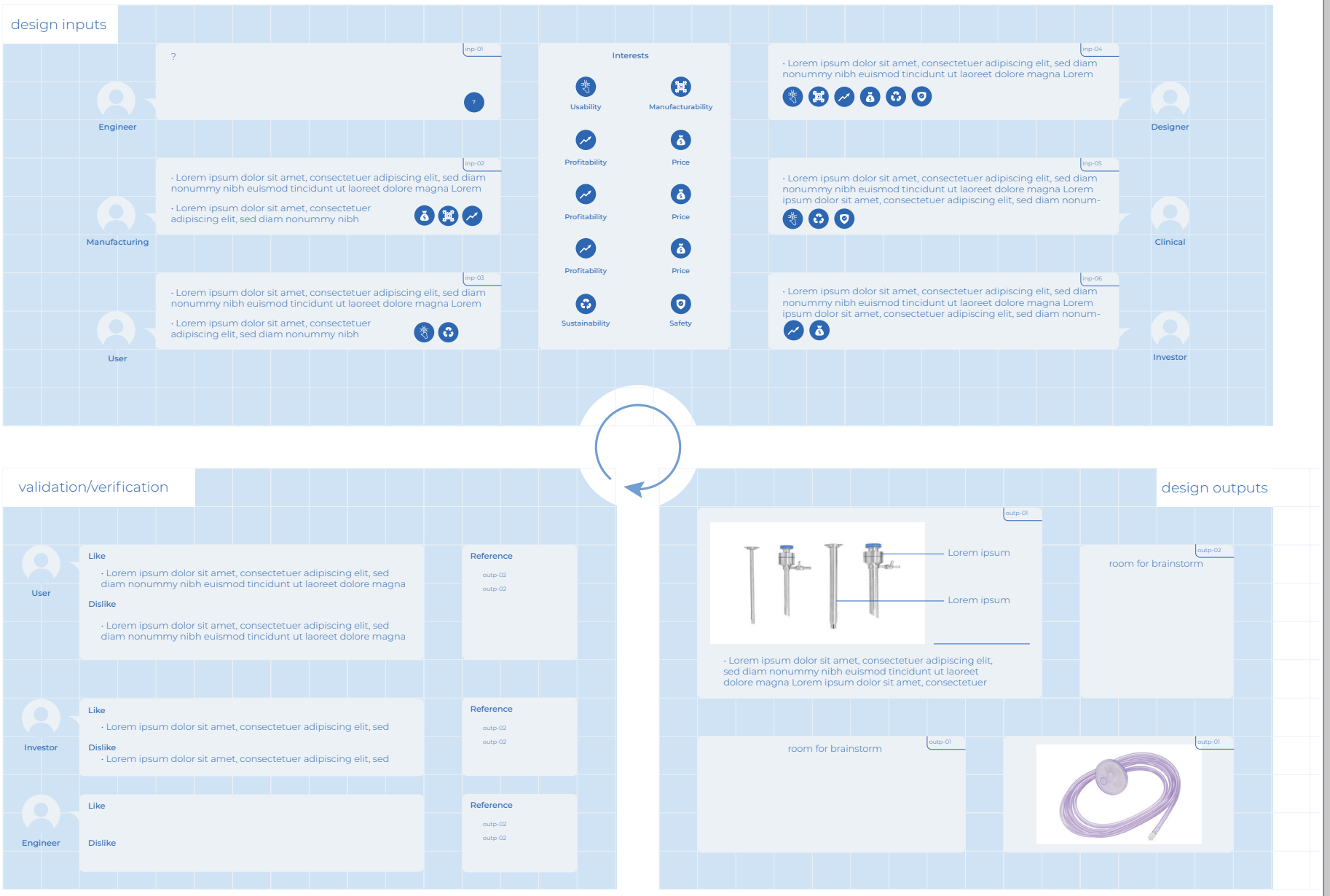


Figure 30 | First digital ideation

Second Digital Ideation

During the second digital ideation phase, further improvements and additions were made to enhance the design process (figure 32). Notably, design inputs were now categorized based on their input category and date, allowing for better organization and traceability. To address the previous space constraint, additional room was allocated for the output or idea generation step, providing participants with ample space for creative exploration. A significant enhancement was the introduction of a validation mechanism, empowering participants to assess the outputs. This was facilitated through the use of colored rectangles, where a green rectangle indicated a promising design direction, an orange rectangle denoted uncertainties, and a red rectangle highlighted a showstopper. To provide a quick overview of the overall progress, a status indicator in the form of a circle was incorporated. The color of the circle, whether red, orange, or green, was determined based on the amount of remaining uncertainty regarding the subject. These new additions not only improved the organization and evaluation of design inputs but also enhanced the visual representation of the design process, promoting efficient collaboration and decision-making.

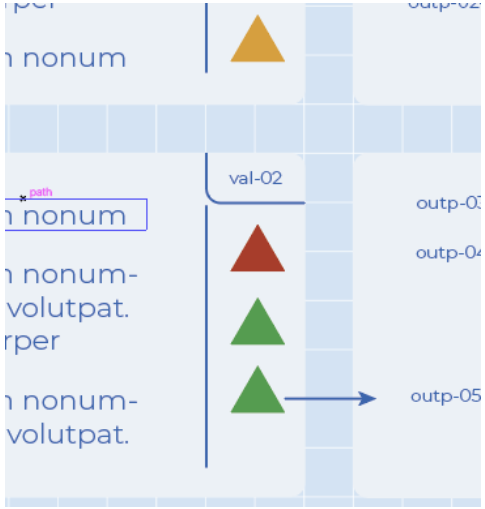


Figure 31 | Colored use cues

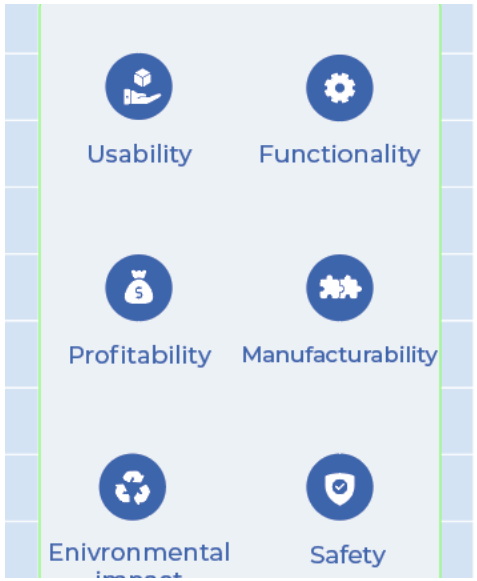


Figure 32 | Categorization icons

Visual Cues

Visual cues in the form of colored triangles can play a significant role in providing an effective overview of stakeholder feedback on design outputs. By assigning different colors to the triangles, such as green, orange, and red, the tool can visually represent the nature and level of feedback received. The green triangle indicates a promising design direction, reflecting positive feedback and endorsement from stakeholders. The orange triangle signifies areas of uncertainty, highlighting aspects that require further exploration and clarification. On the other hand, the red triangle flags potential show-stoppers or critical concerns that need immediate attention. These visual cues enable a quick and intuitive understanding of the overall sentiment and areas of focus, allowing designers and stakeholders to prioritize actions and address feedback in a more informed and efficient manner.

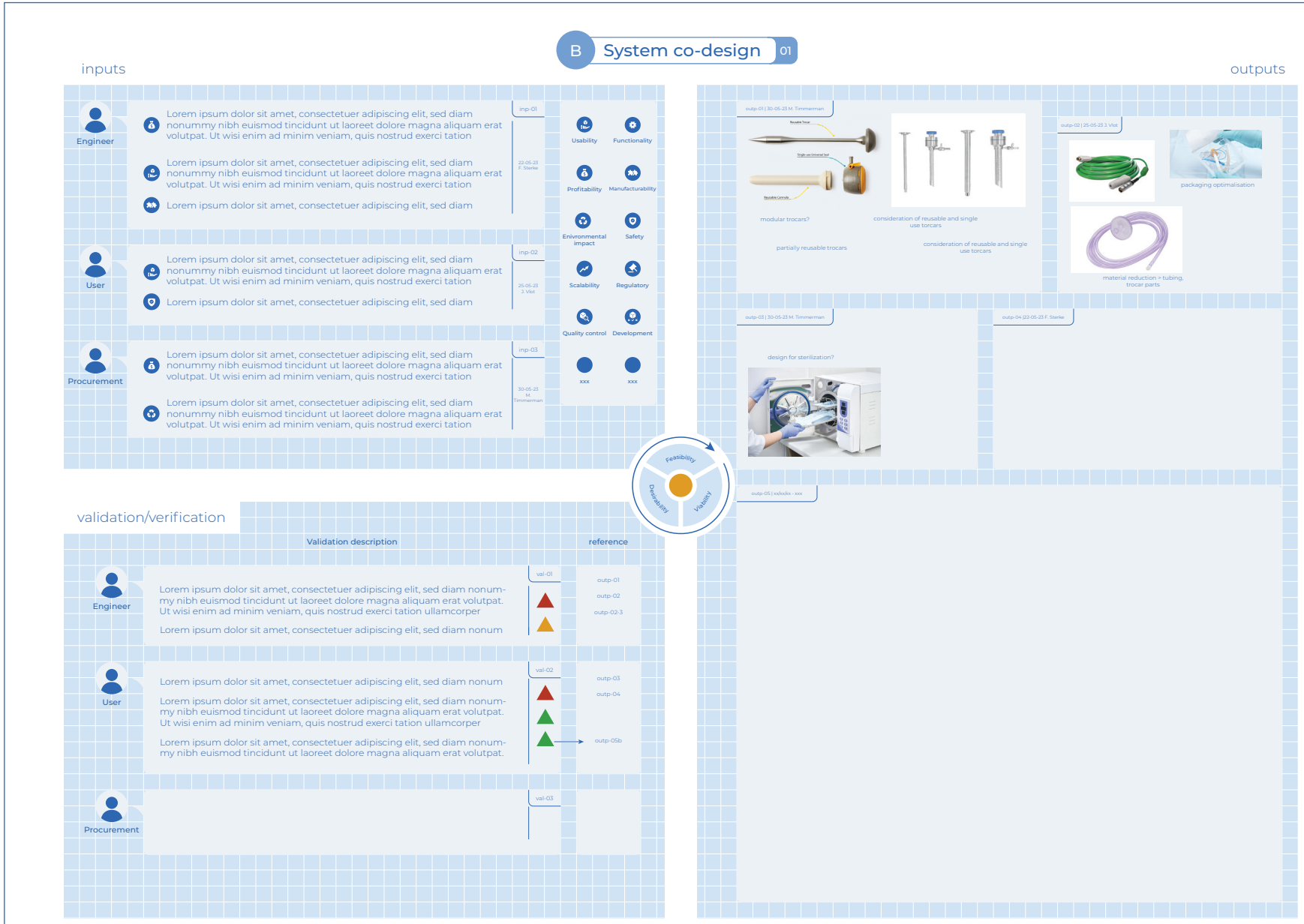


Figure 33 Second digital ideation

05

The Final Concept

5.1 The Final Concept

General Description

The final concept is a physical co-design tool for Dune Innovation aimed at facilitating fruitful discussion during the fuzzy front end of medical device development (figure 33). It is designed to address the lack of qualitative communication between Dune Innovation and its stakeholders. The line of approach is to use the valuable time with stakeholders as efficient as possible. To do so, the tool offers a standardized approach to complex problem solving. It is designed to simplify communication of complex matter to lay a foundation for co-design activities with stakeholders.

During a physical 90-minute session, an employee from Dune Innovation will hold the role of the facilitator of the sessions. His or her goal is to guide the interviewee through the session and ensuring prepared questions and uncertainties are discussed properly. The stakeholder interviewee is lead and engaged in co-design activities in this process. The goal is to generate new needs, requirements or ideas related to the project by co-designing with the stakeholder. To support collaboration, the tool offers functionalities for real-time feedback and brainstorming. Stakeholders can provide comments, suggestions, and critiques, all adding to an iterative design approach that should lead to new inputs.

Figure 34 | The co-design tool in use

5.2 System Overview

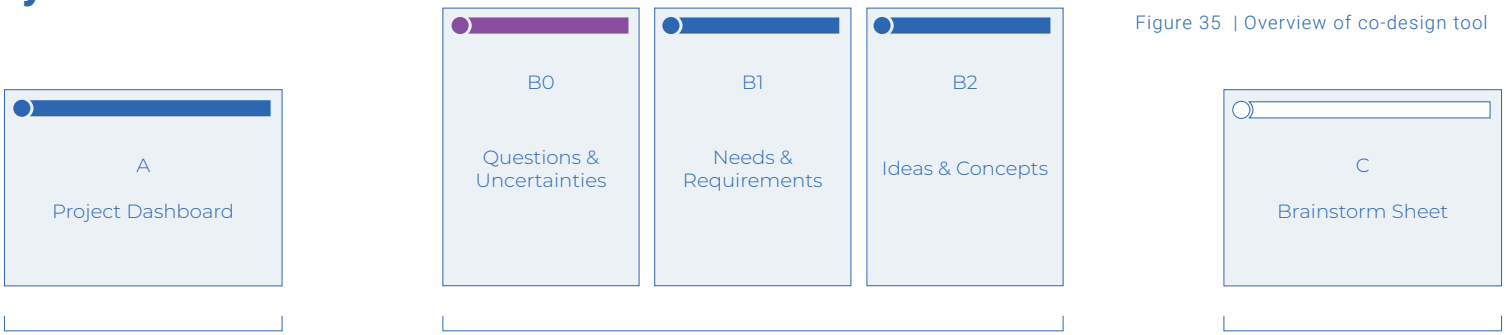


Figure 35 | Overview of co-design tool

The solution can best be described as a digital template which can be prepared for specific interview sessions. The template consists of three parts: Part A, Part B, and Part C. After system description, each part will individually be explained in more detail. The project dashboard (A) serves as the foundation of the session. This template offers predefined spaces to add relevant information on the project that is to be discussed. During the first 15 minutes of a session, part A is used to communicate the essence, goal, and scope of a project to an interviewee until shared understanding is reached. It sets the foundation by explaining the project aim, contextual information, and the procedure of co-design. Throughout the duration of a session, is also functions as a frame of reference to support design thinking.

Part B consists of three sheets that present the iterative circle of problems and solutions within the project scope. The aim is that by making both inputs and outputs transparent to the interviewee they are provided with a chance to understand different perspectives and take part in the design process. Part B is rather an approximation of the inputs and outputs of a project based on the list of requirements.

Part B0 is a sheet that contains prepared questions for the session. This sheet is not essential to the interviewee but is used by the facilitator of the session to structure the meeting and to ensure that relevant questions are answered. The questions help to shape the conversation and are accessible for the interviewee when the situation asks for it.

Part B1 represents a summary of relevant inputs. Those inputs can both be needs or requirements. Where needs can be fuzzy and undefined, requirements are measurable criteria. Needs and requirements are presented next to each other to show their relation.

Part B2 complements part B1. The template provides room to include visualizations that represent ideas, concepts, or design directions. The concepts presented are technically a first translation of the inputs formulated in part B1. It is important to emphasize the undefined nature of these in- and outputs so that they leave room for alterations or new ideas. For the visualization of concepts, sketched are therefore preferred due to their ‘undefined’ nature.

Lastly, part C is an empty sheet that can be used to facilitate brainstorming activities. Both the facilitator and the interviewee should be able to use it for writing or sketching, capturing inputs from the session. It gives the tool a flexible nature and provides freedom to accommodate different needs that might appear with different interviewees.

Figure 36 | Town down overview of the tool in use: stakeholder (L) and facilitator (R)

Part A: Project Dashboard

Part A is named the 'Project Dashboard' (figure 36, 37). The Project Dashboard functions as the foundation of the co-design session. It plays a crucial role in establishing a shared understanding with the interviewee who may be unfamiliar with the tool and project. The primary goal of Part A is to provide contextual information and create a collaborative environment that fosters effective communication and engagement. The project dashboard involves the following key elements:

1. A Project Description. At the top left of the project dashboard, we find a dedicated space for basic description of the project that will be the subject of the session. It should elaborate its functionalities and why it promises to be an improvement compared to current solutions in the market.

2. The large visual underneath the project description is an **envisioned context visualization of the future product**. It provides a top-down view of the product in action where the interaction with its users is a central subject. Next to the context visual, the product is visually divided into sub-systems. This part of the project dashboard is valuable to help the interviewee to imagine the envisioned product and the different design perspectives.

3. On the bottom right side of the project dashboard, a simplified approach of **Dune Innovation's project management** is included. The main reason for this is to bring across the importance of stakeholder collaboration during the discover-phase of medical product development. It also enables the facilitator to explain what the status of the project is, and what milestones are yet to come.

4. Above the project planning, we find a small space to elaborate on **the session scope.** This can be used to include additional information relevant for the session. A scope can define an approach to the session. For instance, during validation rounds, environmental impact on the patient kit was the approach to the session.

5. Lastly, at the top right, a **brief overview of the tool** is visualized. The facilitator can use this to explain the procedure of the session and the different parts the tool consists of.

It is important to note that the content on these example sheets is based on the validation rounds conducted for Spatium Medical. This will be explained in further detail in the validation chapter. This tool is designed to be prepared differently for new projects and sessions. According to the project and the interviewee, other information can be included in the project dashboard to ensure effective communication between the facilitator and the interviewee.

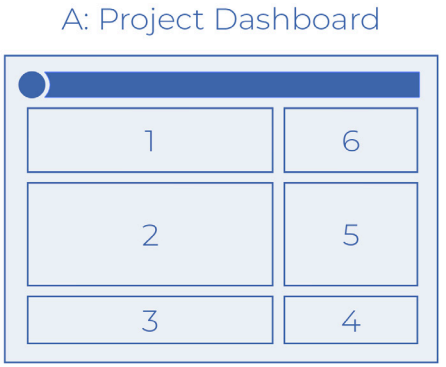


Figure 37 | Project Dashboard

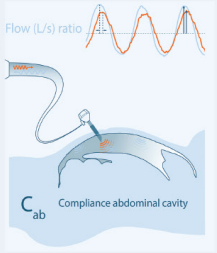
A **Project Dashboard** | **Laparoscopy Patient Kit**

Spatium Medical | The Next Generation Insufflator

Spatium Medical is an innovative spin-off from the Erasmus Medical centre in Rotterdam developing the next generation of insufflation technology.

During laparoscopy, the **abdomen is insufflated** to create workspace for the surgeon. Using the **lowest possible pressure** and keeping it stable to accomplish the surgical task without compromising the surgical outcome.

Spatium Medical's next-generation insufflator uses turbine technology to provide **reciprocal insufflation**, enabling **stabilized pressure**, and oscillation technology that allows selection for **personalized pressures**.

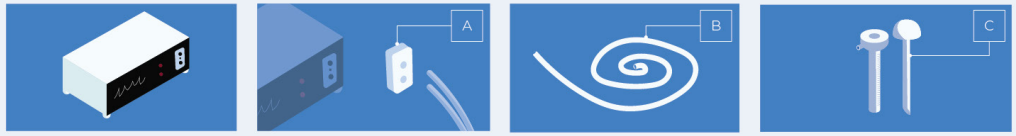


Interview Session

1. Introduction of the project, explanation of procedure and the desirable outcomes of this session — 15 min
2. Co-Design session: Discussing existing needs, requirements and ideas and coming up with new ones — 60-90 min
3. Wrap up: checking all questions, inputs and outputs. Summarizing interview session — 15 min

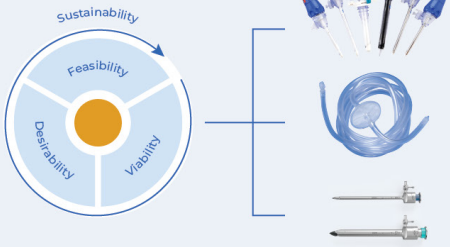
Spatium Medical | The Next Generation Insufflator

Device | Patient Kit

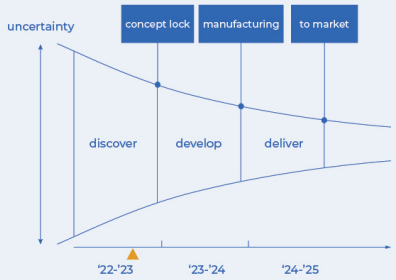


Insufflator | Filter | Tubing | Trocar

Session Scope



Project Planning



Date □□-□□-□□□□ DRN: dune230519r1-ap01ai-A Facilitator _____ Co-Designer _____

Figure 38 | Part A, Project Dashboard

Part B0: Questions & Uncertainties

Part B0, Questions and Uncertainties (figure 38, 39), has the main functionality to guide the co-design activities in a structured manner. This sheet is intended to be used mainly by the facilitator. It is used before the session to formulate relevant questions and uncertainties that need inputs from the interviewee to be (partly) resolved. The design of this sheet offers the facilitator a way to formulate questions and uncertainties in a structures fashion. They can be numbered for traceability reasons and can also be referred to either design inputs (Part B1) or design outputs (Part B2). Status check boxes are included. This way, the facilitator can cross out a question whenever it has been discussed properly. Essentially, this sheet is designed for the facilitator however, it can be shared with the interviewee whenever necessary.

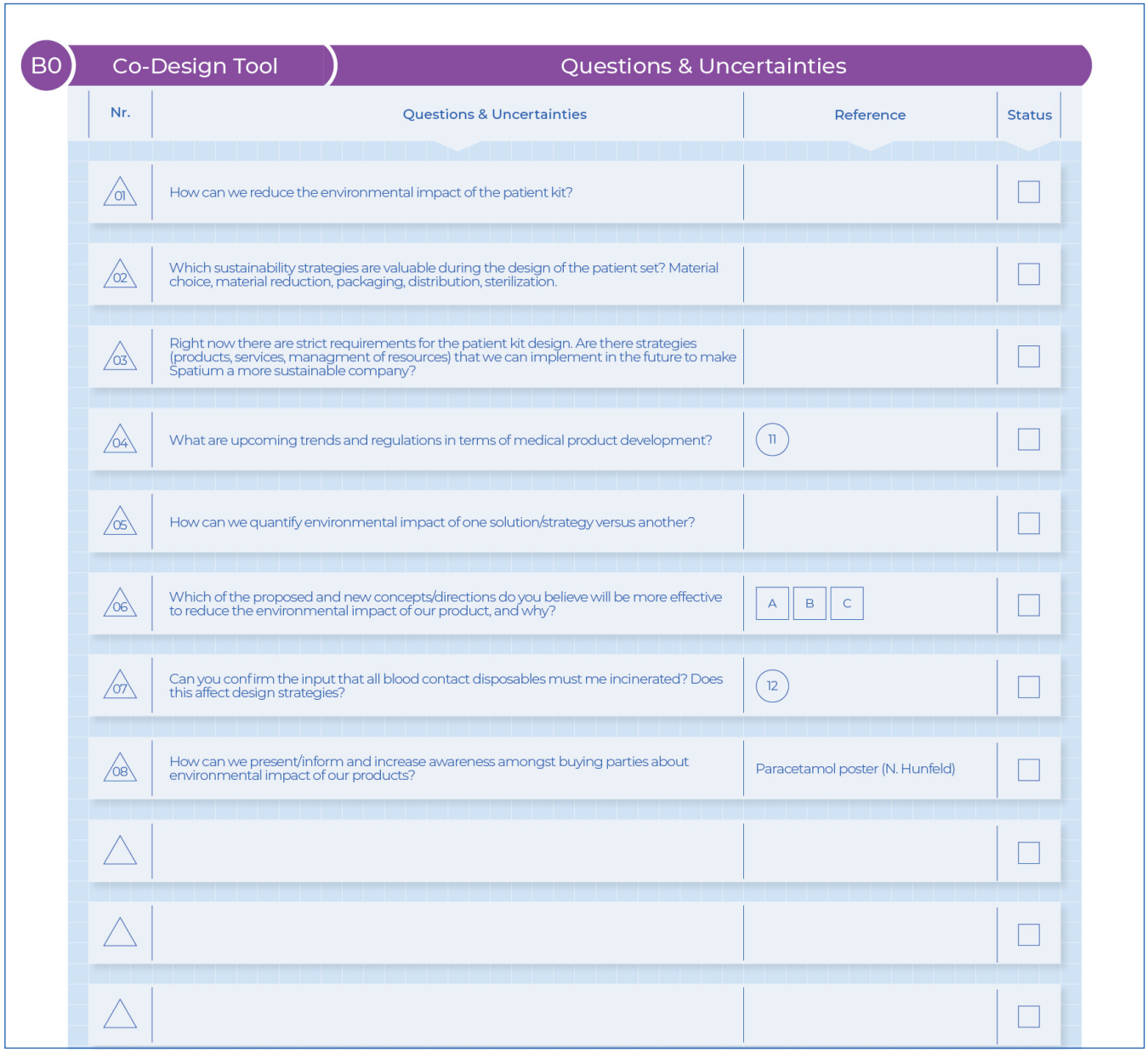


Figure 39 | Co-design Part B0: Questions and Uncertainties

Figure 40 | Co-design Part B0: Questions and Uncertainties

Part B1: Needs & Requirements

Part B1 of the co-design session (figure 40, 41) focuses on capturing the design inputs, which includes the user needs and requirements. It provides transparency on the origin of needs, requirements towards the interviewee. Understanding design inputs enables them to view the project from different perspectives and join in design thinking. This sheet is prepared before a session. A selection of relevant inputs is made by the facilitator. Those inputs are categorized on criteria to make it manageable for the interviewees to understand. Inputs are also related to a source of origin if applicable, to emphasize other perspective towards the project. Finally, the status of the requirement can be indicated with green, orange, or red to suggest to what extend the requirement has been met. After multiple sessions, this document can grow when interviewees generate new inputs. By capturing the design inputs in Part B1, it sets a solid foundation for subsequent ideation and concept development in Part B2, ensuring that the resulting design solutions are rooted in a thorough understanding of the user's needs and requirements.

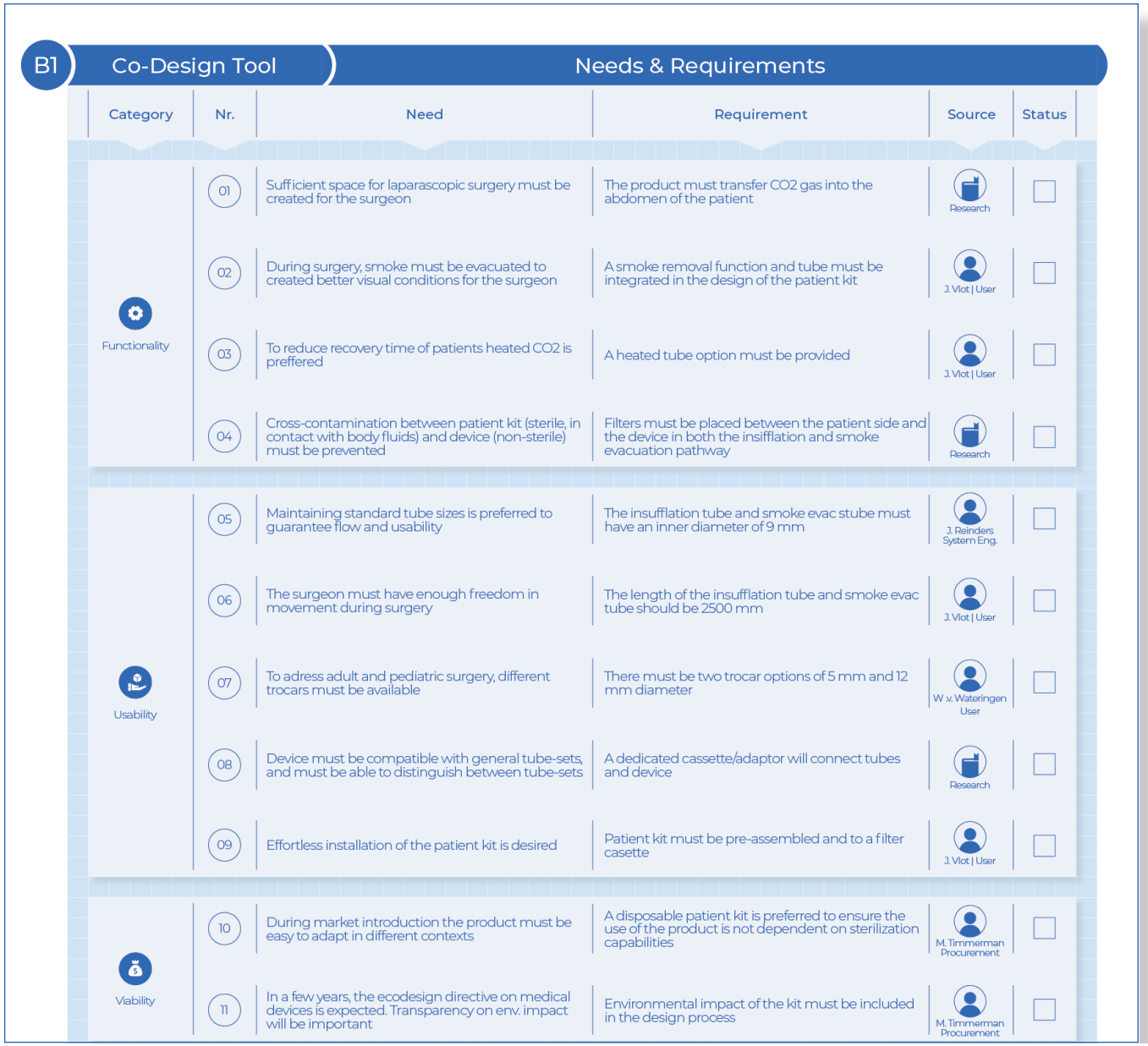


Figure 41 | Co-design Part B1: Needs & Requirements

Figure 42 | Co-design Part B1: Needs & Requirements

Part B2: Ideas & Concepts

Part B2 of the co-design session is dedicated to the generation of design outputs, which involves brainstorming and ideation (figure 42, 43). Building upon the insights gathered in Part B1, this stage encourages both the facilitator and the interviewee to explore creative solutions and generate innovative ideas to address the design challenge.
This sheet provides sketches and concept explorations to open communication and collaboration, allowing for a free flow and sparking ideas. Using the designated paper sheet for Part B2, the interviewee and facilitator can visually navigate the project and organize their generated ideas, concepts, and design suggestions. This process encourages out-of-the-box thinking and design thinking on a product level.
By engaging in this iterative design cycle, Part B2 ensures that a diverse range of potential design solutions can be. These design outputs serve as a start for further evaluation in research during the phase after the co-design process. By involving the interviewee in the ideation process, Part B2 evokes a sense of ownership and empowers them to contribute to the development of innovative and user-centric design concepts.

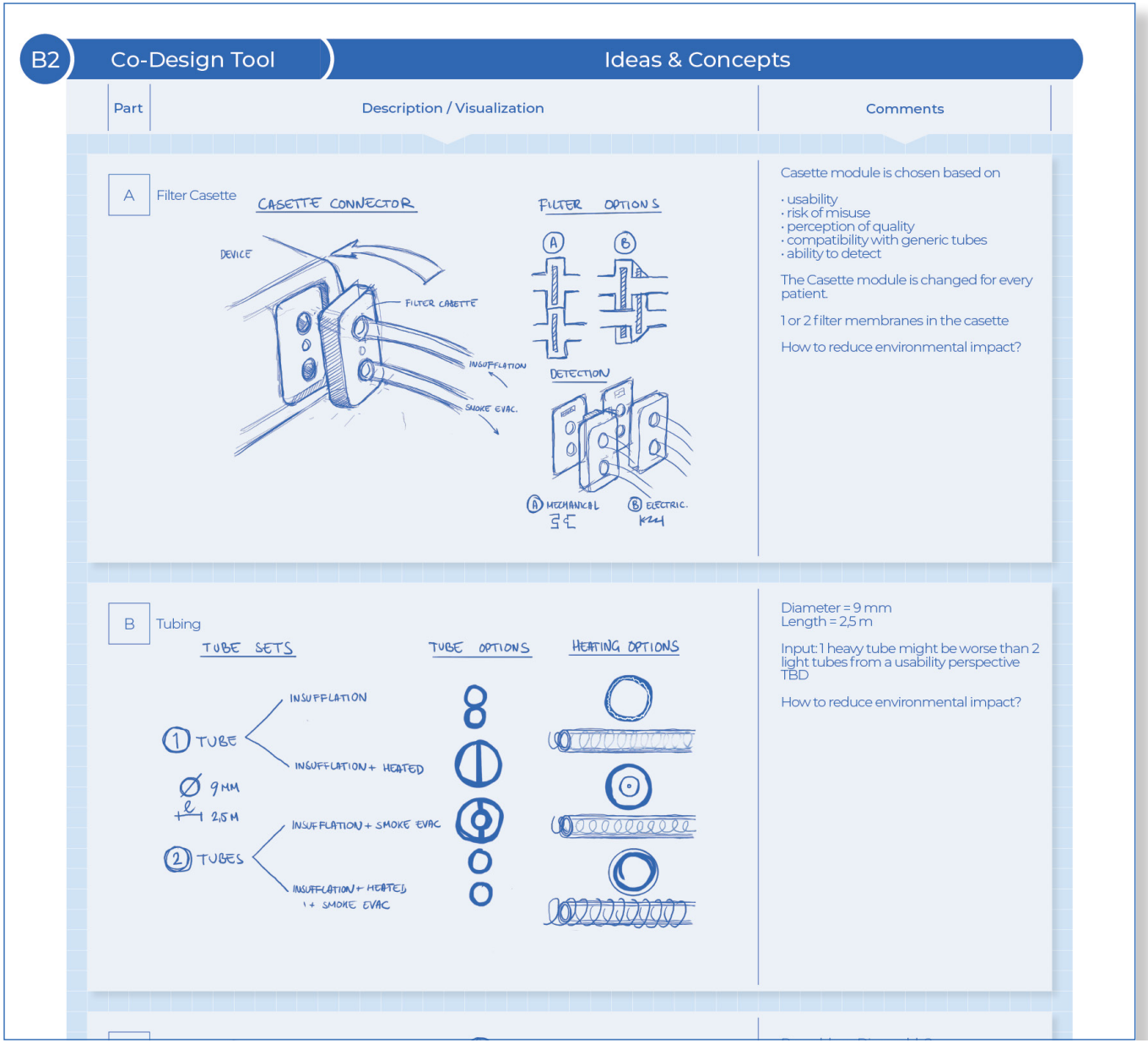


Figure 43 | Co-design Part B2: Ideas & Concepts

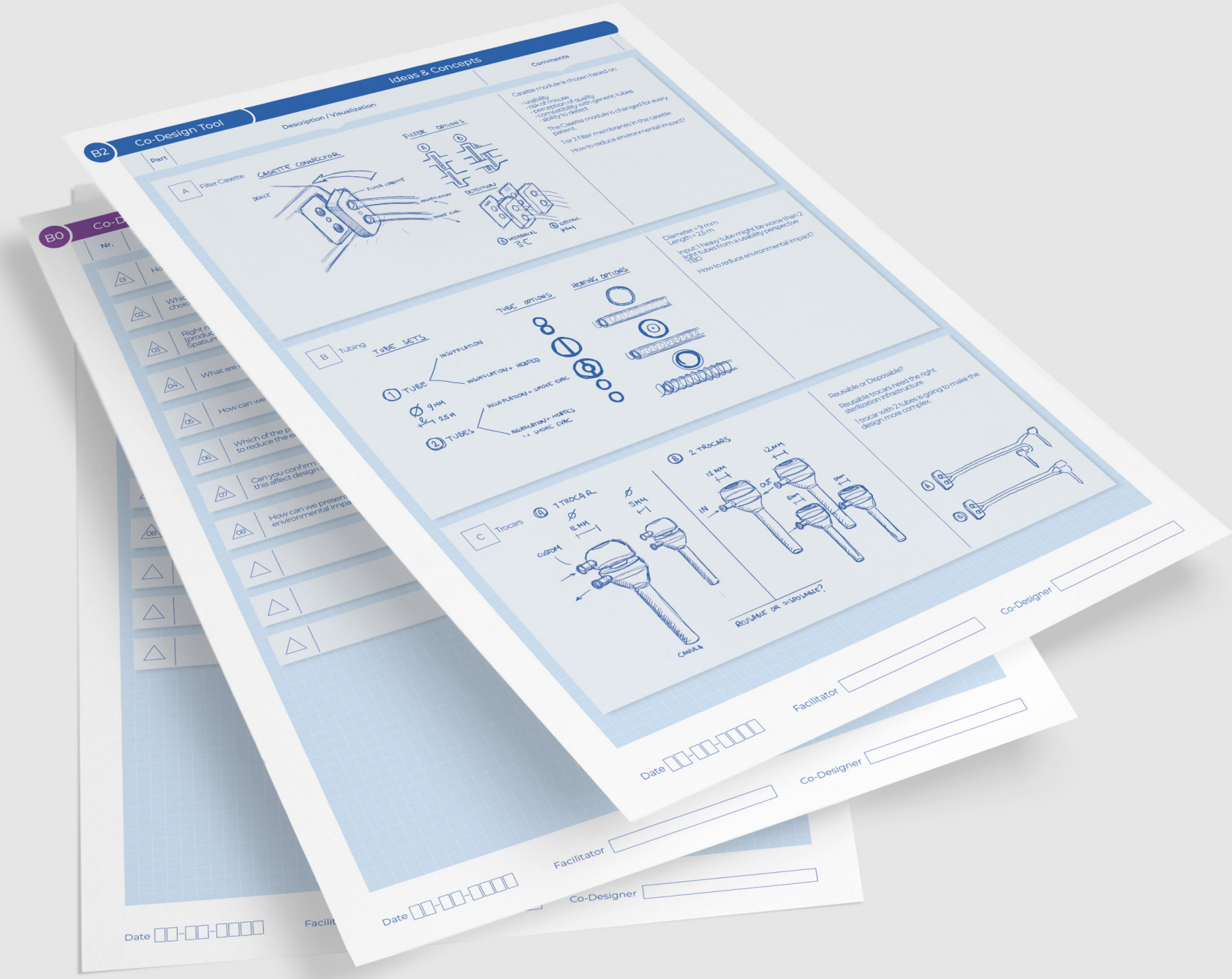


Figure 44 | Co-design Part B2: Ideas & Concepts

5.3 The Manual

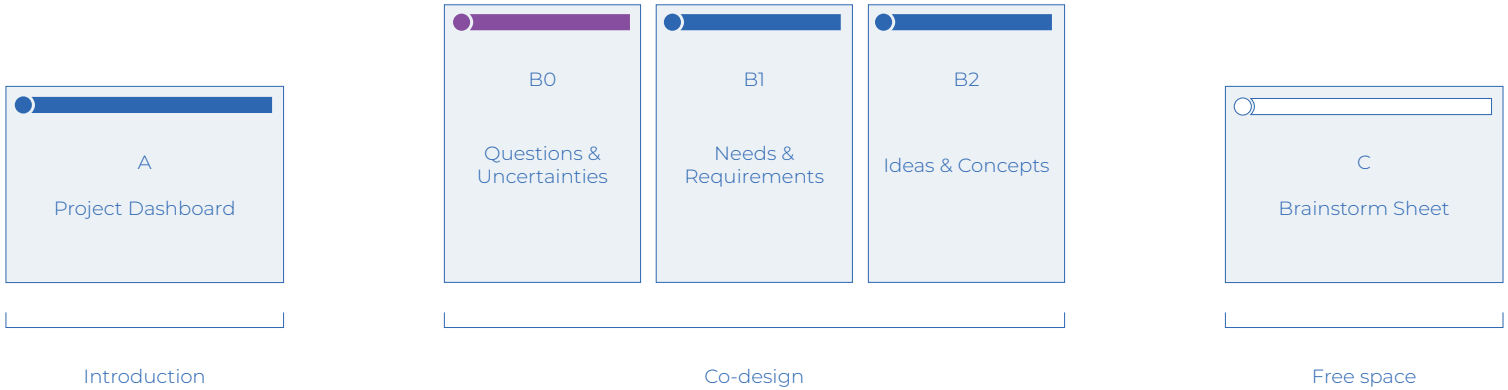


Figure 45 |Overview of co-design tool

The co-design tool offers a new way to collect new insights during medical product development. However, the effectiveness of the session and the quality of output are dependent on good preparation and post processing, before and after the session respectively. This manual will function as a guide on how to prepare and use this tool in its intended way in order to ensure valuable outputs. The manuals are divided in 4 parts. In the next paragraph, the tool and its different components will be explained from a top-down perspective. Subsequently, the next paragraph will elaborate on the preparation phase. Among other things, it will explain how to fill out the tool so that it is optimized for the stakeholder that will be invited for the session. The following paragraphs presents a step-by-step description of the interview session. Finally, after completion of the session, the post processing step will be addressed. This final phase is intended to capture and summarize findings from the session, with the goal to translate them to new need, requirements, or concepts.

This tool is entirely designed to be an analog experience without screens. The intention is to use the tool to present relevant information to reach shared understanding and host a fruitful co-design session. The upcoming paragraphs will guide you in preparing the tool and session.

In advance of the session, the co-design tool consists of 5 empty A3 templates, that all have a different function. Those sheets are divided in 3 parts: Part A, B and C.

Part A: Project Dashboard. The session starts off with the project dashboard, providing an introduction of the project that will be the subject of discussion. This sheet presents a holistic overview of the project, the product architecture, and the user context. Next to that, there is dedicated space to outline the scope of the session. For instance, the scope might be to find new requirements on environmental impact or to explore manufacturing possibilities. The project dashboard also provides room to refer to project planning and to explain the procedure of the session.

Part B: Co-Design Tool. Part B consists of three sheets that form the core of the tool. The sheets are divided in part B0, B1 and B1. Together they form a basis for fruitful co-design when prepared with attention. The sheets don't have to be used in a consecutive order but should rather be used

in an iterative way, switching back and forward between the different sheets.

Part B0 is called, Questions and Uncertainties. On this sheet, the facilitator can formulate and present relevant questions for the planned session. These questions can either be specific or more general, there are no prerequisites in that respect. Ideally, after a session most of these questions are answered to a certain extend. Its main function is to guide the session. The facilitator can keep track of the questions and use them as a way to structure the session.

Part B1 is called Need & Requirements. The goal of this sheet is to present a comprehensive overview of design inputs that are relevant to the project. To simplify the complex nature of this aspect, a selection of most relevant inputs must be made and should be categorized. This way, an interviewee has the opportunity to look into the different design inputs of the project and understand the holistic design challenge. It is important to note that there is a distinction between needs and requirements. Needs represent high-level problems or opportunities that are identified through user input, research, and analysis. Needs can be abstract and undefined. Requirements on the other hand are a translation of these needs into measurable criteria. These criteria must be met for the medical product to succeed.

Figure 46 | Top down overview of co-design tool

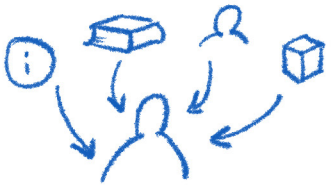
Part B1 provides space for both needs and/ or requirements that may or may not be defined. The source of certain design inputs can be mentioned when relevant.

Part B2 is named Ideas & Concepts. The main function of this sheets is to provide room for visual representation of concept (directions) or ideas. It is advised to use sketches, due to their undefined nature. Sketches suggest an unfinished idea that can still be subject to change. Sketches should be considered depending on the goal of the session. They can be created analog or digitally. There is extra space available for additional text, when necessary. Part B1 and B2 combined form a playground which enables the facilitator and the co-designer to switch between the problem definition and solutions. This is the essence of co-designing. Meanwhile, part B0 is used by the facilitator to guide the session.

Lastly, part C is called the Brainstorm Sheet. Throughout the session the tool should encourage its participants to draw and write wherever they find suitable. To further support that freedom, an empty sheet is provided with the tool which can be used to write or sketch in any way.

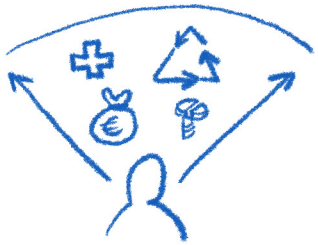
Preparation

01



Understand the project. Before this tool can be used, the intended facilitator should familiarize him or herself with the project, its context, objectives. Internal meetings and research can help in reaching a full understanding of the project on different levels.

02

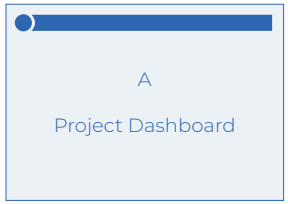


Define session scope: When the facilitator is familiar with the project, a session scope must be defined. The session scope helps to identify the key topic and goals of the co-design session. This will mostly include resolving of uncertainties and generation of new inputs.

03

Reach out to sessions candidates: Look for relevant stakeholders that might be able to provide valuable inputs during the session. Use the session scope to decide which candidates to approach. Send out invitations via email explaining the intention of the session.

04



Prepare/Review Part A: Project Dashboard. After reaching out to session candidates, Part A must be prepared. Based on the knowledge obtained in step 1, the project dashboard must be filled out accordingly.

a. Provide a brief description of the medical device.
b. Insert a visual and optional description of the user context.
c. Add system overview visual of medical device.
d. Visualize project planning and indicate status.
e. Provide session scope (Step 2).
f. Provide short explanation of the co-design session.

05

Prepare/Review Part B0: Questions and Uncertainties. Use this sheet to collect and formulate questions that are relevant to the scope and stakeholder defined in step 2 and 3. These questions will be used as a guide during the session. It is advised to review the questions with a colleague that is involved in the same project.

06

Prepare/Review Part B1: Needs & Requirements. For this sheet, a selection of known needs and/or requirements must be identified and filled in. These can be found in the trace matrix or other traceability documents. The selection of inputs must be categorized to increase readability. These categories can be found on the sheet and selected to fit the scope of the session.
It is advised to review the inputs with a colleague.

07

Prepare/Review Part B2: Ideas & Concepts: This sheet must contain elaborative sketches that help to spark the co-design process. It is advised to provide 1 or more sketches that represent ideas or concepts related to the project and scope. Other visuals are allowed but sketches are preferred. They can be made analog or digitally and should be based on established requirements. Uncertainties regarding these visuals can be added to Part B0.

10

Prepare Tool and Flow: In advance of the sessions, it is advised to practice the session briefly with a colleague. Make sure that the objective of the session is clear, and all questions are presented.

08

Confirm Meeting: Align with a stakeholder and plan a meeting. Agree on location, date, and time. Remember that the location should provide enough room to conduct the session.

09

Prepare Materials: Make sure to prepare the following materials, NDA, printed sheets (5x), pens, post-its and stickers.

The Session

After all the preparatory tasks are fulfilled, the facilitator is ready for the session. Some important do's and dont's are formulated on page 61, which are valuable to check beforehand. The facilitator and the stakeholder meet at the agreed location at the agreed time. Before starting the session, it is advised to have a casual chat with a coffee to get to know each other. This creates a more relaxed atmosphere. In the meanwhile, prepare the meeting room for the session. The sheets should be stack with Part A upfront. Pens and post-it's placed on the table. Before starting, the NDA must be signed by both parties. Ask whether the stakeholder is comfortable and ready to start (figure 46).

Figure 47 | Top down overview of co-design tool

01 **Session Introduction:**

a. Briefly introduce the co-design tool. Emphasize what co-design means, what the goal is of the session, and how much time it will take to complete.
b. Walk Through Part A: Guide the stakeholder through Part A of the tool, including the project description, context overview, product system, and project planning.
c. Discuss Session Scope: Explain the focus and goals of the session, addressing the specific aspects to be explored (e.g., environmental impact, feasibility, viability, desirability).
d. Invite Stakeholder to ask questions: Check regularly whether the explanation of the project dashboard is clear to this point.

02 **Co-Design Session:**

a. Introduce Part B: Transition to Part B of the tool, which includes B0 for questions, B1 for needs and requirements, and B2 for ideas and concepts.
b. Use B0 for Guidance: Use B0 to outline the session's questions, and uncertainties that will shape the conversation and co-design practices.
c. B1: Needs and Requirements: Explain the current set of needs and requirements and how they are related to the ideas and concepts on B2.
d. B2: Ideas and Concepts: Switch between B1 and B2 to facilitate idea a discussion. Encourage the stakeholder to brainstorm on requirements and concepts that align with the session scope.

03 **Encourage Collaboration:**

a. Foster Open Dialogue: Ensure all participants have an opportunity to ask questions and share their insights and ideas without interruption.
b. Build on Ideas: Encourage stakeholders to build on each other's concepts, fostering collaborative ideation.
c. Use Visuals: Leverage the visual cues and icons in the tool to communicate concepts effectively.

04 **Documentation:**

a. Record Ideas: Document the stakeholder's inputs, ideas, and comments using the tool's designated sections by writing or sketching. Invite the stakeholder to join in this practice.
b. Provide Context: write clear explanations for note to ensure clarity and traceability after the session. Make use of traceability icons.

05 **Closing:**

a. When all questions (B0) are addressed or when duration of the session is nearing 90 minutes, the facilitator can wrap up the session.
b. Briefly conclude and reflect on the session. Ask if there are any last question. Suggest future contact moments to stay in touch.
c. Thank the stakeholder for their time and inputs and close session.

Facilitating a co-design session with stakeholders requires careful planning and execution to ensure meaningful collaboration and effective outcomes. Here are some do's and don'ts, along with tips, for successful facilitation:

Do's:

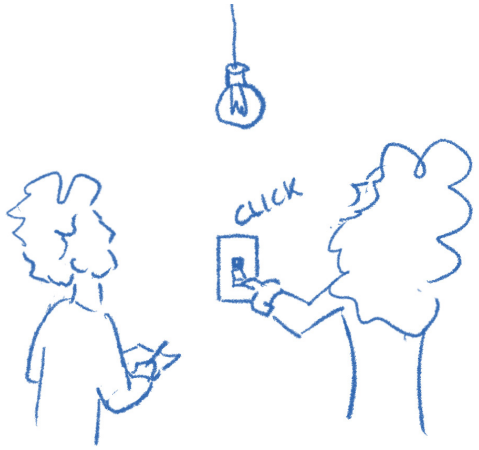
1. Prepare Thoroughly: Familiarize yourself with the tool, its components, and the project's objectives. Review the stakeholder's background to tailor the session accordingly.
2. Create a Welcoming Atmosphere: Begin the session with a warm welcome and introduction. Make the stakeholder comfortable and clearly communicate the session's goals.
3. Guide, Don't Dominate: As a facilitator, your role is to guide the discussion and keep it on track. Encourage active participation and ensure everyone's input is heard.
4. Be Flexible: Adapt to the stakeholder's pace and preferences. Allow for open discussions and encourage sharing of diverse viewpoints.
5. Use Visuals: Utilize the tool's visual aids to enhance understanding. Visual elements facilitate communication and can spark innovative ideas.
6. Promote Collaboration: Encourage stakeholders to build on each other's ideas. Create an environment where they feel comfortable suggesting modifications or new concepts.
7. Empower Decision-Making: Help stakeholders reach consensus on valuable design directions. Support them in making informed decisions based on the generated outputs.

Don'ts:

1. Don't Dictate Solutions: Avoid imposing your ideas on stakeholders. Your role is to facilitate, not dominate the creative process.
2. Avoid Rushing: Give participants ample time to express their thoughts and ideas. Rushing through the process may hinder innovative thinking.
3. Avoid Technical Jargon: Keep language clear and accessible, especially if stakeholders come from different disciplines. Minimize jargon that could cause confusion.
4. Don't Overwhelm: While it's important to capture as many ideas as possible, avoid overwhelming participants with an excessive number of options. Prioritize quality over quantity.
5. Steer Clear of Bias: Stay neutral and unbiased. Your goal is to facilitate, not influence outcomes based on personal preferences.
6. Don't Interrupt: Let participants finish expressing their thoughts before interjecting. Interruptions can disrupt the flow of ideas.
7. Avoid Dominating Discussions: As the facilitator, your role is to moderate rather than dominate the conversation. Ensure everyone has an opportunity to contribute.
By following these guidelines, you can effectively guide the co-design session, foster collaboration, and facilitate the creation of valuable ideas and solutions.

06

Validation



6.1 Validation

An important part in developing this tool is to validate the concept and assess its effectiveness. The aim is to validate the Co-Design tool to in a real-life setting to gather feedback from both the facilitator and the interviewee. By doing so, design decisions based on theory and assumptions can be validated. Moreover, the feedback from this session will be of great importance for improvement and further development of the tool. This paragraph includes a reporting on the method, setup, executing and analysis of the validation session. The key findings from the analysis will be used for evaluation and recommendations in the following chapters.

After the green light meeting, the CEO of Dune Innovation suggested to validate the tool by using it for the Spatium Medical project. This provided a valuable opportunity to test the tool in an existing scenario with real objectives, a facilitator, and a desired interviewee. As stated earlier, the development of Spatium Medical is nearing the concept lock. At that moment, all requirements must be determined, and they should be feasible, desirable, and viable. There are currently still uncertainties and undefined requirements regarding the patient kit of the insufflator and its environmental impact. Dune Innovation aims to gather new inputs by interviewing a specialist on sustainability in medical product development using the Co-Design tool. Based on these requirements and after

Figure 49 | Validation session between Rebecca and Dorien

reaching out to interviewee candidates, one possible test person reacted and was willing to participate in the test setup. The facilitator role would be carried out by a junior engineer from Spatium Medical.

Prior to the test day, preparation of the session and the tool were planned in collaboration with the facilitator Rebecca. During physical meetings we collected requirements, concepts, and questions regarding Spatium Medical's patient kit. Rebecca provided information which was then integrated in the most up to date tool template. Sheet B1 was used to write up needs and requirements. Sheet B2 was used to sketch concept directions for the patient kit. Finally, Sheet B0 (formerly B2) provided room to formulate relevant questions to guide the interview session. The Project Dashboard was improved since the green light meeting, to make it easier to explain Spatium Medical to outsiders.
The session was planned at the faculty of Industrial Design Engineering in Delft, on Friday the 4th of August. The location and time were preferred by the interviewee. Through the faculty, a spacious meeting room was reserved for the session. In advance, all sheets were printed at a copy shop. Extra tools like pens, post-its and extra paper.

6.2 Validation Casus: Spatium Medical

Spatium Medical, the first casus managed by Dune Innovation, is an innovative company focused on developing a next-generation insufflator for laparoscopic surgery. Spatium Medical aims to bring their future product to the market after a decade of research and development with key experts, including John Vlot, Frank Sterke, and Willem van Weteringen.

A short Introduction to Laparoscopy

Laparoscopic surgery, also known as keyhole surgery, is a minimally invasive procedure that allows surgeons to access the abdomen without large incisions. It offers several advantages over traditional open surgery, including shorter hospital stays and faster recovery times. Patients experience less pain, bleeding, and are left with smaller scars. Laparoscopy is commonly used in gynecology, gastroenterology, and urology for both diagnostic and surgical purposes. The procedure involves making small incisions and inserting trocars, which provide access for instruments. Carbon dioxide gas is then used to create a cavity in the abdomen, enabling the surgeon to perform the operation. The surgery typically lasts between 30 minutes to 2 hours, depending on the complexity. After the procedure, patients recover in the hospital.

Figure 50 | Laparoscopic surgery

Downsides of Laparoscopic Surgery

Even though laparoscopy has many benefits over traditional open surgery, it is common that the technique is sub optimal for specific patients. The insufflation technology has been around for decades and hasn't been changed when it comes to its core functioning. One of the limitations of current insufflators is the inability to maintain a constant pressure. Carbon dioxide leaks away from the patient lowering the pressure

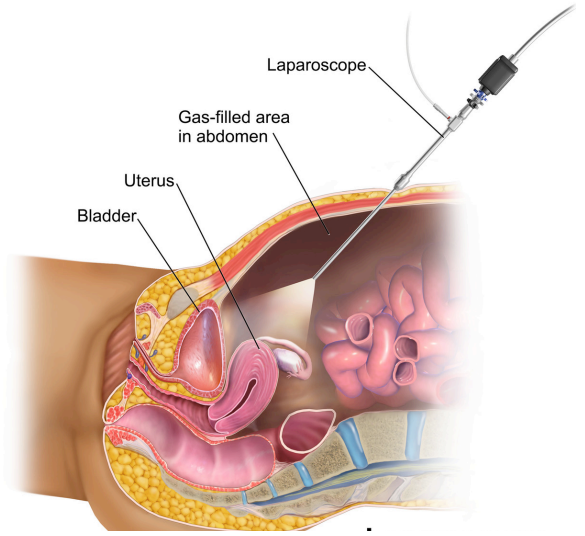


Figure 51 | Abdomen laparoscopy

in the abdomen. To prevent the cavity from becoming too small for surgery, the surgeon is forced to insert peaks of gas into the patient. These peaks can have a great impact on patients in general, but even can make laparoscopy ill-suited for neonates, children or obese patients. These insights (Vlot, 2010) led to the initiative to develop a next generation insufflator which will be designed to solve these issues and adding other smart functionalities.

The Next Generation Insufflator

The company differentiates itself with three unique selling points (Spatium Medical, 2022):

• The EndoFOT technology for automatically calculating ideal patient-specific pressure

• Reduced impact on ventilation pressures through reciprocal insufflation

• Pressure stabilization with rapid measurement and response capabilities

Spatium Medical's case is a perfect example to illustrate the complexity of medical product innovation. It provides an ideal context to apply and test the effectiveness of the tool. The collaboration with Spatium Medical offers a valuable opportunity to iterate and refine the tool's application in a real-life scenario, ensuring its practicality and effectiveness in supporting complex problem-solving during the discover phase or fuzzy front end of medical device development.

How the tool can benefit Spatium Medical

The development of a suitable sub-system is crucial for the adoption chances of Spatium Medical. This sub-system consists of: trocars, filters and tubing. The main challenge is to uncover and integrate environmental impact design requirements

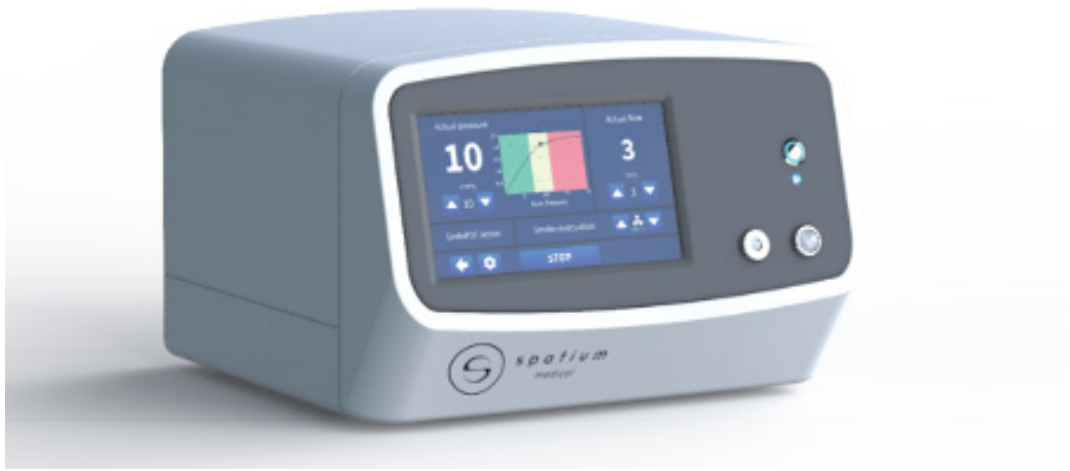


Figure 52 | Early render of Spatium Medical insufflator

for the product's subsystem. Currently, there are no regulations to adhere to. In order to answer to the call of a more circular healthcare, these requirements must be be found and be weighed againstother design inputs. Chosen design directions should be desirable, viable and feasible. Addressing these challenges is essential to ensure the development of safe, effective, and environmentally conscious medical devices that meet the needs of all stakeholders.

6.3 Session 1

Facilitator: Rebecca Breda | Junior Engineer | Spatium Medical
Interviewee: Dorien van Dolderen | PhD Student | Medtech Graduate
Location: IDE Faculty Delft | Meeting room
Tools: Printed Co-Design Tool (Sheets A, B0, B1, B2) | Pens, Post-it's, Paper | Laptop
Duration: 90 min

The participants were timely informed about the location and planning of the session. Together with Rebecca we arrived in time to welcome Dorien with a coffee. After a brief acquaintance and introduction to the project we moved over to the meeting room. Here everything was set up ready for the session. Rebecca and Dorien sat down next to each other while I was sitting at the other end of the room with a laptop to take notes. After the signing of a NDA, the session was kicked-off by Rebecca.
During the first 15 minutes, the foremost objective for the facilitator was to reach a shared understanding with the interviewee on the topic of Spatium Medical. Shared understanding is reached when both parties involved in this session have a common comprehension of the information, the goals and context related to the project that is discussed. Rebecca was able to clearly explain Spatium Medical, and its objective within the set time frame of 15 minutes. Next to that she took the time to explain the aim of the session and the different

Figure 53 | Dorien and Rebecca during test sessions

sheets to the interviewee, while leaving room for questions. After the introduction and discussion, the Project Dashboard, the facilitator moved on to the co-design part of the session. Sheet B1 and B2 (figure 52) were used to explain concept directions and present uncertainties and questions regarding environmental impact. Rebecca was able to clearly explain the requirement of the patient kit together with the different concept directions. During this phase, questions were asked about environmental impact. Dorien replied these questions referring to her graduation project and knowledge about sustainability in the medical world. One of the topics addressed during co-design was the option to offer a reusable patient kit. Dorien thoroughly explained all the positive and negative sides of reusable instruments. One of her thoughts is that the complexity of a part plays a big role in its reusability. The tube would be easier to sterilize according to her. Modularity might be a valuable approach to make parts of the patient kit sterilizable.
At a later moment in the session, Rebecca presents the filter cassette of the patient kit. This part decontaminates the gas that flows through the insufflator but also increases usability by ensuring easy connection of the patient kit to the device. Rebecca points out that this cassette would probably

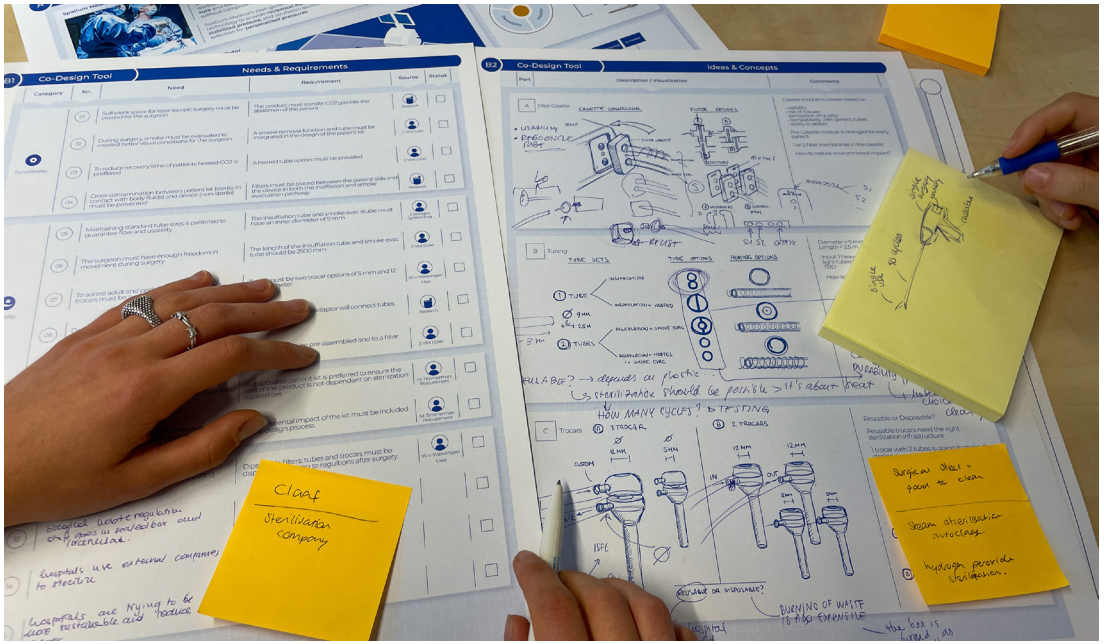


Figure 54 | Co-design sheets in use

significantly increase the environmental impact of the patient kit, due to extra material and production. Following this, a nice brainstorm session starts where Dorien sketches and discusses an option where a cartridge-like solution is integrated within the cassette to make the cassette reusable. During this process the tool was used to draw and write on. This was a great example of brainstorming on a detailed level. Dorien provides tips like the use of CES Edupack in making material decisions and how to approve the use of a material in different situations

Afterwards, Rebecca and Dorien had a conversation about different market implementation strategies, where the company could offer different kinds of patient kits to buyers. They also talk about leasing and refurbishing strategies as a service and to keep control of the products. This shows that the tool allows for brainstorming on different levels. Opposed to a detailed level, this discussion involves more 'macro' strategies and approaches to address environmental impact.

Towards the end of 90 minutes, Rebecca was able to check whether all her questions were properly discussed. She concluded the session with a summary, and Rebecca and Dorien agreed to stay in touch and share knowledge. The session was concluded within 90 minutes like intended. The interview session was transcripted real time using the laptop and Word.

Key findings:

• Sessions was successfully concluded in 90 minutes
• All parts of the tool were used at some point during the session
• The tool was used to write and draw on
• There was some unclarity on where to write/draw
• Facilitator was a bit hesitant to write on the thick paper
• Both participants indicated that they had a positive experience
• Unclear if concrete new requirements and/ or concepts are generated
• Facilitator mentioned that the preparation steps are still undefined

The findings show that from a usability perspective, the tool was received in a positive way. Use cues were properly used as intended and the participants experienced freedom in writing and drawing. In the evaluation chapter, improvements in the design will be suggested following the feedback from the sessions.

6.4 Session 2

Following up on the validation session with Rebecca and Dorien, a second session was planned with Judith van Neerven. She has been an ophthalmologist for many years and is interviewed because of her experience in the medical field as a doctor. This time, the session is facilitated by myself, using the same approach and preparation as the first session.

Facilitator: Alex Pobuda| Graduate Student | TU Delft
Interviewee: Judith van Neerven | Ophthalmologist| Ikazia Hospital
Location: Office | Rotterdamse Rijweg
Tools: Printed Co-Design Tool (Sheets A, B0, B1, B2) | Pens, Post-it's, Paper | Laptop
Duration: 90 min

Similar to the first session, 15 minutes were used to explain the project, its scope and the procedure of the session. Once again, the interviewee was successfully informed about Spatium Medical and the tool within this time span. After the introductory phase, we moved on to the co-design part. Compared to the session with Dorien, there were fewer concrete expectations beforehand since the ophthalmologist was not a specialist on environmental impact. However, the importance of environmental impact in Spatium Medical's development was still presented as the scope of the session. Some of the questions that were prepared for Dorien's co-design session still proofed to be relevant and useful. It showed that the tool has a great potential to provoke unexpected discussions and outcomes. The discussion with the ophthalmologist is summarized below.

Figure 55 | Co-design sheets in use

After the introduction, a first discussion was provoked by the cassette sketched on sheet B2. The explanation of Spatium Medical's device and the drawing of the cassette were associated with a different device, known by the interviewee. She mentioned that during cataract surgery, similar devices are used to remove a lens from the eye. This device called a 'Phaco Emulsificator' has similar functionalities: inserting fluid to create working space, and the removal of residues. She said that the cassette sketch on B2 looks very similar to the cassette system that is used to connect the Phaco device to a patient kit. She indicated that the cassette is a practical way of connecting the patient kit. This is a valuable confirmation for Spatium Medical that a cassette connection is a smart choice, from a usability perspective. Further, the Phaco Alcon Centurion also comes with a hand piece device which is somewhat comparable to a trocar. This hand piece is used to perform surgery in the eye and has two tube connections + a power connection. And interesting find here is that a disposable tip is used to cover the hand piece. After surgery, this tip is disposed of, and the hand piece is sterilized for reuse.

This might be an interesting finding to further investigate.

Later in the session, some questions regarding environmental impact on sheet B0 were asked to the participant. We wanted to learn whether there currently is awareness about environmental impact on the operating room. This question was answered with a clear 'yes' and substantiated with examples. Not so long ago, drapes were mandatory during each surgery. According to the interviewee, medical waste after surgery consists largely of these drapes. Now, these drapes are not mandatory anymore for ocular surgery. This reduces waste drastically since dozens of these surgeries per day were performed. It is valuable to know that medical staff are aware and willing to contribute to reduction of waste and environmental impact. However, the possible measures should not influence the usability aspect. Material reduction in packaging and disposables seems most common in current measures.

Lastly, there was a short discussion on the relationship between medical specialists and hospital procurement. There were interesting insights on this topic. It seems that surgeons have the most control in the purchasing of expensive new equipment. Procurement mainly listens to their requests and try to make good deals with manufacturing companies. They often have established relationships with manufacturers which play an important role in future deals. In terms of disposable products, procurement will most likely prioritize a good deal with existing manufacturing partners. However, when medical specialists insist on obtaining a certain device or instrument, they will receive those in most cases.
For the adoption chances of the Spatium Medical patient kit, she emphasizes that the user experience with the user kit should be as familiar as possible. Reach out to experienced and progressive surgeons to try out Spatium Medical.

This session was once again concluded within 90 minutes. It proved that the tool is a great way to generate unexpected outcomes and is adaptable in different scenatio's and with different stakeholders. This time, the empty brainstorm sheet (B0) was used to take all notes. The participant didn't feel the need to join in with sketching but did write up some comments now and then.

Key findings:

• Spatium Medical system similar to Phaco device (cateract surgery)
• Uses cassette connection for tube set, which works properly
• Phaco Hand Piece is sterilizable, tip is disposable
• Medical staff is very aware of importance of reducing environmental impact
• Not-crucial disposables are eliminated from the operating room
• Measures should not influence usability aspect
• Surgeons have most control in purchasing of new equipment
• New patient kits should handle like other patient kits

• Interviewee related cassette sketch on B2 to a device used in eye surgery.
• Connection between cassette system and Phaco Alcon Centurion noted as practical.
• Discovery of Phaco hand piece's disposable tip raises potential relevance.
• Interviewee indicated awareness of environmental impact in operating rooms.
• Reduction in waste discussed, e.g., no longer mandatory drapes for ocular surgery.
• Material reduction in packaging and disposables commonly addressed.
• Discussion on surgeon-procurement relationship highlighted surgeon's influence.
• Existing relationships between procurement and manufacturers play role in deals.
• User experience emphasized for successful adoption of Spatium Medical patient kit.
• Session lasted 90 minutes, tool adapted to different stakeholders effectively.
• Tool demonstrated potential to stimulate unexpected discussions and outcomes.
• Empty brainstorm sheet (B0) used for note-aking, sketching not essential for participant.

6.5 Session 3

A last session was planned with Wiebke Scheepens. It is the second time that she is interviewed since the start of this project. During the first semester she was interviewed to gain knowledge on different sustainability strategies in the industry. Wiebke is a LCA consultant at Witteveen and Bos. This time, the interview is conducted with use of the tool to find more specific inputs for Spatium Medical.

Facilitator: Alex Pobuda| Graduate Student | TU Delft
Interviewee: Wiebke Scheepens | LCA Consultant| Witteveen & Bos
Location: Office | Graaf Florisstraat
Tools: Printed Co-Design Tool (Sheets A, B0, B1, B2) | Pens, Post-it's, Paper
Duration: 90 min

The session with Wiebke was a welcome new interviewee compared to Dorien and Judtih. While Dorien and Judith both had knowledge on feasibility and desirability criteria respectively, Wiebke initially had less affinity with this specific subject. It was interesting to experience that the session still unfolded in an unexpected and valuable way.

Following up on the introduction phase with the project dashboard, the co-design sheets were presented. Although the project was explained successfully beforehand, it seemed that there was less incentive to address the inputs and outputs one by one. Luckily, that didn't seem to hinder the flow of the session. Making use of the questions and uncertainties sheet, I was able to redirect the focus to more macro related questions. This opened a conversation about different macro sustainability strategies that can be implemented to reduce environmental impact. By referring to Spatium Medical, we managed to envision different strategies that could aid Spatium Medical in becoming a more sustainability driven company. Some valuable thoughts included that quantizing of information is crucial before taking effective measures in reducing environmental impact. Because Spatium Medical is dependent on partners and distant stakeholders, it is a complex task to quantize data about for instance co-2 footprints, energy usage, waste amounts and more. It was suggested that Spatium Medical should define company values on environmental impact, that enable them to set strict requirements in partnerships with suppliers for instance. If Spatium Medical sets up strategies now, they will promote a more transparent approach towards medical product development. This might also lead to the gathering of valuable data which can then be used to take more effective measures to reduce environmental impact. To support this approach, Wiebke mentioned different standards that could help to obtain quantized data from stakeholders.

Figure 56 | The co-design tool prepared in a case

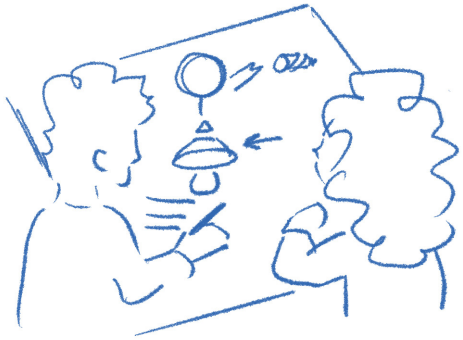
This session proved that the tool has the ability to flow in unexpected directions leading to valuable inputs that were not thought of beforehand. In this case, where the conversation shifted to a macro perspective on environmental impact strategies, it still is valuable to be able to reach back to the product-level presented in the visuals. Part C (the empty brainstorm sheet) helps to accommodate these unexpected discussions.

Key findings:

• Wiebke's session brought new insights despite her initial unfamiliarity with the subject.
• Questions and uncertainties sheet facilitated redirection to macro-related questions.
• Discussed macro sustainability strategies for reducing environmental impact.
• Suggestion for Spatium Medical to define company values on environmental impact.
• Proposal to set strict requirements in partnerships with suppliers.
• Transparency and data gathering for effective environmental impact reduction.
• Mention of standards by Wiebke to obtain quantized data from stakeholders.
• Session showcased the tool's ability to lead to unexpected and valuable inputs.
• Transition from macro perspective to product-level presented in visuals.
• Part C (empty brainstorm sheet) accommodated unexpected discussions.

07

Results & Discussion



7.1 Results

In the previous chapter, the outcomes of 3 validation sessions were presented and summarized. As discussed in the problem definition, organizing stakeholder meetings is a difficult task in the medical environment. Next to that, the requirements from Spatium Medical perspective made validation rounds a delicate step, which needed sufficient preparation. In order to still generate useful feedback within the scope of this graduation project, it was decided to conduct one main validation round with a facilitator from Dune Innovation and an external interviewee. Two more sessions were conducted by me to collect additional feedback on but the tool and Spatium Medical. The most important criterion was the tools' ability to reach shared understanding, generate new inputs, to engage its users and to offer flexibility in use. The main objective was to find new inputs on the aspect of environmental impact for Spatium Medical's patient kit. The mentioned criteria have been assessed based on the three sessions and the feedback from the participants.

Reaching a shared understanding

For starters, the project dashboard (part A) functioned very well in communication the project to be discussed. During each of the three sessions, a common understanding of the project was reached with the interviewee. This was validated by letting the participants answer an open question about Spatium Medical in the feedback form after the session. Being able to successfully communicate a complex subject to a stakeholder within 15 minutes could be a valuable timesaver for Dune Innovation.

Quality of outcomes

The second validation criteria expected generation of new inputs during the co-design session. Earlier in the project, this was formulated as follows: 'The goal of the session in to generate new inputs or outputs for the topic of discussion', referring to new needs, requirements, or ideas (B1, B2). After the validation phase, it is hard to conclude whether this criterion is met. Although much knowledge and information are collected during the sessions, it takes further processing to translate them into new requirements or ideas. For now, it seems that the tool collects valuable suggestions for further research. Generating new requirements and/or concepts may be possible with certain stakeholders that have more experience with design thinking.

Level of engagement

After the session, participants provided feedback through a feedback form. Each individual indicated that they found the tool to be very engaging and a better alternative compared to standard interview methods. Apart from the feedback, it also became evident during the session itself. Participants maintained attention with ease and were engaged for the full 90 minutes. Participants specified that setting of the sessions made them feel comfortable and heard. The collaborative nature of the tool gave them a sense of ownership in the project.

Adaptive use

Lastly, by interviewing stakeholders with different backgrounds the validation rounds were meant to find out whether the tool would be adaptable to different participants and discussions. In this regard as well the tool showed its strengths. Even though the sessions were prepared with the focus on a micro product level, the tool accommodated discussions on different levels or perspectives. The first session facilitated a discussion about material reduction and modularity whereas the last session explored different strategies towards the reduction of environmental impact on a macro level. The empty sheet and post-it's were frequently used to make use of this freedom.

Additional feedback

The results of the feedback form showed that all participants had a positive experience during the session. In their opinion, the session encouraged open discussion and creativity during the project. During this session there were enough moments to ask questions or share

knowledge. Moreover, all participants saw the value in the use of visuals, making the subject understandable. Finally, they believe this solution offers a better alternative to standard interview techniques which, most importantly, is enjoyable to take part in.

7.2 Discussion

In comparison to standard interview techniques that served as a reference in this project, the co-design tool presents a promising alternative. Standard interviews often face challenges in reaching shared understanding, particularly within the complex context of medical product development. These traditional methods might not fully capture the nuances and complexities of stakeholders' perspectives, leading to potential miscommunication and questionable outcomes. Moreover, standard interviews can sometimes lack engagement, limiting the depth and quality of discussions, while also demanding more time.

This co-design tool effectively addresses these downsides by providing a structured and interactive platform that sparks engagement, encourages collaboration, and facilitates unexpected discussions. It allows for real-time feedback and brainstorming, enhancing the quality of interactions and ensuring that stakeholders feel heard and involved. The tool's adaptability to various levels of discussion and perspectives further strengthens its utility, ensuring that it aligns with the diverse needs and backgrounds of stakeholders. Time is costly to stakeholders, and this tool optimizes its use by keeping participants engaged and focused, ultimately making their contribution more effective.

One other advantage is the tool's physical form, eliminating the need for digital screens during sessions. This analog approach promotes creative thinking and active participation, providing a more tangible experience for stakeholders. The co-design tool presents a more efficient approach towards interview sessions for Dune Innovation, improving the quality of outcomes and shortening project lead times. Its ability to generate shared understanding, foster collaboration, and offer a platform for valuable insights aligns well with the company's objectives. This innovative tool empowers stakeholders to collectively contribute their expertise, ensuring that the design process benefits from diverse perspectives while maintaining efficiency and effectiveness.

7.3 Limitations & Recommendations

Moving forward, it's important to acknowledge several limitations and potential areas of improvement for the co-design tool. Firstly, to further assess its validity and applicability, a broader spectrum of validation sessions with a diverse set of stakeholders from varying backgrounds is necessary. Engaging stakeholders from different medical projects and environments could provide a more comprehensive evaluation of the tool's effectiveness. Furthermore, extending validation efforts to include stakeholders with varying degrees of familiarity with design thinking could offer insights into its adaptability.

Secondly, optimizing the tool itself based on received feedback is vital. This means refining its functionalities to better suit the workflow and objectives of Dune Innovation. Strengthening the tool's integration into the company's work environment, enhancing the preparation and post-session phases, and optimizing its usability could significantly enhance its efficiency and utility.

Additionally, delving into the digital realm could yield substantial benefits. Developing a digital version of the tool, for instance utilizing cloud-based applications like Miro, could improve accessibility and ease of use. This digital transformation could facilitate remote collaborations and document sharing, increasing the tool's potential to be adopted.

While the co-design tool presents a promising approach to medical device development, further refinement and exploration are required to maximize its impact. Conducting more extensive validation with diverse stakeholders, refining the tool's functionalities, and exploring digitalization options are recommended steps to enhance its effectiveness and integration into Dune Innovation's innovation processes.

7.4 Conclusion

In conclusion, while the co-design tool is currently in its conceptual stage, its demonstrated potential is promising. Its capacity to overcome the limitations of traditional interview methods and provide a more engaging and collaborative approach shows significant value for innovation projects in healthcare and the people who are involved. This tool addresses the challenges of stakeholder engagement in medical device development and makes efficient use of valuable time. Its adaptability and effectiveness could make it a valuable tool for future project's managed by Dune Innovation. With its capability to make interactions more enjoyable and productive for both the company and its stakeholders.

08

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09

Project Brief

Appendix A: Project Brief

Project Title:

Design of a visualization tool for engaging multi-stakeholder communication in medtech design sprints.

Healthcare organizations are expanding complex systems (Institute of Medicine 2001; Plzek and Greenhalgh 2001) that constantly present society with new challenges to solve. Successful innovation in this field has always been a difficult process, mainly due to the highly intertwined structures, processes and patterns that characterize a complex system (Capra 1996, 2002). A new challenge within medical innovations and design is the increasing demand for reducing the environmental and ecological impact of waste in medical procedures (IPCC, 2022; WHO, 2017). Many stakeholders and strict quality control make successful innovation even more difficult. As a result, undertaking innovation projects in the medical context involves greater risk and uncertainty than before.

Dune Innovation is a start-up realized by Willem Mees van der Bijl that aims to take on these risks by providing and executing an optimized process for medical innovation projects. (van der Bijl, 2022). For each project, the goal is to create a multidisciplinary team that takes responsibility and can successfully deliver a product that satisfies all needs and interests. Throughout this process, the involvement of other stakeholders is crucial to make progress. One of the projects owned by Dune Innovation is Spatium Medical, a next generation insufflator that improves minimal access surgery for both surgeon and patient (figure 2A)(Spatium Medical, 2022). The project is in a critical stage where needs must be translated into design requirements to be followed by a successful development phase (figure 1A). For Spatium Medical, there is a special need to find design inputs regarding environmental impact, in time for the concept lock in spring 2023. An opportunity is identified to design a visualization method for multi-stakeholder communication that can be tested during design sprints for Spatium Medical. This proposal explained in more detail in the following paragraphs.

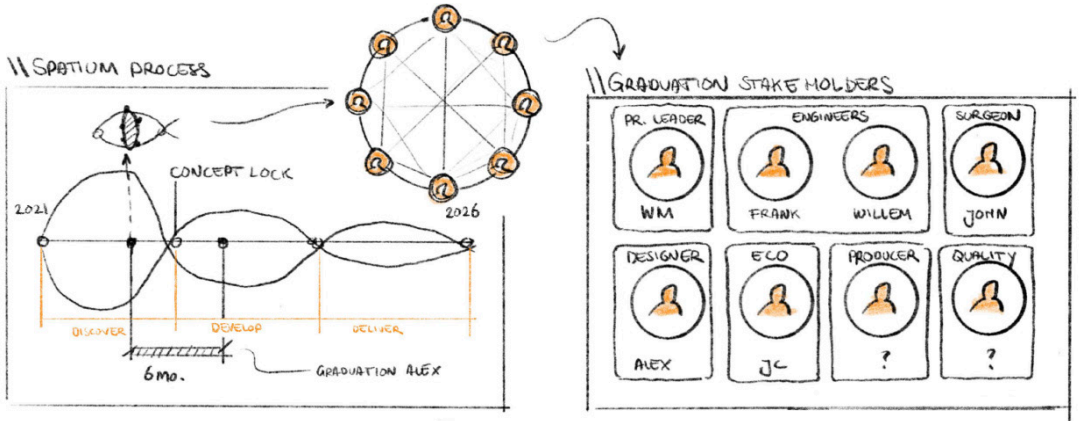


figure 1

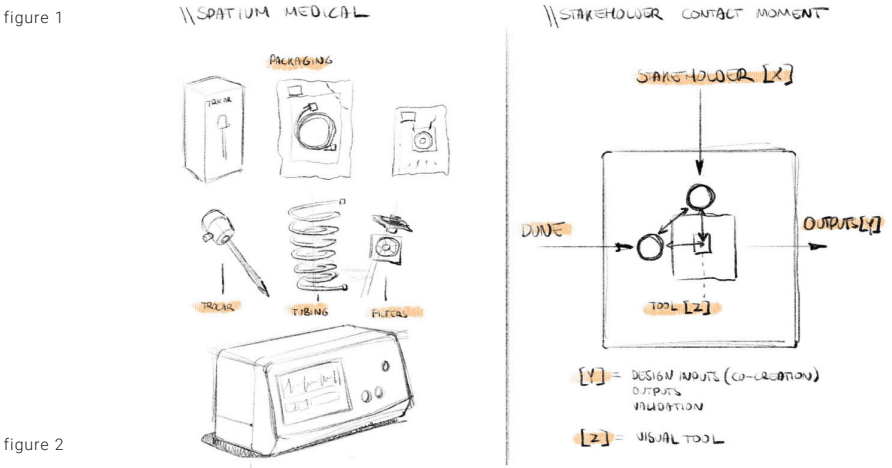


figure 2

Appendix A: Project Brief

Problem Definition

In this moment, standards for environmental impact requirements in medical innovation do not exist yet. Nevertheless, there is a growing demand for sustainability in the medical sector. To capitalize on this demand, Dune Innovation aims to collaborate with different stakeholders to formulate new design inputs on this topic for Spatium Medical. This is a complex task; based on the experience of van der Bijl (2022) it seems that shortage of time and (physical) distance between the stakeholders often causes delay, especially during the discovery phase of a project (figure 1A). During medical product development, the company mostly relies on verbal and written methods to communicate with stakeholders (figure 2B). These methods work but are suboptimal for idea generation. Next to that, they are susceptible to misinterpretation because of complex terminology and jargon. Challenges of establishing clear and effective communication in innovation processes within the medical sector has been described in several studies. Next to that, implementation of visualization methods in this area is also supported by research. For instance, studies from Star and Griesmer (1989) and Henderson (1991) argue that visualization in design engineering has the capacity to be flexible and can be 'read' different by groups particular to their needs. More literature findings suggest that there is reason to integrate visual communication in Dune Innovation's project management. Hence, motivated by these findings and personal beliefs, a visualization method will be designed to increase engagement and effectiveness during Dune Innovation's stakeholder contact moments, with the goal to find new design inputs on environmental impact for Spatium Medical and future projects.

Assignment

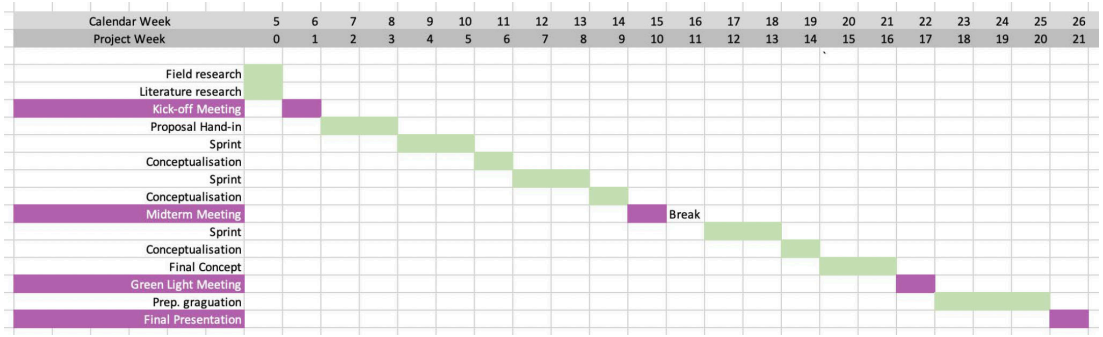
The aim of this graduation project is to design a multi-stakeholder visualization tool (1) to improve the engagement, discussion and quality of outputs during stakeholder contact moments. It will be applied to find environmental impact requirements for Spatium Medical (2).

At the end of this graduation project, I expect to deliver the necessary requirements on environmental impact for Spatium Medical, responding to the demand for a more circular healthcare (2). These requirements will be formulated in collaboration with project stakeholders by using a concept of the proposed visualization tool (1). After multiple iterations a final concept will be presented in the graduation report as a future service recommendation for Dune Innovation.

Appendix A: Project Brief

Planning

The proposed method will be designed by doing, applying it on project level for Spatium Medical. The intention is to test and iterate over this tool during three sprints and stakeholder contact moments. By investigating and developing a tool that will prove its value in this project, the aim is to define a method that will be applicable in future Dune innovation projects. During my graduation project, I plan to work five days a week which results in 20 weeks, an equivalent of 30 ECTS. I have started working on preparation work in week 50, 2022. The kick-off meeting is planned on Monday the 6th of February (week 6). The following midterm meeting will be scheduled in week 15 and the green light meeting in week 22. The graduation project will be concluded with the final presentation in week 26. A one-week break is planned in week 16.



Motivation and Ambition

The motivation for this graduation topic comes from my first Medisign course in 2022, when I learned about the role of designers in healthcare. Design engineers have a unique skill set which enables them to design for many different users and contexts. What strikes me about the field of healthcare is that many interests from different disciplines must be understood and integrated in order to realize successful innovation or 'good design'. I believe that current generation designers must learn to design for these complex systems since they are everywhere around us. Good design for a complex system means objectively good design for multiple parties or stakeholders. To achieve this, communication is key. During my studies, I often made use of visual communication. Intuitively, I'd argue that visualization has verbal language transcending capabilities and can add value to any kind of multi-disciplinary project. I'd like to explore and validate this assumption during this graduation project.

Dune Innovation offers a unique opportunity for this graduation project since it operates within the complex system of the hospital but is autonomous at the same time. Practices and methods can be changed overnight without intervention of a higher body. With this graduation I hope to provide new insights and value for Dune Innovation and accelerate the development of future healthcare projects. My personal goal is to gain in depth knowledge about medical product development and learn which aspects are important to facilitate successful innovation.