

Design of a refillable autoinjector product-service system

project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 12 - 09 - 2022

31 - 03 - 2023

end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Context:

If the global health care sector were a country, it would be the fifth-largest greenhouse gas emitter on the planet [1]. Health care's climate footprint is smaller than that of China, the United States, India, and Russia but larger than Japan's and Brazil's. By contributing to 4,4% of the global net greenhouse gas emissions and toxic air pollutants [1], the healthcare sector is jeopardizing its mission to protect people's health.

This graduation project focuses on reducing the environmental impact of a specific product in this healthcare environment: an autoinjector. Autoinjectors are used to self-inject drugs safely and conveniently in emergency situations such as anaphylaxis (severe allergic reaction), migraine and epileptic seizures or for chronic conditions like psoriasis, multiple sclerosis and rheumatoid arthritis [2]. These injectors are optimized for ease of use, administering the injection one-handed by pushing a button or placing the device onto the skin.[3]

More than 20 pharmaceutical companies have developed nearly 80 autoinjectors until today. Of the around 50 approved drug-autoinjector combinations on the market, 62% are disposable autoinjectors [4]. These disposables generate a large hazardous waste stream that ends up in landfill or incineration. The LCA in figure 1 shows that more than half of the CO2 emissions of an autoinjector are generated during the production. By refilling the autoinjector, these emissions can be reduced since less autoinjectors will be produced.

Based on the research insights during this graduation project, an autoinjector will be redesigned to be optimized for refill by either the producer, pharmacy, or another suited stakeholder.

Stakeholders (see figure 2):

Currently, Johnson and Johnson is launching a takeback scheme for autoinjectors, to enable recycling. However, no system exists for taking back and refilling auto injectors. A complex web of stakeholders is involved in this system; pharmaceutical companies, packaging producers, assembly and waste managers, patients, pharmacies, doctors, etc. The Alliance to Zero expressed that pharmaceutical companies feel the need to reduce the environmental impact of auto injectors, due to upcoming regulations, patient expectations and shareholder ratings [5].

The Alliance to Zero is a non-profit organisation for pharma and biotech supply chain companies that aims to facilitate the transition of the pharma sector to compliance with net-zero emissions, including waste reduction [6]. Together with the faculty of Industrial Design Engineering at the TU Delft, they have initiated a series of graduation projects to design an autoinjector that fits into the circular economy. This graduation project focuses on the 'reuse' loop of the circular economy by designing an autoinjector that is refilled away from the patient. This project will be done under the additional mentorship of npk design, a product design consultancy with valuable practical knowledge on sustainable and medical product design.

Sources:

- [1] Karliner, J., Slotterback, S., Boyd, R., Ashby, B., Steele, K., & Wang, J. (2020). Health care's climate footprint: the health sector contribution and opportunities for action. *European Journal of Public Health*, 30, 165-843.
- [2] R. Vijayaraghavan, Autoinjector device for rapid administration of life saving drugs in emergency, *Def. Sci. J.*, 62 (2012), pp. 307-314
- [3] Global Autoinjectors Market, 2016, Global Autoinjectors Market, 2016, (Accessed 8 August 2022)
- [4] Roy, A., Geetha, R. V., Magesh, A., Vijayaraghavan, R., & Ravichandran, V. (2021). Autoinjector-smart device for emergency cum personal therapy. *Saudi Pharmaceutical Journal*, 29(10), 1205-1215. (see 'planning' for more sources).

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introduction (continued): space for images

Outcome: Product life cycle - emissions

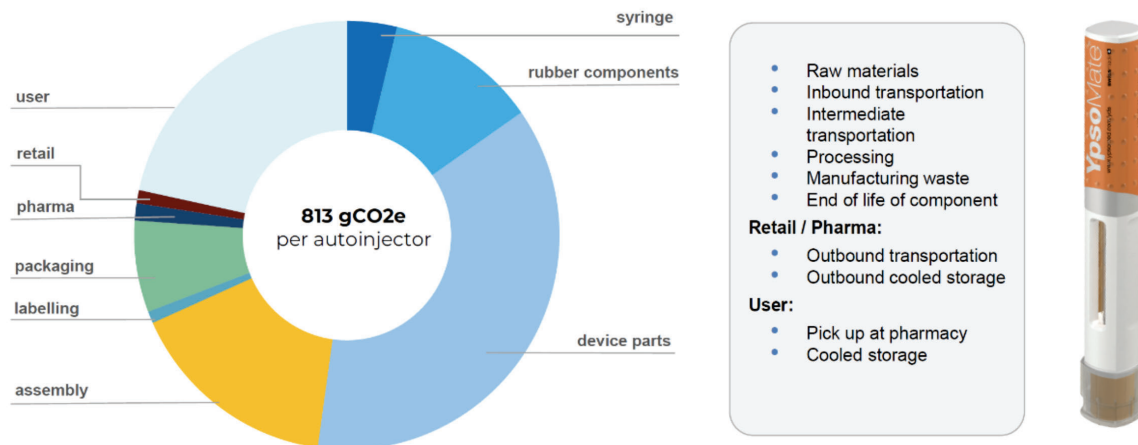
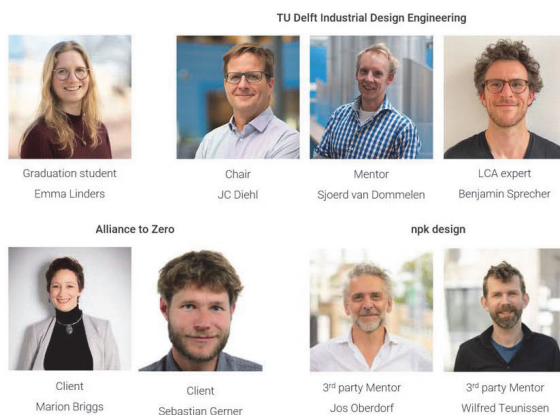


image / figure 1: LCA of autoinjector [6]

Graduation team



Research questions

Research questions autoinjector design:

1. What would the design of an autoinjector be that can be refilled away from the patient to be reused a set amount of times (to be determined)?
 - a. How is autoinjector cleaned and what are the consequences on the design?
 - b. How is the autoinjector refilled and what are the consequences on the design?
 - c. What changes in the design of the autoinjector to make it durable?
 - d. How could the design feature a broad drug portfolio to benefit from the economies of scale?
2. How does the design of the away-from-patient refillable autoinjector influence the following aspects in comparison to a single-use-autoinjector and a patient-refillable autoinjector.
 - a. Environmental impact
 - b. Ease of use
 - c. Comfort
 - d. Safety & hygiene
 - e. Costs

Research questions service system design:

1. Which stakeholder is most suitable to refill the autoinjectors?
2. How could a system look that;
 - a. Collects the autoinjectors from the patients
 - b. Cleans the used autoinjectors
 - c. Refills the used autoinjectors
 - d. Distributes the ready-to-use autoinjectors.

image / figure 2: Graduation support team & Research questions

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

Philips [7], Ypsomed [8], Jabil [9] and other companies launched reusable autoinjectors that can be refilled by the patient. However, refilling adds extra use steps that might be difficult in emergency situations or for infrequent or physically disabled users.

Therefore, the Alliance to Zero asked me to look into opportunities where the producer or other stakeholder, instead of the patient, is responsible for refilling the autoinjector. This could for example be an autoinjector as a service (e.g. access model [10]), where a stakeholder collects, cleans, and refills the autoinjector before delivering it to a new patient. So, one autoinjector could be used by e.g. fifty different patients to reduce waste, material, and energy use. From now on, this will be called the 'away-from-patient refillable autoinjector'.

The main focus of this graduation project will be on the product embodiment of the refillable autoinjector. The goal is to design a refillable autoinjector for a product-service system. Then, to compare this design to existing single-use autoinjectors and patient-refillable autoinjectors based on fast-track LCA's, safety, hygiene, comfort, ease of use and cost-effectiveness.

Since the refillable autoinjector will most likely be a part of a product-service system, the system should also be researched. However, my master, interests and learning goals focus more on product embodiment, so the service around it will get less priority. Therefore, the service will be worked out in less detail on a higher concept level.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

This graduation project aims to propose a redesign for an autoinjector as a service, which is refilled away from the patient. This includes redesigning the product architecture and service for ease of refill and cleaning (away from the patient) to decrease the waste and thus energy and material use. Meanwhile, the (needle) safety, hygiene, comfort, and cost-effectiveness of single use autoinjectors should be maintained.

This graduation project aims to design a product-service system of an autoinjector that is refilled away from the patient. The main focus is the design and embodiment of a refillable autoinjector, which results in the 'research questions autoinjector design' in figure 2.

To answer these research questions, my goal is to deliver a design of the autoinjector at Technology Readiness level 4 [11], which is defined as: "Proof of concept Prototype: testing done on core mechanisms and functions." This design will be used to conduct a fast track LCA, to compare the environmental impact to single-use and patient-refillable autoinjectors. A HotSpot analysis and disassembly map will be used to determine the ease of cleaning parts and reassembly. Moreover, the estimation of cost price, hygiene and safety will be compared to the mentioned status quo autoinjectors.

Furthermore, this design will result in an operational model, which "communicates how the product is used with the potential for ergonomic evaluation." [12]. This prototype will be used to do qualitative user testing to evaluate the ergonomics, ease of use and comfort in comparison to single-use and patient-refillable autoinjectors. Moreover, this prototype will be used in interviews with production & assembly experts (e.g. factory workers) to evaluate the ease of cleaning, refill, and reassembly.

As stated in the problem definition, the service-system around the product has less priority than the autoinjector embodiment. Therefore, the 'research questions service system design' in figure 2 are relevant, but will be researched in less detail, at a higher concept level.

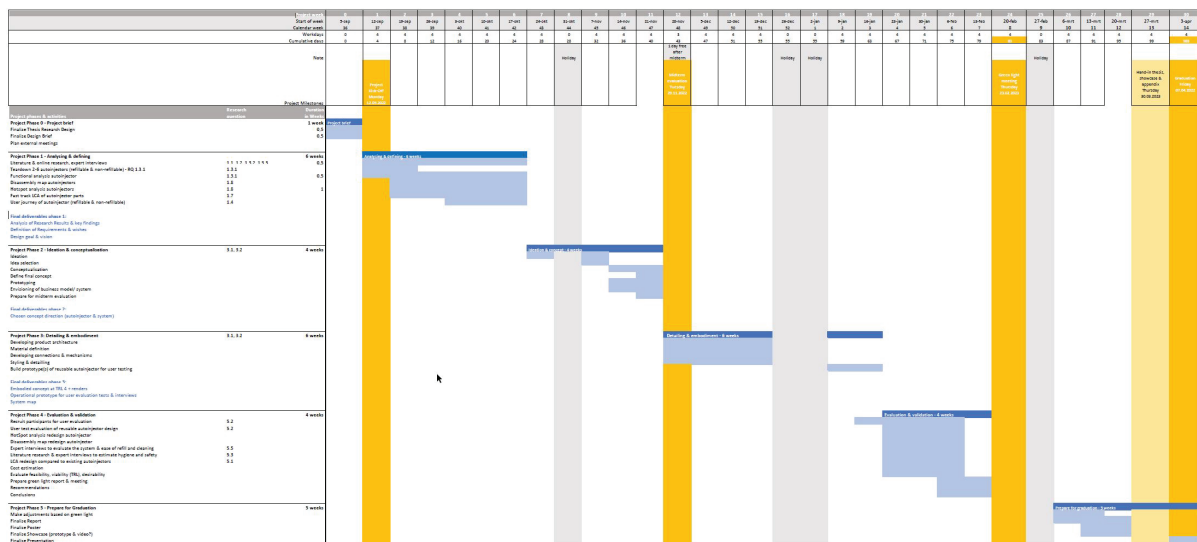
PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 12 - 9 - 2022

31 - 3 - 2023

end date



The graduation project is structured in 5 main phases, with a week of preparations before the kick-off meeting. The project will extend to 31 weeks since I am also a student assistant at the TU Delft for 8 hours a week. Thus, I'll be working on the graduation project for 32h a week instead of 40h. There is also a Christmas holiday scheduled and two one week holidays to take some time to energize.

Main project milestones:
 Kick-off meeting: Monday the 12th of September
 Midterm evaluation: Day 41 - Tuesday the 29th of November 2022
 Green light meeting: Day 81 - Thursday 23 February 2023
 Presentation & graduation: Week 14 2023

Additional sources of previous chapters;
 [5] alliance to zero ppt
 [6] Alliance to Zero. (n.d.). Alliance to Zero - net zero emissions across the pharmaceutical supply chain. Retrieved August 20, 2022, from <https://alliancetozero.com/>
 [7] Philips. (2022, May 5). Smart Autoinjector Platform | Phillips Medisize. Phillips-Medisize. <https://www.phillipsmedisize.com/products/smart-autoinjector/>

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge on a specific subject, broadening your competences or experimenting with a specific tool and/or methodology, Stick to no more than five ambitions.

In the book 'Products that Last' (2010), C. Bakker et al. writes that for circular design, a business is needed that is "based on a credible challenge which is also exiting and fun to tackle." For me, this project provides such a challenge. This project is close to my heart since I use an autoinjector monthly for my migraine medicine. The amount of waste I'm generating shocked me; I have over thirty autoinjectors pilling up in my closet.

Therefore, I am excited to look into ways to reduce this waste and specialize more in circular design. After following multiple courses about sustainable and circular design, I look forward to putting this knowledge into practice. During this project, I would like to use tools such as rapid LCA's, HotSpot maps and disassembly maps.

Moreover, the medical field is an area that I have never explored, thus this project provides many learning opportunities.

During this project, I aim to improve my project and time management skills. During previous projects and my internship at npk design, I did make plannings and kept an overview of my work. However, I sometimes have difficulties with estimating how long a task will take, therefore taking longer than expected in my planning.

My goal is to end this project with a Technology Readiness Level 4 design and performance prototype of a refillable autoinjector. Changing the single use autoinjector into an away-from-patient refillable one has consequences on the (embodiment) design. I would like to explore this among other things through rapid prototyping.

Further, I enjoy making visualisations to clarify designs and processes. I aim to use sketching and rendering throughout my project and would like to improve these skills.

I look forward to advising the Alliance to Zero on ways they could create a sustainable refillable autoinjector. I could envision a career in consulting companies on sustainable and circular product design, so hopefully this graduation project could be a step in that direction.

So, in summary, my learning objectives are;

1. Gaining in depth knowledge on sustainable and circular design.
2. Broadening my design field by learning about medical design.
3. Improving my project and time management skills.
4. Getting hands-on experience in embodiment design and rapid prototyping.
5. Improving visualisation skills through sketches and renders.

Additional sources from previous chapters;

[8] Ypsomed. (n.d.). FixPen – The easy-to-use fixed dose pen. Ypsomed Delivery Systems. Retrieved August 20, 2022, from <https://yds.ypsomed.com/en/injection-systems/pen-injectors/fixpen.html>

[9] Jabil. (n.d.). The QfinityTM Autoinjector Platform | Jabil. Jabil.Com. Retrieved August 20, 2022, from <https://www.jabil.com>

[10] Bakker, C. (2014). Products That Last: Product Design for Circular Business Models. Laurence King Publishing.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Additional sources from previous chapters;

[11] Technology Readiness Levels (TRLs) in Design and Engineering. (n.d.). 4c. Retrieved August 30, 2022, from <https://www.4cdesign.co.uk/blog/technology-readiness-levels/>

[12] Evans, M. (n.d.). iD Cards | School of Design and Creative Arts | Loughborough University. Loughborough University