Erectiometer: A device for measuring nocturnal erectile function

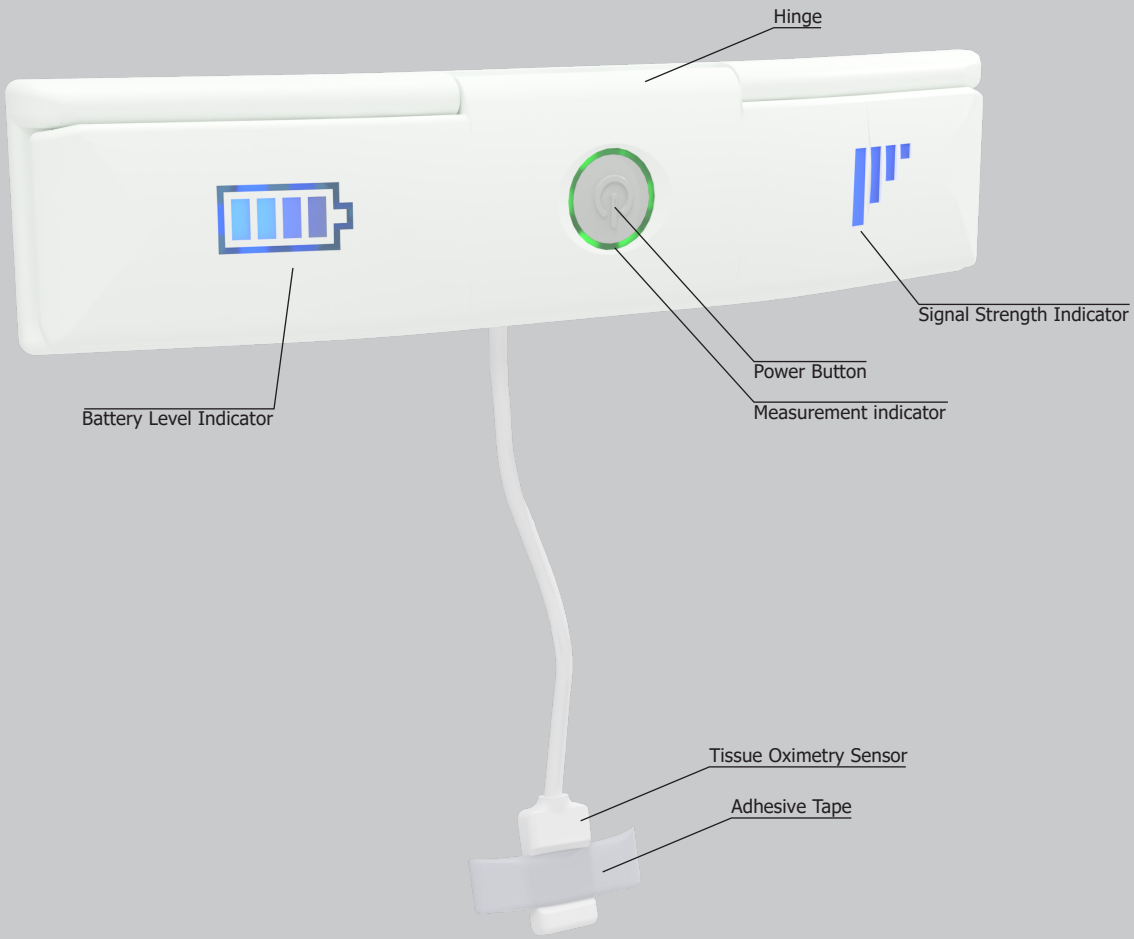

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Table of Contents

1. Introduction

The idea for this project was created by two Urologists at the Erasmus MC in Rotterdam. The design goal was to develop a diagnostic device that can be used to measure nocturnal (i.e. nightly) erections. The current device used to measure nocturnal erections was developed in the 1980s. There is a need for a modern tool that can be used in the diagnosis of erectile dysfunction.

1.1 Erectile Dysfunction

Erectile dysfunction (ED) is defined as the inability to achieve or maintain an erection sufficient to permit satisfactory sexual intercourse (Shamloul et al. 2013). A study from 2017, for the Rutgers Institute, found that in the Netherlands 9% of men suffer from ED (Seksuele gezondheid in Nederland 2017) Broadly there are two categories of ED, (1) psychogenic and (2) organic, each having their own underlying causes.

1.2 Problem

Currently, there are limited diagnostic tools for patients with ED. These diagnostic tools are unable to provide reliable, or accurate data. In addition, these tools are often uncomfortable for the patient or are invasive.

The most common diagnostic tool for ED is obtaining a detailed medical history followed by a sexual health questionnaire. The questionnaire asks a series of questions regarding sexual health and is often paired with a doctor's appointment where the patient will verbally communicate with a urologist regarding their symptoms and complaints. This can be an intimate or sensitive subject to discuss and miscommunications between patients and physicians about specific problems are common.

1.3 Design goal

Following the conclusion of the project, I plan to present a device that can measure the number, duration and intensity of nocturnal erections. The device should provide urologists and researchers insight into the physiology during a nocturnal erection.

1.4 Approach

First, I conducted an in depth analysis both on the anatomy of the penis as well as the physiological changes that occur during an erection (Chapter 2).

Secondly, I examined ED, specifically its prevalence and various causes. I examined the current patient journey and diagnosis for patients experiencing ED symptoms, as well as the presence of nocturnal erections and the use of nocturnal penile tumescences (NPT) monitoring as a diagnostic tool. I then conducted a literature review about all of the current and past methods used to measure NPT. From the review I generated a detailed list of how each of the current methods work and their pros and cons. Once I had an understanding of current methodologies for NPT monitoring and their associated technology, I began researching the possible ways to improve on these measurements and provide insight not only about the external changes that occur during an erection but also the measurable physiological changes of the penis.

During each step of the process I used the weighted objectives method (Roozenburg and Eekels, 1995), to make specific design decisions to chose which methods were most suited for making a device, hereafter called the Erectiometer. I conducted design analysis focusing on the ergonomics of the device looking into both how to attach the sensor directly to the penis and how to mount the associated larger peripheral electronics (Chapter 7: Ergonomics). I present my findings and design plan regarding the nocturnal erection monitoring device: **Erectiometer.**

ANALYSIS

2. Anatomy and Physiology of the Penis

2.1 Anatomy of the Penis

The penis consists of three cylindrical structures of erectile tissue: two dorsal corpora cavernosa and a ventral corpus spongiosum (Quartey, 2006). The corpus spongiosum extends distally into the glans. The glans covers the distal ends of the corpora cavernosa. The urethra transverses the corpus spongiosum and terminates in the glans. Each corpus is surrounded by a fibrous tissue capsule, called the tunica albuginea. The structure of the tunica albuginea provides flexibility, rigidity, and tissue strength to the penis (Brock et al. 1997). The tunica is surrounded by the Buck's Fascia or Deep Fascia. Buck's fascia is a sheet of connective tissue that holds the corpora together (Figure 1).

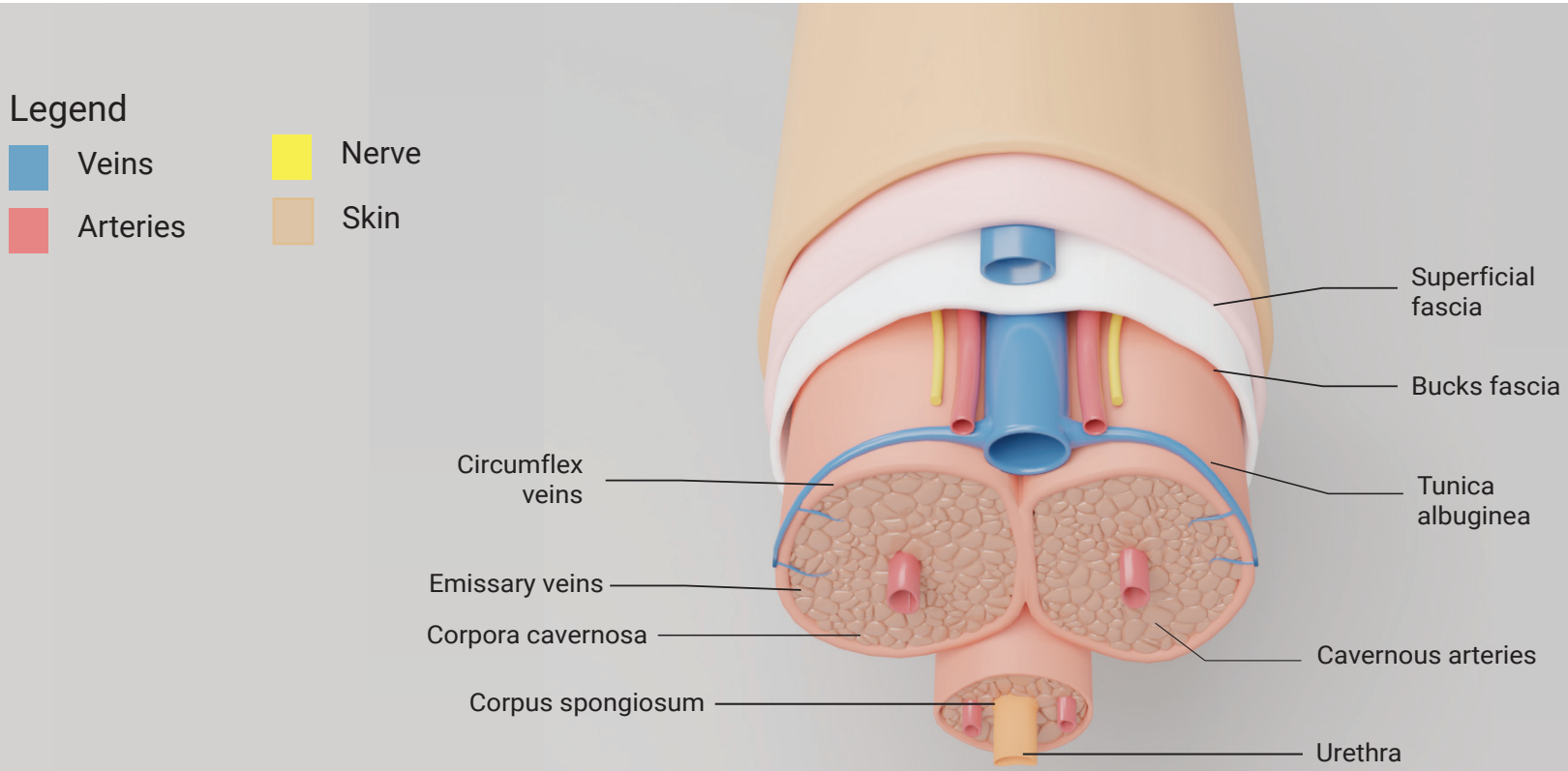

Figure 1. Shows a diagram of the basic penile anatomy. Diagram was adapted from Quartey, 2006.

2.1.1 Corpora Cavernosa

The corpora cavernosa are composed of a mesh of erectile tissue with large interspaces capable of filling with blood. The two corpora are separated by an incomplete septum, which allows blood to flow from one corpus cavernosum to the other (Andersson and Wagner, 1995).

Each corpus cavernosum has an artery in the center called a cavernous artery (Figure 2). The cavernous artery consists of three layers, the endothelium, a layer of smooth muscle tissue, and a layer of connective tissue. In the flaccid state, these cavernous arteries are constricted by the smooth muscle tissue layer, which allows only a small amount of blood to the corpus cavernosum. During an erection, the smooth muscle layers in the cavernous artery relax, allowing more blood to go to the corpora cavernosa. The primary function of the corpora cavernosa is to provide enough rigidity to the penis for sexual intercourse.

2.1.2 Corpus Spongiosum

The corpus spongiosum is also composed of a mesh-work of connective tissue with large sinuses capable of being filled with blood. In the center of the corpus spongiosum is the bulbourethral artery that runs through the center, bringing blood to the tissue (Figure 2).
The main function of the corpus spongiosum is to prevent the urethra from being compressed by the corpora cavernosa and allow for ejaculation. The pressure in the corpus spongiosum remains much lower, compared to the corpora cavernosa.

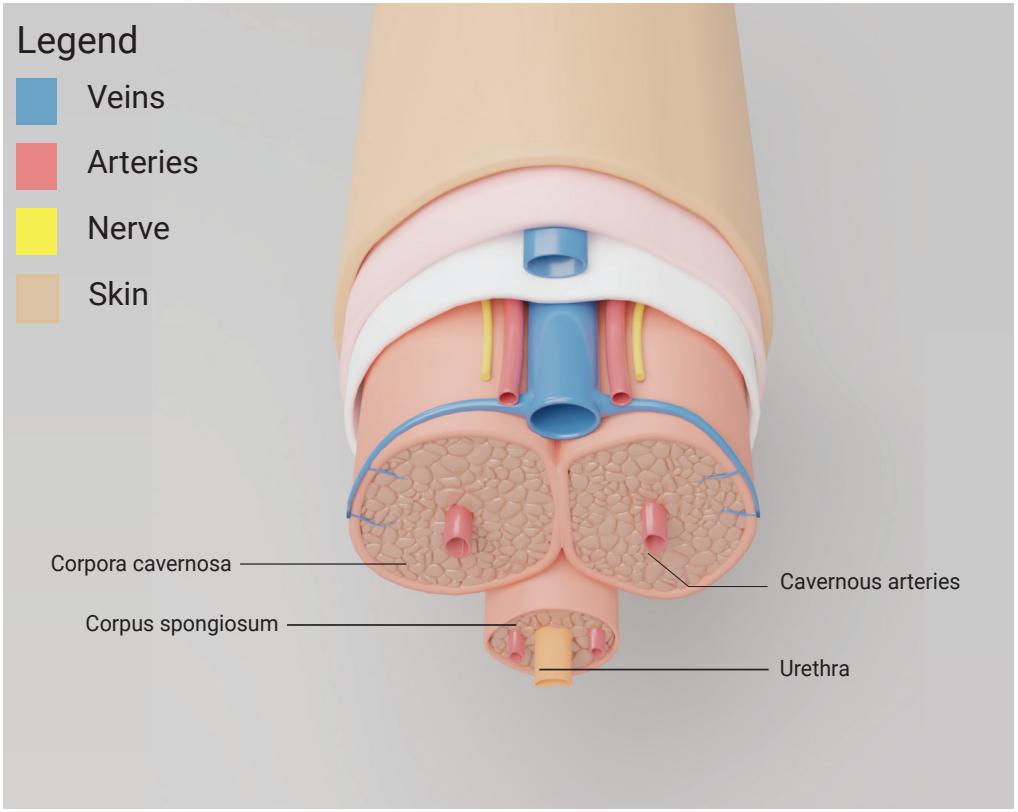

Figure 2. Shows the corpora cavernosa, the corpus spongiosum, the cavernous arteries, and the urethra. Diagram was adapted from Quartey, 2006.

2.1.3 Tunica Albuginea

Each corpus is surrounded by a fibrous tissue capsule, called the tunica albuginea (Figure 3). The tunica albuginea is composed of two distinct layers of fibrous tissue consisting of an outer longitudinal layer and an inner circular layer (Brock et al. 1997). The structure of the tunica albuginea provides flexibility, rigidity, and tissue strength to the penis (Brock et al. 1997). The tunica albuginea surrounding the corpus spongiosum is much thinner (Andersson et al., 1995), which allows the corpus spongiosum to expand more.

2.1.4 Buck's fascia

The tunica albuginea is surrounded by Buck's fascia, which is a structure composed of a single sheet of connective tissue. During an erection, the three corpora expand, which causes the tunica albuginea to get pressed against Buck's fascia. Emissary veins are found within Buck's fascia and are the veins that drain most of the blood from the three corpora. The emissary veins lead into the circumflex veins, which continue into the deep dorsal vein (Figure 3). When the circumflex and deep dorsal veins are constricted there is reduced blood outflow from the corpora cavernosa, causing blood to stay in the erectile tissue leading to an erection.

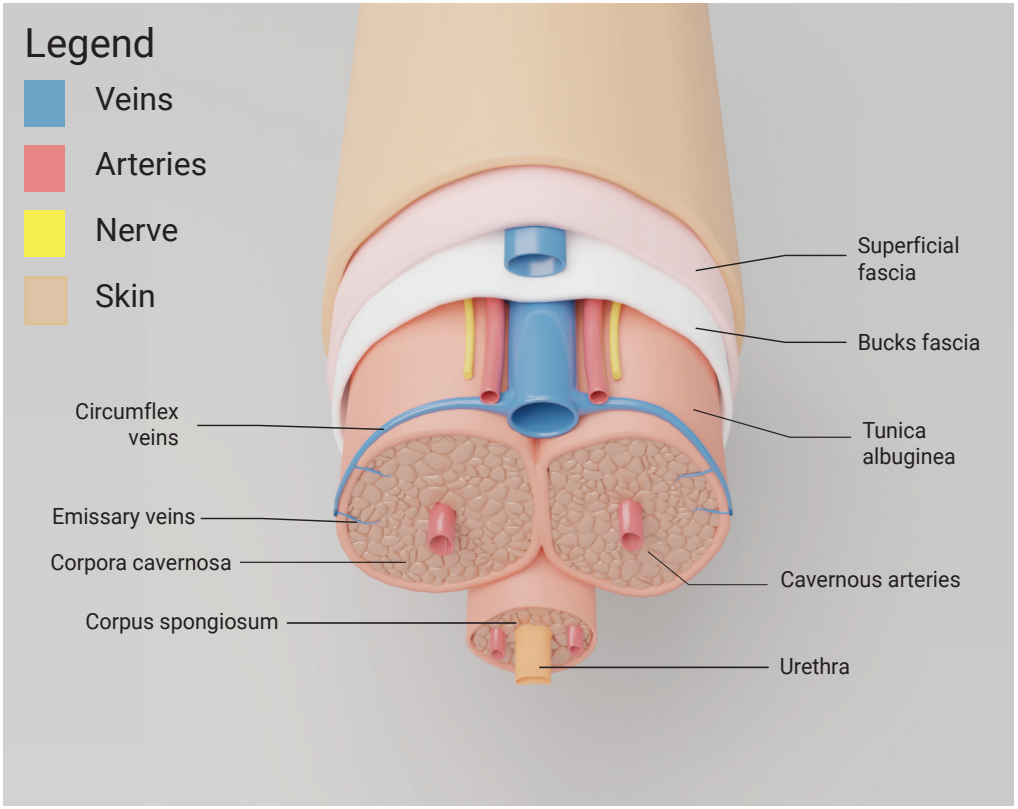

Figure 3. Shows the corpora cavernosa, the corpus spongiosum, the cavernous arteries, the urethra, the circumflex veins, the emissary veins, the tunica albuginea, the bucks fascia, and the superficial fascia. Diagram was adapted from Quartey, 2006.

2.2 Physiology of Erections

2.2.1 Flaccid State

In the flaccid state, the smooth muscles in the cavernous arteries constrict, restricting blood flow to the corpora cavernosa. In the flaccid state, the blood pressure and tissue oxygen saturation are at venous levels (blood pressure < 5 mmHg, StO2 <60%).

2.2.2 Release of Neurotransmitters

In response to a sexual stimulus, neurotransmitters are released, which causes an increase in the production of cyclic guanosine monophosphate (cGMP). The cGMP relaxes the smooth muscle of the arterial walls (El-Sakka et al. 2004), which allows blood to flow into the corpora cavernosa.

2.2.3 Arterial Inflow

The relaxation of the smooth muscles of the arterial walls reduces the flow resistance and allows more blood into the three corpora (El-Sakka et al.,2004). During this relaxation, the blood pressure within the corpora cavernosa rises to arterial levels (i.e., 100mm Hg). With the increase in blood inflow, the tissue oxygen saturation (StO2(%)) increases (Padmanabhan et al., 2007). The tissue oxygen saturation refers to the percentage of oxygen-saturated red blood cells in the tissue.

2.2.4 Stretching of the Tunica Albuginea

The expansion of the corpora cavernosa causes the tunica albuginea to expand and stretch to its capacity. Due to the makeup of the fibers of the tunica albuginea, stretching the tissue will constrict the outflow of the emissary veins that go through the tunica. This reduction in outflow further increases the intracavernous pressure in the corpora cavernosa (El-Sakka et al.,2004), which will result in a more rigid penis, both axial (i.e. along the shaft) and radial (i.e., circumference) (Tal et al., 2009).

2.2.5 Venous Occlusion

As the inflow of blood into the corpora cavernosa increases, the corpora cavernosa expands. This expansion compresses the circumflex and deep dorsal veins against Buck's fascia, which reduces the outflow of blood through the veins . This increase in blood inflow paired with a reduction in blood outflow causes an increase in intracavernous pressure (ICP) in corpora cavernosa. This pressure increase leads to external changes in the penis (Figure 4).

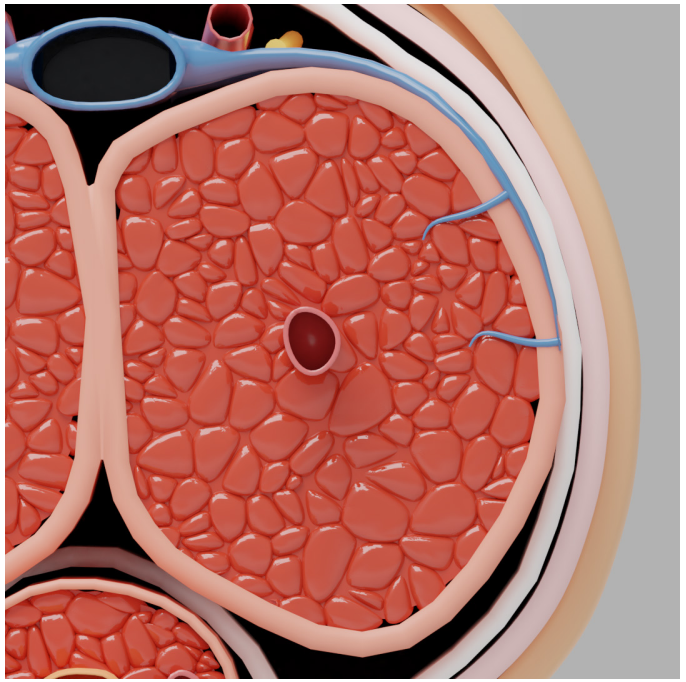

Figure 4. The penis during an erection. The corpora cavernosa are filled with blood, the cavernous artery is dilated and the tunica albuginea is being stretched compressing the emissary veins. Diagram was adapted from Quartey, 2006.

2.2.6 Physiological Changes During Arterial Inflow

There are some distinct physiological changes that can be detected during the arterial inflow phase of the erection (Table 1). Firstly, during the relaxation of the smooth muscles, the blood pressure in the corpora cavernosa rises significantly, which can make the pulse more pronounced. In addition, the blood in the corpora cavernosa will contain less CO_2, compared to the flaccid state, which can lead to an increase in the pH of the blood in the corpora cavernosa. Lastly, the increase in blood flow can lead to an increase in the temperature of the three corpora and eventually the whole penis (Solnick & Birren, 1977).

2.2.7 External Changes During an Erection

An erection event not only changes the physiology of the penis, there are also external changes. For example, during an erection as blood fills the corpora, the volume, density, and weight of the penis all increase. In addition, both the circumference and length of the penis increase during an erection event (Table 1).

Table 1. Internal and external changes that occur during an erection.

Internal Changes in the Penis	
Smooth muscle relaxation	Blood O_2 increases
Blood inflow increases	Visibility of the pulse
Blood outflow decreases	Temperature increases
Blood pressure increase	pH of the blood increases

External Changes in the Penis	
Circumference Increases	Skin Strain
Length Increases	Orientation Change
Volume Increase	
Density Increases	

2.3 Erectile Dysfunction

2.3.1 Erectile Dysfunction

ED is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual activity. Broadly there are two categories of ED, (1) psychogenic and (2) organic, each having their own underlying causes.

2.3.2 Psychogenic ED

Psychogenic ED represents an erectile disorder associated with psychosocial health. Factors such as anxiety, depression, loss of self-esteem, previous traumatic sexual experiences, suspicions in sexual roles, physical disorders in spouses and lack of attraction, sexual myths, or socio-economic factors, play a role in this type of ED (Celik et al. 2014).

2.3.3 Organic ED

There are a variety of factors that can cause organic ED. The major organic causes can be subdivided into (1) vascular, (2) neurogenic, and (3) hormonal (Papagiannopoulos et al., 2015). Erectile dysfunction has an organic basis in approximately 80% of men (DeWire, 1996; Hatzichristou et al., 2002, Figure 5).

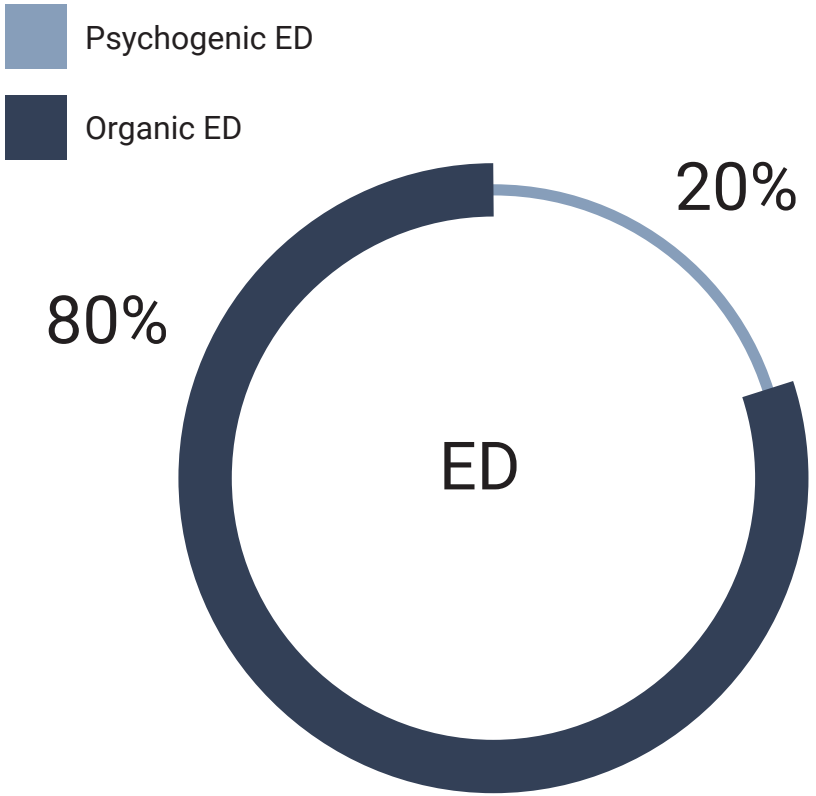

Figure 5. 80% of ED has an organic cause, while only 20% of diagnosed ED has a psychogenic cause.

2.3.4 Causes of Organic ED

Vascular

Vascular diseases can affect blood flow to the penis, which can directly impact the quality and function of erections (Ponholzer et al. 2005). The most common vascular disorders include focal arterial occlusive disease, endothelial dysfunction, and Peyronie's disease (Papagiannopoulos, et al, 2015): (1) Focal arterial occlusive disease is a blockage or narrowing of an artery that results in decreased blood flow (Papagiannopoulos, et al, 2015); (2) Endothelium is the single layer of flattened cells that lines the blood vessels, the heart, and some of the cavities of the body. Endothelium can be damaged by smoking, hypertension, or diabetes. Damage to the endothelium results in the inability of the smooth muscles lining the blood vessels to relax, which prevents dilatation of the blood vessels (Kaya et al. 2006); (3) Finally, in Peyronie's disease fibrous scar tissue develops in the penis, causing an increase in venous leakage.

Neurogenic

Neurogenic ED accounts for about 10% to 19% of all ED cases (Thomas et al. 2021, Figure 6). Neurogenic causes can stem from diseases affecting the central or peripheral nervous systems. The central causes are degenerative disorders such as Parkinson's disease, multiple sclerosis (MS), multiple atrophy, spinal cord trauma, stroke, or central nervous system tumors (Thomas et al. 2021). Whereas, peripheral causes are Type 1 and 2 diabetes mellitus, chronic renal failure; chronic liver failure, and any major urinary or pelvic surgery. Furthermore, many neurogenic conditions have overlapping characteristics, for example, patients with diabetes mellitus may have both a vasculogenic and a neurogenic component (Thomas et al. 2021).

Hormonal (Endocrinological)

Androgens are the hormones that play a role in male reproductive activity. The major androgen in males is testosterone. Studies have shown that a decline in testosterone can be linked a reduction of smooth muscle cells due to increased cell death or apoptosis for smooth muscle cells in the blood vessels (Yafi et al. 2017). This can lead to a decrease in ICP in the penis due to a reduction in blood inflow.

Other

ED can also be caused by surgery in the pelvic region, radiation therapy, or pharmaceutical intervention (i.e., hormone suppression therapy). Patients that have been diagnosed and undergone treatment for prostate cancer have a higher risk for developing ED.

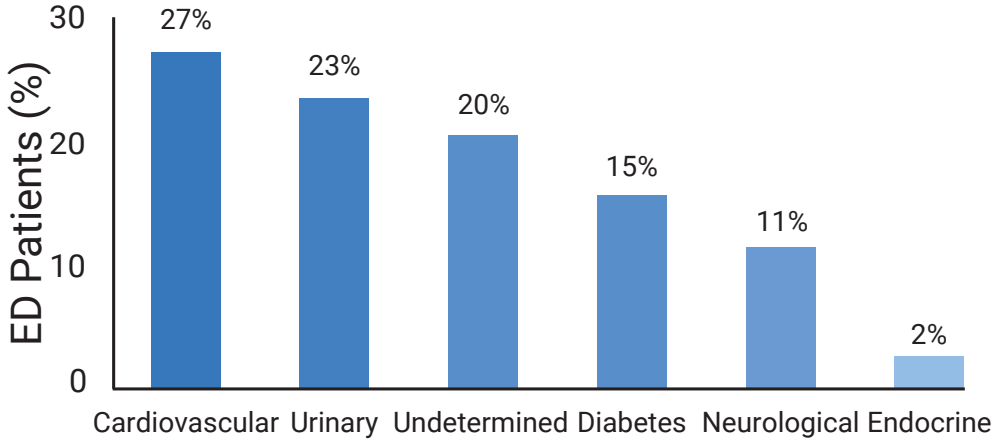

Figure 6. Prevelance of causes in patients with diagnosed organic ED (Hatzichristou et al., 2002)

3. ED Diagnosis

3.1 Patient Journey

The European Association of Urologists has written guidelines for the diagnosis and treatment of ED. When a patient comes in and complains of problems associated with sexual function, the patient journey consists of three steps: (1) Medical and sexual history (2) Physical examination, and (3) Laboratory tests (Figure 7).

Medical History

It is important for the physician to understand all of the underlying risk factors that can contribute to ED. The most important risk factors are age, diabetes, hypertension, coronary artery disease, and smoking (Shah 2002). In addition, it is important to determine if there are any other physical conditions that might be causing vascular injury or endocrine imbalance (Shah 2002).

Sexual History

The urologist needs to obtain a sensitive sexual history in order to define the patient's complaints and distinguish between ED or if the patient is experiencing changes in sexual desire, or disturbances in orgasm or ejaculation (Levine 2000). The doctor can use these specific questions to ascertain if the patient's complaints are ED or if the patient is experiencing a different type of medical condition such as premature ejaculation.

The second part of the sexual history involves the patient filling out a questionnaire called the Sexual Health Inventory for Men. This questionnaire asks various questions about sexual function and experience and asks the patient to respond on a scale of 1-5 (1=least function, 5=most function). Total scores on the questionnaire range from 5-25. Scores of 22 or higher indicate normal erectile function, while in contrast, low scores of below 11 indicate moderate to severe ED (Rosen et al. 1994).

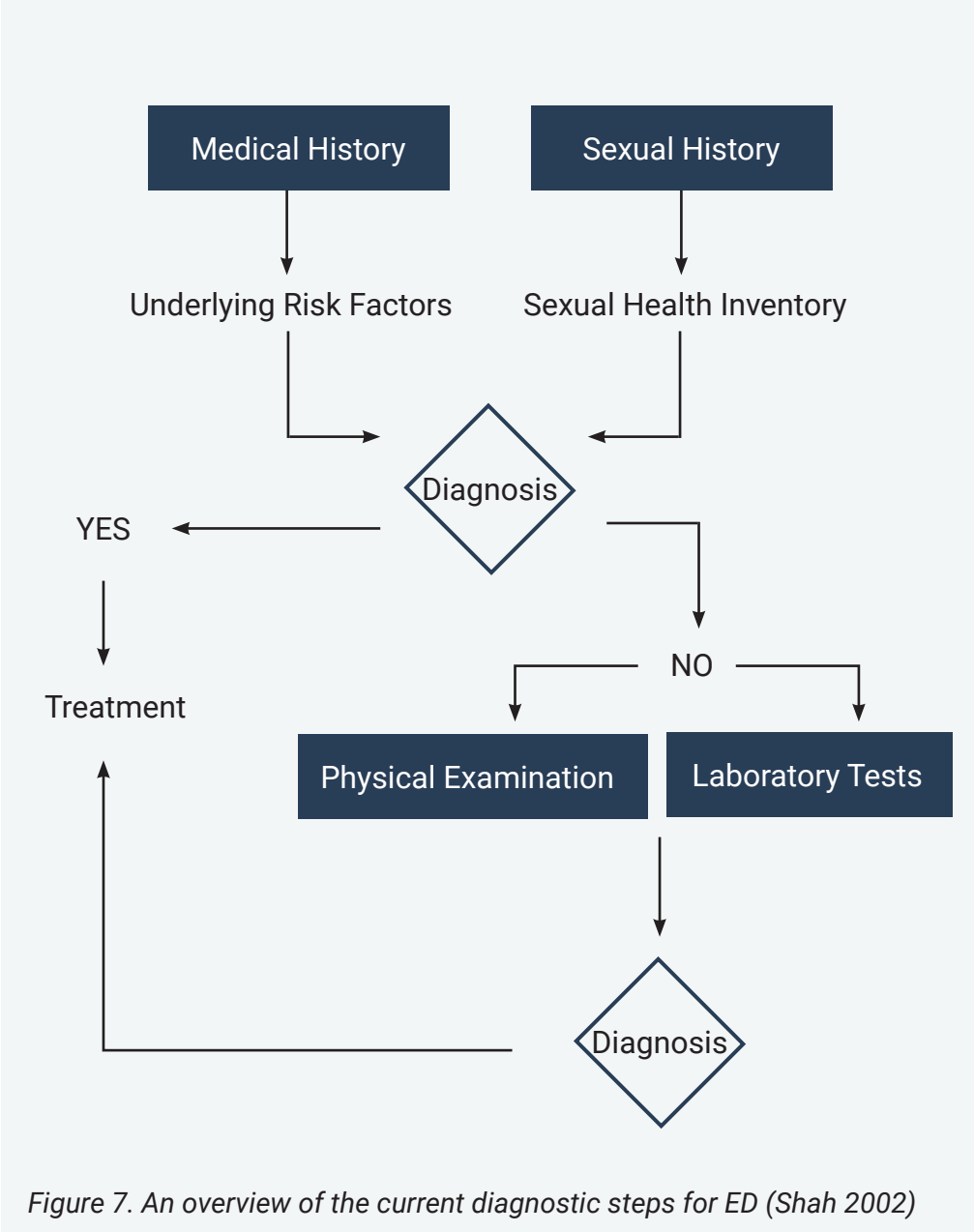

Figure 7. An overview of the current diagnostic steps for ED (Shah 2002)

Patient Expectations
Furthermore, it is important to have a discussion with the patient to determine the expectations that the patient might have with regard to their treatment outcome (Miller 2000). In addition, it is important to be clear about what the patient wishes to achieve from the treatment. It is important to assess the type of sexual contact desired by the patient, and potentially the frequency of sexual contact. Men with erectile dysfunction and their partners often lack a full understanding of sexual processes or have unrealistic expectations regarding sexual performance and satisfaction (Rosen et al., 1994). Therefore, it is important to have clear communication regarding the patient's needs regarding their treatment outcomes.

Miscommunication between doctors and patients
In the current diagnostic method, physicians are reliant on the patient reported symptoms. The information the physicians receive is limited by the patient's lack of knowledge regarding the erection process and the basic anatomy of the penis. Physicians need to find a way to communicate the problem in a way that the patients can easily understand and tailor their communication to different levels of knowledge.

Furthermore, a patient can only report on the symptoms that he experiences and is aware of. One way to mitigate this problem is for doctors to have access to a tool that provides concrete data on the nocturnal erectile function.

Physical Examination
The physical examination should assess the patient's overall health. Particular attention should be given to the cardiovascular, neurological, and reproductive systems, as these systems are directly involved with erectile function (Miller 2000). Cardiovascular system health should be examined by assessing the patient's vital signs (especially blood pressure and pulse) and more specifically looking for signs of hypertensive or ischemic heart disease. In addition, asymmetric or absent lower extremity pulses are indicative of vascular disease, which is a significant risk factor for ED (Miller 2000).

An examination of the genitals should assess the presence of local abnormalities, such as hypospadias, which is a variation in fetal development of the penis in which the urethra does not open from its usual location in the head of the penis, or phimosis, which is defined as the inability to retract the skin (foreskin or prepuce) covering the head (glans) of the penis. In addition, beard, body hair, and voice should be evaluated for signs of hypogonadism. The penis should be palpated to determine the presence of local abnormalities such as fibrous plaques of the fascial covering which can be indicative of Peyronie's disease (Miller 2000).

Laboratory Tests
If the first basic examinations show no apparent underlying cause for ED, it is also critical to identify unrecognized systemic conditions that may predispose to erectile dysfunction. Laboratory tests such as complete blood count, urinalysis, renal function, lipid profile, fasting blood sugar, and thyroid function can give the physician more information about potential causes of the patient's ED (Miller 2000). Furthermore, it is also recommended to do a basic endocrine screening, which involves basic testosterone and prolactin measurements. If these measurements reveal abnormalities, more detailed hormone panels should be conducted (Miller 2000).

3.2 Nocturnal Erections

Nocturnal penile tumescence (NPT) refers to erections that occur during REM sleep. These erections are not caused by sexual stimuli and their exact cause is currently unknown (Tokatli et al. 2006). In healthy men, 3 to 6 erections occur per each 8 hour sleep period (Zou et al. 2019) and typically last an average of 54 min (Tokatli et al. 2006). NPT occurs in healthy men throughout their entire life and functions to keep the corpora cavernosa healthy by bringing oxygen and other metabolites to the tissue (Moreland, 1998).

3.2.1 Psychogenic vs Organic ED using NTP

Measuring NPT can help doctors differentiate between physiological and organic causes of ED (Elhanbly et al. 2014). It is generally assumed that during sleep psychological factors cannot interfere with nocturnal erection. Thus, monitoring the presence of normal nocturnal erections is an effective way to understand if the mechanical aspects of an erection are functioning properly.

3.3 Nocturnal Erection Measurements

Stamp Method

The Stamp method is a simple non-invasive way to measure a nocturnal erection. In this method, four stamps, with a total width of five inches, are applied to the shaft of penis to form a snug wrap. There is a portion where the stamps overlap, which creates a one-half-to-one stamp overlapping seal (Barry et al. 1980). If two stamps break apart at the seal, this is noted as an erection event due to the increased volume necessary to break the seal.

Erection Meter

In this method, a sliding band and a slit tube are used to measure the changes in penile circumference (Qin et al. 2018; Figure 8).

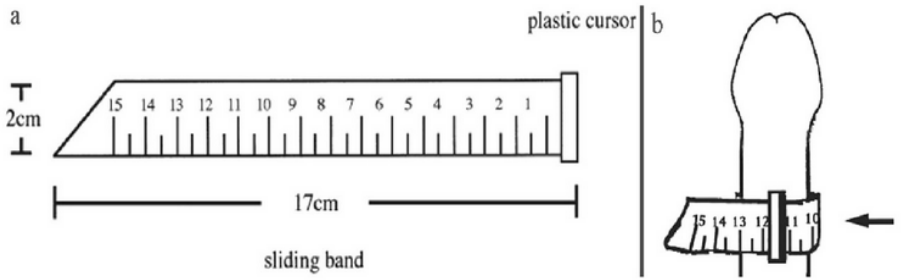

Figure 8. The sliding band (a) is wrapped around the penis (b) and used to measure circumference (Qin et al. 2018).

Snap Gauge

In this method, a piece of non-stretchable fabric with Velcro tape at one end is fitted around the penile shaft. Three snap release fasteners with release forces of 8, 12, and 16 ounces are locked. These release forces represent 90-160 mmHg of intracavernous pressure in the penis. If any of these fasteners are broken after the course of a nocturnal measurement, this is used to estimate rigidity and indicate an erection event (Qin et al. 2018).

Rigiscan
The Rigiscan is used to measure penile circumference and penile radial rigidity (Edgar et al. 2020). The Rigiscan consists of two non-elastic loop cables, which are attached to the penis at the base of the shaft and below the glans (i.e., the tip). These loop cables are attached to a slide potentiometer, which is a sensor that measures the change in penile circumference (Edgar et al. 2020). The circumference of the penis is measured every 15 seconds over the course of the nightly measurement(Chen et al. 2018; Figure 9).

To measure the radial rigidity a motor exerts a known force on the loop cables, this causes the loops to tighten around the penis and a certain displacement. Using this displacement value the radial rigidity can be calculated (Edgar et al. 2020)

An erection event is defined as a change in circumference of at least 3 cm at the base of the penis and at least 2 cm at the tip, with a rigidity of at least 70% for a duration of at least ten min (Allen et al. 1993). Figure 8 shows an image of the rigiscan, that shows how the cable loops are attached to the penis and how the device is attached to the leg (Qin et al. 2018).

3.4 Conclusion
These methods mentioned above have significant downsides when used for the diagnosis of ED. These methods tend to be inaccurate and uncomfortable for the patient, and therefore, they are not reliable as a diagnostic tool for erectile dysfunction. In addition, most of these methods only provide information about external changes during an erection event and shed little light on the underlying physiological changes during an erection. Through the analysis of how each measurement tool works and what is needed to create a new tool for nocturnal erection measurements, I created a list of requirements for the development of the Erectiometer (Appendix A).

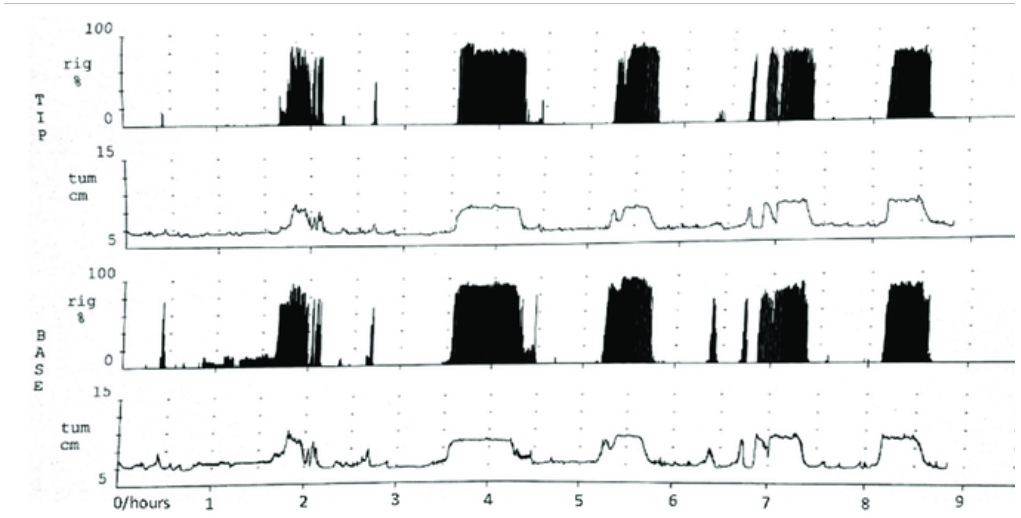

Figure 9. (Top) Rigiscan electronics and penile stain gauges, (Bottom) NPT measurements over the course of 9 hours for a single patient with ED. TIP and BASE: the tip and base of the penis. Rig and tum: the rigidity and tumescence of the penis. (Allen et al. 1993).

DESIGN

4. Nocturnal Measurements

4.1 Overview of Internal Changes

There are five physiological internal changes that occur during a nocturnal erection. Internal changes give doctors more insight into specific physiological changes, compared to external changes. Four of these internal changes can be measured in a non-invasive way: blood flow, blood pressure, blood oxygen, and temperature.

4.1.1 Blood Flow

During the transition from the flaccid to the erect state, smooth muscles in the arterial walls of blood vessels leading into penis relax, this reduces the resistance of flow and allows more blood into the three corpora (El-Sakka et al. 2004). There are multiple methods of measuring blood flow, however, in this project, water based plethysmography is the most feasible.

Water based plethysmography

A pulse-volume-plethysmograph (PVP) is a device that measures blood flow during an erection (Lavoisier et al. 2002). The device consists of a flexible cuff that wraps around the penis. The cuff is attached to a vertical tube going up to a bag filled with water. The difference in height between the cuff and the bag keeps the pressure in the cuff constant. Changes in blood flow in the penis result in a change in volume in the cuff, which can be measured in the tube. This method has been used by Lavoisier et al. 2002 (Figure 10).

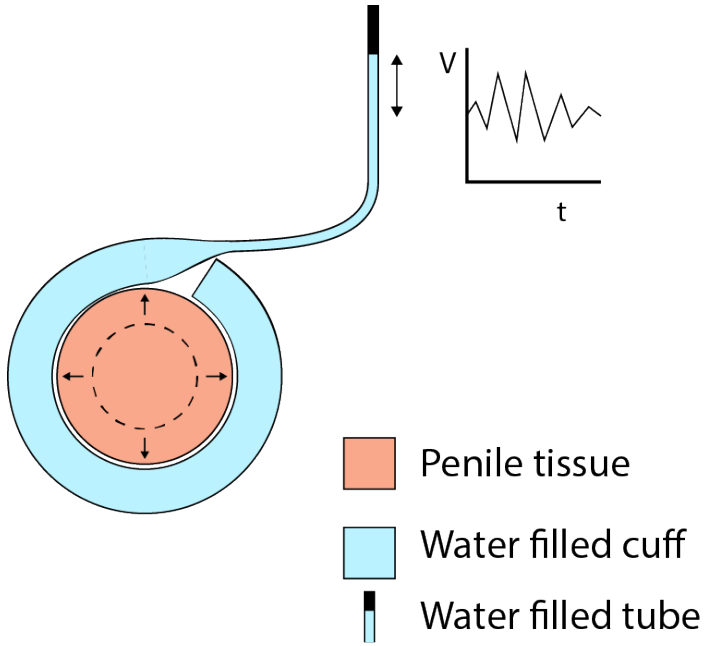

Figure 10. A water filled cuff is wrapped around the penis. Changes in blood flow in the penis result in changes in the volume of the cuff. The graph on the top right shows the change in volume (V) over time (t) in the cuff (Lavoisier et al. 2002).

4.1.2 Blood Pressure

As the blood flow increases during an erection the blood pressure within the corpora cavernosa also increases.

Blood pressure

In this method a strap with air cushions is wrapped around the penis. The air cushions are then inflated to a pressure above the systolic blood pressure. The pressure is then slowly released. Once the pressure is equal to the systolic pressure, the blood pressure in the penis will affect the pressure in the air cushions. This can be seen as fluctuations in the pressure graph (Figure 11). As soon as the pressure in the air cushions is lower than the diastolic pressure of the blood, the blood in the penis will no longer affect the pressure in the air cushion. A pressure measurement could be taken every ten minutes during the nocturnal measurement period. This method is theoretical and the adaptation for use on the penis was derived from Gaskell, 1971, and James and Gerber, 2018.

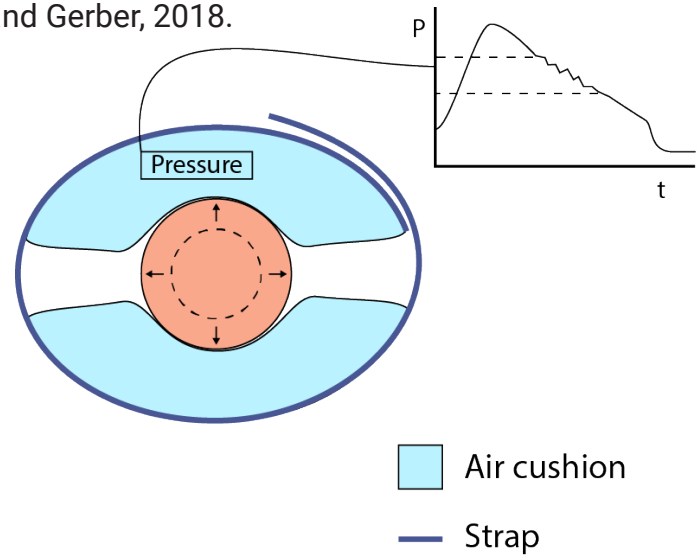

Figure 11. A strap with air cushions wrap around the penis. The blood pressure in the penis will affect the pressure in the air cushions. The graph on the top shows changes in air pressure in the cushions (P) over time (t).

4.1.3 Blood Oxygen

With the increase in blood inflow, more oxygen reaches the three corpora and the blood oxygen saturation increases (Padmanabhan et al., 2007).

Pulse Oximetry

Pulse oximetry includes a red light, an Infrared light (IR), and one photodiode (sensor). There is a differential absorption of light by hemoglobin. Hemoglobin is the main oxygen binding protein in blood. Hemoglobin that is bound to O_2 absorbs more IR light, while hemoglobin without O_2 absorbs more red light (Figure 12). Pulse oximetry makes use of this different light absorption spectra hemoglobin in order to calculate an arterial oxygen saturation (SpO_2).

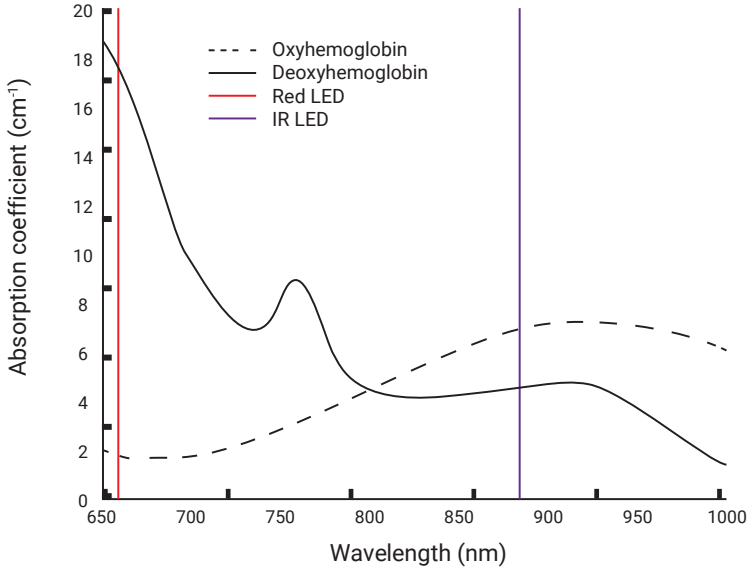

Figure 12. The differential absorption spectrum of Oxyhemoglobin (bound to Oxygen) and Deoxyhemoglobin (not bound to Oxygen). The vertical red and purple lines indicate the wavelengths of light being emitted by the Red LED and IR LED respectively. Diagram was derived from Kim and Liu, 2007.

Tissue Oximetry
Tissue oximetry is a form of near infrared spectroscopy (NIRS). There are a few different approaches to NIRS measurements, however, in this case, I will discuss Continuous Wave (CW) Spatially Resolved Spectroscopy (SRS). This method includes a red light and an IR light source and two photodiodes (sensors). It measures the light absorbance over two distances(Figure 13). This makes it possible to calculate a tissue oxygen saturation (StO_2), which is defined as the ratio between the concentration of oxygenated hemoglobin to the total concentration of hemoglobin (Lindkvist 2013).

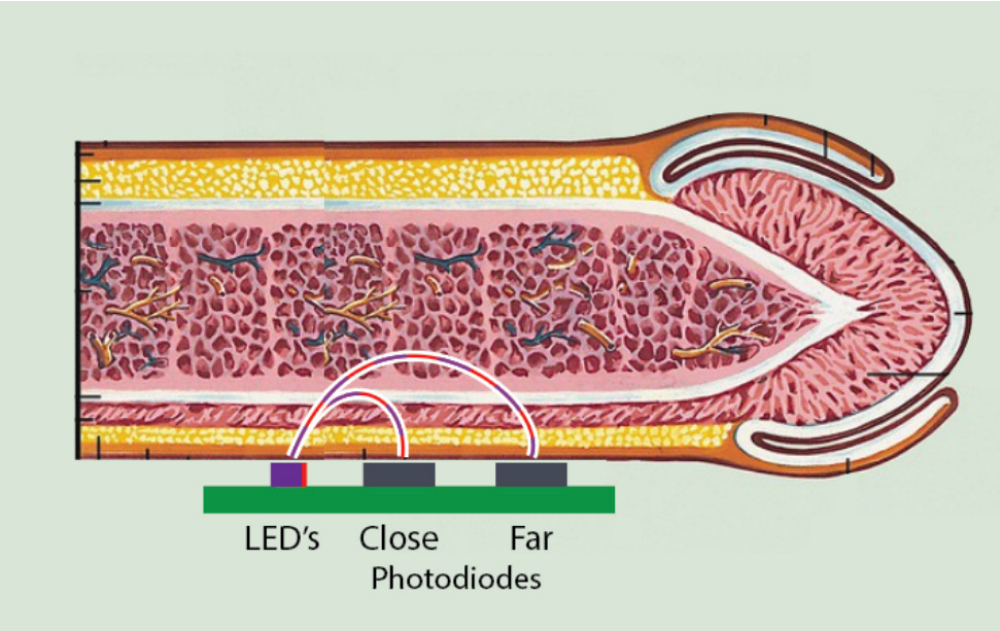

Figure 13. Diagram of the penis showing the path of the light from the LED to the photodiodes through the tissue. Adapted from Sanchez and Cubilla 2020.

4.1.4 Temperature

With increased blood inflow, the internal temperature of the penis will increase. This in turn causes the skin temperature to increase. Temperature sensors can thus indicate if there is increased blood inflow into the penis compared to the flaccid state.

Thermistor
A thermistor is a small sensor (1mm) that makes direct contact with the skin and measures temperature (Figure 14). In this method, the thermistor is embedded in the fabric of the underwear and secured to the penis. Environmental temperatures can be monitored with extra sensors placed at a small distance from the skin.

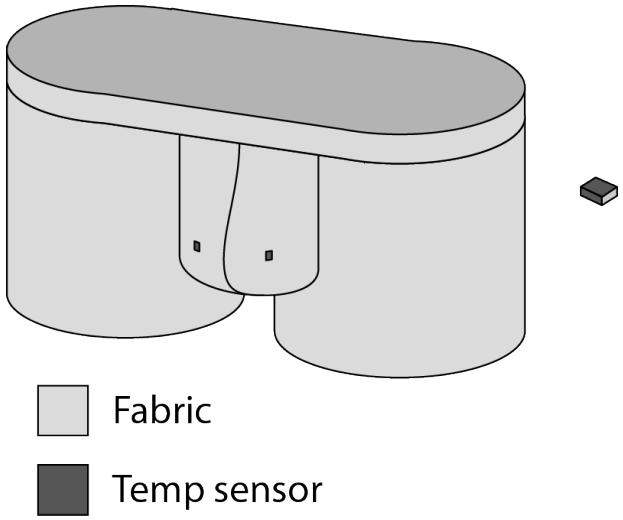

Figure 14. Fabric underwear with an embedded temperature sensor that can be attached to the skin of the penis.

4.2 Measurement Method Choice

To decide which measurement method is best suited for this application, the weighted objectives method (Roozenburg and Eekels, 1995) was used. Each of these measurement methods were evaluated based on four wishes for the device. The wishes are displayed in the rows of table 2. Each wish was given an importance score ranging from (0-10). Each measurement method was then scored 1-10 based on its ability to satisfy that specific wish. These scores are shown in color. The importance score and the satisfaction score were then multiplied together and each measurement method was given an overall score.

The four most important wishes consist of the following (Table 2):
(W1.1) The product should provide as much insight into the physiological functioning of the erection as possible.
(W16.1) Device failure and incorrect measurements should be minimized.
(W1.2 & W1.3) The measurements should be as precise and accurate as possible.

4.3 Conclusion

I concluded that the best method to measure nocturnal erections involves taking measurements of penile blood oxygenation levels. Physiologically speaking, during an erection there is a significant inflow of arterial blood to the penile tissue, whereas in the flaccid state there is relatively low blood volume in the penis and thus, relatively low oxygenation in the penis. Based on this, it is expected that this increase in blood oxygenation would be a good predictor for the presence of an erection event during a nocturnal measurement.

In addition, blood oxygenation sensors provide detailed empirical data for physicians regarding the internal changes occurring during an erection. Based on my research, blood oxygenation measurements are highly suited for this application and were chosen for initial testing. There are two ways to measure blood oxygenation levels: (1) pulse oximetry, and (2) tissue oximetry. Both methods are non-invasive, cheap, and can be made to be very compact and comfortable. Testing was conducted using both pulse oximetry and tissue oximetry to determine which method is suited for this application.

	Wish	Importance	Blood Flow		Blood Pressure		Blood Oxygen		Temp	
W1.1	Erection insight	10	10	100	8	80	9	90	1	10
W16.1	Reliability	6	5	30	5	30	8	48	10	60
W1.2	Precision	5	7	35	8	40	8	40	8	40
W1.3	Accuracy	5	7	35	8	40	6	30	8	40
Total			200		190		208		150	

Table 2. The weighted objective method, used to determine which method of nocturnal erection monitoring is best suited for this device. Blood Oxygen scored the highest meaning that it best satisfies the wishes of how the device should function.

5. Pulse Oximetry

5.1 Theory

Hemoglobin is the main oxygen binding protein in blood. There is a differential absorption of light by hemoglobin. Hemoglobin that is bound to oxygen absorbs more IR light, while hemoglobin without oxygen absorbs more red light. Light is both scattered and absorbed by the tissue. In order to obtain a blood oxygenation saturation, the absorption of light in the blood needs to be isolated from the absorption from the other tissue types. The absorption of light in arterial blood varies with each contraction of the heart as the volume of arterial blood changes (Wukitsch, 1998). The pulsating arterial blood causes small changes in total absorption (Figure 15). By analyzing these changes, the pulse oximeter can extract the oxygen saturation of the pulsating arterial blood (SPO_2).

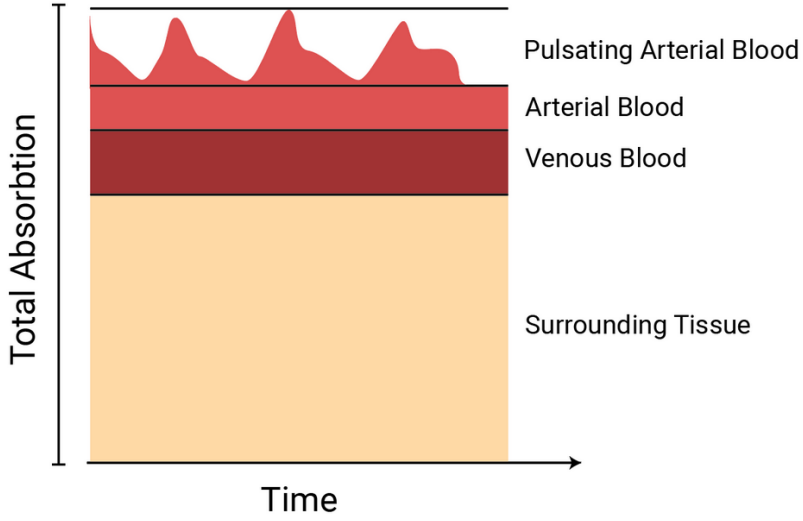

Figure 15. Diagram the absorption of light across the surrounding tissues and the blood. Diagram was derived from Wukitsch et al., 1998.

5.2 How it Works

The pulse oximeter consists of a red LED, an IR LED, and a photodiode. A pulse oximetry sensor was bought as an Integrated Circuit (IC), mounted on a prototyping board (Figure 16). Red and IR light are emitted from the LEDs into the tissue; the amount of light that is emitted by the LEDs subtracted by the total absorption is equal to the amount of light that hits the photodiode (i.e., transmittance). For each LED light the change in transmittance over time indicates how much Red and IR light is absorbed by the pulsating arterial blood. The ratio between the absorption of Red and IR light in the pulsating arterial blood is used to calculate SPO_2.

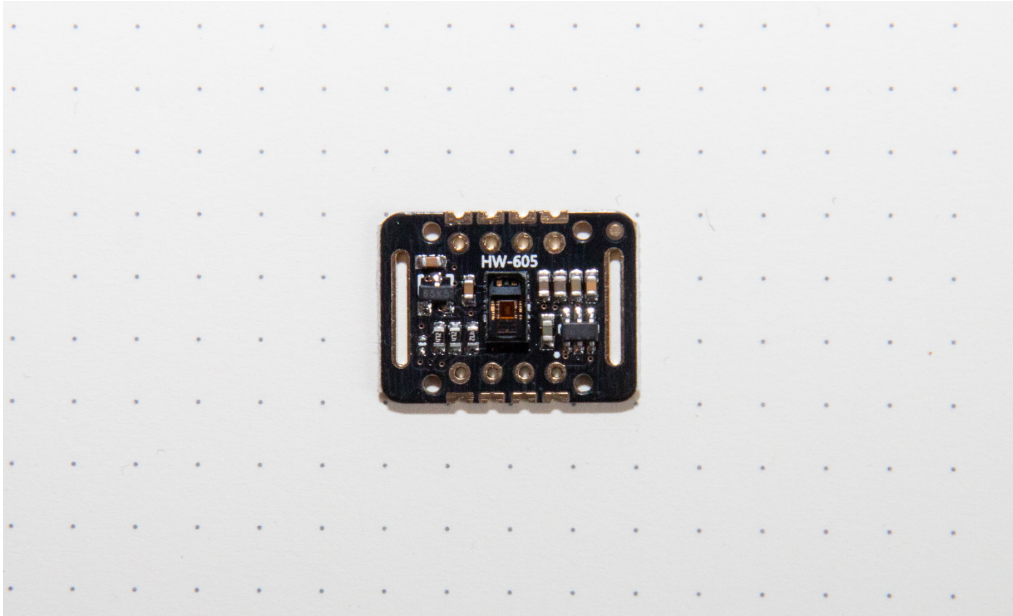

Figure 16. A pulse oximetry sensor as an Integrated Circuit (IC), mounted on a prototyping board, photographed on a 5mm grid.

5.4 Testing & Results

Pulse oximetry measurements were conducted on multiple regions of the body including the finger, the arm, and the penis on the corpora cavernosa (flaccid and erect state). One of the main findings over the course of extensive testing is that during an erection event, blood oxygen saturation does not significantly change, hovering between 90-100%. Due to the fact that there were no significant changes in blood oxygen saturation between flaccid and erect state in the penis, I conducted further tests to determine if the measurement location on the body affected the results. I compared measurements on the finger to multiple locations on the penis and none of the comparative measurements significantly differed.

Data obtained from these tests was in contrast to what I had originally hypothesized. Physiologically speaking the finger should have a high blood oxygen saturation (~99%) due to a high density of capillaries in the tissue. In contrast, to the finger, the flaccid penis should have relatively low oxygen saturation (~60%) because there is limited blood flow to the tissue. Furthermore, compared to the flaccid state there is an increase in blood flow to the penile tissue, which I had expected to correlate with an increase in blood oxygen saturation (~ 70-85).

5.5 Conclusion

Multiple factors were considered for the cause of the unexpected result: a faulty sensor, mistakes in SPO_2 calculations, or mixed up red and IR data labels. However, these were all ruled out as potential causes. The strongest possibility was discovered when I more closely examined the theory behind pulse oximetry. Pulse oximetry specially calculates the blood oxygen saturation in arterial blood and not the oxygenation of the tissue. Thus, the results should be constant regardless of testing location on the body because the arterial blood holds a high percentage of oxygen as it is being pumped directly from the heart. Thus, this explains why the blood oxygen saturation in the finger is similar to that of the penis. My conclusion is that pulse oximetry is not suited for determining the difference in blood oxygen saturation between the flaccid and erect state in the penis because it is only measuring arterial blood. The following section will discuss tissue oximetry, the second method for determining blood oxygen saturation.

6. Tissue Oximetry

6.1 Theory

Tissue Oximetry or near infrared spectroscopy (NIRS) is a way to measure oxygenation saturation in penile tissue and relies on the fact that the absorption of light is linearly correlated to the distance the light travels through the medium. A doubling in distance will double the absorption. In addition, the oxygen binding protein in blood, hemoglobin, absorbs a lot of light compared to other tissues. When hemoglobin is bound to oxygen (oxyhemoglobin) it absorbs more infrared light, whereas when hemoglobin is not bound to oxygen (deoxyhemoglobin) it absorbs more red light. The goal of the tissue oximeter is to generate an tissue oxygen saturation (StO_2).

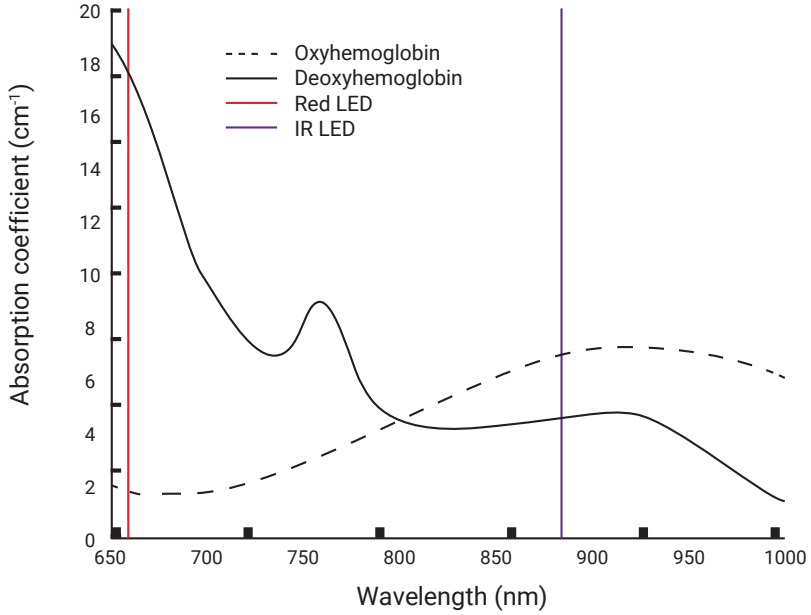

Figure 17. The differential absorption spectrum of Oxyhemoglobin (bound to Oxygen) and Deoxyhemoglobin (not bound to Oxygen). The vertical red and purple lines indicate the wavelengths of light being emitted by the Red LED and IR LED respectively. Diagram was derived from Kim and Liu, 2007.

6.2 How it Works

6.2.1 Continuous Wave Method

There are three different approaches to NIRS measurements: Continuous Wave, Time Domain, and Frequency Domain. Continuous Wave is the most common technique and the one embraced by almost all commercial instruments (Fantini, 2020). In this project we will be focusing on the Continuous Wave method. Continuous Wave uses two photodetectors at different distances to the LED's to calculate an oxygen saturation at a specific depth in the tissue.

In the tissue oximeter sensor that I constructed, there are two photodetectors, a Red and a IR LED. The two photodetectors in the tissue oximeter sensor are referred to as either close or far (Figure 18).

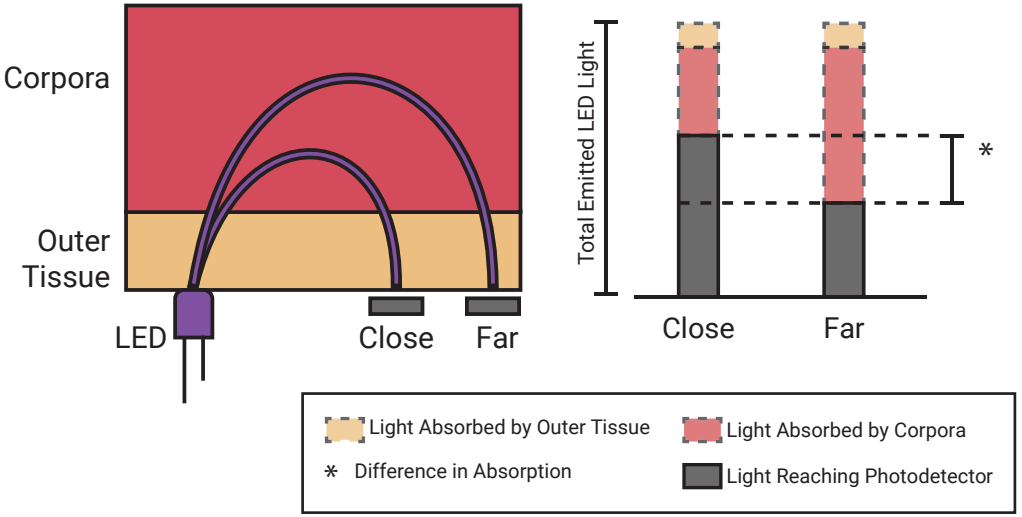

*Figure 18. The path of light from the LED to the photodetectors through the outer tissue and corpora (Left). The transmission of light (gray), the absorption of light by the outer tissue (red) and cavernosa (yellow). The difference in absorption in the corpora between the close and far photodetector is indicated with the *.*

6.2.2 Sampling

For every StO_2 value, the sensor takes three measurements from both the close and far photodiode; (1) the red measurements are taken with just the red LED on, (2) the IR measurements are taken with just the IR LED on, and (3) the ambient measurements are taken without any LEDs on (Figure 19). The red and IR measurements are used to determine the absorption in the tissue, while the ambient measurements are subtracted from both the red and IR values in order to filter out ambient light. This cycle takes 8 milliseconds to complete and can be repeated multiple times a second to obtain an average STO_2 valve.

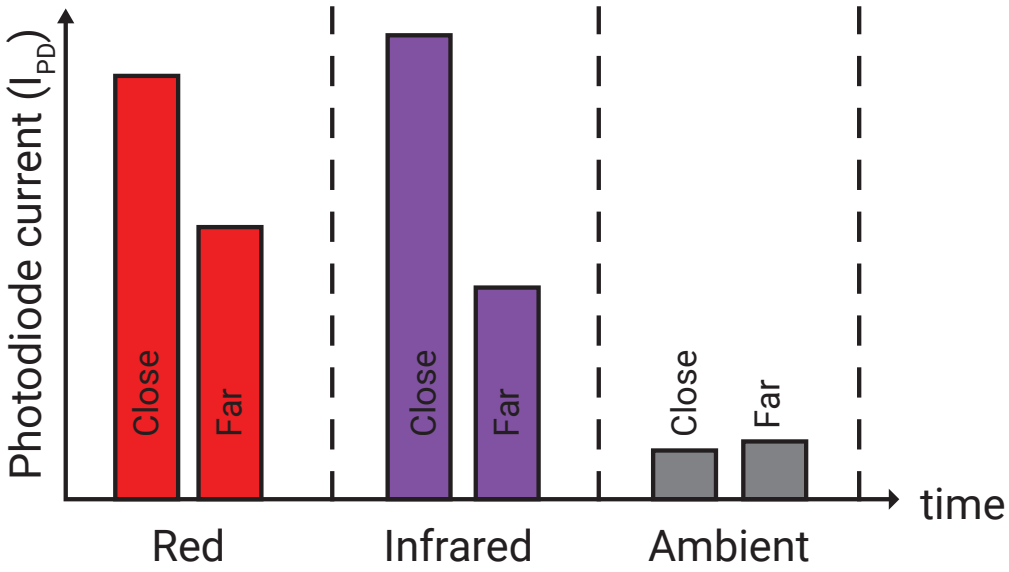

Figure 19. Diagram showing the photocurrents (i.e., amount of current flowing through the photodiode) for red, infrared and ambient light for both the close and far photodiodes. This is proportional to the amount of light hitting the photodiode during each measurement.

6.2.3 Amplification Circuit

Based on the amount of light that hits the photodiode, a small current will flow. This current is proportional to the amount of light that hits the photodiode. In order for the microcontroller to then process this data, it needs to be converted to a voltage and amplified. Once it is amplified the signal gets converted from an analog voltage to a digital number, which can be used in for further data processing and calculation (Figure 20).

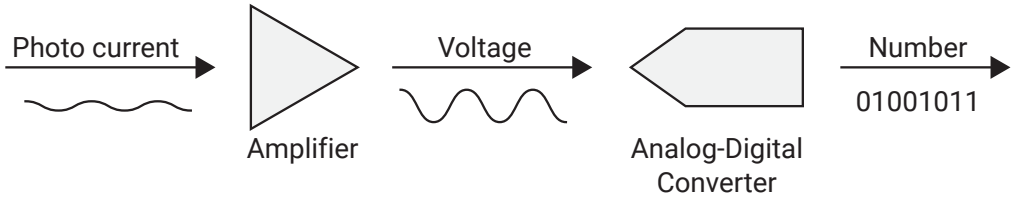

Figure 20. Diagram showing the step by step process from photo current to digital number.

6.2.3 Data Processing

The first step is to filter out ambient light, after this is done, a ratio between the close and far photodiode valves can be calculated for both red and IR light. These two ratios can then be used to calculate the relative absorption of red and IR light in the tissue (Eq. 1). Detailed explanations of these calculations can be found in the research conducted by Lindkvist et al 2013.

(1)
$$k\,\mu_{a,red} = \frac{1}{3\,(1-h\lambda_{red})}\left(\ln(10)\,\frac{1}{2L}\,\log_{10}\left(\frac{I_{red,close}}{I_{red,far}}\right) - \frac{2}{\rho}\right)^2$$
$$k\,\mu_{a,IR} = \frac{1}{3\,(1-h\lambda_{IR})}\left(\ln(10)\,\frac{1}{2L}\,\log_{10}\left(\frac{I_{IR,close}}{I_{IR,far}}\right) - \frac{2}{\rho}\right)^2$$

These relative absorption values can be used to calculate the relative concentrations of oxyhemoglobin and deoxyhemoglobin. Equation 2 shows the matrix calculation that is used.

(2)
$$\begin{bmatrix} k\,c_{HHB} \\ k\,c_{HBO2} \end{bmatrix} = \frac{1}{\ln(10)} \begin{bmatrix} \varepsilon_{HHB,red} & \varepsilon_{HBO2,red} \\ \varepsilon_{HHB,IR} & \varepsilon_{HBO2,IR} \end{bmatrix}^{-1} \begin{bmatrix} k\,\mu_{a,red} \\ k\,\mu_{a,IR} \end{bmatrix}$$

The StO2 is then calculated by dividing the concentration of oxyhemoglobin by the total concentration of hemoglobin (Eq. 3).

(3)
$$StO_2 = \frac{k\,c_{HBO2}}{k\,c_{HHB} + k\,c_{HBO2}}\ 100\%$$

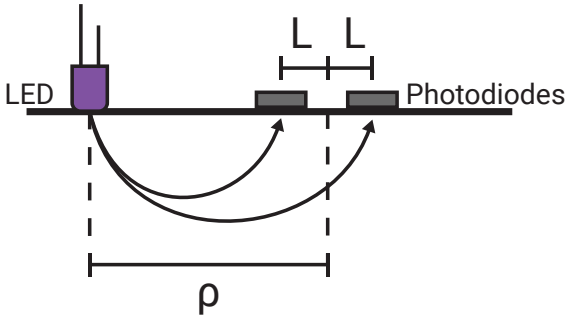

Figure 21. Schematic drawing of the tissue oximeter setup, indicating the distances ρ and L. Adapted from Lindkvist et al 2013.

k = Unknown constant (This constant is canceled out in Eq. 3)
$\mu_{a,red}$= Absorption of red light
$\mu_{a,IR}$= Absorption of IR light

h = Normalized slope (This constant is chosen to fit the StO_2 values from this device to reference measurements)
λ = Wavelength of light
L = Half of the distance from the center of the close photodiode to the center of the far photodiode (Figure 18)
ρ = Average distance from the LEDs to the photodiodes
I = Photodiode current

c_{HHB} = Molar concentrations of deoxyhemoglobin
c_{HBO2} = Molar concentrations of oxyhemoglobin

ε_{HBO2} = Known extinction coefficient of oxyhemoglobin
ε_{HHB} = Known extinction coefficient of deoxyhemoglobin

StO_2 = Tissue oxygen saturation

6.3 Sensor Iterations

The core components of the sensor (i.e. two LEDs and two photodiodes) stayed consistent throughout all iterations of the sensor design. I designed four iterations of the tissue oximeter sensor (A,B,C,D).

6.3.1 Sensor A

The first iteration of the sensor uses the most basic sensor configuration and uses the photodiodes in photovoltaic mode (Figure 22). This means that with an increase in light, the photodiode will generate more voltage, similar to a solar panel. However, in this set-up the output from the photodiode was non-linear. Outside of the linear range of the photodiode, a change in light intensity will not correlate to a change in voltage. This means that photodiode voltage cannot be used to predict the light intensity and thus the value cannot be used to calculate the StO_2.

6.3.2 Sensor B

To ensure that the output of the photodiode remains in its linear range, I switched to a current based system, which allows a certain amount of current to pass through the photodiode depending on the amount of light that hits it. This should produce a wider linear range for the photodiode. However, this was still not enough to keep the photodiode in the linear range. The sensor layout is the same as Sensor A, however, the difference is in the circuitry surrounding the sensor (Appendix Sensor Schematics).

6.3.3 Sensor C

Another solution to keep the photodiode in the linear range is to use a more sensitive photodiode. Unfortunately, more sensitive photodiodes are not easily available, thus, a choice was made to increase the intensity of the Red and IR light and to add a constant light that would act to increase the baseline ambient light (Figure 23). By doing this the photodiode output was moved into its linear range.

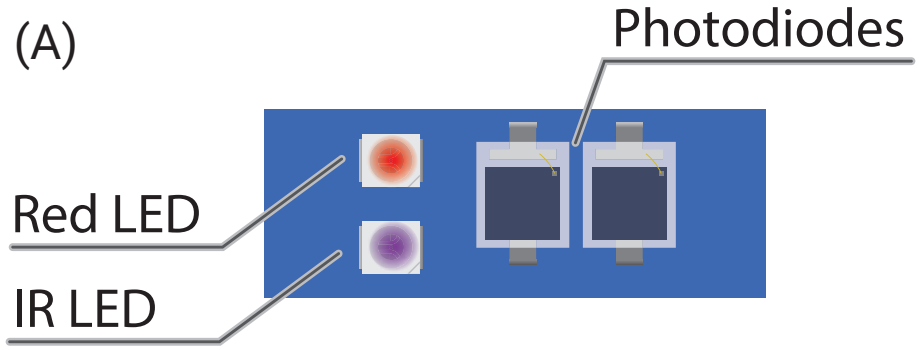

Figure 22. Schematic drawing of the tissue oximeter in iteration A, showing the red and IR LEDs and the two photodiodes. The blue board represents the PCB (22 x 10 x 1.6 mm).

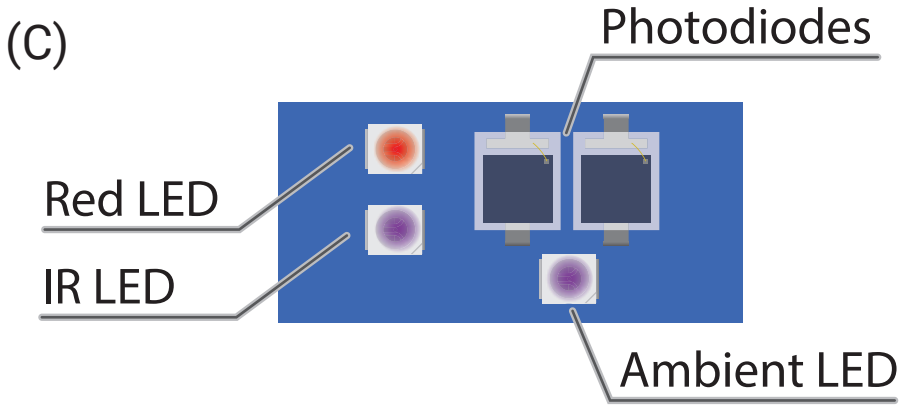

Figure 23. Schematic drawing of the tissue oximeter in iteration B, showing the red, IR , and ambient LEDs and the two photodiodes. The blue board represents the PCB (22 x 13 x 1.6 mm).

6.3.4 Sensor C Testing

I used the sensor in the current iteration (C) to conduct tests on various parts of the body including: arms, fingers, inner thighs, and penis (both flaccid and erect). To validate the accuracy of the measurements, sensor C was compared against a professional tissue oximeter, the Invos 5100C Cerebral/Somatic Oximeter (Somanetics Corporations, Troy, MI, USA; Figure 24).

Measurements using both tools (sensor C and Invos) were taken at the same location under the same conditions (Table 3). In addition to providing blood oxygen saturation in the tissue, the Invos Oximeter also provides an signal strength indication ranging from 1-5 (1= low accuracy, 5= high accuracy) for each measurement. According to the manufacturer, the signal strength indication depends on physiological factors (different from individual to individual) and possible disturbances from secondary sources or influences in the monitor's environment.

However, importantly, the measurements taken by sensor C on the penis, did not align with the Invos measurements (Table 3) or data found in current literature (Padmanabhan, 2007). The data from sensor C on the penis hovered between 60-100% in the flaccid state and between 80 - 100% in the erect state. Due to large fluctuations in the data from sensor C, it was difficult to discern significant differences between the flaccid and erect states. One important note is that measurements taken from the penis using the Invos provided an accuracy score of 1 out of 5, which was the lowest of any region that was tested.

Both sensors were having trouble measuring in the penis, while measurements taken on other regions of the body were consistent and accurate.

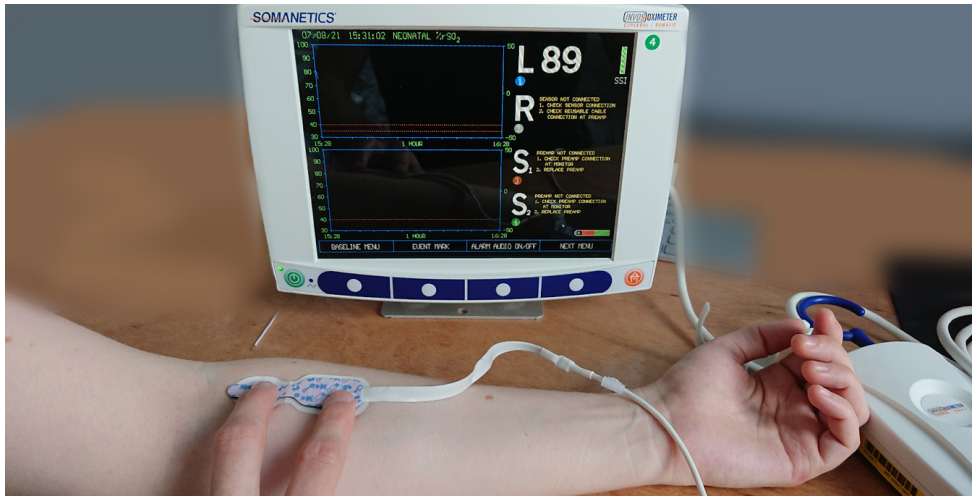

Figure 24. Invos tissue oximeter, showing 89% oxygen saturation in the anterior region of the forearm.

	Sensor C	*Invos*	*Signal Strength*
ARM Inside	65 -75%	60 - 70 %	5/5
ARM Outside	90%	90%	5/5
Thumb	86 - 92%	88 - 96%	5/5
Thigh	83 - 90%	85 - 89%	5/5
CC Flaccid	60 - 100%	62 - 69%	3/5
CS Flaccid	60 - 100%	68 - 76%	5/5
CC Erect	80 - 100%	80 - 91%	1/5

Table 3. Sensor C compared to Invos on various regions of the body. The signal strength recorded at each measurement given by Invos. Score (0-5).

Invos Troubleshooting
After further investigation, into why the Invos sensor was having trouble taking STO_2 measurements in the penis, my initial hypothesis was that Invos sensor has a large distance between the LEDs and the photodiodes in the sensor configuration. The Invos sensor is usually used to take cerebral measurements, in that case, the larger distance between the LEDs and the photodiode is needed in order for the light to penetrate and measure at a greater depth within the tissue. Typically this larger distance also works on most regions of the body, however in the penis there is a large volume of blood that sits directly below where the sensor is taking measurements. The blood has higher absorption compared to the surrounding tissues, and thus, most light is absorbed and very little light hits the far photodiode. This makes the measurement more susceptible to noise and makes measuring small changes in transmission less accurate.

Sensor D
My previous hypothesis was that the inaccuracies in the STO_2 measurements were caused by too much light absorption in the blood and not enough light reaching the far photodiode. I wanted to test this hypothesis by creating a new iteration of the sensor (D). In the previous sensors (A,B,C) the Red LED was emitting wavelengths of 630nm. The 630nm wavelength is highly absorbed by deoxygenated hemoglobin (Figure 17). To reduce the amount of light absorbed by the blood, sensor D utilized a Red LED that emitted at a wavelength of 770nm instead.

Tests with sensor D were unable to provide any useful data, likely due to electrical problems with the sensor. Further research can be conducted to determine if using a higher wavelength for the red light would improve the accuracy of the sensor.

Sensor C Troubleshooting
In contrast to the Inovs sensor, low light intensity at the far photodiode was not expected to be the cause for the inaccuracy in sensor C. During repeated testing the photo current of the far photodiode was significantly higher compared to the reference value. Therefore, I hypothesized that there must be a different underlying cause for the inaccuracy of STO_2 measurements in the penis. Following extensive testing with the prototype electronics, I was able to determine that were some problems associated with the amplification circuit.

The amplification prototyping board
The amplification circuit serves to amplify and convert the photo current to a voltage that can then be converted to a number by the microcontroller. This circuit shared a prototyping board with the circuit that controls the power to the red and IR LED's.

For the amplifier to work it requires a stable reference voltage. In this prototyping board, the reference voltage to the amplifier was connected to the ground on the circuit that controls the LED's, before connecting to the ground. This affected the reference voltage of the amplifier when the LED's were powered on. This caused a offset in voltage that went to the microcontroller. To solve this problem, I created an a new amplification circuit board, where the reference voltage line was directly connected to ground (Figure 25).

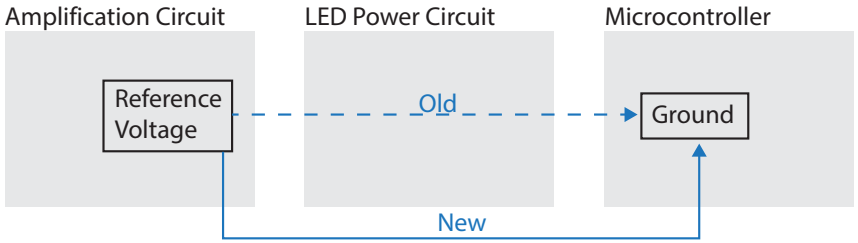

Figure 25. A simplified diagram showing the change in path of the reference voltage to the ground.

6.4 Sensor C Results

Following extensive troubleshooting and testing, I was able to obtain data to validate that tissue oximetry can be utilized to measure STO2 in the flaccid and erect penis. My results show that in the flaccid penis the average STO2 values are between 75% and 85%, and in the erect state the average STO2 values are between 90-95% These are consistent with the current literature values obtained from Padmanabhan, 2007. There is a rise in STO2 values during an erection and there are clear differences in STO2 between the flaccid and erect state.

6.4.1 Test Set-up

All tests were preformed on a single subject, visual stimuli were used to induce an erection. All tests were preformed during the day, while the subject was awake. The tissue oximeter was attached to the penis using a 50mm X 15 mm piece of Brava medical adhesive tape (Coloplast, Minneapolis, MN USA). More information can be found on this attachment method in Chapter 7: Ergonomics.

Sensor C was not tested as a nocturnal prototype and was only tested during the day with a normal erection. The future direction for this project would be to use this tool during a NPT monitoring to validate the results of this project further.

6.4.2 Validation

To validate the results of the measurements taken with sensor C, I took direct circumference measurements using a flexible measuring tape with marks indicating the 10%, 20%, 30%, and 40% circumference increase. I then compared the data obtained from sensor C, with these direct circumference measurements to confirm that a rise in STO2 valves, actually corresponded with an erection event.

The circumference measurements (light blue) and tissue oximeter measurements (dark blue) were taken at the same time under the same conditions. The comparison of the data indicated that an erection occurred at roughly the same point across the measurements (Figure 26).

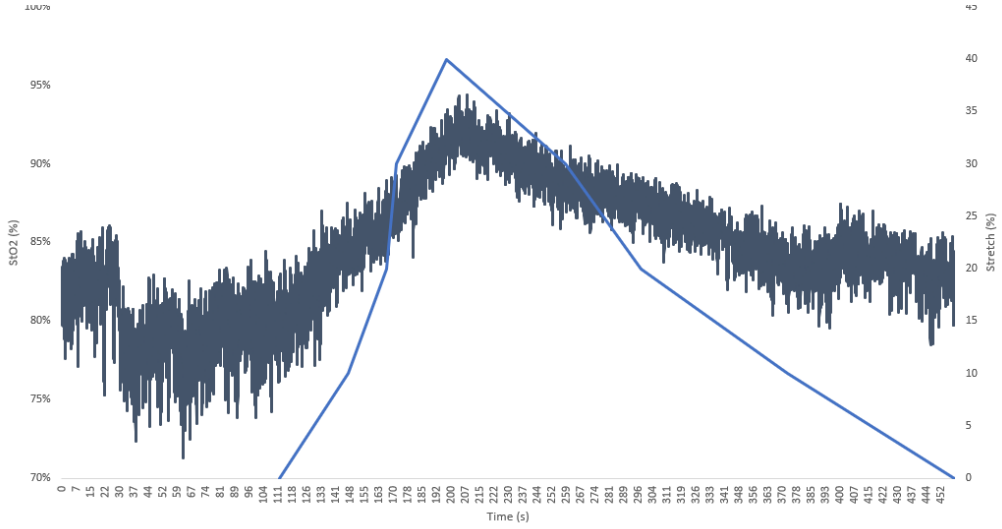

Figure 26. The dark blue line represents a moving average of 20 data points for the STO_2 values measured in the penis. The light blue line is the % circumference increase during an erection.

6.4.2 Stretch Sensor

The stretch sensor was made of a flexible conductive piece of rubber, that was wrapped around the penis and held in place with two clips. When the circumference of the penis increased the resistance of the rubber increased. This change in resistance was measured by an Arduino microcontroller.

However, while building the stretch sensor I encountered a few challenges: (1) the resistance in the rubber is proportional to the amount of stretch, however, when the material starts to be stretched or when the material is relaxed there is spike in resistance, (2) when the material is being relaxed it takes a long time for the resistance to normalize back to baseline levels (Figure 27).

To mitigate the problems associated with the stretch sensor I did some data filtering, in which I eliminated the data points that correlated with a spike in initial resistance during both stretching and relaxing. However, the data from the stretch sensor is not always consistent due to the problems that were discussed above. Thus, I used a different method to validate the results from sensor C.

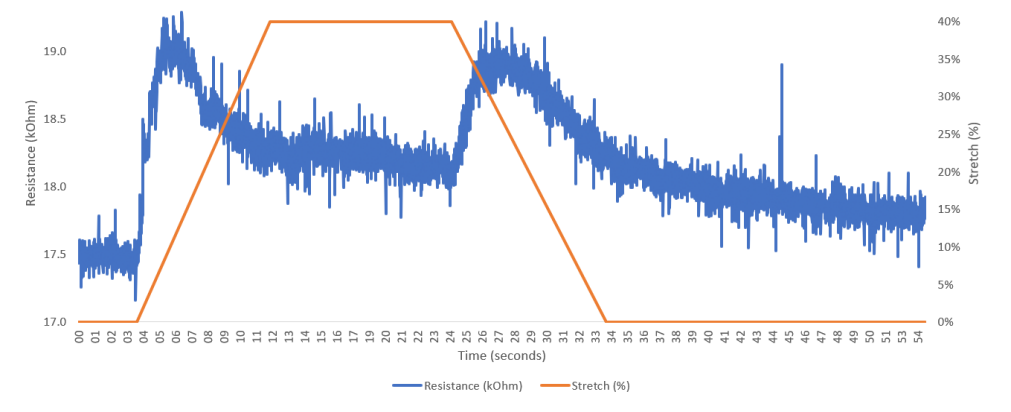

Figure 27. A test of the stretch sensor showing the change in resistance in response to stretching and relaxing of the rubber material.

7. Sensor Ergonomics

7.1 Placement of Tissue Oximeter

To take measurements of blood oxygen saturation the tissue oximeter sensor can be placed on three regions of the penis: (A) the shaft, (B) the glans, or (C) the base (Figure 28). The base of the penis is challenging for placing the sensor because there is limited space and it is difficult for the patient to place the sensor correctly. The glans is also challenging for sensor placement because it is extremely sensitive tissue, which can be uncomfortable for the patient. Finally, along the shaft of the penis, the measurement can be taken on the corpora cavernosa. The tissue oximeter must be placed slightly to the left or the right to avoid placement of the sensor directly on top of a high density of veins and arteries. The tissue oximeter should be placed in a way to ensure that the measurement is being taken directly over the main erectile tissue responsible for the erection function.

7.2 Number of Tissue Oximeters

The corpora cavernosa are connected by an incomplete septum (Andersson and Wagner, 1995). Blood can flow between each corpus cavernosum allowing each side of the penis to receive adequate blood flow during an erection. A single tissue oximeter sensor can be placed on either side of the penis shaft on the corpora cavernosa and should result in the same measurement.

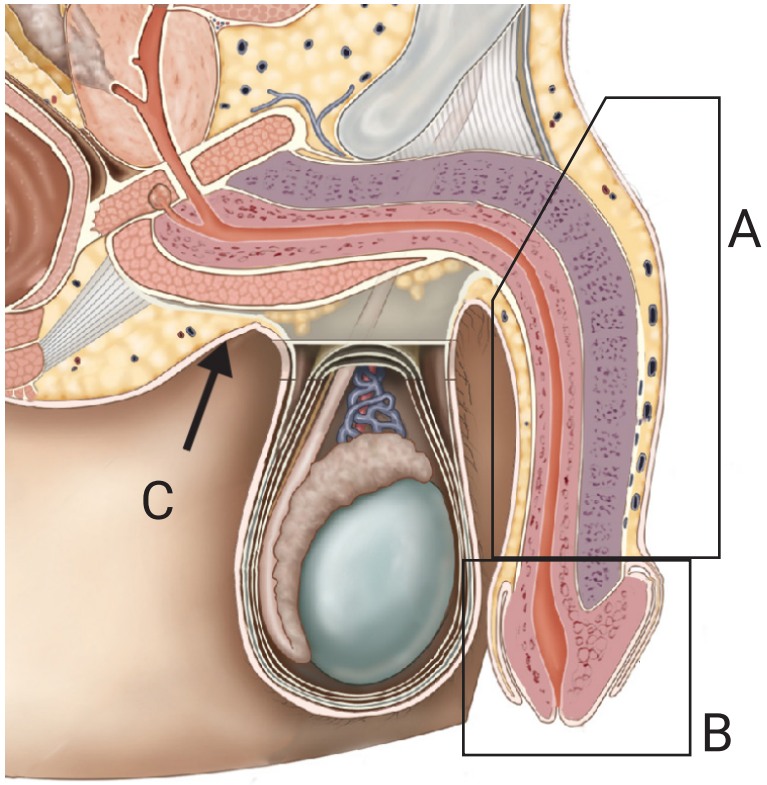

Figure 28. A lateral view of the penis indicating where the tissue oximeter can be placed. (A) the Shaft, (B) the glans, or (C) the Base. Diagram was derived from Britannica, 2020.

7.3 Variation in Penis Sizes

Anthropometry is the systematic measurement of the physical properties of the human body. Anthropometry can be used in ergonomics to optimize the fit and function of products. I compiled data from five different studies conducted in five different countries (Table 4), about the minimum penis size, p1, p5, mean penis size, p95, p99, and maximum penis size from each study in the *flaccid state*.

In addition, I gathered anthropometric data for *erect penises* (Table 5). My device needs to accommodate the smallest flaccid penis and the largest erect penis. This variation in penis sizes (Figure 29) presents challenges for designing an ergonomic solution for how to attach the sensor to the penis.

Table 4. Variation in the circumference of flaccid penises (mm)

N	Location	min	p1	p5	mean±SD	p95	p99	Max	Citation
80	USA	65	70	78	97 ± 11.7	116	124	130	Wessells, 1996
301	India	45	58	65	82 ± 10.2	99	106	130	Promodu, 2007
1500	Iran	44	64	71	87 ± 10.1	100	110	135	Mehraban, 2007
3300	Italy	77	83	90	100 ± 7.5	110	117	123	Ponchietti, 2001
123	Korea	51	59	67	85 ± 11	103	111	119	Son, 2003

Table 5. Variation is the circumference of erect penises (mm)

N	Location	Min	p1	p5	mean±SD	p95	p99	Max	Citation
80	USA	90	93	101	123 ± 13.1	145	153	160	Wessells, 1996
301	India	85	84	93	115 ± 13.5	137	146	165	Promodu, 2007

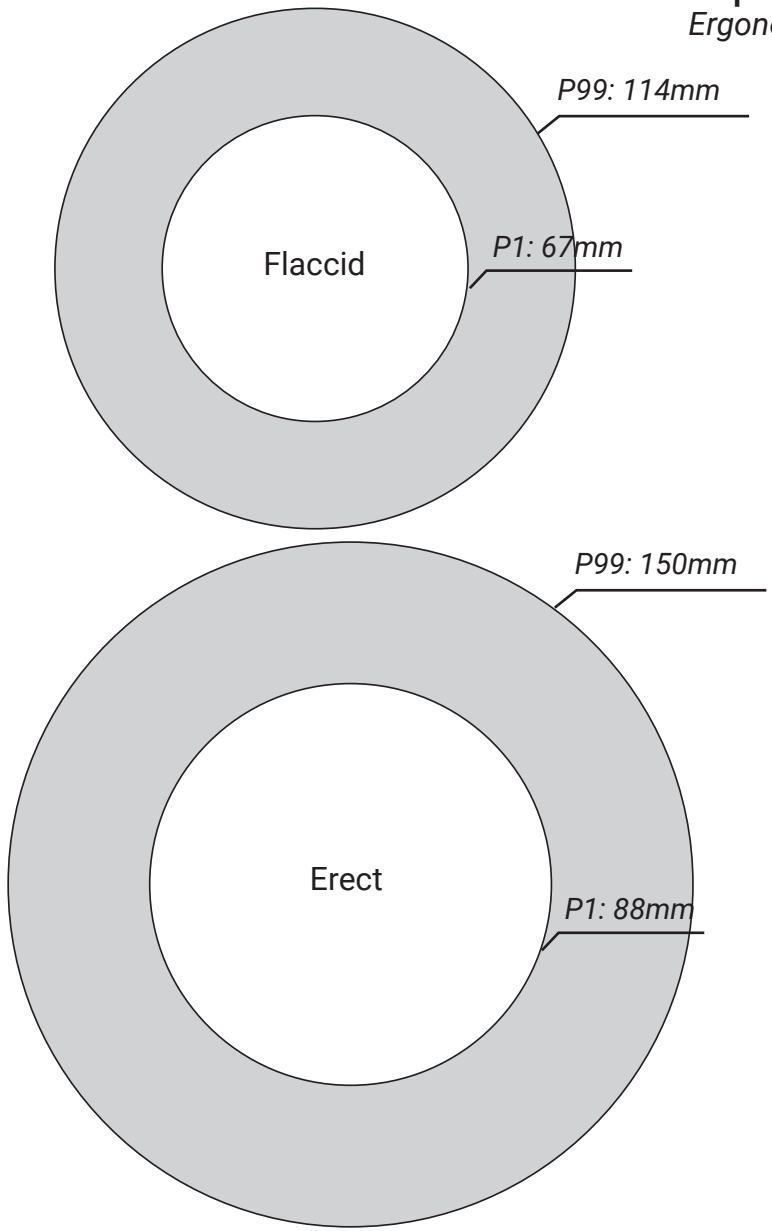

Figure 29. Top: Range of flaccid penis circumferences ranging from P1 to P99. Bottom: Range of erect penis circumferences ranging from P1 to P99. Diagram uses the mean of the available data from table 4 and 5.

7.4 Sensor attachment

There are three possible methods for attaching the sensor to the penis using (1) adhesives, (2) straps that wrap around the penis, or (3) a clamp to secure the sensor to the skin. An important thing to note is that this section of the report is only describing methods of attaching the tissue oximeter itself directly to the penis.

Adhesives
Medical adhesives can be used to secure the sensors directly to the penis.

Straps
A flexible silicone strap that would stretch to wrap around the circumference of the penis. The sensor would be built into the strap and would contact the skin when the strap was adjusted to fit tightly around the penis.

Clamps
Another method of attachment consists of two spring loaded arms that clamp around the penis ensuring that the sensor makes contact with the skin

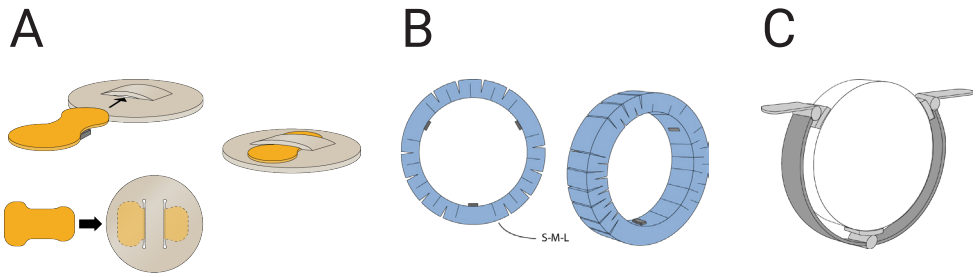

Figure 30. (A) The sensor is shown in yellow and the adhesive is shown in gray. The adhesive will stick directly to the skin of the penis. (B) A flexible strap that goes around the penis. (C) A diagram of the clamp concept design.

7.5 Sensor attachment choice

The same weighted objectives method (Roozenburg and Eekels 1995) was used to determine the best sensor attachment method. The wishes are shown in the rows of table 6 and are ranked on importance. The sticker method was chosen, because it provides the most reliability and comfort. This method is simple, low cost, and has the ability to accommodate all penis types and sizes.

	Wish	Importance	Wrap		Sticker		Clamp	
W16.1	Reliability	10	6	60	8	80	4	40
W15.2	Comfort	8	6	48	9	72	4	32
W23.1	Easy Application	7	6	42	9	63	7	49
W26.1	Quick Cleaning	6	5	30	10	60	5	30
Total			180		275		151	

Table 6. The weighted objective method, used to determine which method of attaching the sensor to the penis is best suited for this device. Sticker scored the highest meaning that it satisfies the wishes for the device.

8. Peripheral Electronics

The peripheral electronics refer to the electronics that can be mounted away from the sensor, in order to limit the size and weight of the sensor.

8.1 Required Electronics

The peripheral electronics include: a LiPo battery, power supply electronics, a microcontroller, data storage, user interface elements, a USB interface, an amplifier for the photodiodes signal, and two transistors (i.e., electrical switches that regulate power to the LEDs) (Figure 31).

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An Arduino MKR Zero prototyping board was used as reference to estimate the sizes of the microcontroller, power supply electronics, and data storage. The Arduino MKR Zero is 62mm by 25mm by 5mm. In addition to the Arduino MKR Zero, a small PCB is needed for the transistors that switch the LED on and off and for the amplifier for the photodiode signals. This PCB will be about 20mm by 20mm by 5mm. Ideally, the sensor will be connected to the peripheral electronics by a digital I2C connection. This allows for the use of less wires to connect to the sensor, making the cable more flexible. To power the electronics, a battery of sufficient capacity is required. The size of this battery was calculated using the estimated power consumption for a 20 hour or two night run time (Table 7).

> The battery size was estimated to be 500mAh. These batteries are usually 5mm thick and available in different sizes. It is also possible to use two batteries of half capacity, for example two 15 x 36 x 5mm batteries. A battery with this capacity will have a volume of about 5000mm3. The total volume of the peripheral electronics is 15000mm3. This is an internal size of about 120 x 25 x 5mm.

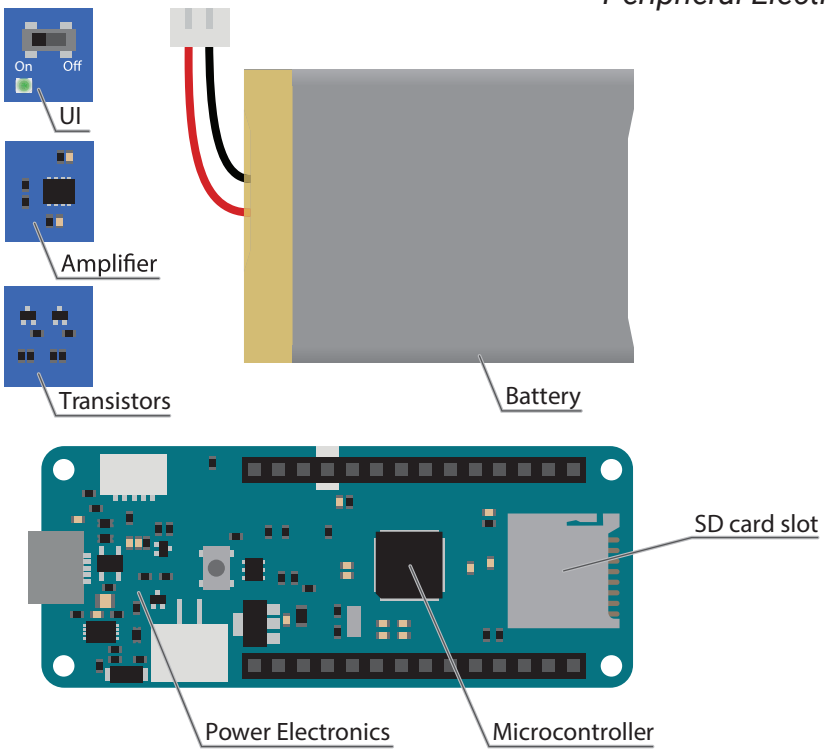


Figure 31. All of the peripheral electronics for the Erectiometer.

	Current (mA)	Power Usage (mAh)
Processor (SAMD21) Max	10	200
Ambient LED	5.2	103
Red LED	5.7	113.3
IR LED	1.5	29.1
Op AMP	0.1	2
Total	22.4	447.4

Table 7. Estimate of power consumption for each electronic component.

8.2 Peripheral electronics attachment

During the ideation process, I developed nine ideas for how to attach the peripheral electronics (Figure 32). The attachment location needs to meet four main requirements: (1) should be as comfortable for the patients to wear, (2) should accommodate as much body shapes and sizes as possible, (3) should be located as close as possible to the sensor, and (4) should be located somewhere where the cable connecting the sensor to the peripheral electronics creates a straight line.

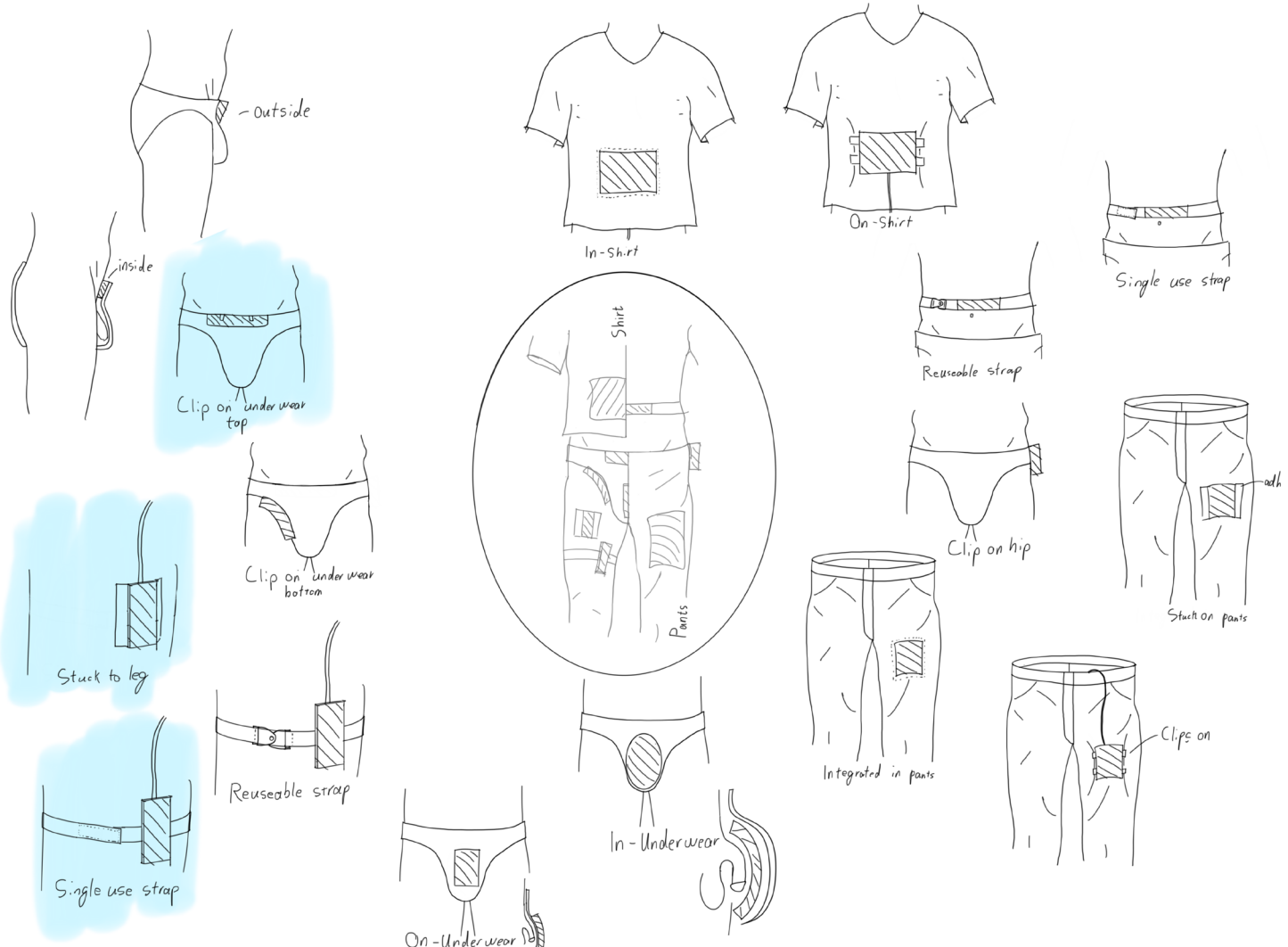


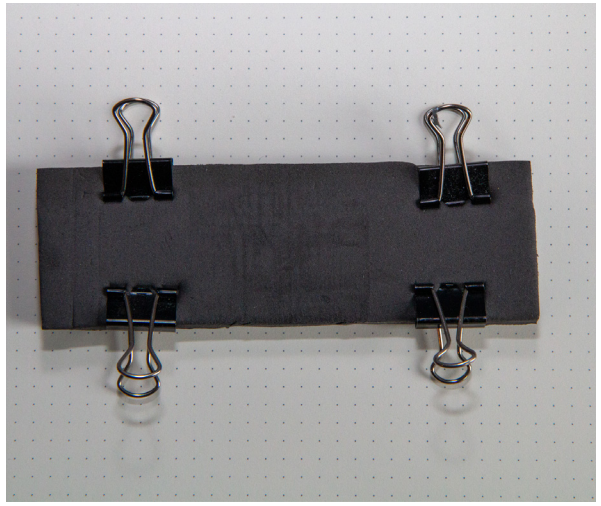
Figure 32. Showing a broad range of the possible peripheral electronics attachment locations. The most suitable attachment locations that were pursued further are shown in blue.

8.2.1 Underwear Concept

Out of the nine attachment locations, three were chosen for further testing and development (Figure 33): The underwear attachment, the leg sticker and the leg strap. These were tested using flexible foam prototypes combined with binder clips or medical adhesive.

There were minimal differences in comfort between the different attachment locations. However, only the underwear attachment idea could easily accommodate all body shapes and types. Thus, the underwear attachment was chosen for further design and development. The weighted objectives method used for making this choice can be found in Appendix D.

A



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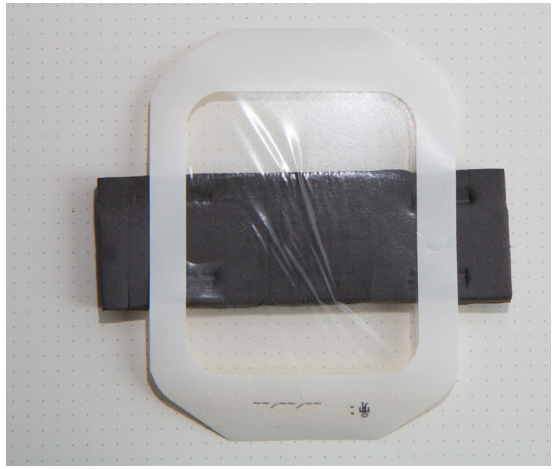


C

Figure 33. Flexible foam prototypes (140x45x12mm) used to test the comfort of different placements on a 5mm grid. (A)The foam prototype used with clips for testing the underwear attachment (B) The foam prototype with medical adhesive for testing the leg sticker. (C) The foam prototype for testing the leg strap.

8.2.2 Anthropometry

I obtained 3D models from DINED, which is a database that complies anthropometry data. I used section views of these 3D models to determine the size and shape of the waist line (Figure 34). By overlaying these section views I determined the shape for the peripheral electronics housing that would be used to attach the device to the underwear (Figure 35). The goal was to create a shape for the peripheral electronics housing that best fits the bodies of the potential users.

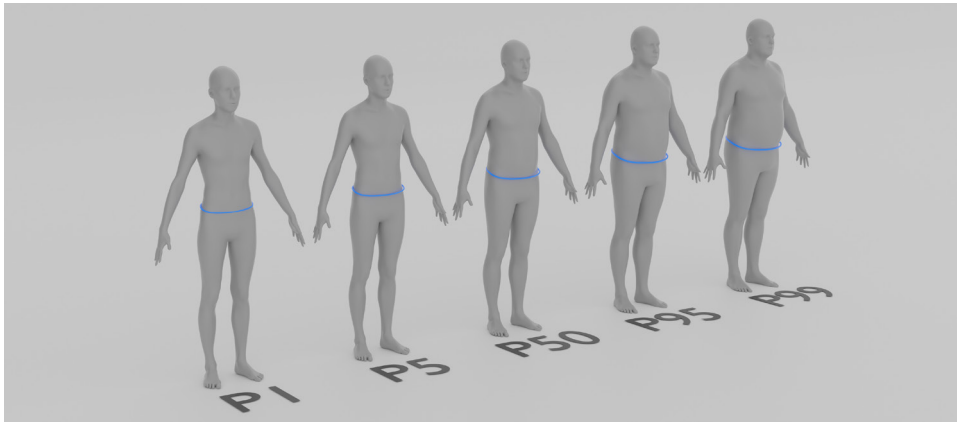


Figure 34. Data obtained from DINED for the size and shape of the waist line in men from P1 to P99.

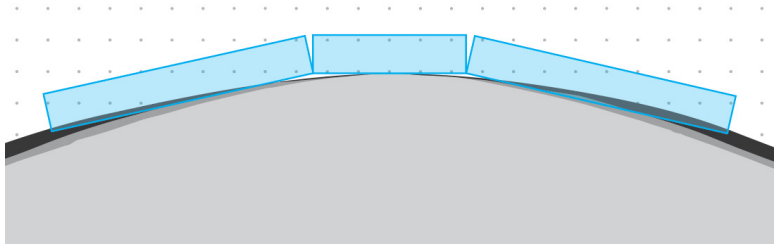


Figure 35. The size and shape of waist lines in men, obtained from DINED, and overlayed on top of each other (light gray is P1, medium gray is P50 and dark gray is P99). The blue, is the shape used to design the housing for the peripheral electronics. The dots make up a 5mm grid.

8.2.3 Rigid Housing Test

The second prototype for the housing was 3D printed in order to test the comfort of a rigid housing against the waist (Figure 36). The prototype was clipped to the underwear using 3D printed clips and tested during a 24 hour period (1 day and 1 night). The housing was comfortable to wear however, it was not very secure. The initial basic clips to attach the housing the underwear needed a redesign.

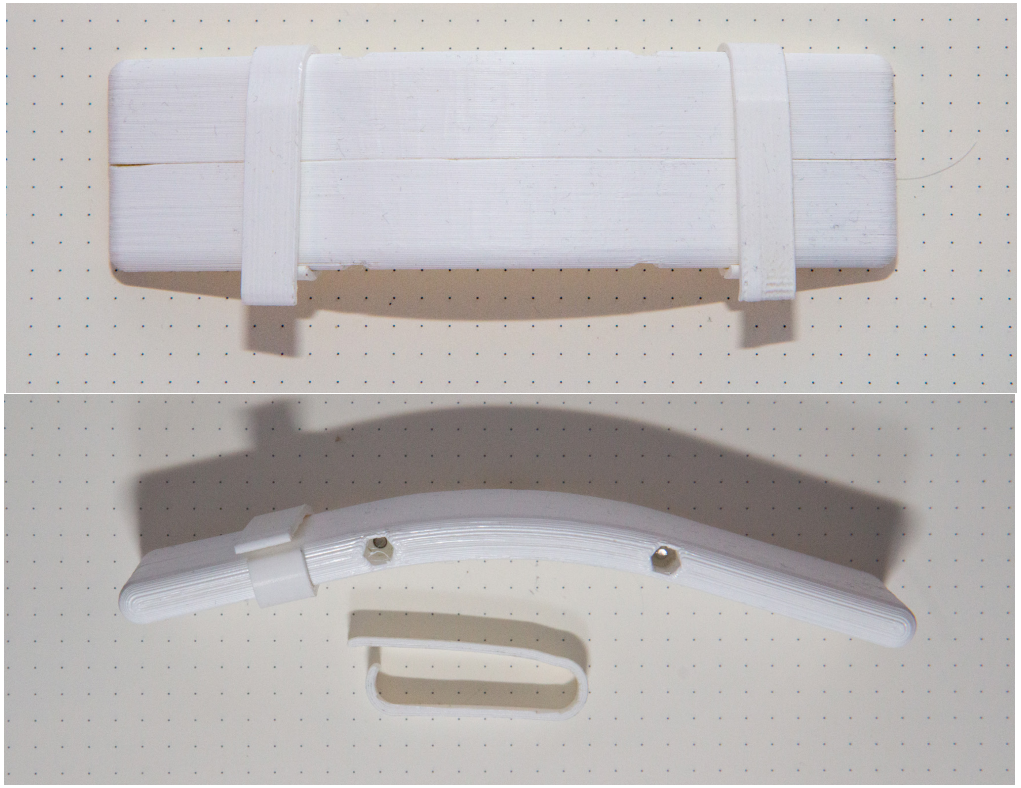


Figure 36. 3D-printed prototypes of the housing of the peripheral electronics for the underwear clip on a 5mm grid. (A) is the front view, (B) is the bottom view with the clip included.

8.2.4 Underwear Attachment

The housing needs to be securely attached to the underwear and it has to be easy for a first time user to attach and remove. To do this I explored ways of attaching the housing to the underwear (Figure 37).

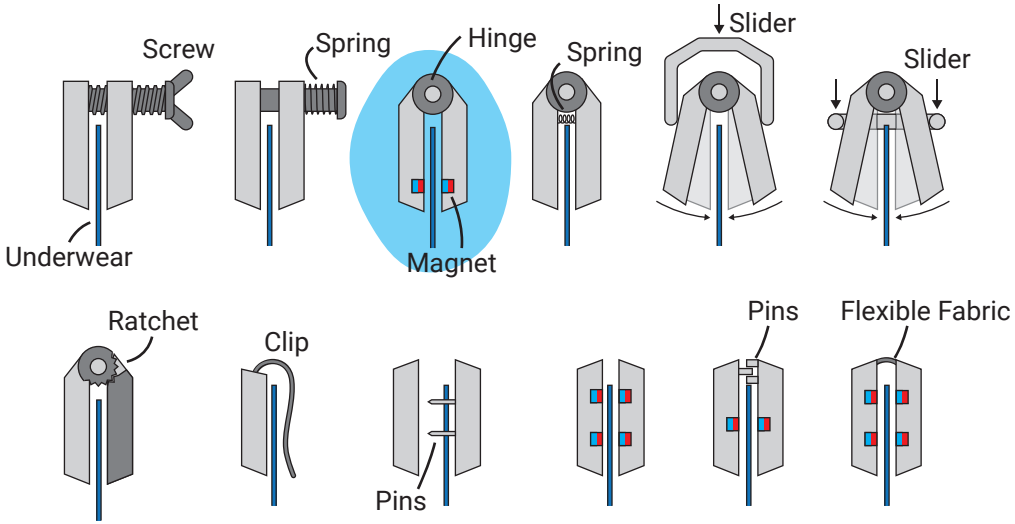


Figure 37. Twelve different ideas for the attachment of the housing to the underwear. The most suitable attachment idea is shown in blue.

The highlighted idea, the hinge with magnets, works by clamping the fabric of the underwear between two parts of the housing using permanent neodymium magnets to apply the closing force. The hinge This idea strikes the best balance between an easy user interaction, secure attachment, and low complexity.

The strength of magnets through underwear lining was tested. As this produced promising results a simplified prototype housing was built based on this idea.

The final prototype showed that the magnets were strong enough to create a secure attachment, while allowing the user to easily attach and remove the housing from the underwear.

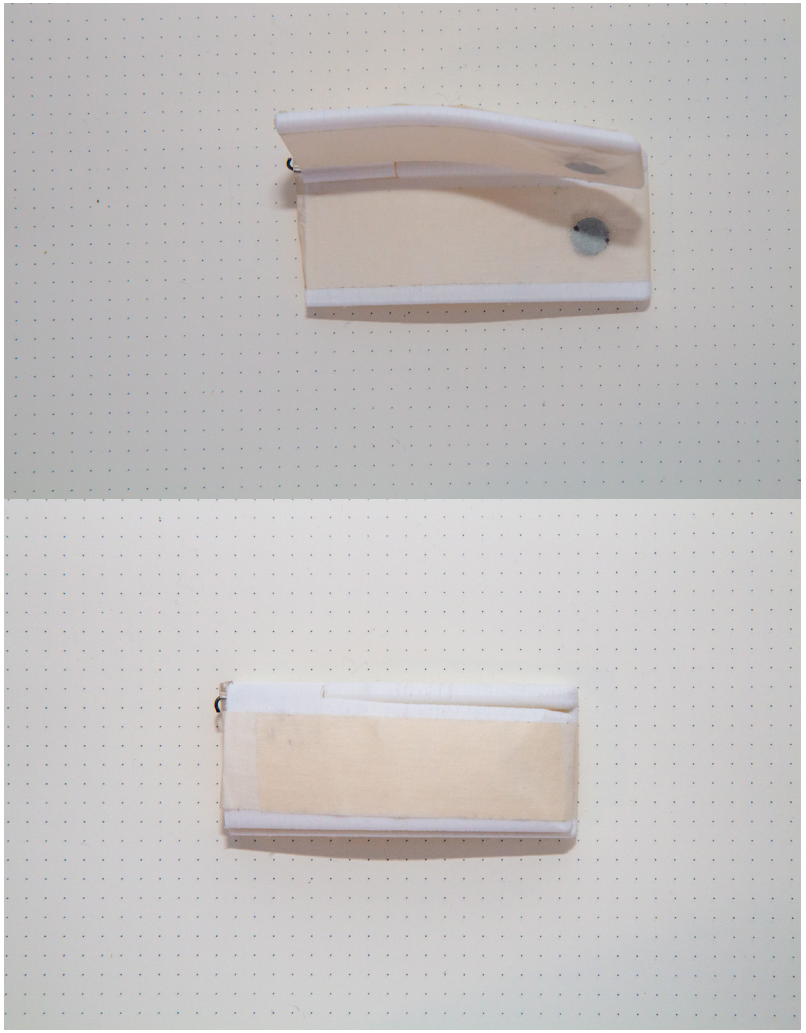


Figure 38. The final prototype in open (Top) and closed (Bottom) position. Note that the prototype only consists of the right half of the design in order to save time in prototyping.

8.3 User Interaction

The Erectiometer has two groups of users (1) the patient and (2) the medical staff. The medical staff, will likely interact with the device on a regular basis and will have the training and background to use the device. The patient, on the other hand, will likely be a first time user using the product in their own home without supervision. Furthermore, the patients come from diverse backgrounds. It is for these reasons that an intuitive patient interaction is especially important. In this chapter the proposed design of the user interaction will be discussed. However, user testing is required when further developing the device.

The patient interaction is designed to be simple and straight forward. In order to use the device the medical staff will need to provide the patient with instructions. These instructions are also provided in the box that the device comes in. The box is designed to be discreet, allowing the patient to bring the device home without revealing the purpose of the device (Figure 39). The instructions provide information on how to use the device, including the meaning on the symbols on the device, and the placement and attachment of the sensor.

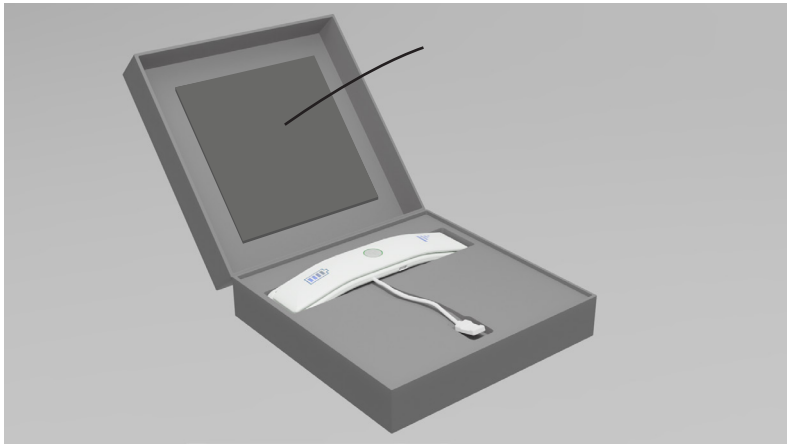


Figure 39. The box containing the Erectiometer indicating where the patient instructions can be found.

Before the patient goes to bed, he will open the box in a private place. The patient will then turn on the device, and the first step is to place the sensor on the designated location on the shaft of the penis (where he was advised by the medical staff). If the signal strength icon is blue this indicates that the signal is strong enough to start measurements. The device will always automatically start taking measurements when the device has a signal. If the signal strength is too low then the signal strength icon will turn red. The signal strength is derived from the signal to noise ratio of the measurements.

In addition, to the signal strength indicator there is also a batter indicator. The battery should be fully charged before a patient receives the device. However, if the patient encounters a low battery the battery icon will turn red. The device can be charged by the patient with any standard USB C charger.

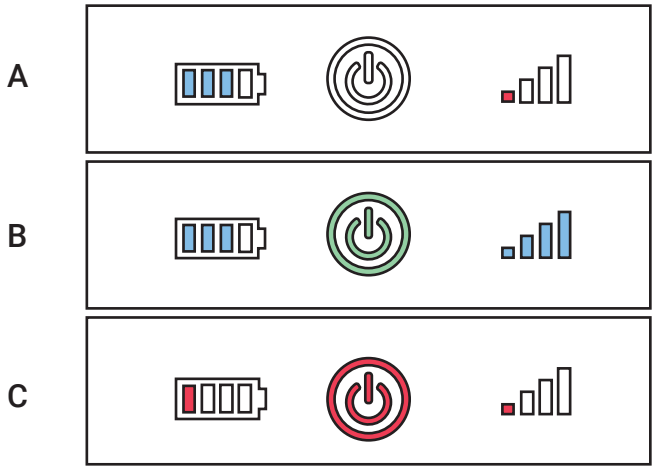


Figure 40. The user interface will light up the battery indicator and signal strength indicator when turned on (A). When the signal strength is high and the battery level is high enough, the device will start measurements and the on button will turn green (B). In case of an error or low battery, the on button will turn red (C).

Once the signal strength is high enough, the patient can remove the liner on the adhesive and stick the sensor securely to the penis (Figure 41).

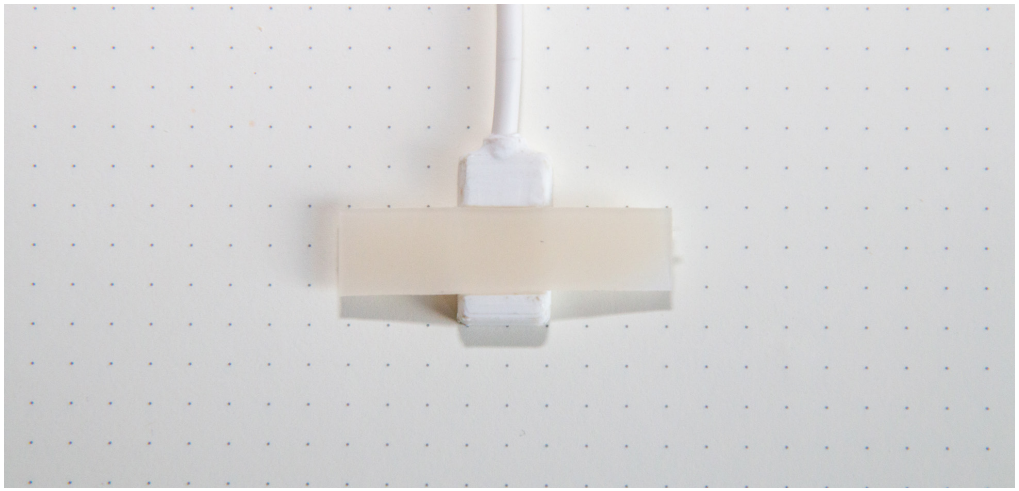


Figure 41. The Sensor with the medical adhesive attached to it on a 5mm grid.

The next step is to attach the peripheral electronics to the underwear (Figure 42). There are no additional buttons that need to be pressed. When measurements are being taken and everything is working properly the start button will light up and turn green. The on button will stay green for the duration of the measurement. To avoid confusion, green light is only used to indicate that the measurements are being taken.

When the patient wakes up in the morning, the device can just be turned off, cleaned, and then placed in the box to be returned to the doctors office.

The medical staff will have to clean and charge the device as well as uploading the data to the server.

Figure 42. The Erectiometer is attached to the underwear. The device is shown in open (Top) and closed (Bottom) position.

10. Conclusion and Recommendations

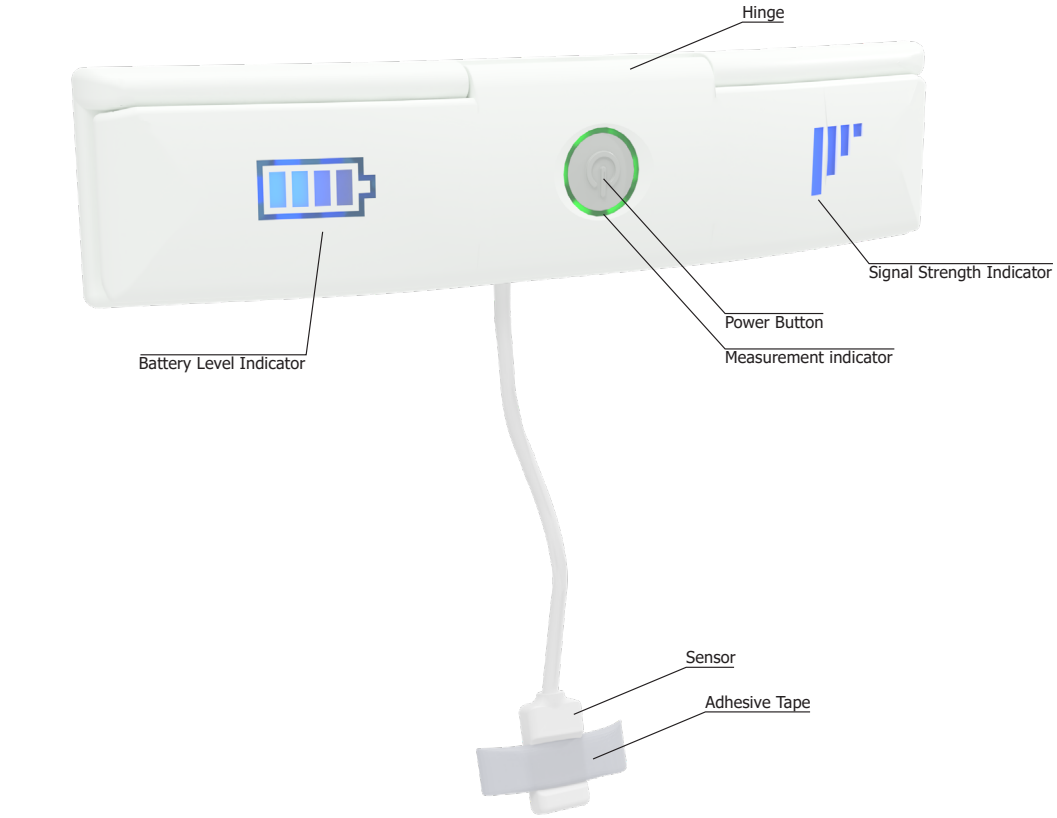
The initial goal of the Erectiometer was to provide urologists with a diagnostic tool that can be used to measure and provide data regarding nocturnal erections.

My results show that it is possible to obtain STO_2 measurements in the penis using a tissue oximeter in both flaccid and erect penises. The final design includes the tissue oximeter prototype, an ergonomic design for the device and a design for the user interaction.

Future Steps

For the continued development of the Erectiometer, more work needs to be done (1) to ensure that the tissue oximeter sensor is robust and able to provide consistent data when tested during nocturnal measurements with more patients, (2) further research needs to be conducted both on user interaction and user ergonomics, and (3) more development needs to be done on the case and external packaging for the device.

This device can not only be used to assist physicians with the diagnosis of ED, but it can also be used in the field of scientific research studying the effects of certain medical procedures on erectile function.



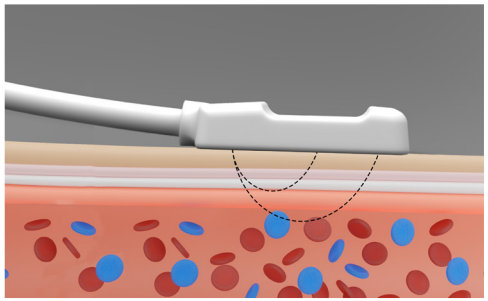


Figure 43. The Erectiometer with its parts highlighted (Top), the Erectiometer on underwear (Left) and the sensor of the Erectiometer on tissue (Right).*
**Note that the blood cells is not to scale.*

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Appendix A: Program of Requirements

Requirements and Wishes		Reasoning
1. Performance		
R1.1	The product must be able to measure the number, duration, and intensity of nocturnal erections of the user.	This is required to give a good indication of the erectile function.
R1.2	The product has have a precision with less than 10% deviation in oxygen saturation.	Oxygen saturation goes up by >20% thus the precision must be less than half still show the change.
R1.3	The product has have a accuracy with less than 15% deviation in oxygen saturation.	The absolute oxygen saturation only gives an indication, so accuracy is less important than precision (i.e. consistency).
R1.4	The product must be able to collect data for two consecutive nights (20 hours total).	First night data can be influenced by the test or chance, two nights will show consistency.
W1.1	The product should provide as much insight into the physiological functioning of the erection as possible.	
W1.2	The product should be as precise as possible.	
W1.3	The product should be as accurate as possible.	
2. Environment		
R2.1	The product must function indoors.	The product is only used indoors and thus does not need weather proofing, UV protection, etc.
3. Life in Service		
4. Long Term Maintenance		
R4.1	The product must last more than 2 years without repairs.	
W4.1	The product should last as long as possible without repairs.	
5. Target product cost		
R5.1	The production cost must to be below €2000,- per unit.	The price of this device must be below the price of a rigiscan device. The price of the consumables must be less than the price of a box of sildenafil (Viagra).
R5.2	The cost of consumables must be below €20,- per use.	
W5.1	The production cost should be as low as possible.	
W5.2	The cost for consumables should be as low as possible.	

6. Transport
7. Packaging

8. Quantity

R8.1	The minimal series in the first year is 1 unit.	
R8.2	The total series size for the first 2 years is expected to be below 200 units.	

9. Production facilities

10. Size and weight

R10.1	The product must have a volume of 15000 mm3 for the electronics.	The product must be able to contain all required electronics.
W10.2	Peripheral electronics should be as lightweight and compact as possible.	A lighter product will cause less sleep disturbance and needs less force to be attached to the user.

11. Aesthetic, appearance and finish

W11.1	The device should be perceived as clean by the patient and staff.	
W11.2	The device should be perceived as durable (e.g. It wont break or come loose when rolled on)	
W11.3	The device should be perceived as discrete.	

12. Materials

R12.1	Materials must withstand water, sweat, lubricants and other fluids around the body.	During use, the product can come in contact with wet skin, sweat, lubricants used for sex, and other fluids around the body.
R12.2	Materials must have excellent alcohol durability (according to CES).	As the product is wiped down between uses with alcohol, the casing needs to be able to withstand it excellently.
R12.3	Materials may not release toxins on the skin.	

13. Product life span

14. Standards, rules and regulations

R14.1	The product must be traceable by means of a serial number.	European Medical Device regulation 2017.

15. Ergonomics

R15.1	The device has to be suited for penis circumferences between 58mm (P1 flaccid) and 153mm (P99 erect).	
R15.2	The device has to be suited for penis circumference increases during erections of 100% to 200%.	
W15.1	The device should fit as many men as possible.	
W15.2	The sensor should be as comfortable to wear as possible	
W15.3	The device should be as comfortable to wear as possible	Less discomfort will cause less sleep disturbance and thus less interference of the measurement.
W15.4	User interfaces should be as clear as possible.	Complex interfaces can scare users and can cause mistakes, especially in patients with low digital literacy.

16. Reliability

R16.1	Device failure during use is non-critical.	If the device stops during a measurement this is non-critical as the measurement can be taken at a later point.
R16.2	Device failure has to be clearly indicated to the user.	If the device stops during a measurement the user needs to know this, so that they can take new measurements.
R16.3	The sensor has to stay in place for the duration of the night.	For the nocturnal measurement it is important that the sensor stays attach for the duration of the night.
W16.1	The device should work as reliably as possible.	Device failure and failed measurements should be minimized.

17. Storage

18. Testing

19. Safety

R19.1	Users may never receive electric shocks when using or operating the product.	
R19.2	The device may not cause damage to skin, E.G. because of strong adhesives or sharp edges.	
R19.3	Sensitive data send over wireless communication or over the Internet has to be encrypted.	As the data collected is very sensitive, data leaks are a serious risk.
R19.4	The device may not cause obstruction or limitation of blood flow.	Obstruction of blood flow can alter measurements and prolonged obstruction can cause hypoxia damage to tissue.
R19.5	The device may not cause damage to the user's skin due to heat (>50°C).	Surfaces above 50° can cause damage to the skin.
R19.6	The device may not cause damage to the user's skin due to heat over a prolonged period of time (>37°C for >1 hour) (erythema ab igne a.k.a. toasted skin syndrome).	Prolonged exposure of surfaces above 40°C can cause damage to the skin.

20. Product policy

21. Societal and political implications

22. Product liability

23. Installation and initiation of use

R23.1	The patient must be able to unpack the device and use it right away.	Users should be able to unpack the device and use it right away to prevent a stressful interaction from altering the measurements.
R23.2	The product may not require manual calibration before use.	As no skilled technicians are present when the device is used, no manual calibration should be required.
W23.1	Application of the device should be as simple and quick as possible.	

24. Reuse and recycling

R24.1	Over 90% of the device by weight must be reusable between users.	Both from a sustainability and cost perspective, reuse should be the goal.

25. Patients

R25.1	The device has to be non-invasive.	Needles and devices used internally bring significant risks of infections and tissue damage.
R25.2	The product must be clean from grease, sweat, hair and the like when given to a user.	

26. Doctors & Staff

R26.1	Doctors must be able to interpret the data, gathered in one night, in less than 10 minutes.	The doctors time is limited, so any data analysis and data processing by the doctor should be limited.
R26.2	The device must be cleaned for reused in less than 5 minutes.	The device must be designed in way that it can be cleaned in a reasonable amount of time.
W26.1	Cleaning of the device should be as simple and quick as possible.	The quicker the device can be cleaned, the better.

Appendix B: Schematic Diagrams

Amplifier Circuit

The sensor use two photodiode with an amplifier. Both amplifier circuits are built around an operation amplifier (Op Amps, marked U1A in figure 1). The Op Amp serves to amplify and convert the photo current to a voltage, this is discussed in chapter 6.2.3. The design of this circuit was based on guides by TI, 2019, and Baker, 2017.

Op Amp

The positive pin (3) of the Op Amp is connected to the reference voltage. The negative pin (2) of the op amp is connected to the cathode of the photodiode. The output of the Op Amp (1) is connected to the analog input of the Arduino microcontroller.

Reference Voltage

The reference voltage connected to the positive input of the Op Amp increases the voltage over the photodiode. This makes the photodiode operate closer to the voltage specified by the manufacturer (5V).
In this design a reverence voltage of 0.77 V was used. This was created using a voltage divider based of a 3.3 and a 1 kOhm resistor (Figure 2).

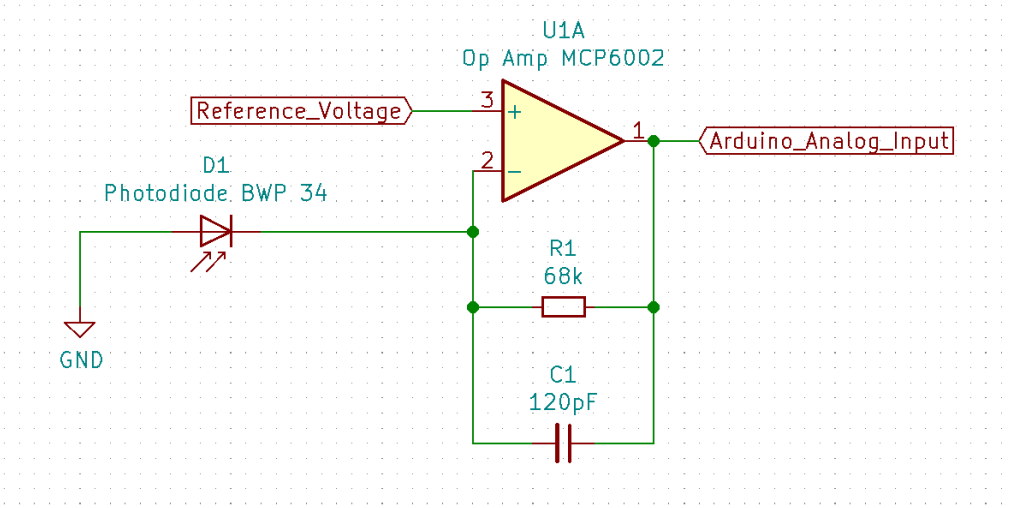

Figure 1. Schematic of the photodiode with the amplifier.

Photodiode

The photodiode in this circuit is used in a negative reverse bias mode. This means that current will flow from the anode (+) to the cathode (-) of the photodiode, to the ground connection.

Feedback resistor

The amount of amplification depends on the feedback resistor (R1). The feedback resistor was chosen so that the voltage that goes to the Arduino input is within range of the Arduino (0-3.3V). The output voltage is equal to the input current multiplied by the resistance. In this case I used a 68 kOhm resistor.

Capacitor

The capacitor (C1) serves to filter out noise. The value of this capacitor is based on the calculations in the guide by TI, 2019, and the characteristics of the photodiode and Op Amp.

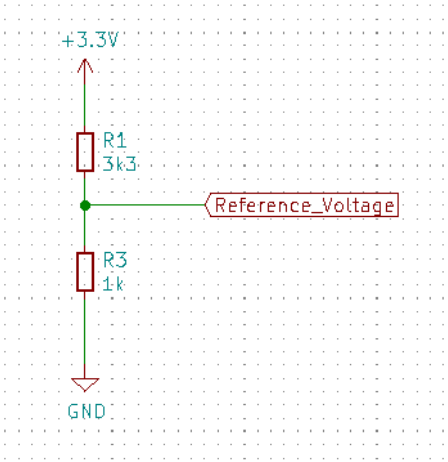

Figure 2. Schematic of the voltage divider for the reference voltage.

Appendix B: Schematic Diagrams (Continued)

LED Driver Circuit

The sensor uses two LED, each with its own driver circuit. This driver circuit is required, because the Arduino microcontroller cannot output enough current to drive the LED.

NPN Transistor

A NPN transistor (Q1) is used as a switch to allow a larger current to flow through the LED when needed. A 660 Ohm resistor is used to limit the current going into the base of the transistor (2). The value of this resistor was calculated by dividing the voltage (3.3V) by the maximum base current (5 mA).

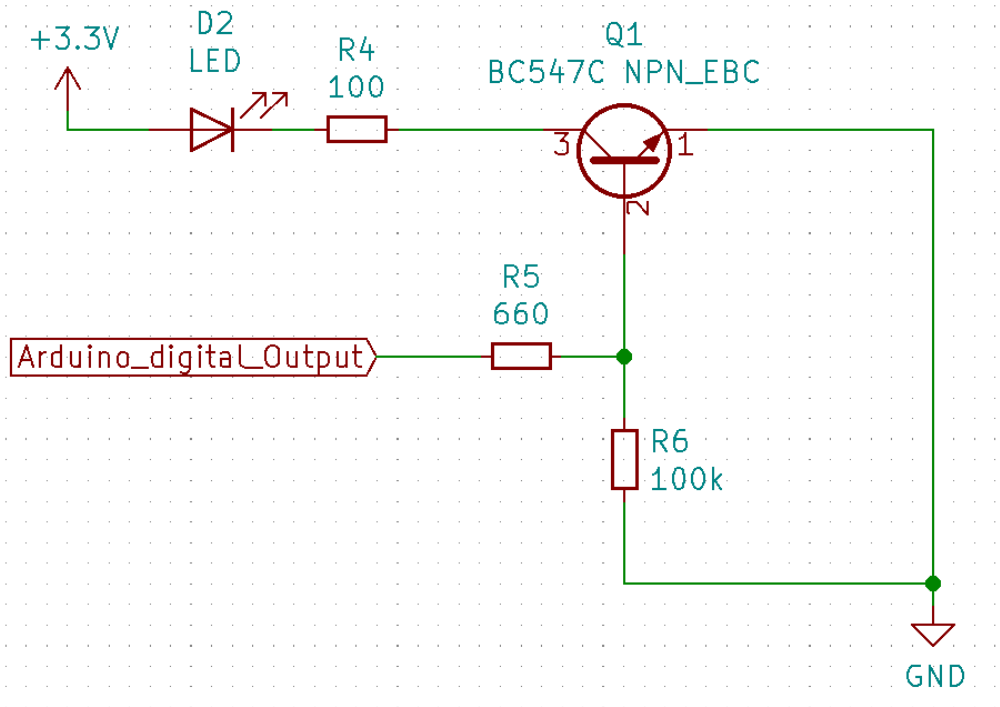

Figure 1. Schematic of the LED driving circuit

Pull down resistor

A pull down resistor (R6) is used to make sure that the transistor closes fully when no voltage is applied by the Arduino microcontroller. A significantly larger resistance is used to prevent the voltage at the base from dropping too much.

Current limiting resistor

To limit the current on the LED and prevent it from burning out, a current limiting resistor (R4) is used. The resistance depends on the required intensity and the voltage drop of the LED.

Appendix C: Images of the prototype circuit

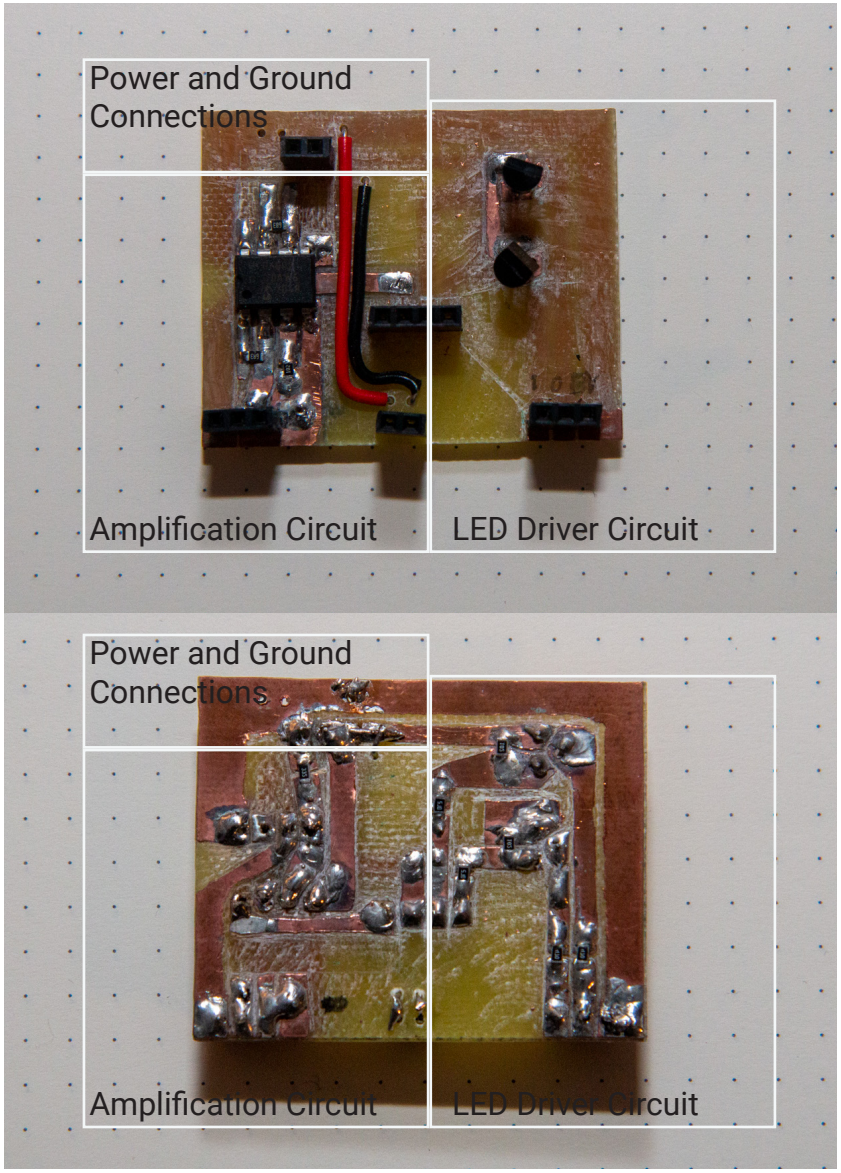

Figure 1. Front (top) and back(bottom) of the amplification and LED driver prototype on a 5mm grid. Left side is for the amplification and the right side is for the LED driver circuit. Bottom image is flipped to make following the traces easier.

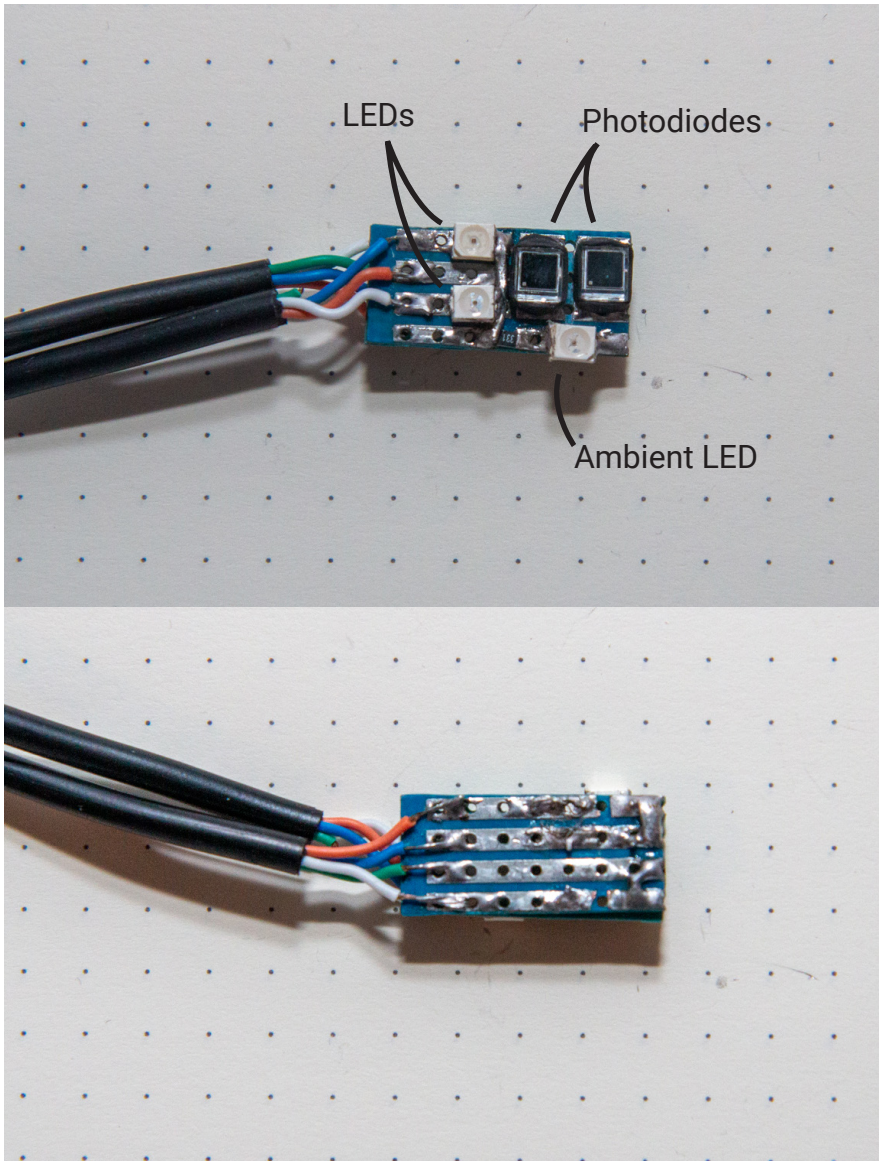

Figure 1. Front (top) and back(bottom) of sensor prototype C on a 5mm grid.

ID	Wishes	Importance	Underwear clip		Leg strap		Leg adhesive	
W16.1	Reliability	10	7	70	8	80	7	70
W23.1	Easy applications	7	8	56	6	42	8	56
W26.1	Quick cleaning	7	7	49	4	28	7	49
W15.1	Peripheral comfort	6	8	48	7	42	2	12
W11.2	Durable perception	5	7	35	8	40	8	40
W11.1	Clean perception	3	7	21	8	24	8	24
W11.3	Discrete perception	3	8	24	8	24	8	24
W4.1	Maintainance free lifespan	3	8	24	8	24	8	24
W5.1	Production cost	2	8	16	8	16	8	16
W5.2	Consumable cost	1	10	10	10	10	6	6
	TOTAL		343		320		315	