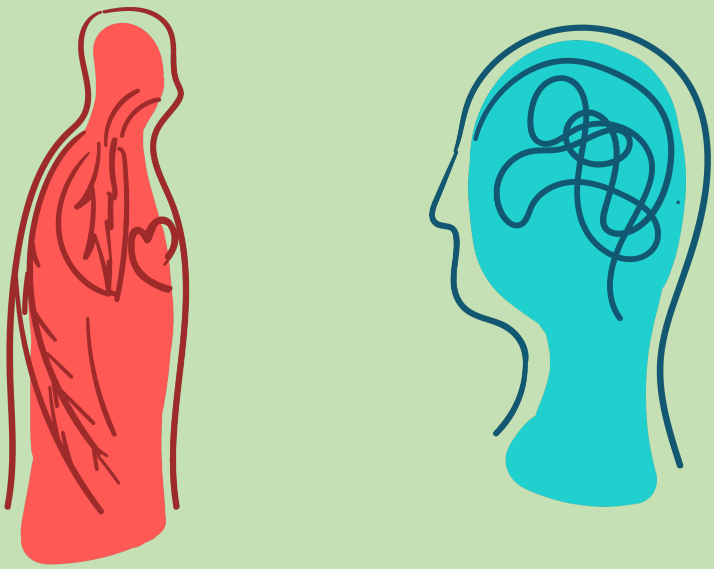
Knitted Breathing Sensors for Medical Wearables



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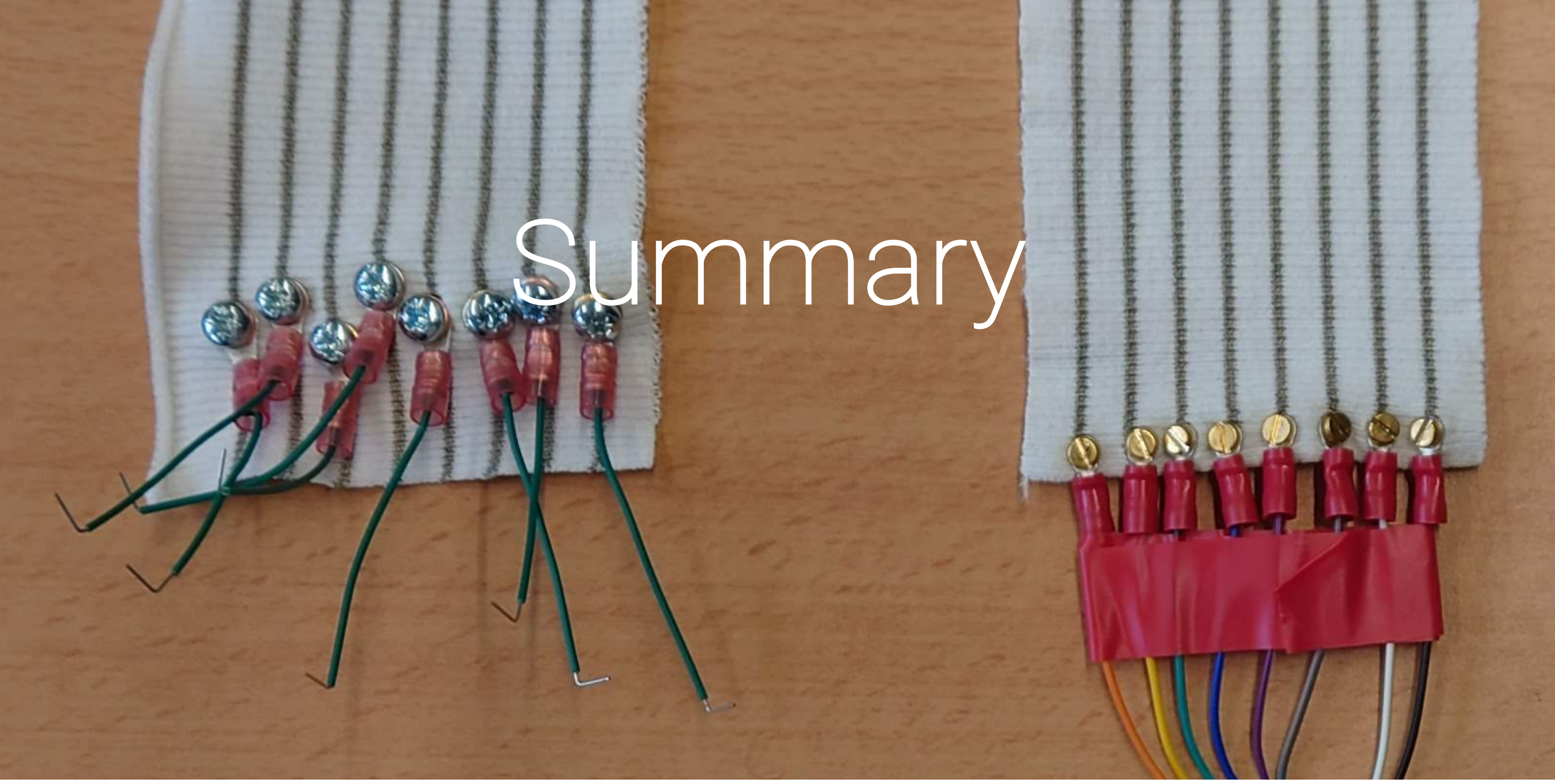

Summary

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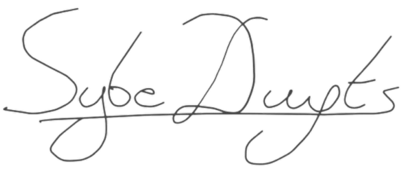


Summary

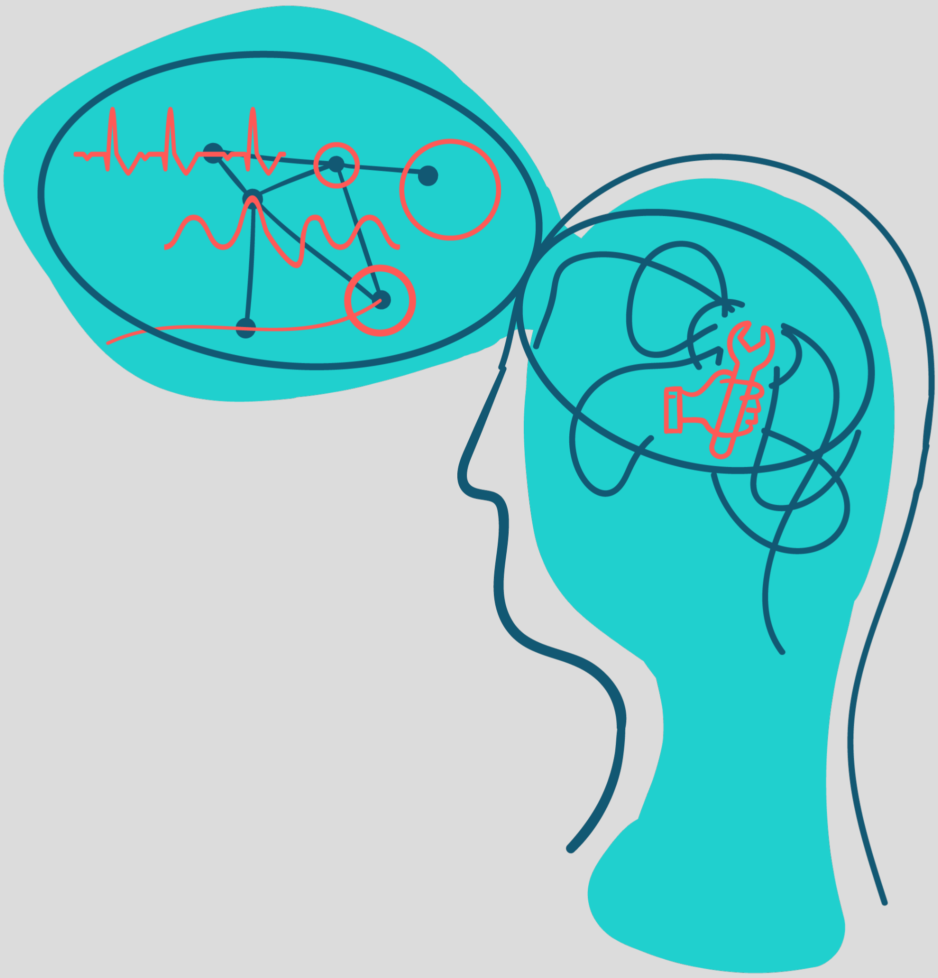
This project focuses on developing a functional wearable prototype that can monitor changes in breathing behaviour by integrating textile sensors. The project was initiated by Mediventic, a healthcare industry start-up aiming to simplify the diagnoses and treatment of Chronic Hyperventilation Syndrome (CHVS) by creating affordable home-use smart clothing embedded with sensors that objectively record a patient's biomedical data. Medical literature highlights the challenges of accurately diagnosing medical conditions in the healthcare industry, particularly CHVS, which is prone to errors due to the unusual range of complaints and symptoms. Medical professionals underline the need for wearable instruments to detect tell-tale signs and provide preventative treatment. On the other hand, current applications of smart textile wearables often lack focus on a specific problem.

To better comprehend the problem and solution space, fundamental medical themes and the current status of wearable technology are reviewed. Important annotations about CHVS are concluded, emphasizing the close link between psychological and physiological elements that drive the self-perpetuating cycle of chronic hyperventilation and the development of symptoms. To assist the patient in gaining respiratory control, the use of wearable technology to support treatment processes is investigated. In particular, 'smart textiles' resemble an attractive medium for the integration of sensors and electronics. Respiratory movements can be captured at various points on the upper body utilizing strain sensors embedded in the textile medium. This allows a wearable to preserve valuable qualities for user experience typical for textiles such as comfort, flexibility, and aesthetics.

During prototype development, performance, manufacturability, and usability requirements are translated into tangible prototypes, such as the fabrication of working knitted strain sensors for tracking breathing behaviour. Different versions are fabricated through iterative steps and intermittently tested for performance and usability. Throughout development, the steps for fabricating and integrating components as a 'textile system' are made insightful. Through user testing, the final prototype is used to evaluate sensor performance and as well assess for comfort and usability. Participants are instructed to wear the prototype in several active positions and perform breathing tests.

Conclusively, the results and development process are contemplated concerning the project's design requirements and initial aim. Although the data's usefulness must be evaluated by medical professionals, the results suggest that utilizing knitted sensors for measuring breathing behaviour is successful enough for real-time data collecting, even with basic prototyping components. Information regarding breathing rate and depth of respiration can be interpreted at different locations on the body. Also, the prototype design appeals to the imagination during user tests. Users associate the prototype with regular clothing and results indicate that the wearable-textile form factor allows for unintrusive monitoring of breathing behaviour. However, developments must be made to improve the reliability of the construction and durability of the sensors. Depending on the definition of signal detail, signal amplification and noise suppression might elevate the quality of information to the next level.

Introduction



1.1 Problem introduction

Accurately diagnosing medical conditions in the healthcare industry is a complex undertaking. The diagnostic process for such conditions demands a nuanced understanding of the patient's situation and a thorough indications evaluation. However, this becomes challenging due to limited time and a diverse range of individuals, making the diagnostic process prone to errors.
Chronic hyperventilation syndrome (CHVS) serves as a prime example of these challenges due to the wide range of symptoms that can occur. Moreover, recent research indicates a surge in CHVS cases related to post-COVID stress, PTSD, and persistent stress, especially among adolescents influenced by online media. This escalation contributes to a rise in depression cases associated with CHVS.

In response to this growing problem, Mediventic, a healthcare industry startup, aims to assist individuals affected by hyperventilation in leading healthier and happier lives. They aim to simplify the diagnosis and treatment of Chronic Hyperventilation Syndrome by creating affordable tools for home use to support treatment and exercise. Mediventic argues that, currently, there is no accurate, affordable, and portable diagnostic tool available. Notably, the necessity for a solution that is effective for practitioners and comfortable for patients is affirmed by doctors, physiotherapists, and other experts interested in breathing behaviour. The demand for innovative solutions to enhance the accuracy of diagnosis and treatment for such conditions is evident and pressing in the healthcare landscape.

1.2 Project introduction

This project explores the potential of wearable sensor technology in measuring breathing behaviour and supporting healthcare professionals in treating hyperventilation disorder. The project will investigate wearable technology, specifically e-textiles, to collect and process biomedical data related to breathing behaviour, which can assist healthcare professionals in accurately diagnosing and treating the condition.

Mediventic, who served as a project sponsor during the initial stages of the project, is developing a sensor and toolkit in smart clothing embedded with sensors that record a patient's biomedical data objectively while they undergo diagnosis and therapy for suspected CHVS. The graduation project aims to incorporate innovative textile sensors into an affordable, portable, easy-to-use smart garment to monitor breathing behaviour. Mediventic was founded by Marco Cevat and Jobst Winter, who have extensive experience in digital transformation, cardiology, health tech startups, management consulting, and cross-disciplined health care. Marco and Jobst will represent the external organization, Mediventic.

The project plans to use textile strain sensor technology developed by Kaspar Jansen, a professor at the materializing futures section of IDE at the TU Delft. The patented sensor used for smart textile applications has impressive sensing properties, making it an interesting candidate for the smart clothing kit that Mediventic is developing. The fully programmable industrial knitting machine and experienced staff at the TU Delft offer an opportunity to refine the prototype's design further.

1.2.1 Design goal

The target result of the graduation project can be summarised as the development of a functional wearable prototype that can monitor changes in breathing behaviour through the integration of textile sensors. The smart garment should obtain objective data that can be used for breathing pattern recognition and, in extended periods, as a diagnostic tool and as a means of monitoring outside a therapeutic setting. A user study will validate the prototype by evaluating the functionality and user experience.

Scope

Therefore, the assignment's scope can be described by the following:

- Modify the sensor garment's design based on the research findings.
- Develop a working version of the respiration sensors built into the designed sensor garment.
- Design a smart garment that meets the requirements for assisting in diagnosing CHVS.
- Create a preliminary mobile app version that receives, handles, and displays data.
- Demonstrate a system prototype in a testing environment (TRL 6).

Preliminary research questions

A set of preliminary research questions is defined to help navigate the topics that need to be discussed in the background research.

- What are the current challenges in accurately diagnosing and treating hyperventilation disorder?
- How can wearable sensor technology measure breathing behaviour and assist healthcare professionals in accurately diagnosing and treating the condition?
- What are wearable technology's potential benefits and limitations in healthcare?

1.3 Design method

Following the Delft Design Method introduced by Roozenburg and Eekels (1998), the aim of this project is to progress through the whole design process from problem definition to evaluation. Each chapter addresses a specific aspect of this process begins with a short introduction and closes with brief takeaways on key topics discussed in the text. The design process is separated into three phases (figure 1), *understanding* the problem, *developing* a solution, and *evaluating* the solution and process.
In the first phase, the aim is to gain further knowledge about the problem-solution space through expert opinions, scientific research, and desktop research. Chapter 2 delves into medical topics related to chronic hyperventilation to get an *understanding* of the difficulties associated with diagnosis and treatment, while Chapter 3 explores the state of the art in wearable technology and its potential role in measuring breathing behaviour.
Following the findings, Chapter 4 moves from knowledge to development by exploring functionalities and compiling design requirements.

In the second phase, a prototype will be *developed* by attempting to translate the ideas presented in the first phase, into materialised components. This phase can be considered experimental in nature as standardized ways of integrating electronics and textiles have yet to be developed. In Chapter 5 through iterative steps, variations on the sensor material are made, after which two functional prototypes are fabricated. Documentation on intermittent testing and fabrication steps is conducted to explore strengths and weaknesses of the construction.
During the last phase, the second prototype will be *evaluated* through user testing. In chapter 6 the critical functions of the design and the sensor performance, as well as the user-experience and comfort are evaluated, and the results are discussed. Essentially intending to validate the design on the basis of the design requirements and identifying areas for improvement.

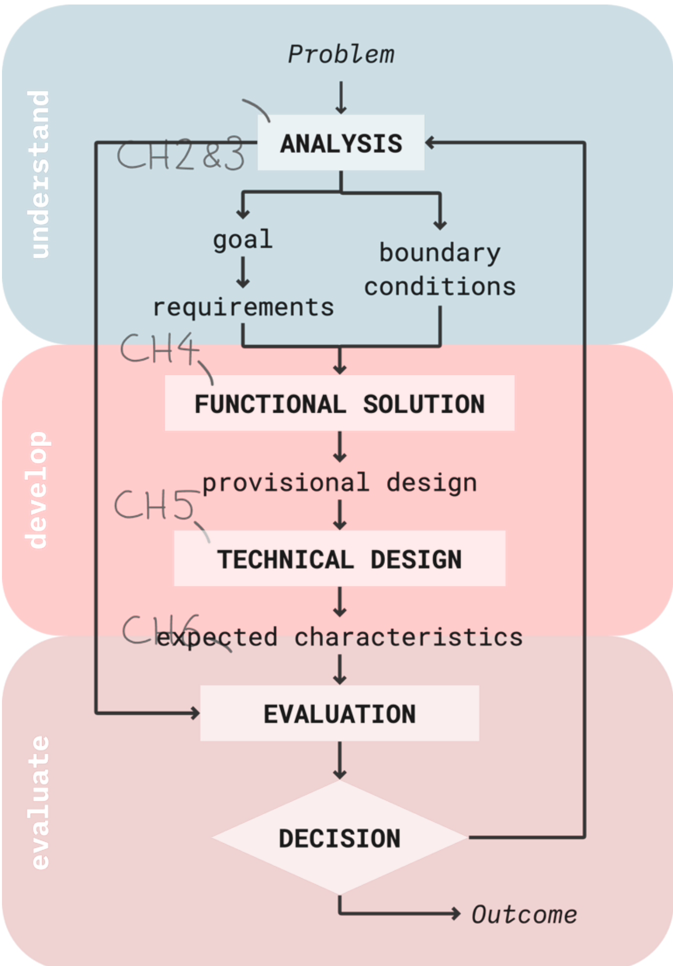
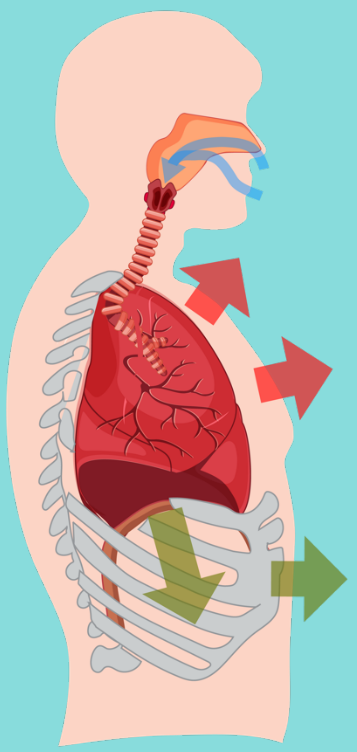


Figure 1: design method

Medical literature



This chapter aims to provide a comprehensive understanding of the patient care process and diagnostic procedure, specifically related to chronic hyperventilation. It explores the challenges clinicians face in accurately diagnosing medical conditions, focusing on the multifaceted challenges presented by patients with breathing disorders.

The chapter begins by delving into the patient care process (2.1), outlining each step in detail, from gathering information to developing a care plan and evaluating outcomes. Next, it examines the complex hyperventilation disorder from various perspectives (2.2), covering the symptoms, mechanisms, and different perspectives on diagnosis and treatment.

2.1 The patient care process

Significant transformations have occurred in medicine and medical training in the last century. The quality of care and subsequent life expectancy has significantly increased since the Age of Enlightenment (Roser, 2013). Driven partly by scientific progress, many diseases and conditions have become treatable. Despite this era of technological advancement, the fundamental human process of clinical reasoning remains at the basis of an accurate diagnosis.

In their research about clinical reasoning, Holmboe and Durning (2014) state that 'diagnostic errors remain to be a serious problem for patients and the healthcare system.' It criticizes the focus on examinations of medical knowledge and posits that contrary to exams, contextual presentation in actual clinical practice is not a controllable element. Jobst Winter, co-founder of Mediventic, confirms this as he sees that over a quarter of his patients with a cardiological referral suffer from misdiagnosed respiratory problems.
This illustrates the challenge of various conditions that might share similarities in their symptom presentation. As Kostopoulou et al. (2008) stated, identifying the origin of the symptoms is to discover methods for enhancing the diagnostic process, especially in challenging presentations of symptoms by patients.

2.1.1 The Care Process

The care process has a clear starting point: the patient experiences a health problem. And a clear endpoint, the containment or resolution of the problem. The description provided in this report is based on the interpretation of the care plan by the GGZ (2022), Balogh et al. (2015), and the Joint Commission of Pharmacy Practitioners (2014).

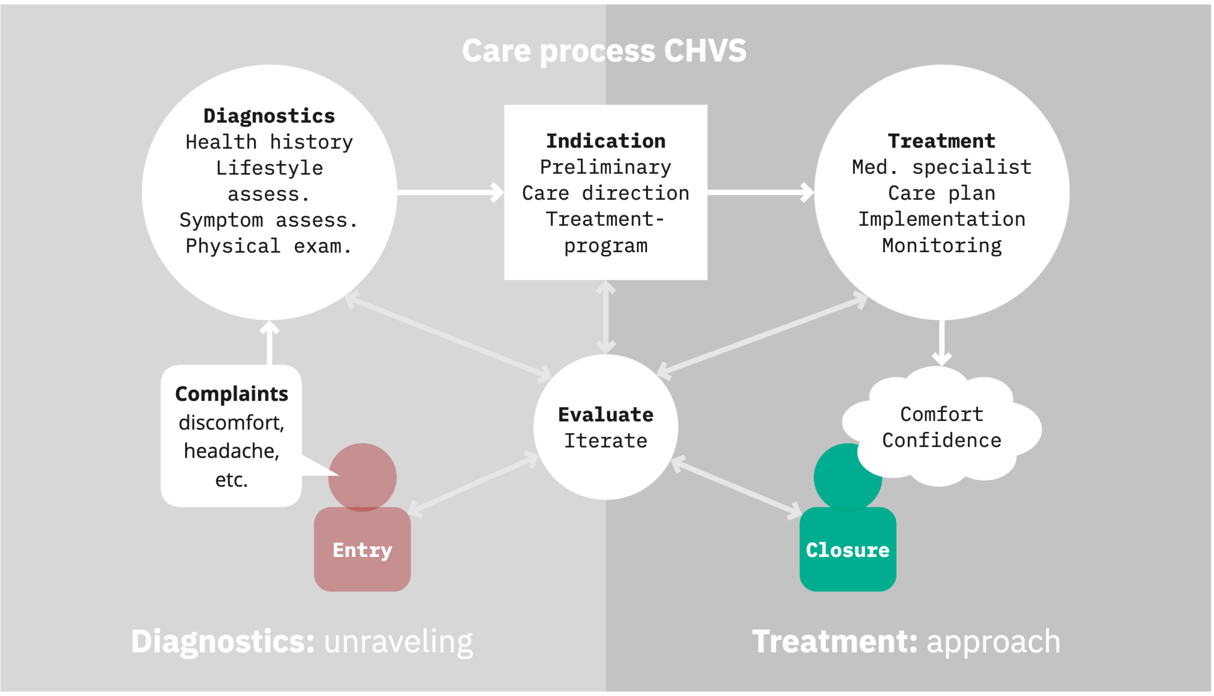


Figure 2: the patient care process

Upon the entry/application (1), the patient seeks medical attention for one or multiple complaints. Often, their first contact will be a general practitioner.
The healthcare professional then gathers information (2) necessary to identify and prioritize problems. This includes subjective and objective information, respectively, provided in the form of a description of the complaints given by the patient, lifestyle habits, and the context and overall presentation. And in diagnostic testing with monitoring equipment or clinical history (of family members).

Next, interpreting the information (3) leading to a diagnosis occurs. The physician describes the nature and severity of the complaints and addresses the issues, and potential connections between the complaints could be determined. The next step is to get to an indication (4) of a plausible causality and a subsequent health plan. The Ph explains the health problem to the patient and sets a health goal. What needs to be achieved, what are the possibilities for the patient, and what does that mean for their situation? Leading up to a 'care plan' is a joint decision made in correspondence with the patient. Finally, the actual treatment (5) and planned care path are based on the diagnosis. If an accurate diagnosis is made, the treatment should be practical, and the outcomes should benefit the patient.

Accordingly, the outcomes are evaluated (6) and could lead to a redefined indication. The importance of evaluation is stressed by many reports, which highlight that evaluation should occur in all steps of the care process. As discussed in their recent report on quality standards in mental care, the GGZ (2022) identifies monitoring, evaluating, and subsequent recalibration of the diagnosis, classification, indication, and treatment as fundamental to a successful outcome.
A good diagnosis results from sufficient information being collected, in which the clinical history, a physical exam, diagnostic testing, and consultation with other clinicians play a role. Based on several focal points, the clinician examines the patient's complaints, problems, and capabilities from various perspectives. Whenever possible, the professional utilizes validated measurement tools such as questionnaires (Balogh et al., 2015).

2.1.2 Challenges in the diagnostical procedure

The diagnostic process is a complex and collaborative effort that appeals to the professional's clinical reasoning skills as well as their level of medical knowledge. The inherent uncertainty in diagnosis does not work in favour of the clinician. As Kassirer (1989) concluded, "No matter how much information we gather or how many observations we make, a diagnosis is a hypothesis about the nature of a patient's illness. Data gathering enhances our confidence, and our task is not to attain certainty, but rather to reduce the level of diagnostic uncertainty enough to make optimal therapeutic decisions."

Complex contexts

The growing complexity of patient presentations due to various reasons may result in more difficulty and diagnostic errors. The chaotic and fragmented clinical environments can make it hard to see the wood from the trees (Holmboe & Durning, 2014). Population trends also add complexity, as symptoms of the exact infectious origin can have a different presentation in older adults. Also, growing cultural diversity in populations can result in communication barriers and a wider variety of physiologic differences (Balogh et al., 2015), illustrating the importance of keeping the care process tailored to the individual instead of applying an analytical average solution.

Fragmentation

As discussed, the fragmentation, or lack of collaboration between clinical experts in the health environment, threatens the possibility of evaluation throughout the diagnostic steps. This segmentation of specialisms is at odds with the motto of collaboration in good diagnostics. This is confirmed by experts (chapter 2.2.7), who believe that clinicians with specific expertise tend to limit their interpretations to the scope of their expertise, even though biological processes transcend those boundaries. On top of that, "akin to the scientific method where you 'start with the end in mind', physicians' diagnostic process is likely affected by what they believe is therapeutically available to the patient" (Holmboe & Durning, 2014). In an age of digital transformation, there must be a way to open information channels between different clinical experts and provide an accessible, if not automated, way to reconnect fragmented levels of expertise in the health sector.

2.2 The Hyperventilation Syndrome

(Chronic) hyperventilation syndrome (CHVS) is a condition characterized by rapid or excessive breathing that leads to a biochemical imbalance of the blood and, subsequently, a wide range of symptoms and complaints. Typically, it is triggered by life stresses and induced by the uncanny discomfort of the complaints, making diagnosis susceptible to misinterpretation and misconceptions about CHVS.

2.2.1 Signs and symptoms of CHVS

The body maintains a balanced exchange of oxygen and carbon dioxide in a regular breathing pattern. However, in the case of hyperventilation syndrome, the significant increase in rate and depth of breathing causes a decrease in carbon dioxide levels (hypocapnia) and an increase in blood pH (respiratory alkalosis), which initiates a sequence of physiological changes responsible for most of the signs and symptoms (Tavel, 1990).
Consequently, a broad range of symptoms can occur. Hypocapnia may produce bronchoconstriction (narrowing of the airways), contributing to the sensation of dyspnea (shortness of breath) and simulating or intensifying (preexisting) asthma (Ferguson, 1969). The inability to inhale a satisfyingly deep breath may manifest in periodic thoracic deep breaths (chest breathing) (Magarian et al., 1983). Paradoxically, while taking deep breaths to relax, the very state a person wishes to avoid is provoked as fatigued respiratory muscles are overworked from excessive respiratory efforts. In such a way, *chest pain* is also variably described as a common symptom, lasting from minutes to hours, likely caused by the excessive use of thoracic musculature (chest muscles) (Magarian et al., 1983). The resulting fatigue of the chest musculature contributes to the immediate sense of *heaviness* and *fatigue* patients almost always experience. They are accompanied by numbness, tingling, and an abnormal sensation of the skin (paresthesias), which may be due to muscle tightness and muscle contractions (tetany) and the chemical changes that occur secondary to temporary alkalinity (Rice, 1950).

Additionally, the lightheadedness may be coupled with some degree of disorientation and mental impairment. Dryness of the mouth also commonly occurs because of rapid breathing through the mouth (Magarian et al., 1983).
At any rate, the various neurologic, cardiologic, respiratory, gastrointestinal, and muscular signs result in an eclectic range of symptoms (figure 3).

Feeling of tenseness	*Palpitations*	*Constricted chest*	*Chest pain*
Feeling unable to breathe deeply	*Cold hands or feet*	*Tingling fingers*	*Stiffness of fingers and arms*
Accelerated or deepened breathing	*Dizziness*	*Blurred vision*	*Sensation of bloated abdomen*
Shortness of breath	*Anxious feelings*	*Confusion*	*Tightness around the mouth*

Figure 3: List of HVS symptoms ordered by prevalence (Vansteenkiste et al., 1991)

2.2.2 The Origin of Hyper-ventilatory Breathing

Hyperventilation and anxiety

Anxiety usually occurs with CHVS and acts as a trigger for the fight or flight mechanism. In which the body prepares for an acute reaction to a possibly threatening situation. Consequently, increasing the adrenaline levels to a hyperadrenergic state provokes rapid respiration, swift breathing, and a hyper-ventilatory response (Tavel, 2021). While hyperventilation could be found in physiological factors, hyperventilation syndrome is typically linked to emotional triggers and the tendency to breathe from the chest. Lum (1975) proposes that an exaggerated tendency to rely on thoracic muscles for breathing is a crucial factor in the initiation and persistence of hyperventilation syndrome.

Moreover, multiple reports have suggested that panic attacks are inherently linked to HVS. As Tavel (2019) believes, this will create the need for physicians to consider HVS as an important contributor to the range of symptoms of panic disorder.
Indeed, emotional states like anxiety and anger can entice the fight or flight reaction and an elevated adrenergic state. Even more so, as illustrated in Figure 4, ongoing daily stresses or new discomforting symptoms resulting from hyperventilation will only contribute to a self-perpetuating cycle of chronic hyperventilation (Magarian et al., 1983). People prone to hyperventilation frequently display obsessive behaviours, heightened awareness of bodily sensations, phobias, feelings of inadequacy, and challenges with adapting to various life stages. Hyperventilation syndrome is evident not just among individuals who openly display signs of stress, anxiety, and depression but also among those who seem outwardly calm as they bottle up their feelings (Magarian et al., 1983).

Hyperventilation and physical causes

While emotional and psychological factors are frequently associated with hyperventilation syndrome, it is essential to recognize that physical causes can also trigger hyperventilation. For instance, asthma, chronic obstructive pulmonary disease (COPD), heart failure, and pulmonary embolism could cause hyperventilation. Other potential causes include fever, infections, and metabolic disorders like diabetic ketoacidosis (Tavel, 2021). Consequently, it is crucial to rule out any underlying physical causes of hyperventilation through medical evaluation and appropriate testing.

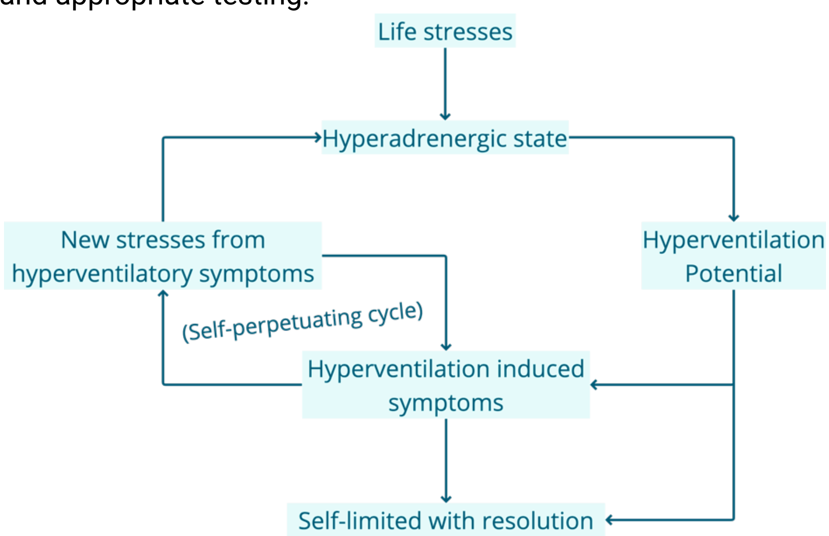


Figure 4: Hyperventilation syndrome pathogenesis (Magarian et al., 1983)

2.2.3 Incidence and Prevalence

The prevalence of HVS is difficult to assess because the broad range of symptoms can make the diagnostic criteria challenging. Tavel points out in his report on why hyperventilation is regularly overlooked (2021) that in 15% of the subjects with long-term disability, hyperventilation played a significant role. Several other reports have made an approximation. According to Jones et al., 2013, Hyperventilation syndrome has a prevalence of 9.5% of all general medical patients and can affect 29% of adults with current asthma (Thomas et al., 2005). Of 104 patients who experienced 'dizziness', 23% had hyperventilation as the sole or prominent contributing factor (Magarian et al., 1983). A study by Taverne et al. (2021) reports a 'high incidence' of HVS after covid-19.

Nederlandse Hyperventilatie Stichting (Dutch Association of Patients) estimated the number of people who at some time in their life experience hyperventilation at over 800,000 (5% of the population), with 80,000 people affected over more extended periods or lifelong.

2.2.4 Mechanism and treatment procedure

As introduced earlier, over-breathing can rapidly increase the amount of carbon dioxide and abruptly lower the levels of pCO2 (the partial pressure of carbon dioxide in the blood), resulting in a rise in pH levels. The body seems to care about its pH level deeply; through interlocking relationships between pH, CO2, and HCO3 (bicarbonate) (figure 5) (Lum, 1975), the body will react to the disbalance by regulating the amount of oxygen available. Without going into too much detail, this results in less blood to the brain and less oxygen, leading to common complaints and illustrating the cause-and-effect relationship between hyperventilation and their symptoms. Viewing hyperventilation syndrome from the perspective of biochemical disturbances is an important nuance.

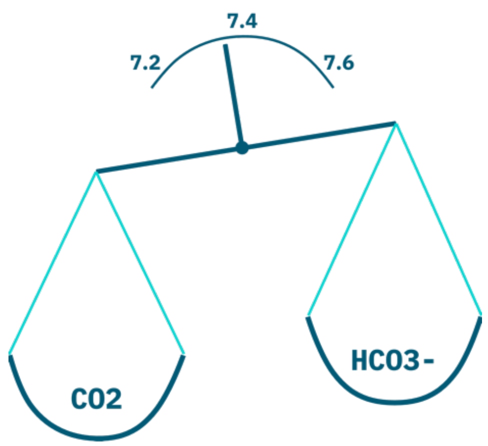


Figure 5: Interlocking relationship between pH, carbon dioxide, and bicarbonate (Lum, 1975)

The diagnosis rests on inducing the patient's symptoms through deliberate hyperventilation so that the patient will recognize the complaints. "This can be accomplished by having the patient breathe deeply at a rate of 30 to 40 times per minute for about 3 minutes. Most patients will recognize some of their symptoms within minutes or seconds. This recognition and subsequent explanation of hyperventilation greatly enhances the potential for improvement" (Magarian et al., 1983).

As Lum (1975) so skillfully remarks, hyperventilation could be seen as a bad habit, "a habit of breathing in such a way that the day-to-day level of pCO2 is relatively low. Given this bad habit, any physical or emotional disturbance may trigger a chain reaction." Tavel (2021) goes on to state that "as such, the fear and anxiety that initiate the panic response are often compounded by the unpleasant subjective complaints caused by the breathing disorder itself."

To summarize, reproducing the symptoms by voluntarily hyperventilating, followed by a simple explanation of the mechanism and respiratory control, will typically help gain control over hyperventilation.
Given that the recognition and subsequent explanation greatly enhance the potential for improvement, and "by demonstrating the causality, the clinician can interrupt this feedback cycle" (Tavel, 2021). As explained by Clark et al. (1985), even the underlying anxiety triggering panic attacks can be corrected by gaining respiratory control. Magarian et al. (1983) also state that 'long-term control may be achieved by relaxation therapy and reinforcing diaphragmatic breathing instead of thoracic breathing.'

2.2.5 Monitoring and Patterns

To get rid of the stigmatization of hyperventilation as an anxiety state and help both physicians and patients recognize that anxiety is usually the product and not the primal cause, monitoring bodily activity may provide insight into the biochemical disturbance.
The type of breathing hyperventilators used is quite characteristic of HVS, a thrusting motion of the upper sternum and the lack of lateral costal expansion are typical (Lum, 1975). Interestingly, sighing employs the same movement. Frequent sighs could indicate hyperventilation, and according to Lum, breathing when under stress or experiencing emotion is an important physical sign patients are usually unaware of.
This illustrates how, by monitoring the respirational rate and movements, underlying breathing disturbances can be perceived as breathing patterns (figure 6). Objective indications can shed light on disordered breathing habits that are subjectively difficult to express and recognize.

Condition	Pattern	Description
Eupnoea		Normal breathing rate and pattern
Tachypnoea		Increased respiratory rate
Bradypnoea		Decreased respiratory rate
Apnoea		Absendce of breathing
Hyperpnoea		Increased depth and rate of breathing
Cheyne-Stokes		Gradual increases and decreases in respirations with periods of apnoea
Biot's		Abnormal breathing pattern with clusters of rapid respiration of equal depth; regular apnoea
Kussmaul's		Tachypnoea and hyperpnoea
Apneustic		Prolonged inspiratory phase with a prolonged expiratory phase

Figure 6: Different breathing patterns and typical breathing behaviour (Wheatley, 2018)

As Lum explains, people who hyperventilate often exhibit symptoms that can be mistaken for heart disease. Physiological alterations in heart function can occur in such a way that it can resemble a heart attack. This further illustrates how, as the title of Tavel (1990) accurately depicts, hyperventilation syndrome can hide behind pseudonyms.

An objective perspective on hyperventilation's subtleties and wide-ranging manifestations can support the challenging, subjective recognition by monitoring breathing behaviour, blood oxygen levels, and heart rate.

2.2.6 Challenges

Altogether, almost every report emphasizes how often hyperventilation syndrome is overlooked. Especially when it 'presents in unusual ways or follows a chronic and insidious course' (Tavel, 1990). Tavel says, 'Even the patients may fail to subjectively recognize the respiratory problem, having been preoccupied with the associated symptoms.' An inaccurate diagnosis is often a reality because of the 'colourful' palette of complaints and symptoms. As well, the symptoms closely resemble those of 'anxiety states.' According to Lum (1975), the most common misdiagnosis that leads to the mislabeling of hyperventilation is that it can be particularly harmful. This diagnosis implies feelings of inadequacy or inherent weakness, which can tempt the physician to dismiss genuine and often painful symptoms caused by a biochemical imbalance as imaginary. Accordingly, it contributes to the increasing use of tranquillizers, which poses a growing threat to the healthcare system.

Furthermore, acute hyperventilation attacks are readily recognized. Still, chronic or recurrent problems make them more challenging to acknowledge, likely due to several factors, such as focusing on a limited set of complaints that do not strongly suggest hyperventilation (Magarian et al., 1983).
When hyperventilation begins, it can persist subtly, even nearly imperceptible, such as occasional deep breaths while maintaining a regular breathing rate. Without awareness, physicians might directly observe this subtle chronic form of hyperventilation without identifying it (Magarian et al., 1983). Alternatively, if they consider the diagnosis, they might incorrectly dismiss it because the expected hyperventilatory breathing pattern is absent.

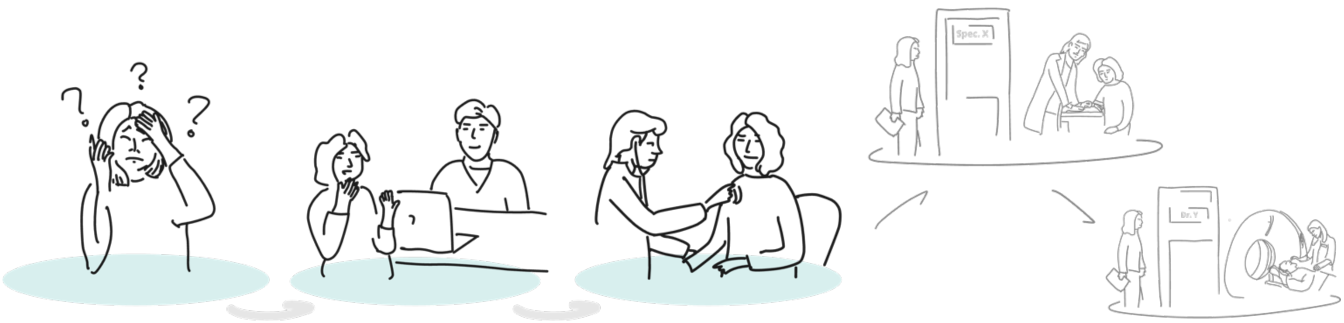


Figure 7: Current diagnosis procedure

As illustrated in the hypothetical example (figure 7), Lum (1975) quotes that in 1935, "patients presenting the well-known pattern of symptoms … are often shunted from one physician to another" – and believes that this was still true at the time of publication. Tavel (2021) states that the "failure to recognize this problem leads not only to much suffering but also to large and unnecessary financial costs to an already overburdened medical system."

The latter indicates that not much has changed despite the high prevalence and incidence we still see today.
According to Tavel (2021), there are multiple physical symptoms that are frequently present alongside breathing issues but lack clear medical evidence. This can cause medical professionals to overlook the root cause of the problem and rarely conduct the necessary testing to make an accurate diagnosis.

2.2.7 Clinical Perspectives

To better understand hyperventilation disorder and its complex challenges, a series of interviews and conversations were conducted from various perspectives. These discussions provided valuable insights and a practical approach to addressing the disorder.

Cardiologist
Various topics were discussed in a conversation with Jobst, a Cardiologist at the Stichting Cardiologie Amsterdam. The key insights from this conversation are shared below.

Balances – everything is a balance; if your body or mind is not in balance, it can result in symptoms of any kind. Your body is trying to give a signal or communicate in the form of an uncomfortable feeling.
As such, this can be seen in how an imbalance in your respiration directly affects your health and can subsequently take the form of symptoms of severe conditions. While actually, your immune system responds to the accumulation of imbalances in your body.

Segmentation – physicians cling too tightly to the boundaries of their expertise. This creates a segmentation that hinders the exchange of information and inefficiencies in iterations during the diagnostic process. Instead, physicians could ask their patients, 'How is life?' Perhaps there is something else at play that, in the first instance, is not mentioned but can be significant.

Objectivity – every immune system is unique, hardwired in genetics, and reacts differently to the same impulse. Hence, the importance of understanding the individual and keeping the human in front of the doctor at the centre of the care process is evident. Physicians have difficulty with doing this, partly with good reason, for it is not easy for them nor the patients themselves to translate the feeling of discomfort in the body into words.

Conclusively, Jobst emphasizes the need to measure patients' discomfort objectively to help physicians and patients identify the root cause of their complaints and bodily functions. With all the external noise and stimuli, hearing what your body is trying to communicate can be challenging.

Respiratory therapist

Valuable insights were gained during a conversation with a respiratory therapist who has extensive experience with breathing techniques. Below are some of the key takeaways from our discussion.

Anatomy – which specific muscle is used for breathing also matters, not just chest vs. abdominal breathing. In chest breathing, external muscles (external intercostals) contract, lifting the diaphragm during inhalation. When the muscles relax, the chest returns to its normal position. In abdominal breathing, the diaphragm muscles contract, pushing the diaphragm downward and enlarging the chest cavity. The back also expands during (chest) breathing.

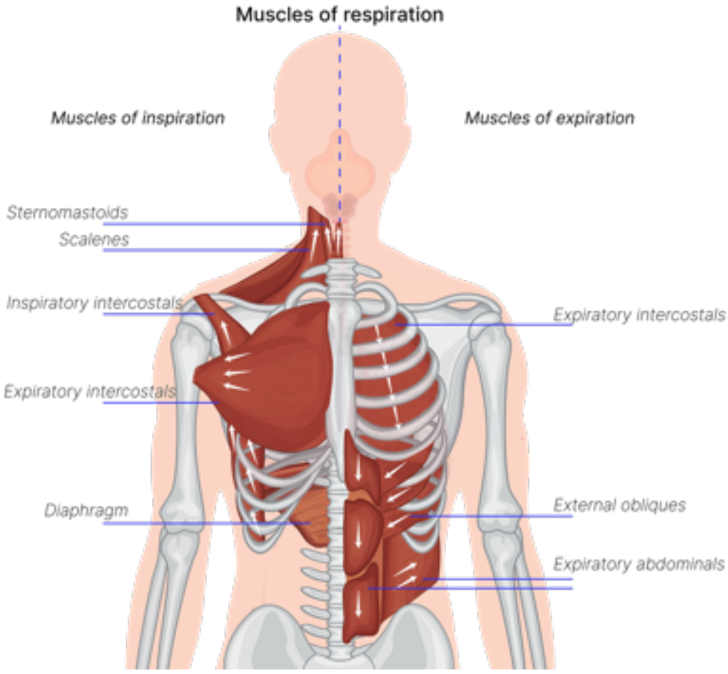


Figure 8: Muscles used for respiration

Balance and tension – the balance between inhalation and exhalation sets the tone for what you demand of your body, whether it is exertion or relaxation.

- Inhalation signifies action, whilst exhalation signifies relaxation.
- Proportionate inhalation and exhalation lead to a stable spine and posture.
- An imbalance leads to built-up tension in the muscles and dizziness due to high CO2.

Patients – typically present symptoms of instability, fatigue, and muscle tension. The relationship between muscle tension and breathing behaviour could interest this project.

> *"Behavior can be unlearned and learned; it all starts with acquiring a stable and healthy form of breathing and learning to relax between exertion."*

Breathing therapy involves finding calmness and following your breathing, ensuring you exhale fully and engage in abdominal breathing. Understanding the impact of breathing on your body is crucial to restoring balance and awareness of bodily processes.
As seen with Hans' patients, their breathing behaviour was disproportionately focused on inhalation, whilst they experienced tension and were out of balance. Focussing on exhalation made them more relaxed and, therefore, more stable and assured.

Patient perspective

During a conversation with one of the people who started this project, he shared his experience with hyperventilation complaints and the complicated process of identifying the root cause of the symptoms. The following describes the story of Marco, who faced similar challenges in determining what was causing his symptoms.

For a while, Marco had been feeling shaky and struggling to get into the pace of his usual endurance sports. Unfortunately, he visited his general practitioner but did not get any answers. Even though he was older, the doctor told him his health was that of a 40-year-old. Marco was left feeling frustrated and confused about what was happening to his body.

He sought a rheumatologist, but the symptoms did not align with endurance sports. So, together with the general practitioner, he scheduled appointments with a pulmonologist, physiotherapist, and cardiologist to investigate everything. However, no murmurs or problems were found, which was baffling.

Feeling lost, Marco turned to Google to search for patterns and fill in the blanks. He asked his doctor if it could be chronic hyperventilation, and he was referred to another physiotherapist. This physiotherapist advised Marco to pay attention to his breathing patterns while talking and doing everyday activities and to do breathing exercises to see how he responded.

Marco also visited a cardiologist who measured his breathing and SPO2, but everything was fine. Marco had a follow-up appointment in a month, and in the meantime, he was advised to continue doing his exercises.

Through his experience, Marco realized that some doctors have a superficial approach, leading to incorrect diagnoses and treatment paths. He believed GPs needed to change their mindset and look for underlying stress symptoms. Marco shared his experiences and suggested creating a database with objective findings that could be shared cross-disciplinarily.
In the end, Marco learned that patience and persistence are essential when seeking answers to health issues. Understanding his body and paying close attention to himself was critical in finding the correct diagnosis and treatment.

2.3 Key takeaways

The fundamental human process of clinical reasoning stands at the basis of an accurate diagnosis. However, the increasingly chaotic and fragmented context in and from which patients present their symptoms to clinicians makes diagnostic errors a severe problem. Typically, the care process begins with the patient's *application* of medical attention. The diagnostical steps then consist of *gathering information, interpreting, and indicating – s*etting the basis for a *treatment* plan. *Evaluating* is the most essential step, and good collaboration and extra data acquisition help to make optimal therapeutic decisions.

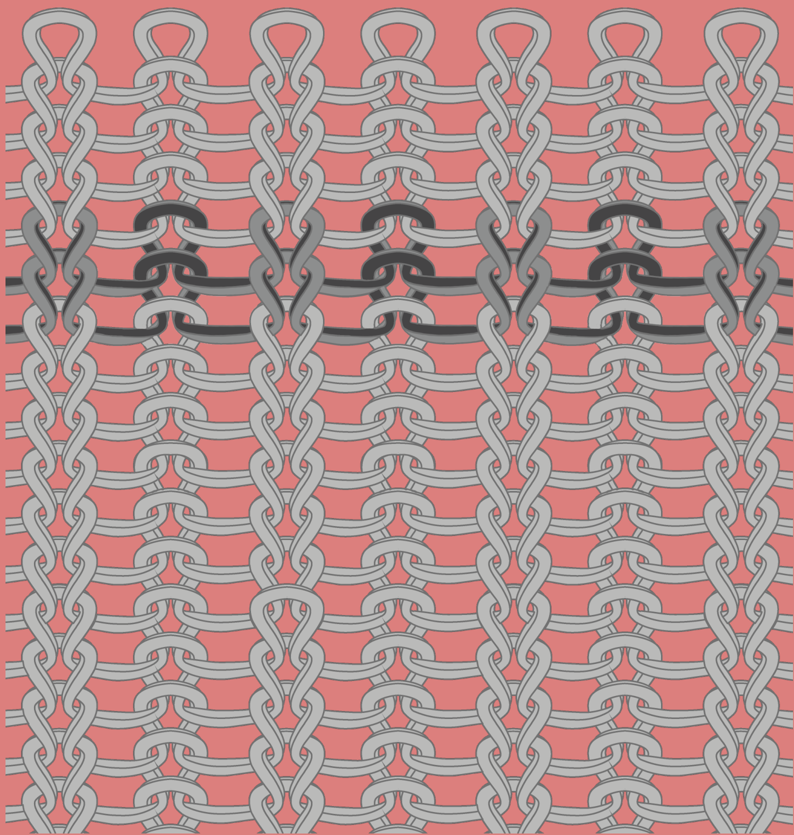
Chronic hyperventilation syndrome (HVS) is characterized by rapid or excessive breathing, leading to a biochemical disbalance that initiates a sequence of physiological changes responsible for most symptoms. These include shortness of breath, dizziness, chest pain, fatigue, weakness, numbness, muscle spasms, and mouth dryness. Not limited to these symptoms, HVS often exhibit symptoms that can be mistaken for heart disease, illustrating how HVS can hide behind pseudonyms.

It is an important nuance to view this from the perspective of the cause-and-effect relationship between his and the symptoms or a biochemical mechanism. Anxiety can act as a trigger for the fight or flight mechanism, increasing adrenaline and provoking respiration. However, the tendency to rely on thoracic muscles for breathing is also crucial. This illustrates how HVS can be described as a dysfunctional breathing habit in which daily stresses or new discomforting symptoms resulting from hyperventilation will only contribute to a self-perpetuating cycle of chronic hyperventilation.
Reproducing, demonstrating, and explaining this causality and gaining respiratory control and diaphragmatic breathing will typically help gain control over his.

Some interesting physiological characteristics can be recognized, such as motion of the upper sternum, frequent sighing, or deep breaths. Vital imperceptible signs that persist subtly and are often overlooked. This, compared with various coexisting complaints lacking objective confirmation, may divert attention from the underlying breathing disturbance.

Independently, clinical experts confirm and build on this image, emphasizing that everything is balanced and that your body reacts if something is out of balance and try to communicate this. The impact of breathing and the balance between inhalation and exhalation sets the tone for what you demand of your body: exertion or relaxation. Even your stability (read dizziness) depends on the relaxation of your muscles and, thus, your respiration.

State of the Art



This chapter will explore wearable sensor technology and its potential role in measuring breathing behaviour. With the increasing prevalence of health monitoring devices, wearables have become a popular choice for tracking biometric data. Numerous advancements in sensor technology and smart textiles can collect biometric data and provide insights into various physiological functions, including breathing behaviour.

This chapter aims to provide an in-depth understanding of wearable sensor technology and its potential applications in healthcare. Firstly, we will delve into wearables, exploring the possibilities and challenges of wearable devices and smart textiles [3.1]. Followed by a review of the possibilities for integrating electronics into garments for sensor technology [3.2].

3.1 Wearable sensor technology

The notion implied in the previous chapter, which can be considered the 'problem space', is to create a digitalised perception of a selection of a patient's physiological functions. Hence, a collection of sensor types to record biometrical data is undoubtedly considered for the' solution space'. However, according to the scope of the assignment concerning time limitations, the focus for this project will be on explicitly measuring breathing behaviour.

3.1.1 Wearable technology

A *sensor* is a device that detects a stimulus in the form of a signal and converts it into a signal in another unit that represents the relevant characteristics of the signal and can be transmitted or recorded. It detects mechanical changes converted to electrical signals to be measured electronically. Worn on a human body, a sensor can be used in a way that suits the focus of this project. Considering this configuration, the collection of electronic components, including the sensor necessary to detect, process, and communicate biomedical data, can be called a *wearable* (Ometov et al., 2021).

Interestingly, the 'wearable' of today is typically seen as a gadget consisting roughly of a case with embedded electronics worn on the body, making them inherently suitable for health monitoring. An example is a smartwatch, an excellent example of how wearables are considered 'smart-by-definition'. However, the excitement about the concept of an electronic wearable from a few years ago has slowly become the norm (Forbes, 2020). The overwhelming number of wristbands and trackers illustrates the need for an upgrade in user experience. Focusing on 'delivering a better experience to the actual users' – as defined by Ometov et al. (2021), wearables could again innovate in enhancing their users' cognitive abilities.

Figure 9: One of the first wearables

The very start for wearables began with the invention of spectacles in 1284, followed by the first pocket mechanical watch, which could be carried around (Yasar & Wigmore, 2023). Until the state of the art of wearable technology as we know it today, ranging from activity trackers to cognitive augmenting devices. A wide variety of classifications of wearable devices is discussed in the paper by Ometov et al.. It can be outlined from various perspectives based on different factors, where the most intuitive way of classification is the placement of the wearable.

In short, many configurations and forms are possible depending on the application scenario and data collection needs. Overall, research in wearable technology is growing, as demonstrated by the number of publications in the domain. A future ecosystem in which the development of personal wearable ecosystems will shift from conventional combinations of an activity tracker and smartphone to more miniaturised technology, possibly incorporated in clothes or hands-free accessories, is expected (Ometov et al., 2021). However, because of the lack of interoperability between different suppliers, integrating diverse electronic components remains one of the most substantial challenges. In addition, battery limitations and a lack of synergy between research from a machine- and human-centric perspective were mentioned. Excessive 'intrusiveness' and consequent discomfort also constitute challenges in user adaptation. The following section will elaborate on this further.

3.1.2 Smart textiles

Comparably to the anecdote of the first wearable, the first 'smart textile' was silk thread having a 'shape memory' (Tao, 2015), which makes you wonder that perhaps attaching electronics to any given medium does not necessarily make it smart.

Zooming into the realm of smart textiles, textile-based sensors could have considerable potential for next-generation solutions for integrating electronics into a wearable format. Cherenack and Van Pieterson (2012) describe that textiles represent an attractive medium for electronic integration and can free electronics from their rigid, confining encapsulation. Current wearable devices are primarily powered by batteries and designed in such a way that limits their wearability and capacity to use the large surface area available on the human body (Komolafe et al., 2021). Especially in health monitoring, the larger surface area offered by garments provides opportunities to expand on biometric data acquirement.

Because textiles have been a fundamental component of our everyday lives for hundreds if not thousands of years, they could significantly improve user adaptation and the lack of synergy discussed before. This is illustrated in a paper by Park and Jayaraman (2003), in which they propose that e-textiles can meet user demands on connectivity, interactivity, wearability, and ease of use. While simultaneously providing the 'ultimate flexibility in system design to serve as an information processing infrastructure for sensing the wearer's stimuli'. Skilfully blending in or integrating electronic components with garments represents a significant opportunity and, at the same time, a big challenge (Cherenack & Van Pieterson, 2012). Imbalanced contributions from the electronic and clothing industry and sorting out the jargon associated with each field make it challenging to achieve full integration.

In conclusion, traditional wearable devices are limited by their confining encapsulation, which results in inconvenience when incorporating them into next-generation non-intrusive wearable applications. At the same time, smart textiles offer a flexible and user-friendly platform for novel sensor applications. Challenges in smart textile development include high mechanical stresses, washability, power supply, and imbalanced contributions in commercialisation.

Smart textile materials

Sensors are integrated mechanically or structurally into a textile (Islam et al., 2020). Subsequently, two trends can be identified (Tao, 2015):

- Making electronic components compatible with a textile garment.
- Transforming electronic components into actual textile structures.

Early e-textile devices were produced with off-the-shelf portable electronic devices, sewn into pockets of existing clothing and mounting cables on the fabric. This approach to manufacturing was cheaper and created design flexibility but did not entangle the textile itself. Hence, it missed opportunities and lacked aesthetics, comfort, and drapability – typical qualities of textiles (Komolafe et al., 2021).
A partial solution can be designed by miniaturising electronic components and embedding them into the fabric. Wearable e-textiles would not be possible without electrical components. The need for connectors to bridge the textile with electronics, electrodes for ECG, or the simple need for a battery to power the components are some examples of how incorporating the shelve components is in most applications still necessary (Gonçalves et al., 2018).

However, in smart textile literature, the emphasis on novel solutions based on structurally integrating sensors and circuitry is most represented and considered promising (Komolafe et al., 2021). Combining traditional fabrication methods of conventional textiles and conductive materials in e-textile production can retain features like textural comfort and flexibility. Electrically conductive materials (ECM) are electrically conductive threads/yarns, electrically conductive films, and narrow filaments (Komolafe et al., 2021). The fabrication method depends on the ECM used. As an additive process, films and filaments can be screen-printed or inkjet-printed using conductive inks or metal deposition methods onto a textile fabric. This way, complex large planar circuitry can be realised, although integration on the fabric also affects breathability and is susceptible to external stresses (Komolafe et al., 2021). Conductive threads can be integrated into textiles as a substitute for passive yarns by various construction methods like weaving, knitting, or sewing. The conductive yarn material used in this method is a complex yarn made up of regular textile yarn embedded with flexible fibres of metal yarn (figure 10).

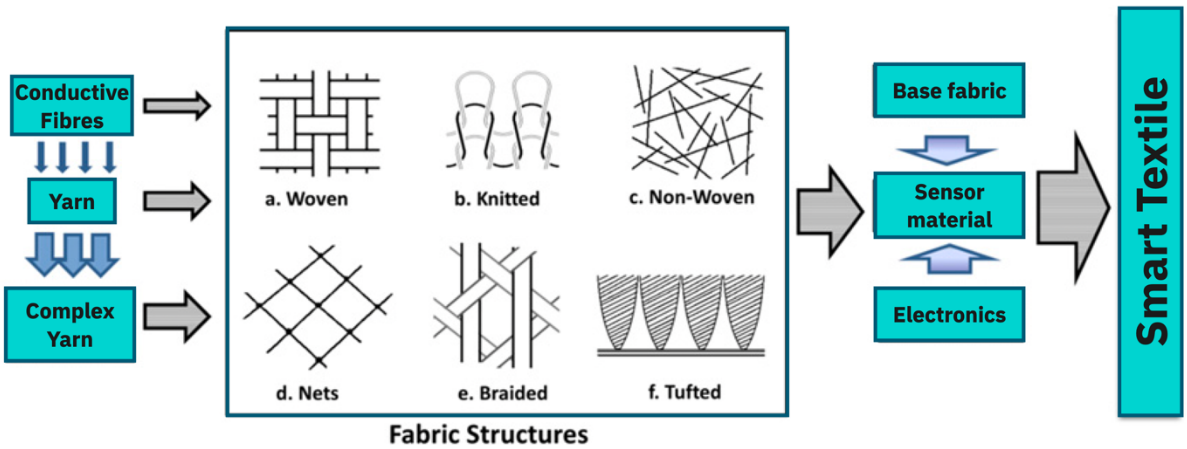


Figure 10: conductive yarns and fabrication methods (Based on: Castano & Flatau, 2014)

3.1.3 Textile-electronics integration

Connecting electronic circuits in e-textiles is a challenge due to embedding circuitry and components into soft objects like clothing. These textiles can measure physiological signals, serve as a human-computer interface, and deliver medical interventions. Despite market predictions, several challenges persist, including a lack of materials and manufacturing methods standards and incompatibility between textiles and electronic manufacturing techniques. Based on research done by Stanley et al. (2021), this section provides an overview of construction and connection techniques for smart textiles.

Construction

E-textile construction techniques can be broadly categorized into three types. The first type aims to replace traditional electronic circuitry with textile alternatives. The second type involves creating electronics on flexible substrates that can be embedded inside textiles. The third type uses printing techniques to print functional inks onto fabrics directly. Most e-textiles combine two or more of these categories.

Joining technologies are critical to this, as connecting e-textile parts in an electrically reliable and durable way without negatively impacting the garment's form, fit, and function remains difficult. One of the critical challenges in e-textile design is creating a flexible and reliable construction. Garments must be pliable, with minimal rigid elements, to ensure they are comfortable to wear and do not cause injury during movement or impact. Unfortunately, many electronic joining technologies rely on rigidity to ensure reliability, making it difficult to find a suitable solution that balances flexibility and reliability.

Wiring

Several wired connection options are available for powering and data transportation in smart textiles. One of the most commonly used methods is standard electrical cabling made of copper strings, which is highly conductive but can be stiff and difficult to integrate into textile carriers. However, there are also some exciting developments in this field, such as fabric flat cables that can transport power and data over multiple wires. For instance, conductive flat cables consisting of 4-8 wires have been created by companies like Ohmatex.

Figure 11: Standard copper wires (RS, 2024); Flat fabric wire (Ohmatex, 2024)

Fixed Connectors

In e-textile design, fixed joining technologies permanently attach electronic components to flexible substrates. Stanley et al. (2021) mentions the following types in their paper.

Stitched Connections

The use of embroidery as an e-textile joining technology has been proposed in research. Embroidering connections using conductive thread can be done by hand, sewing, or embroidery machine. This technique can be used to join conductive thread to other conductive threads or to join conductive thread interconnects to PCB modules. However, connections can relax over time or in response to temperature cycling. Strategies to improve connections include triple sewing each connection and adding additional pressure by adding encapsulation on top.

Soldering

Soldering is a standard and widely used electronics joining technology. Two contacts are joined by melting a third metal, solder, which is usually an alloy with a melting temperature lower than the contacts to be joined. Soldering has been used in e-textiles to connect components to flexible substrates such as conductive thread, flexible copper wire, or polyimide. Soldered connections have low contact resistance but are mechanically brittle, and connections subject to any bending or stretching must be reinforced to avoid breakage in a textile application.

Crimping

Crimping is the process of deforming materials to create a connection. In electronics, crimping is used to connect wires to terminals. In e-textiles, jewellery crimp beads have been soldered to surface mount components, allowing them to be stitched to fabric.

Adhesives

Various adhesive bonding techniques are utilized in electronics; non-conductive adhesive bonding (NCA), isotropic electrically conductive adhesives (ICA), and anisotropic conductive adhesives (ACA) are the most common in e-textiles. Compared to soldering, adhesive bonding requires lower curing temperatures, making it more suitable for fabric applications. Additionally, conductive adhesives can serve as eco-friendly alternatives to lead-based solder. However, such alternatives usually have a higher contact resistance and lower mechanical strength than soldered connections.

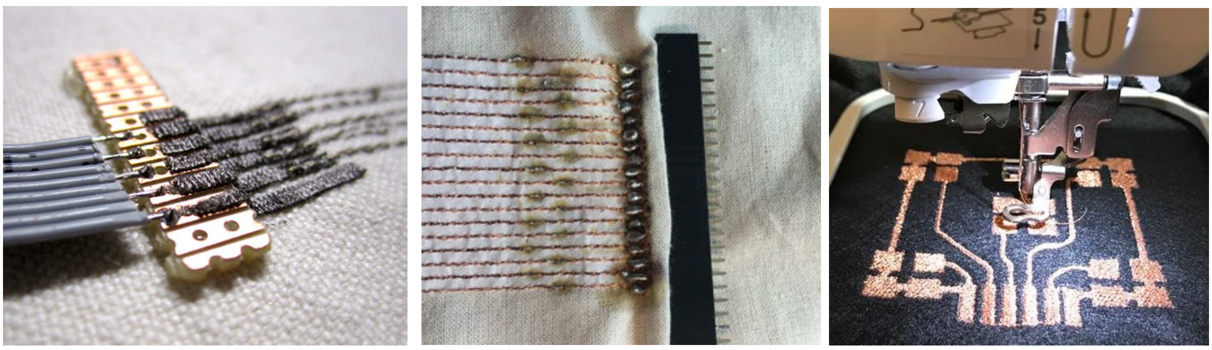


Figure 12: Stitched connection (KOBAKANT, 2009); stitched conductive wires (Staff & Staff, 2021); soldered connection (Instructables, 2019)

Removable connectors

The same review paper mentions different types of removable connectors in e-textile applications used for detachable electronic components such as batteries or processing units.

Snap Fasteners

Snap fasteners are commonly used in e-textiles, but limited research has been done to evaluate their suitability as electronic connectors. However, one study reported positive results on their use for low and medium bandwidth signal transmission. Standards and further research are needed to assess the number of mating cycles as an electronic connector.

Pogo Pins and Magnets

Pogo pins are commonly used in rigid electronics to connect circuit modules with flexible circuitry. They are small and can be housed in a press-fit plastic enclosure or aligned with magnets for electrical connection. Magnets are also used as temporary connectors in the Threadboard prototyping kit.

Conductive Hook and Loop (Velcro) and Other Textile Closure Mechanisms

Silver-plated hook-and-loop (Velcro) is commercially available but has yet to see widespread use in e-textile applications. Conductive hooks and loops have been investigated as connectors for flexible radio frequency connectors and automotive systems. Zippers and buttons have also been adapted into e-textile connectors, with zippers connecting two electrical contacts and buttons making contact with conductive thread sewn around the buttonhole.

Pin Headers and Flexible Electronics Connectors

Pin headers are commonly used in rigid electronics and can be soldered to conductive fabric or thread. They are convenient for interfacing with microcontrollers such as Arduino and can interface between soft circuits and rigid modules.

Figure 13: snap fasteners; magnet connector; conductive velcro; pin header (Stanley et al., 2021)

3.2 Textile sensors

Using conductive yarns in conventional fabrication processes to make specific constructions, so-called 'textile circuit' elements can be made with various electrical properties. Smart
fabric sensors come in many types and designs, with applications in various fields.

3.2.1 Wearable breathing sensors

Although smart textiles have many possibilities and developments, this project focuses on specific applications for measuring breathing behaviour. Various biological signals can be considered, such as the movement of the upper body, the flow of air, bodily sounds, and the electrical activity of muscles (Costa et al., 2019). Traditional respiratory monitoring devices typically measure airflow; however, this alone does not represent respiratory movement completely, including where breathing occurs (chest or abdominal) in the body. Similarly, monitoring lung sounds can provide additional insight into lung health status. However, it must still fulfil the objective of measuring volume, place of breathing, and direction of in- or exhalation.

As discussed in the medical analysis, focusing on the location of breathing movement and body circumference change adds considerable detail. In addition, it is essential to note that the objective of this project is to measure the level of change and not the absolute values. Therefore, the sensors must provide fast, accurate, and repeatable data. In terms of criteria, the sensors must have high sensitivity, be repeatable, durable, low-drift, accurate, and resilient. They should also have low power consumption, be made of inert materials, and provide low noise readings.

Other types of sensors Mediventic wants to include are those that measure load for forces on the body, conductivity for perspiration, thermometer for body temperature, IMU for acceleration and movement, ECG for heartbeat signals, EMG for muscle actuation signals, and oximeter for blood saturation.

[Figure of different types of respiratory movement sensors]

Smart fabric sensors can be used in many capacities and have various applications in sports and fitness, healthcare, military and defence, automotive, and aerospace. They can monitor vital signs, detect injuries, and improve health, safety, and performance. Examples include smart insoles for monitoring foot pressure, pressure mapping for wheelchair users, and smart clothes for motion detection or muscle activity. All have drawbacks, including creep, poor resilience, signal drift, and hysteresis. Compensation for these problems depends on the intended usage and the acceptable operating range.

In light of the intended usage of strain sensors in this project, the focus is on measuring respiration's location concerning the type of respiration and corresponding muscle activity. As intended in this project's scope, this will be done using textile-based strain sensors.

Recording breathing patterns

To detect abnormalities and patterns, the objective is to record chest- and abdominal breathing and the relation between the two – which will be covered in the prototype development section. It is to find the appropriate sensor that requires respiratory behaviour to be described regarding detectable signals.

Respiratory patterns can be described as waveforms. As can be seen in the chapter about HVS, different conditions can be typified by specific waveform patterns. Following signal processing theory, breathing behaviour can thus be described as a signal consisting of the following properties (figure 14):

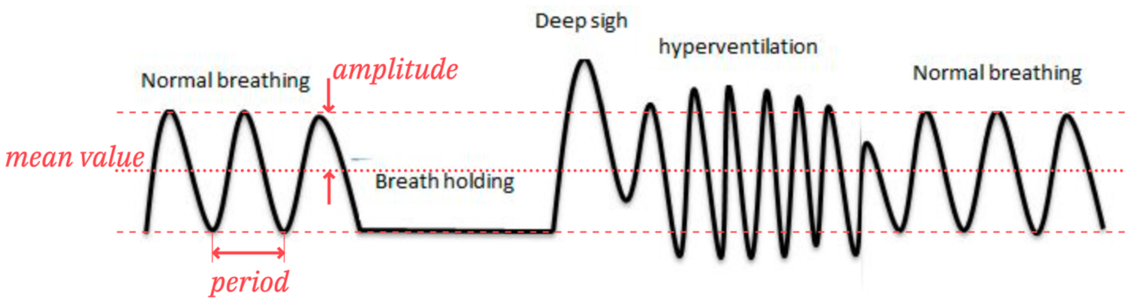


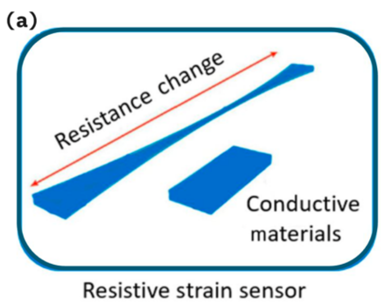
Figure 14: breathing patterns and wave pattern properties

- Breathing rate: in terms of *frequency*.
- Breathing depth: in terms of *amplitude*.
- Breathing consistency: in terms of *period* or *phase shift*.
- Breathing equilibrium: in terms of the *mean value*.

3.2.2 Strain sensors

Several types of strain sensors can be classified based on the sensing mechanism they use. A summary is given of the most common types of applications according to Castaño and Flatau (2014).

Resistive Sensors. These sensors measure pressure and strain by changes in their electrical resistance. Resistive strain sensors are composed of active materials and a flexible substrate that responds to strain deformation by changing the electrical resistance in the sensor. Textile-based resistive strain sensors are popular due to their easy manufacturing process and accessible read-out signals.



Capacitive Sensors. These sensors are designed for pressure and tactile sensing applications. They use an element of two separate electrodes that prevent the current flow from going across the textile electrodes. They can be made using adapted electronics, compressible foams, fabrics, and polymers.

Piezoelectric Sensors. Piezoelectric strain sensors generate a voltage difference when an external stimulus is applied due to the transformation of deformation into electrical energy by piezoelectric materials. These can be materials like quartz or ceramics, which generate a voltage when deformed.

Optical Sensors. These sensors use light to measure pressure or strain. They are made using optical fibres that change their light-transmitting properties when they are deformed. Optical sensors are highly sensitive and can measure minimal changes in pressure. This relatively novel way of sensing has less sensitivity, and the complexity of the construction results in challenges regarding feasibility and, subsequently, costs. [figure: different types of strain sensor working principles (Wang et al., 2019) Optical sensor (Faisal et al., 2019)]

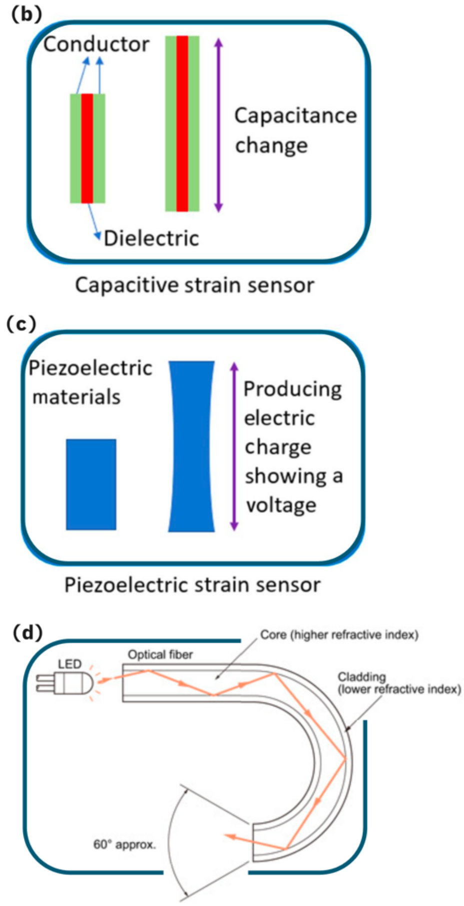


Figure 15: types of strain sensors

Based on a sensor evaluation done by Mediventic (appendix 2), resistive strain sensors are the most promising direction. Resistive strain sensors offer high precision, are less complex to construct and have less background noise than other types of sensors.

Strain sensor properties

In literature, various types of flexible strain sensors are discussed. The essentials for a successful application are *an easily embedded*, *reliable* sensor with a considerable *strain* measuring *range*, good *repeatability* in *cyclic* measurements with good *fatigue* life, and good *sensing* properties (Yi, 2015). According to Yi, resistive flexible fabric strain sensors in smart textiles are mainstream and have large working ranges and high sensitivity properties.

'The sensing behaviour of strain sensors can be demonstrated by sensitivity, represented by *gauge factor (GF)*, defined as the fraction of the electrical resistance increment' (Yi, 2015). Where *R0* = initial resistance, *ΔR* = resistance change due to deformation, and ε = strain.

$$GF = \frac{\Delta R/R0}{\varepsilon}$$

Sensitivity within the working range is then expressed as *ΔR/kg or ΔR/m resulting from stretch as ΔL/kg (Hooke)*.
Another essential value to describe the performance of a strain sensor is the *hysteresis (figure 16)*, which describes how monotonically the resistance acts during stretching, comparing the difference between the two directions (loading and unloading) within the

working range. Hysteresis can introduce inaccuracies in the sensor output since, depending on the direction, the path of the strain curve will differ. As a result, the sensor may not provide consistent and repeatable measurements when subjected to cyclic loading and unloading.

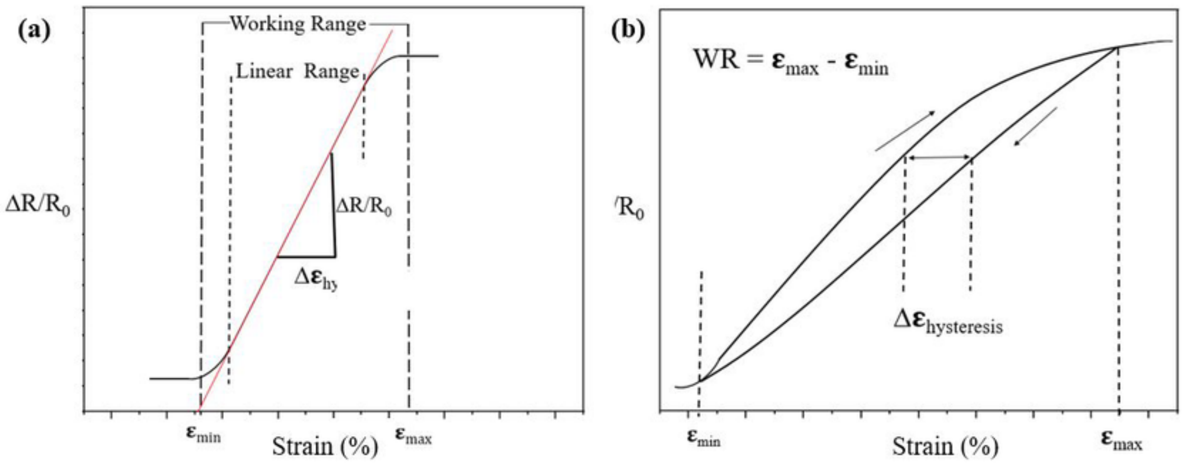


Figure 16: graph showing how to calculate gauge factor and hysteresis (Bozali et al., 2022)

Resistive strain sensors

Various resistive strain sensors exist; conventional strain sensors include mechanical- and polymer strain sensors. That works by the principle of contact points sliding over a resistor plate and elastically deforming a polymer, resulting in a resistance change. These conventional types of sensors are either lumpy, have limited flexibility, are prone to physical damage, have high hysteresis, and have long reset times.
More novel types of strain sensors include *flexible fabric strain sensors*. Compared to the insufficient cyclic performance of polymer strain sensors and the lumpiness of mechanical sensors, fabric sensors offer flexibility, and good repeatability can be achieved in specific configurations (Fan et al., 2020). Researchers mention general properties such as low weight, portability, and breathability compared to standard electrical systems (Cherenack & Van Pieterson, 2012). This could be considered in tune with the requirements for smart health applications.

Fabrics can be made sensitive at different levels of the structure hierarchy; as discussed before, conductive yarns or coatings can be applied to achieve strain-sensing properties. These strain sensors can maintain flexibility and elasticity and have relatively high sensitivity. Although typically, hysteresis is still a problem in fabric strain sensors for achieving good precision (Castano, 2014), different types of materials can be used in various constructions.

3.2.4 Knitted strain sensor

Weaving and knitting (figure 17) are mentioned as automatable fabrication methods to construct fabric strain sensors. Woven fabrics are durable and stable; it is possible to make strain sensors this way, but only by using stretchable yarns. The disadvantage is that the threads have extreme requirements because of the weaving process while being flexible and conductive at the same time. Knitted fabrics are characterized by high elasticity, elongation, and good conformability in mechanically active environments. As well as sound air permeability, thermal retention, and humidity transport properties (Cherenack & Van Pieterson, 2012). Yi (2015) even mentions in the handbook for smart textiles that these strain sensors are suitable for respiration monitoring.

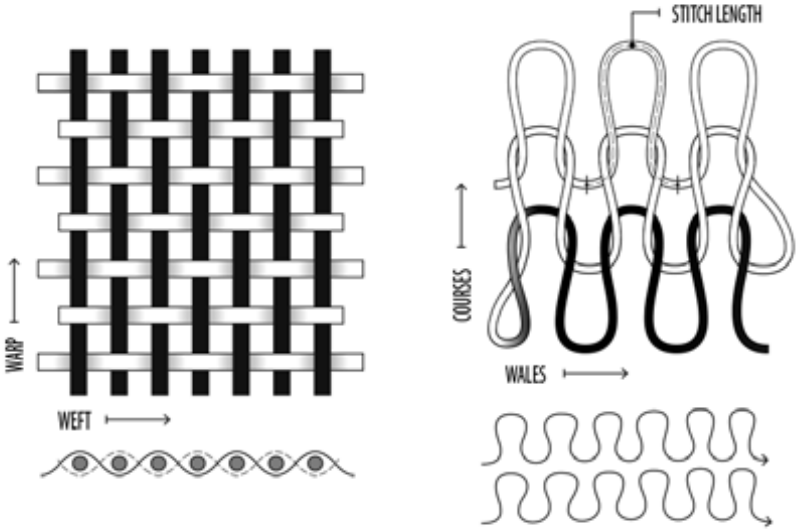


Figure 17: weaving and knitting (Ahlquist, 2015)

Knitted strain sensors 'can be manufactured at low costs in mass production with existing textile equipment' (Bozali et al., 2022). A structure of slipknots gives the sensor-fabric elastic properties. Two parameters affect the performance of knitted strain sensors; one is the *material type*, and the other is the *knitting structure*.
In a recent paper, Bozali et al. (2022) present an advancement in the field of knitted strain sensors. The study investigated the electromechanical performance with different yarn types, knitting densities, and a number of conductive yarn courses. By co-knitting conductive and elastic yarns, a low hysteresis linear sensor with a working range of up to 40% was obtained (Bozali et al., 2022). This recently developed, already patented version of a knitted strain sensor proves to have the electromechanical performance required to fabricate a breathing sensor. Anticipating the sensor and prototype development, the fabrication instructions from this article will be used to make strain sensors for this project.

Knitting technology

At this point, a basic understanding of knitting technology could be relevant to exploring the possibilities of using conductive yarn to create knitted fabric sensors. Though many think of knitted clothing as roughly textured, most clothing items are fine-knitted and produced through industrial knitting machines. Knitting is responsible for producing most stretchable clothing, while woven fabrics are used in non-stretchable clothing, such as jeans and shirts.

Knitting machines can produce entire garments within minutes, thus meeting the high demand of the clothing industry. The fundamental basis of knitting involves creating rows of flat or round loops. Knitted fabrics have two directions: the horizontal course direction and the vertical wale direction. These directions have different structures, resulting in varied behaviour when stretched. Knitting can be done manually or through an industrial knitting

machine, which comes in two types: the flat bed knitting machine and the circular knitting machine.
In a flatbed knitting machine, the needles are positioned horizontally, and a carriage slides over the needle beds, carrying the yarn from left to right. In contrast, a circular knitting machine knits in a circular manner, with needles positioned in a circle that defines the maximum diameter of the created fabric.

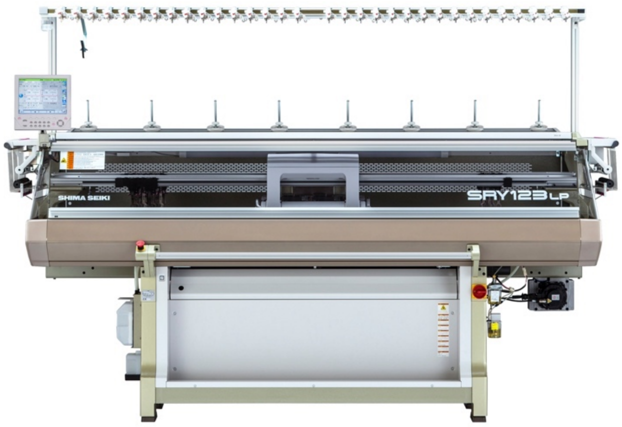


Figure 18: flatbed (Knitting Industry, 2014) vs circular knitting machine (Morton, 2023)

Various other attributes can be assigned to different knitting techniques to create patterns and combine different types of yarns (Li et al., 2009). Without going into detail too much, these include properties such as:

- Stitch types to create various patterns and structures for different purposes.
- Combination of yarn materials, which will be used to fabricate knitted sensors.
- Plating to insulate or trap components between two layers of fabric.

Literature mentions various types of attributes to construct knitted strain sensors, and hence, we return to the knitted strain sensors developed by Bozali et al. (2022). This project uses a Stoll CMS530 flatbed knitting machine provided by TU Delft, which will be used further during sensor development in this report.

3.2.7 Alternatives on the market

Many examples of working products that resemble the idea can be found. There are various reasons why using knitted textile sensors as a basis can result in a differentiating approach compared to the alternatives (figure 19).
The shirt by Coyle et al. (2009) is an example of a shirt made solely for monitoring purposes, without problem or medical application (1). Multiple research projects also use knitted sensors with good performance. However, they are usually technology-oriented and lack collaboration with other disciplines, as stressed in the medical background chapter. Often, they propose technological advancements that are too far ahead to be practically implemented and solve a problem today, resulting in high market prices or lacking a market to serve at all.

A further developed product is Tyme Wear (2), which focuses on measuring and improving endurance (*Tyme Wear*, n.d.). It focuses on individualizing training, uses a breathing sensor that measures your chest-breathing rate, and has a nicely designed detachable electronics enclosure. It uses a screen-printed film and advertises to be machine washable and very comfortable. The LungShirt (3) by KineticAnalysis (*LungShirt | Kinetic Analysis*, n.d.) advertises operating in the same problem space, referring to several medical studies underlying its importance. The shirt is accordingly washable, but only a little information can be found. It seems that the sensor is either screen-printed or stuck to the shirt. Another severe competitor that targets the health market is Hexoskin (Hexoskin, n.d.); with their Astroskin (4), they want to monitor vital signs for medical research. It has multiple sensors and can be considered an advanced monitoring platform for use in the most challenging situations, such as space training. A simpler version targeted towards health monitoring and clinical studies called Hexoskin (5) also measures breathing. It is made from technical base fabric that quick-dries and is machine washable. Both versions use two strain sensors for monitoring respiratory rate and volume, seemingly one for abdominal and one for chest breathing. The sensors that are being used are ‘respiratory inductance plethysmography’ sensors, which, according to Smith et al. (2019) “, capture data with errors and precision acceptable for most field studies given the range in minute ventilation observed for healthy recreationally active people.” Arguably, this project’s scope is not particularly focused on respiratory health problems, and resolving where breathing occurs could be improved. But careful investigation of this competitor is recommended for they have developed a well-functioning product-service system.

Figure 19: alternative health monitoring wearables

Other alternatives include Oxa (6) and Moonbird (7), which both aim for real-time coaching and breathing exercises as tools to help with depression and training to build up inner resilience. Although not mainly aimed at respiratory diseases, their focus on the core of the problem, incorrect breathing, makes them inspirational alternatives. The product Oxa delivers is a seemingly comfortable wearable and well-designed in terms of non-intrusiveness and environmental versatility – it also operates in sleeping conditions. Moonbird is an entirely different format designed in cooperation with breathing therapists. It is a simple and seemingly effective way to teach healthy breathing.

Previous Mediventic prototype

Mediventic aims to develop respiratory monitoring with high precision and high wearability. In the proof of concept (Mediventic, n.p.), it is described that the smart-wear should contain a large number of respiratory movement sensors in order to acquire a rich amount of data concerning where the movement takes place (figure 20). Mediventic wants to innovate based on sensor technology that can currently be implemented and learn from some of the missteps of existing solutions.

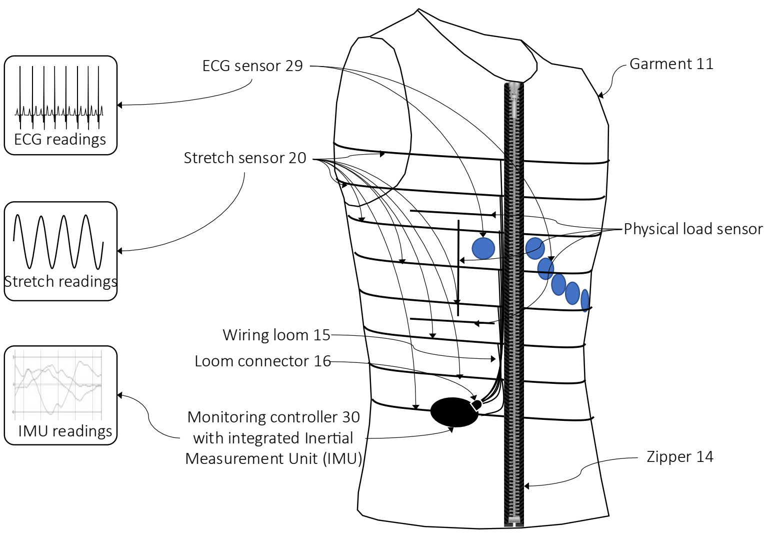


Figure 20: assignment concept and current prototype (Mediventic, n.p)

The first experimental prototype consisted of a single mechanical slider [1] mounted to a strap to get a first grasp of the data that could be acquired. Subsequently, the next iteration tries to use a more flexible stretch sensor [2] consisting of a material that changes in resistance when elastically deformed. The first multi-sensor form [3] can be seen in the version following this. Multiple flexible strain sensors are mounted on a shirt and can be zipped on or off. Following this is the most recent version of the prototype [4], which has multiple flexible material sensor loops to solve the difficulty of making a closed circuit. A rigid thread ensures that the body's deformation translates to the sensors, and a correct fit is assured with individually adjustable zip ties to tighten the sensors.
In terms of prototype development, the next step for Mediventic is to implement state-of-the-art textile stretch sensors to improve performance and wearability.

3.3 Key takeaways

The solution space is a collection of sensor types and electrical components to record biometrical data. Worn on the body, this can be called a wearable, with the grand purpose of delivering a better experience to the wearer. The electronics field still dominates product development; the vision is to move away from conventional wearables. Challenges include a need for more synergy, interoperability in research, and user adaption concerning intrusiveness.

Evolving from the conventional, textiles represent an attractive medium to free electronics from their rigid confining encapsulation. However, fully integrating electronic components with textile garments depends on achieving full multidisciplinary integration.
Compared to integrating off-the-shelve components, integrating electronics structurally into textiles retains valuable qualities such as comfort, flexibility, and aesthetics.

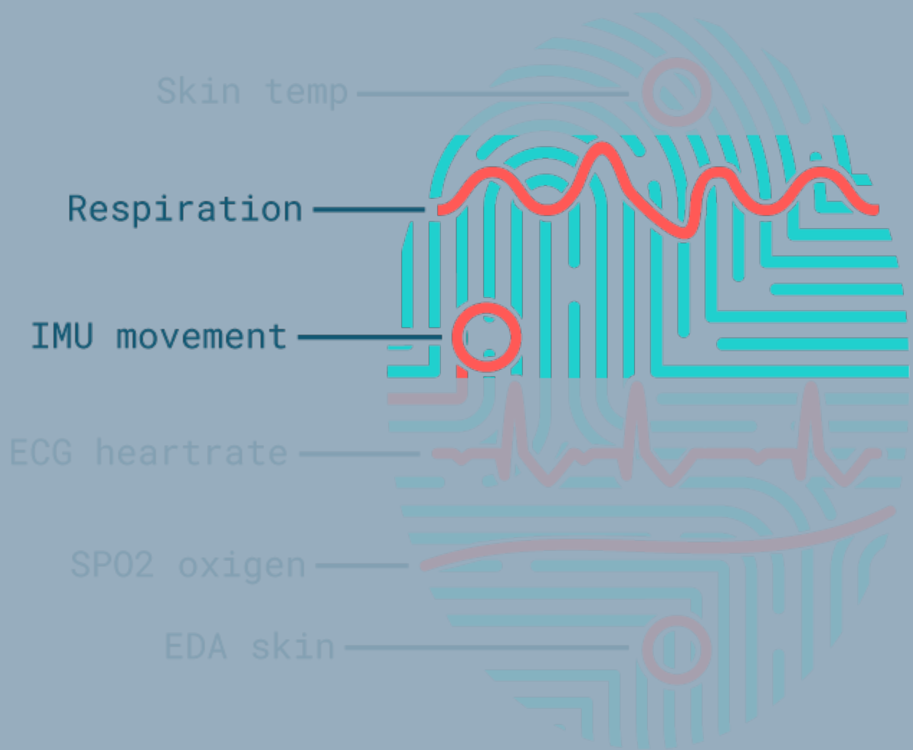
Textile circuit elements with various electrical properties can be created using the combination of traditional textile fabrication methods and conductive yarns or with additive processes and conductive films.

The movement of the upper body can be used as an analogue input for strain sensors, which are more suitable for capturing the direction and location of the muscle movements than other sensors. The essentials for successful applications are easy embeddedness, reliability, measuring range, good repeatability, good fatigue life, and good sensing properties. Although hysteresis (the bi-directional consistency of the strain curve) is still a problem for fabric sensors, knitted strain sensors comply with many essential properties.

A recent paper presented a manufacturing method for obtaining a low hysteresis knitted sensor with a working range of 40%, which will be used as a basis for this project. The waveform breathing data acquired by this sensor can be interpreted in frequency, amplitude, period, and mean value. Moreover, algorithmic filters can minimize possible noise from other body movements.

Alternatives on the market reflect the difficulty of achieving interdisciplinary synergy in product development, as most are either technology-oriented or lack a problem definition. Some share the focus on (respiratory) health (exercises) and can, without doubt, be learned from. However, the gap in the market can be found by focussing on getting a higher resolution for breathing topology and full sensor integration.

Design Direction



This chapter aims to transition from *why* challenges exist for treating hyperventilation disorder by describing *how* wearable technology can support these challenges. The background studies on medical challenges and technical opportunities give an impression of possible directions in which this project could grow. To interpret these, a possible working principle and core functionalities of the concept are defined and contemplated to systematically arrive at a concrete overview of exactly *what* components are required for development.

First, an interpretation of the insights assembled from the background research is communicated by formulating the design challenges and envisioned user scenarios [4.1]. In the chapter that follows [4.2], the working principle of the design is described, and the design functions that the product needs to perform in the user scenarios are considered with the aim of introducing a clear overview of the components that make up the design structure, which is discussed in chapter [4.3]. Conclusively, four fundamental requirement topics are specified to support design decisions throughout the prototyping phase [4.4].

4.1 Design challenges

The *vision* is to help patients regain control over their discomfort by learning to interrupt malfunctioning breathing behaviour. This chapter aims to interpret the takeaways of previous chapters and establish user-centric starting points.

On a medical level, the increasing amount of medical knowledge and specialisms available is making it difficult for clinicians and their patients to indicate the origin of the ailment. Errors in the diagnostical process can occur during every stage (figure 21). Such as during the presentation of the symptoms by the patient, whereby the day-to-day abundance of stimuli prevents one from listening to their body properly (fig. 21-1). Alternatively, during interpretations of the symptoms by a general practitioner whereby, in the limited time available, their focus could be drawn to the most dominantly present symptoms (fig. 21-2) and the most dominantly present treatments. This results in unnecessary visits to specialists and countless hours and money spent (fig. 21-3).

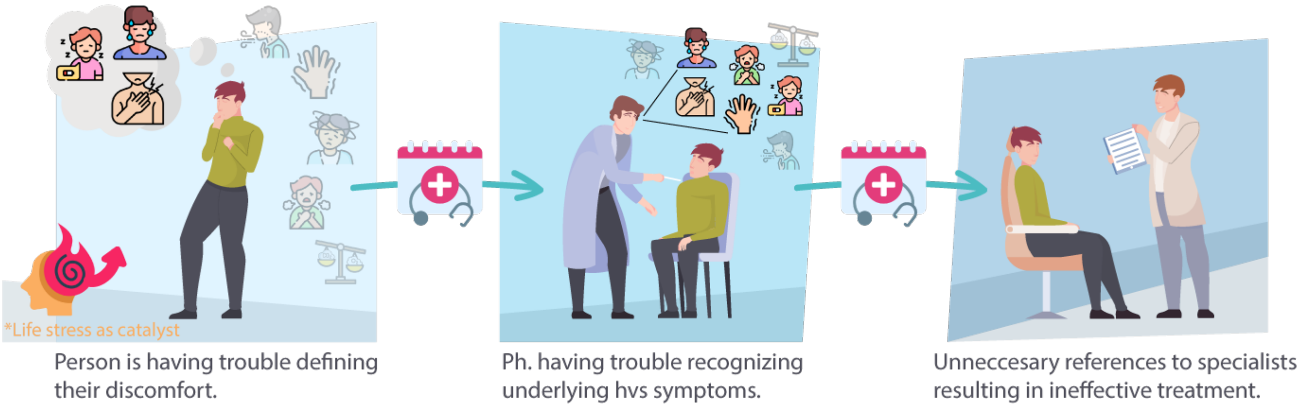


Figure 21: challenges during the diagnostical procedure

One such case is the diagnosis of chronic hyperventilation syndrome. The diagnostical error occurs mainly due to the broad range of symptoms, of which their cause can easily be mistaken. Hence, it is said that HVS can hide behind pseudonyms.

The challenge that needs to be addressed regarding treatment has much to do with the interruption of the self-perpetuating cycle of chronic hyperventilation. As discussed in the medical background chapter, regaining respiratory control is vital to restoring the disbalance of biochemicals in the body, which in its place is crucial to redemption from hvs symptoms.

Envisioned user context

For this, the focus should be on offering support in detecting physiological “clues”, the underlying symptoms that tend to be overlooked. Likewise, it is no exaggeration to emphasise the connection between body and mind. Saturated with an abundance of stimuli, it will become difficult to separate the wheat from the chaff. They make it difficult to listen to what the body is trying to communicate to the mind. This matter illustrates the necessity of precisely adding a technological element to the procedure as an implementation to restore the connection between body and mind if you will.

To emphasise the sole purpose of being of service to a human process, the following section puts this sentiment into more concrete terms. By illustrating possible user- scenarios in which wearable technology can assist in diagnosing and treating chronic hyperventilation syndrome. An extensive list of possible user scenarios can be found in Appendix 3.

Support during diagnosis

The eventual wearable product should assist a person in coming down with something to describe the discomfort they are experiencing. A possible scenario demonstrating the interaction with a future wearable product that could be of support during the diagnostic process can be seen in figure 22.

Figure 22: envisioned user scenario during diagnostics

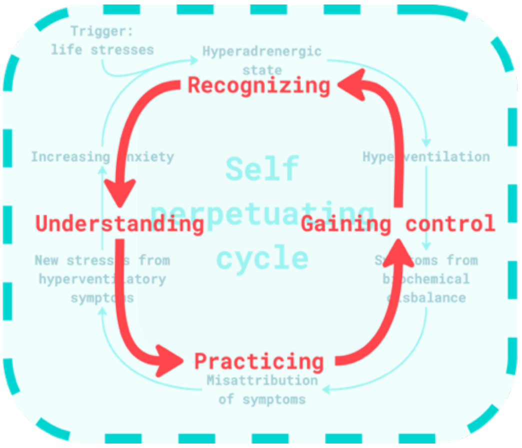
A significant impact can be made by enabling physicians to monitor their patients in the context of their lifestyles. Instead of a “spot check” [3], an extended monitoring period could drastically enhance the information available to base a medical indication. It could perhaps even pave the way for detecting correlations between physiological markers and a patient’s health status.
A system managing these cross-disciplined correlations could stimulate medical professionals to transcend the boundaries of their expertise. Moreover, it possibly increases the efficiency of the care process, for example, by providing a better accessible evaluation of a medical indication.
Despite the exciting range of applications that come to mind, medical professionals are sceptical towards this idea of getting a proper foothold in the short term (interviews).

Real-time preventative treatment

However, a more practical application of monitoring physiological functions can be realised by focusing on the treatment process. Figure 23 shows how a wearable shirt could utilise real-time monitoring [2] to alert users when detecting irregularities [3]. Offering preventative measures to stimulate solidifying breathing behaviour [4].

Figure 23: envisioned user scenario during treatment

For CHVS, "*regaining respiratory control*" plays a significant role in preventing and treating chronic hyperventilation. The defective breathing habit underlying the self-perpetuating cycle of chronic hyperventilation is merely a habit that must be interrupted and replaced by a functional alternative (Tavel, 2021). To counter the chronic hyperventilation cycle, the treatment focuses on the following steps the user will need to follow to correct a dysfunctional breathing habit:



1. **recognizing** the symptoms;
2. **understanding** the cause and effect;
3. **practising** diaphragmatic breathing;
4. gaining respiratory **control.**

Figure 24: countering the chronic hyperventilation cycle

Following the theory discussed in chapter two, the patient regains control over the symptoms by gaining control over the negative spiral loop. Slowly, doubt about their health will make place for regained trust and self-confidence.
Constant monitoring will make sure that signs of dysfunctional breathing behaviour, such as occasional deep breaths/sighs, a period of breathlessness, over-breathing, and reoccurring deep gasps (Rice, 1950), cannot go unnoticed.

As illustrated in the user scenario, the wearable will notify and inform the user via an interface. Likewise, building upon the user's needs, various functionalities can be identified to describe what a wearable monitoring product would require. To give direction to the concrete requirements the design must fulfil, the following chapter attempts to specify the system functions.

4.2 Design functions

It can be concluded that the *primary function* the wearable will need to perform can be described as the following: ***"Realising better diagnostics and treatment of chronic hyperventilation syndrome."*** This chapter describes the working principle upon which the wearable components can be based.

In essence, the concept should support patients during all four treatment steps as earlier discussed – *recognising, understanding, practising, and gaining control*. To gain insight into the flow of information necessary to achieve this goal, the system can be simplified in terms of an input-process-output (IPO) model (figure 25).

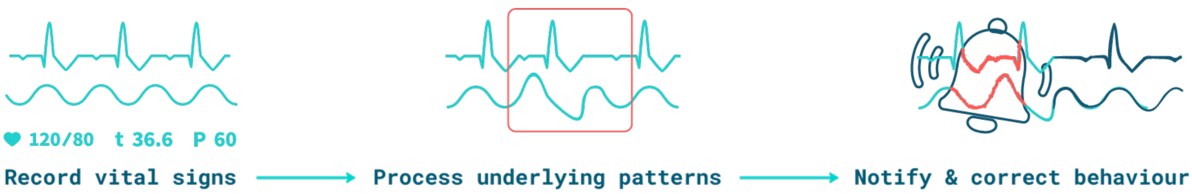


Figure 25: working principle in three steps

1. Vital signs are recorded describing the bodily functions and their subsequent symptoms.
2. Underlying patterns are detected, reflecting deviations from normal/healthy breathing behaviour.
3. Real-time, disturbances are recognized, and the user will be notified. The user will be informed about what is going on and advised to perform a breathing exercise.

In short, sensors will translate the information from analogue to digital, starting with the analogue inputs from the physiological functions. The data set can be processed with the help of pattern recognition software. It is analysed for (in)coherencies between vital signs and used by doctors to establish more accurate diagnoses and a more personalised treatment plan.
Even better, the data can be used to apply real-time education on the relationship between symptoms and how they "operate" their body, for example, by interactively guiding them through training on effective breathing behaviour. The following simple diagram illustrates the desired flow of information in and out of the concept on a main system level.

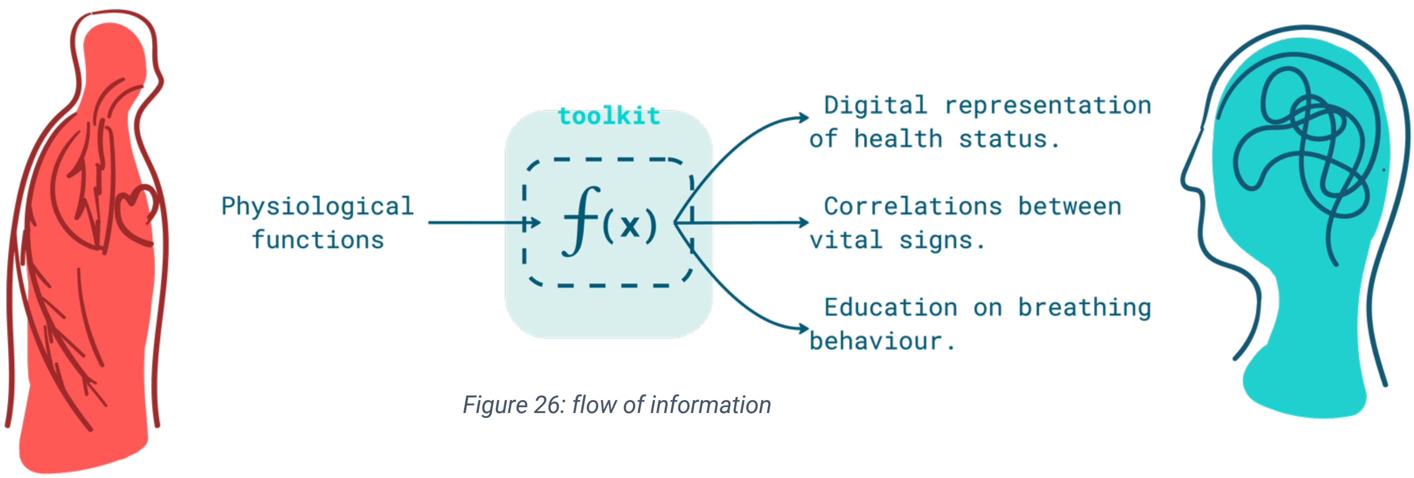


Figure 26: flow of information

Input – vital signs

Altogether, the information from the sensor measurements results in a collection of data (x) that makes up for what can be described as a *"digital representation"* of the body's vital signs or health status – or what could be considered as a unique *"fingerprint"* (figure 27). This fingerprint is made up of the datasets of all the sensors combined. Thus, the complete set of data – the fingerprint, is made up of elements, each representing a specific indicator of a user's physiological functions.
The combined set of data' data' x", also the input for the primary function of the concept "f(x)", can be described by the following sum.

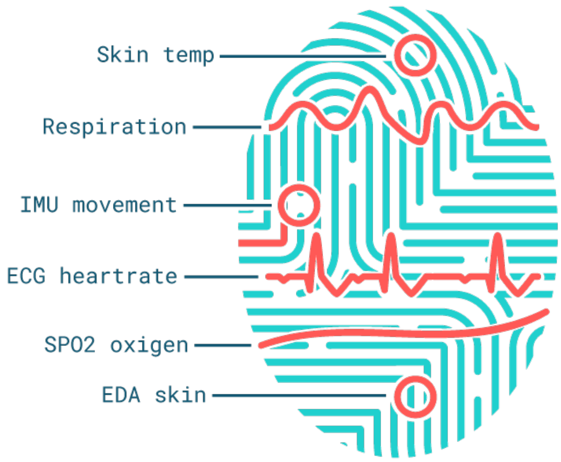


Figure 27: digital health 'fingerprint'

$$x = fingerprint = (T_{skin}, R_{resp}, I_{IMU}, R_{ECG}, Sp_{O2}, EDA_{skin})$$

Dataset	**Sensor type**	**Measurement**	**Physiological function**
$[T_{skin}]$	Thermometer	Skin (armpit) temperature	Body temperature
$[R_{resp}]$	Strain	Body circumference	Breathing data
$[I_{IMU}]$	IMU	Acceleration	Orientation, movement
$[R_{ECG}]$	ECG	Heartbeat signals	ECG
$[Sp_{O2}]$	Oximeter	Blood color	Saturation / SPO2
$[EDA_{skin}]$	Conductivity	Skin resistance	Perspiration

Figure 28: List of physiological datasets

Output – behavioural change

On the other end, the accumulated knowledge and insights about an individual's health status should be broadcast to offer practical understanding and support to the user. In other words, the principles for "improved treatment" discussed in the previous chapter must be translated into an interactive way of learning and improving breathing behaviour.

$$f(x) = (monitor, correlation, education)$$

Figure 29: visual impression of learning about patterns

Systematic overview

Four sub-systems with a specific task process can be derived from the primary function as a starting point, deconstructed into the three sub-functions (figure 30, [1- 4]). These sub-systems could be the starting point for Mediventic's complete project, called the "Mediventic Toolkit", to operate. This "toolkit" combines the product used by the end-user and a service intended for medical professionals to manage medical knowledge.

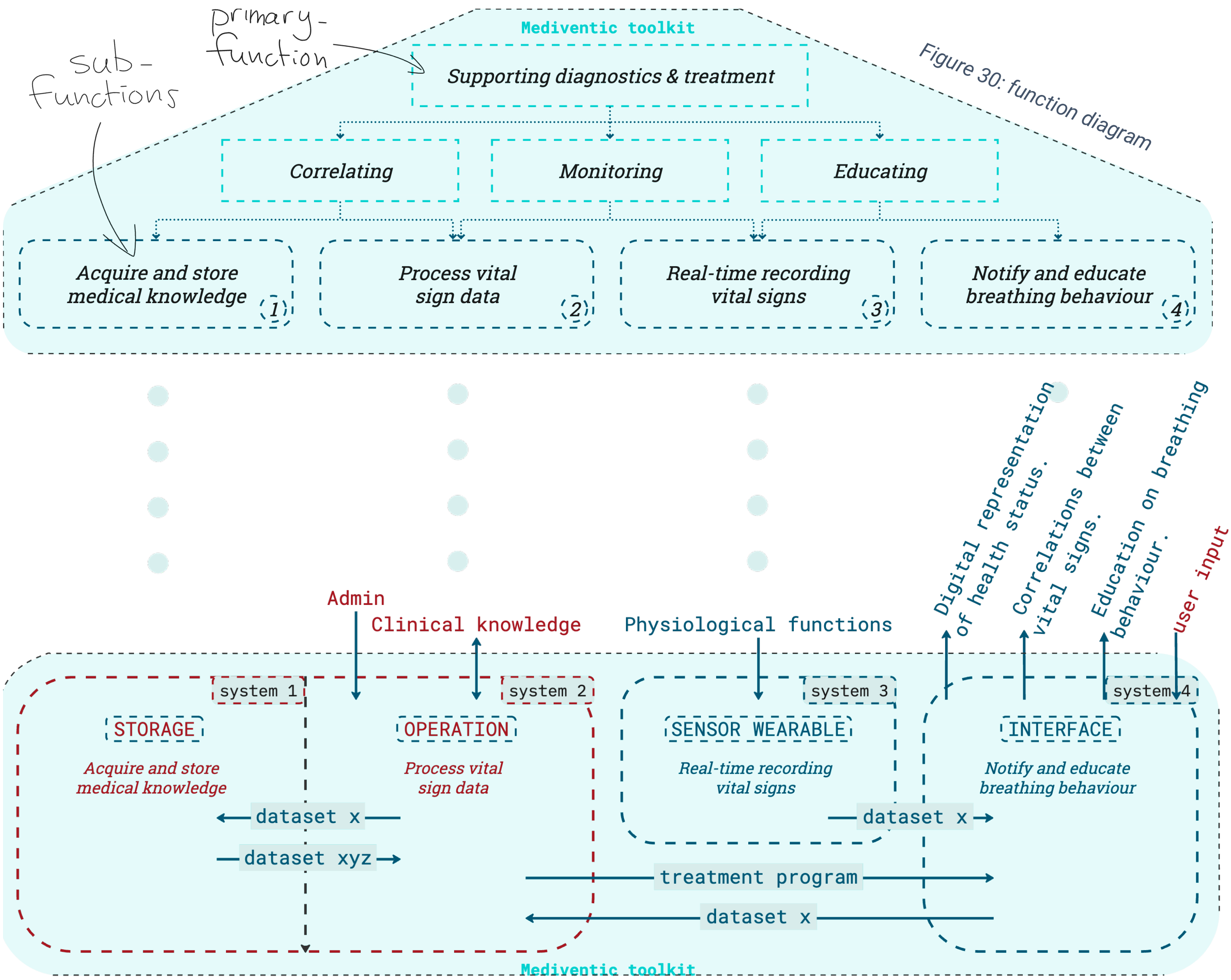


Figure 30: function diagram

The interrelations between processes 1 to 4 can be viewed on a sub-system level. The "fuel" moving back and forth can be described as pure "knowledge", albeit in data. This mainly involves physiological data as input captured by system 3, the wearable sensor itself. Which, in its place, transfers the dataset to an interface that is managed by the user (patient). The interface (system 4) is the gateway from which the user can interact, be notified, be educated, and with which the user can decide to share their data with their physician. On the left, the storage and operation systems (1 and 2) are used by medical professionals and Mediventic to process and acquire medical knowledge. In the following sections, this is discussed in more detail.

The service

Coordinating the latest clinical knowledge is the backbone of effective treatment application. Large datasets generated using the product could fuel the improvement of the pattern recognition software and optimise the treatment program. For example, Figure 31 overviews of the sub-functions required to support this greater purpose.

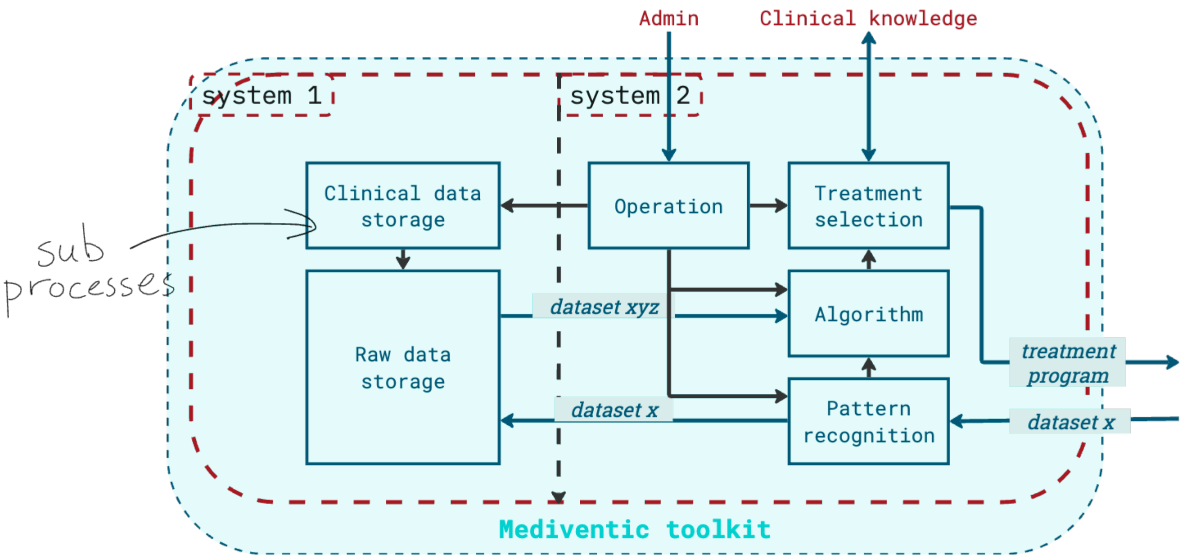


Figure 31: function diagram data management system

The product

The product could act as a gateway for acquiring data about the user's health and vice versa to provide the user with objective information and customized exercises. A wearable sensor (system 3) would translate from analogue measurements to a digital dataset. An interface (system 4) would be a communication channel that allows users to interact with the system. Given this project's scope, further consideration is narrowed to developing a wearable product. The product proposed to be developed can be considered a wearable consisting of a set of sensors that monitor various vital signs to detect respiratory problems." As can be concluded from the technical study, these kinds of textile garments integrated with a collection of sensors and electronics is called a "*textile system*."

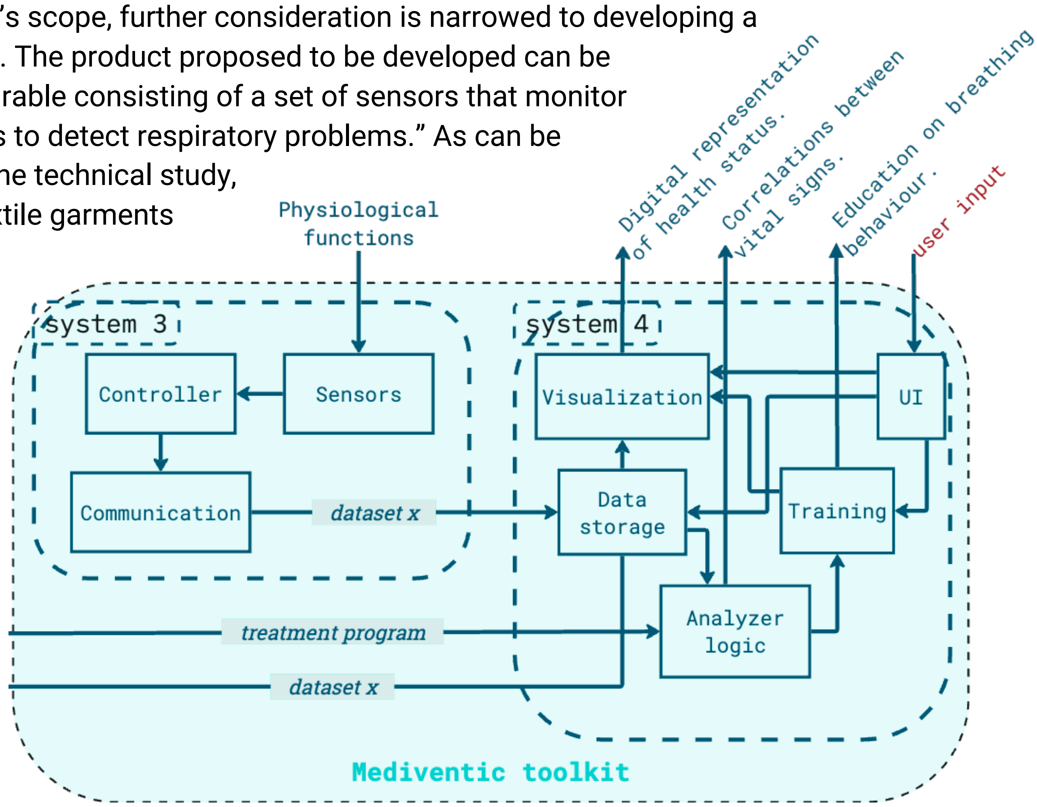


Figure 32: function diagram wearable system

4.3 Design structure

This step sets out to provide a more concrete description, describing the functionalities and positioning of concept components required for development.

Focusing on the user product development, system 3 – from this point referred to as the 'textile system' – can be divided into subprocesses *platform, input, processor, output,* and support components such as the *connections* (Figure 34). Each serves a particular goal, and in the following sections, each part is discussed.

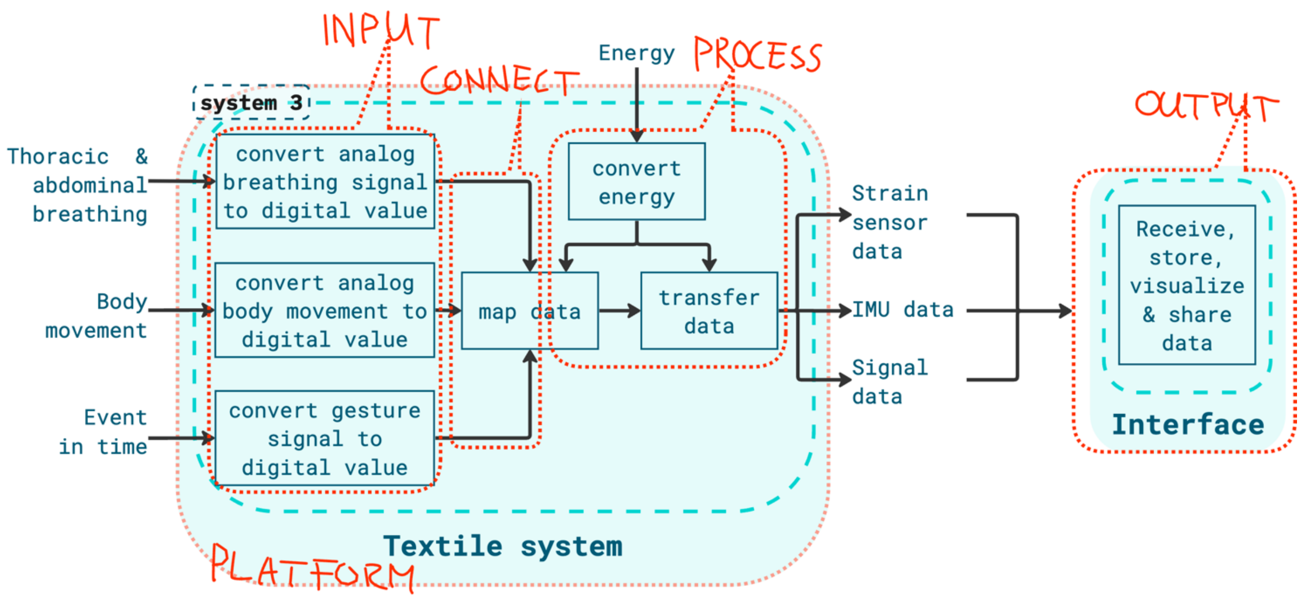


Figure 34: textile system systematic overview

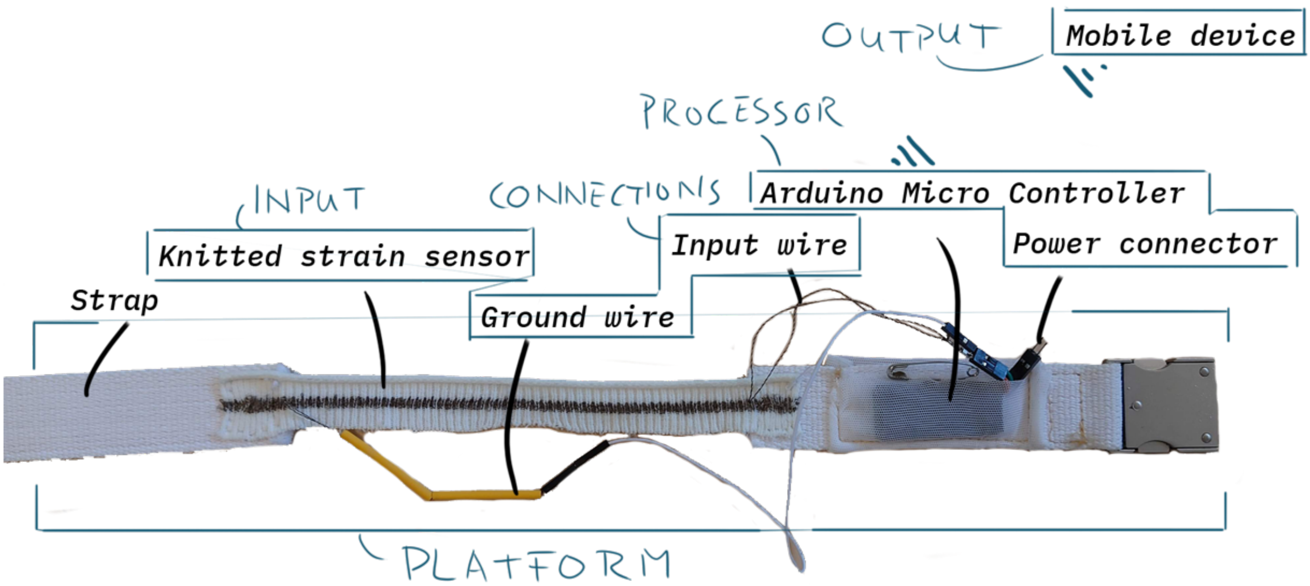


Figure 33: visual overview of textile system components based on the current sensor prototype

Platform: smart fabric

The platform's primary purpose is to provide a feasible foundation for manufacturing and a comfortable user experience. Research about the state of the art in wearable technology suggests that a textile garment format (a piece of clothing) could offer this. Reviewing the benefits:

- It provides a *large service area* for applying sensor placement and other electronic components for optimal functionality (Komolafe et al., 2021).
- *Qualities of textiles* beneficial for performance, durability, and comfort can be used to provide an attractive way of wearing electronics (Cherenack & Van Pieterson, 2012).
- Already, people are wearing textiles daily, thus transforming technological features into a familiar format, stimulating *user adoption.*
- Lastly, existing (industrial) *textile fabrication methods* can be used to manufacture innovative product forms; this especially applies to knitting since the strain sensors developed by Bozali et al. (2022) can be manufactured using conventional machinery.

The undershirt
Regarding user adoption, it is worth focusing on what type of clothing will suit the need for 24/7 wear. As some sensors of the production prototype of Mediventic's toolkit will have to be in contact with the skin, patients must wear the product under their regular clothes. On the other hand, this will allow patients to wear everyday clothes on top, likely promoting user adoption compared to a wearable worn in plain sight.
An undershirt (especially a tank top) is, therefore, a good option. A tank top is primarily not meant to make an appearance at all (Centeno, 2021), can be worn under any clothing, and has a unifying fit for a wide variety of body sizes.

Figure 35: types of undershirts

Input: strain sensor

The sensors are the crucial ingredient; they translate from analogue to digital. During this stage of the development (grad. project), the extensive set of sensors discussed earlier will be limited to data provided by the respiration sensors. The working principle will be further discussed in Chapter 5 – prototype development.

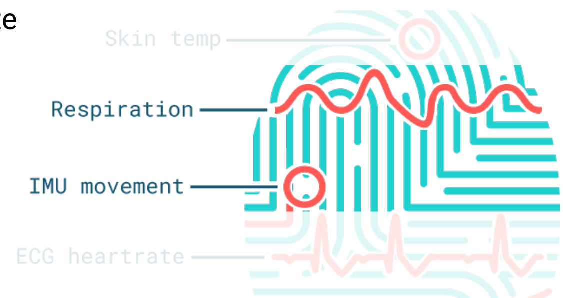


Figure 36: scope of 'vital fingerprint'

Sensor dimensions
Effective placement and dimensions of the strain sensors are essential for acquiring relevant breathing pattern insights. In particular, the difference between abdominal and thoracic breathing is of interest. The bodily movements during inspiration and expiration should be measured to get a high-definition perspective on respiratory behaviour. The placement can be based on the information about the variation in muscle movement. Where sensors 1 to 3 aim to sense thoracic (chest) breathing. While sensors 4 to 8 are expected to measure abdominal (belly) breathing. For this reason, it seems convenient to place the strain sensors in front of the body, where the extension of the body will be the largest. Next to that, only about 7 per cent of the population sleeps on their belly (Skarpsno et al., 2017).

Regarding the amount of expansion during breathing, clinical textbooks mention a lower standard limit of chest expansion ranging from 5 to 7.5 cm and 2.2 cm to 6.3 cm among subjects with respiratory diseases (Derasse et al., 2020).

More recent literature suggests that the reference range of chest expansion varies in different races and mentions an age-wise reduction of chest expansion (Reheem et al., 2020). In the latter study, the normal range of chest expansion was 2-5 cm, whilst an alternative study indicated average values of 4.8 cm and 4.0 cm (Derasse et al., 2020). Arguably, in practice, the working range for the strain sensors will have to deal with all limits mentioned, meaning that a range of 2 to 7,5 cm will have to be used. Throughout further development, the working range can be optimized.

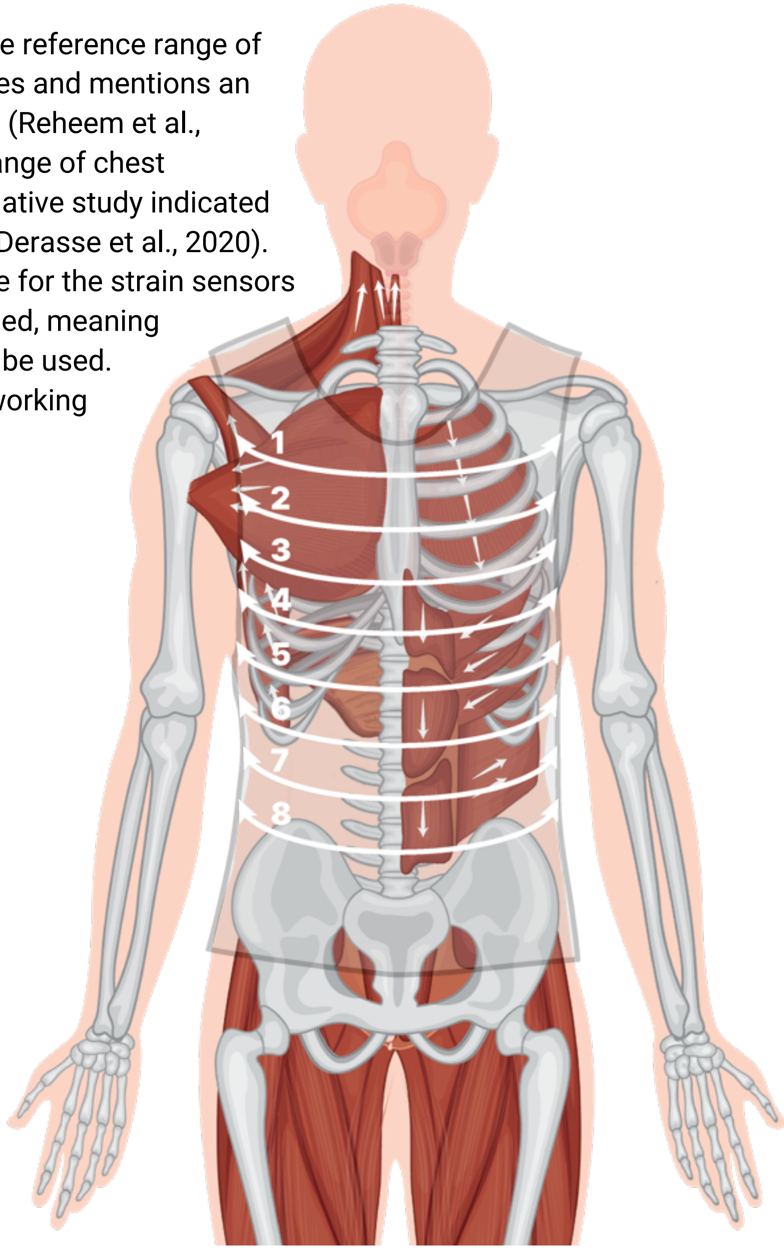


Figure 37: strain sensor placement

Process: controller

Processing the sensor signal and sending it by wireless communication is done by a microcontroller. For example, a previous version of the knitted strain sensor and its supporting electronics can be seen in Figure 33. The working principle and electrical diagrams will be clarified during prototype development. Just like the previous version, during this project's early-stage development, the components used will be sufficient to experiment with. Later, approaching manufacturing levels, a much smaller, dedicated electronics setup can be adopted.

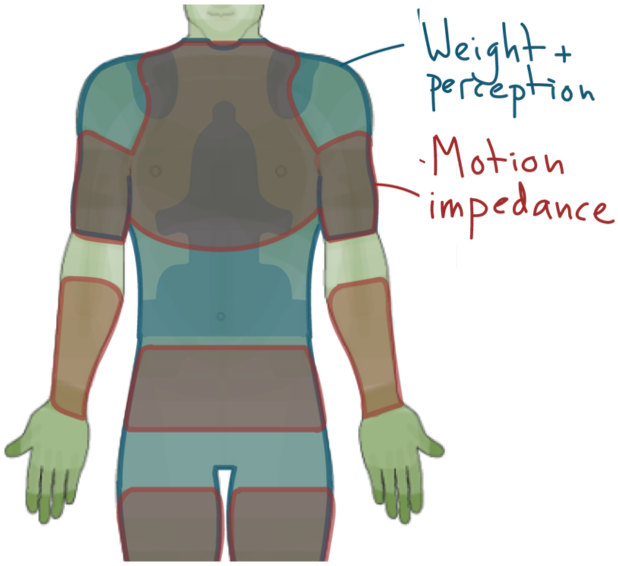


Figure 38: controller placement

Controller placement

In a study by Zeagler (2017), an extensive overview of 'body maps' (appendix 4) is given to determine where wearable technology should be placed on the body. Based on the relevant determinants provided in this study, the placement of various components of the 'textile system' can be found. In Figure 38, three determinants suggesting areas that avoid discomfort due to weight addition (1), an increased perception of self-size (2), and motion-impeding attributes (3) are used to identify a suitable placement for components.

Output: interface

Separate from the textile system, an interface will be used for a wide range of functions responsible for the interaction of the user with the data that is obtained. The processor sends data packages via a communication protocol to a device running the interface. Currently, a web-based interface is used for prototypes (figure 39), which will likely be used throughout development. A Bluetooth connection is made with the controller, and the data that is retrieved is plotted in real-time. A couple of features can be selected, defining, for example, at what rate the data is retrieved. This interface offers enough functionality to test the concept feasibility and rough working prototypes.

Looking at the range of other functionalities the interface needs to cover during a more advanced stage of prototyping; a lot needs to be designed regarding user experience. This, however, could be the starting point for a whole different graduation project; thus, development of this interface is limited to the following description of functionalities supportive of the themes: *notifying the user about possible episodes, educating the user about treatments, managing data permissions, and support for product usage.*

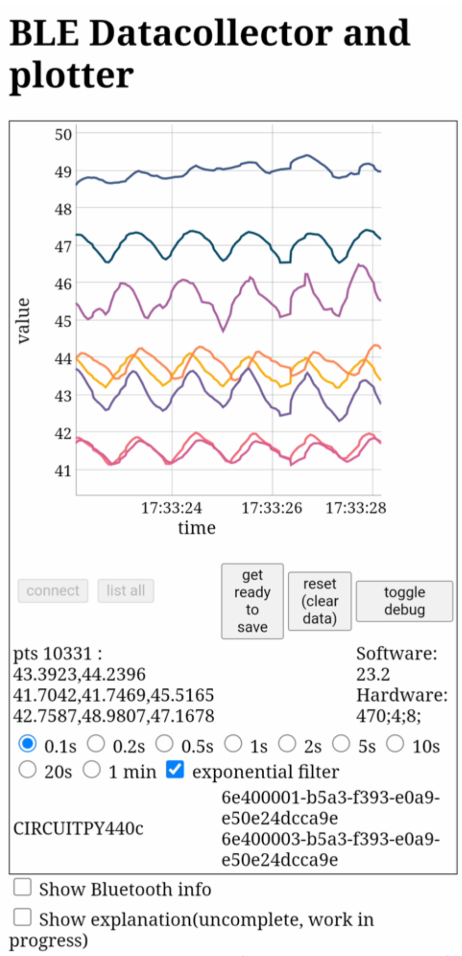


Figure 39: screenshot of datacollector interface

4.4 Design requirements

This section concludes the transition to concrete descriptors in the form of 'design drivers' and product requirements. These will offer a way to guide decision-making during prototype development.

In the previous sections, the concept's functionalities are identified to introduce the building blocks that make up the complete design. Defining practical starting points for prototype development points toward the actual design challenge; this project is about integrating knowledge from a diversity of disciplines (medical, electrical, textile). Following key factors discussed in previous chapters about the user needs, medical challenges, technical possibilities, and design components, an attempt is made to summarize three pillars for prototype development.

These 'design drivers' will give insight into the key factors determining the product's functionalities and specifications. This way, informed decisions can be made during the development of the prototype. Following the design drivers, a complete overview of the more specific list of requirements is given.

1. **Performance.**

The components that make up the whole 'textile system' must produce data that possesses enough fidelity to give detailed insight into a patient's breathing behaviour. The full spectrum of respiratory behaviour can only be captured if the prototype uses an adequate amount of strain sensors to establish at what location the breathing behaviour can, at best, be recorded. The user scenario requires the system to be able to operate in various *environmental conditions (walking, sleeping, working, etc.)* whilst keeping the sensor performance *consistent and reliable*.

2. **Manufacturability.**

The prototype should demonstrate possible manufacturability challenges and opportunities for further development, experimenting with the integration of strain sensors, wiring, connectors, and conventional electronics into a textile form factor. Using existing manufacturing techniques and tactful integration of the various components should keep costs low.

3. **Usability and comfort.**

The mission is to deliver a comfortable experience for the user. The fitting and usability of the wearable should not restrict the user from executing everyday tasks and activities. An unintrusive design involves using materials and component designs that retain the comfortable qualities and familiarity of regular clothing.

List of Requirements

Requirement	Source	
Performance		
1. The breathing movements must be mapped using at least eight sensor streams, reflecting abdominal movement to upper chest movement. a. Measuring the strain of each sensor as a relative change in body circumference. b. At a rate of 20 times per second. c. Expressed as an integer value per sensor greater than 0. d. The value has no absolute meaning or precision; the application is interested only in the relative change over time;	Mediventic functional description V03 (MeFdV03) *on sensor performance*; Ch. 2.2.5 *on monitoring.*	
2. The following properties of breathing patterns must be captured and translated to understandable values. a. Time and a relative value representing the strain in the sensor as a consequence of change in body circumference in such a way that it allows calculation of the properties: frequency; amplitude; period; mean; sensor number; timestamp.	Chapter 3.2.1 *on breathing patterns*	
3. Noise should be recorded and translated to calculable and usable properties. a. Recording body movement b. Discriminating noise in the sensor data.	MeFdV03 *on sensor performance*	
4. The controller should be detachable, and battery powered. No electrical connection between the garment and mains should be possible.	Ch. 3.1.3 *on integration*	
5. A Preliminary version of the mobile app that handles and shows this data is provided. a. The data could be displayed as a digital representation of the body.	MeFdV03 *on app requirements*	
6. The sensor must have an adequate working (expansion) range of 75 mm.	Ch. 4.3 *on sensor dimensions.*	
7. The sensor hysteresis must not be higher than 0.07.	Bozali et al.(2022) *on optimiz. values*	
Environment & safety		
8. The product must be resilient against and functional in conditions during 24/7 wear. a. Various environmental contexts include sleeping, sitting, walking, running, standing, perspiration, and heat.	Ch. 4.1 *on user context*	
9. Every sub-assembly of the product must be IP65 secured for dust and water.	"	
10. The wearable must not contain any materials that are harmful to the skin.	Ch. 4.3 *on platform*	
11. Voltages and resulting currents should be contained and be far less than applicable standards dictate (appendix 5).	MeFdV03 *on safety*	

12. The monitoring controller should be connected to the sensor garment using a rigid waterproof connector.	Ch. 4.1 *on user context*	
Ergonomics		
13. The controller should be small enough to fit under clothing and not be noticeable by the user or others.	Ch. 3.1 *on wear and integration*	
14. The controller should not prevent users from having a good night's rest.	Ch. 4.1 *on user context*	
15. The product should be easy to wear, to put on and to put off. a. The product's fit should not restrict users from executing tasks during the day.	Ch. 4.1 *on user context*	
Durability & maintenance		
16. The sensor must have a good fatigue life and give reliable repeated cyclic tests for 24/7 wear.	Ch. 4.1 *on user context*	
17. The base garment, including the sensors, should be washable at least 100 times using water at room temperature and a mild detergent.	Ch. 4.1 *on user context*	
Production		
18. Facilities: The integrated sensors should be made using traditional clothing production facilities for the production prototype.	3.2.4 *on fabrication technology*	
19. Quantity; Depending on the final prototypes target market an approximation of 2000 to 7000 units will have to be manufactured in Y5.	Mediventic Business Plan V05 *on production volumes*	
20. The design should anticipate on future add-ons and manufacturability by Mediventic's development partners.	MeFdV03 *on project objectives*	
Materials and finish		
21. Functional properties of regular fabrics should be maintained: a. Drapability; flexibility.	Ch. 3.1.2 *on smart textiles*	
22. Comfort properties of regular fabrics should be maintained: a. Breathability, air permeability, humidity transport, thermal retention.	Ch. 3.1.2 *on smart textiles*	

Finally, a series of research questions related to these requirements should be considered when proceeding with prototype development. It will be used throughout the evaluation of prototypes to ensure the relevance of design decisions and iterative steps.

RQ1. What is the effectiveness of using knitted sensors to monitor breathing patterns, ensuring consistent accuracy across diverse activities?
RQ2. What features of the design of the smart shirt impact the user experience, including comfort, ease of use, and aesthetics, during various activities?
RQ3. What are key materials and manufacturing methods that make the 'textile system' both sufficiently integrated and feasible to produce?

4.5 Chapter takeaways

The wearable technology discussed in this chapter is a collection of sensor types and electrical components that record biometrical data. The aim is to deliver a better experience to the wearer and move away from conventional wearables dominated by the electronics field. The challenges that need to be addressed include

- stable performance in various user contexts and activities,
- full integration of electronic components necessary for the design functions and
- unintrusive, comfortable, and flexible product form.

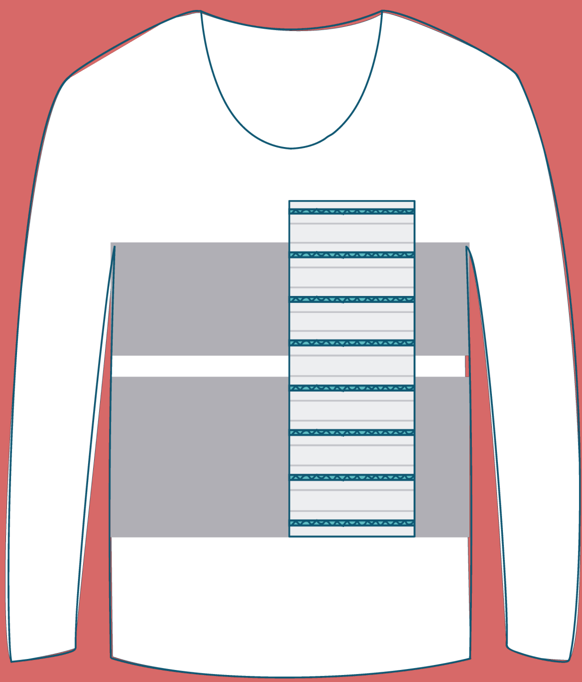
To overcome these challenges, using textiles to integrate electronic components with garments is an attractive solution. This requires full multidisciplinary integration but retains valuable qualities such as comfort, flexibility, and aesthetics. Textile circuit elements with various electrical properties can be created using traditional fabrication methods and conductive yarns or additive processes and conductive films.

Strain sensors are particularly suitable for capturing the direction and location of muscle movements and can be embedded within textiles. The essentials for successful applications are easy embeddedness, reliability, good measuring range, repeatability, fatigue life, and sensing properties. Although hysteresis remains a problem for fabric sensors, knitted strain sensors comply with many essential properties.

While some alternatives on the market focus on respiratory health exercises, they lack interdisciplinary synergy in product development. The gap in the market can be filled by focusing on getting a higher resolution for breathing topology and full sensor integration.

Recent research has presented a manufacturing method for obtaining a low hysteresis knitted sensor with a working range of 40%, which will be used as a basis for this project. The waveform breathing data acquired by this sensor can be interpreted in frequency, amplitude, period, and mean value. Algorithmic filters can minimise noise from other body movements.

Product development



During the development phase, the ideas presented in the previous chapters will be materialized by integrating the components identified into a tangible prototype. To reach a technology readiness level that demonstrates relevance, the aim is to fabricate a working prototype that can be tested in a test environment.

As textile systems are a relatively new area in industrial design, the development phase can be considered *experimental in nature*. Chronologically seen, prototype development took place parallel to conceptualization. The development of the prototype will be presented in such a way that the iterative steps can be observed in various versions of the prototype. In each version of the prototype, the focus will be on a different design driver. Thus, a version will be elaborated in each chapter, presenting the design decisions and insights from experiments or tests.

First, the sensor material developed by Bozali et al. (2022) is explored, focusing on the manufacturability of the material [5.1.1] and its performance and functionality [5.1.2]. The components are incorporated into a prototype [5.2.1], and the second prototype improves performance and comfort [5.2.2]. Brief takeaways are at the end of each subchapter [5.1.4 & 5.2.3].

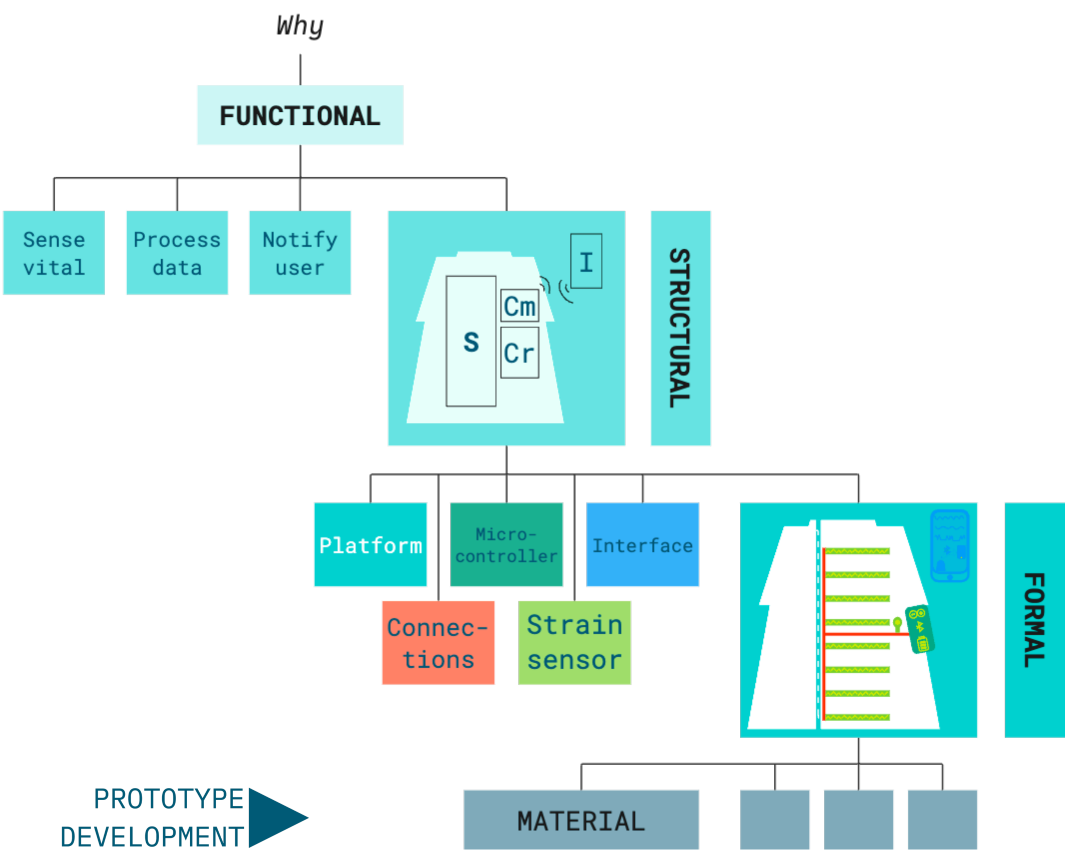


Figure 40: from functional to formal

5.1 Sensor development

During the development of the sensor material, the aim is to learn about the fabrication method and material properties of this textile sensor technology.

From the literature, we can conclude that the essentials for the successful application of textile-based strain sensors are easy embeddedness, reliability, measuring range, good repeatability, good fatigue life, and good sensing properties (Tao, 2015).
Thus, the manufacturability and working principle of the knitted strain sensors, as developed by Bozali et al. (2022), will be demonstrated and assessed for feasibility. To better understand how a textile sensor can technically be integrated into existing textiles.

Different versions of the sensor have been made with different intentions. First, the focus is on how it is physically made, as well as demonstrating the working principle of the sensor. The next version will iterate on the sensor layout, attempt multiple sensor rows and test the sensor performance. Lastly, the integration with electronics and a way to transfer the data is explored.

Sensor version 1: manufacturability

Goal
To understand the process of manufacturing a knitting strain sensor.

Materials

I. *Software. T*he knitting pattern of the weft-knitted strain sensor developed by Bozali et al. (2022) will be used. The technical staff provided the original knitting file **(.mdv file**), in which a **1x1 rib structure** and a **double-plated two-course** conductive embedding are used, with a knitting density of **NP9** (Figure 41-2).

II. *Fabric materials*. Using the material specifications given by Bozali et al., **E1** and **S1**, respectively, **elastic yarn** from Yeoman (Nm 13, 81% Nylon and 19% Lycra) and **conductive silver-plated yarn** from Shieldex (600 Ω/m) was used.

III. *Manufacturing machinery.* A Stoll CMS 530 flatbed industrial **knitting machine**, with 14 needles per inch, was used to fabricate the knitted sensor (figure 41-1). For the two-course conductive embedding, a yarn carrier containing two parallel yarns, also known as **a double-plated yarn carrier** (Figure 43), was used. An important note is that the conductive wire should be spun on the inside (CI).

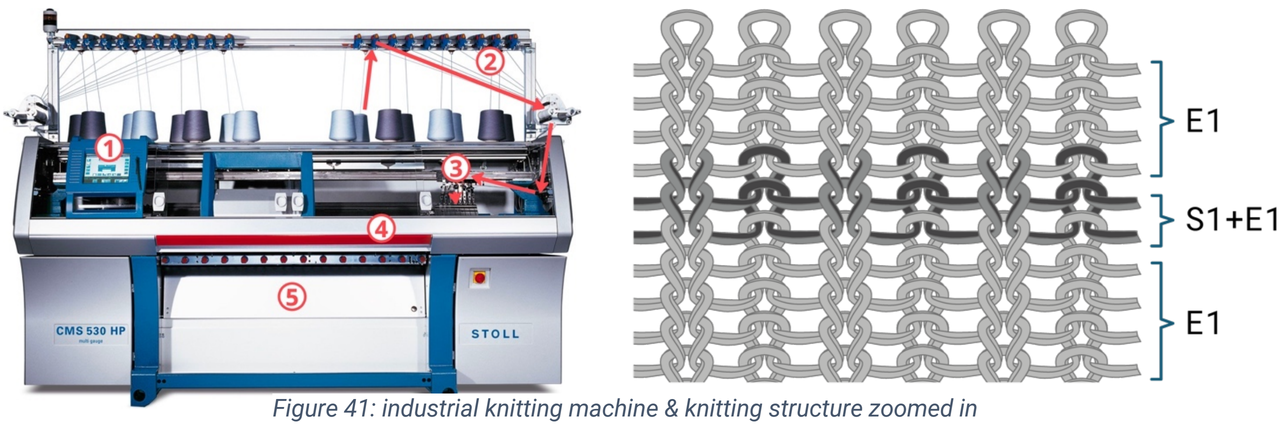


Figure 41: industrial knitting machine & knitting structure zoomed in

Fabrication
A brief overview of the steps needed to fabricate the knitted strain sensor developed by Bozali et al. (figure 42).

1. The original .mdv file was used and loaded into the software of the stoll cms 530.
2. The materials are assembled and mounted on the Stoll, spun via the yarn feeders, and to the yarn carriers.
3. For the combination of E1 and S1, a double-plated yarn carrier is used where the conductive yarn goes in the moon shape and the elastic yarn into the o-shape (Figure 43).
4. The knitting process is started.
5. The knitted strain sensor can be taken out of the machine.


Figure 42: strain sensor by Bozali et al.

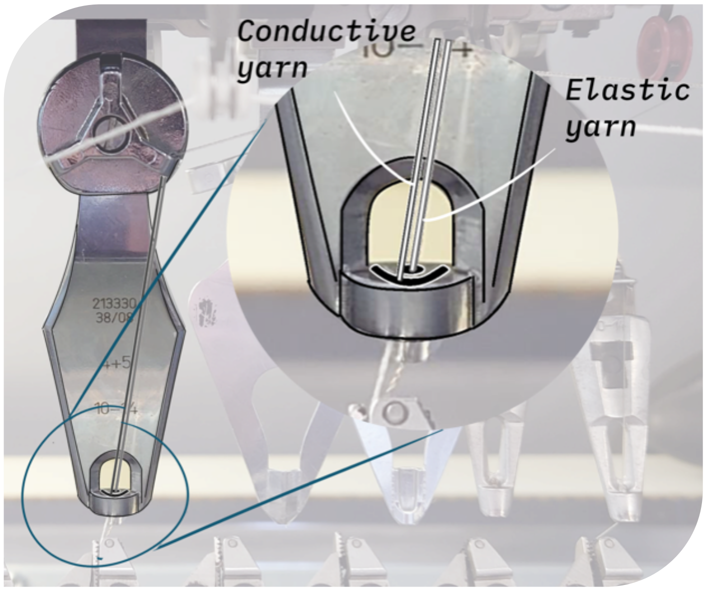


Figure 43: double plated yarn carrier

Result
Resulting is the first version of the knitted strain sensor. Two sizes were knit, [v1.0 & v1.1], with lengths of 700mm and 100mm

Test 1 – working principle

Goal
To test the working principle of changing electrical resistance.

Material & method

I. Sensor v1.0 & v1.1.
II. Multimeter.

Both versions are clamped on the multimeter to measure the electrical resistance in ohms at different lengths.

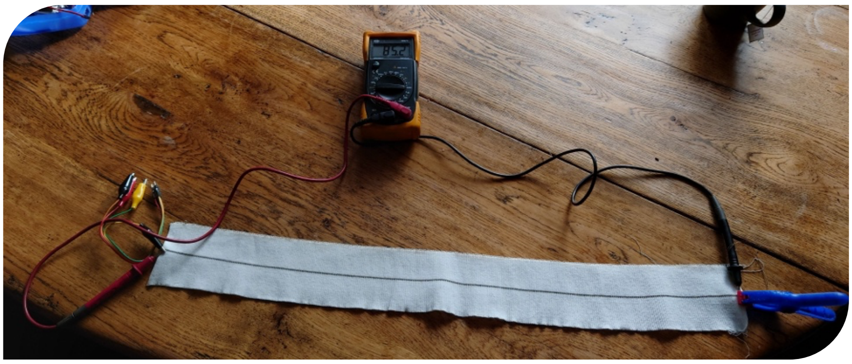


Figure 44: testing setup test 1

Results

v.	Length_0	Length_displ.	**mm change [%]**	Resistance_0	Resistance_displ.	**Ω change [%]**
1.0	700 mm	840 mm	**~ 20 %**	86 Ω	113 Ω	**~ 32 %**
1.1	100 mm	120 mm	**~ 20 %**	18 Ω	26 Ω	**~ 44 %**

This first hands-on test shows the electrical working principle and sensing properties in an introductory manner. It demonstrates that the resistance changes as the material is stretched. Moreover, the percentual change of resistance compared to the percentual change of displacement in v1.1 is considerably larger than in v1.0.
A preliminary conclusion is that in order to get a high enough percentual change in ohms for the prototype, it is recommended to use a short sensor length.

Test 2 – sensing properties v1.1

Goal

To understand if sensor v1.1 has good enough sensing or electromechanical properties. More specifically, the intention is to determine the sensitivity and precision of the knitted strain sensor.

Material & method

I. Sensor v1.1
II. Tensile testing machine (TU Delft)
III. LETT software (TU Delft)

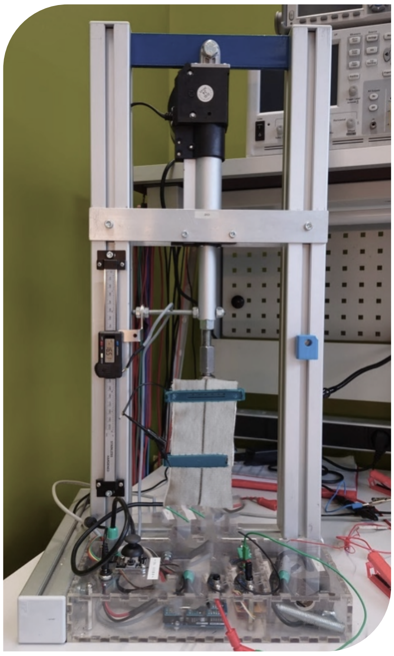


Figure 45: tensile testing setup test 2

V1.1 is clamped into a tensile tester with a starting length of 60mm (L_0). As recommended by the sensor developers, a displacement of 15mm ($l_{disp.}$) was set to get a strain of 25% and a test was run for four cycles.

The relative change ratio describes the strain sensor's sensitivity, the Gauge factor. To determine the precision, the linearity of the sensor behaviour is examined. The slack between the path of tension and the path of relaxation, the hysteresis, is used to define the degree of linearity.

Results

The third cycle is plotted in Figure 46. The complete results can be seen in Appendix 6.

- The estimated Gauge factor is: **GF=0.57**

Discussion

In retrospect, there is a lot of noise and irregularities likely originating from poor electrical conduction or insufficient clamping force in the connectors.

The electromechanical properties are comparable to the average results from the article but considerably less good compared to the Gauge factor of the best-performing sensor presented, with GF=1.19. Regarding sensitivity, a provisional gauge factor of 0.57 is good enough, but the test results are too inconsistent and noisy to draw a definite conclusion or determine the hysteresis.

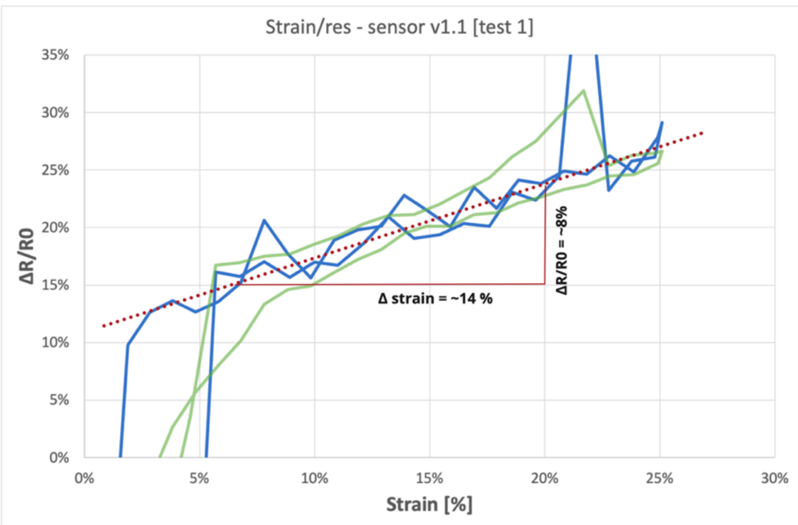


Figure 46: third cycle plot test 2

5.1.2 – Sensor version 2

A follow-up on the sensor material is made version 2. This version is built out of 8 rows of sensors and optimised for tensile testing.

Goal
To fabricate a sensor material that enables testing multiple sensor streams and limiting noise from poor electrical conduction.

Materials & fabrication

I. *Knitting software.* The original file with rib structure, knitting density, and two-course double plating was used. However, the courses are multiplied by 8 in the knitting file to get eight strain sensors on the same knitting piece.
II. *Fabric materials.* The original material specifications were used.
III. *Manufacturing machinery.* The same Stoll knitting machine and double-plated yarn carrier were used.

The material is knit according to the standard steps provided earlier. In addition, with cable lugs and small bolts, the electrical connection is improved by applying a tighter fit and a larger surface area.

Result
Resulting is version 2.1, the first version with eight sensor rows and a comparatively reliable wire connection.

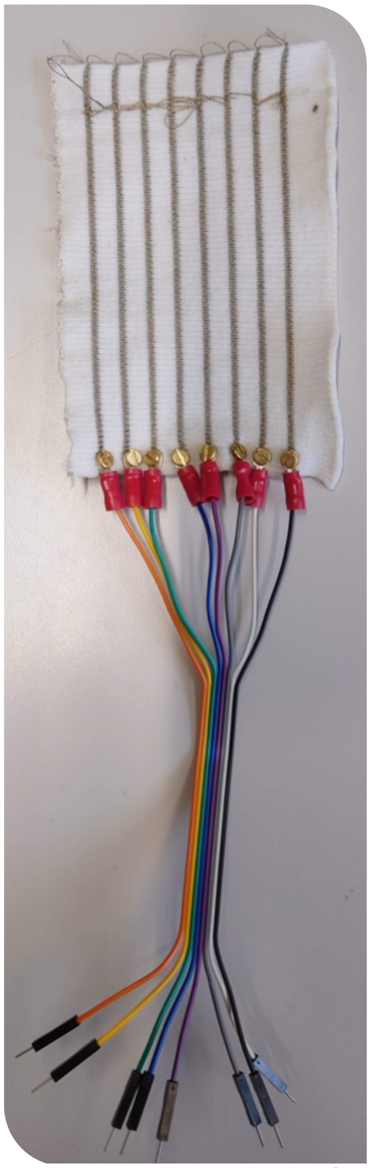


Figure 47: sensor material v2

Test 3 – sensing properties v2.1

Goal
To test if sensor v2.1 has acceptable electromechanical sensitivity and precision compared to the article's specifications.

Material & method

I. Sensor v2.1
II. LETT (Low-End Tensile Tester) machine. A tensile testing machine equipped with an Arduino, specially designed for testing tensile properties in soft electronics, is provided by the TU Delft's technical staff at the Applied Labs IDE.
III. The corresponding LETT software allows changing the type of tensile test and various other settings.

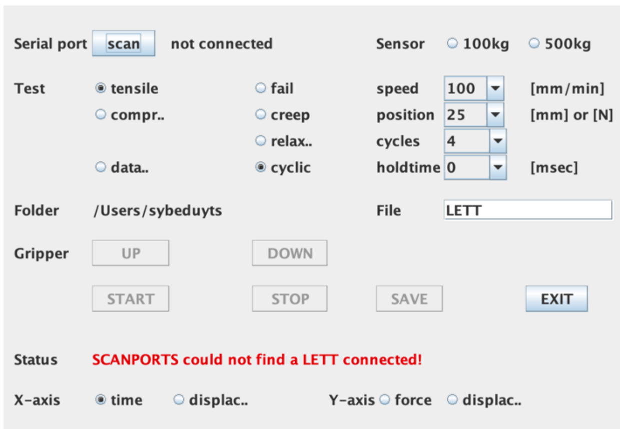


Figure 48: LETT software settings cyclic tensile test

Method:

1. V2.1 is clamped into a tensile tester with a starting length of 70mm ( ). A displacement of 25mm ( ) was set to get a strain of 35%.
2. As the tensile tester can only read one sensor stream, the fifth sensor row is used to analyse the sensing properties.
3. The values of Gauge factor ('sensitivity') and hysteresis ('linearity') are obtained.

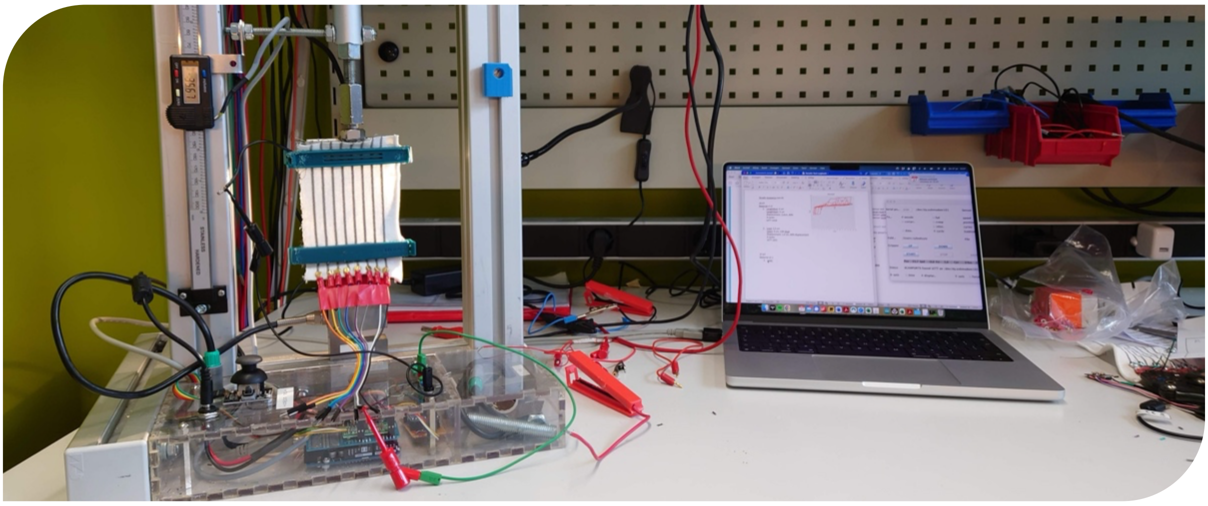


Figure 49: testing setup test sensor v2

Results

The result is plotted in Figure 50. The estimated Gauge factor is **GF=0.68.** The estimated hysteresis is about **10%.**

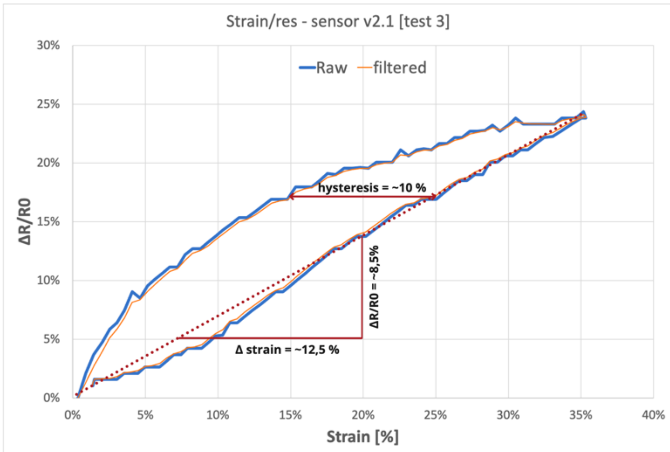


Figure 50: Result sensing properties test 3

Discussion

The first thing that stands out is that the results look more dependable. Likely due to, but not limited to, the improved connections show their impact. However, residual electrical current from adapters or a laptop also results in noise.

Positively, the Gauge factor is higher than the first version but still not comparable to the results from the paper by Bozali et al. The same can be said about the hysteresis value, which does not even come close to the low hysteresis values.

Since the same materials are used, it gives the impression that either something went wrong during fabrication or that the layout of the sensor material indeed results in different sensing properties.

Test 4 – cyclic behaviour v2.1

Goal

To assess the reliability in terms of accuracy of electromechanical performance in repeated strain tests.

Material & method

I. Sensor v2.1.
II. LETT tensile testing machine + software (TU Delft).

Method:

- In the same setup as test 3, v2.1 is tested for cyclic behaviour. Eight cycles are recorded.
- ($L_0 = 70mm$); ($l_{disp.} = 25\text{mm}$); the fifth sensor row is for tests.

Results

The result is plotted in Figure 51. The resistance range shows reasonably repetitive performance, moving approximately between an upper boundary of 16 Ω and a lower boundary of 13.6 Ω. With the mean at ~14.8 Ω, the amplitude is relatively steady at A≈1.2 Ω. The period of one cycle is about T=24 s.

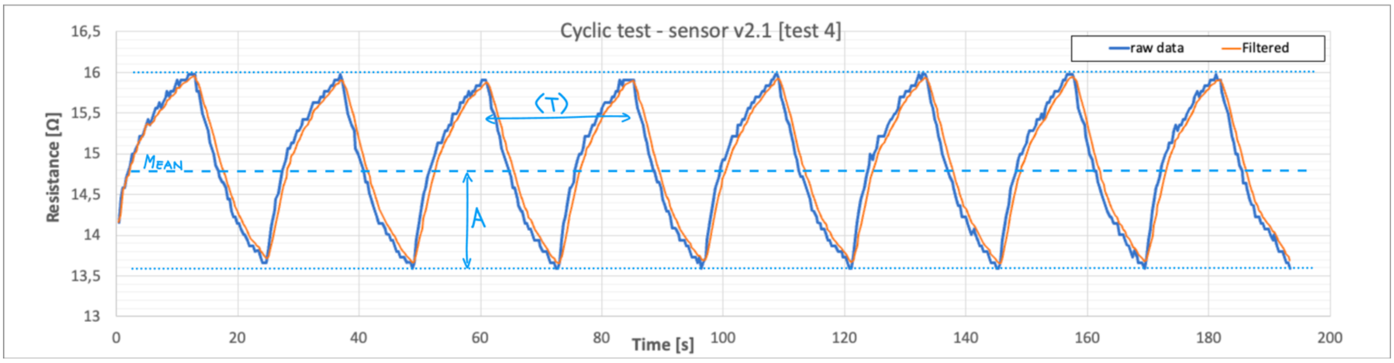


Figure 51: result cyclic test 4

Discussion

This plot illustrates how different properties of the wave pattern could be used to define the cyclic behaviour of the strain sensor. With the use of *frequency (f), amplitude (A), period (T), and mean,* a wave pattern that could be associated with a particular 'breathing behaviour' can be assigned. Additionally, as shown in Figure 52, the sensor displays consistent electromechanical behaviour.

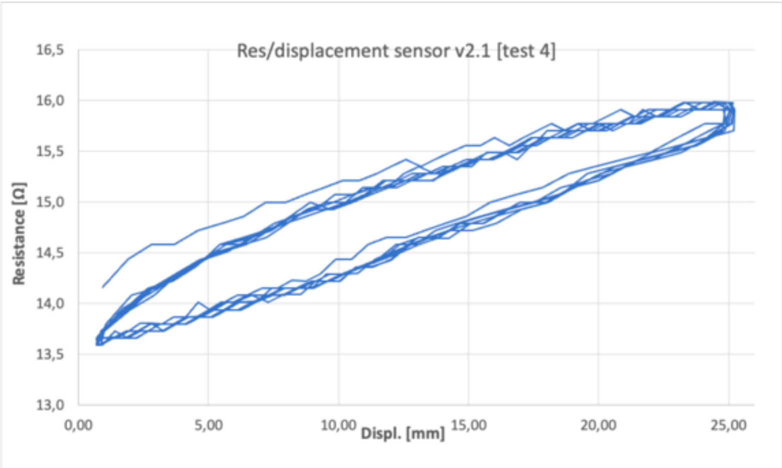
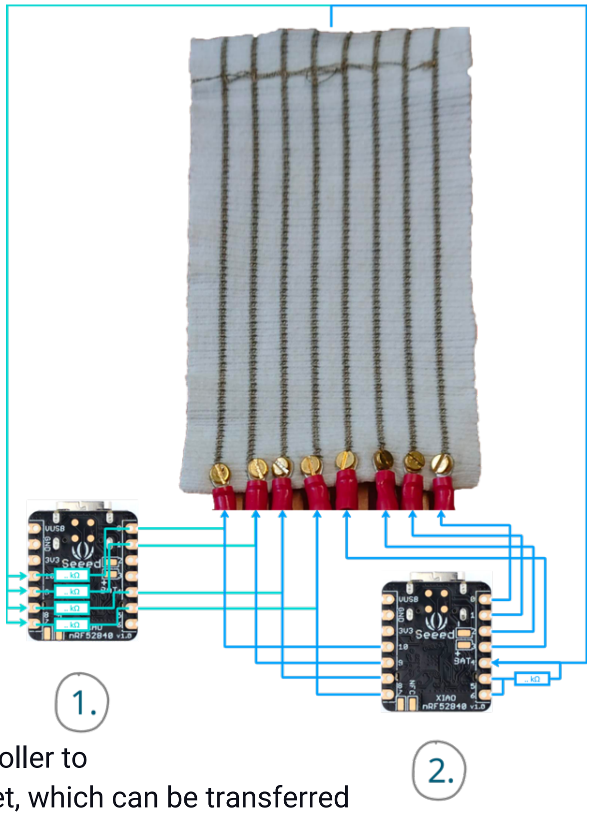


Figure 52: sensing properties test 4

Figure 53: Two iterations of connecting sensor and controller



5.1.3 – Sensor sub-system

Recording the strain sensor properties, translating them, and transferring the dataset to a mobile interface is done by additional electronics. The data from 8 sensor rows can be recorded and transferred via a wireless connection using a simple prototyping microcontroller

Goal

Record 8 sensor rows simultaneously and transfer them via a wireless connection to a mobile device.

Materials & fabrication

1. Sensor v2.1.
2. Seeed Xiao BLE Sense. A small electronic prototyping platform runs on Arduino or micro Python. A code written by the technical staff of Applied Labs is used to instruct this microcontroller to convert the analogue signal into a digital dataset, which can be transferred via the onboard Bluetooth module to a device. A 3.3V power supply can power it.
3. A laptop or mobile device can run the web-based interface and connect to the Xiao via Bluetooth.
4. Web-based interface with which a real-time data feed can be monitored, the refresh rate can be changed, and the data can be saved as a .csv file.

In the first instance, a setup (figure 54, 1) was made to record four sensor streams simultaneously. Using four of the six available analogue inputs on the Xiao, each signal is recorded simultaneously due to the lack of enough analogue ports to record eight analogue signals at the same time; in situation two (figure 54, 2), a technique called 'multiplexing' is used. The controller switches between the power from digital inputs D0-D10 one after another at a fast pace. Each step records the signal of 1 of the eight sensors using the same analogue input. Combined, this provides a near-accurate image of the real-time measurement of all sensors.

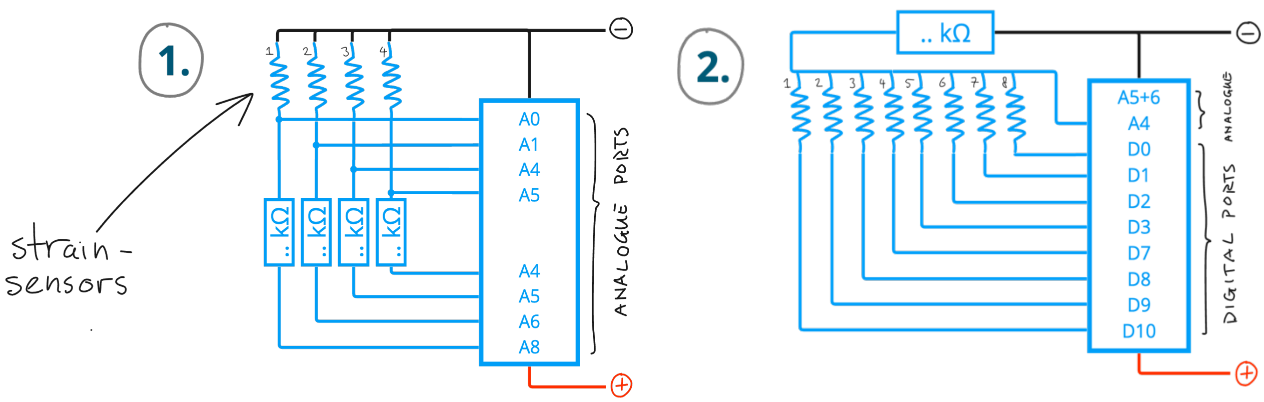


Figure 54: Two variations connection diagrams

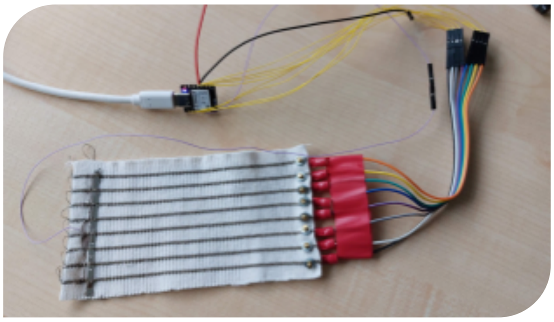


Figure 55: Sensor material assembly

Test 5 – performance of controller and sensor

Goal

To test the quality of data collection of the sensor sub-system.

Material & method

I. *Sensor sub-system v2*, the combination of the sensor material and microcontroller.
II. *Laptop + BLE data collection interface*.
III. *LETT tensile testing machine*.

The Xiao of the sensor sub-system is powered via USB-C and connected via Bluetooth to a laptop. The tensile tester was set up like in test 3, running for four cycles. The starting length is 83mm with a 40% strain of about 33mm.

Results

A plot of the results is given on the right. The absolute values have been altered without affecting the relative change, so the graphs are spread to make the results insightful.

- The amplitudes of each sensor vary between 1.5 and 2 Ω (Figure 57-1).
- The Gauge factor and hysteresis differ between sensors (figure 56).

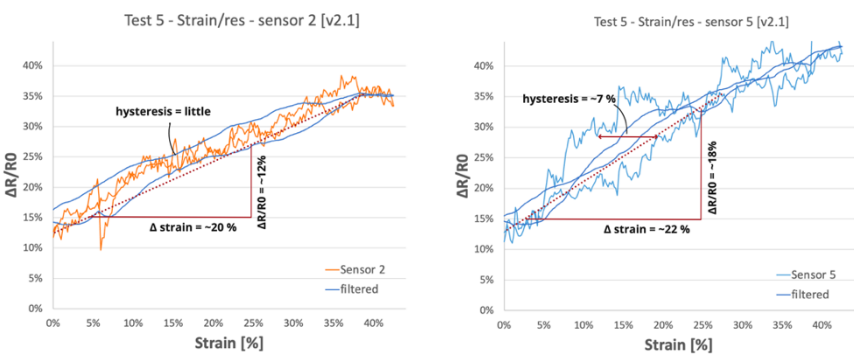


Figure 56: Strain/resistance curves sensor no 2 and 5 - test 5

Discussion

The first noticeable thing is the noise introduced in the new hardware setup. Compared to the raw values of recordings from the tensile tester in test 4 (figure 57-2), a lot less noise can be seen.

However, the difference between the sensor numbers regarding hysteresis, Gauge factor, and amplitude is noticeable in both tests.

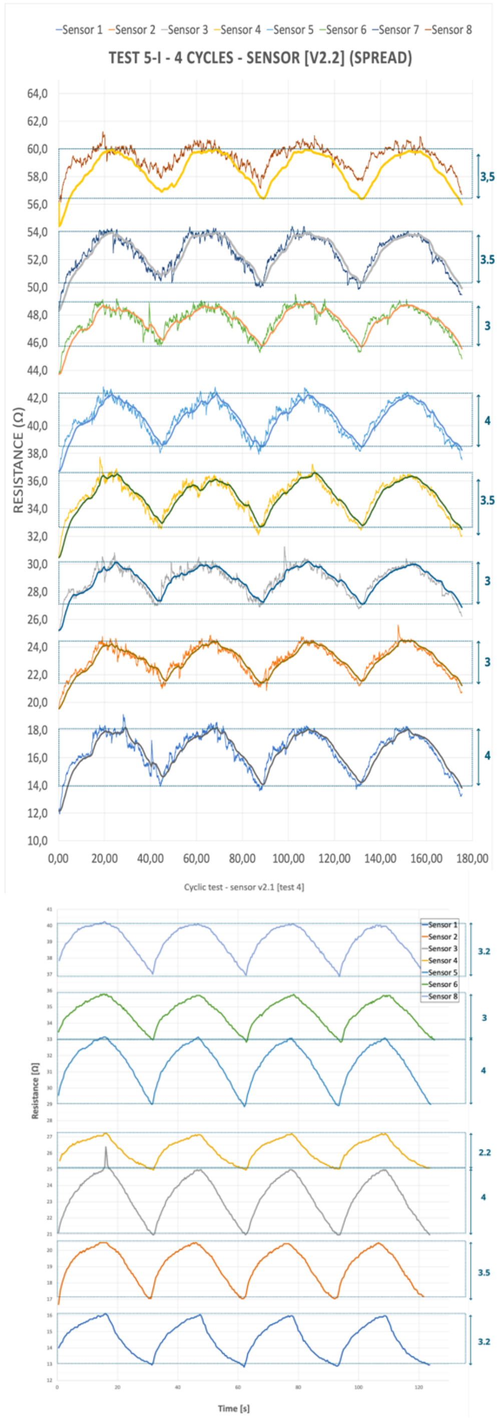


Figure 57: cyclic behaviour all sensor no. - test 5

5.1.4 – Takeaways sensor development

As many factors can affect the electromechanical properties of knitted strain sensors, the difference in wave characteristics between sensors does not come as a surprise.

Residual charges from some parts of the circuit likely cause the noise introduced by integrating electronics and the strain sensor. As it depends on the hardware used, paying attention to the electronic components is essential. The residual charges can originate from but are not limited to, the power supply, low-quality circuitry, or false connections. This, therefore, can be regarded as the first expression of the difficulties of integrating soft- and hard-electronics.

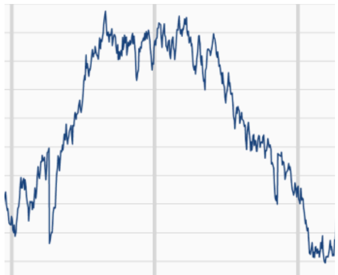


Figure 58: zoom-in illustrating signal noise

The incoherencies in signal *strength*, *sensitivity*, *linearity*, and *repeatability* of the sensor material imply that each sensor (1-8) has different characteristics. These may originate from inconsistencies during the fabrication process or a difference between the wired connections between the knitted sensors and the wiring. The signal equality of *strength* (amplitude) can be improved by ensuring the wiring is consistent. Standardising the manufacturing process could be a big step forward as the current 'hand work' can result in discrepancies. The same can be said about the *sensitivity* (Gauge factor) and *linearity* (hysteresis), which are of lower quality compared to the values presented in the report by Bozali et al. (2021).

Reducing the difference in *absolute values* of the resistances is of lower importance. The focus should be on creating reliable relative change. However, if the absolute values are closer to each other, the circuitry of each sensor number is of consistent quality. Considering the dependency on the circuit's quality, the *repeatability* and *working range* are sufficient for applying strain sensors. The specified required working range of 127 mm is well within the limits of all variations recorded. The repeatability shows promising consistency, as can be seen in test 4. If this works out on a longer timeframe, it has yet to be examined.

Phenomena	Causes	Solution
Signal **noise.**	Residual charges, false connections, etc.	Isolate origin, improve hardware and/or compensate with software.
Varying signal **strength, sensitivity, linearity.** Varying **absolute Ω.**	Inconsistencies in fabrication.	Standardized manufacturing of connections.
Working range, repeatability.		

Throughout the development of a complete prototype, manufacturing the sensor material and embedding a dependable electrical circuit must be finetuned to meet the performance requirements. The relative resistance change is likely sufficient, but a dependable wiring construction needs to be realised to establish a fully functional smart shirt.

5.2 Prototype development

5.2.1 – Prototype version 1

The first step is to assemble the components and build an integrated prototype to test the functional performance of the conceptual design.

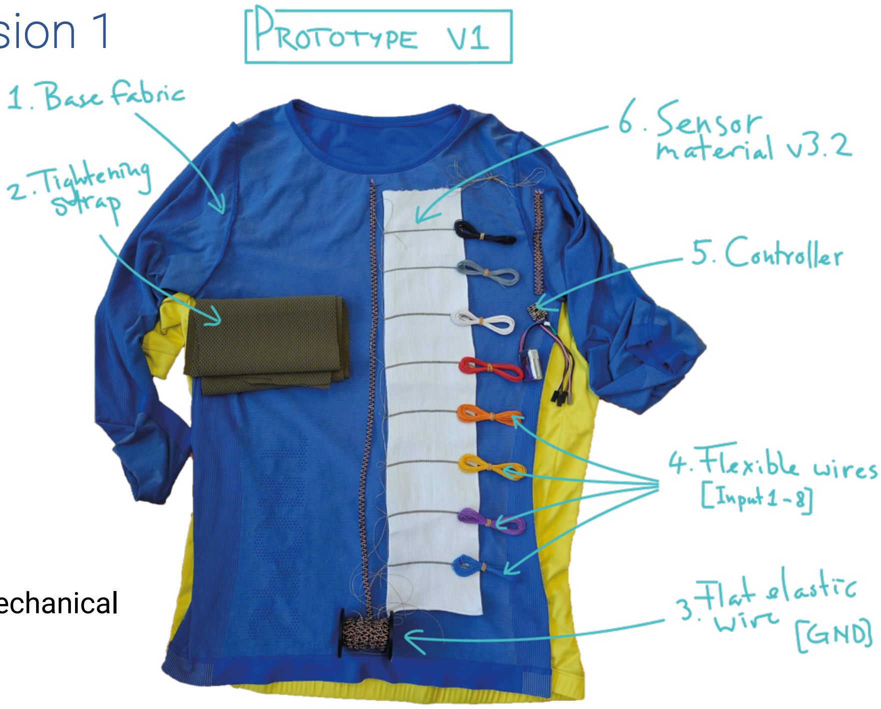


Figure 59: assembly of prototype 1 components

Goal

To integrate the components into a functional prototype. Focus points:

- Explore practical embedding of components.
- Examine the functionality of components in textile format.
- Establish the score of electromechanical performance in context.

Components

I. *Base fabric.*

As a base textile for the prototype, a flexible sporting shirt is made of synthetic elastic threads. This will be the template on which the components can be attached. It is a fabric that is easy to work with and suitable for early experimenting with the configuration of the materials.

II. *Tightening strap.*

A tightening strap is needed to account for the horizontal counterforce needed to focus the elongation on the sensor material rather than the elasticity of the base fabric.

III. *Flat elastic wire.*

The flat elastic wire is specially developed for e-textile solutions. It is designed to keep properties like flexibility and comfort in wearable products. Prototype 1 is a standard ground connection (see electrical diagram chapter 5).

IV. *Flexible wires.*

The flexible wires in eight colours are small-scale regular electrical wires but are relatively flexible and suited for prototyping. They are used to connect each sensor to one of the eight digital inputs of the controller.

V. *Controller.*

The Xiao BLE is used as outlined in the ‘sensor sub-system’ setup. It serves as the central processing unit, reading the sensor signals, processing them into digital format, and sending them via Bluetooth to a computer running the web interface.

VI. *Sensor material v3.2.*

Sensor material version two is adjusted to the required dimensions, 10x40cm. However, the same materials and composition are used.

Figure 60: new sensor material versions

Fabrication

After fabricating the sensor material, the sensor material, a zipper, and the tightening fabric were *sewn* onto the base shirt. Initial testing revealed that a more rigid pre-tensioning was needed for sensor performance. So, a sturdy tightening fabric was attached in combination with Velcro straps. A *zig-zag pattern* was used to sew the sensor material (and other materials) on the shirt to retain stretchability.

Figure 61: soldered and sewn connections

Soft circuitry – a big challenge lies in acquiring reliable connections between the sensor fabric and the controller. As discussed earlier, various ways of connecting textile circuitry and conventional electronics (in this case, the Xiao) are possible. In this version, as recommended by the project supervisor, experiments are done with flat conductive cables and more ordinary flexible cables with a small diameter to create a textile circuit.
Flat textile cabling is used as common ground in the fabric circuit, connecting all the strain sensors with the ground terminal on the controller. Acquiring good contact at the contact points is more complex. The wire in the flat cabling is protected with a coating, so to make contact, the coating needs to be removed at the location of the connection. The contact points are connected by dipping the wire locally in a heated soldering tin, leaving enough tin on the wire, and sewing the contact point onto the sensor material afterwards. The flat ground cable can be quickly sewn onto the fabric, leading a nicely finished flexible wire to the processing unit.

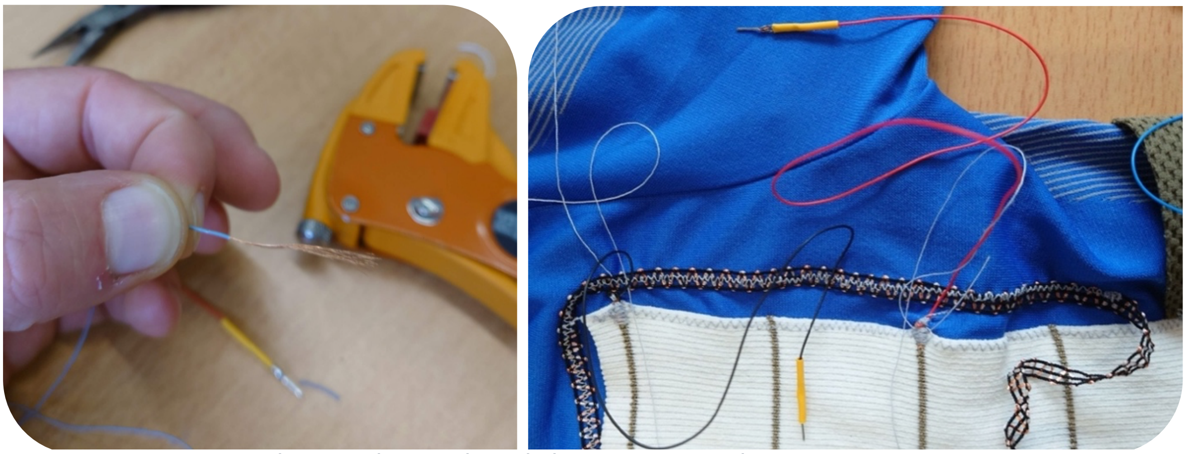


Figure 62: stripping and sewing the wire through the sensor material

On the input side, individual connections are constructed using coloured flexible wires. A connection can be made by stripping the wires and sewing several loops through the other end of the sensors by hand. Subsequently, zig-zag sewing a couple of layers over the contact point ensures extra connection reinforcement. The wires are kept together with a narrow tube and directed to the controller's location.
The processing unit – at the ends of the ground and input wires, Arduino cabling headers are mounted. This way, the Xiao controller that is prepared in advance can easily be re-connected to the soft circuitry. A small pocket is made where the controller can be placed; the controller is powered via the USB-C connection of the Xiao.

Result

The prototype explores the practical integration of components and identifies possible difficulties encountered during construction. Seemingly, sewing on a strain sensor and incorporating the wiring reveals the challenge of combining needlework and the sensitive precision of sensor engineering. The fact that standardised or

Optimal ways of fabricating e-textiles are still in their infancy, leaving room for finding creative solutions.

The fabrication of the prototype already floats to the surface that cross-disciplined know-how is essential to finding creative solutions for integrating components in e-textiles.

Figure 63: prototype version one

Test 6 – functionality prototype 1

Goal

Initial user test to establish understanding of functionality.

Material

I. *Prototype V1*, as described in chapter 6.2.1. An extra non-elastic cloth was attached for more substantial tightening.
II. *Testperson*. Initial prototype testing is done by me personally.
III. *The test interface.* As presented in chapter 6.1.3; a laptop was used.

Figure 64: test 6 setup, improvised tensioning

Method

The prototype is put on, and the controller, powered via USB, is connected to a laptop.
Firstly, the shirt is calibrated by tensioning the Velcro straps so that the strain sensors effectively respond to inhalation and exhalation. The sensor material responded only after adding a water bottle to the tensioning strap. Therefore, a second layer of firm fabric was secured on the tensioning fabric, with which the appropriate responsiveness could be achieved.
Secondly, a recording is started while sitting quietly in a chair, minimising body movement other than respiratory movement. Breathing in a usual manner, the recording is done for about 20 seconds.

Results

The following graph depicts the readout of all eight sensors during testing.

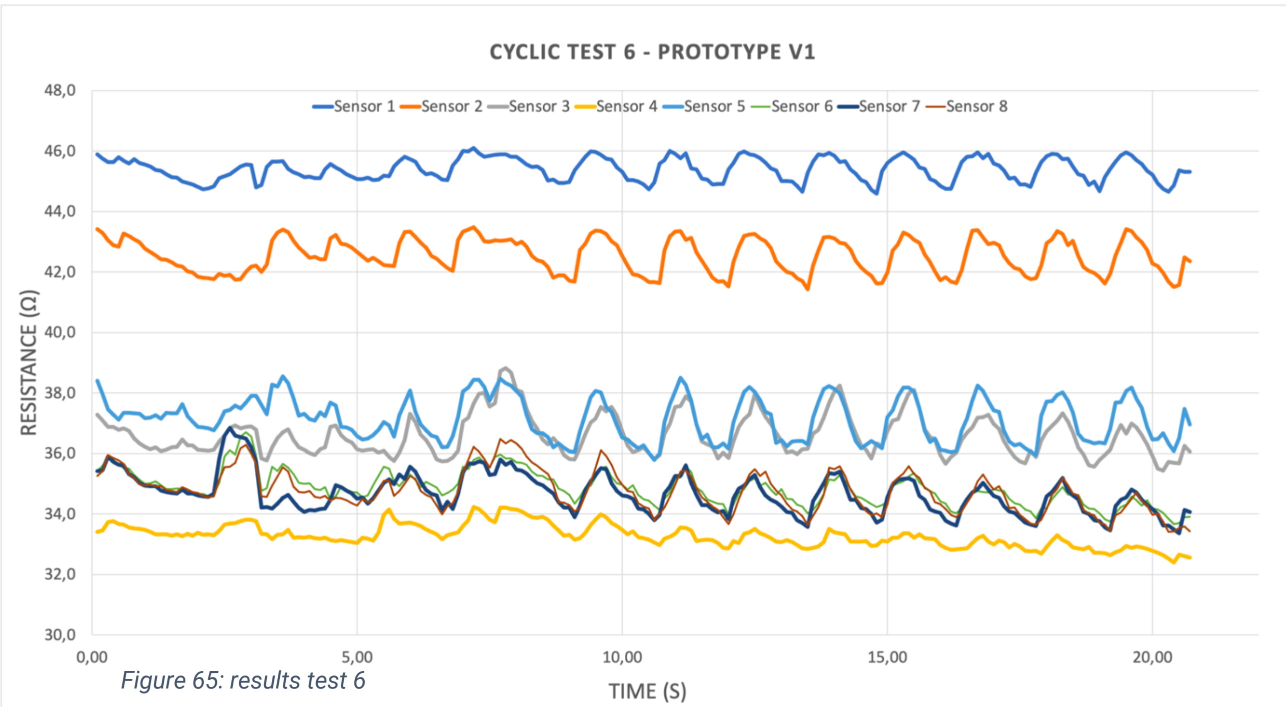


Figure 65: results test 6

Discussion
With as few environmental influences as possible, in terms of functionality, the prototype records the breathing rate successfully. Sensor number one is isolated in Figure 66 – the desired wave properties can be deduced – wavelength, amplitude, etc. By using a moving average (the mean of a specific number of previous data points) as a filter, the lef a noisy line.

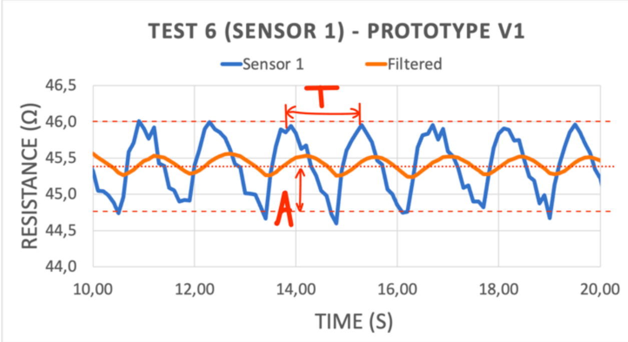


Figure 66: amplitude and period test 6

In terms of usability, the design leaves much room for improvement. The straps must be tightened firmly to set the sensors at the correct tension to respond effectively. Sensor material v3.2, consisting of essentially one large piece of elastic material, requires a high level of counterforce to be stretched (figure 67). Also, likely due to the construction of contact points, more sizeable movements result in spikes in measured values in a couple of sensors.

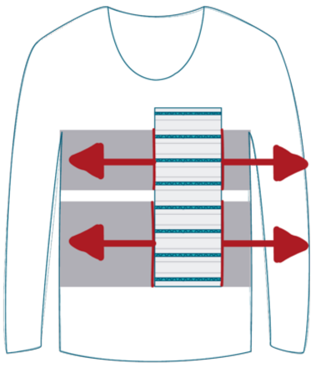


Figure 67: force diagram

Test 7 – prototype 1 performance during movement

Following test 6, the impact of environmental influences on the prototype is tested. Various activities are done to understand the performance in a dynamic context.

Goal
To test electromechanical performance during everyday activities.

Material & method

I. *Prototype V1*, as described in chapter 6.2.1.
II. *Testperson*. Initial prototype testing is done by me personally.
III. *Testinterface* as presented in chapter 6.1.3; a laptop was used.

The same approach as in test 6 is used. In specific order, the shirt is tested for regular 'workplace' circumstances. The shirt is calibrated to the correct tension, breathing exercises are done (specified in the results), and different sitting and standing contexts are tested.

Results & discussion
Figure 68 shows the complete test data; the graphs can be seen enlarged in appendix 7. A first glimpse already depicts a clear result distinction between different contexts over time. In this test, it can first be recognised that in a context where more body movement is required, the sudden change of tension of the sensors results in a drastic change in resistance. Also, two of the eight sensors (the transparent graph lines) seem to react even more intensely to changes in tension with outliers beyond the normal range.

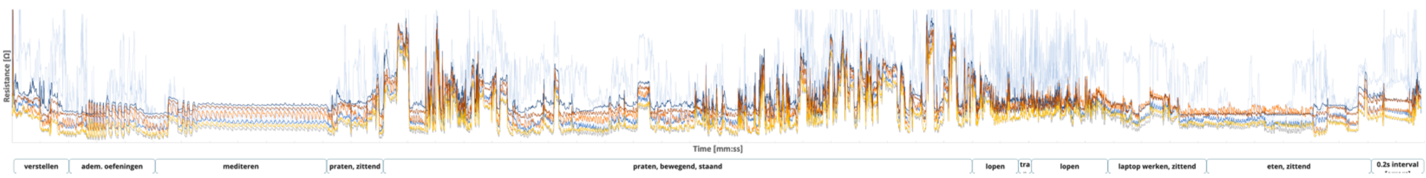


Figure 68: total readout of results test 7

During the first phase (whilst sitting), as seen in Figure 69, the calibration progress clearly shows the difference in 'mean-resistance' depending on the amount of pre-tensioning. A clear distinction in frequency and amplitude can also be made between normal, fast, and slow breathing. Moreover, during a meditating practice, trying to accomplish a constant breathing pattern, a very constant waveform appears like the regular breathing pattern, but with a more extended period.

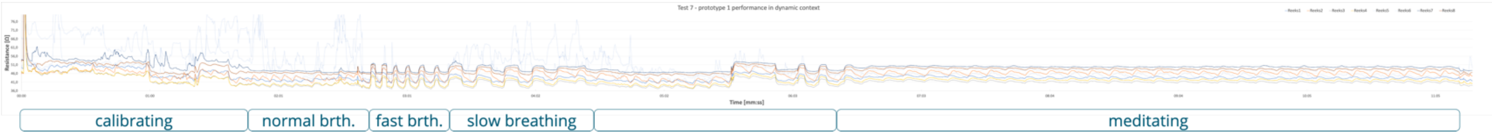


Figure 69: readout of results test 7 part 1

In the second phase, a more aggressive wave pattern appears while talking to a fellow student in sitting and standing positions (Figure 70). Although not timed, one can almost recognise the difference between the times when the test person is listening or is talking (with gestures). Halfway through 'talking, standing', the test person is engaged in a more interactive conversation reviewing a fellow student's project.

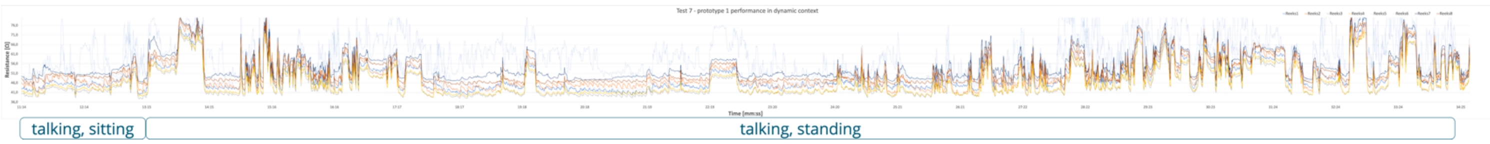


Figure 70: readout of results test 7 part 2

During the third, the person walks across the faculty, opening a door, walking, and using the chairs. The body's movement during walking results in noise, making it challenging to identify which part of the data displays the respiratory movement and which originates from other movements. The signal seems reliable once the test person sits and works on a laptop. Still, a slight shift in working posture already results in a different tension and a change in mean resistance. Finally, sitting and eating seem to result in a less disrupted signal.

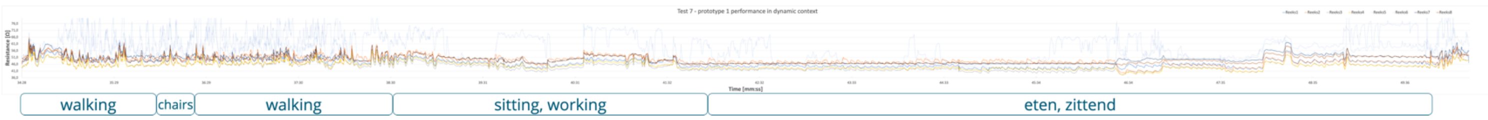


Figure 71: readout of results test 7 part 3

Conclusion

Challenges include the signal strength relative to the noise resulting from various user contexts. The noise drowns out usable data. This will continue to be a challenge throughout the design process. Creative ways of countering this need to be found since many variables can be of influence. Isolated from the rest of the textile circuitry, the sensor material gives a good signal with minimal noise. Hence, the signal noise originates from various circuit parts. For example, cheap electrical components in the processor, stray voltages from the power supply, or loose contacts can result in inconsistent measurements. The sensor wires could also act as an antenna, mixing radio waves in the environment with sensor readings (Woodford, 2024).

On the comfort side, a lot is also left to be desired. The tightness that needs to be imposed to create sensors that are reactive enough decreases the flexibility vastly, which results in restricted freedom of movement.

5.2.2 – Prototype v. 2

The prototype's second version aims to improve the usability and electromechanical properties and evaluate the performance and comfort.

Figure 72: Prototype version two assembly

Goal
To iterate on prototype one and construct a more reliable textile circuit. At the same time, experimenting with improved comfort and usability.

Components

I. *Base fabric.*

The second prototype utilises a tank top undershirt made of cotton as a base. An elastic shirt proves unnecessary and perhaps even counterproductive when trying to fix the stretch on the sensor material.

II. *Tightening fabric.*

Woven bands were used as material to create a rigid one-directional framework for the strain sensors.

III. *Flat elastic wire and flexible wiring.*

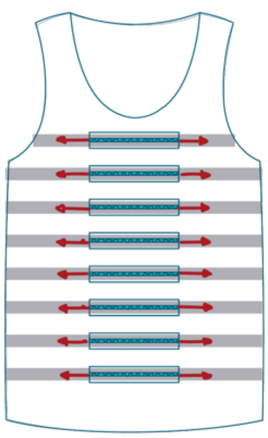
The same wiring setup is used for the ground and input wires: the flat elastic wires as the ground and the coloured flexible wires as input cabling.

IV. *Controller.*

The Xiao BLE is used as outlined in the 'sensor sub-system' setup. Intentions to apply an amplifier for the sensor signals were examined, which resulted in a hardware setup (4b). However, due to time restrictions, further exploration of this attempt to improve the resolution of the signal will be done outside this project's scope. More information can be found in the recommendations.

V. *Sensor material v3.3.*

Sensor material version three is adjusted, and a faulty interpretation of a manufacturing step is restored. Now, the conductive thread is on the inside instead of the outside, which, in effect, is an essential ingredient for linear sensitivity. Also, the sizing is adjusted to get better wearability and comfort. Instead of a single piece of knitted material, smaller pieces of sensor material will require less tension to get the required stretching behaviour (Figure 73).



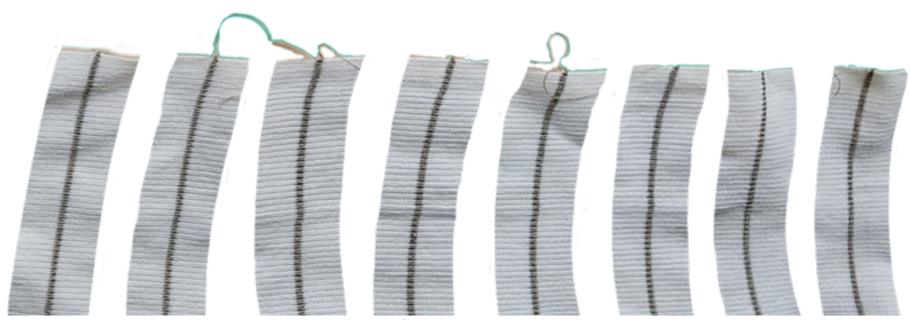


Figure 73: next version sensor material, seperate sensors

Fabrication

Cutting the base fabric over the entire length, about 7 cm to the left of the shirt's middle, ensures that the sensors are centred in the middle of the body. This illustrates how the complete shirt could be knitted in the future (see recommendations) and enables it to work freely with the base fabric during manufacturing.

After attaching the zippers to the shirt, the sensor material can be sewn directly onto the shirt using zig-zag sewing. In line with the sensors, the woven bands can be sewn. They will be sewn onto the shirt for the first 20 cm to leave enough room to adjust the tightness during usage with the Velcro attached at the other end of the bands. This 'skeleton design' is supposed to provide the horizontal support needed for the sensors whilst enabling flexibility in the vertical and shear directions (figure 74).

Figure 75: fitting the tensioning straps

Figure 74: freedom of movement

The wires are fixed on top of the textile components to showcase how the wiring runs. As opposed to the prototype, standard wiring is used to connect all the grounds. The wire is split and twisted through the sensor material several times to get firmer and more reliable contact. On top of the wires, a wide zig-zag pattern is then sewn to protect and fix the wires in place. The exact process is done on the input side, and fixing the wires on top of the rigid bands creates a sturdy construction. The same electronics setup is used and fixed in place with safety pins.

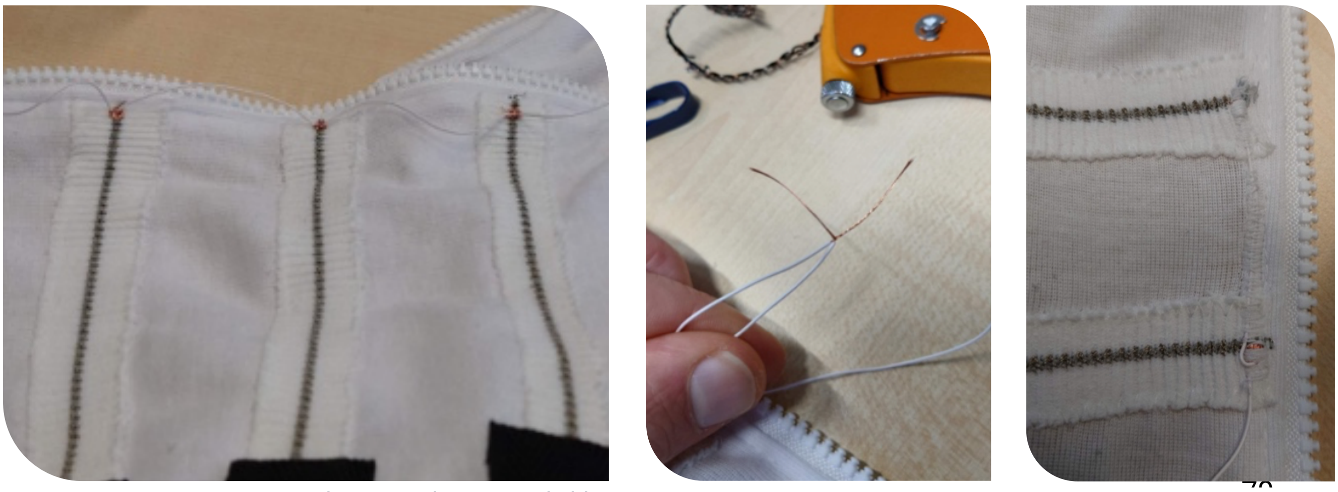


Figure 76: strapping in stripped wires makes up a reliable connection

Test 8 – Performance trial

Goal

To test whether the electromechanical performance of prototype 2 is improved and reliable for user testing.

Material & method

I. *Prototype V2*, as described in chapter 6.2.2.
II. *Testperson*. Initial prototype testing is done by me personally.
III. *The test interface* as presented in chapter 6.1.3; a laptop was used.

A quick test is done to verify the performance of prototype 2. In the first part (8.1), a steady, standard breathing style is applied to test and provide insight into the electromechanical performance. To better overview the waveforms of the different sensors, a scalar is added to sensors 2 to 8 to 'spread out' the waveforms relative to each other. This can be done because the relative change is essential, not the absolute.
In the second part (test 8.2), no particular order of test exercises is done, but different positions and breathing styles are applied.

Results & discussion

A large share of the 'random' peaks in data have been resolved. A much more reliable image of each sensor stream can be observed. One sensor, in particular, shows little activity. This could be due to the exact location of the sensor on the upper chest. At this exact location, it is more challenging to pre-tension the sensor. Comparing the two tests, the same sensor has a different sensor number assigned to it due to a change in connectors. The user test will be improved by standardising the connectors.

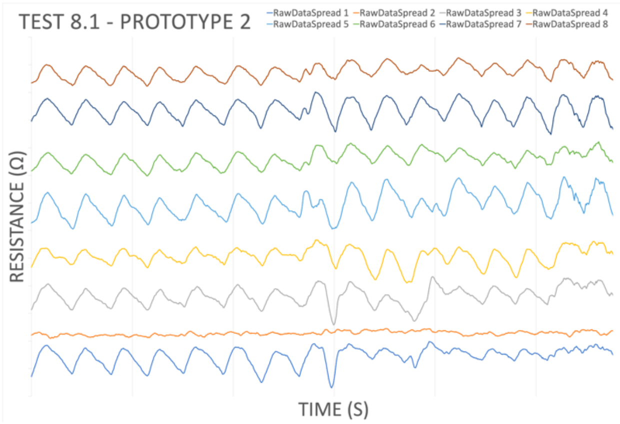


Figure 77: Test 8.1 normal breathing

Overall, the result looks promising compared to prototype 1 — the change in connection of the wiring results in a less fragile construction. Next, the shirt is much more stretchable, resulting in significantly more comfortable wear.

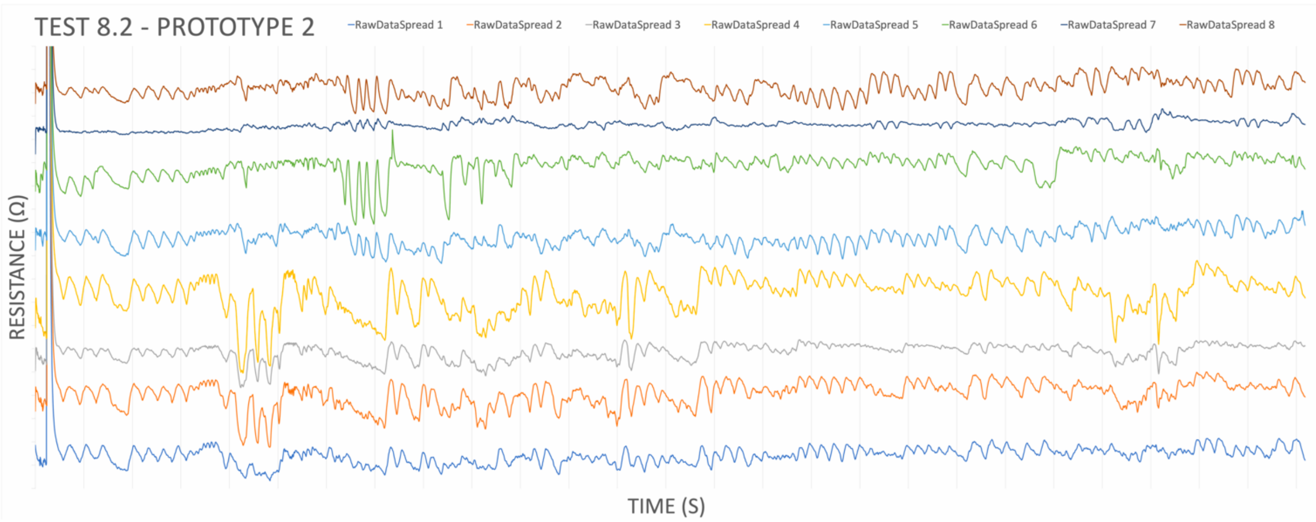


Figure 78: Test 8.2 free test of sensor behaviour

5.2.3 – Takeaways prototype development

The challenges of integrating craftiness from various expertise become apparent during prototype development.

Noise continues to be a topic of discussion. Depending on the amount of detail desired, the original sensor signal noise on a small scale still plays a role. However, the noise introduced during more active user contexts has more impact on the signal's readability. The signal quality also increases depending on the quality of engineering of contact points. This can be seen comparing the tests of prototypes 1 and 2. As applied in prototype 1, sewing soldered contact points (figure 79) results in connections prone to error. Strapping stripped wires through the sensor material provides considerably more reliable results, as with prototype 2. However, it could be considered less valid on an industrial scale. The question remains: How much noise is too much? Moreover, what other ways apart from filtering are available to deal with the noise? An extensive list of factors that can be of influence will be given in the recommendations section.
Of course, the wiring is somewhat experimental, chosen to proceed to an operational model at a fast pace to confirm the feasibility of the concept. However, it does point out the areas for improvement in the design, which are not surprisingly located at the intersections between two different materials/disciplines: the knitted sensors and conventional electronics. In the final design proposition, a recommendation concerning the manufacturability of these intersections will be given.

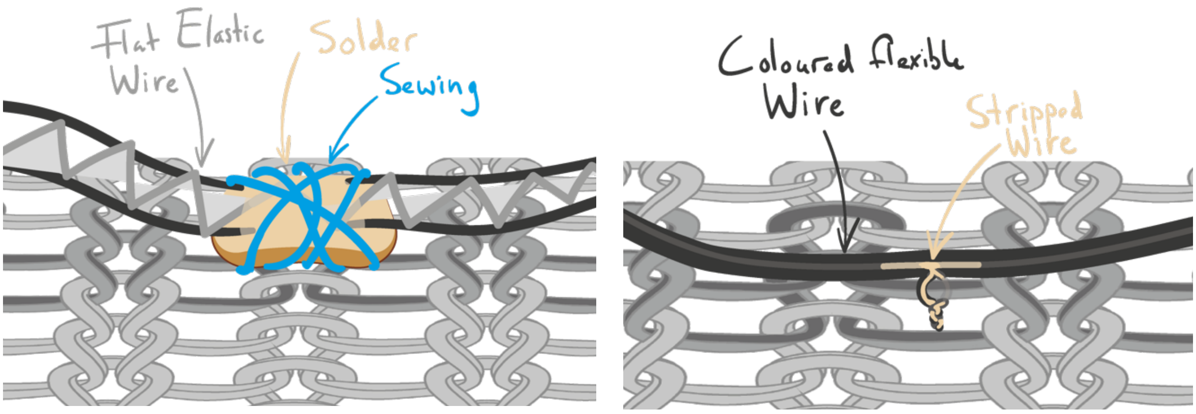


Figure 79: two ways of establishing a connection

The first tests of the prototypes resulted in sensor readouts of which waveform can be adequately analysed, which could be considered functional for user testing to be carried out. The strain sensor values can help characterise the horizontal strain at its respective location using the amplitude and period. Taking all eight sensor values in relation to each other could show an image of the user's overall breathing behaviour. In the next chapter, a comprehensive analysis will be done through user testing.
In the next chapter, *comfort* will be reviewed by the test persons. The change from a single piece of sensor material to multiple pieces made wearing the prototype a much more excellent experience. Using horizontal 'tension straps' gives the user much more freedom of movement, paving the way for transforming the prototype into a well-fitting item of clothing. The structural design could pose an example for the component layouts of the following versions.

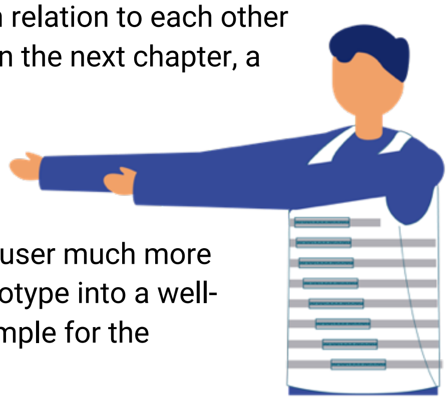


Figure 80: comfort through free movement

Evaluation

The next step in the design process is to evaluate the critical functions and demonstrate the prototype's performance. The functionality and comfortability are assessed through user testing, and conclusively, final design recommendations are given.

In the first part of this chapter, the user test plan is presented, and the test results are discussed [6.1]. Following this, the general conclusion is presented concerning the design requirements [6.2]. Finally, extensive recommendations considering viability, feasibility, and desirability for further research and development [6.3].

6.1 Prototype validation

Through user tests focused on obtaining qualitative results, the aim is to obtain insights about the prototype design in a relevant environment/context. Verification of the performance of critical functions, level of comfort, and an exploration of the ease of use should paint a picture of further challenges and opportunities. In anticipation of the user test, a physiotherapist specialising in breathing exercises is consulted to define a set of practical exercises that could act as a basis for breathing practices.

Goal

To evaluate the functional performance and assess the user experience.

Research questions:

1. How comfortable is the shirt to wear?
    a. Participants will be asked to wear and prepare the shirt for data collection. A series of questions will be asked in which they are asked for their opinion on the topics of non-intrusiveness, comfort, and aesthetics.
    b. Following the possible user scenario in home diagnostics, participants will be asked to perform various activities to validate the shirt's comfort in various positions.

2. How do different positions and activities affect the data quality and functionality?
    a. The participants will perform exercises simulating various breathing conditions to test data functionality. Afterwards, the data collected during the study will be evaluated for usability and pattern recognition.

Method

Participants

Five participants (students, male, size large/50) are recruited. They have no background in *respiratory health diseases* and have never experienced hyperventilation. Their standard clothing size is taken, and a short list of questions about their stress levels and state of mind will be asked, which can be read further in this chapter. Their answers will be *anonymised*; details can be read in the data management plan (appendix 5).

Setting and equipment

Since the product should eventually be used during everyday activities, the setting in which the prototype will be tested can resemble either a home, work or any other regular setting. Therefore, the setting will not be necessary for the test. Instead, the focus will be on the interaction with the shirt and the influence on the performance depending on the activity and interaction. The tests are done in a work setting at room temperature. For this test, prototype version 2 is used.

Data collection

Based on a study about preferred comfort questionnaires by Anjani et al. (2021), the comfort level is determined based on a *body region discomfort map*. In addition, interviews are done in the native language of the interviewee to qualitatively assess the participant's perception of comfort, appearance, and practicality. Next to that, in an explorative fashion, the data collected in different positions and during several breathing exercises will help verify the performance of the critical functions of the design.

Intro: Usability and comfort [5 min]

The study will consist of four parts. The introduction focuses on the user's perception of *wearability* and *user-friendliness*, primarily by observing the degree of (intuitive) usability, which will be documented. An introduction to the user scenario will be presented, and subsequently, the activities will be done during the study. Next, note down the measuring size and the amount of tightening participants apply. An introduction is also given on using body diagrams to define the comfort level during the activities.

Time	*Activity*	*Metrics*	*Assistance*
1 min	Introduce	-	*Introduce to scenario*
.5 min	Sign forms	-	*Request to read/sign forms*
.5 min	Check fit	Measurements	*Take size measurements*
1 min	Share first impression	Observation	*Ask about first impression*
.5 min	Put on shirt	Observation	*Ask to put on the shirt*
1 min	Calibrate sensors	Measurements	*Measure strain applied*
.5 min	Comfort intro	Body diagram	*Intro to body diagram*

Part 1: Activities and positions [15 min]

In the first part, different *conditions* in which the shirt will be used are tested. Following the user scenario, some conditions in which the shirt must operate are simulated during this study. From this, insights about the *sensor performance* and the *comfort level* during different activities will be collected. During each activity, participants are asked if and how the shirt restricts them from free movements. Also, to simulate breathing patterns, on the advice of a breathing therapist, a specified series of breathing exercises are done.

Figure 81: performed activities (Freepik, nb.)

Time	*Activity*	*Metrics*	*Assistance*
1 min	Sitting (focused; relaxed)	Data; body diagram	*Ask to sit, ask for comfort.*
1 min	Standing	Data; body diagram	*Ask to stand, ".*
1 min	Walking (normal; hurry; run)	Data; body diagram	*Ask to walk, ".*

1 min	Lying down	Data; body diagram	*Ask to lie down, ".*
1 min	Daily tasks	Data; body diagram	*Ask to perform some tasks, ".*
1 min	[pause]	Questionnaire	*Explain breathing exercises.*
2 min	Normal breathing [30s]	Data	*Guide normal breath.*
	Belly breathing [30s]		*Guide belly breathing.*
	Chest breathing [30s]		*Guide chest breathing.*
1 min	Fast breathing [20s] Fast belly [20s] Fast chest [20s]	Data	*Guide fast breathing.*
2 min	Deep breathing [30s] Deep belly [30s] Deep chest [30s]	Data	*Guide deep breathing*
1 min	Take off prototype	-	*Ask to take off prototype*

Part 2: Post-use interview [10 min]
During the second part, a series of *questions* is asked to evaluate the overall experience. First, review the body diagrams and continue discussing the topic of *comfort*. The underlying denominator is *non-intrusiveness*; therefore, the participant's perception of the *location* of the *components*, the *materials* used, and the *fit* are to be discussed. An open question about the *aesthetic qualities* of the shirt and personal considerations about the form of the shirt, in general, can be reviewed. The functionality in terms of *ease of use* is a topic of discussion and should shine light on whether the design is intuitive.
After the series of questions, the user study is done, and the participants will be thanked for their time. They will also be assured that no personal data will be used, and all insights will be anonymised.

Question	*Topics*
"Why was your input for the body diagrams: …"	*Comfort*
"Do you feel affected in your ability to move freely?" – materials, fit, components.	*Non-intrusiveness.*
"Do you have any other remarks?" + thanks.	*Misc.*

Part 3: Post-study validation of data functionality
After the study, the answers will be documented, and the breathing data will be saved according to the specifications of the HREC (appendix 5).
Following data collection, the functionality and performance need to be determined. Firstly, processing the data according to the activities and breathing exercises, ensuring timestamps match and the breathing behaviour is labelled. Secondly, analyse the results for patterns and similarities between participants. Optionally, the data can be blindly tested by two experts. The experts will get an overview of the possible activities and types of breathing in the form of several patterns, as well as cut-outs of the wave pattern data of a participant. They identify the suitable activity or breathing exercise by analysing the patterns.

Test results

An overlap of the combined results from the body diagrams can be seen, giving insight into the participants' comfort experience. A selection of readouts from the data collected during parts one and two illustrates the performance. All collected readouts can be viewed in appendix 9. Instead of plotting the absolute values of the sensors, results are 'spread' by adding or subtracting a standard value to get a more organised overview of each sensor's values. This does not affect properties like the amplitude or frequency.

Results part 1: comfort

How comfortable is the shirt to wear?

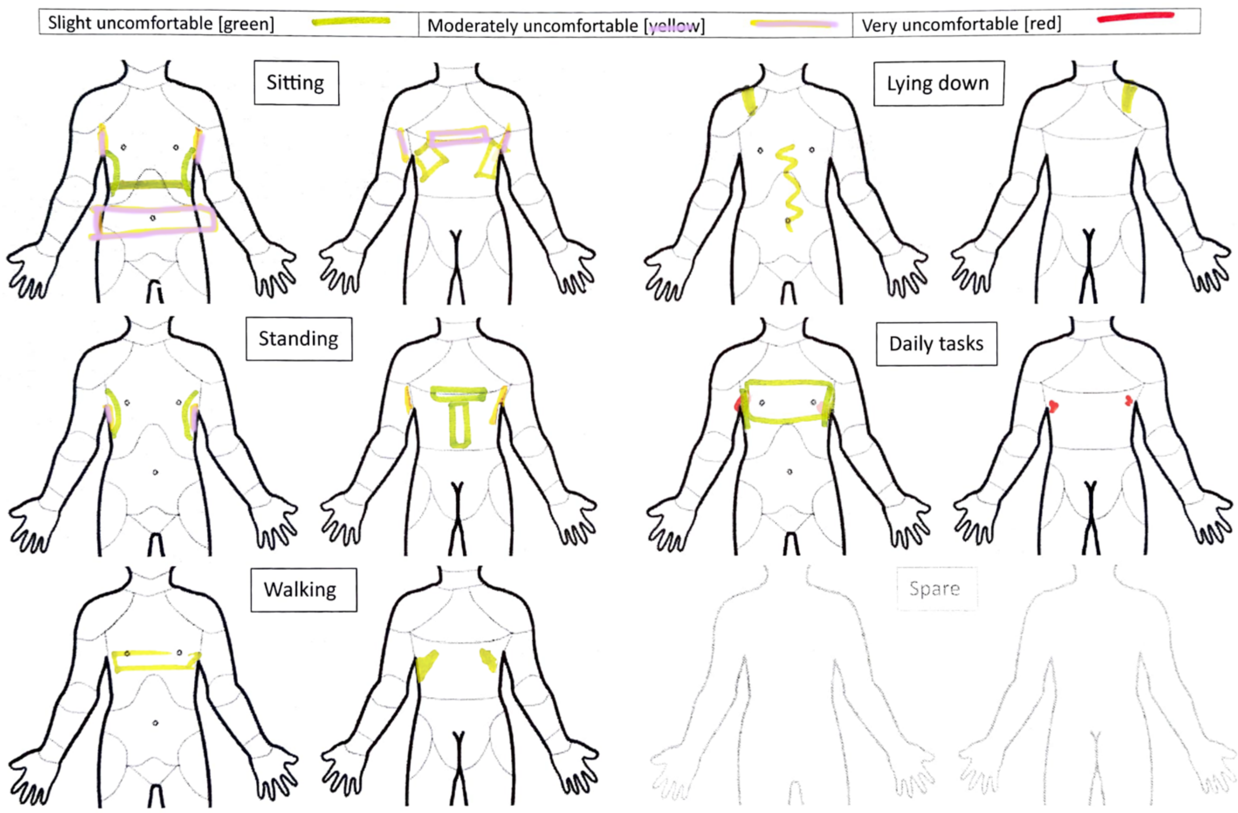


Figure 82: Overlay of all comfort diagram results

Comfort

- Feedback suggests a mixed comfort experience. While sometimes it is found to be acceptable, other times it is described as tight, akin to a harness used in extreme activities.
- The area around the chest has slightly to moderate discomfort in most positions. Mainly in a sitting position, participants describe a feeling of tension around the area of the chest. One participant noticed that the stiff fabric gets uncomfortable, especially in areas with less subcutaneous fat (e.g., the ribs).
- The vest's material, especially around the armpit area, is acknowledged as sturdy but considered necessary. Some liken the feeling to wearing 'thicker gloves', noticeable but not overly uncomfortable.

- For most participants, lying down is perceived as relatively comfortable, with the vest feeling less constrictive.
- Participants positively indicate a “posture corrective fit”, inviting them to keep a straight back. They mention that the free shoulders improve the range of motion but also mention that during daily tasks (cooking), the corrective fit restricts them from bending over.
- Overall, wearing the vest for a day is manageable, and the discomfort is tolerable.

Appearance

- Observations indicate that the vest, when worn, appears cool, like a “piece of machinery or equipment” or “contemporary experimental outdoor wear” rather than typical clothing.
- Participants note its similarity to a tool or device and question its visual appeal, especially if worn to a club or social setting.
- All participants suggest that hiding it under regular clothing is preferable, emphasising the desire for a discreet appearance.

Practicality

- The zipper mechanism, however, is preferred in the middle and is seen as practical for putting on and taking off the vest.
- Some participants raised questions about its adaptability to different body shapes and sizes. Suggestions include incorporating a small amount of stretch in the material and a flexible system to fix sizing. Visual cues for correct tightening and the potential incorporation of a mechanism like bra hooks for secure fastening are proposed.
- Limited feedback is provided on the electronic components, emphasising the importance of discreetly integrating them into the design.

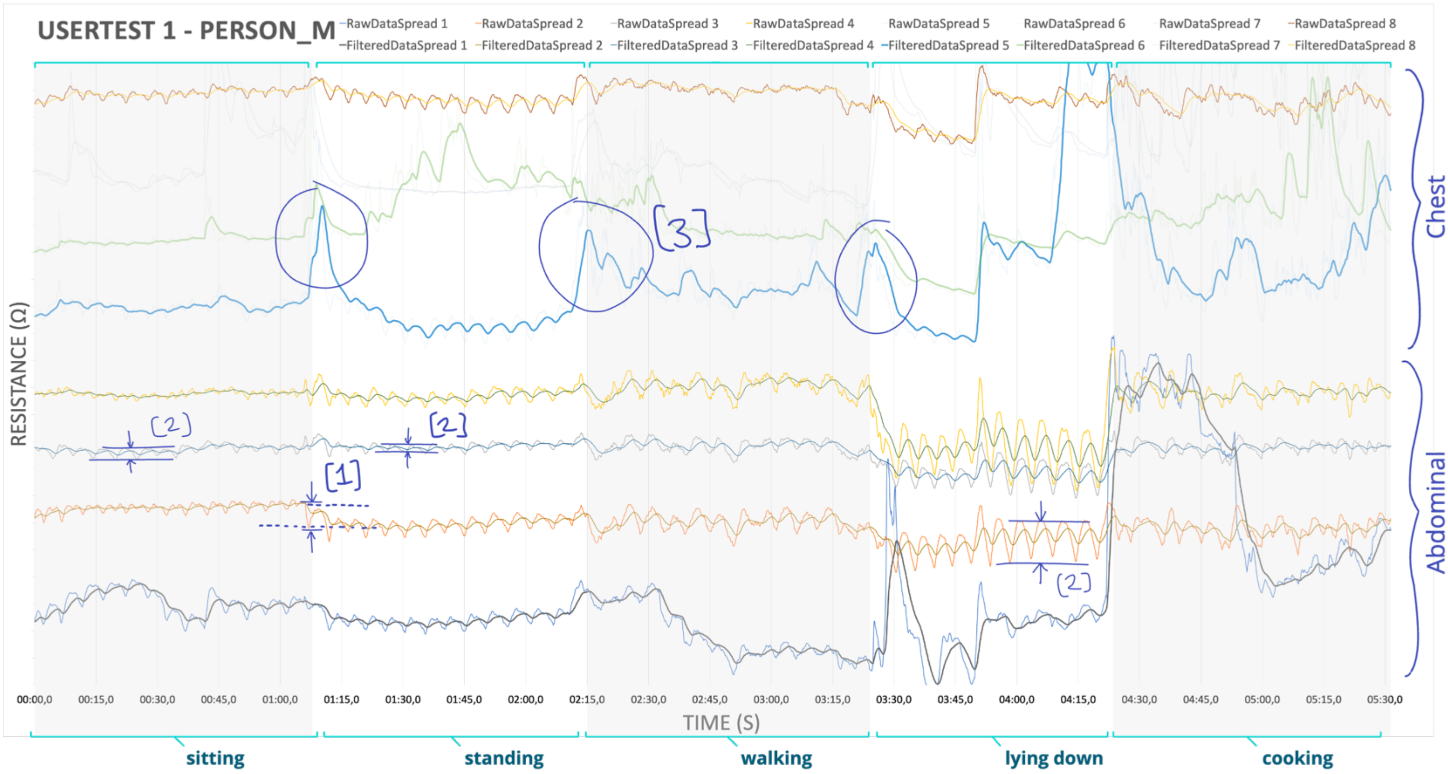


Figure 83: readout of successful usertest 1 - person M

Results part 1 and 2: performance

How do different positions and activities affect the data quality and functionality?

The data from part 1 (figure 83) is, for the large part, too inconsistent to derive or recognise any form of pattern. However, some variation in wave pattern characteristics can be identified in some cases. Remarkably, the data of one participant is sufficient to make a couple of observations:

- The median resistance of sensors changes depending on the activity performed by the participant [1]. Indicating a change in the amount of strain applied to a sensor in the initial state.
- A variation in amplitude can be observed [2]. Indicating a shift in depth of breathing at different locations in different positions. Especially when lying down, an increase in the depth of abdominal breathing can be seen.
- When a posture change is performed, the sensors (in different magnitudes) tend to spike [3], probably due to body movement.

Although the results from the participants differ, the data collected during the second part of the user test is more usable overall. The best readable result is presented in Figure 84; all results can be found in Appendix 9.

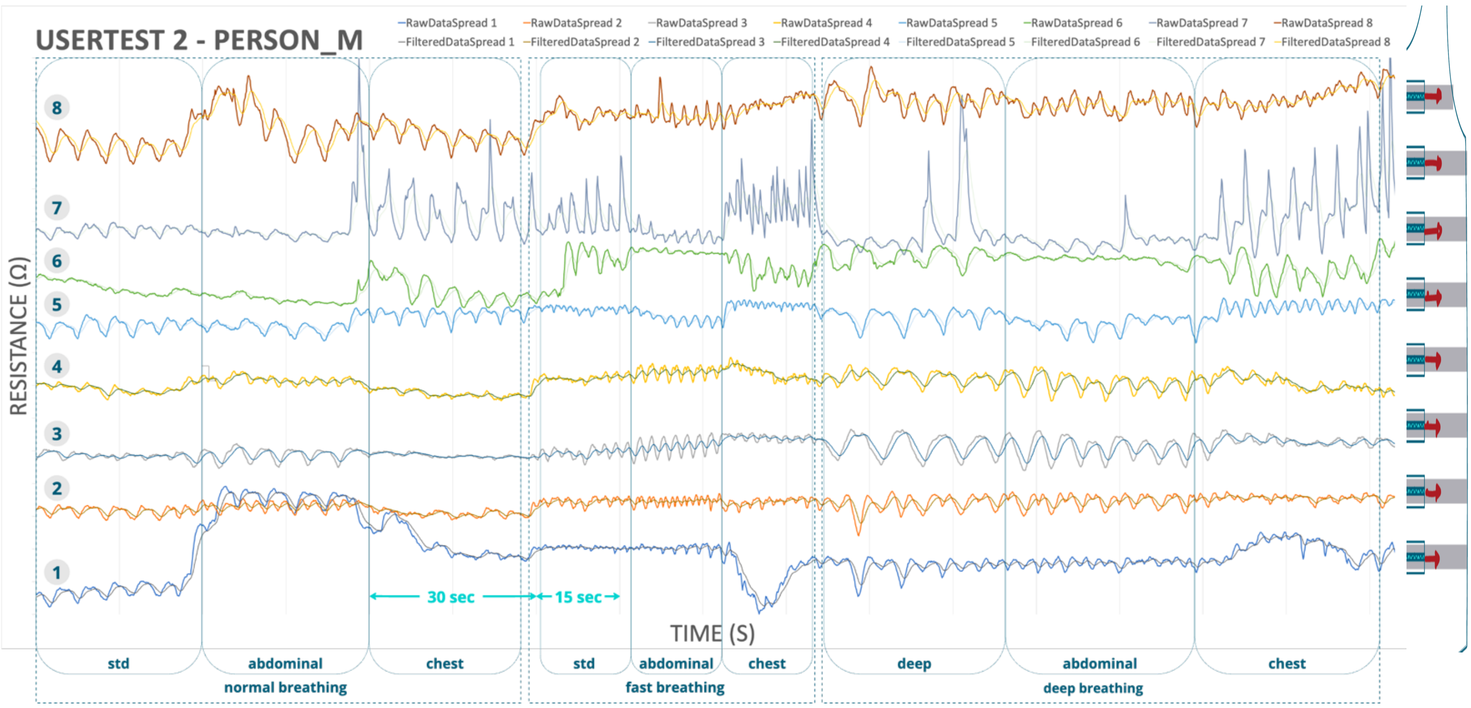


Figure 84: readout successful usertest 2 - person M

- Though only sometimes consistent, a difference between standard, abdominal, and chest breathing is noticeable. Variations in amplitude between the sensors depicting abdominal breathing (1-4) and the sensors depicting chest breathing (5-8). Depending on the breathing test, the *emphasis* changes between the sensors.
- The *period* and *amplitude,* indicating respectively fast and deep breathing, can be deducted from the readout.

- In terms of noise, the example in Figure 84 offers insight into the weak spots in the construction. Sensors 6 and 7 tend to spike when stretched out more than standard breathing. This can be seen on a bigger scale, most often with the other participants.
- As an example of poorer quality data, figure 85 shows the two-part result from participant D. During the first part this participant tended to test the limits of their reachability in each position. Resulting in data with a lot of spikes and random values. In the results of their second part of the test, the data from most sensors can be used, but a couple of sensors show extreme spikes and changes in median value. Some are made transparent to increase the visibility of the rest of the data. These same couple of sensors result in spikes during other test results as well, indicating malfunctioning connections or values that possibly exceed the working range of the sensors.

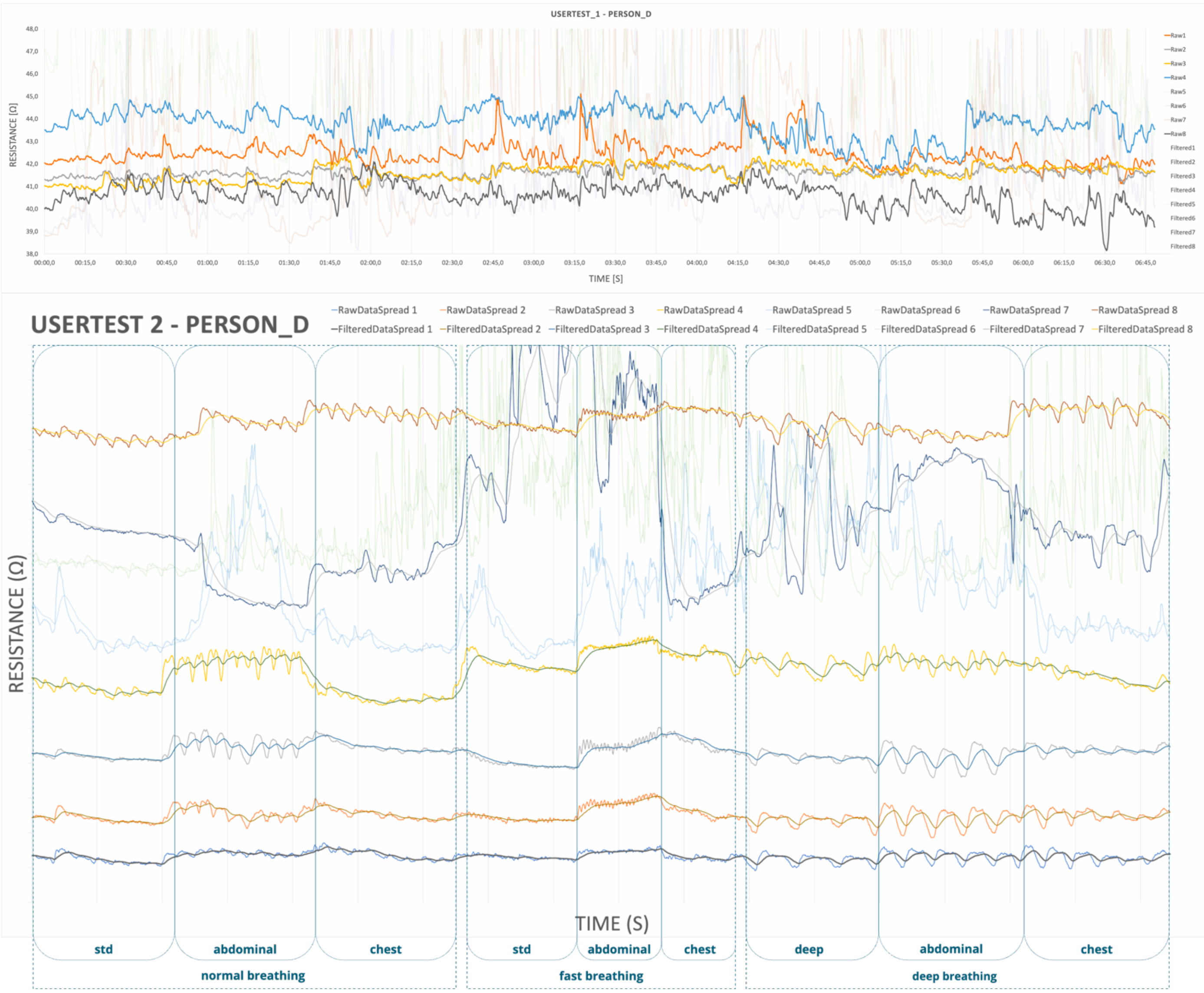


Figure 85: readout less successful usertests - person D

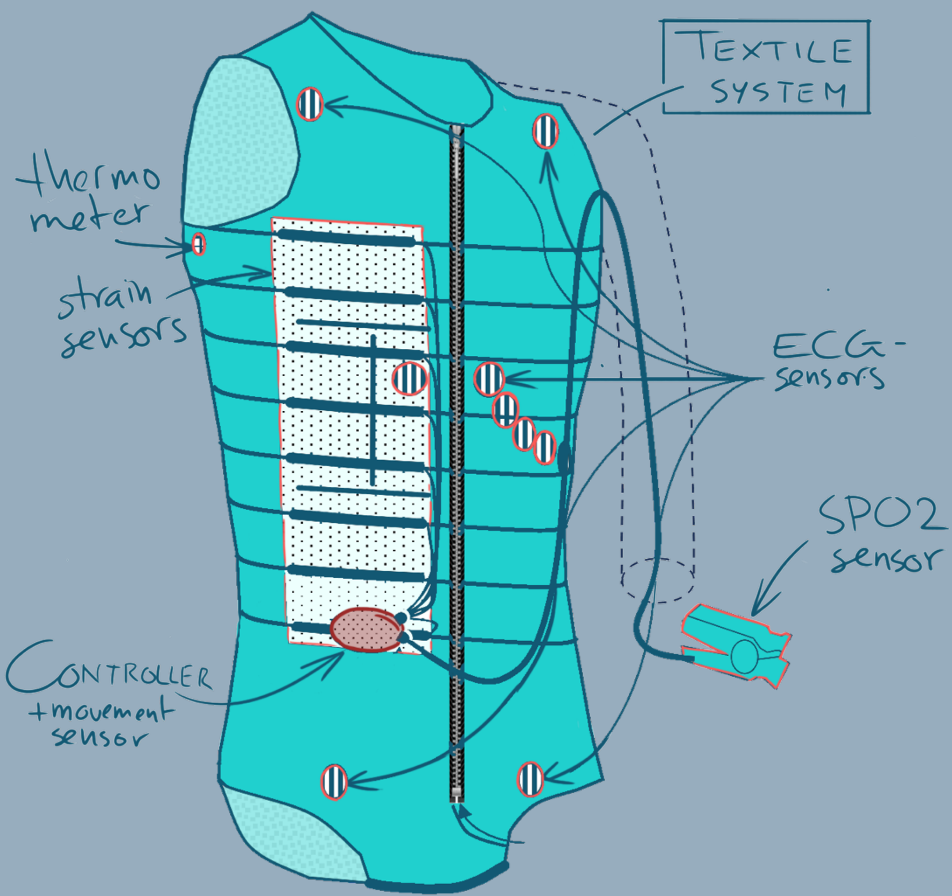
Test discussion

The user test conducted for the prototype design aimed to provide insights into critical functions, comfort, and ease of use in a relevant environment. The overall goal was to evaluate functional performance and assess the user experience by incorporating both subjective and objective measures. In response to the research questions, the following could be suggested.

User experience:
During the user study, participants were intrigued by the prototype and found it appealing. They felt tempted to try it out like a piece of clothing while shopping, which indicates a good user experience. With aesthetic adjustments to reduce the mechanical look, the shirt is considered socially acceptable when worn with regular clothing. However, the tight fit around the armpits was constraining and impacted the freedom of movement, which should be addressed. Overall, the participants liked the practicality of the zipper, but the sizing system urgently needs to be more flexible, and stretchable materials could be incorporated to improve practicality. The design needs refinement for broader social acceptance, and balancing functionality with aesthetics is crucial.

Performance:
The data collected during the breathing exercises in the user study shows that the respiration rate and depth can be measured with relative consistency. The proportionate change in body circumference at the respective locations of the sensors is also apparent, which makes it possible to observe a difference in data values during abdominal or chest breathing. The knitted strain sensors show usable results during various positions and activities, including sleeping in different positions, walking, and standing. However, the data collected during the study's first part was inconsistent, making it challenging to derive recognisable patterns. Improving the consistency of data collection is crucial to establishing a reliable construction in the following prototype versions.

Discussion



TEXTILE SYSTEM
thermo meter
strain sensors
ECG-sensors
SPO2 sensor
CONTROLLER
+movement sensor

7.1 General discussion

In the discussion, the results from the prototype study are evaluated regarding the design requirements and findings from previous chapters. The goal is to validate what areas of the design and development contribute to the design objectives and what areas have limitations.

Design Benefits:

Several design benefits regarding the effectiveness of the knitted strain sensors can be highlighted. One of the most significant observations is the confirmation that collecting real-time data related to a patient's breathing behaviour is possible. Even with elementary prototyping components, readable results can be achieved. Comparing prototype version two to the first, the horizontal tension straps present a step in the right direction, providing several beneficial properties regarding performance and comfort.

Performance

The data collected during the breathing exercises in the second part of the user study shows consistency. It is demonstrated that variations in amplitude and period are measurable. This makes it possible to deduct the respiration rate and respiration depth. Although limited by prototype construction, the relative change in body circumference at the respective locations of sensors is also apparent. This makes it possible to observe a difference in data values during abdominal or chest breathing. Resulting in a representation of the relative change in body circumference at the respective locations on the shirt.

It is tempting to observe the sensor readouts and make quick (amateur) associations, such as participants' different types of breathing and their standard breathing patterns. For example, when "asked to take a deep breath, the data confirms that the patient relies on abdominal breathing." That being the case, it is not far-fetched to state that with optimization of the components and connections, results can be achieved with which physicians could gain a better understanding of the patient's condition and support an accurate diagnosis. Although arguably sensitive to the limits of participants' manoeuvrability, the knitted strain sensors show usable results during various positions and activities, including sleeping in different positions, walking, and standing.

Manufacturability

Already, an elementary web-based version of an app gives direct insight into the status of a participant's breathing behaviour. However, much must be done to improve the patient's control over their health and progress during treatment.
Eight signals can be transferred to a mobile device even with a relatively simple microcontroller for prototyping. Experiments on additional electronics support acquiring a better-defined signal and confirm the many variations that can be made to improve the performance and functionality of knitted strain sensors.
Much is possible regarding the dimensions and placement of supportive electronics necessary for running textile systems. Considering the step from prototyping electronics to custom-designed processing and communication modules, a textile wearable offers much versatility depending on the intended use.

This versatility can also be witnessed in integrating electronics in a textile-based format. Although wiring and connectors have resulted in difficulties during development, the possibilities for integration are vast and impossible to cover in one graduation project only. A selection of wiring options is considered during prototype development. Most of the construction can be done by hand, which gives much creative freedom during the development of textile wearables. Little standards have been established for the construction of textile circuitry.
A handful of companies providing knitting technology services in the Netherlands can provide the prospective production of larger quantities of a manufacturing prototype. With their know-how of knitting machinery, they claim to be able to fabricate complex structures, and examples of techniques they would use to integrate wiring and electronics can also be found in the literature.

Usability and comfort
In terms of user experience, the prototype appeals to the imagination. Upon introducing the prototype and context of usage, user study participants feel tempted to test out the shirt, as if testing out a piece of clothing on a day of shopping in the fashion store. Aesthetically, the participants consider the shirt as socially acceptable, especially if worn with regular clothing, they suggest.
The second prototype has significantly improved comfort and freedom of movement compared to the prototype. The separate horizontal straps provide much more flexibility in multiple directions. Although suggestions for improvement were given, participants showed positive reactions to features like the zipper and tank-top format in terms of practicality.
In addition, a safety report was developed in anticipation of the user test. Findings on potential dangers of wearing the sensors directly on the skin concluded that the potential hazard could be considered negligible.

At this point, the upside benefit of non-invasive wearable sensor technology is clear: Unlike traditional diagnostic procedures, wearable sensors do not require invasive procedures or patient discomfort. This can lead to a more positive patient experience and greater patient compliance with treatment.

Design Limitations

However, some design limitations are encountered during the project and development. A couple of limitations can be identified by looking at the design methods used. Firstly, the initial project assignment included the use of knitted strain sensors, and some worked concept functionalities as well. Consequently, some parts of the 'natural' design process have not received the attention they deserve, which resulted in the absence of an actual divergence of variety in design solutions. E.g. the lack of brainstorming, creative idea development, conceptualization, and a clear 'choice between concept variants.' Next, regarding evaluation, a blind test by health professionals concerning the recognizability of breathing patterns could help bring validation to the next level.

Performance
Depending on the detail necessary to study the signal, the **noise** continues to impact the sensor performance. This makes it more difficult because noise could originate from

numerous sources in textile sensor applications. Residual charges from electronic parts and a consistent disturbance inherent to the strain sensors – that could find their origin anywhere in the complex construction of yarns play a role. However, the interpretation of this ‘problem’ depends on the requisites of the use case.

Several solutions can be applied to remove the noise. One is to use a filter, especially a moving average filter, to smooth out a noisy line. However, this could affect the synchronicity of the analogue to digital representation of the biomedical signal. Another solution that is tried is using an amplifier connected directly to the sensors to create a stronger signal. However, initially meant to amplify the signal so that the noise would disappear in the background, this amplified the noise. Due to time limitations, further investigation of this direction must be done in the succession of this project.
Additionally, a wide range of alternative factors that could impact sensor performance has not been investigated but is expected to have an impact. These include:

- The impact of electromagnetic waves on the conductive yarns and wiring, as these could act as a receiver.
- The fatigue life of the knitted strain sensor, as the sensors need to undergo many cycles during the user scenario.
- The sensor's washability, particularly the silver-coated conductive yarn, is of high priority, as research indicates fragility.

Most of the results from the user tests were inconsistent due to spikes in the data. This limits the ability to conclude with complete confidence that the data is reliable. Improving the consistency of data collection is a number one priority. Understanding the origin of the inconsistent readings is essential to establishing a reliable construction in the following prototype versions. Reliable data collection will significantly enhance the quality of the research-based design process.

Manufacturability
Although not proven, weak spots in construction are expected to lead to spikes in specific sensors during stretching. Stretching means spikes in the data appear when a participant tests the boundaries of the range of movement by physically stretching. The following limitations in the design are identified:

- The working range of the sensors is insufficient for the prototype’s functionality.
- The soft-hard electronics connections are, in essence, improvised prototyping methods but too fragile to function.

The sensor’s dimensions significantly impact both the sensors’ working range and the comfort experienced by participants. In hindsight, the length of the sensors is too small for the range of motion as it needs to address a stretch of up to 7.5 cm, and that excludes the amount of pre-stretch required. That also excludes the amount of pre-stretch required to calibrate the sensors. The sensor length is about 10 cm, giving it a working range of 4 cm (40% x 10 cm). However, under normal circumstances, that would be enough, and this limitation also does not consider the stretch that more stretchable straps could cover in future prototype designs (more about this in the recommendations).
The placement of the sensors is static, and each human body is unique in its measurement, further complicating the optimal locations of measurement.

Fabrication of connections and cabling is still in its infancy, resulting in a risk for development costs. However much knitting technology companies promise, the measure of unforeseen implications on sensor performance during knitting processes is relatively significant considering the novelty of this area of expertise.

The last point of discussion for manufacturability is the focus on prototyping elements during this project. The learning curve in each specialistic area of expertise (soft electronics, knitting technology, sensor technology, pulmonology, algorithmic pattern detection, filtering, etc.) is considerably large. During the graduation project, it was practically impossible to make considered design choices that combined all this expertise. Therefore, the focus on prototyping during this project limits the ability to truthfully conclude in what direction of manufacturability the benefits can be reaped.

The somewhat experimental application of connectors and types of wiring used to fabricate the prototype will do the job in the first stages of development. However, every extra step in manufacturing a textile system, or every material added, makes the integration of components more complicated. Therefore, a logical conclusion would be that a successfully integrated solution equals the solution with the least number of components to integrate. Less is more. The less integration, the better.

Comfort and usability

In terms of comfort, the mixed user feedback indicates that while the overall experience is acceptable, the tight fit is experienced as constraining. The posture-corrective tightness around the armpits impacts the freedom of movement while bending over. Exploring materials with more flexibility and adjusting the design around areas critical for a range of motion should be addressed.

Participants liked the practicality of the zipper. However, concerns about adaptability to different body shapes highlight the need for a more flexible sizing system with visual cues. This is reflected in the difficulty of correctly pre-tensioning the straps. Incorporating stretchable materials and mechanisms for secure fastening could improve overall practicality.

In terms of aesthetics, participants’ perceptions of the shirt as machinery or experimental wear suggest a need for refinement in design for broader social acceptance. Balancing functionality with a more aesthetically pleasing appearance is crucial. Monochrome colouring and tightly incorporated electronic components will help serve this cause.

7.2 Conclusion & recommendations

The project emphasises the importance of leveraging innovative technology to enhance the quality of the care process, especially that of patients with breathing disorders. Such conditions demand a nuanced understanding of each patient's unique situation and enhance the accuracy of diagnosis and treatment. The symptoms of Chronic Hyperventilation Disorder hide behind pseudonyms, which underlines the need for instruments that detect indicative factors. Conversely, current applications of smart textile wearables often lack focus on a specific problem. However, can a textile wearable equipped with knitted sensor technology support medical professionals and patients make more accurate indications and preventative treatments?
The evaluation of the prototype's development and performance aimed to provide insight into the effectiveness, user experience, and manufacturing of smart textiles for monitoring breathing patterns. The report presents the potential role in diagnoses and treatment and demonstrates the relevance of a wearable monitoring device.

In pursuit of realising the potential, the results of the prototype evaluation indicate the following points of attention. The outcomes are discussed in response to the three design objectives:

1. To retrieve data that provides reliable information about a patient's breathing behaviour in various circumstances.
2. To deliver a comfortable experience to the user and not restrict them from performing everyday tasks.
3. To demonstrate possible manufacturing challenges and opportunities of integrating textile strain sensors.

1. Effectiveness of using knitted sensors for measuring breathing behaviour:
The project confirms that collecting real-time data related to a patient's breathing behaviour is possible, and readable results can be achieved even with elementary prototyping components. The knitted strain sensors demonstrate usable results during various positions and activities, including sleeping in different positions, walking, and standing. The prototype collects data during breathing exercises, making it possible to deduct the respiration rate and depth at different locations on the upper body. Thus, information about the breathing pattern of an individual can be interpreted. Optimising the sensor dimensions, electronics, and connections makes the results more consistent and reliable. In addition, considering the expected amount of fidelity necessary in future project applications, it has become evident that further investigation into signal amplification and noise suppression is essential. Next to that, healthcare professionals need to confirm the assumptions about the usefulness of the data in developing a better understanding of the patient's condition.

2. Impact of features on the user experience:
In terms of user experience, the prototype appeals to the imagination, and participants feel tempted to test out the shirt as the prototype is associated with regular clothing. Compared to the first prototype, horizontal tension straps in the second version provided several beneficial properties regarding comfort and performance. Although user feedback on the comfort of the second version was mixed, the overall user experience is acceptable. With a range of improvements, a prolonged positive experience for the user scenario is likely achievable. Aesthetically, the participants consider

the shirt socially acceptable, especially if worn with regular clothing and finished in a less eye-catching fashion. Important suggestions in pursuit of subsequent prototypes include facilitating clear sensor calibration cues, variable sizing, and optimisation of the placement of straps to improve comfort.

3. Manufacturing knitted sensors:
Regarding the key materials and manufacturing methods, the study has shown that a lot is possible regarding the dimensions and placement of supportive electronics necessary for running textile systems - too much to cover in one graduation project only. The materials and manufacturing methods employed during development demonstrate only a few possible techniques for constructing textile systems. Even the topics outlined during the analysis of smart textiles' state of the art do not cover all possibilities. What is clear is that even the slightest variation in attachment or wiring can significantly impact the electromechanical properties, especially when working with textile sensors. Therefore, careful consideration is justified for prospective production collaborations with manufacturing companies.
As emphasised in the report, the techniques used in prototyping for connecting components are experimental and used to manufacture a functional prototype that can be tested for performance. However, results immediately pointed out the biggest weakness in smart textile systems: the electrical contacts. Although using conventional wiring in the prototype results in considerably reliable results, researching durable and scalable techniques for creating electrical contact between textiles and electronics is highly prioritised for improving data quality and evaluation. Likewise, other areas impacting the data quality and scalability of the construction have been identified, and recommendations have been given on possible sub-projects supporting future development.

As a final note, the positive sentiment in the healthcare landscape around user-friendly ways of monitoring breathing behaviour hints at its potential in other contexts that would otherwise be difficult to monitor. For example, applying textile sensors for monitoring breathing behaviour could help gain perspective on factors that influence sleeping apnoea that would otherwise stay under the radar. Accordingly, this project illustrates the fascinating interdependency between utilising medical knowledge to design wearables and generating medical knowledge through the development of wearables.

Recommendations

The recommendations include suggestions on possible research and design directions. They aim to offer insight into essential topics for iterating on the work done in future development or offer starting points for follow-up projects.

Increasing the effectiveness of the utilization of knitted sensors.

- **Sensor placement** in relation to physiology.

As argued by a breathing therapist, an alternative placement of the sensors could be to place them according to the physiology of the muscles used for respiration. Presumably, valuable information about the breathing behaviour of the patient can be deducted not only from the area of expansion on the body but also from the specific muscles that are used, and which are not. A vital interpretation is that malfunctioning breathing is directly linked to built-up muscle tension, which restricts a person from sustaining a balance between in- and exhalation. As illustrated in Figure 86, applying this knowledge could result in placing strain sensors in line with the essential muscles for respiration. Or alternatively, by using sensors to measure muscle activity.

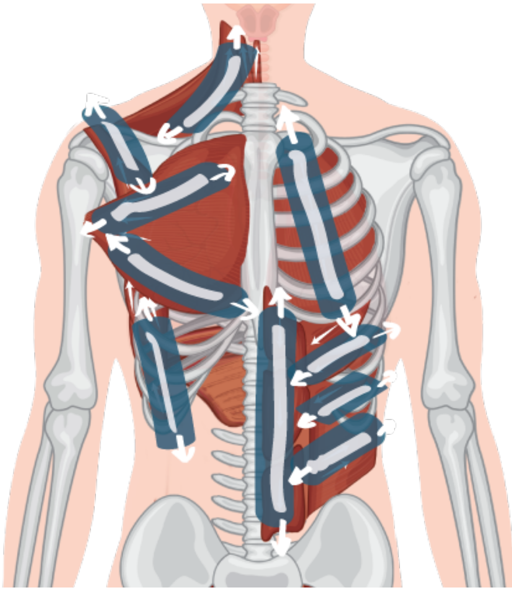


Figure 86: sensor placement in relation to muscles used for respiration

- Optimising the sensor **working range.**

The user tests pointed out that for multiple reasons. In terms of performance, the working range of the strain sensors should be optimised to get the most out of the 40% range the knitted strain sensors can provide. Solving this issue could lead to fewer data glitches and be considered highly important. Two suggestions are given.

- Optimising the **sensor length**. The length of the sensors determines the relative change in resistance. Given the typical expansion during breathing (2 to 7.5 cm expansion), the optimal sensor length is between 5 and 18.75 cm. With pre-tensioning, this could be larger to create a tight fit to the body, and depending on the target group, this could differ. In any case, further research should be done on the impact of the sensor length on the working range.
- Designing a mechanism for adjusting and **pre-tensioning the sensors.** Patients should be able to set the right amount of pre-tensioning for optimal sensor performance by themselves. During the user testing, participants appointed this fact as well; it could even be the case that the absence of such a mechanism is partly why the data quality of participants' results deviates. Participants suggested visual clues and a plain mechanism for adjusting exactly how tight the shirt needs to be tensioned. Alternatively, it has been suggested that the user be guided to use an app during the project.

○ Signal **amplification** to enhance definition.
Amplifying the sensor signal has become a big topic during the prototype's development. In short, the reasoning is to increase the level of detail captured in data. The simple controller (Arduino) used in the prototyping is well suited to measuring signals of a few volts from a low-resistance source. The knitted strain sensors, however, produce only minimal changes in resistance and have a high resistance to begin with. So, by amplifying the signal, the range in which the Arduino can capture data can be enlarged, improving the amount of detail (figure 87). Another reason is that by amplifying the signal, potential noise from the textile circuitry will disappear into the background.

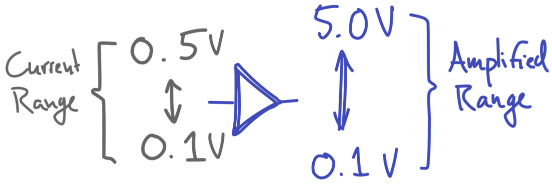


Figure 87: Simple example of amplified signal range

For this purpose, conventional electronic OpAmps/ADCs (Analog to Digital Converter) can be used, and they should be placed as closely as possible to the sensors. The first steps in applying OpAmps in the prototype have already been taken (Figure 88).

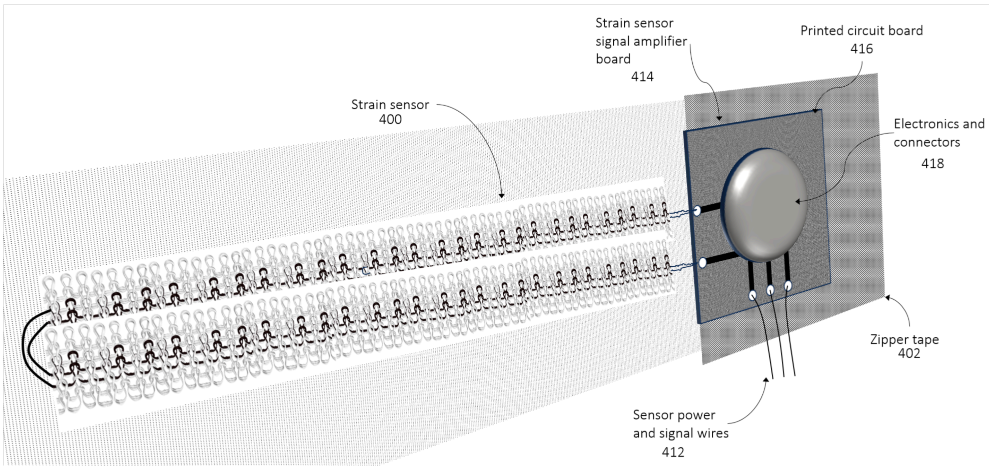


Figure 88: Placing opamps to amplify the signal (Mediventic, n.p.)

More experimentation is needed to understand better how feasible this solution is in terms of integration into the textile garment. However, early experimenting suggests that noise exists inherent to the structure of knitted strain sensors at a magnified level of detail. This confirms the notion that careful attention must be paid to the level of detail needed for the wearable application. Additionally, as suggested earlier in the report, a moving average filter could be applied to counter the noise, which may delay synchronicity but may be an ideally suited interim solution.

○ Durability tests: **washability** of sensor material.
A topic untouched during the project but essential to the concept's viability is the durability of the strain sensors in the user context. Recent experiments done by Mediventic point out a difference between electromechanical properties before and after being washed. Presumably the silver coating of the conductive yarns oxidizes in contact with water or sweat. This could be a serious threat to the design's viability, and if the effect of proofs to be true, alternative sensors that use yarns that are more resistant need to be developed. For example the use of carbon yarns could offer a solution to the issue of durability, but further research need to be done on the electromechanical performance and reliability.

Suggestions on shirt designs for user experience.

- **Areas** for **improvements** of comfort.

Based on the results of the user tests, some areas for improvement in comfort can be identified. The straps around the armpit areas should mainly be modified. By positioning the straps differently, focused areas of discomfort can be avoided. Other areas of discomfort identified may also be resolved by improving the tensioning mechanism, as explained earlier, and using elastic straps instead of rigid straps. For the latter, a degree of elasticity smaller than that of the sensors should be used to avoid restraining the sensor performance. This involves finding an optimal balance between providing sufficient comfort and enough change in the length of the sensor.

$$F_{respiration} = (k_{sensor} \cdot x_{sensor}) + (k_{strap} \cdot x_{strap})$$

In the situation where a force [Frespiration] is applied by breathing out, and the sensor [with a spring constant of Ksensor] is fixed to a strap [with a spring constant of Kstrap], the change in length of the sensor [Xsensor] is dependent on the ratio between the two spring constants. A feasible solution can be found by optimising this ratio, e.g., finding the right Kstrap that results in sufficient Xsensor.

- Suggested user interaction for **treatment procedure**.

Monitoring is the first step in the effective treatment of breathing problems. For example, as the report explains, a patient's awareness of muscle tension and sustained imbalance breathing can be considered the first step towards restoring a relaxed body and mind. As accurate monitoring is the starting point, it has been the main focus throughout this project. Now, in continuation of the solution Mediventic wants to offer, the focus needs to shift towards implementation for treatment. Conclusively, the advice is to use real-time data to make patients understand the nature of the beast. As noted by one of the participants, the risk that needs to be averted is a focus on the 'inadequacy' of their breathing behaviour. Which could only drive the sense that 'something is wrong.' Therefore, notifications need to enforce good breathing behaviour with a positive tone. Anyhow, designing a workable user interface that promotes the concepts presented could be a development component all on its own.

Suggestions key materials and manufacturing methods.

- **Manufacturing blueprint** for knitting process.

Realising the next step in textile wearables entails that the strain sensor, wiring components, and possibly other textile circuitry be part of a one-piece garment that can be knitted 'in one go' using an industrial knitting machine. This piece of textile circuitry is the part of the product that should retain all the beneficial properties of conventional clothing. The tightening straps, base garment, and sensor material are loose components sewn together in the prototype. They can be regarded as a blueprint for the one-piece smart textile of future prototype versions (figure 89). A detachable encapsulation must be designed to collect conventional electronics that cannot (yet) be knitted, such as the microcontroller and the battery. Points of inspiration may include a swappable battery and a magnetic connection to the fabric garment.
Only a tiny fraction of the possibilities for textile wearables are touched upon during this project's fabrication of the strain sensors. Finding ways of incorporating wires in the knitting

process that do not interfere with sensor performance and designing durable connections that offer reliable contact points between soft and hard electronics should be significant in future endeavours. Focusing on developing a durable and reliable construction will give Mediventic a strong manufacturing foundation, which can be expanded into new areas of health monitoring and create a competitive advantage.

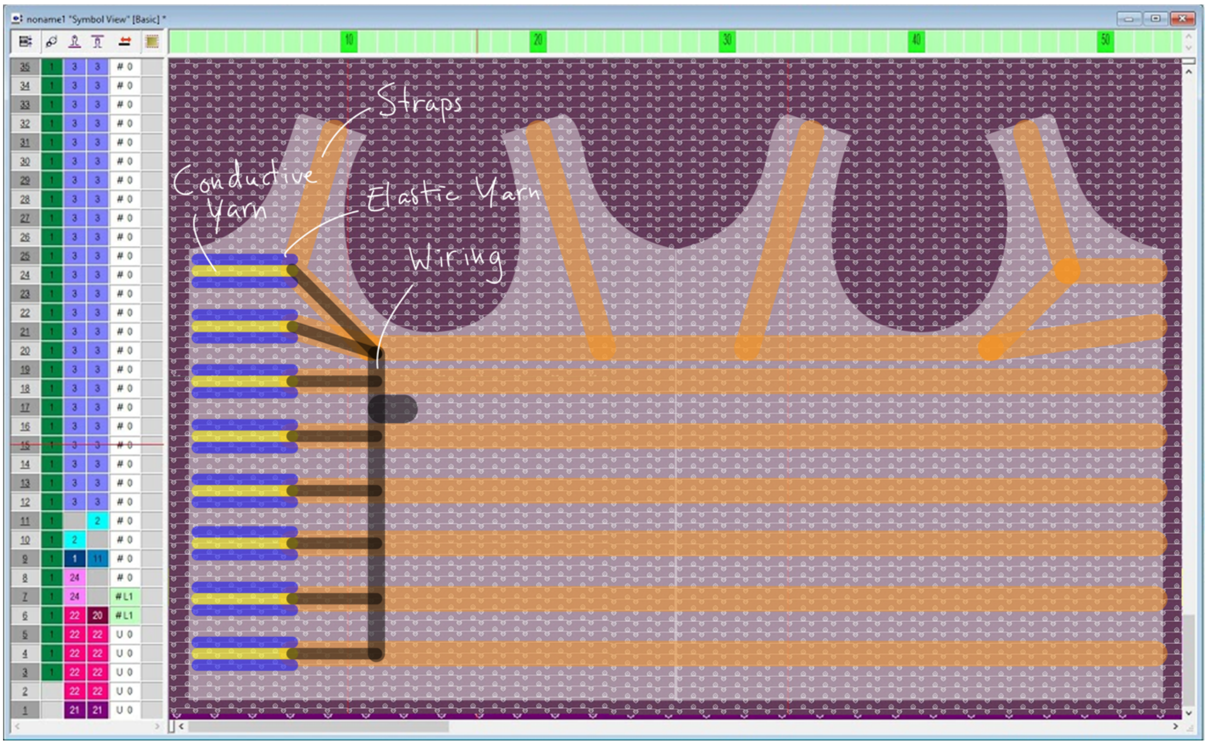


Figure 89: Example of software blueprint for a fully integrated knitted wearable shirt complete with sensors, straps, wiring, and base fabric.

As a final note, throughout prototype development, it has become evident that when assembling individual components, each additional component increases the risk of points of failure. Therefore, it is fitting to claim that the less assimilation and the more embedding of functionalities into one, the better. With this intention, the simplest way of integrating electrical properties with the least bells and whistles should be chased. Despite the teething problems, steep development curves and multidisciplinary challenges, textile wearables offer a strong likelihood of achieving this goal.

Overview of follow up projects:
- **User experience**: expanding on treatment procedure and user interaction; app interface.
- **Construction**: expanding on physiological breathing mechanisms to measure more precise; integration of wiring and connectors in a knitted wearable ready for the manufacturing process.
- **Sensor optimisation**: signal amplification and noise reduction; sensor durability and reliability; optimising
- **Medical expansion**: exploring potential impact on medical knowledge and integration of other types of sensors.
- **App development**: designing back-end IT structure of a unifying medical knowledge base.

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Appendices

List of appendices:

1. Project brief
2. Sensor evaluation (compiled by Mediventic)
3. User scenarios
4. Body Maps (Zeagler, 2017)
5. Safety Report
6. Sensor development test results
7. Prototype development test results
8. User test plan
9. User test results

Appendix 1

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT

Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: Duyts
initials: S. J. given name: Sybe
student number: 4477243
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): ★ IPD / DfI / SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: Honours Programme Master
specialisation / annotation: Medisign / Tech. in Sustainable Design / Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Prof. dr. ir. Jansen, K.M.B. dept. / section: SDE / Emerg. Materia
** mentor: Fredrik Karlsson dept. / section: DOS / CardioLab
2nd mentor: Marco Cevat
organisation: Mediventic
city: Amsterdam country: The Netherlands

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Prof. dr. ir. Jansen, K.M.B. date 14 - 06 - 2023 signature

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: ________ EC

Of which, taking the conditional requirements into account, can be part of the exam programme ________ EC

List of electives obtained before the third semester without approval of the BoE

YES all 1st year master courses passed

NO missing 1st year master courses are:

name ________ date - - signature ________

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED NOT APPROVED

Procedure: APPROVED NOT APPROVED

comments

name ________ date - - signature ________

Mediventic Smart Shirt

project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 13 - 06 - 2023 | 14 - 11 - 2023 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Chronical hyperventilation syndrome (CHVS) is an urgent and increasing problem. Over the last years research has shown an increase in the number of cases of anxiety and related CHVS, caused by post-Covid stress, PTSD, and permanent stress/peer-pressure - mainly in adolescence through online media. They are cause for a surge in cases of depression and related cases of CHVS.
Mediventic, a startup in the healthcare industry, wants to help people affected by stress or anxiety lead a healthier and happier life by making diagnosis and treatment of Chronic Hyperventilation Syndrome (CHVS) easier.
Helping patients to prevent lapses, by constructing affordable tools for home use to support treatment and exercise. According to Mediventic, at the moment there is not an accurate, affordable, and portable tool for diagnosis available.
Interestingly, the need for a solution that can be effectively used by practitioners and comfortably worn by patients, is confirmed by doctors, physiotherapists, and other experts interested in breathing behaviour.

Mediventic is developing a 'sensor and tool-kit' in the form of a smart clothing with sensors measuring heart rate and breathing. The kit keeps objective records of a patient's breathing behaviour during diagnosis and therapy of (suspected) CHVS. Mediventic is founded by Marco Cevat and Jobst Winter, who together have yours of experience in digital transformation, cardiology, (health tech) start-ups, management consulting, and cross-disciplined health care. They will be representing the external organization, Mediventic.

It is intended to use textile strain sensor technology developed by among others Kaspar Jansen, professor at the materializing futures section of IDE at the TU Delft. The patented sensors for smart textile applications can achieve low hysteresis values and a functional working range of 40% strain. Making up for an integrable strain sensor seemingly ideal for the smart clothing kit under development by Mediventic. Access to the fully programmable industrial knitting machine and staff at the TU Delft with experience using, offer the opportunity to further advance the design of the prototype.

The main opportunity for this project is: to integrate the knowledge and recent developments available at the TU Delft about knitted sensor technology, with the appropriate requirements from different stakeholders involved in the diagnosis and treatment of CHVS. This involves the close cooperation with industry experts and their view on the diagnosis process.

Limitations could be time management with regards to using the knitting machine and the time it takes to do a full-period user study.

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introduction (continued): space for images

image / figure 1:

image / figure 2:

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

At this moment, there is no affordable, portable, and easily applicable way to record a patient's breathing behaviour objectively. Neither as a diagnostic tool nor as a means of feedback during exercise. More specifically there are no solutions to record and report a patient's breathing patterns over longer periods of time. Whilst 'longer periods of time' are a requirement for practitioners to accurately diagnose a patient's condition.

Therefore the graduation will deal with a scenario in which the patient will wear a measuring device for a given amount of time. Depending on the context research that will be conducted together with cardiologists and pulmonologists, this could be a period of 24 hours and/or 7 days. Which means that the measuring device is exposed to some challenging working conditions and ergonomic requirements.

By using the textile strain sensor technology - mentioned in the introduction, a smart garment that uses this technology will be the basis for the prototype's functional structure.
Thus the challenge functionally will be to design the sensor garment in such a way that it accurately measures the variations in body/chest circumference without it being too intrusive or prone to variations in body size/type. As well, converting the data produced by the sensors into readable information for the practitioner to use, will to a certain extent be done in order for the garment to be tested.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

During my graduation I will conduct research on the strain sensor material, and learn how to implement it into a functional smart-garment. At the same time I will learn about the user perspective and context requirements the smart-garment will have to operate in. The concluding requirements will be the basis on which I will iterate the current prototype, to a pre-production prototype that is validated/demonstrated in a

The goal of the graduation project is to integrate innovative knitted sensors into an affordable, portable, and easily applicable smart-garment for the specific goal of monitoring breathing behaviour. The garment should obtain objective data that can be used for breathing pattern recognition, and can be used in longer periods as a diagnostic tool, and as a means of monitoring outside a therapeutic setting.

Thus, the scope of the assignment can be described by the following targets.
- A revised design of the sensor garment based on the conclusions of the research.
- A working version of the respiration sensors, built into the designed sensor garment, including the required motion sensors, transmission device, interface, relevant data, and receiving app.
- A smart garment design that fits the requirements for assisting the diagnosis of CHVS.
- A system prototype demonstrated in a testing environment. (TRL 6)

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 13 - 6 - 2023 | 14 - 11 - 2023 end date

Taking the basic cyclus of the design process as described by Roozenburg and Eekels as base for my planning, I have divided the process into 4 phases: analysis, synthesis, simulation, and evaluation. By dividing each phase into a diverging and converging subphase (e.g discover - define) I aim to secure enough iterations, as well as sub-deadlines to create a sense of urgency and maintain momentum.
Next to that I tried to create a bit of overlap and buffers to keep the planning from becoming too linear, and at the end of each phase I aim to report my findings to more effectively organize the information I have gathered, to ensure proper documentation.

Remarks:
- In the first week of July I will be working at the North Sea Jazz Festival.
- I have scheduled a week of vacation early in August.

Initials & Name S. J. Duyts Student number 4477243

Title of Project Mediventic Smart Shirt

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

I got in contact with Kaspar as I wanted to graduate at the Materializing Futures section. To finish my master IPD I wanted to really create something tangible during my graduation. Next to that I have been interested in the domain of material science as it is such an interesting and fundamental building block to solve societal issues in innovative ways. After my bachelors I doubted if I should switch to the masters Materials Science or BioMedical Engineering, eventually I figured that there is a reason why I switched to IDE in the first place, I like the creative nature of design engineering.

As a child I wanted to be an inventor, and I think that it is not that far-fetched from reality. My broad interests enables me to be a good listener and be open for different points of view.
Bringing together and streamlining information from stakeholders, orchestrating the complete design process without losing overview and integrating insight into a full-fledged product will be the challenge. I think the Mediventic project will enable me to prove to myself that I can fulfil that role.

Therefore the project came at the right time and at the right place. It is good fit on multiple fronts and enables me to both further develop my competences and learn new ones. Be it to explore my interest in both materials and biomedical engineering, or building on the previous experience with co-founding a company, where I think my 'professional skills' and 'taking initiative' have gotten a boost. As well it is in line with my apparent inclination towards choosing project that adhere to a social purpose. And my appreciation of quality fabrication of clothing.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

I want to express my graditude for the accidentally perfect timing of this project. Recognizing this as an opportunity for all parties involved is a good start of a succesful project.

Appendix 2

Sensor evaluation

Sensor types

Sensor	Measures	Gives
Strain	Body circumference	Breathing data
Load	Forces on body	External load
Conductivity	Skin resistance	Perspiration
Thermometer	Armpit temperature	Body temperature
IMU	Acceleration	Orientation, movement
ECG	Heartbeat signals	ECG
EMK	Muscle actuation signals	Diaphragm movement
Oximeter	Blood color	Saturation
IMU "click"	User's signals	Event

Objective

We need just to measure the level of change; we are not interested in absolute values. But when they do, we need fast, accurate and repeatable data.

Criteria

We looked at sensor technology to find the sensor best fitting following requirements:

Requirement	Expressed as	Examples / thresholds
Sensitivity	Change of reading or output is high per measured unit	Resistive sensor: in rest resistance is xΩ. 1mm change changes that by y%. The higher, the better.
Repeatable	Difference between a series of readings under same condition	Delta of reading of X units for every load of Y newton between readings
Durability	Characteristics remain reliable over long periods of use, expressed as the number of movements of the sensor under normal circumstances.	Clinical use: 200 days, 3 hours per day, 20 breathing cycles per minute = 720,000 cycles
Hysteresis	Input and output differ depending on direction of change.	Change of resistance in most conductive sensors reacts slower to contraction than expansion.
Low drift	Output value does not change under constant load	At a load of X newton, the reading stays at Y units over a period of at least Z seconds (with Z as long as possible) under similar ambient conditions
Accuracy	Measurement expresses the load (only) and contains no artifacts.	Polymer sensors have the tendency to lag, so their resistance could still drop while being put under strain. Is neglectable, though.
Tolerance	Sensors of the same type must return the same delta per unit of change	1mm of change on the strain sensor on the lower body must – within a known percentage – return the same change in value as a 1mm of change on the strain sensor on the upper body

Speed	Sensor should respond instantly to change	No, or a known constant, lag between the onset of the change and the output
Resilient	Must be usable under external load, and conditions around a human body	37°C, 99% humidity, aggressive chemicals from perspiration and make-up
Washable	Must be unaffected by submerging in cold water with mild detergent for at least 100 times.	
Power consumption	Battery power available is max 5V. Currents must comply with ISO standard.	Consumption: the lower, the better. 100µA under normal conditions or .5mA in case of failure.
Inert	Materials used should not cause health impact when worn on the body.	Check for allergies.
Isolation	Power between end points should never cause currents over the skin that exceed ISO standards.	100µA under normal conditions or .5mA in case of failure.
Low noise	Signal contains as little noise as possible	

Evaluation result

Type	**Construction**	**Comments**	**Source**	**Usability**	**Tested**	**Use**
Inductive	Distance	Accurate over short distances only; needs oscillator; measurement by changing frequency of circuit. Impacted by objects in vicinity.	1	Not accurate	No	No
	Linear	Metal rod inside coil; needs oscillator; measurement by changing frequency of circuit. Industry standard for high precision and big loads (Linear Variable Inductive Transducer (LVIT)).	2	Lumpy. Actuators prone to mechanical loads.	No	No

Type	Construction	Comments	Source	Usability	Tested	Use
Capacitive	Distance	Accurate over short distances only; needs to emit an electrical field; power consumption might be an issue; best for binary sensing (like touchpad)	3	Not accurate	No	No
	Linear, sliding	Pack of plates sliding between isolators; overlap determines capacity; actuated by the movement of objects; needs oscillator; measurement by changing frequency of circuit.	4	Lumpy. Actuators prone to mechanical loads. Fragile.	No	No
Resistive	Mechanical	Contact point sliding over resistor plate. High precision. Small power requirements.	0	Lumpy. Fragile, prone to mechanical loads.	Yes	No
	Polymer	Mechanical strain changes resistance of flexible materials.	0	Low sensitivity, long reset time, good accuracy, low repeatability. Elastic and self-correcting. Washable	**Yes**	**Test**
	Knitted	Mechanical strain changes number of 'short circuits' in resistor materials.	5	High sensitivity, good response, high repeatability, fast reset. Sensitive to external load; bad results from washing	Yes	Test failed~~Test~~
Piezo-electric	Film	Could not get it to work		Undetermined	Yes	No

Type	Construction	Comments	Source	Usability	Tested	Use
Muscle movement EMG	Pick-up	Easy setup, good sensitivity, lots of noise.	6	Shows there is breathing, not amplitude	No	No
	Implants	Out of scope (intrusive)			No	No
Optical	Reflective	Time travelled by a Light Pulse indicates distance between sender and receiver.	0	Rigid light path, so inflexible packing. Accurate, low sensitivity.	No	No
	Optical fibre	Can be knitted in. Washable. Requires specific type of fibre, and complex emitter and receiver.	0	Complexity might translate in high costs. Needs fundamental material research. Rejected.	No	No
	Camera	External observation, then process image.	7	Complex, requires patient to remain within view. Some patents filed for this.	No	No
Radio	Radar	External observation, then process reflections.	8	Complex, requires patient to remain within view. Inaccurate, to low resolution. Some patents filed for this.	No	No
Inertia	Motion	Accurate and fast.	9	Low sensitivity. Lots of noise from body movements. Extremely complex software.	Yes	**Test**

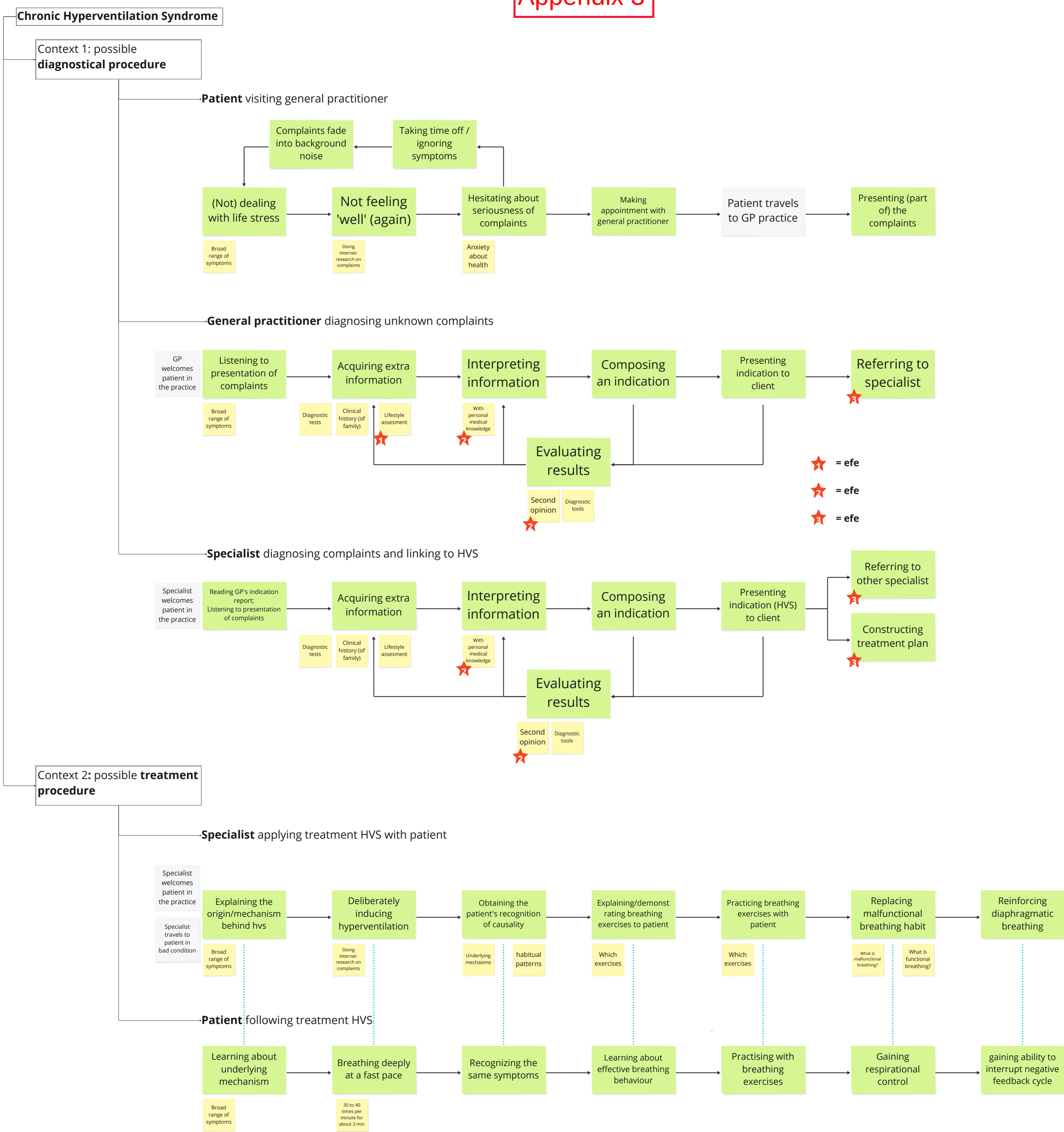
Type	Construction	Comments	Source	Usability	Tested	Use
ECG, EMK	Pick-up	State-of-art	0	Low sensitivity. Lots of noise from other body movements. Off-the-shelve and freeware software.	Yes	**Test**
Temperature	Thermistor (LM35)	State-of-art	0	Accurate; gives absolute value; fast	Yes	**Test failed~~Test~~ *)**
	Thermo Coupler (MAX6675)	Off the shelve	0	Not suitable for small changes at low temperatures	Yes	No
	Resistor (NTC)	Off the shelve	0	Accurate; gives relative value; slower than thermistor	Yes	**Test**
Conductivity	Pick-up	Easy setup, good sensitivity, lots of noise.	0	No alternatives found (?)	Yes	**Test**

*) LM35 did not work in initial test; NTC results seem adequate; may retest in the future, but not needed

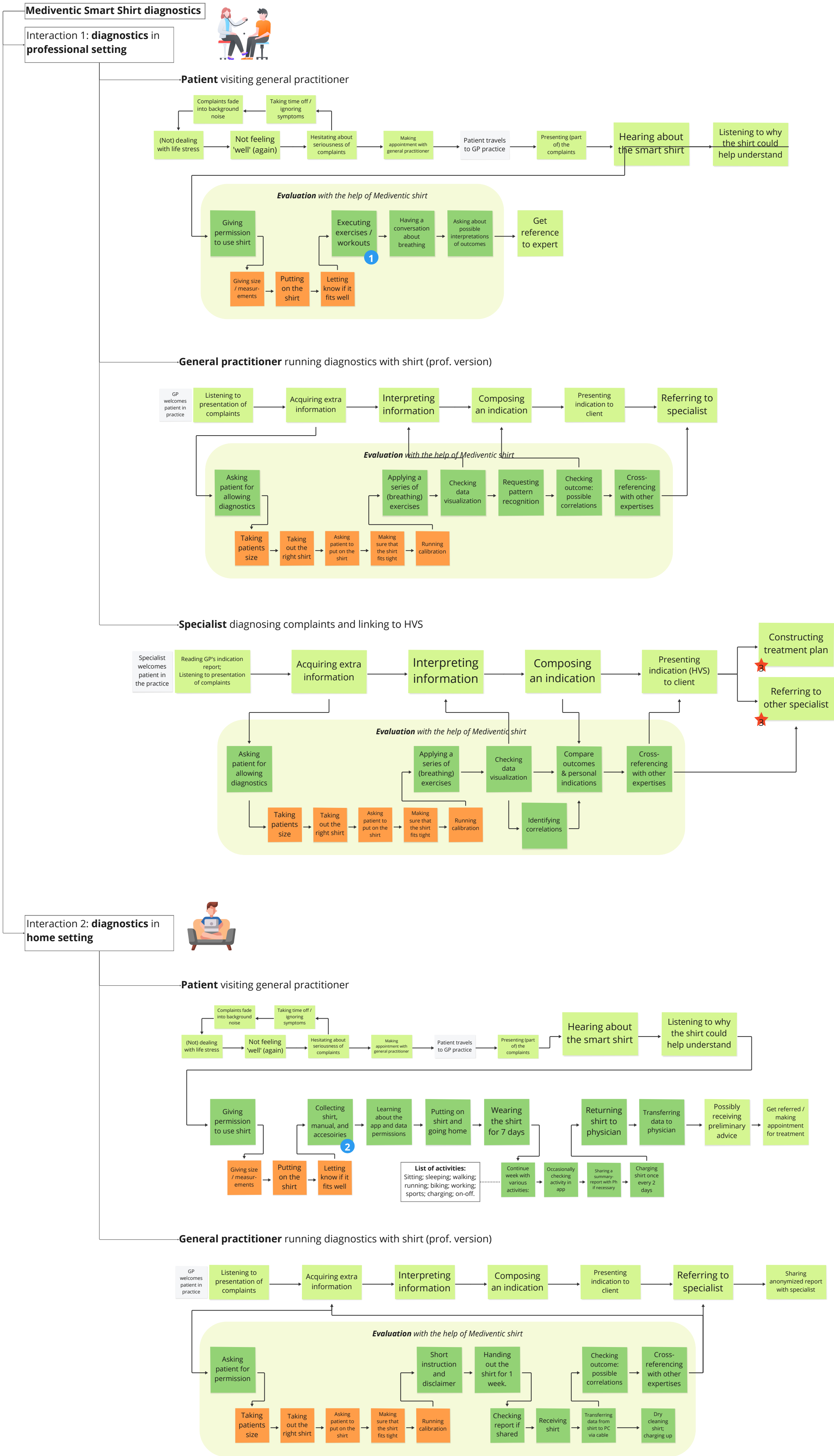
Sources

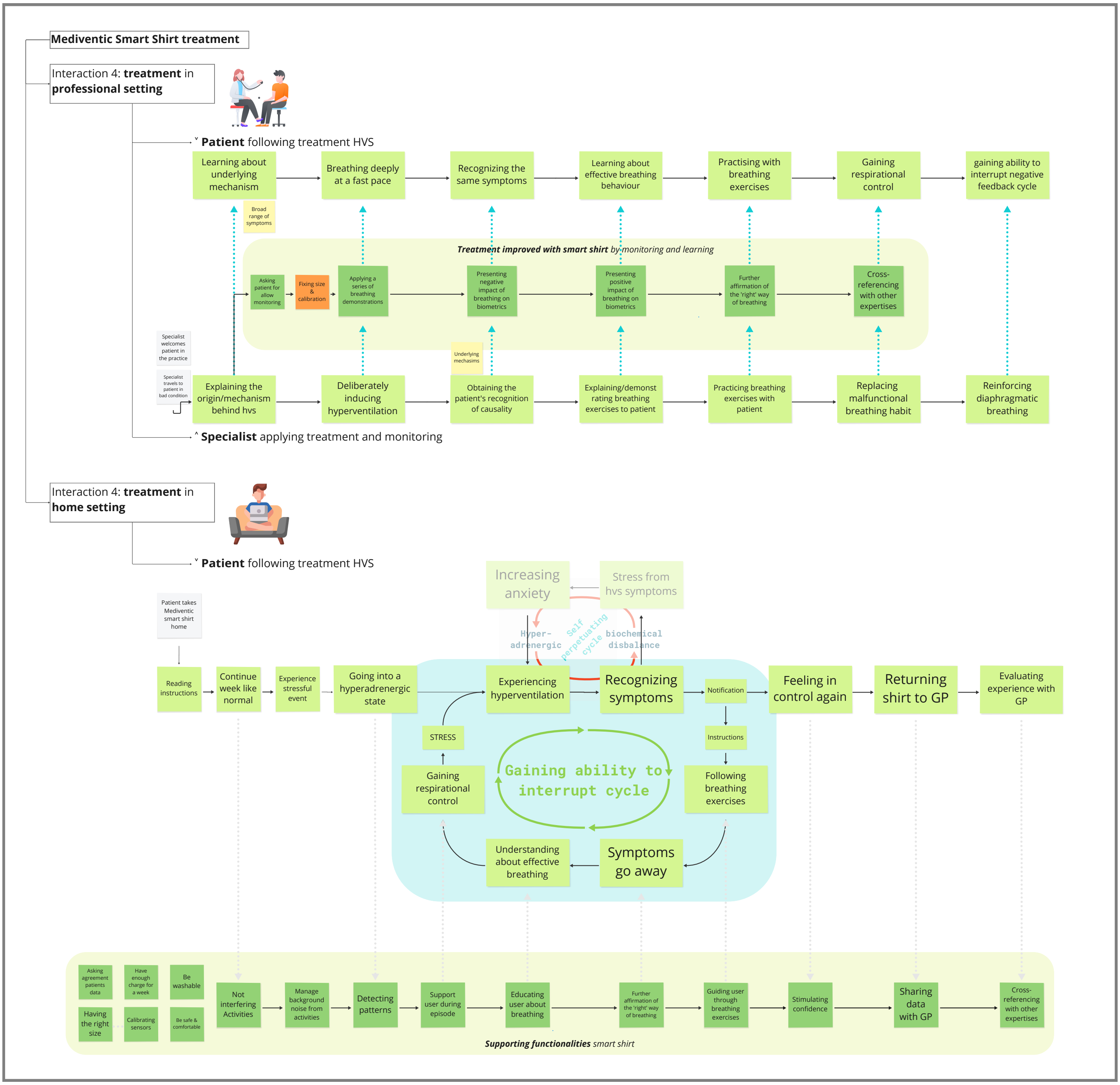
0 mediventic own research; prototypes available
1 https://realpars.com/inductive-sensor/
2 https://doi.org/10.3390/app112110134
3 https://www.thomasnet.com/articles/instruments-controls/proximity-sensors/
4 https://www.chegg.com/homework-help/questions-and-answers/mechanical-engineering-archive-2015-april-11
5 TU-D patent WO2023014224A1 knitted strain sensors
6 https://journals.physiology.org/doi/full/10.1152/jappl.2000.88.6.1955
7 Patent WO2008029121A1 for a patient monitor; other solutions patented too
8 Patent EP3868291A1 Respiration Detection Using Radar
9 Patent CA3200939A1 Sensors And Methods For Determining Respiration

Appendix 3

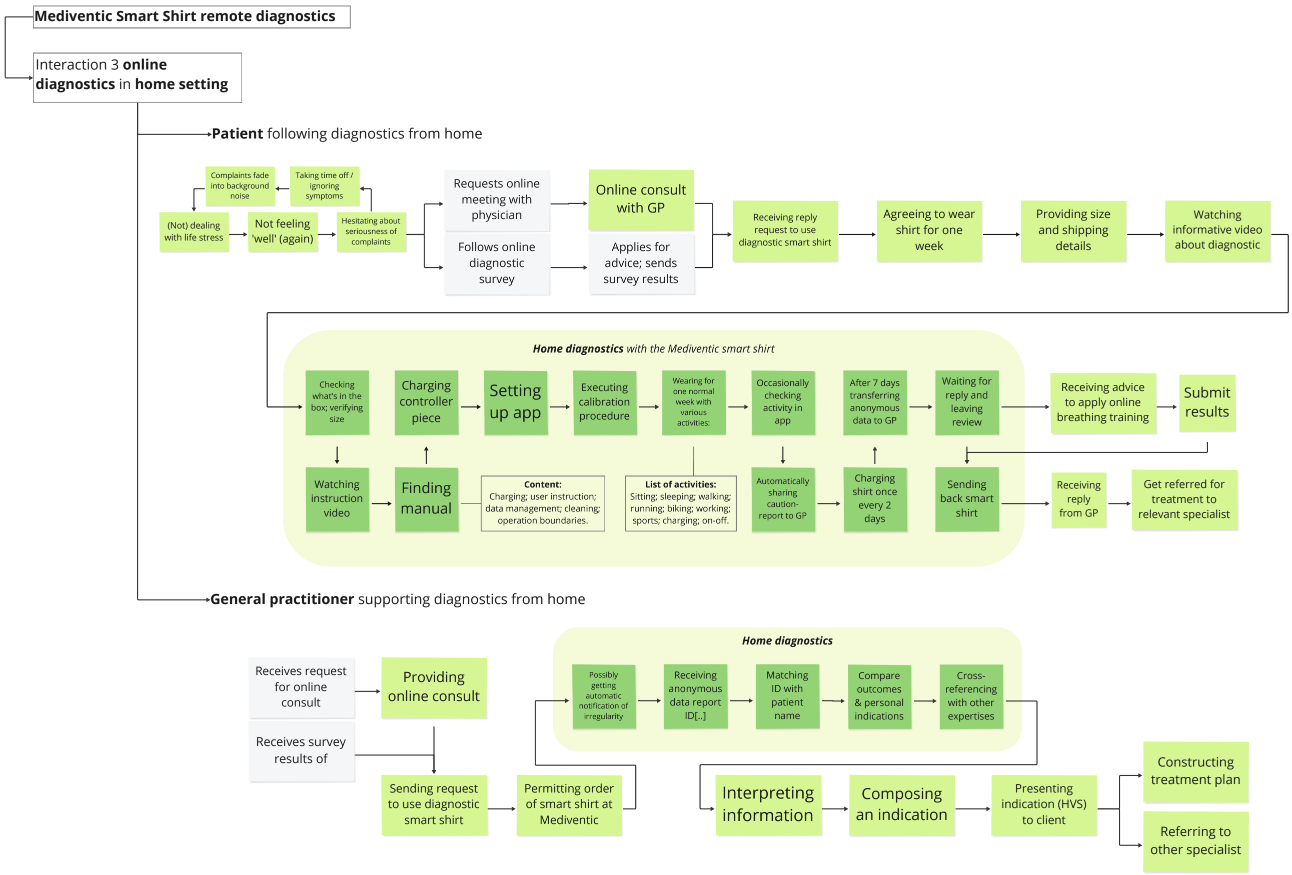


Chronic Hyperventilation Syndrome
Context 1: possible diagnostical procedure
Patient visiting general practitioner
Complaints fade into background noise
Taking time off / ignoring symptoms
(Not) dealing with life stress
Not feeling 'well' (again)
Hesitating about seriousness of complaints
Making appointment with general practitioner
Patient travels to GP practice
Presenting (part of) the complaints
Broad range of symptoms
Doing internet-research on complaints
Anxiety about health
General practitioner diagnosing unknown complaints
GP welcomes patient in the practice
Listening to presentation of complaints
Acquiring extra information
Interpreting information
Composing an indication
Presenting indication to client
Referring to specialist
Broad range of symptoms
Diagnostic tests
Clinical history (of family)
Lifestyle assesment
With personal medical knowledge
Evaluating results
Second opinion
Diagnostic tools
= efe
= efe
= efe
Specialist diagnosing complaints and linking to HVS
Specialist welcomes patient in the practice
Reading GP's indication report; Listening to presentation of complaints
Acquiring extra information
Interpreting information
Composing an indication
Presenting indication (HVS) to client
Referring to other specialist
Constructing treatment plan
Diagnostic tests
Clinical history (of family)
Lifestyle assesment
With personal medical knowledge
Evaluating results
Second opinion
Diagnostic tools
Context 2: possible treatment procedure
Specialist applying treatment HVS with patient
Specialist welcomes patient in the practice
Specialist travels to patient in bad condition
Explaining the origin/mechanism behind hvs
Deliberately inducing hyperventilation
Obtaining the patient's recognition of causality
Explaining/demonstrating breathing exercises to patient
Practicing breathing exercises with patient
Replacing malfunctional breathing habit
Reinforcing diaphragmatic breathing
Broad range of symptoms
Doing internet-research on complaints
Underlying mechasims
habitual patterns
Which exercises
Which exercises
What is malfunctional breathing?
What is functional breathing?
Patient following treatment HVS
Learning about underlying mechanism
Breathing deeply at a fast pace
Recognizing the same symptoms
Learning about effective breathing behaviour
Practising with breathing exercises
Gaining respirational control
gaining ability to interrupt negative feedback cycle
Broad range of symptoms
30 to 40 times per minute for about 3 min


Mediventic Smart Shirt diagnostics
Interaction 1: diagnostics in professional setting
Patient visiting general practitioner
Complaints fade into background noise
Taking time off / ignoring symptoms
(Not) dealing with life stress
Not feeling 'well' (again)
Hesitating about seriousness of complaints
Making appointment with general practitioner
Patient travels to GP practice
Presenting (part of) the complaints
Hearing about the smart shirt
Listening to why the shirt could help understand
Evaluation with the help of Mediventic shirt
Giving permission to use shirt
Giving size / measur-ements
Putting on the shirt
Letting know if it fits well
Executing exercises / workouts
1
Having a conversation about breathing
Asking about possible interpretations of outcomes
Get reference to expert
General practitioner running diagnostics with shirt (prof. version)
GP welcomes patient in practice
Listening to presentation of complaints
Acquiring extra information
Interpreting information
Composing an indication
Presenting indication to client
Referring to specialist
Evaluation with the help of Mediventic shirt
Asking patient for allowing diagnostics
Taking patients size
Taking out the right shirt
Asking patient to put on the shirt
Making sure that the shirt fits tight
Running calibration
Applying a series of (breathing) exercises
Checking data visualization
Requesting pattern recognition
Checking outcome: possible correlations
Cross-referencing with other expertises
Specialist diagnosing complaints and linking to HVS
Specialist welcomes patient in the practice
Reading GP's indication report; Listening to presentation of complaints
Acquiring extra information
Interpreting information
Composing an indication
Presenting indication (HVS) to client
Constructing treatment plan
Referring to other specialist
3
3
Evaluation with the help of Mediventic shirt
Asking patient for allowing diagnostics
Taking patients size
Taking out the right shirt
Asking patient to put on the shirt
Making sure that the shirt fits tight
Running calibration
Applying a series of (breathing) exercises
Checking data visualization
Identifying correlations
Compare outcomes & personal indications
Cross-referencing with other expertises
Interaction 2: diagnostics in home setting
Patient visiting general practitioner
Complaints fade into background noise
Taking time off / ignoring symptoms
(Not) dealing with life stress
Not feeling 'well' (again)
Hesitating about seriousness of complaints
Making appointment with general practitioner
Patient travels to GP practice
Presenting (part of) the complaints
Hearing about the smart shirt
Listening to why the shirt could help understand
Giving permission to use shirt
Giving size / measur-ements
Putting on the shirt
Letting know if it fits well
Collecting shirt, manual, and accesories
2
Learning about the app and data permissions
Putting on shirt and going home
Wearing the shirt for 7 days
List of activities:
Sitting; sleeping; walking; running; biking; working; sports; charging; on-off.
Continue week with various activities:
Occasionally checking activity in app
Sharing a summary-report with Ph if necessary
Charging shirt once every 2 days
Returning shirt to physician
Transferring data to physician
Possibly receiving preliminary advice
Get referred / making appointment for treatment
General practitioner running diagnostics with shirt (prof. version)
GP welcomes patient in practice
Listening to presentation of complaints
Acquiring extra information
Interpreting information
Composing an indication
Presenting indication to client
Referring to specialist
Sharing anonymized report with specialist
Evaluation with the help of Mediventic shirt
Asking patient for permission
Taking patients size
Taking out the right shirt
Asking patient to put on the shirt
Making sure that the shirt fits tight
Running calibration
Short instruction and disclaimer
Handing out the shirt for 1 week.
Checking report if shared
Receiving shirt
Transferring data from shirt to PC via cable
Dry cleaning shirt; charging up
Checking outcome: possible correlations
Cross-referencing with other expertises

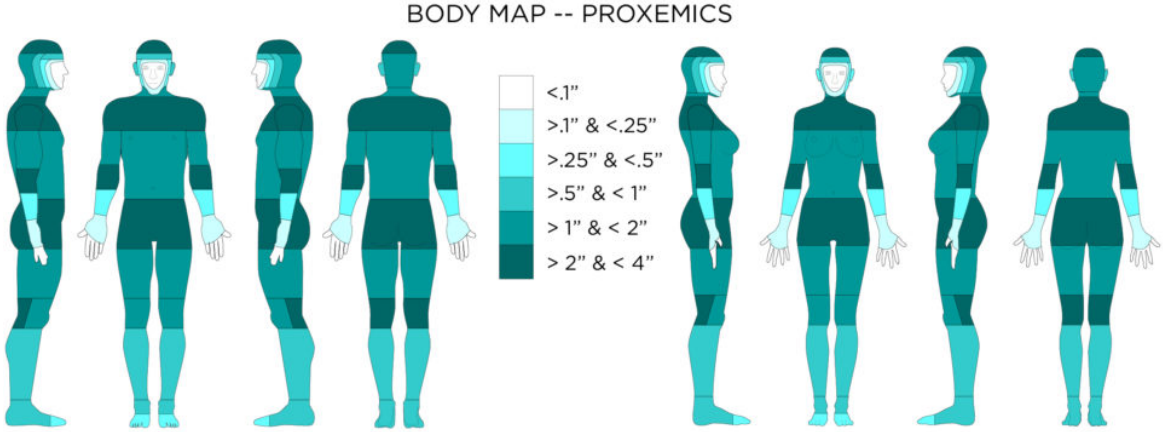


Mediventic Smart Shirt treatment
Interaction 4: treatment in professional setting
Patient following treatment HVS
Learning about underlying mechanism
Breathing deeply at a fast pace
Recognizing the same symptoms
Learning about effective breathing behaviour
Practising with breathing exercises
Gaining respirational control
gaining ability to interrupt negative feedback cycle
Broad range of symptoms
Treatment improved with smart shirt by monitoring and learning
Asking patient for allow monitoring
Fixing size & calibration
Applying a series of breathing demonstrations
Presenting negative impact of breathing on biometrics
Presenting positive impact of breathing on biometrics
Further affirmation of the 'right' way of breathing
Cross-referencing with other expertises
Specialist welcomes patient in the practice
Specialist travels to patient in bad condition
Underlying mechasims
Explaining the origin/mechanism behind hvs
Deliberately inducing hyperventilation
Obtaining the patient's recognition of causality
Explaining/demonstrating breathing exercises to patient
Practicing breathing exercises with patient
Replacing malfunctional breathing habit
Reinforcing diaphragmatic breathing
Specialist applying treatment and monitoring
Interaction 4: treatment in home setting
Patient following treatment HVS
Increasing anxiety
Stress from hvs symptoms
Hyper-adrenergic
Self perpetuating cycle
biochemical disbalance
Patient takes Mediventic smart shirt home
Reading instructions
Continue week like normal
Experience stressful event
Going into a hyperadrenergic state
Experiencing hyperventilation
Recognizing symptoms
Notification
Feeling in control again
Returning shirt to GP
Evaluating experience with GP
STRESS
Instructions
Gaining ability to interrupt cycle
Gaining respirational control
Following breathing exercises
Understanding about effective breathing
Symptoms go away
Asking agreement patients data
Have enough charge for a week
Be washable
Having the right size
Calibrating sensors
Be safe & comfortable
Not interfering Activities
Manage background noise from activities
Detecting patterns
Support user during episode
Educating user about breathing
Further affirmation of the 'right' way of breathing
Guiding user through breathing exercises
Stimulating confidence
Sharing data with GP
Cross-referencing with other expertises
Supporting functionalities smart shirt

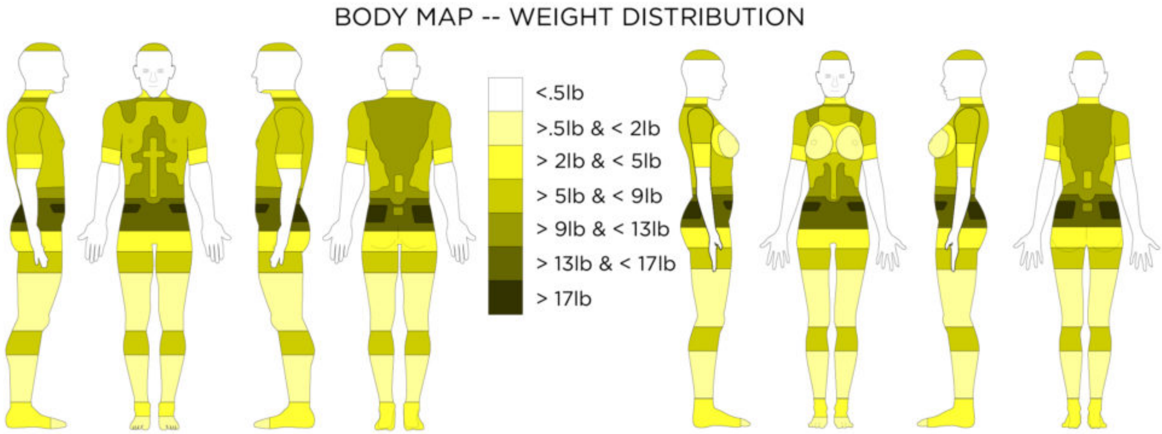

Mediventic Smart Shirt remote diagnostics
Interaction 3 online diagnostics in home setting
Patient following diagnostics from home
Complaints fade into background noise
Taking time off / ignoring symptoms
(Not) dealing with life stress
Not feeling 'well' (again)
Hesitating about seriousness of complaints
Requests online meeting with physician
Follows online diagnostic survey
Online consult with GP
Applies for advice; sends survey results
Receiving reply request to use diagnostic smart shirt
Agreeing to wear shirt for one week
Providing size and shipping details
Watching informative video about diagnostic
Home diagnostics with the Mediventic smart shirt
Checking what's in the box; verifying size
Charging controller piece
Setting up app
Executing calibration procedure
Wearing for one normal week with various activities:
Occasionally checking activity in app
After 7 days transferring anonymous data to GP
Waiting for reply and leaving review
Receiving advice to apply online breathing training
Submit results
Watching instruction video
Finding manual
Content:
Charging; user instruction; data management; cleaning; operation boundaries.
List of activities:
Sitting; sleeping; walking; running; biking; working; sports; charging; on-off.
Automatically sharing caution-report to GP
Charging shirt once every 2 days
Sending back smart shirt
Receiving reply from GP
Get referred for treatment to relevant specialist
General practitioner supporting diagnostics from home
Receives request for online consult
Providing online consult
Receives survey results of
Sending request to use diagnostic smart shirt
Permitting order of smart shirt at Mediventic
Home diagnostics
Possibly getting automatic notification of irregularity
Receiving anonymous data report ID[..]
Matching ID with patient name
Compare outcomes & personal indications
Cross-referencing with other expertises
Interpreting information
Composing an indication
Presenting indication (HVS) to client
Constructing treatment plan
Referring to other specialist

Appendix 4

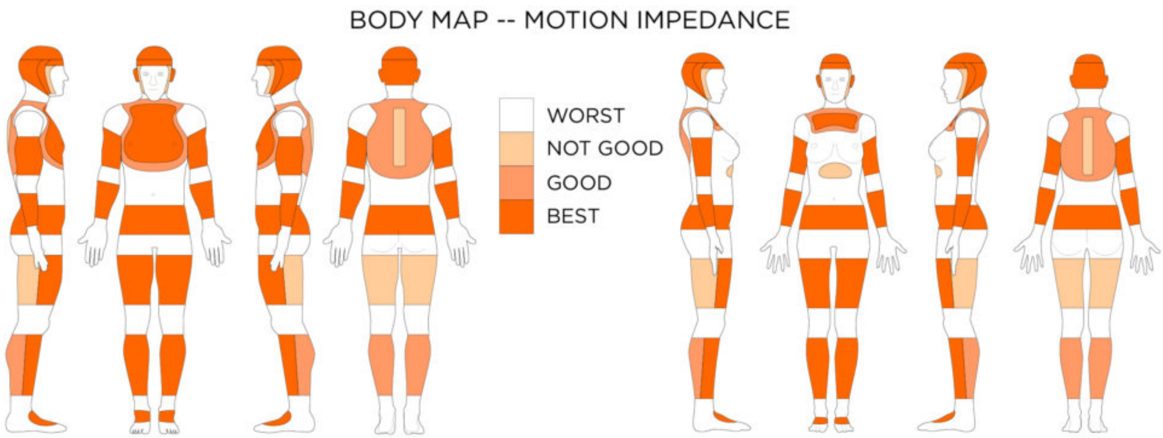
Comfort



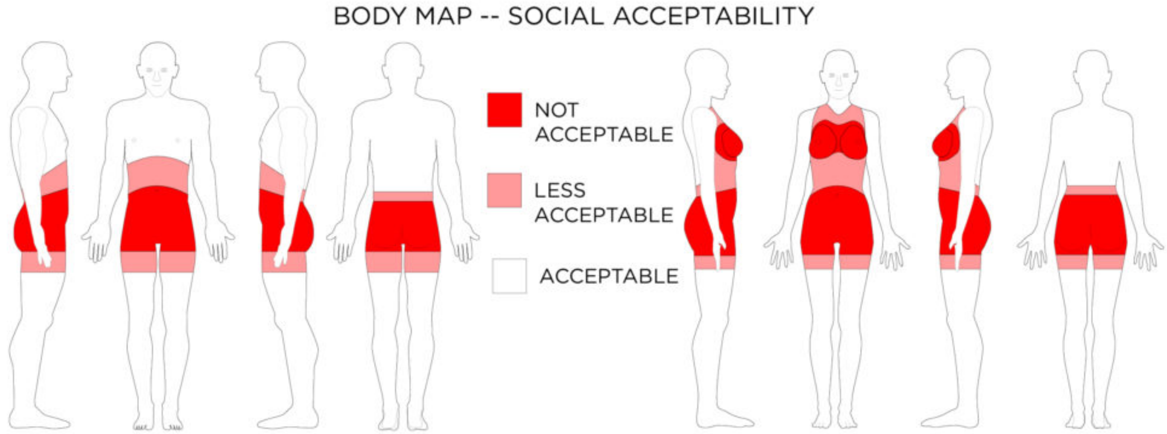
perception of self-size



amount of pressure before it becomes a discomfort

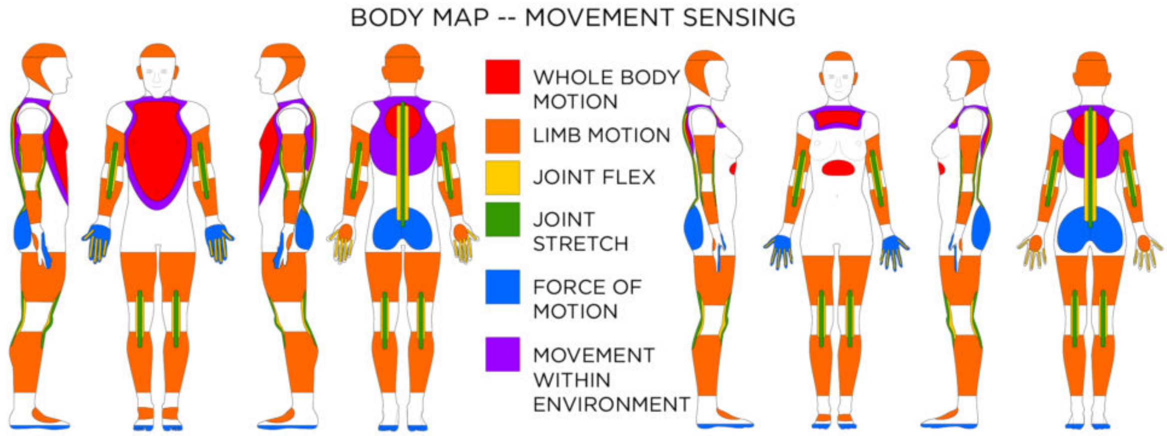


least obtrusive as amount of body motion impedance

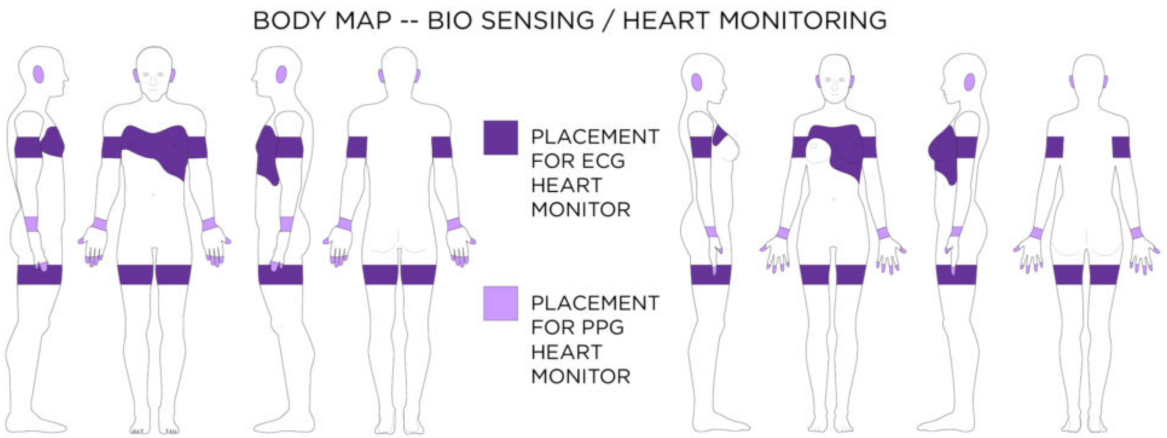


Socially acceptable placement for device interactions

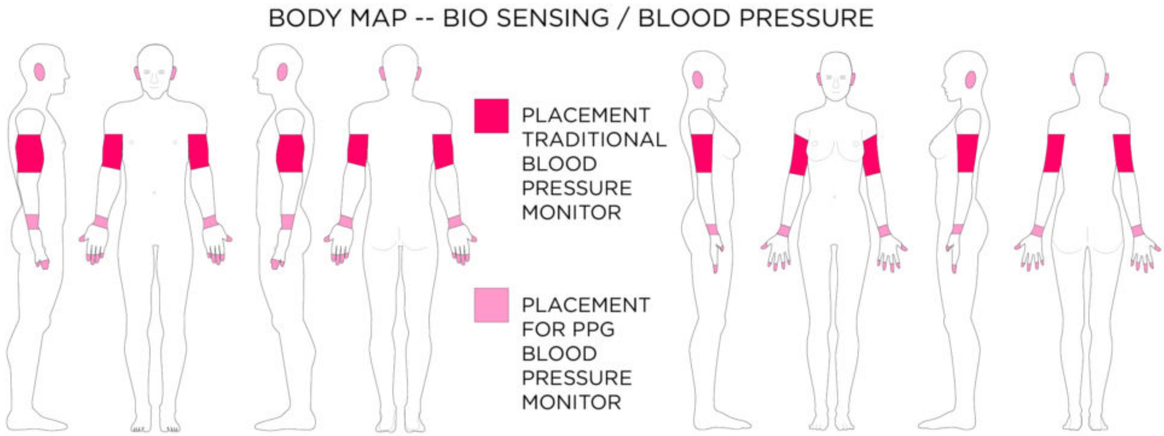
Sensing



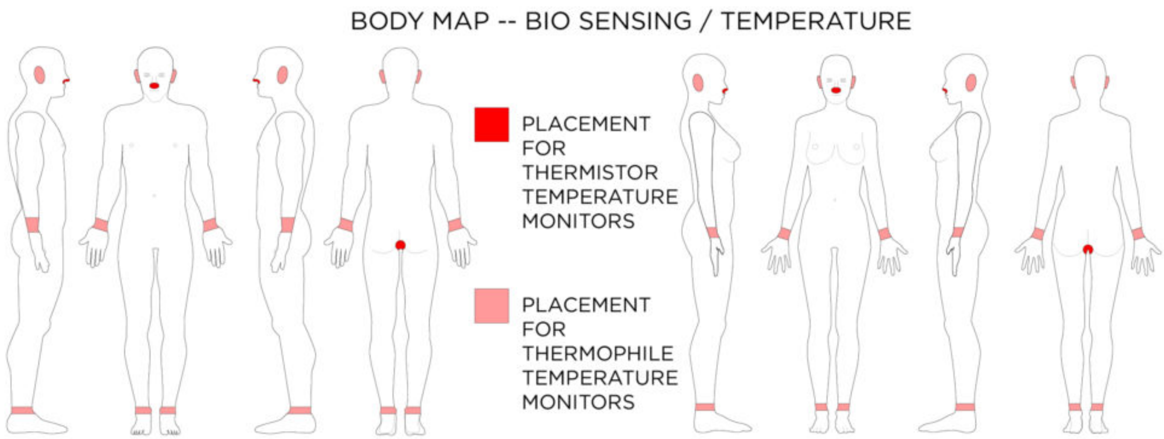
sensing body motion



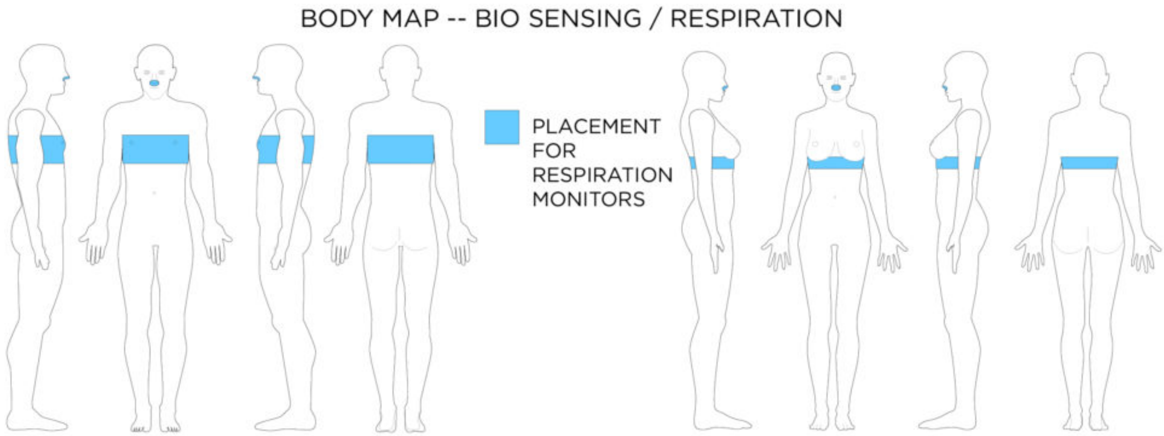
Locations for heart rate sensor / ECG



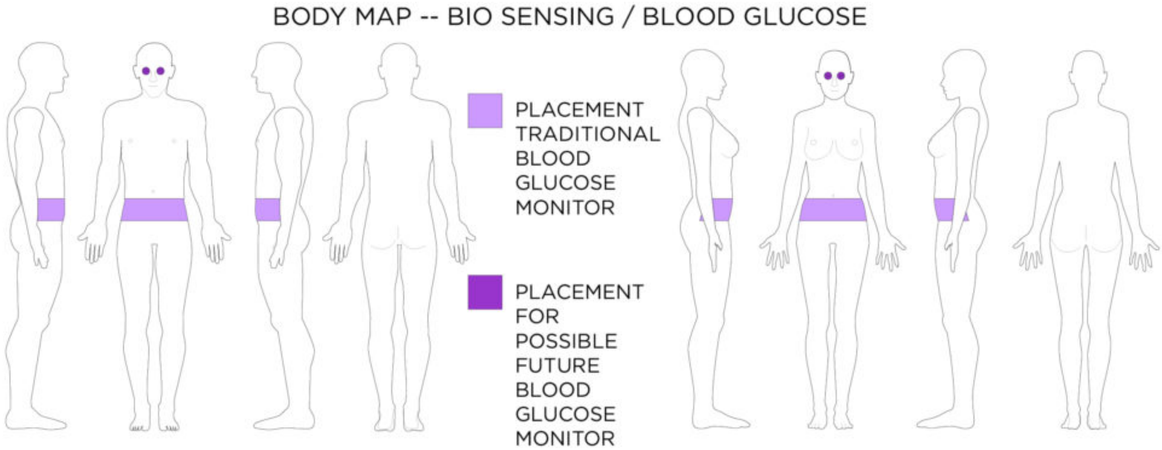
Locations for blood pressure sensor



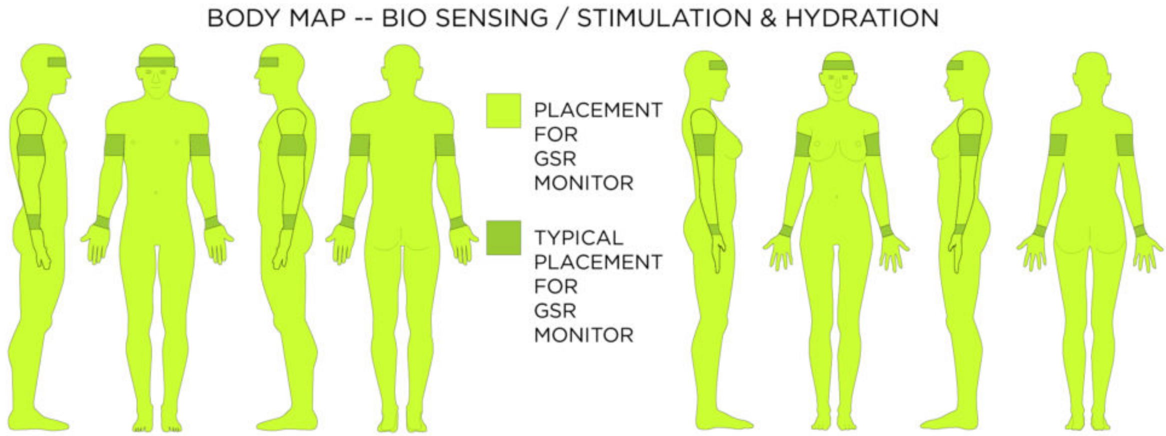
Locations for temperature sensor



Locations for respiration monitoring

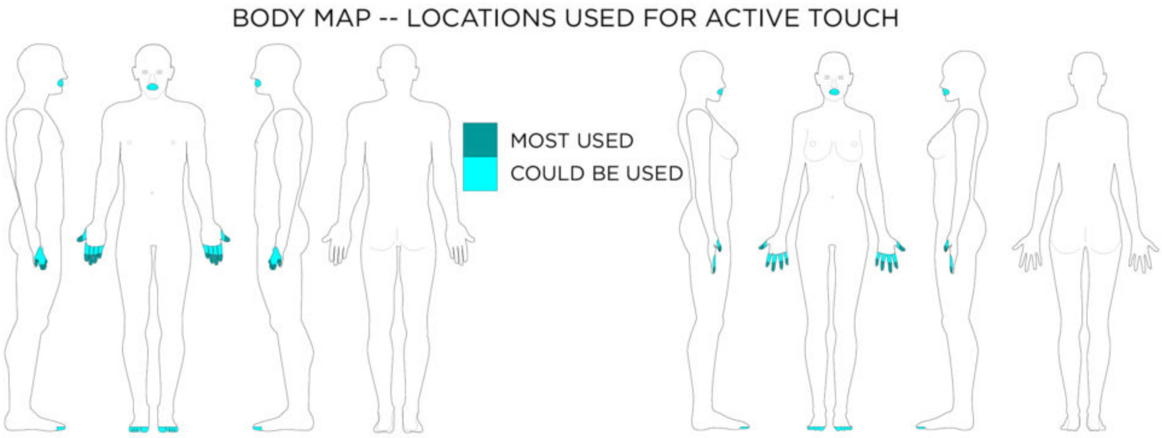


Locations for glucose monitoring

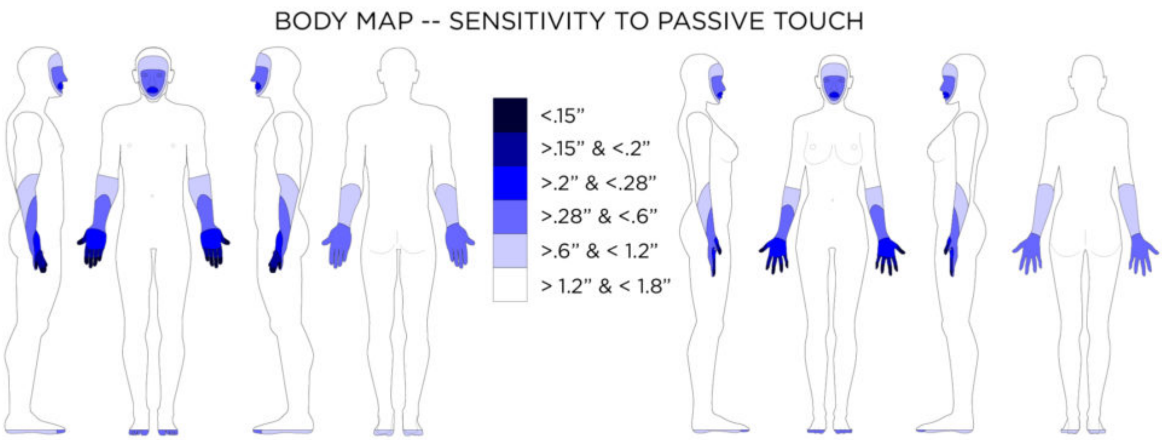


Locations for GSR data

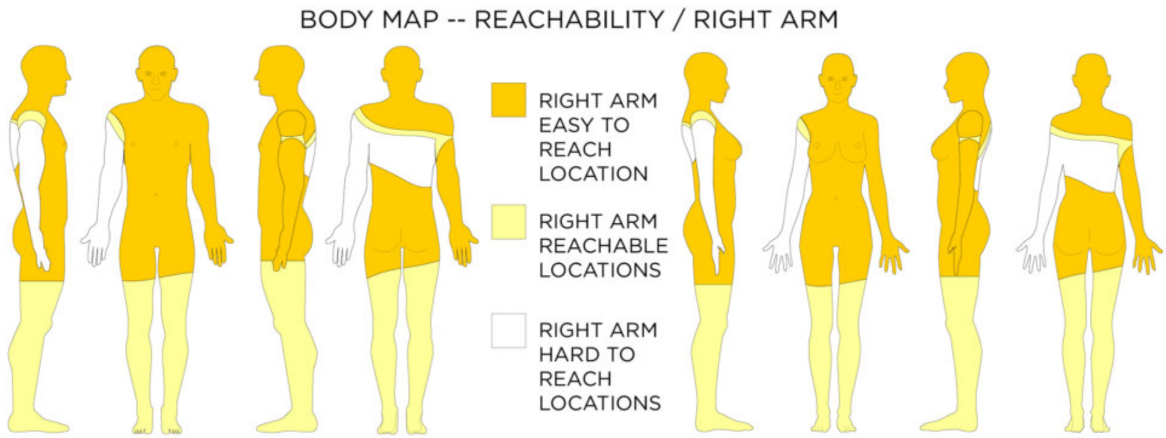
Interaction



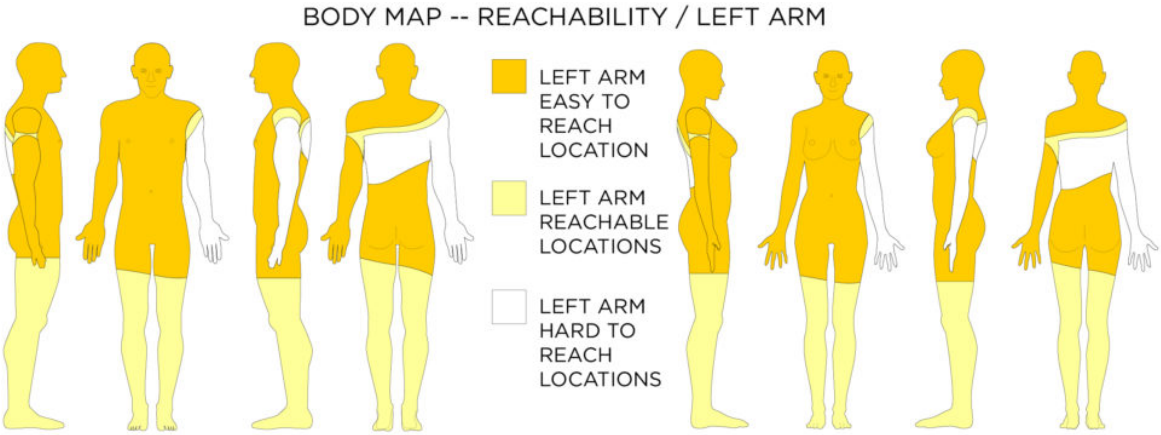
exploratory action of touching



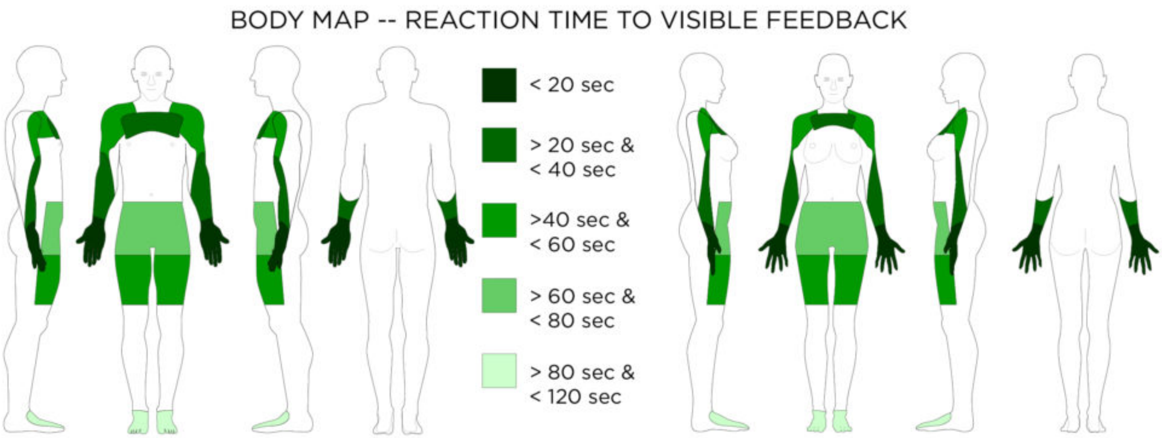
sensitivity for haptic feedback



Easy to reach locations with right arm

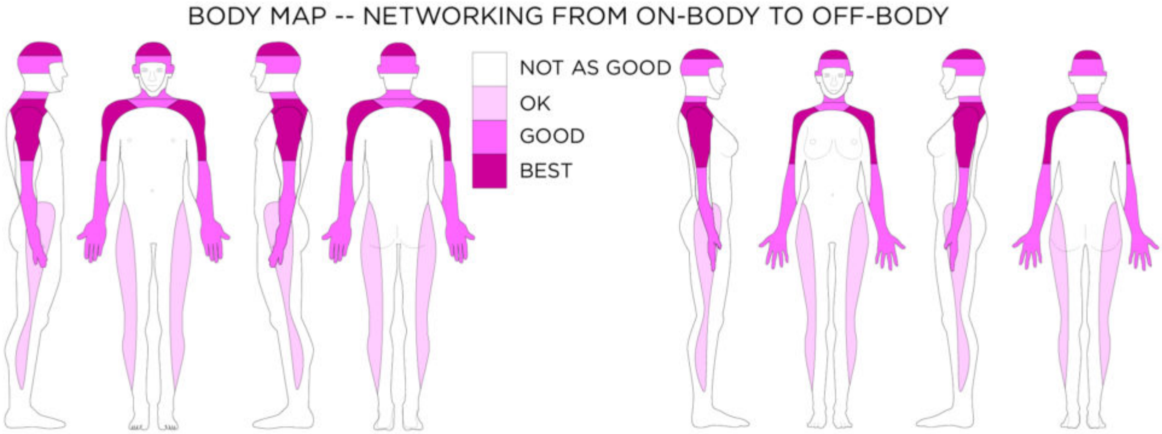


Easy to reach locations with left arm

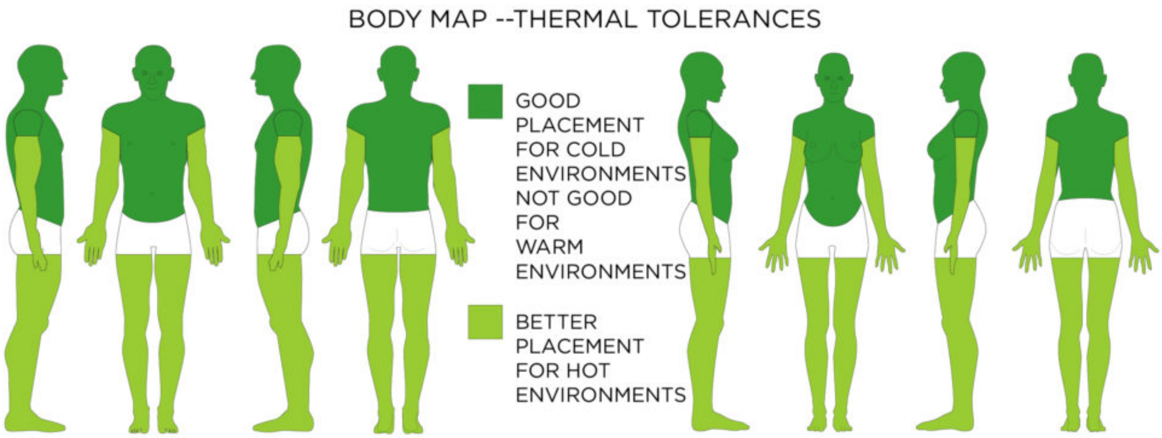


Location for visible feedback

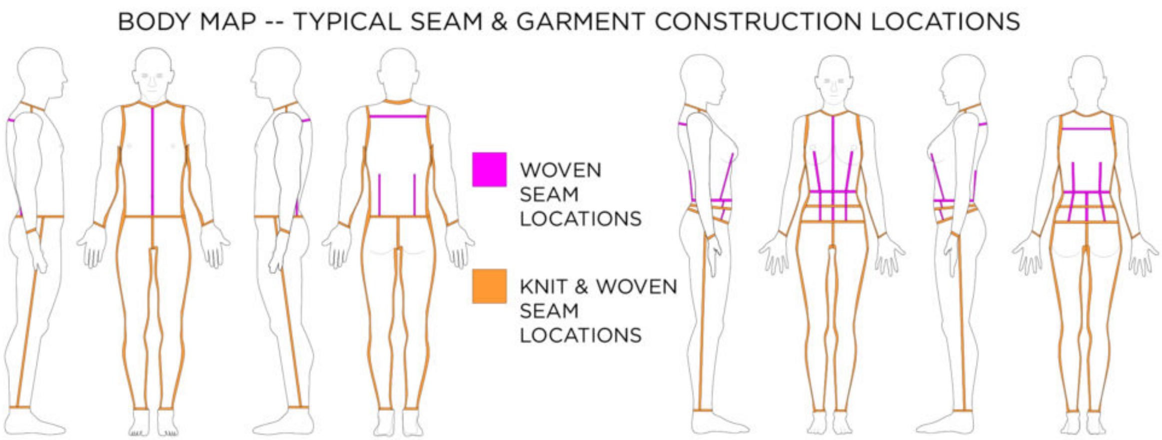
Manufacturing



Locations with least network interference by body mass



where to place technology which could heat up



Design considerations for incorporating wiring

Appendix 5a

Delft University of Technology
INSPECTION REPORT FOR DEVICES TO BE USED IN CONNECTION WITH HUMAN SUBJECT RESEARCH

Device identification (name, location):	Mediventic smart shirt
Configurations inspected:	NA
Type of experiment to be carried out on the device:	Record breathing behaviour and ergonomics of prototype
Name(s) of applicants(s):	Sybe Duyts
Job title(s) of applicants(s):	Master student
Supervisor:	Prof. dr. ir. Jansen, K.M.B.

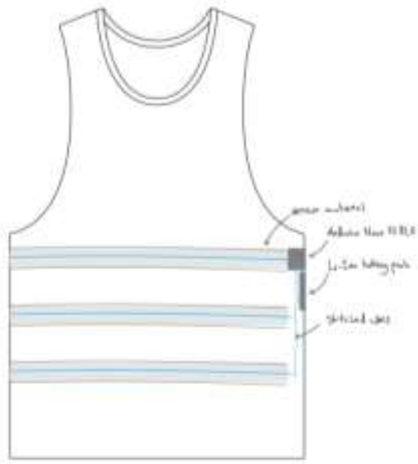
Date: 27-9-2023

Signature(s): Kaspar Jansen

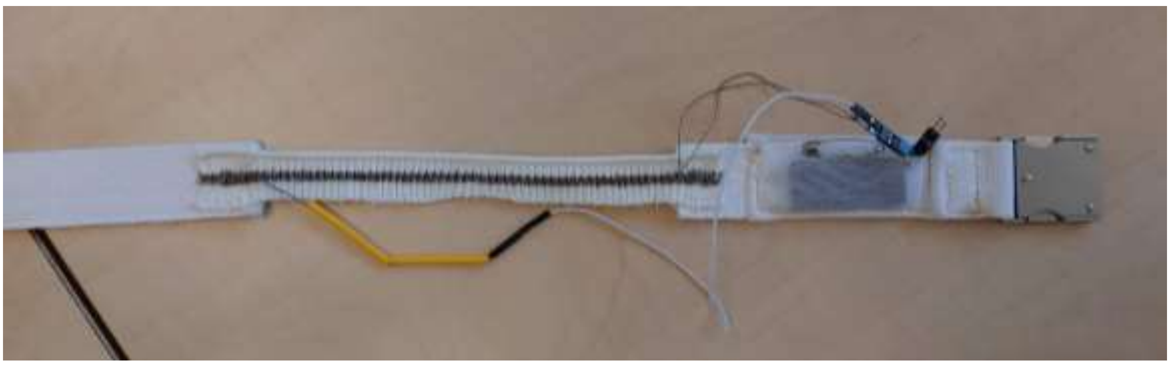
Setup summary

The prototype can be described as a 'smart shirt', and will be used to measure breathing activity, or more specifically the changes in circumference of the upper body. It will consist of a base fabric, either a shirt or a vest of elastic material; the tensile-sensor material or 'smart garment' which is knitted on the base layer; and the processing unit consisting of an Arduino Nano with connectivity adapter and battery.

The garment will in first instance be a shirt that is bought in a clothing store and the sensor itself does not contain any sharp materials. A series of three stretch sensors will be used to measure breathing of the participants. During this human subject research study, the prototype will be tested for comfort/ergonomic metrics, as well as on performance during (different types of exercises of) breathing. Possibly, the opinion on the user interface of the controller device will be asked.



Sample of a sensor material. The same set up as will be used in the prototype, except that the prototype will use multiple sensors and the wiring will be more incorporated into the fabric of the shirt.



Applicable standards

EN 60601-1 Part One or General Standard; covers basic safety and essential performance for all medical electrical equipment.

EN 60601-2 Part Two or Particular Standards; include the requirements for specific product groups

NEN / IEC 60601-1-11:2015: Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Industry regulations concerning electricity on the skin in consumer products do not exist or are hard to find. An example from the building environment (https://www.chilweebattery.com/news/what-is-the-safety-voltage-and-safe-current-of-23656444.html):
The safety voltage is not higher than 36V, the continuous contact safety voltage is 24V, and the safe current is 10mA. The minimum current value that can be felt is called the sense current. For AC that is 1 mA and for DC is 5 mA. The life-threatening current is called the lethal current and is 50mA. In the case of protection against electric shock, the current allowed for the human body is generally 30 mA. Table in appendix 1 shows the safe levels of current in the human body for 100 Volts, according to an American university L-Safe-Levels-of-Current-in-the-Human-Body.pdf (umn.edu).

Conclusively, death or serious injury is unlikely to occur in this project, since the current the skin is exposed to is 30 µA. Which is far below the 50 mA which is considered life threatening and the 30 mA that is allowed for the human body. As well, even below the threshold of perception of 0.2 mA (appendix 1).

Risk checklist

Hazard type	Present	Hazard source	Mitigation measures
Mechanical (sharp edges, moving equipment, etc.)	no		
Electrical	Yes, minimal	The battery and/or processing unit	Threshold: 36V and 1mA. The processing unit consists of an Arduino nano 33 BLE which holds several safety and health certifications, for more info: https://docs.arduino.cc/static/455424c2e00f50de7c758956e45bdba2/Arduino_ABX00030-DoC_CE_with%20or%20without%20headers.pdf The Arduino requires 5V and uses not more than about 250 mA, which is too little power to cause serious/fatal shocks. Making sure that the Arduino is powered with a voltage not higher than the required voltage will help minimize the risk of electrical hazard. that is as well certified with health directives will help minimize the risk of electrical hazard.
Structural failure	Yes	Battery	Current lithium battery power usage will always contain potential hazards when the battery is structurally damaged. By adhering to quality and safety standards, following UN/DOT, IEC, UL, CE requirements when selecting the battery, will help mitigate risks. Espacially IEC 62133-2:2017 certification is a recognized standard for safe installation and operation in for example wearables, evaluating factors like capacity, voltage, temperature tolerance, and safety features.
Touch Temperature	Yes, minimal	The battery and/or processing unit	By avoiding overpowering (max 5V) of the electrical components and by responsibly using the battery, plugging it out when it is not necessary, the potential risk of skin burns can be minimized.
Electromagnetic radiation	no		
Ionizing radiation	no		
(Near-) optical radiation	no		
Noise exposure	no		
Materials	Yes	Allergies	100% silver is inert. If the wires contain alloys, they could be the culprits; therefore, check the specifications (who has them?). Solution: use silver-plated yarns with pure silver (e.g., https://www.texcraf-protection.com/Functional-yarn/Silver-

			plated-conductive-yarn.html), or possibly test titanium yarns; composed of pure Ti deposited on a polymer (e.g., https://www.swicofil.com/commerce/products/titanium/675/grades). Allergy to contact points, connections, and solder is possible. Nickel, chromium, and cobalt frequently cause allergies, lead and copper to a lesser extent. Therefore, we should check the specifications and consider using other materials if necessary. Solution: choose the right materials and, if needed, exclude them through insulation.
Chemical processes	Yes	Electrolysis	When the sensor would come into full-length contact with the skin, there would be 5V over a distance of 10cm. Skin resistance is approximately 100kΩ/cm but decreases to 10kΩ/cm during perspiration. Then, the maximum current is 50 µA/cm. Corrosive effects of very low electrical voltage and currents on the skin: there is no literature available on this subject. The best I have read is https://pubmed.ncbi.nlm.nih.gov/19907637. The only known effect is opposite: electrical voltage appears to promote healing, see https://doi.org/10.1089%2Fwound.2019.1114. Corrosion at 5V and <0.1mA is unlikely, but by definition, it cannot be ruled out in the very long term. Testing is impossible because it strongly depends on the amount and composition of perspiration. A sample is meaningless by definition. Solution: none. This (thus) needs to be addressed in the usage and instructions: if users observe discoloration or irritation, stop immediately and inform the respective medical professional.
Fall risk	no		
Other:			
Other:			
Other:			

Appendix 1

Here, you may add one or more appendices describing more detailed aspects of your setup or the research procedures.

SAFE LEVELS OF CURRENT IN THE HUMAN BODY

Death or serious injury is unlikely to occur if current/time values are kept under:
1,000 milliamps for 30 milliseconds (1½ cycles) or 100 milliamps for 3 seconds *

Limiting current flow in the human body to safe levels is entirely dependent on the resistance of the short-circuiting jumper. To achieve this safe current level the voltage across the human body must not exceed 100 volts.

The following calculations apply:

Resistance of jumper $R = \frac{V}{I} = \frac{\text{Voltage across Jumper}}{\text{Fault current}} = \frac{\text{100 Volts}}{\text{10,000 Amps}}$ = 10 mOhms

Voltage across person/jumper V = IR = 10,000 amps x 10 mOhms = 100 Volts

Current through person $I = \frac{V}{R} = \frac{\text{Voltage across Person}}{\text{Resistance of person}} = \frac{\text{100 Volts}}{\text{1000 Ohms *}}$ = 100 milliamps

TABLES FROM I.E.C. 1000-05 AND ET 213:2007

Current (mA)	Effect	Time Duration
0.2 to 1.0	Threshold of perception	Not critical
10 to 16	Limit of 'let go', muscles contract	Minutes
30*	**Breathing difficult, 'safe' limit**	**Seconds**
50	Irregular heartbeat	1 heart beat or about 1 second
60	Respiratory problems, cannot breathe	
>60	Heart fibrillation, electric burns	

Magnitude of the Current	Physiological Effects
From 0 to 0.5mA	Perception possible (10 secs)
From 0.5 to 5mA	Perception and involuntary muscular contractions likely but usually no harmful electrical physiological effects (5 secs)
From 5 to 50mA	Strong involuntary muscular contractions. Difficulty in breathing. Reversible disturbances of heart function. Immobilization may occur. Effects increasing with current magnitude. Usually no organic damage to be expected. (2 secs).
From 50 to100mA	Patho-physiological effects may occur such as cardiac arrest, breathing arrest, and burns or other cellular damage. Probability of ventricular fibrillation increasing with current magnitude and time up to 1 sec. Above 2 secs probability of ventricular fibrillation is approaching 50%.

Device inspection

(to be filled in by the AMA advisor of the corresponding faculty)

Name: Peter Kohne

Faculty: IO

The device and its surroundings described above have been inspected. During this inspection I could not detect any extraordinary risks.

(Briefly describe what components have been inspected and to what extent (i.e. visually, mechanical testing, measurements for electrical safety etc.)

Date: 27-09-2023

Signature:

Inspection valid until[1]:

Note: changes to the device or set-up, or use of the device for an experiment type that it was not inspected for require a renewed inspection

1 Indicate validity of the inspection, with a maximum of 3 years

Appendix 5b

Delft University of Technology
HUMAN RESEARCH ETHICS
CHECKLIST FOR HUMAN RESEARCH
(Version January 2022)

IMPORTANT NOTES ON PREPARING THIS CHECKLIST

1. An HREC application should be submitted for every research study that involves human participants (as Research Subjects) carried out by TU Delft researchers
2. Your HREC application should be submitted and approved **before** potential participants are approached to take part in your study
3. All submissions from Master's Students for their research thesis need approval from the relevant Responsible Researcher
4. The Responsible Researcher must indicate their approval of the completeness and quality of the submission by signing and dating this form OR by providing approval to the corresponding researcher via email (included as a PDF with the full HREC submission)
5. There are various aspects of human research compliance which fall outside of the remit of the HREC, but which must be in place to obtain HREC approval. These often require input from internal or external experts such as Faculty Data Stewards, Faculty HSE advisors, the TU Delft Privacy Team or external Medical research partners.
6. You can find detailed guidance on completing your HREC application here
7. Please note that incomplete submissions (whether in terms of documentation or the information provided therein) will be returned for completion **prior to any assessment**
8. If you have any feedback on any aspect of the HREC approval tools and/or process you can leave your comments here

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I. Applicant Information

PROJECT TITLE:	**Graduation Project Brief – Sybe Duyts**
Research period: *Over what period of time will this specific part of the research take place*	**August 21st - November 17th**
Faculty:	**Industrial Design Engineering**
Department:	**SDE**
Type of the research project: *(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)*	**Master's graduation**
Funder of research: *(EU, NWO, TUD, other – in which case please elaborate)*	**Mediventic – project assignment holder**
Name of Corresponding Researcher: *(If different from the Responsible Researcher)*	**Sybe Duyts**
E-mail Corresponding Researcher: *(If different from the Responsible Researcher)*	
Position of Corresponding Researcher: *(Masters, DreamTeam, PhD, PostDoc, Assistant/ Associate/ Full Professor)*	**Masters**
Name of Responsible Researcher: ***Note:** all student work must have a named Responsible Researcher to approve, sign and submit this application*	**Fredrik Karlsson**
E-mail of Responsible Researcher: *Please ensure that an institutional email address (**no Gmail, Yahoo, etc.**) is used for all project documentation/ communications including Informed Consent materials*	
Position of Responsible Researcher : *(PhD, PostDoc, Associate/ Assistant/ Full Professor)*	**PhD candidate**

II. Research Overview

***NOTE:** You can find more guidance on completing this checklist here*

a) Please summarise your research very briefly (100-200 words)

What are you looking into, who is involved, how many participants there will be, how they will be recruited and what are they expected to do?

Add your text here – (please avoid jargon and abbrevations)
During my graduation I will conduct research on textile strain sensor material, and learn how to implement it into a functional smart-garment. At the same time I will learn about the user perspective and context requirements the smart-garment will have to operate in. The concluding requirements will be the basis on which I will iterate the current prototype, to a pre-production prototype that is validated/demonstrated in a testing environment. The goal of the graduation project is to integrate innovative knitted sensors into an affordable, portable, and easily applicable smart-garment for the specific goal of monitoring breathing behaviour. The garment should obtain objective data that can be used for breathing pattern recognition, and can be used in longer periods as a diagnostic tool, and as a means of monitoring outside a therapeutic setting.

b) **If your application is an additional project** related to an existing approved HREC submission, please provide a brief explanation including the existing relevant HREC submission number/s.

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Add your text here – (please avoid jargon and abbrevations)
/

c) **If your application is a simple extension of, or amendment to,** an existing approved HREC submission, you can simply submit an HREC Amendment Form as a submission through LabServant.

III. Risk Assessment and Mitigation Plan

NOTE: *You can find more guidance on completing this checklist here*

Please complete the following table in full for all points to which your answer is "yes". Bear in mind that the vast majority of projects involving human participants as Research Subjects also involve the collection of **Personally Identifiable Information (PII)** and/or **Personally Identifiable Research Data (PIRD)** which may pose potential risks to participants as detailed in Section G: Data Processing and Privacy below.

To ensure alighment between your risk assessment, data management and what you agree with your Research Subjects you can use the last two columns in the table below to refer to specific points in your Data Management Plan (DMP) and Informed Consent Form (ICF) – **but this is not compulsory**.

It's worth noting that **you're much more likely to need to resubmit your application if you neglect to identify potential risks**, than if you identify a potential risk and demonstrate how you will mitigate it. If necessary, the HREC will always work with you and colleagues in the Privacy Team and Data Management Services to see how, if at all possible, your research can be conducted.

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
A: Partners and collaboration						
1. Will the research be carried out in collaboration with additional organisational partners such as: • One or more collaborating research and/or commercial organisations • Either a research, or a work experience internship provider[1] [1] *If yes, please include the graduation agreement in this application*	x		**The graduation will be in collaboration with the client Mediventic (the company/assignment-owner). The following risks can be identified:** **1. Conflict of interest that could compromise the integrity and objectivity of the research.** **2. Changing scope according to recent discoveries, not in line with the research progression.**	1. Develop a collaborative agreement that explicitly addresses potential conflicts of interest and ensures the independence of the research. 2. Engage in open communication with the commercial partner, highlighting the importance of maintaining the highest ethical standards throughout the research.		
2. Is this research dependent on a Data Transfer or Processing Agreement with a collaborating partner or third party supplier? *If yes please provide a copy of the signed DTA/DPA*	x		**A copy of the DPA is provided, some personal data could be asked, the data needs to be stored for it to be used in decision making throughout the process.**	As can be read in the DPA in more detail, the data will be stored in the SURF drive of TU Delft. Audio material will be transcribed and personal data will be anonymized. Video/photo will be taken and potentially blurred following the participants preference.		
3. Has this research been approved by another (external) research ethics committee (e.g.: HREC and/or MREC/METC)?		x				

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			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
B: Location						
4. Will the research take place in a country or countries, other than the Netherlands, within the EU?		x				
5. Will the research take place in a country or countries outside the EU?		x				
6. Will the research take place in a place/region or of higher risk – including known dangerous locations (in any country) or locations with non-democratic regimes?		x				
C: Participants						
7. Will the study involve participants who **may** be vulnerable and possibly (legally) unable to give informed consent? (e.g., children below the legal age for giving consent, people with learning difficulties, people living in care or nursing homes,).		x				
8. Will the study involve participants who **may** be vulnerable under specific circumstances and in specific contexts, such as victims and witnesses of violence, including domestic violence; sex workers; members of minority groups, refugees, irregular migrants or dissidents?		x				
9. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children, own students or employees of either TU Delft and/or a collaborating partner organisation)?		x				
10. Is there a high possibility of re-identification for your participants? (e.g., do they have a very specialist job of which there are only a small number in a given country, are they members of a small community, or employees from a partner company collaborating in the research? Or are they one of only a handful of (expert) participants in the study?		x				
D: Recruiting Participants						
11. Will your participants be recruited through your own, professional, channels such as conference attendance lists, or through specific network/s such as self-help groups	x		**In order to demonstrate the prototype in a testing environment 'pseudo-patients' are needed and will be recruited through my own/Mediventic's professional channels.**	With caution, partipants will be selected who are willing to serve as a demo-group. As TRL 6 is the focus, these are not necessarily people with respiratory health issues.		
12. Will the participants be recruited or accessed in the longer term by a (legal or customary) gatekeeper? (e.g., an adult professional working with children; a community leader or family member who has this customary role – within or outside the EU; the data producer of a long-term cohort study)		x				

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			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
13. Will you be recruiting your participants through a crowd-sourcing service and/or involve a third party data-gathering service, such as a survey platform?		x				
14. Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation?		x				
E: Subject Matter *Research related to medical questions/health may require special attention. See also the website of the CCMO before contacting the HREC.*						
15. Will your research involve any of the following: • Medical research and/or clinical trials • Invasive sampling and/or medical imaging • Medical and *In Vitro Diagnostic Medical* Devices Research	x		**Medical research up to TRL 6, no clinical trial. The breathing (and possibly heartrate) of test subjects will be measured during the testing of the prototype. Results will be used for design iteration.**	The personal health issues of the subjects will not be the focus for the research. Rather the performance and quality of the prototype will be tested. Therefore any insights about the personal medical situation will not be used as data.		
16. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants? *If yes see here to determine whether medical ethical approval is required*		x				
17. Will blood or tissue samples be obtained from participants? *If yes see here to determine whether medical ethical approval is required*		x				
18. Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants in their life outside research?		x				
19. Will the study involve discussion of personal sensitive data which could put participants at increased legal, financial, reputational, security or other risk? (e.g., financial data, location data, data relating to children or other vulnerable groups) *Definitions of sensitive personal data, and special cases are provided on the TUD Privacy Team website.*		x				
20. Will the study involve disclosing commercially or professionally sensitive, or confidential information? (e.g., relating to decision-making processes or business strategies which might, for example, be of interest to competitors)		x				
21. Has your study been identified by the TU Delft Privacy Team as requiring a Data Processing Impact Assessment (DPIA)? *If yes please attach the advice/ approval from the Privacy Team to this application*		x				
22. Does your research investigate causes or areas of conflict? *If yes please confirm that your fieldwork has been discussed with the appropriate safety/security advisors and approved by your Department/Faculty.*		x				

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			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
23. Does your research involve observing illegal activities or data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences *If so please confirm that your work has been discussed with the appropriate legal advisors and approved by your Department/Faculty.*		x				
F: Research Methods						
24. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g., covert observation of people in non-public places).		x				
25. Will the study involve actively deceiving the participants? (For example, will participants be deliberately falsely informed, will information be withheld from them or will they be misled in such a way that they are likely to object or show unease when debriefed about the study).		x				
26. Is pain or more than mild discomfort likely to result from the study? And/or could your research activity cause an accident involving (non-) participants?	x		**At most mild discomfort due to misfitting of the prototype could occur.**	Accidents are highly unlikely. The focus is on designing a comfortable wearable shirt. As well, the voltage rates (~5V) at which the prototype's integrated processing parts operate are well below a level that is dangerous for human beings.		
27. Will the experiment involve the use of devices that are not 'CE' certified? *Only, if 'yes': continue with the following questions:*	x		**The prototype that will be tested is not CE certified.**	Whilst designing the prototype the criteria on which devices are CE certified, can be used as guideline.		
• Was the device built in-house?	x		**The prototype will be built in-house.**	Keeping in contact with a safety expert at the TU Delft during the testing of (different versions of) the prototype Could be an effective way to verify that the chance of an accident when wearing the shirt are negligible.		
• Was it inspected by a safety expert at TU Delft? *If yes, please provide a signed* ***device report***		x				
• If it was not built in-house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? *If yes, please provide records of the inspection*		x				
28. Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?	x		**Yes, there will be face to face encounters and possible close contact as well.**	By following the current guidelines provide by the Dutch government, I aim to mitigate the changes of possible infections.		
29. Will your research involve **either:**		x				

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			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
a) "big data", combined datasets, new data-gathering or new data-merging techniques which might lead to re-identification of your participants **and/or** b) artificial intelligence or algorithm training where, for example biased datasets could lead to biased outcomes?						
G: Data Processing and Privacy						
30. Will the research involve collecting, processing and/or storing any directly identifiable PII (Personally Identifiable Information) including name or email address that will be used for administrative purposes only? (eg: obtaining Informed Consent or disbursing remuneration)		x				
31. Will the research involve collecting, processing and/or storing any directly or indirectly identifiable PIRD (Personally Identifiable Research Data) including videos, pictures, IP address, gender, age etc and **what other Personal Research Data** (including personal or professional views) will you be collecting?	x		**Yes; photos, interview audio, anonymized data on age, body measurements, biometric data, will be collected during the research.**	Any indirectly identifiable data or personal data will be destroyed at the end of the graduation, or will be found in an anonymized form in the graduation report. More info can be found in the DMP report.		
32. Will this research involve collecting data from the internet, social media and/or publicly available datasets which have been originally contributed by human participants		x				
33. Will your research findings be published in one or more forms in the public domain, as e.g., Masters thesis, journal publication, conference presentation or wider public dissemination?	x		**The project could possibly be part of a patent application. The data that is collected and is relevant for the graduation, will be shared together with the graduation delivery.**	Anonymised data will be shared as being a part of informed design decisions which can be seen in the graduation report. And as insights into validation for the cooperating company.		
34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?		x				

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H: More on Informed Consent and Data Management

NOTE: *You can find guidance and templates for preparing your Informed Consent materials) here*

Your research involves human participants as Research Subjects if you are recruiting them or actively involving or influencing, manipulating or directing them in any way in your research activities. This means you must seek informed consent and agree/ implement appropriate safeguards regardless of whether you are collecting any PIRD.

Where you are also collecting PIRD, and using Informed Consent as the legal basis for your research, you need to also make sure that your IC materials are clear on any related risks and the mitigating measures you will take – including through responsible data management.

Got a comment on this checklist or the HREC process? You can leave your comments here

IV. Signature/s

> ***Please note that by signing this checklist list as the sole, or Responsible, researcher you are providing approval of the completeness and quality of the submission, as well as confirming alignment between GDPR, Data Management and Informed Consent requirements.***

Name of Corresponding Researcher (if different from the Responsible Researcher) (print)

Sybe Duyts

Signature of Corresponding Researcher: [signature]

Date: 2023-07-04

Name of Responsible Researcher (print)

Fredrik Karlsson

Signature (or upload consent by mail) Responsible Researcher: [signature]

Date: 2023-07-01

V. Completing your HREC application

Please use the following list to check that you have provided all relevant documentation

Required:

- **Always:** This completed HREC checklist
- **Always:** A data management plan (reviewed, where necessary, by a data-steward)
- **Usually:** A complete Informed Consent form (including Participant Information) and/or Opening Statement (for online consent)

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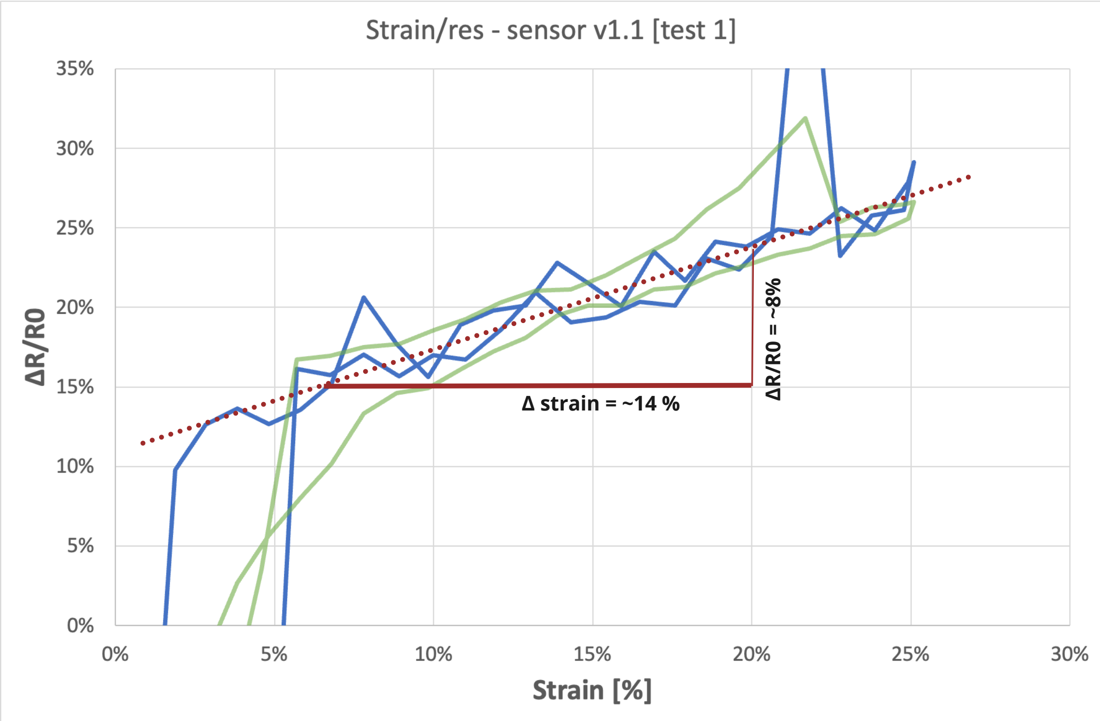
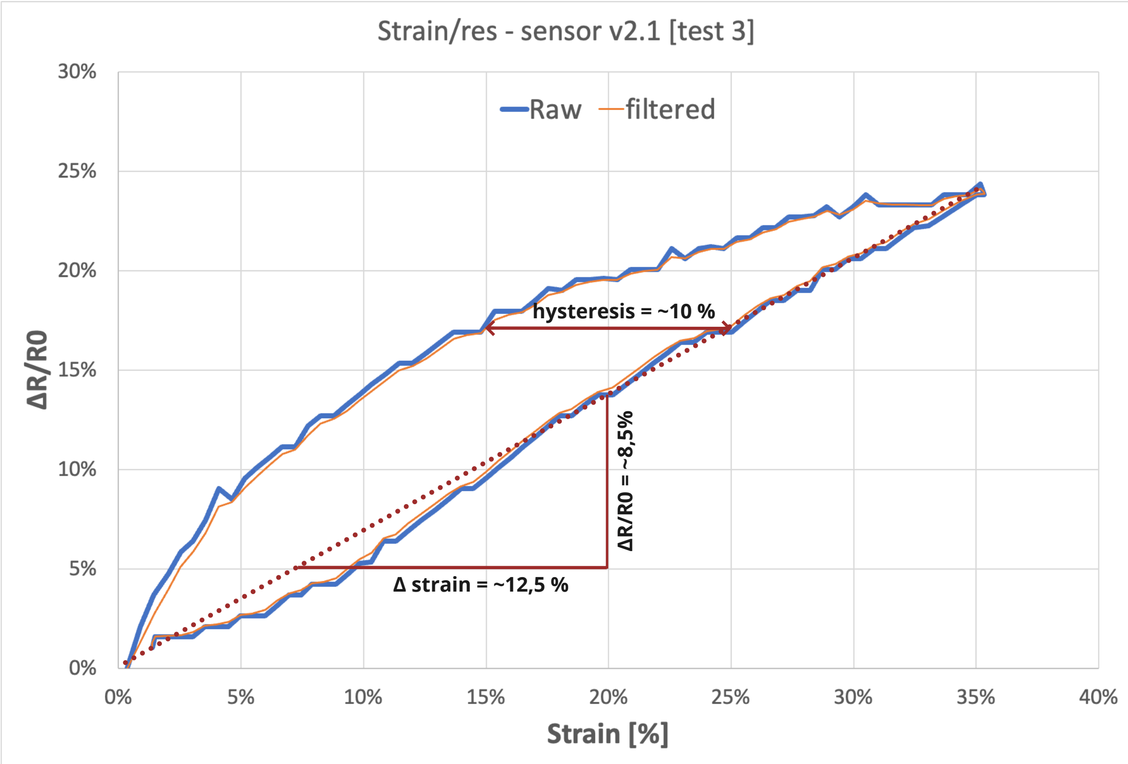
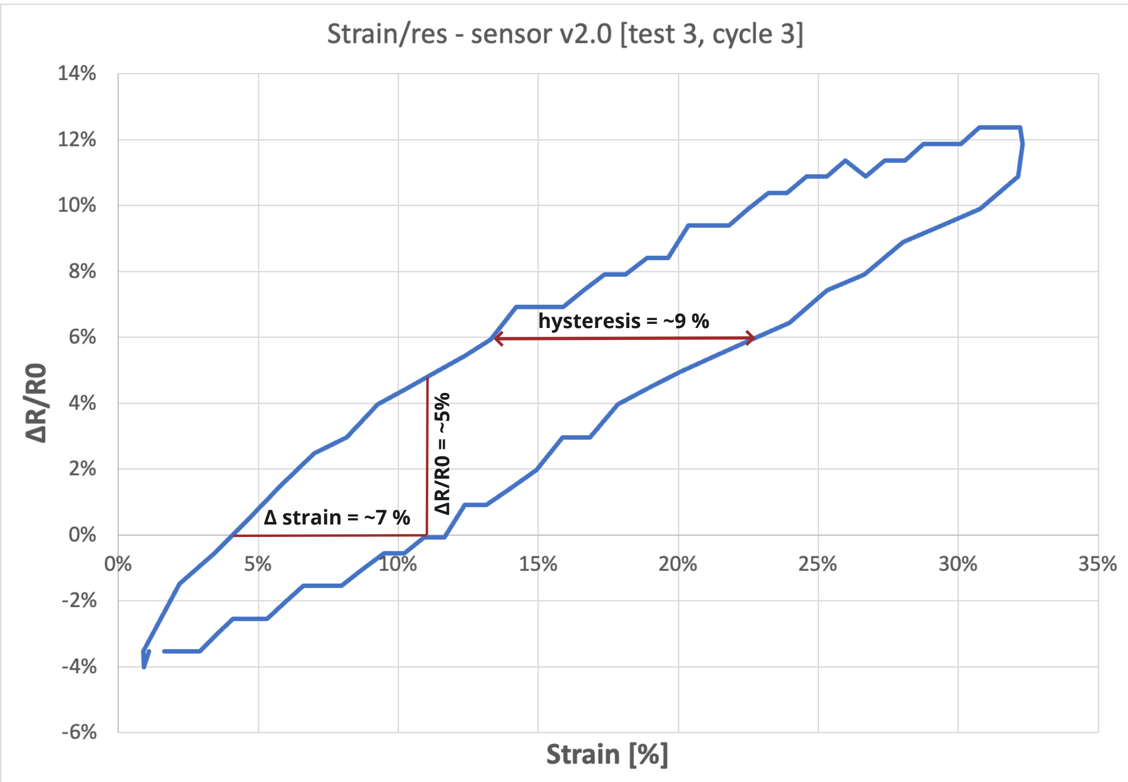
Appendix 6

Test 2

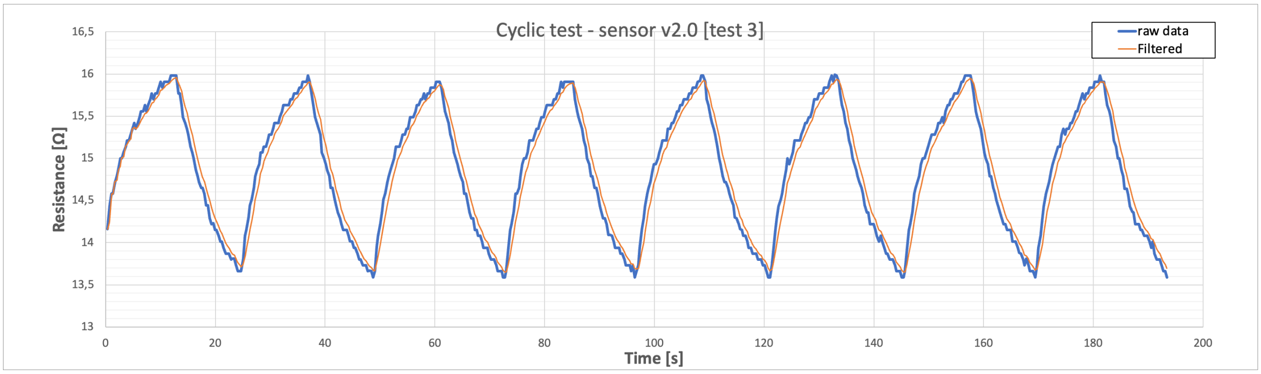


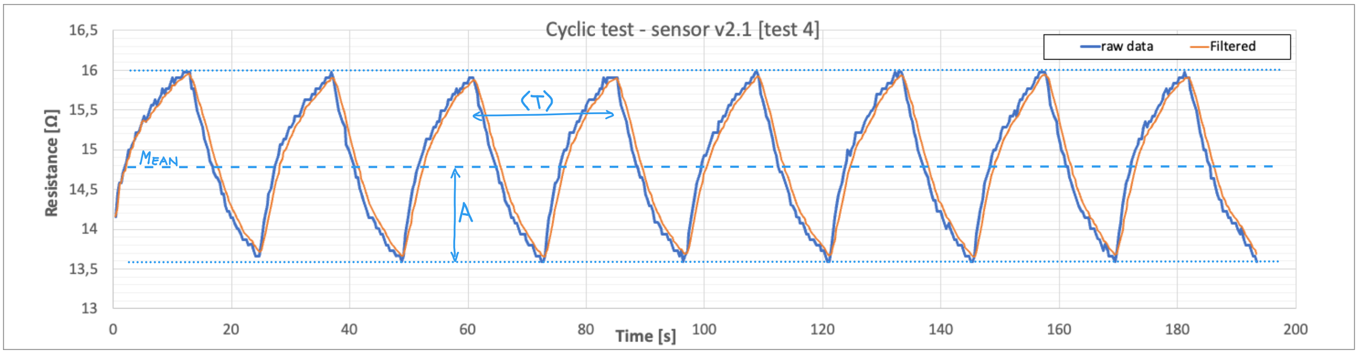
Test 3

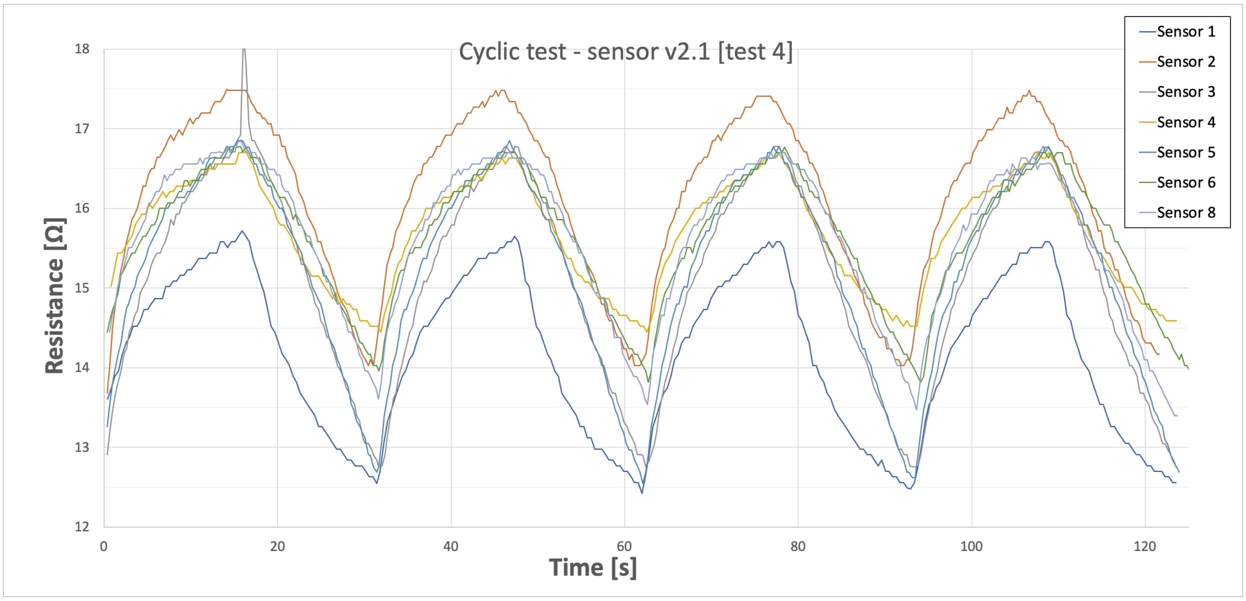

Strain/res - sensor v2.1 [test 3]
Raw
filtered
hysteresis = ~10 %
ΔR/R0 = ~8,5%
Δ strain = ~12,5 %
ΔR/R0
Strain [%]
30%
25%
20%
15%
10%
5%
0%
0%
5%
10%
15%
20%
25%
30%
35%
40%

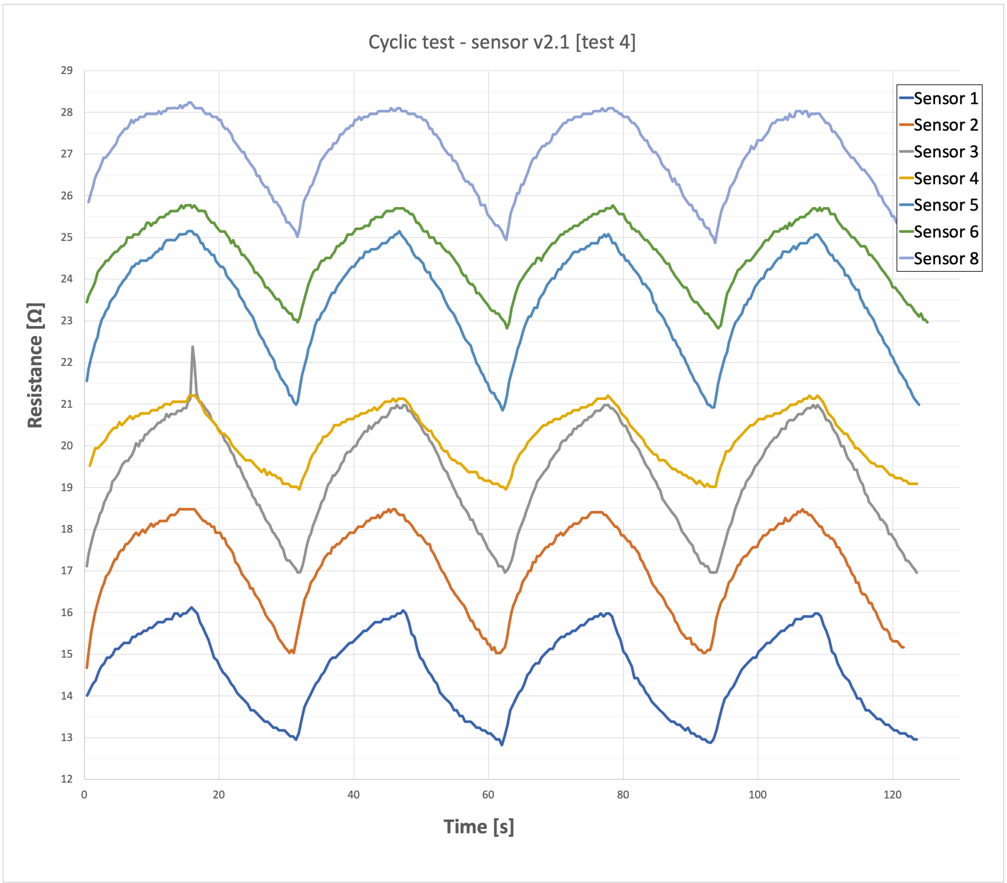

Strain/res - sensor v2.0 [test 3, cycle 3]
hysteresis = ~9 %
ΔR/R0 = ~5%
Δ strain = ~7 %
ΔR/R0
Strain [%]
14%
12%
10%
8%
6%
4%
2%
0%
-2%
-4%
-6%
0%
5%
10%
15%
20%
25%
30%
35%

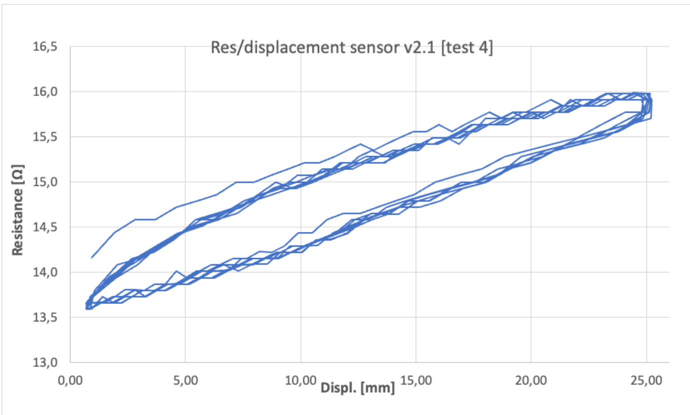
Test 4


Cyclic test - sensor v2.0 [test 3]
raw data
Filtered
Resistance [Ω]
Time [s]

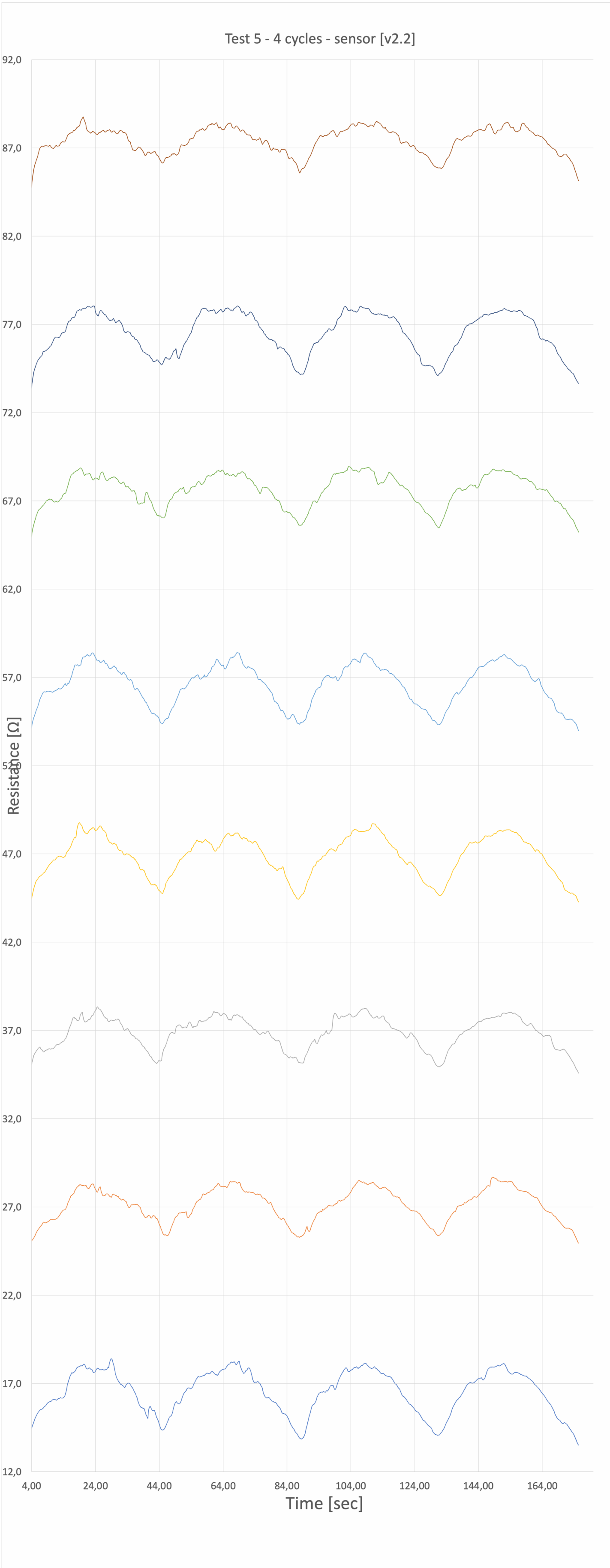

Cyclic test - sensor v2.1 [test 4]
raw data
Filtered
MEAN
(T)
A
Resistance [Ω]
Time [s]


Cyclic test - sensor v2.1 [test 4]
Sensor 1
Sensor 2
Sensor 3
Sensor 4
Sensor 5
Sensor 6
Sensor 8
Resistance [Ω]
Time [s]

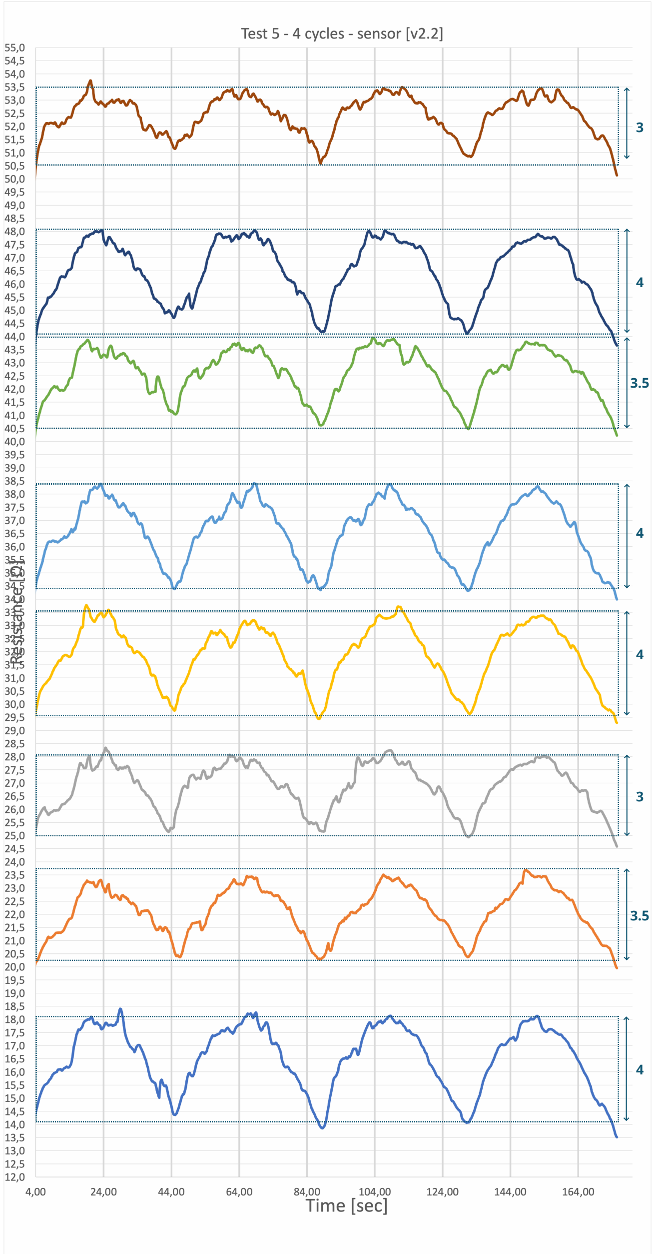

Cyclic test - sensor v2.1 [test 4]
Resistance [Ω]
Time [s]
Sensor 1
Sensor 2
Sensor 3
Sensor 4
Sensor 5
Sensor 6
Sensor 8
29
28
27
26
25
24
23
22
21
20
19
18
17
16
15
14
13
12
0
20
40
60
80
100
120


Res/displacement sensor v2.1 [test 4]
Resistance [Ω]
Displ. [mm]
16,5
16,0
15,5
15,0
14,5
14,0
13,5
13,0
0,00
5,00
10,00
15,00
20,00
25,00

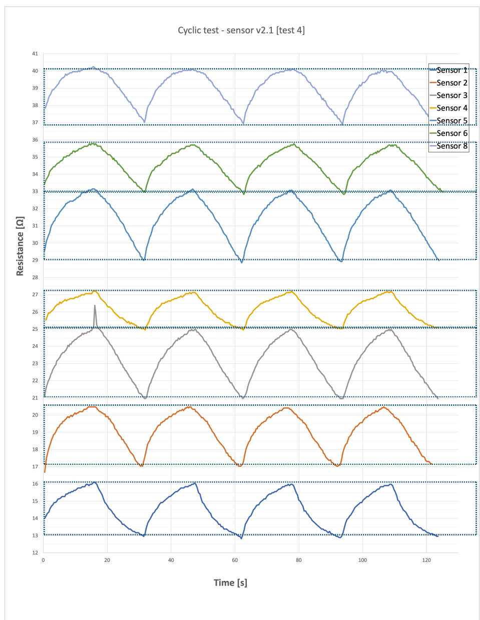
Test 5



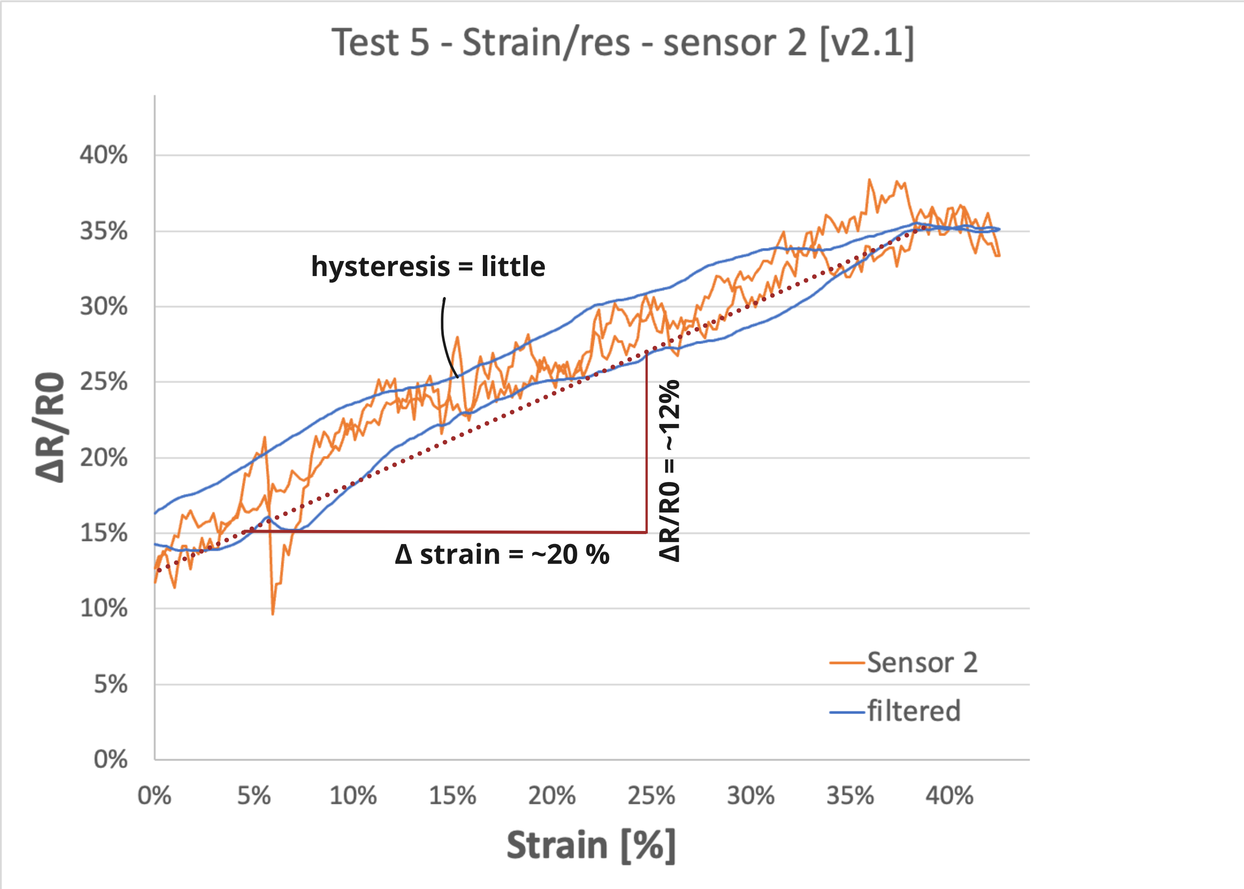
Test 5 - 4 cycles - sensor [v2.2]
Resistance [Ω]
Time [sec]

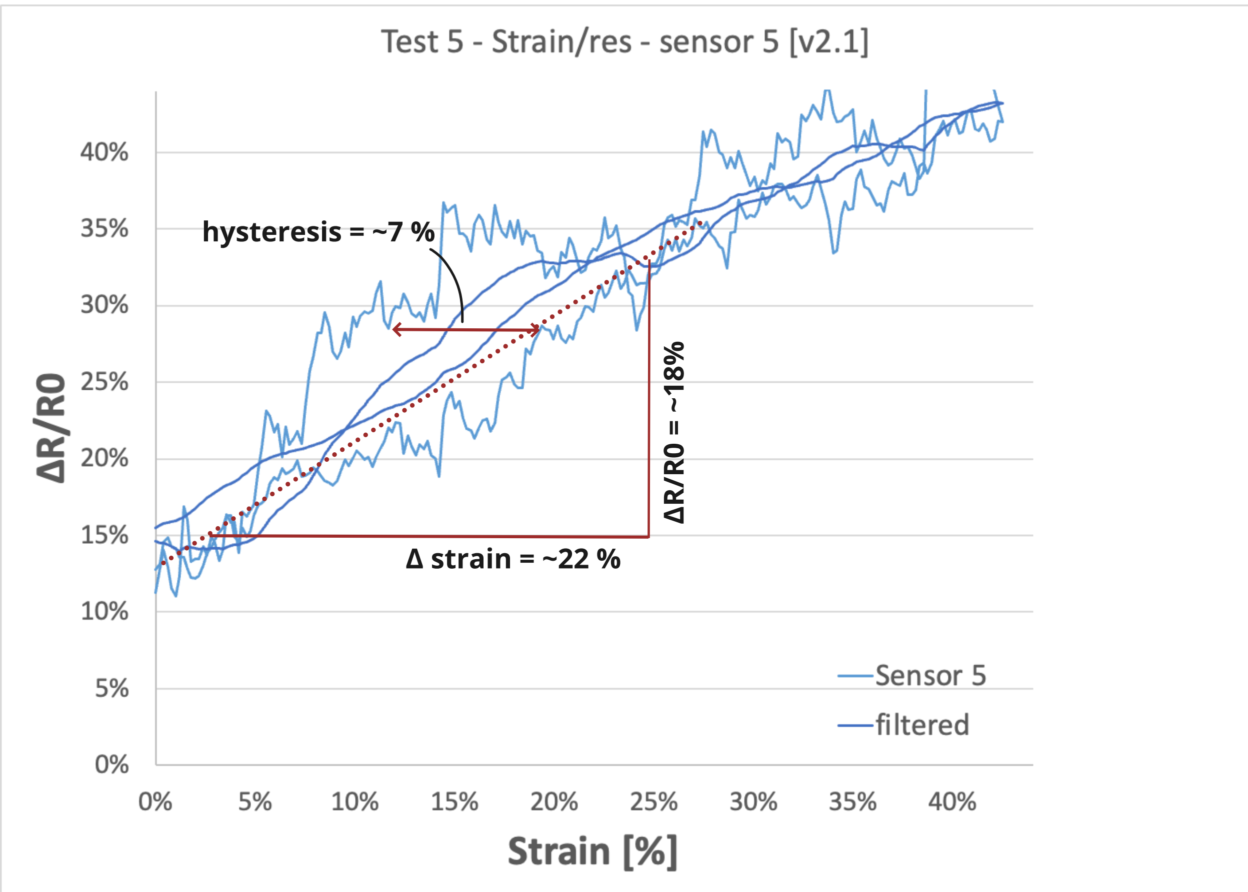


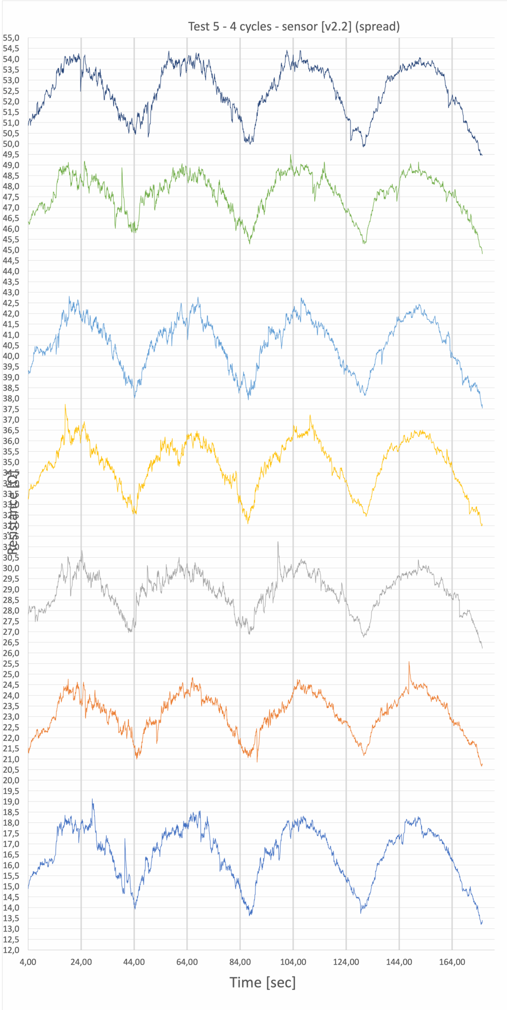
Test 5 - 4 cycles - sensor [v2.2]
Resistance [Ω]
Time [sec]
3
4
3.5
4
4
3
3.5
4

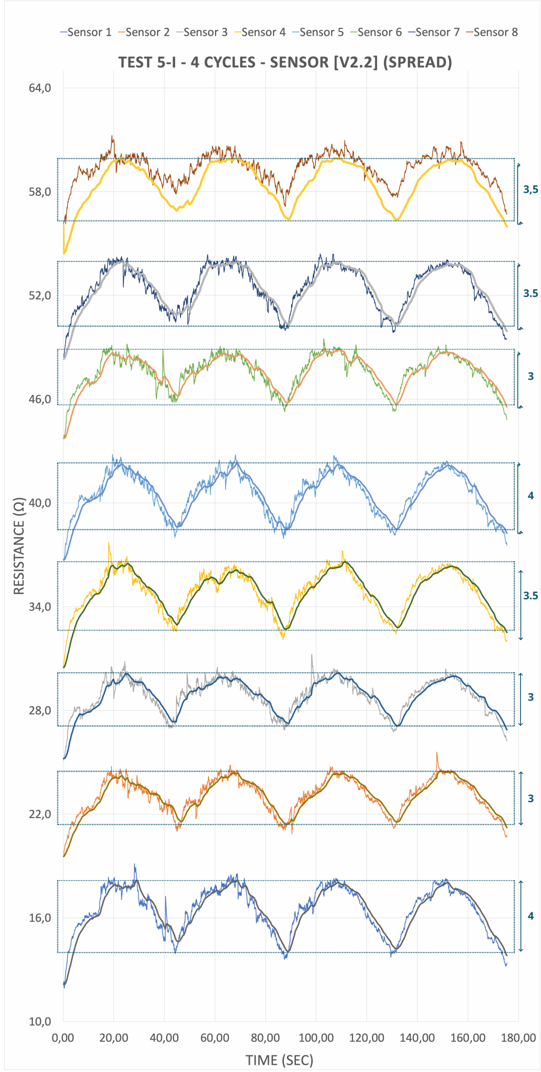


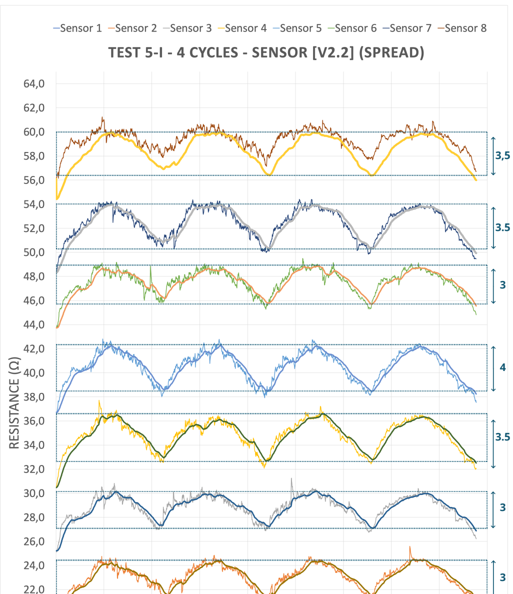
Cyclic test - sensor v2.1 [test 4]
Sensor 1
Sensor 2
Sensor 3
Sensor 4
Sensor 5
Sensor 6
Sensor 8
Resistance [Ω]
Time [s]
3.2
3
4
2.2
4
3.5
3.2

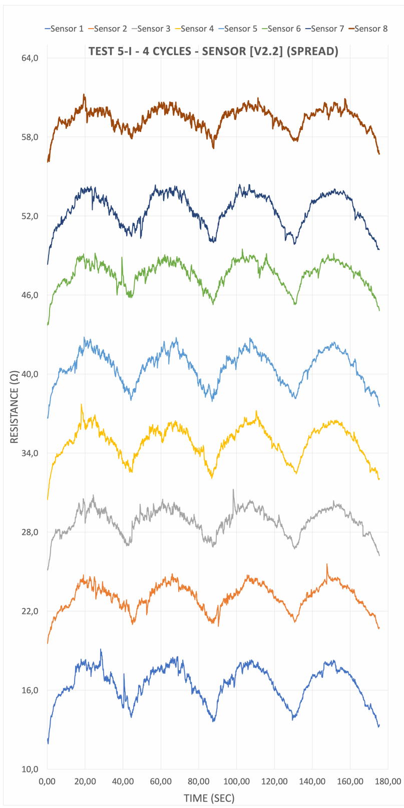

Test 5 - Strain/res - sensor 2 [v2.1]
hysteresis = little
Δ strain = ~20 %
ΔR/R0 = ~12%
ΔR/R0
Strain [%]
Sensor 2
filtered
0%
5%
10%
15%
20%
25%
30%
35%
40%

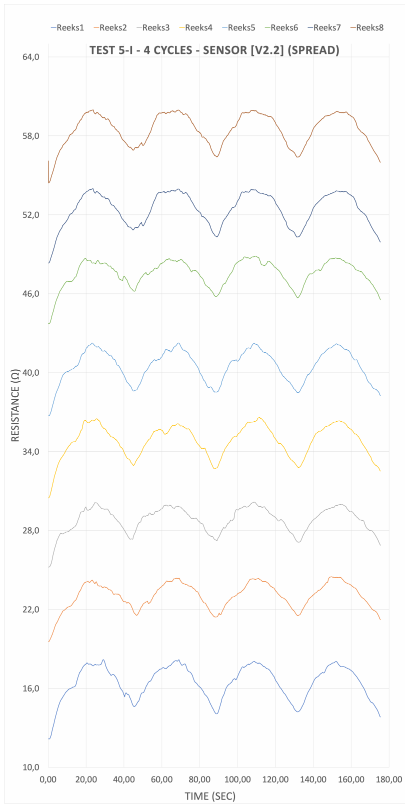

Test 5 - Strain/res - sensor 5 [v2.1]
hysteresis = ~7 %
Δ strain = ~22 %
ΔR/R0 = ~18%
ΔR/R0
Strain [%]
Sensor 5
filtered
0%
5%
10%
15%
20%
25%
30%
35%
40%


Test 5 - 4 cycles - sensor [v2.2] (spread)
Time [sec]

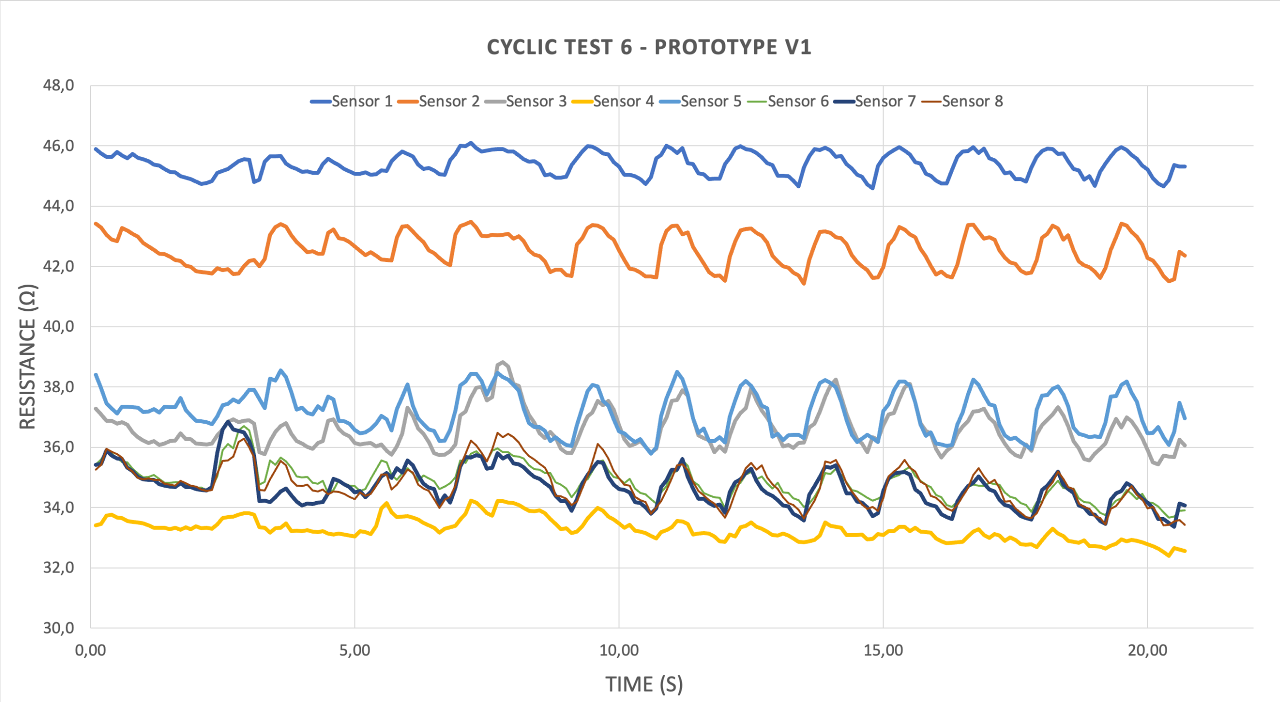

Sensor 1 Sensor 2 Sensor 3 Sensor 4 Sensor 5 Sensor 6 Sensor 7 Sensor 8
TEST 5-I - 4 CYCLES - SENSOR [V2.2] (SPREAD)
RESISTANCE (Ω)
TIME (SEC)


Sensor 1 Sensor 2 Sensor 3 Sensor 4 Sensor 5 Sensor 6 Sensor 7 Sensor 8
TEST 5-I - 4 CYCLES - SENSOR [V2.2] (SPREAD)
RESISTANCE (Ω)
TIME (SEC)

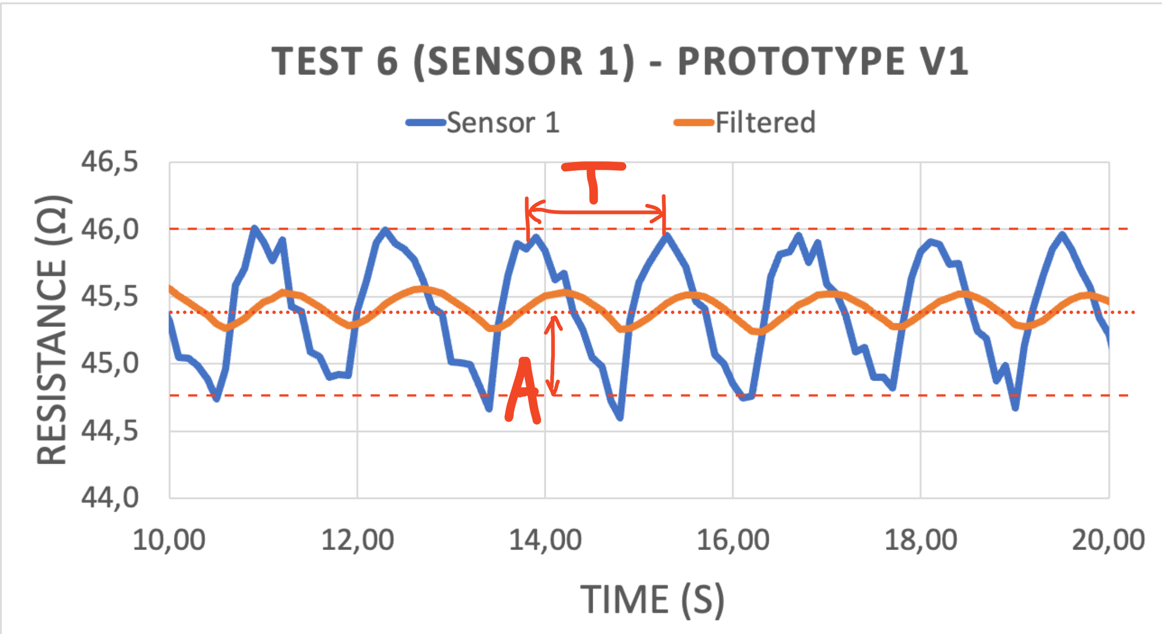

Sensor 1 Sensor 2 Sensor 3 Sensor 4 Sensor 5 Sensor 6 Sensor 7 Sensor 8
TEST 5-I - 4 CYCLES - SENSOR [V2.2] (SPREAD)
RESISTANCE (Ω)
TIME (SEC)


Reeks1 Reeks2 Reeks3 Reeks4 Reeks5 Reeks6 Reeks7 Reeks8
TEST 5-I - 4 CYCLES - SENSOR [V2.2] (SPREAD)
RESISTANCE (Ω)
TIME (SEC)

Test 6

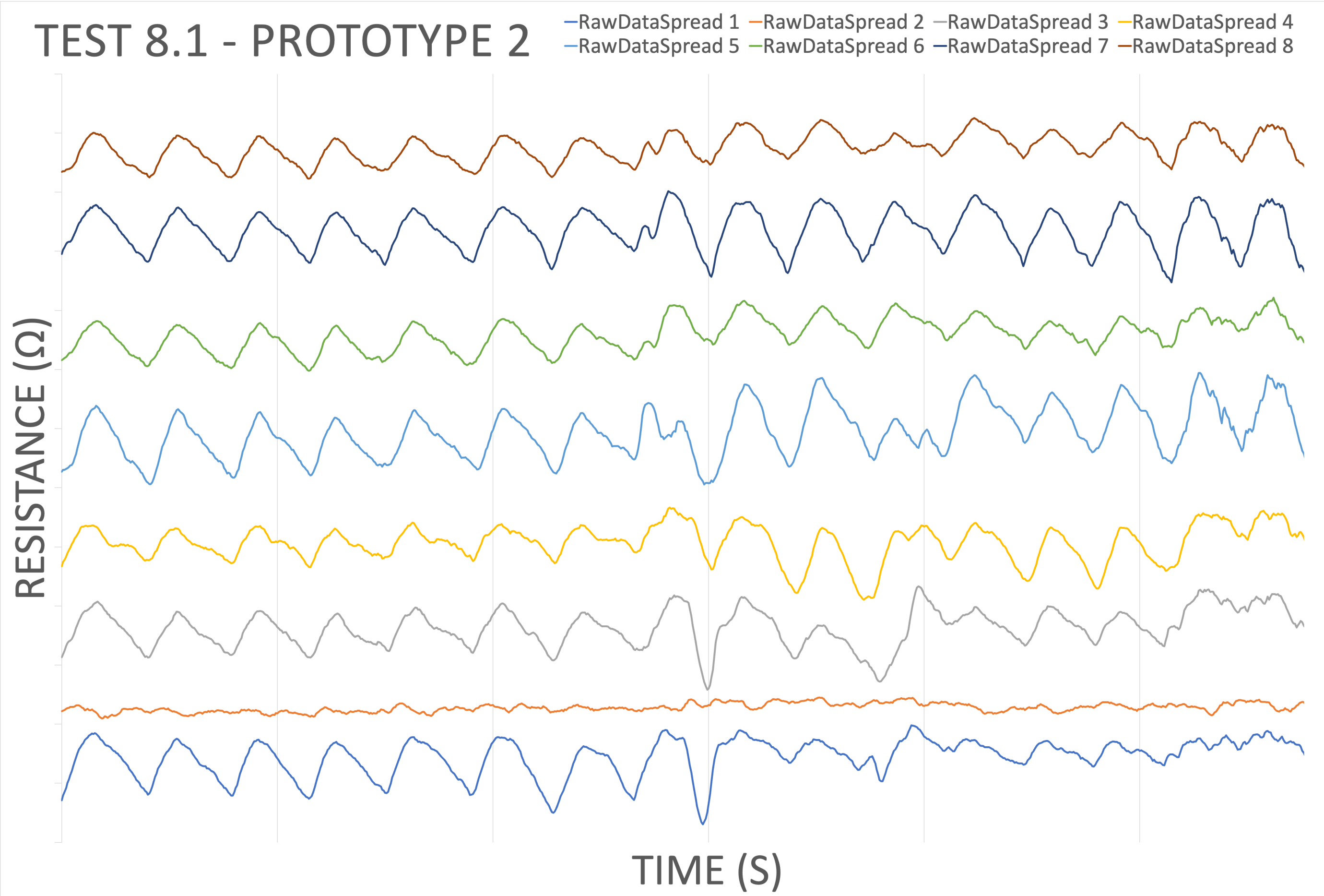


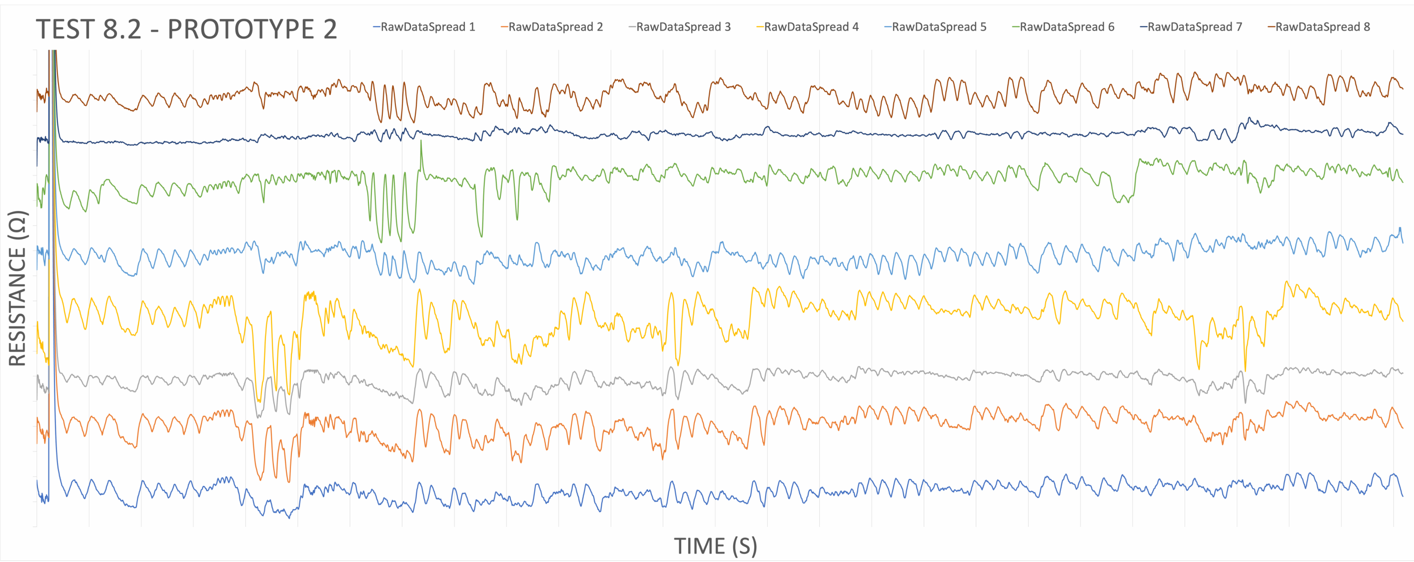
CYCLIC TEST 6 - PROTOTYPE V1
Sensor 1 Sensor 2 Sensor 3 Sensor 4 Sensor 5 Sensor 6 Sensor 7 Sensor 8
RESISTANCE (Ω)
48,0
46,0
44,0
42,0
40,0
38,0
36,0
34,0
32,0
30,0
0,00
5,00
10,00
15,00
20,00
TIME (S)

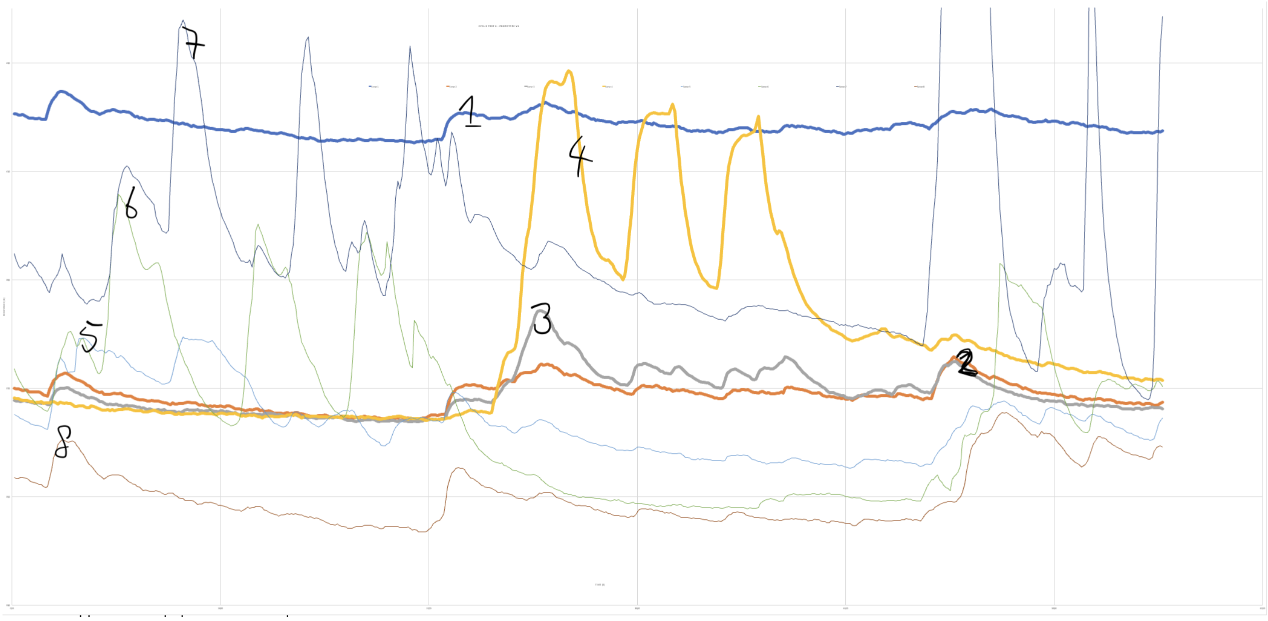


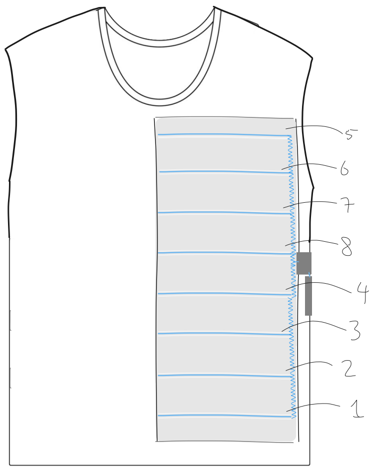
TEST 6 (SENSOR 1) - PROTOTYPE V1
Sensor 1 Filtered
RESISTANCE (Ω)
46,5
46,0
45,5
45,0
44,5
44,0
10,00
12,00
14,00
16,00
18,00
20,00
TIME (S)
T
A

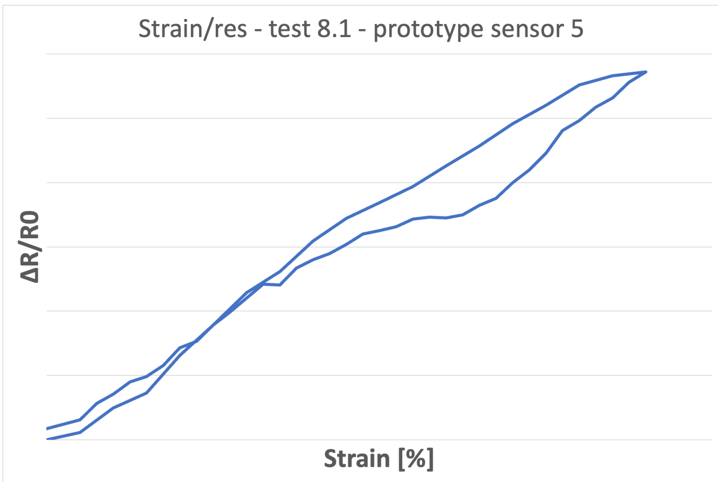
Test 8


TEST 8.1 - PROTOTYPE 2
RawDataSpread 1
RawDataSpread 2
RawDataSpread 3
RawDataSpread 4
RawDataSpread 5
RawDataSpread 6
RawDataSpread 7
RawDataSpread 8
RESISTANCE (Ω)
TIME (S)


TEST 8.2 - PROTOTYPE 2
RawDataSpread 1
RawDataSpread 2
RawDataSpread 3
RawDataSpread 4
RawDataSpread 5
RawDataSpread 6
RawDataSpread 7
RawDataSpread 8
RESISTANCE (Ω)
TIME (S)

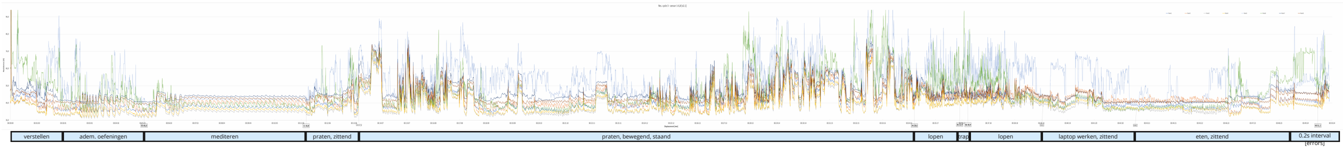

7
1
4
6
5
3
2
8

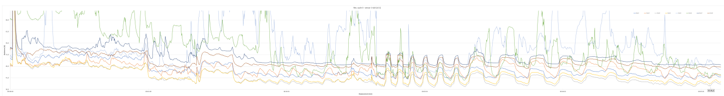

5
6
7
8
4
3
2
1

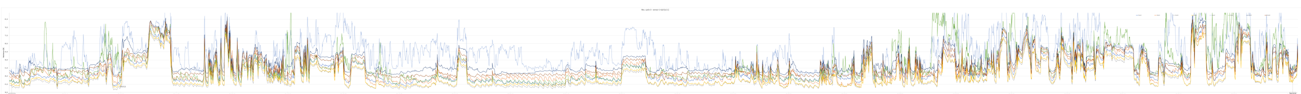

Strain/res - test 8.1 - prototype sensor 5
ΔR/R0
Strain [%]

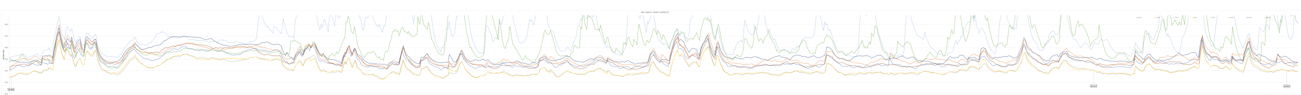
Appendix 7

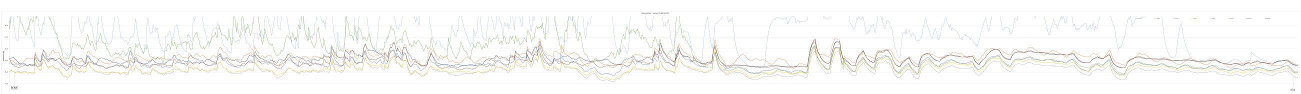
Prototype 1 - test 2.1

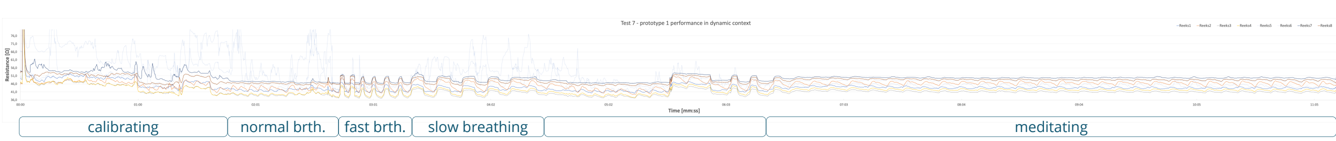


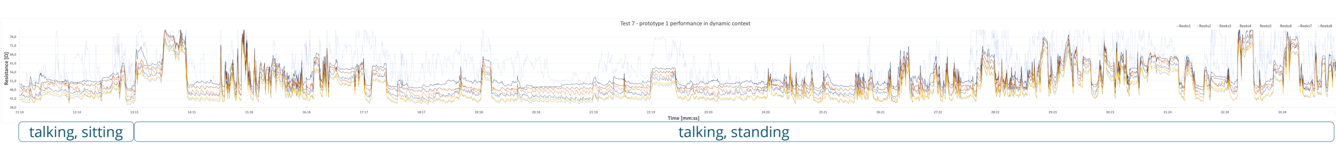


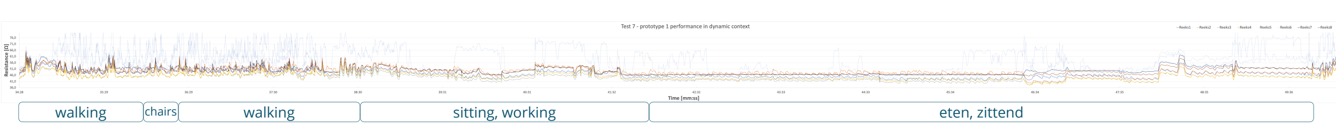


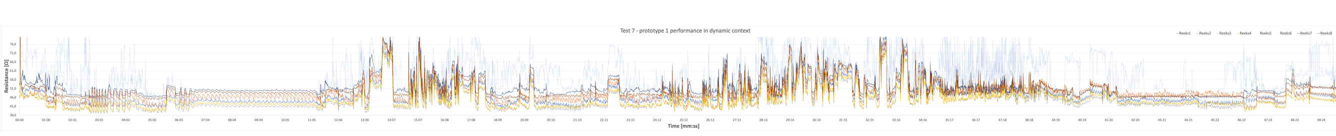




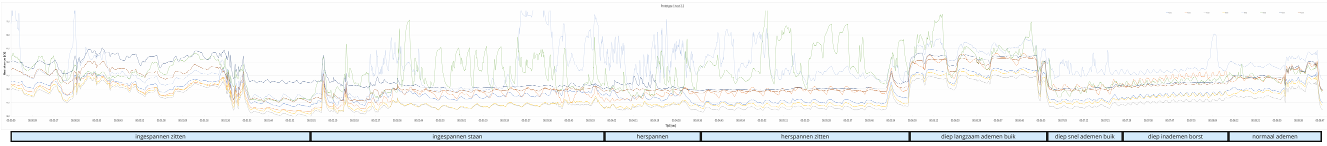


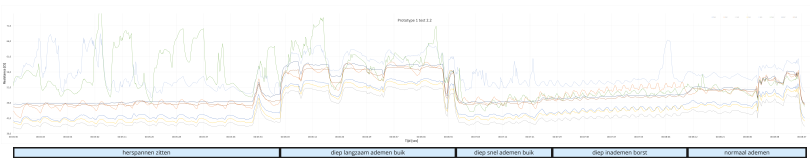


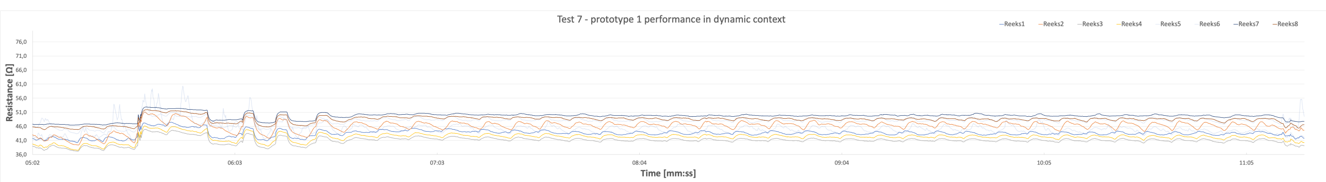


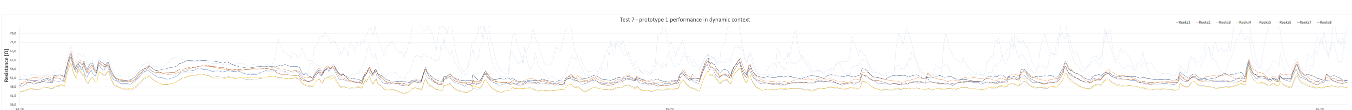


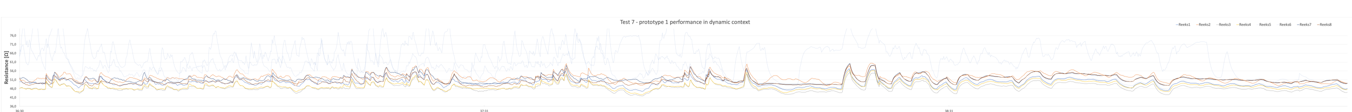
Prototype 1 - test 2.2

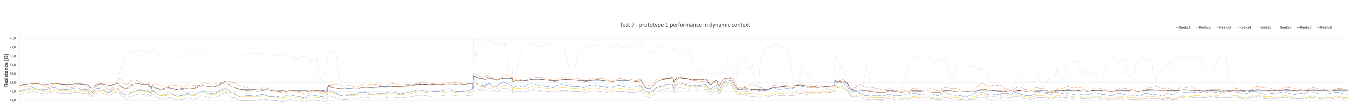


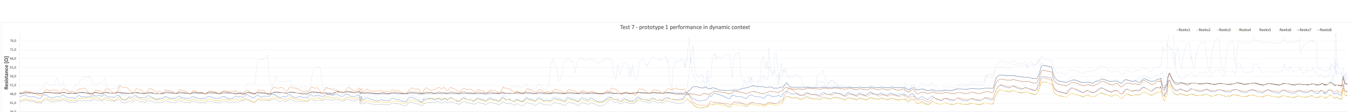


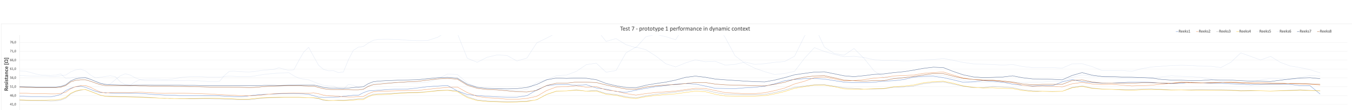












Appendix Chapter 6.1

Checklist set & setting: Work/home setting; room temperature; battery charge; electronic setup

Time	*Activity*	*Topic*	*Note*
	Part 1: Usability and comfort [5 min]		
1 min	Introduce	Scenario	*Introduce research + scenario*
.5 min	Sign forms	Forms	*Request to read/sign forms*
.5 min	Check fit	Measurements	*Take size measurements*
1 min	Share first impression	Observation	*Ask about first impression*
.5 min	Put on shirt	Observation	*Ask to put on the shirt*
1 min	Calibrate sensors	Measurements	*Measure strain applied*
.5 min	Comfort intro	BD	*Intro to body diagram*
	Part 2: Activities and positions [15 min]		
1 min	Sitting (focused; relaxed)	BD	*Ask to sit, ask for comfort.*
1 min	Standing	BD	*Ask to stand, ".*
1 min	Walking (normal; hurry; run)	BD	*Ask to walk, ".*
1 min	Lying down	BD	*Ask to lie down, ".*
1 min	Daily tasks	BD	*Ask to perform some tasks, ".*
1 min	[pause]	Questionnaire	*Explain breathing exercises.*
2 min	Normal breathing [30s]	Data	*Guide normal breath.*
	Belly breathing [30s]		*Guide belly breathing.*
	Chest breathing [30s]		*Guide chest breathing.*
2 min	Fast breathing [15s] Fast belly [15s] Fast chest [15s]	Data	*Guide fast breathing.*
2 min	Deep breathing [30s] Deep belly [30s] Deep chest [30s]	Data	*Guide deep breathing*
1 min	Hyperventilation [20s] canceled	Data	*Guide heavy breathing*
	Meditation [30s] canceled		*Guide meditating*
1 min	Take off prototype	-	*Ask to take off prototype*
	Part 3: Post-use interview [10 min]		
3 min	"Why was your input for the body diagrams: …"		*Comfort*
3 min	"Do you feel affected in your ability to move freely?" – materials, fit, components.		*Non-intrusiveness.*
2 min	"Do you have any other remarks?"		*Misc.*
2 min	Thank you for participating, thank you for your time. No personal data will be kept, here's a reward.		*Thanks, data, reward.*

Aantekeningen:

D

- ~~Beetje compr~~essive hierzo, midden.
- Strak maar acceptee
- Past binnen de modetrends van het hedendaagse, experiementele nike, outdoor wear.
- Doet denken aan de hurt locker
- Zitten: beweegt een beetje rond, maar verder okee. Niet overdrijven zit priem
- Staan: beweegt een beetje rond, test of het goed zit, of je genoeg bewegingscrijheid. Beperkt de bewegingsvrijheid.
- Lopen: kijkt echt naar bewegingsvrijheid.
- Liggen: christelijke manier liggen; kan hier prima mee slapen; geen last meer van heen en weer slingeren omdat je dat niet doet
- Snijden: als het normaal shirt was geweest had ik het uit gedaan.
- Hoe zit het met maatvorming.
- Alles in het wit/creme/grijs zodat het netjes weggewerkt kan worden
- Ritsshirt is prettige manier van aan doen
- Stuk met rits doet zn werk, heeft aanpassingen nodig.
- Geen uitgebreidde mening over de electronica, moet plat weggewerkt kunnen worden.

H

- Veel sensoren
- Stoer, maar ook een dwangvest
- Alsof je op een eletro stoel gezet wordt
- Maar ook vet
- Observatie:
    - Wat is de achterkant
    - Terug naar 2006, dat iedereen gilet
    - Gewoon rits in het midden
    - Subtiele strakheid
    - Draag normaal losse kleding, dan is zo'n wife beater even anders
- Zitten: helpt niet dat we net hebben gegeten
- Staan:
- Lopen: corrigerend in de houding, als kind liep ik ook niet recht, geen bepaalde meer of mindere mate
- Liggen: meer aanweziger, misschiein omdat ik mij er nu op concentreer, maar zou ook wennen. Zelfde als met sportkleding dat zit ook strak. Voelt niet comfortabel genoeg om rond te draaien of echt te relaxen. Extra ronde.
- Dagelijkse dingen: ben je afgeleid dus minder gefocust op discomfort (2:00)
- Misschien makkelijker van borst naar buik, in plaats van andersom, buik is standaard dus ik heb de neiging om te corrigeren. Hoe ga ik ook alweer terug naar borstademhaling?
- Skinny aan mode onderhevig?
- Kan ik hier een trui over dragen?
- Als toepassing zou ik willen signalen vooraf die wel worden gedecteerd door het shirt, om te voorkomen.
- Monitoring is niet aantrekkelijk, het moet mij echt helpen te voorkomen wat ik zelf niet kan voorkomen.
- Voorkomen dat het een bevestiging is dat je ziek bent.

R

- Goed met die straps
- Final product iets meer sensoren iets minder strak qua vering
- Klein beetje stretch in het materiaal
- Als die persoon bij de huisarts is,
- Zoals bij skieen haakpositie zoals bij bh vastzetten op basis van maatvoering
- Een mechanisch flexibel systeem om de maatvoering te fixen
- Iets visueels om te zien tot waar hij moet spannen
- Eerste indruk? **Ja. Gek. Nou, je ziet het een beetje als, ja, het is gewoon een apparaat die je kan dragen. Een apparaat. Ja, dat is wel grappig. wat machinery bijna. Machinery, een stuk gereedschap**

- Fit? **hoe strak moet het zitten**? Ja. **Ga ik het helemaal los doen en dan? de rits aan de rechterkant. Ja**
- **Deze is best wel klein voor mij. [04:51 - 05:03] Mijn hourglass figure. Hourglass**
- **Gewoon normaal ademen. Ja. Dat is wel grappig. Ik let er een beetje op nu. J**e
- **Waar let je op dan? Adem. Je ademhaling.** Ja. [06:35 - 06:46] **Ook omdat het strakker zit.**
- **Ik voel wel dat het strak is, maar is het oncomfortabel? Oké, oké. Oké. Het is wel een beetje gek. Ja**. Stakker**? Ja, vooral bij m'n... Hier bovenaan. Hier boven? Ja. Hier? Ja, want als ik nu diep ga ademen**...
- **Ik heb niet last van m'n pijks zoals je zou verwachten als ik zit en sta. Oké. Dat het opeens strakker zit. Ja. Daar zijn die sensoren dat wel heel flexibel voor zeggen. J**a. En **er zijn ook minder strap aan de onderkant**. Ja.
- **Ook, ja, de ribben kan zitten, dus het is gewoon wel... harder materiaal**, **Tegen de sensoren gaan. Je vel is dunner, zeg maar**, *daar... Oké, dat is interessant. Niet dunner, maar gewoon harder.* **Dus hier, als je vet hebt, dan gaat het vet in een beetje. Compressie een beetje, maar een bot kan niet komen.** Oké.
- Lopen: Geen verschil met staan, hè? Nee, nee. Niet ergens hier, of met mijn **handen ook niet. Omdat er geen mouwen zitten.** [10:06 - 10:12] Als **je bukt, voel je wel strak uit. J**a. **Maar het is nog steeds niet oncomfortabel.**
- Liggen**: hoe lig jij zo nu? Sowieso meestal. Meestal? Ja. Het is zijzwaard. Het is zijzwaard**.
- Koken: **Genoeg spelen**. **Het is helemaal prima.**
- Algemeen draagcomfort: Je voelt dat het strakker is? Ja, gewoon hier**. Op die bepaalde plek waar je ademt**. Oké. **Ja, niet oncomfortabel. Maar wel gewoon strakker**.
- Je merkt ervan, maar je lichaam reageert er heel snel op. En dat is niet veel aan te passen. Ja, ja. Het is net zoals als **je iets dikkere handschoenen aan hebt tijdens iets doen**. Ja, ja. Je merkt het heel snel. Oké. Het is niet lastig of zoiets. Oké.
- En heb je nog andere dingen die je kwijt wilt over deze ervaring? **Nee, vooral, ik zou het wel heel makkelijk een dagje kunnen dragen, misschien één keer. Maar het is zeker niet oncomfortabel genoeg om er last van te hebben**. Ja.
- **als prototype is het heel goed, maar als je naar club wil gaan dan wil je misschien erop denken**.
- Wat zou je willen veranderen? **Ja, ik weet het niet zo goed, want het is moeilijk. Het is vooral, ja, dit (rond de oksel) is best wel sterk. Ja. Dat is nodig natuurlijk. Ja**.
- [19:19 - 19:31] Maar het is wel, ja, ik weet het, het is moeilijk. Ik weet niet hoe andere dingen zijn.
- **En ik denk als arts kun je dit gewoon geven en zeggen, ja, het voelt wel een beetje strak**, [19:31 - 19:42] **maar zo wordt het. Zo is het.** Dus je mag een beetj**e, het mag een beetje discomfort zijn. Dat is, j**a. Ja, maar alsnog is het niet het gevoel, is gewoon iets.

T

- Doet de rits aan in het midden
- Mental discomfort
- Harnas als je gaat bungeejumpen
- Staat onder stroom
- Onder kleding aan is prima, geen mooi shirt, als je het weg kan werken
- 7 dagen is guur
- 7 dagen maakt anders,
- Helpt postuur, onderuitzakken is kutter, rechtop zitten is beter, dus een beetje corrigerend
- Blijft beetje rechtop staan , als ik buk is het kanker
- Midden van je rug neperkter, 7 dagen maakt vervelend
- Beperkt in je bewegingsvrijheid
- Lopen @2:30
- Is niet anders dan staan, eigenlijk best comfortabel, alsof je een rugzak om hebt, bij iedereen is het een andere plek
- Alsik zou moeten buken zou ik
- Beperkt zijn
- Liggen @ 3:40; zij @3:55
- Liggen is relatief gezien heel comfortabel. Lijkt alsof ie minder strak zit
- Koken @4:50
- Omdat mn schouders vrij zijn, genoeg vrijhedi
- Dacht aan wim hof, zag niet zo veel in die grafieken

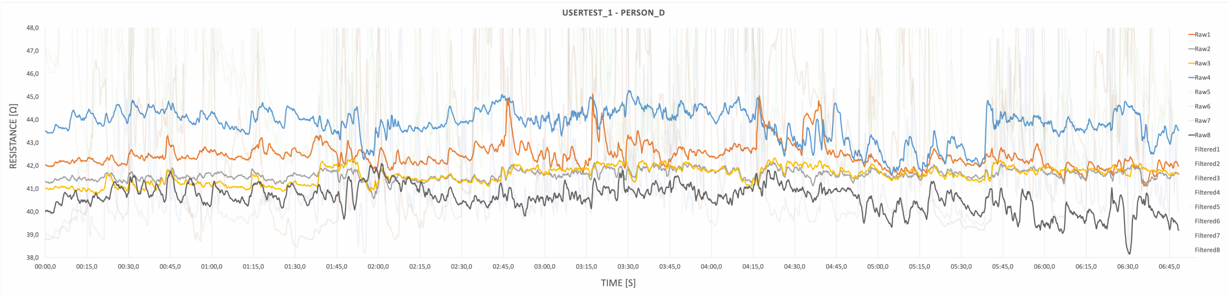
R testgesprek

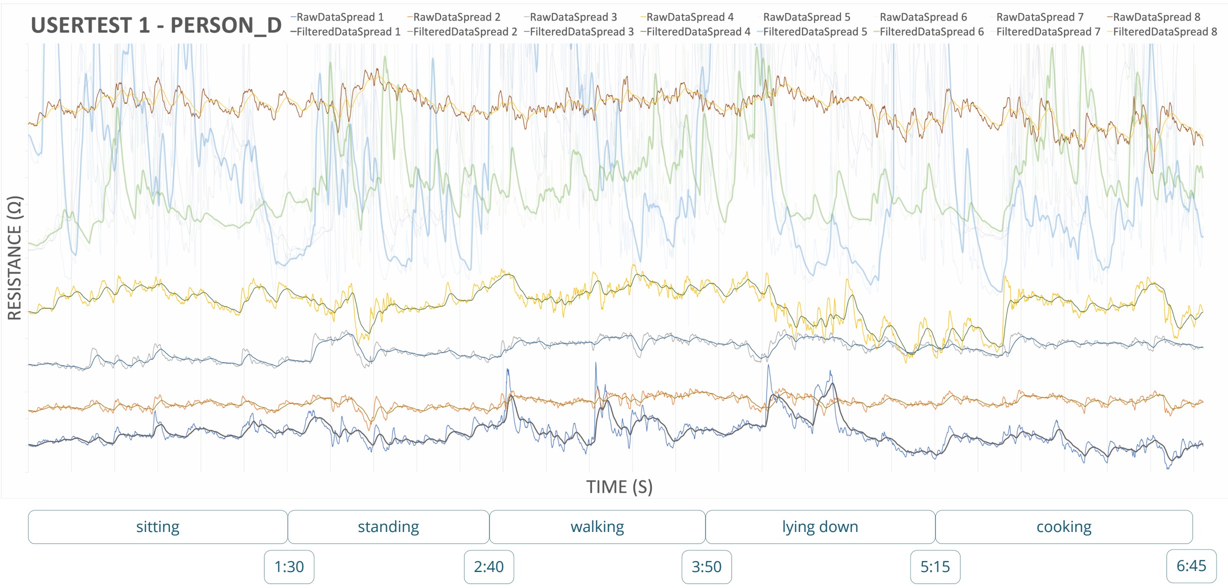
[00:03 - 00:07] Dus ja, ik geef je deze mee. Oké.
[00:10 - 00:22] Drie kleurtjes, daarin kun je aangeven of je je ergens een oncomfortableness voelt. Ja. We kunnen trouwens dit gesprek ook in Engels hebben, want soms is het makkelijker om je
[00:22 - 00:31] in je native language te uiten. Oh, een Nederlands boek. Zo niet, dan zeg ik wel. Oké.
[00:33 - 00:41] Dus we gaan straks eerst een paar activiteiten doen, of activiteiten, verschillende houdingen testen.
[00:41 - 00:51] We beginnen met zitten en daarna staan, lopen, liggen en koken. Ja, oké.
[00:52 - 01:00] En daarna een paar, hoe heet het, ademhalingsoefeningen en dan zijn we klaar, het kan zo voorbij zijn. Ja.
[01:01 - 01:11] En als ik iets merk, dan moet ik het, het gaat over comfort, of ze te strak zitten ergens of iets. Ja. Oké. Ja, precies, precies.
[01:11 - 01:22] En wat is je eerste indruk van het shirt, zoals je het nu zo ziet? Eerste indruk? **Ja. Gek.** Gek? Ja. Wat vind je er gek aan?
[01:22 - 01:29] **Nou, je ziet het een beetje als, ja, het is gewoon een apparaat die je kan dragen. Een apparaat. Ja, dat is wel grappig.**
[01:29 - 01:40] Ja, dat is wel grappig, **wat machinery bijna. Machinery, een stuk gereedschap** of zo. Ja. Oké.
[01:43 - 01:55] Zo. En dit, hier kan ik, ja, oké**, hoe strak moet het zitten**? Ja. **Ga ik het helemaal los doen en dan? . Het zit helemaal aan deze kant. Oh ja**

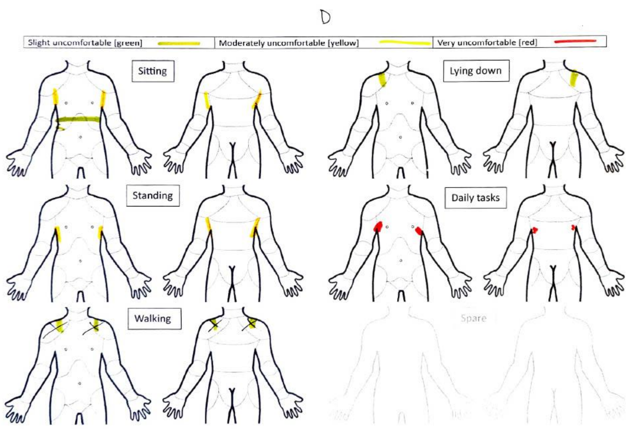
[01:56 - 02:09] Ja, je kan het helemaal los doen. Het idee is eigenlijk dat, nou ja, het is best wel goed, want je hebt dus **de rits aan de rechterkant. Ja**. Ehm. En dan kan je het even, ja, zowel naar links zetten als naar rechts. Zo, ja. Ja, precies. Je hebt het van de as.
[02:09 - 02:20] Moet dat zo? Ja. Ja, moet dus iets meer naar links want het idee is dat die dingen in het midden zitten. Ja, klopt**. Het zit helemaal aan deze kant. Oh ja.**
[02:20 - 02:28] Maar het moet gewoon, niet heel strak maar gewoon. Dan moet ik het zo, dat is een beetje, dit is de bovenste. Oké.
[02:47 - 02:57] Parkwinkel. Ja, de parkwinkel. Oké, top. Oké, dan kan je hem even hier, ik vind dat van de andere kant, ja, is hij een een Je kunt het best even aansluiten.
[03:12 - 03:26] Connect, Circuit Pi, you can do it.
[03:34 - 03:42] Misschien dat we nog even iets strakker moeten spannen. Je hebt een beetje op gevoel hoor.
[03:43 - 03:50] Je moet gewoon goed aansluiten, er moet geen speling tussen zitten.
[03:50 - 04:12] Oké, dus dat zo.
[04:13 - 04:21] Nu moet je alles buiten uitzetten. Oké, alles uitzetten.
[04:26 - 04:36] Geweldig, dan kan je gaan zitten. Zeker een stap genoeg. Ik kan wel even proberen.
[04:37 - 04:49] Nou, het is goed. Deze is een beetje... Ja, hier is het. **Deze is best wel klein voor mij.**
[04:51 - 05:03] Mijn hourglass figure. Hourglass. Oké, perfect. Nog een keer dat inademen. Nee hoor, het is goed. Zitten?
[05:03 - 05:16] Ja. Zo, nu is het weer in eten. Oké, dan gaan we beginnen met... Ik ben natuurlijk niet voorbereid.
[05:18 - 05:21] Hallo. Ik moet het vuil zoeken.
[05:43 - 05:55] Appendix, appendix, appendix. Oké. Ja, dan gaan we dus eerst één minuut zitten. Oh, kut.
[05:55 - 06:00] Ja, ik had net goed al... Ik moet starten, maar goed. Ik ga even hier maar...
[06:00 - 06:12] Kan je gewoon stil blijven of gewoon... Ja, ik kan gewoon stil blijven hoor.
[06:13 - 06:22] Ja. **Gewoon normaal ademen. Ja. Dat is wel grappig. Ik let er een beetje op nu. J**e let er een beetje op, ja? Ja, maar ik...
[06:23 - 06:34] Ik moet gewoon nog iets lezen. **Waar let je op dan? Adem. Je ademhaling.** Ja.
[06:35 - 06:46] **Ook omdat het strakker zit.** Ook omdat het... Maar is het niet oncomfortabel? Niet oncomfortabel? Nee, ik voel wel dat het wel strak is, maar... Mag ik praten trouwens? Ja.
[06:47 - 06:58] **Ik voel wel dat het strak is, maar is het oncomfortabel? Oké, oké. Oké. Het is wel een beetje gek. Ja**. En misschien... Je ziet ook niet echt een bepaald gebied waar het nu...
[06:59 - 07:10] Oncomfortabel is? ...starer zit of oncomfortabel is**. Stakker? Ja, vooral bij m'n... Hier bovenaan. Hier boven? Ja. Hier? Ja, want als ik nu diep ga ademen**...
[07:13 - 07:24] Ja, ja, ja. Maar is niet erg. Het is niet oncomfortabel, gewoon strak. Ja, oké. Ik heb er geen last van. Nee. Zelfs als we strakker termen hebben.
[07:25 - 07:38] Ja. Stakker termen. Oké. Misschien dat we nu even verder gaan met het staan? Ja. Daar waar beter meneer kan staan. Ja, kan staan. Oké.
[07:44 - 07:56] What are your thought? Ja, het komt gewoon prima. Ook prima? Ja. **Ik heb niet last van m'n pijks zoals je zou verwachten als ik zit en sta. Oké. Dat het opeens strakker zit. Ja.**
[07:58 - 08:08] Dat niet. Ja. En dat het aardig Baek is. Nee, d**aar zijn die sensoren dat wel heel flexibel voor zeggen. J**a. En **er zijn ook minder strap aan de onderkant**. Ja.
[08:08 - 08:12] Hier is het wel wel een beetje strak, met de strap. Voel ik. Ja, ja.
[08:14 - 08:26] En het is **ook, ja, de ribben kan zitten, dus het is gewoon wel... harder materiaal**, die tegen de... Ja.b
[08:27 - 08:36] **Tegen de sensoren gaan. Je vel is dunner, zeg maar**, daar... Oké, dat is interessant. Niet dunner, maar gewoon harder.
[08:36 - 08:46] **Dus hier, als je vet hebt, dan gaat het vet in een beetje. Compressie een beetje, maar een bot kan niet komen. Oké.**
[08:49 - 08:50] Lopen dan? Ja, je kan zeker lopen.
[09:01 - 09:02] Ja, zoiets.
[09:12 - 09:25] Hè? Ja, hetzelfde. Geen verschil met staan, hè? Nee, nee. Niet ergens hier, of met mijn **handen ook niet. Omdat er geen mouwen zitten.**
[09:26 - 09:36] Dat ik mijn handen volledig... ...beweeg. Omdat er geen mouwen zitten. Sorry? Omdat er geen mouwen zitten.
[09:36 - 09:48] Ja, maar ook niks van de schouders. Of ja, dat is ook een mouw, maar helemaal geen mouw. Ja. Oké. Oké.
[09:49 - 09:51] Tot. Gaan we zitten? Ja.
[10:06 - 10:12] Als **je bukt, voel je wel strak uit. J**a. **Maar het is nog steeds niet oncomfortabel**.
[10:19 - 10:28] Dit voelt prima? Ik hoor gewoon niks. Ik herhaal het gewoon steeds een beetje, want anders dan hoort de microfoon er misschien niet. Maar het voelt allemaal prima? Ja, het voelt allemaal prima. Ja.
[10:32 - 10:45] En **hoe lig jij zo nu? Sowieso meestal. Meestal? Ja. Het is zijzwaard. Het is zijzwaard**. Ik voel me pas op mijn telefoon.
[10:45 - 10:49] Ja. Dus je kan gewoon zijzwaard tegen ze laten zien. Ja. En dat is prima.
[10:57 - 11:04] Oké, top. Dat is goed zo. Ja. En ik ook. Ja.
[11:17 - 11:19] En dat kan je dan mooi even opuschatten.
[11:20 - 11:40] Het is erg veel details.
[11:40 - 11:46] Ik heb nog steeds genoeg**... Genoeg spelen**. **Het is helemaal prima.** Ja. Ja. Ja.
[12:04 - 12:06] Ik ga de meeting nu stoppen, maar je mag gewoon doorgaan hoor.
[12:41 - 12:53] Sorry, sorry. Ik zeg ja. Je moet me aanhouden. Sorry. Want we kunnen nog die aanmalingsoefeningen doen. Oké. Dat duurt misschien een paar minuten of zo. Ja, prima.
[12:53 - 13:02] We zitten of we staan? Ja, we zitten. Dit gaat meer over de data. Dus we gaan ook iets minder praten dan.
[13:07 - 13:08] Oké, dus we gaan nu...
[13:11 - 13:22] Eerst gaan we normaal ademen, dan in je onderbuik ademen, dan boven ademen, dan
[13:22 - 13:32] gaan we snel ademen, over het algemeen, snel ademen in je buik, snel ademen in je borst, dan diep ademen, diep ademen in je buik, diep ademen in je borst. Oké.
0,0001736 [13:34 - 13:39**] 00:00 Dus we kunnen nu beginnen met normaal ademen. Nu moet je normaal ademen.**
[14:04 - 14:07] We doen dit 30 seconden, dus ik geef straks aan als je kan switchen.
[14:21 - 14:26] 00:45 Ja, we gaan switchen. Naar buik ademen dus, ja.
[14:28 - 14:40] Het gaat goed, goede resultaten.
[14:47 - 14:49] 01:15 Dan mag je nu naar borst ademen.
0,0012152 [15:17 - 15:20] 01:45 Dan gaan we nu naar snel ademen, dat doen we 15 seconden.
[15:35 - 15:37] +0:15 Ja, en dan gaan we naar snel aan de buik.
[15:51 - 15:52] + 0:15 En snel ademen. En snel ademen naar borst.
[15:53 - 16:08] 00:00 En dan mag je nu diep rustig ademen.
[16:36 - 16:38] +:30Mag je nu diep met je buik ademen.
[16:39 - 17:05] +:30 Mag je nu diep met je borst ademen.
[17:33 - 17:34] Oké. Dat was hem.
[17:45 - 17:58] Ik weet... Vond je het moeilijk om te switchen tussen buik en borst enzo? Nee, maar ik **voel wel dat het een beetje strakker** is. Dat is wel even, maar ik vond het niet moeilijk.
[17:58 - 18:09] Je voelt dat het strakker is? Ja, gewoon hier**. Op die bepaalde plek waar je ademt**. Oké. **Ja, niet oncomfortabel. Maar wel gewoon strakker**.
[18:09 - 18:19] Je merkt ervan, maar je lichaam reageert er heel snel op. En dat is niet veel aan te passen. Ja, ja. Oké. Het is gewoon niet zoals je merkt.
[18:19 - 18:31] Het is net zoals als **je iets dikkere handschoenen aan hebt tijdens iets doen**. Ja, ja. Je merkt het heel snel. Oké. Het is niet lastig of zoiets. Oké.
[18:32 - 18:44] Mooi. Nou, hartstikke bedankt. Jij ook. Bedankt voor het kijken. Bedankt voor het kijken. En heb je nog andere dingen die je kwijt wilt over deze ervaring? **Nee, vooral, ik zou het wel heel makkelijk een dagje kunnen dragen, misschien één keer**
[18:44 - 18:56] uitdoen. **Maar het is zeker niet oncomfortabel genoeg om er last van te hebben**. Ja.
[18:57 - 19:07] Dus ik denk, **als product jeep is het heel goed, maar als je naar club wil gaan dan wil je misschien erop denken**. Wat zou je willen veranderen?
[19:09 - 19:19] Ja, ik weet het niet zo goed, want het is moeilijk. Het is vooral, ja, dit is best wel sterk. Ja. Dat is nodig natuurlijk. Ja.
[19:19 - 19:31] Maar het is wel, ja, ik weet het, het is moeilijk. Ik weet niet hoe andere dingen zijn. **En ik denk als arts kun je dit gewoon geven en zeggen, ja, het voelt wel een beetje strak**,
[19:31 - 19:42] **maar zo wordt het. Zo is het.** Dus je mag een beetj**e, het mag een beetje discomfort zijn. Dat is, j**a. Ja, maar alsnog is het niet het gevoel, is gewoon iets. Ja, precies.
[19:43 - 19:51] Dus, nee, het is goed. Het is wel goed. Oké.
[19:54 - 20:05] Ja, ik heb niks anders te merken eigenlijk. Ja. Geweldig. Zal ik het uit elkaar halen? Twintig minuten.
[20:06 - 20:18] Ja, ik kan het maar laten staan. Ja. Ja, ik heb het. Ja. Ja, ik kan het. Ja. Ja. Ja. Ja. Ja.
[20:21 - 20:29] Ja. Ja. Ja. Ja. Ja. Ja. Ja. Ja. Ja. Ja.
[20:59 - 21:10] Heb je nog tijd om mij te afzetten? Natuurlijk, natuurlijk. Dat heb ik beloofd. Ja, dan ook iets laten eten en dan aanvullen.
[21:11 - 21:14] Natuurlijk, geef het maar aan. Ik zit hier. Dankjewel.

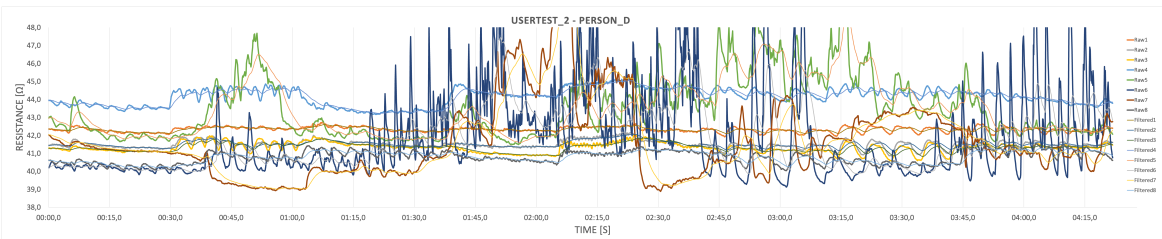
Test 1 Appendix 9

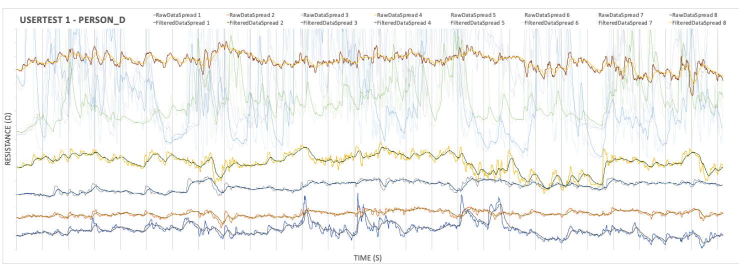
Person D



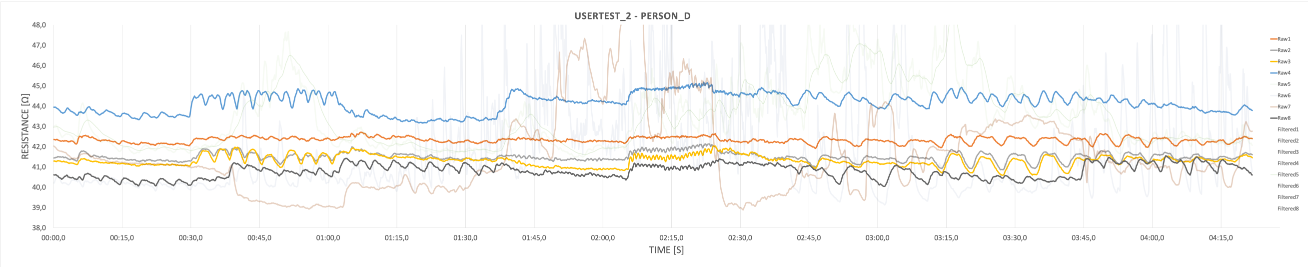




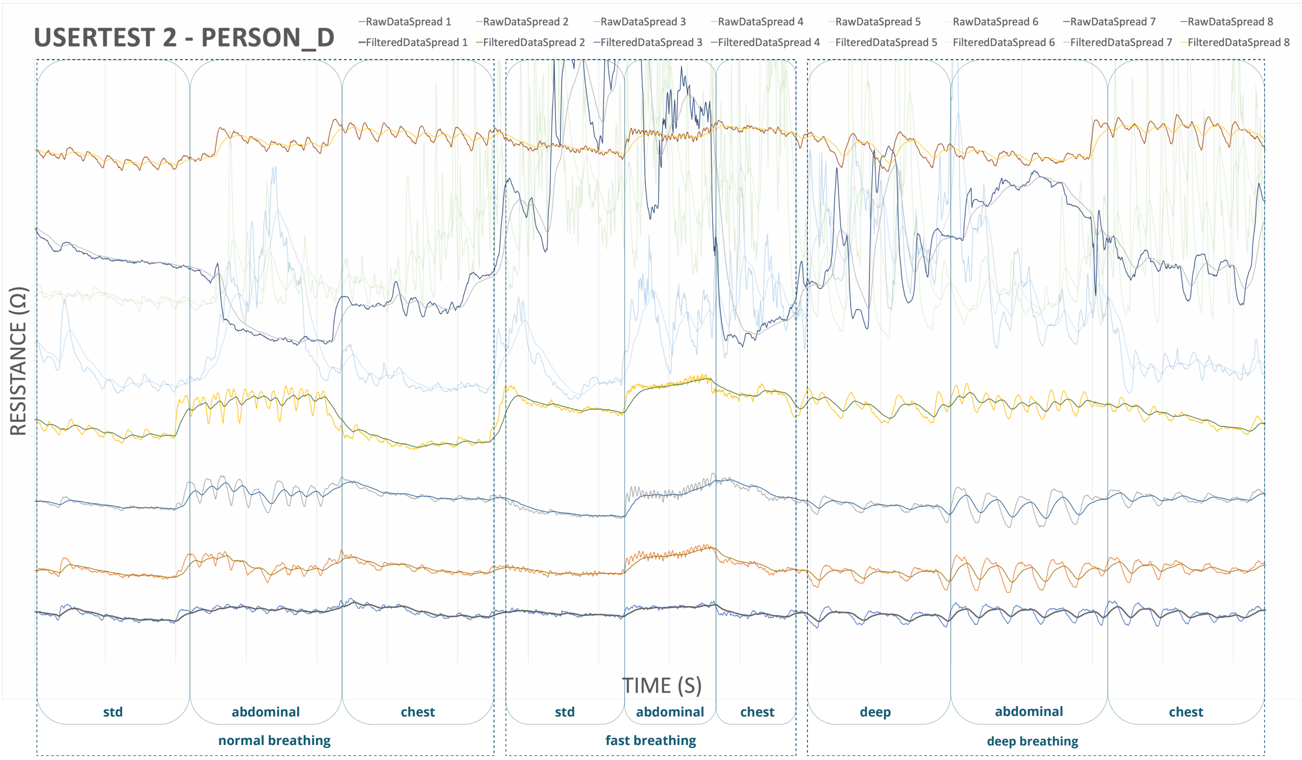




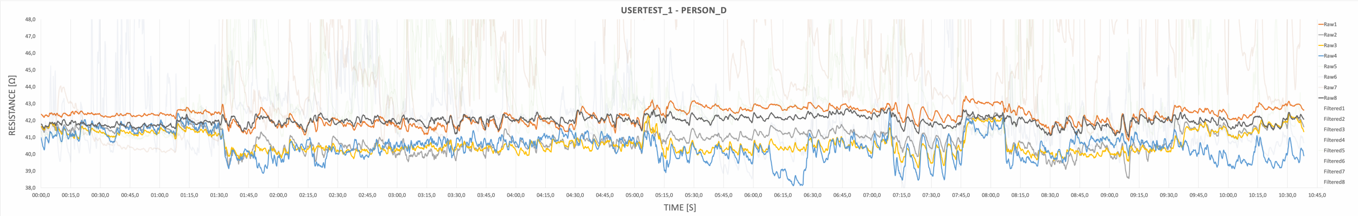
Test 2

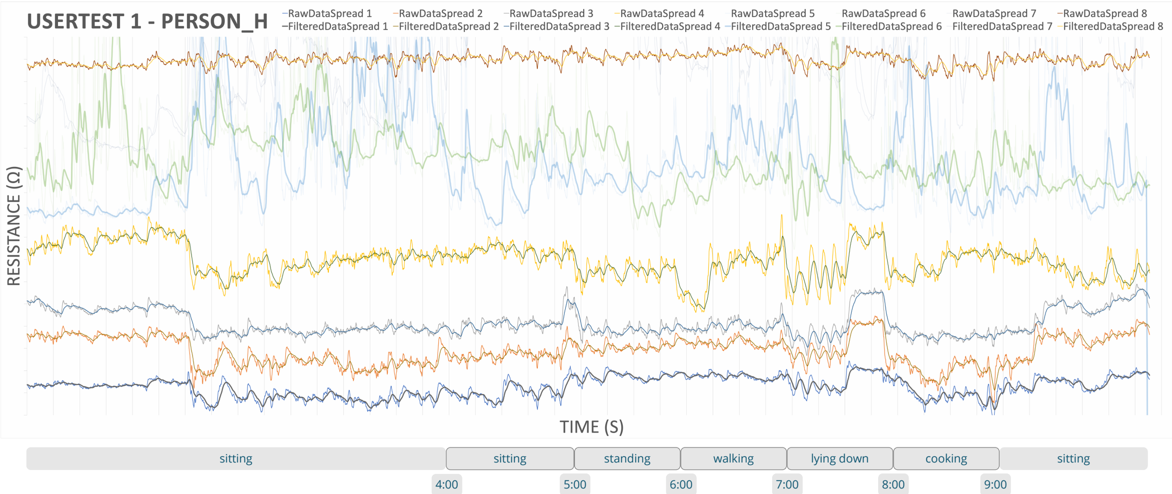


Person D

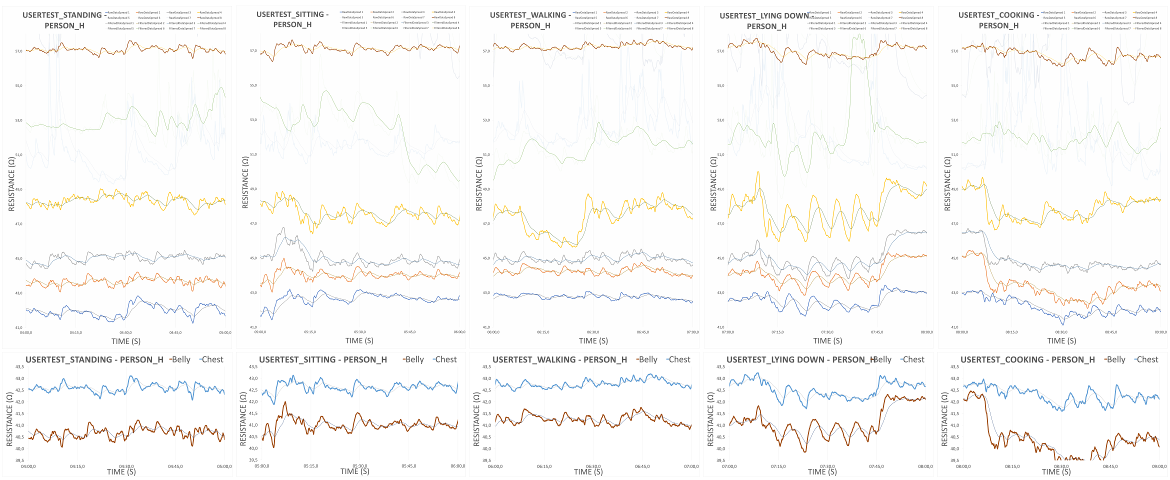


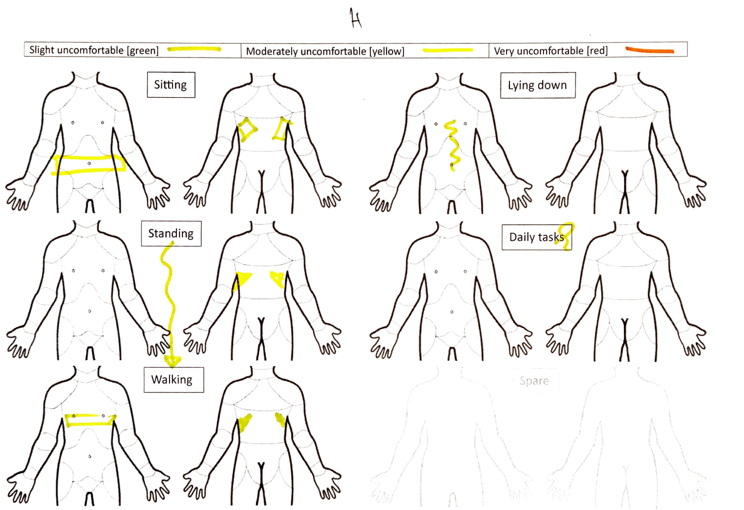
Test 1



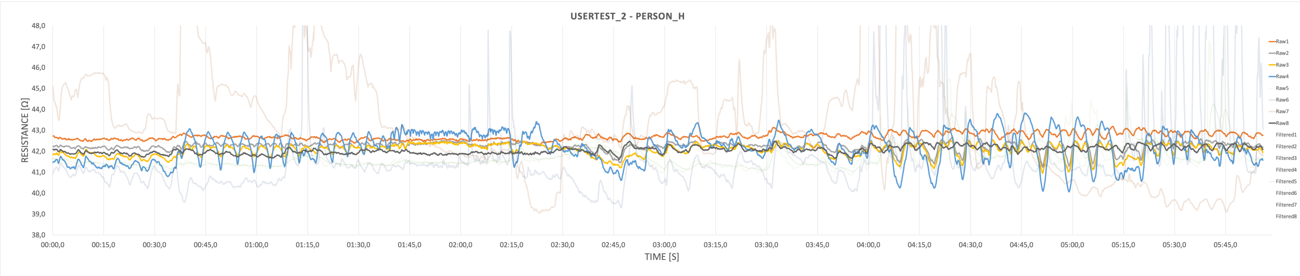


Person H

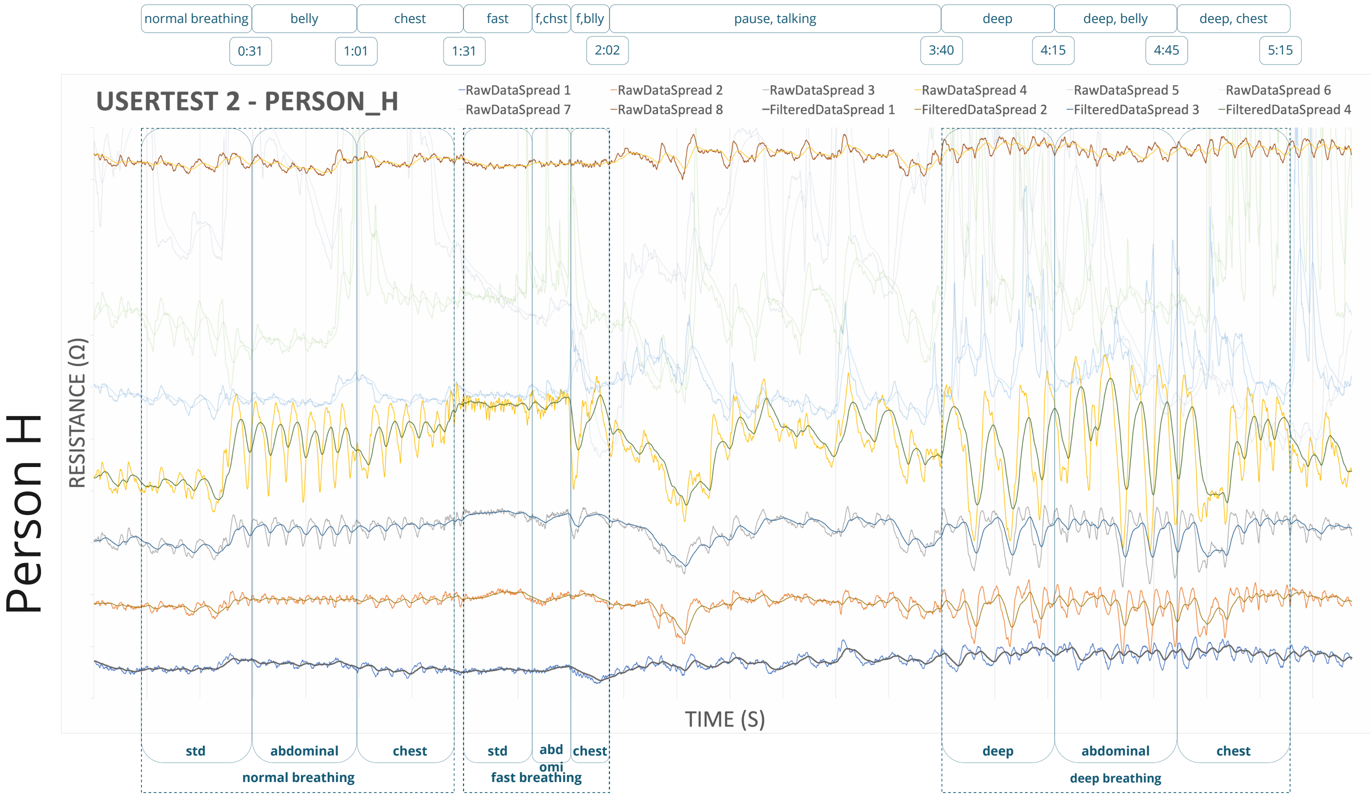




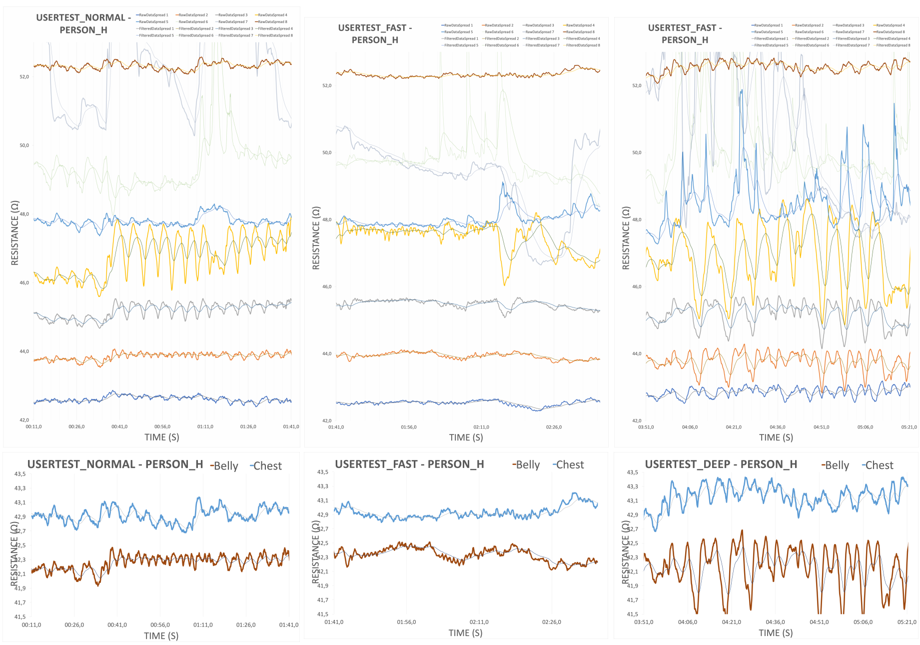
Test 2



USERTEST_2 - PERSON_H
RESISTANCE [Ω]
TIME [S]

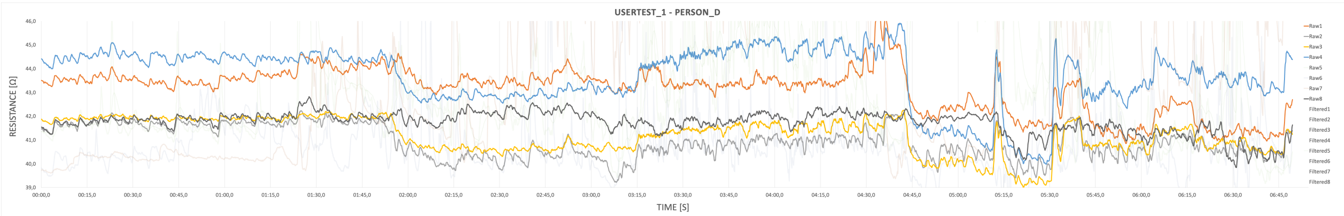


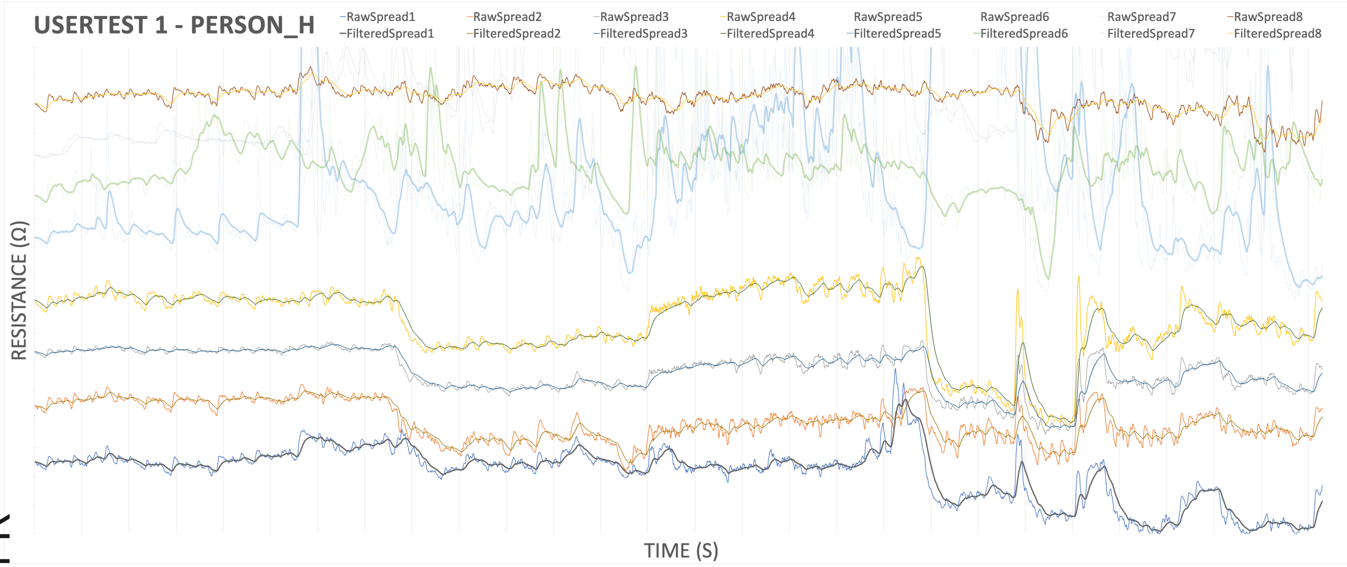
normal breathing
belly
chest
fast
f,chst
f,blly
pause, talking
deep
deep, belly
deep, chest
0:31
1:01
1:31
2:02
3:40
4:15
4:45
5:15
Person H
USERTEST 2 - PERSON_H
RawDataSpread 1
RawDataSpread 2
RawDataSpread 3
RawDataSpread 4
RawDataSpread 5
RawDataSpread 6
RawDataSpread 7
RawDataSpread 8
FilteredDataSpread 1
FilteredDataSpread 2
FilteredDataSpread 3
FilteredDataSpread 4
RESISTANCE (Ω)
TIME (S)
std
abdominal
chest
normal breathing
std
abd omi
chest
fast breathing
deep
abdominal
chest
deep breathing



USERTEST_NORMAL - PERSON_H
USERTEST_FAST - PERSON_H
USERTEST_FAST - PERSON_H
RESISTANCE (Ω)
TIME (S)
USERTEST_NORMAL - PERSON_H
USERTEST_FAST - PERSON_H
USERTEST_DEEP - PERSON_H
Belly
Chest

Test 1

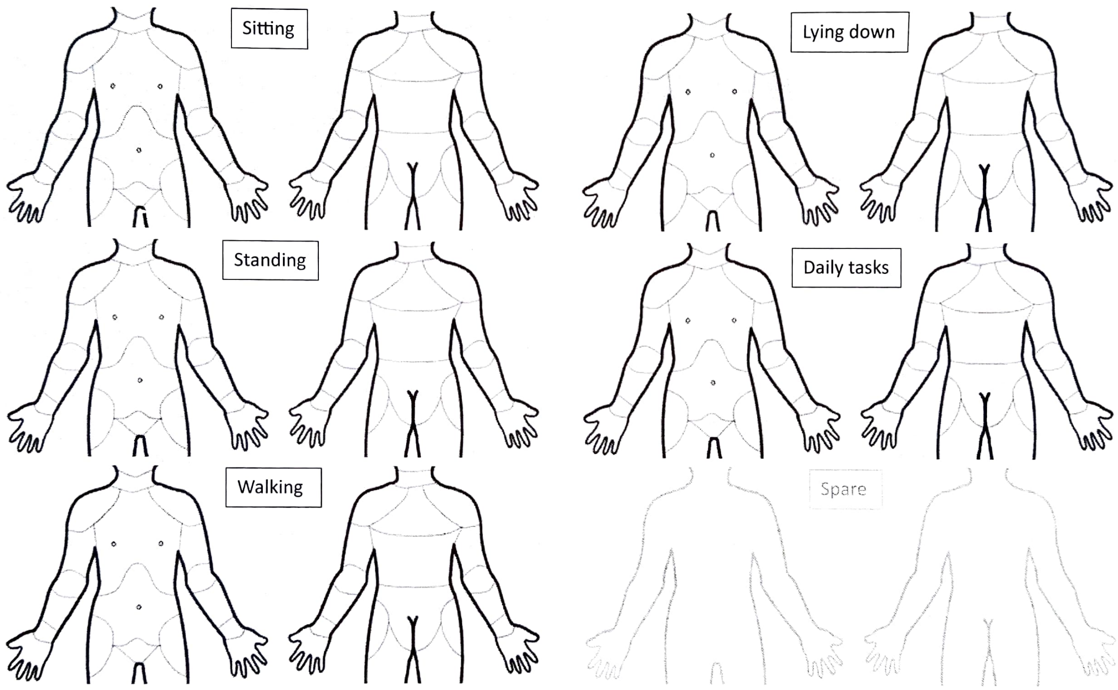




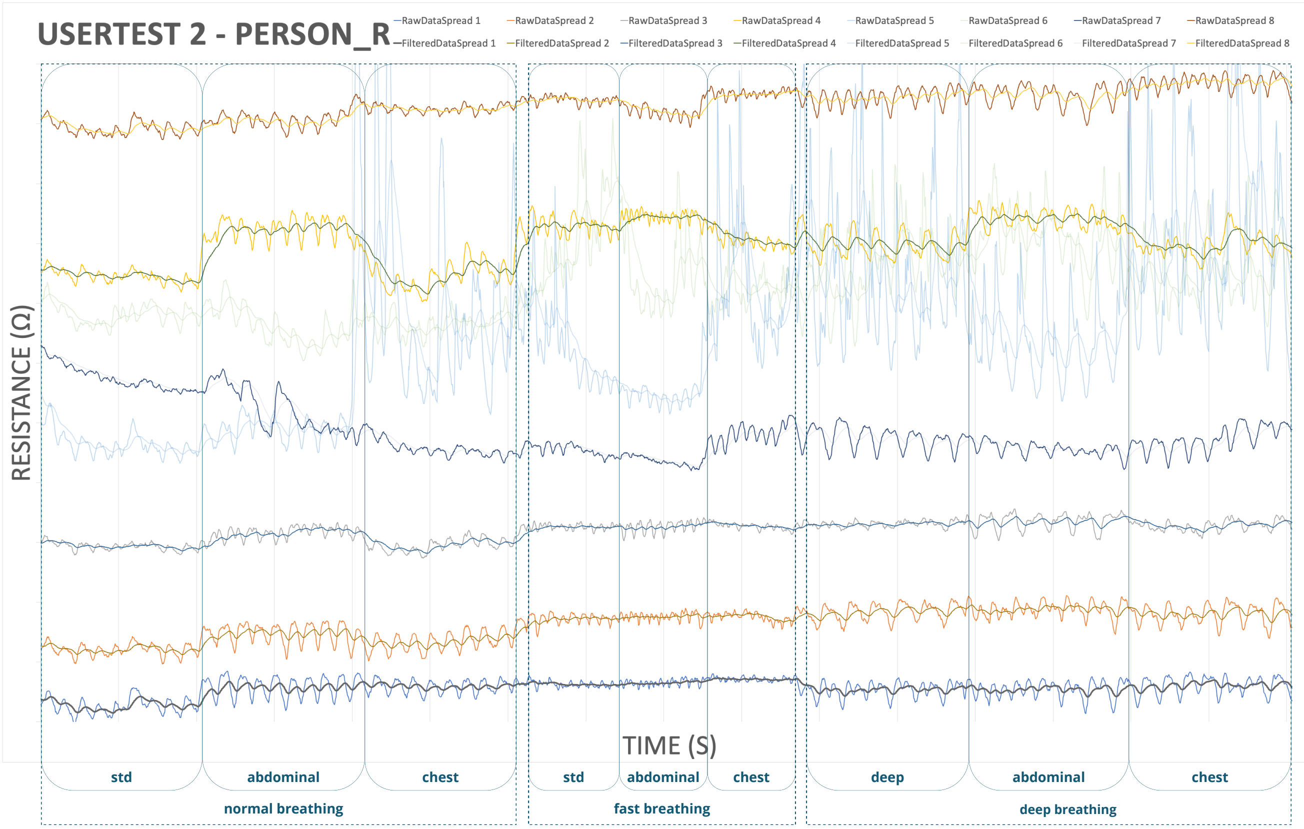
Person R

R.

Slight uncomfortable [green]	Moderately uncomfortable [yellow]	Very uncomfortable [red]

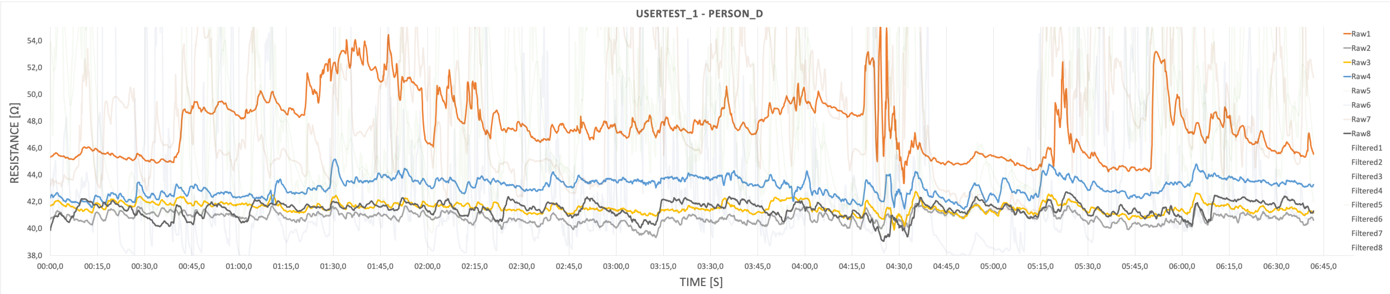


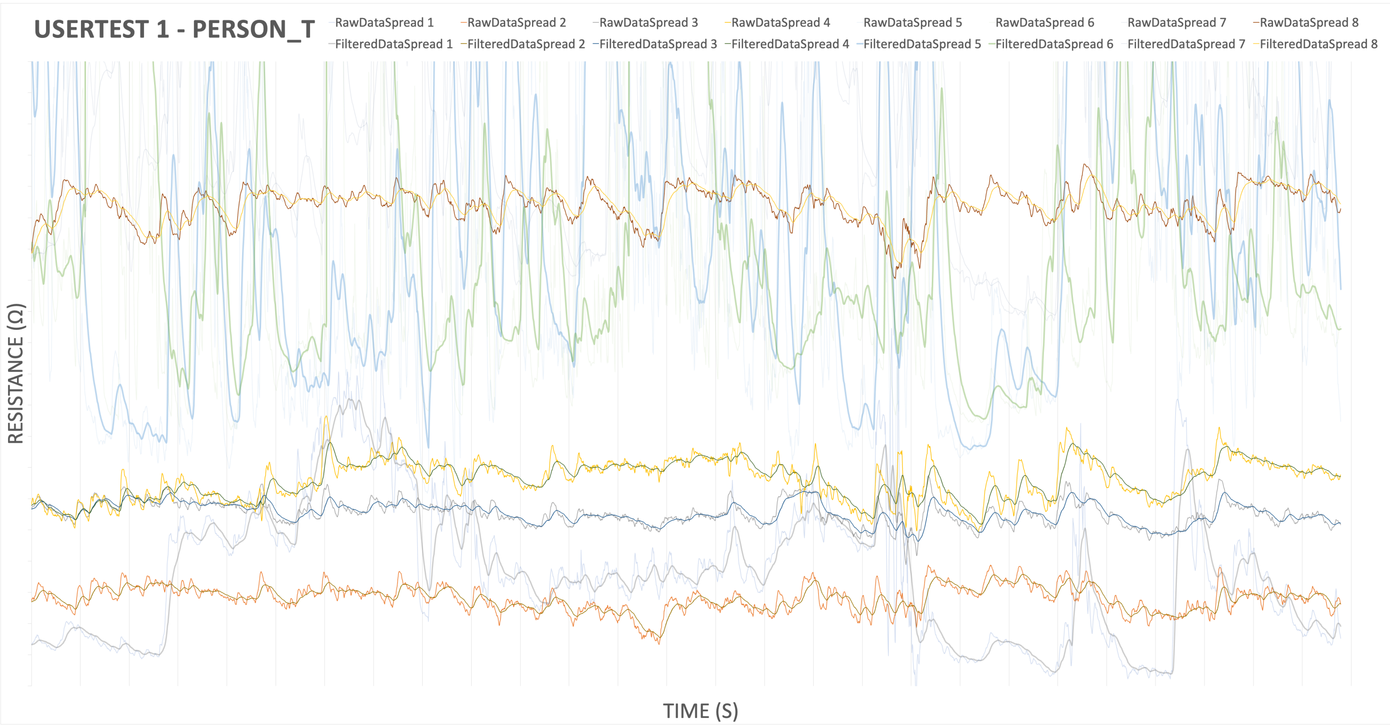
Test 2



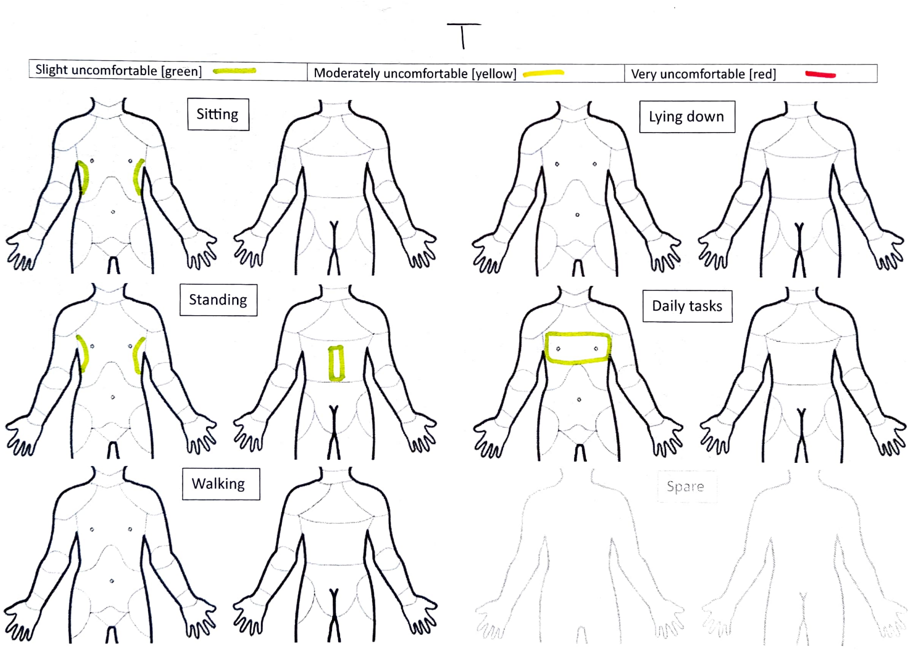
Person R

Test 1

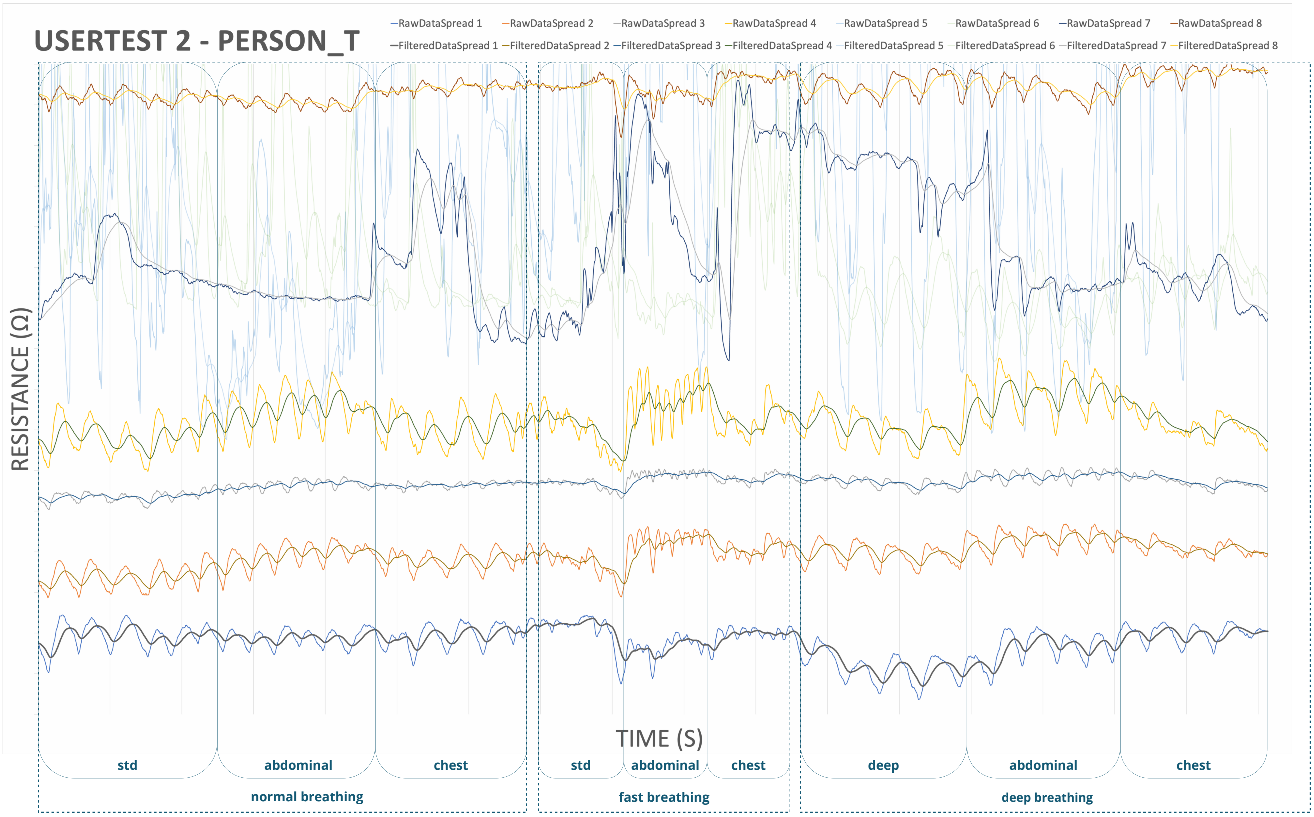




Person T

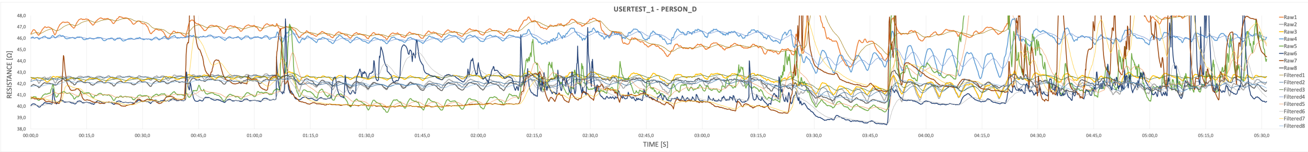


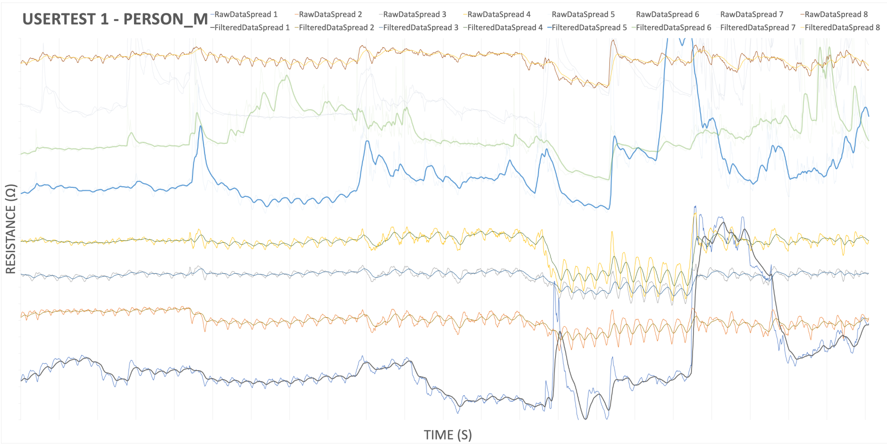
Test 2



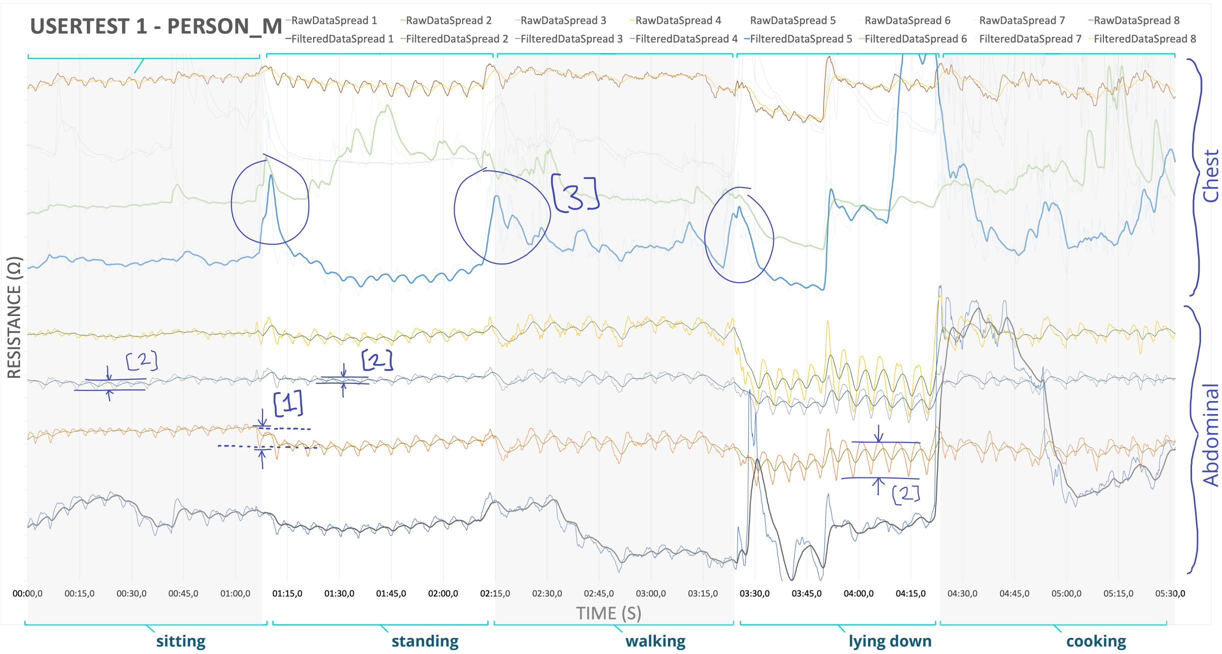
Person T

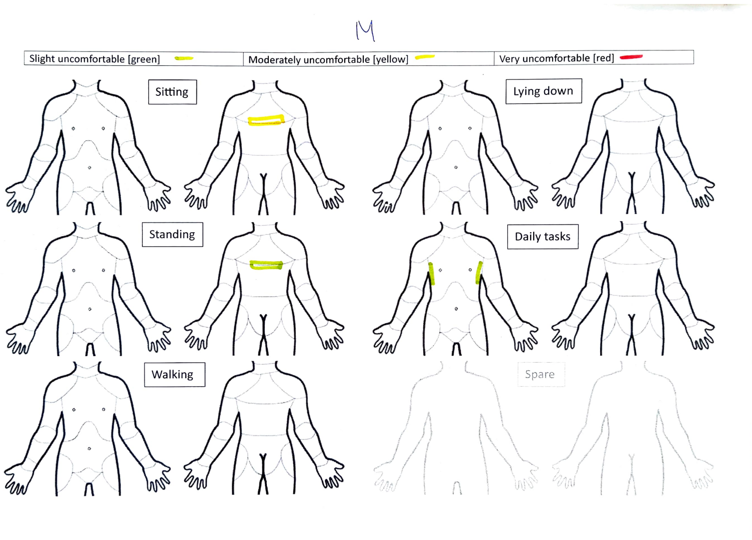
Test 1





Person M





Test 2

Person M