Automatic regulator for vertical position of medical equipment

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Abstract

External ventricular drainage (EVD) is a widely used method in neurosurgery to reduce elevated intercranial pressure caused by excessive amounts of cerebrospinal fluid. The procedure is performed by implanting a catheter into the ventricles of the brain in order to drain cerebrospinal fluid into an external container. The fluid flow rate is controlled by maintaining a height difference between the catheter inlet and outlet.

A desired height difference for an acceptable flow rate is set by a doctor. The outlet of the catheter is then fastened to a stand at the correct vertical distance from the patients head by a nurse. When the patients head moves, the height difference between inlet and outlet changes, forcing the nurse to adjust the catheter outlet position.

Innovation Skåne is an innovation company owned by Region Skåne, the county council of Scania. They develop solutions and products that stem from ideas by employees, in regards to improvements and efficiency. They have been contacted by a nurse at a local hospital regarding the inefficient and unergonomic way of operating the EVD system. The aim of this thesis was to solve these problems by developing an automatic height regulator for the EVD system based on an Innovation Skåne patent.

To this end an iterative design process was used, beginning with a pre-study to verify the technical feasibility of the patent. Interviews and literature searches were then performed to build a broad understanding of the context of the EVD-system and the associated customer needs. This acted as a foundation for the concept development phase of the thesis where concepts were iteratively developed and tested using rapid prototyping.

The final product was a prototype of a working automatic height regulating system designed to be easy and ergonomic to use and to increase the accuracy of the EVD system.

Keywords: Automation, Medical, Prototype, Neurosurgery, Height sensor

Sammanfattning

Ventrikulärdränage är en vedertagen metod vid behandling inom neurokirurgi för att dränera cerebrospinalvätska som producerats på grund av förhöjt intrakraniellt tryck. Ingreppet görs genom att operera in en dränageslang till hjärnans hålrum, ventrikelsystemet, vilket tillåter cerebrospinalvätskan att dräneras till en extern behållare. Flödet kan styras genom att bibehålla en viss höjdskillnad mellan kateterns inlopp och utlopp.

Den önskvärda höjdskillnaden som ger upphov till korrekt flöde bestäms av en läkare. Kateterutloppet monteras sedan på en droppstång av en sjuksköterska, vid rätt vertikal höjd från patientens huvud. När patienten rör sitt huvud förändras höjdskillnaden mellan inlopp och utlopp, vilket gör att sjuksköterskan tvingas justera kateterns utloppsposition.

Innovation Skåne är ett innovationsbolag som ägs av Region Skåne, landstinget i Skåne län. Bolaget utvecklar produkter till sjukvården som skall bidra till effektivisering och förbättring. Idéerna härstammar från regionanställda. De har varit i kontakt med en sjuksköterska vid ett lokalt sjukhus angående den ineffektiva och oergonomiska arbetsgången vid vårdförloppet för en patient med ventrikulärdränage. Målet med examensarbetet var att lösa dessa problem genom att utveckla en automatisk höjdregulator för ventrikulärdränagesystemet baserat på ett patent från Innovation Skåne.

Till detta ändamål användes en iterativ designprocess, som började med en förstudie för att verifiera den tekniska genomförbarheten av patentet. Intervjuer och litteraturstudier låg till grund för den djupare förståelse som behövdes för systemet och de kundbehov som fanns. Det var även detta som var grunden till konceptutvecklingsprocessen av examensarbetet, i vilket koncept utvecklades genom en iterativ process och testade genom rapid prototyping.

Den slutliga produkten var en fungerande prototyp av en automatisk höjdregulator, utvecklad för att vara enkel och ergonomisk att använda samt öka precisionen på ventrikulärdränagesystemet.

Keywords: Automation, Medicin, Prototyp, Neurokirurgi, Höjdsensor

Acknowledgements

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Acronyms

CSF	cerebrospinal fluid
DC	direct current
DFMA	design for manufacturing and assembly
ECG	electrocardiography
EI	environmental interface
EVD	external ventricular drainage
FT	fluid tube
ICP	intracranial pressure
IV	intravenous
LA	linear actuator
LDI	linear device interface
MDF	medium density fibre board
PI	patient interface
PCB	printed circuit board
PID	proportional-integrative-derivative
PVC	polyvinyl chloride
SLS	selective laser sintering
SUHL	skåne university hospital lund
TSI	tube sensor interface
U&E	ulrich and eppinger
UI	user interface

1 Introduction

This thesis was conducted in collaboration with Innovation Skåne AB and ÅF Industry AB. The introduction chapter presents a background to the thesis, a problem formulation, and the scientific basis behind the thesis. The goals of the thesis is presented at the end of the chapter

1.1 Background

In the medical field, many procedures used for the treatment of patients are carried out by human interaction. By automating simple tasks, the workload can be redistributed to activities that are in greater need of human supervision. Time consuming but simple processes that are carried out by a nurse still exist, and the need for the automatic regulator of vertical position described in this thesis has been verified by a nurse at Skåne University Hospital Lund (SUHL).

Innovation Skåne is the regional innovation company in Skåne, active in the healthcare sector. They provide innovation management and support to Region Skåne, the county council of Scania responsible for healthcare.

ÅF Industry AB is a subdivision of ÅF AB, a Swedish engineering and design company within the fields of energy, industry and infrastructure. ÅF Industry has provided supervision for this thesis.

1.2 Physiological circumstances

The function of cerebrospinal fluid (CSF) is to provide buoyancy and support for the brain and spinal cord. CSF is continuously secreted by the choroids plexus of the two lateral ventricles at a rate of approximately 20-25 ml per hour. At any time, approximately 100 - 150 ml of CSF is contained within the cerebral ventricles (cavities in the brain). The intracranial volume of CSF has

a critical point where the pressure exerted on the skull and brain increases exponentially [1].

Due to swelling of the brain after a patient has undergone neurosurgery or sustained a head injury, tubing is surgically inserted through the patients skull at Kocher's point [2] into the brain so that CSF can be drained [3]. This procedure is called a Ventriculostomy, and the external drainage system that is connected is known as an External Ventricular Drain (EVD), illustrated in figure 1.1.
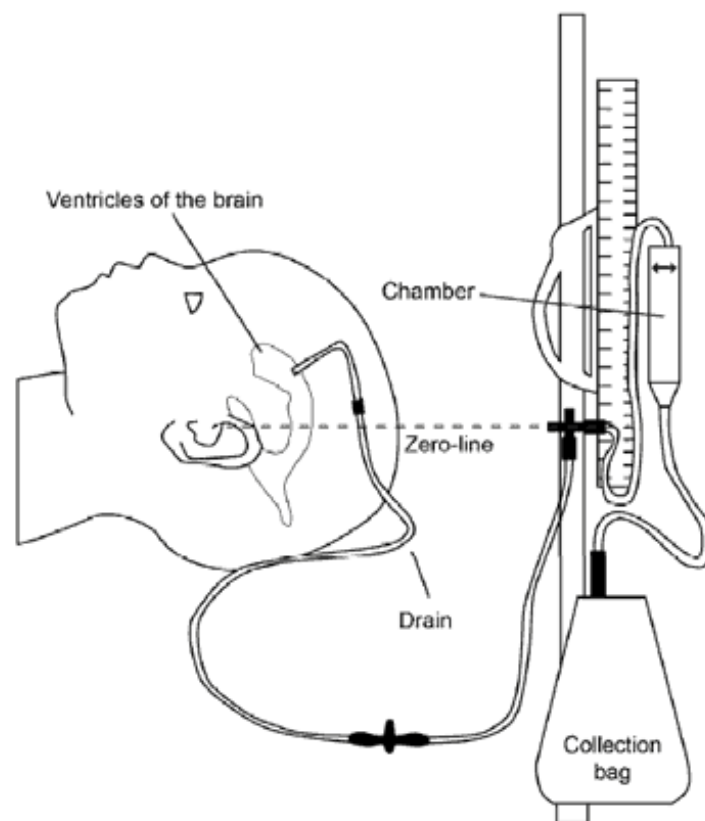
Figure 1.1: Schematic of EVD

The CSF drain rate correlates linearly with the pressure difference at the tubes inlet and outlet, and thus with the height difference between the two ends. This means that for a desired drain rate, the responsible doctor will calculate and prescribe a desired height difference to be maintained. Typically the vertical distance is measured from the tragus (the small lobe near the ear

canal) if the patient is supine, and the interventricular foramina (between the eyebrows) if the patient is lateral. There are medical devices like the Duet External Drainage and Monitoring system [4] which are used to set the correct height difference.

1.3   Problem formulation

When a patient has an implanted EVD, the height difference between the drain tube inlet which is located in the brain and outlet, where the CSF exits, is manually adjusted by a nurse. This height difference needs to be kept very close to the prescribed value. Every time the patient shifts position the EVD has to be re-zeroed and adjusted manually. This requires constant monitoring of the patient by nursing staff which is time consuming. A patient is not allowed to adjust the beds position or touch the drain. If the patient does, incorrect flow rate might occur which can have severe consequences. Nurses at a neurosurgical intensive care unit have forwarded this information to Innovation Skåne to see if this process can be improved by a technical solution.

1.4   Current EVD system by Neuromedex

The current system that is used at SUHL is a system manufactured by Neuromedex GmbH, named VentrEX. The whole system is pictured in figure 1.2. It consists of a ruler, slider and attachment points for the disposable components.
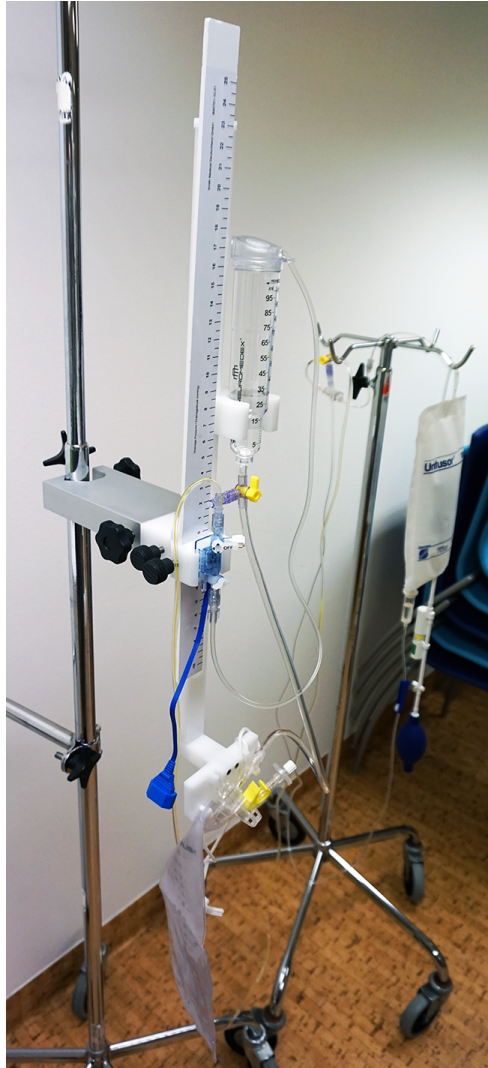
Figure 1.2: Current EVD system in use by SUHL

When a patient is in need of an EVD, the system is setup like in figure 1.2. The rightmost bag of saline solution is in place to simulate a patients inter cranial pressure (ICP) and CSF.

The VentrEX system from Neuromedex GmbH [5] contains four replaceable standardized components shown in figure 1.3. Systems produced by other manufacturers vary slightly in shape and size but contain essentially the same components.
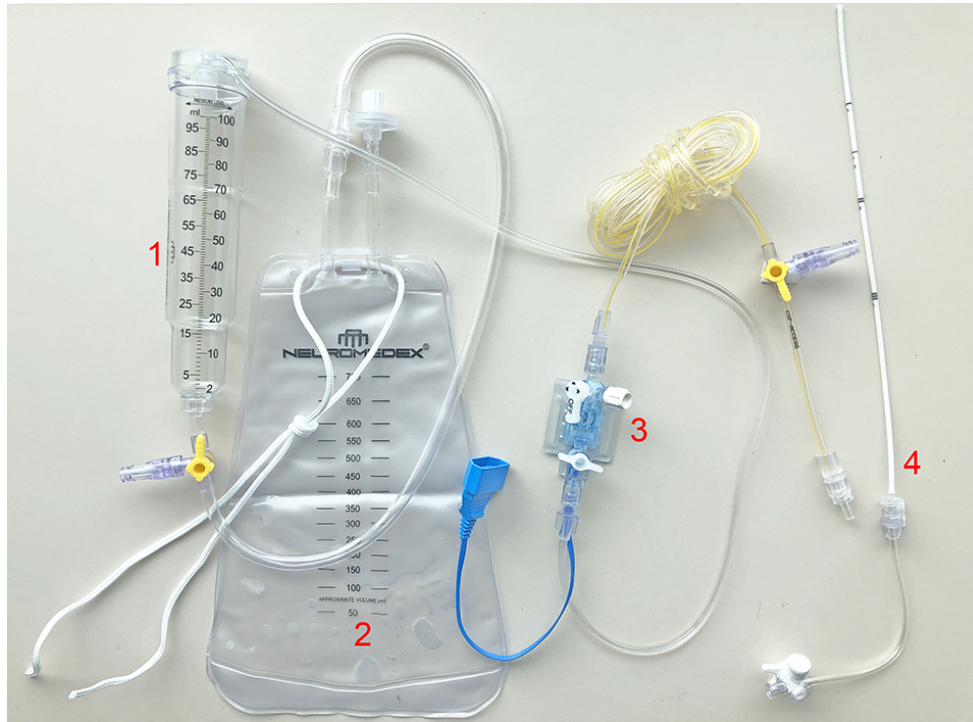
Figure 1.3: The disposable parts of the current EVD kit that can be replaced

The components are described as the following:

1. Drip chamber, where the hourly fluid drain rate can be measured. The drain outlet sits at the top of the drip chamber.

2. Collection bag, where the accumulated CSF in the drip chamber can be emptied after measuring the CSF drain rate.

3. Transducer, a standardized pressure sensor that connects to a monitor. Before opening the drain, the transducer has to be zeroed to atmospheric pressure by setting the drain outlet and transducer at the same vertical level and pressing a button on the monitor. The transducer is then moved to the desired height setting on the EVD system.

4. Detachable catheter, the component that is surgically inserted into the brain. This is the drain inlet tube.

When the patient is lying in a hospital bed, a spirit level and laser pointer is placed on the aluminum platform that attaches to the stand. By loosening the clamp screw at the drip stand, the whole platform including ruler and

EVD components can be moved vertically. The laser pointer is aimed at the tragus, as seen in figure 1.1, by sliding the whole setup vertically along the stand.

The nurse adjusts the drip chamber outlet so that it is level with the transducer, presses a button on the monitor to set atmospheric pressure on the monitor, then moves the drip chamber to the desired pressure on the scale printed on the ruler. Lastly, the drain is opened by rotating a knob on the tube. In a situation where the patients head position is changed, the nurse has to unscrew the attachment, slide the whole system to the desired height and aim the laser pointer at the tragus and then fasten the attachment.

In order to avoid erroneous drainage rates whilst adjusting the EVD system the drain is closed by twisting a yellow knob. If the outlet is positioned at a lower vertical position than the inlet, high drain rates occur which is dangerous for the patient.

1.5 Innovation Skåne patent

Due to the costly and time consuming process currently used to manage the EVD post implantation, Innovation Skåne has developed a patent (patent no. WO2019088902) that describes an automatic regulation of the height difference between the catheter inlet and outlet. The patent is based on using a fluid filled tube with pressure sensors at both ends to measure the height difference between the catheter inlets and outlets. One end of the tube is fastened to the patients head and the other on a platform containing the EVD outlet. The platform can then be transported vertically depending on the sensor readings in order to maintain the correct height difference between the inlet and outlet [6].

1.6 Scientific basis

The scientific foundation of the thesis was based on several different fields such as fluid mechanics, electronic circuitry and automatic control.

1.6.1 Fluid mechanics

According to Bernoulli's principle, the density of a fluid parcel in most flows of liquids can be considered to be constant regardless of pressure variations in the flow in an incompressible fluid. The equation (1) is valid at any arbitrary point along a streamline:

$$\frac{v^2}{2} + gz + \frac{P}{\rho} = constant \tag{1}$$

where v is the fluid flow speed at a point on a streamline
g is the gravitational constant
z is the elevation of the point above a reference plane, with positive z direction upwards
P is the pressure at the point
ρ is the density of the fluid

Equation (2) is valid for two reference points along the same streamline, denoted by the subscripts 0 and 1.

$$P_0 + \frac{1}{2}\rho v_0^2 + \rho g h_0 = P_1 + \frac{1}{2}\rho v_1^2 + \rho g h_1 \tag{2}$$

The height h of a liquid column with the flow rate $v \approx 0$ can be calculated by measuring the pressure at the bottom and top of the water column, with P_0 = pressure at the bottom of the water column, P_1 = pressure at the top of the water column. If the reference plane is level with h_0 ($h_0 = 0$), the height difference is calculated according to equation (3):

$$h_1 = \frac{P_0 - P_1}{\rho g} \tag{3}$$

With a pressure sensor measuring the pressure at the ends of the column, a fluid with a known density and gravitational constant, the vertical height difference between the ends of the fluid column can be calculated.

1.6.2 Electronics

A single board computer (SBC) is a fully functioning computer built on a single circuit board, with integrated memory, processors and connections for

data input and outputs. They are typically used in applications such as embedded devices and system development.

Common manufacturers of consumer SBCs are Arduino and Raspberry Pi. These platforms support a wide array of peripherial devices such as sensors, displays and motors. Peripheral manufacturers often support their products with open source code libraries and programming examples to allow quick interfacing with an SBC. Communication between an SBC and peripheral is often handled with standard communication protocols such as SPI, I2C or LoRa.

Pulse width modulation (PWM) is a technique used to vary the average power delivered by an electronic signal. It works by turning a power supply connected to a load on and off at a high frequency. The longer time the power is turned on compared to the time it is turned off, the more total power is delivered to the load. PWM is well suited to controlling the speed of motors.

1.6.3 Automatic control

A closed automatic control loop in its simplest form consists of a controller that compares a measured value of a process with a desired set value, and processes the resulting error signal to change some input to the process, in such a way that the process stays at its set point despite disturbances.

An example of automatic control is sensor outputs being interpreted by a micro controller which is also capable of driving a motor. The controller can continuously read the sensors and drive a motor at various speeds depending on the sensor data in a simple closed loop control system, as seen in figure 1.4.
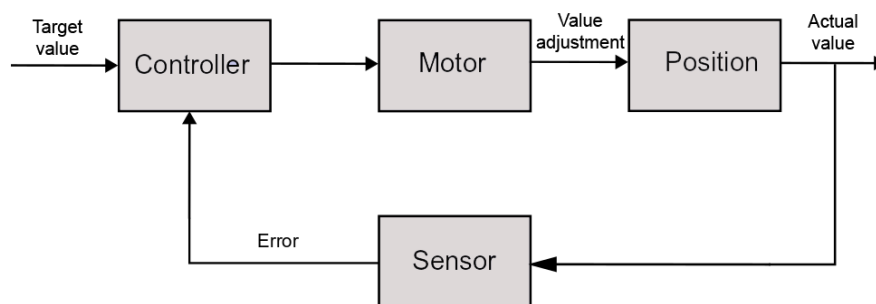
Figure 1.4: Feedback Control System

Typically sensor readings exhibit a large amount of noise, which can result in false outputs. The common solution to this is using an algorithm to filter the sensor data. In this thesis a Kalman filter was used, also known as linear quadratic estimation. This method estimates a joint probability distribution for a given variable at a given time. The filter works in two steps. In the first, the algorithm estimates the current state variables along with their uncertainties. During the second step the filter observes the outcome of the following measurement to adjust its estimation of further measurements using a weighted average. The algorithm is recursive and can be run in real time. Figure 1.5 displays sensor output before and after filtering.
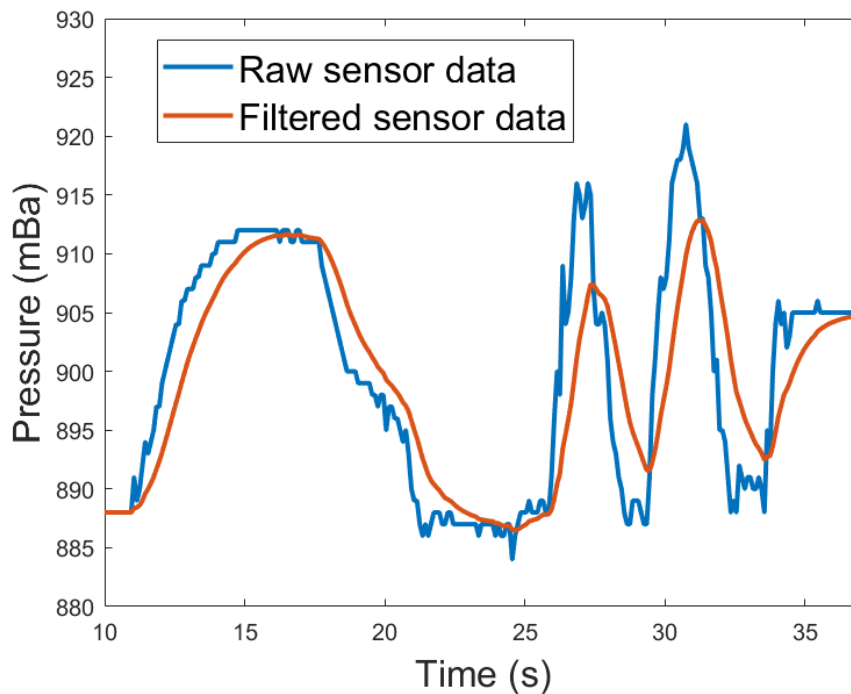
Figure 1.5: Sensor output before and after filtering

When the controller adjusts its output to counteract a sudden shift in sensor readings there is a risk of overshoot occurring as illustrated in figure 1.6. There is also a risk that the physical system will fluctuate around a set point, never reaching a steady state. To compensate for this a PID controller can be used. PID stands for proportional-integral-derivative and is a feedback mechanism that is widely used in robotics and industry. The algorithm is tailored to the application by choosing correct P, I and D coefficients. The

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optimal coefficients can be obtained based on experience or techniques such as the Ziegler-Nichols tuning method and software auto tuning.
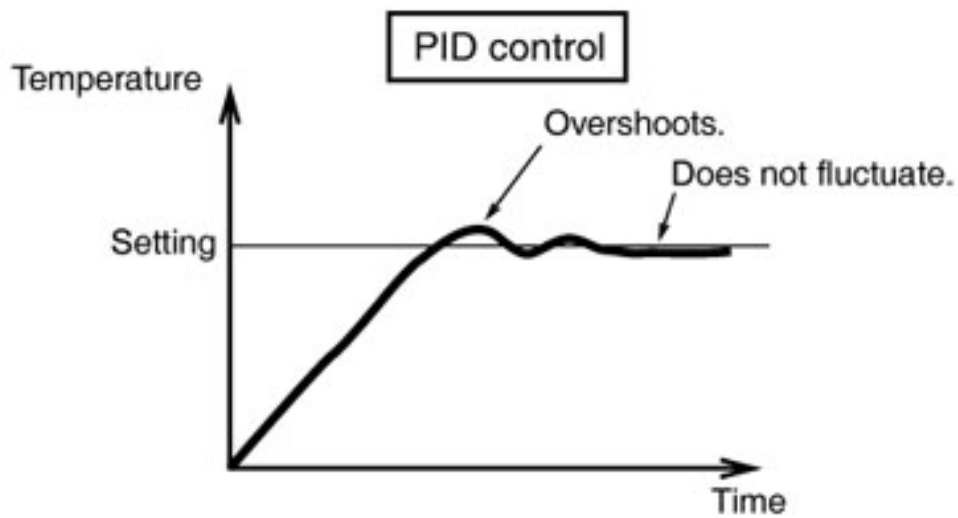
Figure 1.6: PID step response for a temperature controller

1.7 Goals of the Thesis

The goals of the thesis were set in collaboration with Innovation Skåne and were as follows:

1. Verify the feasibility of the automatic control system outlined in the Innovation Skåne patent.

2. Break down the automatic height regulator into sub systems and develop the necessary components for it to work.

3. Build a high fidelity prototype.

4. Make recommendations regarding the further development of the automatic height regulator.

1.7.1 Delimitations

Constraints were determined by the project members and Innovation Skåne. The automatic regulator would use the sensor system as described by the Innovation Skåne patent [6]. A prototype was to be produced to demonstrate the function of the system, but not for testing on patients.

Other constraints that limited the thesis were the project members limited knowledge and experience with electronics, determining manufacturing costs for medical equipment, and not being able to use some manufacturing methods for the thesis. The strict requirements for products within the medical field were not followed while manufacturing the prototype.

2 Methodology

This chapter describes the methodology used during the thesis. A description of each sub activity in the concept development process is given and the design principles used are explained.

The product development process as described by Ulrich and Eppinger (U&E) [7, pp. 73-165] was used as a framework for the thesis due to both project members being familiar with the methodology and the nature of the thesis. Some of the areas, such as system level design, have not been included since the product does not have a product family in the traditional sense. The phases followed throughout the project and the relevant sub activities are listed below.

0. Planning

    - Establish Time Plan
    - Form a Mission Statement

1. Concept Development

    - Identifying Customer Needs
    - Research
    - Benchmarking
    - Generate concepts
    - Build and test experimental prototypes

2. Testing and Refinement

    - Prototyping
    - Reliability testing
    - Performance testing
    - Implement design changes

3. Results and Evaluation

    - Present final results
    - Evaluate test results

2.1 Sub activities of the concept development process

Identifying customer needs

The process of identifying customer needs is an integral part of the product development process. By identifying customer needs, the development team ensures that a future product will be satisfactory and have features that are appreciated by the customer. The customer needs are independent to the particular product that might be developed, and any given attribute desired by a customer should be labeled a need, not a want. A five step method to identify customer needs is presented below.

1. Gather raw data from customers

2. Interpret the raw data in terms of customer needs

3. Organize the needs into a hierarchy of primary, secondary, and (if necessary) tertiary needs.

4. Establish the relative importance of the needs

5. Reflect on the results and process

Establish target specification

The target specifications are established after the customer needs have been identified but before concepts are generated and selected. They are the goals of the development team, and describe a product that is believed to succeed on the market. The process of establishing the target specifications contains four steps:

1. Prepare the list of metrics.

2. Collect competitive benchmarking information.

3. Set ideal and marginally acceptable target values.

4. Reflect on the results and the process.

Concept generation

A concept is usually expressed as a sketch or as a rough three-dimensional model. It is an approximate description of the technology, working principles and form of the product. The process of concept generation begins with the customer needs and target specifications, and results in a number of product concepts. A good concept can be poorly implemented into a final product, but a poor concept will rarely result in a good final product, and cannot be manipulated to be one. It is therefore important to generate many, sometimes hundreds of product concepts to explore the full space of alternatives. Between five and twenty of these concepts will be seriously considered during the concept selection.

A five step method to generate concepts is presented below. The method breaks a complex problem into simpler subproblems.

1. **Clarify the problem.** Understanding the problem, breaking it down into several sub problems

2. **Search externally.** Gather information from users, experts, literature, related products

3. **Search internally.** Using personal and team knowledge and creativity to generate concepts.

4. **Explore systematically.** Navigating the space of possibilities by organizing and combining solutions to the sub problems

5. **Reflect on the solutions and the process**

Concept selection

To choose from the concepts generated in the previous stage of the product development process, several different methods can be used. The methods commonly used are the following:

- **External decision:** Concepts are turned over to the customer, client or some other external entity for selection.

- **Product champion:** An influential person in the team chooses a concept.

- **Intuition:** The concept is chosen by intuition, it is the one that just seems better.

- **Multivoting:** Each team member chooses several of preferred concepts, and the one with most votes is selected.

- **Web-based survey:** The concepts are rated by an online survey.

- **Pros and cons:** List the strength and weakness and a choice is made from the teams opinion

- **Prototype and test:** Prototypes are built and tested and the selection is made based on the test data

- **Decision matrices:** The different concepts are rated against selection criteria, and could also be weighted.

Concept testing

The goals of the concept testing is to gather information from potential customers on how to improve a concept, and to estimate the sales potential of the product. To perform the concept testing, the development team solicits a response to a description of the product concept from the potential customers. The method of concept testing is described below.

1. Define the purpose of the concept test.

2. Choose a survey population.

3. Chose a survey format.

4. Communicate the concept.

5. Measure customer response.

6. Interpret the results.

7. Reflect on the results and the process.

Final specifications

When the choice of concept has been made, the specifications are revisited. The broad range of target values are now refined. There can be trade-offs

when finalizing the specifications due to inverse relationships between two specifications. Trade-offs are frequent and almost always occur between technical performance and cost. A spreadsheet of the final specifications are often the results from setting the final specifications.

2.2 Design for X

Much of the concept development process was based upon design for X principles. In particular, design for cost, assembly and robustness have been prioritized.

Design for cost principles applies to both component and system design [8]. The cost of a given component is influenced by several variables such as material choice, manufacturing method and post processing. On a system level the cost is also influenced by assembly method. Some of the most important rules when designing for cost are:

- **Don't reinvent the wheel.** Buy a component off the shelf, copy it, re-use from similar projects.

- **Keep it simple.** The more simple a component is mechanically or electronically, the more reliable it is likely to be. This includes manufacturability. Components with function integration are usually more economical.

- **Decisions can be made at different design levels.** As new information is obtained, existing solutions, concepts and specifications can be altered as needed.

Robust product design is defined as reducing variation in a product without eliminating the causes of the variation. This can be expressed as the degree to which a system can function correctly in the presence of invalid inputs or stressful environment conditions [9].

Design for manufacturing and assembly (DFMA) means keeping the production of a system or component in mind during the design phase [10]. A selection of the DFMA guidelines that were utilized during the design process is listed below:

- **Integrate parts.** Parts that do not need to move relative to the rest of the assembly, be of a different material than their neighboring parts, or

be separated from the rest of the assembly for access or repair purposes can be physically integrated with neighboring parts.

- **Manual assembly consists of three properties:** handling, insertion and fastening. A component is considered easy to handle if it can be grasped and manipulated with one hand without grasping tools and has end-to-end and rotational symmetry. A component is considered easy to insert if it falls into place, is self-aligning and easy to insert. It is considered good practice to eliminate fasteners such as screws where possible.

- **Use the same linkages.** If a linkage is required in more than one application, try to use the same linkage in the entire assembly.

- **Keep the z-axis parallel.** The z-axis is the axis of insertion for a given part. If the z-axis of the different components are parallel, assembly is greatly simplified.

- **Part handling and ergonomics.** Sharp edges and fragile components should be avoided. A component should not require special tools for assembly.

2.3 Plastic design principles

The design of the plastic components was based upon the 10 design rules for thermoplastics as described by Bruder [11, pp. 149-168]:

1. **Remember that plastics are not metals.** When replacing metal parts with plastics in order to reduce production costs, it is necessary to make a total redesign of the component.

2. **Consider the specific characteristics of plastics.** Amongst other attributes plastics have nonlinear and time dependent stress-strain curves and exhibit anisotropic behaviour. However they are easy to assemble, design and process cost effectively.

3. **Design with regards to future recycling.** Most plastics are easily recycled and can be melted down and used in new products. They can also be incinerated and generate a high energy output. In order to facilitate recycling the component it should be: easy to dismantle, made in as few plastic materials as possible (preferably standard materials),

coded so that the materials can be identified and designed so it will be easy to clean.

4. **Integrate several functions into one component.** Due to the design freedom afforded by plastics it is possible to reduce the number of components in an assembly. The manufacturing and assembly costs can be lowered by integrating functions such as snap fits, pipe connectors, seals, slide bearings, ribs and threads into a single component.

5. **Maintain an even wall thickness.** The wall thickness needs to be thin enough to maintain a low weight, but thick enough to meet functionality and load requirements. Sudden increases in wall thickness leads to warpage.

6. **Avoid sharp corners.** Plastics are sensitive to notches and small corner radii. Sharp corners lead to stress concentrations which can cause the component to break under moderate loads. As a rule of thumb, the corner radius should be at least half the wall thickness.

7. **Use ribs to increase stiffness.** The alternatives to using ribs is to either increase the wall thickness, or increase the Youngs modulus of the material by adding fiber reinforcements. Ribs can reduce the material use and cost of adding fiber.

8. **Be careful with gate location and dimensions.** The choice of gate location and dimension affects the mold filling process, part dimensions, tolerances, mechanical properties and surface finish. The weakest part of an injection molded component is typically the gate and weld lines.

9. **Avoid tight tolerances.** The tolerances of a part should only be as tight as required for the functionality of the part. Increases in tolerances are associated with an exponential increase in cost.

10. **Choose an appropriate assembly method.** Components that need to be disassembled should be designed with this in mind. Where possible, snap fits and integrated threads should be used instead of screws.

2.4 Design principles for medical devices

For medical devices, human factors analysis needs to be performed early and often during the design process. One third of medical device incidents involve user error, and more than half of device recalls are due to design problems

involving the user interface (UI). Responsibility for use-related incidents have shifted from users to manufacturers, and when seeking Food and Drug Administration approval (for release on the US market), manufacturers must submit evidence of systematic human factors analysis of use errors and how they will be controlled throughout the product development process [12].

The ways humans react to stimuli and process information are all addressed from the human factors analysis. Goals of the analysis are to design a product that matches human capabilities and limitations, and to validate the design with usability testing. The process is implemented throughout the development process, starting with concept development activities and can be implemented even if a project is in late stages.

Usability testing can discover likely opportunities for user error. If errors are found, manufacturers can decide to change the products design (early response), provide more labelling or training, or just alert its users that the error can occur. Documented evidence of a systematic human factor analysis can usually include:

- Task analysis that expresses user needs when interacting with the product.

- Use-error analysis to identify the risks when a user doesn't perform an action correctly.

- Evaluations that can reveal potential use errors and erroneous use instances.

- A plan to mitigate or control anticipated or observed use errors. Mitigation can consist of product redesign, more labels and warnings, or product training.

2.5   Nielsen and Molich's UI design guidelines

Nielsen and Molich's ten UI design guidelines consists of a set of rules that should be followed when designing a UI. The ten usability heuristics are the following:

1. **Visibility of system status.** The system should always keep users informed about what is going on

2. **Match between system and the real world.** The system should speak the users' language and use words, phrases and concepts that

are familiar to the user rather than system oriented terms. Real world conventions should be followed, making information appear in a natural and logical order.

3. **User control and freedom.** Users often choose system functions by mistake and need an "emergency exit" to leave the unwanted state without having to go through an extended dialogue.

4. **Consistency and standards.** Users should not have to wonder whether different words, situations or actions mean the same thing.

5. **Error prevention.** It is better to prevent a problem from occurring at all than spending time creating an intuitive error message.

6. **Recognition rather than recall.** Objects, actions and options should be visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable when necessary.

7. **Flexibility and efficiency of use.** Systems can be designed to cater to both experienced and inexperienced users. Frequent actions can be assigned to hotkeys to speed up interaction.

8. **Aesthetic and minimalist design.** Dialogues should not contain information which is irrelevant or rarely needed. Every additional piece of information competes with the relevant information for the users attention.

9. **Help users to recognize, diagnose and recover from errors.** Error messages should be expressed in plain language and not in codes. They should accurately describe the problem and suggest a solution

10. **Help and documentation.** Even though it is better that the system can function without documentation it may be necessary to provide anyway. Any documentation should be easy to search, be relevant to the users tasks, list concrete steps to be carried out and not be too large.

3 Planning

This section describes the necessary steps that were taken to plan the different stages of the thesis. The system was broken down into sub components and a mission statement was formed.

At the beginning of the planning stage, several areas of the abstracted automatic regulator were identified as having distinct functions. This lead to the imagined system being broken down into two subsystems - a leveling system and a sensor system. These subsystems were then assigned components with distinct functions as can be seen in figure 3.1.
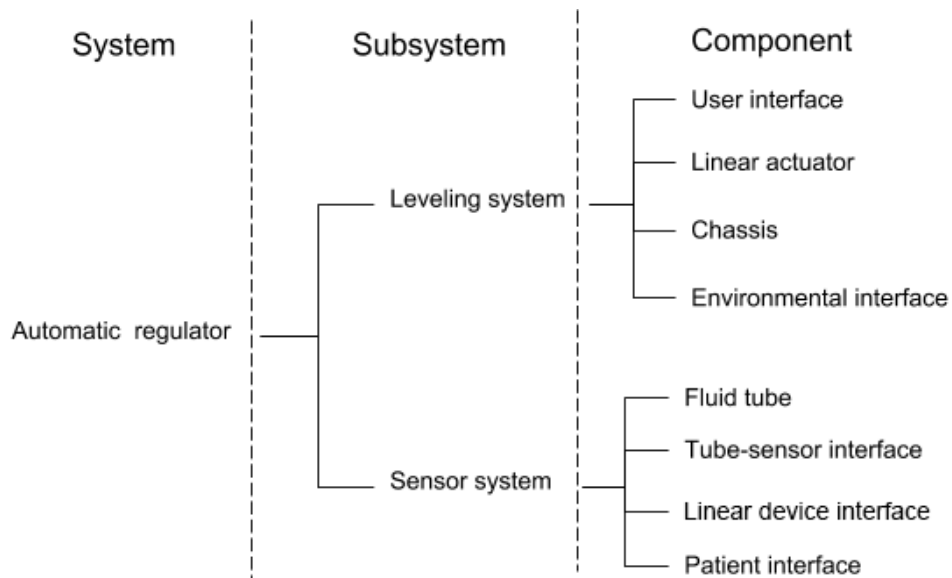
Figure 3.1: Overview of system, subsystems and components

3.1   Component description

A brief description of the eight different components is listed below for better understanding of each components function.

- **User interface (UI)**. The hardware used to output and input data from the user. Desired height setting of drain outlet and an enable/disable button are examples of user data that needed to be input to the automatic regulator.

- **Linear actuator (LA)**. The component that generated the linear motion to move the sensor and outlet tube attached to the EVD vertically.

- **Chassis**. An enclosure for the electronics. Served two purposes; to create a more aesthetically pleasing device and to protect the internal parts from debris and liquids.

- **Environmental interface (EI)**. The interface with which the automatic regulator interacted with the room. The automatic regulator could be attached to the wall, have its own floor stand or be integrated with preexisting hospital equipment.

- **Fluid tube (FT)**. The flexible tubing which contained the liquid used for the pressure readings. The fluid tube ends were attached to the tube sensor interface.

- **Tube sensor interface (TSI)**. The enclosures for the pressure sensors. The tube-sensor interface consisted of two subcomponents, one attached to the patient interface and the other attached to the leveling device interface.

- **Linear device interface (LDI)**. The component that connected the tube sensor interface to the linear actuator and held the replaceable EVD kit.

- **Patient interface (PI)**. The component that connected the tube sensor interface to the patients head.

An example of the system and components is illustrated in figure 3.2. Note: the chassis and UI not pictured.
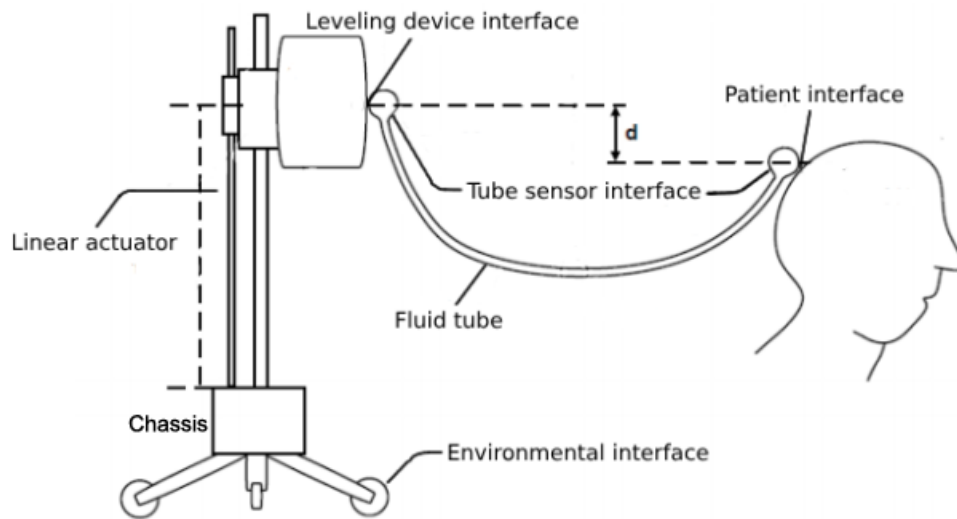
Figure 3.2: Example of where components are placed in a system

A work breakdown structure was created to break down the master's thesis into manageable sections. It is shown in figure 3.3. This laid the foundation for an initial time plan which was illustrated by a GANTT chart, highlighting the time allocated to the different activities and their respective deadlines. The time plan acted as a basis for the day-to-day activities of the thesis and can be seen in Appendix A. It was followed up by marking when the activities were completed. To verify that the time plan was being followed, the daily work performed was noted in a diary.
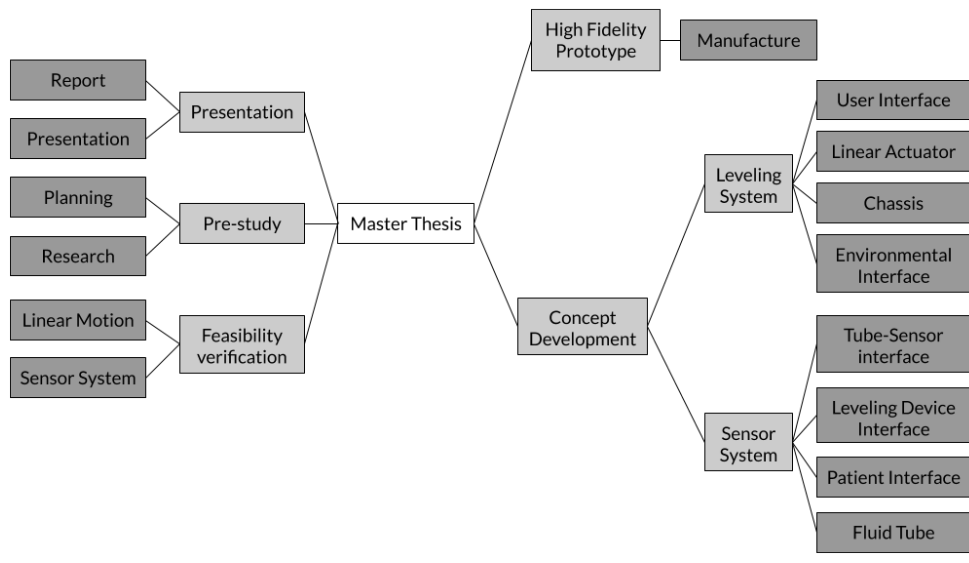
Figure 3.3: Work Breakdown Structure

3.2 Mission Statement

A mission statement is a detailed definition of the target market and the assumptions under which the development team will operate. The product development opportunities for the project had already been identified by Innovation Skåne and were subsequently summarized in the mission statement.

Table 3.1: Mission statement

Mission statement:	
Automatic regulator of vertical position for medical equipment	
Product description	A device to automatically set and maintain the desired height of a drain outlet for bodily fluids
Advantages	Reduces the workload of medical staff by automating a simple but time consuming task
	Increased accuracy when performing EVDs
Key business goals	First product of its kind in market areas
	Capture 100 percent of device sales in the primary market
Primary market	Hospitals with operations including bodily fluid drainage
Stakeholders	Purchasers
	Hospital staff
	Patients
	Manufacturers of off the shelf-components

4 Prestudy

This section describes how and why a prestudy was conducted prior to the start of the development of the automatic regulator.

During the initial part of the project, it was decided that a prestudy was needed in order to gain an understanding of the basic principles of hospital devices in general and the EVD in particular. Various height difference measuring techniques were researched in order to verify that there was not a more convenient way to measure the height than the solution outlined in the Innovation Skåne patent. Techniques such as ultrasound, draw wire sensors and lasers were some solutions that were found, but were deemed to be too complex or unpractical.

Since neither of the project members had any experience with pressure sensors and only a limited experience of electric motors, a feasibility verification was deemed necessary. To this end basic supplies were obtained and a rudimentary prototype was constructed. This consisted of a water filled tube with a plug on one end and a pressure sensor on the other end, shown in figure 4.1.
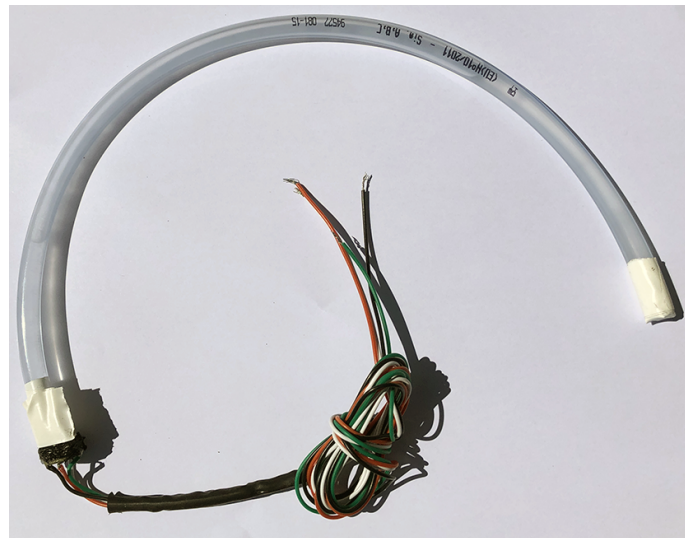

Figure 4.1: Setup to test the sensor

The pressure sensor was connected to an Arduino micro controller, which in turn was connected to a computer in order to read its output. The height difference between the tube ends was then changed and measured with a ruler in order to investigate whether there was any correlation with the output of the sensors. Whilst there were some irregularities, the prototype worked as intended and provided confidence in that it could work as the height measuring component of the sensor system.

A literature search was conducted to gain a deeper understanding of the ventriculostomy procedure and the risks it entails. It was discovered that patients who have undergone the surgery have a high mortality rate stemming from infection. This was reflected in the customer needs and target specifications in terms of demands on hygiene and cleanability of the parts of the height regulator used in close proximity to the EVD implant site.

Data on the number of patients on which an EVD was placed at SUHL during 2017 and 2018 was acquired from Innovation Skåne. During 2017 a total of 141 patients were equipped with EVDs, and during 2018 140 patients underwent the procedure [13]. Around 1.34 million people live in Skåne and have Region Skåne as their healthcare provider. Extrapolating the number of EVD surgeries to the whole population of Sweden yields 1045 surgeries per year, and extrapolating to the population of the EU yields 53 600 surgeries yearly. The number of patients with implanted EVDs at SUHL varies between 0-8 at a given time. On average the EVD remains implanted in the patient for a week, but on rare occasions it can be attached for up to a month[13].

A study visit was carried out at SUHL. An IV drip bag was filled with fluid, pressurized and then attached to the current EVD system to simulate an elevated cranial pressure. A nurse with a long experience of maintaining an EVD was interviewed in order to gain a deeper understanding of the procedure. The current EVD system was also examined and measured, and a drainage system was obtained for testing purposes.

5   Concept Development

The Concept Development chapter covers the individual concept development of the eight different components. In some cases, one or more of the front end activities were not performed. Some of the components were developed side by side while others were developed at a later stage.

The concept development phase was performed both for the automatic regulator as a whole, and selected components which were deemed to need non-standard solutions. It went into varying depth depending on the priority and innovative value of the components. Components that are available off the shelf were focused less on than components that had to be custom made for the project. The development process is visualized below in figure 5.1.
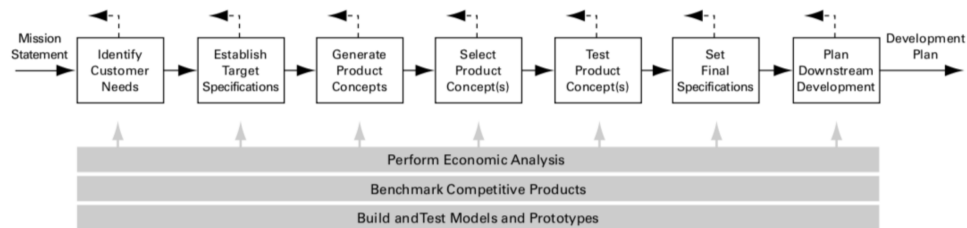
Figure 5.1: Front end activities in the concept development process

The components of the subsystem were subsequently developed individually using the front end activities such as concept generation, selection and testing.

An external search was conducted by patent searching, comparing other manufacturers devices for EVD kits and observations from a patient room in the neurology unit at SUHL.
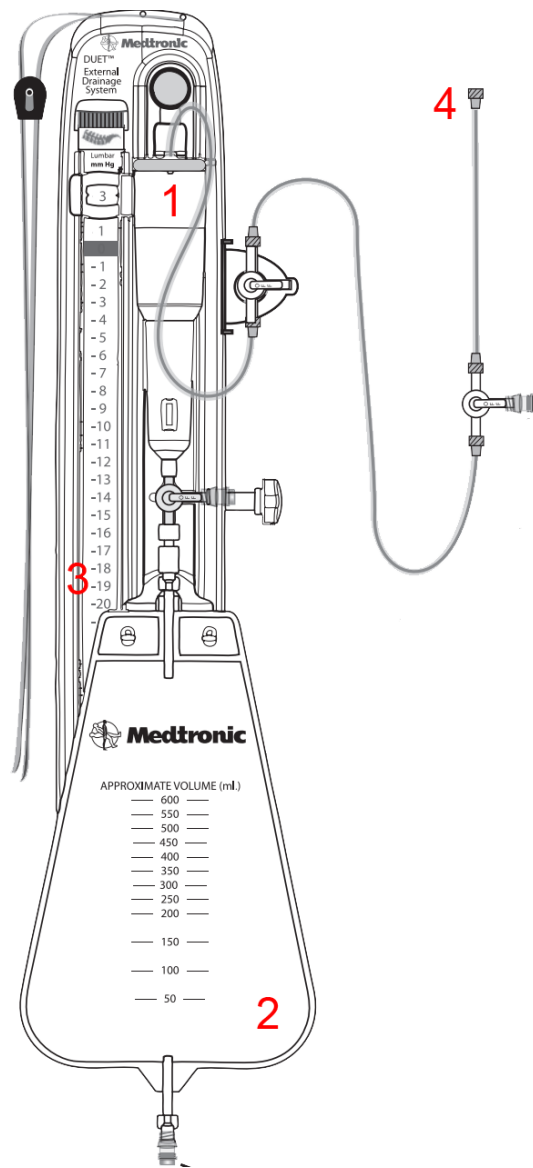
Figure 5.2: EVD model Duet by Medtronic

The information that was gathered regarding equipment used to install an EVD shows that in all cases devices similar to Medtronics EVD-system Duet, shown in figure 5.2, are used by healthcare professionals. The components are similar to the ones used in the system by Neuromedex, where 1 is a drip chamber, 2 is the collection bag, 3 is the pressure ruler and 4 is the connector to the inlet.

5.1 Interview and observations from patient room

An interview with medical staff from the neurosurgical unit at SUHL was the foundation for most of the established customer needs. It was conducted in combination with a study visit. The interviewee was the nurse who brought attention to the problem and forwarded it to Innovation Skåne. The purpose of the interview was to gain knowledge of the activities involved in the EVD process, like the continuous manual adjustment of the height of the drain outlet. Also, some of the concepts that had been generated before the interview took place were presented to the medical staff for feedback. The purpose of the study visit was to gain a deeper understanding of how an EVD procedure is conducted and to observe the equipment in person. This resulted in new discoveries regarding the patient interface (PI), which highlighted problems that constituted additional customer needs. These discoveries are further discussed in the section covering the development of the PI. An EVD system from the manufacturer Neuromedex [5] of the type shown in figure 1.3 was acquired from the study visit and used later during the development process.

5.2 Identifying customer needs

The customer needs were defined for the system as a whole. They were interpreted from data gathered during interviews with employees and observations from a patient room in the neurology unit at SUHL. The questions asked during the interviews are shown in Appendix C. By gathering raw data from the interviews, a high quality information channel was established.

5.2.1 Organization of needs

The result of the interviews was a list of need statements. These were organized into a hierarchical list, and can be seen in table 5.1. The list consists of a set of primary needs, each further characterized by a set of secondary needs. Importance ratings for the secondary needs are indicated by the number of *'s, with *** denoting critically important needs.

Table 5.1: Organized needs

	Customer Needs
	The automatic regulators vertical positioning is precise
**	The vertical position speed is faster than manual adjustment
*	The automatic regulator has low delay when position is changed
***	The tolerances of the vertical position is within +/- 0.5 cm
	The automatic regulator is easy to operate
*	The automatic regulator is easy to move around
*	The automatic regulator is easy to store away
***	The automatic regulator allows for replacement of EVD components
***	The automatic regulator can be setup by a nurse
	The patient interface fits many different patients
***	The patient interface stays in place on the patient
**	The patient interface is easy to mount onto the patient
***	The patient interface will not cause pressure ulcers
	The automatic regulator does not decrease the patients mobility
*	The fluid tube does not obstruct the patients mobility
***	The automatic regulator does not hinder the patient from being moved within the hospital
**	The automatic regulator functions while patient is standing
**	The automatic regulator functions while patient is sitting
*	The automatic regulator functions while patient is using the toilet
	The automatic regulator fits current equipment
*	The automatic regulator prototype will fit EVD system made by Neuromedex
*	The automatic regulator will fit a standardised pressure sensor included in Neuromedex EVD systems
***	The automatic regulator is secure when positioned in the patient room
	The automatic regulator is approved for use in hospital environments
***	The automatic regulator does not use toxic materials
***	The automatic regulator follows appropriate ISO-standards

5.2.2 Relative importance of customer needs

The hierarchical list itself does not provide any information on the relative importance of the customer needs. Therefore, a new list of a subset of the needs was created, with a numerical importance weighting. The approach used was relying on the consensus of the team members based on their experience.

Table 5.2: Relative importance of customer needs

No.	Needs	Imp.
1	The automatic regulators vertical position is precise	5
2	The automatic regulator is easy to operate	4
3	The automatic regulator allows for replacement of EVD components	3
4	The automatic regulator will not hinder the patient being moved within the hospital	1
5	The automatic regulator does not decrease the patients mobility	3
6	The automatic regulator is approved for use in hospital environments	5
7	The patient interface fits many different patients	4
8	The patient interface will not cause pressure ulcers	5

5.3 Target specification

The method to establish the target specification is usually a four step process where competitive benchmarking information is one of the steps. Since the automatic regulator is a brand new product, there were no comparable competing products on the market at the time of the thesis. Instead, the target specifications in table 5.3 were based on metrics from the manual height adjustment process currently used.

Metric one was based upon the time required to adjust the height of the EVD mounting system during the manual process. During the manual process, the nurse has to shut off a drain valve to stop the drainage process, loosen the clamp attaching the mounting system to the drip stand, re-adjust its height and aim with a laser pointer at the tragus in order to re-zero the position.

An ideal value of 0.2 m/s for the automatic regulator was deemed sufficient during the interview to readjust the height in a similar time frame.

Metric two was determined from how precise the manual process was and feedback from the SUHL interview. A similar tolerance was required for the automatic regulator.

The linear stroke length, specified as metric three , was set to 0.5 - 1 meters. It was also a metric that had to be similar to the manual process, and the range of the stroke length was set in accordance with information gathered from the study visit. According to the nurse, some of the common activities done by the patients were to lay in bed, sit on the bed, stand up and sit on a toilet.

The amount of steps needed to install the automatic regulator was determined to be 5 as ideal and 10 as marginal. These values could be adjusted for an end product, but the amount of installation steps was desired to be kept as low as possible to avoid unnecessary complexity for the operator.

Table 5.3: Target specification

Metric No.	Need Nos	Metric	Imp.	Units	Marg. value	Ideal value
1	1	Speed of vertical movement	5	m/s	0.05	0.2
2	1	Tolerance of vertical position	5	mm	± 15	± 5
3	1	Linear actuator stroke length	4	mm	500	1000
4	2	Amount of steps to install	3	-	10	5
5	2	Easy to operate EVD	4	Binary	Yes	Yes
6	3	Possibility to replace EVD	3	Binary	Yes	Yes
7	7	PI fits many patients	4	Binary	Yes	Yes

5.4 Prototyping and testing

In accordance with U&E methodology, several prototypes were built during the design process on both the system and component level using rapid prototyping principles. These had varying purposes, from testing function and performance to aesthetics and feel. Their complexity ranged from simple

cardboard models to complex 3D printed parts with integrated electronics. The prototypes were iteratively built and improved upon as new information was obtained and design decisions were made. At the end of the concept development phase, a fully functional prototype was built to test all of the components and to give an overall impression of the system. It can be seen in figure 5.3. After the functional prototype was thoroughly tested, the final prototype was built at full scale. During the design process, the experience gained from the functional prototype was used to introduce new features and revise old ones. The final prototype had two purposes: to verify the feasibility of the overall concept of the height regulator as described in the patent, and to act as a tool for Innovation Skåne during the next step in the development process after the thesis.
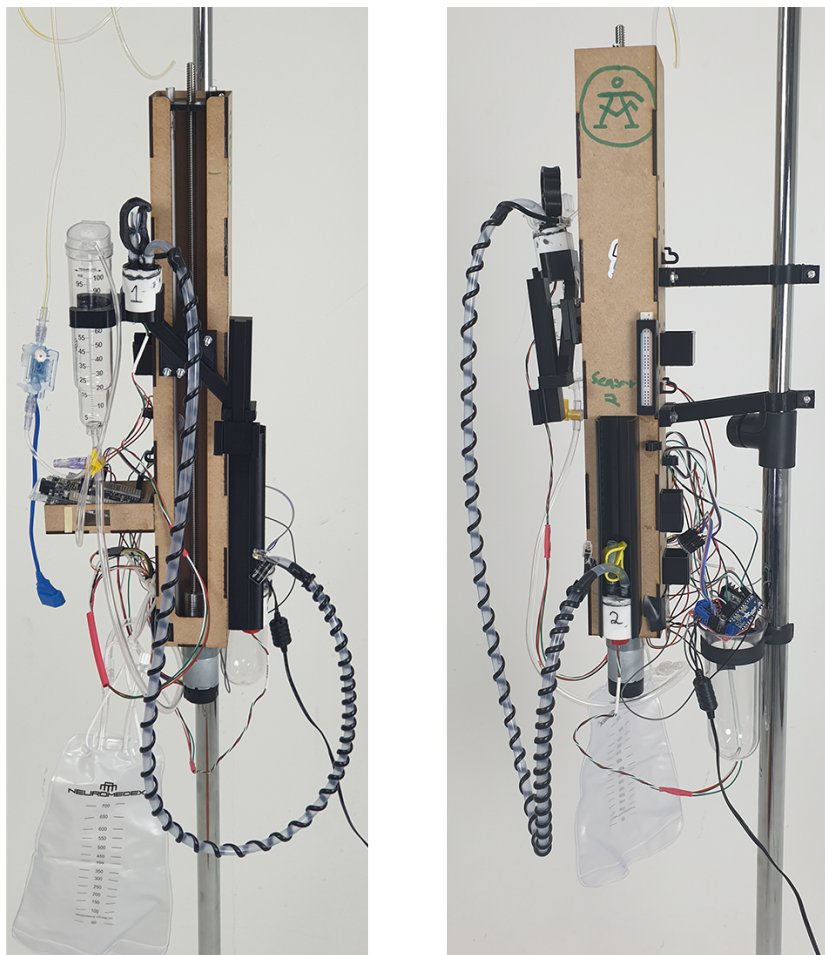

Figure 5.3: The first fully functional prototype

The prototypes provided a great deal of information and verification. They were also used as a complement to sketches when showcasing ideas to medical personnel in order to test the concepts in accordance with the concept development process described by U&E. Laser cutting and 3D printing was utilized in order to enable rapid prototyping. Several parts were cut from MDF (medium density fibre board) to allow simple post manufacture modification.

The electronical components were prototyped using solderless breadboards and an Arduino microcontroller to allow for easy modification of circuits. The components where chosen for their ease of use and compatibility with the Arduino platform.

5.5 Linear actuator (LA)

Several of the target specifications pertain to the linear motion and its functionality, such as the speed of vertical movement and tolerance of vertical position. These specifications are affected by the choice of method for the linear motion. To find different ways of achieving a linear motion, an external search was conducted. A concept classification tree seen in figure 5.4 shows ways of achieving linear motion. It can be achieved mechanically using cog wheels and gears, and hydraulically using liquids and cylinders.
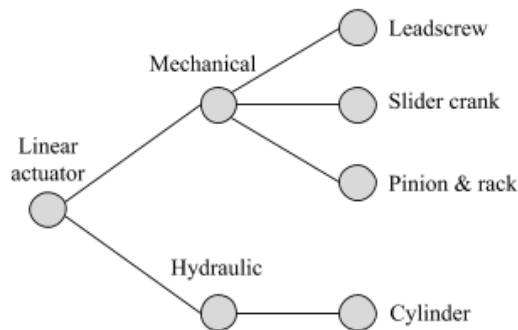

Figure 5.4: Concept classification tree for linear mechanisms

5.5.1 External search

When conducting the external search, solutions to achieving a linear motion, as described by the classification tree, were found and are shown in figure 5.5. A pinion and rack creates a linear motion by rotating the pinion, which in turn moves the rack linearly. The slider crank is similar but the angle of rotation to move a set linear distance is usually smaller, unless a large pinion is used. A leadscrew utilizes a nut and threaded rod where the nut is moved a fixed distance when rotating the leadscrew. The hydraulic cylinder uses an incompressible fluid that is pushed into a chamber and forces a piston to move in a linear motion.
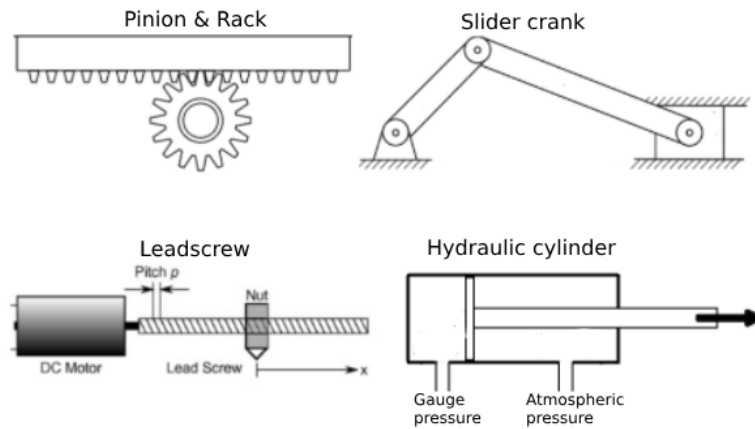
Figure 5.5: Different mechanisms for linear motion

5.5.2 Selecting concepts

In order to select the LA best suited for the automatic regulator, a selection matrix was utilized. It can be seen in table 5.4. The slider crank, leadscrew and hydraulic cylinder were chosen to be compared to the pinion and rack as a reference concept. This resulted in the leadscrew mechanism being chosen for further development. The leadscrew mechanism has low complexity, is precise and can be enclosed as a small unit. A leadscrew mechanism barely needs any maintenance, there are no seals that can deteriorate and lubrication of the friction surfaces is seldom necessary.

Table 5.4: Concept selection matrix for linear motion

Selection Criteria	Pinion and rack	Slider crank	Leadscrew	Hydraulic cylinder
Complexity	0	-	0	-
Precision	0	-	+	-
Few components	0	-	0	-
Space claimed	0	-	+	-
Longevity	0	0	0	-
Net score	0	-4	2	-5
Rank	2	3	1	4

38

Linear motion systems using a lead screw can be either custom made or ordered off the shelf, and can be enclosed as shown in figure 5.6. An enclosure was deemed necessary to prevent equipment and clothing snagging on the rotating bar and to protect the moving parts from dust and biological matter.

Figure 5.6: Enclosed linear system

5.5.3 Testing product concepts

A lead screw LA prototype was built in order to test a step motor and discern the level of performance that could be attained. A rendered image of the prototype used for testing can be seen in figure 5.7. The prototype was a simple setup consisting of a motor, a metric M5 threaded rod, two guide rails and 3D printed plastic mounts. When the motor runs, the blue plate is moved along the guide rails. If the motor is run in the opposite direction, the blue plate switches direction accordingly.
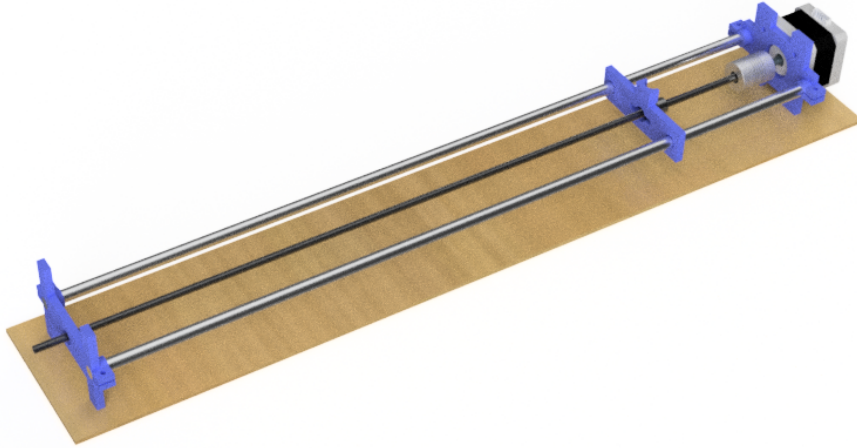
Figure 5.7: Initial LA prototype

The LA was built from scratch instead of sourcing a complete unit, since an Arduino micro controller would be used to control the motor. It was deemed easier and cheaper to build a simple LA than to source an off the shelf unit, since the goal of the thesis was to produce a prototype and not a final product ready for use in a hospital environment. There were also uncertainties regarding the compatibility of the motor on the complete unit and the Arduino.

To test the function of the LA, the motor was connected to an Arduino Uno and run at full speed. The threaded rod with M5 thread immediately proved to be a bad choice. Metric threads have a low pitch and efficiency and are commonly used to join components. Typically a trapezoidal thread profile is used in applications where the threaded rod needs to carry axial loads.

A new threaded trapezoidal rod with with an 8 mm pitch was procured. Because of the trapezoidal thread, a more quiet and effective translation at higher speeds while running at the same motor RPM was attained.

Initially, a NEMA 17 stepper motor was used. Stepper motors have very precise movements and high torque. However, driving the motor at a high speed and making real time adjustments depending on the sensor output proved to require a lot of processing power. In addition to the inherent choppiness and noise level this prompted a switch to a direct current (DC) motor, which typically have a smoother rotation and are more quiet during operation.

The second prototype of the LA is shown in figure 5.8. This prototype was an enclosed version of the first prototype using the same lead screw. It also had an interface allowing the sensor system to be mounted on the LDI using screws

and tested. The mounting plates were low tolerance 3D printed parts and the enclosure was laser cut from MDF. This prototype became the foundation to the first functional prototype attached to a drip stand with attachment points for the disposable EVD parts.

Figure 5.8: Enclosed LA prototype

5.5.4 Final specifications

The final prototype had a 935 mm stroke length, long enough to demonstrate the function and size of the final product. The stroke length was deemed sufficient for the different scenarios where the automatic regulator would be used (laying in a bed, standing up, sitting on the toilet). It was considered important to keep the total size of the component as small as possible in order to make it lighter, less ungainly and to occupy less space during storage.

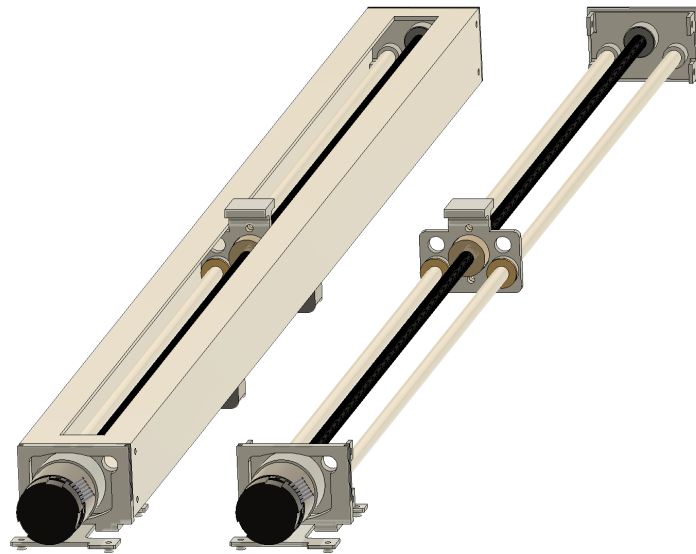The complete LA can be seen with and without the aluminum enclosure in figure 5.9.

Figure 5.9: Final prototype LA with and without aluminum enclosure

The LA consisted of seven subcomponents:

- **1x aluminum enclosure.** Dimensions (WxDxL) 60x40x1000 mm. A rectangular pipe with a 2mm wall thickness was used as the enclosure for the LA. The front had a 24 mm wide slot for the LDI to attach to the middle plate. Two square hoops were attached to the back side. These hoops were used to hang the LA onto the environmental interface (EI). A small hook for the EVD collection bag was attached at the bottom end of the LA. The aluminum enclosure can be seen in figure 5.10.
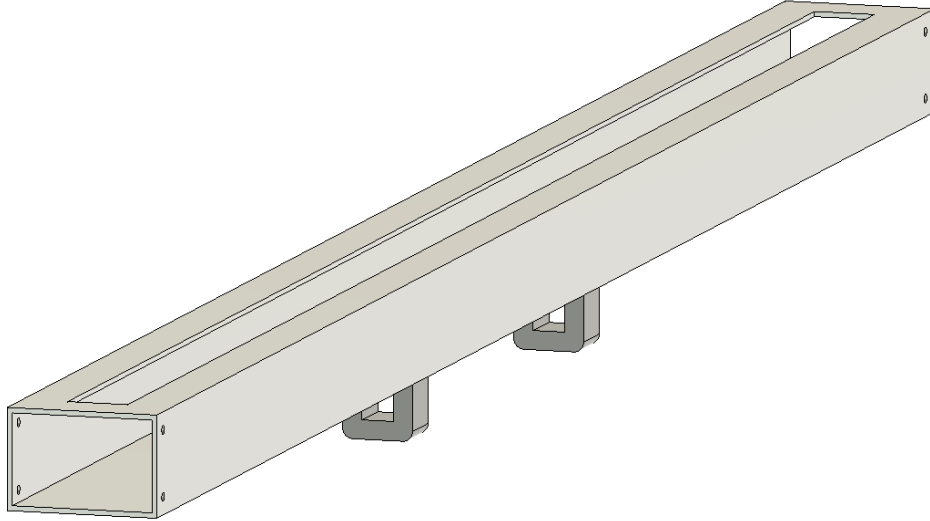
Figure 5.10: Aluminum enclosure, with hoops to attach to EI

- **2x Aluminum guide rails**. The guide rails diameter was 8 mm and keeps the middle plate locked in two directions, preventing rotation.

- **1x DC-motor**. A 12V brushed DC motor with a 30:1 metal gearbox manufactured by Pololu.

- **1x Trapezoidal threaded rod.** The rod had a 15 mm thread pitch and 8 mm diameter. It connected to the DC-motor using an axial coupling. The motor allowed the threaded rod to spin at 350 RPM (no load), making the lead screw move at up to 50 mm per second vertically.

- **1x Top plate.** The top plate had four tabs with 3,5 mm holes to attach to the aluminum encasing using screws. Two sleeves locked the guide rails in place, and a ball bearing secured the threaded rod whilst still allowing it to rotate. The top plate can be seen in figure 5.11.
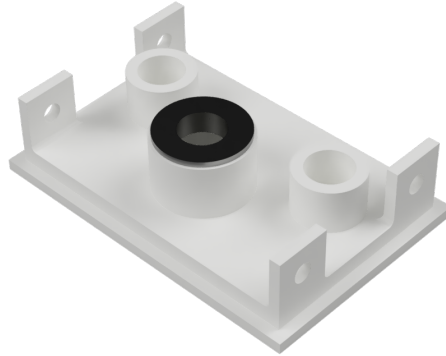
Figure 5.11: Top plate with ball bearing

- **1x middle plate.** The middle plate had two oil impregnated brass bushings that prevent the middle plate from rotating and allowed for a linear motion along the guide rails. A threaded nut was attached to the middle plate using screws which allowed the middle plate to move when the threaded rod rotated. The middle plate can be seen in figure 5.12.
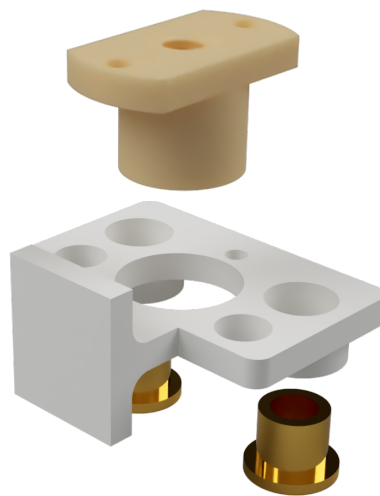
Figure 5.12: Middle plate with threaded nut and oil impregnated brass bearings

- **1x bottom plate.** The DC-motor was attached to the bottom plate using screws, and the bottom plate attached to the aluminum encasing in the same way as the top plate. Two slots on the sides of the bottom plate provided an attachment point to mount the chassis. Additional slots were used to attach the mounting plate that the Arduino micro controller was screwed onto. The bottom plate and Arduino mounting plate can be seen in figure 5.13 and figure 5.14.

Figure 5.13: Bottom plate with mounting plate for Arduino micro controller
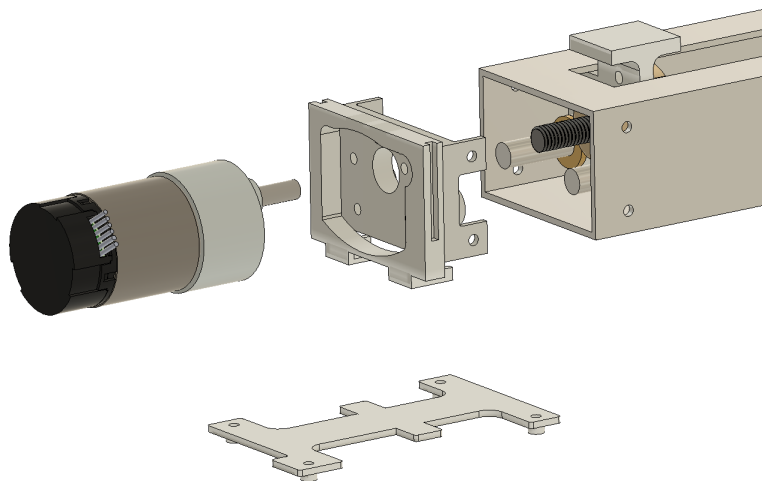
Figure 5.14: Bottom end of LA

5.6 Environmental interface (EI)

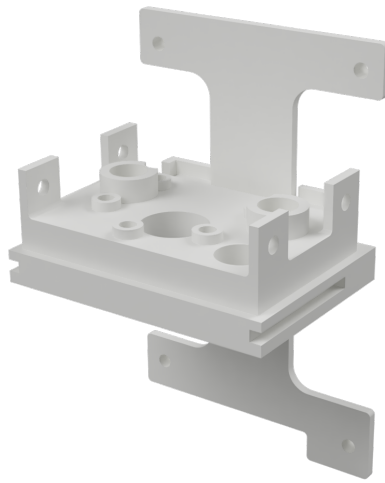Several of the customer demands for the height regulator were especially important during the design of the EI. The EI constitutes the parts of the height regulator that fixes it in space relative to the physical world around it. This includes the way it is transported around the hospital and the way that it is locked in place near the patient.

5.6.1 External search

An external search was conducted for the EI to explore the solution space. Patents for medical equipment were investigated and competing products were examined. Many of the products that were found during the search were tripod stands or bed mounted stands, some of which are presented in figure 5.15. Some of the patents found are displayed as patent number 4-7 in Appendix G.

Figure 5.15: Results from the external search

5.6.2 Internal search

During the internal search brainstorming was performed and basic concepts were generated. This resulted in the authors agreeing on the desired features of the EI. The EI was supposed to be easily mounted without tools in seconds.

5.6.3 Concept generation

The scope of possible concepts for interaction between the automatic regulator and the environment was initially broad, but later narrowed down. By attaching the automatic regulator using a wall mount or ceiling mount, mobility would be limited. No real benefit of using a permanent installation was found compared to using a similar setup to the current EVD systems. Currently EVDs are attached to a metal drip stand similar to the ones used for gravity IV drips. Creating a new dedicated stand for the height regulator was deemed inefficient, since it would require more parts, raise manufacturing costs and require more storage space at hospitals - something that is already in widespread shortage [14]. A more elegant solution would be to utilize existing equipment in the mounting solution.
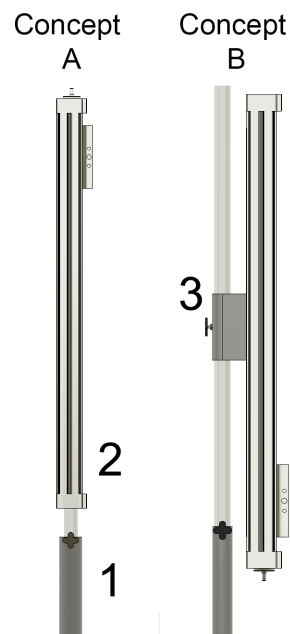

Figure 5.16: EI concept generation

The two concepts A and B in figure 5.16 illustrates the possibility of utilizing preexisting equipment. The lower part (1) of concept A in figure 5.16 is a typical stand used for IV drip, but with the top half of the stand replaced by the automatic regulator (2). In this concept the top half of the stand is removed and replaced by the automatic regulator by sticking the rod into the stand.

Another possibility is attaching the automatic regulator using the IV drip stand as-is, using an attachment (3) as shown in figure 5.16. Concept B uses a clamp, in grey, to attach to the stand.

5.6.4   Selecting concepts

During talks with Innovation Skåne it was discovered that the pole diameter of the IV drip stands are non-standardized and that not all of them have a telescoping function. This necessitated an EI that can clamp on to poles with varying diameters, which lead to concept B being chosen for further development.

Figure 5.17: The existing EI

Figure 5.17 shows the EI for the existing EVD mounting system. It is based on a clamp with a triangular notch into which a pole can be placed and secured with a screw. This has proven to be a good way to attach the EVD mounting system to a variety of drip bag stands since the current system uses this solution.

Other clamp attachments were researched, as seen in figure 5.18. The clamp
to the right is the one currently used by SUHL.
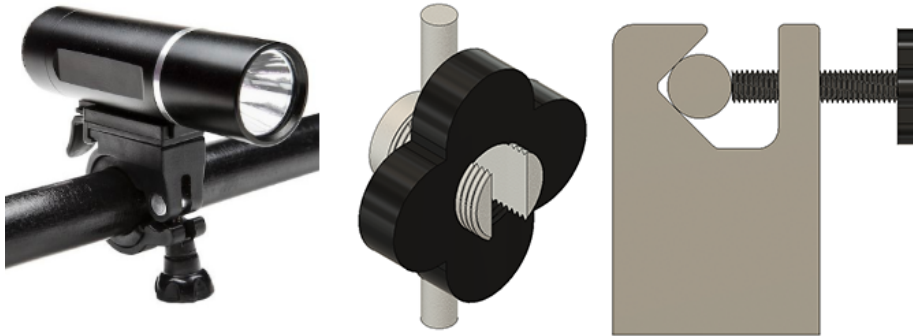
Figure 5.18: Different ways of attaching to a pole

5.6.5 Further concept development

Since the new LA was significantly longer and heavier than the current EVD
mounting system, it was decided that two clamps would be necessary. Using
two clamps provides more gripping force on the mounting pole, and prevents
the LA from swaying. The first working prototype used a simple EI that is
pictured in figure 5.19. Two clamps were used to secure the LA to the drip
stand.
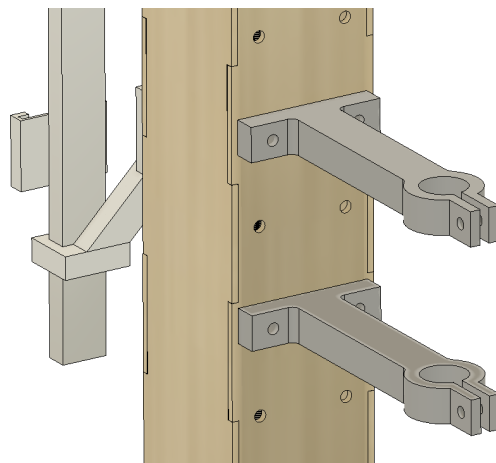
Figure 5.19: EI of first working prototype

An issue that came up during the study visit and interview at SUHL was that it is difficult to secure the EVD mounting system to the drip stand alone. The user is required to hold the system in one hand whilst aligning it with the drip stand pole and use the other hand to fasten the screws. Since the system is bulky and large, this is ungainly and unergonomic - especially since the user is required to do this every time the patient moves. This prompted a design decision to allow the user to first mount the EI to the mounting pole, and then the rest of the automatic regulator to the EI.

This was accomplished by integrating a peg into each clamp and joining the clamps with two rods. The rods provide the correct distance for two integrated hoops on the LA to slip over the pegs and secure the system. In accordance with design for assembly principles circular rods were chosen to act as self-aligning guides when inserting the hoops. The square shape of the pegs prevent the hoops from rotating around them.
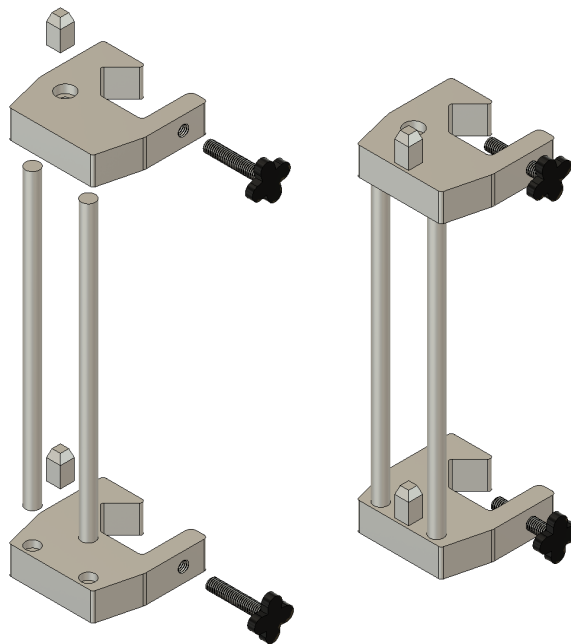
Figure 5.20: The final EI concept

The pegs have slanted tops to allow them to be located easier when fastening the LA. A slot was incorporated into the top clamp to allow mounting of the articulated arm holding the touch screen later described in the UI chapter on the EI. The entire EI was constructed from aluminum to reduce weight. It can be seen in figure 5.20.

5.6.6 Final specifications

The final EI prototype consisted of two clamps, two fastening screws, two pegs and two rods. The clamp profiles were water cut, the screw holes were threaded and the rods and pegs were then welded on. A countersunk hole was bored into the top clamp to allow mounting of the articulated arm of the UI system. The EI mounting procedure is described in figure 5.21.

Figure 5.21: Mounting the EI to the drip stand, and LA to EI

1. Place the EI with the pole flush against the V-shaped notch.

2. Tighten the screws against the pole.

3. Insert the LA hoops between the circular guide rods and lower it onto the pegs.

5.7 Patient interface (PI)

The PI was initially considered to be a custom made part, where off the shelf-components could not be used without customization or modification. Both an external and an internal search was conducted.
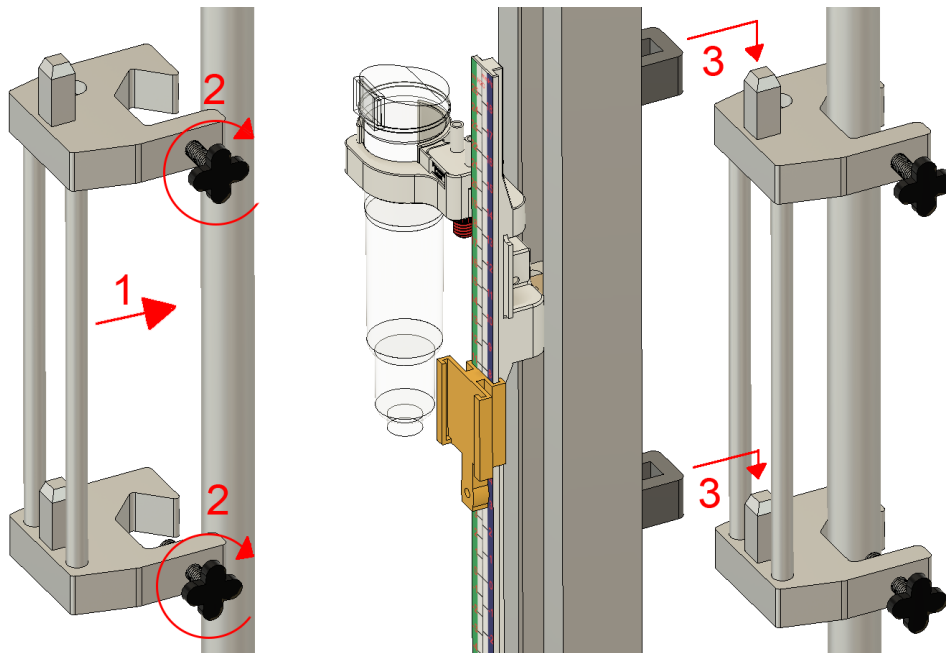
Several of the customer needs pertain to the PI, such as fitting many patients, staying in place on the patients and being easily attached to the patients. Since the PI connects the patient to the automatic regulator, its ability to stay in place and be easily fastened to a variety of patients was considered crucial.

5.7.1 External search

The patent filed by Innovation Skåne described a fluid filled tube attached to the head of a patient. During the external search for the PI different products that attach to the head of a person were investigated. Many of the products that were found came from sporting applications, some of which can be seen in figure 5.22. Several patents were looked at, a selection of which can be seen in patent number 1-3 in Appendix G. The results of the external search served as inspiration for the concept development of the PI.

Figure 5.22: Different head attachments found during the external search

5.7.2 Internal search

During the internal search brain storming was performed, which resulted in a mind map exploring the solution space and desireable features for the PI. This constituted a base for further development of the concepts. Some of the attachment solutions found were straps, hooks, and adhesive. A variable fit was also desired, which could be attained by using velcro, a buckle or an elastic strap. If the PI needed to be replaced for some reason, it also had to be separable from the fluid tube (FT) to avoid replacing too many parts, hence keeping it as simple as possible. The mind map can be seen in figure 5.23.
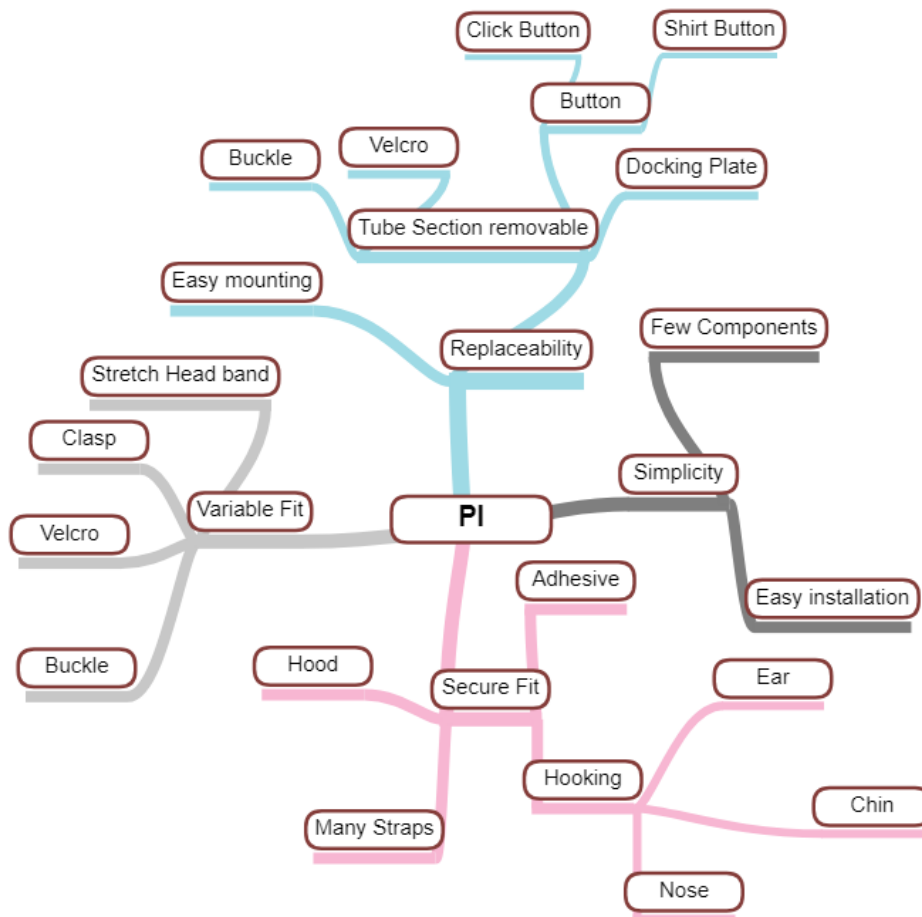
Figure 5.23: PI Mind Map

5.7.3 Concept generation

Based on the internal and external searches, several basic concepts were generated with a simple drawing made for each concept. The drawings of the concepts can be seen in figure 5.24. A short description of the seven concepts is listed below:

- **C1 Balaclava.** The FT is attached to a balaclava, which is then worn by the patient.

- **C2 EVD Attachment.** The FT attaches to the patient by securing it to the drain tube that is surgically attached to the patients head.

- **C3 Hat.** The FT is attached to a hat that can be placed on the patients head.

- **C4 Glasses.** The FT is attached to a pair of glasses that is worn by the patient. The side of the glasses is positioned just above tragus.

- **C5 Straps and ear hook.** FT is mounted to a single strap with an additional support against the ear.

- **C6 Straps.** The FT is mounted to a multi strap attachment.

- **C7 Adhesive.** The FT attaches to the patients head with a sticky residue.
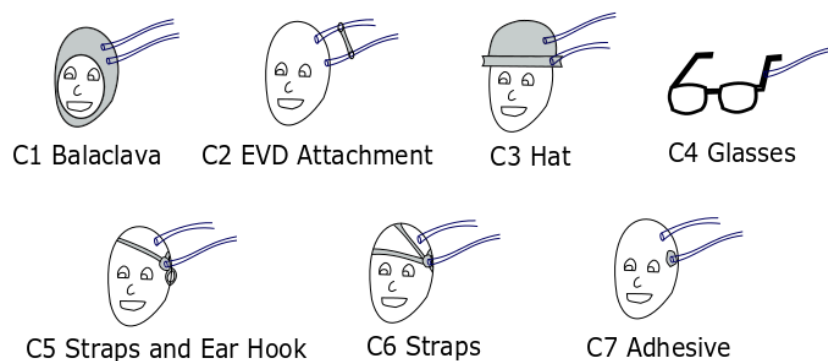
Figure 5.24: Concepts for PI

5.7.4 Selecting concepts

To narrow down the number of workable concepts a screening matrix, seen in table 5.5, was utilized. This resulted in two of the original concepts being chosen for further development. Concept 6 was chosen as a reference concept and the other concepts were compared with C6.

Table 5.5: Concept selection matrix for PI

Selection Criteria	C1	C2	C3	C4	C5	C6	C7
Secure fit	0	-	0	-	+	0	+
Versatile fitment	0	+	0	-	0	0	+
Easy to mount	-	+	0	+	+	0	-
Interference with EVD	-	-	-	0	0	0	0
Comfortable	+	-	+	-	0	0	-
Easy to keep clean	-	0	-	0	0	0	-
Net score	-2	-1	-1	-2	2	0	-1
Rank	4	3	3	4	1	2	3

The concepts chosen for further development were ranked as #1 and #2. These were concepts C5 Straps and Ear Hook, and C6 Straps. Concept C2 attained the same rank as C5, but was discarded since it was considered disadvantageous if the PI would interfere with the EVD. The two selected concepts were then further refined into different variants for each concept, which can be seen in figure 5.25.

5.7.5 Further development
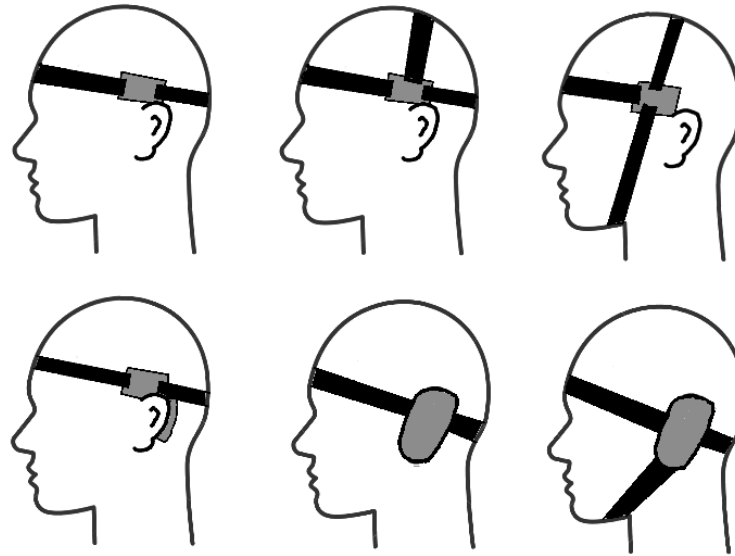
Figure 5.25: Further development of PI concepts

The top row of figure 5.25 shows possible configurations for a strap attachment and the bottom row possible configurations for a strap and ear attachment. The top row has a gray mounting surface where the FT can be attached, and the bottom left has an ear hook with a corresponding surface. The middle and rightmost concepts on the bottom row utilize an ear cover where the tube can be attached.

At this stage prototypes of the concepts were made and tested, one of which is displayed in figure 5.26. The subsequent evaluation resulted in the strap and ear hook being chosen as the final concept as it had a more secure fit and only required a single strap to keep it in place. Since the vertical distance to the FT attachment point is measured from tragus, it was deemed advantageous to have a product that was centered over the ear.

Figure 5.26: 3D print of strap and ear attachment, including TSI

The strap and ear hook concept was developed further with iterative prototyping and evaluation. It was decided that planar symmetry was desirable in order to be able to use it on both sides of the head. In order to accommodate ears of various shapes and sizes, the component was designed to have ample space for the auricle.

At the hospital study visit the latest prototype of the PI was presented to medical staff for feedback. During this meeting concerns were raised over the fastening solution. Since the elastic band keeps the PI in place by tension, pressure is generated on the parts of the head that are flush against the PI. This can quickly result in pressure ulcers, which is a common cause of infection and bacterial growth.

During the resulting discussion the seven concepts displayed in figure 5.24 were presented to the group. The adhesive concept was revisited and discussed at length.

In the concept selection phase, concept C7 was given a worse score than the reference concept in the "easy to keep clean" and "easy to mount" criteria. It was thought that using an adhesive on the skin would result in unhygienic

residue such as that left behind from band aids. It was also imagined that applying the adhesive and then attaching the rest of the sensor system would require time for the adhesive to set, during which everything would have to be kept still.
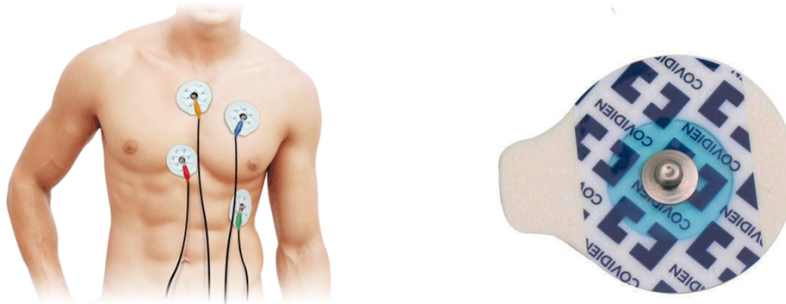
Figure 5.27: ECG pads

However, it was pointed out by the medical staff that electrocardiography (ECG) pads use adhesive and are routinely used on patients that have undergone surgery. They are not known to cause infection. To test the fit of the pads they were applied to skin and tugged and twisted. They were discovered to be surprisingly secure and have integrated "push-button" fits which provide an easy mounting point for the TSI.

The pads are associated with a significant reduction of development and manufacturing cost; they are standard equipment at hospitals and are available in a wide range of sizes and shapes. Using pads as opposed to a custom designed ear hook and strap design is in full accordance with design for cost principles. As they are already a mass produced component with several different manufacturers, any minor alterations should be easy to implement. Different materials are also available as can be seen in figure 5.28.
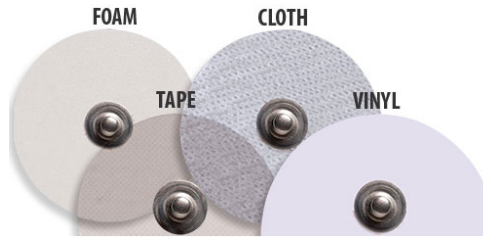
Figure 5.28: ECG pads in different materials

Due to the fact that as much of the pads adhesive area as possible need to be in contact with skin, circular pads make it difficult to attach the TSI close to the tragus. ECGs are available in a wide array of shapes and sizes. One that might allow the TSI to be mounted close to the tragus whilst providing a lot of adhesive area is a moon-shaped pad of the type shown in figure 5.29.

Figure 5.29: Moon shaped ECG pads

5.7.6   Connection to TSI

It was considered advantageous to be able to mount the PI on the patient without having the FT connected to it. This was mainly due to the PI being regarded as less delicate and more disposable. The most versatile way to do this is to use snap fits to connect the PI and TSI. Metal push buttons and snap fits are easily integrated into a part when designing in plastic and provides an easy and secure way to lock two components in place relative to each other rapidly.

The idea of having a detachable FT was still applicable to the new version of the PI that was developed after the discoveries made during the study visit. The new PI uses a push button to connect the TSI and PI together.

5.7.7 Final design

At the early stages of the development process a strap and ear hook design was deemed the best solution for the PI, and as the functional prototype. From the new information that surfaced during the study visit, the PI would ideally be off the shelf adhesive pads in a moon shaped form, as seen in figure 5.30.
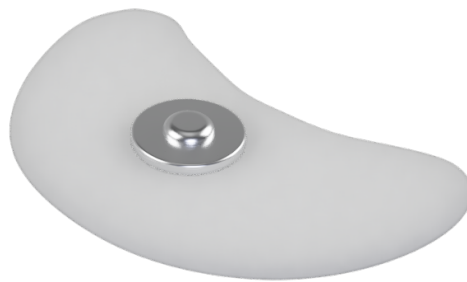

Figure 5.30: Final design of the patient interface

5.8 Tube sensor interface (TSI)

The TSI is the housing for the sensor and is permanently attached to the FT. The FT uses two sensors, one on each side of the tube, to measure the pressure difference. Both a functional and mock-up design prototype were produced. In the functional prototype, the TSI consisted of two identical housings with integrated sensors. The design prototype was produced as a complement to the functional prototype in order to demonstrate how small the TSI on the PI side of the FT can be in an end product.

In order to work as intented, the TSI needs to be small enough to attach to the patients head without being bulky. However, producing a small enough functional TSI for an end product requires manufacturing methods not available during the thesis.

5.8.1 Bluerobotics Bar02 sensor

The sensor used in the TSI can be seen in figure 5.31. It was very small, with dimensions of roughly 4x4x4mm. However, the housing of the available version seen in figure 5.32 was several times larger, and the figure highlights the fraction of the Bar02 housing occupied by the sensor and PCB. The sensor built into the housing is sold under the name "Blue Robotics Bar02 Ultra High Resolution 10m Depth/Pressure sensor" [15].
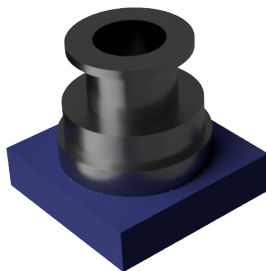
Figure 5.31: Pressure Sensor

The size of the sensor housing affected the development process greatly; when developing the prototype the large housing of the Bar02 sensor necessitated an even larger TSI. To demonstrate the function of the prototype, the TSI was designed to accommodate the Bar02 sensor, and connect to the FT so that liquid remains in contact with the sensor.
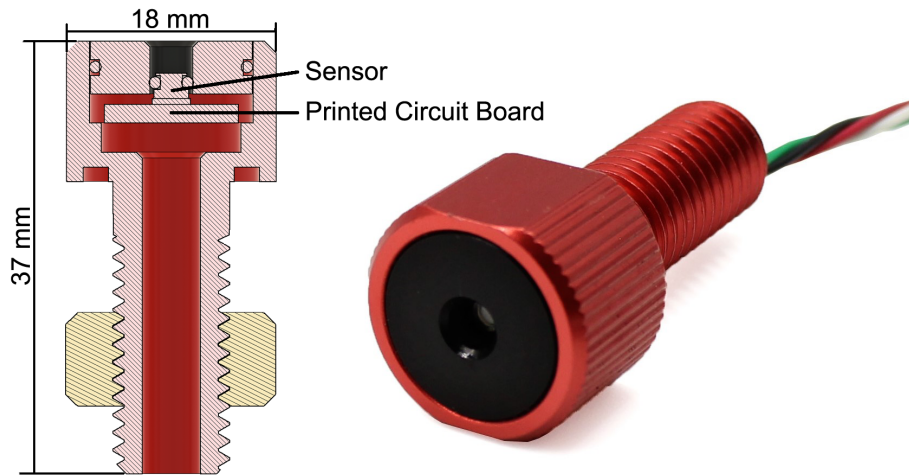
Figure 5.32: Pressure Sensor Housing, Bluerobotics Bar02

The sensor is mounted to a printed circuit board (PCB), which includes solder pads for the four data and power cables. On the PCB, there are several subcomponents necessary for reading the sensor. Since the PCB has large solder pads to enable manual soldering and simplify handling, it was deemed possible to make the PCB even smaller if one was to be custom made for a specific application, like a future TSI. This means that the sensor package can be miniaturized greatly. The PCB is pictured in figure 5.33 and is included with the Bar02 sensor.
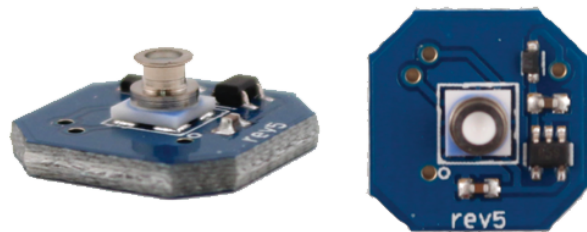
Figure 5.33: Pressure sensor mounted on PCB

The enclosure had to be waterproof, fit the Bar02 sensor and be attachable to the LDI. Fulfilling these needs while still maintaining a small form factor proved difficult. Figure 5.34 illustrate the basic function of the enclosure. The top part of the Bar02 sensor is enclosed. An opening allows water from the FT to reach the sensor.
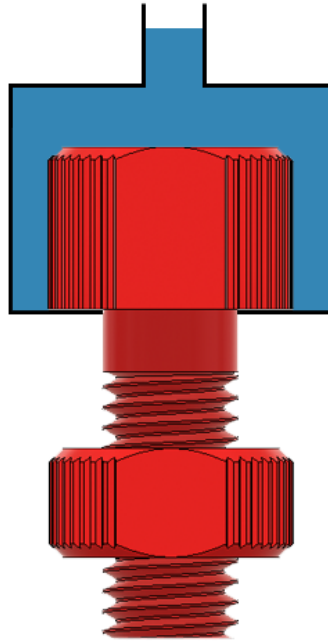
Figure 5.34: Water in contact with sensor

5.8.2 Functional prototype concept development

An enclosure that could be disassembled and thus enable reuse of the Bar02 sensors for the final prototype was deemed necessary. Metric threads were used so that the enclosure could be separated. A Bar02 sensor was cut apart to see if the PCB and sensor could be extracted from the housing, but they were discovered to be glued together and not separable.

The TSI development was in its early stages conducted in parallel with the PI. Different types of connectors were considered, one being the "GoPro-style" snap connector where the snap connector would lock the TSI to the PI. Inspiration for this type of connector came from the external search of information during the PI development process.

Concept 1

Concept 1 of the TSI enclosure is pictured in figure 5.35. The following functions have been integrated:

- "GoPro" style snap connector to PI
- Nipple to attach FT
- Threads to allow separation of TSI to reuse Bar02 sensor
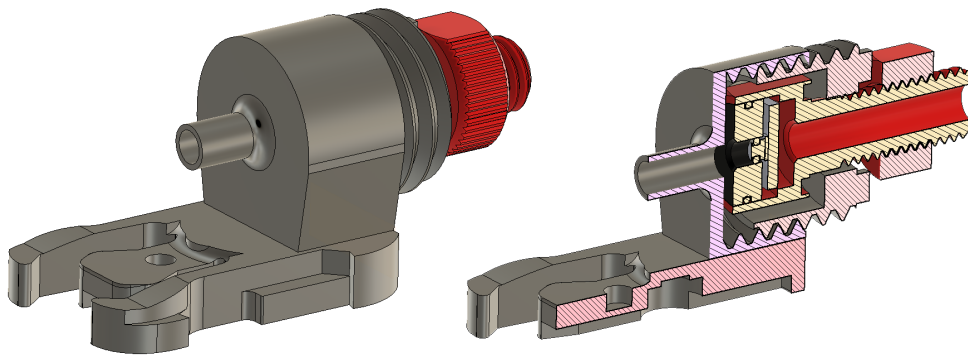
Figure 5.35: TSI concept 1

This enclosure was designed before the study visit was conducted. Due to the redesign of the PI after the study visit, the snap fit solution was discarded from the functional TSI prototype.

Concept 2

While creating the concepts for the TSI and testing the sensor subsystem, a problem was encountered whilst filling the FT with water. Air bubbles were trapped in the FT and proved hard to remove as illustrated in figure 5.36.
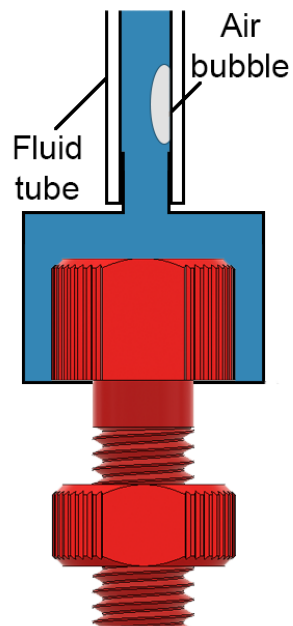
Figure 5.36: Trapped air bubbles

For the second TSI concept, a solution for flushing air bubbles out of the enclosure was designed and incorporated into the housing. The concept consisted of three parts with the following functions:

- Top part with FT attachment
- Middle part where Bar02 is fastened
- Bottom part, lid that is closed when air bubbles are gone

This particular concept, which is seen in figure 5.37, was not functional since the parts did not fit together. The bottom part is colored purple in the cross section.
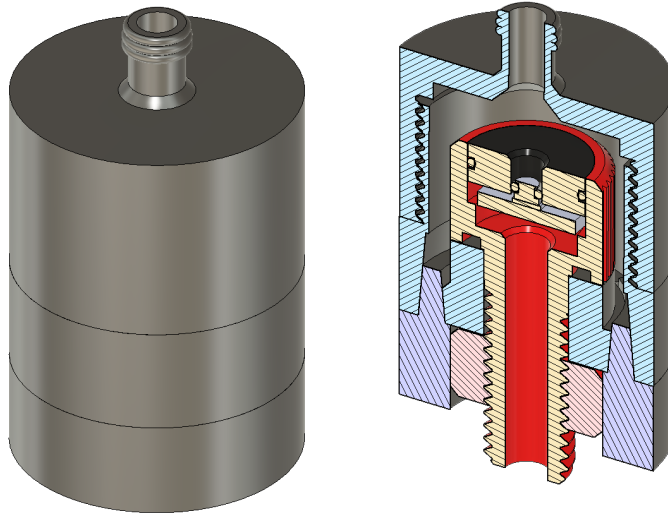
Figure 5.37: TSI concept 2

Concept 3

Two tube attachment nipples were used for this concept, to enable air to escape during filling. When flushing water through the FT and the trapped air has left the FT, the outgoing tube attachment is sealed with a clamp, similar to bleeding a brake line on a vehicle. The direction of the flow can be seen in figure 5.38.
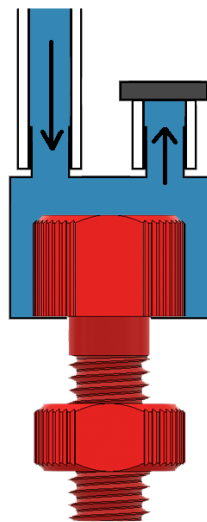
Figure 5.38: Bleeding the TSI

Concept 3 is shown in 5.39 and had the following features:

- Threads, making the TSI separable
- Two nipples to enable bleeding of the FT
- Flat bottom to enable placing the PI-side TSI on flat surfaces without rolling during testing
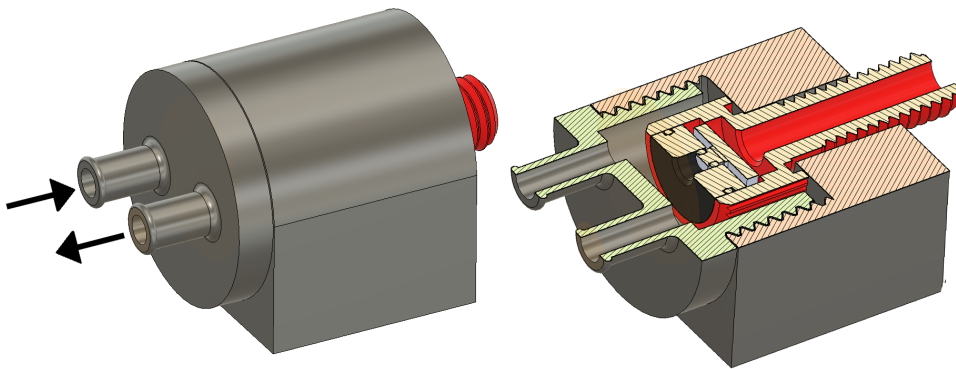
Figure 5.39: TSI concept 3

In an end product, the TSI attached to the leveling device interface can differ from the TSI attached to the PI. However, two identical TSIs were utilized during the thesis in order to simplify the development process. Two 3D printed copies of the third concept were used to test the sensor system, and were included in the first fully functional prototype. Since they worked well, they were refined and used in the final prototype.

There were initially problems with leakage around the tube attachments, the nipples that the FT attaches to. Leaking also occured through the threads. To stop the leakage, thread seal tape was used on the threads and silicone sealant was spread onto the other mating surfaces. A prototype of the third TSI concept is shown in figure 5.40.

Figure 5.40: 3D print of TSI concept 3. The black splotches are silicon sealant used to waterproof the prototype

5.8.3 Final functional TSI prototype

The final concept for the functional prototype was a physically smaller, permanently sealed enclosure similar to the third concept. Threads were removed due to the large volume they require. The concept used the same type of solution to remove trapped air as the previous one. A black colored line and text on the enclosure aligns with the pressure level indication printed on the drip chamber. The alignment is illustrated in figure 5.41.
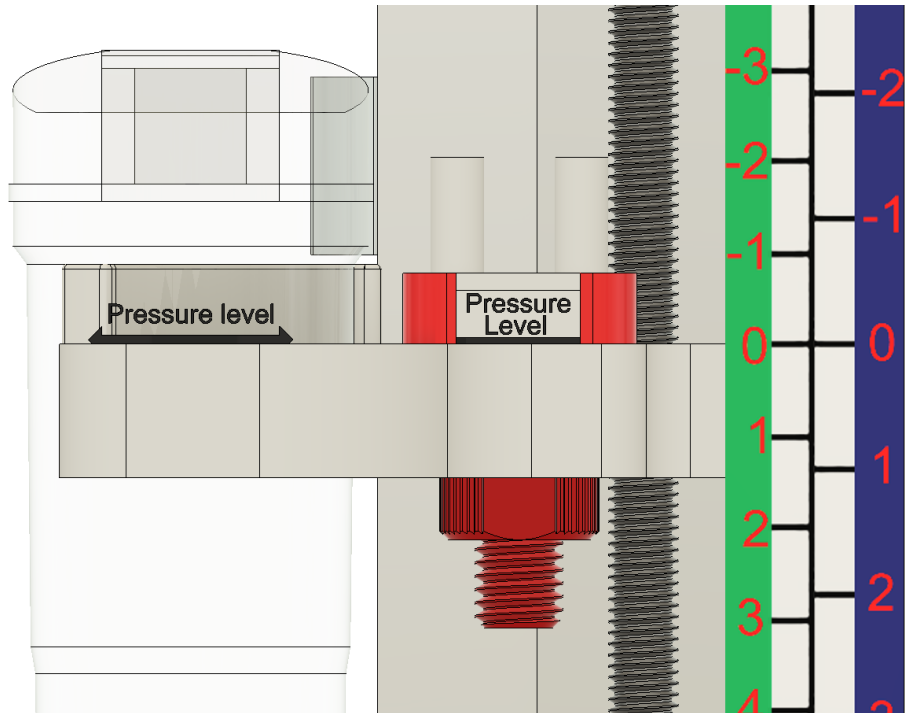
Figure 5.41: Alignment of drip chamber and TSI, vertically aligned with zero-level on ruler

The Bar02 sensor was first inserted into the bottom half of the TSI which was then glued together with a lid to enclose the sensor. A spiral cable for data and power to the sensor was routed along the fluid tube, and is shown later in the section for the fluid tube. To allow the routing of the sensor cables from the sensor itself to the spiral cable, a hook was incorporated into the design. This allowed the sensor cables for power and data to be fastened to the TSI with adhesive and avoided putting stress on the sensor cable solder junction. The features of the final TSI prototype are displayed in figure 5.42. Its size relative to the Bar02 sensor is shown in figure 5.43.
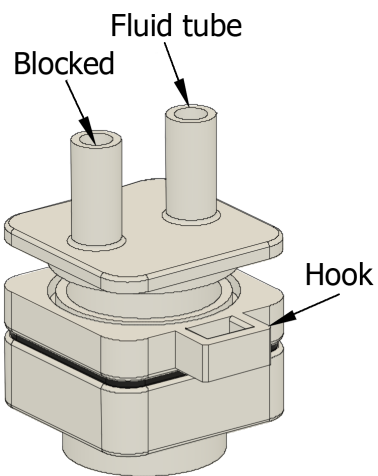
Figure 5.42: Functions of final TSI prototype
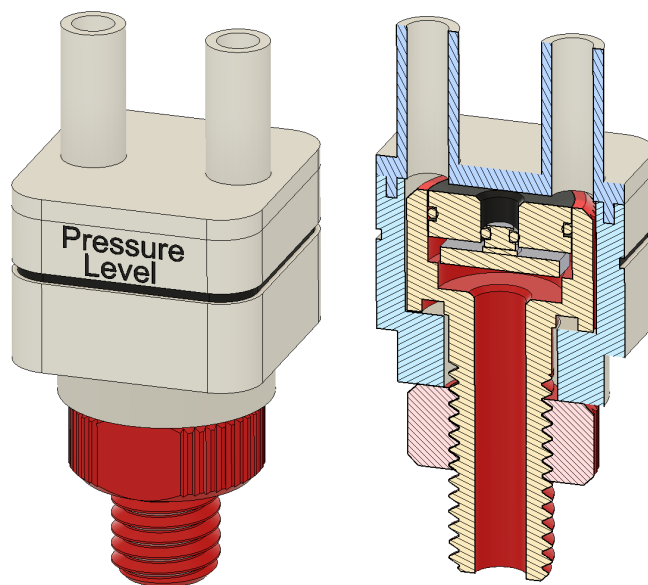
Figure 5.43: Final prototype of TSI assembled with the Bar02 sensor

5.8.4 Design prototype development

The majority of the TSI development was conducted for the functioning prototype, but a design prototype was also developed and manufactured. The

design prototype was developed in order to demonstrate a possible design of the patient side TSI in an end product, and to illustrate the small size attainable without superfluous subcomponents. The TSI needed to have space for the sensor as well as the attached PCB. A solution for routing the power and data cables along the FT was also necessary. Since it would be constantly attached to a patient during the EVD process, size was an additional factor to take into account so as not to cause discomfort for the patient.

Figure 5.44 shows the TSI design prototype. It can be attached to the PI with a metallic snap button, similar to ones found on clothes. Also pictured is the PI.
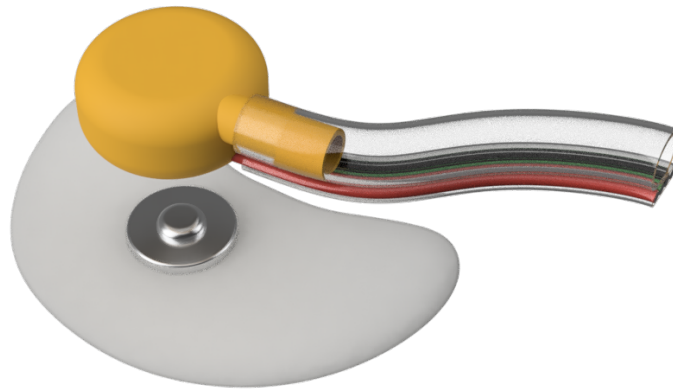
Figure 5.44: Design prototype

The upper cavity where the water is contained can be seen in figure 5.45. It is in contact with the sensor, which is placed in the lower cavity of the TSI. An O-ring or seal (not pictured) sits around the sensor to stop water from entering the PCB compartment. The top half of the TSI is fused to the bottom half during the manufacturing process. An exploded view of of the components can be seen in figure 5.46
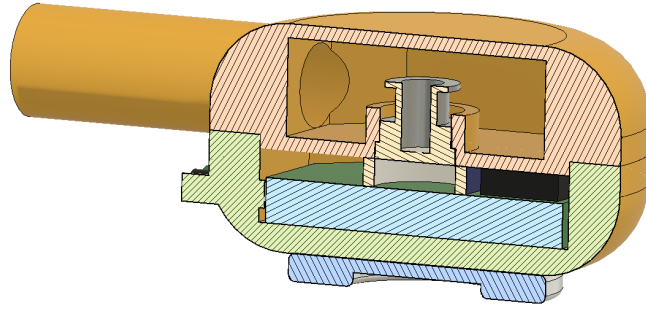
Figure 5.45: Section of design prototype
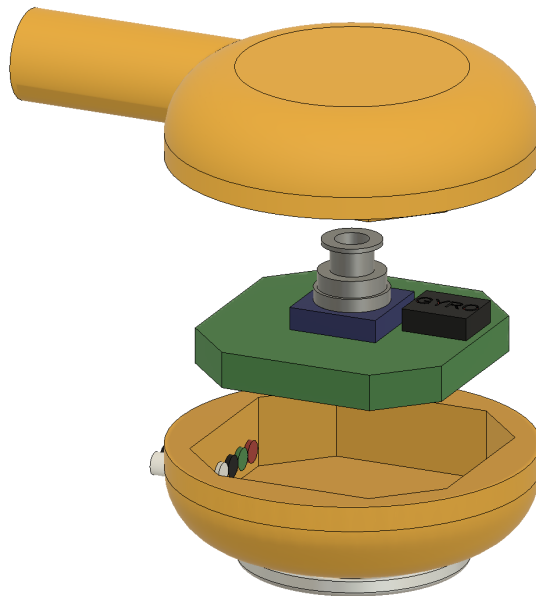
Figure 5.46: Exploded view of design prototype

Different solutions for the cable management were explored. It was decided that routing the cables along the FT was necessary in order to prevent tangles. One way of routing the cables was running the cables parallel to the FT, as in figure 5.44.

72

Another way could be utilizing a spiral cable that runs along the FT as seen in figure 5.47.
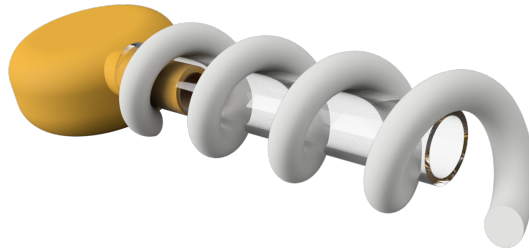
Figure 5.47: Alternate way of cable management

The dimensions of the design prototype is shown in figure 5.48.
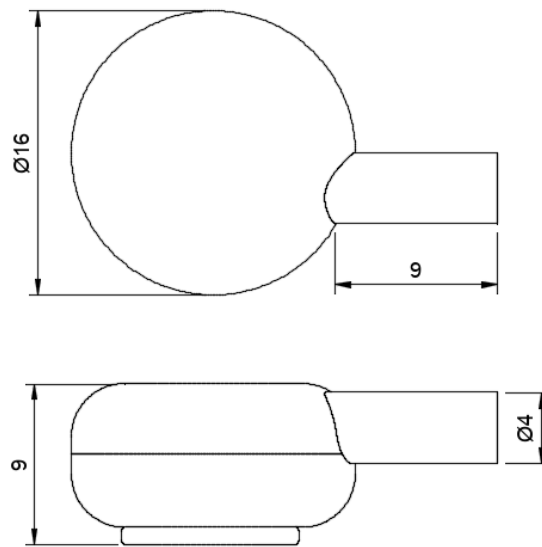
Figure 5.48: Dimensions of design prototype

The installation steps of the PI and design prototype of the TSI can be seen in figure 5.49. It is a two step process that allows for the PI to be interchangeable.
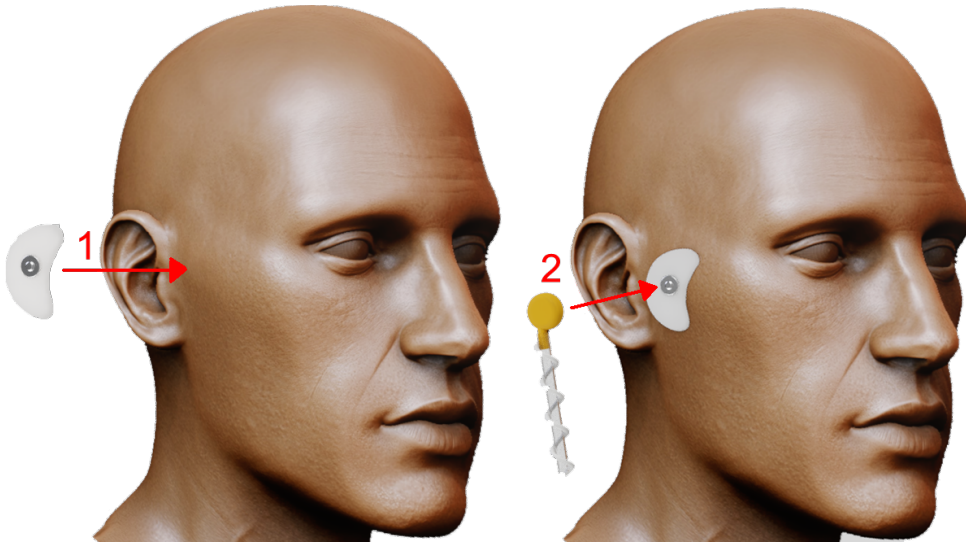
Figure 5.49: Installation of PI, TSI and FT onto patient

1. Remove cover and place adhesive surface of the PI on tragus
2. Attach the TSI to the PI by pressing the snap buttons together

5.9   Fluid tube (FT)

The FT consisted of a fluid and a tube. Its primary functions were to provide a fluid column for the sensors to measure and to attach them physically. Since the sensors measure pressure, the choice of fluid had an impact on the accuracy of the height measurement with a heavier fluid exerting more pressure for a given fluid column height.

The sensor system was based upon a fluid filled tube with sensors at both ends as described in the Innovation Skåne patent. Because of this predetermined setup, the FT was deemed to be unsuitable for a traditional U&E concept development process. Instead, the existing concept was analyzed and refined.

Table 5.6: Potential fluids for use in FT

Fluid	Density (kg/m^3)	Pressure per cm fluid height (kPa/cm)	Fluid column height per kPa (cm/kPa)
Water	997	0.1	10.2
Ethanol	790	0.08	12.9
Glycerine	1260	0.12	8.1
Saturated H2O-NaCl sol.	1193	0.12	8.5
Glucose Syrup	1400	0.14	7.3
Mercury	13594	1.33	0.7

Several factors were taken into account when deciding on which fluid to use. By using a fluid with higher density, a less sensitive sensor can be used. It was considered desirable to avoid substances that are toxic and incompatible with plastics. During the prototyping and validation phases water, which has a density of 997 kg/m^3 at room temperature, was used and generated acceptable results. Using a saturated saline solution with 26% NaCl with a density of 1193 kg/m^3 was considered as a cheap alternative with a 19.3% increase in accuracy. Whilst the density of fluids is temperature dependant, variations due to this were neglected since the atmospheric and temperature conditions in a hospital is strictly controlled and monitored. Some of the other fluids considered can be seen in table 5.6.

During the prototyping phase a 4 mm polyvinyl chloride (PVC) tube was used due to low cost and availability. However, the PVC tube proved to be quite stiff. In a real world application a softer tube more akin to the one integrated into the existing EVD set would be more desireable.

The process of filling the FT is visualized in figure 5.50. To fill the FT, water was injected with a syringe through a port (1). Water was run through the tube until no visible air bubbles could be seen, after which the secondary port (2) was closed with a clamp (not pictured). A second clamp was used to close port 1 and the syringe was then removed.

Figure 5.50: Procedure to fill the FT using the TSIs

The diameter and thickness of the tube walls affect the ease of filling the tube with fluid and the resistance to kinks and bends along the tube length. During testing a smaller tube was used initially but proved difficult to fill. This prompted a switch to a larger tube with an internal diameter of 6mm.
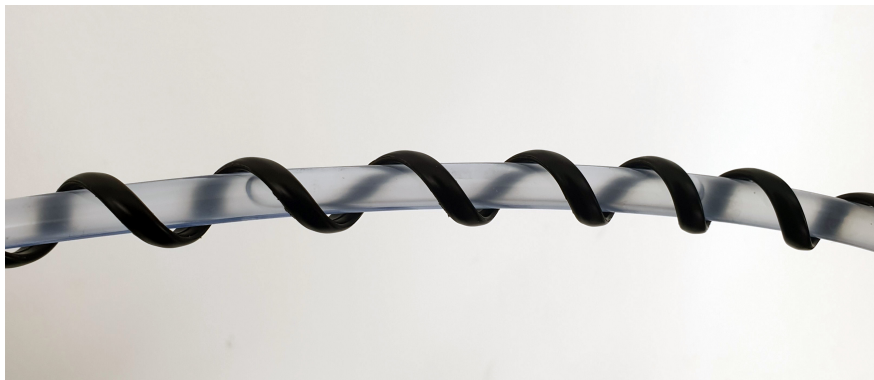
Figure 5.51: Air bubble trapped in FT

During the FT development, a problem was encountered when filling the FT prototype with water. It proved difficult to completely fill the tube without introducing air bubbles of the type seen in figure 5.51. This is problematic due to two reasons; Bernoullis equation assumes an incompressible fluid, and the calculations performed by the microcontroller to calculate the fluid column height assumes that the entire fluid column has a homogeneous density. The air bubbles introduce regions of compressibility and varying density into the FT and consequently gives rise to erroneous calculations.

When investigating this problem it was discovered that the formation of air bubbles within the tube was caused by two different phenomenons. Insufficient seals between the TSI and the FT caused water to leak out of the tube and be replaced by air, which caused the bubbles to grow larger over time. During the filling process microscopic air bubbles were injected along with the water and then coalesced into larger ones. To obtain a completely gas free FT, degassing and filling under vacuum conditions is necessary. This requires specialized equipment not readily available during the project. In an end product, the FT will be sold as a prefilled and degassed unit with incorporated TSIs.

5.10 Linear device interface (LDI)

The LDI was a component that had several integrated functions. The LDI served as a link between the sensor system and leveling system, and was attached to the LA via the middle plate that moved vertically when a change in pressure was detected. Since the outlet of the drain was located on the LDI, the patients ICP drain rate was maintained when the patient moved due to the repositioning of the LDI by the LA.

The basic features integrated into the LDI were:

- **Clamp attachment for the drip chamber of the EVD kit.** The outlet of the drip chamber was required to be kept at a constant vertical distance from the patients head.

- **Attachment point for the sensor in the TSI that measured the pressure at the drip chamber.** The sensor needed to be level with the drip chamber at all times.

- **Attachment point for transducer that reports ICP data to monitor.** Had to be zeroed relative to the drip chamber when setting atmospheric pressure before activating the automatic regulator, and then moved to the desired height.

- **Ruler for transducer.** This was required in order for the user to be able to set the prescribed height difference of the drain after the atmospheric pressure has been zeroed.

The current EVD mount system as shown in figure 5.52 utilizes a clamp for the drip chamber (1), where the drip chamber can be moved relative to the transducer (2) in order to maintain the correct height difference between the two. A similar design was desired for the LDI of the automatic regulator to speed up the development process.
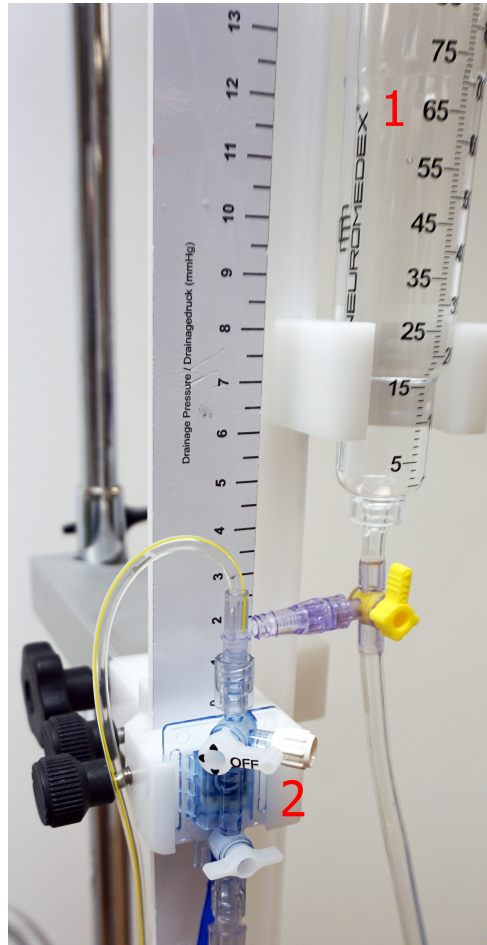
Figure 5.52: Ruler and transducer holder of Neuromedex EVD mount system

The functions listed previously were sketched on a paper in order to visualize and understand the necessary functions of the LDI and its design limitations. The sketch is displayed in figure 5.53. An insight gained from the sketch was how the TSI location needed to be designed. The drain outlet, TSI and zero level of the ruler all needed to be horizontally aligned. Whether the clamp holding the drip chamber should be moveable in relation to the transducer or vice versa was discussed.
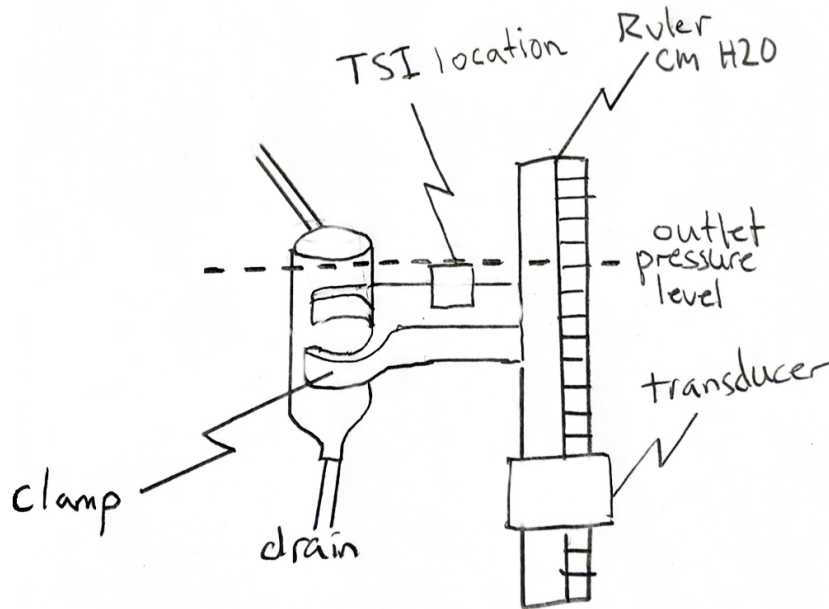
Figure 5.53: LDI sketch

Design and concept development activities were not initiated until after the study visit. The LDI was designed to accommodate the system from Neuromedex since it was to be included in the final prototype. A Neuromedex EVD system acquired from the study visit was the foundation for the generated design concepts. Several iterations of design concepts were created.
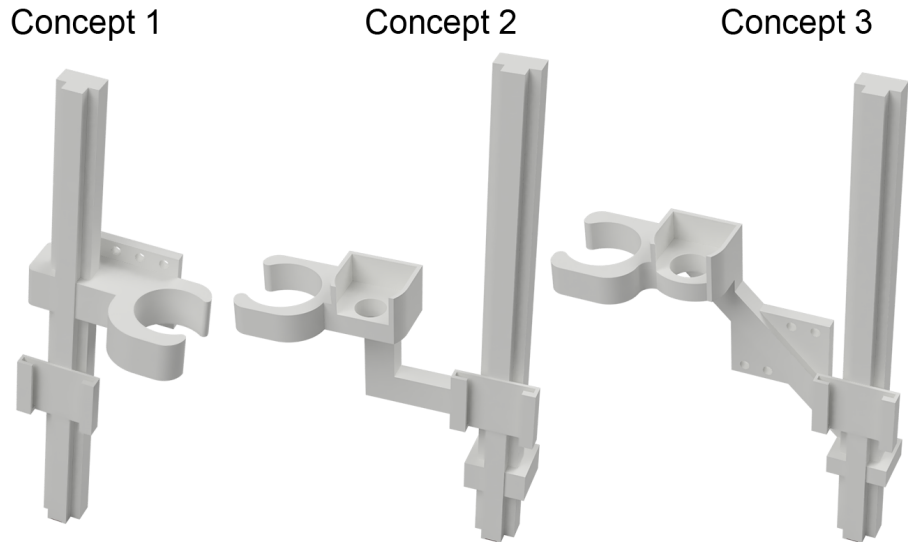
Figure 5.54: LDI concepts 1 - 3

Concept 1

Concept 1 shows one of the earliest concepts, which was also the most similar to the design of the current system manufactured by Neuromedex. This concept was 3D printed in polylactic acid (PLA) in order to get an initial feel of overall strength, size and fit and to verify that the drip chamber would stay securely in the clamp without sliding. This concept did not have an attachment for the TSI. The ruler and the holder for the transducer was designed as one part which moves relative to the clamp.

Concept 2

The design space was explored more systematically for concept 2. The ruler and clamp were moved further apart and an attachment was made for the TSI. The clamp was moved from the right side to the left side of the LDI to allow easy access to the sampling port of the drip chamber which can be seen in figure 5.52, with the yellow valve beneath the drip chamber. The ruler and clamp remained unchanged from concept 1.

Concept 3

The third iteration included an attachment to the LA, in which a diagonal cross member was used instead of the L-shaped design of iteration two in order to simplify the geometry. This design was also 3D printed and used for the first fully functional prototype. The LA attachment consisted of a plate

with six holes to enable the LDI to be screwed onto the LA.

Figure 5.55: LDI concept 4

Concept 4

The fourth and final iteration added a lip to the clamp for the drip chamber to rest on. This allowed the drain outlet to always be level to the sensor. The LDI was attached to the middle plate of the LA using only a screw and an integrated slot acting as a guide. The ruler was redesigned and fused with the LDI, with the yellow transducer holder being able to slide along the ruler. The fourth iteration also resulted in a more compact design similar to the first concept, but also accommodating space for the TSI. It can be seen in figure 5.55.
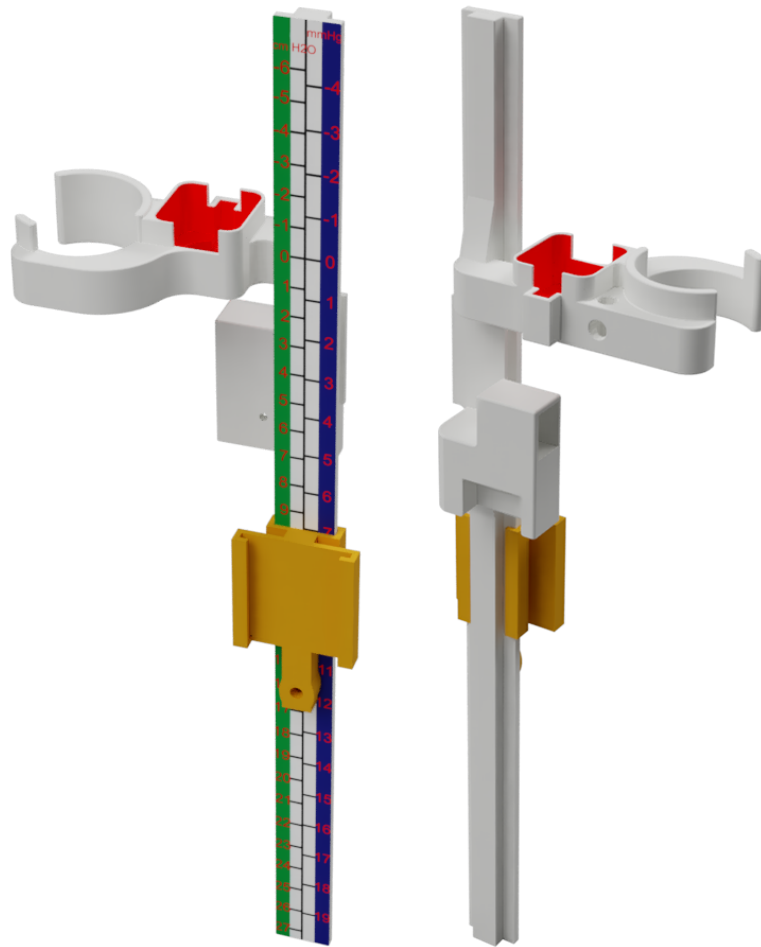
Figure 5.56: Final design of the LDI

Final design

The final design was a compact LDI with as many integrated functions as possible. It was based upon concept 4 with slight modifications and can be seen in figure 5.56. The transducer sits in a slot on the yellow capsule that can be moved along the ruler and fastened with a screw at the desired distance from the pressure sensor. Due to using a screw, the capsule does not slip and slide on the ruler during operation. This ensures that the correct intracranial pressure is reported on the monitor.

The ruler shows the pressure in mm Hg and cm water column to allow for different pressure measurement standards. Sharp edges were avoided and radii were incorporated at corners to prevent stress concentrations.

The CSF drip chamber can be easily mounted in the gripping clamp which flexes to provide a secure fit.

The red pit near the drip chamber clamp holds the TSI. A mounting slot for the associated electronics and grooves for the sensor cables were incorporated. In order to be able to connect the sensors to the arduino a RJ10 female connector was built into both the LDI and chassis. This allows the two to be connected and disconnected after assembly, which simplifies testing and re-assembly. Removable connectors for the sensor cables allow the FT to be removed as well.

To demonstrate the functionality of the LDI, an example is shown in figure 5.57.
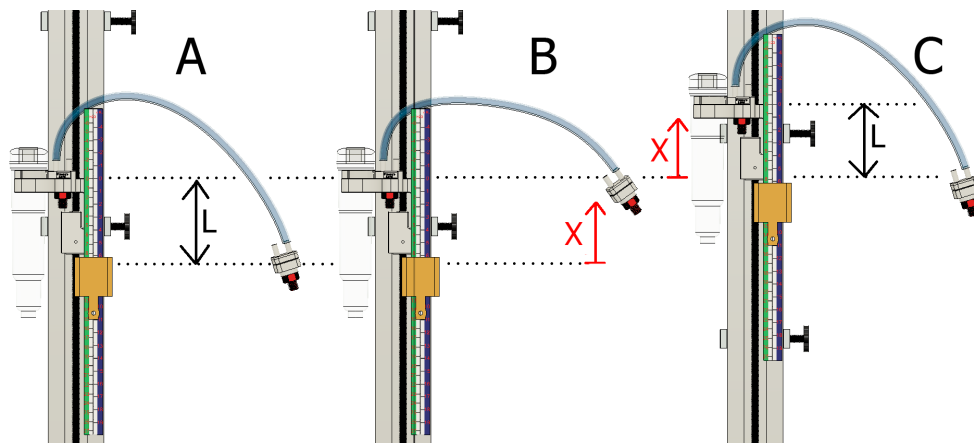
Figure 5.57: Principal functionality of the height regulator

- **Sequence A.** The LDI and patient end TSI are stationary and located a vertical distance L from each other, indicated by the black arrow.

- **Sequence B.** The patient end of the TSI is moved a vertical distance X indicated by the red arrow.

- **Sequence C.** The system recognizes a difference in pressure in the FT and responds by moving the LDI the same distance X, indicated by the red arrow so that the vertical distance L between the LDI and patient end TSI is maintained.

5.11   User interface (UI)

The UI is the component which the user interacts with to control the automatic regulator. When a patient is required to have surgery to implant an EVD, a height difference between the EVD inlet and outlet site is prescribed by a doctor to ensure an optimal drain rate. This height difference must be input to the automatic regulator in some way, thus requiring a UI. The UI must be able to interpret a numerical value and display which current value is set.

There are several ways to input information to a device - for example by physical interaction or voice. For simplicity it was decided that some kind of tactile input would be used. In order to keep the chassis easily cleanable it was considered advantageous to minimize the amount of protrusions, seams and gaps. To this end, a touchscreen was decided to be the most hygienic solution as it integrates and combines the input and output properties of the UI into a single component. It also allows post launch modification of the user experience by updating its software.

The output of the UI was decided upon based on discussions with nursing staff [14]. Development was based upon Nielsen and Molich's ten UI design guidelines.

The UI system can be divided into inputs and outputs. A touchscreen was deemed to be a good option to perform the majority of the user inputs since they constitute a widely known and intuitive technology. Furthermore, touchscreens made specifically for the medical industry exist which are easily cleanable [16].

Several input actions are required for the user to operate the system. The desired height target to be maintained must be set and the height adjustment process should be easily paused and resumed. The transducer needs to be able to be moved relative to the TSI to output the correct pressure. Most of the inputs can be made on the touchscreen.
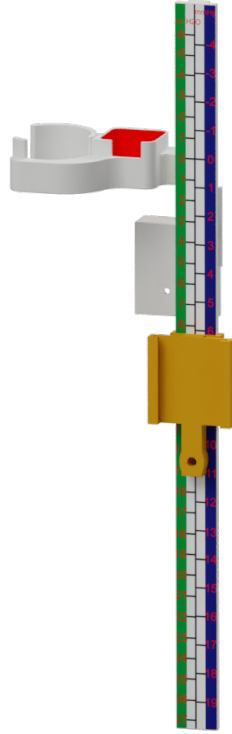
Figure 5.58: Capsule and ruler concept

Since the transducer needs to be physically moved it cannot be easily operated by a touchscreen. Instead the sensor is manually placed in a holder which can slide up and down a ruler. The ruler has a scale to allow the operator to place it at the correct distance from the LDI zero point. The scale includes unit labels for pressure in mm Hg and cm water column. To enhance user friendliness the capsule the ruler and centimeter markings have contrasting colors. The capsule and ruler concept is shown in figure 5.58.

The screen can be used for the majority of the outputs. The display should show both the actual height difference and the targeted height difference in real time. Interviews with medical professionals indicated that a graph displaying how the height has varied over time would be useful in determining how much the patient has moved when not under supervision.

The UI should display the state of the automatic regulator in a consistent manner with a clear connection to what is happening at the moment. This is accomplished by the interactive parts of the screen changing color when

selected. The display has three display modes. Table mode shows the most important information in a large font and allows a nurse to discern if the EVD drainage outlet is positioned at the correct height above the patient at a glance. A pause and play button allows the user to pause and resume the operation of the system. Table mode can be seen in figure 5.59.
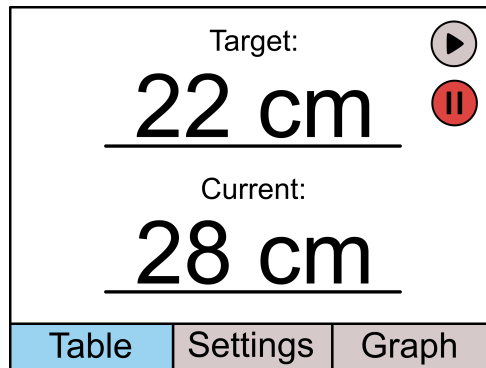
Figure 5.59: "Table mode" displayed on touchscreen

Settings mode allows the user to input the required data for the automatic regulator to operate and can be seen in figure 5.60. The target height is the desired height difference between the EVD inlet and outlet sites to be maintained. The alarm limits is the maximum allowed distance from the target height. If the EVD outlet moves outside this interval an alarm will sound. The speaker icon to the right indicates whether the alarm sound is turned off or on. The yellow box at the top gives the user real time updates on the height regulating status whilst operating the system.
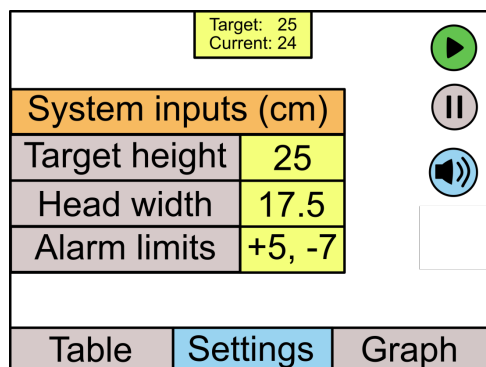
Figure 5.60: "Settings mode" displayed on touchscreen

Graph mode displays a graph of the measured height over time. This provides nurses with information regarding how the system has been acting over a time period. The time interval of the graph can be selected on the right side of the screen, and the height interval adjusts automatically to fit the entire graph. Pressing somewhere on the curve gives a more precise time stamp and height value. As in the settings mode, the yellow box at the top gives the user real time information on the state of the height regulator.
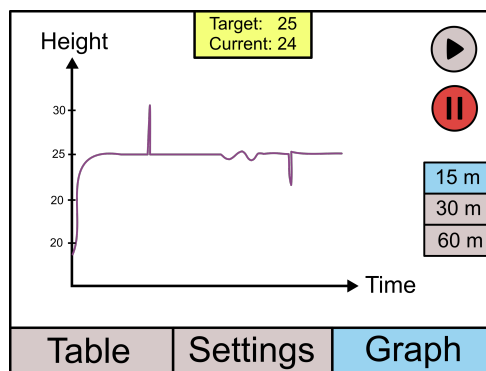
Figure 5.61: "Graph mode" displayed on touchscreen

In order to exhibit the touchscreen concept in relation to the rest of the height regulator a prototype was built. Since a lot of money and time would have been required to program a functioning touchscreen and interface it with the automatic height regulators software, only a design prototype was built. Like many of the other components it was 3D printed in an selective laser sintering (SLS) printer, sprayed with plastic filler, sanded and painted. To enhance realism, a mock-up image of the UI was printed and inserted. A pane of clear acrylic was inserted on top of the image to make the prototype look more like a screen. A rendering of this prototype is shown in figure 5.62.
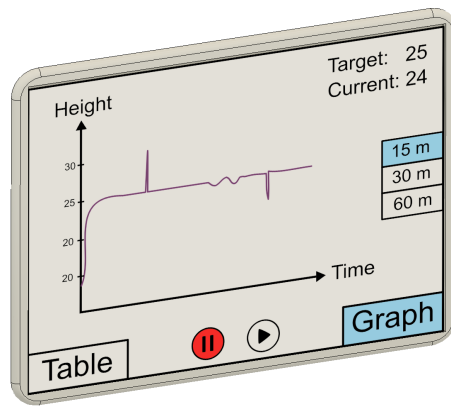
Figure 5.62: CAD model of the touchscreen prototype

To allow for easy and ergonomic mounting and adjustment of the touchscreen, an articulated arm was used. One end of the arm can be fastened to the EI using a countersunk hole in the EI and a locking nut. The other end can be fastened to the touchscreen by using a slot and locking nut as seen in 5.63.
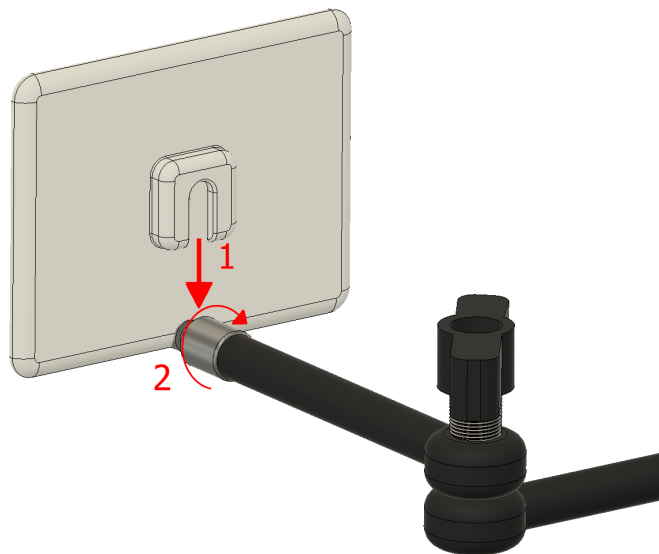
Figure 5.63: Mechanism for fastening the touchscreen to the articulated arm

5.12   Electronics

5.12.1   Hardware

The electronic hardware were the components needed to read the sensors and perform the linear movement of the automatic regulator.
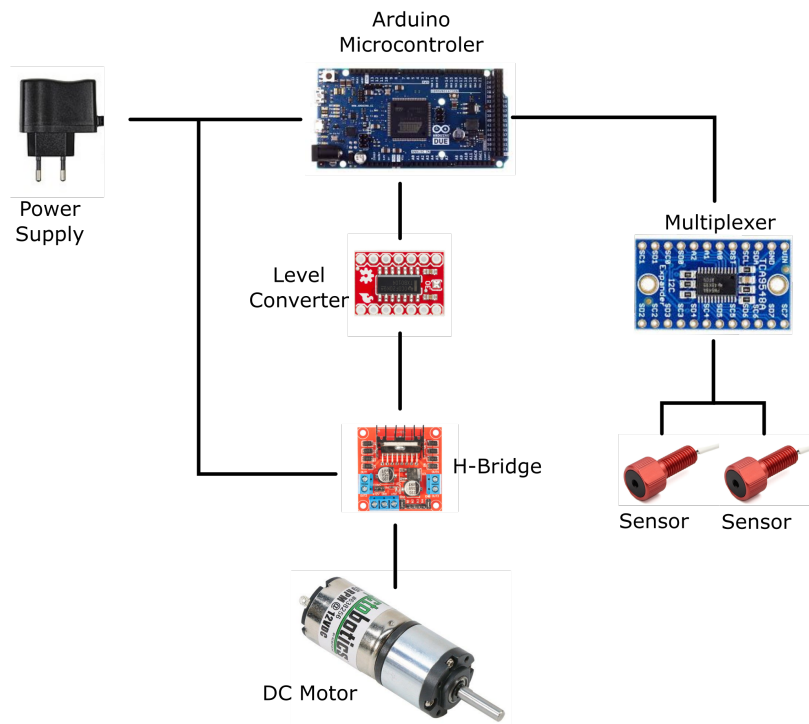
Figure 5.64: Electronic hardware components

Several electronic components were used in the height regulator. They consisted of a DC motor and driver, two pressure sensors, a level converter and an Arduino micro controller. Figure 5.64 illustrates how the components were connected. The Arduino was chosen due to its versatility and the wide range of commercially available modules and open source code. Initially an Arduino Uno was used. As the software used became more advanced and more code was added, it was discovered to lack sufficient processing power which prompted a switch to the more powerful Arduino Due.

The pressure sensors used are manufactured by Blue Robotics for use in submersible vehicles and are the Bar02 Ultra High Resolution 10 m Depth/Pressure sensors, with a water depth resolution of 0.16 mm. They were chosen due to them having existing Arduino libraries, an array of example projects being available online and their excellent depth resolution. Since two identical sensors were used and they have the same communication address, a multiplexer chip was utilized to allow the microcontroller to address each individually.

At first a stepper motor was used to rotate the threaded rod in the LA. It was thought that the precision afforded by a motor of this type would be necessary for the height regulator. When testing the functional prototype with a stepper motor it was discovered that driving the stepper motor at a high speed whilst reading the sensors yielded a very high processor load. This was due to the Arduino needing to calculate the velocity, acceleration and position of the motor before making a step. Running the PID software concurrently proved unfeasible. This prompted a switch to a DC motor which has a much simpler operation since the speed at which the motor spins is directly proportional to the input voltage.

To control the motor, an off the shelf H-bridge chip was utilized. These type of driver chips provide a simple interface between the Arduino and the motor. Since the driver requires 5V logic and the Due operates at a 3.3V logic level, a level converter was utilized to interface the two.

5.12.2 Software

The Arduino was programmed using the native Arduino IDE environment which is based on the C programming language. Where possible, pre-made and well documented software libraries were utilized to reduce workload. The Arduino code can be seen in Appendix E. To visualize the behaviour of the height regulator graphs were created in Matlab. These were used to troubleshoot and tune the Kalman and PID parameters for the system. The Matlab code can be seen in Appendix F.

The algorithm that was developed continuously reads the two sensors and filters the data to remove noise from the measurements. A Kalman filter is utilized to this purpose. The difference between the two sensors is then multiplied by a constant factor as outlined in the simplified form of Bernoulli's equation. The obtained value is the height difference between the FT ends and is used in the algorithm to calculate how far the TSI is from the patient in the vertical axis.
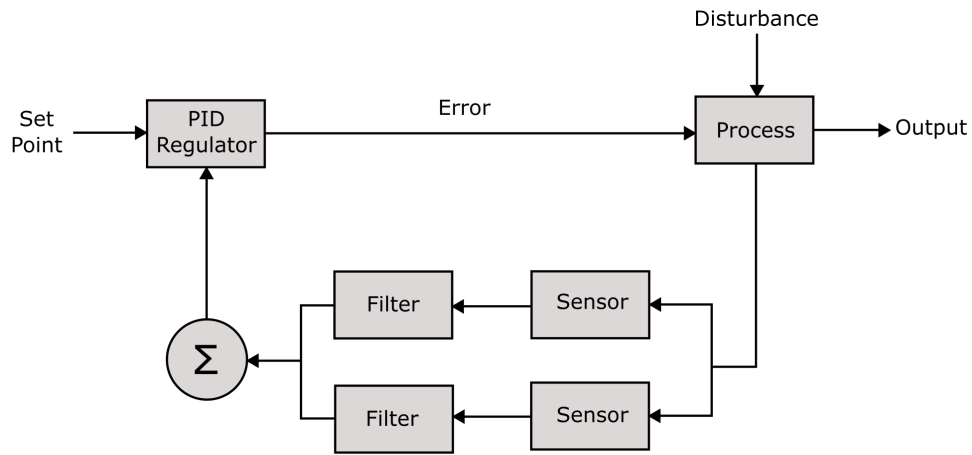
Figure 5.65: The automatic height regulating algorithm

This data is then input into the PID algorithm, which varies the motors speed in order to allow rapid movement when the LDI is far from the target and slow movement when it is close in order to prevent overshoot. The speed is varied via pulse width modulation output from the arduino. The process is illustrated in figure 5.65.

5.13   Chassis

The chassis was considered to be an essential component with multiple functions. Its main purpose was to house the electronic control system, and in an end product protect the internal components from dust and liquids. Although other components were encased in protective housings, only the electronics housing was considered to constitute an individual component.

Development of the chassis did not begin until the LA and EI were far along in their individual development processes and the electronic system was somewhat functioning. Some of the components in the electronic system were added during testing activities and some components were exchanged for others, which necessitated modifications to the internal space of the chassis during the development process.

The surface of an end product needs to be easy to clean, resistant to solvents such as alcohol, have a smooth surface and made from a high-end plastic suitable for the conditions where the automatic regulator would operate.

5.13.1   External search

A thorough external search was conducted. Both functional and aesthetic design features were investigated by examining patents, consumer products and medical equipment. Some of the patents that were investigated are listed as patent number 8-10 in Appendix G. A number of enclosures that served as inspiration are pictured in figure 5.66.

Figure 5.66: External search results for chassis

5.13.2 Internal search

During the internal search brainstorming was performed. These sessions were mostly focused on the location and shape of the chassis. Ideas on how to fasten the chassis to the LA were also investigated.

The main constraint regarding the placement of the chassis was that it could not be in the way of the LDI whilst moving or the IV drip stand attached to the EI. It was considered advantageous to place it on the lower part of the LA to lower the regulators center of gravity and to make the electronics accessible during testing. A solution that also encased the DC motor was considered beneficial.

5.13.3 Concept generation

When generating concepts, the main focus laid on the chassis being easy to mount and dismount from the LA. It was considered advantageous to include a removable lid of some sort in order to allow for quick access to the electronic

components and wiring when testing the automatic height regulator.

The use of a sliding lid, like in the classic game pick-up sticks was a feature that was the foundation to the idea to concept 2. The shelf for compact discs is another feature which spawned an idea for a solution for attaching the chassis to the bottom plate.

In an end product, the chassis lid would need to have integrated seals to ensure its particle impermeability.
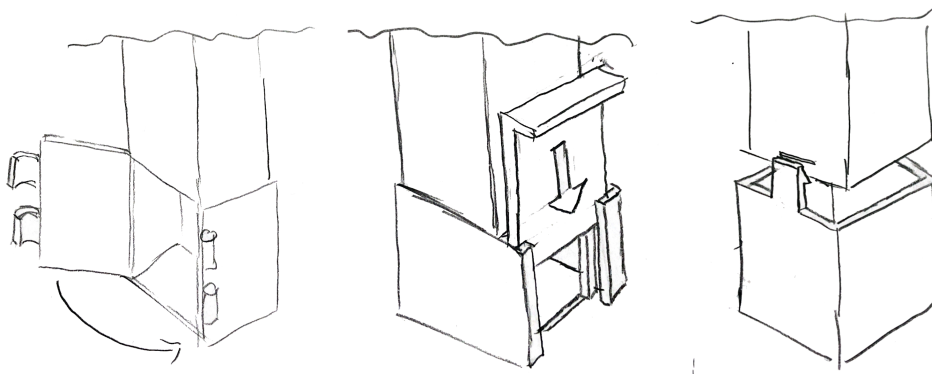
Figure 5.67: Different chassis concepts

Different concepts for the chassis were generated, three of which are shown in figure 5.67. The first was a concept that utilized a hinge and lock, which could be manufactured from polypropylene, a material commonly used for applications where a hinge is integrated in the manufacturing process. The second concept had a sliding guide, where one of the chassis sides could be removed for access to the electronics. Finally, the third concept had snap fits that held the chassis secured to the LA.

5.13.4 Selecting concepts

The manufacturing methods that could be used to build the prototype limited the design freedom of the chassis. When using manufacturing methods for mass production like injection moulding, characteristics like the strength of snap fitments are impacted. The chassis was made in an SLS 3D printer in order to keep its manufacture as simple as possible.

When discussing which concept to choose it was pointed out that the middle

concept of figure 5.67 had the simplest geometry and would still fulfill the functional requirements. It was thought that there would be an associated risk of the snap fits being too stiff when manufactured. Since only one SLS 3D print was possible due to the high cost associated with the technique, it was decided to proceed with the second concept.

The sliding function inspired by the external search is shown in figure 5.68.
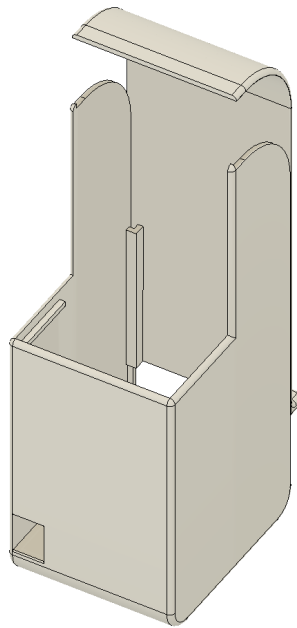
Figure 5.68: Sliding lid of chassis

5.13.5 Final specifications

The chassis body and lid were designed with design for cost, manufacturing and assembly principles. Screws were completely eliminated by integrating slide guides into the chassis and the bottom plate of the LA which allowed for secure fastening to the LA. This also removed the need for special tools during assembly. Sharp edges were filleted or chamfered to improve ergonomics. In accordance with plastic design principles sharp corners were avoided and an even wall thickness maintained in order to reduce stress concentrations. Ribs were included to increase the stiffness of the lid whilst reducing material use. Only polyamide was used for the prototype and it was designed to be easily dismantled to allow for both recycling and modification.
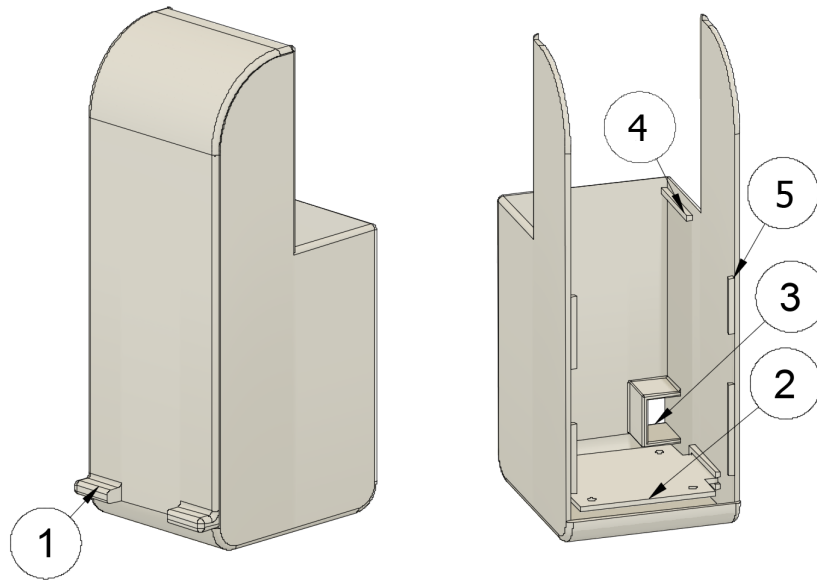
Figure 5.69: The features of the final chassis concept

The final concept for the chassis can be seen in 5.69. It has a lid which slid upwards by pushing the tab (1). The guide rails for the lid (5) act as a guide when inserting it. A mounting hole for the RJ10-connector (3) enables connection of the cable running between the chassis and LDI for sensor communication. A mounting plate (2) for the H-bridge can be slid in and out of the chassis when the lid is off. Space was allocated for the other electronic components and associated wiring. The chassis can be mounted to the bottom plate using guide rails (4). The attaching procedure can be seen in figure 5.70.
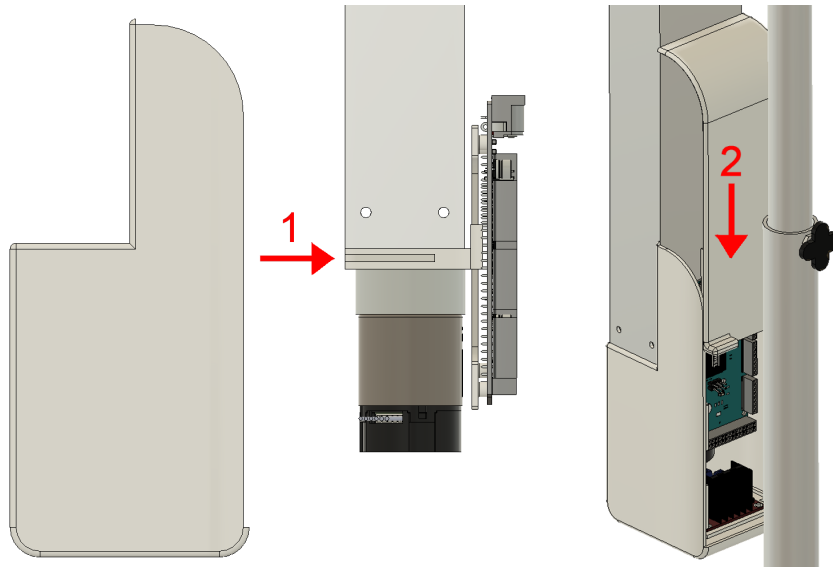
Figure 5.70: Attaching the chassis to the LA

The attaching procedure was simple due to the design for assembly principles that were incorporated into the chassis design.

1. Slide chassis into bottom plate
2. Close lid (after electronic components have been installed)

5.14 Testing

Testing on the system level was carried out to measure the performance of the height regulator and to verify the target specifications.

To measure the speed of the system, a ruler was taped to the side of the LA, and the DC motor was run at max speed. The time it took for the LDI to travel a fixed distance was measured several times with a stopwatch to obtain an average speed.

To measure the tolerance of the vertical position the PI sensor was moved a known vertical distance and then held there in order to allow the system to stabilize. The final position of the sensor mounted on the LDI was measured before and after the movement with a ruler.

To demonstrate the function of the automatic regulator, the patient end of the FT would be held in the hand of the demonstrator and raised and lowered to simulate the patients movement.
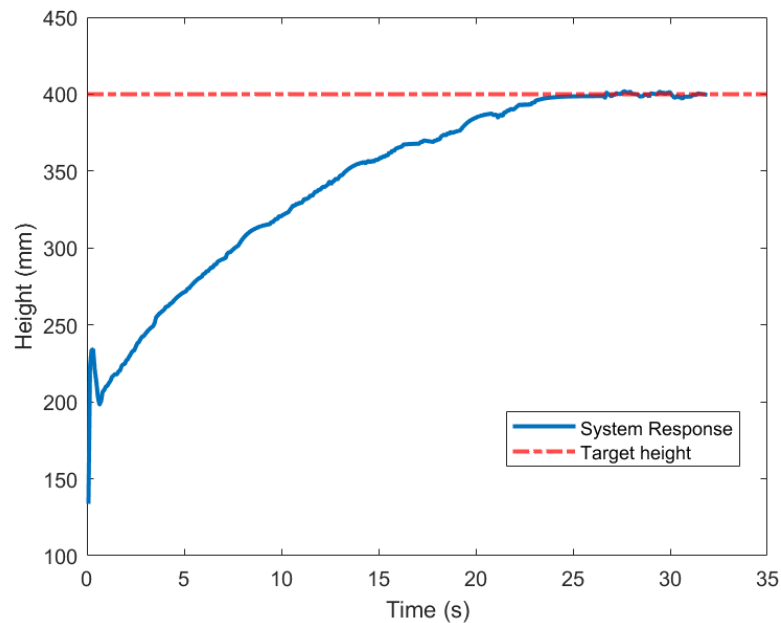
Figure 5.71: Step response during tuning process

The performance of the automatic control system was measured by plotting the step response of the height regulator in MatLab as seen in figure 5.71.

These plots were then used to tune the PID algorithm coefficients and review the system response. To tune the system, both automatic tuning software and Ziegler-Nichols method were unsuccessfully tried. This led to an iterative process of manually varying the parameters until adequate performance was reached.

6 Economic Analysis

This chapter describes the method used to calculate the salary cost of nurses monitoring a patient and how it is impacted by the implementation of the automatic height regulator.

A cost calculation for the automatic height regulator was not performed due to several reasons. Whilst some of the components such as the LA are standard systems that can be bought off the shelf, it is very difficult to estimate the quality of components necessary to meet the stringent demands imposed by medical certification standards.

Manufacturing techniques such as degassing the liquid in the FT and filling it without trapped gas bubbles are difficult to cost estimate. The price of the electronic components necessary for the system to work at the desired level of performance is troublesome to evaluate. Finally, the cost of further development and the certification process itself will be heavily reflected in the price of the final product. These considerations render a cost estimation complex, and it was decided to be outside the scope of the thesis.

Instead the salary cost of having two nurses monitoring a patient was calculated. Three scenarios were created to illustrate the potential economic impact of the automatic height regulator. The first scenario was the current one with completely manual supervision. The second one represented an intermediate automation level and the third one a full automation level.

The data was gathered by using salary statistics [17] to calculate the hourly wage of an average nurse in Sweden. General payroll tax and insurance paid by the employer was calculated to be 54% of the gross salary using the Bolagsverket calculator [18]. An interview with a nurse at the neurological ward at SUHL was conducted in order to obtain information regarding how much time the nurses spend working with the EVD system for a given patient. This information was then used to estimate a daily cost. The underlying calculations can be found in Appendix H.

To account for the nurses being able to perform other work whilst supervising the patient a nurse was asked how much active supervision a typical patient required and how much passive supervision was required. This was used to calculate a percentage of active and passive supervision. During the active

supervision the patient moves almost constantly, and the nurse estimated that 95 % of the available attention was required.

During passive observation three different sets of tasks are performed routinely. Once every hour the nurses measure the amount of drained CSF, which takes 5-10 minutes. The patient is rotated on average 4 times per shift, with one shift being approximately 8 hours long. During this time the EVD system is closed to prevent erroneous drainage. This takes 10 minutes. The drainage tube has to be drained when full, which takes 5 minutes and is done on average 1-3 times each day. Typically a team of two nurses perform the tasks.

The first scenario was the current one where one nurse and an assistant nurse perform all of the tasks together.

The second scenario was an intermediate one with partial automation. This represents an intermediate step in the development cycle of the regulator during which the system is not mature enough to be utilized completely unsupervised. In this case it was assumed that the nurses would not have to close the EVD system when turning the patient and that supervision would only be required for 60 % of the active time.

In the third scenario full automation was assumed. This will only be possible when the system is fully developed, understood and sufficient fail safes are in place to allow unsupervised operation. In this case it was thought that the nurses would not have to close the EVD system when rotating the patient and that during active time only 10 % of the nurses and 20 % of the assistant nurses time would be required.

Table 6.1: Associated salary costs with different levels of automation

	Current scenario	*Partial automation*	*Full automation*
Daily cost (SEK)	6869	4121	987

The calculated salary costs are displayed in table 6.1. In the near term, the main economic benefit of the height regulator lies in alleviating the work performed by the nurses whilst the patient is active. If the patient is awake and agitated, the full attention of at least one nurse will still be required to prevent the patient from interfering with the operation of the automatic height regulator. However, most of the active time consists of the patient moving slightly whilst asleep or awake and calm. Assuming a correctly functioning automatic regulator, the nurses only need to provide supervision when the

patient is getting out of bed or moving about. If the patient has sufficient cognitive function, unsupervised toilet visits and eating should be possible due to the mobile design of the height regulator when attached to a movable drip stand.

7   Results

This chapter presents the final product and the results visually with images of the product and descriptions. The automatic regulators height adjustment functionality is also described.

All parts were created in CAD prior to building the final physical prototype. This way parts could be 3D printed with low effort and assembled according to the CAD model. An overview of the CAD assembly is shown in figure 7.1. The EVD system and FT are not included.
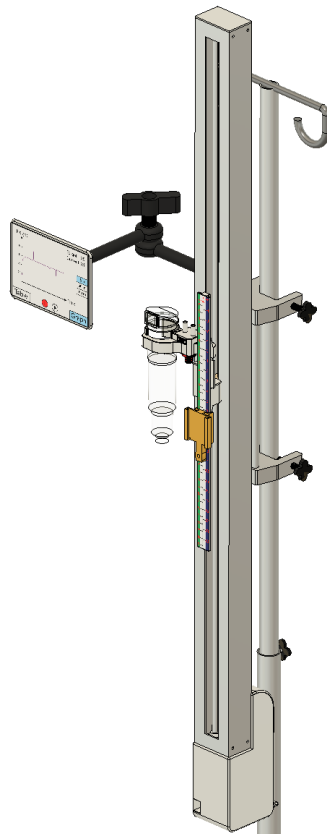
Figure 7.1: Automatic regulator CAD assembly

7.1 Physical prototype

The thesis resulted in the high fidelity prototype displayed in figure 7.2. Various manufacturing methods and post processing techniques were utilized to achieve a high quality finish. The plastic parts were 3D printed using SLS printing technology. This method allows more advanced shapes to be printed at a higher resolution than extrusion methods. The printed parts were the chassis, the plates used in plates of the LA, the LDI, TSIs and the UI. The 3D printed parts were sanded, sprayed with filler, sanded again and finally painted to achieve aesthetically pleasing surfaces.
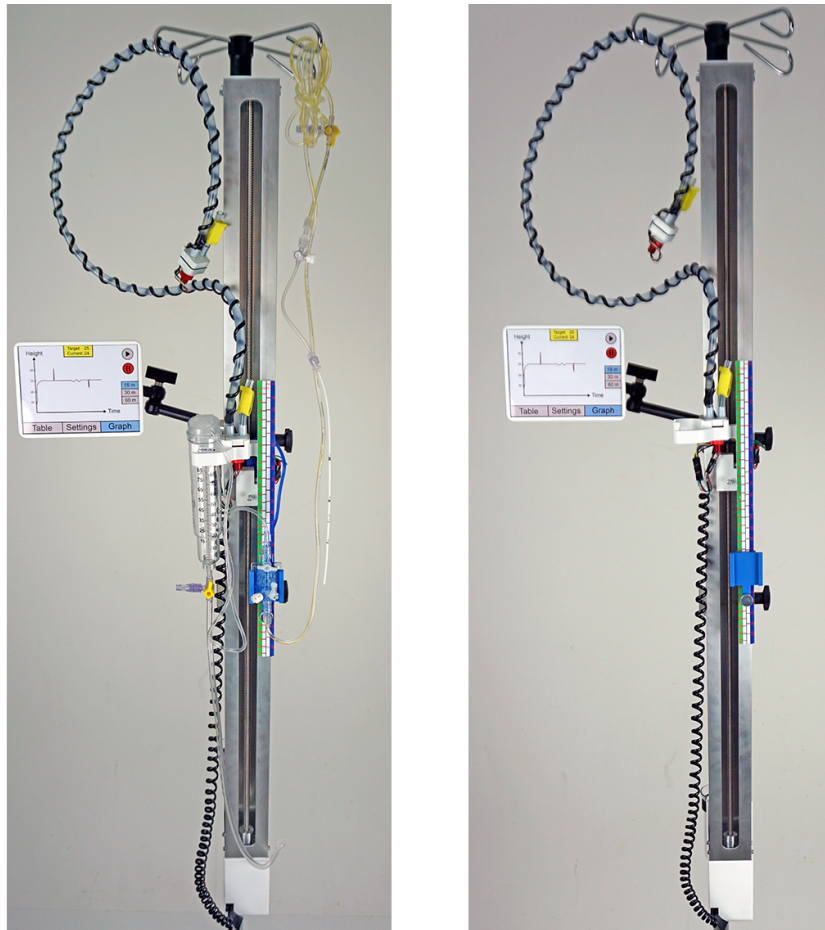
Figure 7.2: Finished high fidelity prototype with and without removable EVD components

The slot in the aluminum pipe used for the LA was milled and sanded with coarse sandpaper to remove major imperfections and stains. A milled block of aluminum was water cut in order to manufacture the rear hoops. They were then joined to the LA by TIG welding. The clamps of the EI were also cut by water jet, and holes were drilled and threaded for the screws. The subcomponents of the EI were joined by welding. Figure 7.3 shows the finished EI and the rear of the LA.
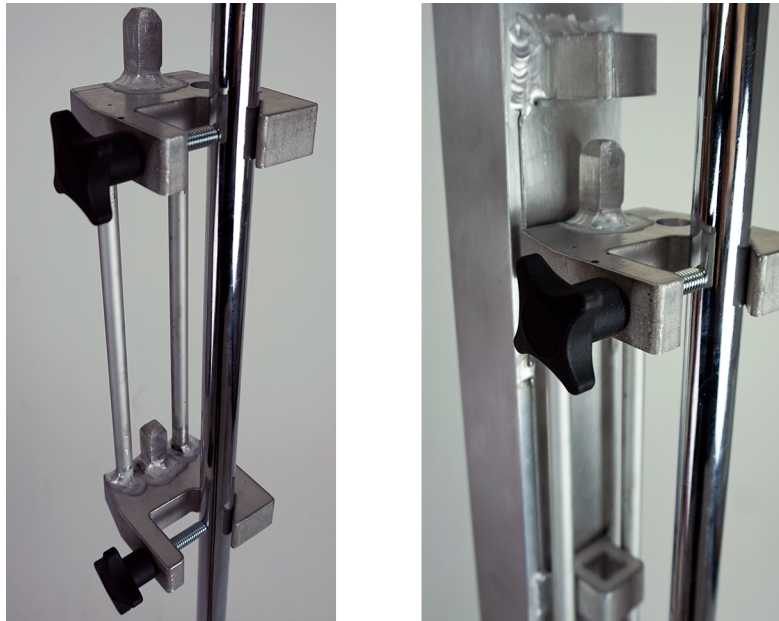
Figure 7.3: EI of finished prototype

The LDI was printed in two parts by splitting the ruler in half due to the limited printing volume of the 3D printer. Epoxy glue was then used to assemble the two halves. The scale for the ruler was printed on adhesive paper in order to create a sticker that could be placed on the ruler. Space was allocated for the multiplexer on the rear of the LDI so that a single cable could be used to transmit pressure data from the two pressure sensors in the FT. Adhesive was used to attach the multiplexer. An RJ10-connector for the spiral cable was soldered and mounted to the LDI. The finished LDI can be seen in figure 7.4.
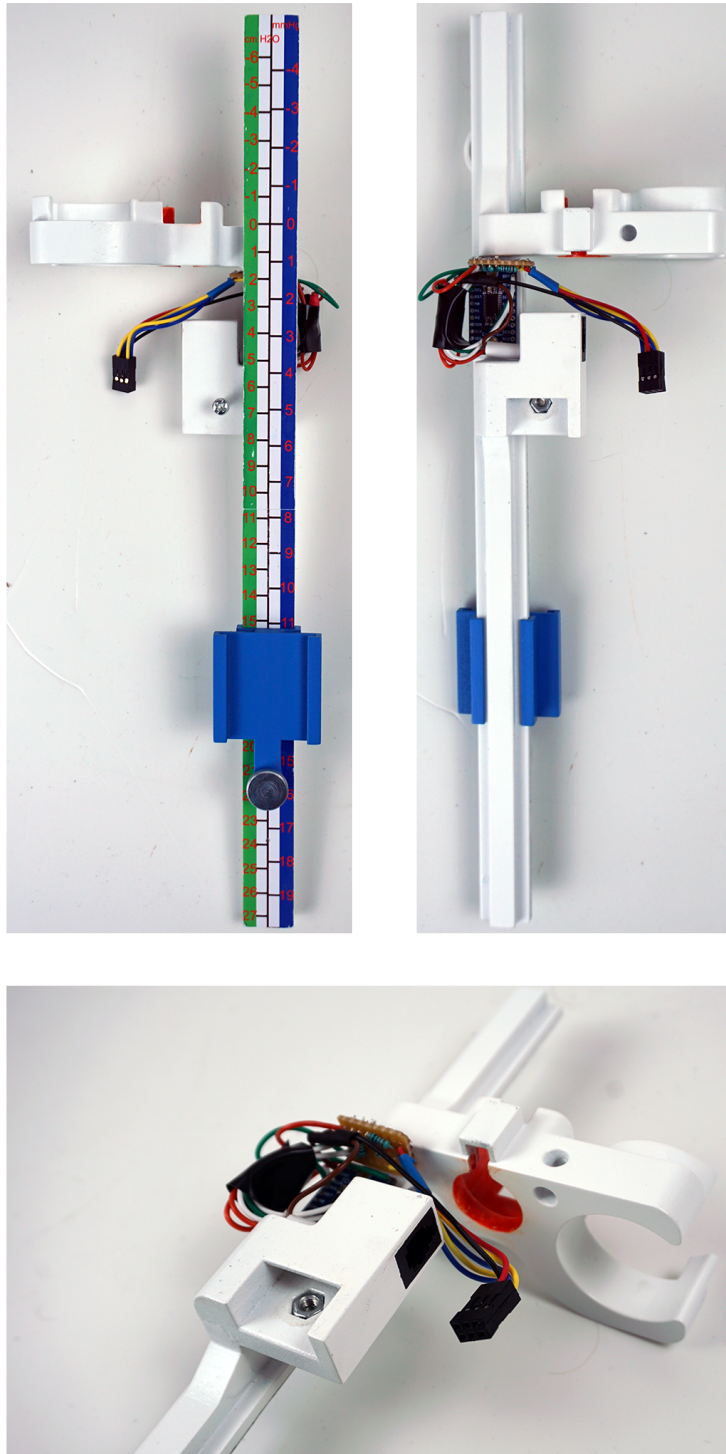
Figure 7.4: Finished LDI with close up of the electronics

The way the replaceable EVD components fit into the LDI can be seen in figure 7.5.
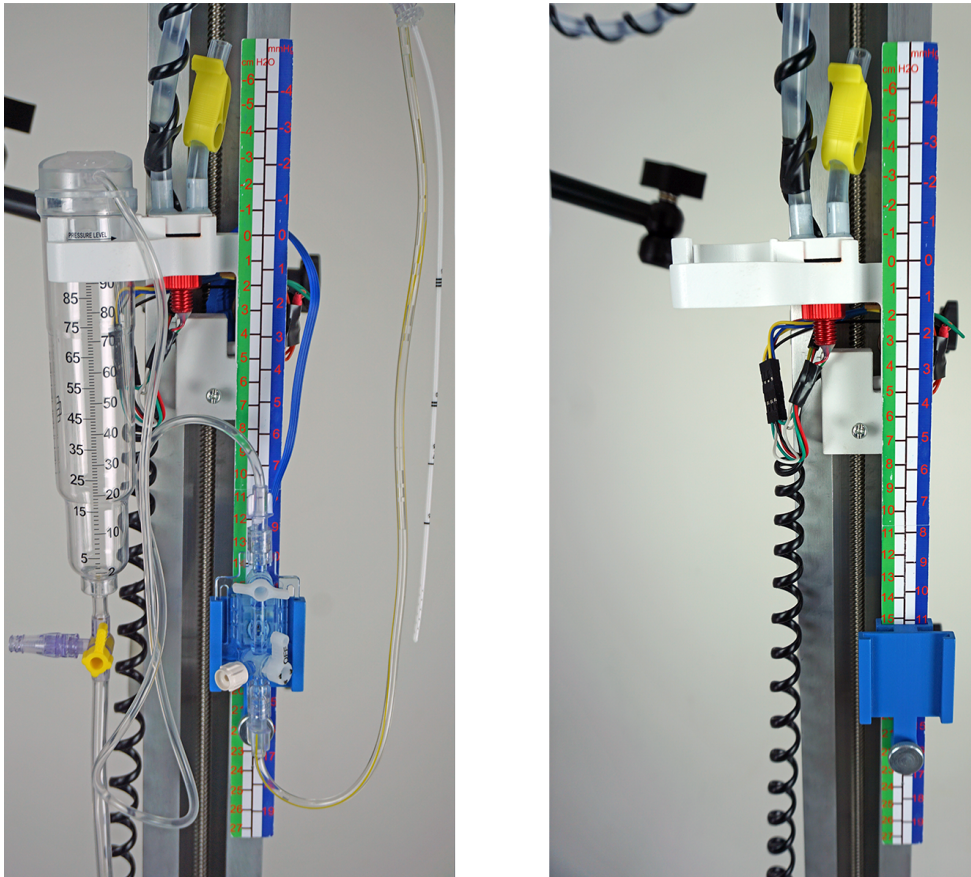
Figure 7.5: Finished LDI with and without removable EVD components

The UI was 3D printed, and the mockup of the graphics was printed on a paper. To create a nice looking design prototype, a piece of acrylic glass was laser cut to mimic the depth of an LCD display. The UI is shown in figure 7.6 and 7.7.
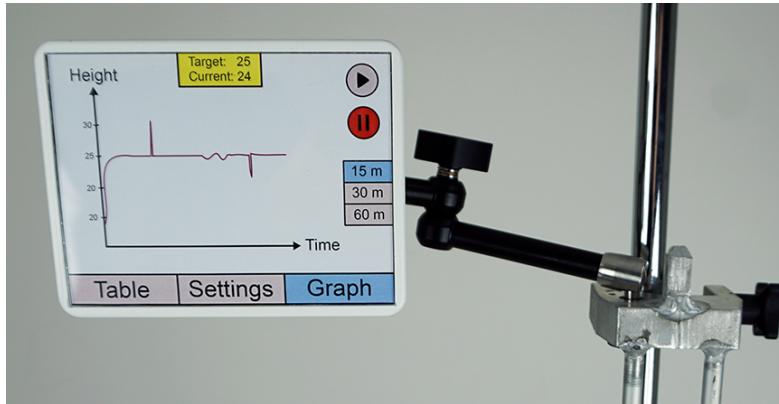
Figure 7.6: UI shown from the front

Figure 7.7: UI shown from the rear

Large handled screws allows the EI to be mounted to drip stands of various diameters without tools, after which the LA and touchscreen can be easily attached. An articulated arm meant for photography was used to connect the mock-up touchscreen to the EI. Its threaded ends fit into slots on the touchscreen and EI where it can be fastened using locking nuts.

The TSI used in the functional prototype is shown in figure 7.8

Figure 7.8: The finished TSI functional prototype

The TSI design prototype is seen seperately and mounted to a head in figure 7.9.
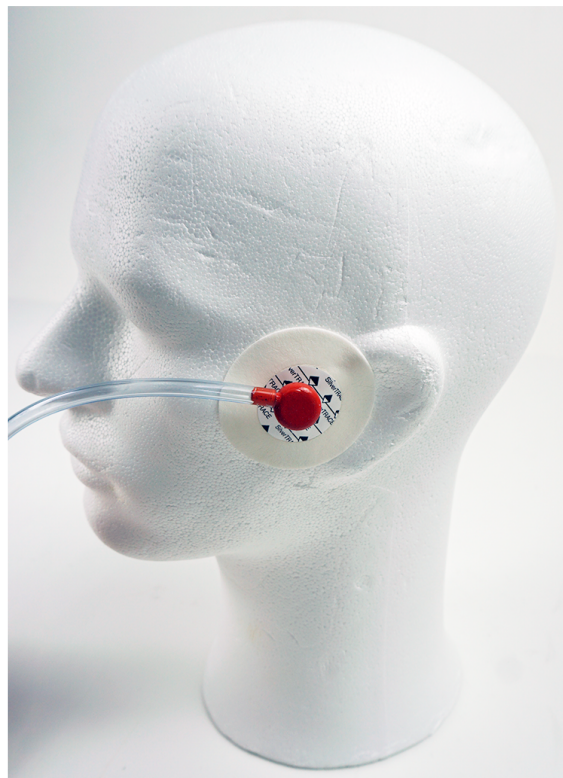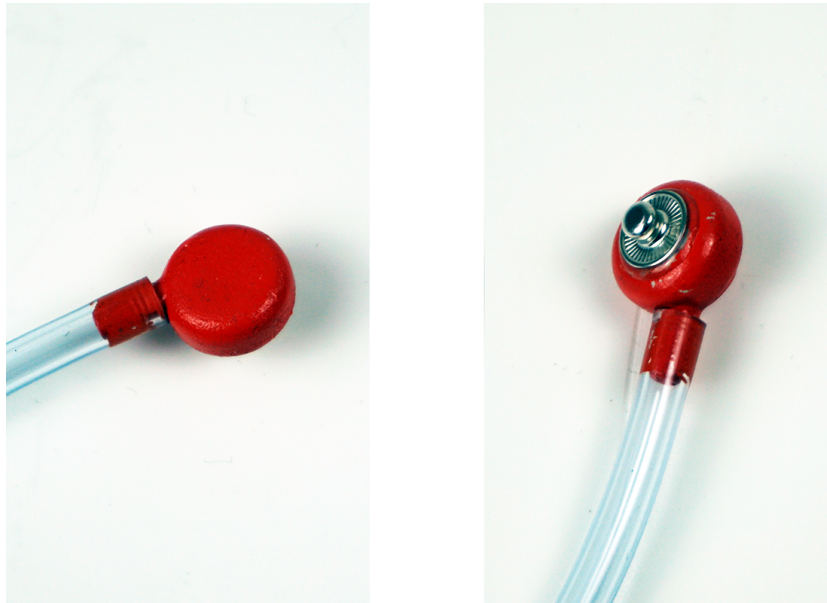
Figure 7.9: The finished TSI design prototype

A mock-up rendering of the design prototype and PI attached to a person is shown in figure 7.10. Both cable styles are displayed.
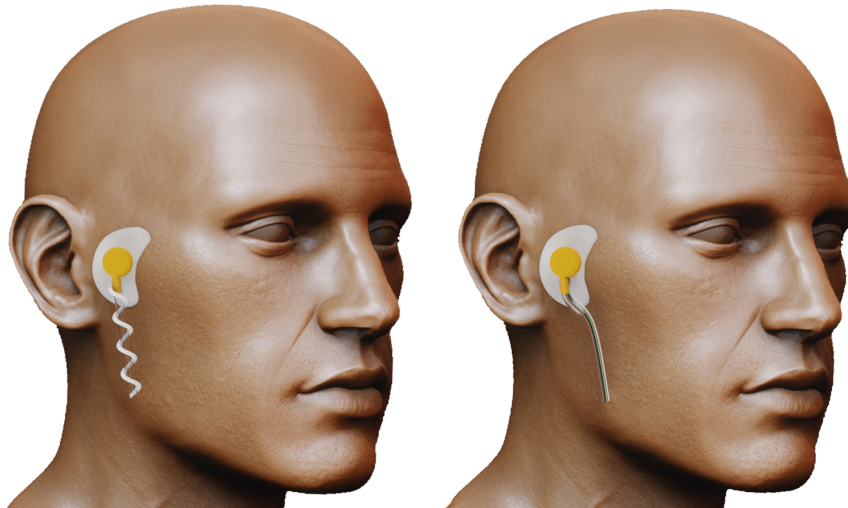
Figure 7.10: TSI and PI design prototypes attached tohead

The filled FT with two attached TSIs utilizing a spiral cable can be seen in figure 7.11.
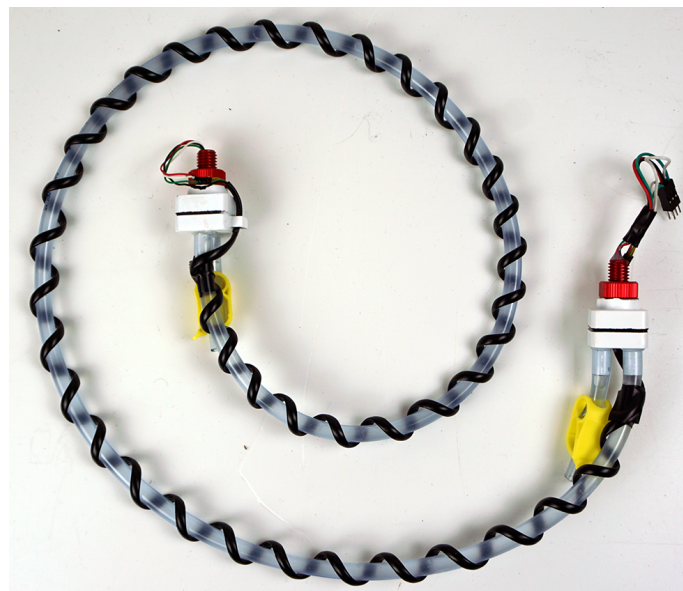
Figure 7.11: The finished FT

The finished chassis is shown mounted to the LA in figure 7.12.

Figure 7.12: The chassis for the functional prototype

7.2 Sensor system and leveling system functionality

The sensor system worked as expected. The PID-parameters were fine tuned to the point that the motor activated in a quick response when a change in relative pressure was detected. The LDI also settled to a fix point as expected, but took some time doing so.

A high level of precision was obtained in the final prototype. When the patient end sensor was moved a known vertical distance, the LDI moved a corresponding distance. However, both sensors exhibited a significant systematic error in their measurement. This meant that when programmed to maintain a set height difference, the observed height difference between the sensors varied a constant amount.

Responsiveness of the height regulator was perceived to be adequate. The system switched directions quickly in response to changes in the sensor outputs. The speed of the regulator was deemed to be a bit slow, but still within an acceptable range.

7.3 Final specifications

The final specifications for the prototype are listed below in table 7.1. The LA allowed the LDI to travel vertically at 0.05 m/s, and stop at the desired position within ±5 mm. With a stroke length of 935 mm, the LDI operated within a large vertical range. Eight steps are needed to setup the automatic regulator:

1. Attach the EI to a drip stand
2. Attach the LA to the EI
3. Attach EVD components
4. Attach FT to LDI
5. Attach PI to the patient
6. Attach FT to PI
7. Attach UI touch screen to regulator
8. Input desired height to UI

Table 7.1: Final specifications

Metric No.	Metric	Units	Value
1	Speed of vertical movement	m/s	0.05
2	Tolerance of vertical position	mm	± 5
3	LA stroke length	mm	935
4	Amount of steps to install	-	8
5	Easy to operate	Binary	Yes
6	EVD replaceability	Binary	Yes
7	PI fits many patients	Binary	Yes
8	Drip stand diameter	mm	18-32

8 Discussion and Conclusion

This chapter contains a discussion about the potential of the prototype and potential end product as well as recommendations on further development. A conclusion is presented at the end of the chapter.

The four goals of the thesis outlined in chapter 1.5.4 were to verify the feasibility of the automatic control system, develop the subsystems and necessary components, build a high fidelity prototype and make recommendations regarding further development. All goals were considered to have been achieved.

8.1 Further development

8.1.1 TSI and PI

The current functional TSI is quite ungainly. This is mainly due to the large housing for the Blue Robotics 02 sensor. As demonstrated by the TSI design prototype, the TSI can be miniaturized in order to fit more comfortably on the patients head. The design prototype TSI still needs to be tested extensively with the PI pad concept in order to verify that the button snap fit is secure.

Since the TSI is fastened to the same point on the patients head at all times, problems might arise when the patients tilt their head. When the head is rotated the center of the ventricles remain fixed in space, but the around will rotate around this point and change position vertically. This can be mitigated by including a gyroscope sensor in the TSI to track the axial tilt of the patients head. If the head width is measured, the vertical distance between the TSI and the ventricles can be calculated using trigonometry. The vertical distance can then be added to the target height by the automatic regulator.
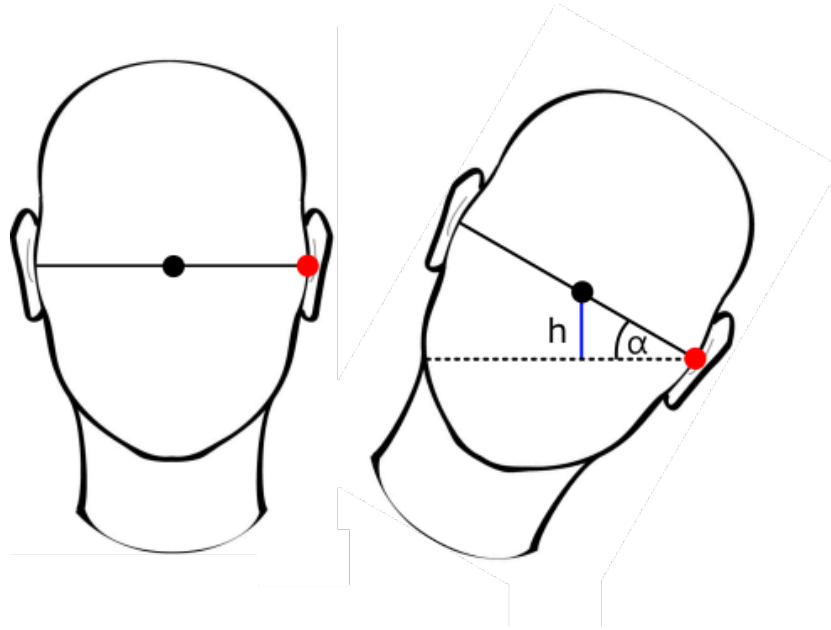
Figure 8.1: Erroneous vertical position reported by the PI sensor due to head axial tilt

The way the head axial tilt affects the measurements of the PI sensor is illustrated in figure 8.1. The black dot signifies the assumed position of the ventricles when placing the PI at the tragus, which is located at the red dot. This line intersects the center of the ventricles as long as the head is kept perfectly level. The dotted black line is the vertical level reported by the sensor. If w is the width of the head, the error in vertical position h can be be calculated according to equation 4:

$$h = \frac{w}{2} sin(\alpha) \qquad (4)$$

During discussions with medical staff, concerns were raised regarding how secure the PI would be on the patients head. The adhesive used to fasten the ECG pads to the skin was deemed strong enough to work. However, further testing needs to be done in this area to ensure that the pads maintain their adhesion under different conditions. Nurses might need to shave patients to ensure a solid connection between skin and electrode. It is also possible that the pads might need to be periodically replaced and the area under them cleaned due to moisture and grease buildup from the skin. This should not prove to be too complex to solve since ECG pads are standard hospital equipment with a long history of use.

Another potential problem lies in the integrated button snap fit. In order to be reasonably easy to fasten and comfortable for the patient, the buttons cannot require too much force during attachment. This also means that they cannot be too hard to separate, which might result in the TSI being torn off the PI if the FT or a cable snags. If the TSI hangs loose at the wrong vertical distance it will output an incorrect height to the height regulator, causing it to move the EVD drainage outlet to an incorrect position.

A solution to this is to incorporate the electrode in the ECG pad into the height regulator. The electrodes detect the small electrical changes that the heart beat generates through the skin. A software condition can be added in the height regulator that stops it from adjusting the EVD outlet position when contact with the skin is no longer detected. An auditory alarm can be added to alert nurses to the fact that the TSI has fallen off the PI.

8.1.2 Micro controller, software and interference

At the beginning of the project an Arduino Uno was used. This micro controller operates at a 5V logic level. When the switch to the Arduino Due was made and the final prototype was built a problem was encountered with the communication between the micro controller and the sensors. The Due operates at 3.3V which makes signals communicating with it more sensitive to disturbances from sources such as radio waves, crosstalk or interference. When building the final prototype, longer cables were used to accommodate the larger size compared to the previous prototypes. This introduces an increased electrical resistance which is detrimental to signal integrity.

Since a final product will have a substantially longer FT and thus a longer cable between the sensor attached to the PI and the LDI, the severity of this problem might increase. However, there are several ways to mitigate it. During the thesis the I2C protocol was used for communication between the sensors and micro controller due to its ease of use and it only requiring two wires. Other protocols are more suited to long distance communication. Techniques such as shields and twisted wire pairs can be used to reduce the electrical noise affecting the cables. Higher voltage can be used in the cables to mitigate this.

The responsiveness of the system is directly related to the processing power of the micro controller. Faster processing allows the system to sample the sensors, filter their output and perform the necessary calculations for the PID algorithm more often. Although the system performed at an acceptable level with the Arduino Due, performance can be increased by switching to

a industry-grade microcontroller specifically designed for automatic control. Better results can also be obtained with more accurate sensors and by choosing better PID parameters.

8.1.3   UI development

The touch screen selected for the end product should be able to withstand cleaning agents without being damaged, and should be operable whilst wearing plastic gloves. Its graphical UI also needs to be revisited in order to follow the conventions of other devices found at hospitals.

Further development of the LDI might be necessary to optimize the user friendliness. The capsule and ruler concept needs to be user validated to ensure its ease of use.

8.1.4   Cable management and FT wiring

Due to the high number of wires, tubes, bandages and other peripherals commonly present in a hospital environment, there is a risk of loose hanging wires snagging on something and causing problems. To mitigate this risk and simplify cleaning, external wiring should be avoided wherever possible. In a future product the spiral cable connecting the LDI to the chassis could be routed internally through the LA instead. The cable connecting the touch screen to the chassis could be routed through the articulated arm to the LA and from there to inside the chassis.

The wires running along the FT can be routed in several different ways. The current solution of having a spiral cable running along the length of the FT is advantageous from a manufacturing standpoint, but adds quite a bit of bulk to the FT. Using a double-molded FT with one of the tubes holding the fluid and the other the cables results in less bulk, but increases stiffness significantly. Using a circular profile with the cables routed through the fluid is another possibility that would generate the least extra bulk, but is more complex to manufacture and might affect the sensor system. Choosing an economic and flexible cable management solution necessitates trade-offs between manufacturability, cost and performance.

8.1.5 Cleanability and particle impermeability

One of the leading causes of complications in EVD patients is infection [19]. It is therefore important to ensure that all surfaces on the EVD are easily accessible and cleanable. This necessitates that all outer plastic components be resistant to cleaning solutions and disinfectants commonly used at hospitals. The components might also need to be redesigned to remove nooks and crannies that are hard to clean.

Since the PI is disposable, no special material is needed beyond that necessary for its function. For the other plastic components, PVC is a good choice. It is cheap, has a low density and good chemical resistance. A major advantage of the plastic is its resistance to microorganisms. It is the worlds third most common plastic and is often utilized in single-use items such as blood bags in the health-care sector [11, p. 17].

To prevent internal particle and fluid build-up, seals can be utilized at the chassis hatch opening and along the gap between the chassis and LA. Protecting the LA is more problematic due to the front slot. There are waterproof LAs available on the market that might be more suitable.

8.1.6 MRI use

Patients often require MRI scans when undergoing EVD care. While these are performed, no metal objects are allowed in the vicinity of the machine to prevent magnetic interference. This precludes the automatic height regulator from being used during the scans since it contains several metal components and a redesign with only non-metal parts is unfeasible. Consequently, the EVD kit must be easily dismountable from the LDI and transferable to a non-metallic stand.

8.1.7 Certification of medical equipment

The automatic regulator cannot be released on the market until it has a CE marking - a certification mark that indicates conformance to health, safety, and environmental protection standards for products sold within the European Economic Area[20]. Conformance to the requirements of Swedish law (1993:584) regarding medical products and the regulations (LVFS 2003:11) of the Swedish Medical Products Agency is also required.

The necessary process for releasing a Class 1 product on the market includes the following steps[21]:

1. Verify if it is a medical product
2. Verify if it is a class 1 product
3. Proceedings before market release

   (a) Fulfill the necessary requirements
   (b) Gather the technical documentation
   (c) Contact the necessary agencies
   (d) Produce a technical manual

4. Create the EG assurance agreement
5. CE Marking
6. Report to the Swedish Medical Products Agency
7. Document, evaluate and report accidents or incidents
8. Gather experience from previously released products

8.1.8   Integrating the existing ICP sensor

Utilizing the existing ICP sensor (transducer) was outside the scope of the thesis. However, there is considerable potential in integrating it into the automatic height regulator. Instead of the doctor having to calculate a new target height for the height regulator, the ICP sensor could be used to detect when the ICP is changing and update the target height automatically. The patient side TSI will still be necessary to measure the height difference since the patient ICP has a delayed response. Additionally, when the catheter inlet valve is closed the ICP sensor will register an erroneous pressure.

8.1.9   Mobility

When attached to an IV stand with wheels or a pole on a movable hospital bed, the height regulator has the potential to be mobile and to follow the patient. This is an advantage when the patient goes to the bathroom or moves around the hospital.

To this end, a battery pack needs to be integrated into the height regulator to power the electronics whilst not plugged into a wall outlet.

8.1.10   Noise level

During the development process concerns arose regarding the noise level of the system. If the patient suddenly sits up in bed and the LDI has to move a large distance quickly to accomodate this, some noise is permissible. However, when the height regulator is making minor adjustments during normal operation, the noise level should be as low as possible in order to not be distracting and aggravating. To this end, the chassis and aluminum encasing needs to be optimized to prevent resonance. A motor that is quiet during operation is also necessary.

8.1.11   Safety

A sudden large shift in sensor readings can cause the LDI to accelerate at a high speed and impact the top or bottom of the LA, possibly damaging the system. This can be caused by the patient falling out of bed or standing up suddenly. This can be solved by installing micro switches at the extreme positions of the LA to detect when the LDI is about to impact. Software constraints can also be used to prevent the LDI from moving past a certain range of motion.

Figure 8.2: Industrial emergency stop button

For added safety and redundancy, an easily identifiable emergency stop needs be included in the height regulator and placed accessibly. It should also give both physical and visual feedback when operated. A emergency stop of the type found on industrial equipment and shown in figure 8.2 was deemed suitable for this role. These buttons have a long travel distance and need to be rotated to reset, which provides feedback on their status. Additional

feedback can be provided by generating a message on the touch screen when the stop button is engaged.

In order to make sure that the LA stays in place on the EI if a person bumps into it or an agitated patient strikes it, a locking mechanism needs to be incorporated into the pegs on the EI holding the LA in place.

8.2   Discussion

Product potential

The finished high fidelity prototype verified the functionality of the technical solution described in the patent filed by Innovation Skåne [6]. Although only consumer-grade sub components were used, the automatic regulator worked well enough to prove the feasibility of the product. In hindsight, researching and acquiring several different sensors to test during the early stage of the thesis might have allowed for a smaller TSI prototype. If using a different sensor, there was a chance that less sensor noise would occur and that the functional TSI might have been more akin to the design prototype. With more advanced electronics, more sophisticated plastic components and a medical grade LA the system will perform at a substantially higher level. When the height regulating concept was presented to the assistant chief physician at the neurosurgical ward at SUHL, he expressed great interest in the product and was positive regarding its potential.

During the pre-study attempts were made to find a height sensing system similar to the one proposed in the Innovation Skåne patent, but none were found. If one were to replace the PI with another fastening mechanism such as screws, the sensor system could be used in any number of applications involving measuring the height difference between objects.

According to the final specifications, the automatic regulator is perceived to be easy to use. The authors of the thesis set the final specification without testing them with the end user, which makes this specification uncertain.

Time plan

The time plan is shown as a Gantt chart in Appendix A and was followed continuously without delays of activities. The time allotted to the different activities was sufficient, however it would have been beneficial if the study visit had been conducted earlier.

This would have resulted in unnecessary development of the PI not being performed.

Method

The automatic regulator has been developed using U&Es product development method. It is not a typical consumer product and the defined appearance and technical solutions for the different components would probably differ from an end product. Because of this, some of the sub activities of U&Es product development method were not applicable for the thesis. The methodology used did however provide a stable base to build the thesis upon, specifically concept generation, selection processes, defining customer needs and creating several prototypes of various components to test functionality.

Fulfillment of customer needs

Some of the customer needs were not applicable for the prototype, such as the automatic regulator being easy to operate. Nonetheless, the prototype was still designed with many of the needs in mind. Many of the critical needs such as allowing for replacement of EVD components and the tolerance of vertical position were fulfilled. Other needs were not fulfilled, such as the automatic regulator being approved for use in hospital environments. However, suggestions for fulfilling the needs that were not realized are given in the further development chapter.

8.3 Conclusion

The type of automatic height regulator outlined in the Innovation Skåne patent is technically valid and could constitute a significant improvement to the post operative care of neurosurgical patients with implanted EVDs. Potential for significant reduction of the workload experienced by nurses working with these patients also exist.

There are other possible applications for the sensor system. As far as the authors have been able to discern, there are no similar sensor systems in wide spread use.

Due to the height regulator being a medical product, a high amount of testing and certification is necessary. There is also a lot of further development that needs to be done on the product itself. Both of these factors are cost drivers and necessitate a thorough economic analysis in order to discern whether the solution will be cost effective.

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Appendix A Time Plan
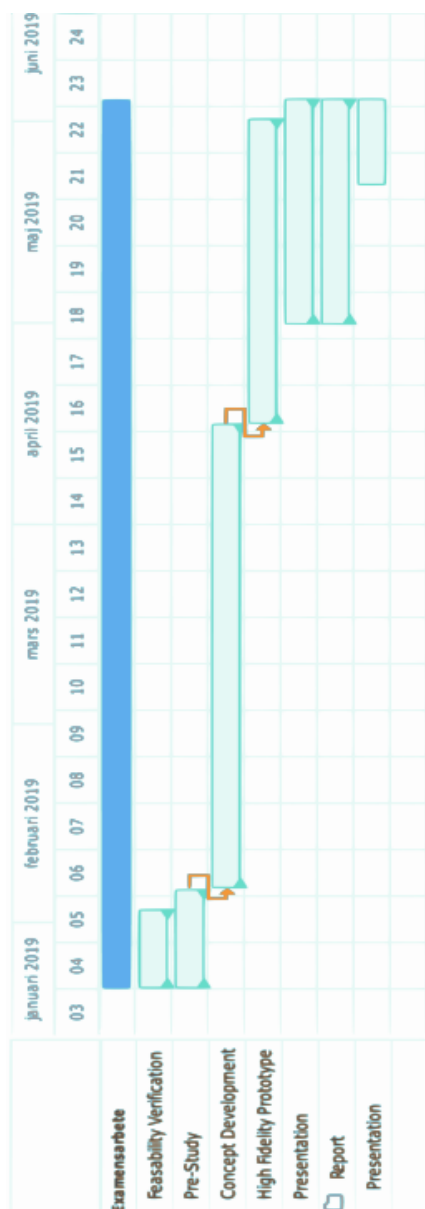
Appendix B Electronical Schematics
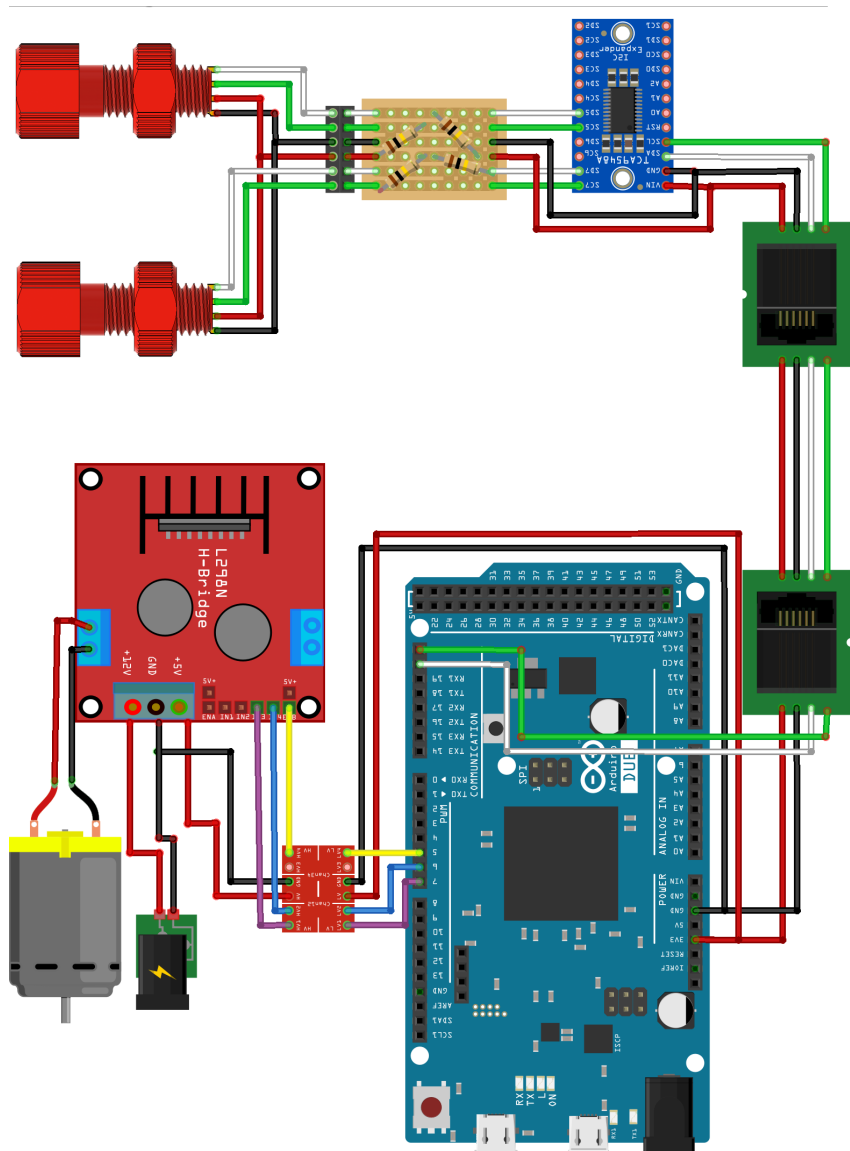
Appendix C Interview questions

Berätta hur processen går till från att dränaget opereras in till att patienten blir utskriven.

Vilka moment är jobbigast, och vilka är mest tidskrävande?

Sitter dräneringsslangen alltid på eller finns behovet att byta ut den?

Vad känner du (undersköterska) inför att automatisera övervakningen och justeringen av dränageslangen?

Hur snabbt behöver man ändra höjden på slangen när patienten har rört sig, innan det blir farligt?

Hur precis behöver höjdskillnaden vara?

Kör ni iväg patient i säng med dräneringsslang till några andra platser i sjukhuset?

Ligger patienten under hela vårdförloppet? Sitter hen också?

Vilken medvetenhetsgrad har patienten?

Inom vilket höjdintervall justeras dränagets utlopp? Vad är minsta respektive högsta höjden från patienten? Alternativt, vilket tryckintervall är det som krävs för korrekt dränering?

Vad är era spontana tankar kring att fästa en sensor vid örat som sitter fast under vårdförloppet?

När ni sitter vid patienten, drar ni några slutsatser från hens rörelsemönster? Hur rastlös patienten är osv.

Är dränage-systemet standardiserat? Är det alltid samma fabrikat på utrustningen? Eller används annan utrustning, t.ex blodpåsar?

Ligger patienten på rygg eller får patienten ändra liggposition, så att patienten ligger på sidan?

Kan man ta och använda befintliga droppstativ på sjukhuset? Finns det extra droppstativ att använda?

Vad tycker ni om vår tänkta lösning?

Kopplas dränaget ihop med någon annan utrustning för övervakning av trycket?

Appendix D Raw data

Fråga	Kundutlåtande	Tolkat behov
Vilka moment är mest tidskrävande?	Den konstanta höjdändringen	Slippa lägga tid på att manuellt ändra höjd
Finns det behov att byta ut slangen?	Ja, om det blir stopp	Möjlighet att byta ut dränageslangen
Behöver man kunna ändra höjden snabbt?	Om patient skulle resa sig behöver man snabbt vara framme och höja 20-30 cm	Höjdändringen ska ske snabbt och direkt
Hur precis behöver höjdändringen vara?	Det bör vara centimeterprecision	Höjdändringen ska ha precisionen +/- 0.5 cm
Förflyttas patienter till andra platser på sjukhuset?	Ja, kan vara till neuroröntgen. Då flyttas patient till annan säng och dränage monteras på droppstången på sängen	Regulatorn ska inte hindra förflyttning av patient på sjukhuset
Ligger patienten under hela vårdförloppet?	Patienten kan ligga ner, sitta upp, stå och gå på toaletten	Regulatorn ska kunna användas när patient står, ligger, sitter och är på toaletten
Vilken medvetandegrad har patienten?	Från 1 till 8 på Glasgow coma scale	Regulatorn ska kunna användas både när patient är nedsövd och vid medvetande
Inom vilket höjdintervall ska höjden kunna justeras?	Inom gränsen för att patienten kan ligga, sitta och stå	Regulatorn ska kunna regleras i ett intervall från liggandes till ståendes höjd
Vad tror du om möjligheten att fästa en sensor på en öronkåpa?	Det går inte då det skapas ett tryck på patientens skalle som kan leda till trycksår	Sensorn vid patientsidan ska inte ge upphov till trycksår
Är dränagesystemet standardiserat?	På SUS används samma system, från Neuromedex. Ska byta mot ett liknande från samma tillverkare.	Prototypen av regulatorn måste passa Neuromedex EVD-system
Kan man använda befintliga droppstativ som finns på sjukhuset?	Ja, det är så dom gör nu	Regulatorn ska fästas på befintliga droppstativ
Kopplas dränaget in i någon annan utrustning på sjukhuset?	En standardiserad sensor som finns med Neuromedex EVD-system kopplas in i övervakningsmonitorn	Regulatorn ska användas med en standardiserad trycksensor som följer med Neuromedex EVD-system

Appendix E Arduino Code

```
1.  #include <Wire.h>          // I2C library
2.  #include "MS5837.h"        // Sensor linrary
3.  #include "Kalman.h";       // Kalman library
4.  #include <L298N.h>         // Motor driver library
5.  #include <PID_v1.h>        // PID library
6.
7.  #define EN 7               // Motor enable pin
8.  #define IN1 5              // Motor input pins
9.  #define IN2 6
10. double Speed;             // Motor speed (PWM)
11. double topSpeed = 220;    // Motor max speed
12.
13. L298N motor(EN, IN1, IN2); // Motor object
14.
15. MS5837 sensor1;           // Sensor declaration
16. MS5837 sensor2;
17.
18. double q = 1;             // Kalman variables
19. double r = 72;
20. double p = 1023;
21.
22. Kalman filter1(q, r, p, 0);    //Kalman objects
23. Kalman filter2(q, r, p, 0);
24.
25. double height;                  // Height difference between sensors
26. double heightTarget ;           // Desired height difference to be maintained
27. double heightInterval;          // Deadband around target height in which
    motor wont move
28. double lowLimit, highLimit;     // Limits of deadband interval
29. double targetDistance;          // Distance between current and target height
30.
31. double pressure1, pressure2;    // Pressure variables to store sensor data
```

```
32. double offset = 40;                  // Constant offset to account for sensor
    miscalibration
33. double filterPressure1, filterPressure2;    //Filtered pressure
34.
35. const int readInterval1 = 50;              // Sensor read interval in
    milliseconds
36. unsigned long currentMillis1 = 0;        // Stores the value of millis() in
    each iteration of loop
37. unsigned long previousReadMillis1 = 0;   // Stores timestamp of last time the
    sensors were read
38. double startMillis;                      // Stores timestamp of when loop
    begins
39. double seconds;                          // Stores how long the loop has been
    running in seconds
40.
41. const int density = 997;                 // Fluid density
42. const double g = 9.81;                    // Gravitational constant
43. double conversionFactor;                 // Const. factor used to convert
    pressure
44.                                          // to fluid column height
45.
46. double Kp = 5, Ki = 0, Kd = 1;           // PID coefficients
47.
48. PID myPID(&targetDistance, &Speed, 0 ,   // PID Object creation
49. Kp, Ki, Kd, P_ON_E, REVERSE);
50.
51. #define TCAADDR 0x70                      //Multiplexer I2C adress
52.
53. void tcaselect(uint8_t i) {              // Function for selecting desired
    channel
54.                                          // on multiplexer
55.   if (i > 7) return;
56.   Wire.beginTransmission(TCAADDR);
57.   Wire.write(1 << i);
58.   Wire.endTransmission();
59.
60. }
61.
62. void setup() {                          // Setup code run once before main loop
63.
64.
65.   Wire.begin();                                     // Initialize I2C and
66.   Serial.begin(115200);                             // serial communication
67.   Serial.println("System Starting...");
68.                        133
```

```
69.   tcaselect(5);                                    // Select sensor 1 on
70.                                                     // multiplexer
71.   sensor1.init();                                  // Sensor 1
   initialization
72.   sensor1.setModel(MS5837::MS5837_02BA);           // Sets sensor model
73.   sensor1.setFluidDensity(density);
74.
75.   tcaselect(7);                                    // Select sensor 2 on
76.                                                     // multiplexer
77.   sensor2.init();                                  // Sensor 2
   initialization
78.   sensor2.setModel(MS5837::MS5837_02BA);           // Sets sensor model
79.   sensor2.setFluidDensity(density);
80.
81.   heightTarget = 300+offset;                       // Sets the height
   difference
82.   heightInterval = 10;                             // Sets the deadband
   interval
83.   lowLimit = heightTarget - (heightInterval / 2);  // Low boundary in the
   deadband
84.   highLimit = heightTarget + (heightInterval / 2); // High boundary in the
   deadband
85.   conversionFactor = 100000 / (density * g);       // Calculates conversion
   factor
86.
87.   motor.setSpeed(0);                               // Freeze motor during setup
88.
89.   myPID.SetMode(AUTOMATIC);                        // PID initialization and mode
   select
90.   myPID.SetOutputLimits(0, topSpeed);              // Output interval for PID
91.   myPID.SetSampleTime(readInterval1);              // Sample time for PID
92.
93.   delay(3000);
94.
95.   Serial.println("  ");
96.   Serial.println("  Startup complete");
97.   Serial.println("  ");
98.
99.   startMillis = millis();
100.
101.     }
102.
103.     void loop() {                                 // Main loop
104.
105.        readSensorState();                         // Calls the sensor read function
```

134

```
106.
107.        if ( height < lowLimit ) {              // Rotates the motor in the
108.                                                // correct direction
109.          motor.forward ();
110.
111.        }
112.
113.        if ( height > highLimit )   {
114.
115.          motor.backward();
116.
117.        }
118.      }
119.
120.      void readSensorState() {                  // Reads both sensors at the
   desired
121.                                                // time interval and sets a
   new target
122.                                                // for the motor. Also shows
   output
123.                                                // in serial
124.
125.        if ( millis() - previousReadMillis1 >= readInterval1) {   // Only reads
   sensor if
126.                                                // it is time
127.          tcaselect(5);                                           // Sensor
   1 read
128.          sensor1.read();
129.          pressure1 = sensor1.pressure();
130.
131.          tcaselect(7);                                          // Sensor
   2 read
132.          sensor2.read();
133.          pressure2 = sensor2.pressure();
134.
135.          filterPressure1 = filter1.getFilteredValue(pressure1);    // Sensor
   1 filtering
136.
137.          filterPressure2 = filter2.getFilteredValue(pressure2);    // Sensor
   2 filtering
138.
139.          height =  conversionFactor * (filterPressure2 - filterPressure1);  //
   Height calculation
140.
```

```
141.        targetDistance = abs(height - heightTarget);        // Target
    distance calculation
142.
143.        myPID.Compute();                                   // PID
    output compute
144.
145.        motor.setSpeed(Speed);                             // Motor
    speed input from PID
146.
147.        //    Serial.print("      Height : ");              //Code for
    monitoring output,
148.        //    Serial.print(height);
149.        //    Serial.print("      Distance to target: ");
150.        //    Serial.print(targetDistance);
151.        //    Serial.print("      Speed : ");
152.        //    Serial.println(Speed);
153.
154.        seconds = (millis() - startMillis) / 1000;         //Code for
    matlab output
155.
156.        Serial.print(height);
157.        Serial.print(" ");
158.        Serial.println(seconds);
159.
160.        }
161.    }
```

Appendix F Matlab Code

```matlab
%% Import data from text file%

%% Setup the Import Options
opts = delimitedTextImportOptions("NumVariables", 2);

% Specify range and delimiter
opts.DataLines = [1, Inf];
opts.Delimiter = " ";

% Specify column names and types
opts.VariableNames = ["VarName1", "VarName2"];
opts.VariableTypes = ["double", "double"];
opts.ExtraColumnsRule = "ignore";
opts.EmptyLineRule = "read";
opts.ConsecutiveDelimitersRule = "join";
opts.LeadingDelimitersRule = "ignore";

% Import the data. Change path if using another text file
PIDdata = readtable("C:\Users\jonat\Desktop\PID_data.txt", opts);

%% Convert to output type
PIDdata = table2array(PIDdata);

%% Clear temporary variables
clear opts


x  = PIDdata(:,2);    % TIME
y1 = PIDdata(:,1);    % HEIGHT

hold on

figure

plot(x,y1,'LineWidth',2)
yline(400,'-.r','LineWidth',2)

xlabel ('Time (s)')
ylabel ('Height (mm)')
legend('System Response', 'Target height')
```

```matlab
%% Import data from text file
%
%    filename: C:\Users\jonat\Desktop\Kalman_data.txt

%% Setup the Import Options
opts = delimitedTextImportOptions("NumVariables", 6);

% Specify range and delimiter
opts.DataLines = [1, Inf];
opts.Delimiter = "\t";

% Specify column names and types
opts.VariableNames = ["VarName1", "VarName2", "VarName3", "VarName4", "VarName5", "VarName6"];
opts.VariableTypes = ["double", "double", "double", "double", "double", "double"];
opts = setvaropts(opts, 6, "TrimNonNumeric", true);
opts = setvaropts(opts, 6, "ThousandsSeparator", ",");
opts.ExtraColumnsRule = "ignore";
opts.EmptyLineRule = "read";

% Import the data
Kalmandata = readtable("C:\Users\jonat\Desktop\Kalman_data.txt", opts);

%% Convert to output type
Kalmandata = table2array(Kalmandata);

%% Clear temporary variables
clear opts
x  = Kalmandata(:,3);   %%Timestamps
y1 = Kalmandata(:,1);   %%LDI sensor readings
y2 = Kalmandata(:,2);   %%Filtered PI readings
y3 = Kalmandata(:,4);   %%PI sensor readings
y4 = Kalmandata(:,5);   %%Filtered LDI readings

diffReal = ((y3-y1)*10000)/(997*9.81);    %%Unfiltered height difference
diffFiltered = ((y4-y2)*10000)/(997*9.81); %%Filtered height difference
targetDistance = ((y4-y2)*10000)/(997*9.81)-20; %% Distance to target height

hold on

figure
plot(x,y1,x,y2,'LineWidth',2)
```

```matlab
title('Kalman Filter','FontSize',16)
legend('Raw sensor data','Filtered sensor data','FontSize',16)
xlabel ('Time (s)','FontSize',16)
ylabel ('Pressure (mBa)','FontSize',16)

xlim([10 37])
ylim([880 930])

hold on

figure
plot(x,diffReal,x,diffFiltered,x,targetDistance)

title('Height Difference')
xlabel ('Time (s)')
ylabel ('Height (cm)')
```

Appendix G Patent List

Patent Number	Title	Publication Number	Keywords	Source	Retrieval Date
1	Ergonomic head band apparatus	US5608917A	headband	Google Patents	2019-02-05
2	Electrode supporting head set	US5800351A	head set, headband	Google Patents	2019-02-05
3	Nasal cannula headband apparatus	US6684883B1	nasal, fastener, headband	Google Patents	2019-02-05
4	Adjustable stand for cameras, light and the like	US3064932A	stand, collapsible, adjustable	Google Patents	2019-02-12
5	Wheeled stand apparatus for hanging containers of medical fluids	US4966340A	medical, stand, wheeled	Google Patents	2019-02-12
6	Movable power operated instrument stand	US6575575B2	stand, medical, motor	Google Patents	2019-02-12
7	Device for coupling an IV stand to a patient transport	US6179260B1	stand, IV, telescope	Google Patents	2019-02-12
8	Plastic box having integrally molded latch	US3737067A	box, latch, plastic	Google Patents	2019-02-13
9	Plastic box furniture	US3722971A	box, plastic, latch	Google Patents	2019-02-13
10	Electronic controller box	US20120212883A1	box, cover, electronics latch	Google Patents	2019-02-13

Appendix H Economic calculations

Patient Status

Passive		Active	
Task	Work hours per day	Task	Work hours per day
Documentation	3	Managing EVD height	23
Rotating patient	2		
Emptying EVD tube	0.2		
Total	5.2	Total	23
Passive hours	16	Active hours	8

Salary Cost

Position	Monthly Salary	Hourly Salary	General Payroll Tax	Hourly Cost
Nurse	36100	225.6	121.8	347.5
Assistive Nurse	28000	175	94.5	269.5

Scenario

Current

Staff	Number	Work hours	Cost (SEK)
Nurse	1	11.13	3868
Assistant Nurse	1	11.13	3000
Total Cost			6868

Partial automation

Staff	Number	Work hours	Cost (SEK)
Nurse	1	6.68	2321
Assistant Nurse	1	6.68	1800
Total Cost			4121

Full Automation

Staff	Number	Work hours	Cost (SEK)
Nurse	1	1.11	387
Assistant Nurse	1	2.23	600
Total Cost			987