FluidBalance

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

APPENDICES

Graduation Report

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Appendices

1 Existing measuring methods

1.1 Laboratory tests

Measurement of haematocrit or haemoglobin concentration in the blood by performing a blood analysis. Both these values are based on the whole blood and are therefore dependent on the amount of plasma inside the blood. The means if the patient is severe dehydrated the values will appear higher (concentration increases) and the other way around. (Billett, 1990)

Measurements of Sodium concentration inside the blood. The working principle is the same as for haematocrit and haemoglobin. The values will be high when a person is dehydrated and lower when a person is hyper hydrated. This process is used as well to check on progress when a patient is suffering from kidney diseases. (WebMD, 2017)

BUN (Blood Urea Nitrogen) tests can be helpful to show whether a person is dehydrated or not. This test is performed by measuring the concentration of urea which is present in the urine of the patient. High concentrations urea can be caused by heart failure, kidney failure or a high protein diet. (Shirreffs, 2003)
Osmolality measurements in urine can determine the state of fluid balance. Osmolality is the concentration of the osmolalitly active substances per kilogram of solvent. This also states that a high osmolalitly could mean that the person is dehydrated. (Yoshino, 2015)

A breath test can determine the body water by on - line measuring by using Deuterium oxide ($D2O$ or $2H2O$) as a tracer. A study performed by: Simon Davies, Patrik Spanel and David Smith revealed that such a testing method leads to an estimation with an error of <300 mL (0,5%). This methods knows three phases. The first peak is due to the HDO which is remaining inside the mouth, the second peak is reflecting gastrointestinal absorption and the finally equilibration with the body water. The incremental increase in breath deuterium abundance between baseline and equilibration was used to calculate the total body water. (Davies, 2001).

1.2 Objective non-invasive tests

Body mass comparisons.
Large differences in body weight can suggest dehydration or hyper hydration. Intake and output measurements. A summation of all the measurable fluids entering the body minus all the measurable fluids exiting the body.

Measurements of how much water is entering the body and exiting the body by posting up the differences.
Urine colour measurements. The urine colour changes due to the state of fluid balance in a human body. When a person is hyper hydrated the urine can be almost transparent and when a person is hypo hydrated the urine colour can turn into a dark yellow, almost orange tone. (Shirreffs, 2003). Urine can be divided into eight colours. There is a linear relationship between these colours and the amount of osmolality and specific gravity.

Bioelectrical impedance analysis (BIA) are measurements with the help of a small (50kHz) electrical current which is going through the human body. Calculations to determine the total amount of body water are based on the principle that the impedance of a biologic system is related to conductor length, cross section, and frequency. (James et. al, 2009) To perform a BIA the person needs to by in a standing position while being connected to the device with their hands and their feet.

Axillary moisture measurements with the armpit moisture meter is a form of bio-electrical impedance analysis which is combined with temperature measurements

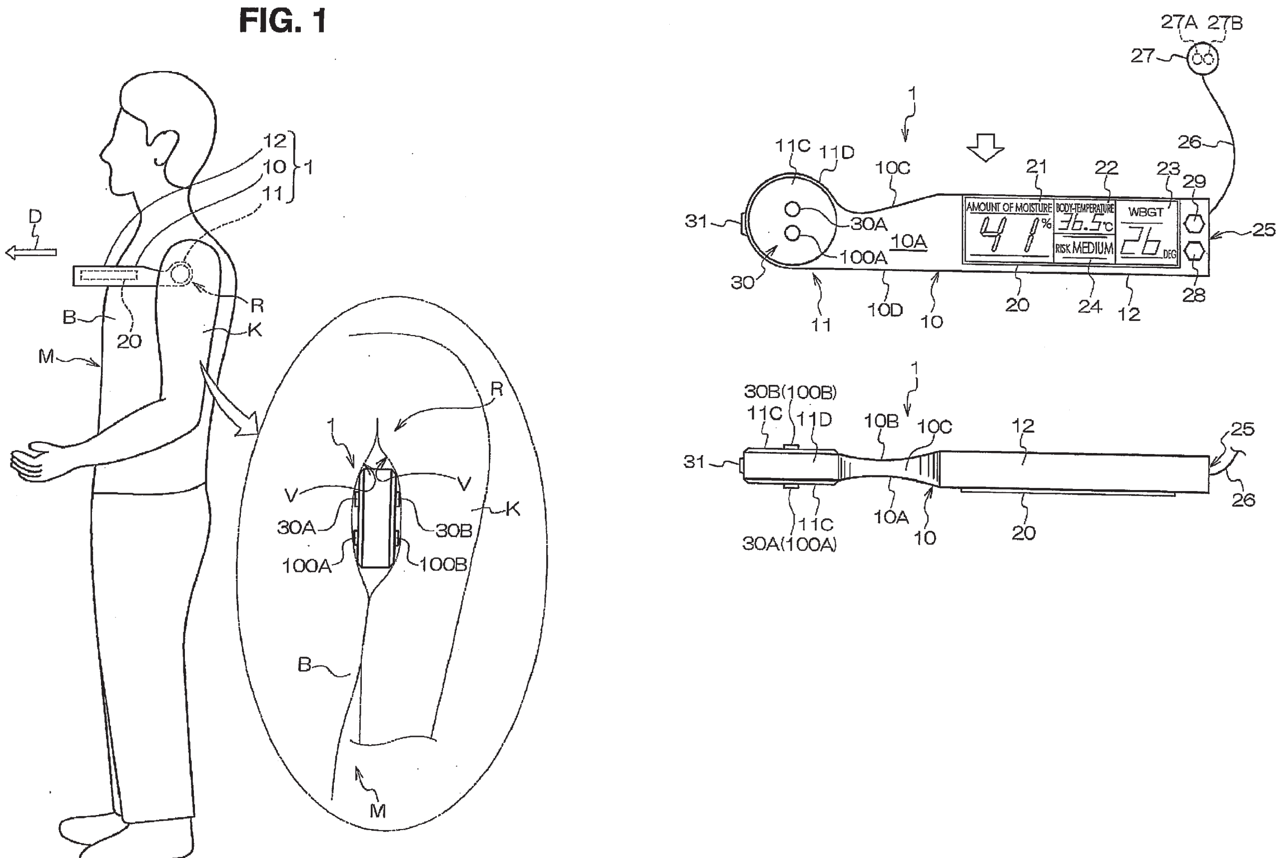


Figure 2.2: Patent on armpit measurements. Retrieved from: https://www.google.com/patents/US20130261407eu

and can be performed in a sitting position. Together this igives more precise and accurate results.(Yoshino, 2015) This idea was published in a patent in 2015. An image of the product can be found in figure 1.1.

Non invasive measurements of Haematocrit and Haemoglobin concentrations inside the blood using the OrSense NBM 200 system for example. This device can determine internal measurements by placing a small device around the finger of the patient (OrSense, 2017)

1.3 Subjective non-invasive tests

Comparing the degree of elasticity of skin, sometimes referred to as skin turgor. The assessment of skin turgor is used clinically to determine the extent of dehydration, or fluid loss, in the body.

Asking the patient if he or she is feeling thirsty. In general a person should never feel thirsty. If someone is thirsty this means he or she is dehydrated to a certain extent already.

Oral cavity moisture measurements on i.e. tongue mucosa, cheek mucosa or palate mucosa are performed with used of the L-Salivo moisture tester. This test gives a value between zero and 3 and can tell if the patient is dehydrated or not. (Yoshiyama, 2012)

2. CE Certification routes

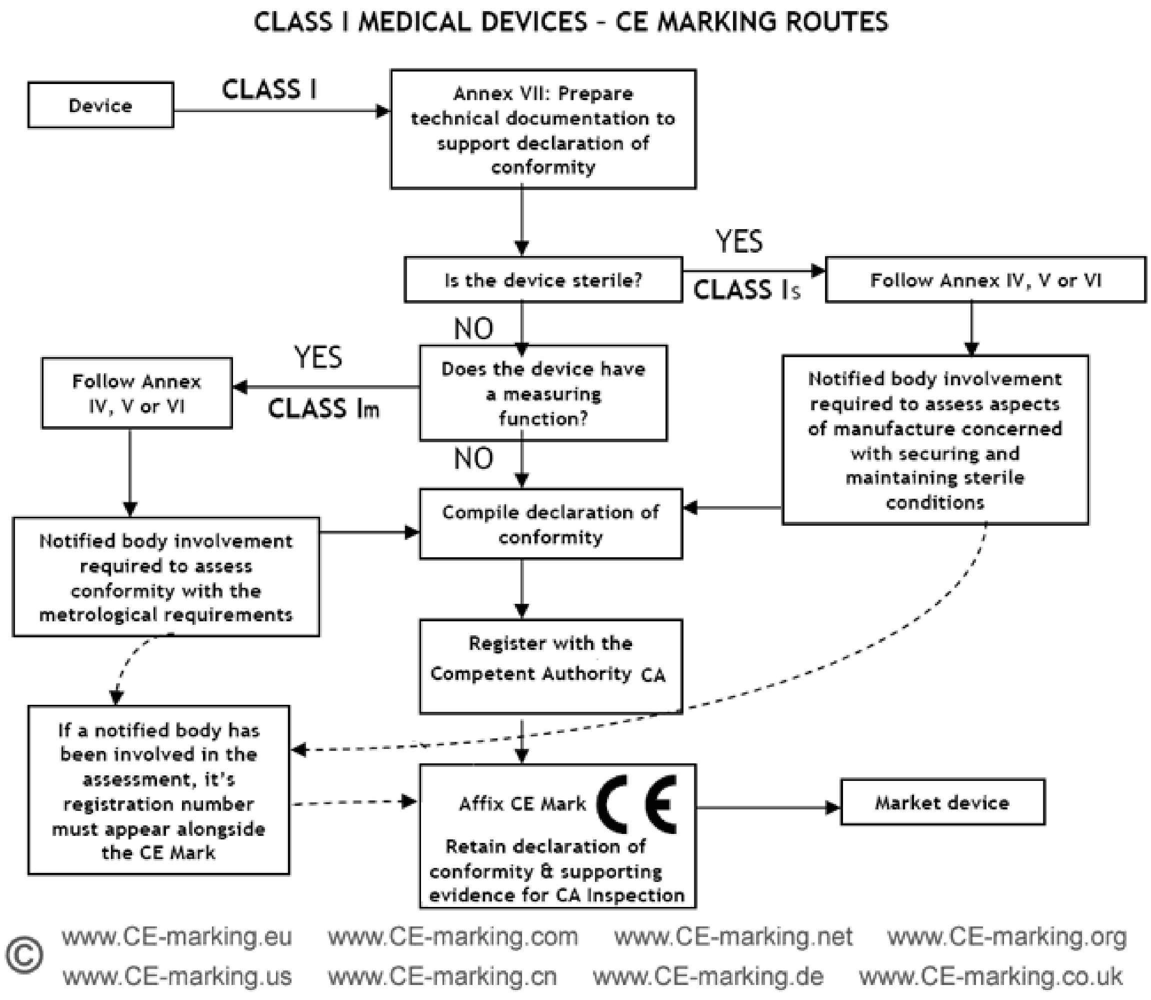


Figure 2.1: CLASS I devices. Retrieved from: www.CE-markers.eu

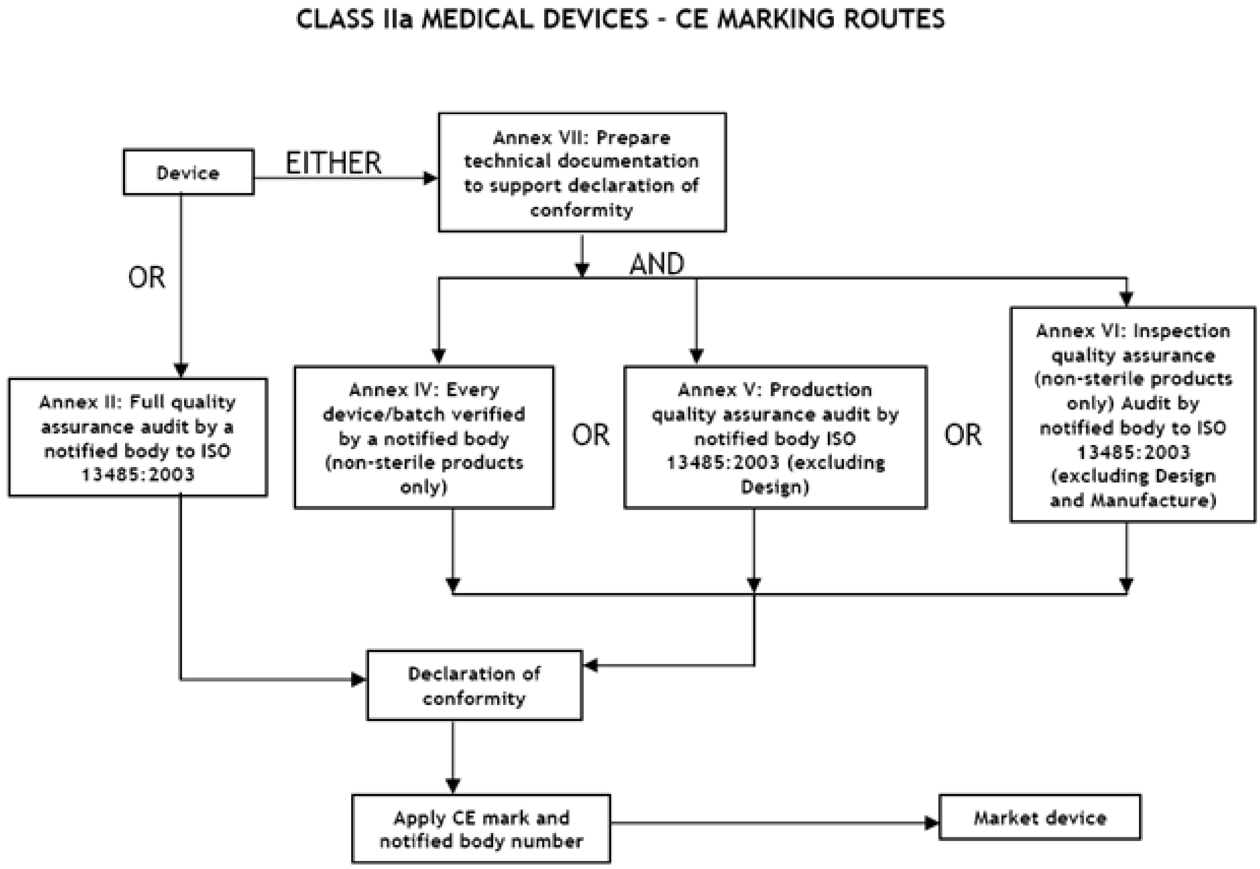


Figure 2.2: CLASS IIa Devices. Retrieved from: www.CE-markers.eu

3. Guiding questions ISO14971

What is the intended use and how is the medical device to be used?

The intended use of the product is to increase accuracy (to make it accurate enough for hospital environments) and to decrease the amount of workload for the nurses. The product is going to monitor input and output through IV bags and catheters. Furthermore the product will provide the possibility to enter drinking input and urination output into the system and calculate the fluid balance once per hour. This could be used on 1 out of 4 patients and will be used on heavy hospital departments in general (nephrology, cardiology, intensive care, post-operative, urology, etc.) Indications to use the product are: the need of a catheter bag and/or IV or the need to measure hourly in and output very carefully. The medical device does not sustain or support life. Manual readings need to be performed if the product fails.

Is the medical device intended to be in contact with the patient or other persons?

The medical device will partly be in contact with the patient. Some parts of the product are used by the nurse (and kitchen employees) only. Other parts will be used by the (family of) the patient.
Factors that should be considered include the nature of the intended contact, i.e. surface contact, invasive contact, or implantation and, for each, the period and frequency of contact.

What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?

The medical device will be in contact with fluid bags (catheter, drain, IV, etc.) and will be partly in contact with the patient's hands.
Factors that should be considered include:

 with relevant substances;
 compatibility with tissues or body fluids;
 whether characteristics relevant to safety are known;
 is the device manufactured utilizing materials of animal origin?
NOTE See Annex I and also the ISO 22442 series of standards[19].

Are measurements taken?

The product performs measurements which includes accuracy issues. The precision of the measurements (under 3 mL difference) does not include major consequences. Until a difference of 100 mL it does not lead to major consequences. (0,5% of total body water is approximately 200mL)
Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.

Is the medical device interpretative?

The data measurements are used to calculate differences and to present the fluid balance. In the first place this will be it. In further products this data will be used to interpret new data, make comparisons and optimize treatment programs.
Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms used, and confidence limits. Special attention should be given to unintended applications of the data or algorithm.

Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?

The product needs to be able to function together with the IV poles and should not take too much space on them. Other products should still be able to be hung on the IV poles as well. The product weight should not be influenced by other products. The product needs to hang freely to be measured accurately.

Factors that should be considered include identifying any other medical devices, medicines or other medical technologies that can be involved and the potential problems associated with such interactions, as well as patient compliance with the therapy.

Are there unwanted outputs of energy or substances?

Due to the use of Bluetooth this could be the case. The device will communicate to the patient and the nurse when needed. Not all of this communication is happening in the patient's environment, but sounds, vibrations and or lights could be used.

Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric or magnetic fields.

Substance-related factors that should be considered include substances used in manufacturing, cleaning or testing having unwanted physiological effects if they remain in the product.

Other substance-related factors that should be considered include discharge of chemicals, waste products, and body fluids.

Is the medical device susceptible to environmental influences?

The device must not be influenced by temperatures, oxygen rich environments, vibrations (bumping against the bag). The battery (if chosen to be used) should not be influenced by early charging times and function less due to this. Furthermore the product should still be functioning if water is dropped over it.

Storage and transport are important too. The products need to be stored in the hospital. This could be partly on the IV poles already (by never taking them off).
Factors that should be considered include the operational, transport and storage environments. These include light, temperature, humidity, vibrations, spillage, susceptibility to variations in power and cooling supplies, and electromagnetic interference.

Does the medical device influence the environment?

Due to the use of Bluetooth this could be the case. The device will communicate to the patient and the nurse when needed. Not all of this communication is happening in the patient's environment, but sounds, vibrations and or lights could be used. Finally EMC covers might be needed since the product is transferring data.

Factors that should be considered include:
- the effects on power and cooling supplies;
- emission of toxic materials;
- the generation of electromagnetic disturbance.

Are there essential consumables or accessories associated with the medical device?

Enough space on IV poles needs to be provided to use the product.
Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these.

Is maintenance or calibration necessary?

Calibration of the connection between load cell and amplifier is needed. This is needed only once during assembling of the product. Furthermore the buttons on the device need to be used when interacting with the device.

Factors that should be considered include:
- whether maintenance or calibration are to be carried out by the operator or user or by a specialist;
- are special substances or equipment necessary for proper maintenance or calibration?

Does the medical device contain software?

The product is being delivered with software on the product. It is still an option to integrate an application which needs to be downloaded by the patient. The software (whether it is installed already or not) needs to be partly used by the patient, kitchen employees and nurse and partly by the nurse only.

Factors that should be considered include whether software is intended to be installed, verified, modified or exchanged by the operator or user or by a specialist.

Are there any delayed or long-term use effects?

Mechanical fatigue, loosening of straps, decreases in accuracy of the load cell need to be investigated.
Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, long term material degradation.

To what mechanical forces will the medical device be subjected?

Depending on the positioning of the device.
Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user or controlled by interaction with other persons.

What determines the lifetime of the medical device?

Battery lifetime, accuracy decrease of load cell?
Factors that should be considered include ageing and battery depletion.

Is safe decommissioning or disposal of the medical device necessary?

Materials which are recyclable need to be used. No hazardous materials.

Factors that should be considered include the waste products that are generated during the disposal of the medical device itself. For example, does it contain toxic or hazardous material, or is the material recyclable?

Does installation or use of the medical device require special training or special skills?

As little as possible. Explanation of use is needed especially for the nurses. If applicable the patient needs a short description only and should be able to use the product without trainings.

Factors that should be considered include the novelty of the medical device and the likely skill and training of the person installing the device.

How will information for safe use be provided?

Warnings on the product? wThe fact that it is installed on the IV poles which is considered a product that deserved care.

Factors that should be considered include:

- whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals or pharmacists and whether this will have implications for training;
- commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills;
- based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required.

Will new manufacturing processes need to be established or introduced?

Try not to included new techniques! Factors that should be considered include new technology or a new scale of production.

Is successful application of the medical device critically dependent on human factors such as the user interface?

Depending on the choice for integration of the load cell it is important that the device is connected to the IV pole in a proper way. Furthermore as much human (nurse and patient) errors should be prevented as possible by including limitations in the software/hardware and/or physically on the product.

Can the user interface design features contribute to use error?

As less freedom as possible needs to be integrated into the design. More freedom could lead to more mistakes. System should be design to leave no options for interpretation mistakes. Usage of symbols, warnings and software should be tested very carefully.

Factors that should be considered are user interface design features that can contribute to use error. Examples of interface design features include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software driven devices, visibility of warnings, audibility of alarms, standardization of colour coding. See IEC 60601-1-6[25] for additional guidance on usability and IEC 60601-1-8[26] for guidance on alarms.

Is the medical device used in an environment where distractions can cause use error?

The device is used in a hospital room with in the worst case four care demanding patients. This means that distractions are very common problems. The device needs to lead the way and remind the nurse when a task is not finished.

Factors that should be considered include:

- the consequence of use error;
- whether the distractions are commonplace;
- whether the user can be disturbed by an infrequent distraction.

Does the medical device have connecting parts or accessories?

Depending on the amount of different devices included in the product the nurse could hang the wrong product or forget to bring accessories of the product. This should be prevented as much as possible.
Factors that should be considered include the possibility of wrong connections, similarity to other products' connections, connection force, feedback on connection integrity, and over- and under-tightening.

Does the medical device have a control interface?

Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions.

The FluidBalance hanger has a few buttons to control the device and the tablet has an interface to control the system. For both a FMEA risk analysis is required to make sure that mistakes are covered and will not lead to major errors and therefore complications.

Does the medical device display information?

The medical device displays information which needs to be able to be understood by all users. This includes used icons and text.

Is the medical device controlled by a menu?

Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.

For both button usage and interface usage a FMEA risk analysis is required to make sure that mistakes are covered and will not lead to major errors and therefore complications.

Does the medical device use an alarm system?

The device uses an alarm system for both nurse and patient. Patient is not sure yet.

Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the medical staff's possibility of understanding how the alarm system works. Guidance for alarm systems is given in IEC 60601-1-8[26].

In what way(s) might the medical device be deliberately misused?

Product alarms can be ignored by the nurse(not very likely). Alarms can be ignored by the patient (does not involve major problems, is more the kind of an extra reminder). Wrong connection of devices when wireless solutions are being used.

Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer's recommended maintenance.

Does the medical device hold data critical to patient care?

Critical to a certain extent. The patient is not likely to die due to failure, but the device can play an important role in early releases.

Factors that should be considered include the consequence of the data being modified or corrupted.

Is the medical device intended to be mobile or portable?

The device will be hang on a mobile IV pole. It might need to be able to be moved on this IV pole during different phases of use. It could even be the case that a patient needs to be able to do this him or herself.
Factors that should be considered are the necessary grips, handles, wheels, brakes, mechanical stability and durability.

Does the use of the medical device depend on essential performance?

Since the product is used only once per hour. This risk will not be very high.

Factors that should be considered are, for example, the characteristics of the output of life-supporting devices or the operation of an alarm.
Essential Performance (EP) is defined as the performance necessary to achieve freedom from unacceptable risk. The standard also notes: Essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.
While the 3rd Edition of IEC 60601-1 now includes EP requirements, the manufacturer's EP requirements may vary from the standards, depending on the proposed use of the device. For example, a laser device used for the removal of tattoos will follow less strict EP criteria than a laser device used for eye surgery. All applicable fault condition testing cannot be identified without identifying EP in the Risk Management File (RMF). Conversely, all fault conditions that should not be evaluated cannot be adequately justified without the RMF.

	Hazards	Applicable	Possible failure	Possible harm	Possible cause	P (probability)	S (severity)	P*S (Risk)
	ENERGY HAZARDS							
	Electromagnetic Energy	yes						
1	available voltage	yes	no available voltage	empty product	malfunctioning socket or malfunction electrical network	1	2	2
	Leakage current	no						
	Electric fields	no						
	Magnetic fields	no						
	Radiation energy	yes						
2	wrong interaction in connections	yes	disfunctioning of interrupted products	depending on interupted product	interference with other products in the environment	3	4	12
3	wrong interaction in connections	yes	disfunctioning of product	wrong diagnosis	interrupted by wireless connections from other devices	3	4	12
	Failing of internet connection	yes	no information is sent to the nurse/doctor	changes in fluid balance will not be noticed	disconnection / breakdown of internet connection	4	4	16
	failing of internal communication	yes	no information is sent between parts of the system	incompleet measurements of fluid balance	disconnection / breakdown of iinternal connection	4	4	16
	Thermal energy	no						
	High temperature	no						
	Low temperature	no						
	Mechanical energy	yes						
	Gravity	no						
4	- falling	yes	fastening method fails	product breaks down	bumping against something or something against the product	2	5	10
	- suspended masses	no						
5	Vibration	yes	too high or too low outcomes	incorrect fluid balance	crudal behavior of family members, patient, nurse, etc.	4	3	12
	Stored energy	no						
	Moving parts	no						
	Torsion, shear and tensile force	no						
6	Moving and positioning of patient	yes	disconnection patient - device	lost fluids which are not measured	patient decides to stand up but forgets catheter or IV	1	3	3
	Acoustic energy	no						
	- ultrasonic energy	no						
	- infrasound energy	no						
7	- sound	yes	interuption of sleep of other patients in the room	irritations among the patients	error in product functioning	4	1	4
	High pressure fluid injection	no						

	BIOLOGICAL AND CHEMICAL	yes						
	Biological	yes						
8	bacteria	yes	bacteria getting spread between patients	bacteria getting spread between patients	nurse forgets to wash hands in between patients	1	5	5
9	Bacteria	yes	leakage of catheter content onto the product	bacteria getting spread between patients	clumsy behavior of nurse or patient	1	5	5
	Viruses	no						
	Other agents (e.g. prions)	no						
	Re- or cross-infections	no						
	Infection	no						
	Chemical	yes						
	Exposure of airway, tissues, environment to foreign materials	no						
10	- Acids or alkalis	yes	material can not stand chemicals	chemical reaction with gasses or break down of product	wrong material choice	1	4	4
	- Residues	no						
	- Contaminates	no						
11	- Additives of processing aids	no	material can not stand chemicals	chemical reaction with gasses or break down of product	wrong material choice	1	4	4
12	- Degradation products	no	material can not stand chemicals	chemical reaction with gasses or break down of product	wrong material choice	1	4	4
13	- Medical gasses	no	product can not stand oxygen-rich air	chemical reaction with gasses or break down of product	wrong material choice / wrong assembling / coverage	1	4	4
	- Anesthetic products	no						
	Biocompatibility	yes						
	Toxicity of chemical constituants e.g.:	no						
	- allergenicity/irritancy	no						
	- pyrogenicity	no						
	OPERATIONAL HAZARDS	yes						
	Function							
	Incorrect or inappropriate output or functionality	no						
14	Incorrect measurement	yes	wrong bag weight connected to the calibration	incorrect fluid balance	Product is not resetted properly	3	3	9
15	Erroneous data transfer	yes	wrong ID is connected to the patient	wrong fluid balance	nurse makes a mistake during entering details	2	4	8
16	Loss or deterioration of function	yes	stop measuring without notice	no measurements during certain time span		3	3	9
	Use error	yes						
17	Attentional Failure	yes	Person can push wrong buttons on the device	incorrect fluid balance	patient adds fluid which he did not drink or forgets to	3	3	9
	Memory failure	no						
18	Rule-base failure	yes	Person can push wrong buttons on the device	incorrect fluid balance	unclear design of buttons or unclear instructions	2	3	6
	Knowledge-based failure	no						
19	Routine violation	yes	person pushes button or selects without watching	incorrect fluid balance	laziness regarding the device / device does not ask enough attention to confirm choices.	1	3	3

5. Medical risk management analysis

Risks do not mean that the product development is on risk. It is just important to know the risks and to come up with a way to be able to control the risks. The three groups of unacceptable risks will be discussed shortly.

The first and most important risk is:

- failing connections internal (within the device)

Thid tisk is always included when (partly) wireless connections are being used. The fact that the product needs to communicate internally and make calculations based on these measurements creates a risk of failure. If one of the components is not working properly this could lead to a wrong calculation. Options to manage this problem could be to include a way to do a small check up before doing the measurement. In example Dyson included a way to check whether the correct battery pack (including the correct batteries) is connected to the system before turning the device on. A warning could be a means to communicate a problem if one of the input values is lacking.

The second group consists of:

- failing connections external (to other devices)
- interruption by other products in the environment
- interrupting of other products in the environment
- vibrations by means of bumping against other products or creating swings with the fluid bag which could have an influence on the measured output.

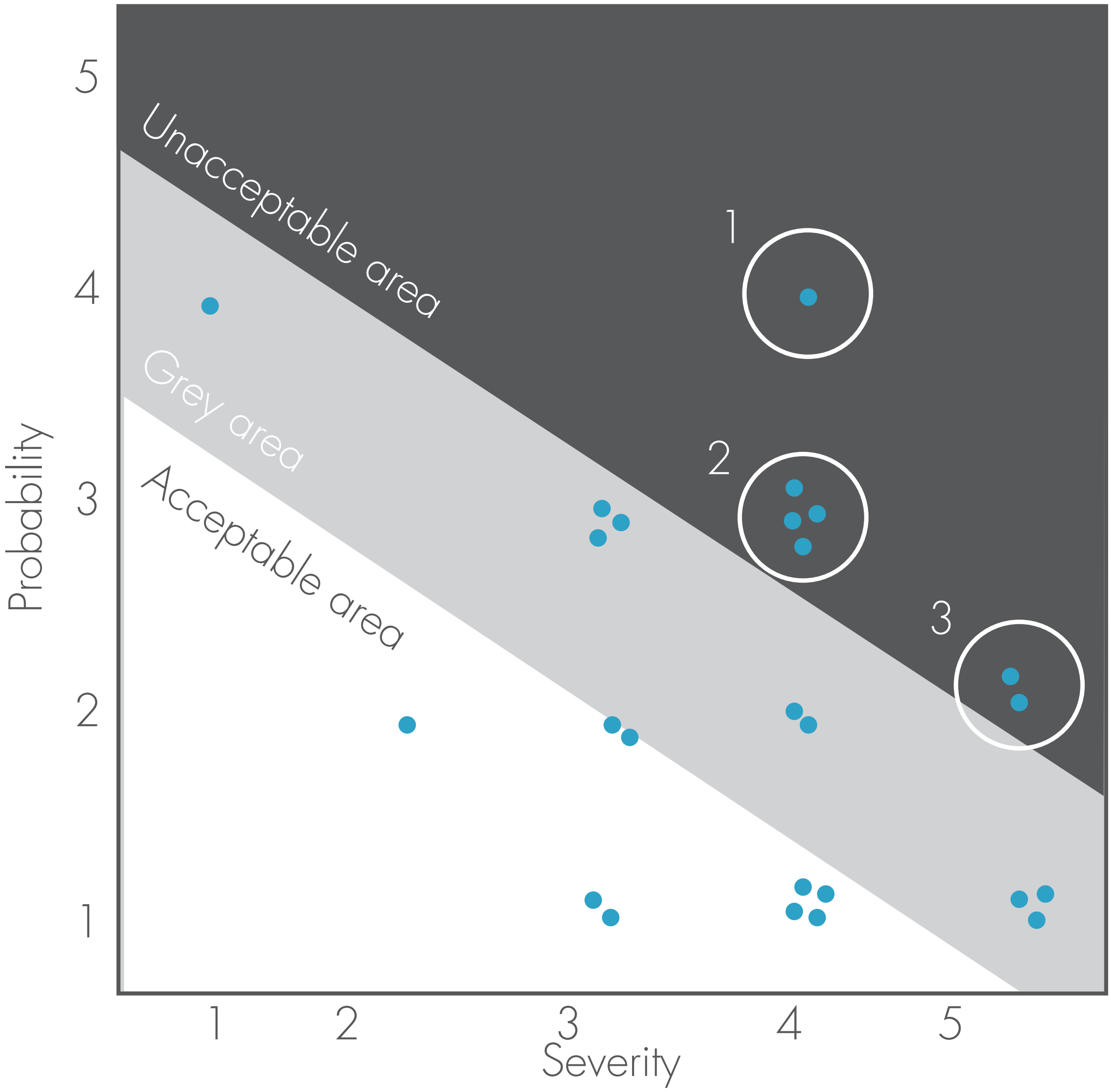
Connection failure is still happening quite often due to different reasons. Due to the fact that measurements are done only once per hour it is not too important that the connection is good continuously. It is important that the product is able to send information to then nurse just after great differences in fluid balance are identified by the device. It is important that the device shows whether it is connected or not. Multiple devices in the hospital depend on WI-FI connections, so a breakdown for more than an hour will not happen without further notice. Due to the fact that multiple devices are connected to the internet or via bluetooth it is important to secure the data transfer and make sure that the right data is sent to the right device. Choosing a reliable network and designing a reliable printboard is a way to manage these risks. The same accounts for interruption the other way around.

Most of the patients are able to walk around through the hospital and this is even recommended by the doctors and nurses to keep fit and to keep the blood flow running. This means that the device will be moving with the patient. It should not be the case that the patient needs to lay in bed during the hourly check-ups, this would create limitations for the patients which is not preferred. Therefore it is important that the device needs to able to function while being attached to the IV pole. It is likely that the patient will bump against walls, doors or other products when moving around with the IV pole. These vibrations should not influence the results of the test. Integrating a way to inform the patient about when a test is being performed and that he or she needs to stand still for the next five seconds or finding a way to make sure that these bumps and swings of the fluid bag do not influence the result would be means to manage this risk.

The third group consists of:

- Failure of the fastening method of the FluidBalance Hanger.
- Creating a product which is too complex to use

The product will be attached to a product which is always in the environment of the patient (night closet, infusion pole or the bed). The product fastening method can fail due to for example a bump. This means that the product will fall onto the floor and break down or not. Managing this risk could be through performing heavy bump and drop tests on the product. Furthermore a line



should be drawn up to when it is product failure and when it becomes misuse of the product. Misuse of the product should be taken into account but up to a certain level of course.

Creating a product which is too difficult to use would lead to nurses forgetting important features and/or increase of the workload of the nurse. Both of these consequences is undesirable. Managing this risk includes close contact with nurses and doctors and performing (cognitive) ergonomics tests to conclude whether the product can be easily used or not. Furthermore it is of course the task to keep the product as simple as possible without decreasing essential functionality.

6. Patient involvement in healthcare

6.1 Patient's interest in involvement

S. Vahdat (Department of Health Service Administration, Science and Research Branch): "Since adoption of any policies or decisions associated with health and treatment services eventually affects patients' lives, patient participation in health affairs and development of macro health policies are considered among people's civil rights". Of course it needs to be considered if changes in fluid balance treatments are considered healthcare decisions in which patient involvement is preferred and to what extent a patient is able to choose between treatment methods.

Since generally spoken elderly people need more care than younger people. Statistics from the CBS (CBS, 2012) show that around 85% of hospitalized people are above 65 years old ((7400+5500+5500+5000) / 27100 *100 = 86.3%) (figure 6.1) The fact that we are still coping with an aging population leads to the assumption that FluidBalance will be mainly used to perform fluid measurements on elderly people.

Involving the patient in decisions regarding his or her medical treatment is gaining more and more interest among different hospitals and their patients. In the year 2000 a study on 2197 people (Neeraj et. al, 2000) showed that the majority (69 percent) of patients with diseases like: hypertension, diabetes, myocardial infarction, congestive heart failure, and depression preferred to leave their medical decisions to their physicians. A study on 826 participants from February 2017 (Sak et. al, 2017) showed that 86,5% of elderly people wanted to be involved (active decision-making: 35,6% and collaborative decision-making 50,9%) in decision-making regarding their medical treatment. Another study (Michaelis et. al, 2017) on 798 mentally ill patients showed that among these patients 57,5% wanted a collaborative decision-making process and 16,2% even an autonomous decision-making process. All three researches made use of the CPS (Control Preference Scale) which is widely considered a valid method to investigate preferred level of involvement in medical treatment processes. (Michaelis et. al, 2017) The scale consists of a single question with five response statements indicating preference for an active, shared active, collaborative, shared passive, and passive role in decision-making. Considering these three studies a trend towards more involvement can be seen.

The trend towards more involvement is facilitated by increased access to proper education and/or information regarding diseases. Being able to spot faulty (or contrasting) decisions decreases the trust in the physician. Furthermore, the influence of age on the wish whether to be involved or not appears to be overestimated. Elderly want to be as involved as younger people. Crucial influences on the the possibility to involve patients are: the severity of the (mental)illness, the type of decision and the knowledge that is required to make the specific decision. (Sak et. al, 2017).

6.2 Nurse and patient involvement

A nurse has a different perspective on the fluid balance of a patient than the patient. Alexandra van der Wilk (a nurse from the Urology department of the RDGG) describes measurements of fluid balance as:
"the main factor on which the total medical treatment plan is based." According to her, most of the patients are described as: "dazed after heavy treatment, mentally unstable, irresponsible, too confused, etc." These pronunciations were made based on the assumption that the patient needs to actively enter information into a system during the day. According to Alexandra: "Involvement in general changes in treatment methods is more common nowadays, but fluid balance decisions do not offer a choice between different options (in which patient involvement could be the case). you either act according to medical requirements or not."

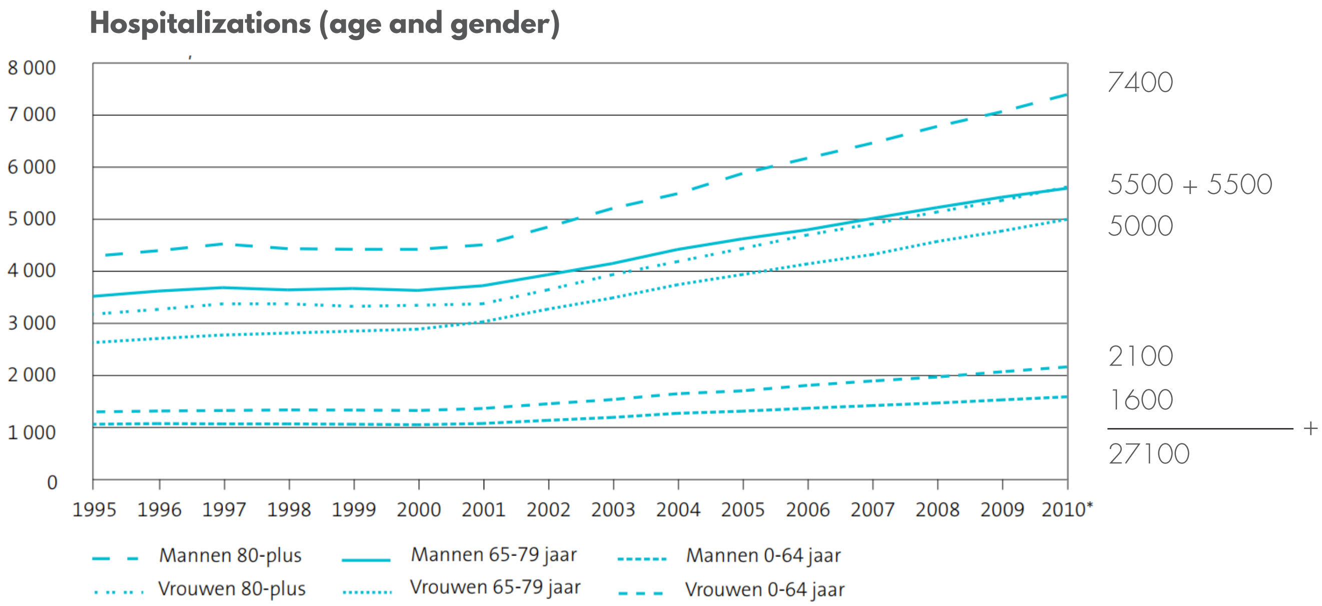


Figure 6.1: CBS Statistics 2010 (Retrieved from: CBS - Gezondsheidszorg en cijfers 2012)

6.3 Factors to determine involvement

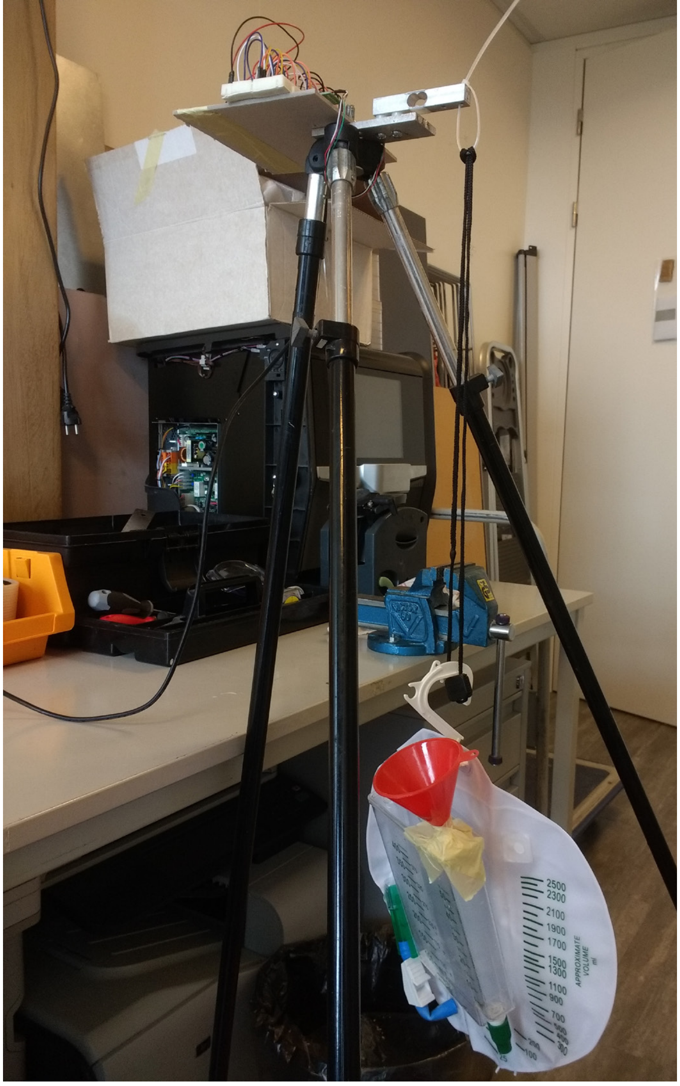
Apart from the severity of the illness and the personal characteristics (mentally okay, ability to express him- or herself, educated, etc.) there are other factors that determine whether or not it is wise to involve the patient in decision-making. First the level of assimilatie is important. The patient needs to be able to fully understand the doctors to be able to participate in the decision making process. Furthermore, the beliefs, values and practices concerning health and care can differ per culture. Regarding the severity of the illness it is important to know what type of illness the patients has and whether they are expected to fully recover or not. Decision-making that involves a terminal cancer patient is different from making a decision regarding a kidney surgery that is most likely to succeed. In the first case the decision does not depend on fluid balance measurements which means that decision-making happens at a totally different level. The patient is probably less interested in small changes in his fluid balance. In the second case a correct fluid balance is very important for the recovery of the patient which is why involvement is more likely. Other factors that determine whether patient involvement is being accepted in general or not is the cultural background and communications skills of the medical health experts and the healthcare settings (procedures and regulations, cultural influences, competence of the hospital, etc.) (Vahdat et. al, 2014).

During the first tests It was the goal to find out how to work with the load cell, how accurate the load cell was and whether the weight fluctuates a lot when a little push is given to the bag.

Since this test was mainly meant to get to know the product and not to provide scientific outcomes no graphs or specified outcomes are made.

Important learnings from this first test were:

- The connection of the load cell. One end of the load cell needs to be fixated in a very stiff way to make sure the measurements are correct.
- The load cell can measure very precisely and is already more precise than the urimeter (catheter bag that was used and is visible on the pictures)
- Moving the bag is not too bad for the measurements.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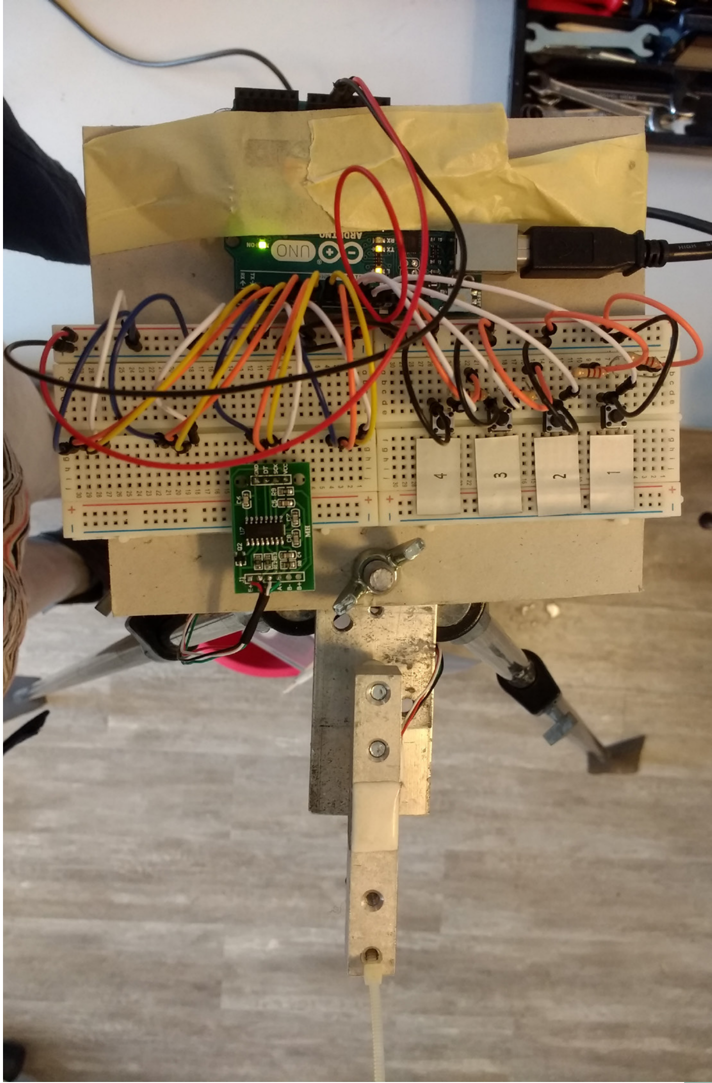
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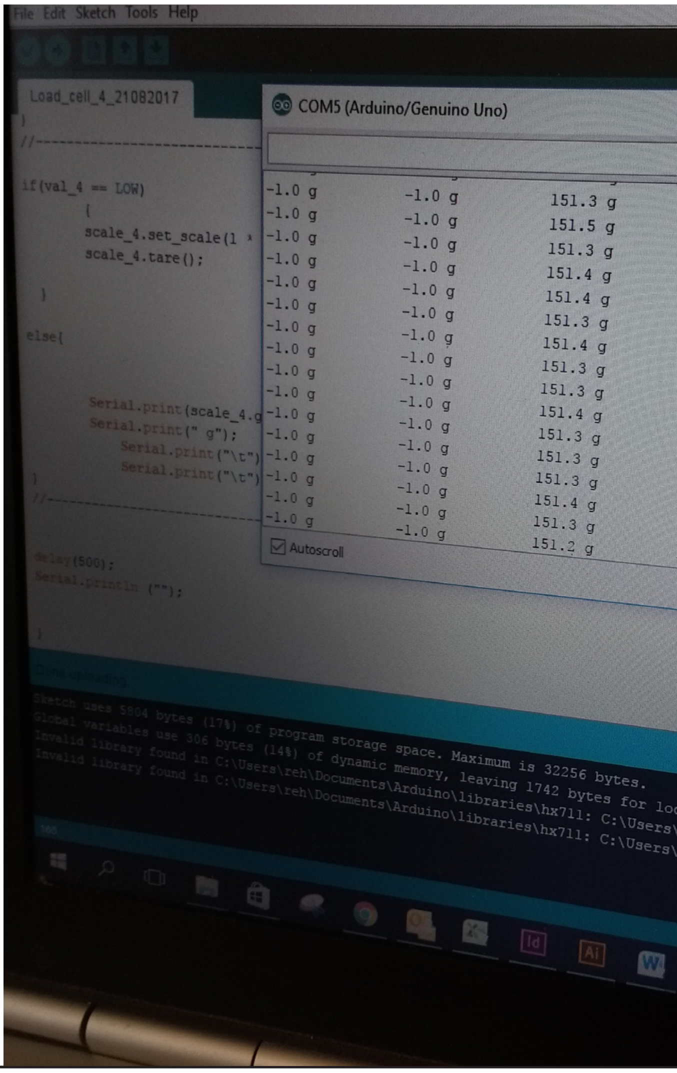
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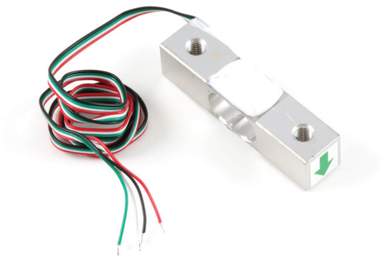
Datasheet

3133 - Micro Load Cell (0-5kg) - CZL635



Contents

What do you have to know?

A load cell is a force sensing module - a carefully designed metal structure, with small elements called strain gauges mounted in precise locations on the structure. Load cells are designed to measure a specific force, and ignore other forces being applied. The electrical signal output by the load cell is very small and requires specialized amplification. Fortunately, **the 1046 PhidgetBridge will perform all the amplification and measurement of the electrical output.**

Load cells are designed to measure force in one direction. They will often measure force in other directions, but the sensor sensitivity will be different, since parts of the load cell operating under compression are now in tension, and vice versa.

How does it work - For curious people

Strain-gauge load cells convert the load acting on them into electrical signals. The measuring is done with very small resistor patterns called strain gauges - effectively small, flexible circuit boards. The gauges are bonded onto a beam or structural member that deforms when weight is applied, in turn deforming the strain-gauge. As the strain gauge is deformed, it's electrical resistance changes in proportion to the load.

The changes to the circuit caused by force is much smaller than the changes caused by variation in temperature. Higher quality load cells cancel out the effects of temperature using two techniques. By matching the expansion rate of the strain gauge to the expansion rate of the metal it's mounted on, undue strain on the gauges can be avoided as the load cell warms up and cools down. The most important method of temperature compensation involves using multiple strain gauges, which all respond to the change in temperature with the same change in resistance. Some load cell designs use gauges which are never subjected to any force, but only serve to counterbalance the temperature effects on the gauges that measuring force. Most designs use 4 strain gauges, some in compression, some under tension, which maximizes the sensitivity of the load cell, and automatically cancels the effect of temperature.

Installation

This Single Point Load Cell is used in small jewelry scales and kitchen scales. It's mounted by bolting down the end of the load cell where the wires are attached, and applying force on the other end **in the direction of the arrow.** Where the force is applied is not critical, as this load cell measures a shearing effect on the beam, not the bending of the beam. If you mount a small platform on the load cell, as would be done in a small scale, this load cell provides accurate readings regardless of the position of the load on the platform.

Calibration

A simple formula is usually used to convert the measured mv/V output from the load cell to the measured force:

*Measured Force = A * Measured mV/V + B* (offset)

It's important to decide what unit your measured force is - grams, kilograms, pounds, etc.

This load cell has a rated output of 1.0±0.15mv/v which corresponds to the sensor's capacity of 5kg.

To find A we use

*Capacity = A * Rated Output*

A = Capacity / Rated Output

A = 5 / 1.0

A = 5

Since the Offset is quite variable between individual load cells, it's necessary to calculate the offset for each sensor. Measure the output of the load cell with no force on it and note the mv/V output measured by the PhidgetBridge.

Offset = 0 - 5 * Measured Output

Product Specifications

Mechanical	
Housing Material	Aluminum Alloy
Load Cell Type	Strain Gauge
Capacity	5kg
Dimensions	55.25x12.7x12.7mm
Mounting Holes	M5 (Screw Size)
Cable Length	550mm
Cable Size	30 AWG (0.2mm)
Cable - no. of leads	4
Electrical	
Precision	0.05%
Rated Output	1.0±0.15 mv/V
Non-Linearity	0.05% FS
Hysteresis	0.05% FS
Non-Repeatability	0.05% FS
Creep (per 30 minutes)	0.1% FS
Temperature Effect on Zero (per 10°C)	0.05% FS
Temperature Effect on Span (per 10°C)	0.05% FS
Zero Balance	±1.5% FS
Input Impedance	1130±10 Ohm
Output Impedance	1000±10 Ohm
Insulation Resistance (Under 50VDC)	≥5000 MOhm
Excitation Voltage	5 VDC
Compensated Temperature Range	-10 to ~+40°C
Operating Temperature Range	-20 to ~+55°C
Safe Overload	120% Capacity
Ultimate Overload	150% Capacity

Glossary

Capacity
The maximum load the load cell is designed to measure within its specifications.

Creep
The change in sensor output occurring over 30 minutes, while under load at or near capacity and with all environmental conditions and other variables remaining constant.

FULL SCALE or FS
Used to qualify error - FULL SCALE is the change in output when the sensor is fully loaded. If a particular error (for example, Non-Linearity) is expressed as 0.1% F.S., and the output is 1.0mV/V, the maximum non-linearity that will be seen over the operating range of the sensor will be 0.001 mV/V. An important distinction is that this error doesn't have to only occur at the maximum load. If you are operating the sensor at a maximum of 10% of capacity, for this example, the non-linearity would still be 0.001mV/V, or 1% of the operating range that you are actually using.

Hysteresis
If a force equal to 50% of capacity is applied to a load cell which has been at no load, a given output will be measured. The same load cell is at full capacity, and some of the force is removed, resulting in the load cell operating at 50% capacity. The difference in output between the two test scenarios is called hysteresis.

Excitation Voltage
Specifies the voltage that can be applied to the power/ground terminals on the load cell. In practice, if you are using the load cell with the PhidgetBridge, you don't have to worry about this spec.

Input Impedance
Determines the power that will be consumed by the load cell. The lower this number is, the more current will be required, and the more heating will occur when the load cell is powered. In very noisy environments, a lower input impedance will reduce the effect of Electromagnetic interference on long wires between the load cell and PhidgetBridge.

Insulation Resistance
The electrical resistance measured between the metal structure of the load cell, and the wiring. The practical result of this is the metal structure of the load cells should not be energized with a voltage, particularly higher voltages, as it can arc into the PhidgetBridge. Commonly the load cell and the metal framework it is part of will be grounded to earth or to your system ground.

Maximum Overload
The maximum load which can be applied without producing a structural failure.

Non-Linearity
Ideally, the output of the sensor will be perfectly linear, and a simple 2-point calibration will exactly describe the behaviour of the sensor at other loads. In practice, the sensor is not perfect, and Non-linearity describes the maximum deviation from the linear curve. Theoretically, if a more complex calibration is used, some of the non-linearity can be calibrated out, but this will require a very high accuracy calibration with multiple points.

Non-Repeatability
The maximum difference the sensor will report when exactly the same weight is applied, at the same temperature, over multiple test runs.

Operating Temperature
The extremes of ambient temperature within which the load cell will operate without permanent adverse change to any of its performance characteristics.

Output Impedance
Roughly corresponds to the input impedance. If the Output Impedance is very high, measuring the bridge will distort the results. The PhidgetBridge carefully buffers the signals coming from the load cell, so in practice this is not a concern.

Rated Output
Is the difference in the output of the sensor between when it is fully loaded to its rated capacity, and when it's unloaded. Effectively, it's how sensitive the sensor is, and corresponds to the gain calculated when calibrating the sensor. More expensive sensors have an exact rated output based on an individual calibration done at the factory.

Safe Overload
The maximum axial load which can be applied without producing a permanent shift in performance characteristics beyond those specified.

Compensated Temperature
The range of temperature over which the load cell is compensated to maintain output and zero balance within specified limits.

Temperature Effect on Span
Span is also called rated output. This value is the change in output due to a change in ambient temperature. It is measured over 10 degree C temperature interval.

Temperature Effect on Zero
The change in zero balance due to a change in ambient temperature. This value is measured over 10 degree C temperature interval.

Zero Balance
Zero Balance defines the maximum difference between the +/- output wires when no load is applied. Realistically, each sensor will be individually calibrated, at least for the output when no load is applied. Zero Balance is more of a concern if the load cell is being interfaced to an amplification circuit - the PhidgetBridge can easily handle enormous differences between +/-. If the difference is very large, the PhidgetBridge will not be able to use the higher Gain settings.

9. Program of requirements

From the previous research and the main functions the product needs to full fill the program of requirements (POR). These requirements will serve to test different concept directions to find out whether they meet the required needs or not. The POR will be divided in ten different parts. Finally wishes for the product will be formulated to be able to rank different concept directions.

9.1 Size and looks

Requirements:

- The total of products needed for one patient cannot exceed the maximum force an IV stand can withstand. The most simple IV stand can withstand 18 kg in total. 2kg per hook and 10 kg extra kilograms.
- User needs to be able to hold the product with one hand.
- Modern and slim looking product that fits into the current hospital environment
- Maximum weight of FluidBalance hanger is 500 grams (since IV poles can not handle endless forces)

Wishes:

- Product makes sure that urine of the patient is hidden for his or her visitors.
- The product blends in into the environment and is not the first thing to notice when entering a hospital room. Product can be described as unobtrusive.
- Product (each system part) does not exceed a size of one litre.
- Product is as light as possible.

9.2 Functionality / performance

Requirements

- Product service system needs to be more time effective than current method. Which means that it should take the nurse less than one hour per day (when hourly measurements are needed).
- Product can be used on its own and can be connected to other products.
- Product offers reliable (<0.1% error) values of the volume per bag.
- Product offers reliable and safe data transfer
- Product shows confirmation of being connected to data transfer technologies.
- Product shows confirmation of being enabled or not
- Product checks different necessary input points before calculating fluid balance and notifies an expert if one of the system parts is not functioning.
- Product offers the option to resend information when connection failed before.
- Product saves daily information regarding intake and output in its memory.
- Product offers possibility to transfer data through a wire if wireless connection fails or the possibility to enter input and output values manually (emergency cases).
- Product is still reliable if cloud connecting technology is temporarily out of order.
- Product shows current fluid balance digitally at the patient's side.
- The product warnings can be set per department. For example if people do not urinate enough for a specific time.
- Product allows a way to integrate emptying and /or replacement of fluid bags in between measurements.
- Product sends alarms to the nurse when a bag is almost full (catheter, drains, etc.) or empty (IV)
- Product (or product-service) offers the possibility to enter intake and output by both nurse and assistant.
- Product allows different levels of administrator rights for the nurse, assistant and patient when entering data.
- Product shows battery status
- Product allows easy battery charging and replacement.
- Product battery needs to last at least one week before battery charge / replacement is necessary.
- Product draws attention to the nurse to remind him or her to replace the battery in time.
- The product should be able to hold 10 kg. The internal load cell should be able to hold 10 kg as well (with a save overload of 200%)

Wishes:

- Products take the nurse less than 20 minutes per day (when hourly measurements are needed).
- Product allows the patient to use the product as notebook when the assistant is not around.

9.3 (Cognitive)Ergonomics/Comfort

Requirements

- Font and button sizes should be big enough to be able to be used by elderly / very ill/weak people.
- The product offers a clear screen which can be

watched /used in standing position (nurse/kitchen employees).
- If it is needed that the patient watches the screen he or she needs to be able to do that in ergonomic and sitting position.
- Product interface is understandable for the nurse after reading the instructions or receiving a short explanation/ demonstration.
- Product parts that serve to enter intake and output values of the patient is operable from sitting (patient) and standing (nurse/kitchen employees) position.

Wishes:
- As less effort as possible to perform daily tasks like entering the amount of urine / drinks.

9.4 Hygiene and materialisation

Requirements:
- Product is IP44 proof can be cleaned with water without a problem.
- Product needs to be steam proof. Condensated water needs to be able to leave the product. Electronics need to be protected from steam
- Product materials can resist any cleaning chemicals.
- Product finishing is smooth to make sure as less dirt as possible will stick to / lay on the product.
- Product should be able to withstand oxygen-rich environments.

Wishes
- Product contains as less edges, openings and slots as possible.

9.5 Safety and regulations

Requirements:
- The product meets the requirements of ISO60335, ISO60601, ISO13485 and ISO14971.
- The product fastening method needs to withstand a person (80 kilograms) leaning against the product from the side and pushing/leaning on the product from above.
- The product needs to give a warning when a certain high peak force is measured.
- All internal product parts need to be certified and tested.

Wishes:
- The product needs to withstand a drop from 1.5 meters without consequences.

9.6 Production

Requirements
- Product needs to be designed for a total of 10.000 products.
- Product should have product life span of at least 5 years.

Wishes:
- Product production costs as low as possible. Target: below 100 Euros
- The product (including needed investments, software and production facilities) should not exceed the maximum cost price of 1000 Euros per piece.
- No new production facilities need to be involved in the production since this would include high costs.

9.9 Placement

Requirements:
- Nurse is able to place the product onto the IV pole after reading the instructions and / or watching a short demonstration
- Placement and installation of the product should not take longer than two minutes.
- The end of the catheter hose (before it reaches the catheter bag) should be able to be placed at a height of at least 50 mm below the bladder of the patient. (Mochizuki, 1988)
- Product needs to offer enough space for the bags to hang freely and not influence the weight of the bag.
- Product can be combined with both an IV pole on wheels and an IV pole which is inserted into the bed.
- Product is place in such a way that it does not interfere with other necessary products that need to placed on the IV pole.

Wishes:
- The product should be able to be stored without being damaged and / or requiring more space than three litres.

9.10 Maintenance (environment)

Requirements
- Battery replacement should be possible. Charging needs to be able to be done inside the product and outside the product.

Wishes:
- Product contains as little parts as possible.
- Product contains as little environmental impact materials as possible.
- Main product parts can be de-assembled to be recycled separately
- Product battery lasts as long as possible. One week minimum.
- Product charging takes as little time as possible.

10. Configurations

Comparing different configurations

The product consists of multiple parts. How many parts is not determined yet. On the next four pages six interesting configurations of the product will be visualised and explained. These six configurations are all still possible and are interesting for different reasons. After explanation a comparison between these configurations will be made to find out which one(s) are/is the most promising solution(s).

For all the six configurations it is assumed that the connection to the nurse and/or doctor is the same (wirelessly). Furthermore the situation in which three brackets are needed is shown in case a patient has a catheter, IV bag and colostomy or wounddrain. The connection to the patient is not taken into account yet. This will be discussed later on. The fact that a wired or wireless connection will be used depends on the location of the product parts and the possibility to create a reliable enough wireless connection which will be investigated later on as well. Finally it is important that the product parts are not specifically placed on a location which is relative to each other. This is not determined yet. The configuration need to be interpreted like all the product parts are laying nextg to each other on a table without specified locations.

The first configuration consists of three parts. The main device which is the device that does the calculation work, sets the alarms and communicates the results to the nurse (and patient). The other two devices only measure the weight, save it and send it to the main device. These devices can be relatively cheap since the control and communication can be done by the main device.

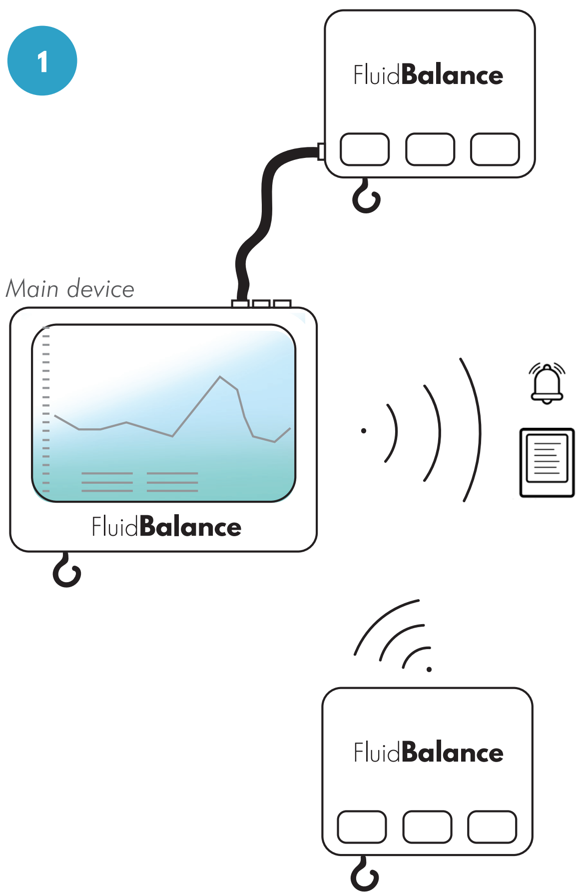
The second configuration consists of three exact same products. In this configuration one of the three products will be selected to serve as communicator to calculate the fluid balance and send the alarms if needed.

The third configuration consists of three devices which are connected to a seperate external device with a screen. The screen does all the calculations and communication. The other three devices only weight their bags and save and send this data over to the external device with the screen.

The fourth configuration is based on the fact that some of the fluid bags always need to hang above the patients and the other fluid bags need to hang beneath the patient. These two groups could be combined into a product that can weigh multiple bags seperately from each other. This means that only two devices are needed in all cases.

The fifth configuration consists of only one big product. This product is always hanging on the highest position (where the IV bags need to be placed) to make sure reading on the device is easy. The brackets from the bags that need to hang in a low position can be extended to make sure the bags can hang as low as needed.

The sixth configurations consists of three the same products with a simplified screen. The calculation and communication happens in an application on the tablet or COW of the nurse. The advantage is that the device can be less smart since the calculation power is not neccessary anymore.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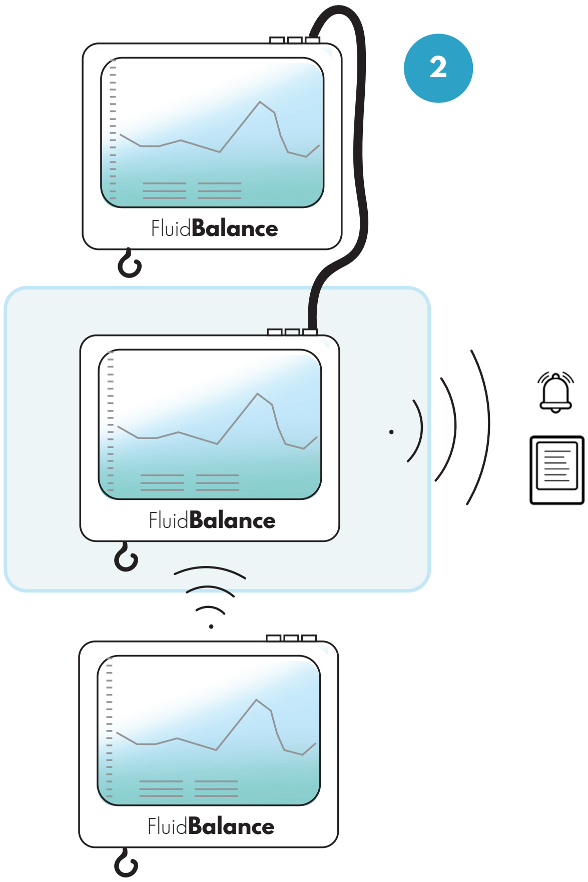
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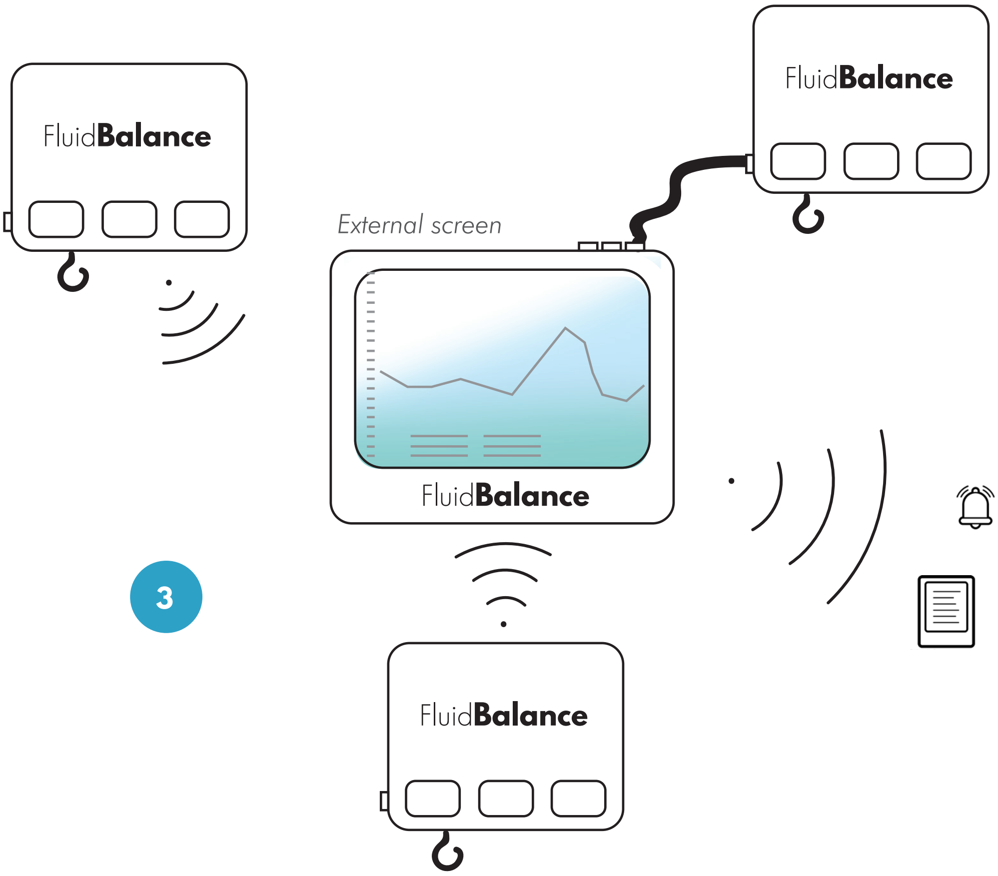
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FluidBalance
External screen
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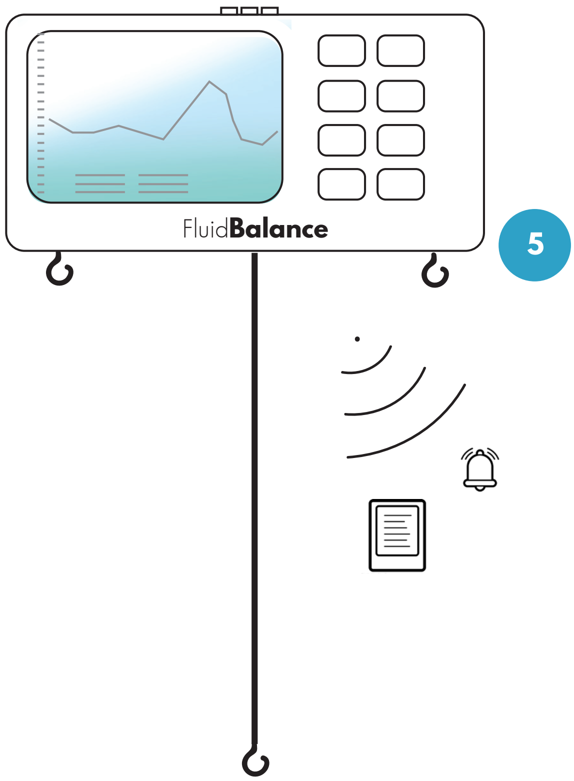
3
FluidBalance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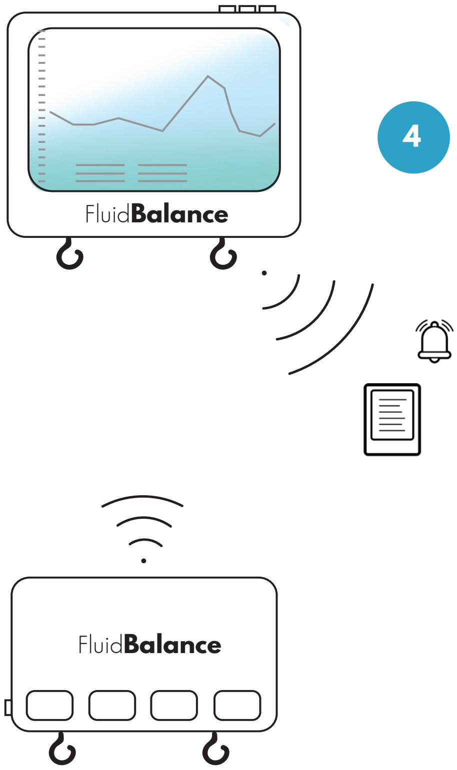
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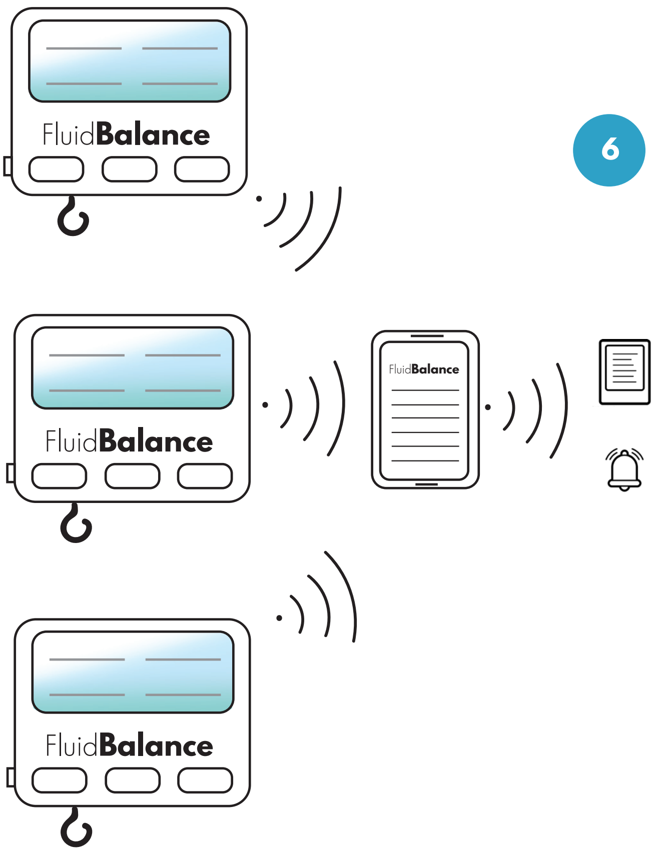
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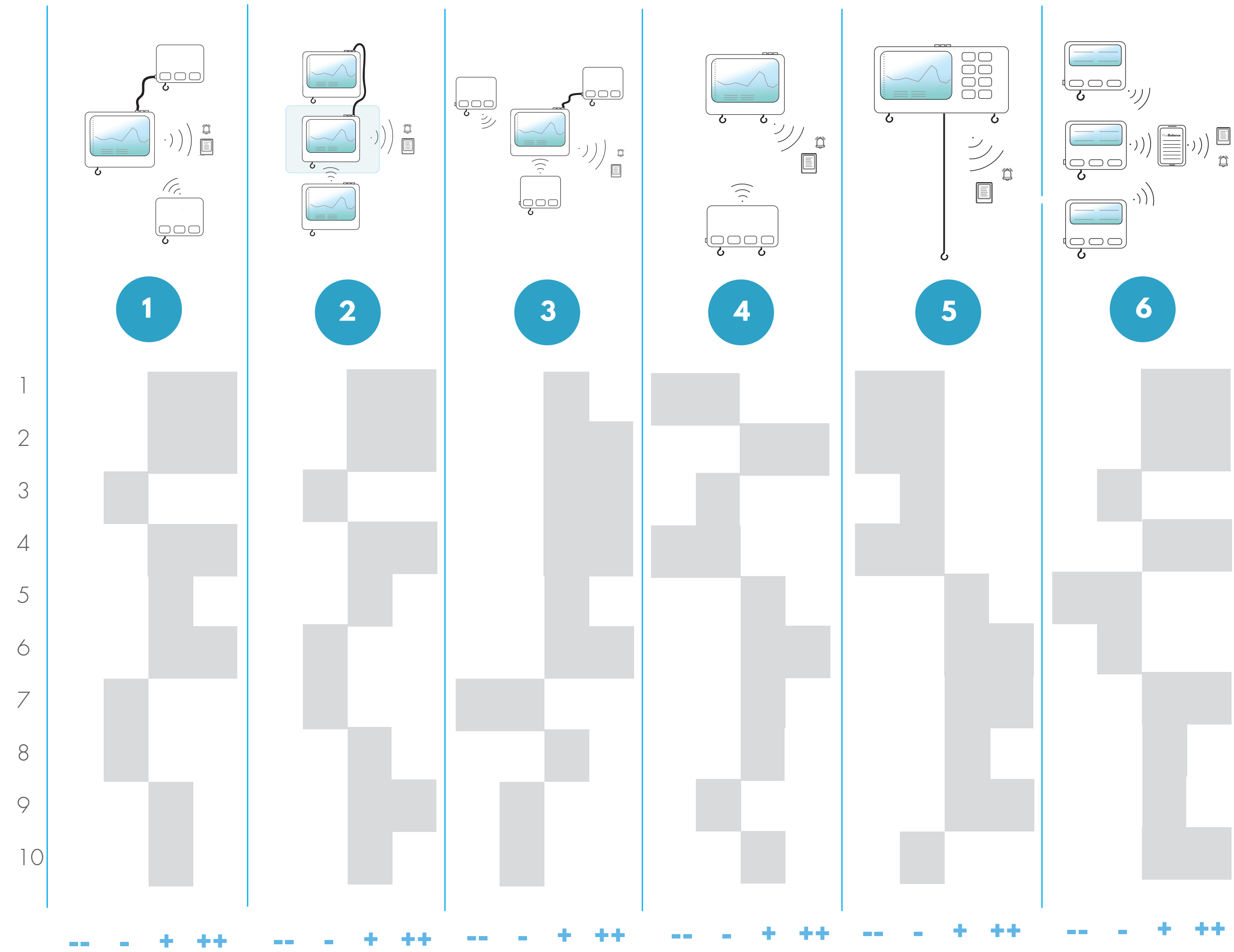
FluidBalance
FluidBalance
FluidBalance



Criteria:

1. Investment when only IV monitoring is needed (- - : too much, - : much, + : neutral, ++: relatively low)
2. Easy to combine with other necessary products (- - not at all, - : badly, +: okay, ++ good)
3. Ergonomics for the nurse (- - : very bad, - : somewhat bad, +: okay, ++: good)
4. Possibility to extent the product (attach more bags) (- - : not at all, - : badly, +: okay, ++: good)
5. Level of external connectivity required (- - : much, - : okay amount, +: nice amount, ++: little amount needed)
6. Clarity which screen to use for oral input monitoring (- - : very bad, - : somewhat bad, +: okay, ++: good)
7. Level of internal communication required (- - : very much, - : okay amount, +: nice amount, ++: little amount needed)
8. Possibility for errors (nurse places wrong wards) (- - : high chance, - : chance, + neutral, ++: low chance)
9. Installation workload nurse (amount of wardss) (- - : very much, - : okay amount, +: nice amount, ++: little amount)
10. Level of unobtrusiveness (- - : very bad, - : somewhat bad, +: okay, ++: good)

Overview of Harris profiles of different configurations

Fluid balance related Work flow Nephrology nurse

7:30 — Start of the day

The nurses including the managing nurse gather in the meeting room to discuss patients. Approaches and specialties are discussed. Couples are formed and a division is made who will be responsible for what during this particular duty.

8:00 — First measurements

In the morning the night urine is emptied from the catheter into an orange bottle. Male patients who do not have a catheter pie into this bottle immediately. These bottles are placed at the beginning of the room and being picked up by the department assistant Nephrology. This task takes one to two minutes per patient. He writes down the values into the red pile from which the nurse can calculate the result. At the moment this is written down on paper, but from the end of 2017 this will be done digitally with help of the program: EPIC. The nurse notices big differences in amount of pie and asks the patients if they defecated during the night or not. If so, she writes this down in the file.

8:30 — Weighing moment

Every morning, all patients are weighed to be able to notice big differences between the weighing moments before. Furthermore this is compared to the weight of the patient when he or she entered the hospital. This weight is used as reference value. Al together this task can take two to ten minutes per patient depending on their level of fitness. Patients who are already out of bed can be weighted quite easily, but patients who have troubles need to be assisted and or supported when being weighed.

9:00 — Check-up moment

The nurse performs the first check-up of the fluid balance after calculation.

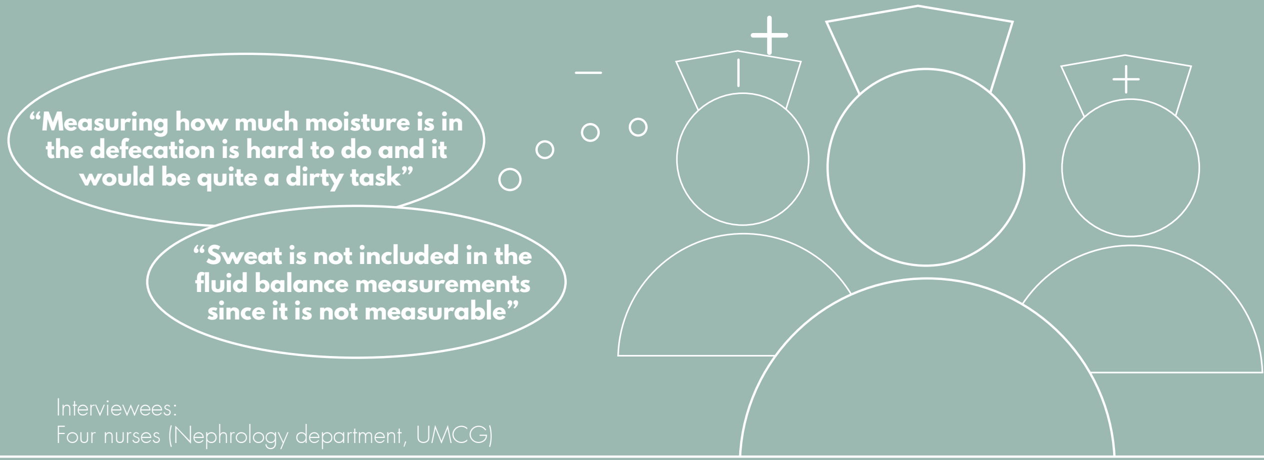
- Walk to the patient
- Write down the how much is left inside the IV bag and the catheter bag
- Check the patients fluids list and remind the patient to keep track of the fluids taken
- Check other fluid outputs if applicable (wound drain, medication, colostomy, etc.)

This takes three to five minutes depending on amount of volumes to check and if the nurse needs to walk far.

20:00 — Calculating Fluid Balance

The nurse calculates the fluid balance with all the information which is gathered about the patient during the 24 hours. The nurse needs to pick up the fluid lists, the notification papers and take them to the correct patient pile. The values need to be put together and manually a balance is calculated. Calculating the fluid balance takes five to ten minutes at the moment. Time between check ups depends on the patient and situation.

umcg



Interviewees:
Four nurses (Nephrology department, UMCG)

During the hospital visit there was a chance to talk to four different nurses about nursing activities regarding fluid balance. The interview was done partly during patient visitation and during coffee breaks.

How long does it take to perform one fluid balance measurement? *Normally it takes two to five minutes. It depends if they have both an IV and a Catheter and if they have other sources of fluids like a wound drain.*

How often per day do you perform a fluid check up? *That depends on what the doctor wants. Mostly an hourly check up is performed on the day after surgery, once per three hours on the second day after surgery and after that only once per duty.*

How often do you replace an IV bag during the day and how do you keep track of the amount of bags used? *An IV bag is always replaced every 24 hours and furthermore if it is empty. It is written down on the patients notifications list if we place a new bag. When the fluid balance is calculated, the list is used to see how many bags were used since one duty is only eight hours and the fluid balance is made up every 24 hours.*

So you need to check whether a bag is empty or not every few hours? *Yes, that is true, but it will mostly be noticed during other tasks around the patients.*

Which parameters are taken into account when the fluid balance is calculated? *Urine output, IV Input, wound drain output, input from fluids in food, colostomy, drinking water and vomit if it can be measured.*

How do you keep track of how much the patients defecates and urinates during the day? *Urination with males is easy since they can pie into the bottle immediately. They often keep track of the urine themselves since the nurse is not always around. Females pie in a metal tray and keep track on paper. Once per day (mostly in the morning) the nurse asks if the patient defecated and writes down if this is the case. The amount of fluid in the defecation is not included into the fluid balance.*

How is the amount of fluid inside the food determined at the moment and who keeps track of this? *The food is compiled by the dietician. The kitchen knows or looks up how much fluid is in different types of food and writes this down on the patients fluid list when they bring the food. They also check if the patient ate everything from the plate and make sure that leftovers are scratched from the list. If the patient is adequate enough the kitchen employees just tell the patient how much it is and leave the writing to them.*

What about transpiration? Prednisone can make you sweat very much for example. Does this not influence the fluid balance in a bad way since it can be up to 500mL per day? *"Sweat is very hard to measure. Of course it influences the fluid balance, but we are very careful with fluid balance already compared to other departments since we pay a lot of attention to the kidneys and the urine." It is not possible to see how much fluid is lost due to sweat, but the patients temperatures are written down if they are high due to fever. Because things like sweat can not be measured and put into the fluid balance a weight check-up is done every morning.*

So this is the same for vomiting, diarrhea, diapers and other difficult things to measure? *Yes that is true. If the patient is vomiting or having diarrhoea very much it can become important to take it into account when making up the fluid balance, but mostly it is not important. Still it is hard to see how much fluid is in it exactly since there are pieces of food and poop laying in it which influences the amount.*

How many patients does this hospital accommodate? How many of them need active fluid balance check ups? *An estimation was made about this during lunch time and led to approximately 1000 patients of which 300 need active fluid balance check ups.*

Which information is given to the patients regarding fluid balance? *Patients are told to write down their input and output in fluids and that it can influence their recovery. On this department people can have fluid limits as well. Mostly a one litre fluid limit is set for transplantation patients during the first phase after surgery.*

Do patients complain about the visibility of their urine when they have visitors for example? *No patients have complained to the nurses to far. They think it is just a part of the illness and the patients accept this.*

Fluid balance related Work flow nurse

06:00

Start of the day

The nurses make their first round with their patients. They do a check up on fluid balance and write down the differences in the digital system (Chip soft). During this check the catheter bag is emptied.

07:30

Duty transfer

The nurses including the managing nurse, the assistants, kitchen, nutritionists, etc. (everyone who will be working on the specific department that day) gather in the meeting room to discuss patients. Approaches and specialties are discussed and changes are made.

08:30

Weighing moment

Patients are only weighted if the doctor requires this. It is not a standard task. Al together this task can take two to ten minutes per patient depending on their level of fitness. Patients who are already out of bed can be weighted quite easily, but patients who have troubles need to be assisted and or supported when being weighed. If patients need support with getting out of bed weighing is mostly done at the same time since you need to offer support anyway.

09:00

Fluid Check-up moment

The nurse performs a check-up every few hours (specified by the doctor and different per department)

- The nurse needs to walk to the patient which can take 10 - 30 seconds depending on the size of the department.
- The nurse picks up a measuring cup (which is mostly available in the closet on the patient rooms) and empties the catheter bag (1-2 minutes)
- The nurse washes her hands (1 minute)
- The nurse logs in to the system on the COW (computer on wheels) and fills in the values (20 seconds)
- She does the same for the IV bag and the wound drain if applicable which will take an additional 2-3 minutes.

Altogether the task takes four - six minutes per fluid measurement.

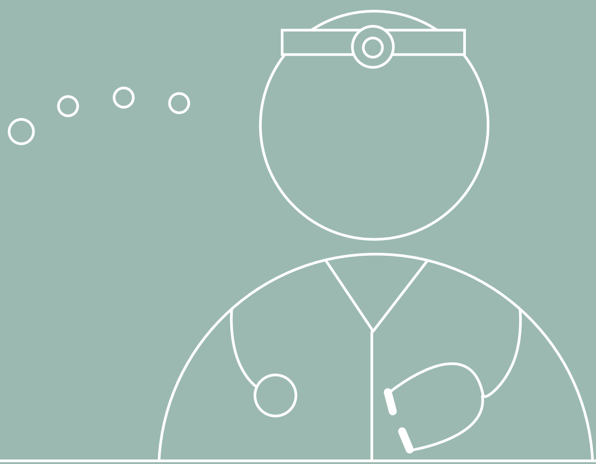
00:00

Calculating fluid balance

Fluid calculations are done automatically when all parameters are entered into the system. The only additional information which is needed is how much the patient drank and urinated that day which will be entered into the system by the nurse. The patient posts up his in and output on a paper list. Before the hospital went digital this was done at 00:00 as well, because it was a relative quite moment in the hospital which meant time for things like the fluid balance calculation. (Postma, 2017). At the moment it only takes two minutes.

Reinier de Graaf Groep

“Although some of the fluid related out puts and inputs are not monitored having precise measurements regarding urine is still needed



Interviewees:
Rick Pleijhuis (assistant doctor, UMCG)

After talking to four nurses and writing down their answers it became clear that not all the questions could be answered by them. Furthermore it is interesting to see if both nurse and doctor give the same answer to specific questions and see if communication is a problem as well, like it is in many companies.

The nurse explained to me that they only look at urine, IV input, drinking water, food and wound drains as sources of fluid intake and fluid output. What do you think of this? *At the moment this is the best we can do. Sweat is very hard to measure and the same accounts for diarrhea and vomit. It is always better to measure all the factors that can be measured to increase accuracy of the total fluid balance.*

Is it still useful to measure urine output and IV input on a level of millilitres when all of the factors like mentioned before are not taken into account? *Urine output is very important, especially in critical patients. It can be a huge difference if a patient has a urine output of 15mL or 0mL if an error range of 15mL is taken for example.*

Do wound drains have big influence on the fluid balance and how often does it happen that a wound drain is used? *It is hard to say how many times since it differences a lot and it also differences per department. The wound drain can be of significant difference depending on the wound drain of course.*

How often does it happen that the fluid balance is incomplete? *At the Nephrology department less often luckily since a lot of attention is paid to the kidneys and therefore the urine production. On other departments like cardiology and geriatrics it happens more often.*

Is it possible to make up a fluid balance every hour, since from kidney transplantation patients it is known that they mostly pie a lot more during the night than during the day? *That is true, so it is not the case that a certain level of fluid balance is particularly good or bad for every patient. Of course this depends on the disease pattern. Too little information about the “normal” fluid balance from different patients is being available nowadays. It would help to have reference material when prescribing a treatment.*

The Infusion computers which are used on infusion poles to enter how much fluid (in CC) needs to be served to the patient every hour. Can these computers also serve to calculate fluid balance from in an accurate way? *This will not always be accurate since the computer does not know when a patient is really connected to the infusion pole al the time. The nurse could for example set the computer on a certain amount of CC and perform other tasks before literally connecting the patient to the IV bag. Another example is when the bag is empty. If the bag is not filled in time the computer will still think a certain amount of CC is entering the patients body.*

The nurses estimated that there are a 1000 patients inside the hospital every day from which 300 patients need active fluid measurements. Do you agree with this? *A more active and accurate fluid measurements can have a positive effect for one out of four patients.*

12. Contextual research

General findings UMCG

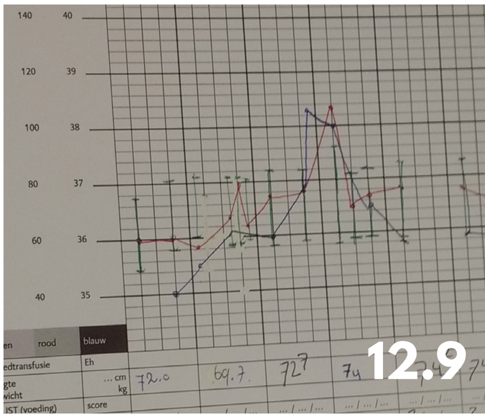
During the morning the workflow of the nurses and the environment in the rooms was studied. During this study a few interesting points were noticed:

- The catheter bag was laying on the floor. This was on purpose since the height difference (between bladder and end of the catheter hose) was to little when the bed is in the lowest position. When the bed is in a higher position the bag is placed on two different spots depending on the preference of the nurse or patient. (figure 12.1c). The universal bracket can be used for placement at different locations (figure 12.10).
- Two types of cather bags are being used depending on how critital how critital the situation of the patient is and therefore how important an accurate fluid balance overview is. The cheap bags are about fifty eurocents and the more expensive ones (Image 12.2) are almost three Euros. The expensive catheter consists of three parts that have different levels of accuracy. The first entrance is directly connected to the hose, the second part can be reached by turning the catheter to the side and the third compartment can be reached by turning the catheter over on it's back. This catheter is turned over by the nurse every hour just after operation and every three hours the day after operation to be able to post up the amount of urine which is produced by the patient accurately.
- IV bags are always used in combination with IV poles. The IV bags (water and medicines) and are placed high up in the poles and the catheter bag is placed halfway on the pole (image 12.3).
- Patients are being weighed every day. This happens with help of the weighing chair (image 12.4). Depending on the condition of the person this happens with or without lifting support. On the intensive care this will be integrated into the beds from October this year (Image 12.5). This bed has an alternating function (can become hard and soft on different places which differences during time to prevent decubitus). The beds can be set to zero and provide quite accurate weighing measurements. Although this could be a reason to doubt the nessesity of FluidBalance this is only applicable to the intensive care since the beds are far too expensive to integrate into the rest of the hospital. Furthermore the weight is used only as backup information to confirm the outcomes of the fluid balance overview.
- In the UMCG three different types of beds are used. The Hillrom bed (image 12.1), the Likamed bed (Image 12.6) and the bed on the intensive care (image 12.5). Al of these beds have different forms on the side of the bed which needs to be considered when designing a product that needs to be able to be placed on different types of beds.
- The rooms provide wall sockets which can be used for continuous power supply if needed. (image 12.7)
- The IV pole mostly contains an IV computer (image 12.8). This computer is used by the nurse to set how much CC IV is being provided by the intravenous bag per hour. This product is only made for confirmation of how much the patient should receive, it does not measure how much the patient actually received.
- In the patient map an overview is drawn of the fluid balance. (image 12.9) This overview is used to discuss progress between nurse shifts and with the doctors.

12.3

12.8

12.4



12.9

12.2A

12.2b

12.1c

12.2

12.5

12.10

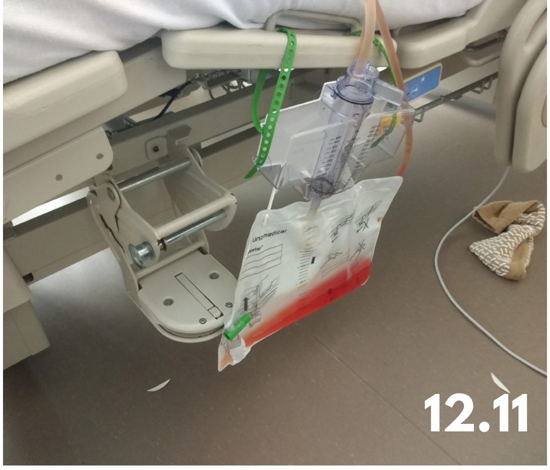
12.7

12.6

General findings RDGG

The visit to the RDGG as a reference hospital to be compared to the results of the UMCG was planned on 13th of September. The visit mainly contained a visit to de different departments (cardiology, intensive care, orthopedics and urology) where the focus was on discovering different types of beds, catherter bags and IV poles. During the visit several things were noticed:

- Again the catheter bag was laying on the floor. This was done because the straps to connect the catheter to the bed are quite difficult to attach. This patient was walking around quite often which is why the bag was placed on the floor to be picked up easily. (figure 12.12).
- Also intensive care had a different type of bed (image 12.20) compared to the rest of the hospital. Most of the beds were the Hillrom beds again (image 12.22 (bed in the front)). One other type of bed was spotted (image 12.19). Although this bed was never used according to nurses the bed was spotted inside a hospital room next to a hillrom bed (image 12.22).
- At the RDGG three different types of IV poles are used at the moment (image 12.13 - 12.15). Only if the patient is not moving the pole which is attached to the bed is used.
- Different wall sockets are available for use. Some are restricted since they need to be available if powered emergency equipment needs to be used (Image 12.21).
- Catheter bags are placed on the side of the bed with a small bracket. The placement location differs per bed and per nurse/patient. As long as there is enough height difference between the bladder and the catheter the placement is less important. At the intensive care the beds are placed in a higher position since the patient is not able to move much and the chance to fall out of bed is small. This means that is is easier to create enough height difference between bladder and catheter to be able to attach it to the bed (image 12.17 and 12.20).
- The hospital used two different types of catheters just like the UMCG. The cheap version (image 12.16) is used in low risk situations and the more expensive version that allows more accurate hourly measurements (image 12.11 and 12.12) is used in critical situations.


12.11


12.12


12.13


12.14


12.15


12.16


12.17


12.18


12.19


12.20


12.21


12.22

Appendix 13

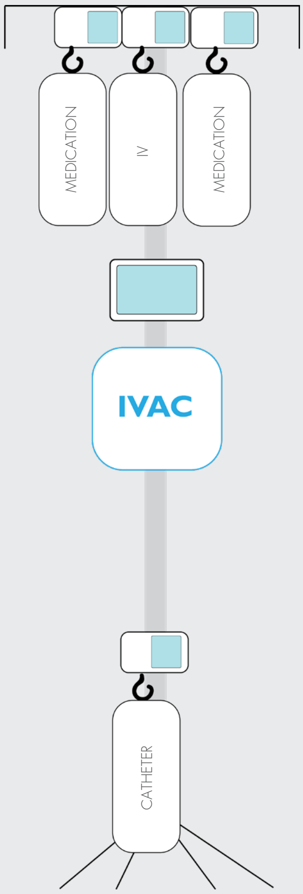
35% of FluidBalance patients

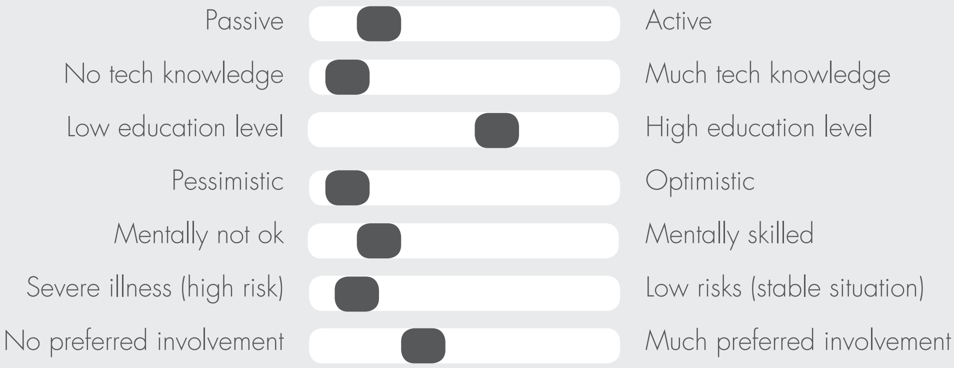
AAD BRANDSMA (89 YEARS OLD)

Aad is a widow. His wife past away three years ago. Aad already needs help with daily life. He has three children from who one lives nearby the hospital. Aad likes to go outside with his children and grandchildren and mostly sits in the general living room of the nursing home with other residents. Aad has troubles to remember things more and more.

MEDICAL STATE:

Last week Aad had a stroke for which he needed immediate surgery. Now he is still recovering from this and still needs to sleep a lot since he is very tired. Aad has troubles getting out of bed and needs nursing support to wash himself. Aad receives IV since he forgets to drink enough and he has a catheter.





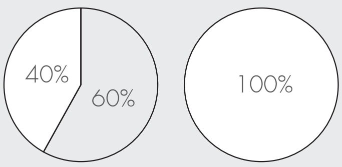
FRUSTRATIONS
- Not able to go outside
- Always tired
- Not being able to talk to people

GOALS
- Get well enough to go back to the nursing home
- Be able to take care of himself like he did before the stroke

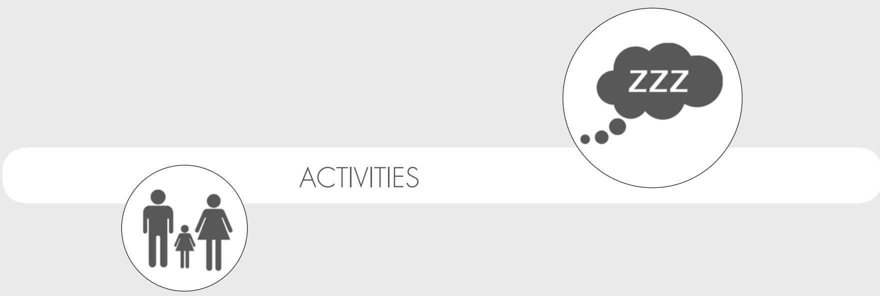
GREATEST FEARS
- Afraid to fall
- Afraid he will not completely recover from the stroke, considering quality of life

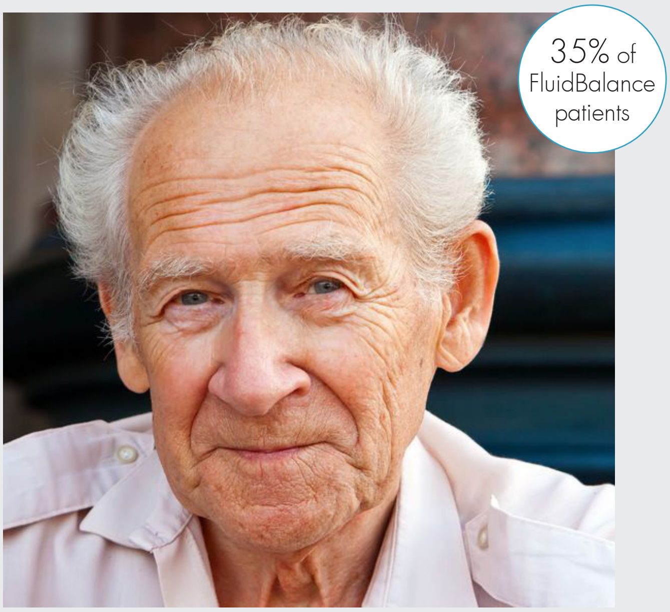
MOTIVATIONS
- Seeing his family
- Being able to go outside

INPUT OUTPUT



Oral intake / urination (toilet/po)
Automated input/output



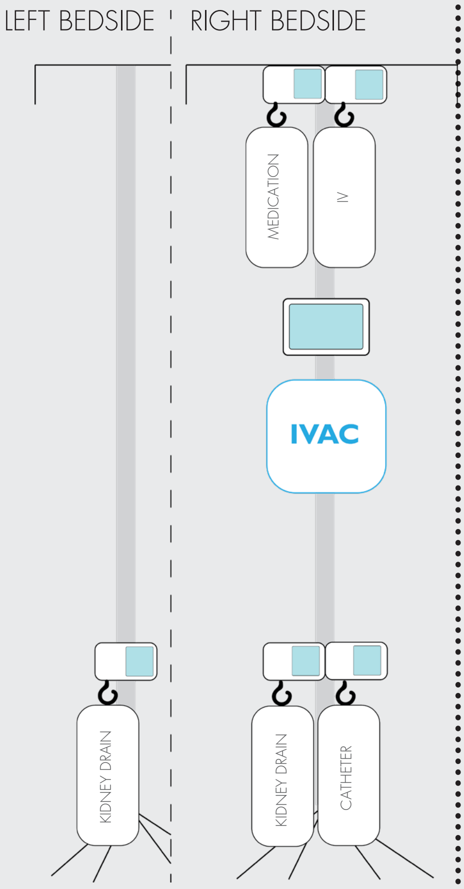


LEO VAN WOERDEN (73 YEARS OLD)

Leo lives with his wife in Leimuiden. He grows his own vegetables and for his family. He cycles a lot and he loves to be outside go on a fishing trip. Leo and his wife are married for 48 years. Together they have four children and five grand children. Leo loves to watch his grandchildren play soccer and visits them often.

MEDICAL STATE:

Leo is in the hospital for five days already. He is able to take a small walk once a day and receives medication. He has a kidney drain on the right and left side and a catheter. Leo looses a lot of urine during the day and receives extra fluids through the IV.



FRUSTRATIONS

- Being dependent of care
- Not being able to exercise
- Not being able to go outside

GOALS

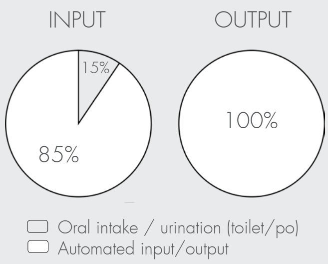
- Go outside
- Go home as soon as possible
- Walk multiple times a day
- Get rid of the drains

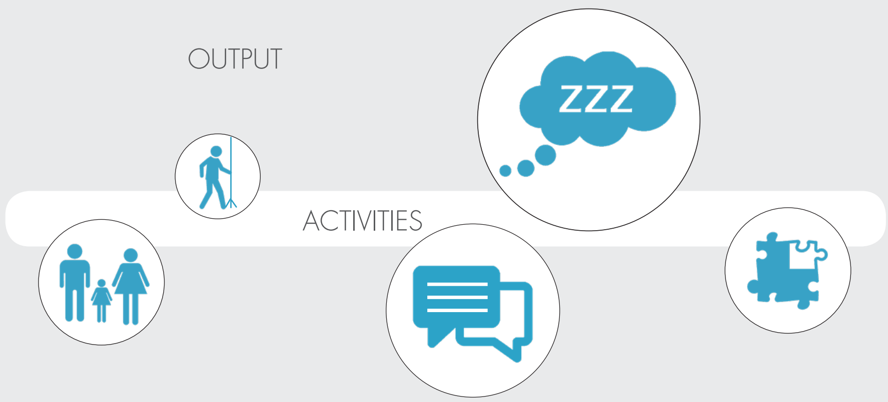
GREATEST FEARS

- Afraid to be less independent afterwards.
- Afraid to scare his grandchildren because of all the tubes around him

MOTIVATIONS

- Contributing to the recovery process





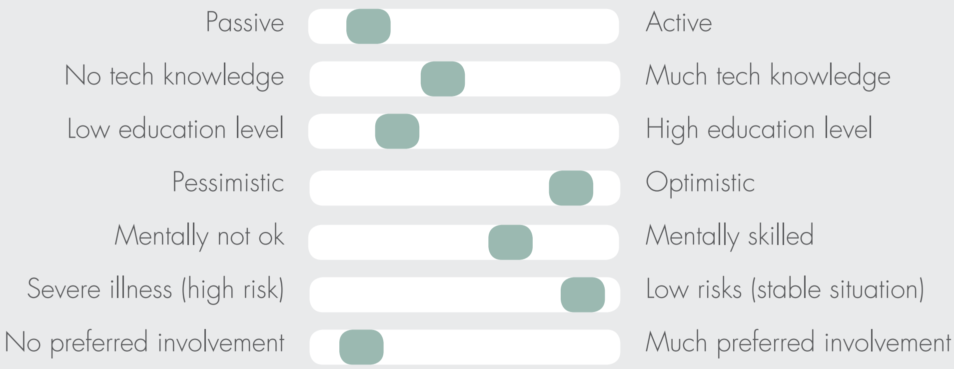
15% of FluidBalance patients

ALEKSA DRAGOVICĆ (69 YEARS OLD)

Aleksa is originally coming from Servia. She moved to the Netherlands with her husband 27 years ago. Although she has been in the Netherlands for a very long time she still has difficulties to understand everything. Her (grand)children sometimes need to translate for her. Aleksa is a widow, but has a lot of family and friends surrounding her in the Netherlands.

MEDICAL STATE:

Aleksa had surgery for her knee, but unfortunately some complications happened afterwards. She has to stay in the hospital to check on the wound and her fluid balance. She only has an IV at the moment and receives support from her family or the nurse to go to the toilet several times a day.

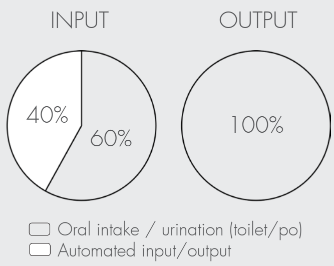


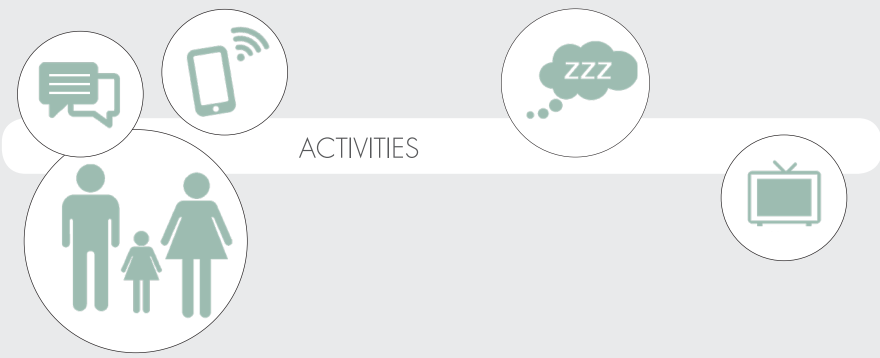
FRUSTRATIONS
- Not being able to understand everything that is said by medical experts
- Not being able to help her family at home

GOALS
- Be able to walk
- Being able to help her family during daily routines

GREATEST FEARS
- Afraid to miss-understand
- Being in pain
- Not being able to walk
- Falling again
- Complications get worse

MOTIVATIONS
- Being surrounded by people she trusts (family)
- See progression



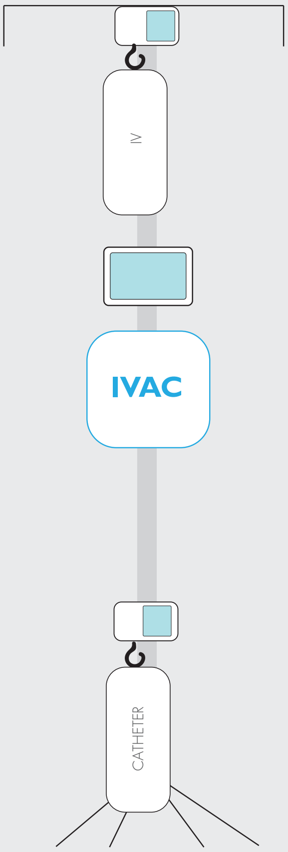


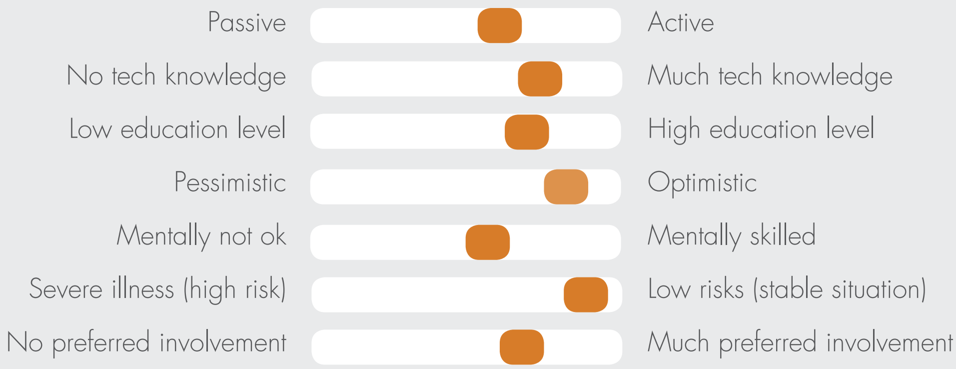
CHANINE VAN DAM (27 YEARS OLD)

Chanine and her husband just moved to Veenendaal and just finished (mostly finished) all the work that needed to be done in the house. She works as a consultant for a marketing bureau which she loves to do. Furthermore she likes to play hockey in her free-time and enjoys going out with friends.

MEDICAL STATE:

Chanine just gave birth to her first child. Unfortunately the labour was not going as expected. She had to go for an emergency caesarean section. Afterwards she still had a catheter because of the spinal cord that was injected.



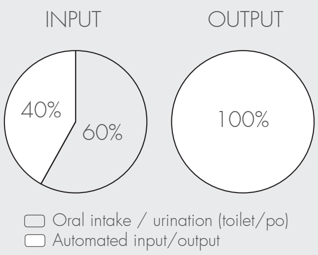


FRUSTRATIONS
- Being dependent
- Pain from catheter and birth
- Having to stay in the hospital

GOALS
- Get fit as soon as possible
- Loose weight and go back to sporting
- Spend a lot of time with the newborn

GREATEST FEARS
- How to be a mum?
- Something forgotten
- Not being able to sport soon again

MOTIVATIONS
- Baby inspiration pictures
- Hugging the baby
- Showing the baby to friends

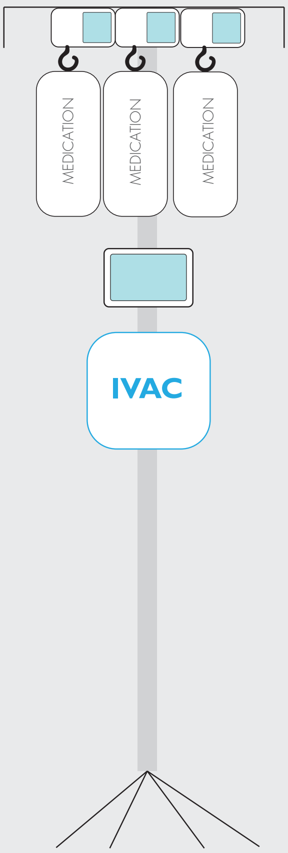


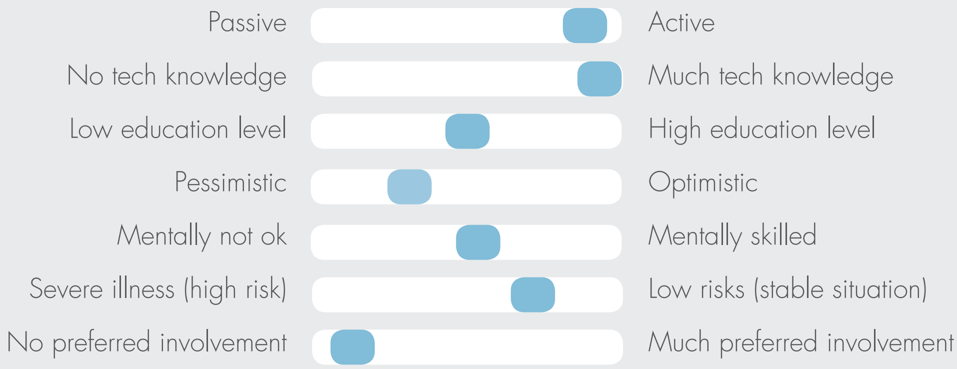
RICK VAN DE BERG (14 YEARS OLD)

Rick is a smart and enthusiastic boy, currently living in Ypenburg. He is in the second class of middle school and does not like his homework. He plays soccer three times per week and like to play video games with his friends. He has a mother, a father and an older sister.

MEDICAL STATE:

Rick has Leukaemia which needs to be controlled closely. Rick has been in the hospital for three weeks already. He has found his way in the hospital and walks around several times a day. He receives medication and is being checked upon regularly.



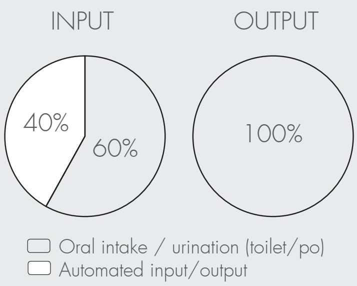


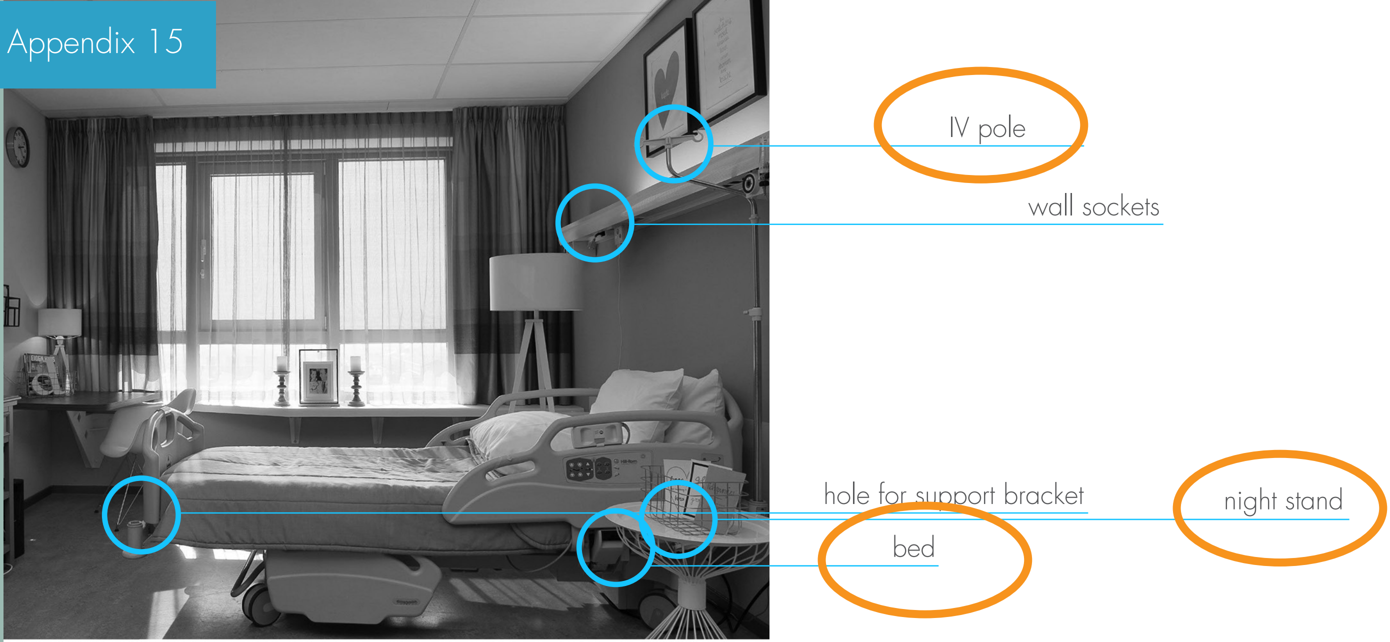
FRUSTRATIONS
- Not being able to play soccer
- Feeling tired and depressed due to the treatment
- Being bored inside the hospital

GOALS
- Play soccer again
- Become cancer free
- Go on a big backpacking trip with his friends
- Finish school

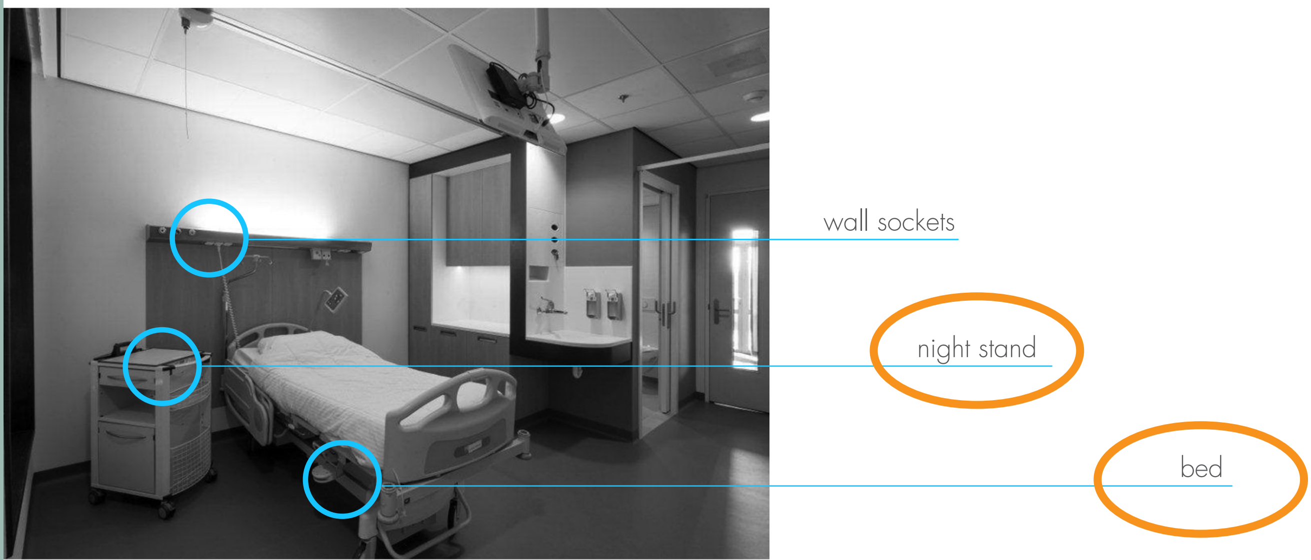
GREATEST FEARS
- The message that the doctors can not help him anymore
- Having to stay in the hospital for most of his life

MOTIVATIONS
- Progress in situation
- Joining his friends in online games

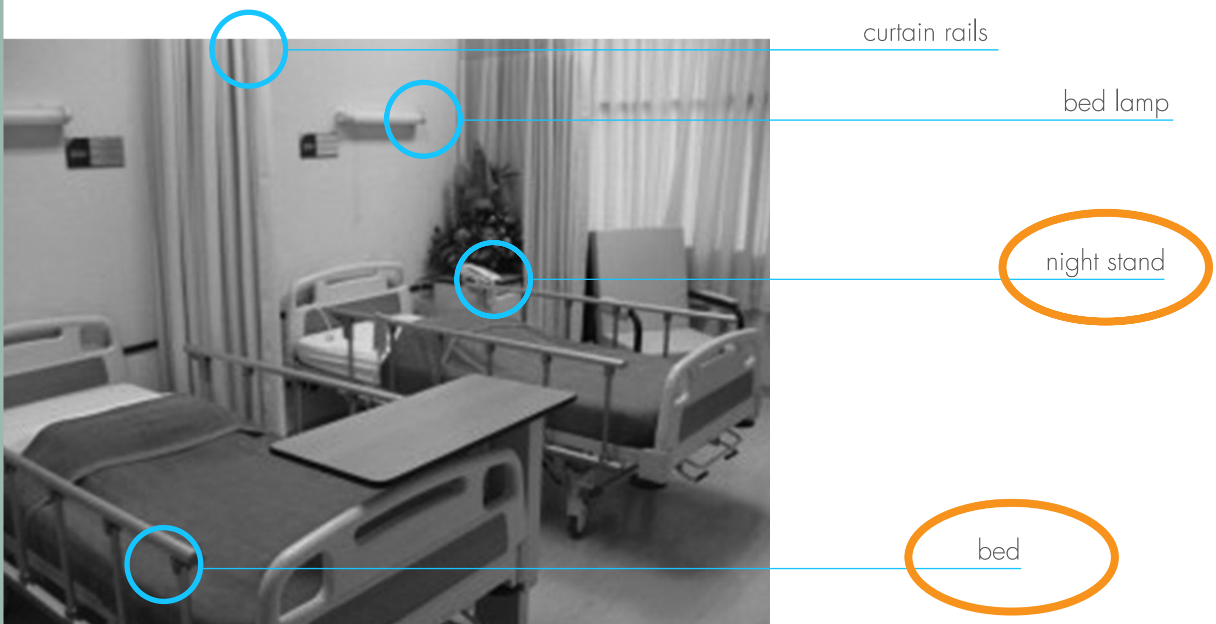




Spaarne hospital, Haarlem

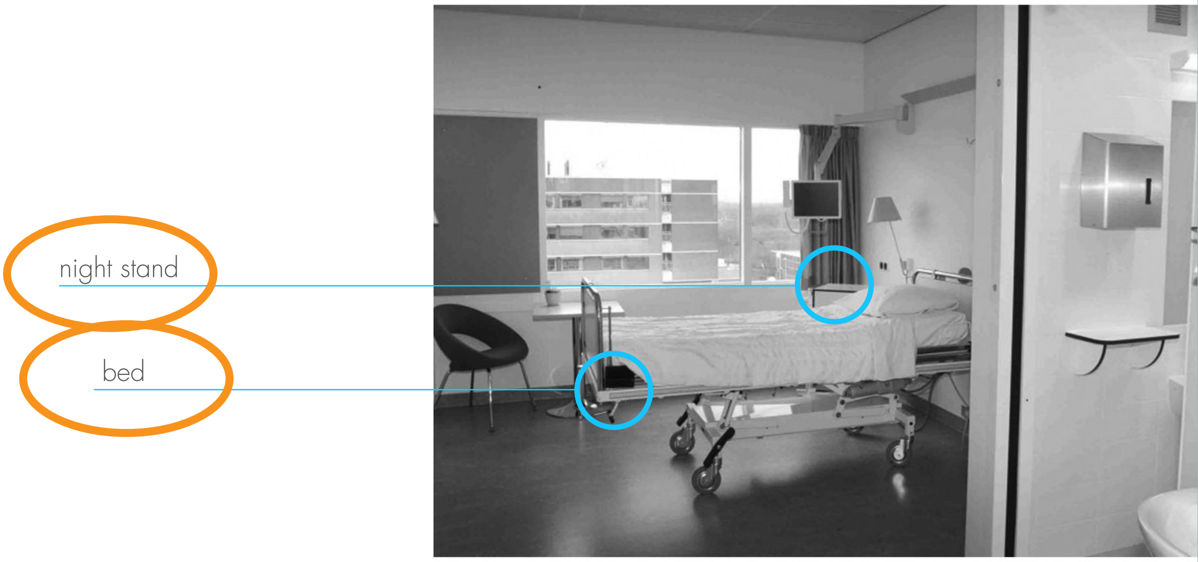


Reinier de Graaf hospital, Den Hoorn

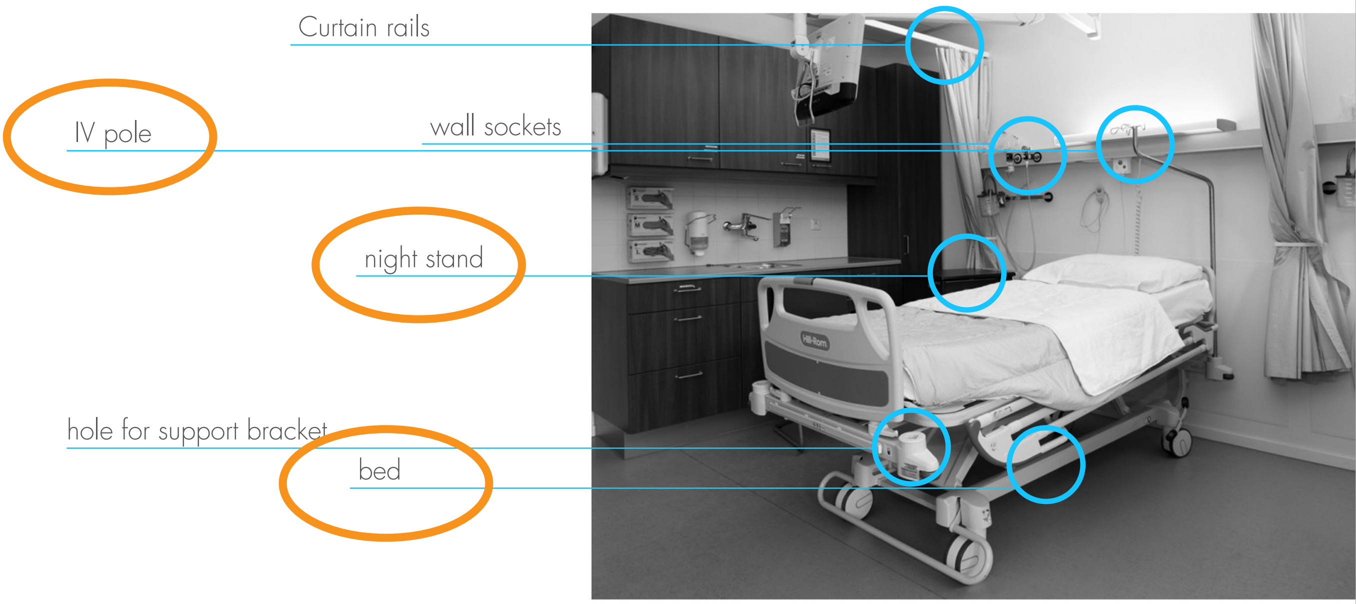


Haga hospital, The Hague

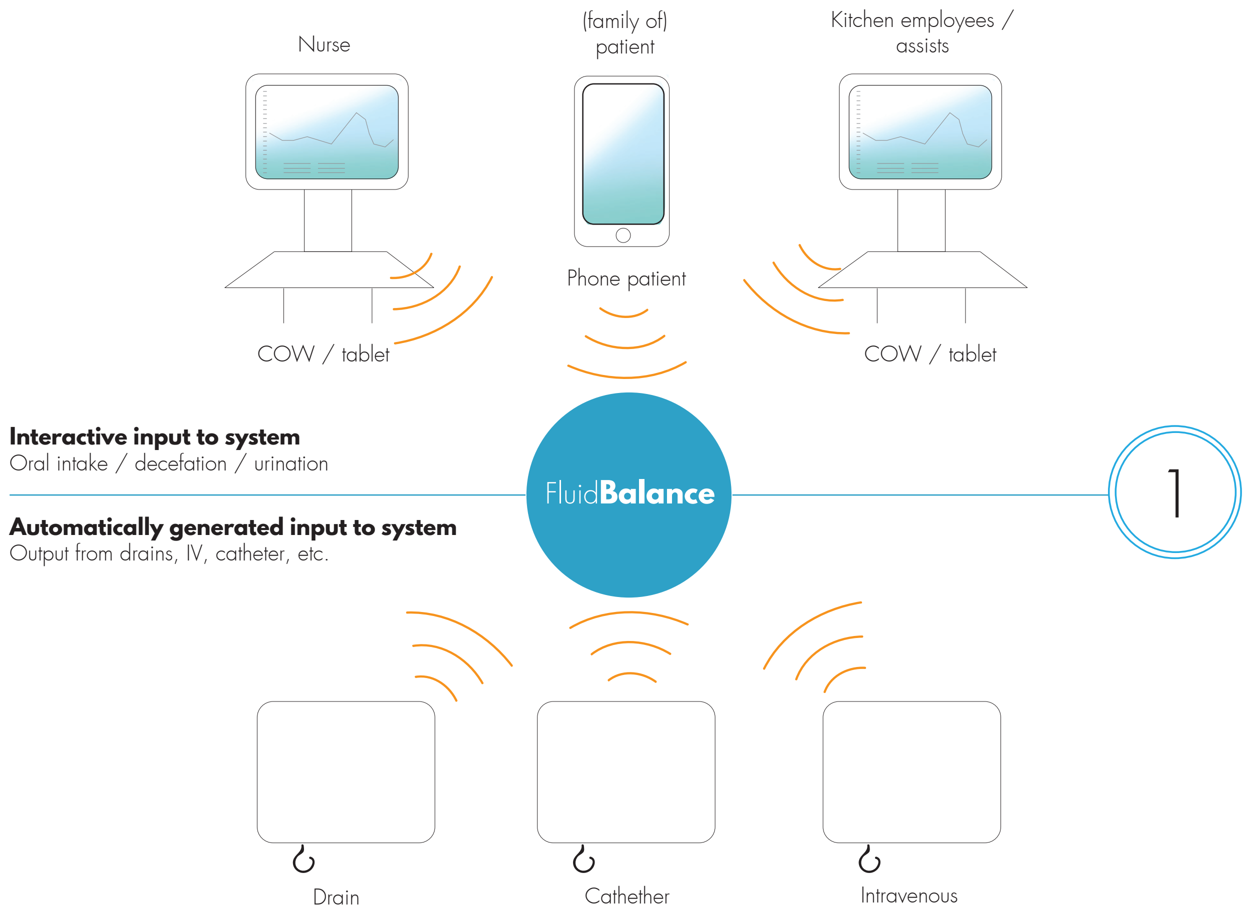
Erasmus hospital, Rotterdam

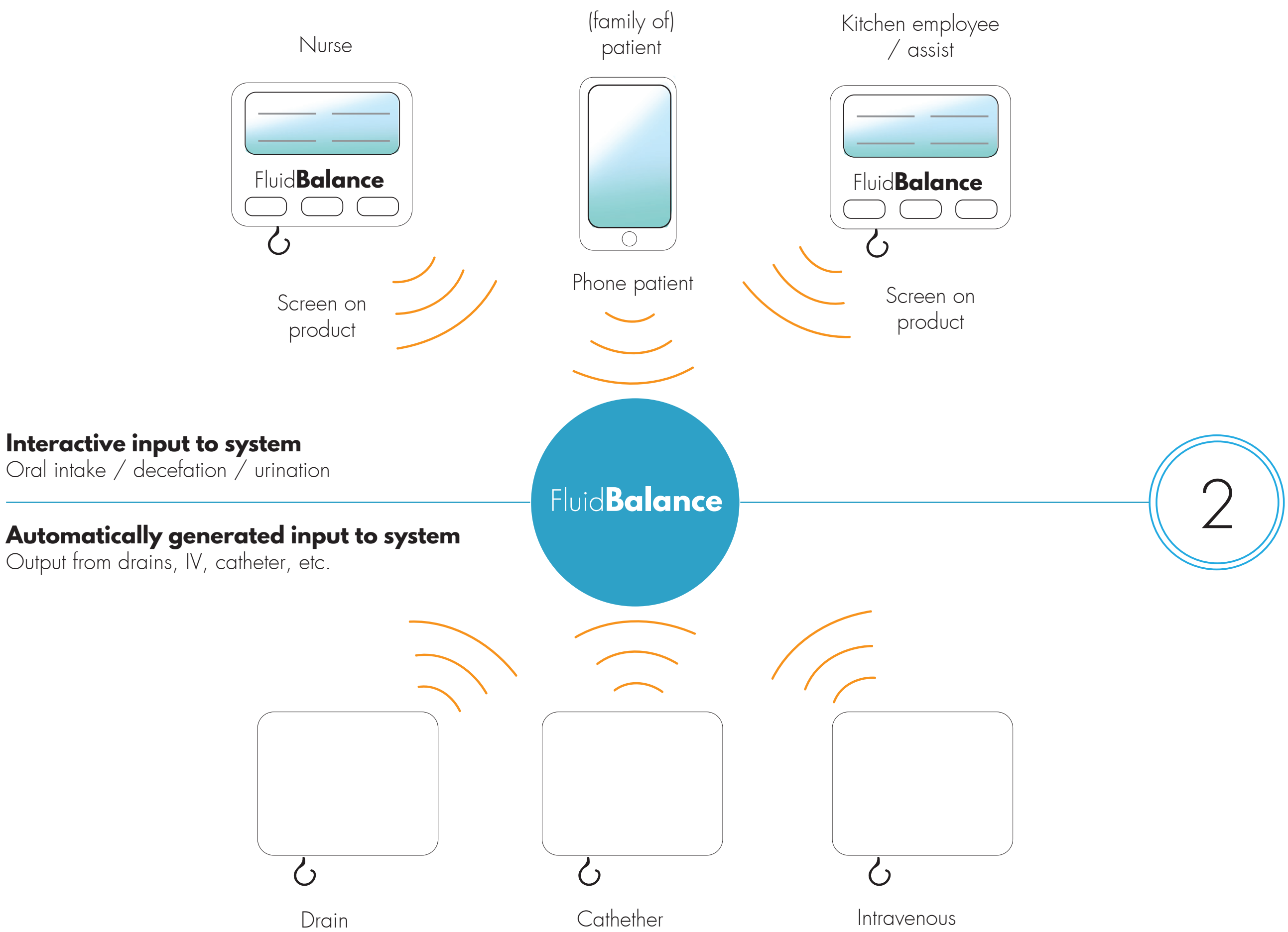


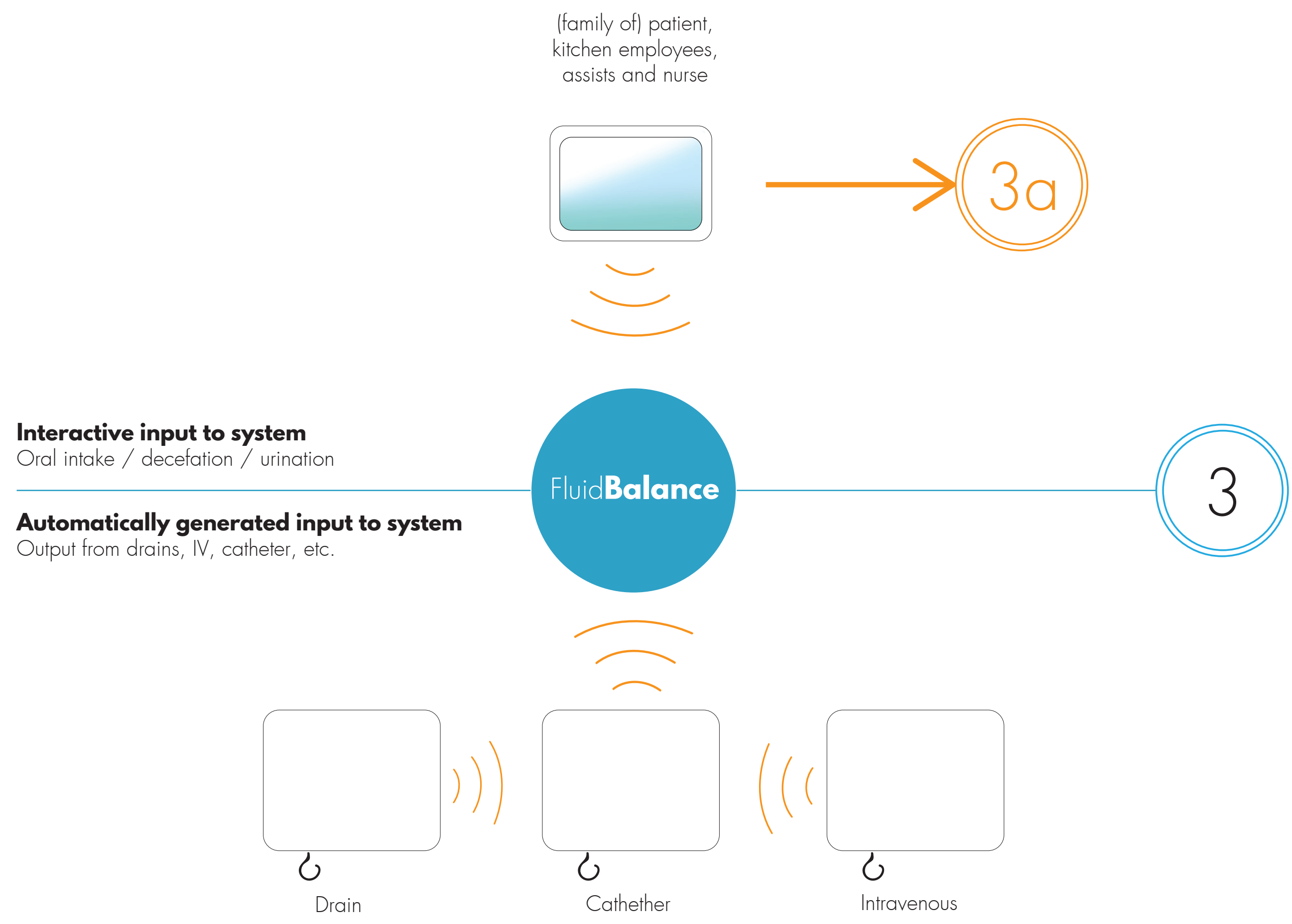
ETZ hospital, Tilburg

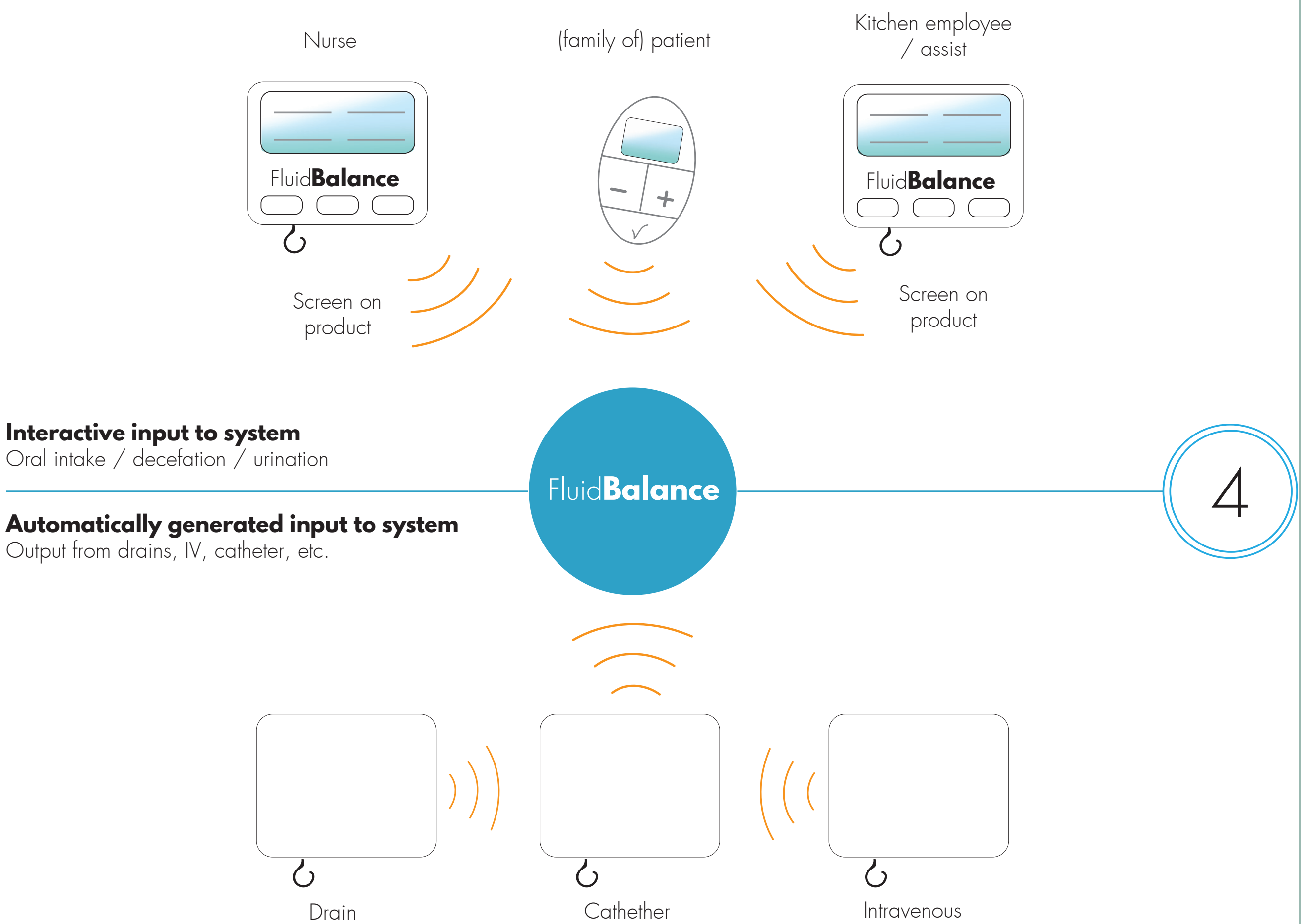


Maasstad hospital, Rotterdam


Nurse
(family of) patient
Kitchen employees / assists
Phone patient
COW / tablet
COW / tablet
Interactive input to system
Oral intake / decefation / urination
FluidBalance
1
Automatically generated input to system
Output from drains, IV, catheter, etc.
Drain
Cathether
Intravenous


Nurse
(family of) patient
Kitchen employee / assist
FluidBalance
FluidBalance
Phone patient
Screen on product
Screen on product
Interactive input to system
Oral intake / decefation / urination
FluidBalance
2
Automatically generated input to system
Output from drains, IV, catheter, etc.
Drain
Cathether
Intravenous


(family of) patient,
kitchen employees,
assists and nurse
3a
Interactive input to system
Oral intake / decefation / urination
Automatically generated input to system
Output from drains, IV, catheter, etc.
FluidBalance
3
Drain
Cathether
Intravenous


Nurse
(family of) patient
Kitchen employee
/ assist
FluidBalance
FluidBalance
Screen on
product
Screen on
product
Interactive input to system
Oral intake / decefation / urination
Automatically generated input to system
Output from drains, IV, catheter, etc.
FluidBalance
4
Drain
Cathether
Intravenous

“It is important that I have the possibility to look into the current intake and output level of the patient at the patient’s bed since I do not always bring the COW with me”.

Interviewee:
Sanne Kneppers-Kooi (Nurse maternity ward Haga Hospital)

A short discussion was held regarding the product before going into detail. The concept was explained with help of the six configurations and the main image provided by TIM Solutions. During this conversation important care related problems were notified that need to be taken into account during the design process:

“What happens if the patient needs to take a shower? At the moment we detach the IV from the IVAC (intravenous computer) and we detach the catheter bag from the bed. The catheter bag is placed on the floor during showers. When it is still attached to the IV pole this could lead to unnecessary problems for the patient and or the nurse during the cleaning process”.

“When will the product be attached to the infusion bag? Patients who need to go for surgery switch from IV pole several times. Would this mean that you need to reset the product every time this switch happens? The get an IV in the preparation room where it is hung to and IV pole. Then they are moved to the OR while the IV is just laying on the bed and hung to a different pole in the OR. After OR they stay in the recovery room for (half) an hour. The bags are laying on the bed or hanging on the bed again during movement to the final ward and they are hung on the IV pole of the patient.”

After explaining that the product will probably be used after OR only (starting from the ward) the four different options (appendix ...) were shown and the seven product service solutions were shortly explained and discussed.

While discussing the four different options for the interactive input (oral intake and urination) it became clear that Sanne did not think that the mobile phone and the COW should be used for this purpose.

“The mobile phone is not reliable since it can be empty, not understood by everyone, not owned by everyone and sometimes applications do not work on different phones which leads to problems. The COW is a shared product which is not always taken along when visiting patients and kitchen employees do not even use one. Furthermore I think that the device or application should be as simple as possible since patients are ill or old which means that they do not want to be disturbed too much by difficult devices or applications.”

The discussion about the seven context and communication related options lead to the following outcomes:

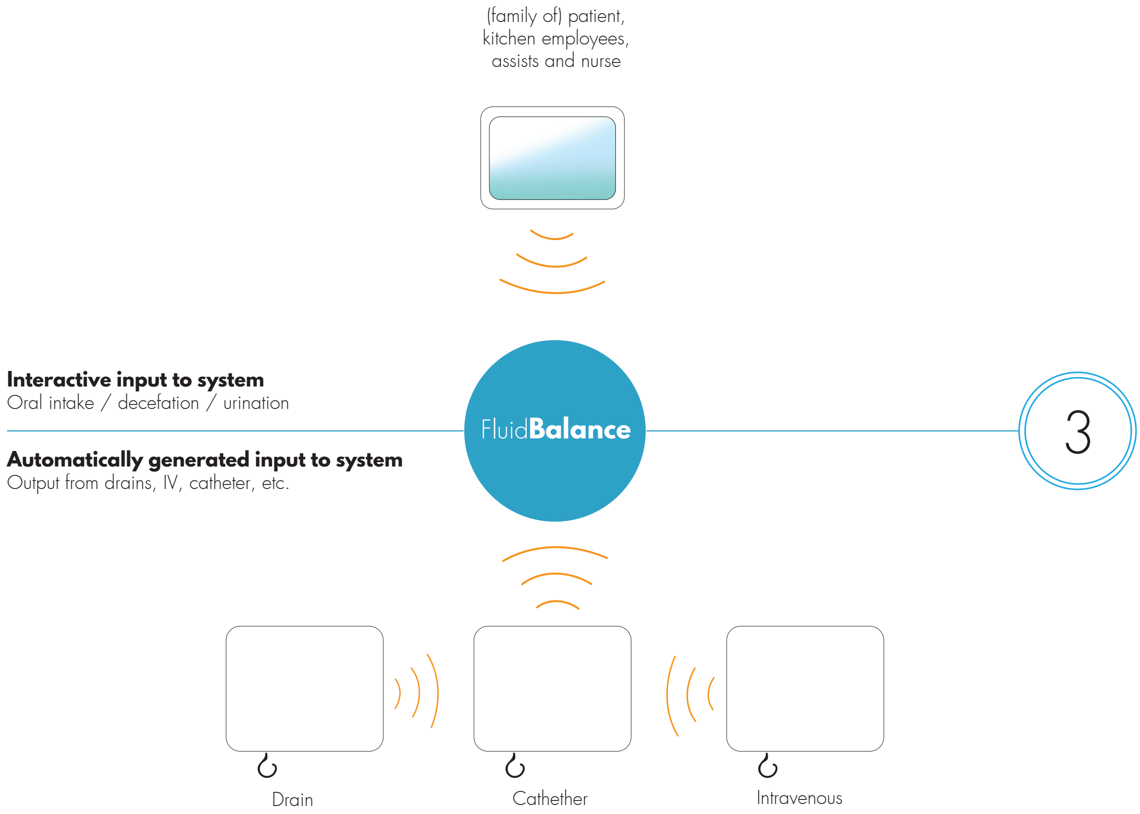
Hardware / communication combination option 1 (figure C.2 at page 45:
“This sounds like a good solutions. The advantage is that it is connected to the pole which means that is cannot get lost. Of course the cable needs to be long enough for the patient to be able to use it in bed. I prefer bluetooth over Wi-Fi since the Wi-Fi connections a bit slow at the Haga hospital. Of course the Wi-Fi connections are being used for our “

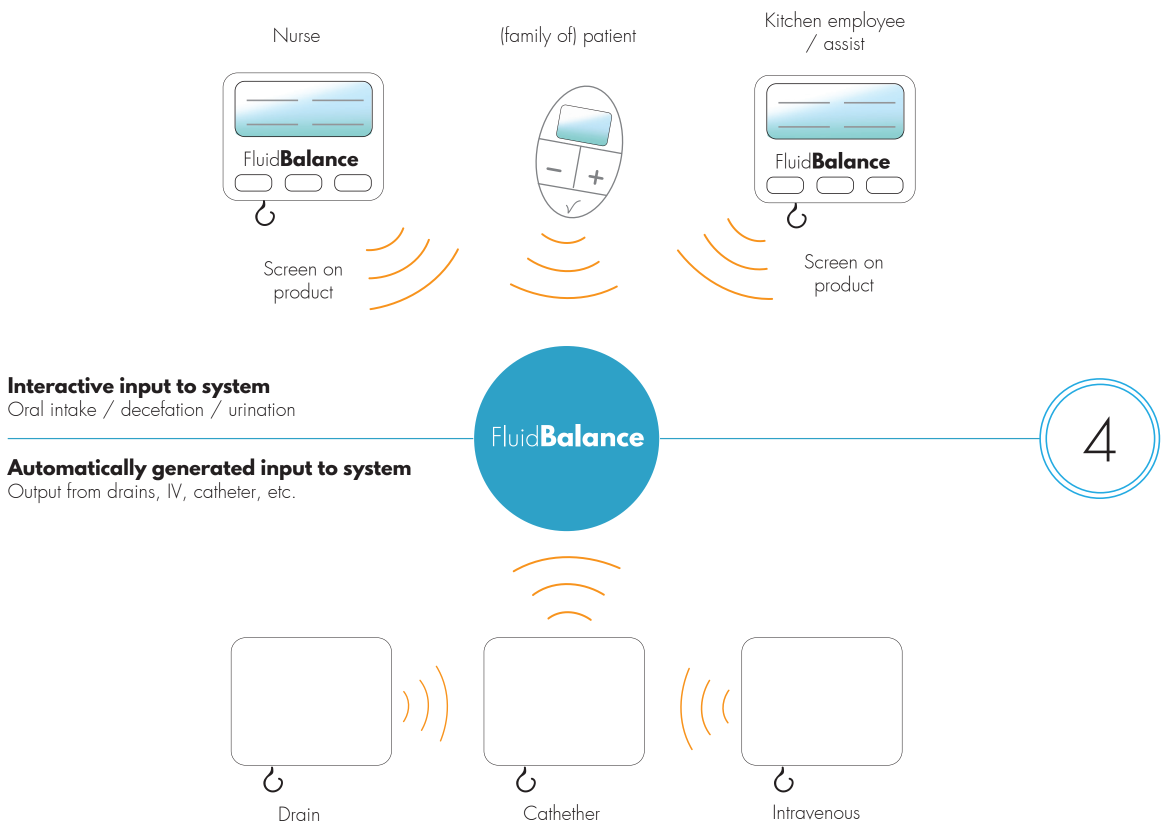
Hardware / communication combination option 2 (figure C.2 at page 45: :
“Nurse cannot enter information about the patient apart from using the small remote control of the patient. As a nurse you do not have an overview of the fluid consumption and output. Furthermore having cables involves the risk of cables getting lost. This happens a lot with the charging cables of the IVAC which is a loose cable and is something every nurse is searching for when needed. The remote control is a good solution for the patient since it can only do what it is meant for and it does not offer different side options like the tablet of concept one”

Since you do not always bring the COW to the patient when checking upon him or her using the COW as an interface next to the bed of the patient for looking into the fluid balance throughout the day is not an option. How often do you look at the COW’s interface? Every hour?

“You look at it even multiple times per hour. Everything that you do as a nurse, like in my case feeding a baby needs to be entered into the EPD (on the COW or on another computer on the hospital department).”

So, using the COW to communicate problems about the fluid balance or notifying the nurse to empty the catheter bag would be an option?


(family of) patient,
kitchen employees,
assists and nurse
Interactive input to system
Oral intake / decefation / urination
Automatically generated input to system
Output from drains, IV, catheter, etc.
FluidBalance
3
Drain
Cathether
Intravenous


Nurse
(family of) patient
Kitchen employee
/ assist
FluidBalance
FluidBalance
Screen on
product
Screen on
product
Interactive input to system
Oral intake / decefation / urination
Automatically generated input to system
Output from drains, IV, catheter, etc.
FluidBalance
4
Drain
Cathether
Intravenous

"Yes for sure. You or the other nurse will definitely get the notification. If it does not concern my own patient I can still go to the patient depending on the urge of the problem or I will notify my colleague about her patients needs. Of course sometimes you save some information on in your notebook to put it in the system all in once since you are busy. It would be great if we could enter the information directly into the system at the bedside of the patient. This is possible already on the screens next to the beds. However these screens mostly do not work properly and they are very slow which means that is does not save time."

"When bluetooth is being used as connection method this means that the products need to find connection among each other and that the nurse needs to make sure that the correct device is selected. Furthermore connection to the correct EPD is needed, probably with use of the ID (patient number)."

"This means that you can also find the device of the neighbour. This could lead to problems. Entering patient numbers could be time consuming. These numbers are mostly quite long and they differ only in a few numbers. This could be error sensitive."

Hardware / communication combination option 3 (figure C.2 at page 45:
"The first thing to notice is that the device is hanging lower. The position you want to use for entering information and the position that is used to hang the IV bag are probably different. This means that you need to move the device up and down when using it. This could lead to a problem with the IVAC since it is connected to the IV bag which will be moving. If the IV bag can hang in a lower position since you have a small patient (like children) which means that you do not need to move the device up and down it still means that the IVAC will be placed a certain distance below the device and maybe mean that entering information on the IVAC will become a problem. Furthermore this device is not connected with each other which means that the results are only visible on the COW. Like I said before this can be annoying when a patient asks a question about his or her fluid balance and I as a nurse need to walk away from the patient to take a look at the EPD first and come back to discuss the information."

"For as far as I understood so far is it important to you that you are able to look into the fluid balance of the patient without the need for a COW to be used. Is this also the case if you do not have to look into the Fluid balance of the patient anymore since the device will take over the task and give you a warning when needed?"

"Yes, this is very important since the COW is shared and it is quite a hassle to take it with you all the times. You still want to be able to look into the fluid balance of the patient. The patient might ask if what the current status of their fluid balance is (especially when they are on a fluid limit) to see how much they drank that day already. A total fluid balance over several days at the patients bed is necessary, but the possibility to see what happened that day is required."

Hardware / communication combination option 4 (figure C.2 at page 45) :
"This option has the same problem as three. The device does not calculate the result at the device but in the COW which is not preferred. The problem with the movement is gone, but now four different devices are needed instead of three. This is actually a bad version of option one."

Hardware / communication combination option 5 (figure C.2 at page 45:
"This option has the problem of the need to move the product as well. In combination with cables this is even a bigger problem I think. Furthermore this option contains a phone again which is not the best solution in my opinion."

From these findings and options Sanne tried to formulate what would be her ideal device and communication method. This lead to general needs and preferences:

"Moving the product up and down after every time you use the product is not preferred. Not being able to see anything about the current fluid balance at the patient's bedside is a big disadvantage. Furthermore I do like the option of a very simplified device for the patient to be able to enter his or her fluids intake and output into the system. At the moment I prefer option one in combination with the remote control for the patient although this means that I would have to install four products. It is option six, but instead of the phone a remote device."

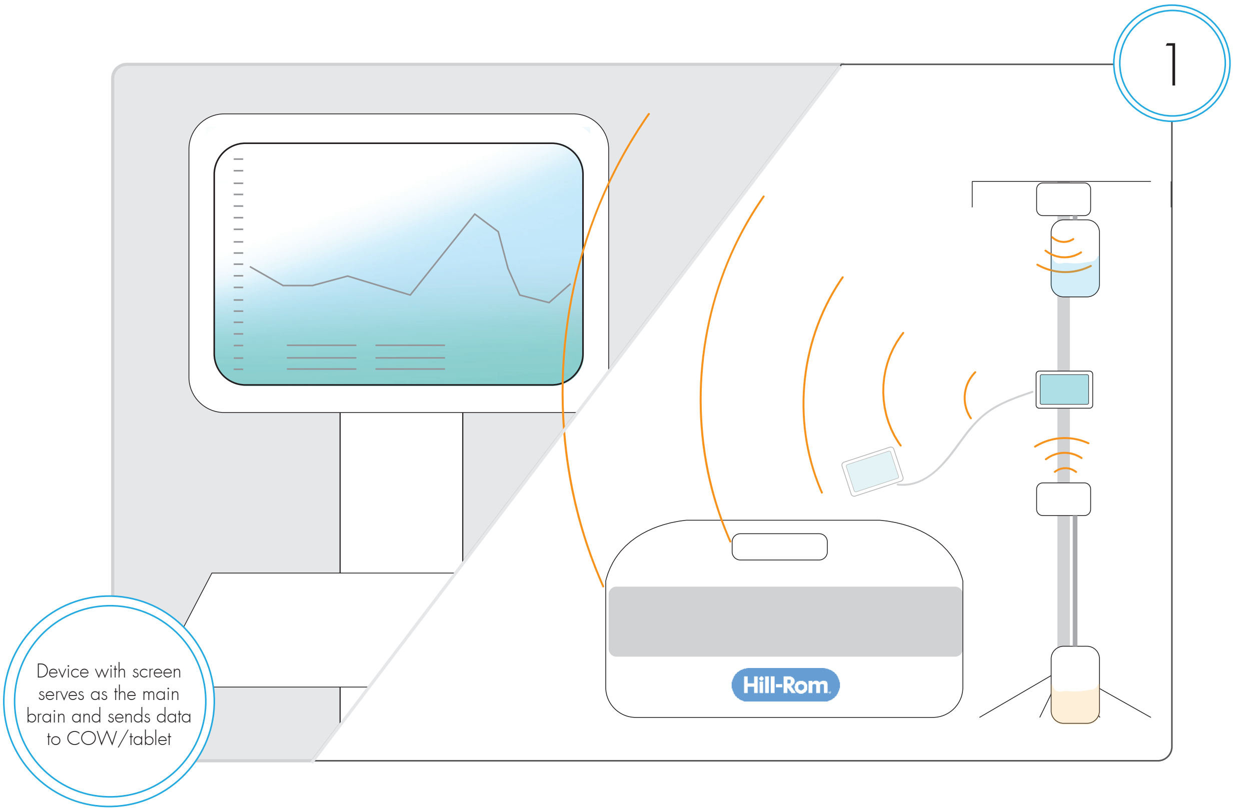
The screen is interpreted as very complicated for elderly and therefore less suitable than the remote control. After explanation of the simplicity of the screen to decrease this prejudgement Sanne agreed that a screen could be simple as well. Although it still looks like a screen and therefore it implies that it is a difficult device.

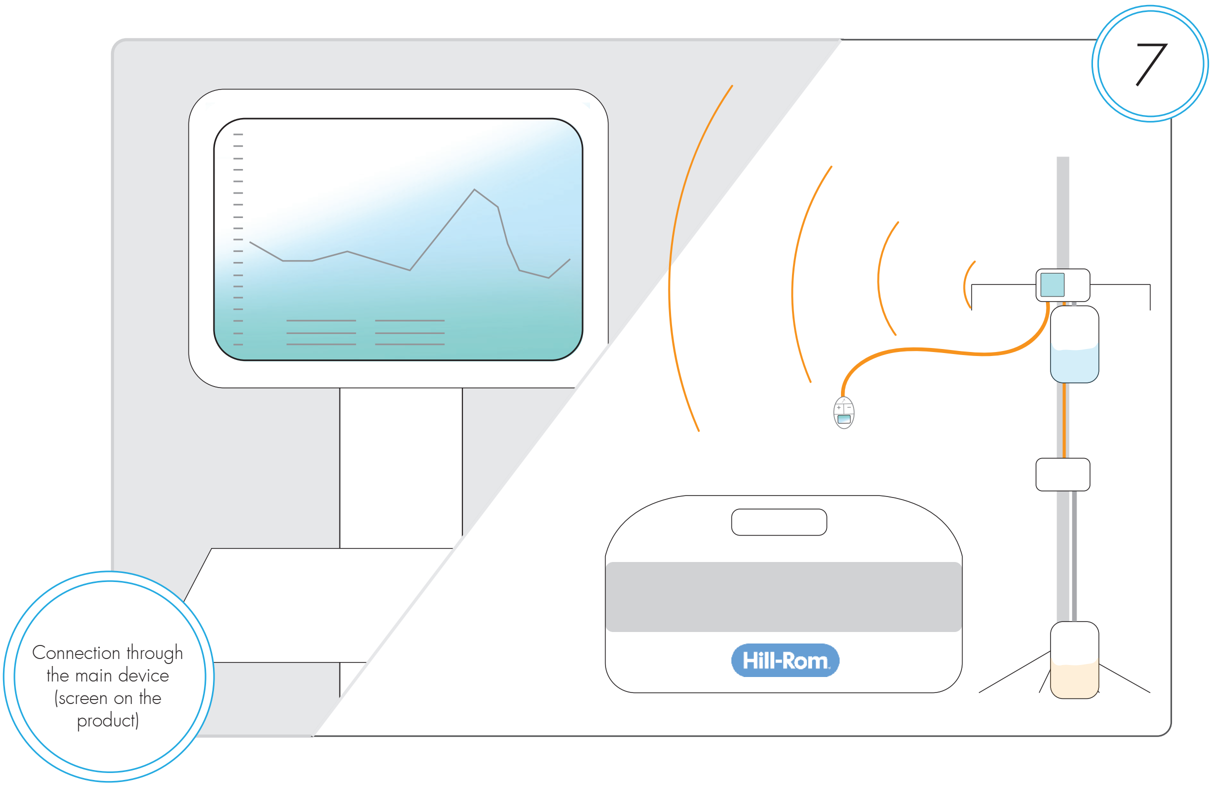
Hardware / communication combination option 7 (figure C.2 at page 45:
"After discussing the amount of product that need to be attached to the pole by the nurse I might consider moving the product up and down less annoying than having to pick up multiple devices when installing and the product. In that case option seven would be good since it meets the needs for a simplified device for the patient, the possibility to look into the fluid balance next to the patient's bed and it takes less space on the pole / less different devices to attach."

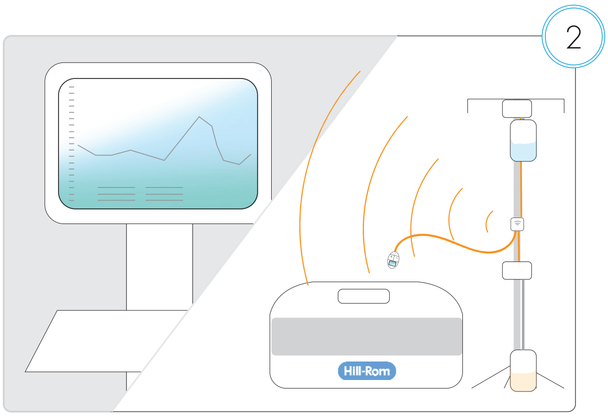
The discussion about the seventh option lead to a discussion about the storage of the devices and the IV poles.

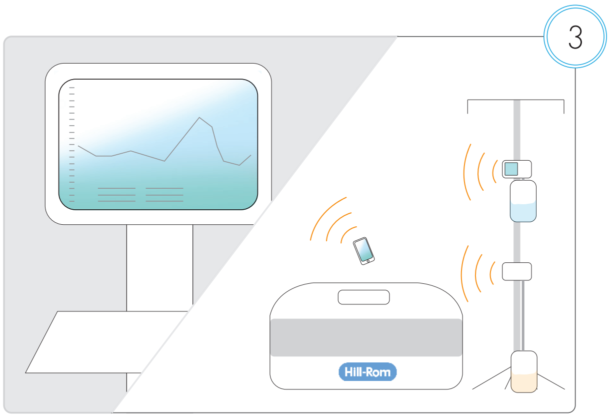
"All the devices that are needed for an IV should stay installed on the device. In the case of option seven I think that the FluidBalance hanger should be on the IV pole and the remote control should be attached as well or stored nearby."

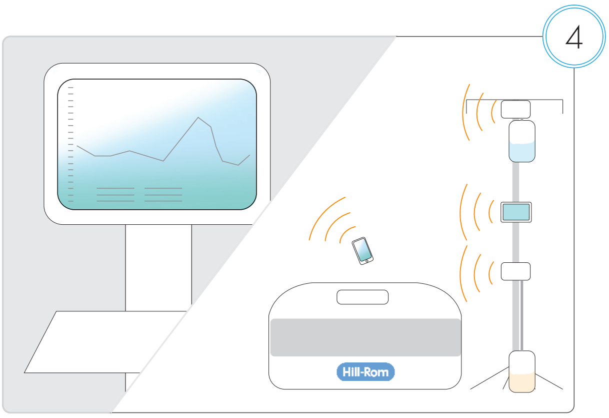
Regarding the IVAC it is noted that this device can already calculate how much fluid is supplied to the patient. Although it is important that the nurse is accurate with time when the Fluid bag is disabled or stopped when it is not yet empty. Limitations and guidance from the device is needed to help the nurse walk through all the steps of replacement to make sure that the outcomes are accurate in an environment full of distractions. During a discussion about the functionality of the IVAC it was concluded that the IVAC might not be necessary anymore after introducing Fluid Balance. This will be researched in more depth and might be an interesting feature to add.

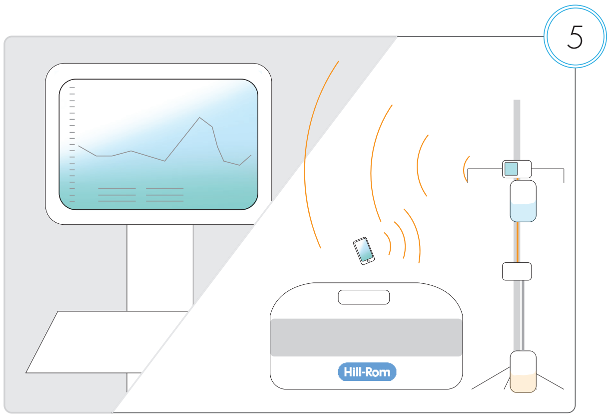

1
Device with screen serves as the main brain and sends data to COW/tablet
Hill-Rom

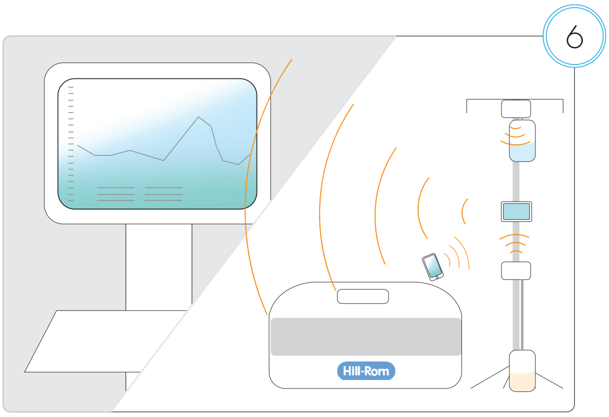

7
Connection through the main device (screen on the product)
Hill-Rom


2
Hill-Rom


3
Hill-Rom


4
Hill-Rom


5
Hill-Rom


6
Hill-Rom

The people who are adequate and responsible enough to enter their own information regarding oral intake and extra output (apart from weighed output) are more or less ten percent.

Interviewee:
Alexandra van der Wilk (Nurse Urology, RDGG)

A short discussion was held regarding the product before going into detail. The concept was explained with help of the six configurations and the main image provided by TIM Solutions. Before discussing the seven design solutions with the nurse several general things about the project were discussed which lead to interesting notes.

"Here in the RDGG we do everything on the COW and if you see how much is forgotten you would almost want to go back to the old times when we still worked on paper."

"Choice for the IV pole is good. We already have brackets for the catheter bag on the pole on which we hang the current bags when the patient want to walk. During the night we already hang everything on the pole to make it easier for the patient to go to the toilet."

"It is important that the device can get wet in the shower. We do not always stop the IV when the patient needs to take a shower. That depends on how critical the IV is for the patient. Altogether this means that the pole is joining the patient during a shower."

Discussion on replacement of the IVAC lead to the following answer:

"The most important thing about the IVAC, apart from the possibility to enter how much fluid needs to enter the body per hour, is measuring if the fluid is being entered to the patient. The position of the hand (or elbow/neck) (where the IV is inserted) of the patient determines whether fluids can enter or not. Now the IVAC gives an alarm if this is the case. The nurse needs to come to look at the alarm and notifies the patient that he or she needs to watch the position of his or her hand. Alarms should be included in the new device as well. Apart form IVACS that are needed to serve specific medicines over a time span not having to use the IVAC for fluid balance measurements would lead to far less IVACs being necessary!"

The seven images were discussed and during these discussions important remarks were made:

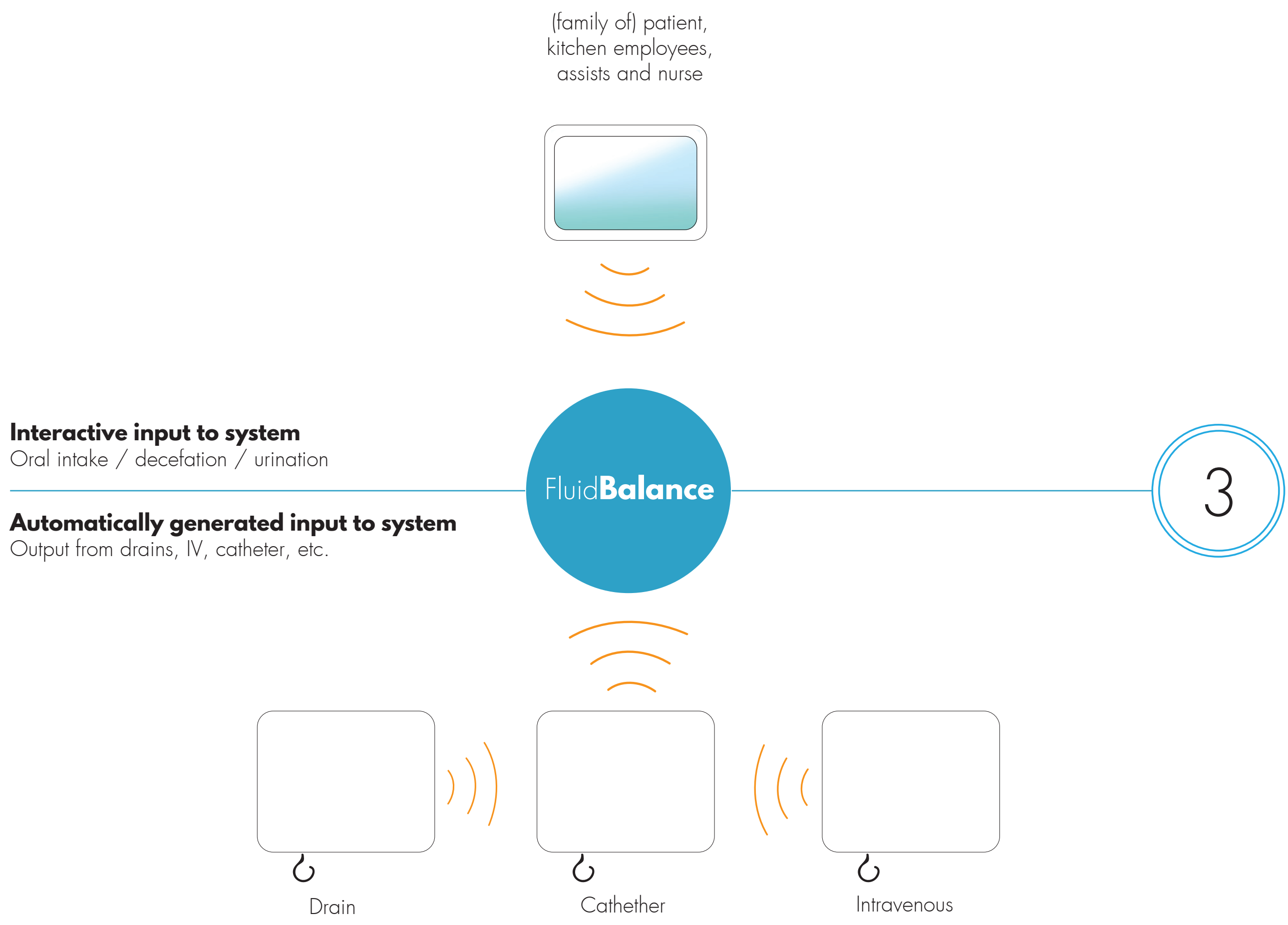
"Attaching everything to one pole is not always possible. Most patient at my department have a colostomy, kidney drain, catheter and an IV. The left kidney drain needs to hang on the left side of the patient and the right kidney drain on the right. When the patient wants to walk we put everything on one pole, but when he or she is laying in bed this is not an option since he or she would get stuck in all the connected cables. Furthermore it is important that multiple outputs of urine can be selected. It is important that the system creates an overview of how much fluid came from the catheter, the left kidney drain and the right kidney drain. "

"The IV Pole needs to hang above the head of the patient. The hight the bag, the better the fluid drip is, but still it depends a lot of the positioning of the hand, elbow or neck of the patient. When the IV needs to hang higher the pole itself is extended by the nurse. This means that the nurse does not need to be very tall to hang the IV on the highest position."

"Responsibility of entering the oral intake and output of urine on the toilet (or in a po) should not be with the patient. For example people are afraid of IV and they will fill in an extra glass of water on the paper while they did not drink it. The people who are adequate and responsible enough to enter their own information regarding oral intake and extra output (apart from weighed output) are more or less ten percent.

At the moment the assist (who is hired as a hospice to serve the patient with food, drinks and snacks) mostly writes down what the patient drinks and if the patient drank everything that is served by him or her when the left overs are being picked up. At the moment the assist is not allowed to enter information into the EPD since this contains a lot of medical information which does not concern the assist. Having a separate device for them to enter the information regarding fluids without the need to enter the EPD would be amazing and save a lot of time for the nurse. The nurse is always final manager and needs to check if the assist did write down the fluids intake every time they serve the drinks."

"Entering the oral fluid intake could be done by the assist and every hour output (apart from the catheter)


(family of) patient,
kitchen employees,
assists and nurse
Interactive input to system
Oral intake / decefation / urination
Automatically generated input to system
Output from drains, IV, catheter, etc.
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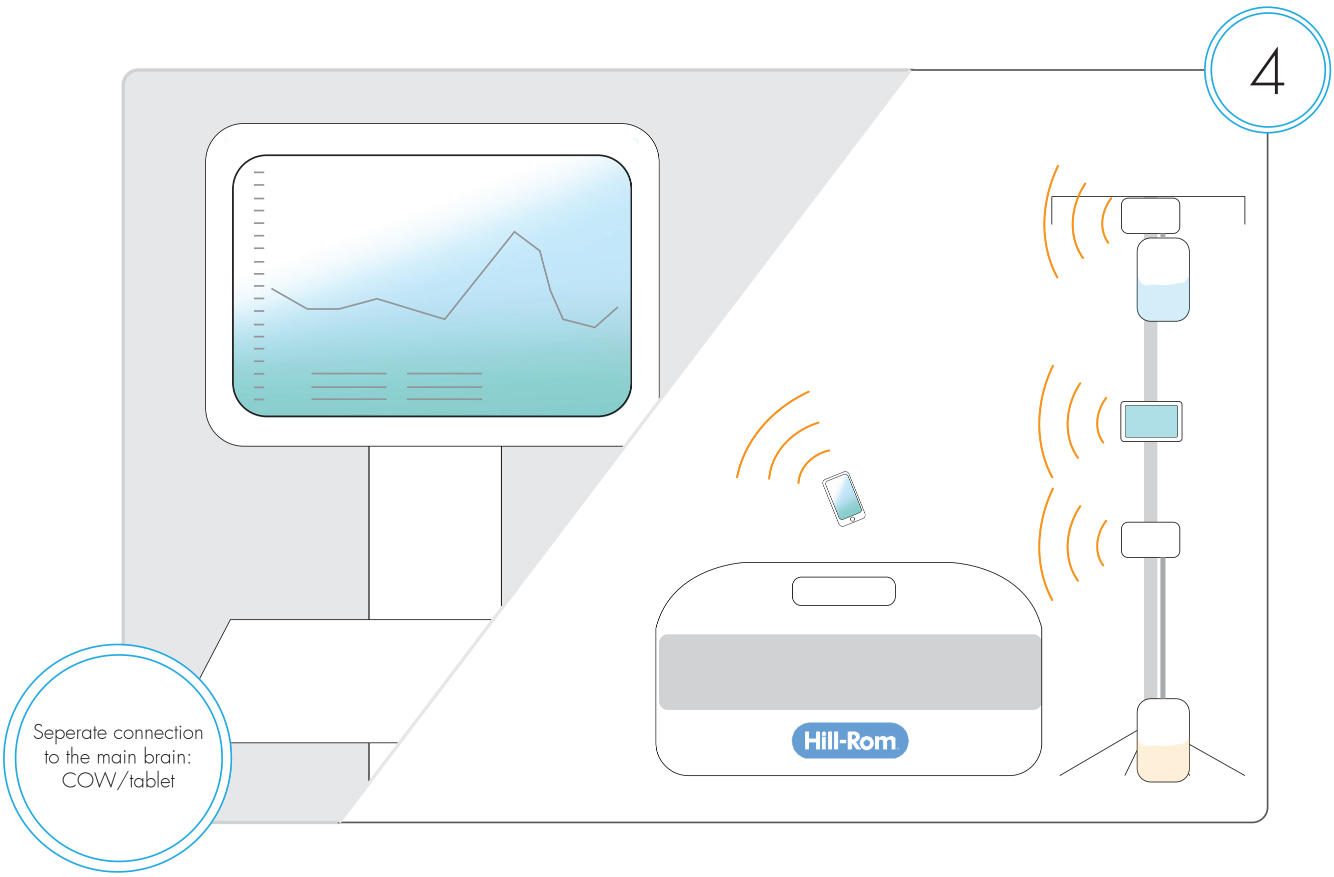
3
Drain
Cathether
Intravenous


4
Hill-Rom
Seperate connection
to the main brain:
COW/tablet

is never needed, since patient who need hourly check ups do not go to the toilet, but urinate only through the catheter."

"I know the principle of PCC, but I still think this is not preferred for most of the patients. Especially when it comes to the fluid balance since deviations can lead to a totally different treatment. I understand that people want to make the choice whether they want to go into surgery or not, but regarding fluid balance it is the task of the nurse to make sure the patient's balance is correct. It is very important to discuss fluid balance with the patients and to make them aware how important it is, but the real time information input should be done by an expert and not the patients themselves."

"Cables is very annoying during installation especially when one of the poles is standing on the other side of the bed. On the other end having wireless connections and bluetooth everywhere around the patient is not preferred as well. Especially since the big discussion about insomnia of teenagers is coming up and the relation between different diseases and Wi-Fi radiation is becoming more clear. Lately we had a woman who did not want to sleep in a certain room since their were too many radiation providing devices around her. We had to place her into another room."

"The screen on the pole is preferred over the remote control on the cable since the patient already has the bell, pain killers (also a device on a cable with a button they need to push if they want more morphine), headphones on the side of the bed, etc. The people get confused on what device to use for what purpose."

"It is not the case that people who can drink are able to enter this information into the system. Especially after introducing the new way of doing surgery with the robot which means that they patients suffers from far less damage than before and can go home sooner. People undergo very heavy surgeries which takes for example eight hours, but they can already leave within a day. After surgery it takes a while for patients body to recover from all the drugs that are used on them. This mostly makes them confused, dizzy and a bit dull. Drinking water is easy, but thinking about entering fluids and how to use a new device is not."

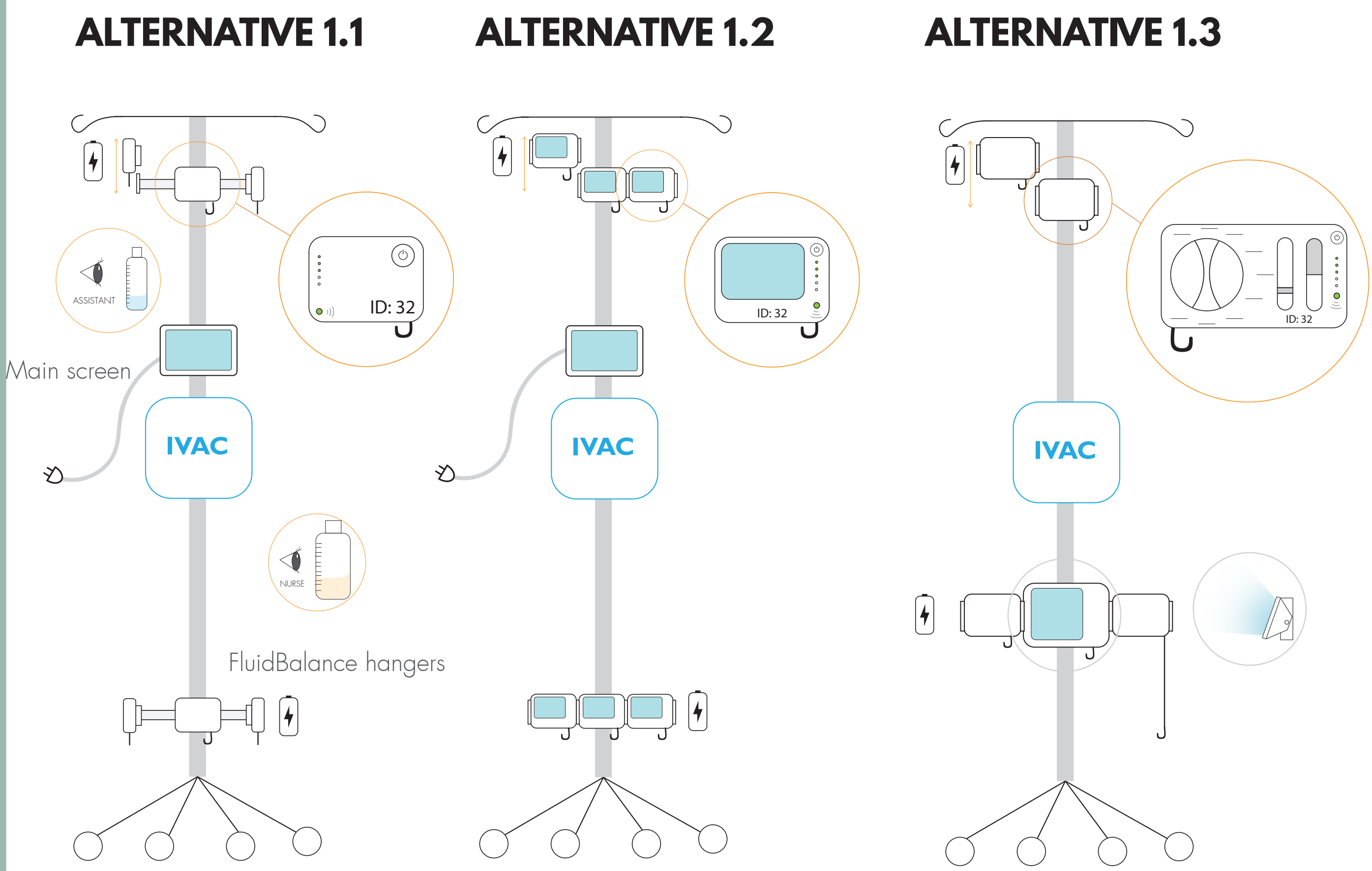
"During OR this device could be very interesting since this is the location where the patient only receivers fluids through IV and fluids exit the body through catheter. At the moment this is a demanding task which is performed by nurses which includes human errors. "

"Calculating the fluid balance nearby the patient is not necessary. I personally do not need to know the current status of the fluid balance nearby the patient since I can read it on the COW. Of course it depends on the department and how many COWs per department are available for the nurses. The more critical the patient the more chance that this person has a personal guard (the nurse) with a COW in the room."

"I hope people will still look at the device several times a day to do a check up if it is still working properly. Especially on this department (Urology) where people are in the hospital only to have a correct fluid balance and to be monitored. The device is a responsibility of the nurse and he or she should have a look now and then to check its functioning."

Which option or combination of options has your preference?

"No phones, no cables, in my opinion there is no connection to the patient and everything is kept on the pole for the assists. Saving the information nearby the patient has no extra value, so from the images shown my preference would be image four without the phone."



Description alternative 1.1

The IV pole is used as basis product. The FluidBalance hangers are relatively cheap since as less interaction as possible is happening at these devices. The devices are turned on, bluetooth connection light goes on, battery level is shown and when the nurse needs to replace/empty the bags (which means that she needs to work at the level of the bags anyway) the amount of fluid (since the fluid balance needs to be continued afterwards) needs to be frozen during replacement. The rest of the interaction (fluid selection, size of bag selection) happens at the main screen. The device is connected to the bracket which is always attached to the pole and when multiple devices are needed they can be connected to the other ends of this bracket. The oral intake is entered into the system on the main screen by the assist. Urine output is entered by the nurse or the patient (if adequate enough). Since most people (for whom regular fluid balance calculations are required) need help from the nurse to go to the toilet which is why entering the information by the nurse does not seem to be a big problem. The small devices contain batteries and the main screen will probably need to be connected to the wall socket some times.

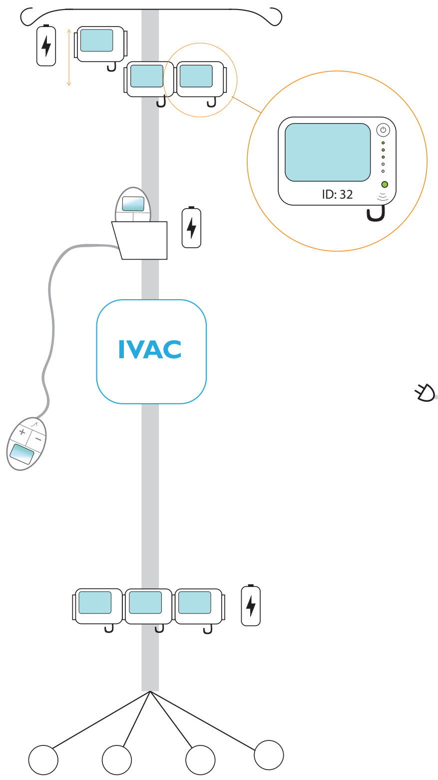
Description alternative 1.2

The two main differences between alternative 1.1 and 1.2 are the connection to the IV pole, the connection to each other and the level of interaction which is required at the main screen/ FluidBalance hangers. Alternative 1.2 does not require a bracket which is always attached to the IV pole. The device itself can be connected to the IV pole. Furthermore the devices can be connected to each other by sliding them into the integrated slots on the side of the product. This is considered to take in as less space on the IV pole as possible since the IV pole is used for storing other devices as well. Interaction regarding the FluidBalance hanger all happens on the FluidBalance hanger itself. This results in less possibility to interact with the wrong FluidBalance hanger, compared to operating the FluidBalance hangers from the main device, but will require a bigger battery (or more regular replacements) and a slightly more expensive product.

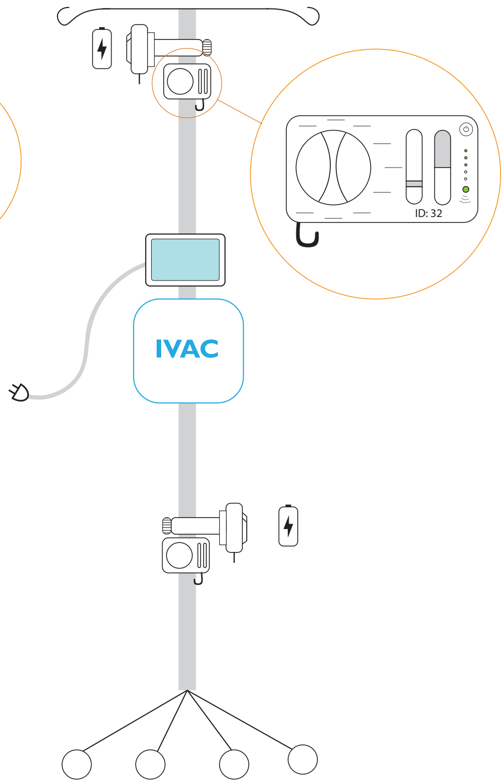
Description alternative 1.3

In alternative 1.3 the same connection method to the pole and between devices is used. Furthermore the concept is different since there is no longer a main screen. This alternative consists of two different types of FluidBalance hangers. The main FluidBalance hanger

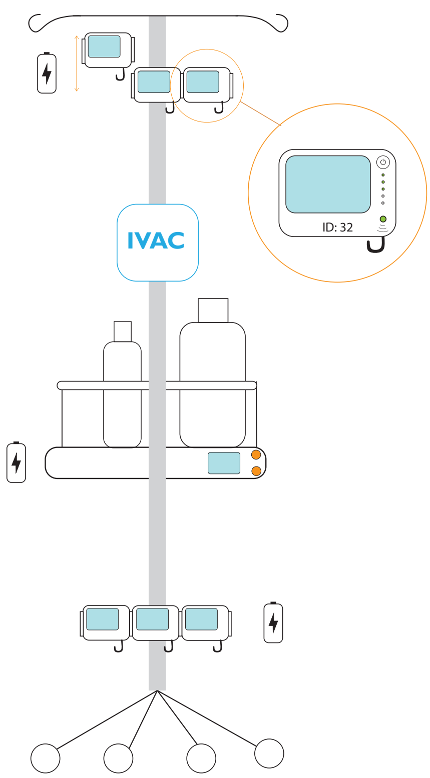
ALTERNATIVE 1.4



ALTERNATIVE 1.5



ALTERNATIVE 2



and the additional FluidBalance hanger. The main FluidBalance hanger is either connected at a height of 1,70 meters or 1,00 meters depending on what part of the fluid balance is installed first (catheter or IV). This means that lengthening of the cable is needed to hang the catheter on the require position. The main device will be used by the assist and the nurse to enter oral intake and urination/defecation values. The interaction regarding the set up of the FluidBalance hanger happens with the physical buttons on the devices themselves.

Description alternative 1.4

This alternative is very similar to alternative 1.2. The big difference is the choice to have a small remote like device which will serve to input fluid values apart from the values which are automatically generated by the FluidBalance hanger (food, drinks, urination). When a small and simple device is used including defecation into the process becomes more difficult. An advantage of using a small and simple device with less possibilities is the fact that the patient is able to use the device for entering urination / fluid intake values when the assist or the nurse is not around. Using a smaller and more simple device also leads to less energy consumption which means that batteries might be able to full fill this function.

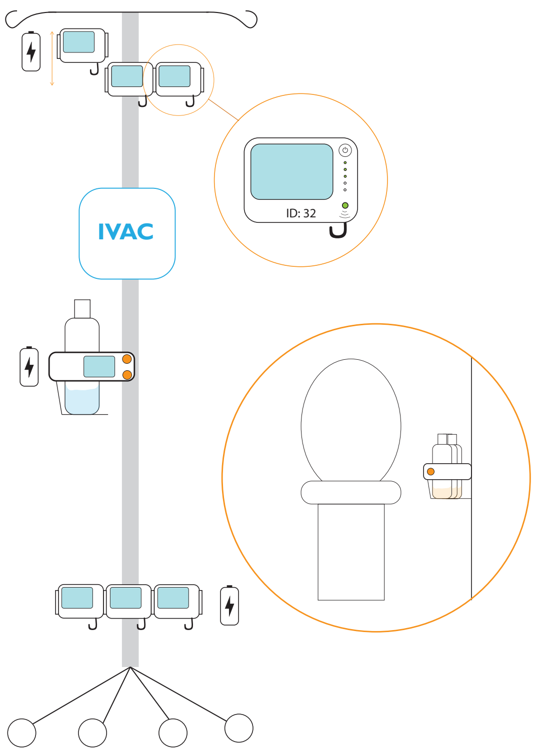
Description alternative 1.5

Alternative 1.5 is comparable to alternative 1.1 and 1.3. The main differences between 1.1 and 1.5 are the connection of the physical product to the pole and to each other. Like mentioned in the description of alternative 1.3 more interaction is happening on the FluidBalance hanger with use of different types of knobs and buttons.

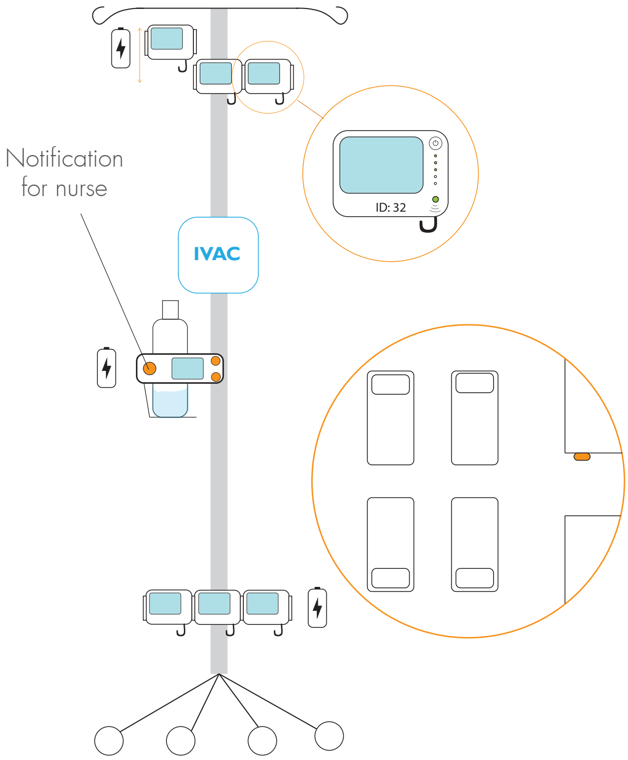
Description alternative 2

This alternative contains the same principle, interaction level and physical connections as alternative 1.2. The big difference is the addition of the scale to measure the weight of drinking water and urine (apart from measurements by the FluidBalance hangers) and the lack of the main screen. In this alternative the patient always needs to put his or her drinks in the holder after drinking. This accounts for the urine output as well. The patient is asked to gather all the urine output into one bottle which is placed in its holder on the pole. The nurse does not need to be involved into the process and the assist needs to be able to enter additional fluid intake which is present in the food of the patient.

ALTERNATIVE 3



ALTERNATIVE 4



Description alternative 3

Apart from the same connection methods and interaction level of the FluidBalance hangers this alternative is focussed on as less required loose input as possible. The drinking is measured by the scale and the urine is measured by another scale which is placed in the toilet. The patient needs to place the urine bottle into his own holder. In this way a standard place for the urine bottle is created, less work for the nurse is involved and the urine bottle does not need to leave the toilet. Since a smaller and smart interface is needed a battery will probably be enough to provide the required energy.

Description alternative 4

This alternative is comparable to the previous one. The differences are the placement of the bottles (on a place that is easily accessible for the nurse) and the level of responsibility of the patient. The patient is not the one who will be responsible for the weighing of the bottle, but the nurse. This requires communication between the patient and the nurse when toilet was used (by integrating a toilet button on the device for example) or regular check ups by the nurse. The patient probably does not go to toilet every hour. So when choosing for a toilet button the nurse only needs to check upon the specific patient when FluidBalance received input from this button.

Description alternative 5

Alternative 4.1 both has physical interaction with the fluids and automated scale. The drinks are being measured by the automated scale, but the urine is measured by the nurse by reading how much was urinated and filling it in onto the scale. The patient notifies the nurse with the button or regular check ups are done by the nurse.

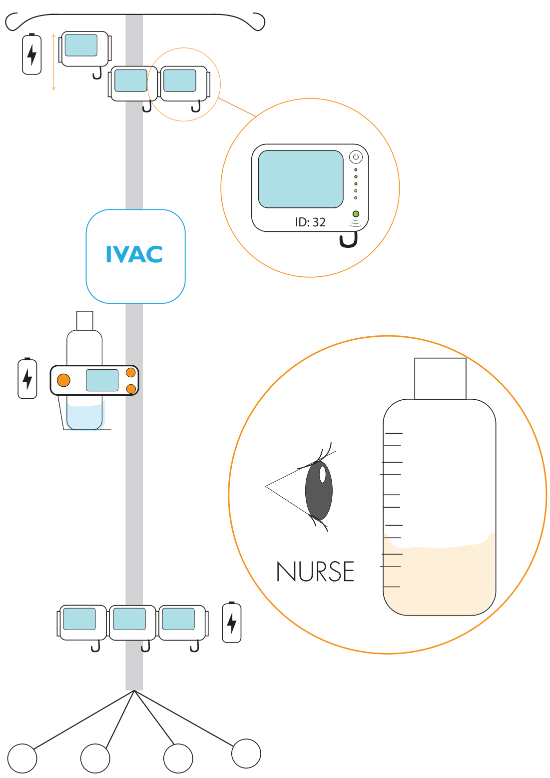
Description alternative 6

The only difference between alternative 4.2 and 4.1 is the responsibility for entering the fluid values of the urine. In this case the patient reads the values from the bottle and enters this into the system.

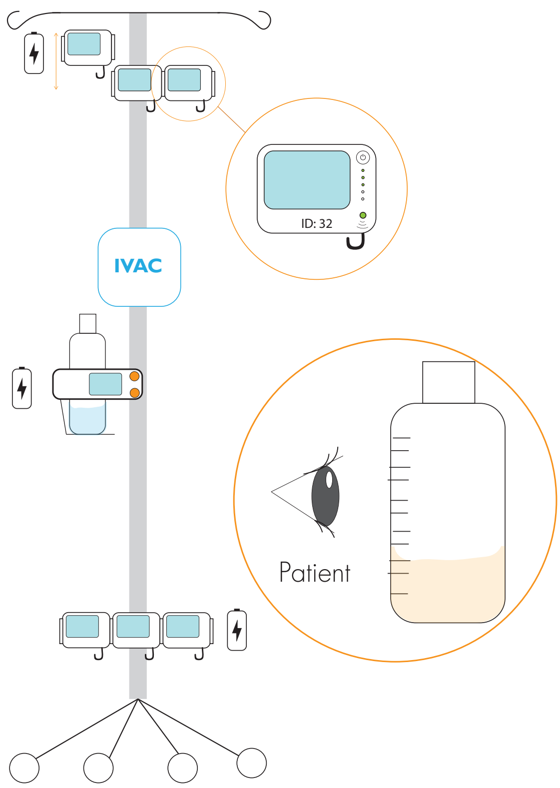
Description alternative 7

In alternative 5.1 it is not the nurse but the assist who needs to enter information into the system. The assist uses the main screen to enter information about drinking consumption and the fluids in the patient's food. The patient is responsible for urinating into the bottle and placing the bottle where it belongs. The measurements of urine volume will be done by the scale (in the toilet).

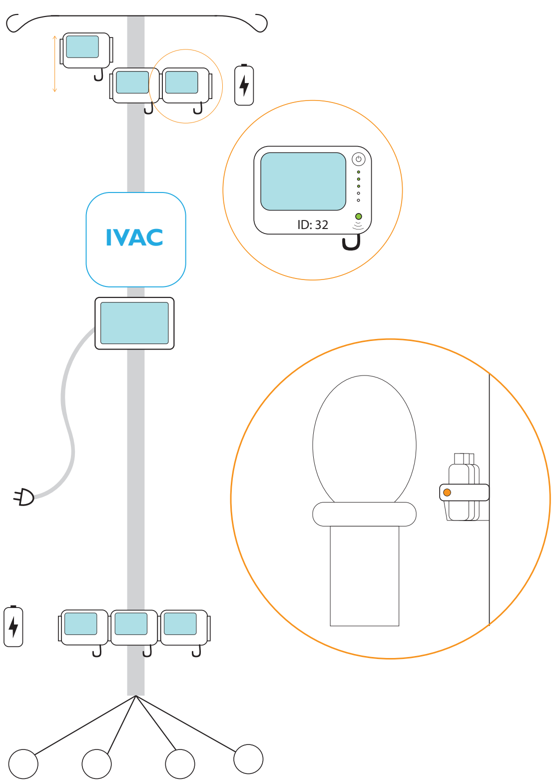
ALTERNATIVE 5



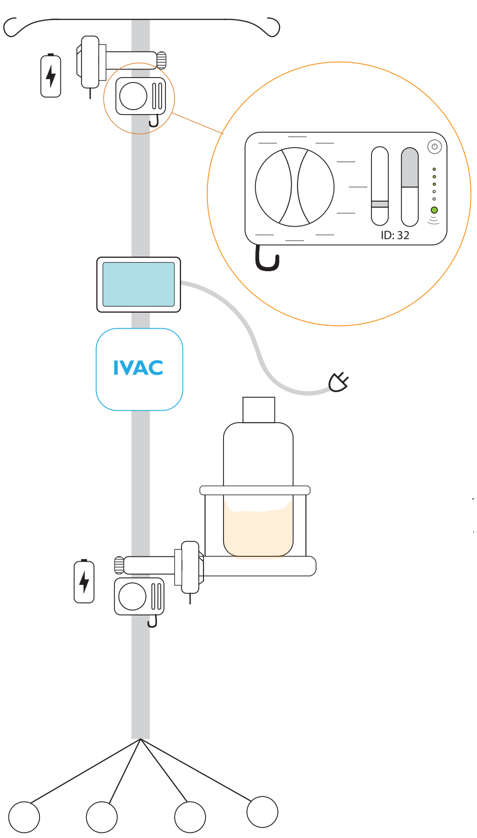
ALTERNATIVE 6



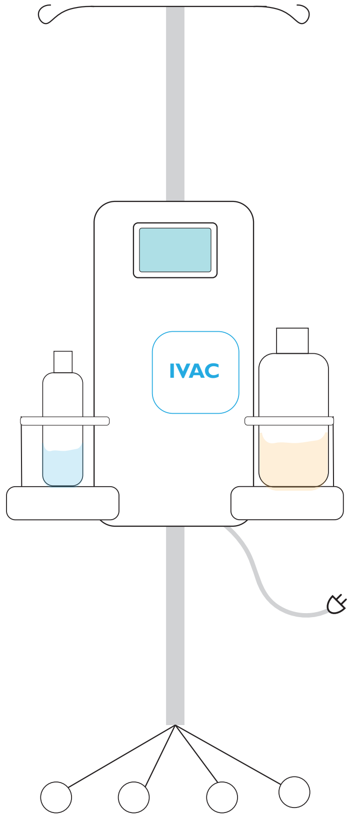
ALTERNATIVE 7



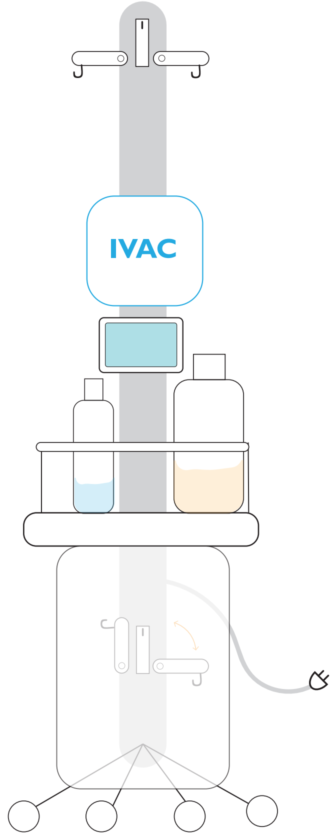
ALTERNATIVE 8



ALTERNATIVE 9



ALTERNATIVE 10



Description alternative 8

In Alternative 5.2 the scale is moved to the IV pole of the patient which means that it will be more directly connected to the FluidBalance system since it can be clicked onto the FluidBalance hanger.

Description alternative 9

Alternative 6 is a complete integrated product in (or behind) which both the IV bag and the catheter are hidden. Both urine and drinks are weight which means that both nurse and assist (only for fluids in food) do not have to enter (much) information into the system. Since both bags are not hanging on the position they normally need to hang to create enough flow a vacuum pump is needed to make sure that the fluids will either enter the patient's body or enter the catheter bag. The vacuum pump (image ...) works by placing the fluid hose into the pump and having a rotating part pressing onto the hose. The fluid is only able to go up. Most mini vacuum pumps are able to pump up to three meters height which is more than enough.

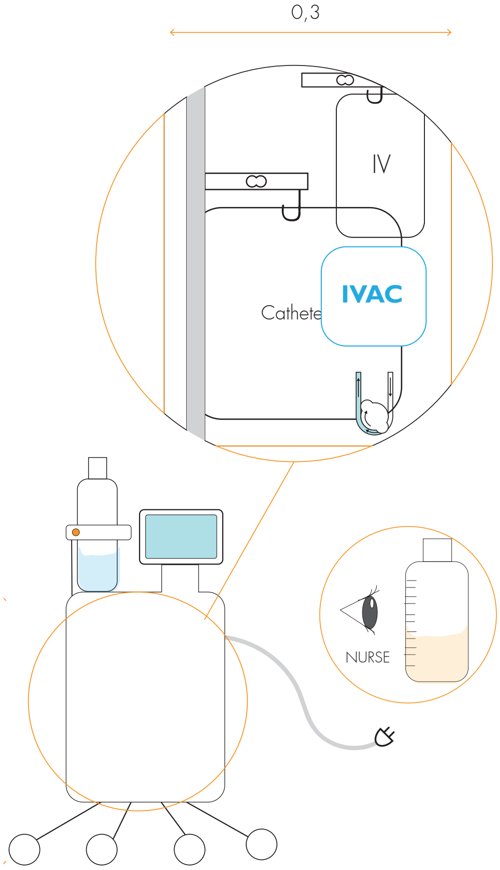
Description alternative 10

This alternative is a complete integrated solution. A separated IV pole is designed with integrated technology and weigh modules. The modules can be rotated before connecting a bag that needs to be monitored. By integrating the technology into the IV pole it is able to have one charging point. Furthermore it is easier to integrate ways to hide the urine bags from the user. In this alternative both the drinking water and the urine is being weighed which means that the nurse and the assist do not need to come by very often to enter information into the system. The separate screen is placed at an ergonomic height. Choosing this system means that every user (also users who only require oral intake and urination monitoring) need to have such a pole next to their beds.

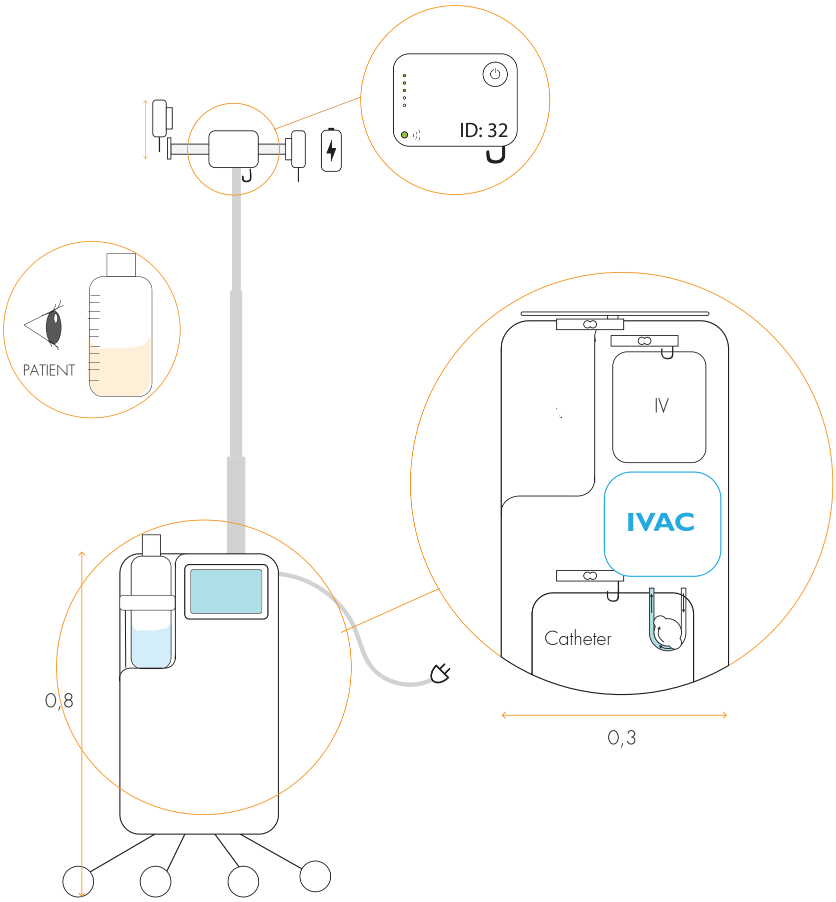
Description alternative 11.1 and 11.2

In alternative 8.1 and 8.2 special attention is paid to hiding the bags and creating an as unobtrusive device as possible. The same vacuum pump as discussed in alternative six will be necessary to create enough pressure to move the fluids. The product needs to be at least 40 cm heigh and not higher than 90 cm since the patient needs to be able to reach the drinking bottle/

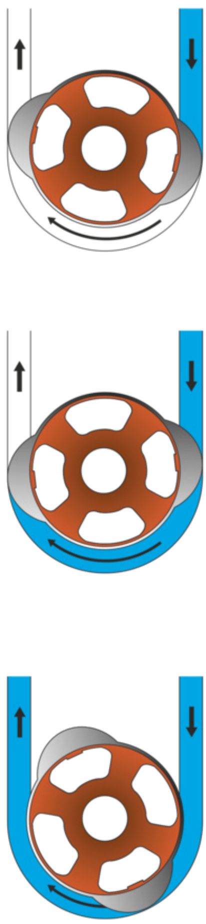
ALTERNATIVE 11.1



ALTERNATIVE 11.2



glass from the bed. The IV requires a certain vertical distance for the placement of the IV bag, the IVAC and vacuum pump. Since the catheter bag is 28 centimetres wide a minimum width of 30 centimetres is required. In alternative 8.1 the thickness of the box is used by placing the IV parts in front of the catheter parts.
These alternatives are very suitable for be used in situations where the patient only needs a catheter (and IV) for a longer period and needs to take the catheter home or back to the care home. Expanding this alternative with more bags above the patient can be solved with an extendible arm on top of the product. Expanding the product with multiple bags beneath the patient is not the best solution since either the total device will become very large or a crowded situation in which the nurse needs to be on her knees to enter the bags arises.

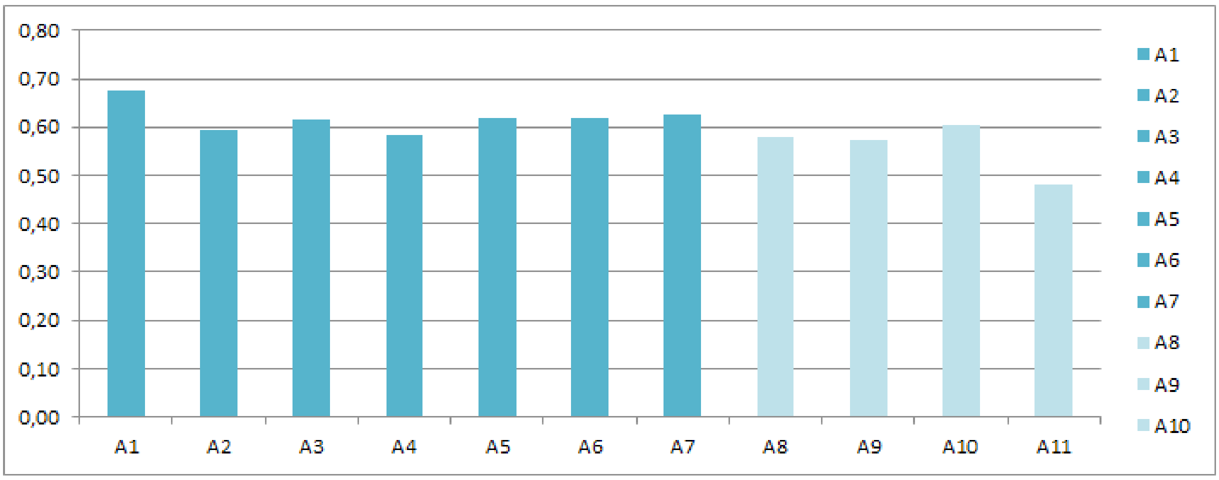


Comparison and conclusion

With help of hard requirements and wishes a comparison of the alternatives was made. The criteria were mutually compared to find out which criteria are the most important and how much their weight needed to be in the comparison. The first three criteria are hard requirements that need to be met. This is why alternative 8, 9, 10 and 11 will not be considered since they score below 0.5 (0.5 = sufficient). The other alternatives mostly had very similar outcomes since they score good and bad on evenly important criteria.

Alternative 1 had the best score and can therefore be interpreted as the best solution. Since the other solutions are still very interesting further preferences regarding the alternatives will be researched during interviews with medical experts (and patients) in the UMCG.

Criteria	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11	Weight
Easy use in all required situations	0,9	0,7	0,7	0,7	0,7	0,7	0,9	0,2	0,2	0,2	0,3	1,00
Possibility to expand the product	0,9	0,9	0,9	0,9	0,9	0,9	0,9	0,9	0,2	0,9	0,2	1,00
Easy to combine with other necessary products	0,9	0,7	0,8	0,8	0,8	0,8	0,6	0,6	0,8	0,6	0,4	1,00
Possibility to decrease patient responsibility	0,9	0,5	0,6	0,6	0,7	0,4	0,7	0,7	0,5	0,5	0,7	1,00
Ergonomic work height nurse and assist	0,9	0,7	0,7	0,7	0,7	0,7	0,9	0,9	0,9	0,9	0,4	0,80
Assist workload level	0,5	0,9	0,9	0,9	0,9	0,9	0,5	0,7	0,9	0,9	0,9	0,90
Clear overview of current balance for the nurse	1,0	0,7	0,7	0,7	0,7	0,7	1,0	1,0	1,0	1,0	0,7	0,50
Nurse workload	0,5	1,0	1,0	0,5	0,5	1,0	1,0	1,0	1,0	1,0	0,5	1,00
Nurse workload on installing the product	0,7	0,5	0,5	0,5	0,7	0,7	0,5	0,5	0,9	1,0	0,9	0,80
(Personal) contact moments	1,0	0,5	0,6	0,8	0,8	0,5	0,8	0,8	0,5	0,5	0,8	0,60
Complexity of system (investments)	1,0	0,6	0,6	0,6	0,8	0,8	0,6	0,6	0,6	0,3	0,4	0,70
Hygienic (feeling)	0,7	0,7	0,7	0,7	0,7	0,7	0,6	0,6	1,0	1,0	1,0	0,70
total	0,68	0,59	0,62	0,58	0,62	0,62	0,62	0,58	0,57	0,60	0,48	



Research UMCG – applicability / preferences

Introduction

Since the criteria method led to the fact that the different alternatives scored quite similar. This was mainly due to the fact that an important criteria like: "possibility to decrease patient responsibility" and "nurse workload" are both very important. A low score on one of these criteria led almost automatically to a high score on the other criteria which lead to the discussion which of these criteria is the most important, if it is true that the workload differs as much for the different alternatives and what the opinion on applicability is of medical experts of different departments based on their experience. A selection of alternatives was made which contains important factors of all the ideas that need to be tested. The alternatives, called "concepts" can be found on the bottom of this page (image P.1). The different alternatives differ on workload for the nurse, the assist and the patient. Furthermore they differ on interaction with the different screens to find out what option is preferred by which departments. The qualitative interviews will not serve to make a direct choice between the different "concepts", but rather to find preferences regarding system parts, interaction and division of responsibilities.

Research question

How much of the process needs to be automated to keep / lower the workload of the nurse while keeping in mind level of patient responsibilities and possible errors?

Sub questions

- How many contact moments are there on a regular day on the different departments?
- Are these contact moments still there when FluidBalance is introduced?
- What is preferred comparing multiple screens to enter information which requires less interaction steps (in the interface) or having one screen on ergonomic height which requires more steps?
- What new insights does a research on the different departments are gained for the project?

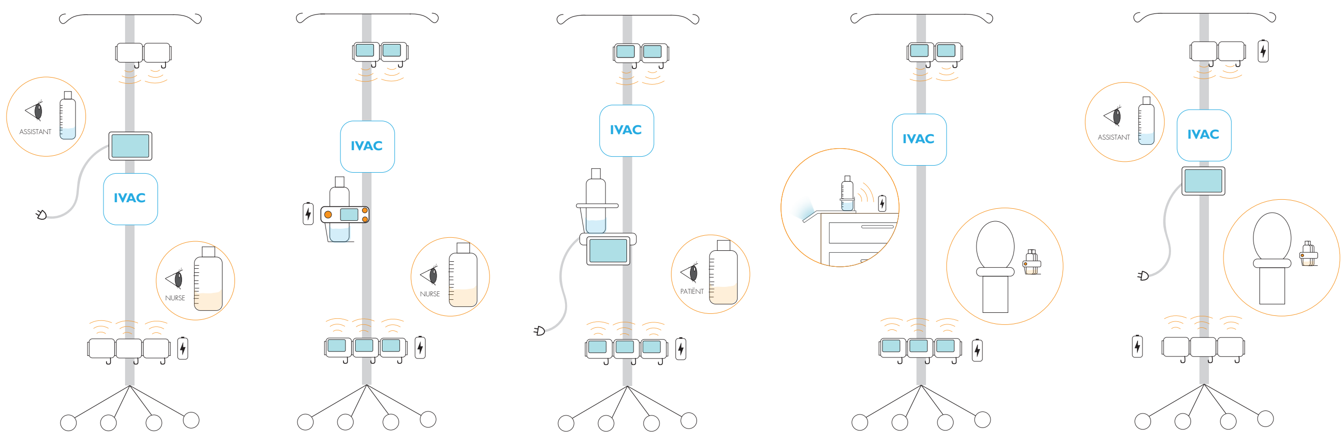


Figure 19.1: Selection of different levels of automating the system for the research at the UMCG

Method

Participants
The core purpose of the research was to talk to the different departments that would be the first facilitators of FluidBalance since the patients on these departments can encounter the most benefits from a healthy fluid balance. Therefore the following participants were chosen:

- Bert, Eric and Rolf from the intensive care department
- Harmke and John from the elderly care department
- Ingrid from the nephrology department
- Miriam from the cardiology department

The participants differ in age between 30 and 60 years old. Their amount of experiences differ between 10 and 27 years.

Stimuli / apparatus
For the conversation several visuals were created which were used as both underlayer and discussion material. One phone was used to record conversations.

- Underlayer daily contact moments (appendix 20)
- Print outs of the application (appendix 21)
- Print out of the total overview of the applications (appendix Q)
- Print outs of the selected "concepts" (figure 19.1)
- The patient personas (appendix 14)

Location
The conversations were held at different spaces since the participants worked at different departments. Most of the spaces contained a table and were quiet enough to discuss about the alternatives.

Procedure
The research consisted of two different phases. The first phase started with a small introduction on what the goal of the project is. Secondly the underlayer was explained and together we discussed about the daily activities. The researcher asked clarifying questions when needed. Finally this phase ended by discussing the different personas and giving a short explanation of what types of patients can be expected at that specific department and what types of patients are rather exceptional than usual. Figure 19.2 shows what the table looked like during this phase.
The second phase consisted of the assessment of the different "concepts" and their applicability to that specific department (figure 19.3). The researcher first explained the concepts (Figure 19.1) and showed what kind of application could belong to this concept including the amount of steps that need to be taken when entering specific information. The daily overview that was just filled in by the nurse was kept on the side to see if the concept could fit the department regarding workload for the assistant and the nurse. The piles of the interface were placed on the table as well to show what size the interface will approximately be and what the nurse thinks of this size. Figure 19.4 shows the other two application options. Concept one and five were combined with application type A, concept two was combined with application type B, concept three and four were combined with application type C according to their screen sizes and whether they can be administered by one main screen or multiple screens of the FluidBalance hangers themselves. After discussing the several combinations and preferences a score form was given by the nurse to score the different concepts on: user friendliness, workload for the nurse, workload for the assistant, the riskiness of the concept, the total fit of the concept on that specific department and whether such a concept would be better than the current situation.

Data analysis
The preferences will be mostly written down by the researcher , recorded and written down in the assessment form.

Results

The results regarding daily overview and the preference for the amount of screens and system parts are put into overviews per department. The next few pages will show these overviews.

Each overview contains a big circle with contact moments. The orange dots are the contact moments of the nurse and the blue dots are the contact moments of the assistants. The light blue drops represent check up moments when every hour check up is required. In the middle of the circle the patient profiles (like described before) that are present at that specific department are shown. Finally the left side of the image shows the preferred concept and interesting notes.

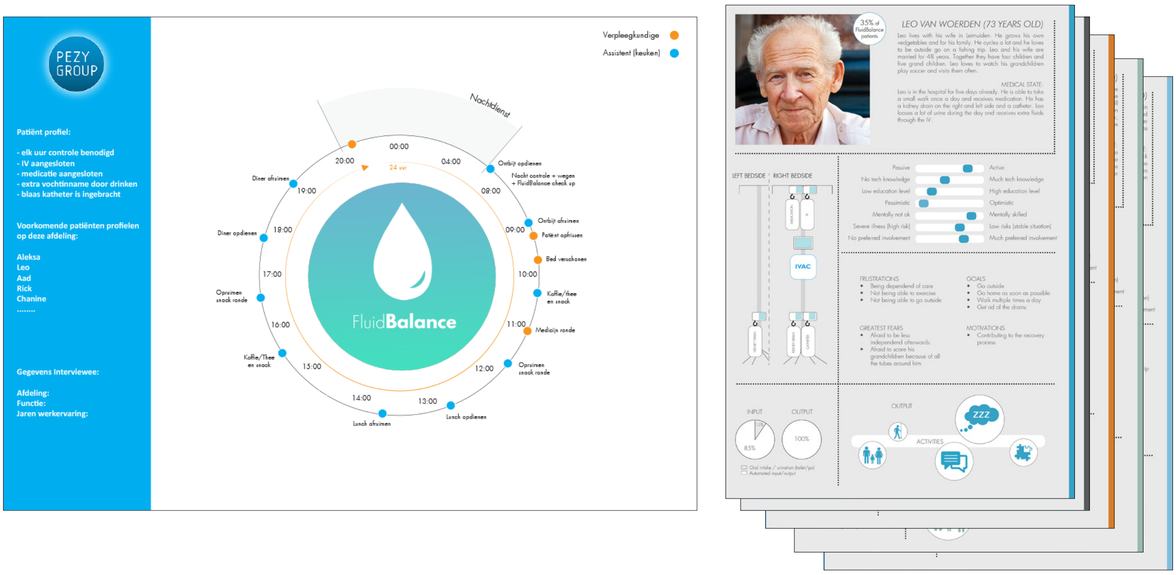


Figure 19.2: Phase one of the reseach at the UMCG

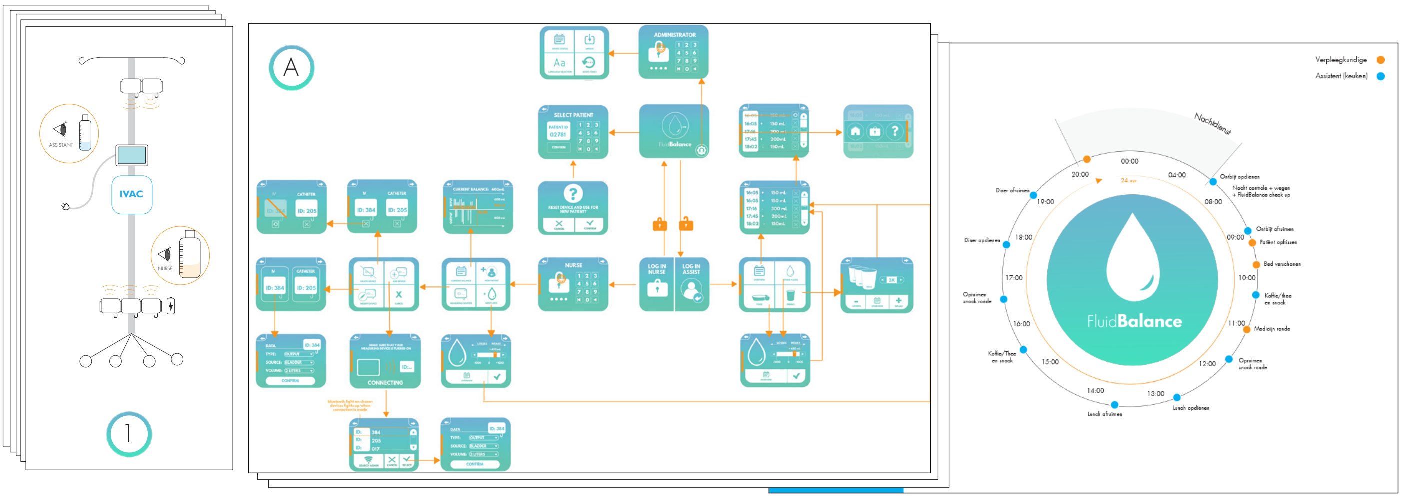


Figure 19.3: Phase two of the research at the UMCG

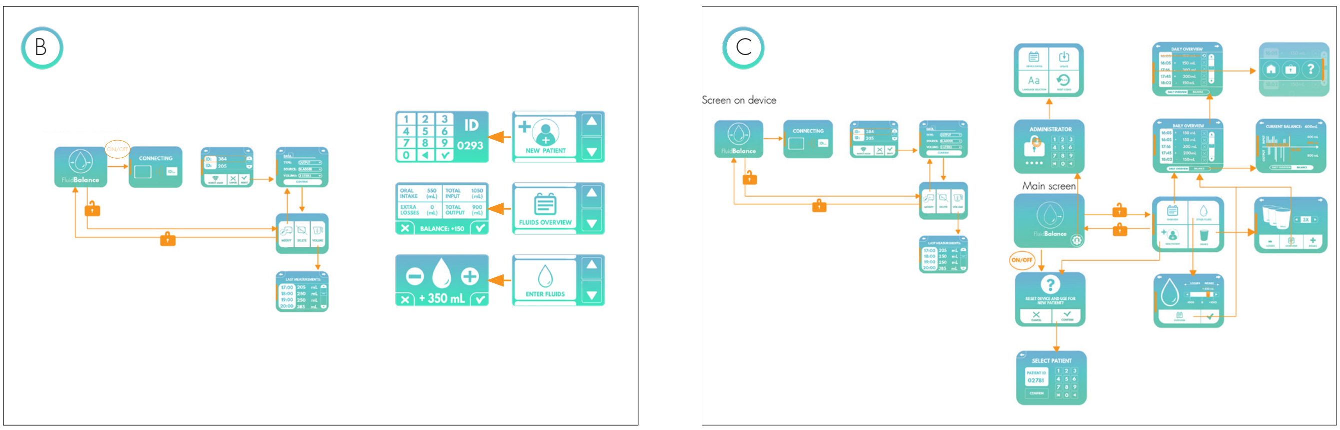
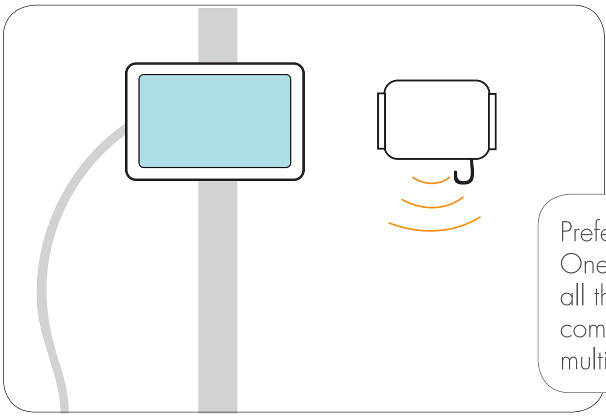


Figure 19.4: Two other applications overviews

INTERESTING NOTES



Preference:
One screen to enter and read all the information. Rather more complicated application than multiple screens.

At the moment all the IV bags are replaced around the same time. This is to prevent nurses from having to walk around to replace bags all the times and having to remember which bags need to be replaced when.

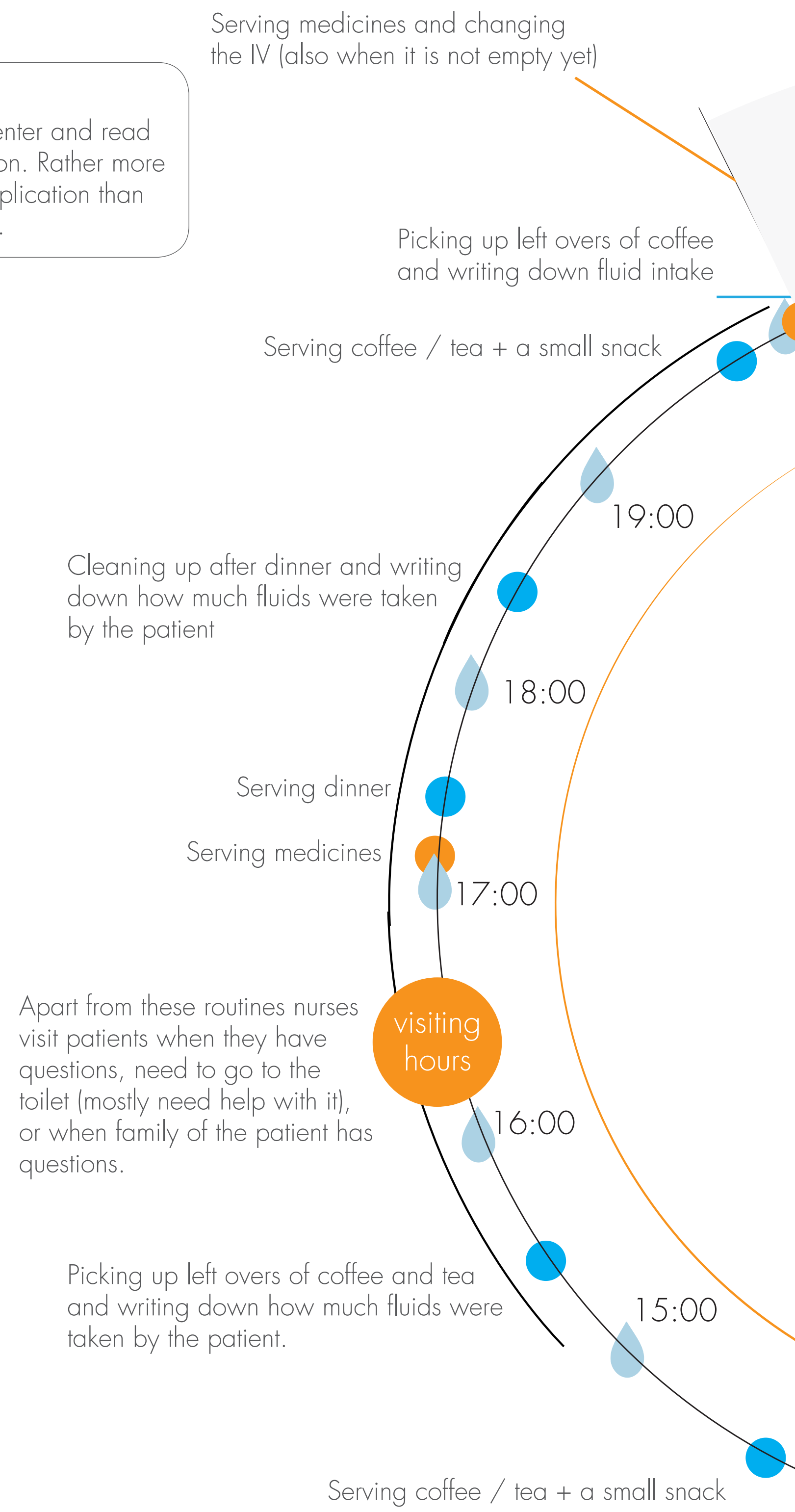
A bolus (administer a medicine via the IV) needs to be entered into the system as well since it contains fluids. Where do you draw the line? Only liquid medicines are entered? When serving medical pills the nurse mostly offers a cup of water to swallow the pills with. This glass of water is written down on the fluid list by the nurse.

Urine is not saved in a bottle for 24 hours. Urine is only saved when this is required. It is mostly written down and thrown away immediately. This is why option two and five are not applicable to this department. Weighing of the drinking water would be interesting to increase accuracy on the amount of water that is being drunk by the patient. Unfortunately this requires patient cooperation and since most of the patients are slightly confused and very old this is not preferred and would only evoke more error possibilities.

NURSE

ASSISTANT

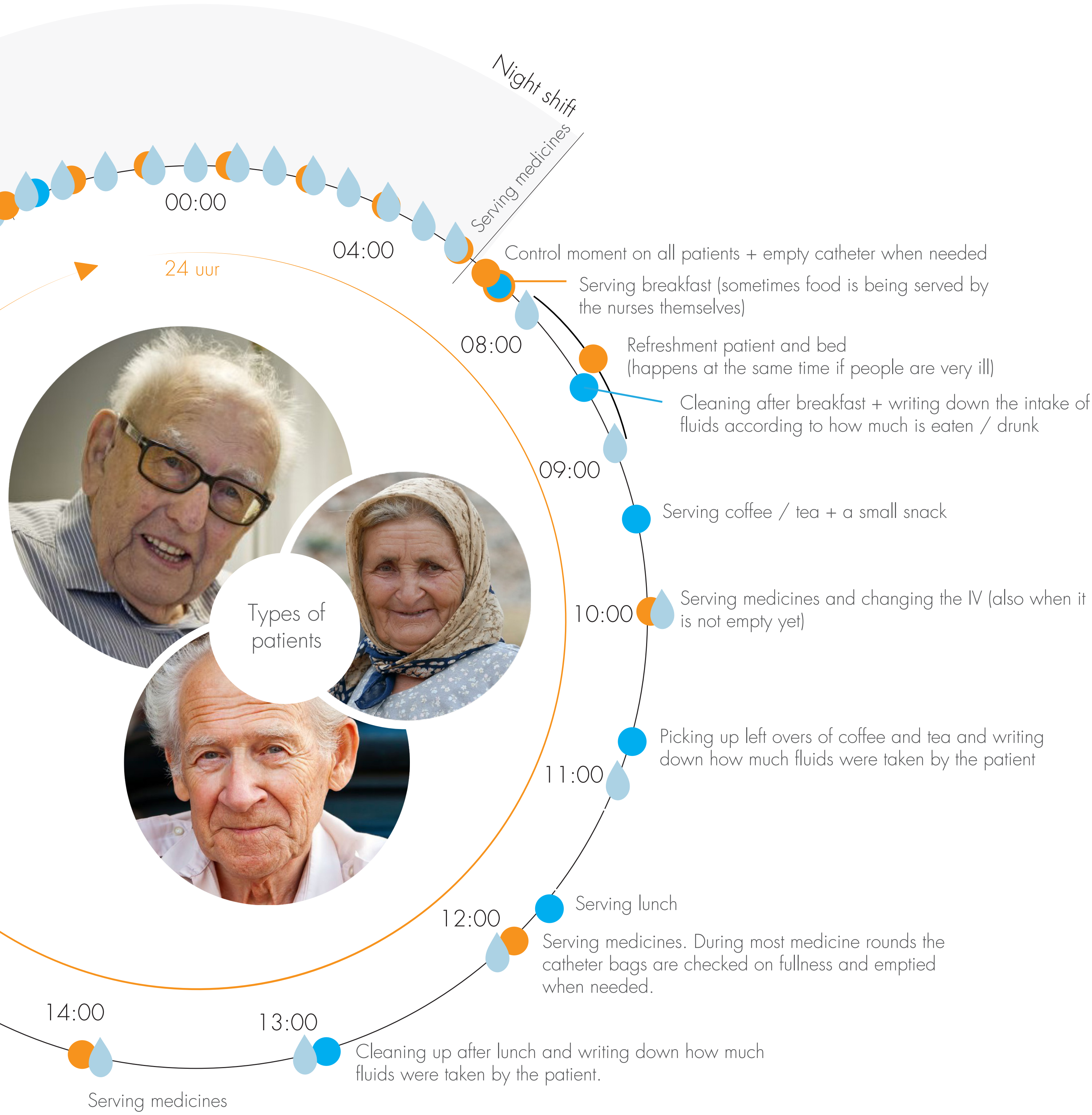
CURRENT CHECK UP MOMENTS FOR FLUID BALANCE



Most common patient profile:
confused people
need a lot of help (with toilet, walking, etc.)
drinks are served by nurse (with medicines) or assistant
fluid balance every 24 hours. Sometimes every 6 hours.

DEPARTMENT: ELDERLY CARE (GERIATRICS)

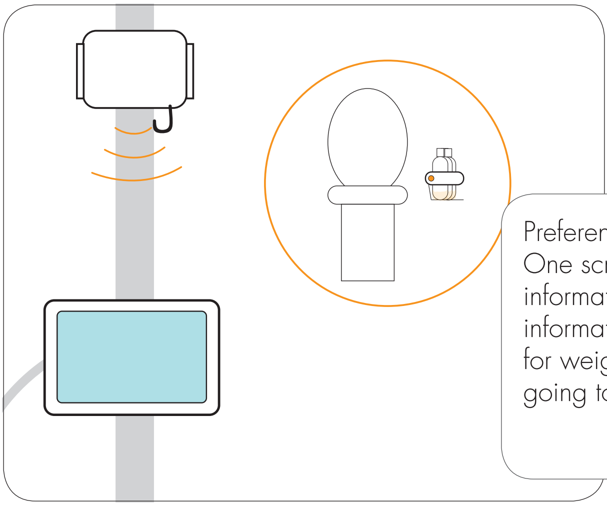
During the night the standard control moments are every two hours.



General information interviewed nurses:
Harmke (head nurse of ICV4)
John (nurse at ICV4)

FluidBalance

INTERESTING NOTES



Preference:
One screen to enter all the information and reading information. Interest in a platform for weighing the urine after going to the toilet.

The nefrology department and the intensive care hospitalize more younger people compared to for example the geriatrics and the cardiology. The intensive care hospitalizes people who are very ill, need continuous monitoring and are not able to take care of themselves. At the nefrology department this is different. Patients still needs accurate monitoring to make sure that their kidney is functioning properly, but most of them (60% was estimated by two nurses of the UMCG) is able to take care of their own fluid list and they often do this. At the nefrology department (which is different from the other departments) most people do understand the importance of a correct fluid balance since this is the main reason that they are hospitalized.

Interested in a standardized place for the urine bottles since a part of the patients can go to the toilet themselves and is able to place a bottle back on the same place to weigh how much urine is added. It is not necessary to save the urine anymore when all urine is being entered into a system automatically after a patient went to the toilet.

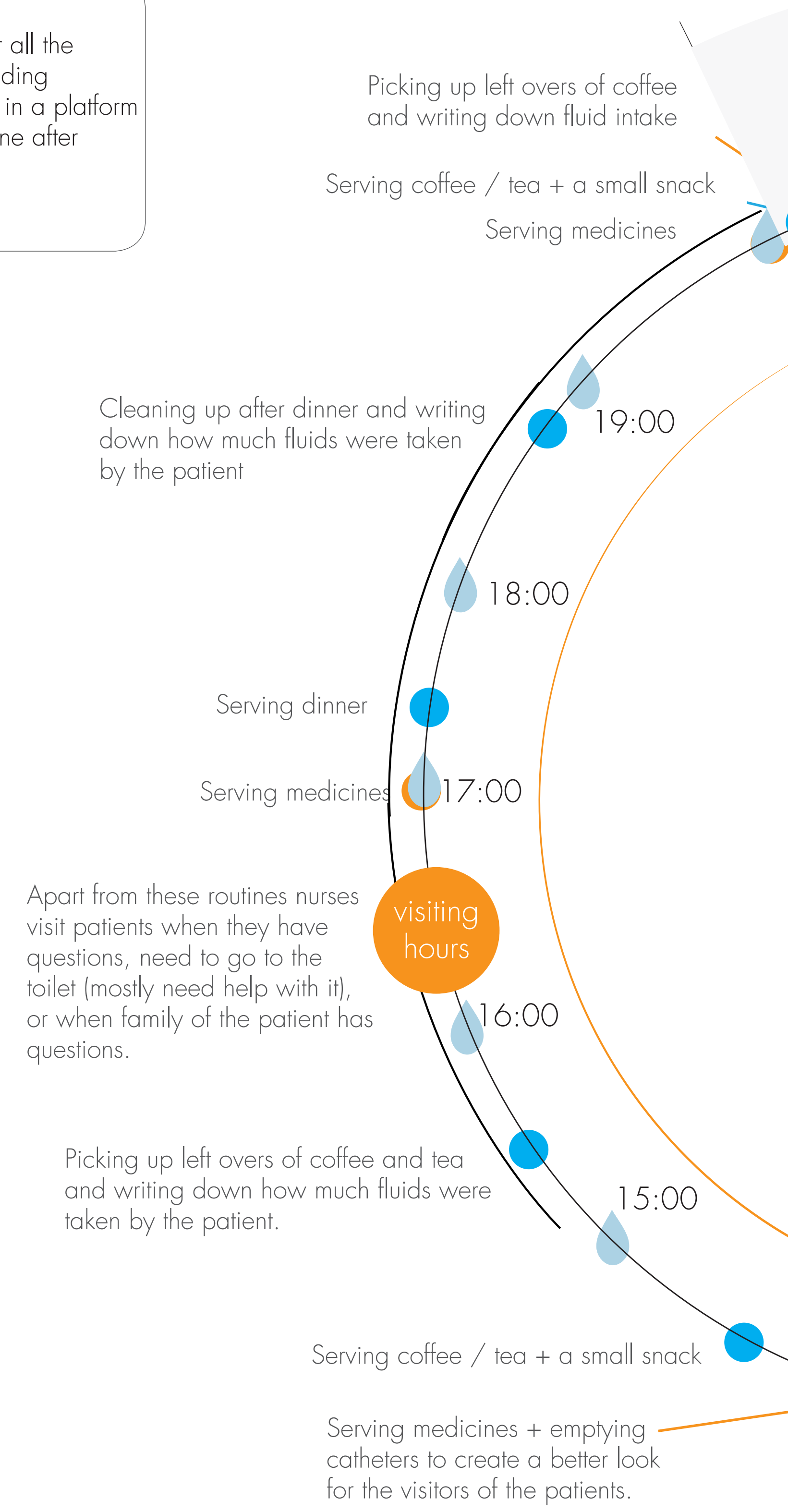
The difference between man and women is important too. Man can just pee into their urinal or into the saving bottle directly. Women need to pee into a po first and pour it over into the saving bottle which is a difficult task when you had surgery on your kidneys.

In general urine is more important than oral intake at this department since the functionality of the kidneys is being monitored. Ingrid's opinion on having a weighing platform for drinks is therefore less positive. Apart from the fact that she thinks it will only lead to more errors, limitations for the patient to place their drinks where they want and the placement of the IV pole is more limited. The night closet is loaded with too much stuff of the patient and creates even a bigger risk of influences of the weight.

NURSE

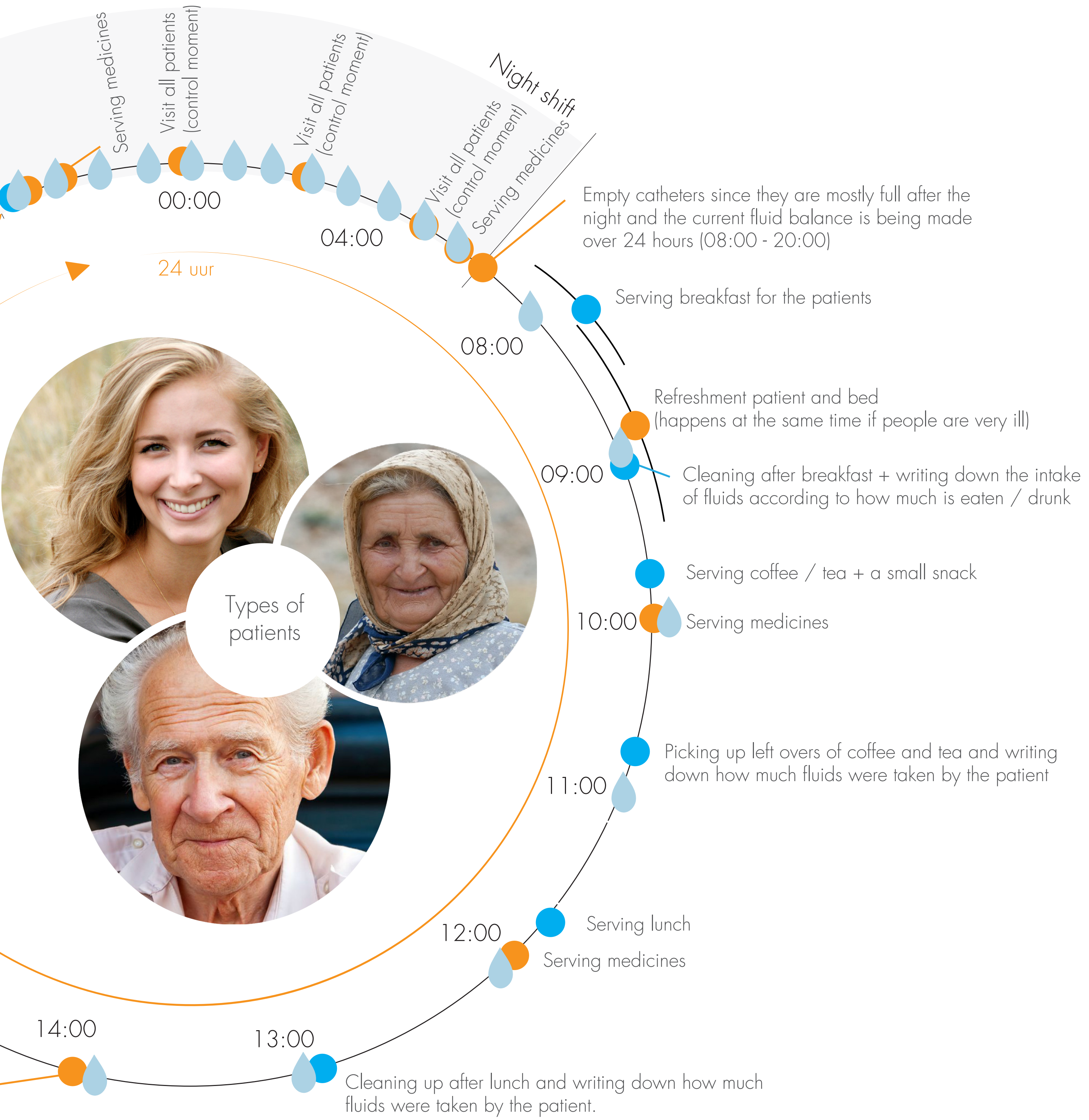
ASSISTANT

CURRENT CHECK UP MOMENTS FOR FLUID BALANCE



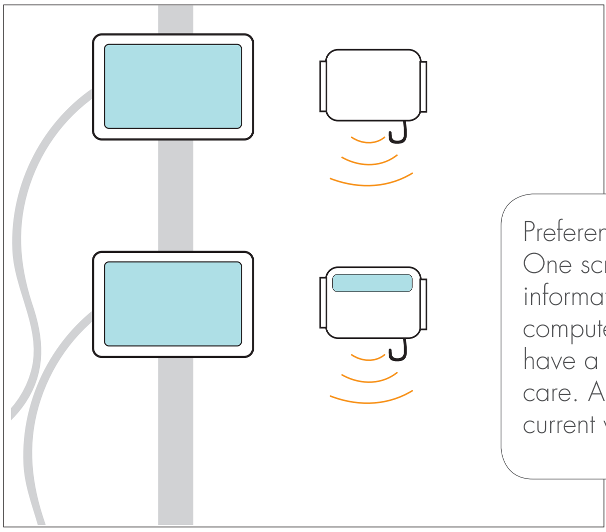
Most common patient profile:
drinks are served by nurse (with medicines) or assistant
fluid balance every 24 hours. Sometimes every 6 hours.
mentally healthy and able to take care of themselves partly
known by the people that urine needs to be saved for 24 hours.

DEPARTMENT: NEFROLOGY (INTERNAL HEALTHCARE)



General information interviewed nurses:
Ingrid (nurse at Nefrology)

INTERESTING NOTES



Preference:
One screen to enter all the information. This might be the computer as well since all beds have a computer at Intensive care. A small interface with current volume and type of fluid.

On the intensive care it is all about efficiency and being able to quickly look into things when needed since most actions are critical and unplanned. Logging in would take too long in some of these situations. The tag (which will be introduced in 2018) will already make a big difference.

All three nurses independently preferred to have one screen instead of multiple places to enter information. One of the nurses mentioned that having a small screen on the devices would help to see whether the correct connection between the main screen and the device is being made. "Some times blood losses need to be monitored every 15 minutes,which means that all the steps that need to be taken are actually one too many". He suggested having the option to set priorities on which screen appears immediately when the interface is being touched.

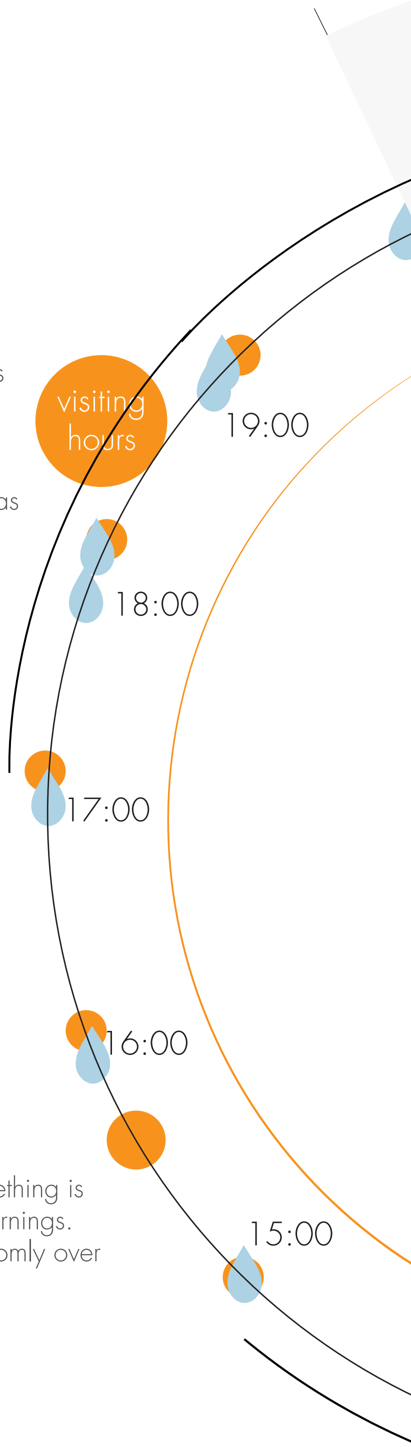
Since fluid losses are very critical at the intensive care all possible measurements are taken. Diarrhoea is being weight since it is captured with the FLexi Seal, an inserted hose through the anus to help the diarrhoea flow towards a bag (image below). Research is being done on how to measure transpiration on intensive care patients. Puke is nowadays not being measured since it is very hard to control the moments and since the people are not very mobile it mostly ends up somewhere in the bed. Sometimes an estimation is being made and written down on the fluid list.

NURSE

ASSISTANT

CURRENT CHECK UP MOMENTS FOR FLUID BALANCE

Apart from these routines nurses visit patients when they have questions, need to go to the toilet (mostly need help with it), or when family of the patient has questions. (17:00 - 07:00)



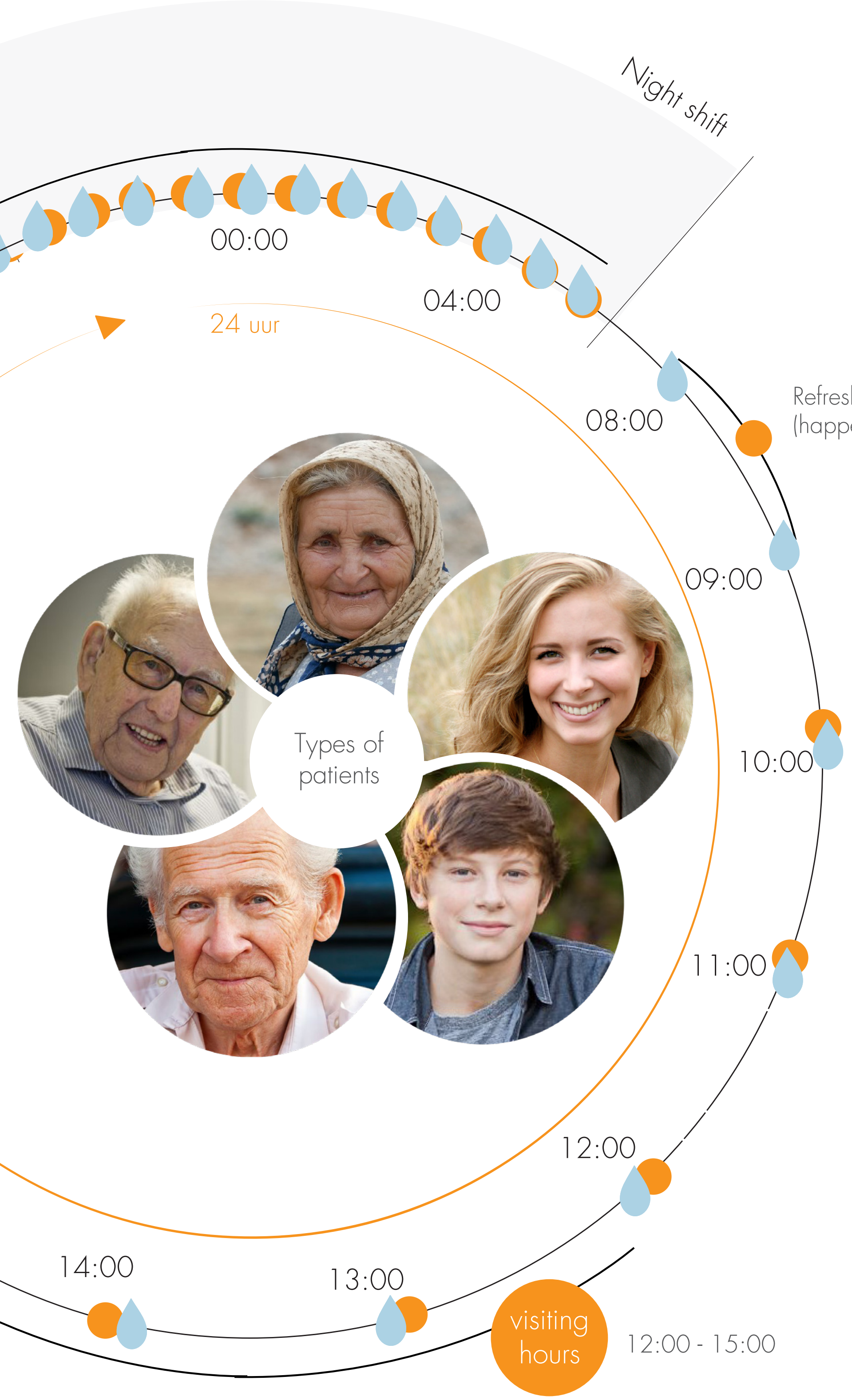
Emergency check ups when something is going wrong and we receive warnings. These moments are divided randomly over the day and different patients.

Patient profile:
multiple bags ingoing and outgoing
not being able to walk
drinks are carefully monitored by the nurses
every hour control on vital functions is necessary

DEPARTMENT: INTENSIVE CARE ADULTS

During the night the standard control moments are still every hour. The ICV is a 24 hour care department.

At the Intensive care normally no food assistants or healthcare assistants are present since most of the patients are not able to eat by themselves and do not drink. Furthermore the situation is mostly too critical to leave medical tasks assistants.



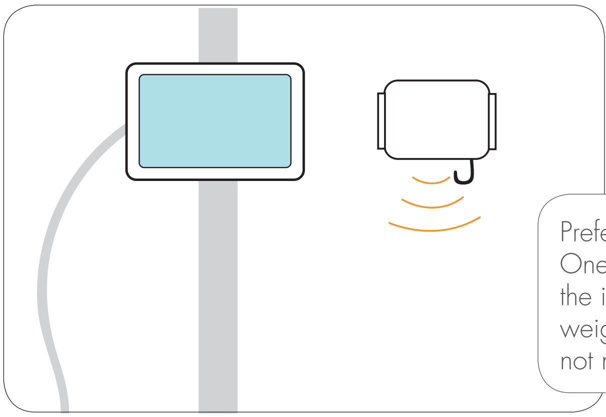
Refreshment patient and bed
(happens at the same time if people are very ill)

Hourly control on every patient
catheter check (turn over and write down values)
medication control
IV control
control of other drains
Redon drainage (when vessels are removed)
control of vital functions of the human (heart rhythm, blood pressure, etc.

General information interviewed nurses:
Bert (head nurse of ICV4)
Eric (nurse at ICV4)
Rogier (nurse at ICV4)

FluidBalance

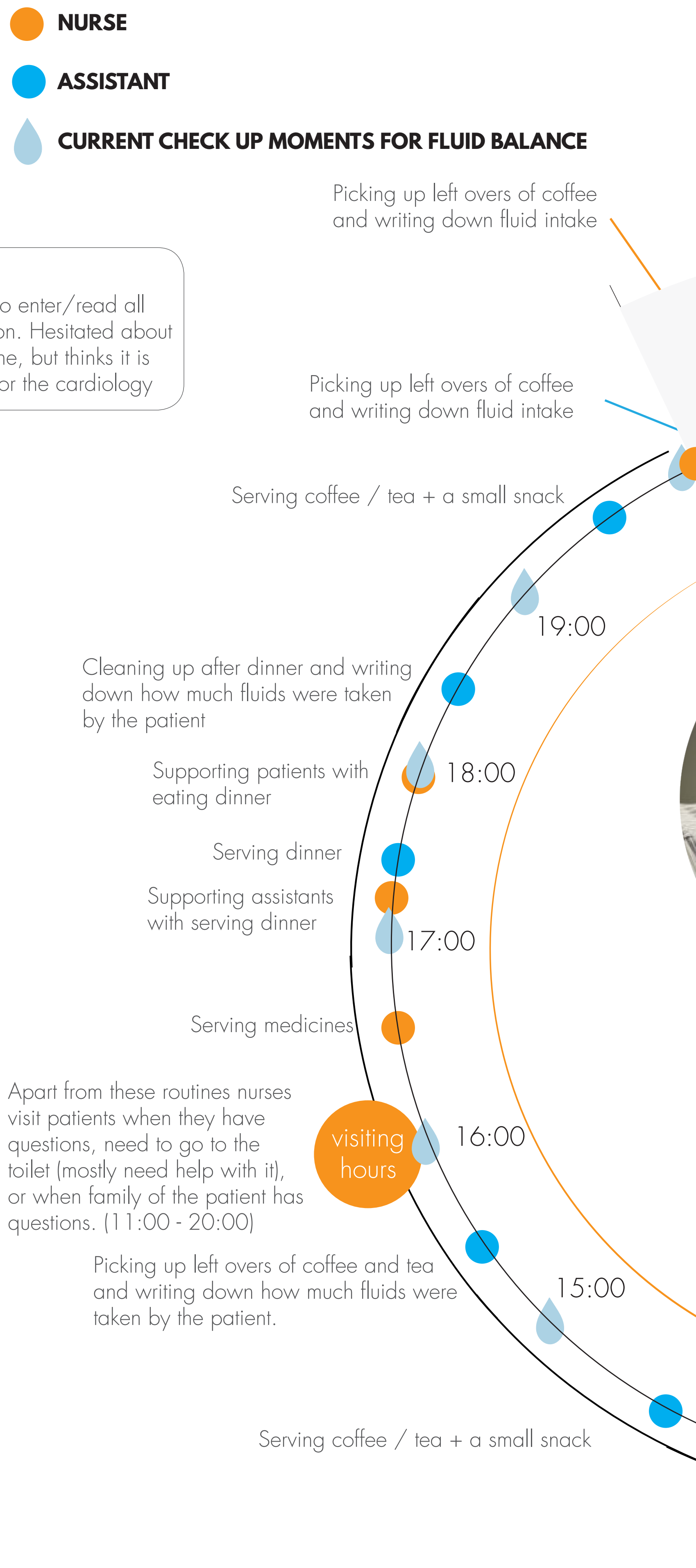
INTERESTING NOTES



Preference:
One screen to enter/read all the information. Hesitated about weighing urine, but thinks it is not needed for the cardiology

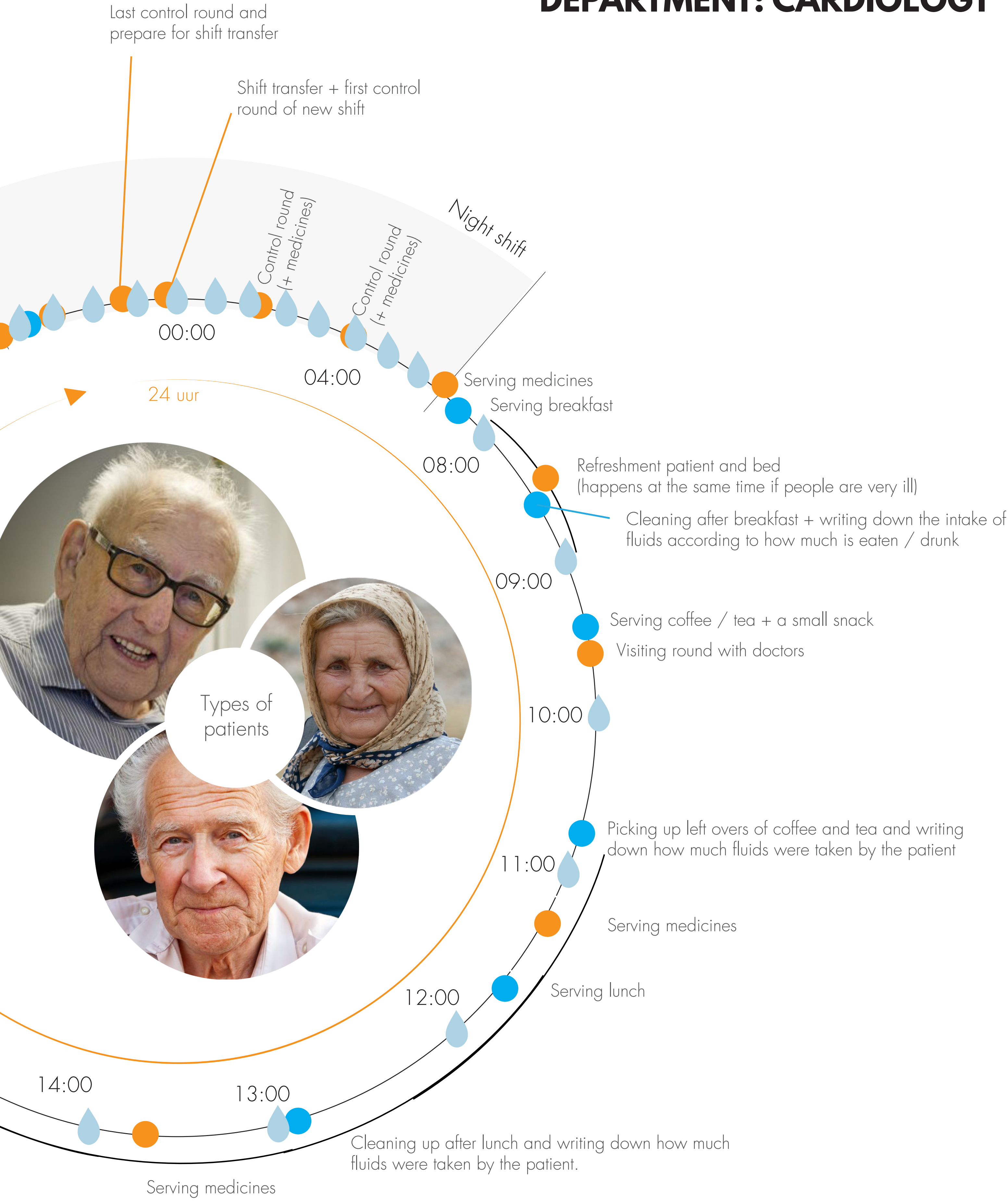
At the cardiology again mostly elderly people are hospitalized. Most of the elderly need support when going to the toilet. Since the cardiology does not keep 24 hours track of the urine production in a big bottle like is done on the nefrology department it would be interesting to have a place where people can store their urine which automatically weighs the urine and puts it into the EPD. Despite this advantage it would still be too risky to give this responsibility to the elderly patients. She would rather have a standard place for them where they keep the urine if they went to the toilet without the need of (and without notifying) the nurse. She would be able to enter the information into the system.

Due to the same reason of too much risks and error possibilities Miriam also disliked the idea of having a platform to weigh the drinks of the patient. Mobility of elderly is a problem too. They will not be able to reach the IV pole and placement on the night stand is more likely to be interrupted by other stuff accidentally being placed onto it.



Most common patient profile:
confused people (elderly in general)
need a lot of help (with toilet, walking, etc.)
drinks are served by nurse (with medicines) or assistant
fluid balance every 24 hours. Sometimes every 6 hours.

DEPARTMENT: CARDIOLOGY



General information interviewed nurses:
Miriam (nurse cardiology)

Discussion

When comparing the different departments, the Intensive care is clearly different from the other three since it does not work with assistants. At the intensive care the majority can not eat themselves. They receive their nutritionists via a stomach probe. Like the small description about the "typical patient" on the result pages shows, the patient can not walk themselves and mostly even not drink themselves. These factors would make the intensive care the easiest department to find a perfect fit for concept one of fluid balance. The fact that most of these people cannot walk means that mostly they do not have a IV pole on wheels, but more like an IV wall (image J9) which is sometimes on wheels. These walls are overfilled with machines and bags which leaves little space for FluidBalance devices. Maarten Nijsten (internist - intensivist, UMCG) preferred having the option to hang the product both on an IV pole and the bed since the beds at the intensive care are placed in a high position (ergonomic work height for the medical experts) as the patient is not able to get out of bed anyway.

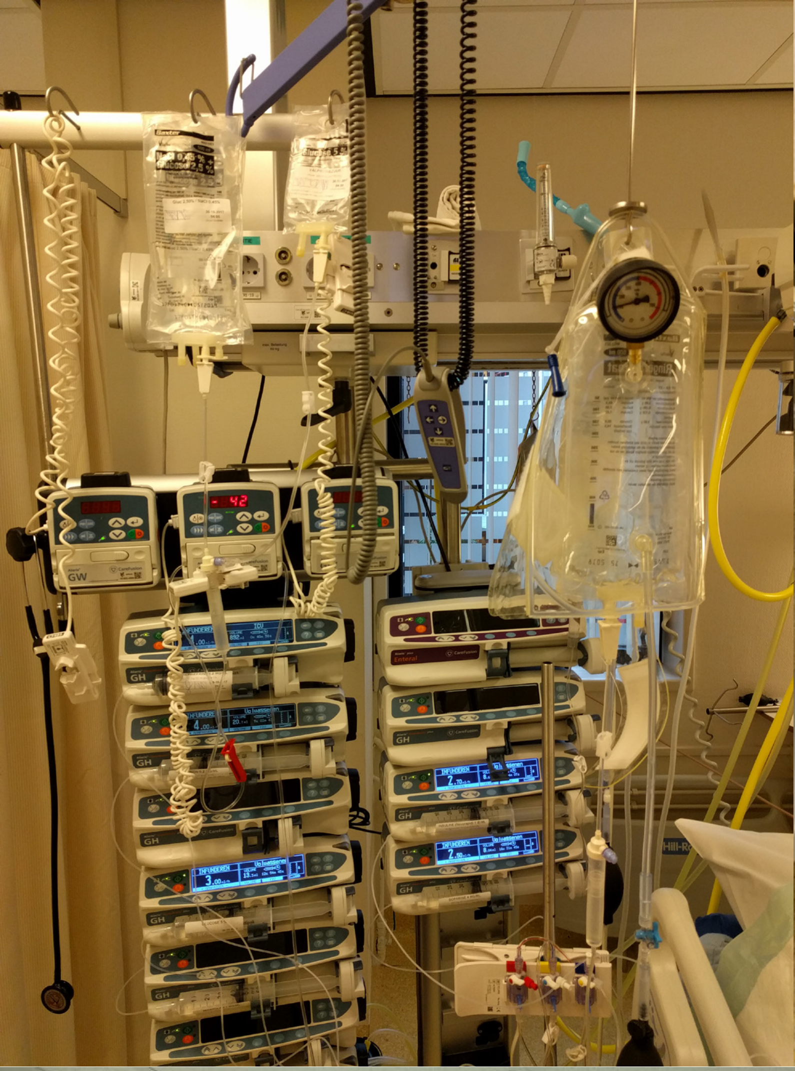
The other three departments are more similar. Only the Nefrology department saves the urine 24 hours and makes up a fluid overview afterwards. The other two departments write down the urine amount just after the patient went to the toilet and then throw away the urine. Another clear distinction between the nefrology and the other two departments (cardiology and elderly care) is the age of the patients. The patients at nefrology differ far more than at the other departments. Nefrology patients can be quite young. The nefrology department showed interest in having a spot to weigh urine before and after going to the toilet. Especially since putting the urine into the urine bottle (which is saved for 24 hours) is the most difficult task (since the have a belly wound) for the patients. 60% of her patients would be able to weigh their urine after they went to the toilet without a problem.

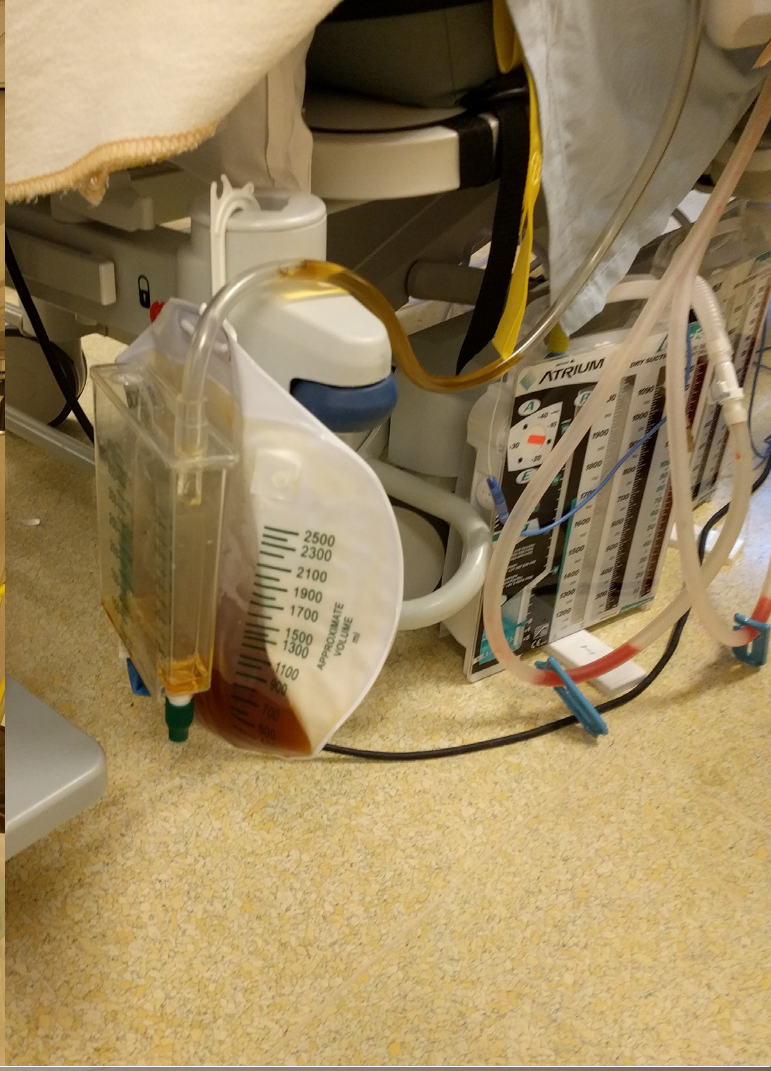
For the two most similar departments it was clear that concept one is preferred by far over the other two. The nurse is (almost) always around when the patient uses the toilet since they need support when going to the toilet. If they do not need support the nurse still wants the patient to call when he or she goes to the toilet and keeps a close look at his/her patients over the day since most of the patients are old and tend to forget important things like writing down their urine output.

One nurse of the intensive care showed interest in having a small screen on the devices 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 chosen FluidBalance hangers). The rest of the nurses all preferred to have the most simple option where everything is done from one main screen.

Of course these outcomes are not representative for all four departments since only seven people were involved in the research. Although it does give a clear overview of needs, logistics and patient types on the different departments and will push the project forward.

The assessment forms turned out to be too time consuming and felt like more or less writing down the same things that the discussion was about. Only two out of seven people had enough time / took the time to fill in the assessment forms. Fortunately the outcomes were promising: 4 out of 5 on how well concept one will fit on the elderly care department and 4 out 5 as well regarding whether concept one is an improvement for the department compared to the current situation. The other assessor (cardiology nurse) was convinced about the concepts, but wanted to work with it first before saying whether it is better or not compared to the current situation. She did believe that concept one would fit 3 out of 5 into the cardiology department for sure.




ATRIUM
2500
2300
2100
1900
1700
1500
1300
1100
APPROXIMATE VOLUME
ml


PHILIPS
Alaris Pump
Baxter

Patiënt profiel:

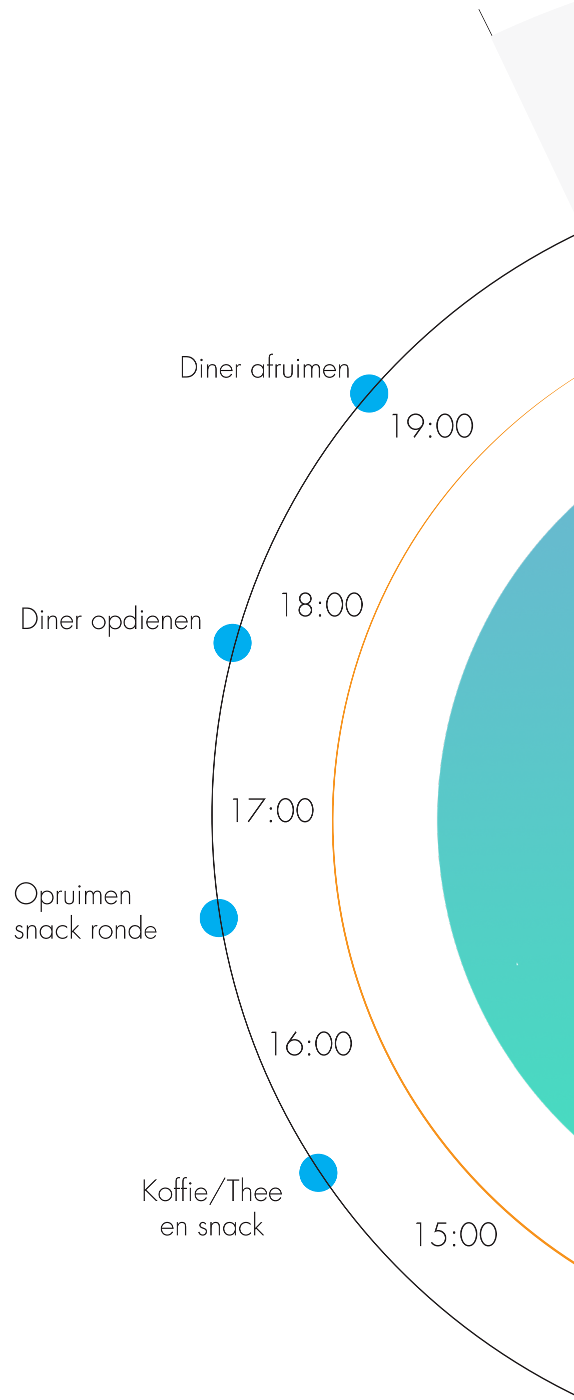
- elk uur controle benodigd
- IV aangesloten
- medicatie aangesloten
- extra vochtinname door drinken
- blaas katheter is ingebracht

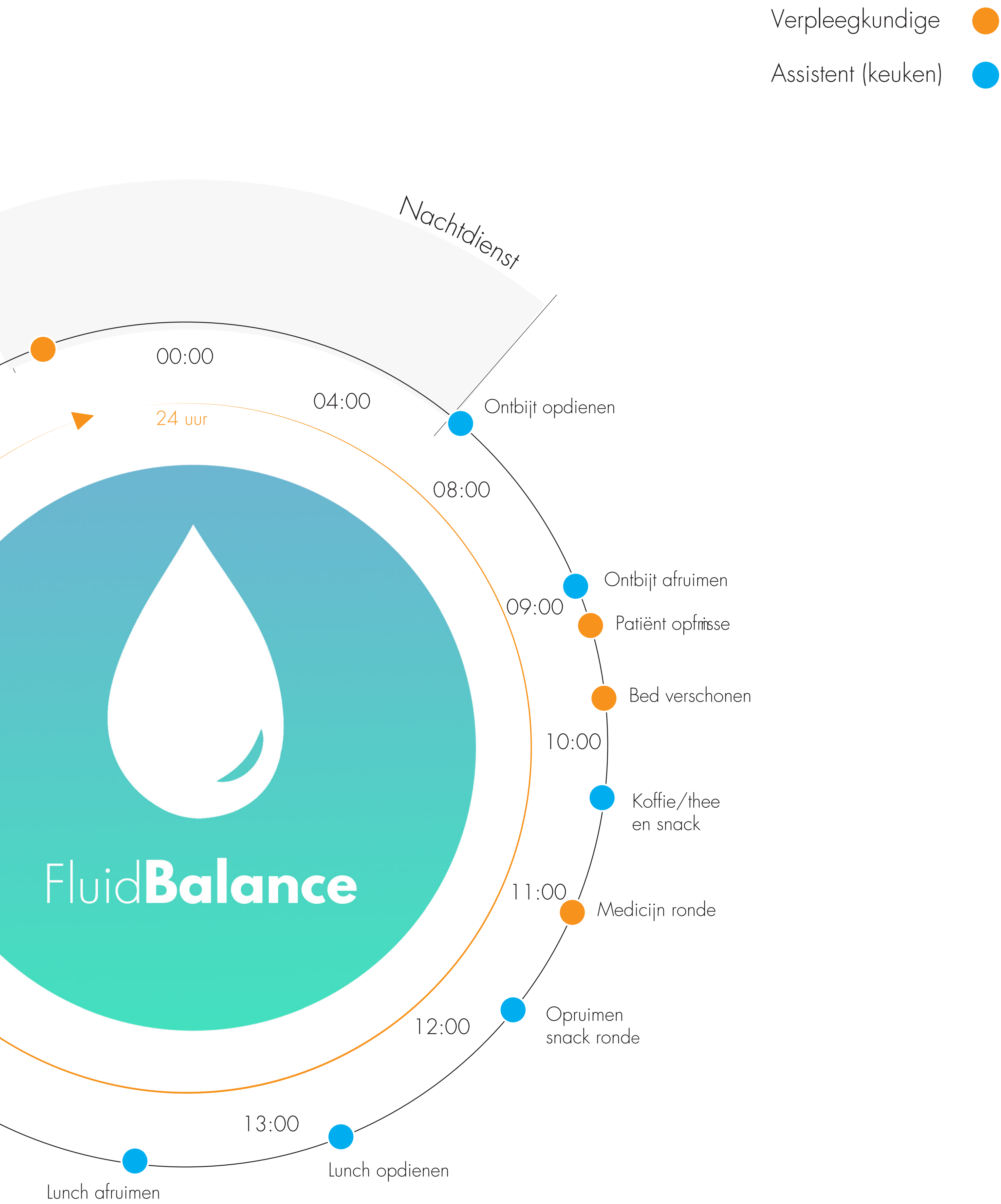
Voorkomende patiënten profielen op deze afdeling:

Aleksa
Leo
Aad
Rick
Chanine
....

Gegevens Interviewee:

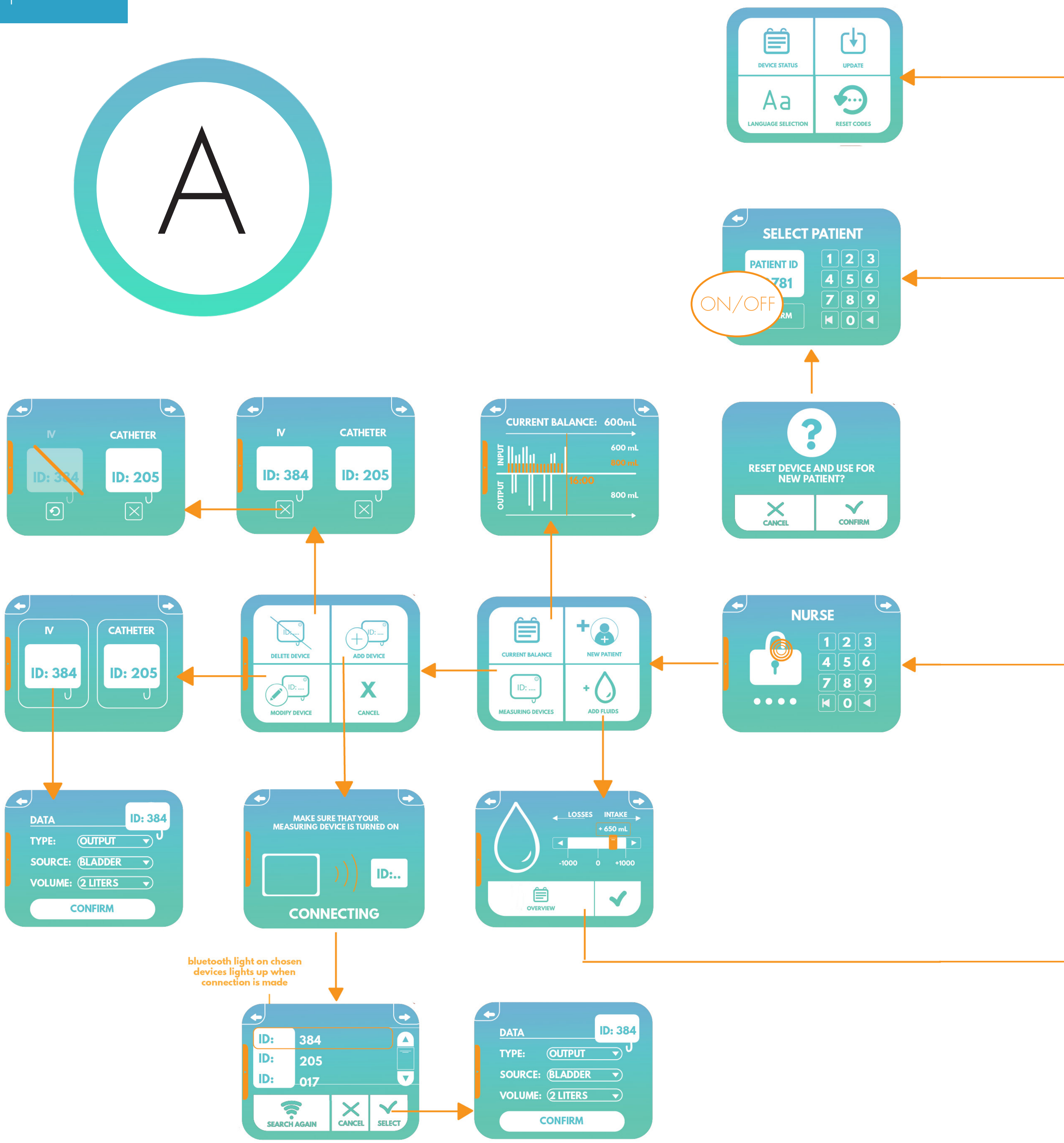
Afdeling:
Functie:
Jaren werkervaring:

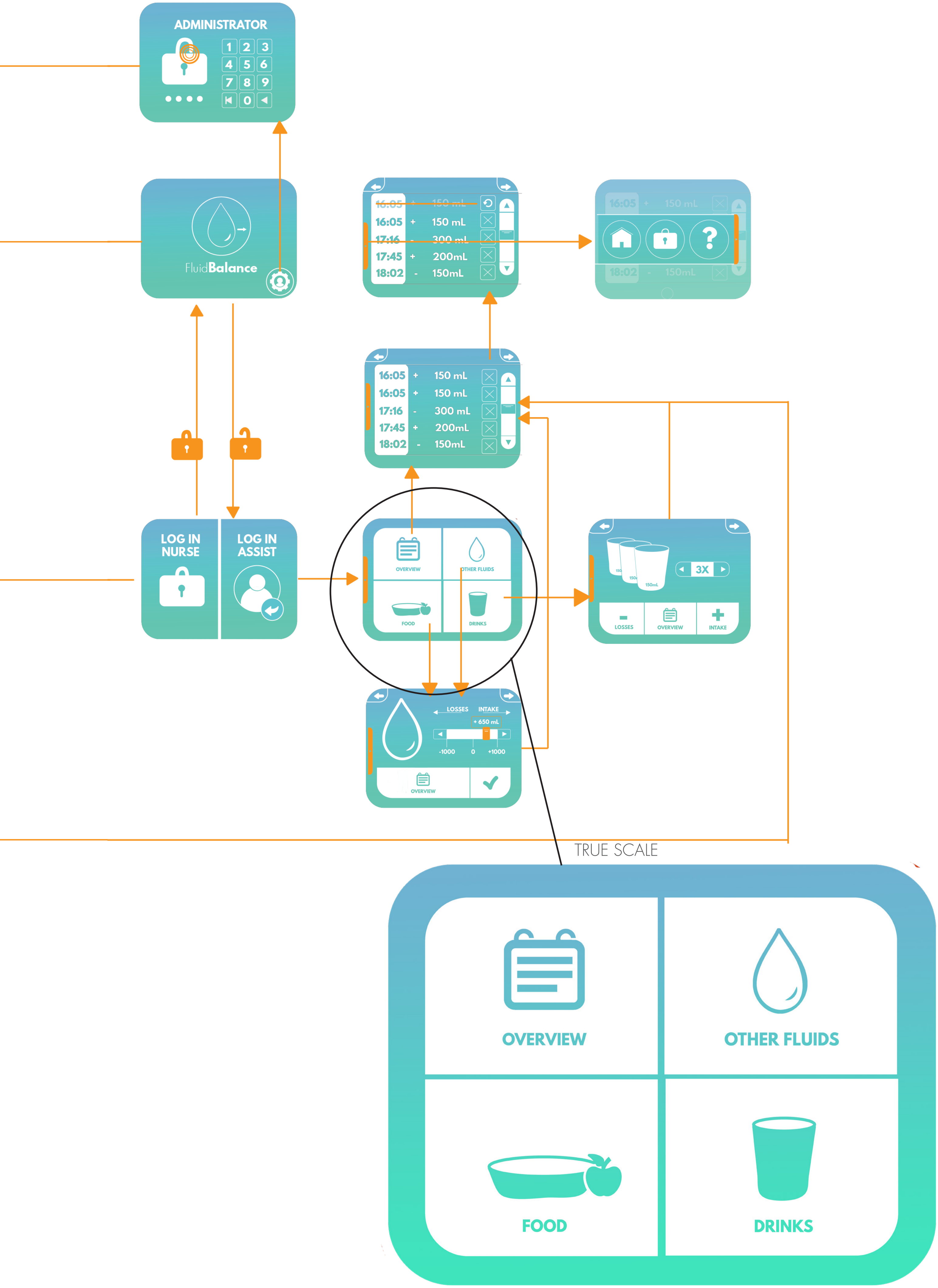



Verpleegkundige
Assistent (keuken)
Nachtdienst
00:00
04:00
24 uur
08:00
09:00
10:00
11:00
12:00
13:00
FluidBalance
Ontbijt opdienen
Ontbijt afruimen
Patiënt opfrisse
Bed verschonen
Koffie/thee en snack
Medicijn ronde
Opruimen snack ronde
Lunch opdienen
Lunch afruimen

Appendix 20

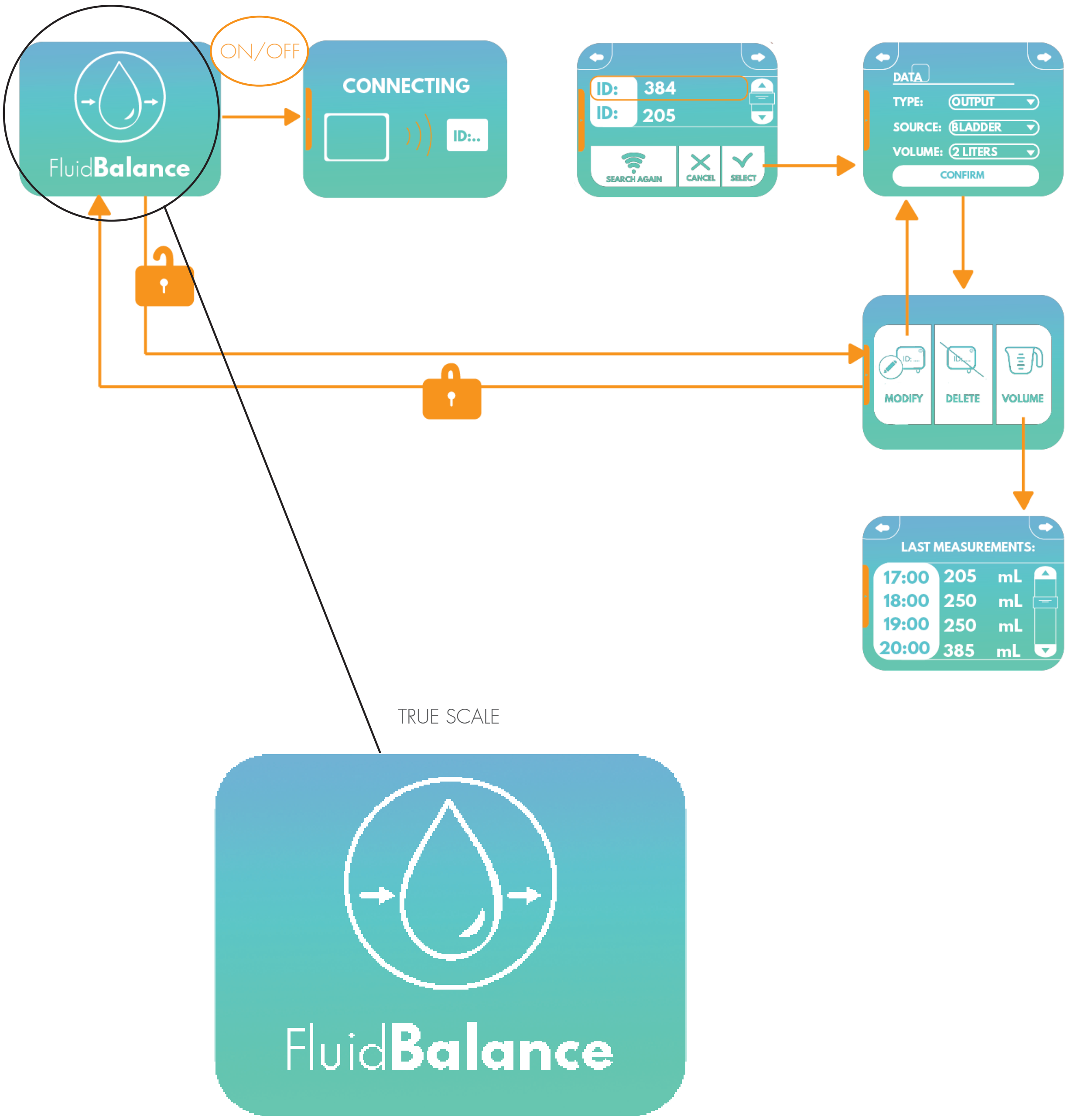
Appendix 21


A
DEVICE STATUS
UPDATE
LANGUAGE SELECTION
RESET CODES
SELECT PATIENT
PATIENT ID
ON/OFF
RESET DEVICE AND USE FOR NEW PATIENT?
CANCEL
CONFIRM
NURSE
IV
CATHETER
ID: 384
ID: 205
CURRENT BALANCE: 600mL
INPUT
OUTPUT
600 mL
800 mL
DELETE DEVICE
ADD DEVICE
MODIFY DEVICE
CANCEL
CURRENT BALANCE
NEW PATIENT
MEASURING DEVICES
ADD FLUIDS
DATA
TYPE: OUTPUT
SOURCE: BLADDER
VOLUME: 2 LITERS
CONFIRM
MAKE SURE THAT YOUR MEASURING DEVICE IS TURNED ON
ID:..
CONNECTING
LOSSES
INTAKE
+ 650 mL
-1000
0
+1000
OVERVIEW
bluetooth light on chosen devices lights up when connection is made
ID: 384
ID: 205
ID: 017
SEARCH AGAIN
CANCEL
SELECT

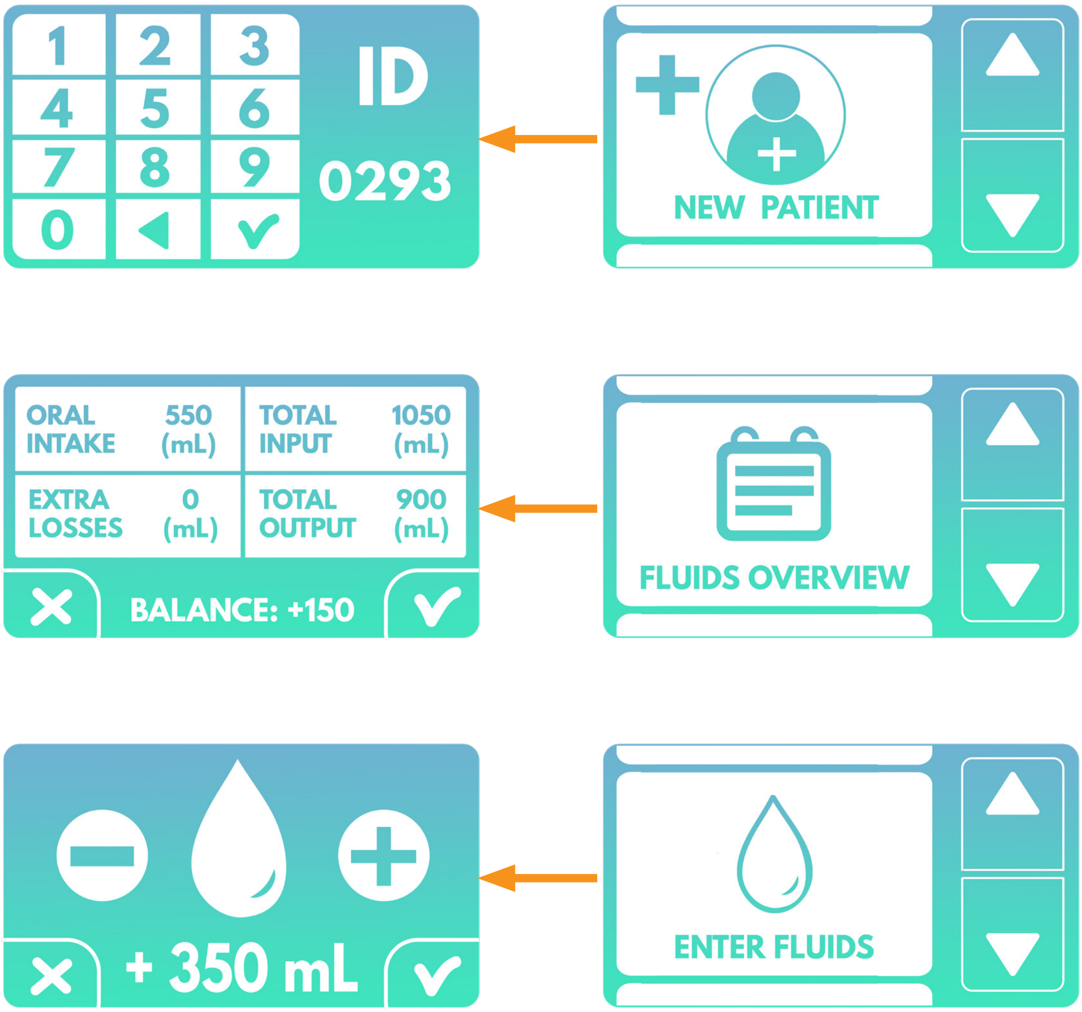

ADMINISTRATOR
FluidBalance
LOG IN NURSE
LOG IN ASSIST
16:05 + 150 mL
16:05 + 150 mL
17:16 - 300 mL
17:45 + 200mL
18:02 - 150mL
OVERVIEW
OTHER FLUIDS
FOOD
DRINKS
3X
LOSSES
INTAKE
+ 650 mL
-1000
0
+1000
TRUE SCALE

B

Screen on device

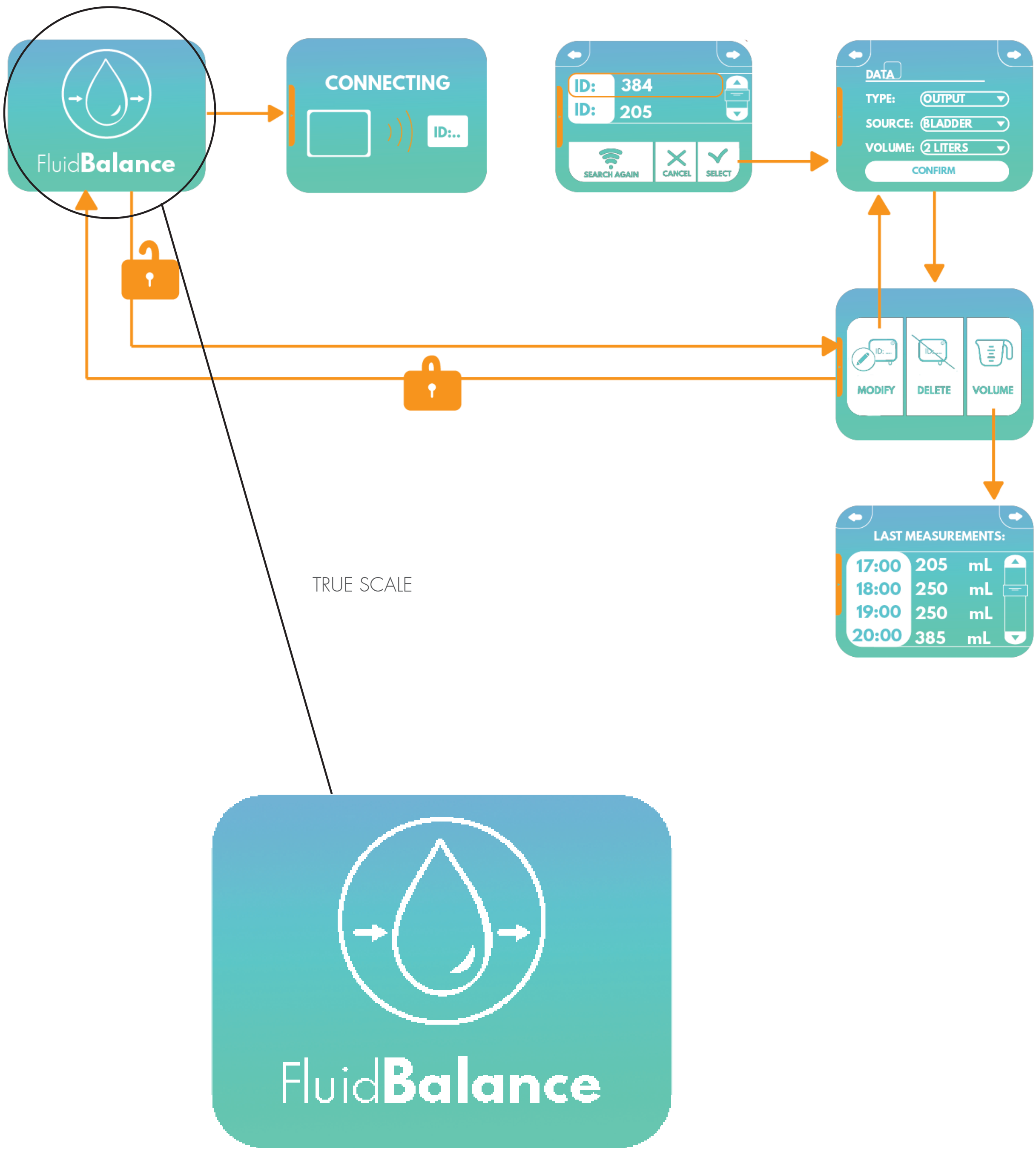


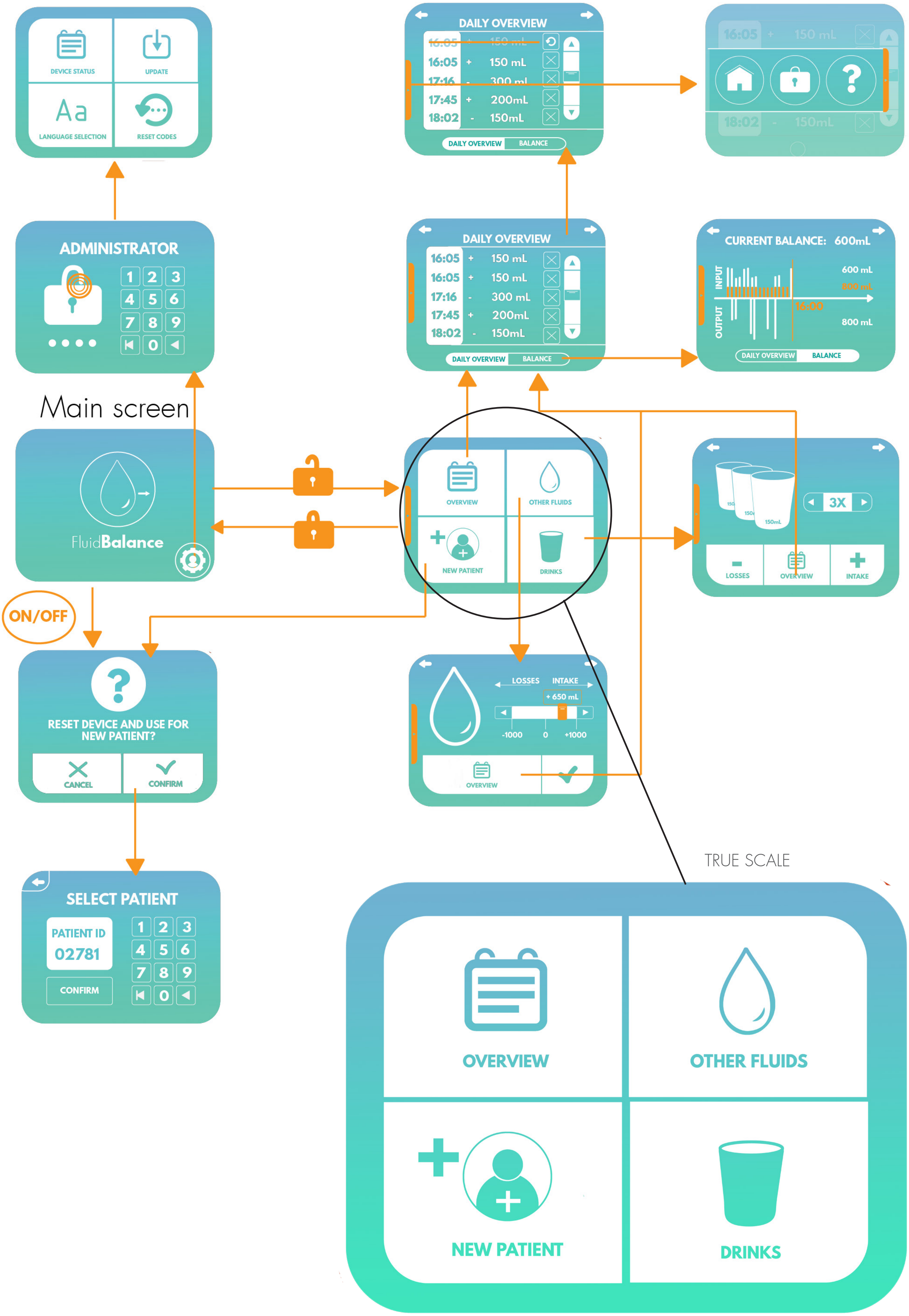
Screen on scale (true scale)



C

Screen on device





DEVICE STATUS
UPDATE
LANGUAGE SELECTION
RESET CODES
ADMINISTRATOR
Main screen
FluidBalance
ON/OFF
RESET DEVICE AND USE FOR NEW PATIENT?
CANCEL
CONFIRM
SELECT PATIENT
PATIENT ID
02781
CONFIRM
DAILY OVERVIEW
16:05 + 150 mL
16:05 + 150 mL
17:16 - 300 mL
17:45 + 200mL
18:02 - 150mL
DAILY OVERVIEW
BALANCE
CURRENT BALANCE: 600mL
INPUT
OUTPUT
600 mL
800 mL
16:00
OVERVIEW
OTHER FLUIDS
NEW PATIENT
DRINKS
150mL
3X
LOSSES
OVERVIEW
INTAKE
LOSSES
INTAKE
+ 650 mL
-1000
0
+1000
OVERVIEW
TRUE SCALE
OVERVIEW
OTHER FLUIDS
NEW PATIENT
DRINKS

Figure 22.1: sticky notes with e-paper. Retrieved from: digitaljournal.com

Figure 22.2: Example of electrowetting possibilities. Retrieved from: thecoolgadgets.com

22.1 Different types of interfaces

The screen on the FluidBalance hanger will be used as feedback screen only. Input for the FluidBalance hanger will happen from the main screen. The screen needs to be bright enough to be seen during the night and between 1.8 and 2.8 inch in size. Below several different screen types that could be suitable are discussed.

Scott Soong, CEO, Pervasive Displays: "the highest power requirement is almost always the display " TFT LCDs (touch and no touch) are the most power consuming displays. (Soong, 2017). Bistable display technologies (E-paper) (figure 22.1) are designed for the IoT and only consume power when updating an image on the screen. During these updates currents are used to move particles to different positions (figure 22.5). In the time in between the screen is still visible, but not power is consumed. "In an application where a 2-inch. display is updated six times daily, an e-paper display can use as little as 0.01 mAh of power per day, whereas the typical, equivalently sized, LCD display would use 720 mAh" (Soong, 2017) . Estimating that the screen would need to update every 10 minutes (144 times per day) this means 0,24 mAh per day. Disadvantage of the e-paper is its visibility in very dark environments and refresh time that takes up to 10 seconds. Separate lights are needed to create more visibility which will increase energy consumption. The e-reader market invented the front light module to provide equally divided light on the paper. E-paper is being more widely applied on multiple devices and is an upcoming technology since it is very well suitable for the IoT (figure 22.3 and 22.4). This is not only due to its low energy consumption. The screens are more visible for outside use as well since no backlight is being used to form the images.

In OLED screens the organic layer internal creates backlight by moving electrons. Furthermore the light is created for individual pixels separately. In the case of a bright white image this means that energy consumption is sometimes even higher than LCD screens, but when using very dark images a lot of energy can be saved. Plasma displays deliver less brightness but are better regarding amount of reflections. On energy consumption Plasma is comparable to LCD and OLED.

Regarding prices, OLED screens are 20 - 30% more expensive than LCD screens. e-paper (providing the colours: red, black and white) screens are available for a comparable price as LCD screens. Adafruit LCD screen 2.2 inch costs 24 Euros and an 2.7 inch colour e-paper costs 23 Euros (Pervasive displays, 2017). Visionect works on using the same technology as e-paper, but than for all colour spectrums (figure 22.6).

Another upcoming solutions is electrowetting. The current industry of e-paper (electrophoretic) uses charged titanium particles in oil to create shades of grey. Electrowetting uses the same under laying technology, but replaces the titanium particles with layers of coloured oil and water (Liquivista, 2017). Liquivista is investing in creating a display which uses the e-paper technology for real-time interactive screens (figure 22.2). These technologies are not yet available so price indications are hard to give. CLEARink uses a different way to move the particles e-paper works with which offers quick refreshing times and even the possibility to play movies and animations(Linder, 2017). Both CLEARink and Liquivista said to launch their first products on the market in the beginning of 2018.

Finally the use of segment displays can be suitable. Segment displays are available for numbers and with squares/circles. The combination of lights forms the message that needs to be communicated.

Figure 22.3: example of a smartphone case with e-paper. Retrieved from: Technobuffalo.com

Figure 22.4: e-paper being applied in digital watches . Retrieved from: geek.com

22.2 Conclusion

In short it can be stated that multiple technologies that offer low power use, enough brightness and sometimes full colour are (or will be) available on the market. E-paper (and it's variations) turn out to be the most efficient and therefore suitable for a battery driven device. Segment displays are still possible as well.

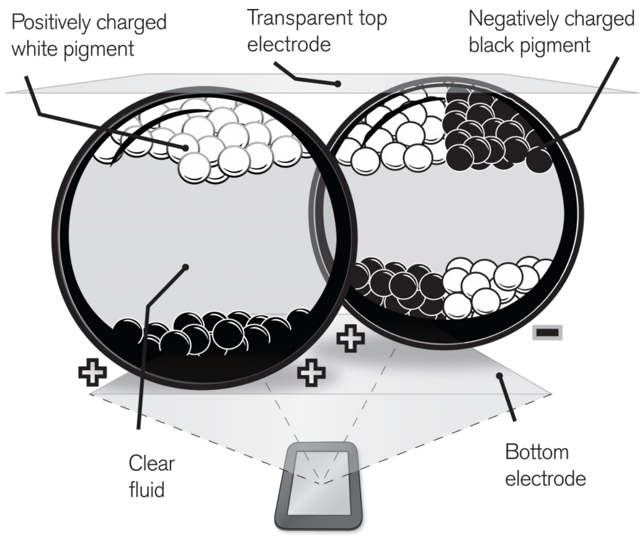


Figure 22.5: e-paper working principle (retrieved from: IDTechEx, 2017)

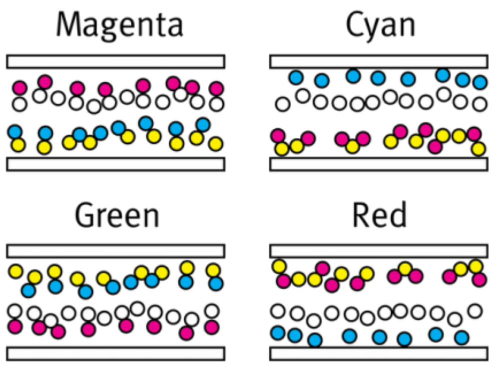


Figure 22.6: e-paper in different colours (retrieved from: Mashable tech, 2016)

Features & Benefits

High energy density and voltage
Long, stable power with a flat discharge voltage
Ideal for portable communications, portable computing, and robotics.

Specifications

Rated capacity[1]	Min. 1250mAh
Capacity[2]	Min. 1250mAh Typ. 1300mAh
Nominal voltage	3.7V
Charging	CC-CV, Std. 1250mA, 4.20V, 3.0 hrs
Weight (max.)	25.1 g
Temperature	Charge: 0 to +45°C Discharge: -20 to +60°C Storage: -20 to +50°C
Energy density	Volumetric: 432 Wh/l Gravimetric: 184 Wh/kg

Dimensions

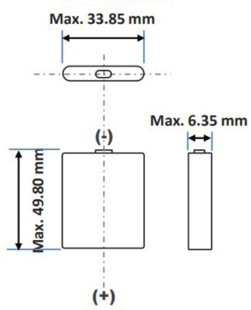


Figure 23.1: Specifications of panasonic battery (UF-653450S) (Panasonic 2017)

Figure 23.2: Image of panasonic battery (panasonic 2017)

Power consumption

E-paper (Soong, 2017)
0,24 mAh (updating screen every 10 minutes)
0.24* 3 V / 1000 = 0.00072 Wh
= 2,6 Joules per day (Wh * 3600 = joules)

Bluetooth: (Atmel, 2017)
3-4 mA in active mode (3.6 Volt)
3.5 * 0.0036 = 0,0126 Watt
144 (1 sec) moments of sending per day
144 * 0.0126 Watt = 1,8 joules per day

0.001 mA in passive mode (3.6 volt)
0.001 * 0.0036 = 0.0000036 Watt (Joules/s)
60*60*24 = 86400 sec per day
0.0000036 * 86400 = 0.3 joules per day

In total 2.1 joules per day

LED (ledlightsworld, 2017)
50 cm (30 LED/meter) = 1,2 Watt
+/- 25 cm nodig = 0,6 Watt (joules /s)
LED only on when button is pressed for reading (in dark surroundings). Estimation: 20 times per day, 5 seconds on when pressed: 100 seconds in total per day.
100 * 0,6 = 60 Joules per day

Microprocessor SAM L21 (Atmel, 2017)
900nA in active mode (3.6 volt)
0.009 * 0.0036 = 0.0000027 Watt (joules/sec)
60*60*24 * 0,0000027 = 0,3 Joules per day

LED matrix screen
approximately 30 extra LED
being used appoximately 20 times per day being on for 5 seconds after being pressed:
120 Joules (based on other LEDs (ledlightsworld, 2017)

4 digit 7 segment display (RS-components, 2017):
Average consumption: 1,17 Watt (joules/s)
1,17*100 seconds = 117 joules

Battery size

For example the panasonic flat battery (1300 mAh) (figure 23.1 and 23.2) that runs on 3.6 volt:

1300 * 0.0036 = 4.7 Watt hours

4.7 * 3600 = approximately 16920 Joules.

Total amount of days the device can be used with described usage and the panasonic battery:

16920 / (2.6 + 2.1 + 60 + 0.3) = 260 days.
This is eight and a half months.

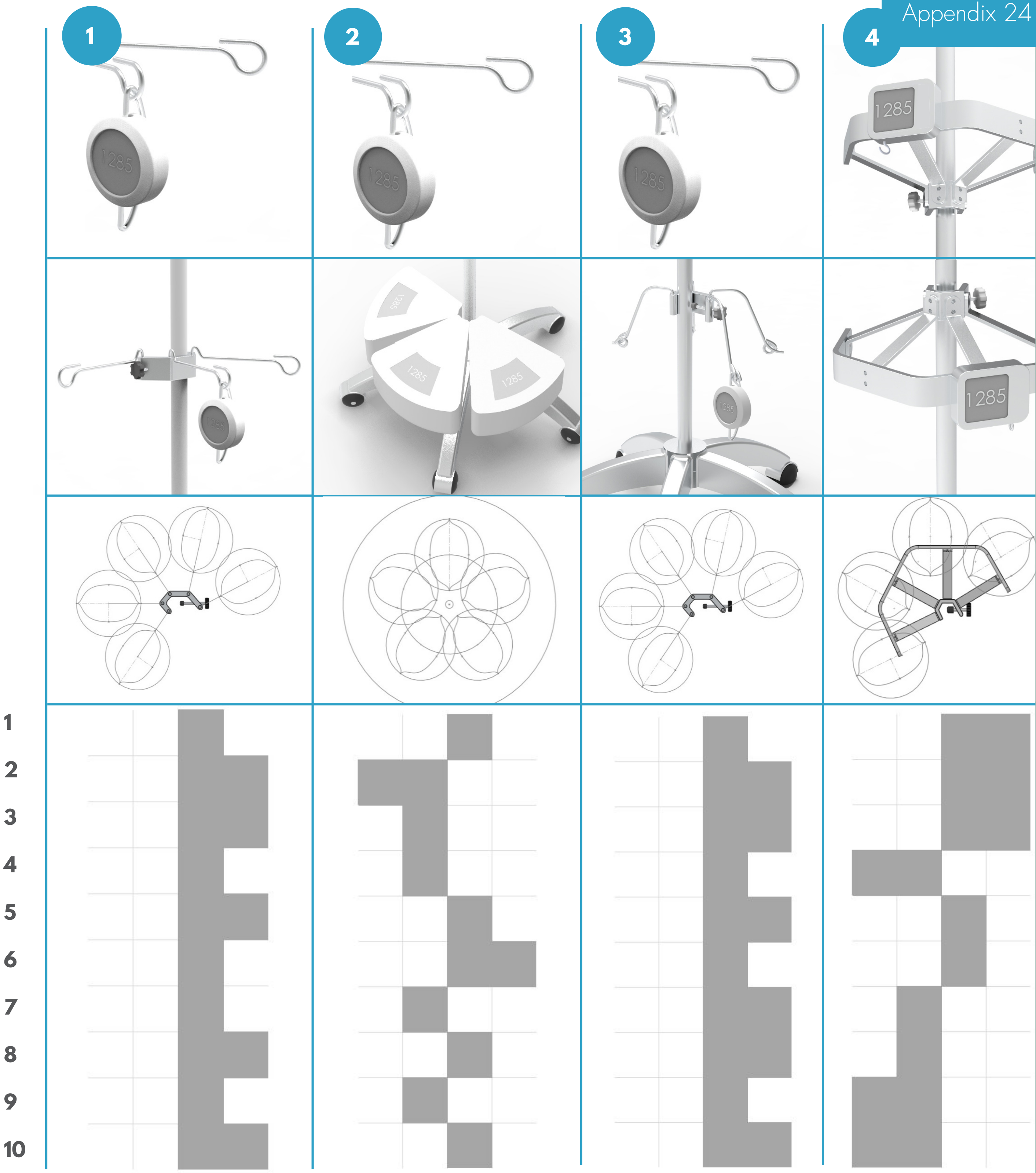
Including the LED matrix (without e-paper):

16920 / (2.1 + 60 + 0.3 + 120) = 92 days.
This is around three months.

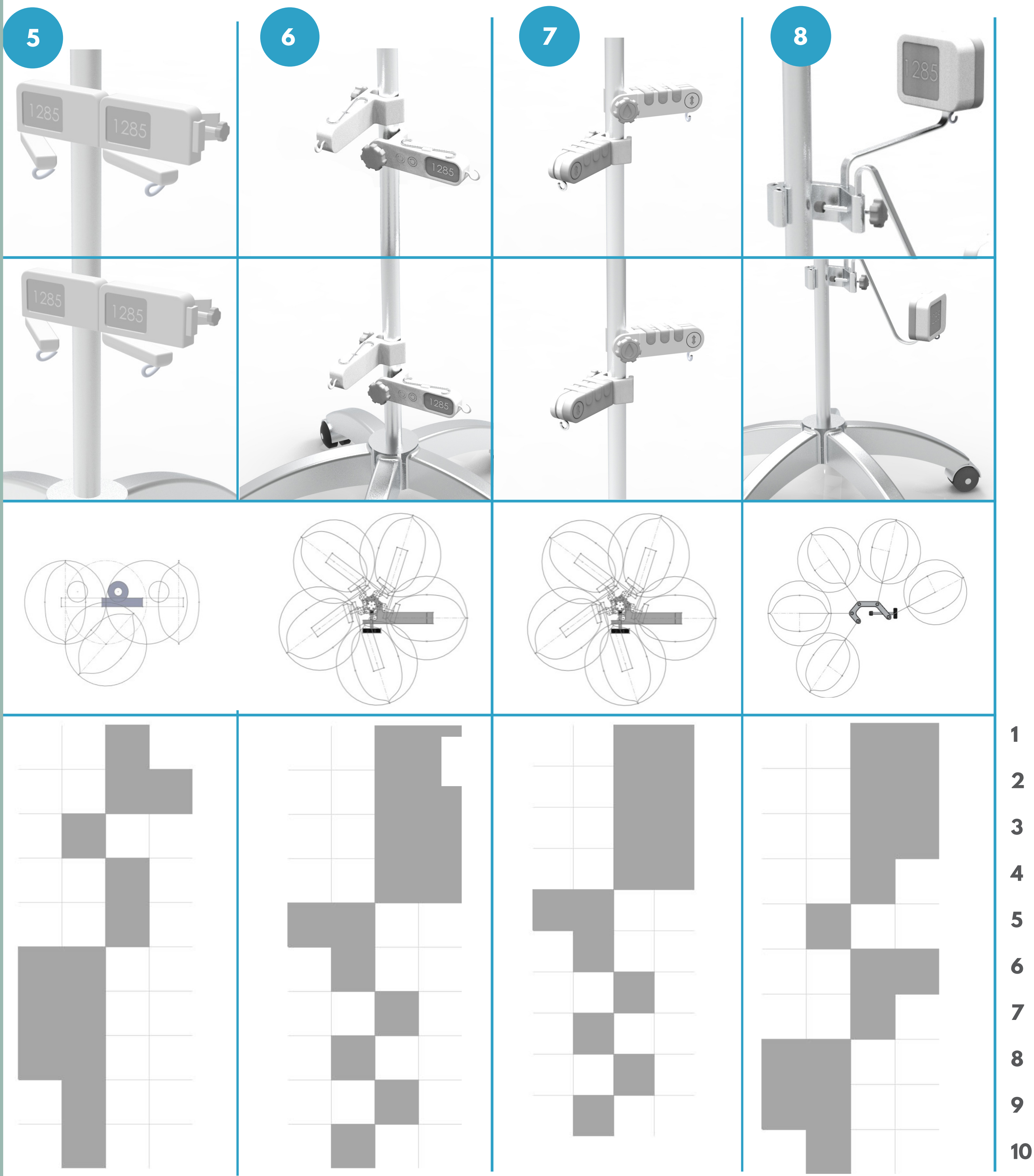
Including the 4 digit 7 segment display:

16920 / (2.1 + 60 + 0.3 + 117) = 94 days
This is around three months as well.

Of course all of these calculations are estimations. Apart from these estimations we can also look at other existing products where we will discover that a simple kitchen scale can last for years on a coin cell battery handling four connected load cells and a digital display.



CRITERIA:
Accuracy (- - : not accurate, - not accurate enough, + accurate enough, ++ accurate)
One product solution (- - Totally different products, - little difference, + very little difference, ++ no difference)
Mobility patient (- - Attached to bed, - few tasks before moving, + small task before moving, ++ no tasks)
Needed fixed space around the bed (- - Much, - some, + little, ++ no fixed space)
Visibility screen/buttons (- - bad, - okay, + good, ++ very good)
Possibility to extent cable (- - not at all, - little effort needed, + okay, ++ good)
Complexity (- - very complex product (moving parts i.e.), - complex, + quite simple, ++ simple)
Required product stiffness (- - much stiffness required, - some, + little, ++ not at all)
Extra attachment extensions needed (- - much, - little, + one, ++ none)
Applicable at IC (- - badly, - okay, + good enough, ++ easily)



CRITERIA:
Accuracy (- - : not accurate, - not accurate enough, + accurate enough, ++ accurate)
One product solution (- - Totally different products, - little difference, + very little difference, ++ no difference)
Mobility patient (- - Attached to bed, - few tasks before moving, + small task before moving, ++ no tasks)
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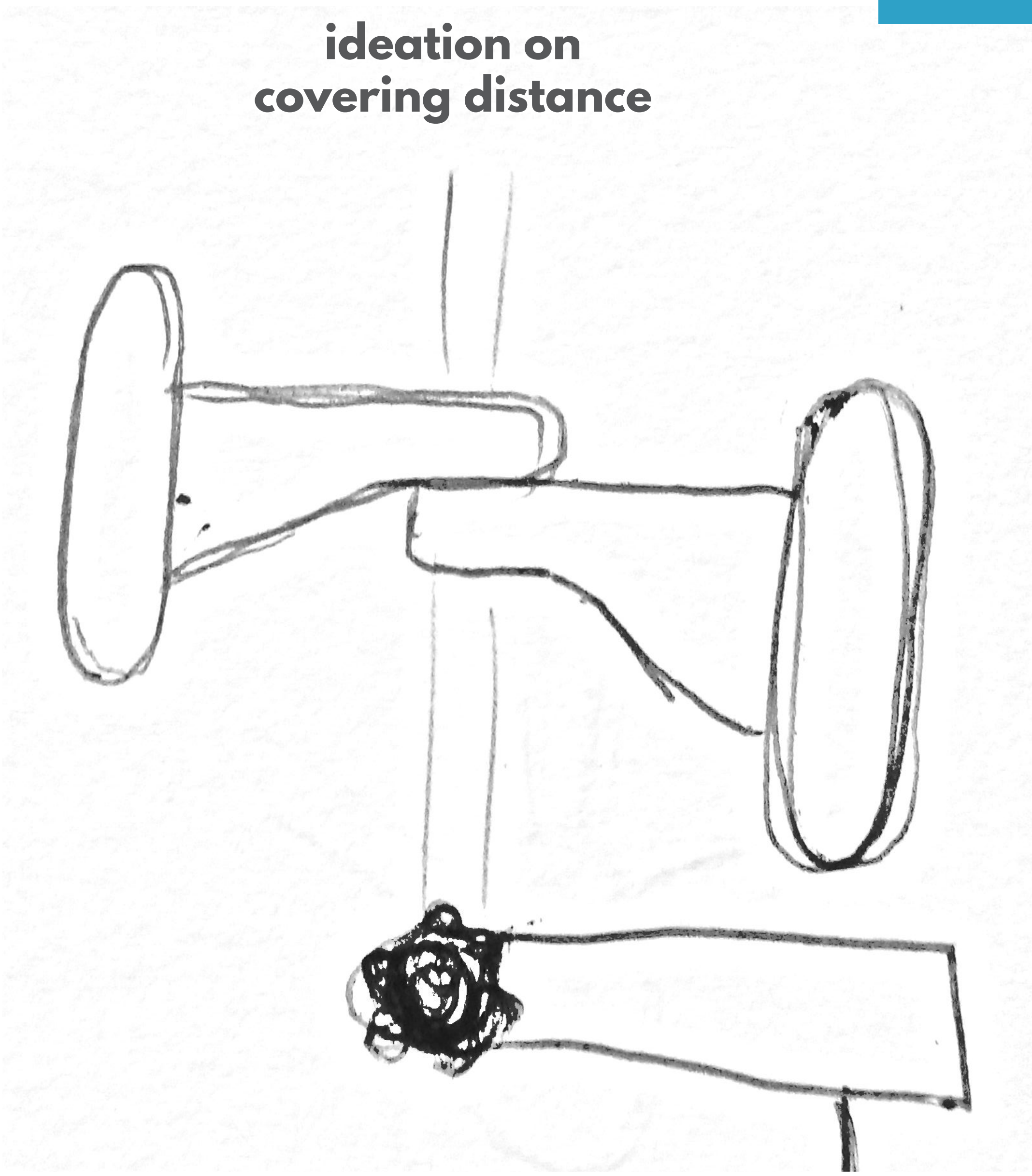
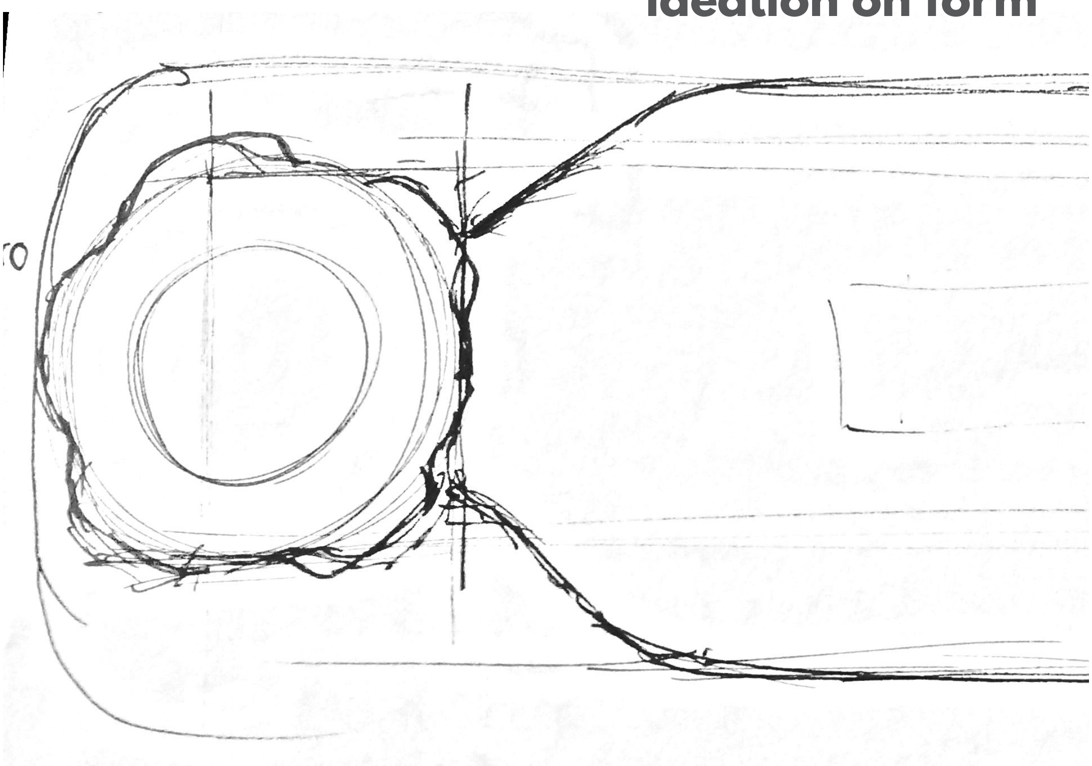
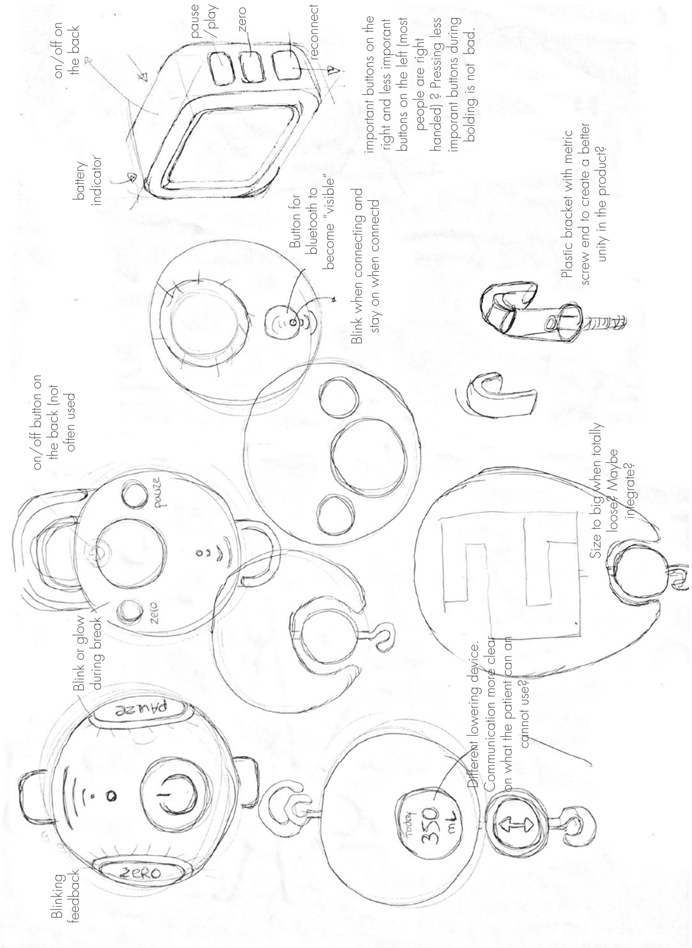
Visibility screen/buttons (- - bad, - okay, + good, ++ very good)
Possibility to extent cable (- - not at all, - little effort needed, + okay, ++ good)
Complexity (- - very complex product (moving parts i.e.), - complex, + quite simple, ++ simple)
Required product stiffness (- - much stiffness required, - some, + little, ++ not at all)
Extra attachment extensions needed (- - much, - little, + one, ++ none)
Applicable at IC (- - badly, - okay, + good enough, ++ easily)

ideation on covering distance

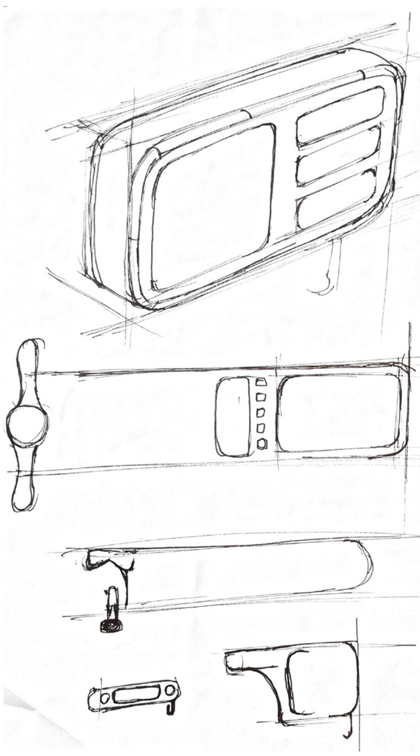


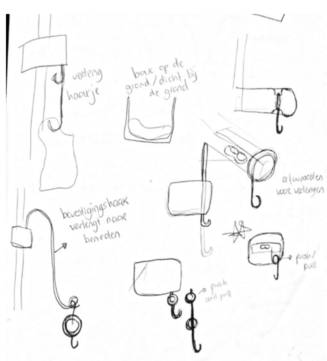
ideation on form

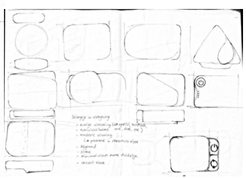


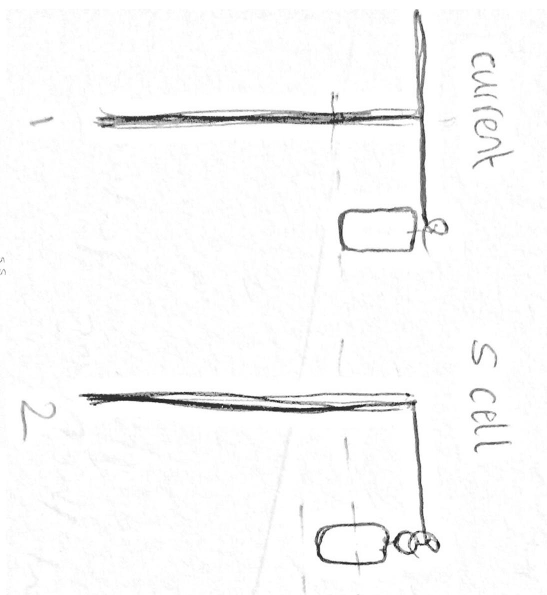


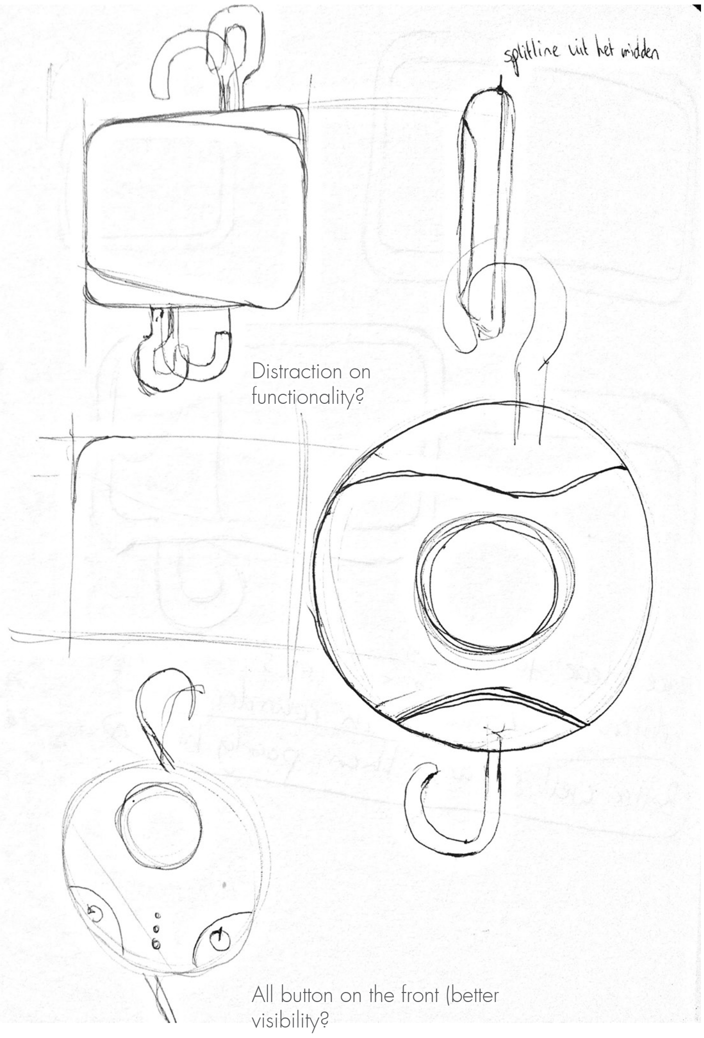
ideation on forms and distance between device and IV pole



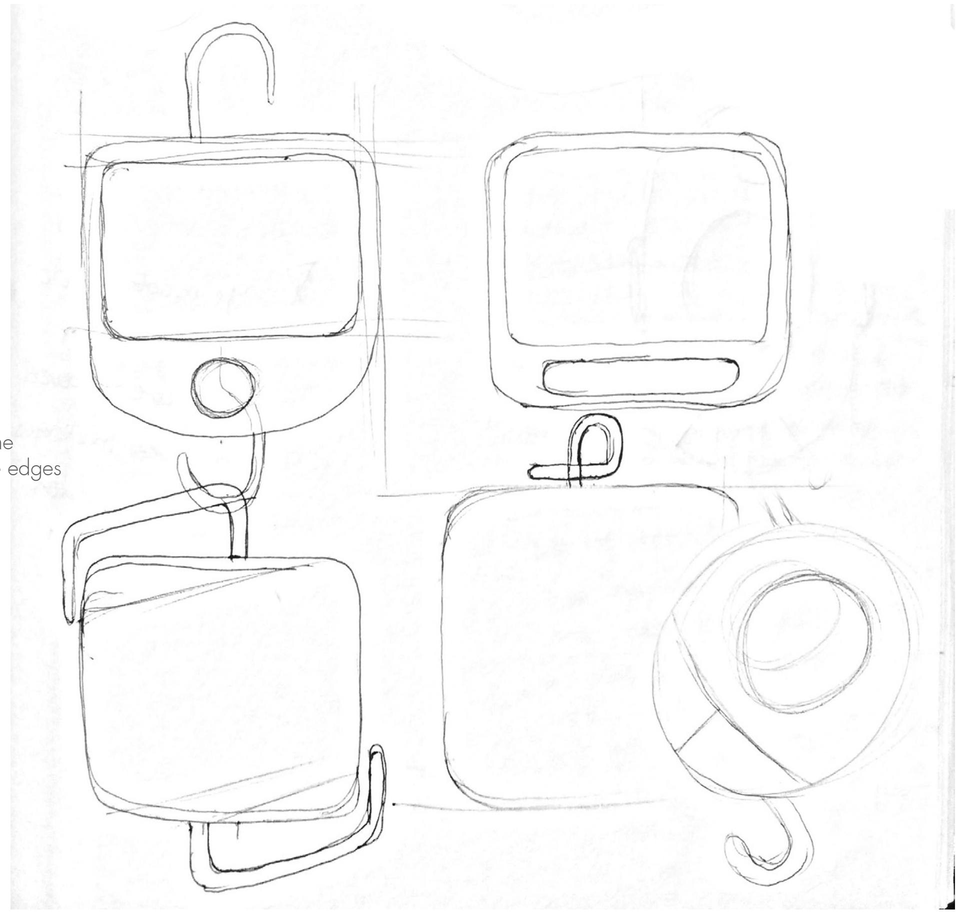


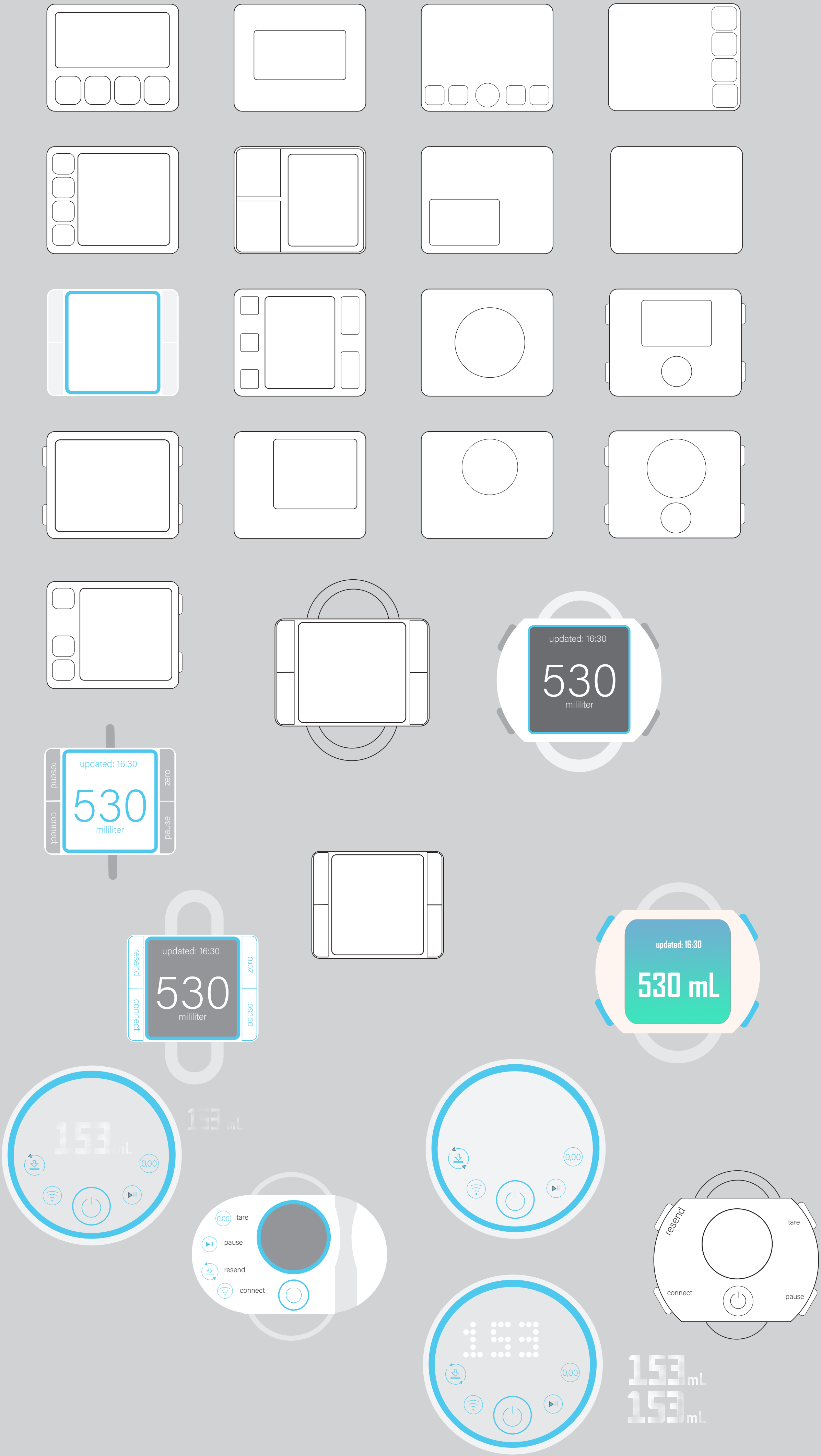




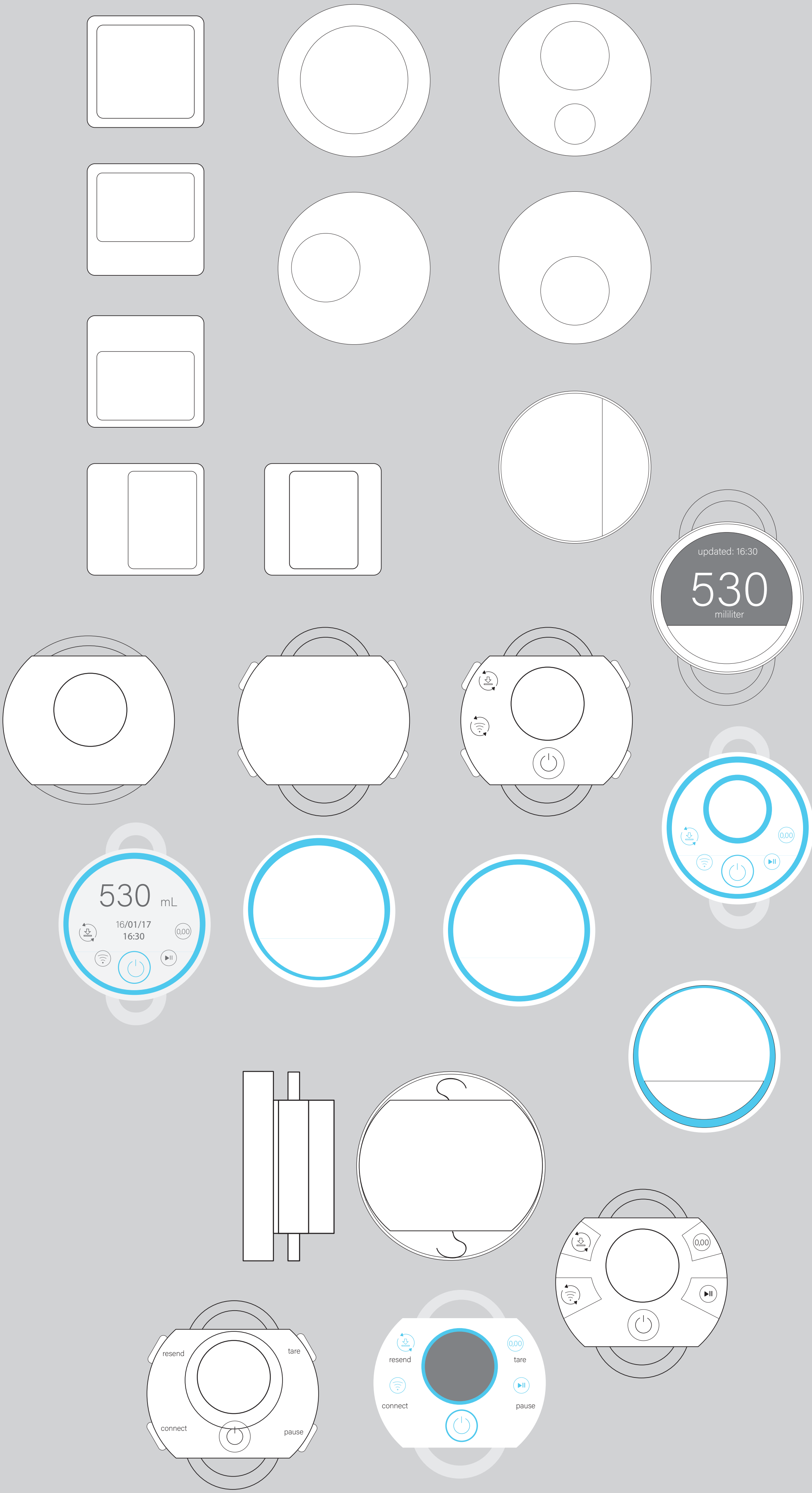


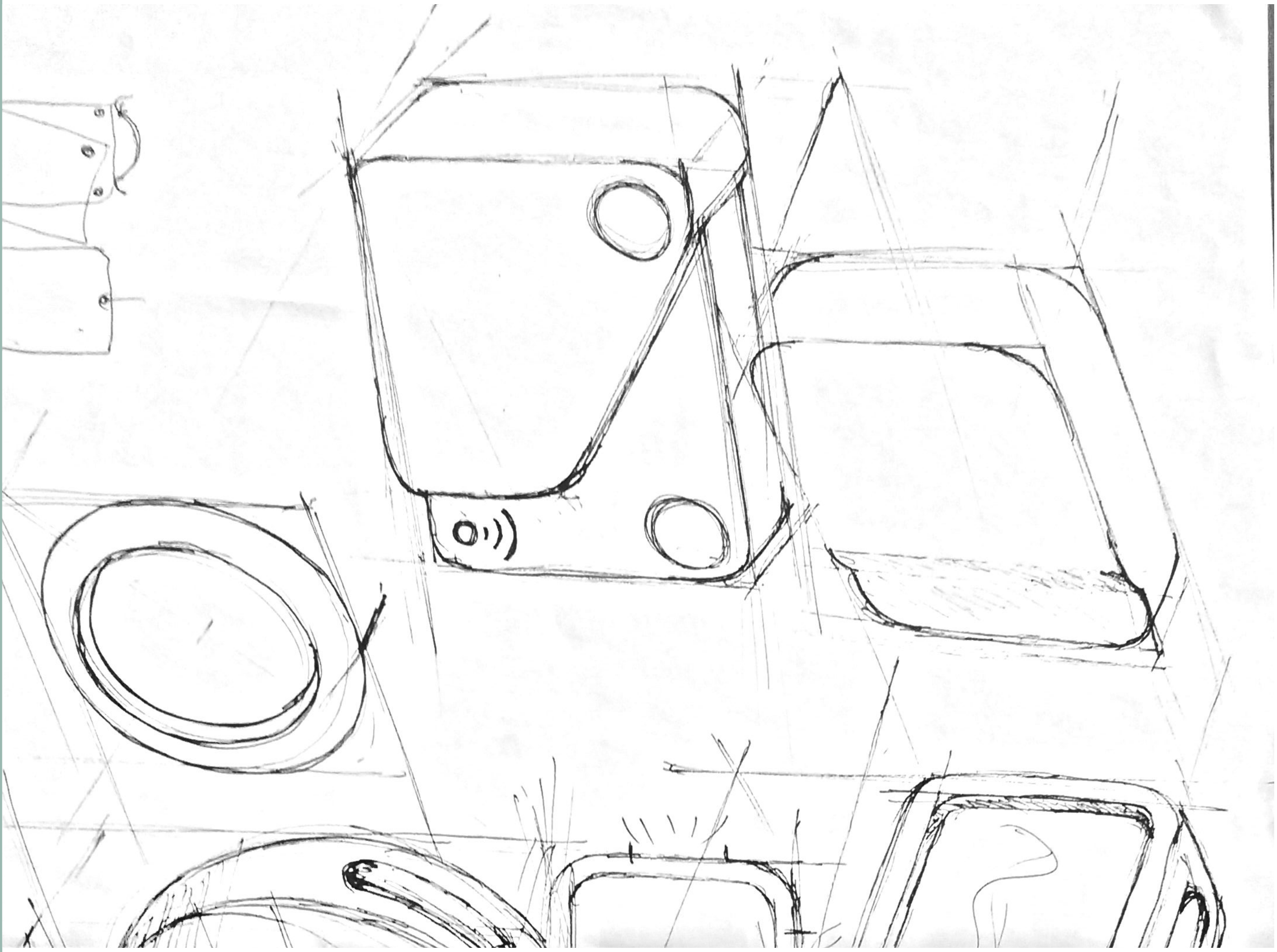
integration of the brackets. Same edges

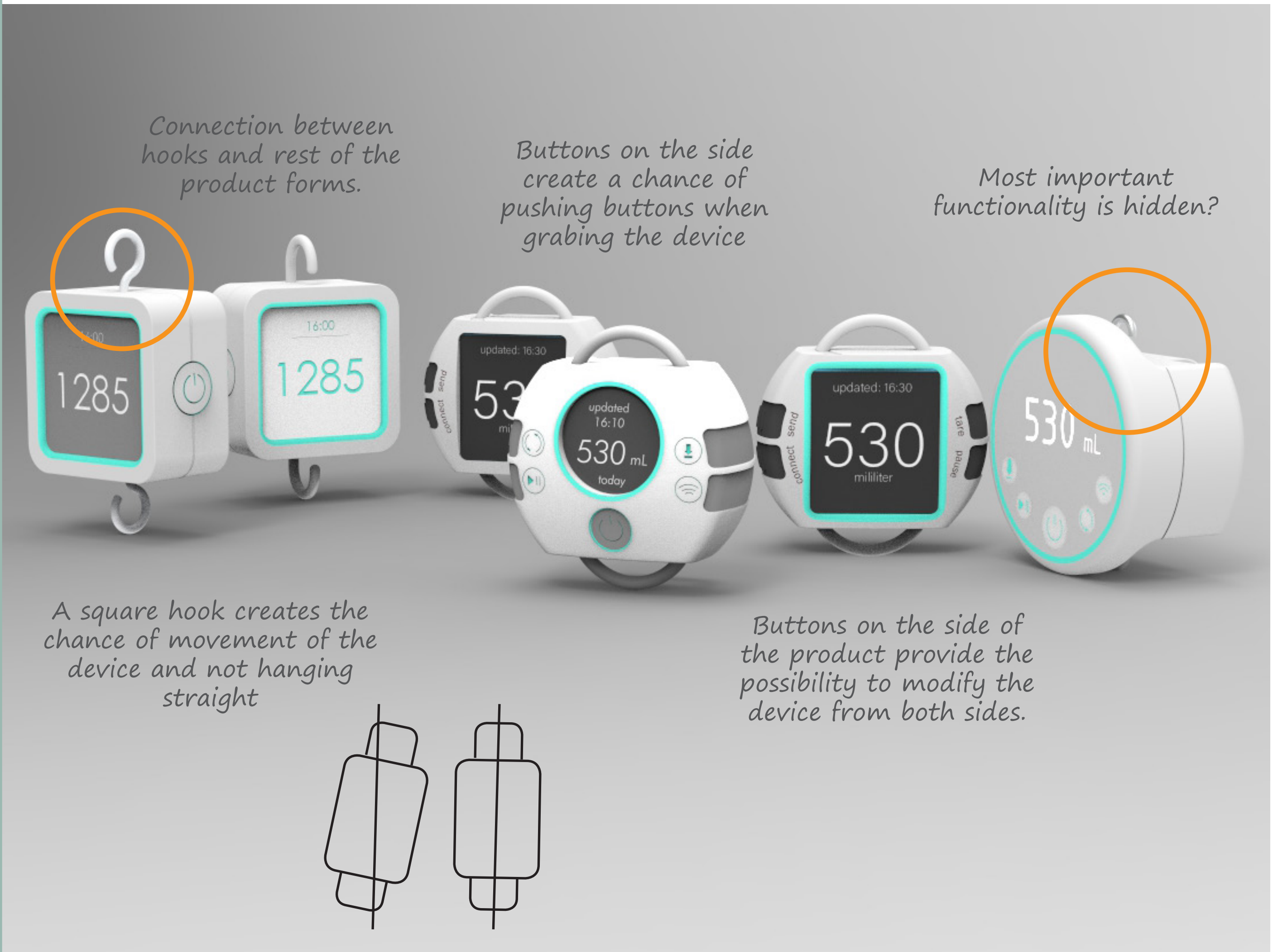




updated: 16:30
530
mililiter
resend
connect
zero
pause
updated: 16:30
530
mililiter
updated: 16:30
530
mililiter
resend
connect
zero
pause
updated: 16:30
530 mL
153 mL
0,00
153 mL
0,00
tare
pause
resend
connect
0,00
resend
tare
connect
pause
0,00
153 mL
153 mL


updated: 16:30
530
mililiter
530 mL
16/01/17
16:30
0,00
resend
tare
connect
pause

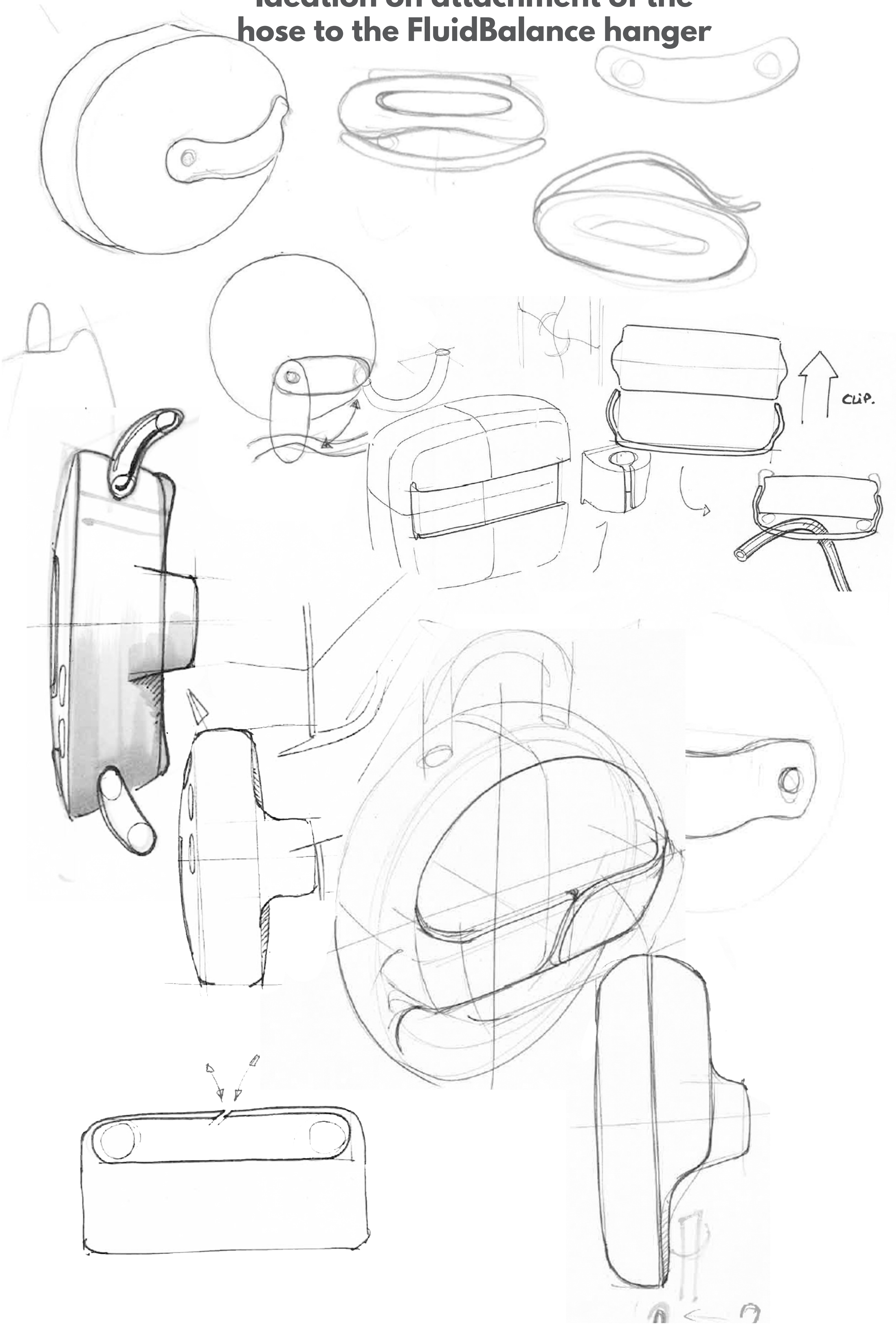




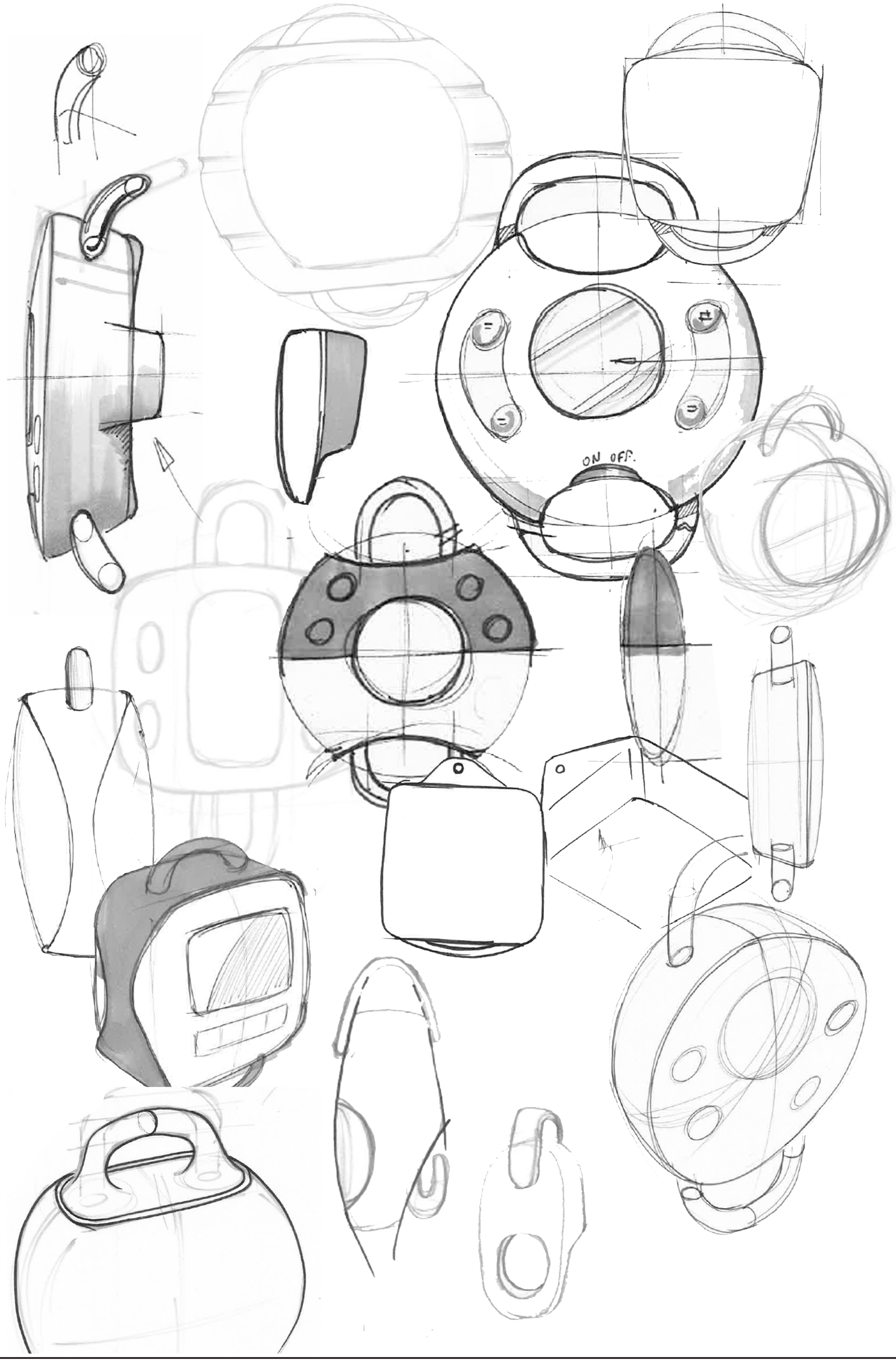
Connection between hooks and rest of the product forms.
Buttons on the side create a chance of pushing buttons when grabing the device
Most important functionality is hidden?
1285
16:00
1285
updated: 16:30
updated 16:10
530 mL
today
updated: 16:30
530
mililiter
connect
send
tare
pause
530 mL
A square hook creates the chance of movement of the device and not hanging straight
Buttons on the side of the product provide the possibility to modify the device from both sides.

Ideation on increasing usability of bag placement

Ideation on attachment of the hose to the FluidBalance hanger



Ideation on total product



Testing two different load cells

Goals of the test is to find out whether the S-beam load cell type is less accurate than the bar shaped load cell due to more swing and less stiff connections. The images below show the set up of the test. Tests were performed with extension cables (figure 27.3), with both s beam cell and bar shaped cell, with fixated s beam construction, Arduino cable downwards and upwards and with both and empty bag and a filled bag (+/- 60mL) (figure 27.1 - 27.6). The Arduino cable serves as influence from the catheter hose since this will be the case in real-life as well.

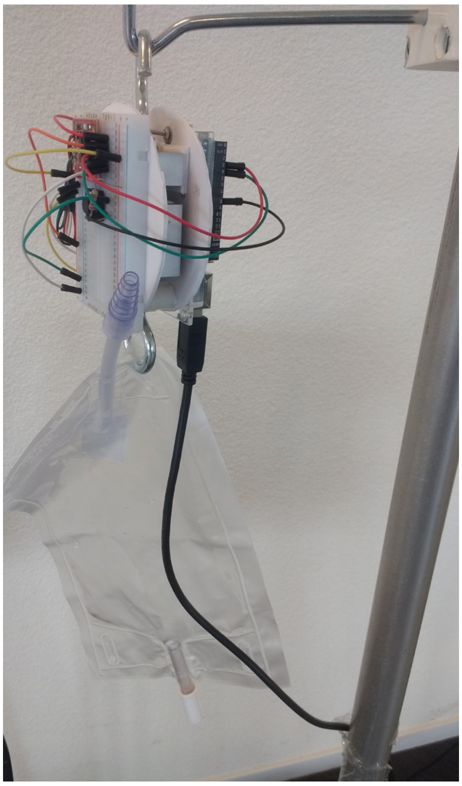


Figure 27.1: Arduino cable downwards

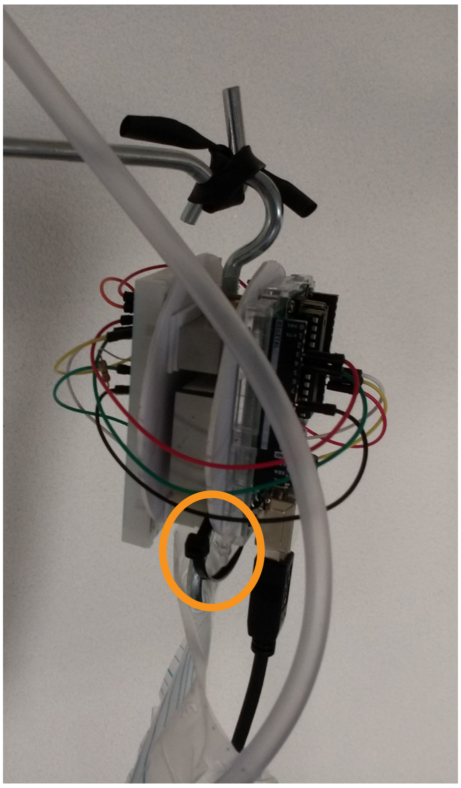


Figure 27.2: Tie rib that disturbs the measurements

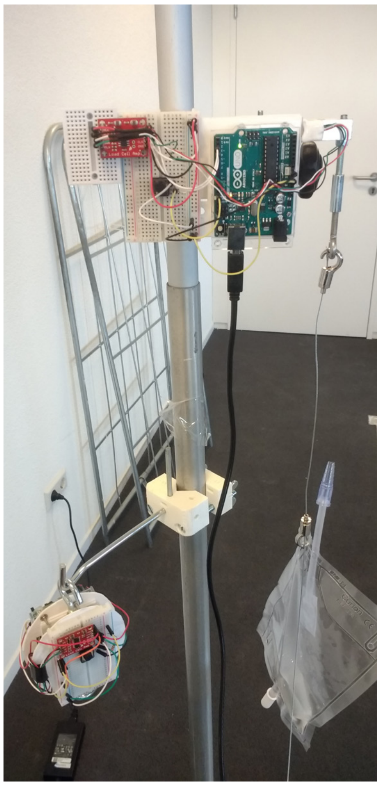


Figure 27.3: Extension cable connected to bar shaped load cell

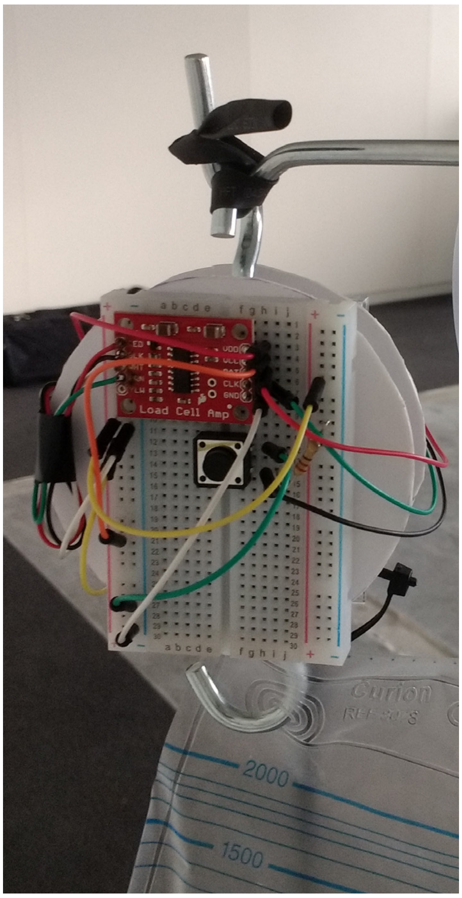


Figure 27.4: Fixated connection of s beam to the hook

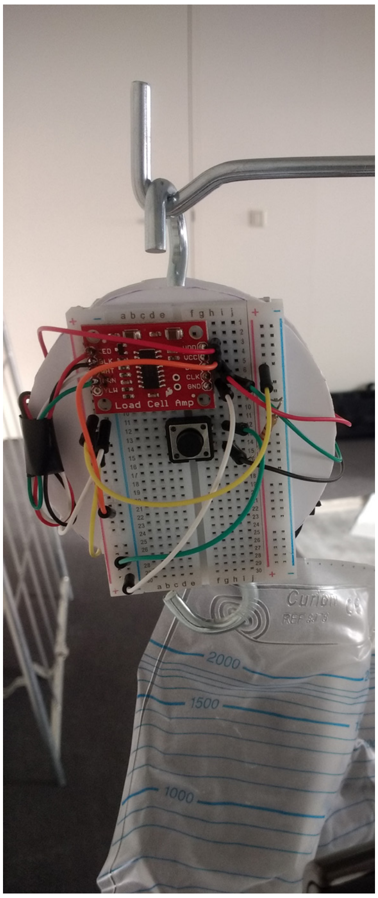


Figure 27.5: Loose connection s beam

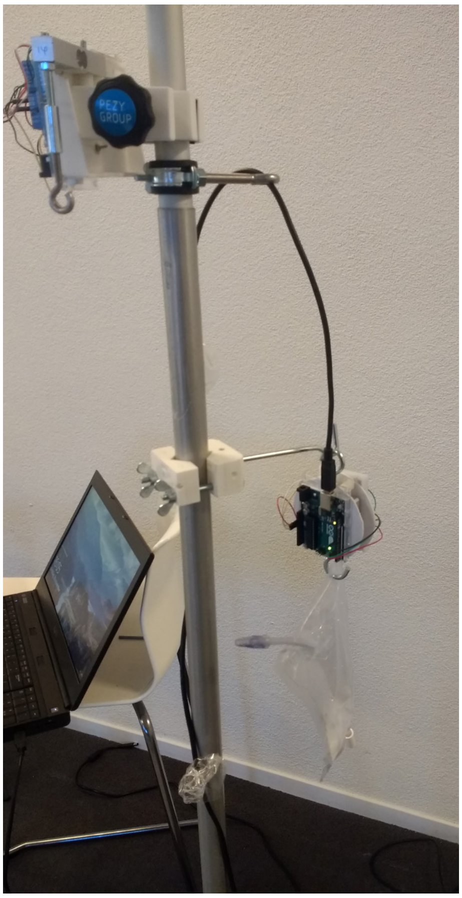


Figure 27.6: Arduino cable going upwards

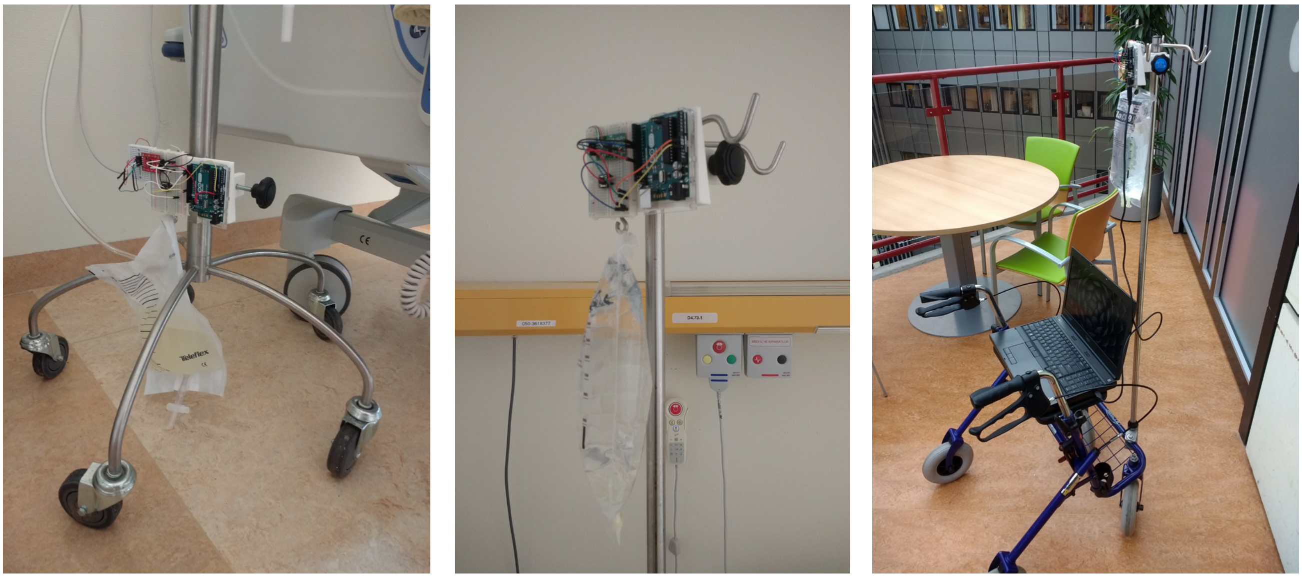


Figure 27.7 - 27.9: Setup in the UMCG hospital

The bag needs to hang freely

During a short test in the UMCG hospital the fluctuations are visible as well. Here it was found that more space around the IV bag is needed since the bag was touching the IV stand when being place onto the FluidBalance hanger (figure 27.7 - 27.9).

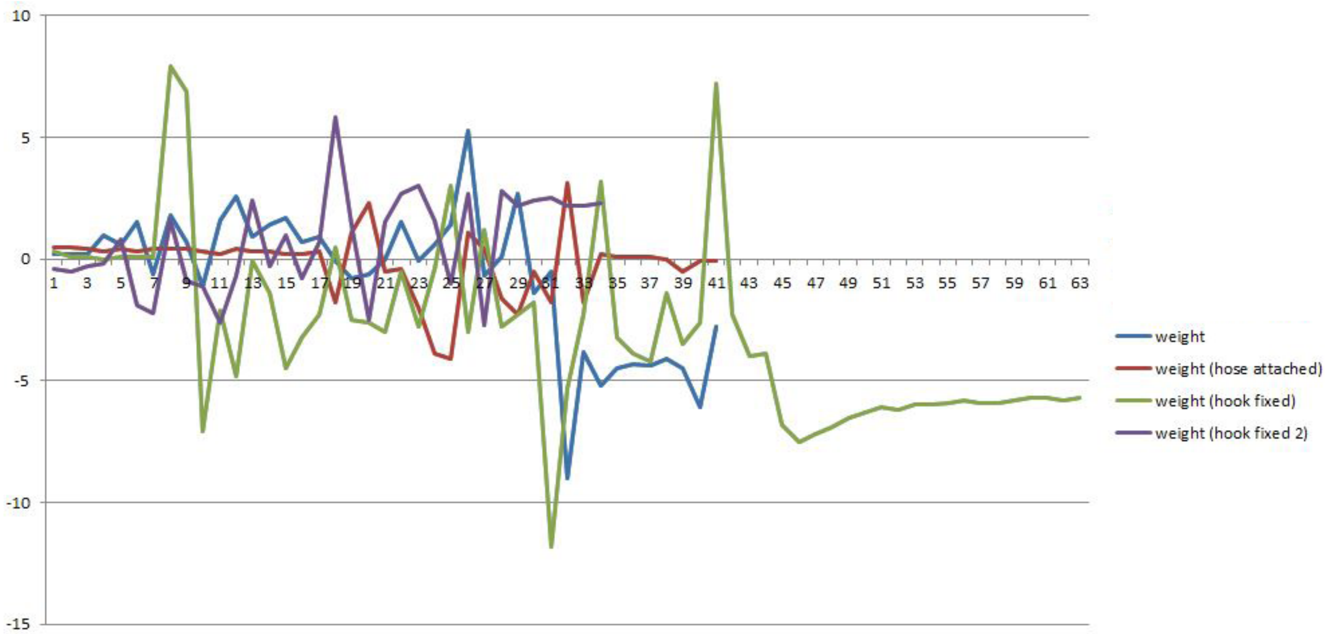


Figure 27.10: Errors in tests due to the tie rib

Influence of tie rib (figure 27.2)

During the first small tests big deviations were found after moving the bag around and wanting to go back to the start weight (zero grams). It turned out that the small tie rib in the middle of the prototype was touching the load cell. After removing the tie rib it did no longer happen that the weight of the bag (which was supposed to be zero grams) ended up at a value of -5 grams. Furthermore it was found that fixating the upper hook (figure 27.4) does not have a positive impact on the measurements. It is best to let this hook move around. It that case it can compensate along with the movement of the bag which leads to less deviations.

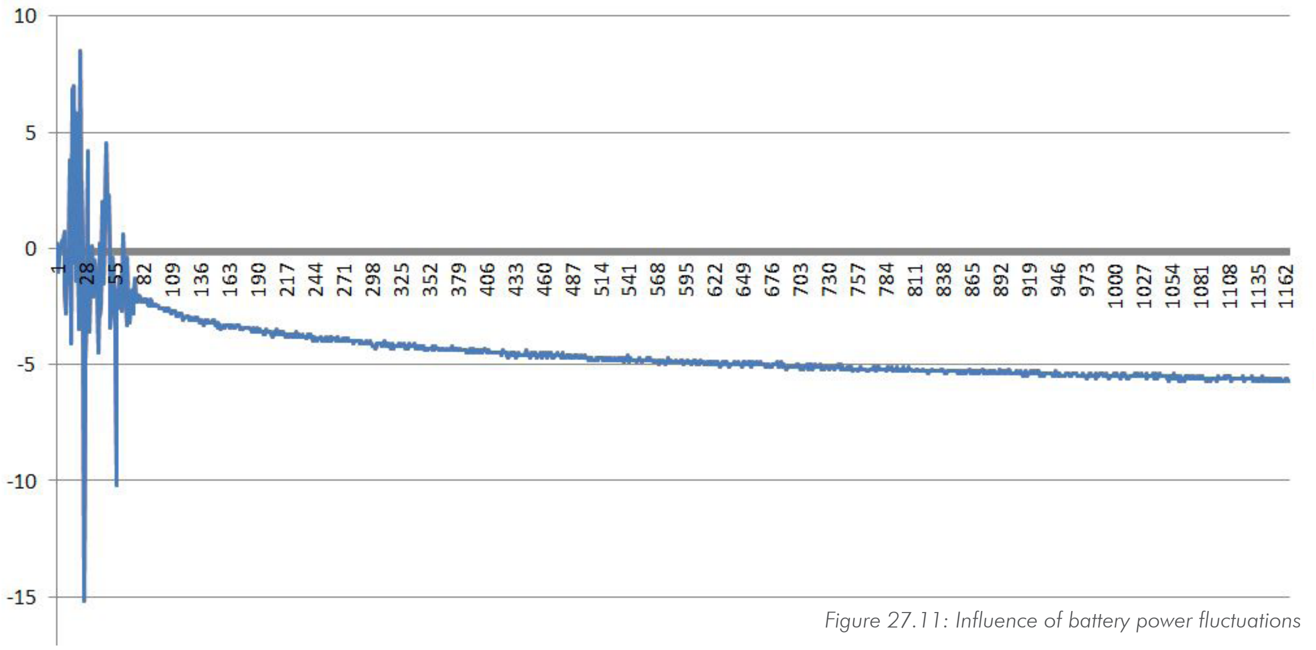


Figure 27.11: Influence of battery power fluctuations

Influence of the `laptop battery

Due to differences in power of the laptops battery pack it became visible that the load cell did not respond very well on this (figure 27.11). A compensation for the changes in power needs to be made. More testing with the battery is required to find out how the load cell reacts on its own battery. The computer is not only used for the load cell so fluctuations could also be increased by the fact that other programs and software require different amounts of power. Fortunately Li-Po batteries tend to have a very steady power supply until the battery is almost empty.

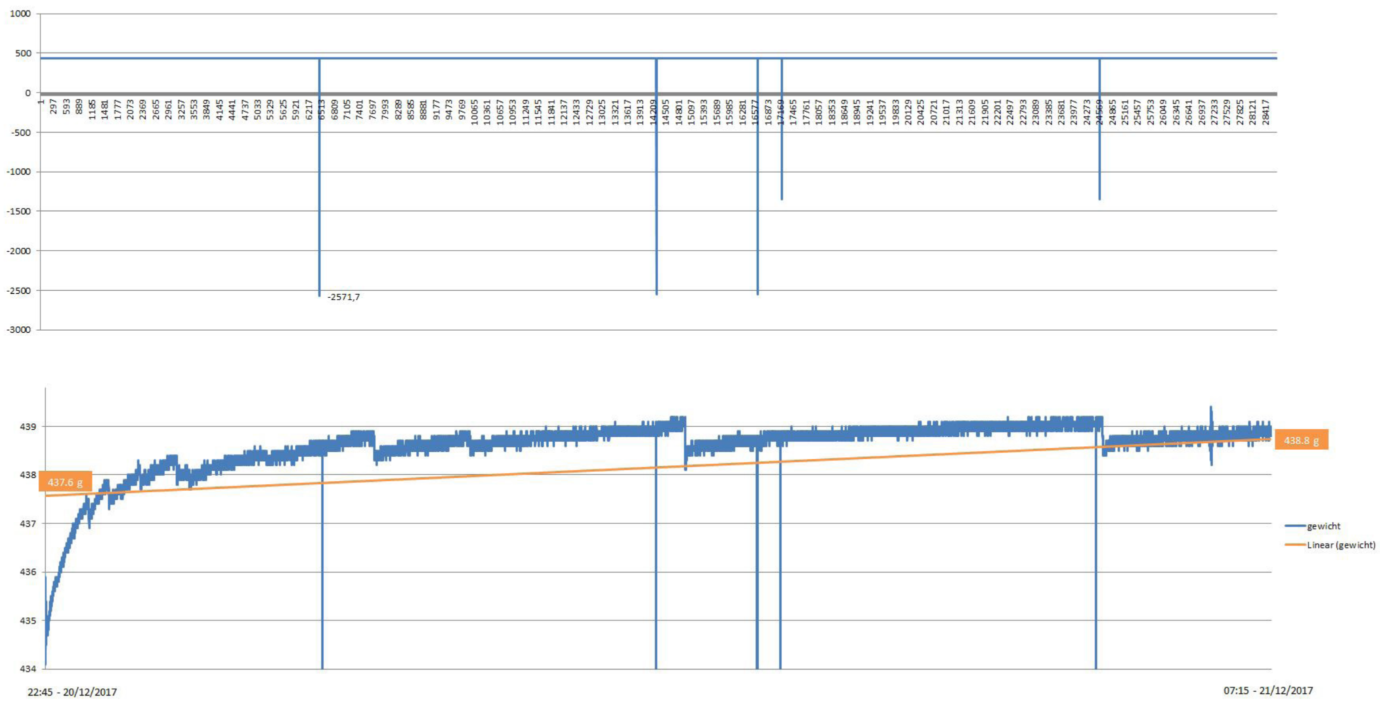


Figure 27.12: outcomes of 8.5 hours measuring the same weight (normal and zoomed in)

Change in weight over 8,5 hours

When leaving the load cell on for 8,5 hours with a fixed weight being attached to it a small change in weight is visible (figure 27.12). It is interesting to see that the load cell resets itself every few hours to stay within a specific measuring reach. The exact reason for this is still unclear and needs further research. Apart from these "reset moments" five big deviations are visible. This can be due to anything. Fortunately the deviations can be left out easily by neglecting large changes within a very short time span.

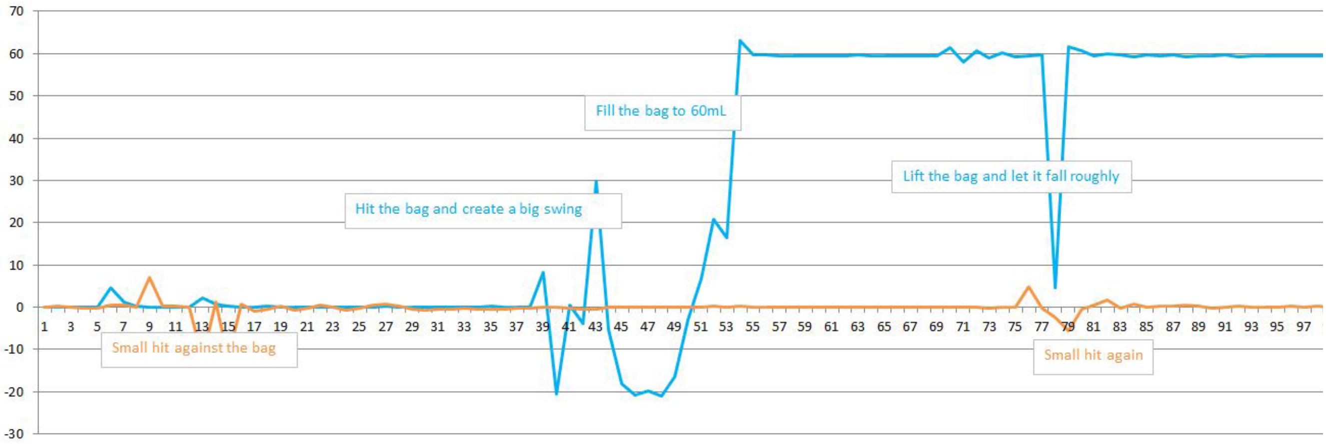


Figure 27.13: Testing the S beam load cell

Testing the S beam load cell

After implementing the first findings (Arduino cable upwards and leaving the s beam cell hang freely without any fixation) the graph above was formed. The blue graph represents moving with an empty bag and filling the empty bag with 60 millilitres of water. The different jumps are present due to lifting and swinging the bag. It is a positive finding to see that the measurements are recovering very fast from these influences. It only takes five seconds (from 75 seconds to 80 seconds) to provide the measurements correctly again. The orange line represents small movements with a filled bag (60 millilitres) (figure 27.13).

Figure 27.14: Testing the bar shaped load cell

Testing the bar shaped load cell

The bar shaped load cell was tested as well (filled with 60 millilitres interpreted as zero grams). The main reason maybe not to continue with the s beam load cell (although the Harris profile in appendix T shows that this architecture is preferred) is if the bar shape load cell's deviations during movement are within a reach of three grams only. The graph above shows however that fluctuations of ten and sometimes even twenty grams are common as well for the bar shaped load cell. It was found that the loose connection of the s beam shows even less fluctuations than the fixated bar shape load cell (figure 27.14).

Fluidbalance hanger

#	Hazards	Possible failure	Possible harm	Possible cause	D (detectability) 5 = bad 1 = good	P (probability) 5 = probable 1 = not likely	S (severity) 5 = severe 1 = unsevere	P*S (Risk)	Risk control measurements
	ENERGY HAZARDS								
	Electromagnetic Energy								
1	available voltage	Change in voltage supply when battery empties	changes in load cell measurements	wrong measurements and wrong input for fluid balance	4	5	4	20	corrections in calibration for changes in voltage or make sure the device provides a stable current. If this current is not available the device should not
2	Leakage current	Different voltage supply	changes in load cell measurements	wrong measurements and wrong input for fluid balance	4	2	4	8	Designing a solid electronic sytem and check regularly on possibilities for leakage.
	Radiation energy								
3	wrong interaction in connections	disfunctioning of interrupted products	depending on interupted product	interference with other products in the environment	4	3	4	12	Test the sensitivity of the product and make sure it is closed off for interrupting radiation with help of i.e a
4	wrong interaction in connections	disfunctioning of product	incorrect fluid balance	interrupted by wireless connections from other devices	4	3	4	12	Test the sensitivity of the product and make sure it is closed off for interrupting radiation with help of i.e a
5	failing of internal communication	no information is send to the tablet	incorrect fluid balance	failure of bluetooth connection	3	4	4	16	Make sure a warning is send to the nurses when this is the case. Tablet should register whether it receives information from all connected sources
	Thermal energy								
6	High temperature	wrong measurements	deviations in fluid balance	load cell is being influenced by temperature differences in	4	4	4	16	Pause the device when entering the shower
7	Low temperature	wrong measurements	deviations in fluid balance	load cell is being influenced by temperature differences in environment	4	1	3	3	Perform tests with the load cell in different temperatures. When big differences are discovered a temperature sensor might be needed to detect changes and adapt calibration
8	Temperature differences	malfunction of product / dangerous substances could go into the air	deviations in fluid balance / patient breaths poisonous air	reaction of product material due to oxygen rich environment and	4	1	5	5	Choose materials that can easily handle oxygen rich and humid environments,
	Mechanical energy								
9	Gravity	wrong measurements	incorrect fluid balance	uneven division of weight in the product which causes it to hang	1	3	3	9	counter weight in the bottom of the product or divide the weight evenly over the product
10	falling	fastening method fails	Product is broken partly but still goes on. In this case a partly working (possibly)	bumping against something or something against the product	1	2	5	10	test fastening method with different forces or make it able to catch movement
11		product falls	Product is broken partly but still goes on. In this case a partly working (possibly)	nurse accidentically drops the product	2	2	5	10	product runs a checkup round to check upon its own electronics before starting to measure
12	moving masses	wrong measurements	incorrect fluid balance	movement of bags due to a patient	2	5	3	15	set the product in pause mode when walking
13	Vibration	influence on measurements	deviating measurements	vibration as feedback in buttons	1	1	3	3	Use different feedback method without vibration such as lights
14	Vibration	wrong measurements	incorrect fluid balance	crudal behavior of family members, patient, nurse, etc.	2	2	3	6	IV stand is considered a device that should be treated with care. Use this image.
15	Stored energy	Li-Po battery catches fire	fire in the patients room/hospital	Overcharging the product/ not being able to cool down	2	1	5	5	most batteries are protected against this. Choose the correct battery and pay attention to protection
16	Moving parts	buttons get stuck	product becomes unusable	dirt is compiling around the buttons	2	3	3	9	Design buttons that cannot collect / can collect
17	Moving and positioning of patient	disconnection patient - device	lost fluids which are not measured	patient decides to stand up but forgets catheter or IV	2	1	3	3	This is being done already: make sure the catheter and IV hose are connected to another body part apart from the insertion location (i.e. with help of tape)
18	sound	interuption of sleep of other patients in the room	irritations among the patients	pressing buttons with sound	2	4	1	4	Use a different way of providing feedback about button usage to the nurse (without sound)
19	sound	interuption of sleep of other patients in the room	irritations among the patients	error in product functioning	2	4	3	12	Use a different way of providing feedback about button usage to the nurse. i.e. send warning signals to the nurse over the internet instead of with help of loud sounds.

	BIOLOGICAL AND CHEMICAL								
	Biological								
20	Re- or cross-infections	bacteria getting spread between patients	bacteria getting spread between FluidBalance hangers	nurse forgets to wash hands in between patients	4	1	5	5	patient does not need to interfere with the product which makes direct contact with bateria less likely
21	Bacteria	leakage of catheter content onto the product	bacteria getting spread between FluidBalance hangers	clumsy behavior of nurse or patient	2	1	5	5	Product is hanging above the catheter bag. Furthermore it should be easily cleanable.
22	Infection	less control moments on bags	infections in the uninary tract	Cathether bag is not changed often enough	3	3	4	12	Warnings shoudl be given when a bag needs to be replaced. This should happen every 72 hours.
	Chemical								
23	- Acids or alkalis	material can not stand chemicals	chemical reaction with gasses or break	wrong material choice	4	1	4	4	Select a material that can stand the substances
24	- Additives of processing aids	material can not stand chemicals	chemical reaction with gasses or break	wrong material choice	4	1	4	4	Select a material that can stand the substances
25	- Degradation products	material can not stand chemicals	chemical reaction with gasses or break	wrong material choice	4	1	4	4	Select a material that can stand the substances
26	- Medical gasses	product can not stand oxygen-rich	chemical reaction with gasses or break	wrong material choice / wrong	4	1	4	4	Select a material that can stand the substances
	OPERATIONAL HAZARDS								
	Functionality (components)								
27	small deviation in performance over time	measurement outcomes start to deviate	different outcomes and deviation in fluid balance measurements	fatigue of load cell	5	2	5	10	Extensive testing report of load cell analysis. Use a CE certified load cell that is tested extensively
28	malfunction of the battery	no power to the device	device cannot be used	disconnection of cables	1	3	2	6	electronic parts should be potted into both shelves. The rubbery substance should be able to withstand drops from a certain height. Other parts (detectable) should fail before the potted part dissimulates.
29	malfunction of the e paper screen	measurement values and feedback is not being displayed	product cannot be used	disconnection of cables	1	3	1	3	electronic parts should be potted into both shelves. The rubbery substance should be able to withstand drops from a certain height. Other parts (detectable) should fail before the potted part dissimulates.
30	malfunction of the load cell	no measurements take place	tablet will not receive values despite of being connected via bluetooth	disconnection of cables	1	3	4	12	electronic parts should be potted into both shelves. The rubbery substance should be able to withstand drops from a certain height. Other parts (detectable) should fail before the potted part dissimulates.
31	malfunction of the accelerometer	walking is not being detected	incorrect / deviating measurements are being send	leakage of water / disconnection of cable due to falling	4	3	4	12	electronic parts should be potted into both shelves. The rubbery substance should be able to withstand drops from a certain height. Other parts (detectable) should fail before the potted part dissimulates.
32	leakage of water despite of being water tight	electronics might fail or function differently	product failure during measurements.	maybe due to falling, the gasket or other rubbery material loosens and	4	2	4	8	Product should be quite easy to replace when failure is being detected. When
	User errors								
33	Press the wrong button	product does not react	frustrated nurse	Product is not turned on	1	2	2	4	proper education on how to use the product
34	Attentional Failure	Nurse presses connection instead of pause	Product is not being paused during replacement which leads to incorrect fluid balance overview	Nurse is distracted from her task	2	1	3	3	Make pressing a button a consious choice by having to press for 3 seconds before something happens. / proper education / proper feedback on the screen.
35	attentional failure	nurse places the device upside down facing	buttons and feedback are not easy to read. Measurements won't change due to the fact that an S-beam load cell is used.	nurse pays to less attention when placing the device	1	1	1	1	Clear difference between up and down. Word to indicate where the bag is supposed to be placed could help too.
36	Knowledge-based failure / attentional failure	Nurse presses on on/off button instead of pause button	device will turn off when this is not required. This leads to a stop in measurements.	misunderstanding between on/off button and pause/play button	2	2	5	10	proper education on how to use the product / warnings when turning off the device. Button needs to be pressed for three seconds. Meanwhile i.e. "product is turning off" is shown on the screen. Product should only turn off when it is being deleted in the tablet (no connection is present)

37	Knowledge-based failure / attentional failure	Nurse presses pause/play button instead of on/off	Device will pause instead of turning off. This means that the battery will still drain when the product is not in use	misunderstanding between on/off button and pause/play button	2	2	2	4	Battery drainage is not nice, but no big deal. The device will give a warning when it is being on pause for too long which reminds the nurse to turn it off. Proper education is again a must
38	Knowledge-based failure / attentional failure	nurse presses connectivity button to resend information after a connection failed. Or forgets to press "resend" after connection is restored	incorrect fluid balance, due to lacking information Is het echt belangrijk om te weten wat een patient ieder 10 sec plast? Is het ook voldoende omt te weten	Nurse is distracted from her task	4	3	4	12	Software should send a warning about reconnecting the device (after bluetooth failure) every minute. After connection is restored a backup of the last 10 measurements should be resend to the tablet. When the device is being connected for the first time (to a patient) there are no measurements to send.
39	Attentional Failure / routine violation	nurse presses one of the buttons when grabbing the device	something unexpected happens which influences the measurement outcomes	nurse is distracted from her task / pays to less attention to her task.	2	3	4	12	Awareness around pressing buttons needs to be created. Pressing for multiple seconds increases awareness already.
40	Attentional Failure	nurse forgets to set the device to zero	Measurements are not started	Nurse is distracted from her task	4	2	4	8	proper education on how to install the product. This is the main task of the product
41	Routine violation	Nurse presses pause instead of connection	Product is not visible when the nurse tries to find it with the tablet to create a connection. This couuld lead to frustration for the nurse	Nurse is distracted from her task / to less attention is paid to the task	2	2	1	2	Tablet should show possibilities to solve the problem and point out what to do. Use sentences like: "When your product was not found, make sure to press the connectivity button until it appears on
42	Memory failure	product cannot save measurements	part of fluid balance input is missing.	memory is full	4	1	4	4	Design should provide more than enough memory
43	Rule-base failure / neglecting rules	patient presses connectivity button	connectivity is being formed again	neglecting rules and playing around	4	1	2	2	Connectivity button only activates bluetooth signal and does not form /influence the connection. The connection is being formed via the tablet which is locked for the patient
44	Rule-base failure / neglecting rules	patient presses on/ off button	Device turns off which stops measurements	patients wants to save the nurse time by pressing buttons him- / herself	3	1	3	3	Product should only turn off when it is being deleted in the tablet (no connection is present)
45	Rule-base failure / neglecting rules	patient presses pause/play button	devices pauses during specific amount of time	neglecting rules and playing around	4	1	4	4	When product is set to pause manually a warning is given after half an hour to activate the device again to make sure measurements are performed at least every hour
46	Rule-base failure / neglecting rules	patient presses zero button	devices resets value wrongly	neglecting rules and playing around	4	1	5	5	
47	Rule-base failure / neglecting rules	patient presses resend button	device resends values	neglecting rules and playing around	4	1	3	3	resending information should be able to be done whenever pressed without a problem. The software should be able to order the information according to time stemps.
	INFORMATION HAZARDS								
	Labeling								
48	Incomplete instruction for use	Wrong use by nurse	wrong outcomes which result in wrong fluid balance and treatement plan	unclear instruction / too complicated product	3	2	4	8	User tests about understanding the product system and improments on usability should be performed.
	Operating Instructions								
49	Over-complicated operating instructions	steps are forgotten / not performed	wrong fluid balance	nurse forgets some of the steps to handle the device	3	2	5	10	User tests about understanding the product system and impроments on usability should be performed.
	Warnings								
50	battery level	empty battery	wrong fluid balance / no fluid balance	unclear / too subtile warnings for battery level drops	2	2	5	10	Device should not turn itself on when less than 5% of battery power is left. (at least two weeks before the end of the battery life)
51	clearness of warning	no clear distinctions between warnings	patient is worried because of nothing	same sound for different warnings, sound in the patient room not necessary?	2	1	3	3	As less sounds around the patient as possible. Most warning are send to the phone of the nurse / COW
	Specification service/maintenance							5	
52	lack of service and maintenance	lack of service check ups	unreliable device is being used	no clear specification on when check ups are needed	4	1	5	5	Most hospitals have a policy to check products regularly (for example yearly)
53	lack of service and maintenance	nurse does not bring the product to the maintenance department after dropping it	unreliable device is being used	nurse is in a hurry and does not want to pick up a new device	4	2	5	10	Instruction should be very clear and maybe even the presence of sensitive technology needs to be mentioned for the nurse to understand importance of reporting drops

FluidBalance system

	Hazards	Possible failure	Possible harm	Possible cause	D (detectablility)	P (probability)	S (severity)	P*S (Risk)	Risk control measurements
	Thermal energy								
	Mechanical energy								
1	- falling	fastening method fails	product breaks down	bumping against something or something against the product	1	1	5	5	Design the adapter in such a way that unintentional falling is impossible
2	Vibration	vibration function of tablet influences	one of the two breaks down	vibration function is not turned of before	3	1	4	4	possibilities within the tablet should be totally
3	Moving parts	moving part to place tablet gets stuck	tablet adapter gets ruined trying to	dirt compiling on the moving part and	2	2	3	6	product needs to be able to be disassembled
4	- sound	interuption of sleep (other) patient (s)	irritations among the patients	error in product functioning	2	3	1	3	Only very important sounds that need to interrupt the patient or are ignored by the nurse for too long should be heard at the patients bedside.
5	Bright screens	interuption of sleep (other) patient (s)	irritations among the patients	usage of screen during the night	2	3	1	3	Design a way to make the use of the screen during the night as less needed as possible
	BIOLOGICAL AND CHEMICAL								
	Biological								
6	Re- or cross-infections	Nurse uses the same gloves for serving the tablet as she used for another patient	bacteria getting spread between tablets	nurse forgets to replace gloves	5	1	3	3	Maybe it would be interesting to deliberately choose to make the tablet only usable without gloves to prevent this issue. (capacitive screen)
	Chemical								
7	- Acids or alkalis	material of tablet can not stand chemicals	chemical reaction with gasses or break down of product	wrong material choice	4	1	4	4	Search for the right tablet and make sure it can withstand all involved substances and environments
8	- Additives of processing aids	material of tablet can not stand chemicals	chemical reaction with gasses or break down of product	wrong material choice	4	1	4	4	Search for the right tablet and make sure it can withstand all involved substances and environments
9	- Degradation products	material of tablet can not stand chemicals	chemical reaction with gasses or break down of product	wrong material choice	4	1	4	4	Search for the right tablet and make sure it can withstand all involved substances and environments
10	- Medical gasses	tablet can not stand oxygen-rich air	chemical reaction with gasses or	wrong material choice / wrong	4	1	4	4	Search for the right tablet and make sure it can
	OPERATIONAL HAZARDS								
	Functionality (components)								
11	malfunction of buttons	Home button / sleep button is broken	not being able to use the product properly	anility	2	2	4	8	When the tablet is broken a new one should be placed. New installation of the FluidBalance hangers is needed. The measurements of the day should be send over to the new tablet using the "resend" button.
12	touchscreen (partly) fails	not being able to use certain functions	not being able to use the product properly	anility / rough usage	2	2	4	8	When the tablet is broken a new one should be placed. New installation of the FluidBalance hangers is needed. The measurements of the day should be send over to the new tablet using the "resend" button.
13	touchscreen totally fails	touchscreen breaks down	measurements are not collected and processed	anility / rough usage	1	2	5	10	When the tablet is broken a new one should be placed. New installation of the FluidBalance hangers is needed. The measurements of the day should be send over to the new tablet using the "resend" button.
14	component failure (bluetooth connector, internal memory, wi fi connector, battery)	storage on internal memory not longer possible	product does not function properly which results in wrong /delayed output of the fluid balance values	unknown	4	1	4	4	All calculations are send over to the COW as back up. Furthermore a warning (to involved nurse)should be given on the tablet when it is not longer possible to write data on the internal memory card. When the tablet is broken a new one should be placed. New installation of the FluidBalance hangers is needed. The measurements of the day should be send over to the new tablet using the "resend" button.

15	Loss or deterioration of function	stop working without notice / empty battery (after all warnings are ignored)	no measurements during certain time span	unknown	4	1	5	5	COW can check if it is still receiving values from the tablet. When this is not the case a pop-up on the COW (visible for all nurses) is given
	Use error								
16	Erroneous data transfer	wrong ID is connected to the patient	wrong fluid balance / treatment plan	nurse makes a mistake during entering details	4	2	5	10	Feedback on patient identials should be given towards the nurse. The tablet is connected to Wi-Fi and should be able to show which name is connected to the ID. This provides a check-up method to she whether the correct name appears
17	Attentional Failure	Nurse confirms information about a FluidBalance hanger which was entered	wrong information about FluidBalance hanger is used in the calculation.	not paying attention	4	2	5	10	Only possible combinations (catheter and output, IV and input) need to be able to be formed.
18	Attentional Failure	Nurse confirms wrong bag size about a bag connected to FluidBalance hanger	Wrong notifications about when the bag is empty or full are send to the nurse	not paying attention	3	2	3	6	Nurse will not receive messages about when to replace a bag, but the (family of) the patient, the nurse and other nurses can still see whether a
21	Attentional Failure	Nurse connects the wrong FluidBalance hanger (the one of the neighbour) with the tablet	incorrect fluid balance	not paying attention	4	1	5	5	Only "visible" devices can be connected. So only if another nurse is connecting a FluidBalance hanger to the patients neighbour at the same time (devices are visible for a few minutes only) and the nurse does not pay attention to her work this could happen. To prevent confusing visible devices should be ranked according to their connection strength (the closest device has the strongest connection)
22	Knowledge-based failure	Icons are understood wrongly	Wrong actions are taken or nurse does not know what to do	lacking education / knowledge nurse	2	2	3	6	Whether icons and the application is understood should be testen extensively. Furthermore all buttons should have a description next to an icon. Finally the nurse and the care assistant will learn by practising often and using the product system
23	intentionous failure	tablet gets stolen by a visitor / patietn	lot of costs involved	tablets are not savely stored	2	3	5	15	Tablet holder should be locked and only be able to open when a nurse holds her tag against it.
24	Routine violation	Nurse forgets to enter the amount of fluid that is already in the bag when the patient enters the nursery room.	Fluid balance is started from that moment (without prior losses of fluid)	not paying attention	4	2	3	6	This is not a big problem since patients are considered "in balance" when they come out of surgery. They are monitored during surgery.
	INFORMATION HAZARDS **Labeling**								
25	Incomplete instruction for use	Nurse does not receive proper education	mis understanding / wrong usage of system	nurse was ill on instruction day, ignores the fact that education is needed for the sytem	2	1	4	4	Place user scenarios and explanations in the storage place on a big poster. Furthermore, make sure that education programs are monitored closely to prevent this from happening
26	Inadequate performance specification	possible user scenarios are not considered	nurse does not know what to do and acts wrongly which results in wrong measurements / overviews	not enough testing during earlier phases of the project	3	1	5	5	extensive testing over longer period adding different parts of the system after smaller parts are tested to make sure the total system is prepared for everything.
27	Inadequate specification of intended use	possible user scenarios are not considered	nurse does not know what to do and acts wrongly which results in wrong measurements / overviews	not enough testing during earlier phases of the project	3	1	5	5	extensive testing over longer period adding different parts of the system after smaller parts are tested to make sure the total system is prepared for everything.
28	Inadequate disclosure of limitations	user scenario images are not clear	mis understanding / wrong usage of system	not enough testing during earlier phases of the project	3	1	4	4	Make sure to test all facets of the product system
	Operating Instructions								
29	Over-complicated operating instructions	steps are forgotten / not performed	wrong fluid balance	nurse forgets what to do in tablet	2	2	5	10	extensive testing of system and create a system that is as easy as possible. Focus on a system that does not need specified knowledge on how to use it. It should speak for itself.

	Warnings							
30	battery level	empty battery of the tablet	wrong fluid balance / no fluid balance	unclear / too subtile warnings for battery level drops	1	2	5	10	extensively testing in first testing phases of the system. Never testing the system on its own (with no back up measurements) before all of these bugs are filtered)
31	clearness of warning	no clear distinctions between warnings	patient is worried because of nothing	same sound for different warnings	4	2	3	6	extensively test warning system, understanding by the nurse, attention of the nurse and how they respond on warnings. They have requested warnings themselves, so ignorance seems odd.
	Specification service/maintenance							5	
32	lack of service and maintenance	lack of service check ups	unreliable device is being used	no clear specification on when check ups are needed	3	1	5	5	Most hospitals provide this service themselves. A clear description about service requirements (maybe based on CE certification and requirements) needs to be added to the product descriptions / instructions

FluidBalance integration

	Hazards	Possible failure	Possible harm	Possible cause	D (detectability)	P (probability)	S (severity)	P*S (Risk)	Risk control measurements
	ENERGY HAZARDS Electromagnetic Energy				5 = bad 1 = good	5 = probable 1 = not likely	5 = severe 1 = unsevere		
1	available voltage	detailed overview cannot be viewed on COW	Information from tablet cannot be send to the COW	COW is out of power	1	1	2	2	COW is used for multiple purposes (low chance of happening). Talking to current users and current measurements that are taken to prevent such a thing from happening
2	Magnetic fields	FluidBalance hanger does function bad due to magnetic fields in the	wrong measurements	magnetic field is being created by other devices in the hospital	4	1	5	5	extensive testing in context
	Radiation energy								
3	compatibility	only Wi-Fi or ZigBee is available in the	product cannot be used without	budget issues of hospital	1	3	5	15	make the product compatible with both networks
4	Failing of internet connection	Wi-Fi network is used by too many users	bad functionality	Wi-Fi is used by many devices and users in a hospital	3	3	5	15	When it turns out that this is the case we could use a different network like ZigBee which is less often used by mobile phones for example.
5	Failing of internet connection	COW is disconnected from Wi-Fi	Information from tablet cannot be send to the COW	network down	2	1	3	3	network down has influence on much devices in the hospital. Find out how this is managed now or use a different network type (like ZigBee) as well
	Thermal energy								
6	High/ low temperature	storage rooms are too cold for the devices	devices do not function properly	load cell gets influenced by temperature	2	2	5	10	Testing of system, researching temperature differences in hospital storage rooms and bathrooms (when in use) and investigate the reaction of the load cell on it.
	INFORMATION HAZARDS authorization								
7	no authorization	no authorization to enter information in	system is not accepted	does not meet requirements that	4	2	4	8	Clear insights in requirements of the hospitals
	Warnings								
8	compatibility	Warning system not compatible with phones	warnings system cannot be used	not enough testing on compatibility with different systems	2	1	5	5	extensive testing in context (different hospitals)

Testing procedures

2018

Price validation

The total price of the system still needs to be determined. This will depend on the extensiveness of the application, development time, certification time and costs, type of tablet (holder), etc. The product can save a lot of money and is relatively cheap which means that there is a way to earn money for further development. To get to know how much a buyer will pay for the solution a simple model can be used. The "price sensitivity model" from van Westendorp (Appolonsky, 2018) is shown on the next page in figure ... A way to do this is by having different buyers judge different costprices on:

- How much do they think the system is worth
- How much they would be willing to pay

This will lead to an expected price range.

Technical validation

First testing with the prototype consisting of:

- Testing of the code
  - Amount of updates required
  - Influence of patient movement during a whole day of testing. Maybe adjust the five grams in the code (how much the values can deviate from the average value)
  - Testing with new board (huzzah feather ESP32) and connect pause/play button
  - Ideation on when alarms would be required for different wards.

This will lead to new insights that can be implemented into the next versions of FluidBalance.

Bench marking tests

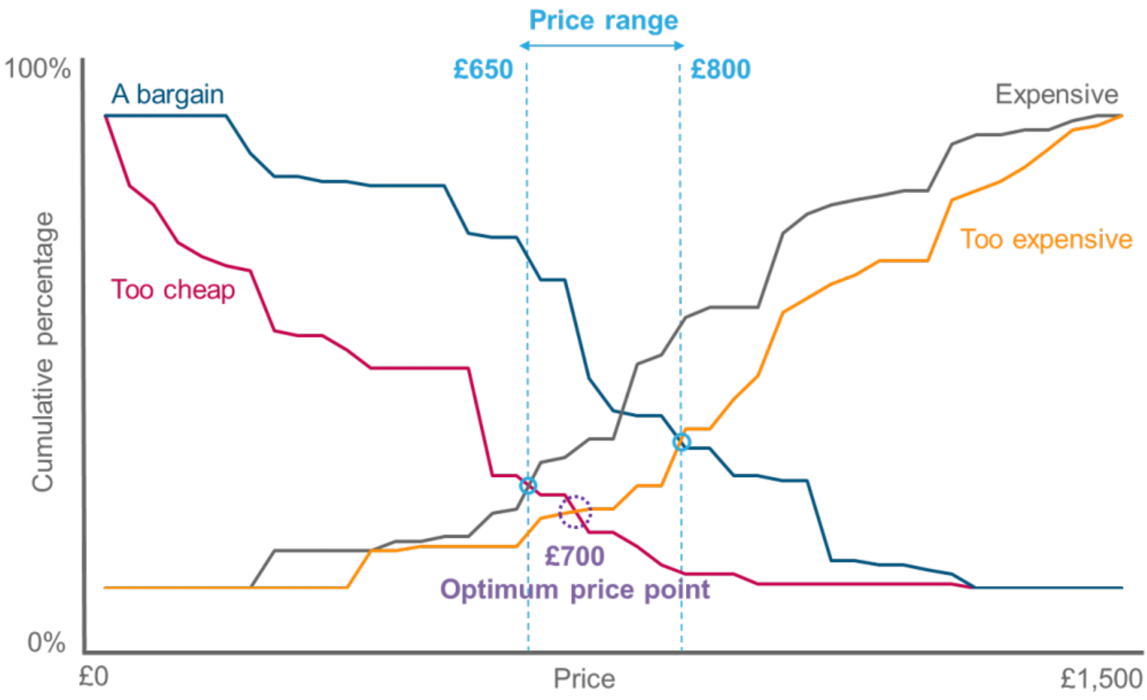
Compare the working and improved model to the Urimeter and find differences.

- Test differences when entering a specific amount of water into both systems. The Urimeter will show more deviation than the FluidBalance hanger which will help to convince buyers.
- Perform a test between an existing competitive device (for example the Sippy or the Accuryn) and find out how accurate the FluidBalance system can be. These devices are certified already and these companies aready claim a specific level of accuracy which makes it better to compare FluidBalance with it.

Application improvements

Build a first prototype of the application. A way to do this (without the need to program an app) is by using a application called: POP. This application allows simple interaction possibilities and is suitable for testing.

- Improve the application according to the recommendations
- Test the application together with the current prototype to find out if the scenarios are thought trough enough. This test is easy to perform in a focus group of nurses. With help of the app prototype and the FluidBalance hanger prototype a real like situation can be simulated and explained.
- A second step would be to let the nurses perform different tasks with the system, based on daily routines.



Price for total system	Too cheap	fair price	expensive	too expensive
50	O	O	O	O
200	O	O	O	O
500	O	O	O	O
1000	O	O	O	O
1500	O	O	O	O
2000	O	O	O	O
3000	O	O	O	O
5000	O	O	O	O

2019

Compatibility testing

A working application that communicates with the FluidBalance hangers and with the Smartlinx system to create a correct value about the current fluid balance that needs to be send to the EPD.

- Test the total compatibility of the system inside the UMCG.
- Preferably, test the total compatibility of the system in three other hospitals.

Testing in other hospitals could be done after the working concept is proved inside the UMCG first.

2020

Value perception testing

When the system is properly checked and regularly tested a pilot of usage can be realised. Several FluidBalance systems need to be available at two different hospital wards at the UMCG (and preferably at another hospital).

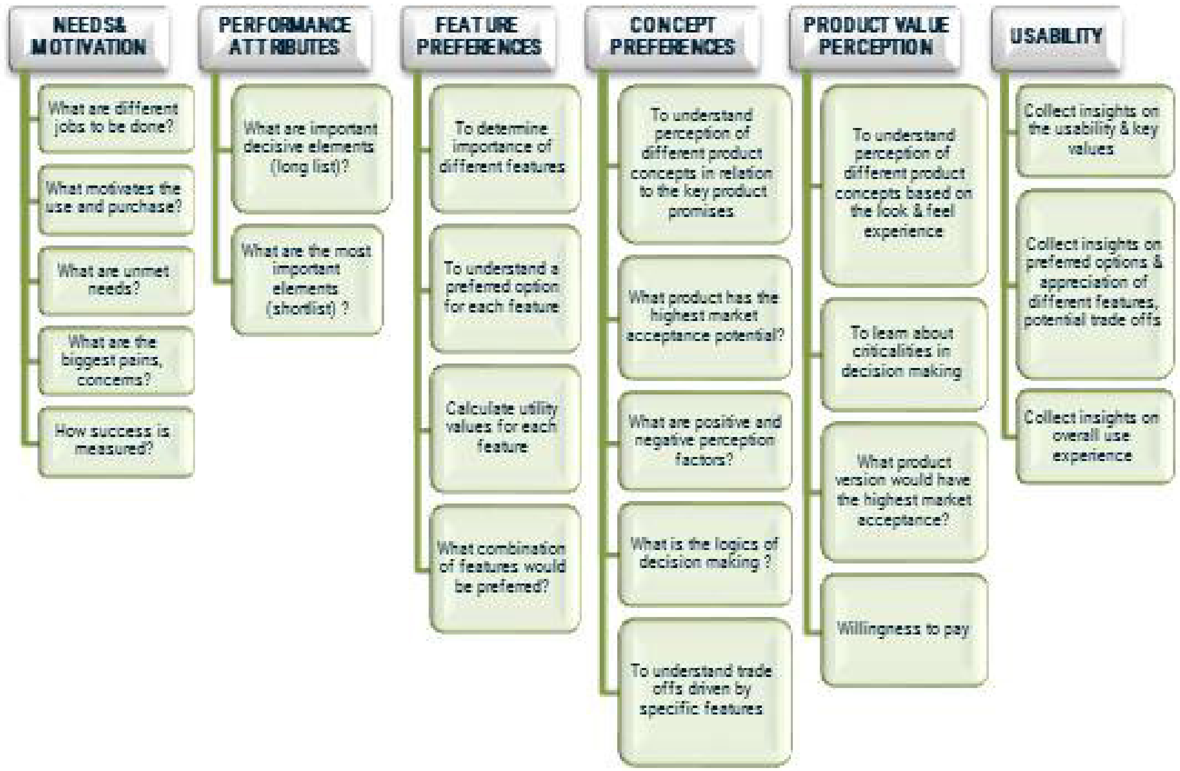
- It would be interesting to observe people working with the system to be able to find detailed problems. This accounts for both nurses as assistants.
- Questionnaires or short interviews are a good way to gain insight into the wishes of the nurse and how they would score the FluidBalance system compared to the old situation (assuming they were working with Urimeters).

Of course all gained insights will be used for improvements

CONFIDENTIAL

IDENTIFY CUSTOMER KNOWLEDGE GAPS IN YOUR PROJECT

1. Discuss in duo's the assessment of your validation maturity
2. Use the below questions to identify gaps



Cost Estimator

New Estimate | Save | Recent Estimates | View Workspace | Share | Units

General | Injection Molding | Reports | Additional Processes

Cost Summary | E-Mail to a friend

General Information

Name: Front shell
Description:

Part Information

Quantity: 20,000
Material: Polycarbonate, Molded
Envelope X-Y-Z (in): 3.50 x 3.50 x 1.00
Weight (oz): 1.04
Tolerance (in): Moderate precision (<= 0.01)
Surface roughness (μin): Smooth (Ra <= 32)

Process Parameters

1. Injection Molding

Material
Defect rate (%): 5.00
Material price ($/lb): 2.00
Part weight (oz): 1.04
Regrind ratio (%): 0.00
Additives ratio (%): 0
Material markup (%): 25.00

Production
Machine clamp force (tons): 50
Hourly rate ($/hr): 30.00
Machine setup time (hrs): 8.00
Machine uptime (%): 95.00
Production rate (parts/hr): 212
Post-processing time (hrs.): 0.00
Production markup (%): 10.00

Tooling
Number of cavities: 1
SPI mold class: Class 104
Mold-making rate ($/hr): 65.00

Cost Summary

1. Injection Molding	$48,512 ($2.426 per part)
Material cost	$3,804 ($0.190 per part)
Production cost	$3,371 ($0.169 per part)
Tooling cost	$41,337 ($2.067 per part)
Total cost	**$48,512 ($2.426 per part)**

General Information

Name: Grip band
Description:

Part Information

Quantity: 40,000
Material: Polypropylene, Molded
Envelope X-Y-Z (in): 3.00 x 0.80 x 0.20
Weight (oz): 0.23
Tolerance (in): Moderate precision (<= 0.01)
Surface roughness (μin): Smooth (Ra <= 32)

Process Parameters

1. Injection Molding

Cost Summary

1. Injection Molding	$21,670 ($0.542 per part)
Material cost	$824 ($0.021 per part)
Production cost	$3,536 ($0.088 per part)
Tooling cost	$17,309 ($0.433 per part)
Total cost	**$21,670 ($0.542 per part)**

Cost Estimator

New Estimate | Save | Recent Estimates | View Workspace | Share | Units

General | Injection Molding | Reports | Additional Processes

Cost Summary | E-Mail to a friend

General Information

Name: **On/Off button**
Description:

Part Information

Quantity: 20,000
Material: Acrylonitrile Butadiene Styrene (ABS), Molded
Envelope X-Y-Z (in): 0.80 x 0.80 x 0.40
Weight (oz): 0.09
Tolerance (in): Moderate precision (<= 0.01)
Surface roughness (µin): Smooth (Ra <= 32)

Process Parameters

⊞ **1. Injection Molding**

Cost Summary

1. Injection Molding	$19,651 ($0.983 per part)
Material cost	$352 ($0.018 per part)
Production cost	$3,486 ($0.174 per part)
Tooling cost	$15,813 ($0.791 per part)
Total cost	**$19,651 ($0.983 per part)**

Cost Estimator

New Estimate | Save | Recent Estimates | View Workspace | Share | Units

General | Injection Molding | Reports | Additional Processes

Cost Summary | E-Mail to a friend

General Information

Name: bracket catheter hose
Description:

Part Information

Quantity: 20,000
Material: Acrylonitrile Butadiene Styrene (ABS), Molded
Envelope X-Y-Z (in): 0.60 x 1.60 x 0.50
Weight (oz): 0.07
Tolerance (in): Not critical (> 0.02)
Surface roughness (µin): Smooth (Ra <= 32)

Process Parameters

⊞ **1. Injection Molding**

Cost Summary

1. Injection Molding	$9,783 ($0.489 per part)
Material cost	$309 ($0.015 per part)
Production cost	$3,486 ($0.174 per part)
Tooling cost	$5,988 ($0.299 per part)
Total cost	**$9,783 ($0.489 per part)**