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Process Report

A medical device for cheaper and more accessible diabetes tests in developing countries

Synopsis
This Master's Thesis focuses on diabetes in developing countries. The project is based upon qualitative data collected during field studies at clinics and hospitals in Senegal and Gambia, West Africa, and the overall vision is to design a medical device for cheaper and more accessible diabetes tests and monitorings of blood glucose levels in developing countries. The product developed in the project incorporates a newly developed electro-chemical measuring method that ensures a significantly lower price for each test while not being dependent on expensive extra supplies that clinics in developing countries do not have access to.

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PREFACE
AND ACKNOWLEDGMENTS

Acknowledgments
This Master's Thesis is written by two persons, but a number of other persons have been involved in the genesis of the project. In different ways they have contributed with help, advice, sparring or supervision, and we would like to thank them for their contributions to the project.

Thank you to Dr. Jan Lankelma from VU University, Amsterdam, for sparring and helping us understanding the elctrochemical system.

Thank you to Roland Schindler from Diabetes-Projekt the Gambia e.V., Germany, for help with contacts to clinics and hospitals in Gambia, and thank you to Dr. Alieu Gaya from Pakala Clinic in Banjul, Gambia, for letting us visit his clinic. Additionally we would like to thank Mette Lotus who is living in Abéné, Senegal, for helping out with visiting the local health clinics.

General information
The project consists of a process report and a product report, the process report is aimed at our supervisors and examiner for assessment of the process behind our product proposal, while the product report functions as a presentation for companies as well as for our supervisors and examiner.

Text about our process and planning as well as theoretical framework can be found in Appendix.

We have chosen to refer to ourself, the project team, as "we" throughout the report and not in a passive form as this project and the process behind has been characterised by active choices and a willingness to work with the exact problem area and research methods that we have always wanted to do.

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INTRO

WHAT IS THIS PROJECT ABOUT?

Designing the missing link
In our Master's Thesis we have chosen to work within the field of diabetes in developing countries focusing on sub-Saharan Africa. If treated correctly, people can live a good life with diabetes without complications. However, 81% of people with diabetes in sub-Saharan Africa are not diagnosed yet (IDF atlas), and many die from diabetes-related complications without ever being tested for diabetes and diagnosed. We have chosen to focus on this missing link.

Through field studies conducted at clinics and hospitals in Senegal and Gambia, West Africa, we have identified that disposable test strips for blood glucose meters are too expensive and too difficult to get for both small health clinics and regional hospitals, causing that testing for diabetes and regular monitorings of blood glucose levels are too expensive. This problem results in a limited access to important measurements that can prevent severe complications and deaths.
We are approaching the problem by developing a new device for measuring glucose levels without the need of disposable test strips by using a new and cheaper electrochemical measuring method that is not used in any product yet. The goal is to design a solution that can contribute to make testing of diabetes and regular monitorings of blood glucose levels more accessible and thereby prevent needless complications and deaths.

Diabetes in sub-Saharan Africa
Diabetes is a rising problem in the developing world where four out of five people with diabetes live, and sub-Saharan Africa has the highest mortality rate due to diabetes. (diabetes atlas) Until now, poverty and communicable (infectious) diseases like HIV/AIDS and malaria have dominated the way we look upon the health situation in this part Africa, but due to rapid urbanism and adaptation of Western eating habits and sedentary lifestyles, non-communicable diseases (diseases that cannot be transferred) like diabetes are advancing quickly, and diabetes is now the cause of 6.1% of all deaths in this region. (diabetes atlas) With predictions showing that the number of people with diabetes in sub-Saharan Africa will almost double during the next 20 years counting 23.9 million by 2030 (diabetes atlas), diabetes is a time bomb under Africa's health system. Thereby, it is a field where action is needed - now.

Field studies
Most accessible research and publications about diabetes (and health care in general) in developing countries are based on quantitative rather than qualitative studies. When focusing on design with a user-centered approach, however, qualitative research is essential. The essence of user-centered design is to work on identifying and analysing the end user's needs and problems and actively use this obtained knowledge in the process of developing and designing appropriate and relevant solutions responding to the user's needs (Liem and Sanders, 2011). Instead of basing the project on estimates and quantitative data we decided to base it on 'microdata' and qualitative studies conducted through field studies in order to really understand the end users and their needs, as well as the different factors influencing the context and the problems we are approaching.
Another important reason for choosing to base the project on qualitative data and field studies is that one of the biggest 'traps' when designing medical devices is usability. According to U.S. Food and Drug Administration (FDA), 44% of medical devices are recalled because of design problems that are resulting in use errors. We are using the field studies to actively address this risk factor.

We visited different clinics and hospitals in Senegal and Gambia, where we made observations and talked to patients and staff about diabetes


We saw that testing for diabetes and monitoring of blood glucose levels is too expensive, resulting in a limited access to important measurements that can prevent severe complications and deaths

FIELD STUDIES IN AFRICA

In this section, the different contexts in which we have conducted field studies will be presented along with an introduction to what we have done and how we have done it.

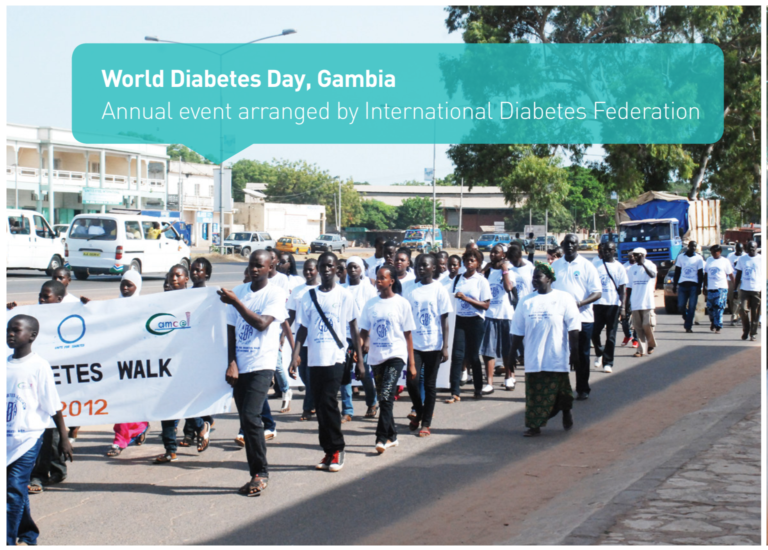
Quickly we found out that deciding to conduct field studies is one thing, while finding the right contacts is quite another. We started with contacting some of the bigger charity organisations regarding the possibilities of conducting field studies in their environments with already established contacts, but due to very strict policies regarding economics and legal responsibilities, none of these requests were successful.
Due to more outreaching work, however, we succeeded in establishing contact to two different partners interested in cooperating with us; a German diabetes project in Gambia, 'Diabetes-Projekt The Gambia e.V.', and a Danish woman who lives in a village in Senegal and is involved in local health clinics in rural areas of the southern part of Senegal. Gambia and Senegal are neighboring countries situated in West Africa, and both countries can be characterized as relatively politically stable which was an important factor for us.

We decided to allot five weeks for the field studies (5th of November - 12th of December 2012) to make time for both the planned schedule and improvised activities dependent on the situation we met in Africa. The different contexts and the timeframe create a big potential for experiencing the impact and challenges of diabetes in Senegal and Gambia within very different contexts regarding education of staff and patients, economics and availability of equipment and medication, which serve as a solid foundation for the project's field studies.

Pakala Clinic, Banjul, Gambia
Pakala Clinic is a private clinic situated in Gambia's capital, Banjul. The clinic is run by Dr. Alieu Gaye who is one of the country's most prominent specialists within diabetes and has for several years been cooperating with the German charity project 'Diabetes-Projekt The Gambia e.V.', which is sponsoring 60 young type 1 diabetics. Our contact person is Roland Schindler who is the president of the diabetes project from Germany, and he travelled to Gambia at the same time as we on one of his two annual trips providing the clinic with insulin and diabetes-related equipment and conducting consultations with the diabetes patients in the sponsored program.


Pakala Clinic
Private diabetes clinic in Banjul, Gambia


Royal Victoria Teaching Hospital
Public referral hospital in Banjul, Gambia


World Diabetes Day, Gambia
Annual event arranged by International Diabetes Federation

Local health clinics
Local clinics in four rural villages in Senegal: Abéné, Kabadio, Boune and Kafountine

At the clinic, we followed and participated in consultations, saw the clinic's facilities including laboratory and pharmacy and interviewed patients, doctors and health staff.

Use of methods: Observations, situated and qualitative interviews, acting out

Royal Victoria Teaching Hospital, Banjul, Gambia
Royal Victoria Teaching Hospital in Banjul is Gambia's leading referral hospital, and contact to the hospital is established through Dr. Alieu Gaye from Pakala Clinic. The hospital has diabetes consultations once a week with 150-300 patients. At the hospital, we talked to a consultant doctor, followed two doctors during diabetes consultations and saw the hospital's facilities.

Use of methods: Observations, situated interviews with doctors, acting out

World Diabetes Day, Gambia
The International World Diabetes Day is held on the 14th of November each year with the purpose of creating awareness about diabetes. World Diabetes Day 2012 in Gambia had - among other activities - speeches from the country's Minister of Health and Social Welfare and the country's representative from WHO on the program. We participated in a parade, "Walk Against Diabetes", where we talked to diabetics and people involved with diabetes.

Use of methods: Observations, situated interviews

Local health clinics, Casamance, Senegal
Casamance is a region in the southern part of Senegal, and with 100 km to a small hospital in the region and 400-500 km to the capital Dakar it is both difficult and very expensive for the local population to consult health staff educated within diabetes. During the stay in Casamance our Danish contact person, Mette Lotus, who has been living in the area for twenty years and has contacts within local health initiatives, helped establishing contacts to four smaller health clinics situated in the rural villages Abéné, Kabadiou, Kafountine and Boune. At the clinics, we talked to patients and health staff and saw the clinics' facilities including laboratories and pharmacies.

Use of methods: Observations, situated and qualitative interviews with doctors and patients, acting out.

Home visits, Gambia
With help from Roland Schindler we had the opportunity of visiting some of the type 1 diabetics sponsored by Diabetes-Projekt the Gambia e.V. in their homes. The home visits gave us the opportunity of experiencing the problems and challenges the diabetic and his/her family must deal with on a daily basis and provided us with a broader perspective on the individual person living with diabetes.

Use of methods: Observations, situated interviews with diabetics and their relatives, acting out

Workshop with diabetes patients, Gambia
With contacts established to a number of diabetes patients at Pakala Clinic we invited some of the patients to participate in a creative workshop as a method to getting a deeper understanding of the diabetics' daily life and their thoughts and reflections about living with diabetes. Besides talking about diabetes the diabetics were challenged with a creative task of designing tomorrow's blood glucose meter based on their own needs and experiences.

Use of methods: Situated interviews, co-design game

Home visits
Visiting sponsored type 1 diabetics from Pakala Clinic and their families in their homes

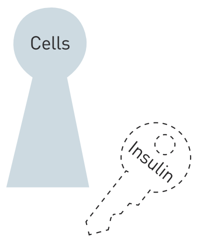
Workshop
Creative workshop with young type 1 diabetics

RESEARCH & ANALYSIS

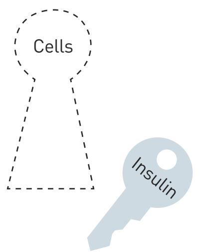
WHAT IS DIABETES?

Two types of diabetes
Diabetes is a physical condition caused by too much glucose in the blood. There are two types of diabetes; in type 1 the pancreas is not producing enough insulin, and in type 2 the body is unable to effectively use the produced insulin. [IDF.org] The physiological differences between the two types of diabetes can be illustrated in this way [diabetes.org.uk]:

Type 1: There is no key (insulin) to unlock the "door" to the cells



Type 2: The key (insulin) is unable to unlock the "door" to the cells properly and/or the key (insulin) is there but the lock does not work properly



Insulin
Insulin is a hormone produced by the pancreas. The insulin allows the glucose that we ingest through food and drink to go from the blood and further into the body's cells, so it can be used as 'fuel' for energy making the body function optimally, and in the long term insulin is vital for the body.

Risk factors
Type 1 diabetes is partly caused by genetic factors, but the cause of the disease is not entirely understood yet. It can occur in all age groups, but primarily children and young people are diagnosed with type 1 diabetes. If people with type 1 diabetes are not treated with insulin, they will not survive. [idf.org]

Type 2 diabetes is primarily caused by factors related to lifestyle, and some of the main risk factors are obesity ,diet and physical inactivity. About 90% of all diabetics are type 2s. Some ethnicities develop type 2 diabetes at a lower BMI than other ethnic groups, and changes in lifestyle, diet and level of physical activity due to rapid urbanisation are increasing the number of people developing diabetes. [idf.org]

Diet
For diabetics, a rule of thumb is to avoid foods containing lots of sugar, carbohydrates and saturated fats as well as limiting consumption of alcohol. Avoiding this kind of products helps stabilising and keeping down the blood glucose level. [idf.org]

Treatment
It is not possible to cure diabetes, and after being diagnosed with type 1 diabetes lifelong medical treatment with insulin is necessary. Depending on the severity of the diabetes it is necessary to inject insulin between two and six times every day as well as measuring the blood glucose levels.
Some type 2 diabetics are treated with tablets (for instance Metformin), some with insulin, and some can keep their diabetes down with correct diet and physical activity. [idf.org]

Measurement of blood glucose levels
It is important to monitor and measure the levels of glucose in the blood regularly, and two overall products are used for this:

Blood glucose meter: Measurement showing the current concentration of glucose in the blood. Both used by the patient in the daily monitoring (especially type 1 diabetics) and by clinics/hospitals. Unit: mmol/l. The meter uses disposable test strips to measure the blood glucose levels.

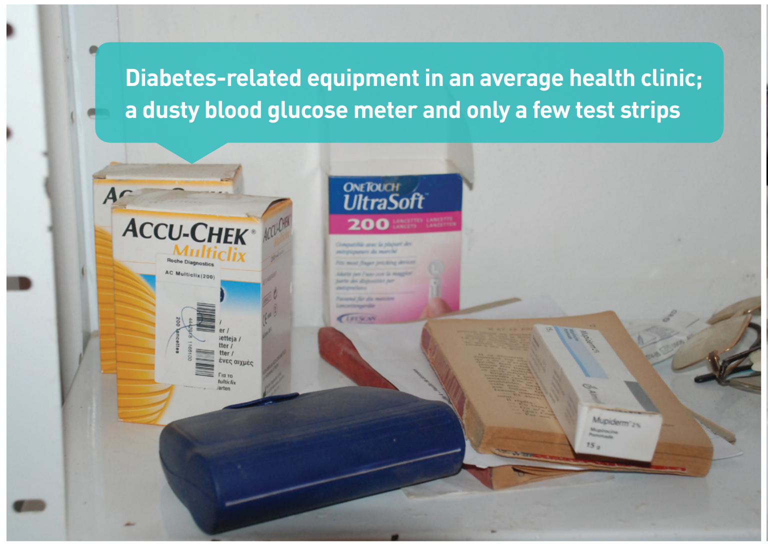
HbA1c test: Measurement based on a small blood sample showing the average blood glucose level over the last 8-12 weeks. Only for use at clinics/hospitals. Unit: mmol/mol.

Complications
No treatment or non-compliance in the treatment of diabetes can lead to serious complications. Some of the complications are:

- Reduced vision/blindness
- Kidney failure
- Nerve diseases (can lead to ulceration and amputation of toes, feet and lower limbs)
- Cardiovascular diseases
- Gingivitis and periodontal diseases
- Gastro paresis (delayed gastric emptying)
- Sexual problems (both men and women)

[International Diabetes Federation - Complications of Diabetes]

A typical lab environment with patients sitting next to machines, blood samples, chemicals etc.



Diabetes-related equipment in an average health clinic; a dusty blood glucose meter and only a few test strips

Products and surfaces are often covered in dust and dirt

One of the many donations that are not being used: An ambulance collecting dust behind the laundry

A well-equipped local pharmacy with the most basic medication and medical supplies

UNDERSTANDING THE CONTEXT

A typical public health clinic in Senegal and Gambia

During the field studies in Senegal and Gambia, the project team visited a public hospital, various public clinics and a private clinic. Even though the size and economy of a public hospital and a small health clinic in a rural village cannot be compared, many of the observed problems and characteristics are the same, and in this section the impressions from the field studies conducted in these contexts will be used to describe the average public health clinic. The purpose is to map the main characteristics of a typical public health clinic in West Africa in order to get an overall understanding of the context and its characteristics and derive a list of requirements for a product in this context.

A private clinic is only accessible for a very limited number of the population, and the problems observed here are not representative for the general situation due to clinic's and patients' economy. Therefore, the project team decides to focus on the public sector.

Facilities

The typical clinic is built and financed by the government and situated in a village. Well-reputed clinics treat patients from the village and neighbouring villages, while clinics with damaged credibility only treat patients from the local community who cannot afford to travel to one of the well-reputed clinics.

Most clinics have a single consultation room, a laboratory and a "pharmacy" containing a small selection of medical equipment. In all clinics, economy is a big issue and products and supplies need to be as cheap as possible if they should have a chance ending up here. Bigger clinics have a few beds for hospitalised patients. Additionally, the most well-equipped clinics have a broad selection of medication and supplies, while the smallest clinics only have access to the most basic equipment and find it difficult to get new supplies. The local clinics cannot treat diabetic patients with insulin, but they can test for diabetes, advise and conduct regular monitorings of the blood glucose levels.

Products and machines

The average clinic has basic machines for clinical use in the laboratories, e.g. microscopes. Machines that need expensive extra supplies in the daily use or that are too expensive or difficult to repair are not being used when they run out of supplies or break. It is not unusual to see products and machines suffering this fate ending up in a corner collecting dust.

When looking at diabetes-related products, all the visited clinics have a single blood glucose meter for testing and monitoring blood glucose levels. However, the clinics rarely use the machines (and only in extreme cases); they are afraid of running out of test strips because they are both expensive and difficult to get. The price for a blood glucose test is 2-2.5 $ plus the consultation fee, which is expensive for most patients. At the same time, the clinics cannot have a lot of test strips in stock because they have an expiration date, and after exceeding this date the test strips will not function.

HbA1c machines are not used at the public clinics because the machine itself and single tests are very expensive, and only the private clinic has an HbA1c machine. Actually they have two machines, but they have to use the oldest one because running tests on the new machine is too expensive. The patients have to pay 18 $ for an HbA1c test. The public hospital we visited used to have a machine, but after it broke it was too expensive to repair, and therefore it is not used anymore.

Physical environment in the lab

The physical environment is characterised by a very messy and crowded appearance where several patients and relatives often are present in the laboratories and consultation rooms at the same time. Everything (products, machines, paper, boxes with supplies, blood samples, tools, instruments, chemicals etc.) are placed on tables and open shelves, and there is no space for storing products and equipment that are not currently being used. At the same time, waste is not always handled correctly, and it is not unusual that trash is thrown on the floor or left on a table. Besides being inadequate, the

open shelves and crowded tables also make cleaning and tidying difficult. The laboratories and consultation rooms do not appear clean and sterile, and it is not unusual that surfaces are covered in dust and dashes of blood or fluids. Most surfaces do not appear with their intended colours because of dirt etc., and because the products and machines are not designed for these external conditions the clinics have to make their own protection solutions from fabric, plastic bags etc.
The use of colours and decorations in the laboratories and consultation rooms are also different from what a white, sterile clinical environment looks like in Western countries; in Senegal and Gambia there are many colourful fabrics, wooden surfaces with ornamentations and patterned floors in colourful combinations.

Communication
Both patients and staff are instructed and educated through simple, comic style posters about everything from prevention of malaria and AIDS to the use of a microscope in the laboratory. The communication is very visual containing simple symbols showing what is right and what is wrong and only very little text.

Staff
The average health clinic has around five employees; two people taking care of patient care and consultations, two in the laboratory and one handling medication and prescriptions in the "pharmacy". In best case, the staff is educated and sent by the government. There are no doctors at the local clinics, but nurses, midwives and "medical laboratory assistants". In worst case, the employees have no education and are only trained by their predecessor. The uneducated employees often make mistakes due to their lack of training and theoretical knowledge. However, all employees met during the field studies can both read and write and seem to take pride in doing their job as well as possible. Areas of responsibility and knowledge are often divided between the employees of the clinic, and typically only one of the employees handles diabetic patients.

Requirements
When having experienced a local health clinic and its physical environment it is clear that products need extra attention in a number of areas in order to be appropriate and succeed in this context. Based on the observations a list of requirements is created. The list will be used as guiding principles further on in the process in the ideation and development phases in order to ensure that the final product solution relates to the specific context and its conditions.

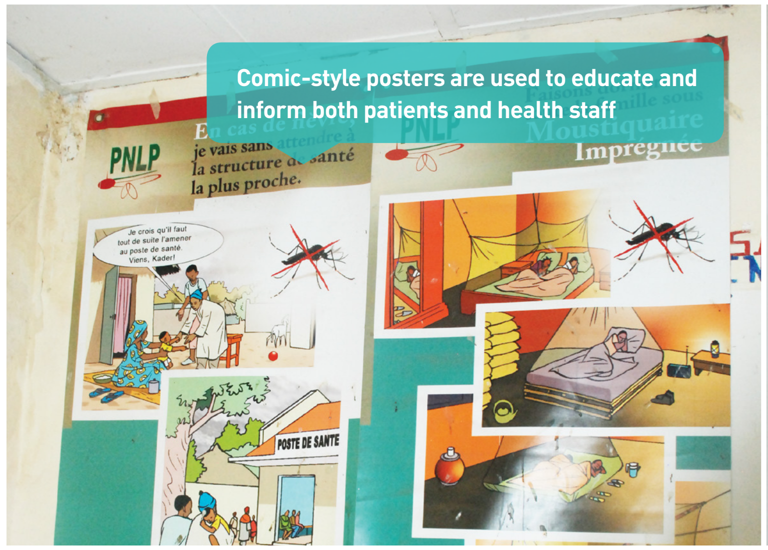
Requirements

→ The product and its vital parts should be protected against dust and dirt
→ The product should not depend on extra supplies that are expensive and/or difficult to get
→ The product should be as cheap as possible
→ The components of the product should, as far possible, be easy and cheap to repair or replace
→ The product should not contribute to creating more mess in the physical environment
→ The product should be adapted to a humid and warm climate
→ The product should be easy to clean
→ The product should be easy to operate for both educated and uneducated staff
→ Instruction material should be as simple and visual as possible


A typical, colourful lab environment. Homemade solutions made from fabric are used to protect the lab's machines from dust and dirt


Tables and surfaces are filled with paper and supplies for products and machines


A typical consultation room. Also here the tables and surfaces are covered in paper and mess


Comic-style posters are used to educate and inform both patients and health staff


Extra supplies are not always available; in this clinic the medicine cabinet is almost empty

DIABETES-RELATED PROBLEMS

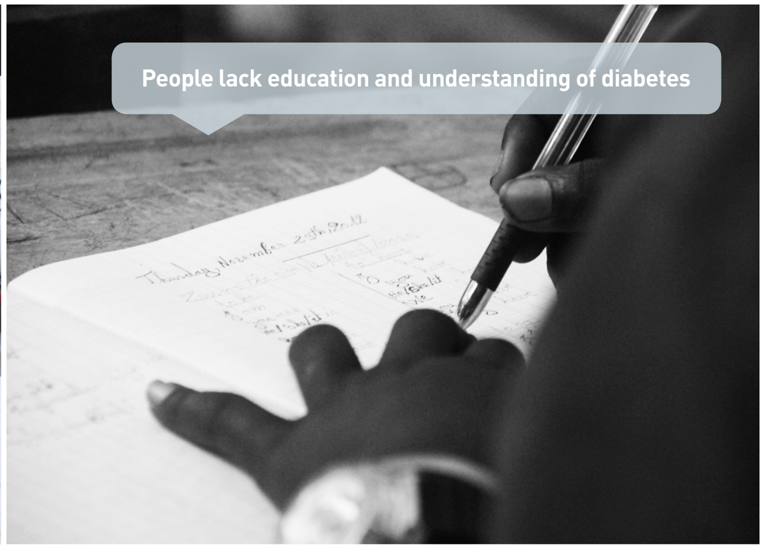
During the field studies we saw that diabetes causes many problems within very different areas in the visited contexts. This section gives an overview of the main problems we observed, and the purpose is to narrow down in order to start focusing on a specific problem area.

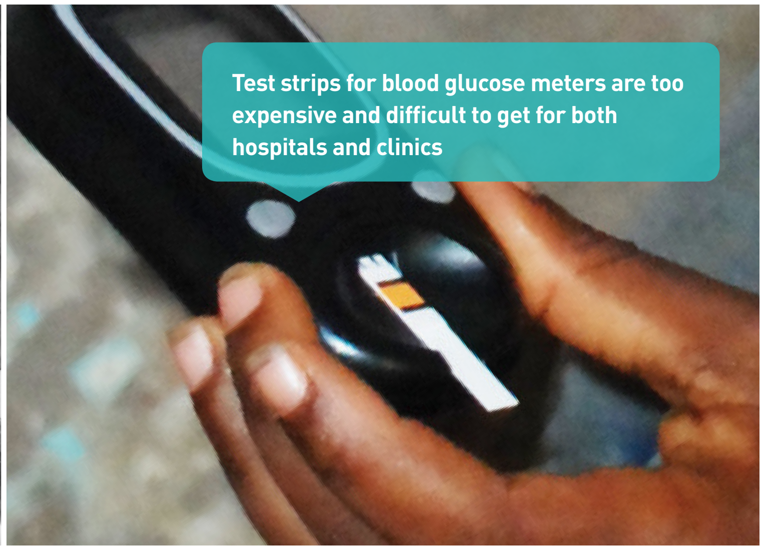
The eight main problems are visualised through the images below. Common to the problems is that they are very extensive and dependent on economy. Some of the problems are more oriented towards system- and service design than product design, e.g. the ones about education, diet and non-compliance. We chose to delimit the project from focusing on these problems because there is already well executed education material focusing on these areas, e.g. at the private diabetes clinic we visited - it is just not widespread among the general population. At the same time, our own primary interest and the learning goals defined in the study guide point towards a product design project.

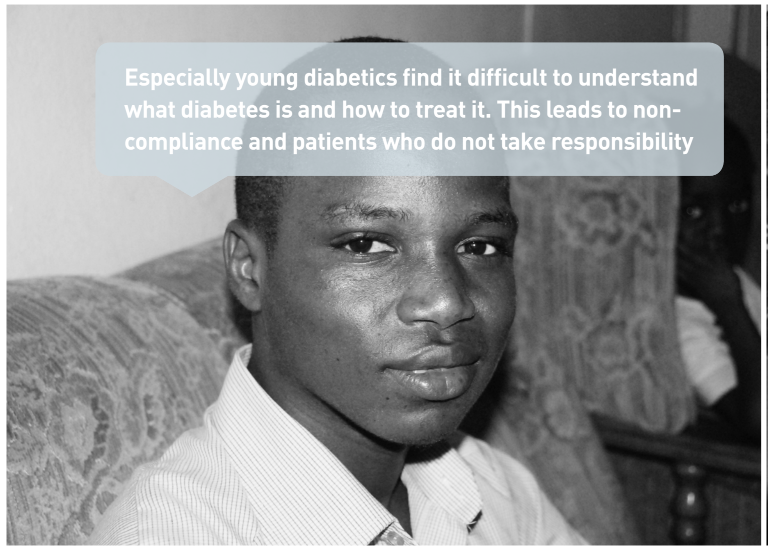
The problems about dispose of medical waste and storage of insulin at the right temperature are very interesting and relevant problem areas; however, there are already solutions on the market focusing on these specific problems. Again, the main problem is that the existing solutions are not widespread in the contexts we visited.

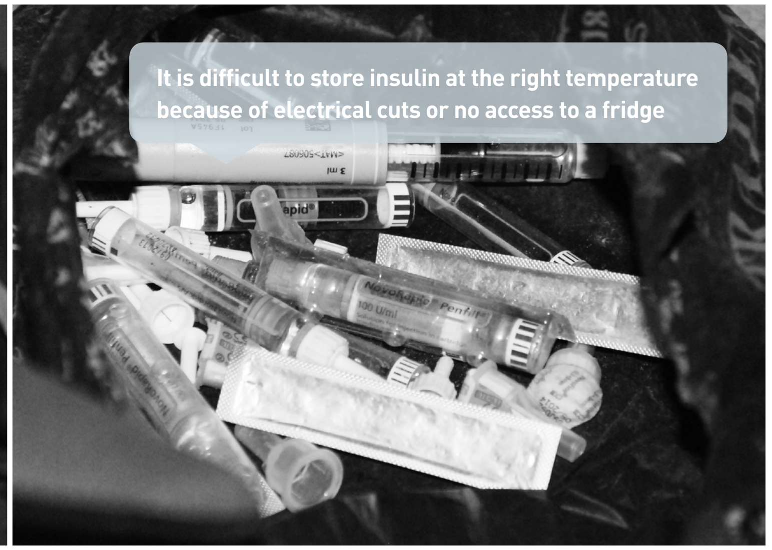
In both Senegal and Gambia we saw that disposable test strips for blood glucose meters are too expensive and too difficult to get for both small health clinics and regional hospitals, causing that testing for diabetes and regular monitorings of blood glucose levels are too expensive. Indirectly, this problem results in a limited access to important measurements that can prevent severe complications and deaths. Both the price for a single test and the lack of distribution of the test are some of the main reasons why people are not tested for diabetes before they have severe complications, or die before they are tested.

Based on this we see a big potential in working within the area of blood glucose measurements. We want to focus on this area with the main motivation being to increase the accessibility of blood glucose measurements.









UNFOLDING THE PROBLEM

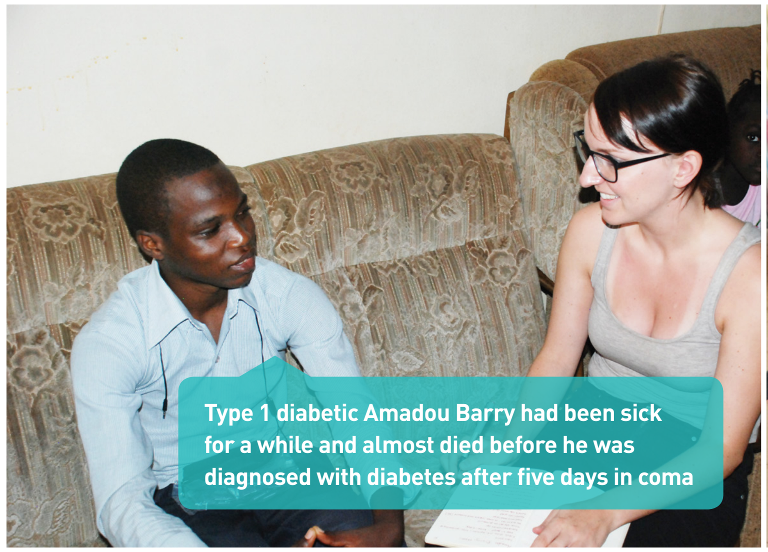
The importance of regular monitorings and early detection of diabetes - from a qualitative perspective

During our stay in Senegal and Gambia we talked to a number of diabetics and their relatives, and it was clear that limited access to diabetes tests has caused serious problems for many of them. Some have lost parents and other relatives who died from diabetes because they had developed fatal complications before they were diagnosed, and some were very close to dying themselves before they were referred to a bigger hospital and - in the end - tested for diabetes. Others struggle with critical complications such as blindness and leg amputations as a result of too late diagnosis or inadequate monitoring of blood glucose levels and management of the diabetes. Common to all of them is that losing a family member or having a very ill or disabled person in the family puts a lot of extra economic pressure on the remaining family members or - in the worst case - destroys an entire family's livelihood. Thereby, early detection and regular monitorings of diabetes are a matter influencing not only the individual diabetic but the future of entire families.

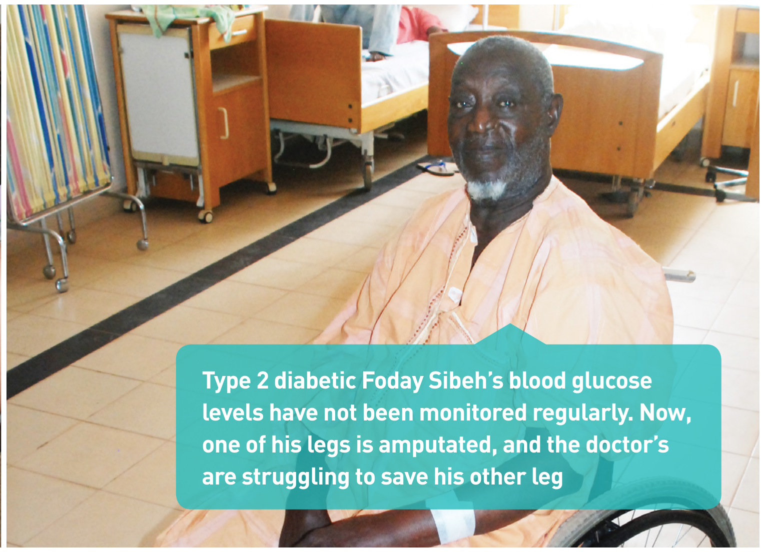
Elaborating the problem

When talking about blood glucose measurements we are focusing on measurements of the current blood glucose levels in the context of a clinic using a regular blood glucose meter. This is the only kind of measurement that is available in the visited contexts except from the private clinic with sponsored diabetics. In developed countries that do not have limited resources, all diabetics have access to their own blood glucose meter for daily measurements at home (sometimes 4-6 times a day), testing for diabetes is an integrated part of health care, and clinics and hospitals can measure the diabetic's HbA1c helping the doctor and patient to see how the blood glucose levels are managed over a period of time. In Senegal and Gambia, that is not the case. Even a single test at a clinic is too expensive for many people; some patients have to travel very far to get to a clinic, and because travelling and the consultation itself is very expensive for the general population many people cannot afford to pay for additional tests (e.g. for diabetes). Both the price for a single test and the lack of distribution of the test are some of the main reasons why people are not tested for diabetes before they have severe complications, or die before they are tested.

Also monthly routine checks (which is the way diabetes is managed in the visited context) are too expensive for many locals, resulting in lack of control of their diabetes, non-compliance in managing the disease and complications. In Senegal and Gambia, the price for testing the current concentration of glucose in the blood with a blood glucose meter is 2-2.5 $ plus the consultation fee.



Type 1 diabetic Amadou Barry had been sick for a while and almost died before he was diagnosed with diabetes after five days in coma



Type 2 diabetic Foday Sibeh's blood glucose levels have not been monitored regularly. Now, one of his legs is amputated, and the doctor's are struggling to save his other leg

For clinics and hospitals, it is both difficult and expensive to get disposable test strips for the blood glucose meters. The test strips are very expensive themselves, and for clinics in rural areas it takes several days to travel to the nearest supplier, which is both time-consuming and expensive for the clinic. Half of the visited clinics had no test strips left and were unable to test any patients for diabetes, and the others only had a few in stock. Additionally, the test strips have an expiration date, and if the strips are not used before reaching this date they will not function anymore causing that the clinics only want to buy a small amount of test strips to have in stock.

Focus area

Based on the observed problems we want to focus on reducing the price of each blood glucose test and removing the dependency on expensive extra supplies in order to make blood glucose measurements cheaper and more accessible.

At the same time, we want to delimit the project from focusing on the development of a new HbA1c machine. A cheaper HbA1c test seems like the ideal solution as it does not require the patient to be fasting before taking the test. However, the current price level for an HbA1c machine is 1800-2700 $, and the price for a single HbA1c test at the private clinic in Gambia is 18 $. We do not think it is realistic (in this project) to reduce the price for an HbA1c machine enough to make it relevant in this context where tests need to be as cheap as possible in order to make testing and monitoring of diabetes more accessible.

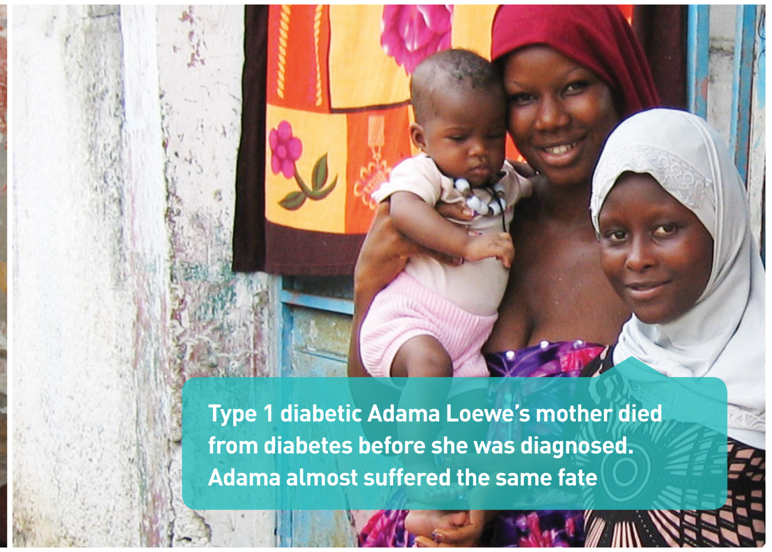
Requirements

These observations set the ground for some more requirements related to the development of a new machine for measuring blood glucose levels. The requirements are:

Requirements

- → The product should not use expensive disposable test strips
- → The product contributes to making diabetes tests and monitoring of blood glucose levels more accessible and widespread
- → The price of a single test should be lower than 2 $

Type 1 diabetic Sira Jallow is only able to have her own blood glucose meter because she is sponsored by a German diabetes project



Type 1 diabetic Adama Loewe's mother died from diabetes before she was diagnosed. Adama almost suffered the same fate

PROBLEM STATEMENT

How to design a new medical device for measuring blood glucose levels to use for making diagnosis and monitoring of diabetes cheaper and more accessible while meeting the specific needs of health clinics in Senegal and Gambia?

WHAT IS ON THE MARKET?

A simple market analysis is conducted in order to study which products used for measuring blood glucose levels are already on the market. The purpose is to find out if any of the existing technologies and measuring methods are suitable to use in the development of a new product; primarily in order to see if there are any measuring methods and products on the market not using disposable test strips.

Blood glucose meter

- + Quick results
- + Small
- + Cheap product price

- ÷ **Uses disposable test strips**
- ÷ Disposable needles for finger pricker

Lab. b.g. meter

- + Many tests per hour
- + Can measure HbA1c

- ÷ **Uses disposable test strips**
- ÷ Very expensive
- ÷ Disposable needles for finger pricker

iPhone b.g. add-on

- + Simple product
- + Electronics is "out-sourced" to the iPhone

- ÷ **Uses disposable test strips**
- ÷ Requires an iPhone
- ÷ More expensive than regular blood glucose meter
- ÷ Disposable needles for finger pricker

Urine strips

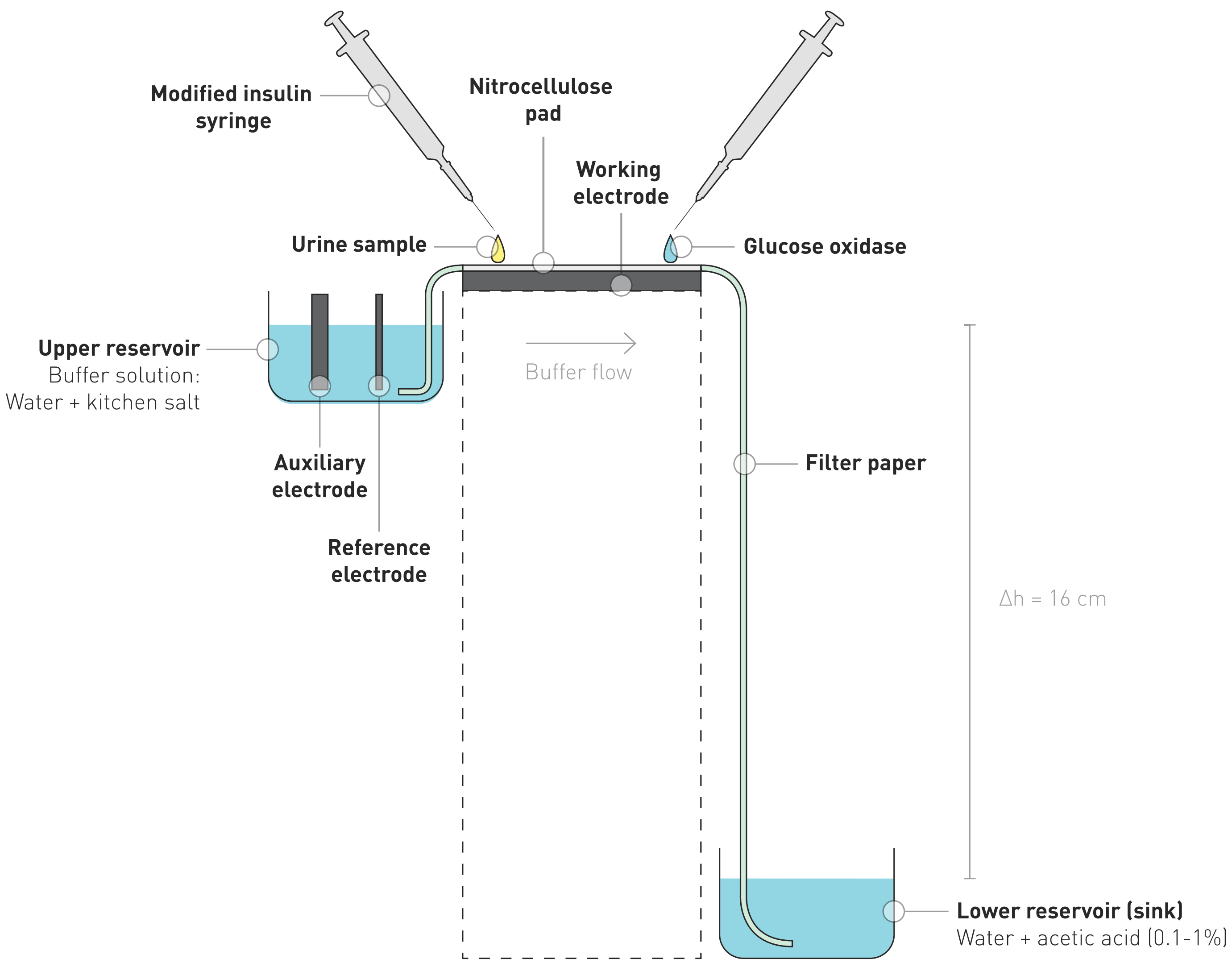
- + Non-invasive (no break in the skin)
- + Cheap
- + Requires no electronics

- ÷ **Uses disposable test strips**
- ÷ Not precise enough (results are interpreted from colour codes and no numbers)

Common to all the products that are already on the market is that they rely on test strips, which - as previously mentioned - is one of the biggest problems when looking at measurements of blood glucose levels in the visited contexts in Senegal and Gambia. If a new product should be able to contribute to making testing and monitoring of diabetes more accessible we see the test strips as a very critical point, and we do not think it is appropriate to build the development of a new product on a measuring method that requires an infrastructure and economy that does not exist in the context we are designing for. Therefore, we choose to look for other measuring methods to use in order to find a cheaper alternative that does not require disposable test strips.

A CHEAPER MEASURING METHOD

In the search for a cheap measuring method that does not require disposable test strips we found a newly developed electrochemical method that has been published in Analytical Chemistry. The "paper-based analytical device for electrochemical flow-injection analysis of glucose in urine" is developed by scientists from VU University Amsterdam, Harvard University, University of Maryland and Universidade de São Paulo, and in the publication it is stated that the system is suitable for resource limited contexts due to its low cost. The purpose of this section is to get a deeper understanding of the electrochemical system in order to develop a list of advantages and disadvantages to use in the process of determining whether this measuring method is the right one to use in the development of a new product for measuring blood glucose levels. Unless otherwise indicated, all information about the system is from the publication (Lankelma, 2012).



How does it work?

The electrochemical system is based on filter paper facilitating a gravity-driven flow of a buffer solution (tap water and kitchen salt) from an upper reservoir to a lower reservoir (sink). The system is built from two reservoirs, a nitrocellulose pad, two filter paper strips and three electrodes (see illustration). The nitrocellulose pad is placed on one of the electrodes and connected to both the upper and the lower reservoir using filter paper strips. The filter paper strips automatically stick to the nitrocellulose when wettened, and the physical dimensions of the system are designed to optimise a constant flow rate.

A sample of 0.3 µl of urine is injected onto the nitrocellulose pad near the upper reservoir using a modified insulin syringe. Driven by gravity and capillary wicking the urine sample moves along the paper along with the buffer solution towards the lower reservoir. Immediately after the urine sample is applied to the nitrocellulose, an oxidation of unidentified components of the sample occurs and generates an oxidation current that decays within a few minutes. When the glucose in the urine sample is in contact with the immobilized glucose oxidase, it is oxidized to gluconic acid in a reaction generating hydrogen peroxide. This creates a glucose-specific current (emission of electrons) that, subsequently, is detected as an oxidation of the working electrode. An amplifier reads the current from the working electrode, and the data can be logged using a hand-held multimeter or data logging software on a computer.

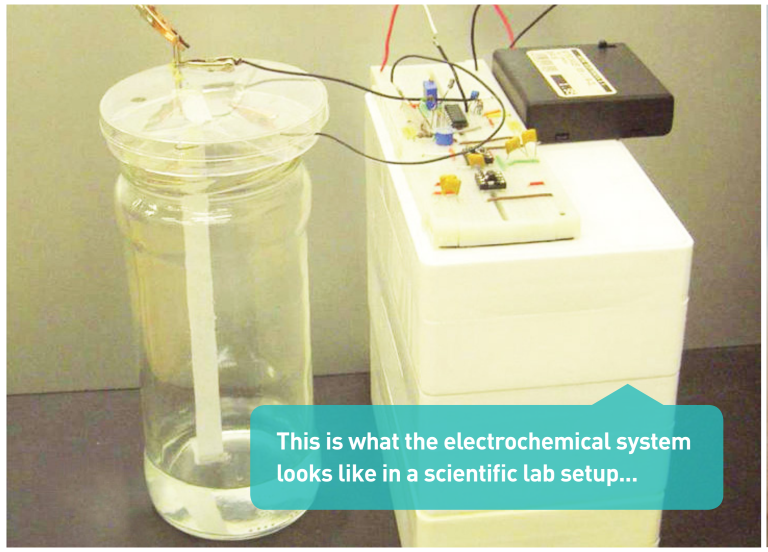
The constant buffer flow cleanses the working electrode and nitrocellulose between each test, and a new test can be introduced after 15 minutes. In order to maintain the constant flow, it is important that the system does not dry out. When set up, the system can be used for 100-200 tests during 10 days. After this, the system has to be reconfigured.

Configuration of the system

1. Fill upper reservoir with buffer solution (tap water and kitchen salt)
2. Fill lower reservoir with fluid (tap water and acetic acid)
3. Wetten nitrocellulose pad in buffer solution and place it on the working electrode
4. Wetten two filter paper strips in buffer solution and connect the nitrocellulose to both reservoirs
5. Apply glucose oxidase to the nitrocellulose (near the lower reservoir)

Physical dimensions of the system

The dimensions of the nitrocellulose pad (8 x 30 mm) and the height difference between the surface of the fluids in the upper and lower reservoirs (160 mm) is designed to optimise the constant flow rate driving the system. The



This is what the electrochemical system looks like in a scientific lab setup...

... and this is what a "quick and dirty" test of filter paper and fluids looks like in our group room distance between the spot where the urine sample is injected onto (on the nitrocellulose pad) and the spot where the glucose oxidase is applied is 20 mm. The two factors deciding the system's geometry are to reduce the time of a single test without forcing the electrochemical reaction and increase the risk of errors if the urine and glucose oxidase are placed too close to each other. The flow rate is approximately 2 μl/min.

Buffer solution in upper reservoir
In chemistry, a buffer solution is a mixture of an acid and its corresponding (matching) base. The purpose of a buffer solution is to reduce changes in pH caused by adding an acid or a base. The buffer solution used in this system is a mixture of tap water and kitchen salt in the ratio of 50 ml tap water and 0.5 tea spoon of kitchen salt.

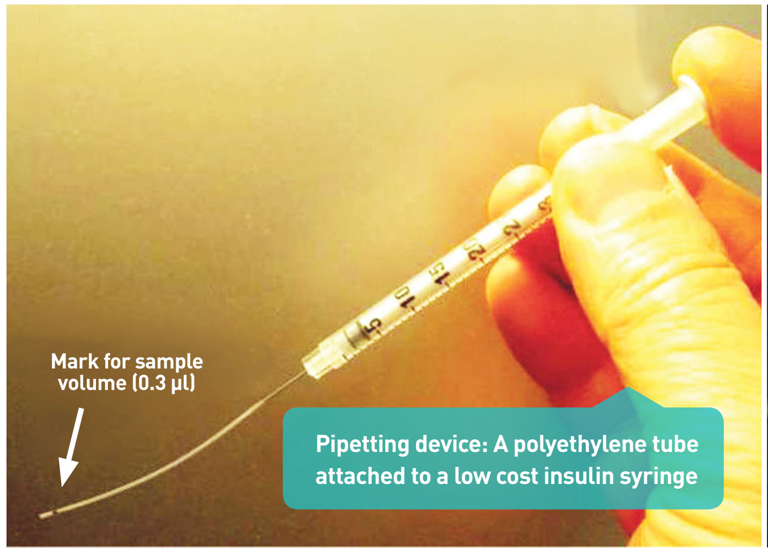
Fluid in lower reservoir (sink)
The fluid added in the lower reservoir consists of tap water with a little bit of acetic acid (final concentration: 0.1-1%) in order to inhibit microbial growth as the urine samples end up in the lower reservoir.

Nitrocellulose pad
The purpose of the nitrocellulose pad is to immobilise/bind the glucose oxidase and define a certain flow rate of the system. The dimensions of the nitrocellulose pad is 8 mm x 30 mm and it has a thickness of 140 μm.

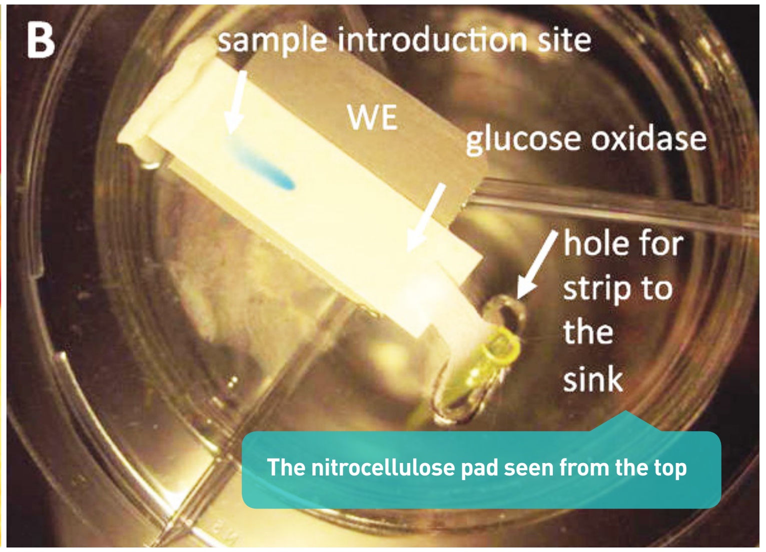
Filter paper strips
The filter paper strips (8 mm wide) used in the lab setups are made from polyester-cellulose blend paper. The filter paper facilitates capillary wicking (drawing up of liquids in a porous material) which transports the fluids through the paper.

Electrodes
The system is based on amperometry which - in chemistry - is a measuring method where a fixed potential is used to measure the current's dependency of a given quantity by analysing changes in the electric current.
The system consists of three electrodes; a working electrode, a reference electrode and an auxiliary/counter electrode.
The working electrode consists of a thin layer of platinum sputtered on a solid surface (e.g. glassy carbon or glass). The working electrode is operating at a fixed potential, and the electrochemical reaction (the oxidation of glucose in urine) that is analysed in this system occurs on the working electrode.
The reference electrode and counter electrode are distinct from each other which defines a potential that other potentials can be measured against. The counter electrode is made from stainless steel and the reference electrode from a fine silver wire.

Glucose oxidase
An oxidase is an enzyme used to catalyse oxidation of a substance, and in this system glucose oxidase is added to catalyse oxidation of glucose in urine. Glucose oxidase is a relatively cheap enzyme. A volume of 0.9 μl is applied to the nitrocellulose pad, and the nitrocellulose immobilises/binds the glucose oxidase which remains on the nitrocellulose for approximately 50 tests.



Pipetting device: A polyethylene tube attached to a low cost insulin syringe



The nitrocellulose pad seen from the top

Pipetting device
It is important to apply the correct amount of urine (0.3 μl) to the nitrocellulose pad, because every glucose molecule (theoretically) delivers two electrons to the working electrode. If a bigger amount of urine is applied, the test result will be incorrect (too high) and vice versa.
The urine samples are applied onto the nitrocellulose pad using a low-cost 0.3 ml disposable insulin syringe onto which a polyethylene tubing (inner diameter: 0.28 mm) is attached. The polyethylene tubing (on which a mark indicates the 0.3 μl) facilitates precise dosing and does not damage the nitrocellulose pad. A piece of elastic silicone tubing is placed around the syringe's plunger and makes it act as a spring when slightly pressed and in contact with the urine sample. The syringe can be used for hundreds of samples and is rinsed by tap water between each test.

Data logging
An amplifier reads the current from the working electrode, and a data logging software or a multimeter can be used to analyse the measurements.

Using urine instead of blood
The advantage of using urine is that it is a fluid that is accessible non-invasively (no breaks in the skin). Glucose is found in urine when the cocentration of glucose in the blood exceeds 10 mmol/l. In Denmark, the definition of diabetes is a fasting blood glucose level of 7,0 mmol/l or higher, and the concentration of glucose in the blood ranges from approximately 4,0-8,0 in a person without diabetes [apoteket.dk]. Thereby, using urine is not as precise as using blood for running the measurements. However, diabetics with a blood glucose level of 10 mmol/l were considered as being okay, and it was not unusual to see diabetics (that were even treated with insulin) with very high blood glucose levels over 20-25 mmol/l in the private diabetes clinic we visited. In order to get a correct result of the measurements it is important that the patient has been fasting before the test, just like when using the existing blood glucose meters.

Advantages
+ Does not require expensive, disposable test strips
+ When the system is set up, the price is the same whether you run 1 or 200 tests
+ The price of a single test is approximately 1/100 of the price of a test using a regular blood glucose meter (according to the inventors of the system)
+ Using urine is a non-invasive measuring method and does not require disposable needles for a finger pricker
+ The system produces results similar to those from more expensive, commercially clinical instruments (according to the inventors of the system)

Disadvantages
÷ Slower test results (15 minutes)
÷ More extensive user interaction (placing of filter paper strips, nitrocellulose pads, applying glucose oxidase and fluids for the reservoirs)
÷ Not as precise as measurements using blood

Conclusion
We see a big potential in using this system because of its low cost, because it does not use disposable test strips for each test and because it - compared to the products already on the market - is the only system where it is just as cheap to run quantitative tests as single tests once the system is configured. This unique feature supports our vision of designing a product that contributes to making blood glucose measurements more accessible very well. Based on this we consider the advantages as overshadowing the disadvantages and decide to use this electrochemical measuring method in the development of a new medical device for measuring blood glucose levels.

We contacted Jan Lankelma from VU University, Amsterdam, who is the corresponding author of the publication. He was very interested in cooperating and sparring with us, and at the moment he is working on optimising the system. He has provided us with clarifying knowledge about the system, and we have provided him and his colleagues with information about the contexts we have visited in Senegal and Gambia to use in their further development of the system.

MEDCIAL DEVICE DESIGN

Reduce use errors
When designing medical devices there are some specific factors to consider in order to reduce the risk of use errors. As previously mentioned, 44% of all medical devices are recalled due to design problems resulting in use errors, and when designing for a context where the user has only little or no education, user interaction is an area that needs special attention.
U.S. Food and Drug Administration (FDA) has developed a list named "Key safety concepts in design" [cs.umd.edu] containing seven steps to consider in the development of medical devices in order to reduce the risk of use errors. The seven steps in the guideline are:

- Make things visible
- Simplify the operation
- Avoid reliance on memory
- Avoid reliance on vigilance
- Use natural mappings
- Use forcing functions
- Make it easy to reverse an error

The first two steps on the list are already among the requirements we have derived, while the remaining five steps are requirements that we can add to our list of requirements for interaction, in order to actively work on reducing the risk of use errors.

Delimitation
At the same time, we want to delimit the project from focusing on the authorisation procedures related to approval of medical devices as well as CE markings and other authorisation procedures related to the approval of electronics.

REQUIREMENTS SPECIFICATION

The requirements specification is a total list of the requirements derived during the Research & Analysis phase. The requirements are listed as requirements related to the context and requirements related to interaction with the product, and the requirements will be used for developing design principles in the upcoming Ideation phase as well as for evaluating concepts and the final product proposal.

Context

- → The product and its vital parts should be protected against dust and dirt
- → The product should not depend on extra supplies that are expensive and/or difficult to get
- → The product should be as cheap as possible
- → The components of the product should, as far possible, be easy and cheap to repair or replace
- → The product should not contribute to creating more mess in the physical environment
- → The product should be adapted to a humid and warm climate
- → The product should not use disposable test strips
- → The product should contribute to making diabetes tests and monitoring of blood glucose levels more accessible and widespread
- → The price of a single test should be lower than 2 $

Interaction

- → The product should be easy to clean
- → The product should be easy to operate for both educated and uneducated staff
- → Instruction material should be as simple and visual as possible
- → The product should not rely on the user's memory
- → Interaction with the product should not rely on vigilance
- → Interaction with the product should be intuitive and natural
- → Interaction with the product should not rely on the user's memory
- → Interaction with the product should be characterized by forcing functions
- → It should be easy to reverse an error

IDEATION

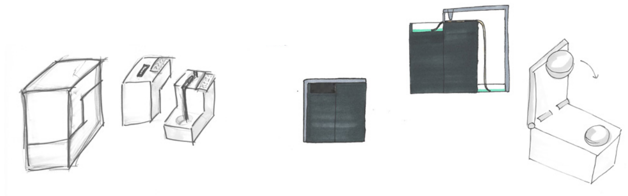
DESIGN PRINCIPLES

We addressed the creative process and idea generation by developing conceptual ideas based on the requirements derived from the Research & Analysis phase. In the beginning, we distinguished between ideas based on the requirements for the context and ideas based on the requirements for interaction with the product in order to ensure that we worked with all relevant requirements. Under each requirement we developed different design principles as a tool for developing and testing ideas based on the problems we observed when visiting the contexts. The principles and active use of the requirements helped us ensuring that we considered the entire problem area in the idea generation process. The principles are presented here with a selection of sketches, 3D-models and physical models used to visualise ideas. The selected principles will be used in the development of concepts in the next section.

Contextual requirements and principles

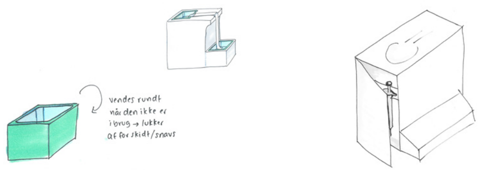
The product and its vital parts should be protected against dust and dirt

Closed when not in use:
The product is closed when not being operated in order to keep dirt and dust out of the product and its electrochemical system.



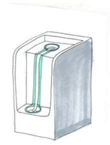
The product should be as cheap as possible

Multifunctional components:
The product consists of multifunctional components reducing the amount of parts in order to make the product as cheap as possible.

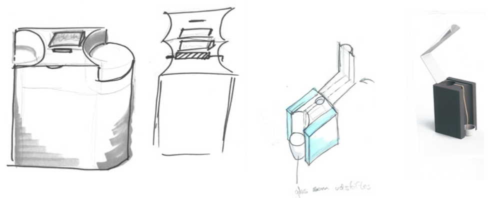


The components of the product should, as far possible, be easy and cheap to repair or replace

Including shape:
The product contains as few loose components as possible in order to minimise the risk of components disappearing or breaking.



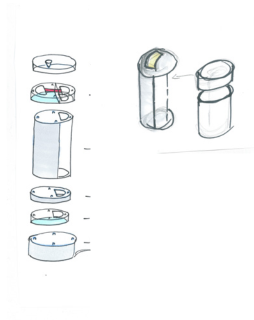
Replaceable standard components:
The product uses the principle of whatever means available. If a single component breaks it can be replaced by an available standard component ensuring that the product will not end up in a corner collecting dust if it breaks.



÷ It cannot be ensured or controlled that the new components are suitable and appropriate to use

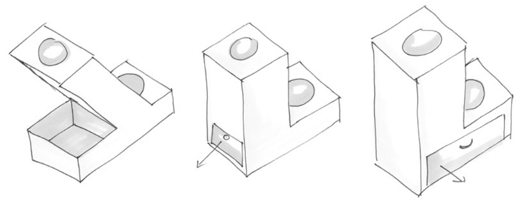
Modular system:
The product is built from different modules in order to make repairs and possible replacements as easy as possible.

÷ A modular structure makes the product appear more confusing and complicated than necessary and makes interaction with the product more difficult. Additionally, a modular system will add joints that can make the product more fragile.



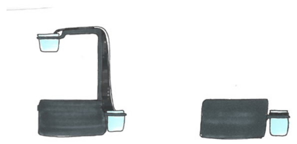
The product should not contribute to creating more mess in the physical environment

Integrated storage of supplies:
The storage of the product's extra supplies is an integrated part of the solution in order to avoid more mess in the laboratories and in order to avoid supplies disappearing.



Foldable construction:
The construction can be folded when not in use in order to only take up a limited amount of space in the laboratories.

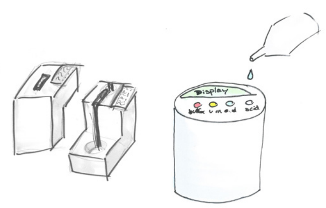
÷ Movable parts and joints make a construction more fragile and make it break easier



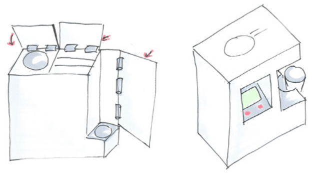
Interaction requirements and principles

The product should be easy to clean

Clean surfaces:
The product's outer parts are easy to clean due to smooth and clean surfaces and a minimal of detailing in order to make the product more appropriate for the specific physical environment.



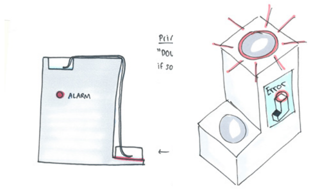
Easy access to inner parts: ✓
It is easy for the user to get access to the product's inner and vital parts in order to make cleaning easy and intuitive.



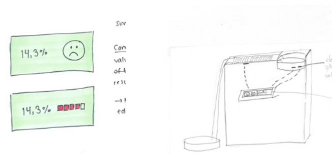
The product should be easy to operate for both educated and uneducated staff

Transparency: ✓
The product is transparent when in use in order to ensure that the user has an immediate understanding of the system and an overview of reservoirs, filter paper etc. to make it easier for the user to see if there are any errors.

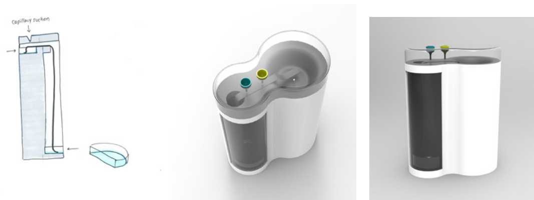
Double indication of errors: ✓
The product tells the user if there is an error and shows specifically where the error is located (e.g. a display telling what the error is and a light showing where the error is).



Multiple output on interface: ✓
The result of a test is shown in multiple ways in order to ensure that the result is readable, understandable and relatable for both educated and uneducated staff.

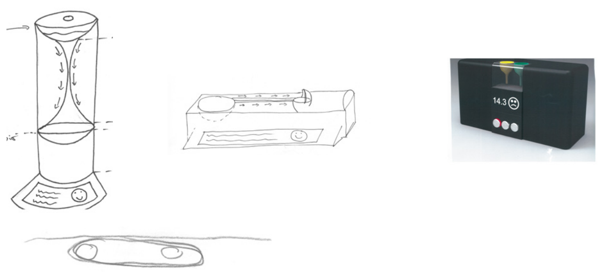


Automatic dosing of urine: ✓
The product doses the correct amount of urine itself because it is difficult for the user to dose the very small amount of urine precisely.

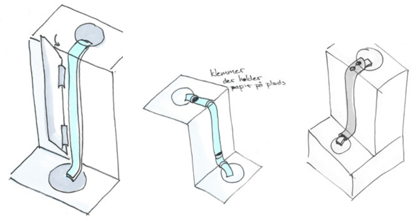


Avoiding filter paper: ✗
The electrochemical system is not dependent on filter paper in order to minimise the user's interaction with the product.

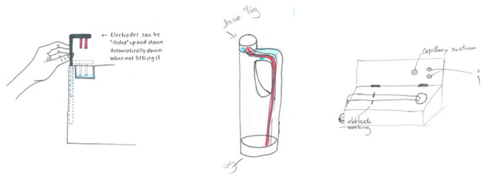
÷ It is not possible to replace the filter paper with an electric pump or mechanical solution because it is very difficult and too expensive to make a stable flow similar to the gravity-driven flow through the filter paper.



"Bulletproof" placement of filter paper: ✓
It is impossible to place the filter paper incorrectly in order to avoid the risk of mistakes caused by the user.

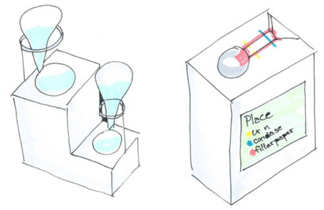


Built-in electrodes: ✓
The electrodes are incorporated and built into the product in order to ensure that the electrodes are always placed correctly.



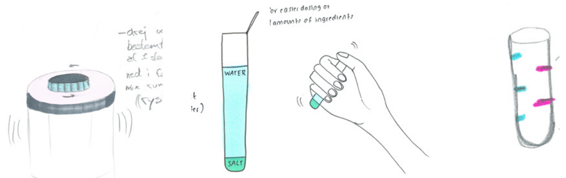
Automatic filling of fluids in reservoirs: ✗
The product doses the correct solutions and fills up the reservoirs automatically.

÷ Automatic filling will depend on extra electric or mechanical parts increasing the product's risk of breaking. In case this would happen the user would not know how to dose the correct solutions and the product would not be used.)



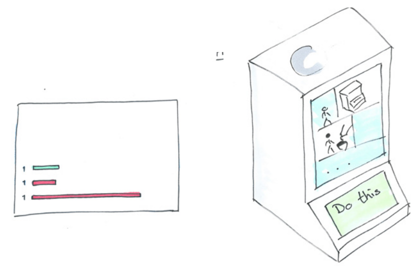
Easy dosing of ingredients in reservoirs: ✗
The product makes it easy for the user to dose the correct amount of ingredients for the fluids in the reservoir in order to minimise the risk of errors caused by the user's interaction with the product.

÷ The dosing is quite, therefore simple we consider that a special dosing device is not necessary.

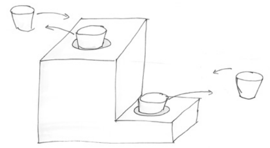


Instruction material should be as simple and visual as possible

Integrated instruction: ✓
Instruction is an integrated part of the product eliminating the need of a user manual that might disappear or not being used. This eliminates the risk of errors caused by the user and ensures that instructions always are right where they are needed.



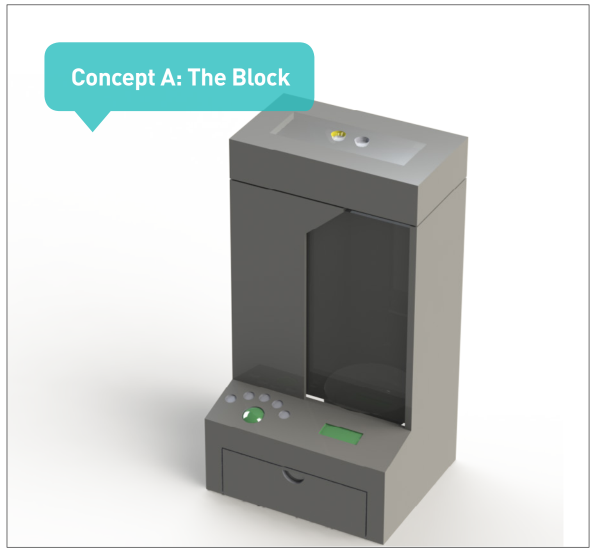
Replaceable parts: ✓
The reservoirs and additional components in contact with fluids can be replaced when cleaned by similar components coming with the product in order to make cleaning and maintenance of the system easier.



CHOICE OF CONCEPT

The approved principles developed in the previous section are used for another idea generation process where the goal is to combine as many of the chosen principles as possible into a few concepts. In this section the two concepts including most of the principles are presented with the purpose of evaluating them using a selection matrix. [Ulrich, Eppinger, p. 130] The concepts will be evaluated on the basis of the requirements regarding the product's functionality and shape, but not regarding the electrochemical method that we have already decided to use. The concepts and their main principles are described below.

Selection matrix
In the matrix on the following page the concepts and requirements are set up against each other in order to see which of the concepts fulfills the requirements the most. If the project fulfills a requriment it will get a +, if not a -, and if a requriment has not been discussed in a concept but might be able to fulfill it, it will get a 0. The concept which fulfills the most will be selected as the final concept to use in the development phase.



The Block
One of the main principles incorporated in The Block is easy access to inner parts making it easy to configure the system which is done with a transparent screen protecting the lower reservoir and a lid covering the upper reservoir. Another incorporated principle is integrated storage of supplies visualised through an integrated drawer securing the supplies. Additional principles consist of built-in electrodes, bulletproof placement of filter paper and transparency in the lid and door so the user can see if any errors should occur.

The cylinder
The main principle used in the cylinder is transparency making it easier for the user to understand the system and see if anything is wrong. Besides transparency this concept also has built-in electrodes, bulletproof placement of filter paper and automatic dosing of urine.

Selection criteria	Concept A	Concept B
The product and its vital parts should be protected against dust and dirt	+	+
The product should not depend on extra supplies that are expensive and/or difficult to get	+	+
The product should be as cheap as possible	0	-
The components of the product should, as far possible, be easy and cheap to repair or replace	0	-
The product should not contribute to creating more mess in the physical environment	+	+
The product should be easy to clean	+	-
The product should be easy to operate for both educated and uneducated staff	0	0
The product should not rely on the user's memory	0	0
Interaction with the product should not rely on vigilance	+	+
Interaction with the product should be intuitive and natural	+	+
Interaction with the product should not rely on the user's memory	0	0
Interaction with the product should be characterized by forcing functions	0	0
It should be easy to reverse an error	0	0
Sum of +'s	7	6
Sum of 0's	8	5
Sum of -'s	0	4
Total score	7	2

Concept A, The Block, has the highest score and will be used in product development in the upcoming Development phase.

DEVELOPMENT

DESIGN
FOR MANUFACTURING AND ASSEMBLY

Design for Manufacturing and Assembly
In order to kick-start the Development phase, we have been working with Design for Manufacturing and Assembly (DFMA). As already pointed out in the Research & Analysis chapter, one of the main issues in the clinics we visited in Africa is economics. In order to meet the requirements of a cheap and affordable product that can compete with the current blood glucose meters, it is necessary to consider manufacturing and assembly very early in the development phase of the product in order to reach as low production costs as possible.
The three main points that have to be considered and will be investigated in this section is material, production methods and assembly methods. These studies will take their outcome in the selected concept and will be integrated in the development of a product proposal.

Material
When choosing material for the product, different factors have to be considered. The criteria we look at are based on what we experienced in the contexts during the field studies as well as general requirements for materials to use for medical devices. Overall, we have looked for two different materials for the product: One material for the main body and all non-transparent parts, and one material for the transparent parts. The criteria to consider are:

Criteria for choice of material

- Base resistance (resistant to fluids in a lab)
- Acid resistance (resistant to fluids in a lab)
- Resistant to high temperatures and humidity
- Shock-proof
- Low cost
- Accepted for use in medical devices

For the main body, we have looked for both plastics and metals on the market and evaluated them against the criteria above. The material we find most suitable for the use while fulfilling all the criteria above is the plastic material polypropylene (PP). PP is often used for medical equipment and is resistant to both bases and acids. Along with PE it is one of the cheapest plastics on the market. Additionally, PP has excellent hinge qualities. [Plast.dk] [Primo.dk]

For the transparent parts of the product we looked for materials traditionally used for transparent plastic parts, e.g. acrylic plastic (PMMA), but these materials do not have the same qualities as PP regarding resistance to acids, low cost and resistance to high temperatures. However, it is also possible to manufacture PP in transparent, and we choose to use PP also for the transparent parts.

For the final finish of the different surfaces we choose to use on finish, Mold-Tech MT-11001, with depth of 3 μm for the inside of the reservoirs to symbolize that this area is meant for fluids, and a rougher finish, Mold-Tech MT-11540 with depth of 46 μm for the main body of the product. Common for the chosen surface finishes is that they should be easy to clean. The reason for choosing a rougher material for the main body is that it should not be too easy to see every little dust grain and dirt on the product which the product to a great extent will be exposed to in the African clinics.

Additionally, a few other materials will be needed for display, electronic devices and buttons etc. We choose to delimit the project from focusing on these materials as they will come from an external supplier.
Potentially additional materials will be presented in the developing phase.

Manufacturing method
Once the manufacturing method has been chosen it is important to consider the number of products that will be sold. Normally, a new product will be produced in a smaller number in the start-up phase while the amount of produced products will increase as the demand and sales figures increase if the product becomes a success. When designing specifically for developing countries we are looking at a market that is not commonly seen upon as a profitable market. In order to get potential investors or manufacturers interested in investing in the product and this market it is important to work on bringing down the required start-up capital and to ensure a rather quick break even.
When working with plastics injection moulding is very widely used. However, injection moulding requires a high start-up cost for tooling, and break-even will occur later and possibly scare away potential investors. Therefore, we have been looking for alternative production methods meeting the requirements of a low start-up cost. Based on this we consider vacuum casting as being a favourable production method in the start-up process when introducing the product to the market. Vacuum casting has many of the same qualities as injection moulding, but as the main mold is made from silicone the tooling is much cheaper. On the other hand, the tooling it needs has to be replaced with a new mold for each 20-30 units. [Thompson] Vacuum casting gives a moderate unit price which seems reasonable compared to the tooling cost and shape possibilities. Additionally, the method gives a very high surface finish, which might save some subsequent processing later on. As the tooling for vacuum casting is a mold made from silicone, the mold is more flexible and gives a few more possibilities than injection moulding regarding slight re-entrant angles and undercuts. [Thompsen p. 41]
We choose to focus on using vacuum casting for the start-up phase, and if the product becomes a success production methods such as injection moulding suitable for higher numbers of produced units should be considered.

Assembly method
For assembling it is very important to choose a method that will spare not only cost but also time for manual assembly and thereby salary for the employees, especially when designing a low cost product. Another important aspect is to keep down the number of parts that need to be assembled; rather a few more complicated parts than an extra part. [Boothroyd, chapter 3]
The cheapest assembly method is snap function, and after having studied products using this assembly method we choose to use it where it is possible. [Boothroyd, p. 89]
At the same time, we will actively work on reducing the amount of parts. In order to work with a wide use of snap functions it is important to incorporate this in the design very early in the design and development process.

Polypropylene (PP)

Mold-Tech textures

RESERVOIRS AND ELECTRODES

When developing the upper and lower reservoirs, cleaning and the risk that the reservoirs could be used for other purposes, disappear or break are important factors. During the field studies, both at the clinics and in general, we saw that products intended for one thing are used for multiple other purposes, and we want to design a solution that actively meets this problem or special characteristic related to the context.
The obvious solution is to work with an including shape where the reservoirs are an integrated part of the product that was one of our developed design principles. However, the two reservoirs have different requirements and need to deal with the problem in different ways.

Upper reservoir
The upper reservoir only contains tap water and salt and does not have special requirements regarding cleaning because it is not in contact with bacteria or organic material. At the same time, the reference and auxiliary electrodes need to be placed in the upper reservoir. We want the user to interact as little as possible with the electrodes in order to keep interaction with the system simple.
Based on this it is decided to integrate the upper reservoir directly in the product with the electrodes built into it. The constant flow through the system keeps the electrodes clean, and they will only need very little cleaning making this solution possible. Also the working electrode on which the nitrocellulose pad is placed can be built into the product.
When the upper reservoir needs to be emptied or cleaned it is not very appropriate that the reservoir cannot be removed. We have tried to develop different kinds of drains, but all suggestions require extra elements adding weak links to the product as they can disappear or break. Therefore, we decided that emptying the reservoir with a cloth or a syringe is a more appropriate solution considering the context.

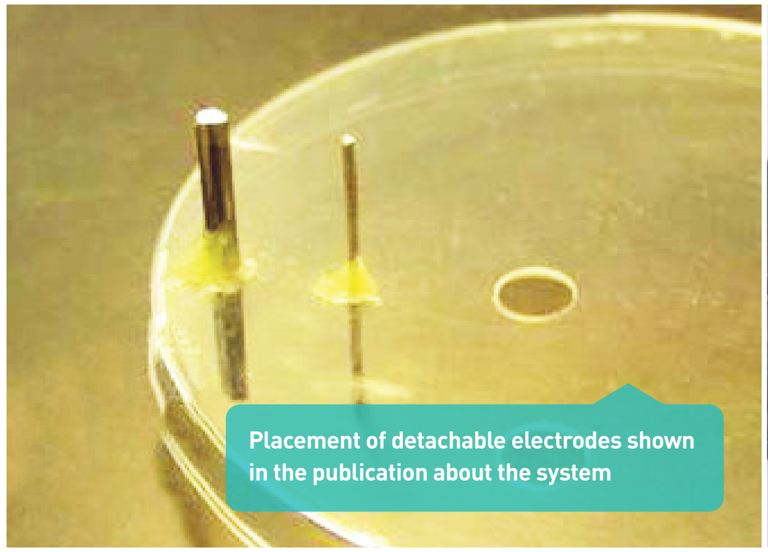
Lower reservoir
While the upper reservoir only contains tap water and salt, the urine applied for each test ends up in the lower reservoir with tap water and acetic acid, and in order to inhibit microbial/bacterial growth this reservoir needs to be removable in order to clean it properly. This is the solution we tried to avoid as a removable item increases the risk of the item disappearing or breaking. Thereby, it is important that the lower reservoir can be replaced by a similar-sized container if this should happen.
We did not find any suitable standard containers that we can rely on are accessible to clinics in Africa, and had to think in alternative solutions in order to find a container that is accessible everywhere.
This made us think of the Coca Cola can that you can find on every street corner even in the most rural areas of the world. The aluminium can is very suitable for the purpose as it is designed to contain coke and other soft drinks containing small amounts of acids, and a coke which contains phosphoric acid is actually more acidic than the solution of 0.1-1% acetic acid required for the electrochemical system in the lower reservoir. [EngineeringToolbox.com] A quick test showed that you can easily cut the top off the aluminium can using a regular scissor, and thereby we decide to base the design of the lower reservoir on the design of a Coca Cola can so that it is easy to replace the reservoir if it should disappear or break.

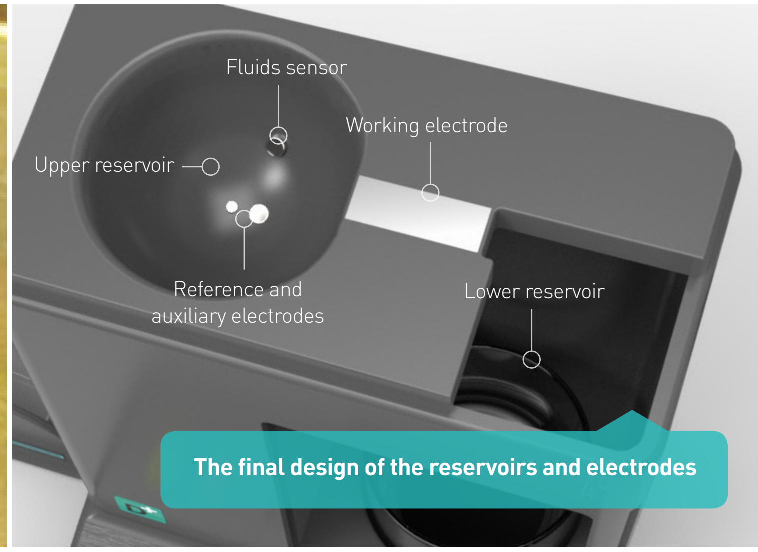
Dimensioning and design
While the lower reservoir is dimensioned with an outer diameter and overall shape as an aluminium can, we use the same diameter for the upper reservoir in order to ensure an approximate even height difference between the two reservoirs when the water starts to evaporate. However, the upper reservoir needs to be more organic in its shape in order to make cleaning easier.

Sensor for fluid level
A very important aspect when using the electrochemical system is that the fluid in the reservoirs, the filter paper strips and nitrocellulose pad should not dry out. Otherwise, the system does not work and it should be reconfigured. In order to meet this problem we decide to incorporate a sensor in the upper reservoir alarming the user when the buffer solution is running low. As we want the lower reservoir to be removable and not incorporated we decide to make the user put a little more water in the lower reservoir. Thereby, the upper reservoir with the sensor will always be the first one to dry out.

Even in the most rural areas of the world you can find a Coca Cola can on each street corner


Mock-up of lower reservoir made from a cut-off aluminium can


Placement of detachable electrodes shown in the publication about the system



The final design of the reservoirs and electrodes

DOSING
OF URINE AND GLUCOSE OXIDASE

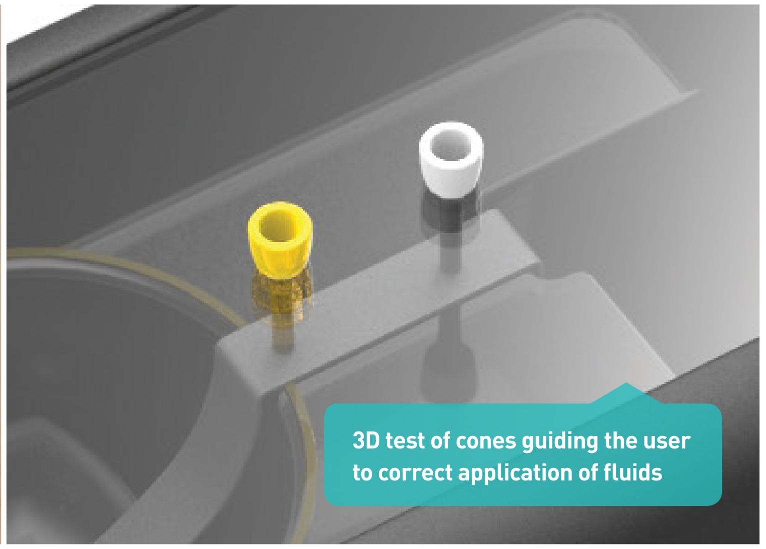
When looking at dosing of urine and glucose oxidase there are two main aspects to consider in order to prevent errors: Applying the correct amount and applying it to the right spot. In the Ideation phase we experimented with automatic dosing of the urine and glucose oxidase. The advantages of an automatic dosing system are that it removes the risk of the user dosing an incorrect amount and/or applying it too close to each other, which can lead to incorrect results. The problem when using automatic dosing is that it will increase the cost significantly, conflicting with the requirement of keeping the product as cheap as possible. When looking at automatic pipettes on the market the problem about cost is the same. Another problem is that automatic dosing adds an extra electrical part adding a weak link to the product because it - potentially - can break and make future use of the product impossible because there are no qualified personnel to conduct repairs.

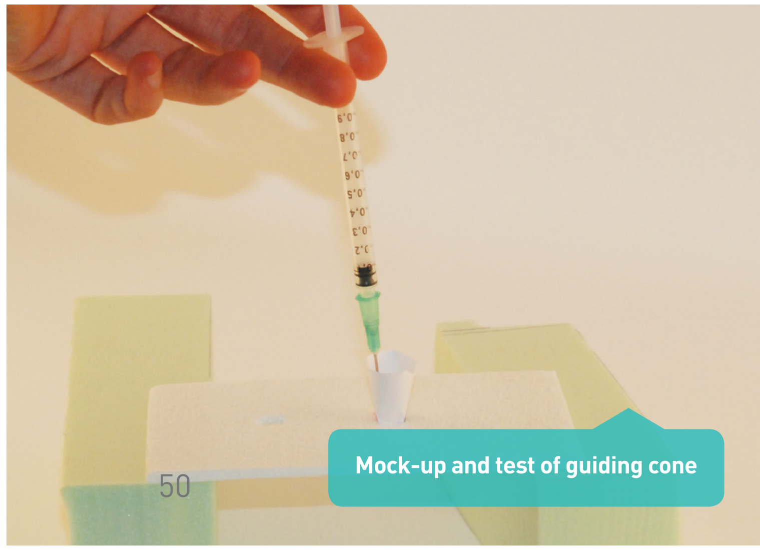
Modified insulin syringes
According to the scientists who have developed the electrochemical measuring method we are using it is quite simple to dose the correct amount of urine and glucose oxidase using a slightly modified low cost insulin syringe, and it requires only a little training. We conducted our own experiments with syringes and tubings and found that it is quite easy. Therefore, we choose to use a standard insulin syringe attached to a silicone tubing with a mark indicating the correct amount of fluids (previously described).

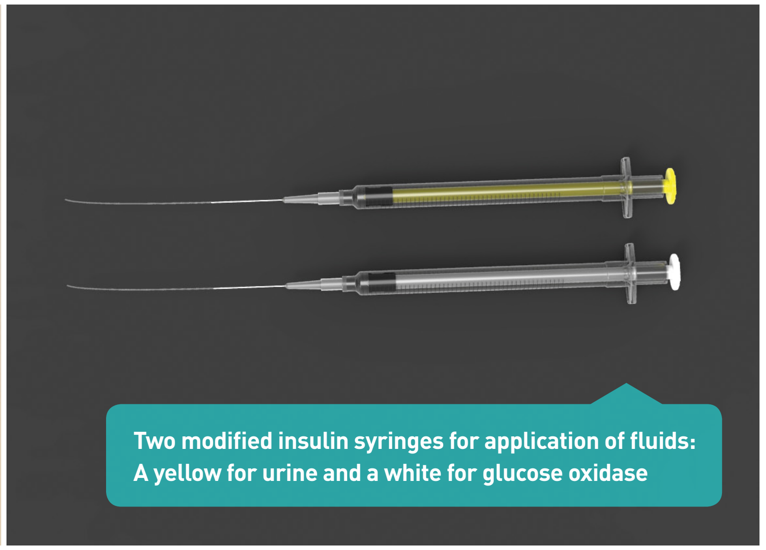
Application onto the right spots
In order to ensure that the fluids are applied to the correct spots we worked with different ways of guiding the user. Our solution is small cone-like shapes mounted on the top of the product. The cones guide the user in a simple way by leading the silicone tubing on the syringe ensuring that fluids are always applied to the right spots. Additionally we decide to integrate markings directly on the product next to spots where the fluids should be applied in case the guiding cones disappear.

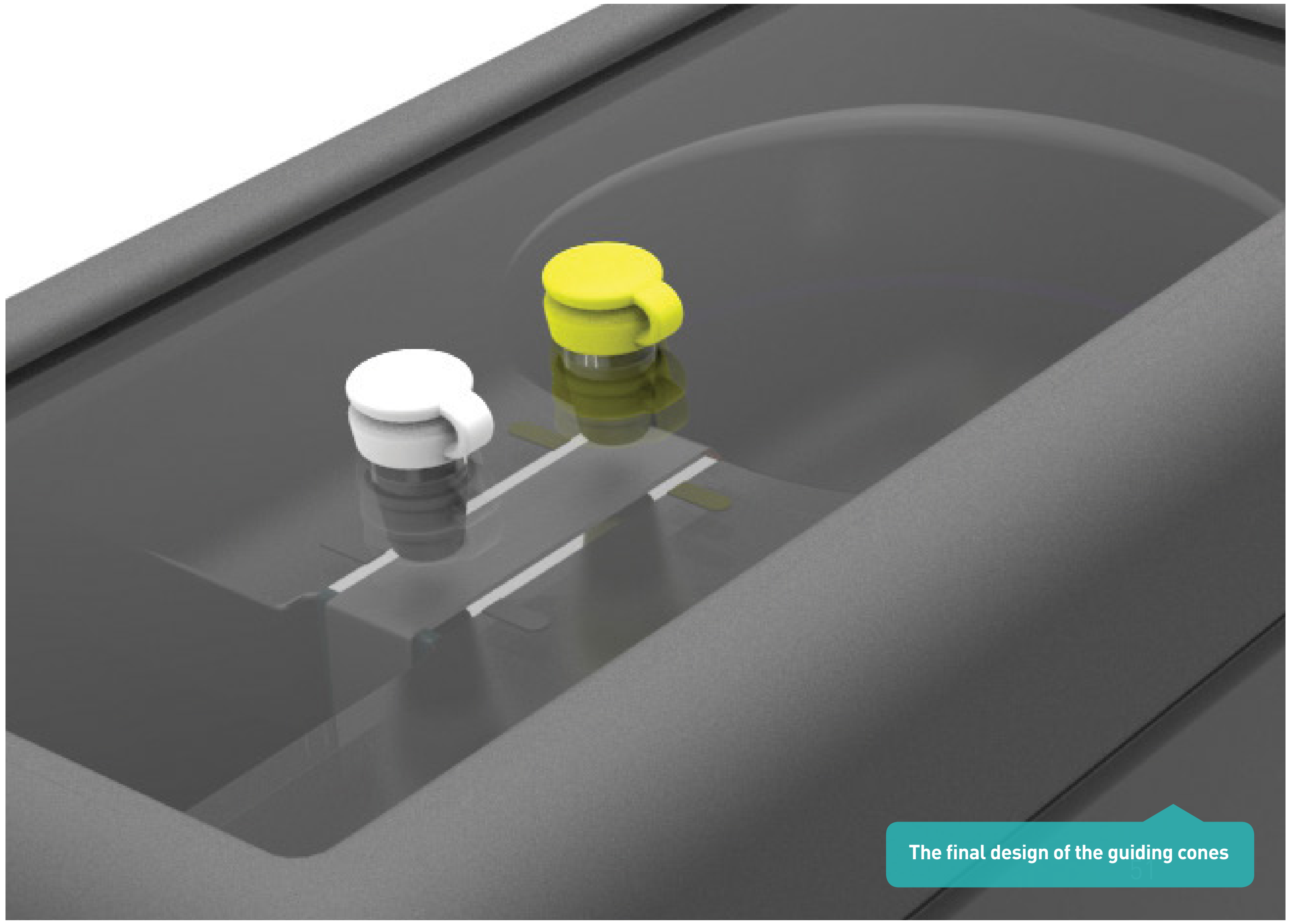
Colour codes
In order to ensure that the right cone is used to apply the right fluid we decide to colour code both syringes, cones and markings next to the nitrocellulose (yellow for urine and white for glucose oxidase). Thereby it should be easy for even untrained users to apply the correct fluid to the correct spot.


Acting out and model experiements


3D test of cones guiding the user to correct application of fluids

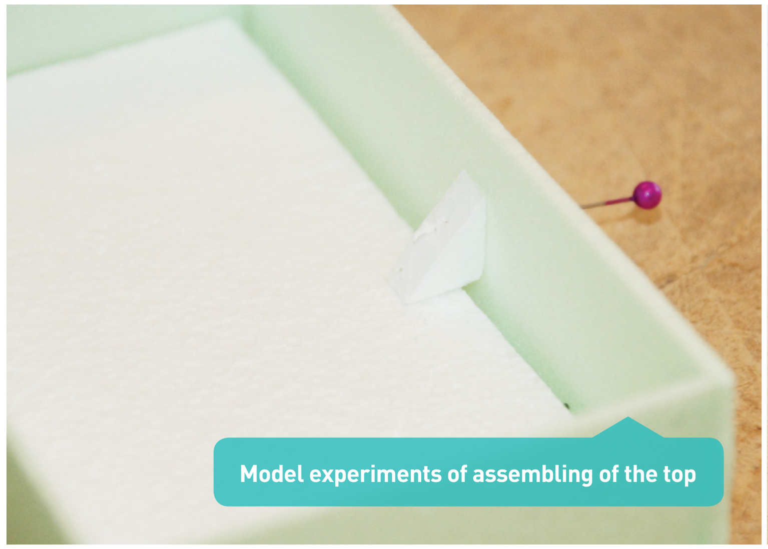

Mock-up and test of guiding cone

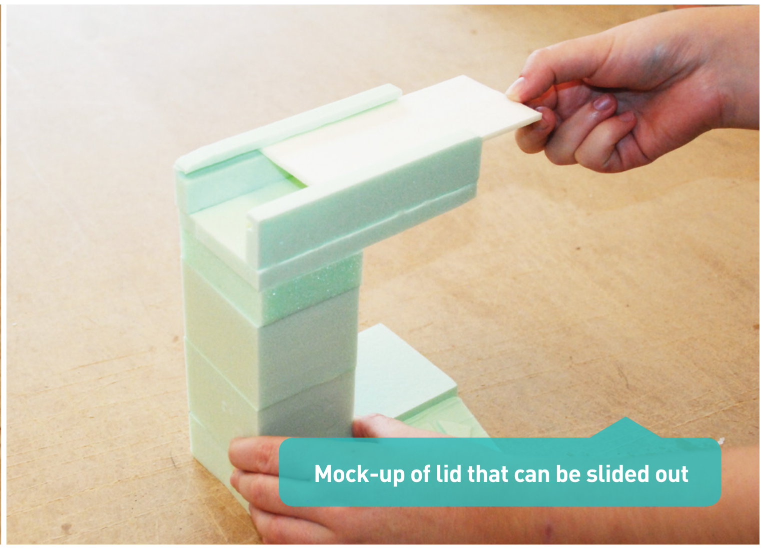

Two modified insulin syringes for application of fluids: A yellow for urine and a white for glucose oxidase

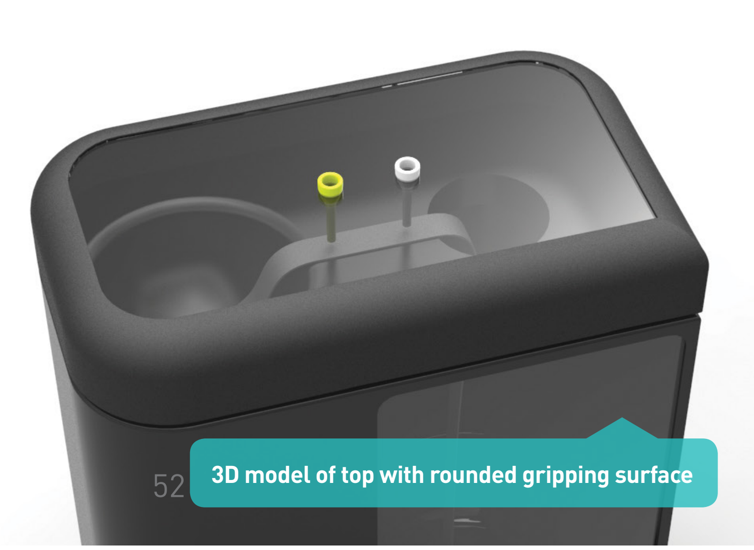

The final design of the guiding cones

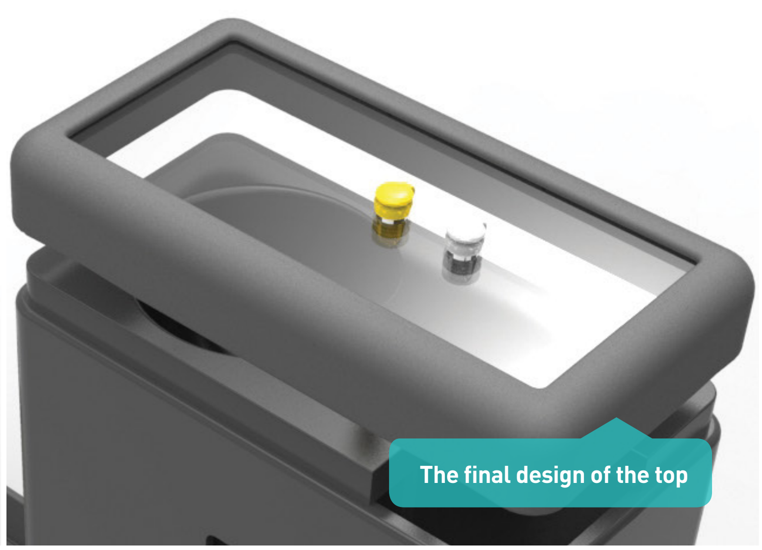
PROTECTING
TOP

The purpose of the top is to protect the upper reservoir, electrodes, nitrocellulose pad and filter paper strips from dust and dirt. At the same time, the user should have easy access to these parts when configuring the system and cleaning the product, and - as mentioned in the selection of the concept - we want to keep the system transparent in order to ensure an immediate understanding of the system and to easily detect errors. The cones guiding the user to dose the correct amount of fluids also need to be incorporated in the top.
After having tried out different solutions for a protecting top that can be slided out and lifted off, we decide to develop a "lid" for the product with a transparent, rectangular plate surrounded by a sturdy gripping surface. The transparent plate can be clicked in place, which makes it easy to replace the transparent plate if it breaks.
The gripping part has rather big fillets to help ensuring that the top is comfortable for the user to touch while helping to protect the product from damages if bumped into e.g. a wall.
In order to ensure a better and safer grip when the user lifts off the lid we decide to paint the gripping surface with soft touch paint. Besides ensuring a better grip the different surface texture indicates that the lid is an interaction point.
The meeting between the top and the main body of the product is emphasized through a bigger fillet than the fillets used to even out tolerances where two parts are assembled in order to indicate that the top and the main body are two different parts.


Model experiments of assembling of the top


Mock-up of lid that can be slided out


3D model of top with rounded gripping surface

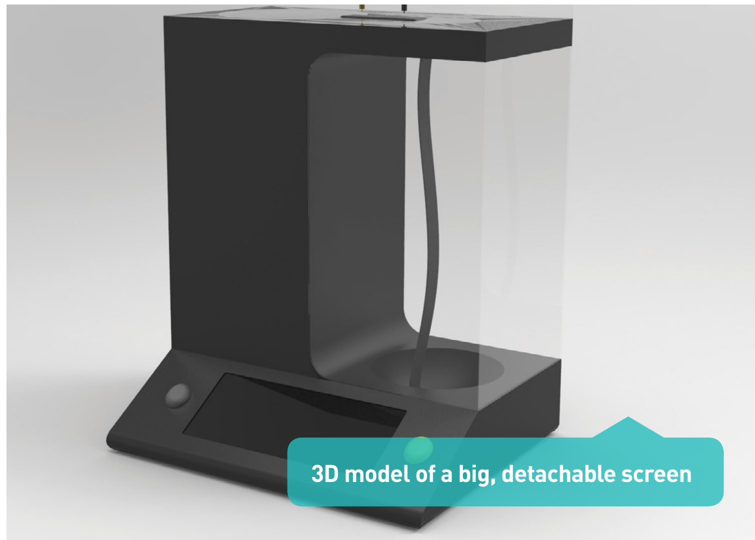

The final design of the top

PROTECTION
OF LOWER RESERVOIR

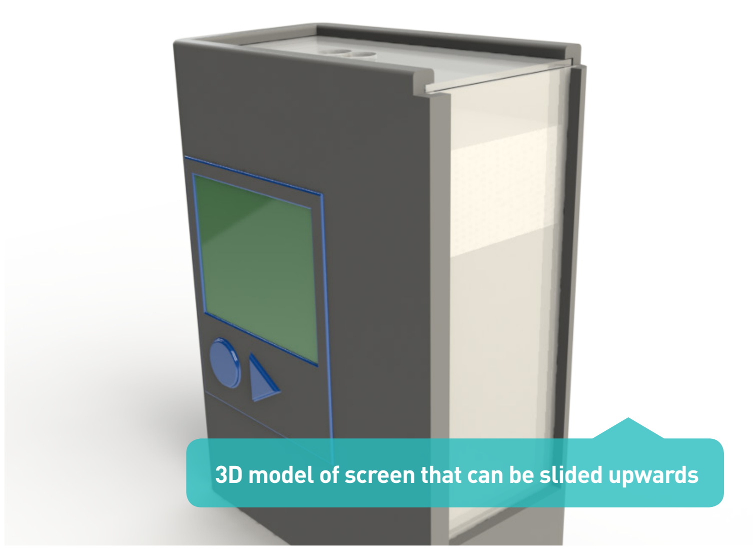
In order to protect the lower reservoir from dirt and dust a protecting screen needs to be developed. Just like the top/lid the protecting screen needs to be transparent in order to ensure an immediate overview of the system. Another important aspect is to keep cost as low as possible and not adding any unnecessarily fragile/weak elements.

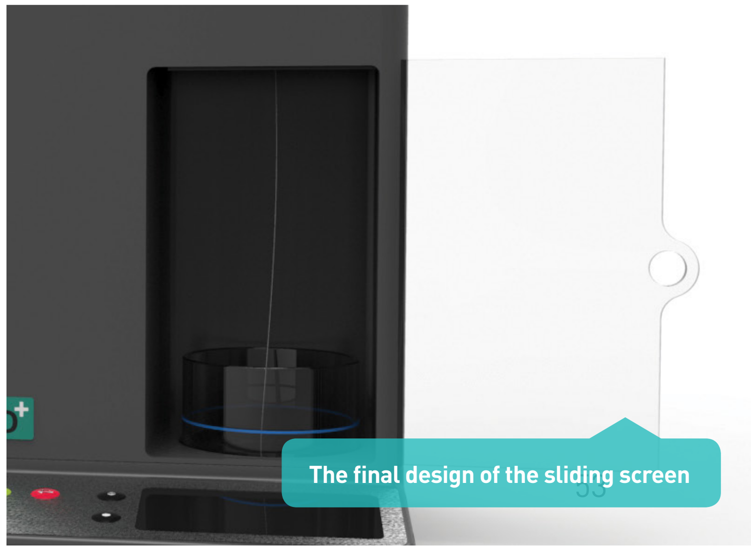
We experimented with different ways of opening/removing the screen with the main issue being that the screen should not be detached from the product when opened because it increases the risk of the screen being used for other purposes, or that it disappears or breaks. At the same time it is important that the screen can be cleaned on both sides if an accident with the fluids happens inside the product. Also, it should be quite easy to replace the door if it breaks, and it should not rely on fragile hinges that can break easily.

The solution meeting these requirements is a screen that is slided in two furrows in the direction away from the product which makes it easy to clean it on both sides. Additionally, the furrows help keeping out dirt and dust. A small tap prevents the screen from sliding all the way out, and thereby it can only be detached from the product if using force. The screen has a rectangular shape, and besides the small tap it is cut with an integrated handle in the form of a circular arc and a hole


3D model of a big, detachable screen


3D model of sliding screen

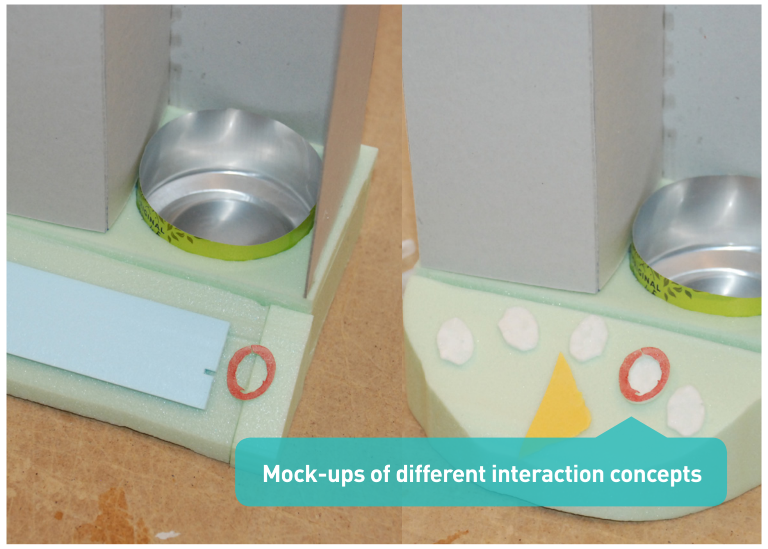

3D model of screen that can be slided upwards

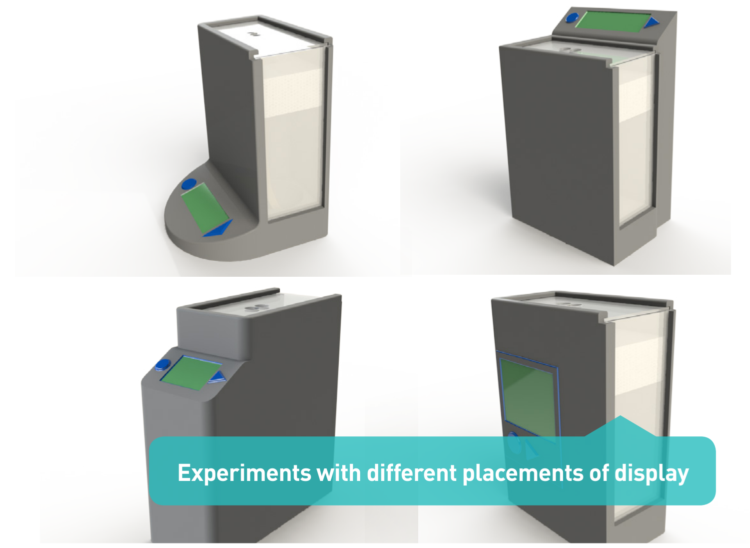

The final design of the sliding screen

DISPLAY, BUTTONS AND INTERACTION

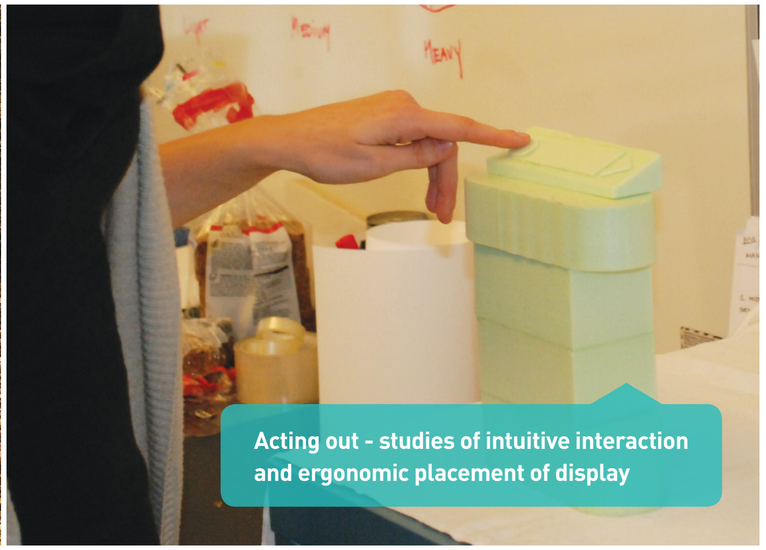
In the development of interaction with the product simplicity, forcing functions and low cost have been the main factors to consider. We investigated and tested different interaction concepts such as single buttons, touch screen and a combination of buttons and a display, and found that the latter solution was the one meeting the criteria in the most favorable way. In order to meet the requirements of forcing functions, make it easy to reverse an error and interaction that does not rely on the user's memory we chose to equip the display with four buttons: One "home" button, one "go back" button and two buttons making the user able to interact with the input on the display.

For safety reasons and in order to keep out dirt, dust and fluids the display and buttons will be covered with a foil like seen on e.g. blenders for kitchen use.
The correct placement of the display and buttons was also investigated, both in order to ensure an ergonomic, user-friendly and intuitive interaction and understanding of the product. We decided to place the display on a lower part in front of the product in order to "reach out" for the user. The placement at the bottom feels safe and secure when pressing the buttons and does not bring the product into imbalance.


Mock-ups of different interaction concepts


Experiments with different placements of display


"Quick and dirty" test of colours and their abilities to camouflage dust and dirt


Acting out - studies of intuitive interaction and ergonomic placement of display

Colour
Regarding the choice of colour it was important for us to choose a colour where dust and dirt is camouflaged as much as possible. In the clinics we visited almost all surfaces were covered in dirt, dust and different fluids, which was very clear on the white products that are designed for clinical labs in western countries. In order to meet this problem we conducted a "quick and dirty" test of different colours that we exposed to sand, earth etc. The colour that did best in the test was a middle grey with a slight touch of brown (CMYK 5, 5, 5, 65).
Also the colour of the foil covering the buttons and display will have the same colour tone as the rest of the product, but with an aluminium-like finish, indicating that this interaction area is different from the rest of the product while being more resistant to and camouflage greasy finger prints.

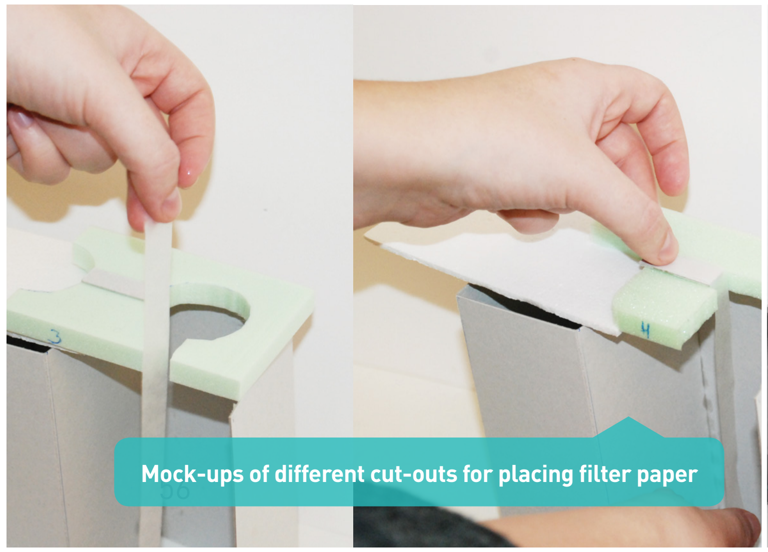

The final design of the display and buttons

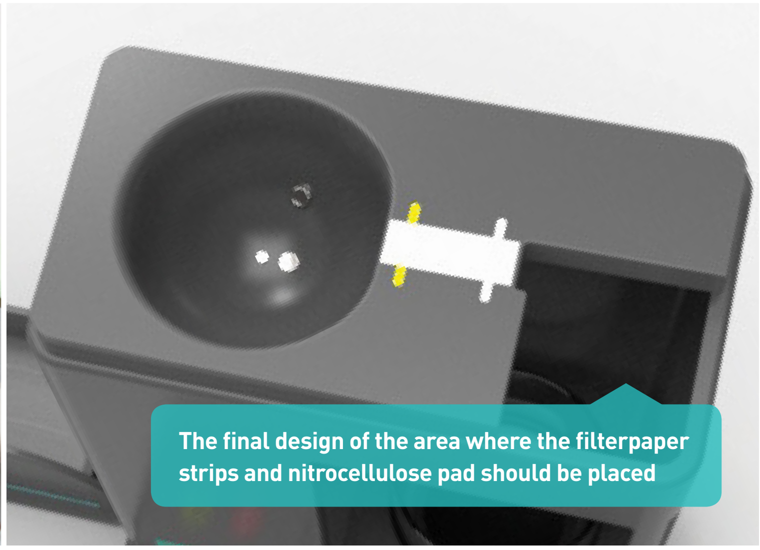
PLACING
OF FILTER PAPER AND NITROCELLULOSE

Placing the filter paper strips and nitrocellulose pad correctly is very important in order to ensure that the electrochemical system works. We have both worked on making it as intuitive as possible for the user to place the filter paper and nitrocellulose correctly as well as making it easy to tear off the right length of filter paper.

Filter paper strips
Today, most filter paper comes in the form of sheets, and to use it for this system it has to be cut into the right size. (8 mm wide and respectively 6 and 21 cm for the upper and lower reservoir). We contacted the suppliers of the filter paper regarding the possibilities for selling the filter paper on rolls instead of in sheets, which they were positive about if it concerns a bigger order. In order to make user interaction as simple as possible we decided to focus on using filter paper on rolls.
Through experiments with mock-ups we found out that especially the long filter paper strip can be a little difficult to place correctly depending of the geometry of the surface it has to be placed upon. After having tested different ideas we decided a simple geometry with a clear cut indicating where to place the filter paper. At the same time, the cut helps indicating where to place the filter paper. In addition to the indication in the physical design of the product we decided to colour code the areas where the filter paper strips should be placed upon, and combined with markings coded in the same colours on the body of the product showing the length of the two filter paper strips it is easy for the user to tear off the filter paper strips in the correct length every time without using a ruler or guessing how long it should be.

Nitrocellulose pad
Just like the filter paper the nitrocellulose comes in sheets intended for different chemical analyses, and in order to use the nitrocellulose in the electrochemical system the sheets have to be cut in pieces measuring 8 x 30 mm. We would like to avoid that the users have to do this themselves in order to prevent use errors and in order to make use of the system as simple as possible. Therefore we contacted the suppliers of the nitrocellulose sheets, and they were also positive about the idea of selling the nitrocellulose sheets in 8 x 30 mm pieces if it concerns a bigger order.
Regarding correct placement of the nitrocellulose pad it has to be placed onto a working electrode which is a small platinum-sputtered plate almost the same size as the nitrocellulose pad built into product. The electrode itself makes it easy to place the nitrocellulose pad correctly.


Mock-ups of different cut-outs for placing filter paper

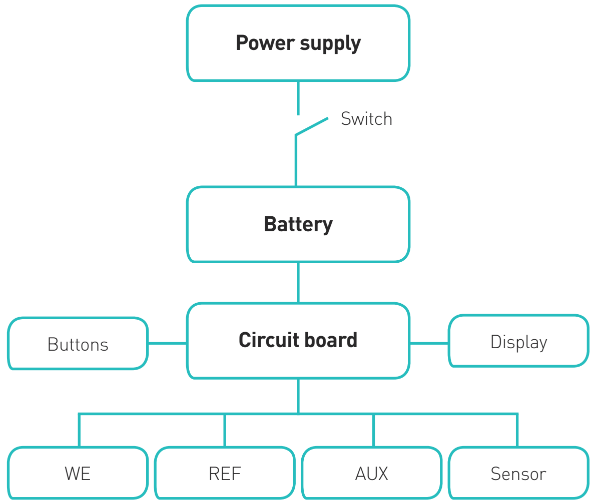

The final design of the area where the filterpaper strips and nitrocellulose pad should be placed

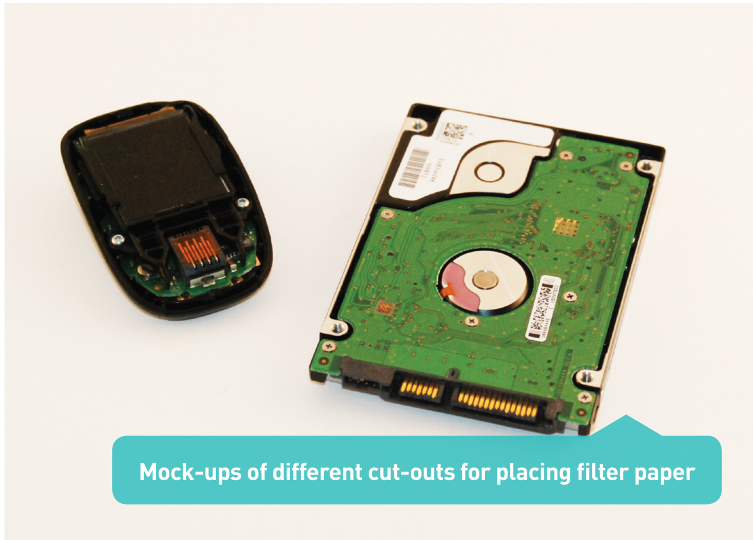
POWER
SUPPLY AND ELECTRONICS

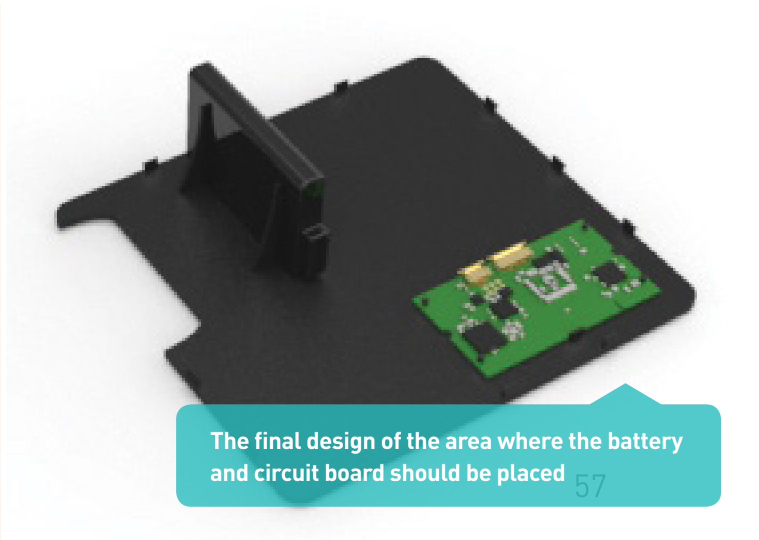
Power supply
Based on what we experienced at the clinics in Senegal and Gambia we decided that the product should be powered by electricity. All of the visited clinics had access to electricity generated either from an external source or powered by solar cells or a small windmill sponsored by the government. However, we experienced that power cuts are very common in Senegal and Gambia; sometimes the power disappears for a couple of hours, and sometimes for couple of days. Therefore it is necessary to support the powered system with a battery for these situations. As the product does not consume a lot of power we find that a battery with a size ranging from the battery in a mobile phone to the battery in a small laptop will be sufficient. Inside the product there is plenty of space to place the battery in the bottom of the product free of other components in order to prevent possible problems from heating of the battery.
We choose not to use solar cells because they will add extra cost to the product while increasing the need of maintenance as the solar cells will have to be replaced once in a while.

Circuit board
As for the battery, the size of circuit boards in different products have been studied. The product is not close to being as complicated as a computer and requires programming quite similar to the already existing blood glucose meters. In order to be on the safe side we dimension the circuit board in a size between these two. The circuit board is placed under the display and buttons because most of the installations are placed here.

The product's technical circuit is visualised through the diagramme below:




Mock-ups of different cut-outs for placing filter paper


The final design of the area where the battery and circuit board should be placed

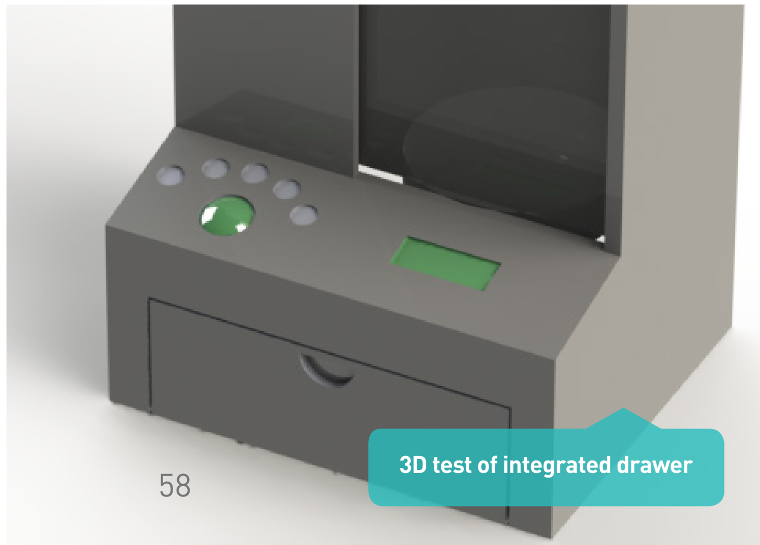
INTEGRATED STORAGE

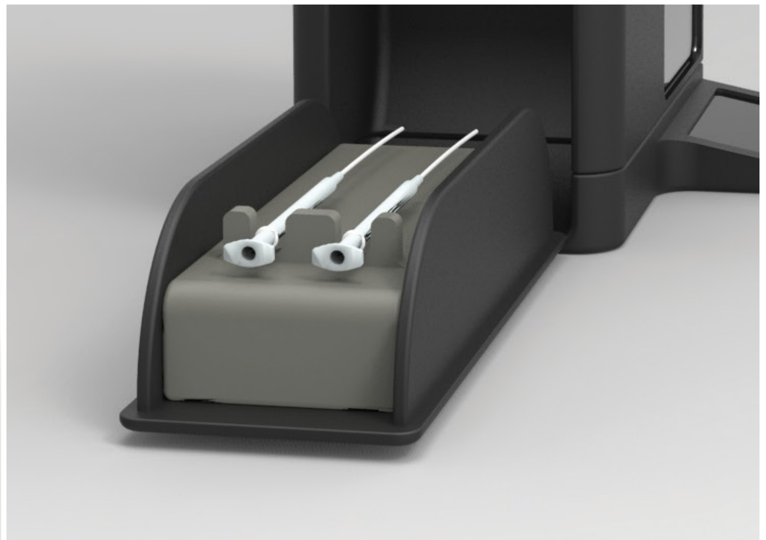
In order to protect the equipment used to operate the system and in order to design a product that does not contribute to creating more mess in the already very messy lab environments we saw in Africa, we are working with an integrated storage module for syringes, filter paper and nitrocellulose pads.
We experimented with different storage concepts like integrated drawers and cabinets, and the challenge was to find a solution that did not increase the volume (in order to keep down cost for material, packaging etc.) of the product while storing the syringes and other equipment safely.

Two layers of interaction
At the same time, we worked with two interaction layers in the development of the storage module: The syringe for urine that is used for each test should be easy to access and put down in a safe place, while the filter paper strips and nitrocellulose pad that is only used for every 50 test (or every 10 days) do not have to be directly accessible for the person conducting the test if he is not educated in configuring the system. Thereby, the design of the product can contribute to a natural division of "users" and "administrators" operating the product.


Mock-up of "drawer" for syringes etc.


Usability test of "cabinet" for syringes etc.


3D test of integrated drawer



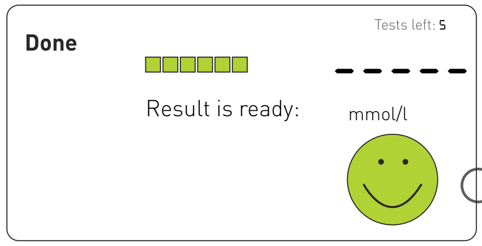
Fold-out cabinet
The solution is a fold-out "cabinet" moulded in the same process as the product's lower part. This solution takes advantage of the PP material's excellent hinge qualities while contributing to keep down the number of parts and thereby production costs. The cabinet makes use of the products already defined (and unused) space in height and width while ensuring that syringes, filter paper and nitrocellulose can be stored in a safe place away from dirt and dust. At the same time, the equipment is kept away from employees in the clinic that might find the equipment useful for other purposes.

The cabinet has two chambers; the upper chamber is the one that the user meets when opening the cabinet and contains the two syringes. The second chamber is hidden under the other chamber and is accessible by sliding away the holder for the syringes. It contains a holder for a roll of filter paper and space for a box of nitrocellulose pads.

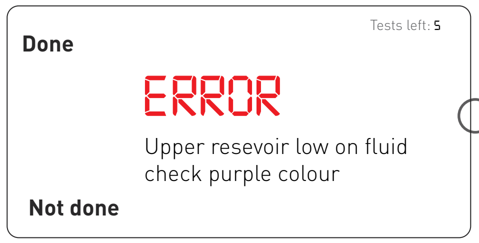

Rendering of the developed storage solution

DISPLAY
WALK-THROUGH

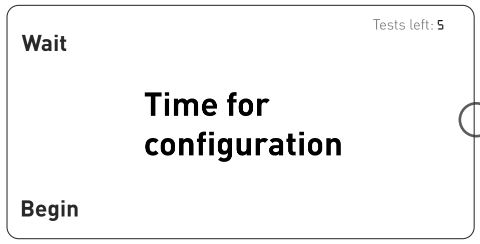
In this section we are giving an example of the intended interaction via the product's display. The interaction is characterised by forcing actions, where the user is told exactly what to do. At the same time, the user has to confirm that he has conducted the required action.
There are four buttons connected to the display: One green button with a house symbolising "Home" which leads the user to the system's front page, one red button with an arrow symbolising "Go back" in order to make it easy for the user to reverse an error, and two black buttons next to the display that the user has to use when interacting with the system.
On the opposite side we give an example of the interface the user will meet during a linear interaction process for running a test on the product.
The procedure for configuring the system is not very different and is therefore not shown, but there will be more questions that the user would have to reply "done" or "not done" to, an example of this could be: "Wetten the nitrocellulose."
Below are examples of other interfaces that the user might meet when using the product.



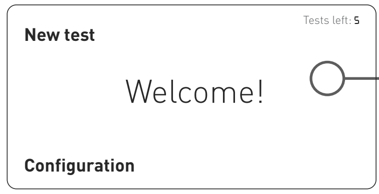
Blood glucose levels can be measured in the urine from 10 mmol/l and up. The system is not able to measure lower glucose levels than 10, but as a blood glucose level under 10 mmol/l is not critical the system will interpret it as acceptable and show a happy smiley



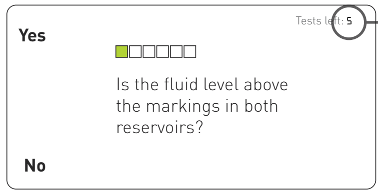
If the product detects an error, as an example that the fluid level in the upper reservoir is too low, and error sign will occur, and in this case the user will have to solve the the problem before proceeding with the test



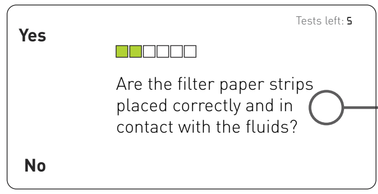
When it is time for a reconfiguration of the system this text will show up. The user will not be able to conduct more tests before the system has been reconfigured.



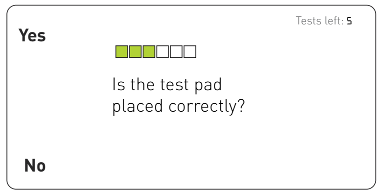
On the system's "main page" the user can decide if he wants to configure the system or run a new test

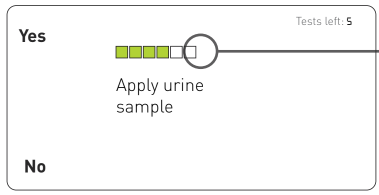


Reminder showing the user when the system needs to be reconfigured. Is shown by 5 tests left or 1 day before configuration in order to not stress the user

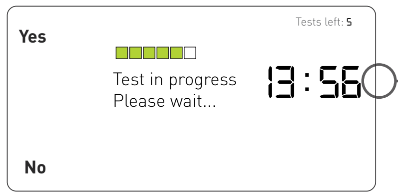


The user is forced to confirm each step in the process, by answering yes or no, in order to secure that nothing is forgotten

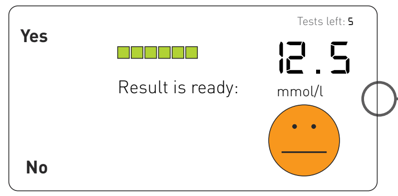




Indication showing how many steps the user needs to go through



Countdown - time left before the test result is ready



The test result (mmol/l) is supported by a smiley indicating if the result is good, not so good or bad

USER
ROUTINES

The diagrammes below map the three routines a user of our product proposal will go through when using the product.
The first routine is for running glucose tests using the product. This routine is very simple and only requires a little training why it will be possible for all staff at a clinic to go through this routine.

The second and third routines are both conducted when the system has to be reconfigured. The second routine might be a bit challenging, and we suggest that only a few "administrators" should be conducting this routine. However, the user is guided through all routines on the display in order to not rely on the user's memory.

The configuration needs to be configured every 10th day or every 50 test although the filter paper, nitrocellulose and reservoir fluids can be used up to 100-200 tests. However, the glucose oxidase has to be added for every 50 test, and we find it more user-friendly and simple for the user if everything has to be changed at the same time In addition it will be recommended to the clinics to have a weekly diabetes day as we saw on Royal Victoria Teching Hospital in Gambia. In this way it is easier to utilise the configurations to their fullest and thereby save money instead of having patients arriving with several days interval, and the configuration therefore might only be used for a few tests.

Test of glucose levels in urine

All users

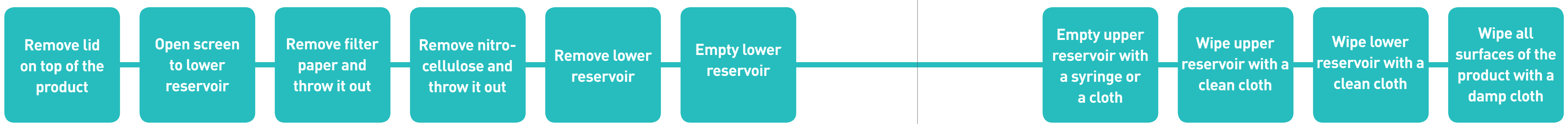
Administrators

Configuration of the system

Needs to be done every 10th day or for every 50 tests

Cleaning routine

Needs to be done before every reconfiguration of the system



FINAL PRODUCT

As a result of an integrated use of design for manufacturing and assembly the final product consist of a very small amount of parts. he parts are combined with snap solutions for quick assembling without the need of screws or spare parts.
The final product proposal consists of ten unique parts that need to be manufactured:

1. Cones (rubber)
2. Soft touch painted lid (PP)
3. Translucent screen (PP)
4. Top part (PP)
5. Main body (PP)
6. Translucent screen (PP)
7. Removable reservoir (PP)
8. Holder for syringes (PP)
9. Display and storage module (PP)
10. Bottom (PP)

IMPLEMENTATION

SWOT
ANALYSIS

Usually a SWOT analysis is used to create knowledge about new market possibilities. In this situation, however, we are using the models to clarify why potential investors should invest in the product, which gap the product fills out in the existing market and which possibilities it might open up for an investor.
The product is not designed to give away for charity; only very few products can survive using this model. In order to ensure that a product can survive it has to be a good business for everyone in the value chain. During the entire process it has been a requirement that the product is designed not only for the end user but also to make profit for the investors, e.g. regarding choice of production method.

The SWOT analysis outlines the product proposal's strengths, weaknesses, opportunities and threats and is used in order to get a broader understanding of the product's main selling points regarding potential investors. [toolbox.systime.dk]
At the same time the clarification of threats and weakness's gives the project team a chance to prevent or reduce those problems either in the actual product design or in the implementation of the product.

	S	W
Internal	- New technology - No expensive test strips - Cost for tests are cheaper and cheaper the more it is used - Very cheap compared to other blood glucose tests - Non-invasive (no break in skin) - Knowledge about local culture	- New technology - Slow measurement - Not a "snapshot" of the glucose levels in the blood
	O	**T**
External	- No competition - New market, new customer segment - New technology, possibility for further development	- Financially weak customer segment

PRICE
ESTIMATE

One of the biggest problems in developing countries is the economy, which means that many companies do not see Africa as a potential area of business and therefore do not develop products specifically for this continent: **[collections.infocollections.org]**.

> The developing countries lack access to proper medical equipment, and less than 1% of the world's production of medical equipment goes to sub-Saharan countries.

There is a need of focus on new business models with the agenda of making profit on this overlooked market in order to even out the statistics and not just focusing on charity. We see a quick return of investment as the main selling point in order to attract potential investors.

Price estimation
In order to study if the product actually has an earning capacity we have calculated a price estimation. As previously mentioned it is a good idea to start producing a smaller amount of the product in order to test it on the market and ensure that there actually is a demand for it.
On the basis of this we have made two price estimations. The first estimation is calculated from a number of 25 pieces as this is the approximately number a vacuum casting mould can produce, before a new mould is needed. The tooling price here is very low, but in return the unit cost is moderate. It is acceptable that the unit price is a bit higher than it is intended to be as this production method is intended for the process of testing and introducing the product to the market.

In the second estimation, injection moulding is chosen as the production method. Injection moulding is suitable for mass production where the high cost for tooling can be counterbalanced by a very low unit price. The second estimation is based on a number of 1000 pieces.

[collections.infocollections.org]

Both prices are estimates as many factors in the production cycle is still unknown. Therefore, the estimated production unit price prices will be multiplied with 2 in order to be on the safe side. In order to reach an actual sales price considering the manufacturer's profit the prices will be multiplied with 2,5. This gives a final price of:

First edition (vacuum casting): [collections.infocollections.org]
Material pr. unit: 0,26 x 4 = 1,04 euro
Tooling cost: (230 x 4) / 25 = 36,8 euro
[collections.infocollections.org]

Production cost pr. unit: 4,59 x 4 = 18,36 euro
Assembly cost (5 sec. pr. snap, 15 parts): 8 x 5 = 40 seconds pr. unit, work salary: 40 euro / hour ≈ 1 euro pr. unit
Total price pr. unit x 2 x 2,5: 286 euro
Included company profit: ≈ 172 euro pr. unit

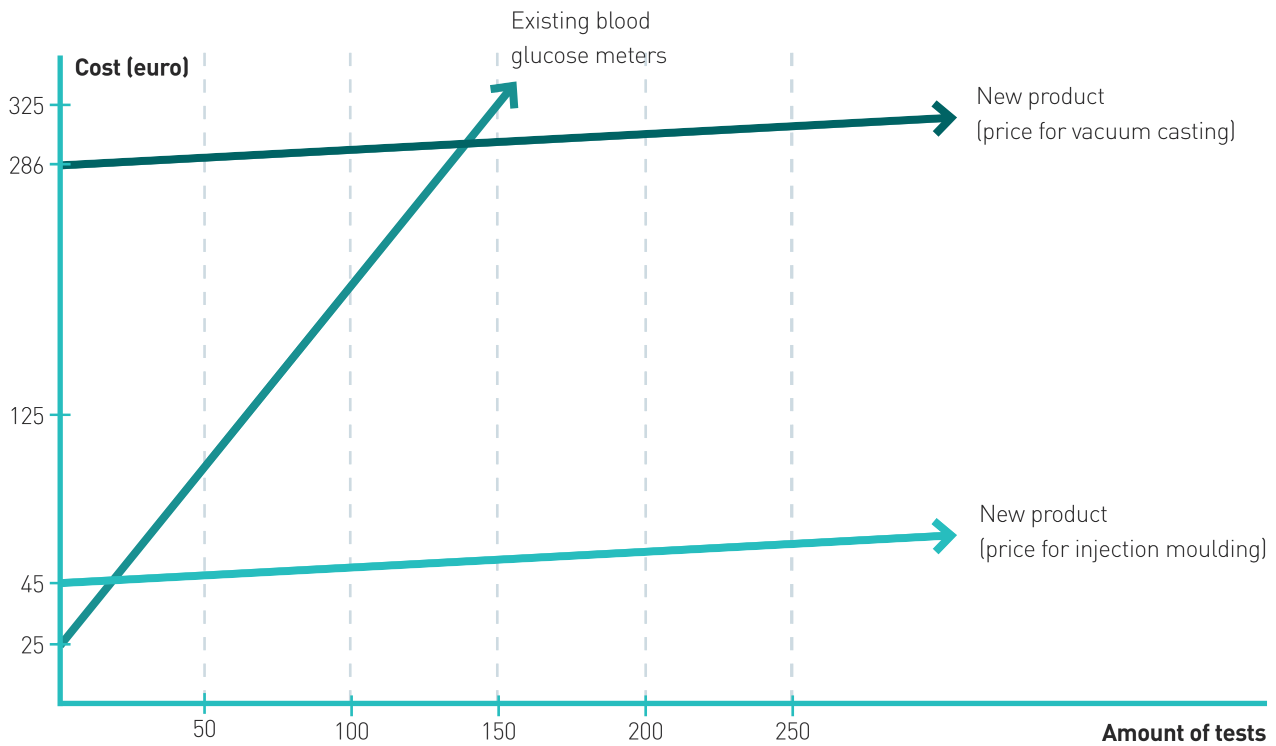
Second edition (injection moulding): [collections.infocollections.org]

Material pr. unit: 0,22 x 4 = 0,88 euro
Tooling cost: 0,313 x 4 = 1,25 euro
Production cost pr. unit: 0,44 x 4 = 1,76 euro
Assembly cost (5 sec. pr. snap, 15 parts): 8 x 5 = 40 seconds pr.unit work salary 40 euro / hour ≈ 1 euro pr. unit
Material + tooling + production + assembly = 4,89 euro
Total price pr. unit x 2 x 2,5: **24,45 euro**
Included company profit: ≈15,50 euro pr. unit

As seen above the company profit for the vacuum casted model is much higher than for the injection moulded model which raises the price more than necessary. If the company profit should be the same for the vacuum casted product as for the injected moulded product the final price of the vacuum casted product would be: 286 euro - 172 euro + 15,5 euro = **129,5 euro**.

BREAK-
EVEN

Break-even - from the clinic's point of view
In the financial aspect of the project one of the main areas of interest is to find out if our product solution actually is a profitable investment for the clinics in developing countries. Reducing the price of a single blood glucose test is one of the requirements for the product, and we are using a break-even graph to study how many tests it requires before our product solution is a more profitable investment for the clinics than the existing blood glucose meters.
The graph below (Break-even graph 1) shows the break-even from the clinic's point of view. When using the calculated prices for injection moulding and vacuum casting the product breaks even after respectively 25 tests for the injection moulded product and 150 tests for the vacuum casted (and more expensive) product.



Break-even graph 1: From the clinic's point of view

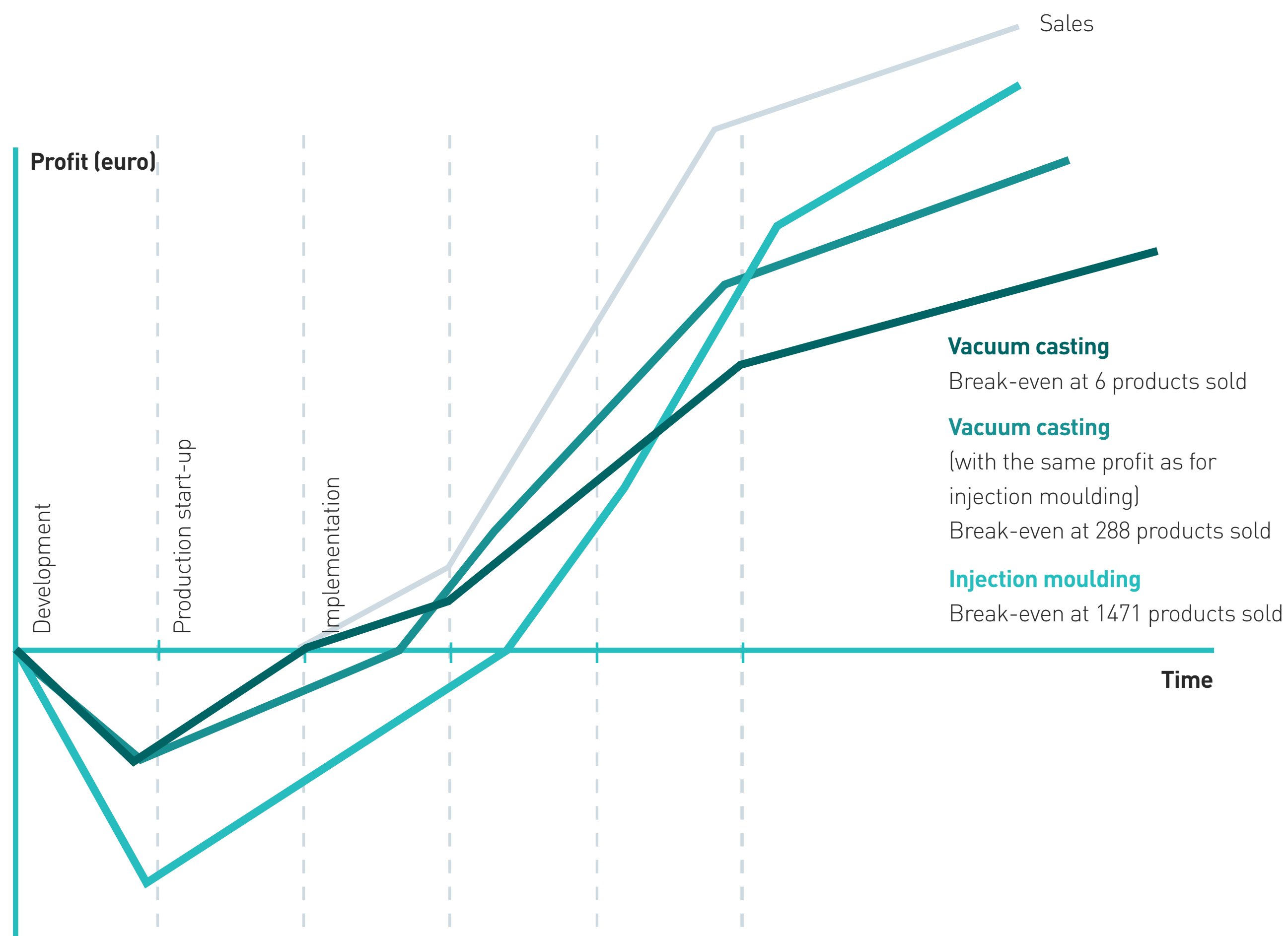
Break-even - from the investor's point of view
Another area of importance when regarding economics is to investigate if the product solution is a good investment for the investors. It is not possible for us to say how long time it will take for the graph to reach 0, which is the break-even point, as it depends on how many products will be sold within X time, therefore we have estimated how many products the investor will have to sell in order to reach zero. As the company profit is different when looking at the two different production methods we have made a calculation for each of them, but as the company profit is much higher for the vacuum casting an additional calculation is made with the vacuum casting tool expenses but with the same profit as for the injection moulding.

Break-even point for vacuum casting:
(230 * 4) / 172 = 6 sold products

Break-even point for injection moulding:
(5700 * 4) / 15,5 = 1471 sold products

Break-even point for vacuum casting
(with same profit as injection moulding):
(((230 * 4) / 25) / 15,5) * 25 = 288 sold products

The numbers and time for break-even are visualised in the break-even graph 2 below.



Break-even graph 2: From the investor's points of view

INVESTOR AND BUYER

Investors, market and competition
In order to estimate who could be interested in investing in a product like this we have looked at already existing companies within the field of medical devices for blood glucose measurements. If a company already on the market for blood glucose meters chooses to invest in this product it might open up a door to an entirely new market. A risk is that a big company would buy the rights in order to prevent a new competitor. However, we do not see our product solution as a competitor to existing blood glucose meters on the market as it is not targeting users that can afford to pay for traditional blood glucose measurements. The disadvantages of our product solution compared to existing products is the extended user interaction, slower test results and the disability of measuring blood glucose levels through the urine if they are lower than 10 mmol/l, and this targets the product against users that do not have other options because of financial limitations. Therefore, our product solution will never be able to compete with most of the existing products, but will open up for a new market where there is no alternative. The current measuring methods are very expensive, and instead of being a choice for the user between already existing products and our product solution it is a choice between our product solution or nothing.

Purchaser
As it is the government which is economically responsible for the health clinics in Senegal and Gambia today, it will also be the government that will be the purchaser of our product solution. At the moment there is a on-going discussion on a political level about how to spread the knowledge about diabetes, decentralisation of health care and the possibilities for making testing for diabetes an integrated part of health care and much more accessible than it is today. Our product solution can be seen as an important "player" in order to reach these goals because of its low cost for each test.

Our product proposal is the only product on the market for measuring blood glucose levels where the expenses for a test decreases the more the product is used. When the system is configured, the price is the same whether you run 1 or 50 tests.

When visiting Pakala Clinic in Gambia, Dr. Alieu Gaye pointed out that there is a big need for decentralisation of the diabetes care making it an integrated part of health care in general. In that way, the knowledge about diabetes will also spread. But it is not only in Gambia that diabetes is looked upon from a political level.
A more detailed insight into the strategy against diabetes can be found in 'The African Diabetes Declaration' developed by International Diabetes Federation (IDF), World Health Organisation (WHO) and the African Union. The declaration is a strategy targeting everyone from governments of African countries to the individual diabetics, and the mission is to **provide access to quality and affordable services for the prevention and care of diabetes.**

Knowing that the government in Gambia and international organisations are focusing on diabetes and calls for action now might open up doors for our product proposal as it is designed to make testing for diabetes and regular monitorings of blood glucose levels cheaper and more accessible in developing countries.

OUTRO

CONCLUSION

Based on field studies conducted at clinics and hospitals in Senegal and Gambia we have developed a medical device for cheaper and more accessible testing for diabetes and regular monitorings of blood glucose levels. Combined with incorporating a new electrochemical system and cooperation with one of the developers of the system, Jan Lankelma from VU University, Amsterdam, the project and the product proposal is characterised by very technical analytical methods combined with a user-oriented design process focusing on the development of a medical device fulfilling a serious gap in the health system in developing countries while meeting the specific requirements of clinics and users in this context. We have actively worked with the requirements throughout the ideation and development phases in order to ensure a correlation between the problems we experienced in Africa and our final product proposal.
This has resulted in a product that meets the requirements, not only by lowering the price of a single diabetes test significantly for both the clinic and the patient, but also a product that has the potential of becoming a profitable investment for manufacturers or investors. An important aspect ensuring this is our integrated work with design for manufacturing and assembly. We found this significantly important because developing countries are not commonly seen upon as a potential market for business, and in order to convince potential investors to put their money into a project like this we found that a quick return of investment is a very important factor. This strategy is incorporated into the product through our choice of manufacturing methods.

We believe that we have designed a product that has an actual potential of making a difference to a widespread and very serious problem by contributing to cheaper and more accessible diabetes tests, not only in Senegal and Gambia, but in all developing countries.

Requirements	D+
→ The product and its vital parts should be protected against dust and dirt	√
→ The product should not depend on extra supplies that are expensive and/or difficult to get	√
→ The product should be as cheap as possible	√
→ The components of the product should, as far possible, be easy and cheap to repair or replace	√
→ The product should not contribute to creating more mess in the physical environment	√
→ The product should be adapted to a humid and warm climate	√
→ The product should not use disposable test strips	√
→ The product should contribute to making diabetes tests and monitoring of blood glucose levels more accessible and widespread	√
→ The price of a single test should be lower than 2 $	√
→ The product should be easy to clean	√
→ The product should be easy to operate for both educated and uneducated staff	√
→ Instruction material should be as simple and visual as possible	√
→ The product should not rely on the user's memory	√
→ Interaction with the product should not rely on vigilance	√
→ Interaction with the product should be intuitive and natural	√
→ Interaction with the product should not rely on the user's memory	√
→ Interaction with the product should be characterized by forcing functions	√
→ It should be easy to reverse an error	√

REFLECTION

From the very beginning of the project we had to make an important decision. A decision between cooperating with a company or following our own wishes for an interesting project. Even though working with a company offers many possibilities in the form of real life experience with customer needs and requirements plus important contacts, we both found it difficult to reject the opportunity of pursuing the project we have always wanted to work with and to have the opportunity of really exploring and using field studies in a completely different context than the one we normally work within. This choice gave us the possibility of focusing 100% on the problem, and instead of a company with its own interests in mind the problem was the controlling factor in our project. This total focus on the problem has both been very interesting to work with and given an extra dimension to the problem. At the same time it means that there have not been any limitations besides the ones we have drawn ourselves, and in retrospect we were not good enough at limiting the project from the very beginning because of our own enthusiasm towards working within this exciting problem area.

Another aspect that has made limitations difficult is the mixture of micro and macro data we have worked within. Prior to our fieldtrip to Africa we conducted a lot of desk research and investigated a lot about diabetes in general and about the overall situation in Africa, about what other researchers find necessary and about needs and requirements when designing for developing countries. This mixture of micro and macro data ended up confusing us as we had opened up for a lot of theories etc., and it was difficult to narrow down and find focus as we wanted to incorporate as much aspects as possible.
We decided to (almost) forget about the macro data and focus 100% on the data we had collected ourselves, and this helped us a lot in the further process.

The vision of keeping costs as low as possible has made us make many compromises along the way. Throughout the entire process it has always been a choice between the ideal solution and the realistic (and cheaper) solution. It has been very educational to work under these constraints where you have to make the best of very limited resources. It has learned us a lot about production and integrating production and assembling processes very early in the design and development of a product. In this project manufacturing and assembly is a part of the product's "DNA".
Another very educational aspect has been to work with the incorporation of an electrochemical system. Prior to the project we knew almost nothing about electrochemistry, but consistency and a willing to learn it to our fingertips brought us into contact with the scientists behind the electrochemical system. We have had very interesting correspondences with the scientists from VU Amsterdam, and it has been an eye opener for us to experience that they were very interested in the micro data we have collected to use in the optimisation and further development of the measuring method.

PERSPECTIVE

The product proposal is designed to meet problems found in Senegal and Gambia, but the problem about diabetes, poor people and expensive diabetes testing is worldwide. Therefore it is likely that the final product has the possibilities to reach much further, not only in Africa but also to India and the rest of south/east Asia, the Middle East and South America where diabetes in developing countries is an increasing problem. Thereby the product has a potential of reaching out to a potentially very big, worldwide market.

Right now, the scientists behind the electrochemical system are working on optimising the system, and an additional advantage of the product is that it has the possibilities to also being able to measure other contents than glucose in urine, e.g. cholesterol. This is possible by using other enzymes than glucose oxidase, as an example cholesterol oxidase or lactate oxidase. Additionally it is also possible to measure these things through blood for a more precise result. This development would make the product versatile for more general clinical use, which would mean that the local clinics would have many more possibilities of testing their patients than they have today, and the patients would have better chances to get tested for many other things as they would not only avoid paying for the transport to clinics in the bigger cities, but also get the test much cheaper than today.
This possible development, though, is not only an advantage for the health clinics as the product with development also will be able to measure water quality by using anodic stripping voltammetry, and thereby help villages avoid severe problems as a results of contaminated water. Thereby, there are great future possibilities for the further development of the electrochemical system and for development of products incorporating these extra features.

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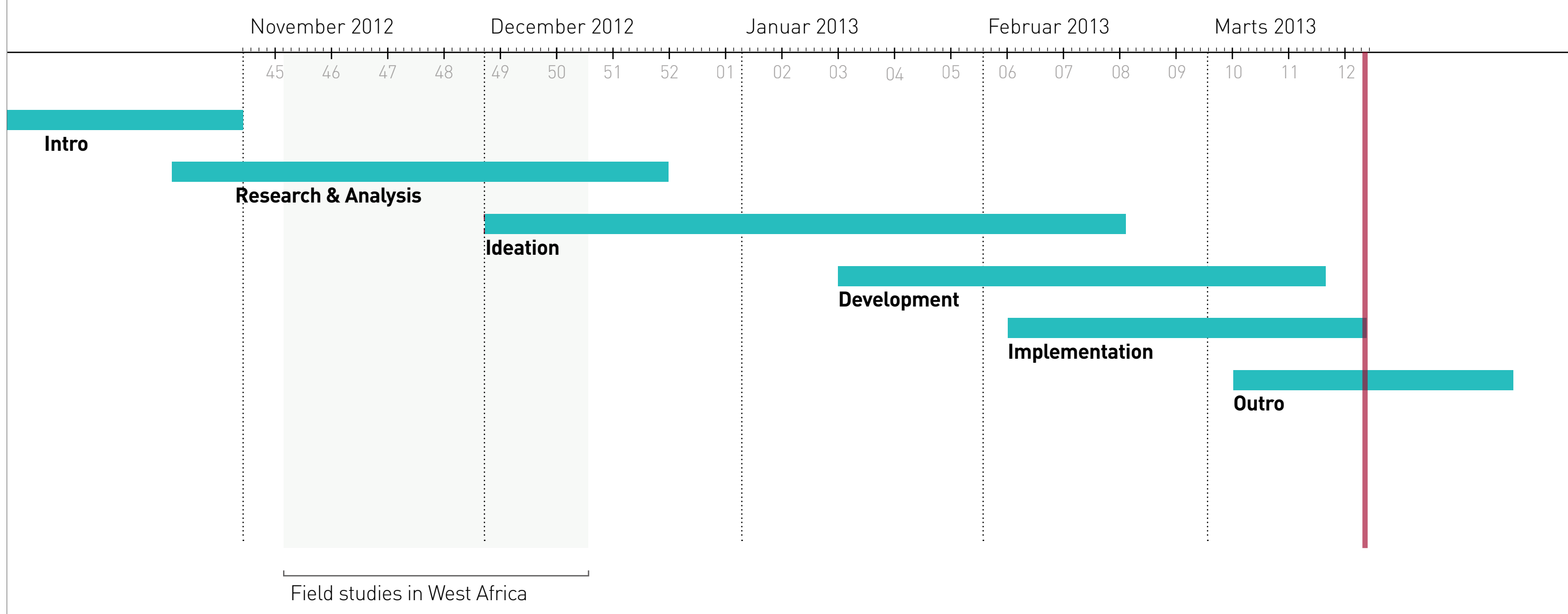
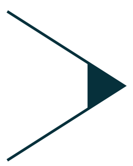
APPENDIX

PROCESS AND PLANNING

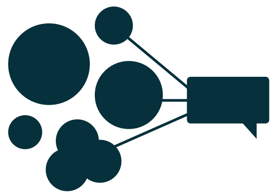
This section describes the overall planning of the project and process. In the report, the process appears as a linear process in order to simplify the communication, but in reality the process is organic and iterative with overlapping phases.
The process is divided into six different phases helping in the planning and management of the process. The illustration shows the phases in a time schedule managing and visualising the planning and process. Below is a short description of each phase of the project.





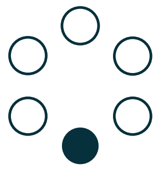
1. Intro

The first phase is about identifying the project's field and theme as well as planning and creating a common understanding of the project among the project team.



2. Research and Analysis

Research and analysis focuses on gathering empirical data and information about the project's theme and using this knowledge in the process of defining a problem statement and developing design criteria forming the basis of the project.



3. Ideation

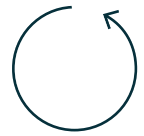
Ideation is about generating ideas and concepts based on the design criteria and knowledge obtained in the previous phase. Selected concepts will be explored, tested and evaluated on the basis of the design criteria resulting in a final, well-defined concept and a product specification.

4. Development

In the development phase the chosen concept is developed into a detailed solution based on the design criteria and product specification, focusing on an integrated design process.

5. Implementation

Implementation focuses on the factors relevant in the process of realising the project and bringing it into its supposed context.



6. Outro

The last phase is not a direct part of the design process and development and is characterized by a reflecting and discussing approach to the project and process.

THEORETICAL FRAME-WORK

The purpose of having a theoretical framework is to define the skeleton of the project based on the project's theoretical approach to design.

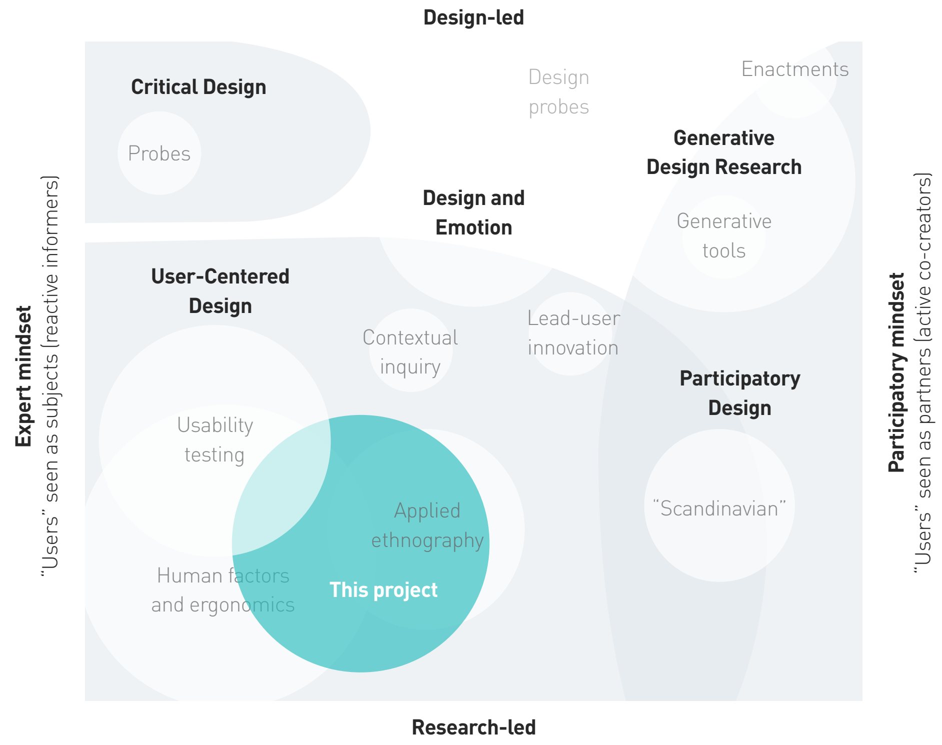
What is user-centered design and why use it?
User-centered design has during the last couple of decades developed into a popular way of working and thinking within the design industry. The essence of user-centered design is to work on identifying and analysing the end user's needs and problems and actively use this obtained knowledge in the process of developing and designing appropriate and relevant solutions. (Liem and Sanders, 2011)

> **Understanding people and their needs, desires, abilities, contexts, and cultures is a necessity when developing useful, desirable, and valuable products; we cannot rely on "lucky punches".**
>
> (Søren Bolvig - http://ludinno.wikispaces.com/file/view/video+as+designmaterial.ppt.pdf)

In user-centered design, field studies are often used as the primary way of getting to know the users and their needs, because observing and talking to the users in their own context makes the users feel more comfortable and makes observations more realistic. According to Arnold Wasserman, in-depth knowledge about the users not only creates extra value for the users; it also contributes to developing products that have a higher chance of succeeding on the market:

> **Design based on field research tends to foster better solutions to design problems and it reduces the risk of the product failing on the market.**
>
> (Arnold Wasserman, 2004)

In order to define the project's approach to design, Liz Sanders design landscape is used as a tool. The illustration shows the positioning of the project which is research-led and a bit closer to 'participatory mindset' than 'expert mindset' because of a decision of involving the users in relevant parts of the process. The project is positioned within the field of user-centered design focusing on applied ethnography.



Ethnography in design
Ethnography is a qualitative research method used to describe cultures and cultural differences. The ethnographic method is gathering and interpretation of information based on intensive, first-hand study of a particular culture, (Doing Cultural Anthropology, http://fasnafan.tripod.com/anthroresearch.pdf p. 19) and ethnographic methods are often used when conducting field studies in design projects. However, there are some major differences in the use of ethnographic methods relative to whether you are an ethnographer or a designer (McCleverty, 1997):

These differences are important to keep in mind during the field studies as the role of a designer and an ethnographer are not the same; neither is the desired output of field studies. While the ethnographer aims to become one with the people he studies, the designer has to operate simultaneously both as an insider and as an outsider (Sperschneider and Bagger, p. 42) and find the balance here.
In this project, specific ethnographic methods will be used actively during the field studies as helping tools in the process of defining problems and needs in the chosen context.

Ethnographer
Looks for generalities
Concerned with analysis
Avoids making judgments
Prolonged activity

Designer
Looks for specifics
Concerned with synthesis
Required to make judgments
Requires information quickly

DIABETES IN AFRICA

1. Transition | **2. Double burden of chronic and infectious disease** | **3. Health system's infrastructure** | **4. Earlier age at onset of diabetes** | **5. Access to medications** | **6. Cultural beliefs**

Diabetes in developed countries and diabetes in Africa cannot be compared in all respects. According to the report 'The African Diabetes Declaration and Strategy' developed by International Diabetes Federation (IDF), WHO and the African Union, there are six steps forming the difference: Transition, Double burden of chronic and infectious disease, Health system's infrastructure/delivery of health care, Earlier age at onset of diabetes, Access to medications and Cultural beliefs. In this section, the six steps described in the report will be elaborated in order to get an overall understanding of the extra challenges diabetes causes in the context of Africa and in order to start focusing on an initial problem area. (http://www.idf.org/webdata/docs/Diabetes%20Declaration%20&%20Strategy%20for%20Africa_full.pdf p. 21-22)

1. Transition
While most countries have developed from hunter-gatherer to agriculture based societies, from agriculture based to industrialized societies and from industrialization to globalization over a period of time, Africa is experiencing all three socio-economic stages simultaneously. This situation is very complex, and the evolving economies are threatened by the pressure that chronic diseases like diabetes put on the health systems.

2. Double burden of chronic and infectious diseases
Most health initiatives in Africa have focused on coping with communicable diseases like malaria, HIV/AIDS, and tuberculosis, and the rising burden of chronic and non-communicable diseases like diabetes now causes a double burden on the African health systems that they are not built to cope with.

3. Health system's infrastructure/delivery of health care
In Africa, most health services have been developed for reactive rather than proactive reasons and are characterized by an unsystematic approach, and there are many factors influencing the delivery of health care. One factor is that patient attendance is very low caused by lack of money and poor infrastructure. The absence of free health care in many countries places an economic burden on many patients and their families, and places for treatment of diabetes are only present in the biggest cities.

Another problem is that consultation times are very short, leaving no time for educating the individual patient. Patient education is generally rare and not an integrated part of health systems, although it is essential when focusing on diabetes patients. Education is also a problem among the staff that in many cases need training, and there is not enough staff available. Furthermore, the way complications are handled and monitored is not systematised, and the control of glucose and blood pressure is poor.

4. Earlier age at onset of diabetes
Estimations show that the biggest group of people developing diabetes by the year 2025 is the younger age groups, which will burden the health system even more because of the fact that there is more time to develop complications. People dying prematurely put pressure on both families and societies.

5. Access to medications
The availability of medications in sub-Saharan Africa is not stable, and even larger hospitals have problems getting for instance insulin. At the same time, prices at the private outlets are unaffordable for most people in the region, and prices vary dramatically from country to country.

6. Cultural beliefs
The traditional belief in rural and less educated areas is that a person with diabetes is bewitched. At the same time, people believe more in traditional healers than in medical doctors, and most people would consult a traditional healer before going to a hospital if they are sick. Another problem is overweight, which in some areas is seen as a symbol of status and wealth. This is a big problem in for instance the treatment of type 2 diabetes, where people often are advised to lose weight and change eating habits in order to control the disease.

Output
The six steps from 'The African Diabetes Declaration and Strategy' provide an understanding of the overall challenges sub-Saharan Africa is dealing with in relation to diabetes.
It is clear that it is a very complex area to work within, and there are many influencing factors to consider.