SODOS

Smart Optical Diagnostics Of Schistosomiasis

Master thesis by Mirte Vendel

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The EC,

A device to diagnose urinary schistosomiasis in Ghana,
designed for local facilities as well as large-scale community screening.

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EC
1
Turn on device
2
Check battery level
If empty, place solar panel in the sun
Press start
3
Shake sample
Pour in funnel on top
4
Wait until the device is finished
5
Check the result on the screen
RESULT
Write down the result
6
Place cleaning tube on top
Fill with water
7
Turn off the device
RESULT: 22 EGGS

Preface

This project was one of the best experiences within my master. Not only did I got the chance to go to Ghana, I got the opportunity to work together with so many enthusiastic, inspiring and supportive people. I would like say *thank you* to all of you who have helped and encouraged me along the way.

First of all to JC, my supervisor, for the great opportunity to explore such a beautiful country as part of my graduation. And for all the inspiration and guidance throughout the project. You always seemed to know when I needed support or someone to think with me.

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Thanks to Kim for reading through so many pages and to all my friends who made my tea breaks the best breaks of the day. Thanks to Marije, Jozine, Louise, Emma, Lot, Rebekka, Cheron for participating in my sessions, thinking with me or helping me out when I needed it. And especially to Jozine and Rebekka, for spending hours with me to fix a completely crashed InDesign file.

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Thank you so much and I hope you enjoy reading this report!

Executive summary

This report is the result of a graduation project about Schistosomiasis, a neglected tropical disease caused by the Schistosoma parasite. And about a new technology to detect the parasitic infections. More specifically, to detect the urinary Schistosoma type, called *S. haematobium*.

Within Africa, a large number of countries are affected by this parasite. The transmission happens via water and is almost impossible to stagnate. It influences children and adults by reducing their ability to grow, learn or work on full capacity. Both the economy and living conditions of entire communities suffer from this worm, which lays its eggs in the human bladder.

Ghana is an example of an endemic country in which the entire population is at risk of infection. By the support of the government, they have established a nationwide control programme, with annual Mass Drug Administration (MDA) in all the high risk areas to control the morbidity. Ghana was therefore selected as main scope within this project.

The new technology detects the parasitic infection by counting the number of eggs in urine samples. This new technology is faster, easier and more reliable than current methods and able to add value for different types of users. A literature study and three weeks of user research in Ghana revealed the diagnostic needs of five user groups: researchers, control programmes, urban hospitals and rural health facilities in low and high endemic areas.

The greatest value can be added for researchers and rural health facilities and a product is designed to fit the main requirements of both user groups. This resulted in a main product (The EC) and an additional application on a tablet for the researchers.

The product is easy to use and maintain for remote facilities. Those areas are confronted with a lack of resources and specialist. The new product enables lower educated people to execute diagnoses and takes away the need for specific medical equipment.

For researchers, the additional application will facilitate digitalised data collection. The product is robust and portable as the researchers will take it with them on field trips, for large-scale community screening. The product will be much faster than the current procedures, saving a lot of time in the field and thereby money.

The EC is designed for Ghana, with a side focus on Nigeria. With some small adjustments and a slightly different implementation plan, the same product can serve these different countries.

The report will end with the recommendations needed to further develop and scale this product until it is suitable for implementation in the other endemic countries.

Glossary

CVD	Context Variation by Design
GHS	Ghana Health Service
HC	Health Centre
MDA	Mass Drug Administration
NTD	Neglected Tropical Disease
NTDP	Neglected Tropical Disease Programme
PC	Preventive Chemotherapy
WHO	World Health Organisation

Content

Introduction

Main goal

"Define a diagnostic purpose for a new, smart, sensitive and affordable technology to diagnose the S. haematobium infection. And design a product to facilitate this desired use."

This report will share the results of a graduation project of the master Integrated Product Design of the faculty of Industrial Design Engineering at the TU Delft. The project dives into the diagnoses of schistosomiasis, a neglected tropical disease caused by the Schistosoma parasite. This parasitic worm has contaminated a tremendous amount of water sources in (sub)tropical countries all over the world. Over 200 million people are infected and more than 700 million people are at risk of the spreading disease [85]. The infection does not necessarily kill the human host, but comes with chronic health complications, reduced ability to learn or grow and hereby significantly decreases the development and living standards of entire communities.

This report will address one major problem in the current fight against the parasite: the diagnoses. The project is established and executed in cooperation with the Leiden University Medical Centre (LUMC) and the faculty of Mechanical Engineering at the Delft University of Technology (TU Delft). The LUMC, and in particular Dr. A.S. Amoah, has been involved as medical expert and client, due to the extended research experience on schistosomiasis as well as the involvement in a large number of diagnostic research projects in rural areas of several (African) countries.

The department of Mechanical Engineering is currently developing a new technology to detect the parasitic infections. The technology uses a smart optical mechanism to detect parasitic eggs (ova) in the patient's urine.

Technical performance

Figure 1 show a simplistic illustration of the basic elements in this technology. A urine sample will be poured in the device, where it flows through a small tube towards the part where an optical construction is able to detect the shapes of any particle inside the urine (e.g. the ova). An algorithm shall be able to distinguish the eggs from other particles inside the liquid and even from the different Schistosoma types. Hereby, the number of eggs per sample entry will be counted in order to detect infections as well as to define the infection severity.

In contrast to currently available technologies, this device will enable affordable though sensitive testing within a reduced amount of time due to the smart and (semi) automatic mechanism. The technology is being developed parallel to this project and the exact specifications are not yet known, but the following information is available:

- The technique recognises the shapes of the particles in the urine, not the colours. If ova lay on top of each other, the shape might be difficult to detect. So, the device will not reach a 100% sensitivity rate, but a sensitivity of at least 95% is feasible.
- Eggs can get stuck to the walls (e.g. in the tube) or any other surface the urine gets in contact with. Parts that touch the urine during the test must be cleaned or replaced after each sample.
- Detecting and calculating the amount of eggs in the sample, will take about 2 to 3 minutes.

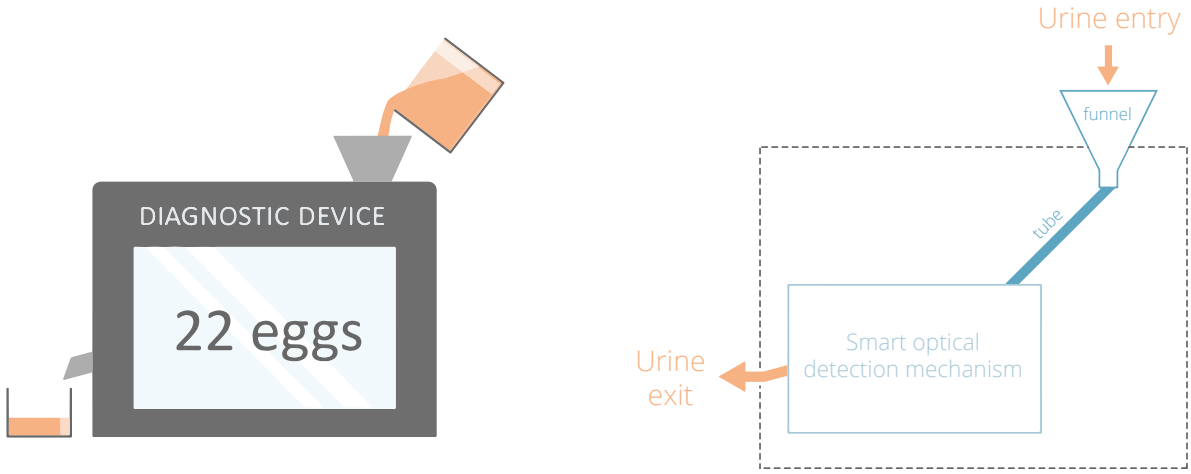


Figure 1. Basic principle

Project setup

The main goal of the project was to define the context and potential users who would benefit from this new diagnostic technology. And to design a product around the diagnostic mechanism to facilitate the desired use and enables successful implementation in rural Africa. To achieve this goal, the project was divided in three parts.

1. Background analysis
A background analysis is conducted to create an overview of the parasite itself, its impact, current diagnostic matters and the different purposes diagnoses can fulfil. The main goal of this part is to create a set of design criteria for the technology.

2. Context exploration and user research
The initial focus is laid upon Ghana and a literature as well as a field research is conducted to define the potential users in Ghana and their desires. The main goal of this second part is to define the final target group and create an extended programme of requirements for the final product development.

3. Product development
Based upon the collected knowledge in part 1 and 2, the final part will focus on the product design itself. The product interaction, design features and product casing will be development and evaluated on feasibility as well as implementation opportunities.

The decisions upon the final interaction will add extra requirements for the technical performance. As the technology is still under development, it is possible to adapt extra functionalities and features to the mechanism. However, the possibilities of the technology are finite and there are always limitations to consider. Throughout the whole project, several reflective meetings were organised with the department of Mechanical Engineering to validate the feasibility of the desired functions. For example material choice, cleaning procedures, processing speed and sample volumes. This assured deliberate decision making about the features of the final device.

Research questions

The first two project parts are meant to collect all the information, needed to develop a product to suit the context, the user and the diagnostic requirements, to enable an improvement of the current situation and create significant added value. In order to collect enough information, the following research questions were set as directive guidelines in the research phase:

Part 1

RQ1. *What is the current situation?*
RQ2. *What are the technical requirements for a new diagnostic technology to improve the current situation?*

RQ3. *Who is the foreseen end user?*

Part 2

RQ4. *What are the functional requirements for the new product in order to fulfil the needs of the end user(s)?*
RQ5. *What product interaction matches the habits, skills and desires of the end user(s)?*
RQ6. *What product features and qualities does the design has to fulfil?*
RQ7. *What are the key requirements for successful implementation?*

Each question is further specified with several sub questions, which can be found in appendix A. The questions will be answered throughout the first two parts of the project and part 3 will use the collected knowledge to design the functions, interaction, features and qualities of a the final diagnostic product in order to work towards successful implementation of the new technology in the targeted context.

PART 1

Schistosomiasis

Background analysis

Introduction

In this first part of the project, a literature review is conducted on the Schistosoma parasite. An analysis is done on the parasite itself, the symptoms in case of human infections and the available medication.

The worldwide impact is explored together with the (global) effort and approaches to get the disease under control. The role of diagnoses and the currently used techniques are discussed together with a set of important diagnostic qualities.

The purpose of this analysis is to understand the current problems and context around the disease (research question 1), in order to define the desired purpose and set goals for the new diagnostic technology (research question 2). As an addition, the findings are used to determine a possible project focus. Part 2 will further explore these potential users (research question 3).

Source: Africa.com (n.d.)

1 The Schistosoma parasite

This chapter will introduce the Schistosoma family and their unfortunate way of reproduction via human infection, to create a better understanding of the symptoms, the diagnostic challenges and the difficulties in the disease control.

1.1 The Schistosoma family

Within the Schistosoma family, there are different types of Schistosoma parasites. Some are only threatening animals. When these parasites infect humans, the symptoms are limited to some rash [31]. However, the five following Schistosoma types [82] are actually dangerous for humans:

1. Schistosoma haematobium (*S. haematobium*)
2. Schistosoma mansoni (*S. mansoni*)
3. Schistosoma japonicum (*S. japonicum*)
4. Schistosoma intercalatum (*S. intercalatum*)
5. Schistosoma mekongi (*S. mekongi*)

The *S. haematobium* is a urinary parasite, locating itself in the bladder [82], while the other four types are all intestinal. When infected, the parasite lays its eggs (ova) inside your body. Due to the different locations, urinary and intestinal schistosomiasis have slightly different symptoms requiring various diagnostic procedures. In case of a *S. haematobium* infection, a part of the ova leaves the body via urination. While the eggs of the four intestinal parasites will appear in the stool. Consequently, the parasitic infection can be identified by detecting the specific ova in either the stool or urine [15].

Figure 2 shows ova of the most common species (i.e. *S. haematobium* and *S. mansoni*) [31]. As can be seen in the picture, the ova of the parasites differ from shape, some are more rounded or elongated than others, and all types have a unique spine (terminal or lateral), making it possible to distinguish the different types of eggs.

1.2 Worldwide prevalence

Figure 3 shows an overview of the worldwide measured prevalence of schistosomiasis, revealing the highest prevalence in (Sub-Saharan) Africa. Figure 4 specifies this information, by showing the distribution of the specific type of the Schistosoma family.

As mentioned in the introduction, this project is about an optical diagnostic technology to count the eggs in urine. Since the *S. haematobium* can be found by examining urine samples this research will be centred around this urinary parasite. The *S. haematobium* is present in parts of Africa, the Middle East and in Corsica [12][14][82] and often shares the endemic areas with *S. mansoni* infections (figure 4)

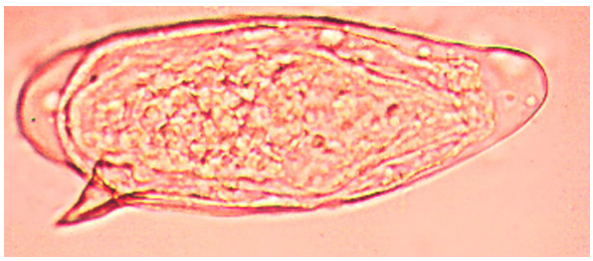


Figure 2a. S. mansoni egg

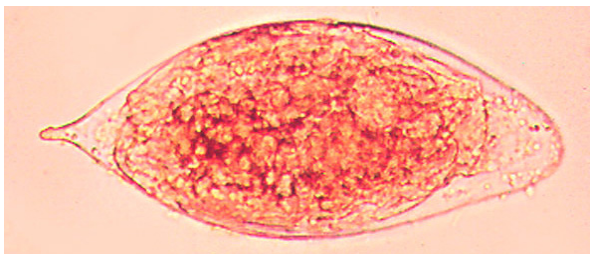


Figure 2b. S. haematobium egg

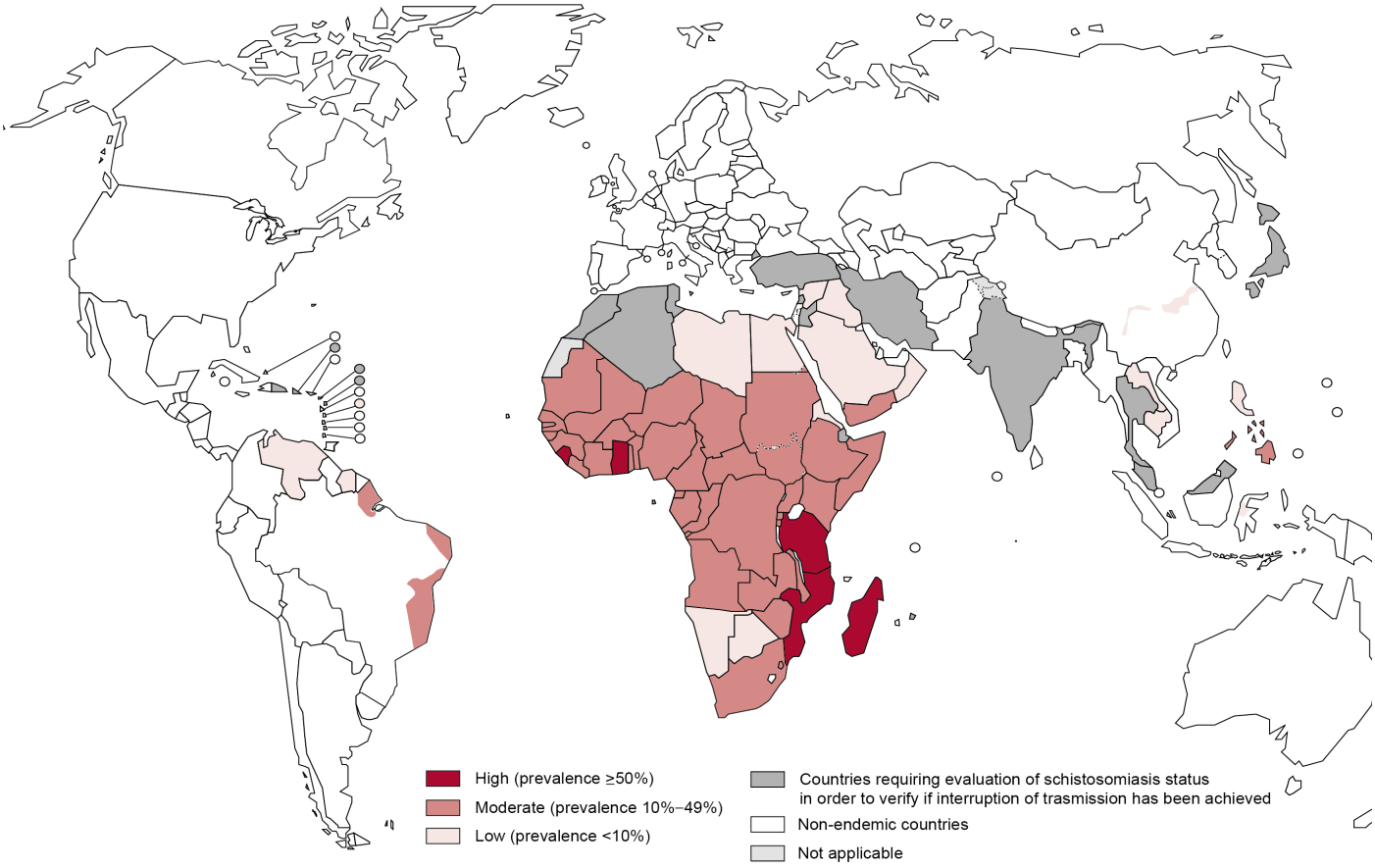


Figure 3. Worldwide prevalence in 2012 [79]

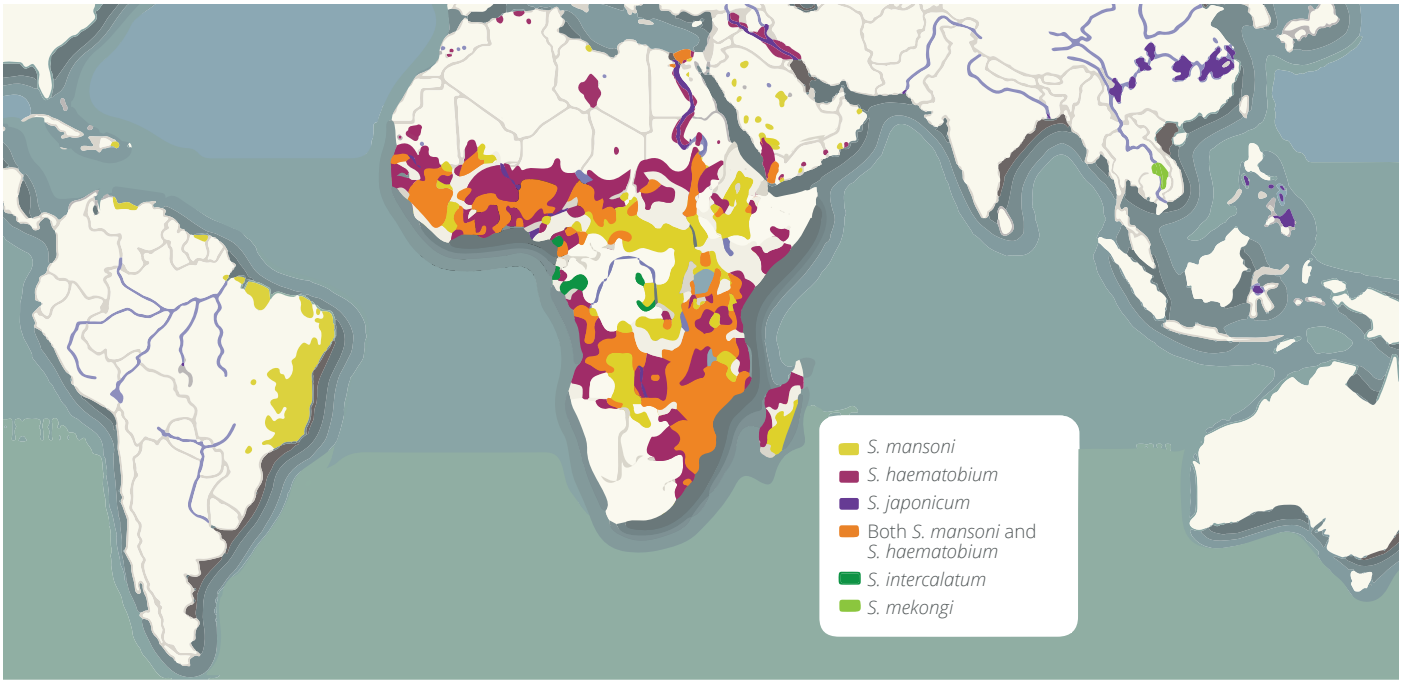


Figure 4. Schistosoma types

1.3 Life cycle

Figure 5 shows the life cycle of the *S. haematobium* parasite. The ova and cercariae can only survive in fresh water [44] within a temperature range of 18°C to 33°C [24], making lakes and rivers of (sub) tropical countries the perfect breeding ground for the water borne *S. haematobium* [84].

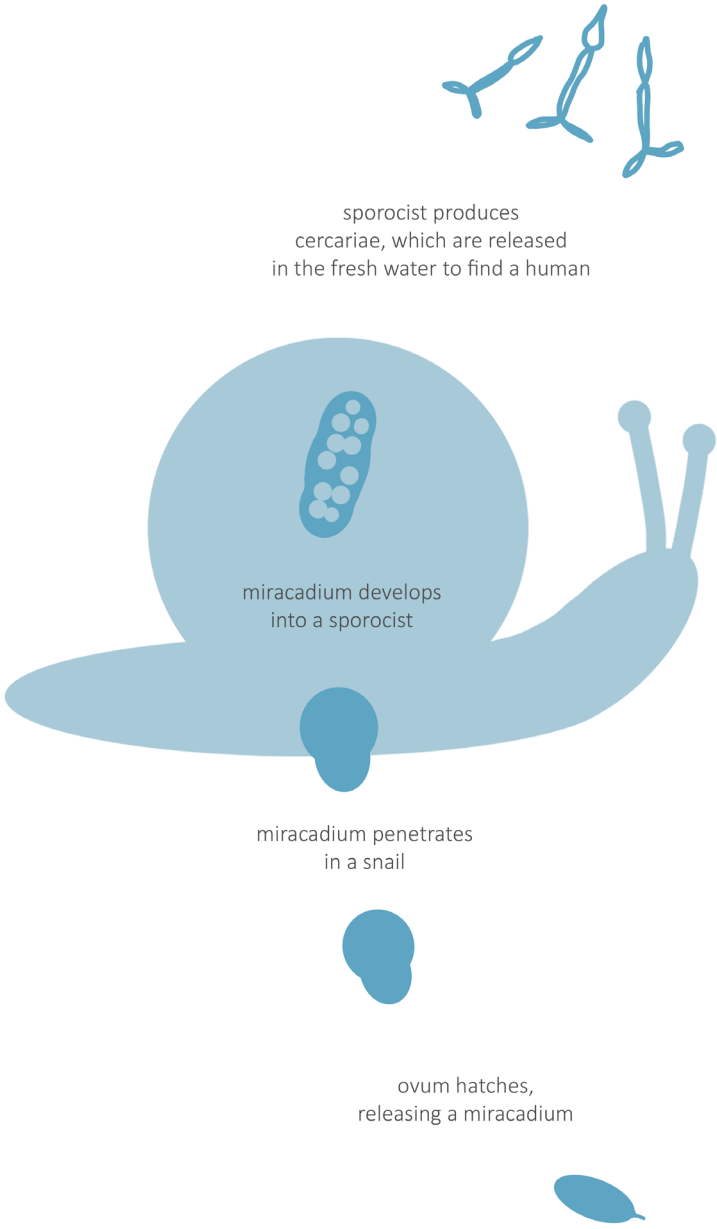
The parasite's ova need a specific type of snail as an intermediate host to produce the infective cercariae. The required snail differs per Schistosoma species and the urinary parasite needs the Bulinus snail, who preferably lives in between 22°C till 26°C (The European Centre for Disease Prevention and Control [24], which matches the sub tropical living environment of the parasite.

Someone can get infected by touching the contaminated water. When the cercariae penetrate the skin, the schistosomae migrate through the body, mature in the liver and finally settle in the bladder. In here the worms start to produce a significant number of eggs which partly end up in the urine. In case of inadequate sanitation [85] the urine can get in contact with the important water sources causing further contamination. When this life cycle (figure 5) is not interrupted, endemic areas are created threatening the health and development of local communities.

1.4 People at risk

Within contaminated areas, frequent water contact can get people (re)infected on daily basis. The parasite can easily survive up to decades in the human bladder (keeping the infection active). And each time someone enters the water, more cercariae penetrate the skin increasing the intensity of the infection.

Groups at risk are for example young children who play in the water, women washing the clothes, fishermen or those working full days in rice fields [82]. School-aged children (5 – 15 years) are identified to be at the highest risk of infection [58] and are therefore the main target group of most national control programmes. These programmes execute mass drugs administration (MDA), providing medication for the high risk population [58]. Unfortunately, after treatment, people can easily get re-infected and the infection cycle then remains uninterrupted. More about the impact, risks and control effort will be discussed in the following chapters.



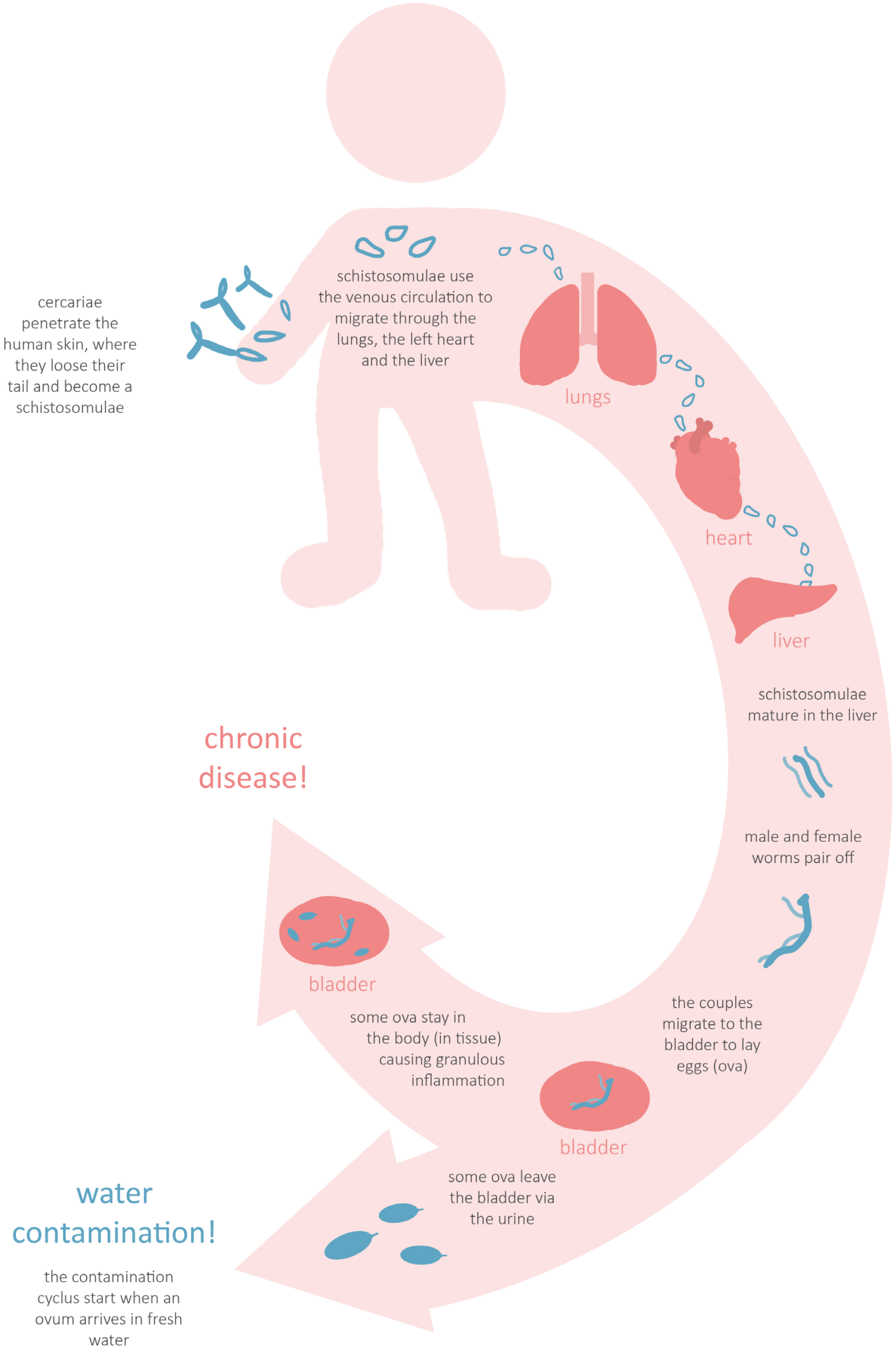


Figure 5. Life cycle S. haematobium
Sources: [24][31][33][42][70]

2 Symptoms and impact

The urinary disease has a broad range of possible symptoms and each person can react differently on the parasite. The symptoms can be divided in three phases [70]. As shown in figure 6 all connected to another part in the parasite's life cycle *[12][31][33][35][70]*.

Phase 1. Cercarial dermatitis
A reaction of the skin on the penetrating cercariae.

Phase 2. Katayama fever
An allergic reaction on the migrating schistosomulae within the longs, heart or liver.

Phase 3. Chronic infection
Granulomatous inflammation in the tissue due to an allergic reaction on the eggs production.

Not everybody will experience or notice all three phases and some people are even asymptomatic [16]. Werf et al. (2003) estimated that only 60–63% of the infected individuals experience the symptoms, making it difficult to discover infections in an early stage.

Besides, the severity of the symptoms depends on the sensitivity of the immune system and the amount of parasites inside the body (heaviness of the infection). The reaction on the penetrated worms varies not only per person, but also per age [35] and it changes after a first infection [35].

This chapter will discuss the possible symptoms of an *S. haematobium* infection in all three phases as well as the worldwide impact of this parasite.

2.1 Cercarial dermatitis

This phase consist of a skin reaction, starting at the moment the cercariae penetrates the skin [31]. At initial exposure a mild skin reaction might appear almost directly or within several hours after infection, like a prickling or irritating feeling on your skin [35], sometimes followed up by a skin rash within several days [33] [70].

During following exposures the immune system is able to recognise and attack the penetrating parasites. Those schistosomulae, effectively eliminated by the defence, end up dead underneath the skin. This causes a more severe skin rash compared to the first exposure [37]. This dermatic reaction is characterised by a reddish skin, itchy bumps, vesicles or swellings [35].

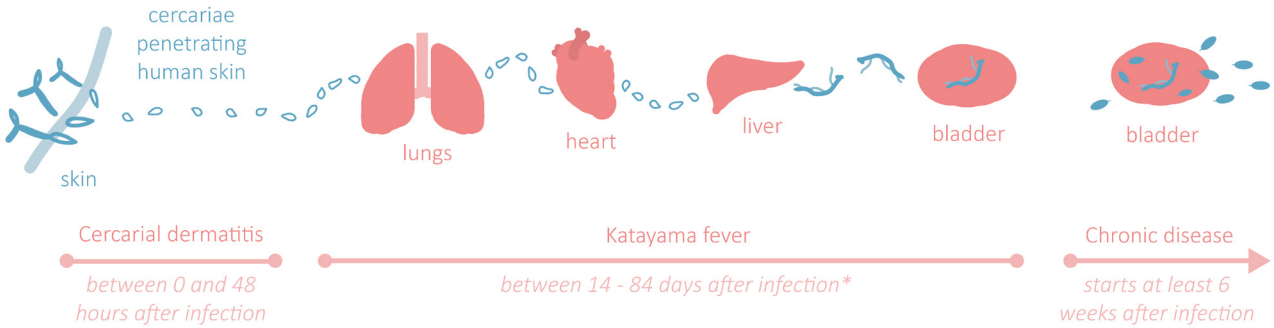
2.2 Katayama fever

When the schistosomulae have entered the body, they use the venous circulation to migrate towards the bladder. As a consequence, the parasite travels through different organs. Katayama fever can appear as a result of a "*hypersensitivity reaction against the migrating schistosomulae and/or the onset of egg production*" [35]. The fever is mostly present in first exposures to the parasite. For example by travellers who visited the infected regions for the first time [33] and rarely diagnosed in endemic areas [35].

When suffering from the Katayama syndrome, one can experience a broad range of symptoms related to the organs the parasite is passing by. Although the appearing symptom differ per case, the following signs are frequently related to this phase.

- Fever
- Fatigue
- Malaise

Figure 6. Three phases of symptoms



- Muscle pain
- Sweats and chills
- Cough or other lung complaints
- Headaches
- Diarrhoea
- Weight loss
- Abdominal pain
- Toxaemia (blood poisoning)
- Hepatosplenomegaly (enlarged liver or spleen)
- Right upper quadrant pain
- Rash

Sources: [16][31][33][35][42][70]

This phase of the disease might last for several weeks before it spontaneously ends [35]. If the fever does not resolve itself, the infection can become deathly if no treatment is given [42].

2.3 Chronic infection

When arriving in the bladder, the worms are mature and the egg production starts. One pair of mature worms can lay 200 to 2000 eggs a day [6]. A part of these ova will leave the body via urination but the rest get stuck in the tissue of the urinary system [33]. An attempt of the body's immune system to fight the unwanted ova results in granulomatous inflammations. Since the parasites can stay in the bladder for decades, this phase will result in a chronic disease. Within this phase, one can distinguish the symptoms of an early stage from the long term consequences.

2.3.1 Early stage

In an early stage, the inflammations in the bladder will cause [33][35]:

- Pain while urinating (dysuria)
- Gross or microscopic haematuria (blood in the urine)
- More frequent ore sudden need to urinate `

2.3.2 Long term infection

Over time, the spreading ova start to damage the kidneys and bladder in a more severe way. The presence of the parasite and ova, causes:

- Proteinuria (high protein concentration in urine)
- Calcification of the bladder
- Water in the kidneys
- Decreased fitness
- Impaired cognition
- Renal (kidney) failure or damage
- Bladder cancer

Sources: [12][19][33][35][45][60][70][73]

On top of this, studies showed that the infection can facilitate the transmission of HIV [29] [33].

2.3.3 Impact on children

In children, the parasite can decrease both mental and physical development. Common symptoms for children are [82]:

- Growth retardation
- Reduced learning ability
- Anaemia

2.4 Other complications

As an addition to the previous described symptoms in the urinary system, the *S. haematobium* eggs can reach out to the neural system or (female's) genitals.

2.4.1 Neuroschistosomiasis

Neuroschistosomiasis is a complication which can be caused by different Schistosoma types, including the *S. haematobium* parasite [70]. The specific impact on the neural system varies per parasite type. The *S. japonicum* ova can reach the cerebrum, while the *S. haematobium* in case of Neuroschistosomiasis affects the spinal cord [35]. Symptoms of Neuroschistosomiasis depend on

the severity of the infection, but they can include [35]:

- Loss of bladder control
- Paralysis of the legs/lower body
- Loss of sensation
- Rash near the spinal cord

2.4.2 Female genital Schistosomiasis (FGS)

FGS is a common complication by women infected with the urinary parasite. According to Gray et al. (2011) a third of the infected women will develop FGS and the World Health Organisation (WHO) (December 2017) estimated the worldwide number of FGS infections around 20 – 56 million. FGS is characterised by inflammations, an enlarged uterus or menstrual disorders.

Women risk the following consequences:

- Severe anaemia
- Vaginal bleeding
- Infants with a low birth weight
- Infertility
- An increased chance on maternal mortality or infant mortality

Sources: [82][83]

Although the name refers to female victims, even men can get genital schistosomiasis with hemospermia as a main symptom [35].

2.5 Worldwide impact

Even though schistosomiasis is part of the 'neglected' tropical diseases, the impact is tremendous. According to the WHO (2018), almost 240 million people are infected by the Schistosoma parasites. The current contaminated water bodies are spread over 78 countries of which 52 are endemic [82] and over 700 million people live in those endemic areas, being at constant risk of infection. Within these areas, almost 100% of the inhabitants will at least once in their live become infected by the parasite [41].

In some cases, the parasite can live on for decades in someone's body before it causes deathly organ failure. But, as can be read in the previous paragraphs, even before it gets deathly, the infection's impact is significant. It decreases the living standard by deteriorating someone's fitness and ability to work [82] and children's (mental and physical) development will be slowed down. As a result education, work, development and health of an infected population is negatively affected [41]. Unfortunately, the economic and health consequences are usually insufficiently measured, limiting the acknowledgement for the impact of the disease [41].

As false negative diagnoses are still common and, some lesions remain, even after treatment, due to (partly) irreversible damage, King (2010) appraises the number of affected people significantly higher than the estimated number of the WHO (October 2017).

Source: SCI Schisto Control (2018)

3 Treatment and control

3.1 Treatment

The standard medicine is Praziquantel, a drug able to kill the mature parasites. It has been proven to be safe for both children and adults [35], except for pregnant women or children younger than 4 years old. But many receive the medicine anyway since the consequences of the disease are more threatening [16].

Unfortunate Praziquantel is solely effective against the mature worms and can only be used when the egg production has already begun. In earlier phases, for example in cases of severe and life threatening Katayama fever, another medicine called Corticosteroids is usually subscribed [33].

The Praziquantel dosage depends on the person's body weight and about 40 mg/kg is given [74]. A single cure is in the majority of cases (66-95%) enough to eliminate all the parasites in the body [33] and repetition of medication is not common. However, according to Gray et al. (2011) the curing rate could be optimised to 95% or even 100% by repeating the treatment after 4 to 6 weeks. So, when designing for treatment related situations it should be considered that not all patients will fully cure after their first treatment.

Once cured, the medicine cannot prevent from further infections. Vaccinations are being developed but it might still take decades before any vaccine will be realised and available for commercial use [37].

3.2 Schistosomiasis and poverty

Schistosomiasis is "*entrenched in prevailing social-ecological systems*" [67]. It is fuelled by poverty while being a source of poverty itself (figure 5) [41].

For example the lack of adequate sanitation is a major cause of further contamination of water. When no action is taken, a newly infected water source can quickly turn into a high transmission area [67]. Communities, especially in remote areas, often highly depend on their local water source for the daily activities. When this one source gets infected, they might be unable to avoid water contact. And limited access to healthcare and a lack of health education minimises the chance on accurate transmission prevention to reduce the impact of the disease. Finally, the inability to learn and work on a maximum capacity (due to the side effects of the disease) diminishes the development to fight poverty.

3.3 Control methods

Due to increasing advocacy, the awareness for this neglected disease raised, accompanied with the financial and technical support for control efforts [67]. A crucial step towards control, is the interruption of the contamination cycle (figure 4). Based on the parasite's life cycle, several approaches are possible [42]:

1. *Snail control*
   By eliminating the intermediate host from infected water sources, the parasites cannot produce the infective cercariae.

2. *Improving sanitation*
   To reduce the number of people who urinate near important water sources.

3. *Providing substitute safe water sources*
   To decrease the need of entering or even touching the infected water sources.

4. *Protective clothing are medical protecting salves when touching the water*
   This might prevent cercariae from penetrating the skin. The usefulness of this solution depends on the financial possibilities of the user, the specific activities in the water and the frequency of water contact.

5. *Providing (mass) medication*
   Population-wide periodical or symptom based treatment to control the intensity of infections under populations.

All methods can be successful if introduced properly, but the mass medication programmes happened to be the least expensive [41] while also being the most effective in reducing morbidity on the short term [42]. In the long term, King (2011) recommends to invest in safe water and improve the health education.

3.4 WHO approach

3.4.1 Mass Drug Administration (MDA)

In 2002, the WHO defined (periodical) mass drug providence with Praziquantel as the standard approach to control Schistosomiasis in endemic areas [35]. It is proven that this Mass Drug Administration, further referred to as MDA, is able to effectively decline the infection intensity and its morbidity [35]. The Global Target is set on treating "*at least 75% of all school-aged children at risk of infection*" [35]. Besides, the WHO wants this MDA combined with the improvement of sanitation, water provision and health education in the endemic areas to improve long term efficiency.

3.4.2 Mapping the prevalence

Prior to the MDA, the WHO advices a (national) mapping phase [79] to map the local schistosomiasis prevalence throughout all regions. The country is divided in (ecological) zones. For each zone, school-aged children of multiple schools are diagnosed [77]. At least 50 children per school [11] are tested, which happens via a simple questionnaire asking for haematuria (bloody urine) or by examining urine samples on microhaematuria or parasitic eggs [77] resulting in the identification of high, moderate and low risk areas (table 1). Based on the prevalence of Schistosomiasis among the tested school children, a specific medication approach is recommended for each zone, based on the WHO guidelines as shown in the right columns of table 1 [77]. The outcome of the mapping phase can suggest an annual MDA for all the school-aged children in the high risk areas. In of lower prevalence areas, the regularity of the treatment wanes [77].

3.4.3 Target group

The original MDA approach only targeted school-aged children, until a research in 2006 showed that even the lightest infections can cause non-negligible morbidity. Since then, all adults considered at risk (e.g. fishermen, women, younger children) were added to the WHO MDA guidelines as shown in the right column of table 1 [78]. This change would significantly increase the number of required treatments per country raising the costs and effort. According to the available data of the WHO database [75] only a few African countries started to target both children and adults in 2006. Some countries followed a few years later but many national programmes are still solely focussing on children.

3.4.4 Drawbacks MDA in practice

The WHO has chosen this approach in 2002, but even with the WHO-guidelines it remains difficult to control the disease. Previous cases in for example Egypt, Brazil and China have shown that governmental support and the recognition of both, the socio economic burden and the impact on public health, are key factors in the

Table 1. WHO medication protocol [77] [78]

Prevalence among school-aged children		**Risk**	**WHO protocol[1]**	
Based on parasitical diagnostic methods	*Based on haematuria questionnaires*		*School-aged children (both enrolled or not)*	*Adults (included since 2006)*
≥ 50%	≥ 30%	High	Annual MDA	Treat adults at risk
≥ 10% and < 50%	> 1% and <30%	Moderate	MDA every other year	Treat adults at risk
≥ 1% and < 10%		Low	Each child receives MDA at the start and the end of the primary school period	Make Praziquantel available for symptom based treatment

[1] In all cases sanitation, water and health education should be improved too for better results [78]

implementation of an effective control programme [58]. Unfortunately, success has been lacking in most affected countries and thereby "*many health systems may still be too weak and overburdened to sustain*" such programmes [35].

The Praziquantel is relatively cheap with average treatment costed of around 0,20 – 0,30 USD [74]. But, due to the large amount of people in need for medication and the additional diagnostic costs like tools, training and salaries, the total costs of the MDA are often too high for local governments [37]. As a consequence, most MDAs are (partly) donor-driven, creating a weak financial basis for sustainable programmes. When the donations end, the prevalence can raise again and might be "*back to preintervention values (...) within 18–24 months after treatment is stopped*" (Inobava et al., 2014).

A welcome solution is provided by Merck, the producer of the Praziquantel. Merck started to cooperate with the WHO in 2007 to work towards schistosomiasis control and elimination, called "*The Merck Praziquantel Donation Programme*" [48]. Merck has been donating 25 million tablets to the WHO each year and they want to scale this up towards an annual 250 million tablets [47]. Since each child needs approximately 1 to 5 tablets [74], it becomes possible to treat around 100 million children with the donated medicines [56].

This donation is an advantage, but the task remains to use the medication in the most efficient way. One of the bigger challenges is to reach all the infected people. According to King (2010), even one infected individual is able to contaminate a water source, creating a high risk area within only a few months. Diagnostic tools should be as sensitive as possible to notice even the lightest infection. Besides, as discussed earlier, the drugs should not only be provided to children. Moreover, it must not be forgotten that the medicine might not cure 100% of the patients after a first treatment. The efficiency can be increased by post-treatment evaluations and providence of a second cure when needed. Unfortunately, double treatment is not part of the MDA protocol and might leave some of the infected population unhealed [41].

Finally due to the worldwide massive use of Praziquantel [35] the risk of resistance exists. Due to the lack of a adequate substitute drugs, this is definitely something to keep in mind. Therefore again, diagnostics are important to control the use of the medicine.

3.5 Need for diagnostic improvement

Diagnoses are an important part of the fight against schistosomiasis. By further technological development, the accuracy can raise or similar results can be achieved for a lower price. In the current approach, there is a significant need for further improvement.

First of all, proper diagnoses (which can identify even the lightest infections) are the key to clarify the total number of infected people. This knowledge will help to increase awareness and appreciation for the impact of the disease, which can indirectly lead to more effort of the responsible parties to set up effective control programmes.

Next to this global awareness, improved parasite detection will also increase the quality of the mapping phase in MDAs, making the WHO approach more reliable and trustworthy. When all infections (both heavy and light) are detected, the calculated prevalence per area becomes more accurate and the suitable medication protocol (table 1) can be chosen more fairly. Furthermore, the risk of unnoticed infections leading to new water contaminations could be reduced.

And, even more important, by treating the light infections it helps to prevent people from irreversible (organ) damage.

Finally, as mentioned earlier, the expenses of the MDAs stagnate the control progress. Unlike the medicines, the diagnostic tools are not for free and the costs are limiting the amount of diagnoses to be performed. Further development can facilitate cheaper but still accurate tools, making it affordable to reach more people.

Source: Centre of Schistosomiasis and Parasitology (2018)

4 Diagnoses

As discussed in chapter 2, schistosomiasis affects entire communities and requires a country broad approach to increase the chances on the necessary control. Paragraph 3.5 points out the urge of diagnostic improvements for either morbidity control or nationwide impact. Diagnoses are conducted by both public and private organisations. And the technicians (who are educated to execute such diagnoses) either belong to research institutes, health facilities or both. Within the endemic countries, the following diagnostic purposes can be classified:

1. *National control programmes*
   The WHO control programme guidelines require community screening to map the endemic areas. Information about high or low risk zones are needed to choose the correct medication approach for the preventive chemotherapy (PC).

2. *Endemic studies*
   Diagnoses are part of extended research on the disease and its impact. Community screening is for example used to test new control methods and improve (diagnostic) technologies.

3. *Local diagnostics in health facilities*
   (Rural) health facilities execute their own diagnoses to screen local patients, for proper medical attention and treatment.

For *S. haematobium*, microscopic egg count in urine samples is chosen as standard approach [34]. However, multiple techniques are available. Some methods analyse urine to identify the parasite, others examine blood, look at biopsy or use imaging studies. All techniques are characterised by (dis)advantages making them useful for different purposes.

In order to develop a new way of diagnosing, it is important to know the current technologies to define the unfulfilled needs. This chapter will therefore start with an analyses of the today's available methods. As two of the three purposes (control and research) mainly focusses on community scale screening, it is decided that the new device should definitely be suitable for large community screening. So, only those techniques, suitable for larger size examinations (see appendix B) will be taken into account in this analysis.

Thereafter, important diagnostic qualities are identified to evaluate the existing diagnostic methods. Revealing both, the strengths as well as lacking characteristics of the available techniques. Finally, a set of diagnostic goals can be defined, to make sure the future device will perform better than the current standard.

4.1 Current methods

This paragraph will discuss the existing methods. The procedure of egg detection in urine samples will be discussed in more detail for two reasons: It is the most common method and it is based on the new future device of this project will be using this same egg count principle. The other screening techniques will be shortly introduced. All methods are summarised on page 26 and a more extended explanation per method can be found in appendix B and C.

4.1.1 Microscopic egg count

Counting the eggs starts with catching them, which can be done via filtration or centrifugation. Preferably the sample is filtered (as shown in figure 7), followed by a microscopic examination of the filter to identify and count the eggs that are stuck in the filter (figure 8). If no filters are available, one can spin the sample in a centrifuge to generate a sediment, which will also be evaluated via microscopy. This second option is less accurate and the WHO advices filtration.

When using filtration, technicians collect samples of at least 10 ml, in accordance with the WHO instructions. Smaller samples cannot be used for official mapping activities, larger samples have to be resized to 10 ml, for administrative reasons.

Figure 7. Urine filtration

Figure 8. Microscopic egg count

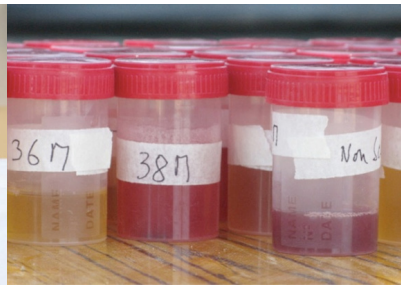


Figure 9. Haematuria

Figure 10. Dipstick test

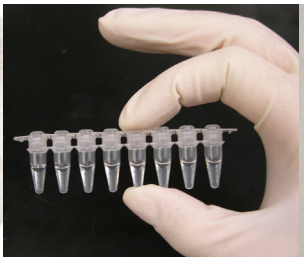


Figure 11. PCR

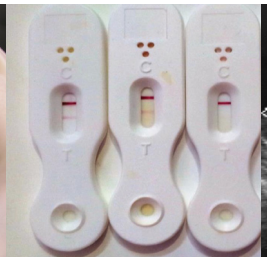


Figure 12. Antigen

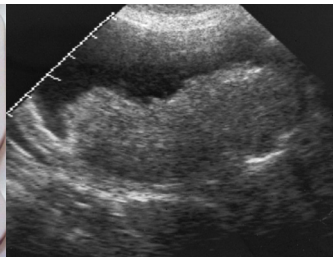


Figure 13. Ultrasonography

The count provides quantitative data and indicates the severity and intensity of the infection [7]. More than 50 eggs per 10 ml is qualified as a heavy infection and less is defined as mild or light infected [51]. Due to the microscopic examination it is possible to distinguish the different Schistosoma types by looking at the characteristic shape and the terminal spine of the ova (figure 2).

However, the method has some fallacies. First of all, the counting is done by hand and one can easily miss some of the eggs [5]. As a result, light infections are often misdiagnosed [41] causing many false negatives [12] and heavy cases might accidentally be confused with a light infection. In addition, since everything is done by hand, only trained lab technicians can perform the diagnoses [5] influencing the flexibility of the planning.

A second fallacy is due to an inconsistent egg production. The number of eggs varies over time and the amount can be stimulated by for example physical activities [54]. As a consequence, the amount of ova per urine sample differs from day to day [72] influencing the correlation of the number of eggs and the infection intensity. Based on the parasite's egg excretion pattern, the best moment to collect the urine is in between 10 am and 2 pm [32] and most samples are collected within this range.

Ideally, to improve sensitivity, a patient's urine should be examined for several days [24]. However, this is not likely to be used on large scale since it is both time consuming and increases the costs.

Another limitation is associated with the filters used to catch the ova. They cannot be reused and significantly increase the costs of the procedure. Finally, after the Praziquantel kills the parasites one might still find ova in the urine up to several weeks. If the diagnosis is used on recently treated individuals, the dead ova might cause some false positive results. A viability test could be added to the procedure to determine whether the counted eggs are coming from an (in)active infection [3]. Those viability tests are mainly used to evaluate if a cure was successful, but are not part of community screening.

4.1.2 Other techniques

Haematuria questionnaire (figure 9)

In heavy cases, the urine colours dark due to the presence of gross haematuria. The WHO uses morbidity questionnaires in which they ask school children for visible haematuria as a quick and cheap mapping method, but this is definitely not the most reliable technique [11].

Dipsticks for microhaematuria and proteinuria (figure 10)

In contrast to gross haematuria, microhaematuria might already appear in much lighter infections and you need a microscope to see those micro blood particles. An easier technique to detect this haematuria is the use of a dipstick. Such a reagent strip can also detect other parameters referring to a possible infection like high levels of protein.

Polymerase Chain Reaction (PCR) (figure 11)

Polymerase Chain Reaction (PCR) is a sensitive and specific method to identify the parasites DNA in urine samples [7], but mainly used in a laboratory.

Antigen (figure 12)

Antigen are sometimes confused with antibodies. Antibodies appear when infected, but they will stay in your body even if the infection is cured; it cannot differentiate active and cured infections [3]. Antigen are only present during active infections and happen to be an affective indicator found in both blood and urine samples. The circulating antigen can be detected by a Rapid Diagnostic Test (RDT).

Ultrasonography (figure 13)

Ultrasonography has been used to screen community morbidity and determine the efficacy of given treatment [59]. The technology is able to screen the bladder wall on irregularities or unusual thickening and identifies

enlarged parts of the kidneys or the presence of urine inside the kidneys (hydronephrosis) [25].

4.2 Early stage detection

Despite the large amount of different diagnostic techniques it remains difficult to diagnose an infection in an early phase. When looking at the symptoms, in rare cases even Katayama fever can be fatal and an infection should preferably be detected in the earliest possible stage. Unfortunately, this is still a significant limitation of most diagnostics.

4.2.1 Cercarial dermatitis

During the dermatitis phase, proper diagnoses are barely possible. An infection can be suspected after contact with possible contaminated water combined with a recognition of symptoms like the red and/or itchy skin. But no medical proof can be found in the blood or urine yet [54].

4.2.2 Katayama fever

If the Katayama fever appears, this can be used to discover an infection before the worms mature. However, those fever related symptoms can be easily confused with other diseases or infections [12] particularly in less endemic or non-aware areas where schistosomiasis is not the first threat to be considered by the local population. A travel and medical history (including water contact and dermatitis symptoms) can be useful in the identification of an infection [33]. Next to the symptom based consultations, serological antigen detection is the only diagnostic technique capable of detecting the disease within this early stage [54].

4.2.3 Chronic infection

After 6 to 8 weeks, the egg production starts and the egg count method can be effective and the DNA can be found by PCR. Inflammations arise due to the appearance of the mature worms and its ova, excreting blood in the urine enabling the use of dipsticks or haematuria questionnaires.

The ultrasonography is meant to detect damage or complications within the body, so this method will only become useful after the first lesions appear, which is too late if one wants to minimise the damage.

4.2.4 Conclusion

To conclude, the majority of the diagnostic techniques (including the egg count) are not able to detect the infection before the patient is able to contaminate water sources. Since egg count is the standard principle for the new device, this creates extra challenges for schistosomiasis control. And it is therefore even more crucial to detect the infection as soon as possible, preferably already from the first egg.

4.3 Diagnostic qualities

4.3.1 Reliability data

Unfortunately, misdiagnoses are still not excluded and false results are leading to untreated infections (false negatives), over-treatment (false positives), lacking trust or underestimated mortality rates [67]. To minimise the risk of incorrect results, the test should be repeated several times [35], but this would increase the overall costs [28] [12] and is not commonly done [5]. Therefore another set of criteria are formulated, to maximise the reliability of the tests.

First of all, it is important to know which indicator is used to diagnose the infection. Some techniques only look at the symptoms (e.g. haematuria, proteinuria or damaged organs) while others look at the parasite's DNA or eggs. As there are other (neglected) tropical diseases with comparable symptoms [12], which require different medical attention, symptom based diagnoses are not the most reliable methods.

To make it even more complex, a significant part of the endemic countries are contaminated with both *S. haematobium* and *S. mansoni*. And for both mapping and research purposes, it is essential to have a specific diagnoses [66], able to even distinguish the different types of schistosomiasis [54].

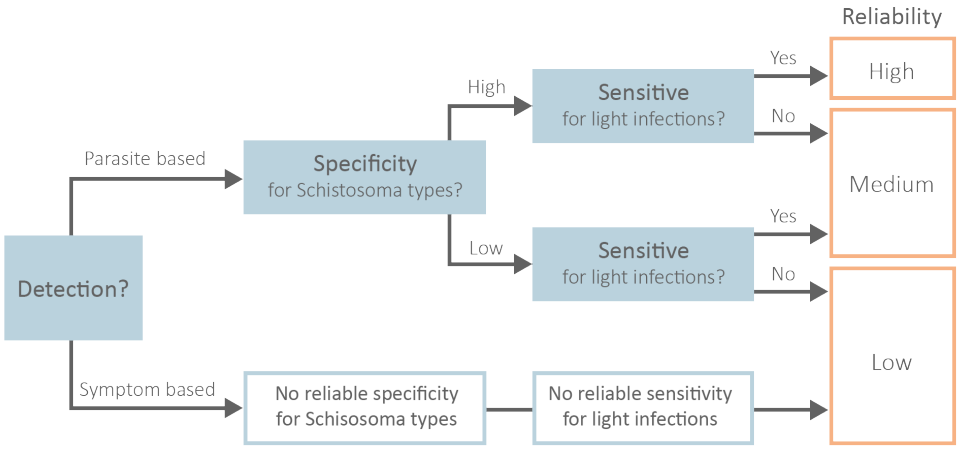


Figure 14. Factors influencing the reliability

Figure 15. Goal

Furthermore, even light infections may have significant health or economic consequences. As long as no cure is given, the eggs continue to damage the tissue and spread through the whole body, injuring organs. And each time the patient enters the water, they can get infected with new cercariae, raising the number of parasites trapped in the bladder. In the end, the light infection becomes a heavy one resulting in even more serious lesions [3] due to the higher amount of ova produced per day. So, in order to minimise the damage, a sensitive diagnostic technique is needed to detect already the lightest infection [66].

Figure 14 summarises how the origin of detection (symptom or parasite based), the specificity and sensitivity influences the reliability of the test results. A symptom based examination will result in low reliability. A parasite based detection can result in low or high reliability, depending on the other characteristics.

Of course, reliability is not only influenced by the discussed qualities. False results can also be due to contextual or environmental influences (e.g. light, temperature or dust), failing technology (after falling or power problems) and human errors (especially in complex technologies which require highly trained people to perform the tests). These factors are difficult to measure and are not taken into account during the comparison. But they should be considered in the further design process. One could for example keep the usage as simple as possible or provide better training for the technicians.

4.3.2 Purpose specific qualities

Reliable data is useless if it is not revealing the needed information. As mentioned before, this project focusses on community level diagnoses. For most research or mapping purposes, quantitative data is preferred over qualitative data [12] [66] in order to determine the severity of the infections.

Since large groups of people have to be tested in one day, a large throughput is another important quality for community screening [66].

Besides, the overall costs should be as low as possible [66] to make the large screening sessions affordable and thereby more sustainable. There are no sources available defining the exact maximum costs or throughput time, but the ultrasonography equipment is for example slow and relatively expensive compared to a rapid diagnostic tool (RDT). An RDT is an example of a cheap and fast solution, saving money and time in large screening situations [66].

4.3.3 Comparing diagnostic methods

Page 26 summarises the different diagnostic methods currently available for community screening. On page 27, all techniques are evaluated on the discussed diagnostic qualities. As can be seen, none of them is sensitive, specific, quantitative, cheap and fast at the same time. An ideal diagnostic technique for mapping *S. haematobium* on community scale would address all these qualities for an affordable price.

4.4 Development goals

To conclude, the diagnosis would ideally be parasite based, sensitive for light infections and specific enough to distinguish *S. haematobium* from other Schistosoma parasites. It should provide quantitative data for a relative low price with a high throughput. Besides the risk of environmental influences, human errors and technological failure should be kept to a minimum. However, none of the existing methods fulfils all desired qualities.

Urine samples are the easiest to collect and the egg count is still the golden standard to provide the needed quantitative data. Nowadays, the egg count requires trained experts to perform the test and light infections are still easily misdiagnosed. When developing a new device to count *S. haematobium* eggs, those qualities need to improve. The tool should be easy and fast in use and able to detect each and every single egg (figure 15).

Diagnostic methods

sample	indicator	technology
urine	eggs	egg count (filtration or centrifugen combined with a microscopic examination)
	gross haematuria	haematuria questionnaire (examination with the eye)
	microhaematuria	dipstick
	proteinuria	
	DNA	PCR
blood	antigen	antigen RPD
image of organs	damage tissue or alocated fluids	ultrasonography

Evaluation diagnostic qualities

	detection	reliable data		community scale screening		
egg count	parasite based (eggs)	insensitive	specific	% #	€€ med. price	medium throughput
questionnaire	symptom based	insensitive	lacking specificity	% # not quantitative	€ cheap	high throughput
dipstick	symptom based	insensitive	lacking specificity	% # partly quantitative	€€ med. price	high throughput
PCR	parasite based (DNA)	sensitive for light infections	specific	% # partly quantitative	€€€ costly	medium throughput
antigen detection	parasite based (antigen)	sensitive for light infections	lacking specificity	% # partly quantitative	€€€ costly	medium throughput
ultrosonography	symptom based	insensitive	lacking specificity	% # not quantitative	€€€ costly	low throughput

Sources: [42] [12] [3] [54] [11] [24] [35] [20] [6] [66]

5 Project focus

As stated in the introduction, the department of Mechanical Engineering of the TU Delft is developing a smart optical diagnostic technology to detect the *S. haematobium* ova in urine samples via (semi) automatic optical diagnosis. The aim of this project is to successfully implement this technology into a diagnostic tool, which can be used in endemic countries. The goal of the new device is to perform better than currently used methods for community screening. The previous chapter already discussed the desired diagnostic qualities. Though, when narrowing the scope to a specific context, more context and user oriented requirements will arise. This chapter will discuss the potential diagnostic purposes as well as the initial context to focus on within the project.

5.1 Context variation by design (CVD)

Due to the high amount of countries infected by the urinary parasite, the final goal would be to fit all possible contexts variations in all endemic areas. In case of the *S. haematobium* parasite, this will mainly include African countries.

Limited by the time of this particular project, the context exploration has to start small in only one or a few endemic countries, but the larger scale implementation will be a leading long term goal. And, in order to design towards a scalable solution, the project will integrate the Context Variation by Design (CVD) approach. This CVD method stimulates to explore the different contexts in an early stage and with an open mind to detect similarities as well as differences between countries or areas. This will enable the designer to become aware of the challanges in future scaling and look for a shared solution space of the compared contexts in order to avoid any of these scaling difficulties. The "*CVD provides an approach and stimulates a mindset (...) to acknowledge complexity and from that acceptance use it to their benefit in their attempts to design, test and implement solutions for issues that exceed the scope of one context. The results are better solutions, quicker scaling and lower overall costs.*" [39]

5.2 Possible diagnostic purposes

As discussed in chapter 4, diagnoses can be used for control programmes, research activities or symptom based treatment in (local) health facilities. Page 30 and 31 show the three contextual possibilities and how a future (automatic) device would be used for each of them. As can be seen, control and research projects would use the device in field trips, where they visit a number of communities and execute large scale screening. While health facilities only diagnose when a patient comes to them and execute the tests their own laboratory. Based on the different use, page 31 shows the most important design qualities for usability and technological requirements, to compare the contextual similarities and variations.

As shown in the figure, designing for control programmes (option 1) seems to overlap with most design qualities of the other two options. Besides, control programmes were endorsed to be the main global strategy to fight the infection [66], making it look like the highest priority at the moment. However, there are too many knowledge gaps to fill before an actual user can be chosen and a further context exploration (in part 2 of the project) will show whether control programmes should indeed become the main focus with endemic areas.

5.3 Ghana and Nigeria

In order to analyse how diagnoses will fit in the user's needs, part 2 will combine a literature review and a field research to explore the context in detail. To improve the efficiency of a field trip, the location is chosen based on existing contacts, which included Ghana and Nigeria.

Both are (at least partly) endemic for *S. haematobium* and *S. mansoni* (figure 16). Ghana has made promising progress in control activities and is achieving a more structural implementation of the MDAs on national scale [82]. Nigeria seems to be involved in some control effort as well, but there approach is less developed compared to Ghana.

As concluded in paragraph 5.2, control programmes are an important step towards control and Ghana is therefore chosen as starting point and main focus of this project, to see how their control programme is developing and whether this device can help to assist in these activities. Though, a second researcher will analyse Nigeria, parallel to this project, enabling a CVD based comparison throughout different stages of the design process

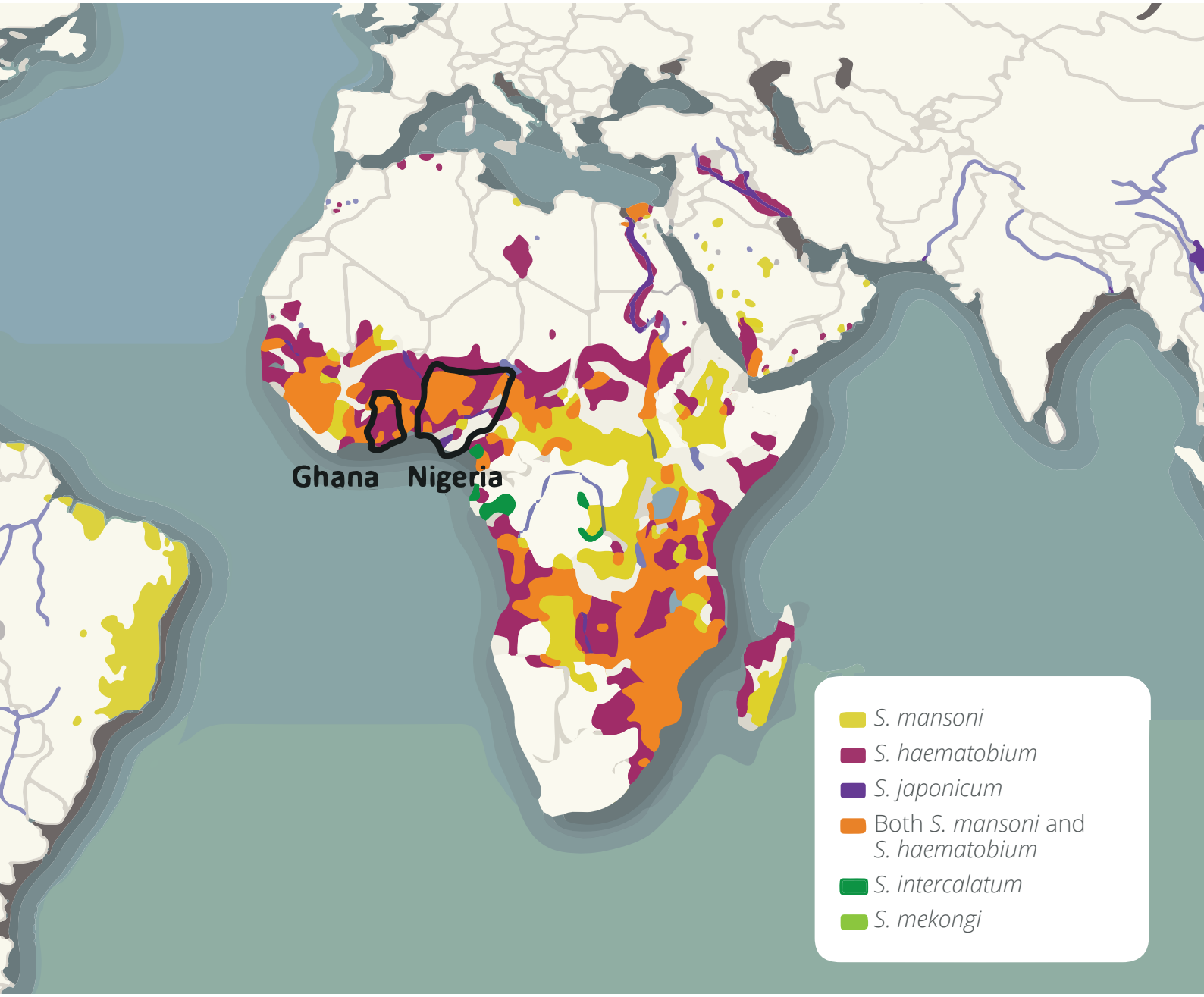


Figure 16. Schistosomiasis prevalence

Context

Use of the device

1.

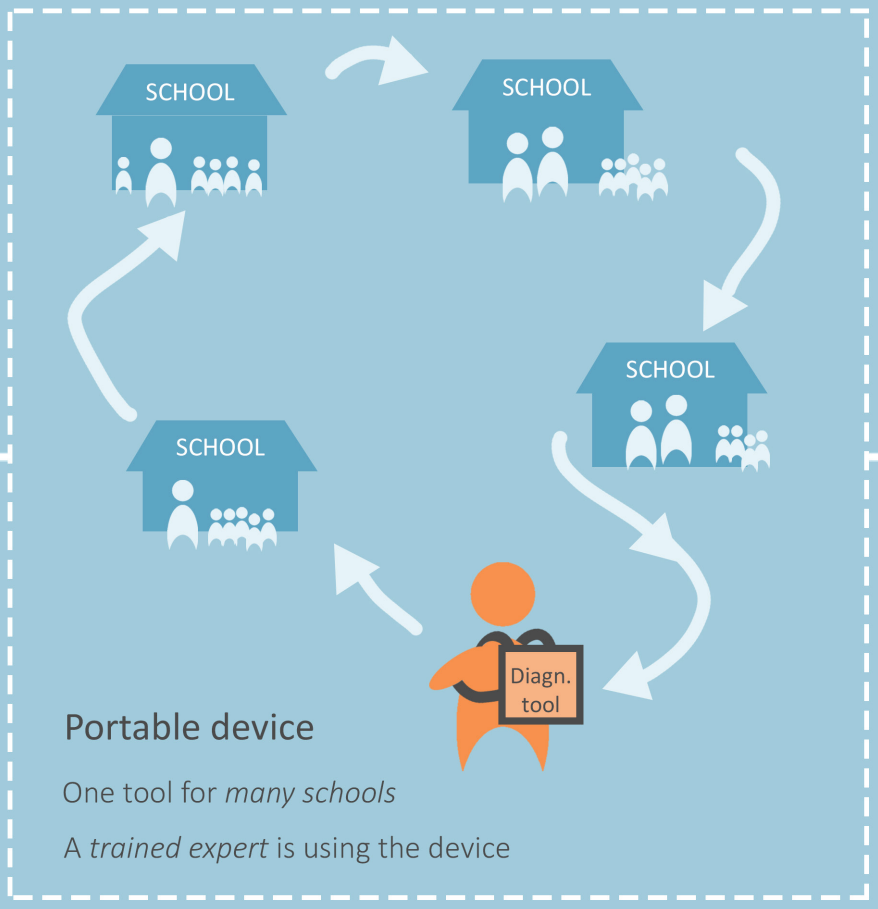
Control programme

Purpose: Determine mass medication approach

2.

Endemic studies

Purpose: Knowledge



Portable device

One tool for *many schools*

A *trained expert* is using the device

3.

Local diagnostics

Purpose: Symptom based treatment

Local Health Centre (HC) owns device

One tool *per HC*

Someone from the HC is trained to use the device

Target group

Most important design qualities

Usability

Technology

Children only

School aged
(> 4 years)

portable

fast

€€
low cost

specific

light
infections

% #
quantitative
data

Various groups

portable

fast

specific

light
infections

% #
quantitative
data

easy to use

fast

€€
low cost

light
infections

6 Conclusion

Research questions part 1

1. What is the current situation?
2. What are the technical requirements for a new diagnostic technology to improve the current situation?
3. Who is the foreseen end user?

This chapter will discuss the main findings of the first project phase. As stated in the introduction, this analysis will answer the first two research questions and expose the first insights for the third research question. The results of question 1 are summarised in the problem definition as well as the first description of the target group for improved diagnostics. Question 2 led to a set of criteria as visualised in figure 17. Due to the first exploration of question 3, the requirements are expended with some user related criteria.

6.1 Problem definition

The urinary schistosomiasis is a neglected tropical disease with an enormous infection reach within Sub-Saharan Africa. It is able to impact the (economical) development of a country as well as the living quality of infected individuals. The WHO has introduced nationwide control programmes, using MDA as a strategy to fight such neglected diseases. Such programmes include a mapping phase to determine the infection prevalence in different areas. Based on these diagnostic results, mass drug treatment is executed. The exact treatment frequency depends on the infection density of an area. Besides, diagnoses are needed for research purposes as well as symptom based treatment in (local) health facilities.

Due to lacking sensitivity of the currently available diagnostic techniques and procedures, the reliability of the current mapping data is insufficient. Diagnosis should be improved in order to:

1. Clarify the number of infected people and increase awareness of the burden caused by the disease, to arouse the responsible parties to investments in more effective control programmes.
2. Raise the reliability of the WHO approach by more accurate prevalence measurements leading to better treatment procedures. This minimises the risk on unnoticed and thereby untreated infections leading to new water contaminations.
3. Prevent people from irreversible (organ) damage by detecting the infection as early as possible.

6.2 Target group

Ghana is chosen as a starting point. In the meanwhile, a second researcher will explore the *S. haematobium* diagnoses in Nigeria to evaluate if the solution for Ghana could also fit in Nigeria. In the end, the long term goal is to reach all endemic countries. Though, the main users and beneficiaries will be comparable in the different countries.

6.2.1 User

Those who are educated to execute the diagnoses, called (lab) technicians, either belong to research or health facilities for public or private organisations. They are the current users of the available diagnostic devices. However, if a new tool will be much easier to use, the '*user*' of the product might be reconsidered.

6.2.2 Beneficiary

The beneficiary of this device will at first be the Ghanaian population who are at risk of the parasite. However, it is the long term vision to make the device available for all infected countries to address the worldwide population at risk.

Another party who profits from such development is the government. They will directly benefit if the new device will reduce the costs of the national control activities. Furthermore, the country will benefit indirectly by an eliminated disease, since it will increase the national (economic) development.

And finally, when the device would be suitable for control programmes, the WHO will be a stakeholder too, as they are concerned about the progress in the disease elimination.

6.3 Requirements

The current diagnoses are performed by counting eggs in filtrated urine samples. The new device will use the same principle of counting ova in urine, but should reach for better results as is visualised in figure 17. It must be:

1. Sensitive (preferably detect even a single egg)
2. Affordable for remote areas
3. Specific for S. haematobium

To achieve acceptance for the device and create feasible implementation opportunities, the device should not only perform better than the current tools, but also fit the approached country and the needs of the final user. The following criteria have to be taken into account:

4. Perform independent of human errors and environmental influences
5. Easy to use, not only for the trained specialist
6. Enables a fast procedure to increase the throughput
7. Be portable for field trips
8. Fit the national health system of Ghana
9. Fit the cultural habits and user routines

And finally, as the long term goal is to reach all endemic countries. It should be possible to:

10. Scale the implementation towards other endemic countries

6.4 Continuation of the research

In the next phase, the Ghanaian context including its health system will be analysed. A field research will be executed to further explore Ghana used to formulate functional requirements of the target group, integrating the cultural, organisational and technological needs of the context.

To make sure the final design will fit the users to an optimum, their diagnostic procedures as well as their habits and expectations will be analysed in detail to see how a new device could optimise the current approach.

Parallel to this, active cooperation with the technical team will provide a broader expertise and assure feasible decision making. An additional research on diagnoses in Nigeria will enable critical evaluation on scaling opportunities.

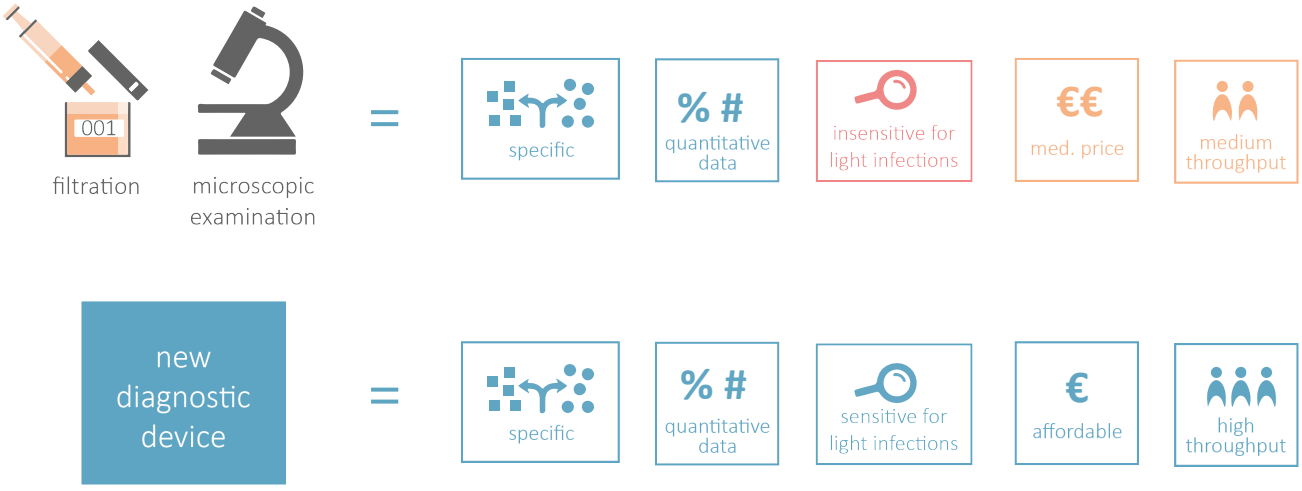


Figure 17.

PART 2

Ghana

Context exploration

Introduction

As the scope is narrowed down to Ghana, this second part of the project will dive into the specific context and the potential users. The first chapter will start with the results of a literature review, which is conducted to gain both knowledge and understanding about the country and its relation to (urinary) schistosomiasis.

Thereafter, Ghana was visited for three weeks of exploratory research. Together with a short summary of the research approach, the report will focus on the relevant findings and results which are needed for the final product development.

Chapter 3 will discuss the Ghanaian control effort and the skill set and habits of the various users in order to choose a final user (research question 3) and define the functional requirements (research question 4), interaction guidelines (research question 5) and the most important implementation criteria (research question 7).

As an addition to the user oriented research, chapter 4 discusses the product related insights of the research (research question 6).

The final conclusion of part 2 will be the starting point of the actual product development phase (part 3).

1 Literature review

1.1 Country profile

1.1.1 Ghana in general

Ghana is located at the coast of Western Africa. Out of the 29 million Ghanaians [89], 2.4 million are living in Accra, the capital [90]. And at least 2.6 million are living in Kumasi, a city that is located more inland [18] (figure 18).

The country is divided in 10 regions. Each of them is separated in several (sub)districts, resulting in a total of 216 administrative districts, a number that is still expanding over time [30]. Besides the high degree of administrative areas, there are also hundreds of local languages [22].

The Ghanaian population values tradition and possess an optimistic attitude. The country has a hierarchical society with a high power distance [36], which should be kept in mind when aiming for community acceptance.

1.1.2 Rural and urban living environment

As in many countries, the differences between rural and urban areas are enormous. Remote communities are confronted with poverty, a lack of accessibility to health and education [22], inadequate sanitation and poor water access. On top of that, Ghana shows a major division in income, infrastructure and educational development between the northern and southern regions [21] [1] creating an enormous contrast between the living conditions of rural northern regions and the bigger cities in the south. Finally, due to an increasing urbanisation rate, the urban areas are getting overpopulated [1]. As a result, urban slums are growing accompanied by inadequate sanitation and other hygiene problems [1].

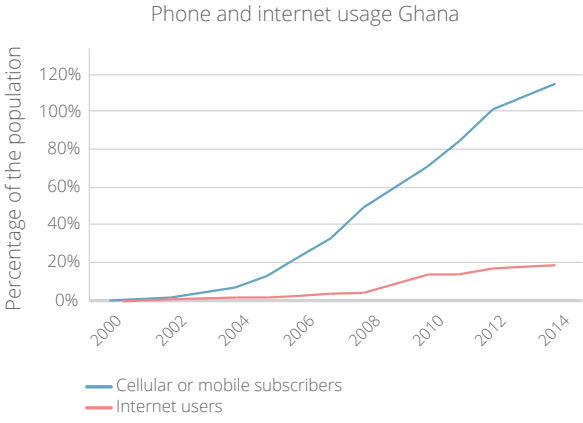
1.1.3 Technological development

The Ghanaian power supply is not very reliable as frequent power cuts disrupt the energy supply for unpredictable periods of time [1] [9]. However, the use of technology is rising over the years. The number of cellular subscriptions has grown significantly (graph 1), even up to more than a 100% [88] (which could be

GHANA – country profile

Capital	Accra
Regions	10
Districts	216
Population	29 million
Area	238 533 km^2
National language	English
Life expectancy	61 – 64
Traditional healers	45 000

Sources: [30] [80] [22] [52] [80] [84] [89]



Graph 1. Phone and internet usage in Ghana [38] [88]

Figure 18. Map Ghana

explained by double subscriptions per person). The internet usage increased a little in 2010, but the use of digital data is still relatively uncommon as summarised in graph 1 [88] and it cannot be assumed that each community possesses a smartphone.

1.1.4 Education and literacy

In 2013, the overall adult literacy in Ghana was estimated to be almost 70% [65]. Though, as the younger generation has benefited improved access to education, the literacy among young adults is much higher. Within the age range of 15 till 24 years, respectively 88% and 83% of the men and women are able to both write and read [65]. And over 80% of the children is enrolled in primary education [63].

Unfortunately, due to the earlier mentioned interregional differences, those numbers are not consistent throughout the nation [27] [62] and "*in three regions literacy rates are less than 50%*" [1]. Besides this, the inequalities between boys and girls are still higher within these remote areas [27] [62].

1.2 Health system

The Ghanaian healthcare is the responsibility of the Ghana Health Service (GHS). Which is funded by the government but operating independently [52]. "*The GHS has an administrative role and functions at all levels:*

National, Regional, District, Sub-District and Community" [10]. As an addition on the public health system, there is a growing private sector offering hospitals and clinics [52][22]. In 2004, Ghana introduced the National Health Insurance Scheme (NHIS) to foster the health accessibility and "*fund basic healthcare*" [52]. More than half the population is enrolled but in particular the poorest Ghanaians can barely afford it [22].

The health system is most developed in the bigger cities (Accra and Kumasi) [22]. The rural areas are challenged by inadequate infrastructure, funding gaps, limited diagnostic facilities and equipment which is broken or lacking [22] [1]. Around 25% of the population has to travel at least 15 km to see a doctor [52] and health facilities are short in personnel and especially in specialists. The available hospitals are crowded and the few specialists have to make long working hours [22] [1]. This might be a reason why a significant part of the people relies on traditional healers, of which there are around 45 000 in Ghana [52].

1.3 Schistosomiasis in Ghana

Large scale Preventive Chemotherapy (PC) via annual MDA was assigned as key strategy by the WHO. And as "*schistosomiasis is one of the most widespread Neglected Tropical Diseases (NTDs) in Ghana, it continues to pose a significant public health problem. In spite of numerous efforts put in place for control in the past*" [10], Ghana follows these WHO guidelines [50] in an attempt to fight the parasite.

This paragraph will discuss the impact of the disease in Ghana, how the government integrated the control programme in the GHS and the challenges to face when controlling such an easily transmitted disease.

1.3.1 Endemic areas

The parasitic infections can be found throughout the whole country and "*the entire population of Ghana is considered at risk*" [57]. This risk includes both urinary and intestinal schistosomiasis, as most areas are threatened by *S. mansoni* as well as *S. haematobium*.

Figure 19 shows the results of an extended mapping study [92] on the average intensity of the *S. haematobium* infections among 4527 school children throughout the whole country. Most areas are primarily dealing with light intensity infections (hereinafter: Low endemic areas). However, the same research revealed that "*42% of the S. haematobium infections are of heavy intensity (>50 eggs/10 ml of urine)*" [92] and the heavily infected areas are dealing with a relatively higher amount of infected individuals per zone. Those high risk areas (high endemic areas) are mainly found outside the cities near inland water bodies (figure 19). And the highest infection prevalence of *S. haematobium* is found among children from 10 to 14 years old [6].

As the cities are low endemic and the access to healthcare is much higher, the control programmes are mainly targeting rural areas [5]. However, urban schistosomiasis (caused by infected water sources in the cities itself) does exist, but is in generally underestimated. And even though it might be worth to pay attention to, the consequences and prevalence are barely brought under attention and the focus remains on rural areas only.

1.3.2 Community awareness

In high endemic communities, urinating blood (haematuria) has not always been recognised as a sign of illness. Some communities accepted the blood

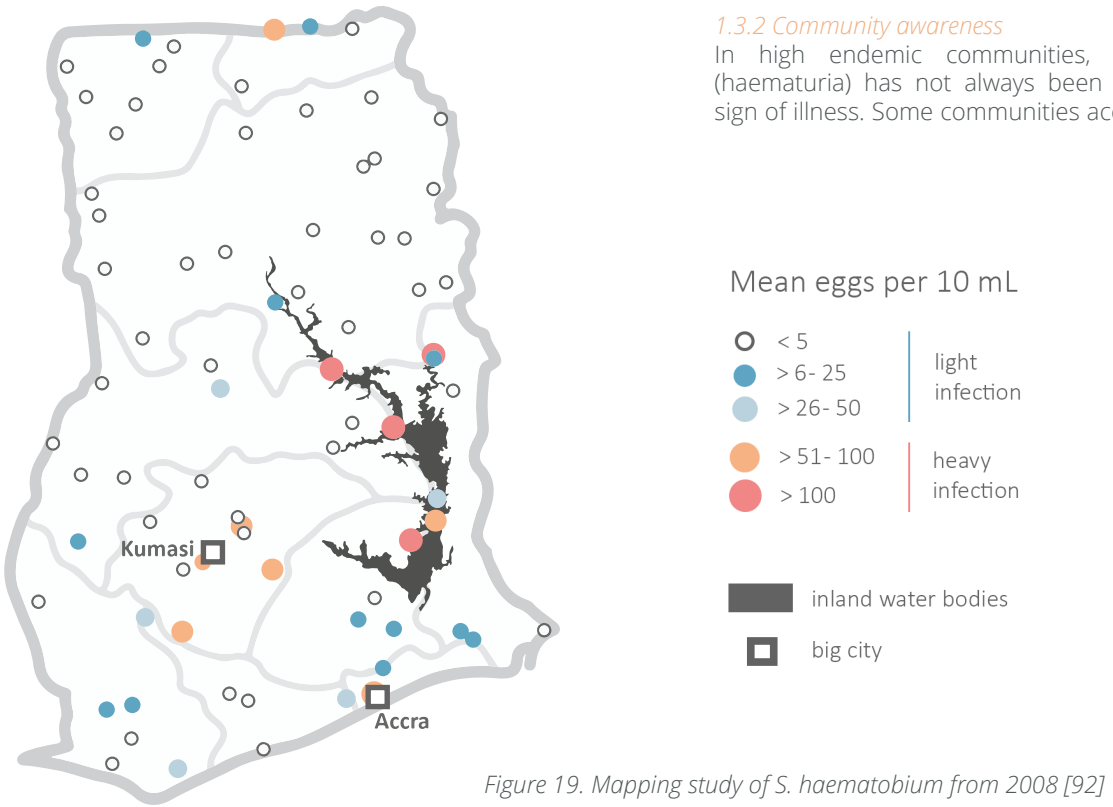


Figure 19. Mapping study of S. haematobium from 2008 [92]

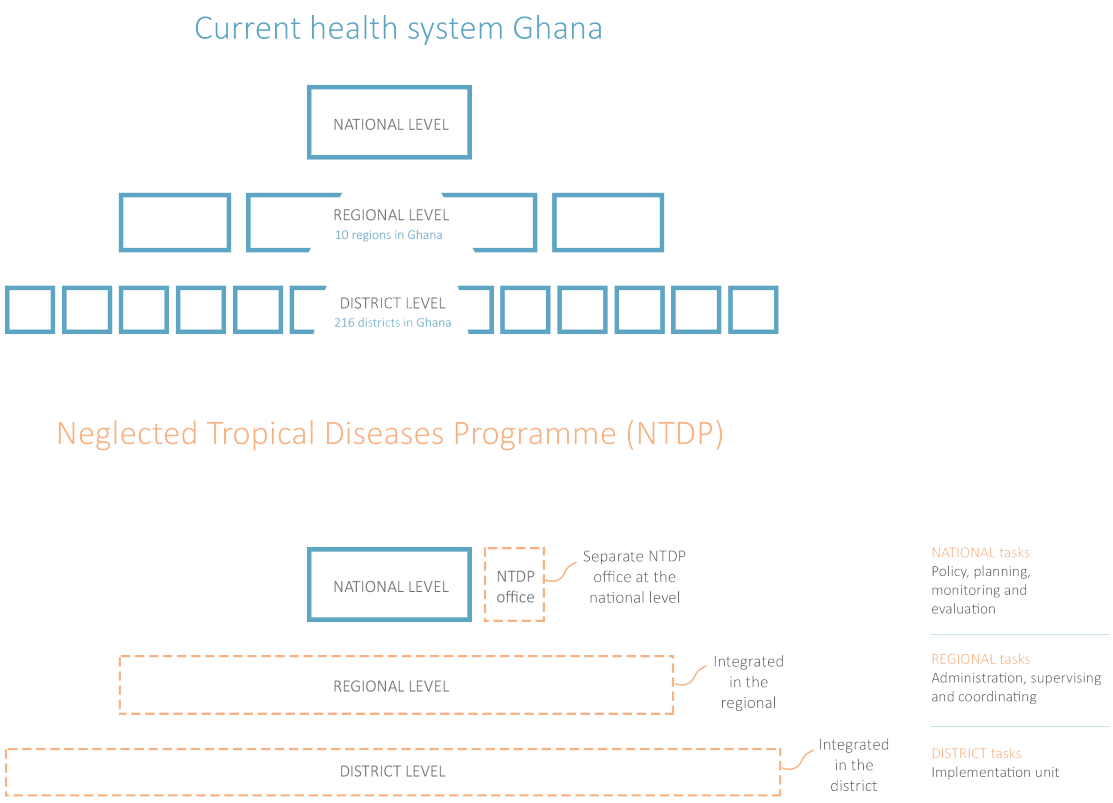


Figure 20. NTDP integration in the Ghanaian health system [46]

as part of the childhood, assuming children will get better when they get older. Or it was seen as a sign of maturity, where those without haematuria were called abnormal instead of healthy (Antwi, Aboah & Saprong, 2014). Others who did acknowledged the blood as a sign of illness, indicated the infection source wrongly. Blaming witchcraft, crossing a goat's urine or (sexual) contact with infected people instead of the infected water sources (Onyeneho, Yinkore, Egwuag & Emukah, 2010). Due to these misapprehensions, some patients rather hide the disease out of shame, causing an insufficient number of people to request medical attention (Onyeneho, Yinkore, Egwuag & Emukah, 2010).

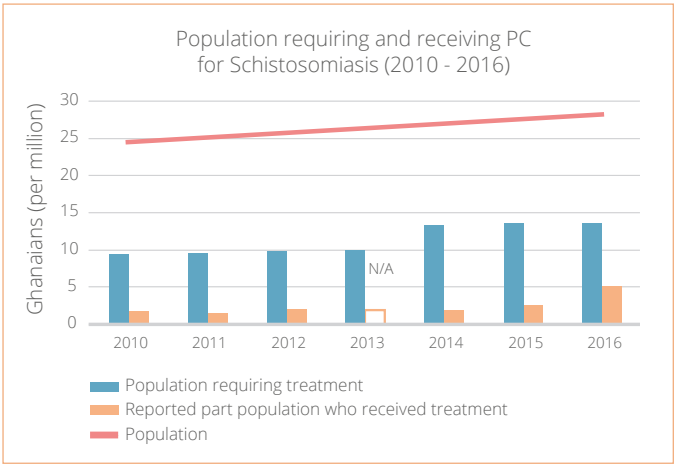
Nowadays, as will be discussed in chapter 3, Ghana has achieved some level of awareness due to years of extensive health education effort. But it should be kept in mind that not all communities will acknowledge the disease nor be willing to cooperate with diagnostic activities.

1.3.3 Integration Neglected Tropical Disease Programme

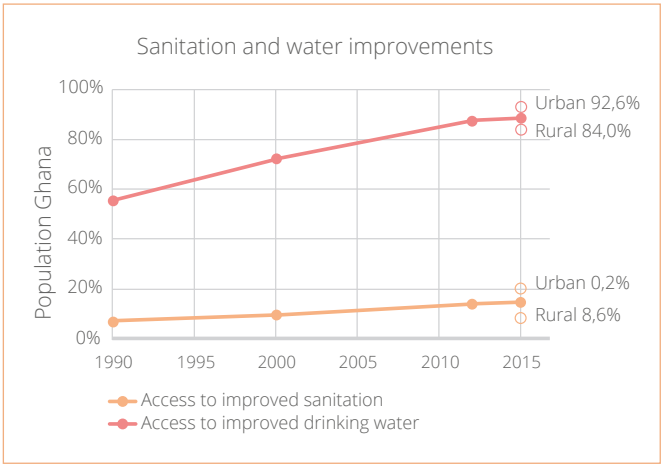
Besides schistosomiasis, there are some other Neglected Tropical Diseases (NTDs) in need for governmental control programmes. Ghana established the Neglected Tropical Diseases Programme (NTDP) to eliminate these NTDs in a structural manner [46]. As a result, it became possible to combine the diagnostic field trips of Soil Transmitted Helminths (STH), *S. haematobium* and *S. mansoni*, which are found in similar areas. Unlike the urinary *S. haematobium*, the STH and *S. mansoni* can both be found in the stool. So, each diagnostic field trip will have to combine urine diagnoses and stool examinations. As the final product will only test the urine, it should take the stool detection into account as inevitable side task.

An assigned NTDP office at the national level is governing the programmes as a separate public entity, which could be described as a so called targeted (or vertical) approach [46] (figure 20). Though, on the regional and district level, the NTDP makes use of the existing health system, referring to a more integrated (or horizontal) implementation approach. As shown in figure 20, the national department is in charge of the planning (i.e. needs assessment, priority setting and resource allocation), monitoring activities and the evaluation. While the district level is there to implement the assigned activities [46].

When introducing a new diagnostic device, the national level will be in charge of the decision making. However, as the final interaction with the device is done by the executers (technicians) in the district health facilities, both the higher and lower levels are important for successful implementation and acceptance of a new device.



Graph 2. Sources: [61] [76] [89]



Graph 3. Sources: [18] [57] [81] [86]

1.3.4 Schistosomiasis control progress

Ghana has been actively fighting the schistosomiasis for years and according to the WHO (October, 2017), the country was able to scale the control programme nationally. With urine filtration as a main tool to map the prevalence of urinary schistosomiasis, the first national mapping assignment was done in 2008 [50]. In the following years, MDA only targeted school-aged children up to 2015. That year, the scope was broadened to include the high risk adults in the programme [75] and a second national mapping phase was proceeded.

Despite all efforts, the progress is still limited. Graph 2 shows the part of the population requiring PC and the reported amount of received treatments known by the WHO database [76]. The data shows an increasing reach of the MDA as well as a growing need for the drugs. Which is both positive and concerning at the same time. The information of the WHO might be incomplete, since it is not known whether all treatment activities are reported. But after all, it should be kept in mind that a part of the light infections is not detected due to limited sensitivity of the current diagnoses, and the numbers are likely to be much higher.

As an addition on the mass medication, the WHO guidelines advices investments to improve both water and sanitation in endemic areas. As shown in graph 3, the sanitation is barely any better than 20 years ago [75] which will only stimulate further contamination of the water bodies. But there is progress in water safety. According to the CIA World Factbook (2015), 84% of the population in rural areas has access to improved water sources (graph 3). Though, whenever the future device is used by the other 16% of the people, it must be considered that there is not always perfectly clean water available to clean the device.

1.4 Implementation challenges

When implementing a new device, this should be done carefully and deliberate to make it suit the needs of the users. This paragraph will discuss a few of the challenges that came out of the literature review, to keep in mind in the following product developing stage.

1.4.1 Regional differences

Due to the primary focus of the control programmes on rural areas, differences between rural and urban areas might be less prominent. However, differences in language, culture, income, religion, education and health exist throughout the various (rural) regions (e.g. between northern and southern regions or even in between communties) [1]. Some communities are aware of the alarming symptoms, the necessity of treatment or even the source of contamination. While others hide symptoms, trust on traditional healing methods or are not aware of the disease at all. Such a wide range of context varieties within only one country causes difficulties to "*scale-up development*" [10] [1].

A final diagnostic solution should be suitable for all circumstances to implement a nationwide approach. Not only within one country, but also within a whole continent.

1.4.2 Cooperating resistance population

As explained in part 1, only one infected person is enough to contaminate an entire water source and effective control depends on the cooperation of all infected individuals to stop further transmission. Unfortunately, the medicines taste bitter and come with side effects such as feeling nauseous, sleepy or even worse in case of heavy infections [5]. As there are still communities who do not see the urge of treatment, such side affects will only ask for more resistance against the drugs.

If possible, the final design should look trustful and could be used as a communicative tool to show even the illiterate patient the diagnostic result.

1.4.3 Data sharing

Another challenge, identified during Ghana's first National Schistosomiasis Control Forum in 2012 [10] is to avoid double work by combining the knowledge or actions of all expertise in the field. Many organisations and parties are willing to work towards control, but alignment of the activities is lacking. "*For example, a number of NGOs undertake programmes and activities within the districts and communities, sometimes without the knowledge of the district health authorities*" [10]. It is needed to increase closer collaboration with the relevant stakeholders in endemic communities, synchronize programme activities and findings should be shared [10].

One major demand within this desired cooperation is the ability to share data. It might not be the case yet, but in the (near) future data transfers will become more important and the device would preferably be able to collect, process and share the desired data to assist this development.

1.4.4 Donor dependency

The current control programme is almost exclusively donor driven [46] which makes the programme less sustainable [10]. As mentioned in the first part of the project, when the programme gets interrupted (due to a donation cut) the achieved progress of the MDA will be undone within 1,5 to 2 year (Inobava et al., 2014).

First of all, the costs of the device should be kept to a minimum. Though, to continue the diagnoses even when the available budget is decreasing, the device should be operational as long as possible. To increase the lifespan, the need for maintenance should be brought to a minimum or enable maintenance with local resources.

1.5 Knowledge gaps

Based on this literature review, it can be said that the device should be able to *adapt to all kind of cultural differences*; enable *clear communication of results* to the patient; *share or process data* digitally and increase sustainability by *extending its lifetime* to a maximum.

However, these insights come with a number of knowledge gaps:

- It is needed to investigate the *potential users and their skills*. As concluded in this chapter, not all Ghanaians will be experienced in the use of smart devices nor internet. Besides, due to the large amount of languages and the possible illiterate end user, clear communication between the device and its user could be a challenge.
- The remote areas will most likely be the most challenging to design for and it should be clear to what extent of context variations the device has to satisfy. Besides, to minimise any cooperative resistance, it is necessary to explore current habits to ensure the final interaction to fit in *cultural differences.*
- When making the product robust enough to ensure long term use, it is important to know which *environmental (damaging) circumstances* will threaten the device.
- It is important to know what the *implementation criteria* are from the organisational perspective in order to design for possible short term implementation.

To fill as much of these gaps as well as extend the understanding of the final context, a field trip to Ghana was conducted. This will be further explained in the following chapter.

2 User research in Ghana

In order to fill the knowledge gaps of the literature review and to create a better understanding of the potential users and their needs, (three weeks of) user research was conducted in Accra, the capital of Ghana. The main goal of this research was to define a final user focus, specify their needs, their desires and the main requirements for successful implementation of a future diagnostic device.

As the initial focus was laid upon control activities, technicians were interviewed with experience in field trips for control programmes as well as for research purposes. However, it became clear that health facilities were at least as important and visits were organised to meet technicians of several available hospitals.

To facilitate the communication of the concept, a mock-up was brought to the field (figure 21) with an integrated tablet. This made it possible to discuss physical aspects of the design as well as the interaction with an optional smart device.

Figure 21. A mock-up to communicate the idea

Table 2.

	Research institutions*	NTDP	Total
Organisational level	4	1	5
(Research) technicians	6	**	6
Student researchers	3	-	3

* Noguchi Memorial Institute of Medical Research (hereinafter: Noguchi), National Public Health and Reference Laboratory, Centre for Plant Medicine Research & Council for Scientific and Industrial Research
** The technicians of the research institutions and some of the hospital technicians have all participated as NTDP technicians too.

Table 3.

Number of interviews in urban hospitals*	
Doctor	3
Head of the technicians	3
Technician	2

* 37 Military Hospital; Legon teaching hospital; Ridge Hospital (regional hospital)

2.1 Expert interview up front

As a final preparation of the trip, an expert interview was arranged with Dr. L. van Lieshout, the Head of Leiden Clinical Parasitology Group at the LUMC. She shared her insights and experience of diagnoses for either control programmes and research purposes in several rural areas. The goal of this interview was to validate some assumptions and get a better understanding of the situation in the field, before actually going to Ghana.

Two of the discussed topics were important for some final additions to the interview setup as well a confirmation of earlier found results.

First of all, the increasing need for digitalisation (chapter 1), to avoid double work and lower administrative costs was confirmed. Though, it could not be said for certain which data to collect exactly, as this might differ per country or project.

In order to design for data collection, it should be known what specific data the users need to process. And whether all users would benefit from digitalisation, or only the control programmes. These questions were taken into consideration and further explored during the field research in Ghana as will be discussed in chapter 3.

A second topic was the added value of standardising the measuring methods, to make all diagnoses of the same quality, no matter how experienced the user is. With such a semi-automatic counting device, this goal will be achieved and even lower educated users can do the diagnostic work. This might save costs but it also raised the question about the acceptance of such a solution in the community. As mentioned in chapter 1, authority is important and if everyone can do the diagnoses, the position of the technician might be damaged or dishonoured. These are cultural characteristics that might differ per country and is further verified in Ghana.

2.2 Research approach in Ghana

As concluded in chapter 1, when aiming for the implementation of a new product as well as the adaptation of the final user, both the organisational as well as the district level of the health system are important to take into account in the user research. This, combined with the various user groups to target (the NTDP, researchers and health facilities), resulted in a broad range of potential users to interview in a limited time. Subsequently, a qualitative research with a broad orientation was prioritised over the quantitative user research.

Table 1 and 2 show the number of people interviewed per user group. The technicians of 4 different research institutions were interviewed, but the majority of interviews took place at the Noguchi Memorial Institute of Medical Research (NMIMR) in Accra, which is the main institution for parasitical research and assists the NTDP in the organisation and execution of monitoring activities.

Furthermore, three hospitals were visited: a military hospital, a teaching hospital and a regional hospital, all located in the capital. The interviewed technicians and doctors were all familiar with the situations in the smaller, more rural, health facilities and able to provide insights about their rural circumstances and requirements. However, as the remote areas were not visited personally, this information had to be confirmed. To do so, back in the Netherlands, the findings were presented to Dr. A. S. Amoah of the LUMC to evaluate the insights and discuss the final focus.

2.3 Documentation results

Appendix D gives a summary of the trip, the activities and the main findings. Appendix H discusses some more specific insights like implementation, trust and data collection. But the most relevant and influential results will be discussed in the following chapters, to answer the set research questions.

3 Potential users

As stated in part 1, researchers, control programmes and health facilities are the three potential users for the future device. Both research and control activities are based on large scale community screening. Field trips are organised to the rural areas in order to test the local communities. Such field trips come with limitations and the urge for a portable product, able to screen hundreds of samples a day. Appendix I gives an overview of the journey and steps included in such a field trip.

Health facilities on the other hand, are only diagnosing when a doctor suspects an infection, which are executed in their own facility (laboratory). However, the user research in Ghana revealed a large number of similarities and differences between the 3 users. This chapter will discuss both, together with the findings of the current control approach of the national NTDP.

4.1 NTDs in Ghana

Out of the 17 worldwide known Neglected Tropical Diseases (NTDs), 12 are prevalent in Ghana. of which five[1] are part of the NTDP, as these are all in need of Mass Drug Administration (MDA). The other seven are treated via case management. NTDs are concentrated in remote rural areas, urban slums or conflict areas. Fortunately, Ghana has been stable for 25 years and conflicts were no limitation for control, but schistosomiasis is still endemic (either high or low endemic) in all 10 regions of Ghana.

Besides MDA, the WHO guidelines describe several other action points for schistosomiasis control (e.g. snail control, clean water provision and better sanitation). The snail control is tried, but happened to be too expensive. And as the systematic improvement of water and sanitation for all communities is an almost impossible task to achieve, Ghana decided to focus on only three control measures:

1. MDA
2. Morbidity Control and Management (MCM)
3. Health education

MDA and health education are the responsibility of the NTDP, while MCM is depending on the health facilities.

4.3.1 MDA

To implement MDA effectively, the WHO created a general step by step approach used for all five NTDs in Ghana.

Step 1: *National Mapping Phase*
As a first step, all areas are systematically diagnosed to determine the prevalence and infection intensity throughout the country.

Step 2: *MDA*
Based on the mapping results, the frequency of MDA is determined. To assess the progress of this treatment, the following side activities are included in the guidelines of the WHO:

- Reporting drug coverage after each MDA
- Assessment of some high transmission zones. These areas are supposed to be diagnosed before and after each MDA, to monitor the progress.
- Transmission Assessment Survey (TAS) after the sixth MDA to determine if the level of infections has been reduced to a point where transmission is no longer sustainable. If so, the programme can continue to step 3.

Step 3: *Surveillance*
In step 3, the MDA ends and 5 years of surveillance will monitor whether the transmission definitely stagnated.

Step 4: *Verification of the data by the WHO*
The WHO examines the results to check whether the evidence for absent transmission is correct. If so, the disease is officially eliminated.

[1]*Lymphatic Filariasis (LF), Onchocerciasis, Trachoma, Schistosomiasis and Soil Transmitted Helminths (STH)*

Figure 22.

For some NTDs, following these steps lead to successful elimination. However, the national mapping phase of schistosomiasis was completed in 2008. But since the transmission is extremely difficult to interrupt, Ghana has been stuck in step 2 ever since. And neither the NTDP nor the researchers expect the schistosomiasis control to complete step 2 anywhere soon.

4.1.2 Need for diagnostic improvement

Within this protocol, an automatic device could be of significant value in the large scale mapping phase (step 1). In 2015, Ghana has repeated the mapping phase, most likely to avoid outdated data. But according to interview results, it does not seem necessary to repeat step 1 a third time. Subsequently, when designing for Ghana, it would not be of much use to focus on the national mapping phase.

A more relevant focus would be the monitoring activities as part of the annual mass treatment. According to the protocol, a few 'hotspot' areas have to be screened before and after every MDA. However, until 2 to 3 years ago, no monitoring was conducted at all due to the additional costs of such diagnostic activities.

This changed in 2015 when the NTDP gathered about 40 technicians and (micro) biologists from all areas in Ghana to train them for the execution of the monitoring field trips. Those technicians normally work for the Ghana Health Service (GHS) and not all of them were familiar with the desired quantitative diagnoses. Therefore, the NTDP asked the researchers of NMIMR in Accra (Noguchi Memorial Research Institute of Medical Research), to train the GHS technicians in filtration and microscopic egg count.

From that year on, field trips are organised annually in which a selected group of communities is screened (prior to the MDA) by these GHS technicians. Though, as the researchers are more experienced in the microscopic egg count, the research department was asked to assist for some technical support during the field trips. Dr. Ayi from the NMIMR expect the annual pre MDA diagnoses to continue and the NMIMR is most likely to stay involved when needed.

Figure 22 summarises the assistance of the GHS and research institutions in the national NTDP.

4.1.3 Health education

The first nationwide experience with deworming MDA in Ghana, took place in 2007 and resulted in extreme chaos. Due to the Praziquantel side effects, like stomach pain or sleepiness, parents panicked and directly brought their children to the hospitals. Due to the shortage of information, there were fights between parents and teachers or others involved in the MDA. It was a shocking experience and from that moment on, health education was implemented as part of every field trip (either to treat or to diagnose).

A survey was conducted to explore the existing stigmas around the disease and based upon these results, they designed a protocol for systematic health education which is successfully implemented in the NTDP approach. Hereby, Ghana has limited the amount of community resistance significantly and eliminated one of the major challenges in schistosomiasis control.

4.1.4 Challenges

But even with increasing health education and the absence of conflict areas, there are some other challenges. According to Dr. Marfo, the manager of the NTDP, Ghana do have to deal with:

1. CDD apathy (Volunteers who lose their interest to cooperate after so many years)
2. Community inertia (Communities getting tired the annual sampling for monitoring activities, since the annual monitoring field trips always target the same communities)
3. Weak monitoring and supervision
4. Cross border issues (People are moving and it is difficult to synchronise the control activities with neighbouring countries)
5. Retirement of highly skilled staff
6. A decreasing political commitment

Number 3 and 5 are directly related to the diagnoses and tackled when the final device is both easy to use and providing more reliable results. Indirectly, when a more sensitive device reveals a much higher percentage of light infections, it might raise the awareness and commitment of governments as well as donors (challenge 6).

Challenge 4 might not be easily dealt with by the NTDP on its own. In the future, further digitalisation might bring some other opportunities to ease the international cooperation and data sharing. And hopefully, a digital product will be able to motivate volunteers.

Diagnoses in the field

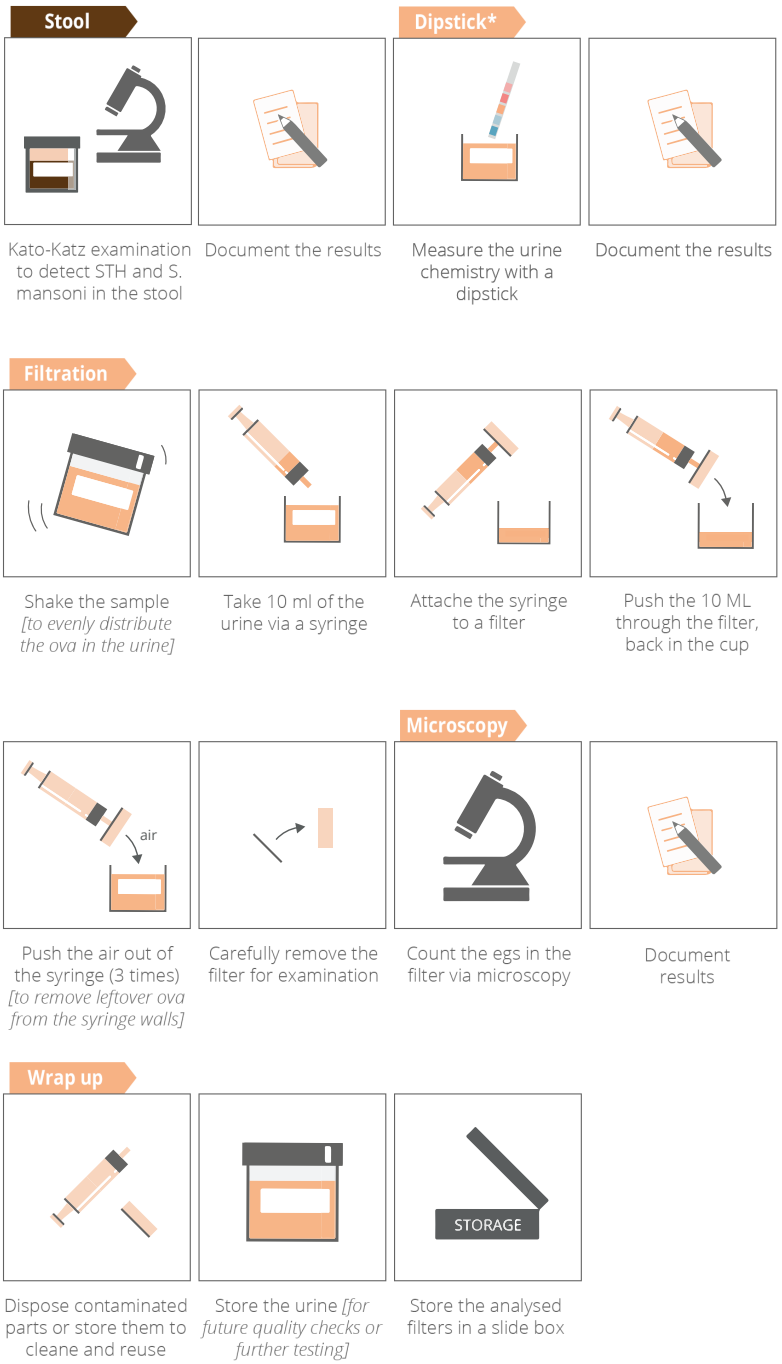


Figure 23.

**Dipsticks are not used by the control programmes*

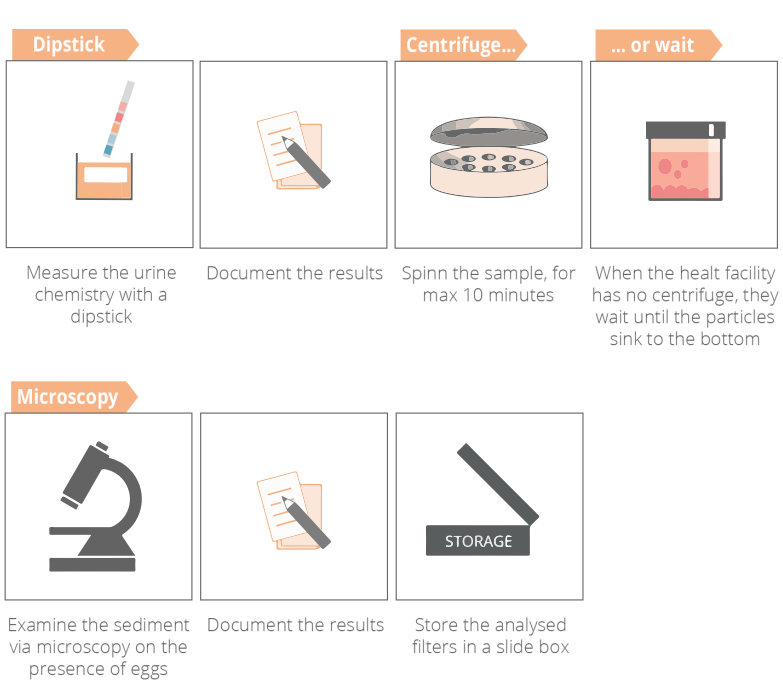


Figure 24.

4.2 Various diagnostic procedures

Each user group has its own diagnostic protocol which will influence their requirements and expectations of a future tool. The methods used in the field trips (by researchers and the control programme) are shown in figure 23 and figure 24 illustrates how health facilities examine the urine.

For the final product, it is important to know the current procedures to make the new device fit their habits. For example, as shown in figure 23, researchers measure *10 ml of urine with syringes*. When measuring the correct amount of volume with the new device, the use of the syringe would be an intuitive choice for researchers, while hospitals might just want to use the *full sample*.

Both in the field trips and in the interviewed hospitals, the dipstick is part of the protocol and technicians are trained to always take someone's urine chemistry into account. When the device will *digitalise the data* analyses, the *dipstick results* should be included in the data entry to fit the device in the current protocol.

Researchers (and the GHS technicians who participate in the control activities) are trained to count the exact amount of eggs and they learned the *value of such quantitative methods*. However, this is not the case for all potential users. Most heath centres only determine the intensity of the infection by a quick look at the sediment, assessing whether they see no eggs, a few or many (rated as -, + or ++). These examinations are much faster than the microscopic egg count in the field. And if the new device wants to add value for remote health facilities, it has to *compete with the quick sediment examination* (which will not take more than 5 to 10 minutes).

Something else to consider, is the contaminated equipment. Plastic products are normally *disposable* while glass product can easily be *cleaned*. The interviewed researchers just need the most economically beneficial option, while rural HC with only a few spare parts in stock would rather reuse the syringes.

Lastly, the interviewed researchers and hospitals *store the samples afterwards*. Either for further examination in the lab or for quality checks. When designing for these users, the device cannot dispose the sample after the test and the urine preferably returns in the original cup. Other experts in the Netherlands (appendix P) confirmed that not all facilities nor researchers store the samples afterwards, and it is assumed that the most remote facilities will *dispose the urine* after the test.

Those behavioural variations will help to design a more intuitive and appreciated product interaction. They are added to the final programme of requirement (appendix J) and used in the final design of the product interaction as can be found in report part 3.

4.3 User profiles

However, there is no user interaction without a product to implement. The following pages will dive into some more fundamental implementation requisites and functional requirements for each potential target group in order to fill the gaps in the market.

User profile *Control*

The control programme has several challenges to face. First of all, the annual monitoring field trips highly depend on the limited amount of trained technicians and the NTDP needs to be flexible and act upon the available specialists and equipment.

Moreover, when doing diagnoses in the field, the circumstances vary per community. Sometimes a classroom can be transformed into a temporary lab, but the technicians might also be forced to do the diagnoses outside. Figure 26 show the several variables and constant parameters for the field trips.

Implementation criteria

The control programmes are, as explained earlier, depending on a tight budget. Both the NTDP manager as well as involved professors and technicians confirmed that costs are a limiting factor in all their decisions. And, when implementing this new device, it should definitely reduce the overall costs and suitable for the large scale projects.

Moreover, before the NTDP is willing to implement any new technology, it must be tested on sensitivity and specificity by the NMIMR research department. However, the NTDP follows the WHO guidelines to the letter. So if the WHO does not change those rules, the NTDP is not likely to change either. To convince the WHO, the researchers should be able to prove the benefits of the new device.

Figure 25 summarises the current methods, including the challenges

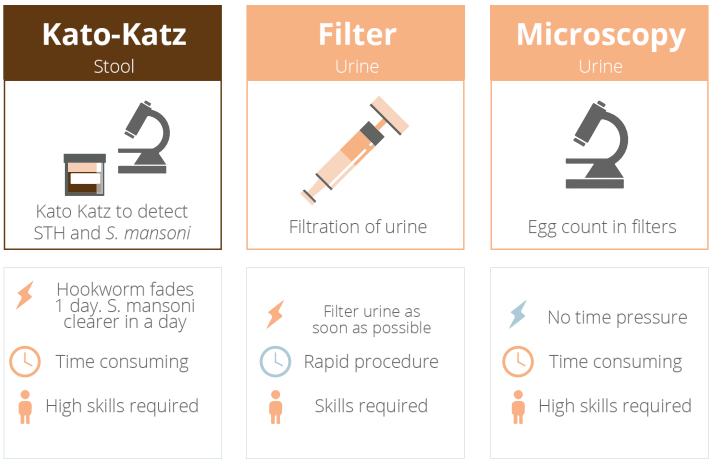


Figure 25. Diagnostic tasks control programmes

or fallacies of each procedure. As shown in the figure 25, they do not use dipstick. For the NTDP, the main goal of the monitoring field trips is to define the intensity and presence of the infections among the populations. Dipsticks would extended the results, but it would also raise the costs of the programme. Limited by the budget, the NTDP has decided to leave the dipstick out of the procedure and only count the number of eggs per 10 ml urine.

The quality of the results highly depend on the technician's skills. But, even an experienced technician gets tired after dozens of examinations, reducing the sensitivity of the microscopic examination. Moreover, the time consuming procedures (as well as the low number of trained technicians) forces them to stay in the field for longer periods of time, something that significantly increases the costs of the project. To reduce those spendings, time should be saved without lowering the quality. An automatic device would be able to solve both issues: time and skill dependency.

Besides the urine examination, field trips directly test the community on the *S. mans*oni parasite and Soil Transmitted Helminths (STH), which has to be done via stool examination (with the so called Kato-Katz method) As stool contains a lot of particles, both the preparation of the test as well as the microscopic examination is more difficult and time consuming than the urine examination.

On top of that, the hookworm (one of the STHs) fades away within a day or sometimes even in a few hours, creating time pressure for the technician. The *S. mansoni* eggs on the other hand, are actually more clear after at least one day and the prepared slides are preferable examined twice (once for the STH and the second day for *S. mansoni*).

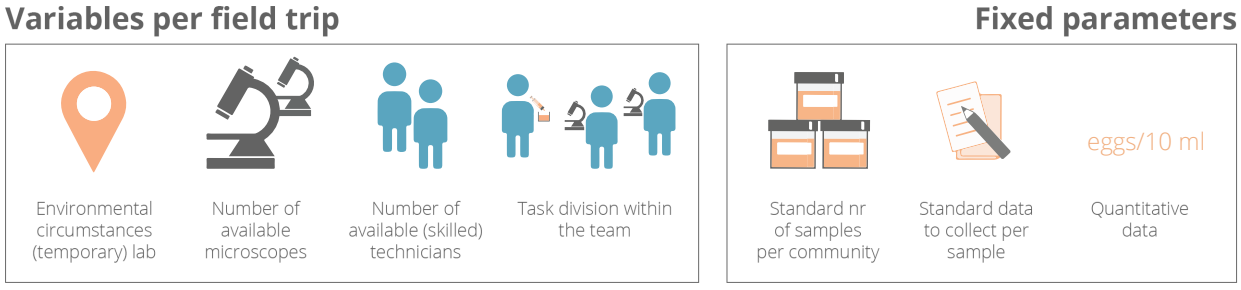


Figure 26. Variables and fixed circumstances per field trip

So, urine filtration might be time consuming and skill dependent, but the stool examination is even a heavier burden for the field trips. As Dr. Osei (2018) formulated: "*You can work on a solution for S. haematobium, but without tackling its big brother S. mansoni, you cannot solve the whole problem. They are like brothers.*" On the short term, this new technology will only examine urine. Though, it might be possible to mix stool with water to be examined by the same technology. When focussing on control programmes, the possibilities of stool examination should be further explored.

Tasks, pains and gains of the control programme

Figure 27 summarises the discussed procedures, criteria and desires of the NTDP in relation to the field trip diagnoses of *S. haematobium*. When further designing for the control programme, these will be leading requirements for the further product development.

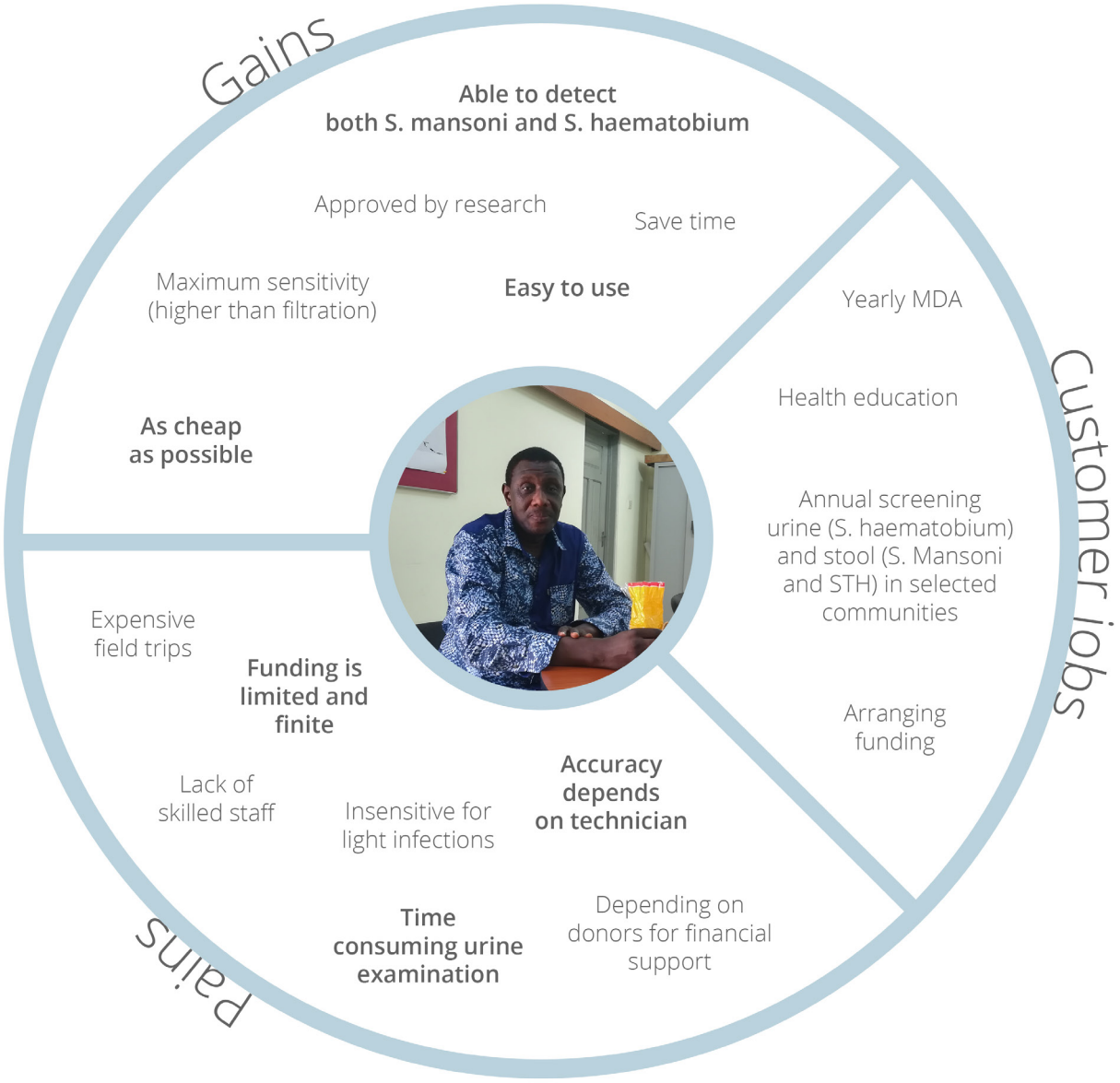


Figure 27. Control programme

User profile *Research*

Just like the NTDP, research institutes organise field trips, but then for all kinds of purposes. As they have their own laboratory in the research institution, some of the testing happens in their own lab, with all possible equipment available (e.g. to use more reliable methods like PCR). However, the biggest challenge is to have an accurate technology to use in the field, for the large scale community examinations. So, assuming that a device, suitable for the field, would also be able to please the needs in the lab, this project will only focus on their needs for field trip related activities.

Compared to the monitoring field trips of the NTDP, researchers have to deal with much more variation in their work (figure 29), depending on the specific research goals. For example the amount of samples to collect can differ from dozens to hundreds per community. As they often have to test several communities, researchers can spend weeks in the field.

One major advantage of the research department, is that their technicians are always well trained and used to the quantitative data collection. Unfortunately, there are not always enough researchers to cover all the work. And with a select number of technicians, the field is still time consuming.

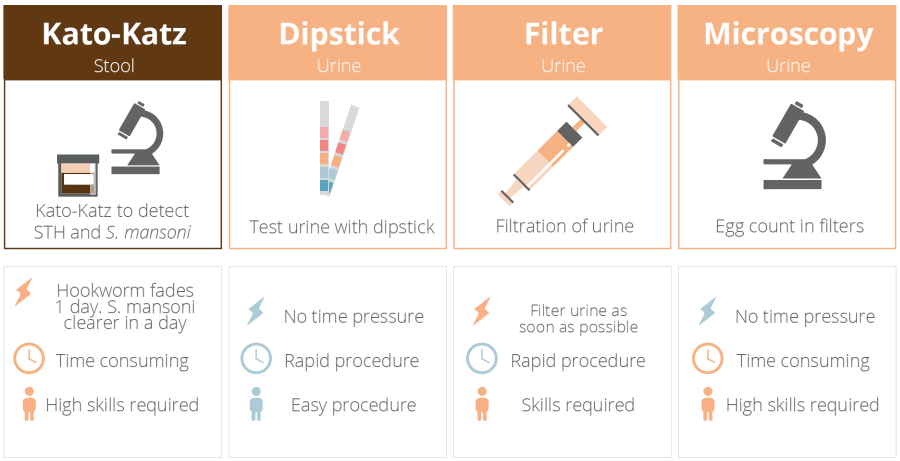


Figure 28. Diagnostic tasks researchers

Another difference with the control programme is the amount of data to collect, as the exact data differs per project. However, the NMIMR has made a standard form for their urine and stool analysis results (appendix E and F) for the data they always collect:

1. Number of eggs per 10 ml
2. Dipstick chemistry results
3. Sample colour

When the final product digitalises the data collection, this data should be taken into account.

Implementation criteria

The criteria of the researchers are comparable to the control programmes, but they have a higher need for complete and extended data collection.

The egg count will not always be sufficient. After years of infection, more and more eggs will get stuck in the tissue and in the end, the ova will no longer appear in the daily urine (appendix D). Furthermore, when for example only infected with male or female worms, the egg count will give a false negative. In these cases, the dipstick test is able to reveal the parasites via the presence increased protein levels. Therefore, the researchers will always include the dipstick test in the urine examination (figure 28). Although completeness of the collected data is of higher

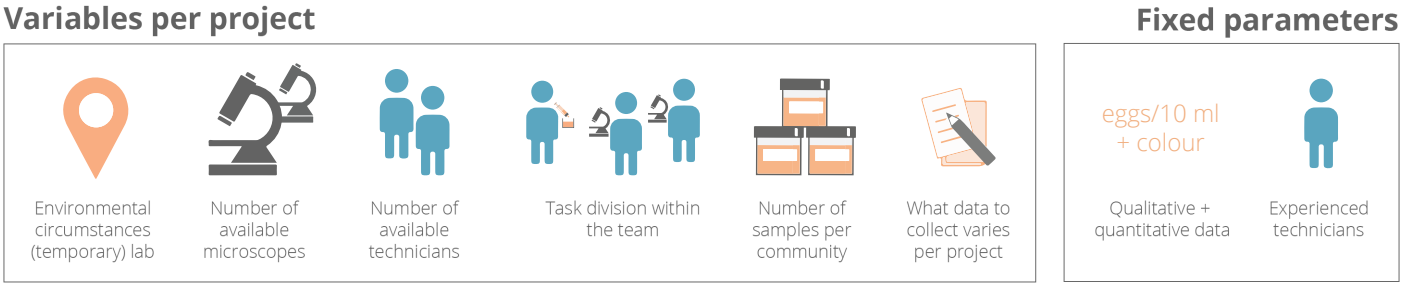


Figure 29. Variables and fixed circumstances per field trip

priority than the total costs, they too are depending on a limited budget and want to save time and money whenever possible.

Finally, a major criteria is the quality of the device. Before implementation, they need to do a quality check to see if the device is indeed sensitive and specific enough. Thereafter, regular quality checks will be executed while the device is used, to always confirm its performances.

Tasks, pains and gains of the researcher

To summarise their main needs and problems to tackle, figure 30 shows the gains, pains and tasks of the Ghanaian researcher. Which will be used as leading requirements and criteria to fulfil when designing for this user group.

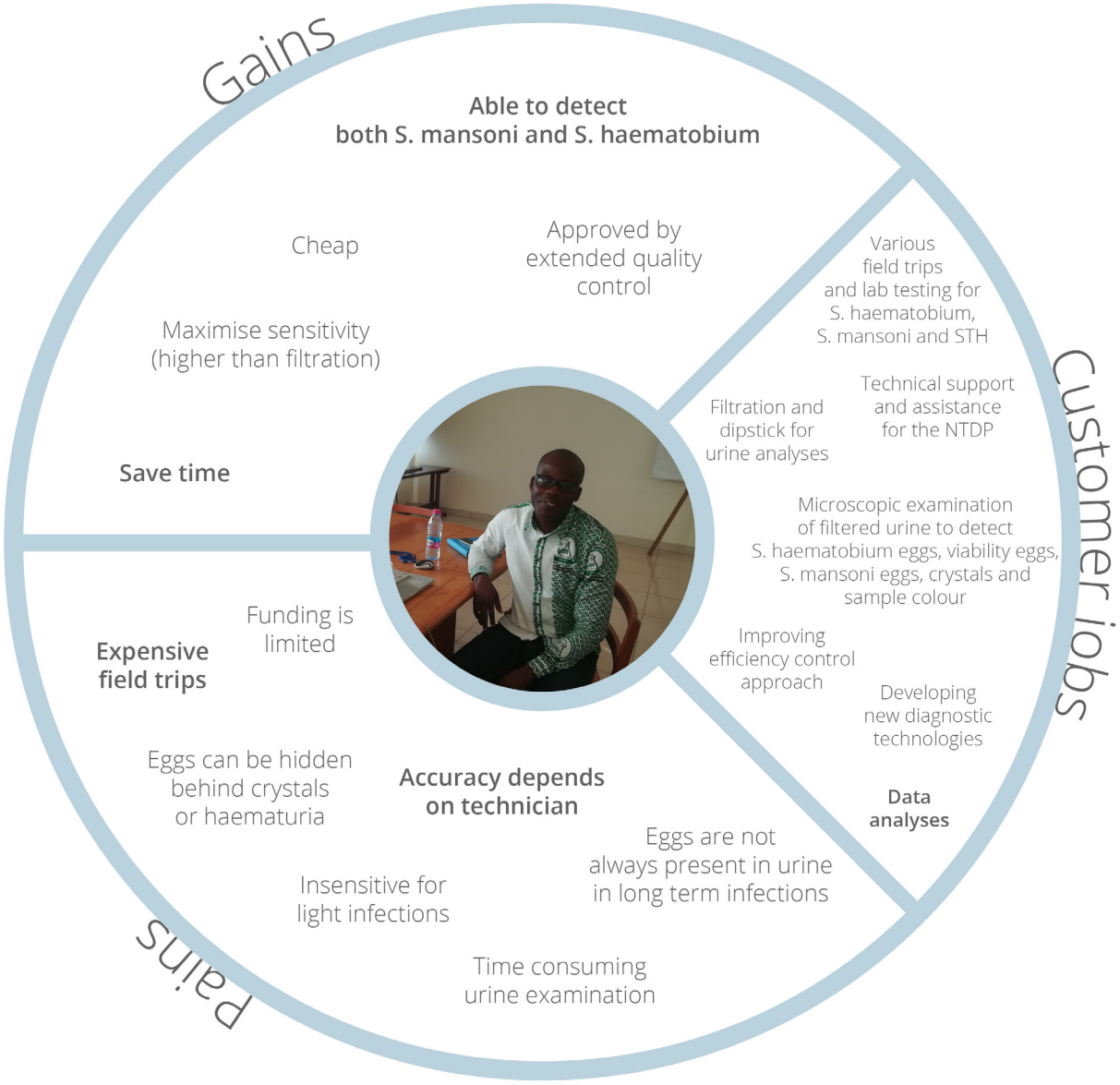


Figure 30. Researchers

User profile *Health facilities*

Health facilities differ a lot from the previous discussed users as they perform symptom based treatment instead of community screening. In contradiction to the field trips, the health facilities do not have to combine stool and urine examination. Besides, they use centrifugation (or just wait for hours) to analyse the created sediment via the microscope.

Figure 31 and 32 show the current methods, the challenges, variables and fixed parameters per health facility. As discussed earlier, their methods are fast, but insensitive and the quality depends on the skills of the technician as well as the motivation to do an extended microscopic analysis or just giving it a quick look.

Subcategories

Within the category of Ghanaian health facilities one can identify many variations: rural versus urban; high endemic versus low endemic areas; national, regional or district level and public versus private health. For this project, a distinction is made between rural and urban facilities, as they differ for example in the available equipment and trained specialists (figure 32) and thereby their ability to execute proper diagnoses (figure 31). A second differentiation is made between low and high endemic area as this might influence the awareness about the urge of diagnosing and amount of cases to process per day. The Ghanaian health facilities are divided in three groups, with different requirements for a future device:

1. Urban health facilities
2. Rural health facilities in low endemic areas
3. Rural health facilities in high endemic areas

In other countries, the urban facilities would have been divided in low and high endemic, but this categorisation is left out since the bigger cities of Ghana are both located in low endemic areas.

During the research in Ghana, three urban hospitals were visited providing information about the urban settings. Unfortunately, none of the rural facilities could be visited. Though, some of the interviewed doctors and (hospital) technicians lived, worked or visited the rural health areas long enough to provide information about the needs and working conditions in remote areas. The following information is based on the findings that were either in line with the literature study or discussed afterwards with the Dr. A. S. Amoah, at the LUMC, for further validation.

All three types of facilities will be shortly discussed within the following pages, together with their diagnostic and logistic requirements.

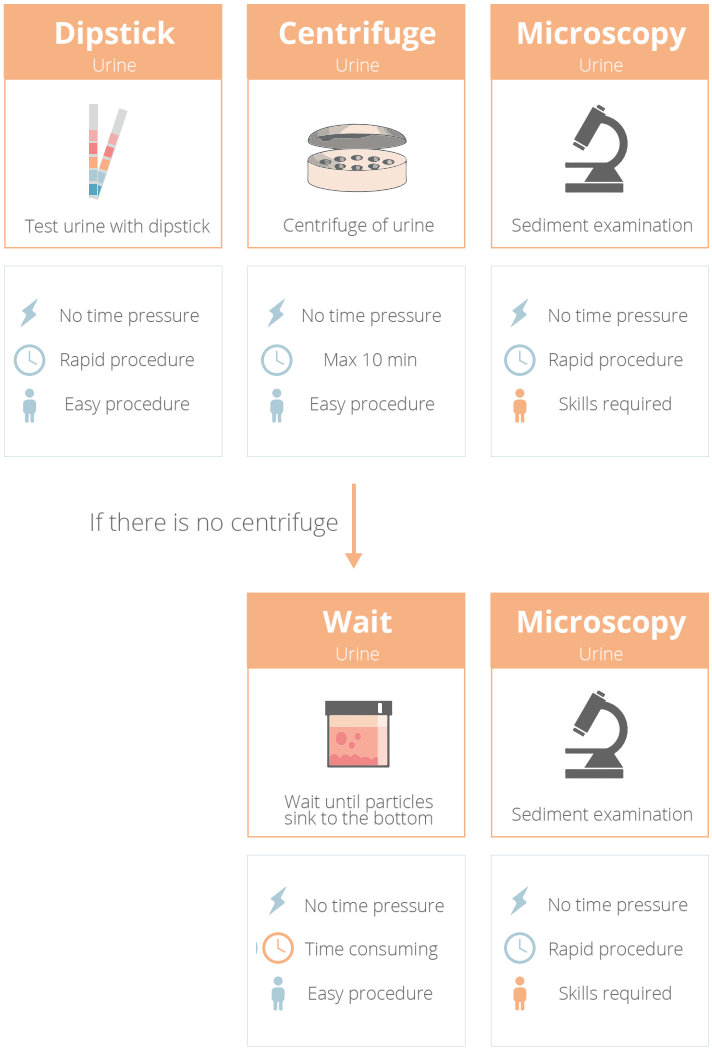


Figure 31. Diagnoses health facilities

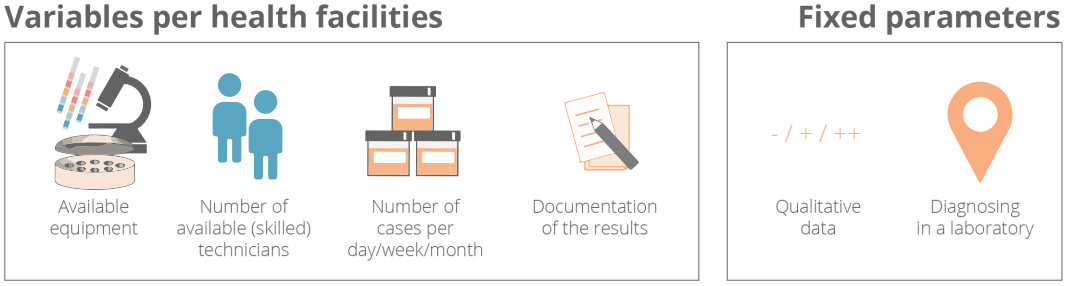


Figure 32. Variables and fixed circumstances per health facility

Urban health facilities

Cities like Accra and Kumasi are considered as low endemic areas where the number of cases has been dropping in the last couple of years. Some of the bigger hospitals receive the referred patients from smaller HCs who could not get the sufficient treatment in their village. But generally, most of the (urban) hospitals are barely doing any schistosomiasis diagnoses. Some assumed that this is caused by increasing awareness and health education. But, as discussed earlier, urban schistosomiasis is an underestimated phenomenon and it might be the case that (even in Accra) many people are infected without knowing.

Especially in low endemic areas, the majority of the prevalent infections are light, making sensitivity a main criteria for the urban facilities. But in general they would prefer a device to detect more than the parasitic infection. Despite the low amount of schistosomiasis diagnoses, they execute daily urine analyses for other purposes (via microscopic sediment examination) to detect pus cells, epithelial cells, yeast cells, red blood cells, various types of crystals and cast in urine. If the device would be able to detect these particles too, it would be of great value for the urban facilities and significantly increases the usage frequency. If only detecting schistosomiasis, the technician still has to do microscopic examination to detect the other particles, and the device would not be able to save any time.

Furthermore, when buying a new technology, facilities do not only look at price and quality, but compare suppliers also on maintenance service.

Figure 33 summarises the main desires of the urban facilities.

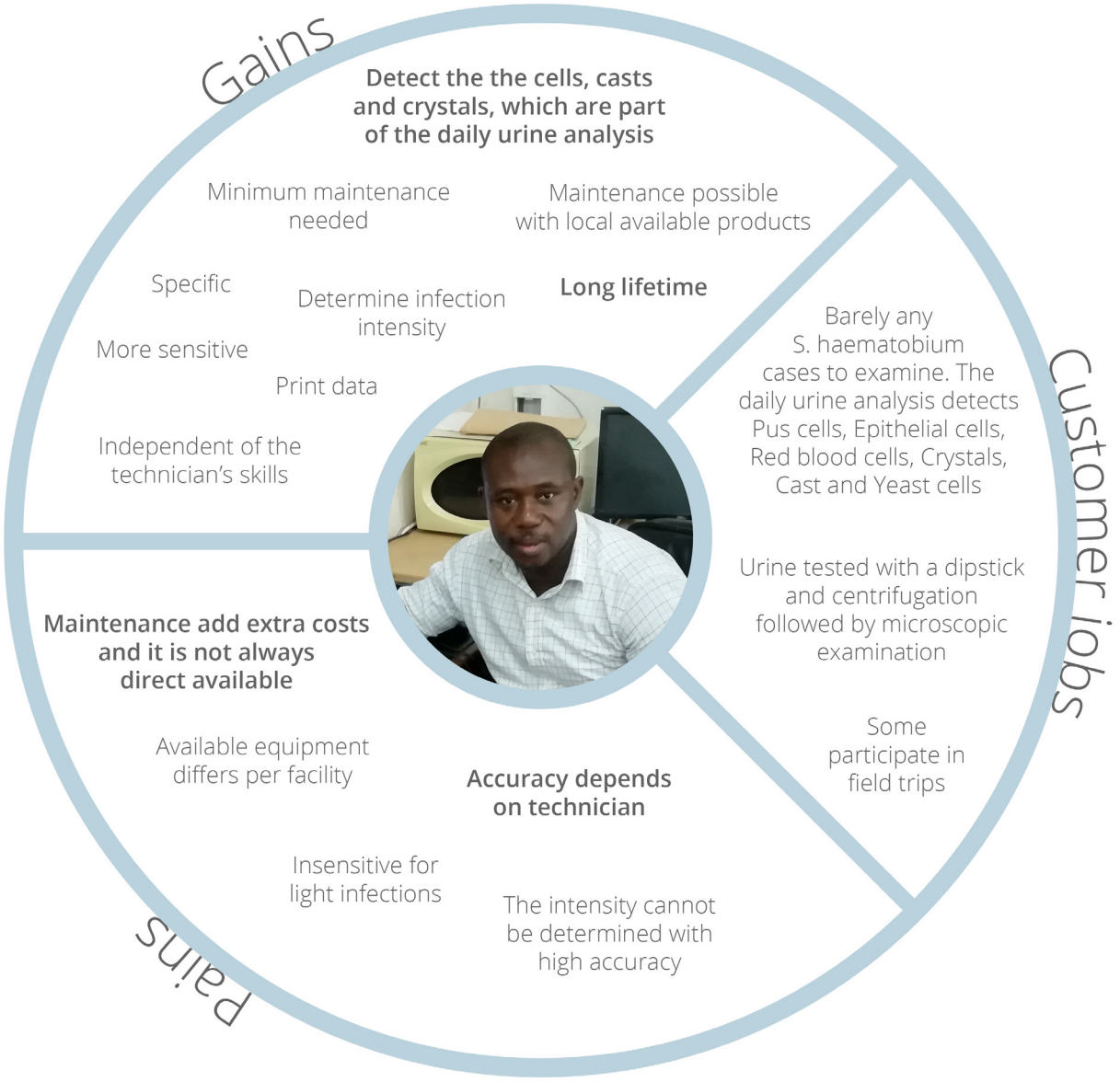


Figure 33.Urban facilities

Rural areas

As explained before, rural areas have some bigger challenges to face compared to the urban facilities. There is no assurance for available equipment or specialists and many remote areas do not have access to any maintenance service. Therefore, once broken, equipment cannot easily be repaired if it requires anything else than the local resources: "*you can give them a screwdriver, but if it breaks they will not be able to replace it*." (Dr. Damba, 2018). The main priorities for the final design would be a device that is easy to use as well as to easy to repair. Ideally, it will not even break.

The current diagnoses only provide rough estimations of the infection intensity and are mainly used to determine whether a patient is infected or not. Though, the interviewed technicians explained that knowing the exact intensity is of added value for monitoring the infections and more accurate medical advice. So, the device would be able to benefit the user, as long as it fulfils the requirements of maintenance and usability.

Low endemic

For the low endemic areas, schistosomiasis will not be the highest priority and it can be assumed that a product must be very cheap to get their attention. However, the sensitivity is again of high importance, since there might be a high number of light infections, of which not all facilities are aware.

If the device is be able to detect more than only urine, this would help to make it more attractive to invest in.

High endemic

Rural areas on the other hand are, according to the interview results, dealing with much more cases to detect. And a device that only detect schistosomiasis would already be interesting, especially if it is easy to use, fast and sensitive.

Figure 34 summarises the results of both low and high endemic areas.

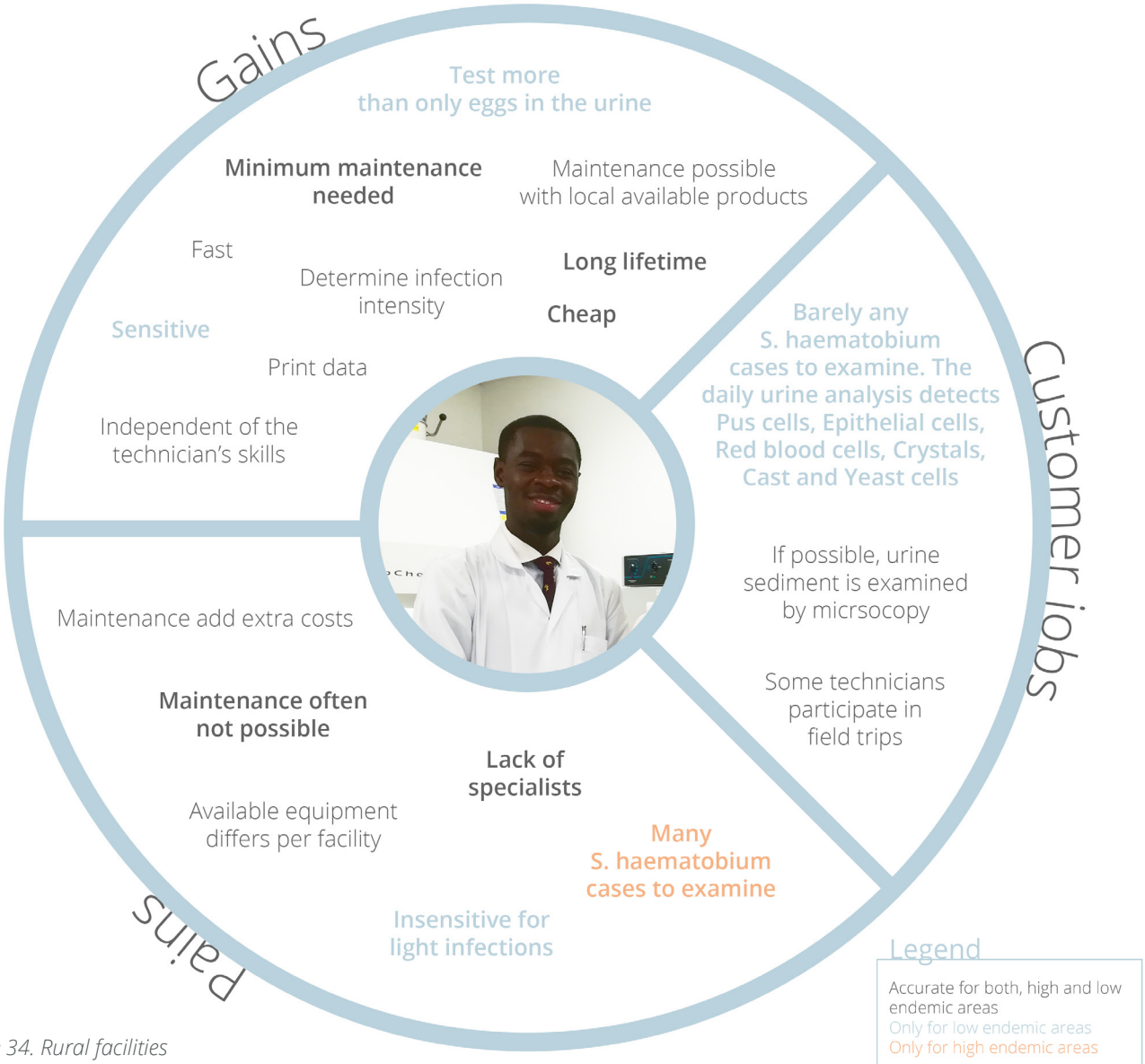


Figure 34. Rural facilities


NO EATING,
DRINKING OR
SMOKING IN
THE
BD

4.4 Conclusion

The NTDP is, as mentioned in chapter 1, using the current health system (the GHS) to execute their control activities. The technicians participating in the control programme are actually GHS technicians, trained by the research (technicians). In short, the NTDP depends on both researchers and health facilities to provide either knowledge and experience or the man power for the annual monitoring activities (figure 35).

Furthermore, figure 35 summarises the schistosomiasis related activities of the main 3 user groups. The next page shows the complete overview of all potential users together with their most important requirements for the future device.

Initially control programmes were identified as the most urgent group to design for. However, as monitoring activities are probably the first activity to eliminate from their protocol when the budget decreases, the NTDP could not be seen as a reliable customer due to the inconsistent use of diagnoses. Besides, they will only change their method when the WHO approves.

Therefore, the researchers are a much more crucial group to focus on. They will be able to prove the added value of the device in field trips, publish results (to convince the WHO) and introduce the device to the control programmes to facilitate internal acceptance of the technology by the NTDP.

Looking at the health facilities, the urban facilities want to do more than only schistosomiasis detection to make it profitable to invest in such a device. Unfortunately, the cells and crystals they want to detect are much smaller than the Schistosoma ova and the technology will not be able to detect this for now. Consequently, the urban faculties will not be the prior focus of the device.

More likely will the technology, with some additional research, become able to do the stool examination. This would be a great additional value for the research and control field trips.

For the rural high endemic areas, the device would be essential due to the high infection prevalence, as long as it is affordable. But besides the price, successful implementation in rural areas depends on a few key criteria. The device should be easy and preferably self explaining for those without a specific training or education. The risk on any damage should be minimised and whenever something breaks, it should be easy to repair in remote settings.

And finally, the low endemic rural areas is a group that is often underestimated. The number of light infections might be much higher than so far examined and when neglecting those areas, they could easily turn into high endemic regions.

So, the researchers and the rural health facilities are the two user groups that will definitely benefit from such a new device and a solution will be created to please both. Whenever this succeeds, the control programmes will be able to use it too as they are less demanding. Only the urban hospitals will not to be completely satisfied with the current technology and therefore not included in the further project scope.

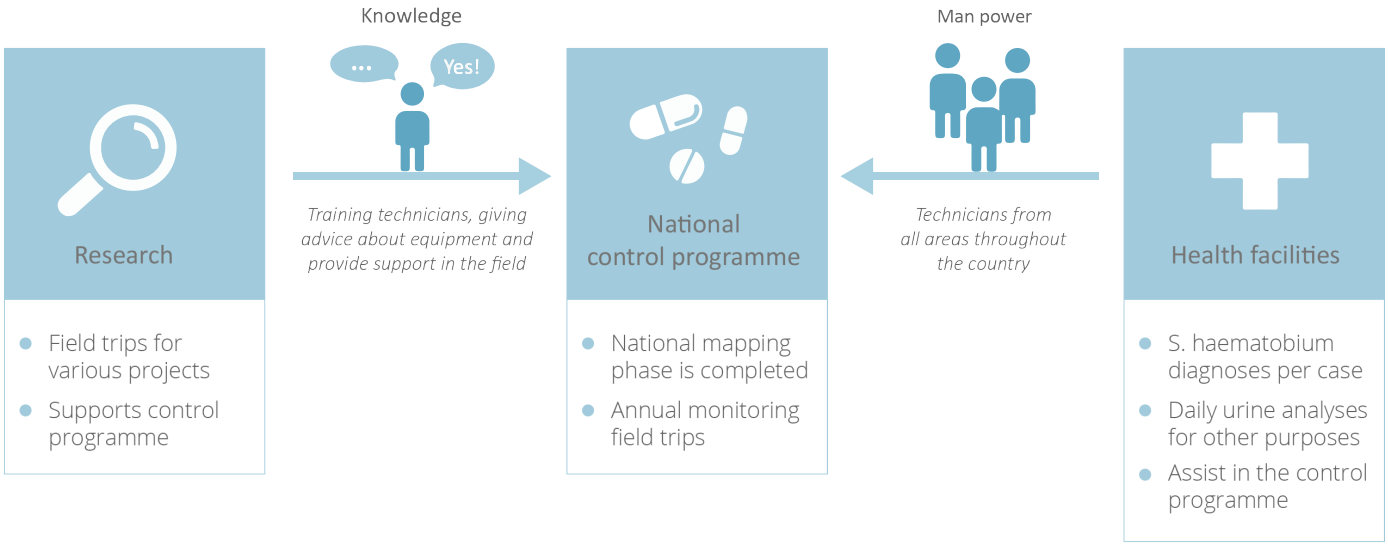
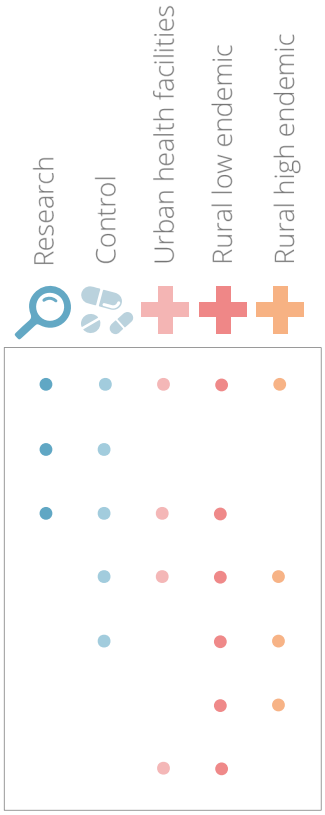


Figure 35. Tasks and responsibilities per user group



High priority implementation criteria

Specific

Save money by saving time

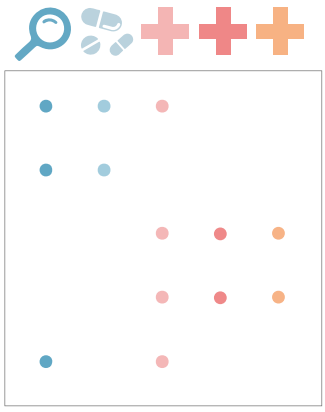
Sensitive for light infections

Cheapest option

Easy to use / little trainging required

Minimal maintenance needed or easy to repair locally

Detect more than only eggs in urine



Other criteria

Digitalise data processsing

Able to analyse stool

Faster than sediment examination

Low maintenance costs

Combine results with more data
(e.g. dipstick or urine colour)

4 Product related insights

The previous chapters discussed the potential users, current protocols and their main requirements related to the functionalities and usability of the product. Though, there are many practical product features to design. As the previous chapter describes a smart device, one should think about options to send or save data. Are wireless connections even an option, or does it need to have a USB port? And what does the device be able to resist and withstand? How long should it work without electricity?

And when stating that a product must be simple, how to achieve this without the creation of an unprofessional distrusted appearance? And which qualities are more important: beauty or function?

This chapter will discuss the design related insights of the user research. Creative interviews were done to discover desired design qualities. Moreover, a mock-up of the device was brought to each interview to discuss some practical features based on the experience in the field or laboratories. The results are divided into two subcategories: product features and design qualities.

All the product related insights will be added to the programme of requirements in appendix J.

4.1 Product features

This paragraph will discuss specific product features and problems to take into account for the final product development. The majority of the problems will be solved within the third and final part of the project, but some other criteria will be passed on to department of Mechanical Engineering, to take into account in their technical choices.

4.1.1 Data and what to do with it

Data is currently documented on paper by all five user groups. Some of the users (like the remote health facilities) do not need to digitalise the data as they work with a paper administration and mainly need to know whether to treat the patient or not.

However, researchers and the NTDP currently enter everything in the computer by hand when back from the field. And, as mentioned earlier, digitalising this process would save a significant amount of time and double work.

If one wants to collect this data digitally, there are a few design criteria to consider. When spending weeks in the field, the device should have enough memory to store all collected data or able to save the data in between on an external memory storage. When using

an SD card inside the device, the researchers can bring several extra SD cards, in case the card is full.

Even when everything is digitalised, paper backups are trusted over the digital information and researchers and technicians explained that paper administration might not completely be replaced by digital storage. In order to share the data with others, the device should allow data transfer (wireless, via the SD card or by cable) to a second device, this device can be used to print the data whenever a paper backup is required.

To conclude, when the device will facilitate digital data processing, it should at least be able to save and share the data. Those connections can be wireless (e.g. NFC, Bluetooth or Wifi) but these technologies might not always be available and thereby limit the user to transfer the data whenever needed. It would be easier to use SD cards, USB ports or maybe more basic communication methods like SMS.

4.1.2 Fool proof

As discussed before, little to no training should be required and the interaction must be self-explaining. But there is more to consider. All user groups are facing the challenges of lacking educated staff. It would be of added value for all, and a necessity for remote areas, to make the design completely *fool proof*. This includes the prevention of any damage in case of unintended use or whenever it falls. The device should not easily break nor fall. Subsequently, it must be easy to carry around to prevent from slipping through someone's hands and has some anti-slip at the bottom to prevent it from sliding of a table. Next to this, the scenarios of spilling urine must be brought avoided. And even without training, the device must be properly cleaned.

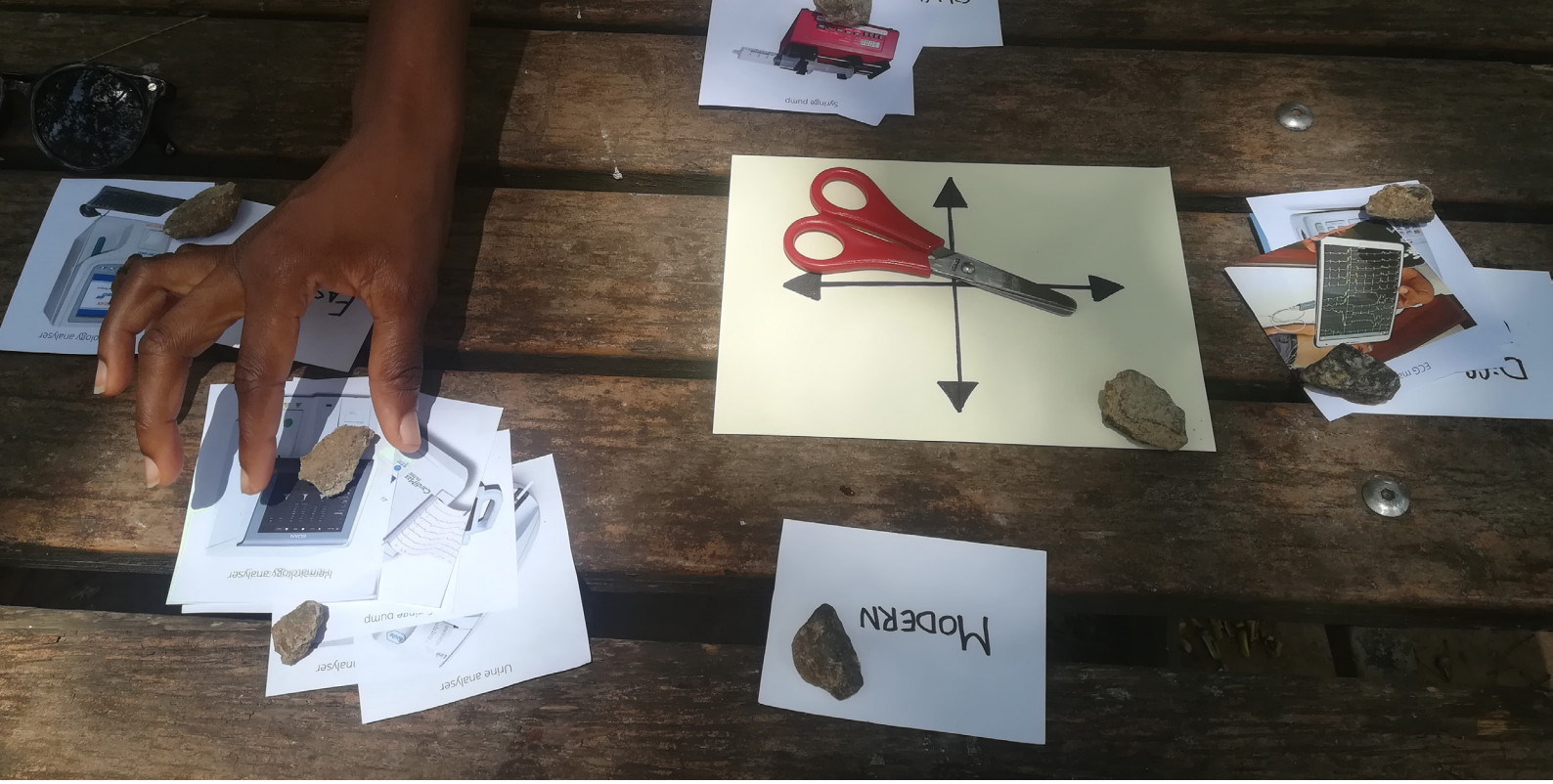
Furthermore, when working on a large scale project in the field, or in a crowded understaffed hospital, the technician might be using several devices at the same time and loose attention for one of them. If a device needs any attention in between, the product could give a sign or alarm to keep the work of the technician as efficient as possible.

The final user might have little knowledge of schistosomiasis in general and a manual should be included to avoid any misinterpretations of the results. As an addition, it cannot be said for sure that each user will be literate, the manual must be visual to be understood by everyone.

4.1.3 Circumstances in the field

The exact circumstances in the lab can differ a lot per facility, but the most extreme working conditions will be experienced during field trips. The temperature can rise over the 40 degrees or it can rain the full day. The amount of samples per community usually vary from 50 to 200 per community, and several communities might be visited in one trip. So, the device must withstand these extreme weather circumstances from early in the morning till deep in the night. It should be water and dust resistant and the information on the device must always be visible, even in bright sunlight.

Lastly, the transport itself can be rough too and the product must be protected from damage during occasional bumps in the road. Furthermore, for both remote health facilities as well as field trips, power supply will be a challenge. Not all areas will have power available and peak currents are common, which will significantly decrease the product's lifetime.



4.2 Design qualities

At the NMIMR, small qualitative research is conducted with an experienced researcher, a research assistance and two research students who all work in the lab or participated in field trips (appendix G). Two of the participants were asked to evaluate a couple of medical devices. All devices had a screen, but a complete different appearance, varying in colour, material, shape, interaction and many more. Each researcher was asked to express their preferences by thinking out loud. The aim of this interview was to gain general knowledge about valued product qualities.

In the two other interviews, the participants were asked to rate a set of devices on four predefined evaluation criteria: beautiful versus ugly; easy vs. difficult to use; professional vs. unprofessional and modern vs. old fashioned. These results were used to formulate design guidelines to assist in the final product design (part 3).

This paragraph will discuss the most interesting and inspiring insights, valuable and relevant for the final design. A more detailed discussion of the approach and an overview of the given answers can be found in appendix G.

4.2.1 Functional convenience over physical appearance

As a designer, we often assume users notice and value aesthetics as much as we do ourselves. However, when asking the researchers which product was most appealing to them, they all referred to the convenience of certain functionalities like "*portability*", "*easy to use*", and "*with a suitable power supply*" were suggested.

Digital devices like tablets were pointed out as beautiful, but again mainly due to the added functionalities like wireless data transfer. When the actual looks were discussed, they preferred the colours which are currently used in the lab or hospital environments (e.g. white, black and pastel blue) and the design should not be bulky or unnecessarily big.

So, it seems like the functional performances are much more important than the beauty of the design. Though, the current hospital tools could work as an example for the final design (figure 36)

4.2.2 Professional appearance versus easy to use

A professional product should save time and make your work easier. But, according to the technicians, you should need some kind of training and experience in order to use it correctly. In other words: one needs to be a professional before using professional tools, which fits the earlier described hierarchical culture.

Figure 36. Impression of current laboratories

This would be in contradiction with the other design goal: making it easy to use for the 'non professionals'. And a balance should be found in those two opposites for the final design. Making it look professional enough for experts, while easy accessible with little required training for the less experienced users. This might be achieved by a slightly different product variation for each user: one with complex and extended functions for the researchers while a more basic product could server the remote health facilities.

5.1.3 Modern but fragile

Modern products were described as *easy to control*, *providing all necessary information* and *making the work a lot faster*. Especially the use of a touchscreen increases the modern look and creates the flexibility to add endless extra functions. However, some downsides were recognised too, such as the larger power demand and a screens that easily breaks.

For the final product, it should be considered whether those digital functions are worth if they decrease products life time and usability in the field.

5.1.4 Design guidelines

Figure 37 shows the most preferred criteria for the future device, as mentioned by the four participants. These qualities are based on the opinions of only four researchers and, although the research department will be part of the final target group, the other users might see it differently. Therefore, the qualities as described in figure 37 will be used as wishes, rather than requirements for the final product (appendix J).

4.3 For technical department

As an addition on the design considerations and product features, the user researched revealed some results regarding the technology:

- For a constant quality, the device should ideally have the same sensitivity regardless of any blood, crystals, dead eggs, *S. mansoni* eggs or any other particle in the urine.
- Besides, as suggested before, the technology might be able to diagnose stool as well as urine and it might be possible to mix a small amount of stool in a suitable liquid to be able to pour it through the design. The technology needs to be further developed in order to enable such variations, but it seems as a future possibility.
- Some of the users requested to distinguish the dead eggs, crystals, cells, yeast, cast, sample colour or dipstick chemistry parameters. Unfortunately, these are less likely to be detected with the current technology. But a lot of developments are going on and if in the end another technology will chosen, this request should be reconsidered.

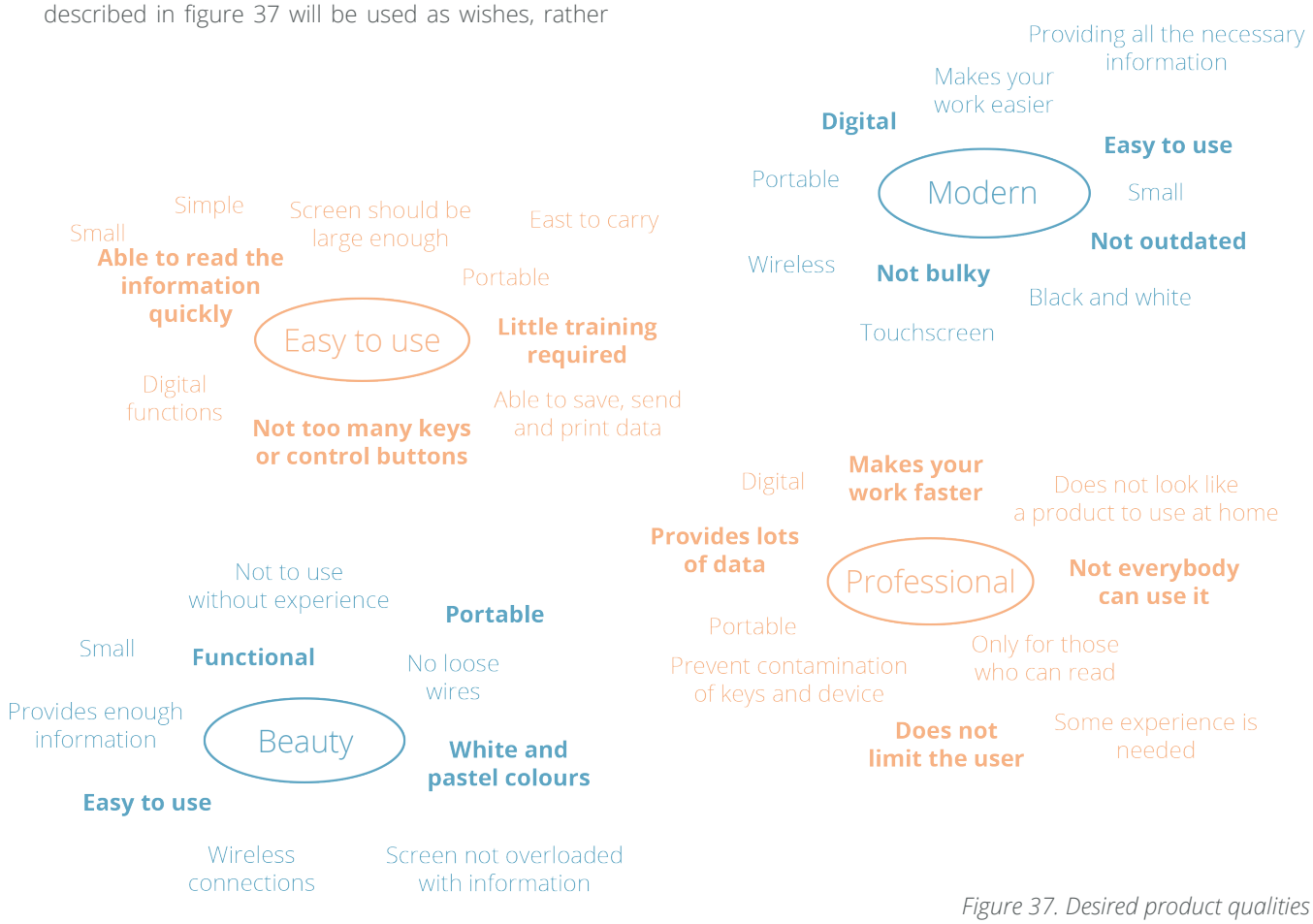


Figure 37. Desired product qualities

5 Conclusion

Research questions part 2

3. Who is the foreseen end user?

4. What are the functional requirements for the new product in order to fulfil the needs of the end user(s)?

5. What product interaction matches the habits, skills and desires of the end user(s)?

6. What product features and qualities does the design has to fulfil?

7. What are the key challenges for successful implementation?

Compared to other endemic countries, Ghana has already made a lot of progress in the organisation of a nationwide control approach. Annual MDA is executed and since several years, the MDA is combined with monitoring activities. Though, after all the effort, schistosomiasis is still widely spread.

Different users are fulfilling various purposes in the fight against the parasite. Researchers are looking for ways to optimise the approach while health facilities are key for effective case management. An extended literature review and a user research in Ghana were conducted. The results from the field research were first of all discussed with the engineers, who are responsible for the technology, to see which of the wishes from the field were feasible to realise. Thereafter, a meeting was organised with Dr. A.S. Amoah, an expert in schistosomiasis diagnoses in rural Africa, and together, a final direction and focus group was determined, which was the start of the actual design process.

The collected information was used to answer research questions 3 to 7 of which the main conclusions will be discussed in this conclusion.

5.1 User group

To answer research question 3, five potential users were identified within the Ghanaian context:

1. Monitoring field trips for the NTDP by trained technicians of the GHS
2. Field trips for research purposes
3. Urban health facilities
4. Rural health facilities in low endemic areas
5. Rural health facilities in high endemic areas

Figure 38 summarises the amount of demands per user (the more demanding, the bigger the circle), categorised on their main requirements. The orange rectangle shows the limits of the technology, which do not cover all the demands. For example, the urban facilities are mainly interested in a multi purpose device, which is not possible anywhere soon.

The low and high endemic areas are combined as one, since they basically have the same demands. The only difference will be that the low endemic areas might lack the motivation to invest in a device, but this is mainly related to the final implementation plan instead of the design requirements.

The control programmes are least demanding and somewhere in between the desires of the remote health facilities and the researchers.

For the continuation of the project, it is decided to focus on the two most extreme users, which still fit within the technical limitations: the researchers and the remote facilities. Whenever suiting them both, the control programme will benefit for sure. Hereby, one product could suit all possible users within the technical opportunities. The interaction might differ for each group, but when the device itself is the same, the product will reach a larger market and is more likely to fit the other countries too.

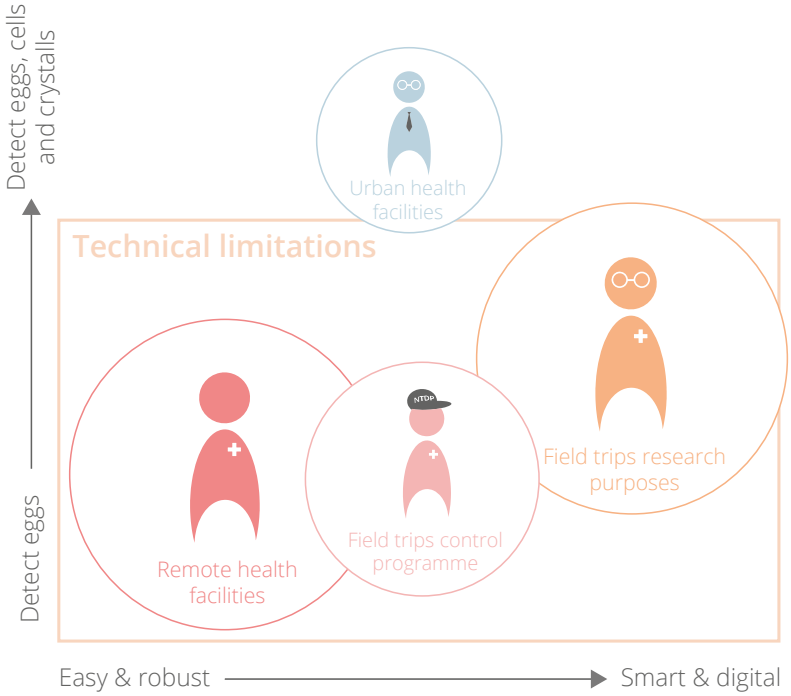


Figure 38.

5.2 Design requirements

The results of research questions 4 to 6 are summarised in a programme of requirements which can be found in appendix J. These requirements are related to functionalities, interaction and the product design itself. Part 3 will integrate the criteria in a final product to serve both user groups.

When designing for the two types of users, the criteria are rather divers. The main requirements for the remote health facilities are:

- Operational by non experienced users
- Cleaning, charging and maintenance must be possible with the local resources
- All should be purchased for an affordable price

The main requirements for the researchers are:

- Enable digital data collection, storage and sharing
- Achieving a maximum quality by optimal cleaning and precise urine entry
- Saving money by saving time to spend in the field

As explained in chapter 4, these aims can cause contradicting design criteria and a perfect balance or a slightly different solution for each of the two users has to be found.

5.3 Implementation challenges

In the Ghanaian hierarchical culture, the governing authorities are key for implementation and their criteria are included in the programme of requirements. In the meanwhile the needs of the users are in there too, to make sure the product can be accepted in their procedures and habits. So a first challenge towards implementation is to fulfil all these criteria.

However, there are some other implementation challenges to take into account regarding the health facilities. They might face low awareness of the diagnostic urge and the diagnoses have to compete with traditional healing. Furthermore, no matter how affordable the product is, not all facilities will be able or willing to pay for such a new device, especially in the low endemic areas. While especially in these areas, better diagnoses are needed to prove the exact prevalence and raise awareness. Funding or other financial support models must be considered to make sure the product will reach all areas.

The researchers are open to a new technology and willing (and able) to test the quality to approve implementation in their field trips. But, the NTDP is restricted by the WHO. And when aiming for worldwide scaling to assist in the other endemic countries, it is important to get the approval of the WHO. Therefore, scientific proof is needed, which can be reached via the researchers.

So, the health facilities are able to treat and help their patients directly to facilitate better case management. The researchers are mainly needed for the long term implementation goals.

5.4 Product development

In part 3 (the product development) the requirements are implemented to design a final product (interaction).

PART 3

The EC

Product development

Introduction

Based upon the final conclusions of part 2, there are two users to focus on (rural health facilities and researchers) and a list of requirements to fulfil.

In the first chapter, the design process will be shortly introduced. Thereafter, the basic concept is discussed which balances between smartness and simplicity in order to satisfy both users.

As a next step, the interaction is defined for each of the users. A simple and easy interaction for the remote areas and a smart interaction that strives towards a maximum quality.

Thereafter, the product is further designed according to some specific user needs. Product features and qualities like maintenance, portability and power supply are brought under attention. To finish with the production and assembly of the final product.

A final usertest is conducted to review the interaction with some medical expertise and a CVD session was used to reflect upon a future scaling towards Nigeria.

As a conclusion of part 3, the final design and implementation measures are presented and an number of recommendations to facilitate further continuation of the project.


SODOS
User manual
AX356

1 Design process

Within this third and last part of the process the findings from both desktop and field research are brought together to design the functions, usability and appearance of the diagnostic device.

The end result of this project will include a user friendly product with a lifespan that will surpass the average medical device within rural areas. It will suit the untrained user in remote health facilities and the researchers who use it on field trips but still want the highest quality.

1.1 Main design challenges

As a result of the various user groups, the product had to fulfil a large amount of demands, which could be split in interaction related demands and product requirements. The interaction includes urine entry, result documentation and cleaning. Part 2 revealed two main challenges for the interaction:

- Easy and self explanatory for remote health facilities
- Smart, professional and precise for researchers

The product related challenges varied from small details such as an SD card to store data to larger topics as maintenance. Out of all requirements, the three following challenges are chosen as main focus in the product development, as all three are essential to make implementation possible in either the health facilities or the field trips:

- Power supply in every area
- Maintenance in remote areas
- Withstand rough transport circumstances

Those challenges, both interaction and product related, will be discussed one by one in the following chapters. In the end, all is brought together in a final design chapter.

Figure 39a. First mock-up for in Ghana.

Figure 39b. Paper model for technological dimensions.

Figure 39c. Paper model to optimise the dimensions.

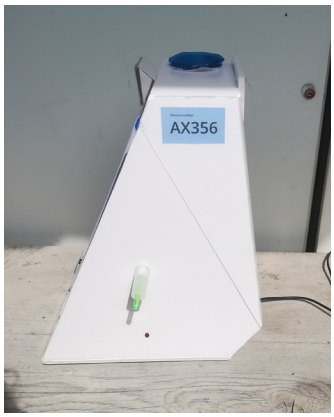


Figure 39d. Functional prototype to test the interaction

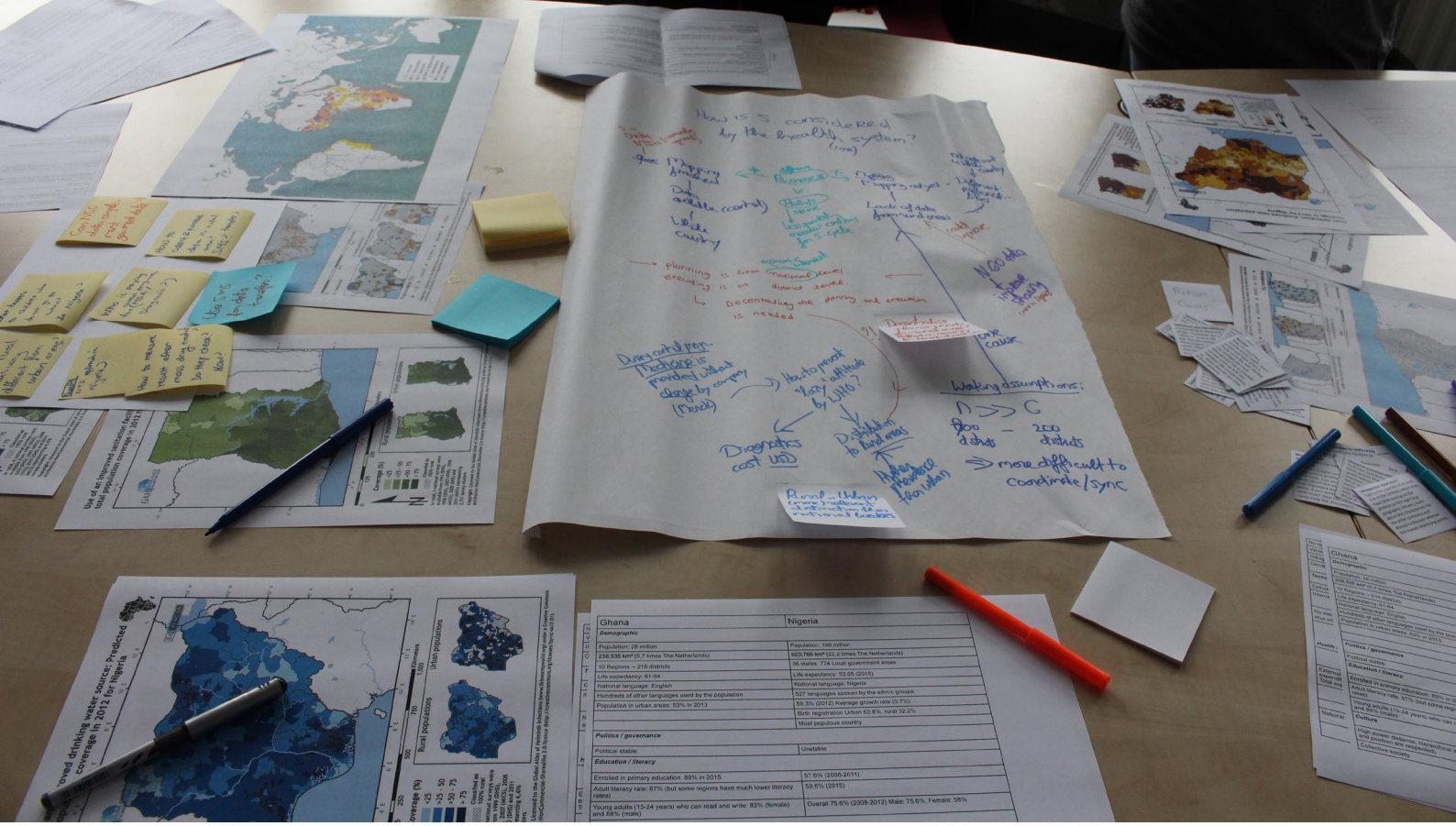


Figure 40. Concept Variation by Design; comparison Ghana and Nigeria based on desktop research.

1.2 Sessions and prototypes

To bring all these subchallenges and solutions together in one design, several *mock-ups* and prototypes were made to facilitate expert discussions and evaluate dimensions (figure 39).

To come to the end result, an *iterative design process* was executed, including expert meetings, prototyping and several moments of validation. Due to a time limit, not every detail is designed and the further design challenges are added to a list of recommendations.

To involve a broader range of design experience, a *creative session* was organised (figure 41) which served as an inspiration throughout the whole design process. Details about the goals, the participants' experience with design for developing countries and the final results can be found in appendix K. And within some of the design decisions, there will be referenced towards this session.

A final design iteration was made in the end of the project, after an evaluative *user test* with four researchers at the LUMC. All were experienced in diagnosing schistosomiasis in rural areas of at least one African country. The session provided valuable insights of which some were directly implemented in the design. More about this will be discussed in the design validation (chapter 9) but, since a part of the results is integrated in the final product, some chapters will refer to this test.

Furthermore, several sessions and meetings were organised to compare the Ghanaian context with the situation in *Nigeria* (figure 40) to keep the differences and similarities of the contexts in mind throughout the entire project. In the end, the concept was compared with some field research results from Nigeria to validate the possible scaling of the product.

All this will be discussed and explored in the following chapters. The solutions will be presented with regard to the user interaction as well as the integration of the solution into the final design.

Figure 41. Creative session

2 The basic concept

Before going into detail about the specific interaction of each user, the right balance had to be found between the easy and robust aim of health facilities and the desired smartness by digitalised and extended functionalities for the researchers.

2.1 Smartness and simplicity

2.1.1 Simple rather than smart

The device can be designed as a smart product with modern technologies and able to digitalise the large amount of data of large scale field trips (figure 42a). Based on the findings in Ghana, this would be an ideal product for the researchers. Unfortunately, the smart technology comes with some flaws for the other users. By adding all these extra functionalities, the required electronics become specialised and relatively fragile. Which makes it difficult if not impossible to replace or repair the product without educated mechanics or special tools. Besides, it will raise the costs while health facilities do not even need these modern functions. In short, such a smart device would not suit the demands for the remote areas at all.

To fulfil the needs of the health facilities, the design must strive for simplicity (figure 42b). By a minimum of buttons and simple technology, the device will be kept as robust and 'fool proof' as possible. This will reduce the price and increases the amount of maintenance that can be done with only a manual and some simple tools.

Even such a simple device will definitely be faster than the current microscopic egg count. And even this simple version would be able to save time (thus money) for the researchers during a field trip. So, simplicity would benefit both the researchers as well as the remote symptom-based treatment. For this reason, the development of a simple device is preferred above the smart one and it is chosen to keep the basic product as minimalistic as possible, but extra

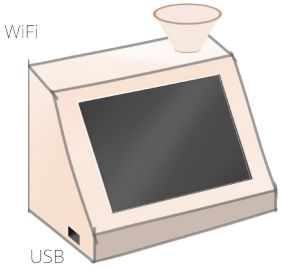


Figure 42a. Smart device

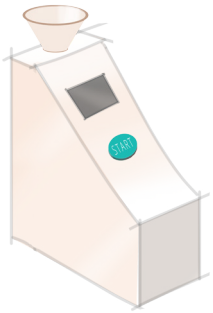


Figure 42b. Simple device

functionalities can be added to still suit all demands of the researchers.

2.1.2 Additional smart data collection

For the researchers, the main advantage of a smart device would be the digitalised data flow, but one does not necessarily need the diagnostic device to do this. Other smart devices can be used alongside the product to facilitate the desired smart data collection.

An application will be developed to collect the data, process it and enables data transfer via WiFi or USB. So with the addition of a tablet (or smartphone) and an application, the simplistic device will be able to suit both user groups (figure 43).

Researchers or research departments would be the first of all user groups to possess either a smartphone or a tablet. And when buying the diagnostic device, they will get access to the developed application. Though, it might happen that they do not have enough tablets.

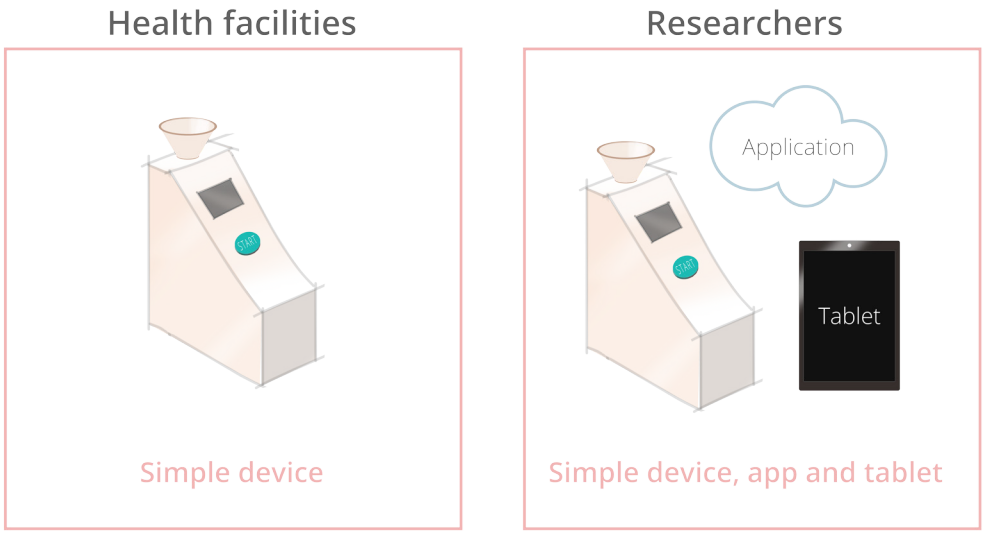


Figure 43. Adjusted solutions per user

In that case, for a small additional price a tablet will be added to the device. The health facilities can just buy the cheapest option (only the device).

2.1.3 Professional versus easy

Together with the functional requirements, this solution solves one of the challenges regarding the professional image of the product (part 2, chapter 4). Professionalism was among others linked to a modern product in need for some extent of training. The interaction with the diagnostic device can be kept simple for those (illiterate) users without any experience in the medical world. But, to keep the professional status of the researchers in tact, the tablet will provide interaction for which the user must be able to read and know how to use a tablet, it can use modern technologies such as the camera, voice recognition and wireless connections.

2.2 The basic product (interaction)

Within the next chapters, the product (interaction) will be discussed in more detail. The goal is to develop only one diagnostic device, which will fit all different circumstances. The only difference will be in the interaction with the device and in the fact that the researchers will add a tablet to the product.

To get an idea of the final design, figure 44 shows one of the final prototypes of the end result. As can be seen, the front of the device is kept relatively broad as all controls will be placed on the front. The urine entry will be on top and the exit on the right side.

Figure 45 shows the basic steps in the interaction with the product. Furthermore, the device will have a small (robust) LCD display to show the results. And, beside some guiding LED lights, the only components placed on the outside are an on/off switch and a start button. Both are difficult to break, and if needed easy to replace. All the other components, belonging to the necessary diagnostic mechanism, will be covered and placed inside the device.

Figure 44. Final design

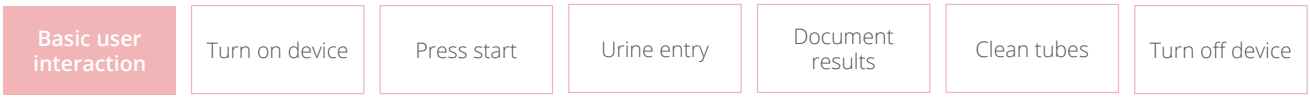


Figure 45. Basic interaction with the device

3 Interaction for health facilities

Due to a lack of specialists, the ideal product for the remote areas could be handled by anybody, no matter what medical experience.

To do so, it is important to think about everything that could go wrong, to make sure the design can prevent this from happening. The before mentioned creative session, was organised with some designers who have experience with third world countries (appendix K) to brainstorm among others about all the possible 'disaster scenarios'.

One major issue was addressed in relation to hygiene and cleaning procedures. And a simple though thorough cleaning interaction will be discussed in paragraph 3.1. A second challenge, pointed out by these disastrous situations, is related to possible malfunctioning, damage or broken parts. The solutions to minimise these risks are explained in chapter 5 and 6.

And most relevant for the interaction, were the addressed scenarios in which the foreseen interaction is not followed as intended. The user might either be inexperienced, illiterate, clumsy, lazy or just careless. And, especially in the most remote areas, unavailable resources can cause unwanted improvisation (reusing syringes without cleaning) or result in obsolescence of the device.

This chapter will discuss how the product is made as easy as possible to prevent these scenarios from happening. For this final health centre oriented interaction, the insights of the user test at the LUMC (appendix P) was decisive in the chosen urine entry method, the cleaning procedure, the manual design and the location of the usecues. A list of the exact changes, made due to the user test can be found in appendix Q.

3.1 Diagnostic procedure

First of all, the procedure itself should be kept to a minimum of steps and should not depend on resources as syringes or funnels, which can get lost or out of stock. For this reason, the facilities prefer to reuse products, however it cannot be guaranteed that they have the proper ways of cleaning.

3.1.1 Urine entry

Unlike the researchers, NTDP and urban hospitals, the remote areas are not necessarily restricted to WHO guidelines, who ask to only test 10 ml. So, the remote areas can simply pour the urine in the device and choose themselves whether they test the full sample or only a part of it (figure 46). This saves any need of measuring tools and as discussed in part 1, testing the full sample would actually even increase the sensitivity.

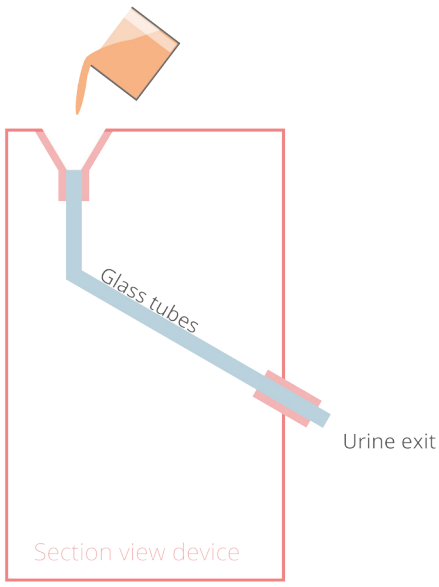


Figure 46. Urine entry

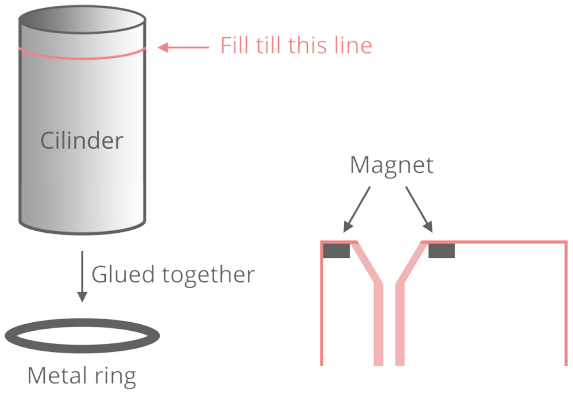


Figure 47. Cylinder with a metal ring and magnets in the device

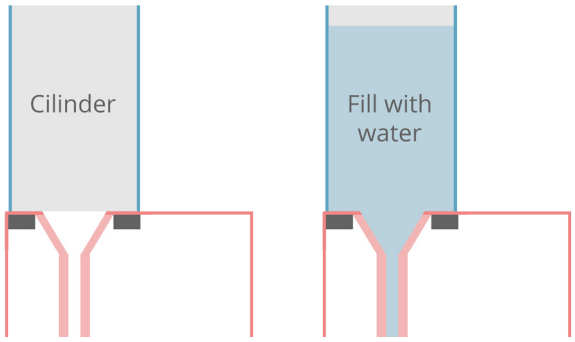


Figure 48. Cleaning procedure remote health facilities

When pouring in the urine, the device must be prepared for all different volumes. Therefore, the entrance will be funnel shaped and, since 50 ml urine collection containers are commonly used (appendix D), the funnel must at least be large enough to contain at 50 ml without overflowing.

3.1.2 Documenting results

In most facilities, the results are still documented on paper. To make the new device fit in their current routine, they will continue to use their own way of documentation.

Whenever the result is finished, the number of eggs is shown on the LCD screen. To assist the user in the interpretation of the result, an indication light will turn green, orange or red when the patient is respectively not infected, lightly infected or heavily infected. This will also enable the communication of the result to illiterate patients.

3.1.3 Cleaning the tubes and funnel

An essential task after every test is to clean the tube as well as the funnel entrance properly, since any leftover eggs can mix with the next sample, influencing the following test results. However, the final user might not be aware of the importance of proper cleaning and the cleaning procedure is brought to a minimum of steps.

Based on all possible 'disaster scenarios' (appendix K) it is decided to clean the tubes while they are still clamped inside the device. Other options were taking them out for thorough cleaning, but this would risk any unnecessary damage. Disposable tubes were considered too, but disposed waist can become a source of new infections when the garbage management is not organised correctly. So, any disposable product sare avoided as it is not known whether all facilities will have proper waste management.

To enable cleaning without opening the device, the tubes are made of glass, which can just be flushed with water to remove the eggs.

Due to limited resources, the cleaning equipment ideally consists of locally available materials or locally producible parts. Furthermore, there might not be any clean water available and local water sources will be used instead of bottled water. As the only purpose of the cleaning water is to flush away the eggs and the main requirement is to use '*egg free*' water. And since any viable eggs will start to hatch when arrived in the fresh water source, it is for now assumed that the local water will not contain a significant amount of eggs anymore. But this should be validated in a later stadium of the project.

The urine entrance is funnel shaped, which eliminated the need of a separate funnel. To clean this funnel, and the tubes, a certain amount of water should be flushed through. To make sure the funnel holder is flushed completely, it has to be filled to the edge with water.

To facilitate this process, a plastic cylinder will be placed on top of the device, over the funnel opening (figure 48). A metal ring is attached on one end of the tube (figure 47). And some magnets are placed around the funnel opening (on the inside) to connect the cylinder to the device. Whenever water is poured into the cylinder, the water level will decrease very slowly due to the narrow tubes inside the device. This will allow the user to fill the cylinder up to the red line (figure 47).

3.1.4 Collecting the processed urine and cleaning water

As explained in part 2, the urine can be disposed after the diagnosis. Both the cleaning water and the processed urine can be collected in the same way. Though, a lot can go wrong in this phase. First of all, the user might forget to place a cup or container underneath the urine exit, causing all the urine to just fall on the ground. Besides, the disposal must be done carefully to prevent the environment from getting infected (when throwing away out in the open).

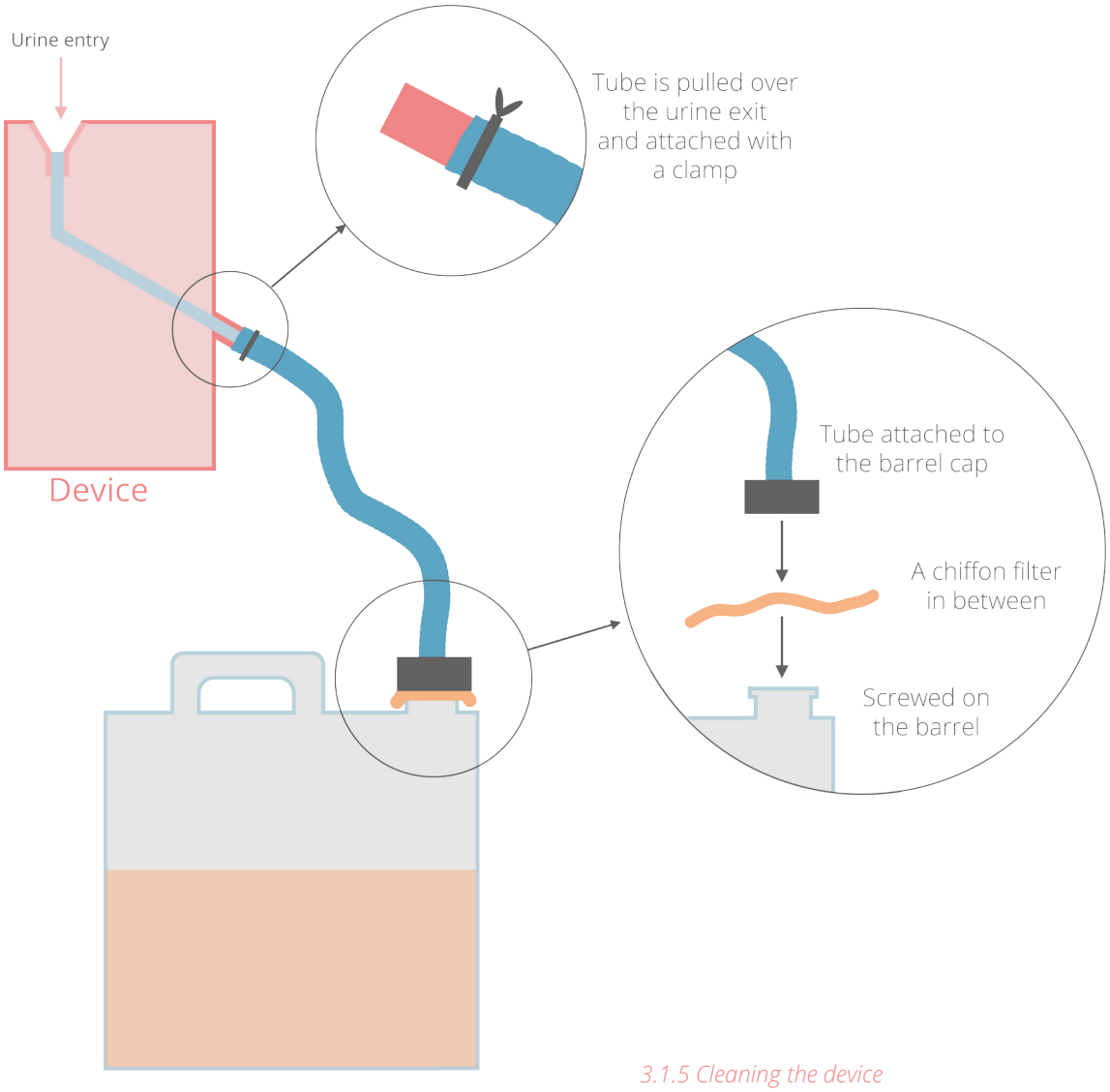


Figure 49. Collecting all in a barrel

To make the collection easy, everything that leaves the device can be collected in one big container. The urine exit will be connected via a long (flexible) tube (figure 49) to a large water barrel on the ground.

To make sure the collected urine will not contaminate the environment, for example when emptying the container outside, the eggs should not even enter the barrel. A piece of chiffon textile will be placed in the container opening, to filter out the eggs [2] before the urine enters the container.

The connection tube can be attached by the user with a (thumb screw) clamp, which only needs to be done once. The chiffon filter can be cleaned once in a while by boiling it or using cleaning chemicals such as bleach, if this is available. The exact way to do this will be explained in the user manual, but some extra instructions can be placed on the container (for example with a sticker).

3.1.5 Cleaning the device

Finally, even if the urine entry is surrounded by a funnel and the urine exit is properly connected to the collection container, there is always another way to spill urine. Besides, the technicians wear gloves which could have been in touch with infectious substances and thereby contaminating the device whenever they touch it.

To motivate the user to actually clean the device when needed, it must be an effortless action. The Ghanaian user research pointed out the necessity of a smooth surface for optimal hygiene. So, the device will be made of plastic to assure the surface to be as smooth as possible, especially near the urine entrance, underneath the urine exit and at the front side where the other interaction takes place. Furthermore, the material will be resistant for any existing cleaning chemical (chapter 8) to make sure the user cannot use the wrong chemicals. And the product is made completely water proof to protect the electronics inside, as will be discussed in chapter 5.

Sometimes the tubes might need to be replaced or removed for thorough cleaning, for example when any dirt gets stuck inside. In this case, the tubes can be removed by opening the device (chapter 5).

3.2 Manuals

In order to communicate the procedure to the user, two manuals will be made. One short summary on top of the device and a second extended manual, stored inside a special department of the device.

3.2.1 Extended manual

First of all, just like every other device, this product will come with an extended manual containing everything you need to know about the device. This manual should not get lost or unreadable over time and will be plasticised (to survive water and urine) as well as attached to the device. A special compartment is made to store the manual when it is not in use (figure 50a). A cord, attached inside this compartment, will make sure the manual cannot get lost (figure 50b). Furthermore the manual has a metal case which will function as a cover to close the compartment. When the manual is placed inside, the metal cover will fasten via some magnets inside the device (figure 50c). This way, the manual can either be used without loosing it or stored in a compact way, without any loose wires hanging around.

3.2.2 Instructions on the device

The extended manual is relatively long and will most likely only be used the first time or during a training. As shown in chapter 2 (figure 45), the interaction includes a large amount of steps and even after some experience, it cannot be assumed that the user will always remember everything.

To remind the user of the basic steps, without the need of the full manual, a summary of the instructions is placed on the device (figure 51). More specifically, it is located on the front so it cannot be missed. The instructions will combine some keywords with visuals.

Figure 51. A manual attached on the front of the device

3.2.3 Manual design

At the LUMC, different user manual designs were evaluated (actual pictures versus the use of figures and icons). According to the LUMC participants *"actual pictures are easier to follow"*, which is especially important when one sees the device for the first time. So, to make the extended manual comprehensible for all, even during first use, this manual will be illustrated with actual pictures. Users can just imitate the pictures until they are experienced enough to do without.

For the summarised instructions, icons are preferred over pictures, as pictures are unnecessarily detailed and an icon can be seen in just a quick glance. The design guidelines (appendix J) describe a preference to

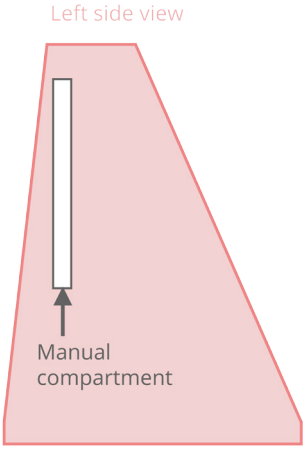


Figure 50a. Manual compartment

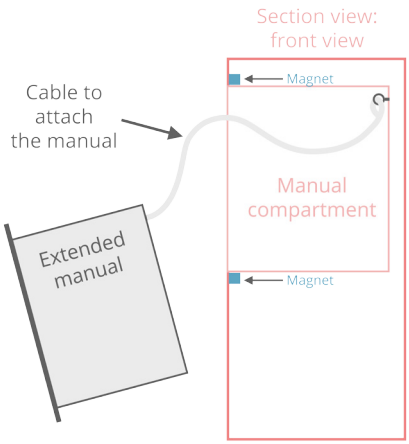


Figure 50b. Manual removed from the compartment

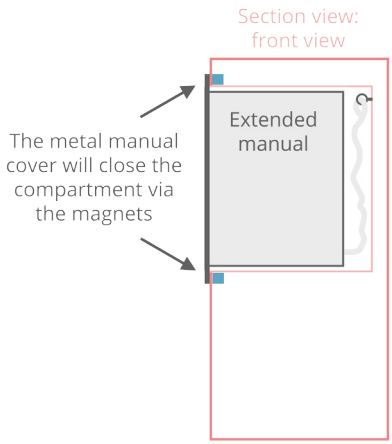


Figure 50c. Manual placed inside the compartment

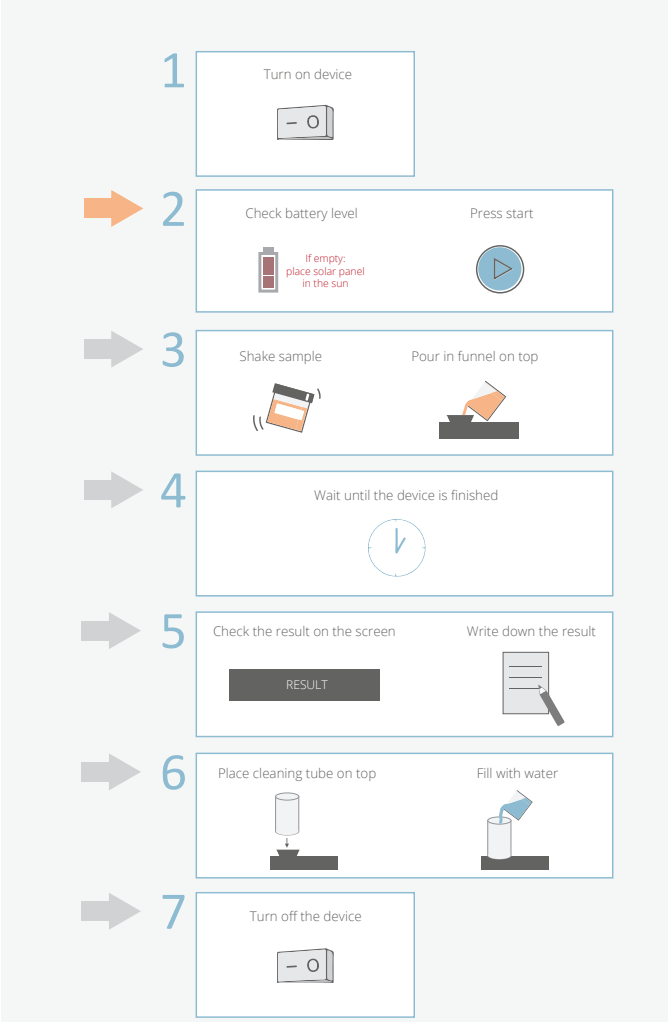


Figure 52a. Instruction on top of the device, with guiding light arrows

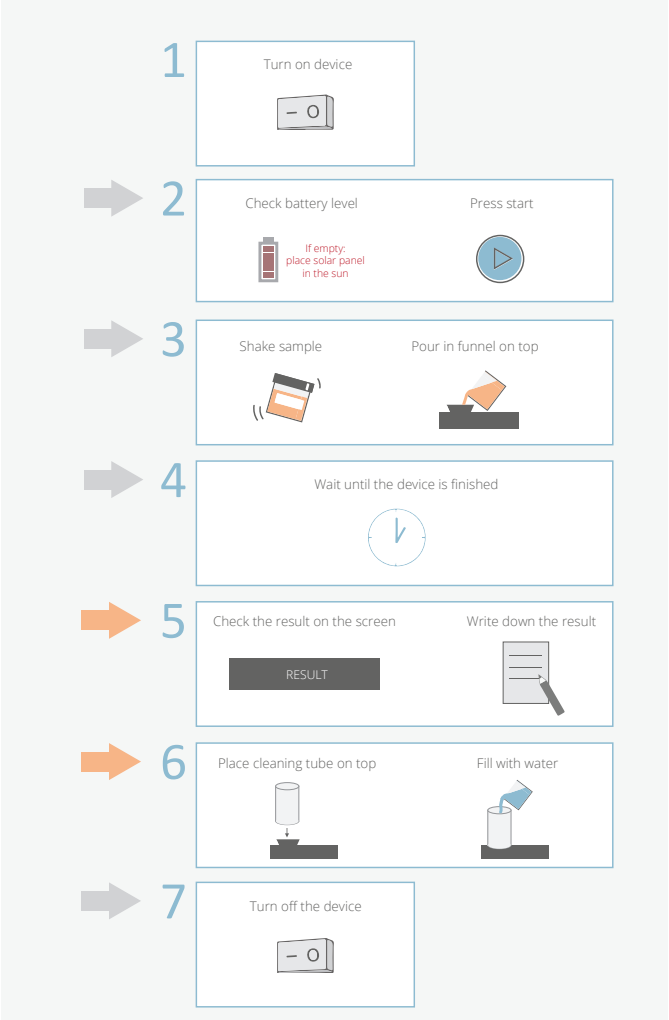


Figure 52b. Step 5 and 6 light up simultaneously

limit the colours to pastel blue. A few more colours are added to point out some specific details, but in general, the use of colour is kept to a minimum. Furthermore, the use of detailed visuals were preferred over simple icons due to the extra details. The final design of the manual is shown on page 77.

3.3 Interactive guidance lights

Even with a manual on top of the device, the user test at the LUMC confirmed that it is still possible to miss some important steps. Besides, after doing the tests for a hundred times, one probably does not want to read through all steps anymore. This is why interactive guidance is added to instructions on the device, to highlight the important steps at the right moment. This should draw the eye in to the urgent steps, even if not paying any attention. The guidance consists of attention lights and sound effects.

The following paragraphs will explain the basic idea of this interactive guidance and page 76 and 77 give an overview of the user interaction and usecues needed for this interaction. An extended interaction journey can be found in appendix M.

3.3.1 Attention lights

First of all, the instructions are categorised in 7 steps (figure 52a). Attention lights, in the shape of an arrow, are added in front of each category (except for step 1, since the power is at that point not yet turned on). To make sure that the lights are noticeable, even in bright sunlight, it is decided to light a relatively large surface, which led the decision to arrow shaped lights instead of single LEDs.

To enlarge the impact of the lights, a coloured light is used instead of white. So if one does not see the brightness, they might still notice the colour.

To make sure the device knows when to activate the correct lights, the LED activation is linked to measurable user actions, like the on/off switch and the start button (page 76 - 77). Furthermore, the optical mechanism inside will detect anything that flows through the tubes. This way, it can detect when someone pours the urine (or cleaning water) in the device.

Only for step 5, where the user has to document the result, the device has no way of knowing when the user is finished. So, step 5 and 6 will light up simultaneously (figure 52b).

3.3.2 Sound effects

When the urine is poured in, it might take several minutes for the device to calculate the results and in the meanwhile, the user can get distracted by other tasks. As suggested in part 2, an gentle sound will attend the user about the *finished diagnosis*.

Furthermore, it is important that the user *turns off* the device when finished, to save power. So when the user arrived at step 7, but does not take any action for several minutes, an alarming sound will be activated. This will be combined with a blinking arrow in front of step 7, to address the purpose of the alarm. And, to make it even more obvious, is the on/off switch placed directly next to the instruction of step 7 (page 77).

There might always be a good reason for a delay in following the instructions and the alarm should not become a disturbing continuous alarm, but it will repeat one sound every 30 seconds. If these sounds are ignored, the device will turn in a sleeping mode after 10 minutes to further save the battery.

When only adding interactive effects to correct users, they might become afraid to make mistakes. Especially those without training could use some encouragement whenever they are doing it correctly. Therefore, some confirming sounds are added, to improve their confidence. When switching the power on, the device will give a signal to assure it is still working. Furthermore, when the start button is pressed and when the cleaning is fulfilled, a positive feedback sound is given.

3.4 Recommendations

3.4.1 Results

In order to light up the correct colour, as an indication of the results (green, orange or red), the device must calculate the heaviness of the infection. To do so, the device needs to know the number of eggs per 10 ml. Since the sample volume differs per test, the technology should indicate the volume by measuring the time it takes until all urine is processed.

3.4.2 Cleaning the tubes

The efficiency of the suggested cleaning methods have to be tested, to see if flushing is enough to remove all eggs. And to define how much water is required.

3.4.3 Collecting the urine and cleaning water

The container, which collects all urine, might overflow when the user does not pay attention to it. So, to avoid this form happening, it might either be part of the daily routine to empty the container at the end of the day. Or an instruction will be added to the manual on the device, telling them to check the container. But if this happens to be insufficient, a small sensor can be placed in the container to measure the water level. This sensor might even activate an alarm whenever the container is almost full. However, this should be tested to see if there is even need for such an alarm.

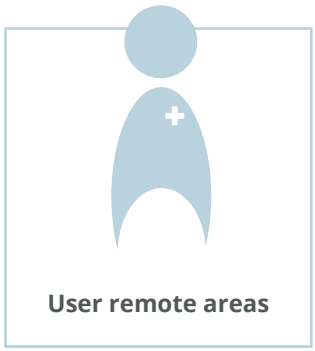
Furthermore, the exact mechanism of attachment to the barrel should be further detailed. For example, a small air gap must be made in the cap, to make sure the urine can flow in without pressure. However, this might cause some unwanted smells and it might be needed to close the barrel when not in use. This will be recommended to further detail in the follow up projects.

3.4.2 Interactive guidance

The current interactive guidance is designed as if only one sample will be tested, and the user is asked to turn of the device after each test. However, one might also directly start a new test by pressing the start button again. To keep the instructions simplistic, this is not mentioned in the manual. However, it should be tested whether such instructions should be added after all.

It should be tested whether the guiding lights are indeed large enough to be noticed in bright sunlight.

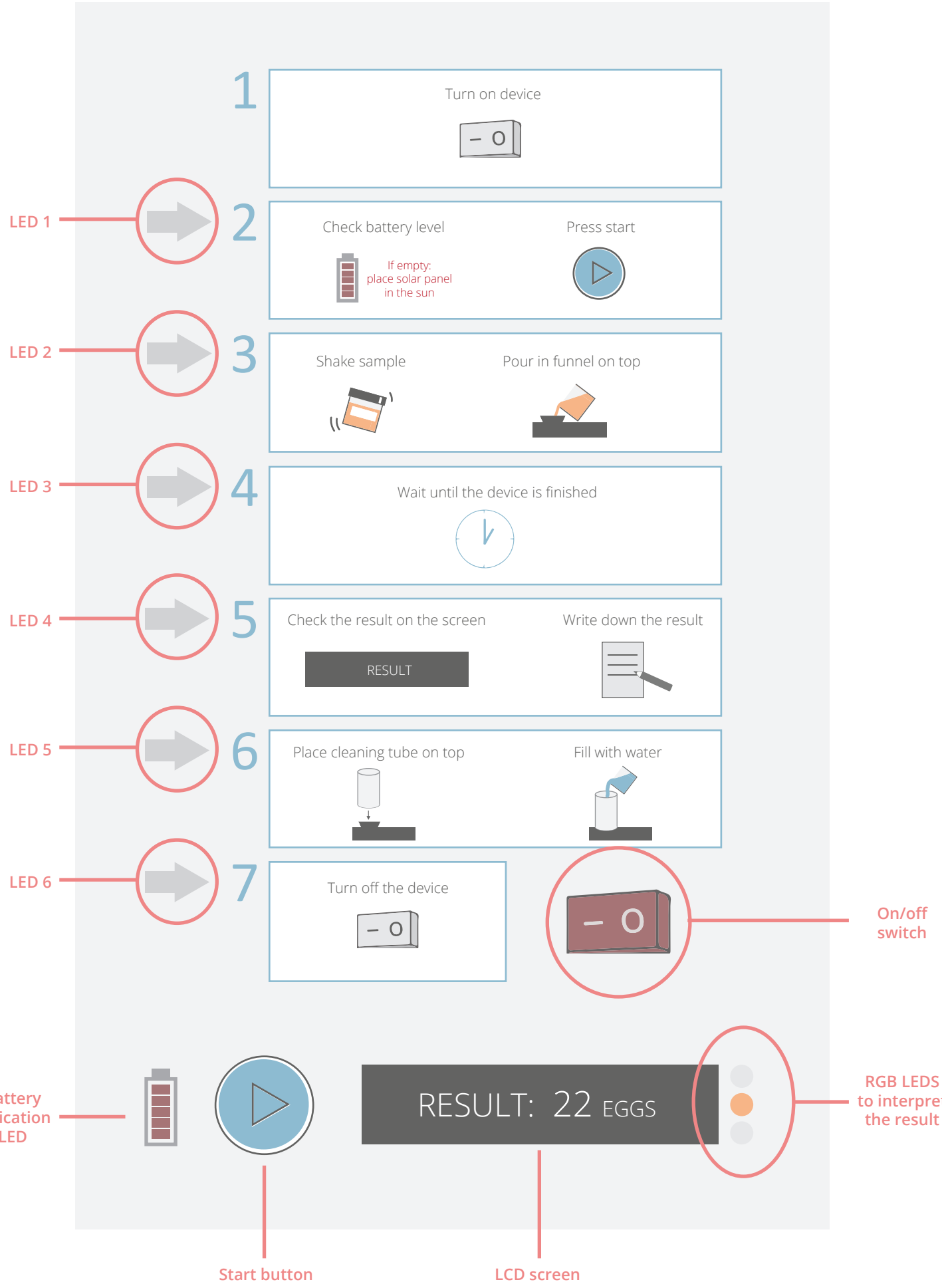
The sound effects have to be further developed and specified. Besides, everybody can interpret sounds differently and the final result should be tested with the actual users to refine the settings. Furthermore, it should be considered how a user can ‘overrule’ the alarm when it is making sounds at the wrong moment. For example, a volume button or a specific on/off switch for the sounds should be added.



User remote areas

Device

Turn on the power	On/off switch	LED 1 lights up	Confirmation sound 1	Turn battery indication LED on
Check battery level				
Press start	Start button	LED 2 lights up	Confirmation sound 2	LED 1 turns off
Shake sample				
Pour urine in the funnel				
Wait		LED 3 lights up		LED 2 turns off
Read out result		LED 4 & 5 light up	Alarming sound	Display & RGB LED show result / LED 3 turns off
Document result				
Place cleaning tube on funnel				
Fill tube with water				
Wait till all water is gone		LED 6 lights up	LED 4 & 5 turns off	
Turn off device	On/off switch	Shut down everything		


1
Turn on device
LED 1
2
Check battery level
If empty:
place solar panel
in the sun
Press start
LED 2
3
Shake sample
Pour in funnel on top
LED 3
4
Wait until the device is finished
LED 4
5
Check the result on the screen
RESULT
Write down the result
LED 5
6
Place cleaning tube on top
Fill with water
LED 6
7
Turn off the device
On/off
switch
Battery
indication
LED
RESULT: 22 EGGS
RGB LEDS
to interpret
the result
Start button
LCD screen

4 Interaction for research field trips

Even though the diagnostic device is exactly the same for all users, the interaction of the researcher differs a lot from the health facilities, due to the desire to digitalise data collection and the aim for the highest possible quality.

As explained in chapter 2, the researchers will add a tablet to the interaction with an application to collect and process the diagnostic results. This chapter will discuss the interaction with the tablet, including the possible technologies to optimise this interaction,and the attachment to the device as well as the options to charge, clean and lock the tablet.

The second challenge, the maximum quality, is related to the cleaning precision and the extended cleaning procedure will be explained in paragraph 4.4.

4.1 Data entry technologies

As explained in part 2, researchers document the sample number, dipstick results, urine colour and the final number of eggs. Whenever entering the data in the tablet, a touch screen is the most obvious choice of interaction. However, the user research in Ghana revealed the request to avoid any contact with the tablet, as it will get contaminated by every touch. The tablet will be protected by a waterproof cover (figure 53) with a relatively smooth surface to clean with minimal effort. Though, when doing hundreds of samples a day, every added task can make a difference in the overall procedure time. And to save a lot of cleaning in between, the options of a complete touchless interaction were explored. This paragraph discusses how easy accessible technologies, can take over the physical interaction with the tablet. This does not only save cleaning time, it will also increase the modern professional appearance of the interaction.

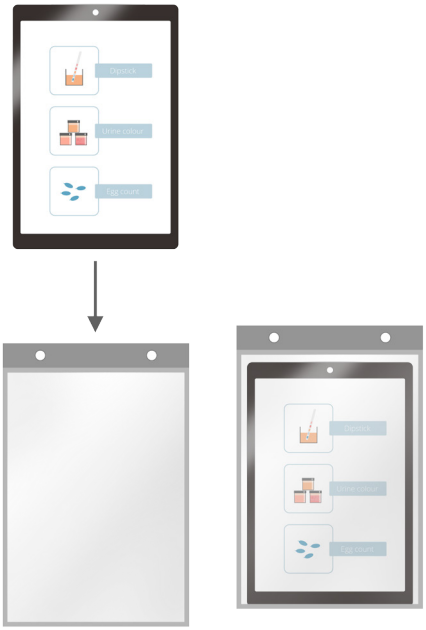


Figure 53. Tablet protected in a water resistant cover

Any information collection before the diagnoses (names, date and location entry) can just use the touchscreen, as the contamination is only a problem during the actual urine tests.

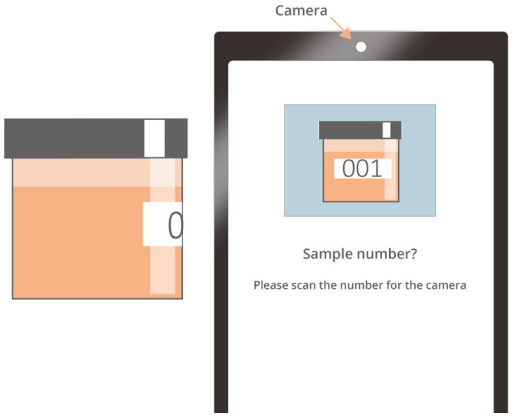


Figure 54. Scan sample number

Figure 55. Central Station Rio de Janeiro, a recording booth for illiterate people to create and print a written postcard

4.1.1 Camera and ICR software

Nowadays, almost every tablet or phone possesses at least one camera. By the use of software like ICR (Intelligent Character Recognition), the tablet camera will be able to read the handwritten sample number on the sample cup (figure 54) [53][91].

4.1.2 Voice recognition

Another commonly used technology is voice recognition of which the quality is continuously improving. One beautiful example is a project, organised by HP Inc. who used Google Speech API to document the stories of illiterate Brazilians [4]. A book was published with their stories and a as an addition, a recording booth was placed at the central train station of Rio de Janeiro which gave local citizens the opportunity to send a written postcard to their loved ones (figure 55).

This technology will be used to enter the dipstick results and the sample colour. However, due to all the local languages, technicians might all speak with different accents. This will make it challenging for the tablet to recognise full sentences and the data entry is organised in such a way, that only short commands are needed.

4.1.3 NFC or Bluetooth

Most of the modern smartphones and tablets are equipped with NFC (Near Field Communication) chips, able to communicate data within a short range. When the tablet is attached to the device during the diagnoses, this short range communication technology will transfer the diagnostic result from the device to the tablet. Whenever the researchers are using their own smartphone or tablet, without NFC chip, Bluetooth can be used instead.

4.2 User interaction

Page 80 and 81 give an overview of the interaction between the user, the tablet and the device, together with an impression of the interface design. An extended overview of the exact interaction, including the egg count and cleaning procedure, can be found in appendix N.

4.2.1 Preparation up front

Before the researchers go into the field, the supervisor decides what results the technicians need to collect and who gets access to the data entry in the application. The supervisor will create an account in the application in which all data can be collected. All participating researchers will receive a password to access the application and to add results during the field trip. It is coded with a password to ensure that only the qualified users can add results.

4.2.2 Arriving in the field

Once arrived at location, the technicians can log in on the application and ender some basic information:

- Location (via GPS tracking on the device)
- Date
- Name(s) of the technician(s)
- ID number(s) of diagnostic device(s)

Each diagnostic device will have an identification number (figure 56). In case a device appears to be broken or less reliable, they can trace back which results were collected with the broken device.

4.2.3 Urine examination

When a sample number is scanned (figure 54) the data collection page for the urine examination will start. Within this page, there are 3 types of data to enter: dipstick data, colour indication and the egg count. The tablet will open the result pages whenever the user says “dipstick”, “*colour*” or “*egg count*”, as illustrated on the next page.

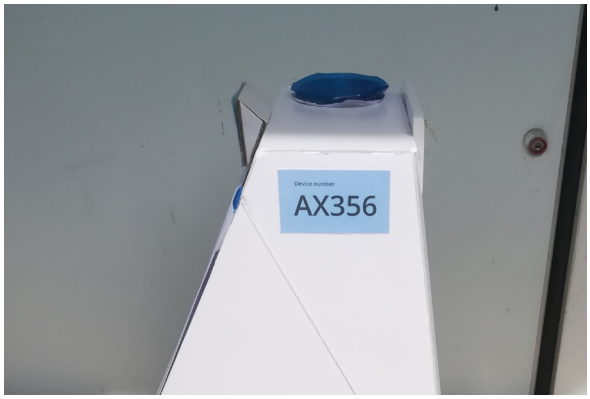
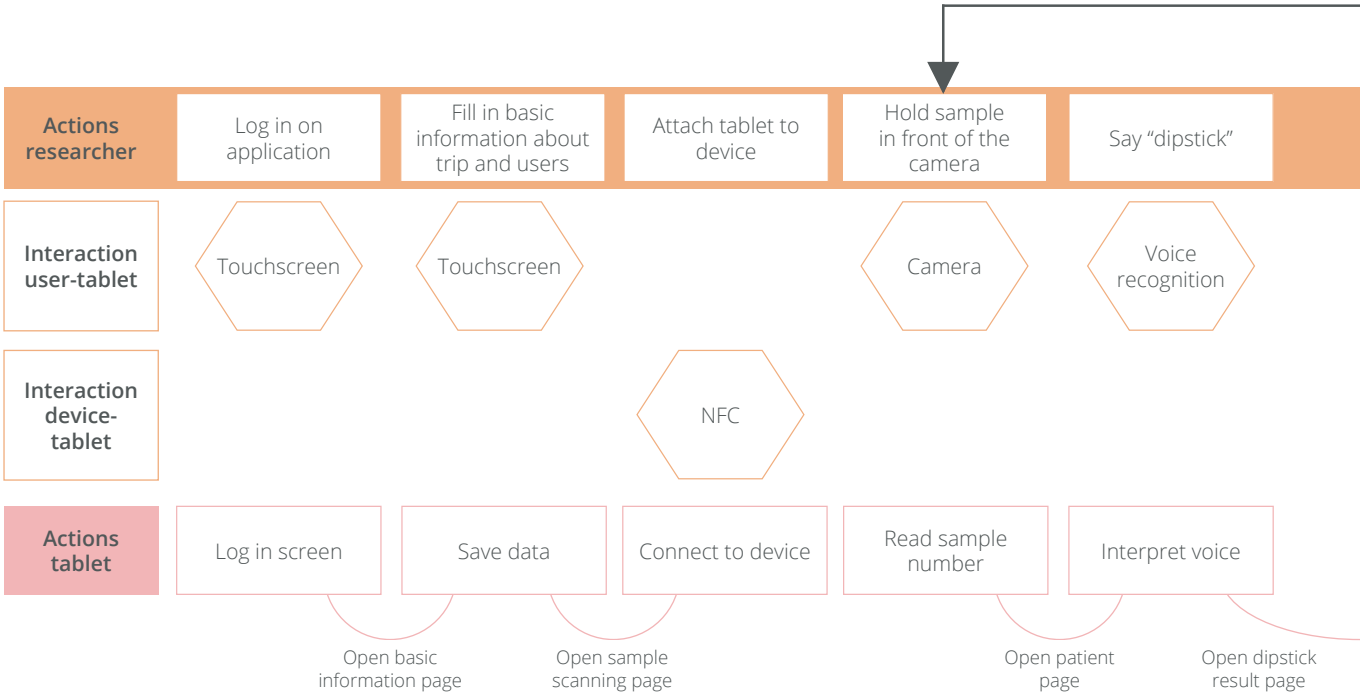
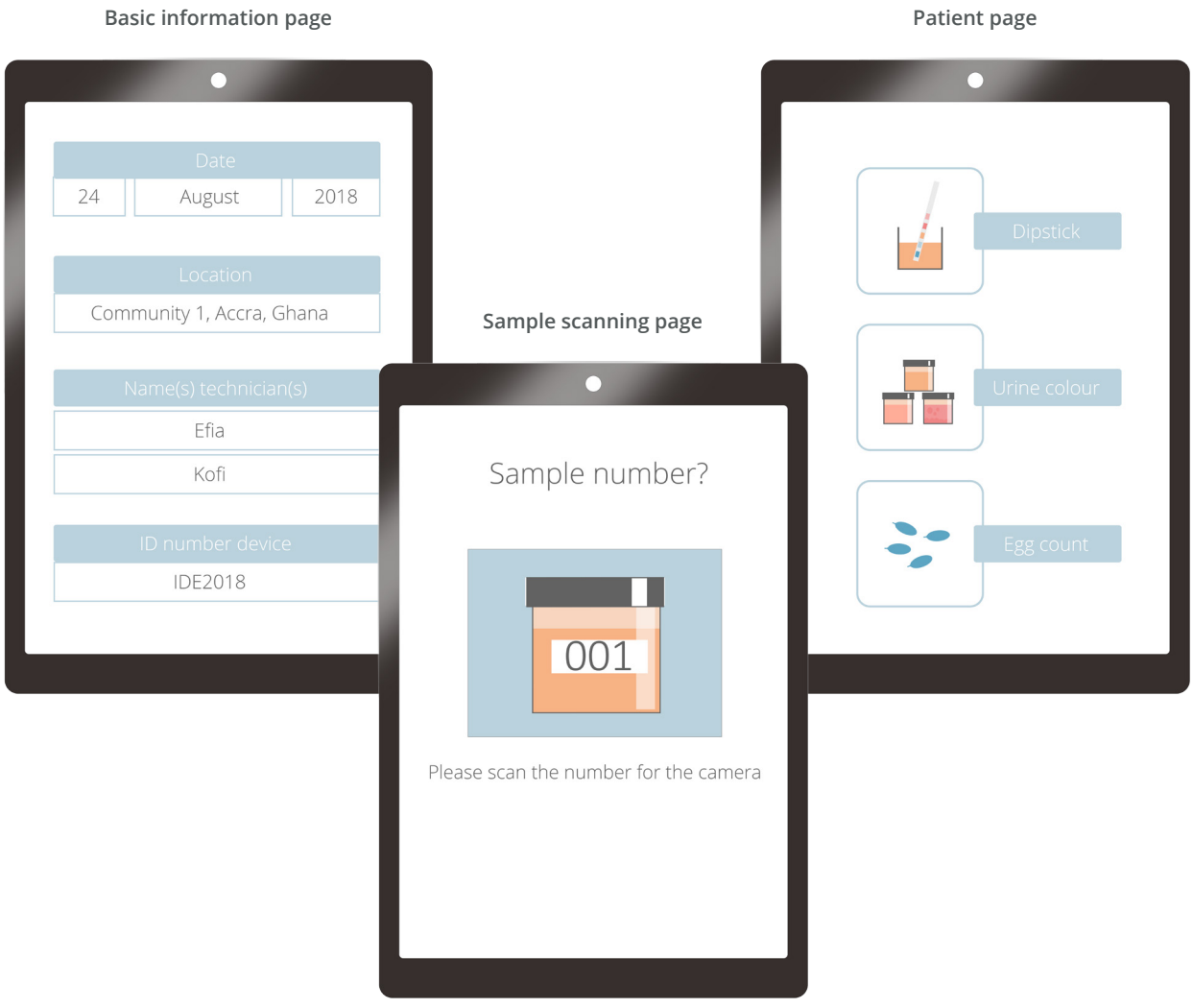
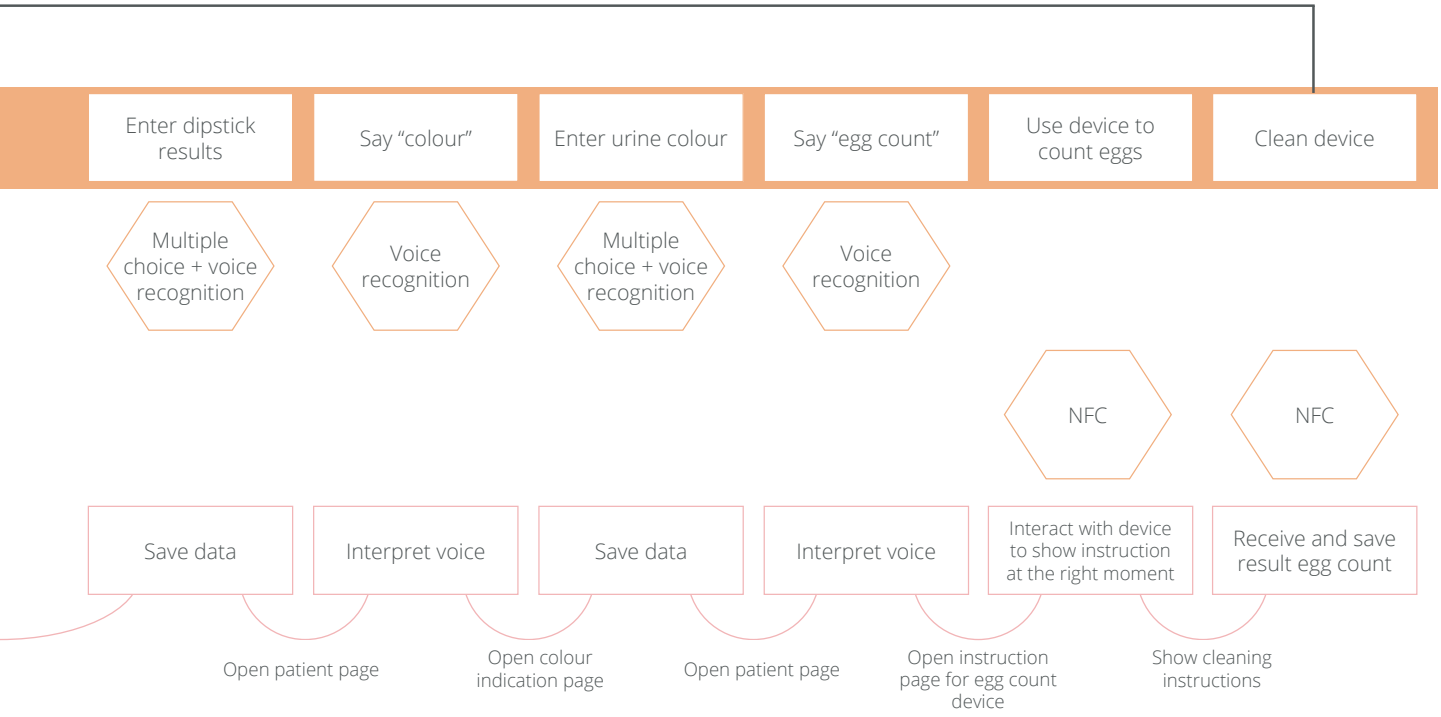


Figure 56. Identification number on the device


Actions researcher
Log in on application
Fill in basic information about trip and users
Attach tablet to device
Hold sample in front of the camera
Say "dipstick"
Interaction user-tablet
Touchscreen
Touchscreen
Camera
Voice recognition
Interaction device-tablet
NFC
Actions tablet
Log in screen
Save data
Connect to device
Read sample number
Interpret voice
Open basic information page
Open sample scanning page
Open patient page
Open dipstick result page


Basic information page
Patient page
Date
24
August
2018
Location
Community 1, Accra, Ghana
Name(s) technician(s)
Efia
Kofi
ID number device
IDE2018
Sample scanning page
Sample number?
001
Please scan the number for the camera
Dipstick
Urine colour
Egg count



Dipstick result page

First page of egg count instructions

Colour indication page

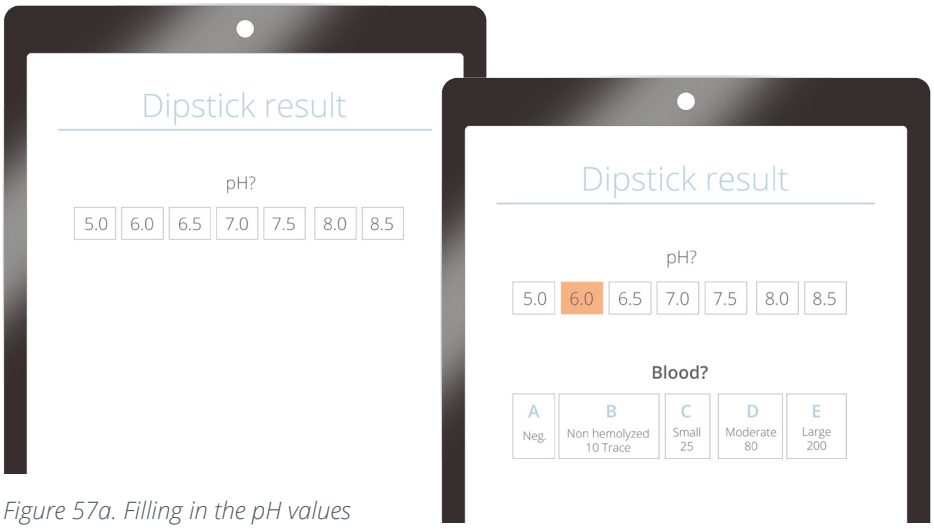


Figure 57a. Filling in the pH values

Figure 57b. Filling in the blood values

By the command "*dipstick*", the dipstick result page will be opened. To read out the dipstick values, the technician compares the colours on the stick with a colour scheme on the dipstick packaging to see what each colour means (figure 58). Consequently, there is a limited amount of results possible. When using the voice recognition to enter the results, the complex values can be turned into multiple choice, as shown in figure 57a and 57b. When all results are collected, the colour indication page can be opened, and the user can select (by multiple choice) the colour of the sample. Currently, they describe the colours in text, however, to make it more intuitive the indicated as was shown on the previous page.

But the most important results to collect are the number of eggs, which will happen automatically with the NFC connection. To assist the user in the diagnoses, the tablet will give the user instructions about the use of the device. To facilitate this digital guidance, the tablet will not only receive a NFC signal about the number of eggs, but also when the user has turned on the device, pressed the start button, poured the urine in the device and whenever cleaning water is flowing through the tubes (chapter 4). The complete interaction journey can be found in appendix N.

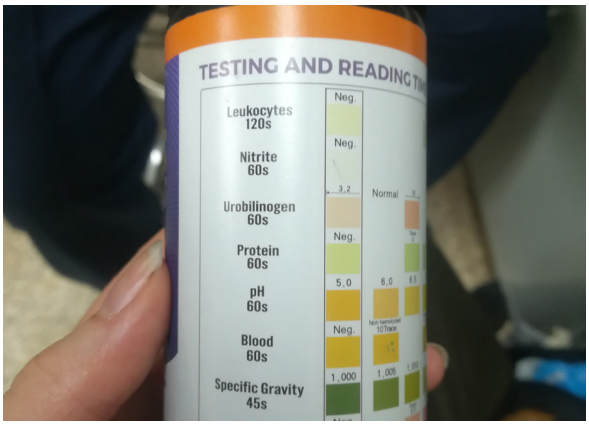


Figure 58. Dipstick packaging container

4.3 Integration in the design

For the NFC connection to work, the tablet has to be attached closely to the device. Besides, when digitalising the manual, the manual on top of the device will not be needed. So, the tablet will be placed on the front, covering the other manual (figure 59). This comes with the advantage that the urine entry is around the corner. So even if someone overturns the sample cup, the urine shall not reach the tablet.

4.3.1 Attachment

It is chosen to make the attachment easy and fast to stimulate the technician to actually place the tablet in the correct way. And, if the tablet is needed somewhere else, it can be removed easily.

Furthermore, as the health facilities do not need the tablet, the attachment mechanism should be subtle and integrated, as if belongs in the design itself. Only when placing the tablet, one should realise the purpose of this detail.

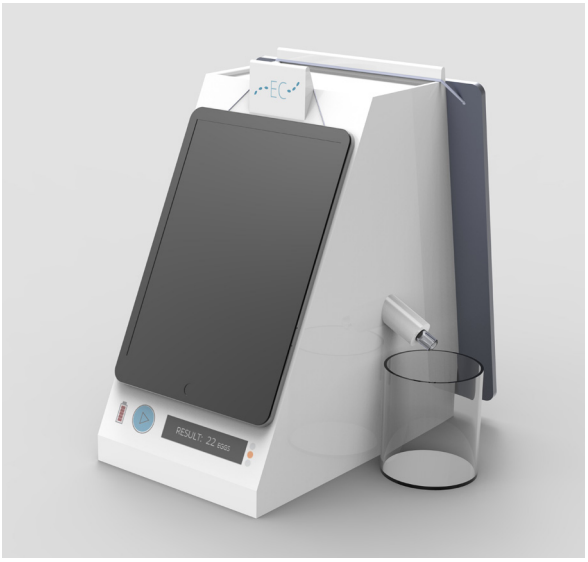


Figure 59. Tablet on the device

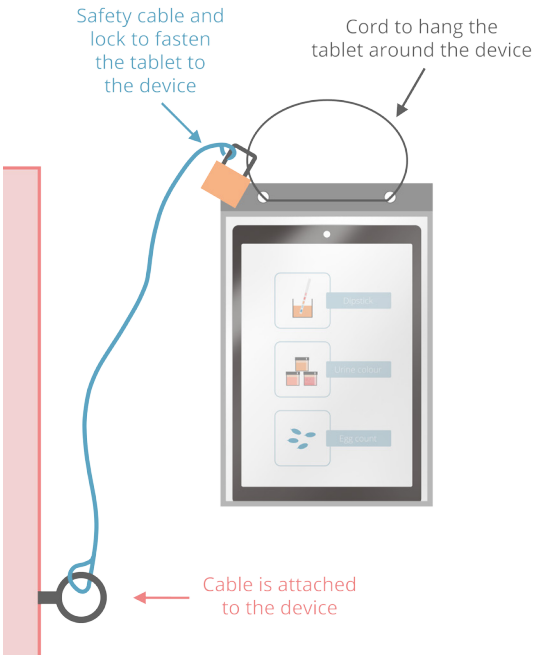


Figure 60. Lock the tablet to a cable, which is attached to the device

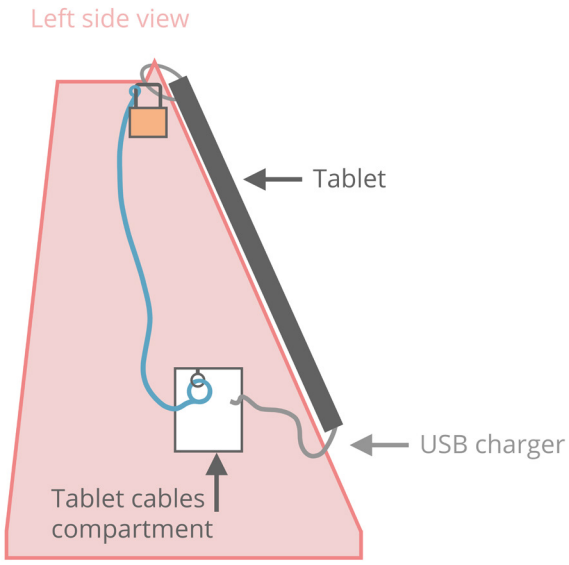


Figure 61. A compartment for the charge cable.

This led to the idea of a small upstanding edge. Via a cord, attached to the tablet cover, the tablet can be hung around this edge. As the edge is decorated with the logo, it will just look like a part of the branding for the health facilities. And as an extra advantage, this solution avoids the need for any clamps or other attachment instructions, which create difficult edges to clean.

4.3.2 Lock the tablet

The only side effect of an easy removable tablet, is that it can be stolen with the same lack of effort. It should be possible to lock the tablet in case the technicians are leaving for a break, or when distracted by anything. Therefore, a safety cable is attached to the device (via a small ring) with a loop at the end. With a simple lock, the tablet can be secured to this cable and thereby to the device (figure 60).

4.3.3 Charging

A charging cable for the tablet comes from inside the device, in which it is connected to an internal power source (chapter 7 and figure 63). The cable is carefully clamped between two parts of the casing (figure 62 and 63), to make sure the casing is still waterproof, even where the cable comes out.

However, this charging cable should only be exposed when using the tablet. Any other moment, the cable is rather hidden from dust and water. Therefore, a special compartment is made in which the charging cable is coiled (figure 61). A metal cover closes the compartment via a magnetic connection (figure 62). Whenever the cable is needed, one can remove the metal plate and reveal the cable.

Since the locking cable is only needed when the tablet is in use, this cable is stored in the same compartment (figure 61 and 63).

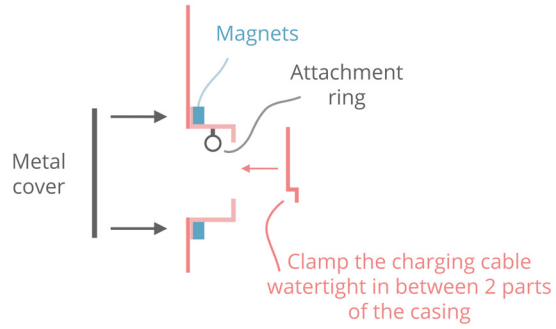


Figure 62. Close up of the compartment and its particles.

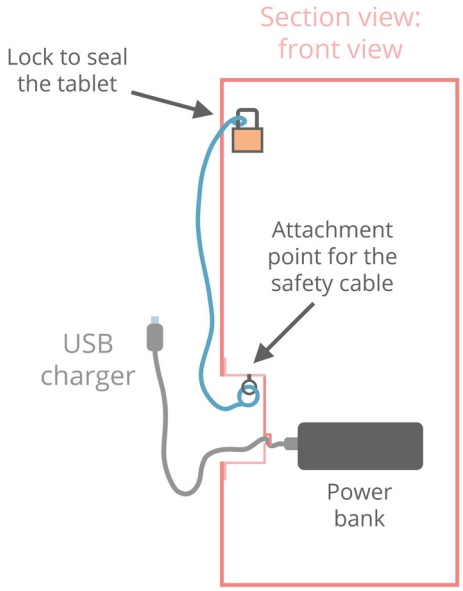


Figure 63. Section view

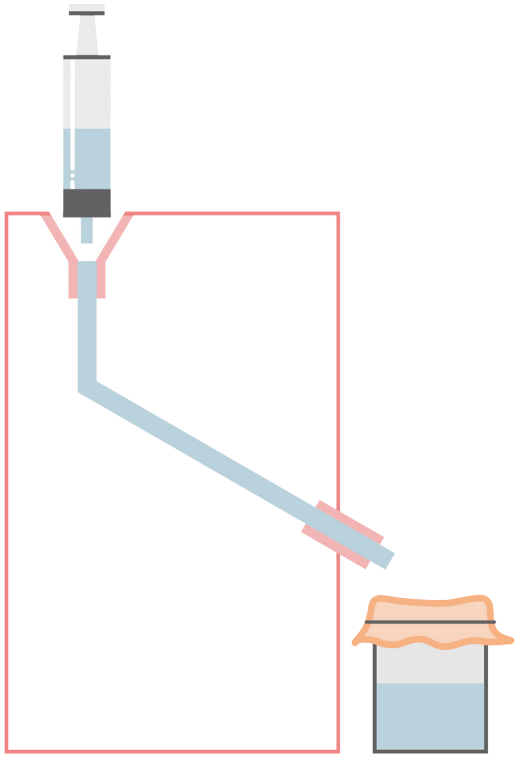


Figure 64a. Pour the urine in via a large syringe

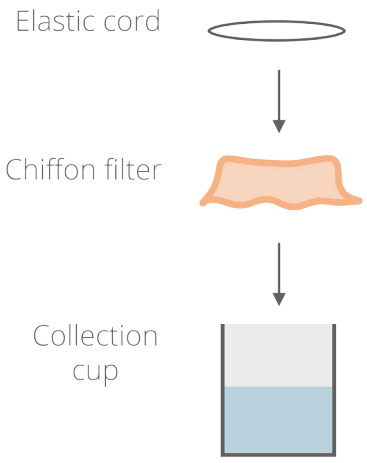


Figure 64b. Chiffon filter tied around collection cup

4.4 Diagnostic procedure

The final undefined part of the interaction is the diagnostic procedure itself. The research procedure for both, the urine entry and cleaning, is more extended than for health facilities to maximise the performance.

4.4.1 Recollect urine

As mentioned before, the researchers will have to recollect the processed urine in the sample cup to store for further research. So, they have to place the sample cup underneath the urine entry at the start of each diagnosis. As they are experienced and trained, it is assumed that they will not forget to place this cup. It is considered to use a sensor to detect the presence of a cup but due to the different types of cups (varying in size, material and shape) a sensor would only made the system error prone or significantly increases the costs. So, the digital user instructions will tell them to place the cup and it is decided to trust the researchers to follow the manual correctly. And in case they forget, researchers (unlike the health facilities) will also be able to clean it properly due to the available cleaning equipment and experience.

4.4.2 Replaceable funnels

The health facilities use the funnel shaped entrance as funnel. For optimal quality, the researchers will use glass funnels which can be removed for more thorough cleaning. The funnel will be replaced after each test and enough funnels will be brought to postpone the disinfection to the end of the day.

4.4.3 Cleaning procedure

As they recollect the urine, the tubes must be completely clean to not change the chemical values of the next urine sample. To accomplish this, local water resources might not be good enough and they need to bring bottled water to the field. If this is not possible, they have to boil the locally available water. The cleaning procedure consist of the following steps:

1. Remove the funnel
2. Place a collection cup, covered with a filter
   When using the same water collection system as the health facilities (with the barrel) this system has to detached after each sample to make room for the recollection of the urine. To evade the effort, a collection cup will be placed instead (figure 64a). The chiffon filter is tied around the opening to filter the eggs of the cleaning water (figure 64b).
3. Clean the funnel holder
   Even though the funnel shaped entrance was covered with the glass funnel, some dirt could have come in. To clean this, one can just pours a small cup of water in the funnel holder.
4. Clean the tubes
   To clean the tubes faster and more accurate, a syringe is used to add pressure to the cleaning water. A large syringe will be filled with 50 ml of water, a nozzle is placed on top of the syringe and which will fit in the tube entry (figure 64a).
5. Collect the cleaning water
   The chiffon filter have filtered out the eggs from the cleaning water. When removing the filter, the

collected water is free of ova and can safely be disposed (or boiled for reuse).

6. Clean the chiffon filter
   This filter can be reused multiple times, but should be cleaned at the end of the day. This could be done by letting it soak in chemicals (e.g. bleach) for a night, as suggested by one of the experts of the LUMC user test.

Besides the clean water, the team has to bring bleach, extra funnels, collection cup for cleaning water, chiffon filters, 50 ml syringes and an some syringe nozzle which help to fit the syringe in the tube.

4.5 Recommendations

4.5.1 Further development tablet interaction

The interaction is designed, but a final flow chart and interface design has to be developed before the application can be further realised.

This project was mainly focussed on the urinary schistosomiasis and the exact way of documentation for the STH and *S. mansoni* results is not yet explored. As all field trips examine stool, the options of digitalising the stool should be further explored.

Furthermore, it might happen that the sun is too bright to have a smooth interaction with the tablet. For further development, options to create shadow could be explored. If this is not an option, other types of displays, like as e-paper, could be considered where the sun does not lower the readability.

4.5.2 Technologies

The chosen technologies are still improving each year. It is assumed that they will work sufficient enough at the moment, and perform even better in a few years. However, when the technologies happen to have some flaws, making them less user friendly, it will still be an option to use the touchscreen instead.

4.5.3 Charging

Most tablet cases do not allow the user to charge the tablet and charging has to be done when the tablet is taken out of the waterproof cover. Whenever the tablet is out of power, the diagnoses have to be interrupted or an extra tablet have to be brought. It might be sufficient to charge the tablets over night, but if this is forgotten, or during very long working days, a way should be found to attach the charger to the water proof cover. However, this will be a design challenge for further development, to integrate this in the final design.

4.5.4 Cleaning procedure

At the moment researchers use bleach for cleaning during field trips, which could be another solution instead of the chiffon filters for researchers. However, only cleaning the chiffon with bleach will be much better for the environment, than adding bleach to all the cleaning water.

5 Maintenance in remote areas

Lack of possible maintenance happened to be one of the main problems in the remote facilities. This chapter will dive into the different solutions to bring the lifespan to a maximum. The problem of maintenance can be divided into two parts: prevention and accessible maintenance.

5.1 Prevention

The environmental circumstances will be tough. The high temperatures, large amount of rain and the constant presence of dust are most likely to destroy an average electronic device in the field. On top of that, the device has to withstand any unintended use or disaster scenarios (appendix K).

Some measures like high quality materials (chapter 8), avoiding peak currents (chapter 7), extended user manuals (chapter 3) and extra protection for transport (chapter 6) have gotten a main focus in the design. But there are some other minor details that can extend the life of the device without any crucial design changes:

1. Tablet protection
The tablet is protected by a (shock absorbing) protective case (figure 66) as well as a water resistant cover (figure 65). As described in chapter 4, so the waterproof cover has to be attached on the outside to keep the outer surface smooth for cleaning.

2. Durable and resealable connections
The device will be fully closed to keep water and dust outside and all sensitive electronics or other components are placed inside. Though, it must be possible to reopen the device in case of any maintenance. So, glue and other irreversible connections are not even an option. Furthermore, snap connections are avoided since they easily break under pressure or after using them a certain amount of times. So, watertight screws are chosen as main connection to close off the electronics watertight and enable the device to open whenever needed.

For connections that do not enclose valuable electronics (like the manual and charger compartments), magnetic connections are used. Magnetic connections are easy, resealable and durable. As long as these magnets are small, they will not influence the diagnostic technology.

3. Shock absorption for the electronics
Even when the most robust components are chosen (e.g. LCD instead of touchscreen), there are still some vulnerable components, like the optical diagnostic technology. For the extra protection, some shock proof material will be placed around the most fragile electronic parts to absorb any shocks and to keep everything in place (figure 67).

4. Tube protection
To make sure the (infected) urine will not leak over the device when leaving the tube, the end of the tube protrudes a few centimetres from the device. This

Figure 65. Waterproof cover

Figure 66. Shock protection

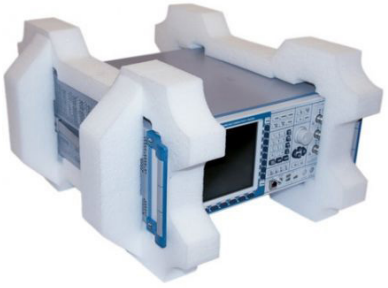


Figure 67. Foam as shock absorption

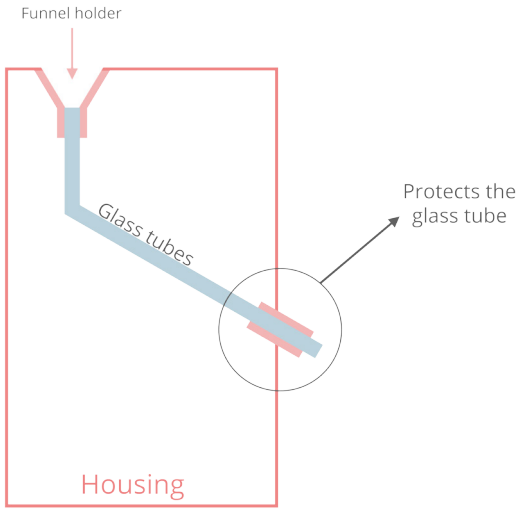


Figure 68. Protecting the glass tubes

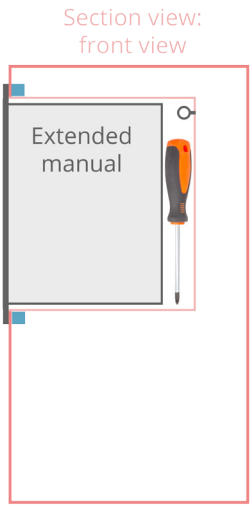


Figure 69. Screwdriver in manual compartment

glass tip might easily break if anything bumps against it. Some chips in the end would not be a disaster, but the part of the tube inside the device might not get damaged to avoid leaking urine. Therefore a small protection cover will keep the glass in place and protects it for cracking near the device (figure 68).

5. Side functions might never influence the durability
As discussed in chapter 3, guiding lights and sounds are added to stimulate the correct use of the device. The components are installed and programmed in such a way that, when one of these lights or speakers stops working, this will not influence the main functionality of the product: counting eggs.

5.2 Easy and accessible maintenance

If, after all protective measures, maintenance is still required to prevent obsolescence by the first malfunction. Many problems can be solved with some spare parts, the right tools and a little knowledge about how to address the problem. Unfortunately, those elements are not always available and the device should be able to facilitate its own maintenance.

5.2.1 Standard parts
A new diagnostic device might not be available in a nearby shop, but some areas might have access to standard parts like USB cables or power banks in nearby villages. To make sure that broken parts can easily be replaced standard components are used whenever possible.

5.2.2 Spare parts
Some communities will not be able to get these standard parts, let aloe any other electronic components like buttons or displays. To make sure that even the most remote areas are able to replace some broken parts, spare parts will be included. Those parts will be stored in a separate compartment (the maintenance box).

5.2.3 Access to tools and equipment
To replace anything at all, the device needs to be opened by the earlier mentioned screw connections. Since it cannot be assumed that all will have a screwdriver, this tool is included. Whenever the user needs to open the product, the extended manual will be needed for any guidance. The screwdriver is placed in the same compartment (figure 69). The manual is attached to a ring screw to make sure it cannot get lost and the same is done for the screwdriver.

Some other tools, needed to install the specific spare parts, are placed in the maintenance box, next to the spare parts.

5.2.4 Help and guidance
When replacement is easy due to standard parts and all tools are available, maintenance will still be impossible without any electronic knowledge or experience. Guiding is needed to know what to do and how. Therefore a special manual will be included with pictures and explanations to recognise the problems and how to fix things.

The manual will include the most predictable malfunctions, but it will never catch all problems. Besides, not everybody will be motivated enough to read through a whole manual or they might lack the confidence to think they can understand it. And above all, the majority of the actions will be too difficult to explain in visuals only. So, the pictures will be accompanied with textual explanations. When illiterate it is not likely that the manual is fully understood.

For all these situations, there will be a phone number of a help desk available. The user can call, text or contact the number via WhatsApp for help. This number will be written on the device as well as in the manual.

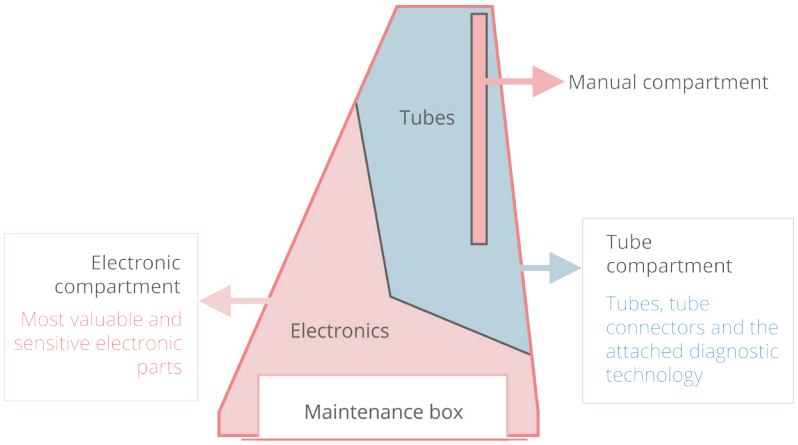


Figure 70. Compartment division

5.3 Locating all maintenance elements

Previous paragraphs explained the need to open the device to replace the tubes, repair the electronics and get access to some maintenance tools or spare parts. When opening the device, water, dust and other dirt can easily get in and damage the electronics. Therefore the most sensitive electronic parts are preferable only revealed if absolutely necessary. Luckily, the tubes, electronics and spare parts are not always needed at the same time and will be located separately to make it possible to open the compartments one by one (figure 70-73).

As mentioned earlier, all different parts will be connected with watertight screws. As a consequence all parts are reachable by one screwdriver making it relatively easy to steal some electronic parts. However, the ability to repair in local areas is assigned prioritised over the prevention of theft. Since theft can be avoided in other ways (locking the device in a closed room) while maintenance is a necessity for the implementation.

4.4.1 Tube compartment

The tube compartment might be opened most frequently. To maintain the quality of the diagnoses, tubes might be replaced once in a while (e.g. once a year during a quality check). Or, if some dirt gets stuck in one of the tubes, they should be removed for proper cleaning.

The opening to reach the tubes need to be on top, since the tubes are located in the upper part of the device. To ensure enough space to replace or reach the parts easily, it is decided to enable the user to remove the full upper part of the housing as shown in figure 71.

4.4.2 Electronic compartment

When the device does not work properly or stops working at all, this will most likely be due to electronic damage or loosened wires. In these cases, one needs to open the electronic compartment to check or repair it. Some of the diagnostic components are connected to the tubes and located in the tube compartment. Though, all the other electronics are placed behind an extra (waterproof) cover (figure 72a). When removing the cover, there is a large opening to reach the electronic parts easily (72b).

4.4.3 Maintenance box

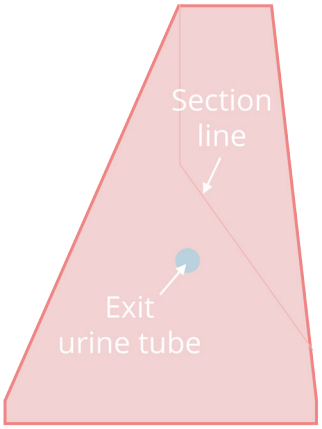
The maintenance box is hidden in the bottom. As shown in figure 73, the compartment is placed in the lower part of the device and can be reached via the bottom plate. This location is chosen for several reasons.

First of all, the tubes will not reach the bottom, leaving an open space to fit all tools and spare parts. Furthermore, in case of any water damage while opening the electronic department, the spare parts are safely stored in a separate box. Next, this box is assumed to be opened the least often of all compartments and the opening does not need to be reached as easily as the others. And, unlike the other compartments, the box is only a storage space and not a location for maintenance activities, so a small entrance is enough. Finally bystanders might not notice this maintenance box, making it less tempting to steal the spare parts for other purposes then this device.

4.4 Recommendations

For the hygiene, it was said to strive for a perfectly smooth surface. Screw connections, especially if one should reach the screws easily, will not be ideal for cleaning. However, based on the research in Ghana it became clear that maintenance is one of the main priorities to focus on. For the most rural areas it is of higher value to have a device which can be repaired and used for years, instead of perfect hygiene.

This does not mean that the hygiene requirements will be ignored and the screws will not be placed underneath the urine exit nor on top of the device. To lower the chance of any urine to be spilled on these screws. In further development of the product, solutions can be explored to cover the screws in a smooth way.



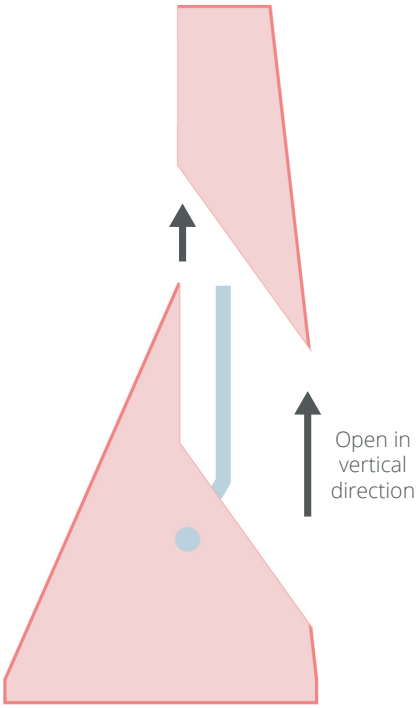


Figure 71: Opening the device to reach the tubes

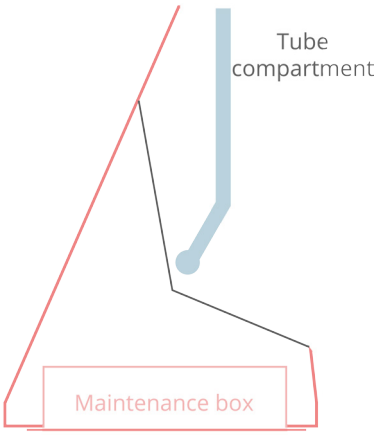


Figure 72a. Section view: Tube compartment directly available

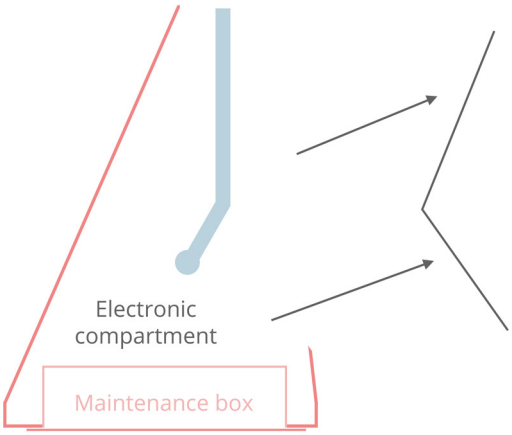
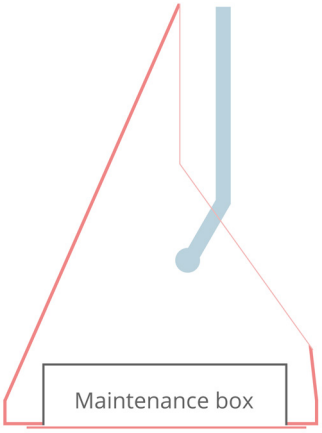


Figure 72b. Section view: Electronic compartment available after opening the separation wall



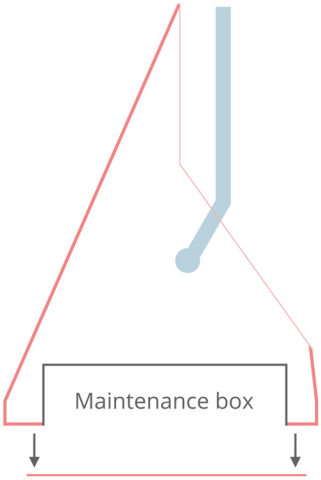


Figure 73. Section view: Maintenance box

6 Stable but portable

Due to the various user scenarios, the product sometimes needs to fulfil contradicting needs. On the one hand it should be portable and easy to carry or lift. On the other hand it might not fall or slide from the table when accidentally pushing the product. This chapter will discuss the design solutions used to find the balance between stable and portable. Besides, portability is in this case more than weight. When taking the product on a field trip, it should be easy to hold and extra protection must be added during transport.

6.1 Stable during use

To make sure that the product stays in place when somebody accidentally pushes it aside, two measures are taken.

6.1.1 Lowering the centre of gravity

Lowering the centre of gravity will increase the needed force to outbalance the device. One way to do this, is by placing all the heavy parts at the bottom. As explained earlier, the bottom is used to store spare parts, but they might not weight enough to make an impact.

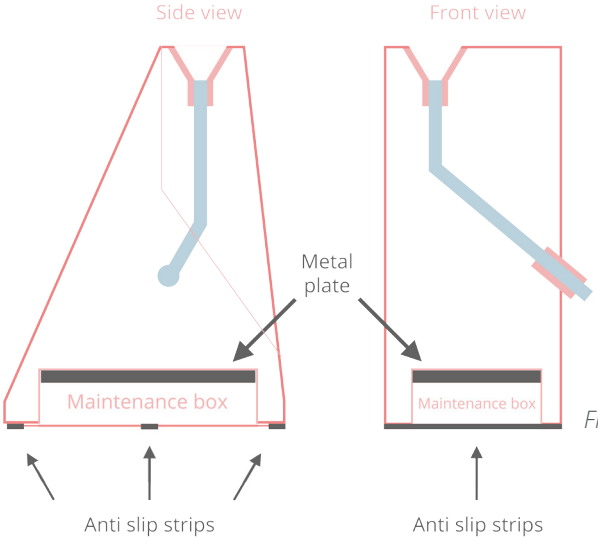


Figure 74. Improving stability

To lower the centre of gravity more drastically, a heavy plate will be attached to the bottom of the maintenance box (figure 74).

6.1.2 Shear force

The product housing will be made of plastic to gain a smooth and cleanable surface. However, a plastic object does not have a large shear resistance. And despite some extra weight, the device can start sliding when placed on a wet surface. To raise the resistance, some rubber stripes will be placed on the bottom to create an anti slip surface (figure 74).

6.2 Portable for transport

6.2.1 Dimensions and weight

During field trips, portability is very important. The product must be small enough and not too heavy to carry. Therefore, the balance has to be defined between light weight and stability. According to Dr. van Dam (2018), an expert from the LUMC (chapter 9), the weight should be limited to 3 or 4 kg to make sure it can be brought in the hand luggage when travelling by air. This suggestion will be used as a guideline until further testing is done with the end user. When the exact weight is known from all components, the metal plate will add extra weight up to 4 kg.

Moreover, this suggestion limits the maximum dimensions. In general, a product of 20 cm x 35 cm x 55 cm will suit about every airline's regulations for hand luggage [55].

6.2.2 Protection and easy to hold

Two final issues to address, are the protection (during transport) and a handle to easily carry the product (e.g. when bringing it from the lab to the car and from the car to the temporary lab in the field). Both are combined in one solution (figure 79).

Figure 75. Isolation foam

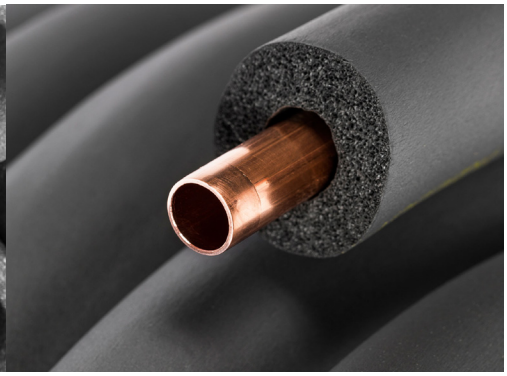


Figure 76. Soft material wrapped around a pipe

Figure 77. Bending a metal pipe

Figure 78. Recycle car tires

The protection is only attached when carrying the device. So, in the HCs or once installed in the field, the protection can be removed which means it does not have to be fulfil all strict cleaning requirements.

The protection (figure 79) will be made of a simple metal frame (figure 77), covered with protective softer material like rubber or isolation foam (figure 75 and 76). This frame will be tied around the device with simple straps. All materials are locally available and the protection foam could even be replaced by recycled (and properly cleaned) bicycle or car tires (figure 78).

The metal frame can be made by simply bending and welding metal pipes (figure 77). This locally producible protector will directly provide enough handle like wraps to hold the device with ease.

6.3 Recommendations

Test the preferred weight with the final users. And determine the needed mass in the maintenance box. Furthermore, to stimulate local production, producers should be found to make these protection covers.

Figure 79. A metal frame, wrapped with isolating material, is tight around the device with standard cables.

7 Power supply

The only disadvantage of this device, compared to the current method, is the inability to function without electricity. This chapter will discuss the considerations regarding the power supply of the future product as well as the integration in the design.

7.1 Solar energy

7.1.1 Solar panel

As concluded in part 2, power cuts are common and there are still communities without access to electricity, making solar energy the most reliable power source.

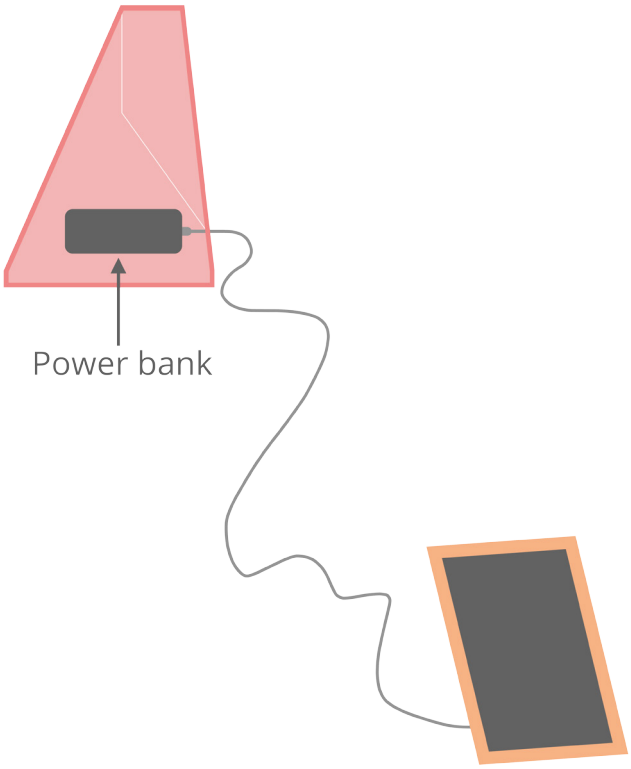


Figure 80. Solar panel.

During the user research in Ghana, it was suggested to combine solar energy with mains electricity, depending on the situation. However, when using mains electricity, peak currents can cause significant damage. It is possible to filter out these peak currents, but if such filters break, it must be noticed in time and replaced directly, which is not likely to happen. The safest way is to fully avoid the mains electricity and always use a solar power.

As the panel might not get lost or stolen, it will be connected to the device with a (long) charging cable (figure 80).

7.1.2 Other components

A solar panel needs an external battery to store the energy. As defined in chapter 5, standard parts should be chosen whenever possible and a power bank is chosen as energy storage. For the researchers, a power bank with at least two USB outputs is required. A first USB cable will be used to power the device itself and a second to charge the tablet.

The energy consumption of the device itself is not yet known and the exact power demand of the tablet will depend on both the tablet's quality as well as the final tablet tasks. Due to the limited time, both will not be determined within this project. Though, when the tablet is chosen, the price will most likely be one of the main criteria resulting in a tablet with a relatively low battery capacity.

To reduce the risk on shortage in power, even when working till late in the evening, or during rainy season when the sun is less bright, a large power bank (at least 20 000 mAh) is needed for the researchers. In remote HCs, the device might not be use continuously, neither do they have a power consuming tablet. For them, the smaller and cheaper power banks will be sufficient. But the exact amount of energy storage needs to be further defined.

Figure 81. Solar panels integrated in bicycle baskets

Figure 82. ToughStuff solar panel

7.1.3 Criteria for the panel

Solar panels can be found in various versions and sizes. Increasing the size, will raise the energy collection. Though, during transport or when the battery is fully charged, the panel will be attached to the device, which limits the dimensions. Besides, a large panel would be not be convenient for field trips and it is decided to limit the panel to a maximum of 30 by 30 cm. Nowadays, due to the growing interest in solar energy, the market offers a large collection of relatively cheap solar panels within these dimensions, for public use (figure 81) or even specifically for remote areas (figure 82).

To increase the efficiency of a panel, it is important to find the right angle towards the sun. Unfortunately, there are barely any panels with clear feedback about the correct angle towards the sun. One option is the *BioLite solar panel 5* [8], which has an integrated sundial (figure 83) for maximum charging opportunities. This, and other panels of comparable size, can produce 5 Watts per hour in bright sunlight [8]. When the final energy consumption is known, it should be calculated whether this panel size would be sufficient.

Figure 83. *BioLite solar panel, including sundial*
On the Left: Wrong position; On the right: Correct position

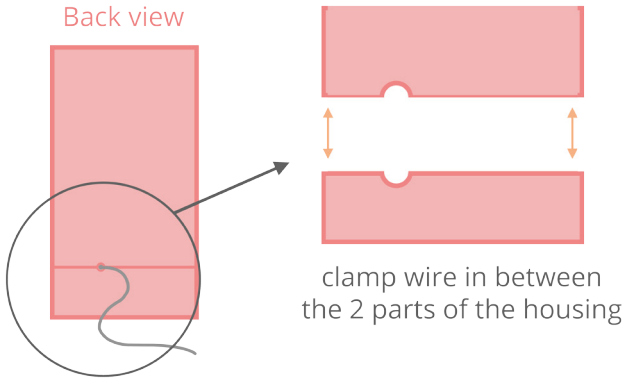


Figure 84. Cable stuck in between 2 parts

7.2 Integration

7.2.1 Cable attachment and length

The solar panel charges the power bank via a standard micro USB port. As the power bank is placed inside the device, the cable leaves the device at a rounded cut-out, clamped in between the upper and lower part (figure 84). When the cable needs to be replaced or disconnected for any reason, the cable can be disconnected when opening the device.

The wire that connects the solar panel to the power bank has to be long enough to reach some nearby sunlight, even when the device is located inside a health facility without much windows. A power cable

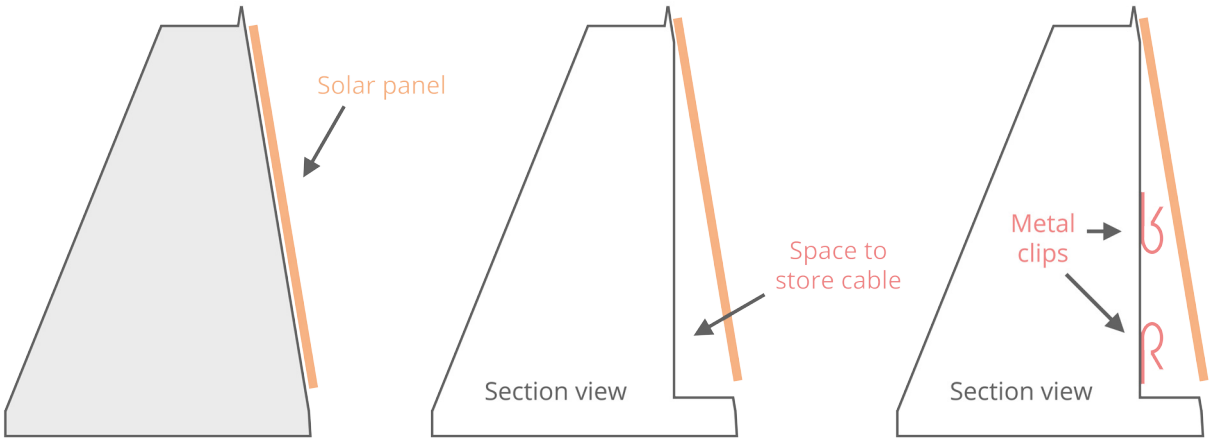


Figure 85. Placing the panel on the back of the device

of at least 5 meters long is chosen as a standard length, which makes it possible to place the panel in a next room. Due to the use of standard USB cables for charging, the length can be customisable in case a longer or shorter cable is preferred.

7.2.2 Compact storage

Whenever the power bank is fully charged, the solar panel can be tied to the back of the device via a simple raised edge on top (figure 86 and 88), similar to the tablet attachment. However, the 5 meter of cable have to tied up too. As shown in figure 85 and 89, there will be an open space in between the panel and to place the cable, compactly hidden away behind the solar panel. Unfortunately, cables are tempted to spread to each possible direction and something is needed to bundle or clamp the wire to keep it in place (figure 87). Different clipping and clamping options were evaluated and tested (appendix O). One touch point happened to be insufficient for such a long wire and it is decided to fasten the wires with metal clips in two places (figure 85 and 89). Such metal clip will not easily deform when the user pulls too hard and can be produced locally.

7.3 Conclusion and recommendations

In a next stage of the project, when the technology is finished or at least further defined, the exact energy consumption can be calculated to validate whether a 5 Watt per hour is efficient enough. If not, other options have to be explored. If the final panel does not have a sunlight indicator, a separate sundial can be added manually to assure this function.

For the user interaction, it is important to have a battery indication light on the outside, to check the battery level anytime. It must be explored if there is a simple tool to measure the battery level of the power bank.

The sundial is easy to use when one knows how to read it. When using it for the first time, some explanation is needed and an explanation should be included in the extended user manual, or instruction stickers can be placed on the solar panel itself.

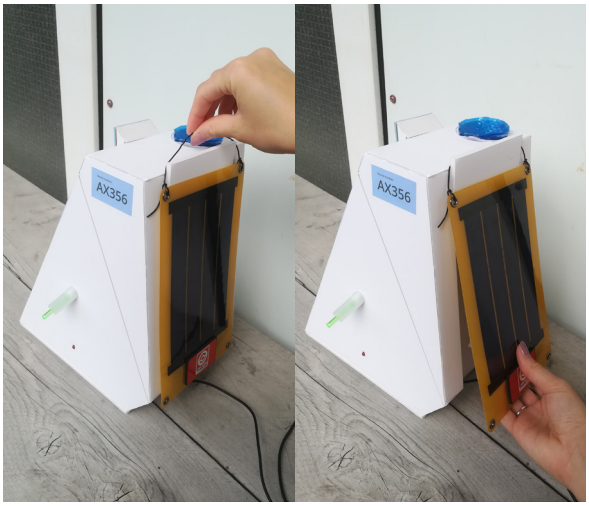


Figure 86. Placing the panel on the back of the device

Figure 87. A clip to keep the cables in place

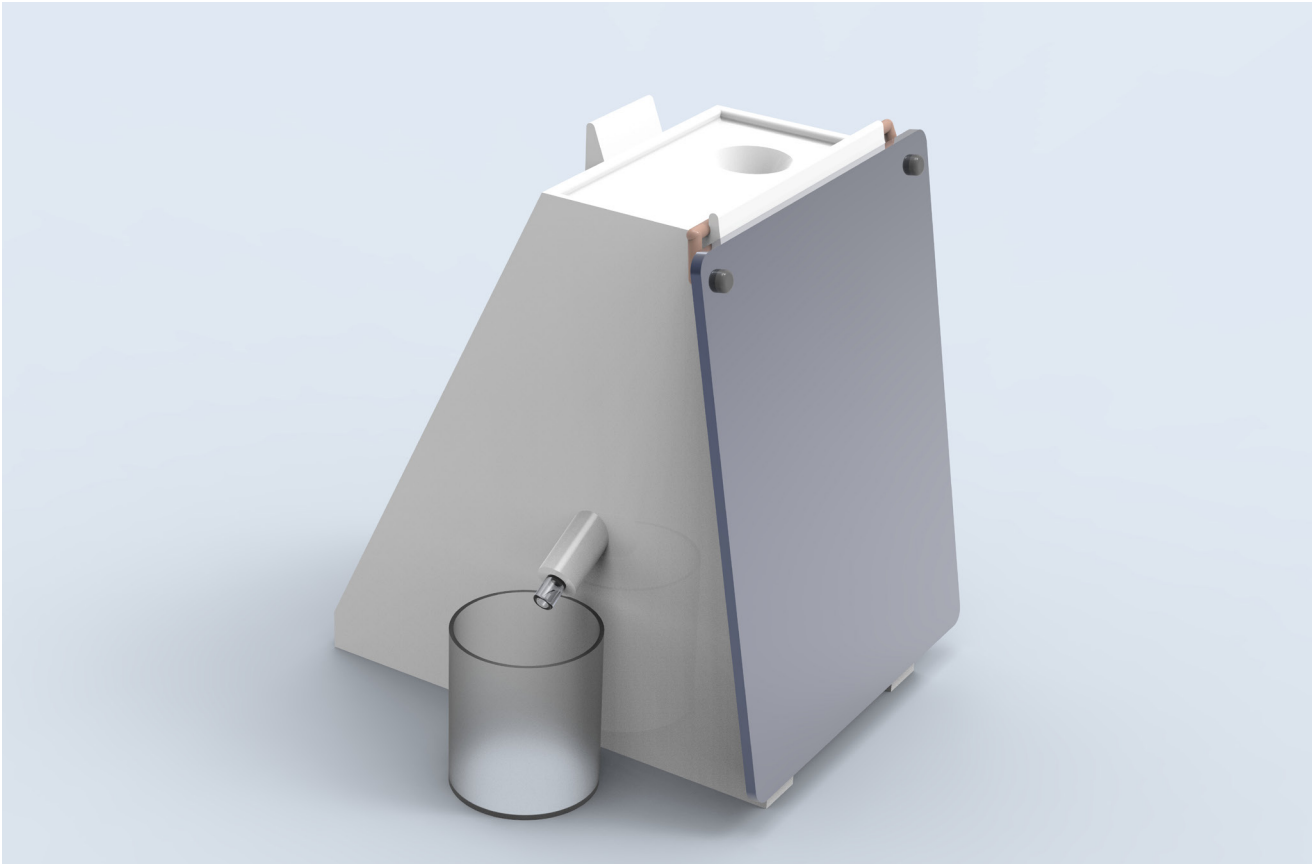


Figure 88. Solar panel attached to the device

Figure 89. The clips and space to store the wires

8 Production

8.1 Production

8.1.1 Production technologies

Three feasible production methods are 3D printing, injection moulding and thermoforming.

For the final choice, production cost is one of the main criteria. The implementation will start with small batches, first of all to only prove the value within only one or a few countries. When the customer's attention is drawn successfully, the batch size can increase. But even on the long term, the product is not likely to target mass production. Besides, the production mould might have to be adjusted in between (e.g. after further exploration of the other approachable countries). Therefore, 3D printing and thermoforming are most convenient.

When comparing those two, 3D printing would provide a larger form freedom for the design. However, 3D printing has some fallacies of its own. Injection moulding and thermoforming are both able to create a hygienic smooth surface. 3D prints are characterised with a slightly rough surface. To create a smooth surface after all, post-processing is possible, but this will be time consuming and comes with additional costs. Finally, it cannot guarantee the same surface quality as a thermoformed product.

Furthermore, 3D printed models are not per definition watertight: "*Visually, a 3D print might appear to be water tight, but it's possible that there are very small gaps at points where the layers meet*" [26]. This creates an unintended porous material and it is not recommended to make watertight products with the general 3D printing technologies [87]. Some measures can be taken to avoid or minimise the risk on such a porous surfaces [26], however, it is decided not to take the risk. Especially as this product will be in contact with all kinds of liquids on daily basis (urine, water and cleaning chemicals).

To conclude, thermoforming is chosen as main production technology for product housing.

8.1.2 Product shape

The only down side of thermoforming, is the limited form freedom. It will not be possible to make the device out of 1 piece.

The product consists of several compartments. One for the tablet charging cable, another (narrow) opening for the extended manual and a maintenance box in the bottom. Those will be produced separately and assembled afterwards. This can cause some edges that are difficult to reach for cleaning, the attachment points and section lines are therefore avoided near the urine entry and exit.

The main casing has to be split in two parts, as the upper part must be removable for maintenance. And figure 91 illustrates how the upper and lower part are formed (in section views), together with the bottom. These housing parts are thereafter screwed together (figure 90).

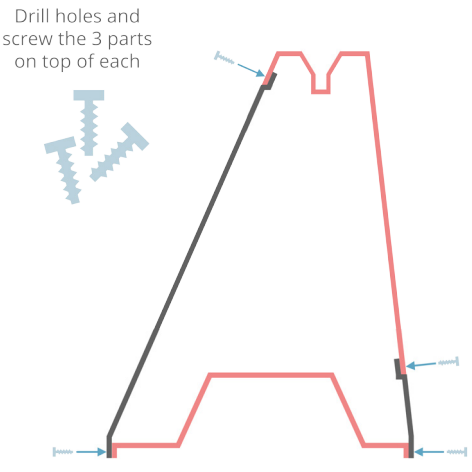


Figure 90. Connect all parts with screws

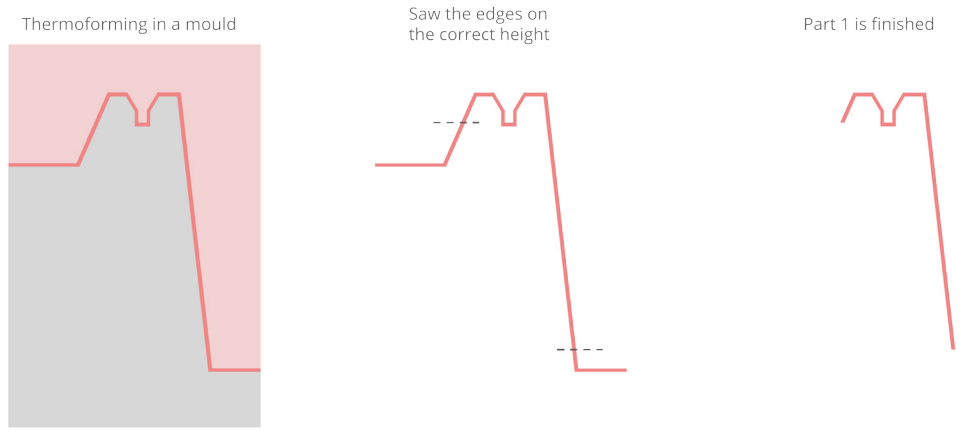


Figure 91a. Thermoforming the upper part

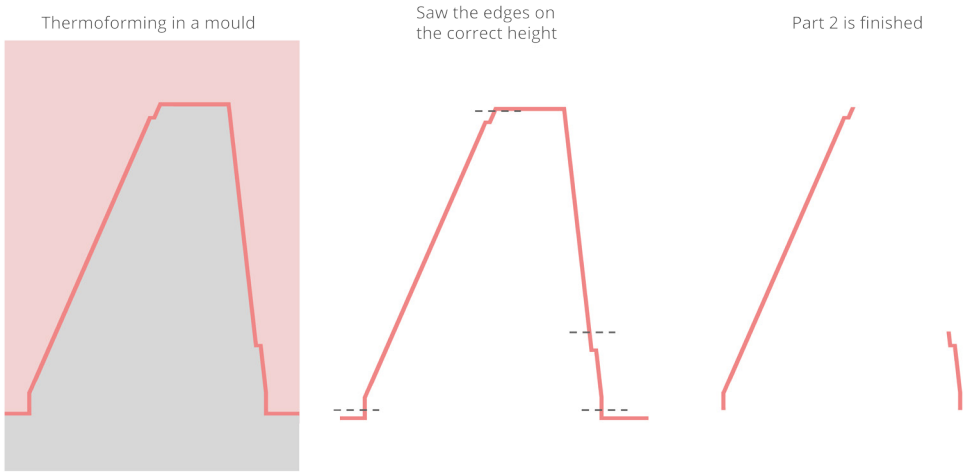


Figure 91b. Thermoforming the lower part

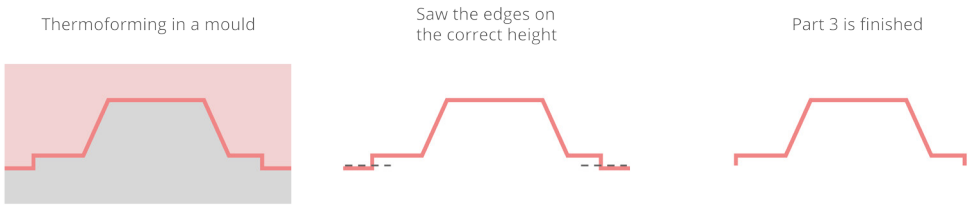


Figure 91c. Thermoforming the bottom

8.2 Assembly

The assembly of all separate compartments, magnets and other components is done with glue or screws.

As a first step, sawing is needed to create the openings for the different compartments. Than, the compartments for the charging cable and the extended manual can be glued inside. Magnets are glued around the compartment openings and the urine entrance. Furthermore, the heavy plate inside the maintenance box, some attachment points for the electronic compartment and the tube protector are attached with glue as summarised in figure 92.

Figure 93 shows the components which are attached by screws, including the bottom plate (to cover the maintenance box), the cover of the electronic department and the background plate of the charging compartment. This last part will clamp the charging cable in place and it should be explored whether any rubber needs to be added to keep the device waterproof.

Finally, some small tasks are left: the anti slip strips have to be placed on the bottom, some clips are needed on the back (to keep the solar panel cable in place) and the urine/water collection barrel need to be installed for the health facilities.

To complete the product, the electronic and diagnostic components need to be installed on the inside. When the technology is further finalised and the needed components are defined, it must be considered to place some division walls or clips to fasten the separate parts.

8.3 Material choice

Both Polyoxymethyleen (POM) and Polypropylene (PP) are common materials in the medical world. Not all of the medical equipment are exposed to so much outdoor influences as will be the case for this product and appendix J discusses a set of requirements and wishes for an optimal material choice. The most important criteria are:

- Suitable for thermoforming
- Maximum service temperature of at least 60°C to make sure the quality does not degrade in extreme temperatures.
- Resistance to organic solvents, UV radiation, strong alkalis, strong acids and (fresh) water.

CES EduPack (2017) was able to find one material to fulfil all requirements: Polypropylene (impact copolymer, UV stabilized). This specific PP variant can handle for all kinds of acids, alkaloids and solvents and has a unique UV resistance. Besides, PP is described as a "*low cost alternative to engineering plastics, such as ABS, PA and POM*" [13]. Based on this information, it is decided to use PP (impact copolymer, UV stabilized), which will ensure a stable quality, even after years of exposure to sunlight, chemicals and water without increasing the costs.

8.4 Costs

Both, the production method and material are kept relatively cheap. Though, all the required accessories and elements, such as the solar panel, power bank and especially the diagnostic components increase the costs significantly. A first (rough) calculation of the diagnostic components estimated the price on €600 to €700 for the tubes and optical mechanism only. The other components will probably increase the price with another €100 to €200.

One of the Ghanaian technicians of the NTDP explained that a microscope will be at least a thousand euros. Moreover, the main savings are made by reducing the time in the field. Not only is this device cheaper than the current equipment, it will increase the speed of the field trips and it will create the opportunity to hire lower educated users for the diagnoses. So, for the researchers and the NTDP, the product will be an investment worth making.

Only the health facilities might not have enough budget to buy this without any financial support. Chapter 10 will discuss how the product will be made affordable, even for the most remote facilities.

8.5 Requirements

For further development, the material has to be tested on strength and scratch resistance (appendix J). Based on this, the wall thickness can be determined.

3D printing would be able to print all compartments at once and save assembly time. Further developments in the field of smooth and waterproof printing should be followed to see if any suitable solution is found.

Components attached with glue

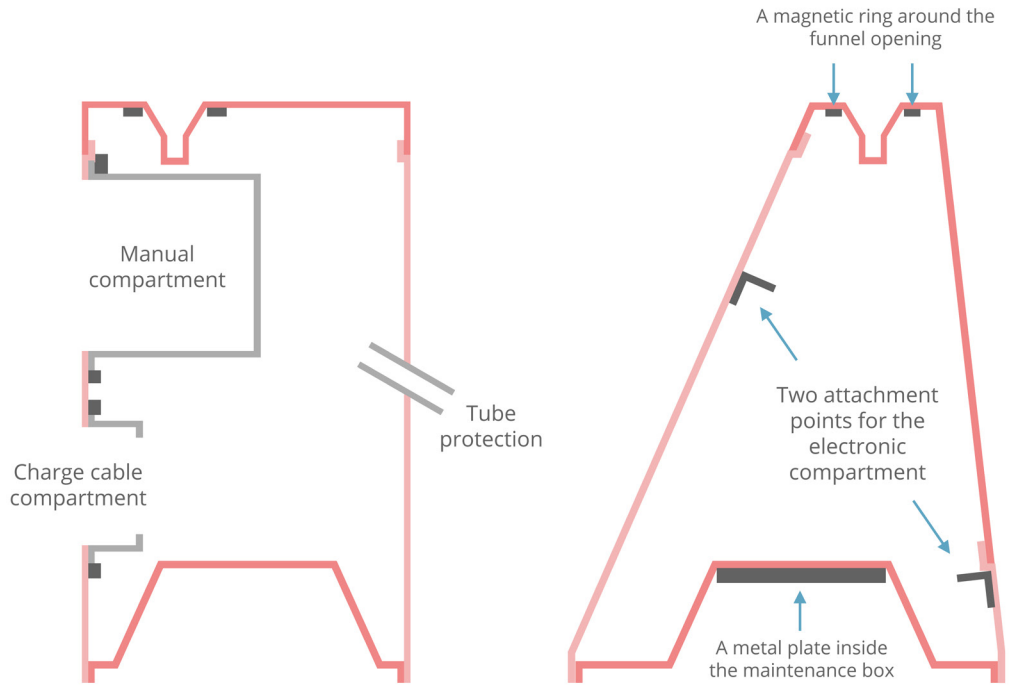


Figure 92. The compartments, magnets, a metal plate and some attachment points are glued inside.

Components attached with screw connections

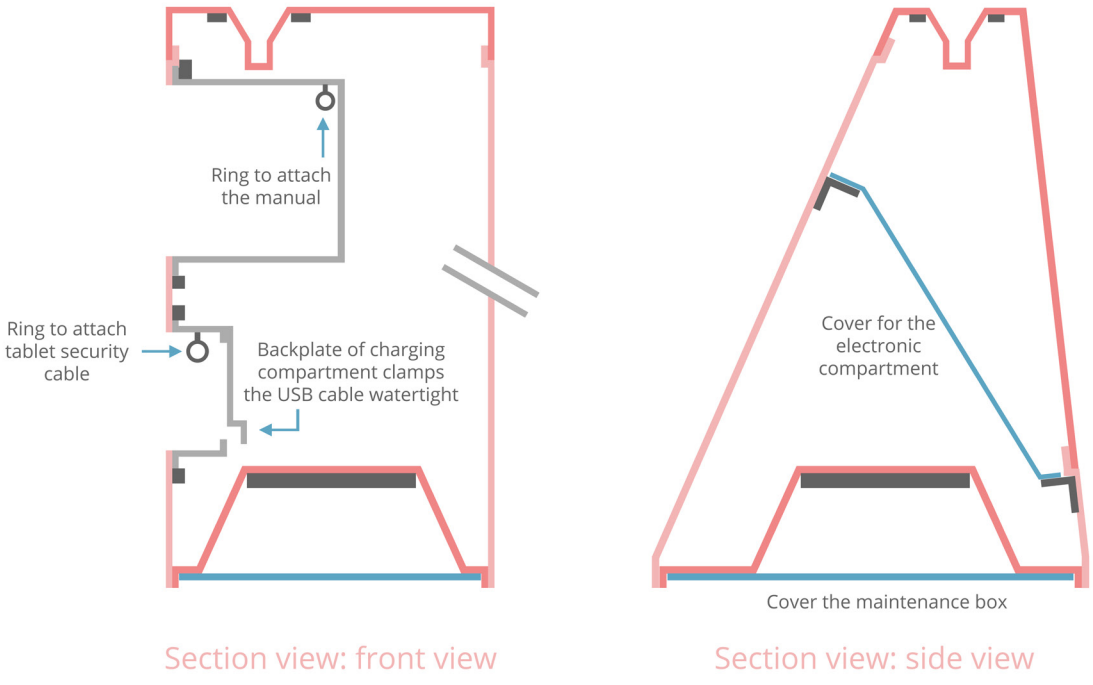


Figure 93. The covers and screw rings are connected with screws.

9 Validation

The final design is validated in several ways. A qualitative user test was conducted to evaluate the interaction with three PhD students and one biomedical researcher at the LUMC. All participated in field trips of at least one African country. Thereafter, the concept was discussed with Dr. G. J. van Dam, a senior researcher at the Leiden Parasitology Diagnostics Group of the LUMC, who has a broad experience and interest within the field of schistosomiasis diagnosis.

Besides the expert validation, a CVD session was organised in cooperation with a junior researcher who went to Nigeria to see how they organise schistosomiasis control. Nigeria is the country with by far the largest amount of schistosomiasis cases [78] and the first to consider for further scaling. The findings from Ghana and Nigeria were compared to examine what adjustments were needed to scale the device to the Nigerian market.

This chapter will discuss the main insights of the different validation activities. Some of the findings are included in the final design, others are added to the recommendations for further improvements. The extended results of each test and session an be found in appendix P, Q and R.

9.1 User test

A prototype was built to facilitate the user test (figure 94). By the use of a (fake) sample, syringes, collection cups and funnels, the participants were asked to do conduct a diagnosis. The manual on the device was the only guidance for the participants to figure out how to use the device. Afterwards, the interaction as well as the clarity of the manual were discussed in a semi structured interview. Furthermore, different types of manual designs were evaluated and the potential users were evaluated in relation to their skills, available equipment and possible cleaning procedures.

9.1.1 Design iteration

The test led to improvements of both the content as well as the design of the instructions on the device. Besides, it was decisive for the relocation of the on/off switch and helped to define training strategies. But most importantly, the suggestions contributed to the simplification of the user interaction and cleaning instruction for remote areas. Most of these changes were mentioned in the previous chapters, but a complete overview of the adjustments in the user manual and product interaction, can be found in appendix Q.

9.1.3 Cleaning

For the cleaning procedure, both cleaning chemicals (like bleach) and water were considered. Since all participants confirmed that flushing the tubes with water should be sufficient to remove some leftover eggs, the final cleaning procedure is only water based, which is, unlike bleach, available in every facility.

The designed cleaning procedure for researchers includes disinfecting syringes, funnels and chiffon filters. The participants explained that this will not be a problem at all, since the current methods already require a lot of cleaning at the end of each day.

The chiffon filters will be boiled (health facilities) or cleaned with chemicals (researchers). The participants explained that researchers always use bleach to disinfect everything, so cleaning with bleach would fit their current habits. Unfortunately none of them was not able to confirm whether those methods would indeed kill *all the eggs* in a filter and the experts suggested to test this for further verification.

In Ghana, both the researchers and hospital staff explained to recollect the tested urine after every diagnosis (while remote areas might dispose the urine). This led to the assumption that all researchers will do the same until two of the four participants explained that even researchers are sometimes

Figure 94. User test at the LUMC

disposing samples. So, this will differ per country or research institution. When urine is collected, the procedure will be followed as was designed in chapter 4. But when researchers dispose urine during field trips, they can choose to save time and effort by using the same collection system (with the large barrel) as was designed for the health facilities.

9.1.4 Acceptance, training and manual improvements

One of the experts explained that this new device should be easier than the current methods to assure complete acceptance. This was one of the many reasons to for maximum simplification of the procedures for health facilities, to make sure it is the easiest option.

Furthermore, all confirmed that at least some training is needed for the lower educated user groups. Due to the clear instructions on top, reading the manual would be sufficient for most researchers. For the others it would be advised to have at least some kind of briefing or short training.

Lastly, it became clear that the formulation of certain words could be crucial for the user to interpreted the instructions correctly. For example, to point out the difference between the sample cup and the cup to collect cleaning water. This confusion pointed out the urge to use the correct terms and names in the manual. And the final manual should be validated with the actual user groups before implementation.

9.2 Expert assessment

A meeting was arranged with Dr. G.J. van Dam to discuss schistosomiasis in general and evaluate the final results. Due to his years of experience, some interesting insights came up (appendix P).

First of all, the benefits of diagnosing larger volumes were discussed. Despite that fact that the WHO advices 10 ml testing, it was suggested to make it at least possible for the device to process larger volumes of urine. This was already included in the design (for remote areas) but the researcher confirmed this decision.

A second topic was trust. It was explained that especially adults are not eager to participate in diagnoses, due to a lack of knowledge nor awareness about the disease. The fear exist that the medication is fake, and that the drugs are actually tablet for birth control. One of the best ways to create some acceptance is to show the patient some proof that the urine is infected. Whenever the device can show, in simple means that someone is contaminated, this would help to convince patients to take the Praziquantel. This is why the RGB LED was integrated, which gives colour indication of the result (healthy, lightly infected or heavily infected), next to the written result on the screen. To communicate the result to the community (especially when dealing with illiterate patients). This device would be "*a perfect tool to serve for acceptance*" (Dr. G.J. van Dam, 2018).

9.3 Scaling to Nigeria

9.3.1 CVD sessions

As explained in part 1, various contexts (Nigeria and Ghana) would be compared via the CVD (Context Variation by Design) approach. Throughout the whole project, several CVD sessions were scheduled to combine the Ghanaian insights with knowledge about the Nigerian situation. Parallel to this project, a second researcher was in charge of an exploration of the Nigerian context.

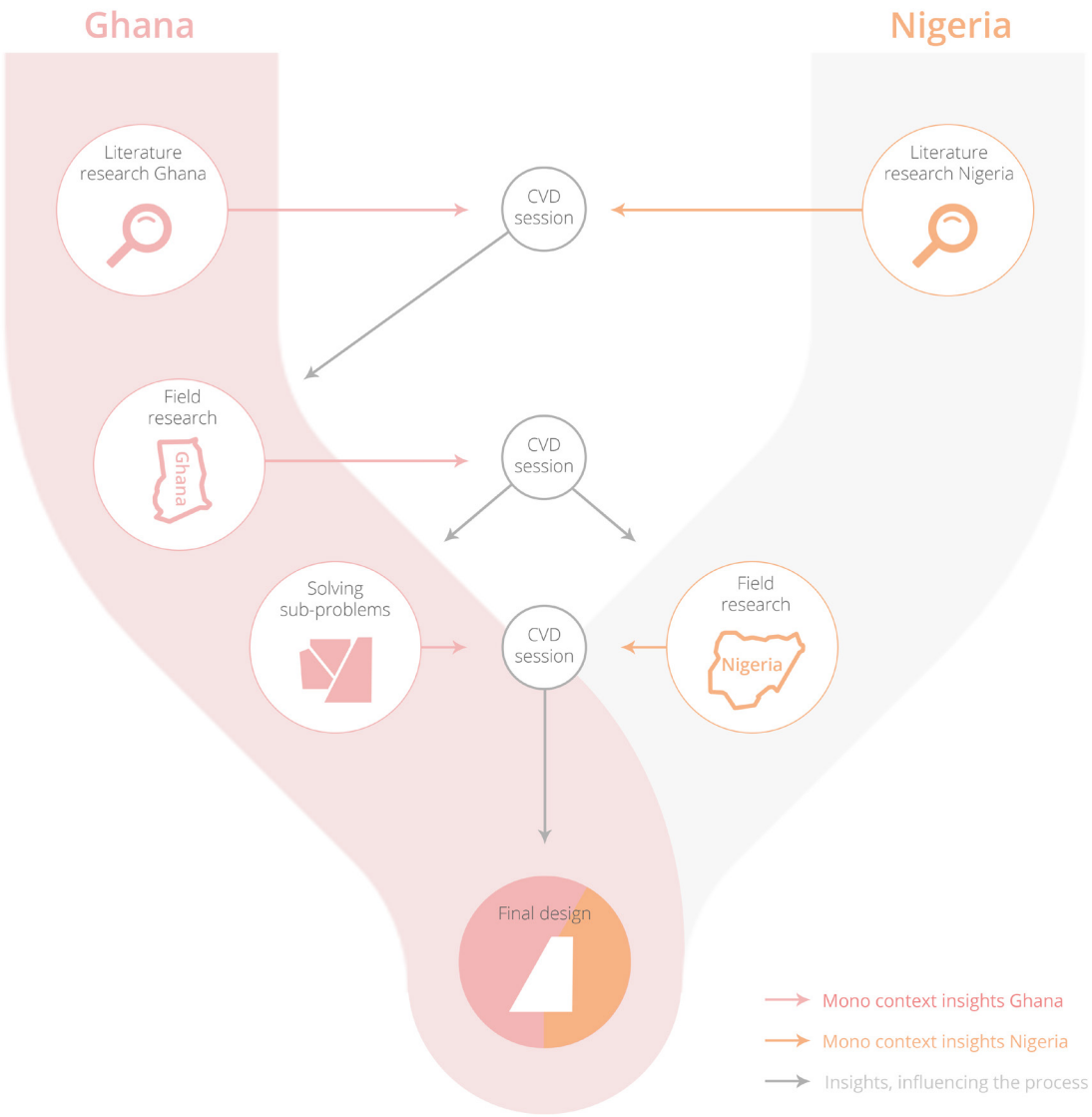


Figure 95. CVD integration in the project

Three moments of evaluation were chosen (figure 95). In a first exploratory session, insights of literature reviews were compared. Thereafter, the Ghanaian context was analysed during three weeks of extensive field research, which significantly enriched the Ghanaian knowledge. At this point, a new CVD meeting was scheduled to discuss the results of Ghana and set relevant research goals for an upcoming field trip to Nigeria. During the Nigerian field research, this projects arrived in the product development and the final concept was developed based on the Ghanaian insights and the literature review of Nigeria.

The final and most important CVD session took place after the Nigerian field trip. Within this session, the Nigerian key insights were compared with the Ghanaian findings to define complementing as well as contradicting desires of both contexts and to validate how the final design could fit the Nigerian context. This paragraph will point out the key findings and the extended results can be found in appendix R.

9.3.2 Insights Nigeria

National mapping activities in Nigeria are much more challenging than in Ghana. The remote areas in Nigeria are not only hard to reach, several conflict zones decrease the safety of field trips.

Some prior mapping activities were conducted, but it was no success as not all communities wanted to cooperate. Due to a lack of awareness and health education, many did not trust the drugs nor did they wanted to give away urine samples as urine can be used for spiritual rituals. And this resistance among communities grew even more after MDA, due to the several side effects of the medication. As a consequence, mapping data is lacking and there are no plans to repeat such mapping activities anywhere soon. There are however some areas with MDA, but without a structured approach due a knowledge gaps.

Like Ghana, Nigeria has various users to target with this new device. Researcher institutions are included,

but control programmes are now mainly doing MDA without testing. To compensate for the lacking mapping information, school based interventions (by the help of teachers) are considered to achieve structural data collection. Furthermore, Nigeria seems more aware of the existing of urban schistosomiasis, which adds the urban hospitals to the list of potential users. But in the end, the lowest levels of the health system are most important in order to reach all endemic areas, even the remote or unsafe ones. This device could enable rural HCs or even pharmacies or local health volunteers to do local diagnoses, as they are the only users who are present in even the most unreachable areas. And, unlike the research technicians, these people have earned the trust of the community, which will be needed to create acceptance and awareness.

9.3.3 Additional requirements to the design

In the first CVD session it was concluded that the rural situations in both countries would not differentiate a lot ad as the product was designed for the uneducated users in remote Ghana, the scaling towards the remote areas in Nigeria will not be a problem. Neither will the implementation for the Nigerian researchers. But, even though the user groups are be comparable, the Nigerian research revealed some additional product requirements for the device.

Ghana has already completed two national mapping phases, while Nigeria is still unaware of the impact and prevalence in the different areas. As a result, there is a need for structural and standardised data collection (by the schools, remote facilities or other local volunteers). The diagnostic device would be a perfect tool to facilitate such structural data gathering as it always measures with the same standards. When the product saves all test results on an SD card (together with the date and the time of each diagnosis), researchers can visit the HCs annually to copy the data of the SD cards in all areas. This would provide an overview of the number of diagnoses per area, the percentage of actual infections among the tested patients and the time of the year in which the number increases.

When Nigeria (or the WHO) are interested in such data collection, the options could be explored to further complete the data by entering more patient information in the device (such as age, sex or patient ID to filter the double tests per patient). However, even without this extra information, the data collection would already be an improvement of the current situation and most likely be an eye opener if the number of infections happen to be much higher as expected.

A second requirement is trust. In Ghana, health education is successfully integrated to increase the acceptance of the MDA and field trips. As this is clearly not the case in Nigeria, the earlier mentioned suggestion of Dr. G.J. van Dam, to make the device show the results to the patient, will be a first step towards acceptance of results.

A third and final insight addresses trust from another angle. In Ghana, technicians explained to trust the device whenever it has passed the regular quality checks. However, the technicians in Nigeria asked for a way to check the quality themselves, even in remote facilities. And this will be a next design challenge for further development. One could test the device on false positives by diagnosing clean water: whenever the machine works correctly, the result should be zero eggs. To check the device on false negatives, the urine samples have to be compared with another diagnostic method such as microscopy or PCR, as the researchers do quality checks). However, this is not possible in facilities without a microscope. For the further development, it must be explored whether the quality checks are an important implementation requirement or only a wish for added value. If it is important, a way has to be found to enable quality checks, which would make the devices more reliable.

9.4 Conclusion

The several experts were able to confirm the choices for the final diagnostic and cleaning procedures. Furthermore, the CVD evaluation showed that the chosen user groups of Ghana happened to be relevant for Nigeria too.

For further scaling, the main product is most likely to stay the same, but variations in the user interaction and implementation will differ. For example, in Nigeria this product will be able to standardise data collection by remote facilities to collect quantitative data of prevalence among tested patients. While in the Ghanaian health facilities, the main goal of the product would be to fulfil the need for proper case management of light infections.

9.5 Recommendations

The efficiency of the chosen cleaning methods have to be tested with a final device and actual urine infected samples. Furthermore, the final manual has to be tested with the end users to customise the needed explanations.

To scale the implementation to Nigeria, the options of quality checks must be explored. And, to further define an implementation plan for Nigeria, further user research is needed to extend the knowledge of this enormous country.

10 Final design: The EC

The EC (Egg Counter) is the final result of this graduation assignment. It is a product suitable for researchers who perform large scale community screening, for the remote health facilities who do not have the specialism or equipment for proper case management and for all users who fit in between the requirements of those two extremes. Page 106 summarises the features of the product to facilitate both scenarios.

The previous chapters discussed how the interaction slightly differs per user group, but the product itself can be used by both. It was not only a challenge to fulfil all needs in Ghana, as many more countries are dealing with the same problem.

Within one of the first CVD sessions, it was concluded that the differences within one country might be bigger than the variations in between the endemic countries. This was proven to be true when looking at Ghana and Nigeria. It was a challenge to fulfil the contradicting requirements of the user groups within Ghana. But only small changes are needed to implement the final product in Nigeria.

10.1 Added value researchers

Researchers can choose to add a tablet or other smart device to the interaction, which creates a professional appearance due to the appearance of the tablet itself and the various modern technologies such as voice recognition and NFC.

The tablet can connect with the device to digitalise the data automatically. The collected data will be more accurate and less time consuming than the current methods. Saving time and money while increasing the quality and efficiency.

Furthermore, the product will provide its own electricity due to a portable solar panel and a power bank. And all the features are adjustable to the user's needs. The cable length can be changed as well as the capacity of the power bank, due to the standardised parts inside.

The standard procedure for researchers is shown on page 105. Here too, it leaves some freedom to adapt the procedure to their own habits. They can customise the application for data collection. There are options to recollect the tested urine or to dispose it. And finally, they can decide upon the quality and want to achieve with their cleaning procedure. If they want to save time, they can always do choose the easiest method, as is designed for the health facilities. Or they bring enough equipment and disinfect every detail.

It will save the research institutions money by saving time. The quality will no longer be user dependent and increases the reliability. This will extend the reach of the projects, more communities can be tested to increase the awareness and knowledge about the prevalence. And, above all, to assist in more efficient control activities to fight this disease.

10.2 Added value rural health facilities

In contrast with the researchers, remote health facilities prioritise ease of use over the professional looks. The product literally explains itself and interactive guidance will encourage and instruct the user during the procedure. Page 105 summarises the procedure of both user. As can be seen, the procedure for health facilities is simplified throughout the entire interaction.

The procedure does not dependent on any (medical) equipment except for the device itself. All necessary parts are included. Some are even attached to the device, like a screwdriver, solar panel and manuals. Others, like the cylinder to clean the tubes, can be locally reproduced in case it gets lost.

With the EC, diagnosing become accessible for all facilities. And to optimally benefit from this device, obsolescence must be avoided in any case. Therefore, local maintenance was a crucial request. Due to included spare parts, tools, an extended manual, and a phone number for assistance, this product can be repaired by everyone who can read or call.

Research procedure

Main activities

Remote health facilities procedure

- Turn on the power
- Prepare device
  - Check battery level
  - Place a clean funnel
  - Shake sample
  - Place sample beneath the urine exit
  - Check battery level
- Press start
- Urine entry
  - Take 10 ML urine with a syringe
  - Pour urine in the funnel
  - Shake sample
  - Pour urine in the funnel
- Wait...
- Document result
  - Automatically saved on tablet
  - On paper
- Clean tubes
  - Remove the sample cup for storage
  - Remove the contaminated funnel
  - Tie a chiffon filter on an empty cup
  - Place this cup beneath the urine exit
  - Flush the funnel holder with a cup of water
  - Fill a clean syringe with 50 Ml water
  - Press the water through the tubes
  - Place the cleaning tube on top of the device
  - Fill tube with water
  - Wait till all water is gone
- Turn off device
- Side tasks
  - Dispose cleaning water
  - Disinfect funnels and syringes for reuse
  - Boil chiffon filters
  - Other diagnoses: dipstick test, urine indication and stool examination
  - Attach collection barrel to the urine exit
  - Dispose urine and cleaning water when the collection container is full
  - Boil the chiffon filter once a week

The EC
in rural health facilities

1. **Guidance one cannot miss**
   by simple and visual instructions, interactive guiding lights and correcting or confirming sounds.

2. **Facilitate maintenance**
   with spare parts, equipment and guidance via a manual and a phone number for assistance

3. **Minimised risk on damage**
   due to robust components, protection foam inside, a water and dust proof housing, anti slip strips on the bottom and a low centre of gravity.

The EC
in research field trips

1. **Digital data collection**
   by a tablet that connects via NFC with the device to collect all results within one application. The tablet can save, share and process the data digitally.

2. **Saves money by saving time**
   as the automated procedure is faster than the current methods, performs without a break and no longer depends on the limited amount of trained employees.

3. **Made for in the field**
   due to locally produced protection for transport, a material that can survive years of sunlight, dust and water proof housing, a solar panel to ensure power and the option to charge the tablet with this same source.

10.3 Implementation

Such a product might sound convenient on paper, but some effort is needed to actually bring it on the market. Before any implementation is possible, the technology and the product itself need to be further developed, tested and refined. The manual must be customised for the specific users, with local languages and some variations in procedures. A training protocol has to be set up and financial support need to be arranged.

10.3.1 Technology

For the technology, the first goal is to make the product work for the *S. haematobium* examination. As a next step, the options to even use it for stool examination have to be considered.

10.3.2 Training

Even if the usage is self explaining, the experts at the LUMC confirmed that at least a short training is needed (especially for the health facilities) to maximise the understanding about the device, its purpose and what to do in case of malfunction.

The training can use actual devices as well as pictures to clarify the use. The same pictures are used for the extended manual. Hereby, users can always look up it up whenever they forget some parts of the training. And, as the use is simple, the trained users can easily pass along the information.

This way, they only need to train a few users per area. Thereafter, they can visit the nearby facilities of their area, to further explain the product.

10.3.3 Financial support for remote facilities

The researchers have their own budget, but the health facilities depend on the GHS to invest in these new devices. To give as much facilities as possible access to the product, the following three business strategies are suggested.

Sell data

All result will be saved on SD card inside the EC. This data could be annually collected to monitor the number of diagnoses, the infection rate among the tested patients and the average infection intensity in even the most rural health facilities. This data is valuable for worldwide (research) institutes like the LUMC or the WHO. In exchange for the data, the institutions could sponsor the implementation.

Advertisement

The device will reaches all corners of the country, which creates a unique opportunity for brands to advertise even in the most remote areas. Due to limited access to internet, the non-digital branding is still an effective strategy to reach these areas. It could be possible to let those companies (partly) pay for the device in exchange for advertisement space (e.g. on the back or on the side, where it does not disturb the interaction).

Product sponsors

Companies can also be approached to sponsor certain components instead of buying advertisements. For example, solar panel companies might be interested in the upcoming market of remote areas, and could donate the solar panels of this device, in order to create brand awareness by their future market.

10.3.4 Short term implementation goals

For the health facilities, the implementation should start in the high endemic areas as they need this device the most. When the product is successfully implemented here, it will be easier to convince the low endemic areas of the advantages. Besides, the results of the high endemic areas can be used to tease extra sponsors.

Parallel to the rural facilities, the researchers can implement this technology. After a (successful) quality check, the device can be implemented in their field trips.

This project only designed the procedures for these two users. For other users, the ideal procedure might be a combination of those two. And it should be evaluated per user which exact procedure suits them the most.

10.3.5 Long term implementation goals

On the long term, the Ghanaian low endemic areas should be approached as well as high endemic facilities of other endemic countries. The final goal is to scale the use to all countries in need, but extended user research is needed to do so.

When researchers have proven the added value of the device in field trips, the WHO can be approached to see if they are willing to implement this new diagnostic method in their (worldwide acknowledged) guidelines. If so, further cooperation with the control programmes can be arranged to make this tool available for both mapping and monitoring activities.

In the end, the CE should ideally become part of the standard routine in every HC or hospital. At the moment, urine examination is done on daily base for some basic patient screening, while schistosomiasis tests are only conducted when the infection is suspected. When the EC makes schistosomiasis tests almost as easy as a dipstick, it can be implemented in the standard routine control. This way, the number of screened patients will rise significantly, which can decrease the number undetected or ignored infections.

11 Recommendations

The EC is designed to fulfil the main requirements, revealed by the Ghanaian research, but not all could be achieved within this project. Based on the final result, as presented in this report, there are already many recommendations for further development. These exact recommendations were summarised at the end of every design related chapter in part 3. This chapter will not repeat them all, but the most important steps will be discussed.

11.1 Technology

When the final technology is further developed, certain product specifications have to be defined:

- Sensitivity
- Specificity
- Production cost
- Operational costs
- Sample time

The initial focus of the technology is to detect the *S. haematobium* ova. Within this project, it became clear that users are interested in more than only the eggs. It should be explored what is feasible with the technology, or what can be achieved by a simple addition to the mechanism. Requested functionalities are:

- Detect whether eggs are viable
  [For research & HCs with post treatment evaluation]
- Examine *S. mansoni* ova and STH in stool, for example by mixing the stool with water. *[For research, control programmes & health facilities]*
- Measure the sample volume that flows through the tube (to calculate the number of eggs per ml urine, which is needed to show the heaviness of the infection). *[For remote health facilities & health volunteers]*
- Detect pus cells, epithelial cells, yeast cells, red blood cells, various types of crystals and cast in urine. *[For health facilities]*

11.2 Test quality

When the technology is working, the quality of the chosen cleaning procedures have to be tested. To see if flushing with water is able to remove all the eggs in the tubes.

Besides, it should be tested if anything can influences the quality. Currently, researchers of the NMIMR document the presence (or unusual amounts) of epithelial cells, pus cells, red blood cells, casts and crystals for every examined sample. It is assumed that this is done to evaluate the diagnostic quality. The eggs can hide behind any of these particles, reducing the sensitivity of the microscopic examination. It should be tested whether the sensitivity of the new technology is also influenced by the presence of any of those particles. If so, the presence should be detected to indicate the sensitivity.

11.3 Price optimisation

Within this project, the main focus was laid upon usability and maintenance, but this lowered the attention to affordability. Optimisation will be required to further improve the product. And of all aspects to optimise, the costs should become a priority. Due to the different opportunities to get financial support (e.g. advertising or selling data), the product will most likely be accessible for all users, despite the price. However, money is important and it should not happen that the implementation fails due to the costs.

Price reduction is not only achieved by optimising the design, the majority of the costs are made by the diagnostic technology inside and it should be evaluated whether these components can become cheaper.

11.4 Improve and validate interaction

The final design has to be tested with the end user to further improve the concept. Especially the remote facilities (as they have not been interviewed yet) have to be involved, to confirm their needs. And to test whether the product is indeed self explanatory.

Furthermore, the interaction with the tablet should be further defined. But there are also some aspects to test. For example, the current design let users do the dipstick before the egg count, but this might be done simultaneously to save a lot of time.

11.5 Scaling

Ghana is used as starting point to narrow the scope. But the main challenge will be to reach all infected areas. As far as Nigeria is explored, some quality checks happened to be the main added criteria. In general, the differences between both countries are only related to the implementation strategy instead of the product itself.

For further scaling to other endemic countries, the specific user groups have to be defined per country to create adjustable implementation strategies.

11.6 Facilitating mapping data

The device is able to improve the mapping activities of control programmes significantly. For example in Ghana, the device can help to relieve at least 4 of the 6 challenges in the control programme: weak monitoring, cross border issues, retirement of skilled staff and a decreasing political commitment.

However, most countries follow the guidelines of the WHO for national mapping activities. And to implement a new technology, the support of the WHO is required. So, the WHO should be contacted to find out what their requirements are to change the guidelines.

And finally, for countries where field trips are not an option, there are other options. When the device is implemented in several remote facilities, the internal SD card collects saves all the results. And as mentioned in chapter 10, this data can serve as a replacement of official mapping data. However, this should be further explored to see which data is needed (think for example about age or sex).

11.7 Conclusion

So, user research, technical development, materialisation and optimisation are all crucial to make the product ready for successful implementation. And the different expertises should be combined in the further development of the product.

Conclusion

"Define a diagnostic purpose for a new, smart, sensitive and affordable technology to diagnose the S. haematobium infection and design a product to facilitate this desired use."

The main goal of the project is achieved by combining research and product design. Extended research was needed define the final purpose and potential users for the new diagnostic technology. A design phase was used to create a product around this technology, to fit the requirements of the selected user.

Purpose and users

With Ghana as a main scope, a user research in Accra identified five potential user group: control programmes, researchers and health facilities in remote (low/high) endemic areas or urban settings.

The following two diagnostic purposes were chosen:

1. Increase the efficiency of large scale communities screening for research projects. The researchers will be able to prove the added value of the new technology to facilitate implementation in worldwide control activities on the long term.
2. Creating access to diagnoses in remote health facilities. These facilities are needed for effective case management and morbidity control.

Product development

With the new technology to increase accuracy and sensitivity as a starting point, a final product was developed to fulfil both purposes: The EC.

In the rural health facilities, the EC enables low educated users to do the diagnoses with a better quality than current specialists do with microscopic examination. It generates its own power and facilitates its own maintenance for a maximum lifespan.

The use is not limited to the laboratories, researchers will take the EC with them on field trips, where the product can execute egg counts for hours in the rain or in bright sunlight.

The final goal will be to further reach the endemic areas of other countries, as lack of specialism is a problem most rural areas encounter. And to assist in the fight against this neglected tropical disease. Besides Ghana, the same device can serve several users in Nigeria. And, when the WHO will support this technology, it can be implemented in worldwide control activities.

This project was able to prove the value of the new diagnostic technology and revealed the opportunities for further scaling to benefit those in need. Further development will be necessary and the project will continue to work towards a complete product, able to implement and help those in need.

Discussion

Other technologies

The egg count is the standard method of the WHO and improving this counting principle would be a great opportunity to improve the worldwide protocols.

However, part 1 revealed that this principle of counting eggs comes with some drawbacks. Due to an inconsistent egg production, false negatives can never be completely eliminated. Furthermore, when infected for years, the eggs might not leave the body anymore, making the egg count not fully reliable. A second fallacy is the incapacity of detection in one of the early stages. Only when the egg production starts, is diagnosis possible.

Fortunately, most infections can be detected with a general egg count and the improved mechanism is supposed to detect even the lightest infections as long as there are eggs in the urine.

And this new egg count technology is able to improve the current situation significantly. However, even this technology is not perfect. For example, the tubes are fragile and one cannot see if the tubes are properly cleaned. Currently, many more promising technologies are being developed and a final validation should be done to see which of these new technology would suit the context the best.

CVD

The CVD sessions was implemented to broaden the scope, already in an early phase. It did not only give extra requirements, it was also a source of inspiration and strengthened the concept.

However, as Ghana already consisted of several different contexts within its own borders (researchers versus health facilities, urban versus rural areas) the design for Ghana did already include some CVD challenges. And in the end, the differences between the users in Ghana was even bigger than the variation between Ghana and Nigeria.

As the final product was able to fit all the different contexts (within Ghana and between Ghana and Nigeria), it could be said that the goal of the CVD approach was achieved.

However, this approach kept the research very broad due to the large amount of users to analyse. As a result, a large part of the project was research based, and less time was left to specify the final product features. On the other side, this broad research created a strong base to make accurate user decisions which were validated with several experts. For other projects in the field of schistosomiasis diagnoses, the same research can be used as a basis for further development.

Completing the user research

But still, one of the main user groups, the remote health facilities, are not interviewed personally and the information about them is based upon the stories of others who have been there. To complete the overview of all users, and especially since the final product will be made for those remote areas, it is of great importance to visit them too to validate the assumptions.

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Appendices

Part 1
A. Research questions
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Part 2
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F. Result form stool analysis
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Part 3
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N. Interaction journey research field trips
O. Attachment power cable
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R. CVD session

Appendix A. Research questions

Research Question 1. What is the current situation?

Sub question 1.1 What is the impact of the parasite?
Sub question 1.2 What can be done to reduce the impact?
Sub question 1.3 What is already happening to reduce the impact?

Research Question 2. What are the technical requirements for a new diagnostic device to improve the current situation?

Sub question 2.1 What technologies are currently available?
Sub question 2.2 How do the current technologies excel?
Sub question 2.3 What can be improved compared to the current methods?

Research Question 3. Who is the foreseen end user?
Sub question 2.1 Who are already doing diagnoses?
Sub question 2.2 Who are in need of an improved diagnostic technology?
Sub question 2.3 Which user would benefit the most?

Research Question 4. What are the functional requirements for the new product in order to fulfil the needs of the end user(s)?

Sub question 4.1 Which functions are required by this user?
Sub question 4.2 Which functions are desired by this user?
Sub question 4.3 Which functions are feasible to implement?

Research Question 5. What product interaction matches the habits, skills and desires of the end user(s)?

Sub question 5.1 What are the current habits of the final users?
Sub question 5.2 What are the skills of the final user?
Sub question 5.3 What are the users desires for future interaction?
Sub question 5.4 What interaction matches these skills and habits?

Research Question 6. What product features and qualities does the design has to fulfil?

Sub question 6.1 What environment influences does the product has to withstand?
Sub question 6.2 What does the user interpret as user friendly?
Sub question 6.3 What does the user interpret as user professional?
Sub question 6.4 What does the user interpret as user easy?
Sub question 6.5 What does the user interpret as user beautiful?

Research Question 7. What are the key requirements for successful implementation?

Sub question 7.1 Who is in charge of the implementation?
Sub question 7.2 What are the implementation requirements on the short term?
Sub question 7.3 What are the implementation desires on the long term?
Sub question .4 What is required to scale towards other endemic countries?

Appendix B. *S. haematobium* diagnoses

What to examine?	Infection indicator	Used method(s)	Suitable for community screening in endemic areas	
Urine	*Counting eggs*	*Microscopy examination* (by the use of (centrifuged) sedimentation or filtration)	YES	The 'Golden Standard' for Schistosomiasis diagnosis
	Egg viability (as an addition on the eggs count to do a post treatment evaluation)	*Observation with the eye* (of hatching eggs in water) or *microscopic examination*	NO	Used for post treatment to determine whether a cure was succesful
	Gross or *microhaematuria*	*Observation with the eye* (morbidity questionnaires) or *microscopic examination*	YES	Haematuria is the main symptom of S.Haematobium and usually present when infected
	Detection of - *angtigen* - *DNA* - *proteinuria* - *leukocyturia* - *other related urinary infections*	*Chemical reagent strip* or *PCR*	YES	Simple method
Blood	Detect *antibodies*	*Chemical reagent strip*	NO	Antibodies remain after an infection is cured
	Detect *antigens*	*Chemical reagent strip*	YES	Antigen detect only active infections
Tissue from the: - liver - bladder - vagina - cervix - skin	Detect *ova stuck in tissue*	*(Surgerical) biopsy*	NO	Used for individual clinical diagnosis
Imaging studies of the: - urinary system - genital area - kidneys - liver - lungs - heart - spinal cord - cerebrum	Visualise *damage and/or irregularities*	*Radiography* or *Ultrasonography*	NO YES	Used for individual clinical diagnosis Used for both, individual and communal level

Source: [3] [11] [12] [24] [35] [54]

Appendix C. Extended information community screening methods

Urine sample: Haematuria questionnaire, dipstick or microscopic examination

Haematuria (blood in the urine) is a main symptom in *S. haematobium* infections [24] and therefor an accurate indicator. In cases of gross haematuria, the blood is visible with the eye (figure 7). The WHO uses morbidity questionnaires in which they ask school children for visible haematuria as a quick and cheap mapping method, but this is definitely not the most reliable technique [11]. More reliable are dipsticks or microscopic examination to identify micro haematuria. The only disadvantage is the inability to distinguish the urinary Schistosomiasis from other infections as a cause of blood.

Urine sample: PCR

Polymerase Chain Reaction (PCR) is a sensitive and specific method to identify the parasites DNA in urine samples (figure 8) [7]. In some cases of (light) infected individuals, urine sample might contain barely any eggs, often resulting in false negative results during microscopic egg counts. But even without eggs, the parasites DNA might still be present in the samples enabling the PCR to detect light infections with a 85,2 % sensitivity (and 100% in heavy infected cases) [7]. Though, maybe due to many accurate alternatives, PCRs are nowadays less used as before [5].

Urine and blood sample: Antigen

Antigen are sometimes confused with antibodies. Antibodies appear when infected but they will stay in your body even if the infection is cured; it cannot differentiate active and cured infections [3]. Antigen are only present during active infections and happen to be an affective indicator found in both blood and urine samples. Urine samples are easy to collect and more sensitive for light infections than the blood diagnosis, but blood examination is more specific [35].

A simple tool, comparable with a pregnancy test (figure 9) is used to detect circulating antigen, which is "*roughly correlated with the intensity of infection, suggesting that antigen detection may be a useful means of identifying and quantifying active infection*" [41].

Unfortunate, the antigen method is only genus specific instead of species specific [54] and cannot specify the different Schistosoma parasites. So it is not able to see the difference between for example S. haematobium and *S. mansoni* and therefore less useful in areas with several active parasites. But there is still research going on to further improve the circulating antigen detection and increasing sensitivity and specificity [20].

Urine sample: Reagent strip / dipstick

Besides blood, DNA, antigen or eggs the urine can also reveal high levels of protein, a common symptom of urinary Schistosomiasis. Other parameters to detect are leukocyturia, unusual PH or signs of related infections which can be correlated to a *S. haematobium* infection. These dipsticks are easy to use and provide fast results.

As shown in figure 10, a dipstick can perform different measurements at the same time. When the urine contains haematuria and high protein levels while living in endemic areas, an *S. haematobium* infection is most likely the cause [49].

The use of reagent strips is mainly related to the detection of haematobium and is a rapid tool, useful for control programs. But sensitivity and specificity can vary per study [72].

Ultrasonography

Ultrasonography (figure 11) has been used to screen the community morbidity and determine the efficacy of given treatment [59]. The technology is able to screen the bladder wall on irregularities or unusual thickening and identifies enlarged parts of the kidneys or the presence of urine inside the kidneys (hydronephrosis) [25]. These images are used as part of health education to show the possible health impact [25].

The technology is able to expose organ or tissue damage, caused by the infection but it cannot detect an infection before any visible damage is done and it will lack in the detection of early stage infections.

Appendix D. Field trip summary

This appendix will discuss the activities and findings of the field research in Ghana. Starting with an overview of the kind of people who were interviewed. Followed by a discussion of the activities and findings for each of the three weeks in the field. This is only a summary as there is too much done to write down.

Participants in the interviews

The research in Ghana consisted of interviews with people from different backgrounds and the different potential user groups: the manager from the NTDP, several people in four research institutions, a number of doctors and technicians in 3 urban hospitals and even two who came from the Northern region themselves, which is the poorest and most remote area of Ghana. The following number of people were interviewed per sector:

1. Neglected Tropical Disease Programme (NTDP): Programme manager

2. Research institutions

			Noguchi Memorial Institute of Medical Research	Council for Scientific and Industrial Research (CSIR)	National Public Health and Reference Laboratory	Centre for Plant Medicine Research
Work(ed) together with the NTDP	Experienced in schistosomiasis diagnosis	Organisation	2	1	1	-
		(Research) technician	5	-	-	1
		Student researcher / technician	3	-	-	-

3. Urban hospitals

	Ridge Hospital (regional hospital of the region Greater Accra)	37 Military Hospital	Legon Teaching Hospital
Doctor	1	1	1
Head of the hospital laboratory	1	1	1
Lab technician	1		1

4. Northern Region

Two people were interviewed who came from the Northern region themselves. One of them was a doctor who was involved in several development projects

Activities week 1

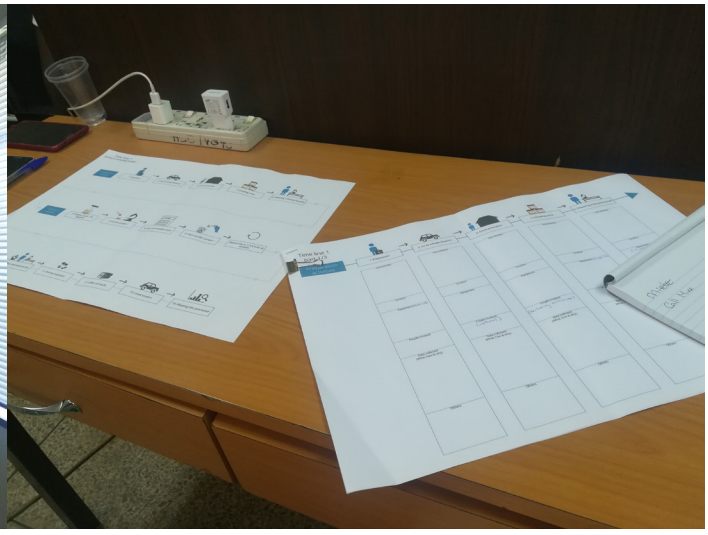
Monday

My first week started at Noguchi Memorial Institute for Medical Research and the CSIR water research institute where I got introduced to many people and got a tour through the different research departments. I met for example Mike, who would help me to arrange contacts, and on Monday we already scheduled the meetings for the first week.

Furthermore I directly got the chance to interview Irene, who has many years of experience with Schistosomiasis, for research purposes but she is also involved in the trainings given to the staff of the Ghana Health Service (GHS).

Tuesday

On Tuesday I got introduced to a first professor, who himself was more involved with STH and is currently working on research around treatment failure, which according to him is often related to the need for multiple dose treatment instead of only one dose. Afterwards he introduced me to one of the expert on snail research. He was neither involved in the control programme but told me something more about the snail research they have been doing. Lastly I got introduced to a research assistant who is working as a technician too, Linda, who I would interview later in the week.



Wednesday

This day started directly with an interview of Josseph, a technician who already worked at Noguchi for 26 years and has been in the field many times. He took the time to explain the whole procedure and gave his opinion about the different user scenarios.

Afterwards I went to the CSIR to be introduced to Dr. Marfo, the manager of the Neglected Tropical Disease Programme (NTDP) and a next meeting was scheduled to interview him. To close the day, I got to interview Mike, the head of department of Environmental Biology and Health at the CSIR who was involved in diagnoses more on the organisational level.

Thursday

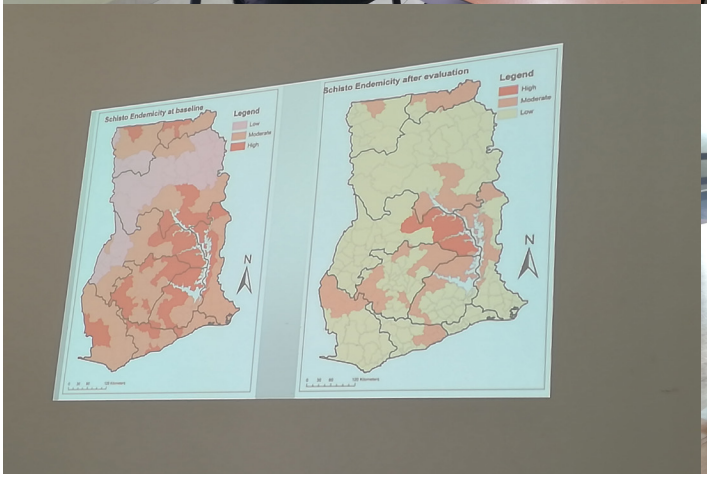
Thursday I met a second Joseph who was another technician with again 26 years of experience. He did not only allowed to interview him for more than an hour, he also showed me the lab they work in and the tools they use. Next week he will demonstrate the diagnoses procedure to me.

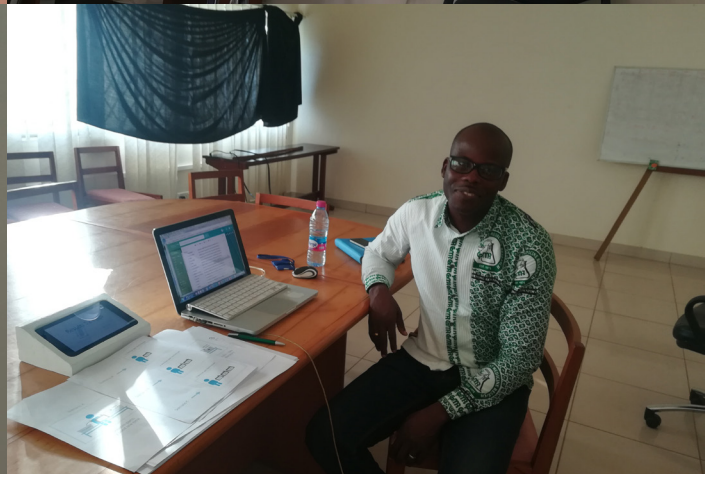
Thereafter, I could interview Linda, who does work as a technician. And finally I got introduced to Daniel, a researcher with many experience in the diagnoses for Schisto, currently working at the Centre for Plants and Research. We arranged an interview for Friday and he will introduce me to the director of Noguchi. All of them were really enthusiastic about the prototype and the function it should fulfil.

Friday

On the last day of the week I had a meeting with Dr. Marfo, the NTDP manager, located in the same building as the Malaria control programme. Instead of just an interview, he offered me a whole presentation about all the activities of the neglected tropical disease programme in Ghana and I was able to ask all my questions in a 2,5 hour session. In the end he also introduced me to another technician and expert on Schisto, who works for the Ghana Health Service. We discussed the device and he gave feedback on their main criteria for new devices.

In the afternoon I went to Noguchi to interview Daniel. He was a very smart guy who could really think with me on more practical issues like the different functionalities for different target groups and shared some of his research with me too.





Findings week 1

Procedure

When going to the field, the community leaders are approached and when they give permission, the session starts with health education. This makes sure people know what Schisto is, why to participate and what to expect and do. There used to be little awareness, even near Accra, but nowadays people are aware and mostly willing to cooperate.
They always try to do the diagnoses in the field instead of a laboratory to test the samples as fast as possible. Especially for the stool examination, since the hookworm will fade out over time. After the stool is tested, they diagnose the urine. Currently, the lab in the field is quite comparable to the normal laboratories, since they take all things they need with them. Think of cool boxes with ice (which can keep the samples good for several days), foldable tables and cleaning chemicals.

The main differences are:

- Electricity, which is not always available. Field microscopes are used with mirrors to catch the light or solar powered lights.
- Sometimes it is in open air. But even when it is insight the temperature might become very high (temperatures above 40 degrees are common).
- Within the car, things can easily break due to the bad roads. It must be robust enough and glass parts should be avoided.
- It is a dusty environment
- Samples or other infectious materials might easily be spilled on the device.

The NTDP approach in Ghana is as follows:

Step 1: Mapping
Step 2: Yearly MDA (Mass drug administration)

- Reporting drug coverage after each MDA
- Assessment of sentinel spots (some endemic areas with high transmission are sometimes diagnosed before and after the MDA, to see the progress. But different people give different information about whether this is yearly done for Schisto or not)
- Transmission Assesment Survey (TAS) after the sixth MDA to determine if level of infection has been reduced to a point where transmission is no longer sustainable. If so, continue to step 3.

Step 3: Surveillance is used to monitor infection levels for 5 years after the MDA has stopped
Step 4: Verification of the data to check on correct evidence that the transmission is absent, by the WHO

In the case of Schisto, mapping for the control programme has only taken place twice: 2008 and 2015. It is not clear when (or if) a next national mapping will take place. Schisto is currently in step 2 of the approach, ideally a disease should be under control after around 6 years (to go to step 3) but Schisto is difficult since so many factors are involved. Therefore it might take many many more years and they are unfortunate not close at all to elimination yet. In theory step 2 (mass drug administration) would include yearly screening of a few endemic areas. But different people told me different stories about this, so I have to further verify the data. But diagnoses for the control programme will be done at max once a year for the control programme.

The research department does not have enough people to do the mapping themselves, but they often cooperate in field trips The research institute is training the staff of the GHS to make sure they can fulfil the tasks of the control programme. Besides, once or several times a year the research department is organising field trips to endemic areas to diagnose for research purposes. In these cases, they often also give treatment.

Possible users

Basically there are 3 target groups who do diagnosis (as discussed already in The Netherlands). But I have received some more insights in the basic differences:

1. Control programmes

At max once a year they diagnose a few endemic areas to see the progress of the MDA. For these sessions it is solely important to know who is positive and negative, the number of eggs might be used as some extra knowledge but are in general not needed.

A country wide mapping phase (of all areas instead of only some “hotspot areas”) is in general only done once per neglected disease, by Schisto it was done twice but it is not clear whether this will happen again for Schisto.

2. Research projects
One or a few times a year, only in endemic areas. But for these projects egg count itself is not enough, it is always combined with a dipstick, testing on proteinuria, haematuria, PH, etcetera.

3. Hospitals and health centres
Especially in endemic areas, there are many patients who need to be tested on schisto. They often need to know more than just the number of eggs and dipsticks are common. Besides, the results need to be printed directly, so an easy connection with a printer or direct printing from the device is needed.

In general the usage of the three target groups are comparable and one device might serve all. But for research and health facilities there is more data needed than the egg count.

Implementation of the future device
For implementation in general, the most important criteria are costs and performance. It should be more sensitive and specific than the currently used standard (filtration and microscopic egg count). Each question asked about the device is answered based on the cheapest option which still provides quality. Besides it should be much faster than the current procedure. A major cost of the field trips are the teams being in the field for several days to finish all the work. When the procedure is reduced in time, much money will be saved on accommodation and men hours.

When using the device, there is no need to check the pictures of the results. The technicians mention to trust a device if it has completed a quality control before implementation.

The control programme is advised by the research institute for the choice of equipment. Before implementation in the actual control programmes, it will be used for research diagnoses (and field trips). If the researchers are enthusiastic, it can be implemented in the diagnoses sessions of the national programme. But an extra criteria for the NTDP specifically is the use on mass scale. So it is important to know how many samples can be diagnosed in what time.
So for implementing in control programmes, it should first be tested on performance. If better than egg count, it will first be implemented by the research department. If they are convinced it works good enough, and it will be able to be used on large scale, then it will be introduced by the control programmes. So maybe the control programmes itself can be an end goal, but researchers will use them too.

Product specific issues
It must be robust enough, dust free and easy to clean if infectious samples are spilled on the device. This might include a protective cover with no ledges or ribs and easy to clean.

It must be portable, small with maybe a handle to hold.

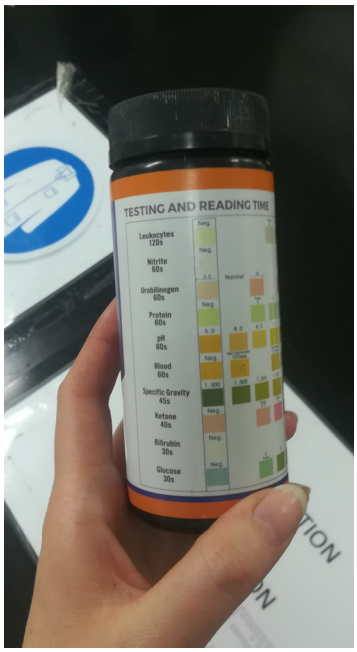
Currently they use both, disposable parts/products and those which can be cleaned and re-used. Cleaning can often be done on location as long as it does not require specific machines to clean. And some technicians rather had cleaning because they do that with most materials. But others prefer disposable since cleaning might not always be done properly. But both cleaning and disposable is an option, as long as it is the cheapest choice. So costs is the main criteria again.

For the data, there are no standard formats for the diagnoses, since it depends per project purpose and each institution uses its own system. Digital data is a great advantage, but a data backup is more trusted then digital data. So it should either be printed or written down to fit their current administration.

All technicians ask for the volume that it can process. I assumed it will be 10 Ml like the standard, but maybe even higher volumes could be tested to increase sensitivity in light infections.

Added value
- This device will reduced the number of people needed in the field and thereby save cost
- It will save process time, to make sure the time in the field could be reduced what again saves costs.
- It will give a same quality for all regions, independent of the technician who uses this
- It requires less training

Shortcomings
Some people are only infected with female or male worms. They will suffer from anaemia but no eggs can be detected. In this case the protein in the blood must show the presence.



Adults who are suffering from the chronic infections for years have a higher chance on dying from severe symptoms. But in these cases the eggs stay stuck in the tissue and are not found (or barely found) in the urine. And even the bloody urine is not always the case after so much time. Only children or those who are recently re-infected will definitely have eggs in the urine when infected.

So in those situations egg count itself is not enough. Besides, when the device is used by researchers the samples need to be tested on all dipstick values (see picture on the right).

And finally, the *S. mansoni* detection takes more time than *S. haematobium* detection. If you really want to reduce work, a future device would do the stool examination too.

Activities week 2

After week 1, I had already spoken to all available technicians as far as my contacts could provide. Nevertheless there were still some activities to do. I wanted to visit the director of the research institute, do some creative sessions, ask some more questions about the current procedure to fill some leftover knowledge gaps and verify the findings of the first week.

Besides, after week 1 I realised it might be useful to compare the three possible user groups (1=control programmes; 2=research; 3=health facilities) to see whether one device would suit all needs or in what matter they would differ. I already spoke to those of the control programmes and research department, so my next mission would be to get into contact with health facilities.

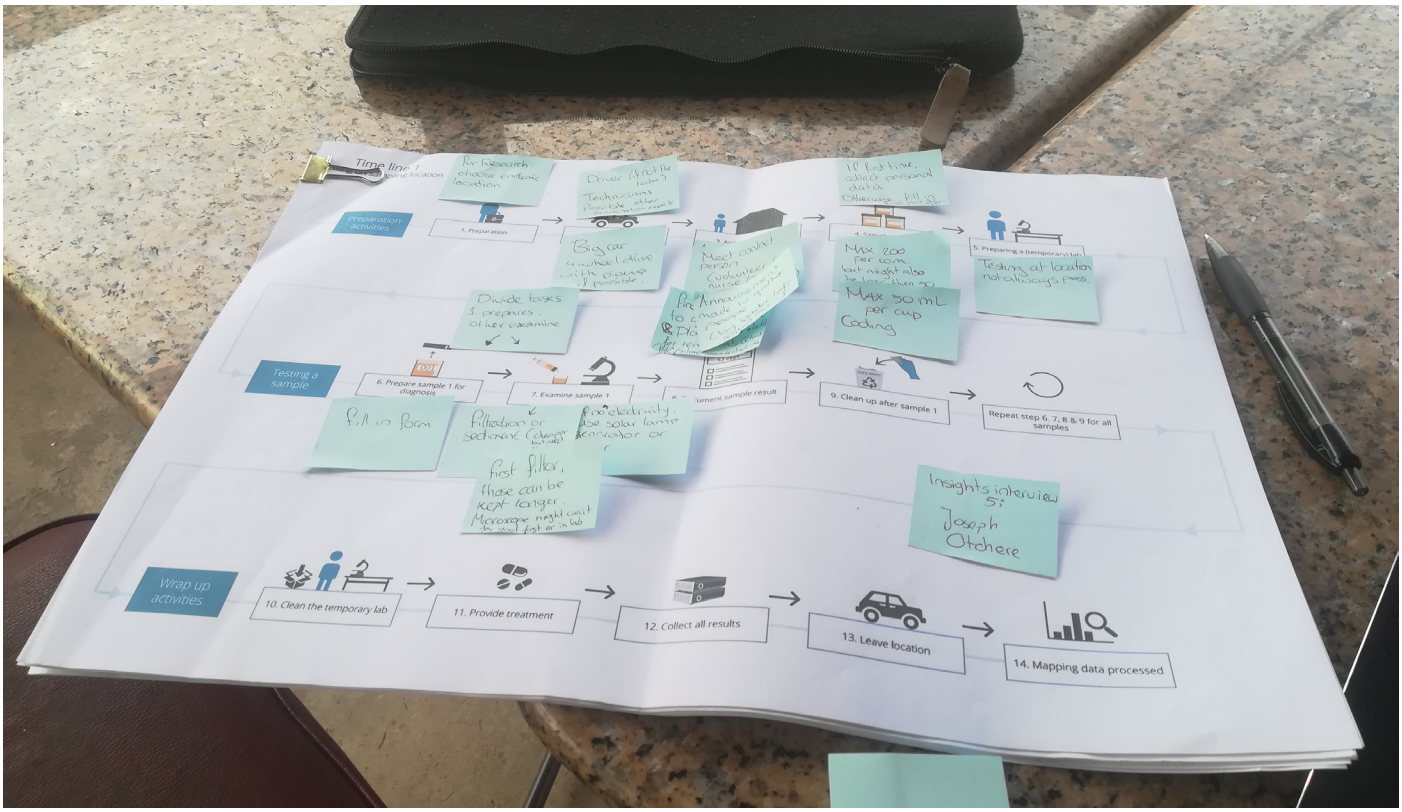
Monday

This day I would initially have a meeting with the director of Noguchi. Unfortunate, when I arrived he did not have time and I could only shortly introduce myself. And a new meeting had to be scheduled later in the week. And another appointment, to see the diagnoses in the lab, was unfortunately cancelled too.

But it gave me the opportunity to contact the different managers and professors to see whether they could bring me in contact with any hospital or health facility in Accra.

Tuesday

This was Labour day, a national holiday, so this meant no interviewing. But it gave me some time to process last week's data,



Wednesday
This day I finally got the chance to have some more creative interviews with two researching students to evaluate different medical devices and rate the designs on professionalism, ease of use, modern looks and aesthetics. Thereafter I got a second interview with Irene, who I already spoke to in the first week. In that week many people told me different things and sometimes contradicting stories about who is diagnosing and when. She could clarify this further and also verify the information I received from the NTDP manager, since she had been involved in the trainings given to the NTDP technicians.

The meeting from Monday with the director of Noguchi, was postponed to this day. And he was directly very enthusiastic about the new device. He gave me more insights about the added value of such technology as well as some practical tips based on all his years of experience with *S. haematobium*.

Thereafter, I heard an appointment was made for me on Friday at the 37 military hospital, one of the biggest hospitals in Ghana.

Friday
At the 37 hospital, I first spoke to a doctor who had also been working in the Volta Regional Hospital, which is located in an area with much more Schisto cases. Thereafter, he introduced me to the one of the lab technicians of the hospital who showed me their current equipment and machines.

Findings week 2

Researchers and the control programme
Diagnosing the whole nation (National mapping phase) is completed in 2008 and 2015. And a next nationwide screening is not expected to take place until the mass drug administration (MDA) is getting the Schisto under control. The main focus of the Neglected tropical disease programme (NTDP) is to provide MDA to all endemic area on yearly basis.

According to the protocol of the NTDP, a few "hotspot" areas have to be screened before and after each MDA to see any progress of the treatment. But until 2 or 3 years ago this was not done for Schisto (due to the costs). In 2015, this changed and the NTDP asked technicians and (micro) biologists from all areas in Ghana to come together. They work for the Ghana Health Service (GHS) and within their local health facilities, they mainly use simple and fast diagnostic methods to analyse urine and stool, just to see whether somebody is negative or positive in order to provide drugs. But the NTDP asked the researchers of Noguchi to train the GHS technicians how to do quantitative diagnoses (the use of filtration and microscopic egg count). From that year on, a selected group of communities is supposed to be screened each year before the MDA by the GHS technicians, but sometimes with the help of the researchers. Last year(s) the Noguchi researchers are asked for some technical support in the field. Dr. Ayi expect the annual Pre MDA diagnoses to continue and Noguchi is most likely to stay involved when needed.

Health education
After the first nationwide deworming mass medication, it was chaos. Due to the side effects of the drugs, parents panicked when the children got nauseous or sleepy. And there was much confusion and unwillingness to cooperate. Afterwards Noguchi did a survey under communities to find out

Health facilities
So far, I only spoke to the biggest hospital in Accra, the 37 Military Hospital. Who actually have so little cases to diagnose (since this happens at the lower levels of the health system) that they seem to have no struggle in diagnosing them by hand. Besides, they only need to see IF there are eggs and not the intensity, so a very quick microscopic look at a centrifuged sample is enough.

However, the smaller health facilities and especially in endemic areas near water bodies, have much more cases and might benefit more from such a device.

Three user groups of Schisto diagnoses
The following table summarises the main similarities and differences (as found so far) between the three main users of Schisto diagnoses: control programmes, researchers and health facilities.

	Control Programme	**Research**	**Health facilities**
By who?	Diagnoses done by GHS, sometimes with technical support of researchers	The main research institute in Ghana is the Noguchi memorial institute of Medical Research in Accra. But working together with NTDP when needed.	National, regional or district level health facilities
Frequency	Yearly screening of a few endemic areas, prior to MDA Depending on funding. When the budget decreases, diagnoses might be stopped.	Frequency of field trips depend on the project	*Big hospitals:* Barely any cases to diagnose. The diagnoses are often done in smaller facilities, and only severe cases are referred to the hospital to give special care *Smaller hospitals/health facilities* The frequency of diagnoses depend on the prevalence of Schisto in the area

Location	Each year the same area (and people) are tested	Always visit endemic areas. Chosen communities can differ per project, as well as the amount of data collected per sampled patient.	In health facility
Used methods	Counting eggs via filtration No dipsticks are used (to cut down costs)	Always use egg count Always use dipsticks	Diagnoses done with urine analysing machine or via centrifugation and microscopic examination
Disposed or reused?	Both is possible, depending on costs and availability	Both is possible, depending on costs and availability	Big hospital: All are disinfected and reused Smaller facilities: ?
Documented results	Positive or negative & identify intensity	Positive or negative & identify intensity Dipstick results to detect haematuria and/or protein levels, which might indicate an infection, even when no eggs are found Document possible crystals found in the urine as well as the urine colour	Only interested to indicate: negative or positive. Not the intensity Completeness of reported data differs per facility, think of categorisation of data (like pregnant women and per age group)
Data collection digital or on paper?	Data is collected on paper and afterwards processed digitally	Data is collected on paper and afterwards processed digitally	Big hospital: All data directly digitally collected in a standard computer system Smaller facilities: ?
Data processing	Data is processed by the GHS	Data is processed by researchers	Have to report data to ministry: The number of cases per week/month or year

What about other countries?

Next to the different users within one country, more Important might even be the international differences between all countries who need this. Both, the director of the Noguchi research institute as well as the manager of the NTDP do not expect many differences between the other countries. They expect the need for such diagnoses to be the same in all endemic (African) countries even though some organisational aspects might differ.

The device

- Should not only identify the *S. haematobium* eggs, but also the *S. Mansoni* eggs and whether the eggs are not dead.
- Bloody urine and possible crystals in the urine (which might appear over time, for example when the samples are not directly examined). These parameters should not influence the sensitivity of the device.
- Currently, glass parts are cleaned and reused. While plastic parts are disposed after use. When choosing between disposable and recycling, choose the cheapest option.
- If disposable and hundreds of spare parts are taken into the field, the funnels should fit easily into each other or be stored at minimum size (to save storage space in the car).
- The material use of tubes and funnels should be chosen carefully. With some materials, relatively more eggs stick on wall of the tube, when the fluid passes through.

Design preferences (only based on 2 interviews so far, to be further extended)

- Keep the device small, portable, wireless and digital
- Use of natural colours and pastel colours.
- Make the work of the researcher easier and faster
- To make it easier to use: not too much keys and options
- Make sure the product will not be easily contaminated
- A device is rated as professional, if people are not able to use it at home, and any training is required and if the data is only understood by professionals.

Activities week 3

Activities week 3
Since I already talked to all the available technicians, my third and final week of my field research was focussed on the exploration of the needs and requirements in a hospital setting and or health centres. As this was not organised before I travelled to Ghana, this was a bit of a challenge and I had to use all different contacts to see what could be arranged. I already visited one of the largest hospitals in Accra in week 2, the 37 Military Hospital. But since we need more than one opinion to be critical about the collected data, I wanted to visit some more.

Monday
Another well known hospital is the Legon University hospital. Due to its connections with the University of Ghana, one of the professors (professor Wilson) offered me to write a recommendation letter to arrange a meeting with one of the doctors. I went by his office on Monday morning and directly went to the hospital afterwards. Once arrived at the Legon hospital, this doctor happened to be in a meeting and it was not possible to meet today. They promised to call me back whenever there was time.

Tuesday
Via a friend, I got the number of a doctor who worked in the Regional hospital of the Greater Accra region, also referred to as Ridge hospital. This Tuesday I met him to introduce myself and my project and he would help me to arrange a meeting with the head of the technician department. Since this person was not available, the appointment was postponed to Wednesday.
He is a young doctor, born and raised in the Northern Region of Ghana, one of the poorer and more remote areas. He had been studying Public health, with a focus on development and visited about 18 remote communities for several projects in the past 8 years. He was able to tell me about the big differences between these villages and the bigger cities, some main challenges when working in these areas and some of the progress made in the past 10 years in for example health education and accessible technologies.

Wednesday
Today I could meet the head of technicians in the Ridge hospital. This hospital had a new building and since only 8 months, everything was done digitally and the lab looked very professional. Even though they did not have many cases of Schisto in their hospital, he asked another technician to join who had more experience in other regions with more cases. But all were very certain such a device would increase the performance of diagnoses and especially with a low number of infections, sensitivity becomes even more important.

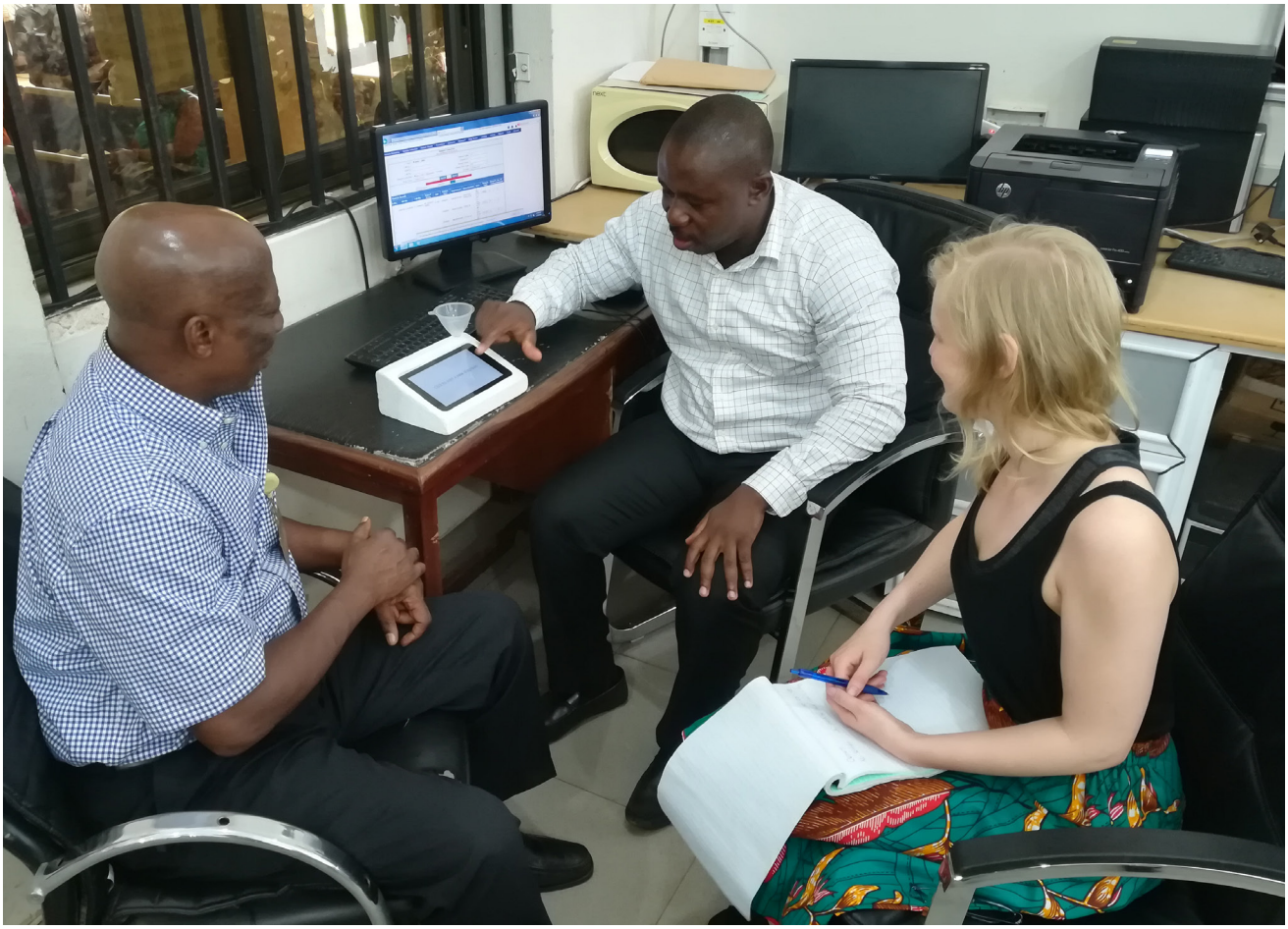
Meeting at Ridge hospital: From left to right: Doctor, Me, Head of the lab, other technician

Thursday

Since the Legon hospital did not contacted me yet, Professor Wilson offered to come with me to personally introduce me to the head of the lab. Besides the fact that he was extremely busy, he took the time to answer my questions and was very interested in the further development of the device. He was well informed about the organisational structures and what is needed before a hospital buys a new device.

Since urine is diagnosed on more than Schisto, he introduced me to one of the technicians of the biomedical lab where they do all urine testing. And I could interview him as well to determine what requirements they would have for the device.

Friday



Professor Wilson from Noguchi (left) and head of the lab in the University hospital

Centrifuge

Microbiology lab

Technician of the microbiology lab

As Friday was already my final day, I send it to pack my bag, enjoy the warm weather for the last time and say goodbye to all those who made my stay a very great experience!

Findings week 3

This week's findings are organised per interview/visit. But there are definitely many similarities between the different hospitals. And one thing is very clear: the MDA and health education is working and the number of schisto cases is declining according to the city hospitals. All refer to the endemic areas near the water bodies, where this device would definitely be of added value due to the higher number of cases to diagnose. But even when a hospital has a low number of cases, they all mentioned that the device would offer a much more sensitive method enabling the light infections to be detected. And since less heavy infections are found, it probably means that the number of light infections could be raising. Furthermore I discussed what their current methods are, but also what functions the device should have to make it also useful in the city hospitals.

My intention of this third week was to discover the needs of some other users of schistosomiasis diagnoses, so we can make a fair comparison and see whether we make one device suiting all user scenario's (research, control programmes and health facilities) or that we choose one target group to focus on. Besides, I spoke some people from the Northern region, which offers a total different context than the big city hospitals.

Northern region

- Northern Region is one of the poorest regions
- Awareness is increasing each year, but not all are aware of the actual damage caused by the parasite
- When designing for the remote communities, you should use locally available recourses. To enable maintenance when something breaks down. Because "you can give them a screwdriver, but if it breaks they will not be able to replace it." (Dr. Damba, 2018)
- Some villages will not have electricity, then phones are charged on the market place.

Regional hospital Accra: The Ridge hospital

Diagnoses:

- Diagnoses take place when a patient has found blood in the urine
- A diagnosis includes the following steps:
    - Let the patient jump a few times
    - Collect urine sample
    - Spin the sample
    - Microscopic examination to see whether *S. haematobium* are present
- No viability test, no filtering nor quantitative data collected in the hospital
- Since 8 months a new digital system in the hospital, all devices are connected with each other
- Barely any schisto cases, only 1 or 2 cases last year! The number of cases are dropping since the annual MDA
- Daily urine examinations are done, but they are not checked on schisto, but on other crystals, blood cells or worms. Hereby dipsticks are used for health measurements

Feedback on the device

- This device would provide the sensitivity to detect light infections. Especially when the number of cases is dropping like nowadays, the light infections are getting more important to find.
- Device would provide objective measurements, independent from the technician's eye
- Digital data makes the device valuable
- For a hospital context were the prevalence is very low, it would be of added value if the device could screen the urine on more than just Schistosomiasis. For example on crystals or other worms.

University hospital Accra: Legon Hospital

Insights from interviewing the lab manager

- Barely any cases. It used to be 2 or 3 cases a day, but now it is almost none. Children used to swim in lakes near the city, but this does not happen anymore (health education is increasing)
- They use the same diagnostic method as the 37 Military hospital and the Ridge hospital. But they try to quantify the results by counting the eggs in the centrifuged samples via the microscope. Based on the number of eggs, the result is notated as "-", "+", "++" or "+++"
- In case no eggs are found, the test will be repeated to double check the result. But only when the patient is a male.
- The used centrifuge might vary in size per health facility, depending on the frequency of *S. haematobium* cases.

If no centrifuge is available, they let it stand for a while.
- A supplier is chosen on price, quality and provided service.
- Machines often break, in small villages this might take a week to be replaced are maintained.
- Hospital technicians can be asked to participate in control programmes
- All Schistosomiasis cases used to be referred to the Korle Bu teaching hospital in Accra. Even if they already tested the sample, than the patient is still referred to Korle Bu for confirmation. So Korle Bu will have the highest number of Schisto cases of Accra to test.
- Nowadays, more and more HCs are having suitable diagnostic equipment (microscopes and centrifuges) to do the schisto diagnoses themselves, so references to larger hospitals becomes less necessary.

Added value of the device:
- Recently a new device for malaria diagnoses is introduced to the Legon hospital, which makes it possible to replace the +, ++ and +++ for an exact and specific result. This is valued a lot since the technology is more accurate and reliable than a technicians eye and microscopy.
- Digitalised data is seen as a great advantage.
- Important to keep necessary maintenance low and provide easy replaceable parts.

Insights from interviewing one of the technicians in the microbiology lab, specialised on urine samples
- Schisto is not common anymore, but the microbiology lab of the University hospital in Accra tests urine on daily base. Using dipsticks and thereafter microscopy. Microscopy is used to detect:
  - Pus cells
  - Epithelia cells
  - Red blood cells
  - Crystals
  - Cast
  - Yeast cells
- If testing on schisto via the new device, you still have to test the sample under the microscope for the other cells and crystals as listed above. It would be of great added value for the Legon hospital if the device could also detect those cells and crystals, but they are much smaller and more difficult to detect. If only testing on Schisto, it would not be used often.
- The whole testing procedure is done in 10 – 15 minutes (spinning the urine only takes 1 minute)
- If the device only tests on Schisto, the sample should be divided in two parts: one part for the schisto device, the other for the microscopic analysis for other parameters. Or it should be possible to reuse the sample after the device is finished with the egg count.
- Data is documented on paper in self drawn tables, afterwards all is documented in the computer.
- If only schisto, the advantage will be in the accuracy. But microscopy has to take place for other parameters, so the device will not safe time, but only add extra steps. In hosptials with many schisto cases, it might still be interesting.
- But all see the urgent of such technology, especially in the more endemic regions. There is only one concern: "I really like this new device, but I hope it does not take 50 years for Africa to get it" (Saviour Atsika, 2018)

Dr. Mike Osei
The head of the department of Environmental Biology and Health at the Council for Scientific and Industrial Research (CSIR)

When saying goodbye to Dr. Mike, he requested me to ask the "Dutch engineers" to look at the possibilities of *S. mansoni* diagnoses (stool examination). And whether stool diagnoses could be considered as well with this device. Since stool examinations are more time consuming than the urine tests and therefor also more expensive. Moreover, stool and urine tests are always combined in Ghana.

According to him, only 0.41 gram of stool is analysed with current diagnostical methods. When mixing this small amount with water, he believes a similar technology might be used to detect the eggs in the dissolved stool. And otherwise, he hopes the stool detection could be a next challenge after this device, because his interest is very high.

Professor Wilson
From the Noguchi research institute

There are NGOs active, but mainly involved in MDA, not in diagnoses
Besides, he told me to " stay in contact for further evaluation of the technology. We would love to test it in the field and compare to current methods." So if any opportunity is there, they love to be involved in a next steps to make sure the technology can be tested in the field.

Appendix E. Research result form urine analysis

UNIVERSITY OF GHANA	NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH			
	DEPARTMENT OF PARASITOLOGY			
	Document Name	URINE EXAMINATION REPORT FORM		
	Document Number:	PAR065FRM	**Version Number**	V1

PATH. NO.....

Name..... Age..... Sex.....

Hospital..... Med. Officer.....

Date of sample collection ...../...../..... Date Examined...../...../.....

MACROSCOPIC EXAMINATION

Appearance .....

Colour .....

CHEMICAL EXAMINATION

Glucose ..... Ketones .....

Bilirubin ..... SG .....

Blood ..... pH .....

Protein..... Urobilinogen .....

Nitrite ..... Leukocyte .....

DEPOSIT

Epithelial Cells ..... Pus cells .....

RBCs ..... Casts .....

Crystals ..... Others.....

Technologist

Date ...../...../.....

Head of Department

Date ...../...../.....

Appendix F. Research result form stool analysis

UNIVERSITY OF GHANA	NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH			
	DEPARTMENT OF PARASITOLOGY			
	Document Name	STOOL EXAMINATION REPORT FORM		
	Document Number:	PAR064FRM	**Version Number**	V1

PATH. NO.....

Name..... Age..... Sex.....

Hospital..... Med. Officer.....

Date of sample collection..... Date examined .....

MACROSCOPIC EXAMINATION:

Colour.....

Consistency.....

Presence of blood.....

Segments of worm.....

MICROSCOPY

Vegetative forms of protozoa.....

Cystic forms of protozoa.....

Ova of worms.....

Blood cells.....

CONCENTRATION

Ova.....

Cysts.....

Technologist

Head of Department

Date ...../...../..... ...../...../.....

Appendix G. Product quality sessions

Part 1

In two interviews, the interviewees were asked to rate several medical devices (i.e. ECG machines, patient monitors and pulse oximeters as shown below) to discuss which would be most preferred and which design they liked best. The results are shown on the following 2 pages.

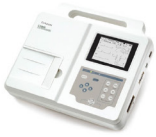
ECG machines
(Sources: ECG machine 1 – 6)

Patient monitors
(Sources: Patient monitor 1 – 6)

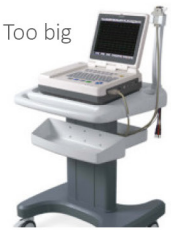
Pulse oximeters
(Sources: Pulse Oximeter 1 – 6)

Unwanted qualities

Screen too small



Too big



No handle

Too much wires

"Screens are expensive to repair"

Screen might break

Desired qualities

Colours: black or white
"just like the other machines we use"

"Make sure that the case is easy to clean"

"Simple product"

"Plastic screens instead of glass"

These are okay

Portable

Nice

Broader screen

Able to print

Beautiful

I pad is beautiful

Portable

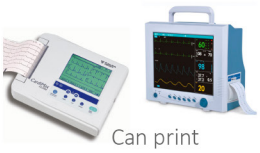
Handle

Research assistance at Noguchi

Desired qualities

"Now I can only look at beauty, and maybe convenience....
I like the portable ones"

Should be able to print, directly or
able to connect with a printer (wires or wireless)



Can print

Portable

Touchscreen

Modern
design

Can save and
send data

More digital

Favourite

Unwanted qualities

"In this case, I can only
look at portability. I cannot
look up the specifications,
what I do before choosing"

Less durable due
extra printing options

Less portable

Need to be connected
to another devie

Researcher at Centre for Plant Medicine Research

Part 2

To get a more detailed idea about what product features and qualities are desired, 2 other interviews were conducted. This time with a broader range of medical devices to show, including some interfaces and consumer products. The interviewees were asked to rate the devices on 4 criteria: Beauty; Professional appearance; Easy to use; Modern.

Approach:

Tools

- Diagram 1 with the parameters:
  - Beautiful versus ugly
  - Professional versus unprofessional
- Diagram 2 with the parameters:
  - Modern versus old fashioned
  - Easy to use versus difficult to use
- About 40 pictures of medical devices including interfaces, various colours, different amount of buttons and all sizes and shapes. 20 pictures were used for each diagram

Method

1. Explain diagram 1
2. Ask to place the first 20 pictures in the diagram where he/she thinks it belongs
3. When finished, reflect on all parameters:
   a. Why do you think these are beautiful / professional / ugly / unprofessional? What product features or qualities influenced your decision?
   b. What parameters are most important for a diagnostic device (in the field)?
4. Repeat step 1 to 3 for the second diagram, with 20 new pictures.

Goals

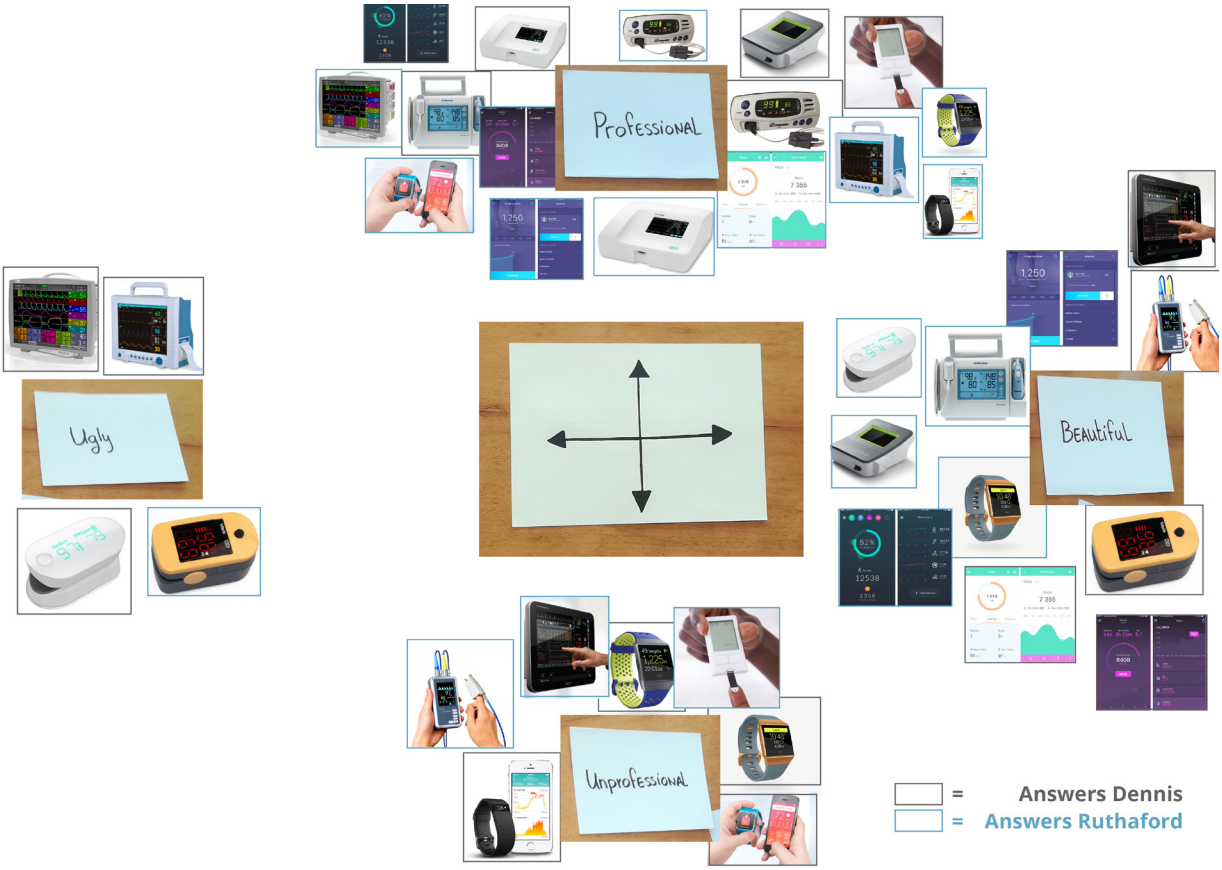
- Defining design criteria
  - What makes a product look professional and modern?
  - What is seen as aesthetic?
  - What makes a product easy to use?
  - What qualities are most important?
- Defining the differences between the preferences of researchers versus health facilities

Results

This interview approach was used in 2 interviews of which the results are shown on the following pages. The results start with the diagram of the divided visuals is shown. The answers of both interviewees are combined in one overview. A next diagram is filled with their argumentation behind the rated visuals, which show the qualities they value most.

Diagram 1: Beautiful versus ugly & Professional versus unprofessional appearance.

1A. Rating medical devices on beauty and professional appearance, by Ruthaford and Dennis



1B. Reasoning behind the rated designs by Ruthaford and Dennis

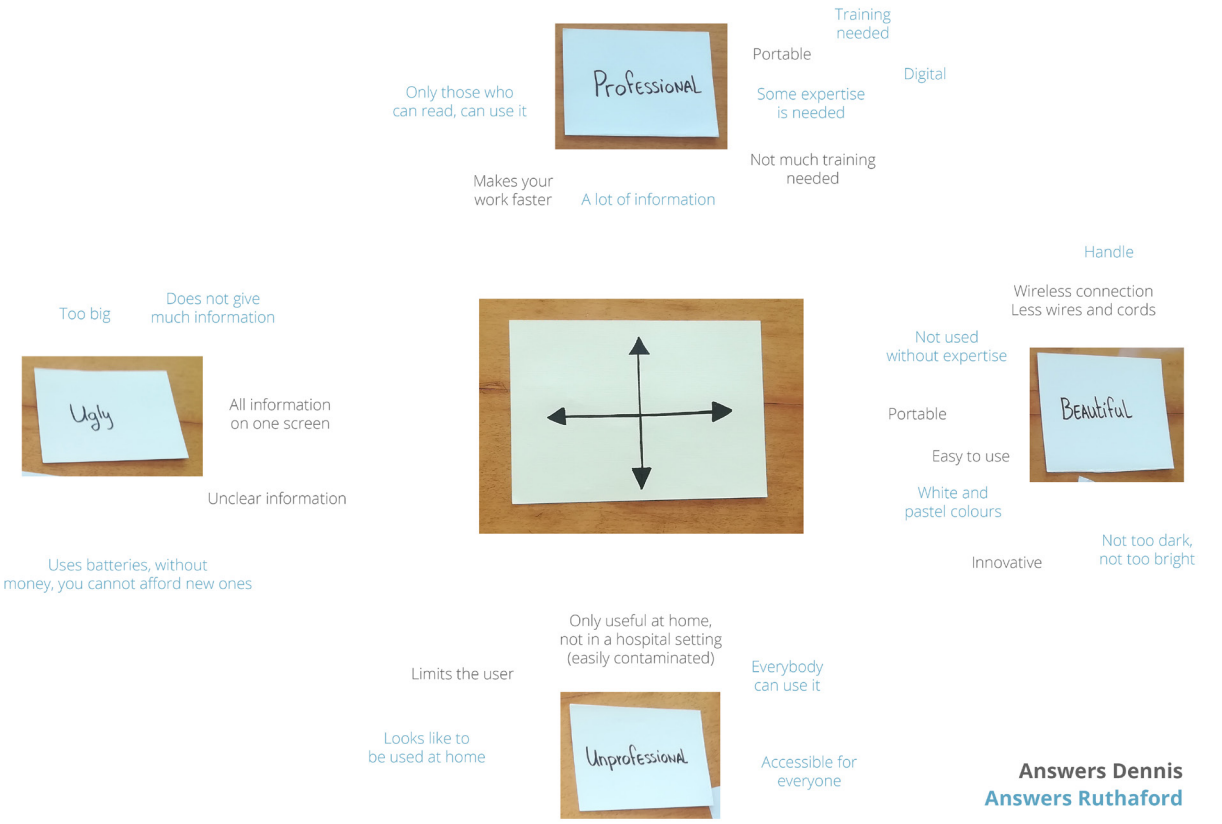
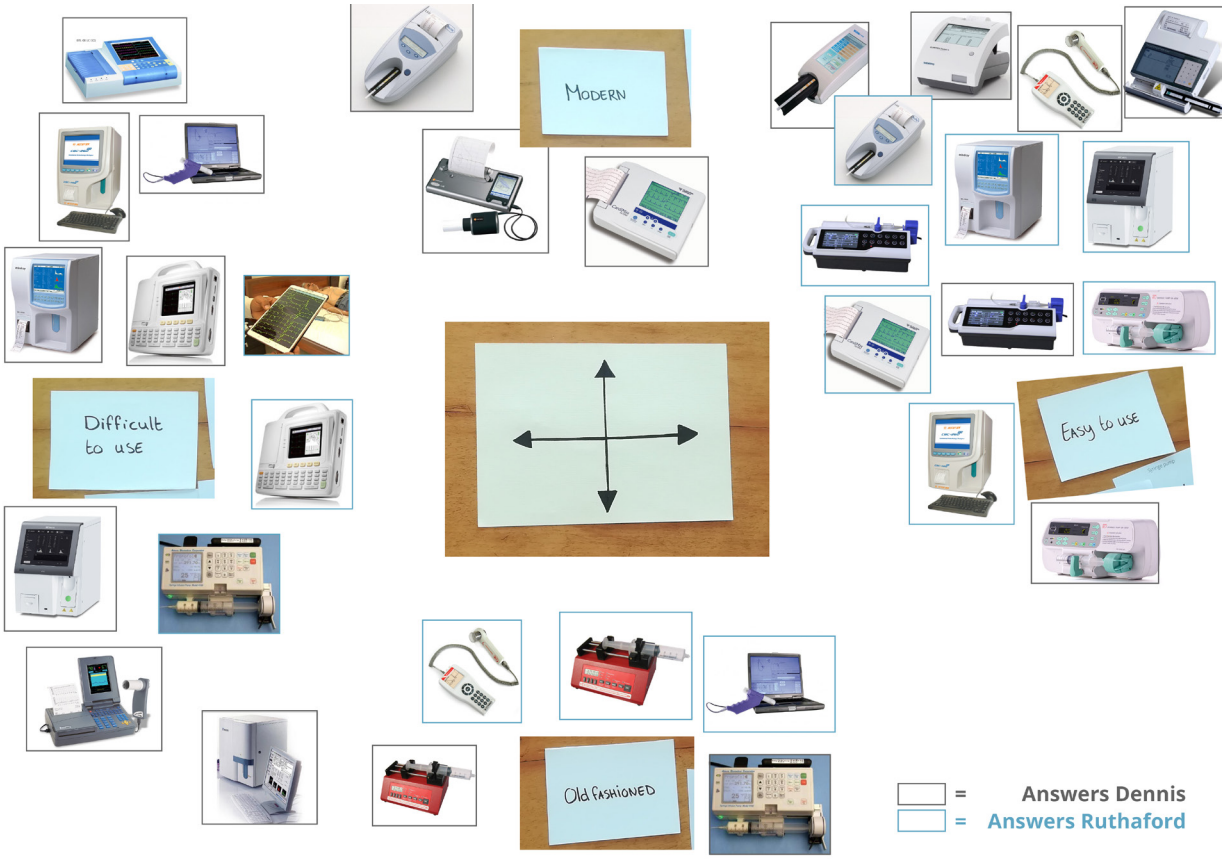
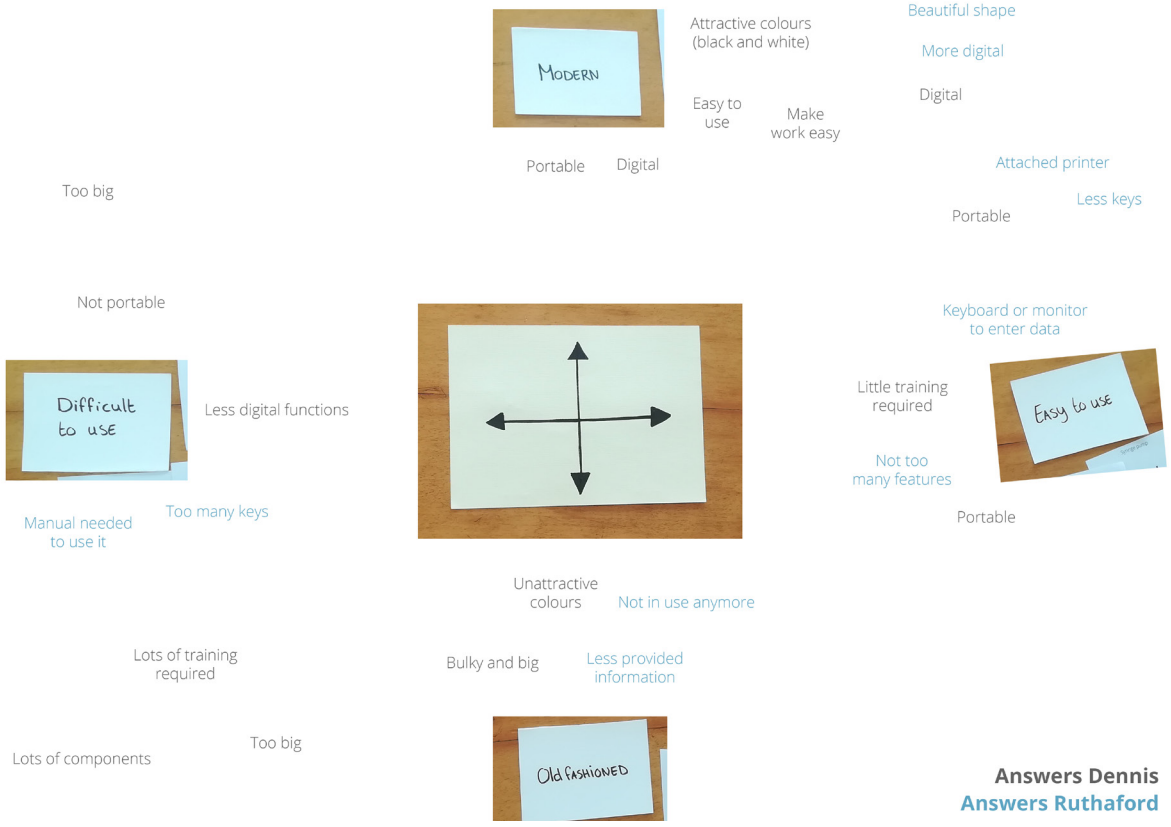


Diagram 2: Easy versus difficult to use & Modern versus old fashioned appearance.

2A. Rating medical devices on easy of use and modern appearance, by Ruthaford and Dennis



2B. Reasoning behind the rated designs by Ruthaford and Dennis



Appendix H. Extra insights Ghana

Implementation and scaling

Other countries, for example neighbouring countries like Togo or Burkina Faso have similar control programmes since it is according the WHO guidelines. Dr. Bosompon (director of Noguchi) as well as Dr. Marfo (NTDP), both think the differences per country will not differ much.

Before implementation, it is important to now the amount of samples to test in one day as well as the time and costs per sample. Besides, the new device must compete with the golden standard on sensitivity and specificity. The result is checked by the DNA tests.

Normally, at least a year of training is required for the technicians, but with this device, much less is needed.

Of all NTDs, schistosomiasis is to be expected to stay for a very long time, due to high risk on reinfection. Improved technology would be useful for a very long period of time.

The current cost are difficult to calculate. All kinds of aspects have to be taken into account, such as people, microscope, membrane, slides, etc. The only information collected about the price, was that a microscope usually is already more than $1000. For the field trips, the cost are raised by materials, the number of technicians and especially by the length of the stay in the field since accommodations, dinner have to be paid for).

Maintenance of machines and devices is an extra expense for health facilities. Some suppliers approach the hospitals or call to supply the machines for free. As a payment, they charge extra money for the reagents. First, before bringing a machine, they come to see how many tests the hospital is running. Depending on the frequency it is determined whether it is profitable to give them a device. And if so, they make a contract, for example for 3 years. After those years, the hospital owns the device. If something is broken, the supplier pays for the maintenance as long as the contract is running. After the contract, the hospital needs to pay in case the machine breaks or gets problems. Those machines break often and it gives a lot of problems to face. Especially in the villages this is a problem. It might take days or a week to get something replaced.

According to the NTDP manager and one of the technicians, this device would reduce needed personnel for control programmes.

On the long term, the technology should ideally detect both *S. mansoni* as well as *S. haematobium* eggs with the same device. Furthermore, ideally, the device would see the difference between viable and dead eggs.

The training for GHS technicians was sponsored by FHI360 (which also published a book for schistosomiasis education as a teachers manual).

Quality and trust

The researchers explained that they did not need to see the actual images of the detected ova in order to trust the results. They will do their own quality check before implementation and trust that quality check. Furthermore, some in between quality checks will be performed in between to check the quality once a while. However, this might differ per country, culture and user, which means that it should be kept in mind for further scaling.
A main advantage of this device is, the ability to provide objective measurements, independent from the technician's eye.

Another part of trust has to do with the communities to trust the technicians. If the community leader does not trust them, people will not take the medicines. Sometimes, they will bring somebody with a uniform from, for example, a nearby clinic to be recognised.

Digitalisation

Digital data is now used in the bigger hospitals and even for them it is often a new phenomenon to do all processes digital. But this shows a slow movement towards more digital data transfer and administration. For the smaller health centres and those in rural and remote areas, the results are most likely to be documented on paper first.

Data processing in field trips

Data to collect per person: name, age, sex and occupation. Furthermore, each person gets an identification number. And, when coming back to the same community (to analyse possible progress), the researchers need to test the same people each time. However, these people might not show up, for example if they got tired of cooperating or passed away. So, it should be documented whether they actually participated.

Whenever the researchers are helping the control programmes, the data is not meant for the research department and they have to pass the data through to the NTDP.

Health facilities
Health facilities have to report the amount of schistosomiasis cases to the government. This happens not at all facilities and it differs per facility how well they kept track of these results.

Why dipsticks is needed (at least for researchers)
In chronic infections, the eggs do not come out anymore, because all are trapped in the tissue. But the protein can show their presence, while no eggs and haematuria is not found. Without the dipstick test, it would be assumed that these people are not infected, while they are actually most likely suffering from long term chronic symptoms.
If you only have one sex of parasite penetrated the body (only male or female in the infection) these parasites will be able to affect the body, but no eggs are produced to detect. And the dipstick is an easy method to still find the proteins of those worms. For example when infected with 5 males, they still take your blood and you can get tired from the infection. But the hospital will not treat you because they cannot find eggs. When using the dipstick, this will show the presence. The chance is small but still present. And "*maybe we don't know, because we don't detect*" (Daniel, 2018) but in the lab, some mice did even have up to 15 females without males.
The only down side is that protein detection is not specific. Therefor they are trying to develop dipstick tests, able to detect (the specific) antigen.

NGO's and other research institutions
Some NGOs were involved in water project, which built a dam. Even while this is a noble idea and the dam is able to improve the chances of a region, such dams caused and explosive growth of schistosomiasis cases. NGOs are now providing some annual mass treatment around the Volta lake. However, these activities only include treatment and no diagnoses, as this would increase the costs.

There are several other research institutions in Ghana. One is from one of the other universities in Ghana, and is working together with the University of Hamburg, but they have a bit of a different focus. Noguchi has many various departments and many projects are running.

Northern region
The Northern Region is one of the poorest regions. Awareness is increasing each year, but not all are aware of the actual damage caused by the parasite.

Appendix I. Overview current field trips

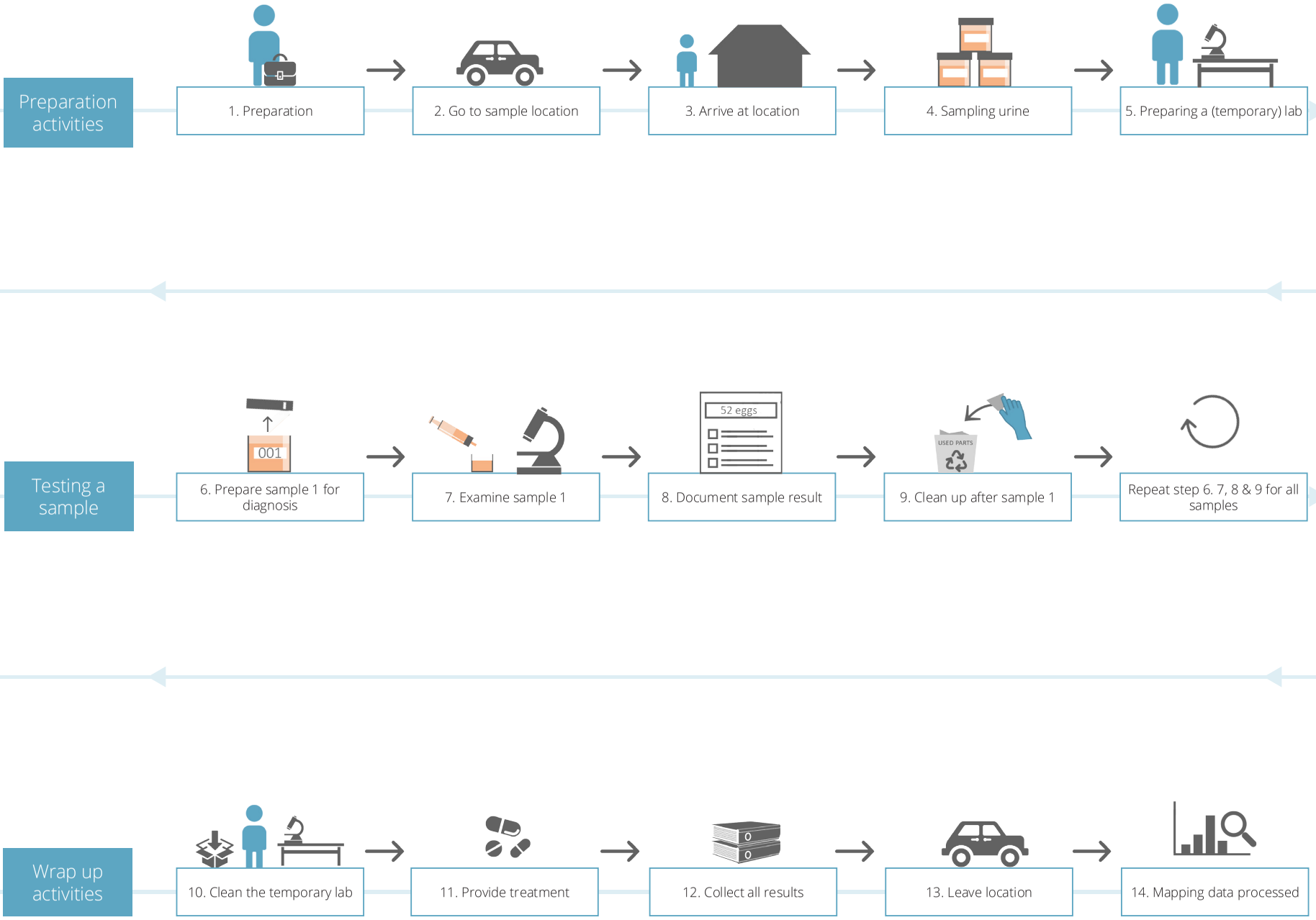
Field trips journey

When the technicians go on a field trip, the following procedure is followed:

- A big car is needed to take all work material and people.
- When arriving at location, look for leaders, volunteers, nurses, teachers, etc: The people governing that community.
- The community is gathered together in a common place, school, church, opine place for example under a tree. This moment is used to also provide some health education.
- Sometimes there is a conflict, if so you must be extra careful and maybe talk to the military or police too. Then you might be safe in the opine location. So they always discuss the location with authority to make sure it is safe. Sometimes there are conflicts between opine leaders. Therefore, you should first go to your contact person (nurse, teacher, volunteer, ...) and then they tell you who to talk to.
- Volunteers of the community are sometimes involved, for example by collecting the samples.
- Insurance card is asked from the people, to note down their name and age.
- The personal identification codes to use during sampling can be generated in different ways. Some use a combination of the community nr., house number, individual number per person of the house, etc. But there is no general coding system. Therefore the device must allow each combination of numbers (and letters) to be used as a sample code.
- You might have data entry personnel. They will process the data and store them in the receivable procedure. In the end, the PIO (Public Information Officer) is in charge of the data.
- It happens often that you go back to the same people each time, to check the progress. If so, the personal data is already known up front (after the first session). But it might happen that some do not show up, so it must be documented whether somebody has delivered a sample.
- When doing research, they are sometimes able to buy some medicines. And then, treatment is given at the end of the study. But treatment is only given if there is permission to treat.
- Some people might not be present during the treatment, during the field trip. In that case, the technicians visit their homes in the evening. Some might be travelling and are not there, then we fix another day to go back to the field to treat. Or, the medication is left by the school head master of community representative. They all know him and he will give the treatment.
- At the end, the lab has to be cleaned. And disinfect the benches. And all that needs to be recycled is recycled.

A more extended timeline was made to discuss with the Ghanaian technicians to create a clear overview of the procedures and protocols in the field. The following pages show the timeline as well as the extra notes, based on the findings of the research in Ghana.

Time line
Field trip



Time line 1 part 1/3

Preparation activities

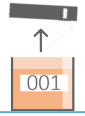




1. Preparation	2. Go to sample location	3. Arrive at location	4. Sampling urine	5. Preparing a (temporary) lab
Sub activities (NTDP) Use software to pick location (Research) Choose endemic area Sometimes location is the same each time, they come back each 3, 6 or 12 months. Let the contact person and/or community leader of community know you are coming. Decide on the size of the team, the available nr of devices and divide tasks per technician	**Sub activities**	**Sub activities** Meet contact person and discuss who to be introduced to first. Visit community leader and sometimes also health facility/nurses, teachers, religious leader (if this is not the comm. leader), police or military in case of conflict areas Find location for lab, preferably with electricity Let comm. leader make announcement to gather the target group together	**Sub activities** Give health education (for S. haematobium, S. mansoni and STH, the medication, how to prevent contamination, the risks, the protocol of the programme, etc.) First data collection Give cups (for both stool and urine) Collect samples Lable samples	**Sub activities** Look for possible electricity (and an extention cord if needed)
Location At the office	**Location** Bumpy roads	**Location** For example: opine location, community leader office, church, health facility, school, police station	**Location** Health facility / community centre / school / opine location / church / outside / others	**Location** Health facility / community centre / school / opine location / church / outside / others
Equipment (NTDP) Software (Research) Database or mapping info from 2015 national mapping	**Equipment** A big car, mostly 4-wheel drive Preferable with pickup	**Equipment**	**Equipment** 50 ml urine cups Markers and labels Paper forms or paper to document data	**Equipment** Foldable tables Diagnostic equipment Gloves Cleaning material Bowls to wash hands
People involved For sure: Technician & the manager of the specific project Optional:NTDP manager / managers / technicians / driver / community leaders / volunteers / school	**People involved** Technicians Optional: an extern driver, other medical experts for different diagnoses	**People involved** Technicians and community leader Optional: volunteer, nurses, teachers, police, military	**People involved** Technicians and/or volunteers /teachers / nurses	**People involved**
Data collected (What, how & why)	**Data collected (What, how & why)**	**Data collected (What, how & why)**	**Data collected (What, how & why)** Personal data (if **not** collected up front) Who gives a sample (if the personal data is collected up front) Specific data depends on project: Name/date/id sample number/region/ district/community/housenumber/age/ sex/occupation/etc On paper: (Standard) forms or written in tables	**Data collected (What, how & why)**

Time line 1 part 2/3

Testing a sample



6. Prepare sample 1 for diagnosis

Sub activities

Fill in part of the sample form

Sometimes: write down sample colour

Location

Temporary lab

Equipment

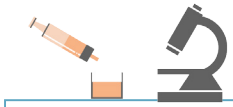
People involved

Technicians

Data collected (What, how & why)

Depending on the project purpose:

Code/date/colour of the urine/name technician



7. Examine sample 1

Sub activities

Dipstick
Filtration (most common) or centrifugion (this is cheaper but not always available)

If time is available: microscopy. But this might also be done a next day or later when back in the lab. The stool often has to be diagnosed before, since those can be used less long after sampling than the filtered urine.

Location

Filtering: always at temporary lab
Microscopic examination: In temporary lab or in HC or lab after the field trip

Equipment

If no electricity: generator/solar lamp/ mirror for the microscope
Cool boxes with ice packs in case the samples have to be stored for a while

People involved

Technicians

Data collected (What, how & why)

Depending on the project purpose:

Dipstick values/examination values/ etc.

8. Document sample result

Sub activities

Happens during step 6 and 7
Start with the urine colour and the dipstick results
After microscopic examination the examined results are written down.

Location

(Temporary) lab

Equipment

Paper (forms)

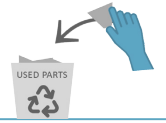
People involved

Technicians

Data collected (What, how & why)

Depending on the project purpose:

Signature



9. Clean up after sample 1

Sub activities

Dispose syringes to clean afterwards

Location

(Temporary) lab

Equipment

Nothing

People involved

Technicians

Data collected (What, how & why)

Repeat step 6. 7, 8 & 9 for all samples

Time line 1 part 3/3

Wrap up activities

10. Clean the temporary lab

Sub activities

Clean tables and all reusable equipment.

Location

(Temporary) lab

Equipment

Cleaning chemicals

People involved

Technicians

Data collected (What, how & why)

11. Provide treatment

Sub activities

This only happens when permission is given and medicines are available. Otherwise the people will receive medication during the MDA or a referral has to be given. Sometimes, they come back later on to give treatment. This all depends on the project.

If the team needs to leave, one person of the community (such as the head teacher) can be given the responsibility to distribute the medicines.

Location

At a central place in the community or the medicines are brought to the homes, when they did not show up.

Equipment

People involved

Technicians / teachers / volunteers and the community

Data collected (What, how & why)

Who was picking up the treatment.

12. Collect all results

Sub activities

Location

Equipment

All information is collected on paper

People involved

Technicians

Data collected (What, how & why)

13. Leave location

Sub activities

Location

Equipment

People involved

Data collected (What, how & why)

14. Mapping data processed

Sub activities

Digitalise the data

Keep a paper record as a backup

Location

Equipment

People involved

Researchers or NTDP department. If results are collected for the control programme, researchers are not the ones processing the data.

Data collected (What, how & why)

Appendix J. Programme of requirements

Table of content

1. General requirements

- Facilitate communication of results to (illiterate) patients
- Fit in all the regional differences
- Long lasting life with minimal maintenance
- Deal with insufficient power supply
- Replace the need for a specialist
- Perform independent of human errors and environmental influences
- Fit the cultural habits and user routines
- Scalable to product use towards other endemic countries

Product features

- Memory to store the data of at least four weeks of fieldwork.
- Share data with other devices, avoid dependency of wireless connections.
- Manual attached to device
- Make the manual visual to be understood by illiterate people
- Avoid scenarios where urine can be spilled
- Make the device easy to carry
- Attach anti slip on the bottom
- Include an alarm whenever the device needs attention.
- Information visible, even in bright sunlight
- Water and dust resistant
- Withstand temperatures up to 45 degrees
- Handle 50 to 200 samples per day
- Avoid peak currents
- Still able to work when there is no main current available to charge the battery
- Protected during rough transport
- Easy to clean properly, even without training.

2. Technical mechanism

Requirements

- Sensitive (preferably detect even a single egg)
- Affordable for remote areas
- Specific for *S. haematobium*
- Diagnose 200 samples in one day

Wishes

- Able to detect Pus cells, Epithelial cells, red blood cells, crystals, cast and Yeast cells.
- Able to do both: urine and stool examination
- Distinguish viable and dead eggs
- Find every egg

3. Researchers

Requirements

- Digitalise data collection (and processing)
- Dipstick part of protocol (and data collection)
- Save money by saving time in the field

- Sensitive for light infections
- Highest possible quality
- Approved by their own quality check
- Able to recollect and store sample after test
- Portable

Wishes
- Enables a fast procedure to increase the throughput
- Able to do both: urine and stool examination
- Able to detect viable eggs
- Use syringes
- Test 10 ml
- Most economical beneficial option
- Option to make a paper backup

4. Control programme

Requirements
- Most economical beneficial option
- Save money by saving time
- Approved by the WHO
- Sensitive for light infections
- Quality constant, independently from the final user
- Digitalise data collection (and processing)
- Portable
- Fit the national health system of Ghana

Wishes
- Enables a fast procedure to increase the throughput
- Use syringes
- Test 10 ml
- Easy to use, by low educated technicians
- Tested by the NMIMR
- Able to do both: urine and stool examination
- Option to make a paper backup

5. Remote health facilities

Requirements
- Dispose sample after test
- Easier and faster than current centrifugation
- Paper data collection
- Maintenance possible with local resources
- Low cost price
- Sensitive for light infections
- Easy to use for low educated users
- Able to clean without 'clean water'
- Fit the national health system of Ghana

Wishes
- Minimise maintenance
- Able to detect Pus cells, Epithelial cells, red blood cells, crystals, cast and Yeast cells.
- Rather reusing than disposable parts
- Able to print result
- Operational without a syringe
- Test either 10 ml or full sample

6. Urban health facilities

Requirements
- Minimise maintenance costs and a long lifespan
- Find light infections

- Able to detect Pus cells, Epithelial cells, red blood cells, crystals, cast and Yeast cells.
- Able to store and recollect sample after test
- Fit the national health system of Ghana

Wishes
- Dipstick part of protocol
- Rather reusing than disposable parts
- Minimise human error

7. Design guidelines

Easy to use
1. Simple
2. Small
3. Able to read the information quickly
4. Easy to carry
5. Portable
6. Little training required
7. Able to save, send and print data
8. Not too many keys or control buttons

Modern
1. Digital
2. Providing all the necessary information
3. Makes you work easier
4. Easy to use
5. Not outdated
6. Black and white
7. Small / not bulky
8. Touchscreen
9. Wireless
10. Portable

Professional
1. Makes your work faster
2. Digital
3. Does not look like a product to use at home
4. Not everybody can use it
5. Only for those who can read
6. Some experience is needed
7. Does not limit the user
8. Portable
9. Prevent contamination of keys and device
10. Provides a lot of data

Beauty
1. Portable
2. Functional
3. No loose wires
4. Not to use without experience
5. Small
6. Provides enough information
7. Easy to use
8. Wireless connections
9. White and pastel colours
10. Screen not overloaded with information

8. Materials

Requirements
1 Excellent durability in water (fresh and salt)

2 Excellent durability for acids and alkalis
3 Suitable for injection moulding or thermoforming
4 Temperatures up to 60 degrees Celsius must be sustained without any deformation
5 Must not break or deform when it falls on the ground or when a fully grown person (100 kg) will sit on it.

Wishes:
1 Be opaque rather than translucent or transparent for the preferred clean look.
2 High galling resistance (to prevent from scratches after sliding over rough surfaces)
3 Self-extinguishing or non-flammable
4 Recycled materials
5 Biodegradable
6 Low cost
7 Excellent durability for sunlight (UV radiation)

Appendix K. Creative session

A creative session was organised on the 20th of June 2018 with five master students and one young professional. All experienced in designing for developing countries or developing business strategies. The main goal of this creative session was to define all possible disastrous scenarios of what could go wrong when using the device in order to prevent these mistakes from happening by the final product design.

Date
20-06-2018

Goals
Defining all possible disaster scenarios
Exploring possible business strategies
Brainstorm for some of the sub problems

Participants
Six participants were chosen with either a strategic background or experience in Bottom of the Pyramid (BoP) projects, but preferably both. Out of the six participants, 5 were master students:

- 1 follows the master Integrated Product Design (IPD) with a biomedical expertise
- 1 follows the master Design For Interaction (DFI)
- 3 follow the master Strategic Product Design (SPD)

And there was one former SPD student (graduated in 2017). Four of the participants have done at least one BoP project themselves and the other 2 both study SPD and have been to at least one third world country.

Planning & setup
1. Short introduction of the project

2. Define the "*Disaster scenario*"

- Explanation of the interaction via 18 steps, drawn on large paper sheets.
- Brainstorm in teams of 3 about what could go wrong in each of those 18 interactions steps

3. Creative session to solve six sub problem:

- How to collect data in a phone or tablet?
- How to earn money with this product (as supplier or producer)?
- How to replace the tubes fast and easy?
- How to make sure the user press start before each new sample?
- How to enable maintenance in rural areas?
- How to make it as cheap as possible?

4. Create concepts in pairs
A concept had to be made which prevent some situations of the 'Disasters scenario' to happen, combined with a business implementation plan.

Results

The following pages show the results. These results are used throughout the whole design process. Some are literally implemented or used as inspiration. Others lead to recommendations for further design phases.

Insights 'disaster scenarios'

Many problems can be caused when the user does not follow the rules, forgets something, does not understanding the correct way of usage, acts uncareful or out of laziness. Moreover, things can break, needed parts or materials can get out of stock or one can simply not know how to clean parts properly causing either unreliable results or further contamination of the environment due to insufficient hygiene.

Some specific noticeable scenarios to take into account are listed below:

- If the collection cup (for the urine or cleaning water that flows out of the tube) might be placed incorrectly causing spilled urine.
- When several tasks are done at the same time, cups or results could get mixed up.
- Buttons (like the on/off switch) can break and should be replaceable to make sure such a simple damage will not make the complete device useless.
- When the device is processing the results for a few minutes, the user might assume that the device is broken if it does not directly gives the result. It should be clear what is happening and how long you have to wait.
- Cleaning the tubes by taking them out each time, would take too much time and they might forget the cleaning. Besides nobody knows where the garbage is disposed.
- When the off switch is accidently touched during the process, the diagnosis is interrupted. On the other hand, one could forget to turn off the device, wasting energy.
- When not able to close the device properly, dust can come in. This is why the electronics are placed behind an extra cover.
- One might not know how much cleaning is sufficient.

Another insight: The dipstick test could also be done after the schistosomiasis diagnoses, as an extra check in case of negative test result.

Results How To's

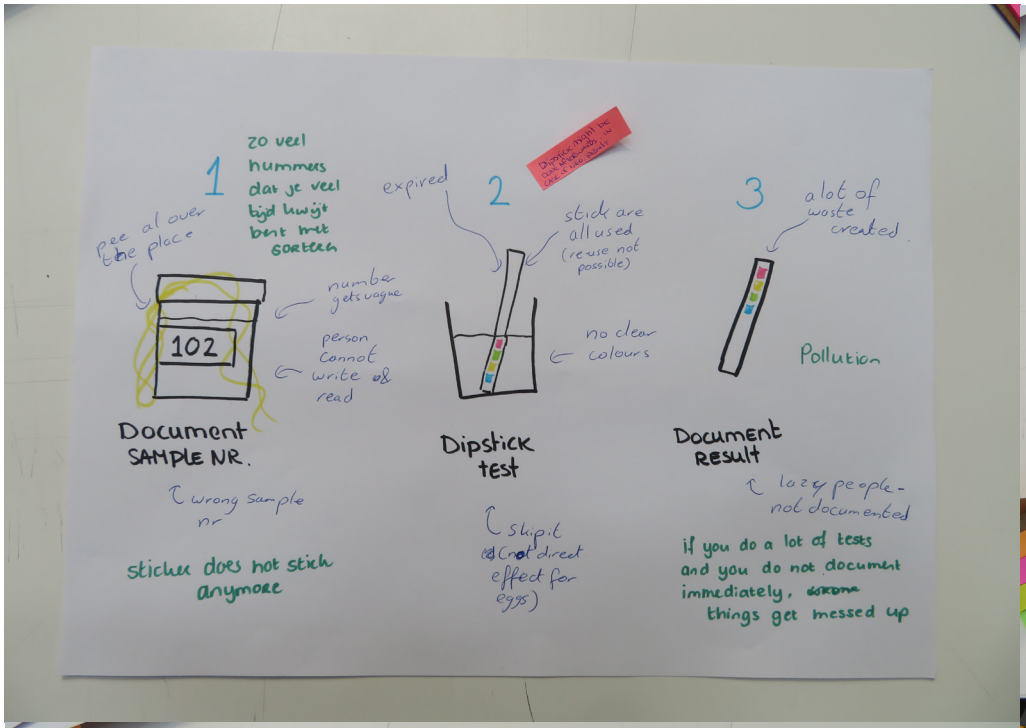
The results are shown on the pictures on the following pages. The following insights are used in the further design process, either as inspiration, serious consideration or actual integration in the final design:

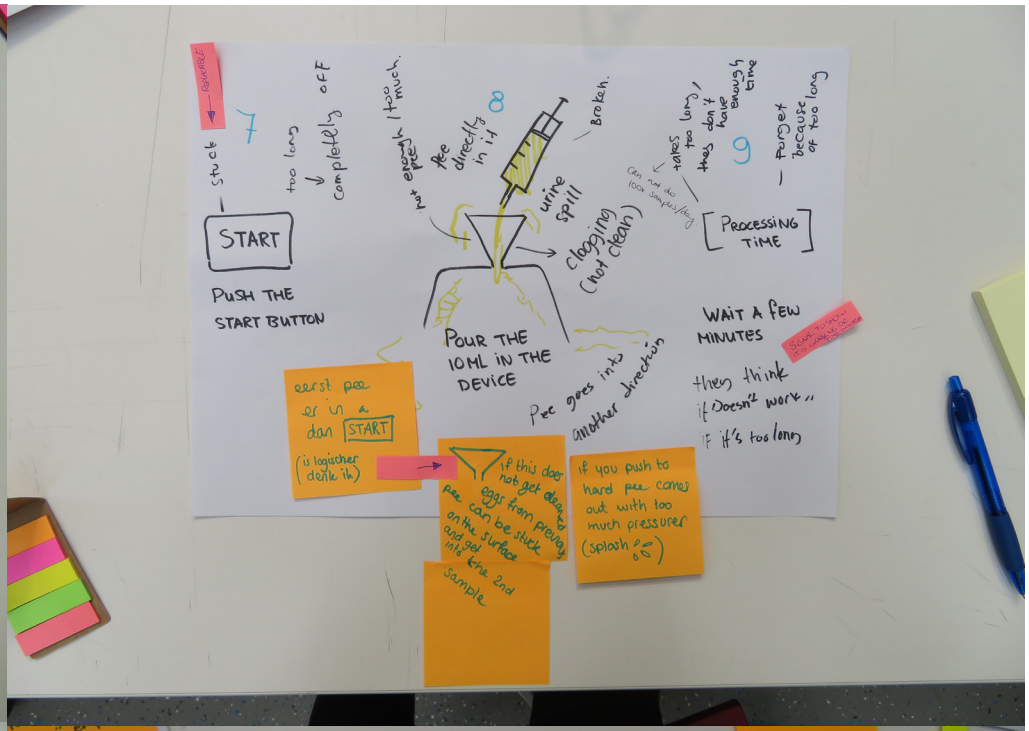
How to make it as cheap as possible?
- Maximise the economic scale
- Maximise lifespan
- Share the device in a bigger area
- Local production and locally available materials

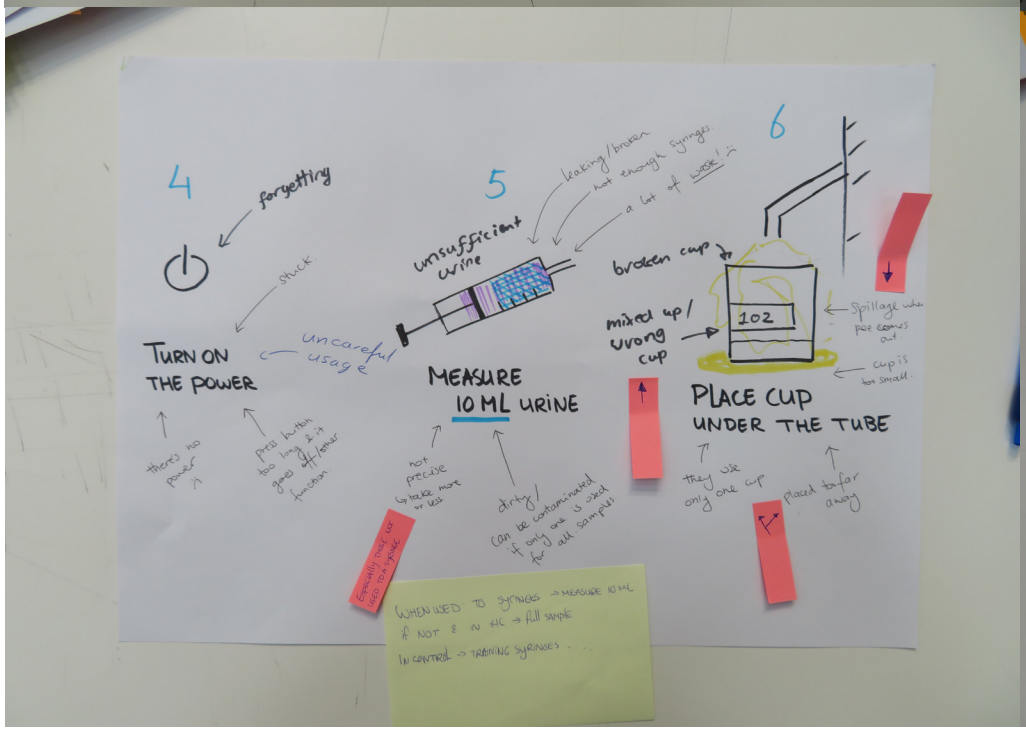
How to enable maintenance in remote areas?
- Online instructions available
- Only use standard parts
- Repair with local parts
- Make maintenance so simple, everybody can do it
- Train local people to do the maintenance
- Manual for maintenance
- Contact an expert via a phone number

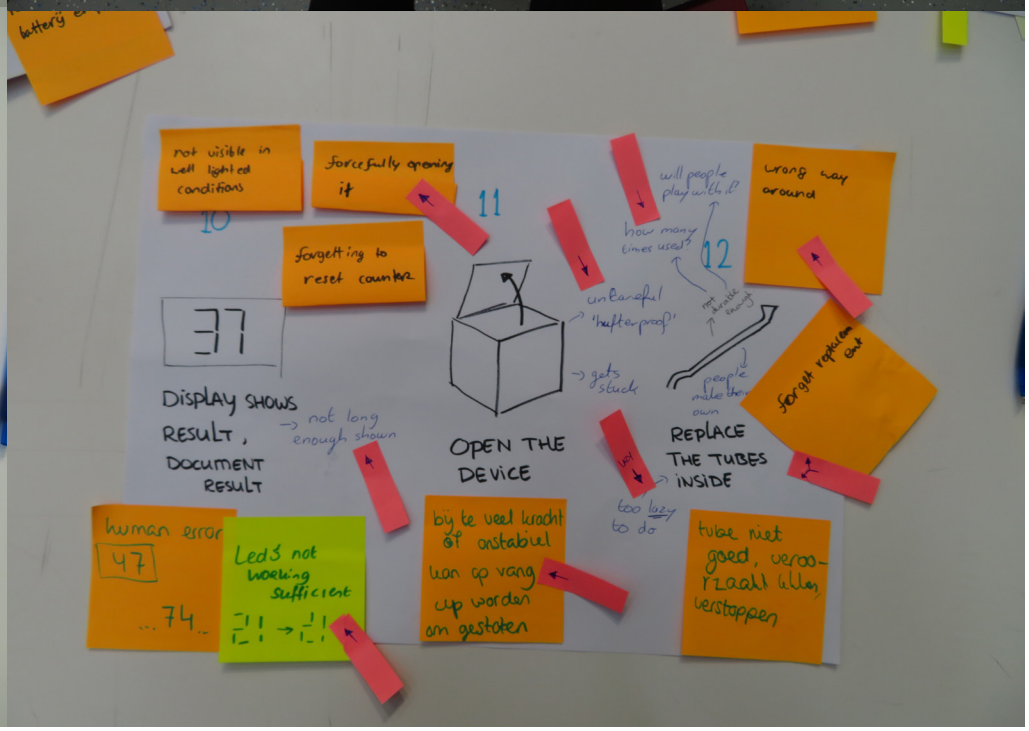
How to collect the data in a phone or tablet?
- Let the parts of data entry appear after each other.
- For the number of eggs, the colours of the result lights could be matched with the colours of the tablet options.
- Keep the interface easy

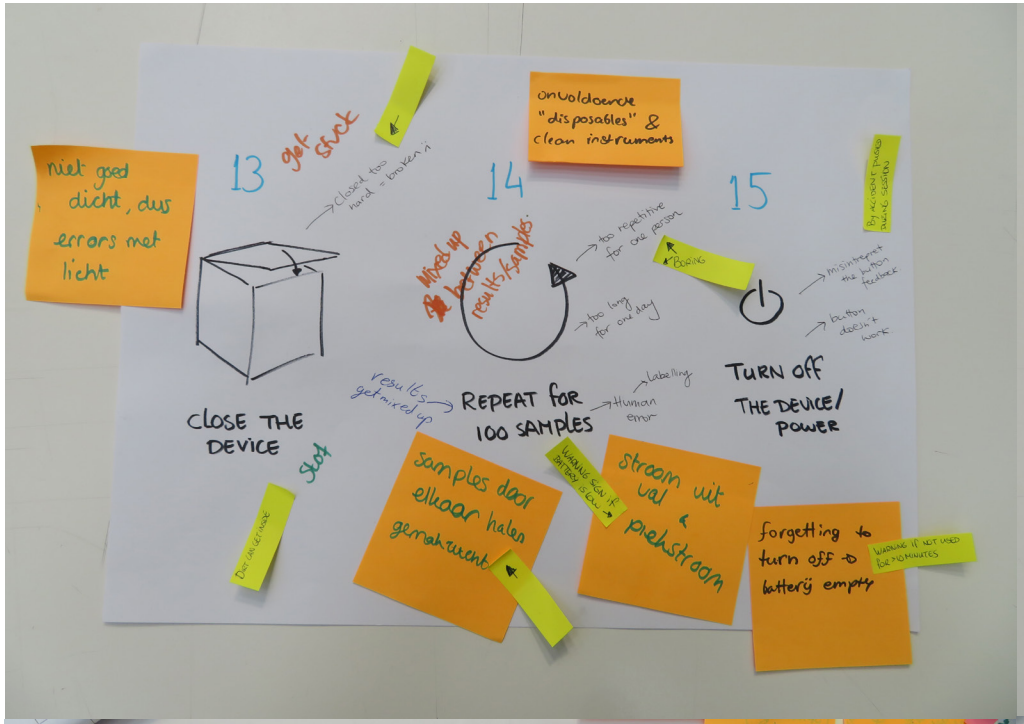
How to earn money as supplier/producer?
- Buy 1 give 1
- Find more commercial use for the technology and make profit in other fields
- Some people pay more, some pay less
- Sell the data
- Service subscription

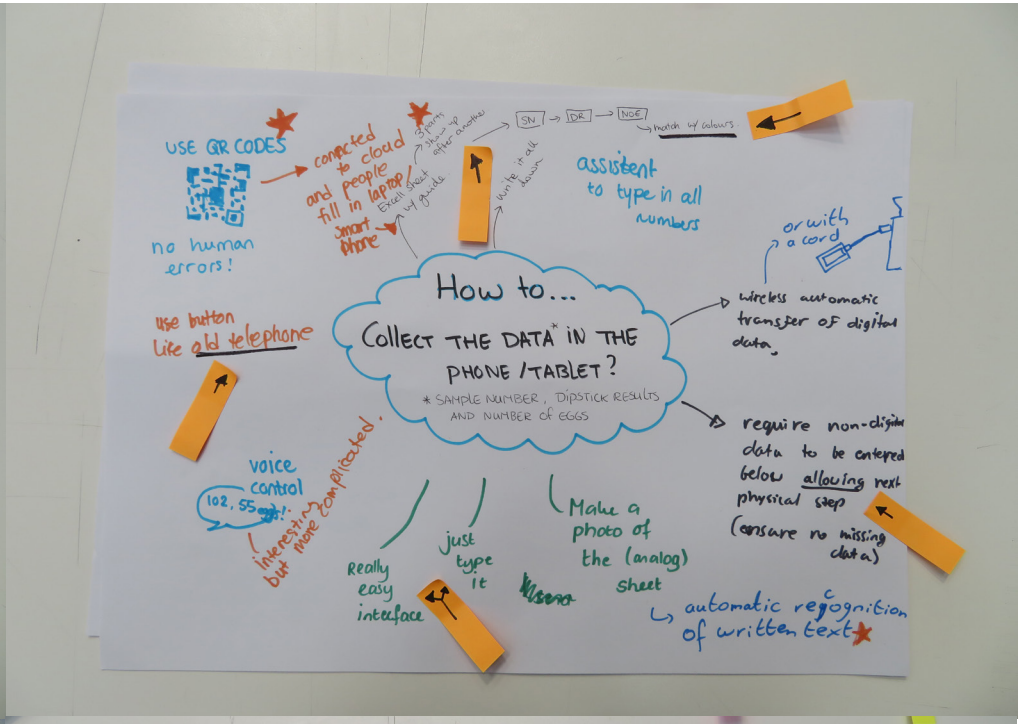

1
zo veel nummers dat je veel tijd kwijt bent met sorteren
pee al over the place
number gets vague
person cannot write of read
102
Document SAMPLE NR.
wrong sample nr
sticker does not stick anymore
2
expired
Dipstick test
stick are all used (re-use not possible)
no clear colours
skip it (not direct effect for eggs)
3
a lot of waste created
Pollution
Document Result
lazy people - not documented
if you do a lot of tests and you do not document immediately, things get messed up


7
stuck
too long
completely off
START
PUSH THE START BUTTON
8
pee directly in it
broken
urine spill
clogging (not clean)
POUR THE 10ML IN THE DEVICE
9
takes too long / does not have enough time
Can not do 100% completely
[PROCESSING TIME]
WAIT A FEW MINUTES
they think it doesn't work ...
if it's too long
eerst pee er in a dan START
(is logischer denk ik)
if this does not get cleared eggs from previous pee can be stuck on the surface and get into the 2nd sample
Pee goes into another direction
if you push to hard pee comes out with too much pressure (splash pee)

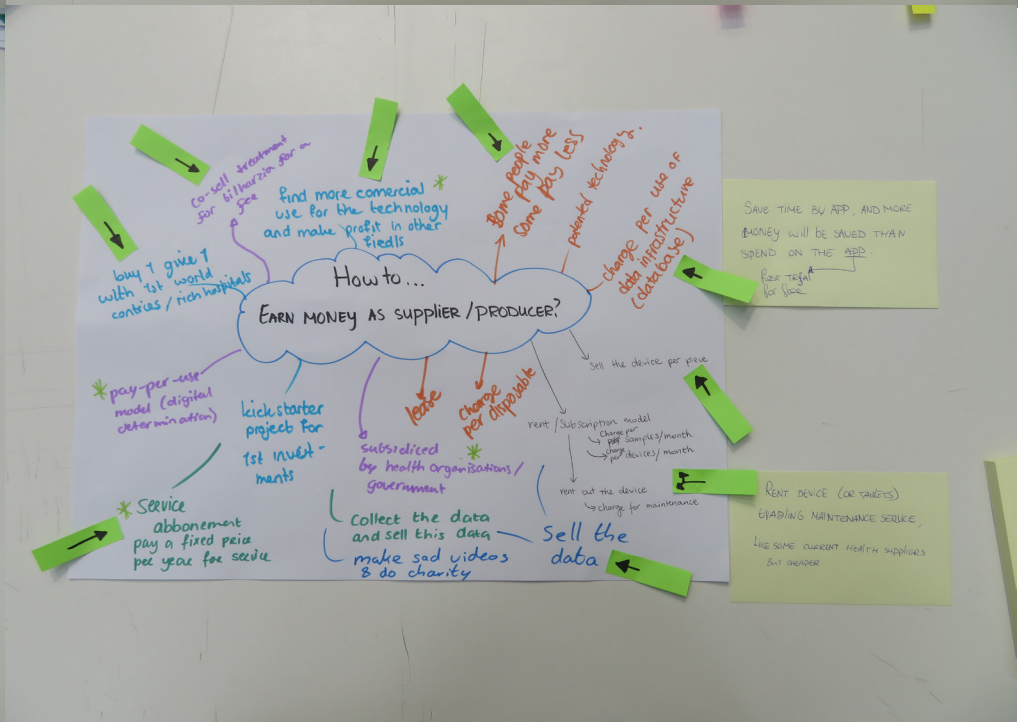

4
forgetting
stuck
uncareful usage
TURN ON THE POWER
there's no power
press button too long & it has good/other function
5
leaking/broken
not enough syringes
a lot of WORK in
unsufficient urine
MEASURE 10 ML URINE
not precise to take more or less
dirty/ can be contaminated if only one is used for all samples
6
broken cup
mixed up/ wrong cup
102
Spillage when pee comes out
cup is too small
PLACE CUP UNDER THE TUBE
they use only one cup
placed to far away
WHEN USED TO SYRINGES → MEASURE 10 ML
IF NOT & IN THE → FULL SAMPLE
IN CONTROL → TRAINING SYRINGES

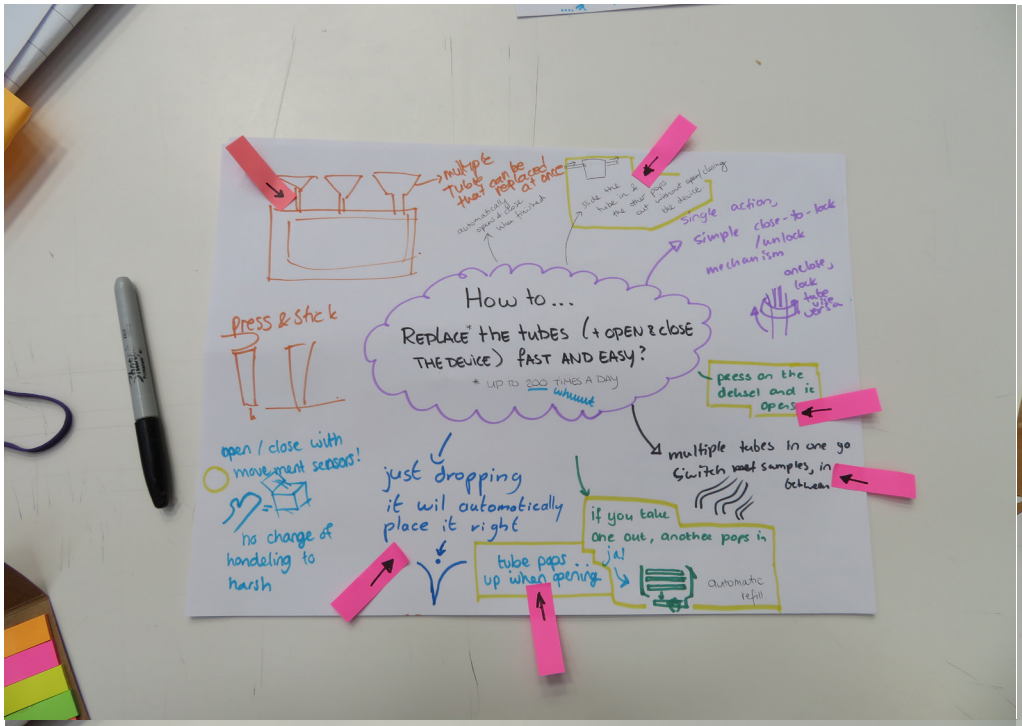

battery
10
not visible in well lighted conditions
forcefully opening it
forgetting to reset counter
37
Display shows RESULT, DOCUMENT RESULT
not long enough shown
11
unbeautiful
"shatterproof"
gets stuck
OPEN THE DEVICE
12
will people play with it?
how many times used?
wrong way around
forgot replacement
not durable enough
people make their own
too lazy to do
REPLACE THE TUBES INSIDE
human error
47
74
Leds not working sufficient
bij te veel wrijving of instabiel
kan op vang cup worden aangestoken
tube niet goed, veroorzaakt lekkage verstoppen

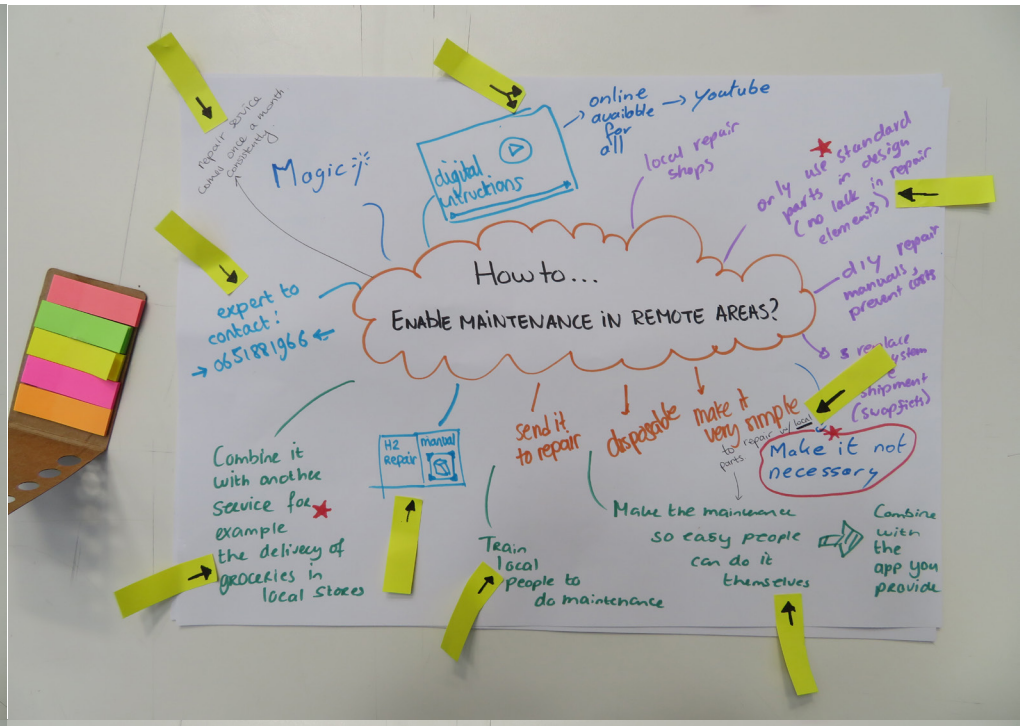

13 get stuck
niet goed dicht, dus errors met licht
14
onvoldoende "disposables" & clean instruments
15
CLOSE THE DEVICE
REPEAT FOR 100 SAMPLES
TURN OFF THE DEVICE/ POWER
samples door elkaar halen gemakkruent
stroom uit val & piekstroom
forgetting to turn off → battery empty

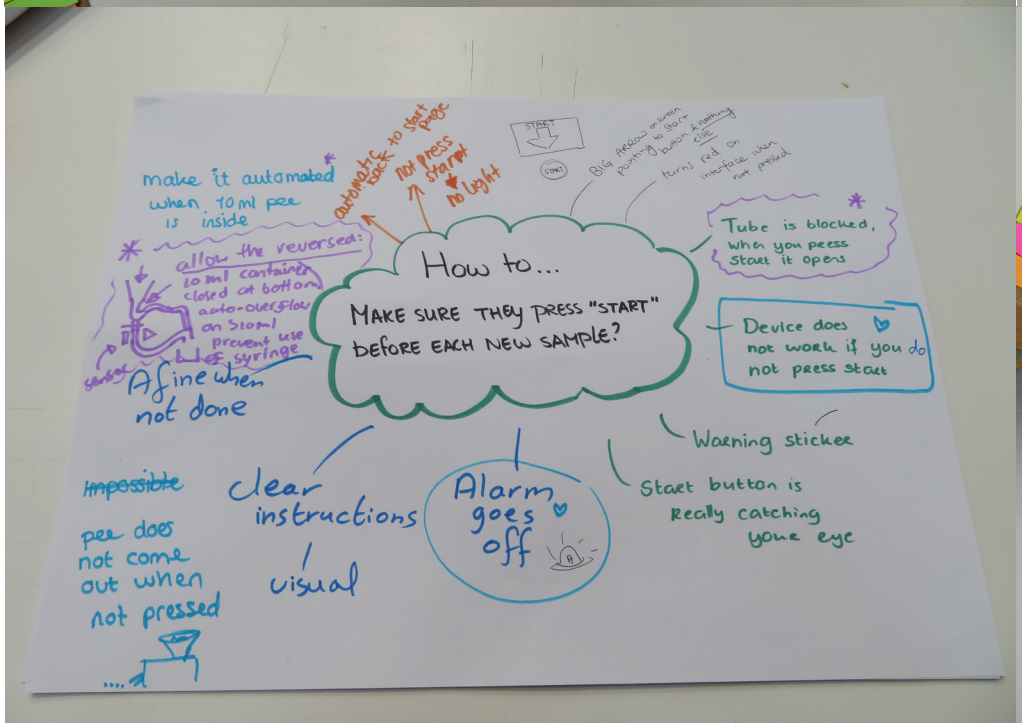

USE QR CODES
no human errors!
connected to cloud and people fill in laptop/ smartphone
assistent to type in all numbers
How to...
COLLECT THE DATA* IN THE PHONE / TABLET?
* SAMPLE NUMBER, DIPSTICK RESULTS AND NUMBER OF EGGS
wireless automatic transfer of digital data
or with a cord
require non-digital data to be entered below allowing next physical step (ensure no missing data)
use button like old telephone
voice control
interesting but more complicated
Really easy interface
just type it
Make a photo of the (analog) sheet
automatic recognition of written text

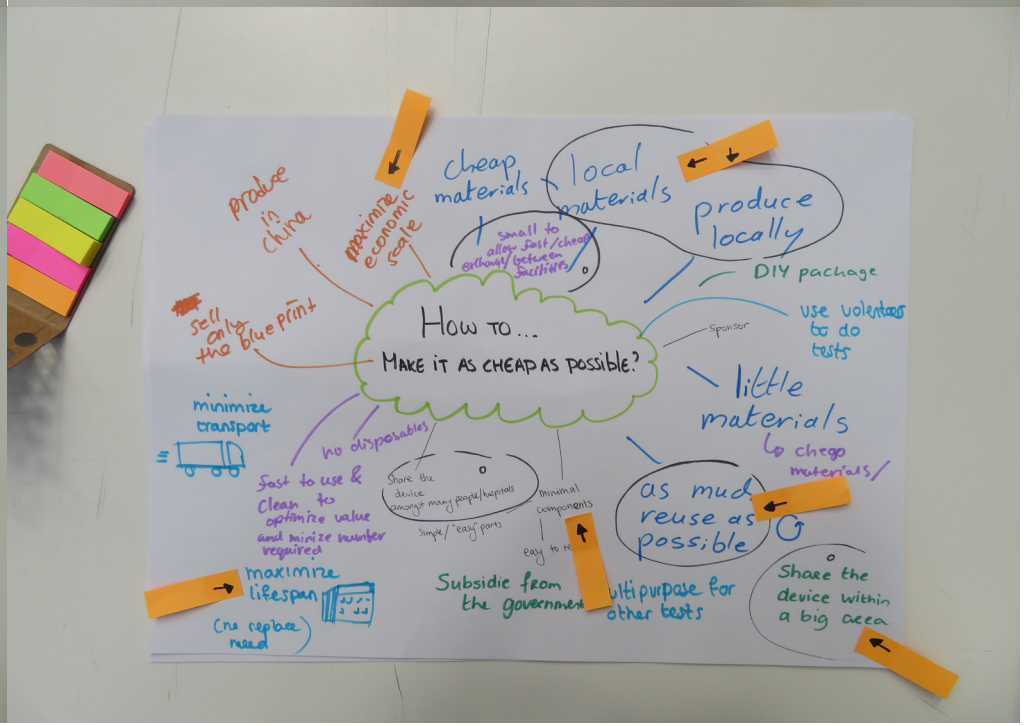

16
too often that some material scratched come off
CLEAN / disinfect THE DEVICE
wrong cleaning middle
takes too much time
forget cleaning
insufficient protection of hand/skin
17
DISPOSE THE USED TUBES...
OR
... CLEAN THEM ALL
Where do they throw these garbage?
Near water?
Not really environmentally friendly
18
cleaning affects transparency of tubes
unsufficient cleaning (false positives)
contamination
the tube broken
Water used for cleaning ends up in public water
people handle it wrongly
BORROW / RENT TUBES, (OR FREE IF RETURNED) TO CLEAN AT ONE CENTRAL POINT
COMBINE WITH EXISTING MODEL
ATTRACT FOR CONTROL
RESEARCH MIGHT BE ABLE TO DO IT THEMSELVES


How to...
EARN MONEY AS SUPPLIER / PRODUCER?
Co-sell treatment for bilharzia for a fee
find more comercial use for the technology and make profit in other fields
some people pay more some pay less
patented technology
charge per use of data infrastructure (database)
buy 1 give 1 with 1st world contries / rich hospitals
pay-per-use model (digital determination)
kickstarter project for 1st investments
lease
charge per disposable
subsidized by health organisations / government
Service abbonement pay a fixed peia per year for servie
Collect the data and sell this data
make sad videos & do charity
Sell the data
Sell the device per piece
rent / subscription model
rent out the device
charge for maintenance
SAVE TIME BY APP, AND MORE MONEY WILL BE SAVED THAN SPEND ON THE APP.
RENT DEVICE (OR TABLETS) ENABLING MAINTENANCE SERVICE
LIKE SOME CURRENT HEALTH SUPPLIERS BUT CHEAPER

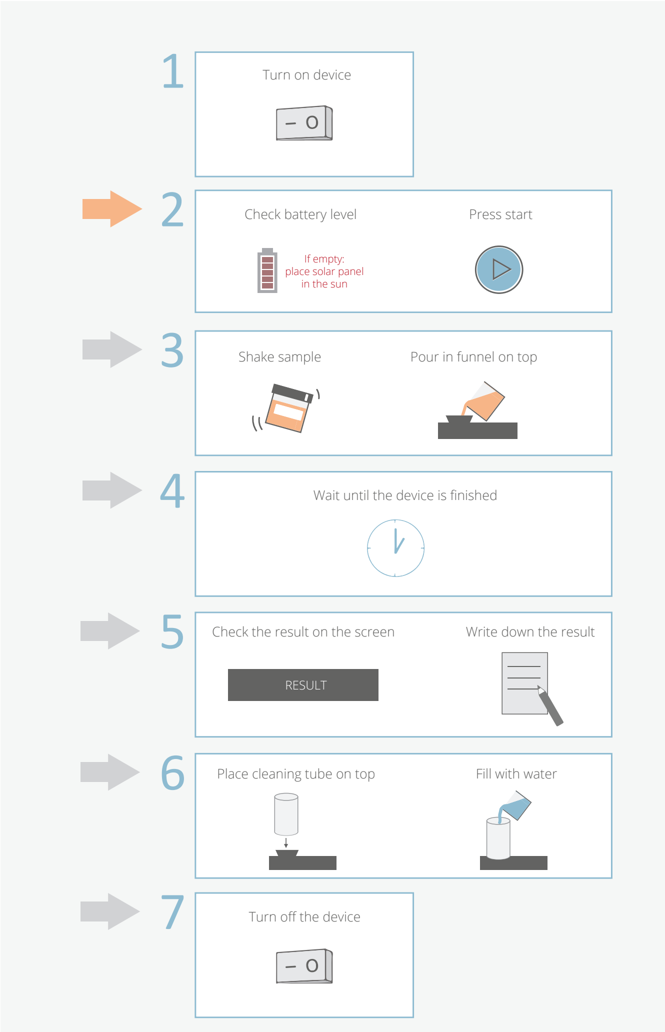

How to...
REPLACE the tubes (+ OPEN & close THE DEVICE) FAST AND EASY?
* UP TO 200 TIMES A DAY
multiple Tubes that can be replaced at once
Slide the tube in & the other pops out (ensure spacing between the devices)
single action
simple close-to-lock / unlock mechanism
press & stick
open / close with movement sensors!
no change of handeling to harsh
just dropping it wil automatically place it right
tube pops up when opening
if you take one out, another pops in ja!
automatic refill
multiple tubes in one go (switch vast samples, in between)
press on the deksel and it opens

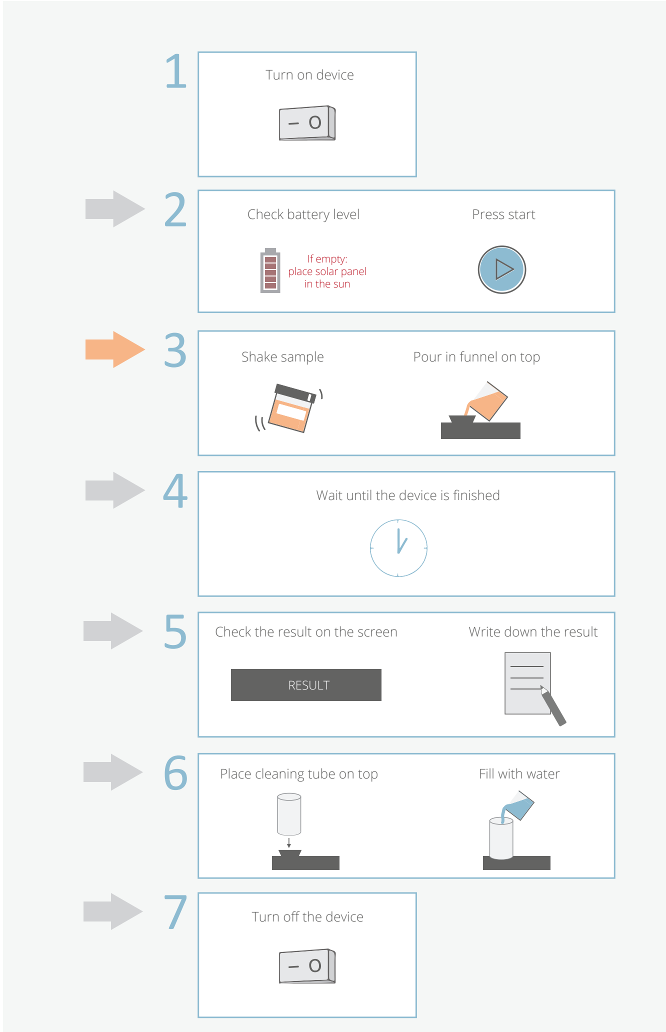

How to...
ENABLE MAINTENANCE IN REMOTE AREAS?
Magic
digital instructions
online available for all → youtube
local repair shops
repair service comes once a month consistently
only use standard parts in design (no lack in repair elements)
diy repair manuals prevent costs
expert to contact: 0651881966
Combine it with another service for example the delivery of groceries in local stores
H2 Repair manual
send it to repair
disposable
make it very simple
Make it not necessary
Make the maintenance so easy people can do it themselves
Train local people to do maintenance
Combine with the app you provide

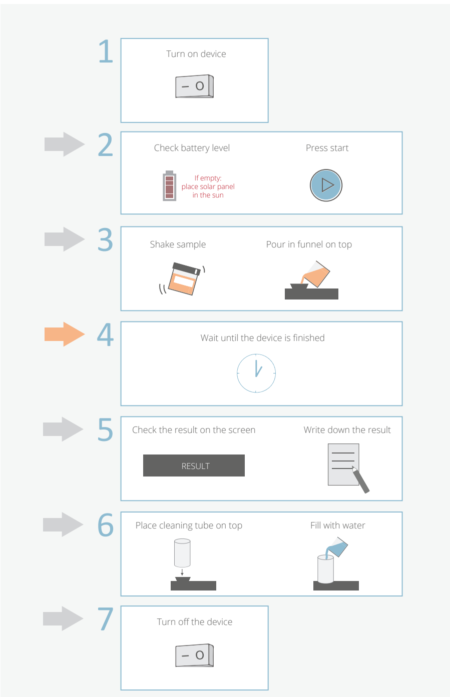

How to...
MAKE SURE THEY PRESS "START" BEFORE EACH NEW SAMPLE?
make it automated when 10ml pee is inside
automatic back to start page
not press start = no light
START
Big arrow or sign pointing to start button & pulsing light
turns red on interface when not pressed
allow the reversed: 10ml container closed at bottom auto-overflow at 31ml prevent use of syringe
sensor
A fine when not done
Tube is blocked, when you press start it opens
Device does not work if you do not press start
Warning sticker
Start button is really catching your eye
Alarm goes off
clear instructions / visual
Impossible
pee does not come out when not pressed

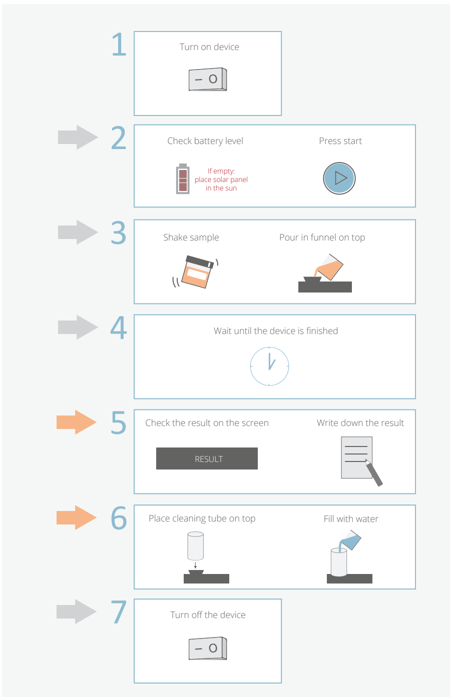

How to...
MAKE IT AS CHEAP AS POSSIBLE?
produce in China
maximize economic scale
cheap materials
local materials
produce locally
small to allow fast/cheap exchange between facilities
DIY package
sell only the blue print
Sponsor
use volenteers to do tests
little materials
cheap materials
minimize transport
no disposables
fast to use & clean to optimize value and minize number required
share the device amongst many people/hospitals
simple/easy parts
minimal components
easy to
as much reuse as possible
maximize lifespan
one replace need
Subsidie from the government
multipurpose for other tests
Share the device within a big area

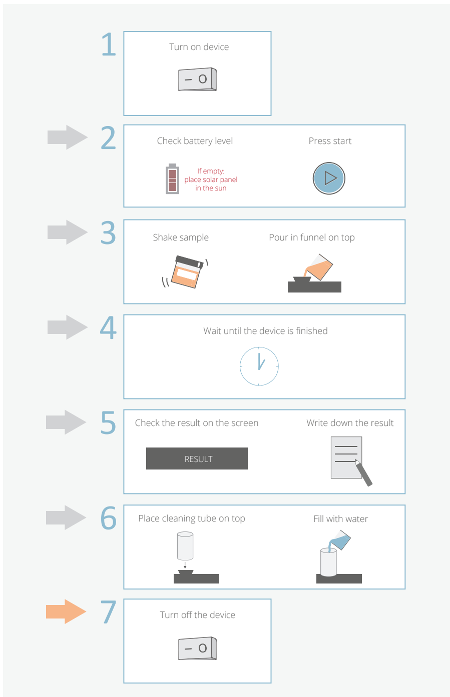
Appendix L. Interaction lights control panel

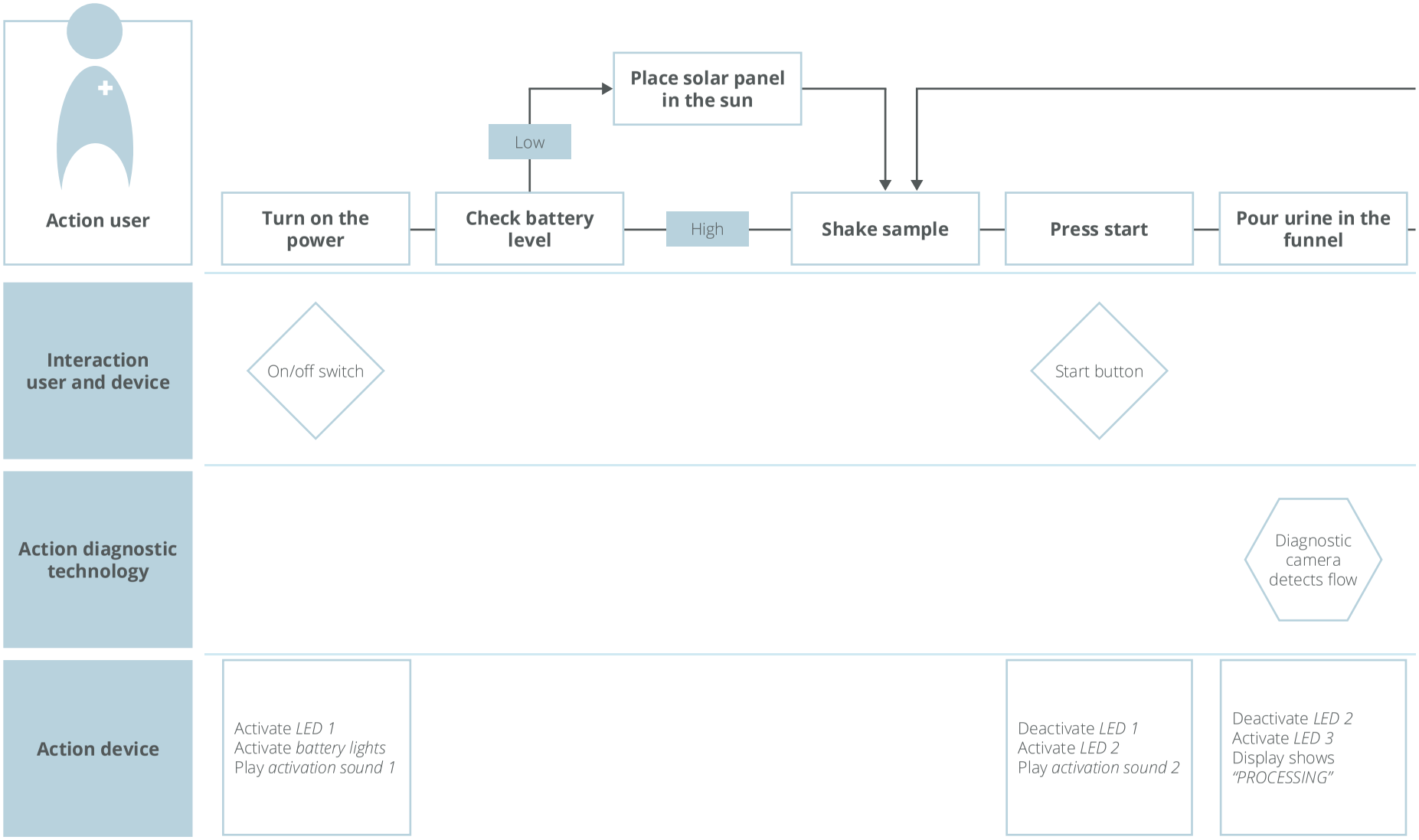












LED 1 points at instructions to prepare the device and sample
LED 2 points at instructions to pour the urine in the funnel
LED 3 points at instructions to wait until device is finished
LED 4 points at instructions to document results
LED 5 points at instructions to flush the tubes with water
LED 6 points at instructions to turn off the device / start new diagnosis
RGB LED indicates results (no infection = green; light infection = yellow; heavy infection = red)
Battery lights indicates whether the battery is full, half full or empty
Activation sound 1 to confirm that the power is turned on
Activation sound 2 to confirm that the start button is pressed
Alarming sound to alarm the user that the diagnosis is finished


Wait till result is ready
Read out result
Document result
Place cleaning tube on funnel
Fill tube with water
Wait till all water is gone
Turn off device
Display & RGB LED
On/off switch
Counting the ova
Diagnostic camera detects flow
Diagnostic camera detects flow
Deactivate *LED 3*
Activate *LED 4 & 5*
Play *alarming sound*
Display shows result
Activate *RGB LED*
Save result, date and time on SD card
Deactivate *LED 4 & 5*
Activate *LED 6*
Deactivate *LED 6*
Deactivate *RGB LED*
Turn off display

Appendix N. Interaction journey research field trips

This appendix will show the interaction journey for the researchers. While the user in remote areas only interacts with the device, the researcher interacts with both, the device and tablet.

An overview of the interaction with the tablet is shown on the next pages. The tablet interaction of the flow chart does refer to the different interfaces of the application. This project does not include the complete interface design, but the main pages are designed as shown in figure 1 to 6.

In the next pages, the interaction is shown by the use of a flowchart. This flowchart is split up in two parts:

1. *Basic tablet interaction flowchart*
   This overview shows the interaction with the tablet during the full urine analysis.
2. *Egg count interaction flowchart*
   This overview will show the interaction between the tablet and egg counting device as well as the specific interaction for researchers with the diagnostic device.

Figure 1. Sample scanning page

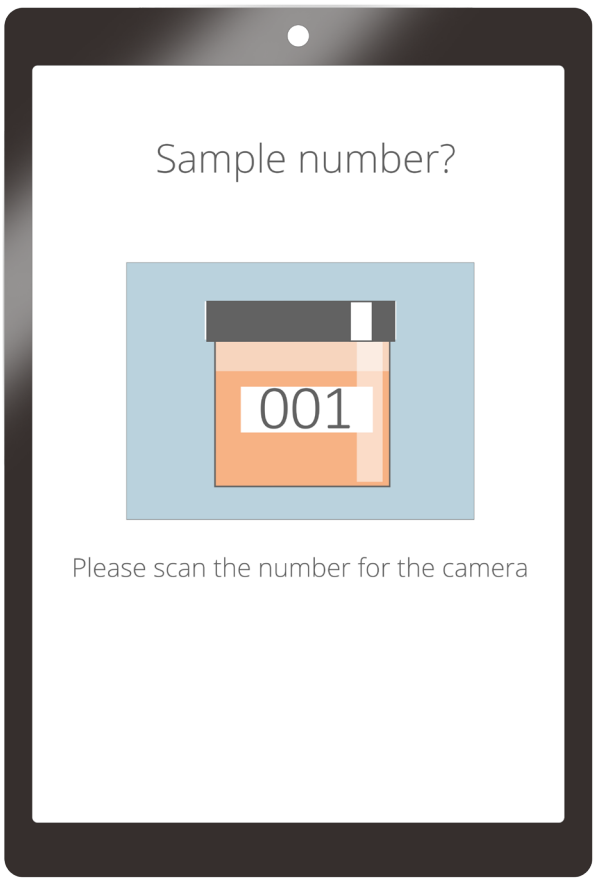


Figure 2. Start page

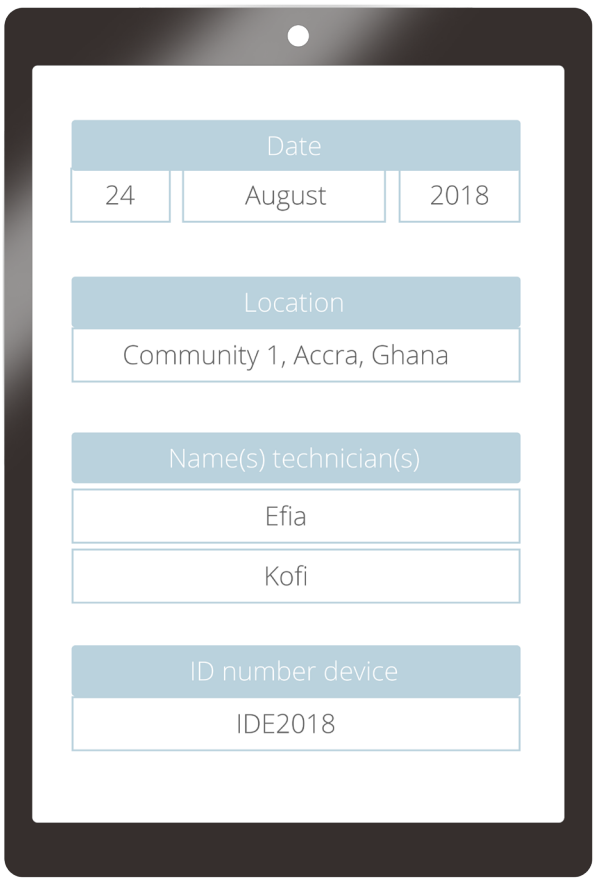


Figure 3. Patient page

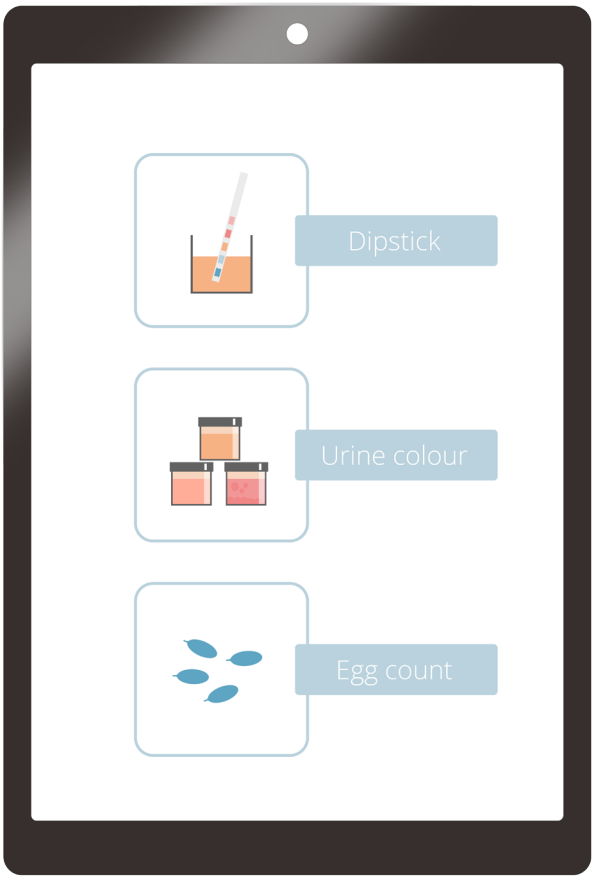


Figure 4. Dipstick result page

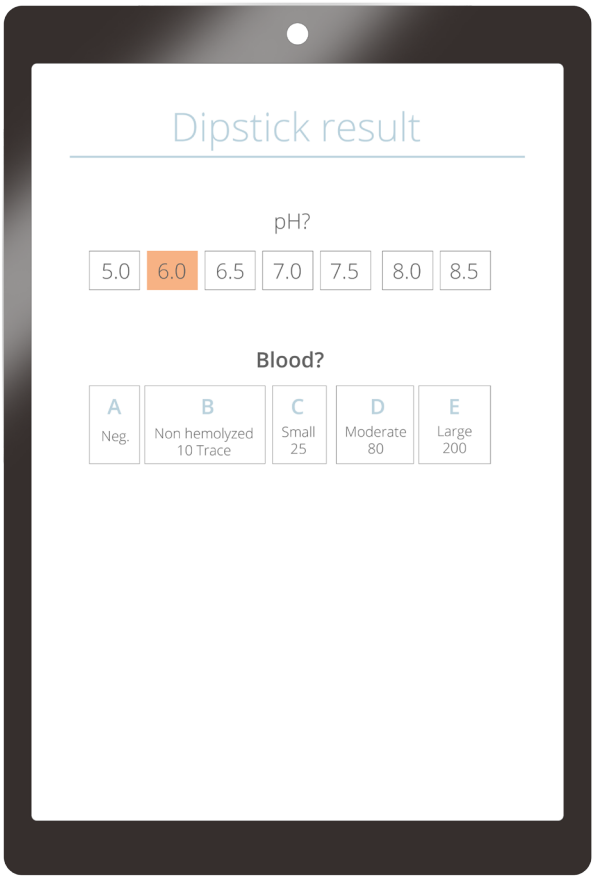


Figure 5. Colour indication page

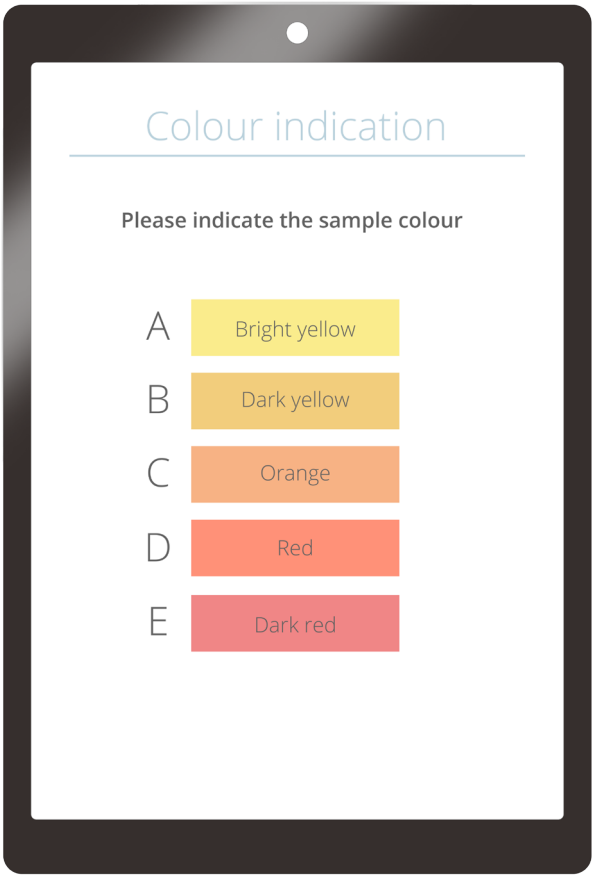
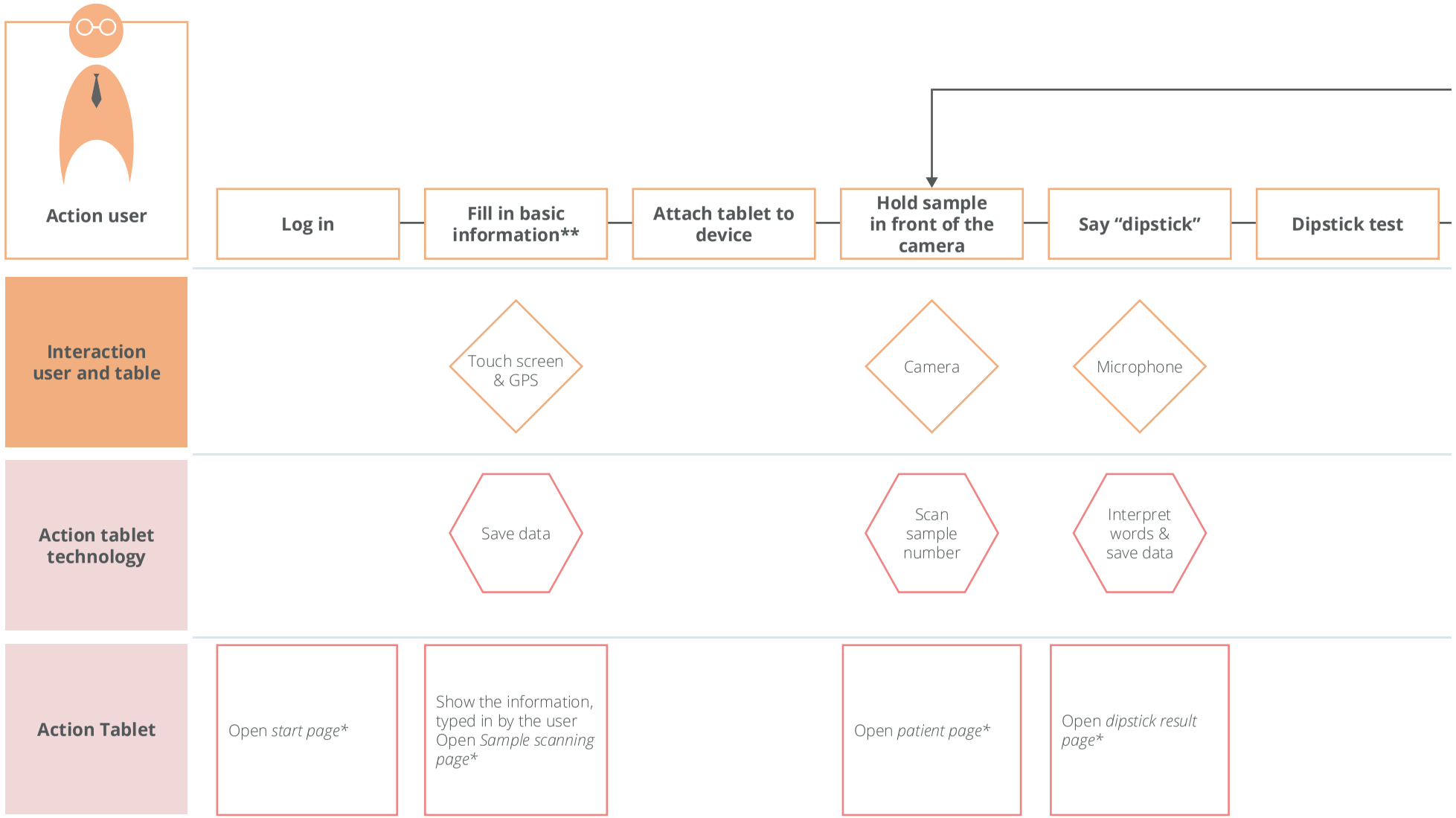
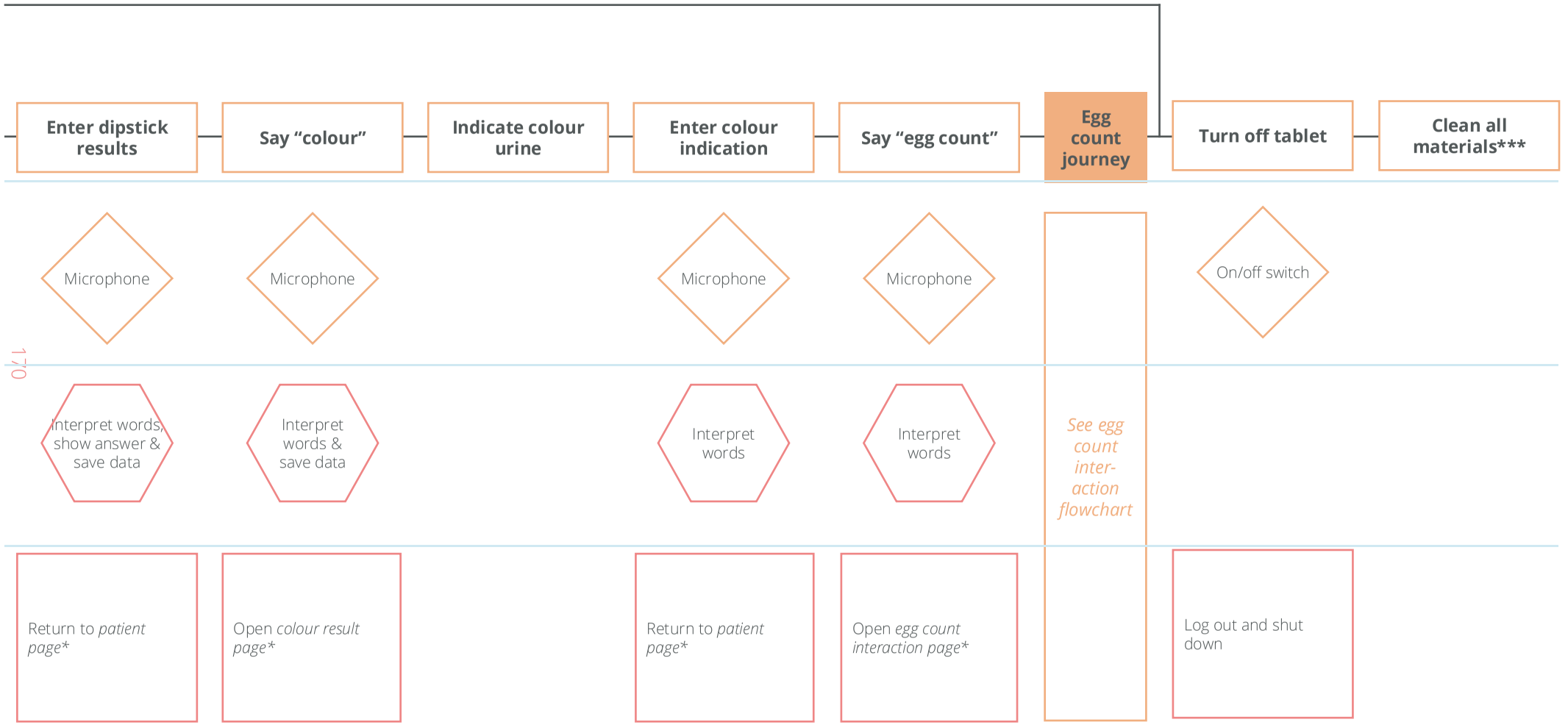


Figure 6. First page of the egg count instructions

Basic tablet interaction flowchart



* See previous page
** Basic infromation = Name technician, device identification number, date and (GPS) location



* See previous page
*** Clean syringes, funnels, chiffon filters & dispose cleaning water

Egg count interaction flowchart

Action user

Turn on the power

Check battery level

Low

Place solar panel in the sun

High

Place a clean funnel

Shake sample

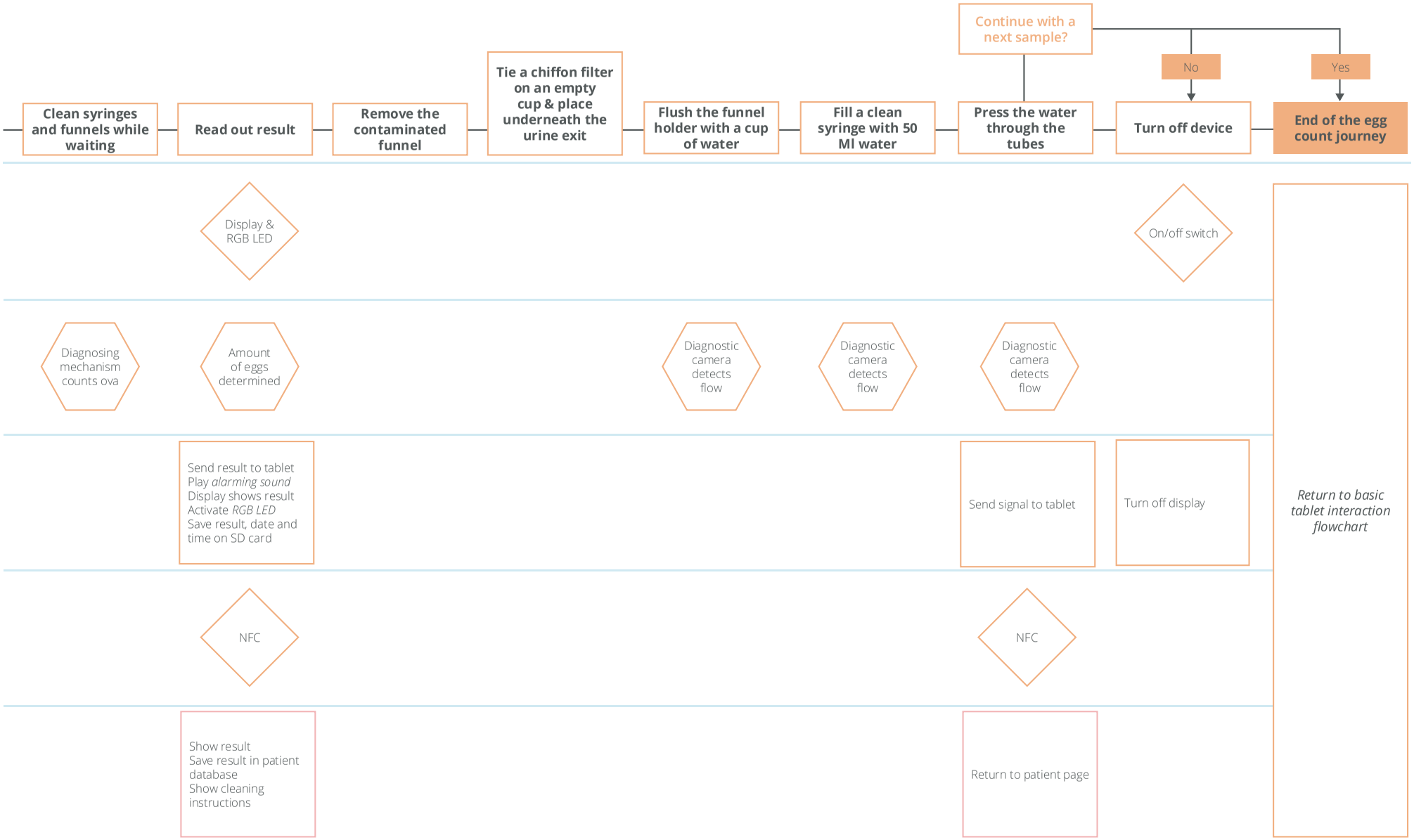
Place sample underneath urine exit

Press start

Take 10 ML urine with a syringe

Pour urine in the funnel

Interaction user and table	On/off switch					Start button		
Actions diagnostic technolgy								Diagnostic camera detects flow
Action device	Activate *battery lights* Play *activation sound 1*					Send signal to tablet Play *activation sound 2*		Send signal to tablet Display shows *"PROCESSING"*
Interaction device and tablet						NFC		NFC
Action tablet	Show instructions about sample preparation					Show instructions about how to pour the urine in the device		Show instructions about what to do while waiting


Clean syringes and funnels while waiting
Read out result
Remove the contaminated funnel
Tie a chiffon filter on an empty cup & place underneath the urine exit
Flush the funnel holder with a cup of water
Fill a clean syringe with 50 Ml water
Press the water through the tubes
Continue with a next sample?
No
Yes
Turn off device
End of the egg count journey
Display & RGB LED
On/off switch
Diagnosing mechanism counts ova
Amount of eggs determined
Diagnostic camera detects flow
Diagnostic camera detects flow
Diagnostic camera detects flow
Send result to tablet
Play alarming sound
Display shows result
Activate RGB LED
Save result, date and time on SD card
Send signal to tablet
Turn off display
Return to basic tablet interaction flowchart
NFC
NFC
Show result
Save result in patient database
Show cleaning instructions
Return to patient page

Appendix O. Attachement the power cable

As explained in chapter 7 (part 3), the cable of the solar panel should at least be 5 meters long. When the solar panel is not in use, it can be attached to the product by hanging it on the back, but the 5 meters of wires would still be laying around. Therefore a clip is preferred to place the wires neatly and compact in the intended position.

Inspiration

To keep wires in place, different options are available (see figures below).

1 

2 

3 

4 

5 

6 

7 

8 

9 

Criteria

To choose the most suitable method, the following criteria are taken in mind:

1. Easy; detach and place the wire without struggles. Wires are always a source of frustration when getting all tied up and 5 metres of wire will not be easy to handle. When the attachment is not easy enough, the user might still choose to let the wire lay on the ground.
2. Cheap; this is an accessory which is not of high priority for the functionality. Therefore, the price should be negligible compared to the total costs. It might not cost more than 1 Euro, but preferable as cheap as possible.
3. Robust; it cannot be expected anyone will be carefully attach the cable. And when a lot of force is used to loosen the wire, it should not break.
4. Replaceable; in case it still breaks. Especially for the researchers who bring the devices with them in the field, this wire clip makes the total product more portable and compact and therefore needed it the most. Those users are coming back to the bigger cities to eventually buy some new clip, so it must be possible to buy a new one in local shops.
5. Easy to clean and able to withstand cleaning chemicals. Not all materials can handle those chemicals, especially from cheap products. And even though it will be placed in the back of the device, where it will most likely not get dirty on daily base, it must always be possible to clean it in case some urine or other infectious fluids are spilled over the device. So, small edges and rough surfaces should be avoided if possible.
6. Attached to device with a waterproof connection. It is not for sure, that this tool can be integrated in the housing. So if it is a separate part, it should be attached for example by screws without creating impossible edges to clean.

Selection

The easiest solutions might be a clip as shown in option 1, 3 and 8 which can easily connected via screws to a flat surface. Options like 2 or 4 will create some extra challenges for cleaning as well as the option to replace them when broken. Option 7 is both easy to clean as to attach. However, compared to the others you need to actually roll up the full wire instead of clipping it behind some barricade. Option 5 and 6 will both be the strongest options, where 6 is easier to clean than 5 especially since this one can be taken of the device to clean separately. Finally, option 9 is a very interesting solution, but it is questionable if such a product can be attached to the device without creating nasty edges, while also being strong enough. As mentioned earlier, snap connection are not preferred. One could also think of other connections such as magnets or a simple cord.

So, there are a few suitable solutions:
Idea 1. A clip like option 1, 3 or 8 would be a simple and locally producible option.
Idea 2. Option 6 is strong as well as simple to attach and substitutes are most likely to be found in each city.
Idea 3. A simple cord to bind the wires together.

Testing

The three methods are tested with simple attachments on one of the latest prototypes (figure 1, 2 and 3), to see how well each clip can position the wires and to evaluate the needed effort. As can be seen in all pictures, one touch point was not enough for neither of the methods and a second clip was placed below, to support the cables. This second clip was kept the same in all three tests.

For idea 1, a plastic clip was used to test the principle. Within this test, it became clear that idea 1 (figure 1) would definitely be too fragile when made of plastic, as it was already bending with a little force. The clip should instead be made from a material like metal to prevent it from breaking under pressure. Furthermore, the clip was very easy to use and the wires stayed perfectly in place.
In idea 2 (figure 2), a carabiner was used to bundle the cables together. Unfortunately, the carbiner could turn around its axis which gave the cables the freedom to move away from the product surface. This was in contrast with the plastic clip

Figure 1. Idea 1

Figure 2. Idea 2

of idea 1, which was able to push the wires closer to the device to limit the needed space. So, even though the carabiner was a stronger tool, it was not able to keep all cables near the device if not wrapped tightly around the touch points. Besides, the carabiner did not open smoothly, which made it difficult to detach the cables. With old or cheap carabiners, there is a high chance this detaching will even be a bigger struggle.

For idea 3, a simple cord was used to tie in a loop around the cables. It was definitely the fastest method but the cables were spreading in all directions, even worse as in test 2. The cord did not give any support at all.

This test was only done with a cable of 1 metre. When the cable length increases the effort of binding it together will raise even more. Since the clip was giving most support, this will be used in the final design as will be further explained in chapter 7. Furthermore, it was concluded that one touch point is not enough to keep the wires in position.

Figure 3. Idea 3

Appendix P. User test LUMC

Test setup

Date: 11-07-2018

Participants & planning

10:30 – 11:00 Participant 1 (Post-doc LUMC)
11:00 – 11:30 Participant 2 (PHD LUMC)
11:30 – 12:00 Participant 3 (PHD LUMC)
12:00 – 12:30 Participant 4 (PHD LUMC)
12:30 – 13:00 Evaluation Dr. G.J. van Dam (hereinafter: Dr. van Dam), an expert in Schistosomiasis diagnoses.

Goals

- Verify interaction (completeness & suiting current habits)
- Improve manual (ease of use & completeness)
- Manual design
- Discuss users and required training per target group
- Evaluate and explore cleaning possibilities

Setup

- Introduction project
- Introduction users
- Part 1: Test prototype
    - o Test interaction with manual attached (without tablet) + thinking out loud
    - o Interview questions afterwards to discuss the interaction
    - o Questionnaire questions: How intuitive was the interaction? How much training is required for the different users?
- Part 2: Manual designs
    - o Show 3 designs for the manual: Colourless & sketchy; Coloured & detailed figures; Actual pictures
    - o Evaluate via interview questions
    - o Questionnaire questions: Which design was preferred and why? And which would suit each user?
- Part 3: Cleaning the device
    - o Interview questions: propose current ideas and evaluate
    - o Show options on slides & discuss

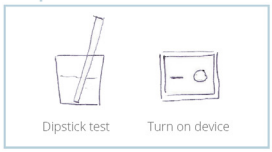
Materials and equipment

- Camera
- Prototype + manual attached
- Lights inside the prototype, for light effects
- Mobile phone with sound effects
- Separate
- (Fake) urine in sample cup + sample number
- Cleaning water
- Syringes (10 ML and 60 ML)
- Cups
- Trash bin
- Textile “filters” + elastics to tie over a cup
- 3 Manual designs (as shown on the next page)
- Slide show cleaning ideas

User manual

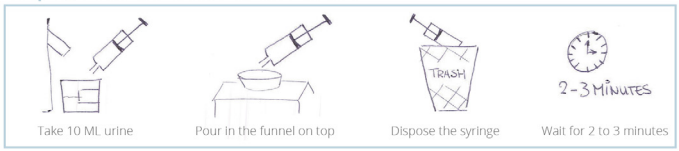
S. haematobium diagnoses

Step 1: Start



Step 2: Prepare device

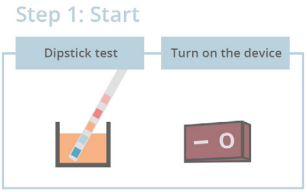
Step 3: Pour the urine in the device



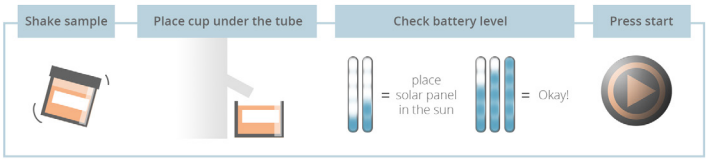
User manual

S. haematobium diagnoses

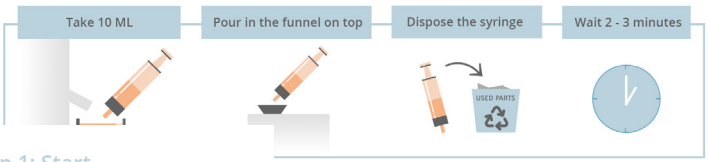
Step 1: Start



Step 2: Prepare device



Step 3: Pour the urine in the device



User manual

S. haematobium diagnoses

Step 1: Start

Turn on device

Step 2: Prepare device

Shake sample | Place cup | Check battery level. If low, place the solar panel in the sun | Press the start button

Step 3: Pour the urine in the device

Take 10 ML urine | Pour in the funnel on top | Dispose the syringe | Wait for 2 to 3 minutes till the result appears

Results

The results are split up in questionnaire results and interview results and will end with some insights of an evaluation discussion with the senior researcher. This appendix will summarise the main findings of the user test, but the final insights are discussed in the product validation (chapter 9).

Questionnaire results

1. Was the interaction with the device intuitive? (1 = not at all; 5 = very much)

Participant	1	2	3	4	5	Why?
1				X		Very intuitive, but I did not notice the cleaning requirements.
2					X	-
3			X			I think the steps can be more clear to improve comprehension without needing someone to be sure we are doing good.
4				X		-

2. How much training do you think is advisable for each user group, to use this device correctly?

	No training	Reading a manual	A short briefing (one hour)	One day training	Several days of training
Urban hospital technicians	X	X X	X	X	
Remote HC staff	X	X X		X	X
VHTs		X X	X	X	X
Teachers		X	X X	X	X

Answer participant 1 = X ; Answer participant 2 = X ; Answer participant 3 = X; Answer participant 4 = X

3. Rate the designs on the following characteristics (1 = not at all; 5 = very much)
Design 1 = black & white
Design 2 = colour
Design 3 = pictures

Does the manual look professional?	1 (not at all)	2	3	4	5 (very much)
Design 1		X X		X	X
Design 2			X	X	X X
Design 3			X X		X X

Does the manual look appealing?	1 (not at all)	2	3	4	5 (very much)
Design 1		X			X X
Design 2			X	X	X
Design 3			X	X	X

Does the manual look easy to use?	1 (not at all)	2	3	4	5 (very much)
Design 1			X		X X
Design 2			X	X	X
Design 3			X		X X X

4. Which manual would suit the different user groups?

	Design 1	Design 2	Design 3
Urban hospital technicians	X X	X X X	X X
Remote HC staff	X X X	X X	X X
VHTs	X	X	X X X X
Teachers			X X X

Answer participant 1 = X ; Answer participant 2 = X ; Answer participant 3 = X; Answer participant 4 = X

5. Which would you prefer? And why?

Participant	Preference	Why?
1	Design 3	Actual pictures are easier to follow. Since it seems more real.
2	Design 1	To the point. "*Niet teveel poespas*."
3	Design 1 & 3	Design 1 is suitable for the device and easy to understand. Design 3 is more suitable for training, then trainees can see in reality what they have to do.
4	Design 2	I would prefer the colours

Interview results

Participant 1

Experience
- Post-doc / biomedical researcher
- Experience in Ghana and Gabon

Interaction
- Gloves are normally used
- What to do with the 50 ML syringe?
- Not clear that the sample cup was used to recollect the urine, that comes out of the device.
- Cleaning is forgotten, especially the steps after documentation of the results. When completing this task, it is assumed to continue to the next line.
- Familiar aspects of cleaning are recognised and assumptions are made about how to clean, making it easy to miss one of the steps
- Explanation about the filter was needed to understand its purpose
- Cleaning might get a separate LED light and mark around it, as if it is a new step.
- Attaching the filter is a bit of a struggle.

Cleaning and wrapping up
- Syringes are not thrown away in the field trips. But cleaned afterwards.
- They currently use bleach to clean the water, but this might not be available in all HCs
- Not for sure if bleach kills the eggs, but it is the standard approach
- In the field, washing already takes some effort and time, so a bit of cleaning effort is not a problem.
- The used cleaning water is poured down in the sink
- The sample cup is not needed underneath the tube, the recollected urine might be disposed since it is only 10 ML of the sample.

Participant 2

Experience
- PHD student LUMC
- Experience in Gabon

Interaction
- "On button forgotten". She assumed she could skip that line since she did not needed to do a dipstick test. This might also be the case if they walk away to do the dipstick test and come back afterwards. The steps "turn on the device" and "dipstick test" could for example be switched to avoid this problem.
- Attaching the cleaning filter in the cleaning phase, was not clear. Neither the purpose of the filter.
- "Result" and "cleaning" could be split up in two separate boxes to avoid confusion.
- "Shake sample" should become "Shake urine sample"
- Explicitly tell them to use a clean syringe
- An option would be to work with colours (or lights) to show which parts should be disposed or cleaned and which to reuse without cleaning.
- Solar panel was not visible and easy to miss when sitting in front of the device, the same happened with the on/off switch on the side.

Design manuals
- Design 2 visualises what full and empty battery levels are

Cleaning
- Does not know how sticky the eggs are, but flushing seems to be sufficient
- Eggs are hard to kill, they might survive for weeks but this should be checked
- 10 years ago, everything was cleaned with chlorine, by letting it stand for at least 12 hours in chlorine. This could also be done with the filter.
- Nowadays they use chlorine tablets, which are for sure not available in all remote areas.
- You need to be sure the filter catches everything.
- Boiling the eggs to kill them, must be tested.
- When the temperature is high enough they will likely hatch. Otherwise they stay ova and die after a while. But the eggs are tough and it would not surprise her if they can survive for weeks in the urine.

Participant 3

Experience
- PHD student LUMC
- Experience in Gabon

Interaction
- How to shake?
- Assumed to open and close the sample cup.
- The purpose of the cleaning filter in the end, was not clear.
- Tell explicitly to get a "new" cup when the cleaning starts.
- Tell what to do with the collected urine after the test.
- Dipstick test is already in their routine and it might be confusing if the device is telling them to do it. Dipsticks are often also part of other diagnoses and standard tests and might have happened already. When the device asks for a dipstick test, they might think the results are needed for the device, or that they have to do it again. Leaving it out of the manual would save this problem and they can continue their own protocols.
- Shaking should be done later, just before taking the urine of the cup. So maybe when you already pushed start. Or at least after checking the battery levels. Urine is, especially in this way, only taken from the top. So shaking is crucial or the syringe method has to change.
- You could also collect the tested urine in a separate cup, it is thrown away afterwards.

Training and design manuals
- They will still need someone to explain it.
- The time needed will depend on the group size.
- You could also let them just try it as we did now and use this to further improve the manual.
- Pictures are more real.
- People will follow the manual if it is easier than their current method.

- Design 1 will be more easy to use. But the pictures are the most clear, but might be more suitable for in a separate manual. Or they could be used in the training.
- All look professional.

Cleaning
- Bleach tablets are used, placed in the collection cup to clean all collected urine.

Participant 4

Experience
- PHD student LUMC
- Experience in Gabon

Interaction
- Place “sample” “under the tube” instead of “place cup”
- Funnel holder “of machine”
- The manual says “low battery” while the machine says “empty”
- It should be more clear when the battery is too low. For example by individual lights or stripers for the indication
- The manual said “red infection” instead of “heavy infection”
- It must be more clear how to document result. For example “write down result for patient record” or print the result.
- When looking back to the results for example on the SD card, it is important to know the date, time and sample number (in case people lose the paper records).
- In Gabon, patients have to come back 3 days in a row, in case the eggs do not show up the first test, but a person is infected.
- Specify what kind of water to use, instead of just “clean water”. This might be “distilled water” or “mineral water”.
- Specify what kind of syringes, are they disposable or reusable?
- Specify what to do with the urine after the test. And the funnel.
- “Remove sample” instead of “remove sample cup”.
- One could collect all urine in one big vat.

Evaluation with Dr. G.J. van Dam

Dr. van Dam is an expert in the field of schistosomiasis diagnoses. He visited the test setup and had about 30 minutes to discuss the design and share his expertise. The following interesting topics were discussed:

- Testing full samples instead of 10 ML would improve the sensitivity and the device should be able to process larger volumes if relevant.
- It should fit in hand luggage.
- It must be strong enough to survive falling.
- It must be closed from water and dust. “*Dust will kill it*”.
- It should be heavy, but not more than 3 or 4 kg to keep it portable.
- You could use the tablet, but you could also just read out the chip afterwards.
- A built in GPS to connect the results to the location in the field, would be a huge benefit.
- People / patients might not trust the results. Sometimes it is most efficient to do the testing in the middle of the community/village to show what you are doing with the urine and what the result is. It has been proven to be effective to do the dipstick test and show that something is out of ordinary to make them believe that something is wrong. Especially adults are difficult to convince. People are afraid that it is birth control instead of a medicine. So this device would be a perfect tool to “*serve for acceptance*”.
- Flushing seems the best method to clean.
- Teachers are not ideal group to do diagnoses. They are paid less and people trust them less. Furthermore, they do not want to get the responsibility and they are not educated for it. Not all teachers are able to handle such device. But this device would suit the HCs perfect, since you do not need microscopic skilled/trained people to control it. So a much larger scope is targeted. And when they can deal with it, the hospitals are definitely be able to use it too.

Appendix Q. Changes made to the interaction, based on the user test

Indication lights were used to guide the participants and confirmed certain steps. However, due to the bright lights in the room, only 1 out of the 4 noticed the lights and it could be assumed that stronger effects are needed to be noticeable within bright sunlight.

Shaking the sample was originally done as one of the first steps, to make sure users would not forget. However, 2 participants suggested that this might be too early, leading to new sediment creation. To minimise this problem, shaking the sample is the last thing one has to do before starting the device (after checking the battery level and placing the cleaning funnel. For the health facilities, shaking might not even have been necessary as the full sample will be analysed. However, shaking is added just in case they might only pour in a part of the sample.

A first version of the manual mentioned that the user had to place the solar panel in the sun, whenever the battery level was low. However, feedback was given to visualise what an empty battery signal looked like.

The steps had to become more clear. Even with icons and text, it was still difficult to understand the exact interaction. This would not be a problem for the researchers who can have an extended manual on the tablet and some training. However, for the health facilities it is not sure whether each user will receive a training and the usage had to be simplified. This is done by decreasing the amount interaction of steps for the remote areas, especially in the cleaning procedure. Initially, it was decided to let the remote facilities use syringes too, for cleaning the tubes. But, beside the fact that syringes can easily get lost or dirty ones can be reused, the interaction requires some more explanation than simply flushing the tubes with water. Especially when an interaction or method is not as expected (for example new cleaning methods), the participants became confused and did not understand the manual. This confirms the choice to adjust the usage on the specific user habits of the target group (testing 10 ml with syringes for researchers, while the remote areas can pour the whole sample directly in the funnel).

And for the cleaning method, as the use of the chiffon filter was not familiar, it raised a lot of questions before it was used. This aspect should definitely be explained in the training. And, the researchers are nowadays using bleach tablets to disinfect the cleaning water before disposing it in the sink. The use of a chiffon filter will reduce the need of chemicals and less damaging for the environment. Though, as it is not in line with their current habit it should be implemented in the research training, including an explanation.

It should be more clear what to do with the used parts (e.g. syringes, cups, water, urine). To make this as simple as possible, the interaction for health facilities does not include any separate parts to clean or dispose, others than their own urine collection cups, which they are familiar with. For the researchers it should be implemented in the digital manual.

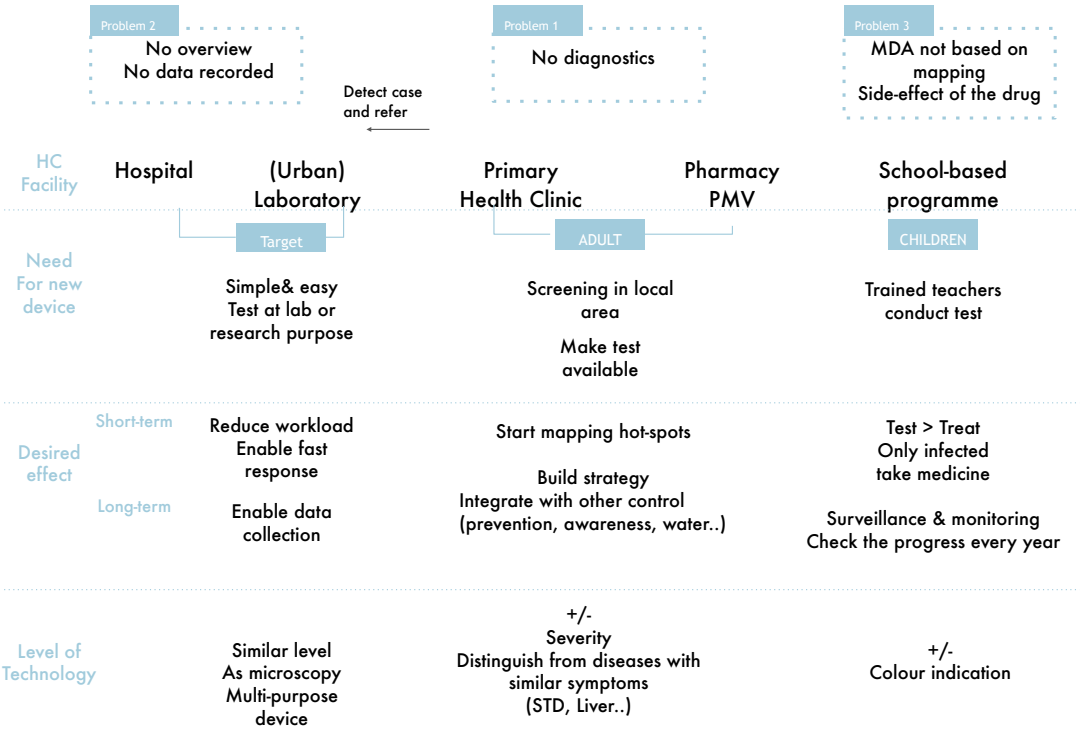
Firstly, documentation of results was combined with the cleaning instructions. But as this gave confusion and participants did forget to look at cleaning instructions after finished with the documentation, they are now separated in the design.
Confusion existed about when to use a new or clean syringe or cup. For the remote facilities, this problem is eliminated by leaving all these syringes, funnels and collection cups out of the interaction. This will not only avoid any confusion, but prevent cleaning mistakes to influence the results.

Appendix R. CVD session

The results of the CVD session are summarised by MSC G. Van, who executed the field research in Nigeria.

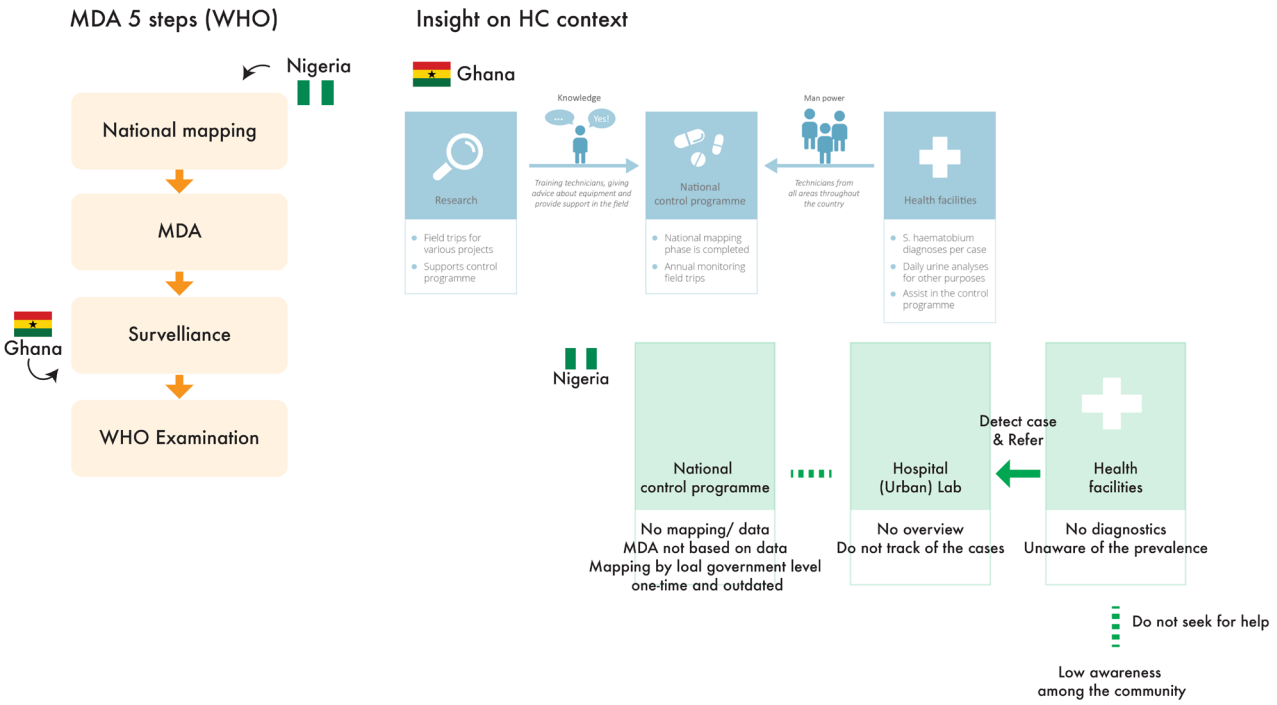
Schisto- CVD

Summary of Nigeria context



Schisto- CVD

Current situation



Key findings

Ghana		Nigeria
	Shared Insight Session	
Opportunity areas		
Control programme & Remote HCs		Start screening & data collection
What is needed the most		
1) Integrate into the current system and make use of current resources 2) Overcome limitations such as budget, lack of personnels..		1) Make the diagnostic available at the lower level of HC 2) Start collecting data to build strategic response

Shared solution

Making the diagnostic more available and affordable
Making the diagnostic more efficient and easy to use

Variations

Diagnosing will be the first to cut when the budget is low. "Saving money by saving time"	Enabling "Test & treat" instead of MDA Finding the hot-spots

Schisto- CVD

Shared solution space (Design requriements)

Ghana

Nigeria

Opportunity areas in the HC System

Control programme	Research	Urban HC	Rural HC
School-based intervention	Hospital Urban lab	Primary HC	Pharmacy PMVs

Design requirements

Suitable for field trip and control activity Digital data processing Less training required Saving money by saving time Robust for transport Portable Small & easy to carry Not too light	Cheap Fool-proof Self-explanatory Easy to use Easy to clean Local maintenance Paper "back-up"
Use available human resources User-friendly & clear information	Efficient and systemic data processing Standardized data collection & storage Increase trust in such a simple device Add simple way of quality check