Designing a Tourniquet for a Fully-Automated Venipuncture Device.

Master Thesis for the Mechanical Engineering Program
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Abstract

Phlebotomy - the drawing of blood - is essential for medical diagnostics, but there are problems with inconsistent sample quality, complications and high operational costs. Automation of the phlebotomy process may solve these problems; however not all steps of the phlebotomy process are currently automated. Automatic vein detection and needle puncturing have already been developed, but the tourniquet, a device used to cease the flow of blood, still needs to be automated. This study aims to design and evaluate an automated tourniquet for a fully-automated venipuncture device.

In this study, two concepts were explored. The elastic tourniquet uses a strap tightened by an electric motor. The pneumatic tourniquet uses an air filled bladder, which is inflated to a standardized pressure. Both prototypes were realised and verified according to the system requirements. After verification a validation was conducted with seventeen participants, to determine usability and test user requirements. The participants used both prototypes and scored them on *ease of use*, *comfort* and *sense of safety*.

Both prototypes did not meet three out of nineteen requirements during verification, but the shortcomings were deemed only minor. Both prototypes were considered easy to use, reasonably comfortable and instilled subjects with a high sense of safety. The pneumatic prototype scored slightly higher on comfort and safety. Users were able to apply the elastic tourniquet significantly faster and less mechanical noise was produced during operation.

This study shows that it may be possible to implement automated tourniquets in fully-automated venipuncture devices in the near future. I conclude that the elastic prototype is best suited for automated phlebotomy. The shortcomings can be solved with little difficulty, whilst the design is less complex and more scalable. For this, I recommend performing clinical device testing to validate the performance of this novel tourniquet concept.

Acknowledgements

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Contents

1 Introduction

Phlebotomy - the drawing of blood - is one of the most common invasive medical procedures [1]. The procedure is performed 1.4 billion times annually in the United States alone [2] and influences diagnostic decision making greatly [3]. Phlebotomy is currently a manual process performed by a trained phlebotomist, but a lack of standardization of this process is causing problems [4]. These problems include inconsistent results, risk of complications and high cost of labor [5]. Automating phlebotomy improves standardization, which may lead to improved results and decreased complications, whilst also reducing cost [6]. Automated phlebotomy devices are currently in development, but no autonomous device currently exists on the market, that incorporates all steps of the phlebotomy process [7]. One element of the phlebotomy process that influences results and can be automated, is the tourniquet [8]. The tourniquet is a device to increase visibility of the vein and aid in insertion of the needle through dilation [9]. In this research I set out to design an automated tourniquet that will lead to consistent and representative results whilst being comfortable to the user.

1.1 Phlebotomy

Blood is a mirror to the condition of the human body. Blood contains analytes that reflect the functioning of organs. Nutrients and waste products are being transported to cells throughout the body and immune system cells are circulated to combat infections [10]. These analytes, in conjunction with blood pressure, temperature, heart rate and other physiological parameters allow physicians to diagnose current or future conditions and treat their patients accordingly [11].

Phlebotomy, the drawing of blood, has been used to treat various ailments with varying success, from ancient Egyptian and Greek societies well into the Middle Ages [12]. This so-called bloodletting usually involved opening the veins with crude instruments or leeches and allow blood to flow out, as shown in figure 1.1. Phlebotomy as a diagnostic tool however, has only been around for the last 150 years, when analytes such as hemoglobin, white and red blood cells could be more accurately estimated [13]. In this thesis I will refer to the drawing of blood for diagnostic purposes as phlebotomy, hereby ignoring the archaic blood lettings.

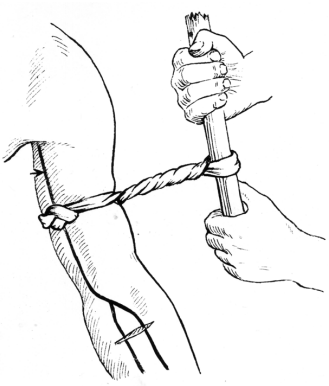

Figure 1.1: Early use of a tourniquet for bloodletting purposes.

The modern phlebotomy process involves only a minor invasive procedure, where blood is drawn into tubes from a vein. The following process is a widely adopted standard in a phlebotomy department, as described by the European Federation of Clinical Chemistry and Laboratory Medicine [14]. This process has twenty distinct steps, a short summary is given below.

The phlebotomist starts by verifying patient data and selecting and labeling the required amount of tubes of the appropriate size and type. The patient is seated and a suitable vein is selected, for adults usually at the cubital fossa - the inner elbow. The vein is selected by visual and tactile inspection. A tourniquet is placed four to five finger widths above the puncture site and the site is cleaned with a disinfectant solution. After cleaning, a hollow needle is inserted into the vein and the first tube is filled. The tourniquet is removed during the filling of the first tube. After any subsequent tubes are filled, the needle is removed and a bandage is applied to the punctured arm. This concludes the procedure and the tubes are send to the lab for analysis.

The standardized phlebotomy process is is described in detail in many different guidelines, from the World Health Organisation (WHO) [15] and other international [14] national [16] and local [17] organisations. One could conclude from the multitude of guideline documents, that the phlebotomy process is already well standardized, but it is a process with many variables, amongst which time, pressure, needle type, insertion angle and tube mixing. Each of these variables may influence the results or cause complications. In some cases existing guidelines are not followed accordingly [18] and many countries do not have standardized guidelines in the first place [4]. Moreover, following the standardized steps for a wide range of patients with diverse skin tones, arm sizes and vein topologies, while keeping process variables constant, is not an easy task for a human phlebotomist. Some patients are more difficult to puncture, because of venous depth, elevation area or collapsing veins [19]. Failed venipuncture attempts may damage a puncture site, making it temporarily or permanently

unavailable. Lastly, different phlebotomists may have different skill levels or prefer different approaches, further increasing process variability.

The variability in the process can translate into variability of the test results: red blood cells can rupture (Haemolysis) from incorrect tourniquet application or needle insertion angle [20], fist clenching can cause Potassium concentrations to rise [21] and incorrect tube sequences can cause samples to spoil. Inaccurate results may cause over- or underdiagnosis, leading to delayed, insufficient or unnecessary health care, which may, in extreme cases, even lead to death [11]. More direct effects of these variations are complications that occur from insertion of the needle. The most common minor complications are bruising and hematoma, occuring in over 12% of venipunctures [22]. These minor complications cause discomfort to the patient, but can also make a vein unsuitable for future punctures. More serious complications such as loss of consciousness or seizures are also observed, but only rarely ($< 1\%$) [22]. Finally, close proximity of patients to the phlebotomist may lead to transfer of pathogens [23].

The financial costs of testing inaccuracy include the need for retesting, unnecessary procedures and medication [15]. Retesting leads to increased workload for phlebotomists [24], where the need for labor limits the scalability of phlebotomy when emergencies demand more capacity. Phlebotomy has an average cost of around 150USD per puncture, a large part of which can be attributed to labor costs [5].

1.2 State of Automation

The problems caused by process variability may be solved by automating phlebotomy. Automation has the potential for more reliable results, whilst reducing costs and complications [25]. This is accommplished by integrating information from different sensors to locate a vein with submillimeter accuracy [6]. This integrated sensor data give more information about the vein topology, such as depth and vein size, but also on how suitable a vein is. It can be hard to judge the health of the veinous wall with the naked eye.

Time is also an important parameter in the process. Tourniquet application time [26], tube fill time [27] and tube inversion times [28] are shown to have a significant effect on specimen quality and patient comfort and safety. Time variations are negligible for modern computer systems, meaning steps can be performed in a more standardized timeframe.

Currently, multiple efforts are being made worldwide to develop an automated system, with the ability to resolve these issues. The first introduction of automation into the field of phlebotomy were illuminator devices [29]. These devices use near-infrared light to aid in vein selection. Although a phlebotomist is still required for the process, some complications may be avoided with this technology, as some patients may have poorly visible veins [9]. More complete venipuncture systems are also being developed, but no such device has currently come to market [2].

One of the companies that started development of an automated venipuncture solution is VEEBOT, aiming to reduce failed insertion attempts, decreasing patient discomfort and minor complications [30]. However, no recent publications have been made concerning VEEBOT.

Another company with this objective, Vasculogic, takes it a step further developing an end-to-end solution. This device is not only capable of puncturing, but also integrates common lab tests [2]. The aim of the device is to standardize not only the phlebotomy process, but the entire diagnostic process, further decreasing variability in blood testing. Integrated testing may also lead to shorter times between test and result. The team behind Vasculogic is now working on a different approach, with a handheld scan and puncture device, shown in figure 1.2 [7]. This is not a fully automated machine and requires a physician to identify a suitable vein. The machine features ultrasound to accurately locate the vein before puncturing.

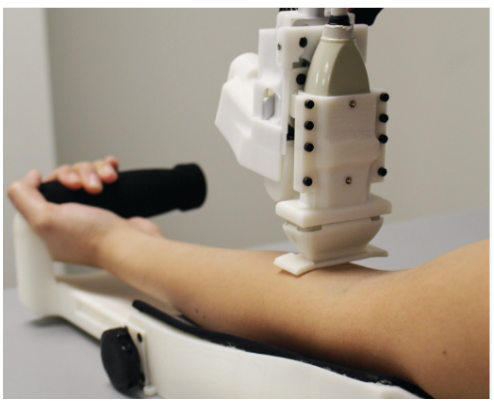

Figure 1.2: The novel hand-held venipuncture machine, from Leipheimer et. al. [7]

As mentioned before, the phlebotomy process consists of about twenty steps. To completely automate the phlebotomy process, steps such as labeling tubes, swapping needles and applying the tourniquet, also have to be automated.

1.3 The Tourniquet

A tourniquet is a device that stops the blood flow in a limb, a process called cessation [31]. Tourniquets are used for three different purposes: the creation of a bloodless field

(for surgery or emergency use), the measurement of blood pressure and venipuncture [32]. I will focus on tourniquets for venipuncture applications, although I am aware of devices that exist for other applications. The tourniquet helps with venipuncture, by stopping veinous flow [15]. Because the arterial pressure is higher than the venous pressure, blood may still flow into the limb. After about 20 seconds, the pressure in the veins reaches a maximum [33]. Increased veinous pressure accomplishes two tasks. Firstly the vein is dilated, making it more tactile and visible, therefore aiding in finding a venipuncture site. Secondly, a higher pressure leads to a higher stiffness of the vein, making it less likely for the vein to roll away from a needle or the needle puncturing through the the vein [34].

Figure 1.3: A simple elastic tourniquet, tied in a knot.

Research has shown improper application of the tourniquet to have significant adverse effects on concentrations of many analytes [35, 36, 37], patient comfort [38] and risk of complications [39, 22]. I have performed a systematic review of literature to identify relevant process parameters, such as tourniquet pressure and width [33, 40], application time [41], sampling time after removal [27] and contacting materials. The results of this research are included in appendix **??**. Automation of the tourniquet, with standardized, repeatable process is an essential part of automating phlebotomy.

The tourniquet is still required for automated phlebotomy, to enlarge the veins and aid in venipuncture. The tourniquet has the added effect of fixating the arm, so the vein stays in the same location. After an exhaustive systematic review of literature and medical device patents, no automated venipuncture tourniquets were identified. Automated tourniquets are employed for blood-less field [42] and blood pressure meters - Sphygmomanometers [43]. However, these applications have very different requirements and operate at different capacities.

1.4 Aim of this Research

I am performing this thesis as part of my Masters Program in Mechanical Engineering at the Delft University of Technology, in The Netherlands. Leading up to this thesis, I explored the influence that tourniquet parameters have on the phlebotomy process in a literature review. Next to that, I have identified what types of tourniquet exist and defined possible working principles. In this research I will design, realize and test different automated tourniquet design, specifically for use with a fully automated venipuncture device.

A traditional method-results-discussion structure does not fit the design process well. A well-known process of structuring a systems engineering project is the Engineering Design Process (EDP) [44], also known as the the V-model [45] see figure 1.4. In this research I will follow this process, because it is a valuable tool for keeping track of the project definition, specifications, requirements and design [46].

The V-model starts by determining the objective or the purpose, in this case **designing an automated tourniquet for a fully automated venipuncture device.** The next step is to set requirements based on this objective, divided into user and system requirement. I will go into detail about the differences between these two in chapter 2. After setting the requirements, in chapter 2, chapter 3 discusses the design and realisation processes. As part of the realisation, components are tested and assembled until a finished prototype is produced.

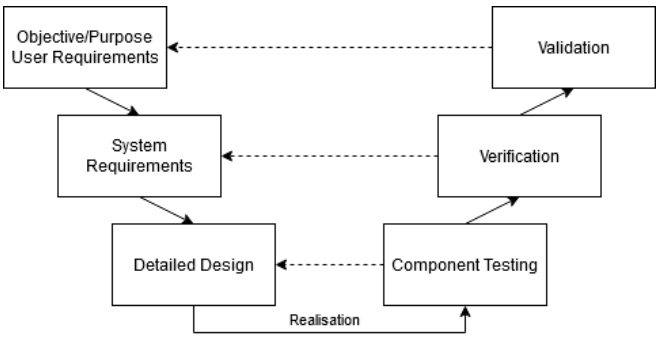

Figure 1.4: The V-model visualized.

In chapter 4 I verified finalized prototypes, to test whether they meet system requirements. Chapter 5 I validated the prototypes, in order to test if they meet user requirements. Each of the steps in the V-model contains a feedback loop, where for instance a failed validation can cause the user requirements to change, leading to new system requirements and an updated design, which is subsequently verified and validated again.

2 Requirements

During the design process, it is of utmost importance to keep the functioning and purpose of the design close at mind. One method of accomplishing this is to determine requirements the product should meet. Carefully developed requirements guide an engineer through the design process [46] and are a tool to communicate and approve decisions at an early stage. Requirements are divided into two categories: user and system requirements. User requirements are mostly qualitative requirements, where system requirements define quantifiable goals. In this chapter I will discuss the user requirements and how these are determined. Secondly, in section 2.2, the system requirements are discussed and linked to their relevant user requirements.

2.1 User Requirements

It is important to know the objective for and context of a design before settings user requirements. The tourniquet is a subsystem of a larger venipuncture device. This device will be used to draw blood in a hospital setting, for diagnostic purposes. Multiple machines may be supervised by a single phlebotomy technician, meaning the user will have to be able to use the machine independently and with little supervision. The tourniquet ceases the veinous flow of blood, to increase visibility of the vein and aid needle insertion. It will be situated on the venipuncture device, around the upper arm.

The user requirements are derived from the purpose and usability of the tourniquet. The are to usually validated by performing a usability study or market research. The user requirements for this research are given in table 2.1, in no particular order.

Table 2.1: Tourniquet User Requirements

Identifier	Description
User.Cessation	The tourniquet shall cease the veinous flow of blood when applied, but not when relaxed.
User.Transparancy	The tourniquet shall not have a significant effect on diagnostic results obtained from the venipuncture.
User.Usability	The tourniquet shall be usable with low supervision.
User.Safety	The tourniquet shall not cause harm to the user.
User.Comfort	The tourniquet shall be comfortable to the user.
User.Universality	The tourniquet shall be usable by a specified intended patient population.
User.Manufacturability	The tourniquet can be manufactured within the system boundaries.

User.Cessation defines the main purpose of the tourniquet; to create veinous distension to increase visibility of the vein and aid needle insertion [47]. Distension is caused by applying external pressure to the limb with the tourniquet, causing blood flow to seize. This pressure needs to be high enough for cessation, but not too high, causing unnecessary discomfort.

User.Transparancy defines the need for consistent, reliable blood testing results. The tourniquet can affect blood test results adversely [48]. Incorrect results may cause misdiagnosis, which may lead to retesting or incorrect medication usage [49]. This influences the next user requirement as well.

User.Usability defines the ability of the patient to apply and remove the tourniquet independently. Successful application and removal must be possible within a certain time frame.

User.Safety defines that the tourniquet shall not physically harm the user, but also that it does not increase the risk of complications.

User.Comfort defines the need for the tourniquete be comfortable in use. The tourniquet should cause only cause up to minor discomfort and may never cause pain to any degree.

User.Universality defines that the tourniquet should be usable on both the left or the right arm, by the intended patient population consisting of:

- Adults and children over the age of 16.
- Patients who are able to sit for at least 5 minutes.
- Patients who are able to hold their arm still.
- Patients with ergonomic dimensions between the 1st percentile and 99th percentile of North American and European adult populations.

User.Manufacturability defines that the tourniquet should be manufacturable within system and business limitations, such as cost and integration with existing systems.

2.2 System Requirements

These user requirements are translated into system level requirements. These requirements are more technical in nature. The verification of these requirements is discussed in chapter 4.

Table explanation

The system requirements are shown in table **??**. The requirement identifier shows whether the requirement is user or system level. The individual requirements will be referred to by their *identifier* from this point on.

The *ValMin* and *ValMax* can add quantitative values to a requirement, where applicable. Please refer to the description for units.

The requirements table features an importance rating. This rating has three levels: *must*, *could* and *may*. *Must* implies that this requirement is mandatory for the functioning of the finished product. *Could* refers to a requirement that is non-critical to the functionality, but good reasons exist to include the requirement. Perhaps alternatives can be found that replace the requirement or it can be omitted entirely. *May* indicates an optional requirement.

Finally the source column shows which user requirements the system requirement was derived from.

[REDACTED]

3 Design and Realisation

Now that the requirements are set, the tourniquet can be designed. This process starts by brainstorming, conceptualizing and capturing design choices in a morphologic chart. Three concepts are drafted and the concepts are evaluated. After evaluation, usually one design is chosen to elaborate and realize; however, I deemed two designs equally viable and decided to realise both. During the detailed design, decisions are substantiated. Finally, the realised designs are presented and discussed.

3.1 Existing Designs

The first step in conceptualizing is gaining inspiration from existing designs. During my literature review, I explored existing tourniquets and their auxiliary functions, of which I will give a short summary. The full report can be found in appendix **??**. I performed a search for existing products using search engines and online stores, additionally a patent search was also performed using Google Patents.

Tourniquets can be divided into three classes, based on working principle: Elastic, Mechanical and Pneumatic, see figure 3.1. Elastic tourniquets are most commonly used for phlebotomy and consist of a strip of elastic material and a method of joining the ends together. Elastic tourniquets are only found as manual tourniquets.

Figure 3.1: Example tourniquets for each of the working principles. Elastic (left), Mechanical (middle) and Pneumatic (right)

Mechanical tourniquets are similar, but feature a rigid strap instead. Often a mechanism is added to provide mechanical advantage for applying force. All identified mechanical tourniquets were to be operated manually. These tourniquets are usually meant to stop bleeding of a limb, but a product indented for phlebotomy use was also identified.

The last class of tourniquet is the pneumatic tourniquet. This tourniquet consists of a cuff, containing a bladder and a pump. This cuff is tied loosely around a limb, after which pressure is applied by pressurizing the bladder. The pneumatic tourniquet comes in manual variants, but fully automated systems also exist. This type of tourniquet is used for sphygmomanometers; devices to measure blood pressure, since the pressure is easy to measure. The tourniquets are also used to make a limb free of blood during surgery. Phlebotomy guidelines suggest using pneumatic tourniquets as a suitable alternative to elastic tourniquets [15]. The fully automated systems, however, are not designed for use in phlebotomy applications.

Auxiliary functions such as timers, quick-releases, easy-to-use buckles and pressure gauges have also been identified. The buckle types have been incorporated into the morphologic chart.

3.2 Morphologic Chart

After the review, a brainstorm session was held with a number of systems and mechanical engineers, where different tourniquet concepts were envisioned. The concepts from the brainstorm session were analysed and the specific functions were separated. Every concept has different ways to accomplish each function, called options. When combining all different options into a table, a morphologic chart is formed. This chart shows the entire possible design space. A design may be made by combining a different option from each function. Some combinations are more obvious than others.

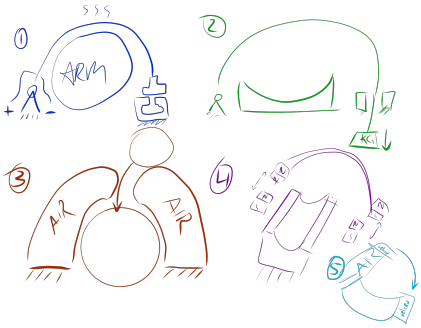

Figure 3.2: A few of the brainstorm concepts

By using a morphologic chart, the designer is able to explore the entire design space and can show that all other options have been considered. The morphologic chart for the automated tourniquet features 12 different functions, and is shown in table **??**. Each option has pros and cons associated with it. Below the table a conclusion is given with the most likely choices for each function.

[REDACTED]

Conclusions

Level of Automation There are two important factors: Sense of control and pressure regulation. The user should have a high sense of control, because automated phlebotomy may be outside the comfort zone. Steps such as manual tourniquet application and removal may help in retaining some degree of control over the process. The regulation of pressure is best to leave automated, to guarantee a standardized process. I conclude that automated pressurization, combined with manual application and release is the most viable option. This combines a high sense of control with the potential for good pressure regulation and relatively low complexity. Incorporating automated release may serve as an added safety option, but the user should always have the possibility of manual release.

Power Source Both electric and pneumatic application are viable options. Pneumatics are functionally quite similar to hydraulics. However, the pressures are quite low, which suits pneumatics better. The need for a hydraulics oil is also a drawback over pneumatics, which can utilise air sources that may already exist in the hospital. Electric power is readily available and many types of actuator exist that use electricity.

Actuator Use of a pulley is well suited for a strap-based design, whereas a bladder would be better suited to a pneumatic system.

Direction of Actuation Pressurization around the arm has been the used method for all existing tourniquet designs. The pressurization from above is an interesting alternative, because it does not require a closed loop. Experimentation is necessary to validate this principle.

Contact Surface The strap, cushion and bladder all comform to the surface of the arm, distributing the pressure and feature soft materials. The rigid surface is non-porous, which may make desinfecting easier, but the lack of comformity makes it less suitable. The jointed finger is an interesting design, but overly complicated without any apparant advantages over a cushion.

Arm Rest The consideration for the arm rest is very similar to the contact surface, the strap, cushion and bladder are all viable options, because they are soft and transfer the contact forces of the arm.

Adjustment Velcro is a good choice for the adjustment, but only if also used as the connection. The pulley provides a good option when used in conjunction with a strap based contact surface, especially when this pulley is also the actuator.

Connection The buckle is the most promising option, because it is easily implemented and intuitive to use. It can be easily released, especially when integrating a release button similar to a car seatbelt. Velcro is also a good option, but only if it is also used as an adjustment option. Magnets are viable, but would have to be combined with some sort of hook in order to aid in positioning and withstand the force of applying the tourniquet.

Break Away Mechanism The requirements demand a break away mechanism, which allows users to always remove themselves from the tourniquet. When no specific break away mechanism is in place, the machine may fail in other, unintended places instead.

Break Away Point The break away point at the connector is preferred, as the experience for the user is the same as removing the tourniquet.

Pressure Limiter The (air)pressure limit is a good solution for pneumatic-based tourniquets, whereas a current limit should be used for any tourniquet that uses an electric actuator, without too much friction. The other options add too much complexion, without providing more functionality.

Ambidextrous Having a symmetric design or a design that just works from both sides, without any preference towards specific solutions, because the complexity is lower and no duplicate parts are required.

3.3 Three Concepts

Fully Automated Mechanical Tourniquet

[REDACTED]

The first concept uses a cushioned plunger to apply pressure to the arm from above. The plunger uses a linear actuator to apply this pressure, driven by an electric motor. Force is measured with a strain gauge to determine the applied pressure. The surfaces can be disinfected with the use of alcohol. The application and pressurization are both fully automated.

I have chosen this concept because the tourniquet does not encompass the arm like a traditional tourniquet, the device consists of two seperate pieces, the actuator assembly

and the arm rest. This allows the arm to be placed from either side and accommodates a wide range of arms. The sense of control may be lower, because no patient action is required to apply the tourniquet, but the system is clearly visible in operation.

Because this concept uses a plunger to apply force only from above, which is an unproven technique, experimentation is necessary to determine feasability. I performed an experiment, where I placed a plunger on the arm, after which pressure was applied using a 1500g weight hanging from the plunger by a strap. An ultrasound probe was used to identify and measure a vein in the cubital fossa. The results obtained after testing three different arms, were inconsistent and not statistically significant. I decided that further research on the novel working principle is outside the scope of this thesis and abandoned the mechanical concept.

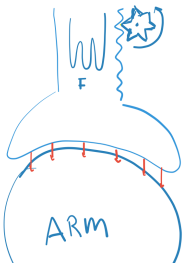

Figure 3.3: Concept: Mechanical tourniquet

Pneumatic Tourniquet

[REDACTED]

The second design uses a cuff containing a pneumatic bladder, with a pump and a pressure sensor to inflate the bladder. The cuff is held around the arm with a velcro flap, which also serves as the adjustment mechanism. The applied pressure is limited by a pressure limit in the pneumatic system. The choice for a rigid arm rest is made, because the cuff itself provides some damping. The system breaks away when the arm is removed, because the velcro only delivers a certain amount of holding force.

Because the velcro has hooks and loops on either side, the tourniquet can not be symmetrical. Therefore a different approach must be chosen to make the design ambidextrous.

The pneumatic cuff is already used for phlebotomy purposes and automated cuffs also exist, which makes this an ideal candidate. This type of automated cuff has never been applied to phlebotomy purposes and these cuffs deliver pressures that are much higher than the **system.pressuremax** requirement [43].

Either an existing cuff has to be modified to suit phlebotomy use or a completely new design is required.

Elastic Tourniquet

[REDACTED]

The third design is inspired by existing elastic phlebotomy tourniquets. It uses a elastic strap that unwinds from a pulley. The strap is pulled against the arm by an electric motor, connected to the pulley. The other end of the strap is connected to the device using a buckle with a release button. The buckle also functions as a mechanical fuse, releasing the strap when forces exceed the maximum allowable force. The pressure is limited by the electric current that the motor can receive. The strap is removable and washable.

I have chosen this concept because it uses a proven method; however, automating an elastic tourniquet is a novel concept that has not been found in the literature search.

3.4 Pneumatic Prototype - Detailed Design

After the concept phase, I planned to choose one concept to design in detail and realize. However, because both the pneumatic and elastic tourniquet looked promising, I decided to realize both. In this section I will explain how each design works and how I came to the component selection and design decisions for the pneumatic tourniquet. The bill of materials (BoM) can be found in appendix **??**.

There are seven parts to the pneumatic design: The *cuff, bladder, pump, valve, pressure sensor, power supply* and *control software*. The complete system is shown in figure 3.4.

The components are laid out in a schematic representation in figure 3.5.

Figure 3.4: The cuff of the pneumatic system, the arm is inserted at the white line on the cuff

The user applies the cuff loosely around their arm. The inflating bladder will fill the space between the arm and cuff, ensuring a good connection. A computer maintains a constant pressure, by controlling the valve and pump through the power supply, based on the pressure sensor reading. Pressure is maintained for a set amount of time, after which the valve reverses the direction of the pump and the tourniquet is depressurized. The pump is energized to remove any residual air from the tourniquet, resetting the system for the next use. The user removes the tourniquet after depressurization and the cycle is repeated.

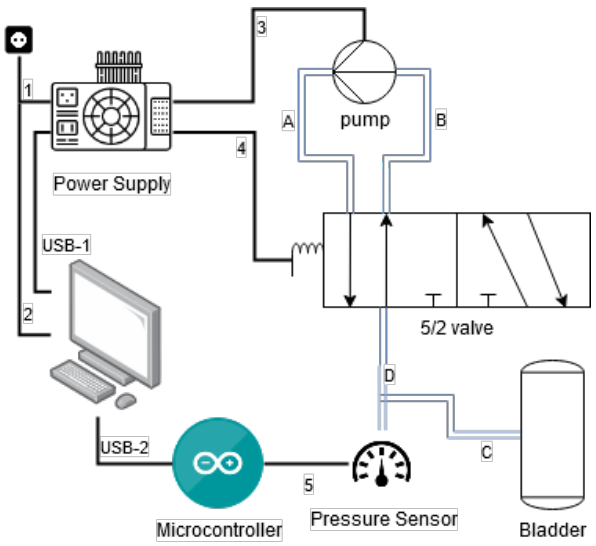

Figure 3.5: Topology of the Pneumatic System.

Cuff and Bladder

Pneumatic tourniquet cuffs already exist for blood-pressure purposes. I opted to re-use an existing cuff, because of the wide range of available options. The cuff has to fit the range of arms described by my requirements, make use of a single pressure port and preferably feature a removable bladder. I selected the Riester Ri-San, because it met these criterea with the lowest cost.

All pneumatic cuffs feature a velcro connector, but there are two styles: The first style loops the end of the cuff through a metal slot and closes it back on itself, this style is easy to operate one-handed and is usually found on home-use sphygmomanometers. The second version closes in the wrapping direction, this style requires two hands to operate. Unfortunately neither style is suitable for the automated tourniquet, because the first one forms a loop into which the user has to insert their arm. The second style is not suited for one-handed operation and thus requires assistance.

The problem was solved by using a plastic preform to keep part of the tourniquet in a three-quarter loop shape. The user is able to insert the arm from the side. Figure 3.6 shows the cuff (purple). with the cuff inserted (yellow). The preform keeps the cuff in this shape, so only one end of the cuff needs to be manipulated. A small shelf (orange, left) keeps the flap of the tourniquet within arms reach.

The cuff can slide away from this preform, allowing the user to remove their arm without disconnecting whilst protecting the user and the device from damage. The connection to the bladder is made with a soft hose type that slides off the connector when the break-away is required, or when pressure becomes high.

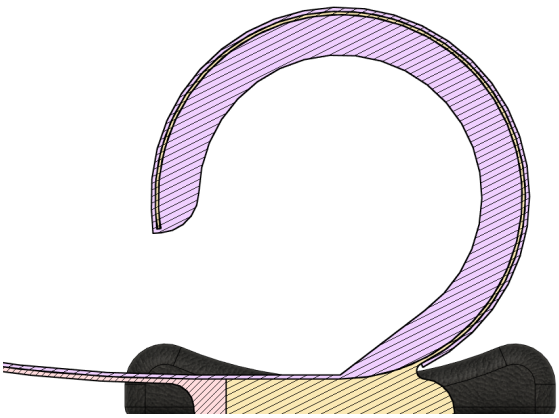

Figure 3.6: A section analysis of the preform inside the cuff.

The bladder was shortened by half, to prevent the arm from being lifted by the air pressure. Otherwise the bladder is original. For spygmomanometer purposes it is very important that the bladder has good overal connection to the arm, because the heart-rate is measured through this bladder. For the purposes of our tourniquet, only the overal applied pressure is important.

Pump

There are two different pump principles, Positive Displacement and Centrifugal pumps. A positive displacement pump works by alternately filling a cavity and discharging it, it always displaces a set volume of fluid, regardless of system pressure. A centrifugal pump uses an impellor to increase the velocity of the fluid. For this application either principle can be used, but the positive displacement pump gives an advantage, as only a small volume needs to be displaced. The tourniquet contains up to 1 liter and can be filled in 6 seconds with a pump that delivers 10L/min. The positive displacement pump is also self-sealing, meaning no backflow is allowed. This means the pump does not have to be energized when the working pressure is reached. A centrifugal pump needs to stay energized to maintain pressure.

There are different types of positive displacement pumps, but the most common type is the reciprocating pump, which usually comes in the form of a diaphragm pump. This pump works by moving a diaphragm up and down over two one-way check valves, at the inlet and outlet. The inlet valve allows fluid to enter the cavity under the diaphragm, but not in reverse direction. The outlet valve allows the fluid to discharge from the outlet port. By design reciprocating pumps are always uni-directional and can only maintain a positive outlet pressure. A reciprocating pump features a non-constant pressure profile, because air is only discharged for part of the operation.

A diaphragm pump model KNF NMP850KNDC, with three chambers was chosen, that was already in stock. Three diaphragms allow for a smoother pressure profile, because air is discharged in three overlapping bursts. The pump can provide 10L/min and uses 24VDC.

Diaphragm pumps pump a constant volume per stroke, the pressure profile of these pumps is quite noisy. To counteract pump noise, a small butterfly valve was implemented after the valve and just before the sensor. The reduced air flow caused by this restriction dampens the pressure spikes by limiting the velocity. Diaphragm pumps operate with a constant volume per stroke, meaning the total inflation time is not affected by the addition of this valve.

Valve

When first testing the prototype, the bladder would deflate until the air pressure inside the cuffs equals the the ambient pressure. When the cuff was not applied firmly around the arm, a residual volume would build up inside the bladder. This volume would increase with each loose application, until the range of operation was limited. Removing the air from the bladder proved to be necessary between each cycle. Using the pump to deflate the bladder is a practical solution, but as mentioned before the pump is unidirectional. Using a valve or combination of valves would solve this problem. Four connections need to be made to the valve, the bladder, the pump in- and outlet and the ambient air (our reservoir). The valve requires two different states: an inflate and a deflate state.

This is called a 4/2 valve, which is usually used for pneumatic cylinder actuation. The valve features an A and B port to connect to a cylinder and a reservoir (R) and pump (P) port, see figure 3.7. When the valve is not energized, the bladder (A) is connected to the pump inlet (R) and the B valve to the pump outlet (P). When energized, the A and B ports reverse direction and the bladder (A) is connected to the pump outlet (P) instead. The 4/2 valve has the added benefit of serving as a release valve, because the motor can only sustain a positive outlet-inlet pressure. This allows air to flow from the bladder through the check valves in the pump into the ambient air freely.

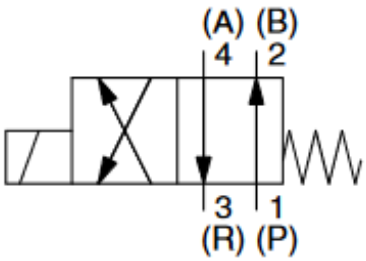

Figure 3.7: A 4/2 valve, with spring return and non-latching.

There are several important parameters to pneumatic valves. The first is the actuation method, valves can be actuated electrically, mechanically and pneumatically. Electrical actuation is suitable when no pneumatic or mechanical control is present. The automated venipuncture device features 24 VDC, so an electrically actuated valve is chosen. Because the valve acts as the release valve too, a momentary spring return model is chosen, so the bladder is allowed to deflate when power is lost. Some valves need external pressure to actuate, called pilot pressure. Because the system does not have a constant supply of pressurized air, I need to select a valve that does not require pilot pressure.

Valves feature a minimum working pressure of the system as well. The pressures inside the system are very small compared to industrial pneumatic applications and deflating the tourniquet even requires a small negative pressure differential. This means the operating pressure range needs to encompass at least 0 mmHg to 100 mmHg, or 0 MPa to 0.013 MPa.

I have selected a valve that features a momentary, spring return 24VDC solenoid operation. The valve did not require the use of pilot-pressure and has a working range of 0 -

0.7MPa. At the time of ordering no 4/2 valves were available, in one-off quantities from my supplier, so I opted for a 5/2 valve instead. A 5/2 valve is similar to a 4/2 valve, but has two separate reservoir ports. When these ports are connected together, it functions exactly like a 4/2 valve. The SMC EVK3120-5DO-M5-Q valve was selected, because it met all requirements for a reasonable price.

Pressure Sensor

A pressure sensor is required that can measure at least 0 mmHg to 100 mmHg (0 kPa to 13.3 kPa), with 0.5 mmHg resolution. This resolution allows for smooth PID control. The Honeywell ABPDANT005PGAA5 was chosen for this purpose, because it features a range of 0 kPa to 35 kPa, with a 0.5 V to 4.5 V analog output. This sensor is connected to the computer using an Arduino Mega's analog to digital converter (ADC). The ADC has 10-bit resolution between 0 V to 5 V, which leads to a measurement resolution of $35\text{kPa} \cdot 4\text{V}/(5\text{V} \cdot 2^{10}) = 0.0427\text{kPa} = 0.32\text{mmHg}$.

Power Supply

A Rigol DS832 power supply was chosen to interface the control software to the pump and valve. This power supply accepts commands over USB to set and read the voltage and current. The power supply can deliver 30 volts at up to 3 amperes from two isolated channels, which is more than enough for the pump and valve, both operating at 24 volts. The power supply uses the National Instruments VISA protocol, which has good support for Matlab.

Control Software

The control software was written in Matlab and can be found in appendix **??**. The controller communicates with the power supply through the VISA protocol and uses RS232 serial communication to read the pressure sensor from the Arduino Mega. There are three phases of operation, inflation, pressure hold and deflation. During inflation, the pump is energized at the maximum voltage until the pressure setpoint is reached.

The controller moves to the pressure hold phase subsequently, using a PID controller to keep the pressure stable. The pump was found to operate at voltages as low as 1.5 volts, meaning the control output can be analog. The valve is used to remove small amounts of air when the pressure becomes too high. This phase is necessary to compensate for small movements the patient may make and to compensate for air lost in the pneumatic couplings.

After 60 seconds of pressure hold, the controller moves to the deflate phase, where the valve is de-energized, causing the pump to remove air from the system. The pump is energized at 24 volts, until the pressure drops below zero for half a second. Then the power supply outputs are turned off as a safety measure.

The controller also features a safety that detects when inflation takes too long, which may indicate no arm is inserted, a possible leak or that the tourniquet is too loose. A second safety indicates when the tourniquet is removed during the pressurization phase. A third safety detects a leak during deflation, by comparing the amount of air that is impelled to the expelled air. The final safety indicates when the pressure exceeds the safe pressure limit provided by literature and stops operation. The tourniquet is deflated when any of these safeties are triggered and an error message is shown.

3.5 Pneumatic Prototype - Realisation

The cuff is connected to a 40-40 extrusion through the preform. The preform and shelf are both 3D-printed using PLA material. Because the material is only 0.75 mm thick it is flexible enough to incorporate different arms. The cuff has been modified, by cutting a slot in the bottom, 50mm away from the center bladder opening. This allows the cuff to be slid over the preform. The bladder is folded in half, so no part of the bladder sits underneath the arm.

Figure 3.8: The cuff and preform in place

The pneumatics are controlled from a separate control board, shown in figure 3.9. On the left the Arduino board connects to the pressure sensor on a breadboard. The valve is located under the breadboard and connects to the pump on the right through two pneumatic lines. The control board is situated underneath the test setup, out of view from the user. A single pneumatic tube connects the controller to the cuff. Power is provided by a standard IEC computer cable and a single USB cable connects to the control computer.

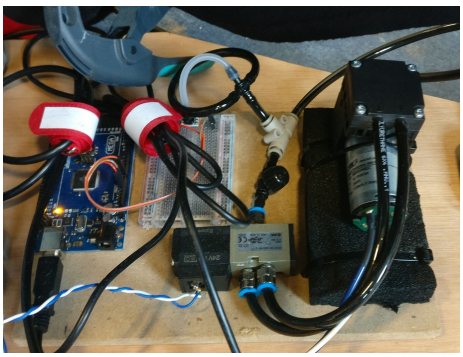

Figure 3.9: Pneumatic controller

The prototype is attached to a arm-rest which mimics the venipuncture system, as shown in figure **??**, however this arm rest is not considered part of the tourniquet.

3.6 Elastic Prototype - Detailed Design

The elastic prototype features an elastic strap which is tensioned by a motor with a pulley. The user can apply and remove the tourniquet with a seatbelt like buckle. The elastic prototype features an elastic strap which is tensioned by a motor with a pulley. The user can apply and remove the tourniquet with a seatbelt like buckle.I will discuss the three main components of the elastic prototype: The buckle, the pulley and the motor. The completed system is shown in figure 3.10. The strap is an actual elastic tourniquet, which had its original buckle removed. All parts of the housing, pulley and buckle were 3D-printed. Appendix **??** features a Bill of Materials, listing all components.

Figure 3.10: The second version of the elastic tourniquet, showing the motor on the bottom right of the white housing.

Buckle

The buckle needs to be intuitive. I conducted a search of different buckle and latch designs during the concept phase. The most ubiquitous, intuitive and easy to use buckle design seems to be the seatbelt. The shape of the 'hook' is uniform across makes and models of cars and invokes an immediate familiarity to the user. I copied this hook design and the button layout.

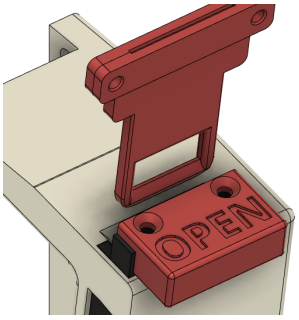

Figure 3.11: The seatbelt inspired hook and button, the tourniquet is clamped into the top slot. The button opens the connector.

The connector consists of a latch, a button and two springs. The button has an L-shaped track that guides a pin sideways. This pin is attached to the latch, which unlatches the hook, when the button is pressed. A cross section of the connector mechanism is shown in figure 3.12. The latch (green) is pushed against the hook (red) by a spring (not shown, notches in right indicate position). The L-shaped track is cut in the button (black), behind the latch. A rod (grey) is inserted through the latch, into the L-shaped track. When the button is pushed down, the track forces the latch to retract from the hook, allowing the hook to be disconnected. A spring (not shown, located in top black rectangle) pushes the button back up, to reset the mechanism. The bottom line of the 'L' allows the latch to retract, when the hook is inserted without pressing the button.

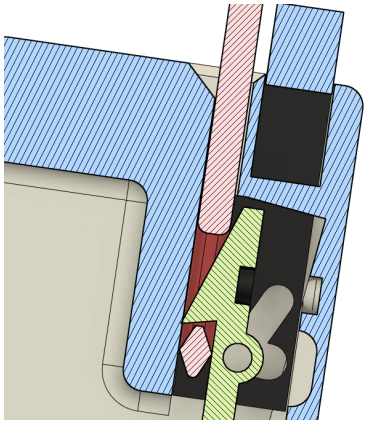

Figure 3.12: The buckle, consisting of a hook, latch and button.

The hook attaches to the tourniquet strap with a clamping mechanism, featuring a plate and two screws. By adjusting the torque of the screws, this clamping mechanism

doubles as the break-away mechanism.

Pulley

The pulley serves two purposes in this design: Coverting the motor's rotary motion into linear motion and storing excess tourniquet strap. The first parameter in designing the pulley, is to know how much tension is required in this tourniquet. When pulling on the tourniquet, a tension is created, which needs to be translated to the applied pressure. The relation between the tension and the pressure is given in equation 3.1, where T is the tension in the tourniquet, r is the radius of the arm, t is the width of the tourniquet and p is the applied pressure [50]. To be able to use this formula, I assume that the arm cross section is circular, instead of the oval cross section obtained from literature.

$$T = r \cdot t \cdot p \tag{3.1}$$

Literature specifies a required pressure exerted on the arm by the tourniquet, of 40-80mmHg, which is 5333-10666 Pa in SI units. The smallest arm circumference (p1) and largest arm circumference (p99) are 208mm and 453mm respectively. Based on the circular assumption, the associated radii are 33mm and 72mm. The tension has a linear relation to both the radius and the pressure. Because the ratio between the p1 and p99 radii is larger than the ratio between the lowest and highest allowable pressure, a tourniquet cannot operate with a constant tension, meaning the tension would have to increase for larger arms.

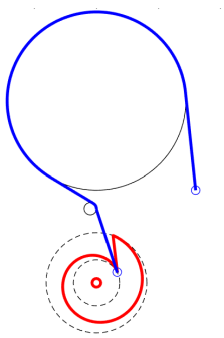

Figure 3.13: The spiral pulley in place in the tourniquet system. The arm is shown above, a guide roller in the middle guides the tourniquet to the pulley below.

The pulley converts the torque of the motor to a tension in the tourniquet through a well known formula, equation 3.2, where T is again the tension in the tourniquet, M is the motor torque and R represents the pulley radius. To change the tension for different arm radii, two approaches can be taken. The arm diameter could be determined and the motor torque controlled accordingly, or the radius could change when the tourniquet is extended to accomodate a larger arm, keeping a constant motor torque. The second approach is much less complex and has a certain elegance, this is the approach I chose.

$$T = \frac{M}{R} \tag{3.2}$$

To design the shape of the pulley, I used matlab, all relevant files can be found in appendix **??**. The script models the tourniquet and arm in place, as the position on the pulley relies on the retraction of strap material required to accomodate a specific arm size. First the tourniquet length is calculated for the range of patient arms, to the guide roller in the middle, shown in figure 3.13. Subsequently the pulley shape is defined. A archimedean spiral shape was chosen, because its mathematics are well defined and easy to understand. Equation 3.3 shows the radius as a function of pitch a, the angle of rotation θ and the center point c.

$$R(\theta) = a \cdot \theta + c \tag{3.3}$$

The spiral length is determined to be the difference in tourniquet length in step one, as this is the amount of tourniquet retraction required between the p1 and p99 sizes. The ratio between the radius of the innermost part of the spiral and the outermost part, the pitch, is defined as the ratio between the required tourniquet tension to apply 60mmHg in the p1 and the p99 arms, calculated with equation 3.2. The length of the spiral section can be determined from equation 3.3. This length should be able to the difference in length required by the range of arm sizes, calculated before.

$$L = \int \sqrt{R(\theta)^2 + a^2} d\theta = \Delta l_{p1,p99} \tag{3.4}$$

The pulley features screws to hold the tourniquet and to clamp to the axle. The finished design is shown in figure 3.14.

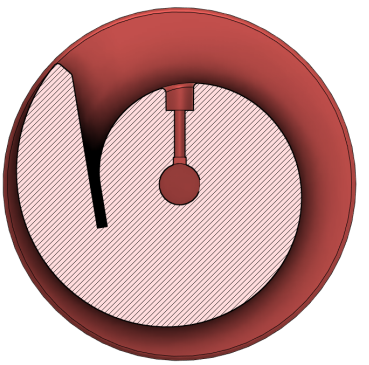

Figure 3.14: The final pulley design.

After determining the pulley parameters, I was able to plot the pressure curves, following the equations in reverse. The resulting plot can be found in 4.16, which compares the pressures of a normal linear pulley, a quick estimate for a non-linear pulley, the calculated non-linear pulley and the real world measurements of the pulley (determined during verification).

Motor

All the tension control is incorporated into the pulley, which means the motor only needs to provide a constant torque of 0.3Nm. DC-motors feature a linear current-torque relation, meaning a constant current provides a constant torque. There are some considerations for chosing the motor: The motor must be zero cogging, meaning the torque is constant over the entire rotation and should preferably not use a gearbox, as the losses will reduce the output torque by an unknown factor.

I decided upon a Clearpath BLDC-servo by Teknic, because the motor has a built-in controller with a torque controlled mode and provides data output over USB, which may be useful during testing and verification. The model I selected is the CPM-MCVC-2311S-RLN, which features a continuous torque of 0.4Nm and an operating voltage of 24V, which is present in the system. This package is cheaper than other separate motors and controllers.

To control the motor, an Arduino Mega2560 was selected, because it was already available. The motor only requires a simple Pulse Width Modulated input, where the torque is directly proportional to the duty cycle. The control software simply switches from a low torque setting (0.04Nm), in order to retract the tourniquet slowly, to a high torque setting (0.4Nm), causing cessation. After 60 seconds the controller automatically returns to the low torque setting.

The included software was used to limit the motor to 0.4Nm. The motor's internal control circuitry determines applied torque and will enforce this limit.

3.7 Elastic Prototype - Realisation

The final tourniquet design is shown in figure 3.10. The white plastic housing supports the buckle components and serves as an arm rest. The tourniquet features a 3D-printed housing and buckle components. These components require smooth surfaces and tight tolerances to operate correctly.

The components were printed oriented with the mating surfaces down, to allow better surface finish. Where this was not possible, the surfaces were ground with emery paper and filed down to smoothen operation. A small amount of ball bearing grease is applied to mating surfaces to reduce friction. The buckle components are covered by a 3D-printed cover plate, shown in figure 3.15. This plate prevents the user from touching the moving parts within.

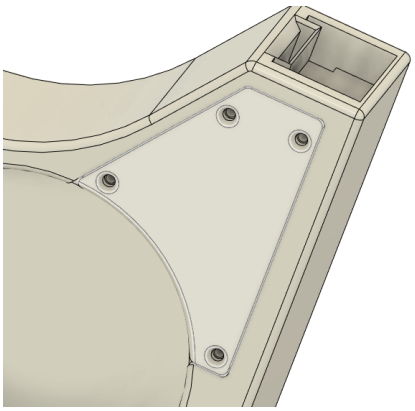

Figure 3.15: A small cover plate, to be held in place with four M3 nuts.

Inside the housing, the motor is directly couppled to the pulley. The pulley was 3D-printed in PLA, using a water soluble support material. This material allows tighter tolerances in places where regular support is difficult to remove. It also allows a smoother surface finish, because the layer contact between print and support can be much greater. Two M3 screws hold the pulley in place on the motor shaft and two additional screws clamp down on the tourniquet strap to affix it to the pulley.

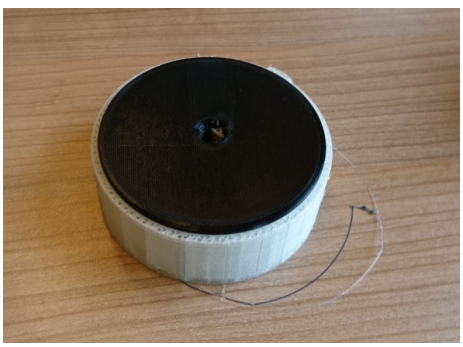

Figure 3.16: The pulley (black) supported by water-soluble PVA support material.

Underneath the prototype, the motor is connected to a power supply and an Arduino, which allows the control laptop to set the torque. The Arduino is connected to the computer via a USB-B cable. Power is delivered using a regular IEC computer cable.

The prototype is attached to a arm-rest which mimics the venipuncture system, as shown in figure **??**, however this arm rest is not considered part of the tourniquet.

4 Verification

The next step after realizing the prototypes is to verify if all system requirements are met. In this chapter I will first discuss how each system requirement will be verified and show the relevant measurement devices. Afterwards the results of the verifications are given per requirement, for each of the two prototypes. Finally, the results are discussed per prototype.

4.1 Verification Tests

Some of the verifications were performed during validation testing, indicated a per requirement basis. Please refer to chapter 5 for more information on experimental setup and methods.

System.Adjustability The system should accommodate arms between the smallest 1% ($p1$) of arms and the largest 99% of arms ($p99$). The $p50$ value is also tested, to make sure that the tourniquet functions correctly for the average arm as well. The cross-sectional dimensions and circumference are shown in figure 4.1, based on anthropometric data from literature [51].

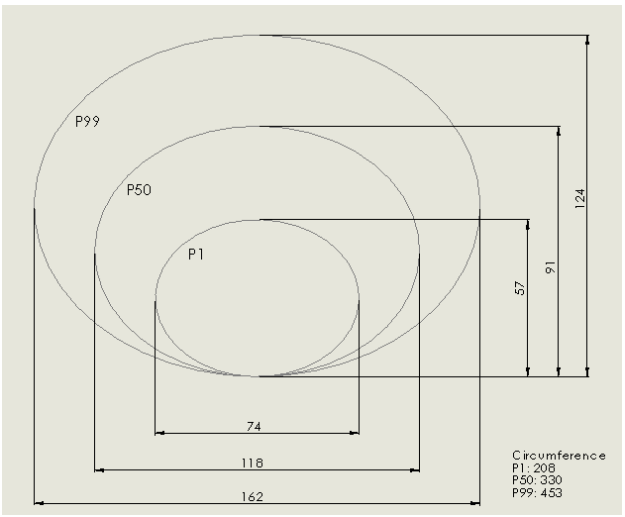

Figure 4.1: Anthropometric data of the cross-section of the arm

Three arm cross-sections have been 3d-printed, with a length of 180 mm, the maximum supported print height. This allows them to be tall enough to fit the prototypes completely, with 15 mm stick-out at the ends. No flex of any of the three forms was perceived during testing. The three arm shapes are color-coded, with green being the $p50$, red the $p99$ and orange as the $p1$, as shown in figure 4.2.

The shapes are to be placed in the tourniquet prototype during functional verifications, to make sure that the prototypes function at the mean, as well as the limits of operation. The verification is passed when all forms fit inside the tourniquet and the tourniquet functioning is not visibly hindered by each form.

Figure 4.2: 3D-Printed arm cross sections, used for testing

System.Ambidextrous The tourniquet should be usable with either the left or right arm. This requirement will be verified during the validation in the next chapter. The requirement is met when test subjects can use the tourniquet with either arm, while still being perceived as comfortable and meeting the System.Don and System.Doff requirements.

System.Biocompatible The tourniquet should be constructed from biocompatible materials, where the prototype is likely to touch the patient. Biocompatibility means that a material does not create a potential toxicological reaction resulting from contact of the material with the body [52]. Materials usually come with a data sheet or safety sheet that shows whether it can be considered a biomaterial. The verification is passed, when the materials are specified as biocompatible by their manufacturer.

System.Comfort The system should be comfortable and not cause pain or major discomfort. This requirement will be verified during the validation in the next chapter. The requirement is met when test subjects do not experience pain or major discomfort.

System.Cost The system should not exceed a cost of € 1000. A bill of materials should be drafted for any design. The cost of the components is easily obtained from this bill of materials. The cost of labor is not considered in this early stage, as it is impossible to determine before the design for manufacturing stage. The verification is passed when the total combined cost does not exceed € 1000.

System.Disinfection The system should be disinfectable,

where any of the parts touch the patient. Low-level disinfectant is sufficient, meaning spraying with alcohol or chlorhexidine solution is a suitable method of disinfection [53]. The verification is passed when all of the surfaces are resistant to the two disinfectants and can be reached for cleaning.

System.Failsafe The system should fail in a safe manner, when power is lost to any combination of subsystems. To test this, all individual subsystems will have their power removed whilst in operation on the $p50$ arm form. To pass this verification, the system should relax the tourniquet, to allow the patient to remove it. The removal process may not be changed by the loss of power.

System.Position The tourniquet should be placed 75-100 mm above the cubital fossa. This requirement will be verified during the validation in the next chapter, by measuring the distance from the center of the cubital fossa to the bottom edge where the tourniquet meets the arm, shown in 4.3. The requirement is met when the tourniquet is placed in this range for all test subjects.

Figure 4.3: Measurement of the bottom of the tourniquet to the center of the cubital fossa.

System.PressureMax The system should not exceed 100 mmHg of pressure. This will be measured with two different methods. For the pneumatic prototype, a calibrated pressure gauge is used parallel to the tourniquet, type Riester Ri-San shown in figure 4.4. This gauge was part of a sphygmomanometer and has a measuring range of 0 mmHg to 300 mmHg, with 1 mmHg resolution. The expected values are in the 40 mmHg to 100 mmHg range.

Figure 4.4: Riester Ri-San calibrated pressure gauge.

The elastic prototype delivers a force that induces the appropriate pressure in the arm. The forces have been calibrated in the previous chapter. A digital force scale is used to determine whether enough force is supplied, type Kern GDB-N shown in figure 4.5. The scale has a range of 0 gram to 5000 grams, with a 1 gram resolution. The expected values are in the 700 gram to 1500 gram range.

Figure 4.5: Kern HDB-N digital scale.

The verification is passed when no pressures over 100mmHg are observed during operation, even when applying external perturbations to the tourniquet.

System.PressureOperate The operating pressure is determined with the same gauge and scale as the maximum pressure. The verification is passed when the pressure remains in the predefined range of 40mmHg to 80mmHg during normal operation.

System.Removability The user should be able to remove the tourniquet without help. The user should be able to remove the tourniquet at any time.

System.TimeOperate The tourniquet should operate for 60 seconds during normal operation. A stopwatch is used to measure the time of operation. The verification is passed when the operation time does not exceed 60 seconds.

System.Usability The tourniquet should be usable without assistance. This requirement will be verified during the validation in the next chapter. The requirement is met when no physical aid is required to remove or apply the tourniquet.
System.Breakaway Measures should be in place to allow the patient to remove their arm when an emergency occurs, even without following the regular removal process. The verification is passed when such measures are in place and are tested to release the tourniquet when standing up from the machine whilst the tourniquet is applied, without causing damage to other parts of the device.
System.Constrained The arm should not move more than 5 mm radially. This requirement will be verified during the validation in the next chapter. The requirement is met when subjects are unable to move the arm more than 5 mm.
System.Don The user shall be able to apply the tourniquet within 60 seconds. This requirement will be verified during the validation in the next chapter. The requirement is met when subjects are able to apply the tourniquet within this time.
System.Doff The user shall be able to remove the tourniquet within 30 seconds. This requirement will be verified during the validation in the next chapter. The requirement is met when subjects are able to remove the tourniquet within this time.
System.Feedback The user should be provided with feedback when the tourniquet is correctly or incorrectly applied. The verification is passed when such feedback is provided.
System.Application The user should not have to put their arm through a closed loop when applying the tourniquet. The verification is passed when the tourniquet can be applied without such a loop present.

4.2 Pneumatic Prototype - Results

Pneumatic.Adjustability - ***Pass*** - All three arm forms were placed inside the pneumatic prototype, as shown in figure 4.6. The tourniquet was operated at the standardized working pressures, for 20 minutes. This increased time was used to assess control stability and rule out any low frequency oscillations, that may be caused by small air leaks in the system.

Figure 4.6: The p1 (left), p50 (center) and p99 (right) arm forms fit in the pneumatic prototype

The pressure was logged ten times per second with the built-in calibrated pressure transducer, the resulting graph of the p99 form is shown in figure 4.7, the p1 and p50 forms resulted in very similar graphs. The graph shows that peaks caused by controller jitter were very short and did not cause the pressure to go outside of the boundary conditions.

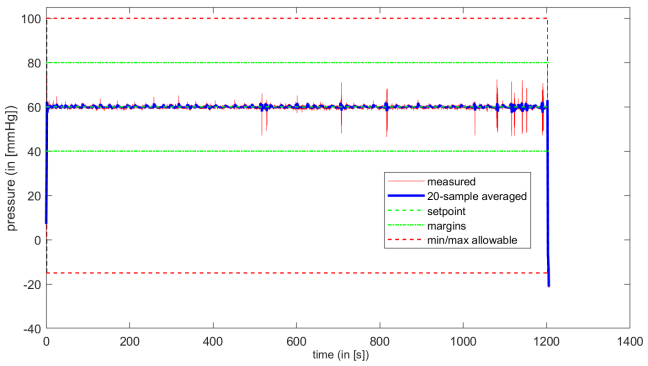

Figure 4.7: Pressure graph of the p99 form at a set point of 60 mmHg for 20 minutes.

Pneumatic.Ambidextrous - ***Pass*** - The pneumatic prototype was tested by 8 subjects on their left arm and 9 subjects on their right arm. In both groups, no comfort score below 2 was given, where 1 is very uncomfortable and 5 is very comfortable. None of the respondents experienced pain on either arm during use of this prototype. The maximum Don and Doff times were 15 and 23 seconds for the left and right arm respectively, well within the 60 and 30 seconds limits.
Pneumatic.Biocompatible - ***Pass/Fail*** - The user may come into contact with three parts of the system. The arm rest, the bladder and the 3D-printed parts. The arm rest is made from biocompatible synthetic leather [54]. The bladder is based on a modified *Riester Ri-San* sphygmomanometer cuff. This cuff is made from a latex-free material and specifically meant for short term contact with human skin [55]. The 3D-printed parts are made from a bio-plastic called Poly Lactic Acid (PLA). This plastic has shown to be biocompatible for skin contact and even shows promising results for use in implants [56]. However, plastics contain additives to improve their properties for specific applications. The PLA used for the prototype does not provide a data sheet, which specifically mentions biocompatibility. Therefor I can not conclude that the PLA parts are biocompatible.
Pneumatic.Comfort - ***Pass*** - Only minor discomfort may be experienced, without pain. A comfort score of 4.2 out of 5 was reported by 17 respondents, with a minimum comfort score of 2, which was represented as 'somewhat uncomfortable'. No pain was reported by any of the 17 respondents.
Pneumatic.Cost - ***Pass*** - The Bill of Materials in appendix **??** shows a total cost of € 776.82, which is below the required

maximum of €1000.

Pneumatic.Disinfection - ***Pass*** - The user may come into contact with three parts of the system. The arm rest, the bladder and the 3D-printed parts. The arm rest is made from a synthetic leather, which is suitable for disinfection [54]. The cuff is made from a latex-free material, which is washable up to 60 degrees Celcius with the specific intention of disinfecting [55]. The 3D-printed parts are made from a bio-plastic called PLA. This plastic is not suitable for higher level disinfection methods [56], but can be sterilized with isopropanol or chlorhexidine without affecting the properties of the material [57].

Pneumatic.Failsafe - ***Pass/Fail*** - The pneumatic prototype consists of 6 parts, connected by wires and pneumatic line: The pump, pressure valve, pressure sensor, power supply, microcontroller and controller PC. To test how safe the prototype fails, several tests have been performed, removing lines and wires.

The system topology is shown in figure 4.8, which was also shown in chapter 3 but has been repeated for ease of reference. The numbered wires are power supply wires, the lettered lines are pneumatic and two USB cables have been labelled as USB.

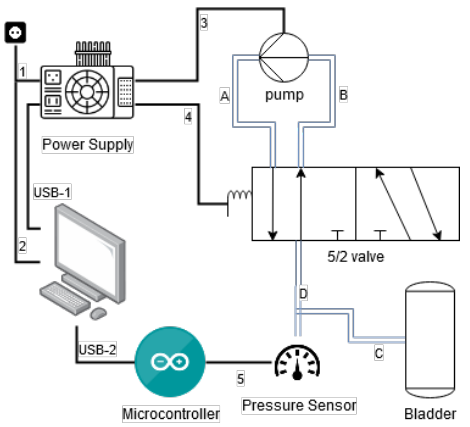

Figure 4.8: Topology of the Pneumatic System.

- Remove line *A* - ***Pass*** - The system no longer supplies air to the tourniquet. The controller detects no change in pressure and an error message is triggered.
- Remove line *B* - ***Pass*** - The pump no longer can remove air. A residual volume exists after operation and an error message is triggered by the controller.
- Remove line *C* - ***Pass*** - The system no longer supplies air to the tourniquet. The controller detects no change in pressure and an error message is triggered.
- Remove line *D* - ***Pass*** - The system no longer supplies air to the tourniquet. The controller detects no change in pressure and an error message is triggered.
- Remove wire 1 - ***Pass*** - No more power is supplied to the pump, no air is displaced. The controller detects the absense of the power supply and triggers an error message.
- Remove wire 2 - ***Fail*** - When power to the controller is lost during operation, the power supply remains in its current state. This means the pump may stay active even when pressures exceed 100 mmHg.
- Remove wire 3 - ***Pass*** - The system no longer supplies air to the tourniquet. When the controller detects the no change in pressure, the system is shut down and an error message is triggered.
- Remove wire 4 - ***Pass*** - The pressure release valve is chosen to vent when power is removed. The system depressurizes and the controller detects this change in pressure, powers down the system and triggers an error message.
- Remove wire 5 - ***Pass*** - When power or signal to the pressure sensor is removed, the controller detects an overpressure condition and shuts down. The error message will indicate an overpressure event, although this not the specific cause of this error.
- Remove USB-1 - ***Fail*** - When communications to the power supply is lost during operation, the power supply remains in its current state. This means the pump may stay active even when pressures exceed 100 mmHg.
- Remove USB-2 - ***Pass*** - When communications to the pressure sensor microcontroller are lost during operation, a timeout condition occurs within 1000 ms. The pump may stay active up to this timeout event, but will shut down after. No pressures above the maximum allowable pressure have been observed during this failure. If power is lost before operation, the system will not power up and an error message is shown.

Pneumatic.Position - ***Pass*** - The bottom of the tourniquet was positioned at an average height of 84mm, which is inside the range of 75-100mm in required.

Pneumatic.PressureMax - ***Pass*** - The controller for the tourniquet polls the pressure sensor at 10 Hz. If the unfiltered, unaveraged pressure exceeds the threshold of 100 mmHg, the system cancels inflation immediately, the pressure release valve is opened and depressurizes the tourniquet. After depressurization the system is shut down and an error message is shown to inform the operator.

The implementation of the controller, including the safety features is shown in Appendix **??**. This system has been tested on all three arm forms repeatedly and reliably.

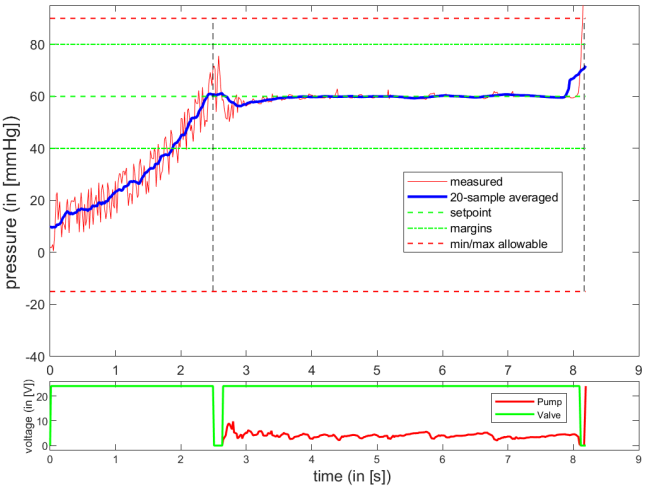

Figure 4.9: Pressure graph of the p50 form at a set point of 60 mmHg. A perturbation is applied after 8 seconds and the system shuts down.

Pneumatic.PressureOperate - ***Pass*** - The operating pressure was tested on all three arm forms; p1, p50 and p99. The graph in figure 4.10 shows the pressure at a set point of 60 mmHg, with the standardized 60 seconds of operating time. The pressures remained within the 40 mmHg - 80 mmHg operating pressure range at all times.

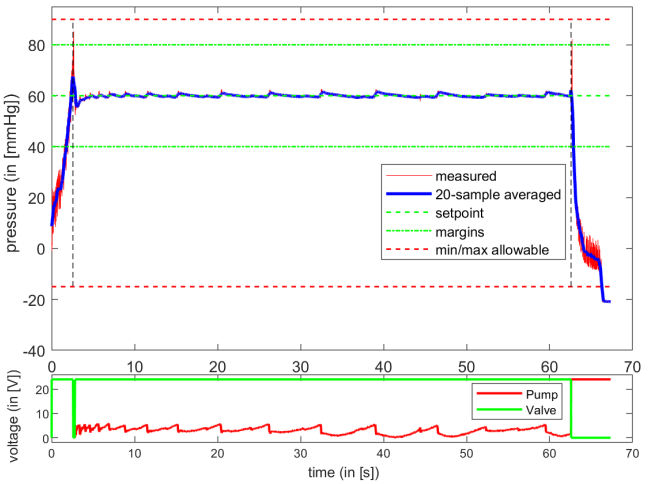

Figure 4.10: Pressure graph of the p50 form at a set point of 60 mmHg for 60 seconds. The bottom graph shows the control inputs of the pump and pressure release valve.

Pneumatic.Removability - ***Pass*** - All of the subjects were able to remove the tourniquet without intervention from the researcher, even when no instructions were provided. There was no difference between the left and right arm.

Pneumatic.TimeOperate - ***Pass*** - The time of operation has been timed with a stopwatch over the course of five applications, three of which on the *p50* form and one each on the *p1* and *p99* form. The application time is exactly 60 seconds between the moment of pressurization until depressurization.

Pneumatic.Usability - ***Pass*** - All of the subjects were able to apply the tourniquet correctly without instructions or intervention from the researcher.

Pneumatic.Breakaway - ***Pass*** - The system is equipped with a PLA preform that holds the cuff in shape. The cuff is not attached to this preform, but rather slid over it. This allows the cuff to be removed from the preform without breaking any of the parts, as shown in figure 4.11. The preform is flexible enough that the angle of removal is not critical. The cuff remains attached to the pneumatics through a silicone tube, which is friction fit over the bladder port and easily pulled off.

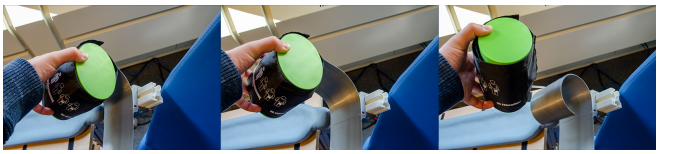

Figure 4.11: The cuff can be removed from the rest of the system.

Pneumatic.Constrained - ***Fail*** - The arm was only constrained to ±10.1mm on average, with a maximum recorded transversal movement of ±17.5mm, as shown in 4.18. This exceeds the required maximum of ±5mm.

Pneumatic.Don - ***Pass*** - The average application time was recorded to be 8.9 seconds, with the maximum time of application being 23 seconds. This is under the required 60 seconds. Figure 4.12 shows the spread of the Donn time, as well as the differences between the first and second application.

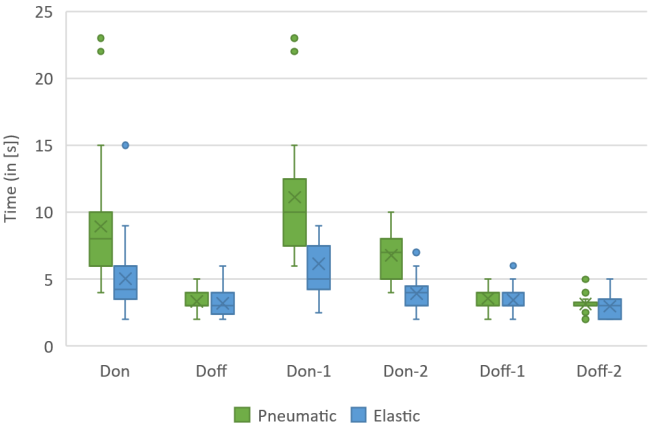

Figure 4.12: Donn and Doff times obtained from validation

Pneumatic.Doff - ***Pass*** - The maximum time of removal was 5 seconds, well under the required 30 seconds. The average removal time was 3.4 seconds. Please refer to figure 4.12.
Pneumatic.Feedback - ***Pass*** - Six error messages have been coded into the controller, to provide feedback of operation and application. The user is provided feedback in the following cases:

- The tourniquet is too loose.
- The tourniquet is not closed.
- The tourniquet was removed during operation.
- The tourniquet is leaking.

Pneumatic.Application - ***Pass*** - The pneumatic tourniquet features a cuff, formed around a so-called preform. This preform should help the user to close the cuff with one hand more easily. The arm can be inserted into the cuff at the point of the arrows, without the need for a closed loop around the arm. The user closes the loop around their arm, by latching the hook-and-loop strap.

Figure 4.13: The pneumatic tourniquet, showing the cuff around the preform.

4.3 Pneumatic Prototype - Discussion

[REDACTED]

4.4 Elastic Prototype - Results

It is important to note that I performed the verifications on the first version of the elastic prototype, which is functionally identical to the latest version, but ergonomically different. More information on the differences between the two versions can be found in secton **??**. The photos in this chapter have been taken after the initial verification and actually show the second version; however, the verifications were all performed on the first prototype.

Elastic.Adjustability - ***Pass*** - All three arm forms were placed inside the pneumatic prototype, as shown in figure 4.14. The tourniquet was operated at the standardized torque of 300 mNm for 60 seconds. The operation went as expected for each of the arm forms.

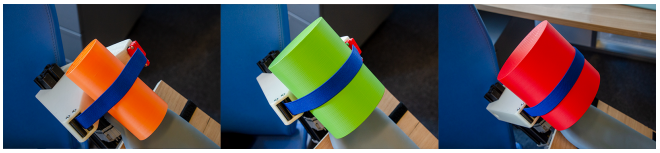

Figure 4.14: The p1 (left), p50 (center) and p99 (right) arm forms fit in the elastic prototype

Elastic.Ambidextrous - ***Pass*** - The elastic prototype was tested by 9 subjects on their left arm and 8 subjects on their right arm. In both groups, no comfort score below 2 was given, where 1 is very uncomfortable and 5 is very comfortable, this was interpreted as only minor discomfort. None of the respondents experienced pain on either arm during use of this prototype. The maximum Don and Doff times were 15 and 9 seconds for the left and right arm respectively, well within the 60 and 30 seconds limits.
Elastic.Biocompatible - ***Pass/Fail*** - The user may come into contact with three parts of the system. The arm rest, the strap and the 3D-printed parts. The arm rest is made from biocompatible synthetic faux leather [54]. The strap is made from latex free synthetic fabric, with the specific intent of human skin contact [58]. The 3D-printed parts are made from PLA bio-plastic, the same as with the pneumatic prototype. For the same reasons as mentioned above I can not conclude that the PLA parts are biocompatible.
Elastic.Comfort - ***Pass*** - An average comfort score of 3.9 out of 5 was reported with a minimum of 2. The score of 2 is interpreted as minor discomfort.
Elastic.Cost - ***Pass*** - The Bill of Materials in appendix **??** reports a total system cost of €475.53, well below the required maximum cost of €1000.
Elastic.Disinfection - ***Pass*** - The user may come into contact with three parts of the system. The arm rest, the strap and the 3D-printed parts. The arm rest is made from a synthetic leather, which is suitable for disinfection [54]. The strap is made from a latex-free material, which is washable up to 60 degrees [58]. The 3D-printed parts are made from a bio-plastic called PLA. This plastic is not suitable for higher level disinfection methods [56], but can be sterilized with isopropanol or chlorhexidine without affecting the properties of the material [57].
Elastic.Failsafe - ***Pass*** - The system consists of three main parts, an intelligent brushless motor with power supply, a microcontroller and a control PC. When power is removed from the motor, the system can no longer produce torque

and the tourniquet is relaxed. When power is lost to the micro, the enable and torque signals to the motor are no longer produced and the motor disables on its own. When power is lost to the control PC, the microcontroller also loses power and is no longer able to send the enable and torque signals. This also leads to a safe failure of the system.

Elastic.Position - ***Fail*** - The tourniquet was placed as high as 103 mm for some individuals, exceeding the 100mm maximum height. The tourniquet was placed at a height of 98mm on average.

Elastic.PressureMax - ***Pass*** - The pressure for this requirement and the following one was obtained by measuring the tension at the extremes of the pulley radius, resulting in a minimum of 830g and a maximum of 1485g, shown in figure 4.15. The resulting pressure curve is obtained from matlab, shown in the getPressureMeasured.m file in appendix **??** and shown in 4.16. The maximum pressure recorded is 74 mmHg, below the required value of 100 mmHg.

Figure 4.15: The minimum and maximum tension, at both extremes of the non-linear pulley.

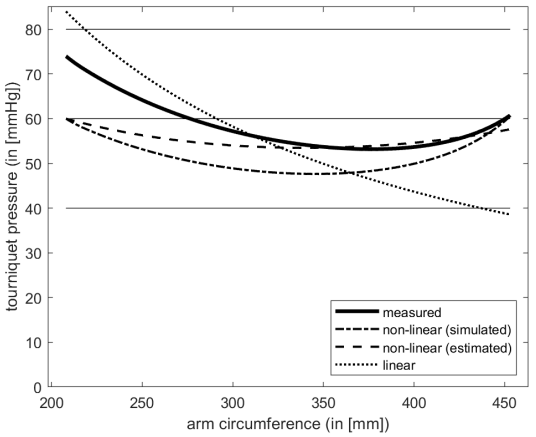

Figure 4.16: The resulting pressures from the linear pulley, an estimate of the non-linear pulley, a compensated calculation and the measured torque in the final product.

Elastic.PressureOperate - ***Pass*** - The elastic tourniquet delivers pressures between 53 mmHg and 74 mmHg over the operating range, as shown in figure 4.16. This is within the range of 40 to 80 mmHg.

Elastic.Removability - ***Pass*** - All of the subjects were able to remove the tourniquet without intervention from the researcher, even when no instructions were provided. There was no difference between the left and right arm.

Elastic.TimeOperate - ***Pass*** - The tourniquet is applied for a total of 60 seconds by the control software shown in appendix **??**.

Elastic.Usability - ***Pass*** - All 17 subjects were able to apply the tourniquet correctly without instructions or intervention from the researcher.

Elastic.Breakaway - ***Pass*** - The elastic band is held in place with a friction fit clamp, at the hook end. This acts as a built-in weak spot in the system and allows the user to retract their arm, even when the hook is still clasped. The friction fit release works especially well, for forces that are non-axial to the direction of the tourniquet. The system has been tested three times, by removing the arm form from the prototype until the breakaway.

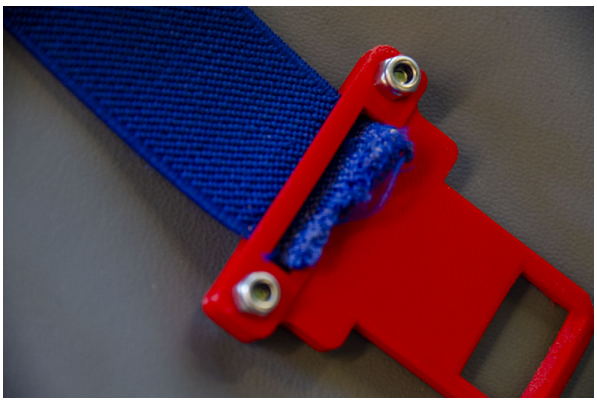

Figure 4.17: The elastic band is held in place with a friction fit clamp.

The force required has not been measured, as it varies with the angle. A mechanic will be needed to reattach the hook, making it a non-resettable break-away mechanism.

Elastic.Constrained - ***Fail*** - When prompted to move their arm in a side-to-side manner, an average transversal movement of ±11.6mm was recorded, with a maximum of ±25mm, as shown in figure 4.18. This exceeds the set maximum of ±5mm.

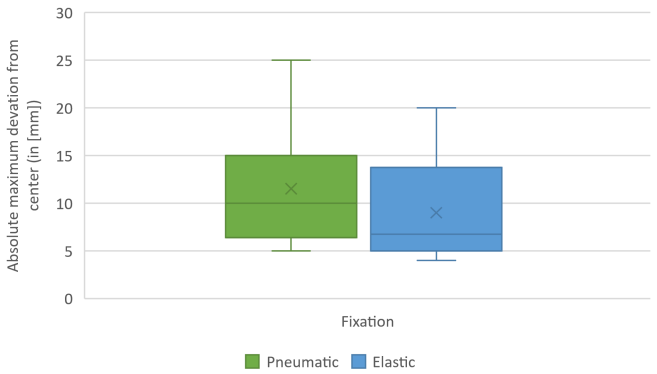

Figure 4.18: Fixation of tranversal movement, obtained from validation

Elastic.Don - ***Pass*** - The respondents were able to apply the tourniquet in 5.0 seconds on average, with the maximum application time being 15 seconds. This is well within the set maximum of 60 seconds. Please refer to figure 4.12.
Elastic.Doff - ***Pass*** - The average time of removal was 3.2 seconds, with a maximum of 6 seconds. This is well within the maximum removal time of 30 seconds. Please refer to figure 4.12.
Elastic.Feedback - ***Pass*** - The tourniquet features a clicking sound when the seatbelt-like mechanism is closed sufficiently. This form of feedback is similar to the feedback experienced with an actual feedback and should provide users with a sense of familiarity.
Elastic.Application - ***Pass*** - The tourniquet does not feature any closed loops and uses a seatbelt-like mechanism to close around the arm. The user is expected to close this mechanism themselves.

4.5 Elastic Prototype - Discussion

[REDACTED]

5 Validation

[REDACTED]

6 Discussion

[REDACTED]

7 Conclusion

[REDACTED]

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Appendix A: Appendices

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