Needle free injector

Design for a needle free tattoo machine for permanent make up

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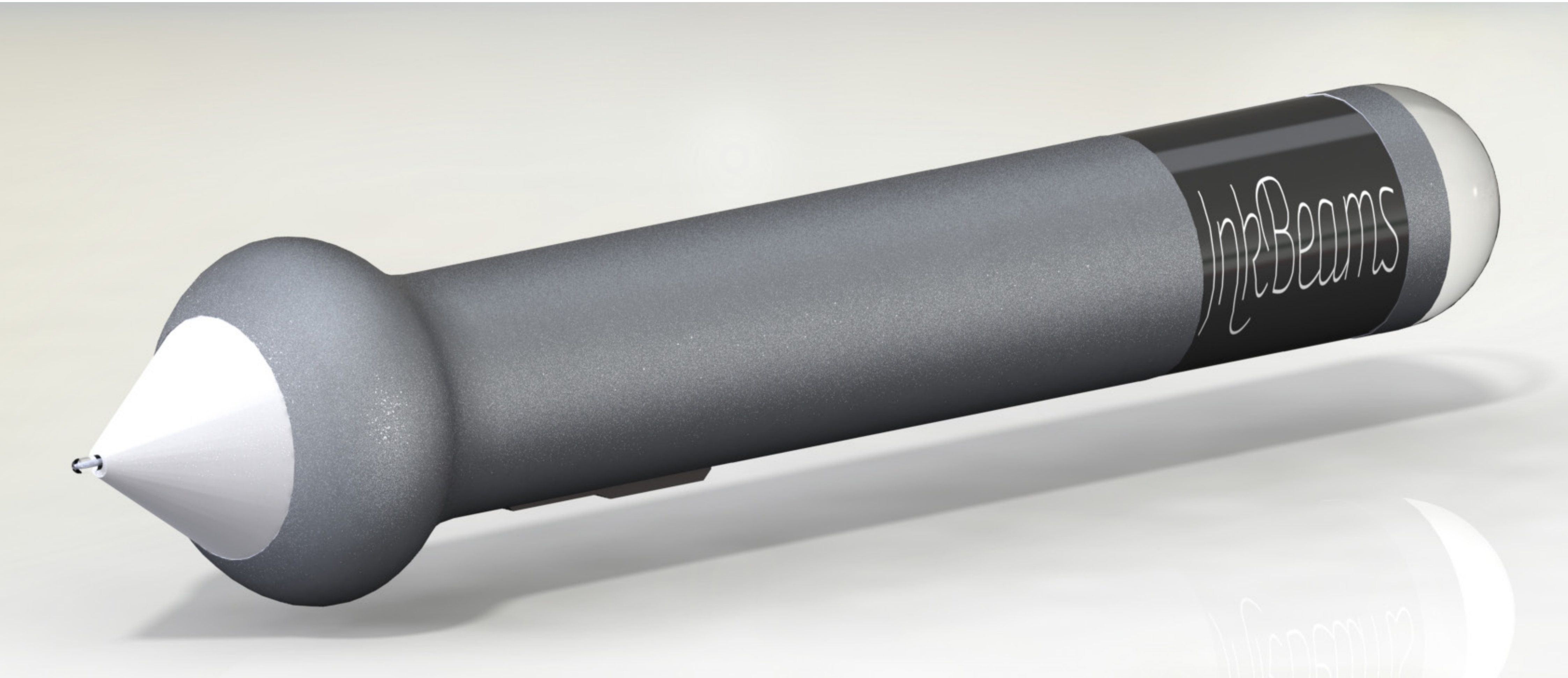

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Preface

Before you lies the written result of my bachelor assignment. This assignment is done as conclusion to the bachelor programme Industrial Design Engineering at the University of Twente. In this report you will read about my design for a needle free tattoo injector for InkBeams.

I want to take this chance to thank David Fernandez Rivas for all his help, supervision, patience and for this challenging assignment. I also want to thank Juan Jauregui Becker for his support and feedback on my progress.

Next I want to thank Ilona Groeneweg for all the useful information on PMU and for participation in the user test.

Glossary

The developer
the assignment's client David Fernandez Rivas will be called the developer for the rest of the report.

Splash back
When liquid is shot into the skin with high velocity, it could occur that not all of the liquid goes into the skin. This liquid splashes back at the injector. Splash back increases the risk on cross contamination and it results in not delivering the total dose.

Abstract

David Fernandez Rivas developed a new technology for needle free injection. With this technology, he wants to participate in the needle free injector market. The assignment is to design a needle free injector for either vaccines, insulin or pigmentation.

Injecting needle free is done by shooting liquid at a high velocity as a thin jet that creates its own needle to penetrate the skin. This new technology works with a laser that beams in the liquid, which causes a bubble to grow. This bubble creates so much pressure that the liquid will leave the chamber via a narrow channel, which causes a high velocity jet.

The pigmentation application has been chosen for further development. So the injector is going to be a needle free injector for tattooing. The focus is not on the ordinary tattoo industry, but on the Permanent Make Up industry. This is a specialized type of tattooing of the eyebrows, eyelids, lips and also scarring and nipple areolas. In case of scarring and nipple areolas, the tattoo is meant as repigmentation of the skin.

Needle free tattoo machines do not exist yet, so this could be a very interesting new product for the industry. Needle free injectors for vaccine, anaesthetic or insulin delivery do exist, but are somehow not well known.

The final concept is based on a pen, since the intention is to draw on the skin. The ink will be inside a cartridge, which is inserted in the injector. The injector will be wireless, by using battery power and Bluetooth connection with a control panel. The concept uses a foot pedal for shooting the ink jets.

After performing a user test, it became clear that the design needs some modifications.

Samenvatting

David Fernandez Rivas heeft een nieuwe technologie ontwikkeld voor naaldvrij injecteren. Met deze technologie wil hij graag de naaldvrije injector markt op. De opdracht is het maken van een ontwerp voor een naaldvrije injector voor vaccinaties, insuline of pigment.

Naald vrij injecteren kan door vloeistof met hoge snelheid af te schieten als een dunne straal. Deze dunne straal creëert zo zijn eigen naald waarmee het de huid doorboort. Deze nieuwe technologie werkt met een laser die in de vloeistof straalt, wat het ontstaan van een bubbel tot gevolg heeft. Deze bubbel zorgt voor een hoge druk in de kamer waar de vloeistof in zit, waardoor de vloeistof moet ontsnappen door een dunne uitgang. Omdat deze uitgang zo dun is, zal de straal net zo dun worden en met een hoge snelheid de kamer verlaten.

De pigmentatie applicatie is gekozen voor verdere ontwikkeling, dus het zal een naaldvrije tatoeage injector worden. Er wordt niet zozeer gefocust op de gewone tatoeage industrie, maar op die van de Permanente Make-Up. Dit is een gespecialiseerde tak van de tatoeage industrie die zich focust op wenkbrauwen, oogleden, lippen en ook littekens en de tepelhof. In het geval van littekens en de tepelhof gaat het om repigmentatie.

Er bestaan nog geen naaldvrije tatoeage machines, dus dit zou wel eens een heel interessant product kunnen zijn in deze industrie. Er bestaan al wel naaldvrije injectors voor vaccinaties, verdovingen en insuline, maar die zijn op de een of andere manier niet bekend onder de specialisten hier in Twente.

Het eindconcept is gebaseerd op een pen, gezien je wil kunnen tekenen op de huid. de inkt zal zich in een cartridge bevinden, welke je in de injector stopt. De injector zal draadloos werken door middel van een batterij en Bluetooth verbinding met een control panel. Het concept maakt gebruik van een voetpedaal voor het schieten van de inkt.

Na een korte gebruikerstest is het duidelijk geworden dat er nog een aantal aanpassingen moeten worden gedaan op het ontwerp.

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1. Introduction

1.1 Client

The assignment came from David Fernandez Rivas, one of the researchers of the University of Twente at the MCS department. He developed a new technique to shoot a liquid jet with high velocity. This jet is so thin and fast that he thought it was a great new way for needle free injection.

A few month in the assignment, he started a spin off company called InkBeams.

for the rest of this report, he will be called the developer.

1.2 Motive

Coming from a tropical region in a developing country, Cuba, Rivas is familiar with the difficulties in controlling diseases spread by vectors such as mosquitos: malaria, dengue and more recently, the zika virus for which no cure has been found yet. In many parts of the world these diseases present major problems, as the costs to vaccinate, the infrastructure and workforce needed are not easy to guarantee by all governments.

A commonly used method for vaccination is by injecting the drug formulation with a syringe and needle that is operated by a health worker. The fear for large needles (needle-phobia) is also felt in developed countries, where patients avoid the stinging moment of insertion of the needle in their skin or their babies. There is a severe risk when injecting with needles, and it is the danger for health care workers worldwide to be infected with diseases such as AIDS (Acquired Immune Deficiency Syndrome) and hepatitis, among others. Regardless of how well trained they might be, it is estimated that nearly 2 million (!) needle-stick incidents occur each year.
This scenario is aggravated by inadequate disposal, and waste contamination caused by used syringes and needles, which are not always processed properly and pollute the environment.

1.3 Goals

The goal of this assignment is to design a needle free injector that could be an addition to the Dutch market. With this design, Rivas can show investors what a needle free injector could look like and what the cost will be.

Before designing, an analysis of the technology, injecting and market will be done. The markets that will be analysed are that of needle free injecting and the tattoo industry. Out of these analysis’s, a requirement list will be made.

After choosing the application direction, there will be several concepts made. One of these concepts will be chosen based on the requirements list. This concept will be worked out with material choice, manufacturing methods and costs estimation. Also a user test will be done to test ergonomic requirements of the injector.

The technology is a new way of injecting a liquid, by shooting the liquid through skin at high speed. For now, it is only possible in very small volumes of micro litres. Also, for now, it's only possible to use it with collored liquids. For now, because this new technology is not fully developed yet.

2.1 How it works
To pressurize the liquid, a bubble is created inside the liquid. This bubble is created with a laser. The liquid is held inside a small glass container with an even smaller channel exit. The laser shines into the liquid, just at the edge of the container. The bubble forms and grows. Because of the pressure this creates, the liquid is forced out of the container through the channel, which results in a hair thin, high speed jet. Figure 1 shows a schematic picture of the container and Figure 2 shows the laser that makes a bubble, which causes the liquid to shoot away as a jet.

2.2 Application possibilities
At the start of the assignment, the developer was already focussed on some different applications of the technology. These were mainly medical applications of needle free delivery of vaccines, anaesthesia, antibiotics, insulin or hormones, but also tattooing. The first five are all practically the same, since they are all delivered quite the same way now with a needle. Tattooing on the other hand, is something quite different, since it is puncturing ink into the skin at a high frequency. For the laser-bubble technique, it does not make a big difference which application is chosen. Right now, the amount that can be shot at once is so small, that a burst of several shots is required to deliver the volume of medication. For tattooing, this high frequency is needed to be able to draw. So the application of the technology itself is practically the same for all of those options.

2.3 Requirements
For this technology to work, it requires several things, namely a laser, a chamber with the perfect amount of liquid, a container with the rest of the liquid that needs to be injected, some way to connect the chamber and the container and, finally, power for the laser. (See Figure 3)

The developer's team is still researching the possibilities for the laser. It should work with a laser pointer laser, so just an ordinary laser which is not too dangerous, visible and won't get hot. The only thing that will get hot though, is the focus, which will be right on the edge of the chamber.

In order to let the laser do it's work, it needs a source of power and energy. This can be achieved by using a battery or by using the AC. The exact specification of the power source will be determined in the detail phase of the chosen concept.

The glass chamber in which the laser will beam is probably also not fully developed yet. For now it is so small, it will probably fit in anything. The container has to be connected to the chamber and has to be able to hold the volume of liquid which is needed. How the device will finally work lies out of the scope of this assignment.

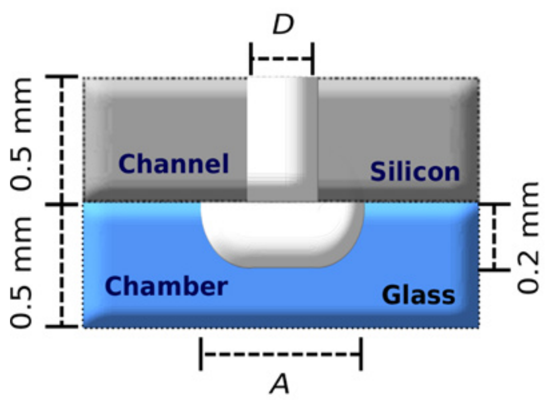


Figure 1: *Injection chamber and channel*

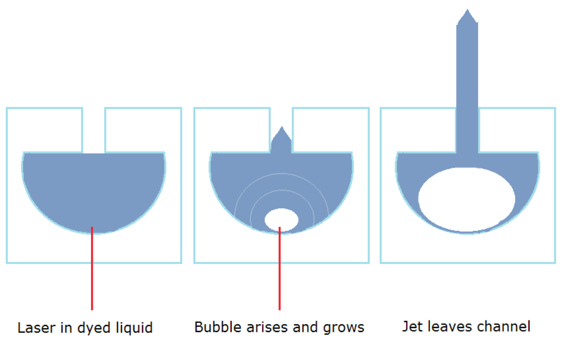


Figure 2: *Laser beams into the ink, Laser causes bubble, bubble grows and creates jet*

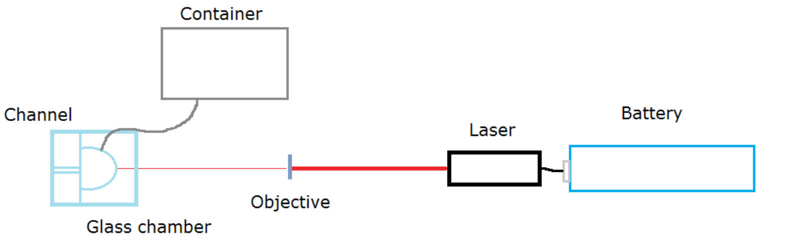


Figure 3: *The technology requires the chamber, cartridge, laser and power source*

At the start of the assignment, there were three directions in which the new needle free injection method could possibly be used. These three directions were determined by the client and by possible investors. The first direction is for injection of mass vaccinations, either for Dutch vaccination programs or for third world vaccination programs. The second direction is injection of personal medicine, such as insulin. In this direction, investors were interested in a very young target group, namely 0-2 years old. The third and last direction is injection of ink, also known as tattooing.

First, I did some research in vaccination and injection of insulin at toddlers and then the tattooing.

3.1 Vaccinations
For details about the injecting techniques used for delivering medicine to the different target groups, I spoke with several injection specialist. Marianne is a nurse on the oncology ward in MST hospital. On her ward, she has to administer medication to (seriously) ill patients, using injections. Barbara Beuvink and Gerla Kenkhuis are both doctors at GGD Twente. They have experience with vaccinating both children and adults. The interviews can be found in Appendix B. Vaccines are delivered using intramuscular injections, so in the muscle. This is mainly done in the upper arm (in the triceps) for children and adults, and in the upper leg for babies and toddlers. Different needles for the different age groups do not exist, so for babies, toddlers, children, teenagers, adults and seniors the same type of needles are used. It does not matter in which muscle the vaccines will be delivered. People usually choose the triceps because this muscle is easily accessible.

3.2 Insulin for babies and toddlers
Insulin is injected subcutaneously, in the fat layer just under the skin. For this type of delivery, short needles are used. Although Gerla Kenkhuis is a paediatrician for the GGD Twente, she could not give a lot of information on injecting insulin into babies and toddlers. She did tell me that babies and toddlers with a coagulation disorder do get their vaccines subcutaneously. Also for this procedure, the same type of needles as for adults are used, but Kenkhuis was not sure whether it is possible to inject in the navel area. Although Kenkhuis could not give me any more details on injecting insulin into babies and toddlers, she could give me a clear image on injecting this age group. Babies do not immediately make connections between the things they see and what they feel afterwards. They need more experience for connections to be made. The first few injections babies get are fairly easy to deliver, because babies do not start kicking yet. Of course, they do experience the pain, so they start to scream and cry immediately. From experience, Kenkhuis knows that the screaming stops quickly after the child is back in its parent's arms. When they are one year old, babies do move their legs a lot more and they now have more experience with sharp objects in their home situation. So from this age, babies are probably afraid of the needle and they move, which means they have to be held still while injecting in the upper leg.
For older children, it is important that something fun and nice comes right after the injection, so they get distracted from the pain of the injection.

3.3 Why needle free injection?
One of the big issues with needle injections are puncture accidents. When such an accident happens, for instance when a nurse punctures herself on a just used needle from a patient, there is a possibility of cross contamination. The nurse could then be infected by blood transmitted diseases such as HIV. To decrease the chance of puncture accidents happening, safety needles have been developed and are now used in hospitals and doctor's offices. Figure 4 shows a syringe with a safety needle. The purple part is a plastic cap which has to click on the needle after injecting is finished. When the cap is clicked on the needle, it is impossible to puncture yourself on the needle.

Besides the cross contamination risks, puncturing with needles is not pain free. A lot of people experience pain when they get an injection and get tense and/or afraid of the outlook of having to get an injection. This is confirmed by the short survey I held via Facebook (see Appendix A for the results), and also the three medical specialists I interviewed support it. Although it is not known yet what the injections of this new technology will feel like, current needle free injectors suggest that the injections will be significantly less painful. [1]

Figure 4: *Syringe with safety needle*

3.4 Tattooing
Tattooing is also a form of injecting, it is injecting ink in the dermis, which is the layer of skin right underneath the epidermis. To reach this layer, the tattooing needle punctures up to 1,5 mm deep. There are two types of tattoo machines that are mostly used in the tattoo industry. The first works with coils that will move the needle up and down using a magnetic field. The other works with a rotary motor, which moves the needle up and down with a non centre lined axis. Figure 5 and Figure 6 show the coil and rotary tattoo machines respectively. This way, a needle will be moved up and down 80 to 150 times per second.

3.5 Cosmetic tattooing and PMU
Besides the ordinary tattoos everybody knows, since the beginning of the 21st century a new form of tattooing is booming, namely the cosmetic tattoos or Permanent Make Up (PMU). PMU tattoos that are done most are eyebrow tattoos and eyeliner tattoos. These tattoos are for women who do not want to do their make up every day over again. Besides that, when done correctly, eyebrows and eyeliner will always be perfect every day and won't come off in the water.

Cosmetic tattoos are not just for the face, but also for other body parts, such as breasts or for scars. Women who had to undergo a mastectomy, because of breast cancer, are left with a chest without a nipple or maybe even both nipples. With cosmetic tattooing, the missing nipple's areola can be recreated. Also scar tissue can be covered up by tattooing the scars with the original skin tone. This is only recommended to do on dark skin types, since skin tones of lighter skin types vary over the year. PMU can be useful for people who lost their eyebrows due to chemo therapy. Their skin is different form healthy skin, which means they need a different approach for the treatment of tattooing their eyebrows. Healthy skin needs 2-3 treatments to get the wanted result. The less healthy the skin, the more treatments it will need.

Figure 5: *Coil tattoo machine*

The tattooing of PMU tattoos is done in the epidermis, so in a layer above that of ordinary tattoos. The epidermis is the top skin layer, so it constantly renews itself. This means that the tattoo will fade in about four years. The needles used for cosmetic and PMU tattoos are the same as the ones in the tattoo shops. The PMU specialists do not have all the colours of ink, just different shades of brown and black.

Some of the ordinary tattoo shops offer cosmetic and PMU tattoos, but nowadays the treatment is done in beauty salons, spa's and there are even specialized salons for PMU. Besides these, plastic surgeons perform PMU tattoos as well. 99,4% of the PMU specialists are women according to a survey study of Society of Permanent Cosmetic Professionals of 2015. [2]

Figure 6: *Rotary tattoo machine*

3.6 Why needle free tattooing?
Just like injections, there is a risk of puncture accidents with tattoo needles. Besides that, the frequent puncturing causes blood to come up to the skin, so the tattoo artist and PMU specialist will get in contact with their client's blood. Tattooing needle free will eliminate the puncture risk, but it is not known yet whether it will decrease the bleeding. So the cross contamination risk shall be decreased, but maybe not eliminated.

Besides this, needle free tattooing could reduce the amount of waste per tattoo. There is a waste of ink, because not all of the ink stays in the skin when the needle pulls back out of the skin. This ink will be whiped off the skin by the tattoo artist and thrown away. Since it is possible to prevent splash back with needle free injection, this waste should be reduced significantly and result in a more economic use of ink.

Further, getting a tattoo is a painful experience. In the PMU industry, specialists ask their clients to put on anaesthetic cream before coming to their appointment. When a client is not able to do this, it is included in the procedure, which takes about 20 minutes to seep in and numb the skin. The sensation of this new technology's jet is not known yet, but because of other needle free injection experience, it can be assumed to be significantly less painful. This means that the procedure will be significantly more comfortable. This is an advantage for the PMU industry, because the people who get these procedures do not want to experience pain.

The market analysis consist of an analysis of the market of needle free injectors and tattooing machines.

4.1 Needle free injectors

Although not a lot of people know of the existence of needle free injection, it does exist already more than a century. The first needle free injector has been developed in 1860 in France and the first patent is from 1936. [3] Nowadays, there are several needle free injectors on the market.

Figure 7 shows a collage of needle free injectors. Injectors A to F are so called Multi-use Nozzle Jet Injectors (MUNJIs), which means they have an interchangeable nozzle. These injectors have been rejected and pulled out of the market because of splash back and risk on cross contamination. Injectors G to N are injectors that are currently on the market. These are known as Disposable Cartridge Jet Injectors (DCJIs).

The thing that all of these needle free injectors have in common is that they shoot a jet using high pressure. The injectors in the collage either use a spring or pressurized gas to obtain the needed pressure. These methods have some advantages, such as that they do not need any electrical power to be able to work. This makes them suitable for third world vaccine programmes.

Some injectors of the pressurized gas type can also be connected to a larger gas tank, so it can be used many times after another. A disadvantage of this larger gas tank is that the product becomes quite heavy and difficult to move. The injectors that do not have this problem are for instance the J-Tip (H in Figure 7) and the Biojector 2000 (Figure 8). The big difference between these two is that the J-Tip is

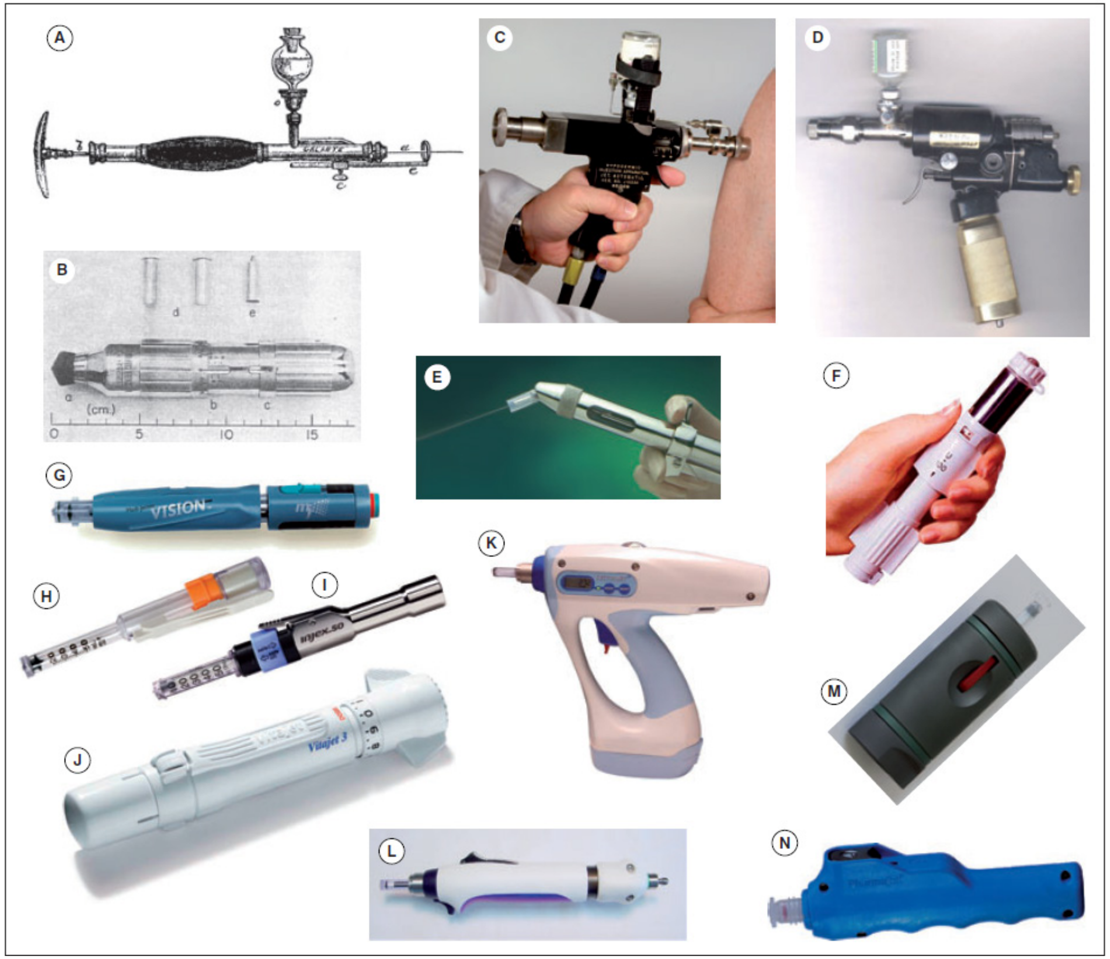


Figure 7: *Collage of needle free injectors, of which the following are DCJIs:*
(G) Medi-Jector® VISION®,326 used primarily for self-administration of insulin.
(H) J-Tip®,352 fully disposable upon single use; powered by compressed nitrogen gas.
(I) Injex®,339 metal spring compressed by separate cocking device.
(J) VitajetTM 3,50 used for self-administration of insulin and licensed under other tradenames (Table 61–1) for growth hormone.
(K) and (L) Investigational LectraJet® HS (high-speed motorized) and LectraJet® M3 (manual) models,335 which utilize common cartridge capable of rapid, fingers-free loading and unloading from magazine.
(M) Investigational VitavaxTM,50 designed primarily for routine immunization with manual cocking of springs; different autodisabling cartridges for SC, IM, and ID injections.
(N) PharmaJet®,358 powered by metal spring compressed with off-tool device; blue model for adults, green and violet (not shown) for children-elderly and infants, respectively; spring power varied for SC, IM, and ID injections via common cartridge.

for one-time-use and the Biojector 2000 is for multiple uses. The Biojector 2000 has a bigger tank that is replaceable.

The injectors that work with gas always make noise. This noise is the sound of escaping gas. This sound could scare people if they do not expect it. Also it may be a risk factor for kids staying still during the injection. For now, needle free injections are not suitable for little children, because the patient has to stay still for a significant longer time than needed with needle injections. Besides that, I don't think that it will be less painful, because the tip of the injector has to be pressed down quite firmly for it to be able to work properly. Appendix B has a link to an instruction video on how to use the Bioject 2000.

The injectors that make use of a spring to have the right amount of pressure, can simply be reused by tensioning the spring. This can be done by turning a ring or part of the injector or by pushing a pin inside the injector. The spring injectors are often used for personal daily use, such as insulin or hormones. Examples of spring injectors are the Medi-Jector VISION (G Figure 7), the Vitajet (J in Figure 7) and the InsuJet (Figure 9). The Injex (I in Figure 7) also works with a spring, but is developed for injection of dental anaesthetics.

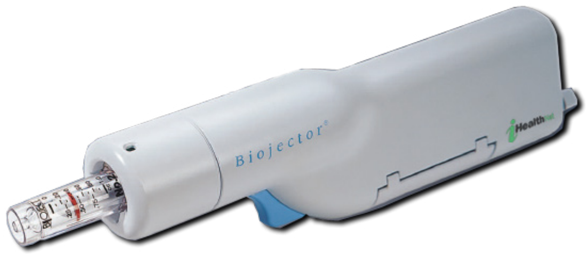


Figure 8: *BioJector 2000*

4.2 Tattoo machines

Needle free tattoo machines do not exist yet. As said in the previous chapter, there are a few different tattoo machines, namely the coil and rotary machine. In the ordinary tattoo industry, these machines are robust and you can see components. In the PMU industry this is different. There the machines have a nice colour and much of the technology is hidden in the shell of the machine. The rotary machines are mostly chosen by PMU specialists, because they make the least noise. This is especially desirable in spa clinics.

Recently there has been an innovation in one of the rotary tattoo machines. This newer machine is able to deliver the ink at the same depth with each puncture. This makes the effect of the ink everywhere the same, so lines will have equal depth and opacity. (Figure 10)

Next to the coil and rotary machines, in the PMU industry also a method is used called microblading. This is not a machine, but a pen with a brush shaped needle tip. With this needle the ink is scratched into the skin. This technique is only used for eyebrow tattoos.

It is not commonly in use yet, but also the 3D-printer has been converted to a 3D-tattooing machine. This is a 3D-printer with a tattoo machine as head. This way, people can come with their own design and 'print' it on their skin. [4]

Figure 9: *The InsuJet, a needle free insulin injector which you can buy at the pharmacy*

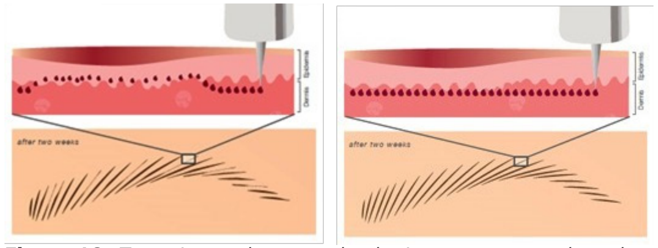


Figure 10: *Tattooing at the same depth gives a more equal result*

Figure 11*: Microblading tool with needle tip*

5. Application Choice

Before I had to make a choice in which direction I should design this injector, an investor contacted the developer. This investor was very interested in the tattoo application for cosmetic and medical tattooing. So the application has been chosen by them.

Even though I did not choose the application, I do think it is the best option. The technology askes for a dyed liquid in order to work. Ink is dyed liquid, so you do not have to modify the liquid you want to inject first. Besides that, there is already a market in needle free injectors for vaccines, insulin and anaesthetics, while the tattoo industry does not know the needle free concept yet. From the market analysis and the interviews I had with the injection specialist, the needle free injector market is bigger than I thought, but very unknown, non of the ladies ever heard of a needle free injector. So in order to really stand out and make a needle free injector that does become well known and much used, more unique selling points than just working with a new technology are needed. For now, I do not see such unique selling points, so going in that market would be a really big challenge.

Besides that, I was not able to find the exact reason why needle free injectors are so unknown here in the Netherlands, or at least here in Twente. This makes it hard to find the correct requirements so it would break through in the Netherlands.

6. Requirements

In the requirements list the technical and user requirements and wishes are listed.

The requirements with an * are the requirements I am able to test in either a user test or in a simulation programme like Solid Works.

Functional Requirements

- All the injections have to be injected at the same depth
- Replacing the cartridge may not take longer than 10 seconds *
- There may be no more than 30% waste of ink while tattooing
- Injecting must be possible in both the epidermis and the dermis
- It has to be clear to the specialist whether an injection was successful
- The injector's life time has to be at least 10 years

Interface Requirements

- It has to be clear to the specialist where he/she is going to inject *
- It has to be clear to the specialist in which skin layer he/she is going to inject *
- Switching between types of injections must be possible within 30 seconds *

Ergonomical Requirements

- The injector's mass may not be higher than 500 grams *
- The injector must be easily usable while wearing rubber gloves *
- The injector may not make louder sounds than 20dB
- The client of the specialist (the person who gets the tattoo) may not feel any vibrations
- The injection may not be painful
- Whish: The injector has to work wireless *

Failure Requirements

- The injector must survive a 2 meter fall *
- The laser of the injector may not turn on when the chamber is empty
- When colours are being switched, there may not be any ink of the last colour be present in the chamber
- No more than two injections per minute may be painful

Safety requirements

- The injector may not accidentally inject *
- The outside of the injector may not become hotter than 44 degrees Celsius * [5]
- The separate parts of the injector that (may) come in contact with micro-organisms have to be sterilized before use
- The other parts of the injector have to be disinfected before use *
- The injector may not have any sharp points and/or edges *
- While injecting, there may not be any occurrence of splash-back

Appearance Requirements

- The injector must have a comforting appearance. (It should not be scary looking or give you the impression you are at the dentist) *

7. Morphological analysis

Some of the requirements ask for a solution on the device, but there are more optional solutions. In this morphological scheme you see different solutions for indicating and setting the injection depth, spot and surface and for obtaining wireless energy.

The green line represents the first concept and the pink line the second concept.

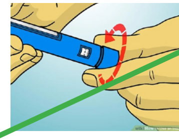
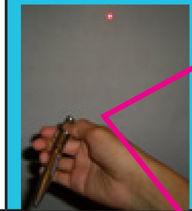
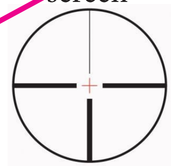
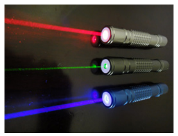
Setting the injection depth	Type cartridge	Rotary button 	Slider 	Buttons and screen 	Rotative component 	Separate buttons 
Indicate injection spot	Laser 	Cross on screen 	Sticking out component from which shoots the jet			
Indicate injection depth	Colour laser 	Indicate on screen	Light on injector 			
Setting injection surface	Type cartridge	Rotary button 	Slider 	Buttons and screen 	Rotative component 	Separate buttons 
Wireless energy	Batteries 	Solar cells 	Energy from movement 			

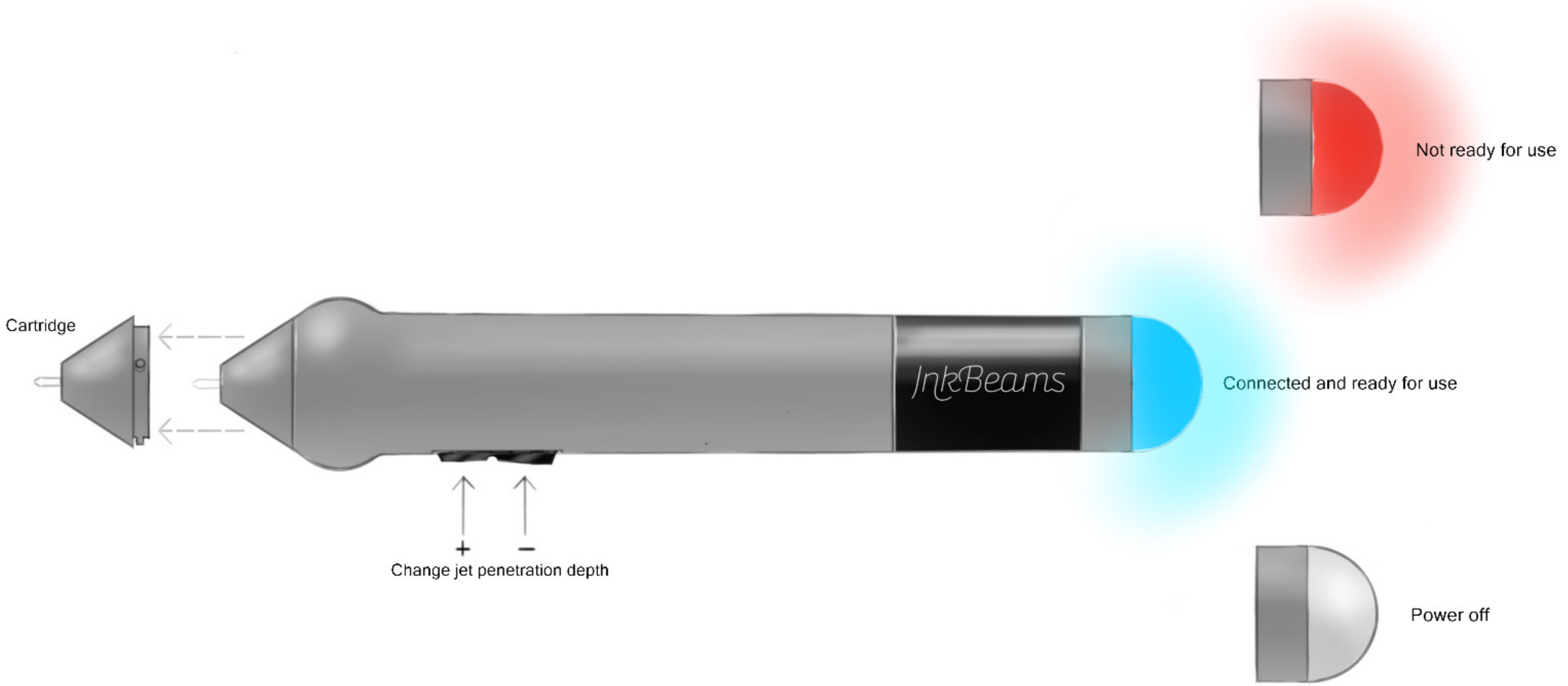
Table 1: *Morphological scheme*

8.1 Concept 1

Since the goal of this device is to be able to draw on the skin, the first concept is inspired by a pen. It will be bigger than a pen though, because all the electrical components have to fit inside.

This pen has just two buttons for quickly changing the penetration depth of the jet. The injector will turn on when there is contact with a cartridge. First, the light on the back will be red. This means that the injector does recognize a cartridge, but it can not use it yet. Reasons for it not being ready to work are that the cartridge is not securely inserted, the injector does not have Bluetooth connection with the control panel and/or the cartridge is empty. The light will turn blue when the injector is ready for use. The shape of the light is inspired by erasers on the back of pencils and also to make the shape more organic.

To inject, the user has to press a pedal with his foot. This way you can't accidentally shoot ink jets while picking up the injector.
The battery will be charged by an induction charger, so the injector does not need any sockets for wire charging.
The control panel is a touchscreen with all the needed information you need to know while tattooing, such as penetration depth of the jet and battery status.



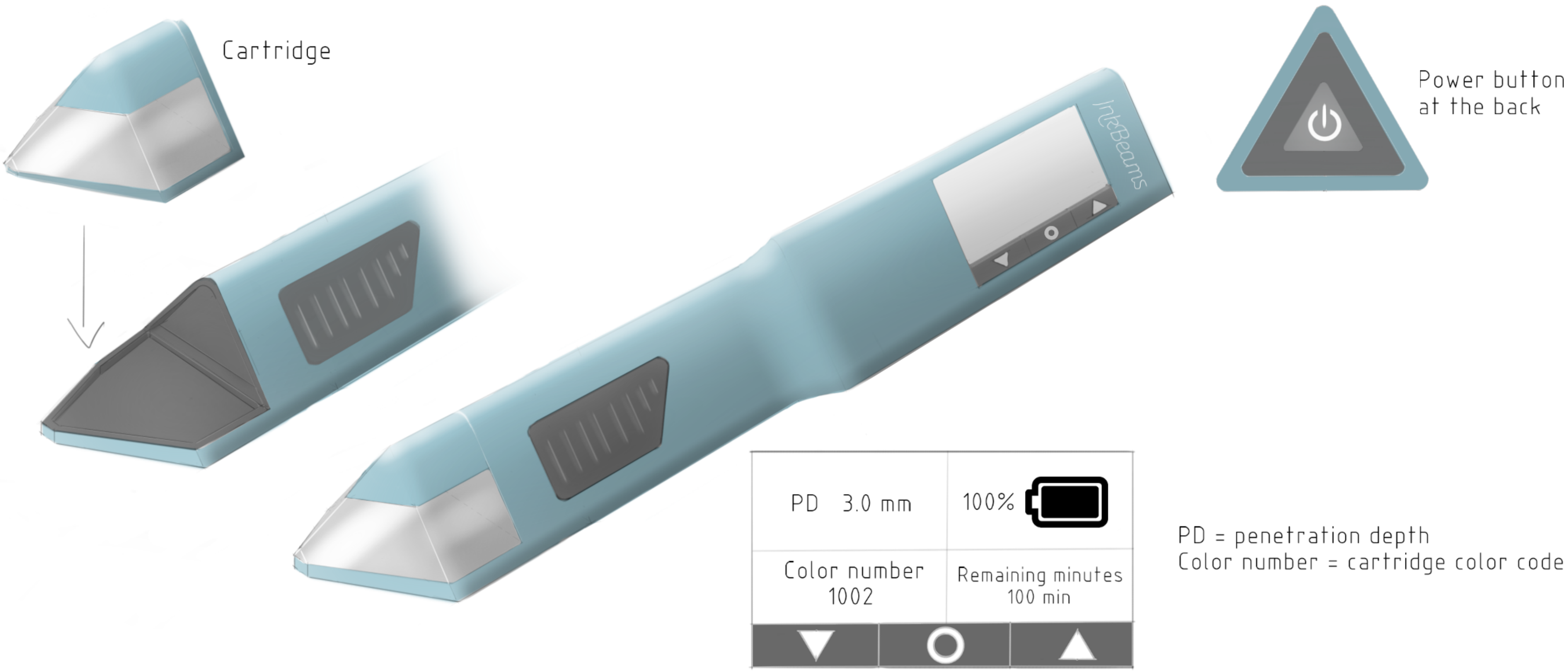
8. Concepts

8.2 Concept 2
This is an all-in-one solution. With this concept all you need is in the injector. This means that the user only needs this injector and is ready to go.

The screen shows the penetration depth, battery status, which cartridge is in use and the remaining tattoo time. The buttons under the screen are for setting the penetration depth. The triangular shape is to compel the user to hold the injector always the same way. The button in the front starts the injections. The idea is that you can also see the ink in the cartridge, so you know for sure you have got the right colour and as indication on how much ink is left in the cartridge.

At the back of the injector, there is a power button. This button turns the injector on and off.

In the front, there will be a laser pointer that indicates the injection spot at the skin.



8.3 Concept choice

The choosing of the concept will be based on the requirement list. Because you can not know for all the requirements whether you meet them, I made a selection of the requirements that can be judged. For each requirement, the concepts get a score from 0 to 3; 0 being very bad, 1 bad, 2 can be better and 3 great. The maximum score the concepts can get is 21. Concept 1 scores 18/21 and concept 2 scores 14/21, so concept 1 scores better in meeting the requirements than concept 2.

Concept 2 needs something like a laser to point where the injection is going to be, since the nozzle will be too big to exactly see. Concept 1 has a fine tip that is small enough so you can see. Besides that, after researching the existing needle free injectors, the chances are that the nozzle has to be on the skin in order to inject the ink. It is also easier to draw when you can touch the surface you want to draw on, instead of holding it a few millimetres above.

Both concepts have a screen which shows the injection depth. The specialist should know in which skin layer he is injecting from this information, but the system does not tell him. Besides that, the user has to look for the number on either a very small screen on the injector or on a separate screen beside him.

Both concepts will work with a battery, so they both score great on the wireless wish.

Concept 2 has a safety issue, because of the injection button. This button makes it possible to accidentally start injecting while picking up the injector. Now this could also happen with the pedal, but to me that seems less likely. Besides that, pushing a button while holding the injector in place is hard. Chances are that you want to start injecting at a certain sport, and eventually starts injecting at another spot near where you wanted to start. With the pedal, it is easier to hold still on the spot where you want to start.

The injectors have to be cleaned after every treatment. The more buttons that are on the body surface, the harder it is to properly clean this surface, buttons and edges.

Further is the appearance of concept 1 more comforting than that of concept 2, because of the round shape. The triangular shape seems more technical and masculine and thus less friendly and reassuring.

For the rest of the assignment, I will work further on concept 1.

Requirements	Concept 1	Concept 2
It has to be clear to the specialist where he/she is going to inject	3	2
It has to be clear the specialist in which skin layer he/she is going to inject	2	2
Whish: The injector has to work wireless	3	3
The injector may not accidentally inject	2	1
The other parts of the injector have to be disinfected before use	3	1
The injector may not have any sharp points and/or edges	2	3
The injector must have a comforting appearance. (It should not be scary looking or give you the impression you are at the dentist)	3	2
total	**18**	**14**

Table 2: *Requirements evaluation*

9. Final Concept

In this chapter the details of the final concept will be discussed. Starting with a Solid Works model of the injector and cartridge including an estimation of the electronics inside the injector. Then the materials, manufacturing methods and a price estimation will be discussed. After knowing the materials, a force simulation can be done to test whether the injector will survive a fall of 2 meters high.

9.1 3D model
In the following five figures (Figures 12-16) you can see several renders of the injector and the cartridge. The cartridge can be correctly placed inside the injector by placing the pins in the slots and turning the cartridge a few degrees. At first, the red LED will turn on, when correctly inserted and connected to the control panel via Bluetooth, the blue LED will turn on. When the injector does not recognize a cartridge, the LEDs and the rest of the injector will be turned off.

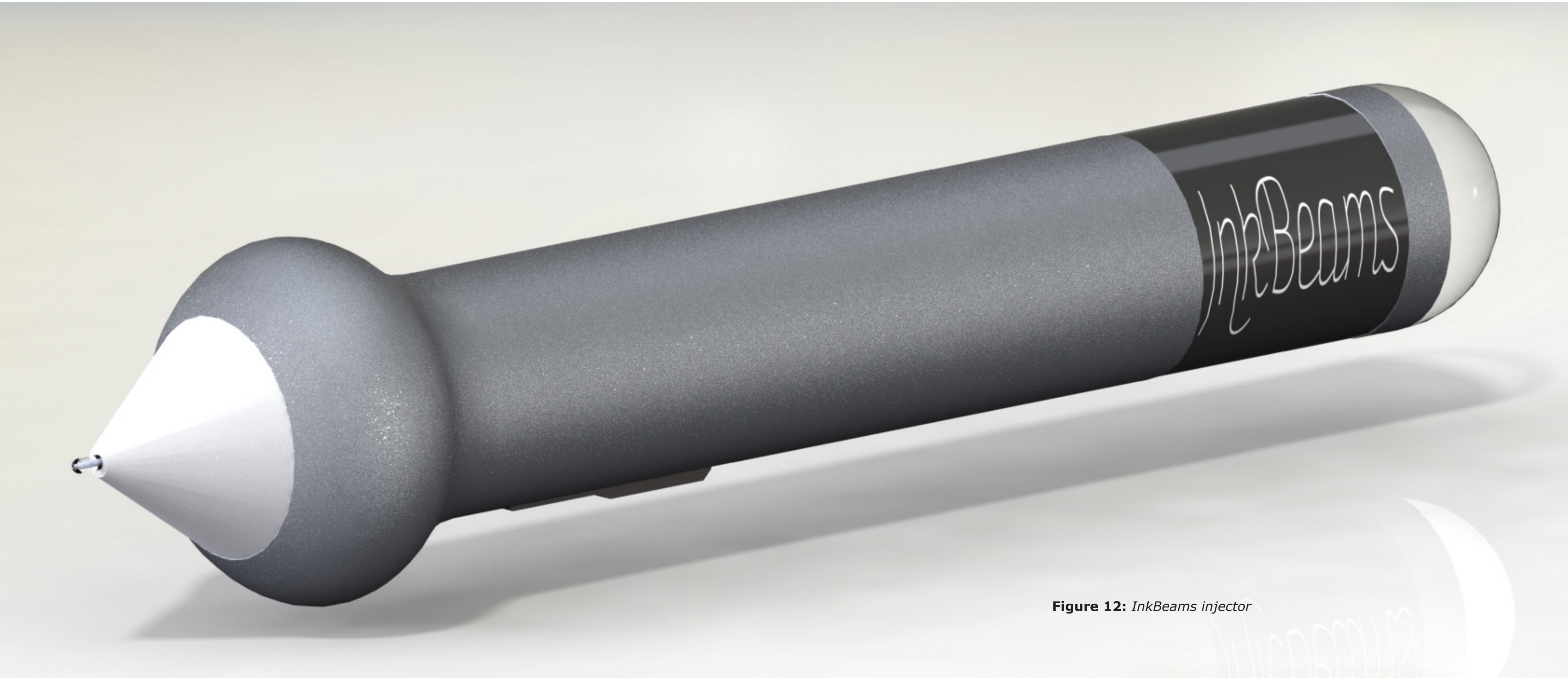


Figure 12: *InkBeams injector*

9. Final Concept

Figure 13: *InkBeams injector cartridge out*

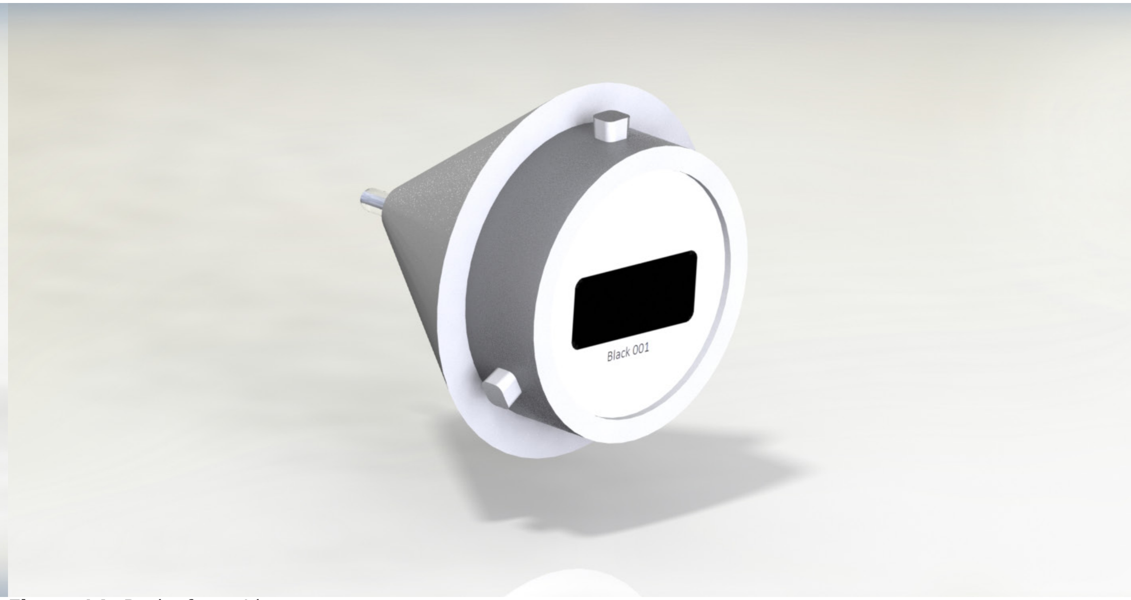


Figure 14: *Back of cartridge*

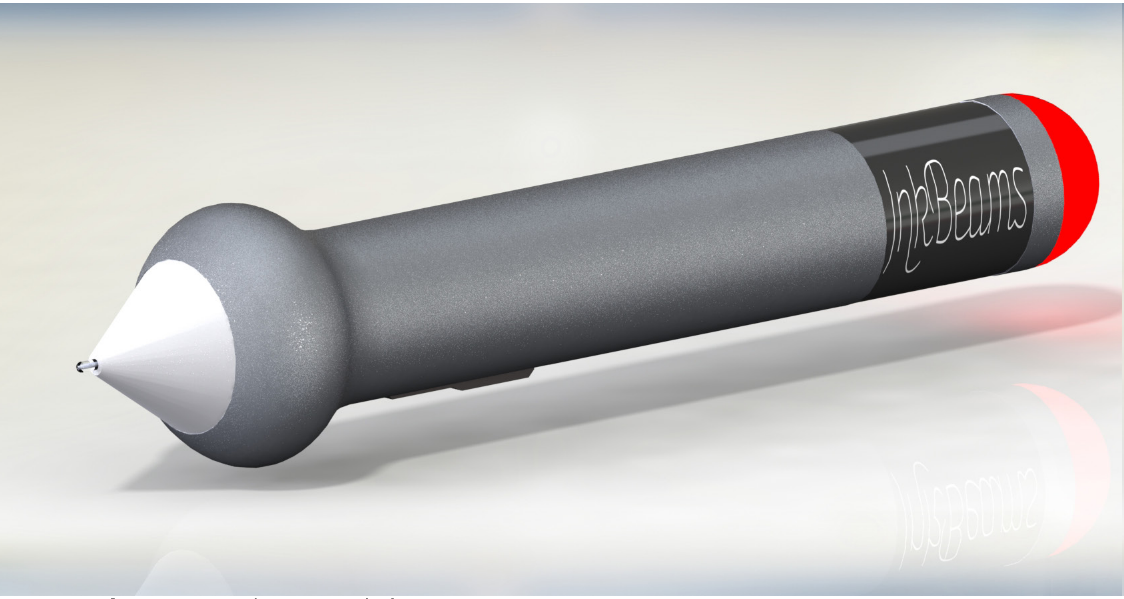


Figure 15: *On, but not ready for use*

Figure 16: *Ready for use*

9.2 Electronic components
The electronic parts that have to fit inside are the laser, battery, Bluetooth, other computer like PCB for information processing and some coil for the induction charging.

The laser can be just an ordinary laser pointer diode. These can be fairly small, I found one of just 5,6mm diameter. [6] Diodes need a constant current, but batteries give a constant voltage. So the diode also needs a small electronic board that converts this. These boards can be about 18*10*6 mm.[7] To eventually get the focus of the laser at the most ideal point and area, it needs an objective lens and some distance between the diode, the lens and the cartridge. This distance and objective lens are not known yet, since the developer's team is still researching the ideal laser power at the focus. For now I expect it to be enough room if I reserve 25mm for this.

In order to make it possible to connect the injector with the control panel via Bluetooth, it needs a BLE microcontroller chip. This chip can be placed on a PCB together with the rest of the information processors and the red and blue LED lights. After talking with an electrical engineering student, I expect to have enough PCB space with an area of approximately 20*30mm.

The battery I chose is the 18650 lithium battery. The battery has to be a lithium battery, since it must be re-chargeable. I chose for a rather large battery, so there would be enough energy for all the components for a working day. The 18650's capacity is probably a lot larger than that, but that also gives room for it to become older and empty faster. At the back of the injector, inside the housing, there will be some copper wire inserted to form a coil. The coil is necessary for the induction charging. Fortunately, this takes little space, since you can already achieve this with very thin copper wire.

You can see the placement of the electronic components in Figure 17. The laser diode is now placed 25mm from the front. Right behind the laser diode will be the battery. The battery will be the heaviest component inside the injector. This way, the centre of mass will be near where you hold the injector while tattooing.[Appendix D] This is fortunate for the ergonomics of the injector. The PCBs will be placed at the back. The laser diode, the buttons and the cartridge recognition will be connected with the PCBs with wires. The red and blue LEDs will be placed on the middle PCB.

Now the components are floating in the render. Of course they need to be held in place somehow. Especially the laser diode should not be able to move. The battery needs some sort of housing which holds the battery, connects the battery to the circuits and it could also be the base for the PCBs.

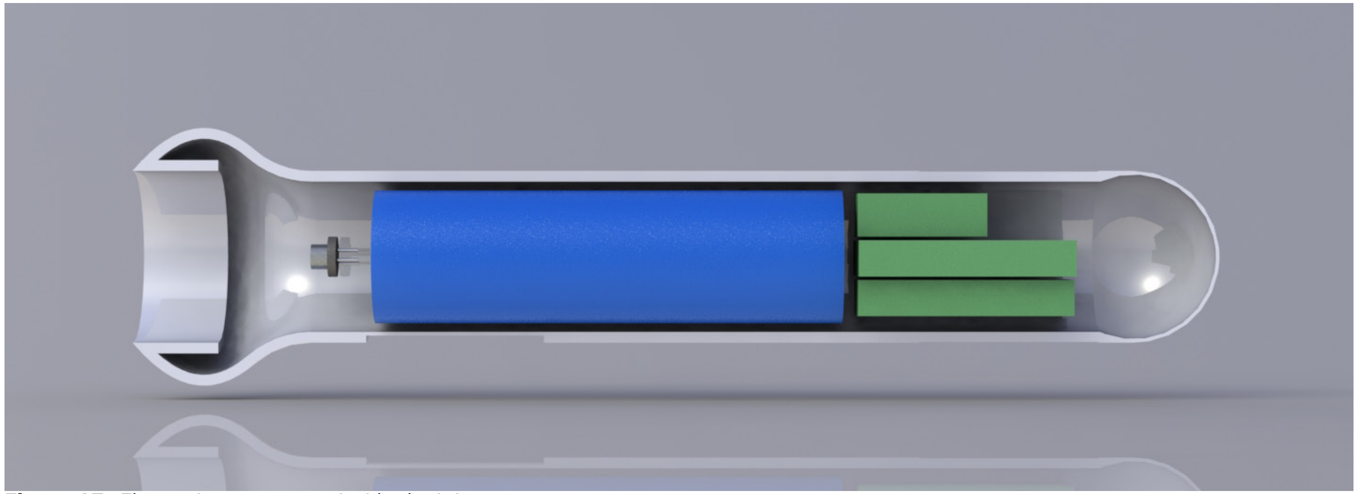


Figure 17: *Electronic components inside the injector*

9.3 Materials

The housing of the injector has to be made out of a strong material from which the surface can be made smooth and won't erode. Using CES, a computer program for selecting materials, I found that Cast Al-alloys, Commercially pure titanium and Carbon Fiber were the best options for the casing of the injector, because these are light weight and do not corrode. To be able to compare the three materials, a table has been made with some of the material characteristics that I found most important for selecting the material. the table is based on the data from CES.

The price is in Euro per kilogram material. This is not the most important characteristic, since the market is used to high priced devices and the injector does not need that much material. Thermal conductivity however is important, because the heat from the laser has to be transferred out of the device, so the injector does not overheat.
Electronic conductivity is less important than thermal conductivity, but it is important that the user does not get an electrical shock picking up the injector.
Processabilities are the ways you can process and manufacture the material. The more ways you can process it, the more freedom in manufacturing you have.
If the material is recyclable, that would be a nice bonus. Same goes for a low CO_2 footprint.

From this table, aluminium seems to be doing very well, especially in thermal conductivity and processability. But when performing a drop test simulation in Solid Works, Carbon fiber is the winner. (Figure 18) Also when you look at the material's appearances on the injector (Figure 19), personally I think carbon fiber does look better than aluminium or titanium. Thermal

	Aluminium	**Titanium**	**Carbon fiber**
Price (Eruo/kg)	2.41	12	38.10
Thermal conductivity	Good Conductor 160 W/m.°C	Poor Conductor 18 W/m.°C	Poor Insulator 2.6 W/m.°C
Electronic conductivity **Electrical resistivity**	Good Conductor 8 μΩ.cm	Good Conductor 57 μΩ.cm	Poor Conductor 9.46e5 μΩ.cm
Processabilities	Casting: good Forming: sufficient Machine: good Welding : sufficient Solder/Brazing: not sufficient	Casting: sufficient Forming: sufficient Machine: not sufficient Welding : good Solder/Brazing: bad	Machine: not sufficient Moulding: good
Recycle	V	V	X
CO_2 footprint (kg/kg)	12.7	41	36.4

Table 3: *Material evaluation of aluminium, titanium and carbon fiber*

conductivity is quite important though, so with carbon fiber there must be thought of another solution to how to get rid of the diode's heat. To conclude, it is probably best to choose aluminium. So I want to propose that the aluminium version is standard, and the carbon fiber version a deluxe version of the injector.

At the back of the casing, there is a diffuse bulb from which you can see the red and blue LED light. This bulb can be made from glass or plastics like PP, PE and PET. Glass is a very sensitive material which breaks quite easily. Since the injector gets picket up, laid down, packed and unpacked from a case every day, this sensitivity is not desirable. PP, PE and PET are significantly less breakable.

The material of the cartridge should protect the users from burning their hands when removing the cartridge from the injector.

9.4 Drop test

In the requirements list, there is a requirement that states that the injector should survive a fall from 2 meters height. To test this, I used the simulation tool of Solid Works which can perform a drop test. I changed the thickness of the casing to 2mm and filled up the space in the bulging in the front of the injector. As said in the previous subchapter, I performed the drop test three times, for an aluminium, titanium and carbon fiber casing. In Appendix E you can see the results of this test and in Figure 18 the displacements. The injector seems to be bending a little bit. If that happens, the injector is broken, because the laser won't beam in exactly the right direction anymore. However, it is not clear to me whether this displacement is temporary or not.

So depending on how definitive the displacement really is, it may meet the falling from 2 meters requirement if the casing is made of aluminium or carbon fiber.

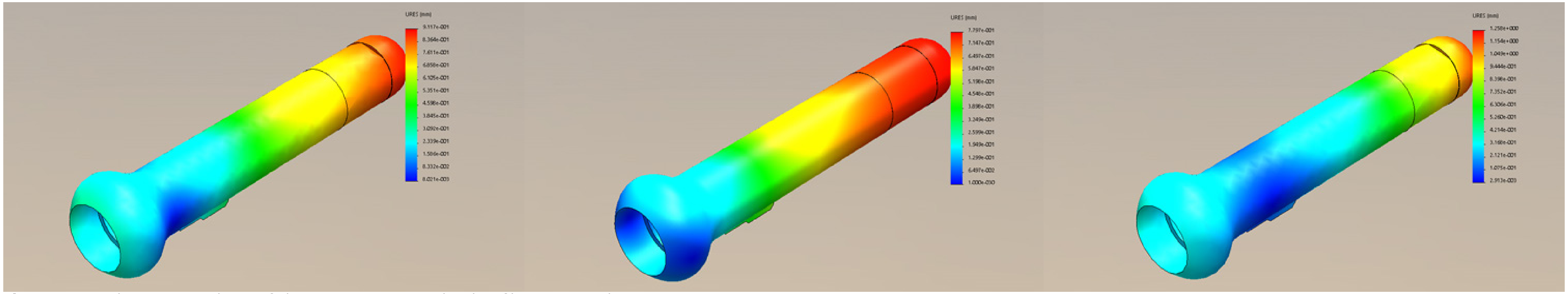


Figure 18: *Displacement simulation of aluminium, titanium and carbon fiber respectively*

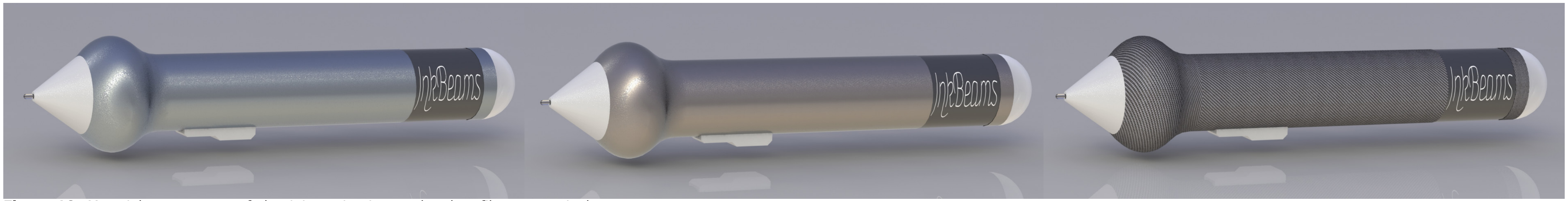


Figure 19: *Material appearances of aluminium, titanium and carbon fiber respectively*

9.5 Manufacturing

There are multiple ways of manufacturing the injector’s casing from aluminium. It could be made as one piece with turning, or with casting. The casing being made as one piece is desirable, because the surface has to be as smooth as possible for hygienic reasons. Casting asks for a mould in which liquid aluminium can be poured. Making this mould will be quite expensive, since it has to be thoroughly calculated for shrinking of the aluminium from cooling down. This method is very useful when the quantity of the product is high.

Searching for ‘permanent make up’ at the Kamer van koophandel, results about 750 PMU specialist with a kvk number in April 2017. [8] If all of those companies have one to three tattoo devices each, you are looking at a quantity of about 2000 machines in the Netherlands. Ideally that would mean that up to 500 devices per year could be made. It can be concluded that the quantity won’t be high. So casting the casing would be an expensive option.

For this type of quantity, turning and other machine manufacturing methods are a good solution. A massive piece of aluminium is needed from which material will be removed until it is the desired shape. For this shape it would mean that more than half of it’s mass has to be removed, so there is a lot of material waste. Luckily, aluminium is not that expensive and not as bad for the environment as other materials. Besides that, this waste could be recycled, so it is not totally wasted.

Manufacturing the casing from carbon fiber however, does not have that many options. The only thing you really can do with carbon fiber is moulding it. This means that either a positive or negative mould has to be made. Next the carbon fiber (with epoxy) has to be placed in or on the mould, with possibly different layers of other materials such as fiber glass. Then the layers of carbon fiber have to be pressed against the mould, which is usually done by making a vacuum bag. When the epoxy is all hardened out, the carbon fiber part is finished.

Making the casing out of carbon fiber would be very expensive. The mould would be a high cost for a very small quantity. The material is also very expensive and not recyclable, so every bit you waste is lost money. This manufacturing method is also very time consuming, so it takes a lot longer to make the casing out of carbon fiber than out of aluminium.

Besides the manufacturing of the case, also the assembly of the parts inside should not be forgotten. Since there is a preference of making the casing as one piece, it won’t be easy to assemble the parts one by one inside the casing. It would be better if it could be all assembled outside the casing and than put in the casing as a whole. Then the last parts, like the button and the light bulb at the back can be attached with a snap fit.

9.6 Cost estimation

I found this part very difficult, since this estimation is based on a lot of numbers that I don’t know.

For the estimation of the production costs of the casing, the following formula was used: [9]

$$K_F = F_{OM} \times (C_E + C_{RO}/X + C_p/Y)$$

in which F_{OM} is the overhead manufacture, C_E the execution costs, C_{RO} repetitive order costs, C_p preparation costs, X the amount of components and Y the quantity of the production series. In Appendix F you can find the full calculations.

The only part of this formula that I was able to calculate a little bit was the C_E. The execution costs are calculated from the material costs and manufacturing costs. The material costs for an aluminium casing were doable, I came to an estimation of 261,65 EUR per casing. This seems like a lot, but also the waste and manufacturing are calculated in it, so maybe it is okay.

From there I didn’t know any numbers of all the different costs that will be made, so I had to guess all of those, which makes this entire estimation even more unreliable. I guessed both the C_{RO} and C_p to be 200 EUR, and the F_{OM} to be about 10% of the total rest of the costs. Which then gives a total production costs estimation of 508.26 EUR per aluminium casing.

The electronic components can mostly be bought, except probably for the ‘smart PCBs’ with the Bluetooth BLE microchip, LEDs and other controllers to make the injector do what it is supposed to. The components to buy will be the battery, battery case, the laser diode, the laser's PCB the BLE microchip, LEDs, buttons, copper wire for induction and more wires connecting the PCBs, the control panel and pedal.
In Appendix G you can find the list of all the separate components costs. The total costs of the electrical components would be about 150 EUR.

Further the injector needs to be assembled. I think a trained person should be able to this in an hour, so I think this can be done for 25 EUR [9] per injector. This gives a total production cost estimation of at least 400+30+25= 455 EUR per injector.

The cost for software development still need to be added.

10. User Test

The user test was an evaluation for six requirements, namely:

- Replacing the cartridge may not take longer than 10 seconds
- It has to be clear to the specialist where he/she is going to inject
- It has to be clear the specialist in which skin layer he/she is going to inject
- The injector bust be easily usable while wearing rubber gloves
- The other parts of the injector have to be disinfected before use
- The injector must have a comforting appearance. (It should not be scary looking or give you the impression you are at the dentist)

For the test I made a physical model. (Figure 20 and Figure 21)The main part of the injector was turned on the lathe, the rest was either 3D-printed or thermoformed. Also there is an electric system in it so a red LED will light up when you are trying to insert a cartridge and a blue LED when you inserted it correctly. Besides this, also an idea for a charging station has been 3D-printed. The control panel was created with a PowerPoint on a tablet. In Figure 22 you can see a screenshot of the control panel.

The user test was performed by one PMU specialist, Ilona Groeneweg. You can find the user test preparation and results in Appendix H Ilona gave very useful feedback on ergonomics. The charging station needs to be redesigned, because it is not easy to clean. Also she found the injector too big in the front. She compared it to trying to draw very fine lines with a big pencil, so she thinks it will have a negative effect on her accuracy. Further she told me that the pedal idea was quite OK, but it would be better if the safety was in two contact points on the injector and the

Figure 20: *Me holding the injector protoype*

Figure 21: *Injector prototype with cartridge and charging station*

cartridge. So it can only inject when the cartridge touches the skin and the user touches a certain spot on the injector. This because Ilona wants to be able to walk around her client without having to move the pedal with her.

She did not have any difficulty inserting and removing the cartridge from the injector. Also while wearing rubber gloves, she did not have any problems controlling the injector. She did have a problem with the idea not being able to create the perfect shade of ink for her client's skin. So there has to be thought of a way to manually fill the cartridges with ink.

The interface of the control panel was clear to her and she thought it gave her all the information she needs. There was no difficulty in changing the jet penetration depth either.

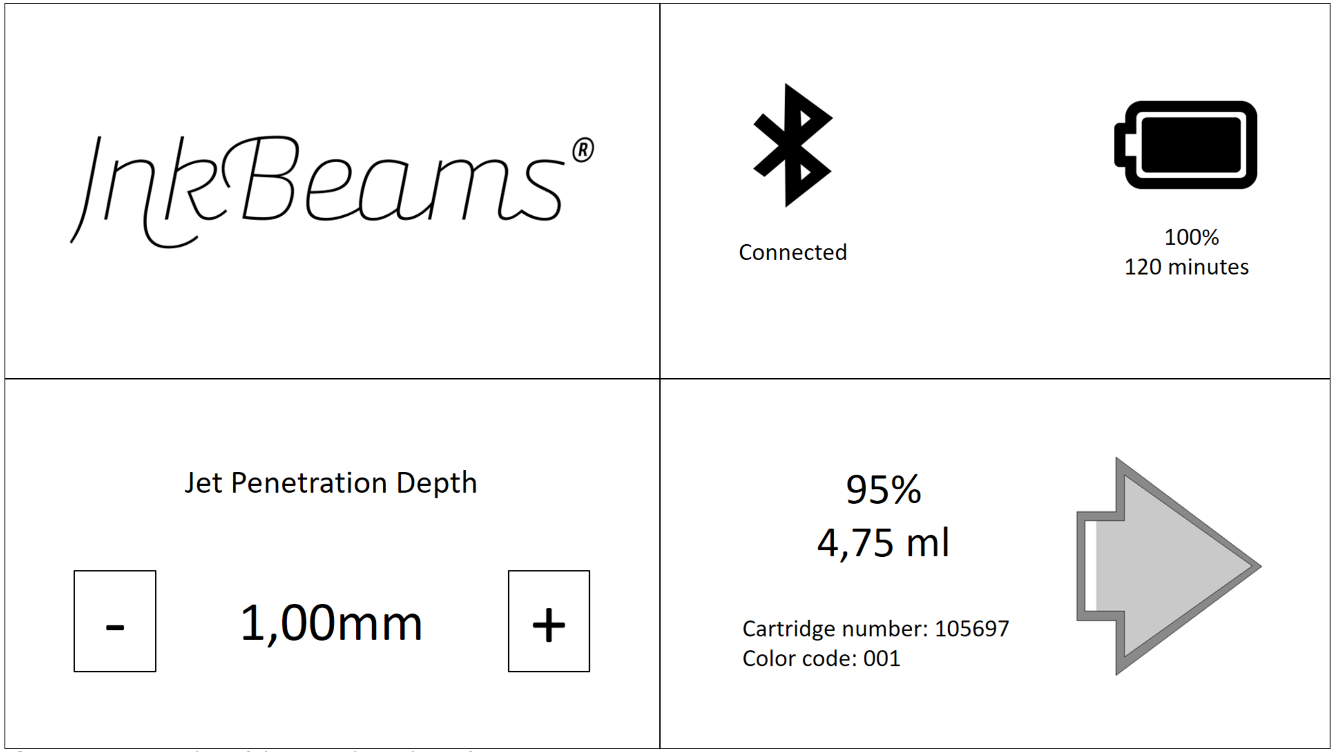


Figure 22: *Screenshot of the control panel interface*

11. Conclusions and Recommendations

The assignment was to design a needle free injector that would fit inside the Dutch market. The precise application was not known yet, but the focus was on vaccinations and personal use at first. Besides this, the developer had an idea of it also being applicable for injecting pigments.

During the injection analysis, the focus of application changed over time. First for vaccines, then insulin injection for 0-2 year olds, back to vaccines and eventually tattooing. The latter promised to be serious, since there is an investor for it. The developer started his spin-off company, now called InkBeams.

After the market analysis, I found this to be a good decision. The needle free injector market is bigger than you would think for something that even specialist never heard of. I was not able to find the exact reason why needle free injectors are so unknown here in the Netherlands, or at least here in Twente. This makes it hard to find the correct requirements so it would break through in the Netherlands.

The concepts were based on the morphologic scheme decisions and also from an ergonomic pen holding view. The chosen concept is based on the Wacom pen for the Intous Pro.

The cost estimation has only been done for an aluminium casing. It should have been done for carbon fiber as well, but that would have been an even more unreliable estimation. One thing that is certain is that it will be significantly more expensive than aluminium because of material price, the fabrication of a mould and it being a very time consuming process. The carbon fiber option also needs a solution for the heat transfer of the laser diode.
In the user test it became clear that this shape was less ergonomical when it is this big. So the shape has to be changed to something slimmer in the front.

For the user test there was also a quick design made for a charger station. This design was not very well thought through, and that resulted in it not being suitable for the PMU and tattoo industry. It has to be redesigned so it is easier to clean the charger, or there should be a separate open structured standard on which the specialist can put the injector in between treatments. It has to be open structured, so it can be easily cleaned with alcohol swipes after each treatment.

There are also points that the developer should continue doing research in, before trying to put the injector on the market. During the user test, the specialist indicated that she should be able to mix the ink herself, so it would be the perfect match with her client's skin. There has to be thought of a way to insert ink manually in the cartridge.

The cartridge was designed for this assignment, but without any knowledge on how this would look on the inside and other requirements for it to be able to work. The design of the cartridge is thus only an idea, and not definitive. It is important however, to keep the nozzle as small as possible, so the specialist can exactly see where she is going to inject.

It can be concluded that the design of the injector is not good enough as it is right now.

What also is good to investigate is what the CE requirements for the injector will be. It was not clear to what type of product the injector can categorised. It could be seen as a medical instrument of class IIb according to the quick scan on www.cetool.nl. This is quite a high risk class and so the injector has to be judged by a notified body which tests whether the injector meets guideline 9342EEG concerning medical instruments. This has to be done in order to bring the product on the market.

12.1 Resources

[1] Ravi AD, Sadhna D, Nagpaal D, Chawla L. Needle free injection technology: A complete insight. Int J Pharma Investig 2015;5:192-9

[2] http://www.spcp.org/wp-content/uploads/2012/07/SPCP_Vision_2015_Final.pdf

[3] Weniger B.G., Papania M.J., (2007) *Alternative vaccine delivery methods.* Section 3: Vaccines in development and new vaccine strategies

[4] http://www.cosmetictattoo.org/article/robot-tattooists.html

[5] Ungar E, Stroud K. (2010) *A New Approach to Defining Human Touch Temperature Standards*

[6] http://www.uocnet.com/pdf/LD/U-LD-650543A..pdf

[7] http://www.lasermate.com/driver.htm

[8] https://www.kvk.nl/zoeken/#!zoeken&q=Permanent%20make%20up&index=4&site=kvk2014&start=0

[9] Kals H.J.J., Buiting-Csikós Cs., van Luttervelt C.A., Moulijn K.A., Ponsen J.M., Streppel A.H. (2012). *Industriële productie, het voortbrengen van mechanische producten* (Hoofdstuk 15 pp. 397-411). Den Haag: Academic Service.

12.2 Figures

Figure 1 Biomicrofluidics 10, 014104 (2016); doi: 10.1063/1.4940038

Figure 4 http://www.azamedical.com/boutique/images_produits/aiguille_secbd2-z.jpg

Figure 5 screenshot https://www.youtube.com/watch?v=kxLoycj4pJY

Figure 6 screenshot https://www.youtube.com/watch?v=kxLoycj4pJY

Figure 7 Weniger B.G., Papania M.J., (2007) *Alternative vaccine delivery methods.* Section 3: Vaccines in development and new vaccine strategies

Figure 8 https://www.injectneedlefree.com/wp-content/uploads/biojector-300x165.png

Figure 9 https://images-eu.ssl-images-amazon.com/images/I/41r%2BWKaFvCL.jpg

Figure 10 http://www.cosmetictattoo.org/article/amiea-sense-why-people-are-so-excited.html

Figure 11 http://www.lovbeautyshop.com/blog/wp-content/uploads/2015/07/microblading-needle.png

Morfologic scheme:
Rotary button: https://webshop.drabbe.nl/WSData/WSItemAttachments/import_4635_726-2_1_40px_40px.jpg

Slider button: https://v1.std3.ru/d3/af/1429512801-d3af0ce92761d2519f2da03c4c3c03b4.png

Rotative component: http://pad3.whstatic.com/images/thumb/f/fc/Use-an-Insulin-Pen-Step-8.jpg/aid2388218-v4-728px-Use-an-Insulin-Pen-Step-8.jpg.webp

Separate buttons: http://l7.alamy.com/zooms/6de4d68290a347128badd7f3a38480db/iphone-4s-plus-and-minus-buttons-with-switch-in-off-position-cpbx70.jpg

Laser: http://laserpointerforums.com/attachments/f50/23534d1254540454-how-mod-pot-mod-5mw-red-laser-s4020548.jpg

Cross on screen: https://ae01.alicdn.com/kf/HTB19GIIIVXXXXbxXpXXq6xXFXXXO/Vector-Optics-2-5-10x56-Shooting-Rifle-Scope-30mm-Monotube-Glass-4A-Red-Cross-Reticle-High.jpg

Colour laser: https://upload.wikimedia.org/wikipedia/commons/0/02/Laser_pointers.jpg

Lighted button: http://eleshop.jp/PRODUCTS/CATALOG/PARTS_SW/PHOTO/las216fpgr.jpg

Batteries: http://www.voorbeginners.info/scheikunde/batterijen.jpg

Solar cells: https://www.museon.nl/sites/default/files/styles/detailpage_main_image/public/import//SILICIUMCELLEN.JPG?itok=NaQQTnH5

Flash light: https://ae01.alicdn.com/kf/HTB1L0j5NpXXXXXZXXXXq6xXFXXXX/NEW-Hand-font-b-Crank-b-font-Battery-Free-Flashlight-Camping-font-b-Lights-b-font.jpg