How To Design And Build A Penile Sensor Monitoring Nocturnal Erections To Aid In The Diagnosis Of Erectile Dysfunction?

Bachelor Thesis Creative Technology

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Abstract

This project explores the development of a wearable sensor system designed to monitor nocturnal penile erections, aiming to aid in the diagnosis of erectile dysfunction. The system integrates multiple sensors, including thermistors, a stretch sensor, a pulse oximeter, and an accelerometer, managed by the Arduino Nano 33 BLE Sense Rev2 microcontroller. The sensors monitor key parameters such as penile temperature, circumference, blood saturation, and movement.

Key findings include the identification of the Semitec 203AT-2 thermistor for its precision in capturing temperature changes and the selection of a flexible stretch sensor over a bend sensor due to its reliable performance in monitoring circumference changes. The MAX30102 oximeter was validated for arterial pulse measurement but encountered challenges in accurately measuring blood saturation levels, suggesting the need for further development or alternative solutions.

The 3D-printed casing provided a secure and compact housing for the system. Future iterations should address user comfort by incorporating thinner wires and optimizing component integration. The study also highlighted the need for improved data transfer via Bluetooth Low Energy (BLE) and potential enhancements like a user-friendly app and an indicator LED for system status.

Overall, the project presents a promising proof-of-concept for a low-cost, effective nocturnal erection monitoring system, with recommendations for future research and development to enhance its functionality and user experience.

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1 Introduction

Erectile dysfunction (ED) is a prevalent condition characterized by the inability to maintain an erection firm enough for sexual intercourse. It affects millions of people worldwide and has a significant impact on the quality of life and intimate relationships [14]. In order to provide a proper treatment strategy, the origin of erectile dysfunction needs to be diagnosed. Two types of erectile dysfunctions exist; psychogenic and organic. The latter comprises of vascular, neurogenic, iatrogenic or endocrine causes [15]. A distinction on the origin of the dysfunction is made based on the presence or absence of nocturnal erections during REM sleep. Currently, the gold standard for measuring nocturnal erections is the RigiScan®, developed by Bradley et al. [16] in 1985 (Figure 1). This diagnostic device measures penile rigidity and circumference overnight. The device operates using two cable loops worn around the base and tip of the penis. The loops are wired to a microcomputer that processes the data. The rigidity is calculated every fifteen seconds by applying an external force onto the cable loops and measuring the change in circumference. The data can be read and extracted using the RigiScan® Plus software installed on a computer running Windows XP [17].

The RigiScan® however, has several disadvantages that limit its use. First of all, the microcomputer of the RigiScan® is large and uncomfortable, this limits the patient's sleep, resulting in the absence of REM sleep, making data invalid. Secondly, the RigiScan® uses external pressure to collect data. This can be uncomfortable for the patient, influencing REM sleep and thus the validity of the data. Thirdly, the data can only be extracted using a Windows XP computer, making the software outdated and in some cases unusable. At last, the RigiScan®'s loops are susceptible to detaching during nocturnal use, which makes the data unusable.

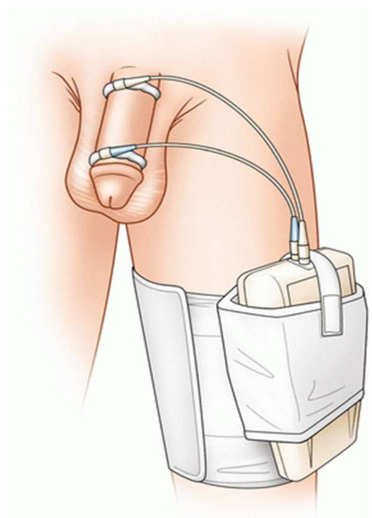
Figure 1, The RigiScan® setup [5].

These disadvantages show the need for a new diagnostic tool, one that is more comfortable for the patient and produces more reliable data on more parameters of the nocturnal erection. Combined with the rapid development of new sensor technology, the development of a new diagnostic tool shows promise.

In order to develop and build such a new concept sensor system, to detect nocturnal erections to aid in the diagnostics of erectile dysfunction, three questions have to be answered:

- *How can the sensor be designed to minimize discomfort during nocturnal use?*
- *What components are required to make a sensor monitoring nocturnal erections that is sufficiently comfortable, sensitive and reliable?*
- *How does the accuracy and reliability of the sensor compare to existing diagnostic methods?*

Using the Background Research in Chapter 2, the Methods and Techniques in Chapter 3 and the Ideation in Chapter 4 these questions can be answered.

2 Background Research

In this chapter, all relevant topics and components for the development of the penile sensor will be discussed. By analyzing existing literature and research, this chapter aims to clarify the key components that will be used in the first prototype of the penile sensor.

2.1 How To Minimize Sensor Discomfort During Nocturnal Use?

To ensure the sensor is wearable and minimizes discomfort during nocturnal use, it must be designed to be small, lightweight, and safe. The microcontroller, power system, and data storage are the primary components that will determine the overall size of the penile sensor. Therefore, this section will focus on these components. The sensors, which also play a crucial role in the overall design, will be covered in the subsequent section.

2.1.1 Microprocessor

The microcontroller serves as the central processing unit of the penile sensor system. It facilitates data acquisition, data processing, and wireless communication. Due to the importance of the microcontroller, selecting the appropriate microcontroller is fundamental to designing a sophisticated and functional sensor.

2.1.1.1 System Requirements for Microcontroller

To select a sophisticated microcontroller, it is essential to define the system requirements that the microcontroller must meet:

Processing Power

The microcontroller should possess sufficient processing capabilities to handle data from multiple sensors. Data logging should be of sufficient speed, with a required minimum sampling frequency of 1 Hz per sensor. Modern microcontrollers have processing powers in megahertz (MHz) ranges, so this should not form an issue.

Sensor Interfacing

The microcontroller should be compatible with various sensor types and communication protocols, which is essential to ensure seamless integration and data acquisition.

Power Efficiency

The microcontroller must minimize power consumption as this is critical for optimizing battery life, especially for a wearable device intended for nocturnal use. The sensor system is required to operate for at least 10 hours on one battery charge to span an entire night. This will be defined in section 2.1.2.1 “System Requirements for Battery”.

Size and Form Factor

The microcontroller's physical dimensions must align with the size constraints of the sensor system, facilitating compact and unobtrusive integration. The sensor should, therefore, be as small as possible.

Either:

Wireless Communication
The microcontroller must allow support for wireless communication protocols, such as Bluetooth or Wi-Fi to enable remote data transmission and enhance user convenience.

Or:

Local Storage
The microcontroller must allow for local storage options to enable data logging in situations where wireless transmission is impractical.

2.1.1.2 Available Microcontroller Options
Research amongst available microcontrollers will be conducted, hereby considering familiarity with coding in combination with popular brands. This results in a list of Arduino, Raspberry Pi, ESP and PocketBeagle. For each brand, a suitable microcontroller is chosen and compared to the others using the above-formulated requirements. An overview is shown in Table 1.

Table 1, Overview of different microcontrollers and their properties

Brand	Model	Processing Power	Power Efficiency	Size and Form Factor	Wireless Communication	Local Storage Capacity
Arduino [18]	Arduino Nano 33 BLE Rev2	64 MHz	20 - 30mA	Small	Bluetooth Low Energy	External MicroSD Card optional
Raspberry Pi [19]	Raspberry Pi 5	2.4 GHz	540mA	Large	None	USB drive, MicroSD Card
ESP32 [20]	ESP32 U4WDH	240 MHz	160 - 260mA	Medium	Wi-Fi, Bluetooth	External MicroSD Card optional
Pocket-Beagle [21]	Pocket-Beagle	1 GHz	140 – 230 mA	Medium	None	MicroSD Card

2.1.1.3 Conclusion
The Arduino Nano 33 BLE Rev2 emerges as the most fitting microcontroller for the penile sensor system due to its compact size, sufficient processing power, efficient power consumption, and built-in wireless communication capabilities. Its small form factor allows seamless integration into a wearable device, ensuring minimal discomfort during nocturnal use. Despite its size, the Arduino Nano 33 BLE Rev2 offers sufficient computational capabilities to handle data from multiple sensors and perform real-time analysis, crucial for the accurate monitoring of nocturnal erections.

Additionally, the Arduino Nano 33 BLE Rev2 offers multiple inbuilt sensors that can be used in the system. It includes an accelerometer, temperature sensor, humidity sensor, microphone and IMU's. The accelerometer will be useful for this system and will be further discussed in section 2.2.3.4.

Besides this, efficient power management ensures prolonged battery life, essential for extended monitoring periods. The built-in Bluetooth Low Energy (BLE) capability enables, energy-efficient wireless data transmission to an external device, facilitating remote monitoring and analysis of nocturnal erectile data. Overall, the Arduino Nano 33 BLE's combination of size, processing power, power efficiency, and wireless communication make it the optimal choice for the penile sensor system, ensuring accurate and reliable diagnostic capabilities.

In this report, the Arduino Nano 33 BLE Rev2 may sometimes be referred to as Arduino Nano BLE for simplicity.

2.1.2 Power system

When considering the power system for the penile sensor system, several options are available. These options range from traditional disposable batteries to rechargeable batteries, or a wired system. Each has its own set of advantages and limitations. A wired power system, while offering consistent and uninterrupted power, is not preferred for a wearable sensor due to comfort concerns. The presence of wires could restrict movement and cause discomfort during nocturnal use. As such, alternative power solutions are better suited to ensure both reliability and user comfort for prolonged monitoring sessions. Therefore, in this discussion, we will primarily focus on exploring battery-powered solutions that offer both convenience and comfort for the user.

2.1.2.1 System Requirements for Battery

To select a sophisticated battery, it is essential to define the system requirements that the battery must meet. The selected microcontroller, the Arduino Nano BLE, runs on a 3.3-volt input supply [22]. The required battery voltage should therefore be at least 3.3 volts or higher. For this prototype, the battery should be rechargeable as this is more convenient than single-use batteries. Using rechargeable batteries eliminates the hassle of constantly purchasing and disposing single-use batteries during the testing phase.

Voltage Compatibility

The selected battery must provide a voltage output of at least 3.3 volts to power the Arduino Nano BLE effectively and ensure reliable operation of the penile sensor system [18].

Rechargeable Capability

For a prototype, the battery should be rechargeable, as this is more convenient.

Energy Capacity

The battery should contain sufficient capacity to power the sensor system for the desired duration of nocturnal monitoring sessions, considering the power consumption of all components. The system must run for one night without the need to charge, therefore the minimum time without charging is 10 hours as concluded by Torenvlied et al. [23]. Based on this value, a broad estimation can be made for the total required battery capacity.

A study by Sabovic et al. [24], identified the current draw of the Arduino Nano BLE in different operation modes. They conclude that the Arduino Nano BLE uses around on average 4.2 mA when actively transmitting or receiving data. These values, however, only depict the Arduino's status in transmitting or receiving data. Other processes will be run simultaneously too, so to be on the safe side, the current draw is rounded upwards. This results in a current draw of around 5mA for the Arduino Nano BLE.

For the different sensors used in the system, an even rougher estimation has to be made. A total of five sensors will be used. On average, a single sensor, regardless of its use, draws around 5mA of current. This creates a total current draw of 5 sensors * 5mA = 25mA.

This results in a total current draw of 30mA for microcontroller and sensors. But, due to the roughness of the estimation, and to be on the safe-side, we increase the current draw to be around 50mA.

To calculate the minimum power a battery has to store to last for at least 10 hours, we use the following equation:

$$Battery\ Life\ (hrs) = \frac{Battery\ Capacity\ (mAh)}{Load\ Current\ (mA)}$$

$$Battery\ Capacity\ (mAh) = Battery\ Life\ (hrs) \cdot Load\ Current(mA)$$

$$Battery\ Capacity\ (mAh) = 10hrs \cdot 50mA = 500\ mAh$$

Therefore, the battery should have a total capacity of at least **500 mAh**.

Since the above estimates are very rough, a more accurate calculation should be conducted during the testing phase. The system's power consumption can be measured using the Arduino Power Profiling Kit II [25]. A sophisticated battery can, after this power testing, be chosen accordingly and installed later on.

Size, Form Factor and Weight
The battery should have a compact size and appropriate form factor, whilst minimizing total weight to fit within the wearable device comfortably without causing discomfort to the user.

Safety
The battery should be reliable and safe for operation to prevent potential hazards, such as overheating, leakage, or fire risk. This is especially important during extended nocturnal use. A CE certification is therefore required.

Weight
Lightweight design to minimize the overall weight of the wearable device and enhance user comfort during nocturnal wear.

2.1.2.2 Available Battery Options

Based on the requirements outlined for the battery system of the penile sensor, several available battery options have been evaluated. In

Table 2, an overview of different batteries and their properties are shown.

Table 2, Overview of different batteries and their properties

Battery Model	Rechargeable	Voltage (V)	Capacity (mAh)	Size (l x w x h)	Weight (g)	Safety
Lithium Ion Battery - 3.7v [26]	Yes	3.7	1200	Small 50 x 35 x 5 mm	20	Safe, CE certified
RS PRO 3.7V Lead Terminal Lithium Battery [27]	Yes	3.7	1800	Medium 53.5 x 35 x 10.4 mm	36	Safe, CE certified
9V Type-C Li-Ion Battery [28]	Yes	9	1000	Medium 48.5 x 26.5 x 17.5 mm	45	Safe, CE certified
EEMB 3.7V Lipo Battery [29]	Yes	3.7	600	Small 44 x 30.5 x 5.3 mm	12	Safe, CE certified

2.1.2.3 Conclusion

In conclusion, the EEMB 3.7V LiPo battery will be the most promising option for powering the penile sensor system. With its rechargeable capability, voltage compatibility, and capacity of 600mAh, it meets the essential requirements for sustained operation during nocturnal monitoring sessions. The compact size and lightweight design of the EEMB battery make it suitable for integration into the wearable device, ensuring minimal disruption to the user during wear. As a second choice, the first and second batteries would also be a possible option, however, they are larger in size due to their increased battery capacity. This makes them less suitable than the EEMB 3.7V LiPo battery. The 9V Type-C Li-Ion Battery is an easy option during testing, but due to its 9v output, this requires more electrical circuitry. This battery is also more bulky, making it likely to cause more discomfort.

2.1.3 Transfer of Acquired Data

During nocturnal use of the penile sensor, data is constantly being acquired. The Arduino Nano BLE has very limited storage capacity. As a result, it becomes necessary to establish a mechanism to transfer data to an external storage device. Data transmission on the Arduino Nano BLE is very convenient due to its compatibility with Bluetooth Low Energy.

2.1.3.1 Bluetooth Low Energy

Bluetooth Low Energy (BLE) is a wireless communication technology designed for low-power devices, allowing them to exchange data over short distances. It enables efficient data transmission between devices, such as sensors, smartphones, and wearables, while consuming minimal energy.

By transferring data to an external storage device, such as a smartphone, tablet, or dedicated BLE-enabled storage unit, the system can ensure that all sensor readings are collected securely. This external device can be physically disconnected from the penile sensor system, allowing its storage capacity to be more than sufficient. In Figure 2, a connection diagram is shown, data is transferred from multiple penile sensor types to the Arduino Nano BLE. This data is processed and transmitted to an external storage device.

Figure 2, Connection diagram displaying how data is transferred in the system

2.1.4 System Dimensions

In determining the dimensions of the penile sensor system, several factors must be considered to ensure optimal comfort and functionality. The system should be compact and lightweight to minimize intrusion and discomfort during nocturnal wear. In addition, the system must accommodate all essential components, including the microcontroller, power system, sensors, and any additional circuitry. The overall size should be small enough to allow for discreet placement and seamless integration with the user's body.

Since the battery and the Arduino Nano BLE microcontroller are the largest components of the system, the minimum dimensions are 44 x 30.5 x 5.3mm and 45 x18 x 5mm respectively. This means that the bare minimum system dimensions would be 45 x 30.5 x 5.3mm. However, more space will ultimately be needed in order to accommodate the sensors, extra wiring and potential housing.

2.1.5 Conclusion

To conclude, the microcontroller, power system and data transfer method are defined ensuring that all requirements are met. In Table 3, a final overview of the system's components can be seen. In Figure 3, the connection diagram of these system components can be seen.

Table 3, Overview of System Components

Component	Conclusion
Microcontroller	The **Arduino Nano BLE Rev2** emerges as the most fitting choice due to its compact size, sufficient processing power, efficient power consumption, and built-in wireless communication capabilities.
Power System	The **EEMB 3.7V LiPo** battery stands out as the most promising option, offering rechargeable capability, voltage compatibility, and sufficient capacity for sustained operation during monitoring sessions.
Transfer of Acquired Data	**Bluetooth Low Energy** (BLE) provides a convenient and energy-efficient solution for transferring data to an external storage device. This ensures a secure collection of sensor readings, with enough storage capacity.
System Dimensions	The system dimensions must be carefully balanced to ensure optimal comfort and functionality, with a focus on compactness, lightweight design, and sufficient space for all components. The bare minimum system dimensions are **45 x 30.5 x 5.3mm**, but larger dimensions are needed to accommodate wiring, sensors and potential housing.

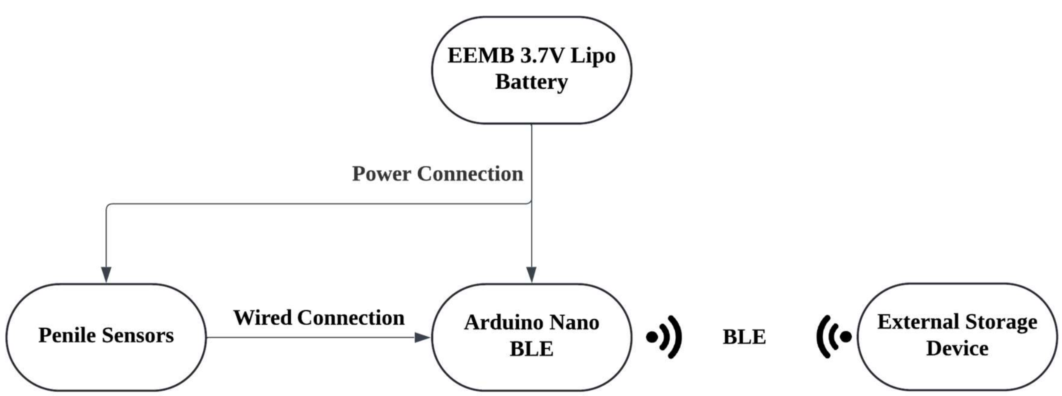

Figure 3, Connection diagram of system components

2.2 How To Measure Nocturnal Erections?

Through the analysis of existing literature and research, this section aims to clarify the key parameters that will be used to detect nocturnal erections. For each of these parameters, a suitable sensor will be researched and implemented in the first prototype of the penile sensor. At the end of this section, the results will be used to ultimately create a theoretical sensor system for measuring nocturnal erections.

2.2.1 The Penile Erection

In order to measure nocturnal erection, the physical changes within a human penile erection must be well understood. The process of penile erection is primarily a vascular phenomenon. Blood reaches the penis via terminal branches of the internal pudental arteries, located in the pelvic area. The blood then enters the penis through the cavernous arteries (located in the center of both the left and right corpus cavernosum). Once the smooth muscle cells in the corpus cavernosum relax, blood is able to flow out of the main cavernous artery and fill up the corpus cavernosum. As the blood accumulates in this area, the emissary veins are compressed shut, which reduces the venous outflow of the penis [30]. On top of this, the musculi at the base of the penis squeeze shut, trapping more blood inside the penis [31]. As a result of this trapped blood, and an increased blood inflow, the penis goes from flaccid to an erect state, as seen in Figure 4. During this state change, the penis grows in both circumference and length.

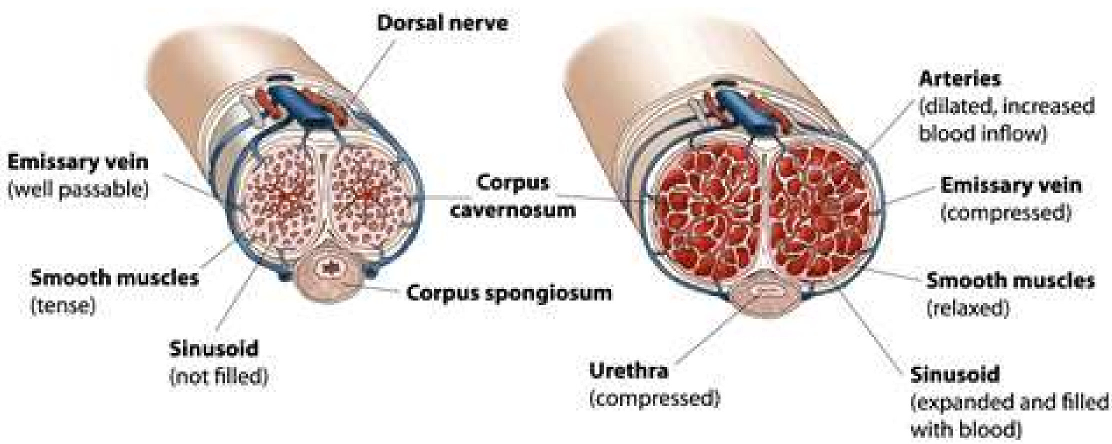

Figure 4, Cross-sectional diagram of the anatomy of penile structures in flaccid (left) and erect (right) state [2].

2.2.2 Parameters and Sensor Requirements

Based on our understanding of the penile erection, several physical penile parameters can be utilized to detect nocturnal erection. Previous research has shown that up until now, there are five measurable penile parameters possibly feasible for application in nocturnal erection detection; Penile temperature, circumference, blood saturation, arterial pulse and acceleration [16]. These parameters provide insights into the physiological changes associated with nocturnal erections and can help to accurately detect them.

2.2.2.1 Temperature

In order to detect nocturnal erections, measuring the penile temperature overnight can be an effective method. The average penile temperature increase during nocturnal erections is 0.67°C as described by Torenvlied et al. [32]. This is the result of the corpora cavernosa filling with warm, oxygenated blood. By measuring this increase in temperature, a nocturnal erection can be detected. A suitable penile temperature sensor needs to have special requirements to precisely acquire the required data. The sensor should be of thermistor type, as this type of sensor has high precision and good accuracy and stability [23]. Additionally, the sensing system should incorporate one or multiple reference temperature sensors. These extra sensors are used to address potential inaccuracies during data analysis, where the act of getting into a warm bed might mistakenly be registered as a rise in penile temperature, suggestive of an erection. However, this temperature increase is caused by the warming effect of the bed rather than an actual erection. Therefore, by monitoring both the reference and penile temperatures, any simultaneous increase upon entering the bed can be interpreted as a non-erection event, accurately distinguishing it from genuine penile temperature changes associated with nocturnal erections.

An extra reference sensor on the abdomen is also useful. Research has shown that a decrease in abdominal temperature occurs during the start of an erection. By monitoring this abdominal temperature, an observed increase in temperature can help indicate the end of an erection [33]. This helps the system more accurately track the full cycle of erections during sleep.

Besides this reference sensor, other requirements are defined by Torenvlied et al. [23], in their research for a penile temperature sensor:

Patient Safety & Comfort

The temperature sensor should not influence patients' sleep quality, the sensor should be safe to use and the time it takes to attach the sensor to the body should be minimized. The sensor should be attached to the penis using a sticker or plaster.

Sensor Size, Weight & Location

The contact temperature sensor should be applied to the skin using a flexible and adhesive plaster. This plaster should be strong enough to remain attached to the penile skin during an erection. The sensors should be disc-shaped, to ensure maximum contact area with the penile skin. The sensor should also be small and light enough to not cause discomfort.

Environmental Disturbance

Disturbance of the environment to the sensor should be minimized. This can be done by insulating the temperature sensor. Protecting it from outside temperature variations.

Calibration & Range

The temperature sensor should be calibrated correctly, and the range of the sensor at least between 20°C and 45°C. The lower temperature range can be used to detect disconnection of the sensor during nocturnal use, the upper is the maximum body temperature.

Sampling Frequency

The sampling frequency of the temperature sensor should be at least that of the Rigiscan®, namely once every 15 seconds or $\frac{1}{15} = 0.067Hz$. A higher sampling frequency is preferred to get a more continuous reading.

Precision

Since the average increase in penile temperature is around 0.67°C, a precision of maximal 0.1°C is required. The accuracy of the sensor is less important as only the change in temperature is of importance.

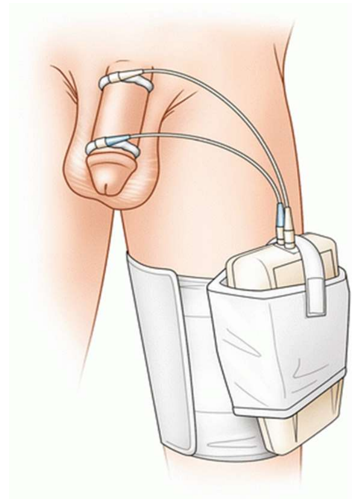

Figure 5, The Rigiscan® setup, with 2 cable loops attached around the base and below the glans of the penis [5].

To conclude, the penile temperature sensor must prioritize patient safety and comfort, ensuring minimal disturbance to sleep quality. It should be small, lightweight, and securely attached to the skin using a flexible adhesive plaster. Environmental disturbances should be minimized through sensor insulation. Calibration and readout must be accurate within the range of 20°C to 45°C, with a sampling frequency of at least once every 15 seconds. A precision of up to 0.1°C is necessary to detect the average increase in penile temperature during an erection accurately. Additionally, one or more additional reference temperature sensors are necessary to mitigate the risk of erroneously detecting erections triggered by the act of going to bed.

2.2.2.2 *Circumference*

Measuring penile circumference is another method to detect erections. The current golden standard, the Rigiscan® makes use of this method. During an erection, there is an increase in blood flow to the penis, causing it to expand and increase in circumference. By measuring this change in circumference, an erection can be identified. Besides the circumference, the length of the penis also changes during an erection. However, due to large variations in penile length, this measurement is not feasible for application in nocturnal erection detection [34].

The Rigiscan® makes use of 2 non-elastic loop cables that are attached to the penis at the base of the shaft and below the glans, see Figure 5. The loops are connected to a slide potentiometer, which measures the change in penile circumference. However, due to the external force applied to the penis (e.g. resistance of the loops) discomfort is caused. This can influence the quality of sleep and thus the reliability of the data, Therefore, this method of measuring circumference is not ideal.

As a result, when developing a new penile circumference sensor, the external force applied to the penis must be minimized. To do so, ring-like structures that enclose the entire circumference of the penis must be avoided. Besides this, the penile circumference must meet other requirements:

Patient Safety & Comfort

The circumference sensor should not influence patients' sleep quality, the sensor should be safe to use and the time it takes to attach the sensor to the body should be minimized.

Sensor Size & Weight

The contact circumference sensor should be applied to the skin using a flexible and adhesive plaster. This plaster should be strong enough to remain attached to the penile skin during an erection. The sensor should stretch to follow the increasing penile circumference during an erection. The sensor should also shrink back as the penis returns to a flaccid state. The sensor should also be small and light enough to not cause discomfort.

Calibration & Placement

The circumference sensor should be calibrated correctly, and the range of the sensor should cover at least half of the penile circumference. Placement of the sensor around the top of the shaft using a medical sticker, see Figure 6 and Figure 7. By using this location the blood saturation sensor and pulse sensor can be combined. This ensures an effective location for all measurements and simplifies the setup process. Covering at least half of the penile circumference ensures that the sensor can accurately capture changes in circumference associated with nocturnal erections. Also, it allows for flexibility in sensor placement and adjustment, accommodating variations in penile size and shape among individuals.

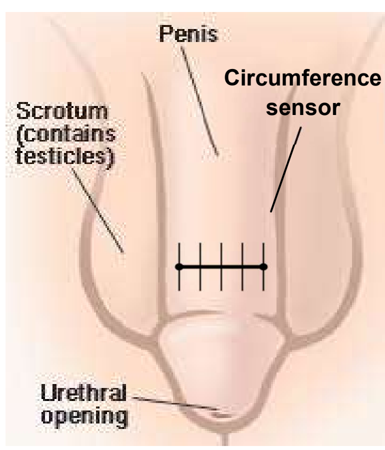

Figure 6, Circumference sensor attached to the penis [3].

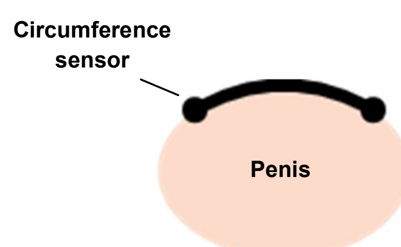

Figure 7, Front view of the penis, with circumference sensor attached.

Sampling Frequency

The sampling frequency of the circumference sensor should be at least that of the Rigiscan®, namely once every 15 seconds or $\frac{1}{15} = 0.067Hz$. A higher sampling frequency is preferred to get a more continuous reading.

Precision & Range

Given that the sensor covers only part of the penile circumference, its length should be sufficient to accommodate variations in penile size. To determine an appropriate length, we consider the average penile circumference in both flaccid and erect states. A study by Schoots [35], examined multiple other studies to calculate the average penile circumference. Data shows that the penile circumference in a flaccid state is approximately 95 mm and 120 mm in an erect state.

The sensor's length should be able to capture the change in circumference well. As only half of the penile circumference needs to be covered, the minimum range of the sensor should be around 45 to 60 mm. However, due to variations in penile sizes and discussions with H. Torenvlied, a minimum range of 45 to 80 mm is required.

Regarding precision, the sensor should offer the smallest possible margin of error to ensure accurate detection of changes in circumference. A precision of 5 mm would be minimal for this application.

In short, the design of a penile circumference sensor for detecting nocturnal erections requires careful consideration of patient comfort, sensor size, calibration, sampling frequency, and precision. The sensor should be designed to minimize discomfort during nocturnal wear, with a flexible and adhesive plaster for secure attachment to the penile skin. Calibrating the sensor correctly and ensuring it covers at least half of the penile circumference is essential for the accurate detection of changes associated with erections. Additionally, a high sampling frequency and precision are necessary to capture subtle variations in circumference and provide reliable data for diagnosing erectile dysfunction.

2.2.2.3 Blood Saturation

Measuring blood saturation in the penile tissue is another method to detect nocturnal erections. Blood saturation refers to the amount of oxygen present in the blood, which can vary during an erection due to changes in blood flow. Monitoring blood saturation levels in the penile tissue can provide valuable insights into the physiological changes associated with nocturnal erections.

In a flaccid state, penile saturation lies around 96.1%. This number is defined as the percentage of oxygenated hemoglobin (HbO_2) compared to deoxygenated hemoglobin (Hb) [31]. Due to the increased blood supply at the start of an erection, blood oxygen levels will rise. Once a full erection is reached, new blood supply is stopped. This results in a decrease in blood saturation, as penile cells continue to consume oxygen from the blood, without it being replenished [31]. When the penis returns to a flaccid state, this blood supply is continued again, resulting in a rise to normal blood saturation levels. The fluctuations in blood saturation should make this a possible parameter to detect nocturnal erections.

Previous research by Been et al. [31] studied different methods for using spectroscopy to detect a change in penile blood saturation. Pulse oximetry and NIRS (Near Infra-Red Spectroscopy). Both methods work based on the principle that light can penetrate biological tissues, including the penis, allowing it to interact with hemoglobin in the blood. By measuring the absorption of this light, these methods estimate the levels of oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) in the corpus cavernosum. The study by Been et al. [31], advised NIRS to be used as a penile blood saturation method. However, a study by Kahn et al. [36], has found that commonly eaten vegetables have NIRS measurements similar to those of healthy humans. This raises concerns about the reliability of the NIRS method and therefore makes it unsuitable for penile measurements. Therefore, pulse oximetry will be used to detect blood saturation in the penis.

A study by Florax [37] has further researched the use of pulse oximetry for detecting penile blood saturation. She concludes that a combination of red and infrared light needs to be used to detect blood saturation in the corpus cavernosum.

A reflective pulse oximetry setup consists of light sources (LEDs) that emit red light into the tissue combined with photodetectors (PDs) that measure the light that is reflected from the tissue, see Figure 8.

Probes containing both light sources and detectors can be placed on the surface of the penis to obtain measurements. The photodetectors receive the reflected light and transform it into electrical energy through the photoelectric effect. This captured light intensity generates a waveform known as photoplethysmography (PPG), consisting of a steady component (DC) and an alternating component (AC).

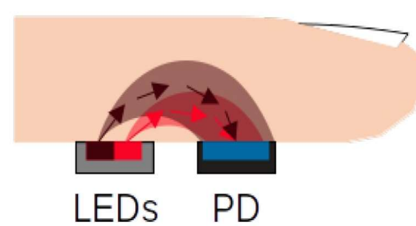

Figure 8, Diagram of reflective pulse oximetry with Light-Emitting Diodes (LEDs) and PhotoDetectors (PD) [13].

The steady component represents structures through which the light travels. In the context of the penis, this encompasses various tissue layers such as the skin, dartos fascia, Buck's fascia, the venous blood, and the tunica albuginea. (Figure 9) [37].

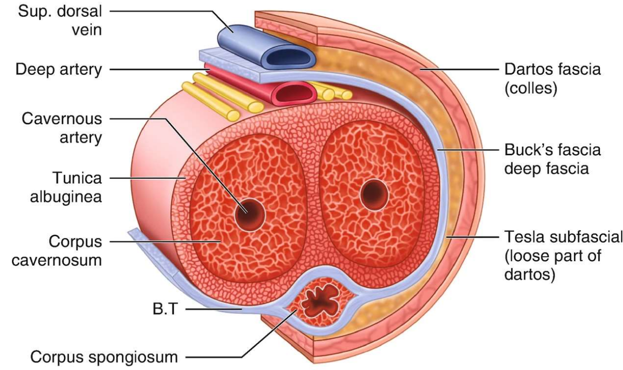

Figure 9, Anatomy of the penile tissue layers [11].

The alternating component represents the time-fluctuating structures which are the arteries. Due to the cardiac cycle, a changing blood volume is present, this can be observed in the PPG. The PPG will be further explained in section 2.2.2.4.

Blood saturation is assessed by comparing the absorption spectrum differences of oxygenated and deoxygenated hemoglobin for both red and infrared light. The "ratio-of-ratios" (RRs) method calculates the ratio of the alternating current (AC) to direct current (DC) components for red and infrared light. This ratio is then used in the formula [31]:

$$RR = \frac{\left(\frac{AC_{red}}{DC_{red}}\right)}{\left(\frac{AC_{IR}}{DC_{IR}}\right)}$$

Using the obtained R-value, blood oxygen saturation (SpO2) is determined using calibration coefficients a, b, and c in the equation:

$$Blood\ saturation(\%) = aR^2 + bR + c$$

Experimental measurements provide calibration coefficients for a, b, and c, allowing the calculation of blood saturation based on the R-value. Figure 10 illustrates an example demonstrating the correlation between blood saturation (%) and the R-value using these calibration coefficients [9].

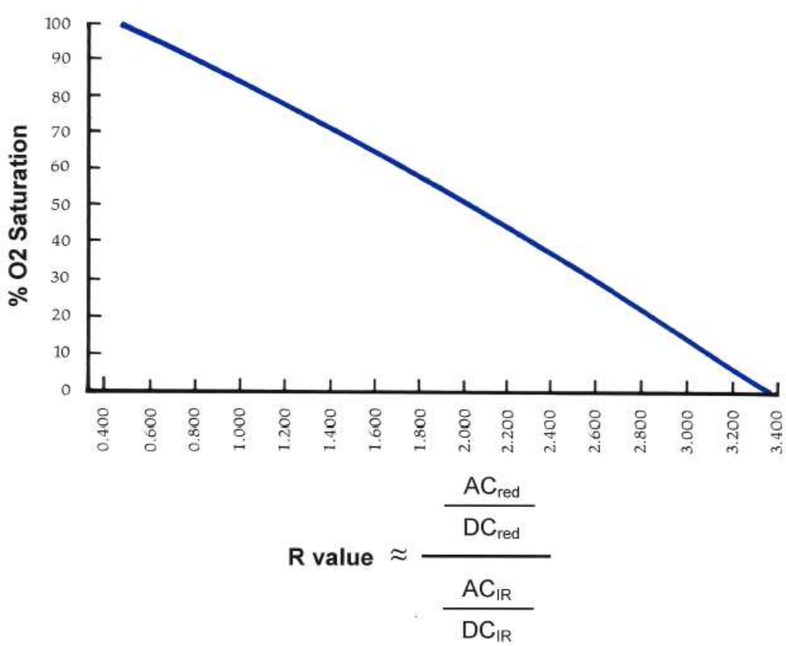

Figure 10, An example of an R-curve, showing the correlation between blood saturation (%) and the R-value [9].

To accurately assess blood saturation in the corpus cavernosum, a pulse oximeter equipped with both red and infrared light is essential. This setup allows for the precise determination of the AC and DC components of blood in the corpus cavernosum. While the pulse of the dorsal artery or cavernosal artery can be measured using only a green light oximeter setup. For measuring blood saturation in the corpus cavernosum, which lies deeper below the skin surface, red or infrared light is required. These wavelengths are able to penetrate deeper into the skin [31].

The depth of light penetration is directly linked to its wavelength, as shorter wavelengths possess higher energy and are absorbed more rapidly. Consequently, red and infrared light offer substantially deeper penetration depths, reaching around 5.0-6.0 millimetres within the skin, in contrast to the reach of green light, ranging only 0.6-2.5 millimetres [31].

Given these considerations, opting for a pulse oximeter utilizing red or infrared light is required for accurate blood saturation detection in penile arteries and cavernosal structures [31].

A blood saturation sensor needs to cope with the following requirements:

Patient Safety & Comfort

The saturation sensor should not influence patients' sleep quality, the sensor should be safe to use and the time it takes to attach the sensor to the body should be minimized.

Sensor Size & Weight

The blood saturation sensor should be designed to be applied to the penile skin using a flexible and adhesive plaster. This plaster should securely attach the sensor to the skin without causing irritation or discomfort. The sensor should be lightweight and compact to ensure it does not interfere with sleep quality.

Calibration & Placement

The sensor should be calibrated accurately using medical calibration curves to measure blood saturation levels within the penile tissue [31]. The sensor should be placed on the side of the penis since the dorsal vein is bigger in diameter than the venules on the side of the penis. This minimizes the impact of compression due to the expanding corpus cavernosum on the venules on the side of the penis [31].

Sampling Frequency

The sampling frequency of the blood saturation sensor needs to be sufficient to capture rapid changes in blood flow during a nocturnal erection. A high or continuous sampling frequency is desirable to ensure accurate and timely detection of changes in blood saturation levels. If a continuous sampling frequency is not possible, due to system limitations, a minimum sampling frequency of 32 Hz should be the baseline [37]. This is the minimum frequency required to accurately distinguish systole and diastole.

Precision & Range

The sensor's range should encompass the expected variations in blood saturation during nocturnal erections. This requirement, however, may be disregarded, as commercially manufactured saturation sensors are already designed to cover the range of human blood saturation levels, including those expected during nocturnal erections. The same holds for the precision of the sensor.

In conclusion, utilizing pulse oximetry to measure blood saturation offers a non-invasive and convenient method for monitoring penile blood saturation levels. This allows for the detection of nocturnal erections. However, ensuring patient safety, comfort, and accurate calibration remain important considerations in sensor design.

2.2.2.4 Arterial Pulse

Penile arterial pulse measurements can provide insights into the presence of nocturnal erections. Bancroft et al. [38] observed a positive correlation between the increase in penile diameter and the increase in pulse in the dorsal artery. This correlation is a result of the increased blood flow during the penile filling phase, marking the onset of an erection. Consequently, there's a variance in blood volume between systole and diastole. Pulse oximetry can detect this increased difference as an amplification in pulse amplitude (Figure 11). This enlarged pulse amplitude might also be present in the cavernosal artery. This is because, at the initiation of an erection, the filling of the corpora cavernosa causes intracavernosal pressure to rise to values equal to systolic pressure. This results in a fully rigid erection. Similar to blood pressure measurements, when external pressure equals systolic blood pressure, vasoconstriction occurs, causing the arterial pulse to disappear. This absence of this arterial pulse is expected to happen in the cavernosa during full rigid erection. Thus, measuring the arterial pulse can effectively assess erection quality without a pressure component [37].

Arterial pulse and blood saturation are both measured using pulse oximetry, this makes measuring these penile parameters convenient. In the diastolic phase, arterial blood volume is relatively lower, resulting in reduced light absorption. Consequently, the intensity of transmitted light is comparatively higher, leading to a heightened AC component in the PPG. On the other hand, during the systolic phase, arterial blood volume is relatively higher, leading to increased light absorption. As a result, the

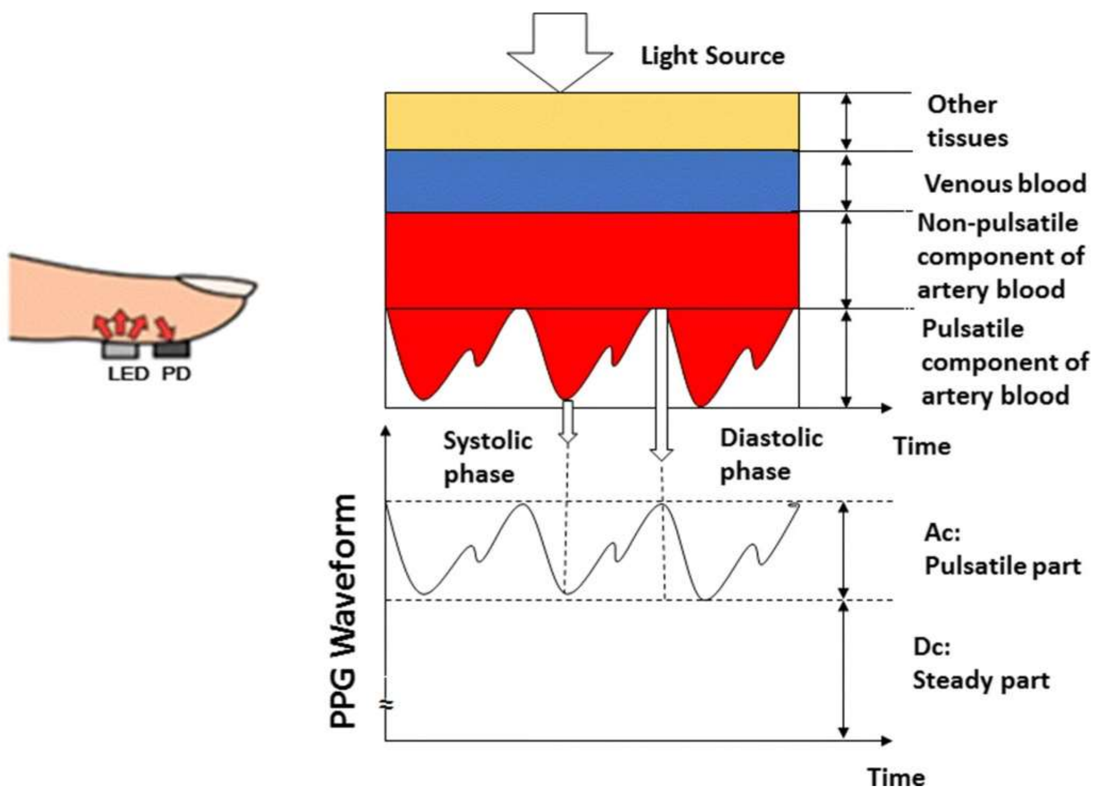

Figure 11, An example PPG derived from reflectance pulse oximetry. Light emitted from the source penetrates the tissue and its reflection is detected. As arterial blood pulsates, the cardiac cycle becomes visible in the PPG waveform [12].

intensity of transmitted light diminishes, contributing to a reduced AC component in the PPG. This is visualized in Figure 11.

The AC component of the PPG signal simplifies pulse rate calculation, as it correlates directly with the difference in light intensity between diastole and systole. This correlation can be expressed by the following equation [37]:

$$PPG_{Pulse} = diastolic\ light\ intensity - systolic\ light\ intensity$$

In order to utilize pulse oximetry as a sensor to detect arterial pulse, the following requirements have to be met:

Patient Safety & Comfort

The pulse oximetry sensor should not compromise the patient's sleep quality or safety. It should be designed to minimize discomfort and irritation during nocturnal wear.

Sensor Size & Weight

The sensor should be compact, lightweight, and designed for easy attachment to the penile skin using a flexible adhesive plaster. Its size and weight should not interfere with sleep quality.

Calibration & Placement

Accurate calibration using medical calibration curves is essential to measure arterial pulse effectively. The sensor should be placed on the top side of the penis, below the glans, to minimize the impact of compression due to the expanding corpus cavernosum on the venules. The sensor should make proper contact with the penis, as this ensures the most accurate measurement of pulse amplitude.

Sampling Frequency

The sensor should have a high or continuous sampling frequency to capture rapid changes in blood flow during a nocturnal erection. A minimum sampling frequency of 64 Hz is recommended to ensure accurate and timely detection of changes in pulse amplitude [37].

Precision & Range

The sensor's range should encompass the expected variations in pulse amplitude during nocturnal erections. Since commercially manufactured pulse oximetry sensors already cover the range of human pulse amplitudes, this requirement may be disregarded.

In brief, arterial pulse measurements using pulse oximetry offer valuable insights into the presence of nocturnal erections. By correlating with changes in penile diameter, pulse amplitude serves as an indicator of increased blood flow during the penile filling phase, marking the onset of an erection. To ensure effective arterial pulse measurement using pulse oximetry, it is essential to maximize patient safety, comfort, and prioritize accurate calibration. Additionally, proper sensor placement and a high sampling frequency are required for precisely measuring changes in blood flow during nocturnal erections.

2.2.2.5 Penile Acceleration

As a final parameter, penile acceleration could provide insights into the presence of a nocturnal erection. During an erection, the penis moves, which can be captured by using accelerometers. To detect such movement, two accelerometers are required, one on the penis and the other serving as a reference point. The reference accelerometer is positioned in a location that remains relatively stationary during an erection. The pubic bone and the leg are the best options as they remain mostly stationary during REM sleep. During this sleep stage, muscle paralysis occurs, preventing movement and ensuring these areas stay mostly still [39]. The penile accelerometer is ideally placed at the tip of the penis, as this area exhibits the most significant positional changes relative to the reference accelerometer. This positioning maximizes the accuracy of measuring acceleration on the penis [31].

Initially, both accelerometers measure static gravitational acceleration since the penis typically lies on the belly when sleeping. This static gravitational acceleration is around 1g, along a specific axis (usually the Z-axis). However, when an erection occurs, the penis moves, this acceleration causes a change in the static acceleration force detected by the accelerometer on the penis. This change indicates movement and acceleration of the penis, thereby detecting the onset of an erection [31].

The study by Been et al. [31] analyzed different types of accelerometers for this purpose, they concluded that the capacitive accelerometer is best suited. Also, the gravitational acceleration principle should be applied. Besides this, the sensor must also fulfil the following requirements:

Patient Safety & Comfort

The penile acceleration sensor should not compromise the patient's sleep quality or safety. It should be designed to minimize discomfort and irritation during nocturnal wear.

Sensor Size & Weight

The sensor should be compact, lightweight, and designed for easy attachment to the penile skin using a flexible adhesive plaster. The reference accelerometer should be firmly attached to the patient's leg. Its size and weight should not interfere with sleep quality.

Calibration & Placement

The reference sensor should be placed on the leg, and the penile accelerometer at the top of the penis, below the glans.

Sampling Frequency

According to Been et al. [31], the minimal sampling frequency should be in the range of 0 – 10 Hz. The higher the frequency the more accurate the readings become.

Precision & Range

The range of the sensor should be between -2g and 2g [31].

To conclude, penile acceleration sensors could help in detecting nocturnal erections. By using 2 capacitive accelerometers, one positioned at the tip of the penis and one on a stable part of the body like the leg, the changes in static acceleration can be measured. These changes help detect nocturnal erections. Important requirements for these sensors are patient comfort and safety, a compact lightweight design, penile placement below the glans, a minimum sampling frequency of 0-10 Hz and readings possible within a range of -2g to 2g.

2.2.2.6 Parameter Conclusion

In Table 4, an overview of different penile parameters and their sensor requirements is shown.

Table 4, Overview of different penile parameters and their sensor requirements.

Penile Temperature	- Small, lightweight design, attachment using plaster - Thermistor type sensor - Disc shape - Outside temperature insulation - Range between 20°C and 45°C - Sampling frequency ≥ 0.067Hz - Precision ≤ 0.1°C
Penile Circumference	- Safe, comfortable attachment using plaster - Accurate calibration - Sensor should cover ½ of the penile circumference - Range of 45 to 80 mm - Placement at the top of the penile shaft - Sampling frequency ≥ 0.067Hz - Precision ≤ 5 mm
Penile Blood Saturation	- Safe, comfortable attachment using plaster - Accurate calibration - Placement on the side of the penis - Sampling frequency ≥ 32 Hz - Range and precision already covered by available sensors - Use of red and IR oximetry sensors
Penile Arterial Pulse	- Safe, comfortable attachment using plaster - Compact, lightweight design - Accurate calibration - Placement below glans - Sampling frequency ≥ 64 Hz - Range and precision already covered by available sensors - Use of red and IR oximetry sensors
Penile Acceleration	- Safe, comfortable attachment using plaster - Compact, lightweight design - Accurate calibration using gravitational acceleration - Reference accelerometer placement on the leg, penile accelerometer placement at the top of the shaft - Sampling frequency ≥ 0 - 10 Hz - Range: -2g to 2g

2.2.3 Suitable Sensor Types

In this section, suitable sensor types are researched and compared in order to measure each parameter correctly. The formulated requirements from section 2.2.2 are used to identify a proper sensor.

2.2.3.1 Temperature Sensor

To detect changes in penile temperature, a suitable sensor has to be used. This sensor needs to suffice the following requirements extracted from Table 4.

Penile Temperature	**- Small, lightweight design, attachment using plaster** **- Thermistor type sensor** **- Disc shape** **- Outside temperature insulation** **- Range between 20°C and 45°C** **- Sampling frequency ≥ 0.067Hz** **- Precision ≤ 0.1°C**

Torenvlied et al. [23], compared 10 types of thermistors to find the best suiting sensor. The Shenzhen Medke Ohmeda 3P T3312 [40] was found to be best suited due to its sufficient measuring range, stable calibration curve, medical safety certifications and insulation. However, due to the high sensor cost, this sensor was not suitable for this system.

In this research, additional thermistors are compared. The requirements from Table 4 are used as a guideline. The sensor properties weight and safety are excluded from the comparison, as all sensors are lightweight and require a low operating voltage, preventing them from causing discomfort or potential safety hazards.

In Table 5, entries marked as "sufficient" denote instances where precise data was not available to determine whether the requirement was fully met. However, based on logical deduction of the sensor's purpose, it can be concluded that the necessary criteria were satisfied.

Table 5, Overview of compared temperature sensors.

	Size & Form	Insulation	Measuring range	Sampling frequency	Accuracy
Shenzhen Medke Ohmeda 3P T3312 [40]	⌀ of 6mm Disc shape	Yes	0 to 70°C	Sufficient	0.143°C
Semitec F-micro Miniature Temperature Sensor [41]	1.8 x 0.3 x 0.5 mm Cylindrical shape	No	-10 to 70°C	20ms (50Hz)	0.14°C @37°C
Starboard Medical Skin Temperature Sensor [42]	Sufficient Disc shape	Yes	Sufficient	Sufficient	0.10°C @37°C
Benjamin Care Micro Skin Temperature Sensor [4]	⌀ of 15mm Disc shape	No	Sufficient	Sufficient	0.10°C @25 - 45°C

As seen in Table 5, two sensors are not insulated, however, this is required to minimize external temperature influences. This issue may be solved by applying aluminium foil tape to the sensor sticker (Figure 12). This can help to prevent external temperature influence on the sensor making uninsulated sensors suffice the requirements too.

The temperature sensor should be positioned at the neck of the penis, directly below the glans, as this area exhibits the highest temperature increase during nocturnal erections. The sensor cannot be positioned on the glans itself, as this may cause discomfort due to the restricted movement of the foreskin [30].

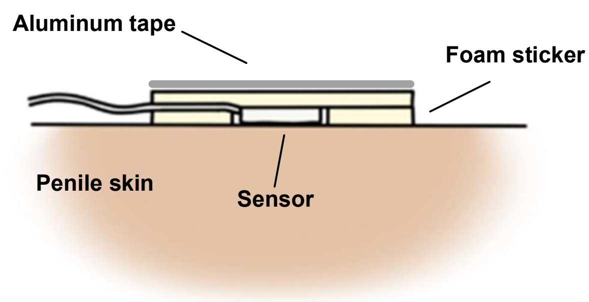

Figure 12, Diagram of the sensor attached to the penile skin [4].

Based on the comparison in Table 5, the Starboard Medical Skin Temperature Sensor and the Shenzhen Medke Ohmeda 3P emerge as a viable option for measuring penile temperature during nocturnal erections. However, after this research, supply issues proved to be a problem. Long delivery times made these sensors less than ideal. After discussing with H. Torenvlied, suggested opting for non-medical sensors instead, citing their cost-effectiveness and improved availability.

Therefore, after considering the availability and cost-effectiveness of medical versus non-medical thermistors, it has been decided to proceed with testing non-medical thermistors for measuring penile temperature during nocturnal erections.

Six thermistors from different manufacturers have been selected for testing due to their availability and overall high precision:

Semitec [43]:

103AT-2 (10kOhm, 1%)

203AT-2 (20kOhm, 1%)

103AT-5-1P-FT (10kOhm, 1%)

Vishay / BC Components [44]:

NTCLE100E3103GB0 (10kOhm, 2%)

NTCLE100E3103GT1 (10kOhm, 2%)

NTCLE100E3682GB0 (6.8kOhm, 2%)

These thermistors were chosen based on their varying resistance values and tolerances, which will allow for a comprehensive evaluation of their performance. They all lack insulation but are small, have a sufficient measuring range and have high sampling frequency and accuracy.

Future testing will involve assessing each thermistor's accuracy, stability, and reliability in measuring penile temperature under simulated conditions. By subjecting the thermistors to controlled temperature changes and monitoring their response, we aim to determine which sensor best meets the requirements of our monitoring system.

The results of this testing (described in section 6.1.1) will inform the final selection of the most suitable thermistor for integration into the monitoring system. This systematic approach ensures that the chosen sensor will provide accurate and reliable measurements of penile temperature during nocturnal erections, contributing to the overall effectiveness of the monitoring system.

2.2.3.2 Circumference Sensor

To detect changes in penile temperature, a suitable sensor has to be used. This sensor needs to suffice to the following requirements extracted from Table 4.

Penile Circumference	**- Safe, comfortable attachment using plaster** **- Accurate calibration** **- Sensor should cover ½ of the penile circumference** **- Range of 45 to 80 mm** **- Placement at the top of the penile shaft** **- Sampling frequency ≥ 0.067Hz** **- Precision ≤ 5 mm**

Two types of strain sensors can be used to detect changes in penile circumference. A flexible stretch sensor and a flexible bendable sensor.

Flexible stretch sensors are designed to monitor alterations in the length or stretch of an object, such as the penile circumference during an erection (Figure 14). Typically made of stretchable materials like conductive rubber, these sensors change their resistance as they stretch. When fixed to the penile skin, they expand or contract in response to changes in circumference. This stretch or shrinkage is then translated into electrical signals, which are analyzed by the microcontroller to quantify the extent of penile expansion.

On the other hand, flexible bendable sensors are engineered to detect variations in the curvature or bending of an object, like the curvature of the penile shaft during an erection Figure 14. Consisting of flexible materials or structures, these sensors bend or deform as the shape of the penis changes. When applied to the penile shaft, they sense the bending or curvature alterations associated with an erection. Similar to stretch sensors, bendable sensors convert these mechanical changes into electrical signals for measurement and analysis.

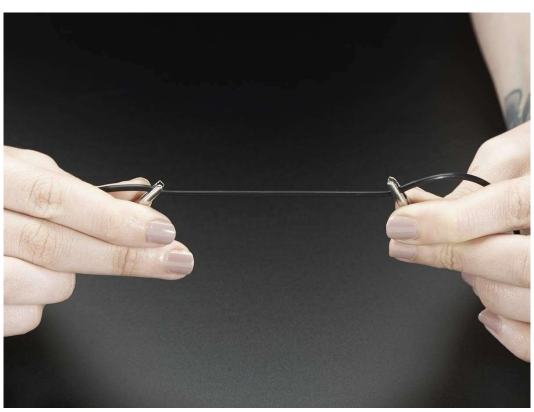

Figure 14, Strech sensor consisting of conducting rubber cord [8].

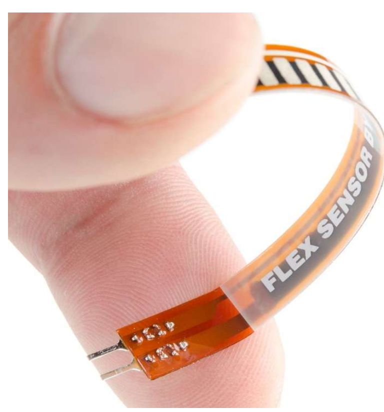

Figure 14, Flex/Bend sensor [1].

Since both flexible stretch sensors and flexible bendable sensors offer potential solutions for detecting changes in penile circumference, it is essential to thoroughly research and test both sensor types during the prototyping phase. While literature provides valuable insights into their functionality and application, real-world testing will provide a clearer understanding of each sensor's performance in the intended context. Therefore, both sensor types were ordered and evaluated to determine their suitability for accurately measuring penile circumference during nocturnal erections. These results will be discussed in section 6.1.2. By using this comprehensive approach, we ensure that the final sensor selection aligns closely with the project's requirements and objectives.

For the flexible stretch sensor, a small conductive rubber cord will be used like the one in Figure 14. It can be tailored to size and be attached using medical plasters. It has a high precision and the sampling frequency can be determined by the microcontroller and is thus sufficient. The sensor requires 2 pins on the Arduino, a ground pin and an analog pin.

For the flex-bend sensor, the Adafruit short flex sensor will be used [45]. This sensor has a length of 6cm and is very lightweight. It has a high precision and the sampling frequency can be determined by the microcontroller and is thus sufficient. It requires 2 pins on the Arduino, a ground pin and an analog pin.

In conclusion, the selection of a suitable sensor for measuring penile circumference during nocturnal erections requires thorough testing. Both flexible stretch and bendable sensors offer promising solutions, each with unique properties. Real-world evaluation will determine the most effective option for accurate measurement, ensuring alignment with project objectives for safety and precision.

2.2.3.3 Blood Saturation Sensor & Arterial Pulse Sensor

To effectively monitor penile blood saturation levels and arterial pulse during nocturnal erections, it's necessary to identify a suitable pulse oximetry sensor that aligns with the predefined requirements from Table 4. Since arterial pulse and blood saturation can be measured with the same oximetry sensor, only one sensor is needed, this saves space and increases comfort.

Penile Blood Saturation	**- Safe, comfortable attachment using plaster - Accurate calibration - Placement on the side of the penis - Sampling frequency ≥ 32 Hz - Range and precision already covered by available sensors - Use of red and IR oximetry sensors**
Penile Arterial Pulse	**- Safe, comfortable attachment using plaster - Compact, lightweight design - Accurate calibration - Placement below glans - Sampling frequency ≥ 64 Hz - Range and precision already covered by available sensors - Use of red and IR oximetry sensors**

All pulse oximetry sensors compatible with Arduino utilize the MAX30102 module, which incorporates both infrared (IR) and red LEDs. An Arduino-compatible sensor is preferred as this simplifies sensor integration and testing during the prototyping stage. The MAX30102 (OT3546)oximetry sensor, is the smallest sensor board available [7] and allows for both pulse and blood saturation readings.

The sensor has a power consumption of 0.6mA and requires 4 wires to be connected to the Arduino Nano BLE. V_{in} for 3.3 power supply, GND for ground connection, SDA (Serial Data) and SCL (Serial Clock) for I^2C communication protocol.

In conclusion, for effective monitoring of penile blood saturation levels and arterial pulse during nocturnal erections, the MAX30102 (OT3546) oximetry sensor will be used.

Figure 15, The MAX30102 (OT3546) pulse oximetry board [7].

2.2.3.4 Acceleration Sensor

The penile acceleration sensor must meet the following requirements outlined in Table 4.

Penile Acceleration	**- Safe, comfortable attachment using plaster - Compact, lightweight design - Accurate calibration using gravitational acceleration - Reference accelerometer placement on the leg, penile accelerometer placement at the top of the shaft - Sampling frequency ≥ 0 - 10 Hz - Range: -2g to 2g**

The sensor is designed to detect and quantify the acceleration or movement of the penis, providing valuable insights into the frequency, intensity, and duration of erections throughout the night.

The penile acceleration sensor consists of 2 sensors. A reference accelerometer on the leg and an accelerometer sensor at the top of the shaft. The difference in acceleration is used to determine the presence of an erection.

Numerous acceleration sensors are accessible in the market. However, to narrow down focus and efficiency, this comparison will primarily focus on the three most widely discussed accelerometers found in the literature [46]. In Table 6, an overview is provided. Since all the boards can accurately detect inclination changes of less than 1.0 degrees, and their sampling frequencies are more than sufficient for the intended purpose, these parameters are not included in Table 6.

Table 6, Overview of compared acceleration sensors.

	Size (mm)	Measuring range	Power Consumption
ADXL335 [47]	20 x 19 x 3.14	-3g to 3g	0.35 mA
ADXL345 [48]	20 x 16 x 3	-16g to 16g	0.30 mA
ADXL356 [49]	20 x 16 x 3	-10 to 40g	0.15 mA

Comparing these accelerometers, the ADXL345 (Figure 16) proves to be most effective for penile use. This board is small, has sufficient measuring range and has good power efficiency. Besides this, the board is easy to operate and is well documented on the internet, making future troubleshooting more easy.

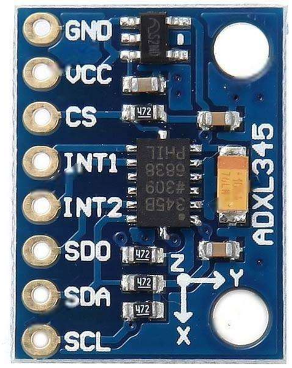

Figure 16, ADX345 board [6].

The board requires 5 connections to the Arduino; GND to the ground pin, VCC to the 3.3 v pin and SDA and SCL to the I2C bus on the Arduino (A4 and A5 pin).

As a reference accelerometer, the Arduino Nano BLE includes a built-in 3-axis accelerometer (IMU), the LSM9DS1 [50]. This IMU has variable range settings, ranging from ± 2g to ± 16g and has a high sampling frequency. As the microcontroller will most likely be mounted somewhere on the body of the patient, this accelerometer can be used as a reference.

2.2.3.5 Sensor Conclusion

In developing a comprehensive monitoring system for nocturnal penile erections, a range of sensors has been carefully selected and evaluated based on their ability to meet the specific requirements outlined in Table 4. These sensors play a crucial role in accurately measuring various physiological parameters, associated with the penile erectile function.

The careful choice of sensor for measuring penile temperature during nocturnal erections is essential due to the sensitivity required for accurate detection. Although medical-grade sensors like the Starboard Medical Skin Temperature Sensor were initially considered, supply issues and prolonged delivery times have led to the selection of non-medical thermistors for testing. Six thermistors from different manufacturers, such as Semitec and Vishay/BC Components, have been chosen for their small size, disc shape, sufficient measuring range (20°C to 45°C), high sampling frequency (≥ 0.067 Hz), and precision (≤ 0.1°C). Future testing will determine which thermistor provides the best performance under simulated conditions. The sensor will be positioned at the neck of the penis, directly below the glans, to capture the highest temperature increase during nocturnal erections. An additional reference sensor will be placed on the leg to compensate for temperature fluctuations caused by getting into bed.

For monitoring changes in penile circumference, both a flexible stretch and a bendable sensor will be used. Further testing will determine which of the two sensors will be most suited to measure a change in penile circumference.

The MAX30102 (OT3546) oximetry sensor has been selected to effectively monitor penile blood saturation levels and arterial pulse during nocturnal erections. Its compact design, compatibility with Arduino Nano BLE, and utilization of red and IR oximetry sensors make it a decent choice for this purpose.

Among the available accelerometer options, the ADXL345 accelerometer stands out as the most effective choice for detecting penile acceleration. Its small size, sufficient measuring range, and power efficiency make it well-suited for monitoring penile movement during nocturnal erections.

In summary, the chosen sensors collectively enable the comprehensive monitoring of various physiological parameters associated with penile erectile function. This marks the foundation for the development of an effective nocturnal penile erection monitoring system. In Table 7, an overview of the selected sensors can be seen.

Table 7, Overview of sensors to detect each parameter change.

Sensor Name	Parameter	Required Arduino Nano BLE Pins	Power Consumption
3x Thermistor (testing will determine thermistor type)	Penile Temperature	GND V_{in} 3x Analog	Not specified
Flexible Stretch Sensor & Flexible Bend Sensor	Penile Circumference	GND Analog	Not specified
MAX30102 (OT3546) oximetry sensor	Penile Blood Saturation & Arterial Pulse	GND V_{in} 2x Analog	0.60mA
ADXL345 accelerometer	Penile Acceleration	GND V_{in} 2x Analog	0.35mA

In conclusion, the specific requirements outlined in Table 4 have laid the groundwork for the development of a comprehensive monitoring system for nocturnal penile erections. Each sensor chosen addresses a crucial aspect of penile erectile function, from temperature and circumference changes to blood saturation levels, arterial pulse, and penile acceleration. Through testing and consideration of factors such as insulation, measuring range, sampling frequency, accuracy, and power efficiency, the selected sensors demonstrate suitability for their respective roles in the monitoring system. While further testing may be required to determine the optimal sensor for measuring penile circumference, the overall combination of sensors provides a robust foundation for accurately monitoring physiological parameters associated with nocturnal penile erections.

2.3 Accuracy and Reliability

In this section, sensor precision and calibration will be discussed as well as comparing the system to existing systems.

2.3.1 Accuracy and reliability of the system

The accuracy and reliability of the monitoring system are crucial for its effectiveness in clinical practice. Several factors contribute to ensuring the system's accuracy and reliability, including sensor precision and calibration, data acquisition methods, and system calibration.

2.3.1.1 Sensor Precision and Calibration

Each sensor selected for the monitoring system undergoes evaluation during prototyping to ensure its precision in measuring the targeted parameter is sufficient. For instance, the pulse oximeter is chosen due to its ability to use red and infrared light to detect blood saturation and pulse. By testing the sensor, calibrations can be done. This is to ensure high precision and stability. Besides this, the accelerometer and temperature sensors need special calibrations, due to the use of reference sensors. The circumference sensor needs special comparative testing, as this sensor has two options in which a choice still has to be made, a flex-bend sensor or a stretch sensor.

During the testing and calibration phase, each sensor will be calibrated and tested separately in a test environment first. By using controlled objects and environments, data precision and accuracy can be tested. Using predefined changes in different parameters, such as temperature variations, simulated penile movements, and changes in blood saturation levels, the precision and accuracy of each sensor can be thoroughly evaluated. Any deviations from the expected results are noted, and calibration adjustments will be made accordingly to ensure optimal accuracy.

This testing and calibration phase also allows for the identification and resolution of any potential issues or limitations with the sensors. If they are soon discovered, then adjustments can be made early on in the process. Adjustments can range from sensor changes to minor calibration issues.

2.3.1.2 Data Acquisition Methods

The reliability of the system heavily relies on the methods used for data acquisition and processing. By employing Arduino microcontrollers, the system can accurately sample data from various sensors at predetermined frequencies. This ensures that the change in parameters, such as penile temperature, circumference, blood saturation, and acceleration, are captured in real-time with minimal delay or data loss. By transferring the data to an external mobile device, we ensure data safety and can have a live view and analysis of the data. This makes the detection of any problems visible before nocturnal use.

2.3.1.3 Conclusion

In conclusion, ensuring the accuracy and reliability of the monitoring system is crucial for its effectiveness. Through intensive testing, sensor precision and calibration, data acquisition methods, and system calibration, the monitoring system is prone to provide valid and useful data. By thoroughly testing each sensor in controlled environments and addressing any issues early in the process, the sensor should be able to detect nocturnal erections reliably.

2.3.2 Comparison to Existing Systems

The Rigiscan® has long been considered the gold standard in the field of nocturnal erection detection, primarily due to its ability to measure penile rigidity using loops placed around the penis during sleep. However, this method poses several limitations. Firstly, the use of loops attached to cables can cause discomfort and may interfere with natural sleep patterns. As sleep patterns are disrupted, a patient might not sufficiently reach the REM sleep phase. As a result, nocturnal erections happen less frequently or may be absent at all. This may severely affect the quality and validity of the data collected. Additionally, the Rigiscan is limited in its ability to measure other different penile parameters associated with erections, such as temperature, blood saturation, arterial pulse, and acceleration. Measuring multiple parameters may give more insights into the quality of the erecitons. This narrow focus by the RigiScan® restricts the comprehensive assessment of penile erectile function, potentially overlooking important physiological changes.

In contrast, the proposed monitoring system offers several advantages over the Rigiscan. By integrating multiple sensors, the system can comprehensively monitor various aspects of penile erectile function beyond just rigidity. This includes parameters such as temperature, blood saturation, arterial pulse, and acceleration, providing a more detailed view of nocturnal erections. Moreover, the proposed system aims to minimize discomfort by utilizing non-invasive sensors attached to the body with minimal interference, promoting more natural sleep patterns and potentially improving the quality of data collected. Allowing for the assessment of the quality of the nocturnal erections.

Furthermore, the proposed system's ability to transmit data to an external mobile device allows for real-time monitoring and analysis. Using the internet, future prototypes of the concept system may be able to upload data to cloud servers so that patients and caregivers can view their data on mobile applications. While the Rigiscan has been a valuable tool in clinical settings, the proposed monitoring system offers significant advancements in terms of comfort, accuracy, and the comprehensive assessment of penile erectile function during nocturnal erections.

2.4 Conclusion

In this chapter, the focus was on the selection and integration of key components needed for the development of a nocturnal penile erection monitoring system. Besides, selecting components, calibration and data validation have also been discussed.

Beginning with the microcontroller choice, the Arduino Nano 33 BLE emerged as the optimal solution due to its compact size, low power consumption, and Bluetooth Low Energy (BLE) capability, facilitating wireless data transmission. The battery choice centred on the 3.7V LiPo rechargeable battery, offering a balance between power output and size, ensuring system operation for at least one night without the need to recharge. For the transfer of acquired data, BLE technology is used, enabling communication between the monitoring device and a designated smartphone for data analysis and storage.

In terms of system dimensions, a compact and lightweight design was prioritized to enhance user comfort during nocturnal monitoring. The monitoring device's small form factor ensures discreet placement and minimal interference with sleep patterns. Each penile parameter was considered, with specific sensors chosen to accurately measure temperature, circumference, blood saturation, arterial pulse, and acceleration.

For temperature measurement, six non-medical thermistors from manufacturers such as Semitec and Vishay/BC Components were selected for testing due to their availability and cost-effectiveness. These thermistors will be evaluated for their appropriate measuring range and sampling frequency. One sensor will be located on the penis, one will serve as a reference sensor on the leg and one reference sensor located around the abdomen.

Flexible stretch and bend sensors were chosen to monitor changes in penile circumference, offering flexibility and precision in capturing variations during erections, however, further testing needs to be done to definitively choose between one of the two.

The MAX30102 (OT3546) oximetry sensor was designated for monitoring penile blood saturation levels and arterial pulse, providing reliable readings in a compact form factor using red and infrared light.

Finally, the ADXL345 accelerometer emerged as the optimal choice for detecting penile acceleration, offering excellent sensitivity and power efficiency. As a reference accelerometer, the built-in accelerometer on the Arduino Nano BLE will be used for this purpose.

Besides component choices, extensive testing and calibration for each component of the system and its accuracy are necessary. This ensures that the reliability, and effectiveness can be improved to be able to obtain valuable data in the diagnosis and treatment of erectile dysfunction.

In Table 8, a comprehensive component list summarizing the key elements discussed. This list focuses on the development of a nocturnal penile erection monitoring system.

Table 8, Final overview of different components to be used in the prototype.

Component	Description
Arduino Nano 33 BLE Rev2	Microcontroller chosen for its compact size, low power consumption, and Bluetooth Low Energy capability.
3.7V LiPo Rechargeable Battery	Selected for its balance between power output and size, ensuring nocturnal operation without the need to recharge.
Mobile device supporting Bluetooth	Used for data storage and analysis.
Non-medical Thermistors	Six thermistors from different manufacturers such as Semitec and Vishay/BC Components will be tested. Positioned on the penis, leg and on the abdomen for reference.
Flexible Stretch Sensor	Sensor chosen to monitor changes in penile circumference, offering flexibility and precision.
Flexible Bend Sensor	Alternative sensor for monitoring changes in penile circumference, offering flexibility and precision.
MAX30102 (OT3546) Oximetry Sensor	Selected for monitoring penile blood saturation levels and arterial pulse, compact form factor using red and infrared light.
ADXL345 Accelerometer	Chosen for detecting penile acceleration, offering excellent sensitivity and power efficiency.
Optional: Arduino Power Profiling Kit II	*To precisely measure the system's power consumption, and make more accurate calculations regarding the minimum battery capacity needed.*

3 Methods and Techniques

This chapter provides an overview of the used methods and techniques throughout the project.

3.1 Design Process

The selected design process follows the Creative Technology design process [10]. This design process consists of four distinct phases (Figure 17). First is the ideation phase, where background research is done to provide information on what technologies are already present. Following this is the specification phase, where system requirements and system architecture are defined. In this case, requirements for each penile parameter are formulated, and a suitable sensor is chosen. Subsequently, in the realization phase, the design will be constructed based on the specifications established in the specification phase. This design will be extensively tested and undergo several rounds of reflection and improvements, In the end, the system will be evaluated and adjusted if needed to meet the client's demands for a reliable penile sensor measuring nocturnal erections.

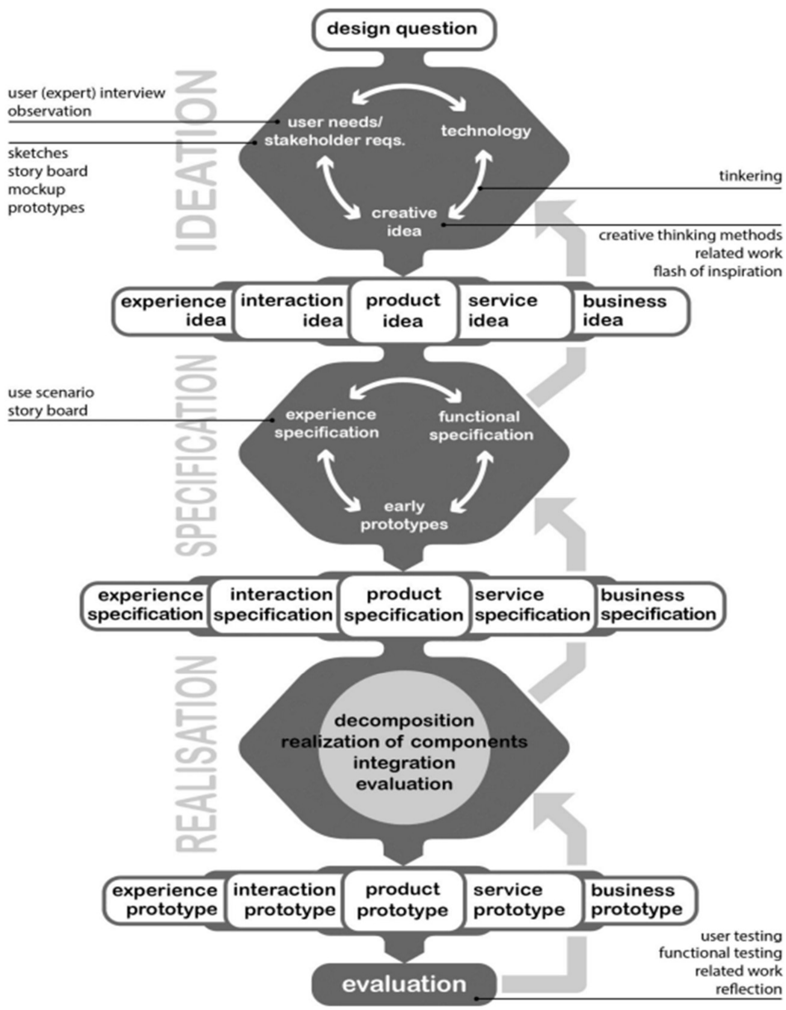

Figure 17, Creative Technology design process diagram [10].

3.2 Stakeholder Analysis

Understanding project stakeholders is crucial, as each has unique needs and interests. Stakeholder analysis, using the Interest/Power matrix, categorizes stakeholders based on their power and interest in the project [51]. High Power, High Interest stakeholders wield significant influence and require active engagement. High Power, Low Interest stakeholders, such as executives, need periodic updates. Low Power, High Interest stakeholders, like end-users, necessitate feedback and involvement in testing. Low Power, Low Interest stakeholders require minimal management but should be kept informed. By aligning communication strategies with stakeholders' power and interests, project managers can ensure support and mitigate risks throughout the project.

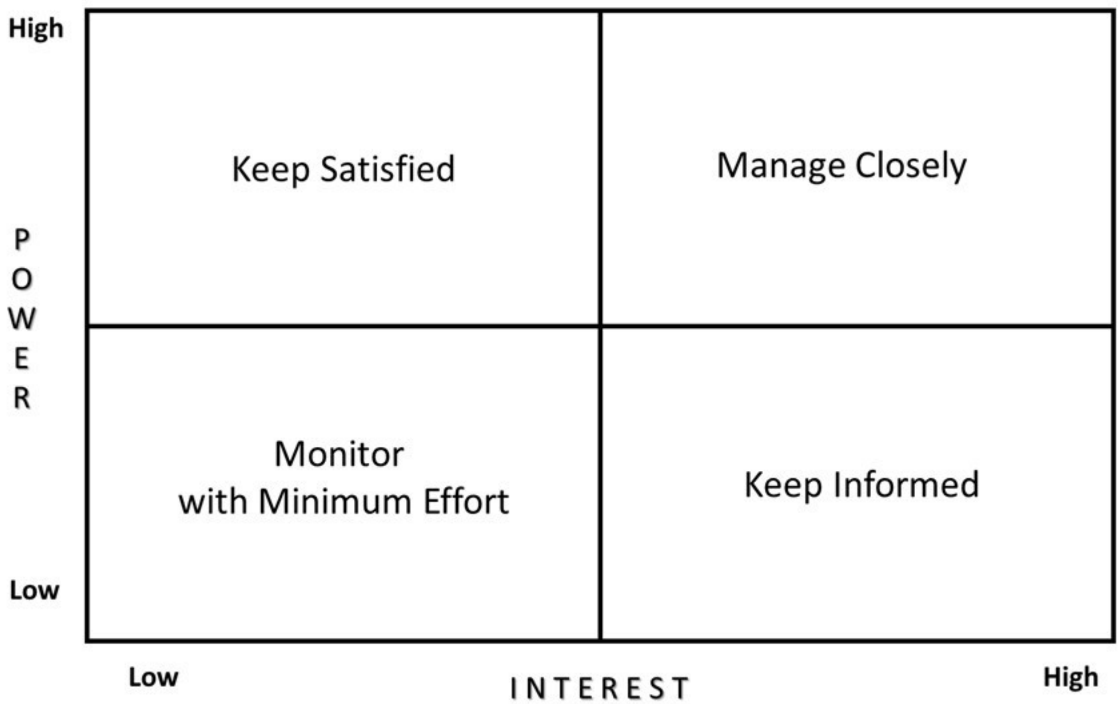

Figure 18, Stakeholder interest and power matrix [51].

Stakeholder needs will be categorized using the MoSCoW technique, which prioritizes requirements based on their level of importance [52]. The MoSCoW technique prioritizes stakeholder requirements into four categories: Must have, Should have, Could have, and Won't have. This helps to maintain focus on critical needs first while allowing flexibility for less important features. As a result, all stakeholder needs will be discussed and taken into account.

4 Ideation

Within this chapter, the needs and requirements of stakeholders are discussed. Besides this, a prototype concept is shown and discussed.

4.1 Stakeholder Needs and Requirements

4.1.1 Stakeholder Identification

For this graduation project, multiple stakeholders are identified and their related power. An overview is listed in Table 9.

Table 9, Identification of stakeholder and their interest

No.	Stakeholder	Description	Interest	Power
1	Julian Klep (author)	Student conducting research for the graduation project.	Delivering a working prototype within the timeframe of 10 weeks. Gaining experience and knowledge in research and technical solution development.	**High -** Directly responsible for developing the prototype, making key decisions, and ensuring project success.
2	Client (Hille Torenvlied)	Client of the graduation project and researcher at St. Antonius Ziekenhuis Nieuwegein.	Receiving a working prototype to conduct further testing to ultimately improve the diagnosis of erectile dysfunction at the hospital.	**High -** Client and main beneficiary of the project outcomes, providing guidance, feedback, and resources.
3	University Of Twente (Project supervisors: J. Berendsen & C. Salm.)	Project supervisors providing guidance, support, and feedback to the student.	Ensuring the successful completion of the graduation project by offering guidance, support, and feedback.	**Medium -** Supervisors provide critical guidance and feedback, influencing project direction and quality.
4	St. Antonius Ziekenhuis Nieuwegein	Hospital facilitating research and providing funding via the "Innovatiefonds."	Receiving a working prototype to contribute to a more noninvasive and accurate diagnosis of erectile dysfunction.	**Low -** Major stakeholder providing funding and resources, with a vested interest in the project's success.
5	Dutch Department of Urologists	Identified erectile dysfunction and its treatment as a priority in urology, leading to the need for a new monitoring tool.	Having a working prototype to address the gap in diagnosis and treatment of erectile dysfunction.	**Low** - Influential in the medical community, advocating for better diagnostic tools but with less direct involvement in the project.

No.	Stakeholder	Description	Interest	Power
6	General Practitioners and Sexologists	Need a new and more accurate measuring tool for erectile dysfunction to make informed referrals to psychologists or urologists based on patient complaints.	Having a new and accurate measuring tool to improve referrals to specific caregivers and patient care. Relieving pressure on hospitals by decreasing unnecessary referrals.	**Low -** Users of the diagnostic tool, benefit from improved accuracy but are not directly involved in development.
7	Patients	Use the prototype for diagnosing erectile dysfunction and aim for improved comfort during the diagnostic process.	Improved comfort during the diagnosis of erectile dysfunction. Receiving accurate diagnosis and appropriate treatment based on the prototype's results.	**Low -** End-users who will benefit from the final product but have limited influence on the project development.

4.1.2 Stakeholder Analysis

Each stakeholder holds a unique position of influence and interest within the project. Their prioritization is determined by both their power to impact decisions and their level of engagement with the project's outcomes. Figure 19 illustrates the categorization of stakeholders using the power/interest model, providing valuable insights into their roles and importance in the project's success. The numbers in the matrix correspond to the numbers of the different stakeholders in Table 9.

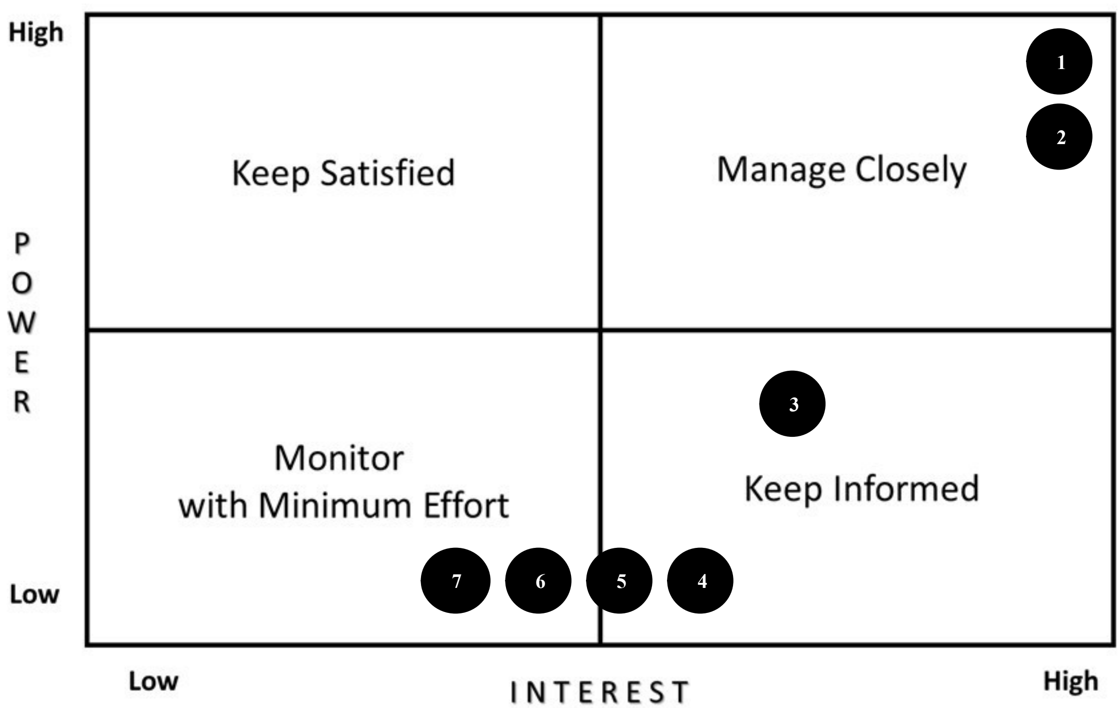

Figure 19, Stakeholder interest and power matrix, with the different stakeholders positioned [51].

4.1.3 Stakeholder Needs

The MoSCoW method was employed to identify stakeholder needs. This represents system requirements and aligns with stakeholder interests. The stakeholder needs are listed below in Table 10. These needs are broad requirements; the specific requirements are covered in Chapter 2, Background Research.

Table 10, Stakeholder needs using MoSCoW technique.

No.	Requirement	Type of Requirement
1	The final prototype must accurately and reliably detect nocturnal erections using the discussed penile parameters.	Must
2	The final prototype must not influence the patient's (REM) sleep.	Must
3	The final prototype must use safe, non-invasive sensors to ensure patient comfort.	Must
4	The final prototype must have a battery life sufficient for overnight monitoring.	Must
5	The final prototype should use cost-effective components to minimize production costs.	Should
6	The final prototype should securely transmit data to a mobile device for storage and analysis.	Should
7	The final prototype should be easy to set up and use by the patient without assistance.	Should
8	The final prototype should be reusable to reduce waste and reduce costs.	Should
9	The final prototype could include a feature to alert the user if a sensor detaches.	Could
10	The final prototype could be water-resistant to prevent damage from perspiration.	Could
11	The final prototype could provide real-time feedback to the user via a mobile application.	Could
12	The final prototype could have modular components for easy replacement and maintenance.	Could
13	The final prototype could have a connected app to allow users to access their data.	Could

4.2 Preliminary Concepts

4.2.1 Concept Properties

For each of the preliminary concepts provided in this chapter, sections 4.2.1.1 and 4.2.1.2 give the main system properties of each concept.

4.2.1.1 Concept Components

Based on Chapter 2 Background Research, and Table 8, the total components can be listed. The overview can be seen in Table 11.

Table 11, Overview of components in the sensor system and their connections.

Component	Connections
Arduino Nano 33 BLE Rev2	Wired connections to all the different penile sensors. Wireless connection to mobile device using BLE. Wired connection to the battery. Optional: *Wired connection to Arduino Power Profiling Kit*
3.7V LiPo Rechargeable Battery	Wired connection to Arduino Nano 33 BLE Rev2
Mobile device supporting Bluetooth	Wireless BLE connection to Arduino Nano 33 BLE Rev2
Non-medical Thermistors	Wired connection to Arduino Nano 33 BLE Rev2
Flexible Stretch Sensor	Wired connection to Arduino Nano 33 BLE Rev2
Flexible Bend Sensor	Wired connection to Arduino Nano 33 BLE Rev2
MAX30102 (OT3546) Oximetry Sensor	Wired connection to Arduino Nano 33 BLE Rev2
ADXL335 Accelerometer	Wired connection to Arduino Nano 33 BLE Rev2
Optional: Arduino Power Profiling Kit II	Wired connection to Arduino Nano 33 BLE Rev2

4.2.1.2 Concept Circuit Diagram

The circuit diagram in Figure 20 provides a comprehensive visual representation of the electrical circuit with the various sensors integrated. The different sensors are displayed (thermistors, accelerometer, oximeter, stretch sensor, battery and Arduino Nano BLE). Note that the second accelerometer is housed inside the Arduino Nano BLE, and is therefore not displayed.

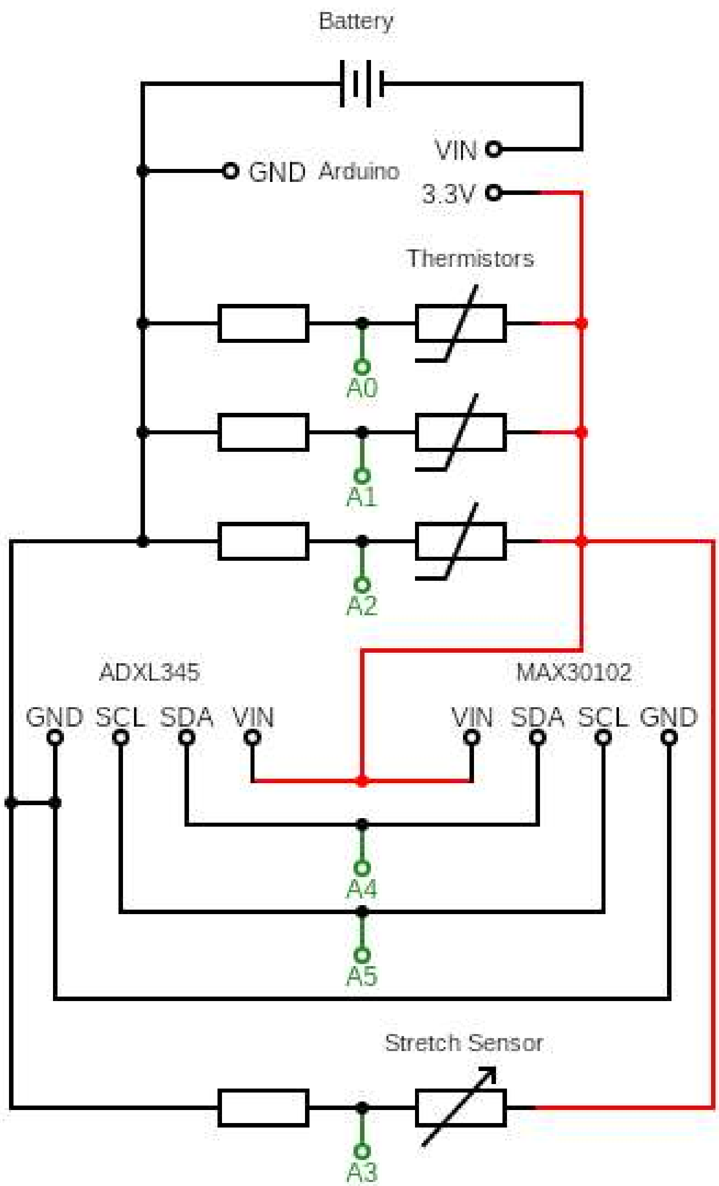

Figure 20, Wiring diagram of the system.

4.2.2 System Concepts

In this section, three distinct sensor systems are discussed, each adhering to the same previously discussed system properties. All three concepts differ in sensor positioning.

4.2.2.1 System Concept 1

Figure 21 illustrates the first concept of the practical application of the system, demonstrating its attachment to the body for nocturnal monitoring of penile erections. The main microcontroller and battery housing are securely attached to the upper leg using an elastic band. Medical plasters are utilized to safely guide wires towards the penis, preventing tangling and discomfort. Sensors are affixed to the penis with the same plasters, ensuring consistent skin contact throughout nocturnal use and optimal functionality of the monitoring system. Data is transferred from the Arduino Nano BLE to the mobile device using Bluetooth Low Energy.

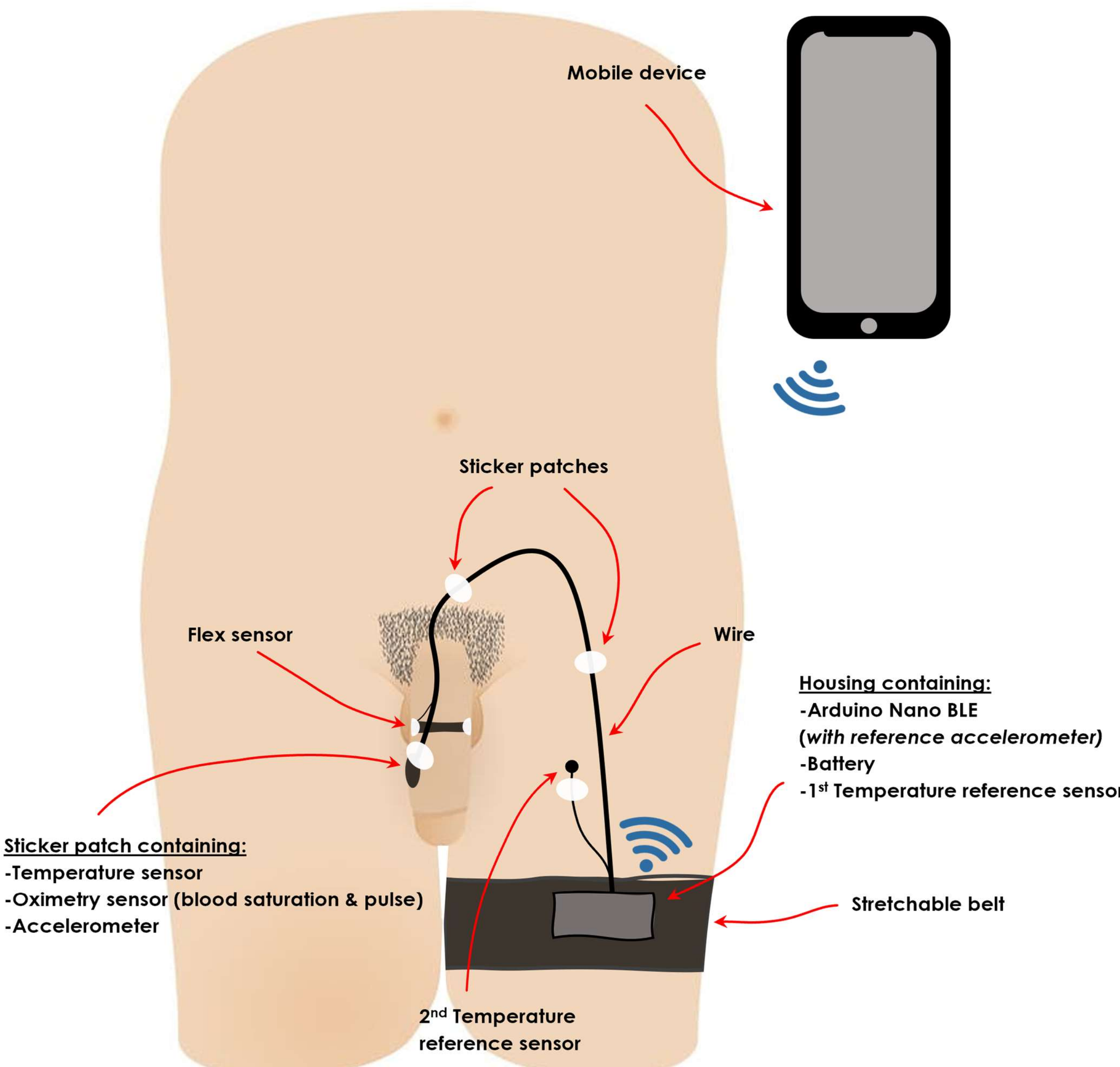

Figure 21, System Concept 1 shows the complete system attached to the leg and penis using sticker patches and a stretchable belt.

4.2.2.2 System Concept 2

Figure 22 illustrates system concept 2, within this concept, the elastic battery and microcontroller belt are relocated to the hips to enhance comfort. Sensors are affixed to the penis with patches, ensuring consistent skin contact throughout nocturnal use and optimal functionality of the monitoring system. Data is transferred from the Arduino Nano BLE to the mobile device using Bluetooth Low Energy.

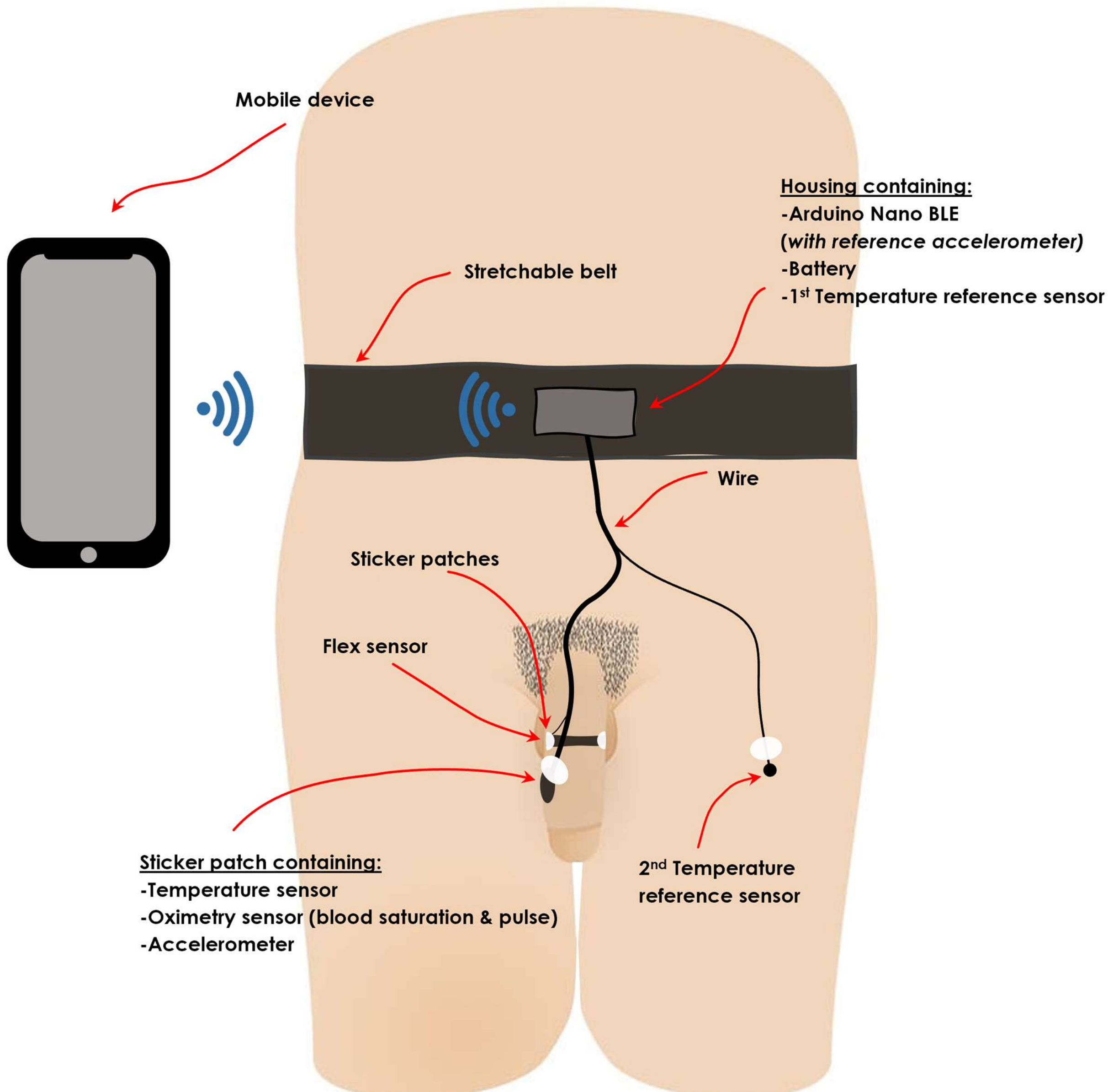

Figure 22, System Concept 2 shows the complete system attached to the hips and penis using sticker patches and a stretchable belt.

4.2.2.3 System Concept 3

Figure 23 illustrates system concept 3, within this concept, the microcontroller and battery housing are moved to the abdomen and fixed in place using a large medical sticker. Sensors are affixed to the penis with patches, ensuring consistent skin contact throughout nocturnal use and optimal functionality of the monitoring system. Data is transferred from the Arduino Nano BLE to the mobile device using Bluetooth Low Energy.

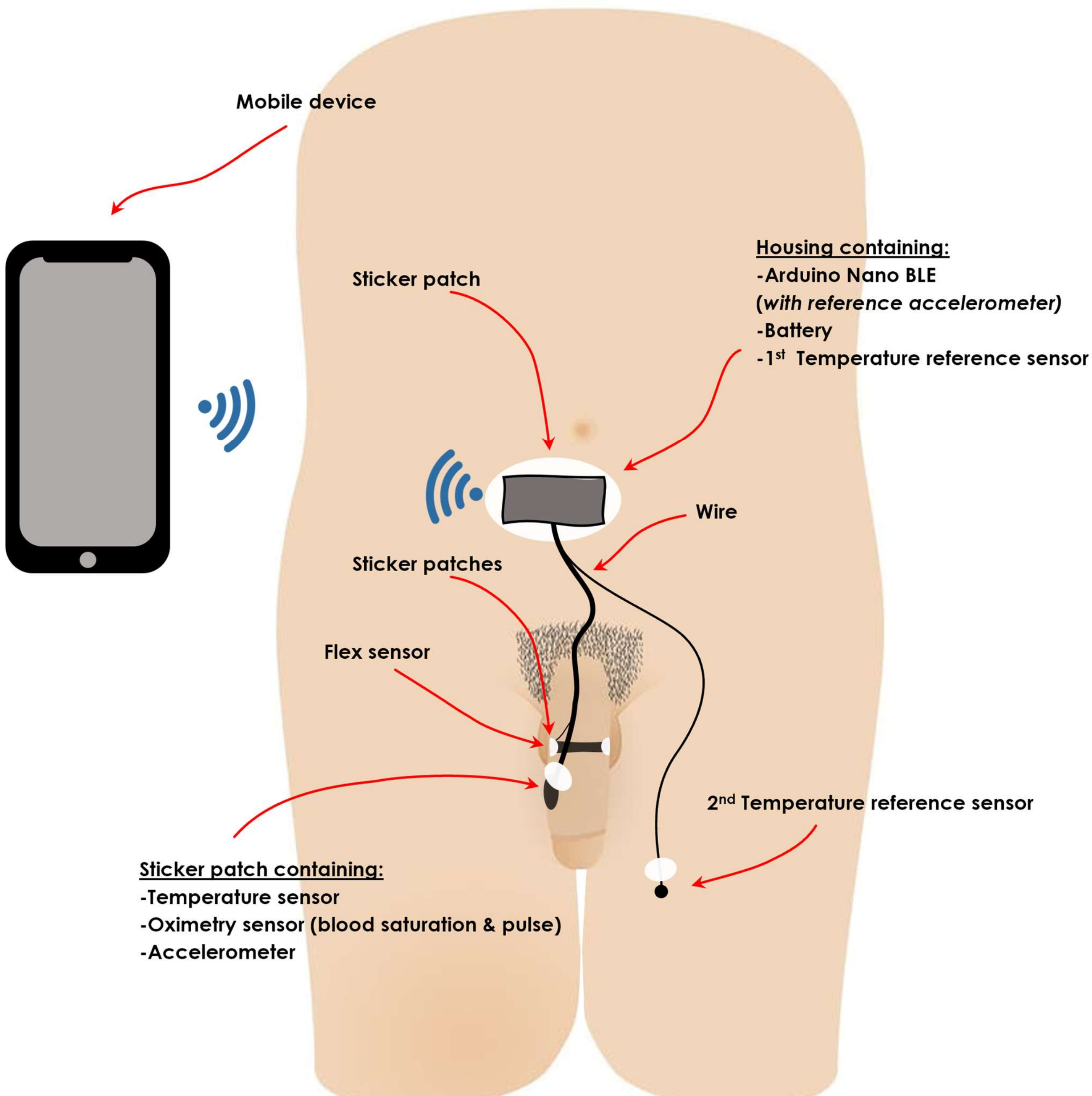

Figure 23, System Concept 3 shows the complete system attached to the abdomen using one large medical plaster.

4.3 Final Concept

System concept 3 emerges as the most favourable choice as a final concept. This is primarily due to its simplicity and minimal preparation requirements. With only five application plasters needed (which could be further reduced), this can be quick and easy. The short, non-entangling wire ensures the most comfort for the user. Unlike other concepts, it eliminates the need for an elastic belt around the leg or hips, further enhancing user comfort. By reducing the complexity of the setup, System Concept 3 streamlines the process of nocturnal erection monitoring, making it more user-friendly.

4.4 Final Concept Summary

This section provides a comprehensive summary of the final concept for the nocturnal penile erection monitoring system, including the selected components, pending testing requirements, the chosen design concept, and an overview of the wiring diagram.

Final Component Choice as Shown in 4.2.1.1:

- Microcontroller: Arduino Nano BLE
- Power System: EEMB 3.7V LiPo battery
- Data Transfer: Bluetooth Low Energy (BLE)
- Temperature Sensor: To be determined during testing
- Circumference Sensor: To be determined during testing
- Blood Saturation and Arterial Pulse Sensor: MAX30102 (OT3546) oximetry sensor
- Acceleration Sensor: ADXL345 accelerometer

Chosen Design Concept:

The chosen design concept prioritizes user comfort and data accuracy. The monitoring system will be compact, lightweight, and unobtrusive to minimize discomfort during nocturnal use. The sensors will be strategically placed to ensure accurate measurements while maintaining ease of use. The system will utilize BLE for real-time data transfer to an external mobile device, allowing for continuous monitoring and analysis. The third concept will be chosen as described in 4.3. Within this concept, the circuit diagram of 4.2.1.2 will be used.

Decisions Pending Further Testing:

- Thermistor Selection: Final determination of the most suitable thermistor among the six selected options to ensure optimal performance and accuracy.

- Circumference Sensor Selection: Decision between the flex sensor and the stretch sensor based on their reliability and precision in capturing changes in penile circumference.

5 Specification

This chapter consists of a persona, and an interaction scenario and includes the complete system requirements.

5.1 Persona and Interaction Scenario

In this section, we define the target user persona and outline an interaction scenario to illustrate how the nocturnal penile erection monitoring system will be used in a real-world context.

5.1.1 Persona

To ensure that the monitoring system meets the needs of its primary users, a detailed persona is created. This persona represents the typical patient who will benefit from the system. The persona can be seen in Table 12.

Table 12, Persona information.

Attribute	Details
Name	John Doe
Occupation	Office Manager
Demographics	- 45 years old - Male - Married, 2 children
Health Background	- Diagnosed with mild (IIEF-5 score 17) erectile dysfunction. - Generally in good health, but experiences occasional stress due to work.
Goals	- To determine the cause of his erectile dysfunction. - To understand if the issue is physiological or psychological. - To find a comfortable and non-intrusive method to monitor nocturnal erections.
Challenges	- Feels embarrassed discussing erectile issues with doctors. - Finds current diagnostic methods uncomfortable and disruptive to sleep. - Prefers a solution that can be used at home without constant medical supervision and the requirement of undergoing an invasive diagnostic test.

5.1.2 Interaction Scenario

The following interaction scenario illustrates how John Doe would use the nocturnal penile erection monitoring system.

Evening Routine:

Preparation: John receives the monitoring kit after consultation with his urologist, which includes the main sensor housing, temperature sensors, circumference sensors, pulse oximeter, and accelerometers. He reads the quick-start guide that provides step-by-step instructions.

Setup: Before going to bed, John attaches the sensors as instructed in the manual. He places the temperature sensor on his penis and positions the 2 reference temperature sensors on his leg and abdomen. He secures them using the medical stickers included. He then secures the main sensor housing to his abdomen and makes sure the wires are not tangled.

Activation: Using the smartphone provided by the hospital, John pairs his device with the sensor system using Bluetooth. He starts the monitoring session after the app confirms all sensors are properly connected and functioning.

During the Night:

Data Collection: As John sleeps, the system continuously monitors penile temperature, circumference, blood saturation, arterial pulse, and acceleration. The data is wirelessly transmitted to his smartphone, where it is securely stored.

Comfort: The lightweight and non-intrusive design of the sensors ensures that John sleeps comfortably without disruption.

Morning Routine:

Data Review: Upon waking, John checks the smartphone and stops the measurements.

Removal: John then packs the monitoring system and smartphone to be sent back to the hospital for cleaning and further use. The sensors are designed for easy detachment without causing discomfort or skin irritation.

Analysis: John’s urologist analyses the data from the measurement.

Follow-Up:

Consultation: Based on this collected data, John schedules a follow-up appointment with his urologist. The comprehensive data helps his doctor understand his condition better and recommend appropriate treatment or further diagnostics.

This interaction scenario shows the system's ease of use, comfort, and ability to provide valuable insights into John's erectile function, aiding in the diagnosis and treatment of erectile dysfunction.

5.2 System Specifications

This section outlines the detailed specifications for the developed penile sensor system, designed to monitor nocturnal erections to aid in diagnosing erectile dysfunction. The system is structured around four primary components: sensors, Arduino Nano BLE, the user, and an external device for data analysis and storage. Each component plays a crucial role in ensuring the system's functionality and reliability.

5.2.1 System overview

The system consists of multiple interconnected blocks: Sensors, Arduino Nano BLE, User, External Device and penis. These blocks work together to detect, process, and analyze physiological changes associated with nocturnal erections (Figure 24).

5.2.1.1 Components and Interactions

Sensors

The sensors are the primary interface with the penis, detecting physiological changes such as temperature, stretch, pulse, blood oxygen levels and movement. These sensors are attached to the penis and continuously monitor various parameters, generating sensor data.

Arduino Nano BLE

The Arduino Nano BLE acts as the central processing unit of the system. It requests data from the sensors and processes it accordingly. The Arduino collects, processes, and then transfers this sensor data to the external device via Bluetooth Low Energy (BLE).

External Device

An external device, such as a smartphone or laptop, receives the sensor data from the Arduino via BLE. This device is responsible for displaying the data overview to the user and can also issue commands back to the Arduino, such as starting or stopping the measurement process.

User

The user interacts with the system primarily through the external device. They can start or stop measurements and view the data overview to monitor the system's operational status. The user also turns the device on or off and ensures it is functioning correctly.

Penis

The penis is the biological component where physiological changes are detected by the sensors. These changes are critical for monitoring nocturnal erections, providing essential data for further analysis.

5.2.1.2 Conclusion

The penile sensor system designed for monitoring nocturnal erections integrates several key components to ensure comprehensive and accurate data collection. Sensors attached to the penis detect important physiological changes, such as temperature, stretch, pulse, and blood oxygen levels. The Arduino Nano BLE serves as the central processing unit, collecting and processing sensor data before transferring it to an external device via Bluetooth Low Energy (BLE). The external device, typically a smartphone or laptop, displays the data to the user and can issue commands to the Arduino. The user interacts with the system through this external device, managing the operational status and ensuring proper functionality. The user can also interact with the Arduino Nano BLE itself, by turning the device on / off and checking its status.

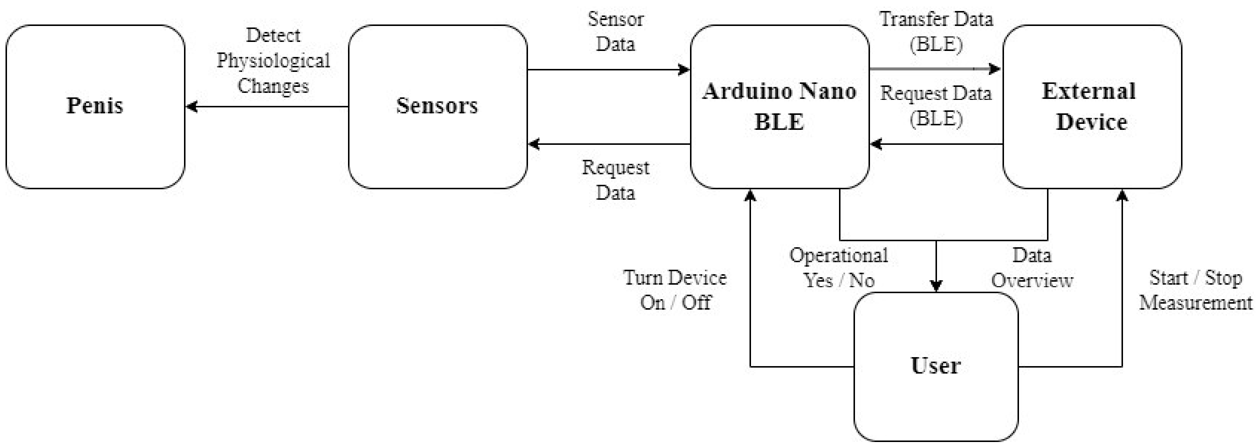

Figure 24, System overview with interactions between the main components and the penis.

6 Realisation

This chapter outlines the process of realizing the proposed monitoring system for nocturnal erections. It covers the validation and testing of the different sensors, battery considerations, data transfer challenges, and the integration of components into a functional prototype sensor system.

6.1 Sensor Validation and Testing

In this section, the testing and validation processes for each sensor under controlled conditions are discussed to ensure they meet the previously set-up requirements. Also, final sensor decisions are made based on the acquired data.

6.1.1 Temperature

To determine the most suitable thermistor for measuring penile temperature, several controlled tests were conducted in the laboratory. These tests aimed to evaluate the accuracy, response time, and stability of six different thermistors under varying temperature conditions. The thermistors tested as described in 2.2.3.1 were:

- Semitec 103AT-2 (10kOhm, 1%)
- Semitec 203AT-2 (20kOhm, 1%)
- Semitec 103AT-5-1P-FT (10kOhm, 1%)
- Vishay / BC Components NTCLE100E3103GB0 (10kOhm, 2%)
- Vishay / BC Components NTCLE100E3103GT1 (10kOhm, 2%)
- Vishay / BC Components NTCLE100E3682GB0 (6.8kOhm, 2%)

6.1.1.1 Method

A laboratory method was designed to measure the resistance across the different thermistors by changing the water temperature. The wiring setup, as shown in Figure 25, was designed for this purpose. By measuring the output voltage (Vout) using the Arduino Uno (chosen for its ease during testing) and the code in Appendix A – Arduino Code, the resistance of each thermistor at known water temperatures was calculated using the voltage divider formula. Note that the wiring diagram shown in Figure 25 was replicated six times, once for each thermistor. The Vout was connected to an analog read pin on the Arduino (A0 to A5 for six thermistors). GND and 5V were also connected to the Arduino GND and 5V pin.

The voltage divider formula used for the calculations is:

$$V_{out} = V_{in} \cdot \frac{R_{Fixed}}{R_{NTC} + R_{Fixed}}$$

Rearranging this to solve for R_{NTC}:

$$R_{NTC} = R_{Fixed} \cdot \frac{V_{in} - V_{out}}{V_{out}}$$

Here, R_{Fixed} is equal to the thermistor's resistance at 25°C. These thermistor-specific values can be seen in the list of thermistors above (after the name). For example, the Semitec 103AT-2 has an R_{25} of 10kΩ and this R_{Fixed} is also 10kΩ.

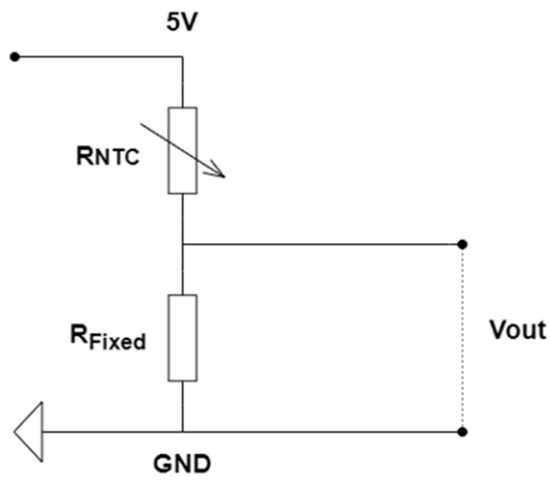

Figure 25, The wiring setup used in the lab sessions. 5v And GND are supplied by the Arduino.

6.1.1.2 Test 1

In the initial test, all six thermistors were connected to an Arduino Uno, with the setup shown in Figure 26. The Arduino was linked to a laptop for data recording. The thermistors were submerged in a glass container filled with water, which also housed a magnetic stir bar and a heating element. A primary thermometer monitored the water temperature. The objective was to record the resistance values of the thermistors at varying water temperatures as the heating element gradually increased the temperature of the water.

During the test and subsequent data analysis, several issues were identified:

- The heating element consistently overshot the set temperature, preventing the water temperature from stabilizing.
- The small glass container allowed external temperatures to influence the water temperature significantly.

As a result, the data was not consistent and thus invalid. A second test is deemed necessary.

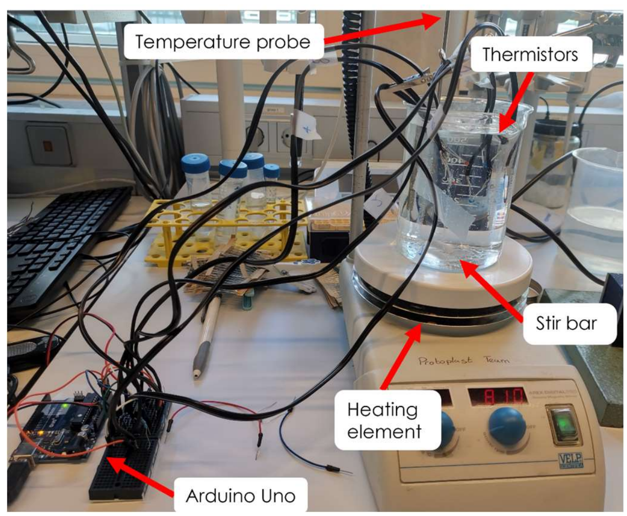

Figure 26, Lab 1 setup showing all the lab components.

6.1.1.3 Test 2

To address the issues from the first test, the second experiment used an insulated container and multiple thermometers to measure the water temperature. An average of these thermometer readings was used to determine the actual water temperature. Instead of using a heating element, preheated hot water and cold water were used to reach the desired temperatures (see Figure 27 for the new test setup).

Despite these improvements, the data analysis still showed significant variation and deviation in the results. The main issues identified were:

- The absence of a stir bar, due to changing the container and not using the heating element resulted in uneven water temperature distribution.
- The use of multiple inexpensive thermometers led to inconsistent average temperature measurements.

After the second lab test, some data was usable. And this preliminary data indicated that the three Vishay/BC Component thermistors were less precise than the Semitec thermistors. But, due to the issues experienced, a final lab test has to be performed, including only the Semitec thermistors.

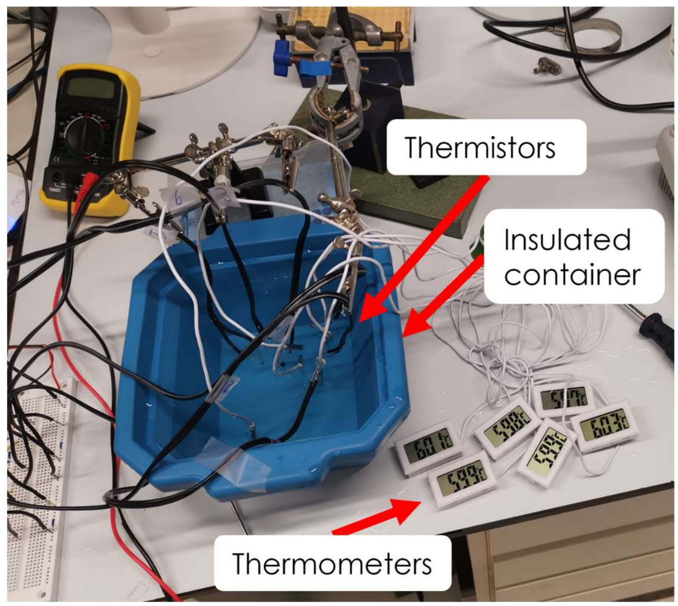

Figure 27, Lab 2 setup.

6.1.1.4 Test 3

For the third experiment, the setup was further refined to ensure reliable and consistent results (see Figure 28). An insulating water container was used again, but this time a stir bar was added to mix the water. The container could be placed onto the heating element without turning the heater on, allowing the use of the stir bar. This ensured that the water was stirred thoroughly, maintaining a constant temperature across the three thermistors. Additionally, only one high-precision lab thermometer (accurate to 0.2°C) was used to measure the water temperature, replacing the less accurate thermometers from previous tests.

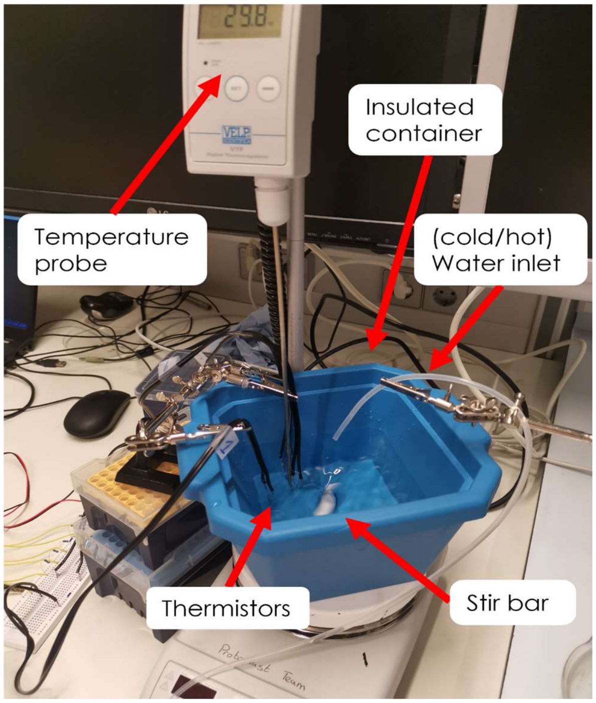

Figure 28, Lab 3 setup.

The procedure involved:

1. Starting with cold water in the container.
2. Gradually heating the water using preheated water injected with a syringe until it reached around 40°C. Measuring the resistance values at certain temperatures.
3. Lowering the temperature again by adding cold water using the syringe. Again, measuring the resistance values at certain temperatures.

This refined setup yielded reliable results, with accurate and stable temperature readings from the thermistors. The precise mixing of water and the use of a high-accuracy thermometer provided consistent temperature conditions, allowing for a valid evaluation of each thermistor's performance.

6.1.1.5 Data Analysis and Conclusion

The final lab test yielded the data presented in Figure 29 and Figure 30. The data used in both figures comes exclusively from the heating phase of the experiment, as combining heating and cooling cycles led to inaccuracies due to the different thermal responses of the thermometer. Figure 29 plots the output voltage (Vout) against the temperature, while Figure 28 uses this Vout to calculate the thermistor resistance.

From the data, it is evident that similar deviations occur across all three thermistors, suggesting that the thermistors themselves are accurate and that any discrepancies are likely due to measurement errors. However, an anomaly was observed: at 25°C, the resistance values for the thermistors should be 10kΩ, 20kΩ, and 6.82kΩ respectively (R_{25} - value). Instead, the measured resistance values were approximately half of these expected values. The cause of this discrepancy remains unclear but does not significantly impact the overall thermistor analysis.

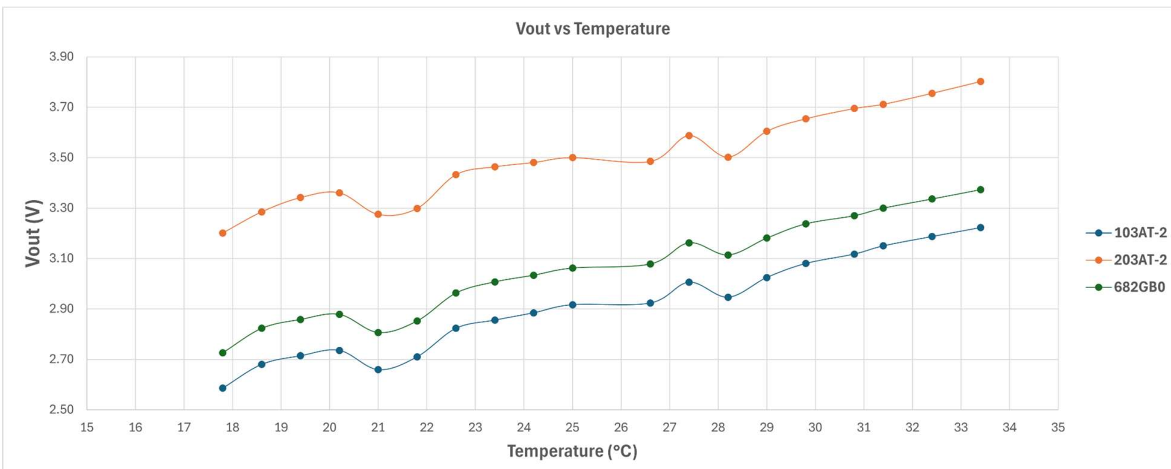

Figure 29, Vout vs Temperature.

Upon closer examination of Figure 30, it is evident that the Semitec 203AT-2 exhibits the steepest decline in resistance, at 250Ω per °C. This indicates that the Semitec 203AT-2 can capture changes in temperature with the highest precision. Therefore, the Semitec 203AT-2 thermistor will be selected for the sensor system. It is important to note that the R^2-value could potentially be higher, as most variations in the data are likely induced by the experimental setup rather than the thermistor itself. This reinforces the reliability of the Semitec 203AT-2 in accurately measuring temperature changes, making it the optimal choice for the monitoring system.

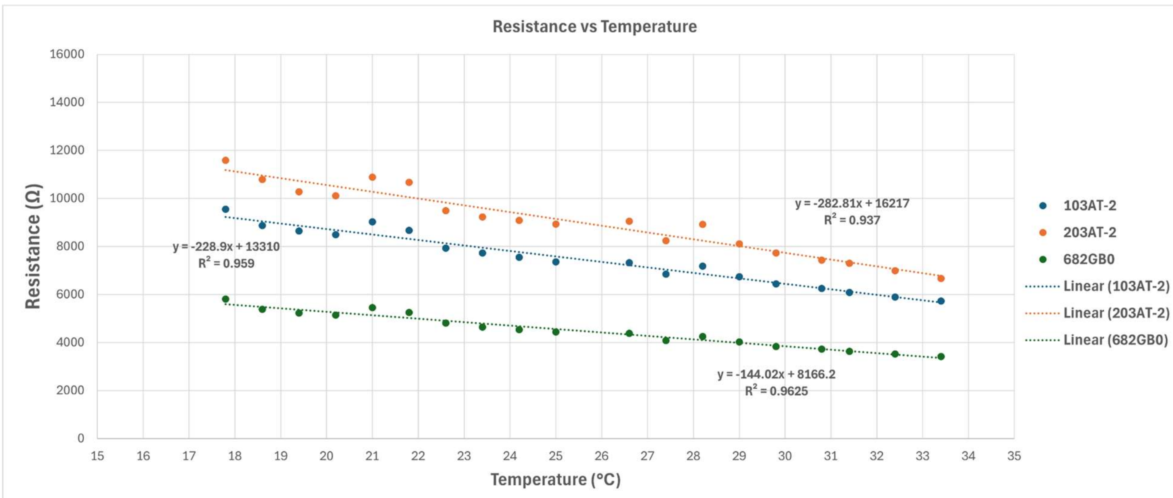

Figure 30, Resistance vs Temperature. Derived from the voltage divider formula and based on measurements from Figure 29.

6.1.2 Circumference

To accurately measure changes in penile circumference, a flexible stretch sensor was tested in a controlled lab environment. The primary goal was to validate the sensor's capability to detect precise changes in length, corresponding to changes in penile circumference during nocturnal erections. The results of this test should also decide whether to use the stretch or flex sensor to determine the penile circumference.

6.1.2.1 Method

The test setup involved the use of a flexible stretch sensor and an Arduino Uno microcontroller to measure the sensor's resistance at fixed stretched lengths. The wiring scheme can be seen in Figure 31.

The sensor was securely attached to a stable platform to ensure consistent stretching conditions. A series of predefined lengths were marked along the sensor to represent various degrees of stretch. The sensor was gradually stretched to each marked length, and the corresponding resistance was recorded using the Arduino Uno running the code from Appendix A – Arduino Code. This process was repeated multiple times to ensure the reliability and repeatability of the measurements.

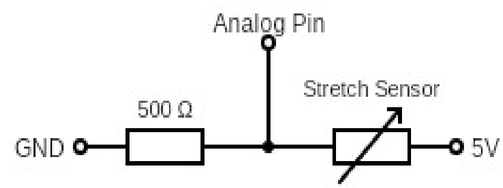

Figure 31, Wiring scheme of the stretch sensor setup.

6.1.2.2 Testing

During the testing phase, a conductive rubber wire was used as the stretch sensor. The initial length of the sensor was 4.5 cm. The testing procedure involved gradually stretching the sensor in increments of 0.5 cm until a maximum length of 8.5 cm was achieved, representing an increase of approximately 88%. After each incremental increase, the resistance of the sensor was measured and recorded using the Arduino Uno. This approach allowed for a systematic assessment of the sensor's performance across its entire range of stretch. The results obtained from these measurements provided valuable insights into the sensor's responsiveness and reliability.

6.1.2.3 Data Analysis and Conclusion

The graph in Figure 32 illustrates the relationship between the length (in centimetres) and the resistance (in ohms) of the stretch sensor. The measured range is 4.5 to 8.5 cm, and this covers the required range as set in 2.2.2.2. Two datasets are plotted (two repetitions): one represented by blue data points and the other by orange data points, each accompanied by a linear trendline.

Both datasets ensure a high R^2-value, which indicates a strong negative linear correlation between the length of the sensor and the resistance. The slopes of both datasets are nearly identical, with the blue data having a slope of −52.5Ω/cm and the orange data having a slope of −52Ω/cm. This indicates that the change in resistance per unit length is consistent across both measurements, with around 52Ω/cm. Additionally, the y-intercepts for the trendlines are close to each other (blue = 861Ω, orange = 857Ω), this suggests that the baseline resistance of the sensor is consistent across different tests. This further supports the high reliability of the sensor's performance across different tests.

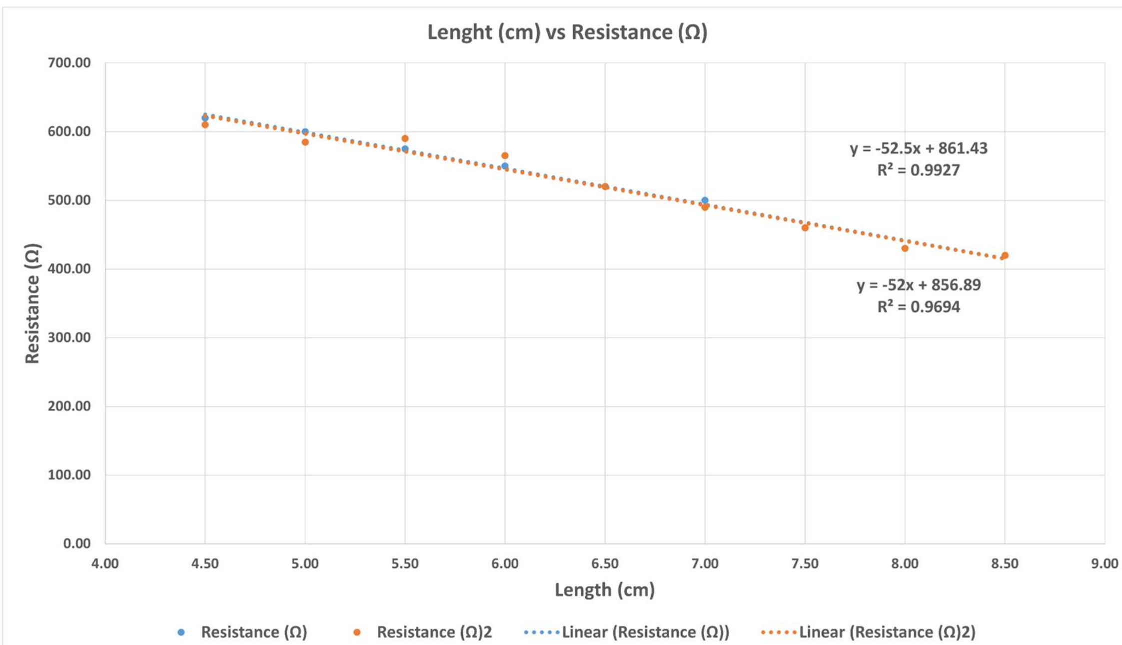

Figure 32, Stretch sensor data Length vs Resistance.

The strong linear relationships and high R^2-values confirm that the stretch sensor provides a reliable and predictable change in resistance with varying lengths. This consistency is crucial for accurately measuring changes in penile circumference during nocturnal erections. The sensor's predictable behaviour allows for precise calibration, making it a suitable choice for integration into the monitoring system. This also means that the flex sensor is obsolete, therefore, this sensor is not tested and is left aside.

In Figure 33, a quick prototype of the stretch sensor can be seen around a balloon used by artists to make shapes. This way, it clearly shows how it can be used to detect changes in penile circumference.

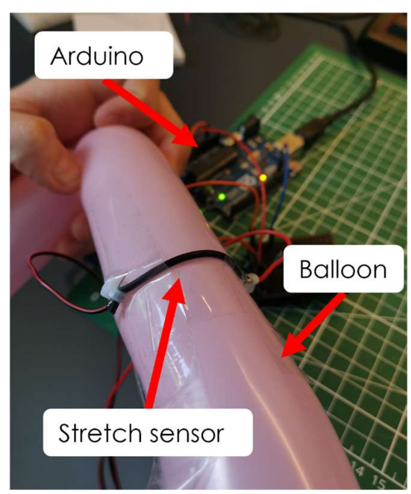

Figure 33, Stretch sensor around an inflatable balloon.

6.1.3 Blood Saturation

For the accurate measurement of penile blood saturation levels, the MAX30102 oximetry sensor was selected due to its compact size and capability to measure both blood saturation and arterial pulse using red and infrared light.

6.1.3.1 Method

Initial testing of the MAX30102 oximetry sensor was conducted using a straightforward electrical setup involving an Arduino Uno microcontroller and the MAX30102 sensor (see Figure 34). The code run on the Arduino can be found in Appendix A – Arduino Code. For the tests, a finger was placed gently onto the MAX30102 sensor, and data was gathered via the Arduino and transmitted to a connected laptop. The primary objective was to assess the raw data output and evaluate the sensor's capability in accurately measuring blood saturation levels.

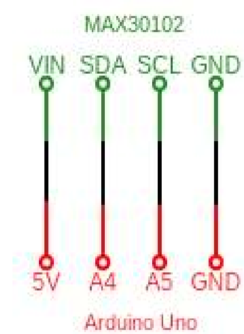

Figure 34, Circuit of test setup for the MAX30102 oximetry sensor.

6.1.3.2 Testing

During these tests, the raw data from the oximeter was visible after placing the finger on the sensor. However, a significant issue was observed: the data stream was highly sensitive to finger movement. Even slight movements caused considerable fluctuations in the data, making it challenging to obtain stable readings. Despite this, the raw data did show clear relations to expected data trends, which is further elaborated in the arterial pulse testing in section 6.1.4.

6.1.3.3 Data Analysis and Conclusion

One critical challenge encountered was the data processing required to achieve SpO2 readings. This process relies on an Arduino library due to its complexity, creating a "black box" situation where the internal workings cannot be modified or inspected. In this initial test, the library did not perform well, leading to unreliable SpO2 readings. After further tests, by minimizing ambient light around the sensor or trying manual data analysis, the result did not improve.

Despite showing promising results in capturing raw data, as seen in Figure 35, the SpO2 calculations from this raw data were inconsistent and unreliable. This figure is made by placing a finger on the MAX30102 pulse oximeter and capturing the data. The graph shows two constant pulsating lines for IR light reflection and red light reflection. However, even little movement of the finger made the data very inconsistent, as a result, the raw data to SpO2 calculations resulted in unreliable data.

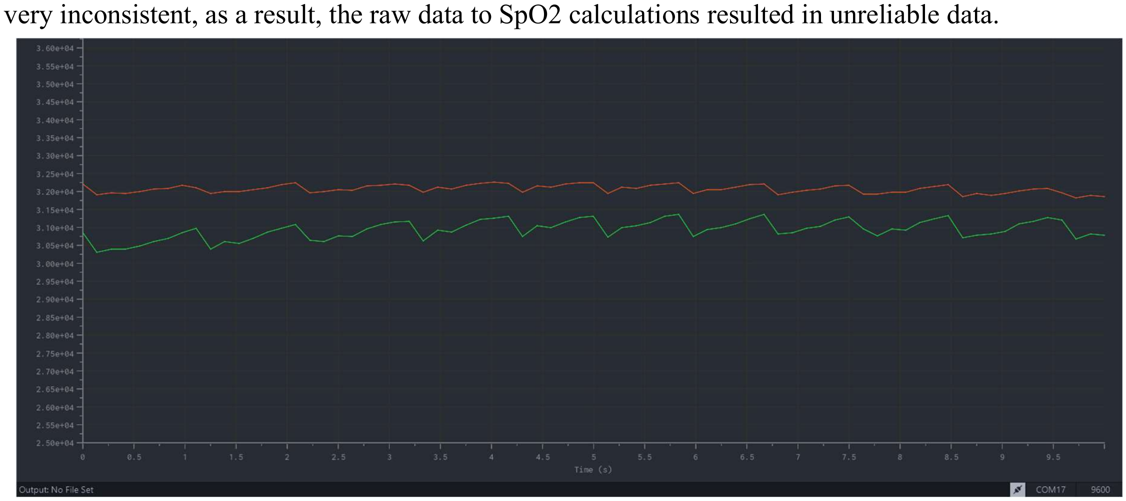

Figure 35, Raw data MAX30102 pulse oximeter.

Additionally, achieving medical-grade validation of blood saturation measurements would require adherence to ISO 80601-2-61 test requirements, which involve invasive blood sampling from subjects. This level of testing is beyond the project's scope and is considered too invasive [53]. Therefore, the focus has shifted from measuring blood saturation to concentrating on arterial pulse measurement, which can be reliably tested and validated within the project's parameters.

Consequently, it has been discussed that the focus should be shifted away from measuring blood saturation. Instead, the project will concentrate on arterial pulse measurement, which can be reliably tested and validated within the project's parameters.

6.1.4 Arterial Pulse

For the accurate measurement of penile blood saturation levels, the MAX30102 oximetry sensor was initially selected due to its compact size and capability to measure both blood saturation and arterial pulse using red and infrared light. However, during the testing phase, several challenges were encountered that affected the reliability of the sensor's readings.

6.1.4.1 Method

The primary objective of testing the MAX30102 sensor was to determine whether it could reliably capture the raw data necessary to calculate Beats Per Minute (BPM). The setup involved connecting the MAX30102 sensor to an Arduino Uno, as illustrated in Figure 34. The test procedure included capturing the raw data from the red light reflection on the MAX30102 using the Arduino code provided in Appendix A – Arduino Code. The IR light was not needed to determine arterial pulse, only the red light. To visualize the data, a serial grapher software called ProcessingGrapher by Chillibasket was used, which allowed both the red and IR values to be displayed in real-time [54]. To calculate the BPM, the following formula was used:

$$Beats\ per\ Minute\ (BPM) = \frac{number\ of\ beats}{time\ in\ seconds} \cdot 60\ seconds$$

This approach allows for measurements and calculations of heart rate using the MAX30102. However, to fully validate the MAX30102 capability of arterial pulse measurements, a comparison to an existing certified method needs to be performed as well.

6.1.4.2 Initial Testing

During the first test, the MAX30102 sensor was connected to the Arduino Uno, and raw data was captured. The sensor was placed on a fingertip, and the data was recorded through the Arduino's serial output. While the raw data was acquired successfully, aligning the recorded data stream over time proved challenging. The Arduino outputs raw data in samples rather than time-stamped entries, making it difficult to correlate data points with specific times.

To address the issue of aligning the recorded data stream with time, a function was implemented in the Arduino code to count the time taken by the Arduino to measure one sample. This is achieved using the "millis()" function in the code. The calculated time is then used to determine the sampling frequency of the Arduino. This sampling frequency is subsequently employed to convert the samples into timestamps, allowing the data to be plotted against time accurately. By using Processing Grapher, the data can be visualized correctly with this calculated sampling frequency as a settings input. This approach resulted in the first usable graph, as shown in Figure 36. The purple lines were added manually to indicate single pulses.

Following Figure 36, 16 vertical lines, or 16 pulses can be observed. The first pulse occurs at t = 1,45s and the last pulse at t = 19.10s. Using the BPM formula, the average BPM is calculated as follows:

$$\frac{16}{(19.10 - 1.45)} \cdot 60 = 54\ bpm$$

Figure 36, Output data from Processing Grapher. The vertical lines were later added to clarify and indicate a single pulse.

6.1.4.3 Validation Test

To validate the results obtained from the initial test, it is essential to compare them with a system that has already been validated. For this purpose, the Consensys Shimmer3 was used as an ECG reference [55].

The Shimmer3 device was equipped with four electrodes to capture accurate measurements. The electrodes were located in predefined locations as seen in Figure 37. These electrodes were wired to the Shimmer3 device, which wirelessly transmitted the data using Bluetooth to a laptop running the Consensys software. This software was used to record and store the data from the Shimmer3 device.

To start a recording, it is crucial to start the recording of both the Arduino Uno and Shimmer3 simultaneously. To do so, extra software on the laptop was installed to automatically hit record on both the Shimmer and the Processing Grapher software at the exact same time. The software also made sure data collection was halted at the exact same time.

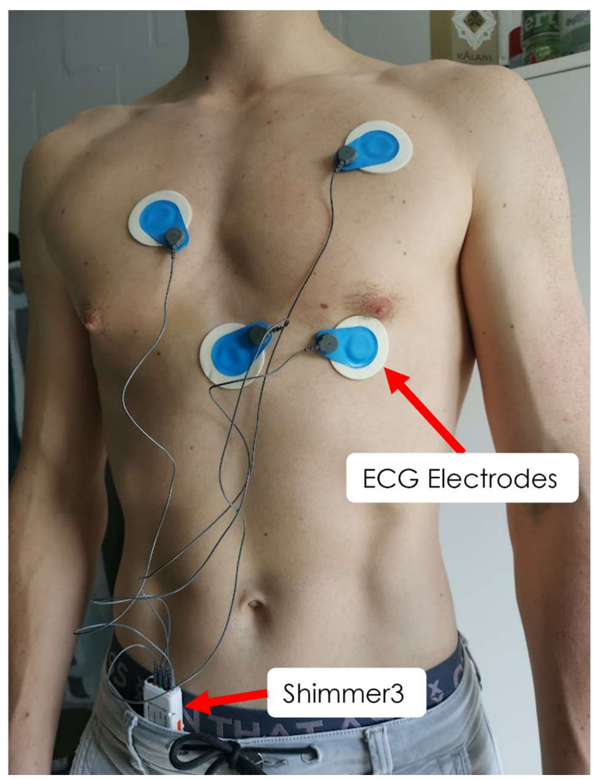

Figure 37, ECG electrodes placed on the chest and connected to the Shimmer3.

6.1.4.4 *Data Analysis and Conclusion*

Once the data collection was complete, which lasted around 30 seconds, the datasets from both the Arduino Uno and the Shimmer3 were exported and imported into Excel. By overlaying these datasets, it was possible to align the pulses detected by both devices and evaluate the accuracy of the MAX30102 sensor against the validated Shimmer3 system, as shown in Figure 38. This comparison is crucial for determining the reliability of the MAX30102 in measuring arterial pulse.

As seen in Figure 38, the pulse from the MAX30102 trails the ECG pulse slightly. A clear correlation exists between the QRS complex of the ECG signal (red) and the peaks (black) of the heart rate detection of the MAX30102 (blue). There is a physiological delay of approximately 0.25s at a heart rate of 55 bpm for both pulse measurements. This delay is constant throughout the entire dataset, implying that the MAX30102 is accurate in capturing the arterial pulse.

However, it is worth noting that changes in the peak height of the MAX30102 readings result from movement artefacts. Despite these artefacts, the consistent delay and correlation with the ECG signal confirm the reliability of the MAX30102 for arterial pulse measurement. This validation confirms that the MAX30102 can be effectively used in the monitoring system for capturing arterial pulse, though care must be taken to minimize movement artefacts during data collection.

Besides this, I want to address the minimum sampling frequency requirement of 64Hz for the oximeter, as described in section 2.2.2.4. This has not been achieved for the MAX30102, obtained frequencies were in the range of 10Hz. This has not been achieved for the MAX30102, with obtained frequencies around 10Hz. However, this lower frequency is not an issue, as the data from the MAX30102 still provides a clear and accurate representation of the pulse.

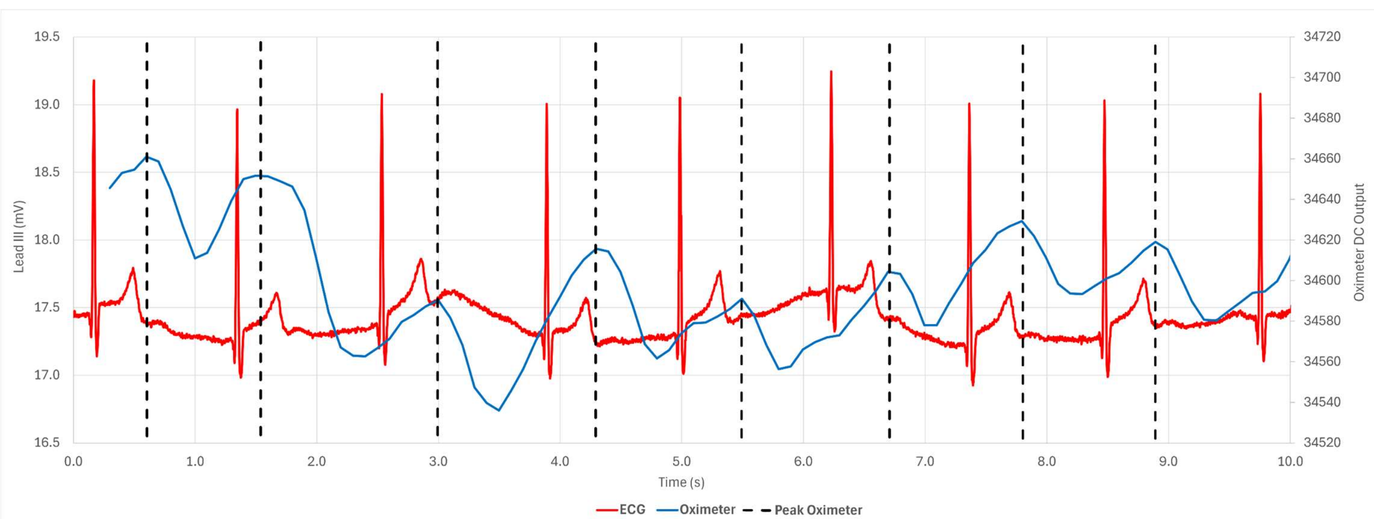

Figure 38, Comparison of arterial pulse measurements between the ECG (red) and MAX30102 oximeter (blue). The black dashed lines indicate peaks detected by the MAX30102 oximeter, showing a consistent physiological delay of approximately 0.25 seconds compared to the ECG signal peaks.

6.1.5 Acceleration

To accurately measure penile acceleration during nocturnal erections, the acceleration sensor testing was performed using both the built-in IMU of the Arduino Nano BLE and the ADXL345 accelerometer. The goal was to determine the precision and reliability of these sensors in detecting changes in angles and acceleration.

6.1.5.1 Method

The testing setup involved the Arduino Nano BLE, which has an integrated LSM9DS1 IMU (Inertial Measurement Unit), and the ADXL345 accelerometer. The tests were conducted in a controlled environment to ensure accurate and repeatable results. The angle of both the ADXL345 and the Arduino Nano BLE was changed incrementally by 10 degrees. Both the x, y, and z values were recorded at each angle change across both the Y-roll and the X-roll. The measuring setup consisted of clamps to hold the sensors and a geo triangle to measure the angles accurately (Figure 40).

The connection schematic for the ADXL345 accelerometer was created to ensure proper interfacing with the Arduino Nano BLE (Figure 39). The Arduino code used for data collection is available in the Appendix A – Arduino Code. The schematic and code facilitated the accurate capture of acceleration data at each specified angle.

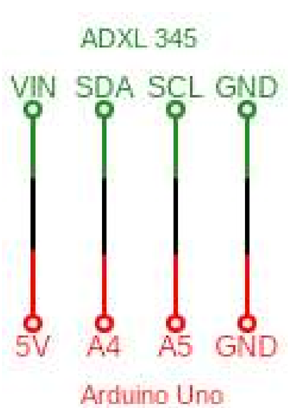

Figure 39, Circuit of test setup for the ADXL345 sensor.

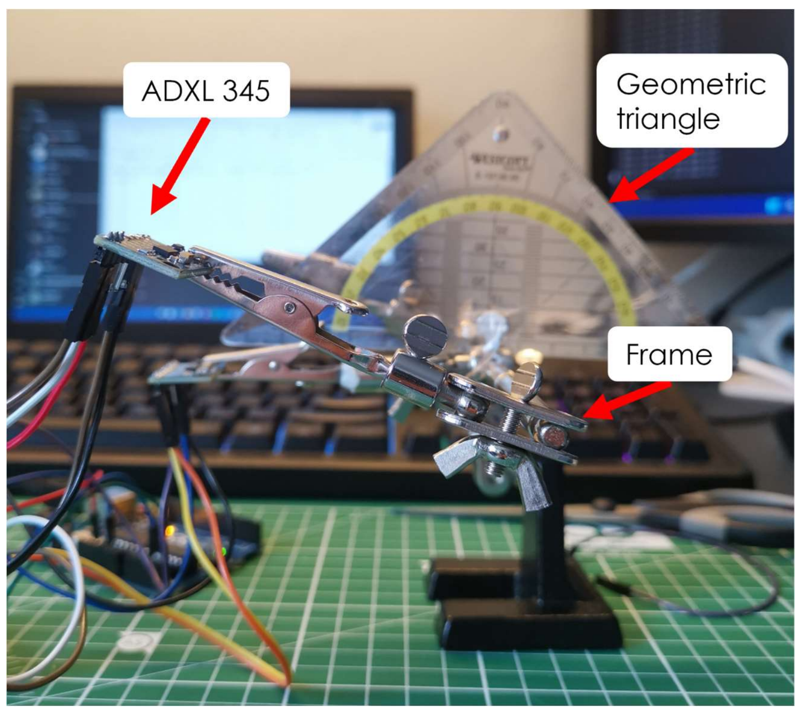

Figure 40, Setup used to test the accelerometers.

6.1.5.2 Testing

During testing, the sensor setup was adjusted in 10-degree increments, and the x, y, and z acceleration values were recorded for both sensors. This was done for both the Y-roll and X-roll of the sensor. The recorded data was systematically logged in an Excel file for further analysis. The method ensured that the sensors' response to changes in angle could be thoroughly evaluated.

The procedure involved:

1. Fixing the sensor in a stable position using the clamps.
2. Measuring the initial angle using the geometric triangle.
3. Adjusting the sensor angle by 10 degrees.
4. Recording the x, y, and z values from both the Arduino Nano BLE and the ADXL345 accelerometer.
5. Repeating the process for the entire range of angles (0-90 degrees), covering both Y-roll and X-roll movements.

6.1.5.3 Data Analysis and Conclusion

Once the data was collected, the datasets from both the Arduino Nano BLE and the ADXL345 accelerometer were imported into Excel for analysis. The graphs generated from this data illustrate the relationship between the angle changes and the recorded acceleration values.

X-Roll Analysis

As shown in Figure 41 and Figure 42, there is a clear linear relationship between the angle and the recorded acceleration values for both sensors. The R-squared values for the linear fits are high (0.9 – 0.98), indicating a strong correlation and confirming the sensors' accuracy in measuring acceleration changes with respect to angle.

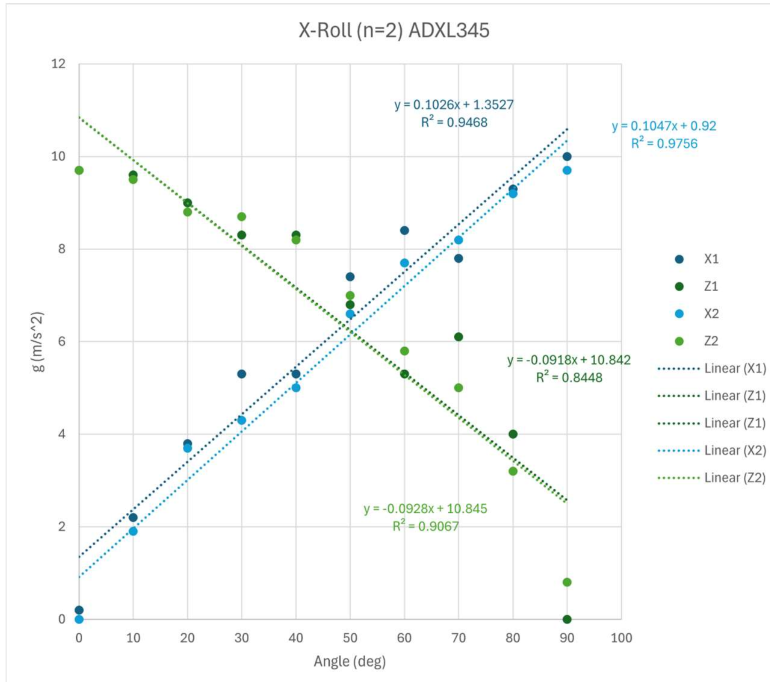

Figure 41, X-Roll acceleration data for ADXL345.

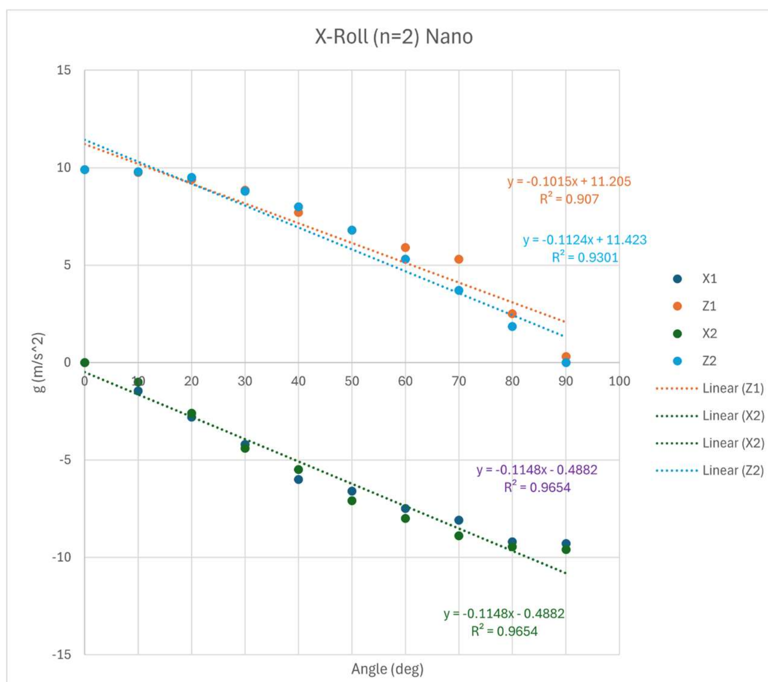

Figure 42, X-Roll acceleration data for Arduino Nano BLE.

Y-Roll Analysis

Similar to the X-roll, the Y-roll analysis shows a linear pattern between the angle and the acceleration values. The linear trend lines in the graphs confirm the accuracy and reliability of the sensors in capturing changes in acceleration with respect to angle. Again a high R-value confirms these results. (Figure 43 and Figure 44).

Overall, the data demonstrates that both the Arduino Nano BLE and the ADXL345 accelerometer provide accurate and reliable measurements of acceleration changes. The linearity observed in the data across different angles and movements confirm the sensors' suitability for inclusion in the monitoring system for detecting penile acceleration during nocturnal erections.

In conclusion, the Arduino Nano BLE's built-in IMU and the ADXL345 accelerometer have been validated as effective tools for measuring penile acceleration. The consistent linear relationship between angle changes and recorded acceleration values across both sensors ensures reliable performance in the intended application.

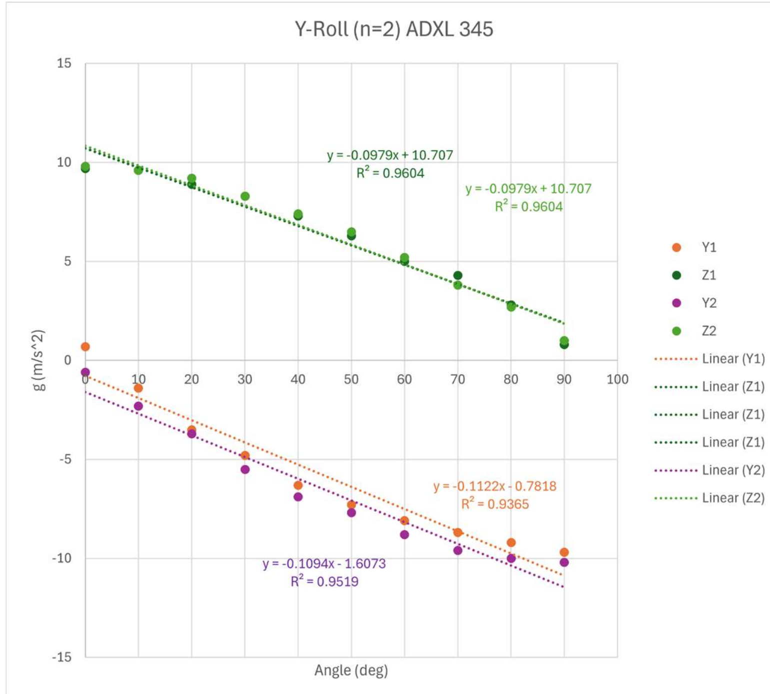

Figure 43, Y-Roll acceleration data for ADXL345.

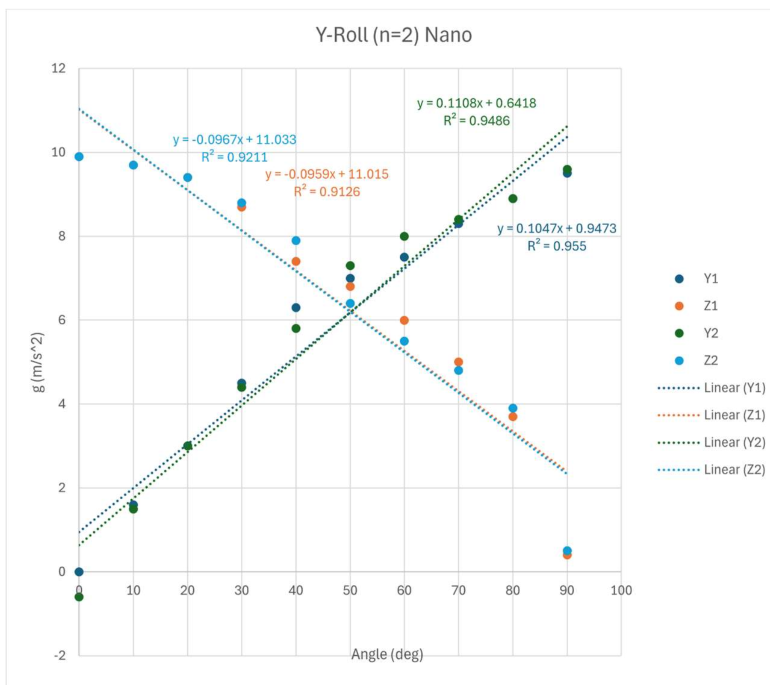

Figure 44, Y-Roll acceleration data for Arduino Nano BLE Sense.

6.1.6 Sensor Test Conclusion

The testing and validation of various sensors for the nocturnal penile erection monitoring system have led to insights and decisions regarding the optimal components for the system.

Temperature Sensor Testing

The thermistor tests identified the Semitec 203AT-2 as the most suitable option due to its precise response to temperature changes, showing a steep decline of 250Ω per °C. Despite initial anomalies in resistance measurements, consistent and accurate results were obtained under controlled lab conditions. The final selection of the Semitec 203AT-2 thermistor ensures reliable temperature measurement critical for the monitoring system.

Circumference Sensor Testing

Testing of the flexible stretch sensor confirmed its suitability for capturing penile circumference changes accurately, leading to the decision to exclude the bend sensor. This decision was based on the reliable performance of the stretch sensor in detailed testing, making the bend sensor redundant for this application.

Blood Saturation Sensor Testing

Initial tests of the integration of the MAX30102 oximetry sensor indicated difficulties in obtaining consistent and reliable SpO2 readings. Challenges in data processing and the necessity for ISO 80601-2-61 validation for medical use led to the exclusion of blood saturation measurement from the project’s scope. The focus was thus shifted entirely to measuring arterial pulse.

Arterial Pulse Sensor Testing

Validation tests for the MAX30102 sensor involved comparing its output to the Shimmer3 ECG system. The results demonstrated a clear correlation between the sensor's pulse detection and the ECG readings, with a consistent physiological delay of approximately 0.25 seconds. Despite minor artefacts due to movement, the MAX30102 proved reliable for arterial pulse measurement, confirming its suitability for the monitoring system.

Acceleration Sensor Testing

Testing of the Arduino Nano BLE’s built-in IMU and the ADXL345 accelerometer involved measuring acceleration at various angles. Both sensors displayed linear patterns in their data, though minor variances were observed due to the basic setup. The consistent and accurate results validated the use of the Arduino Nano BLE’s IMU for monitoring penile acceleration, ensuring precise measurement of nocturnal movements.

In short, the sensor testing phase has successfully identified the following most suitable components for the monitoring system:

- **Temperature**: Semitec 203AT-2 thermistor.
- **Circumference**: Flexible stretch sensor.
- **Arterial Pulse**: MAX30102 oximetry sensor.
- **Acceleration**: Built-in IMU of the Arduino Nano BLE and ADXL345.

These concluded sensors and the validation data obtained have been utilized and documented by H. Torenvlied et al. in their submission to the IEEE Sensors Conference, scheduled for October 2024.

6.2 Battery

The predefined battery option, as outlined in section 2.1.2, included a 3.7V LiPo battery. However, during the building and integration phase, it became evident that this battery was incompatible with the sensor system. Several factors contributed to this incompatibility:

6.2.1 Compatibility Issues

The Arduino Nano BLE can be powered using the Vin pin, which requires an input voltage of 5-18 volts. This is contrary to the initial assumption that it could be powered with 3.3V or slightly higher.

Although the Arduino Nano BLE can be powered using the 3.3V pin, this requires a precise 3.3V input. The 3.7V output from the LiPo battery exceeds this specification and using it could risk damaging the board due to the lack of internal voltage regulators.

6.2.2 Potential Solutions

To power the Arduino Nano BLE via the Vin pin, the voltage must be increased from 3.7V to a minimum of 5V. This can be achieved using a voltage booster, such as the Adafruit MiniBoost TPS61023 [56]. While this is a viable option, it reduces power efficiency and is not feasible to implement and test within the project's timeframe.

An alternative solution is to source a different battery with a higher voltage compatible with the Vin pin requirements. These would be batteries with an output voltage ranging between 5v and 18v. Another practical solution is to power the Arduino Nano BLE using its micro-USB connector, which requires a 5V USB power source, such as a power bank. However, this solution introduces the potential issue of automatic power bank shutoff due to low current draw and the bulky size of most portable power banks.

6.2.3 Considerations for Future Testing

Future testing could explore the integration of a voltage booster to step up the 3.7V from the LiPo battery to 5V. This would involve evaluating the power consumption and efficiency of the booster to ensure reliable operation throughout the night.

Testing should include evaluating batteries with voltages within the 5-18V range to power the Vin pin directly. This approach simplifies the power setup and reduces dependency on additional components like voltage boosters.

Evaluating the possibility of using a power bank to supply power via the micro-USB connector should include monitoring for potential issues related to automatic shutoff due to low current draw. Solutions could involve using power banks designed to remain active even under low current conditions or incorporating a low-power consumption load to maintain the power bank's output. Additionally, the bulkiness of power banks needs consideration, as they could add unwanted size and weight to the system, potentially affecting user comfort during nocturnal monitoring.

6.2.4 Conclusion

The initial choice of a 3.7V LiPo battery for the sensor system proved incompatible due to voltage requirements and the risk of damaging the Arduino Nano BLE. Future efforts should focus on either integrating a voltage booster to step up the battery voltage to 5V, selecting an alternative battery with the appropriate voltage, or using a USB power bank with considerations for continuous operation. Further testing is required to determine the most efficient and reliable power source for the system.

6.3 Data transfer

Bluetooth Low Energy (BLE) was selected as the preferred method for data transfer due to its low power consumption and suitability for continuous data streaming.

6.3.1 Testing

During testing of the BLE connection with an external device, the following was observed. Pairing and connecting the Arduino Nano 33 BLE with a smartphone application, such as nRF Connect, was successful [57]. However, the actual transfer of data proved unsuccessful due to the complexity involved, necessitating further testing and research to achieve reliable functionality.

The code used to test the BLE data transfer can be found in Appendix A – Arduino Code. This code sets up a BLE service with a single characteristic, “counterChar,” which increments every 5 seconds and sends the updated value via BLE. On the receiving end, however, the data was not observed coming in. This issue is likely due to the format in which the data was sent using BLE. Additional software is required to reformat this data into a readable format. But, unfortunately, due to time constraints, this was not tried.

6.3.2 Conclusion

Despite these challenges, BLE remains a promising solution for wirelessly sending acquired data to an external device for real-time analysis and storage. Future efforts should focus on resolving these issues by exploring different BLE libraries and further investigating the issue.

6.4 Casing

The casing for the sensor system was designed using Fusion360 and fabricated with an Ender 3 V2 3D printer. This design process was iterative, involving multiple prototypes and adjustments. Initially, a physical sketch was made on paper, where the Arduino Nano BLE and battery were laid out, and a box was drawn around them. Measurements were then taken from this sketch to inform the initial design in Fusion360. The measurements of the Arduino Nano BLE were also taken, in order to model it inside Fusion360, to make designing the case more convenient.

6.4.1 Prototyping

The first prototype focused solely on the box without a lid (the base). After printing, the Arduino Nano BLE and battery were placed inside to confirm the size was correct. Subsequently, slots for the Arduino Nano BLE's micro-USB cable and the male 10-pin connector were added (Figure 45).

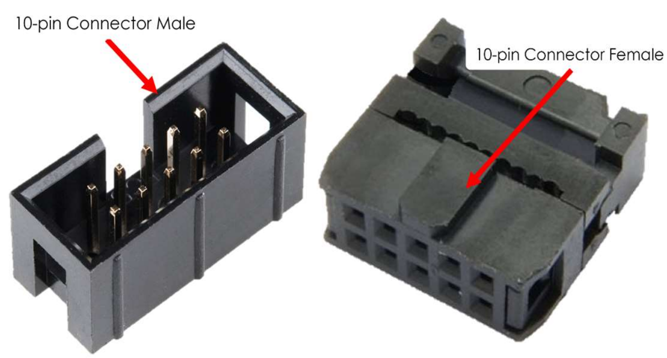

Figure 45, 10-Pin connector used for connecting the external sensors to the Arduino inside the case (male left, female connector right).

A second prototype verified the fit of these slots (Figure 48). During testing, the 10-pin connector was able to slide all the way through the case without obstruction. This created an issue as pushing the male connector in from the other end, would cause the female connector to slide through and fall completely inside the case. This issue was then adjusted by adding internal walls to hold the male connecter firmly in place (Figure 47).

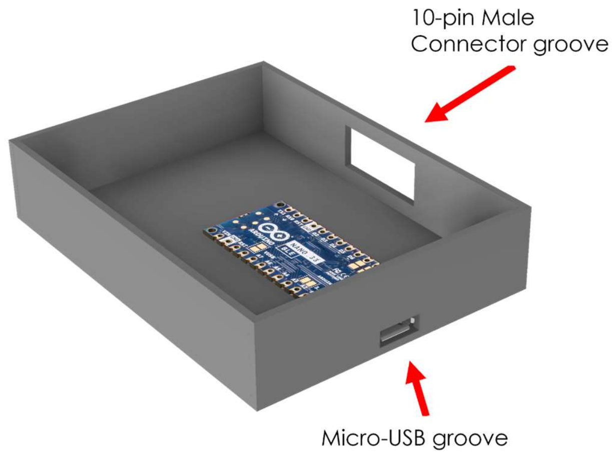

Figure 48, First prototype of the case design. The base without the lid and with grooves for the micro-USB and male end of the 10-pin connector.

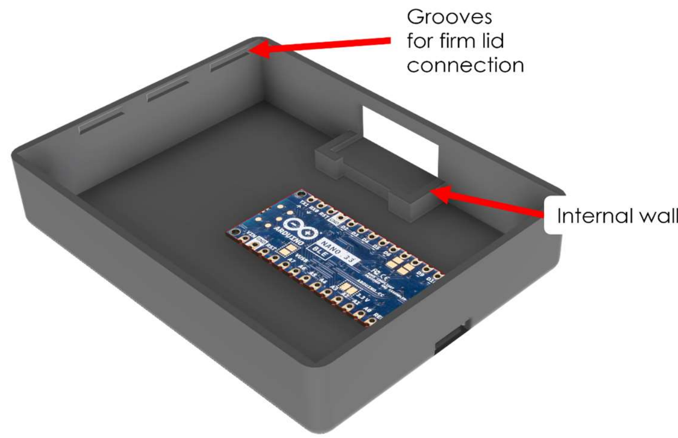

Figure 47, Second prototype of the case design (base). Note the improved internal walls to keep the male connector in place and the grooves in the wall to establish a firm lid connection.

The third prototype incorporated a roof with a downward-reaching structure attached to secure the Arduino Nano BLE in place once the case was closed. The initial lid print only partially restricted the Arduino's movement, prompting a redesign to fully lock it in place. The fourth and final print of the lid securely locked the Arduino inside the case; the structure surrounds the back of the Arduino Nano BLE, preventing it from moving once the lid is closed (Figure 46). To improve usability, grooves were added to the walls of the base part to allow the lid and base to 'click' together, facilitating easy opening and closing of the case for improved accessibility. The lid contains notches that slide and click locked in the grooves of the base. (Figure 46 and Figure 47). Edges and corners were also rounded to enhance patient comfort once the case is attached to the body (Figure 49).

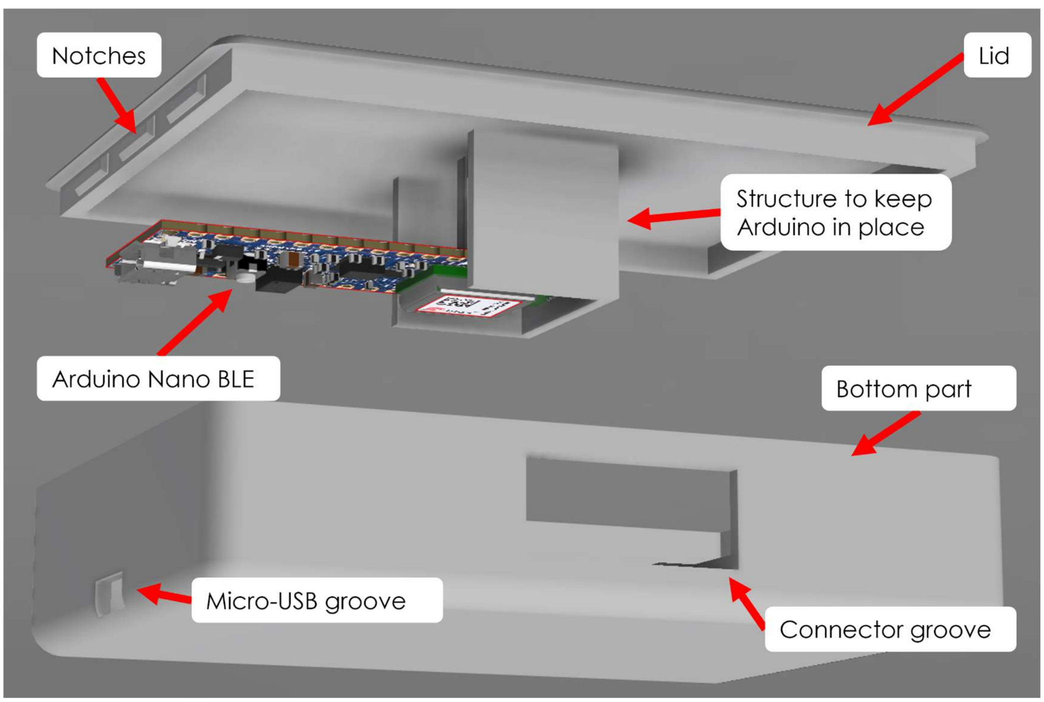

Figure 46, Final prototype. Case is depicted with the lid opened. Important design features are depicted.

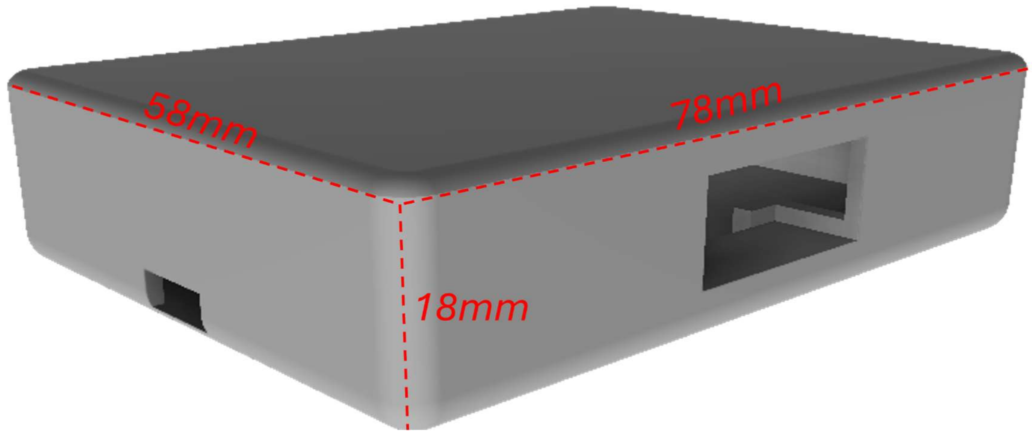

Figure 49, Final prototype with the lid closed and the outside dimensions shown (78 x 58 x 18mm).

Throughout this iterative process, Cura slicing software was used to prepare the models for printing. Given that a Fused Deposition Modeling (FDM) 3D printer builds objects layer by layer, support structures were modelled and added using this software to ensure successful prints and prevent failures.

6.4.2 Conclusion

The final assembled case provides a compact, secure housing for the Arduino Nano BLE, ensuring that all components fit snugly and are well-protected during use. The case design incorporates a connector that allows for easy connection and disconnection of the sensors, enhancing user convenience. Additionally, the removable lid facilitates easy access to the internal components for maintenance or adjustments. The slot for micro-USB access ensures straightforward connectivity to an external device, enabling quick updates or modifications to the Arduino codes. This thoughtful design ensures both functionality and ease of use, making the system efficient and user-friendly.

6.5 Component Integration

The integration of components into the finalized casing marked a crucial phase in the development of the sensor system. This process was executed methodically to ensure all components were securely housed and properly connected for optimal functionality.

6.5.1 Soldering the Sensors

Upon completing the casing, the first step involved soldering wires of sufficient length to all the sensors. These sensors included the thermistors, stretch sensor, MAX30102, and accelerometer. The sensors are split into two groups as seen in Figure 50. The sensors inside the blue square lead to the penis, and the sensors in the green square to the abdomen and leg. Each sensor wire was then connected to a female 10-pin connector. This connector was chosen to allow for easy attachment and detachment of the sensors and the case, facilitating straightforward maintenance and future upgrades.

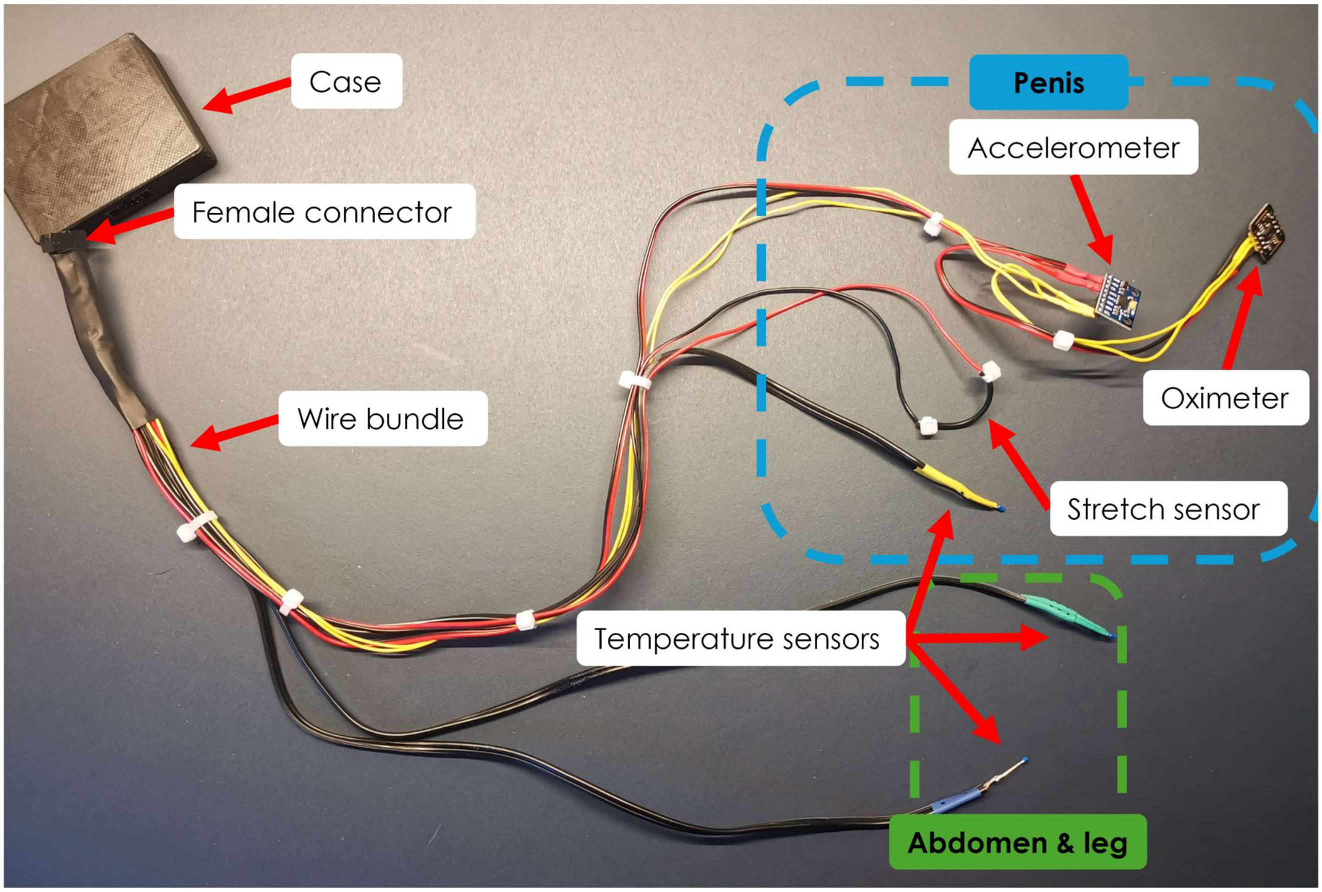

Figure 50, The complete system. The sensors are split into two groups. The sensors in the blue square lead to the penis, and the sensors in the green square to the abdomen and leg.

6.5.2 Soldering Internal Assembly

Next, the internal wires were soldered to the male 10-pin connector, which was fixed on the inside of the casing. This male connector was designed to interface seamlessly with the female connector, ensuring a stable and reliable connection from the sensors to the internal Arduino Nano BLE.

Each wire from the male connector was carefully soldered to the corresponding pins on the Arduino Nano BLE. The wiring diagram (in section 4.2.1.2) was strictly followed to ensure correct pin assignments and connections (Figure 52). Required resistors were soldered to the appropriate pins on the Arduino Nano BLE (Figure 51). Note that the hypothetical battery is virtually placed inside the casing.

With all components soldered and connected, the Arduino Nano BLE was secured inside the casing using the designed down-reaching structure of the lid. This structure ensures that the microcontroller remains in place and does not move during operation (Figure 52).

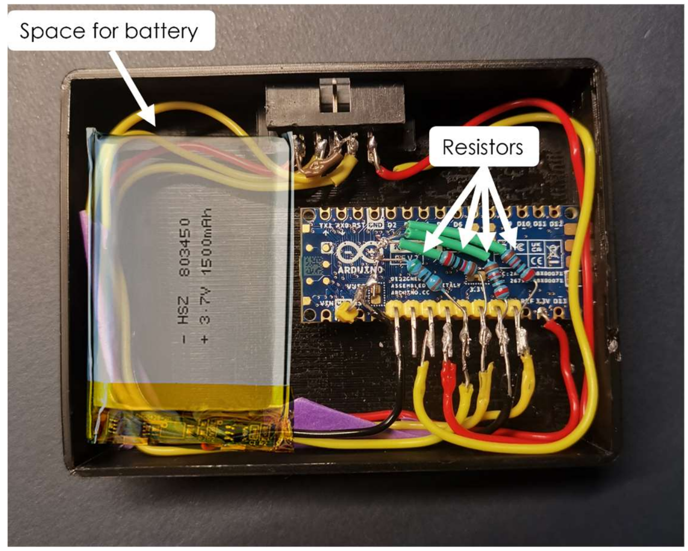

Figure 51, The internal wiring with resistors, the hypothetical battery has also been placed inside.

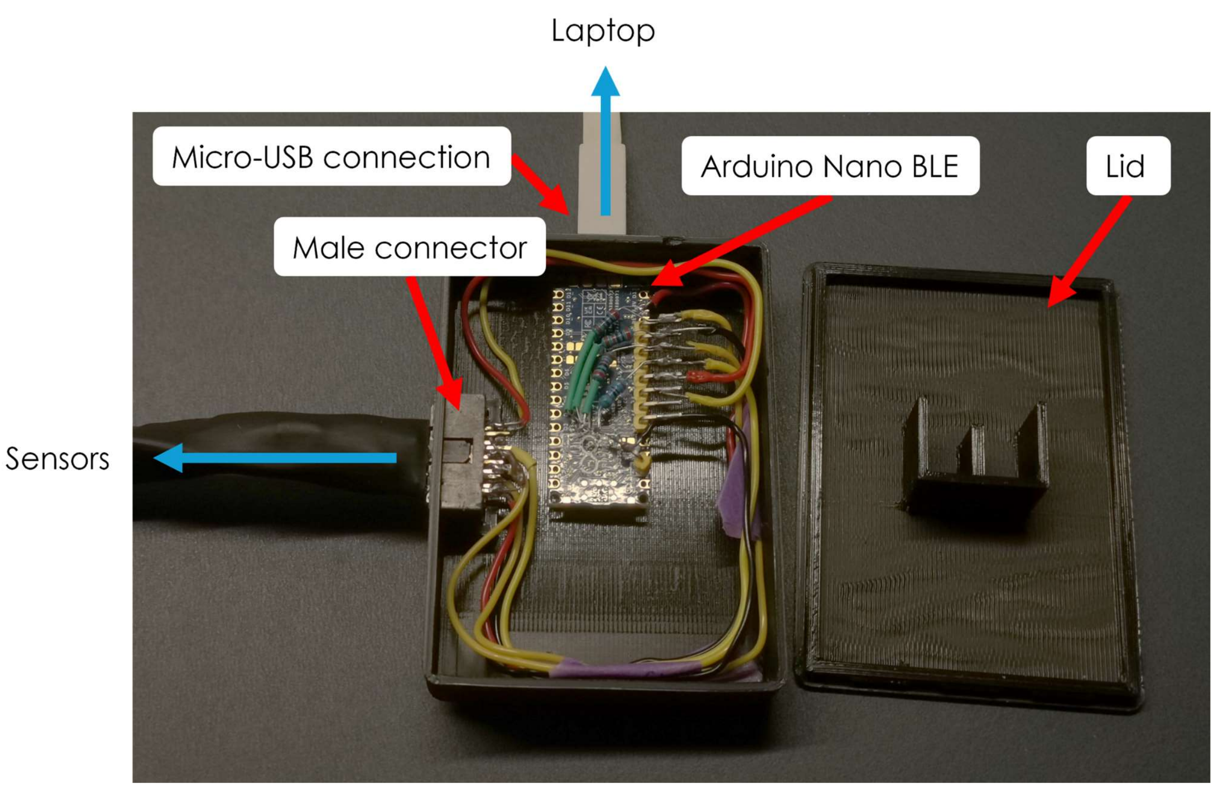

Figure 52, Internal wiring inside the case. The incoming sensor wires are connected to the Arduino Nano BLE. The lid of the case can be seen on the right.

In Figure 54, the wiring diagram from section 4.2.1.2 is displayed with labels. This diagram includes the resistors used for the thermistors (20kΩ each) and the stretch sensor (500Ω). These resistors can also be seen in Figure 53. The analog pins A0 – A5, which are connected to the sensors, are modelled in Figure 54 and can also be observed in Figure 53, where the actual soldered connections inside the casing are shown. Both diagrams illustrate the connections to the GND and 3.3V power lines. However, it is important to note that while Figure 54 includes a battery in the setup, Figure 53 does not, as the current battery was found to be incompatible with the system requirements.

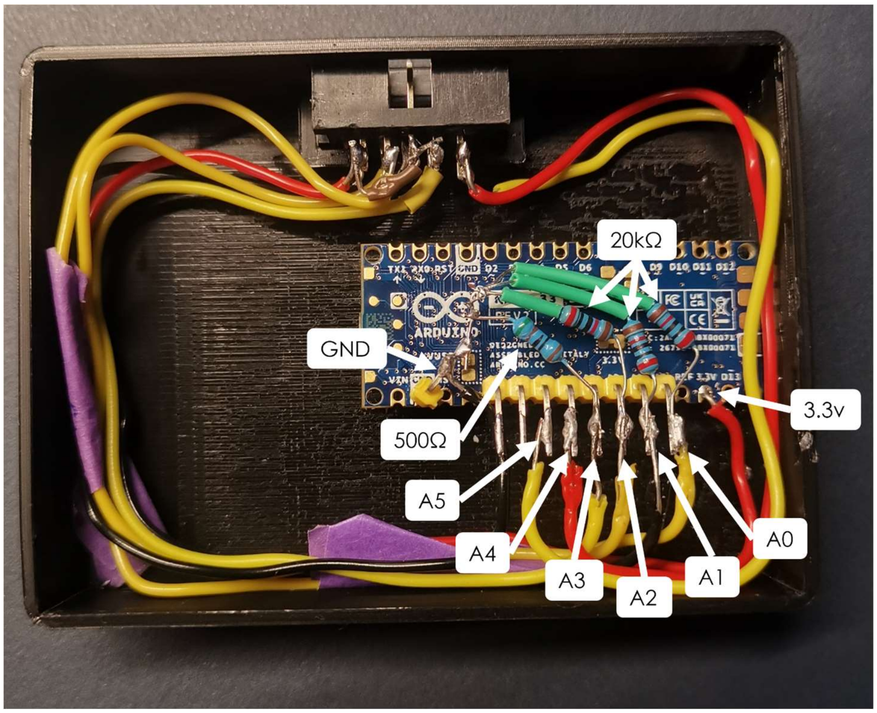

Figure 53, Wiring inside the casing.

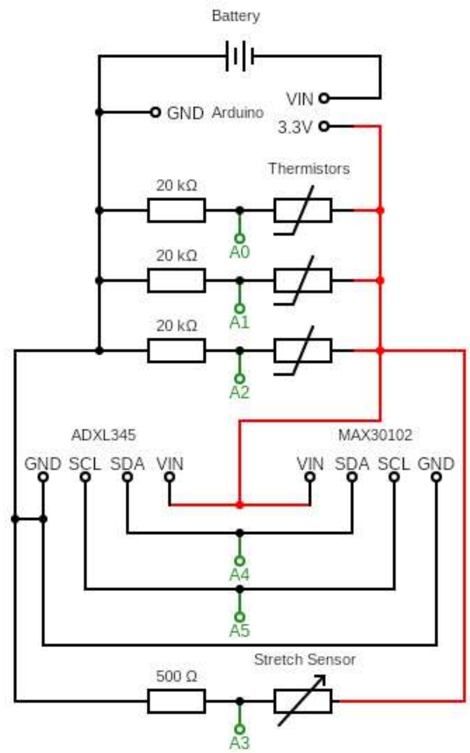

Figure 54, Wiring diagram as described in section 4.2.1.2 with labels.

6.6 Final System Testing

Testing the integrated sensor system is important to validate the accuracy and reliability of the components and their combined functionality. This testing focused on evaluating the individual sensors under controlled conditions, as they are now all connected. The details of the Arduino code used for testing and the data collection process are discussed below.

6.6.1 Arduino Code

The Arduino code was developed to interface with various sensors, including the "ADXL345" accelerometer, the "MAX30102" oximeter, the strain gauge, and the thermistors. This comprehensive setup allows for the collection of data from multiple sensors simultaneously. The code can be found in Appendix A – Arduino Code. Snippets of this code are used to describe the main functionalities of the code.

The code begins by including the necessary libraries for each sensor. The "Wire.h" library facilitates I2C communication, which is essential for interfacing with the ADXL345 and MAX30102 sensors. The "Adafruit_Sensor.h" and "Adafruit_ADXL345_U.h" libraries are specific to the ADXL345 accelerometer, while the "MAX30105.h" library is used for the MAX30102 oximeter. Additionally, the "Arduino_BMI270_BMM150.h" library is included for using the built-in IMU of the Arduino Nano BLE.

```
#include <Wire.h>
#include <Adafruit_Sensor.h>
#include <Adafruit_ADXL345_U.h>
#include "MAX30105.h"
#include "Arduino_BMI270_BMM150.h"
```

Then specific pins and constants are defined to configure and read data from the strain gauge and thermistors. The stretch sensor is connected to analog pin 3, thermistor 1, 2 and 3 to analog pin 0 , 1 and 2 respectively. The fixed resistor value of 20kΩ and the 3.3v supply voltage are also defined.

```
const int strainGaugePin = A3;
const int thermistorPin1 = A0;  // Thermistor 1
const int thermistorPin2 = A1;  // Thermistor 2
const int thermistorPin3 = A2;  // Thermistor 3
const float Rfixed = 20000.0;   // Fixed resistor value in ohms
const float Vin = 3.3;          // Supply voltage
```

Next, the sensors are initialized. The ADXL345 accelerometer is set up using the "accel345.begin()" method. If the sensor is not detected, an error message is displayed, and the program enters an infinite loop. The same procedure is followed for the MAX30102 oximeter. The built-in IMU is also initialized to read acceleration data.

```
// Initialize ADXL345
if (!accel345.begin()) {
    Serial.println("Ooops, no ADXL345 detected ... Check your wiring!");
    while (1);
}
Serial.println("ADXL345 detected!");

// Initialize Oximeter (MAX30102)
if (!particleSensor.begin()) {
    Serial.println("MAX30102 was not found. Please check wiring/power.");
    while (1);
}
Serial.println("MAX30102 detected!");
```

```
// Initialize built-in IMU
if (!IMU.begin()) {
    Serial.println("Failed to initialize IMU!");
    while (1);
}
Serial.println("IMU initialized!");
```

In the “loop” function, the code reads data from each sensor. For the ADXL345 accelerometer, the “getEvent()” method retrieves the acceleration values. Simultaneously, the built-in IMU's acceleration data is read using “IMU.readAcceleration()”. The differences between the IMU readings and the ADXL345 readings are calculated to obtain the relative acceleration.

```
if (accel345.getEvent(&event345)) {
    // Read built-in IMU
    if (IMU.accelerationAvailable()) {
        IMU.readAcceleration(x, y, z);
    }

    // Calculate the difference in acceleration
    diffX = (x * 9.8) - event345.acceleration.x;  // Convert IMU readings to m/s^2 and subtract
ADXL345 readings
    diffY = (y * 9.8) - event345.acceleration.y;
    diffZ = (z * 9.8) - event345.acceleration.z;
}
```

The MAX30102 oximeter's red and infrared light values are read using “particleSensor.getRed()” and “particleSensor.getIR()”. These values are used for determining arterial pulse and potentially blood oxygen levels.

```
redValue = particleSensor.getRed();
irValue = particleSensor.getIR();
particleSensor.nextSample();  // Move to the next sample for continuous reading
```

The strain gauge's analog value is read from the specified pin using “analogRead()”. Similarly, the thermistors' analog values are read and converted to voltages. The resistance of each thermistor is calculated using the voltage divider formula, which is essential for determining the temperature.

```
// Read Strain Gauge
strainGaugeValue = analogRead(strainGaugePin);

// Read Thermistors
int thermistorValue1 = analogRead(thermistorPin1);
int thermistorValue2 = analogRead(thermistorPin2);
int thermistorValue3 = analogRead(thermistorPin3);

// Convert the analog readings (which go from 0 - 1023) to voltages (0 - 3.3V)
float Vout1 = thermistorValue1 * (Vin / 1023.0);
float Vout2 = thermistorValue2 * (Vin / 1023.0);
float Vout3 = thermistorValue3 * (Vin / 1023.0);

// Calculate the thermistor resistances
float Rthermistor1 = Rfixed * (Vin / Vout1 - 1.0);
float Rthermistor2 = Rfixed * (Vin / Vout2 - 1.0);
float Rthermistor3 = Rfixed * (Vin / Vout3 - 1.0);
```

Finally, all sensor values are printed to the serial monitor for analysis. The values are separated by commas for easy readout and logging. These values are the values that go to an external device for visualization.

```
// Print all sensor values separated by commas
Serial.print(diffX, 2);
Serial.print(", ");
Serial.print(diffY, 2);
Serial.print(", ");
Serial.print(diffZ, 2);
Serial.print(", ");
Serial.print(strainGaugeValue);
Serial.print(", ");
Serial.print(redValue);
Serial.print(", ");
Serial.print(irValue);
Serial.print(", ");
Serial.print(Rthermistor1, 2);
Serial.print(", ");
Serial.print(Rthermistor2, 2);
Serial.println(Rthermistor3, 2);

delay(100);  // Adjust the delay as needed
```

This Arduino code enables the simultaneous collection of data from multiple sensors, ensuring a robust and integrated monitoring system for nocturnal erections.

6.6.2 Testing

The testing phase involved validating each sensor individually by observing their data responses in real-time using Processing Grapher software. This was done to ensure the sensors were functioning correctly and could accurately capture the required physiological data. During the testing phase, each sensor in the system was manipulated in a controlled manner and the resulting output was monitored.

6.6.2.1 Thermistor

To test the thermistors, one of the three thermistors was held closely in a warm hand to observe changes in the data reading. As the thermistor warmed up, the value displayed in Processing Grapher decreased rapidly, indicating a temperature rise. This inverse relationship is due to the reversed wiring of the fixed resistor and the thermistor, which causes the thermistor to output a negative response to an increase in temperature. Although this was a soldering error, it does not impact the functionality of the sensor. After this rapid decrease, the thermistors' value slowly climbed up again. The test confirmed the thermistor's responsiveness to temperature changes, demonstrating its capability to detect and reflect temperature variations accurately.

In Figure 55, the blue line represents thermistor 1, the purple line represents thermistor 2, and the pink line represents thermistor 3. The two untouched thermistors maintained a steady value throughout the measurement, further validating the sensor's reliability and stability under unchanged conditions. This test effectively demonstrated the sensor's functionality and assured its accuracy in real-world applications.

Figure 55, Arduino serial data displayed using Processing Grapher. The blue line is thermistor 1, the purple line is thermistor 2 and the pink line is thermistor 3. A clear decline and steady rise can be observed in the blue line.

6.6.2.2 Stretch Sensor

To test the stretch sensor, the sensor was gradually stretched and then released to observe changes in the data reading. The value displayed in Processing Grapher decreased as the sensor was stretched, indicating an increase in resistance due to the elongation of the sensor. Upon releasing the stretch sensor, the value steadily returned to its nominal value. This behaviour is depicted in Figure 56. The yellow line represents the stretch sensor's response, showing a clear decrease in the value as the sensor is stretched and a subsequent rise as it returns to its original state. This test confirmed the stretch sensor's responsiveness to changes in length, demonstrating its capability to accurately reflect variations in penile circumference.

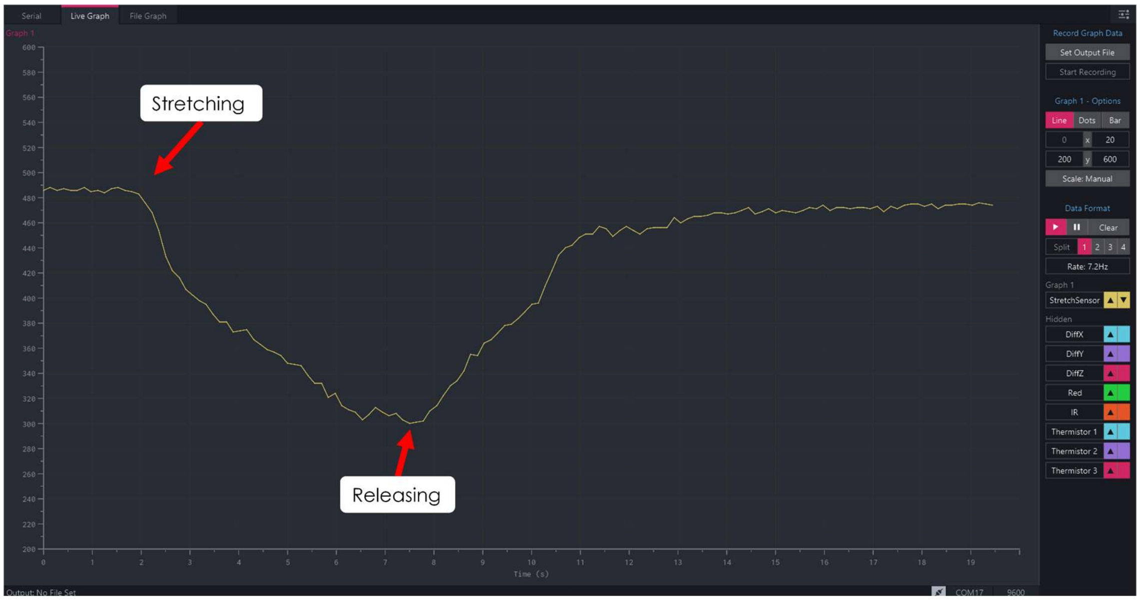

Figure 56, Arduino serial data displayed using Processing Grapher. The yellow line is data from the stretch sensor. A clear stretch and release point can be observed.

6.6.2.3 *Oximeter*

The oximeter was tested by placing a finger on the sensor to observe the red and infrared light readings. The data captured displayed a clear pulsating pattern, indicative of the detection of the arterial pulse.

Figure 57 shows the results of this test. The red line (representing the infrared light readings) and the green line (representing the red light readings) both exhibit pulsations, which align with the expected behaviour of detecting the arterial pulse. This confirms the functionality of the oximeter in accurately measuring the arterial pulse through the reflection of the red and infrared lights, thereby validating its integration into the sensor system.

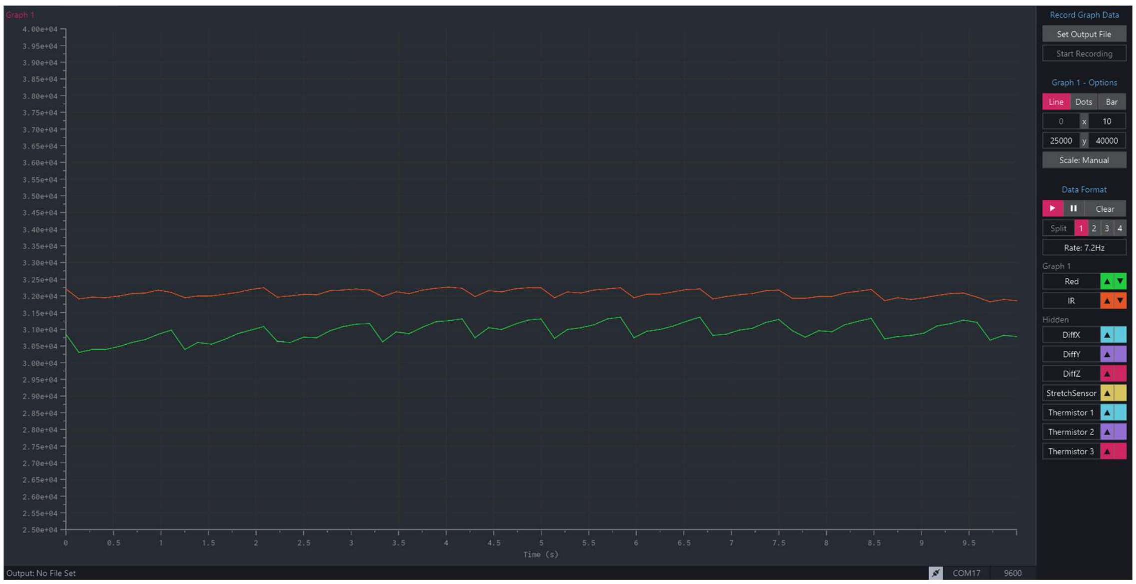

Figure 57, The pulsating pattern can be observed during the test. The IR light (orange) and red light (green) both show a wave pattern.

6.6.2.4 Accelerometer

For the final test, the accelerometer's performance was evaluated by observing its response to movement. The ADXL345 accelerometer was rolled across the x-axis, and its data was recorded and monitored using Processing Grapher. This produced the first bulge in the graph. Subsequently, the Arduino Nano BLE was rolled across the x-axis, resulting in the second bulge. The values in the plot represent the differences in the x, y, and z values in g's. The graph demonstrates the accelerometers' responsiveness to these movements, confirming their functionality and accuracy. The mildly fluctuating lines in between the bulges are due to unintended movements of the sensor.

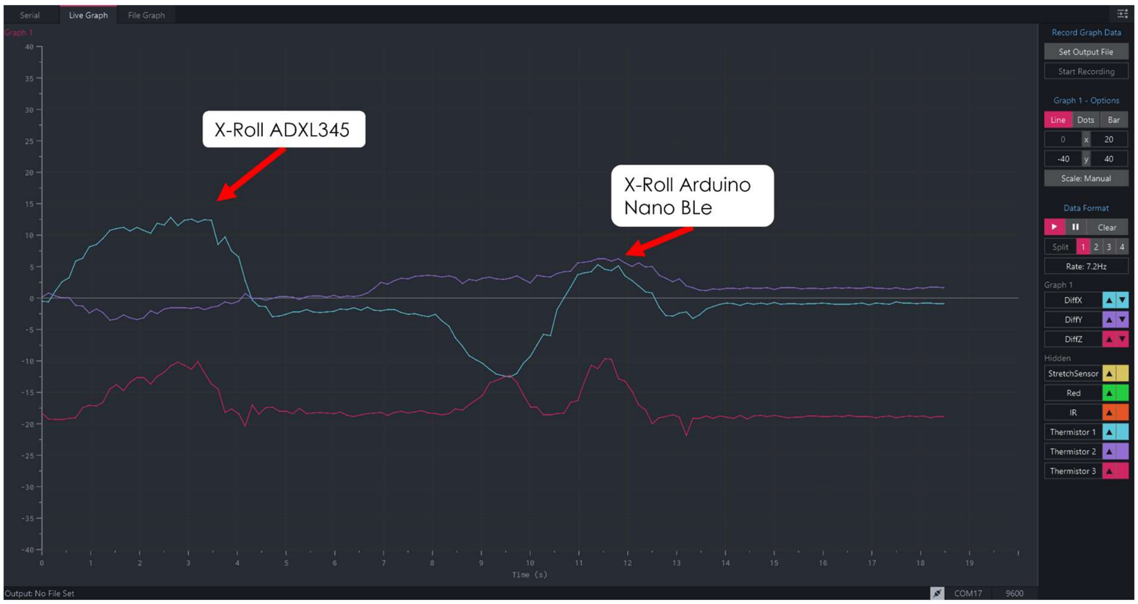

Figure 58, Arduino serial data displayed using Processing Grapher. The blue line is the difference in X values, the purple line is the difference in Y values and the pink line is the difference in Z values. Two similar bulges can be seen during the testing of the X-roll.

6.7 Final System Conclusion

This section presents the conclusions drawn from the development and testing of the penile sensor system. This innovative system was designed to monitor nocturnal penile erections with a high degree of sensitivity and accuracy. The aim was to create a reliable, comfortable, and effective diagnostic tool for erectile dysfunction.

6.7.1.1 Design and Prototyping

The design and prototyping phase involved an iterative process that incorporated multiple prototypes and adjustments to refine the system. A physical sketch and initial measurements informed the creation of a basic case using Fusion360, which was 3D printed and tested with the components. Subsequent iterations added necessary slots for connectors and cables, leading to the final design that securely housed the Arduino Nano BLE and battery.

6.7.1.2 Component Integration

The component integration phase focused on soldering and connecting the sensors and the Arduino Nano BLE. This involved detailed work to ensure that all components were securely attached and functioned correctly within the compact casing. The integration was important in ensuring the system's overall reliability, comfort and performance during nocturnal use.

6.7.1.3 Testing and Validation

The testing phase validated the functionality of each sensor. Thermistors were tested for their responsiveness to temperature changes, the stretch sensor for its ability to measure penile circumference, the oximeter for detecting arterial pulse and blood saturation, and the accelerometer for tracking penile movements. The data from these tests confirmed that the sensors operated as intended.

Thermistor Testing

One thermistor was held in a warm hand to observe data changes. The rapid decrease in values, followed by a gradual return to nominal values, confirmed the sensor's responsiveness to temperature changes, despite the reversed wiring of the fixed resistor and thermistor.

Stretch Sensor Testing

The stretch sensor was slowly stretched and released, showing clear and responsive changes in the data, which confirmed its ability to accurately measure changes in penile circumference.

Oximeter Testing

Placing a finger on the oximeter showed a pulsating pattern in the red and infrared light readings, confirming the sensor's capability to detect arterial pulse and its future potential for SpO2 readings.

Accelerometer Testing

The accelerometer tests involved moving the sensors around the X-axis. The data showed clear changes in acceleration, confirming the sensors' ability to detect penile movements accurately.

6.7.1.4 Cost Overview

The following table lists all the components used in the project along with their respective costs. Since components like the currently chosen 3.7v battery were not compatible with the system the replaced component's prices are an estimation.

Table 13, Total cost overview of the system.

Component	Quantity	Unit Cost (€)	Total Cost (€)
Arduino Nano 33 BLE Sense Rev2	1	€30.00	€30.00
Semitec 103AT-2 Thermistors	3	€2.00	€6.00
Flexible Stretch Sensor	1	€15.00	€15.00
MAX30102 Oximeter Sensor	1	€3.00	€3.00
ADXL345 Accelerometer	1	€3.00	€3.00
5 – 18v Battery	1	€15.00	€15.00
Adafruit MiniBoost TPS61023	1	€5.00	€5.00
10-Pin Connector	1	€0.50	€0.50
Case (3D Printed Material, PLA)	1	€1.00	€1.00
Miscellaneous (Wires, Solder, Resistors, etc.)	1	€10.00	€10.00
Total			€88.50

As depicted in Table 13, the estimated price of a single sensor system is around €90. However, if the sensor systems were to be produced in higher quantities, prices are expected to drop significantly.

6.7.1.5 Conclusion

The final assembled system successfully provides a compact, secure housing for the Arduino Nano BLE and associated sensors. It ensures that all internal components are protected during use. The design allows for easy access to the Arduino via a micro USB slot, enabling adjustments to the Arduino code as needed.

In conclusion, the developed penile sensor system meets the design goals of being small, lightweight, and comfortable for nocturnal use. It incorporates modern sensor technology to monitor key parameters of nocturnal penile erections, providing a valuable tool for the diagnosis of erectile dysfunction. The system's accuracy, reliability, and user-friendly design position it as a promising alternative to existing diagnostic methods like the RigiScan®, addressing its limitations and offering improved patient comfort and data accuracy.

7 Discussion and Future Work

The final system design demonstrates promising results, indicating the potential for a comprehensive and effective nocturnal penile erection monitoring system. However, this project serves more as a proof-of-concept, and further research and development are necessary to enhance its performance and reliability.

One significant area that requires additional attention is the measurement of blood saturation. Although the MAX30102 sensor shows potential, the current setup struggles with accurately detecting SpO2 levels. Future work could involve using a different sensor specifically designed for blood saturation or developing a custom algorithm for SpO2 detection with the MAX30102, as the raw data appears clear and promising.

Another consideration is the improved integration of components. The current setup uses relatively thick wires, which could cause skin irritation and discomfort during use. Future iterations should incorporate much thinner wires to improve comfort and reduce the risk of skin irritation. Additionally, more thought needs to be given to the attachment mechanism for the sensor casing. Attaching the casing directly to the body may not be the most comfortable solution. An alternative could be to clip the casing to the user's boxershorts, as conceptualized by G. Shoots [35].

The ADXL345 accelerometer and the MAX30102 oximeter should be connected without the use of a built-in breakout board to improve the system's compactness and comfort. Direct integration onto a custom PCB could enhance the overall design and user experience.

Regarding oximetry sensing, it is crucial to consider the effects of skin colour on the readings. Research should be conducted to understand how different skin tones impact the accuracy of the measurements and to develop algorithms that can compensate for these variations.

The Bluetooth Low Energy (BLE) functionality needs further development to enable reliable data transfer and external storage. This would enhance the system's usability by allowing real-time monitoring and data analysis on external devices.

Incorporating a variable-length stretch sensor to accommodate different penile sizes could be beneficial. For example, a hospital-provided penile monitoring test kit could include various sizes of stretch sensors to ensure a proper fit for every patient, thereby improving the accuracy and comfort of the measurements.

The system's fairly low cost compared to other medical devices is a significant advantage, and costs are expected to decrease further with mass production. Future enhancements could include developing an app that lets users view their data on a well-presented dashboard, offering insights and trends over time.

Additionally, incorporating a status indicator on the casing of the system would be a useful extra feature. This could display crucial system information, like power status (on / off, correctly or incorrectly placed sensors and measuring on / off). This could be done using a simple LED that is nondisruptive This would provide users with immediate feedback on the system's status and functionality, enhancing user experience and preventing incorrect readings due to misplaced sensors.

In summary, while the current system shows significant promise, continued research and development are necessary to address the identified limitations and improve the overall design. Future efforts should focus on refining sensor accuracy, enhancing user comfort, and ensuring reliable data transfer and storage.

8 Conclusion

The development and testing of the penile sensor system for monitoring nocturnal erections have yielded promising results. The system, designed to be compact, lightweight, and comfortable, integrates multiple sensors, including thermistors for temperature measurement, a stretch sensor for monitoring penile circumference, an oximeter for detecting arterial pulse and blood saturation, and an accelerometer for tracking penile movement.

Throughout the project, the Arduino Nano 33 BLE Sense Rev2 microcontroller has proven to be an effective central unit, facilitating data acquisition and processing. The iterative design and development of a 3D-printed casing have ensured a secure housing for the components, enhancing usability and comfort.

While the system shows significant potential, it is essential to acknowledge the need for further research and refinement. The proof-of-concept nature of this project highlights several areas for improvement, particularly in blood saturation measurement and component integration. The current setup struggles with accurately detecting SpO2 levels, indicating the need for either a different sensor or the development of a custom algorithm for the MAX30102.

Moreover, to enhance user comfort, the integration of much thinner wires and improved attachment mechanisms for the sensor casing is necessary. Addressing the impact of skin colour on oximetry readings, improving Bluetooth Low Energy (BLE) functionality for reliable data transfer, and developing a user-friendly app for data visualization are also crucial steps for future work. Additionally, incorporating an indicator LED in the casing to display system status and sensor placement can further enhance usability.

The system's relatively low cost compared to other medical devices is a notable advantage, with the potential for further cost reductions through mass production. Overall, this project lays a solid foundation for future advancements, aiming to provide a comprehensive, reliable, and user-friendly solution for monitoring nocturnal penile erections to aid in diagnosing erectile dysfunction.

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Appendix A – Arduino Code

Thermistor Testing

```
int ThermistorPin1 = A0;  // Analog pin A0 connected to the junction of thermistor 1 and fixed
resistor 1
int ThermistorPin2 = A1;  // Analog pin A1 connected to the junction of thermistor 2 and fixed
resistor 2
int ThermistorPin3 = A2;  // Analog pin A2 connected to the junction of thermistor 3 and fixed
resistor 3
int ThermistorPin4 = A3;  // Analog pin A3 connected to the junction of thermistor 4 and fixed
resistor 4
int ThermistorPin5 = A4;  // Analog pin A4 connected to the junction of thermistor 5 and fixed
resistor 5
int ThermistorPin6 = A5;  // Analog pin A5 connected to the junction of thermistor 6 and fixed
resistor 6

int Vo1, Vo2, Vo3, Vo4, Vo5, Vo6;  // Variables to store the analog readings

void setup() {
  Serial.begin(9600);  // Start serial communication at 9600 baud rate
}

void loop() {
  // Read analog values
  Vo1 = analogRead(ThermistorPin1);  // Read the analog value from thermistor pin 1
  Vo2 = analogRead(ThermistorPin2);  // Read the analog value from thermistor pin 2
  Vo3 = analogRead(ThermistorPin3);  // Read the analog value from thermistor pin 3
  Vo4 = analogRead(ThermistorPin4);  // Read the analog value from thermistor pin 4
  Vo5 = analogRead(ThermistorPin5);  // Read the analog value from thermistor pin 5
  Vo6 = analogRead(ThermistorPin6);  // Read the analog value from thermistor pin 6

  // Convert analog readings to voltage
  float V_ntc1 = Vo1 * (5.0 / 1023.0);
  float V_ntc2 = Vo2 * (5.0 / 1023.0);
  float V_ntc3 = Vo3 * (5.0 / 1023.0);
  float V_ntc4 = Vo4 * (5.0 / 1023.0);
  float V_ntc5 = Vo5 * (5.0 / 1023.0);
  float V_ntc6 = Vo6 * (5.0 / 1023.0);

  // Output the voltages to the serial monitor
  Serial.print(V_ntc1);
  Serial.print(", ");
  Serial.print(V_ntc2);
  Serial.print(", ");
  Serial.print(V_ntc3);
  Serial.print(", ");
  Serial.print(V_ntc4);
  Serial.print(", ");
  Serial.print(V_ntc5);
  Serial.print(", ");
  Serial.println(V_ntc6);

  delay(500);  // Delay for readability
}
```

Stretch Sensor Testing

```
int sensorPin = A0; // Pin connected to the stretch sensor
int sensorValue = 0; // Variable to store the sensor value

void setup() {
  Serial.begin(9600); // Start serial communication at 9600 baud rate
}

void loop() {
  sensorValue = analogRead(sensorPin); // Read the analog value
  Serial.println(sensorValue); // Print the value to the Serial Monitor
  delay(500); // Wait for half a second
}
```

Blood Saturation Testing

```
#include "MAX30105.h"

// Oximeter (MAX30102)
MAX30105 particleSensor;

void setup() {
  Serial.begin(9600);
  while (!Serial)
    ;

  Serial.println("Initializing...");

  // Initialize I2C
  Wire.begin();
  Serial.println("I2C initialized");

  // Initialize Oximeter (MAX30102)
  if (!particleSensor.begin()) {
    Serial.println("MAX30102 was not found. Please check wiring/power.");
    while (1)
      ;
  }
  Serial.println("MAX30102 detected!");

  particleSensor.setup();
  particleSensor.setPulseAmplitudeRed(0x0A);  // Turn Red LED to low to indicate sensor is
running
  particleSensor.setPulseAmplitudeIR(0x0A);   // Turn IR LED to low to indicate sensor is
running
  particleSensor.setPulseAmplitudeGreen(0);   // Turn off Green LED
}

void loop() {
  // Variables for sensor readings
  long redValue = 0, irValue = 0;

  // Read Oximeter (MAX30102) raw data directly
  redValue = particleSensor.getRed();
  irValue = particleSensor.getIR();
  particleSensor.nextSample();  // Move to the next sample for continuous reading

  // Print oximeter values separated by commas
  Serial.print(redValue);
  Serial.print(", ");
  Serial.println(irValue);

  delay(100);  // Adjust the delay as needed
}
```

Arterial Pulse Validation

```
#include "MAX30105.h"

// Oximeter (MAX30102)
MAX30105 particleSensor;

void setup() {
  Serial.begin(9600);
  while (!Serial)
    ;

  Serial.println("Initializing...");

  // Initialize I2C
  Wire.begin();
  Serial.println("I2C initialized");

  // Initialize Oximeter (MAX30102)
  if (!particleSensor.begin()) {
    Serial.println("MAX30102 was not found. Please check wiring/power.");
    while (1)
      ;
  }
  Serial.println("MAX30102 detected!");

  particleSensor.setup();
  particleSensor.setPulseAmplitudeRed(0x0A);  // Turn Red LED to low to indicate sensor is
running
  particleSensor.setPulseAmplitudeIR(0x0A);   // Turn IR LED to low to indicate sensor is
running
  particleSensor.setPulseAmplitudeGreen(0);   // Turn off Green LED
}

void loop() {
  // Variables for sensor readings
  long redValue = 0, irValue = 0;
  static unsigned long lastTime = 0;
  static unsigned long sampleInterval = 0;

  // Read Oximeter (MAX30102) raw data directly
  redValue = particleSensor.getRed();
  irValue = particleSensor.getIR();
  particleSensor.nextSample();  // Move to the next sample for continuous reading

  // Get the current time
  unsigned long currentTime = millis();


  // Calculate the interval between samples
  if (lastTime != 0) {
    sampleInterval = currentTime - lastTime;
  }
  lastTime = currentTime;

  // Print timestamp, interval, and oximeter values separated by commas
  Serial.print(currentTime);
  Serial.print(", ");
  Serial.print(sampleInterval);
  Serial.print(", ");
  Serial.print(redValue);
  Serial.print(", ");
  Serial.println(irValue);

  delay(100);  // Adjust the delay as needed
}
```

Acceleration Testing

```
#include <Wire.h>
#include <Adafruit_Sensor.h>
#include <Adafruit_ADXL345_U.h>
#include "Arduino_BMI270_BMM150.h"

// ADXL345
Adafruit_ADXL345_Unified accel345 = Adafruit_ADXL345_Unified(12345);

void setup() {
  Serial.begin(9600);
  while (!Serial)
    ;

  Serial.println("Initializing...");

  // Initialize I2C
  Wire.begin();
  Serial.println("I2C initialized");

  // Initialize ADXL345
  if (!accel345.begin()) {
    Serial.println("Ooops, no ADXL345 detected ... Check your wiring!");
    while (1)
      ;
  }
  Serial.println("ADXL345 detected!");

  // Initialize built-in IMU
  if (!IMU.begin()) {
    Serial.println("Failed to initialize IMU!");
    while (1)
      ;
  }
  Serial.println("IMU initialized!");
}

void loop() {
  // Variables for sensor readings
  sensors_event_t event345;
  float x, y, z;

  // Read ADXL345
  if (accel345.getEvent(&event345)) {
    // Read built-in IMU
    if (IMU.accelerationAvailable()) {
      IMU.readAcceleration(x, y, z);
    }

    // Print all sensor values separated by commas
    Serial.print("ADXL345: ");
    Serial.print(event345.acceleration.x, 2);
    Serial.print(", ");
    Serial.print(event345.acceleration.y, 2);
    Serial.print(", ");
    Serial.print(event345.acceleration.z, 2);
    Serial.print(" | IMU: ");
    Serial.print(x * 9.8, 2);  // Convert IMU readings to m/s^2
    Serial.print(", ");
    Serial.print(y * 9.8, 2);
    Serial.print(", ");
    Serial.print(z * 9.8, 2);
    Serial.println();
  }

  delay(100);  // Adjust the delay as needed
}
```

Bluetooth Low Energy Testing

```
#include <ArduinoBLE.h>

// BLE service and characteristics
BLEService sensorService("180C");  // Custom service UUID

BLEIntCharacteristic counterChar("2A77", BLERead | BLENotify);

unsigned long previousMillis = 0;  // Stores the last time data was sent
const long interval = 5000;        // Interval at which to send data (milliseconds)

int counter = 0;

void setup() {
  Serial.begin(9600);
  while (!Serial)
    ;

  Serial.println("Initializing...");

  // Initialize BLE
  if (!BLE.begin()) {
    Serial.println("starting BLE failed!");
    while (1)
      ;
  }

  // Set BLE device name
  BLE.setLocalName("ArduinoNanoBLE");
  BLE.setAdvertisedService(sensorService);

  // Add characteristics to the service
  sensorService.addCharacteristic(counterChar);

  // Add service
  BLE.addService(sensorService);

  // Start advertising
  BLE.advertise();
  Serial.println("Bluetooth device active, waiting for connections...");
}

void loop() {
  // BLE poll
  BLE.poll();

  // Get the current time
  unsigned long currentMillis = millis();

  // Check if 5 seconds have passed
  if (currentMillis - previousMillis >= interval) {
    previousMillis = currentMillis;

    // Increment the counter
    counter++;

    // Update BLE characteristic
    counterChar.writeValue(counter);

    // Print the counter value to the serial monitor
    Serial.print("Counter: ");
    Serial.println(counter);
  }

  delay(100);  // Small delay to reduce CPU usage
}
```

Testing Code

```
#include <Wire.h>
#include <Adafruit_Sensor.h>
#include <Adafruit_ADXL345_U.h>
#include "MAX30105.h"
#include "Arduino_BMI270_BMM150.h"

// ADXL345
Adafruit_ADXL345_Unified accel345 = Adafruit_ADXL345_Unified(12345);

// Oximeter (MAX30102)
MAX30105 particleSensor;

// Strain Gauge and Thermistors
const int strainGaugePin = A3;
const int thermistorPin1 = A0;  // Thermistor 1
const int thermistorPin2 = A1;  // Thermistor 2
const int thermistorPin3 = A2;  // Thermistor 3
const float Rfixed = 20000.0;   // Fixed resistor value in ohms
const float Vin = 3.3;          // Supply voltage

void setup() {
  Serial.begin(9600);
  while (!Serial)
    ;

  Serial.println("Initializing...");

  +
    // Initialize I2C
    Wire.begin();
  Serial.println("I2C initialized");

  // Initialize ADXL345
  if (!accel345.begin()) {
    Serial.println("Ooops, no ADXL345 detected ... Check your wiring!");
    while (1)
      ;
  }
  Serial.println("ADXL345 detected!");

  // Initialize Oximeter (MAX30102)
  if (!particleSensor.begin()) {
    Serial.println("MAX30102 was not found. Please check wiring/power.");
    while (1)
      ;
  }
  Serial.println("MAX30102 detected!");

  particleSensor.setup();
  particleSensor.setPulseAmplitudeRed(0x0A);  // Turn Red LED to low to indicate sensor is
running
  particleSensor.setPulseAmplitudeIR(0x0A);   // Turn IR LED to low to indicate sensor is
running
  particleSensor.setPulseAmplitudeGreen(0);   // Turn off Green LED

  // Initialize built-in IMU
  if (!IMU.begin()) {
    Serial.println("Failed to initialize IMU!");
    while (1)
      ;
  }
  Serial.println("IMU initialized!");
}
```

```
void loop() {
  // Variables for sensor readings
  sensors_event_t event345;
  float x, y, z;
  long redValue = 0, irValue = 0;
  int strainGaugeValue;

  // Variables for differences
  float diffX = 0, diffY = 0, diffZ = 0;

  // Read ADXL345
  if (accel345.getEvent(&event345)) {
    // Read built-in IMU
    if (IMU.accelerationAvailable()) {
      IMU.readAcceleration(x, y, z);
    }

    // Calculate the difference in acceleration
    diffX = (x * 9.8) - event345.acceleration.x;  // Convert IMU readings to m/s^2 and subtract
ADXL345 readings
    diffY = (y * 9.8) - event345.acceleration.y;
    diffZ = (z * 9.8) - event345.acceleration.z;
  }

  // Read Oximeter (MAX30102) raw data directly
  redValue = particleSensor.getRed();
  irValue = particleSensor.getIR();
  particleSensor.nextSample();  // Move to the next sample for continuous reading

  // Read Strain Gauge
  strainGaugeValue = analogRead(strainGaugePin);

  // Read Thermistors
  int thermistorValue1 = analogRead(thermistorPin1);
  int thermistorValue2 = analogRead(thermistorPin2);
  int thermistorValue3 = analogRead(thermistorPin3);

  // Convert the analog readings (which go from 0 - 1023) to voltages (0 - 3.3V)
  float Vout1 = thermistorValue1 * (Vin / 1023.0);
  float Vout2 = thermistorValue2 * (Vin / 1023.0);
  float Vout3 = thermistorValue3 * (Vin / 1023.0);

  // Calculate the thermistor resistances
  float Rthermistor1 = Rfixed * (Vin / Vout1 - 1.0);
  float Rthermistor2 = Rfixed * (Vin / Vout2 - 1.0);
  float Rthermistor3 = Rfixed * (Vin / Vout3 - 1.0);

  // Print all sensor values separated by commas
  Serial.print(diffX, 2);
  Serial.print(", ");
  Serial.print(diffY, 2);
  Serial.print(", ");
  Serial.print(diffZ, 2);
  Serial.print(", ");
  Serial.print(strainGaugeValue);
  Serial.print(", ");
  Serial.print(redValue);
  Serial.print(", ");
  Serial.print(irValue);
  Serial.print(", ");
  Serial.print(Rthermistor1, 2);
  Serial.print(", ");
  Serial.print(Rthermistor2, 2);
  Serial.print(", ");
  Serial.println(Rthermistor3, 2);

  delay(100);  // Adjust the delay as needed
}
```