Fluid**Balance**

"A Product-Service-System for accurate and efficient fluid balance measurements on hospitalized patients."

Graduation Report

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FluidBalance

Client:

TIM

Supervision:

PEZY GROUP innovation accelerators

TU Delft Delft University of Technology

"

a Product-Service-System for accurate
and efficient fluid balance measurements
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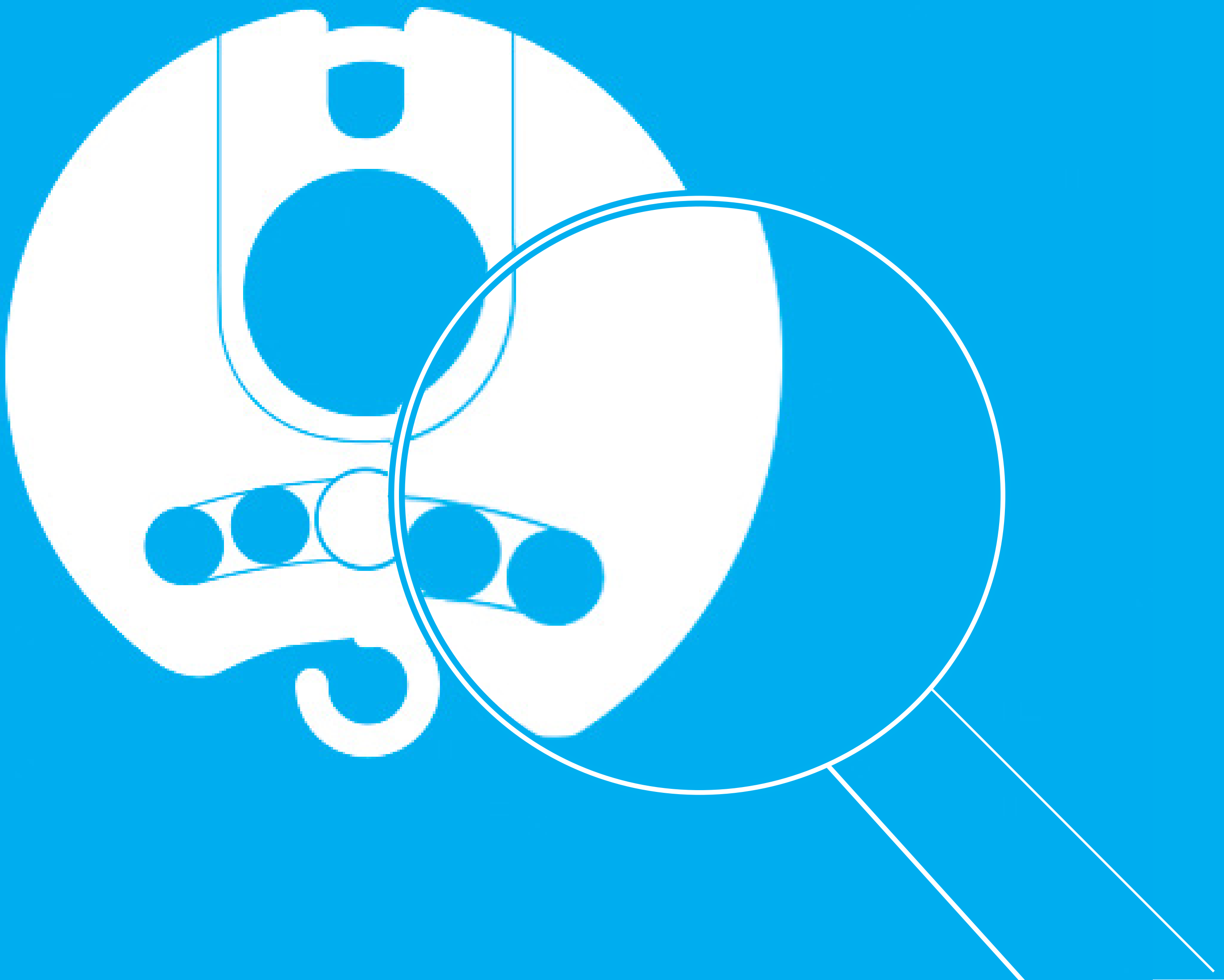
"



A thesis submitted in partial fullfillment of the requiements for the degree of

MASTER OF SCIENCE

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Preface & acknowledgements

This graduation project marks the end of what will be the next step in my life. The project brought me much joy, new knowledge, frustrations, much hours or work, proudness and most of all a job! Working by yourself on a project that you can call your own for half a year led to both positive and negative findings about myself. Motivation is defenitely not the problem, I will always give everything I have to make each project a success. Having to make decisions all by yourself, I was sometimes afraid to overlook important aspects that would lead to problems lateron. This is why I want to thank my supervisory team for making time for me whenever I needed it. I could literally just walk into Stefan's office to talk about the project (or other things) for about two hours. Especially in the beginning I came by almost weekly. I want to thank Ruud for providing feedback whenever asked for and for pointing me into directions that were just a little away from the path I was walking. This made me think even more holistic and improved the completeness of the project. Thanks to both of you for always supporting my choices, giving me the freedom to come by when I thought it was necessary and not pushing me otherwise.

Furthermore I want to thank Dennis Vervoorn for our weekly meetings on Wednesdays. Thank you for providing feedback and listening to my lists of work that I had prepared. Thank you for being honest with me about my work and about possible bottlenecks. I hope that we can work together on future projects and to learn even more. Also thanks to my other collegues, Jasper, Dennis van Swieten, Lotte, Mathieu, Luuk, Gernout, Erik-Jouke, Roy, Dirk Soeterman, Sander, etc. for listening to my enthusiastic stories and sometimes even helping me out with battery calculations,load cell questions, ideation on system parts, etc. Of course I want to thank all my collegues for involving me in interesting and someimes somewhat weird stories.

The company TIM Solutions also added much value to the project by offering medical knowledge and guiding me when I needed to visit the UMCG. Thanks to Rick Pleijhuis it was easy to move around within the UMCG and to talk to different stakeholders. Rick helped to arrange meetings with different people like: Eric Bartens (Connectivity department), Jan Bos (buying department), Maarten Nijsten (Intensice Care ward), Hendrika Wollerich (leading nurse at the nephrology), etc. who provide valuable knowledge for the project. Also thanks to all the nurses from the UMCG, HAGA hospital and RDGG that provided feedback on my concepts and concept scenarios. TIM Solutions also gave me the possibility to joint the ESA Rocket program where I got to meet fellow participants and two people from Verthaert (Stijn and Filiep) who though me inspirational lessons about how to start a startup. Thanks for this opportunity.

Finally, I want to thank my friends, familiy and my boyfriend for supporting me throughout the project. Special thanks to my fellow students Tine Hoogterp and Debbie Rouw for all the talks we had about our projects and the moments that we worked together.

List of abbreviations

IV	Intravenous
EPD	Electronic patient file
COW	Computer on wheels
UMCG	Universitair Medisch Centrum Groningen
RDGG	Reinier de Graaf Gemeenschap
IVAC	Intravenous Computer
TIM	Technical Innovation in Medicine
PCC	Patient Centred Care
IC	Intensive Care
FMEA	Failure Modes & Effects Analysis
V-model	Verification and Validation model
E-paper	electronic paper
MDIS	Medical Device Information System
HL7	Health Level Seven
PCB	Printed Circuit Board
PC	Poly Carbonate
PLA	Polymerized Lactic Acid
PA	Polyamide
SLS	Selective Laser Sintering
LNAG	Landelijk Netwerk Assortimentscoördinatoren in de Gezondheidszorg

Executive summary

The problem encountered by TIM Solutions was mainly based on experiences of their own in different hospitals. The project was therefore started with mapping the wishes of possibile users and mapping the current context. Already in the beginning it turned out that fluid balance measurements are well based estimations as not all aspects are being monitored and recorded. Aspects like sweating, vomitting, heavy diarrhoea were not taken into account. Frustrations about the paper fluid lists getting lost, not knowing when to replace intravenous (IV) bags and communication between different care takers became clear. The different departments more or less created a way to work aournd the issues. For example, replacing of IV bags at the geriatrics department was sometimes done far before the bag was really empty to avoid forgetting to replace it. This means that the old IV bag will be thrown away before it is fully used.

Another important aspect was the division in responsibility around registering the fluid balance. It turned out that there is a big difference between involving the patient and giving the patient responsibility. Involvement is preferred by both patient and nurse, but responsibility needs to be avoided at all times. Most patients from whom an (hourly) fluid balance overview is required are quited ill and therefore incapable (mentally or physically) to take over tasks that contribute to their recovery. Patients need to have insight in how to contribute to a quicker recovery in a positive way (involvement), but the nurse is responsible in the end.

The product-service-system was divided in different system parts. These different system parts were eventually combined to several concepts that were discussed with multiple nurses at the following wards of the UMCG: geriatrics, nephrology, cardiology and intensive care. Furthermore three nurses from the Haga hospital and the RDGG provided feedback throughout the process.

Most wards preferred to have a product-service-system that is being controlled by the nurse (and assistant) and can be used by the patient when the nurse approves. The final product-service system consists of one tablet (including tablet holder), one adapter, multiple hooks and multiple FluidBalance hangers.

Interaction wise it was prefered to assemble as much functionality into one place at an ergonomic height, meaning that the FluidBalance hanger only requires interaction when (un)installing. Further interaction will happen on the FluidBalance tablet and computer on wheels (COW).

The FluidBalance hangers will gather information about their attached bags. This information will be send to the tablet using Wi-Fi. The tablet will be a central entrance point for all other gained and lost fluids and will calculated the patient's fluid balance. This information will be send to the COW which means that it will be added to the patients electronic hospital file (EPD). (figure 1)

After defining the overall product-service-system the focus shifted to the conceptualisation and embodiment of the FluidBalance hanger. Both internal and external embodiment were investigated and tested. Several prototypes were used to investigate: accuracy, how to control influences due to movement of the patient, how to attach the product somewhere around the patient's bed and how to compile the right components to make sure that the product will last for a few months. Findings based on interviews with nurses and trials with different Arduino codes have led to the first working model of the FluidBalance hanger (figure 1).

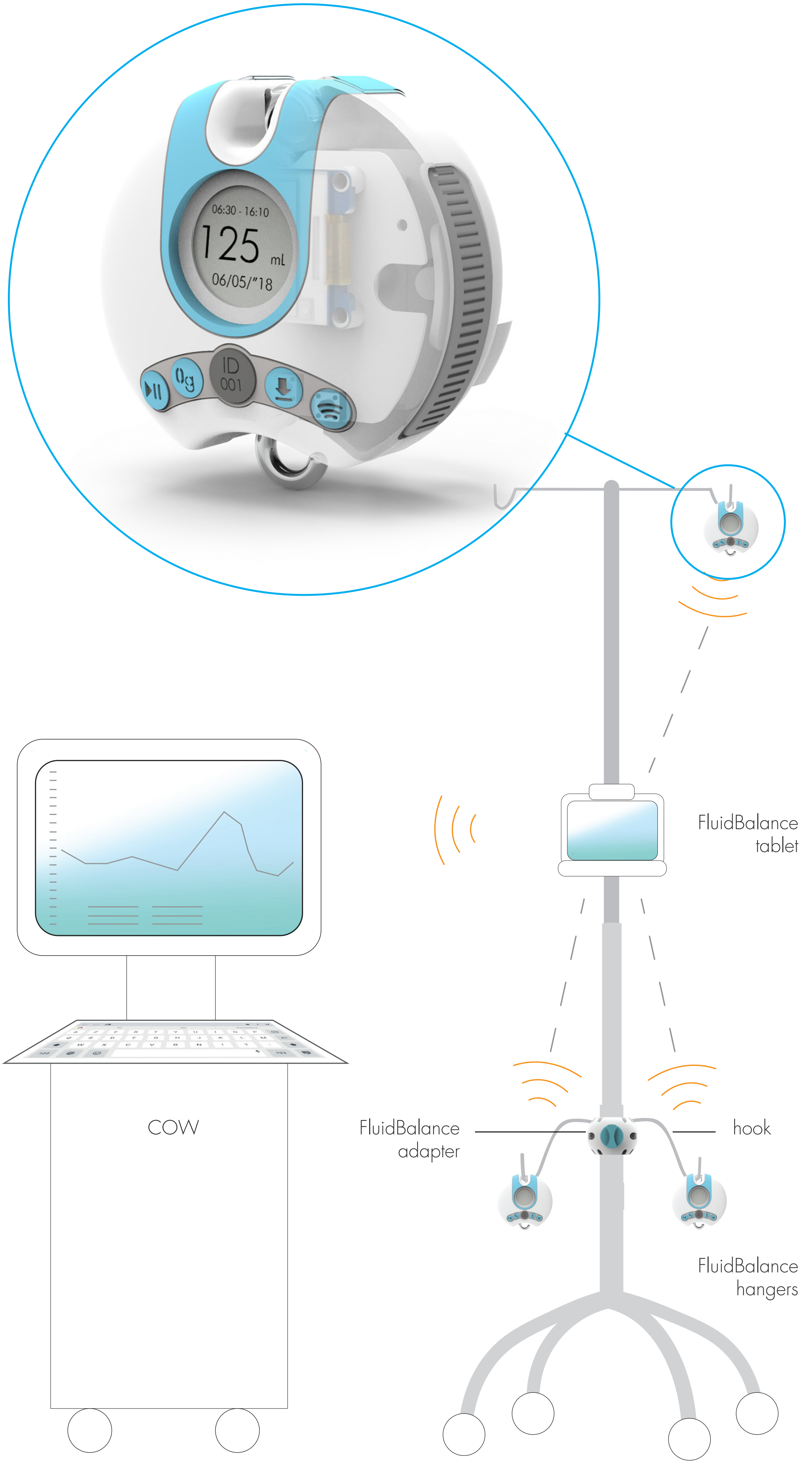

Figure 1: Overview of Product-Service-System

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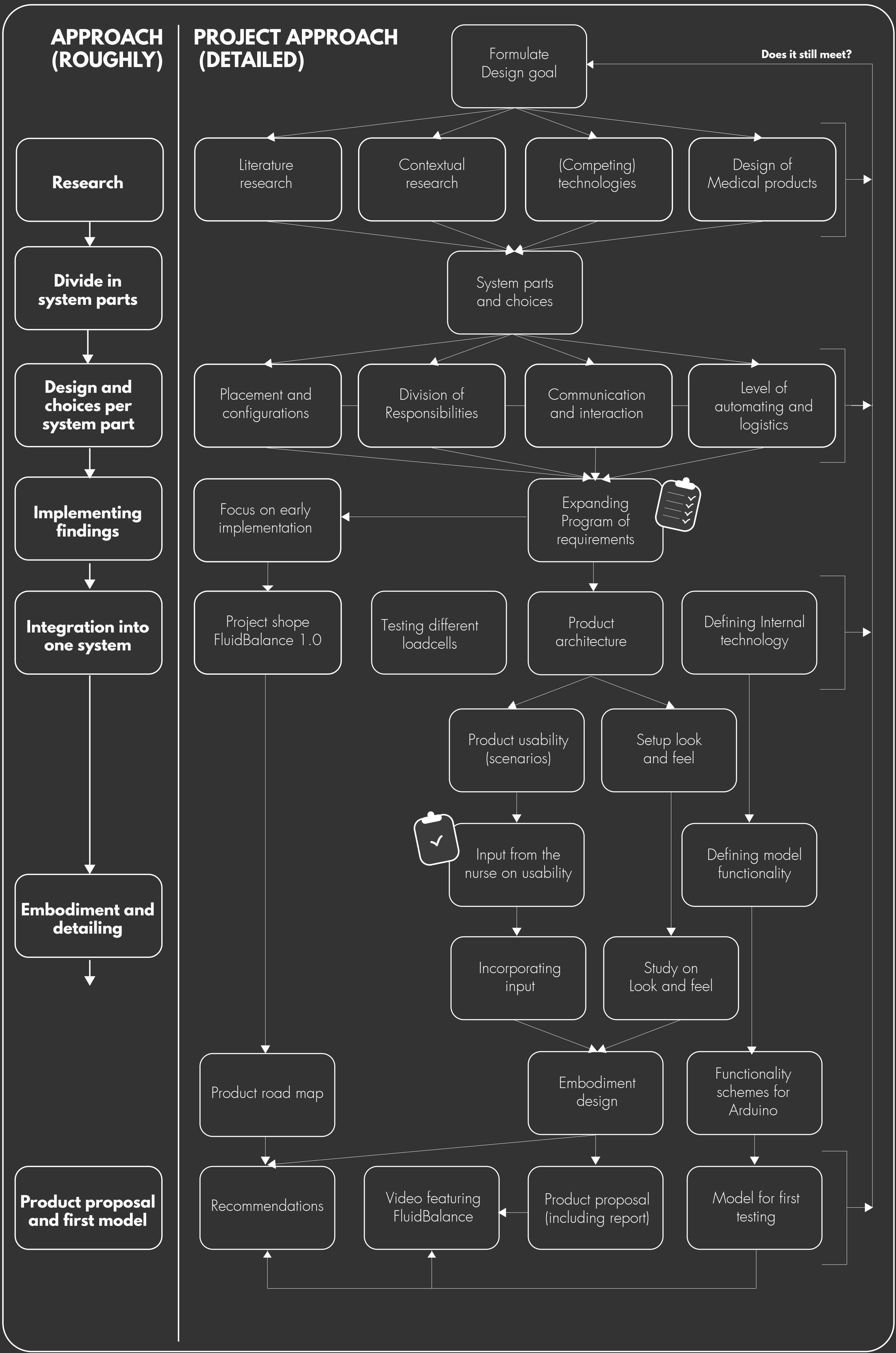

APPROACH (ROUGHLY)
PROJECT APPROACH (DETAILED)
Formulate Design goal
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A. Introduction to the project

1 Project

Fluid balance (Euhydration) is the balance between all the fluids that enter the body minus all the fluids that exit the body. It describes the state or situation of being in water balance (Shirreffs, 2003). For a normal and healthy person, this process is regulated by the body itself as long as a person drinks 1,5 - 2 litres per day. The fluid balance can become positive (hyper hydration) or negative (hypo hydration). Chapter three will provide a more in-depth explanation of the fluid balance components and their contribution to the total balance.

1.1 Fluid balance and complications

Due to multiple factors like illness, undergoing an operation and transpiration a person can get dehydrated. In that case rehydration by drinking enough fluids or gaining water via intravenous bags is necessary. A correct fluid balance is very important for a healthy body and effective recovery. In fact, a shortage in fluid and nutrients can lengthen and even block the recovery process (Gelmers, 2010). To reduce risks during treatment there one is aiming for maintaining a normal/high filling value of the veins. The degree of recovery is partly determined by whether or not a bleeding disorder is occurring. This depends on the filling state of the veins and therefore on the fluid balance as blood vessels are partly filled with water. (Hoff, 2008).

Improving accuracy in calculations of patients' fluid balances will reduce the length of hospital stays due to the fact that the medication and intravenous input can be customized even better. Omar Hertgers (Assistant doctor) estimated that 50% of cardiology patients and 25% of geriatrics patients are currently being hospitalized for too long because of fluid balance inaccuracies.

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1.2 Problem definition

Each year approximately 250.000 patients (in The Netherlands only) need regular (sometimes hourly) fluid balance measurements which need to be written down in their patients files. Fluid balance measurements and reminding the patient to drink are currently done by nurses in person. This task is time consuming, interrupting the nurse during other tasks and most of the time inaccurate (Spaan, 2017). Furthermore, as fluid balance measurements serve as input for the treatment plan, an inaccurate fluid balance means that patients receive wrong medication, which often leads to a stay inside the hospital longer than needed which leads to bad experiences and high costs for the hospital. Finally, expensive transparent fluid and urine bags are needed for "accurate" registering which lead to high costs as well.

1.3 Project goal

A product should be designed that will take over the process of manually measuring and posting up fluid balance values by automatically performing (hourly) measurements (depending on the state of the patient), calculating the current fluid balance of patients and give warnings when needed. This product needs to be used within the existing environment and be able to be combined with current products like different fluid bags and the IVAC (computer that regulates IV input per hour). Moreover, the product needs to be easily placed on and/or around the bed of the patient, needs to be easily understood by nurses, and needs to fit within the environment regarding look and feel Additionally, the product should not endanger caregivers and patients, and medical norms need to be consulted and considered.

1.4 Project scope

The product's main goal is to provide a more accurate fluid balance, reduce workload of the nurse who should be able to customize treatment plans better and earlier. To reach this point several steps need to be taken. The addition chip that is being researched by ESA (European Space Agency) will be able to perform laboratory tests on the composition of urine at the bedside of the patient, which will lead to earlier feedback about how the treatment plan is affecting the patient's recovery. Other fluid losses like heavy transpiration, vomiting on the floor and injection fluids, require more research which will not be a part of this graduation assignment. The focus during this graduation assignment will be on the design of the FluidBalance hanger and incorporating the logistics around fluid intake and output apart from the fluids derived from bags (figure 1.1).

The project aims to provide a product proposal for the FluidBalance hanger (orange circle in figure 1.1) and a testable model which allows to performing first tests and lead to proof of concept. The model needs to be reproduced a few times for testing at different departments at the same time.

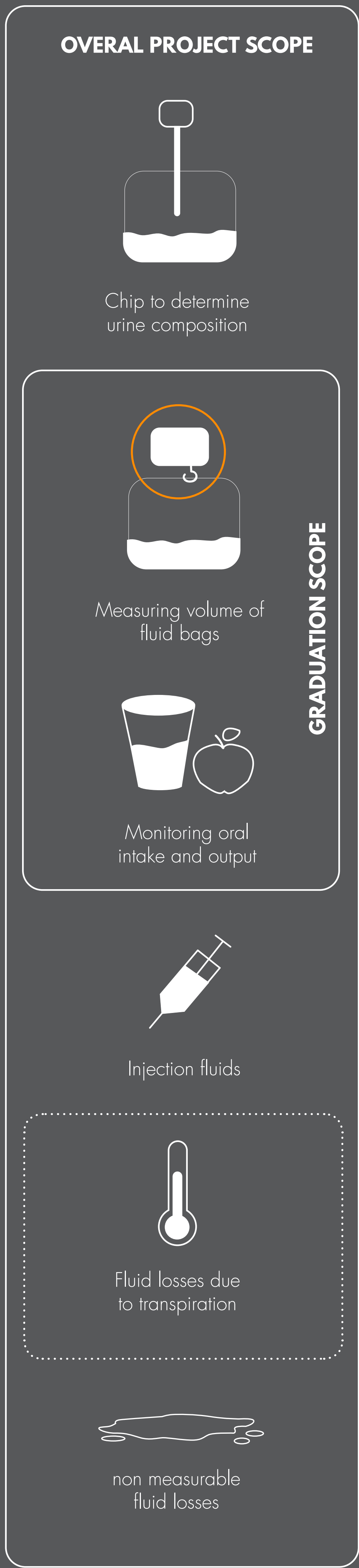


Figure 1.1: Scope overview graduation project

Relevance

Stakeholders (involved parties) determine whether a project is going to be a success or not. They are the people the designer and the client need to consider and involve in decisions where needed. This chapter will introduce the main involved parties and present an overview of the most important stakeholders regarding influence on implementation, interest in a better product and financial connections.

2 Involved Stakeholders

During this project, multiple parties will be involved. Apart from TUDelft, which is the involved Technical University, the main involved parties are TIM Solutions and Pezy Group. First a short introduction of these companies and their interests will be presented.

2.1 TIM Solutions

TIM Solutions is a young cooperation run by medical and technical professionals. TIM solutions' core values are: innovation, improving patient care quality and patient safety (TIM Solutions, 2017).Together they make sure that promising and inspiring ideas do not get lost because of two worlds functioning separately from each other. The founders of TIM Solutions are mostly doctors who are working in the field and therefore have a lot of experience regarding frustrations and problems in the hospitals. TIM Solutions comes up with ideas and develops them to such a stage that start-ups or existing companies can come in and proceed with (or buy) the idea to develop it further or to launch the product or service on the market (Jansen, 2017). So far TIM Solutions introduced four ideas, one of which (Evidentio) is available in the app-store already. This application helps doctors to find, use, make and validate medical calculators and prediction models . The three other ideas: DiagnOSAS, PerfectPose and FluidBalance are still being tested and /or developed. TIM Solutions is a cooperation that tries to create awareness for certain problems in the healthcare industry by coming up with promising ideas. They give life to their ideas by finding investors and providing medical knowledge and experiences from the field to support development until a start-up company is founded. Their goal is to use their (practical) knowledge to boost their ideas into the market and create innovation in the healthcare industry.

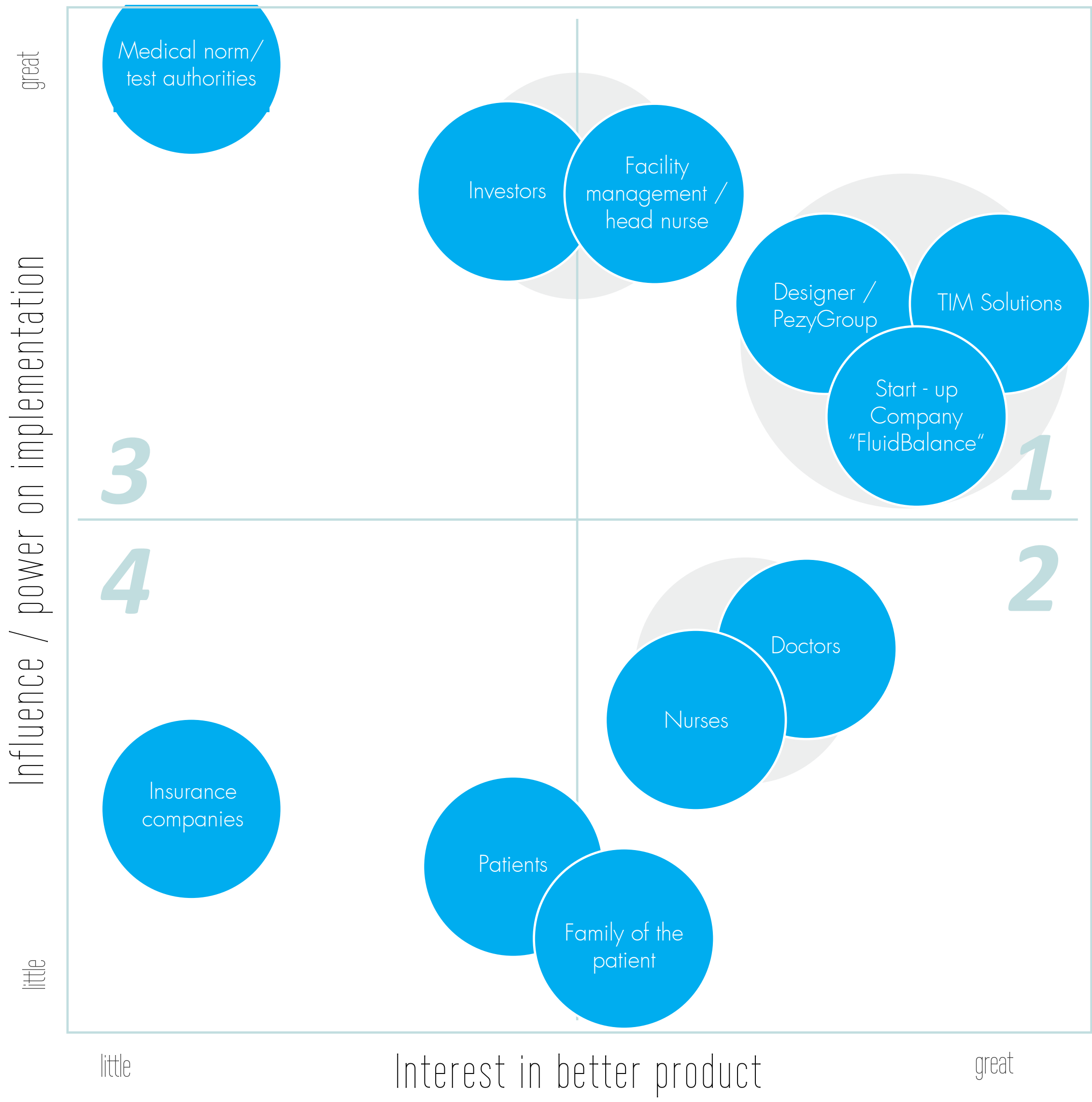
2.2 Pezy Group

Pezy Group is a design agency who describe themselves as: "a hands-on innovation agency. We want to deliver unique innovative solutions with the most engaged work force around" (Pezy, 2017). Pezy Group has more than one hundred employees and has created products for hundreds of companies which led to more than 400 patents. Pezy Group became the first design bureau in the world to be certified with: Cradle to Cradle (Pezy, 2017).

Pezy Group started in 1993 under a different name: CE masters. The following years CE Masters developed until it was a self-functioning design bureau and engineering bureau. In 2008 CE Masters was taken over by Pezy Group which was still located in Groningen. Due to the large demands of customers Pezy Group started a second location in Eindhoven, a third location in Amsterdam and a fourth location in Houten. The different locations have different focus areas. Amsterdam is mainly focussing on the strategic part of the project, Groningen and Eindhoven focus mostly on consumer products and the location in Houten focusses on products for the mechanical engineering. Together they have knowledge about the whole design process and can even create the first batch of small consumer products to test market reactions. The main approach of Pezy Group is based on risk analysis and research on which ideas to pursue (Hoekstra, 2017).

Through this project Pezy Group wants to offer their client, TIM Solutions, a low budget way to investigate their product idea and create the first working prototype for testing purposes. Pezy Group would like to see this project continue to grow and continue working on the project together with TIM Solutions after this graduation project. Eventually Pezy group wants to introduce a well-developed product that is ready to be sold on the market (de Regt, 2017).

Figure 2.1: Stakeholder overview based on influence and interests



2.3 Stakeholders (Influence and interest)

Not all of the stakeholders have the same level of interest and influence on the implementation of the product as others. The overview in figure 2.1 shows the positioning of the different stakeholders involved. The numbers refer to:

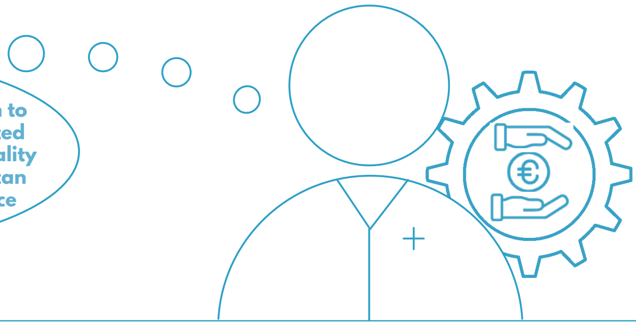
1: Most important stakeholders
2. Most interaction with the new product. This group needs to be consulted for advice and kept in the loop of updates.
3. This group needs to be considered, but does not have much influence on the project.
4. This group needs to stay satisfied

Medical norms determine whether a product is allowed on the medical market or not. They set the limitations for the product and the project. The investors need to be considered as they provide the company with money as long as they think the project will be/or become profitable for them. The facility management of the hospital needs to see the advantages of FluidBalance as they have to divide the yearly budget which is provided by insurance companies, based on the number of patients they have. If FluidBalance saves the hospital money or will save money in a few years it will be interesting enough for the hospital's purchasing department to take a look at it. The start-up company (or TIM Solutions itself) wants to sell the product and start their own company. Nurses and doctors want to provide their patients with the best care and therefore are interested in better products as long as their workload is not increased. The patient and his or her family want him or her to get healthy and leave the hospital as soon as possible and want to be treated with dignity. They need to be satisfied with the product and might need to interact with the product which means their opinion should be taken into account. Insurance companies need to stay satisfied, but do not play a big role in this project as long as the costs are not changing.

People with the highest interest (doctors, nurses, company and facility management of the hospital) are people who will be involved with the product most and therefore the best source to consult for information. The product's profits should be made clear to the hospital, company and investors because they have the most influence on the implementation of the product.

"Hospitals depend on the amount of DOTS which are set for a specific treatment. Saving days in hospitalwould mean: saving money"

"University hospitals have less freedom to choose their products. They are obligated to choose the cheapest (which meets quality requirements) while smaller hospitals can make their own choices regarding price and quality ratios"



Interviewees:
Hendrika Wollericht (Head nurse, quality manager UMCG)
Eric Flach (Controller facility company, RDGG)

2.4 Stakeholders (financial connections)

Understanding the (financial) connections between the companies helps to determine how different stakeholders view each other and why they make certain decisions. The overview in figure 2.2 shows a rough overview of connections and who depends on who, separated in three main groups.

The first group has a big influence on the opportunities of hospitals and the healthcare industry in general. Unfortunately, this is determined by the government and cannot be influenced by external parties. The product should not depend on the governmental subsidies as economization on the healthcare industry can change due to different types of reasons.

The second group determines whether there is enough budget for the hospital to buy new products. The insurance companies provide the hospital with money based on the number of procedures the hospital estimates for the next year. These estimations are very important for the hospital as they need to meet their targets. If they, for example, estimate to perform 300 knee surgeries in a year, but only perform 250, it will become very difficult for them to make sure that the insurance companies will provide enough money for 300 knee surgeries the next year. If the hospital performs more than 300 knee surgeries they do not get compensated for those surgeries by the insurance company which means that they have to cover for it themselves. It so happens that hospitals do not perform certain surgeries anymore after reaching their yearly limit.

Per department, the head nurse is responsible for using this money in an efficient way. The head nurse makes the decisions regarding buying the product or not while keep an eye on the budget. Some hospitals choose to outsource their purchase orders to an external company. The Reinier the Graafschap in Delft does so. This means that they, together with five other hospitals chose ZXL (Zorgportaal XL) to be responsible for finding the best price to quality ratios in products. As this organisation can buy large amounts for these six hospitals, prices can become less high which can be interesting for the hospital. Not all purchase orders are made by these companies. Mostly the "easier products" like disposables, food, chemical, etc. are ordered by these companies. The more complex products are purchased by the head of the department in collaboration with the facility department. Innovative products are mostly purchased by this last group of people (Flach, 2017).

The fourth group, which consists of the development team, the manufacturers and the suppliers determines the limits of the cost price regarding production technologies. Due to the fact that FluidBalance is a medical product, certification of the product and proof of reliability will be necessary. This should be taken into account in an early stage during the selection of internal technologies. Internal technologies should be certified. If this is not the case, all products need certification before they can be sold. (Vervoorn, 2017)

The fifth group is still to be determined. The UMCG provides the first 50.000 Euros as a start-up budget. Furthermore, this group contains external investors who want to support innovation in the healthcare industry and want to spend their own/their company's money to do so.

The sixth group consists of the financial possibilities of the company. The investors and especially the number of investors determine how much money is available for development and marketing of the product and services. Clear perspectives and evidence of success is needed to keep investors on board and to find new ones.

2.5 Conclusion

The financial department of the hospital determines the amount of money available for each department. Finally the nurses and assistants are the ones to score the product on user friendliness. Whether the product will be a success or not will depend on convincing these parties, so close contact should be kept with these stakeholders.

Financial connections FluidBalance

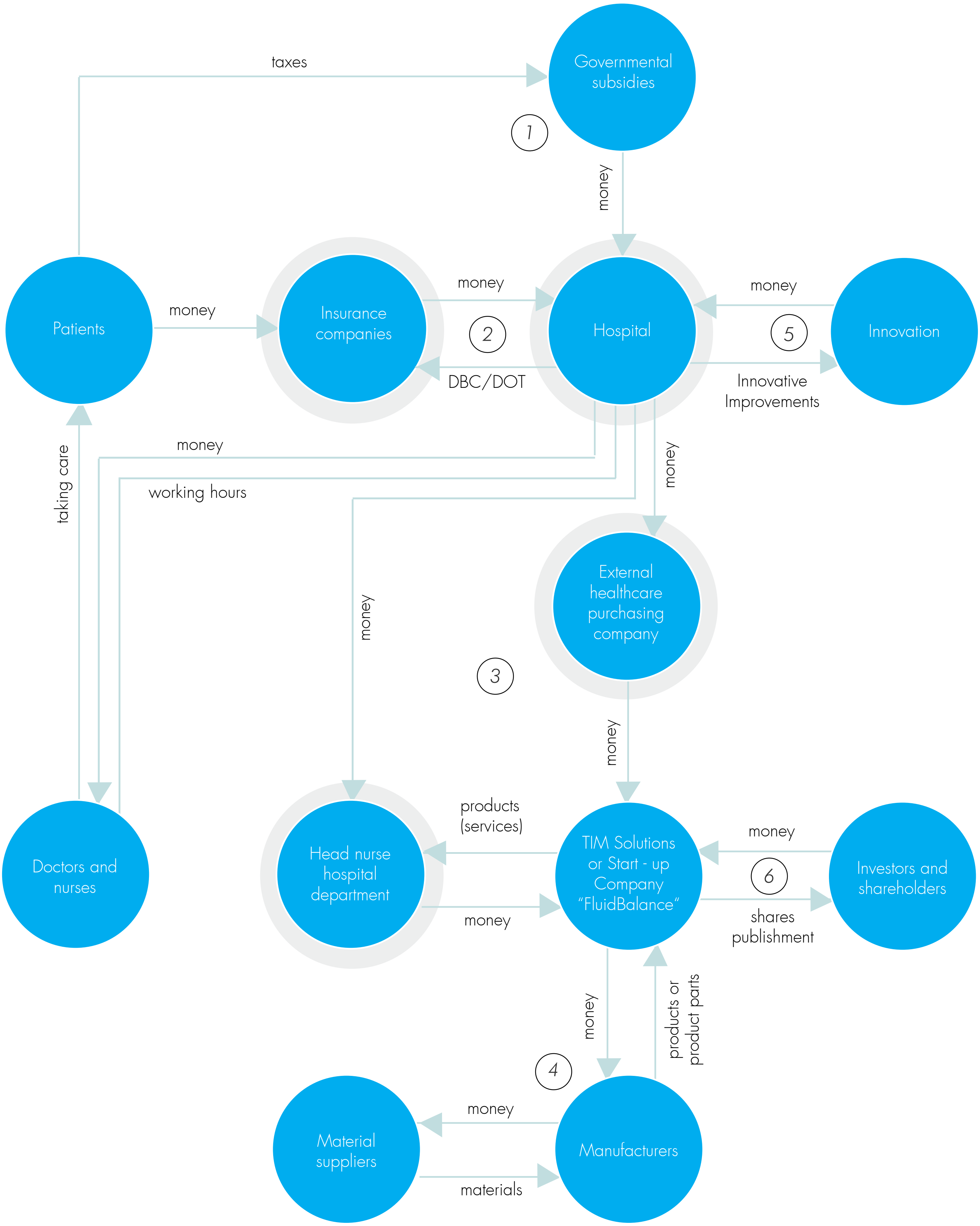


Figure 2.2: stakeholder overview based on financial connections

FluidBalance related research

Relevance

To create the best product it is best to do research into similar existing products, read information about the background of the problem and try to understand the context of the product as well as possible. This chapter will provide background information related to the product that is to be designed.

3 Competing measuring methods

This project requires knowledge on the medical industry and the working principle of fluid balance. First, different methods of performing fluid balance measurements and why they can or cannot be used in this project will be discussed.

3.1 Fluid balance in humans

A balance between the fluids is the total of all the fluids entering minus the fluids exiting the human body. A human body contains 50-75% water. Average adults contain 50-65% water, but children under the age of one contain 75% water which will drop to 65% before they reach one year of age. The amount of water in the body can be gender-dependent as women naturally have more fatty tissue than man and fatty tissue contains less water than lean tissue. On average men contain around 60% of water and a woman around 55%. Overweight people contain less water. The less lean tissue overweight people have, the less water they contain. The body water is not divided homogeneously throughout the body. 1/3 of the body water is in the intracellular fluids (fluids inside the cells) and the rest is in the extracellular fluids (Helmenstine, 2017). 20% of the total volume of body water is found in the blood which accounts for one or two litres. The table below(figure 3.1) shows important parts of the body and how much water they contain (Lumen, 2017).

To make up a fluid balance it is important to know what fluids are entering the body and what fluids are exiting the body. Figure 3.2 shows this in an overview. The grey areas and the colostomy apply only for ill people (patients). As can be seen 2500-3000 millilitres of fluid is entering and exiting the body every 24 hours. Not all of these values are needed to create a valid fluid balance overview. This will be explained more in depth later on.

Figure 3.1: Table about fluid percentages in different body parts

Body part	*Percentage of water*
Brain	*80-85%*
Teeth	*8-10%*
Lungs	*75-80%*
Heart	*75-80%*
Liver	*70-75%*
Bones	*20-25%*
Blood	*50%*
Skin	*70-75%*
Kidneys	*80-85%*
Muscles	*70-75%*

3.2 Existing methods and applicability

Measurements on the fluid balance can be performed in different ways. In general, these methods can be divided into three groups: laboratory tests, objective non-invasive measurements and subjective non-invasive measurements. These three groups contain different measuring/estimating methods. These methods are explained in appendix 1.

Some of the discussed methods are very promising and others are rather general and rough. The hospital requires a certain level of accuracy regarding the measurements, but might not require the most accurate solutions. Accuracy always goes hand in hand with involved investments and workload for the nurses.

The subjective methods (appendix 1) are far below the level of accuracy that is required. Furthermore, they are not always reliable when applied to elderly people. For example, level of the skin turgor and the feeling of being thirsty changes when people age. Elderly have less moisture in their skin and are less sensitive to the feeling of being thirsty (Yoshino et. al, 2015).

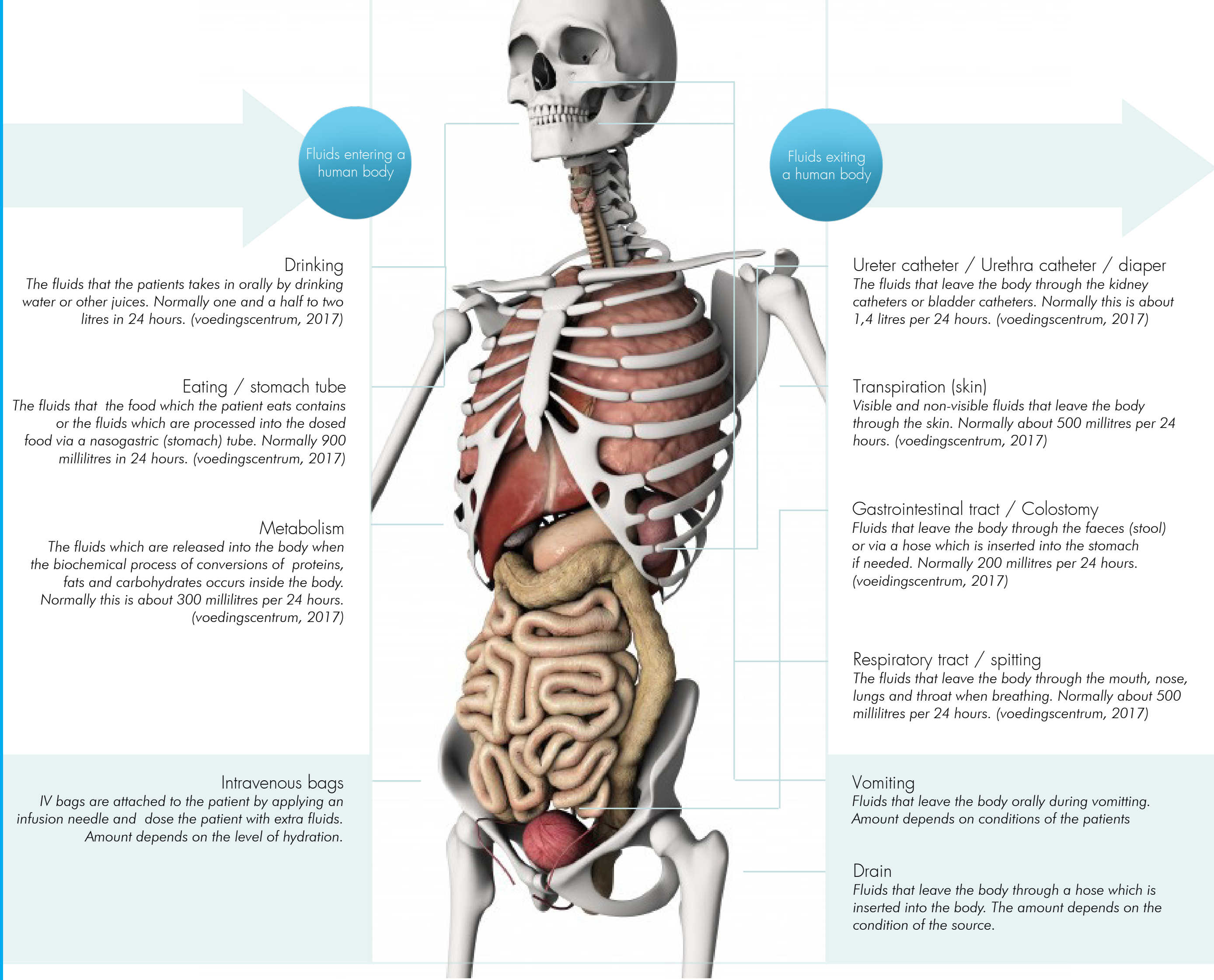


Figure 3.2: overview of fluids entering and leaving the human body (Picture is retrieved from: Freepik.es)

Another important aspect is the difference between healthy people and patients. Measurement methods like calculating the total body water from blood values such as haematocrit, haemoglobin and sodium always depend on standard ratios. This also accounts for measurements of urea concentration or osmolality in urine of patients and performing BIA (Bioelectric Impedance Analysis) tests or axillary tests on patients. In addition to the fact that differences in urea concentrations can be a marker for other things besides hypo- or hyper hydration as well, mentioned methods are based on comparisons with non-ill people. The problem with patients is the fact that their division of body water and therefore calculations based on blood values can be different in each case. This makes calculating total body water based only on blood values(haematocrit -, haemoglobin-, sodium concentrations, etc.), urine values (urea concentration) and by means of comparing the conductivity of a human body (BIA and axillary measurements) unreliable for patients. (Pleijhuis, 2017) .

Finally, some of the mentioned measurements are quite strenuous with regard to the actions that need to be performed. The breath test needs to be performed on-line during the day, which means that the patient needs to be connected to respiration all day, the nurse needs to check the breath values every hour or the patient becomes responsible for breathing into the system every hour. All of these methods are not desirable.

The only methods that are left after discussing these limits are monitoring how much water is entering/ exiting the body and weighing the body every hour. Limitations of the first method are the responsibility of the patient and/or nurse. It is their responsibility to enter the amount of fluids that the patient drinks, eats, defecates, vomits or loses due to drains. A limitation of the second method is the sensitivity of the system that is needed. The bed is used by the patient, but contains many other devices which are much heavier than the patient. Moreover, people will lean on the bed, bump against the bed and products like a plate full of food and drinks will be placed onto the bed as well. Furthermore, the weight does not only depend on the amount of moisture inside the body. It also depends on factors like eating more or less, being stressed and exercizing less than normal. The intensive care of the UMCG is currently looking into alternating beds which also contain an option to weigh the patient. These beds are very expensive and will therefore only be used at the intensive care. Altogether this leaves monitoring fluids as the most plausible solution for the problem.

3.3 Competition & Competitive advantage

Monitoring the fluids can be executed in different ways. At the moment, the accuracy of fluid balance measurements differs per nurse, per department and per hospital. Most Dutch hospitals currently make use of the manual urimeter which is available in different types (figure 3.3 shows an example). Other competitors provide solutions to automatically monitor the urine output and sometimes even send the values to a computer over Bluetooth. Two patents were found regarding the same type of solution. The competitors and patients will be discussed briefly and a conclusion will be drawn on how these competitors have influence on FluidBalance and what can be done to keep competitive advantage.

Manual Urimeter

The urimeter is a simple solution to increase accuracy in the manual readings of urine output. The urimeter consists of a hard-plastic part and a bag. The plastic part consists of two main containers which differ in accuracy. The nurse needs to come by to empty the hard container into the bag by opening the valve. The hourly output needs to be recorded manually as well.

Automated Urimeter

FlowSense (Baxter), Sippi (Navamedic), FOM-200 (Biometrix) and Accuryn (Medline) (figure 3.4 - 3.7) all try to automate this process by measuring the flow in drops that enters the urimeter and automatically passing this information through when a certain amount of urine is reached. Accuryn is a somewhat more advanced version of the four competitors. "Accuryn uses proprietary electromechanical designs and advanced software algorithms to deliver automated, real-time actionable data including urine output, core body temperature and intra-abdominal pressure (IAP). The IAP measurement is taken directly from the catheter tip with just a push of a button, helping to reduce setup time, potential errors, and infection risk. Additionally, innovative active drain line clearance can overcome urine drainage issues that may make urine output measurements unreliable." (Rubenstein, 2017). Due to these advanced features , it is likely that this system is more expensive than the others.

Figure 3.3: Urimeter Flexicare Medical (retrieved from: Flexicare Medical

Figure 3.4: Accuryn (retrieved from: MedLine)

Figure 3.5: Sippi Urine monitoring wards (retrieved from: Sippi)

Figure 3.6: Flowsense (retrieved from: Flowsense)

Figure 3.7: FOM-200 (retrieved from: BioMetrix)

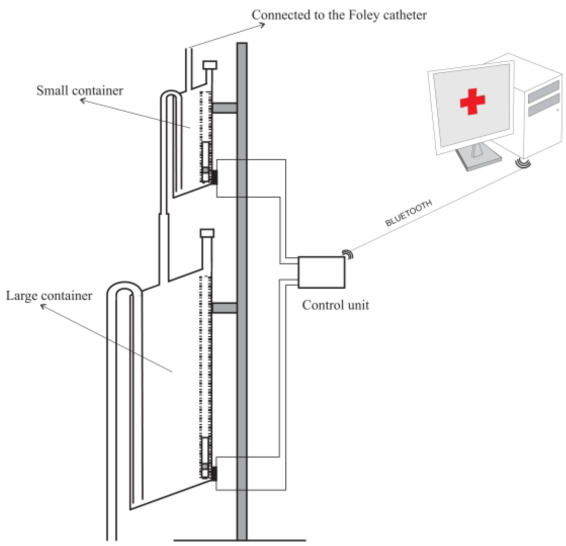


Figure 3.8: first patent (retrieved from: NBCI - A Low Cost Wards for Monitoring the Urine Output of Critical Care Patients)

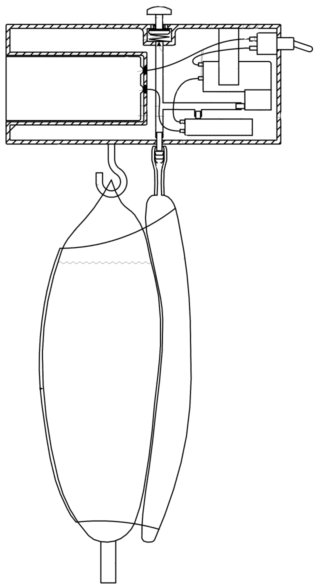


Figure 3.9: Patent US8579859 B2 (retrieved from: University of Texas - Fluid balance monitoring system with fluid infusion pump for medical treatment

Patents on automating urine monitoring
The first patent (figure 3.8) uses the siphon method (building up pressure when filling a tank until a certain limit is reached) to empty the small container into the bigger container. The disposables are said to be slightly more expensive than the current manual urimeters (2,50 euros). The other patent found (figure 3.9) describes the same method as TIM Solutions intends to use within FluidBalance. The patent was approved in 2013 and belongs to the university of Texas. The use of load cells to perform weight measurements and the use of accelerometers to compensate for movement are mentioned in the patent.

Creating competitive advantage
Figure 3.10 shows an overview of how the different competitors can be placed ranked on permanent costs over the years and extensiveness of the product. The big difference between the intention of FluidBalance and the competition on the market is the costs of the disposables involved. Except from the patents in which it is not specified what type of catheter bag will be used, all competitors have customized (expensive) catheter bags. Their product can only be used together with their specific disposables. Another big difference is the fact that the competition only focuses on the urine and not on the total system of monitoring the total fluid balance of the patient. Finally, the competitive products are focused on the bed of the patient which does not encourage the patient to move more as it will always be a hassle to move the product to the IV pole. Sippi provides a simple bracket to move the products and FOM-200 provides different separate add-ons to increase usability.

Current focus market
Biometrix (FOM-200) is located in The Netherlands and Slovakia and provides medical solutions worldwide (biometrixmedical,2017). Since the beginning of February this year MedLine and Protrero Medical have joined forces to improve Accuryn (medicalproductoutsourcing, 2017). Both of these companies are located all over the world. Navamedic is a company in Sweden and mainly focuses on the Nordic, Benelux and Baltic markets (Navamedic, 2017). Flowsense is originally from Israel, but was recently bought by medical device giant Baxter for 9.5 million dollars (Sarvestani, 2017). Baxter has not presented Urinfo2000 on its website yet, but is probably working on an improved version of Urinfo2000 before publishing.

Conclusion
Altogether it can be stated that it is important to keep the disposable bags as simple as possible and offer the possibility to combine different types of bags with the system. Another option is to recommend a specific, but cheap, disposable bag of their own that can be easily combined with the FluidBalance system.

Furthermore, the competitive advantage regarding the focus on the patient, hospital logistics and taking into account the total fluid balance of the patient, needs to be emphasized as this is what differentiates FluidBalance from the competition. It is important to keep in mind the total costs and to keep the product as simple as possible.

Competitive advantage

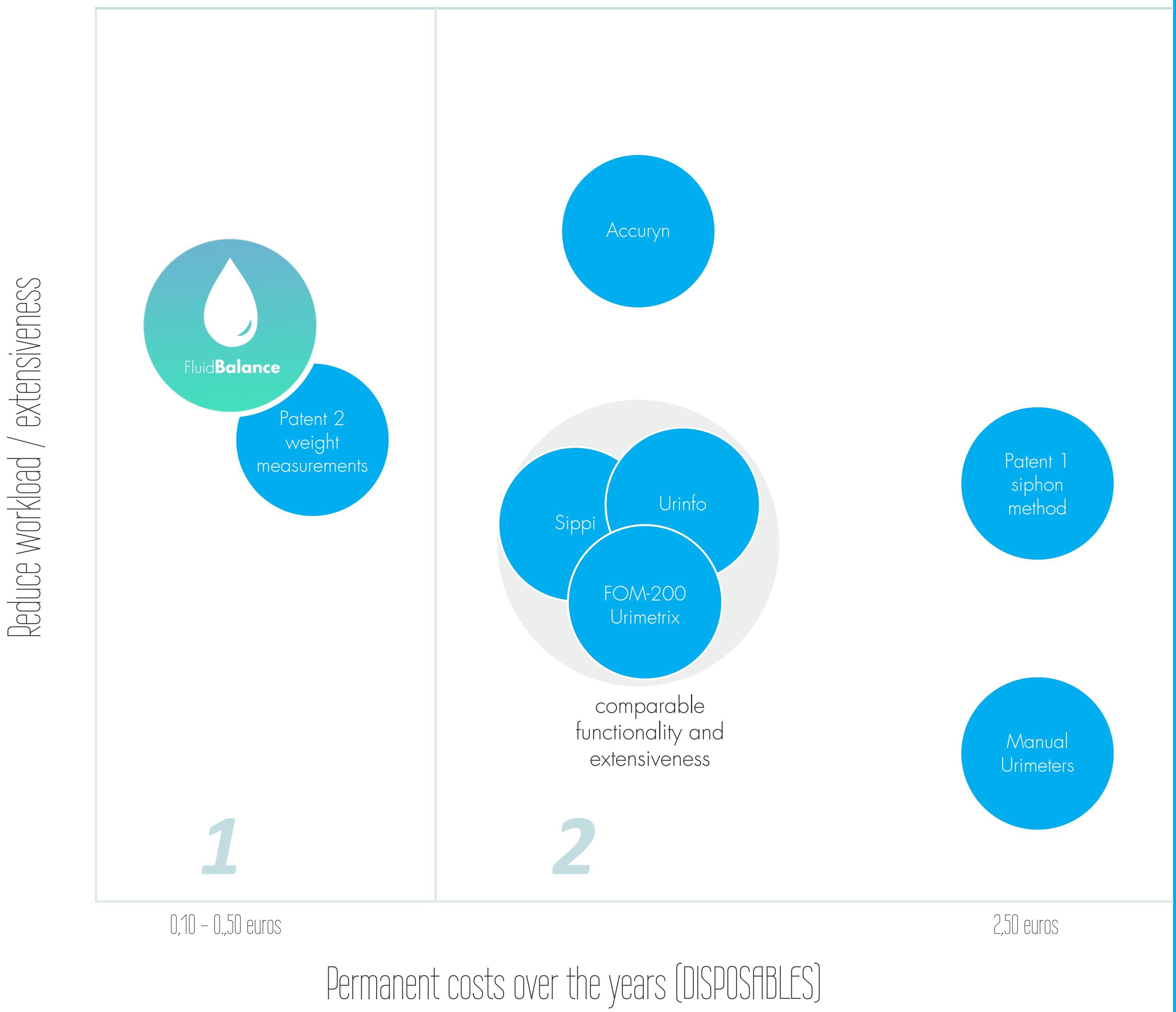


Figure 3.10: Overview on how to create competitive advantage. Prices are based on current prices for different types of catheter bags at the UMCG.

Relevance

Medical wards have to meet more requirements than regular products. Also, risk factors need to be monitored more closely than required for non-medical products. These requirements are written down in NEN norms and Directives. Acting according to the requirements and looking at the risks can mean success or failure for the product which is why looking into these matters at an early stage is recommended.

4. Risks and limitations

Due to the fact that medical devices are being used on, in and around patients, requirements should be met. Important factors are the "risk classification" which will determine the route to a CE certificate and which ISO norms need to be met. The latter contains a list of questions, which can serve as a good start to take into account during the design process.

4.1 MEDDEV classification

The main purpose of MEDDEV classification is to apply an appropriate conformity assessment procedure. (CEparts4u, 2010). The MEDDEV document (MEDDEV 2 12-1 rev. 8) helps to determine which class is applicable to the product that is being designed. By reading the document and following the procedure it can be determined that FluidBalance could be in class IIa, which can be found under RULE 10 (CEparts4u, 2010). This is mainly due to the fact that it is an active device which is monitoring a process that leads to a diagnosis. Products that are in this category are for example: electrocardiographs, cardioscopes with or without pacing pulse indicators, electronic thermometers, and electronic blood pressure measuring equipment. Due to the fact that the product is not measuring a vital physiological process itself (blood pressure, respiratory rate, etc.) itself it could be considered less risky. Therefore it could also be the case that the product will still be in class one. The most important difference between the two classes is the amount of effort it will cost to receive a CE certification (appendix 2) IIa products require a longer and more outsourced certification process.

4.2 ISO norms that need to be met

Medical devices need to meet the norms of ISO60335, ISO60601, ISO13485 and ISO14971. ISO14971 contains a list of questions to ensure safe usage of the product. These questions have been assembled as a guideline through the design process. ISO14971 has been prepared by the technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" of the International Organization for Standardization (ISO) (NEN-EN-ISO, 2017). The main purpose of the norm is to prevent hazards in any type of situation and any type of matter.

The answers to guiding questions are presented in appendix 3 Another important tool is the overview of risk management activities for medical devices (appendix 4). During the design process it is important to know the greatest risks and to ensure that those risks are decreased to "a manageable level". Risk analyses should be performed in different phases of the project to keep track of risks and prevent unfortunate surprises.

4.3 First FMEA Risk analysis

To be able to identify risks and their importance, FMEA's (risk management sheet) will be used. The results (appendix 5) show that seven possible hazards have been identified (figure 4.1). It is important to identify ways to manage these risks in an early stage to ensure that they will be manageable in a later stage. Furthermore, nine grey area hazards need to be kept into the loop as they might need managing later on in the project.

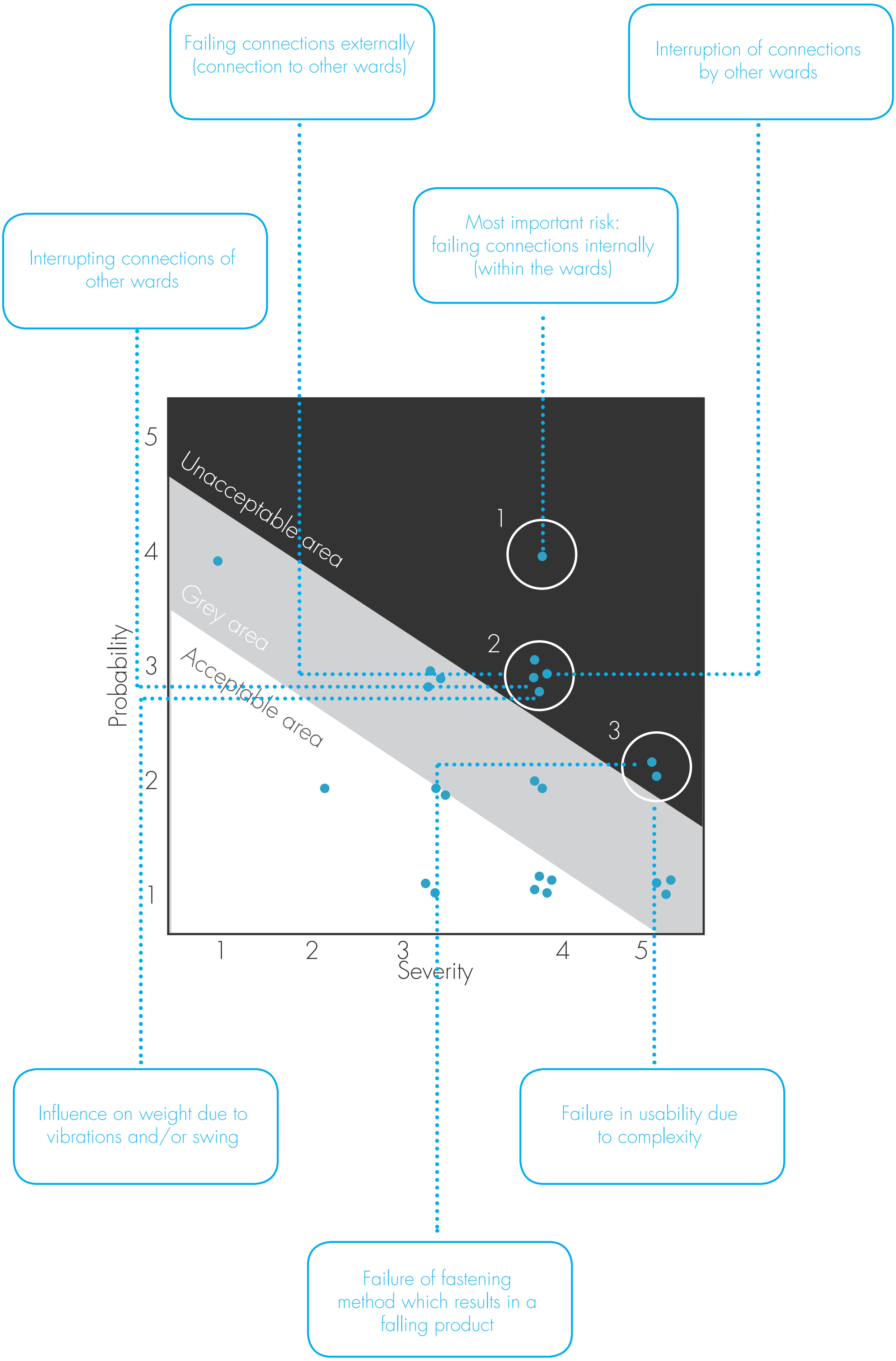


Figure 4.1: possible hazards first FMEA FluidBalance

5 Applicable technology

During this project, multiple technologies need to be combined into one main output. To determine which technologies will be the most suitable, differences will be explained and compared below.

5.1 Communication (data transfer)

Communication happens between the different parts of the system (FluidBalance system, computer on wheels (COW), the electronic patient files (EPD), etc.) which are used by both nurses and assistants. Both wired and wireless solutions are possible. Figure 5.1 shows different wireless options. ZigBee and Sub-GHz are mostly used to monitor values, while Wi-Fi is mostly used to transmit bigger files (biggest bandwidth). This means that Wi-Fi seems over-qualified for the job. An advantage of using Wi-Fi is the fact that it is already being used for multiple other devices in hospitals all over The Netherlands. A Wi-Fi connected device can therefore easily be integrated without the need to setup a totally new network. On the other hand, it can be an advantage to use for example Sub-GHz as it operates on lower frequencies than most of the other existing connections. This means that it can handle interference better. (PlugintoIOT, 2016) Bluetooth seems to be the best solution for transmitting small distance, low power, small sized data, and it does not require a setup of a totally new network. A combination of Bluetooth and Wi-Fi seems to be the best solution for the first version of FluidBalance.

5.2 Measure volume differences

Volume differences over time can be measured by measuring the direct flow in the tube, measuring how much volume disappeared (or was gained) over time by using a load cell or load sensor and by manipulating the flow to measure the number of drops like most competitors do. The problem is that in the case of FluidBalance we do not always deal with (transparent) fluids, but also with solids, like kidney stones, and very dark urine. A flow sensor could be disturbed by these stones, get blocked by these stones or a tarnish layer could block the view of the sensor. Another problem of flow sensors is the required speed of the flow. Urine can be flowing extremely slow and in small volumes. This means that expensive flow sensors would be required for accurate measurements. One of the advantages of FluidBalance is the fact that the system can be combined with different types of cheap catheter bags.

What is left to be implemented are the load cell and/or the load sensor. Relatively cheap load cells already have a resolution of 0.1 grams with a deviation of 0.5 gram (see appendix 7) which was encountered during quick testing.

Figure 5.1: wireless connection possibilities

	ZigBee	Sub-GHz	Wi-Fi	Bluetooth
Battery life (days)	100-1000+	1,000+	0.5-5	1-7
Bandwidth (kbits/s)	20-250	0.5-1000	11000	720
Application focus	monitoring & control	monitoring & control	Web, email, video	Cable replacement
Range (meters)	1-100+	1-7000+	1-30+	1-10+
Optimized for	Reliability, low power, Low cost, scalability	Long range, low power, low cost	speed	low cost, convenience

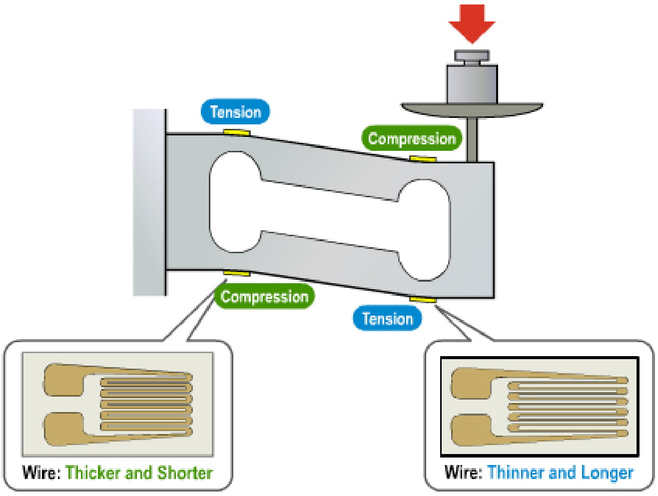


Figure 5.2: Tension and compression single point load cell

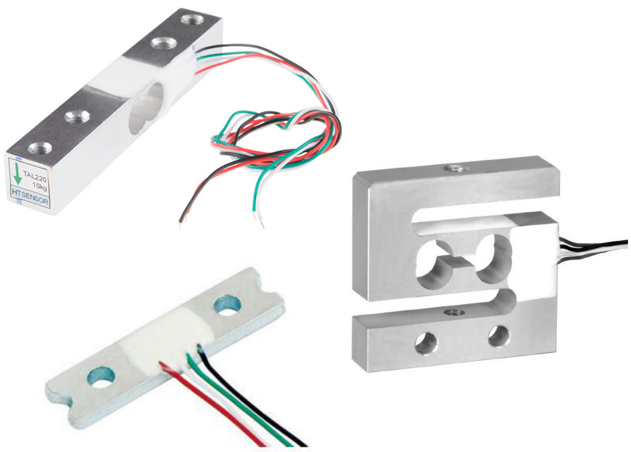


Figure 5.3: Single point load cells

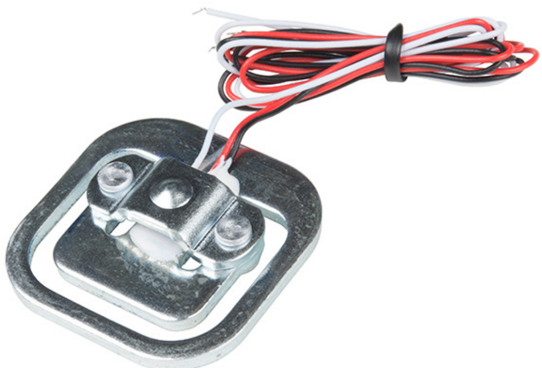


Figure 5.3: Load sensor that needs to be combined with others to measure pressure on a larger surface .

5.3 Load cell types and precision

A load cell is designed to measure pressure differences in a specific direction. Other directions will be ignored. With the help of strain gauges which are being placed carefully on the load cell, tensions caused by force are being registered. Some load cells need to be combined as they need to cover a surface which is too large to be covered by one single point load cell. These load cells, which are more often referred to as load sensors, can be distinguished by having three connection cables instead of four (figure 5.4). This principle is often applied to human and kitchen scales. The single point load cells (available in different configurations) (figure 5.3), like the name indicates, measure the pressure and compression on a single point of the load cell. The strain gauges measure compression and tension (figure 5.2) . Both of these load cells are designed to measure both pressure and tension forces and are relatively cheap. The single point load cells come in different forms which will be discussed later on when being applied in a suitable housing.

The price of a load cell varies among suppliers. This is mainly caused by the certification, sensitivity and capacity of the load cells.

Sensitivity of load cells and sensors can be quickly found when looking at the maximum amounts that they can measure. Load cells that can weigh up to 500 kilograms are logically less sensitive than load cells that can weigh up to 10 kilograms. Furthermore, when interpreting the precision of the load cell it is important to look at specifications like: capacity, creep, non-linearity, non-repeatability, safe overload and zero-balance. These terms are explained in appendix 8.

5.4 Energy consumption and storage

The devices will use energy, which requires a battery or other power supply. The use of cables and batteries will be researched in more depth considering battery lifetime, battery size, and usability. Data (about fluid balance measurements) that is being collected by the FluidBalance system will be stored separately. TIM Solutions already has contact with different storage suppliers which will not be further discussed within this graduation assignment.

5.5 Conclusion

(Dis)advantages as discussed within this chapter need to be taken into account. Specific types of load cells, battery requirements and how to fit the product within the logistics of the different hospitals will be discussed in later chapters.

Relevance

Accurate measurements and decreasing workload are very important, but they are not the only aspects around the system that matter. The patient and especially the treatment of the patient is very important too. This chapter will give insights into this aspect of the FluidBalance system in a hospital environment.

6. Social aspects and patient involvement

6.1 Patient involvement

Patient involvement is an important part of the product. Decisions need to be made regarding the level of responsibility for the patient, the nurse (and doctor) and the care assistants. Wishes and differences in authorization level of these three user groups needs to be considered in order to create a reliable and suitable treatment plan. Research was conducted on whether or not patients want to be involved in decision making, regarding their treatment plan. Also the general capability of the patient to be involved in specific decisions, was considered.

Based on the literature that was consulted (different user perspectives can be found in appendix 6 it can be stated that patients would like to have more involvement in their treatment plan. In some cases, nurses and doctors have a final say in this as they determine the situation of the patient (mental state, severity of illness, etc.) to see if it is wise to take the patient's wishes into account.

In most cases, changes in fluid balance are managed and adjusted accordingly by the nurse. Decisions regarding fluid balance require medical education and differ per disease. Some of the tasks can be outsourced to assistants, but the medical expert stays responsible in the end. The patient should be kept up to date about his or her current situation and nurses should always be able to explain changes in the fluid balance and/or treatment plan to the patient. This counts for close family as well.

6.2 Healthcare as a medical practice

Healthcare is no longer the "science of medicine". Today healthcare is more "the practice of medicine" (Khosla, 2012). As too many people are still being diagnosed wrongly and receive the wrong treatment technology is needed to increase accuracy.

"New technologies will make the receptive doctors better at their jobs – quicker, more accurate, and more fact-based. There is a tremendous opportunity in the influx of data that has never before been available. Once we have a large enough dataset, and an addressable database of research studies, we'll be able to identify patterns and physiological interactions in ways that weren't possible before." (Khosla, 2012)

However, apart from the fact that medical care is necessary to help the patient recover from an injury or illness, improvements and progress due to personal contact and mental support should not be underestimated. It is very important that the human aspect in healthcare survives all technological advancements. However as mentioned in one of the quotes on the next page these people do not need to be experts in medicine. It would be even better if they are experts in understanding the human being in order to provide the best compassionate care possible. Altogether this new way of providing healthcare does not require medical experts to be replaced. It does, however, require them to provide care in a different way.

6.3 integration social aspect

FluidBalance is a perfect example of a medical task that is currently being performed by nurses and assistants, which leads to unnecessary errors and therefore lengthened hospital stays of patients. Apart from this, performing measurements during the day requires a nurse (and an assistant) to come to the patient's bedside. When all of these measurements are taken over by an automated process there is less need to visit the patient for this specific matter.

On the other hand, we could say that automating the process partly saves the nurse time which he or she can spend on informing the patient about the effects and complications that a bad fluid balance causes.

"Physicians will have MORE time to spend talking to their patients, making sure they understand, socializing care, and finding out the harder-to-measure pieces of information because they'll spend less time gathering data and referring to old notes. And, they will be able to handle many more patients, reducing costs." (khosla, 2012)

It should not be forgotten that fluid balance measurements are just a part of the treatment steps that need to be taken to keep a healthy fluid balance. Serving the drinks, picking up the drinks, emptying the catheter bag and replacing the fluid bags still need to be done when the system is installed.

6.3 Conclusion

The role of the nurse is changing and maybe less education is needed to perform fluid balance measurements. Since personal contact is more about compassion than medical advice this task could be partly taken over by an assistant instead of a nurse. The system will lead to more information regarding the fluid balance of different diseases (due to increased accuracy and saving different cases to make comparisons and algorithms). These new insights will lead to more personalized plans for the patient's treatment. Although a lot of contact moments regarding the fluid balance will still be necessary, the patient should not experience less human involvement.

Patient involvement needs to be considered as this is the patient's wish. Nevertheless, the nurse stays responsible as fluid balance calculations forms an important input for the treatment plan and requires specific knowledge. These aspects need to be considered when making decisions throughout the process.

7. Contextual research

In order to get a better grasp on the context and the products in the environment two different hospitals will be visited. The first hospital, UMCG (Universitair Medisch Centrum Groningen) was visited on the Monday the 11th of September. The other hospital, RDGG (Reinier de Graaf Gemeenschap) will be visited on Wednesday the 13th of September. These two represent two groups of hospitals, the big university hospitals and the smaller provincial hospitals. The visit at the UMCG, Nephrology ward, was quite extensive and consisted of both contextual research, and observations and interviews with a patient, nurses and a doctor. Both visits will be discussed and the most important findings will be noted to take along during the project.

7.1 General findings

During the day many different things were discovered. The most important findings are the placement of the Urine bags on the floor (figure 7.2), bed (figure 7.1 and 7.6), IV pole handle (figure 7.3) and the fact that the patient needs to walk with the catheter bag. The other important finding is that in both hospitals already three different types of beds are used (figure 7.2, 7.4 and 7.5. The total overview of findings is presented in appendix 12

7.2 Work flow and interviews

At the UMCG interviews (appendix 11) were held with nurses, the ward manager and one of the doctors. This led to interesting information regarding the fluid balance measurements and the possibility to create an overview of the work flow of the nurse regarding the fluid balance. At the RDGG a short version of the interview was held with the innovation manager and former nurse (José Postma) to be able to make a comparable work flow and to be able to notice the differences (appendix 11).

The most important difference between the two work flows is the use of a digital system (ChipSoft). The RDGG is a bit further ahead of the UMCG regarding this system. At the UMCG a comparable system will be introduced (EPIC) which will change the work flow of nurses drastically depending on the level of digitalisation that the hospital wants to introduce. In the RDGG COW's (computer on wheels) are used to enter patient information and to record fluid balances. This information can be entered from any location which decreases the walk distances for nurses and other employees who need to have access to the system (kitchen employees, nutrients, doctors, etc.).

7.3 Conclusion

Although getting rid of all the manual calculations and using COW's helps prevent papers from getting lost, the task of performing fluid balance measurements is still time consuming in both situations. The nurse still needs to walk to the patient, needs to measure the amounts, needs to write it down or post it up into the computer. These tasks take approximately 3-6 minutes per check-up and 2-6 minutes per 24 hour calculation. Integration of FluidBalance could save up to two hours of working time per 24 hours.

Figure 7.1: Placement of the Urimeter on the bed

Figure 7.2: Placement of the Urimeter on the floor

7.3: Handle on the IV pole

Figure 7.4: hospital bed on Intensive Care

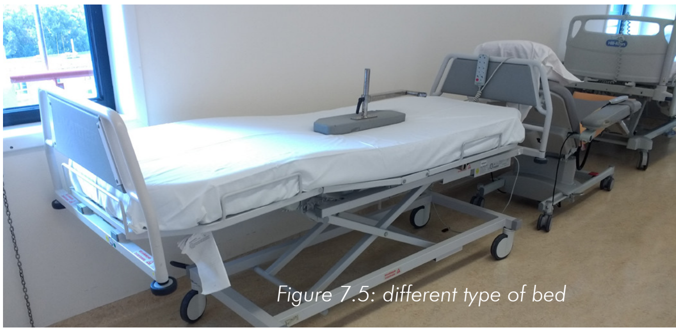


Figure 7.5: different type of bed

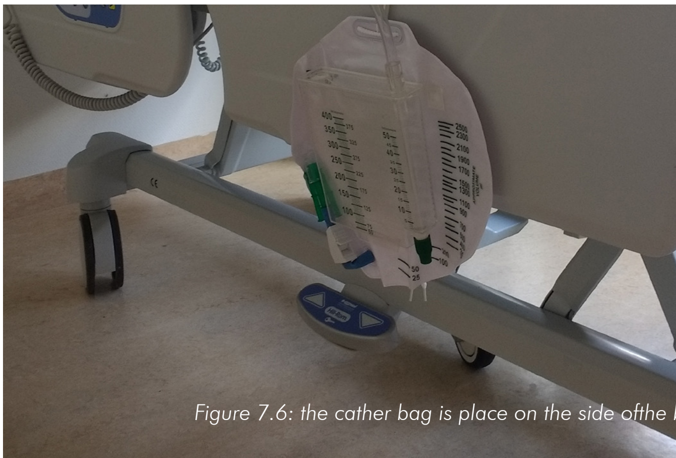


Figure 7.6: the cather bag is place on the side ofthe b

8. Difference between users

The total product service system will be used by different people (figure 8.1). The users of the product will be: nurses, patients, doctors, family and friends of the patient, kitchen employees and department assistants. All of these different users have different expectations of the system and are in the need of different information about it. This means that their relationship with the device(s) will differ from each other as well. To be able to compare concept directions and make decisions it is very important to have a clear overview of these needs and wishes from your different user groups. This chapter will explain the different perspectives and what this will mean for the device.

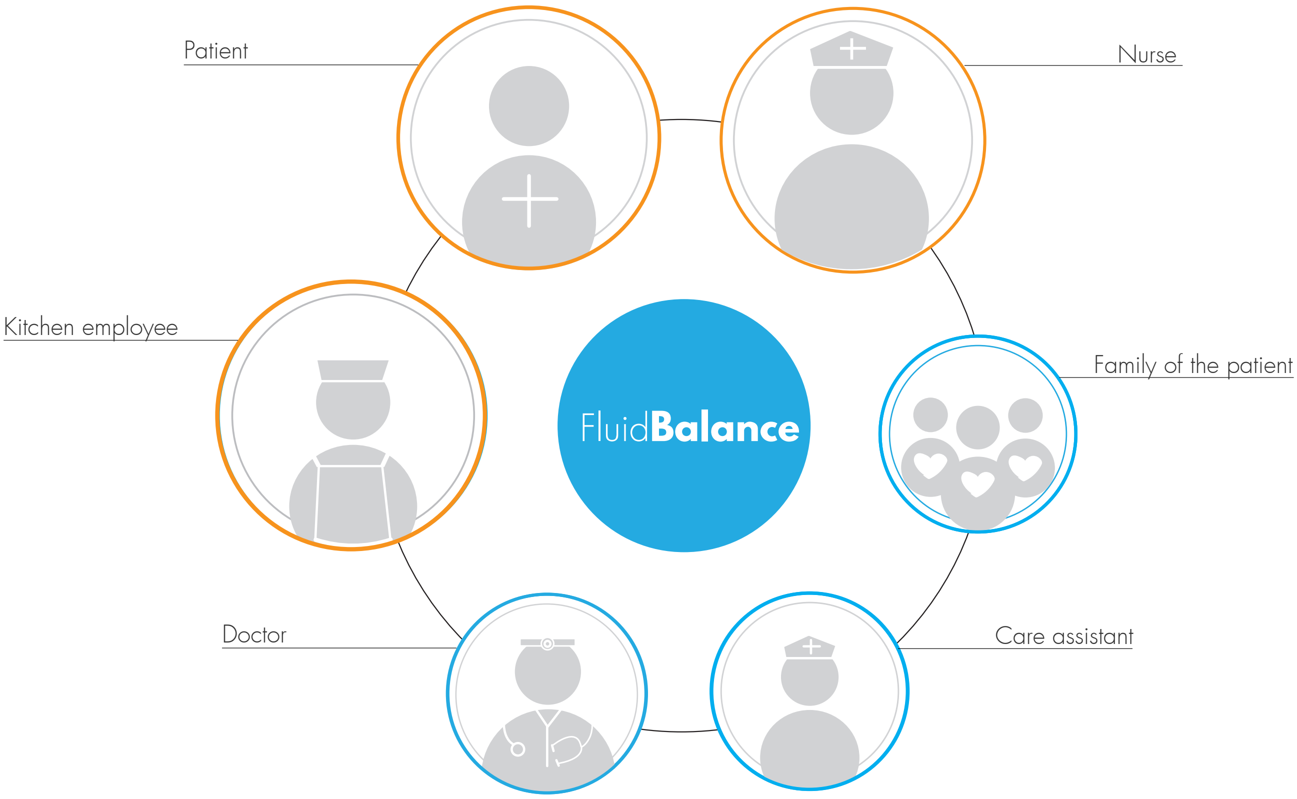


Figure 8.1: Overview of different user groups

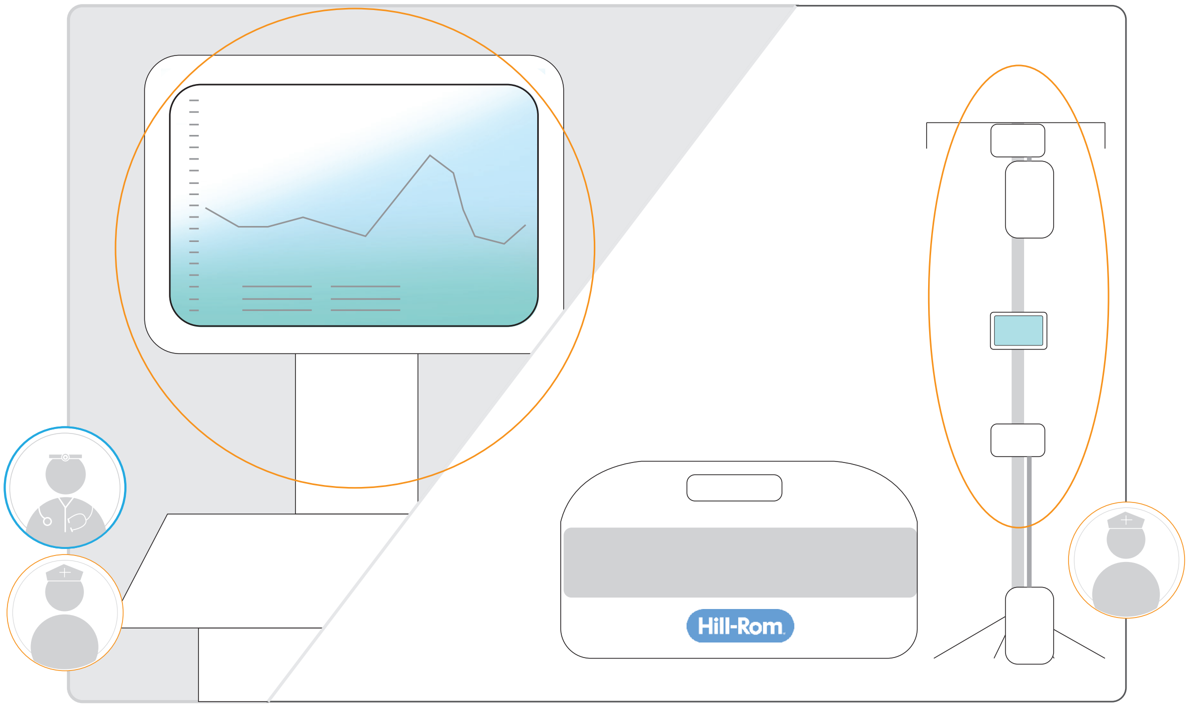


Figure 8.2: Overview of system parts nurse and doctor.

8.1 Main care givers involved

The nurse and the doctor will be considered the main care givers for the patient. Especially the nurse will work much with the system and is therefore an important user. The nurse needs to work with the COW, FluidBalance hangers and the interface while the doctor probably only works with the COW (figure 8.2). The needs for the nurses and the doctors are still different from each other as these groups have a different level of involvement regarding the measurements of the fluid balance of patients. The needs of both groups will be explained below. This information is based on conversations with both user groups.

Nurses want to be able to help people by providing the suitable care, knowledge and (mentally) support them in all possible ways. Having to perform administration tasks means being distracted from what they really want to do: offer personal attention and make people feel welcome and supported. A quote from the Cleveland hospital is: "Healthcare is much more than cure, it is more about care". FluidBalance will be a part of the nurse's working day during which she uses the product to fullfill a part of her duties. Based on the interviews and observations at the UMCG a fist list of the most important wishes and needs of the nurse was created:

- Easy installation of system parts on the IV pole (physically). As few steps/ loose product parts as possible.
- Easy and understandable interaction on the physical product (cognitive ergonomics)
- Well-functioning and time efficient products. During product use the nurse cannot pay full attention to his or her patients.
- Ergonomics of the design, like ergonomic heights when using the product and/or interface
- A clear overview of outcomes on the COW/ tablet and a possibility to look into the fluid balance next to the bed of the patient (to advise or answer questions) without the need to use the COW or another shared tablet.
- Warnings when needed (failing connections, empty/full bags and crucial deviations in the fluid balance of the patient)
- Being able to use all other required wards in combination with fluid balance without problems.
- Not much effort to enter oral intake and or urination values
- Offer the best experience for patients and be able to send them home as soon and as happy as possible.
- Being able to offer personal attention when needed.

Having all these wishes in mind different set-ups for the total composition of the product will be made and shown to several nurses. Comparing different options will lead to new ideas and better insights for FluidBalance. Based on these interviews and the first interviews at the UMCG two personas were made for the nurse which will be used as a reference of the main product user throughout the project (page 38/39).

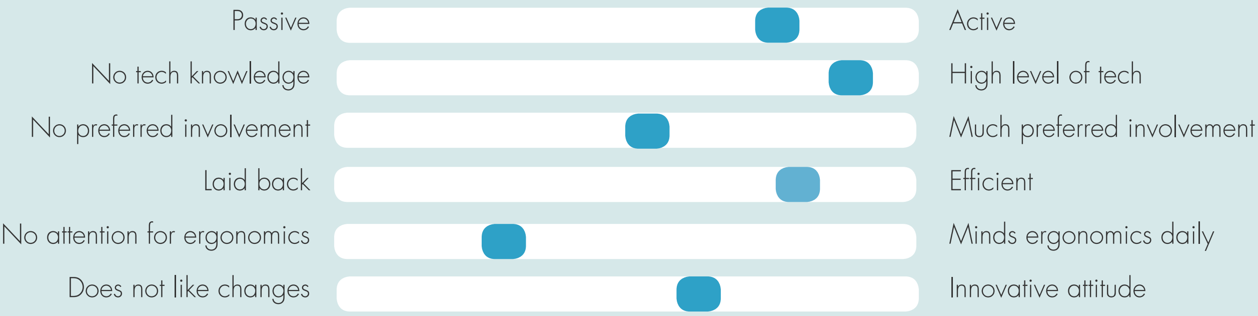
INGE VAN DER MEER (28 YEARS OLD)

Inge, her husband and her two children (6 and 9 years old) live in Haren. Inge always liked to work with people and use her knowledge to help people recover. Inge loves her work, but being at home with her children and spending time with them is very important to her. Due to her irregular job she sometimes needs to work in the weekend which means that she needs to plan her time efficiently around her schedule.

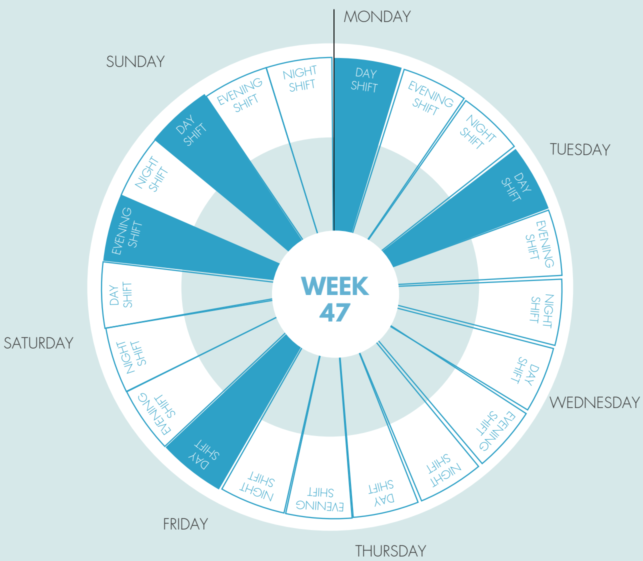
MEDICAL EXPERIENCE

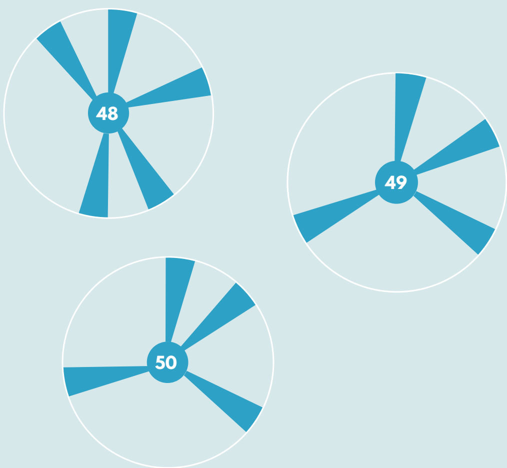
Inge has been a nurse for six years and she started working at the Nephology ward at the UMCG right after her internship. Inge likes the Nephrology, but she would like to work on different wards as well.

PERSONAL CHARACTERISTICS



EVERY WEEK DIFFERENT WORKING SHIFTS





WORK RELATED

FRUSTRATIONS

- Running out of time
- Leaving patients to wait
- Administrative tasks

GREATEST FEAR

- Making big mistakes that have an influence on the health of the patient

GOALS / MOTIVATIONS

- Giving her patients the best experience
- Receiving positive reactions on her caring
- Being able to assist the patient in all his or her needs

THOUGHTS

CONNY DE HOOG (53 YEARS OLD)

Conny de Hoog lives in Sneek together with her husband. She and her husband have three children who have all left home for college. Conny spends a lot of time at her mums place because she recently suffered from a stroke. Conny loves to visit her children and her first grandchild. Her hobbies include: reading, gardening and walking her dogs.

MEDICAL EXPERIENCE:

Conny has been working at the UMCG for 17 years. She has worked at the Cardiology ward for seven years and ten years at the elderly care ward. Before this she worked at the Antonius hospital for 16 years. Next to her job as head nurse she educates young students to become a qualified nurse as well.

PERSONAL CHARACTERISTICS

Passive – Active

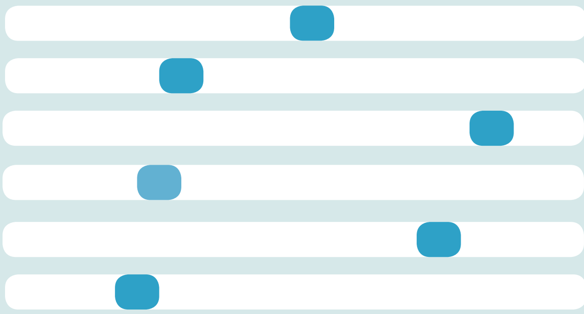
No tech knowledge – High level of tech

No preferred involvement – Preferred high involvement

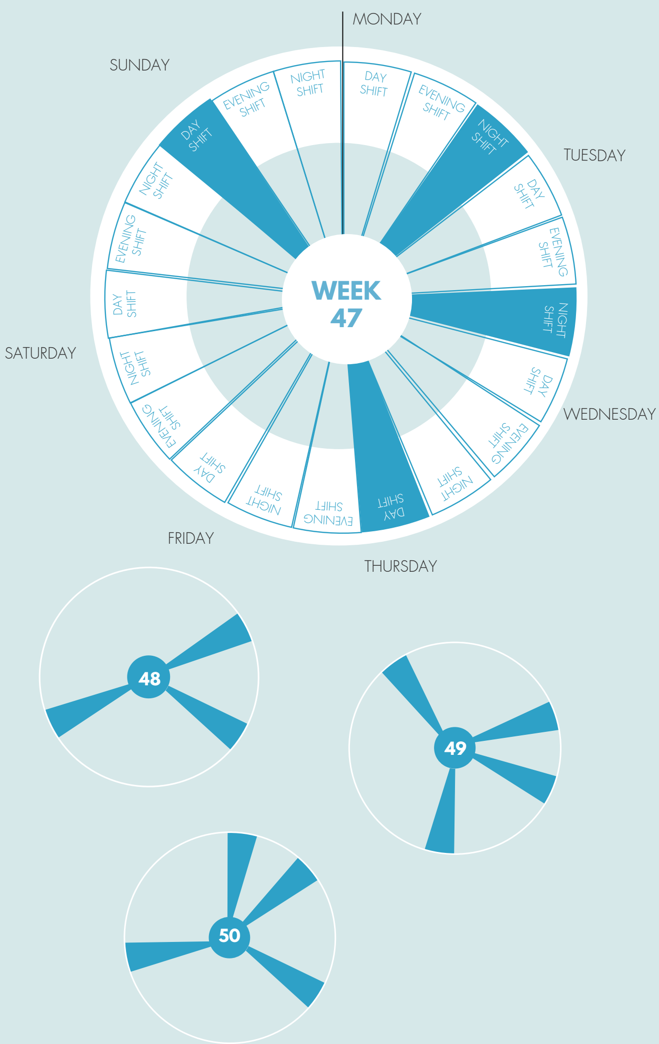
Laid back – Efficient

No for ergonomics – Minds ergonomics daily

Does not like changes – Innovative attitude



EVERY WEEK DIFFERENT WORKING SHIFTS



WORK RELATED

FRUSTRATIONS

- Not knowing how to deal with modern technology
- Lack of time to spend on mentally supporting the patient.

GREATEST FEAR

- Negative experience of patients due to her caring

GOALS / MOTIVATIONS

- Educating young nurses to become qualified caretakers
- Providing the best experience for the patient
- Being able to work as a nurse as long as possible and therefore pay attention to ergonomics and workload

THOUGHTS

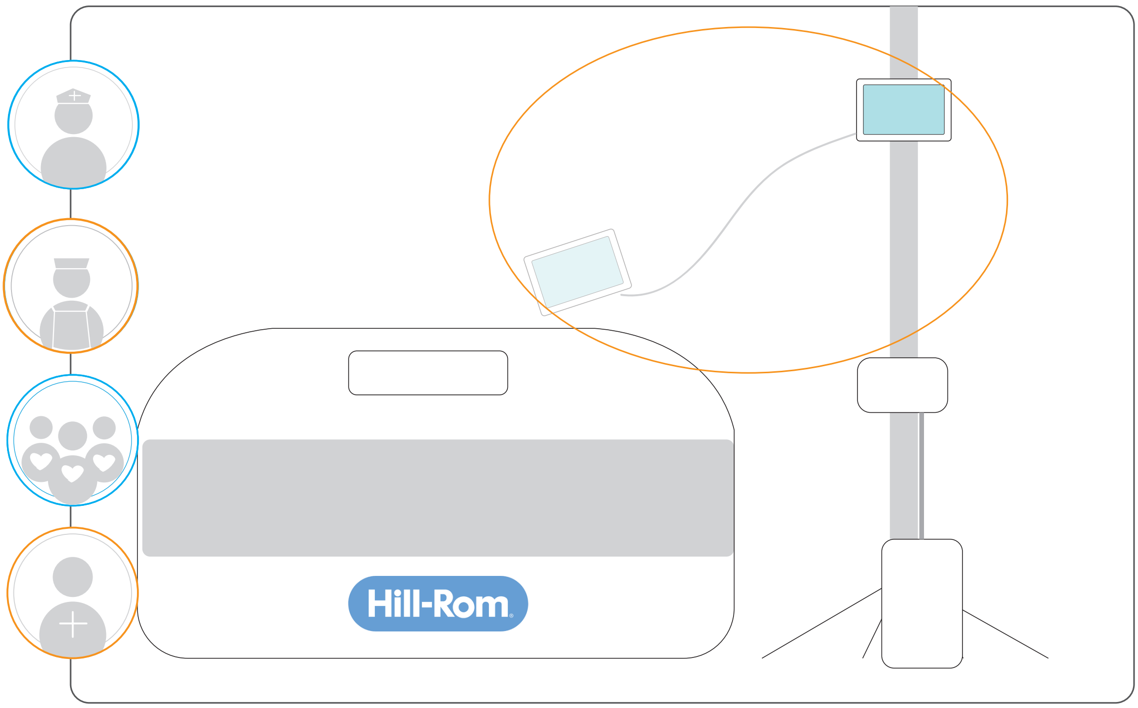


Figure 8.3: Overview of system parts for the assistant and (family of) patient

Doctors have different preferences. They are less involved with the patients and focus more on the treatment part of the recovery. Although they are still in personal contact with the patient the contact moments are limited and accompanied by nurses. FluidBalance will offer the doctor a more reliable overview of the fluid intake and output of patients which means treatments can be customized even better. Main wishes of the doctors are:

- A clear overview of the patient's fluid balance on the COW and in the EPD (which can be opened from anywhere in the hospital).
- Reliability in fluid balance overviews which involves the least chance of encountering human/technological errors.
- Having an overview of patients' fluid balance as complete as possible, taking into account vomit, diarrhoea, normal defecation and fluid losses due to transpiration.
- Being time efficient is very important to the doctors because they have a lot of responsibilities in the hospital which all require attention.

In general, physical interaction with the product is not important for the doctors. They just need to be able to trust the outcomes and use it to provide the correct treatments.

8.2 Other involved caretakers

The other users of the product are care assistants or kitchen employees. They only use a part of the FluidBalance system (figure 8.3). The nurse is not always around the patient and because the nurse needs to be able to focus on patient care and support as much as possible, other domestic and hospitality tasks (like cleaning, providing drinks and food) are performed by assistants and/or kitchen employees. In both hospitals the job as "kitchen employee" is being taken over by only care assistants. The patient is unfortunately not always adequate enough to make notes about their fluid intake and output, therefore assistants / kitchen staff take care of this tasks. Especially as they mostly provide the patient with drinks and food they know how much fluid is inside everything and how much is taken by the patient. The main wishes of these "other care takers" are:

- A clear overview of total intake and output next to the bed of the patient (to advise and/or answer questions) without the need to use the COW or other shared tablets.
- Not much effort to enter oral intake values.
- Offering the best experience for patients
- Being able to offer personal attention when needed.

Altogether the nurse and the assistant do show commonalities in needs. The assistant or kitchen employee, unlike the nurse, is not involved in decision making regarding treatment.

8.3 (Family of) the patient and PCC

The patient is in the hospital for a different reason than the nurse and other employees. His or her concern only is to get well as soon as possible and to be able to go home feeling confident, healthy enough and well informed. The family of the patient has approximately the same wishes and needs, but is sometimes more aware than the patient which means that they will ask more questions and be more critical regarding treatment decisions. The role of the patient regarding decision making has changed over the years mainly due to better access to information (internet, direct-to-consumer marketing of pharmaceuticals, greater media coverage for healthcare, etc.). This means that patient participation is being integrated into hospitals more and more. (Robinson, 2008).

Research has shown that Patient Centred Care (PCC) has a positive effect on the health outcomes of patients. L.C. Callister (College of Nursing, Brigham Young University, assistant professor): "Effective PCC practices were related to communication, shared decision making, and patient education." Disturbances in fluid balance can prolong the stay at ICU (Intensive Care Unit) and increase mortality (Lee, 2010). This means that depending on how critical the situation of the patient is, the fluid balance can be of great importance. In these cases family involvement could be even more important and required. The needs of the patient can be summed up as:

- Get well and go home as soon as possible
- Transparency regarding state of situation and treatment. Introduction of PCC is preferred which requires more education for the (family of a) patient to be able to understand consequences of decisions.
- Feel respected, comfortable and informed
- Easy understanding of products that they need to use.
- Possibility to rest and walk whenever they want to. No limitations from FluidBalance.
- Everything essential on easy reach distance from lying position.
- Does not want to be disturbed by annoying/scary sounds from the product.
- Needs to be reminded to drink (and use the toilet).

The family of the patient needs to be involved when the patient is not able to be involved or make proper decisions regarding the treatment.

To be able to distinguish differences between patients and be able to empathize with different patients, five personas were made. These five personas will be used throughout the project to check whether the product is still suitable for most of the involved patients. The patient personas can be found in appendix 14.

8.4 Conclusion

All users have different interests regarding care and therefore different requirements for FluidBalance as well. The nurse will be the main user who will be the most important to consult when usage and workload are being investigated. The doctor and the nurse are responsible for estimating whether a patient is capable to register a part of his or her fluid balance. The patient needs to stay satisfied, feel respected, informed and experience the best care (Robinsonl, 2008). These factors need to be considered during design decisions later on in the project. Although handing over parts of the responsibility to the patient does not always seem a good idea, it should be possible when the patient is considered capable and responsible enough by the caretakers.

Product system parts and responsibilities

9. Functionality and requirements

The product needs to fulfill different functionalities to be successful. These functionalities lead to different requirements that need to be combined to one solution. The main functionalities of FluidBalance and their requirements will be discussed below.

Urine monitoring
FluidBalance needs to provide reliable insights into the current fluid balance of patients. Therefore it needs to weigh the volume accurately and compensate for errors that can occur while the patient is walking around with the IV stand and when different types of fluids are being measured.

Communication and responsibility
To create a reliable fluid balance overview it is important that all relative parameters are communicated and registered clearly. Communication is important when something is wrong with the system, especially when replacement of a bag is necessary or the fluid balance of the patient is drastically changing. Furthermore communication is needed between the different involved caretakers and the patient. It needs to be clear which tasks need to be performed by who and who is responsible for what. For example the information about the patient's state and how many times fluid balance needs to be calculated needs to be clear for all parties.

Connectivity
FluidBalance contains internal technology that needs to form a connection with other parts of the system. Back-up solutions and warnings when internal or external connections fail is very important in order to provide accuracy at all times.

Product usability
Apart from the technical performance of the product the product needs to meet specific requirements regarding placement, understanding, fixation and ergonomics as well. What is more, cleaning and materialisation of a medical device requires more care than in case of non medical devices. Smoothness of the surface, being able to withstand oxygen rich environments and being able to withstand water contact in some scenarios are all important factors that need to be considered during the design of the product.

Interfaces and cognitive ergonomics
The total system will be partly digital by means of an application. Smooth communication, understanding of the interface and integration of the application with the FluidBalance hanger which is performing the measurements are important requirements.

Contextual fit
Last be not least FluidBalance will not be the only product to provide care to the patient. The hospital contains many more products of which some of the products are present around the bed of the patient as well. FluidBalance needs to blend in with the current logistics and and be easy to use in combination with other products in order to be a success.

Program of requirements
Together with the upcoming research, interviews and tests a total list of requirements will be built. Apart from the requirements wishes are formulated as well. The full Program of requirements (and wishes) can be found in appendix 9. A list of requirements is a working document and needs to serve as criteria during decision making.

“To create a product (product service system) which can optimize fluid balance measurements to create enough accuracy in Fluid Balance measurements in an unobtrusive, reliable and affordable way. This should be accomplished without decreasing the experience of the patient and the nurse. The design should be such that it could be implemented within five years.”

- Design Goal -

10. Configurations and placement

Before designing the product, it is useful to have a good overview of the different parts which can be included in the design. As the product can be extended endlessly, this does not always mean improvements.Determining the extensiveness of the product in general will serve as an input for the next steps.

10.1 Comparing configurations

Apart from the extensiveness of the system (defined in project scope), the composition of the FluidBalance hanger is still undetermined too. Different configurations of where to place the interactive screen, size and placement of the weighing modules were compiled and compared using a subjective haris profile (appendix 10). The ranking and formulation of the criteria was based on the contextual research, interviews with the nurses and formulated requirements.

Conclusion

From the profiles it can be concluded that configurations four and five are the least favourable. Configuration three seems to be the most promising (figure 10.1). An important factor to determine whether this configuration is suitable will depend on the level of patient involvement are taken into account.

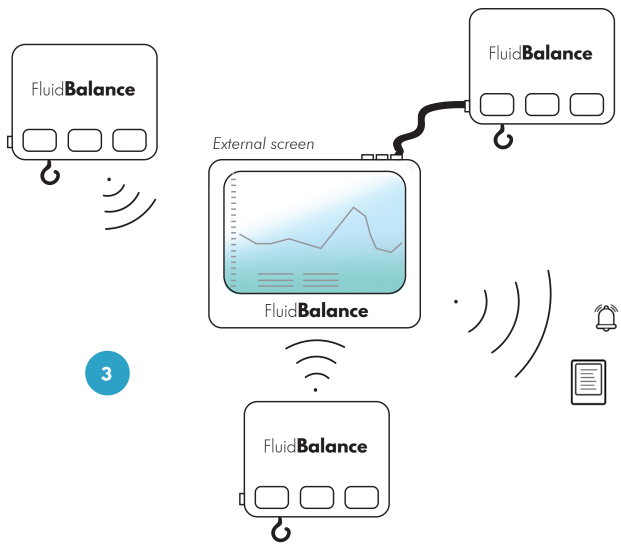


Figure 10.1: most promising composition

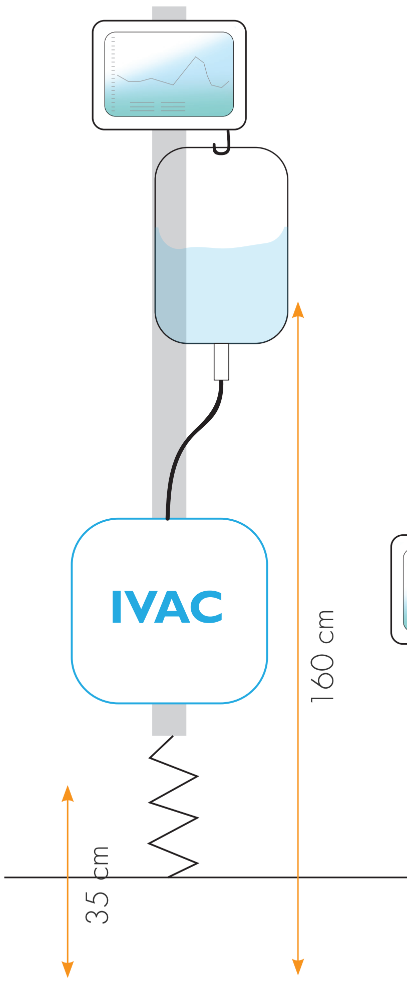


Figure 10.2: End of the IV bag height and catheter height

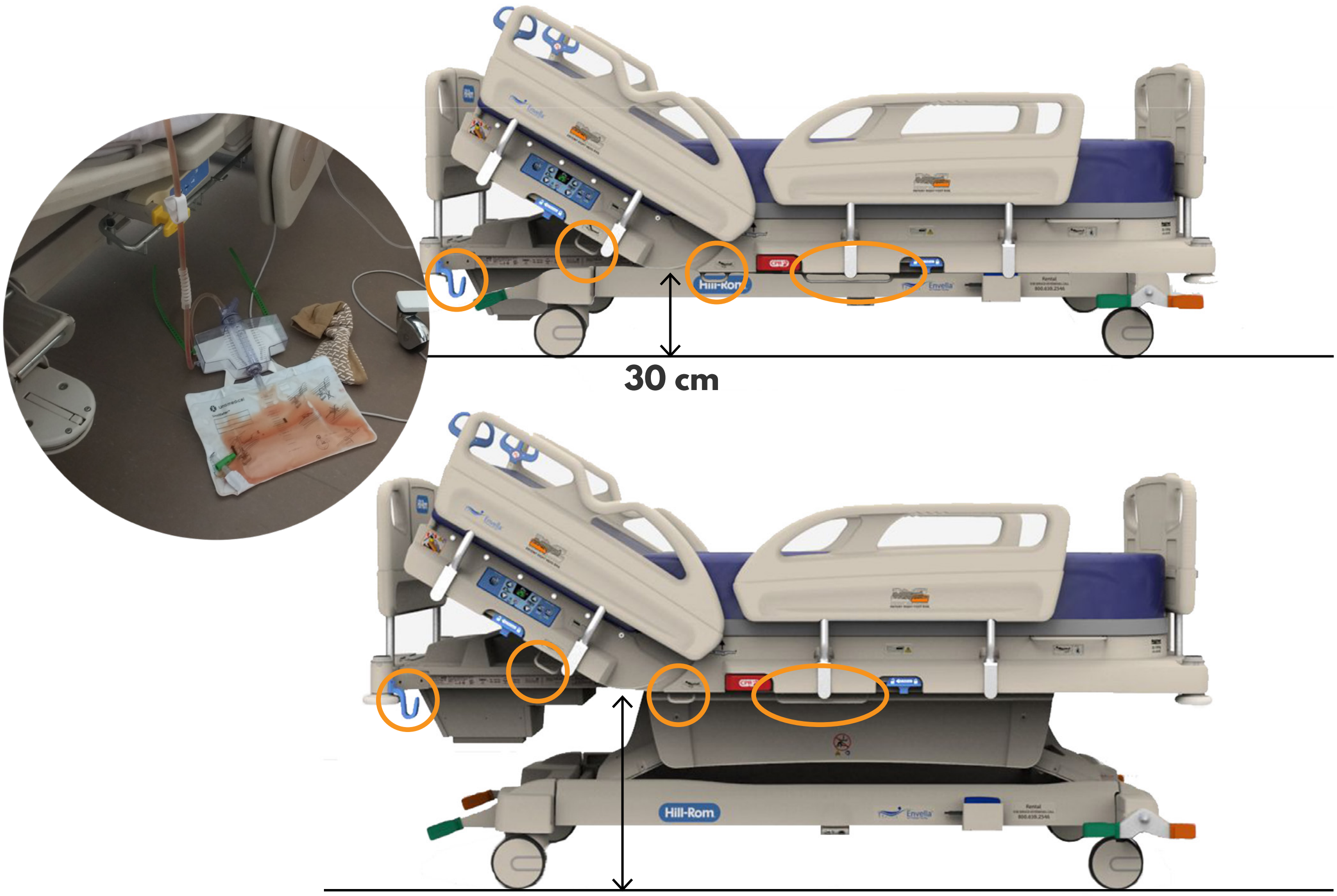


Figure 10.2: Placement of catheter bag on the bed is not possible when the bed is put in the lowest position. (Hillrom, 2017)

10.2 Placement in the environment

The product needs to be placed at a location around the bed of the patient (appendix 15). At first the idea was to use both the bed and the IV pole. After performing contextual research (chapter 8 and appendix L), looking at the users' wishes and the FluidBalance system as a whole it was decided to use the IV pole as much as possible as the only place for hanging system parts. This choice was made due to the following reasons:

- The total system on one place together makes it easier to move the system when the patient needs to be placed somewhere else.
- Having the system on one place makes it easier for the patient to go for a walk which provides the patient with a feeling of being less dependent. Apart from that, walking is being promoted by medical experts as it helps the patient to regain strength and mobility.
- Less chance that the patient feels the need to touch/ move the system when he or she wants to go for a walk. Or calls a nurse to move the system to the pole.
- Patients consider the IV pole as an important medical device which means that the system will be treated with ease and respect. The bed and the night stand are used for a lot more of other purposes (not medical only).

Despite all of these advantages choosing for the IV pole brings along important issues that need to be considered during the design process. The first issue is the fact that the IV pole is not used for the IV bags only (appendix 13). IVACs (IV computers), wall sockets and other devices are connected to the IV poles too. The FluidBalance system needs to be able to be used together with these devices or a different solution to avoid usage with these devices needs to be designed. The second issue is the required height. The IV bag needs to hang above the patient's head. Using the screen for input and interaction could become a problem. As an IV pole on wheels does not move along with the patient when the bed is put in a higher or lower position it is good to know what parameters determine the lowest and highest point for the placement of the bags. For the IV bag this results in approximately 1,60 meters and for the catheter bag approximately 0.35 meters above the ground (figure 10.2). When the bed is placed in the lowest position to prevent patients falling from their beds and get hurt the space left for the catheter bag to hang is too little (figure 10.3).

Relevance

After looking into the product configurations and finding what are important issues to consider, the product can be divided into parts with different functionality. By using "how to's" (Delft Design Guide, 2017) different functions will be explored and combined afterwards. These combinations will be an input for the creation of different concept directions. These chapters will summarize the most important outcomes of these ideation sessions.

11. Communication and responsibilities

11.1 Ideation Communication

Judging the different configurations, it turned out 1, 2, 3 and 6 were still interesting options. These options were therefore integrated into different ideas for the total system (including the COW, the communications streams and the patient's input). This led to seven interesting options which served as input for two interviews with nurses from different hospitals. The full interviews can be found in appendix 17, but the most important outcomes and findings will be discussed below.

During the interviews, several different communication options were shown (appendix 16 Figure 11.1 and 11.2 show the most preferred options. The discussion led to the following preferences:

- The nurse needs to be able to look into the current state of the fluid balance of the patient next to the bed without the need to use a COW. This means that information needs to be collected and fluid balance needs to be calculated at the pole and not at the COW.
- Use of the mobile phone is not preferable due to the fact that most patients (estimation: 90%) will not be able to enter their own information and entering this information should always be the nurse's (or assistant's) responsibility.
- An assistant is not allowed to enter information into the EPD. This is why a separate input device (apart from the EPD) would be required to create a way for the assistant to enter fluid information into the EPD.
- Bluetooth is preferred over cables because cables can get lost and get stuck with other necessary cables on the pole.
- Moving the product to a lower position (approximately 20 centimetres) towards a more and ergonomic working height for the nurse is not preferable as the IVAC (IV computer) would need to move as well. This is due to cables being fixed as tight as possible (without pulling the IV bag downwards) and loose hanging cables can get stuck. Finally the IV bag could hang over the IVAC when moving the FluidBalance hanger up and down. (image 11.3)
- As little responsibility for the patient as possible. Patients are mostly not capable of registering their own fluid intake as they are physically and or mentally unstable.

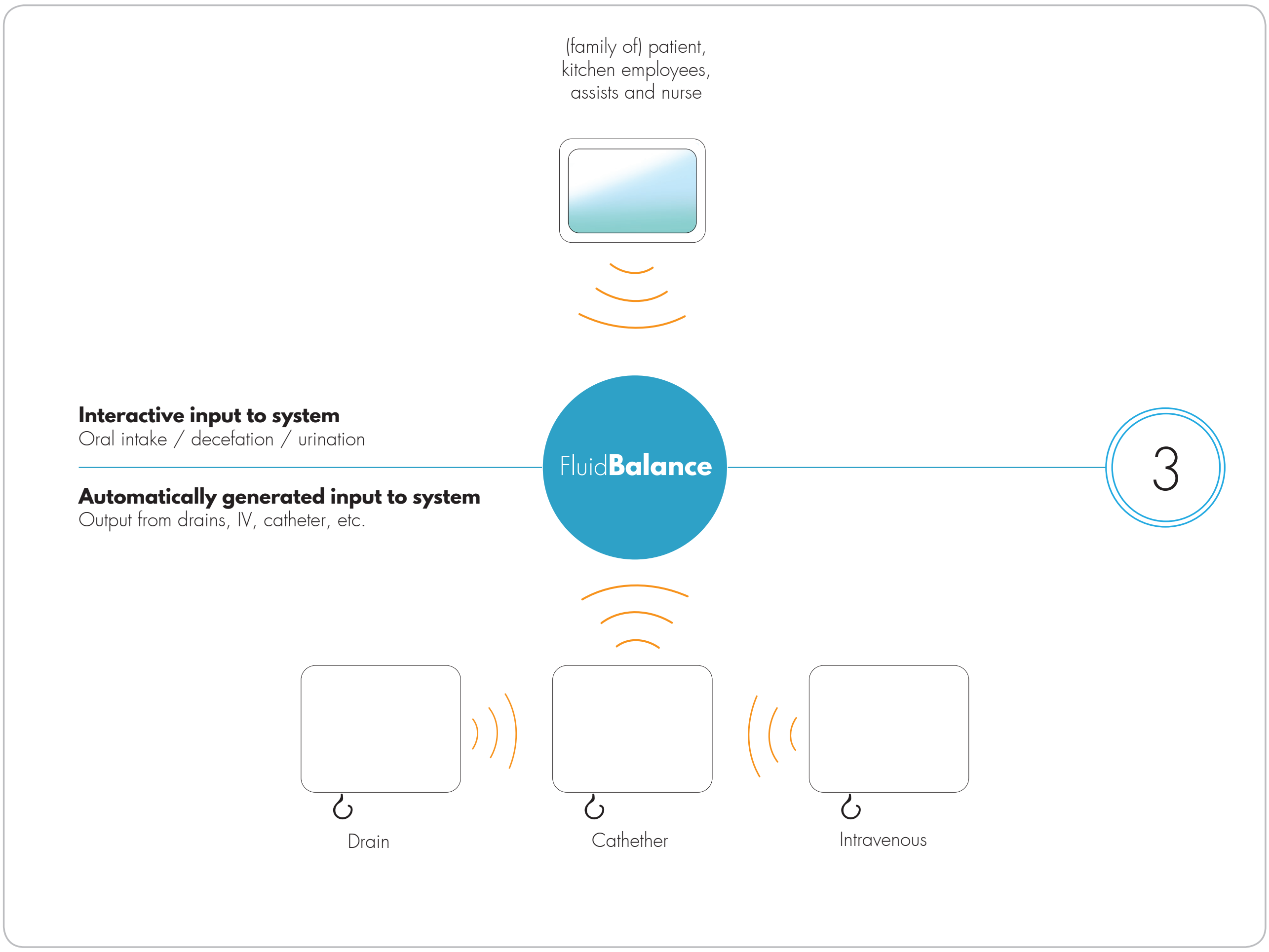


Figure 11.1: Communication possibility one

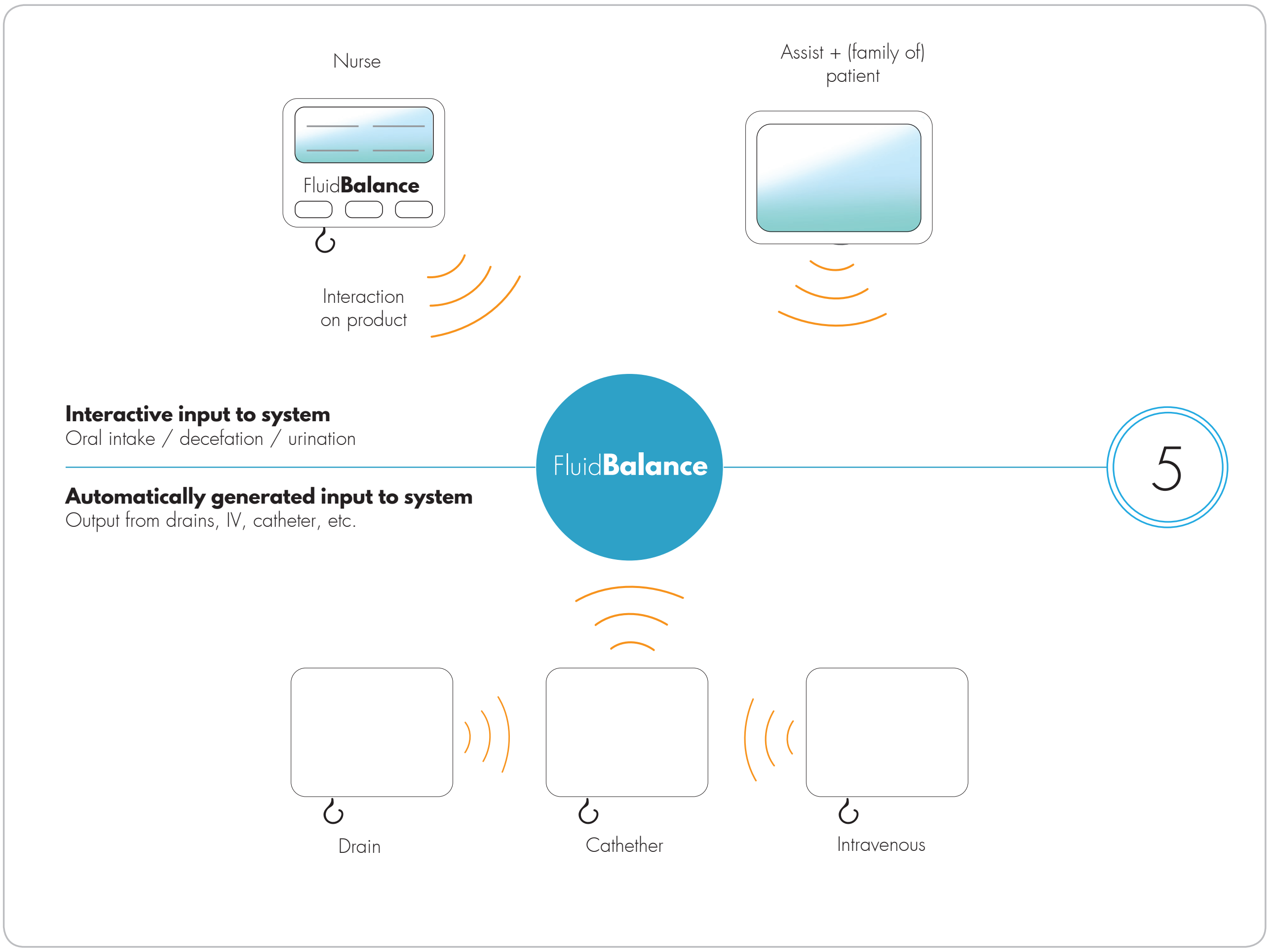


Figure 11.2: Communication possibility two

From the seven presented ideas, idea one almost fitted perfectly into the wishes of both nurses (figure 11.4). The only disadvantage is the remote controller. Patients already need to deal with different remote controls which is already confusing sometimes (especially for elderly patients). If the patient is capable of registering their own fluid intake this can easily be done from the same screen as the nurse (and assistant). It is important to keep the entering process as easy as possible and divided from other medical information / controls for IV and catheters.

11.2 Conclusion

The discussion led to new requirements and insights into preferences of the nurse. The fact that patients are mostly not capable of registering their own fluid intake means that the logistics regarding daily contact moments need to be investigated. This is necessary to find out if manual monitoring by caretakers will be sufficient to create a complete fluid balance. These main findings and wishes were used as input for the next steps in the ideation process.

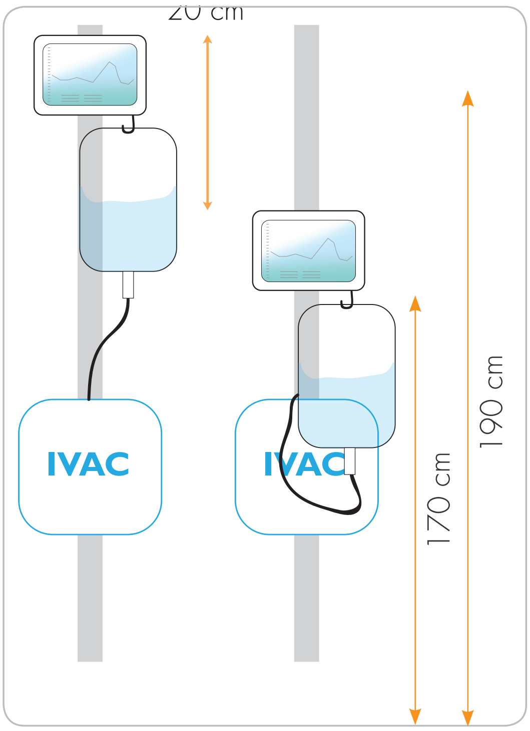


Figure 11.3: Overview of ergonimc height difference

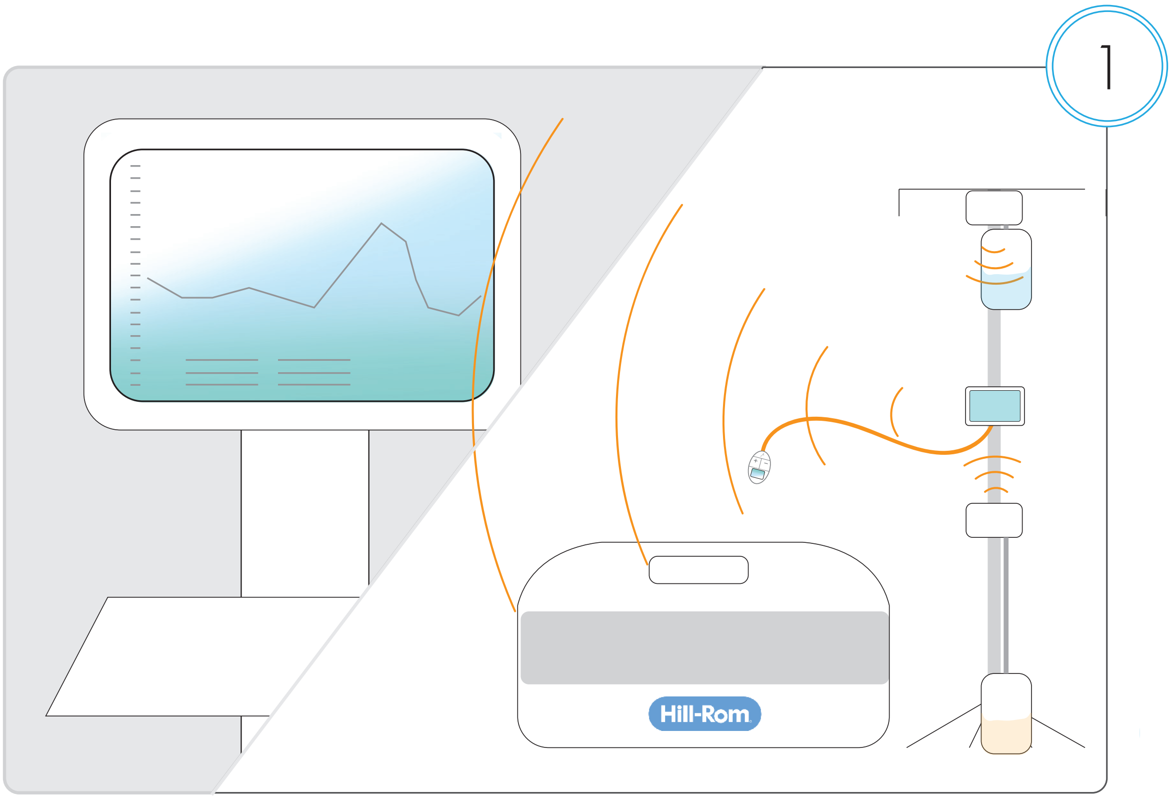


Figure 11.4: Possible composition of total system

12. Level of automating and responsibilities

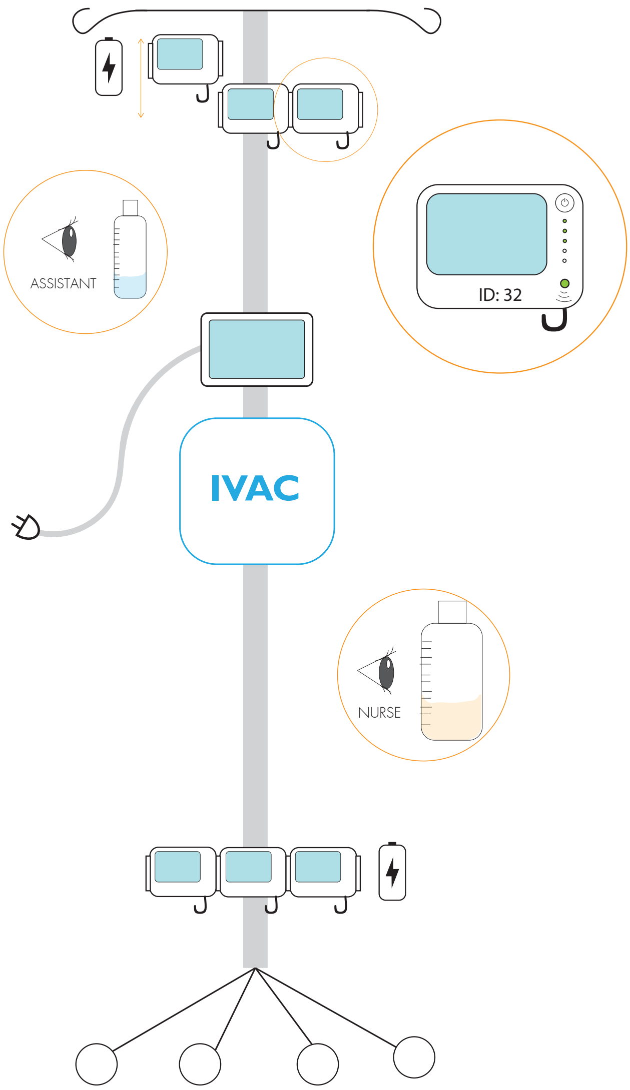


Figure 12.1: Overview system parts outcome of criteria method

12.1 Ideation system parts

Based on the newly gained input and considering the amount of automated input that should be gathered by the system, five important system parts were investigated separately to form different alternatives: oral intake monitoring, output apart from weighable catheters, integrated system parts versus loose system parts, patient experience and who is responsible for what. To make sure that the alternatives were compared fairly, weighted criteria were used. Based on these criteria a few options were no longer considered interesting. Appendix 18 gives a clear overview of the criteria and descriptions of the different alternatives.

12.2 Comparisons and conclusion

The difference between the alternatives is very small, this is mainly due to the fact that all alternatives either score high on one important factor and low on the other important factor and the other way around. Altogether this leads to almost evenly divided scores. To get a better insight into the different alternatives scenarios will be compiled for the four most interesting alternatives to be further compared with each other during interviews with medical experts (and patients). For now alternative 1 can be interpreted as the most favourable option (figure 12.1).

12.3 Research of logistics at UMCG

The full research setup, results and findings can be found in appendix 19. This chapter will only explain the main outcomes of the latest research in the UMCG and what insights to continue with for the project. The next page (figure 12.2) shows a simplified overview of several hospital wards, depicting the different times throughout the day during which nurses interact with their patients. Also shown are the different types of patients that are generally hospitalized in these wards. In the simplified images, the current contact moments for fluid balance measurements are left out to see what a day would look like if the FluidBalance system were used. It is clear that all wards have contact moments at the patients' bedside every hour. As expected, the Intensive care ward turned out to be very different from the other three.

The intensive care can be considered the best organized ward to control the patient's fluid balance as there is close control (strictly every hour) on oral intake (sometimes there is no oral intake at all), other fluid input, urine output and other fluid output.

The other wards (Cardiology-, Nephrology- and Geriatrics) are more similar. Only the Nephrology department saves a patient's urine for 24 hours, making a fluid overview after each day. The other two wards note down the patient's urine output right after the patient went to the toilet, then throw it way. Another clear distinction between the Nephrology ward and the other two wards is the age of the patients. The age of the patients in a Nephrology ward differs more than in other wards. Nephrology patients can be quite young. The Nephrology ward showed interest in having a spot to weigh urine before and after going to the toilet. For Nephrology patients, pouring their urine into a urine bottle is the most difficult task as they moslty have a belly wound. 60% of the patients would be able to weigh their urine (which would be recorded in their patient files) after they went to the toilet without a problem which makes saving and pouring over the urine redundant.

For the two most similar wards (Geriatrics and Cardiology) it was clear that concept one (manually noting down urine and oral intake) is preferred over the others. The caretakers are around often enough when a patient uses the toilet as patients often need support when using the restroom. If they do not need support the nurse still wants the patient to call when he or she goes to the restroom. The nurse keeps a close eye on his/her patients throughout the day because most of the patients are old and tend to forget important things like remembering their urine output.

One nurse of the intensive care showed interest in having a small screen on the wards for feedback to make sure that the right information, which is entered on the main screen, is connected to the right bag. Furthermore, he preferred to have the latest measurements visible on the device or have a priority screen on the main screen as screen saver (which shows the latest values of a selected FluidBalance hanger). The rest of the nurses all preferred to have the most simple option where all interface interaction is done from one main screen.

Of course, these outcomes are not totally representative for all four wards as only seven people from one hospital were involved in the research. Although it does give a clear overview of needs, logistics and patient types in the different wards.

12.4 Involvement Intensive Care

The Intensive Care (IC) differs a lot from the other wards. When looking at the possibility to save time on manual controle moments, the logistics in intensive care show opportunities for improvement as multiple fluid input and output sources are present. On the other hand the need for more accuracy there is less high as current protocols and control moments are already regulated better (compared to other wards) and only performed by the nurse (not an assistant) due to the critical situation of IC patients.

The IV poles at the intensive care differ from the IV poles on the other wards and are used for far more other appliances than just the IVAC. An idea to solve this problem is to create an extension for the fluid balance hanger to attach it to other products or have it stand alone. This requires more research which will not be the main focus of this graduation project. Due to time limits it is decided to focus on the other three wards first.

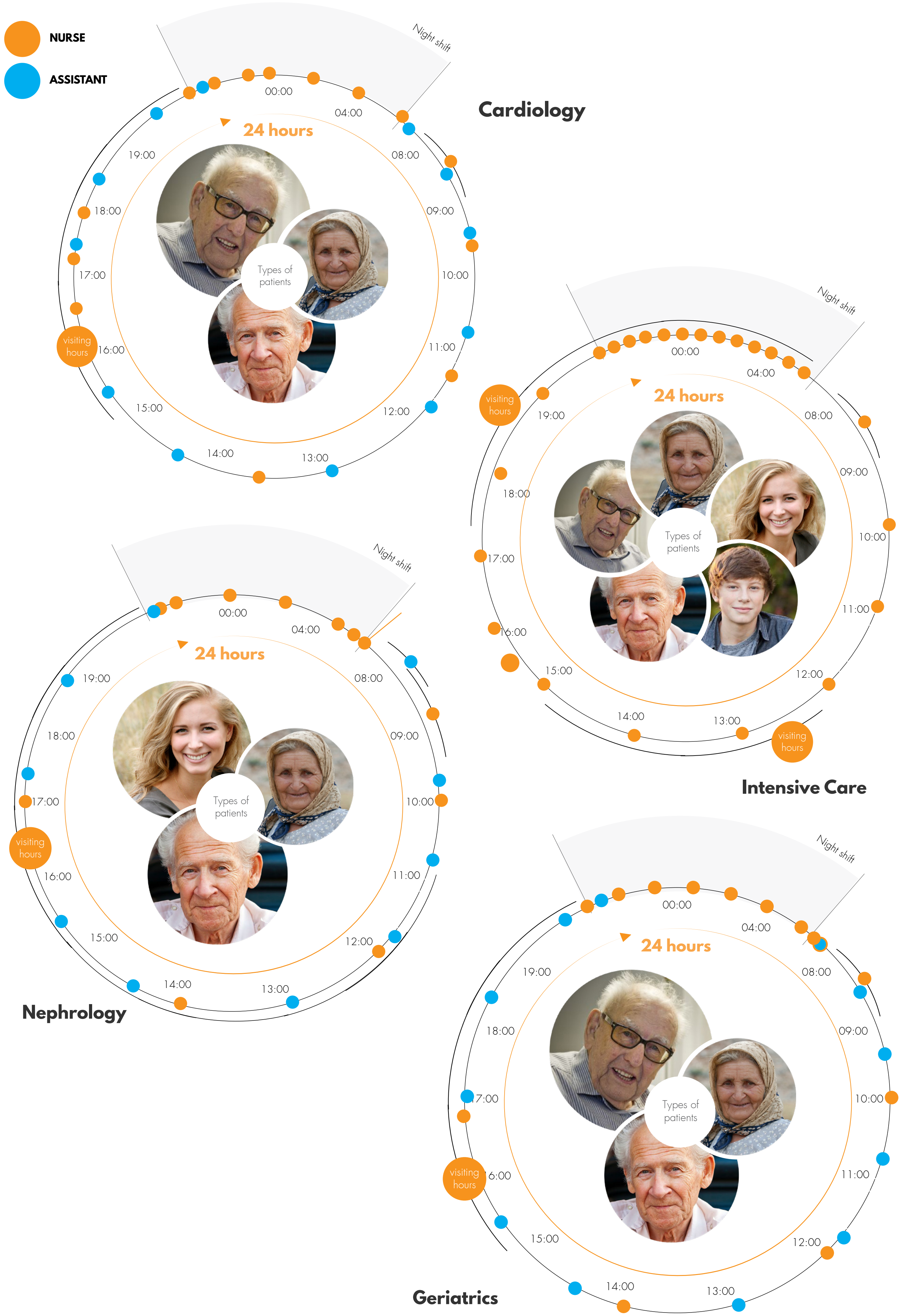


Figure 12.2: Simplified overview of contact moments without fluid balance check ups.

ASSIGNMENT:
To create a product (product service system) which can increase accuracy in Fluid Balance measurements in an unobtrusive, reliable and affordable way without decreasing patient experience which could be implemented tomorrow.

12.5 Conclusion on level of automating

In chapter three different ways of how the body gains and loses water were discussed. After interviewing several nurses from two different hospitals, developing different concept directions for the level of automating and responsibilities, discussions with TIM Solutions (in their role as doctor) and talking to different wards at the UMCG a choice was made on what parts to automate and what parts to leave for manual input. Table 12.3 on the next page shows a summary of the outcomes. The reasoning behind these outcomes will be discussed below.

To explain which parts are left out of the measurements and why accuracy needs differ for different fluids, it is good to look back at the main assignment of this project (shown above). Important points are: reliability, affordability, no decrease in patient experience and being able to implement the product soon.

Earlier research at the UMCG and RDGG showed a wish for the possibility to automate monitoring the output from catheters and different types of drains. Especially monitoring urine output is important. On all of the wards where people were interviewed it is important to notice differences in urine output as soon as possible in order to act accordingly within the treatment plan. Automating this output and integrating alarms when specified limitations are reached offer enough accuracy on this topic. When close monitoring is needed and the patient's situation is critical (intensive care and the first day after heavy surgery) the patient mostly wears a catheter which is why control of the urine output without a catheter is often less critical. Of course, it needs to be integrated into the total fluid balance, but the amount can be estimated and filled in manually.

The total input of fluids is less critical than the total output. Of course a difference of 100mL or more should be noticed, but medical treatment plans are mainly based on urine output. This means that manual input for drinking and IV would be an option. Manually entering the amount of fluids which are drunk by the patient is relatively easy to integrate into the current logistics. The hospital has hired assistants to support the nurse in her tasks and to take care of the drinks, snacks and meals of the patient. The timing of these moments is approximately the same for the Cardiology, Nephrology- and Geriatrics wards. The IV is a different type of task as it can vary for different patients and the logistics around it is a less standardized process. Apart from this, integrating the IV into the automated part of the system is relatively easy as it cannot be influenced by the patient (with drinks a patient can choose between different types) and it's always in a bag which can be weighed.

Of course, the more accurate the system, the better the total fluid balance is. This is why the application should provide a way to enter different types of fluids (vomit, diarrhoea, and normal defecation) from which the amounts can be estimated by the nurse or assistant. A possibility is to express the amounts of these fluids compared to how many cups it would fit in. As these output fluids are all different in structure and composition, are disposed on random moments and sometimes at random locations it is hard to create a customized solution for all of these outputs. This solution depends on the ability of the nurse to estimate weight and amount of fluids. This is why it would be interesting to have one general scale per hospital room to weigh the amount of different outputs. The application could provide a multiple choice from one till three representing a different liquidity of the substance for example. Within this graduation project the scale will not be developed; no research will be done on liquidity

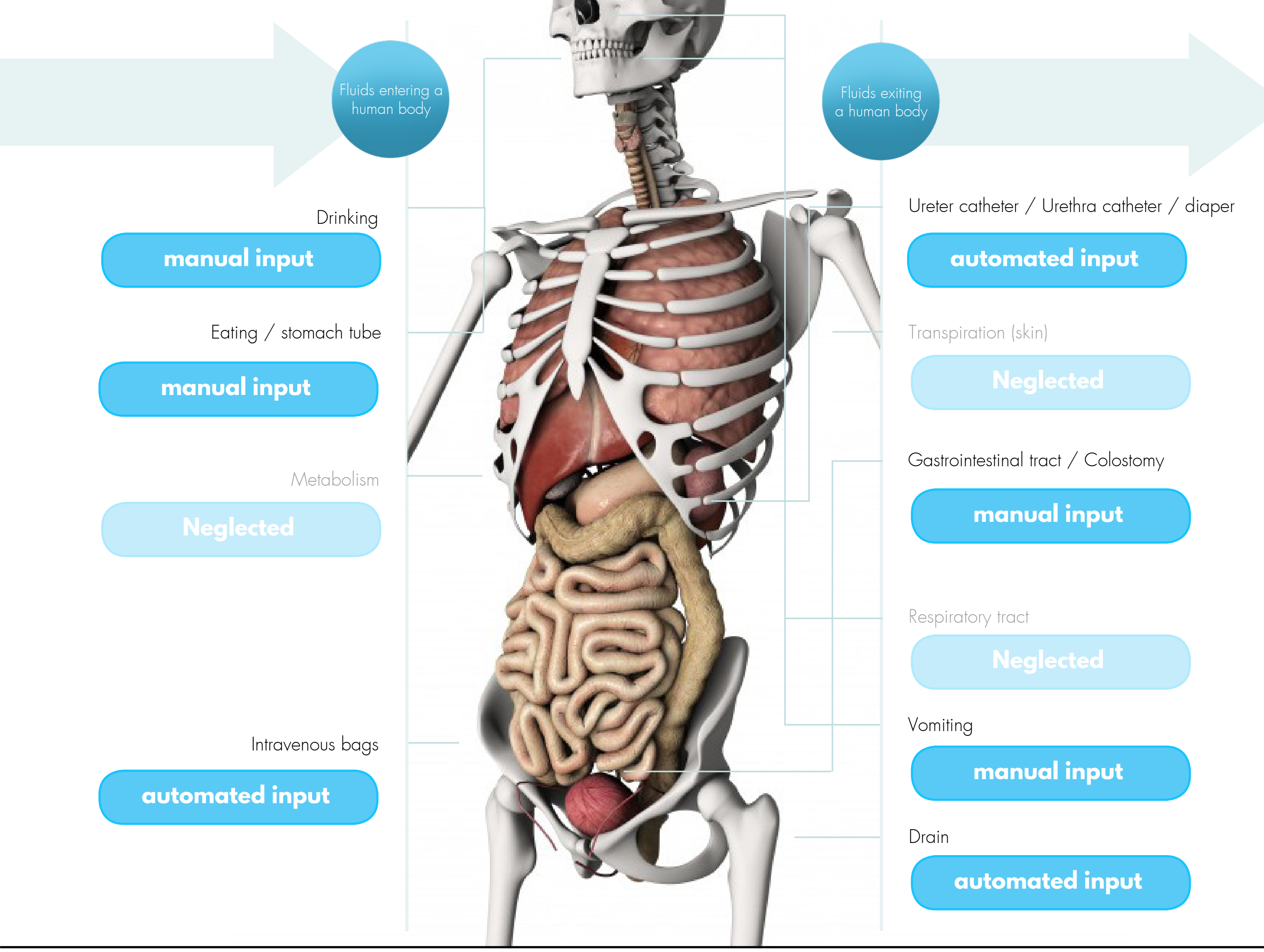


Figure 12.3: Overview of fluids and whether they will be neglected, automatically - or manually monitored.

of different substances. For this project these fluids are considered "other fluids" which require manual input and estimation.

Apart from the automated and manual input, three sources are neglected in the total overview. Two of these sources (metabolism and respiratory tract) cannot be captured by measurements and do not influence the patient's situation much (and therefore the treatment plan) which is why they are not integrated. Transpiration can differ per patient based on their body temperature. Compensation on fluid losses due to sweating have not been integrated into the solution yet, but require interpretation of the nurse or doctor. Temperatures are measured every day for all patients at all wards and are written down in the patient file (which will become the EPD soon). Together with knowledge about temperature and the level of fluids in the skin of the patient a more accurate overview of the measured fluids is formed. At the moment research is being done on how to integrate fluid losses due to sweating into the fluid balance calculations (Nijsten, 2017). The outcome of this research could be integrated into fluid balance in a later stage, this will not be integrated into this graduation project as this project focusses on a product that can be implemented as soon as possible.

Altogether input from IV, gastric feeding tube and medication in bags and output from catheters and drains will be measured automatically. Manual intake by the patient and output, apart from the automated output, will be entered into the system manually within this version of FluidBalance.

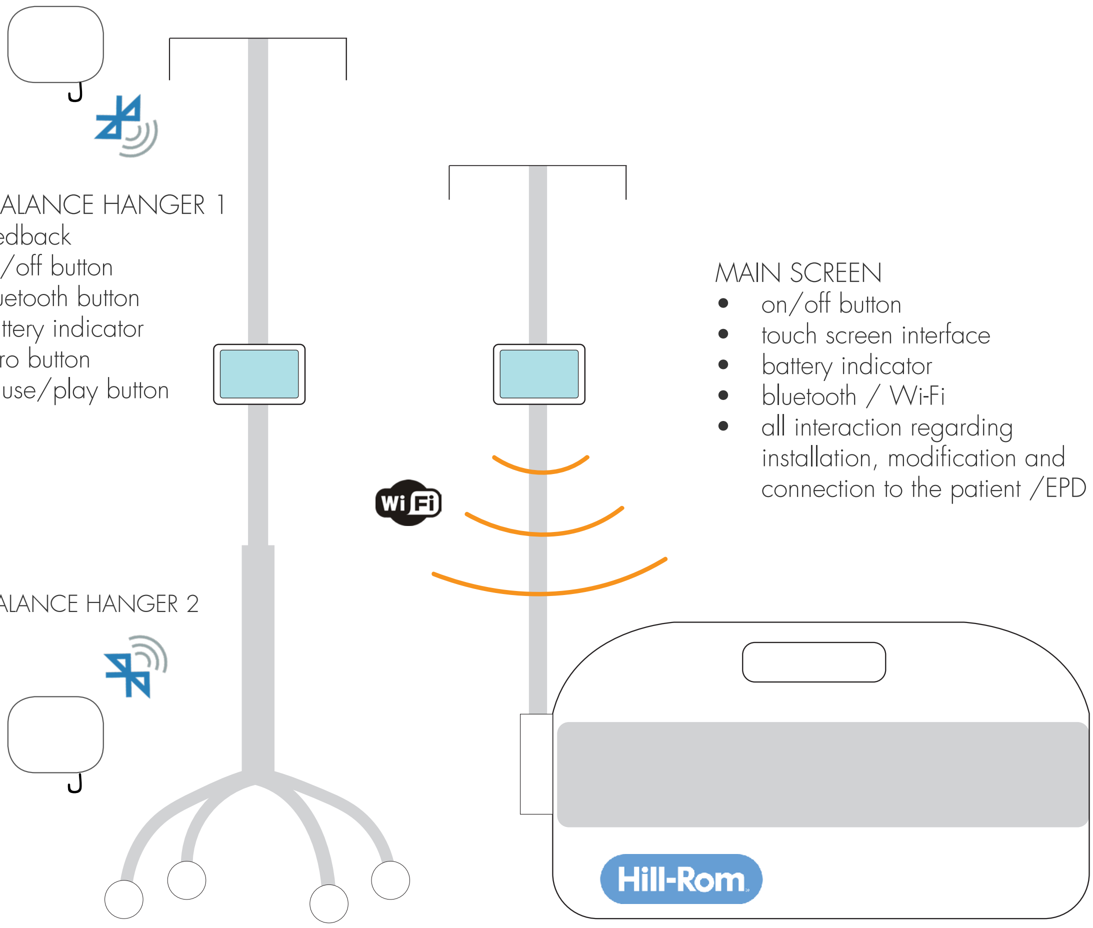
12.6 general conclusion

Taking into account all the preferences of the interviewed nurses and conclusions of the field research at the UMCG concept direction one (manually measuring oral intake and urine output apart from the catheter) came out as the best suitable option.

Conceptualisation FluidBalance hanger

TOTAL OVERVIEW FLUIDBALANCE SYSTEM

Within the FluidBalance hanger specific technologies are needed to perform the required tasks. Page 58 and 59 show an overview of the final outcomes from the research on interaction, logistics and responsibilities.

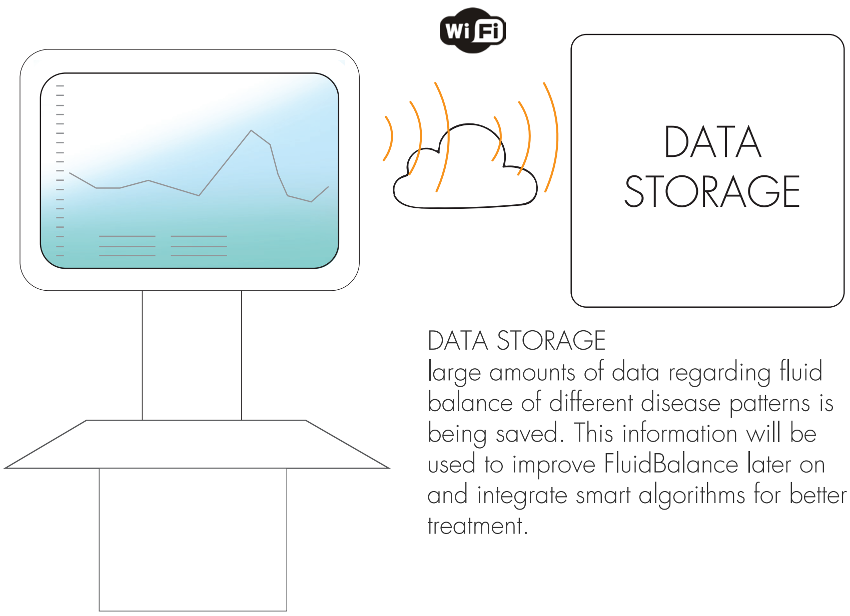


FLUIDBALANCE HANGER 1
- feedback
- on/off button
- bluetooth button
- battery indicator
- zero button
- pause/play button

FLUIDBALANCE HANGER 2

MAIN SCREEN
- on/off button
- touch screen interface
- battery indicator
- bluetooth / Wi-Fi
- all interaction regarding installation, modification and connection to the patient /EPD

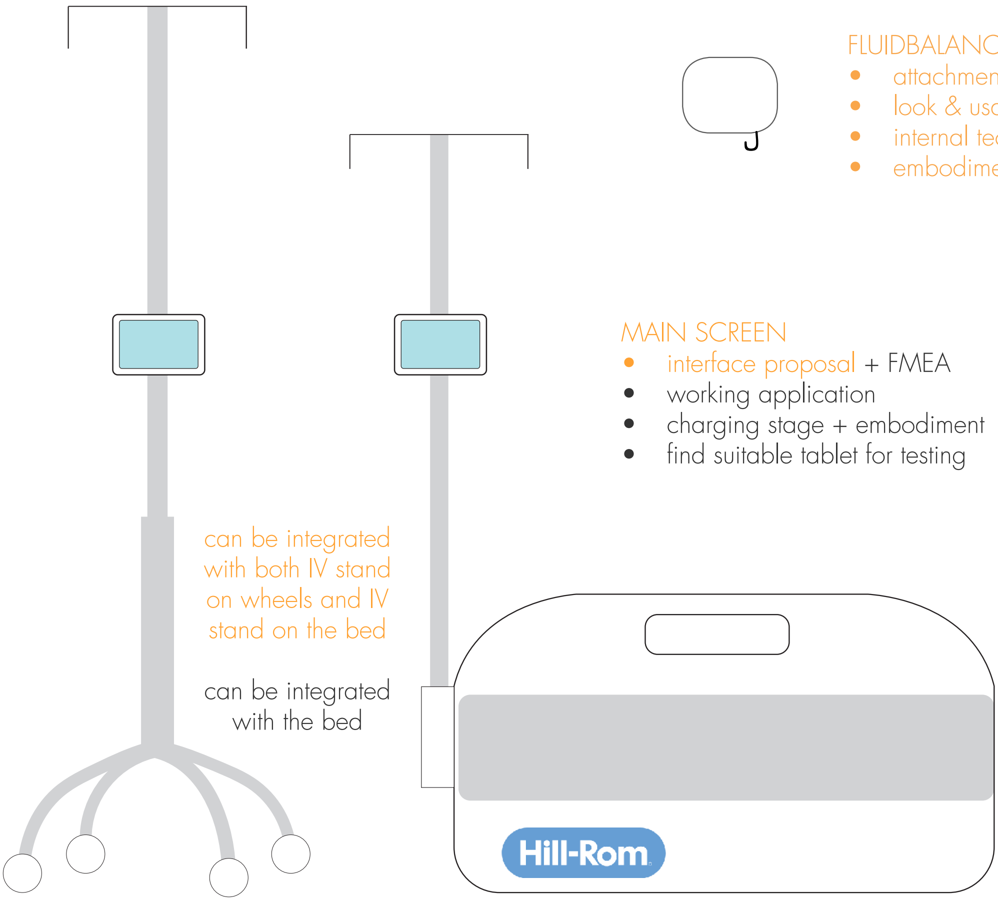
COMPUTER ON WHEELS
- All information on main screen is visible on the COW as well. Information on main screen cannot be modified from the COW.
- COW offers more in depth overviews of patient fluid balance of multiple days/months.
- Access to many other applications and medical tasks.



DATA STORAGE
large amounts of data regarding fluid balance of different disease patterns is being saved. This information will be used to improve FluidBalance later on and integrate smart algorithms for better treatment.

FOCUS DURING GRADUATION PROJECT

To achieve the functionality and interaction which is shown on the previous page several steps need to be taken. Within the graduation project the focus will be on the orange parts (page 71) as these parts are the most important for the first tests on performance and usability.



FLUIDBALANCE HANGER

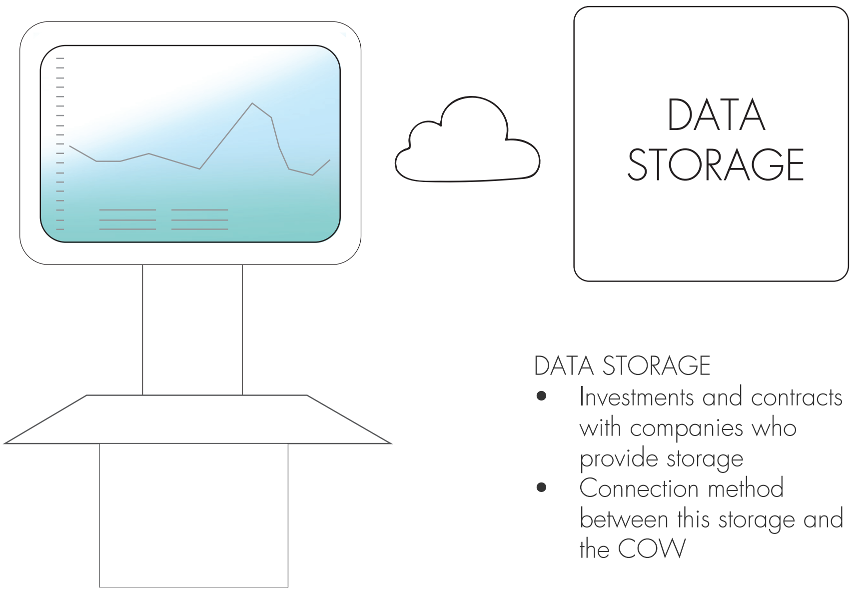
- attachment
- look & usage
- internal technology
- embodiment proposal

MAIN SCREEN

- interface proposal + FMEA
- working application
- charging stage + embodiment
- find suitable tablet for testing

COMPUTER ON WHEELS

- Application FluidBalance
- Connection to EPD



DATA STORAGE

- Investments and contracts with companies who provide storage
- Connection method between this storage and the COW

Relevance

Integration of the technology will partly determine the possible looks of the product. The size of the product, the form of the product and the weight of the product are all determined by its internal technology. Especially, as the product needs to be able to be used for half a year without the need for charging, careful calculation on what battery size is needed and what screen uses how much energy is important.

13. Internal technology

Some of the technologies are already discussed in chapter five and therefore skipped here. This chapter will mainly focus on battery life and size, types of load cells, different types of screens including their energy consumption and bluetooth energy consumption.

13. 1 Suitable load cells

The idea is to keep the product small enough to make it fit in one hand due to weight and distance between measuring tool and bag requirements. What is more, the product should be able to hold 10 kg (and have a save overload of 200%), a weight needs to be attached by means of a hook and it should be available for less than twenty euros. Finally the product needs to be available with a CE certificate or other highly tested results that prove performance of a mass-produced product. (see appendix 9 for total list of requirements)

Since the Fluidbalance hanger will be hanging on the IV stand two types of load cells are left to be implemented. The single point load cell in bar shape as discussed in chapter five has one disadvantage. The load cell works well if one end of the product is fixed in a stiff way and the other part is loose from any other part but the hook and therefore the bag. The load cell in figure 13.4 does not have this disadvantage. The upper hole is attached to a hook and the lower hole as well. This means that the product can hang more freely. A disadvantage of this load cell could be the fact that it is able to move more and cause more noise when measuring. Load cells do not require much energy. Kitchen scales can run for years on only one coil cell battery.

13.2 Display selection

Different types of displays are available, but the energy consumption is the most important because battery replacement on a regular basis does not fit into the hospital logistics. E–paper with front light turned out to be the best fit for the job as it uses very little energy and the image is always visible during the day. Nowadays e-paper still takes around 10 seconds to refresh, but some companies are working on improvements on this and integrating full colour. For a more in-depth explanation of the energy usage and differences between several interesting displays, please read appendix 22. Figure 13.1 shows an other application that reveals possibilities of e-paper.

13.3 Bluetooth energy consumption

Bluetooth low energy (BLE) (figure 13.5) in itself does not use energy. Forming the connection, being active (or in sleep mode) and sending data is what consumes the energy. The BLE module itself only performs the function, the hardware and software requirements around it determine how much energy it uses (Rijfkogel, 2017). This means that energy savings can be gained by creating an energy efficient design. Possibilities are definitely there. Timers can be used to make sure that the screen, the BLE en other modules are turned on only when needed. The bluetooth module would only need to be on every 10 minutes when information is being sent to the tablet. Sending over one result requires around 7,65 micro watt (around 50 bits per message). This means that sending every ten minutes would require 0,66 W per day which is very little (informatik Berlin, 2014). A bluetooth module and its hardware should be able to run for years on a single coin cell battery.

13.4 Accuracy load cell and movement

During a test with both the S-beam load cell and the fixed load cell (figure 13.4) information was gained on accuracy during movement on the IV Pole. Both load cells encounter influence of movement on the measurements, especially if the catheter hose (in the test the Arduino cable) hangs next to the bag and therefore

Figure 13.1: example of a smartphone case with e-paper. Retrieved from: Technobuffalo.com

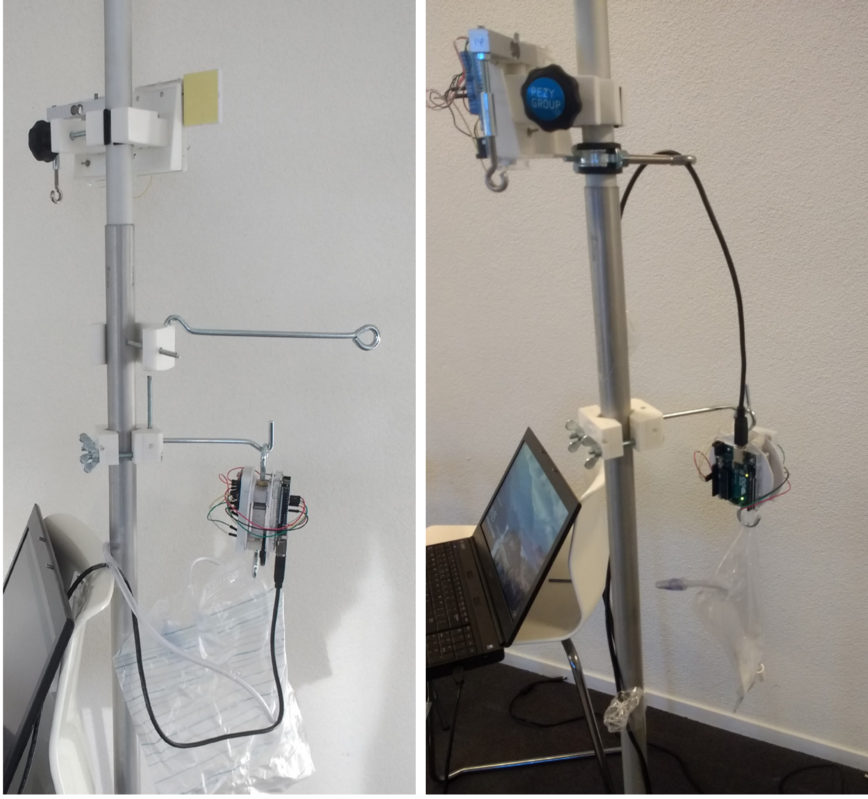


Figure 13.2 and 13.3: Setup testing accuracy

can get tangled up with the bag during movement. Both cells quickly recover from these movements (within seconds) which means that long term swing and longterm sloshing of the fluids is not the case. The fixed load cell does encounter less extreme influence on movement, but recovery from movement (back to the stable signal) requires the same amount of time. Both load cells would require adjustment for movement as the signals gained deviate too much from the stable signal. This adjustment can be included by means of an accelerometer and by ignoring big weight steps in the software already. Figure 13.2 and 13.3 show the test setup. The full results of the test are presented in appendix 27.

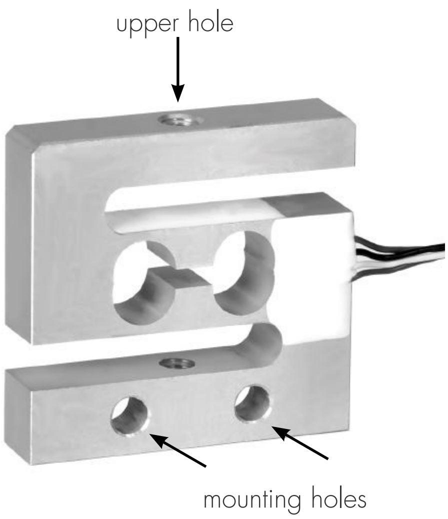


Figure 13.4: S-Beam type load cell

13.5 Battery life time and size

Battery lifetime is determined by energy consumption of all hardware inside the FluidBalance hanger. This includes the screen, sending messages with bluetooth, providing feedback with lights, performing data averaging calculations on the microchip, the accelerometer and the normal drainage of the battery over years. For a product that needs to last six months a 46x34x6mm sized flat battery (1300 mAh, 3.6 Volt) should be enough for a battery lifetime of more than half a year. (appendix 23).

13.5 Conclusion

Altogether it can be stated that the whole technology will fit into a hand sized product (figure 14.3 - 14.6). These insights will be used during the embodiment of the total FluidBalance hanger and the first model.

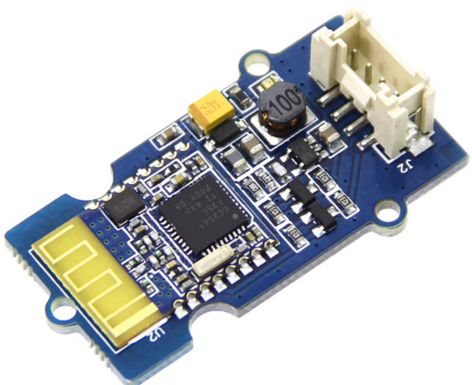


Figure 13.5: BLE module example

Relevance

Before starting off with the look and feel of the product it is good to make decisions early on about usage and preferred architecture to prevent too much effort being put into architectures which might not be used.

14. Architecture

It has been determined that within this first version of FluidBalance the IV pole will serve as main connecting attribute as it provides mobility to the patient of today. Another study can be performed on how to improve the experience of walking around with an IV pole as that is out of the scope of this graduation project. This means that a combination needs to be found to make a fitting product for both the IV pole which is placed inside the bed of the patient and the IV pole on wheels. This leads to new ideas and a combination of ideas into concept directions. This chapter will only present the main findings and comparison of the concept directions.

14.1 Correct placement of bags

At the moment bags can be placed on the floor when the possible urine flow is not good enough. Besides that, bags can be placed against the IV pole or bed and against each other. When using FluidBalance, proper placement and free space around the bag will be required to perform correct measurements (figure 14.2). Finally an important restriction is the maximum height that the FluidBalance hanger can be as the IV bag already needs to hang at approximately160 mm distance from the floor (figure 14.1) This means that the hanger should be as short as possible. The device should not exceed 100 mm (including brackets).

14.2 Comparing concept directions

Ideation on covering the distance between the bag and the device, distance between IV pole and forms was performed to be able to create first concept directions for the FluidBalance hanger. (Page 61 and 62 give a first impression on these ideas) Some of the sketches used are presented on the next two pages. Based on these findings combination between these ideas were formed and subjected to criteria. The full description and comparison is presented in appendix 24. The criteria are based on gained experience inside the hospital after talking to caretakers, the logistics inside the hospital and keeping the product as simple and low cost as possible to improve competitive advantage. To compare the concept directions a Harris profile is used.

14.3 Conclusion

The comparison of the concept directions (appendix 24) shows a preference for concept direction three. Concept direction six, which scores quite well as well, does not make use of the current IV pole hooks which means that more extras are needed. Furthermore applicability at the intensive care as the employees from the IC wish to have the possibility to easily move the FluidBalance hangers and even hang them on the bed is better for concept one. The next step is to integrate this architecture into different forms and create different look and feel experiences. Furthermore a solid solution, fitting the looks and functionalities of the FluidBalance hanger, for the adaptor on the IV pole requires further materialisation and designing.

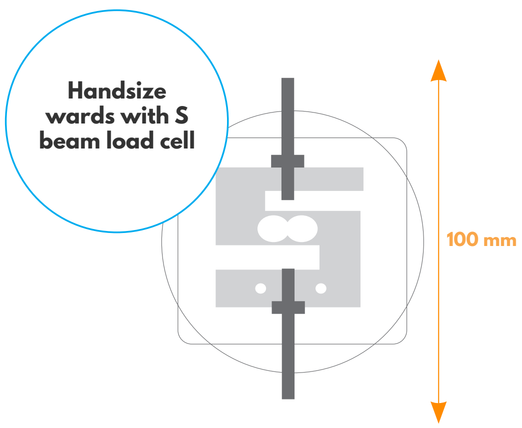


Figure 14.1: Maximum height of FluidBalance hanger

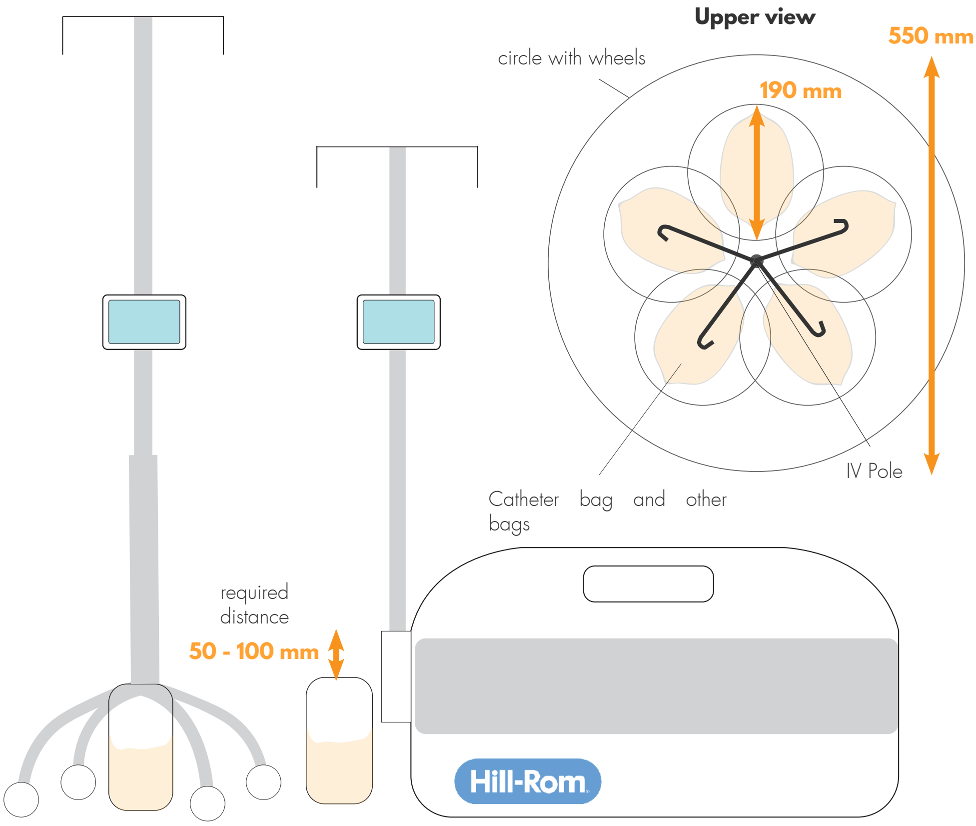
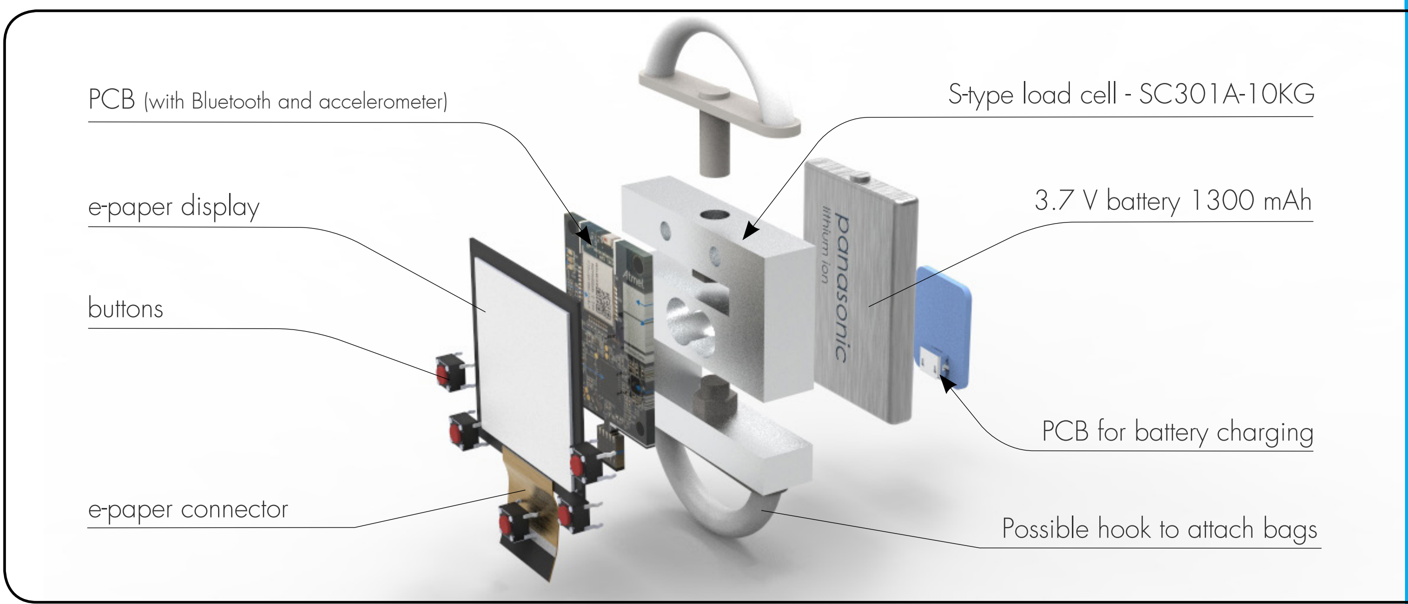


Figure 14.2: Placement requirements FluidBalance hanger



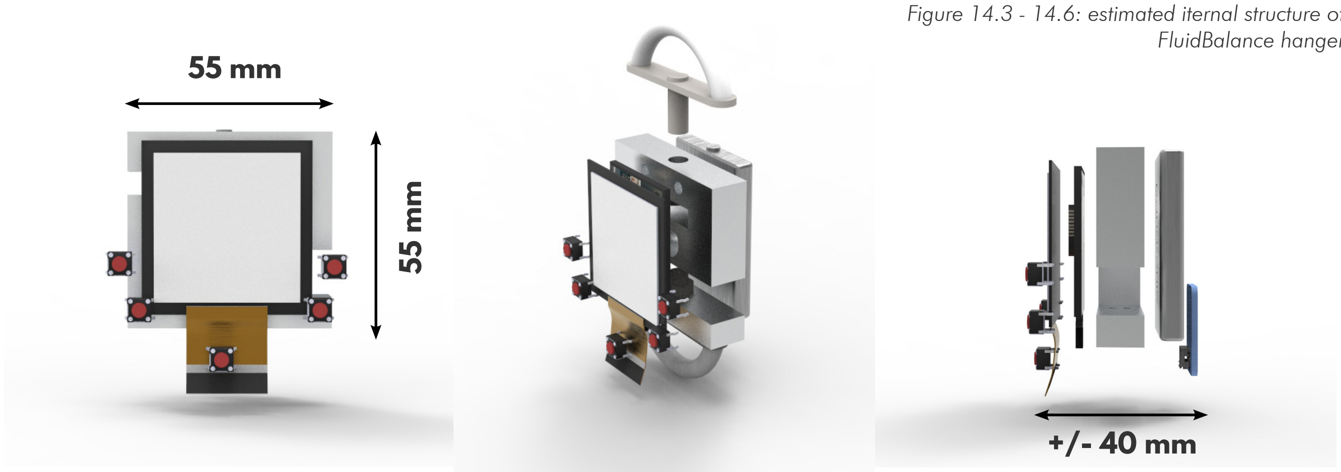
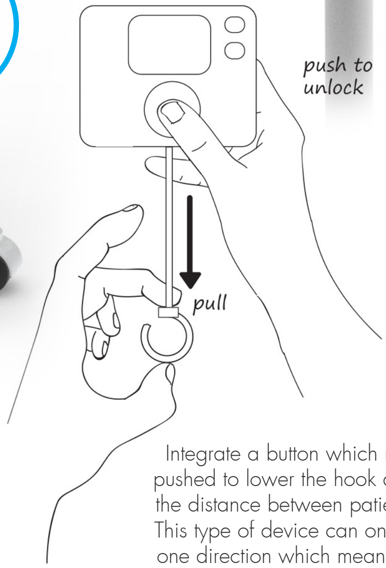


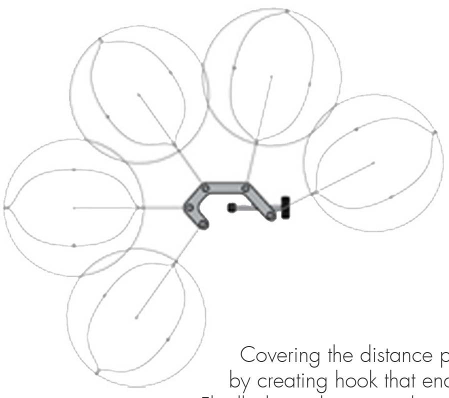
Figure 14.3 - 14.6: estimated iternal structure of FluidBalance hanger

A different device for the IV and catheterbag measurements which can stand on the floor or be attached to the IV stand in between the wheels.

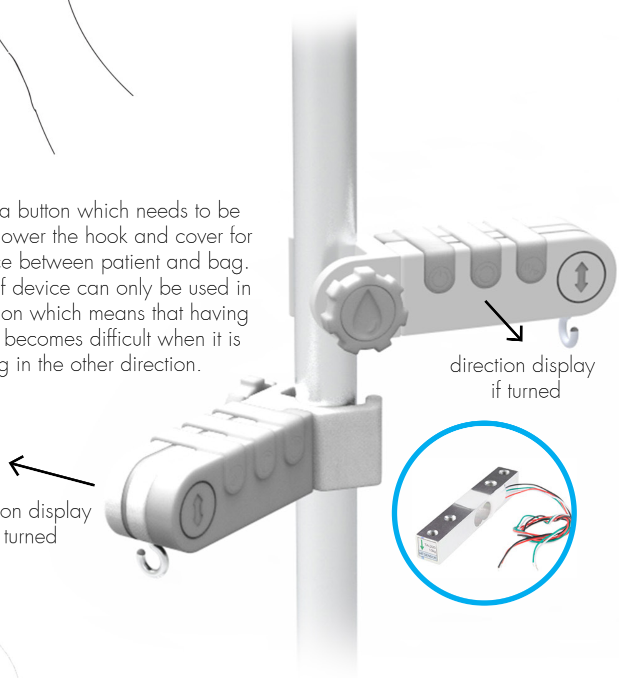


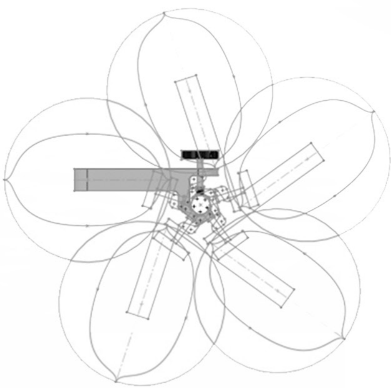
This architecture should contain a button to extend the length between hook and FluidBalance hanger as well. Orientation of this architecture is important.

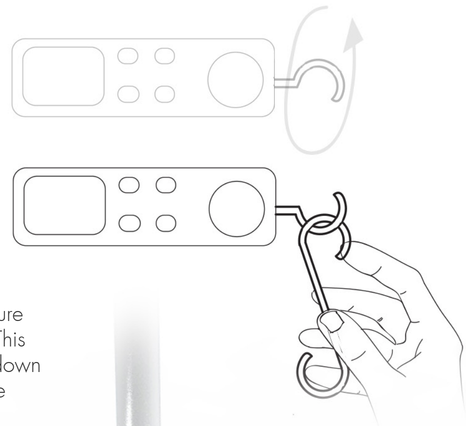
Integrate a button which needs to be pushed to lower the hook and cover for the distance between patient and bag. This type of device can only be used in one direction which means that having a display becomes difficult when it is facing in the other direction.



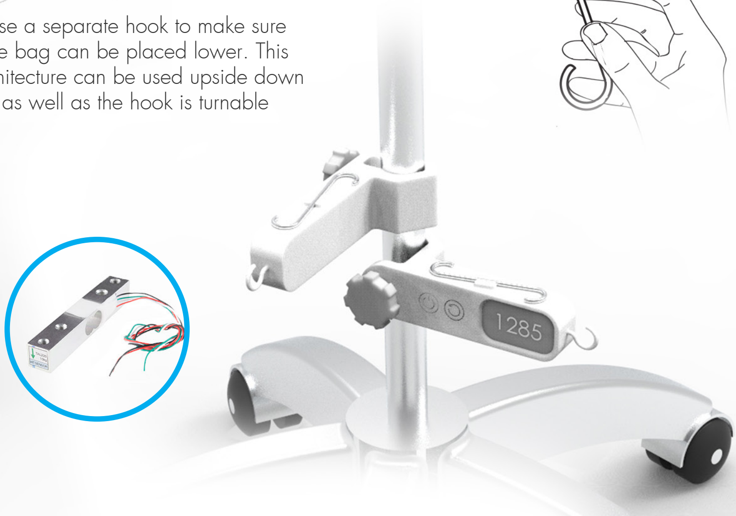
Covering the distance problem by creating hook that enables the Fluidbalance hanger to hang somewhat lower than the adaptor

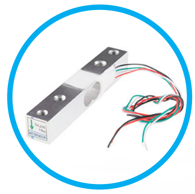




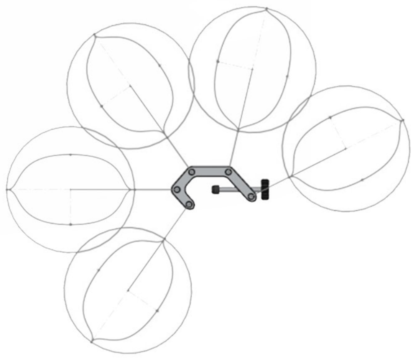


Use a separate hook to make sure the bag can be placed lower. This architecture can be used upside down as well as the hook is turnable

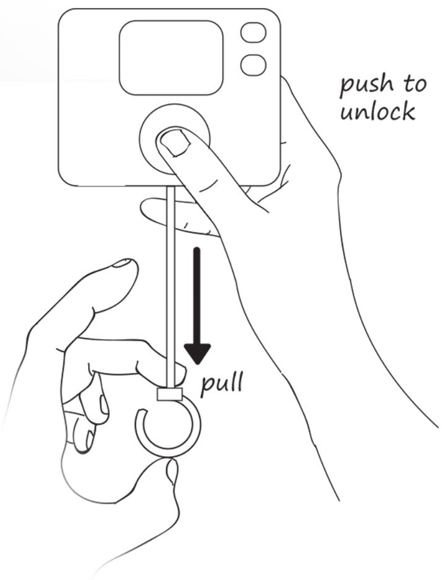




Another way to create enough free space around the bag is by having a standard adaptor that covers for this distance already.



This adaptor covers for small distance between FluidBalance hanger and the connection to the pole already in its design. When this is not the case, again some kind of exention for the cable is needed to create enough distance.



The method that was used in combination with the hanging devices can be used with a fixed device as well.

The FluidBalance hanger itself can cover for the provided free space around the bags by integrating a rotatable part.

15. Look and feel

The internal composition and functionalities (including amount of buttons) of the FluidBalance hanger are mostly determined. The size of the product is considered as well. Together these findings form the start of the appearance and form of the total product. Hospital environments are mostly clinical, minimalistic and the colour blue/ soft green is often used.

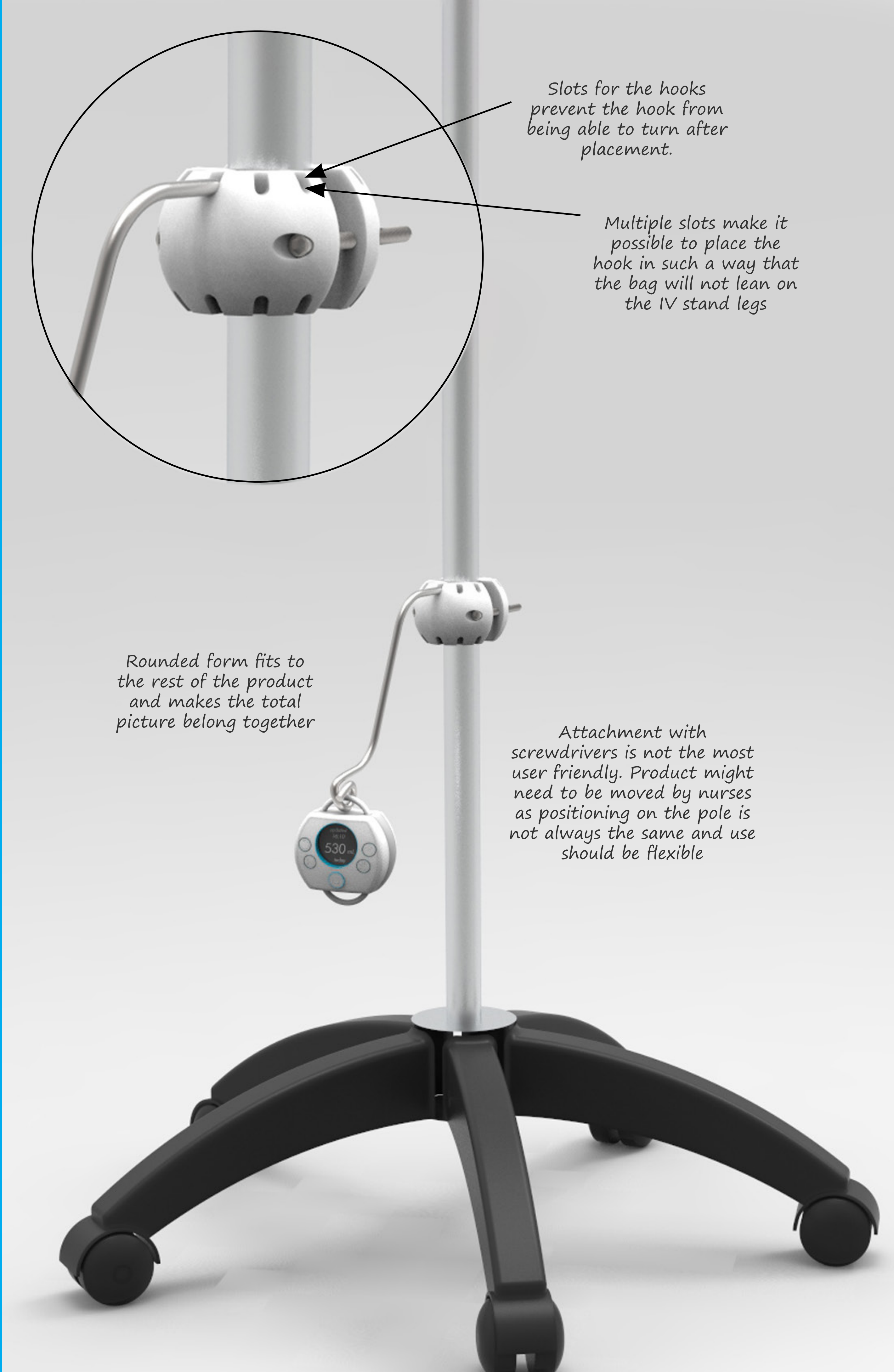
FluidBalance needs to become a part of the hospital environment. Together with unobtrusiveness, which is mentioned in the project goal, this lead to the collage on the next page (figure 15.1). Apart from the colleges the presentation by Sam de Visser: "a good or a bad designer" was used. This led to the following important design aspects:

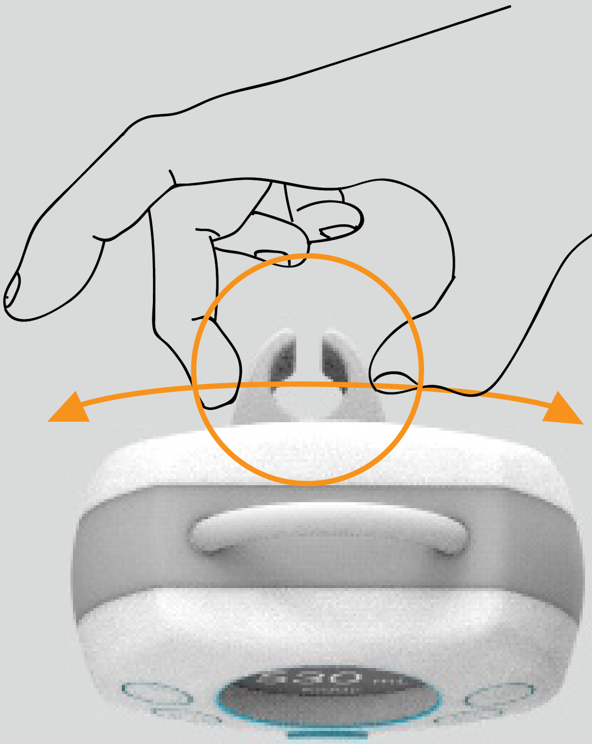
- Balance (not always symmetry)
- Essence and simplicity
- Contrast in material and colour
- Space around forms (do not make things look too crowded)
- Unity (the product forms need to fit together)
- Smooth and rounded forms which are easy to clean

These collages and principles were used as inspiration ideating on different forms, colours and looks (appendix 25). Together these sketches led to several 3D models and making real sized mockups.

Based on the 3D printed models of the first design proposal (page 66 and 67) several areas were marked to be improved in further iterations. These findings will be taken along in a short study on look and feel (appendix 26).

Figure 15.1: Inspiration look and feel - images were found using google image search terms: modern thermostat, unobtrusive, lean design, smooth design, medical devices, minimalism, etc.


Slots for the hooks prevent the hook from being able to turn after placement.
Multiple slots make it possible to place the hook in such a way that the bag will not lean on the IV stand legs
Rounded form fits to the rest of the product and makes the total picture belong together
Attachment with screwdrivers is not the most user friendly. Product might need to be moved by nurses as positioning on the pole is not always the same and use should be flexible
530 mL



Movement is either tight or smooth. Smooth movement requires the edges to be closed off which requires an extra part

Button is emphasized more than the other buttons, but in case of using an e-paper display, this button is used less often than the other buttons.

Placement of the bag (when it is filled) is hard with such a small entrance.

Relevance

Based on the product shown on page 64 and 65 user scenarios were made. These user scenarios served to gain first input from nurses at Reinier de Graaf hospital and Haga hospital. These small discussions were important to keep track of the opinion of the future user and to make sure no possible scenarios were forgotton.

16. User(s) scenario(s)

The system needs to fit different scenarios which can all occur in the hospital. The following scenarios are explained on the following pages

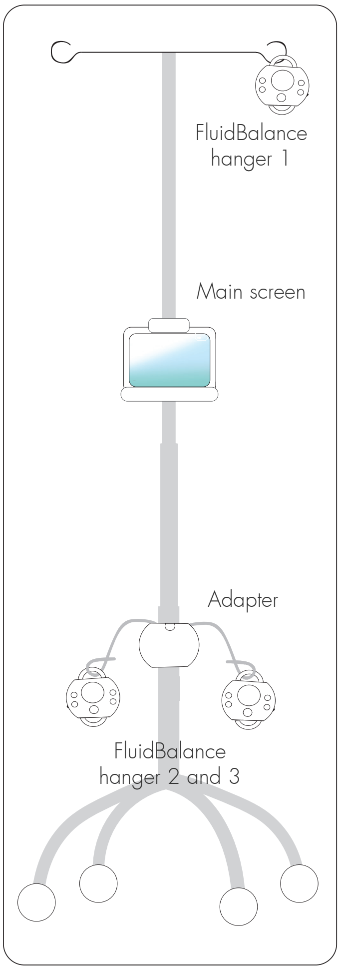
- Installing a catheter bag on a FluidBalance hanger
- Modifying or deleting a FluidBalance hanger
- The patient goes for a walk
- The patient needs to go to the toilet
- The assistant wants to add drinks
- The patient wants to go for a shower (critical and less critical patients)
- Warnings for the nurse (empty/full bag, a connection that fails, etc.)

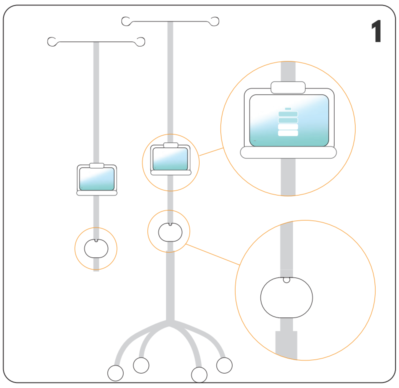
These scenarios describe most of the situations and possibilities that fluid balance has. These scenarios were discussed with several nurses to make sure they were understood and no important scenario was skipped. To make sure the names of the system parts are associated with the correct parts figure 17.1 shows an overview of the used names.

Feedback from the user
Feedback from three nurse lead to the following interesting outcomes:

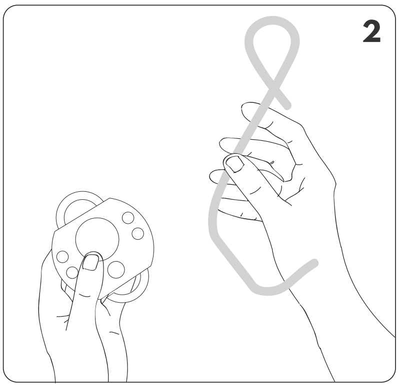
- Work phone instead of COW for alarms. The messages on the COW are received by all nurses. Messages on the work phone are only received by the nurses that are appointed to a specific group of patients. The last one makes more sense to be used within the FluidBalance system.
- Include warnings when to replace a bag (a bag should be used for 72 hours maximum) as this is often forgotten.
- When tablet is taken off the IV stand for showering it could be confused with the neighbours tablet (both in pocket of the nurse).
- Partly filled catheter bags cannot be entered into the system yet.
- Asking for the latest information from the COW would be interesting.
- Alarms should be set per department generally.
- Warnings per patient might be interesting, but would probably increase difficulty of the device.

Conclusion
The nurses were enthusiastic about scenarios and could not think of more scenarios. Most of the feedback did not involve major changes and will be mostly covered by the software and compatibility of the system.

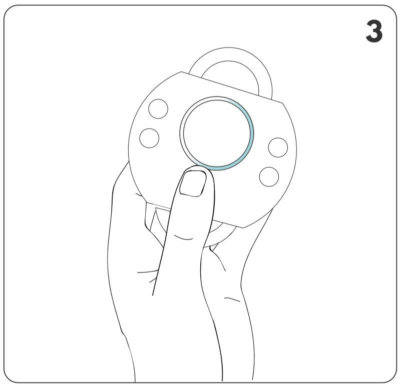




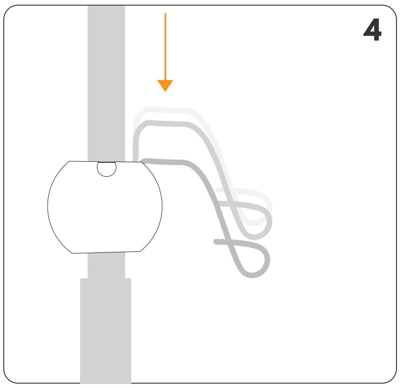
Pick up an IV stand from the stockroom containing both a tablet and a hook adapter



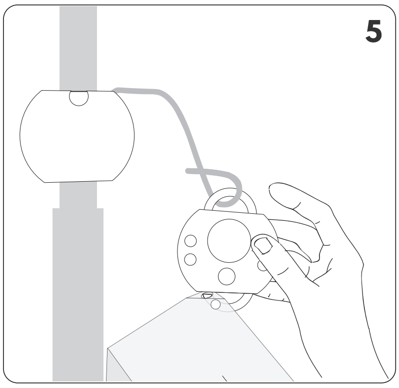
Grab both a hook and a FluidBalance hanger and bring them along to the patient



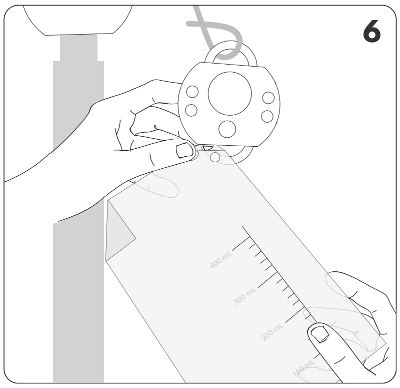
Before going back to the patient, check the battery status by turning on the device



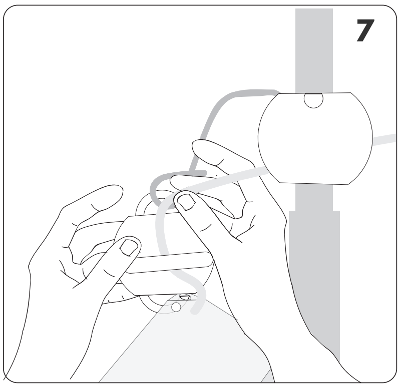
Place the hook into the adapter



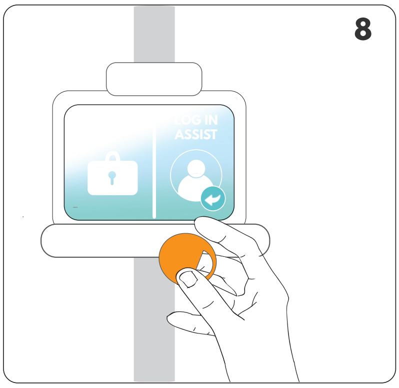
Attach the FluidBalance hanger to the end of the hook and press bluetooth button to make the device "visible"



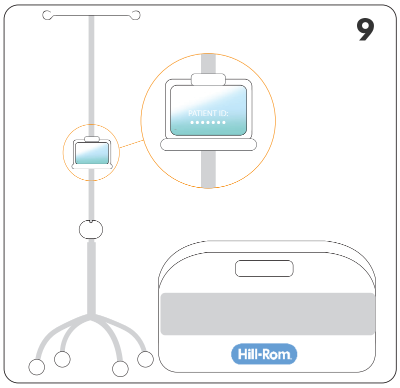
Attach the bag to the other end of the FluidBalance hanger.



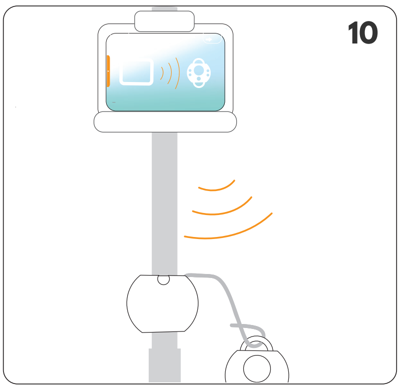
Lace the catheter hose through the back of the FluidBalance hanger to prevent the cables from getting tangled up.



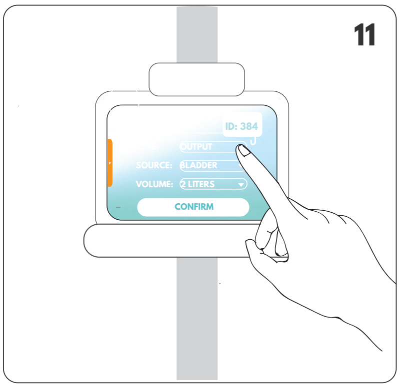
Log in into the tablet with your tag



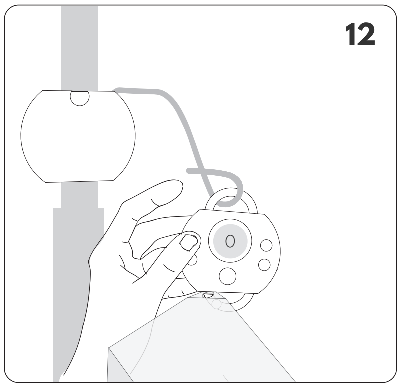
Connect the tablet to the patient ID under which he or she is registered into the EPD



A connection is being formed between the main screen and the FluidBalance hanger

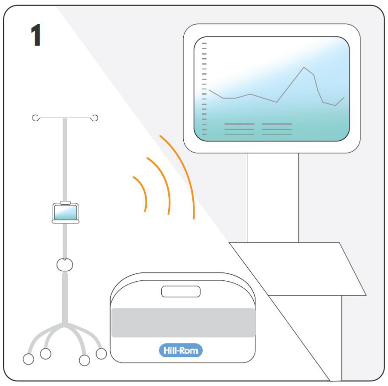


Select the applying information for the bag and click to confirm

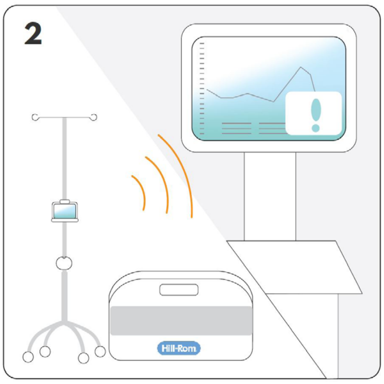


Press the reset (zero) button to start measuring and to set the FluidBalance hanger to zero

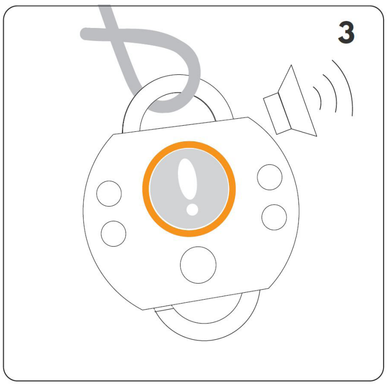
Warnings for the nurse and doctor



The main screen sends the FluidBalance overviews over to the COW (Computer on Wheels)

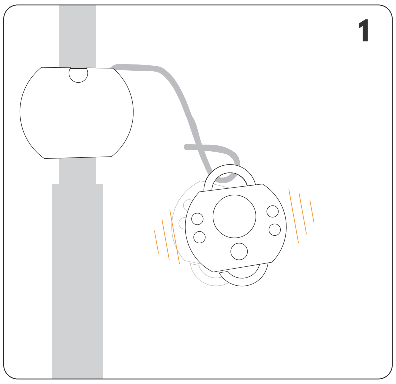


When something is wrong (full/empty bag or no connection) the nurse receives a notification

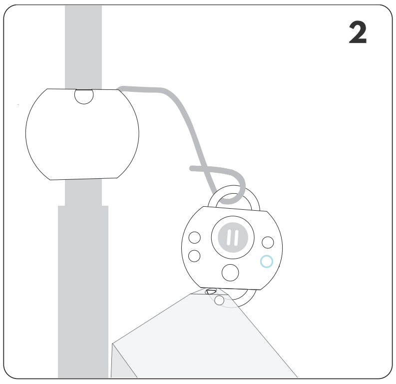


When the nurse misses all her notifications a message is sent from the device to make the patient (and others present around the wards) aware that something is wrong and that the nurse needs to come. The patient can help by calling the nurse using the bell

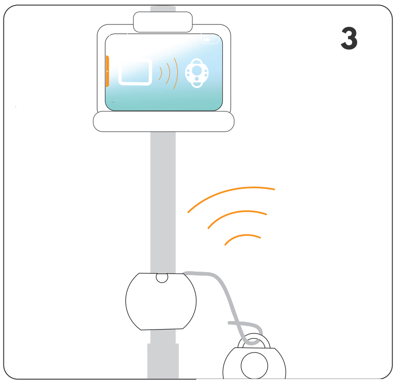
Patient goes for a walk with IV stand



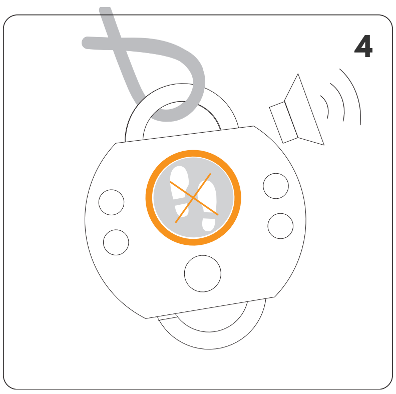
The FluidBalance hanger registers movement with its accelerometer



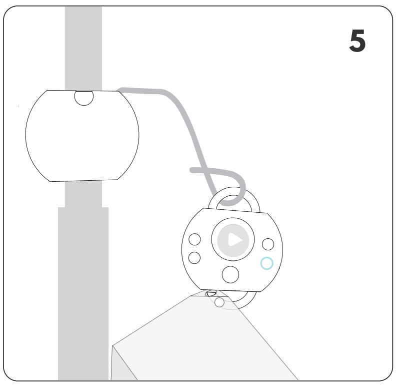
The FluidBalance Hanger will automatically go into the pause mode



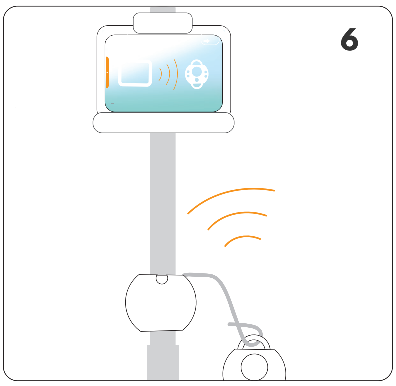
A signal is given to the main screen to inform that no information should be expected



When the patient is moving for more than 30 minutes (not very often) a warning is given to perform a measurement which requires the patient to stand still for a few seconds

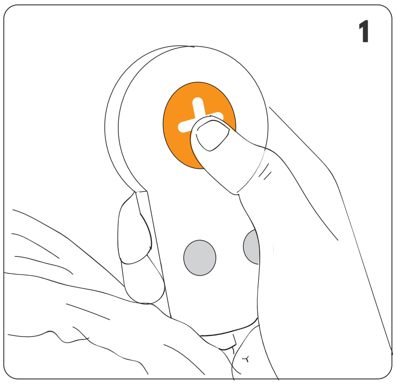


The FluidBalance Hanger will automatically unpause when it is hanging still for several seconds again

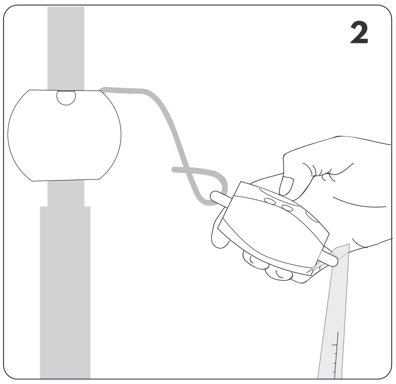


A signal is given to the main screen to inform that information should be expected again

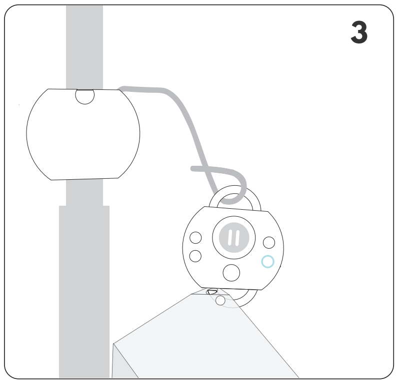
Patient wants to go for a shower (devices are disconnected)



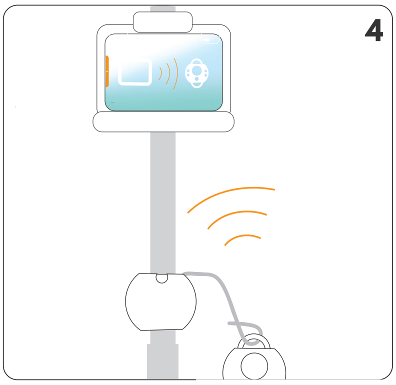
The patient presses the bell to alarm a nurse.



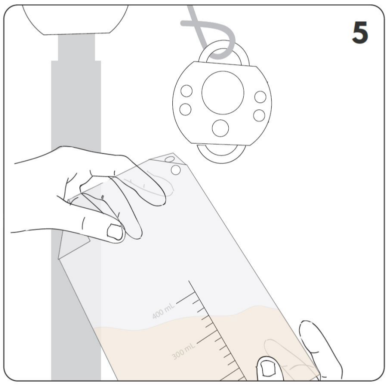
The nurse grabs the FluidBalance hanger and presses the pause button



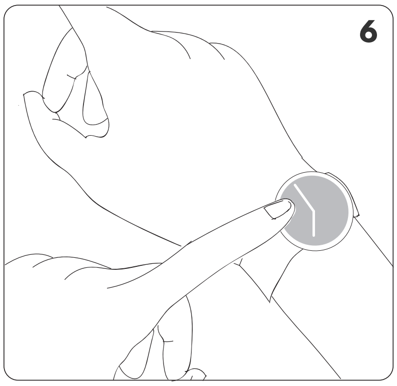
The FluidBalance hanger sets itself to the paused mode



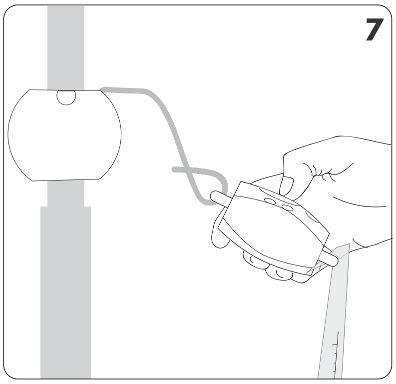
A signal is given to the main screen. The main screen knows not to expect values from the FluidBalance hanger



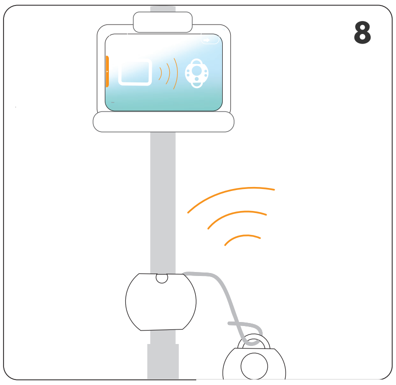
Disconnect the catheter bag from the wards. The patient can take it under the shower and place it on the floor



The nurse reminds the patient that she will be back in around 15 minutes to help him or her to connect again

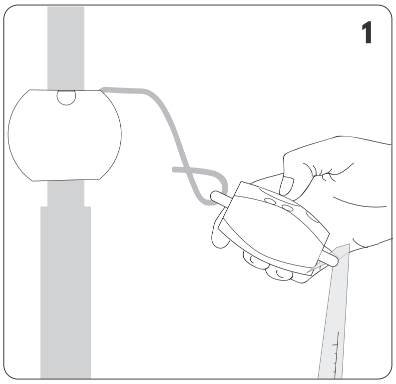


After showering the FluidBalance hangers are turned back on and a measurement is being performed

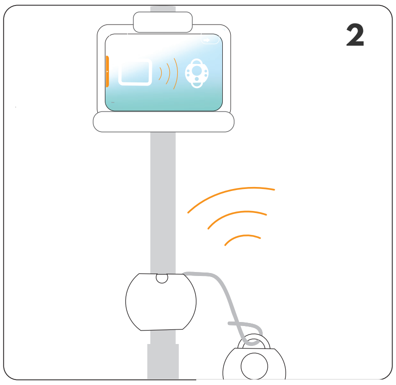


A signal is given to the main screen. The main screen knows to expect values from the FluidBalance hanger again

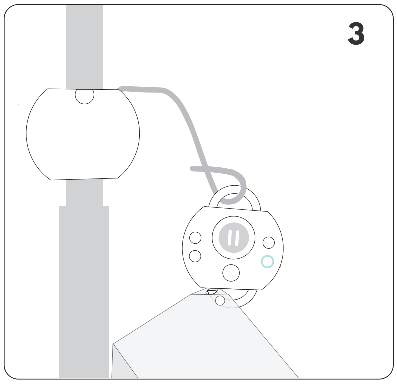
Patient wants to go for a shower (IV is not disconnected)



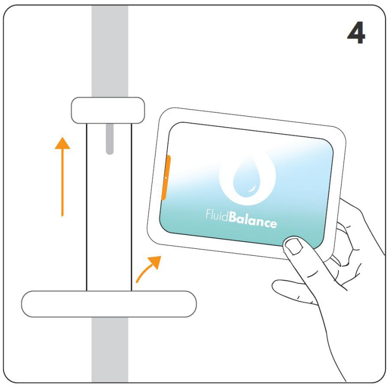
The nurse grabs the FluidBalance hanger and presses the pause button



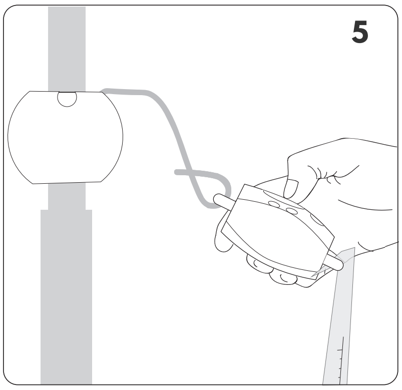
A signal is given to the main screen. The main screen knows to expect values from the FluidBalance hanger again



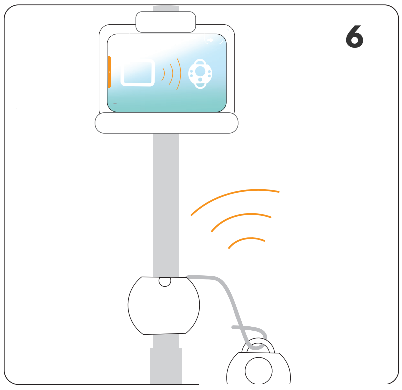
The FluidBalance hanger sets itself to the paused mode



The tablet is being disconnected. The rest of the IV stand (including FluidBalance hangers) goes into the bathroom

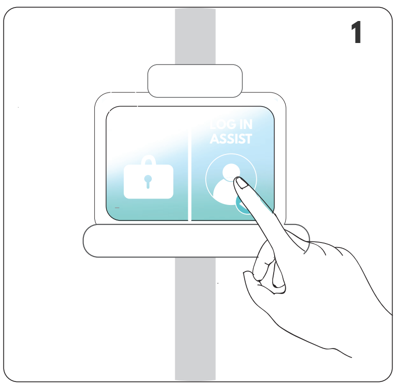


After showering the FluidBalance hangers are turned back on and a measurement is being performed

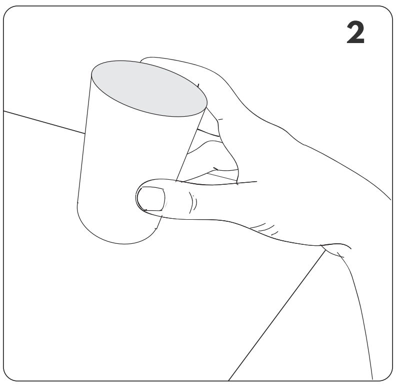


A signal is given to the main screen. The main screen knows to expect values from the FluidBalance hanger again

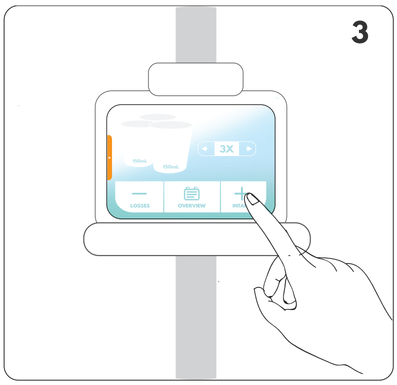
Assistant or nurse wants to register drinks



Go to the assistant menu (nurse can reach it via nurse menu as well, but tag registration is needed in that case)

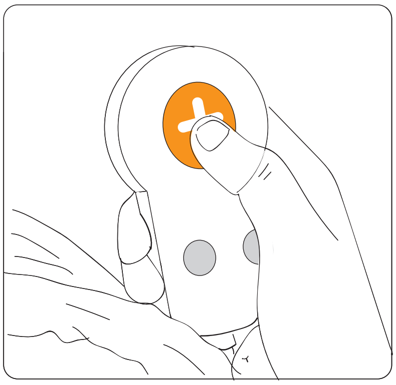


Pick up the empty drinks

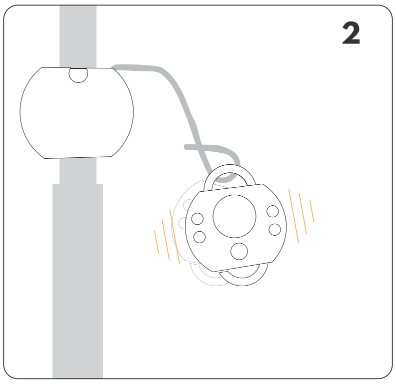


Enter the amount of drinks and press confirm. The drinks will be added to the overview

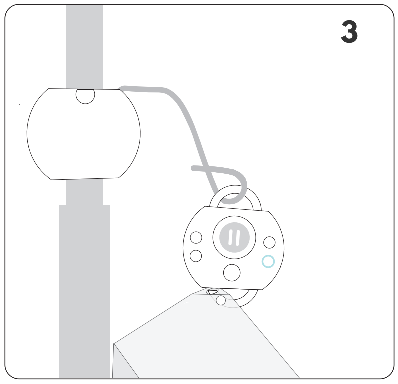
Patient needs to visit the toilet



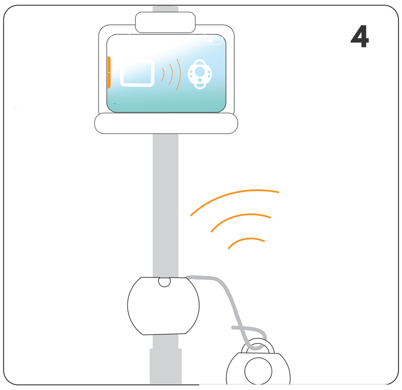
The patient presses the bell to alarm a nurse. Is done afterwards if the patient does not need assistance



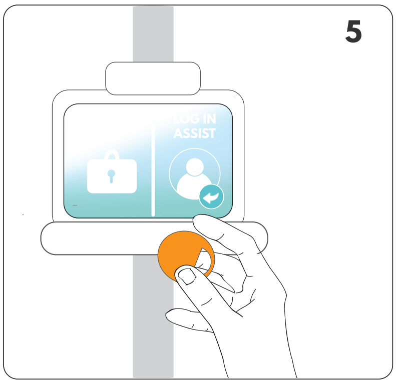
The IV stand goes into the toilet with the patient or is disconnected. The device will be paused.



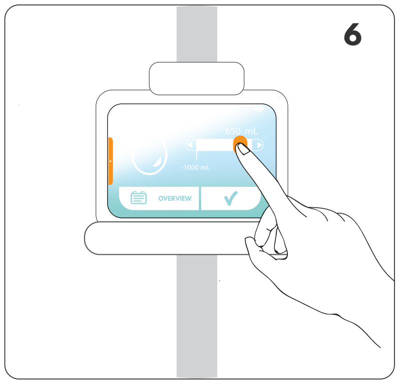
The pause mode appears on the screen



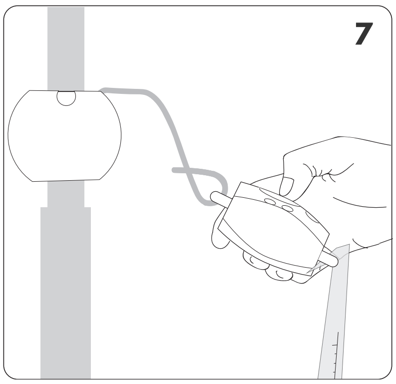
A signal is given to the main screen. The main screen knows not to expect values from the FluidBalance hanger



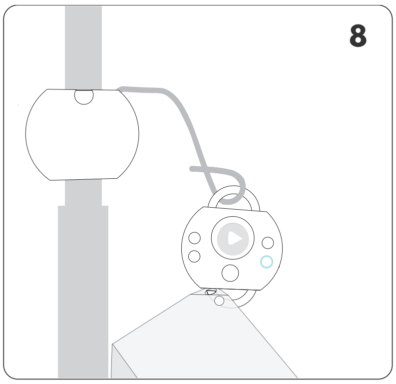
Nurse logs in into the main screen with her tag



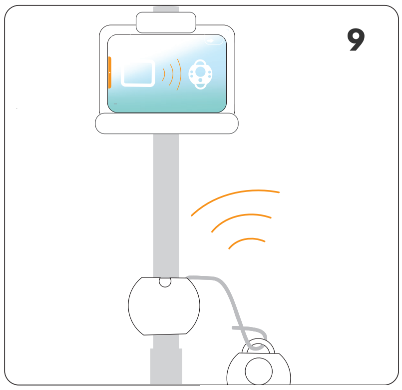
The nurse registers the amount of urine



After the process the nurse presses the pause/play button again

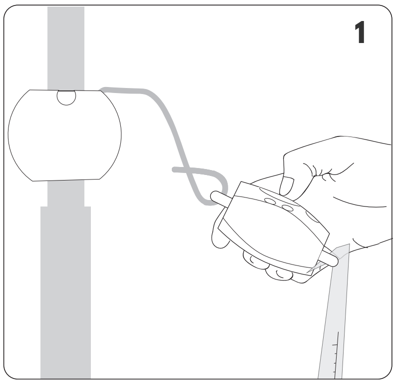


The FluidBalance hanger will automatically unpause when it is hanging still for several seconds again

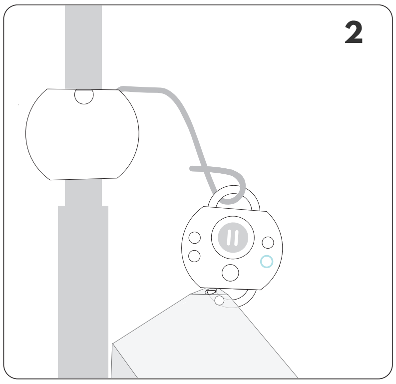


A signal is given to the main screen. The main screen knows to expect values from the FluidBalance hanger again

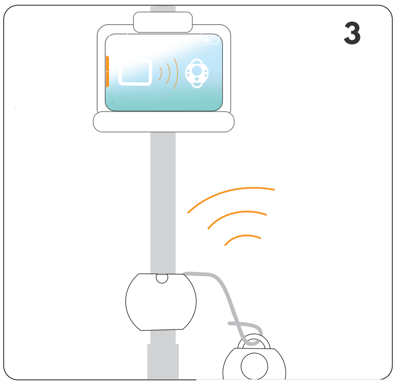
Modifying or deleting a catheter bag



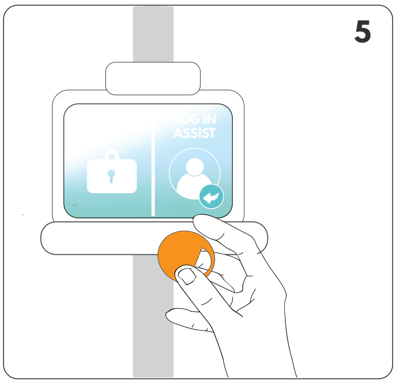
The hanger is being paused (only paused wards can be modified via the main screen to prevent errors)



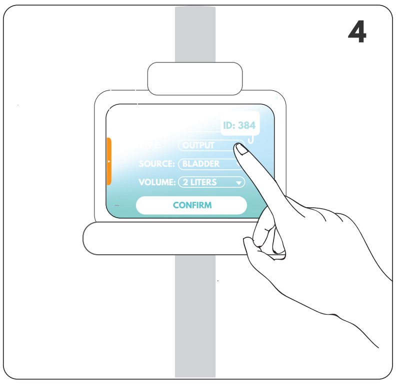
The FluidBalance hanger goes into the pause mode



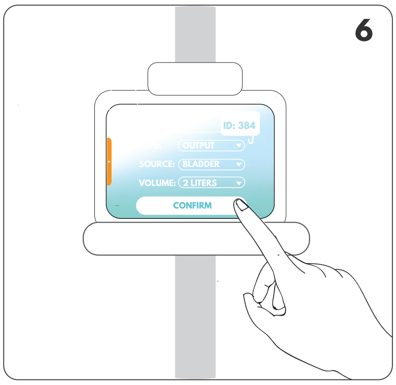
A signal is given to the main screen to inform that no information should be expected



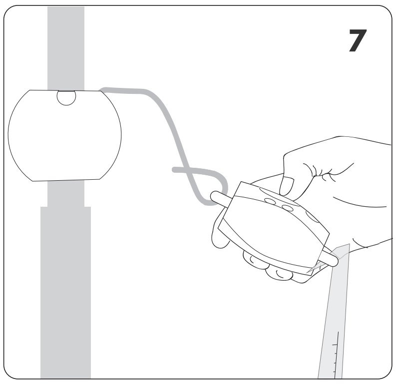
The nurse logs in into the main screen with her tag



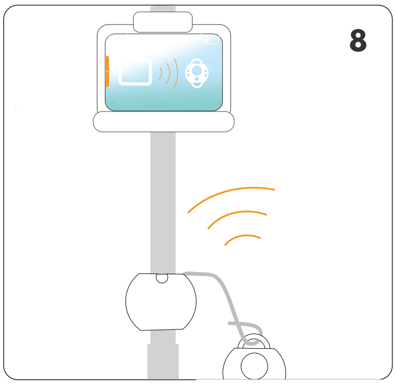
The nurse goes into the modify or delete menu



Afterwards she confirms her actions



Afterwards (in case of modifying) the FluidBalance hanger is being unpaused



A signal is given to the main screen to inform that no information should be expected

17. Final concept design

Based on the earlier design sketches and the findings from the 3D printed model (page 64-65) a redesign was made for the FluidBalance hanger. For the redesign the focus was on: reducing the struggle to connect a bag to the device, to create a less hard look on the edges of the product, to find a better placement for the buttons on the product and to create a better way to attach the cather hose to the back of the product.

Ideation sketches are shown below (figure 17.1) and on the next two pages. Two concept were evaluated by creating different variations and asking mulitple designers which one scored the best on simplicity, being friendy looking, and of course the most fitting look for the hospital environment. The final concept design is still a roudn product as this was aesthetically considered the best choice.

The choice fell on the solution that was the most simple of all and still offered better grip, button usage (figure 17.2) and a better overal unity.

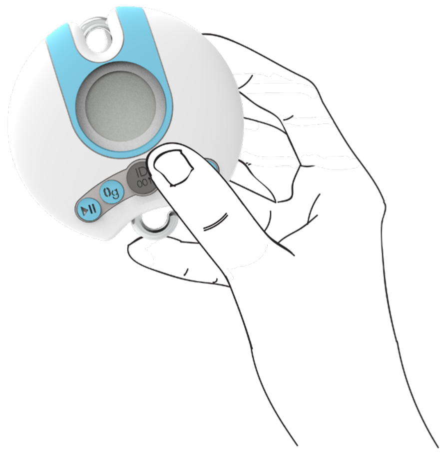


Figure 17.2 Holding final design while using the buttons

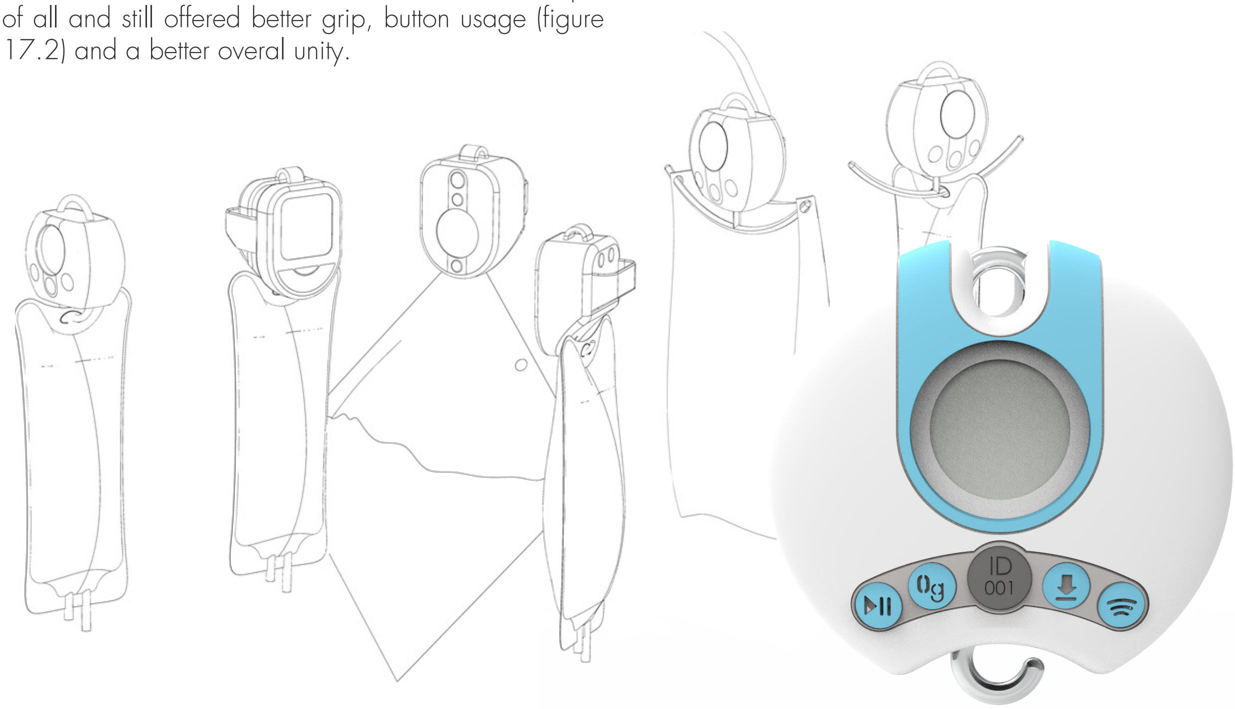
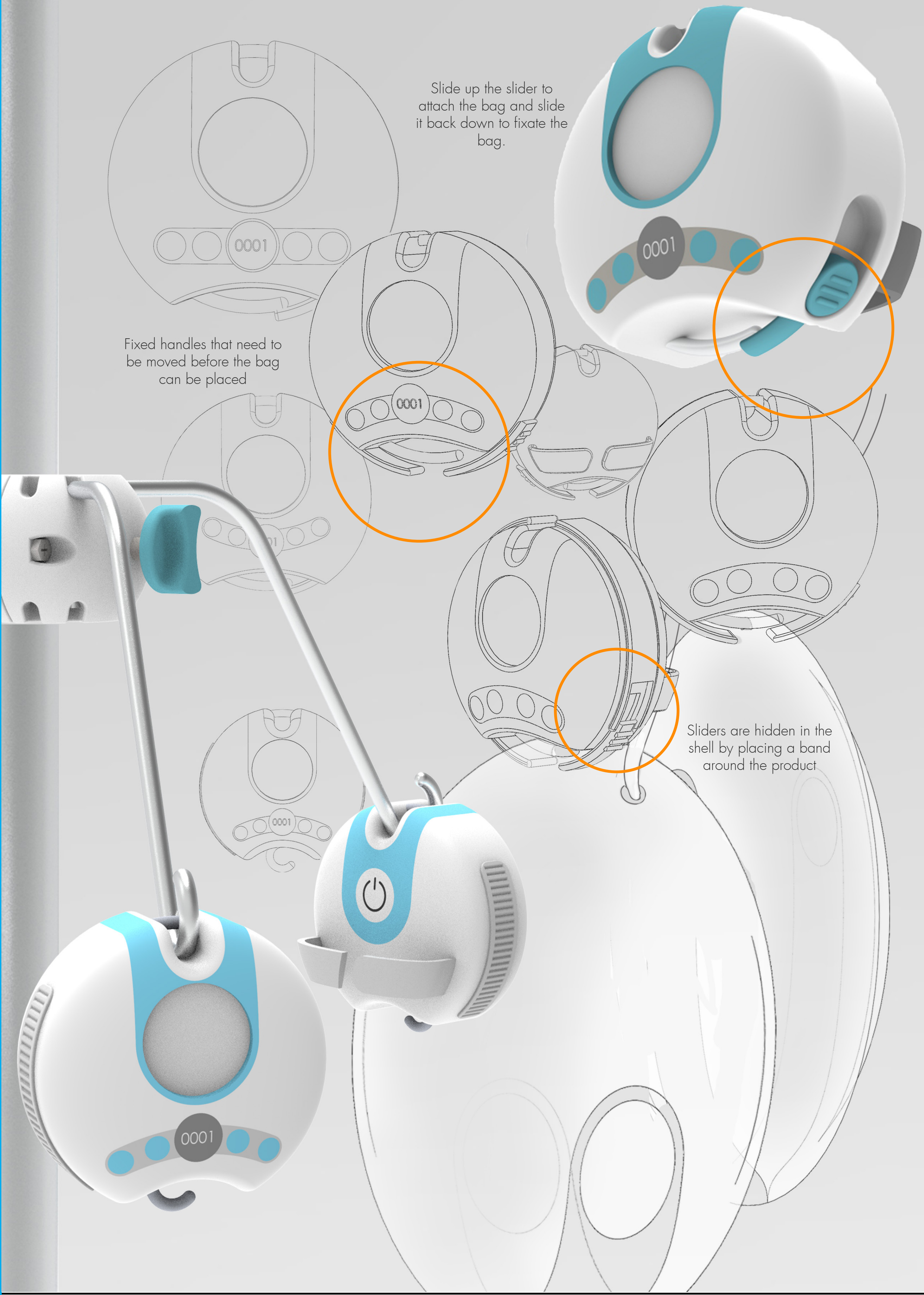


Figure 17.1 Ideation and final concept design

IDEATION FLUIDBALANCE HANGER 1

Points of attention (based on the earlier design) were the effort to connect bag, the hard edge on top of the product, the visibility of the on/off button and the overall placement of the buttons. Several sketches were made and compared.

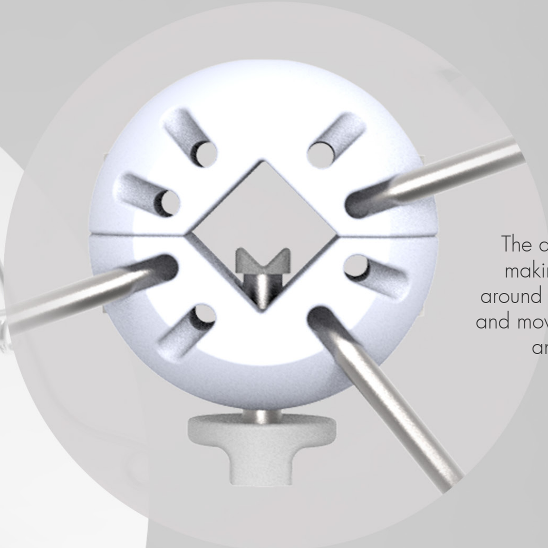


IDEATION FLUIDBALANCE HANGER 2

The other option which has both hooks rotated was investigated as well. For both versions internal architecture and fit were taken into account, which led to several size requirements. The overall look and color were chosen based on inspiration presented in figure 16.1. Also very important was that the colors and look of the product suited a medical environment.

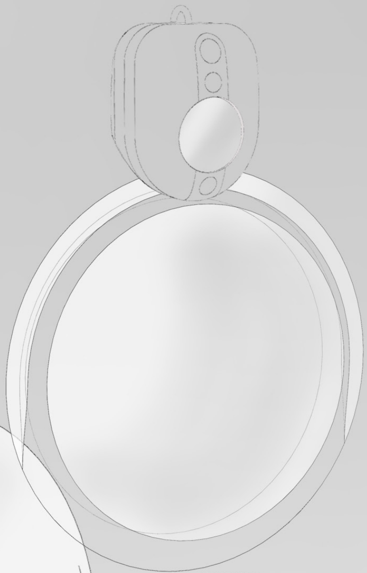
IDEATION BAG AND ADAPTOR

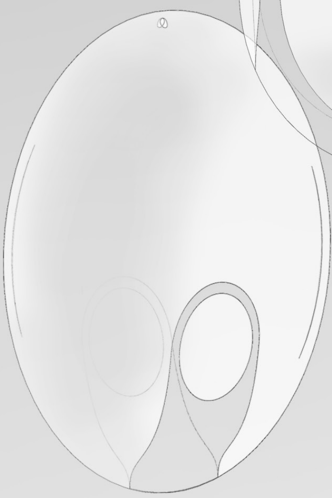
FluidBalance is focused on offering cheap disposables as this is the advantage of using a system that weighs the content. Hiding the urine is still a wish to increase patient experience, increase the unity (in look and feel) within the FluidBalance system parts and overall image of hygiene.

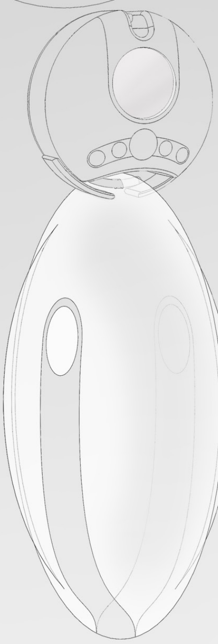


The adapter is fixed by screws making sure the adaptor stays around the IV stand. Further fixation and movement is done by loosening and fastening the knob.

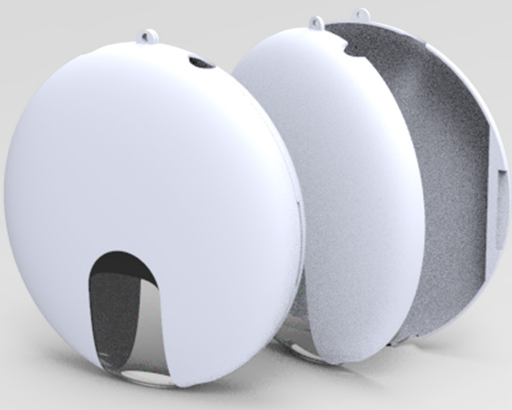
Difference in material use and looks. To be a part of the system it can have the same looks as the IV stand (aluminum) or as the rest of the FluidBalance system (white and blue).







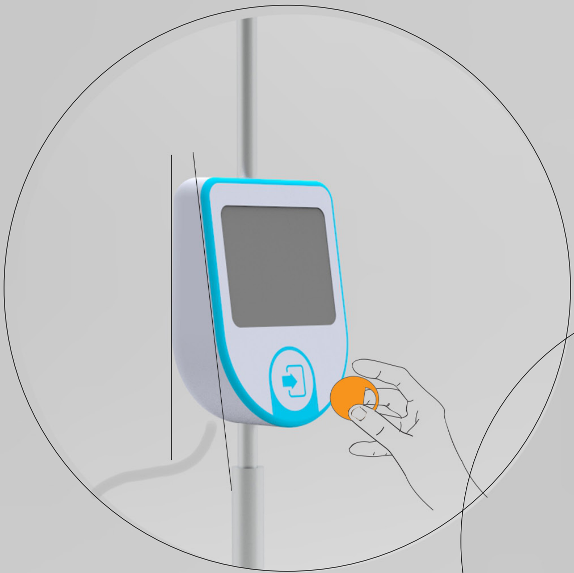
Simple disposable bags that hide the urine partly, increase unity and overall feeling of hygiene. They still offer the possibility to the nurse to see the color of the urine when needed as they are party transparent.

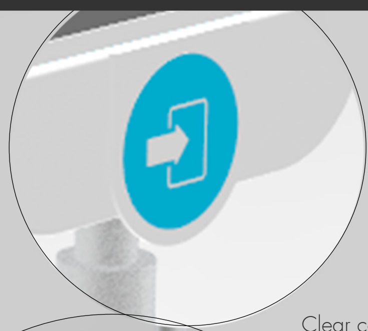


Hard plastic case to surround the catheter bag. The cover is not disposable, but the catheter bag inside is. The input and output hose of the catheter bag should be able to reach easily. The holes make sure the bag cover does not need to be opened.

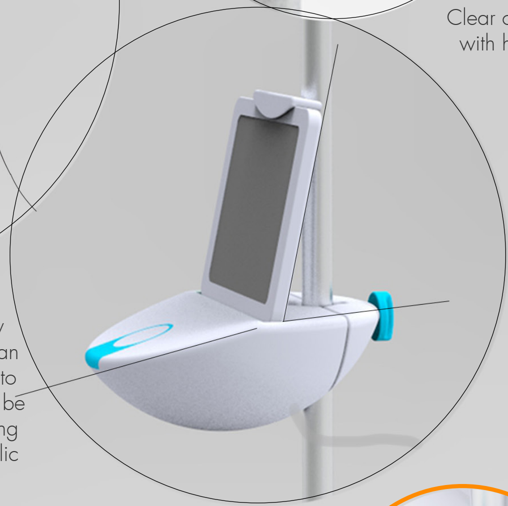
IDEATION TABLET HOLDER

the tablet holder is not a part of this graduation project. Despite this the FluidBalance system needs to look uniform (form and color language). This sheet shows several ideas on how to create unity and also other features that were discovered during this project.

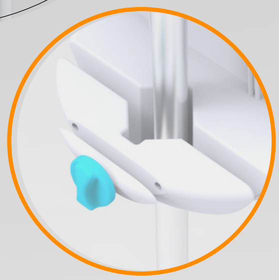




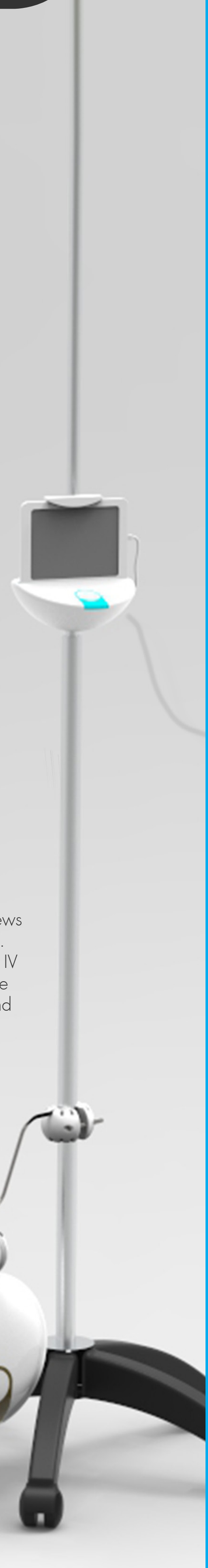
Clear communication with help of icons.

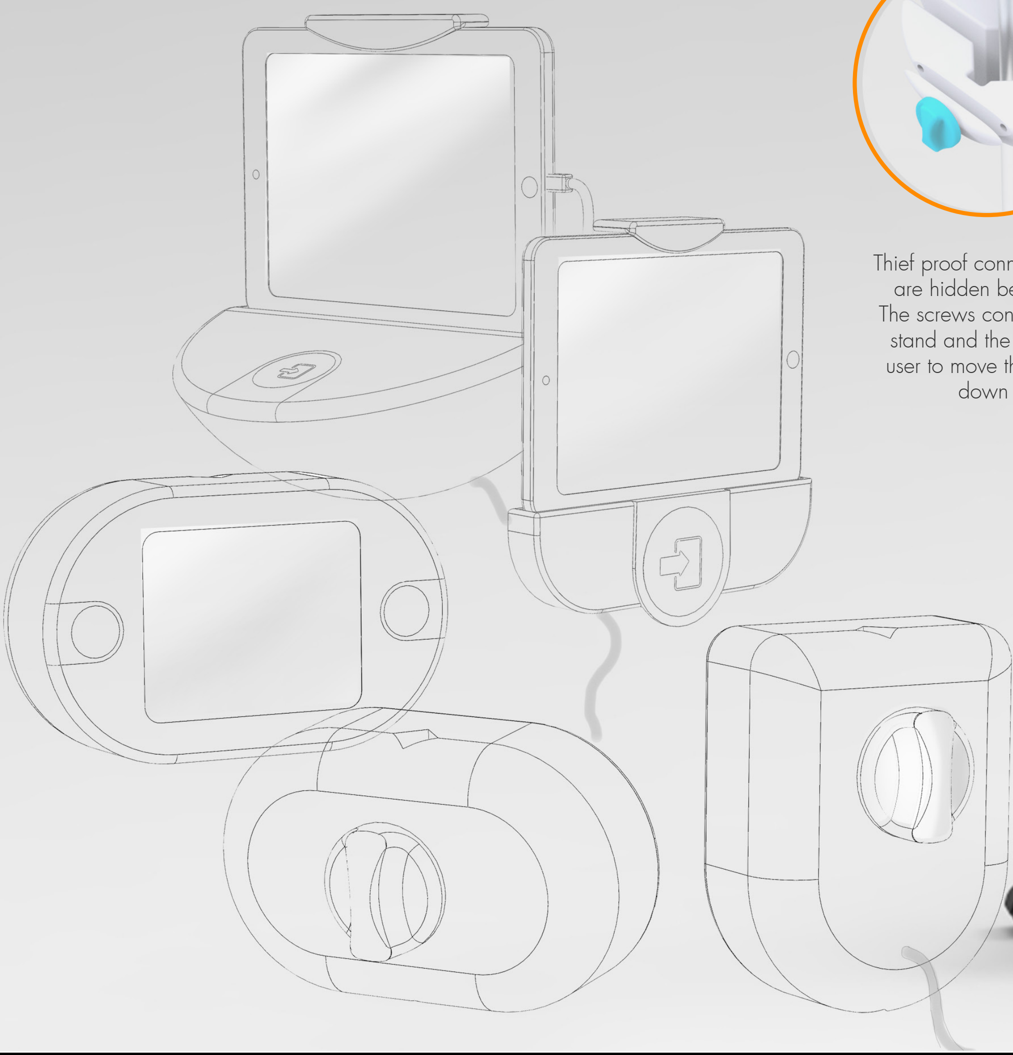


Slight angle in the interface which can be a totally integrated version where the tablet is hidden (1) or an open version (2). The second one allows the tablet to be taken off when showering. The first one needs to be water resistant or should be taken off in total. Logging in like this is recognizable because of usage in public transport (check in with OV chip card)



Thief proof connection where the screws are hidden behind a clickable cap. The screws connect the holder to the IV stand and the blue knob enables the user to move the tablet holder up and down when needed.





18. Risk assessment and validation

During the verification and validation phase of the concept, that will partly take place within this graduation assignment, the V- model (Firesmith, 2013) will be used (figure 18.1). During the graduation process attention is paid to the product-service-system, the FluidBalance hanger in specific. The grey area shows therefore the area which is covered by this graduation assignment. Within the levels: Functional specifications, High level specifications and Low level specifications, different risks can occur and need to be managed. A general risk analysis on the safety of the system will be performed for these three levels. The main issues will be discussed in this chapter. The full risk analyses and how different risks can be managed is presented in appendix 28. Figure 18.2 shows the different risks ranked on the probability of happening and severity of the issue.

18.1 Risks - FluidBalance hanger

Most of the risks are connected to the need for more in-depth testing of the system, such as differences in measurements due to differences in temperature, and defining which internal technology will be used. CE Certification and being sure the components will function like specified in their datasheets is a must. Furthermore, several issues are linked to software-based problems that can limit the amount of errors in usability. Maintenance requirements and provided reliability after a FluidBalance hanger was dropped by the nurse are risks that will play an important role when testing the final design of the product and a CE certificate needs to be granted. Finally, providing a simple system and education on how to use the product is a common thing in hospitals that is important for the FluidBalance system as wrong usage will lead to wrong measurements and therefore incorrect treatment plans.

18.2 Risks - FluidBalance total system

The total system consists of the FluidBalance hangers, the tablet with the application and the users (nurse, care assistant, (and patient)). The main issues around this system are based on either connectivity or usage of the application/FluidBalance hanger. Limitations can be set by the software and education on usage will be provided to prevent most issues. Apart from this testing the warning system and observing usage to improve the system is required to make the product successful and error proof.

18.3 Risks - FluidBalance integration

Issues regarding the integration of the FluidBalance system into different hospitals mainly involved compatibility with different EPD systems, wireless connection networks, and communication systems that are used by the nurse. Creating convincing test results and visiting multiple hospitals for research on how to integrate the system will lead to a system that can be widely used.

18.4 Conclusion

These risk analyses on different levels are the first step into defining the difficulties of the project. The different levels contain major and minor risks (figure 18.2). A method for managing all risks is provided in appendix 28. Together with this knowledge plans can be formulated on the steps that need to be taken first after this project ends. Testing of the FluidBalance hanger components and how it behaves in the context is the first step to take. Multiple risk analyses on, for example, the risk that could occur during development of the FluidBalance hanger are needed in later stages of the project to make sure the product will not fail unnecessarily.

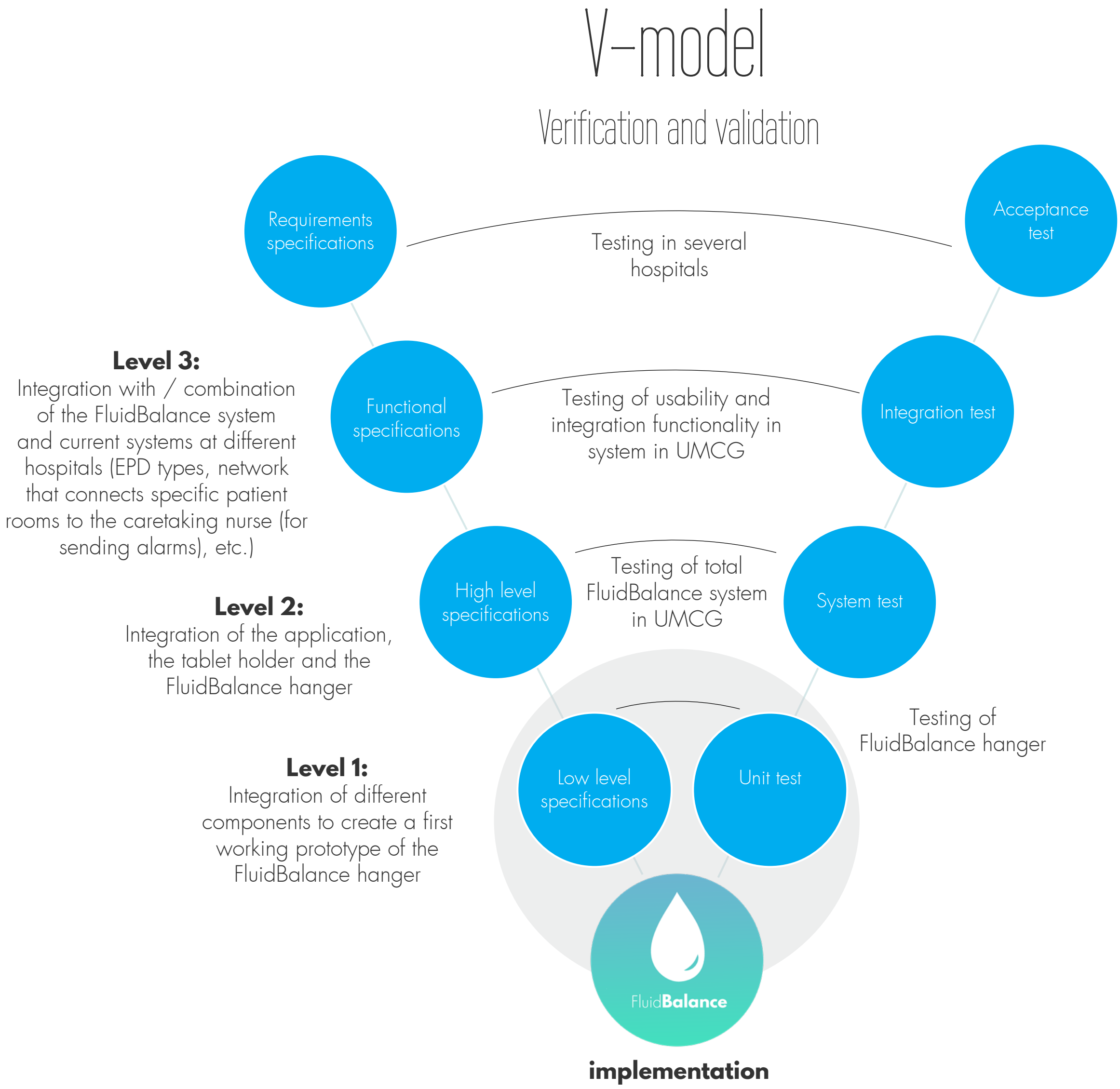


Figure 18.1: V-model (verification and validation)

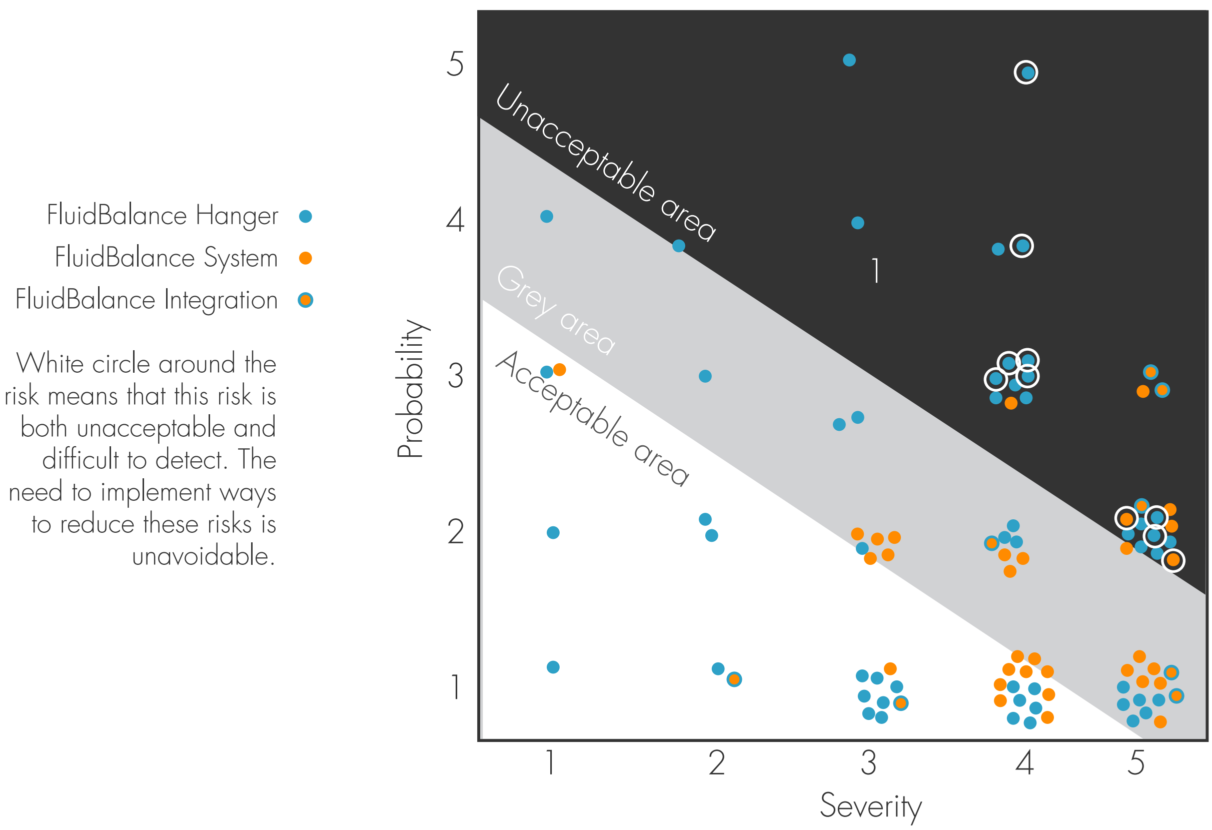


Figure 18.2: FMEA overview of risks

Embodiment
FluidBalance hanger

19. Assembling working model

For the first tests of the FluidBalance hanger within the hospital it is possible to use the provided prototype. Probably multiple versions of the prototype will be needed, which is why a proper embodiment, that is reproducible, is provided. This embodiment uses the current PCBs which are used to create the first working prototype. This version is not water resistant and cannot be taken into the bathroom. The housing is organized in a way that it can be taken apart. Moreover it will be possible to reload code on the prototype to increasing testing possibilities. Only one button is included as the Huzzah Feather provides only 9 pins that can be used for programming. The scheme on the next page shows in an overview how the different parts need to be connected. The functionality scheme of the working prototype is shown in figure 19.1. It was chosen to work with Wi-Fi instead of Bluetooth for now as the online environment (Adafruit.io) was already available for creating nice overviews of the gathered data. When a Bluetooth module is used the raw data still needs to be put into a customized viewer. This does mean that the model uses more energy than was expected, but this can be reduced by integrating a "sleep mode" into the current software. With this additional code the life time of the prototype (including the 2000 mAh battery) can be extended from 22 hours (energy consumption of 90mAh) to 10 days (energy consumption of 8 mAh) (Foxworth, 2017). The accelerometer was skipped as the goal of using the accelerometer was to know when measurements are not trustworthy enough due to movement. This correction is now integrated into the software. The measurement is only updated when it is considered trustworthy enough by the software.

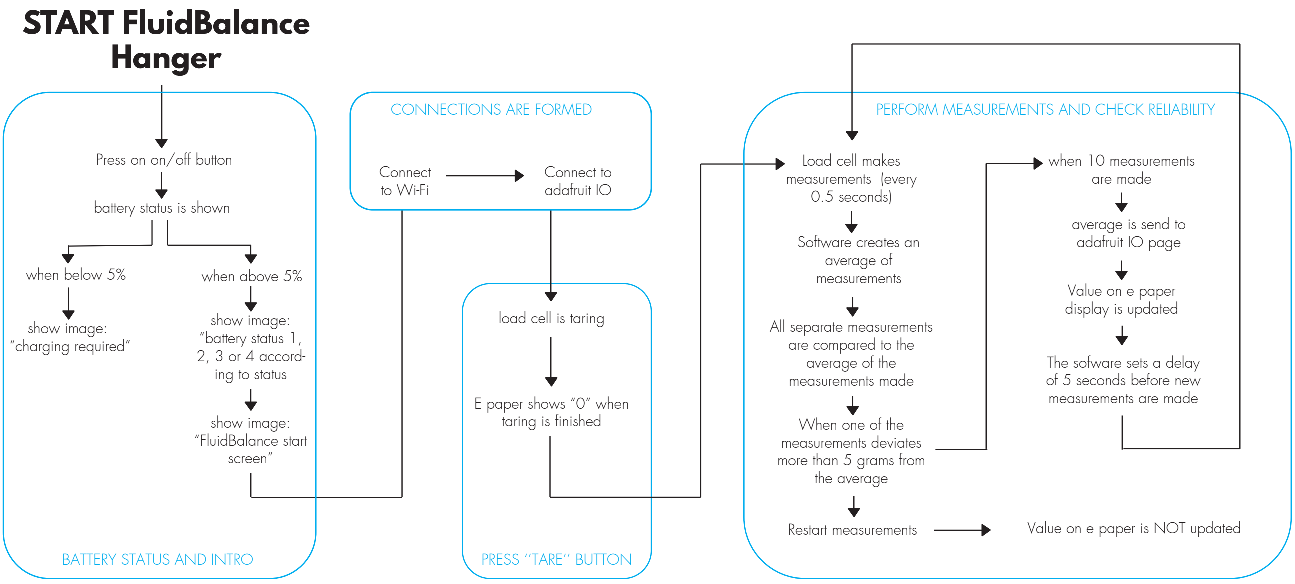
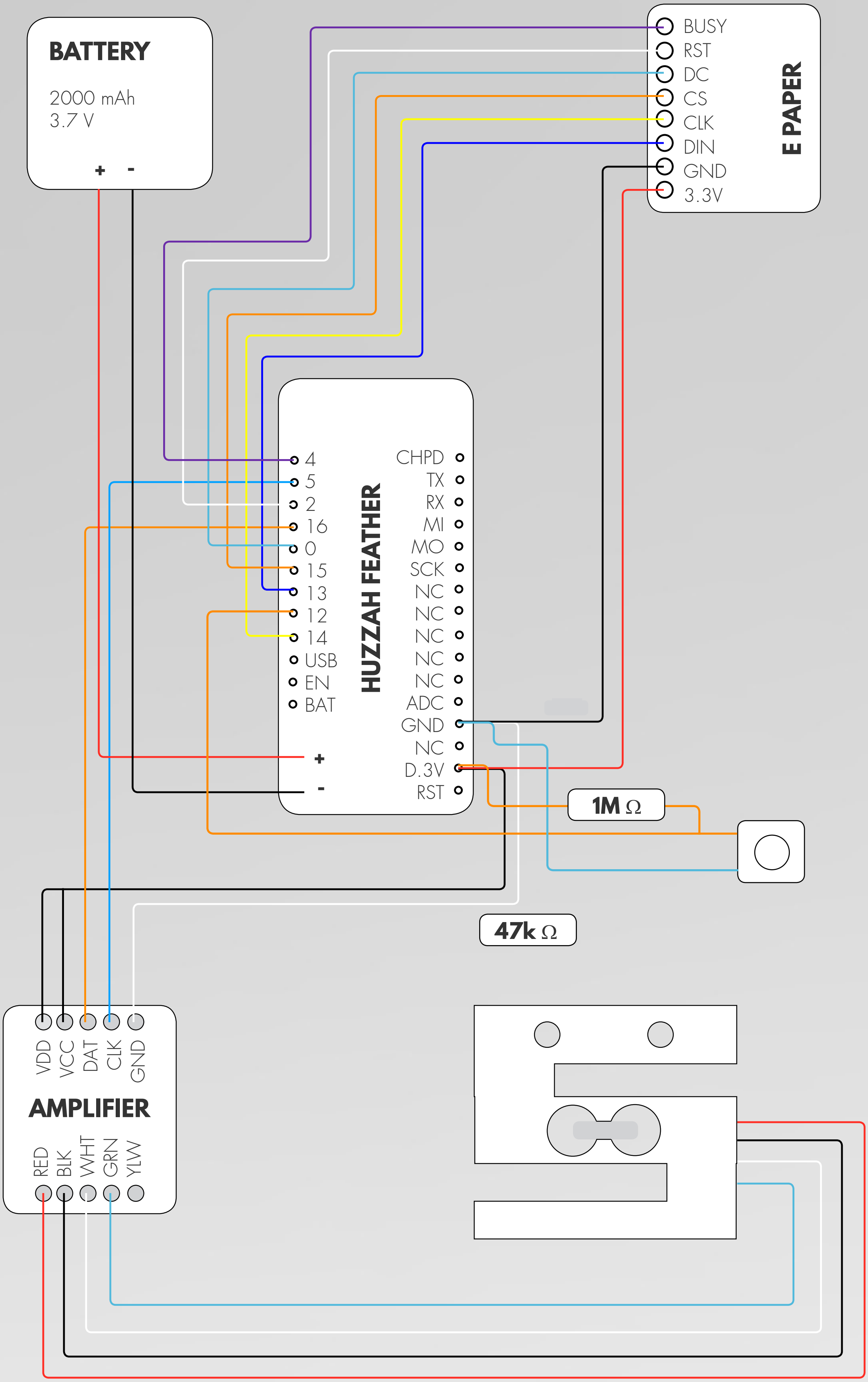


Figure 19.1: functionality scheme prototype

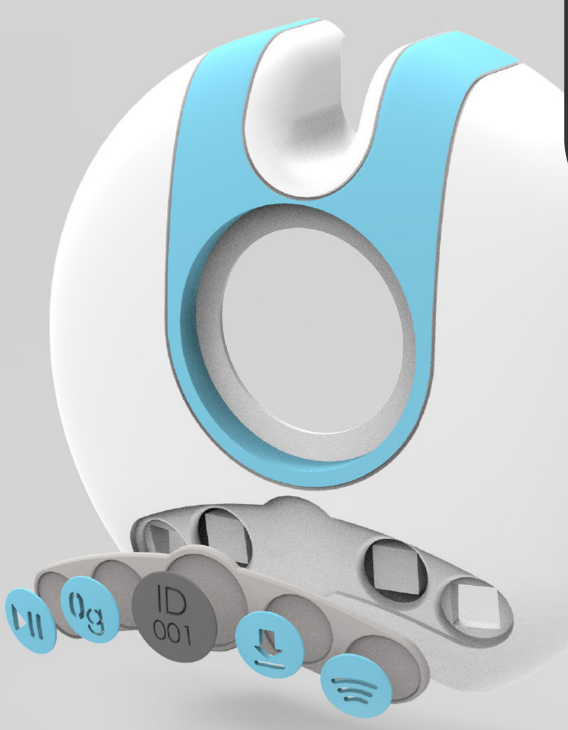
CONNECTION SCHEME PROTOTYPE

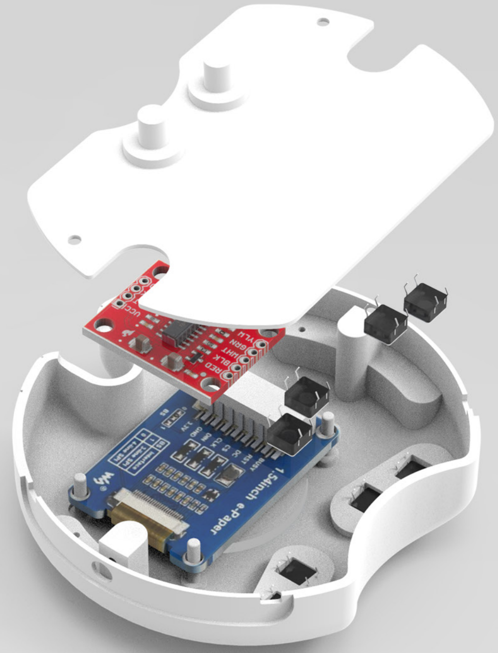
Overview of the connections between the different PCB's. When an other board is used, different pins might be required for the e-paper display. Online forums will provide more information on this matter.



ASSEMBLING MODEL

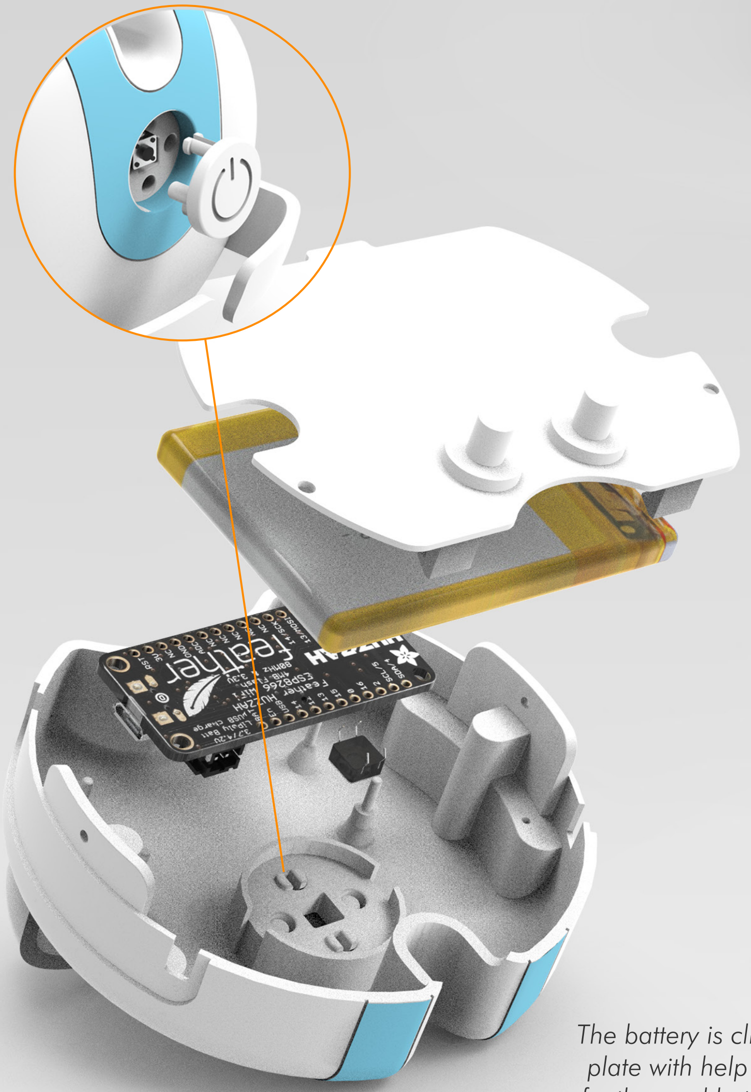
The model was designed to be (dis)assembled easily and to fit all necessary parts inside. These pages will show in a visual overview what the assembling process looks like.

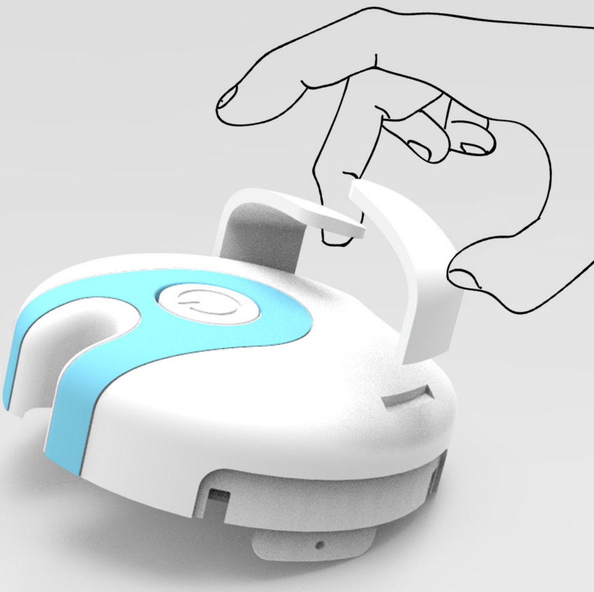




The flexible button cover is glued onto the top of the front shell. The amplifier is fixated on the e-paper before it is placed into the front shell. The buttons are fixated into the correct holes and the divider plate closes off this part of the assembly

The brackets are glued onto the back shell and the on/off button is placed by pressing the pins together. After releasing the pins, the button will not fall out of the product.

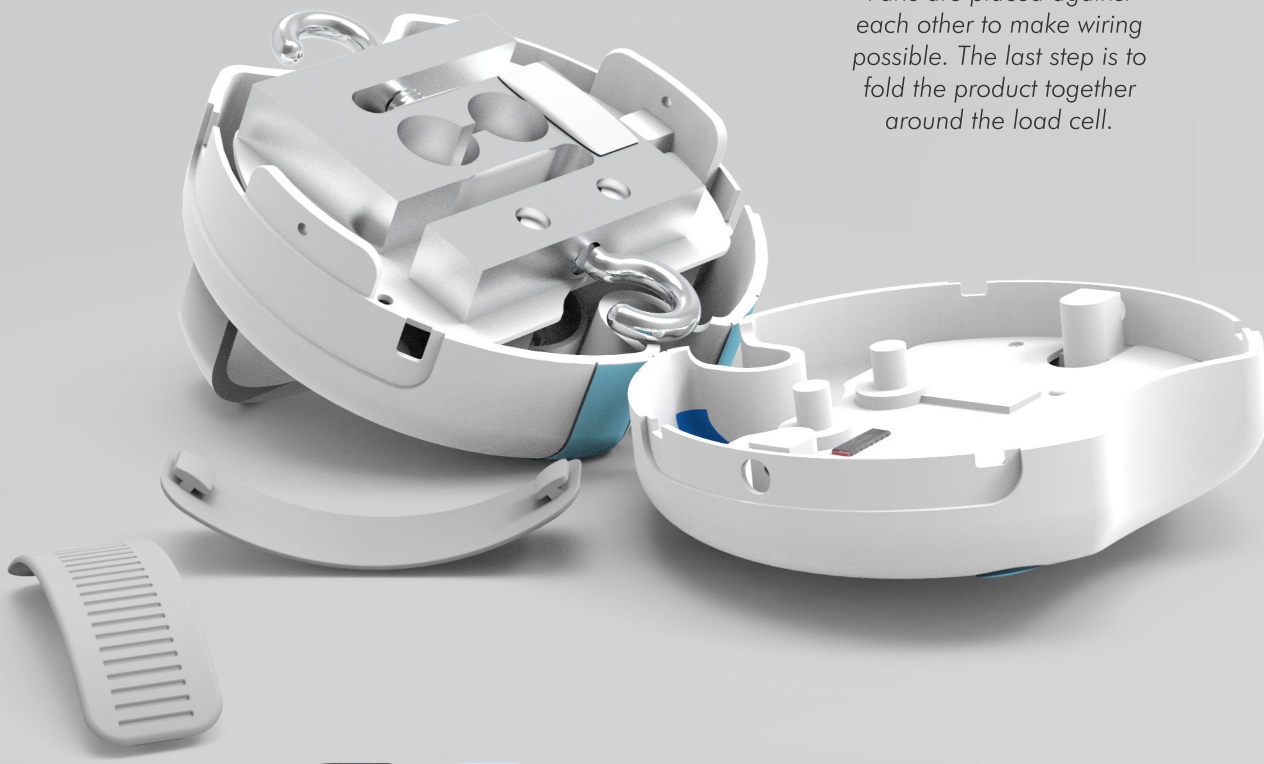


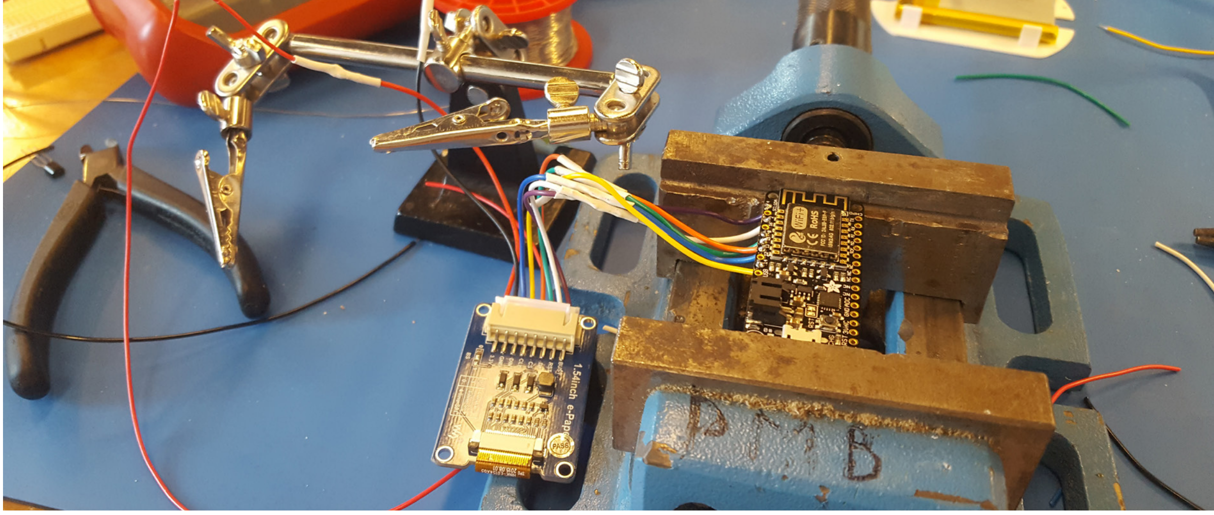


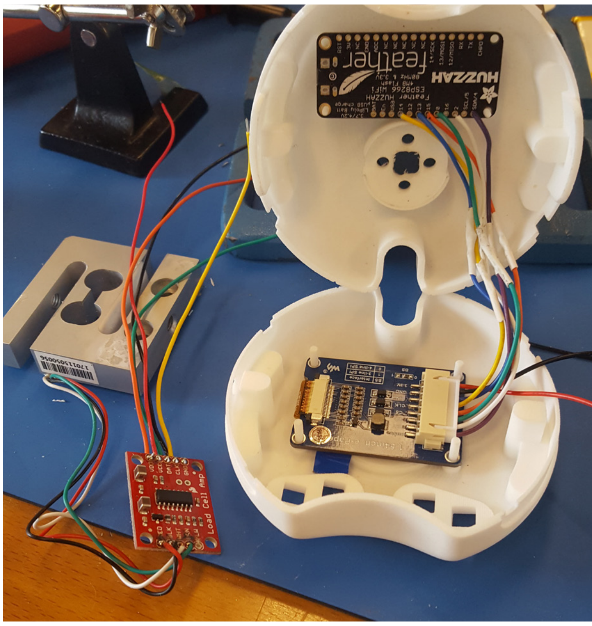
The battery is clicked on the second dividing plate with help of click fingers. The huzzah feather and button are placed into the back shell as well.

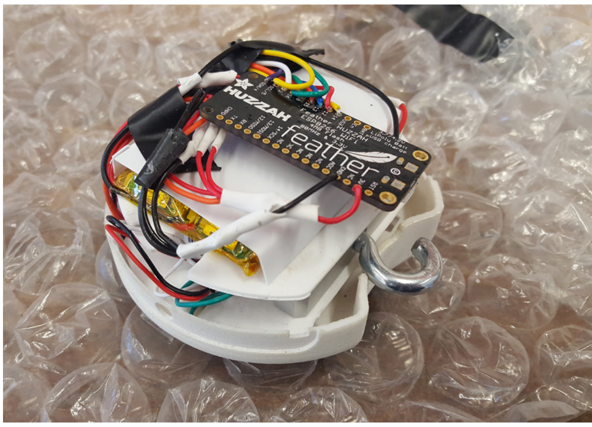
ASSEMBLING MODEL

Parts are placed against each other to make wiring possible. The last step is to fold the product together around the load cell.

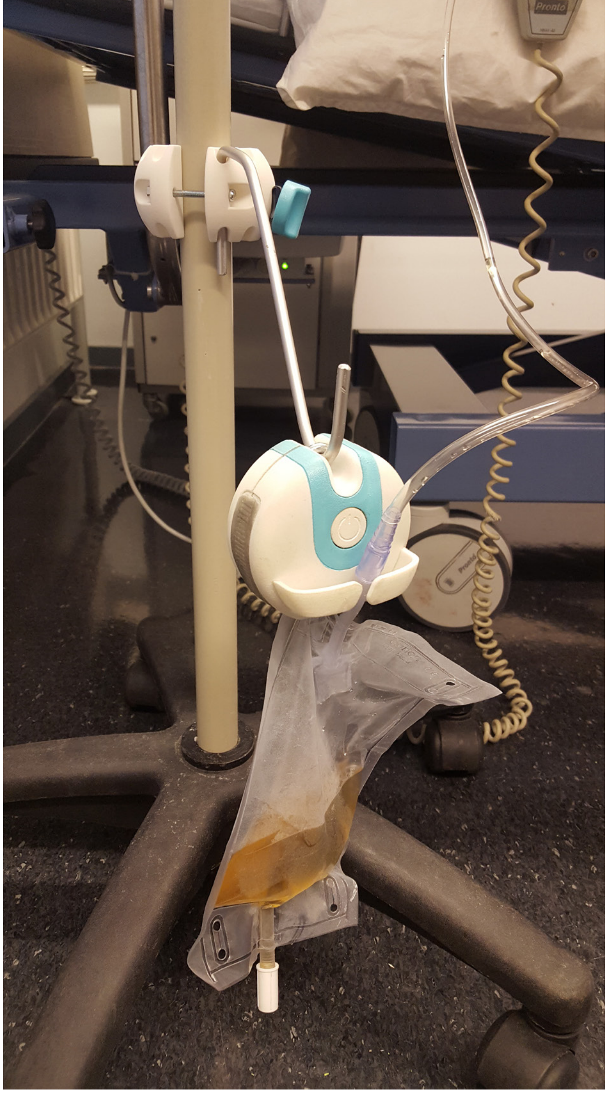



1.54inch e-Paper


feather
HUZZAH


HUZZAH
feather


3M
255P
P320




06:30 - 16:10
125 ml
06/05/'18
ID 001

19.1 Findings and recommendations

Based on building the assembly for the prototype, attaching a catheter bag to it and placing it on the IV stand, insights were gained for the rest of the prototype. This chapter will provide an overview of these insights that either need to be improved or need to be researched during further research.

FluidBalance hanger

- After a discussion with the UMCG it became clear that Wi-Fi will be a far better solution for wirelessly connecting than Bluetooth as it is more trustworthy. The disadvantage of using more energy needs to be accepted, but can be made as small as possible by integrating the "light sleep mode" function of the Wi-Fi module.
- The Prototype including all the needed cables turned out to be quite small. For further prototyping with the same internals it is recommended to print a slightly larger housing. This is already done for the second prototype.
- The on and off button should be a sliding button instead of a push button as this is easier to integrate into the system, requires less space and it is easier to see when the product is on or off without the need of a light. Nevertheless, attention needs to be paid to the fact that the product shells still need to be water resistant which is easier for a push button.
- The easiness of placing the bag and guiding the hose through the brackets was much improved compared to the first prototype already, but it can be improved even more as the bag tends to rotate slightly.
- When the on and off button becomes a slider, it cannot be used to show battery level anymore when pressing shortly. This is why a battery level button is required. It is not recommended to show the battery level at all times on the screen as it is very small already. All of its space should be used for communicating the weight and updating time.
- A bigger font for the e-paper is necessary to create a better interface. This font needs to be programmed.
- Time stamps need to be send along with the message.
- It is recommended to use a different version of the Huzzah feather. Not the ESP8266, but the ESP32. This newer version (ESP32) contains more pins which allows extension of the prototype (five extra buttons can be added). One button could be used to reset the board when it is not functioning properly. Resetting now requires opening the product and pressing the hardware reset button on the board itself. Also on/off, pause/play and resend buttons can be added.
- More stable code for integration with the adafruit website (Adafruit.io) is required for testing properly. The code tends to stop sometimes when the connection is broken.
- A buffer function for data on the FluidBalance hanger itself needs to be added to save data when the connection is broken. The micro USB port needs to be able to function as a download port for the saved data.
- Adding code for connection with multiple networks. A back-up network that can take over if the original one fails for example.
- The smaller load cell does not contain easy-to-use holes for fastening, so a way to fasten the new load cell is required when choosing to use it.
- A suitable design for the adapter. This adapter is mainly built to be used during first tests and to making sure a unity in form and color language is formed with the FluidBalance hanger.

FluidBalance application

During user research conducted among several nurses the following notes were made about the application:

- The application should offer a possibility to connect a catheter bag that was already attached to the patient when entering the ward (and partly filled).
- The application should offer a possibility for the administrator to select a ward (that corresponds with a specific pattern of warnings).
- The "home" bar on the left of all interfaces was not understood at all.
- Confirmation from the system that the right person is connected (after filling in the patient's personal number) would be nice.

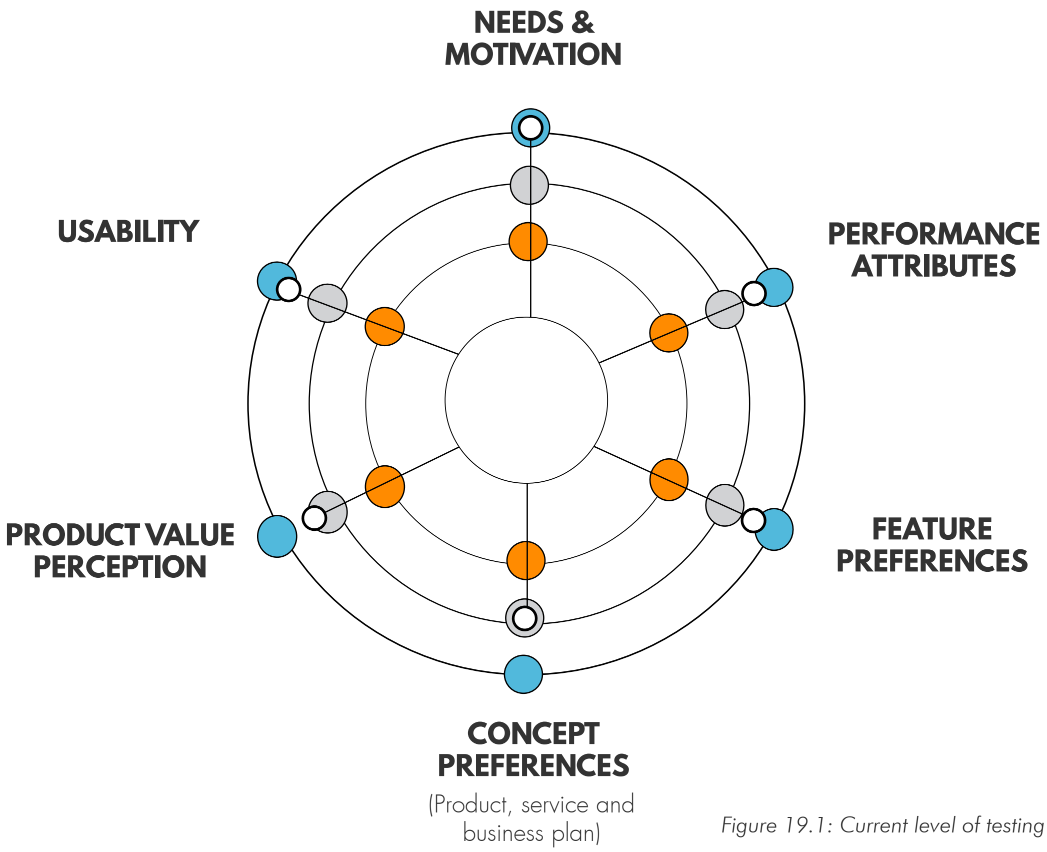


Figure 19.1: Current level of testing the concept

19.2 Further testing

Figure 19.1 gives an overview of the different parts that are needed to assess the validation maturity (Verhaert, 2018). Explanation of the six areas is presented in appendix 30. During this graduation project the focus was mostly on the product system as a whole and the FluidBalance hanger in specific. At first the business concept was partly addressed, but this will require further investigation regarding the willingness of the buyers to pay. This will require a solid overview of all savings on a yearly basis, which can be compared to the current situation. The information gathered will lead to increased knowledge on the "concept preferences" area. In parallel performance tests with the FluidBalance hanger and the combination of the FluidBalance hanger with the application are required. Appendix 29 shows in an overview which tests are necessary and in what order it is recommended to perform them. It is recommended to start with the certification process of the product service system when it is likely that the product will not change much anymore. Contacting different notified bodies to make arrangements about certifications and when to start with it should, however, be done as soon as possible as this tends to take very long (Verhaert, 2018).

Finally, the compatibility of the system and which safety requirements need to be met to be able to connect the system with multiple EPD's inside different hospitals needs to be investigated. This was partly discussed with Eric Bartens (connectivity and reliability department of the UMCG). Bluetooth is considered unreliable compared to Wi-Fi. The UMCG works with the company Capsule which is a company that provides drivers for products that need to work with help of Wi-Fi. Each department of the hospital has the Smartlinx Neuron. "Smartlinx is an enterprise-wide MDIS that can be deployed in virtually any environment where a medical device is used for patient care" (Capsultetech, 2018). Smartlinx contains drivers to manage the data that is received from the product. Data is being send in form of a HL7 message. "HL7 ADT messages are used to exchange the patient state within a healthcare facility. HL7 ADT messages keep patient demographic and visit information synchronized across healthcare systems" (Heath Standards, 2018). A specific driver is needed for the FluidBalance program to make it compatible with this system. This requires working together with Capsule before implementation. Capsule is widely used by multiple hospitals in the Netherlands, but not in all hospitals. An overview of the working principle is shown in figure 19.2. Altogether it means that time needs to be reserved for implementation and compatibility within different hospitals. The sooner it is clear how many hospitals use Capsule and what other companies will be involved the smoother the process of implementation will be.

19.3 Conclusion

Further fine tuning of the prototype and a way to get closer to a solid product-service-system will evolve from the first tests already. Close contact between stakeholders and early tests are necessary to make sure no important issues are overlooked. All tests need to be documented well to make sure a CE certification is possible in the end.

CONNECTIVITY SCHEME

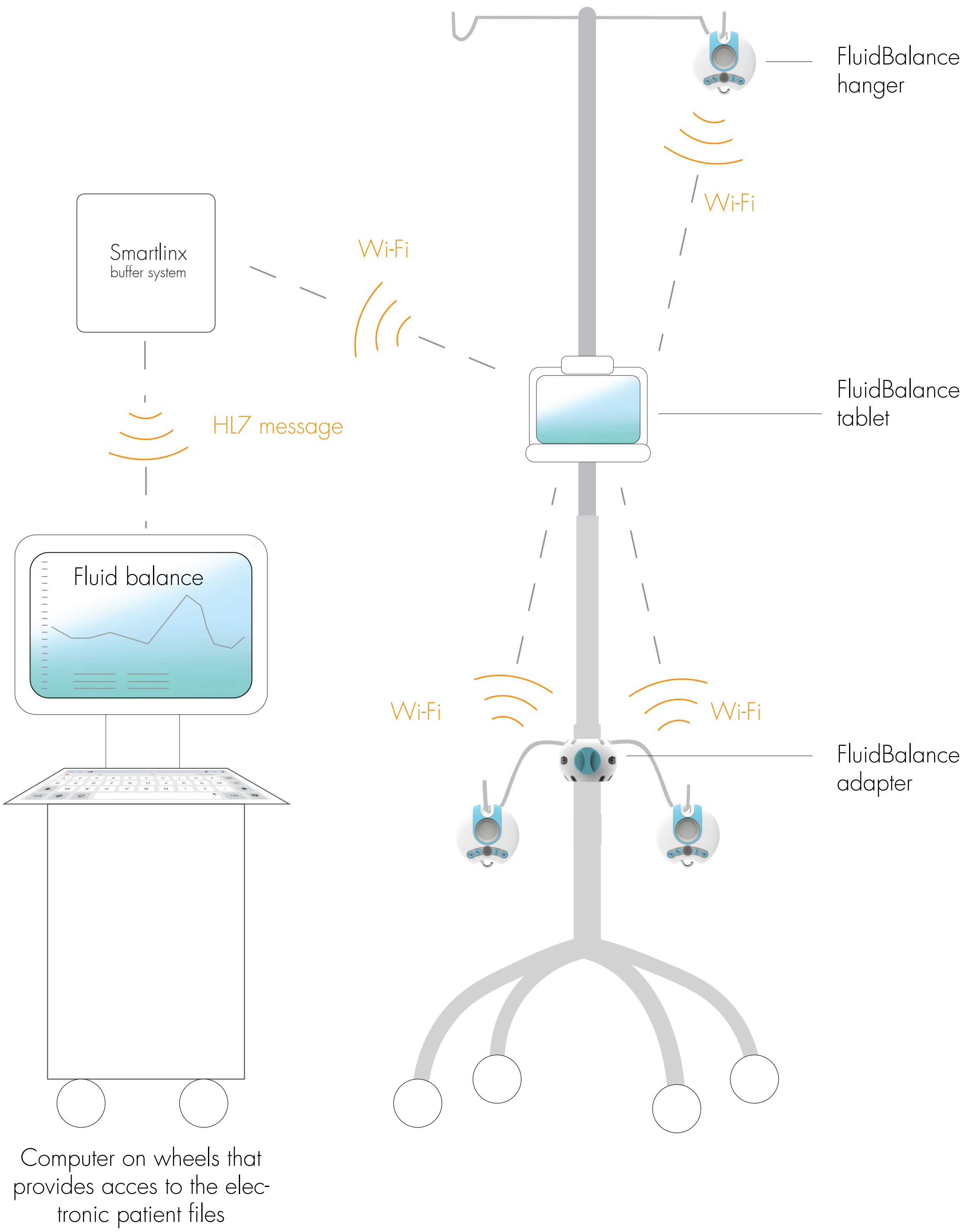


Figure 19.2: compatibility hospital environment UMCG

20. Product proposal

The prototype was the first step into the direction of creating a solid product. Of course the prototype is different form the final product. The main differences will be discussed shortly. The collage on page 91 represents the latest view on the product proposal.

20.1 Customized PCB

Especially the inside will be different as the separate boards that are currently used (load cell amplifier, huzzah feather and e paper board) will be replaced by a customized PCB. This PCB will already include buttons already and will not contain any other features than necessary. This means that space will be saved, a more logic form will be chosen and, most important, energy will be saved. The customized PCB will contain buttons with RGB lights (already on the right position), holes for fixation and an integrated e-paper display. Having this main PCB in front of the product means that only six cables (two for power and four for the load cell) need to go from the front of the product towards the back of the product. For the prototype 18 cables were needed to go from the front of the product towards the back of the product.

20.2 Smaller load cell

The smaller load cell will save a lot of space. The bigger laod cell in combination with m6 hooks needed to be 90 milimetes minimum. With the smaller load cell this can be reduced to 75 milimeters in height. The thickness of the product can be reduced as well because the smaller load cell is only six milimeters thick. The bigger version is twelve milimeters thick.

20.3 Water resistance

The front and back shell will be made with multiple color injection molding as two different colors are required to give the product it's intended look and feel. As both shells need to be water resistant and loose buttons can get stuck due to dirt, it is best to integrate the button covers into the shells themselves. For multiple medical devices (the IVAC for example), some type of foil is used to cover buttons. This foil is inserted into the mould of the product and is therefore attached to the shell during molidng. The e paper display will be placed lateron when assembling, so a transparant screen that closes off the shell (attached during molding or attached during assembling) is necessary to guarantee water resistance. Both shells are not optimized for injection molding yet as they contain thicker areas. These areas are used for easily (ds)assembling the model. The seals will close off both shells before placing the load cell in between. This will be mostly the same as with the prototype. Connecting the shells to each other will be the last step of the assembling process.

20.4 Integrated with composition chip

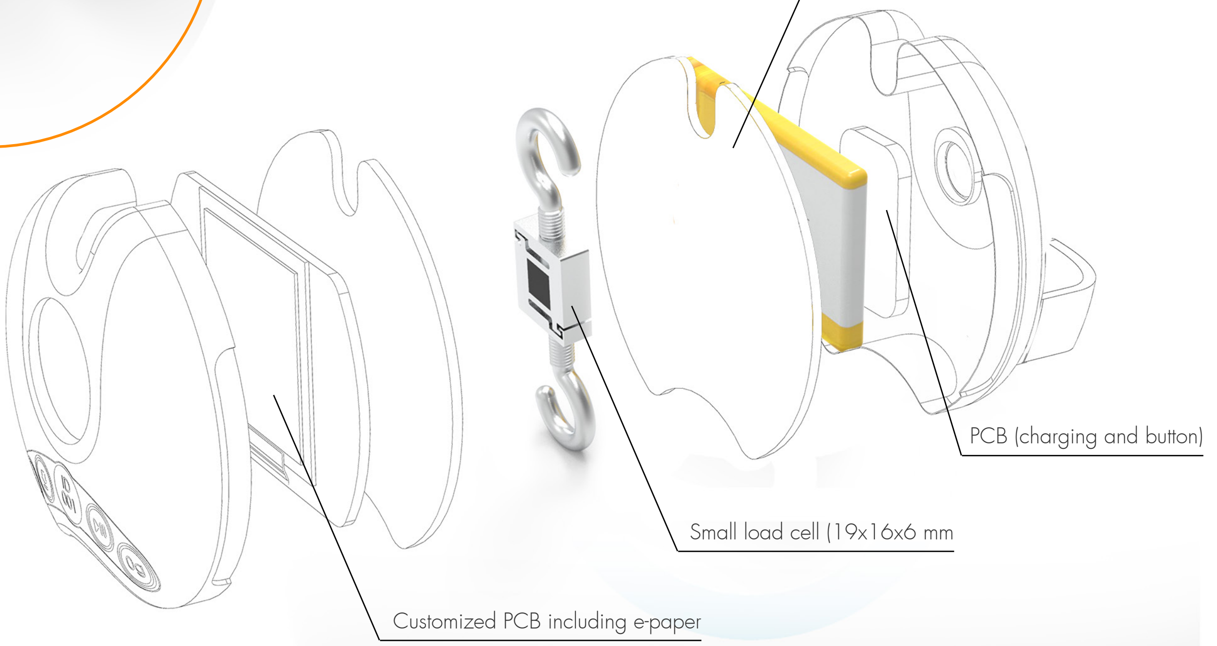
The plan is to come up with a new way to detect the urine composition at the bedside of the patient. Before deciding to finalize this product proposal it is important to know how this chip and the usability around the chip will be. If integration with the FluidBalance hanger is possible somehow it will defenitely increase the product's value.

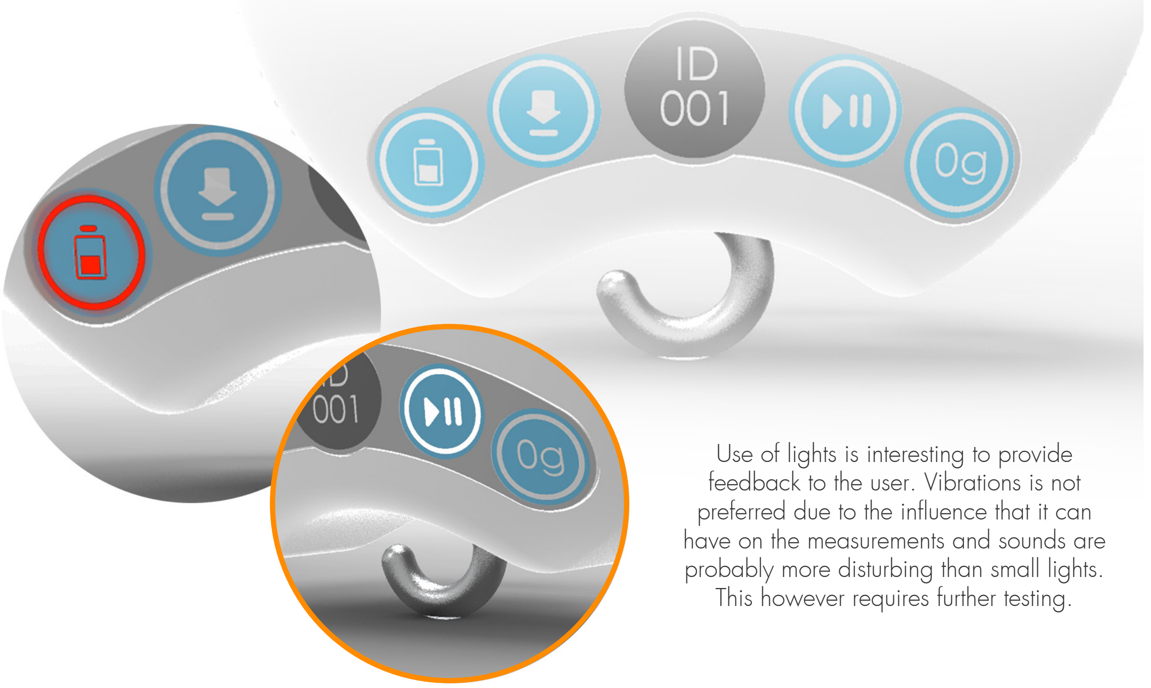
20.5 Conclusion

Several steps need to be taken before coming up with the final design of the product. It is the best to stick to 3d printed prototypes untill everything is defined and all required research is done to avoid mistakes and therefore high costs.

Prototype **Product proposal**

Difference between the current prototype and the possible product when using the smaller version of the load cell.





Use of lights is interesting to provide feedback to the user. Vibrations is not preferred due to the influence that it can have on the measurements and sounds are probably more disturbing than small lights. This however requires further testing.

COST PRICE ESTIMATION

Variations between the prototype and the product propsal lead to a different cost price. An estimation for the costprice is provided on the next page. An estimation about the amount of products produced was set to 20.000 assuming that the product will not stay in the netherlands only, but also spread to other european countries.

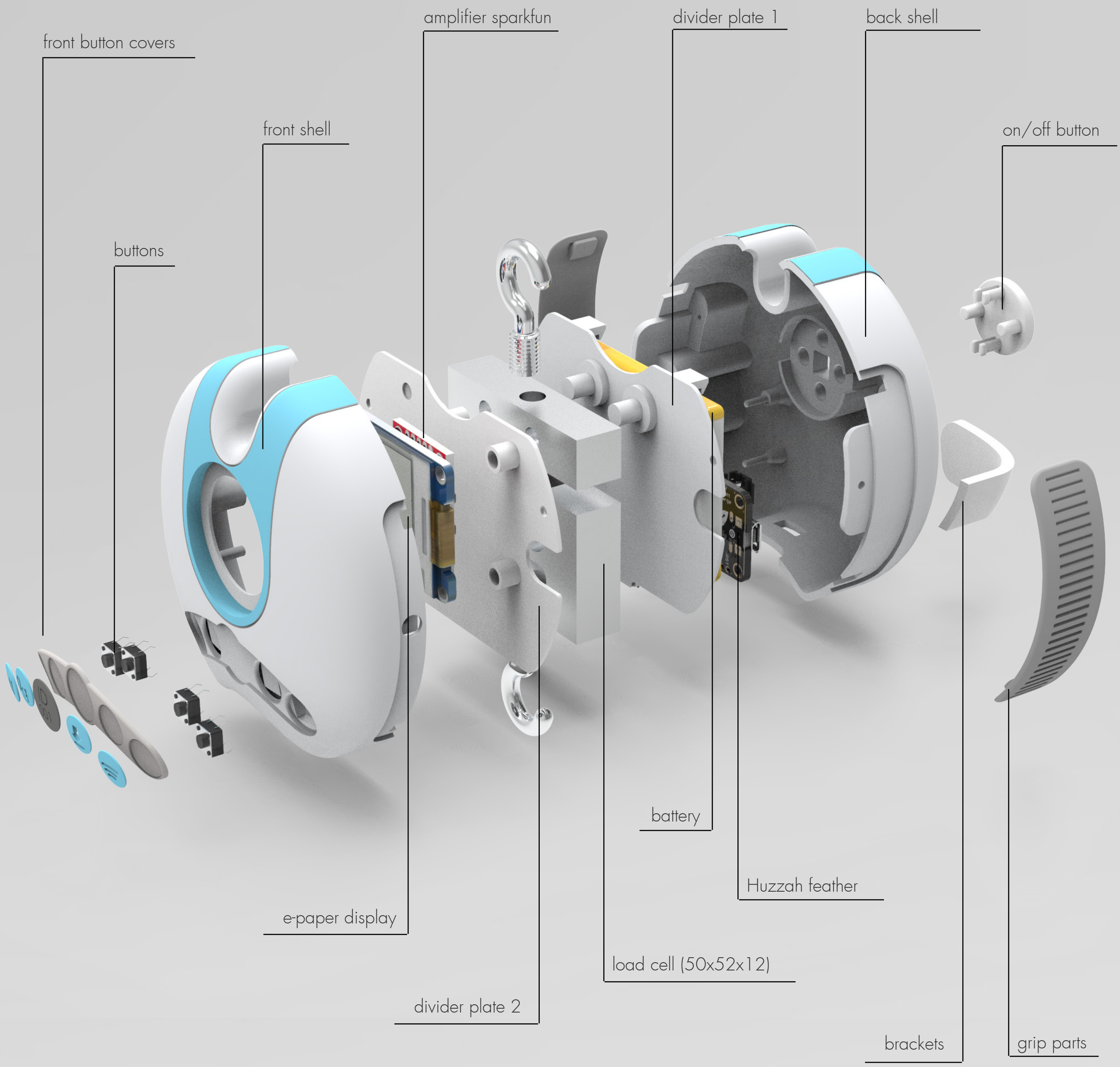


Figure 21.3: exploded view of model including the descriptions of the different parts

	WORKING MODEL (20 prototypes)			PRODUCT PROPOSAL (20.000 producten)		
Parts	**Production method**	**material**	**costs (eur)**	**Production method**	**material**	**costs (eur)**
Load cell (50x52x12mm)	purchased part	aluminum	33	purchased part	aluminum	19*
Load cell (16x19x6mm)	-	aluminum	-	purchased part	aluminum	43*
amplifier Sparkfun	purchased part	multiple	12	-	multiple	-
Huzzah feather adafruit	purchased part	multiple	18	-	multiple	-
e paper screen	purchased part	multiple	33	purchased part	multiple	8**
battery	purchased part	multiple	16	purchased part	multiple	10
5 buttons	purchased part	multiple	1	-	multiple	0,2
2 internal hooks (M6)	purchased part	chromed steel	1	purchased part	chromed steel	0,2
brackets catheter hose	3D printing (SLS)	PA12	5	injection molding	PC*****	1****
on/off button	3D printing (SLS)	PA12	3	injection molding	PC	1****
front shell	3D printing (SLS)	PA12	20	multiple color injection molding (with insert)	PC	2,50****
back shell	3D printing (SLS)	PA12	27	muliple color injection molding	PC	2,50****
dividing plate 1	3D printing (SLS)	PLA	5	laser cutting	PC	0.5
dividing plate 2	3D printing (SLS)	PLA	5	laser cutting	PC	0.5
front buttons cover	3D printing (SLS)		6	customized foil	multiple	0,5
customized PCB	fritzing prototype	mulitple	30***	custom made	multiple	15
grip parts	3D printing (SLS)		8	injection molding	PC /rubber	1****
		total 1:	**+/-193**	**Incl. big load cell**	**total:**	**+/- 61**
	incl. customized PCB	**total 2:**	**+/- 127**	**Incl. small load cell**	**total:**	**+/- 85**
Adapter parts + hooks	**production method**	**material**	**costs (eur)**			
Two shells	3D printing (SLS)	PA12	54			
2 hooks	bending	aluminum	1			
knob (incl. M8 metric bolt end)	3D printing (SLS) + purchased parts	PA12and steel	7			
2 m6 bolts and nuts	purchased parts	steel	1			
		total	**+/- 63**			
		total together 1	**+/- 256**			
		total together 2	**+/- 190**			

* Taxes and importation costs (invoercalculator, 2018) are taken into account as well. Prices are based on Sensor Con (SensorCon, 2018) load cells which are used for the prototype and during testing.

** Price is based on the WaveShare e paper display that was used for the prototype as well. This e paper display is available on a testing board and as a loose part (WaveShare, 2018).

*** A customized PCB can be created in different types of programs like Fritzing or KiCAD. Mostly this involves around 100 euros starting costs and a specific amount per component. The rough costs estimation for FluidBalance was made by Richard (PCB engineer, Faculty Industrial Design Engineering).

**** The costs for the injection molded parts are estimated based on a similar size and look as the working the prototype. The estimations were made with help of an online tool (customepartnet, 2018). In appendix 31 a calculation examples are shown.

***** PolyCarbonate is suited for medical devices as is it highly resitant to chemicals (van Royen, 2015)(Radley, 2003). When combined with rubber, PC is also suitable to be used for flexible parts (Amin, 2011).

Business perspective

21. Value chain and selling price

The product will initially be focussing on the Dutch market. Altogether approximately 250.000 patients require fluid balance measurements (estimation client). The main competitor (as explained in chapter 3) within the Netherlands is Biometrix. When deciding to expand to a broader area like the United States or other European countries more competition needs to be beaten.

21.1 Market size

Per hospital it will vary how many products are needed per day. The Netherlands count eight University hospitals and approximately 280 regular hospitals. (zorgkaartnederland, 2017) An estimation regarding the amount of patients was made at the UMCG: 1000 patients in a big hospital like the UMCG of whom 25% could benefit from more accurate fluid balance measurements.

Estimation: 25 - 60 big hospitals (Per province two to five) big hospitals need 200 to 400 products, small hospitals need 80 to 150 products. Assuming that two FluidBalance hangers per patient are needed. An estimation for the Dutch market:

25*200 + 255*80 = 25.400 hangers at least and a maximum of 60*400 + 220*150 = 57.000 hangers.

21.2 Pricing and possible savings

Based on the design of the Fluid Balance hanger a part of the cost estimation can be formed. As mentioned before production price will be 60-80 euros. The other parts of the system (application design and implementation, the adapter for the tablet renting or buying storage for data storage) need to be determined in further detail. Within the world of hospital products, the value that the product brings is more important than the production price (Tchang, 2017). This means that the most important factor for buying is how much money can be saved over the coming years. As mentioned before currently used Urimeters that contain a hard plastic part to make readings more accurate cost around 2,50 euros. The cheaper bags cost 0,50 euros which leads to a saving of 2,00 euros per catheter bag. Savings per year calculated:

At some departments almost everyone needs a FluidBalance system and at other departments only a few. Roughly 20 patients per department of whom 25% needs the FluidBalance system (5 patients). Urimeters need to be used for a maximum of 72 hours (according to hospital protocols) to prevent infections. This means that on a yearly basis a department can save: 365*24 (hours per year) /72 = 121 bags per bed. Per department: 121 x 5 = 608 bags. The savings per department per year in this case are: 2,00 euros x 608 bags is roughly 1200 euros. Divided over the patients this means 1200/5 = 240 euros per year.

These savings are only based on the savings regarding the catheter bags. Savings on days that a patient needs to spend in the hospital due to complications and inaccurate measurements (600-800 per day) need to be calculated after a year of usage.

Finally, the direct savings in fulltime-equivalent (fte) needs to be taken into account. Literature and expert opinion suggest that the average time spent for monitoring the fluid balance per patient is 3 minutes (walking to patient, noting urine production and manual input of this number in the computer).

An average of 5 patients per department and either 12 or 6 urine output checks (2- or 4- hourly intervals per 24 hours) would imply 18 (3*6) or 36 (3*12) minutes of work per patient per day. On a weekly basis this implies either 2.1 hours (18*7=126 minutes) or 4.2 hours (36*7=252 minutes) of time saved per patient. For 5 patients between 10-20 hours every week or 40-80 hours per month (1-2 fte). On a yearly basis we are looking at savings around: 480 - 960 hours. A nurse costs between 29 and 35 euros per hour (financieel.infonu.nl, 2017) which means rough savings of: 13.000 - 33.000 per year.

Of course these savings should not be taken too literally and other costs like service costs, education costs, time to spend on the new system and other factors should be considered as well. Nevertheless, mentioned savings lead to enough space in cost price to develop the most suitable system.

21.3 Possible value chain

As not only the nurse will be involved in using, buying and maintaining this system it is important to take a look at the total value chain. Financial connections, interests and influences have been discussed in chapter two already. Figure 22.1 on the next page shows an overview of the value chain regarding the FluidBalance system.

Whether the product will be sold or leased to the hospital immediately, sold via a supplier or payments will be made upon amount of use is still open. To get a first idea on how this usually works for other hospital products an interview was held with the advisor and co-buyer of medical equipment at the UMCG, Jan Bos.

The most important findings were firstly the fact that hospitals are able to make their own decisions on what equipment they buy. Secondly, they buy equipment via suppliers and companies themselves depending on the product. Thirdly, LNAG advisors could be of importance on spreading knowledge about the product. Convincing the right people who need to work with the product and presenting their opinions to the LNAG advisor of the specific hospital can play an important role in the buying process. Finally, different selling models are used within the hospital. Some products are being rented, especially very expensive products. For less expensive products it is less common to rent them as it is well-known that renting is more expensive than buying all at once. The hospital likes to buy rather than rent and maintain the products themselves within a specific hospital department. This department is responsible for yearly product check ups (according to hospital protocols) and stays connected to the supplier in case of unsolvable issues.

21.4 Conclusion

Further research, as recommended in chapter 19, on the total costs and the willingness of the buyers to pay will provide a better insight in the possible business opportunities.

Figure 21.1: possible value chain for the FluidBalance System.

KEY PARTNERS

A partner who will be responsible for the application development (party in Haaksbergen) who will work closely together with the hardware developing party Pezy Group (embodiment of FluidBalance hanger, adapter and the tablet holder)

An expert on mechatronics who will support the development of the programming software which is required for the system.

Contact with the LNAG advisors (Jan Bos, UMCG)

Production and assembling suppliers

CE cerfication experts

KEY ACTIVITIES

Active testing and improviing the device and its performance. Spreading these test models over different departments and showing the differences. Having a lot of people working with and/or trying the wards to increase support level.

KEY RESOURCES

Enthusiasm of nurses and their wish to use FluidBalance during their job.

Enthusiasm of doctors about outcomes and accuracy rates

Support from different departments in the UMCG and other hospitals

VALUE PROPOSITION

FluidBalance offers a system to save money whilst increasing the accuracy on fluid balance measurements. Less demanding and annoying tasks for the nurse and a better experience for the patient (less hospitalization times and less interrupting check ups)

Over time a more accurate treatment plan can be formulated based on knowledge about fluid balance patterns within different diseases.

CUSTOMER RELATIONSHIPS

Customers expect to have a working product service system. The hospital has its own department to control errors in medical products. They control the contact with the suppliers and services

CHANNELS

Enthusiasm about the product from the nurse's perspective is important to convince LNAG advisors at the hospital. These advisors are spread over 30 hospitals already (in the Netherlands). This will serve as first channels. The LNAG network can serve to broaden the knowledge about the system.

CUSTOMER SEGMENTS

Although hospitals are quite common it can still be intepreted as a niche market with specialized requirements . The value proposition is targeted at the hospitals (users and buyers). The needs of the users are taken into account and the financial advantages are calculated to target the buyers.

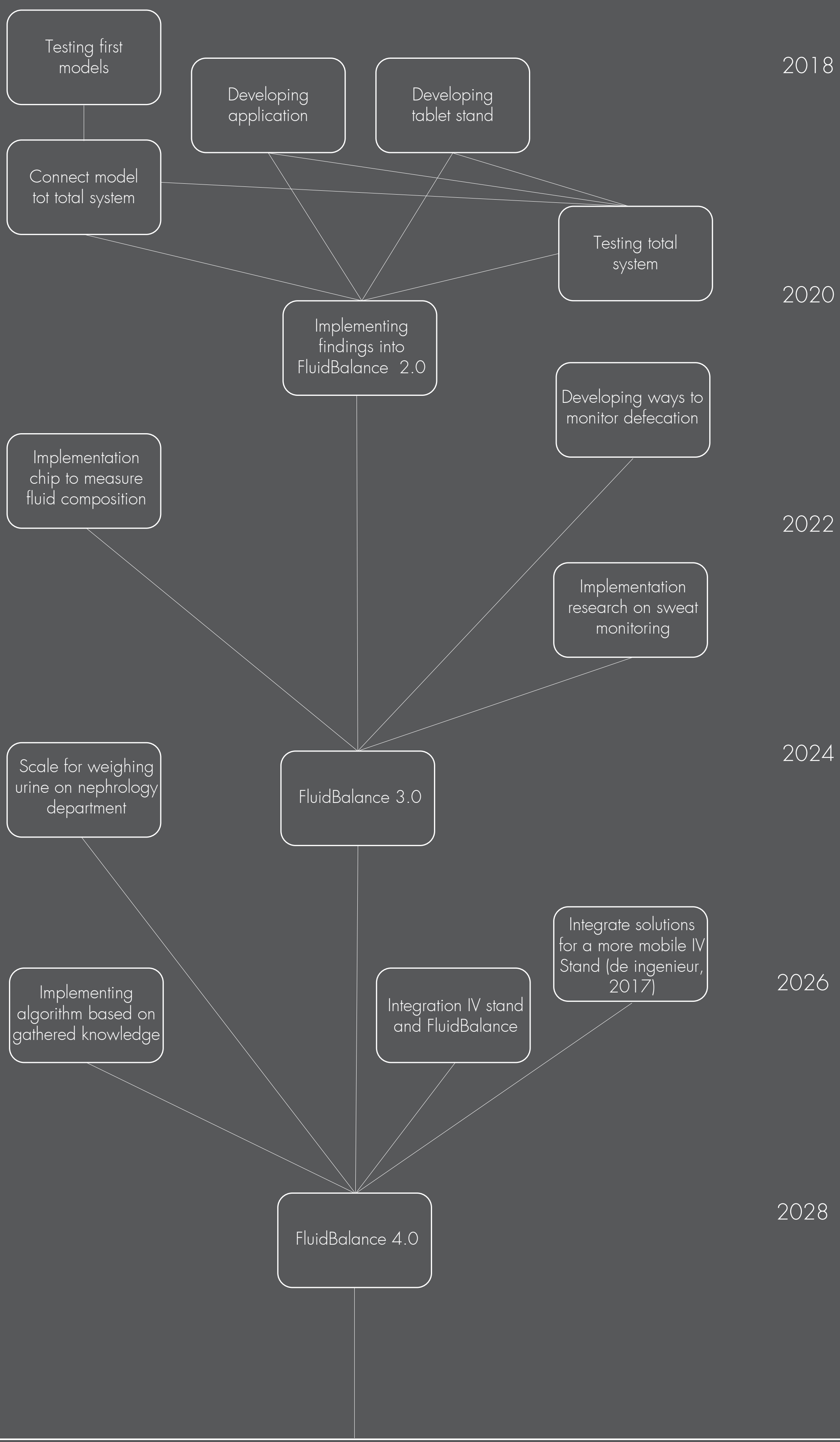
COST STRUCTURE

The product product service system (tablet, adapters, FluidBalance hanger and the application) are bought by the hospital. Administrators need to be assigned who will be responsible for updating the wardss. Storing data will cost money as well. Margins on the customer price will cover these costs and serve as development money for future versions and improvements.

REVENUE STREAMS

Customers are willing to pay for a working system that saves them time, money and increases experiences. Most medical products are bought by the hospital and maintained by a department in the hospital itself.

PROJECT ROAD MAP (10 years)



Personal evaluation

Let me start with mentioning that the final result of the project is amazing and it matches my hopes I had at the beginning of this project. I selected this project based on a few things. Firstly, the company, PezyGroup, was an important factor to go for this project. For my graduation period I always wanted to select a company that fits my wishes for the company I would like to work for and could ltherefore ead to my first job. I have to say that this turned out perfectly. Already in December I had conversations about working for PezyGroup that were initialized by the Business Leader himself. From the beginning of March I will be working for PezyGroup as a product developer with a lot of interesting and challenging projects in near future! Moreover, my own graduation project will be continued and the client especially asked for me to continue on the job.

Secondly, I wanted to work on a medical project with focus on the embodiment and conceptualisation phase. In the end, it turned out that the real embodiment parts (designing the CAD files for injection molding) were not realistic within this time span. Fortunately they will be in the future as this project will not end here.

Thridly, I looked for a project that offered something interesting for me to learn. This project contained quite some electronics (afterwards even more than expected) which was kind of new for me. During my earlier project for Philips Floorcare I started already with getting to know the basics of Arduino again, but this project defenitely added much knowledge on this part. Looking back, the electronics part became a very big part of the project. I expected to get more direct support , but it turned out that my ideas for the project were not that easy to program. Several bottlenecks were overwon, also a few bottlenecks are left for further research, but most important aspects were tackled. I have learned very much about Arduino by reading information online and talking to a variaty of experts. Sometimes it is necessary to find out how things work by trial and error as they have never been combined in a specific way before. I learned to work in steps, how to deal with errors and how to solve them.

If I have to mention something that I would have done differently afterwards, I would say a part of the research phase. My first period of time I only talked to the nephrology ward (which turned out to be the most diverse ward of all possible FluidBalance required wards) which gave me a somewhat narrow look on the situation. Much time was spend on finding different and innovative solutions that could be of even more value than the current system. Although this was very interesting and highly supported by the supervisory team of the TU Delft I think too much time was spend on this matter. It was already the end of November when I finally got to talk to the other three interested departments which led to totally new insights. On the other hand, I would not have been able to offer such in depth variaty of concepts when I would have known all limitations already. In the end I did manage to deliver all required aspects that were set before the graduation project.

Looking back at all the things that we have accomplished together and what good things came out of it, I think the project is defenitely a success!

References (including appendices)

Amin, S. (2011) THERMOPLASTIC ELASTOMERIC (TPE) MATERIALS AND THEIR USE IN OUTDOOR ELECTRICAL INSULATION, Retrieved from: http://www.ipme.ru/e-journals/RAMS/no_12911/02_amin.pdf

Appolonsky, D. (2018). EASY GUIDE: HOW TO RUN A VAN WESTENDORP PRICING ANALYSIS . Retrieved from: https://apollonsky.me/how-to-van-westendorp-analysis-excel/

Atmel. (2017). Low Power. Retrieved from Atmel: http://www.atmel.com/technologies/lowpower/default.aspx

Billett, H. H. (1990). Clinical Methods: The History, Physical, and Laboratory Examinations. 3rd edition. Boston: Butterworts.

Biometrixmedical, (2017). FOM-200. Retrieved from: http://www.biometrixmedical.com/Products.html

Customepartnet, (2018). Estimation injection molding, retrieved from: http://www.custompartnet.com/estimate/injection-molding/

Davies, S., Spanel, P., & Smith, D. (2001, October 1). Rapid measurement of deuterium content of breath following oral ingestion to determine body water. Retrieved from IOP Science: http://iopscience.iop.org/article/10.1088/0967-3334/22/4/301

Firesmith, D. (2013) The Latest Research in Software Engineering and Cybersecurity. Retrieved from: https://insights.sei.cmu.edu/sei_blog/2013/11/using-v-models-for-testing.html

Flach, E. (2017), Interview aboutl financial connections and logistics in the RDGG. Interviewer R. Hulst.
Foxworth, T. (2017) MAKING THE ESP8266 LOW-POWERED WITH DEEP SLEEP. Retrieved from: https://www.losant.com/blog/making-the-esp8266-low-powered-with-deep-sleep

Gelmers, H. J. (2010). Neurologie voor verpleegkundigen. Gorcum B.V., Koninklijke van.

HealthStandards, (2018). What is an HL7 ADT Message? Retrieved from: http://healthstandards.com/blog/2006/10/05/what-is-an-adt-message/

Helmenstein, A. M. (2017, December 29). How Much of Your Body Is Water? Retrieved from Thoughtco: https://www.thoughtco.com/how-much-of-your-body-is-water-609406

Hill-Rom. (2017). AvantGuard 1200 Bed. Retrieved from LIKO: http://www.liko.com/Documents/en/beds/avg1200/acute/Avg1200Acute_Brochure_EN.pdf

Hoekstra. (2017, September 29). (R. Hulst, Interviewer)

Hoff R G, v. D. (2008). Fluid balance and blood volume measurement after aneurysmal subarachnoid hemorrhage. Retrieved from US National library of Medicine: https://www.ncbi.nlm.nih.gov/pubmed/18172784

InfomatikBerlin (2014). Low power wireless standarts. Retrieved from Informatik Berlin: https://www2.informatik.hu-berlin.de/~hs/Lehre/2014-WS_SP-CPS/20141028_Low-Power-Wireless-Standards_1.pdf

Invoercalculator (2018), invoerrechten berekenen, http://www.invoercalculator.nl/

ISO-EN-NEN (2017) ISO Guide 13485:2017 en
ISO 13485 - Medical devices - Practical guide Possible

to retrieve from: https://www.nen.nl/NEN-Shop/Norm/ISO-Guide-134852017-en.htm. Retrieved from: Pezy Group local disk.

James S. Powers, L. C. (2009, Februari 19). Rapid Measurement of Total Body Water to Facilitate Clinical Decision Making in Hospitalized Elderly Patients. Retrieved from US National Library of Medicine: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2800804/

Jansen. (2017, July 5). (R. Hulst, Interviewer)

Khosla, V. (2012, December 4). Technology will replace 80% of what doctors do. Retrieved from Fortune: http://fortune.com/2012/12/04/technology-will-replace-80-of-what-doctors-do/

Lee, J. W. (2010, December). Fluid and Electrolyte Disturbances in Critically Ill Patients. Retrieved from US National Library of Medicine: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043756/

Ledlightsworld, (2017), How to select appropriate transformer for 12V LED Strips. Retrieved from: http://www.ledlightsworld.com/page.html?id=38

Linder, B. (2017, Januari 6). CLEARink's color ePaper displays are sunlight viewable. Retrieved from Liliputing: https://liliputing.com/2017/06/clearinks-color-epaper-displays-are-sunlight-viewable.html

Liquavista. (2018). Technology. Retrieved from Liquavista: https://www.liquavista.com/technology.html

Lumen (2017). Body Fluids and Fluid Compartments. Retrieved from Lumen: https://courses.lumenlearning.com/ap2/chapter/body-fluids-and-fluid-compartments-no-content/

CEpartner4u (2014) MEDDEV 2.4/1 rev.9 Classification. Retrieved from: http://www.cepartner4u.com/wpdm-package/meddev-2-41-rev-9-classification/

Medicalproductoutsourcing, (2017). Medline Joins Forces with Potrero Medical to Transform Critical Care Monitoring Retrieved from: https://www.mpo-mag.com/contents/view_breaking-news/2017-02-21/medline-joins-forces-with-potrero-medical-to-transform-critical-care-monitoring/

Michaelis, S. (2017) Predicting the preferences for involvement in medical decision making among patients with mental disorders. Retrieved from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0182203

Neeraj, K. et. al (2000). Patient Preferences for Medical Decision Making: Who Really Wants to Participate? Retrieved from: https://insights.ovid.com/pubmed?pmid=10718358

Navamedic (2018). Navamedic. Retrieved from Navamedic: http://www.navamedic.com/about-navamedic/

Nijsten, M (2017) Interview about applicability on the Intensive Care at the UMCG, inteviewer: R.Hulst

OrSense. (2017). The NBM 200 system:. Retrieved from OrSense: http://www.orsense.com/product.php?ID=49

Pervasive. (2017). 2.71"E ink display (iTC). Retrieved from PervasiveDisplays: http://www.pervasivedisplays.com/products/271i

Pezy, H. (2017). ''We want to deliver unique innovative solutions with the most engaged work force around'' Retrieved from: https://pezygroup.com/about/

Pleijhuis. (2017). (R. Hulst, Interviewer)

Plugintoiot, (2016, October 30). What is Sub 1Ghz RF , its range & the importance of Sub 1Ghz for wireless IOT applications. Retrieved from Plugintoiot: https://www.plugintoiot.com/sub-1-ghz/

Radley, H. (2003). Thermoplastic elastomers in medical applications. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/12774579

de Regt, S. (2017, July 5). (H. R, Interviewer)

Rijfkogel. (2017). PezyGroup. (R. Hulst, Interviewer)

Robinson, J. H., Callister, L. C., Berry, J. A., & Dearing, K. A. (2008, August). Patient-centered care and adherence: De nitions andapplications to improve outcomes. Retrieved from Online Library Wiley: http://onlinelibrary.wiley.com/doi/10.1111/j.1745-7599.2008.00360.x/epdf?r3_referer=wol&tracking_action=preview_click&show_checkout=1&purchase_referrer=onlinelibrary.wiley.com&purchase_site_license=LICENSE_DENIED_NO_CUSTOMER

van Royen, R. (2015). Flexible working: TPEs are materials of choice for medical devices. Retrieved from: https://www.medicalplasticsnews.com/news/flexible-working/

Rubenstein, S. (2017) Study Demonstrates New Standard of Care for Accurately Measuring Intra-Abdominal Pressure in Critical Care Patients. Retrieved from: https://www.businesswire.com/news/home/20170613005846/en/Study-Demonstrates-New-Standard-Care-Accurately-Measuring

RS-components, (2017), Vishay TDCG1060M 4 Digit 7-Segment LED Display, CC Green 4 mcd RH DP 10mm. Retrieved from: https://uk.rs-online.com/web/c/displays-optoelectronics/displays-industrial-monitors/led-displays/
Sak, G. et al (2017). Assessing the predictive power of psychological empowerment and health literacy for older patients' participation in health care: a cross-sectional populationbased study. Retrieved from: https://pdfs.semanticscholar.org/9b1d/ccdbdca99f91082be1de363e900965036105.pdf

Sarvestani, A. (2013, September 11). Baxter makes a smaller buy with $9.5M acquisition of FlowSense. Retrieved from MassDevice: https://www.massdevice.com/baxter-makes-smaller-buy-with-95m-acquisition-flowsense/

SensorCon, (2018) SC516MD S type load cell 1-50kg description. Retrieved from: http://www.sensor-con.com/index.php?ac=article&at=read&did=606

Shirreffs, S. M. (2003, december 18). Markers of hydration status. Retrieved from Nature: http://www.nature.com/ejcn/journal/v57/n2s/full/1601895a.html?foxtrotcallback=true

Soong, S. (2017, June 14). Choosing the Right Display for IoT Devices. Retrieved from DigiKey: https://www.digikey.com/es/articles/techzone/2017/jun/choosing-the-right-display-for-iot-devices

Soong, S. (2017, February 10). Designing Low-Power Displays for the Battery-Powered IoT. Retrieved from ElectronicDesign: http://www.electronicdesign.com/displays/designing-low-power-displays-battery-powered-iot

Spaan, M. (2013, December 31). Project Vochtbalans. Retrieved from https://prezi.com/ysoykjcxewoo/copy-of-project-vochtbalans/

Tchang, B. (2017) CEO Usono, interviewer R. Hulst

TIM-Solutions. (2017, December). (R. Hulst, Interviewer)

Vahdat, S. 2014) Patient Involvement in Health Care Decision Making: A Review. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3964421/

Verhaert, (2018) ESA rocket program course from verhaert design bureau. Retrieved information during ESA Rocket program: http://www.esa-bic.nl/rocket-program/

Vervoorn. (2017, September 6). (R. Hulst, Interviewer)

Voedingscentrum (n.d.). Vocht en drinken. Retrieved from Voedingscentrum: http://www.voedingscentrum.nl/encyclopedie/trefwoord/vocht.aspx

Waveshare, (2018), 200x200, 1.54inch E-Ink raw display panel. Retrieved from: https://www.waveshare.com/product/1.54inch-e-paper.htm
WebMD, (2017). Sodium (Na) in Blood. Retrieved from WebMD: https://www.webmd.com/a-to-z-guides/sodium-na-in-blood#1

Yoshino, K. et.al.(2015). Patent No. EP20150161438. Retrieved from: http://www.google.sr/patents/EP2915482A1?cl=en&hl=nl

Yoshino, K. et. al. (2015) Body moisture meter EP 2915482 A1. Retrieved from: http://www.google.sr/patents/EP2915482A1?cl=en&hl=nl

Yoshiyama, T. (2012). USEFULNESS OF HYALURONIC ACID SPRAY FOR TREATMENT OF DRY MOUTH IN ELDERLY PATIENTS AT A COMMUNITY PHARMACY. Retrieved from J-Stage: https://www.jstage.jst.go.jp/article/orltokyo/55/Supplement1/55_s56/_article

Zorgkaart Nederland, R. (2015, July 13). Het gebruik van tablets in de zorg, voor arts én patiënt een uitkomst. Retrieved from Zorgkaart Nederland: https://www.zorgkaartnederland.nl/feiten-en-cijfers/het-gebruik-van-tablets-in-de-zorg-voor-arts-en-patient-een-uitkomst

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