MSc Mechanical Engineering
Graduation Assignment

Material selection process for flexible substrates in medical wearable device applications

M. Hernandez Garcia

Supervisor: Prof. Dr. Ir. Gabriëlle Tuijthof (University of Twente)
Mark Grob (Benchmark Electronics)
Dr. Ir. Richard Loendersloot (Chairman)
Dr. V. Kalpathy Venkiteswaran (External member)

April, 2023

BE-918
CONFIDENTIAL

Faculty of Engineering Technology
Department of Mechanical Engineering

UNIVERSITY OF TWENTE.

Acknowledgements

I begin by thanking Robin Kamphuis and Mark Grob from Benchmark Electronics for giving me the opportunity to work on a graduation assignment at Benchmark. Specially to Mark Grob for proposing the theme of this thesis, allowing me to define it according to my master specialization and provision of means to carry out the assignment. I also want to highlight your help and availability in the preparation and guidance of this work. I would also like to thank my supervisor Gabrielle Tuijthof for her initiative in accepting and guiding this particular assignment. Your availability, feedback and suggestions were important for the development of the entire thesis. And finally, I would like to thank the colleagues I met at Benchmark, who were available for any question or help needed in the practical work.

Special thanks to my parents, Gabriela Garcia and Rodolfo Hernandez (who I would also like to dedicate this thesis to) and my brother Guillermo Hernandez who always supported me, accompanied me and made an effort to provide me with the best opportunities. I would like to thank my boyfriend, Carlos Garces, for his support, companionship and inspiration which he has given me in recent years.

Agradecimientos

Comienzo agradeciendo a Robin Kamphuis y Mark Grob de Benchmark Electronics por darme la oportunidad de trabajar con ellos para completar mi tésis de maestría. En especial a Mark Grob por proponer el tema de esta tesis y brindar los medios para llevar a cabo el encargo. También quiero destacar su ayuda y disponibilidad en la elaboración y orientación de este trabajo. También me gustaría agradecer a mi supervisora Gabrielle Tuijthof por su iniciativa al aceptar y guiar este trabajo. Su disponibilidad y sugerencias fueron importantes para el desarrollo de toda la tesis. Me gustaría agradecer a los colegas que conocí en Benchmark, quienes estuvieron disponibles para cualquier pregunta o ayuda en el trabajo práctico.

Agradecimiento especial a mis padres, Gabriela García y Rodolfo Hernández (a quien también me gustaría dedicar esta tesis) y mi hermano Guillermo Hernández quienes siempre me apoyaron, acompañaron y se esforzaron por brindarme las mejores oportunidades. Quisiera agradecer a mi novio, Carlos Garces, por su apoyo, compañía e inspiración que me ha brindado en los últimos años.

Contents

0.1 Abstract . . . 4

1 Introduction **8**
1.1 Objective . . . 9
1.1.1 Research question . . . 9

2 Background **10**
2.1 Wearable devices in healthcare . . . 10
2.1.1 Physiological monitoring: ECG . . . 11
2.1.2 Biocompatibility . . . 13
2.1.3 Substrate and sensor material considerations . . . 13
2.1.4 Manufacturing and producibility . . . 14
2.2 Case Study . . . 17

3 Methodology **19**
3.1 Requirement definition . . . 19
3.1.1 Wearable device substrates . . . 19
3.1.2 Benchmark expertise . . . 20
3.1.3 Translation to Material Properties . . . 21
3.2 Material screening . . . 23
3.2.1 Materials for flexible wearable devices . . . 25
3.2.2 Database structure . . . 26
3.3 Quantitative method for selection . . . 27
3.3.1 Weighted Index Properties Method . . . 27

4 Results **30**
4.1 Material Selection . . . 30
4.1.1 Engineer selection . . . 32
4.2 Evaluation with case study . . . 34

5 Discussion **36**
5.1 Benchmark Requirements . . . 36
5.2 Application of WIPM . . . 37
5.3 Material results . . . 37

6 Conclusion **40**

7 Future Work **41**
7.1 Material selection user interface . . . 41
7.2 Prototype and implementation . . . 41

8 Appendix **45**

0.1 Abstract

In the medical healthcare industry, there is a growing demand for physiological measuring wearable devices that can be mass-produced and incorporate flexible materials to enhance patient comfort. A current challenge in developing these devices is the proper selection of the substrate material due to the integration of rigid sensors and other electrical components. One of Benchmark Electronics' clients, Bambi Medical, developed a vital signs monitoring wearable device with specific material requirements including biocompatibility, permeability for extended wear, flexibility and durability. The device monitors the heart rate and respiratory rate of babies with a single-use silicone belt placed below the ribcage. The liquid silicone rubber presented limited compatibility with the integrated metal sensors. This incompatibility can lead to delamination or cracking of the metal components.

The objective of this thesis is to develop a material selection tool that identifies viable alternatives to liquid silicone rubber, by conducting a thorough review of the existing literature on physiological sensors and flexible substrates. Based on the results of the research, a material database that included a range of filtered materials through a requirement screening is created with specified mechanical, chemical and physical properties. The weighted properties method is the quantitative tool for material selection. This involved assigning weights to specific material properties based on their relative importance in the wearable device application.

By using this method, the list of alternative materials was narrowed and the most suitable material for the application was selected. One of the top ranked materials was SBS, a thermoplastic elastomer that meets the pre-established requirements for a flexible substrate. This same material was evaluated with the study case baseline in properties and processability. Proving a feasible alternative for liquid silicone rubber to be manufactured with injection molding.

Nomenclature

CTE Thermal expansion coefficient

DL Digital logic

ECG Electrocardiogram

EMG Electromyography

EPDM Ethylene Propylene Diene Monomer

LSR Liquid silicone rubber

MDR Medical Device Regulation

MODM Multi-objective decision making

NICU Neonatal Intensive Care Units

PA Polyamide

PCB Printed circuit board

PDMS Polydimethylsiloxane

PET Polyethylene terephthalate

PGA Polyglycolic acid

PI Polyimide

PSA Pressure sensitive adhesive

SBS Styrene butadiene styrene

SIS Sturene-isoprene-styrene

Tg Glass transition temperature

TPA Polyamide thermoplastic elastomer

TPC Copolyester thermoplastic elastomer

TPU Themoplastic polyurethane

WIPM Weighted Index Properties Method

List of Figures

1.0.1 Common types of wearable devices [1] 8

2.1.1 Types of wearable sensors [2] 11
2.1.2 Holter monitor compared to ECG patch device [3] 12
2.1.3 Electrical coupling of the skin–electrode interface for various electrode types. (A) Wet-contact gel-based Ag/AgCl, (B) dry-contact, (C) thin-film metal plate, and (D) non-contact metal plate [through hair or clothing] [4] 12
2.1.4 Typical configuration of a flexible device: substrate, active layer and interface layer between them [5] 14
2.1.5 Schematic illustration of printing techniques a) Inkjet printing b) Screen printing. [6] 15
2.1.6 Roll-to-roll screen printing process [7] 15
2.1.7 Health patch schematic [8] 16
2.1.8 Health patch [8] 16
2.1.9 COVID-19 smart health patch [9] 16
2.1.10 QUAD Patch schematic [9] 16
2.2.1 Bambi belt by Bambi Medical [10] 17
2.2.2 Bambi belt design schematic 18

3.0.1 Material selection methodology 19
3.2.1 Material screening methodology 23
3.2.2 Ashby plot of Young's Modulus and Density of the different material families . . 24
3.2.3 Material screening flow chart 26
3.2.4 Data entry user interface 27

4.2.1 Radar plot comparing the required properties between LSR and selected materials by the WIPM 35

7.2.1 ECG measuring interface 41
7.2.2 Bambi Belt hardware early stages prototype 41

List of Tables

3.1 Set of requirements for wearable devices [11] . . . 21
3.2 Requirement translation to material property . . . 22
3.3 Researched and reference material databases . . . 25
3.4 Determination of relative importance of performance goals using the DL method [12] 28
3.5 Objective of required properties to be achieved . . . 29

4.1 Calculated emphasis coefficient per requirement . . . 30
4.2 Calculated weight factor and ranking of test run . . . 31
4.3 Property values of candidate materials from material database . . . 31
4.4 Scaled property values of the materials' attributes . . . 32
4.5 Test run performance index results of highest values . . . 32
4.6 Requirement Ranking comparison of engineers and test run . . . 33
4.7 Selected materials with engineer ranking . . . 33
4.8 Second test run performance indices results . . . 34
4.9 Case study substrate material and WIPM material properties . . . 35

8.1 ECG Patch Heart-Rate Monitors . . . 45
8.2 List of common materials for flexible substrates in wearable devices [13],[14] . . . 46
8.3 Material categories for the suitability of the material for injection molding processes 47

Chapter 1

Introduction

In recent years, wearable device technology has gained significant interest in personalized medical care, with the potential to shift from hospital patient-curing to preventive patient-care at home. Wearable devices integrate sensors to the human body in the form of clothing, ornaments, tattoos, and internal implants, enabling physiological sensing, data storage, and mobile calculation, some examples of these devices worn on the body are shown in fig. 1.0.1 [1]. Despite the advances in wearable technology, some devices still face limited mounting options, poor ergonomics, lack of comfort and bulkiness [15]. This limitation is being addressed in the fabrication of distinct types of soft sensors, flexible substrates and integrating them into hybrid electronic systems.

Wearables are increasingly incorporating soft electronics and wireless connectivity as essential features, enabling non-invasive monitoring by interfacing with skin in real-time and on a continuous basis [16]. However, current wearables face challenges such as conventional sensing modalities, battery requirements, soft electronics fabrication limitations, and size restrictions to maintain skin compatibility. The developments of flexible/stretchable devices with good adherence to biological tissues is in great demand due to the complex attributes of the human body. Flexible substrates, which can conform to the shape of the human body, provide a comfortable and seamless experience for the user. Nevertheless, current research is limited to address the mechanical mismatch between soft materials and rigid electronic materials.

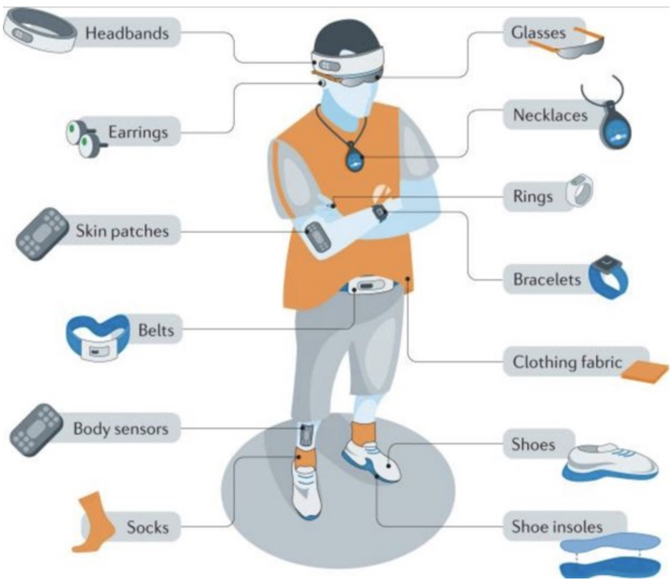


Figure 1.0.1: Common types of wearable devices [1]

Indeed, there remain other fundamental gaps toward wearable integrated sensing system in that biology and electronics are virtually distinct systems. They differ in materials composition, functional mechanism, fabrication, and working environment. Multidisciplinary collaboration is crucial across academia and the medical industry to close this gap. Such is the case for Benchmark, a global company that offers creative product design, engineering services, technology solutions, and advanced manufacturing services. With over 40 years of experience, Benchmark specializes in building and supporting a wide range of medical devices for high-growth customers. These include: connected medical devices, fluid management devices, radiological imaging devices, optical imaging devices, handheld devices, energy delivery devices, and medical robotics. The medical devices built by Benchmark fall under Class I, II, and III categories [17]. A current need at Benchmark Almelo in the Netherlands is to research and test feasible alternatives for physiological measuring wearable devices that can be mass-produced and incorporate flexible materials to enhance patient comfort. This thesis aims to address a challenge encountered by one of Benchmark's clients, Bambi Medical. The company is currently working on their first product, the Bambi belt, a wireless medical device that can non-intrusively monitor vital signs such as body temperature, pulse rate, respiration rate, and blood pressure through a silicone belt. To this end, the thesis will follow up on Benchmarks' current research and propose material alternatives for silicone, used in Bambi's Medical device, to be applied to flexible substrates. These materials will need to be biocompatible as the end application involves direct contact with patients, and thus must undergo medical device testing or have been already approved.

1.1 Objective

The goal of this thesis is to propose a material selection methodology, material database and present results according to a selection tool. The initial research will cover potential fabrication processes and examine the challenges associated with the compatibility of different materials when integrating wearable sensors into flexible substrates, including issues of durability, sensitivity, and accuracy.

1.1.1 Research question

By studying the case study from Benchmark and previous studies regarding wearable devices the challenge of material selection is to be addressed by answering the formulated research question: What is the optimal material selection process for feasible material alternatives to liquid silicone rubber for a flexible physiological measuring medical wearable device substrate?

Chapter 2

Background

This chapter provides an overview of wearable devices in healthcare, their relevance and current advancements into flexible components and device compactness. Furthermore, it provides a more detailed analysis of the case study from Bambi Medical and Benchmark's involvement in wearable medical devices. The review aims to provide a comprehensive understanding of the current technologies for wearable devices applied in physiological measurements.

2.1 Wearable devices in healthcare

There is high demand for smart sensors that can be integrated into a complete wearable system. Benchmark's medical device roadmap aims to meet this demand. The company started by offering low-volume, complex assembly of medical products and have since expanded to provide comprehensive solutions for high-reliability devices. Their expertise makes them the go-to partner for customers in need of reliable and efficient medical device solutions. Benchmark has mainly focused on physiological measuring wearable devices, which have a diverse range of potential applications in healthcare, such as remote patient monitoring, chronic disease management, physical activity monitoring, and rehabilitation/physical therapy. Some examples shown in fig. 2.1.1. Advanced technologies and improved manufacturing processes have spurred tremendous growth in the medical device market, which was valued at 21.3 billion USD in 2021. It is projected to expand at a compound annual growth rate (CAGR) of 28.1% from 2022 to 2030, driven in part by the growth of industries such as home healthcare and remote patient monitoring devices [18].

The trend of flexible wearable devices is expected to go beyond the conventional rigid wafer and planar circuit board technologies. Flexible technologies enable the fabrication of large substrate devices and the creation of thin and highly flexible sensing systems that maintain their functionality even when rolled or folded. As a whole, the market of printed and flexible sensors is expected to grow from $3.6 billion USD to $7.6 billion USD by 2027 [19]. Advances in materials science and device architecture have made large-scale manufacturing of flexible devices economically viable, leading to progress in the development of wearable sensors. Carbon-based materials have been extensively researched for such applications. In addition, combinations of materials and device architectures have enabled the enhancement of conductivity and deformability in flexible structures. [19]. As wearable devices continue to advance, the integration of flexible substrates with rigid components has become an essential task. To facilitate the application of wearable sensors in ambulatory settings, various approaches have been investigated. These include the development of electrodes that do not require wet surfaces, flexible sensor arrays that can be easily strapped onto a limb, and electrodes that can be integrated into textiles. Elastomeric patches with wireless communicating capabilities and tattoos are also being explored [19].

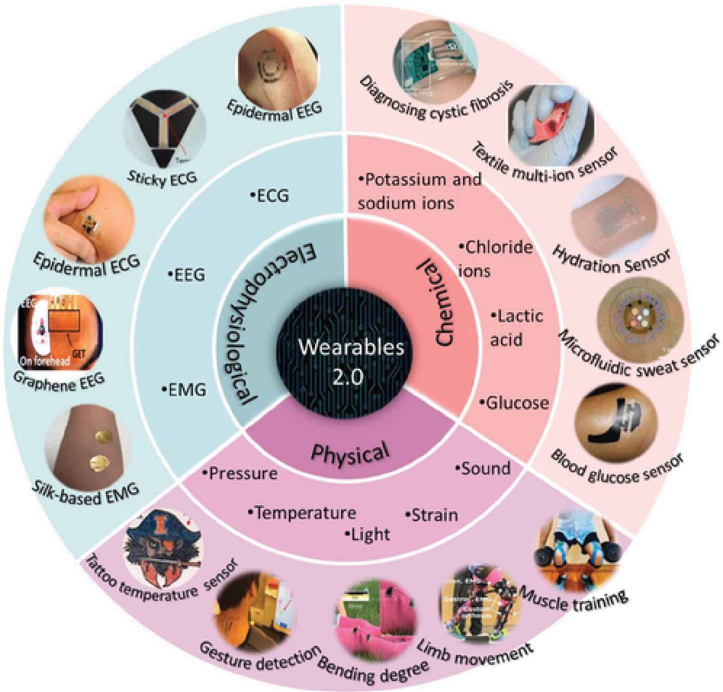


Figure 2.1.1: Types of wearable sensors [2]

2.1.1 Physiological monitoring: ECG

The Bambi belt solution is a medical device that measures physiological measurements of premature babies. Physiological monitoring refers to the continuous or periodic measurement and analysis of a patient's vital signs such as heart rate, blood pressure, respiratory rate, oxygen saturation, and body temperature [14]. This monitoring is relevant because it provides important information about a patient's health status and enables healthcare professionals to detect early signs of deterioration and intervene promptly. These measurements can be obtained through various methods, including non-invasive techniques. One particular area of interest in physiological measuring is electrocardiogram (ECG) monitoring. ECG is a common diagnostic tool that measures the electrical activity of the heart, and is widely used in medical settings to diagnose and monitor a variety of cardiac conditions. However, traditional ECG monitoring is typically performed in a clinical setting and is limited to short-duration measurements. Flexible and biocompatible ECG sensors integrated into wearable devices can enable continuous, non-invasive monitoring and early detection of cardiac abnormalities, revolutionizing the management of cardiac patients.

Wearable ECG monitors have several advantages over traditional devices like the Holter monitor, which is still widely used in healthcare. Unlike the Holter monitor, which requires the patient to carry around a bulky device with multiple wires attached to electrodes on the chest, wearable ECG monitors can accurately measure the heart's electrical activity wirelessly and without the need for cumbersome equipment. In particular, the development of wearable patch ECG monitors has been a significant advancement. These devices attach directly to the skin with good adhesion and require no electrodes or wires, allowing for more comfortable and convenient long-term monitoring of critical patients. With wearable ECG monitors, clinicians can gather valuable data about a patient's heart health while they carry out their daily activities, enabling better diagnoses and more personalized care [20]. A comparative image of these two devices is shown in fig. 2.1.2.

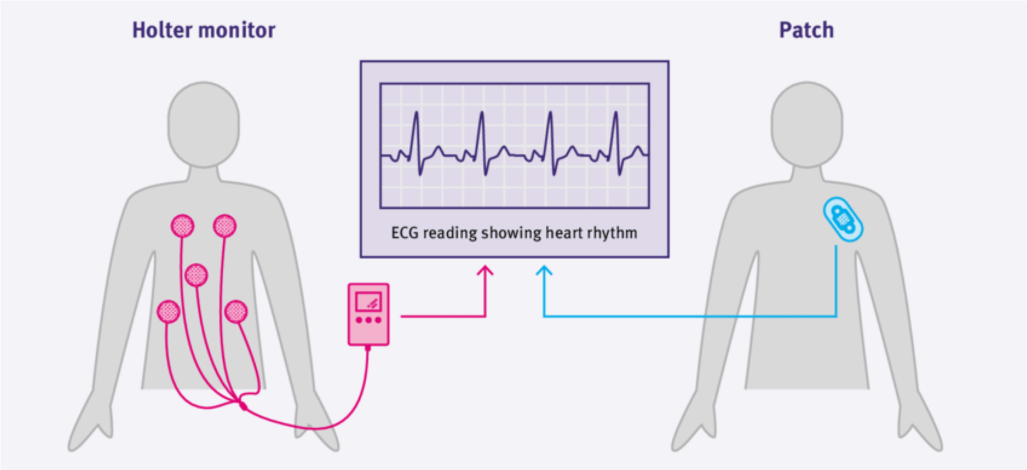


Figure 2.1.2: Holter monitor compared to ECG patch device [3]

Physiological signals can be measured with electrodes that are attached to the skin, for example, ECG electrodes are commonly placed on the chest. The electrodes pick up the electrical activity generated by the body, which is then amplified and recorded by an ECG monitor. Broadly speaking, there exist three classes of physiological electrodes in literature: wet (A), dry (B-C), and non-contact (D) shown in fig. 2.1.3 [4]. The electrodes should possess high electrical conductivity, low contact impedance, high mechanical flexibility, and durability. Although silver/silver chloride (Ag/AgCl) electrodes, also known as wet electrodes, are the current standard for ECG measurement in clinical practice, they have several drawbacks. These electrodes require an electrolyte gel or paste to establish a reliable skin-to-electrode connection, which can dry up within a few hours, making them unsuitable for extended measurements [4]. Another disadvantage is that the setting up process is time consuming (skin preparation) and requires a professional for proper application. To overcome these issues, dry electrodes have been proposed as a stable alternative. These electrodes have a significant advantage over wet electrodes as they do not need extensive preparation, making them less time-consuming. Dry electrodes can be made from a variety of materials, such as metals, polymers, carbon rubber, or conductive textiles, and can be integrated into textiles or attached to the skin with medical-grade adhesive tape, elastic bands, or flexible substrates.

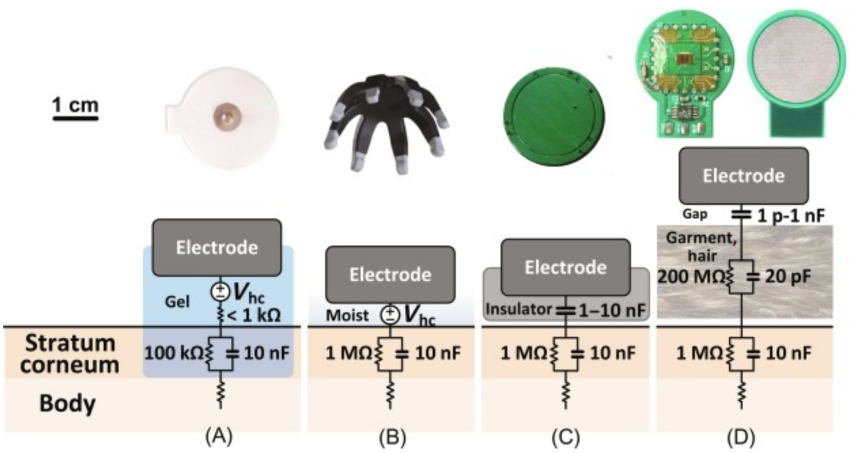


Figure 2.1.3: Electrical coupling of the skin–electrode interface for various electrode types. (A) Wet-contact gel-based Ag/AgCl, (B) dry-contact, (C) thin-film metal plate, and (D) non-contact metal plate [through hair or clothing] [4]

Continuous monitoring of vital signs is also essential in infant care, especially for premature infants or those with certain medical conditions. Long-term ambulatory ECG monitoring is one such technique that can be used for monitoring heart function in infants. There is a need for user-friendly wireless solutions that are as well lightweight, flexible, and biocompatible. Such devices can be particularly useful in infant care where continuous monitoring is critical for detecting early signs of deterioration and ensuring timely intervention. The Bambi belt is an example of how dry electrodes are being integrated into flexible substrates for long-term physiological monitoring. The Bambi belt, using dry electrodes, allows for non-invasive monitoring of infant health and reducing the need for invasive procedures. By eliminating the need for conductive gel, the device is easy to apply and comfortable to wear [10].

2.1.2 Biocompatibility

For the case of the Bambi belt, since infants have sensitive skin and are more vulnerable to irritation or allergic reactions, it is important to ensure that the device is made of biocompatible materials that will not cause any harm or discomfort to the infant. In Europe, wearable devices are classified as medical devices under the Medical Device Regulation (MDR) and are categorized according to their risk level to the patient or user. The MDR requires that manufacturers demonstrate testing for aspects such as electrical safety, mechanical safety, software validation and biocompatibility of their devices [21]. ECG monitors and devices are classified as either Class IIa or Class IIb depending on the risk associated with the device. Class IIa devices, such as ECG for non-diagnostic purposes, have a lower risk profile than Class IIb devices, ECG for diagnostic purposes. The concept of biocompatibility initially arose in the context of implantable medical devices, and the early definitions of the term reflected this particular situation. The definition of biocompatibility that is widely accepted is that it 'refers to the ability of a material to perform with an appropriate host response in a specific application' [22]. The immune system defends the human body against external threats like bacteria, viruses, fungi, and parasites. However, healthcare applications that use non-biocompatible materials can trigger an immune response. Therefore, all medical devices must undergo biocompatibility testing, including ISO 10993 standards that evaluate the biological risks associated with medical devices. The ISO 10993 classification categorizes medical devices based on their anticipated contact with human tissues and outlines relevant biological endpoints for each device category [23].

2.1.3 Substrate and sensor material considerations

A flexible substrate, see fig. 2.1.4, serves as the foundation for the electronic components and sensors in wearable devices, such is the case for liquid silicone rubber from the Bambi belt. The use of flexible substrates allows sensors to provide expected responses on non-flat surfaces, which is not achievable by rigid sensors fabricated using conventional microelectronics techniques [24]. When selecting a flexible substrate, the material is of utmost importance, as the properties can significantly impact the behavior of the integrated system [25]. A flexible substrate should be highly deformable and mechanically robust, capable of maintaining its shape and integrity over time, even after repeated bending and stretching. It should also exhibit essential properties, such as dimensional stability, thermal stability, and a low coefficient of thermal expansion (CTE) [25] for adequate manufacturing and producibility. In addition, the substrate material must exhibit excellent solvent resistance, as well as good barrier properties for moisture and gases [25].

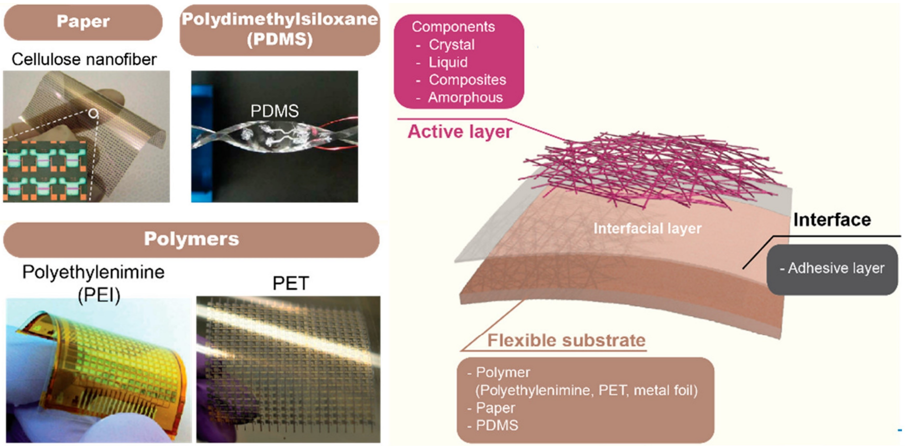


Figure 2.1.4: Typical configuration of a flexible device: substrate, active layer and interface layer between them [5]

Advances in wearable device technology have led to improvements in material selection for flexible substrates as well as dry electrodes. Various types of dry electrodes have been proposed, including textile electrodes, micro-tip electrodes, and foam electrodes, which offer good conductivity and eliminate the negative effects of wet electrodes [5]. However, these dry electrodes are unsuitable for integration with flexible substrates and do not exhibit self-adhesive properties, requiring additional attachment pressure [5]. Polymer electrodes with conductive composites, made of PDMS and conductive particles such as silver nanowires, carbon nanotubes, and carbon black, are extensively used in wearable devices as an alternative. These electrodes are flexible, have good adhesion, and can be integrated with flexible substrates, making them an excellent choice for wearable devices [26].

2.1.4 Manufacturing and producibility

Ensuring wearable device producibility at scale is critical for their widespread adoption. The producibility factors are a combination of design, manufacturing processes, and material properties that must be optimized for cost-effectiveness, reliability, and consistency. The design must balance the functional requirements of the device with the constraints of manufacturability, such as the number of components and assembly complexity. Manufacturing processes must be scalable, efficient, and reliable to produce consistent quality devices. The producibility of wearable devices is further complicated by the integration of sensors and electronics, which require specialized manufacturing processes such as microfabrication and flexible electronics [25].

Flexible wearable devices are manufactured through various processes in the industry, each with its own benefits and drawbacks. Printed electronics is a new method of printing electronic solutions on thin and lightweight materials. This printing technique is versatile as it can be done on thermoplastic substrates, textiles, paper and other flexible materials, allowing electronics to adapt to different shapes and situations. Common manufacturing methods include injection molding, overmolding, Roll-to-Roll (R2R) processing, inkjet printing and screen printing, illustrated in fig. 2.1.5 and fig. 2.1.6. Injection molding can be used to produce complex shapes with high precision and consistency, making it a useful process for creating intricate wearable device components. It can also be used to produce parts with varying wall thicknesses, which can be useful for creating wearable devices that fit comfortably and securely on the body. Overmolding involves placing a pre-existing component, such as a flexible substrate or electronic component, into a mold and injecting a second material, such as liquid silicone rubber or thermoplastic elastomer, around it to create a layer or coating. This process can add functionality, protection, or aesthetic features to the flexible wearable device. R2R processing is a continuous manufacturing technique that employs flexible substrates such as polyethylene terephthalate (PET) or polyimide (PI) to create electronic components on a large scale. The process involves feeding the substrate from one roll, depositing or printing the desired material or component on the substrate, and then winding the completed product onto another roll [7]. Inkjet printing, on the other hand, is a method of printing electronic components onto a substrate utilizing liquid ink droplets. This process allows for high-resolution printing of conductive and semi-conductive materials, thereby enabling the production of flexible electronic components. Screen printing is a technique that involves forcing ink or paste through a stencil onto a substrate to create a pattern. This method is commonly used to produce conductive traces and patterns on flexible substrates [6].

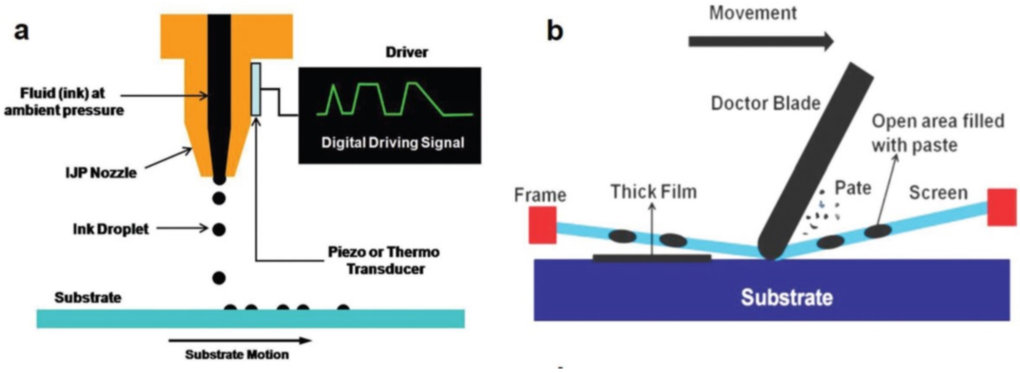


Figure 2.1.5: Schematic illustration of printing techniques a) Inkjet printing b) Screen printing. [6]

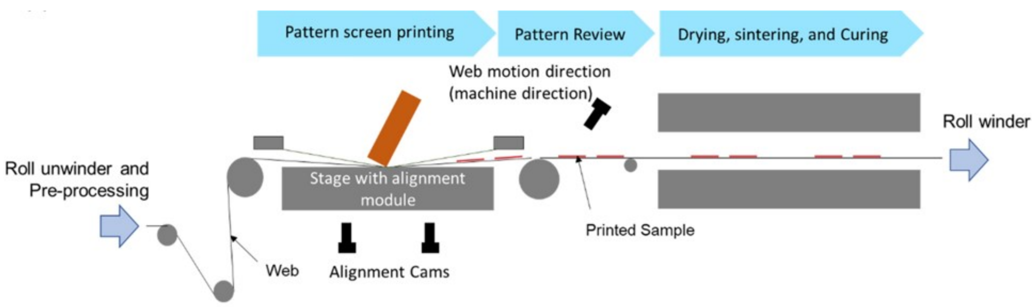


Figure 2.1.6: Roll-to-roll screen printing process [7]

Manufacturing methods such as textile technologies, inkjet printing, and 3D printing, are commonly used in laboratories to prepare sensing electrodes. However, the large-scale production of sensing electrodes using these methods is limited, and the consistency between each electrode is not sufficiently high. Consequently, these manufacturing methods are not suitable for widespread utilization of wearable sensors, and are only suitable for laboratory research [6]. One of the main challenges in scaling up these type of devices is the materials required which are still in the development phase and are not yet produced at large-scale production rates, increasing their cost. Further research is necessary to improve the producibility and scalability of flexible wearable devices to make them viable for commercialization.

Holst Centre, an R&D center specializing in wireless autonomous sensor technologies and flexible electronics, has been a consultant for Benchmark in the development of wearable devices [8]. They conduct research in an open innovation setting and dedicated research trajectories. Recently, in collaboration with TNO, they developed a Health patch using skin-friendly and biocompatible materials. The patch uses a flexible and elastic thermoplastic polyurethane (TPU) material as its base substrate, and printed electronics technologies for most electronic functionalities [8]. Integrated dry electrodes provide a reliable and superior electrical connection to the body, while a soft silicone adhesive is used for long-term adhesion with high comfort. The Health patch is shown in fig. 2.1.7 and fig. 2.1.8.

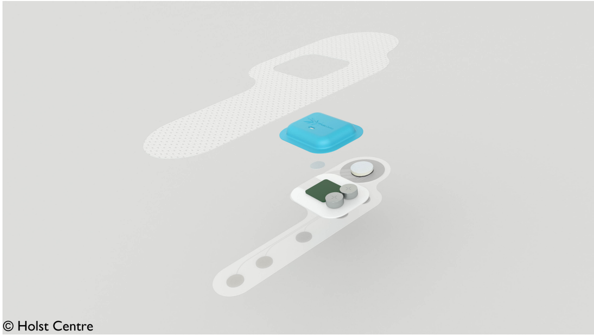


Figure 2.1.7: Health patch schematic [8]

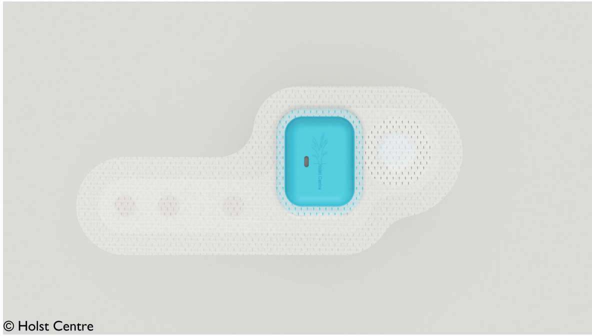


Figure 2.1.8: Health patch [8]

Quad Industries collaborated with six medical and technological firms to create a cutting-edge smart health patch that enables constant, remote, wireless tracking of the breathing rate, heart rate, and temperature of individuals suffering from coronavirus. This patch is shown in fig. 2.1.9 with a detailed schematic of materials and sensor position in fig. 2.1.10. Illustrating the application of new technologies such as screen printing and flexible electronics to wearable devices increasing comfort to the patient and eliminating the use of wet gel electrodes. These new processing technologies have allowed medical companies such as Holst Centre and QUAD to develop physiological measuring patches without the need of bulky monitors, other examples can be found in table 8.1.

Figure 2.1.9: COVID-19 smart health patch [9]

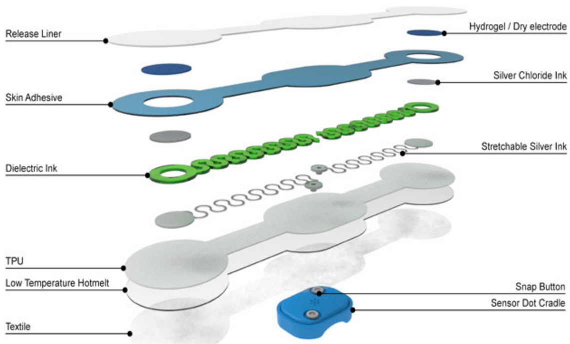


Figure 2.1.10: QUAD Patch schematic [9]

Developments in ECG flexible patches are offering promising insights for studying the material selection of feasible substrate materials for the same applications. These patches are designed for large-scale manufacturing, creating thin and ultra-flexible perceptive systems that can be rolled or folded without altering their functionality. This progress has been made possible by advances in materials science and device architecture, enabling the enhancement of both conductivity and deformability of flexible structures. By studying the material compatibility of these devices and their integration with rigid components, valuable insights can be gained into the most suitable materials for creating wearable sensors. This can contribute significantly to the development of more comfortable, effective, and non-invasive devices for monitoring patients' health in various settings.

2.2 Case Study

The Bambi belt, shown in fig. 2.2.1, is a wireless belt designed to monitor cardiorespiratory activity in (pre)term infants in Neonatal Intensive Care Units (NICU). It aims to improve parent-child bonding by eliminating the use of traditional wet electrodes and adhesives that can cause pain, stress, and skin damage [10]. The belt uses dry electrodes for monitoring, making it a non-invasive and comfortable solution for infants. The dry electrodes measure electrical activity of the diaphragm via transcutaneous electromyography. The data is wirelessly transmitted with the sensor module to a receiver module that processes the diaphragm activity to obtain the electrocardiogram, respiration signal, heart rate and respiratory rate [27]. The device consists of a single-use silicone belt that is placed below the rib cage of the neonate patient. The data is transmitted to both the patient monitor and the NICU alarm management system through the Bambi Bridge, which is attached to the belt, and the Bambi Interface, which is connected to the patient monitor.

Figure 2.2.1: Bambi belt by Bambi Medical [10]

The device is comprised of three dry electrodes attached to the silicone belt, which serves as an encapsulation layer. The device components are shown in fig. 2.2.2 (1) liquid silicone rubber (LSR), (2) Ethylene Propylene Diene Monomer (EPDM) coated with a conductive material for the dry electrodes and (3) polyamide (PA) for the flexible printed circuit board (PCB). To process the device, the dry electrodes are first adhered to the flexible PCB and then fully encapsulated with an LSR layer. The end product presented the main challenge of combining different materials in flat form, belt design. As well as the proper adherence of the dry electrodes between the flexible PCB and the LSR encapsulation layer. Combining flexible substrates, for this case LSR, with rigid data acquisition systems, such as the dry electrodes, presents mechanical differences in properties between rigid and flexible materials, which result in stress concentrations on the connection points, ultimately leading to prompt failures in the less rigid component [25]. The manufacturing process for scaling up the device is required to meet the forecast volumes of 80,000 units for 2022, 120,000 for 2023 and 240,000 for 2024, presented by Bambi Medical. The implementation of a flexible PCB in the design, along with the manufacturing capabilities of production companies like Benchmark, make injection molding and over molding viable options.

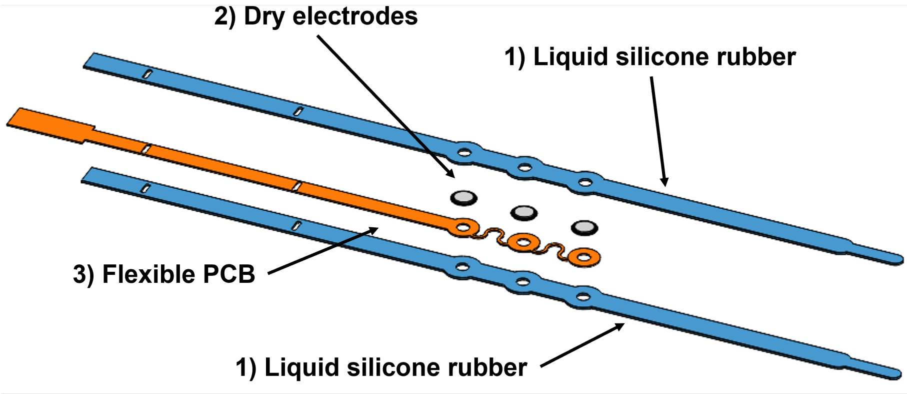


Figure 2.2.2: Bambi belt design schematic

LSR as a substrate material presents certain limitations and challenges in the fabrication process. The processing of LSR can be expensive due to the requirement for specialized equipment and molds, which may have limited availability, impacting production timelines and costs. The design and fabrication of the injection mold can pose challenges in achieving the desired shape and surface finish of the LSR substrate. Proper curing of the LSR material and post-molding processing, such as cleaning and sterilization are also important factors to ensure functionality. In addition, LSR presents challenges in achieving the appropriate mechanical properties such as elasticity, stiffness, and tear resistance, to ensure good contact and adherence with the skin. Another challenge of using LSR as a substrate material is its high surface energy, which may cause adhesion problems with some electrode materials [28].

In terms of material compatibility, LSR is generally compatible with other silicone-based materials, but it can have limited compatibility with metals due to differences in their thermal expansion coefficients. This can lead to delamination or cracking of metal components when integrated with LSR-based wearable devices [28]. To overcome this challenge, techniques such as surface modification or the use of adhesives can be employed to improve the adhesion between LSR and metal components. Additionally, the selection of appropriate metal alloys and the use of thermal management techniques can also improve the compatibility between LSR and metal-based components in wearable devices. While a cohesive bond to many metals can be achieved, LSR will fatigue at the bond interface if subjected to cycling. To prevent failures, one solution is to first overmold a thermoplastic and then bond the LSR to it. Inserts must also not contain any substances that interfere with the cross-linking reaction. Sulfur particularly affects LSR cure and must be avoided [28]. Evaluating the outcome of material incompatibility in the Bambi belt components is crucial for ensuring proper functionality and comfort of the device. By understanding the challenges and opportunities associated with flexible wearable devices, material alternatives and manufacturing processes are needed for new device development and improvement of prototype devices.

Chapter 3

Methodology

In this chapter, the material selection process is described in detail, which involves selecting material properties, weighting these properties, and creating a material database. The approach allows the identification and prioritization of properties critical to the end application. Based on this prioritization, the most appropriate material can be selected afterwards.

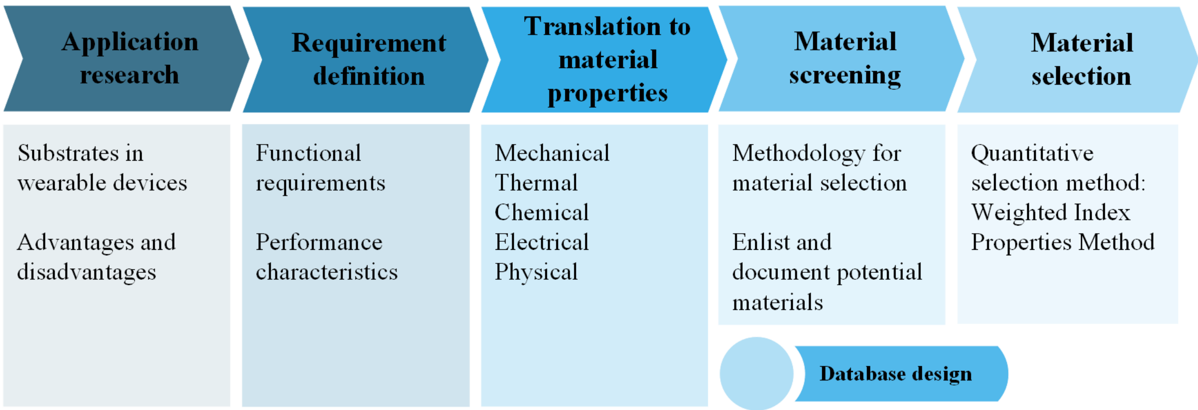


Figure 3.0.1: Material selection methodology

3.1 Requirement definition

To properly design and produce wearable devices, it is crucial to have a thorough understanding of their requirements. This includes specifying the performance requirements of all components during the design phase and broadly outlining the main material performance and processing requirements. By doing so, the initial screening of materials can be done, and certain classes of materials and manufacturing processes can be eliminated while others can be chosen as likely candidates.

3.1.1 Wearable device substrates

Specific considerations for the substrate requirements is researched. Substrates used in flexible electronics need to meet various requirements such as thermal, chemical and mechanical properties. Further description of these requirements are enlisted bellow.

1. Thermal properties: For flexible substrates, such as polymers, the ability to withstand

high temperatures is crucial, specifically the glass transition temperature (Tg) should align with the maximum fabrication process temperature (Tmax). In order to endure reasonable processing temperatures, the substrate must have a sufficiently high melting temperature or Tg [25]. Furthermore, it is important that the coefficient of thermal expansion (CTE) is sufficiently low. If the film or substrate undergoes excessive expansion or contraction during heating, the layers deposited on top (which are usually a blend of inorganic materials with low CTEs) are prone to cracking or detaching, similar to the impact of external stress [25]. Thermal stability is primarily critical for the purpose of fabrication since achieving extremely low processing temperatures is still an area of active research. For heat extraction, relying on the substrate's inherent heat dissipation capability, without external aid such as a heat-sync, is the preferred method due to their thinness and potential large surface area. A substrate with high thermal conductivity is desirable and should be compatible with other thermal management solutions if required [25].

2. Chemical properties: The substrate must be non-reactive to process chemicals and free of any contaminants, unlike glass substrates which are typically impermeable to gases, plastic substrates allow for some degree of gas permeability. Ideally, a flexible substrate should possess excellent barrier properties against air and moisture. Additionally, it should resist solvents and chemicals commonly employed for etching the layers involved in constructing the active devices on the substrate [25].

3. Mechanical properties: The substrate should have the ability to bend or stretch without cracking or deteriorating in other ways. It would be advantageous if the substrate could undergo repeated bending or stretching without substantial long-term damage, but there are instances where a one-time bend is sufficient. As conducting and semiconducting polymers continue to progress, the eventual realization of fully flexible and stretchable electronics is possible [25]. Apart from external physical stresses, there are internal stresses such as thermal stability to consider. Uneven surface flatness may result in irregular gaps between the top and bottom substrates. It is crucial to avoid asperities and roughness over short distances. Although it is desirable to have highly smooth substrates, they must also adhere strongly to the deposited layers to withstand the stress of bending [25].

3.1.2 Benchmark expertise

To further identify, classify, and enlist the substrate material requirements, a set of nine questions were asked to four design engineers at Benchmark. These engineers were selected due to their different technical backgrounds such as bio-mechanical and electrical engineering who were also directly involved in medical wearable projects, the Bambi Belt study case and in the health industry overall. The questions are as follows:

1. What mechanical and physical properties are most important for materials used in medical devices?

2. What factors do you consider when choosing between different materials for a medical device, such as cost, availability, and processing requirements?

3. What role does user feedback play in the material selection process for medical devices?

4. What design features do you consider essential for a flexible medical wearable device?

5. What types of materials have you used in the past for flexible medical wearables and what were their benefits and drawbacks?

6. How do you balance the need for flexibility with the need for durability and reliability in medical device design?
7. What design features do you consider essential for a physiological measurement wearable device?
8. How do you balance the need for accuracy with the need for comfort and ease of use in wearable devices?
9. How important is accuracy in ECG measurement in the design of wearable devices?

As a result of the meetings carried out with the design engineers and literature research, a set of requirements was enlisted and is presented in table 3.1.

Table 3.1: Set of requirements for wearable devices [11]

Requirement	Remarks
Flexibility	The ability of a material to bend or stretch without breaking. Low mechanical stress at the interface of the human skin and the device requires low force for direct contact
Permeability	High permeability to gas (air, oxygen) and water is required to prevent skin inflammation during long-term wearing and tight adhesion
Biocompatibility	The wearable substrate on the skin should have low or non-toxicity for long-term retention
Adhesion	Proper strain transfer between two surfaces is guaranteed with adequate or adjustable adhesion through chemical, van der Waals forces, or electrostatic force
Conductivity	The device should detect vital signals seamlessly and maintain reliable electrical conductivity under high strain over time without being degraded by external environments
Producibility	Good processability, high stability during processing, low shrinkage, and high thermal stability

3.1.3 Translation to Material Properties

Having specified the performance requirements of the component, the material properties can be established for each of them, table 3.2. These properties may be quantitative, essential or desirable. Following the translation from requirement to property, a short summary explaining their relevance for each property is explained.

Table 3.2: Requirement translation to material property

Requirement	Property
Flexibility	Mechanical: Young's modulus, Tensile Strength, Elongation, Shore Hardness
Adhesion	Physical: Surface Energy
Producibility	Thermal: Glass transition temperature and thermal expansion coefficient
Conductivity	Electrical: Electrical conductivity

The *Young's Modulus* is a measure of material's stiffness, units are Pascal (Pa) [29]. To maintain the desired mechanical and electrical properties of materials in a wearable form factor, researchers have downscaled the substrate or film thickness below a certain established threshold, resulting in a low modulus (2-600 kPa corresponding to the skin's modulus) that exhibits the desired characteristics even in a broad stress range up to high failure strain [11].

Shore Hardness is a physical property that quantifies a material's resistance to indentation. It is the preferred method for rubbers and thermoplastic elastomers, and is also commonly used for 'softer' plastics such as polyolefins, fluoropolymers, and vinyls [29]. The Shore A scale is used for 'softer' rubbers while the Shore D scale is commonly used for 'harder' ones. When a material has a Shore hardness of 95 A, it will have a similar feel to plastic over a flexible material. At this point, the Shore A and Shore D scales will temporarily coincide. The A scale is used for bendable rubbers, while the latter is related to rigid materials.

Tensile Strength is a material's maximum load-bearing capacity when stretched without fracturing, divided by the initial cross-sectional area of the material [29]. A substrate's tensile strength is important because it affects the device's ability to conform to the body's shape and movements without causing discomfort or irritation. If the substrate is too weak, it may tear or break under the stresses of normal use, leading to device failure and potential harm to the wearer. Conversely, if the substrate is too rigid, it may not be able to conform to the body's contours, which can cause discomfort and irritation.

The *Glass Transition Temperature*, represented by Tg, is the temperature at which a material changes from a hard, glassy state to a rubbery, viscous state. Glass transition temperature helps determine various flexible and rigid applications for a material [30]. The Tg of a substrate material is important because it affects the material's ability to maintain its shape and mechanical properties under different conditions, such as changes in temperature and humidity. If the Tg of the substrate is too low, the material may soften and lose its mechanical integrity at body temperature, leading to device failure or discomfort for the wearer. Conversely, if the Tg of the substrate is too high, the material may be too stiff and brittle, which can also lead to device failure and discomfort. Furthermore, the Tg of the substrate material can also affect the device's biocompatibility, as a substrate with a low Tg may release potentially harmful chemicals or compounds when in contact with the skin or body fluids.

Vapour *permeability* is a material's ability to allow a vapour (such as water vapour or, indeed any gas) to pass through it. To be more precise it is a measure of how much vapour is transmitted through a material under a given set of circumstances. The greater the permeability value of the material, the faster vapour can permeate through it [29]. The permeability of a substrate can affect the rate of oxygen and carbon dioxide exchange between the skin and the environment, which is important for the regulation of body temperature and the prevention of skin irritation or damage. Similarly, the permeability of the substrate can affect the transmission of sweat and other bodily fluids, which can impact the device's comfort and durability. A substrate with low permeability can help to maintain the sterility and integrity of the device, while also protecting the wearer from potentially harmful substances.

Elongation at break is a defining attribute that indicates the maximum percentage of elongation that a tensile sample undergoes at the point of fracture. It therefore describes the deformability of a material under tensile load [29]. The substrate material must be flexible and durable enough to withstand repeated stretching and bending while maintaining its structural integrity.

Electrical resistivity, also known as specific electrical resistance, is a measure of how strongly a material opposes the flow of electrical current. It is the property of a material that determines how much electrical resistance it has per unit of length or area. In general, materials with high resistivity are poor conductors of electricity, while those with low resistivity are good conductors. The SI unit of electrical resistivity is the ohm-meter (Ωm) [29]. The resistivity of the substrate material affects the device's ability to conduct electrical signals accurately and efficiently. High electrical resistivity can result in poor signal transmission, signal distortion, and reduced accuracy. On the other hand, substrates with low electrical resistivity can result in better signal transmission and accuracy.

3.2 Material screening

The process for selecting the appropriate material for a flexible substrate requires a comprehensive database of materials with known biocompatibility, mechanical flexibility, permeability, electrical conductivity properties and processability parameters. A material database was generated which includes various types of flexible materials such as polymers, elastomers, and conductive materials. This database was compiled by reviewing literature, already existing material databases and consulting with experts in the field. The following methodology, presented in fig. 3.2.1, enables the identification of the most suitable materials for the development of a flexible wearable device.

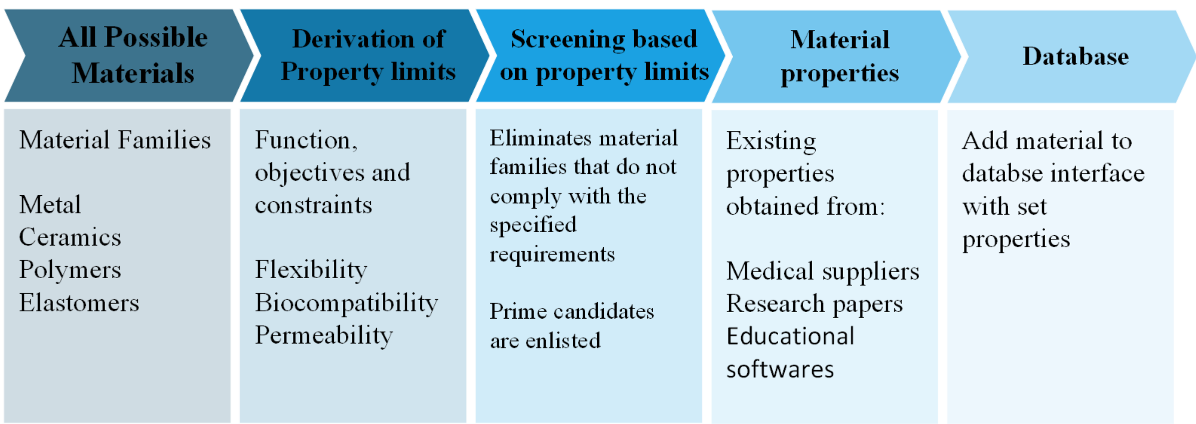


Figure 3.2.1: Material screening methodology

The initial step in screening materials is filtering material families by the established requirements and properties. Ashby's approach is one of the most commonly used multi-objective decision making (MODM) methods as it optimizes alternatives based on the prioritized objectives. The approach tells how to characterize the appropriate material for desired performance depending upon their attributes. The identification and shortlisting of these attribute profiles are done by screening and ranking set by the user [31]. Granta EduPack, a software with a database of materials and process information, material selection tools and a range of supporting resources. The software provides access to Ashby charts for different materials and properties and allows the user to plot material properties according to their specific applications. The properties plotted using Granta EduPack were Young's modulus and density, shown in fig. 3.2.2, to identify materials that have a high stiffness-to weight ratio, a critical property for a flexible substrate. This approach allows to narrow down the list of potential materials and focus on those that are most likely to meet the performance requirements.

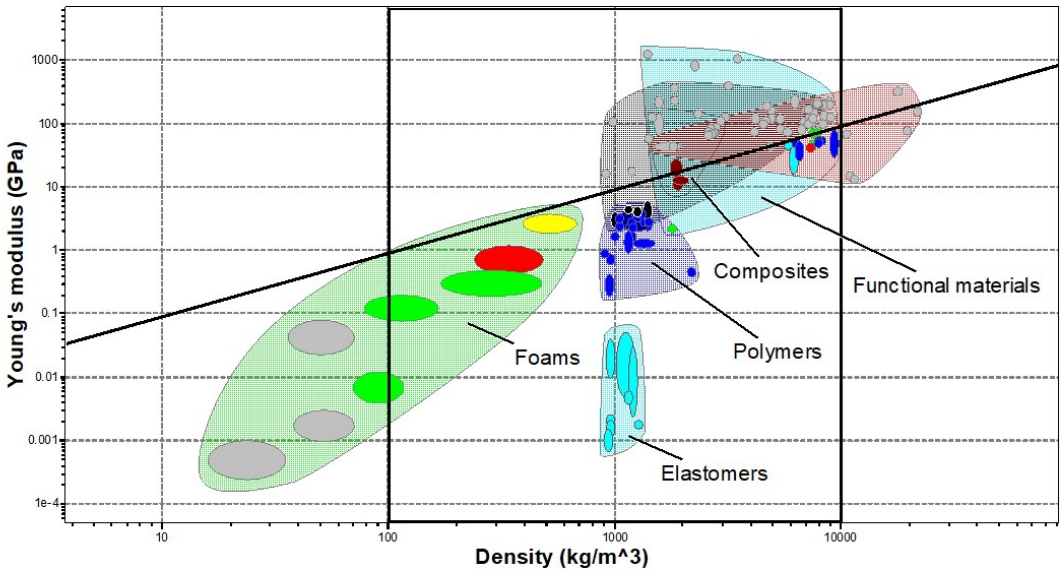


Figure 3.2.2: Ashby plot of Young's Modulus and Density of the different material families

Polymer materials have a wide range of properties, such as high strength, flexibility, and durability, which make them useful in various applications, including healthcare and electronics. Elastomer materials, also known as rubbers, are a type of polymer that exhibits elasticity when stretched and returns to its original shape when released. Elastomers have unique properties such as flexibility, resilience, and chemical resistance. Foam materials offer several advantages such as low density, high strength-to-weight ratio, and excellent energy absorption. These properties for the three material families are suitable for the end substrate application.

However, all specified requirements need to be further filtered. This software allowed the screening of feasible materials to be added to the material database. Already existing databases were consulted to further expand this thesis database, including literature and medical grade material suppliers, found in table 3.3.

Table 3.3: Researched and reference material databases

Database	Description	Reference
Granta EduPack	Software with database of materials and process information, material selection tools and a range of supporting resources	[32]
Omnexus	Database to select Plastics and Elastomers, 97 609 Technical Datasheets available	[29]
Handbook of Polymers, Second Edition	Includes practical data on the most widely used polymers for engineers and materials scientists in design, manufacture, and applications research	[33]
GlobalSpec	Detailed specification guides of a wide range of industrial products and services	[34]
Modern Plastics	High performance medical grade plastics for the medical device industry	[35]
efunda	An online portal for the engineering community, where working professionals can quickly find concise and reliable information on materials, design, processes, etc.	[36]

3.2.1 Materials for flexible wearable devices

A wide range of substrate materials have been researched and developed to meet the previously discussed requirements. This section provides an overview of substrate materials commonly used in wearable devices, including their characteristics, applications, advantages, and limitations. Polydimethylsiloxane (PDMS) is a widely used polymer for substrates due to its stretchability, biocompatibility, and easy processing. Other elastomers such as polyurethane (PU) and acrylic elastomer are used as skin sensors. Single walled carbon nanotubes (SWCNT)/silicone rubber composites give an advantage of being able to stretch up to 300%. Ecoflex® rubbers and polyimide (PI) films are also popular substrates due to their stretchability, flexibility, and good resistance to various factors [14]. PI films have good creep resistance and high tensile strength, and they play an important role in the micro-manufacturing process of wearable sensors.

Besides synthetic substrates, some natural materials have also been considered and researched for manufacture of wearable substrates. Biomaterial is the largest material system in nature. It has good biocompatibility, biodegradability, versatility, sustainability, and low cost. Fibers and textiles are considered to be the most suitable materials for wearable devices owing to their proximity to the natural feel of human skin [37]. Natural silks are a biomaterial that is both abundant and visually appealing while also meeting the demands for irregular deformation. In the field of wearable healthcare devices, materials such as nanowires (NWs), metal nanoparticles (MNPs), conductive polymers (CPs), and carbon materials have been employed due to their impressive mechanical and electrical properties. Inorganic nanomaterials, which have high adaptability, a large surface area, excellent sensing capabilities, and compatibility with low-cost manufacturing, are commonly utilized in the development of wearable sensors [38].

3.2.2 Database structure

After conducting thorough material screening and literature research, a flow chart diagram, see fig. 3.2.3 has been developed to outline the process for adding feasible materials to the database. This flow chart illustrates the various stages involved in selecting a material that meets the necessary criteria, such as biocompatibility, flexibility, and durability. The screening process involved evaluating the material's properties, assessing its compatibility with the application, and reviewing its regulatory compliance. Additionally, the literature research phase involved gathering information on previously used materials, analyzing their performance, and identifying potential areas for improvement.

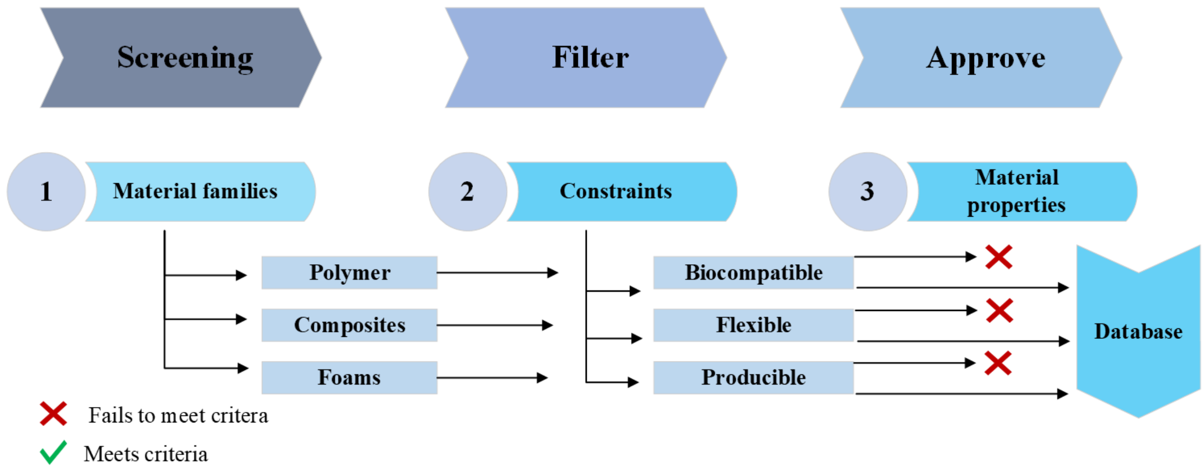


Figure 3.2.3: Material screening flow chart

The database structure is a critical component of any data-driven system. In the context of this thesis, the database structure refers to the organization of data related to the materials used in wearable devices. This section will discuss the design and implementation of the database structure, which was developed to facilitate the collection, storage, and retrieval of information about materials used in flexible wearable devices. The database structure was designed with the aim of providing an organized and efficient system for managing the data related to the materials, which is essential for supporting the analysis and decision-making process for material selection in wearable device design. Figure 3.2.4 shows the designed user interface for Benchmark, where the user can add new materials from further research or material science advancements. The complete database includes a total of 63 materials that meet the criteria including the properties for the LSR used in the case study.

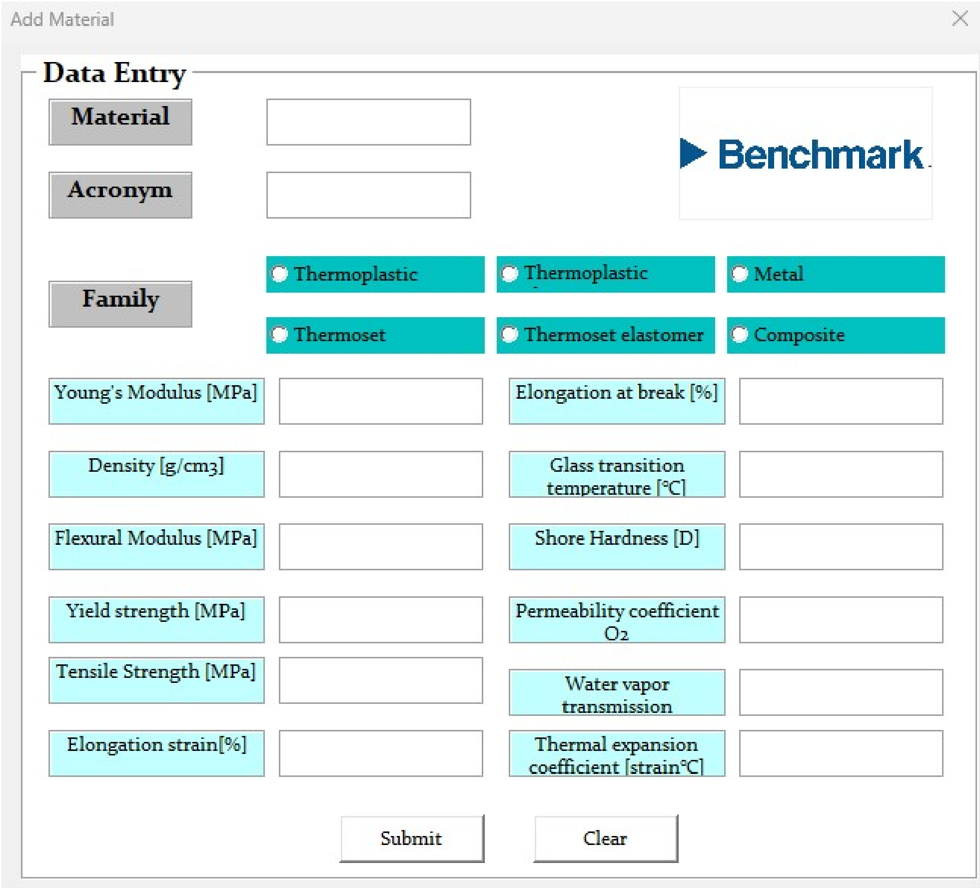


Figure 3.2.4: Data entry user interface

3.3 Quantitative method for selection

Quantitative selection methods have been developed to analyze the large amount of data involved in material selection, enabling systematic evaluation. Concurrent engineering considers materials and manufacturing processes in the early stages of design and progresses through concept, incorporation, and detail stages. As each material has its own advantages and limitations, a multi-criteria decision-making (MCDM) approach can be used to determine the most feasible alternative for enhancing device performance. For this thesis, the MCDM chosen is the Weighted Index Properties Method. Other MCDM methods, such as Analytical Hierarchy Process (AHP), Technique for Order Preference by Similarity to Ideal Solution (TOPSIS), and Multi-Attribute Utility Theory (MAUT), have their own advantages and disadvantages compared to the WIPM. For example, AHP is a more comprehensive and flexible method that can handle more complex decision problems, but it requires more effort and expertise to implement. TOPSIS is a relatively simple and intuitive method that does not require weights, but it may not be appropriate for highly uncertain or incomplete information. And finally, MAUT is a more general framework that can handle both quantitative and qualitative criteria, but it requires more data and analysis than other methods [12]. Ultimately, the choice of the MCDM method depends on the specific requirements of the decision problem and the resources available for implementations.

3.3.1 Weighted Index Properties Method

The Weighted Index Properties Method (WIPM) is the method in which the specified material property is assigned a certain weight, depending on its importance. A weighted property value is obtained by multiplying the scaled value of the property by the weighting factor (α). The individual weighted property values of each material are then summed to give a comparative materials performance index (γ). The material with the highest performance index (γ) is considered as the optimum for the application. When multiple material properties are specified, and their relative importance is uncertain, assigning weighting factors (α) can be mostly based on intuition. However, this approach reduces the reliability of material selection [12].

The digital logic (DL) approach evaluates material properties by considering only two at a time. Each possible combination of properties or performance objectives is compared, and the evaluation requires a simple yes or no decision without any uncertain aspects. A table is then constructed to determine the relative significance of each property, table 3.4. The properties are listed in the left hand column, and comparisons are made in the columns to the right [12].

Table 3.4: Determination of relative importance of performance goals using the DL method [12]

Goals	**Number of possible decisions [*N=n(n-1)/2*]**										**Positive decisions**	**Relative emphasis coefficient (α)**
	1	2	3	4	5	6	7	8	9	10		
A	1	1	0	1							3	0.3
B	0				1	0	1				2	0.2
C		0			0			1	0		1	0.1
D			1			1		0		0	2	0.2
E				0			0		1	1	2	0.2

In comparing two properties, the more significant property is given a numerical value of one (1) and the less significant is given zero (0). The total number of possible decisions is calculated by $N=n(n\text{-}1)/2$, where n is the number of evaluated properties [12]. A weighting factor or relative emphasis coefficient, α, for each property is obtained by dividing the number of positive decisions for each property into the total number of possible decisions (N), eq. (3.3.1) and $\sum \alpha = 1$.

$$Weightfactor(\alpha) = Positivedecisions/N \tag{3.3.1}$$

A significant drawback of the WIPM is that it involves combining dissimilar units, which can lead to illogical outcomes. This is especially true when different mechanical, physical, and chemical properties with varying numerical values are merged [39]. To address the issue of a property with a higher numerical value having a disproportionate influence, scaling factors are introduced. These factors ensure that no property has a numerical value exceeding 100. During the evaluation of candidate materials, each property is considered individually, and the highest value in the list is rated as 100 while the rest are scaled proportionally. This scaling facilitates the conversion of normal property values to dimensionless scaled values. For a given property, the scaled value β for a given candidate material is equal to [39]:

$$\beta = \text{ scaled property } = \frac{\text{numerical value of property } \times 100}{\text{maximum value in list}} \tag{3.3.2}$$

For properties were a lower value is desirable, the lowest value is rated as 100 and β is calculated as:

$$\beta = \text{ scaled property } = \frac{\text{minimum value in list } \times 100}{\text{numerical value of property}} \tag{3.3.3}$$

Finally, after scaling the different properties, the material performance index, γ can be calculated as

$$\gamma = \sum_{i=1} \beta_i \alpha_i \tag{3.3.4}$$

To evaluate the properties, it is necessary to establish objective values between maximum and minimum limits for each one. These objective values, as indicated in table 3.5, are used to calculate the scaled property according to eq. (3.3.2) and eq. (3.3.3). Specifically, for shore hardness and Young's modulus properties, the objective is to minimize their values, while for permeability, elongation at break, tensile strength and glass transition temperature, the objective is to maximize their values.

Table 3.5: Objective of required properties to be achieved

Requirement	**Objective**
Young's Modulus	Minimum
Tensile Strength	Maximum
Elongation at break	Maximum
Glass transition (Tg)	Maximum
Shore hardness	Minimum
Permeability	Maximum

The WIPM can be used with both positive and negative property values. However, when using negative property values, it is important to consider the impact of those negative values on the overall weighted index value. For example, if a material has a negative value for a certain property, such as glass transition temperature, and this property is assigned a high weight factor due to its importance for the specific application, then the negative value may significantly lower the overall weighted index value. In such cases, it may be necessary to adjust the weight factors or consider alternative materials with more favorable properties. Therefore, while it is possible to use negative property values in the weighted index property method, it is important to carefully consider the impact of those negative values on the overall performance evaluation and to make appropriate adjustments as necessary [39].

To include negative values of Tg using the WIPM, one approach is to adjust the weights assigned to Tg based on the magnitude and significance of the negative values. For example, if the Tg is one of the properties being evaluated, the weight assigned to Tg could be adjusted to account for the negative values. In such cases, a negative weight could be assigned to Tg, indicating that materials with lower Tg values are preferred. Another approach is to use a modified Tg value that considers both the magnitude and the direction of the Tg values. One such approach is to use the absolute value of Tg or the difference between Tg and a reference temperature as the measure of Tg. For example, if the reference temperature is room temperature, the difference between the Tg and room temperature can be used as a measure of Tg.

Chapter 4

Results

In this chapter the results from the material selection process are presented and will be further discussed in chapter 5.

4.1 Material Selection

A test run is performed in order to evaluate the effectiveness and accuracy of the method in selecting materials that meet the desired criteria. It also allows for any potential issues or limitations in the method to be identified and addressed before using it with Benchmark or industry engineers. Furthermore, a test run can provide insight into the feasibility and practicality of the method in terms of time and user interface. The DL method is used to evaluate the properties, where the superior property is assigned a score of 1 for a positive decision and 0 for a negative one. With six properties to evaluate, the total number of decisions equals $N(N\text{-}1)/2{=}6(5)/2{=}15$. The different decisions are given in table 4.1. By using eq. (3.3.1), the relative emphasis coefficients were calculated to determine the importance of each property. A simple interactive computer program using Excel can be written to facilitate the determination of the emphasis coefficients. Excel provides a user-friendly interface that allows for easy data entry and manipulation, which simplifies the process becomes more efficient, and multiple runs can be performed to test the sensitivity of the final ranking to changes in some of the decisions.

Table 4.1: Calculated emphasis coefficient per requirement

Requirement	**Number of possible decisions [*N=n(n-1)/2*]**															**Positive decisions**	**Emphasis coefficient**
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		(α)
Young's Modulus	1	0	1	0	0											2	0.13
Tensile Strength	0					1	0	0	0							1	0.07
Elongation		1				0				1	0	1				3	0.20
Tg			0				1			0			0	0		1	0.07
Shore hardness				1				1			1		1		1	5	0.33
Permeability					1				1			0		1	0	3	0.20
Total																15	1

Table 4.2 provides the ranking according to the emphasis coefficient from highest to lowest for the test run, which shows that shore hardness was given the highest priority for the flexible substrate, while both glass transition temperature and tensile strength were ranked with the lowest priority. The calculated emphasis coefficient for permeability and elongation at break was the same at 0.20, and for tensile strength and glass transition temperature it was 0.07. Although some requirements had the same emphasis coefficient, the total sum of the weighted factors was equal to one (1), as mentioned previously in section 3.3.1. As a result, the requirements with the same emphasis coefficient share the same ranking value.

Table 4.2: Calculated weight factor and ranking of test run

Requirement	Weight factor	Rank
Shore hardness	0.33	1
Permeability	0.20	2
Elongation at break	0.20	2
Young's Modulus	0.13	3
Tensile Strength	0.07	4
Glass transition (Tg)	0.07	4

The properties of a sample of candidate materials are listed in table 4.3. The complete list of materials can be found in chapter 8, Appendix. The next step in the WIPM is to scale the properties given in table 4.3 by obtaining the minimum and maximum values previously stated in table 3.5 for each requirement. Following this step, the scaled value β for a given candidate material is calculated using eq. (3.3.2) and eq. (3.3.3) accordingly. The results of the scaled values of the sample materials are shown in table 4.4.

Table 4.3: Property values of candidate materials from material database

Material	Acronym	Young's Modulus[1]	Tensile strength[1]	Elongation[2]	Tg[3]	Shore hardness[4]	Permeability[5]
Polyether-etherketone	PEEK	3950	117	150	157	46	0.1
Polyethylene	PE	896	44.8	490	-90	29	45
Polyethylene Terephthalate	PET	3000	60	70	83.9	95	2.4
Polyimide	PI	2760	118	90	260	92	10
Polylactide	PLA	3600	72	3	59.9	57.7	17
Polypropylene	PP	1020	50	500	-16.2	31	63

[1] MPa [2] % [3] °C [4] D [5] $cm^3.mm/m^2.day.atm$

Table 4.4: Scaled property values of the materials' attributes

Acronym	βYoung's Modulus	βTensile Strength	βElongation	βTg	βShore hardness	βPermeability
PEEK	2.91E-03	13.15	18.75	60.38	26.09	0.29
PE	1.28E-02	5.03	61.25	-34.62	41.38	1.16
PET	3.83E-03	6.74	8.75	32.27	12.63	0.06
PI	4.17E-03	13.26	11.25	100.00	13.04	0.26
PLA	3.19E-03	8.09	0.38	23.04	20.80	0.44
PP	1.13E-02	5.62	62.50	-6.23	38.71	1.63

Table 4.5 illustrates the performance index evaluated for each of the material candidates with ranked properties. As shown, styrene butadiene styrene (SBS) with a shore hardness value of D12 appears to be the most suitable candidate with regards to its performance index, which is the greatest, followed by polyamide thermoplastic elastomer (TPA) and ethylene propylene diene monomer (EPDM) respectively as the second and third. Within the table, a category for injection molding suitability is also shown. The selected materials are suitable options for this manufacturing process with certain limits. table 8.3 shows a detailed description of each of these categories.

Table 4.5: Test run performance index results of highest values

Rank	**Material**	**Acronym**	**Performance index γ**	**Injection Molding Category**
1	Styrene butadiene styrene	SBS D12	54.47	Acceptable
2	Polyamide thermoplastic elastomer	TPA	40.24	Acceptable
3	Ethylene Propylene Diene Monomer	EPDM	38.38	Limited use
4	Thermoplastic Polyolefin Elastomer	TPO	31.59	Excellent
5	Styrene butadiene styrene	SBS D26	31.54	Acceptable

4.1.1 Engineer selection

The four interviewed engineers, namely E1-4, ranked the requirements according to their experience and the discussed end application, focused in the overall substrate performance. The ranking results using the DL approach are shown in table 4.6, including the ranking from the test run as comparison. The material properties ranked in order of priority are permeability being the highest priority followed by Young's modulus, glass transition temperature, Shore hardness, tensile strength and elongation at break.

Table 4.6: Requirement Ranking comparison of engineers and test run

Requirement	Rank				
	Test run	E1	E2	E3	E4
Shore hardness	1	3	3	4	4
Tensile Strength	4	2	4	3	1
Permeability	2	1	1	2	3
Young's Modulus	3	4	2	2	2
Elongation at break	2	6	2	1	3
Glass transition (Tg)	4	5	3	3	2

The same process as the test run was performed using new property rankings. The top ten materials with the highest performance indices were selected from the 63 materials in the database and are shown in table 4.7. The performance indices for the first ten materials were higher, ranging from 56-20 (γ), while the remaining materials showed no significant differences in value, ranging from 5-20 (γ). The top ten ranked materials offer a diverse range of options that satisfy the required properties, allowing for consideration of trade-offs between the materials' advantages and disadvantages. This can aid in the decision-making process and lead to a well-informed and appropriate choice. The two highest-ranked materials among the test run and the engineer's selection were styrene butadiene styrene (SBS) of D12 Shore hardness and polyamide thermoplastic elastomer (TPA). Copolyester thermoplastic elastomer (TPC) and polyglycolic acid (PGA) followed closely behind. Among the top-ranked materials, there is a noticeable trend: the majority of them belong to either the thermoplastic elastomer or elastomer polymer families. The final selection between the two materials may depend on their availability and cost for direct application. Additionally, materials such as PDMS, PI, and polyurethane (PU), which are commonly used for flexible substrates, were also ranked with high performance indices.

Table 4.7: Selected materials with engineer ranking

	Material				
Rank	Test run	E1	E2	E3	E4
1	SBS D12	SBS D12	SBS D12	TPA	SBS D12
2	TPA	SBS D26	TPA	TPC	SBS D26
3	EPDM	PGA	TPC	TPO	PGA
4	TPO	EPDM	EPDM	SBS D12	TPA
5	SBS D26	TPC	TPO	EPDM	PDMS
6	TPC	TPA	SBS D26	PTFE	PI
7	PE	FPVC	PE	PE	PPSU
8	FPVC	PDMS	PTFE	SBS D26	PES
9	PDMS	PI	FPVC	PP	TPO
10	PP	PEEK	PDMS	PU	PEEK

A second test run is carried out adding the thermal expansion coefficient of the materials in order to evaluate the addition of a property to the WIPM. This property is an important factor to consider when selecting material compatibility. The test run allows to evaluate the addition of new properties to the already established WIPM and material selection methodology. The requirements for the flexible substrate are to be adapted to meet the criteria of the designer. The ranking requirement is set from highest to lowest permeability, tensile strength, CTE, Shore hardness, Young's modulus, glass transition temperature and elongation at break. The performance index according to the ranking is presented in table 4.8 with SBS D12 with the highest performance index followed by flexible PVC and styrene-isporene-styrene (SIS).

Table 4.8: Second test run performance indices results

Rank	**Performance index γ**	**Test run**
1	34.86	SBS D12
2	32.43	Flex PVC
3	28.97	SIS
4	28.05	PC
5	26.65	PGA
6	22.55	SBS D26
7	19.22	EPDM
8	16.23	TPC
9	15.29	TPA
10	13.67	PDMS

4.2 Evaluation with case study

To evaluate the effectiveness of the material selection process, it is essential to compare the material properties obtained through the WIPM to those of the baseline material LSR, presented in table 4.9. This allows for an assessment of the quality of the material selection process. To accomplish this, radar charts are presented to visualize and compare the properties of the two top-ranked materials to LSR. A radar chart is a graphical method of displaying multivariate data in the form of a two-dimensional chart of three or more quantitative variables represented on axes starting from the same point. This type of chart allows for easy identification of similarities, differences, and outliers between the materials. Due to the unrelated units of the compared properties and to ensure they are on a common scale, the values are normalized. The Min-Max normalization technique is used which scales the data between 0 and 1 with the following formula where X_n is the normalized value, X is the original value, $X_{\min}$ is the minimum value in the dataset, and $X_{\max}$ is the maximum value in the dataset:

$$X_n = \frac{X - X_{\min}}{X_{\max} - X_{\min}} \tag{4.2.1}$$

Table 4.9: Case study substrate material and WIPM material properties

Material	Young's Modulus[1]	Tensile strength[1]	Elongation[2]	Tg[3]	Shore hardness[4]	Permeability[5]
LSR	1	5.8	1020	-73	1	4330
SBS D12	1.83	6.88	891	-40	12	3870
TPA	20.6	50	800	-80	25	1130

[1] MPa [2] % [3] °C [4] D [5] $cm^3.mm/m^2.day.atm$

To compare and contrast the material properties of SBS, TPA, and LSR, they were normalized, using eq. (4.2.1) and plotted in fig. 4.2.1. The results indicate that SBS 12 and LSR are the closest in terms of their permeability coefficient. Additionally, TPA and SBS 12 exhibit similar values for shore hardness. However, TPA shows significant differences in other material properties, such as higher values for Young's modulus, tensile strength, and Shore hardness compared to the other two materials. Yet, TPA and SBS 12 share a similar value for Shore hardness. Overall, these comparisons can provide valuable insights when selecting the appropriate material for flexible substrates.

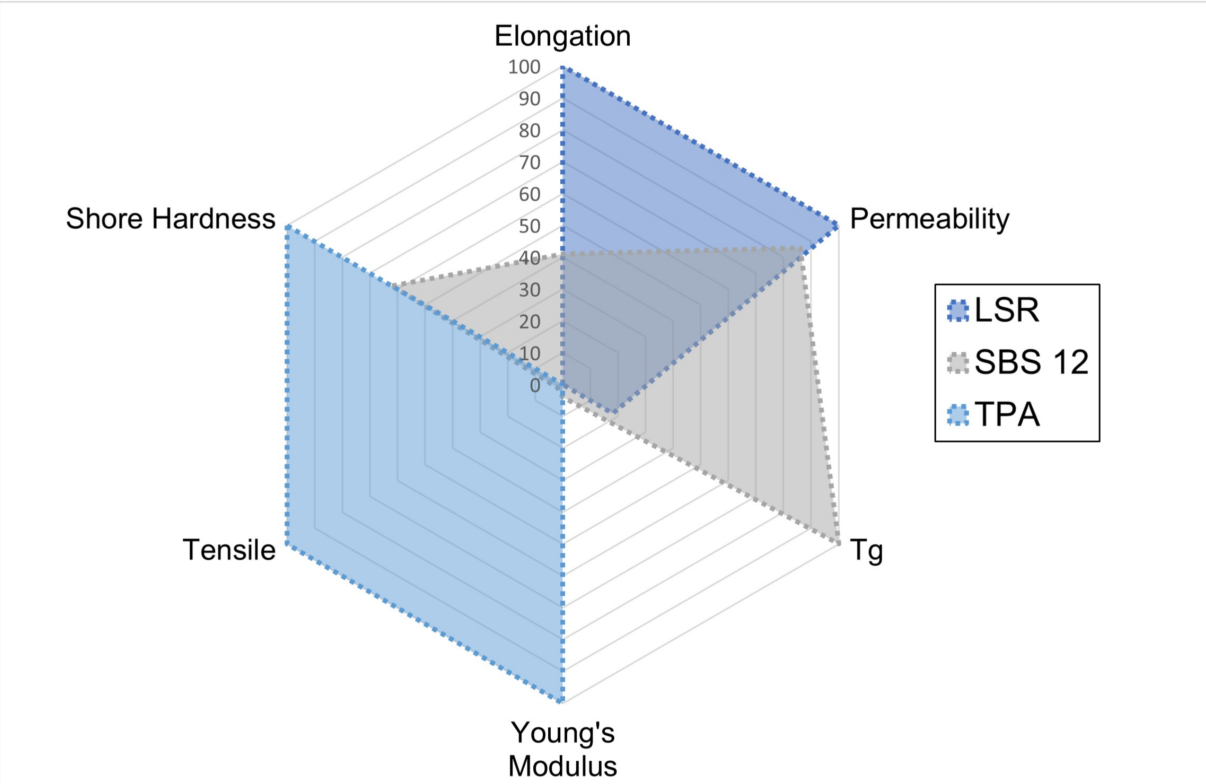


Figure 4.2.1: Radar plot comparing the required properties between LSR and selected materials by the WIPM

Chapter 5

Discussion

In this chapter, the results of the material selection process are discussed, including the selection criteria, weighting factors, and the final selection of the optimal material. Furthermore, a detailed analysis of the selected material's properties and characteristics are presented. Finally, the implications of the material selection process and how it can contribute to the advancement of physiological measuring medical applications will be discussed.

5.1 Benchmark Requirements

Understanding the application of the device was crucial for the next step of defining proper requirements to select feasible materials for LSR. Internal discussions at Benchmark were held as well as with key clients to define functionality aspects. This presented with both advantages and limitations. An advantage was direct contact with engineers involved with the Bambi belt device at the different stages of development, for design, mechanical and electrical areas. In terms of limitations, the set properties were specific for Benchmark's requirements and manufacturing capabilities. Reducing the design restrictions of physiological measuring devices to their specific capabilities as well as their clients. However, with the already discussed advancements in technologies for wearable device manufacturing, Benchmark would be able to expand their client and supplier portfolio to meet the requirements for producing and scaling up flexible substrates that can further be integrated with smart sensors. Such is the case for suppliers in screen printing, inkjet printing and R2R, the current trends for flexible wearable electronics. Another limitation concerning Benchmark was the number of interviewed engineers. In total, four design engineers with different backgrounds were considered to set and rank the properties. However, their expertise was a starting point for filtering materials and requirements. This knowledge also included production and challenges encountered during design and manufacturing compared to some cases in literature where some devices are still in prototype phase.

To overcome the limitations, a more interactive user-interface for the DL method is to be developed. In order to survey a larger set of engineers, project managers and manufacturing experts in the healthcare industry and obtain a less subjective perspective while prioritizing requirements. This interface is also set to allow the application to electrode materials as well as the substrate material for the wearable device.

The WIPM method has yielded different material rankings for each of the engineers' feedback. However, due to their expertise and the end application of the wearable substrate, similar material requirements have emerged, resulting in a trend in the top ranked materials. For instance, based on the results presented in table 4.7, SBS is the most feasible material for a flexible substrate, followed by EPDM, TPO, and PDMS. As discussed in section 3.2.1, PDMS is a well-known material used for this application, which offers advantages in material properties over LSR. The top ten ranked materials, based on their performance index for each engineer, have been displayed, and further discussion is encouraged to continue the design phase of wearable devices while taking into account time and cost limitations of device development.

5.2 Application of WIPM

One of the main advantages of the WIPM is its ability to handle multiple criteria simultaneously. Traditional methods of material selection often prioritize a single property or a small subset of properties, which can result in sub-optimal material choices. The WIPM, on the other hand, allows for a more comprehensive analysis of the materials based on a weighted combination of properties, resulting in a more well-rounded selection process. This approach can be especially useful when dealing with complex systems that require a careful balance of different material properties. Another advantage of the WIPM is its flexibility. The user can customize the weightings of different properties to reflect the specific needs of their application, allowing for a more tailored material selection process. This flexibility also allows the user to adjust the weights as new information or requirements become available.

However, there are also some limitations to the WIPM. One potential limitation is the subjectivity of the weightings assigned to the different properties. The weights are often assigned based on expert judgment, which can introduce bias or uncertainty into the selection process. Specifically in the initial step of the pairwise comparison using DL approach where only two properties are considered at a time. This was presented as feedback of one of the Benchmark engineers as well, mentioning the comparison of certain properties to sometimes be equal rather than one more relevant than the other. To increase the accuracy of decisions based on the DL approach, the priority evaluations of 0 and 1 can be modified by assigning gradation marks. For example, ranging from 1 (no difference in importance) to 3 (large difference in importance). Another potential limitation is the quality of the data used to evaluate the materials. The accuracy and reliability of the data can have a significant impact on the final selection, so it is essential to ensure that the data used is of high quality.

The number of evaluated properties in the WIPM depends on the specific decision problem being addressed. Generally, the more properties or criteria that are considered, the more complex the decision-making process becomes. Evaluating fewer properties can simplify and speed up the decision-making process, but the specific properties being evaluated can still have a significant impact on the outcome. The addition or removal of a single property can change the overall outcome, and the weights of the properties may need to be adjusted accordingly. Thus, it is important to carefully consider the properties being evaluated and their weights to ensure that the decision is well-informed and appropriate for the situation. The addition of the thermal expansion coefficient to the second test run for the material selection shown in table 4.8 illustrates this point.

5.3 Material results

To facilitate the selection of biocompatible materials for specific medical applications, engineers often rely on existing material databases. To create a comprehensive database of existing biocompatible materials, the research conducted in this study drew on referenced databases shown in table 3.3. These databases can be used as a point of reference for engineers developing new medical devices, allowing them to select the most suitable material for their specific application.

For flexible substrates in particular, the existing database can include materials that have been successfully used for similar applications. While each existing database has its own advantages and limitations, those that are open source and available to academia and medical companies are particularly useful. Additionally, some databases have already tested and approved materials for this specific application. It is worth noting that other medical databases exist which contain materials that are more specific to wearable substrates. However, these may not comply with the manufacturing requirements set by Benchmark's capabilities. While the database created in this study is comprehensive, it is not exhaustive, and as advancements in materials science continue, it may need to be updated regularly to ensure its accuracy and usefulness.

SBS 12D was the top-ranked material for the test run, and with the engineer's expertise, it meets the requirements of flexibility, durability, and compatibility with sterilization processes. However, it presents both advantages and disadvantages. On the one hand, it has resistance to wear and tear and is compatible with injection molding processes, which can enable cost-effective manufacturing. On the other hand, its limited temperature range means it can only withstand temperatures up to around 80°C, compared to LSR, which can withstand temperatures up to 200°C. Regarding material compatibility, there are several surface treatments, intermediate layers, and adhesives that can be used for bonding SBS with metal. For example, plasma treatment and corona treatment are two common surface treatments that can modify the surface energy of SBS, improving the adhesion between SBS and metal surfaces. Adhesion promoters, such as silanes and titanates, or primers can be used as an intermediate layer to improve adhesion. The dry electrodes used for the Bambi belt are an example of this.

The second-ranked material, TPA, is a type of thermoplastic elastomer that can be molded and formed like other thermoplastics but still retains the flexibility and elasticity of rubber. TPA has a lower modulus of elasticity and higher elongation at break than LSR, which means it is more flexible and can deform more before breaking. When it comes to material compatibility, TPA is similar to LSR and is compatible with a wide range of materials, including metals, plastics, and other elastomers. However, it may not be as suitable for high-temperature or chemically harsh environments as LSR.

The radar chart in Figure 4.2.1 displays the normalized material properties of LSR, TPA, and SBS 12 for comparison. The comparison of the materials reveals that the properties of SBS and LSR are closer in value than TPA. Specifically, the permeability coefficient of SBS and LSR is similar, indicating comparable gas and liquid barrier properties. Additionally, SBS and TPA have similar Shore hardness values, indicating similar levels of stiffness and deformation resistance. However, the comparison also highlights the differences in the materials' properties. TPA has a higher Young's modulus and tensile strength compared to SBS and LSR, indicating that it is a stiffer and stronger material than the other two. The glass transition temperature of the three materials is not significantly different, suggesting that they have comparable temperature resistance.

SBS is a versatile material that can be used for various medical wearable device applications, including as a pressure-sensitive adhesive for attaching sensors and components to the skin, a protective coating or encapsulant for electronic components, flexible seals and gaskets for medical devices, flexible tubing and connectors for drug delivery systems and blood oxygenation devices, and as a structural material for flexible wearable devices such as braces and prosthetics. SBS can be tailored to meet specific requirements, such as different levels of flexibility, biocompatibility, and resistance to moisture and chemicals. TPA is used in various medical wearable devices, including compression garments for orthopedic braces and supports for stability and protection, sensor mounts and enclosures for sensor integration, adhesive patches for gentle yet secure skin adhesion, strap and band components for flexibility and durability, and surgical meshes for tissue support and regeneration.

The alternative materials for LSR, SBS and TPA, both have their own advantages and limitations in terms of producibility and performance. However, they both are suitable alternatives to be used in a flexible substrate for a medical wearable device, answering the thesis question of selecting optimal materials through a defined methodology for selection. The remaining selected materials are also viable options that could serve as substitutes based on processing cost and availability. In order to further evaluate the selection of this materials, concept designs and prototype development are to be considered.

Chapter 6

Conclusion

The aim of this thesis was to develop a material selection process and database suitable for flexible substrates in wearable devices, addressing the challenge of producibility and flexibility. The material selection process involved narrowing down suitable materials for a flexible substrate based on selected properties for the application, followed by evaluation using the WIPM to identify the most suitable one. The process considered various factors including producibility, mechanical properties, and biocompatibility, with guidance from medical industry experts and design engineers who considered the unique requirements of medical devices. By conducting a thorough investigation and analysis of the Bambi belt, which is a current alternative to traditional wet electrodes that utilizes flexible components, valuable insights are gained into the potential benefits and drawbacks of using such materials in wearable devices. Understanding the factors that make the Bambi belt an alternative to wet electrodes can aid in the development of similar devices, as well as help guide the selection of materials and components for future wearable medical technologies. Therefore, studying the Bambi belt serves as an important step towards advancing the field of wearable medical devices and improving the quality of care for patients.

The choices of materials suitable for a flexible substrate were narrowed down to a few options that met the major objectives of flexibility and producibility. WIPM was then used to evaluate the mechanical properties of these materials, with biocompatibility being the primary focus due to the importance of health applications. The findings of this thesis contribute to the expanding knowledge base in the area of material selection for wearable devices, providing valuable insights for researchers, engineers, and practitioners involved in the advancement of flexible substrates for medical applications.

The research presented in this thesis provides a starting point for similar devices and applications facing similar challenges, such as the Bambi Belt case study. The selection of substrate and encapsulation materials is a critical aspect of designing and constructing flexible systems. By carefully considering the properties of these materials, engineers can ensure that the resulting system performs optimally and meets the specific needs of the application. Further research could refine and expand upon the material selection process, taking into consideration other factors such as environmental impact and cost, to develop even more optimized flexible substrates for wearable devices.

Chapter 7

Future Work

This following chapter focuses on the outlook and scope of future work for this thesis and analyzed case study.

7.1 Material selection user interface

The computer program used for the requirement ranking and WIPM was Excel due to the friendly-user interface. The template for the pairwaise comparison was designed according to the digital logic method and weighted factor calculations. The elaboration of another user interface is proposed to facilitate the material selection displayed according to the weighted performance index ranking. Such an interface can be designed using Excel Visual Basic or a programming software.

7.2 Prototype and implementation

With the aid of the delivered and proposed material selection process and database, further work for this thesis can be carried on. In terms of applying the feasible chosen material, already selected per requirements, to a wearable device prototype. By means of inkjet printing, screen printing or 3D printing the substrate material and testing with already developed electrodes for physiological measurements. Benchmark developed hardware and software systems for measuring ECG so the main focus is on material evaluation.

Figure 7.2.1: ECG measuring interface

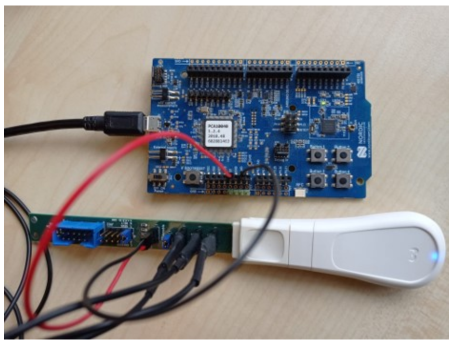


Figure 7.2.2: Bambi Belt hardware early stages prototype

Bibliography

[1] Guanglei Li and Dan Wen. Wearable biochemical sensors for human health monitoring: sensing materials and manufacturing technologies. *J. Mater. Chem. B*, 8:3423–3436, 2020.

[2] Yunzhi Ling, Tiance An, Lim Wei Yap, Bowen Zhu, Shu Gong, and Wenlong Cheng. Disruptive, soft, wearable sensors. *Advanced Materials*, 32(18):1904664, 2020.

[3] Kieran Brophy, Samuel Davies, Selin Olenik, Yasin Çotur, Damien Ming, Nejra Van Zalk, Danny O'Hare, F Guder, and Ali K Yetisen. The future of wearable technologies. *Imperial College London: London, UK*, 2021.

[4] Edward Sazonov. *Wearable Sensors: Fundamentals, implementation and applications*. Academic Press, 2020.

[5] Wei Gao, Hiroki Ota, Daisuke Kiriya, Kuniharu Takei, and Ali Javey. Flexible electronics toward wearable sensing. *Accounts of chemical research*, 52(3):523–533, 2019.

[6] Yihang Chu, Chunqi Qian, Premjeet Chahal, and Changyong Cao. Printed diodes: Materials processing, fabrication, and applications. *Advanced Science*, 6, 03 2019.

[7] Thanh Huy Phung, Anton Nailevich Gafurov, Inyoung Kim, Sung Yong Kim, Kyoung Min Kim, and Taik-Min Lee. Iot device fabrication using roll-to-roll printing process. *Scientific Reports*, 11(1):1–11, 2021.

[8] Holst Centre. Health patch. https://holstcentre.com/expertise/components-devices-systems/health-patch/, 2022. Last accessed 1 March 2023.

[9] QUAD Industries. Covid-19 smart health patch. https://www.quad-ind.com/covid-19-smart-health-patch/, 2020. Last accessed 2 March 2023.

[10] Bambi Medical. Bambi belt improves neonatal vital signs monitoring. https://www.bambi-medical.com/the-bambi-belt, 2022. Last accessed 10 February 2023.

[11] Hyo-Ryoung Lim, Hee Seok Kim, Raza Qazi, Young-Tae Kwon, Jae-Woong Jeong, and Woon-Hong Yeo. Advanced soft materials, sensor integrations, and applications of wearable flexible hybrid electronics in healthcare, energy, and environment. *Advanced Materials*, 32(15):1901924, 2020.

[12] Mahmoud M Farag. *Materials and process selection for engineering design*. CRC press, 2020.

[13] Hedieh Fallahi, Jun Zhang, Hoang-Phuong Phan, and Nam-Trung Nguyen. Flexible microfluidics: Fundamentals, recent developments, and applications. *Micromachines*, 10(12):830, 2019.

[14] Hadaate Ullah, Md A. Wahab, Geoffrey Will, Mohammad R. Karim, Taisong Pan, Min Gao, Dakun Lai, Yuan Lin, and Mahdi H. Miraz. Recent advances in stretchable and wearable capacitive electrophysiological sensors for long-term health monitoring. *Biosensors*, 12(8), 2022.

[15] Quanxia Lyu, Shu Gong, Jialiang Yin, Jennifer M. Dyson, and Wenlong Cheng. Soft wearable healthcare materials and devices. *Advanced Healthcare Materials*, 10(17):2100577, 2021.

[16] Olivier Chételat, Michaël Rapin, Benjamin Bonnal, André Fivaz, Josias Wacker, and Benjamin Sporrer. Remotely powered two-wire cooperative sensors for biopotential imaging wearables. *Sensors*, 22(21):8219, 2022.

[17] Todd Martensen. Benchmark market profile: medical technologies. https://www.bench.com/setting-the-benchmark/benchmark-market-profile-medical-technologies, 2022. Last accessed 10 March 2023.

[18] Grand View Research. Wearable medical device market size, share trends analysis report by type (diagnostic, therapeutic), by site (handheld, headband, strap, shoe sensors), by application, by region, and segment forecasts, 2022 - 2030. https://www.grandviewresearch.com/industry-analysis/wearable-medical-devices-market, 2021. Last accessed 10 February 2023.

[19] Júlio C. Costa, Filippo Spina, Pasindu Lugoda, Leonardo Garcia-Garcia, Daniel Roggen, and Niko Münzenrieder. Flexible sensors—from materials to applications. *Technologies*, 7(2), 2019.

[20] Jiewen Zheng, Yuhong Shen, Zhengbo Zhang, Taihu Wu, Guang Zhang, and Hengzhi Lu. Emerging wearable medical devices towards personalized healthcare. In *Proceedings of the 8th International Conference on Body Area Networks*, BodyNets '13, page 427–431, Brussels, BEL, 2013. ICST (Institute for Computer Sciences, Social-Informatics and Telecommunications Engineering).

[21] J. Smith. Mdr classification and biocompatibility relevance of wearable devices in healthcare. *Journal of Wearable Technology*, 1(1):12–18, 2022.

[22] Woodhead publishing series in biomaterials. In Jean-Pierre Boutrand, editor, *Biocompatibility and Performance of Medical Devices*, Woodhead Publishing Series in Biomaterials, page 518. Woodhead Publishing, 2012.

[23] ISO. Iso 10993-1:2018(en) biological evaluation of medical devices — part 1: Evaluation and testing within a risk management process. https://www.iso.org/obp/ui#iso:std:iso:10993:-1:ed-5:v2:en:sec:3.14, 2018. Last accessed 10 February 2023.

[24] Dinesh Maddipatla, Binu B Narakathu, and Massood Atashbar. Recent progress in manufacturing techniques of printed and flexible sensors: a review. *Biosensors*, 10(12):199, 2020.

[25] Colin Tong. *Substrate and Encapsulation Materials for Printed Flexible Electronics*, pages 221–255. Springer International Publishing, Cham, 2022.

[26] Li Dong, Bing Zhang, Youze Xin, Yanze Liu, Rui Xing, Yawei Yang, Xiaofei Wang, Wenxiu Que, Weihua Liu, and Li Geng. Fully integrated flexible long-term electrocardiogram recording patch with gel-less adhesive electrodes for arrhythmia detection. *Sensors and Actuators A: Physical*, 332:113063, 2021.

[27] Anouk WJ Scholten, Zhuozhao Zhan, Hendrik J Niemarkt, Marieke Vervoorn, Ruud W Van Leuteren, Frans H De Jongh, Anton H Van Kaam, Edwin R Van Den Heuvel, and G Jeroen Hutten. Multicentre paired non-inferiority study of the cardiorespiratory monitoring performance of the wireless and non-adhesive bambi® belt measuring diaphragm activity in neonates: study protocol. *BMJ Paediatrics Open*, 6(1), 2022.

[28] Robert J. Theriaque. Liquid silicone rubber design and capabilities. http://www.dfma.com/forum/2017pdf/Theriaquepaper.pdf, 2019. Last accessed 1 March 2023.

[29] Omnexus. The material selection platform. https://omnexus.specialchem.com/, 2021. Last accessed 1 February 2023.

[30] Anshuman Shrivastava. 1 - introduction to plastics engineering. In Anshuman Shrivastava, editor, *Introduction to Plastics Engineering*, Plastics Design Library, pages 1–16. William Andrew Publishing, 2018.

[31] Navneet Gupta and Kavindra Kandpal. Material selection techniques in materials for electronics. *Multiscale Modelling of Advanced Materials*, pages 1–15, 2020.

[32] Granta Design Limited. Granta EduPack, 2021. Accessed: March 5, 2023.

[33] George Wypych. *Handbook of Polymers, Second Edition*. Elsevier, Oxford, 2016.

[34] GlobalSpec. GlobalSpec, 2021. Accessed: March 5, 2023.

[35] Modern Plastics. High performance medical grade plastics for the medical device industry, 2021. Accessed: March 5, 2023.

[36] eFunda. eFunda, 2021. Accessed: March 5, 2023.

[37] Dalia Saber and Khaled Abd El-Aziz. Advanced materials used in wearable health care devices and medical textiles in the battle against coronavirus (covid-19): A review. *Journal of Industrial Textiles*, 51(1_suppl):246S–271S, 2022.

[38] Yanfei Chen, Yun-Soung Kim, Bryan W Tillman, Woon-Hong Yeo, and Youngjae Chun. Advances in materials for recent low-profile implantable bioelectronics. *Materials*, 11(4):522, 2018.

[39] Ehsan Hamidi, Alireza Fazeli, Muhamad Azizi Mat Yajid, and Nor Azwadi Che Sidik. Materials selection for hip prosthesis by the method of weighted properties. *Jurnal Teknologi*, 75(11), 2015.

Chapter 8

Appendix

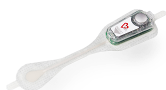
Device	Supplier	Description	Figure
Zio Xt	iRythm Technologies	Single-use monitors designed for simple application — either in clinic, or by patients in their own homes	
Kardiamobile	Alivecor	Six-lead personal EKG, records medical-grade heart rhythm data in seconds and is FDA-cleared to detect up to six of the most common arrhythmia	
Vivalink	VivaLink	Multi-function cardiac patch that can live stream multiple parameters to a mobile device or the cloud. It is reusable, rechargeable, and can record data even in the event of a network disruption	
CAM	BardyDx	P-Wave centric ECG patch monitor, a lightweight, extended-wear cardiac patch monitor that delivers unparalleled clarity, convenience, and comfort	

Table 8.1: ECG Patch Heart-Rate Monitors

Material	Tg (°C)	Young's Modulus	Advantages	Disadvantages
PDMS	-125	<1000 kPa	Commercially available, cheap, biocompatible, non-flammable, chemically inert, and easy processing	Difficult to integrate electrodes on the skin, absorb small hydrophobic molecules, adsorption of proteins on its surface
Ecoflex silicone	-57	40kPa	Safe for skin, highly stretchable with low modulus, excellent printability, and good heat and creep resistance	Poor tear strength, comparably high cost, ultimate tensile and tear are declined with thinner, and poor transparency
PET	69-78	2-2.7 GPa	Inexpensive and available, high resistant to moisture, high strength to weight ratio, high chemical resistance to water and organic materials, easily recycled	Low heat resistance, resins and susceptible to oxides, lower impact strength, lower moldability, more sensitive to high temperatures (60 °C), highly affected by tough bases, boiling water, and alkalis
PI	300-400	2.5 GPa	biocompatibility, high thermal stability, good sealing properties, chemical inertness	opaque, moisture absorption
PMMA		2000 MPa	Good abrasion resistance, low temperature, good track and arc resistance, low fatigue, low water absorption	Poor solvent and fatigue resistance, limited chemical resistance, poor abrasion and wear resistance, cracked under load, prone to attack by organic solvents
Liquid Crystal polymer (LCP)		10.6GPa	High heat resistance, flame retardant, moldability, low viscosity, adhesion, wide processing window, excellent organic solvent, and heat aging resistance	Weak weld lines, chemical resistance, high anisotropic properties, high Z-axis thermal expansion coefficient, less cost-effectiveness, and knit line strength
Thermoplastic polyurethane (TPU)		3.6-88.8 MPa	Excellent abrasion resistance, good impact strength, rubber-like elasticity, toughness but good flexibility, good resistance with abrasion	Short shelf life, less cost-effective, drying is needed before processing, easily degrades with sunlight or UV exposure, easy fracturing feature

Table 8.2: List of common materials for flexible substrates in wearable devices [13],[14]

Suitability	**Description**
Excellent	The material is frequently used for injection molding and does not present any major problems
Acceptable	The material is generally used, but may not be an optimized grade
Limited use	The material may be used in limited cases, or requires additional measures to avoid problems

Table 8.3: Material categories for the suitability of the material for injection molding processes

Material	Acronym	Young's modulus [MPa]	Tensile strength [MPa]	Elongation at break [%]	Glass temp [°C]	Shore Hardness (D)	Permeability coefficient
Cellulose Acetate	CA	4.10E+03	33.5	27.5	203	82	85.4
Cellulose Acetate Butyrate	CAB	1.38E+03	51	52.5	161	90	13.9
Cellulose Acetate Propionate	CAP	1.75E+03	66	42.5	159	61	0.464
Ethyl Cellulose	EC	1.80E+03	62	20	142	95	965
Acrylonitrile butadiene styrene	ABS	2.76E+03	51.7	50	115	58	39.3
Polyamide	PA	2.04E+03	72	300	66	29	0.71
Polycarbonate	PC	2.44E+03	72.4	120	158	46	90.6
Polyetheretherketone	PEEK	3.95E+03	117	150	157	46	11.3
Polyethylene	PE	8.96E+02	44.8	490	-90	29	45
Polyethylene Terephthalate	PET	3.00E+03	60	70	83.9	95	2.4
Polyimide	PI	2.76E+03	118	90	260	92	10
Polylactide	PLA	3.60E+03	72	3	59.9	57.7	17
Polypropylene	PP	1.02E+03	50	500	-16.2	31	63
Polystyrene	PS	3.50E+03	51.7	4	99.9	95	157
Polybutylene Terephthalate	PBT	2.95E+03	50	300	65	95	15.2
Polymethyl methacrylate	PMMA	3.24E+03	72	10	110	90	7.19
Styrene-ethylene butylenestyrene	SEBS	4.30E-01	40	1000	-60	46	1040

Material	Acronym	Young's modulus [MPa]	Tensile strength [MPa]	Elongation at break [%]	Glass temp [°C]	Shore Hardness (D)	Permeability coefficient
Polyoxymethylene	POM	3.20E+03	89.6	75	-50.2	81	2.9
Polyurethane	PU	2.07E+03	62	380	107	46	27
High density polyethylene	HDPE	1.01E+03	51	700	-133	69	110
Low density polyethylene	LDPE	3.00E+02	20	600	-100	55	188
Polysulfone	PSU	2.76E+03	70	100	185	85	90.5
Polyether sulfone	PES	2.83E+03	83	90	220	85	14.6
Polyphenyl sulfone	PPSU	3.60E+03	70	120	220	86	7.4
Poly(p-phenylene sulfide)	PPS	2.89E+03	90	4	92	95	11.8
Polyvinyl chloride	PVC	3.10E+03	68.9	400	82	25	7.9
Liquid Crystal Polymer	LCP	1.54E+04	127	4.60	124	89	0.0326
Polydimethylsiloxane	PDMS	3.70E+00	9.7	90.28	-124	22	600
Polyethylene naphthalate	PEN	2.85E+03	68	60	122	95	0.52
Polyvinylidene fluoride	PVDF	2.20E+03	60	300	-67	80	1.96
Thermoplastic Polyurethane	TPU	7.20E+01	66	300	-66	50	184
Styrene-isoprene-styrene	SIS	2.85E+00	23.2	800	-40	16	3350
Poly-L-lactic acid	PLLA	1.49E+03	70	12	55	87.2	0.18
Polyhydroxybutyrate	PHB	3.00E+03	36	3	1	50	10.8

Material	Acronym	Young's modulus [MPa]	Tensile strength [MPa]	Elongation at break [%]	Glass temp [°C]	Shore Hardness (D)	Permeability coefficient
Ethylene Propylene Rubber	EPR	3.45E+02	38	600	-69	29	668
Ethylene Propylene Diene Monomer	EPDM	6.00E+00	17.5	375	-54.5	19	1735
Copolyester thermoplastic elastomer	TPC	1.15E-01	45	375	-60	46	130
Polyamide thermoplastic elastomer	TPA	2.06E+01	50	800	-80	25	1.13E+03
Thermoplastic Polyolefin Elastomer	TPO	2.36E+02	35	800	-60	39	504
Styrene butadiene styrene	SBS	1.81E+03	39.8	51.03	-95	45	263
Styrene butadiene styrene	SBS 12	1.83E+00	6.88	51.03	-40	12	3.87E+03
Styrene butadiene styrene	SBS 26	4.45E+00	7.50	51.03	-40	26	3.00E+03
Polyglycolic acid	PGA	7.20E+03	890	30	40	84	0.014
Polytetrafluoroethylene	PTFE	5.75E+02	40	500	-97	50	223
Poly(lactide-co-glycolide)	PLGA	2.04E+03	55	10	50	40.4	2.7
Polycaprolactone	PCL	4.41E+02	29	800	-60	57	4.7
Polychlorotrifluoroethylene	PCTFE	1.40E+03	40	250	95	85	4.7

Material	Acronym	Young's modulus [MPa]	Tensile strength [MPa]	Elongation at break [%]	Glass temp [°C]	Shore Hardness (D)	Permeability coefficient
Fluorinated ethylene propylene copolymer	FEP	3.53E+02	30	325	80	56	40
Perfluoro-alkoxy-ethylene	PFA	8.00E+02	27	300	112	60	335
Ethylene tetrafluoroethylene copolymer	ETFE	8.48E+02	45	200	-100	75	39.4
Ethylene chlorotrifluoroethylene copolymer	ECTFE	1.70E+03	54	250	85	75	10.2
Styrene Acrylonitrile	SAN	1.71E+02	75	10	110	95	27.6
Acrylate Styrene Acrylonitrile	ASA	2.60E+03	35	40	115	80	58.4
Methacrylate Acrylonitrile	MABS	2.11E+03	45	20	105	75	78.5
Styrene-Butadiene Copolymer	SBC	1.20E+03	25	150	74	69	180
Polyvinyl alcohol film	PVA	2.25E+03	70	700	85	80	0.5
Poly(vinylpyrrolidone)	PVP	1.50E+03	50	500	180	80	22.5
Ethylene Vinyl Acetate	EVA	1.00E+02	41	860	-42	47	0.092
Polyvinylidene fluoride	PVDF	2.45E+03	40	450	-35	85	1.96